Rewriting the textbook for pharma: how to adapt and thrive in a digital, personalized and collaborative world

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The pharmaceutical industry is undergoing a sweeping transformation, driven by technological innovations, demographic shifts, regulatory changes and consumer expectations. For adaptive players in pharma to excel in this rapidly changing landscape, which will be markedly different from today by 2030 and beyond, they will require a different set of skills, capabilities and mindsets, as well as a willingness to collaborate and co-create value with multiple stakeholders. The industry needs to rewrite the textbook for pharma by embracing and implementing four key dimensions of change: digitalization, personalization, collaboration and innovation. In this article, we will examine how these dimensions of change are reshaping the industry, and provide practical and strategic guidance based on best practices and examples. Specifically, adaptive pharma companies should embrace the use of advanced digital technologies, such as artificial intelligence and machine learning, to streamline processes and solve challenges rapidly. Personalization, both in medicine and patient engagement, will also be key to success in the 'digital revolution', and a collaborative approach involving partnerships with tech start-ups, health-care providers and regulatory bodies will also be essential to create an integrated and responsive health-care ecosystem. Using these ideas for a rewritten textbook for pharma, adaptive players in pharma will evolve to be personalized and digitized health-focused organizations that provide comprehensive solutions which go beyond drugs and devices.

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Introduction

In our brave, new, integrated and 24/7 connected world, the pharmaceutical and associated industries (e.g., health care) are changing at a rapid pace. The increase in digitalization is leading to more personalized medicines and care, a more collaborative environment and greater innovation across the industry. With these changes come unprecedented opportunities and challenges. These trends are creating new and different expectations and demands from both customers and other stakeholders, while also generating novel sources and forms of value and competition for pharma. Such shifts are opening new opportunities for stakeholders to improve and transform their products and services, and to optimize health outcomes, quality of life and customer satisfaction more effectively and equitably.

Navigating these changes will be crucial, because pharma not only affects the health, well-being and quality of life of billions of people, but also affects the economic and social development of nations and regions. However, doing so effectively can be challenging, because this industry is complex, dynamic and highly regulated, and it involves multiple stakeholders (e.g., patients, health-care providers, payers, regulators, researchers and innovators). It also draws from diverse factors, such as science, technology, regulation, policy and the market.

Effective navigation will require a change in perspective among stakeholders of the pharmaceutical industry. The old 'textbook' in pharma, or the traditional operating model and conceptual framework that has historically guided the practices and strategies of the pharmaceutical industry, has revolved around a model that focused on mass production, mass marketing and one-size-fits-all therapeutic solutions. It was largely characterized by a linear pathway from drug discovery to market, with minimal emphasis on customization, patient engagement or leveraging digital technologies for innovation and efficiency. Continuing to follow this path will mean failing to fully take advantage of all the opportunities in this rapidly evolving landscape.

Therefore, the pharmaceutical industry needs to rethink its processes by embracing and leveraging the four key dimensions of change, which will serve as the chapters in this 'rewritten textbook' for pharma: digitalization, personalization, collaboration and innovation. Within this new textbook, we present a practical guide that adopts best practices and case studies from the industry, aiming to assist pharmaceutical companies in incorporating these essential areas into their strategic planning and operational activities (Figure 1). Instead of providing an exhaustive examination of each area, this article presents the transformational trends in the pharmaceutical industry and provides strategic advice for capitalizing on these trends. The guide is intended to facilitate the industry's adaptation to ongoing changes, with the ultimate aim of enhancing product and service offerings, optimizing processes and achieving a more responsive approach to market demands.

Chapter 1: Digitalization

Digitalization, the first chapter in our rewritten textbook, is revolutionizing not just pharma, but every industry. It is being considered as the 'Fourth Industrial Revolution' by the World

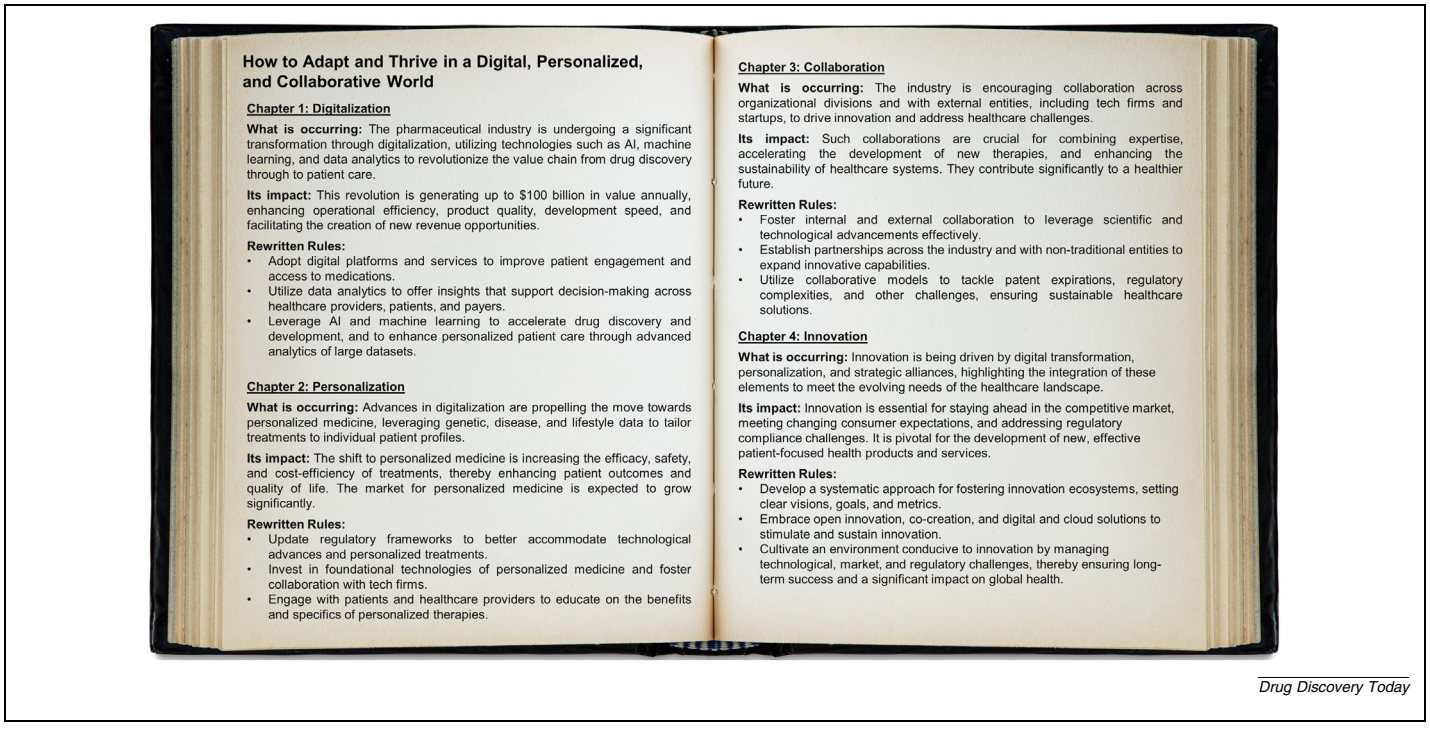

FIGURE 1

The rewritten textbook for the pharmaceutical industry. A framework illustrating the transformative impacts of digitalization, personalization, collaboration and innovation on the pharmaceutical industry, with strategic recommendations for industry adaptation. (Book image from DN6 collection, https://stock.adobe.com.)

Economic Forum, a phase characterized by "a fusion of technologies that is blurring the lines between the physical, digital, and biological spheres" (https://www.weforum.org/agenda/2016/01/the-fourth-industrial-revolution-what-it-means-and-how-to-respond). This revolution encompasses, but is not limited to, technologies such as artificial intelligence (AI), big data analytics, cloud computing, the Internet of Things (IoT), blockchain technology, quantum computing and 5G connectivity. In the pharmaceutical industry, these technological advancements facilitate the efficient processing and analysis of extensive health-care data sets, including electronic health records (EHRs), genomic information, data from wearable technology and insights gathered from social media platforms. Leveraging such data, pharma can enhance various aspects of its value chain, from drug discovery and development to manufacturing, distribution, initiatives and beyond.

This digital revolution is driving significant value for pharmaceutical industry. A McKinsey report underscores the substantial economic potential that digitalization holds for the pharmaceutical field, estimating the generation of up to US$100 billion in value annually (https://www.mckinsey.com/industries/life-sciences/our-insights/digital-in-r-and-d-the-100-billion-opportunity). This estimate is predicated on expected enhancements in operational efficiency, product quality and development speed. Additionally, the introduction of digital products and services is poised to create new revenue opportunities and catalyze growth within the industry.

The pharmaceutical industry's integration of data and technology is pivotal for increasing efficiency, effectiveness, innovation and insights (i.e., data generation enabled by digital), as well as improving stakeholder experience. Three transformation trends emerge from analyzing industry case studies and effective practices: (i) the use of digital platforms and services; (ii) the strategic application of data analytics; and (iii) the increased use of AI and machine learning.

The first strategy, the implementation of digital platforms and services, aims to increase process efficiencies across the entire value chain, improve effectiveness by improving quality in areas from manufacturing to field force effectiveness, and enhance patient engagement and customer experience. Digital platforms and services geared towards improving patient engagement and customer experience, for example, involve the provision of digital aids that allow patients to manage their conditions, track their symptoms and communicate with health-care professionals, while also making medication more accessible and affordable. An example of this strategy is Novartis' initiation of the Novartis Biome (https://www.biome.novartis.com), which aims to foster partnerships with digital health start-ups to create digital solutions addressing health-care gaps. One successful product of this initiative is SMS for Life, a mobile application designed to increase the accessibility and reduce the cost of crucial medicines in regions with low and middle incomes by utilizing SMS technology for managing inventory and pricing at health facilities (see https://www.novartis.com/sites/novartis_com/files/novartis-social-business-report-2018.pdf).

The second strategy recommends the utilization of data and analytics to drive innovation and insights, to create new computational models and to enhance patient care. Enhancing patient care, for example, involves providing data-driven insights and solutions that support the decision-making processes of patients, health-care providers and payers. It also includes measuring and demonstrating the value and impact of the industry's products and services. An example of this approach is Roche's acquisition of Flatiron Health (https://www.fiercehealthcare.com/ehr/roche-flatiron-health-1-9b), which specializes in oncology-specific EHR software and data analytics. Roche's objective is to augment personalized and value-based health care in the oncology industry by applying Flatiron's proficiency in real-world data to generate evidence that influences clinical decisions, research and regulatory and reimbursement policies for cancer-care products and services.

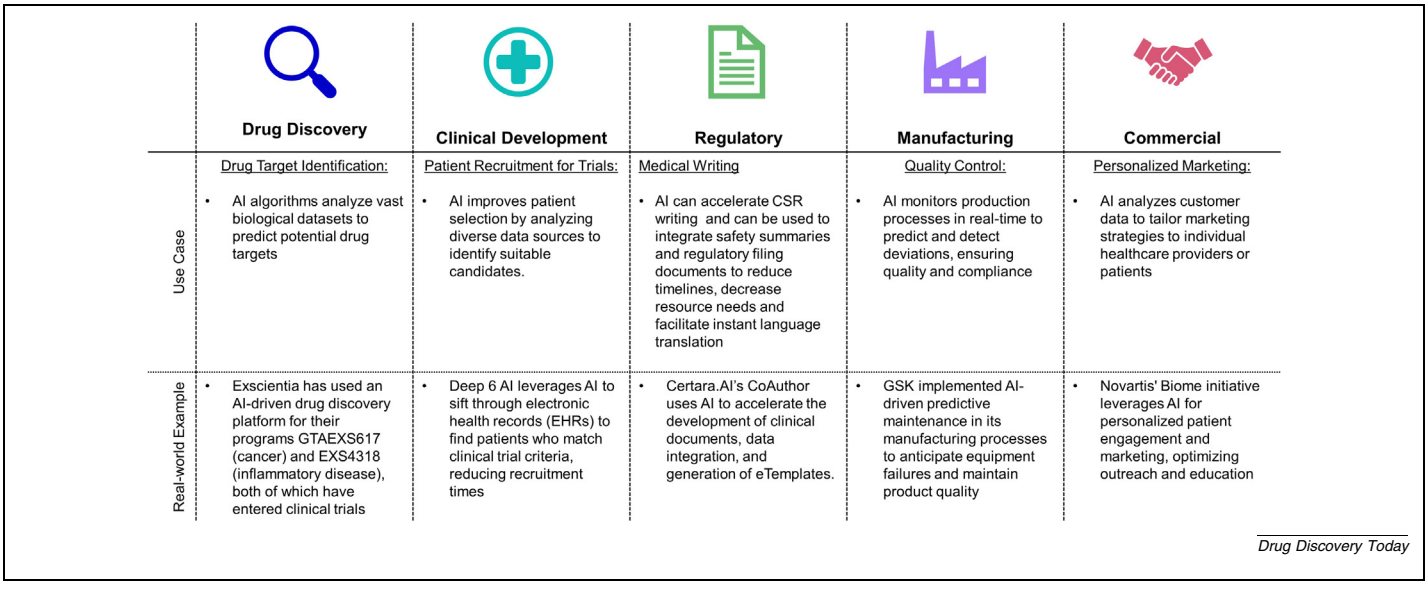

FIGURE 2

Use cases of AI and machine learning in each section of the pharma value chain. URLs: Atomwise, https://www.exscientia.com/pipeline/; Deep6AI, https://deep6.ai; Certara CoAuthor, https://www.certara.com/coauthor; GSK, https://www.gsk.com/en-gb; Novartis Biome, https://www.biome.novartis.com.

Chapter 1.1: The rise of AI and machine learning

The third strategy for navigating the 'digital revolution', taking advantage of the rise of AI and machine learning, deserves its own subchapter in the rewritten pharma textbook. These emerging technologies not only have the potential to enhance the other strategies described above, but also influence all aspects of the pharma industry, from drug discovery and development to commercialization and patient care (Figure 2). AI systems, through the analysis of extensive data sets, such as multi-omics (e.g., genomics and proteomics), enable the extraction of previously unobtainable insights.[p1] The essence of AI involves making decisions based on the data it has been trained on, meaning that the quality of its output is directly related to the quality of the input data (see https://www.purestorage.com/knowledge/what-is-ai-inference.html). Furthermore, rather than replacing jobs, AI is set to reshape roles within the industry. For example, AI is already assisting doctors in rapidly identifying brain tumors, which could eventually lead to tumor identification during surgery, allowing doctors to adjust their strategy in real time.[p2]

The impact of AI and machine learning technology has the potential to extend throughout the pharmaceutical value chain, enhancing processes from the initial discovery phase to the final stages of health-care administration.

At the discovery level, AI is already starting to facilitate the identification of new treatments by analyzing the interactions between different therapeutic approaches and their targets, including the characterization of human physiological attributes from the cells to organs, with the potential of identifying new disease biomarkers.[p3] Although the use of biomarkers for oncology is more advanced than for other indications, their use for treating any disease is still very complex, particularly for diseases in which multiple genes have a role. AI has the potential to improve identification and increase the rates of clinical success. For example, the general machine learning model Stabl has been designed to mitigate the substantial risk of failing to validate retrospective data in prospective clinical studies by applying sparsity-promoting regularization, thereby distilling data sets containing 1,400–35,000 features down to 4–34 candidate biomarkers.[p4]

The use of AI during discovery could result in greater success rates in clinical trials. When used in the field of epidemiology, it could also aid in dissecting tissue inflammation and disease susceptibility patterns, improving diagnostic capabilities. In the clinic, AI has the potential to streamline regulatory processes such as trial enrollment and tracking, as well as the completion of regulatory documents such as clinical study reports (CSRs). The latter was tested as part of a challenge initiated by Pfizer, in which participants used generative AI to create safety tables for CSRs.[p5] The results revealed that, although there is potential for large language models (LLMs) to automate the summarization of tables in CSRs, there is still a need for human involvement and continued research to optimize this technology.

AI and machine learning have the potential to affect pharmaceutical manufacturing by streamlining the procurement process through advanced sourcing strategies, thereby enhancing efficiency and reducing operational costs. AI-driven virtual assistants could enable predictive maintenance and operation optimization, which could markedly increase overall equipment efficiency. In terms of quality management, advanced AI systems could facilitate automated deviation investigations, thereby improving both productivity and regulatory adherence. AI-enabled strategies, such as no-touch planning and real-time inventory management, could also significantly advance supply chain operations by predicting demand fluctuations and optimizing inventory levels accordingly.

Another powerful application of machine learning and AI lies in predicting wastage of active pharmaceutical ingredients (APIs). By analyzing material science and process data, AI technologies can identify potential inefficiencies and bottlenecks throughout the supply chain. Leveraging these insights, the system can suggest process adjustments to mitigate wastage. This capability can drastically cut costs (see https://nexocode.com/blog/posts/artificial-intelligence-in-api-manufacturing). For instance, achieving a more than 30% reduction in API loss during the manufacture of oral medications could result in savings of tens of millions of dollars annually, offering a substantial improvement over existing procedures.

In the realm of commercialization, AI's capability to automate customer interactions and personalize marketing strategies has the potential to significantly elevate the customer experience and provide marketing insights. This technology offers a refined perspective on consumer behavior, enabling precise marketing communications. Marketing initiatives will also gain from the insights derived through AI analysis of social media engagements, facilitating immediate consumer interaction. In patient care, AI can transform the way diagnoses are made and treatment outcomes are measured, ensuring personalized treatment plans are devised according to individual patient profiles. Prospective models might even adapt treatments to match patients' unique genetic and lifestyle characteristics. However, it should be noted that there are privacy concerns among patients regarding the use of customer data (e.g., health data and lifestyle analytics) in health care and therapy. Although some countries have implemented comprehensive regulation to ensure protection of personal data and privacy, such as the European Union's General Data Protection Regulation (GDPR) and the European Health Data Space (EHDS), low levels of trust in institutions could make patients reluctant to share data.[p6] This, in turn, could limit the use of AI for commercialization and marketing, and could reduce the amount of data available to support AI-driven research.

AI and machine learning are also set to change how the pharmaceutical industry conducts research. For example, AI team lead (ATL) is an emerging job role in pharma that entails leveraging AI technologies to enhance aspects such as drug discovery and development processes, with the aim of improving patient outcomes and streamlining pharmaceutical research. ATLs collaborate with AI, overseeing the entire life cycle of an AI-driven drug-discovery program, ensuring data quality and the alignment of the model with research goals, and clearly communicating the findings.

Some companies are already adopting the idea of AI-driven research, particularly in oncology. For example, Pfizer's collaboration with Tempus leverages Tempus's AI-enabled platform and library of de-identified multimodal data to advance the

development of oncology therapeutics (see https://www.tempus.com/news/tempus-announces-new-strategic-collaboration-with-pfizer-to-advance-oncology-therapeutic-development). Furthermore, Sanofi has showcased its innovation by partnering with Aily Labs to create 'plai', an AI platform designed to support drug development decisions (see https://www.pharmaceuticalprocessingworld.com/sanofi-ai-powered-pharma-strategy). Another company, AstraZeneca, has formed key alliances with Oncoshot and BenevolentAI (see https://www.astrazeneca.com/country-sites/singapore/press-releases/astrazeneca-and-oncoshot-establish-strategic-partnership-to-bett0.html# and https://www.benevolent.com/news-and-media/press-releases-and-in-media/benevolentai-achieves-further-milestones-ai-enabled-target-identification-collaboration-astrazeneca), with the latter relationship yielding five new portfolio targets for conditions such as chronic kidney disease and idiopathic pulmonary fibrosis. Bristol Myers Squibb (BMS) is leveraging Exscientia's AI capabilities to expedite the discovery of small molecule drug candidates for areas including oncology and immunology (see https://investors.exscientia.ai/press-releases/press-release-details/2023/Exscientia-Announces-First-in-Human-Study-for-Bristol-Myers-Squibb-In-Licensed-PKC-Theta-Inhibitor-EXS4318/default.aspx).

The use of AI will also allow for the creation of AI communities (AICs), which are networks that use AI to connect patients, professionals and researchers, improving health care through shared data and insights. Through this application of AI, individuals will gain unparalleled access to expansive online data sets, offering deep insights that were previously difficult to obtain. AICs will also allow patients to forge digital connections, facilitating the exchange of experiences and fostering a shared understanding of health-care journeys. Furthermore, through AICs, public and private organizations are anticipated to collaborate in building common data libraries, merging public data with proprietary in-house information.

The digital revolution in the pharmaceutical industry could also expand what we consider to be human. The concept of a 'digital human' introduces a revolutionary idea, bridging the gap between technological innovation and human identity. AI providers (AIPs), for example, are systems that leverage AI to support diagnostic, treatment and care management decisions. Companies have already begun to embrace the idea of AIPs, including Nvidia and Hippocratic AI, which have employed digital nurses to handle low-risk calls and alleviate some of the burden on the health-care system (see https://www.businessinsider.com/nvidia-ai-nurses-treat-patients-2024-3). Several clinical trials have also found that voice-based digital assistants could potentially supplement initiatives to promote transitional care, physical activity, smoking cessation and medication adherence in patients with cardiovascular disease.[p7]

In the future, with improvements to these models, we might be able to build a digital workforce that can provide personalized support, including language and accents tailored to the patient and support for patients with speech and neurological impairments that would serve to improve equity and accessibility of care. They can also be used to both diagnose and treat those with psychiatric diseases.[p8] We might even be able to preserve a person's digital legacy for future generations to interact with and learn from (see https://erictopol.substack.com/p/sid-mukherjee-on-ai-longevity-and). However, for interactions with these 'digital people' to feel natural, there would need to be a transition away from speech-text-speech models (see https://huggingface.co/learn/audio-course/chapter7/speech-to-speech) to true-speech LLMs, in which speech is converted directly to speech. Such true-speech technologies are emerging in the tech industry, such as Alexa's new automatic-speech-recognition (ASR) model (see https://www.amazon.science/blog/alexa-unveils-new-speech-recognition-text-to-speech-technologies).

Chapter 1.2: Navigating the digital revolution

The transition towards digitalization heralds both significant opportunities and significant challenges for the pharmaceutical industry. It enables the exploration of emerging markets such as digital health, e-pharmacy and telemedicine, while introducing disruptive elements that transform the competitive arena and alter consumer expectations. The rise of new and diverse markets has also driven the entry of unconventional competitors, including technology corporations, start-ups and non-governmental organizations (NGOs), each bringing innovative health solutions and creating new competitive pressures for traditional pharmaceutical companies.

Adapting to this evolving landscape demands a re-evaluation of how digital tools are utilized to enhance both the efficiency and effectiveness of the pharmaceutical industry's operations and offerings. There is an imperative need for innovation in product and service delivery that embraces a data-driven, evidence-based and customer-centric approach. Therefore, the industry must consider how it can reinvent its structural model and value proposition by leveraging technological advancements and data analytics. Drawing on the initiatives outlined previously, it is clear that by adopting digital technologies, the pharmaceutical industry can develop strategies to harness the benefits of digitalization while addressing associated risks.

In the current era of digital evolution, the pharmaceutical industry should adopt digital technologies while also preparing for the associated ethical, legal, organizational and technical challenges. Compliance with regulations such as the GDPR (https://gdpr-info.eu/) and the Health Insurance Portability and Accountability Act (HIPAA; https://www.cdc.gov/phlp/php/resources/health-insurance-portability-and-accountability-act-of-1996-hipaa.html) is essential, given the critical nature of data privacy, consent, ownership and security. Furthermore, a paradigm shift within companies towards a digital-centric approach is crucial, necessitating an emphasis on innovation, research and collaboration. This shift requires both the acquisition and cultivation of digital talent, which will be essential for facilitating and maintaining this transition.

Additionally, the process of integrating different data sources and systems underlines the necessity for reliable, high-quality data and algorithms. Thus, the adoption of digitalization is not merely an option but a requirement for maintaining relevance and competitiveness within the dynamic health-care and busi-

ness environment. It will also become increasingly important in countries with rapidly aging populations, where they face increased pressure to address complex health-care needs and ensure the provision of quality care.[p9] Digital technologies offer solutions to these challenges by enabling better data management, patient monitoring and personalized care, thereby supporting an aging society's health and well-being more effectively.

Such a digital revolution has widespread implications, improving operational efficiency, effectiveness and overall experience, and providing insights and innovation, while also enabling the development and delivery of novel products and services that address health requirements in a manner that is both data-informed and centered around the end user. It is also projected to drive value in all sectors of the industry, with a 2024 McKinsey report projecting up to $28 billion dollars in annual value generated by the use of AI in research and early discovery alone (https://www.mckinsey.com/industries/life-sciences/our-insights/generative-ai-in-the-pharmaceutical-industry-moving-from-hype-to-reality). Beyond the adoption of new technologies, the industry must also address and minimize the risks associated with digitalization, ensuring that the transition occurs in a manner that is both responsible and ethical, protecting the interests of consumers and society at large.

Chapter 2: Personalization

Digitalization is enhancing personalization in health care, shifting away from the conventional population-based approach and towards an individualized paradigm. The use of multi-omics data and AI, for example, is enabling the processing and understanding of intricate biological information on an unprecedented scale.[p10] Such large-scale data analysis is leading to a rise in personalized medicine, which takes into account the specific genetic, disease and lifestyle characteristics of patients.[p11] This is particularly true when this data-driven approach is coupled with synthetic biology (the engineering of complex biological systems) and the advancement of gene therapy and other biotechnology fields.

The field of personalized medicine is growing. According to the Personalized Medicine Coalition (https://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PM_at_FDA_The_Scope_and_Significance_of_Progress_in_2019.pdf), the proportion of FDA-approved personalized medicines has escalated from 5% of total approvals in 2005 to 42% in 2019, with expected continuous growth. The market for personalized medicine is projected to grow from $300 billion in 2021 to $870 billion in 2031 (see https://www.alliedmarketresearch.com/personalized-medicine-market-A13388). This growth can be seen in the substantial advancements that have been realized in personalized medicine, in both the oncology and non-oncology domains. In oncology, this means being able to target specific mutations within a tumor. Palbociclib, for example, has demonstrated efficacy in the treatment of ER^+ and $HER2^-$ breast tumors, while encorafenib, in conjunction with cetuximab, has shown effectiveness in patients with colorectal cancer harboring BRAF V600E mutations.[p12],[p13] In non-oncology contexts, personalized therapeutic strategies for type 2 diabetes are meticulously tailored to correspond with the patient's stage within the diabetes continuum, addressing distinct issues such as insulin resistance or deficiency.[p14] Therapeutic interventions designed to help manage rheumatoid arthritis are also increasingly individualized on the basis of factors such as age, sex, disease activity and genetic predispositions.[p15]

There are several factors contributing to the rise of personalized medicine, one of the largest being the transition to big data and digitalization, which is accelerating the pace and comprehensiveness of personalized medicine, allowing for more precise and individualized treatment plans. It is also being driven by an increasing need for personalized medicine strategies to address complex diseases (e.g., genetic disorders). For instance, gene therapies could be designed to rectify defective genes that cause rare and previously untreatable conditions, and vaccines are now being designed using neoantigens, which elicit an immune response that attacks cancer cells specific to an individual's tumor.[p16] These strategies have the potential to enhance treatment effectiveness, safety and cost-efficiency, while reducing the impact of chronic and rare diseases.

The pharmaceutical industry is advancing this field through the integration of various technologies and methodologies to develop treatments tailored to the individual genetic and molecular profiles of patients. A notable example is Pfizer's development of Vitrakvi (larotrectinib), a therapy targeting the neurotrophic tropomyosin receptor kinase (*NTRK*) gene fusion in different tumor types, identified through biomarkers rather than the location of the tumor.[p17] Vitrakvi was shown to shrink or stop 75% of the tumors and to get rid of 22% of them in patients with *NTRK* gene fusion-positive tumors across different ages, tumor types and previous treatments. Novartis leads in the gene replacement field with Zolgensma (onasemnogene abeparvovec-xioi), a gene therapy for spinal muscular atrophy, a severe neuromuscular disorder in infants and children (see https://www.novartis.com/news/media-releases/novartis-presents-new-data-safety-and-efficacy-zolgensma-including-maintained-and-improved-motor-milestones-older-and-heavier-children-sma). Zolgensma works by replacing the malfunctioning survival motor neuron (*SMN*) gene with a functional variant, providing a one-time treatment that has demonstrated the ability to halt disease progression and enhance patient prognosis.

Advancements in biotechnology and synthetic biology, especially using DNA and RNA technology, are facilitating the emergence of novel treatments for complex and individualized diseases such as cancer, which varies from person to person even within cancer types. Merck, for example, is developing V940, a novel mRNA-based individualized neoantigen therapy, with Moderna (see https://www.merck.com/news/merck-and-moderna-initiate-phase-3-study-evaluating-v940-mrna-4157-in-combination-with-keytruda-pembrolizumab-for-adjuvant-treatment-of-patients-with-resected-high-riskstage-iib-iv-melanom). This therapy, consisting of a single synthetic mRNA coding for up to 34 neoantigens, is designed and produced based on the unique mutational signature of the DNA sequence of the patient's tumor.

The move towards personalized therapeutics also alters the roles of health-care providers, patients and payers, necessitating smaller, more adaptable and tailored clinical trials, as well as the formulation of new end points and evidence. It is also foster-

ing partnerships between pharma and emerging entities with a stake in the personalized therapeutics landscape, including technology firms, start-ups and non-profit organizations, to make the most of digital resources and platforms in the creation of personalized therapeutic options.

The development of personalized medicine, however, faces significant challenges, particularly due to the small populations that these treatments typically target and the substantial financial risks associated with such limited markets. Pharmaceutical companies are often hesitant to invest in therapies for rare conditions, such as certain retinal dystrophies, owing to the high development costs and uncertain returns. Demonstrating the efficacy of these therapies through prospective trials with such small target populations further compounds these challenges.

There are also challenges in commercializing personalized medicines. Multiple drugs might need to be combined, which, in turn, could lower sales or increase costs. To achieve the economic viability of personalized medicine, it is essential to focus on improving R&D efficiency through targeted enhancements, such as better success rates and reduced cycle times.[p18] Customized strategies tailored to each company's specific needs, along with data-driven decision-making, can further optimize the development process.[p18]. Additionally, collaborations with external partners can help to distribute the risks and costs.[p18] However, the exact level of R&D productivity required for personalized medicine to be economically viable is still uncertain.

On the other end of the pharma value chain, the rise of digitalization and AI is revolutionizing how personalized content for marketing drug products is produced.[p19] The shift towards automating and tailoring content creation will transition marketing strategies away from a population-based approach to one that emphasizes individualized communications. AI's role in optimizing the content generation process significantly elevates efficiency by minimizing the time and resources dedicated to crafting promotional assets, thereby fostering engagements that are more precisely attuned to the specific needs and preferences of health-care providers and patients. This development significantly advances the shift towards more personalized health care, enabling marketing initiatives to be closely aligned with individual or group-specific health-care requirements.

In application, AI-powered tools are adept at analyzing extensive data sets to delineate distinct patient profiles and ascertain the most impactful communication tactics for varied demographics. For example, leveraging insights gained from an analysis of a patient's genetic makeup, disease condition and treatment trajectory, AI can produce individualized educational content or medication instructions. Such advancements not only improve patient engagement and compliance, but also coordinate marketing activities with the principal objective of providing tailored health-care services. The effects of these technological advancements promise to substantially boost marketing efficiency and accuracy and dramatically lower the costs associated with content production, with one report projecting a more than 20% acceleration in marketing campaign execution speeds (see https://www.mckinsey.com/industries/life-sciences/our-insights/generative-ai-in-the-pharmaceutical-industry-moving-from-hype-to-reality). This shift not only marks a transition to a more patient-oriented marketing model in the pharmaceutical sector, but also highlights the crucial role of digital innovation in improving the precision and operational performance of health-care communications.

Companies are already starting to use generative AI to create personalized marketing content for consumers. Novartis, for example, uses its Biome initiative (https://www.biome.novartis.com), a network of digital innovation labs that focus on leveraging AI and data analytics, to tailor patient engagement. Through the analysis of extensive data sets, Novartis can tailor its marketing content and educational materials to address the specific requirements of diverse patient groups and health-care professionals.

Nonetheless, as described in Chapter 1.1, the shift towards personalization comes with challenges, including ethical and legal issues around data privacy and consent, alongside the need for a cultural and organizational pivot within the pharmaceutical industry towards innovation and digitalization.

Chapter 2.1: Strategies for navigating the evolution towards personalized medicine

In reviewing the strategies employed by Pfizer, Novartis and Roche, it becomes evident that the pharmaceutical industry is encountering a pivotal shift towards personalized medicine. This evolution, similar to the preceding shift towards digitalization, necessitates the adoption of cutting-edge technologies, methodologies and paradigms, including the application of multi-omics and AI to devise treatments tailored to the unique needs of individual patients. This means that the successful realization of this potential is contingent upon the execution of several key directives.

To start with, regulatory frameworks must be updated to reflect the rapid pace of technological progress in the field of personalized medicine. Regulatory agencies need to streamline the approval processes for targeted treatments, preserving patient safety while accommodating innovative clinical trial designs focused on niche patient demographics and incorporating real-world data. The FDA is making strides in this direction through its draft guidance, 'Platform Technology Designation Program for Drug Development' (https://www.fda.gov/media/178928/download). This new guidance aims to accelerate the development and approval of products leveraging novel platform technologies such as mRNA. By providing expedited development timelines, enhanced regulatory support and streamlined review processes, the Platform Technology Development program is crucial for advancing personalized medicines, many of which will be developed using platform technologies. Consequently, although financial and logistical hurdles remain, the evolving regulatory landscape offers a pathway to more feasible development of personalized treatments.

Increased investment in the foundational technologies of personalized medicine will be crucial for this field to advance. This encompasses not only research into genomics and proteomics, but also the creation and refinement of digital systems that are capable of analyzing and synthesizing the extensive data sets produced by such research. The convergence of digital technology with personalized medicine through AI and machine learning will expand the industry's ability to pinpoint the most

effective therapies for distinct patient profiles, thereby reducing both the financial and temporal burdens of drug development.

Effective engagement from pharma with patients and health-care providers is also required to improve knowledge of these therapies as they emerge, particularly because they are likely to be developed using novel strategies or platforms. Clear communication regarding the advantages and constraints of these treatments is necessary to foster a comprehensive understanding of their implications for health-care delivery.

By incorporating these strategic recommendations, pharma companies can mitigate the challenges and risks associated with the shift towards personalized medicine and fully harness the capabilities of customized treatments. Personalization might not only be a solution to many current, hard-to-treat conditions, but also a significant opportunity for the industry to recalibrate its role, improve patient outcomes and position itself at the forefront of health-care innovation.

AIPs, which represent the future in the interface between health-care providers and the technology that underpins personalized medicine, encapsulate many of these recommendations. Using AIPs, health-care payers will be able to establish metrics for improved health outcomes and economics, delineating a new paradigm in value-based care. Simultaneously, academic physician scientists will develop algorithms that integrate multiple risk factors across major diseases, aiming to extend healthy living and prevent the progression of diseases in an aging population. Physicians, using the information compiled by both health-care payers and academic physicians, and leveraging AIPs, will aim to personalize treatments to get better outcomes, more cost-effective care and improved adherence to care plans. With more physicians prescribing personalized medicine, pharmaceutical companies will be compelled to optimize their product data sets, positioning themselves favorably in a new world dominated by AI, in which patients, physicians and payers will use AIPs to mine for the best, patient-specific medical solutions. Through this collaborative and technologically advanced approach, the promise of personalized medicine is closer to becoming a reality.

Chapter 3: Collaboration

That brings us to the third chapter in our rewritten textbook: collaboration. Although this is nothing new in the pharmaceutical industry, the shift towards digitalization and personalization will require collaboration among previously siloed departments and industries. Therefore, to ensure efficient delivery of pharmaceuticals to consumers, there needs to be collaboration among drug manufacturers, payers, physicians and their patients. This requirement for cooperation is particularly evident in areas such as the adult vaccine market, which could potentially see the entry of 100 new products in the next decade.[p20] Navigating this significant rise in product volume, and ensuring that patients receive the vaccines needed, will require coordination across vaccine recommendation agencies (e.g., the Advisory Committee on Immunization Practices of the US Centers for Disease Control and Prevention), those responsible for stocking the vaccines and those who administer the vaccines.

The pharmaceutical industry, especially in oncology, is increasingly fostering collaborations to leverage new scientific and technological advancements. These partnerships, spanning from pre-competitive consortia to focused collaborations, are crucial for combining expertise and capabilities to effectively address patient needs. For cell therapy-based oncology, noteworthy progress has emerged through the US National Institute of Health's Partnership for Accelerating Cancer Therapies (PACT), which brought together 11 pharmaceutical companies to accelerate the development of new cancer immunotherapies (see https://pharmaphorum.com/views-analysis-oncology/the-new-pharma-collaborations-driving-transformative-research-in-oncology).

Collaborative initiatives to align the requirements of health technology assessment (HTA) bodies and regulatory authorities are also gaining momentum.[p21] This push for alignment seeks to streamline regulatory processes and reimbursement pathways, ultimately enhancing patient care, fostering innovation and enhancing health-care system sustainability. Surveys indicate that both regulatory bodies and HTA organizations are increasingly involved in formal and informal interactions across the product life cycle, a crucial step in developing more efficacious and high-quality therapies.

Additionally, the pharmaceutical sector is embracing collaborative operational models to tackle challenges such as patent expiration and the complex regulatory environment. Companies are forging partnerships, even with competitors, driven by technological advancements that revolutionize health-care delivery and drug discovery. For example, major pharmaceutical players such as Boehringer Ingelheim are capitalizing on collaborations with technology companies including IBM to leverage supercomputing and AI to boost antibody drug discovery efforts
(see https://www.fiercebiotech.com/biotech/boehringer-plugs-ibm-trained-ai-model-boost-antibody-drug-discovery-efforts).

These examples demonstrate the pharmaceutical industry's capacity to utilize diverse collaborative ecosystems to amplify innovation and more effectively address health-care challenges. By adopting these collaborative models, the industry is poised to contribute significantly to a healthier future.

Chapter 3.1: Embracing collaborative ecosystems for innovation

To navigate the digital revolution and advanced personalization in pharma, a collaborative approach is required. Drawing from the trends observed in industry, this means leveraging third-party innovation, forming strategic partnerships and initiating projects with a social impact to propel innovation and extend the utility of traditional pharmaceutical products.

However, although collaboration in the pharmaceutical industry is nothing new, the tools and processes enabled by AI provide novel opportunities, offering seamless collaboration that was previously unattainable. In the past, pharmaceutical process typically involved discrete areas or functions within an organization working on their part of a problem or process, and then passing it along in a linear fashion. Now, there is the ability to work in parallel, allowing for marketing and regulatory departments, for example, to start working on the same material simultaneously. This evolution could fundamentally change how we structure and approach problems.

To fully capitalize on the trends discussed in Chapters 1 and 2 of this rewritten textbook for pharma, collaborative efforts need to begin within the organizations themselves. The acceleration of workflows driven by digital technologies will require collaboration across various organizational divisions, embodying a holistic approach in which discovery, commercial and supply chain teams can work together. For instance, advancing personalized medicines demands close cooperation between scientists in discovery and development alongside those in commercial strategies and supply chain logistics. This ensures that innovative therapies can be developed and efficiently delivered to the appropriate patients at the right time.

There also needs to be cooperation among previously distinct organizations. The entry of technology firms, start-ups and nonprofit organizations is notably altering the dynamic of the pharmaceutical industry. These organizations are employing their proficiency in digital technologies, data analysis and consumer engagement to meet previously unaddressed health needs, enhancing access, affordability and the quality of health-care services. Concurrently, they are creating new markets centered on wellness, preventative care and the management of aging, thus introducing competition and delivering additional value to the industry.

With the integration of multiple new organizations entering the space, there is a distinct need for increased cooperation throughout the pharmaceutical industry. The traditional divisions among R&D, production and market operations are fading, necessitated by the integration of digital technologies that allow for a smoother transition from the creation of drugs to marketing. For example, AI systems, such as Narrativia Generative AI, can be used to automate the incorporation of new data into regulatory documents,[p5] which can then be immediately used for marketing purposes upon their approval.

Furthermore, collaboration needs to extend beyond the usual industry limits to encompass diverse stakeholders, including academic institutions, regulatory agencies, insurance firms and patients, as well as 'big tech' and emerging start-ups. Such a collaborative approach will be crucial for addressing the complex challenges facing today's health-care industry. By combining resources and aligning objectives among these diverse stakeholders, it becomes possible to develop and provide innovative health solutions that are more effective, efficient and equitable.

Chapter 4: Innovation

'Innovation' serves as the culminating chapter of our revised textbook aimed at revolutionizing the pharmaceutical industry. It draws upon prior discussions on digital transformation, personalization and strategic alliances, demonstrating the integration of these elements in spurring innovation. Examples are provided in Table 1.

Innovation cycles are shorter than ever, forcing those in pharma to re-evaluate the speed at which innovation occurs. This is largely driven by the rise of digitalization, which has increased our capacity to generate and analyze data at scales never seen before. With RNA vaccines, we have entered the 'digital vaccine' era, in which creating a new vaccine mostly involves pairing an antigen sequence with specific modular components

TABLE 1

Pharmaceutical innovations and collaborations overview

Company	Innovation Initiative	Description	URL
Johnson & Johnson	JLABS	• Provides infrastructure, resources, and expertise to start-ups in biotech, pharmaceuticals, medical devices and consumer health	https://jnjinnovation.com/jlabs
	Without Disease Accelerator	• Focuses on preventing, intercepting and curing diseases through collaborations with academia, biotech companies and patient organizations, promoting preventative health care	https://www.janssen.com/world-without-disease-accelerator
Sanofi	Strategic Alliances	• Emphasizes alliances across biotechnology, technology and academia • Collaborations with Google and Alnylam to use data analysis for disease treatment optimization • Co-developing RNA interference (RNAi) therapeutics for rare genetic conditions, showcasing inter-industrial collaborations	https://www.sanofi.com/en/media-room/press-releases/2019/2019-06-18-05-00-00-1869971
AstraZeneca	Social Impact Initiatives	• Initiatives such as Healthy Heart Africa address health-care access and chronic diseases • Committed to achieving net-zero carbon emissions • Contributions to social and environmental well-being highlight the industry's role in tackling societal challenges	https://www.sanofi.com/en/media-room/press-releases/2018/2018-01-07-20-00-00-1284695
Pfizer	Ignite Program	• Open innovation with biotech companies in oncology and immunology • Offers services to expedite therapy development while allowing partners to maintain control over decision-making • Serves as a model for mutually beneficial partnerships that accelerate innovative treatment introductions	https://www.pfizer.com/about/partners/pfizer-ignite
	Pfizer Innovation Research (PfIRe) Laboratory	• PfIRe Lab is a highly instrumented clinical research facility, the mission of which is to develop and validate novel, patient-centric clinical end points using wearable and environmental sensors • Uses digital health technologies (DHTs) for the collection, development and evaluation of digital biomarkers	https://www.pfirelab.com/

(e.g., an RNA construct and delivery vector) that best suit the disease target.[p22] This is leading to the rapid generation of new vaccines, which could overwhelm the market if stakeholders across the value chain are not prepared for the expanded vaccine volume.[p20] Such innovation cycles will only get shorter with the broad implementation of generative AI.

Generative AI, for example, allows for the use of AI researchers (AIRs) that can revolutionize the design of new modalities, such as gene therapies and mRNA drugs, and enhance the optimization of existing modalities, including oral small molecules and monoclonal antibodies. This approach is specifically designed to tackle systems biology on the basis of risk factor scores for the progression of disease, ultimately aiming to reduce the risk of symptomatic disease and promote healthy aging. AIRs will also allow for new product strategies that aim to prevent illness, treating early signs of disease or asymptomatic patients rather than treating advanced disease. These strategies will integrate new product approaches into existing standards-of-care in a more holistic manner and predict new, transformative drug combinations.

Chapter 4.1: Approaches for cultivating innovation ecosystems

For successful innovation ecosystems, a comprehensive, methodical approach is essential. It entails delineating the roles of various stakeholders, including academia, regulatory agencies, insurers, patients, tech firms, start-ups and NGOs. Methodologies such as the Innovation Ecosystem Map (i.e., a chart describing the stakeholders, organizational layout, and connection points of an area influencing the direction a field/technology), Canvas and Scorecard allow organizations to pinpoint and harness the distinctive capabilities, objectives and contributions of these varied entities.

Setting specific visions, goals and metrics for these ecosystems is imperative. Tools such as the Innovation Ecosystem Strategy (i.e., a strategy to participate in an innovation ecosystem towards an explicit goal), Roadmap and Dashboard are instrumental in tracking progress and ensuring alignment with broader objectives. Identifying and giving precedence to initiatives that satisfy ecosystem requirements, while securing the requisite resources and collaborations for their execution, are processes that can be streamlined by frameworks such as the Innovation Ecosystem Portfolio and Matrix.

The execution of innovation ecosystem endeavors mandates adherence to best practices, including open innovation, co-creation and design thinking, all underpinned by digital, data and cloud solutions. The ongoing evaluation and refinement of these efforts, informed by user and stakeholder feedback and established metrics, guarantees that the innovation pursuits yield tangible benefits and remain responsive to evolving demands and obstacles.

With escalating competition and change, the urgency for innovation in pharma intensifies. Pioneering new solutions and adopting avant-garde technologies and methodologies will empower the industry to stay ahead and fulfill changing consumer expectations. Nonetheless, this path entails challenges such as technological viability, market reception and regulatory compliance. Managing these challenges, cultivating an environment conducive to innovation and developing the necessary skills and infrastructure for enduring innovation will be crucial for long-term achievement.

By combining insights from digital transformation, personalization and collaborative strategies, and by moving beyond the boundaries of conventional methods, the industry can forge a trajectory towards more effective, patient-focused and forward-looking health products and services.

Conclusion

The pharmaceutical industry is currently experiencing significant change, primarily driven by technological advancements, increasing demand for personalized medical solutions, heightened interdisciplinary cooperation and a continuous need for innovation. These factors collectively are redefining industry standards, creating new benchmarks for efficacy and patient care, and opening novel opportunities for improving health outcomes and patient experiences. To remain competitive and successful, it is crucial for the industry to adjust its strategies, incorporating these elements into all areas of operation, including product creation, service provision and organizational practices.

Adaptation in this evolving landscape requires an intentional focus on agility and long-term investment in innovation. By applying the concepts and strategies detailed in this analysis, pharmaceutical firms can secure their place in the future of health care, not merely by overcoming the challenges and uncertainties of this transition, but also by capitalizing on the chance to revolutionize their contribution to the health-care industry. Such an approach will not only increase their value, but also amplify their impact, aiding in the creation of a healthier global community. This rewritten textbook, updated with insights from digitalization, customization, inter-industrial collaboration and innovation, offers a comprehensive strategy and vision for navigating the current complexities of the health-care field, signifying the industry's capacity to bring about meaningful change.

Competing interests

The authors declare no competing non-financial interests, but declare the following competing financial interests: C.H.J., S.M., K.H., M.C., J.M.T. and M.D. report that they are employees of Pfizer Inc. and may hold stock or stock options in the company.

Data availability

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Author contributions

C.H.J.: conceptualized the publication, developed the outline, researched sources, drafted and edited the manuscript, and provided strategic input. **S.M.**, **K.H.**, **M.C.**, **J.M.T.** and **M.D.:** provided strategic insights, edited the manuscript and provided research source material.

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