Preface

by Gianmario Verona[1]

Paraphrasing the influential 2014 book by Erik Brynjolfsson and Andrew McAfee, we are now entering the "third machine age"—an era defined by the rise of Artificial Intelligence (AI). The first age of technological transformation was marked by the advent of computers and digital devices, which, propelled by Moore's Law, became progressively smaller and more powerful. Then came the internet, connecting these devices and unlocking new dimensions of communication and information sharing. Today, we are transitioning into a new phase, in which machine learning and deep learning technologies allow us to harness both small and big data in transformative ways.

Until recently, AI was often regarded as a technology of the future— so much so that it inspired the quip: "AI is any technology that doesn't work yet." That future, however, has arrived. AI is no longer a speculative concept limited to visionaries; it is now a powerful and dynamic force reshaping every industry—and, more importantly, every aspect of our lives.

The launch of OpenAI's ChatGPT, followed by the R&D race among key global competitors, has simplified AI's interface and made advanced tools accessible to all. As Satya Nadella, CEO of Microsoft, aptly noted at a recent World Economic Forum panel, if the internet put information at our fingertips, AI puts skills at our fingertips. Nowhere are the stakes higher – or the potential greater – than in medicine and the life sciences. From research to clinical practice, digital transfromation and AI are reshaping the boundaries of what healthcare systems can deliver.

This book begins with the premise that AI's transformative impact will depend not only on technological advancement but also on the strength of the legal, ethical, and policy frameworks that support it. The authors pro-

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vide a rigorous analysis of the key challenges raised by the integration of AI in healthcare. They start by clarifying definitions and exploring practical applications, then delve into the increasingly complex legal and policy landscape. The final section offers a global perspective, comparing how different jurisdictions—with their own regulatory cultures and strategic priorities—are responding to this rapidly evolving frontier.

What makes this volume particularly compelling and potentially interesting for readers of different fields is its interdisciplinary approach. The authors draw on jurisprudence, public policy, bioethics, and health systems research to examine how societies can govern AI in a way that fosters innovation while safeguarding equity, transparency, and accountability. This is, in my view, the only possibile venue to make a complex technology viable to a complex field like medicine.

The European perspective is presented with particular nuance, highlighting the EU's ambitious effort to build a comprehensive digital health governance framework. Grounded in initiatives like the AI Act and the European Health Data Space (EHDS), this vision aims to promote a human-centric approach that prioritizes human rights, privacy, explainability, and fairness. At the same time, the book explores the United States' approach, where emphasis is placed on post-market accountability and market-driven innovation. This comparative analysis allows readers to appreciate the structural, cultural, and philosophical differences between the two systems—and to consider what a coherent global approach to AI governance might require.

What sets this volume apart is its ability to marry doctrinal precision with practical insight. It not only maps current regulatory tools but also starts tackling deeper normative questions: How can we ensure that AI supports rather than replaces clinical judgment? How do we promote fairness and inclusivity in data-driven medicine? And how do we build resilient systems that anticipate—rather than merely react to—ethical and legal challenges?

The authors wisely recognize that these issues are not just technological or legal—they are deeply human. As AI systems grow in complexity, the patient–clinician relationship remains central to compassionate and effective care. Innovations such as predictive analytics and autonomous decision-making tools must not obscure the fact that healthcare is inherently relational, built on trust, empathy, and shared understanding. These technologies are not mere enhancements; they fundamentally reshape how we think about diagnosis, consent, safety, and accountability.

In this way, the book contributes meaningfully to a broader and urgently needed conversation. It calls on regulators, developers, clinicians, and scholars to engage with AI not merely as a tool, but as a force for system-wide transformation—one that demands new skills, new safeguards, and new

ways of thinking. In the European context especially, where health is seen not only as an individual right but as a collective good, there is a unique opportunity to shape a regulatory model that is forward-looking, ethically grounded, and globally influential.

Throughout my career, I have believed in the power of research and policy to drive innovation that is inclusive, responsible, and impactful. This volume embodies that same conviction and hence it represents a resource for anyone seeking to navigate the evolving landscape of AI in medicine—not with fear or uncritical enthusiasm, but with the intellectual seriousness and vision that this moment demands.