

## Chapter 2

# Introduction Section I: Setting the Scene for Collaborative Healthcare Research

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The BigMedilytics project was ambitious right from the start. With 35 partners across European Union (EU) Member States and beyond, including clinicians, data scientists, technologists, and social scientists, as well as commercial enterprises, the logistics of coordinating the project alone were a significant challenge. But we need to step back at this point. The project did not only depend on successful cross-disciplinary communication between experts in their own fields; this was healthcare, involving vast amounts of special-category personal data shared across organizations and borders. The regulatory landscape alone required careful navigation at a time when the General Data Protection Regulation (GDPR) was still relatively new, increasing the sensitivity of healthcare providers and researchers still trying to understand how to identify and mitigate risks within their control.

Against such a backdrop, the four chapters in this section provide insights to support all future collaborations of this type, no matter how complex. Based on an extensive set of interviews and observational work, Chapter 3: Using causal models to understand and deal with hindering patterns in the uptake and embedding of big data technology introduces a well-known technique from the social sciences (causal modeling) to encapsulate and make sense of the collaboration experiences of

the various project stakeholders in attempting to navigate not only regulatory constraints – avoiding the trap of overly cautious elephant paths – but also to see the ambitious nature of such complex projects realized. The authors identified three causal models, including the Information Road, the Golden Mountain, and the Swamp of Rules, in each case summarizing the main recommendations for targeting the introduction of complex and advanced technologies into an established field (healthcare) where the stakes are high, especially for public trust. While these recommendations provide practical pointers in support of the successful completion of complex projects of this nature, reflection on the causal models themselves provides a valuable technique for all project managers and project teams.

The third causal model, the Swamp of Rules, recognizes the challenges of multidisciplinary collaboration across domains, involving different sets of regulatory constraints. At the same time that researchers in all relevant disciplines were waking up to the potential of big data for healthcare, the GDPR brought in increased nervousness about exploiting that potential. How could researchers get the most out of the data routinely collected as part of existing care pathways in such a risk-averse environment? Taking an explicitly pragmatic approach to support the ambitious nature of the project, Chapter 4: Lessons learned in the application of the General Data Protection Regulation to the BigMedilytics project signposts stakeholders through the complexity of relevant regulation. Indeed, responding to the call for “experts in privacy, security, safety, ethics, and law on the team [to] advise health care professionals and data scientists how they can comply with different rules” from Chapter 3, Chapter 4 is not about ‘no, you can’t’ because of regulation, but rather ‘this is how you can do it’. Furthermore, based on the real-life objectives and results of the BigMedilytics, it takes us from existing regulation forward toward the regulatory frameworks proposed by the EU.

Chapter 4 finishes with a set of recommendations for an appropriate governance model akin to the proposals in the academic literature for Trusted Research Environments. Chapter 5 Ethics: A checklist for investigators, ethics boards, and reviewers picks up on the recommendation to appoint an ethics committee and explores the consent fallacy in Chapter 4 within the context of academic research. Interrogating empirical data from three surveys (two within BigMedilytics and a third from a subsequent project) against the background of research ethics, this chapter suggests 12 points that a Research Ethics Committee (or Institutional Research Board) should consider when evaluating research proposals from Big Data and advanced technologies such as machine learning based on such data. Contextualizing these 12 points against existing trust relationships between patient and clinician on the one hand and participant and researcher on the other, the chapter shifts research consent away from “fully informed” decision-making on the part of

the patient/research participant toward an ongoing trust-based negotiation between the main parties.

The final chapter, Chapter 6: Healthcare platforms businesses – From investigations to platforms, returns to the enterprise focus of the project to provide a synthesis of competing requirements in support of the commercialization of healthcare service provision. For the results of projects like BigMedilytics to be converted into successful healthcare delivery, there is a need to establish suitable business models and delivery contexts, while respecting governance. So, although the main focus of the studies in Sections II to IV was to demonstrate the potential of Big Data in healthcare, from diagnosis, treatment, and self-management to efficient operational delivery, there is a significant need to reap the rewards of those studies. Chapter 6 begins by describing what platform business models entail, including well-known examples from different industries such as Uber, eBay, and Zoom. It then asks if and how such models might apply if the findings of the individual studies are to be exploited in maximizing benefit within healthcare. It picks up on issues such as the core interactions that both Chapter 3 and, to some extent, Chapter 5 present for projects and research, respectively, the governance challenges explained in Chapter 4, and then shows the path to successful commercialization while appreciating the challenges of the domain. As such, Chapter 6 effectively offers a demonstration of meeting the quadruple aims of healthcare – containing costs, improving healthcare outcomes, supporting productivity, and respecting patient expectations – based on tried and tested practice in other enterprise domains.

Section I, therefore, brings together some of the learnings from BigMedilytics to benefit all stakeholders across healthcare. Each of the chapters answers one or more of the implicit challenges of those trying to navigate their way through complex research and innovation in an area often fraught with constraints but which affects us all individually. While the COVID-19 pandemic highlighted all these aspects – collaboration across multiple disciplines, the pragmatic interpretation and compliance with regulation, meeting private citizen expectations around research, and the sustainable commercialization of service delivery – the chapters here provide evidence-based answers to fellow researchers and innovators for them to build on and take these findings forward to improve all aspects of healthcare.