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Regulating Digital Health.

How Does an App Become a Digital Health Application?

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"*One's thinking seems to be a matter of decisive encounters whose effects one pursues in total solitude*"
Bruno Latour (2013b, p. 296)

In the foreword to the Thousand Plateaus, Gilles Deleuze and Félix Guattari (1987, p. 3) write that when writing the Anti-Oedipus "[s]ince each of us was several, there was already quite a crowd". This, for me, at the time and, albeit differently, today, puzzling sentence stuck with me – possibly only because I aborted my first attempt at reading the book due to its incomprehensibility shortly thereafter. Today, at this moment, writing these very lines, four or five years, countless hours of racking my brains over Deleuze, Guattari and related authors, late at night, during long train rides, two years of studying "Science, Technology, Society" at the University of Vienna, months of writing this thesis later, I feel that I have arrived at a modest interpretation of this sentence. The regulations of a Master's Thesis require students to write their Thesis alone and I have done so, in principle. I have written the following pages by myself as required. But this certainly does not mean that I was not several and that there was not "quite a crowd" that was part of writing these pages in one way or another. On the contrary, without this crowd, this Thesis would not have been possible – and this is indeed why I prefer Fleck's (1979) vision of the "thought collective" to Kuhn's (1996) vision of the lone wolf revolutionary that, by himself [sic!], brings down and establishes a new paradigm. I want to use this foreword to make the crowd that I am deeply indebted to visible and to bring from the indiscernible background to the foreground those that made my Thesis possible through their different, invaluable contributions. May these words not be too insufficient to express an approximation of the gratitude I have for each of you.

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Working out the effects of the decisive encounters I have made throughout the last years may or may not have been in solitude because I have been and continue to be several, quite a crowd.

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1 Introduction: There is an App for That?!

“There is an app for that” is the notorious and, let’s be honest, somewhat obnoxious slogan that Apple developed to advertise the new version of the iPhone that came out in 2009. If you’re in a strange city and don’t know where to go – there’s an app for that. If you would like to keep all your digital tickets in one place – there’s an app for that. If you want to know what the weather will be like tomorrow, the day after tomorrow or next week – you’re lucky because there is an app for that, too. These are, of course, rather mundane uses. The broad landscapes of digital apps also have other, more specialized functionalities in (app) store: If you want to train your laboratory rat – there’s an app for that (Wolf et al., 2014). If you’re a sports educator and want to make sure you meet the national standards – you know the drill (Krause & Sanchez, 2014). If you seek to write your master’s the-, well, not quite yet, unfortunately. I will have to do that myself. But the general route of the imaginary this simple slogan evokes is clear: One day, there will be an app available for every problem one might have, for all the smaller and bigger tasks in life.

Given the contemporary challenges of healthcare systems – exploding costs, shortages of medical professionals especially for mental health and in rural areas, the lack of personalized treatments, etc. – it does not seem far-fetched to professionalize and medicalize the slogan “there is an app for that”, as it were. Deploying apps as part of medical treatments, to support or even to substitute medical practice, it seems, would solve all of these issues at once. Indeed, many of the statements on digital health technologies made by policy-makers and entrepreneurs point in this direction – digital health as a promising solution or technological fix for these contemporary ailments (e.g. Geiger, 2020; Geiger & Gross, 2017; Levina, 2017; Lupton, 2014b).

In Germany, policymakers have gone beyond the level of promises, it appears, and “invested in form”, to use Laurent Thévenot’s (1984; see also Cappel, 2021) concept. On December 19, 2019, lawmakers passed the Digital Healthcare Act (*Digitale-Versorgung-Gesetz, DVG*) on the initiative of the then German Minister for Federal Health, Jens Spahn. This law aims to institute and accelerate the digitalization of the German healthcare system. It includes provisions for increased access to video consultations and other forms of telemedicine, expanded funds for innovation projects in digital healthcare and the implementation of an electronic healthcare record that can facilitate administrational processes in the healthcare system and data-driven biomedical research. At the core of the new law is, however, – as the fact that the Federal Ministry of Health (*Bundesministerium für Gesundheit*, *BMG*) highlights this in the announcement of the law on its website illustrates (Bundesministerium für Gesundheit, 2020) – the introduction of health apps as part of the standard coverage of the German healthcare system. In short, the new law entitles citizens insured by the German Statutory Health Insurances (SHIs) to be prescribed and use phone or web applications as part of their healthcare provision. Their healthcare insurance covers the cost of these apps. It is this feature that makes the *DVG* a “first-of-its-kind opportunity” (Gerke et al., 2020, p. 5) among the

countries in the Organisation for Economic Co-operation and Development (OECD). The principle is fairly simple, at first glance, anyways: A patient visits the doctor with a particular condition. Like a traditional drug, the doctor can then issue a prescription for a so-called Digital Healthcare Application (*Digitale Gesundheitsanwendung*, *DiGA*), an app specifically approved and listed in the Digital Health Applications Directory (*Digitale Gesundheitsanwendungen-Verzeichnis, DiGA-Verzeichnis*). This is why these apps have been given the moniker “prescription apps” (*Apps auf Rezept*). The patient then takes the prescription to their health insurance which provides them with a license code for the particular app. With this code, the patient can access the app targeting their indication that they have previously downloaded from one of the usual app stores or access the web application. However, not just any app can be prescribed this way. The *DVG* and its addendum, the Digital Health Applications Ordinance (*Digitale-Gesundheitsanwendungen-Verordnung*, *DiGAV*), provide that apps first need to undergo a three-month approval process at the Federal Institute for Drugs and Medical Devices (*Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM*), the so-called *DiGA* Fast-Track. Only if they pass this assessment they are listed as *DiGAs* in the directory and become eligible for reimbursement by the SHI.

As a scholar-in-training in the Science and Technology Studies (STS), this approval process gave me pause when I first heard about it. There are hundreds of thousands, if not millions of apps classified as health-and-wellness applications in the various app stores. But, as of early June 2022, only 31 Digital Health Applications exist. What distinguishes a Digital Health Application? My initial intuition was that during the approval process at the *BfArM* an ontological transformation occurs. An ‘ordinary’ health-and-wellness app undergoes the assessment and, if successful, comes out of it as a Digital Health Application. This suggests investigating these peculiar apps, first and foremost, as a legal category.It hints at the inextricability of a particular kind of technology based on scientific evidence, apps used to treat medical conditions, and the regulation of this technology (in part through scientific evidence). In other words: Digital Health Applications provide a case to study those intricate entanglements of science, technology and society that STS takes as its object of research. Despite this, with a few notable exceptions (e.g. Diedericks, 2019; Lievevrouw et al., 2021, 2022; Marelli et al., 2020), much of the social science research into digital health has centered on discourses on, the design or use of digital health technologies rather than their regulation. However, how such technologies are designed is closely tied to this regulation. Developers need to be aware of and respect different regulatory frameworks (Williams et al., 2020). For users, it similarly makes a difference whether a digital health technology is approved by a regulatory agency and needs to be prescribed by a physician and can be reimbursed by statutory health insurance. Therefore, the regulation of digital health technologies would seem to deserve more attention.

In the following thesis, I want to address this relative gap by opening up the black box of the approval process that the new regulatory framework in Germany has implemented and illuminating the puzzling transubstantiation effects. Digital Health Applications seem to be an ideal case for this.

Because the law came into force only two years ago, they are the starting point for an exploration of a regulation that is still in the making. Thus, this case harbors valuable lessons on the challenges of regulating digital health technologies more generally. To grasp what happens during the approval process, I have, on the one hand, analyzed documents describing the approval process published by the *BfArM*. These include a guide to this procedure for interested parties, articles published in a special edition of the German Federal Health Bulletin and blog posts from the *BfArM* website. On the other hand, and to complement this, I have conducted interviews with manufacturers[1] of Digital Health Applications that already have successfully undergone the assessment with their apps and a representative of an umbrella organization for digital health. They related to me their experiences and the challenges they faced with their application. The main question I pursued when analyzing these materials harks back to my initial intuition that the approval process effectuates an ontological transformation. I wanted to understand how a health-and-wellness app becomes a Digital Health Application through this process at the *BfArM*.

To answer this question, I develop a theoretical framework that starts with Bruno Latour's (2013a) most recent encompassing research program for investigating what he calls "modes of existence". Through this program, he seeks to describe the different values of the practices of those who consider themselves modern without returning to the language of domains or functional systems. While it does not come without challenges that I will address later, this theoretical framework offers a language to theorize legal proceedings as a distinct type of practice. Latour (2010, 2013a) conceives of the law as a peculiar mode of existence, [LAW], populated by entities and practices that we can justifiably call 'legal'. I will combine this with the lens on socio-material practices of testing adopted by the Sociology of Conventions and Testing (Boltanski & Thévenot, 2006; Potthast, 2021) Accordingly, the overarching argument that I pursue throughout the thesis and propose as an answer to my research question is that the approval process at the *BfArM* constitutes a test which effects the transition of apps to a legal mode of existence as Digital Health Applications as defined by the *DVG*. In the story that follows, I seek to unpack the modalities of this test, from the regulatory framework that defines it over the imaginary of digital health that underlies it to the nitty-gritty of the organization of the test.

To make my argument, I will take five steps (distributed across nine chapters). Beginning with a review of the state-of-the-art (**ch. 2**), I situate my research at the intersection of two strands of research within STS, the emerging literature on digital health and the literature on the regulation of biomedical technologies. I identify the gaps in these bodies of research and develop my research questions. I continue by developing the theoretical framework of my research (**ch. 3**). As already mentioned, this framework fuses Latour's Inquiry into Modes of Existence (AIME) with the concep-

1 "Manufacturers" is the term that the *BfArM* uses to designate those who produce Digital Health Applications, for example, in the English version of the *DiGA Guide*. I think this is a rather clumsy choice of words in the context of digital technologies. Nevertheless, to stay close to the language of my research field, I will also adopt this term. I use it interchangeably with other concepts such as "developer" or "producer".

tualization of socio-material practices of testing in the Sociology of Conventions and Testing inspired by French pragmatism. In the next step, I outline the methodological approach and expound on how I have assembled the empirical material of my study (**ch. 4**). The following five chapters present the findings from my analysis. The first of these provides an analysis of the imaginary of digital health that the *BfArM* puts forward in the documents I have analyzed by following the central metaphor of a 'digital building of healthcare' (**ch. 5**). The approval process itself is the object of the two chapters that follow. Here, I reconstruct the explicit (**ch. 6**) and implicit requirements applicants need to meet to be successful (**ch. 7**). Then, I analyze the relationship between the *BfArM* and the *DiGA* developers (**ch. 8**). This relationship is puzzling because it seems to oscillate between a cooperative and a more agonistic mode. The last analysis chapter explores the different figures regulation takes in the approval process (**ch. 9**). What I call the "regulation multiple" comprises regulation that is performative, distributed, agile and continuous. Finally, I tie my findings back to the literature reviewed earlier and address my research questions. A concluding summary completes the thesis (**ch. 10**).

2 State of the Art

I want to begin by situating my research within existing literature in the social sciences and STS more specifically. The case of Digital Health Applications combines two strands of recent research interests. On the one hand, it speaks to the emerging literature on digital health. On the other hand, it relates to research into the regulation of biomedicine. I will give a brief overview of both of these strands in this chapter. For the literature on digital health (2.1), I start by focusing on the proliferating promissory discourses around different digital health technologies and proceed to research that has looked into the work of designers of such technologies. Concerning the regulation of biomedicine, I concentrate on those strands of the literature investigating the regulation of medical devices and pharmaceuticals (2.2). I then review the literature that condenses both of these research interests by interrogating the regulation of digital health (2.3). This should allow me to highlight the gaps in the literature and develop the research questions I want to answer in this thesis in the final step (2.4).

2.1 The Emerging Literature on Digital Health

The literature on digital health is still emerging. Contributions have proliferated in recent years both in the respective disciplinary discourses (i.e. biomedicine, health informatics, etc.) but also in the social sciences and STS in particular. Therefore, I want to briefly note two decisions I have made to order this deluge of literature. I first limited myself by the type of digital health technologies the contributions I review below take as their research object. In a recent handbook article, Benjamin Marent and Flis Henwood (2022) distinguish between four sub-types of digital health: telemedicine,

eHealth (digital availability of health information), mobile or mHealth and algorithmic medicine that uses ‘big data’. It should be clear that this is a purely analytic distinction. One can easily argue that algorithms shape the availability of online health information or that the latest mHealth platforms take over telemedical functions. Nevertheless, this distinction allows me to order the existing literature. Digital Health Applications primarily belong to the mHealth category and I will focus my review of literature on contributions concerned with all types of mobile health from a socio-technical perspective. I have also set a second limit regarding the contributions my research can make. My research focuses on the approval process for *DiGAs* and draws particularly on the experiences of their developers. Therefore, I situate my research and its results within existing discussions about the development/design of digital health technologies that have thus far only tentatively discussed their relation to legal frameworks.

A review of the state of research in a field should probably begin with a concise definition of the object of scholarly interest. This is not easy for digital health technologies. Many of the contributions in the emerging literature draw on Lupton’s (2018, p. 1) rather broad definition according to which ‘digital health’

> refers to a wide range of technologies directed at delivering healthcare, providing information to lay people and helping them share their experiences of health and illness, training and educating healthcare professionals, helping people with chronic illnesses to engage in self-care and encouraging others to engage in activities to promote their health and wellbeing and avoid illness.

This conceptualization is evidently encompassing but may be *too* broad and abstract to capture the specificities of technologies as diverse as Marent and Henwood’s (2022) classification. The fact that digital health does not only refer to material technologies because it “is, first and foremost, a vision” (Wieser, 2019, p. 428; Cappel, 2021) adds further complexity. Therefore, I begin not by providing and comparing different definitions but by reviewing the literature that has sketched the dimensions of this vision and promise. After that, I summarize the literature on the design of digital health technologies, carving out especially the implied role of regulation in it.

2.1.1 Promissory Discourses on Digital Health

Following work in the sociology of expectations (Borup et al., 2006; N. Brown & Michael, 2003), much of the scholarship on digital health has focused on the promissory discourses that have emerged around digital health. This research highlights the often competing or even contradictory promises different stakeholders attach to digital health and aims to develop a critical perspective that points to what these promises neglect. A common finding is that digital health is frequently portrayed as a ground-breaking innovation, a disruption and a revolution of established ways of practicing healthcare (e.g. Geiger, 2020; Lupton, 2018; Marent & Henwood, 2022; Petersen, 2019; Petersen et al., 2019). For instance, and exemplary of these findings, Lupton (2014b, p. 707) writes that

> [i]n popular forums, among digital developers and entrepreneurs and in the medical and public health literature a constant refrain has insisted on the 'disruptive' and 'revolutionary' nature of these technologies and their potential to address budgetary constraints and healthcare delivery limitations and to facilitate health promotion, preventive medicine and public health surveillance.

Writing on the role of digital health technologies during the Covid-19 pandemic, Richard Milne and Alessia Costa (2020, p. 2) suggest that the experience of the pandemic as a disruption connects with the idea of digital health as a similar disruption. It is constru(ct)ed as a "[m]oment of technoscientific opportunity" and new, digital health futures are formulated in temporal and spatial terms. Susi Geiger (2020) investigates the discourses constructed around and by two digital health companies that offer(ed) direct-to-consumer genetic and blood testing. In line with the broader ideology of Silicon Valley, these discourses amount to what she calls "eschatologies of disruptions" (Geiger, 2020, p. 171). Digital health technologies are construed to break with a demonized status quo – a bureaucratic, patronizing and ossified healthcare system in this case – and to bring about a paradisiacal end of history, that is, the free reign of the empowered healthcare citizen-consumer. With a more narrow focus on mHealth technologies, Marina Levina (2017) analyzes how the trope of disruption and the idea of disruptive innovation, yet another key feature of the rhetoric of revolution put forward by Silicon Valley representatives, are mobilized. She finds that in the case of mHealth, these figures compete with, and indeed seek to put away with, ideas of sustainability and long-term temporalities of public health promotion. They promote an individualized understanding of health and healthcare, ignoring broader socio-economic dimensions relevant to them. The sociology of expectations has related such narratives of disruption or revolution to the early stages in the development of a field: "The whole language of novelty, newness and revolutionary potential is actually part and parcel of the hyperbolic discourse surrounding the early or opening moments of resource and agenda building" (N. Brown, 2003, p. 11). This suggests that digital health is at a similar (early) stage where uncertainty prevails and large claims about its trajectory can be made.

In a more fine-grained perspective regarding the content of such revolutionary promises, for healthcare at the most general level, promissory discourses "mobilize a range of claims about their future therapeutic impact" (Webster, 2002, p. 443). In this regard, two arguments recur in these discourses (Marent & Henwood, 2022). On the one hand, they emphasize the improved "efficiency, effectiveness, and quality of health services" that digital health technologies are imagined to bring as part of a "utilitarian argument" (Marent & Henwood, 2022, p. 265). Here, the discursively enacted digital health technologies promise to tackle the challenges of aging populations and increasing healthcare costs many societies face. They do so through their capacity to decrease the number of necessary face-to-face visits and to engage users in self-managing behaviors.

Other authors have further elaborated on this. Knowledge plays a crucial role in such promises of efficiency. Digital health technologies allow to collect large amounts of data that, the promise goes, make possible a comprehensive knowledge about the body and health that can be used to prevent

diseases (Wieser, 2019). Pickersgill (2019) discusses the promises of digital health concerning the digitization of psychiatry through mHealth. He argues that promissory discourse in medicine and digital health mobilize the "biomedical virtues" of accessibility of medical treatment, the increase of knowledge through user-generated data and related improvements in psychiatric practice, as well as self-care and clinical responsibility. They thus "blur the lines between descriptive and normative dimensions" (Pickersgill, 2019, p. 23). Through this blurring, promissory discourses shape future pathways of digital health technologies.

The second strand in the promissory discourses about digital health makes an "empowerment argument", advocating that "digital technologies provide patients and citizens with personal health data and timely feedback by which they can gain a better understanding of their medical condition and are better placed to manage and participate in their health" (Marent & Henwood, 2022, p. 265). Thus, they empower patients by making them capable of taking care of their health or participating in their healthcare – a vision suggesting profound changes to the relationship between medical professionals and patients. It is especially prominent in the discourses on precision or personalized medicine that is facilitated or even, to a large extent, made possible by digital health technologies. Klaus Hoeyer (2019) analyzes this in terms of what he calls "promissory data": For the Danish case, he argues that the discourse on precision/personalized medicine powered by "data-intensive resourcing" (Hoeyer, 2016; Hogle, 2016) promises the empowerment of patients through knowledge of their own, quantified health. Nevertheless, Hoeyer (2019) also shows that, when put under closer scrutiny, these promises cannot hold because 'personalization' through datafied medicine only refers to the possibility of relating personal health metrics to statistical values on the population level. Relatedly, policy discourse in the UK presents digital health as a solution to ongoing inequalities in healthcare. Emma Rich and colleagues (2019) find that the "equity" evoked here is framed mainly in terms of empowering users of digital health technologies to self-responsibly manage their health, enhance their democratic participation both in the realm of health policy and in medical encounters and endow them with the necessary skills to interpret and act on their health data. This amounts to the emergence of the "digitally engaged patient" (Lupton, 2013). Promissory discourses address lay people as empowered consumers that "are advised that they should use digital health technologies as part of patient engagement practices" (Lupton, 2013, pp. 258–259).

As previously mentioned, the sociology of expectations has emphasized that expectations are "crucial to providing the dynamism and momentum upon which so many ventures in science and technology depend" (N. Brown & Michael, 2003, p. 3). This is especially true at the early stages of research and development where investment and other types of support need to be mobilized. We can readily extrapolate this to digital health technologies more specifically. Visions of digital health technologies have an orienting role for future perspectives and pathways (Wieser, 2019). Pickersgill (2019, pp. 25–26) develops the concept of "performative nominalism" to describe how promissory discourses "talk" new fields of research and development "into existence". Discussing the ef-

fects of promissory discourse, Petersen (2019, p. 4) argues that “regardless of whether digital health evolves in ways imagined, related policies and programs are profoundly refashioning conceptions of self, society and citizenship, and impacting on related notions of truth, privacy, trust, rights and responsibilities”. By anticipating and, more specifically, making promises about potential futures, promissory discourses shape actions in the present that aim to materialize these promised futures.

In this sense, the concept of “promissory discourse” is closely related to that of “hype”. Hype also, more often than not, ultimately turns out to be overinflated expectations but not after it has sparked investments into a particular technology or field (Fenn & Raskino, 2008). Following Nik Brown (2003), hype constitutes a dilemma for any technoscientific innovation. Especially in early phases, expectations and hype are necessary to imagine uncertain future trajectories and attract attention and funding for the innovation. On the other hand, hype likely draws on exaggerated promises and expectations that easily entail disappointment and disillusionment with “disastrous consequences for the reputations not only of individuals but entire innovation fields” (N. Brown, 2003, p. 9). In the past decades, digital health has similarly followed “cycles of legitimation and delegitimation” (N. Brown, 2003, p. 12). Susi Geiger and Nicole Gross (2017) identify three distinct phases of hype. In the first phase, hype concerned the perspective of a digitally connected healthcare system and digital health was closely connected to the medical domain. The emergence of smartphones in the last decade gave rise to a second hype. In this phase, attention shifted to consumer-oriented digital health technologies – this led to the emergence of the category of “technology-enabled self-care and wellness management” (Geiger & Gross, 2017, p. 443) that intersect health/wellness and medical products. After a brief phase in which hype largely died down, the recent years have seen a revival of the promises of digitized medicine and an increasing role of legislators and policymakers (rather than commercial actors) in the efforts around digital health. Arguably, this is the phase in which Digital Health Applications emerge in Germany.

The concept of hype and the cycles of de/legitimization indicate that promissory discourses do not necessarily live up to their expectations. The field of critical digital health studies (Lupton, 2014b, 2014c, 2014a, 2016b) emphasizes this misfit between discourse and reality. It conceives of promissory discourses and hype around digital health technologies as techno-determinist and techno-utopian. They are “techno-utopian” because they posit digital health technologies as the future solutions to pressing problems of contemporary challenges to healthcare sectors without considering alternative trajectories. They are techno-determinist in that they claim the purported positive outcomes of digital health technologies as inevitable, an inherent feature of the technology. By interrogating the “social, cultural, political and ethical dimensions of the digital health phenomenon” (Lupton, 2014c, p. 1347), critical digital health studies seek to go “beyond techno-utopia” (Lupton, 2014b). It focuses on the unintended, undesirable consequences digital health may have (Ziebland et al., 2021). Pursuing this line of research, Rebecca Jablonsky (2021) shows that meditation apps

do not fulfill the promise of increasing their users' attention and decreasing technology dependence. Nevertheless, the promises are the active ingredient in that they re-shape how users interpret their practices that reproduce dominant behavioral patterns of technology addiction.

A puzzling inconsistency in the otherwise encompassing literature on promissory discourses on and around digital health that, as this overview shows, assembles several theoretical approaches and strands is the role of regulation. In their analysis of "hype cycles", Geiger & Gross (2017) argue that after high expectations, big promises and large-scale investments, these are confronted with broader societal concerns, for example, by regulatory actors. Regulation seems unaffected by hype cycles and intervenes in them from the outside. Pickersgill (2019, p. 26) ascribes to governments the role of further stabilizing the fields promissory discourses create by "mirroring" these discourses. The ascription of this role presupposes, however, that a) the origin of promissory discourse is different from governments and funders, b) following the metaphor of the mirror, governments and funders merely echo promissory discourse that seems to travel without transformation and c) governments and funders pre-exist the field-establishing promissory discourses – an assumption that runs counter to his idea of "performative nominalism".

Metaphors such as the "triple helix model" of innovation suggest that regulators may play a more relevant role than the one these accounts grant them. This model describes that technoscientific developments emerge from the close interlinkings of universities, industry and governments (Etzkowitz & Leydesdorff, 2000; Faulkner, 2009a). Moreover, research into the work of regulatory agencies demonstrates that they may also be caught up in the hype and prematurely approve a technoscientific innovation for market access. As Brown (2003, p. 8) writes concerning hype, "policy communities can become uncritically enrolled into unreasonable expectations of future potential and occasionally at great costs to those for whom they have duties of responsibility". For the regulation of pharmaceuticals, at least, Courtney Davis and John Abraham (2013, p. 14) point out that what they call "promissory science" – "promissory claims about the social/health value of the new technology/drug, which create powerful expectations about (and hence the demand for) that technology within wider society, including patients" – influences regulation on two levels. Promises and expectations shape the regulatory framework more broadly, for instance, creating accelerated pathways for the market access of drugs. In addition, they influence regulatory decision-making on individual drugs that seem particularly promising.

Whether the promissory discourses about digital health have similar effects on their regulation and how regulatory agencies more generally relate to these promises has thus far not been a central topic of research. As much of the research seems to assume, it is indeed possible that regulatory agencies – by virtue of their status as "obligatory passage points" (Callon, 1984) for the licensing of medical products and, hence, access to the healthcare market – may slow down hype and expectations by subjecting the promises to critical scrutiny, an already institutionalized form of Lupton's program of critical digital health studies as it were. On the other hand, they may as well be

engrossed in promissory discourse and hype themselves which will shape their decision-making. At any rate, it seems ill-fitted to assume that regulatory agencies take a position outside of promissory discourse as its somewhat neutral arbiters. Situated empirical research is necessary to analyze the multiple possible relations regulators may entertain with promissory discourses and "promissory actors" (Geiger & Gross, 2017, p. 451).

2.1.2 Design of Digital Health Apps

A second strand within the emerging literature on digital health has looked into the development and design of digital health technologies. It echoes many of the findings of early STS that technologies cannot be isolated from 'social dimensions' (e.g. Berg, 1998; Pinch & Bijker, 1984). Designers working on digital health technologies need to consider the broader context of their apps. This includes, for instance, the broader "institutional logics" (Lenz, 2021) of healthcare and markets that digital health technologies intermingle, creating ambivalences and selectively reconciling these institutional logics. It is not only these two logics that digital health intermingles, however. Recent efforts to develop regulatory frameworks for digital health technologies also mean that designers and requirements engineers need "to be aware of standards, rules, and regulations on national, international, and global level, which are typically expressed by legislation, recommendations, and standards" (Thuemmler, 2015, p. 19). Thus, regulatory concerns and considerations play an important role even in the design stage and shape digital health technologies from the beginning. In this context, Ross Williams and colleagues (2020, p. 1177) conceptualize the work of designers of digital health apps as "navigating layered standards". On the one hand, this means navigating the different *technical* standards (e.g. Application Interface Programming, API) set by Big Tech corporations such as Google and Apple. On the other hand, developers "must negotiate a potentially volatile regulatory environment, responsively managing their products" (Williams et al., 2020, p. 1179). An in-depth understanding of how digital health technologies are regulated can illuminate how regulation impacts the design of these technologies and how designers incorporate it into their materiality.

In turn, this type of research can speak to the more normative ambitions of STS as a field. Especially in recent years, STS has sought to impact the technologies and practices it studies (e.g. Farías, 2017; Zuiderent-Jerak, 2010). For digital health technologies, scholars have attempted this through workshops with stakeholders (Lupton, 2017a) or participatory and co-creative research and design (Marent et al., 2018). Lupton (2017a) reports from a participatory design workshop with stakeholders in the field of digital health. The workshop allowed the participants to reflect on the socio-technical dimensions of digital health and speculatively develop future technologies. Crucially, the respondents perceived digital health as largely beneficial but also risking the exclusion of already marginalized groups and intrusions into users' privacy. Marent et al. (2018) describe the similarly ambivalent attitudes of their collaborators in the co-creation of an mHealth platform for HIV

care. The users welcomed the affordances of the platform but were critical about how it would impact the (self-)treatment of their condition and the communication with their healthcare provider. The authors conclude that acknowledging these ambivalences in the design of digital health technologies allows for a greater reflexivity – we might think here of the framework of Responsible Research and Innovation (Demers-Payette et al., 2016; Stilgoe et al., 2013) – and deconstructs all too easy dichotomous views on acceptance and resistance. Although they do not explicitly follow up on this by emphasizing the seemingly inherent ambivalence of digital health technologies, these contributions raise the question of whether and how regulatory frameworks can account for relational and situated perspectives.

Regulatory agencies need to assess the design decisions developers of digital health technologies have made during the development, the "scripts" (Akrich, 1992) that they incorporate into their apps. Notions of risk become particularly important in this context. Taking up the call for a sociology of the risk of digital health technologies (Lupton, 2016c), some scholars have investigated the role(s) risk plays in their design. They flesh out the multiple concepts of risk that are at play. Samantha Adams and Martje Niezen (2016), for instance, follow the different layers of risk apparent in the development of eCoaches to promote healthy behavior. Here, risk is located on three levels. First, the very conception of eCoaches to promote healthier behavior is based on perceptions of risk for both individuals and the broader healthcare system. As we have seen, such ascriptions of risks are at the core of promissory discourses on digital health more generally. Entrepreneurs and policymakers laud digital health technologies as "solutions" against the backdrop of problematic tendencies in national healthcare systems. On a second level, developers deal with the self-reflexive risk of their technologies being ineffective for different reasons if, for instance, they intrude into the users' everyday practices too much or users input false data. This level is closely entangled with the third. eCoaches may themselves produce new socio-technical risks such as a limitation of autonomy, questions of when and how to use these programs responsibly and intrusions into privacy. Although the authors do not extend their argument in this direction, these last two levels of risk are relevant to the regulatory approval of such technologies. The responsible agencies need to make decisions about acceptable risks of ineffectiveness or risks the technology itself causes. This adds to the "politics of risk" that Alison Kenner (2016) has unveiled. The understandings of and decisions about risk that inform the work of designers and become materialized in the apps are not innocent. Kenner (2016) sketches the different dimensions this has in the design of mHealth apps for asthma. First, the designs locate risk "within the individual" (Kenner, 2016, p. 523). Although asthma is an environment-related disease, most apps consider the (non-)adherence to standardized treatment plans and guidelines as the primary issue. This reflects in decision choices *not* to include crowd-sourced environmental data of pollutants in the air but, instead, to draw on biomedical guidelines for managing asthma. Second, the apps digitalize the "emplaced care" (Kenner, 2016, p. 512), the awareness of environmental conditions and strategies of relating to particular places

many asthma patients develop out of the necessity to manage their condition. This digitalization transforms how the body, risk and the body-at-risk are experienced and abstracts from biographical and contextual factors, transforming experiences in the real world in turn. Finally, the use of algorithms to compute risk calculations from user inputs rationalizes care by "nudging" (Schüll, 2016) users to adhere to their treatment and to (self-responsibly) take care of their condition. Despite the critical undertones of her study, Kenner (2016, p. 526) acknowledges that the mHealth apps for asthma, through the choices made by their designers, do particular kinds of "epistemic work". They reinforce the dominance of biomedical knowledge but also add other types of knowledge on asthma. This opens up the space to incorporate additional epistemes and practices – those of governments and regulatory agencies among them (Kenner, 2016, p. 526).

As with much of the literature on digital health more generally, the literature on the design and development of digital health technologies takes efforts in the Global North as the point of departure and objects of analysis. This asymmetric attention is not justified because "much of the advocacy for mHealth concerns its potential in developing countries, where large segments of the population are scarcely served by health services" (Nahar et al., 2017, p. 1). Research into the design and use of digital health technologies in the Global South can make visible the implicit assumptions built into these technologies. In this sense, Papreen Nahar et al. (2017, p. 10) "raise a note of caution" for designers, arguing that such assumptions cannot easily be transferred. In the geographical area where they conduct their anthropological scoping study on the potential of an app for depression treatment, the stigma of depression, patterns of mobile phone use and understandings of the 'self' that is 'empowered' differ from what such apps presume. Moreover, designers would need to consider the particular legal context. Such discrepancies also extend to assumptions of the body, disease and the relationship between doctors and patients that digital applications seek to emulate. Michael Christie and Helen Verran (2014), for instance, have developed the outlines of an app that can allow Aborigines and healthcare professionals to communicate much more symmetrically and beyond the concepts and values of biomedicine. Their sobering conclusion that, at the time of writing, they have not been able to secure funding to launch the application, indicates why these findings are relevant not only to the design of digital health technologies but also for their regulation. Far from being neutral arbiters, regulators and regulatory processes are infused with particular values that inform the assessment of technologies. This influences what can become a legal entity of a 'medical product' or, in my case, a *DiGA*. It grants some ontologies/epistemologies built into and enacted by digital health technologies more legal weight while sidelining others.

Moreover, the context of the design projects for digital health applications in the Global South matters as marine Al Dahdah (2019) shows. She follows the trajectory of the development of an mHealth application for women with (unborn) babies in Ghana from "[e]vidence-based to [m]arket-based [h]ealth", arguing that it is a rather typical example of "philantrocapitalism" (Al Dahdah, 2019, p. 1061). Well-intentioned public health projects turn into commercial products for markets in the

Global South. While this may be an extreme case that intersects digital health with post-colonial asymmetries, the general structure of this conflict between scientific/biomedical and monetary value might be characteristic of digital health more generally (e.g. Levina, 2017). The regulation of digital health technologies magnifies this conflict. The *BfArM* is not only the gatekeeper that decides on future reimbursability (and thus the profitability of the mHealth applications) it also needs to navigate the contradictory claims and values about clinical efficacy, user-friendliness and economic considerations that come together here.

2.2 The Regulation of Biomedicine

I will briefly leave the realm of digital health in this subsection (only to return to it later) by reviewing the literature on the regulation of biomedicine. As I have mentioned, I focus on research into the regulation of medical technologies (2.2.1) and pharmaceuticals (2.2.2).

2.2.1 Regulating Medical Technologies

Two recent encompassing literature reviews illustrate the emerging interest of the social sciences and STS into the regulation of medical technologies (Hogarth & Miller, 2021; Löblová et al., 2020). Among other things, this research asserts a "re-regulation rather than de-regulation" (Hogarth & Miller, 2021, p. 53). Relatedly, Stuarth Hogarth and Olga Löblová (2020) find that the regulation of medical technologies for diagnostics and the respective regulatory bodies have proliferated and expanded in the UK. Several, ever more specialized institutions have emerged that take over gatekeeping functions for their area of responsibility. This creates a "fragmented" system of "regulatory niches" (Hogarth & Löblová, 2020, p. 8) without more encompassing frameworks and institutions.

A crucial insight of research into practices of regulating medical technologies disproves the common understanding "that regulation 'lags behind' innovation" (Faulkner, 2009b, p. 637). Regulation does not limit innovation post hoc in the meaning of "innovation-first/regulation-after" (Faulkner, 2009b, p. 638). Instead, it creates the conditions and gateways that make innovation in biomedical technologies possible in the first place. Much of Alex Faulkner's (2009a, 2009a, 2012a, 2012b) centers around what he calls the "performativities of the law" concerning the regulation of Tissue Engineering (TE) on the level of the EU. He highlights instead that this regulation performs what it regulates. Faulkner (2012a) conducts in-depth and close readings of regulatory documents on Advanced Therapy Medicinal Products (ATMP). He finds that this regulation, on the one hand, constitutes 'fields' or "technological zones" (Faulkner, 2009b) that consist of human and non-human actors, the relations between them, temporalities, visions and expectations. In the case of the regulation of ATMP in the EU, for instance, the framework is indeterminate or, put more positively, flexible for the most part, being most unambiguous about the focus on the marketability of products, the progress they bring and the positions actors have in the process of regulation (Faulkner, 2012a). As part of this, regulation constitutes the "gatekeeping regimes" (Faulkner, 2019) that con-

trol access to the healthcare market and healthcare provision. On the other hand, it creates discursive representations and classifications that serve as structures and "maps to the world of medical devices" (Faulkner, 2009a, p. 29). They set the "boundaries of 'deviceness'" (Faulkner, 2009a, p. 29) of biomedical technologies that orient their regulation. Speaking of "deviceness" speaks to an ontological dimension. The legal classification as a "medical device" changes the status of a technology, subjecting it to legal regimes and the rights and obligations they entail.

Especially hybrids, such as TE, that cut across existing boundaries make for intriguing cases to investigate the performativity of the law. They regularly lead to conflicts and negotiations about their ontology status with far-reaching (economic) consequences. In the EU, the regulation of medical devices is far more lenient than that of pharmaceuticals based on the assumptions that medical devices carry less risk both physiologically and financially compared to drugs (Hogarth & Miller, 2021). In turn, if a hybrid technology is classified and assessed as a medical device this means fewer additional costs for developers. In this context, it is particularly noteworthy that Faulkner (2012b) identifies what he calls a "regulatory pharmaceuticalization" in the regulation of TE. The EU initially sought to make TE into a new (regulatory) category of its own because it blurs the boundaries between existing frameworks for pharmaceuticals and medical devices. Ultimately, however, TE was subsumed under the new one of "advanced therapies", leading to a "regulatory reordering by pharmaceuticalization" (Faulkner, 2012b, p. 398). From a regulatory angle, TE now is a pharmaceutical, regulated in terms of its "mode of production" (Faulkner, 2012b, p. 396). Faulkner (2012c, p. 177) calls such efforts "[s]trategies of commensuration". "Commensuration" is one way of maintaining a connection between emergent technologies and existing regulatory frameworks by creating analogies between them. As the case of TE illustrates, this is not at all a straightforward process. As part of the performativity of the law, the commensuration of tissue engineering, especially in cases where its regenerative elements are combined with medical devices – so-called "combination products" (Faulkner, 2012c, p. 176) – transforms the identities and jurisdictions of the regulatory frameworks and responsible agencies. Moreover, the commensuration of TE with the regulatory frameworks for pharmaceuticals has not cleared up the confusion caused by its hybridity. Instead, it has led to an "institutional proliferation" (Faulkner, 2012c, p. 178) of collaborations between bodies responsible for both pharmaceuticals and medical devices to grapple with the remaining uncertainties.

"Commensuration" is not the only way to react to "innovative technological fields that threaten existing boundaries of regulatory frameworks, as many of the new biomedical technologies do" (Faulkner, 2009b, pp. 644–645), however. Alex Faulkner and Lonneke Poort (2017, p. 226) argue that regulators can either "stretch" regulatory frameworks to commensurate technoscientific innovations or break existing frameworks based on "either the lack of scientific knowledge or scientific knowledge that portrays the new technology as being (very) 'different' from existing standards and modes". Their case studies illustrate that this is not inherent to the technology but rather depends on

expertise and authority. Normatively, the authors favor breaking with existing frameworks to not unduly treat new technologies with new risks and challenges with the insufficient tools of previous regulation. Moreover, they point out that the two approaches can be combined to form "'hybrid' institutional arrangements": "new law, existing institutions; inherited, adapted law, new institutions" (Faulkner & Poort, 2017, p. 223). The decision to break or stretch an existing regulatory framework is informed by different scientific, economic, regulatory or ethical expertise (Faulkner & Poort, 2017). Nevertheless, knowledge about contemporary technoscientific innovations is limited. Uncertainty about their risk makes it difficult to judge their impact and to decide on their regulation. Especially the speed of development makes the regulating biomedical technologies difficult. This is why Webster (2019, p. 5) calls to "accelerate [regulation] responsibly [which] would avoid the danger of moving rapidly to solutions without carefully knowing what the problem is and what success looks like, and what we need to do to adapt if things go wrong". He argues that the "risk-in-the-making" to which contemporary innovation contributes needs to be matched by a "regulation-in-the-making" (Webster, 2019, p. 1) attuned to the multiple temporalities and complexities of technoscience and its products.

Besides the insights on the performativity of the regulation of medical technologies, especially those that cut across existing categories, the methodological approach this research takes is fruitful for my work. Assuming "that legal texts and documents act, and have consequences, given the political provenance inscribed in them", Faulkner (2012a, pp. 767–768) conducts close readings of legislative text to identify how they constitute the outlines of the technological zones of TE, the positions of the different actors within it and the relations between them. He draws on a methodological framework that combines Lindsay Prior's approach to studying documents and Jacques Derrida's perspective on performativity, allowing him to go beyond the view that documents are merely the sediments of prior political negotiations. He calls for more research that similarly takes documents as a starting point for research on the regulation of technologies, arguing that "legislative texts and documents could be accorded a more prominent place in theorising the emergence of new biomedical and other sociotechnological fields" (Faulkner, 2012a, p. 772).

2.2.2 Regulating Pharmaceuticals

In sociological research into the regulation of pharmaceuticals, the main controversy concerns what can explain how regulatory decisions are made, especially in those cases where these decisions turned out to be harmful in the end. Very broadly, the controversy unfolds between two camps. One claims that it is a bottom-up process of patient activists calling for regulatory changes. The other argues that the industry-friendliness of regulatory agencies influences how they make decisions (I follow Davis and Abraham (2011a) in this rough classification). Still, I will also show that there may be overlaps between the two approaches and other approaches that go beyond this dichotomy.

The strand in the existing literature on the regulation of pharmaceutical regulations bears resemblance to existing STS research into the societal contextualization of scientific knowledge. The cases of the French Association of Neuromuscular Disease Patients (Callon & Rabeharisoa, 2003, 2008) and the activism of the ACT UP group in the 1990s (Epstein, 1995, 1996) demonstrate how activists exerted pressure to change regulations. Especially AIDS activists have had a far-reaching impact on how pharmaceuticals are assessed and when they may enter the market. They have, for instance, achieved admission of real-life data to prove clinical efficacy besides the standard of the RTC and changes to the conditions for participating in clinical trials. They have also enforced an accelerated approval of drugs for life-threatening diseases after the second phase of clinical trials (Epstein, 1995, 1996; Pinch & Collins, 1998). This success has led to an "upsurge of health-related activism" (Epstein, 1995, p. 428) in the US other groups have assembled around disease entities and demanded changes to the research and regulation of pharmaceuticals.

Other research focusing on the mechanics of regulation more narrowly resembles these findings. Arthur A. Daemmrich and Georg Krücken (2000) and Daemmrich (2004) have conducted comparative analyses of the German and the US-American contexts of regulating pharmaceuticals. For Germany, they find a "neo-corporatist" (Daemmrich & Krücken, 2000, p. 507) institutional setting of close collaboration among relevant stakeholders. Although medical professionals have traditionally held a powerful position in this process based on the claim that they speak in the name of 'the patient', there is no centralized authority, no real boundary between marketing and review and decisions are usually made consensually without public scrutiny. The predecessor of the BfArM, the Bundesgesundheitsamt, as the authors show, has only been endowed with the task of testing the safety and efficacy of drugs before marketing in the wake of the Thalidomide scandal in the 1960s and only after years of discussion (Daemmrich & Krücken, 2000). In the US, things look differently. Here, the Food and Drug Administration (FDA) is the sole gatekeeper to the first healthcare market and its work is under the scrutiny of the US Congress. This has allowed decisions by the FDA to become politicized and called into action patient activist groups. Other articles often cite Daemmrich (2004) as a representative of the disease politics strand. Nevertheless, his concept of "therapeutic cultures" as the "relationships among the state (including legislatures and regulatory agencies), the pharmaceutical industry, the medical profession, and disease-based organizations" (Daemmrich, 2004, p. 4) suggests that the predominance of disease-politics remains contingent on other, broader contextual factors. This reasoning would put him closer to the premises of the "corporate bias" variant of regulatory capture which I will discuss below. However, *normatively* he seems to favor disease politics and the integration of patients into regulatory decision-making. In the concluding discussion on the role of national therapeutic cultures in efforts of global harmonization he argues that "greater accommodation of patients' perspectives must be an integral part of the policies promoted by international agreements" (Daemmrich, 2004, p. 18).

There are variants to the disease politics argument. Daniel P. Carpenter (2004) argues that the FDA is interested in sustaining and enhancing its reputation, influencing its decision-making.. In this sense, he asserts a “trade-off” (Carpenter, 2004, p. 53) between risk and reputation. When making decisions, the FDA always considers the impact a wrong decision could have on its reputation with different stakeholders, chief among them patients. It is “patients, more than pharmaceutical firms, [who] shape the political costs to the FDA of delaying drug approval” (Carpenter, 2004, p. 52). Thus, in this variant the influence of patients on drug regulation is not immediate through direct action and lobbying but indirectly through the incorporated concerns about securing its reputation with the FDA.

While this strand of explanations may seem normatively appealing – after all, it is the age-old story of publics becoming organized to push through their interests against opposing forces – I should note that this is not uncontroversial. Epstein (1995) has already shown that the success of AIDS activsts was based on particular cultural and social resources that other groups do not have. The consequences of such asymmetric participation may then further the exclusion of already marginalized groups (Benjamin, 2013). The participation of lay publics in science and regulation, therefore, raises questions of who benefits from such participation (and its success), when and under what conditions. Additionally, it illustrates the performativity of regulation, yet again. Ruha Benjamin’s (2013) research on the California Stem Cell Research and Cures Initiative in 2004 shows that ‘the people’ in the will of whom this initiative that aimed to also contribute to the development of new drugs was passed was rather one dimensional – white, economically well-off, desiring to overcome the respective disease through stem cell research.

The regulatory capture or corporate bias approach to regulation is diametrically opposed to the disease politics approach. While they “are not entirely incompatible” – and indeed I will point to contributions that seek to connect them in one way or another below – “the differences in emphases regarding the dominant actors and interests served are stark and unmistakable” (Davis & Abraham, 2011a, p. 734). For instance, in this approach, the evocation of patient needs and demands, in the sense of disease politics, is merely rhetoric to justify regulatory reforms (Mulinari & Davis, 2020) or supported by and therefore at least indirectly in the interests of the industry (Davis & Abraham, 2011a). It instead essentially argues that decisions by regulatory agencies are heavily influenced by or heavily skewed towards industry interests – at times to the detriment of patient interests. Much of this research operates through cross-country comparisons of the regulation of particular drugs to unearth the mechanisms at play. These mechanisms may be “paradigms” (Abraham & Davis, 2007) or “principles” (Abraham & Davis, 2009). Paradigms are “mediating factors between political culture and structural interests, on the one hand, and the outcome of regulatory science (including deficits), on the other” (Abraham & Davis, 2007, p. 399) that can explain why non-steroidal anti-inflammatory drugs (NSAIDs) were regulated differently in the US and the UK. While in the UK, close ties between industry and the regulatory agencies sparked enthusiasm and an ali-

gnment of interests, Congressional oversight over the FDA inhibits such alignments. Nevertheless, paradigms are not static. Scandals over adverse effects may lead to evolutionary shifts and transform regulation incrementally (Abraham & Davis, 2007). Likewise, Abraham and Davis (2009, p. 570) find what they call a “permissive principle” in both the UK and the US, the “tendency to permit a technology on the market even if it does not meet established standards of efficacy (and/or safety)” (Abraham & Davis, 2009, p. 570). In the cases they investigated, the respective regulatory agencies granted an antidepressant market access although the submitted clinical trials did not meet the necessary standards. In the UK, this was again favored by close ties between industry and the regulatory agency whose officials identified with the pharmaceutical companies and the costs they have to bear throughout the production and regulation of the products.

In the US, political pressures to increase the number of approvals favored this more permissive approach. Unlike classical regulatory capture, in which industry-affiliated officials of regulatory agencies work in the interest of pharmaceutical companies (Posner, 2014), corporate bias or cultural capture theory suggests that it is instead the broader political environment that favors industry interests (Abraham & Davis, 2013; Mulinari & Davis, 2020). Especially in recent decades, “the pharmaceutical industry has gained unprecedented, privileged access to the state in the EU and the US, enabling it to work in collaboration with its allies in the executive and legislative branches of government to bring about regulatory reforms in its commercial interests” (Abraham & Davis, 2013, p. 259). This allows companies to claim it is the “will of Congress” (Mulinari & Davis, 2020) that their drug is approved faster. The industry-friendly political context all but forces the FDA to “adopt[.] a conciliatory and cooperative approach to companies” (Mulinari & Davis, 2020, p. 164) and work to approve pharmaceuticals even if they lack the necessary clinical evidence.

Regulatory capture may work in two ways (Carpenter, 2014). First, it takes the form of cartels that split the market among themselves. Regulation therein serves to secure advantages for early movers and raise the bar for later entrants. As Carpenter (2014) argues, the more common form in recent years has been that of “corrosive capture”. Here, the hurdles regulatory frameworks set up are lowered, review times decreased and approval rates increased. This is the result of a cultural capture as “political organizations of the global pharmaceutical industry have come to shape the conversation about how drugs ought to be regulated" (Carpenter, 2014, p. 164). A crucial part of this culture is the fees for the services of regulatory agencies that increasingly see applicants as customers.

This strand of the literature has also developed an alternative perspective of accelerated approvals of pharmaceuticals. While the disease politics approach conceptualizes these as the result of successful patient advocates, the regulatory capture approach understands them as yet another instance of industry-friendly transformations. Historically, such accelerated approval processes have existed before disease-based movements following deregulatory efforts by the Reagan and Clinton administrations. Therefore, accelerated approvals are in many cases the result of “organisational

pressures from FDA management" (Davis & Abraham, 2011a, p. 742) rooted in a wider deregulatory environment. Their mere existence creates the pressure to assess pharmaceuticals more rapidly. In additon, labeling a drug a 'significant breakthrough' that is supposed to warrant such accelerated approvals has been used without the necessary scientific evidence to back it up (Davis & Abraham, 2011b).

But it would be wrong to reduce the literature on the regulation of pharmaceuticals to these two principal strands and their various ramifications. Other research has investigated the role of trust. On the one hand, this concerns trusting the mechanisms of regulation. Henk Bodewitz et al. (1987/2012) argue that trust in RCTs to assess clinical efficacy results from a historical consensus, not from their capacity to produce rational and objective knowledge. By contrast, due to the lack of historically grown standards, there is no similarly accepted method to determine the safety of drugs. The "existing structure of the social system of medical care determines the way in which medical technology becomes assessed scientifically" (Bodewitz et al., 1987/2012, p. 245) and trust is allocated. Only in this way does it become possible that the "registration process" for pharmaceuticals "formally constitutes certain substances as (legalized) drugs" (Bodewitz et al., 1987/2012, p. 238). From today's point of view, however, this finding may have run its course: As other researchers have argued the RTC as the standard for assessing efficacy has come under "crossfire" (Rosemann, 2019; see also Hedgecoe, 2017; Sariola et al., 2019) for a variety of reasons.

On the other hand, research has highlighted the dynamics of trust within regulatory processes. Concerning the relationship between regulatory bodies and manufacturers, this trust may either be "investigative" or "acquiescent" (Abraham, 2008, p. 420). In the former, regulatory agencies conduct their own investigations of the data submitted by manufacturers. In the latter, they accept the submitted data without further investigations and even if they do not meet the requirements. This relationship of trust is particularly interesting for accelerated approval processes where regulators have to trust that the surrogate endpoints reliably project medical benefits and that manufacturers will conduct the required post-marketing trials (Abraham, 2008). Concerning the relationship among regulators, trust is crucial to the success of regulation as an interdisciplinary process. Regulators need to trust each other's expertise (P. Brown et al., 2016) and integrity (Abraham, 2008). This raises questions of *what* or rather *who* is the object of regulation. If trust in individual or collective actors is a necessary component of regulatory decision-making, especially in accelerated approval processes, the assessment is as much one of the actors as it is of clinical trials. Trust may even be *crucial* as clinical trials are likely to suffer from what STS authors call the "experimenter's regress" (Collins & Pinch, 1998) and require 'external' mechanisms for the closure of controversies (Daemmrich, 2004). Nevertheless, these contributions investigate the "chains of trust" (P. Brown et al., 2016, p. 106) only in one direction from regulators to manufacturers (or within the agency) but manufacturers also need to place trust in the regulatory agency (e.g. that their submission will be processed in time and in a fair way).

2.3 Regulating Digital Health

At least in the social sciences, research into the regulation of digital health is scarce. This may be because the "digital health ecosystem" (Marelli et al., 2020) and research into it are only emerging. This also concerns regulation. Most digital health technologies are unregulated (Rich & Miah, 2017) or, at least, regulatory frameworks specifically for such technologies are lacking. There may be multiple reasons for this lack. On the one hand, it is due to the imaginaries of digital health technologies that I have looked into above. Alan Petersen et al. (2019) suggest that these are often informed by technodetermist presumptions. If we think of digital technologies and digitalization as developing by their own logic, it will inevitably seem "difficult, if not impossible to resist or adequately regulate them" (Petersen et al., 2019, p. 379). This framing inevitably also precludes democratic deliberation about the values and ends (among other things) of digital health, even though broad public participation is crucial to its success (Petersen et al., 2019; Vayena et al., 2018).

On the other hand, regulating digital health and mHealth technologies is difficult because they occupy an interstice "between medical devices and consumer products" (Lucivero & Prainsack, 2015, p. 47). Susi Geiger and Hans Kjellberg (2021) have analyzed this in terms of a "combinatorial market innovation". Digital health technologies connect the healthcare and technology markets, creating hybrid actors, products, modes of exchange, representations (e.g. promissory discourses) and market norms (Geiger & Kjellberg, 2021). The moniker of Digital Health Applications as "prescription apps" nicely illustrates this on the level of modes of exchange and market representations. Similar to the example Geiger and Kjellberg (2021) provide, they combine using an electronic access code with the traditional medical model of a prescription. As hybrid products, *DiGAs* and other digital health technologies fuse "core characteristics of medical products (clinical and regulatory validation) and technology tools (shortened R&D cycles, user-centric designs)"(Geiger & Kjellberg, 2021, p. 452).

Regulating such hybrid technologies and markets is not straightforward. Policymakers and regulators face the dilemma of either leaving apps straddling the boundary of medical devices and lifestyle technologies unregulated – potentially risking detrimental outcomes –, or regulating them, jeopardizing innovation and market potential (Lucivero & Prainsack, 2015). Frederica Lucivero and Barbara Prainsack (2015) envision an alternative regulatory framework that embraces the regulatory ambiguity of digital health apps by regulating them in terms of use rather than inherent qualities or functionalities. However, they do not explain how to anchor this degree of flexibility institutionally. Additionally, the situation has changed in the meantime, at least in the EU. The Medical Device Regulation (MDR) has extended the concept of medical devices to include software products. The German *Digitale-Versorgung-Gesetz* goes one step further by granting apps access to the healthcare system, thus adding a further layer of regulation.

In addition to the puzzling position that digital health technologies occupy, recent contributions to the literature have questioned whether established regulatory approaches for technologies are

even “fit for [the] purpose” (Marelli et al., 2020) of regulating digital health technologies. This has an obvious temporal dimension. If technological developments have outpaced legislation (Rosa, 2013), this is especially true for digital technologies. For them, what Cynthia Selin (2011, p. 724) writes about “[e]merging technologies such as nanotechnologies” more generally is true: “They are outpacing regulatory structures, political responses, educational systems, and the leveraging of social choice”. They allow for rapid development cycles of just a few weeks that are much faster than those of other industries in the healthcare sector, such as pharmaceuticals (Geiger & Kjellberg, 2021). Therefore, Heilien Diedericks (2019, p. 66) concludes in her analysis of the digital pill AbilifyMyCite that regulation “lags behind a rapidly evolving digital health sector”. In this case, the possibility to quickly update the software has enabled the developer to slip through a regulatory loophole so that they did not need to provide clinical evidence for added functions, only prove the “substantial equivalence to another legally U.S. marketed device” (US Food and Drug Adminstration, 2020). But newer regulatory frameworks, developed against the backdrop of digital transformations, may not be up to the task, either. The General Data Protection Regulation (GDPR) in the EU, for example, aims to respond to the challenges of digital technologies but when compared with the “societal reconfigurations” (Marelli et al., 2020, p. 450) these co-constitute in healthcare it remains lacking. To a large extent, this is because the GDPR “is still predicated on standards that have their roots in past generations of data protection regulations” (Marelli et al., 2020, p. 452) and the technologies and risks to which these regulations responded. Nevertheless, the GDPR only speaks to one dimension of digital health technologies, data and privacy, while others and the challenges they pose remain out of focus.

In this context, Germany’s regulation of Digital Health Applications may be a fruitful object of research into the regulation of digital health technologies. It offers a more encompassing framework that addresses data and information security but also user-friendliness and clinical efficacy. Before it came into force, the discussions in the literature were somewhat similar to Marelli and colleagues’ reading (2020) of the GDPR. Two years prior, Martin and Melanie Bierbaum (2017) have asserted that the existing regulatory frameworks for medical apps do not include all dimensions relevant to evaluating smartphone apps used for medical purposes. Socio-technical questions of usability and user-friendliness, for example, have been left out. On the other hand, they doubt whether the temporal rhythms of regulation can match the rapid development cycles of digital apps.

These discussions only conceptualize regulation in its prohibitive dimension, trailing innovation in the vain attempt of catching up. But regulation can also have constitutive effects (Faulkner, 2012a). This is especially true for digital health, as Elisa Lievevrouw et al. (2022) have recently pointed out. They argue that “policy events in the US in the aftermath of the financial crisis of 2008 and the Patient Protection and Affordable Care (ACA) Act have constituted an 'assemblage' [...] that opened a favorable window of opportunity for DHT to emerge” (Lievevrouw et al., 2022, p. 15). On the one

hand, the monetary policy in response to the crisis created financial incentives to invest in digital health as a potentially profitable business enterprise. On the other hand, the large-scale reforms favored the use of new methods and technologies to improve the efficiency of healthcare. Interestingly, the authors suggest that promoting digital health technologies was not the goal of such reforms but rather a by-product. In Germany, while the digitalization is embedded in broader transformations of the healthcare system, the adoption of digital health technologies, especially Digital Health Applications has been a targeted process (Bandelow et al., 2020). Thus, this case may offer a striking contrast and respond to Lievevrouw et al.'s (2022) call to investigate the role political cultures and imaginaries play in the emergence of digital healthcare in other countries. Different points of departure shape how countries relate to digital health and its challenges (Vayena et al., 2018).

Finally, two contributions have focused on the regulation of digital applications for healthcare purposes more narrowly. Maike Janssen (2020) tells the story of a development project for a digital health app that tried to avoid its classification as a medical product at all costs. This classification would have changed its status and subjected it to the requirements of the regulatory social world, further expanding its circulation as a boundary object that ties together social worlds with conflicting values and perceptions. The developers circumvent regulation by "black-boxing" (Janssen, 2020) clinical functions by turning them into additional features that clinical customers can acquire and submit to regulatory assessment themselves. In the second contribution, Lievevrouw and colleagues (2021) investigate how digital health apps have become an object of regulation under the purview of the FDA. They describe this as a co-productive process in which digital health and its regulation mutually define each other. Confronted with controversies about the legal status of digital apps for medical purposes, the FDA deviated from previous regulations and developed a framework tailored to such apps. This framework introduced a distinction between lifestyle and medical products which "restricted the 'pool' of health applications and devices presented as 'medical' digital health applications", making the label as a medical app a "quality brand" (Lievevrouw et al., 2021). In this context, the necessary medical trials not only prove efficacy and safety but also become a rhetorical tool for marketing and distinguishing apps (Geiger & Kjellberg, 2021). On the other side of the co-productive relationship, the regulatory framework transforms the identity of the FDA. Vis à vis digital health apps, it takes the position as an "innovation enabler" rather than a "safety watchdog" (Lievevrouw et al., 2021). This is also reflected in the admission of real-world data and the expertise of big tech corporations as evidence. Nevertheless, this has been a process of "slow rapprochement" (Geiger & Kjellberg, 2021, p. 453) between developers and regulators. The former had to become familiar with the mechanics of the regulatory process. The latter had to consider the specificities of digital health technologies.

2.4 Summary and Research Questions

I want to use this overview of the existing literature on digital health and regulation as a point of departure for developing the questions that drive my own research project and situating them at the intersection of the two strands I have reviewed. This will be the foundation for the following sections in which I will sketch the theoretical framework and the methodology I will use to answer these questions.

My overarching research question is inspired by the "proto-idea" (Fleck, 1979) that I had when I first came across Digital Health Applications. As I have written in the introduction, what intrigued me was the approval process and how it apparently creates a distinction between *DiGAs* and all other apps for health. Only the former become part of the regular German healthcare provision as a reimbursable service. Attentive to how this transformation is possible, I thus ask:

MQ: How does a health-and-wellness app become a Digital Health Application through the approval process at the BfArM *introduced by the Digital Healthcare Act in Germany*?

The literature on the regulation of pharmaceuticals implies that regulatory processes matter and make a difference. Bodewitz et al. (1987/2012), for example, argue that regulation is what separates a legal from an illegal drug. The difficulty digital health technologies pose because they cut across the boundary of lifestyle products and medical devices also suggests that an unambiguous classification as a medical device would differentiate them from 'mere' lifestyle products (Lucivero & Prainsack, 2015). Similarly, the classification as a medical device is a potentially financially rewarding distinction from competing offers (Diedericks, 2019; Lievevrouw et al., 2021). The special status of legally-defined medical devices also is why some developers seek to avoid it as much as possible (Janssen, 2020). Thus, the literature indicates that *something* happens when a (digital health) technology enters the legal domain. Still, this is only ever indirectly acknowledged or, perhaps, tacitly presupposed. With my main research question, I seek to unpack this unspecific *something* in the regulation that effectuates the baffling transubstantiation of an app to a legally-approved, reimbursable Digital Health Application.

Three subquestions will help me to address this overarching question. The first of these concerns the approval process itself. Therein, I ask:

SQ1: How is the approval process organized and what is its infra-politics?

In their work on pharmaceuticals, Abrahams and Davis (2013) have clearly shown the importance of conducting situated research on regulatory processes because their micro-dynamics shape decision-making. I want to follow up on this with a similarly situated approach that takes into account the experiences of manufacturers that have undergone the approval process. With this question, I

depart from the literature on the regulation of medical devices (e.g. Faulkner, 2009b, 2012a). This research has drawn on legislative documents to understand the creation of technological zones. In my view, this approach underestimates the role of regulatory agencies that implement legislation and, thereby, wield considerable power. By asking this subquestion, I want to understand the role the different actors, human or non-human, play in the approval process the *BfArM* organizes. The second part of this subquestion points to the fact that this organization is not neutral and seeks to uncover the implicit, yet powerful politics at play.

The second subquestion speaks to much of the existing literature on digital health. With my thesis I want to answer the question:

SQ2: What are the expectations of digital health that inform the approval process and how does the regulatory agency relate to the representations around digital health technologies/apps?

My literature review has shown that digital health technologies are difficult to define. Attempting to capture *all* variations of digital health – for instance, the four that Marent and Henwood (2022) identify: telemedicine, eHealth, mHealth and algorithmic medicine – the definitions end up very broad and delineate only a rough field. Perhaps this is why much of the literature has extensively analyzed digital health as a vision, promise or hype. I have argued that regulation often plays only a secondary role in these contributions. Mostly, it figures as an inhibitor that curbs the initial enthusiasm. With this question, I seek to keep the relationship between promissory discourses and regulation open and try to understand how the *BfArM* imagines digital health and its own role in this context.

With my final subquestion, I aim to capture the hybridity of digital health and the challenges it poses in more detail. Therefore, I ask:

SQ3: How are different types of expertise drawn together during the approval process?

In regulation, various types of knowledge come together and it is an open question which expertise is most important (Faulkner & Poort, 2017). This is especially the case for digital health as a “mash up” (Geiger & Kjellberg, 2021) of the market for digital technologies and medicine. The literature has shown, this has led to several hybridizations between the two that, in turn, created tensions with existing regulatory categories. With my third subquestion, I aim to attend to the confluence of expertise of, at least, digital technologies and biomedicine. I will first look into the types of expertise and then, second, the relationship between them. This way, I will also be able to address potential conflicts and the hierarchization of expertise.

In the next step, I will continue by developing the theoretical framework to address these questions through my empirical material.

3 Theoretical Framework

In the beginning of this project, I had a very disparate set of concepts that did not really fit each other and would have led my research into all kinds of directions, without any hope of bringing everything together. However, over the last couple of months, I have come to think of my theoretical framework as a Russian doll where opening the outer doll reveals another, smaller doll that can itself be opened and so on. In this metaphor, Latour's Inquiry into Modes of Existence (AIME) is the outermost layer (3.1). It is the overarching framework of my research because it allows me to conceptually rephrase the initial hunch that drove my interest from the beginning. But once I got more familiar with AIME and dove into the literature, I inevitably ran into difficulties that posed a challenge for my analysis. Thus, I also draw on the Sociology of Conventions and Testing (3.2) that allowed me to respond to these gaps and forge a potentially fruitful theoretical connection between the two research programs, all while staying true to both their original impetus (or so I hope). With the Sociology of Conventions and Testing I can theorize the approval process for Digital Health Applications as a socio-material practice of testing that has a particular political dimension. But there was another gap here as well: Of what kind is this politics? This led me to the concept of "ontological choreography" to be able to consider how the approval process brings together entities from different modes of existence. In this section, I will unpack the different layers of this Russian doll-like theoretical framework from the outside to the inside.

3.1 An Inquiry Into Modes of Existence

Before I can really get started, I need to rehearse some of the crucial tenets of Actor-Network Theory (ANT) again because it informs AIME to a large extent. Of course, this is no easy task. On the one hand, ANT is not and does not want to be a full-fledged theory (Latour, 1999b). On the other hand, ANT is so heterogeneous that it is barely possible to identify it as a clearly delineated approach.. Latour (2005, p. 96) infamously limits the scope of his version of ANT and STS to his own office. Therefore, I will not even feign to give a comprehensive overview. I instead cherry-pick those components of ANT that re-surface, more or less explicitly, in AIME and are relevant to my own approach here. .

The first of these tenets is that ANT refuses any a priori boundaries, be this between 'nature' and 'the social' or between different domains of 'society' (Latour, 1993). Any ethnographic visit to the laboratory will reveal that doing science means constantly cutting across such boundaries. Doing science and technology "means mixing hydrogen bonds with deadlines, the probing of one another's authority with money, debugging and bureaucratic style" (Latour, 2003, p. 6; Latour & Woolgar,

1986). As we will see in a little bit, this tenet allows ANT to follow the actors in science and technology. But it also creates new problems to which AIME seeks to respond. The second tenet that is important in my context directly follows from the first one. If there are no a priori boundaries between 'society' and 'nature' or between different 'societal domains' it is impermissible to speak of them using different vocabularies as if they were (ontologically) distinct. This is the meaning of the "generalized principle of symmetry" (Callon, 1984). While the first principle of symmetry states that 'true' and 'false' scientific statements should be explained using similar vocabularies (Bloor, 1991), the *generalized* principle of symmetry demands the same for describing humans and non-humans. The second tenet that non-humans can have agency is one of the key characteristics that has set ANT apart, and has indeed entailed much resistance, from other sociological approaches (e.g. Johnson, 1988; Michael, 2016). ANT seeks to describe the "multiplicity of objects any course of action mobilizes along its trail" (Latour, 2005, p. 72). To be sure, this does not mean that non-humans essentially have agency, as a sort of vitalist capacity. The ontology of ANT is strictly relational. This is the third tenet. Actors, be they human or non-human, only exist through and within relations with other actors. Delineating it from substantialist ontologies, Latour (2011, p. 312) calls this "*l'être en tant qu'autre* […] being qua another". This relationality avoids assuming a fixed and pre-given identity of actors. On the contrary, actors only emerge together with and as part of actor-networks. Finally, this relational ontology is also flat which not only means that ANT seeks to deconstruct the dichotomy of structure and individual agency but also that it rejects 'power' as an explanatory category. Actors can *be(come)* powerful but this is a matter of empirical description. To capture such processes, Callon (1984), for instance, has coined the concept of the "obligatory passage point".

3.1.1 From ANT to AIME: Ordering Heterogeneity

> *"So they're right, those who say there is something missing when you say there are no domains: there are, but the question is how do you register them"* (Tresch, 2013, p. 309)

Given these tenets, where and how does AIME come in? Of course, I cannot disentangle the intricate relationship between these two conceptual frameworks or research programs in the scope of this thesis, especially since the literature that has discussed this issue more thoroughly covers the whole spectrum. On one end of this spectrum, some authors claim AIME signals a renunciation of ANT, especially its rejection of any a priori ontological assumptions (Latour & Marinda, 2015). On the other end, other authors see AIME as a continuation of Latour's work from the very beginning and of the tenets of ANT, although they concede that AIME responds to some of its criticisms (Edward, 2016; Kneer, 2016; Laux, 2016; Tummons, 2021a, 2021b). Latour himself has previously emphasized that AIME has been a project he has pursued his entire (intellectual) life and created a linear narrative of its development (Latour, 2013b). In my reading, the one I want to use in this the-

sis to make sense of the regulation of Digital Health Applications, I will follow Nora Hämäläinen and Turo-Kommo Lehtonen (2016). They move the problem of the dis/continuity of Latour's work to a different level. AIME, their argument goes, primarily continues ANT's pragmatic approach to metaphysics. Neither ANT nor AIME seeks to make definite statements about what the world is. They merely provide the conceptual and "metaphysical tools" (Hämäläinen & Lehtonen, 2016, p. 26) to produce descriptions of empirical situations relevant to the actors themselves. Correspondingly, they need to be evaluated regarding their "*functionality*, the way they work" (Hämäläinen & Lehtonen, 2016, p. 31). Thus, I can avoid an ontological misunderstanding, a categorial error in the reception of AIME. Many reviewers of Latour (2013a) seem to impute on him to develop an abstract metaphysical system (Hämäläinen & Lehtonen, 2016). I will admit that there are good reasons for this, not least the fact that Latour (2013a) only indirectly refers to the empirical studies that AIME draws on (Laux, 2016) and that he draws up a seemingly finished table for his categorial framework (Latour & Marinda, 2015). Against this, we should keep in mind that Latour's entire work and AIME in particular is an "*empirical* metaphysics" (Hämäläinen & Lehtonen, 2016, emphasis added).

In this pragmatic sense, I read AIME as the positive response to Latour's (1993) argument that "we have never been modern" because the clear-cut separation between nature and culture on which this illusion had rested never existed in practice. This raises the question: "If we have never been modern, then what has happened to us? " (Latour, 2013a, p. 11). In AIME, Latour (2013a) sends an anthropologist on an expedition to continue the project of an anthropological investigation of those who deem themselves 'modern' to answer this question. The anthropologist in this story is well-versed in ANT and does not accept the self-description of the moderns, that their world is separated into nature and culture and their society consists of "tidy compartments where you will find only science, only economy, only social phenomena" (Latour, 1993, p. 2). We have seen that ANT allows doing this quite well by following how practices routinely deconstruct such boundaries. But the anthropologist also recognizes that the Moderns hold on to particular values that, they argue, distinguish different networks. This brings the anthropologist into a dilemmatic situation. On the one hand, the network perspective has allowed her to go beyond the concept of neatly separated domains. On the other hand, this same perspective cannot capture *any* differentiation between networks. Classical actor-network theory only allows saying "almost the *same thing*" about every network, "namely, that they are 'composed in a heterogeneous fashion of unexpected elements revealed by the investigation'" (Latour, 2013a, p. 35).

In my understanding, this is the point of departure of AIME. It seeks to capture the differences between the networks that the Moderns *value* without falling back behind the insights of ANT. To do so, Latour (2011, 2013a) develops the concept of "modes of existence" – as a conceptual tool or lens, to be sure – drawing on the works of Étienne Souriau (Souriau, 1943/2015) and, to a lesser extent, Gilbert Simondon (Simondon, 1980/2017). This concept has been the crux of the matter that has contributed to the (metaphysicalizing) misunderstandings of AIME. With it, Latour seeks to

make an *ontological* argument about a plurality of modes of existence. The Moderns' values are about different ways of *being*, rather than ways of *speaking* of the same thing (Latour, 2011, 2013a).

Each of the 15 modes of existence that Latour (2013a) presents consists of four (or, depending on the counting. five) components (Laux, 2016; Tummons, 2021a). The first is a peculiar "hiatus" (Latour, 2013a). Here, "the roots of the more familiar Actor-Network Theory […] can be most clearly seen" (Tummons, 2021a, p. 573). In the relational ontology of ANT, an entity can only exist by going through another entity ad infinitum. This introduces discontinuities into its existence. What distinguishes the different modes from one another is how particular "passes" or "trajectories" bridge these discontinuities (Latour, 2013a; Tummons, 2021a). Every mode of existence, in other words, has a unique way of connecting distributed and heterogeneous entities. These connections are not random or coincidental. They come with peculiar conditions of in/felicity as the second component of every mode of existence. Here, Latour draws on John Austin's (1962) theory of speech acts. Like speech acts, albeit under ontological auspices, modes of existence need to fulfill particular conditions to be successful. Latour (2013a, p. 18) calls these "types of veridiction" specific to the respective mode. If the practices meet the conditions of in/felicity the particular entities of the mode of existence under consideration are instaured. "Instauration" is another concept that Latour borrows from Souriau. It designates the mutual emergence of the entities as no single entity has ontological priority. This allows Latour to go beyond the idea of constructivism that, at least metaphorically, implies the existence and action of a preceding creator – the notorious 'prime mover' of ANT (Latour, 2011; Stengers & Latour, 2015). "To say of a work of art that it is 'instaured' is to prepare oneself to see the potter as one who welcomes, gathers, prepares, explores and invents —just as one 'invents' a treasure—the form of the work" (Stengers & Latour, 2015, p. 21). This means that each mode of existence instaures entities unique to it. However, it does not mean that entities are essentially of one mode of existence. Instead, they can circulate through different modes and take different shapes depending on how they become instaured. Following a mode of existence is "to draw our attention to the particular formations of actors (non-human and/or human) that pertain to the mode in question" (Tummons, 2021a, p. 574). Finally, then, each mode is characterized by the particular ways it differs from other modes of existence – what Latour (2013a) calls "alterations". This is particularly relevant for the "crossings" (Latour, 2013a) between modes of existence. These do not come neatly separated (as if we could think about the 'domains' from the Moderns' self-description again) but are intricately entangled. The problem then becomes separating the different modes without committing "category mistakes" (Latour, 2013a, p. 48), mistaking one mode of existence for another. Examples of such errors would be treating fictional documents (in the mode of [FIC]) as if they were reports about the 'real' world (in the mode of [REF]) or mixing up the reference to the world in scientific practice ([REF]) with the world as reproduces itself ([REP]). AIME seeks to make visible the conflicts between the different modes of existence as they

continuously cross and provide a language for diplomatic negotiations between them, e.g. morality and technology (Latour, 2002, 2013a, 2014).

I have described a peculiar crossing of modes of existence in this section, namely the one between [NET] and [PRE]. [NET] is the remnant of ANT within AIME. 'Network' is part of AIME's conceptual language. But networks "are really just one, somewhat heterogeneous mode of existence" (Tresch, 2013, p. 304). [PRE] is AIME's technical abbreviation of "preposition" as a mode of existence. "Prepositions" are the "interpretive key" of a mode of existence and "offer[.] the type of relation needed to grasp the experience of the world in question" (Latour, 2013a, p. 57). "[T]he preposition prepares the position that has to be given to what follows, giving the search for meaning a definite inflection that allows one to judge its direction or vector" (Latour, 2011, p. 309). Thus, it is the peculiar relation between two heterogeneous entities in a network that establishes the mode of existence. It allows understanding these entities as 'judicial', 'scientific' or 'religious' despite their heterogeneity. The crossing of [NET] and [PRE], therefore, notes the elementary form of any mode of existence, the associations of heterogeneous entities that cut across any pre-established boundaries of (ontological) domains and the particular type of relation between these entities that makes them recognizable as belonging to a mode of existence. In the following subsection, I will add some flesh to this conceptual skeleton by looking into the specificities of the law as a mode of existence, [LAW].

3.1.2 A Latourian Approach to the Law as a Mode of Existence

The law has a special significance for AIME. On the one hand, Latour's (2010) ethnography of the *Conseil d'État* includes the first systematic attempt to compare modes of veridiction, science and the law, introducing some of the concepts that figure more prominently in AIME. He foreshadows this work as part of a "broader project of an anthropology of Western forms of veracity applied to the particular case of law" (Latour, 2010, p. 253). On the other hand, the law is a peculiar case because it has "resisted much better than all the other modes the crushing weight imposed by an exclusively epistemological definition of what true and false really mean" (Latour, 2015, p. 332). In other words, unlike most other modes of existence, [LAW] has avoided "double click", the "bad guy" in AIME, the "illusion that we can go back and forth between objective, detached knowledge and the world" (Tresch, 2013, p. 310). This would have denied the law its own way of producing *legal* truth and conceptualized it as something that exists objectively (e.g. in terms of natural justice) (Latour, 2004). Instead, "law is *itself its own metalanguage*" (Latour, 2010, p. 260). Therefore, it would be void to explain the law and reduce it to social forces in a critical-sociological approach (Latour, 2004, 2010, 2013a). It would also be futile to expect too much from the law, for instance, as a bulwark against totalitarian ambitions. This would be just another of the "category mistakes" I have mentioned above. At the same time, this tension allows us to see the delicacy of the approval process more clearly. Developers likely expect other things from the law because, for them, their

app has previously not (primarily) existed in a legal mode. In a first approximation, Latour's approach to the law requires sensitivity to potential conflicts that arise in my material.

But what is the specificity of the law as a mode of existence? As promised, I will go back to the conceptual skeleton summarized above. Before that, it is vital to emphasize that Latour's approach to the law focuses on practices, "*le droit tel qu'il se fait* rather than *le droit tel qu'il se pense*" (Pottage, 2004, p. 256). This keeps him from the temptation of accepting how those working in the legal institutions define the law at face value. The whole problem that AIME seeks to address is that the Moderns lack the proper language to describe the metaphysics they practice[2] (Hämäläinen & Lehtonen, 2016). So what are the four components of each mode of existence in the case of [LAW]? Saying there is a hiatus is almost repetitive for all the reasons outlined above. ANT has successfully established that entities exist only in relation to other entities. Nevertheless, pointing this out is also necessary to highlight what distinguishes Latour's approach from other approaches, especially that of his 'arch-enemy', Niklas Luhmann. The law is not a system, sphere or domain sealed off from its environments. There is a "constant influence on the decisions of many extra-judicial elements" (Latour, 2015, p. 339). In addition, the hiatus in the legal mode of existence takes a peculiar shape. We find "on one side, cases, 'facts,' feelings, passions, accidents, and crises, and on the other, texts, principles, and regulations" (Latour, 2013a, p. 364). To apply this to the case at hand, we will find health-and-wellness apps and their manufacturers with specific expectations, hopes and ambitions on the one side and the requirements that the *DiGAV* and the *BfArM* specify. The (legal) ground connects these very disparate entities. It extracts what is legally relevant from the case and the pertinent provisions from the body of legal text. This two-fold extraction is the task in legal procedures where lawyers and, later on, judges engage in a work of "grounding" (van Dijk, 2015, p. 178), that is, creating connections between both sides of the hiatus to establish the particular trajectory or "passage of law" (Latour, 2010, passim).

The work of grounding has particular conditions of in/felicity, of course. In this sense, there is an interesting transformation in Latour's account of the law that must have occurred sometime between the ethnography of the *Conseil* and the writing out of the program of AIME. In the latter, "hesitation" is the only condition of in/felicity. "Has it been well judged? Yes, provided that there has been sufficient *hesitation*" (Latour, 2013a, p. 367). In the former, things are more complicated. Latour develops a long list of "value objects" (Latour, 2010, p. 127f.), a concept from semiotics: A value object circulates through and animates the plot. This is a concept from semiotics: A value object circulates through and animates the plot. Likewise, Latour (2010) conducts a semiotic analysis of negotiations at the *Conseil* to identify the value objects that circulate in them. Crucially, value objects are

2 In this sense, Latour (2014, p. 305) notes that speaking of "practice" is itself the embarrassment of lacking a proper language to capture the different modes of existence by any other than this generic term. "If everything of late has become 'practice', it is not because it is a good concept; it is simply that the subject–object inherited from the bifurcation is a terrible one. If we were allowed to use different ontological templates, we would have no need for 'practice', since every form of existence would be explicated in its own language and according to its own condition".

not merely defined in legal texts but emerge during the discussions that Latour observed. Hesitation is merely one of them. I believe that for the case at hand it is much more apt to draw on the concept of the "value object" to capture the conditions of in/felicity rather than accepting hesitation as the only one. Given that the approval process is legally limited to three months, hesitation is not an option (as it might be for the *Conseil*). The concept of the value object allows me to be more open and focus on identifying the various value objects of the approval process that emerge from my documents and the interviews with developers.

If the conditions of in/felicity are met, [LAW] populates the world with and instaures particular types of entities for which McGee (2015b), endorsed by Latour (2015), uses the concept of "jurimorphs". This concept captures that legal networks consist of heterogeneous entities that we need to read in the interpretive key of the law. "The various entities and agents at stake are semiotically re-figured – jurimorphised" (McGee, 2015b, p. 64) – once they are legally grounded. This is the essence of the law if one wants to dig out this concept again. "Law is what happens to extra-legal features when they are jurimorphed!" (Latour, 2015, p. 341). But the notion of the jurimorph remains a bit unspecific as it refers to all entities regardless. To differentiate between entities, I will draw on the concept of "socio-legal objects" that Emily Cloatre (2008) develops to refer to objects endowed with a legal status. I complement this with a second concept to refer to the subjects of the law. This is even more necessary as Latour (2013a) 'discovers' the particular alteration of [LAW] compared with other modes of existence in the production of quasi-subjects. It allows tying the constant displacements within networks to these quasi-subjects. Enunciations and actions can be traced back to legal persons that become responsible for them in a legal sense. This is the "very originality of the law" (Latour, 2013a, p. 359).

This summary of AIME and its approach to the law now allow me to rephrase the initial hunch I had when I first encountered Digital Health Applications. During the approval process, the health-and-wellness apps and the heterogeneous networks they are embedded in become jurimorphed. They come to exist as Digital Health Applications in a legal mode. Thus, at least in part, we know what the approval process instaures: *DiGAs* as socio-legal objects. The open question that I seek to answer throughout this thesis is: "'How does something become legal?" (van Dijk, 2015, p. 166) where we can replace "something" with "a health-and-wellness app" that becomes a *DiGA* once it is "legal" (in the sense of the *DiGAV*). With the theoretical framework I have developed from AIME and its treatment of the law as a mode of existence I can investigate the different value objects that need to be assembled for an app to successfully undergo the assessment and for the manufacturers to have a legal ground for their application. While this takes me very far already, it does not quite get me there. As we will see in the next subsection, other authors that have critically assessed the Latourian approach to the law have erected some barriers that require making a couple of detours. However, I hope the reader will bear with me as these detours may reveal themselves as shortcuts when dealing with the intricacies, some might even say self-contradictions, of AIME.

3.1.3 The case of Latour v. Pottage: When is the law?

I have now outlined the type of project that AIME is, the crucial role that the law, to be understood properly as a mode of existence, [LAW], plays in this empirical philosophy and what, in turn, this framework will render visible in my material.However, it is a truism that every theoretical framework allows seeing *some* phenomena at the expense of others. In this subsection, I, therefore, want to look into some of the critiques others have raised against Latour's conceptualization of the law as a mode of existence and that are particularly pertinent to my own project (which is to say that other points of critiques may be and have been raised in other contexts). While this risks committing a categorical mistake, speaking of a contribution in the mode of [REF] in terms of [LAW], I will do so, fitting the matter at hand, by staging a court procedure in which three plaintiffs take the stand to plead their case against the Latourian framework.

The first to take the stand is a group of plaintiffs, a class we could say. Although phrasing it differently, the plaintiffs of this class all accuse Latour's ethnography of the *Conseil d'État* of not being generalizable. They contend that the *Conseil* may be too "atypical" (Levi & Valverde, 2008, p. 813; Saunders, 2015, p. 17) to serve as an exhibit for a sociology of law or a socio-legal approach to studying the law. Indeed, they bring forward this argument as one reason why the reception of Latour's study had been slow (along with its rather late translation into other languages). The *Conseil d'État* is atypical for several reasons. First, it occupies a peculiar position in the French constitution. It is obviously part of the judiciary branch but also part of the executive in that it advises the government on legal issues (Levi & Valverde, 2008; Saunders, 2015). There is also substantial evidence in Latour's ethnography to claim that the *Conseil* even takes some partial legislative functions (Latour, 2010). This is closely related to the second reason why it might be difficult to generalize from this particular study. The *Conseil d'État* is a court for administrative law, a rather specific type of law as the cases the Latour investigates illustrate. The plaintiffs rightly ask, and some of them pragmatically take up the task of answering this question, what would change in our account of the law if one considered a different type instead. A third specificity of the *Conseil* is that it is not only a court for administrative law but the supreme court. Investigating it means beginning "at the end of the legal line at the judgment in last appeal" (van Dijk, 2015, p. 180). Finally, the *Conseil d'État* is special because of its procedures. Unlike other legal institutions, it is not bound to written law but only to precedence. Devised this way by Napoleon Bonaparte, it operates on the "mere interplay of its previous decisions and in the absence of any written text" (Latour, 2010, p. 14). Are these objections to Latour sufficient to be sustained? In the words of [LAW], do they have a ground to jeopardize any approach that draws on AIME to illuminate any law-related research object? Not completely. Latour can call up witnesses who testify that his goal with the ethnography is "certainly not the development of a sociology of law nor a sociology of the Conseil d'État, but rather the empirical exploration of a mode of existence that is specific to the moderns" (Moreau de Bellaing, 2015, p. 209). Additionally, other witnesses can illustrate that the Latourian approach can be adjus-

ted to jettison the traces of the *Conseil d'État* that can be found in Latour's conclusions about law as a mode of existence (McGee, 2015b; Moreau de Bellaing, 2015; van Dijk, 2015). Nevertheless, for my endeavor it will be necessary to adopt a correcting device that prevents the danger of prematurely subsuming the specificity of the approval process under Latour's framework.

A second plaintiff, Alain Pottage (2004) may now take the stand. His accusation is that Latour's study is "adjudico-centric" and cannot accurately capture the "fractured multiplicity of law" (Pottage, 2004, p. 260). This echoes the claims made by the previous plaintiffs but it goes further. Pottage (2004) suspects that the ethnography is informed by the partial understanding that the law is about adjudication. Latour's response that the law may be invoked in other situations outside of the courtroom but even then, just like *in* the courtroom, the law in its "totality" (Latour, 2010, p. 256) is called upon or re-constituted may not hold either. It may only be true for courts of appeal that formally review previous decisions, stripping them of the "facts", but not for other levels of jurisdiction (van Dijk, 2015). A tricky situation that is highly relevant to my use of AIME: My study is not about a court but a regulatory authority with a gatekeeping function for the first healthcare market. I need a concept to rectify this and level out the difference between the courtroom and other situations in which the law is invoked without the only partially applicable assumption of a legal totality that is thus re-constituted.

Pottage leaves the stand only to retake it, this time as Pottage (2012). His accusation is serious: Latour, in the final consequence, has to introduce a pre-existing and immaterial, downright structural knowledge of the distinction between law and non-law through the backdoor despite the initial goal of a description of law as a material practice. Let me explain: In brief, Latour claims that la [LAW] (or any mode of existence, for that matter) can be distinguished from other modes by the particular kinds of connections it creates between the heterogeneous enunciations, the material elements or events in a network. As I have said above, Latour states this is the preposition as a *clef de lecture*, an interpretation key, that marks these as 'legal' and as instaurated in the legal mode of existence. Pottage objects to this, arguing that the qualification of an enunciation, an event or a material element as 'legal' is not pre-given but the result of an "ascription". "The basic technique of law is not to connect ready-made blocks of legal enunciation into chains but to produce legal enunciations by qualifying events or enunciations as legal in the first place" (Pottage, 2012, p. 177). At any step of the way, one would need to determine whether a legal connection between actants can be established. This conforms better with the concept of the conditions of felicity and infelicity conditions that each mode of existence comes with. If the status of an actant as legal is a result of a contingent qualification rather than a pre-conceived property of this actant it is possible for actants to *not* acquire this qualification, to *not* meet the conditions of felicity. We could think here of the case of Simon Cole, for instance, whose expertise in fingerprinting was *not* qualified as legal as part of a criminal trial (Lynch & Cole, 2005). According to Pottage, then, the preposition as an interpretation key that connects the actants within a network would need to be re-defined as a

“binary code […] that produces ‘law’ by distinguishing it from what is qualified as ‘non-law’” (Pottage, 2012, p. 177). While even the concept of the interpretation key seems suspiciously close to cognitivist perspectives – despite all affirmations to the contrary (McGee, 2015a) – this binary code can no longer be material as Latour suggests for the preposition. Pottage draws on Luhmann’s communication theory where binary codes that ensure the continuity of communication are situated on a virtual plane (Farías, 2014). Consequently, “law’s *clef de lecture* cannot exist as a quasi-material form, but only as a disembodied, dematerialized, and ‘non-human’ *structure* that is sustained by the recursive operations of a system” (Pottage, 2012, p. 177; my emphasis). AIME, it seems, would have to fall back into a quasi-cognitivist register if it was to hold on to the idea of legal connections between the heterogeneous constituents of a network. Pottage (2012) does not further concern himself with this issue. He wants to abandon the concept of law as the abstract denominator of a domain, sub-system or mode of existence as a whole and instead return to a description of heterogeneous materialities that form *dispositifs* in the Foucauldian sense. While his general argument is compelling, this solution would not help me. A ‘mere’ description of a heterogeneous network or *dispositif* would not let me make sense of the peculiar observation that was at the beginning of my interest in how *DiGAs* are regulated, the fact that a health-and-wellness app becomes a Digital Health Application by the approval process at the *BfArM*. I will need to add to AIME a theoretical lens that avoids both extremes, the description of a heterogeneous *dispositif* and the atavistic resort to cognitivist structures, be they individual or on the level of (sub-)system. In other words, this theoretical lens would need to afford to interrogate the jurimorph-ing of actants and the passage of the law through the legal grounds as an empirical practice. As I show in the next subsection, I find what I am looking for in the Sociology of (Conventions and) Testing (Potthast, 2021).

3.2 The Infrapolitics of Practices of Testing

STS has been interested in trials and testing from its beginnings. Actor-network theory-based research has looked for “trials of strength” (Latour, 2003) to identify the weak links in a chain of translations. Other research has investigated testing as a social process that depends on (acceptable) “projections” from the testing to the real-life situations and culturally-framed assumptions of similarity between these situations (Downer, 2007; Pinch, 1993). More recently, Nortje Marres and David Stark (2020) have called for a new sociology of testing to account for recent changes in testing practices. They particularly point out that “[w]hereas we traditionally think about testing taking place within a setting, today's engineers are testing the settings” (Marres & Stark, 2020, p. 435) which makes it more difficult to limit such tests in time and space. They, in other words, co-constitute the social. This fundamental finding from the new sociology of testing will allow me to interrogate more thoroughly *what* the approval process for Digital Health Applications puts to the test. Its main tenets would suggest that it does not only test an object, the app but a broader socio-technical ecology that it also co-constitutes (see also Downer, 2010; Robinson, 2020).

So, while this lens gives me an important clue about how to conceptually approach the approval process, I will nevertheless mostly draw on a slightly different version of the sociology of testing as developed in the theoretical frameworks of Luc Boltanski and Laurent Thévenot (2006). They assume that the capacities to critique and justify (course of) actions are universal. This capacity comes to the fore at the "hot spots of uncertainty" (Potthast, 2021, p. 344) or in what Boltanski and Thévenot (1999, p. 359) term "critical moments". In such situations, different ways of ordering reality collide. The established order of reality becomes questionable and disputes over it arise. "The starting situation is something like the following: People, involved in ordinary relationships, who are doing things together […] and who have to coordinate their actions realize that something is going wrong; that they cannot get along anymore; that something has to change" (Boltanski & Thévenot, 1999, p. 359). The actors then begin to put the situation on trial. They stage a "reality test" (Potthast, 2021, p. 348). The reality test may also become subject to a testing procedure itself (Boltanski & Thévenot, 1999; Potthast, 2021). In both cases, the actors dispose of a limited number of moral principles or "economies of worth" (Boltanski & Thévenot, 2006) that they draw on to align a given situation, the positions of both actors *and* material objects, and to give a justification of their assessment. This highlights that these tests during critical moments have an ontological dimension. They are not simply about the correct perception of reality. What is at stake is in what order of worth entities rightfully exist in the situation and how one has to approach them accordingly.

I am not interested in these orders of worth here, and I will refrain from discussing them in detail. The bold theoretical claim I want to make is that we can fruitfully draw on this version of the sociology of testing to bring into view the transitions between modes of existence, especially to [LAW]. Thus, I will be able to respond to the critiques leveled at AIME and Latour's anthropology of the law that I have summarized in the previous section. Admittedly, I am not the first to draw a connection between ANT (or its extension) and Boltanksi and Thévenot's pragmatist framework. On the one hand, some authors have argued that ANT and the latter's sociology of critique are "symmetrical twins" (Guggenheim & Potthast, 2012; see also Bogusz, 2010). They point out their similarities in the pragmatist roots, the attempt to go beyond Pierre Bourdieu's critical sociology and the strictly empirically-oriented research. Henning Laux (2016) even goes so far as to attest to a family resemblance between the conditions of in/felicity and Boltanski and Thévenot's (2006) concept of testing. On the other hand, research that has taken up Latour's approach to the law has found procedures of testing that a "matter of concern" undergoes before it becomes a "matter of law" (McGee, 2015b). McGee (2015b, pp. 68–69; emphasis added), for instance, writes that the mediation of legal devices "allows a trail of legal means enjoying justificatory relevance to appear through a particular – hesitant – sort of *evaluation*". The judge then "tests" (McGee, 2015b, p. 75) the claims made by the parties in the dispute with a "juridimeter" (McGee, 2015b, p. 78) that evaluates whether the entities in question *can* exist in a legally, as it were. Latour (2010, p. 141), to defend him from the accusations that Pottage makes, also writes of an "ordeal" that the value objects undergo

during the legal trial. These remarks indicate that the perspective on testing is virtually present in AIME and Latour's legal anthropology. The Sociology of Conventions and Testing helps to carve it out and theorize it more explicitly.

The theoretical claim that I make through my research is that we can find socio-material tests at those points where modes of existence cross or where entities begin to exist in a different mode. This responds to the third of the critiques above. If we can approach the transitions between modes of existence as situated, observable and socio-*material* practices of testing there is no need to resort to a cognitive structure which enables recognizing the mode of existence. In the case of [LAW], the qualification of an entity as legal is the outcome of such a test. This test assesses the "value objects" disputants put forward in a legal proecdure and probes whether their connection holds. For the approval process at the *BfArM*, I will need to unpack the different value objects it assesses in the application of developers of Digital Health Applications. The concept of "critical moments" helps to extend the narrow focus of Latour's arguments on adjudication or even the Conseil d'État. It permits looking for the various situations in which the viability of entities in a particular mode of existence is on trial. It provides a symmetrical vocabulary to describe these situations in the same register though this does not mean that some actors claim the power to stage these tests and to determine the ontology of entities. This is a matter of empirical description, though. It fits Latour's argument that we can find legal modes of veridiction outside of legal institutions (Latour, 2004). For the case at hand, the concept allows me to conceptualize the approval process as a critical moment in which the *BfArM* assesses whether a health-and-wellness app can be transposed into the legal mode of existence even if the *BfArM* is not a court or a judicial body.

There is an added complexity. Practices of testing are not innocent. This has been clear from the outset. Pierre Bourdieu who, in a way, is the forefather of both Boltanski and Latour (despite their later patricide) and who has made practices of testing an object of social science inquiry has pointed this out (Potthast, 2021). Especially in his early works on the role of testing as a purportedly neutral mode of allocating cultural status, he argues that "[t]he logic of cultural reproduction has not been interrupted by means of testing" (Potthast, 2021, p. 346). Testing includes non-obvious politics making the sociology of testing amenable to a wider socio-theoretical research program. Potthast (2021, p. 348) notes that the Sociology of Conventions pursues this approach as it "owes both to apprehending society as shaped by contemporary forms of testing (Bourdieu) and social change related to a shift in the nature of testing (Latour)". Potthast (2012; my translation) makes this political dimension visible by developing the concept of "infrapolitics" of testing. In the case study of practices of testing the road safety of cars over time, "infrapolitics" serves as a conceptual alternative to symbolist political readings of road safety. In the latter approach, tests for road safety work to deflect more radical critiques, appease concerned publics and, ultimately, support established hierarchies and power (i.e. the predominance of the car industry). By contrast, "infra-political interpretations emphasize different techniques and formats of temporal, spatial and material condensation

of concrete tests and examinations" (Potthast, 2012, p. 556; my translation). Thus, in Potthast's account, "infrapolitics" is a conceptual lens with which renders different configurations of testing procedures over different periods and the conditions that have led to these transformations visible. Testing procedures shape and are shaped by broader (political) contexts. This constitutes *infra*-politics because the political dimension is not explicitly addressed during the tests. Instead, it concerns the organization or, to put it in terms of a concept recently put forward in valuation studies, the "valuation constellation" (Waibel et al., 2021). The lens of the "infrapolitics" of testing practices brings into view the "*positions* and their *relations*, *rules*, and *infrastructures*" (Waibel et al., 2021, p. 33). Working these out from my empirical material should also allows me to develop a synchronous description of the approval process at the *BfArM* (instead of Potthast's (2012) transchronous approach to changes in testing practices).

But what how does this type of politics that underlies practices of testing? In Potthast's (2012) account, it is sufficient to juxtapose infrapolitics and political symbolism because the main argument is that we should take seriously practices of testing as politically meaningful rather than to dismiss them as mere symbolism. I will need a different approach that to make out and theorize how infrapolitics works. The concept of "ontological choreography" seems apt for this. This concept was developed by Charis Thompson (née Cussins) (Cussins, 1996; Thompson, 2005) in her ethnographic research in a reproductive technology clinic. In this setting, it points her "to the dynamic coordination of the technical, scientific, kinship, gender, emotional, legal, political, and financial aspects" and the "deftly balanced coming together of things that are generally considered parts of different ontological orders" (Thompson, 2005, p. 8). This brief definition already speaks to my reading of the approval process informed by AIME. As I have argued, entities belonging to different modes of existence come together and need to be coordinated under the auspices of [LAW] through an ontological choreography. This becomes even clearer once we consider Jonathan Metzger's (2013) comment on the concept of ontological choreography. Metzger (2013, p. 784) is concerned with what he calls "stakeholderization", the process through which actors become stakeholders in urban planning processes. He argues that this requires an ontological choreography in which corresponding "subject positions" (Metzger, 2013, p. 786) are forged for these actors to assume. This is a political process in that these actors who thus become stakeholders become (emotionally) attached to the particular territories at stake in urban development projects. In the example Metzger has in mind, the ontological choreography effects that the stakeholders make a decision that is, at first glance, opposed to their 'objective interests'. Thus, in his version, "ontological choreography" refers to the "reality-crafting practices […] constituting the legitimately concerned parties of any planning processes, generating and fostering stakeholders by manipulating the interests and attachments of actors" (Metzger, 2013, p. 783). I will similarly approach the approval process. As a socio-material practice of testing, its infrapolitics is the ontological choreography of positions for humans and non-humans involved in the process. But the ontological choreography does not determine whether the

entities assume these positions. There may always be resistance and assuming the offered position may provide unforeseen potential for critique (Foucault, 1996). However, being successful in the approval process will likely require taking it in a more or less docile way. In the chapters below where I present my findings, I will carve out the positions and relations the approval process creates from the empirical materials I have assembled.

4 Methodology

Based on its etymology, the word 'method' which derives from the Ancient Greek words "metá", meaning a movement/development towards something, and "hodos", meaning "way", refers to a road to be traveled. So, what I want to write in this section is something like a road map of the research I have conducted for this thesis. As much as possible, I would like it to be a sort of "natural history" (Silverman, 2017, p. 475) of how I have conducted my research. I believe that, on the one hand, this implies a style of writing that is much more captivating than the often dry, hard-to-read (and assumably also hard-to-write) method chapters in many articles or books. On the other hand, it also speaks to an important lesson of ANT. If research is itself an assemblage (Law, 2004) and 'assemblage' or 'network' "does not designate a thing out there that would roughly have the shape of interconnected points" but is "*an indicator of the quality of a text*" (Latour, 2005, p. 129), it is up to the method chapter to capture the assemblage through its writing. Thus, I seek to mobilize the network from which my research has emerged in this section. I outline my (initial) plans, but also address the challenges that arose unexpectedly and how I tried to overcome them by adjusting my approach. I begin with a short description of the case of Digital Health Applications (4.1), followed by a brief sketch of the methods of data generation (4.2) and continue by describing the sampling process through which I attained my empirical material (4.3). I then outline how I analyzed this material (4.4). Finally, I discuss some of the ethical considerations that have come up during my research (4.5).

4.1 The Case of Digital Health Applications

In late 2019, the German *Bundestag* passed the *DVG*, the legal framework that made the introduction of Digital Health Applications possible. This law is part of broader efforts to push the digitalization of services, especially in the healthcare domain in Germany. In April 2020, the *DiGAV*, the addendum that makes more detailed provisions on the approval process, followed suit. Since then, developers of health-and-wellness apps can apply for their apps to be licensed as Digital Health Applications and taken up in the *DiGA* directory. The approval process is situated at the German Federal Institut for Drugs and Medical Devices in Bonn, an institution originally established as the Institute for Drugs in the 1970s to assess and license drugs before they enter the first healthcare market (Kurth, 2008). In the 1990s, surveilling medical devices was added to the agency's purview.

The assessment it conducts is legally defined as a three-month period, thus being called the *DiGA* fast-track. As I will present in greater detail in the following chapters, during this period, the *BfArM* examines whether applicant apps meet several requirements that range from technical questions, such as data privacy and usability, to scientific evidence of the clinical efficacy of the app. Apps can either be listed permanently or temporally. In the latter case, manufacturers need to fulfill all technical requirements but can hand in the results from a clinical trial after one year. During this time, the temporally listed apps can be prescribed by doctors and are reimbursed by the SHI.

The *BfArM* reports that until the Summer of 2021, app developers have submitted 89 applications to be listed in the *DiGA* directory. Of these, 20 were confirmed, 4 were denied and 42 applications have been retracted by the manufacturers (Lauer et al., 2021). The other 3 were still being processed. An overview of the *DiGA* directory at the time of writing (June 2022) shows that 31 apps have been listed. Of these 12 are listed permanently, while the remaining 19 are temporarily listed. Filtered by the targeted indication, available DiGAs currently comprise such that target conditions of the heart and the cardiovascular system (1), hormonal and metabolism issues (5), cancer (1), muscles, bones and joints (4), the nervous system (2), kidneys and urinary tract (1), the ear (2), the psyche (14), digestion (1) and others (2). According to the Innovation Office at the *BfArM*, most consultations and information offers have been taken up by start-up companies (Löbker et al., 2021). This largely matches my observation that most of the apps listed in the directory have been developed by start-ups or small- and medium-sized enterprises (SMEs). Only very few apps are tied to larger, sometimes transnational corporations. Concerning the actual use of Digital Health Applications in the German healthcare market, a recent study has found that after one year only a minority of medical professionals has prescribed a *DiGA* (Obermann et al., 2021). In addition, the respondents of this study had ambivalent attitudes about the potential of the apps in healthcare provision.

Despite the slow take-up in medical practice, I believe that Digital Health Applications nevertheless present an interesting case for a better understanding of the regulation of digital health technologies. As I have pointed out in the introduction, the *DiGAV* is one of the first attempts to regulate digital apps for medical purposes and integrate them into standard healthcare. Thus, it may serve as a blueprint for similar regulations in other countries. Gerke et al. (2020, p. 5) write, for example, that “as other countries and health systems look to implement coverage policies and assessment processes for digital health solutions, further developments and resolution of questions about the DVG will certainly provide valuable insights”. My thesis aims to open up the black box of the approval process through which apps become Digital Health Applications. I seek to contribute to a more thorough appreciation of how the *BfArM* has implemented the new legal framework in practice and the challenges that digital health technologies pose for regulation.

4.2 Methods of Data Generation

The goal of my research is to illuminate the approval process from the perspectives of different actors involved. This makes methods of participant observation unsuitable because they remain li-

mited in time and space. I would only be able to capture distinct episodes from the approval process, not the more abstract 'whole' of the approval process. More pragmatically speaking, the Covid-19 pandemic that was still in full swing when I began my research made participant observations, for example at the offices of the *BfArM*, unfeasible. In addition, the difficulties of negotiating field access that I describe below would have multiplied. Conducting ethnographic research at a field site is arguably more intrusive than interviews of a shorter duration. For these methodological and pragmatic reasons, I chose interviews and document analysis as the methods for approaching the case of Digital Health Applications.

4.2.1 Interviews

As described, to answer my research question I wanted to collect rich accounts of the approval process from different perspectives of "those who have knowledge of or experience with the problem of interest"; I wanted to "explore in detail the experiences, motives, and opinions" (Rubin & Rubin, 2012, p. 3) of those involved in it. This makes qualitative interviewing a suitable method for my study (see also Merriam & Tisdell, 2015). Robin Legard et al. (2003) describe five characteristics of qualitative in-depth interviews. I will dwell on two of these and discuss how I applied them in practice. First, qualitative in-depth interviews "combine structure with flexibility" (Legard et al., 2003, p. 141). Unlike surveys that offer standardized questions and answers to achieve comparability of responses across sometimes large samples, qualitative interviews are only loosely structured. The researcher has an idea of the topics they want to cover "while maintaining the flexibility of exploring interesting threads in the interview as it unfolds" (Jensen & Laurie, 2016, p. 173). The flexible structure also has an ethical dimension because, to an extent the researcher needs to decide upon (ad hoc), it allows interviewees to set the priorities in the conversation (Mason, 2002). Epistemologically, this will let the conversation take surprising turns and create findings beyond what the researcher initially intended. Making the most of combining structure and flexibility was especially important for me. While I had prepared for the interviews by working through the documents I had gathered at least once, my knowledge of the approval process was still superficial. As they are the experts, I wanted to give my interviewees the space to express their experiences. Therefore, I pursued a semi-structured interview and crafted a rough interview guide with the topics I would like to cover. But I remained open to follow-up on other topics that only emerged during the interview.

This relates to the second characteristic of in-depth interviews. They are "interactive in nature" and "material is generated by the interaction between the researcher and interviewee" (Legard et al., 2003, p. 141). This seems to be an obvious and innocuous statement. But it is actually loaded with potential for epistemological conflict. Kvale (2007, p. 19) nicely circumscribes what is at stake with the metaphors of the interviewer as a "miner" versus the interviewer as a "traveler". In the first metaphor, the interview is a quasi-archaeological method in which the researcher uncovers what has always been there, independent of the interview process. This comes close to the positivist version

of the interview as giving access to an objective reality if only all influencing factors are controlled for (Silverman, 2006). The metaphor of the interviewer as a “traveler” is closer to a constructivist understanding of the interview. Here, “interviewers and interviewees are always actively engaged in constructing meaning” (Silverman, 2006, p. 118) (which is why the metaphorical interviewer should actually be a co-traveler). The meaning and knowledge created thus depend on the interview situation. I subscribe to the second of the two metaphors and the constructivist impetus it points to for my own approach. There is no denying that the interview situation has influenced the material I generated, especially because I conducted all my interviews virtually through video conferencing software. This seemed like a feasible response to the challenge of a lack of resources to travel to the different locations of my interviewees across Germany and the Covid-19 pandemic (Lobe et al., 2020). Undoubtedly, the affordances of the software contributed to the process of making meaning and generating empirical material (e.g. statements that were inaudible to a bad internet connection at that moment). I do not perceive this as a disadvantage. The questions about the “stability and validity of interview data” (Legard et al., 2003, p. 140) the constructivist approach to interviews has raised only make sense if one presumes the existence of one objective reality against which the interview data can be evaluated. My theoretical framework compels me to object that reality is plural and that my interview data is part of one particular reality. The findings from my thesis exist in [REF], the mode of existence that captures science as practices of constituting “chains of translations” (Latour, 1999a, 2013a). What I can and hope to do with this methods chapter is to describe the different translations that occurred throughout the research process. These, to be sure, could always be otherwise and produce alternative data and findings.

One of the crucial translations was developing a research guide suitable for generating material that speaks to my research questions. A research guide fits the semi-structured approach to interviewing I have described above. It provides a list of open narrative stimuli and topics the interviewer would like to discuss. This gives the interviewee the space to set their own relevances throughout the interview and bring up issues, subjects and twists that the interviewer has not anticipated. Moreover, interview guides (ideally) afford to adopt the order of the questions in response to the course of the interview, on the fly, as it were (Mason, 2002; Rubin & Rubin, 2012). To devise my research guide, I drew on Helfferich’s (2011) meticulous walk-through of this process. I began by openly collecting questions relevant to my research, drawing especially on my previous readings of the documents. I then sifted through this list of questions. I deleted those that aimed at facts that I could obtain otherwise (as these would not generate narratives but probably rather concise statements), that were not open for interviewees to set their (unanticipated) priorities and those that were too abstract or analytical. After that, I ordered the remaining questions to different topics using color codes with the highlighting function of my office application. The questions that did not fit any topic I left for the end of the question guide, shortly before the final questions. Finally, for each topic, I came up with an open narrative stimulus. I broke the collected questions down into

keywords as topics that I hoped would come up in the narrative or that I could then bring up as exmanent questions depending on and adapting to the course of the interview. The result of this rather laborious but fruitful process was several research guides tailored to the respective interview partners in the format of a spreadsheet with four columns (Helfferich, 2011, p. 186): narrative stimuli, a checklist with topics that I would like to follow-up on if the interviewee does not bring them up themselves, preformulated questions as mnemonics and questions to maintain the interviewee's narrative where applicable.

4.2.2 Document Analysis

Analyzing documents lends itself to my research because, as I report in the following subsection, there is already a pool of documents in the public domain with detailed descriptions and experiences from the approval process. Nevertheless, I do not treat these documents as mere containers of sedimented discussions, as previous social science research has mostly done (Prior, 2008). If I did, this would entice me to analyze their content as representative of the processes 'behind' the text. But this neglects the fundamental assumption of semiotics that language is by no means a window to the world as well as the finding of ANT that "inscription devices" (Latour & Woolgar, 1986) trans-form what they trans-port, that. Documents are "mediators" rather than "intermediaries" (Latour, 2005). If I wanted to investigate the content of documents *qua* content, the better methodological choice would be to conduct a document ethnography (e.g. Riles, 2001) that would follow documents through their construction.

Instead, I approach documents as actors. First, they trace the connections between actors within a network as they circulate through it. This is the perspective that Lindsay Prior (2007, 2008) has suggested. He proposes to "examine how documents as vital objects can drive and shape political, economic, medical and scientific activities just as much as do humans" (Prior, 2008, p. 833). Documents are not passive but implicated in all types of (inter-)action which shape them but which they also co-shape. This will be a background assumption of my work with the documents I have sampled. Because they are all publicly accessible it is fair to assume that they circulate among and connect actors interested in Digital Health Applications – for instance, students writing their Master's Thesis on them. The *DiGA Guide* especially is explicitly addressed to manufacturers, medical professionals and potential users of *DiGAs*. It constitutes a first point of contact with the approval process for manufacturers and co-shapes how they approach it. Conceiving "documents as agents" (Prior, 2007, p. 346) bolsters the importance of documents in and for the approval.

In a way, the second approach to documents that I refer to more explicitly in my analysis return to the content of documents. Still, it does not reduce this content to a mere representation of an independent reality. "Paperwork does not simply describe an external reality 'out there': Documents also take part in working upon, modifying, and transforming that reality" (Asdal, 2015, p. 74). By focusing on what she calls the "modifying work" documents engage in, Asdal (2015, p. 86) develops

a “practice-oriented approach, aiming at describing, as accurately as possible, what a text does, and with what effects and consequences for the objects and issues at stake”. This goes well with the literature on the performativity of regulation and, especially, regulatory documents that I have reviewed above. Faulkner (2012a), for instance, similarly investigates how these construct a technological zone of tissue engineering. Asdal (2015) describes the creation and modification of an issue as a non-issue through a document. My focus will be on how the documents in my sample engage in an ontological choreography that creates and allocates possible subject or object positions to entities in the approval process and the relation between them. This allows me to carve out and unpack the underlying politics of the approval process as a socio-material test.

4.3 Sampling

In the previous subsection, I have described my methodological approach for generating empirical data. Here, I want to continue by sketching the process of finding and recruiting suitable interlocutors and documents. I begin by recounting the process of negotiating access to the field and finding interview partners, focusing on the difficulties I encountered. Then, I will advance to the sampling of documents which was, fortunately, much more straightforward.

4.3.1 The Challenges of Finding Interview Partners

To put it bluntly: Recruiting interview partners for my research was a challenge. At first, this was somewhat surprising. Compared to an earlier version of my project, I had extended the scope of possible interview partners. My naïve thought was that this would automatically translate into more interview partners (at one point, I even had the megalomaniac expectation that I would need to cancel interviews to keep it manageable for a Master’s Thesis!). The reasons for these difficulties only occurred to me at a late point of the process. I think they are illuminating for the field of Digital Health Applications in Germany. Therefore, I will describe the recruitment process before I briefly sketch my sample.

The recruitment process had three phases. For the first phase, I took the cues from some of the documents I wanted to use for my analysis. These were articles written by employees at the *BfArM*, officials at the Ministry of Health and manufacturers who had successfully undergone the approval process. I thought this was a good point of departure because it gave me actual names and the e-mail addresses of those listed as the corresponding authors. Moreover, it provide a good talking point to introduce my research project: “I am writing you concerning the article you have published…”. I devised a contact letter (drawing inspiration from the example Jensen and Laurie (2016, p. 123) give in their book), double-checked it with my supervisor and sent it out along with a brief e-mail introducing myself and my research project. The result was… underwhelming. One manufacturer answered the next day, stating they had little time for conducting an interview but were happy to answer written questions. In hindsight, I should have taken up this offer because it

would have given me another insightful perspective. But at the time, I did not want to surrender as easily and asked whether maybe an employee who was involved in the approval process would be willing to talk to me. I never got an answer after that. The employees at the *BfArM* and the officials at the *BMG* took a little longer to answer. But their response was, likewise, negative. The former similar to the manufacturers declared they had little time for interviews and all my attempts to convince them otherwise proved futile. The latter apologized, stating that they generally do not support master's theses. From all others, I did not get a response at all. I waited for two weeks, then sent out another e-mail, inquiring about my earlier one. To my surprise, this time around, one manufacturer responded positively and was willing to have a conversation with me. This was my first interview. Persistence had paid off!

The second phase roughly began during these two weeks. I had grown increasingly worried about whether I would be able to find any interlocutors at all. I spoke about this with a friend who happened to be a teaching assistant for a well-networked professor for social policy. He offered to ask whether this professor had any suggestions whom I could ask. I agreed and, lo and behold, just a couple of days later, I had two names and the consent that I could use the professor, whom I also knew from my previous studies, as a reference in my e-mail. One of the two people he referred me to actually even worked at the *BfArM*! The other was the representative for a digital health umbrella organization, vulgo lobbyist for digital health. So I send out e-mails to them. The lobbyist almost immediately responded, happy to participate in an interview with me. This was my second interview! The *BfArM* employee took more time and, similar to their colleagues, had to decline my request owing to a lack of temporal resources. Still, they pointed me to two blog posts recently published on the *BfArM* website that I quickly added to my document sample.

In the third phase, which again overlapped with the second, I expanded my approach, trying to contact *all* manufacturers currently listed in the *DiGA* directory, hoping this would increase the chances of positive responses. I created a list of all the companies and gathered their contact details. I also adjusted my approach and did not send a contact letter but described my research project in a short e-mail, offering to provide further information if necessary. Moreover, while I had initially request interviews of one to one and a half hours, I now reduced this to 15 to 30 minutes. I hoped this would increase the willingness of potential interviewees to speak to me. I sent out more than 20 e-mails this time and mostly used the customer support e-mail addresses. The response rate was again very low. Some companies politely declined my request. But from more than half of the companies I did not get any response. At this point, I decided to up the ante and leave my comfort zone. As we will see in much more detail later on, *DiGA* developers need to install customer support that can respond to requests within 24 hours. Many companies solved this requirement by implementing a phone service. I began calling these phone numbers to introduce my research project and ask for short interviews. This way, I could at least ensure that my request passed the spam filter. Again, most of the companies I spoke to declined my request. But phoning them helped

me to understand why that was the case. One person told me that they get similar requests at least twice a week to which, as a small company, they understandably cannot comply. My 'failure' to recruit interview partners is a valuable lesson about my field of study. The approval process is very demanding in terms of necessary (temporal) resources. The negative responses I received likely illustrate this, especially because many of the companies were still only temporarily approved and, hence, in the midst of the approval process. Despite this, two developers I spoke with on the phone agreed to schedule an interview. These were my third and fourth interview partners. During, or more precisely after, one of these interviews, I became aware of another reason for my difficulties. The interlocutor had a lot of questions about the anonymization of data. They stated that usually (negative) experiences of the approval process would be communicated in more generalized and anonymous terms by one of the digital health umbrella organizations. I will discuss this in the subsection about research ethics below. Here, it is important many companies were likely skeptical about supporting support my research project because they were concerned about being tied to critiques of the *BfArM* and the approval process[3].

To sum up: In total, I conducted four interviews, three with developers and one with the representative of a digital health umbrella organization. The interviews lasted between 35 and more than 90 minutes. I conducted all of them via Zoom. Certainly, I would desired to conduct more interviews to get a deeper and richer picture of the approval process through personal narratives. Ultimately, at least in part, the particular situation in the field made it impossible for me to recruit more interviewees, though. Despite this, I assume that I have had access to very interesting and a certain degree encompassing accounts of the approval process from the developer perspective. Many of my interview partners signaled constant exchange among developers and related second-hand experiences that other developers have made.

An obvious limitation, especially concerning my goal of illuminating the Fast-Track procedure from the different perspectives of the actors involved, is the asymmetry of my research material in this context. Because I could not recruit officials at the BfArM I have to rely on documents while I have been able to speak to manufacturers. Still, I believe there is no reason to assume that documents created with public outreach in mind provide fewer insights for my research. Nevertheless, it is necessary to note the differences in the source material. Future research with more temporal, institutionalized cultural (i.e. academic credentials, as some potential participants rejected my request regarding my student status) and economic resources than I had at my disposal will likely be more successful in keeping the symmetry.

The attentive reader will have noted that I have only conducted with developers that have successfully passed the approval process. My sample has a "success bias" due to my recruitment strategy

3 It likely did not help my recruiting efforts that around the time I began the recruitment a German satirical late-night show broadcasted a critical skit on Digital Health Applications for mental health. The skit argued that these are, essentially, an easy way for statutory healthcare insurances to make or, at least, to save money compared with a conventional therapy slot with a registered psychologist or psychiatrist..

because I specifically contacted companies with apps in the *DiGA* directory. This choice is limiting because those companies who have retracted their application or whose application the BfArM has rejected – the vast majority of applications (Lauer et al., 2021) – will likely intimate different experiences than the successful companies. Given the circumstances, I suppose this bias was inevitable: The *DiGA* directory has served as a lever to make contact with the field for me because it publicized company names and contact information. Meanwhile, companies that have been rejected or have retracted their application will most likely *not* publish this information anywhere. I have tried and failed to find any of these companies. The manufacturers who have mentioned that they know some of these companies have kindly declined to forward my request. The *BfArM* is, of course, not allowed to publicize any information about failed applications, either. Therefore, there was no way for me to include this group of manufacturers in my sample.

The same can be said about the second obvious bias in the sample of interviewees: My interview partners have self-selected. There may be underlying factors that have influenced this selection and that easily become invisible. One of the interviewees, for instance, told me that he has a different way of organizing their work than others in his trade and that this is the reason they could take the time to speak with me. My request for an interview might have been unfeasible for other companies with different organizational structures which may also imply differences in the perception of the approval process. In general, I believe biases such as these are inevitable. They are only a fundamental problem to research if one subscribes to the positivist idea that research can/should present a full and neutral picture of reality as it is "out there". STS from its very beginnings has shown that this is impossible (e.g. Fleck, 1979; Kuhn, 1996). It is still necessary to reflect on these biases, their type, and most importantly, what they make in/visible in the research process.

4.3.2 The Ease of Finding Documents

By comparison, finding relevant documents for the analysis was fairly easy. I shall give a brief overview of them. The first document (D1) is the *DiGA Guide* or *DiGA-Leitfaden*. Published by the *BfArM*, the agency recommends it as the first point of information for anyone interested in the approval process (although, given the content, it seems that the primary addressee is manufacturers of *DiGA*). It gives a detailed description of the approval process, the requirements and especially the requirement of a positive healthcare effect. The document is designed to continually develop along with changes in the regulatory framework and emerging experiences from the approval process. For my analysis, I will draw on the English version of the *Guide* published on the *BfArM* website along with the German one.

The second set of documents comes from a special issue in the German Health Bulletin, edited by central German institutes for healthcare. This special issue was edited by the *BfArM*, concentrating on *DiGA* and their regulation. It assembles several contributions from different actors in the German healthcare system. For my analysis, I have selected those contributions by actors immediately

involved in the approval process and its organization, the Federal Ministry of Health, the *BfArM* and developers.

Document	**Brief Summary of Content**
Document 2 (D2): Lauer, W., Löbker, W., Sudhop, T., & Broich, K. (2021). Digitale Gesundheitsanwendungen (DiGA) als innovativer Baustein in der digitalen Gesundheitsversorgung in Deutschland – Informationen, Erfahrungen und Perspektiven. Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz, 64(10), 1195–1197. https://doi.org/10.1007/s00103-021-03420-y	The editorial co-authored by the head of the *BfArM* (Broich), the heads of the innovation office (Löbker), the department for medical products (Lauer) and the department of information technology (Sudhop) very briefly situates *DiGA* within the context of the *DGV* and presents the contributions to the special issue.
Document 3 (D3): Ludewig, G., Klose, C., Hunze, L., & Matenaar, S. (2021). Digitale Gesundheitsanwendungen: Gesetzliche Einführung patientenzentrierter digitaler Innovationen in die Gesundheitsversorgung. Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz, 64(10), 1198–1206. https://doi.org/10.1007/s00103-021-03407-9	This article has been co-authored by officials at the German Federal Ministry of Health. Accordingly, it gives an overview over the intention that the Ministry pursued with the introduction of Digital Health Applications, places it in relation to broader efforts of digitalizing the German healthcare system, the position *DiGA* are to assume in the German healthcare system and discusses especially the role of the legislation as an agile process.
Document 4 (D4): Lauer, W., Löbker, W., & Höfgen, B. (2021). Digitale Gesundheitsanwendungen (DiGA): Bewertung der Erstattungsfähigkeit mittels DiGA-Fast-Track-Verfahrens im Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM). Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz, 64(10), 1232–1240. https://doi.org/10.1007/s00103-021-03409-7	This article, co-authored by the heads of the medical device department, the innovation office and the subdivision responsible for the *DiGA* Fast-Track discusses the organisation of the approval process, the different requirements, information and consultation services at the *BfArM* and first experiences from the approval process.
Document 5 (D5): Löbker, W., Böhmer, A. C., & Höfgen, B. (2021). Innovationsunterstützung im BfArM – Erfahrungen aus den Beratungen zu digitalen Gesundheitsanwendungen (DiGA). Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz, 64(10), 1241–1248. https://doi.org/10.1007/s00103-021-03410-0	Co-authored by the head of the innovation office, an employee in the innovation office and the head of the subdivision conducting the approval process, this article presents the information and consultation services the *BfArM* offers for manufacturers of *DiGA* and gives statistics about previous consultations.
Document 6 (D6): Heimann, P., Lorenz, N., Blum, N., & Schifferings, C. (2021). Erfahrungen von Herstellern digitaler Gesundheitsanwendungen (DiGA) mit dem Fast-Track-Verfahren des BfArM. Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz, 64(10), 1249–1253. https://doi.org/10.1007/s00103-021-03422-w	This article has been co-authored by the CEOs of four companies whose products have successfully undergone the approval proces already. The authors give descriptions of how they have experienced the approval process and give recommendations both to other companies to better prepare for and anticipate for the procedure and to the *BfArM* for its future improvement.
Document 7 (D7): Brönneke, J. B., Hagen, J., Kircher, P., & Matthies, H. (2021). Digitalisierte Gesundheitsversorgung im Jahr 2030 – ein mögliches Szenario. Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz, 64(10), 1285–1291. https://doi.org/10.1007/s00103-021-03416-8	Written by employees of the health innovation hub that was affiliated with the German Federal Ministry of Health, this article develops a scenario for healthcare in Germany in 2030, starting with *DiGA* as the first step toward and a crucial important of the digitalized healthcare system.
Document 8 (D8):	This article discusses the role the *BfArM* aims to play for

Broich, K., Löbker, W., & Lauer, W. (2021). Beitrag des BfArM zur Potenzialentfaltung der Digitalisierung im Gesundheitswesen – digital readiness@BfArM. Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz, 64(10), 1292–1297. https://doi.org/10.1007/s00103-021-03417-7	the digitalization of the German healthcare system. This not only concerns *DiGA* but also the use of big data and artificial intelligence. Additionally, it describes how digital methods are deployed in and for approval processes at the *BfArM*. Thus, the article gives a rich picture of the imagination of the digital transformation of the healthcare system.

Table 1: list of documents from the special issue of the Federal Health Bulletin I draw on for my analysis

One could object that the contributions published in this special issue of the *Bundesgesundheitsblatt* are as much about public relations as they are about a description of the approval process and that, thus, the latter may be influenced by the style of communication favored by the former. I want to insist that with a methodological approach that considers these documents as actors, they, nevertheless, afford interesting insights and perform a, no matter how idealized, version of the approval process. Additionally, the documents fulfill my goal of approaching the approval process from the perspectives of the different actors immediately involved. Finally, in their replies to my request, all of the officials at the *BfArM* (and also a few manufacturers) referred me to these publications as substitutes for the conversations they did not have the resources to have with me. Therefore, I believe this set of documents affords an encompassing view of the approval process in a first approximation that could, of course, always be enriched by further interviews.

The third set of documents, documents that one official from the *BfArM* also referred me to in his response to my e-mail, comprises two blogposts about the approval process published on the blog on the *BfArM* website. The first of these (D9) was authored by Dr. Wiebke Löbker, head of the innovation office. It puts together several hints for *DiGA* developers interested in applying with their app. The second blogpost (D10) was written by Dr. Achim Grünewald, a scientific assistant in the approval process. He writes about the five most frequent shortcomings in the applications hitherto submitted to the *BfArM*. Again, the objection is that these blog posts focus on public relations first and foremost. Here, I would also assert, however, that they provide (condensed) information about the approval process and that they still have performative effects (and, indeed, having the performative effects of preparing manufacturers may be the very public relation the posts aim for). Finally, I also analyzed the Digital Health Application Ordinance (*DiGAV*) as the legal document that frames the approval process and details the procedure (D11).

4.4 Methods of Data Analysis

I downloaded all of the documents. Because they were publicly accessible this was not a problem. The interviews were transcribed verbatim. I opted for a thematic content analysis approach following Carol Rivas (2018). She argues that thematic content analysis aims at “underlying concepts” in the material and “involves looking across the data set rather than within one case” (Rivas, 2018, p. 430). This, I thought, was apt for my approach because I needed to identify underlying patterns

that cut across the different materials to be able to answer my research questions. Moreover, I decided to code inductively, to develop my codes from my material rather than imposing my own pre-existing categories on this material. Nevertheless, I should also note that I do not believe that a purely inductive coding is possible. As Sharran B. Merriam (1998, p. 48) argues, “our analysis and interpretation – our study’s findings – will reflect the constructs, concepts, language,models, and theories that structured the study in the first place”. Moreover, over time and as less new codes emerge, the initial inductive stance does becomes more deductive (Merriam & Tisdell, 2015). Even though I cannot claim that I obtained the saturation, I could still use many of my codes repetitively. This means either that the experiences my interviewees expressed were alike or it could also demonstrate that the diversity of my sample was not marked enough.

I began by familiarizing myself with the documents early in my research process. Indicating what Rivas (2018, p. 432) calls the “zigzag approach” between data collection and data analysis in thematic coding, this allowed me get an initial overview over my research topic and informed the construction of the interview guide, as I have described above. Similarly, I began by reading through the interview transcripts to scan for striking passages or emerging themes that caught my eye. I then started the process of open coding using the *Atlas.ti* qualitative coding software. With this software I could easily organize my material, my codes and, later on, my categories and themes. I will readily admit that at this stage, I fell into one of the most common traps in qualitative coding and developed too many codes. On the one hand, I believe that this was because my data, especially from the interviews, was very rich and spoke to many issues. On the other hand, I took too detailed of an approach. Not wanting to miss anything that might be important, I came up with lots of overlapping codes that I only used a few times in my analysis. Put more poetically, the problem I was facing was the “pain of the attachment-separation grief” (Star, 2007, p. 87) that characterizes every qualitative coding process. Too late in the process did I stumble upon an encompassing introduction to the coding that might have helped me avoid this pitfall (Saldaña, 2013). The abundance of codes complicated developing categories. Still, I tried to constantly compare them across the materials to identify the intricacies, sameness and differences between the experiences of my interviewees and the descriptions of the approval process in the documents. This allowed me to hierarchize my codes. I devised generic codes that I further specified by adding a descriptor. One example of this is the code “evidence of positive healthcare effect – accepted evidence”. The first part describes the requirement to which this code refers. The latter part points to all those passages where the documents or interview transcripts mention the various types of evidence that developers can submit in their applications. Such hierarchies of codes were the first step to developing more abstract categories from the codes and the relations between them. Then, I sorted these categories and codes into emerging themes, using the “code group” function in *Atlas.ti*. The groupings served as the organizing principle for the chapters below in which I present my results.

4.5 Ethical Considerations

I have to admit that I naïvely underestimated the ethical dimension of my research in the beginning and that their true reach, and the corresponding responsibility on my shoulders, only became clear to me while doing my research. In this subsection, I briefly want to describe the issues that have arisen, how they made me reconsider my approach to research ethics and how I devised precautionary measures to respond to the particular ethical challenges of my thesis project.

In the beginning, I thought that the ethics of my research were relatively straightforward and that I 'only' needed to heed the advice/guidelines expressed in the methods literature (e.g. Jensen & Laurie, 2016). The documents I have sampled are doubtlessly in the public domain. They are meant to be read by interested publics. Confidentiality and anonymity were not really an issue here, although this does not mean that these circumstances likewise exempt me from other dimensions of research ethics. For the interviews, confidentiality and anonymitythey were more of an issue. From the outset, I tried to communicate the topic of my research openly. This was not just a matter of creating interest in the counterpart. It was also a means of letting potential interviewees know what they are getting into so they can make an informed decision. In response to the affirmative replies, I asked if they would agree to record the conversation. I also offered alternative possibilities, e.g. me taking notes to memorize the interview content. To these e-mails, I attached an informed consent sheet clarifying the procedure for research participants. Interviews would be recorded and transcribed. Both audio files from the interview and the transcripts would be stored on a password-protected server at the University of Vienna in compliance with the GDPR. The interviews will be anonymized in this thesis and any further publications so that no one would be able to make inferences about the interview partner. I also summarized these points in the e-mail and offered the participants to contact me should there be any questions or concerns.

Because communication with interview partners took place via e-mail or telephone and I conducted the interviews online, it was impossible to take the 'standard' route of signing the informed consent as a sheet of paper. I sought to resolve this issue by sending my research partners the document ahead of time to give them sufficient time to study and consider it and by gathering oral consent before the interview. When conducting the interviews, I reiterated my research goals and summarized my background so interviewees knew to whom they talked and to what use I would put the conversation we were having. Before starting the recording, I also stated once more that all data will be stored securely and that the interviews will be anonymized to prevent re-identification. Additionally, as a feature of the video conferencing software I used for the interviews, a computer-generated voice informed them that the recording had started. A pop-up window asked them to confirm the recording.

Thus, I initially thought I had secured the ethics of my research. It was not until the third interview that I realized that there was a second layer to these ethics that you could call "relational ethics" (Ellis, 2007) as opposed to the "processual ethics" (Guillemin & Gillam, 2004) the previous para-

graphs describe. Relational ethics are about “assuming responsibility for our actions as researchers and the consequences of our stories on those being researched” (Vogel et al., 2017, p. 988). Research inevitably intervenes in the field of research and has consequences for those who participate. I became very aware of this in this third interview. I had already stopped the recording and my interview partner and I were in the debriefing phase when they expressed concerns about anonymity and confidentiality. They emphasized that they would not like to see their name, the name of their company or their app mentioned publicly because “the *BfArM* would know about it and we still need to collaborate with them” (field notes taken after the interview). I have mentioned above that this was an aha moment for me regarding the difficulties of recruiting. Manufacturers might have been reluctant to participate in discussions because they were afraid of negative consequences if they expressed criticism about the approval process. But it also made me realize the full responsibility I bear with my research beyond the procedural dimension of ethics. I began to reconsider my approach and devise measures to maximize the anonymity of my research partners. First, I decided to leave out any information that could lead to the re-identification of my conversation partners. This not only concerns the name of the conversation partner, their company or app but also the condition the respective app targets. Because there are only 31 apps listed in the DiGA directory in total and the numbers for particular indications vary from 1 to 13, mentioning that I have spoken to a manufacturer of an app for condition X might mean that this re-identifies this manufacturer or, at least, limits the number of applicable companies. Second, I have adjusted my phrasing, e.g. using the singular ‘they’ to mask the gender of my interlocutors. In addition, I believe that translating the German interviews into English erased all mannerisms of speech that may allow linking a quote to a particular person (e.g. regional dialects). Third, I have decided to omit all experiences that I, based on a comparison of interviews, consider unique about their company or approach to the approval process. Describing these, even if they might be interesting findings, could allow for conclusions about the interview partner. Finally, in the analysis section, I will not attach passages quoted from the interviews to a particular interviewee (or interview) beyond the denominators of their position (e.g. “manufacturer”, “representative of digital health umbrella organization”). That way, even if despite all precautionary measures a quote can be attributed to a particular manufacturer, it will not be possible to link other quotes to them.

5 The Digital Building of Healthcare

After having outlined the methodological approach I took, I will now move on to present the findings of my study. The following five chapters investigate the imaginary of digital health that informs the work of the *BfArM*, the organization of the approval process and the multiple roles of regulation therein. I want to begin the analysis by interrogating the vision of digital health that the *BfArM* puts forward in the documents and that underlies the approval process. How does the *BfArM* imagine

the digitalization of the healthcare system and the position of *DiGA* within it? Where does it see its role in this process? I make an underlying theoretical argument with this. In the original conceptualization of "socio-technical imaginaries" (Jasanoff & Kim, 2009), the authority to create such imaginaries is limited to policy-makers. In later iterations, the range of those creating and contributing to socio-technical imaginaries is expanded. Now, these imaginaries are defined "as collectively held, institutionally stabilized, and publicly performed visions of desirable futures, animated by shared understandings of forms of social life and social order attainable through, and supportive of, advances in science and technology" (Jasanoff, 2015, p. 4). I will argue that regulatory agencies also construct, contribute and disseminate socio-technical imaginaries, in this case, the imaginary of a digitalized healthcare system.

To do so, I exploit and unfold a "conceptual metaphor" (Lakoff & Johnson, 1980) laid out in the documents in my sample through a close reading of relevant passages from these documents. As a concept, "conceptual metaphor" refers to the way that we "understand[.] and experienc[e] one kind of thing or experience in terms of another" (Lakoff & Johnson, 1980, p. 455). By unfolding such metaphors and following their implications, therefore, we can understand how a person or, in this case, an institution meaningfully structures a particular domain. The metaphor deployed by the *BfArM* is that of a "digital building of healthcare" and of putting together different "digital building blocks". For this building, three things are necessary (at least according to the blueprint that the *BfArM* provides): bricks (5.1), mortar (5.2) and the future inhabitants (5.3). Like any good constructor (or constructivist), I start with the former[4].

5.1 Assembling the Bricks and Building Blocks

Why would one need a digital building for healthcare anyways? Outlining the backgrounds against which the conceptual metaphor is placed, the documents suggest several relevant external conditions. The first of these is an ongoing broader transformation of future healthcare systems. The *BfArM* argues that we cannot say much about the healthcare sector of the future, except that "[i]t will definitely be much more digital" (*D8, p. 1292*). It will be affected by an encompassing process of digitalization that has already begun and will stretch into this undefined future. Besides other domains, it is "also radically changing healthcare at a rapid pace, clearly representing not only a current trend but also a future one with further multiple opportunities for modern, patient-centric and effective healthcare" (*D8, p. 1297*). Taken by themselves, both of these quotes appear to reek of techno-determinism. Even if the future of the healthcare sector is widely unknown, it is inevitable, perhaps, that digital technologies move into the healthcare sector, transforming it from the ground

4 The lobbyist I interviewed used a different metaphor regarding *DiGAs*: "At the moment, the whole thing is just, I would say, a little plant. You know, a seedling where two or three centimeters come out. And that's where we are right now" (*representative of digital health umbrella organization*). This is interesting because both metaphors, building/making and growing have been routinely juxtaposed, with the latter attributed to "nature" and the other to "culture" (Ingold & Hallam, 2016).

up and at their own pace. They will open new chances for a transformed treatment, now and in the future. But it is unclear who could steer or influence this development. In the first excerpt, "becoming digital" is a predicate of the future. In the second sentence, "digitalization" even is the subject of the developments described. Any controlling instance is absent for now.

Other passages in the documents further reinforce this impression. They speak of the growing dissemination and popularity of digital health technologies in the healthcare sector. These technologies "are […] penetrating the healthcare market" (*D8, p. 1292*) in different forms. But this development, these documents go on to lament, goes unchecked and without a possibility for oversight. One document states, for example, that

> [s]ince a systematic, independent and transparent scientific evaluation of the applications available on the market has not yet been available, the need for a corresponding evaluation and comparative overview as an orientation for sensible therapy support has grown along with the variety of products. (*D4, p. 1232*)

Digital technologies in the healthcare sector are proliferating in terms of product variety (associated with the proliferation of technologies more generally), the use of these products and their relevance in healthcare settings. What the documents imply the lack, however, of an institution that orders this rhizomatic growth through evaluation and comparison. The imagery of digital technology unfolding in an undisciplined and uncontrollable way will be complicated once we move on to the mortar, that which holds everything together (and, of course, we can already guess what it will all come down to). At this point, I am interested in the building blocks of such digitalized healthcare, though.

The vision of digitalization of the healthcare sector needs to be considered against the backdrop of other developments in the healthcare sector that are also currently ongoing but will likely stretch into the future. In this context, *D8* lists

> in addition to the opportunities offered by increasing digitalization for patient care, taking into account demographic change, increasing chronic diseases and rising costs for innovative therapies, as well as growing, meaningfully aggregated health data, to master the challenges, such as data protection and information security. (*D8, p. 1297*).

This excerpt qualifies the opportunities of digital health care that some of the previous quotes evoked in two ways. On the one hand, it acknowledges that the chances correlate with challenges. Both need to be attended to – I will return to this soon. On the other hand, these chances are not free-floating but related to particular other developments in the healthcare sector or society more broadly: The demography is changing, chronic diseases and costs for therapies are on the rise and healthcare is increasingly datafied.

This is the two-fold background against which a digital building of healthcare seems to be necessary: at least partially problematic tendencies in the healthcare sector and a digital transformation that is unfolding, seemingly by itself, with both chances and challenges. But what does this digitalization look like? In this regard, the documents emphasize that "[d]igitalization cannot be considered in isolation" (*D8, p. 1297)*. A more encompassing view is necessary:

> Digitalization can only be successful in the overall view of the individual digital building blocks [Digitalbausteine] and interfaces as well as relevant aspects, in particular from the medical, information technology, drug, medical device and social law context. (*D8, p. 1296*)

The concept of "digitalization", hitherto undefined and implied to be a force unfolding by itself, experiences its first complexification. This is the nitty-gritty at the core of the *BfArM*'s vision of digitalized healthcare. In the healthcare system, digitalization is not a monolithic development but rather the integration of several building blocks, "such as DiGA, DiPA, ePA, telematics infrastructure, etc. and designed jointly in interdisciplinary teams and projects" (*D8, p. 1297)*[5]. More yet, the excerpt quoted above also highlights that digitalization does not only comprise such *technological* building blocks but also others that one could classify as *scientific* (e.g. medical building blocks) and *social* (e.g. legal building blocks). The imagination of the digitalized healthcare sector very much resembles the socio-technical assemblages that ANT seeks to describe.

DiGAs, the quote above indicates, are one of the building blocks of this socio-technical assemblage. They cannot be meaningful without being related to other components in this assemblage: "*DiGA* cannot be considered in an isolated way but must be seen as part of digitally enabled healthcare" (*D1, p. 9*). At the same time, the documents imagine the status of Digital Health Applications to be more complicated and ambivalent. On the one hand, *DiGAs* are akin to the groundwork making possible and accelerating the developments of the other building blocks: "The 'prescription app' has thus brought about an overall digitization boost in the German healthcare system" (*D4, p. 1232*). As a primary digital building block, *DiGAs* have agency within the assemblage of building blocks. They push forward digital developments in the German healthcare system. This is, likewise, expressed in the metaphor of *DiGA* as the "nucleus for integrated, digitally supported, patient-centered care processes" (*D3, p. 1204*). The biological imagery of the nucleus suggests that Digital Health Applications are *the* crucial component of digitalized or digitally supported healthcare. They carry the information needed for the development of other such processes. These processes, in turn, shift the focus of healthcare on the patient, the main occupant of the digital building of healthcare, once it is finished[6].

On the other hand, *DiGAs* appear to encounter an already existing digital healthcare system. In this vision, they are not the starting point for digital developments but "must be gradually integrated into the growing e-health infrastructure in the coming years and brought into a dynamic interplay with overarching care processes in terms of both technology and content" (*D3, p. 1205*). This quote

5 Digital Care Applications (*Digitale Pflegeanwendungen, DiPA*) that have been recently introduced and are envisioned to be regulated similarly and based on the experiences made with *DiGA* are a new building block integrated into the ensemble. Fitting the building metaphor at the core of the imaginary, *DiPAs* are seen as a first "*Ausbaustufe"* (*D4, p. 1240*) which can either be translated as "stages of expansion" or as a "buildup".

6 *D3* gives an example of how *DiGAs* contribute to a cascade of other digital transformations as they spill over into other areas of healthcare, for example in the use of digital data and algorithms to evaluate healthcare interventions. "At the same time, however, the possibilities will grow to use *DiGA* to collect suitable outcome parameters and to systematically measure the effects of care concepts systematically measure and evaluate them" (D3, p. 1205).

envisions a challenge as much social as it is technological. *DiGAs* have to become integrated with the other, already existing technologies but also with existing healthcare processes. Integration is necessary because building blocks by themselves do not hold together – this is what the mortar is for.

Additionally, the status of *DiGAs* remains ambivalent because they can be broken down into constituents. So far, in my reading of the way the *BfArM* imagines digitalized healthcare *DiGAs* have been what John Law (1992) would call "punctualized". They have figured as a unified actor that, for instance, can stimulate further digital changes to the healthcare system. This figure crumbles under closer inspection. Although the core function needs to be digital, Digital Health Applications can be entangled both with "other hard (including sensors, wearables)" or "consultations or other medical or psychotherapeutic services" (*D4, p. 1233*). In a way, the imagination of the socio-technical *DiGA* assemblage mirrors that of the broader digitalized healthcare system in two ways as a microcosm. First, the digital component in this assemblage remains at the center. It needs to be the 'active component' for the health effects, echoing the vision of *DiGAs* as a nucleus in and for the broader digital healthcare system. Second, this micro assemblage, too, is socio-technical. It can involve other technological components (wearables, sensors). But it also encompasses particular practices and related human actors.

The *BfArM* imagines the digitalization of the health system to bring several benefits. One of the quotes above already stated that *DiGAs* can bring about "integrated, digitally supported, patient-centered care processes" (*D3, p. 1204*). Another one suggested that digitalization as a whole brings "multiple opportunities for modern, patient-centric and effective healthcare" (*D8, p. 1297*). Other imagined benefits are the "many opportunities for improved, more efficient care, especially in regions with weak infrastructures, and for the development of new therapy options" as well as "the improvement of preventive, diagnostic and medical therapeutic measures" (*D8, p. 1292)*. Additionally,

> *DiGA* can support users in everyday life with simple, understandable information, hints, reminders, questions, bring evidence-based, guideline-based medicine and quality-assured health information in an easily accessible, context-sensitive form, provide instructions and explanations that support patients in their everyday management of the disease, thereby building health knowledge on an occasion-related and individual basis, motivating behavioral changes and practicing them. (*D3, p. 1204*).

These imagined benefits do not differ very much from those imagined benefits that research has unpacked in the discourses around digital health (see ch. 2.1.1). Both parts of the two broader argumentative patterns identified by Marent and Henwood (2022) are covered. First, digitalization in general, and *DiGAs* specifically, are envisioned to *empower the patients*. As a notoriously ill-defined concept in the discourse on digital health technologies (Morley & Floridi, 2020), in the quotes above, 'empowerment' comes to mean that the patient moves to the center of healthcare and that they gets access to medical information relevant to their condition. The use of the concept in this

way hides two unspoken tensions. On the one hand, empowering the patient does not call into question the predominance of biomedicine. Only the conditions of access to biomedical knowledge change, enabling it to spread beyond the immediate doctor-patient relationship. This is in line with what Adele Clarke et al. (2010) have analyzed as “biomedicalization”. On the other hand, biomedical information is supposed to “micro-nudge” (Schüll, 2016) the patient into changing their behaviors according to the medical knowledge.

Second, digitalization and *DiGAs* are thought to *make healthcare more efficient* in multiple ways: They will make healthcare more accessible, especially where resources are scarce (which harks back to the problematic tendencies observed in one of the quotes above). They will generate knowledge, especially where knowledge is lacking. They will improve existing practices based on data collected by *DiGA* and other digital technologies. All this gets a normative impetus: This healthcare is considered to be “modern” which, inversely, suggests that healthcare before its digitalization/*DiGA* has not been modern. Digitalized healthcare appears as a timely update of the health sector, speaking to the motif of disruption in the discourses on digital health.

Even though these visions of the benefits of digital healthcare echo the content of the prevalent discourse on digital, there is an important twist. The language in the quotes above reflects this. It is one of the “opportunities”, of effects digitalization “can” have but will not inevitably have. The initially indicated techno-determinism of digital health is further relativized. The following quote captures this. Digital health technologies in all their diversity, *D8* states,

> not only present opportunities for patient-centered, better and increasingly integrated healthcare, but also bring new challenges and risks - such as data quality, data protection, cyber security, interoperability, ethical issues and others (*D8, p. 1293*)

The first part of this quote summarizes my analysis thus far. Digitalization empowers patients and improves healthcare. The twist is in the second part: Digitalization *also* encompasses (new) challenges that need to be resolved. It is, in other words, essentially undecided and initially affords both opportunities and challenges. That is why it is necessary to move on to the mortar – in the imaginary, what holds the components together in a way that realizes the benefits by solving the challenges and mitigates the risks?

5.2 The Mortar That Holds It All Together

The reader will likely have seen through my setup. In the imagination, the *BfArM* that takes the role of the mortar that holds the digital building blocks together.

> In the convergence and interaction of the individual digital components of modern healthcare, the BfArM is already taking on tasks at central interfaces for the (digitally supported) patient care of the future and is taking on innovative approaches – while safeguarding aspects that are important for users, (*D8, p. 1292*)

The *BfArM* is the missing piece in between the different components of a digital healthcare system. Because it operates at these interfaces and because it "is proactively committed to the opportunities offered by digitized healthcare" (*D8, p. 1293)*, especially for future users, it resolves the indeterminacy between benefits/opportunities and challenges/risks in the direction of the former, realizing the previously virtual benefits of digital health care.

In this vision, the *BfArM* is particularly suitable for the task of working in the interstices and bringing the components together. First, this is because the agency has anticipated these developments in the past and has "recognized the 'digital trend' at an early stage through intensive exchange with manufacturers" (*D8, p. 1296*). For the *BfArM* what may initially have seemed like an uncontrollable, auto-dynamic proliferation of digital technologies came as no surprise. As part of the "digital readiness@BfArM", the title of D8, it was and continues to be prepared. For example, it has established

> a systematic 'horizon scanning' approach to identify emerging scientific and technological trends at an early stage, to analyze their impact on the regulatory environment in order to adapt processes and information at an early stage and to build up and provide expertise. (*D8, p. 1296*).

The second reason why the *BfArM* is envisioned as the most suitable mortar is that it does not stack the building blocks without a plan. It has, to stretch the building metaphor further, a construction plan set down in a report entitled "#bfarmDigitalFuture" (Bundesinstitut für Arzneimittel und Medizinprodukte, 2021a)[7]. In this plan the regulatory agency puts forward "a concrete vision for a digital, interoperable healthcare ecosystem with the topic of digitization" and it is "actively involved in the concrete further development of this ecosystem (*D8, p. 1297*). Accordingly, the *BfArM* transcends its narrow, legally defined role as an executive organ as not only as passive receiver of legal instruction by the legislator but as actively developing a vision of digital healthcare in Germany, shaping the digital transformations in this direction.

Thus, I have touched upon the third way the *BfArM* is imagined as well-suited for holding the building blocks together. It follows a hands-on and proactive approach. It "is actively shaping the digital transformation and helping to prepare the German healthcare sector for the digital future in the best possible way" (*D8, p. 1297*).

Note, that, similar to the imagery of the "ecosystem" this approach not only comprises technologies but shaping the digital transformation and the healthcare sector as a whole. This is what sociotechnical imaginaries are about, "they project visions of what is good, desirable, and worth attaining for a political community; they articulate feasible futures" (Jasanoff & Kim, 2009, p. 123). In this envisioned future, several boundaries become blurred through the hands-on approach by the *BfArM* and its interstitial position (see ch. 8.1.1). First, the boundary between political powers: As

7 I have chosen not to include this report in my sample for pragmatic reasons: *DiGA* and their approval which I am primarily interested in only play a minor role in this report and many of the themes of the report are taken up in the documents in my sample. For an analysis that solely focuses on how the *BfArM* imagines the digital healthcare system this report would, however, be an important starting point.

an executive authority “the BfArM has been intensively involved in the initiative of the Federal Ministry of Health (BMG) to design and establish the new DiGA fast track” (*D4, p. 1232*). Additionally, disciplinary boundaries are blurred: The digital transformation will be shaped “together in interdisciplinary teams and projects” for which the *BfArM* occupies an “important interface” (*D8, p. 1297*). Finally, its hands-on approach blurs boundaries between countries, between the national and the international level. The *BfArM* cooperates “with other players in digital healthcare at national and European level” all with the goal of “ensuring that digital healthcare benefits citizens with tangible added value, also taking into account future digital offerings and trends” (*D8, p. 1297)*.

The language deployed to describe the envisioned role of the *BfArM* is one of “shaping”/”designing” (*gestalten*) or “mastering”: Digitalization of the healthcare sector, an uncontrolled force to some, finally finds its master in the *BfArM*. This master has a several tools at its disposal that facilitate the mastering and shaping of digital health. The first of these is the legislative framework, that is envisaged to order the integration of digital apps into healthcare provision.

> It [the regulation] bridges the gap between technological developments and changing societal demands on the one hand and established principles and structures in statutory health insurance on the other. It opens up a new service area, offers answers to the most important questions and challenges associated with it, and also prepares further development perspectives for the future. (*D3, p. 1198*).

This quote describes the regulatory framework as offering multiple integrations between disparate components of digitalization in healthcare: the integration between established structures and developments – socio-technical – that have outgrown these structures. Further and relatedly, the regulatory framework allows the integration of different timelines: the past of the healthcare system, the present-day requirements and future developments. In particular, the regulatory framework is imagined as open to future developments. It is merely “the starting point of a continuous process of observation, readjustment, correction and extension” (*D3, p. 1208*) along with these developments. Finally, it integrates the different building blocks of digitalized healthcare.

The approval process and the different requirements figure as another tool in the imagined shaping of digitalized healthcare. It is a “future-oriented step towards establishing quality-assured digital health applications in healthcare in Germany (*D4, p. 1239*). In this vision, the approval process contributes to ordering, shaping and mastering the digital transformation of the healthcare sector because it introduces an evaluative framework. The backdrop of this is the concern about rapidly proliferating digital applications without a yardstick for their assessment. The approval process addresses this concern, again with an orientation toward the future, by introducing quality-based distinctions among different applications – endowing (only) one type with the quality of being a *DiGA* – which orders the otherwise disorderly developments.

Moreover, the organizational structures created at the *BfArM*, especially the consultation and information services it offers, are the tools for shaping the digitalization of healthcare. With them, “the BfArM sees itself as a promoter of future-oriented, safe and appropriate patient care” (*D5, p. 1248*).

Digitalized healthcare becomes healthcare provision *tout court*, creating a nominal commonality between digital and earlier forms of healthcare provision. However, only the former is desirable and worthy of support by the *BfArM*. Against the backdrop of previous forms of healthcare provision, the passage further qualifies the particular attributes of digital forms: being future-oriented, safe and appropriate. While there may be a continuity of healthcare, rejecting the idea of radical disruption, there is still a difference in qualities between digital and other forms of healthcare provision. Furthermore, the documents envision the consultation and information services for manufacturers of digital health technologies as a pathway through which the *BfArM* can promote its particular vision of digitalized healthcare. This relates to the vision the *BfArM* has of itself in this regard. Unlike the role as a gatekeeper it is endowed with legally – without passing the approval process no app will be admitted into the first healthcare market –, the *BfArM* sees itself as promoting *DiGA* and digital health technologies based on the broader vision of digitalized healthcare it upholds.

5.3 The Inhabitants: Multiplicities and Asymmetric Relations

The envisioned digital building of healthcare consists of bricks, digital building blocks, and the mortar, the *BfArM* and its role in the digitalization of healthcare. Who will inhabit this building? In other words, whom do the documents envision as the beneficiary of the digitalization of the healthcare sector and the role the *BfArM* plays? This seems fairly obvious, initially. If digitalized healthcare is envisaged to bring a more efficient, patient-centered and empowering healthcare provision, 'the patient' is the primary beneficiary, consequently. Relatedly, the documents present the work of the BfArM as being at their service. The goal of realizing the chances that digital health provides (and, simultaneously, resolving its challenges and mitigating its risks) will, ultimately, bring an "added value" (D8, p. 1293, 1297) for the patient. The Fast-Track, in particular, is envisaged to let them profit "from undelayed access to effective and safe 'digital helpers'" (*D8, p. 1248*). The (accelerated) approval process will be of benefit in two ways. First, it assesses whether the *DiGA* is safe and effective, allowing it to turn into a "helper" and realizing the opportunities of digitalization rather than its downsides. Second, it does this fast to not delay access to the DiGA unnecessarily. Neither assessing safety nor efficiency are perceived to be in tension with accelerated access, both can be reconciled in and *through* the work of the *BfArM*. Notably, all intermediate steps are hidden in this imagination: The patient can get immediate access to the *DiGA* without the mediation of the market, a doctor who needs to prescribe the app (or at least diagnose the respective condition) and the health insurance provider[8].

8 The manufacturers who have co-authored D6 challenge this imagined relation of immediacy between the (end of the) approval process and access to *DiGAs*. They highlight the role of those "mediators" (Latour, 2005) suppressed in the imaginary: the doctors that need to know about *DiGAs* and be ready to prescribe them and the prescription that tends to get lost between the doctor, health insurance company and the patient.

The imagined temporality of the approval process speaks to the literature on accelerated approvals for pharmaceuticals which has shown that the benefit of the patient is always the (imagined) ultimate goal of such procedures (which this literature, to a large extent, denounces as rhetoric, of course) (Davis & Abraham, 2011a, 2011b). Crucially, by implicitly referring to such regulatory reforms implemented for pharmaceuticals for life-threatening diseases, the *BfArM's* imaginary evokes a similar relevance for *DiGA*. This contrasts with the designation of *DiGA* as "digital helpers" and the limitation of eligible applications to low risks classes of medical devices (see ch. 6.1.1). Moreover, the backdrop against which this imagination is designed, the "negative imaginings" (Jasanoff, 2015, p. 5) that every socio-technical imaginary (tacitly) comprise, become obvious in this temporal element of imaginary: an inflated public agency that inhibits innovation in the healthcare sector through slow regulatory procedures. The information and counseling services that the *BfArM* offers for manufacturers in preparation for the approval process are also envisioned to "benefit […] all sides […] in particular the patients by an undelayed entry of DiGA into the regular supply due to higher application quality" (*D8, p. 1243*). The services offered by the *BfArM* will increase the quality of applications which, in turn, will increase the chances for success in the approval process. Far from regulatory capture (at least in the imagination), however, this will benefit the patient who will profit from the accelerated access to *DiGA*.

Things get a bit more complicated, though. First, it is not straightforward that 'the patient' is the primary beneficiary of digital health and *DiGAs*. This beneficiary appears in different roles in the documents. Each of these maintains an alternative relation with *DiGAs*. First, there is 'the patient'. The patient is defined in clinical terms as diagnosed with a particular condition and uses a *DiGA* to treat and manage this condition. Second, the primary beneficiary of *DiGAs* the documents introduce is 'the user'. For 'the user', the *DiGA* is primarily a technological device. Although this has, to my knowledge, previously not been acknowledged explicitly, "patient" and "user" frequently appear in the promissory discourse on digital health. There is a good reason for this role conflict. It illustrates the changing position that digital health technologies occupy between medical devices and lifestyle technologies. The 'patient' relates to digital health technology as medical devices as the 'user' relates to lifestyle technologies. The novel regulatory framework introduces two new figures: the 'insured person' and 'the citizen'. These relate to the *BfArM* as a public regulatory authority and to *DiGAs* as "socio-legal objects" (Cloatre, 2008) to which they are legally entitled. Thus, *DiGAs* are as much a legal disruption as they are a (limited) technological disruption to healthcare services in the documents. "For the first time since the introduction of the statutory health insurance in 1883, this claim does not refer to analog benefits but to digital products" (*D3, p. 1198*). As a result of these multiple roles of the primary beneficiary, the "surplus value" of *DiGa* is one time envisioned to benefit the "healthcare provision for patients" (*D8, p. 1293*) and another time the "citizens" (*D8, p. 1297*).

The second complication stems from the fact that the patient/user/citizen/insured may be the primary but not the only beneficiary. The digital building of healthcare in Germany is co-habited, as it were. In their future deployment, *DiGAs* will be “shared by patients and care providers” (*D3, p. 1204*). Especially the broader vision of a connection between the different “building blocks” of digital health is assumed to be beneficial for healthcare providers. It “ensures that not only the patients, but also the service providers benefit from good and demand-oriented processes that effectively support the daily treatment routine to the same extent. (*D3, p. 1205*). To not be mistaken here, however: Unlike what the imagination of shared benefits “to the same extent” implies, the relationship between the cohabitants is not symmetrical. The sampled documents envision the regulatory framework and the approval process to put “digital innovation in the hands of the patients” (*D4, p. 1205*). It is precisely this which will bring about a better healthcare provision. Additionally, resolving the challenges of the disruption *DiGAs* pose “require a lot of innovation” (*D4, p. 1205*) from healthcare providers (among others), not from the patients.

Meanwhile, the socio-technical imaginary that the *BfArM* documents put forward also provides a role for the neighbors of the German Building of Digital Healthcare, a vision of the global social order in the development of digital health technologies. D8, for instance, states that Germany has taken over a “pioneering task” (*D8, p. 1239*). It leads the way as the first country that has implemented a legal framework integrating health applications into standard healthcare provison. All other countries take the role of interested, albeit lagging observers of both technological and regulatory innovations. On the one hand, the “digital developments” to which Germany has already responded “are also being closely followed outside Germany” (*D8, p. 1239*). This harks back to how the *BfArM* presents itself. It anticipated the developments before they unfolded, allowing Germany to move beyond the stage of observation before other countries. On the other hand, “the DiGA Fast Track is also used as a model for similar procedures in other countries” (*D9*). Especially the speed of the approval seems to be attracting much attention. The manufacturers who have contributed to the special issue on *DiGAs* express that they know of no country that has implemented “[s]uch a fast procedure” (*D6, p. 1249*). In the global order, Germany takes the position of a role model and forerunner for other countries because it has been able to anticipate technological developments and blazed a trail that these countries now follow.

I want to close this subsection on the imaginary of digitalized healthcare in Germany put out by the *BfArM* and its environment with a lengthy quote that portrays an imagined scenario of digital healthcare in Germany in 2030. It succinctly pictures the “desired future” that informs contemporary (regulatory) practices::

> Nele is gently awakened by her smart device, as she does every morning. A quick glance at the display (weather: 17 °C, no rain; ePA: long deep sleep phase, pulse o.k., slightly elevated temperature; calendar: next appointment 8:30 a.m. team meeting in the practice) gets her out of bed. She is very pleased that her deep sleep phases have improved quickly and sustainably thanks to the sleep DiGA-

> so. But elevated temperature for the second day in a row? The ultra-thin multisensor on her wrist seems to be working perfectly. A glance at her health dashboard in the ePA shows the course of her current critical health parameters. And behind today's temperature values, an action item is already noted: "Clarification of infection" with a suggested appointment this afternoon with her family doctor. She confirms it by clicking on it and it appears in her calendar with a brief flash. Her family doctor has recently switched to the fully digital infrastructure. For several months now, Nele has been working at the medical care center as a "digital MFA," i.e., as a medical assistant specializing in digitalization. (*D7, p. 1285*).

This excerpt illustrates the vision of medicine and health in digitalized healthcare. 'Health' is turned into an entity that 'the patient' can and should continuously surveil. The patient role is re-defined itself: One *could*, in principle, always be sick (e.g. having a fever as a symptom of a lingering infection) which data will reveal (echoing Armstrong's (1995) concept of "surveillance medicine" or, again, Clarke et al.'s (2010) analyses of biomedicalization). Through the connection between different building blocks, sensors, *DiGA*, electronic patient records and the telematics infrastructure of the General Practicioner (GP), this monitoring and managing of (potential) medical conditions become possible. The patient is relieved of most of the necessary actions as the digital assemblage provides tentative diagnostics and arranges an appointment. The GP will need to have "switched to the fully digital infrastructure", implying that new dividing lines along degrees of digitalization will emerge. Finally, the digitalization of healthcare is also imagined to bring new jobs and job descriptions that change the understanding of medical practice, medical education, etc. The digital building of healthcare, once all building blocks hold together, encompasses patterns and the organization of the healthcare sector and points to 'society' as a whole[9].

6 The Explicit Requirements in Theory and Practice

I now want to change the perspective of my analysis a bit and consider the approval process itself. More specifically, I focus on the explicit requirements that the law stipulates for Digital Health Applications. These requirements come in two forms. They are, on the hand, abstract requirements formulated both in the Digital Healthcare Act and in the Digital Health Applications Ordinance. I distinguish them from the concrete requirements in the actual practice of the approval process. In this context, the *BfArM* assumes the role of an interpreter as the *DiGA* Guide "explains in detail, among other things by means of numerous examples, how it interprets the normative requirements for inclusion in its assessment practice" (D4, p. 1237). Following this distinction, my argument takes two steps. I begin by presenting the different requirements 'at face value', as it were (6.1). In the second step, I focus on their implementation in practice (6.2). I argue that this reveals an implicit hier-

9 D3 similarly imagines a digital healthcare scenario that is more narrow in that it describes the changed practice from the perspective of a medical professional. It seems rather unfortunate that in this scenario it is one "Mr. K [*Herr K.*]" (*D3, p. 1205*) who takes the position of the patient/user/citizen/insured, given the cross-reference to a Kafkaesque world this evokes.

archy of the requirements-in-practice. I end the subsection by summarizing the value objects we have encountered in these explicit requirements (6.3).

6.1 Approval-in-Theory: The Requirements to Become a Digital Health Application

The requirements for health-and-wellness apps to become *DiGAs* are considered the main novelty of the approval process. D1 states that "[f]or the first time, the Fast Track-procedure defines a full set of requirements for DiGA" (D1, p. 9). Upon their application, interested producers of a *DiGA*-to-be need to meet a range of requirements. Crucially, this 'requirements assemblage' combines social, more specifically legal, technological and scientific requirements.

6.1.1 Before the approval process: Being a Medical Device

The first important observation is that not all requirements are on the same regulatory plane. Later, I will refer to this as an instance of "distributed regulation" (see ch. 9.2). It becomes obvious in the requirement for applicant applications to already be listed as a medical device according to the European Union's Medical Device Regulation (MDR). The app needs to be "basically a software or another product based on digital technologies with a medical purpose which has already been lawfully placed on the market, i.e. a CE-marked medical device with low risk potential" (*D4, p. 1240*). In this sense, the first ontological transformation has already taken place: Eligible apps are not merely technologies (anymore) but already circulate as socio-legal objects within the EU jurisdiction.

Implementing this requirement allows the approval process to circumvent the "boundary work" (1983) that would otherwise be necessary to distinguish between lifestyle technologies and medical devices. The European MDR created what Thomas Gieryn (2008) later called a "settled boundary" between these categories that the framework for *DiGAs* can readily draw on and re-entrenches simultaneously[10]. The settled boundary pragmatically reduces the workload for the *BfArM*. It limits the pool of potential applicants to apps registered as medical devices already (Lievevrouw et al., 2021). The precondition for the application sets up "the first major and also financially large hurdle" (representative of digital health umbrella organization) that potential manufacturers need to overcome. A manufacturer told me confirmed that these regulatory hurdles made them reluctant to have their app registered as a medical device at first. On the other hand, because of the requirement, some of the details of the other requirements are already assessed by the Notified Body. This is the quasi-regulatory body appointed by authorities in the respective EU member state to test whether the device complies with the European legislation. The *DiGAV* states that "the CE conformity marking of the medical device is considered to be proof of safety and functional capabi-

10 Following Gieryn (2008, p. 91) "settled boundaries" are "stable and secure, institutionalized and routinized, structuring and enabling as though on autopilot, needing little or no manifest attention". To a certain degree, they are transparent in everyday practice and can serve as a ready-made resource.

lity" (*D11, §3 (1)*. The *BfArM*, therefore, "only carries out checks on the formal legality of the CE marking for this requirement" (*D1, p. 36*).

The distribution of work between Notified Bodies and the *BfArM* also distributes the responsibility for the risk analysis. The *DiGA* regulation only admits low-risk classes of the MDR (I, IIa) to apply for a listing in the *DiGA* directory. The Notified Bodies assess this classification (Keutzer & Simonsson, 2020). Legally, this releases the *BfArM* for any risk-related responsibility. This is especially clear for preliminarily listed apps in which only the requirements relating to data/information security, interoperability and the medical device registration are assessed while the assessment of the clinical impact of the app is postponed. For temporarily listed devices "the safety of the medical device [basically] is ensured by the medical device law. The DiGA manufacturer is liable according to general principles of civil law and product liability law. (*D1, p. 86*). Likewise, the *BfArM* needs to be notified in case of adverse incidents with the *DiGA.* But this is primarily a provision of the MDR and only indirectly of the regulatory framework for *DiGA*.

The requirement also introduces two temporal components into the approval process. It first establishes a pathway for the further development of the regulatory framework along the risk classes. D4 suggests that

> [a] logical further development in view of the positive results and the expected higher classification of most DiGAs in the coming years should therefore be the inclusion of higher risk classes or, for example, digital in vitro diagnostic devices according to Regulation (EU) (*D4, p. 1240*).

The other side of the coin, however, is that it also limits these developments – especially if one takes literally that the quote imagines them to be "logical" – to existing lines. The path-ways may turn into path-dependencies, depending on how the MDR develops that the regulation of Digital Health Applications is in a constant interplay with.

From the perspective of the producers of Digital Health Applications, the requirement to be listed as a medical device introduces a temporal order to assemble the requirements. "If you are a medical device, then you can go on at all" (*manufacturer*). The manufacturer initially hesitant to have their app registered as a medical device had to change their mind because the registering is "a step that precedes, a very important step" (*manufacturer*). The approval process prescribes a linear temporal order for how manufacturers approach their applications. Although "no exceptions are possible" (*D1, p. 37*) in that the app needs to legally be a medical device at the end of the three-month period, there may be slight deviations:

> I'll put it this way, you can of course do everything in parallel, but then at some point it also gets a bit through. And we now have an arbitration board proceeding from a DIGA, who quite simply say, 'Hey, hello, but we now need a deadline extension in the arbitration board, because, this is the least important thing for us, because, we are in the recognition as a medical device.' (*representative of digital health umbrella organization*).

Deviations may only be possible if the company has the necessary amount of employees to handle both the approval process and the assessment according to the MDR in parallel and before the

end of the three-month deadline of the approval process (which is why the company mentioned here has to ask for a deadline extension). This foreshadows the implicit requirements I will discuss in greater detail below. For now, there is one final thing that is probably obvious and goes without saying. I nevertheless want to make it explicit, not least because it shows one way the approval process positions *DiGAs*. The requirement to be classified as a medical device indicates that they "digital medical devices" (*D3*, *p. 1198, 1204*). Considering the other requirements, this may not be as straightforward as it seems.

6.1.2 The Requirements for Data Protection and Information Security

The documents repeatedly introduce the requirements for data protection and information security as a response to the challenges of digital technologies. As just one example, D4 speaks of "master[ing] […] challenges, such as data protection and information security," (*D4, p. 1297*) that the digitalization of the healthcare system brings. The regulatory framework distinguishes between data protection and information security, also reflected in the diverging ways these two topics are addressed.

Data protection, according to the *DiGA Guide*, aims at "the protection of confidentiality, integrity and availability of all data processed" (*D1, p. 44*). Most of the requirements in this regard are not specific to the *DVG* or the *DiGAV* but (pre-)predetermined by the GDPR. The regulatory framework for Digital Health Applications mainly "specifies and supplements the requirements of the General Data Protection Regulation (GDPR) and other data protection regulations" (*D1, p. 37*). However, D2 further details what the *DiGAV* as the defining regulatory document for such applications adds to existing regulations. "Data processing is geographically restricted, there may be no advertising, and only certain purposes of data processing relevant to the provision of care are permitted" (*D2, p. 1199*).

These further provisions signal how the regulation of *DiGAs* differs from the regulation of health-and-wellness apps that are subject to the GDPR without such specifications. Health-and-wellness apps can and frequently do include advertisements and data is processed for (commercial) purposes. Digital Health Applications may also have existed as a health-and-wellness apps that included advertisements and processed data for commercial purposes before the approval process. Other versions of them may exist in parallel as a health-and-wellness app to which these provisions do not apply. "The BfArM only examines the version or variant of a DiGA for which an application for inclusion in the DiGA directory is made. (*D1, p. 128*).

For data processing, the regulatory framework introduces a distinction between different types. On the one hand, data may be collected for "the intended use, the further development of the application or for the use of the DiGA in the provision of care, for example, for the performance of studies to prove positive effects of care or as a basis for price negotiations and billing" (*D2, p. 1199-1200*). On the other hand, data can be processed for the improvement of the app. For both purposes, the

regulation requires separate and layered electronic consent forms. The *DiGA* needs to provide users with a privacy policy. They need to actively consent to these purposes. The consent for processing data as part of the clinical study is only possible for official participants of the study. Additionally, non-consent to the second of the two permissible purposes of data processing cannot restrict the use of the app.

Information security more closely encompasses the health information collected while using the app. A distinction is made between "Basic Requirements that Apply to All Digital Health Applications" and “Additional Requirements for Digital Health Applications with a Very High Need for Protection” (*D1, p. 44*). Similar to the requirements for data protection, these requirements are informed by standards defined outside of the *DiGAV* and by another German authority, the German Federal Office for Information Security (*Bundesinstitut für Sicherheit und Informationstechnik*, *BSI*). These standards also define the difference between the “basic” and the “additional requirements” based on the expected consequences for the user should their information be disclosed. Interestingly, the *DiGA* requirements define information security not as a technological quality but as a socio-technical quality, not a “conglomerate of technical measures, but rather as a process to be anchored in the company” (*D1, p. 45*). This is a response to the challenges posed by digital health, in particular the speed of development of digital technologies. A “secure DiGA is always only a snapshot: The DiGA evolves in short release cycles, and new threats and risks affect it from outside. Security measures that are state-of-the-art today can therefore be ineffective in just a few months” (*D1, p. 45*). Considered a “process” to be implemented in the companies rather than a one-time query, information security comprises an analysis of the requirements and security demands of the *DiGA* throughout its lifecycle, processes for a “Release-, Change- und Configuration-Management” (*D1, p. 46*) as well as monitoring of risks to information security caused by third-party technologies and software used for the *DiGA*. The *BfArM* investigates the requirements for information and data security through a series of statements as “promises regarding information security which the DiGA manufacturer makes to the BfArM and not least to its customers” (*D1, p. 46*). Only since 1 April 2022 do manufacturers need to prove that they meet these requirements (retroactively) through certificates issued by quasi-regulatory bodies.

6.1.3 The Requirements for Interoperability

In the first subsection, I have shown that a vision of digitalized healthcare informs the approval process. In this vision, digital healthcare is the interconnection of several building blocks. It expects *DiGAs* “to integrate seamlessly into the increasingly networked digital ecosystem in the future” (*D9*). In this context, the documents present the requirement for interoperability as the correlate of this vision. Interoperability is “an essential success factor for the entire digitalization strategy”: Without it “it is not possible to merge large amounts of data, to analyze these data in a meaningful way (e.g. for longitudinal studies or cross-sectoral questions) or to evaluate them for billing purpo-

ses”(*D8, p. 1295*). The *Guide* emphasizes that this also applies to *DiGAs* for which interoperability is the only way they "can be used sensibly and efficiently with network effects being achieved” (*D1, p. 51*). Thus, interoperability means “the usability of the exported data in the context of healthcare” (*D1, p. 59*). Data needs to be “actionable” as defined by Fiore-Gartland and Neff (2015) when exported: Exported data needs to inform further clinical action, an intervention by a doctor or a behavioral change by the user, without the need for additional work. Therefore, the requirement for interoperability is a socio-technical requirement. On the one hand, data needs to be exportable in human- and machine-readable to enable “data journeys” (Bates et al., 2016) across different healthcare sites. On the other hand, the it has to fit the workflows and skills of patients and physicians in these healthcare settings.

‘Interoperability’ takes on different forms as a regulatory requirement. It is “the ability of technical systems to cooperate on a technical-syntactical, semantic and organisational [sic!] level” (*D1, p. 51*). This definition further underlines that interoperability combines *technical* and *social* dimensions to ensure that *DiGAs* can be connected across technological devices, for example, wearables, sensors, or other *DiGAs*, and across organizational boundaries. The latter has a local and a global dimension. Data from Digital Health Applications should be interoperable both “with the ePA” as the global digital infrastructure for healthcare that the *DVG* introduced with the *DVG* in late 2019 and the “IT systems in the doctor’s offices” (*D8, p. 1295*) as the local digital infrastructures.

Several existing standards are provided and required to be implemented for *DiGAs* to achieve this integration. Similar to the requirements for data and information security, the regulatory framework for Digital Health Applications does not introduce these standards itself. They are either listed in a directory managed by *gematik GmbH*, the German National Digital Health Agency, or introduced by the German Federal Association for Statutory Health Insurance Physicians (*Kassenärtzliche Bundesvereinigung, KBV*) in the course of the introduction of the electronic health record (so-called medical information objects, MIOs). The *DiGA Guide* considers that the necessary two-fold orientation of interoperability, to both local and global infrastructures, may lead to conflicts between the global nature of the available standards and the local standards. "For example, if a DiGA must exchange data with certain IT systems in a hospital and therefore must use common interface standards in the hospital environment. (*D1, p. 53*)

In these cases, local standards may be acceptable but need to be justified. Nevertheless, the *BfArM* favors “interoperability” over “completeness” of the exportable content: “If a [sic!] MIO or a standard/profile/guideline recommended in the vesta directory is known, which covers 80 percent of the content that should be exported, then it must be used” (*D1, p. 59*). The provision also applies retroactively. The development of a standard for a MIO by the *KBV* entails that manufacturers implement this MIO within one year if it applies to their *DiGA*. Similar to the requirements for data and information security (at least until recently), the *BfArM* assesses interoperability through a checklist manufacturers need to submit with their application.

The requirement barely ever came up in the conversations I had with manufacturers. Only the lobbyist me that interoperability is more of a sign of the desired future for the healthcare system rather than a requirement for the healthcare system as it currently exists. Interoperability "is, after all, a requirement that we have everywhere in healthcare and that's why we don't have it. […] Yes. Requirement. Period" (*representative of digital health umbrella organization*). Interoperability appears to be a requirement informed by the broader vision for *DiGA* in a digitalized healthcare system, first and foremost. Its realization is not very far advanced.

6.1.4 The Requirements for User-Friendliness and Usability

The requirement for user-friendliness and usability, by comparison, surfaced the least in my empirical material. Nevertheless, I want to provide a brief overview and carve out how the regulatory documents imagine 'the user'. They further distinguish the requirements for user-friendliness and usability into sub-requirements. These distinctions mirror the imagination of who will inhabit the digital healthcare system. For instance, "Support for Healthcare Providers" (*D1, p. 72*) is placed alongside those requirements for the "insured person" – the only figure 'the user' appears as in the *DiGA Guide*.

In this context, manufacturers need to develop a "prototypical process of a care scenario" in which the *DiGA* will be used so "that insured persons and healthcare providers can get an idea of the healthcare approach associated with the use of the DiGA and the tasks assigned to them". (*D1, p. 72*). The *Guide* provides questions that this scenario needs to answer ranging from a description of the roles and their relations to communicative strategies for describing the use of the DiGA to the insured person. They demonstrate that the regulatory framework expects Digital Health Applications to introduce a new healthcare setting. In turn, this novel setting requires a blueprint of the treatment as a social situation with newly defined roles and responsibilities. D8 suggests that this comprises the question of "whether additional physician services are associated with the use of the listed DiGA" (*D4, p. 1234*). Such additional service can then be reimbursed by the German SHI.

The '(insured) patient-related' requirements usability encompass robustness, consumer protection and ease of use. 'Robustness' assumes a user that little tech-savvy and fallible. On the one hand the *DiGA* is within the limits of the "'best-effort' principle" (*D1, p. 65*) required to detect whether external devices work correctly. In case of external events that lead to a malfunction, the app needs to provide easy options for a systems reset. For example, "when connecting a new sensor, a user should not be forced to adapt the configuration of an old sensor but should have the possibility to go through the installation and configuration of a connected device completely new" (*D1, p. 65*). On the other hand, regarding the fallibility of the future user DiGAs need to be able to judge the plausibility of data the user puts into the app (based on other data). They need to make judgments about the normality of lifestyles. "A daily food intake of 10,000 calories is unlikely and one in

100,000 calories is impossible. The first one implies a note to the user, the second one should not be accepted" (D1, 66).

'Consumer protection' as the second concept mobilized to operationalize usability is further broken down. It comprises the transparency of the functionality and compatibility, the limitation of in-app purchases, the prohibition of in-app advertisements and the provision of a customer service capable of answering inquiries within 24 hours, seven days a week. Some of these items again speak to the assumptions of the digital literacy of future users. For example, the *DiGA Guide* explicitly cautions manufacturers that there may be an "information gap between manufacturer and user" that needs to be "assumed for IT and media competence and the handling of digital business models" (*D1, p. 66*). Even interesting is, perhaps, the assumed general understanding of the situation of a future *DiGA* user. The requirement for "consumer protection" is informed by the ideas of "fairness" and empathy. "[U]sers of DiGA find themselves in a special life and/or illness situation simply because of their motivation to use a particular DiGA, which must not be exploited by the manufacturer to take advantage of the users or lead them to make irrational decisions" (*D1, p. 66*).

Finally, 'ease of use' assumes a heterogeneous group of future users. On the one hand, it positions users as having at least basic experiences with digital technologies in general. "The DiGAV demands an alignment with the usual look & feel of digital applications for persons used to dealing with applications guided by the implementation of platform-specific style guides" (*D1, p. 71*). On the other hand, focus group tests with users in the target audience of the app are required. These tests are to be conducted "on people who have been newly won over to the use of digital applications via *DiGA*" (*D1, p. 71*). In addition, manufacturers are strongly encouraged to "ensure that the participants have different previous experiences in handling digital media" (*D1, p. 71*). The heterogeneity of presumed future users also includes people with disabilities. *DiGAs* are required to support or provide operating aids for hearing, seeing or motor impairments (since January 1, 2021). All in all, the requirement for user-friendliness assumes a diverse group of users with little previous experience with digital apps and digitalized healthcare. Like data or information security and interoperability, the *BfArM* assesses usability-related requirements via checklists.

6.1.5 The Requirements for Clinical Evidence of a Positive Healthcare Effect

Producers can provide clinical evidence of the medical efficacy of their app in two ways. For this, the regulatory framework has introduced a new concept into healthcare regulation in Germany, the "positive healthcare effect". This concept aims to depict a broader understanding of the effects a *DiGA* can have on the user. A positive healthcare effect is "either a medical benefit (medizinischer Nutzen, mN) or a patient-relevant improvement of structure and processes (patientenrelevante Struktur- und Verfahrensverbesserungen, pSVV) in healthcare". (*D1, p. 76*). The first is similar to what is assessed in pharmaceutical or therapeutic interventions. These take effect at what D2 calls the "point of care at the patient" (*D2, p. 1204*) and can be measured with similar endpoints: "morbi-

dity, mortality or quality of life" (*D1, p. 77*). The second effect is more far-reaching in that it goes beyond the patient and accounts for healthcare provision more broadly. To achieve this effect, *DiGAs* can, among other things, "promote health literacy, improve the coordination of treatment processes or reduce therapy efforts" (*D4, p. 1235*). Thus, the novel concept stipulates that *DiGAs* can improve either users' health or their healthcare provision. Both are considered equivalent in the assessment of the positive healthcare effect. But especially the latter is be a paradigm change in healthcare because "broke with the primacy of benefit assessment focused on medical outcome parameters and opened up the range of services offered by SHI in favor of patients' needs and perspectives" (*D2, p. 1204*). Nevertheless, D2 also points out that most of the *DiGAs* taken up in the *DiGA* directory at the time of writing provided evidence of a medical benefit rather than an improvement of the structure or processes of healthcare provision.

Clinical evidence of (at least) one positive healthcare effect needs to be provided through a study that compares the use of the respective *DiGA* to "non-application" for each targeted condition. "Non-application" can either be non-treatment, treatment without a *DiGA*, or treatment with another *DiGA* available for the same indication but "must be oriented on the reality of healthcare" (*D1, p. 83*). The healthcare effect must be based on the (digital component) of the *DiGA* "and not on accompanying human services" (*D4, p. 1233*) associated with the use of the application. Study designs can be retrospective, comparing intra- or interindividual data, comparative or prospective. To produce evidence of either of these positive healthcare effects, the "manufacturer is free to choose" (D2, p. 1202) from several accepted methods, including study designs that are considered "alternative" to RCTs (Rosemann, 2019). These comprise "epidemiological studies, methods of health care research, social or behavioral research can be considered" (*D4, p. 1235*). Despite this, one of the two blog posts reports that "[r]andomized controlled trials (RCTs) were submitted exclusively, or at least as the "primary" data basis for the assessment, for the DiGAs currently listed in the directory" (D9).In addition to the quantitative methods that need to be deployed, clinical studies need to be located in Germany (or countries with a comparable healthcare setting), they need to be listed in an official study registry and the results need to be published after the end of the trial.

How and when clinical evidence is provided creates the major difference between applications for a final and a preliminary listing in the *DiGA* directory. As a matter of fact and, frankly, to my surprise, this was the only context in which this distinction emerged in my empirical material. The regulation of Digital Health Applications offers the possibility "of a provisional inclusion in the list and the implementation of a study that was only at the planning stage when the application was submitted" (*D2, p. 1203*). Temporarily listed *DiGAs* can be prescribed and reimbursed for one year (with the option for an extension of another year). To be preliminarily listed, manufacturers need to have their app registered as a medical device and meet the requirements of data/information security, interoperability and user-friendliness. In lieu of a clinical study, they need to provide a "systematic evaluation of data" that "represents the plausible rationale for the improvement of healthcare provi-

sion" (*D9*) through the *DiGA* as well as a concept for the clinical study. This clinical study then has to be submitted at the end of the trial period.

But, again, the possibility of the preliminary listing barely came up in the empirical material I have analyzed. One producer mentioned that the preliminary listing was the only option on the path to becoming a *DiGA* for them. It enabled them to hire a clinical research organization (CRO) to conduct a clinical study: "[B]efore that, we couldn't have paid them at all" (*manufacturer*). As stated above, the German SHI pays for prescribed *DiGAs* even if they are temporarily listed. The revenue provided the necessary funding for paying a CRO for this *DiGA* producer. This financially attractive prospect may, however, also prove treacherous. "[T]hose who went right in first and said, 'I'll take provisional approval.' I would say that 50 percent of them will fail. Because they just didn't think about it in advance" (*representative of digital health umbrella organization*).

A theme that was much more prominent in the material is the difficulty that the requirement for clinical evidence poses in the approval process. It is "one of the most complex in the whole application process" (*D6, p. 1250*). As our conversation went on, the lobbyist suggested this may be because the manufacturers need to re-define the concept of their app in terms of the cornerstones of a clinical trial, intended target group (defined according to the ICD-10 classification), intended effect and the endpoints to measure this effect. "And above all, what do I actually want to improve? Do I want to improve my perception? Do I want to improve my quality of life? How do I get actual mass data?" (*representative of digital health umbrella organization*). Digital applications used for healthcare purposes cut across the boundary of medical and lifestyle technologies. Translating what they do into clinical terms "is not quite trivial" (*representative of digital health umbrella organization*). One manufacturer spoke to this difficulty: "Can I really make an improvement here? Because this improvement that can, can't just be sold somehow on the marketing side, but that actually has to be demonstrated" (*manufacturer*). While marketing would allow making less substantiated claims about healthcare effects, the requirement for clinical evidence requires an additional inscription to back up this claim[11].

In fact, during all of the interviews, the respondents brought up the question of whether the way of providing evidence of a healthcare effect that the approval process requires is suitable for digital technologies.

> People are trying hard to force digital health applications into the mold of pharmaceuticals. From my point of view, I'm trying to put an elephant in a gate somewhere where it doesn't fit. It's just not coherent. When I do something new, digital, I can't work with old themes. (*representative of digital health umbrella organization*)

11 This is what Latour (1988, 2013a) claims to be the main difference between fictional and scientific storytelling, or, in his later terminology, between [FIC], the fictional, and [REF], the scientific mode of existence: Scientific literature adds a final shifting-in that links a document to an inscription as an 'external referent' of this document.

The need to provide evidence of clinical efficacy is a sign of what we could call the "regulatory pharmaceuticalization" (Faulkner, 2012b) of digital health technologies: The regulatory framework for Digital Health Applications applies concepts and methods from the regulation of pharmaceuticals to digital health technologies. Additionally, with the *BfArM* a body primarily responsible for regulating drugs has to take on the new role of regulating digital health technologies. These roles can become entangled. One manufacturer reported that they had gotten a query by the *BfArM* that they thought was "actually more relevant for pharmaceutical products and not so for us" (*manufacturer*). Even though apps need to be registered medical devices to be eligible to become a Digital Health Application, the requirement for clinical evidence of a positive healthcare effect in users of the app, be it for health or healthcare, positions *DiGAs* in the proximity to pharmaceuticals.

6.2 Approval-in-Practice: Prioritizing the Explicit Requirements

In the previous subsection, I have limited myself to the theoretical standpoint of the approval process and how it explicitly defines the requirements. Going on, I reconstruct how the *BfArM* operationalizes these requirements in practice from the empirical material. I contend that there is an asymmetry in how the *BfArM* practically assesses them that favor the evidence of a positive healthcare effect. This is owing to the institutional background and culture of the *BfArM* as the regulatory body traditionally appointed to test pharmaceuticals.

6.2.1 Quanitative Evidence and the Silence of the User

To begin, there is modest *quantitative* evidence for my argument. First, this concerns why producers have retracted their applications or the *BfArM* has rejected them. D4 presents statistics on applications that have hitherto been submitted and assessed by the *BfArM*. Until August of last year, the *BfArM* has rejected four of 66 submitted applications, and another 40 have been retracted. The main reason for these rejections or retractions is, the document goes on to state, the evidence of a positive healthcare effect or, more precisely, the lack thereof: "In most cases, however, manufacturers were unable to provide sufficient evidence for the postulated positive healthcare effects" (*D4,* p. 1238). Initially, these numbers may point to the comparatively greater difficulty of providing this evidence. In the detailed analysis of this requirement, I have pointed out that the applicants perceived this requirement to be the most challenging one. Suggesting another reason, the lobbyist argued that the statistics show that the *BfArM* attaches greater importance to the clinical evidence than any other requirement. In other words, the clinical evidence seems more important because "that's where most kickouts happen" (*representative of digital health umbrella organization*).
Another quantitative clue indicates that the different requirements are weighed unequally in the approval process. It concerns the formal composition of D3 which details the requirements from the perspective of the German Ministry of Health. While these descriptions give the requirement for interoperability and data/information security extensive space and discuss the requirement for clini-

cal evidence in a separate sub-chapter, it only accords to the requirements for user-friendliness 11 meager lines in a three-column document. Additionally, both here and in the *DiGA Guide,* these requirements are introduced as “other requirements for quality” (*D3*, *p. 1201*) or as “Further Quality Requirements” (*D1, p. 64*).

When I asked my respondents about the role of user-friendliness in the approval process, they supported this impression for the most part. One manufacturer I spoke to was surprised to hear that user-friendliness *is* a requirement: “Uhhhhm. User Friendliness? […] So my guess is that we first designed it the way we think it's good and then saw what the BfArM had to say about it” (*manufacturer*). Admittedly, one could also read this differently. The documents may not give more detail because they implicitly assume that manufacturers know how to design a user-friendly app by (intuitively) following “the usual look & feel of digital applications” (*D1, p.* 71). Nevertheless, as a requirement, user-friendliness was neither a key consideration for this manufacturer nor the *BfArM*. They “can't remember right now, that we had hard questions about that” (*manufacturer*). The lobbyist was not very optimistic about this, either, suggesting instead that user-friendliness generally just takes a backseat to other requirements:

> So usability I don't really see as being that forward at the moment. As users, we would now say, ‘It's important.’ But I don't have that impression. But as I said, please, that's not a statistical truth, that's just a personal impression. So my impression is that there is a tendency to take a judicial approach, i.e., if all the requirements are met, then there's a checkmark (*representative of digital health umbrella organization*).

Taken together, the statistical evidence and these passages from my interviews seem to afford the conclusion that user-friendliness is given less attention in the approval process – not only in terms of detail and elaboration in the sampled documents but also in the actual practice of the approval process.

6.2.2 Checklists for Data Security and Interoperability

If user-friendliness is overlooked in the assessment, what about the requirements for interoperability, data/information security and clinical evidence? My empirical material indicates another asymmetry in how the *BfArM* assesses these requirements. This asymmetry has two levels. The *first* is ontological: *What* is being assessed here? The approval process introduces the distinction between the “examination of the manufacturer’s statements about the product qualities” and “the examination of the evidence of the positive healthcare effect of the DiGA provided by the manufacturer” (*D1, p. 7*). For data/information security and interoperability, what is assessed intially is on the level of language, the “manufacturer’s confirmation” (*D4, p.* 1235) that their *DiGA* meets the requirements through a set of statements. By contrast, for the positive healthcare effect the assessed object is on the level of, philosophically speaking, the thing itself, this effect as a thing in the world, made visible through the evidence of statistical calculations. For the latter, the question is whether

the evidence allows the conclusion that the positive healthcare effect exists. For the former, it is the linguistic content of what the manufacturer has stated that the *BfArM* assesses – "yes", "no", or "not applicable"[12].

This list of response options leads to the *second*, epistemological level: *How* are the requirements known and assessed? The quote above suggests an (ideal-typical) distinction between a judicial approach of ticking off boxes and a more fine-grained analysis of submitted evidence. We can take this quite literally as

> some of the total of approx. 170 requirements from areas such as patient safety, data protection, information security, functional suitability, interoperability and quality of medical content can be 'simply' confirmed by the manufacturer with 'Yes' (= the DiGA meets the requirements) without providing proof. (*D6, pp. 1249-1250*)

The *DiGAV* provides two checklists in its appendix, one for data security and privacy, and one for interoperability manufacturers have to fill in and submit with their application. These checklists cover several topics and present statements for which the manufacturers can check "applicable" or "not applicable. The latter also "requires a written justification why the overall criteria of the statement are nevertheless fulfilled" (*D1, p. 36*). Figure 1 shows a snippet of the checklist for data and information security. The statements (the questions in the column titled "Anforderung") are organized by topic. In the three columns on the right, manufacturers must provide a check and a justification.

12 One could put this distinction into the Latourian parlance of "chains of reference" (Latour, 1999a): "Chains of reference" consist of the different inscriptions and translations an (indeterminate) entity goes through on its way to becoming a referent, as something that exists "out there". In the conceptual framework of AIME, "double click" is the move that skips through all the intermediary steps of the chain to identify the representation with the thing that exists in the world (Latour, 2013a). In my interpretation of the quoted sentence from the *Guide*, the *BfArM* does this double click with the clinical evidence: The evidence pinpoints the positive healthcare effect as a thing in the world. By contrast, the assessment of statements stays on the level of representations, the translations are rather loose (Guggenheim, 2015, 2019). As I will show below, however, this does not mean that the *BfArM's* assessment remains on this level; in such cases, the chain of reference has to be re-assembled and followed to its beginnings.

Nr.	Themenfeld	Anforderung	zutreffend	nicht zutreffend	zulässige Begründung für „nicht zutreffend“
Datenschutz					
1.	Datenschutz-Grundverordnung als anzuwendendes Recht	Die Verarbeitung personenbezogener Daten durch die digitale Gesundheitsanwendung und deren Hersteller unterfällt der Verordnung (EU) 2016/679 sowie ggf. weiteren Datenschutzregelungen.			
2.	Einwilligung	Wird vor der Verarbeitung von personenbezogenen und -beziehbaren Daten eine freiwillige, spezifische und informierte Einwilligung der betroffenen Person zu den in § 4 Absatz 2 benannten Zwecken der Verarbeitung dieser Daten eingeholt?			Es wird keine Einwilligung eingeholt, da der Zweck der Verarbeitung aus einer rechtlichen Verpflichtung des Herstellers der digitalen Gesundheitsanwendung resultiert.
3.	Einwilligung	Erfolgt die Abgabe von Einwilligungen und Erklärungen der betroffenen Person durchgängig ausdrücklich, d. h. durch eine aktive, eindeutige Handlung der betroffenen Person?			Es wird keine Einwilligung eingeholt, da der Zweck der Verarbeitung aus einer rechtlichen Verpflichtung des Herstellers der digitalen Gesundheitsanwendung resultiert.

Figure 1: Snippet of the checklist for data security that manufacturers need to fill in and submit with their application from the appendix of the DiGAV (*D11*)

This procedure shifts the responsibility for safeguarding data/information security and interoperability to the manufacturers. The checklists are essentially a “self-commitment” (*manufacturer*). The shift becomes even more visible when we consider that “the BfArM expressly does not check whether each of the manufacturer's claims is correct” but that, at the same time, “if a manufacturer unknowingly makes false statements for compliance with the requirements and a DiGA is thus included in the BfArM list, the manufacturer is liable” (*D6, p. 1250*). The manufacturer must be knowledgeable about all technical and judicial details their application needs and as willing to provide the information truthfully. In an almost Foucauldian twist (1995, 2010), the approval process transfers regulation to the applicant who regulates themselves even if the authority figure is not immediately present. In D6, the manufacturers summarize their response to what they perceive as a concealed “challenge” in this use of checklists for (self-)assessment: “Without audits carried out internally or commissioned by external service providers to check compliance with the requirements prior to submission of the application, a manufacturer may not be able to assess whether the requirements have been met in every respect” (*D6, p. 1250*). They explicitly resist the position they are given in the approval process, here. Manufacturers may *not* be entirely knowledgeable about the details of the requirements and whether their app fulfills them. Therefore, the approval process ‘pushes’ them to either self-assess (if they have the necessary expertise) or enlist external service providers to do an audit. With these audits, to take up the Foucauldian framework again, the manufacturers incorporate a ‘regulatory gaze’ into their organization.

If it places the responsibility to assess data and information security on them, the *BfArM* puts trust into the manufacturers and their disclosure. This pre-supposed trust may entail another, more hidden externalization of responsibility. It further shifts it out not to the manufacturer but the user.

What if a gap in data security slips through the cracks of the (self-)audit? In such cases, the user or those who represent them have to ensure that an app complies with the requirements (e.g. Heidrich & Endres, 2021). For this, the presumed user would need to have the degree of digital literacy necessary to identify such gaps[13].

Of course, using the checklist initially does not mean that the BfArM does not examine any statements on data security, privacy and interoperability more closely. In these cases, the assessment moves from their linguistic content to the entities they refer to. One manufacturer told me that the BfArM, besides the study design for the clinical study, "also looked very closely at the privacy policy of the app itself" (*manufacturer*). Moreover, current developments of the regulatory framework for DiGA (in effect since April 1, 2022) foresee that certificates will replace the self-disclosure via checklists by the manufacturer. Together with other German regulatory agencies, the BfArM has developed

> certificates that cover all essential aspects and requirements of data privacy and information security, quite specifically tailored to the properties of the DiGA (or in the future also DiPA), and can thus be used in the future as proof of verification for corresponding requirements within the framework of the DiGA evaluation process will serve (*D8, p. 1296*).

This development formalizes the approach manufacturers have taken before. They must conduct a formal audit with an accredited to award the necessary certificate. This approach reiterates the MDR, delegating the assessment to quasi-regulatory bodies and standards. The *BfArM* itself does not assess statements/certificates in detail.

6.2.3 Clinical Evidence and Retreating to "The Island That I Know"

Usability is marginalized as a requirement. Data security/privacy and interoperability are dealt with through checklists or certificates. Only for the evidence of clinical efficacy, the regulatory framework requires that "studies [are] submitted or, alternatively, in the case of an application for testing, systematic data analyses and an evaluation concept" (*D3, p. 1199*). These are then examined in more detail by the *BfArM* and this is where the agency will likely have the most questions. One manufacturer said that "you have to be prepared for this" because "they will essentially confront you with the question of what result should come out of it and how you ensure through a suitable evaluation plan that the conditions are met from your clinical study" (*manufacturer*). This resonates with the experiences of another manufacturer who similarly reported that they "felt that the big issue at the end, of course, is always the proof of medical benefit" (*manufacturer*). They went on to express a degree of disappointment that "[i]n the end, it was really just the numbers within the study design that we delivered" (*manufacturer*), that the numbers trumped the specificities of the *DiGA*.

13 It remains doubtful whether this assumption about the user ingrained in the approval process is applicable. Consider this evaluation of digital literacy and experience with digital technologies by one of the manufacturers in the interview: " We see that they are getting younger and younger. But there are also many older people. And with regard to access to digital applications, it's not quite as easy there" (*manufacturer*).

Thus, “there's an extreme focus on the medical stuff right now” (*representative of digital health umbrella organization*). The *BfArM* also acknowledges this. In one two blog post, it qualifies the evidence as “immensely” important (*D9*). But why is there this asymmetry between the requirements in the approval process?

Two answers surface in my empirical data. The first of these has a negative and a positive side. One manufacturer surmised that “the *BfArM* does not want to check [the requirements for data protection and data security] because it can’t check it” (*manufacturer*). As the negative part of the first answer, the manufacturer contends that the *BfArM* does not assess data privacy and interoperability in more detail because it lacks the necessary expertise to do so. That is why the *BfArM* needed external help to define the requirements in detail. It is also reflected in what the *DiGAV* casts into legal form. Unlike the requirement for clinical evidence, the law regulates data/information security and interoperability in detail instead of leaving it to the purview of the *BfArM*. The detailed provisions the law makes 'compensate' for the lack of detail in assessing the checklists. The requirement for clinical evidence, on the other hand, is only an abstract requirement in the law, while the BfArM defines the details. On the flip side, this also seems to imply that “you can discuss the content of this with the BfArM” (*manufacturer*).

The same manufacturer also repeated the advice they give other manufacturers that approach them for advice on the approval process and the requirements for data security. “So I always say to the guys: ‘Hey, if you take note of that, then ask yourselves why that is the case and whether maybe the BfArM is not the authority that checks that. The BfArM is a medical authority’” (*manufacturer*). The positive side of the first answer is that the *BfArM* does not and *cannot* check the technical requirements because these are outside of its usual areas of responsibility as a *medical* authority. It also stands out in one manufacturer’s reflections on who they thought assessed their application. They surmised that the author of one of the deficiency lists they had received “is an expert in the field of pharmaceuticals, i.e. drugs” (*manufacturer*). The employees who work in the approval process primarily have expertise in the technicalities of clinical evidence rather than the other requirements. These would demand expertise in digital technology and informatics instead of statistics and pharmaceuticals.

For the lobbyist, the asymmetry in available expertise is a result of the historically grown role of the *BfArM* as a medical authority, responsible for questions regarding pharmaceuticals: “So that also has a certain basic logic for me, because I always do, prefer to do, what I can do really well. And that is simply their home” (*representative of digital health umbrella organization*). Because this has historically been its purview, the *BfArM* has considerable experience assessing clinical evidence and the agency retreats to what it knows best. “The BfArM knows how to do study design. And then I retreat to the island that I know” (*representative of digital health umbrella organization*). The familiarity with clinical trials could even undermine the legal definition of the requirement for clinical evidence. As I have shown earlier, the regulatory framework allows and welcomes alternative

sources of evidence beyond RCTs. Nevertheless, the *BfArM* states in one of the two blog posts that "[i]n most cases, RCTs are the design that is most suitable for the planned proof and are therefore also envisaged by the manufacturers right from the start" (*D9*).

Likewise, the lobbyist recommends the "classic" way of the RCT "if I want to pass elegantly at the BfArM": "Because I mean, if I now come in with a new study design, then I'm asking my examiner to deal with it as well. [...] So, I create barriers for my counterpart. [...] It makes sense to adapt to it. (*representative of digital health umbrella organization*). Despite recent tendencies to the contrary (Rosemann, 2019), the RCT has been the gold standard for assessing pharmaceuticals. It has become ingrained in the institutional culture of the BfArM. Its employees have the most expertise in this area. To submit a study design that departs from the RCT would go against the existing expertise at the *BfArM.* Employees would need to adjust their approach to clinical trials and familiarize themselves with such alternative designs. Therefore, adapting to the institutional culture incorporated in the *BfArM* increases the chances of success. This may be why the *BfArM's* statistics show that "the focus of the evidence submitted is clearly on randomized controlled trials, although other forms of evidence were also submitted in view of the special nature of the DiGA" (*D4*, *p. 1238*).

One question I had at this point was why the responsibility for the assessment of *DiGA* had been transferred to the *BfArM* if its expertise hitherto has been elsewhere? And what were or are the alternatives to this solution? The lobbyist responded that this was "more out of necessity":

> They tried to put it somewhere in an admissions office. And nobody was really responsible for it. And then, of course, you can say it. A digital health application is supposed to be beneficial to health. Drugs are supposed to do that, too. For me, that is the logical explanation (*representative of digital health umbrella organization*).

They give two answers, here. The first is that there had been no regulatory body specialized in digital health although it had been necessary to find one. The second is that the BfArM, having expertise in pharmaceutical regulation, seemed the most suitable because the requirement for evidence of a positive healthcare effect positions *DiGA* akin to pharmaceuticals. Alternatively, the lobbyist proposed a "separate institution" (*representative of digital health umbrella organization*). that is more tailored to the peculiarities of digital health technologies.[14].

Finally, I want to note that the clinical evidence of the positive healthcare effect is prioritized in a second way. It is the *differentia specifica* that distinguishes Digital Health Applications from health-and-wellness apps and apps registered as medical devices but not as *DiGAs*. What makes a *DiGA* special compared to other apps? "This is another important point and actually the significant differentiating criterion. While these 128,000 health apps have more of an advisory function, we have confirmed their scientific effectiveness" (*manufacturer*). *DiGAs* gain distinction from other apps, especially those giving advice, because the approval process clinically proves their positive impact

14 Neverthless, the lobbyist and other manufacturers also mentioned that the *BfArM* has added additional employees, especially for digital technologies: "So they have really upgraded hard" one manufacturer told me.

on health. Clinical evidence has an 'ontological' priority because it defines how a *DiGA* is different from other apps. Previous research has shown that this way, on the one hand, regulatory frameworks segment the market for digital health technologies (Lievevrouw et al., 2021). On the other hand, this confirmation of efficacy by a regulatory agency creates trust among future users (Bodewitz et al., 1987/2012; Diedericks, 2019). Against this background, the distinguishing criterion of *DiGAs* may be diminished in the future if other risk classes of the MDR become eligible for the approval process as intended. For applications in risk class III, for instance, a clinical investigation is mandatory (Keutzer & Simonsson, 2020). The approval process would no longer endow *DiGA* with a distinctive quality by confirming its medical efficacy as the prioritized requirement.

6.3 Intermediary Conclusion: Taking Stock of the Value Objects I

In this chapter, I have taken two steps. I began by analyzing how the legal framework defines the explicit requirements for Digital Health Applications in theory. In the second step, I have tried to reconstruct how the approval process implements these in practice. Thus, I have surfaced a hidden asymmetry in the requirements. Following the conceptual framework I have adopted for this research, we can theorize these requirements as "value objects". They are the conditions of in/felicity that an application needs to meet for a health-and-wellness app to transition to a legal mode of existence, to become a Digital Health Application.

1) The requirement for apps to be registered as a medical device suggests two value objects. The analysis has shown that the first is a distribution of risk between different regulatory agencies. The apps already need to undergo a risk assessment at a so-called Notified Body to become a medical device which exempts the *BfArM* from assessing risk again (and, accordingly, the responsibility for monitoring risk and adverse events).
2) The second value object of the requirement to be a registered medical device is the temporal order that this requirement prescribes. Manufacturers need to follow a quasi-linear temporal sequence in which they first have their app registered and only then submit an application to the BfArM. Deviating from this is possible to a certain extent but requires that the developer company has sufficient employees to handle both tasks simultaneously.
3) The second requirement states demands for data and information security. It also harbors two interrelated value objects. On the one hand, *DiGAs* need to secure user privacy as outlined in the GDPR (see Marelli et al., 2020).
4) On the other hand, because the regulatory framework conceptualizes information securityas a process that companies need to implement, this also implies a specific organizational structure as the value object that is at stake here.
5) The requirement for interoperability suggests supporting a digital healthcare system as a value object. As I have mentioned, this harks back to the imaginary of digitalized healthcare I have

analyzed in the previous chapter. Apps need to fit this vision by being an interoperable building block of the larger digital healthcare ecology to become Digital Health Applications.

6) The regulatory framework also makes provisions for the usability of Digital Health Applications. As my analysis of the implicit figure of the user thus imagined suggests, the value object this speaks to is the diversity and heterogeneity of users. Digital Health Applications need to be usable also for users who are not digital natives.
7) Quite simply, the value object of the requirement to provide clinical data is scientifically-proven efficacy. Apps need to make a positive impact on the health or the healthcare of the user.
8) By contrast, extracting the value object from the hierarchy of the requirements is a bit more tricky because we are slowly moving towards the implicit dimension of the approval process. Nevertheless, I contend that the value object here is an awareness of the history of the *BfArM*. As my interlocutors have pointed out, the reason for the priority of clinical evidence is that the *BfArM* has traditionally been the institution that assesses pharmaceuticals. There, clinical trials play a decisive role. Manufacturers can only be successful if they know about this traditional role and adapt their efforts for the application accordingly.

These considerations leave us with an initial inventory of value objects that need to be a part of the application for apps to become Digital Health Applications. Table 2 succinctly summarizes this. However, the next chapter will give us ample reason to further expand it.

Requirement	**Value Object(s)**
medical device registration	distribution of risk and responsibilities; temporal sequence of the approval process
data and information security	privacy of the user; organizational structure conducive to information security
interoperability	support of digitalized healthcare system as imagined by the *BfArM*
usability	diversity and heterogeneity of potential users
clinical evidence	Scientifically-proven positive impact on health and/or healthcare of the user
hierarchy of requirements	awareness of the history of the *BfArM*

Table 2: List of Value Objects in Explicit Requirements of the Approval Process

7 What is Being Tested? The Implicit Requirements for Digital Health Applications

The lobbyist has related the case of a company that had asked for an extension of the three-month deadline. The company had appealed to the arbitration body that it did not have the necessary human resources to handle the medical device and the *DiGA* assessment simultaneously. I have foreshadowed that this hints at an additional layer of requirements that the regulatory framework does not explicitly outline. These requirements implicitly stem from he more explicit ones or how the approval process is organized. These implicit requirements raise the question of what the approval process tests. Therefore, I want to flesh them out in more detail in this chapter. I argue that the implicit requirements do not test the DiGA and its effects but its broader ecology. Also, I show that these tacit requirements potentially favor some applicants with particular characteristics over others, albeit without a clear pattern.

7.1 Testing the Sustainability of the Ecology of the Digital Health Application

The first set of implicit requirements that the approval process puts to the test concerns the sustainability of the ecology of the *DiGA*. It encompasses the size of the company, its financial resources, the strength of the cooperation with external service providers, the company's ability to flexibly respond to challenges and manage time. These implicit requirements ensure that developers are up to the demands of maintaining a *DiGA* that is part of the standard healthcare provision in Germany.

7.1.1 Company Size

One manufacturer I spoke to reported that the approval process tied up the human resources. As a result, "many other things just fell by the wayside at that moment" (*manufacturer*). This brief quote and the case of the company that lacked the necessary "manpower" mentioned above (representative of digital health umbrella organization) demonstrate that the approval process requires the developer companies to be large enough to distribute their tasks. This is not only a 'quantitative' issue – how many employees does the company have? – but also of the quality, as I will show later. Almost by definition, this hidden requirement implicitly favors medium-sized enterprises and large corporations that are more likely to have the necessary workforce.

A case in point for this test of the company size is the requirement to provide customer support within 24 hours. This requirement made one of my interlocutors "afraid for a moment that I would have to hire a few people to take care of the support" (*manufacturer*). It overwhelmed the lean structure of their organization and (almost) demanded hiring new employees to fulfill the demand for company size concealed in this explicitly stated requirement. But there is no determinism here:

Other ways of meeting the (explicit) requirement for customer support and the (implicit) requirement for a minimum company size are possible. The statistical analyses that D5 presents show that “[a]bout 70% of the applicants are start-ups or small and medium-sized enterprises” (*D5, p. 1245*). The manufacturer quoted above, for instance, has developed an approach where a Frequently Asked Questions (FAQ) section in the app and on their website answers most questions. This has made it possible they “can still manage that in the morning and in the evening and during the day in a very relaxed way with a colleague” (*manufacturer*)[15]. The approach leaves the company with two employees that work through user questions. It also unveils other hidden requirements. If companies want to find solutions other than increasing their workforce, they need to be creative and have the technical skills to put together an FAQ or a Chatbot (a solution that one manufacturer envisioned)[16]. Another way of circumventing the size requirement is by increasing the workload instead of the workforce. Then, the test is no longer one of the organization (meso-level) but of the individual work ethics of the employees (micro-level), the topic of a later chapter.

7.1.2 Financial Resources

A final way to meet the hidden requirement of minimal company size is to outsource some of the tasks of the approval process to external partners. Due to the costs this entails, this solution is closely related to the second implicit requirement: withstanding the financial burden of the approval process and what comes with it. On its final pages, the *DiGA Guide* gives an overview of the fee schedule for the approval process. Listing an app in the *DiGA Directory*, both temporally and permanently, is set at 3,000€ to 9,900€. For a preliminary listing, assessing the evidence for the positive healthcare effect after one year costs another 1,500€ to 6,000€. These are the costs of the approval process alone. The fees for the information and consultation services at the *BfArM* range from 500€ to 2,000€[17]. In other words, the approval process itself is a costly matter and strains most applicants’ budgets.

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15 I want to use this to show how the requirements for customer support and data/information security may be at odds with one another and how one manufacturer solved this. To make their customer service efficient, one company implemented a customer support software provided by a US-American company. This would meet the requirement for customer support but would violate the one for data security. "But we have put in the privacy policy that if somebody needs support, they do it by email and by the way the email, they then agree to give that and that and that by privacy notice and use [customer service tool]. " (manufacturer). The manufacturer brings both requirements into concordance by separating the customer support from the app itself. The customer support "works completely outside the app" (*manufacturer*).

16 II want to note, though, that these solutions “delegate” the user support. They first delegate it to a non-human and, in the second step, to the inquiring user themselves. This user needs to make sense of the FAQs or Chatbot replies and resolve their issue. This may exclude users that run into problems but, for whatever reason, cannot follow the advice of the non-human user support agent. (Akrich & Latour, 1992; Johnson, 1988).

17 Manufacturers may, however, apply for a reduction of cost. The *DiGAV* specifies that such reductions depend on the expectable revenue and/or the size of the target group for the *DiGA*. Interestingly, this down to the wording resembles previous provisions in the German Medical Device Law and the German Stem Cell Law

Besides the cost of the formal approval process, fulfilling the different requirements, such as the clinical trial to prove the medical efficacy of the app, also comes at a cost. This appears to run counter to the impetus of the regulation:

> "And that's interesting in that the legislator is saying, 'Hey. We want to spur innovation. That's why we're doing this year on a trial basis. And by the way, if you want to be approved permanently, you need a clinical study. A clinical trial costs between EUR 1,000 and EUR 1,500 per subject.'" (*manufacturer*)

The regulatory framework sends contradictory messages. On the one hand, the possibility of preliminarily listing a *DiGA* is supposed to foster innovation. According to *D3*, the option for the preliminary listing is tailored for "[y]oung companies with innovative products that decide to enter the SHI system" (*D3, p. 1203*)[18]. On the other hand, the cost that the requirements create for the manufacturers throughout the approval process counteracts this stated goal.

Earlier, I have argued that by checking data security and interoperability through checklists (and only selectively following up on these checklists), the *BfArM* shifts the responsibility for ensuring both of these to the manufacturers. Many manufacturers responded by enlisting external service providers for audits to ensure that their app fulfills the requirements. Here, financial resources come to play an important role. One manufacturer, for example, had the penetration-test (pen-test) required for the newly implemented security certificates done by an external partner. "I said to them: 'Come on, what does it cost now? I want to have it professionally done externally'" (*manufacturer*). The qualification of the work of the external collaborators as 'professional' is of particular relevance. The same manufacturer later suggested that having this work done externally increases its quality "because my data protection officer and my security officer don't just work for one company. They do it for several companies. That's why they are interested in staying on the ball" (*manufacturer*). Outsourcing these tasks increases the quality of how they are solved, especially if the manufacturer does not have the personnel or expertise to complete them internally. Because external providers charge for their services, more financial resources may increase the quality of an application.

Other expenditures in the approval process arise through (forced) 'inactivity' during waiting times. Interlocutors mentioned two such costly waiting times. By law, the approval process takes three months. That is why it is called "fast-track". One manufacturer had used this duration in their calculations and planning. "But in the end, it took [longer]. [...] You have to be able to do it, I mean, it didn't get us into trouble, but... (*manufacturer*). This delay in the approval subsequently confused the initial plan. The last sentence in the quote indicates that this could have been a financial challenge for the company that gets into (existential) "trouble". A delayed listing will also delay the first

18 This has a financial dimension, of course. One manufacturer repeated multiple times that the opportunity to temporarily list their *DiGA* gave them the financial resources necessary to conduct a clinical trial: "And we actually did everything ourselves until we were listed. And only when we had the trial approval did we look for an external company, a clinical research organization, that did it with us. But before that, we couldn't have paid for it at all" (*manufacturer*).

reimbursed prescriptions. A variant of such delays is the waiting times for consultation which can take three months or more. “But as a start-up, I first have to survive the three months plus. Next financial hurdle” (*representative of digital health umbrella organization*). Being condemned to wait for consultation appointments can delay moving on with the application. Delaying the application postpones market access and the opportunities for remuneration by the insurance providers. Thus, more or less inadvertently and implicitly, the approval process tests the economic survivability of the applicant companies.

Who can survive this test? Insights from my interview point to answers on three levels. First, the background of company founders is crucial. A manufacturer described that without the founders' financial stability “the thing would have gone broke” (manufacturer) before being reimbursable. Of course, experience tells us that not all company founders can draw on such reserves. On a second level, the lobbyist pointed to a lower limit of 150,000€. One manufacturer even suggested that a seven-digit amount would be necessary. Without such funding, “I don’t even need to enter the race, to even think about it”, even “if you want to develop a good and interesting app” (representative of digital health umbrella organization). The test of financial resources may not only limit who can apply for their app to be approved but what can be(come) a *DiGA*. The financial backing seems to be a more decisive factor than app content, although there may be correlations if a “good and interesting app” can attract more investments. “Rolling up a sleeve”, one manufacturer concluded somewhat disillusioned, “is no longer an option” (*manufacturer*).

Finally, the type of company may be decisive. The lobbyist classified the companies on the market based on their survivability into three “clusters”. Perhaps surprisingly, they did not think that start-ups are most at risk. While the “big players”, the spin-off companies of pharmaceutical corporations, “don’t care […] a start-up knows exactly how much money it has and doesn’t have”. SMEs are at risk. For them, it could “come to a, let’s say, company-threatening situation” (*representative of digital health umbrella organization*) because they neither have the financial resources of an industry-backed company nor the financial oversight of investment-dependent start-ups. The uncertainty of future revenue from prescriptions further exacerbates this. Thus, the test of economic survivability may disproportionately exclude particular types of companies. It contributes to shaping the market for Digital Health Applications: “[I]t’s actually almost only spin-offs of corporations that ultimately bring new *DiGAs* to the market” (*manufacturer*).

7.1.3 Ties With Partners and Other Service Providers

Start-Up companies rely on the money from investors for the development of their apps and, as we have just seen, for surviving the approval process. By extension, the approval process also tests the relation with actors external to the company, investors and others. Are the investors, for instance, willing to give additional funding to the start-up company? One manufacturer used the possibility to list a *DiGA* as a resource at a “difficult time” when pleading with their investors:

> And then I just said to them: "Hey, friends. I understand that you think you've blown a million bucks. [...] This law was passed in December. Something is going to come at some point. And I think you guys would be out of your minds if we didn't make the attempt to get into this system, because the only chance we have of even recovering the money that he's invested here now is by getting into this system." (*manufacturer*)

The approval process both subjected the relations between the start-up and its investors to a "trial of strength" (Latour, 2003). Simultaneously, it served as a resource for it. In the end, the relations passed the trial as the developer was able to secure more funding with the prospect of future revenue.

Companies also maintain relations with service providers that support them in fulfilling the explicit requirements of the applications. In these cases, the approval procedure tests the relations not concerning financing but the quality of the service provider and the collaboration. The co-authors of D6 recommend to other manufacturers who seek to prepare for the approval process to "work[.] only with service providers who have a proven understanding of how the requirements of the BfArM are to be implemented" (*D6, p. 1250*). The approval process tests the choice of external collaborators – a sub-type of what I will call meta-expertise below. The manufacturers I spoke to described their external collaborators as key to their successful application. One respondent said that the "very good advice" from outside experts was the reason they "had extremely few queries in our process" (*manufacturer*). Another added that "it was good to have many experts" (*manufacturer*).

Both statements describe things as working out smoothly. The relations with external partners were stable and easily withstood to the test of the *BfArM*. But that is not always the case. Two manufacturers described that the approval process tried the relations with collaborators more severely. In the first case, the manufacturer got a query from the *BfArM* to which an external partner had to reply. They described how this tested the relation of trust they had with their collaborator: "You have to leave the solution to someone else and rely on them". (*manufacturer*). The approval process implicitly tests whether the manufacturer can (blindly) trust their partner to resolve the issue that puts the application at risk[19]? In the second case, another manufacturer reported how a trial of strength by the *BfArM* severed the relations with an external service provider. The *BfArM* took umbrage with the policy for access to the servers of the manufacturer's server provider in response to the provisions of the GDPR. The manufacturer then decided, on short notice, to break up these relations and create new ones with another external service provider. In this case, when confronted with the trial of strength staged by the *BfArM,* the relations could not withstand.

19 This trust may not be completely blind. One manufacturer has enlisted another external service provider to assess the one they collaborated with for the clinical trial. "Because there was money in the account in the meantime, I went there, took another external consultant and had my own Clinical Research Organization checked to see if they had done everything right" (*manufacturer*). At the risk of ending up in an infinite regress (who assesses the assessor?), this manufacturer conducts the test themselves that the *BfArM* then conducts in the approval process

7.1.4 Organizational Flexibility and Time Management

In a three-month approval process, severing existing ties and creating new ones requires a short response time and organizational flexibility. Not all types of organizations may allow for this. “[I]n a large corporation it's not really possible to do something like that, because...” (*manufacturer*). Large Corporations lack the flexible (decision-)structures of a start-up company. Indeed, what disadvantages large, immobile corporations, favors start-ups “because they have an idea of how to work quickly and efficiently” (*manufacturer*).

This already touches upon something I expand on in one of the next chapters: the implicit test of individual attitudes that the manufacturer implies in this last quote. Here, I want to dwell on how the approval process becomes an implicit test of the applicant’s flexibility and temporal organization. This test has to do with what, borrowing from Felt (2017), one could call the “chronopolitics” of the regulatory process for Digital Health Applications (see also Webster, 2019). One of the major complaints by manufacturers and a recurring theme in my interviews were the deadlines for queries by the *BfArM* during the approval process. After applying, a “certain ping pong” (*manufacturers*) unfolds in which the *BfArM* sends out lists with deficiencies that developers need to resolve within a “very very tight and very very strict” (*manufacturer*) fixed time. Some manufacturers described that the deadlines could be as short as a weekend, “Friday morning with the deadline: please solve by Monday morning 8:00” (*manufacturer*). Therefore, developers “sometimes also worked on weekends and also used their service providers on weekends, to meet the deadlines of the BfArM” (D6, p. 1252). Such queries by the *BfArM* also occur mostly at the end of the three months. One manufacturer described this time as a “very intense phase” (*manufacturer*) because they had to resolve all issues with the final deadline looming.

The manufacturers tried to plan for both the intensification of work toward the end of the approval process and the short deadlines by saving up resources and preparing external collaborators. Their time management becomes a crucial success factor for the application. But planning for the short deadlines only goes so far. One manufacturer told me it was pure luck that “I’m in front of the computer and see the thing come in” (*manufacturer*) when a deficiency list arrived shortly before the final deadline. They assume that had they been absent, they would not have been able to meet the deadline which, in turn, would have resulted in a rejection of the application.

The *BfArM*, therefore, *tests* the manufacturer’s capacity to manage their time. But it also *prescribes* time management that one could paraphrase as follows: ‘Be ready to resolve shortcomings the last few weeks before the end of the approval process and, above all, be close to your e-mail account during this time’. It acknowledges this indirectly, stating that “due to the lack of a clock stop”, a temporary suspension of the three months, the procedure is “associated with tight deadlines in order to also allow for the subsequent evaluation of the comment” (*D4, p. 1239*). The reason for the tight deadlines is the legal requirement of the fast-track. If the *BfArM* has to set them this is just because it executes the will of the legislator who has “deliberately designed [the approval process] as a fast

track" (*D4, p. 1239*). This self-positioning markedly deviates from the active role the *BfArM* seeks to take in regulating digital health (see ch. 5.2). Because the *BfArM* cannot change the procedure, manufacturers must plan accordingly. The demand for planning also extends to the time *before* they apply. Ideally, they should consult with the *DiGA* early on because "[e]xperience has shown that the elimination of potential application deficiencies or the supplementation of existing evidence gaps within the legally prescribed procedure period of 3 months is not manageable for the manufacturer. (*D5, p. 1247*). This gives a short glimpse of what I will discuss in another section: The approval process places the responsibility for failing to meet ad hoc deadlines on the manufacturer who did not consult with the *BfArM* ahead of time (see ch. 8.2.3.). Here, it means that the approval process tests how well the manufacturer has planned their time following the envisioned timeframe by the legislator and the *BfArM*.

The need to meet deadlines set by the *BfArM* (and the legislator) does not cease even after the "end" of the actual approval process. This is a consequence of what the documents refer to as "agile legislation" and, by extension, "agile regulation" (see ch. 9.3). Legislation and regulation are continuously adapted to technological and other developments. In part, such changes also apply retroactively to DiGA already listed. This has been the case for the requirement to implement an information security management system passed in the fall of 2021. Itt had to be implemented by all manufacturers in April of 2022. One manufacturer mentioned that an external auditor had told them that "in this time it was actually utopian to build it up at all" (*manufacturer*). Again, the implicit requirement for flexibility may favor start-up companies because "really big companies normally need a year to implement that" (*manufacturer*), while the law required this within six months.

7.2 Testing the Developer's Integrity

After investigating the meso-level, the implicit test the developer companies as organizations are put to, I want to change the observation level and look at the individual level. Here, I will argue, the approval process implicitly tests the motivation of developers to apply, their work ethics and their knowledge and expertise.

7.2.1 Motivation to Apply

Even just the explicit requirements by themselves, in the words of the lobbyist, put up several "hurdles" for the manufacturer. This assertion raises the question of why manufacturers decide to apply for approval, especially since alternatives exist. Instead of applying to list a *DiGA*, manufacturers "could also get a selective contract through the Healthy Hub" (*representative of digital health umbrella organization*). The Healthy Hub is an association of smaller German healthcare insurances that, in parallel to the new regulation, reimburses the prescription of apps if the developers have entered a contract with them. Manufacturers can bypass the approval process and still get access to an albeit limited first healthcare market. The alternative "shortens the process merciless-

ly" (*representative of digital health umbrella organization*), i.e. it establishes an alternative temporality of regulation. Strictly speaking however, apps that have taken this path are not *DiGA* since this is a *legal* qualification that an app attains when it passes the approval process (see ch. 9.1).

A second option is to stay on or enter the free market, just like any other digital app. Financially, the lobbyist perceives this pathway as more viable than becoming a *DiGA*. In the following passage, they describe some of the considerations made together with (potential) manufacturers they represent:

> Then we simply looked at what you're getting on the free market now, in terms of money? How well does it sell? And how high would the investment be to get all these approvals? It hasn't paid off yet. So above all, as long as the highest amounts are still nebulous, you can't really recommend that to anyone anywhere from an economic point of view. If the maximum amount is below the creation costs. (*representative of digital health umbrella organization*)

From an economic standpoint, comparing revenues from listing a reimbursable *DiGA* and from entering the free market with the app, the former option performs worse. "If I can position my health app on the free market at a decent price, then I wouldn't have to go through all this trouble" (*representative of digital health umbrella organization*). The comparatively worse performance has to do with the model for reimbursability that the regulatory framework envisions for Digital Health Applications. For one year, insurance provers reimburse prescriptions with the price set by the manufacturer – the *Guide* refers to this as the "actual price" (*D1, p. 25*). After this period, manufacturers have to negotiate a price with the umbrella organization of German health insurance (*Spitzenverband Bund der Krankenkassen, GKV SV*) – the so-called "remuneration sum" (*D1, p. 25*). These negotiations inevitably pit DiGAs against pharmaceuticals for the same conditions. One manufacturer, discussing another *DiGA* manufacturer's struggles, thought that the medium three-digit price this manufacturer demanded would be impossible to negotiate "because the drugs that are called there [for the same condition], they cost somewhere around [low two-digit price]. And that will be […] will be appreciably difficult" (*manufacturer*). Such difficulties are what the lobbyist in the excerpt above refers to as the "nebulous highest amounts": The remuneration for *DiGA* is still uncertain. That is why an application does not make sense for them from a business perspective[20].

But why do manufacturers apply to become a *DiGA*, despite the hurdles and uncertain revenue, then? The lobbyist told me "there is a lot of enthusiasm to actually improve the world a little bit and to improve treatment" from developers "who [often] are more or less directly or indirectly affected"(*representative of digital health umbrella organization*) by the condition. Perhaps more than any financial consideration, a sense of idealism and the imagination of a better world drive manufacturers to have their product licensed as a *DiGA*. In this sense, the high hurdles that the approval

20 In a later subsection on the performativity of the law, I will discuss a more nuanced understanding. Manufacturers also told me that becoming a *DiGA* was the only financially viable option. That does not necessarily limit my argument in this section because these manufacturers simultaneously mentioned that a particular individual attitude was necessary to apply to become a *DiGA*.

process sets up for the developers test this idealism and a kind of “selflessness” that can be understood as a relative disregard for high(er) profits from the app. This idealism for a better world and improved healthcare provision through Digital Health Applications speaks to and matches the imaginary of digital health that underlies the approval process (see ch. 5). As part of this implicit test of the manufacturer’s motivation, the approval process also tests whether the manufacturer shares this imaginary beyond the actual requirements.

The test for “selflessness” and enthusiasm, especially for start-ups that struggle for funding, may extend to funders, too. Because of the uncertainty of revenues, especially if the target group is limited which, in one way or another, probably is the case for most DiGAs, the “usual” goal of start-up investors, multiplied returns, cannot apply. Instead, the venture capital comes “from people who are wealthy and say, ‘We can give away EUR 80,000 here’, but who are a bit well-intentioned and also interested in supporting innovation” (*manufacturer*). The funders this manufacturer ultimately found were themselves idealists, not necessarily concerning digital health per se, but certainly about innovation. They had have to have enough disposable capital to invest in a start-up which allowed for a particular attitude towards money as, quite literally, expendable even if expectations for returns were low.

7.2.2 Work Ethics of Developers

Above, my analysis has pointed out the challenges that the deadlines pose for manufacturers. Resolving the shortcomings with which the *BfArM* found fault, tests the time management and the flexibility of the developer company. But organizational flexibility and quick response times are closely entangled with individual efforts. Thus, these implicit requirements assess the work ethic of the employees. Let me revisit the example of the company that had to change its server provider at short notice I have mentioned above. This change of service providers required employees to work off-times. They had their “first war-room or solution-finding meeting on Saturday and then thought about it until Monday” (*manufacturer*). Unlike what the war-room metaphor might suggest, it was not only the higher echelons that had to work more. They went on to say that “this was also a very intense time for the tech team” (*manufacturer*) that had to implement the server change. In other words, the approval process, especially the short deadlines set by the *BfArM*, tests whether the manufacturers’ employees are willing to work on the weekends and put in overtime. If not, fulfilling the deadlines would be impossible.

The implicit requirement may disproportionately favor start-up companies. When I first read that companies need to have customer support that can reply to a user request within 24 hours on weekdays and during weekends, I was wondering: Can small start-up companies handle this? So, I asked the lobbyist whether this might be a problem. To my surprise, they answered in the negative: “Let me put it simply. Most start-ups work on the weekend anyway” (*representative of digital health umbrella organization*). The work ethic required to fulfill the requirement of continuously available

customer support and to respond quickly to the deficiency letters by the *BfArM* may not differ too much from how start-up companies work anyways. They likely have an advantage over other types of companies in the approval process[21].

7.2.3 Expertise and Knowledge

The approval process tests the expertise manufacturers have. On the one hand, this should be obvious. Of course, meeting the requirements demands expertise from the manufacturer (or their external collaborators). One has to know the law. One has to have medical knowledge. One has to have technical skills. On the other hand, expertise is already a part of the other tacit requirements. Of course, the tech employees need to be knowledgeable in (applied) computer science to change the server provider in less than a week. I focus on something else in this section, though. The hidden requirements for sociological expertise in the more explicit ones. Additionally, I argue that a meta-expertise is necessary to pass the approval process.

I begin with the demand for quasi-sociological expertise. As the overview of the requirement for evidence of clinical efficacy has shown, developers need to conduct studies against the background of (inter- or intra-individual) non-treatment. The "selected comparison group should be based on the reality of care" (*D2, p. 1202*). Additionally, clinical trials need to be done in Germany or in countries "for which evidence of transferability to the German health care context can be provided (*p. 1202*). Finally, to meet the requirement for user-friendliness, manufacturers need to outline the roles that different actors will play using the *DiGA* in the actual healthcare setting (see ch. 6.1.4). These provisions imply that the assessment tests quasi-social science expertise *DiGA* developers need to possess. I will spell it out in some more detail. Following the first quote, *BfArM* assesses the trial against a non-treatment group that needs to correspond to the reality of healthcare provision. What is the reality of healthcare provision, though? Whose healthcare provision is to be considered here for an adequate comparison? To give an example. Currently, there are several *DiGAs* listed in the directory for depression. If I was to develop another app and conduct a clinical trial for it, would it be suitable to compare the results of my app with that of another *DiGA* for the same condition? Would this adequately depict the reality of healthcare provision, especially given that prescribed *DiGA* account for "the lowest single-digit, if any single-digit percentage range" (*representative of digital health umbrella organization*) of the share of healthcare expenditure in Germany? I could use statistics from healthcare insurance to make inferences about the healthcare reality. But this is only a very particular understanding of this reality. Thus, for the clinical study, manufacturers must present their knowledge of the German healthcare reality.

Clinical trials can be conducted in countries other than Germany if the healthcare context is comparable to Germany's healthcare context. When are the results in one country transferable to an-

21 To further underline this point: Tellingly, after one of the interviews, the recording was already turned off, one interlocutor told me that the start-up culture is characterized by a "you just do it" (*field note taken after interview*) attitude regarding queries by the BfArM.

other? To just get an impression of the complexity of this question. In a recent systematic literature review, Tamara Schloemer and Peter Schröder-Bäck (2018) count a whooping 44 criteria that need to be considered in transferring clinical trial results, including the population(s), the intervention, the environment and the transfer itself. These criteria go beyond the medical knowledge that producing clinical evidence requires. Instead, if manufacturers choose to conduct a study outside of Germany, they need to demonstrate social scientific abilities in ensuring transferability as a "complex concept which needs systematic consideration of the primary and target context" (Schloemer & Schröder-Bäck, 2018, p. 15). They need to be able to make judgments, especially about the population level, the healthcare environment and what transferring the trial design would mean – hence, this "systematic consideration" is one implicit requirement in the assessment. From an STS perspective, the third and fourth quotes might be the most interesting. Here, the manufacturer has to explicate the "script" of their app that usually only becomes visible when technologies fail to work or when users transform them in practice (Akrich, 1992). In a way, the app developer needs to be a sociologist, more in the Tardian than in the Durkheimian sense (Latour, 2005), as they need to assemble the social in a particular way. As part of the implicit requirements, they need to outline the collective and the ideal-typical use situation that their app envisions. This sociology in nuce is part of the implicit testing in the approval process.

The second type of expertise was even more elusive in the interviews manufactured. But it nevertheless needs mentioning. It is a type of meta-expertise that manufacturers need to possess closely related to the cooperation with external collaborators. The approval process tests developers on whether they know the limits of their expertise. One manufacturer told me that it is nearly impossible to conduct the trial yourself because you don't have the scientific prerequisites for what they have to deliver (*manufacturer*). Therefore, this manufacturer advises other manufacturers to "think about who you need, think about how much money you have, when you need a pro" (*manufacturer*). I term this the meta-expertise the procedure implicitly tests: Does the manufacturer know the limits of their knowledge and when to enlist external partners with specialized knowledge? Because the *BfArM* also implicitly assesses the quality of external relations, in a second step, this also requires meta-expertise to choose the "right" external service providers, a "pro" as the manufacturer said. In this case, a "pro" is an external collaborator that knows how the regulatory agency works and implements the respective requirements (a meta-expertise on the part of the service provider).

7.3 Testing the Relations with the BfArM

Finally, my empirical material shows that the approval process also implicitly tests the relations that *DiGA* developers can establish with the *BfArM*. In this sub-section, I want to pursue this dimension. I will argue that it concerns the developer's ability to communicate across institutional cultures and the timing of the application.

7.3.1 Communication Across Institutional Cultures

There is a cultural 'divide' or 'rift' separating the *BfArM* as a regulatory body and the companies developing *DiGAs*, especially start-up companies. I will discuss this in more detail in a later chapter (see ch. 8). Here, I want to point out how the approval process also assesses what we could call the "thought style" (Fleck, 1979) of start-up companies. In the approval process, "different worlds meet. The administrative world versus the innovative world" (*representative of digital health umbrella organization*). This encounter comprises different understandings of risk. Start-up companies are "risk-aware" while the *BfArM* is "risk-averse" (*representative of digital health umbrella organization*). In the approval procedure, this discrepancy likely leads to conflicts about what constitutes acceptable risks. The cultural differences extend into issues of language and ascribing meaning. There is a "linguistic hurdle" (*representative of digital health umbrella organization*) that developers need to overcome for their application to be successful: "When I'm in administration, I talk in an administration language. A start-up talks in a start-up language. And then there are always problems with understanding (*representative of digital health umbrella organization*). The difficulties extend from the beginning of the approval process to the pricing negotiations with the German SHI. A "medium-average start-up with the thinking of a medium-average start-up will fail" (*representative of digital health umbrella organization*). This quote illustrates why I speak of "thought styles". How the (average) start-up thinks is at odds with how the *BfArM* thinks.

Different ways of bridging this gap surfaced in my empirical material. For communication to be successful, the applicant needs to be 'above-average' or distinguish themselves from other start-up companies. One manufacturer told me that their company differs from other start-ups because of their prior experiences of collaborating with public and regulatory bodies. This experience gave them "a certain proximity to them and knew what they expected of me" (*manufacturer*). Being able to anticipate the expectations of the *BfArM* and being familiar with its thought style facilitated communicating with the agency for this manufacturer. They attributed their success to it and believed it had allowed them to accelerate the preparation for the approval process. Thus, the *BfArM* implicitly tests the developers' background and experience, making it easier for them to bridge the 'rift' in thought styles. It also creates a distinction between start-ups that have the necessary experience working with regulatory bodies and those that do not.

There are other ways of bridging the gap, however. If a manufacturer does not have this experience, they may be able to get it 'second-hand', by carefully choosing their external collaborators and only collaborating "with service providers who have a proven understanding of how the requirements of the BfArM are to be implemented" (*D6, p. 1250*). These service providers can compensate for what the manufacturers lack. A second way is to use one of the many communication channels the *BfArM* offers. The co-authors of D6 recommend that applicants should not hesitate to call "your contact person at the BfArM, ask questions, help the *BfArM* team to understand your procedure, to understand your approach so that the *BfArM*, in turn, can clearly take a clear position

and provide an answer" (*D6, p. 1252*). Other possible channels developers can use to approach the *BfArM* and become familiar with its thought style comprise the information or consultation meetings. When I spoke to them, the lobbyist was not convinced by such offers "[b]ecause I mean you can't do that with a little bit of skinny-dipping or a little bit of counseling or something" (*representative of digital health umbrella organization*). Creating an equivocation between the two cultures requires more than just one-time encounters because these do not allow the two sides to understand each other more thoroughly. To bridge the gap, "you first have to get used to the world of DIGA and live in it" (*representative of digital health umbrella organization*).

Therefore, they favored a third option which they called an "interpreter". Companies should enlist external expertise and "engage[.] very closely with someone who is in public affairs et cetera" (*representative of digital health umbrella organization*). Public Affairs managers well-versed in the languages of digital health and regulatory bodies may be better suited than consultations because they are between both thought styles, know both worlds and can more easily switch between them. The lobbyist likened this to the regulation of pharmaceuticals where it is, likewise, Public Affairs managers that lead negotiations with regulators and health insurances, not laboratory researchers. This comparison suggests that corporations may perform better in this implicit test:

> [T]he DiGAs that are attached to a large manufacturer, they don't have a problem, they have access to all the lawyers and so on. They can be adequately represented. But what does [...] the normal small company do now? (*representative of digital health umbrella organization*).

The statistical evidence from the first year of the approval process that D4 presents shows that the field of manufacturers of *DiGAs* is rather heterogeneous. A few of them are associated with large pharmaceutical corporations. These can fall back on all the resources the corporation has at its disposal, especially lawyers and other jurists acquainted with the *BfArM* and sharing the "thought style" of its employees. They do not need an external "interpreter" to establish a communicative relationship with the *BfArM*. In the approval process, this gives them an advantage over the bulk of other companies that need to find alternative ways to meet this implicit requirement.

7.3.2 Timing of the Application

The approval process and the regulatory framework do not only test the ability of manufacturers to communicate across a cultural gap with the *BfArM*. They also test *when* a company has decided to apply to list their *DiGA.* This differs from my analysis of the implicit test of the applicant's time management Here, I am more narrowly interested in the role played by the *timing* (Farías, 2010) of the application as an implicit requirement.

I first realized that timing plays a crucial role after one of the interviews. When I had already turned off the recording, the research participant told me there is something like a "first-mover advantage" (*field notes taken after interview*) in the approval process. Intrigued by this short remark, I was cautious whether this topic also came up in any of the other interviews or documents. My analysis re-

vealed two dimensions of an “early mover advantage”. First, the timing and the related “early mover advantage” concerns waiting times and delays in and around the approval process. Those who decide to apply early have an advantage. Before the *DiGAV* came into force, the *BfArM* staged several information events as part of a “roadshow” (*D5, p. 1242*). During these events, the *BfArM* polled how many manufacturers would be interested in applying. Seeing the large number of potential applicants, one manufacturer thought: “Shit, we’ll have to run away from the front” (*manufacturer*). The high number, 200 developers (for comparison, currently 31 *DiGAs* are listed), would have exhausted the *BfArM’s* resources. This led the manufacturer to move fast to not get delayed. In this sense, early movers had an advantage in that they were ahead of the anticipated rush on the approval process. In the quote itself “early” refers to the timing of the application around the time the regulatory framework came into force. Nevertheless, it likely also applies at other times when a high number of applications exceeds the *BfArM’s* capacity to process them – anticipating such times is what makes the timing of the application a skillful process[22].

The proclaimed agility of the regulatory framework for Digital Health Applications also entails that timing is an implicitly tested skill. “Agile regulation” conveys that the regulatory framework and the requirements are adapted along with experiences from the approval process, the use of *DiGAs* in healthcare and their future development (see ch. 9.3). Such changes also retroactively apply to those developers that have already passed the approval process. They have to implement the new requirements within a timeframe set by the law/the *BfArM*. The interlocutor above initially referred to this when he spoke of a “first-mover advantage”. The main advantage for early movers is that they have to implement the subsequent legal changes incrementally. By contrast, those just now applying for a *DiGA* must surpass a much higher hurdle that stacks up the initial requirements and those added later. This stacking not only concerns the number of requirements. But the regulatory changes also tighten them over time. In my material, I could observe this from both sides. One manufacturer *was* an early mover. They thought that since then and “with every future law, the barrier to getting into the system is going to get bigger”. Their case was a prime example: “We also got in there with [a study design] where I don’t think that would work again” (*manufacturer*). Indirectly confirming this, another manufacturer who applied later found it “kind of very frustrating” that they had to put in more effort “because we saw with what data *DiGAs* that were half a year or a year earlier had been included in the Fast Track” (*manufacturer*). These contrasting yet complementary perspectives nicely illustrate that the timing of the application makes a difference in the chances of success in the approval process. It influences whether one needs to clear all stacked hurdles at once or incrementally and how tight the requirements for clinical evidence are. The implicit require-

22 One manufacturer surmised that the timing of the application correlates with the test of the developer’s time management. “The relevant questions that were complicated, we got them in the last three weeks of the three months. Which for me allowed the conclusion. Eh, they are full and they just started late” (*manufacturer*).

ment to apply early suggests a slowly progressing closure of the bottleneck of the approval process and, consequently, of the market for *DiGA*[23].

7.4 Intermediary Conclusion: Taking Stock of the Value Objects II

Throughout this chapter, I have argued that the explicit requirements are complemented by some more implicit ones that emerge from how the approval process is organized. Further, I have suggested that these implicit requirements influence *who* will more likely be successful in the approval process, although this does not follow a clear pattern. We can take the findings of the implicit requirements that this chapter has presented to continue the list of value objects started earlier. Although the implicit requirements, by definition, cannot be found in the regulatory framework per se, it is necessary to heed Latour's (2010, p. 141) advice when considering the value objects these requirements put forward. "We should not hurry to distinguish which of these vehicles transports 'pure' law and which are mere accompaniments or parasites". Thus, the list goes on:

9. The requirements for organization size, financial viability, stable relationships with external partners and the flexibility of the organizational structure of the developer all point to a similar thing: the sustainability of the Digital Health Application and its ecology. The approval process seeks to make sure that *DiGAs* will be listed for a long time. This goal requires that its ecology is stable and can adapt to external changes.
10. Those requirements situated at the individual, rather than the meso-level, suggest the integrity of the developer as a value object. Developers must bring a particular attitude, an altruistic motivation and particular types of sociological and meta-expertise to be successful.
11. Finally, the applications must establish good relations with the BfArM as a value object. I have shown that this concerns the ability to bridge the cultural gap between the BfArM and the applicants. It also comprises the skill to time the application.

Table 3 summarizes the implicit requirements of the approval process and points to the most likely beneficiaries, i.e. the types of companies that the respective implicit requirement favors.

23 Being a late mover is, of course, also possible. It may not even be without disadvantages. In this case, however, the testing relation is changed. It is not the *BfArM* that tests the manufacturers. The manufacturers turn the tables and assess the approval process and its results instead. Some interested developers "wait for the first evaluations (of their own DiGAs) and in particular the first results of the price negotiations and thus ultimately also the associated market (penetration) opportunities before they introduce further products via the DiGA fast track into the standard care or decide on alternatives in the form of e.g. selective contracts with individual health insurance funds" (*D4, p. 1239*).

Object of Testing	Dimension	Key Questions	Who may have an advantage?
Testing the Organization	Company Size	Does the company have enough personnel to distribute the tasks of the approval process? Does the company have enough personnel to meet the requirement for the customer support?	Medium-sized enterprises and large corporations
	Financial Resources	Does the company have sufficient financial resources to pay for the approval process and its components? Does the company have sufficient financial resources to enlist external service providers? Does the company have sufficient financial resources for unexpected delays/waiting times?	large corporations, start-ups with good financial forecasting
	Flexibility and Time Management	Can the company make rapid changes to its organizational structure? Can the company meet the short deadlines set by the *BfArM*? Has the company adequately prepared its submission to avoid queries during the three-month period?	start-ups
Testing Indivdiual Characteristics of Developers	Motivation to Apply	How important are profits for the company? How important are profits for the funders?	start-ups, especially when founded by affected persons
	Work Ethics	Are employees prepared to work after hours and on the weekend?	start-ups
	Expertise	Does the company have social scientific expertise of the healthcare reality (in Germany and other countries)? Can manufacturers assess the limits of their expertise?	no clear indication
Testing Relations with the *BfArM*	Ability to Communicate Across Cultural Boundaries	Can the company bridge cultural differences between itself and the *BfArM*?	large corporations, start-ups with sufficient experience in working with regulatory bodies
	Timing of the Approval Process	Does the company apply early enough to avoid larger rushes at the approval process? Does the company apply before the requirements are increased? Is it able to clear the added hurdles at once?	early movers independent of type of organization; later: larger corporations, start-ups with sufficient funding

Table 3: Overview of Implicit Requirements of the Approval Process

8 The Relationship Between the *BfArM* and the Developers: Cooperative *or* Agonistic, Cooperative *and* Agonistic?

The relationship the approval process establishes between the *BfArM* and the manufacturers emerged as a key theme from the empirical material during my analysis. This relationship is quite puzzling, however. On the one hand, the documents emphasize a cooperative relationship between the regulatory agency and the developers (8.1). On the other hand, especially in the interviews, the developer's descriptions sometimes oscillate between this cooperative relationship and a more agonistic one (8.2). In this subsection, I want to portray this ambiguous relationship in more detail. I will argue that what connects both types of descriptions is the *BfArM's* ability to influence the design of the *DiGA* and the application.

8.1 The Cooperative Relationship Between the *BfArM* and the Developers

In the empirical material, the extent to which it describes the relationship between the BfArM and the applicants as cooperative struck me. The manufacturers who have co-authored D6, for instance, describe the relationship with the agency as "friendly, competent, professional and solution-oriented" (D6, p. 1249). The BfArM, on its part, states that it "want[s] manufacturers to go through the process successfully" (D9). As another publication on the role of digital healthcare for the BfArM states, the regulatory body understands itself as a "partner of the developers" (Bundesinstitut für Arzneimittel und Medizinprodukte, 2021a, p. 8).

8.1.1 The *BfArM* as a Mediator Between Manufacturers and the Law

A crucial dimension of this cooperative relationship is the position the *BfArM* assumes in the approval process. The documents I have analyzed position the *BfArM* as an organization that mediates between the manufacturers and the law. It summarizes and clarifies legal requirements to communicate them to the manufacturers. This role is a position that the agency not only assumes for the regulation of Digital Health Applications but all domains under its purview. It offers a variety of "support and consulting formats for each product development phase and on all aspects relevant" because specific legal "questions often remain unanswered or the specifications for specific products are not always clear from the developer's and applicant's point of view" (*D5, p. 1241*). This (mission) statement makes this position visible: The *BfArM* appears as an intermediate if more direct relations between the manufacturer and the law fail to stabilize. In these cases, the agency translates the regulatory framework for the respective manufacturer. As D8 states, this is also a position that the *BfArM* has taken for digital technologies from early on, providing "guidance on the classification of apps as medical products" (*D8, p. 1296)* and extending offers to communicate with developers

and others. The document further describes a continuity of this type of engagement with manufacturers and stakeholders. It has led to the establishment of the Innovation Office at the *BfArM* that specifically addresses manufacturers producing innovative digital health technologies. At the preliminary endpoint of this trajectory comes the new regulatory framework for Digital Health Applications. In line with the previous history, the *BfArM* has “informed about the possibilities of the DVG and corresponding consulting offers of the BfArM” (*D8, p. 1296*), for example, through a “roadshow” in multiple German cities.

The *DiGA Guide* illustrates and materializes the position as an intermediate between the legal framework and the manufacturer. Thereby, it takes on different roles. First, it draws together scattered specifications summarizing “the legal principles and requirements, which are set out in various places in the SGB V and in the DiGAV, including annexes, in a comprehensive guideline. (*D4, p. 1237*). Second, the *Guide* also translates the abstract language of the law into concrete exemplary cases. Through it, “the *BfArM* explains in detail how it interprets the normative requirements for inclusion in its assessment practice of numerous examples. This creates the greatest possible transparency with regard to the concrete requirements to be fulfilled” (*D4, p. 1237*). In a similar vein, the *DiGA Guide* itself states that it “interprets the ordinance and supplies details for the practical completion of the procedure at the BfArM” (*D1, p. 8*). Although this distinction does not hold throughout the entire analysis of the approval process, here at least the *BfArM* seems to juxtapose what one could call “law in the books” and “law in action” (Levi & Valverde, 2008). The goal of these translations through the information services that the *BfArM* offers, and of which the *DiGA Guide* is only one, is “to provide manufacturers with planning certainty in view of this new assessment procedure and associated requirements in advance of an application being submitted “(*D4, p. 1237*). They seek to translate the law into the manufacturer’s business-related considerations, specifically the planning.

This goal may not always be fulfilled, leading to a compelling variant or consequence. In D6, the manufacturers describe they had difficulties understanding a particular passage in the law and the *DiGA Guide* “also provided clarity only to a limited extent” (*D6, p. 1251*). It failed to translate what this passage from the law means in practice. As a solution, the authors recommend collaborating with external partners knowledgeable about the law or utilizing the legally-defined *DiGA* Consultation. In this consultation, “any questions about ambiguities should be openly asked and the BfArM should be asked to either agree with the manufacturer's planned approach or to provide appropriate feedback on what needs to change in the approach to meet the requirements” (*D6, p. 1251*). This recommendation indicates that the position as an intermediary is not only one that the *BfArM* seeks to assume but ,perhaps on the flip side, one the manufacturers demand it to take.

8.1.2 Accompanying the *DiGA* through its Life-Cycle

The *BfArM* describes its own work, especially the role of information and consultation offers as "consulting and accompanying" (*D5, p. 1247*) the manufacturers throughout the development of their app as a *DiGA*. D5 states that this is part of the *BfArM's* work in all regulatory domains for which it is responsible. The regulatory agency "offers manufacturers comprehensive support and advice formats for each product development phase and for all aspects relevant to evaluation, individually tailored to the respective consulting needs and time of development" (*D5, p. 1241*) .For Digital Health Applications more specifically, these formats began before the *DGV* and the *DiGAV* came into force. The *BfArM* and the Innovation Office staged a series of events on the new regulatory framework together with the Federal Ministry of Health and its affiliated health innovation hub. The goal of these events was "that all parties involved could inform themselves about the procedure in advance and prepare accordingly" (*D5, p. 1242*).

The documents distinguish between different formats of consultation that are specifically geared to corresponding stages of the application and types of questions. The *BfArM* answers general questions that arise at an early stage of an application "uncomplicated and unbureaucratic by providing information by telephone or in writing" (*D4, p. 1237*). The underlying assumption is that the Fast-Track addresses, first and foremost, "inexperienced actors" (p. *D4, p. 1237*) that need advice in regulatory matters. The so-called "kick-off" meetings mark the beginning of projects to develop applications that are submitted to the approval process later.

> Within the framework of kick-off meetings, project ideas can be discussed openly and informally with the BfArM at an early stage of development. The aim is to inform applicants at an early stage about regulatory framework conditions and prerequisites and to provide orienting support for the DiGA Fast Track. (*D4, p. 1237*)

The guidance the *BfArM* offers to potential manufacturers begins before the project has stabilized. It does not so much target existing (health-and-wellness) apps but rather newly developed and not-yet (fully) developed applications. With the information and consultation offers, the *BfArM* and its Innovation Office seek "to give [manufacturers] orientation in early development phases on the way to market access for their (digital) innovative approaches" (*D8, p. 1296*), accompanying them from the idea stage to the approval process, Thus, they introduce regulatory considerations into the very design of the *DiGAs*-to-be.

These two information and consultation offers, informal responses to general questions and the kick-off meetings, are 'voluntary'. By contrast, the *DiGA* Consultation is a legally-defined format, prescribed in the provisions of the *DiGAV (D11, §23*). While the kick-off meetings comprise a "rather general orientation" (*D5, p. 1242*), the *DiGA* Consultations cover issues from general to "[p]roduct-specific questions […], e.g. technical details of the application procedure for inclusion in the *DiGA* directory and specific questions about the evidence to be submitted" (*D5,* p. 1242). The *BfArM* puts together a group of experts that can give the advice manufacturers need in their

particular situations. Like the kick-off meetings, the experts' advice influences the app design and environment. This influence is an explicit goal of the consultation. It provides the manufacturers with advice "which can be reconsidered in the context of the further development of their projects" (*D5, p. 1244*).

In the interviews, the manufacturers reported that they mostly had questions concerning the clinical evidence. In this sense, they found the *DiGA* Consultation helpful "because experts from the various fields were ultimately also present. Particularly with regard to the requirements and the studies, the responsibility for the studies, the study design, etc., they told us very clearly what they would like to see there and what would be needed" (*manufacturer*). Although the manufacturers also warned not to expect too much – the *BfArM* never says "do it like this and will fit" (*manufacturer*) – they still thought that "[i]t helps to know whether the authority finds something okay or not" (*manufacturer*). From the perspective of the manufacturers, then, the cooperative relationship serves, on the one hand, to share the initial draft of their application with the *BfArM*. Addressing other manufacturers, the authors of D6 recommend it to "help the BfArM team to understand your approach" (*D6, p. 1252*). On the other hand, it allows them to get feedback on this approach. According to the authors of D6, developers should ask the *BfArM* "to either agree with the manufacturer's planned approach or to provide corresponding feedback on what needs to change in the approach to meet the requirements" (*D6, p. 1251*). Before and during the approval process, the manufacturers perceived the contact with the *BfArM* as a viable way to resolve any issues and to find solutions "as quickly as possible, if necessary also with each other" (*D6, p. 1252*).

The close collaboration with manufacturers serves multiple purposes for the *BfArM*, both short- and long-term. From a short-term perspective and concerning individual manufacturers, it avoids that "innovative developments" do not fail due to "unnecessary hurdles" (*D5, p. 1247*)[24]. With the consultations, "questions and challenges can be discussed and resolved with the BfArM in advance of the application procedure, which would otherwise only be clarified during the procedure" (*D5, p. 1247*). The statistical evidence that *D5* presents suggests that a *DiGA* consultation increases the chances of a positive reply to the application. It shows as a column diagram and in writing that the share of rejected or retracted applications is higher for applications that have not taken advantage of a *DiGA* consultation. Additionally, the document states "that the quality and validity of applications from manufacturers who have received pre-application advice is significantly higher" (*D5, p. 1247*). This statement entails that applicants who do *not* take advantage of this offer are responsible for their failure – opening up a different perspective on the relationship between the *BfArM* and the manufacturers I will discuss in more detail below[25].

24 In this sense, in another publication on the role of the digital for the *BfArM*, the head of the Innovation Office, Dr. Wiebke Löbker, describes the role of the Innovation Office as akin to a "pilot who works together with them the way to approval or until use in the healthcare provision" (Bundesinstitut für Arzneimittel und Medizinprodukte, 2021a, p. 10).

25 I shall also mention that the information and consultation offers at the *BfArM* are fee-based, ranging from 250€ to 2,000€. One manufacturer told me in a more critical tone when they discussed this offer that it

Although the preceding might suggest otherwise, the documents also emphasize that accompanying the applications does not solely benefit the manufacturer whose application will have a higher quality and, in turn, is more likely to succeed. It also serves the *BfArM*. In this sense, close collaboration is reciprocal, and "all sides can profit" (*D5, p. 1248*). First, because the *BfArM* has accompanied the *DiGA*-to-be and the application from early on. This guidance increases the quality of the application. An "easier and faster application processing with fewer queries is made possible" (*D5, p. 1247*). From a long-term perspective, second, the experiences from the approval process that manufacturers feedback to the *BfArM* as part of the reciprocal collaborative relationship are used to improve the approval process and the regulatory framework (in terms of their "agility", see ch. 9.3). The close collaboration brings to the fore "aspects that lead to adjustments of technical or regulatory requirements in the statutory regulations" (*D5, p. 1246*). Additionally, through closely collaborating with the manufacturers, the *BfArM* seeks to "[identify] emergent trends and new developments ahead of time" (*D5, p. 1247*). These again allow the regulatory body to anticipate such developments and adapt the regulatory framework.

In line with the imaginary of digitalized healthcare, the *BfArM* expresses more generally that the ultimate beneficiary of the (mutually) cooperative relationship between the regulatory agency and the manufacturers is neither the *BfArM* nor the manufacturer. Because it serves to increase the quality of the applications and their processing and because the experiences the manufacturers feed back serve to improve the regulatory framework along with technological and other developments, the one who ultimately profits the most is the 'user', appearing here as 'the patient'. They will have accelerated access to Digital Health Applications that are still rigorously tested for efficacy and safety. "Through these advisory and support services, the BfArM sees itself as a promoter of future-oriented, safe and appropriate patient care" (*D5, p. 1248*).

Therefore, the imagination of digital healthcare informs and is closely entangled with the collaborative relationship. By "consulting and accompanying" *DiGAs* and applications from very early stages, perhaps even before the app has become stable, the *BfArM* influences the development and can align it with its vision. One manufacturer told me that they "had to adjust some things" (*manufacturer*) in the app during the approval process (although they also highlighted that this did not fundamentally change the app). These adjustments were a process of "trial and error" in which they had to find out "to what the *BfArM* attaches a great deal of importance". The app had to be improved iteratively until the *BfArM* had said "Okay, we can do that" (*manufacturer*).

was still a bit conspicuous [...] that the consultations, of course, also cost money at the *BfArM*" (*manufacturer*).

8.2 The Agonistic Relationship Between the *BfArM* and the Manufacturers

The approval process was not as cooperative as the previous subchapters might suggest. The more agonistic relationship between the *BfArM* and the applicants came to the fore, especially in the interviews. During the approval process, one developer, for instance, "never had the feeling that they were trying together to bring a DiGA to the market, but it was always, we try to bring the DiGA to the market and they try to prevent it" (*manufacturer*). In this section, I want to pursue this dimension more thoroughly.

8.2.1 Culture Clash: Administration and Innovation

I begin with what I have already alluded to earlier. There exist cultural differences between the *BfArM*. Part of what the approval process tests is the developer's ability to overcome this gap (see ch. 7.3.1). The lobbyist told me about the different approaches to risk between the regulatory agency and the manufacturers: While the latter are risk-aware, the former tries to avoid it. Moreover, this is a matter of language because "if I'm in administrative, I talk in an administrative language. A start-up talks in a start-up language" (*representative of digital health umbrella organization*). Therefore, they concluded that "different worlds collide: The administrative world versus the innovative world" (*representative of digital health umbrella organization*). The metaphor of a "collision of worlds" demonstrate that the cultural differences may be one cause for the agonistic relationship between the *BfArM* and the manufacturers.

From the developer's perspective, this was very clear. They assumed that the approval process "is already rather the typical administration, everything comes from the administrative corner [...] somehow" (*manufacturer*) when they reflected on the relationship with the clerk that was their contact person at the *BfArM*. This impression leads some manufacturers to assume that the (perceived) bureaucracy of the *BfArM* and the approval process undermines the intended goal of a digitalized healthcare system. The *BfArM* and the German Ministry of Health "were ultimately the ones who wanted to drive forward digitization in the healthcare sector in an agile and fast manner" (*manufacturer*) but this ended in a bureaucratization from the developer's point of view. The telling example for one of them was the so-called "significant changes" to the *DiGA*. These are changes or updates manufacturers must report to the *BfArM*. The *BfArM* then assesses whether the updated application still meets the requirements (see ch. 9.4). On the one hand, this manufacturer related to me that this had not come up yet "[b]ecause we are […] so deep in the bureaucracy again" (*manufacturer*). Thus, the bureaucratic nature of the approval process by itself counteracts further developments of the *DiGA*. On the other hand, manufacturers thought that this was inappropriate for digital technologies and their affordances.

> "[I]n such an agile, super agile environment like software development, where I have the possibility to iteratively adapt things within weeks, to make things better, to react to feedback, where we end up

> again in such a one-way street or in such a dead-end, where we are somehow presented with product cycles again from the old economy. (*manufacturer*)

Another key area in which this conflict between different worlds came to the fore was the requirements for the evidence of clinical efficacy. The manufacturers perceived this requirement or, rather, the bureaucratic way it was assessed in their perception as not taking into account the specificity of the product. Throughout the interview, this was illustrated by remarks that it was "atom splitters" (*manufacturer*) that assessed the evidence. Another interviewee expressed their frustration that the assessment focused solely on the numerical evidence abstracting from the specificity of the product. The differences between the cultures that encounter each other in the approval process made it difficult for manufacturers to anticipate how some of the requirements would be interpreted, despite the *BfArM's* claim to be a mediator between the law and the manufacturers. Again, this was obvious in the case of the "significant changes". On developer doubted that guidelines from the software industry on what constitutes an update that changes the version number were reliable because "[w]hether that is again what the BfArM means by that, is probably also in the stars" (*manufacturer*).

The most blatant example of the differences I describe in this subsection is the meaning attributed to the approval process. For the documents, successfully passing the approval process constituted the "end" (*D5, p. 1241*) because then the app has become part of the "standard care of the statutory health insurance system" (*D4, p. 1233*). By contrast, for the manufacturers, it is "not the goal, but only the beginning" (*D6, p. 1252)*. In the interviews, some manufacturers described this in economic terms: "[A]fter all, you put the digital health application on the market to get money for it afterward" (*manufacturer*). The Latourian approach allows me to rephrase this particular site of conflict as the difference between [LAW] and [ATT], the mode of existence to describe passions, attachments and interests. While these different perceptions may be self-evident when considering a regulatory body that is the gatekeeper to market access and manufacturers who want to gain market access for their product, they nevertheless suggest that both orient differently to the approval process. These different understandings as part of broader cultural differences can create disagreements. One of such disagreement becomes palpable in the case of the manufacturer for whom the approval process took longer than the expected three months. They expected the final day of the three months of the approval process to be "our start" and had prepared the company structures so that they have "everything prepared to begin" (*manufacturer*). The delay makes visible the discrepancy between approval-as-end and approval-as-beginning as the divergent orientations of manufacturers and the *BfArM* toward the approval process.

8.2.2 The *BfArM* as an Obligatory Passage Point

The manufacturer's quote above indicates the position that the *BfArM* has in the approval process as one clue for a more agonistic relationship. The concept of the "obligatory passage point" (OPP)

(Callon, 1984) stems from the very beginnings of ANT. Other scholars have rightly criticized it for suggesting a Machiavellian or at least entrepreneurial “prime mover” (Michael, 2016; Akrich et al., 2002). The legal role of the *BfArM* as the gatekeeper to the first healthcare market for Digital Health Applications warrants thinking with this concept while simultaneously considering that other actors have installed the *BfArM* in this position and that it is *not* a prime mover. An actor becomes an OPP if they manage to present themselves and their course of action as the solution to the identified problems of all other actors; to ‘get what they want’, they need to go through this actor. In an emerging network, this one actor becomes indispensable to all other actors (not without the capacity of resistance) giving this actor a powerful position in the network.

It should be glaring that the *BfArM* is an OPP *by law* for the first healthcare market. There may be (perhaps even more viable) other options for manufacturers to bring their app to the market. But there is no other way for their app to enter the first healthcare market as a Digital Health Application. D1 summarizes this position by stating that “a DiGA must have successfully completed the assessment of the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) (*D1, p. 7*). Nevertheless, other ways and efforts to establish the *BfArM* as an obligatory passage for different actors surface in the documents. The previous quote mainly addressed the developers. If they want their app to be reimbursable, they need to go through the *BfArM*. The manufacturers can and *should* also go through the consultation offers because they lack the regulatory knowledge necessary. These offers are “a low-threshold consulting format, especially for academic research groups, small and medium-sized enterprises as well as start-up companies, i.e. a target group that tends to focus on scientific-technological issues and is less familiar with regulatory (medical device or social) issues” (*D5, p. 1242*). Beyond the position that the *BfArM* occupies by law, this passage further reinforces the role of the authority as an OPP through a particular construction of a knowledge deficit (Pfotenhauer et al., 2019). While manufacturers have specialized knowledge in some domains, the documents described them as lacking others. To attain *this* knowledge, manufacturers must go through the *BfArM* and *“*the experts of the *BfArM” (D5, p. 1243)*. Thus, the *BfArM* tells the developers “in a roundabout way 'Without you buying a consultation from us, it's not going to happen anyway.'” (*manufacturer*). We will see in a little bit that this becomes normatively charged when manufacturers are made responsible for negative outcomes of their applications *because* they have not gone through the *BfArM* in a particular “geography of responsibilities”.

As the gatekeeper to the first healthcare market, the *BfArM* is also an OPP for future users of *DiGAs*. The information and consultation offer seeks to ensure “so that patients have undelayed access to (digital) innovations” (*D8, p. 1296*). Assuming they want to use Digital Health Applications, they need to go through the *BfArM* that has implemented the Fast-Track to ensure the quality and efficiency of the apps and accelerate the approval. A second dimension to this was mostly expressed in the interviews. One manufacturer also explained that listing their app as a *DiGA* was per-

haps the only business opportunity because patients in Germany are “not accustomed to paying for health services” (*manufacturer*). So, while the manufacturer needs to go through the *BfArM* to access Germany’s first healthcare market, the *patient* needs to go through the *BfArM* if they want to have their digital health technology reimbursed by the SHI.

In line with the principle of generalized symmetry (Callon, 1984) in ANT, according to which the analyst needs to apply the same conceptual tools to both human and non-human actors, the position of the *BfArM* as an OPP extends to digital health technologies. This extension becomes clear in the imagination of digital healthcare that informs the approval process I have analyzed in an earlier subsection. This imagination envisions digital health and corresponding digital technologies as essentially undecided: It bears both chances and challenges/risks for digitalized healthcare provision. To realize the changes and to “master” the challenges, digital health technologies and digitalized healthcare provision need to go through the *BfArM*. The *BfArM* works to “turn the opportunities of digitized healthcare into patient-relevant opportunities with added value for patient care” (*D8, p. 1293*). As an OPP the *BfArM* decides on the “fate” of digital healthcare.

This position creates a hierarchy among the *BfArM* and the other actors at the core of a more agonistic relationship between them. The relative lack of alternatives further strengthens it. While the manufacturers may also decide to market their app on the free market or enter selective contracts with healthcare insurance providers, none of these entail the (legal) consequences of becoming a *DiGA*. Only a *DiGA* can be reimbursed for *all* insured persons in Germany. Only a *DiGA* is granted a distinguishing socio-legal status (see ch. 9.1). Given this position of power in the approval process, the *BfArM* can enforce changes to the app and its environment. It begins with the information and consultation meetings where the *BfArM* gives advice and recommendations for the application. Implementing the ‘suggestions’ is not entirely up to the manufacturer. “If a manufacturer deviates from the recommendations and assessments of the BfArM on the questions and issues addressed in the consultation [...] the reasons must be explained in detail by the applicant” (*D5, p. 1245*). This constraint is not symmetrical because the results are not likewise binding for the BfArM. The asymmetry extends to the protocol of the consultation developers need to provide afterward. The protocol means you “have something in writing but you are still not allowed to refer to it legally” (*manufacturer*).

The *BfArM* can also enforce changes to the application. The lobbyist thought that while it is legally possible to prove the medical efficacy using non-RCT designs this is still not recommendable because “then I'm asking my examiner to deal with it as well. […] It makes sense to adapt to it [the world of the BfArM] (*representative of digital health umbrella organization*). Given the power of the *BfArM* in the approval process, it can more easily force manufacturers to adapt to its culture and its understandings, even if alternative study designs may be easier, more appropriate and explicitly permitted. This is the case, although the *BfArM* purports to assess the evidence of the positive healthcare effect with a “sense of proportion” (*D4, p. 1239*). The discretion the *BfArM* reserves for

itself may lead to ambiguities from the manufacturer's perspective. The role that individual assessors at the *BfArM* with divergent expertise further adds to this. At the end of one interview, one manufacturer told me about another developer's experiences who had applied for approval with more than one application. The queries by the *BfArM* in the second approval process differed from and contradicted those from the first. Importantly, the developers did not complain about this because "if one thinks it just genuinely from the end and says: 'We want that'. Then you just do it at that moment" (*manufacturer*). "Thinking from the end" refers to the positive outcome and the listing as a *DiGA*. Because manufacturers need to go through the *BfArM* to achieve this goal they are ready to give in even if they feel that the requirements may be contradictory.

The exceptions prove the rule: The power of the *BfArM* also shows when it is more lenient with the manufacturers. The developers reported that this is more likely if they yielded to what the *BfArM* wanted to see. For one manufacturer, this facilitated future communication, and for another, the *BfArM* extended the otherwise strict deadlines. In this sense, the respondents mentioned two general responses that seemed possible vis à vis the *BfArM*, an acquiescent approach where the manufacturers yielded to the demands and an argumentative one where the manufacturers argued and justified their application. Deciding between them means to "choose your battle" (*manufacturer*) based on the ultimate goal. Given the position of the *BfArM* as an OPP and as a gatekeeper to the first healthcare market, the argumentative approach remained limited, however – unless the manufacturer was willing to risk a negative outcome. These limits became obvious for one manufacturer who considered legal action regarding a decision by the *BfArM*. "[W]ell, we want approval from the authority. If we start something legal now, then we're just pissing on the leg of the person who ultimately decides about us. So there's no way we can do anything about it" (*manufacturer*). Even though they might have had sufficient grounds to take legal action, the company decided against it to avoid negative repercussions in the assessment. The power of the *BfArM* as an OPP has become almost black-boxed. It overshadows the regulatory framework that installed the *BfArM* as the OPP but could have also provided the grounds for the manufacturer's legal action.

8.2.3 Distributing the Blame for Negative Outcomes

The more agonistic relationship between the *BfArM* and the manufacturers creates its own peculiar, as Akrich (1992) calls it, "geography of responsibilities". The approval process establishes clear responsibilities and corresponding attribution of blame for negative outcomes[26]. In this subsection, I

26 None of this means that the manufacturers did not put forward competing geographies of responsibility in the interviews. Consider, for example, one more time the quote from the manufacturer who reported on attending information events. Here, they imply another distribution of responsibility where the insufficient information disseminated during these events makes it necessary for the manufacturer to become knowledgeable. Furthermore, other manufacturers attributed the responsibility for negative outcomes instead to the tight deadlines and the bureaucratic approach of the BfArM. Given the position of the BfArM as an obligatory passage point, however, it is unlikely that these competing geographies prevail. The case of the manufacturer who considered legal actions but backed down from them because they feared negati-

will follow this geography as it unfolds from before until well after the approval process. The 'responsibilization' of the manufacturer starts with the information and consultation offers. D4 provides evidence for reasons for retractions or rejections. It interprets the relatively high number of retracted applications as a sign that "the extensive advisory services offered by the BfArM have not yet been sufficiently utilized" (*D4, p.1239*). Where manufacturers took advantage of consultation and their application was retracted or rejected, the geography of responsibility of the application procedure still follows a similar pattern. According to D5, the reasons that lead to the rejections or retractions "had not been the subject of consultations prior to the application [...] or the recommendations of the BfArM had not been followed. (*D5, p. 1246*). Ex negativo, these quotes reinforce the role of the *BfArM* and especially the information and consultation as obligatory passage points.

I found two ways the approval process shifts responsibility to the developers. First, this concerns the preparation and the alleged lack thereof. DD4 states the relatively high share of retracted applications is because "the time and content-related challenges of the Fast-Track procedure and the requirements of the law and regulation have been underestimated by the applicants" (*D4, p. 1239*). Some interviewees echoed this view that withdrawals are due to poor preparation. The lobbyist surmised that many manufacturers with a provisional listing provisionally will probably fail "because they just did not think about it in advance" (*representative of digital health umbrella organization*). A manufacturer agreed, stating that if a developer withdraws their application, "he [sic!] is poorly prepared" and that "he [sic!] has not thought about what his evaluation concept looks like" (*manufacturer)*.

In a second way, manufacturers become responsible because assessing data and information security is outsourced to them. As previously mentioned, the *BfArM* staged information events before the *DiGAV* came into force. One manufacturer found them lacking, however. "Someone presents things to me in three hours that I can read myself in one hour. [...] And when he then gets a question, he doesn't know it any better because it hasn't been implemented in practice yet. So you have to take care of it yourself. (*manufacturer*). Thus, the responsibility of understanding the law and anticipating how it may be applied in practice is delegated to the manufacturer. In turn, this is what the approval process tests as it holds manufacturers "responsible for having the requirements in all areas of the application verified prior to submission of the application": "The BfArM examined the manufacturer's claims in part, but not in full" (*D6, p. 1253*).

After the 'end' of the approval process, manufacturers remain responsible in two ways. This first concerns the "agile regulation". This term refers to the continuous adjustments of the regulation for *Digital Health Applications* that change the requirements for apps to become *DiGA* but also apply retroactively to *DiGAs* that have already been listed (see ch. 9.3). The manufacturers must "monitor the legal texts" (*manufacturer*) for changes (and to fulfill the additional requirements within a set deadline). Second, the geography of responsibilities of the approval process shows in the monito-

ve consequences in the interactions with the BfArM illustrates this.

ring of what the *DiGAV* designates as “significant changes” to an app (see ch. 9.4). When I asked one of the manufacturers whose responsibility this is, they answered: “So you yourself. But, so that is formulated as a duty” (*manufacturer*). However, it is an especially tricky obligation because, as I will detail later, there were significant uncertainties among the manufacturers about what constitutes a “significant change” in practice. With a checklist the *BfArM* provides, “the manufacturers are forced to take care of it and to, yes, to evaluate the changes themselves” (*manufacturer*) – under the threat of severe penalties of up to 100,000€.

9 The Regulation Multiple

The overview of existing literature on digital health has shown that its regulation has thus far not been at the center. Therefore, in this chapter, I want to illuminate the meaning regulation takes on vis à vis digital technologies. I contend that in the case of the approval process for Digital Health Applications regulation takes different forms, constituting what, to echo Mol’s (2002) “body multiple”, we can call a ‘regulation multiple’. The regulatory framework is performative (9.1), distributed (9.2), agile (9.3) and continuous (9.4). While these dimensions are entangled, each has specific characteristics I want to flesh out in the following.

9.1 Performative Regulation

The performativity of regulation is one of the pivotal insights of existing STS research into regulation (of medical devices) (Faulkner, 2012a). It signals a shift away from the idea of regulation as merely setting limits to what exists already to regulation as creating new “technological zones” (Barry, 2001; Faulkner, 2009b). In this subsection, I will trace the multiple performativities of the regulation for Digital Health Applications. I add to the literature by differentiating between three types of performativity: socio-legal, organizational and cognitive.

9.1.1 Instauration of Socio-Legal Objects and Subjects

First and foremost, regulation creates *DiGAs*, in this context not as a technological but as a socio-legal object. Apps could not exist as *DiGAs* without the regulatory framework. This was the initial hunch that oriented my research: *Something* happens in the approval process which transforms/ transubstantiates (Latour, 2010) a health-and-wellness application into a *DiGA*. I have already quoted one of the manufacturers above who argued that the clinical evidence is the “differentiating criterion” (*manufacturer*). Similarly, the provisions for data and information security modify existing regulatory frameworks such as the GDPR that also apply unspecifically to other health-and-wellness apps (see ch. 6.1.2). These remarks show that the boundary between health-and-wellness apps and *DiGAs* does not pre-exist the regulatory framework. Through the approval process that asses-

ses the legal requirements of a *DiGA* an app is turned into something different than what it was before. In the language of AIME, the app enters into a "new mode of existence" as a socio-legal object defined by the *DiGA* regulation.

There is an interesting bit in the conversation with the lobbyist approaching this from the other side, as it were. They told me about the rather crushing verdict of an acquaintance about one *DiGA*: "Any fitness tracker can do more" (*representative of digital health umbrella organization*). One could use this quote to question whether are *DiGAs* really necessary if there are already several apps available (and widely used) that have the same and even more functionalities? But this critique, justified or not, would miss what this statement implies about the performativity of regulation. It is not a feature inherent to the app, some specific technical functionality, that makes a *DiGA* stand out from the sea of other applications. What makes all the difference is 'merely' the legal significance it is endowed with if the assessment finds that all legally defined requirements, especially for clinical evidence, are fulfilled[27].

Considered from the manufacturers' perspective, the creation of Digital Health Applications as socio-legal objects also has an economic dimension. One manufacturer told me that the regulation 'saved' their app from being abandoned. They "would have sold it or it would kind of bob around there, but nobody will care about it" (*manufacturer*). In another case, the existence of *DiGA* was the raison d'être of the company. It was formed with the "essential goal to create a digital health application" (*manufacturer*). The two cases demonstrate how becoming a *DiGA can* present a business opportunity for manufacturers. They foreshadow the performative role regulation plays in the creation of markets (Faulkner, 2012a). Before I turn to this below, I want to emphasize that the socio-legal status of the *DiGA* and its consequences made these effects possible. One manufacturer anticipated that "we will only be commercially successful with our product if we get into the DIGA directory" (*manufacturer*). The reason for this is the organization of the German healthcare system. SHI reimburses much of the healthcare which is why "in Germany, no one wants to pay for anything themselves" (*manufacturers*). Only if the app is listed as a *DiGA* it becomes reimbursable. Only then users do not have to pay for it directly.

The economic dimension of the socio-legal status of Digital Health Applications can also show more indirectly. One developer wanted to increase the exposure of their app by enlisting the services of a pharma representative, similar to the sales and distribution models for pharmaceuticals[28]. The company was reluctant and disagreed with a contract "because they would never have gotten their money back" (*manufacturer*). Only after the former health-and-wellness app had beco-

27 To expect anything else, that a *DiGA* is indeed technically superior, for Latour, would be a category mistake: The law does not speak the truth or, more precisely, it does not speak *this* truth. According to him, this is what makes the law so frustrating at times as "we feel the weakness [of the law] every time we despair at seeing that the 'legally justified' decision is not necessarily just, opportune, true, useful, effective" (Latour, 2013a, p. 361). We need to understand the law in its own peculiar way of rendering things, not to be confused with (scientific) truth, economic efficiency, technological usability, etc. Thus, a DiGA is not an app with more or better functions. It is an app that has successfully undergone the approval process and met all the requirements. This is what gives it its peculiar mode of existence.

me a prescriptible and, perhaps more importantly, reimbursable Digital Health Application this changed. A variant of this is the 'rhetorical force' that becoming or being listed as a *DiGA* could unfold in negotiations with investors. I have already referred to this above (see ch. 7.1.2). The listing serves as a guaranty for future revenues from reimbursements by the SHI so that "access to capital is probably easier and the risk for the investor is lower" (*manufacturer*).

The previous examples demonstrate that the regulation creates *DiGAs* as socio-legal objects and what this status "affords" (Latour, 2002). But what about "the Subject of the Object" (Law, 2000)? As John Law (2000) argues, modes of ordering at once co-constitute objects and subjects. Likewise, the law as a mode of existence performs objects *and* subjects, although this is usually not considered in analyses of "socio-legal objects" (Cloatre, 2008; Rooke et al., 2012). Additionally, Latour (2013a) groups [LAW] with other modes of existence that are populated by "quasi-subjects" in his tableau of all modes. It instaurates durable subjects as legal figures to whom propositions and actions can be tied back. In this sense, the regulatory framework for *DiGAs* creates socio-legal *subjects* that (newly) populate the German healthcare system.

The first of these subjects that regulation co-constitutes is the insured person entitled to be described a *DiGA* by being insured by a German healthcare insurance provider (itself a socio-legal status). In one way or another, all documents I have analyzed emphasize that the *DVG* "created a new entitlement to benefits for insured persons in the standard care of the SHI system" (*D2, p. 1198*). A human actant, to use the most neutral term ANT proposes for this entity, is entitled to a Digital Health Application in conjunction with the provisions of the *DVG*. In Latourian parlance, the insurance card as a signum of SHI membership materializes the "ground" that connects the actant to the law, creating the socio-legal quasi-subject of the 'insured person'[29]. Indeed, the documents also emphasize that this is a legal innovation. Previously, this persona (that exists 73 million times, as the documents assert) was only entitled to pharmaceuticals and medical services. The DVG adds the entitlement to digital health technologies. The counterpart of the entitled 'insured person' is the healthcare professional who *also* emerges anew as a socio-legal subject with the right (and, as we will see shortly, the obligation) to prescribe *DiGAs*. The *DVG* provides that "BfArM-listed *DiGAs*" – i.e. socio-legally redefined apps – "can be prescribed by all physicians and psychotherapists in Germany, and the costs are covered by all statutory health insurances" (*D6, p. 1249*).

28 The lobbyist had a similar idea. During our interview, we briefly discussed the lack of knowledge among both doctors and patients. They thought that a "*DiGA* representative" similar to a pharma representative may be a possible answer to the question "how do I introduce DIGAs to a mediocre rural physician who has just now been overwhelmed with e-prescribing?" (lobbyist).

29 One could draw a fruitful analogy here to Latour's (1999a) answer to the question of who kills people, people or guns. It is, of course, neither of the two options by themselves but rather the Citizen-Gun. Only the human actor to whom the infamous US-American Second Amendment applies (materialized by ID, passport or Green Card) can (legally!) carry a gun (additional provisions notwithstanding) and shoot another person, potentially becoming a criminal in the process. DiGAs are not guns but the principle is the same: Only a socio-legal subject is entitled to this corresponding and co-emergent socio-legal object.

The determination that “all” physicians and psychotherapists can prescribe *DiGAs* is particularly compelling. In Germany, previously only *medical* psychotherapists were allowed to prescribe psychiatric drugs. This changes in the context of *DiGAs*, the socio-legal subject of a *psychological* psychotherapist who can give out prescriptions is a novel figure in the German healthcare environment. Thus, the creation of this new socio-legal subject also rearranges the power relations in the psychotherapeutic profession. But the regulatory framework also shifts the power relations in the broader German healthcare system because the ‘insured person’ may become their own counterpart and bypass medical professionals. “Insured persons that can provide their SHI funds a proof of a corresponding indication are also eligible to receive a desired DiGA without a prescription” (*D1, p. 7*). This option signals a fundamental shift in the power relations in German healthcare where the medical profession has traditionally been dominant (Daemmrich, 2004). At the same time, it opens up new opportunities for manufacturers to advertise their *DiGA* because physicians are no longer the gatekeeper to their prescription. These opportunities depart from the approach usually taken with pharmaceuticals, enlisting representatives who ‘advertise’ the drug directly to physicians (although the manufacturer cited above emulated this approach for their *DiGA*).

Manufacturers are also instaurated as particular socio-legal subjects in the regulatory framework. This demonstrates the *obligations* after the approval, for example, the need to report updates of the *DiGA* to the *BfArM* to assess whether this constitutes a so-called “significant change” which is an obligation that a developer of a health-and-wellness app does not have to heed (see ch. 9.4). It also shows in the *rights* that a manufacturer obtains once their app has become a *DiGA*. In response to doctors who refused to prescribe their *DiGA* to patients, one manufacturer announced that they “think this year I'm going to sue another doctor because, yes, this has become malpractice in the meantime” (*manufacturer*). After the *BfArM* has assessed the clinical evidence during the approval procedure, the app that has become a *DiGA* is also considered a legitimate treatment. A physician or psychotherapist now needs good reasons that stand up to *legal* scrutiny for withholding the prescription of an app from an insured person that is legally entitled to it. Vis à vis the medical professional who has the right to prescribe DiGAs and the ‘insured person’ entitled to them, the manufacturer emerges as a socio-legal subject that can demand the DiGA they have produced to be prescribed. The regulatory framework gives them a legal (rather than, for instance, an economic) lever to enforce this entitlement.

9.1.2 Co-Constitution of Market and Organizational Structures

The performativity of the law is not restricted to re-defining the entities that enter into legal associations, be they objects or subjects that become socio-legal in the process. It also “overflows” (Callon, 1998) by influencing developments in other domains. In this subsection I will analyze how regulation in the case of Digital Health Applications performs the organization of markets and the manufacturer companies.

The previous subsection has already pointed to this. Because *DiGAs* themselves did not exist before the regulation neither did a market for *DiGAs*. That does not mean that the market for *DiGAs* was created ex nihilo and nothing existed prior to it, however, What existed before and is the point of departure of the regulation is a rapidly growing market for health-and-wellness apps, some of which later became *DiGAs*. The regulatory framework seeks to order this litte regulated market and to create "comprehensive transparency regarding the digital offers available on the market and positively evaluated by the BfArM" (*D4, p. 1236*). The approval process makes it possible to classify, order and compare the different apps available by introducing a line of distinction (at least) between health-and-wellnes apps and Digital Health Application endowed with a specific socio-legal status. Likewise, the approval process implicitly constitutes the stakeholders in this market, those implied to have the "desire" for information and a comparative overview of the market for medical apps.

As we have seen above, the creation of the market makes *DiGA* an attractive business area. The regulatory frameworks explicitly *invites* companies to submit an existing app for approval or to be established to develop a *DiGA*. It seeks "to create an incentive for the development of particularly good and safe offers and to bring these innovative digital medical products into care in a transparent, rapid process" (*D3, p. 1203*). This passage normatively charges the line that separates health-and-wellness-apps from *DiGAs* Only those apps that are "particularly good and safe" will be allowed to enter. The *BfArM* will safeguard that these conditions are fulfilled. Moreover, the quote connotes that no such incentive has existed so far but is brought into being by the regulation; good and safe apps and a market for them may have existed before but this was not by regulatory design. On the other hand, this new normatively-charged boundary simultaneously inhibits market growth. The lobbyist repeatedly describes this with the metaphor of "hurdles" that have become "so rigid that the approach, I'm doing something new, digital and I'm trying it out is killed along the way" (*representative of digital health umbrella organization*). These hurdles shape which companies are more likely to pass the approval process as especially the implicit ones may favor some rather than others (see ch. 5 and 6). In this sense, juxtaposing the prohibitive and performative understandings of regulation like Faulkner (2012a) may not be tenable as the two are not mutually exclusive. Here, regulation does not either set limits to an existing unregulated market or co-constitutes one. Instead, this case shows how regulation creates a new market by drawing boundaries within an existing one that may be prohibitive of who can enter.

The performance of markets also extends beyond the domain of digital health applications to their broader ecology. The regulatory framework of *DiGAs* and the approval process create or influence secondary markets. In the interviews, this was especially obvious for the requirements for data and information security. One manufacturer thinks it possible that "an industry will form around" (*manufacturer*) the (adjusted) requirement to attain a security certificate for their apps. Furthermore, as a direct result of the regulation, a manufacturer – assuming that developers in countries outside of

Europe are not familiar with European and German law – found the common practice of outsourcing the programming of an application to countries with cheaper workforces unfeasible if one aims to develop a *DiGA*-to-be. The developers need to be able to navigate the regulatory standards and incorporate them into the design of their apps (Williams et al., 2020).

This entices us to move on and consider how the regulation co-constitutes the organizational structures of the manufacturing companies. First, it influences with whom manufacturers can collaborate. For instance, to be successful one should enlist an IT partner "who knows besides the idea and the concept, what data protection, data security mean. So that when you want to have the thing recorded, you meet the prerequisite" (*manufacturer*). This narrows down the pool of collaborators and likely, but by no means necessarily, limits it geographically. The regulation also co-shapes the *internal* structure of the companies. One of my respondents works in the Legal and Regulatory Affairs Department of their company. In the interview, they described how their position in the company had changed during and after the approval process. To avoid updates that may constitute a "significant change", for instance, "there is input from me in the development. […] There has already been a case where a function was desired by a team and then, in the end, it was so no, that's not possible, it's not possible at all in terms of the requirements" (*manufacturer*). The regulation co-shapes the power relations within the company as developers need to consider legal legal provisions in the design. Harking back to the emergence of the *DiGA* as primarily a socio-legal object, even its development the app ceases to exist (purely) in a technical mode of existence which is why legal considerations trump technical feasibility or desirability – for the organizational structure of the company this can mean that the members of the Legal and Regulatory Affairs Department has to "shout loud enough" (*field notes taken after the interview*).

9.1.3 Anticipation

A final theme that emerged from my empirical material on the performativity of the regulatory framework is that of anticipation. This is what one could call the 'cognitive' dimension of performativity and matches existing research that shows how regulation "intrudes" into earlier stages of research and development (Cambrosio et al., 2017; Darling et al., 2015). To a limited extent, the regulatory framework requires and enables manufacturers to anticipate the assessment procedure and plan and prepare accordingly. In this subsection, I will present what made this anticipation possible and what manufacturers needed to anticipate.

Anticipating the regulation becomes possible through the mutual expectations that the *DGV* and the *DiGAV* create. The *BfArM* can legally expect the manufacturers to meet all the (explicit and implicit) requirements on the way to passing the approval process. In return, manufacturers can expect that the *BfArM* processes their application as the regulatory framework states. This especially concerns the duration of the procedure. The law stipulates that "[t]he evaluation period is a maximum of 3 months after complete application receipt, without the possibility of a clock stop" (*D4, p.*

1233). Both sides of the mutual expectations become visible in this quote. Manufacturers need to assemble the application completely and submit it. The *BfArM* will then not take longer than three months to assess the application and present the result. The application portal materializes this tacit agreement. Manufacturers can only upload documents of limited size but in return "the BfArM is then able to assess very quickly" (*manufacturer*). The mutual expectation that underlies the approval process also made the tight deadlines more bearable. Despite all complaints, one manufacturer thought that "that's super. Imagine if they were to take loops again and again, and that would become a never-ending story. I don't think that would work either. But that implies that you have a certain pressure" (*manufacturer*). That is the implicit trade-off that the "chronopolitics" of the approval process constitutes. The manufacturers need to work under (time) pressure and meet the tight deadlines in the approval process but this is a low price to pay when considering the alternative of an approval process without a pre-defined endpoint where manufacturers cannot know the status of their application. Thus, manufacturers and the *BfArM* are mutually committed to each other. The case of the developer where the agency did *not* process the application in three months that I have introduced above demonstrates this ex negativo. Here, the company had anticipated the three months of the approval process and planned accordingly based on the expectation of a symmetrical trade-off. The *BfArM* breached this expectation which unveils the power imbalance of the approval process. Not only did the company (think they had) no way to respond to this breach. But the consequences for not heeding the mutual commitment seem to be distributed unequally.

If the tacit contract holds it allows anticipation in several dimensions. First, the costs: I have suggested the approval process is an implicit test of the manufacturer's financial resources (see ch. 7.1.2). Therefore, the manufacturers need to anticipate the necessary funding, weigh the costs against the prospected profits and calculate the alternatives -- free market, selective contracts with insurance providers, etc. "How well does it sell? And how high would the investment be to get all these registrations? It hasn't paid off yet" (*representative of digital health umbrella organization*).

Second, applicants need to anticipate regulatory requirements. As we have seen earlier, this begins with considering the position of the *BfArM* as a regulatory agency. One manufacturer thought they passed the approval process smoothly "because [...] I have this process of working with public law institutions and anticipating what they actually want to see" (*manufacturer*). This encompassed anticipating that the *BfArM* will likely attach greater importance to the clinical evidence because it has traditionally been a medical authority currently only building the expertise for digital health technology. The quote also shows, however, that anticipation is a prerequisite ability. The manufacturer could only anticipate "what the *BfArM* wants to see" because they had prior experience working with regulatory bodies. For the evidence of clinical efficacy, the developers need to ask themselves: "What do I actually want to achieve with my health app?" (*representative of digital health umbrella organization*). Putting together a clinical trial involves many considerations: What condition does the *DiGA* target? How will one be able to show the impact of the app on this condition?

These may not be easy questions because, especially for apps that have previously offered in the app stores, their description does need to give an indication. Health apps may, by design or not, be unspecific in the targeted condition. However, in the clinical trial, developers need to specify what their app treats under the ICD-10 classification system requiring them to narrow down the target group. In a second step, the way the trial will measure the positive healthcare effect needs to be specified, for instance, in terms of relevant endpoints and methods. Therefore, “it’s worth every minute” (*representative of digital health umbrella organization*) to anticipate what is necessary for the RTC. On a meta-level, manufacturers need to “think about it ahead of time” (*manufacturer*) whether and where they will need the support from external service providers.

My respondents thought that anticipating the approval process was crucial for successfully applying. One manufacturer described the application as “an easy task because we have thought about it beforehand” (*manufacturer*) and that they could subsequently fill it in within just a few hours. But anticipation also has limits. In all of the interviews with manufacturers, they reported being in vivid exchange about the approval process with other companies. That is what allowed them to anticipate some of the challenges. For instance, they knew beforehand that the final weeks of the three months would be particularly busy from other developers’ accounts. They knew *when* the deficiency lists from the *BfArM* would most likely arrive but “what the contents are, we did not know of course. That was also then very specific to our application” (*manufacturer*). A second limit to anticipation is the ‘human factor’ of the assessment, the influence of the individual assessor on the application. This speaks to the experience one manufacturer had heard from another company that had submitted several applications “but then at some point there was a demand for something where they said but it did, we've done that before” (*manufacturer*). In this case, the different assessors set divergent priorities in their work, making pursuing similar approaches difficult. Similarly, manufacturers noted differences between deficiency lists and what the first did not object to the second did. But even though this set limits to anticipating the procedure, they did not consider this a huge problem: “That's just the way it is, people are different, everyone has a different look” (*manufacturer*).

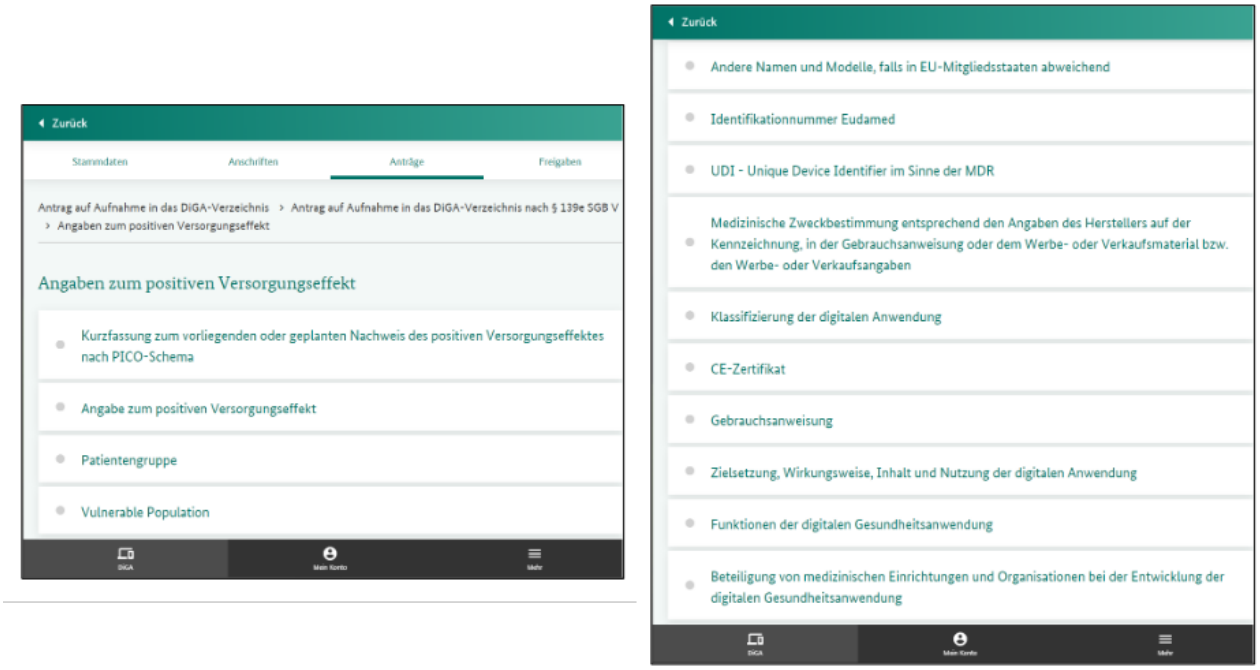

Figure 2: Screenshots of the User View of the DiGA *Application Portal showing the different elements of the application* (taken from Bundesinstitut für Arzneimittel und Medizinprodukte, 2021b)

9.2 Distributed Regulation

I have suggested that not all components of the regulatory framework for Digital Health Applications are on the same level. Instead, the regulation draws together and partially translates the provisions of various other legal frameworks from different political levels. TThis is the case with the requirement for *DiGAs* to be listed as medical devices. It draws on the EU-level MDR, for example. Similarly, the *DiGAV* incorporates and modifies the stipulations from the GDPR. I call this the "distributed regulation" of Digital Health Applications. In this subsection, I will investigate its two dimensions, distributed origins of the requirements and the distributed responsibilities for regulating.

The *BfArM* presents itself as well-networked internationally and maintains close links with other bodies and authorities. It is in "close cooperation at national and European level" (*D8, p. 1293*). This collaboration with other regulatory bodies has its roots in part in previous collaborations in the regulation of pharmaceuticals but, as this quote illustrates, it also extends to the regulation of *DiGA*. More yet, the *BfArM* considers this collaboration crucial for realizing the imagination of the digitalized healthcare system (see ch. 5). The requirements partially stem from such collaborative ties. D4 states that "[t]he requirements placed on the products are oriented by internationally recognized catalogs of criteria" (*D4, p. 1199)*[30]. Moreover, the *BfArM* has and continues to develop the require-

30 This resembles Cambrosio et al.'s (Cambrosio et al., 2017) finding that the regulatory standards of biomedicine are devised by what they call "transnational networks of experts". In the context of the DiGA regulation, this reference takes yet another meaning: Especially because the BfArM has primarily been the regulatory authority for pharmaceuticals, not for digital health technologies, this statement assures that it draws on the expertise of other regulatory bodies or networks (quite similar to the work of referencing in scientific texts) (Latour, 2003).

ments for Digital Health Applications with other German regulatory agencies. The newly introduced certificates for data and information security, for instance, have been developed by the *BfArM*, the Federal Ministry for Health, the Federal Commissioner for Data Protection and Freedom of Information (*Bundesbeauftrager für Datenschutz und Informationssicherheit, BfDI*) as well as the Federal Office for Information Security (*Bundesamt für Sicherheit in der Informationstechnik, BSI*). Thus, assembling the different requirements is based on a sort of 'distributed cognition' in which the expertise of various public bodies comes together. This distribution also increases the authority of the requirements. The *BfArM* is primarily a medical authority. But the other agencies have particular aspects of digital technologies as their purview. The additional expertise compensates for gaps in expertise the *BfArM* may have.

This also applies to the examples I have pointed to above. The regulatory framework for *DiGA* feeds on various other regulatory frameworks.The data processing for *DiGAs* is "generally carried out in accordance with the GDPR", for instance, and "the manufacturer must implement the requirements of the GDPR in his [sic!] organization, in his processes and in his products" (*D3, p. 1199*). Because it draws on these regulatory frameworks from various political levels, the regulation of *DiGAs* also depends on the development of these frameworks. A pertinent example of this that is both explicit and implicit in my empirical material is the so-called Schrems-II-ruling of the European Court of Justice. This ruling stipulates data from EU citizens must not be transferred to servers in the United States. According to D4, this "led to manufacturers having to change their data processing service providers, in some cases at short notice and within the ongoing evaluation process" (*D4, p. 1238*).

Besides other regulatory frameworks, the approval process may be the source of the regulatory framework itself. There is continuous feedback between "law in action" and "law on the books". As I will outline in more detail below, this is part of the agile approach to regulating *DiGAs*. According to this approach, "the initial regulatory framework will continuously be adapted and developed in the years to come – shaped by the experiences gained with innovative products and the administrative procedures used to admit them" (D3, p. 1200). Here, the regulatory framework is distributed internally. The source of adaption of the law is the implementation of this law in the approval process itself. The regulatory framework becomes self-reflexive by incorporating previous experiences in future iterations. The close interconnection between "law in action" and "law on the books" that this unveils supports the case that it is not tenable to juxtapose these two (Levi & Valverde, 2008).

The heterogeneous origins of the regulatory framework do not only have implications for how the content of this framework is assembled but also influence the responsible regulatory body. I start with the role of the MDR because I have discussed this in detail in an earlier chapter (see ch. 6.1.1). To be registered as a medical device, an app must go through a (technical) assessment at one of the so-called Notified Bodies, quasi-regulatory bodies with the credentials to conduct these assessments and grant a device the socio-legal status as a "medical device". Recent updates of

the *DiGAV* foresee a similar development in the implementation of data and information security certificates. With the new provisions, “certificates can be offered by bodies approved in accordance with Art. 42 of the GDPR and Section 39 of the German Federal Data Protection Act (BDSG)” (*D3, p. 1200*). While this brief quote illustrates once more how the *DiGAV* intertextually connects to other legal frameworks, what is most important is that the new provisions outsource assessing and awarding the certificate to quasi-regulatory agencies.

This latter example shows that the new provisions blur the boundaries between public bodies and (semi-)private organizations in the regulation of *DiGAs*. Therefore, actors *not* usually part of (public) regulation in the widest sense of the word play a role in the regulation of *DiGA.* First of all, much of this regulation is distributed to the manufacturers. I have shown this for the checklists for assessing data and information security. I have alluded to this for the so-called “significant changes”. Second, users and representatives take over a quasi-regulatory function. This results from the asymmetric relevance the approval process (implicitly) grants the requirements. In this context, usability takes a backseat and future users need to assess it themselves. One manufacturer told me that representatives of user groups regularly contact them to inquire, for example, whether their app is also accessible for blind people. Finally, Big Tech companies also take over quasi-regulatory capacities. They can set standards and create certificates such as interfaces/APIs that developers need to adapt to (Williams et al., 2020). This power of Big Tech companies may cause tensions between the official legal framework and this more implicit quasi-regulation. Much of the developers’ work concerns updating and adapting the apps to the changed standards of the Big Tech companies. These adaptions can conflict with the requirement to report updates that may constitute a “significant change”. “[Y]ou can't make a significant change every time for that. It just happens too often” (*manufacturer*). The quandary of the manufacturers in this situation is that they are caught between the two regulatory frameworks and need to decide themselves whether to report the changes to the app in response to the actions of Big Tech Companies or not.

9.3 Agile Regulation

I have alluded to this dimension of the regulation several times. The approval process and the regulatory framework that underpins it are self-reflexive. They incorporate the experiences from the procedure in the next iteration. This incorporation characterizes the idea of “law-making as an agile process”:

> The set of rules established so far is not to be understood as final, but on the contrary as the starting point of a continuous process of observation, readjustment, correction and extension, which takes up and affects the dynamic changes in technology and society, the progress in medicine as well as the expectations and experiences in the system again and again. (*D3, p. 1205*)[31]

31 Note, that this quote implies an awareness of the performativity of the law: The law and its constant development impacts the developments it seeks to respond to.

Law-making for *DiGA* is an open process that is constantly ongoing and responds to other developments. In this chapter, I will trace the agility of the regulation of *DiGA* and its consequences.

To begin: My analysis suggests distinguishing between 'internal' and 'external' agility. "Internal agility" refers to the agility that the law itself foresees, i.e. the provisions that aim at developing it further. "External agility" by contrast, is the agility necessary to respond to unforeseen developments outside the law that, nevertheless, make an impact on it. It harks back to the point made above on the distributedness of regulation. As one example, because the GDPR informs many of the requirements for data and information security the framework needed to incorporate the Schrems-II-ruling by the ECJ.

Agility, internal or external, comprises two different, albeit related domains. On the one hand, it refers to the regulatory framework itself. Here, the first iteration of changes to the *DiGAV* already took place in 2021. In this 'updating', the legislator has introduced or modified the requirements, such as the requirement for data/information security certificates we have come across repeatedly. D3 points to the self-reflexivity of this iteration, stating that "it takes into account the initial experience of the *BfArM* within the framework of the testing procedure" (*D3, p. 1199*). But agile regulation does not only refer to these "readjustment [and] correction" of the framework for new and existing *DiGAs.* It also refers to an "expansion" of the subject area beyond Digital Health Applications. In this sense, the documents envision "the inclusion of higher risk classes or, for example, also of digital in vitro diagnostics" (*D4, p. 1240*). In a similar vein, they describe the future implementation of the so-called Digital Care Applications (*DiPA*) "as the first stage of expansion" (*D4, p. 1240*) of the regulatory framework. Neither of these excerpts describes the expansions as a new, stand-alone law. Instead, both are developments from within and beyond the *DGV or* the *DiGAV*. The first quote even describes the addition of other risk classes as a "logical" (*D4, p. 1240*) development following the premises of the law. Thus, 'agility' refers to the enlargements of the existing framework.

On the other hand, besides the changes to the law, the work of the *BfArM* itself is also agile. "Knowledge and experience from the consultations, as well as the findings from the application procedures for inclusion in the DiGA directory, are incorporated into the support services and, in particular, into the further development of the procedure" (*D5, p. 1245*). The early experiences from the approval process are used to develop, adjust, correct and expand the procedure and the information offers. One document expresses this with imagery of 'vitality' when discussing the role of the *DiGA Guide*. This "guide is designed as a living document, which is continuously updated and further developed" (*D4, p. 1237*).

How does this two-fold agility, of the law and the process, become possible? What informs the transformations of the *agile* regulation? The documents suggest two sources of the information incorporated into the regulatory framework. The first of these is the contact with manufacturers. D5 states that "the dialog and the overall experience also result in aspects that lead to adjustments of technical or regulatory requirements in the statutory regulations" *(D5, p. 1246*). This point harks

back to my analysis of the 'cooperative relationship' between the *BfArM* and the developers. As this quote reiters, this relationship is reciprocal. The information and consultation offer serves the manufacturers to increase the quality of the application and, in turn, the chances of success. But they are *also* an opportunity for the *BfArM* to get direct feedback from the manufacturers. We can read D6, an article published by manufacturers on their experiences, this way. The authors themselves state that their observations "may […] serve the BfArM as indications for the further development of the procedure" (*D6, p. 1249*). Similarly, a manufacturer reported that "they have discussed a lot with them" (*manufacturers*), "them" being the *BfArM*.

The second approach to getting information for making the regulatory framework and the approval process agile differs from the first. On the one hand, it gets by without the direct contributions from developers. On the other hand, it is not directed at the past but aims at anticipating future developments. The *BfArM* has implemented a "'horizon scanning' approach to identify emerging scientific and technological trends at an early stage, to analyze their impact on the regulatory environment in order to be able to adapt processes and information at an early stage and to build up and provide expertise" (*D8, p. 1296*). This second approach reverses the anticipatory work that manufacturers engage in before and during the approval process. While the latter aims to anticipate regulation, anticipation here targets the work of (future) applicants. Moreover, we should interpret it in light of the imagination of digital healthcare. By scanning the developments of digital health technologies the *BfArM* seeks to avoid their proliferation with regulatory oversight.

In this sense, agile regulation aims at "keeping pace with dynamic developments and continuously developing existing processes and procedures" (*D8, p. 1293)*. The documents describe iterations of the legal framework as "first further developments and optimizations" (*D4, p. 1240*), suggesting that agile regulation is value-laden and directed. It points to and opens up space for future improvements to the approval process. The current state of regulation is always in need of improvement. By itself, this is not problematic. A rigid regulation that does not take up other developments would be problematic. Only agile regulation can realize the chances that digital health affords. Still, I encountered skepticism about how agile regulation can be, echoing what I have written about the cultural differences between developers of digital technologies and regulatory administration. The lobbyist suggested that "agile regulation" may be an oxymoron because the established structures of self-governance in the German healthcare system are not conducive to agility. "But agile, self-governance and ministry. Try to reconcile that" (*representative of digital health umbrella organization*). Additionally, they mentioned that agility hinges on broader political developments. In December of 2021, a new government came into power. For the lobbyist, at the time of the interview, it was not clear how the new Federal Minister of Health would engage with *DiGAs* and whether this could potentially inhibit further 'agile' developments.

9.4 Continuous Regulation

The agile regulation is closely entangled with the form regulation takes that I want to investigate in this subsection. My main argument is that it is continuous. The regulatory process stretches beyond the discrete timeframe set Fast-Track Approval Process and continues throughout the lifetime of an app as a *DiGA*. The agility of regulation is one reason for this. The second reason for the continuity of regulation is that changes to a *DiGA* need to be monitored and assessed as to whether they constitute "significant changes" that would require a re-assessment of the status as a *DiGA* in turn. In this subsection, I will sketch how the regulation of Digital Health Applications is continuous for these two reasons.

As we have seen in the previous subsection, "agile" is an attribute for regulation continuously developing along with the developments of technologies. This continuous development has consequences for the work of manufacturers. For manufacturers preparing to apply, each iteration raises the bar for them to pass the approval. Some manufacturers spoke about an early-mover advantage which makes the timing the application a crucial skill for this reason (see ch. 7.3.2). But changes also apply retroactively to manufacturers whose app has already been listed as a Digital Health Application. One example of this that came up in the interview was the new security certificates. "[T]his year they made such a law where you need such a security certificate. And that also applies to us" (*manufacturer*). In this case, "us" refers to the already successful manufacturers. They must implement the required changes within newly set deadlines for their app to maintain this status. These deadlines, one manufacturer remarked, are just as strict and tight as in the approval process. They did not see much difference between the time before and after it, stating that "it goes on in principle if you are Diga, the same way" (*manufacturer*). All this does not just mean that the apps need to stay compliant with the requirements that the approval process has assessed. It also means that manufacturers must comply with changes to the law after the approval process and prove this compliance for their app to remain in the *DiGA* directory. Although this was challenging for the manufacturers, they also agreed with the need to develop the regulation. For them, it is a way to respond to the developments of digital health technologies. This is also why most of the iterations thus far concern technical issues. "So you actually only ever have IT problems at interfaces" (*manufacturer*).

The second dimension of continuous regulation is monitoring changes to the *DiGAs* after the approval. It concerns what the regulatory framework refers to as "significant changes". The manufacturers who have co-authored D6 describe significant changes as a crucial part of the "continued close supervision by the *BfArM*" which "ensures that the interaction between DiGA manufacturers and the BfArM continues even after the listing" (*D6, p. 1253*). This "continued close supervision" by the regulatory agency is reminiscent of similar practices in the neighboring regulatory domains of pharmaceuticals (Langlitz, 2009) and medical devices (Zippel & Bohnet-Joschko, 2017). The latter are continuously surveilled, for example, for adverse outcomes, "to somehow that the status as an

approved medical device under the respective conditions […] that it is adhered to and that the classification fits" (*manufacturer*). In other words, the status as a medical device is always provisional. The device may be re-classified or lose this socio-legal status under specific circumstances after the market entrance.

For *DiGAs* this is similar. Under particular circumstances, they may be stripped of this socio-legal status and be "demoted" to a health-and-wellness app again. What makes the regulation of *DiGAs* different from both pharmaceuticals and medical devices is that in *DiGAs* it is not (primarily) the market performance that is monitored. It is the development of the *DiGA* and its environment (even though the post-market performance also has to be monitored because *DiGAs* are also medical devices after all). For this, the *DiGAV* introduces the concept of "significant changes". These are "changes to the DiGA which have a significant influence on the evaluation decision of the BfArM, or which may lead to changes in the information in the directory" (*D1, p. 110*). Thus, this concept refers to two things. On the one hand, perhaps more obviously, changes to the 'substance' of the app or its ecology, on the other hand, "textual changes" (*manufacturer*) to the entry in the *DiGA* directory. If, to give an example I heard about twice in the interview, a developer decides to conduct further clinical trials to add endpoints or indications to this entry, this would also constitute a significant change. Monitoring significant changes is incumbent on the manufacturer. The *BfArM* provides a checklist (see *Fig. 3*) as a guide. "As soon as one of the questions listed there is answered with 'yes', it can be assumed that the planned change falls under the characteristic of a notifiable significant change" (*D1, p. 111*). The manufacturer would need to report this change to the BfArM (under threat of a penalty for failure to provide notification) that "will decide how intensively they will look at it" (*manufacturer*). If it considers the change significant, the update will undergo a new assessment of three months, similar to the initial one. In the end, the *BfArM* will either confirm the change – "After three months, you somehow get a little letter saying, 'it's okay'" (*manufacturer*) – and updates the information in the *DiGA* directory accordingly or the app is deleted from the directory if it does not meet the requirements anymore.

Hat die Veränderung Einfluss auf den Schutzbedarf der DiGA?	Ja
Nachweis der positiven Versorgungseffekte	
Ändern sich vom Hersteller angeführte positive Versorgungseffekte?	Ja
Ändern sich die Patientengruppen, für die die positiven Versorgungseffekte nachgewiesen wurden oder werden sollen?	Ja
Werden Inhalte oder die Darstellung der Inhalte der DiGA maßgeblich geändert, sodass dies einen Einfluss auf den angegebenen positiven Versorgungseffekt haben könnte?	Ja
Werden bestehende Funktionen so verändert, dass sie einen Einfluss auf den positiven Versorgungseffekt haben könnten?	Ja
Verzeichnis	
Ändern sich durch die Veränderung Angaben im Verzeichnis?	Ja
Ändern sich durch die Veränderung Angaben bzw. Erklärungen gemäß Anlage 1 der DiGAV bzw. betreffen diese (z.B. Bekanntwerden	Ja

Figure 3: Snippet of Self-Assessment Sheet for Significant Changes, the left side contains questions, e.g. "Do the positive healthcare effects specified by the manufacturer change?", the right column contains the binary response options (taken from Bundesinstitut für Arzneimittel und Medizinprodukte (2020))

Despite the checklist depicted in Figure 3. (or owing to it, depending on your reading), there was significant uncertainty among my interlocutors, almost across the board. The crucial question that many of them had was: "What exactly do I do with each update? […] Do I have to completely reauthorize every update?" (*representative of digital health umbrella organization*). This is because, on the one hand, the need to report significant changes contradicts common practices of software development in which updates can and usually do rapidly follow one another. One manufacturer described the need to report updates as akin to "product cycles again from the old economy" that do not match the "agile, super agile environment like software development, where I have the possibility to iteratively adapt things within weeks, to make things better, to react to feedback" (*manufacturer*).

On the other hand, the stakes of the uncertainty are high because the responsibility is shifted to manufacturers *and* endowed with the threat of punishment. Manufacturers need to make sense of the concept of "significant change" and the accompanying self-assessment checklist by themselves. They need to adopt a "regulatory gaze" in developing their *DiGA*. Thus, they found various strategies for implementing the monitoring for significant change. One common practice was to adopt new internal classifications specific to the respective company and their understanding of the concept. Some manufacturers distinguished between "mini bug fixes" that "can be implemented in

a relatively short time" (*manufacturer*) and more encompassing and elaborate changes to the medical function of the app. In this classification, only the latter are notifiable. A variant of this is reminiscent of Janssen's (2020) study on the efforts necessary for an app for kidney transplant patients to *not* be classified as a medical device. Here, some changes are left to the user, while a "significant change" is only one that pertains to the inherent functions of the app, independent of the user's actions. A second strategy is to limit changes to the ecology of the app. "You always have to try to do what you change as best as you can outside of the app or through any emails that people see" (*manufacturer*). Third, some manufacturers required meticulous documentation of any changes from their external collaborators and an evaluation of whether these changes could constitute a "significant change". "I demand from my software house that I receive a PCR for every change, i.e. a product change request, where the change is described and where an assessment is made as to whether I need to report it or not. And then I decide for myself whether I have to report it or not" (*manufacturer*). The final strategy is the most radical. One manufacturer told me that "so far, we have tried to avoid it as far as possible" (*manufacturer*). All of these strategies emphasize a point I have made several times throughout the thesis: The regulation impinges on the app design, before and after the approval.

10 Discussion/Conclusion

In this final chapter, I want to pinpoint some of the cross-cutting issues my findings have revealed and tie them back to the existing literature on regulation and digital health. I begin by discussing the role of imaginaries and promissory discourses of digital health in how Digital Health Applications are regulated (10.1). Thereby, I point out the position of the *BfArM*, or regulation more generally, as the crucial difference from the promissory discourses that scholars have previously identified. I then discuss the finding that evidence of clinical efficacy is at the center of the approval process (10.2). In line with arguments on the regulation of tissue engineering, I argue that this amounts to a "pharmaceuticalization" of digital health in which digital health technologies come to be assessed based on the standards of pharmaceuticals and by institutions primarily responsible for regulating drugs. Third, I will shed light on the dynamics of the regulation (10.3). Here, my argument is that the existing literature has treated regulatory capture one-dimensionally as the industry capturing regulatory agencies. The case of Digital Health Applications in Germany suggests a reversal of this relationship. All of this should finally allow me to answer my overarching research question of how a health-and-wellness app becomes a Digital Health Application, i.e. how this ontological transformation becomes possible (10.4). However, I will show that this question forbids an easy answer. It will take me two attempts to approach it. A summary of the main findings rounds off my thesis (10.5).

10.1 Regulatory Imaginaries: Do Regulators Dream of Digital Health?

The review of the existing literature has indicated that digital health is, first and foremost, a vision, an imagination, a promissory discourse (Cappel, 2021; Wieser, 2019). It seems much harder to give a proper definition of digital healthcare than it is to imagine how it will revolutionize healthcare. I have pointed out that this literature does not consider the role of regulation in such promissory discourses. If at all, it figures as an inhibitor to promise and hype. It is the reality check confronting hype and leading to the downturn of the initial heated phase of investments and expectations. This gap in the existing research has informed one of my research questions. In my material, I focused on how the *BfArM* imagines digital healthcare and its role within it. The fact alone that one of the documents in my sample dealt with the "digital readiness" at the *BfArM* made this possible. It outlines the multiple ways the agency engages with digital transformations. This sketch has allowed me to reconstruct the "socio-technical imaginary" (Jasanoff, 2015; Jasanoff & Kim, 2009) that informs the approval process for Digital Health Applications by following the "conceptual metaphor" (Lakoff & Johnson, 1980) of a building of digital healthcare that the documents deploy.

At first glance, it appears that the vision of digitalized healthcare the *BfArM* puts forward in the documents I have analyzed in many ways resembles the promissory discourse on digital health other researchers have identified. Both of the strands that Marent and Henwood (2022) describe are present in this vision. On the one hand, the *BfArM* expects digital healthcare to *empower the patients*. It will provide patients with biomedical knowledge that allows them to manage their health. As the vision of Nele, the personified user of digital health technologies in Germany in 2030, demonstrates, digital health enables these users to better take care of their health. They will be able to constantly surveil and assess vital parameters, only engaging with medical professionals if absolutely – all mediated by digital technologies. These abilities will put the patient at the center, of the (medical) attention and decision-making. Care, the vision states, will be personalized and tailored to the individual patient and their healthcare issues. I have also pointed out that the discourse of the BfArM on empowerment matches other promissory discourses even in that which is rendered absent. 'Empowerment' is a buzzword in these discourses but is rarely defined. Some critics argue that it merely means giving users the power to consume (Morley & Floridi, 2020). This is also true in the vision of digital healthcare that I have reconstructed from the documents. 'Empowerment' and 'patient-centrism' remain vague terms. It remains unclear if and how the vision of patients equipped with biomedical knowledge constitutes an empowerment. Mol (2008) has argued that a "logic of care" is preferable to a "logic of choice" that the language of the 'management' of diseases the *BfArM* uses tellingly implies. In this sense, digital health technologies are expected to "nudge" (Schüll, 2016) patients in particular behavioral directions. This nudging would run counter to efforts to empower patients. In addition, even if digital health technologies seem to make patients more independent from individual healthcare professionals in this vision, the dominance of biomedicine is re-entrenched in sum. Contrasting the idea of empowerment, if these technologies provide patients

with biomedical knowledge, they make them more dependent on this type of knowledge about the body. They contribute to the expansion of medicine into other societal domains (Clarke et al., 2010). The literature that has taken a post-colonial stance concerning the design of digital health technologies illustrates that this is problematic (Christie & Verran, 2014; Nahar et al., 2017). I will later return to the issue of critiquing promissory discourse toward the end of this subsection.

On the other hand, the promissory view the *BArM* puts forward also emphasizes that digital health technologies will make healthcare *more efficient*. The backdrop against which the documents make their arguments is the vision of an aging society with progressively dismantled infrastructures, especially in rural areas, an increasingly costly healthcare system and growing numbers of rare and chronic diseases for which adequate knowledge and successful therapeutic interventions are lacking. Digital health technologies, especially *DiGAs*, are imagined to solve these issues. The *BfArM* draws on the "biomedical virtue" of accessibility (Pickersgill, 2019), arguing that these technologies will bring high-quality healthcare to underserved regions. In addition, their capacities will allow data collection on rare and chronic diseases to develop new types of interventions and to assess the efficacy of existing treatment options.

Together both strands suggest that the *BfArM* expects digital health to bring about radical changes in the healthcare sector. This vision also fits well with other promissory discourses that posit the revolutionary and disruptive effects of digital technologies on healthcare (Geiger, 2020; Levina, 2017; Milne & Costa, 2020). Nevertheless, the documents do not speak explicitly of a *total* disruption or revolution of healthcare. Instead, digital health technologies make possible 'modern' healthcare. The implementation of Digital Health Applications updates a healthcare system that has otherwise run its course, creating continuity with established healthcare provision. What at least one of the documents does consider groundbreaking, however, is the legal innovation of entitling insured persons to attain Digital Health Applications as part of their regular statutory healthcare insurance. This 'revolutionizes' the German healthcare system from a legal perspective as for the first time an 'insured person' is entitled to a digital technology through their healthcare insurance.

This argument points to the dimensions of the vision the *BfArM* puts forward that separate it from other promissory discourses. Empowering patients and making healthcare provision more efficient initally are abstract possibilities of digital health. According to the documents, the status quo is the rapid and uncontrolled proliferation of digital health technologies without oversight. Moreover, it is undecided whether these technologies will be beneficial or harmful. In principle, they harbor both opportunities and challenges. Other promissory discourses appear to neglect any risks and, instead, one-dimensionally emphasize opportunities through digital health. The crucial twist in the imaginary is that the *BfArM* sees itself (and the approval process for *DiGAs*) as the institution that brings order to the current 'chaos'. It provides an overview off available technologies and sorts them by quality. It helps to tip the scale balanced between opportunities/chances and risks in the direction of the former. On a more abstract level, the documents imply that far from inhibiting inno-

vation, regulation is the “obligatory passage point” (Callon, 1984) digital health technologies must go through to unfold their full *positive* potential. This pre-condition for the positive impact of digital health technologies is not present in other promissory discourses that usually consider regulation harmful to innovation (Geiger, 2020).

Furthermore, the vision the *BfArM* holds differs from other promissory discourses to the extent that it is a socio-technical vision that combines expectations for technologies and societal developments. The documents argue that digitalization needs to be understood ecologically. The metaphor of the building of digital healthcare that I have tried to unpack illustrates this. The digital transformation of the healthcare sector is envisaged to consist of several building blocks that need to be brought together (and made held together by regulation) and will connect different actors. This way, it feeds from and into broader digital transformations in other arenas. The digitalization of healthcare, as one of the documents narratively described, will create new job opportunities and new relationships among actors in medicine and beyond. It also encompasses a vision of the global order of digital health. The *BfArM* positions Germany (and itself by extension) as a pioneer of digital health.Other countries are lagging and closely observing the situation and will likely implement similar legal frameworks. Thus, the *BfArM* embeds digital health in a broader, even global vision of societal order.

Underlying this is the argument that we should consider regulatory agencies as circulators of socio-technical imaginaries. Most of the attention in this regard has been on policymakers and, more recently, on social movements that shape counter-imaginaries (e.g. Felt, 2015). The case I have unpacked in this thesis suggests that regulators also produce visions of their own, what we could call ‘regulatory imaginaries’. These imaginaries perform scenarios of how technologies and societies are regulated as well as the position the responsible regulatory agency can or should play. They may be all the more authoritative in that they subsequently inform the work of these agencies. Their performativity becomes apparent in my case. The idea of digital health has opened up the pathway for health-and-wellness apps to become *DiGAs* in the first place. The vision of digital health as empowering patients also informs the temporality of the approval process. The documents repeatedly point out that it has been deliberately designed as a three-month period to give patients early access to safe technologies.

Theorizing this performativity provides an interesting counterpoint to the research program of critical digital health studies (Lupton, 2014b, 2014c, 2016b) that seeks to debunk promissory discourses on digital health by confronting it with a perspective on the social, material and cultural environments of using these technologies. It is certainly necessary to deconstruct their pompous claims. Above, I have tried to make a similar point by pointing out that the empowerment the *BfArM* envisions is actually *dis*empowering patients (see also Ebeling, 2019). However, critique in this way should not lead us to wrongly assume that promissory discourses are merely smoke and mirrors devised by clever entrepreneurs and (captured) policymakers to secure investments and praise

their products. My analysis suggests that in the case of Digital Health Applications, promissory discourses shape regulatory pathways and procedures. Thus, it becomes materially forceful and only by attending to and unpacking the discourses that inform policy- and regulatory decision-making do interventions or alternative imaginaries that inform alternative regulatory configurations become conceivable.

10.2 An Imperfect Regulatory Pharmaceuticalization of Digital Health?

The existing literature on digital health and its regulation has highlighted the difficulties digital health technologies pose to regulatory frameworks. They cut across categorical boundaries and are situated between medical devices and lifestyle technologies (Lucivero & Prainsack, 2015), This situation has led to several hybridizations and "mash ups" between these two economic sectors (Geiger & Kjellberg, 2021). The moniker given to Digital Health Applications, "prescription apps", captures such hybridizations. On the level of exchange, it points to the combination of the prescription as a typical mode of healthcare with the idea of a code to access software products. Thus, patients need a prescription from a physician which they turn in to their healthcare insurances which then sends them an access code. They download the respective app from the regular app stores and enter the code to use the app for the duration of the app-based therapy. On the level of symbolic representations, this also implies the culturally-ascribed trustworthiness of the medical profession in concert with the modernity of digital technologies.

Even though regulatory frameworks that do not speak to the specificities of digital technologies remain in many ways insufficient (Marelli et al., 2020), recent regulatory innovations have mitigated this ambivalence to a certain extent. In the US, the FDA has developed a framework to assess digital health technologies as medical devices in response to controversies around an app used for radiology (Lievevrouw et al., 2021). Similarly, the MDR passed in the EU enables software products like apps to become registered as medical devices. My analysis has shown that the *DiGAV* draws on the distinction between apps that are registered medical devices and lifestyle apps by requiring that applicant apps have already undergone an assessment with a Notified Body. The the application process draws on and reinforces a "settled boundary" (Gieryn, 2008) that gains in (phenomenological) transparency and self-evidence this way. I have also argued that the requirement introduces a temporal sequencialization to the approval process. Manufacturers need to, or at least should, complete the registration process before applying with the *BfArM*. Moreover, this distinction creates a distribution of risk according to which the quasi-regulatory Notified Bodies already have conducted a risk assessment. The *BfArM* merely checks the registration formally.

While the approval process for Digital Health Applications can, thus, circumvent one ambivalence, it creates another. Digital Health Applications are situated at the boundary of medical devices and pharmaceuticals. On the one hand, must to be registered as medical devices, as I have just described. On the other hand, my analysis has shown that the requirement for clinical evidence treats the

apps akin to drugs that likewise have to prove their efficacy through clinical trials. In this regard, it appears that the scale tips to the side of treating Digital Health Applications as pharmaceuticals. The *BfArM* prioritizes the clinical evidence over the other requirements. Unlike the requirement for data and information security, for instance, where it assesses the self-disclosure of the manufacturers in the form of a checklist, it analyzes the clinical studies more thoroughly. Almost in unison, my interlocutors confirmed that the *BfArM* values the clinical study the most and that this requirement poses the greatest challenges. Some manufacturers pointed out that it is necessary to anticipate this focus when assembling the application.

All this points to a similar process of "regulatory pharmaceuticalization" that Faulkner (2012b) has observed for tissue engineering. In his and my case, faced with ambiguous technological innovations that challenge regulatory categories, existing regulatory frameworks were "stretched" (Faulkner & Poort, 2017) to accommodate them. The new technologies were treated *as if* they were pharmaceuticals. In my case, this also included an institutional stretching – somewhat similar to what Hogarth and Löblova (2020) call institutional "regulatory expansion". With the *BfArM*, policymakers have added digital health to the purview of a regulatory agency that has hitherto mostly been responsible for assessing pharmaceuticals. A dilemmatic situation ensued. On the one hand, the regulatory framework assumes *DiGAs* to work similarly to drugs. The *BfArM* is the only agency with considerable expertise in this field. On the other, it lacks expertise in digital technologies. Only recently has it expanded into this area, as my interlocutors reported. This observation shows that the stretching of regulatory frameworks and areas of responsibilities can go along with transforming the institutional identity of the regulatory agencies, similar to what Lievevrouw et al. (2021) have found for the FDA.

Like the example that Faulkner (2012b) investigates, the regulatory pharmaceuticalization of Digital Health Applications remains imperfect. Like tissue engineering (TE), digital technologies and their characteristics resist their subsumption under the existing procedures for pharmaceuticals. This resistance becomes evident in what I have called "distributed regulation". Because the *BfArM* lacks specialized expertise in digital technologies, it cooperates with other German regulatory bodies to establish the criteria and procedures for assessing Digital Health Applications. New opportunities and demands for collaboration among German agencies emerge to account for what exceeds the treatment as a pharmaceutical. These are akin to Faulkner's (2012b, p. 404) "proliferation of organization structures" that emerged in the wake of the pharmaceuticalization of TE and connected regulators of pharmaceuticals with those for medical device. While it is certainly not neutral and the requirements are not weighted equally, the configuration of the approval process, the multiplicity of expertise and value objects, further seeks to pay respect to the characteristics of the digital beyond its pharmaceuticalization. It acknowledges that the digital component of *DiGAs* brings new challenges and risks. Still, it remains unclear whether the regulatory pharmaceuticalization of Digital Health Applications can cover these risks. It seems clear that the harm they might cause for users is

different from the harm that pharmaceuticals pose, requiring us to re-think what it means to be digitally at risk (Lupton, 2016a). Marelli et al. (2020) suggest that one reason why the GDPR is not "fit for purpose" is its focus on the individual entailing individualized notions of risk and harm. With digital technologies and their affordance to collect and classify large amounts of data that inform algorithms and their decisions, they argue, risk and harm become collectivized, however. They are particularly noteworthy because they cut across the digital and the analog. Collecting and classifying data may have detrimental real-life impacts on the user of *DiGAs*. If the GDPR (that informs the checklists for data and information security) cannot account for these new types of harms, it is equally doubtful that clinical trials in their conventional form, as applied to *DiGAs* as part of their regulatory pharmaceuticalization, can do so.

The resistance that the digital dimension of *DiGAs* put up against their pharmaceuticalization is also apparent in the new concept of the "positive healthcare effect". Seemingly innocuous, this new concept conveys an expanded understanding of how treatments may impact a patient. By juxtaposing direct effects at the point of care, akin to pharmaceuticals, and indirect effects through an improvement of health*care* this concept aims to accommodate the affordances of digital health technologies. Unlike pharmaceuticals, these can improve the health of the user in more than one way, for instance, by enhancing the navigation through the German healthcare system. Thus, while the definition of the success of the clinical trial remains the same as part of the regulatory pharmaceuticalization, a positive change in the health of the patient, defined through measurable endpoints, the ways reaching it multiply to accommodate the specific affordances of digital technologies. In addition, the approval process also expands the possible protocols of the clinical trials based on these affordances, allowing for the integration of study designs traditionally considered "alternative" to the standard, double-blind clinical trial (Rosemann, 2019). This way, the pharmaceuticalization of Digital Health Applications can feed back into the regulation of pharmaceuticals, leading perhaps to a 'regulatory digitalization of pharmaceuticals'. At least in the imaginary that I have reconstructed, the *BfArM* envisions *DiGAs* to provide new data to assess the efficacy of treatments and interventions.

For the manufacturers, the regulatory pharmaceuticalization of their products means they must think of them in new terms. Previously, they could market their apps referencing various or vague clinical benefits. Now, the clinical trials require them to clearly define how their app will have a clinical impact and how this can be measured. The requirement to provide clinical evidence also strains the budget of many manufacturers as it seems to be the most challenging and costliest of the requirements. In part, at least, the conflictual relationships between developers and the regulatory body stem from this application of the statutes for pharmaceuticals to digital health technologies. Some of the manufacturers felt that the assessment procedure did not give due diligence to the specificities of their digital products. In other words, they would prefer a "break" in regulatory frameworks (Faulkner & Poort, 2017). As Geiger and Kjellberg (2021, p. 453) argue, for this brea-

king of the established framework, “[i]nvolved actors will likely have to engage in concerted educational, lobbying, and rallying work to create sets of norms over time that are specific to the hybrid market in question”. One alternative to the regulatory pharmaceuticalization from my interviews is establishing a specialized regulatory body for digital health. This approach would position digital health as a third (regulatory) pillar besides medical devices and pharmaceuticals. It would also likely entail specific requirements or, at least, a re-balancing of the existing ones.

10.3 Reverse Regulatory Capture: Regulatory Capture, but in which direction?

In my review of existing at the beginning of the thesis, I have broadly sorted the literature on the regulation of pharmaceuticals into two strands: regulatory capture theory and disease politics and their respective variants. There are certainly contributions that focus on other questions, but these two – and the underlying question of who or what influences the regulation of drugs – appear to be the most eminent topics of discussion. The disease politics strand argues that it is patient activism, for example, in the case of AIDS or Muscular Dystrophy, that has pushed through many changes in regulatory frameworks. My analysis barely speaks to this strand. This gap is certainly a result of the way I have delineated the case of Digital Health Applications. In the approval process, patients are only mentioned indirectly. Not directly involved, they are merely emphasized as the ultimate beneficiaries (the added difficulty that ‘the patient’ appears in different forms as ‘the user’, ‘the citizen’ or ‘the insured person’ notwithstanding). My methodological choices consequently did not include *DiGA* users either as authors of documents or as interlocutors. Sources for this do exist (e.g. Ryll, 2021). Future research in the social sciences should focus on how patients use *DiGAs*. Compared to other studies on the use of digital healthcare applications (e.g. Fullagar et al., 2017; Lupton, 2017b; Maturo & Setiffi, 2016), the role of the legal status that *DiGAs* have and the role it plays for the users would be of particular interest. On the other hand, the indirect appearances of the patient in the documents also point to the organization of the German healthcare system. Here, there is a relative consensus that industry, policymakers and healthcare providers speak in the patient’s name. This is the reason why regulatory decisions are less politicized in Germany than, for example, in the USA (Daemmrich, 2004; Daemmrich & Krücken, 2000).

By contrast, the regulatory capture theory strand of the literature seems to provide a much more productive lens to read the main findings of my research. At first glance, it even seems that the approval process bears signs of more classical forms of capture that Carpenter (2014) argues are a thing of the past. Through my interviews, I have found that the timing of the application matters. There exists an early-mover advantage. With the agile adaptions of the regulatory framework, the hurdles for succeeding in the approval process rise. While such adjustments also apply retroactively to those manufacturers who have already been successful, these have to fulfill the added requirements incrementally. Newcomers need to clear the raised bar at once. The early mover advanta-

ge suggests a closing-off of the sector for *DiGA* as predicted by the classical theories of regulatory captures (Carpenter, 2014). My interviewees have confirmed this, stating that the financial requirements for applications have increased considerably, making it difficult for smaller companies without sufficient funding to enter the market. It favors a small pool of potential *DiGA* developers that receive financial support from pharmaceutical corporations. After just two years of Digital Health Applications, it might be too early to observe such developments. It is a matter of future research to monitor whether any tendencies toward a market closure hold sway.

Besides these indications for classical regulatory capture, the approval process paradoxically also seems to show signs of a variant of corrosive capture and the corporate bias variant of regulatory capture theory (e.g. Abraham & Davis, 2013; Mulinari & Davis, 2020). I have analyzed the relationship between the *BfArM* and the developers. The regulatory agency positions itself between manufacturers and policymakers as a translator of regulatory frameworks. It openly states that it acts as a "partner" for the developers and aims to promote and support the success of applications. Therefore, it offers a wide range of information and consultation services that, although the documents in my sample emphasize that the *BfArM* also profits from them, serve to increase the quality of applications and increase the manufacturers' chances to be successful in the approval process. In its own terms, it describes this as a process of "accompanying" applications throughout their lifecycle from early stages the admission into the first healthcare market. On their part, the developers actively made use of such offers. They perceived them as helpful for assembling their applications and devising solutions throughout the three months of the approval process. What also points to a more cultural version capture is that both the approval process and the consultation services of the *BfArM* are fee-based. As others have argued, this fosters a view in which applicants are customers purchasing a service and regulatory agencies – far from a watchdog and strict gatekeeper that is antithetical to the goals of the entrepreneurs – is the service provider who seeks to satisfy the customer's demands (Carpenter, 2014). In addition, existing research has posited that the digitalization of healthcare and Digital Health Applications were a pet project of the former German Federal Minister of Health, Jens Spahn (Bandelow et al., 2020). Similar to the regulation of drugs, where the broader political environment has created a climate that favors the interests of the pharmaceutical industry, this can indicate that the cooperative relationship between the *BfArM* and *DiGA* developers is also the result of an industry-friendly climate. Although I did not find any direct evidence of this, the documents at least relate the work of the *BfArM* to a broader strategy of digitalization of healthcare the German federal government pursues.

Nevertheless, upon closer inspection, this needs to be complicated. On the one hand, I have also reconstructed traces of a more conflictual relationship between regulators and developers than what the literature on capture may suggest. Following my interviews, there is a significant cultural gap between developers and the *BfArM* that, quite literally, leads to language problems. This conflict is exacerbated by the power the *BfArM* yields as what I have called an obligatory passage

point, drawing on early ANT (Callon, 1984). Therefore, they must adapt their approach to the demands and imaginations of the *BfArM*. The one-sided distribution of blame for a failed application to developers in the documents illustrates this. All this led some manufacturers to believe that the *BfArM* was actually working against them, undermining the idea of a collegial relationship and concerted effort to put Digital Health Applications on the market.

I reflected on this conflictual relationship from an ethical perspective. As I have written in the methods chapter, at a later stage of my fieldwork, I realized that developers were hesitant to speak to me out of concern that they become tied to more critical statements about the approval process. I reconsidered my approach. By anonymizing my interlocutors, I seek to ensure they do not experience any repercussions from openly speaking to me. I believe the conceptual framework of AIME helps to theorize this conflict and 'defuse' it. One reason for the conflictual relationship between the two parties is that they shape and are shaped in different modes of existence. At various points throughout my thesis, I have pointed out that for developers, their apps exist in the mode of [ATT] describing attachments, passions, interests. For the *BfArM*, the apps exist in a legal way characterized by a *lack* of passion (Latour, 2010). In this sense, the conflict is an outcome of this collision. This argument speaks to the "diplomatic mission" that Latour (2013a, 2014) attributes to AIME. Through developing a language to describe the different modes of existence in their specificity, new negotiations about the relationships between these modes become possible. One could also read my analysis as a modest attempt to create a point of departure for such re-negotiations.

On the other hand, my findings suggest that the close relationship between the *BfArM* and the developers not necessarily serves the interests and the benefits of the latter. I do not only refer to the opportunities to better monitor future developments for the *BfArM*. By accompanying would-be *DiGAs* from the beginning, the regulatory agency can influence the design of the apps. At the very least, the manufacturers' anticipatory work that my analysis has surfaced entails that they consider the legal framework from early on. This finding is in line with previous arguments that regulation moves upstream and ceases to be a temporally distinct moment of the research and innovation process (Cambrosio et al., 2017; Darling et al., 2015). The position of the *BfArM* as an OPP further strengthens its influence on the application. Developers need to adjust to and comply with the imaginations of the agency that underlie the assessment to be successful.

Taken together, these findings pinpoint a glaring gap in the literature on regulatory capture. For this literature, it seems clear that industry interests unilaterally capture regulatory agencies directly by buying over officials or influencing the cultural environment of regulatory decisions. My analysis throws doubt on whether this is necessarily so. It raises the question of who captures and who is captured. I have argued that the influence the *BfArM* can exert over the design as developers "navigate" (Williams et al., 2020) the explicit and implicit requirements of the approval process suggests that it is, in fact, the manufacturers that are captured by the regulators not the other way around. I propose to call this 'reverse regulatory capture'. Reverse regulatory capture is a process

in which policymakers and regulatory agencies influence the work and the status of innovators in their interests and according to their imaginations and ambitions. It again harkens back to the importance of tracing the 'regulatory imaginations' that tacitly inform regulators' decision-making.

10.4 How does a Health-and-Wellness App Become a Digital Health Application?

The preceding discussions have prepared the ground for addressing my overarching research question of how the approval process at the *BfArM* makes a health-and-wellness app into a Digital Health Application in this subsection. I have previously mentioned that the answer to this question is not straightforward and that it will take me two tries to get close to an answer. Both answers draw on the theoretical framework I have adopted in my thesis. I have approached the case of Digital Health Applications with Latour's Inquiry into Modes of Existence. Its conceptual vocabulary allowed me to put into words my intuition that an ontological transformation occurs through the approval procedure. Following AIME, this is the transition from one mode of existence to another or a crossing of modes of existence. The app exists differently, in a legal way, once it has passed the assessment and is now a *DiGA* as defined by the regulatory framework.

In the theory chapter above, I have reconstructed AIME and especially its approach to the law as a mode of existence. Like any mode of existence, [LAW] is made up of four components (Laux, 2016; Tummons, 2021a): first, a specific hiatus between heterogeneous elements that needs to be bridged by what Latour (2010) calls the "ground". A "ground" is a specific relationship established between these elements, especially the 'facts' and legal texts by a work of grounding. This work of grounding, in my reading, consists of assessing several value objects that constitute the conditions of in/felicity of a mode of existence. Things can also fail to become legal. If they are successful, however, they become entities of [LAW], the third component of any mode of existence. I have tried to approach these entities through the complementary concepts of socio-legal objects (Cloatre, 2008; Rooke et al., 2012) and socio-legal subjects. Finally, any mode of existence implies a specific alteration. In the case of [LAW], this concerns how it ties enunciations and actions back to origins, thus enabling relations of responsibility. Other scholars in the area of socio-legal studies have criticized Latour's approach to the law. Besides his object of study, the *Conseil d'État*, which these scholars deemed too specific to make general statements about the law, the critiques addressed that Latour does not allow to theorize practices of distinguishing between what is legal and what is not. Especially Alain Pottage (2012; see also Kang, 2018) emphasizes that this forces Latour to introduce a cognitivist binary structure through the backdoor. I do not entirely share his critique, but I took it as a reason to flesh out a subliminal argument about the role of trials and tests that is already virtually there in the Latourian approach to the law. What helped therein is the Sociology of Conventions inspired by the work of Boltanski and Thévenot (Potthast, 2021). On the one hand, it conveniently offers the concept of "critical moment" (Boltanski & Thévenot, 1999) that allows to go

beyond the focus on trials and courts in Latour's legal anthropology and treat different arenas of legal action symmetrical. On the other hand, it focuses on socio-material practices of tests. These tests have ontological implications as they re-establish the ordering of reality that becomes questionable during critical moments. In my AIME-informed reading, a "critical moment" is thus a moment in which the mode of existence of an entity is put to the test. This can be done in courts (van Dijk, 2015), police offices (Moreau de Bellaing, 2015) or, as in my case, regulatory assessments. I sought to investigate the infrapolitics of the approval process, understood as a socio-material test, by following how it creates (subject) positions for the different entities and the relations between them through what I call an "ontological choreography" following Charis Thompson (2005).

My analysis has shown the strength of the connection between AIME and the sociology of testing. These lenses proved to be complementary. They allowed me to focus on how the assessment is organized and what infra-political implications this has. On a broader level, I believe that a focus on testing can help AIME address one of its gaps – the difficulties it has describing the transition between modes of existence – and reach the ultimate goal of depicting crossings of modes of existence. While Latour's (2013a) primary goal has been to extract and describe different modes of existence as a point of departure for further analyses, investigating tests and trials of modes of existence is one way to theorize how modes of existence come together. The ways we organize them and the infra-politics this implies are a crucial building block if we want to realize its stated goal of diplomatic re-negotiations about our common world. On the other hand, the intersection with AIME can help the sociology of testing to new right as a constitutive element of a broader research program (similar to the argument made by Potthast (2017) on the role of the sociology of testing for a social-constructivist sociology of technologies). This conceptual discussion now allows me to continue by interpreting my empirical results through the lens of these concepts.

10.4.1 Assembling Value Objects, Instauring Digital Health Applications and their Subjects

The first version of my answer to my overarching research question is rather conventional. We have seen the various requirements an app needs to meet to become a Digital Health Applications. These cut across different 'domains' and gather 'social', 'technical' and 'scientific elements': usability that includes assumptions about the (social) situation of the user; data and information security that comprises technical issues and requirements about the organization of the developer company and its processes; evidence that requires scientific data from a clinical trial. These are the explicit requirements. Through my analysis, I have also uncovered several requirements that the approval process implicitly assesses. These mostly concern dimensions that would usually be called 'social', such as, for instance, the size of the developer company, its financial resources, its relations to funders, external service providers and the *BfArM* itself. I have further shown that the implicit requirements favor particular types of companies over others even though this does not follow a cle-

ar pattern. While the implicit requirement for a specific company size seems to favor corporations, for example, the requirement for flexibility benefits start-up companies. This motley conglomeration of requirements constitutes the specific *hiatus* of the approval process. It manifests that the materials of the law do not by themselves have a legal origin. Manufacturers must bring together the different elements and bridge the hiatus between them to create the legal ground on which the *BfArM* can issue a positive decision. Interestingly, unlike Latour (2010) who sticks to legal texts, my analysis suggests that informal, non-codified provisions, the implicit requirements, can be as important as legal texts, at least in regulatory decision-making.

To succeed, the application needs to mobilize the value objects of the approval process. I have extracted these from both the explicit and implicit requirements. The result is a list of eleven value objects that constitute the conditions of in/felicity of the approval process. Especially the value objects tied to the implicit requirements point to the desire to establish Digital Health Applications as a long-term ingredient of the German healthcare system. The sustainability and, in the broadest sense, the integrity of the manufacturers are decisive parts of the test that the approval process stages. Moreover, the requirement for interoperability harbors the value object that apps match the imagination of a broader digitalized healthcare system comprising different interconnected building blocks. Finally, the hierarchy of requirements that I have reconstructed from the empirical material, the fact that clinical evidence seems more important than the other requirements, implies that manufacturers need to pay respect to the institutional history of the *BfArM* as an institution previously responsible for assessing pharmaceuticals[32].

If an application contains the value objects of the approval process, several new socio-legal entities become instaured. In the language of Latourian anthropology of law, they become “jurimorphed” (Latour, 2015; McGee, 2015b). I have analyzed this in terms of the performativity of the law. While the legal framework of the *DVG* and the *DiGAV* sets boundaries to what the *BfArM* imagines as a thus far unchecked proliferation of digital health technologies, it still also creates new entities and pathways, similar to the regulation of tissue engineering (Faulkner, 2012a). I have shown, for instance, that the regulatory framework has created a business opportunity for companies. Some of them were founded explicitly to develop a *DiGA*. Thus, the regulation shapes the market for digital health technologies and their constituents, creating a small niche of particularly distinguished apps endowed with a legal status. This status signals the crucial ontological transformation. As such, Digital Health Applications only exist through the regulatory framework and the approval process. The findings from my analysis suggest that codified clinical efficacy is confirmed in the approval process and, to a smaller extent, those parts of the requirement for data and information security that go beyond the GDPR are what sets *DiGAs* apart from other applications used for health purposes. In other words, their existence as “socio-legal objects” makes all the difference. Therefore,

32 I should note that the list of value objects is incomplete resulting from my methodological approach. Had I been able to speak to employees at the *BfArM*, I could have identified further or other value objects as the conditions to successfully establish legal grounds for an app to become a *DiGA*.

in Latourian (2013a) terms, it would be an ontological category mistake to assume that *DiGAs* are technically or in any other way superior or different.

The regulatory framework also populates the German healthcare system with new *socio-legal subjects*. I propose this as a complementary concept for the socio-legal object, in line with Latour's assertion that [LAW] creates a specific type of (quasi-)subjectivity that constitutes its alteration. First and foremost, the regulatory framework creates the figure of the insured citizen entitled to the prescription of Digital Health Applications. Relatedly, doctors and psychotherapists become endowed with the right (and obligation) to prescribe them. This provision is especially noteworthy because this right includes psychological psychotherapists, previously not allowed to make prescriptions. Together with allowing patients to directly claim Digital Health Applications from their health insurance, circumventing medical professionals, this re-arranges the power relations in healthcare. Finally, manufacturers also emerge as specific socio-legal subjects with their *DiGA*. Because the approval process establishes their apps as clinically effective and legally approved elements of healthcare provision, they are entitled to its prescription as a *DiGA*. This entitlement gives them legal grounds to sue doctors that refuse to do so.

Summing up, the first answer to my research question is that for a health-and-wellness app to become a Digital Health Application, manufacturers need to gather the heterogeneous elements defined by the requirements in their application. The application needs to mobilize the value objects tied to the different requirements that constitute the in/felicity conditions of the approval process. This creates the legal ground that allows relating the application to the legal framework provided by the *DVG* and the *DiGAV*. From this interrelation, the *DiGA* emerges together with several newly introduced socio-legal figures in the German healthcare system.

10.4.2 Standing On Slippery Grounds and the (Im-)Possibility of Digital Health Applications

I like to think of the second answer to my research question as the more 'radical' or the 'philosophical' because it unsettles how we understand the law and the capacities to qualify entities as legal. Existing research, even before the conception of Digital Health Applications, has pointed out that the temporality of regulation cannot match the fast pace of digital technologies (Bierbaum & Bierbaum, 2017). My interlocutors confirmed that the provision of reporting updates that may constitute so-called "significant changes", a category that was puzzling to them in itself, to the *BfArM* undermines the affordances of rapidly implementing adjustments or improvements if necessary. Nevertheless, the regulatory framework aims to keep up with technological developments by constantly developing. I used the in-vivo concept of "agile policy-making" or "agile regulation" for this. Regulation of Digital Health Applications is considered an open process. The framework is updated continuously. In part, this is due to its distributedness. My analysis suggests that it gathers provisions from various levels and the purview of different regulatory agencies, such as the GDPR or

guidelines from the German Federal Institute for Information Security. If any of these provisions change, even if for reasons not immediately related to Digital Health Applications, this entails updating the regulatory framework. The ECJ's Schrems-II-ruling is a case in point. Furthermore, the experiences of previous applicants directly feed into the regulatory framework and the approval process with the goal of "improving" it. Through close contact with the manufacturers, the *BfArM* seeks to monitor emerging trends to devise adjustments to the framework and its procedures ahead of time.

Even though some of my interlocutors were skeptical whether the ministerial bureaucracy of the *BMG* and the *BfArM* can implement the agility that would be necessary to keep pace with technological developments, the updates to the regulation make it continuous. Changes apply retroactively. Manufacturers that have already successfully undergone the process need to prove the compliance of their app with the adjusted requirements (with strict deadlines) again. If they do not, the app may be stripped of the status of being a *DiGA*. One example during my interviews was the new requirement to implement data and information security certificates that substitute for the checklist.

The principled interminability or incompleteness of the regulatory framework is resemblant to what Gilles Deleuze (1990) has analyzed as a state of "becoming" as opposed to a state of "being". The latter refers to the existence "of limited and measured things, of fixed qualities, permanent or temporary which always presuppose pauses and rests, the fixing of presents, and the assignation of subjects (for example, a particular subject having a particular largeness or a particular smallness at a particular moment)" (Deleuze, 1990, p. 1). By contrast, becoming is "without measure, a veritable becoming-mad, which never rests. It always eludes the present, causing future and past, more or less, too much and not enough to coincide in the simultaneity of a rebellious matter" (Deleuze, 1990, pp. 1–2). We witness something similar in the case of the regulation of *DiGAs,* where the socio-legal status of a Digital Health Application is only valid until revoked, in principle always in question and in needs to be proven again with every update of the law. These updates themselves, and the fact that they apply retroactively let past and future fall into one. Similar to digital technologies that the *BfArM* imagines to have a "line of flight" (Deleuze & Guattari, 1987, p. 9) that causes them to proliferate and develop rather uncontrollably, the regulatory framework only stands still temporally before a similar line of flight entails a re-arrangement. The stated "vitality" of the *DiGA Guide* illustrates this. The regulation of Digital Health Applications is, in other words, a vitalist 'becoming regulation' which is "rebellious" in that it refuses to be pinned down once and for all.

It is evident that this becoming does not go well with the concept of the ground or the work of grounding. In the Latourian framework I have adopted, this work creates the relation between a 'fact' and the legal text. In my case, this is the relationship between a health-and-wellness app and the *DGV* or *DiGAV* which instaures it as a *DiGA*. Especially if one takes seriously its spatial connotation in a Heideggerian manner, 'grounding' and becoming seem to be opposed to one another.

Van Dijk (2015, p. 179), in his study on how matters of law are created, writes about grounds and grounding:

> This 'path to a ground' highlights not so much the ground, the grounded or the grounder, but the *act of grounding* which has the character of being underway, of proceeding, of seeking to arrive. These acts of grounding are indeed closely related to a judgment in which the ground will bring something (the matter of judgment) to a stand (zum-stehen brengen [sic!]) as an object (Gegenstand) when it will have provided a sufficient (vollstandig [sic!]) account of it.

Bringing something to a stand on the ground of the law in acts of grounding requires that this ground is solid and can carry the weight of what is made to stand. It presupposes that the law is stable and fixed. If the regulatory framework is in flux and in a state of becoming, it cannot provide this necessary support. Health-and-wellness apps can be grounded temporarily, establishing them as Digital Health Applications. But the updates to the regulatory framework cause this ground to become slippery. The socio-legal status is in question until the next temporary grounding. Therefore, the somewhat paradoxical second – and as I hope I have not wrongly promised – the more radical answer to my research question is that a health-and-wellness app never *quite really* becomes a Digital Health Application. The reason for this is that what a Digital Health Application is, i.e. the requirements to attain this status, is itself fluid or becoming owing to the agility of regulation. It remains in limbo as the ontological transformation, the transition from one mode of existence to the other that AIME has allowed me to theorize, is (forever?) incomplete.

10.5 Concluding Remarks

Throughout this thesis, I have engaged with a recent regulatory reform that may have far-reaching consequences for the field of digital health. Since late 2019, digital apps for health purposes have become a component of the standard healthcare provision in Germany. Other researchers have highlighted this as one of the first attempts to integrate digital health into regular healthcare provision (Gerke et al., 2020). Similarly, German law-makers and regulators claim a pioneering role in the digitalization of healthcare. According to the new law, citizens insured with one of the German statutory health insurances are entitled to the prescription of such apps, referred to as Digital Health Applications, and these prescriptions to be reimbursed. This mode of exchange has gotten them the moniker of "prescription apps" (*Apps auf Rezept*). To be eligible, apps first must undergo an approval process at the Federal Institute for Drugs and Medical Devices in Germany. Only after this regulatory agency has assessed both technical details concerning data privacy and usability and the medical efficacy apps can become listed in the so-called *DiGA* directory as the pool of prescriptible apps for various health conditions.

With my thesis, I sought to open up the black box that this approval process constitutes. I wanted to understand better what I initially perceived as an intriguing transubstantiation that it effectuates. Somehow, some way, during its assessment an 'ordinary' health-and-wellness app – of which app

stores offer hundreds and thousands – becomes a Digital Health Application with all the consequences this entails. Thus, the main research question has been how, through the approval process, a health-and-wellness app turns into a Digital Health Application. Answering this question required reconstructing how the *BfArM* conducts the assessment. To this end, I collected publicly available documents authored by the agency or manufacturers. I also interviewed three manufacturers and one representative of a German umbrella organization for digital health. I approached the empirical material thus gathered through a conceptual lens that combines Latour's Inquiry into Modes of Existence with a perspective on the infrapolitics of socio-material testing inspired by French pragmatic sociology. This lens allowed me to investigate the approval process as a test that, if successful, brings about the transition of the app to a legal mode of existence. Although this is not straightforward, I proposed as an answer to my research question that applicants must assemble several value objects for their application to transition successfully.

In the concluding pages of the thesis, I will summarize the main findings that have emerged from my research. The first finding is on the conceptual and concerns Latour's anthropology of the law. Although I do not fully agree with the critique that Latour re-introduces a non-material cognitive structure that has to underlie the law, there is still a conceptual difficulty for AIME and its legal anthropology to grasp the transitions between different modes of existence. I have shown that a combination of AIME and the Sociology of Conventions and Testing can address this shortcoming. On the one hand, it provides the concept of "critical moments" (Boltanski & Thévenot, 1999) which allows going beyond the adjudico-centrism that Pottage (2004) diagnoses in Latour's approach to the law. Thus, I could extend it to non-judicial situations where the law is mobilized as a mode of existence, such as the approval process at the *BfArM*. Critical moments in this framework are situations in which the given order of reality becomes questionable. On the other hand, it highlights socio-material testing practices that (re-)establish this order through mobilizing a limited amount of justificatory regimes. By reading AIME and the Sociology of Conventions and Testing through one another, I jettisoned the idea of these regimes and instead conceptualized tests as moments that assert the modes of existence of entitiesy. This understanding can contribute to AIME's goal of following the "crossings" of modes of existence. Socio-material testing practices are, I argue, one of the instances where such crossings occur.

Second, I have shown that the *BfArM* emerges as an actor that *cares* about digital health. Beyond its task as an executive organ, it actively contributes to adjusting the regulatory framework and puts forward a vision of a digitalized German healthcare system. Unlike other promissory discourses on digital health, this vision acknowledges the undecided fate of digital health technologies that waver between benefits and new risks. The *BfArM* positions itself as the decisive factor for realizing the opportunities of digital health for the patient. This care why what I have called "reverse regulatory capture". "Regulatory capture" usually refers to decision-making by regulatory agencies that skew toward industry interests in the literature on the regulation of pharmaceuticals (Abraham

& Davis, 2013; Mulinari & Davis, 2020). In the case of *DiGAs*, however, I have demonstrated that the *BfArM* potentially influences the design of would-be *DiGAs* from early on in their life through a cooperative relationship with developers. This relationship can, at times, turn into a more conflictual one. This potential led to tensions due to the distinct ways the *BfArM* and the manufacturers care about *DiGAs*. I have suggested that this ties back to the different modes these exist in within the practices of the two parties. In this sense, AIME as a diplomatic project can provide the vocabulary for new ways of communicating about these alterations.

I also found that digital health technologies pose challenges to regulation. Initially, this is hardly a new finding. The limited existing research on this has already extensively covered many difficulties, especially the undermining of existing legal categories (Geiger & Kjellberg, 2021; Lievevrouw et al., 2021; Lucivero & Prainsack, 2015). This difficulty was also visible in my analysis because Digital Health Applications are similarly hybrids combining digital technologies and medicine. While circumventing whether they are consumer technologies or medical devices by drawing on the EU-level Medical Device Regulation, the categorial confusion concerns their status as either medical devices or pharmaceuticals. On the one hand, the requirement for applicant apps to be registered with a Notified Body makes them medical devices. On the other hand, the *BfArM* is the German authority for assessing pharmaceuticals. The requirement of providing evidence of the app's clinical efficacy is also similar to the requirements for drugs. The approval process resolves the confusion about the status of Digital Health Applications through an implicit hierarchization of the requirements.. While these, in principle, cover both technological and biomedical expertise, the evidence for clinical efficacy appears more important. Drawing on Faulkner (2012b), I have called this the "regulatory pharmaceuticalization" of digital health. However, it remains imperfect as digital technologies cannot be fully subsumed under the pharmaceutical framework. On the one hand, the category of the "positive healthcare effect" crucially expands the understanding of the impact of a treatment to also contain digitalized improvements in health*care*. On the other hand, the regulatory pharmaceuticalization does not cover the new, more-than-individual types of risk and harm that digital health technologies bring. One challenge for future regulations of digital health technologies will be to create hybridized frameworks and institutions that can more accurately accommodate the specificity of their affordances.

Interestingly, this conceptual ambiguity was not the main issue that I found, however. The asynchronous temporalities of digital health technologies and regulation create much more fundamental issues. First, manufacturers need to report substantial updates to the *BfArM*. The agency then assesses whether the app still meets the requirements of a *DiGA* in another three-month process. Manufacturers believed that this undermines the capacity to be updated in rapid cycles. Second, the regulatory framework emulates this general fluidity of digital (health) technologies by being fluid itself. It is updated to accommodate new developments. The revised provisions apply retroactively. On a conceptual level, I have argued that this characterizes the regulation as becoming. It parado-

xically entails that apps can never really become Digital Health Applications because the definition of this legal category itself remains incomplete.

Finally, I want to point out two things I have left out of my analysis. The methodological choices I have made have influenced what I could find out. Due to the difficulties in recruiting interviewees, my sample is limited. For instance, I have not been able to speak to manufacturers who have not passed the approval process. This group still constitutes the majority of applicants. A larger, more diverse sample would have allowed me to more thoroughly discuss the role of different company sizes or the type of company plays in the approval process. In addition, I failed to negotiate access to employees at the *BfArM*. While this is itself meaningful research data, it also entailed that I could only approach the agency's perspective through publicly available documents. Conversations with employees could have further enriched the insights I gained from these.

I have not at all addressed the controversies around whether Digital Health Applications are desirable to be integrated into standard healthcare provision. Personally, I do not subscribe to the view that human interaction is necessarily superior to interactions with non-humans in healthcare (Pols & Moser, 2009). Nevertheless, I also believe there is good reason to be skeptical if *DiGAs* are considered quick technological fixes that distract from those problems of contemporary healthcare systems that require structural reforms. At any rate, future research would need to follow the experiences of users to identify whom *DiGAs* benefit and at what costs. Approaching the issue from the angle of regulation is, in my view, a crucial pre-condition for making changes. Only if we understand better the practices of regulatory decision-making, the values that inform them and the entities they instaure, can we start to make interventions and steer it into directions we find more desirable. In this sense, my thesis is also deeply influenced by the activist impetus of STS: The regulation of digital health could be otherwise...

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Abstract

In late 2019 the German parliament passed a new law to facilitate the introduction of digital solutions into the German healthcare system. Among these are Digital Health Applications – also known as “prescription apps”. These are apps designed to help patients with a diverse range of conditions that have been rendered prescriptible and eligible for remuneration by the statutory health insurance with the new law. The only precondition for apps to be recognized is the successful passing of a fast-track, three-month approval process with the German Federal Institute for Drugs and Medical Devices. In my thesis, I trace this process and ask how it turns an ordinary health-and-wellness app into a Digital Health Application. To this end, I develop a theoretical framework that connects Bruno Latour’s research program of An Inquiry into Modes of Existence with a focus on the infrapolitics of socio-material practices of testing informed by Luc Boltanski and Laurent Thévenot’s Sociology of Conventions and Testing. I use this framework to break open empirical data I have generated through a) the analysis of publicly accessible documents on the approval process and b) interviews with manufacturers that have successfully undergone this assessment with their app and a representative of a Digital Health umbrella organization. From the material and through the lens of my theoretical framework, I reconstruct the imaginary of digitalized healthcare that informs the approval process, the explicit and implicit requirements of the assessment, the relationship between the regulatory agency and the multiple roles that regulation plays. Overall, I argue that the approval process is a test that effectuates an ontological transformation through which an app transitions to a legal mode of existence. Contributing to the emerging literature on digital health, my analysis demonstrates the specificity of regulating digital health technologies and the challenges they pose for regulatory frameworks.

Zusammenfassung

Ende 2019 hat der Deutsche Bundestag ein neues Gesetz verabschiedet, das die Einführung digitaler Lösungen in das deutsche Gesundheitssystem erleichtern soll. Dazu gehören auch Digitale Gesundheitsanwendungen – auch bekannt als “Apps auf Rezept”. Diese Apps sollen Patient:innen mit den unterschiedlichsten Erkrankungen helfen und mit dem neuen Gesetz im Rahmen der gesetzlichen Krankenversicherung verordnungs- und erstattungsfähig werden. Einzige Voraussetzung für die Anerkennung von Apps ist das erfolgreiche Durchlaufen eines beschleunigten, drei Monate dauernden Zulassungsverfahrens beim Bundesinstitut für Arzneimittel und Medizinprodukte. In meiner Masterarbeit zeichne ich diesen Prozess nach und frage, wie er aus einer gewöhnlichen Gesundheits- und Wellness-App eine Digitale Gesundheitsanwedung macht. Zu diesem Zweck entwickle ich einen theoretischen Rahmen, der Bruno Latours Forschungsprogramm einer Untersuchung von Existenzmodi mit einem Fokus auf die Infrapolitik sozio-materieller Praktiken des Testens verbindet, der von Luc Boltanski und Laurent Thévenots Soziologie der Konventionen und des Testens inspiriert ist. Ich verwende diesen Rahmen, um empirische Daten aufzuschlüsseln, die ich a) durch die Analyse öffentlich zugänglicher Dokumente über den Zulassungsprozess und b) durch Interviews mit Herstellern, die diese Prüfung mit ihrer App erfolgreich durchlaufen haben, sowie mit einem Vertreter eines Digital-Health-Dachverbands gewonnen habe. Anhand des Materials und durch die Linse meines theoretischen Rahmens rekonstruiere ich die Imagination des digitalisierten Gesundheitswesens, das dem Zulassungsprozess zugrundeliegt, die expliziten und impliziten Anforderungen der Bewertung, die Beziehung zwischen der Regulierungsbehörde und die multiplen Rollen, die Regulierung in diesem Prozess annimmt. Insgesamt argumentiere ich, dass der Zulassungsprozess ein Test ist, der eine ontologische Transformation bewirkt, durch die eine App in den Existenzmodus des Rechts übergeht. Als Beitrag zur aufkommenden Literatur über digitale Gesundheit zeigt meine Analyse die Besonderheit der Regulierung digitaler Gesundheitstechnologien und die Herausforderungen, die sie für den Regulierungsrahmen darstellen.