Book Review

Coravos A, Goldsack JC, Karlin DR, Nebeker C, Perakslis E, et al.

Fast Facts: Digital Medicine – Measurement

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Increasingly, the field of healthcare is leveraging advances in the technologies underlying the collection, processing, and storing of sensor data to improve outcomes for people with disease. However, product managers, engineers, and data scientists who have the expertise needed to build technical platforms are often new to the fields of healthcare and medicine and may not have a background in the design of medical devices or the clinical studies needed to validate them. *Fast Facts: Digital Medicine – Measurement* provides an overview of the field of digital medicine that can be used by these technical teams to more fully understand the clinical and regulatory contexts in which they are building their products. Andrea Coravos and colleagues have put together a concise, pragmatic primer for how to think through the design of digital medicine products that rely on digital measurement. The authors propose a common language around digital measurement and share an overview of the landscape of medical device development, clinical studies, and methods of validation. The primer can be used to guide technical teams without a medical background to set product requirements for software, hardware, or integrated systems aimed at digital measurement of health and disease.

This trim volume begins with a handy glossary, which is helpful for teams trying to navigate a new and evolving landscape. Even the most helpful advisors and experts tend to speak in acronym-based code common to their own field, so for interdisciplinary teams, it is incredibly useful to have a reference on hand that includes terms from the regulatory domain (MDDT = Medical Device Development Tool), the world of tech (ToS = terms of service), and the world of medical devices (CGM = continuous glucose monitor). In addition, Coravos et al. cover concepts such as the distinctions between *digital medicine* and *digital health*, between *intervention* and *combination* measurement products, and between intuitive definitions of *real-world data* and regulatory definitions of the same. What is the difference between a *clinical outcome assessment* and a *digital biomarker*? If a paper questionnaire is validated, can you just digitize it and assume the digital version is valid? What does *Software as a Medical Device* mean? These questions and more are answered in the book, where each chapter ends with a summary of key points and references.

It is helpful that the book is written with an engineering and product development audience in mind. Concepts are broken out using product-focused language, and the authors encourage readers to think about the context in which their product is meant to be used. The

chapter on frameworks for Verification and Validation alone is worth the price of the book. Our team of physicians, scientists, software engineers, and sensor (hardware) engineers usually have different implicit definitions of what it means for a measurement to be “validated”. Using the simple example of step count measurement from a wrist-worn device, a hardware engineer might assume that “validation” means that the values coming off of the accelerometer are in the expected range. A scientist might presume that validity means that the step count estimated from the device is corroborated by a manual count done by an observer. And a physician might assume that step count is only a “valid” digital biomarker if we confirm expected differences in step count across age groups. The authors’ insight in separating the verification of sensor performance from analytical validation of the measurement and from clinical validation has saved our teams from many circular conversations about what “validation” means.

The authors also spend some much-appreciated time demystifying the regulatory landscape. They outline the centers at FDA most relevant to people building digital medicine products (CDER, CBER, CDRH), describe the four main phases of clinical trial research, and provide an overview of the definition and types of medical devices. They provide a chart meant to describe the various pathways for bringing FDA-regulated products to market, and how that interacts with the risk the devices pose, though they acknowledge that the regulatory frameworks for digital tools are still being developed.

This guide can also help managers of cross-functional teams, where tech team attitudes suited to software development (move fast and break things) are currently evolving. Teams are learning to take into account the legal, regulatory, as well as social and ethical implications of building products with real medical impact. The authors present a concise history of and logic behind IRB review and the importance of obtaining informed consent. They also invite readers to think through issues of security, data rights, and governance. The tone empowers developers to be the champions of ethical decision-making rather than simply presenting sets of rules to be followed.

While there is myriad detailed FDA guidance available on digital measurement (e.g., BEST Biomarker Glossary, Biomarker Qualification Evidentiary Framework, Medical Device Development Tools are just a few), this book offers a framework to which to attach them. Having this shared framework and a common language for how we build and validate our products speeds up our development process and creates space for scientific rigor. This guide is one that I share with product managers, engineers, clinical operations, and user experience researchers when they join our team. I recommend it to any cross-functional, tech-focused team dedicated to building novel digital measurements of health and disease.

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