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No place like home? Stepping up the decentralization of clinical trials

The COVID-19 pandemic has catalyzed the adoption of decentralized clinical trials while highlighting the critical benefits of virtual trials and improving the patient and physician experience.

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Clinical-trial sponsors are continually seeking to make clinical trials faster and to improve the experience for patients and physicians. Trial decentralization[1] has emerged as a critical tool in this pursuit. It involves bringing an increasing proportion of a trial's activities to the patients rather than using the traditional paradigm of bringing patients to a trial site.

The COVID-19 pandemic has significantly catalyzed the adoption of decentralized clinical trials, with an increase in trial activities conducted remotely and in participants' homes. As health-system resources became consumed by COVID-19-related care and travel became limited by physical distancing, patients' access to trial sites was reduced by 80 percent.[2] The number of monthly trial starts declined 50 percent from January 2020 to April 2020, and 60 percent of investigators reported a significant reduction in trial activities in May 2020.[3] In the face of such disruption, sponsors mobilized rapidly to preserve the continuity of care and data integrity—for example, by adopting remote consent and patient monitoring, videoconference assessments, and at-home phlebotomy.[4]

While certain elements of clinical-trial decentralization existed before the COVID-19 pandemic, they were not commonly used across trials. The pandemic has accelerated virtualization in both consumer and trial contexts. And with the global pandemic still ongoing, a consensus is emerging that many of the interventions will become permanent fixtures. In one survey, up to 98 percent of patients reported satisfaction with telemedicine.[5] In another, 72 percent of physicians reported similar or better experiences with remote engagement compared with in-person visits.[6] And pharmaceutical leaders at McKinsey's December 2020 Clinical Operations Roundtable agreed that trial adaptations during the pandemic were positive and often helped better address patient needs.

The future trial paradigm: Meeting patients where they are

The concept of meeting patients where they are when conducting clinical trials significantly predated the COVID-19 pandemic and aimed to improve patient convenience and experience. Typically, 70 percent of potential participants live more than two hours from trial sites, so decentralization broadens trial access to reach a larger number and potentially a more diverse pool of patients. Decentralization can also reduce the workload for trial investigators, since traditional site activities (such as drug administration, assessments, and data verification) can be performed remotely by others or by trial participants themselves.

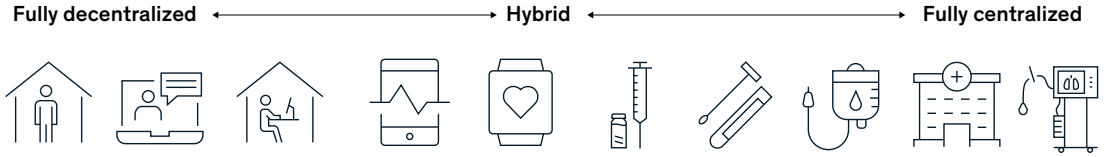
The shift of clinical-trial activities closer to patients has been enabled by a constellation of evolving technologies and services. Tools such as electronic consent, telehealthcare, remote patient monitoring, and electronic clinical-outcome assessments (eCOAs) allow investigators to maintain links to trial participants without in-person visits. Mobile and home healthcare, as well as alternative-care locations, enable more procedures to occur away from research sites (Exhibit 1).

[1] We define a decentralized clinical trial as a trial centered around patient needs that improves the patient experience. The focus of such a trial is on making it more convenient, closer to the patients, or both by using a combination of virtual and physical elements to conduct the required trial procedures.
[2] "COVID-19 and clinical trials: The Medidata perspective," Medidata Solutions, May 4, 2020, medidata.com.
[3] John Z. Xue et al., "Clinical trial recovery from COVID-19 disruption," *Nature Reviews Drug Discovery*, September 2020, Volume 19, pp. 662–3, nature.com.
[4] Gaurav Agrawal, Brandon Parry, Brindan Suresh, and Ann Westra, "COVID-19 implications for life sciences R&D: Recovery and the next normal," May 13, 2020, McKinsey.com; "Maintaining oncology clinical trial integrity during the COVID-19 pandemic," CEO Roundtable on Cancer web conference, April 24, 2020, ceoroundtableoncancer.org.
[5] Jenny Cordina, Eric Levin, and Andrew Ramish, "Helping US healthcare stakeholders understand the human side of the COVID-19 crisis: McKinsey Consumer Healthcare Insights," September 17, 2020, McKinsey.com.
[6] Sermo US COVID-19 HCP Survey, August 2020; McKinsey analysis.

Exhibit 1

Decentralized clinical trials meet patients where they are.

Clinical-trial designs



All trial procedures are conducted virtually, enabled by digital technologies and supply delivery	Less complex trial procedures that don't require in-person visits (eg, vital signs, electrocardiograms) are conducted via telehealthcare, remote data collection, or direct-to-patient supply	Less complex trial procedures that require in-person visits (eg, injections) are conducted via mobile clinicians or alternative sites (eg, mobile clinics, retail sites)	Complex trial procedures (eg, complex screening protocols, cell therapy, magnetic resonance imaging) are conducted via research sites (eg, academic medical centers) or local hospitals	All trial procedures are conducted at a research site (eg, academic medical center)

Those diverse options allow for a broad spectrum of decentralized and hybrid clinical-trial designs. In the most complete articulation, a trial can be fully virtual, with enrollment and assessments taking place in a patient's home, enabled by end-to-end digital tools and the self-administration of medicines. That fully virtual model is gradually migrating from smaller early-phase and postapproval studies toward larger pivotal trials. Nonetheless, in the near term, sponsors, investigators, and research-service providers expect fully virtual trials to remain limited to a narrow set of use cases, such as a well-characterized drug with few adverse events in a mild indication, with end points suited to remote measurement.

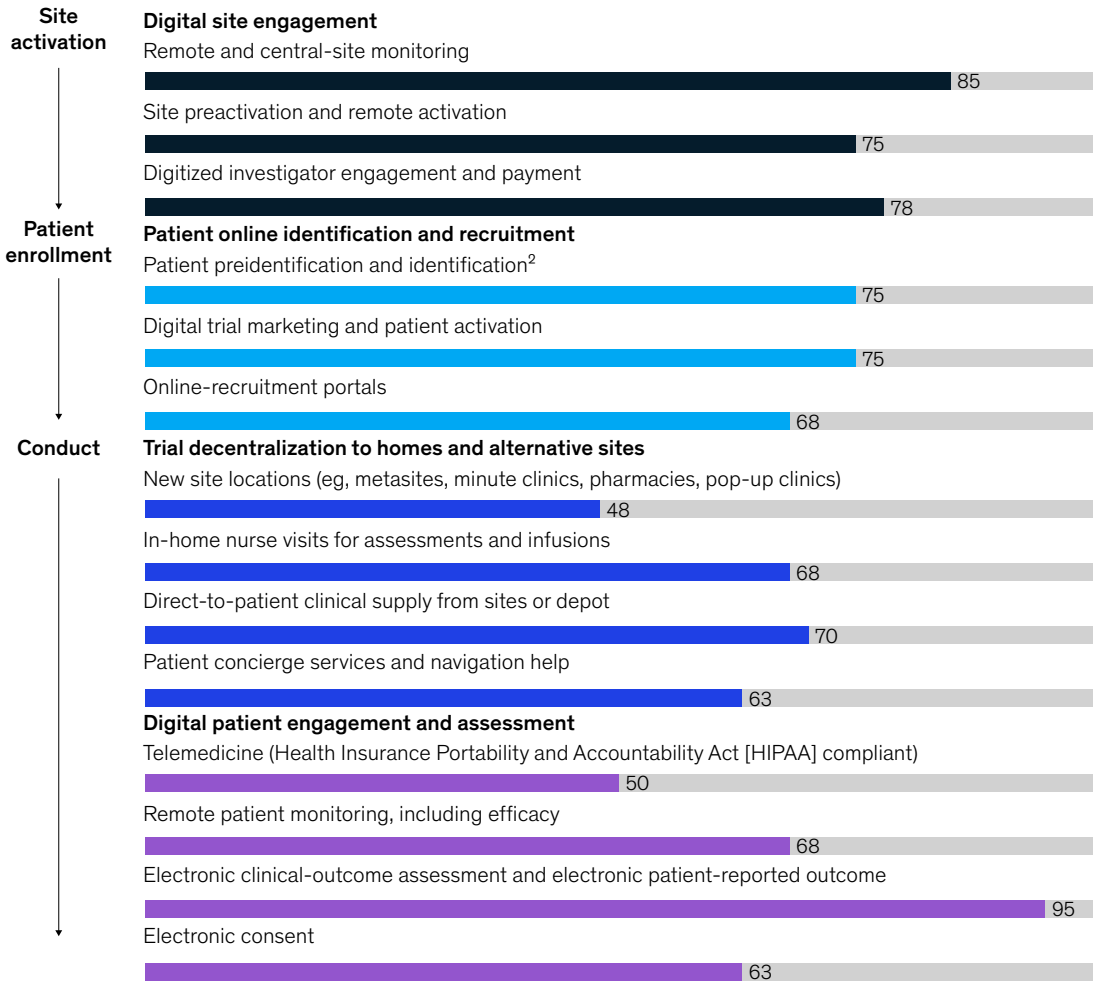
While most clinical trials are not likely be entirely virtual, they will use one or more decentralization elements based on suitability for their end points, patient populations, and treatments. Many such elements have been widely piloted, with 48 to 95 percent of sponsors reporting use in at least one Phase III trial (Exhibit 2). We expect a significant increase in uptake because of experience gained during the COVID-19 pandemic. Before the pandemic, an Industry Standard Research survey in December 2019 found that 38 percent of pharma and contract-research organizations (CROs) expected virtual trials to be a major component of their portfolios, and 48 percent expected to run a trial with most activities conducted in participants' homes. When we asked the same questions a year later at McKinsey's Clinical Operations Roundtable, the responses were 100 percent and 89 percent, respectively.

Decentralization broadens trial access to reach a larger number and potentially a more diverse pool of patients.

Exhibit 2

Most clinical trials won't be entirely virtual but will use decentralization elements based on suitability for the end points.

Activities that enable decentralized clinical-trial conduct, % of respondents[1]



[1]Question: Have you deployed these services in the past (pre-COVID-19 pandemic) in a Phase III trial?
[2]For example, through digital and social media, patient communities, health records and testing, and consumer genomics.
Source: Crunchbase; McKinsey analysis

Clinical-trial sponsors creating hybrid protocols are drawing from the menu of decentralization services and technology interventions, such as remote monitoring of vitals, mobile clinics, and home visits. Traditional site visits will still be needed for complex procedures and specialized assessments, such as screenings and magnetic resonance imaging. So smart, hybrid trial designs will make other touchpoints virtual or closer to the patients—for instance, through mobile clinics and primary-care physicians—whenever possible (Exhibit 3).

Enablers for stepping up decentralization

Biopharma companies and clients of research-service providers tell us that the time is ripe for a step-up in clinical-trial decentralization, propelled by the momentum created during the COVID-19 pandemic and several other factors:

— *Comfort with health technology.* Consumers' uptake of digital health technology has increased year on year. Fitness wearables

Exhibit 3

Clinical-trial sponsors creating hybrid protocols are drawing from a menu of decentralization services and technology interventions.

Illustrative protocol for neuroscience-related Phase III trial (simplified and anonymized)

● In-person visit required
● Possible through digital/remote assessment

Visit	Assessment	Setting	Patient miles traveled
1	● Physical exam ● Neurological exam ● ECG[1] ● Lab and drug tests	Clinical-trial site	89
2	● Vital signs ● Height and weight ● Pregnancy test	Virtual	0
3	● Vital signs ● Height and weight	Virtual	0
4	● Vital signs ● Physical exam ● Neurological exam ● ECG ● Lab and drug tests	Patient home	0
5	● Delivery training ● Vital signs ● Height and weight ● ECG	Virtual	0
6	● Vital signs ● Height and weight	Virtual	0
7	● Vital signs ● Height and weight	Virtual	0
8	● Vital signs ● Physical exam ● ECG	Virtual	0
9	● Vital signs ● Height and weight ● Pregnancy test	Virtual	0
10	● Vital signs ● Height and weight	Virtual	0
11	● Physical exam ● Neurological exam ● ECG ● Lab and drug tests	Mobile clinic	23

[1]Electrocardiogram.

continue to show strong growth, as do online activities (for example, Peloton for workouts and Strava for tracking exercises such as running and biking). Physicians' comfort with remote technologies has also increased because of the COVID-19 pandemic. Clinical-trial investigators predict that a threefold increase in remote patient interactions will persist after the pandemic (Exhibit 4).

— *Importance of patient convenience.* Convenience is increasingly critical to patient enrollment and retention in clinical trials, especially those in rare diseases. Patients and physicians expect sponsors to consider patient convenience in trial designs, and investigators in many countries have predicted an increase in patient-centric trial features following the COVID-19 pandemic (Exhibit 5).

— *Maturing tools.* Tools for remote data gathering (such as mobile eCOA, novel sensors, actigraphy, camera, voice, and video) are increasingly being validated, establishing standards for their broader use. Digital end points are being used more and more as primary end points, accounting for 50 of 166 digital end points crowdsourced by the Digital Medicine Society as of January 17, 2021.[7]

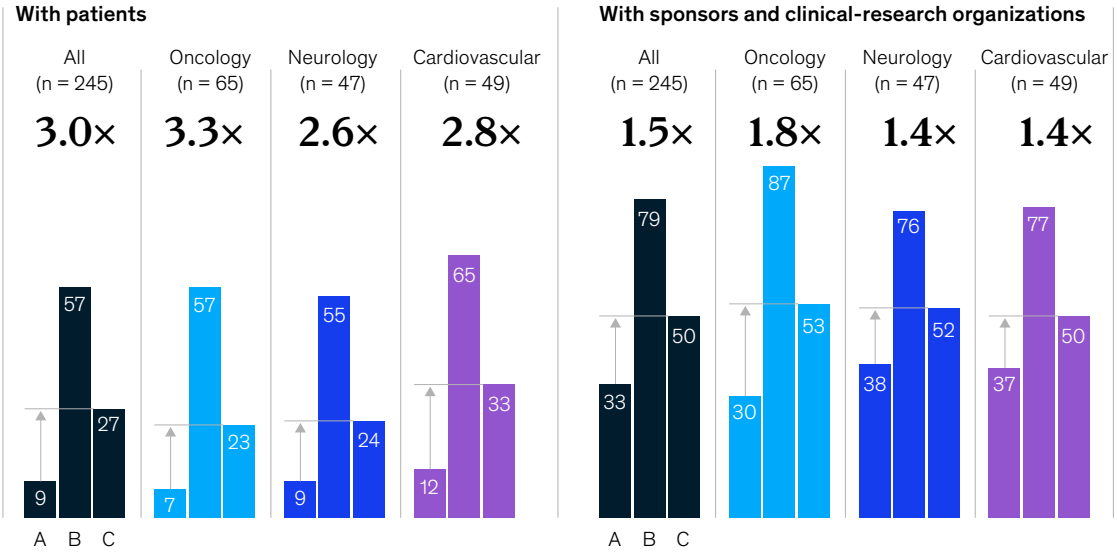
[7] "Library of digital endpoints," Digital Medicine Society (DiMe), January 17, 2021, dimesociety.org.

Exhibit 4

Physicians' comfort with remote technologies has increased as a result of the COVID-19 pandemic.

Clinical-trial investigators' share of virtual interactions, % of respondents[1]

A. Pre-COVID-19 crisis **B.** At crisis peak **C.** 6 months postcrisis



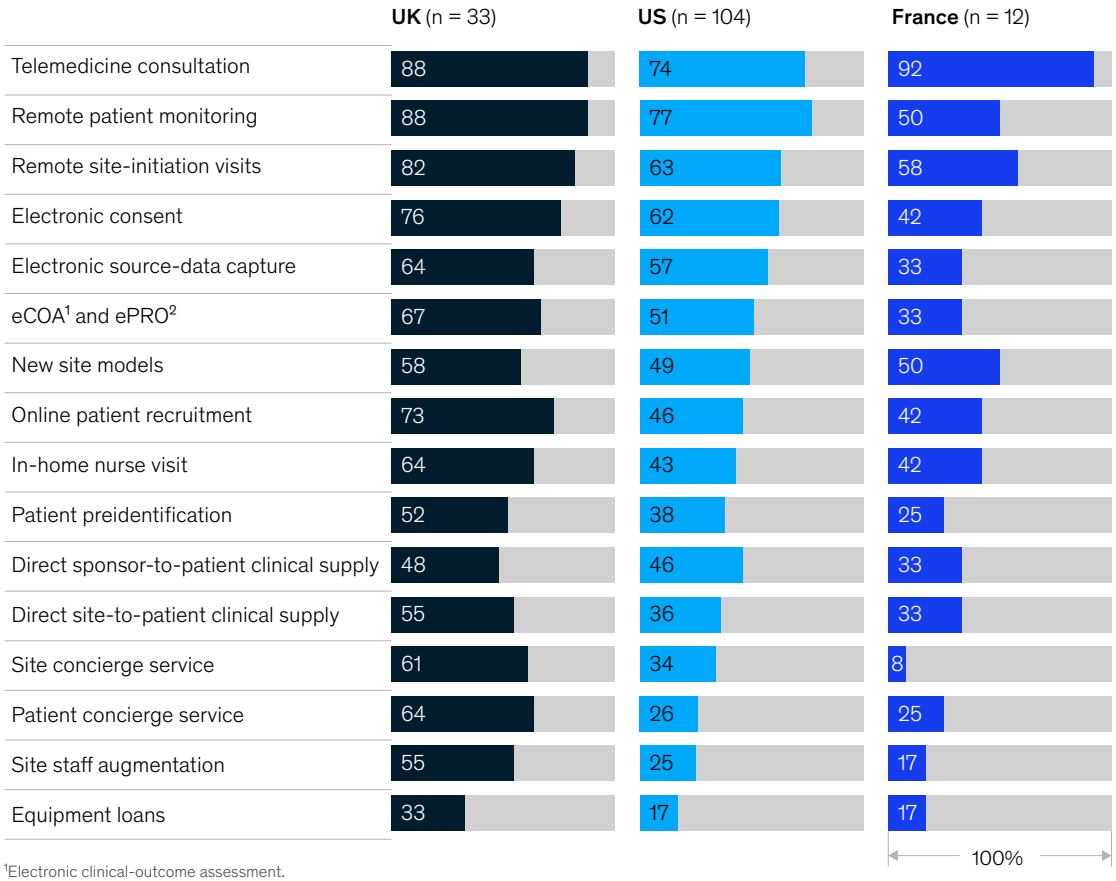
[1]Average reported by investigators. Questions: Within your clinical trials, what share of patient interactions do you conduct remotely? How do you expect this to change in future?
Source: John Z. Xue et al., "Clinical trial recovery from COVID-19 disruption," *Nature Reviews Drug Discovery*, September 2020, Volume 19, pp. 662–3, nature.com; McKinsey Global Survey of Clinical Trial Investigators, May 8–18, 2020

Clinical-trial investigators predict that a threefold increase in remote patient interactions will persist after the pandemic.

Exhibit 5

The aggressive adoption of decentralized clinical-trial services and technology interventions is expected after the COVID-19 pandemic.

Share of investigators expecting increase in use of decentralized clinical-trial procedures after COVID-19 pandemic, % of respondents (n = 245)



[1]Electronic clinical-outcome assessment.
[2]Electronic patient-reported outcome.
McKinsey Global Survey of Clinical Trial Investigators, May 8–18, 2020

— *Regulatory acceptance.* Prompted by the COVID-19 pandemic, regulators have issued guidance permitting the use of alternative clinical-trial approaches (such as remote monitoring, drug shipments to patient homes, home nursing, and alternative sites).[8] Such advice will likely continue to evolve rapidly on a country-by-country basis. The Danish Medicines Agency, for instance, has announced that it will develop a framework for the digitization and decentralization of clinical trials.[9]

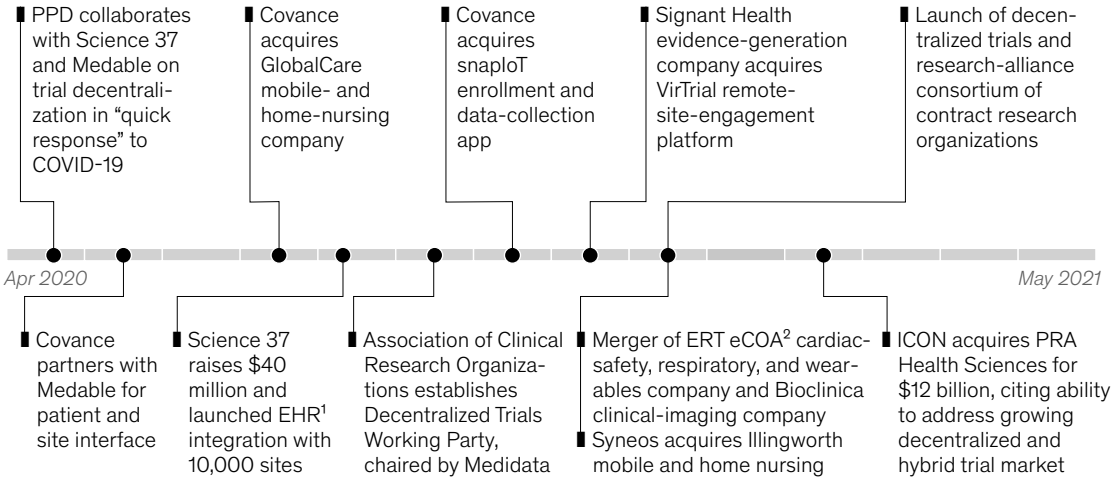
— *Partner ecosystem.* The CROs that provide the backbone of clinical-trial services are investing in the emerging set of decentralization elements. Technology innovators are also investing and are integrating point solutions to provide sponsors with more seamless and complete offerings (Exhibit 6).

[8] "EMA guidance on management of clinical trials during the COVID-19 (coronavirus) pandemic," European Medicines Agency, February 4, 2021, ema.europa.eu; "FDA guidance on conduct of clinical trials of medical products during the COVID-19 public health emergency: Guidance for industry, investigators, and institutional review boards," US Food & Drug Administration, January 27, 2021, fda.gov.
[9] "Clinical trials of the future place the patient at the centre," Danish Medicines Agency, May 4, 2021, laegemiddelstyrelsen.dk.

Exhibit 6

The decentralization capabilities of the clinical-trial industry are expanding rapidly.

Clinical-trial-ecosystem expansion at scale over 12 months



[1]Electronic health record.
[2]Electronic clinical-outcome assessment.
Source: Expert interviews; S&P Capital IQ

Challenges for decentralization

The opportunities for decentralizing clinical trials also bring challenges to an industry often characterized by long cycle times and conservativism. Sponsors and service providers seeking to implement decentralized trials must navigate uncertainties in technology and approach while balancing the needs of each stakeholder group and providing them with a positive, differentiated experience:

— *Data quality.* New clinical-trial approaches also bring new risks, with sponsors often citing preserving data quality when replacing accepted end points and protocols as an area of concern. Apps, electronic patient-reported-outcome (ePRO) tools, and wearable devices require technical and clinical validation—in an evolving regulatory context—to ensure that sensors generate reproducible signals and that signals are relevant to key outcomes. Some sponsors have deployed innovative approaches in more tractable therapeutic areas (for example, dermatology and respiratory) in Phase IV or bridging studies before rolling them out more broadly. We have also seen sponsors and CROs update how they measure quality risk from new data types when remote and real-time tracking can create new opportunities for earlier or more frequent signal detection.

— *Patients.* A clinical trial is already an unfamiliar experience for patients, and it can be made more so with the use of decentralized elements such as data-capture devices and home nursing. Patients vary in their comfort with and access to technology and in their preferences for in-person physician visits versus visits by phone or video. Patient-centric trial design is critical to mitigating such concerns. It can include, for example, patient training and support, user interfaces tailored to specific patient groups, and the option to choose between a decentralized arm and a conventional arm.

— *Sites and investigators.* Most clinical trials will be hybrid and will continue to involve traditional sites and investigators. Sites share patients' concerns of maintaining engagement in a virtual context, and they face even greater technological challenges as they work with multiple platforms to support different studies. Decentralized trials, therefore, need to provide high-quality logistical and technical support, ensure that investigator grants fairly reflect the additional workloads, and optimize the patient–investigator experience.

— *Regulators.* Clinical-trial sponsors must align trials with regulatory guidance, which evolves rapidly and may differ significantly from country to country. Trials conducted in more than one country are subject to additional cross-border data standards, as well as localization and retention rules. Therefore, it is essential for creators of a global trial to use a tailored approach, design an optimal country footprint at the outset, and account for complexities in trial-design planning (such as enrollment expectations by site).

— *Internal change management.* Clinical-trial sponsors need to address some inherent challenges associated with driving a decentralization and virtualization change agenda. The tasks vary in extent by sponsor but can include skepticism about the urgency of adopting such approaches, internal cost pressures, lack of an established operating model for decentralization, and an increased amount of capability that must be built across asset teams, functions, digital and technology groups, and vendor management, among others. Overcoming such challenges requires expertise in performance transformation coupled with a sustained cross-functional commitment from leadership.

Achieving scale

The clinical-trial industry has a unique opportunity to move toward a new patient- and site-centric paradigm, making participation more accessible, convenient, and sustainable for patients and physicians. Many sponsors are now examining how they can convert a patchwork of rapidly deployed interventions, such as consumer-grade videoconferencing and home nursing, into a comprehensive strategic approach to trial virtualization. Answering four questions can help them frame such a strategic review:

— Where can decentralization add the most value to our portfolio, and which technologies and capabilities must we access to capture it?

Different virtualization approaches are relevant to different disease areas, particularly as some require procedures, such as scans, to be conducted in a clinical setting. There are also differences in the maturities of the available technologies and services by therapeutic area and market that will influence where to focus. Against that backdrop, R&D and therapeutic-area leaders can review their portfolios to see where decentralized or hybrid clinical trials could add the most value in improved patient enrollment and retention or patient and physician engagement. Such a portfolio prioritization will identify common technologies and capabilities that a sponsor can deploy across the portfolio.

— Which decentralization solutions and capabilities, if any, do we want to develop in house?

The clinical-trial ecosystem is rapidly evolving as suppliers merge and recombine to offer new and better-integrated products. Many suppliers—traditional CROs and new entrants—are adding capabilities such as patient-facing apps, virtual investigators, and mobile nursing at different levels of readiness and integration. Pharma leaders can decide, based on their portfolios, which capabilities might differentiate them and which ones they should pursue internally rather than source from partners.

— What capabilities do we need to strengthen internally to support a shift toward decentralization?

For clinical-trial decentralization to be operationalized successfully, new tools and services must be embedded into core processes. Asset teams should be aware of the available elements during trial design, relevant functions will need to know how to deploy the solutions, technology platforms should accommodate them, and vendor management and asset teams will need to interact productively with external partners. Individual roles and responsibilities will evolve (for example, new patient-facing roles could emerge to support remote engagement and monitoring). Likewise, direct-to-patient engagement by sponsors for monitoring is becoming more important as data verification shifts from in-person monitoring and verification toward remote coverage and analyses of new data types.

— How can we enable the organization to change?

The scale and pace of decentralization will vary among clinical-trial sponsors. Some will run experimental use cases with individual programs to test technologies and build capabilities. Others will make wholesale shifts in their operating models and underlying technology platforms to deliver virtualization at pace. However, the hallmarks of successful decentralization are likely to remain: leadership articulating strategic intent about the opportunities for patients, physicians, and sponsors; strengthening decentralization capabilities across the organization; embedding reframed processes and systems to support the agenda; and showcasing and celebrating successful decentralized trials across the organization.

The COVID-19 pandemic has exposed the importance of decentralization in making clinical trials more patient-centric. Our conversations with sponsors, investigators, and service providers have highlighted a strong momentum toward more decentralized trial designs. The shift will continue to reshape the industry and improve outcomes for sponsors, physicians, and patients.

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