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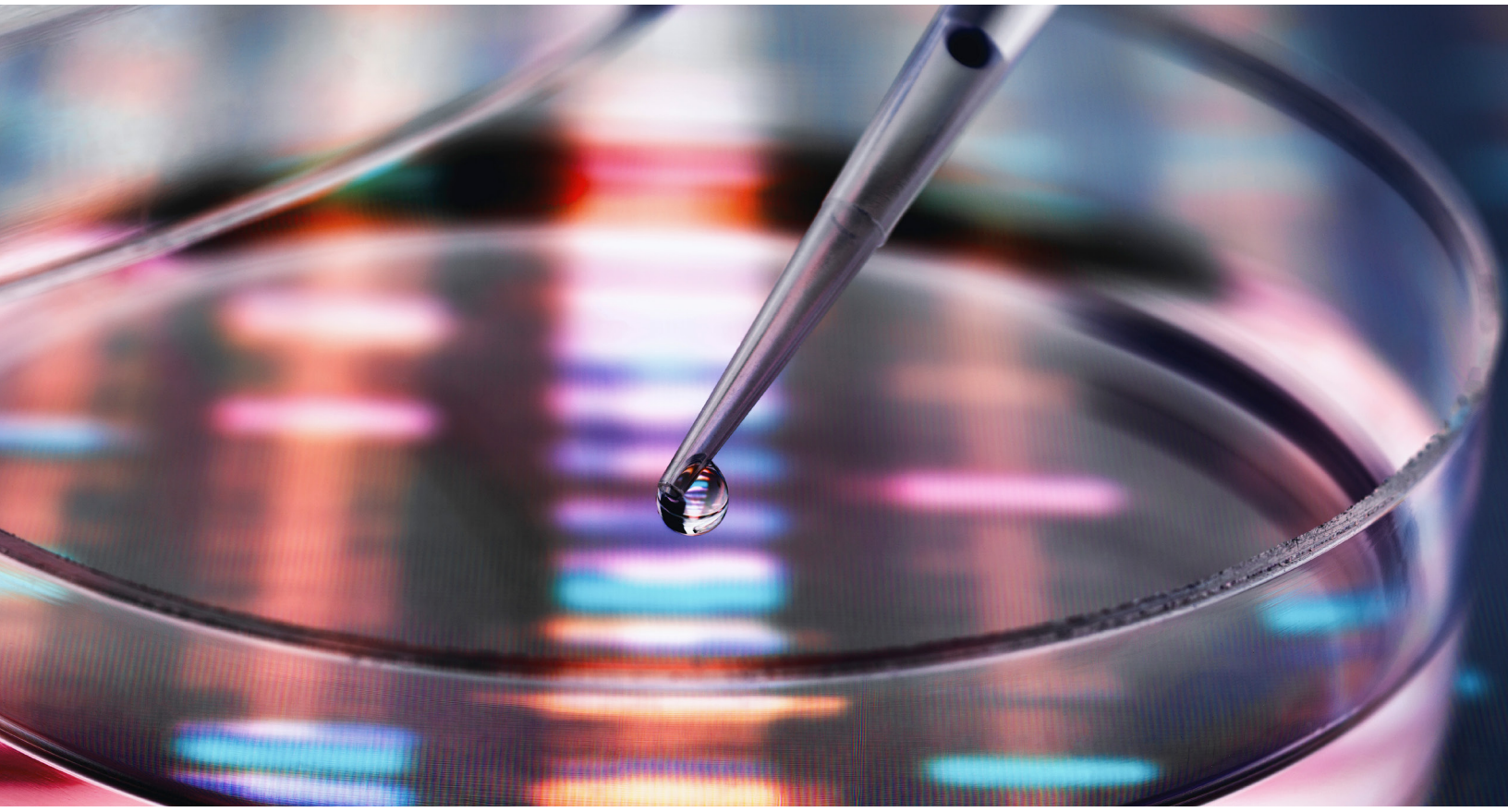
COVID-19 implications for life sciences R&D: Recovery and the next normal

COVID-19 has severely disrupted pharma and medtech R&D. Leaders should prepare along three horizons—safeguarding patients and employees, adapting operations for a recovery, and building for the next normal.

by Gaurav Agrawal, Brandon Parry, Brindan Suresh and Ann Westra



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As the novel coronavirus and the disease it causes (COVID-19) has spread around the globe, it has created profound disruption across communities, patients and clinicians, the way we work, and how we engage to support stakeholders across the ecosystem. Pharma and medtech companies have found themselves front and center—supplying (and rapidly scaling up) vitally important medical products to support patients in their time of need, while also attracting widespread attention as the industry sprints to develop new therapeutics and vaccines for COVID-19. These diagnostics, therapies and vaccines could provide the critical path to whatever next normal we may find on the other side. At the same time, the clinical and product development "engine" has experienced profound disruption as colleagues adjust to remote work environments and lab capacity is reduced. Clinical trials are also being severely affected with disruptions in both new enrollment and in keeping existing patients on therapies..

Against this backdrop, we convened more than 300 R&D functional leaders, including chief medical officers (CMOs), from over 50 global companies in the sector, to explore the implications of the COVID-19 pandemic for the R&D function and identify the imperatives that R&D leaders should be considering in their response to the pandemic and beyond.

Over the near-to-medium term, this response spans three concrete horizons (Exhibit 1):

— *Immediate crisis response (Resolve)*. In this horizon the focus is on safeguarding employee and patient safety and beginning the path forward. Most companies are in the tail-end of this horizon.

— *Charting a recovery (Resilience, Return)*. While the risk of infection and associated localized disruptions continue in this horizon, adaptations to the product development process are introduced to chart the recovery. Most companies report that they are just starting to think through their plans for recovery.

— *Shaping the next normal (Reimagination, Reform)*: This final horizon builds on the innovations that have been rapidly introduced during the crisis to create a new and more sustainable, patient-centric development paradigm.

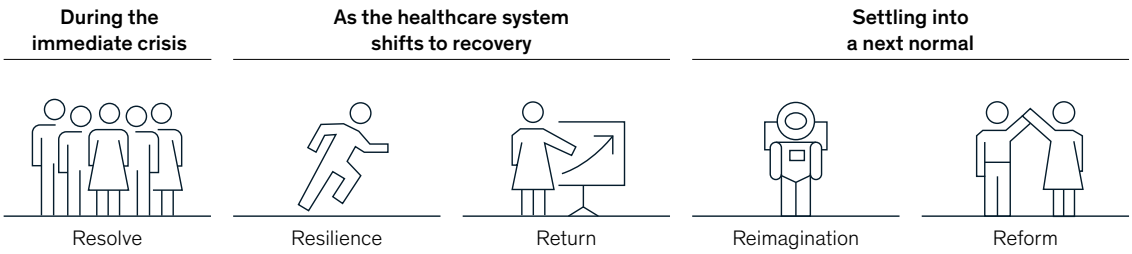
Setting the stage: COVID-19 impact on R&D

Key findings from our recent surveys and roundtables help frame the scale of the impact on development operations:

— As of April 2, 2020, more than 90 percent of the 34 companies we polled reported that they had formally implemented the emergency procedures that were delineated under their business continuity plan.[1]

Exhibit 1

For pharma organizations, we see three potential horizons.



[1] McKinsey Chief medical officer, regulatory affairs, safety, quality, and field medical leaders premeeting surveys, April 1-3, 2020.

R&D leaders say they are spending an average of 40 to 50 percent of their time on crisis management.

— As of April 6, there were more than 2,850 trials and approximately 900,000[2] patients enrolled at trial sites in regions that were in partial or complete lockdown due to COVID-19 restrictions. Some surveys suggest that more than 50 percent of companies have paused recruitment for the majority of trials and 75 percent have paused site activation for the majority of trials.[3] The impact is somewhat uneven, however, as trials for more severe diseases such as oncology or some rare disease have seen relatively less disruption.[4]

— Business-as-usual operations are also clearly being affected, as companies report that R&D labs are operating at below 50 percent of normal capacity.[5] Reported adverse events have also fallen by between 0 and 10 percent on average.[6]

— Across all R&D related groups, companies estimate productivity has fallen by between 25 and 75 percent due to remote working.[7]

Our surveys also suggest the extent to which the crisis has diverted executive attention from normal business. R&D leaders say they are spending an average of 40 to 50 percent of their time on crisis management. That figure rises as high as 80 percent for CMOs and other medical leaders who are members of company disaster response teams.[8] In addition, some reported that in countries with limited staff there has been heightened risk of not meeting critical local regulatory requirements related to routine reporting and registration.

Immediate crisis response: Safeguarding employee and patient safety while charting the path forward

As noted, earlier, most companies we speak to are in the tail end of this horizon. Their response has encompassed these three priorities:

— *Emphasize employee protection.* Protecting employees is a top-of-mind issue, especially for those who must work on-site in laboratories and manufacturing sites or visit various facilities to service equipment. Medical leaders are struggling with the lack of conclusive data on how to keep these colleagues healthy and safe. In its absence, many companies are introducing measures such as routine temperature checks and ensuring supplies of PPE. Others are staggering shifts, reducing total capacity at facilities and strictly limiting personal interaction where facilities remain open.

[2] ClinicalTrials.gov, April 5, 2020.
[3] McKinsey Clinical operations leader survey, April 6, 2020.
[4] Ibid.
[5] McKinsey Chemistry, manufacturing, and controls leader postmeeting survey, March 26, 2020.
[6] McKinsey Regulatory affairs, safety, and quality leaders premeeting surveys, April 2, 2020.
[7] McKinsey Chief medical officer, regulatory affairs, safety, and quality premeeting surveys, April 1–3, 2020.
[8] McKinsey Chief medical officer premeeting survey, April 3, 2020.

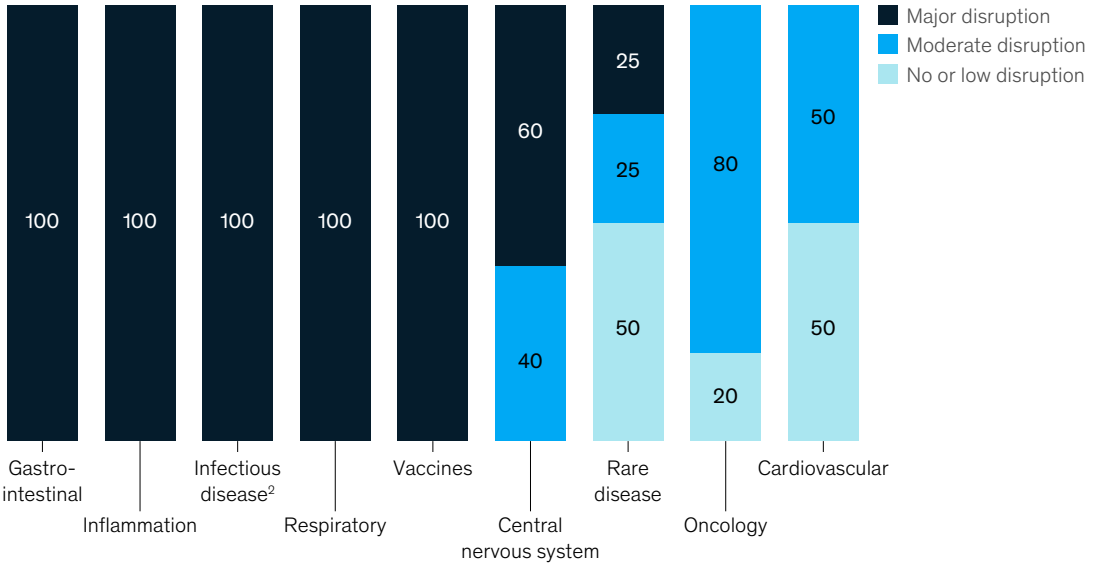
— *Invest in patient safeguarding.* Equally important is patient safety. Sponsors of clinical trials say that the number of reported clinical and postmarket adverse events has fallen as a result of COVID-19. Companies are trying to overcome this by using new and typically third-party data sets to complete the picture of adverse events. They are also introducing more proactive, creative outreach to healthcare providers (HCPs) and patients both for safety surveillance and to address heightened concerns about the risk of infection.

— *Decide on an approach to ongoing and upcoming trials.* A challenging part of managing the crisis is making sound decisions about company policy on trial operations. Pharma companies are reporting significant disruption to trials: patients are missing hospital visits, health systems and sites are overwhelmed with care for COVID-19 patients, and companies are experiencing challenges with clinical supplies. They are eager to continue essential trials for life-threatening indications but at the same time want to avoid putting more strain on already stretched health systems or asking immuno-compromised patients to visit test sites. Either way, the implications of interruption to ongoing trials are substantial—both for patients and for the company's longer-term R&D productivity. Most companies have moved swiftly in revising core components of their trial policies (such as delaying new trial starts or pausing new enrollment) and have actively triaged the feasibility of keeping the trials deemed "essential" running. Our recent survey of clinical operations leaders, while showing variability across therapeutic areas, clearly highlights that sponsors are working diligently to keep trials in high acuity therapeutic areas—such as oncology and rare disease—minimally disrupted (Exhibit 2).

Exhibit 2

The level of disruption varies by therapeutic area.

Reported disruption level[1] of clinical trials, by therapeutic area, % of respondents



[1] Flow disruption defined as <10% slowing to overall development timeline; moderate disruption defined as 10%–30% slowing to overall development timeline; major disruption defined as >30% slowing to overall development timeline.
[2] Excluding vaccines.

Source: McKinsey Clinical Operations Survey (Apr 6, 2020, n = 8)

Charting a recovery: Introducing innovations to sustain operations in a period of uncertainty

As the initial infection peak starts to taper off and regions consider reopening, there is consensus among the R&D leaders we polled that the recovery is likely to have three dimensions: gradual (with some restrictions persisting longer than others), staggered (as some geographies recover faster than others that may still be in the peak of infection), and extended, as the return to "full" normal (or the next normal) takes several months instead of weeks. But numerous uncertainties exist and to prepare for a recovery in clinical trial activity requires thoughtful planning:

— *Developing a recovery plan for restarting trials: the which, where, and when:* As companies consider resuming paused trials and restarting new ones, they should consider a number of critical steps:

  - Conducting an analysis of *which* trials to reopen by weighing factors such as disease acuity and degree of unmet medical need, as well as which compounds contribute to the company's future R&D productivity and whether delays of certain trials could materially erode a company's strategic position at launch. Another important consideration is the healthcare system resources that trials would take up at clinical sites.

  - Thinking critically about *where* to restart trial activities by considering the leading indicators that denote capacity of the health system to focus on trial activity, such as the status of viral transmissions around the world and its impact on rebalancing the location of trial activities, the strength of public health precautions in different areas, and the likelihood of seasonal recurrence or second waves of transmission that could lead to another major disruption in certain geographies.

— Planning *when* to reengage sites based on a detailed assessment of the capacity of local health systems, feedback from trials sites and institutions, and local epidemiological projections regarding the potential of COVID-19 flare-ups.

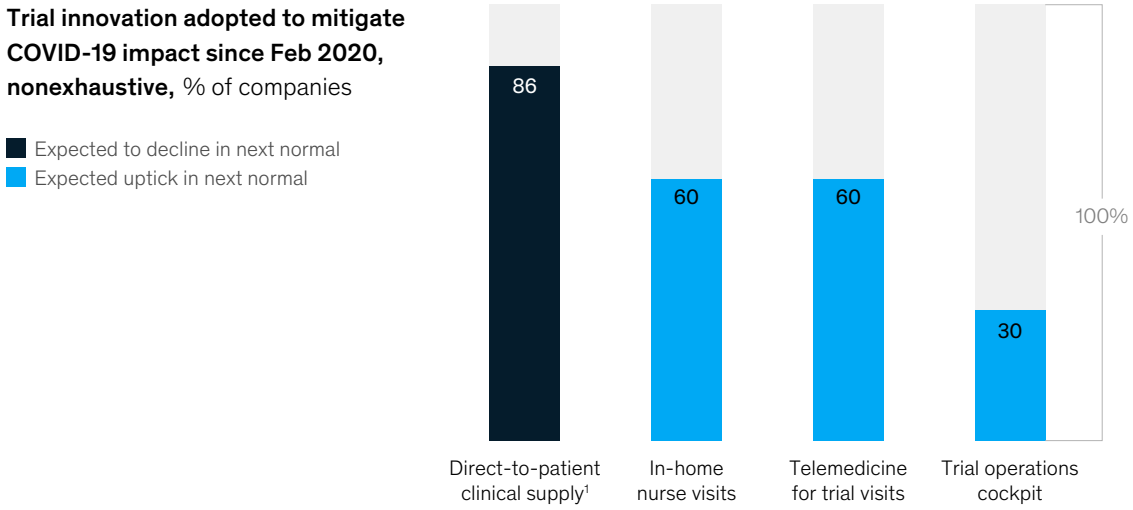
— *Building agility into trials—both in-flight and paused.* The disruption caused by COVID-19 has driven an extraordinary number of deviations in clinical trial operations (such as missed patient visits and lower new enrollment), raising questions about data and broader trial integrity. For the trials that are continuing, clinical leaders have begun focusing on operational agility through a host of digital and "quick win" tools that reduce patient and site burden, including remote patient engagement (and, where possible, the ability to assess end-points virtually), in-home nurse visits, shipping investigational medicinal products directly to patients (with appropriate support), and conducting site-level outreach to ensure monitoring (Exhibit 3).

Given the probability of a gradual and fitful recovery, R&D leaders should consider building resilience in their trial portfolio as they open up new trials and continue the ones already in-flight. This includes expanding the currently deployed "quick win" tools and implementing a holistic set of approaches, especially for the priority trials. Needless to say, the slow pace to date in adopting "virtualization of trials" pre-COVID-19 has shifted into higher gear—and this trend is likely to continue for the several months in the time that companies are anticipating for the recovery phase.

Recovery approaches generally fall into two broad categories: trial-level interventions and site-level interventions (Exhibit 4). Trial-level interventions include enriching trials with increased enrollment for less affected sites and geographies, adapting pragmatic and digitally enabled end points; bio-stats

Exhibit 3

In the past eight weeks, pharma companies have already begun adopting new R&D tools, paving the way to a new trial paradigm.



[1]High costs likely to limit direct-to-patient shipments.

Source: McKinsey Clinical Operations Survey (n = 10 among top 20 pharmacos)

reviews to "salvage" data for existing patients, and increasing the windows for patient visits. Site-level interventions include joining with investigators to address site problems, providing transport for patients, building platforms for remote consultations, or shifting patients to alternate sites—such as pharmacies and retail clinics for monitoring—to give patients a more convenient and lower-risk site of care at a time when hospitals are focused on influxes of COVID-19 patients.

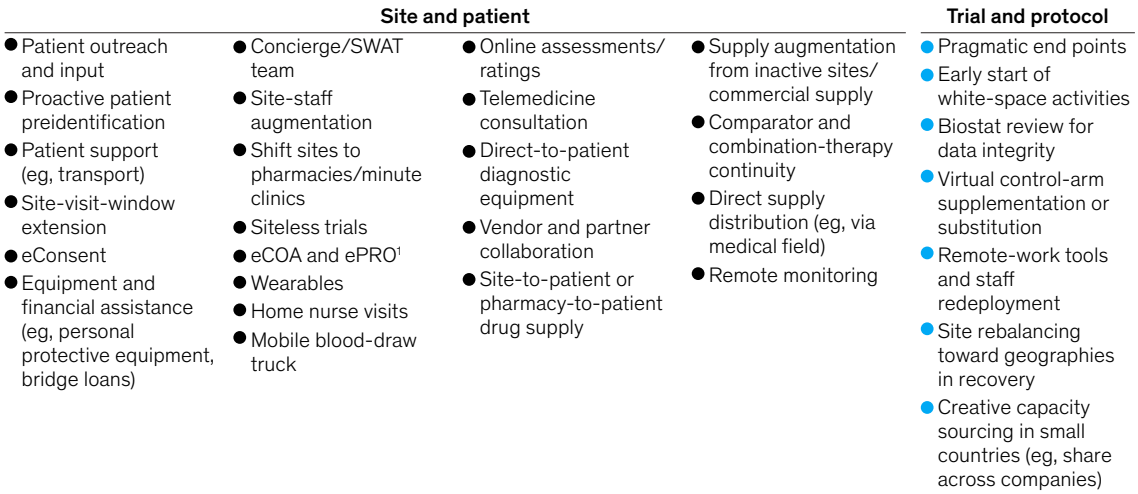
— *Embracing the "digital bridge" beyond trials.* The move to digital channels to build resilience is extending beyond trials. The need to work remotely during the pandemic and the limits placed on face-to-face contact have forced physicians to increase use of digital channels—a conversion that many thought would take years. Our April survey of medical affairs leaders suggests that roughly 95 percent of medical science liaisons (MSLs) globally are engaging physicians entirely remotely, often using virtual engagement platforms rolled out or upgraded in Q1 2020 to quickly support new ways of working. Although some felt that remote engagement has led to excess capacity among MSLs, most global field medical leaders report a drop in productivity of anywhere between 25 and 75 percent compared to prepandemic levels. This was due to the higher demand for medical communications and engagement to help HCPs and patients navigate the uncertainties of the pandemic. Field medical teams are also making time for increasingly crucial but previously neglected activities such as scientific training, role-based training, field resources development, and support for internal partners. Leaders expect virtual tools to remain a critical asset for engagement and anticipate that they could partially—and even completely at some sites—replace in-person interactions.

Digital interactions are taking hold in other functions too as leaders in R&D quality, regulatory affairs and drug safety begin

Exhibit 4

Recovery approaches to building resilience in trial performance generally fall into two broad categories.

Example interventions, nonexhaustive



[1]eCOA = electronic clinical outcome assessment; ePRO = electronic patient-reported outcomes.

Source: External expert interviews; web search

experimenting with remote and virtual internal audits. At the same time, the adoption of such digital solutions to remain productive and ease the burden on sites and patients has been largely reactive. The aspiration will be to design more site- and patient-centric trials for the full range of innovations, many of which the COVID-19 crisis has helped accelerate.

Shaping the next normal: Improving and 'hardening' recent innovations

While much remains unclear about what the future holds, what is clear is that we will emerge postcrisis with a very different view of what's normal. Preparing for the more significant changes ahead is difficult, though, with so much uncertainty in the future. From our conversations with R&D leaders, however, there is agreement on the key considerations for shaping the path to the next normal:

— *Refine business continuity planning.* This pandemic has tested and stressed current business continuity planning and will prompt many organizations to rethink how to prepare for the next disruption and manage for the long term. As an example, weaknesses that have been revealed in this crisis include the breakdown of PV systems when key employees are absent, and critical system downtime due to the disruption of maintenance schedules and lower levels of responsiveness from external partners, such as central labs. Business continuity planning should shift emphasis from how to 'keep the lights on' to laying out the ways and means for maintaining stakeholder relationships across the whole R&D life cycle.

— *Rethink the postpandemic clinical trial of the future.* As they learned to adapt to COVID-19 disruptions, companies had to quickly determine what services could be brought directly to

patients. As a result, proven solutions were scaled up quickly—such as shipping drugs to patient homes and providing lab tests to closer-to-home facilities—and how to virtualize clinical trials by offering virtual consultations, audits and inspections. The next normal is likely to see a greater emphasis on patient- and site-centricity as sponsors look to increase the relevance of their pipeline program for patients, sites and caregivers while also reducing the trial burden on them. This includes design of product value propositions (such as the end points, quality-of-life parameters and convenience aspects that truly matter to patients), trial designs (such as alternate forms of evidence generation, minimized patient burden through protocol design, and reduced patient visits through remote and digitally enabled end points), and trial logistics (such as the convenience of remote consultations for patients, travelling nurses, and directly shipping drugs to patients). The key, however, will be to accompany these changes with a shift toward virtual inspections, especially where investigators have the requisite IT infrastructure. Looking forward, such patient- and site-centric approaches to clinical trials—and drug development more broadly—will help ensure resilience in trial performance in the long term.

— *Reset the medical field model with digital and data.* Reaction to the current crisis has offered "in vivo" proof that virtual engagement is feasible as internal teams, HCPs, and patients have all become markedly more comfortable with these tools. The question remains as to what extent this transformation will continue. The continuation of physical distancing measures that restrict in-person interactions and access to health facilities may increase the long-term acceptance of adaptations such as telemedicine. The virtualization of congresses will also continue to drive the transformation to digital engagement among field medical teams and their customers. This will likely require a significant shift in mindset along with retraining programs for the medical force—both in terms of how to engage their customers but also what to engage their customers with (such as new digital content). A step shift in making these engagements more helpful to customers could come from deploying the power of analytics to understand unmet needs at a more granular level and using that understanding to improve engagement with HCPs—such as providing tailored content and just-in-time training. The restrictions currently encountered by the field force will precipitate a test-and-learn mindset but the shift to applying data and analytics in measuring impact could help build an improved model for medical engagement.

— *Create greater resilience in sourcing models.* The debate between efficiency and resilience will be paramount as companies think about R&D—for example, rebalancing research work by contract research organizations (CROs) across countries or reevaluating clinical supply chain diversification to minimize vulnerabilities, even if it comes at a greater cost. Companies may consider partnering with policy makers as they too look to derisk entire industries as a result of the pandemic.

— *Diversify approaches to evidence generation.* The gradual and staggered path to recovery could lead to a greater emphasis on creative ways to generate evidence. For example, supplementing controlled data with real-world evidence, using master protocols or adding arms to in-flight trials are all top of mind for R&D leaders and likely to figure prominently in discussions with regulators and in health-technology assessments. None of these approaches are unheard of but could gain further momentum in the next normal.

— *Participate in potential regulatory evolution in new drug development.* Companies will continue to seek more regulatory advice in the recovery phase—on missing data, telemedicine, remote monitoring, home nursing, data privacy and more. However, as companies push to accelerate product development and approvals in devices, vaccines, and therapies for COVID-19,

they are likely to engage even more intensively with regulatory agencies. In the shorter term, this will help create greater certainty of outcomes and drive clarity around valid, durable innovations in clinical trial conduct and in the longer term, it could help define an expedient yet robust new paradigm in drug development, especially for indications with high unmet medical need.

In addition to the trends mentioned above, several unknowns remain that could have a profound impact on the next normal for pharma and medtech R&D leaders. Many big-picture questions are unanswered: Will there be a resurgence in interest in infectious diseases and antimicrobial resistance, and will this affect companies' strategic choices? Will the unprecedented level of cross-industry cooperation and partnership that we are seeing today foster a new "collaborative innovation" model? Will COVID-19 accelerate the entry of new players such as Amazon, Google, and Tesla? For their part, will governments rethink the critical healthcare infrastructure?

As the peak and panic associated with the current crisis subsides, R&D leaders will be faced with a crucial choice: attempt to return to some version of precrisis "business as usual" or embrace the change and fundamentally reimagine the drug and device development paradigm. For all its disruption, COVID-19 has, out of necessity, accelerated innovation and experimentation in medical product development and clinical trial conduct in ways that have benefited patients and caregivers. Building on that energy and momentum in a thoughtful but committed way is critical in a rapidly changing development paradigm.

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