WHITE PAPER

Life Sciences Strategy & Innovation

Connecting Clinical Innovation with Commercial Success: An Example from Multiple Myeloma

Contents

Introduction

In the past decade, advancements in scientific research and digital innovation have revolutionized healthcare, with patients, caregivers and clinicians alike reaping the benefits.

At the same time, traditional clinical research has been augmented by new and expanded data sets that have accelerated the ability to identify diseases with precision, leading to targeted and effective treatments. Consider breast cancer: Once broadly defined, it's now categorized by several factors, from specific presentation areas to genetic profiles. As a result, multiple types of breast cancer[1] have been identified, leading to better diagnosis, targeted therapies and greatly improved patient outcomes.

The extraordinary clinical advancements seen in breast cancer are mirrored in other disease categories, most notably multiple myeloma (MM), where clinical improvements go beyond quality of life to possible cures.[2] And while these advancements hint at a bright future for patient outcomes, a noticeable disparity remains: Biopharmaceutical commercial models have not evolved at the same pace to holistically enhance patient outcomes through digital solutions.

So, what can be done to bridge the gap?

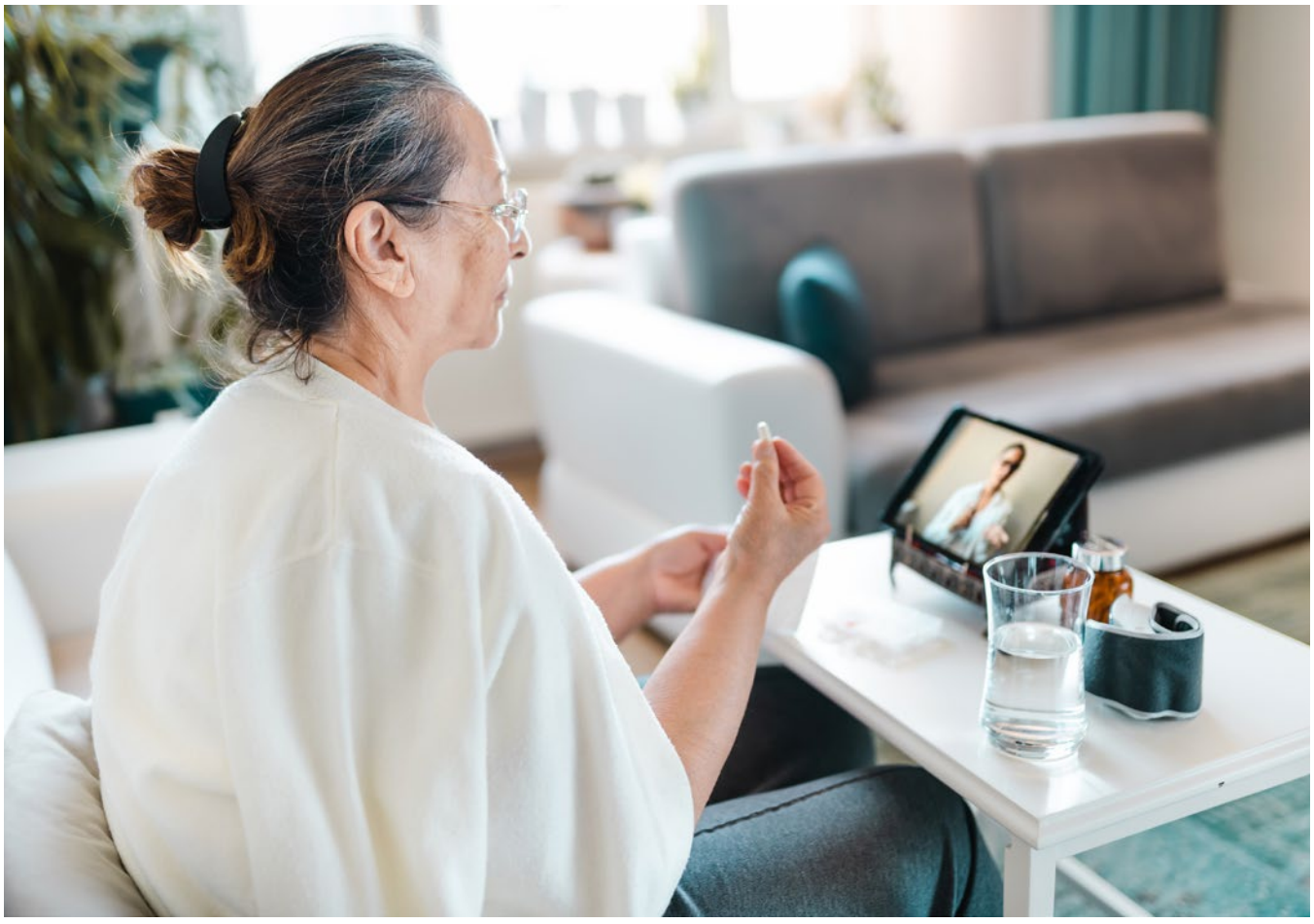
Using MM as an example, this white paper explores the evolution of current biopharmaceutical commercial models. By addressing key considerations essential for every healthcare leader, we illustrate the profound impact of integrating digital assets — from reshaping commercial frameworks and bolstering patient support to deepening clinician engagement and markedly enhancing health outcomes.

Multiple Myeloma: Clinical Gains Support Commercial Innovation

Each year, approximately 35,000 Americans[3] are diagnosed with MM, an historically fatal disease that more commonly affects older men. MM treatment has seen significant clinical advancements thanks to the emergence of immune-based therapies like chimeric antigen receptor (CAR) T-cell therapy. These therapies, whose benefits can be seen across all patient cohorts,[4] are enabling patients to live longer with their disease.[5]

However, in many instances longer life results in lower health-related quality of life (HQoL) due to MM symptoms such as bone pain, anemia, secondary malignancies, cardiovascular events and a higher susceptibility to infections.[6,7] As survival rates improve, HQoL monitoring for MM patients has become increasingly important.

In addition, the CAR T-cell therapy process involves a complex set of activities with varying degrees of challenges such as patient eligibility, timing, availability of apheresis units, observation of adverse events and long-term monitoring after discharge. Many of these steps involve seamless coordination, communication and management between patients, their clinicians and clinical facilities. The juxtaposition of potentially prolonged life with diminished HQoL, paired with the complex orchestration of treatment, underscores the opportunity for leaders in MM treatment to integrate digital solutions with therapy, thereby enhancing patient and clinician experiences.



Case Studies in Commercial Model Transformation

Biopharma companies face the dual challenge of addressing condition-specific treatment concerns, such as toxicity in MM, while simultaneously meeting the patient's desire for improved HQoL. To navigate these dual challenges effectively, it's vital for biopharma commercial models to be fortified with a robust digital- and data-driven strategy that delivers on three pivotal fronts: clinical, technical and human health.

Clinical

Digital health technologies can enable more discrete patient segmentation. By integrating longitudinal data on tolerability, adherence and patient-reported outcomes, including HQoL, they provide a more comprehensive patient profile and enable personalized care pathways. For instance:

- **Elekta Kaiku** (formerly Kaiku Health) developed an adaptive algorithm in collaboration with Tuku University Hospital to track nine of the most common symptoms that occur during MM treatment.
- **Memorial Sloan Kettering Cancer Center** used wearable devices to remotely monitor the activity of 40 newly diagnosed MM patients for six months. The study found that activity improved with treatment and that wearable devices can help doctors understand patient activity, health and treatment response.[8]
- **Click Therapeutics'** groundbreaking, fully remote clinical trial incorporated digital therapeutics as an adjunctive therapy for adults with major depressive disorder. This approach not only allowed for a broader and more diverse participation but also demonstrated the potential of remote patient monitoring and care, opening doors to future innovations in clinical research methodologies.

Technical

From intricate monitoring systems and novel biometric sensors to expanded functionality of consumer hardware and intuitive apps, today's healthcare solutions can seamlessly blend technology with care, ensuring that patients not only receive treatment but also gain access to real-time insight, support and monitoring tools that enhance their healthcare journey. For example:

- **Roche** and **Lark Health** introduced a personalized digital care coaching program that supports its users in improving their cardiovascular health. The app leverages conversational AI and connected devices, including personalized coaching techniques, to support patients in better identifying and managing their risk of developing cardiovascular disease.[9]
- **Otsuka** and **Proteus Digital Health** incorporated sensor technology within the mental health drug, Abilify, ensuring medication adherence and providing real-time data on drug consumption.

Human Health

Digital solutions and platforms have the unique ability to provide personalization at scale. Complex treatment regiments like cell therapy and conditions with multiple co-morbidities such as MM demonstrate how data and analytics tools can create unique opportunities to deliver treatment and improve a patient's quality of life. For instance:

- **Daiichi Sankyo** collaborated with three technology partners to create a combination smartphone application and wearable echocardiogram monitoring device to improve timely detection and diagnosis of atrial fibrillation (AF). Not only does this technology enable detection and diagnosis for otherwise hard-to-reach patients, but it also gives them confidence and autonomy, knowing they can be monitored remotely while still going about their daily activities.
- **Boston Scientific Cardiac Diagnostics** developed the BodyGuardian, a compact wearable heart monitor that provides patients with vital data while ensuring patient comfort and HQoL. Being waterproof, BodyGuardian offers freedom and flexibility, while its integrated digital platform keeps both patients and healthcare providers informed, bridging the gap between clinical care and daily living.
- **VIRGO Project at UC Davis Health**[10] explores the potential of deploying AI to enhance ovarian cancer care. The app enables patients to instantly report symptoms and, integrated with electronic medical records, offers real-time feedback and treatment recommendations, with a goal of improving patient adherence and quality of life.

Each of these examples demonstrates how digitally powered tools and solutions can enable biopharma commercial models to address patients' desire for improved quality of life while simultaneously helping clinicians improve treatment. Unfortunately, we see limited enterprise-wide adoption of integrated therapy and digital solutions that provide commercial and clinical value. Biopharmaceutical commercial teams need to become as well-versed and equipped with data to prove the impact of digital solutions when paired with therapies as they are with therapy specific knowledge. The evidence must underscore how integrated treatment approaches deliver clinical efficacy, technical reliability and human-centric care.

Key Questions & Strategies for Advancing Holistic Healthcare Delivery

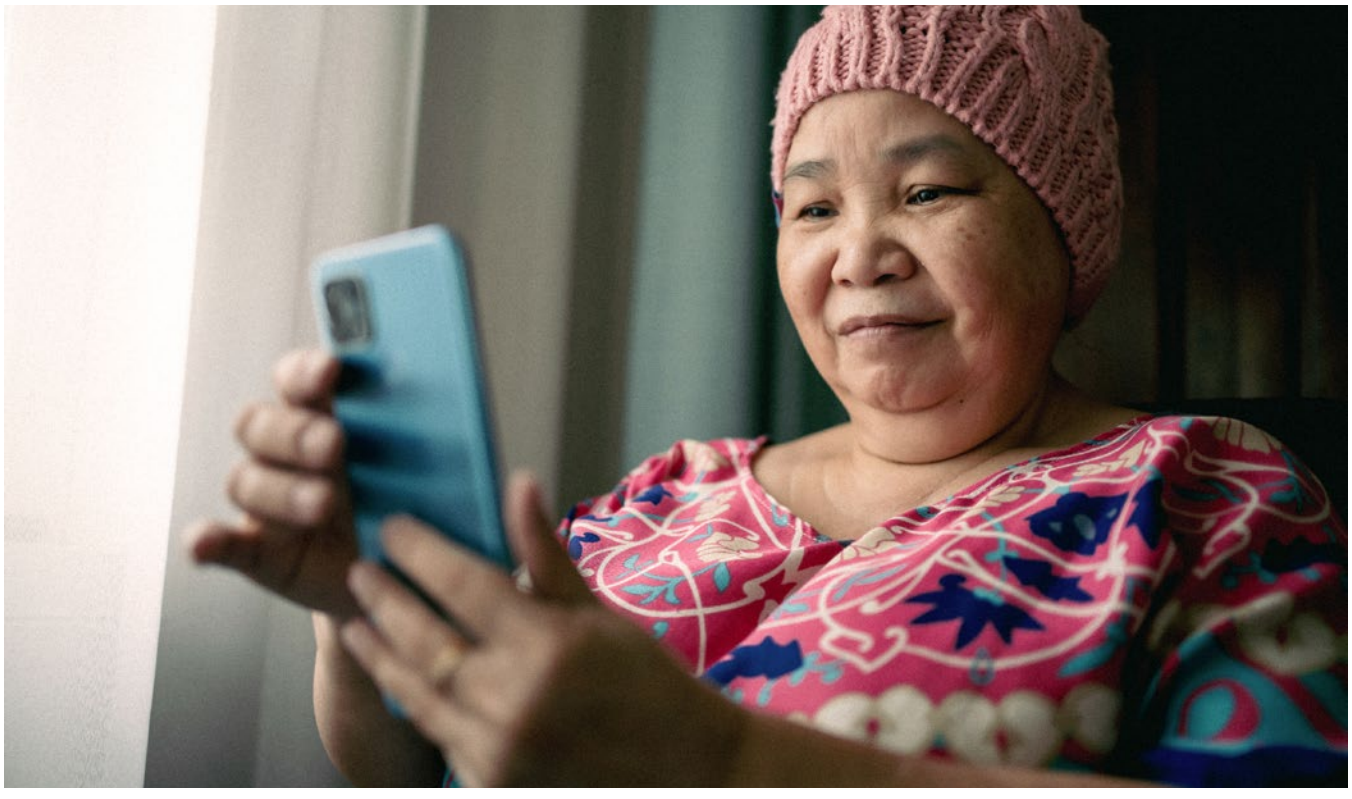
Robust, integrated digital solutions are instrumental to enhancing patient experiences. These digital tools not only provide crucial clinical data on key issues such as tolerability and patient-reported outcomes, including HQoL, but streamline complex treatment regimens to improve adherence across varied treatment settings.[11]

A fitting example is the GuideMe software developed by Fresenius Medical Care for its VersiHD dialysis machines.[12] Recognizing the potential difficulties patients could face in managing at-home hemodialysis, Fresenius introduced this software to guide patients and their in-home caregivers through the dialysis process, step-by-step. Such tools highlight the increasing significance of integrated digital solutions in bridging the gap between clinic- and home-based treatments.

In parallel, technological advancements have made it feasible for treatments like cancer therapies to be safely administered in outpatient settings, reducing the need for hospitalization.

This shift toward outpatient care complements the broader movement to value or outcomes-based reimbursement models, underscoring the importance of delivering high-quality care in the most cost-effective setting. Consequently, the spotlight has shifted to outpatient care due to its often-lower costs compared to inpatient care.

Yet as promising as these new technologies are, they introduce unique operational challenges that are distinctly different from traditional biopharma environments. As commercial leaders look ahead, they should prepare by asking the following questions.



01

Data Ecosystem & Market Sensing

Question: How does a biopharma manufacturer create and sustain a dynamic data ecosystem, including forming new partnerships for diverse data access (e.g., RWD/RWE, claims, patient-generated data including health apps) and integrating emerging data sources?

Recommendation: Biopharma manufacturers launching their first therapy or digital product may wish to start with an existing, robust ecosystem such as Apple's HealthKit and ResearchKit. As an established ecosystem, its governance and standards for integration, portability and quality simplify many of the requirements needed for successful digital solutions. However, not everyone uses an Apple device, and Apple devices may not provide direct or inferred data relevant to and related to a biopharmaceutical manufacturer's targeted disease state. Leaders should have capacity to operate across both IOs and Android platforms as well as seek best-of-breed developers of new biometric sensors and apps.

02

Cloud Infrastructure & Digital Engineering

Question: How should cloud infrastructures be optimally leveraged for data storage, computation and integration?

Recommendation: A multi-cloud strategy adds complexity to any biopharma operating model, but also provides flexibility, cost optimization and capabilities that serve distinct needs. For example, Microsoft Azure Industry Cloud for Healthcare provides FHIR and DICOM APIs, a patient portal, healthcare bots, HIPAA-compliant Teams messaging and telehealth and EHR and medical research integration. AWS for Health delivers advanced analytics, machine learning and data storage capabilities, plus EHR integration, imaging, genomics and diagnostics analytics and tools for telemedicine and personalized care. The Google Cloud for Lifesciences and Healthcare supports innovation in health research, including genomics and drug discovery, plus it supports continuous patient care and telemedicine. Manufacturers should consider a multi-cloud strategy that allows them the flexibility to deploy digital solutions on the cloud environment most aligned to their commercial needs.

03

Team Resourcing, Enablement & Capabilities

Question: How does a biopharmaceutical manufacturer resource and enable a digital and analytics team that can support new field commercial models requiring near real-time engagement?

Recommendation: Leaders need to identify the core technical capabilities that sustain their competitive advantage, which is not a static analysis. Cloud providers will continue to simplify the use of their platforms to enable non-technical staff, such as field leadership, to create new tools and solutions. Microsoft's Copilot and most recently, generative AI, demonstrate the robustness and speed with which new capabilities are deployed to enable digital solution development. Leaders must identify and invest in a core staff that possess differentiated skills in analytics, data and engineering. In addition, they should develop and maintain a robust partner network whose members can provide specialized or novel skills that augment internal teams for new projects, new technologies or bursts of activity, such as the lead-up to a commercial launch.

04

Personalized Engagement & Marketing Segmentation

Question: How can biopharma companies refine their marketing segmentation to specifically target patient cohorts within defined geographic markets and align with distinct customer profiles?

Recommendation: Data analytics and machine learning (ML) techniques can analyze large disparate data sets that when working together with healthcare providers and patient advocacy groups can help identify patterns and trends in patient behavior and preferences supporting more targeted and effective marketing strategies. For example, Veeva Crossix[13] offers a patient insights solution that uses privacy-safe technology and data assets to identify more relevant patient audiences. This solution connects actual patient-level hearth data with demographic, socioeconomic, consumer and media data, allowing biopharmaceutical brand managers to generate custom-defined patient cohorts that can be activated across media channels.

Question: What strategies should biopharma employ to integrate the provisioning and training of digital solutions seamlessly with traditional therapy support programs, ensuring a co-development approach with both pharma medical and commercial teams?

Recommendation: Consumers are conditioned to digital solutions that evolve alongside their adoption and usage. This accelerated dynamic of consumer (patient, caregiver and clinician) expectations for value is asynchronous with the development of clinical insight. Leaders need to adapt product development, commercial functions and compliance to support concurrent operating cycles for digital solutions and traditional product development. Consumer expectations for digital solution engagement and support now demand more direct and real-time interactions than traditional biopharmaceutical products, necessitating an evolution in how manufacturers provide and support these digital solutions.

The O-Bar by Ochsner Health[14] is one example of how a provider system is working with and across its ecosystem to meet consumers expectations for digital support. Going forward, collaboration with providers will be important to deployment and most importantly successful use of digital solutions. In addition, digital solutions present a new set of compliance obligations that in and of themselves are part of an evolving regulatory schema. Provisioning digital solutions and ensuring their ongoing compliance requires a nimbler operating cadence than traditional biopharma commercial models. Leaders will need to harmonize these different operating cycles to ensure success.

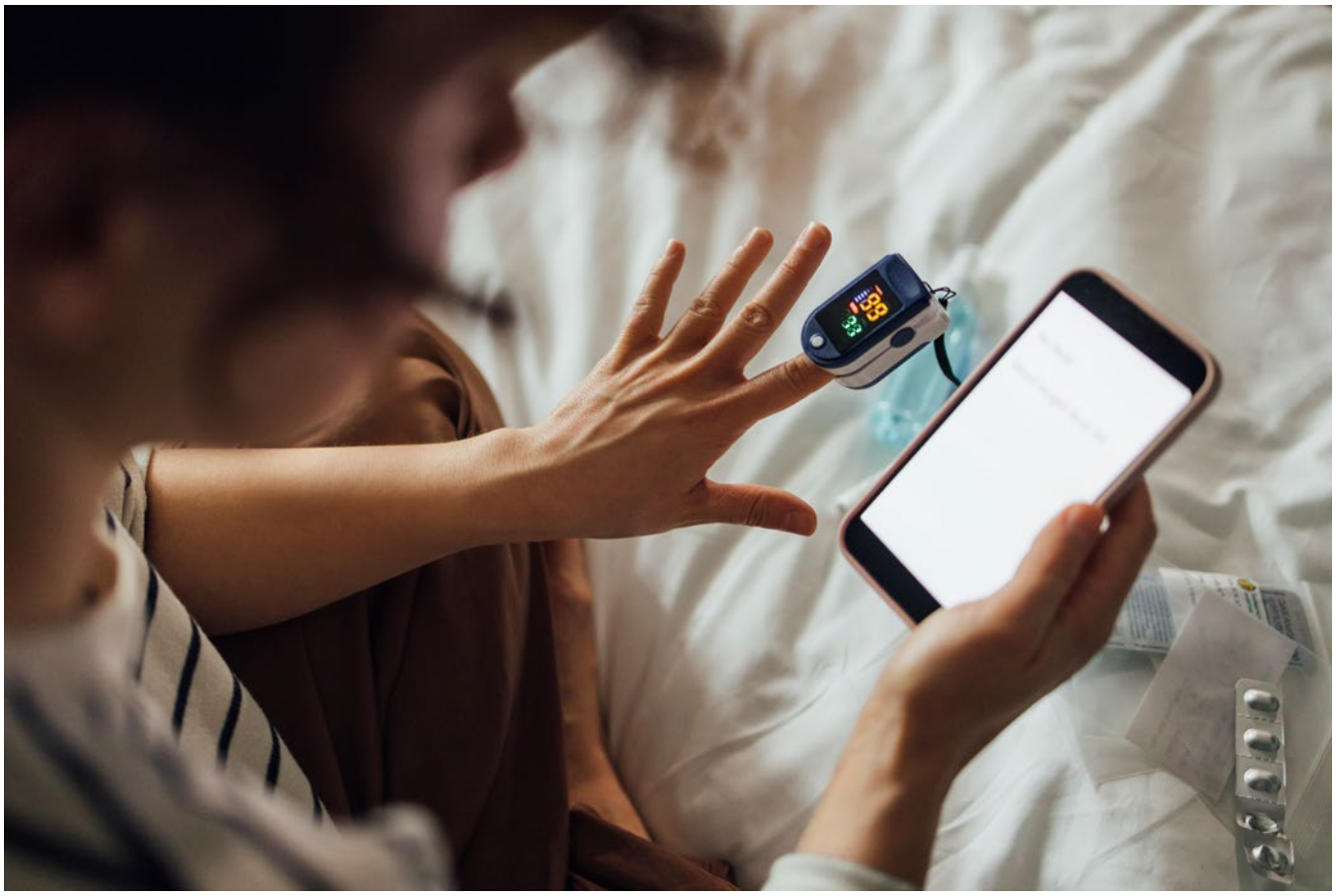
05

Regulatory

Question: How can biopharma companies gain market approvals that encompass both the therapy and an accompanying digital solution, ensuring their combined use achieves optimal health outcomes?

Recommendation: Advances in electronic sensors, computing platforms and digital technologies provide new opportunities to obtain real-time, continuous data from patients in their homes for clinical trial management or remote monitoring of chronic conditions. The successful development of novel devices and digital solutions requires significant collaboration between healthcare stakeholders to address regulatory, technical and life-cycle management challenges. PDUFA VII set out a framework for the FDA to foster industry engagement and promote the adoption of digital health technologies (DHTs), including sensors and digital tools. The FDA actively encourages stakeholders to engage early and directly for the use of DHTs in drug development or other purposes.[15]

The data captured by sensors and digital technologies are the foundation forRWD, and the volume of data collected can be extensive. Ensuring the data is **FAIR** facilitates the conversion of RWD into RWE that may predict disease progression, a patient's response to a therapy or the risk of adverse events. The FDA's clearance of consumer devices such as the Apple Watch and Fitbit for use monitoring users' heart rhythms for atrial fibrillation (AFiB) is another example of how sensors and digital platforms collecting real-time consumer data provide unique opportunities for new biopharma commercial models that integrate digital solutions.[16] In fact, a Bristol-Myers Squibb-Pfizer Alliance with Fitbit[17] seeks to deliver earlier diagnosis of AFiB for individuals at increased risk of stroke and as a result improving AFiB detection and encouraging people to visit their doctor to help reduce their risk of stroke.



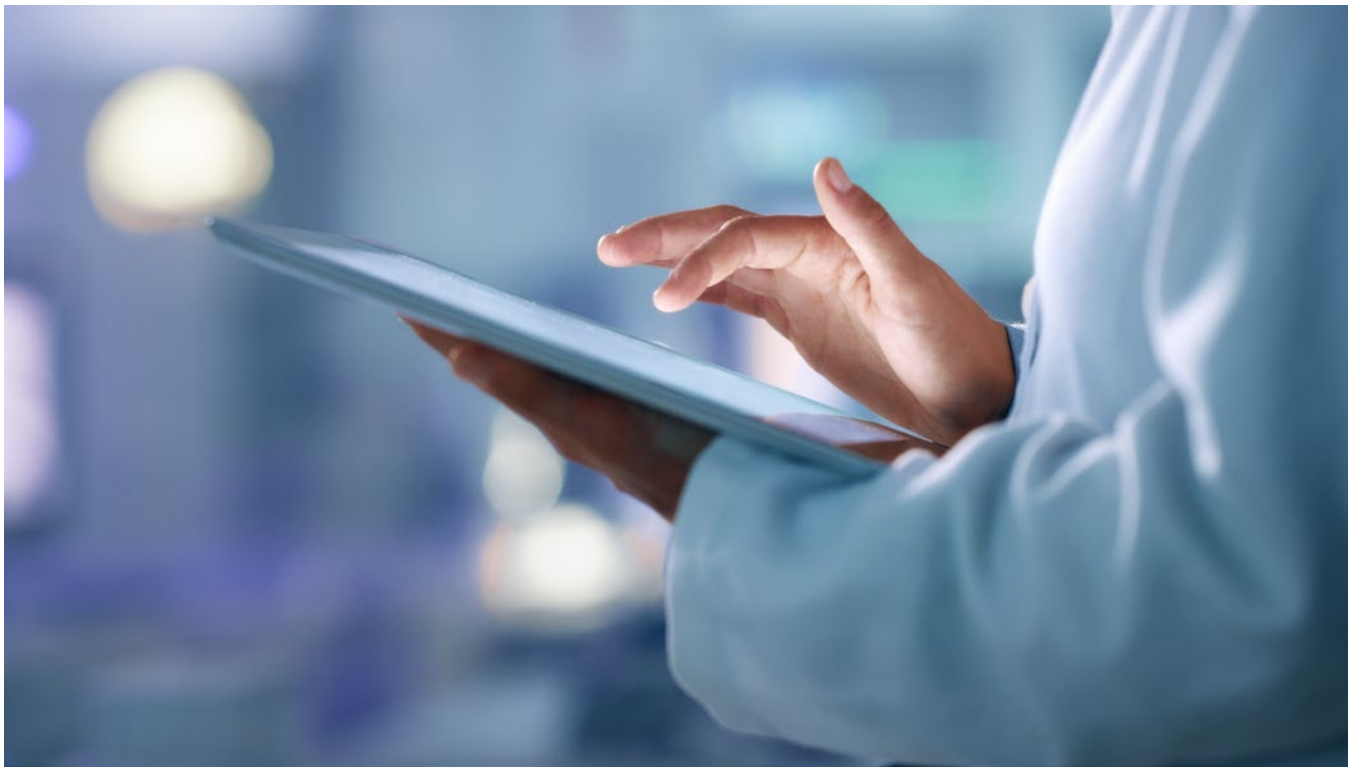
Conclusion

As biopharma commercial teams grapple with their mandate to deliver transformative, cost-effective treatments they have a new opportunity to accompany those treatments with digital solutions that elevate patients' HQoL, supporting new outcomes-based reimbursement models and delivering clinical, technical and health benefits.

The MM scenario is an instructive reminder: While clinical innovation has progressively enhanced patient outcomes, biopharma's commercial models have lagged, struggling to effectively combine digital solutions with HQoL. Leaders must move beyond simply exploring the digital frontier to integrating and deploying fully digital solutions.

As manufacturers assess how to integrate treatment and health solutions that deliver measurable outcomes, they are finding support in broader healthcare initiatives. One driving force is the Centers for Medicare & Medicaid Services (CMS), which is not only pushing for a shift of patients to outpatient settings and tying payments to outcomes but also championing quality improvements across the healthcare spectrum. The increasing emphasis on patient-centered care, preventive approaches and system-wide value, as outlined in the CME Quality Strategy,[18] further underscores the imperative for integration. In this landscape, digital solutions are evolving from mere enhancements to core components of future-ready healthcare models.

The challenge ahead is complex, involving rapid adaptation and a commitment to improving patient outcomes. However, the benefits are significant. Leaders who take on this challenge will not only advance their organizations, they'll also be instrumental in shaping the future of healthcare. In this dynamic narrative, digital solutions integrated within commercial models are no longer nice-to-haves— they're imperatives for any forward-thinking biopharma company.



Risks and Implications

Adapting and implementing new strategies is essential in today's dynamic market and digital solutions present unique challenges to the traditional biopharma operating model. However, evolving consumer demands and regulatory requirements make digital commercial models imperative.

BUSINESS & COMPETITIVE RISKS

The development, deployment and maintenance of digital solutions requires an operating cadence that is asynchronous with traditional biopharma operating models. The internal managerial, financial, regulatory and **operational adjustments** required should not be underestimated. As competitors make platform choices and realize commercial success from pilots and initial commercial launches, those success accelerate digital transformation. Those who are not already driving digital innovation risk lagging further behind.

TECHNOLOGY RISKS

Digital transformation of biopharma commercial models requires key platform decisions, such as cloud and data strategies. These choices must align with talent strategies, determining the essential skills the enterprise needs to maintain its competitive edge. The rapid pace of digital innovation necessitates an active market sensing capability to support an ecosystem of technology partners.

FINANCIAL RISKS

Traditional biopharmaceutical product development can entail substantial investments spread over multiple years. In contrast, digital product development may cost thousands, span only a few months and require an ongoing iterative development cycle. Biopharma commercial and financial teams need to adapt financial planning, modeling and risk models to allow for the more dynamic nature of digital tools and solutions.

These risks highlight the critical need for governance models and supporting operating activities such as financial planning, compliance and commercial activities to adapt to more agile ways of working in a digitally empowered, patient-driven care ecosystem.

The Patient Perspective on Digital Health Adoption

Digital health applications often face challenges in sustaining user engagement beyond the initial 30-60-90 days. From the patient's viewpoint, an ideal application should encompass:

INTUITIVE DESIGN

The **user interface** must be easy to navigate, catering to user needs with a seamless experience.

INTELLIGENT FEATURES

The application must provide clear guidance and support for patients, caregivers and providers, and adapt to changing needs over time.

INTEROPERABLE PLATFORMS

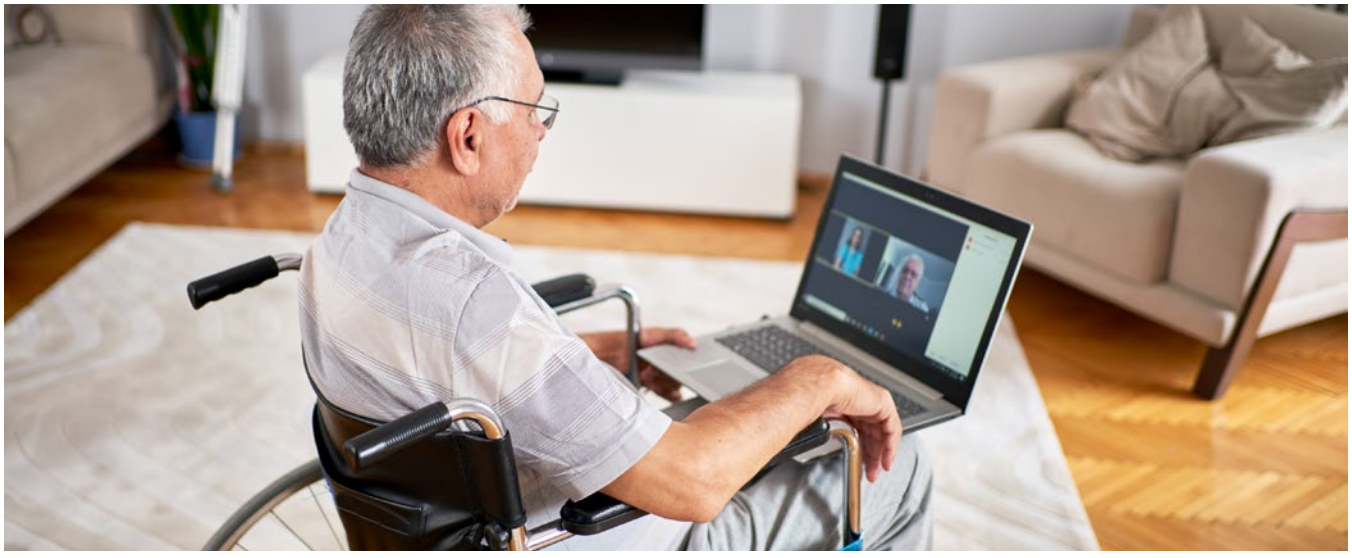
Digital solutions need to deliver out-of-the-box compatibility and reliability across various devices and platforms, whether clinical or commercial, to ensure smooth usage.

INTEGRATED EXPERIENCE

Applications and solutions should fit seamlessly into the **patient's** daily journey and experiences, facilitating engagement and interactions with providers and caregivers.

INVALUABLE INSIGHTS

Digital solutions should provide actionable data and documentation for the benefit of clinicians and patients while also supporting health outcomes and value-based reimbursement models.



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