DT CONSULTING

February 15, 2021

The DT Clinical Trial Digital Tracker

Insights From Our Global Survey On The Adoption Of Digital Tools For Clinical Trials

by Francesca Properzi
with Carlos Capella and Tim van Tongeren

Executive Summary

Randomized clinical trials that evaluate the efficacy and safety of new medicines are a crucial step in pharmaceutical R&D. The traditional clinical trial process, where patients are recruited by and treated and monitored in consolidated research centers, is time-consuming, costly, and poses considerable challenges to participants. Digital technology can transform and accelerate drug development by improving patient experiences and lowering costs. The DT Clinical Trial Digital Tracker Survey is a new methodology to assess the current state of digital adoption by clinical trial sites globally. Results from our inaugural survey indicate that many clinical trial sites are still reluctant to integrate digital technologies into their process and that cost, complexity, and finding the right technologies are the main barriers to digital adoption.

Table of Contents

CLINICAL TRIALS NEED DIGITAL SOLUTIONS TO IMPROVE PATIENT EXPERIENCES

The digitalization of randomized clinical trials is a key priority for the pharma industry. New technologies are already enabling a shift toward decentralized and virtual trials to improve patient experiences and the overall clinical journey. By supporting both patients and investigators, digital tools have the potential to significantly reduce the rate of clinical trial failure and lower drug development times and costs, bringing new, improved, and potentially cheaper drugs to the market faster. When we looked closely at the data surrounding clinical trials, we found that:

- **Most fail in patient recruitment and retention.** Eight in 10 clinical trials don't recruit enough participants on time, causing significant delays or making studies unfeasible.[1] Patient retention is also a substantial challenge: according to one estimate, only 10% of studies' initial participants successfully complete them.[2] Several factors contribute to recruitment and retention issues: unclear patient consent forms and protocols; lack of awareness of and visibility into ongoing clinical trials; poor study design (e.g., inclusion/exclusion criteria); logistical challenges like getting to the research center; and inadequate communication with patients.

- **The largest cost drivers are the number of patients and onsite visits required.** A recent study assessed the costs of all steps in a clinical trial and found that the largest single driver of clinical trial costs is the number of patients required to establish the effects of a treatment, followed by the number of clinic visits, which ranged from two to 166.[3] These two factors, which can exponentially increase the cost of a trial, can be reduced by applying virtual technologies.

The Unprecedented Opportunity to Accelerate Digital Tech Adoption In Clinical Trials

Digital innovation is growing rapidly in healthcare due to the unparalleled availability of new technologies, the global response to the COVID-19 pandemic (including new regulatory requirements encouraging virtual solutions), and an increase in the number of clinical studies launched. We see that:

- **The number of digital solutions and platforms for drug development is increasing rapidly.** The global market for virtual clinical trials is likely to rise at a compound annual growth rate (CAGR) of 5.1%, increasing from $7.4 billion in 2020 to $10.5 billion in 2027, predominantly in North America and in the oncology sector. In the US, the adoption of new technologies for clinical research will be encouraged by government support and greater competition to meet client needs.[4] The Asia Pacific region has the highest projected CAGR (6.2%) thanks to its large patient pool, which enables easy candidate recruitment and fast development and adoption of state-of-the-art digital technologies.

- **COVID-19 is making virtual and decentralized approaches to clinical trials necessary.**[5] The pandemic interrupted or halted 80% of trials unrelated to COVID-19. A month after the outbreak, up to 80% of clinical trial patients were unwilling to go onsite for appointments; 52% of research centers believed that patients did not want to interact with any medical professionals.[6] In response to COVID-19, the US Food and Drug Administration (FDA) issued guidelines calling on sponsors and researchers to determine whether it would be best for study participants to continue in a trial or not and encouraging the adoption of virtual approaches.[7] One study found that virtual consultations and eConsent were the most frequently adopted technologies during the pandemic.[8]

- **Clinical research is increasing and rapidly transitioning to digital approaches**. In April 2020, it looked like more than half of investigative sites were shifting to virtual methods of patient interaction.[9] Our analysis of the clinical trial database indicates that, despite the initial disruption, industry-funded clinical studies that launched increased significantly after the COVID-19 outbreak (see Figure 1). The number of studies that launched in the fourth quarter of 2020 was 32% higher than a year earlier; the number of publicly funded studies was 28% higher.

Figure 1: *The number of industry-funded clinical trials rose steadily throughout 2020*

Source: US National Institutes of Health

HOW CLINICAL TRIAL SITES CURRENTLY USE DIGITAL TECHNOLOGIES

To understand the state of digital adoption in industry-funded clinical trials, we developed the Clinical Trial Digital Tracker to monitor how many active research sites use digital technologies; what digital tools they're adopting; which ones deliver the best results; and what challenges sponsors and investigators face in integrating digital into their traditional operating model. We sent the survey to all global interventional studies that launched from October 2019 through September 2020—the six months before and after the COVID-19 outbreak.[10] We got responses from 261 clinical trial sites—or 6% of global actively recruiting trials—and found that they:

- **Often use no digital tools at all.** Among our respondents, 43% do not use digital tools to support clinical trials (see Figure 2). Of the respondents that use digital tools, 34% said they use digital tools for patient recruitment, 20% for patient adherence, 19% for patient retention, and 14% for other types of patient support; 13% use digital tools to support clinical trial processes not related to patients. There were no significant differences between clinical trials launched before and after the COVID-19 outbreak in March 2020.

- **Adopt digital recruitment channels, virtual visits, and eConsent most often.** When we asked sites which digital tools they were using or planning to use to conduct their trial, 22% mentioned recruitment channels; 14% use eConsent and digital documents; and 13% use virtual consultation channels such as video, phone calls, and messages (see Figure 3). The primary digital recruitment channels that respondents use are social media, websites, and email (see Figure 4).

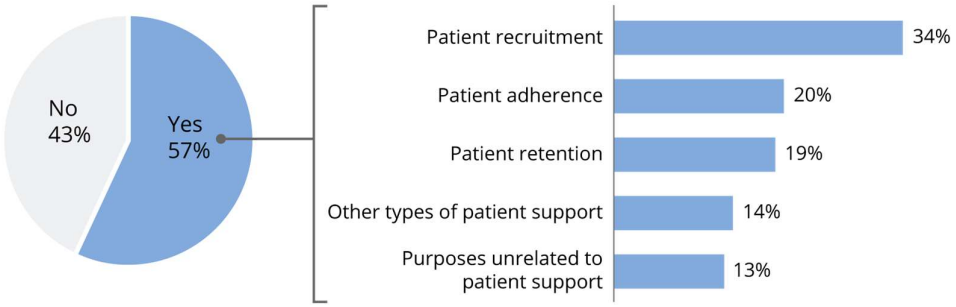
- **Use RWD/RWE tools for patient retention and virtual trial platforms least often.** Only 4% reported using real-world data or real-world evidence. Virtual trial platforms, relationship management portals, and patient experience platforms also had low adoption (5% to 6%).

- **Consider adherence support tools the most effective at improving clinical trial processes.** Three-quarters of respondents using patient adherence tools said that they are very or extremely likely to enable successful trial completion (see Figure 5). A few other technologies did very well: respondents using these technologies said that virtual consultation channels (62%), recruitment channels (56%), and remote monitoring (53%) are extremely likely to have a positive impact on trials. Patient/ provider relationship management portals and education channels and patient-to-patient communication channels were less likely to deliver good results (less than 44% of responses).

- **Find that cost, complexity, and finding the right technology most challenge digital adoption.** Survey respondents said that the three most relevant challenges in digital tool adoption are finding the right tools (20%), lack of funding for these tools (15%), and the complexity of setting up digital tools as part of a trial (12%) (see Figure 6). Following these were a lack of clarity around regulations (9%) and lack of outcome evidence (8%). Repondents using digital tech viewed safety compliance and digital literacy in their organization as less relevant barriers to digital transformation. Several digital adoption challenges rose in significance after the COVID-19 outbreak: after March 2020, there was a sharp increase in the percentage of respondents citing the complexity of technology setup (from 9% to 15%) and the complexity of understanding how digital tools really work (from 3% to 8%) as challenges. Outcome evidence and compatibility with existing IT systems were much less often seen as barriers post-COVID.

Figure 2: *Nearly half of actively recruiting clinical trials use no digital tools to support patient-related activities*

"For this clinical trial, are you using or planning to use any digital tools to support the following?"

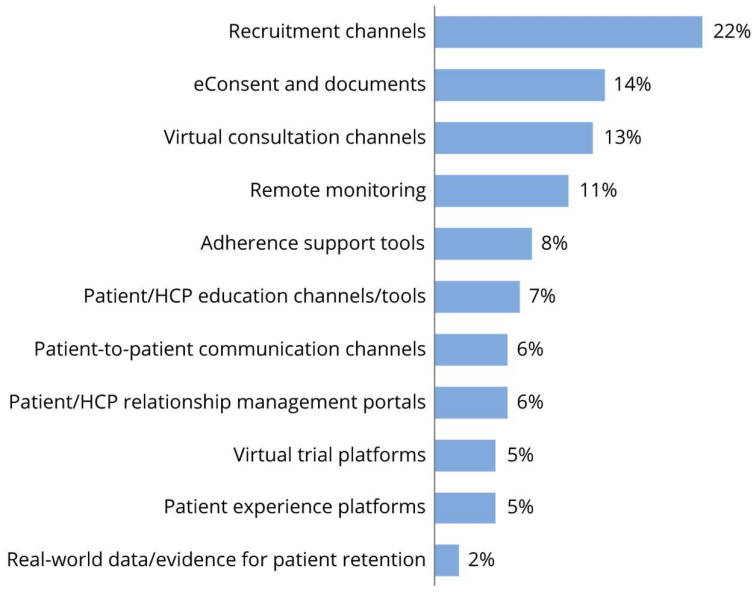


Base: 261 clinical trial sites that were actively recruiting participants (respondents could choose multiple digital tools from the list)

Source: DT Consulting Clinical Trial Tracker Survey, 2020

Figure 3: *Clinical trials most often use digital tools for recruitment and eConsent*

"Which of the following digital tools are you using or planning to use to conduct your study?"

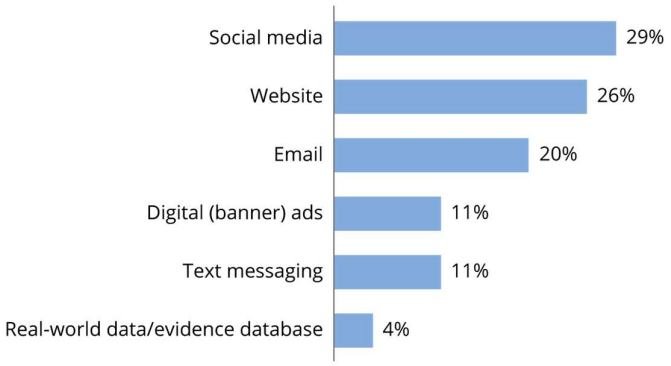


Base: 118 clinical trial sites that were actively recruiting participants (multiple responses accepted)

Source: DT Consulting Clinical Trial Tracker Survey, 2020

Figure 4: *Very few clinical trials use real-world data or evidence for participant recruitment*

"Which of the following recruitment channels are you using?"

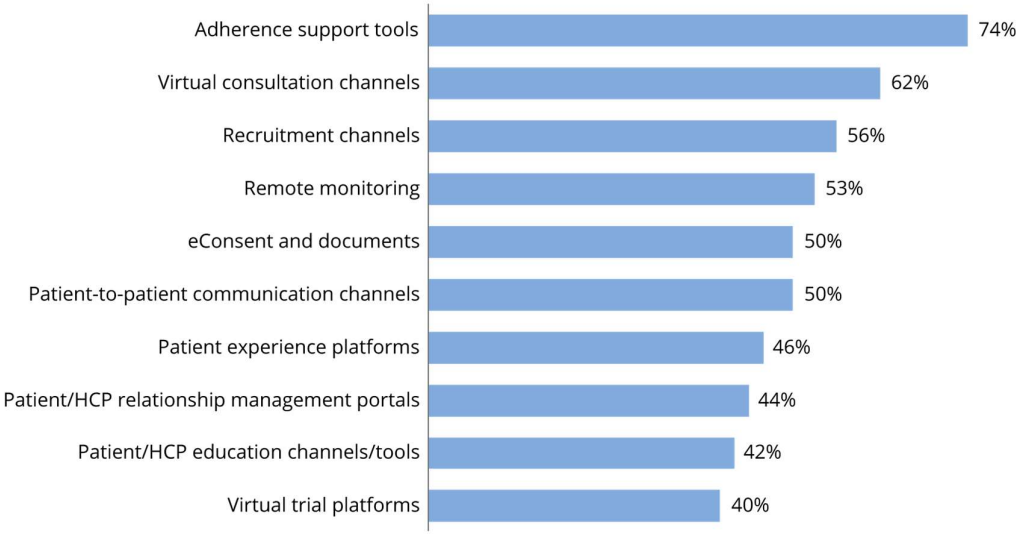


Base: 64 clinical trial sites that were actively recruiting participants via digital channels (multiple responses accepted)

Source: DT Consulting Clinical Trial Tracker Survey, 2020

Figure 5*: Adherence support tools are considered the most effective at improving clinical trial processes*

"To what degree will each of the digital tools that you are using or planning to use support getting the expected number of participants and completing the trial successfully and on time?"
(responses of 4 or 5 on a scale of 1=not at all useful to 5=extremely useful)

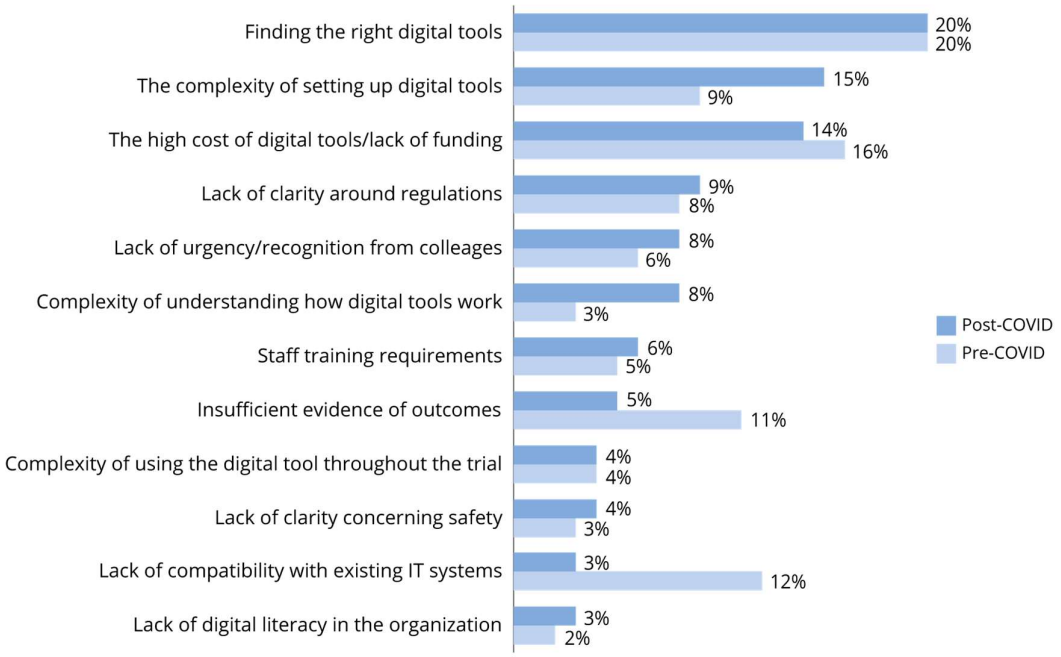


Base: 118 clinical trial sites that were actively recruiting participants

Source: DT Consulting Clinical Trial Tracker Survey, 2020

Figure 6: *Cost, complexity, and tool identification are the top challenges to digital technology adoption*

"Which of the following digital tools are you using or planning to use to conduct your study?"



Base: 96 clinical trial sites that were actively recruiting participants
(multiple responses accepted)

Source: DT Consulting Clinical Trial Tracker Survey, 2020

RECOMMENDATIONS

SHIFT TO A DIGITAL MINDSET AND CROSS-INDUSTRY COLLABORATION

Our research shows that the initiation of clinical trials increased by 40% year over year after the COVID-19 outbreak—although the number of studies that were suspended or terminated doubled. To remain competitive, drug development organizations must implement digital solutions to support the increasing number of studies and new pandemic-related requirements; improve participant experiences; and manage logistics and regulatory processes to get new drugs to market faster. Our Clinical Trial Digital Tracker offers timely insights into the state of digital adoption of actively recruiting studies to provide a unique, up-to-date perspective on the challenges and opportunities of digital transformation for clinical ops organizations. To improve clinical trial patient experiences, we recommend that pharmaceutical firms (see Figure 7):

- **Shift their mindset.** Nearly 45% of industry-funded clinical trial sites surveyed don't use digital tools to support the clinical trial process, suggesting that firms are reluctant to change traditional operating models. Some of the respondents that are not using digital tools commented that the main reason behind their choice was that they were unsure about patients' willingness and ability to use innovative solutions. While the integration of innovative systems is perceived as complex and risky—as indicated by which digital challenges respondents say present the biggest hurdles—pharma firms should encourage a shift in mindset toward digital approaches.

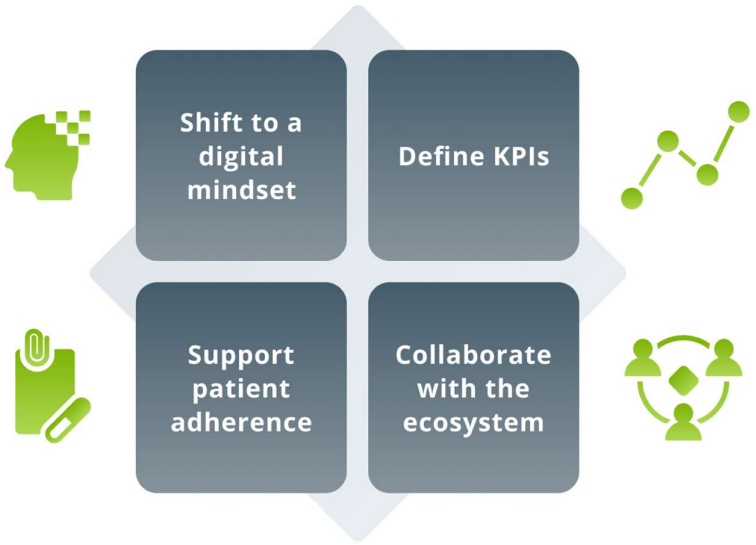
- **Define KPIs and measurable outcomes for digital tools.** Digital recruitment channels are the most used digital tools, but they don't deliver equally good results: only 53% of users were satisfied with their outcomes. Indeed, clinical trial operators looking to adopt new tech said that finding the right tools was their main challenge. One pharmaceutical company created a role in its clinical ops division solely dedicated to finding and understanding the offerings of established vendors and new entrants, including those in digital health. While there is a lively debate around assessing the performance of digital health tools, it's important for clinical operators to define expectations and KPIs with measurable parameters ahead of any new digital implementation.

- **Adopt more digital tools for patient adherence.** Patient adherence tools such as electronic dispensers and apps to manage medication schedules and patient diaries were some of the technologies least adopted by survey respondents. Nevertheless, around 75% of researchers adopting them found them very or extremely likely to support the successful completion of the clinical trial process. Companies need to create environments for their teams to adopt new tools in their trials by addressing learning and development, funding, and tech support.

- **Collaborate with regulators and other key industry stakeholders.** In 2017, the FDA published its Digital Health Innovation Action Plan to guide the adoption of new digital products. While regulators support the use of digital tools, regulatory and data privacy concerns can still slow new technology adoption.[11] Our survey respondents highlighted a lack of regulatory clarity as one of the main challenges to adopting digital technologies. It's important to support open collaboration with other industry stakeholders, including regulators, to identify and share concerns and barriers that may slow the adoption of digital tools in clinical trials.

Notably, more than 85% of survey participants were willing to be contacted for future research on digital transformation. This is encouraging and suggests that clinical trial organizations are willing to collaborate and share their experiences to support faster adoption of new technologies and that the industry has attained good momentum to transition to patient-centric virtual clinical trials.

Figure 7: *DT Consulting's recommendations for adopting digital in clinical trials*



© 2021 DT Consulting

Methodology

The DT Clinical Trial Digital Tracker Survey, 2020 was an email-initiated online survey based on the database at www.clincialtrials.gov. The survey covers all industry-funded interventional studies that launched between October 1, 2019 and September 30, 2020 and were actively recruiting participants—a total of 4,641 studies globally. DT Consulting contacted principal investigators via email in December 2020 and invited them to participate in the survey. 231 clinical trial sites responded to the survey and 124 of them filled out the entire questionnaire. Please note that respondents who use online networks, are triggered by email, and participate in online surveys have more digital experience and are more likely and confident to interact with companies digitally than those with less experience.

Related Research

- "Defining The Capabilities Required To Reach Digital Excellence In Clinical Trials", February 2021
- "The Digital-infused R&D Opportunity in Pharma", May 2016

About the Authors

Francesca Properzi

Francesca has more than ten years of experience in life science and healthcare research projects, including frontline scientific research, digital transformation, and innovative technologies. In her current role as director of research, she is steering the DT thought leadership team to generate valuable insights into customer experiences, specifically in the clinical and medical affairs areas of the biopharmaceutical value chain.

Prior to joining DT Consulting, Francesca was a research manager at Deloitte's UK Centre for Health Solutions, where she led two research projects: one on the state of healthcare digital transformation in the UK and Europe and one on the impact of artificial intelligence in various sectors of the biopharma value chain, including drug discovery and clinical trials. She authored several reports and blog posts on these topics and on other key industry trends. Francesca was previously a principal investigator at the Italian National Institute of Health, researching neurodegenerative diseases and innovative diagnostic and therapeutic approaches. She has contributed to more than forty research publications overall.

Francesca earned a Ph.D. in neuronal regeneration from Cambridge University and recently completed an executive M.B.A. focused on innovation and healthcare at the Imperial College Business School in London.

Carlos Capella

Carlos has over four years of experience in consulting, supporting clients with a range of challenges and opportunities related to their digital transformation efforts. He specializes in methodologies and approaches that help pharmaceutical firms understand their current state of maturity. He advises firms on how to use capability maturity assessments, bespoke market research, landscape benchmarking, and customer experience and analytics tools to deliver critical insights for defining their strategy and generate key inputs for creating their road maps.

Prior to joining DT Consulting, Carlos worked as an analyst at Alfa Consulting, where he led several research efforts to determine the current state of a new contractor model for leading utilities companies in Europe and Latin America. He took on a number of roles to ensure the successful implementation of these models, including project management, stakeholder alignment, and status reporting.

Carlos earned a bachelor's degree (B.Sc.) in economics from the University of Barcelona in Spain.

Tim van Tongeren

For more than fifteen years, Tim has worked with commercial leaders to navigate their strategic and organizational transformations required to thrive on digital technology change. In his current role as Managing Partner, he leads DT's Solutions and Consulting offerings to advise the world's largest pharmaceutical firms on how to best achieve customer experience success through digital transformation. He also directs DT's ongoing effort to provide the pharma industry with the most relevant insights on digital strategy, digital health, and organizational change.

Tim's recent client engagements include digital excellence maturity assessments, customer experience strategy definition, digital capability road maps, embedding CXQ® into the fabric of company-wide customer experience measurement, and training (global) marketing teams on reviewing and improving the customer experience of their digital presence.

Prior to joining DT Consulting, Tim served as senior advisor at Eli Lilly's Digital Hub in Europe and had leadership roles at GlaxoSmithKline's Digital Centre of Excellence to transform its customer experience and digital analytics capability. Before that, he served in SapientNitro's Strategy Consulting, helping firms across industries develop and execute their digital marketing strategies and multichannel presence. Tim started his career at Forrester Research as lead analyst of the customer experience practice in Europe.

Tim holds a bachelor's degree (B.Sc.) in business economics and a postgraduate degree (M.Sc.) in international business and economics from Tilburg University.

About DT Consulting

We help pharmaceutical firms achieve digital excellence to create successful customer experiences. As a specialist consulting firm, we use assessments, benchmarks, bespoke projects, complementary insights from carefully crafted research, and peer networking for executives in digital or related areas to address digital excellence transformation in the pharmaceutical industry. Learn more at http://www.dt-consulting.com/.

Endnotes

[1] Source: Helen Dowden and Jamie Munro, "Trends in clinical success rates and therapeutic focus", *Nature,* May 8, 2019 (https://www.nature.com/articles/d41573-019-00074-z).

[2] Source: Clinical Leader, "Considerations For Improving Patient Recruitment Into Clinical Trials" (https://www.clinicalleader.com/doc/considerations-for-improving-patient-0001).

[3] Source: Thomas J. Moore, James Heyward, Gerard Anderson, and G. Caleb Alexander, "Variation in the estimated costs of pivotal clinical benefit trials supporting the US approval of new therapeutic agents, 2015–2017: a cross-sectional study", *BMJ Open*, June 11, 2020 (https://bmjopen.bmj.com/content/bmjopen/10/6/e038863.full.pdf).

[4] Source: Grand View Research (https://www.grandviewresearch.com/industry-analysis/virtual-clinical-trials-market).

[5] Source: Aaron van Dorn, "COVID-19 and readjusting clinical trials", *The Lancet,* August 22, 2020 (https://www.thelancet.com/action/showPdf?pii=S0140-6736%2820%2931787-6).

[6] Source: Continuum Clinical (https://continuumclinical.com/blog/covid-19-live-updates).

[7] Source: US Food and Drug Administration (https://www.fda.gov/ media/136238/download).

[8] Source: Stephen Le Breton, Mary Jo Lamberti, Adam Dion, and Kenneth A. Getz, "COVID-19 and Its Impact on the Future of Clinical Trial Execution", Applied Clinical Trials, October 22, 2020 (https://www.appliedclinicaltrialsonline.com/view/covid-19-and-its-impact-on-the-future-of-clinical-trial-execution).

[9] Source: Stephen Le Breton, Mary Jo Lamberti, Adam Dion, and Kenneth A. Getz, "COVID-19 and Its Impact on the Future of Clinical Trial Execution", Applied Clinical Trials, October 22, 2020 (https://www.appliedclinicaltrialsonline.com/view/covid-19-and-its-impact-on-the-future-of-clinical-trial-execution).

[10] Base: 4,641 global clinical trials that launched between October 1, 2019 and September 30, 2020. Source: The National Library of Medicine at the US National Institutes of Health (https://clinicaltrials.gov).

[11] Source: US Food and Drug Administration, "Digital Health Innovation Action Plan" (https://www.fda.gov/media/106331/download).