McDermott Will & Emery

Transformational Healthcare Collaboration Opportunities Emerge from COVID-19 Pandemic

We highlight the challenges and opportunities as the digital health and life sciences industry charts a course through the post-pandemic changed healthcare landscape.

The Coronavirus (COVID-19) pandemic suddenly and permanently changed healthcare delivery and the economics of healthcare services and other digital health products and services in the United States and around the world. This seismic, virtually overnight transformation, has flung open doors to innovation, as a diverse cross-section of digital health and life sciences stakeholders mobilize crisis resources; adjust operations for enhanced screening, sanitization and social distancing measures; harness telehealth capabilities to deliver healthcare remotely, and identify opportunities for smarter, better healthcare going forward.

We highlight the challenges and opportunities that digital health and life sciences operators and investors should consider as the industry charts a course through the post-pandemic changed healthcare landscape.

DIGITAL HEALTH

Telehealth and Remote Care Are Here to Stay

Telehealth adoption rates exploded as healthcare providers rushed to leverage this solution to care for patients while complying with stay at home orders and restrictions on elective procedures (defined broadly in many cases), coping with strained provider resources and accommodating social distancing requirements. Providers have largely set aside the debate over whether telehealth allows for quality patient care and are turning to *how* telehealth can facilitate quality care. States and federal governments have removed obstacles to adoption and use, including antiquated licensure and reimbursement policies, at least for the duration of the public health emergency (PHE). Some key takeaways:

- The Coronavirus Aid, Relief, and Economic Security (CARES) Act and subsequent actions supported telehealth services by lowering long-standing barriers to Medicare reimbursement and acknowledging the central role telehealth plays in coordinated care delivery.
- The Centers for Medicare and Medicaid Services (CMS) changed its Medicare payment requirements to allow traditional Medicare beneficiaries to access telehealth services from home, with reimbursement similar to amounts paid for in-person medical services.
- The Office of Civil Rights, the US Drug Enforcement Administration and other agencies loosened restrictions to allow providers to use technology to deliver telehealth services.
- State emergency declarations and orders aimed to expand Medicaid coverage and ease licensure barriers.

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- The increased utilization of telehealth services is likely to be self-reinforcing, as patients adapt to new modalities for care delivery and payors appreciate the cost savings of treatment outside of the acute care setting.

Regulators have signaled that some changes made during the PHE may become permanent. If there is a silver lining to the COVID-19 pandemic, it is that the need for telehealth services has given regulators empirical evidence that, generally speaking, practical benefits far outweigh risks that previously drove regulatory limitations. Moreover, regulatory innovation may be an inevitable need as more consumers become accustomed to telehealth and appreciate the efficiency and convenience remote services afford. Indeed, for higher-risk patient populations, telehealth may become the preferred modality.

Changing attitudes toward telehealth services will continue to spur innovation. For example, we anticipate better integration of telehealth services in skilled nursing facilities, nursing homes, and assisted living and independent living facilities, as infection control will remain an important focus for some time. Looking past the pandemic, we also anticipate continued integration of artificial intelligence (AI) systems into telehealth services to deliver more efficient care, help manage chronic conditions with remote patient monitoring and home-based sensors, and better coordinate the care of patients with multiple diseases and specialists.

Implementation of Digital Tools to Speed Care and Improve Outcomes

Prior to the pandemic, healthcare was centered on in-person provider-patient visits. Even so, health systems, health plans and others eagerly sought innovative and elegant digital health tools to better manage allocation of healthcare resources, monitor and coordinate care between in-person visits, and assist providers and patients in making healthcare decisions. The pandemic underscored the urgent need for such tools and increased provider and patient comfort using digital technologies for healthcare delivery.

This momentum will continue, particularly with increased use of remote monitoring, clinical decision support software, and supplemental patient engagement apps and tools that move toward an enhanced continuum of care. Digital health innovation will need to assist providers with making real-time healthcare recommendations, and improving patient adherence and follow-through on those recommendations. Digital tools also promise to equip stakeholders with additional resources to manage chronic conditions, enhance preventative care, accelerate recovery, and create additional connective interactions between providers and patients.

Technological tools also present new pathways for rapid data aggregation and analysis. These capabilities should allow providers to develop smarter treatment plans adapted to particular patients and conditions, with technological interfaces

that empower clinicians and patients to form a partnership for care delivery and management. That information and the associated outcomes will in turn provide empirical support for new payment models that can truly be outcomes-based.

To fully harness the power of these tools, however, companies must be thoughtful about how patients (and providers) interact with technology, how to acclimate users to technology and how to appropriately integrate digital tools into healthcare.

The pandemic highlighted what many have known for years: our digital health infrastructure lacks the necessary scale and integration

Data Readiness: Crucial to Future Healthcare Systems

All of these innovations are dependent upon more complete, structured data that can move seamlessly among healthcare practitioners, with the patient at the center. Government task forces and committees have worked to enhance data standards and multi-party connectivity, but these regulatory pushes were slowed by the health crisis when they were most needed.

Moreover, the pandemic highlighted what many have known for years: despite stakeholder efforts, our digital health infrastructure lacks the scale and integration necessary to obtain, harness and analyze data in real time across multiple players, including public health authorities. Challenges with broad-based testing and contact tracing during the pandemic exemplified how our disease identification and prevention systems were immature and insufficient. The real opportunity, however, is much broader. A new-found interconnectivity would allow industry stakeholders to identify trends, deploy resources where they are most needed during an emergency, and more actively engage patients in their care.

Enhancements to our global healthcare system data infrastructure are necessary, and the need is immediate. These enhancements include development and adoption of universal and standard data elements, as well as formatting, transmission and receipt technologies. Historical political and regulatory barriers should now be seen for what they were: unnecessary roadblocks that inhibited crisis readiness. The future for data standardization is now, and the COVID-19 crisis may have provided the catalyst for accelerated change.

Efforts to eliminate barriers to data interconnectivity are sure to restart post-pandemic. In preparation, all health system players should review the interoperability of their systems and their API readiness, evaluate their participation in health information exchanges (and even notification services), and identify how and by what methods they communicate with public health authorities to support disease identification and prevention. These information system building blocks will help health systems of the future position themselves to identify trends proactively and ensure that participants in healthcare, especially patients and providers, have the tools and information to respond together to head off disaster, improve access and quality, and lower costs. Privacy and security considerations will need to be addressed, but there must be balance between those considerations and successful data movement for optimal healthcare.

LIFE SCIENCES

As governments, health organizations and public health officials scrambled to mobilize and coordinate a coherent, effective and data-driven response to the global pandemic, the private sector – specifically the life sciences industry – has offered a beacon of hope.

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Speed and Innovation During Crisis

The speed at which the biotech sector pivoted toward innovation in the face of the global pandemic is unprecedented. Time will tell whether this more nimble approach is sustainable or has created its own set of risks that outweigh the benefits of delivering eventual results.

Despite global economic uncertainty, the health, technology and life sciences sectors converged with the investment community to innovate, collaborate and respond to unmet needs caused by the pandemic. The global race to develop successful tests, treatments and vaccines unleashed a dizzying amount of activity from biotech companies. According to Informa Pharma Intelligence, by the end of May 2020, there were 140 experimental treatments and vaccines for COVID-19 in development, including 11 in clinical trials.

Economic Strength of the Life Sciences Industry

The life sciences sector has demonstrated resilience during the economic turbulence caused by the global pandemic. Biotech companies are awash with more cash than at any time in the sector's history, with venture capital funding reaching $5.5 billion in the first three months of 2020, record numbers of strategic collaborations and partnerships, continued strong initial public offering (IPO) activity[1] and the NASDAQ Biotechnology Index nearing a five-year high. Since the beginning of March 2020, life sciences venture capital funds have raised more than $5 billion in new investment funds. Overall, it appears the biotech sector is less sensitive to macroeconomic swings, which provides some confidence that there may be less disruption to drugs and therapies currently under clinical development. While danger from COVID-19 persists, the need for solutions and willingness to make investments in search of those solutions will continue.

Government Investment in Life Sciences

The COVID-19 pandemic has demonstrated that the US government, specifically the Biomedical Advanced Research and Development Authority (BARDA), is willing to invest in the biotech sector. BARDA has awarded more than $2 billion to support COVID-19 vaccine development efforts. Given the severity of the economic downturn and the belief that government support is critical to recovery, it is likely that government support will continue and become more anticipatory relative to future viral and biological risks.

COVID-19 is Reshaping the Pharmaceutical Supply Chain

According to the Chemical Abstracts Service (CAS), the COVID-19 pandemic did not seriously impede production and shipment of pharmaceuticals in the first quarter of 2020. However, the supply chain may be tested in the coming months, as inventories of backup materials will be used and deliveries delayed. Further, as the world has recognized the dominance China plays in the global supply of active pharmaceutical ingredients and their

chemical raw material, the United States has led an effort to rebalance the supply chain. For example, BARDA awarded more than $500 million to two US-based companies for manufacturing and onshoring supply chains.

Machine Learning and AI

AI is also being deployed to screen billions of molecules for COVID-19 treatments. The MIT-IBM Watson AI Lab is funding 10 research projects aimed at addressing health and economic consequences of the pandemic, and various efforts to model the COVID-19 outbreak and provide scientific insights are being leveraged using AI and machine learning tools. There has also been robust private sector investment in companies using AI for drug development. According to PitchBook, there are 210 AI-powered drug discovery companies, with $8.14 billion in capital investments. Exponential growth in AI use can be expected.

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COVID-19 Regulatory Pathways

Almost every major pharmaceutical company worldwide is racing to develop effective therapeutics and vaccines to combat COVID-19. Although some of this effort is aimed at creating, testing and rolling out new treatments and preventatives, a significant part of this push involves taking a second look at existing compounds and possibly repurposing them to treat or reduce the rate of COVID-19 infection. To support this effort and enable faster access to promising treatments, regulators in the United States established several options that loosen or revise certain restrictions and simplify investigative and regulatory approval pathways.

US Food and Drug Administration (FDA)

In response to the COVID-19 crisis, the US Food and Drug Administration (FDA) has used several pathways and initiatives to facilitate or expedite access to COVID-19 therapeutics and vaccines. For example, the FDA issued emergency use authorizations (EUAs) that permit the use of unapproved medical products, or the off-label use of approved medical products, to prevent, diagnose or treat COVID-19 when – among other criteria – no adequate, approved and available alternative exists. The FDA is expediting the provision of feedback on development plans for COVID-19 vaccines and therapeutics through the pre-Investigational New Drug (IND) application process, which intends to help manufacturers address key regulatory questions before beginning clinical (human) trials. The FDA also implemented a Coronavirus Treatment Acceleration Program (CTAP), a special emergency program under which the agency will triage requests from developers of new drugs and biological therapies (excluding vaccines), connect them with appropriate FDA staff and provide rapid, interactive input on product development plans and/or study protocols. Additionally, the FDA has used its expanded access (or compassionate use) program to give patients access to certain treatments outside the scope of clinical trials. The FDA is expected to continue using these tools for the duration of the PHE. However, the agency's willingness to consider aggressive action to expedite the delivery of novel therapeutics and vaccines beyond the pandemic will likely depend on several factors, including (but not limited to) the agency's assessment of the risk/benefit balance of its decisions during the pandemic, and legislative activity that could modify FDA's "usual" regulatory processes.

Finally, the US government launched Operation Warp Speed, which can allow the federal government to select promising COVID-19 vaccine candidates, offer funding and resources, fast-track trial and aid in manufacturing efforts. While this project does not

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create any new regulatory pathway for vaccines, it does highlight a more intensified push by the federal government to infuse greater financial resources into the vaccine development process.

CAPITAL MARKETS

After a two month period of inactivity in March and April 2020, the US capital markets returned with a vengeance in May 2020, with an unprecedented number of public financings, particularly in the biotechnology space. This increase in capital markets activity, which took the form of private investment in public equity (PIPE) offerings, registered direct offerings, and traditional follow-on offerings, continued through 2020, in multiple sectors, including increased IPO activity.

The emergence of the special purpose acquisition company (SPAC) market also deserves special mention. While the SPAC structure has been around for over 25 years, 2020 saw a dramatic increase in the number of SPAC IPO filings, and more importantly, the completion of several SPAC merger transactions, often coupled with simultaneous PIPE financing transactions. The development of the SPAC market opens another avenue for emerging biotechnology, medical device, pharma and other life sciences companies to access the US capital markets.

Private companies looking to the US capital markets should be aware of the various alternative structures available to "go public" in the US. Companies already listed on the Tel Aviv Stock Exchange (TASE), for example, can consider either a dual NASDAQ/TASE listing arrangement, or a process in which a NASDAQ listing is achieved and a subsequent delisting from the TASE. However a company chooses to approach the US market, understanding the increased disclosure requirements (and corresponding increase in liability exposure), as well as the expectations of the public investor sector, are paramount to long-term success in the US capital markets.

As 2020 has demonstrated, while there will be short-term disruptions in the efficiency of the US capital markets for life sciences companies, both the attractive valuations and liquidity offered by these markets makes them a significant long-term opportunity that emerging life sciences companies should consider.

TRANSACTIONS

Although transaction volume in the healthcare industry reached all-time highs in recent years, the sudden and unanticipated cash flow and operational disruptions resulting from the pandemic slowed most M&A and other transactional efforts for strategic and financial investors.

The lasting impact of the COVID-19 pandemic on healthcare transactions is multi-faceted, with an eventual surge in deal volumes seemingly inevitable as parties cope with the financial and operational impacts on current businesses and execute on strategies for the "new normal." A few observations:

- Uncertainty about the duration of public health restrictions continues to inhibit deal-making, with perceptions of a "light at the end of the tunnel" likely unlocking a surge in deal activity. Already investors are exploring ways to beat the curve by underwriting some uncertainty in their valuation assumptions and correspondingly exploring options to hedge that risk through deferred payments and contingencies, which have to navigate a complicated lattice of economic, regulatory, tax and general alignment issues.
- With respect to EBITDA impacts, we anticipate that parties will generally look past short-term, non-recurring negative impacts to EBITDA arising from COVID-19 pandemic restrictions. However, smart investors will not assume a "return to normal," but will endeavor to evaluate what "new normal" will emerge for the target business. This is particularly pertinent for private equity investors looking for new platforms. By contrast, strategic buyers may consider their own COVID-19 experience to afford sufficient insight on a complementary target business's future revenue and expense profile, utilizing pre-COVID-19 pandemic EBITDA numbers, or extrapolations therefrom, for valuation purposes, particularly where purchase consideration includes a sizable equity component.
- The impact of COVID-19 on transaction multiples is less clear, with insight depending on when and to what extent the transactional market ramps back up and how the pandemic experience impacts credit terms. For private equity, the pandemic has stressed platforms built on highly-leveraged, buy and build strategies. Investors that failed to adequately plan for reduced productivity among selling providers have not found their current lenders to be particularly sympathetic in managing through current liquidity needs as a result of stay-at-home orders and elective surgery prohibitions across most states. Even pre-pandemic, some lenders had begun to lose appetite for highly-leveraged, single-specialty physician practice management and dental service organization businesses. Similarly, many equity investors were shying away from sky high valuations that require high leverage and high-consequence financial modelling assumptions. Accordingly, negative lender and sponsor experiences with COVID-19 disruptions to existing investments may ultimately cool (or even depress) multiple expansion from the pre-pandemic highs. At the same time, the systemic drivers toward consolidation, coupled with the continued need for existing "dry powder" (both debt and

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equity) to be invested, could preserve those pre-pandemic multiples.

- Valuation and credit distress during the COVID-19 pandemic is also likely to further depress larger cap buyer appetite to compete for businesses at outsized multiples that have exhibited rapid growth through bolt-on acquisitions without a proven track record of operating in an integrated manner at scale. This trend was developing before the pandemic, and has exacerbated the situation for many, as poorly integrated platforms fracture without the economic, political and cultural integration needed to promote stability and performance through turbulent times.
- The adverse impacts of the pandemic notwithstanding, there will continue to be a premium market for quality assets that demonstrate the economic, political and cultural cohesion to weather the storm. With significant investor appetite remaining, premium multiples are likely to remain if there is a scarcity of scaled healthcare platform businesses that have demonstrated the ability to not only acquire smaller businesses, but integrate and position them for sustainable, organic revenue growth. Relatedly, we expect a renewed emphasis by investors on earnings growth through organic avenues beyond "stacking" acquired EBITDA, including adoption of more efficient staffing models to leverage the accelerated adoption of telemedicine, expanded use of technology and data to improve the patient experience and reduce cost, and efforts to develop alternative care delivery and payment models in a more comprehensive manner than existed before the pandemic.
- The COVID-19 pandemic evidenced a need for greater connectivity among patients, providers, payors and other stakeholders. Overall success will depend on how well healthcare players collaborate to build the system around the consumer. Accordingly, we can expect to see more data and information collaborations, using the right technology with the right sensitivity to patient needs, to bring forth new modes of data use. Systemic improvements need to ensure that current data is available on demand for multiple uses, including treatment, payment, healthcare operations, trend identification, research and population health. Given the exposed vulnerabilities in the current system, the drive to reimagine and implement an even more sophisticated data infrastructure will continue to accelerate.
- The pandemic has exposed gaps in the process of healthcare delivery and opened new opportunities that can be addressed when participants across health, life sciences technology and other subsectors join forces. Many investors are already exploring business combinations, joint ventures and other innovative transactions to capitalize on these opportunities and address the new challenges facing both providers and patients to deliver and receive care safely and effectively.

CONCLUSION

As the health industry continues to tackle the immediate challenges of the COVID-19 pandemic, stakeholders across the board should prepare for a "new normal." The exact parameters of this new normal are still in flux, but this period of transition presents numerous risks for those unprepared or unwilling to adapt and real opportunity for those that are. ■

NOTES

1 According to Renaissance Capital – Biotechs make up almost two-thirds of IPO activity through the end of June 2020

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