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White Paper

DATA, DIGITIZATION AND DISRUPTION

Biopharma confronts the innovator's dilemma

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TABLE OF CONTENTS

INTRODUCTION

Over the last decade a series of market and technological changes has challenged biopharma companies to reimagine how they engage with key customers – and even to reconsider which customers are most important. As physicians increasingly share their central role in treatment decisions with other, often institutional stakeholders, manufacturers' traditional commercial model risks diminishing returns. The treatment decision-making process is shifting as rapid digitization amplifies the explosion of healthcare data sources and information. While the personalization of treatment strategies shows tantalizing promise, it rests upon the integration of multiple sources of information, drawn from multiple stakeholders, to provide tailored, precise treatments. Companies must envision a different model, designed to work across a more complex, multi-stakeholder landscape, in which their own role must evolve.

For many companies, the involvement of multiple decision-makers presents a central challenge, since the prevailing commercial model rests upon the physician as its cornerstone. Today, manufacturers must navigate more complex ecosystems in which physicians play only one part. As these ecosystems develop around therapeutic areas, knitting together a diverse mix of stakeholders – payers, patients, hospital administrators, trial sites, registries, regulators, patient groups, and other data owners – how can companies ensure they remain a critical part of the value chain? Around which customers should companies organize? At what things must a company excel to demonstrate and deliver value to a complex, evolving stakeholder mix? At minimum, companies must confront the transformation of the value chain and secure a lasting role within it.

In this paper, we explore the principal pressures buffeting the industry's commercial model and identify the elements necessary to succeed in this more complex environment. We also identify some notable risks, including some tempting strategic choices likely to fail.

By considering these drivers of change, companies can develop an operating model fit for purpose and quickly adaptable to the scope and speed of changes necessitated by an increasingly interconnected, data-rich customer ecosystem.

Companies must confront the transformation of the value chain and secure a lasting role within it

A CHANGING ENVIRONMENT

In our research we have identified four key trends challenging the prevailing operating model: the proliferation of healthcare data, accelerating digitization, the eclipse of the physician-centric model, and the altered role of manufacturers in the evolving healthcare value chain. We discuss each of these trends below.

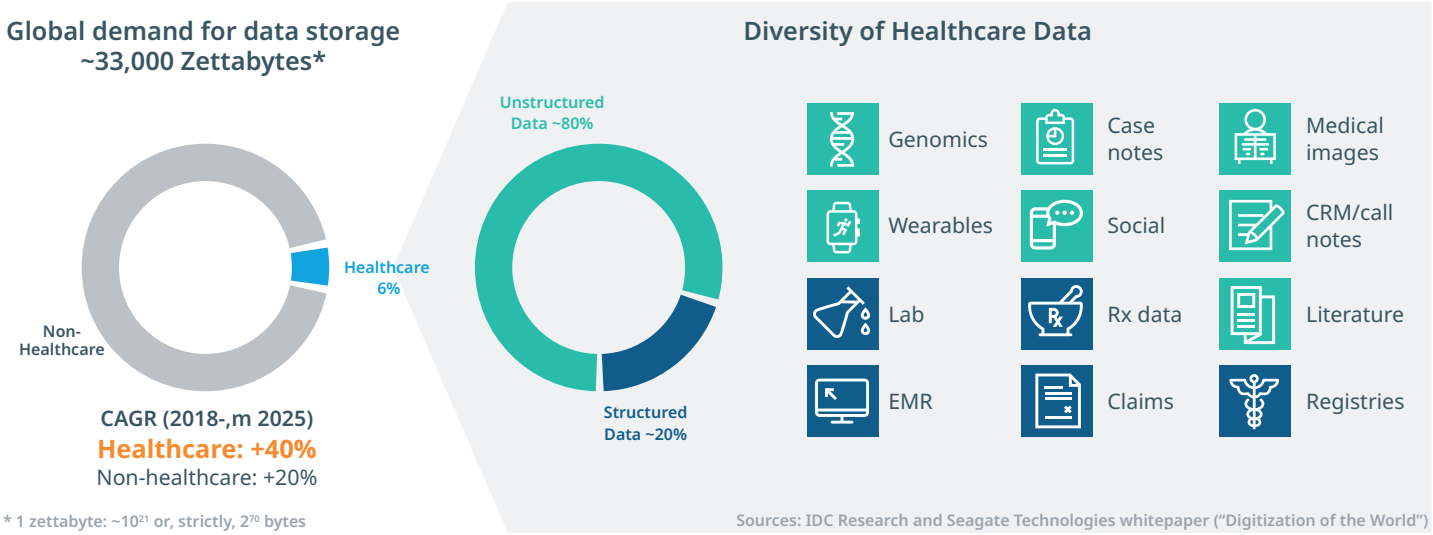
TREND 1: THE PROLIFERATION OF HEALTHCARE DATA ALLOWS CUSTOMERS TO MAKE EVIDENCE-BASED DECISIONS INDEPENDENT OF BIOPHARMA

Institutional and integrated customers increasingly rely on their own or independent data to inform clinical assessments, coverage decisions, and treatment recommendations. Rapid digitization and technological advances enable them to amplify and expand their reach and influence, further eroding the centrality of the physician. In this expanded customer universe, individual stakeholders can leverage their own internal data to determine which treatment strategies work best in their own populations.

Further, they can combine their data with additional information from third parties, including registries, academic institutions and, more recently, technology companies like Google and Apple.

While manufacturers still have a role to play, the expanding customer universe will rely less on industry-provided information as the single source of truth. The near-monopolies over product narratives manufacturers have traditionally enjoyed over the life cycle have rested on information asymmetries that data proliferation and digitization promise to erode. Historically, with limited data available to providers, industry data assumed greater importance, and manufacturers have enjoyed outsized influence,

Figure 1: Growth of healthcare data provides a wealth of information that is directly available to customers



despite biopharma costs representing less than 15% of total healthcare spending in mature markets. But with more data available – and with third parties focused on healthcare treatment and diagnosis – the relative importance assigned to both manufacturer information and the industry itself continues to fall. Although many companies have begun to focus on personalized treatment models, these, too, will challenge current physician-centric approaches. Will physicians continue to drive decision-making, or will they simply prescribe the treatments identified by an algorithm built on integrated third-party data? Ultimately, companies' operating models and engagement strategies must evolve to reflect this fundamental change in industry structure.

Although a company's narrative control has always eroded as a product ages, today the process is accelerated, with important implications for launch and market access. Payers frequently consider initial access to be temporary or conditional, subject to modification pending the availability of more evidence, preferably based on their own data. Similarly, regulators already expect post-approval safety data, and have outlined an increasingly important role for real world data in their decision-making going forward. Payers can use their data to modify marketing authorization or coverage and renegotiate the price if a product's real world outcomes diverge from initial expectations.

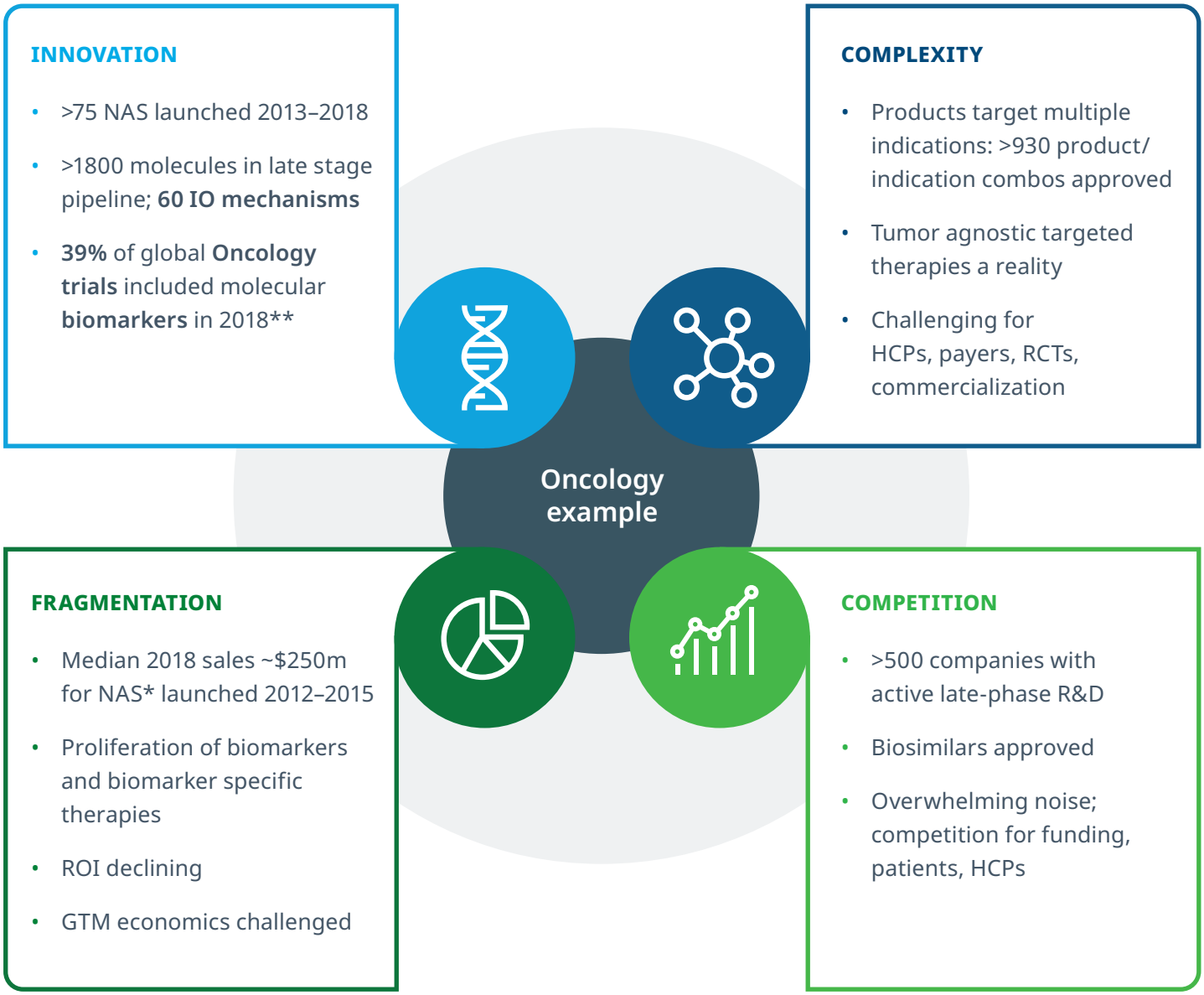
The commitment to generate post-approval data has been a key requirement for many products, often serving as the foundation of innovative access agreements. What represents a new challenge for manufacturers, however, is continuing to be part of the conversation, particularly as payers and hospitals grow more confident in their own data or collaborate with third parties to extract the necessary insights. Indeed, if manufacturers cannot offer greater value to their customers, they risk finding themselves on the sidelines. If the traditional engagement processes no longer create value for customers, those processes will be leapfrogged. And evidence shows that this is already happening.

> A large integrated health delivery system in the U.S. Midwest analyzed its own internal EHR data and determined that in its population, Avastin® delivered inferior outcomes in a solid tumor relative to alternatives, and subsequently deemphasized the product in its proprietary treatment pathway. Whereas manufacturers could historically combat relative disadvantage with attractive contracting offers, disadvantage based on a customer's own clinical outcomes data resists such simple remedies.

TREND 2: ACCELERATING DIGITIZATION AMPLIFIES THE EFFECTS OF DATA PROLIFERATION AND DEVALUES BIOPHARMA'S TRADITIONAL ROLE AS A KEY SOURCE OF CLINICAL INFORMATION AND INSIGHT

The application of digital tools and technologies to massive data sets opens up extraordinary possibilities for innovation, but – crucially – the role of industry in this new environment threatens to be very different. Whereas in the old world, manufacturers enjoyed near-monopoly control over information about their products – information a fragmented provider universe relied upon to inform treatment decisions – today networked providers collaborate using shared data and evidence to deliver high-quality, standardized care. Manufacturers can still find a seat at the table, but the rules – and customer expectations – are changing.

Figure 2: The changing environment brings innovation and new challenges



*NAS: New Active Substance, i.e. branded innovative products with a novel active ingredient which have been launched on the global pharmaceutical market for the first time
Information and all data from IQVIA Institute Oncology Trends Report 2018 unless otherwise specified (https://www.iqvia.com/institute/reports/global-oncology-trends-2018)
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The ubiquity and rapidly declining cost of technology has facilitated horizontal and vertical integration throughout the health system. Consequently, clinical information and healthcare data can be shared widely and easily across and between institutions.

Organizations that were once loosely affiliated, multi-specialty practices can now align on standardized treatment strategies across facilities, often leveraging their own proprietary data. Standardization will help to reduce variation in

costs, quality and outcomes, but it also exacerbates the trend of declining rep access. As provider organizations standardize, the value they assign to promotional activities falls, further eroding the returns from traditional detailing.

In addition, health systems, hospitals and providers have growing access to massive repositories of clinical, real world and genomic data. Combined with proprietary EHR systems, rapidly expanded access to registries, academic centers, and leading experts now enables provider organizations to punch far above their weight. Providers sharing their clinical information and imaging with academic and research centers can help to train diagnostic and treatment algorithms and, in return, benefit from better decision support tools. Shared data connected digitally can also help return value to health systems by informing predictive models to improve operating efficiency and resource use, including optimizing access to and use of scarce resources like infusion suites and specialist consults. Steadily falling costs will only accelerate the adoption of better technologies. As adoption of next generation sequencing (NGS) accelerates, providers will rely less on industry resources to analyze this data and draw their own conclusions from it.

At Moorfield Eye Hospital, the prestigious specialty center in central London, researchers have built a data set of >1 million retinal scans, mostly collected through a network of satellite sites but with a growing number provided by community physicians. The steady improvement of its diagnostic and treatment algorithms allows Moorfield to enhance everything from treatment outcomes to patient throughput, while offering the community better resources with which to manage patients. While the hospital frequently collaborates with industry, it does so as a peer, on its own terms.[2,3]

>1 million
retinal scans data set[1]

TREND 3: CUSTOMERS ARE CONSOLIDATING AND COLLABORATING TO FORM LARGER, MORE COMPLEX ENTITIES THAT REQUIRE A DIFFERENT OPERATING MODEL

Integrated, data-rich, digitally-enabled customers represent an increasingly important part of the healthcare landscape and play a growing role in the value chain. Consolidation and collaboration amplify the effects of data proliferation and digitization by facilitating and accelerating evidence-based standardization of diagnosis and treatment. If our image of a physician was once a white-coated man in his private practice, today and in the future, she is a digital native working in a team, supported by the data, systems and analytics of her hospital, health system or multi-specialty practice – or even an informal network. The renewed growth of telemedicine – catalyzed by digitization and rising patient expectations for real-time online engagement – extends this phenomenon ever further.

At the same time, many of biopharma's key customers now play multiple roles simultaneously. In addition to using manufacturer's products in treatment, many of these same organizations serve as key trial sites during clinical development. More importantly, data-rich providers and health

systems have become suppliers of critical clinical data, real world evidence, and innovative diagnostic and treatment strategies. Engagement with these customers represents a central priority for the industry – a priority for which the traditional physician-centric model appears poorly equipped.

Integration and centralized decision-making result in a more complex landscape for manufacturers to navigate and in which to exert influence. We see examples of this in both private and public health systems.

In Sweden, several county councils *(landstingens)* have formed a coalition to procure products together, collaborating to leverage their collective insight and bargaining power to achieve lower costs. In both Belgium and Italy, hospitals have established digitally connected networks to facilitate data-sharing, collaboration and standardization. We see similar trends in the U.S., with both horizontal and vertical integration creating larger, digitally-empowered organizations exerting growing control over diagnostic and treatment decisions. In all these examples, the effect has been to reduce the number of decision-makers and to standardize product selection and treatment across larger populations. In some cases, this risks creating tension between providers and other stakeholders seeking to optimize, respectively, patient- and population-level outcomes.

Notwithstanding the different incentives at work in markets as diverse as the U.S., Belgium and China, most health systems seek to reduce variation in cost and quality, and to minimize cost growth.

Consolidation and data proliferation, abetted by digitization and the rapid growth of low-cost computing and analytic capability, concentrate decision-making power. Larger organizations, armed with internal analyses of their and others' data, present manufacturers with a fundamentally different customer profile. If in the past a company could devote modest attention to a hospital or a payer to facilitate access to the more commercially valuable individual prescriber, the consolidation of decision-making and standardization of diagnostic and treatment strategies requires a re-examination of the relative priority assigned to key customer groups.

As larger, integrated entities simultaneously play the roles of prescriber, research collaborator, and data supplier, industry must shift to a business-to-business approach, built on true key account management capabilities that provide an accurate, 360-degree view of the customer. At the same time, a manufacturer must acknowledge that it is but one possible collaborator among many, and that exclusive agreements and pilots, especially those that impose high monitoring burdens, hold diminishing appeal for many providers and payers. Different customers have different priorities, so attempting to manage them all with the same, decades-old physician-centric model will yield ever declining returns.

TREND 4: PERSONALIZED HEALTHCARE AND FRAGMENTATION OF TREATMENT APPROACHES REQUIRE ACCESS TO AND MORE COMPLEX COLLABORATION WITHIN PATIENT- OR TA-SPECIFIC ECOSYSTEMS

For much of this century, industry portfolios have shifted towards specialty segments and away from the large chronic care classes that drove growth in the 1990s. The early 2000s brought associated shifts

in field resources, particularly an increase in MSLs and other specialists relative to the number of reps engaging with physicians.

While this trend continues, smaller indications targeting ever narrower subpopulations and the personalization of treatment strategies create additional challenges. The emergence of complex, innovative new therapeutic technologies – ranging from cell and gene therapies to tumor-agnostic, mutation-specific oncolytics – offer tantalizing potential, while simultaneously exposing customers to important financial risks. Organized, data- and technology-enabled customers will seek to limit their exposure to these risks, and many novel therapies, for all their promise, present considerable uncertainty about effect size, patient response and budget impact.

Manufacturers have in the past sought to de-risk their customers through "innovative" pricing and similar agreements. These strategies, while often elegantly designed, tend to solve the industry's problems, rather than those of its customers – a point reinforced by the comparatively high transaction and monitoring costs they impose. Myriad agreements requiring complex tracking and analysis, often across systems with limited interoperability, cannot be a sustainable solution to every manufacturer challenge. Indeed, as industry pipelines bulge with novel therapies, the collective burdens they present to provider organizations will precipitate more assertive responses. Conversely, companies that can de-risk their customers without imposing additional monitoring burdens can build a competitive advantage.

Larger, data-enabled customers can harness their own evidence and collaborate with other stakeholders to build ecosystems around a TA or even a patient. These ecosystems connect different organizations and resources – payers, hospitals, providers, academic centers and registries – to establish a richer, deeper evidence foundation from which to manage risk and complexity, and to ensure that patients benefit from complex therapies. Given their wealth of data and information about their products, manufacturers have a role to play in these ecosystems, if they can adapt their engagement models.

As therapies grow more complex and treatment decision-making is shared within interdisciplinary teams, industry's role must evolve. With stakeholders collaborating across ecosystems to share evidence, interrogate data and develop bespoke coverage and treatment strategies, industry must deploy different skills, ranging from data science and real world data expertise to transformative account leadership. Manufacturers remain important components of the healthcare value chain, but as other stakeholders integrate and collaborate, industry must reimagine its role, and how it creates value for the market, to ensure continued access to emerging ecosystems.

REQUIREMENTS FOR THE FUTURE

The historical fragmentation and diffusion of care delivery and the high entry costs and regulatory hurdles facing non-traditional competitors have helped biopharma remain stubbornly resistant to the massive disruptions that have hampered so many other industries. Today the industry faces a much stiffer test, as the information asymmetries upon which its customer engagement model rests are eroded. If manufacturers cannot adapt and thrive as parts of larger ecosystems that comprise a mix of data-rich, technology-enabled customers, they risk disintermediation.

Many manufacturers view themselves as key partners to their customers, yet in our research we find that most of those customers characterize the relationships as only transactional. Without substantial changes, the industry risks a downgrade in status, perceived as mere supplier of often expensive inputs, rather than a critical component of the evolving ecosystem. Such is what Clayton Christensen called "The innovator's dilemma."[4] How can industry navigate the transition successfully, and avoid the risk of finding itself on the outside, looking in?

THREE KEY PILLARS TO INFORM OPERATING STRATEGIES FOR THE FUTURE MARKET

What must manufacturers do? We identify three critical prerequisites for success in the data-rich, technology-enabled market now emerging:

1	2	3
		
ACCESS TO ASSETS AND DATA COLLABORATIONS	**ACCESS TO INFRASTRUCTURE AND ANALYTIC CAPABILITY**	**TRUST-BASED COLLABORATION**

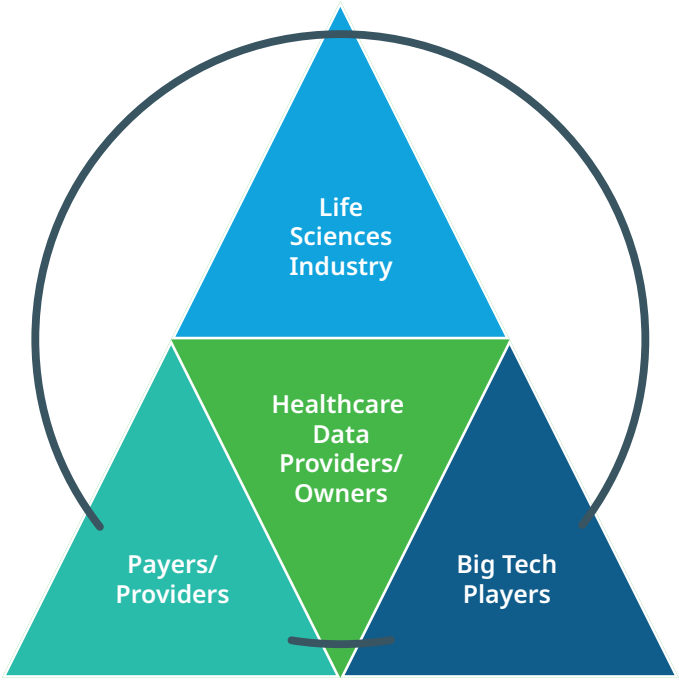
1. ACCESS TO ASSETS AND DATA COLLABORATIONS

In a market in which stakeholders leverage their data to collaborate across ecosystems, biopharma must not only adapt to growing customer data independence, but secure consistent access to customers' data. Not all data and information will be on offer to industry,

particularly without changes to the quality of current relationships and improved trust. Without a role in these emerging ecosystems, manufacturers risk finding themselves without a seat at the table when diagnostic and treatment algorithms are designed and deployed.

In return for access to their assets, customers will expect manufacturers to share theirs, as well, and to go beyond the phase IV studies designed to promote their products. Today, few manufacturers have conceived of a world in which their own massive reserves of data are shared widely with customers and other collaborators. Indeed, despite investments in massive data lakes, many companies still struggle to link their own data, let alone to clean, prepare, and encrypt it for external collaboration. Yet in a market in which access to data is critical, making their own data available to ecosystem collaborators represents an important prerequisite for access to others' data.

Figure 3: Different collaborators are willing to invest in building digital ecosystems



2. ACCESS TO INFRASTRUCTURE AND ANALYTIC CAPABILITY

The flood of data sources has enriched our understanding of many diseases, but at expected growth rates, it will swamp the capacity of most healthcare organizations to contain it, let alone to analyze it. Were 350 million Chinese EHR records suddenly to become available, they would overwhelm the infrastructure of all but a small subset of technology companies. As a result, when ecosystems need to scale or when they require best-in-class analytic and data science capabilities, they will need to secure access to sufficient infrastructure and analytic capability, likely by turning to firms outside the traditional healthcare value chain.

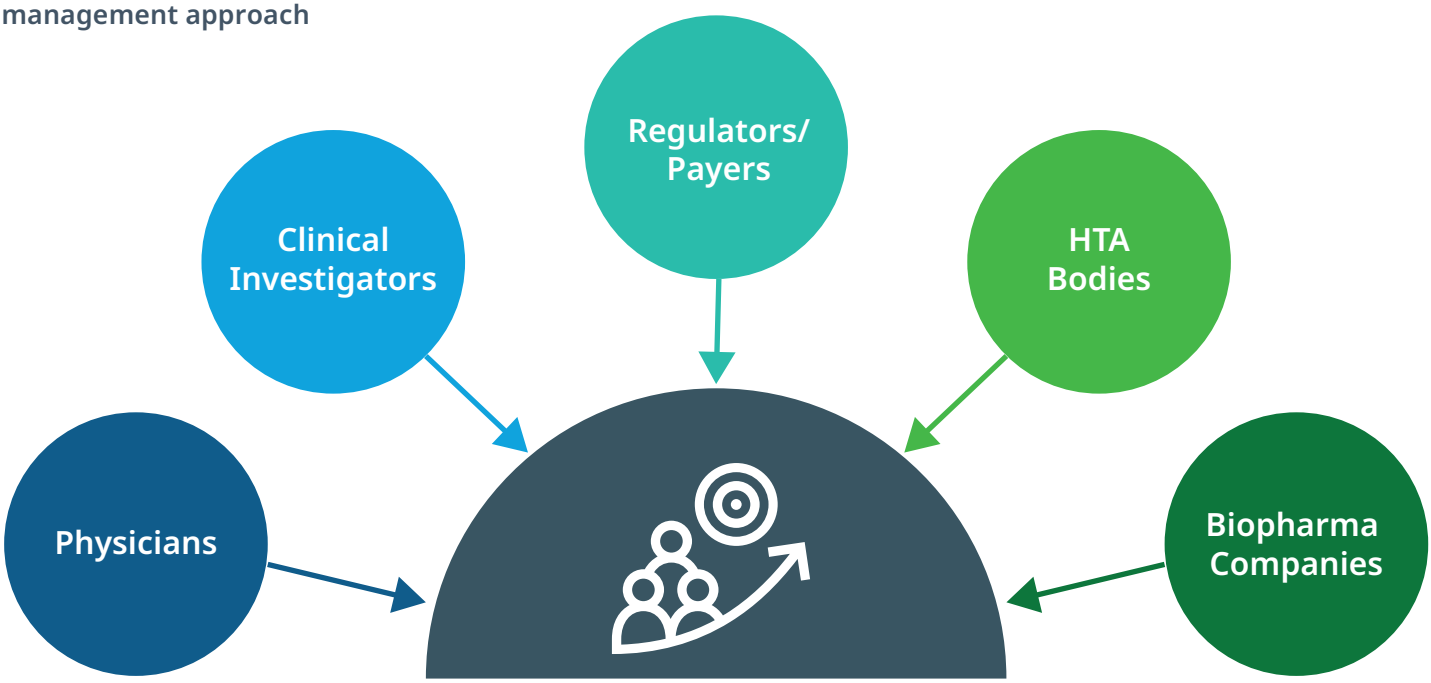
Ecosystem growth means that much of the most important data and information will sit outside of industry's control. New and emerging multi-stakeholder platforms combining data and advanced analytic power will provide significant opportunity for companies to inform everything from research and development decisions to commercial investment. The combined insights and analytic power from these emerging platforms will dwarf anything industry can do on its own.

3. TRUST-BASED COLLABORATION

Continued access to critical customer data and key ecosystems is by no means assured. Becoming a valuable partner in an emerging ecosystem requires both a different skill mix and – more importantly – a fundamental change in operating culture. As healthcare organizations evolve from passive customers to become both key research sites and critical suppliers of healthcare data and real world information, manufacturers must build trust, deepen relationships, and collaborate to achieve aligned healthcare objectives. This requires acknowledging where customers have different expectations for the relationship, unlikely to be satisfied with transactional point solutions.

The diverse combination of stakeholders – from individual clinics to patient associations to technology companies – that make up the ecosystems around a condition significantly increases the complexity of working with customers. Successfully facilitating cross-customer alignment rests on building trust and being perceived as an honest broker committed to shared objectives. While in some markets and systems there will remain a role for traditional promotional resources, manufacturers cannot expect to be accepted as a trusted partner while simultaneously doing their best to drive demand to maximize volume. This necessitates a massive upgrade of key customer-facing skills, expanding to include deeper field-based expertise in real world data, digital health, patient experience and data science. The role of key account managers must evolve to facilitate and manage more complex interactions between sophisticated organizations, and to foster co-creation and development of improved diagnostic, treatment and care delivery strategies.

Figure 4: Multiple stakeholders influence treatment decision-making, requiring an integrated account management approach



We believe these three key pillars should inform the operating strategies for the future market. While each company's portfolio presents different imperatives – the near-term consequences of these market changes can vary by TA and geography – the supply of data will continue to grow, and technology and analytics costs will only decline. As information asymmetries collapse, manufacturers must prepare to operate as true partners and collaborators, rather than the quasi-monopolists of the mass market era.

With that in mind, biopharma must also resist the Siren's song of some other strategic options we believe unlikely to satisfy the demands of the evolving market. Among these, the temptation to "own" the data is perhaps most pronounced. Whereas most other stakeholders in the market see data proliferation as creating opportunities to capitalize on knowledge and improve care, manufacturers, particularly those with assets in late-stage development, view new data as potential risks to their products. As David Shaywitz has noted, this "negative optionality" has led companies to seek to control or own the flow of data – something no longer possible given the sheer scale of available information.[5] Additionally, portfolios evolve and data needs change. Massive investments in data acquisition and ownership reduce agility and can consume capital unproductively. In contrast, the companies that excel in sharing data and collaborating with minimal friction will have a distinct competitive advantage.

Companies also frequently speak of focusing on the patient as a consumer and redesigning their operating models to better respond to consumer choice. This approach has some important weaknesses. Notably, while data proliferation has eroded information asymmetries between industry and data-rich, multi-disciplinary customers, patients remain largely at the mercy of providers, and will generally not drive treatment choice. More importantly, patients themselves play a growing role within treatment ecosystems, beyond that of mere care recipients. With wearables, passive monitoring apps, and other digital tools, patients represent an important source of data about real world product effectiveness and experience living with a condition. As the importance that regulators and HTAs assign to patient experience grows, manufacturers must build the capabilities to understand patient perspectives and deliver the solutions – products, services and experience – patients need. But as with other stakeholders in the ecosystem, this is a two-way relationship, and patients' data has real value. Willingness to share sensitive personal information with biopharma is not assured, so industry must move beyond seeing the patient as merely a consumer, but rather as another key part of the ecosystem.

Finally, many companies have explored potential vertical integration strategies, seeking to augment their current businesses with additional services. In addition to obvious challenges associated with regulatory hurdles, high investment costs and the

Organizations that excel in sharing data and collaborating will have the edge

integration of a different business model likely to offer lower margins, the success of this strategy is also at least partially dependent on being perceived as an honest broker. If other stakeholders distrust industry's motives, how likely will they be to turn to it for care delivery services? Indeed, integration does not solve the central problem of trust. Rather, a strong base of trust represents a pivotal prerequisite for vertical service expansion.

Patients represent an important source of data about real world product effectiveness and experience living with a condition

CONCLUSION

The proliferation of data and rapid digitization have at last begun to transform the delivery of healthcare, breaking what have been called the “traditional constraints of time and place.” Digital tools enable collaboration across geographies and connect central expertise to providers in far-flung satellites. The standardization of diagnosis and treatment strategies offers an important opportunity to reduce variation in cost and outcomes, and the application of advanced analytic techniques to rapidly expanding data sets hints at the promise of steadily identifying biomarkers and patterns to better inform research and treatment.

At the same time, these trends have eroded the industry’s traditional informational advantage, and threaten to further devalue the role of biopharma in the healthcare value chain. Continued improvements in operational efficiency will help, but they cannot compensate for the growing misalignment between an operating model centered around the physician and the transformation of the industry into a business-to-business market.

Data and technology represent essential enablers, and enhanced skills in data- and digitally-based engagement are important prerequisites for success. Most critically, however, manufacturers must plan for a future in which they represent only one part of a broader ecosystem. The size and importance of that role can vary, but it will reflect the extent of openness, collaboration, and trust that characterizes manufacturers’ relationships with data-rich, digitally-enabled customers.

In this new world, companies must redefine who their customers are, and then design their operating models to ensure that each engagement is meaningful and helps to establish and strengthen a foundation of collaboration and trust. This requires a B2B model with payers, health systems, and other institutions at the core, and systems that ensure a 360-degree view of stakeholder interactions. A single institution may be provider, data supplier and trial site, and will expect engagement that reflects each of these roles. Lastly, companies must find new ways to engage with prescribing physicians, a steadily rising share of whom will be digital natives who have grown up in team-based, technology-enabled environments. The alternative risks disintermediation and steadily eroding relevance in a dynamic, valuable healthcare market.

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