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Defining The Capabilities Required To Attain Digital Excellence In Clinical Trials

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Executive Summary

Digital technologies help clinical development organizations address challenges with recruitment costs, patient enrollment, study design, protocol compliance, safety reporting, and participant trial completion. To successfully deliver superior experiences to clinical trial participants, firms must capitalize on opportunities to build and upgrade their digital capabilities. Clinical trial teams should turn their attention to the two broad categories of on-stage and back-end digital capabilities. On-stage capabilities such as virtual communication channels, eConsent, and adherence tools help clinical trial teams create in-trial touchpoints to help patients successfully complete their trial journey. Behind-the-scenes capabilities such as CRM systems, real-world databases, analytical models, and compliance tools are invisible to participants but essential to digital trial platform success.

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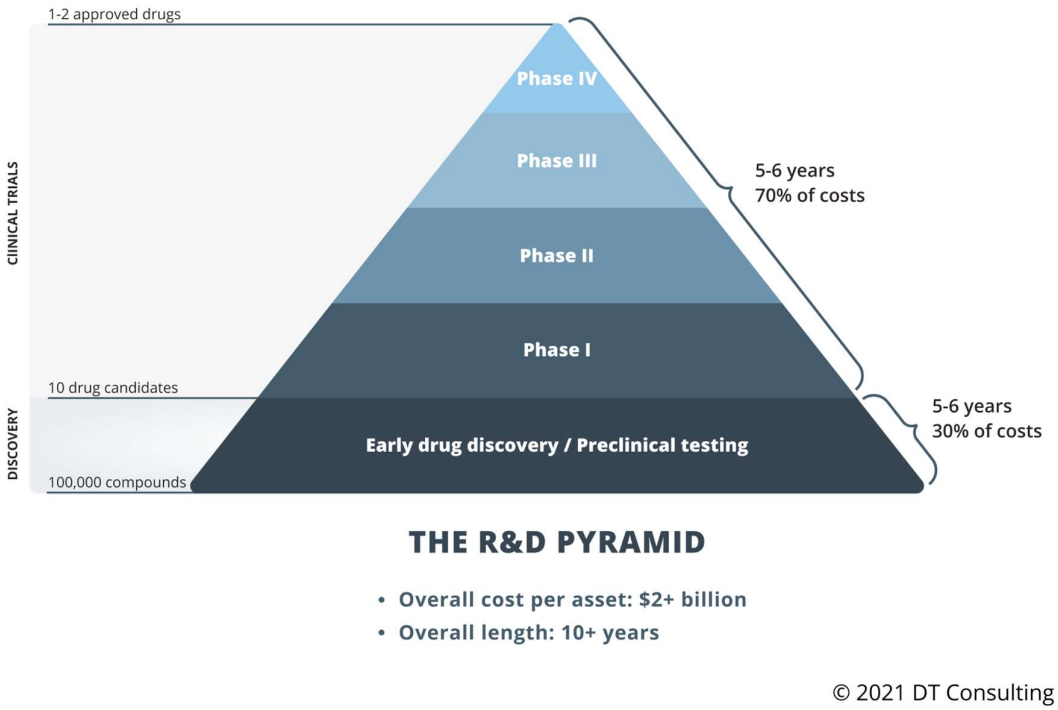
DIGITAL TECHNOLOGIES CAN IMPROVE CLINICAL TRIALS TO BENEFIT ALL PARTICIPANTS

Traditional clinical trials are long and costly: on average, the process lasts more than six years from initial clinical testing to regulatory approval and consumes 70% of a pharma firm's R&D expenditure. Moreover, 90% of new drug candidates fail: for every ten that make it to the clinical trial phase, only one will become commercially available (see Figure 1). As a result, the average cost of delivering a single drug to the market currently exceeds $2 billion.[1] The complex logistics of recruiting and monitoring patients and retaining their participation throughout the trial also dramatically increases failure rates and costs.[2] Digital technologies that respond to patient needs and improve the clinical journey have the potential to transform the clinical trial process from end to end.

Figure 1: *The drug development process*



The Patient Journey Is Complex And Challenging

Starting from the initial diagnosis, patients who want to participate in testing new preapproval drugs face a complex journey. Patient profiles and behaviors, treatment response, logistics, and process-related uncertainties vary widely. Patient experiences can also depend on demographics and geographical location. From beginning to end, the patient journey is an uphill struggle because:

- **Patients are unaware of clinical trials for which they are suited.** Over half of patients in the US, and 85% in the UK, are unaware of ongoing clinical trials and haven't seen any calls to participate in clinical research. Only 15% of patients have participated in clinical research programs—even though 75% say they would like to be involved in new drug testing.[3] A small minority of patients actively seek out suitable studies after receiving their initial diagnosis. To get more participants, healthcare providers (HCPs), investigator sites, and sponsors need to find better ways to raise awareness. Digital recruitment channels to identify candidates—especially next-generation approaches based on electronic health record (EHR) databases, insurance claims, social media posts, and other types of real-world data and evidence (RWD/RWE)—promise to identify and reach a sufficient number of research participants, especially in the context of oncology and low-prevalence diseases.

- **The enrollment process is complex and unsettling.** After contacting a research site, patients undergo initial screening to ascertain their suitability; sign an informed consent agreement to enroll; and be randomly assigned to a treatment group. Many suitable candidates are not convinced that they understand and trust the process, and 35% of patients decide not to join a study or leave early because the informed consent agreement is hard to understand.[4] Over 90% of oncology patients find it important to talk to the doctors and scientists leading the research and the nurses and other patients involved ahead of joining a trial.[5] Multimedia approaches such as electronic informed consent (eConsent) clarify information and improve communication with research staff—who also have access to digital CRM systems—to support the enrollment process and patient follow-up.

- **Medication and treatment monitoring can be logistically difficult.** The hill gets even steeper once clinical testing begins. Medication and biomarker monitoring may require frequent travel to the research center. Adverse effects of the treatment can be unsettling, and reporting these may require additional consultations with doctors. Patients must also update clinical diaries manually rather than use easier digital solutions. Within a few weeks, 40% of patients no longer adhere to the prescribed treatment, and only 7% of the initially identified participants complete a trial.[6] Virtual consultations, wearables, and electronic patient-reported outcomes (ePRO) for real-time symptom monitoring are examples of digital solutions that could help reduce the need to travel and simplify the logistics of the process.

- **Successful medications are often discontinued and unavailable for continued treatment.** At the end of the trial, patients are frequently left without any clinical support—even if they are still experiencing symptoms. When the drug being tested proves effective, patients lose access to its benefits and any possibility to continue treatment with the medication. This can have a negative impact on their willingness to participate in further studies and collaborate with the industry.

Improving Recruitment And Retention With Digital Will Have A Significant Impact On R&D

Pharmaceutical firms can realize significant benefits from holistically understanding and supporting the entire patient journey and using digital technologies to improve patient recruitment, retention, and adherence. This approach will raise pharma companies' return on investment to new heights by:

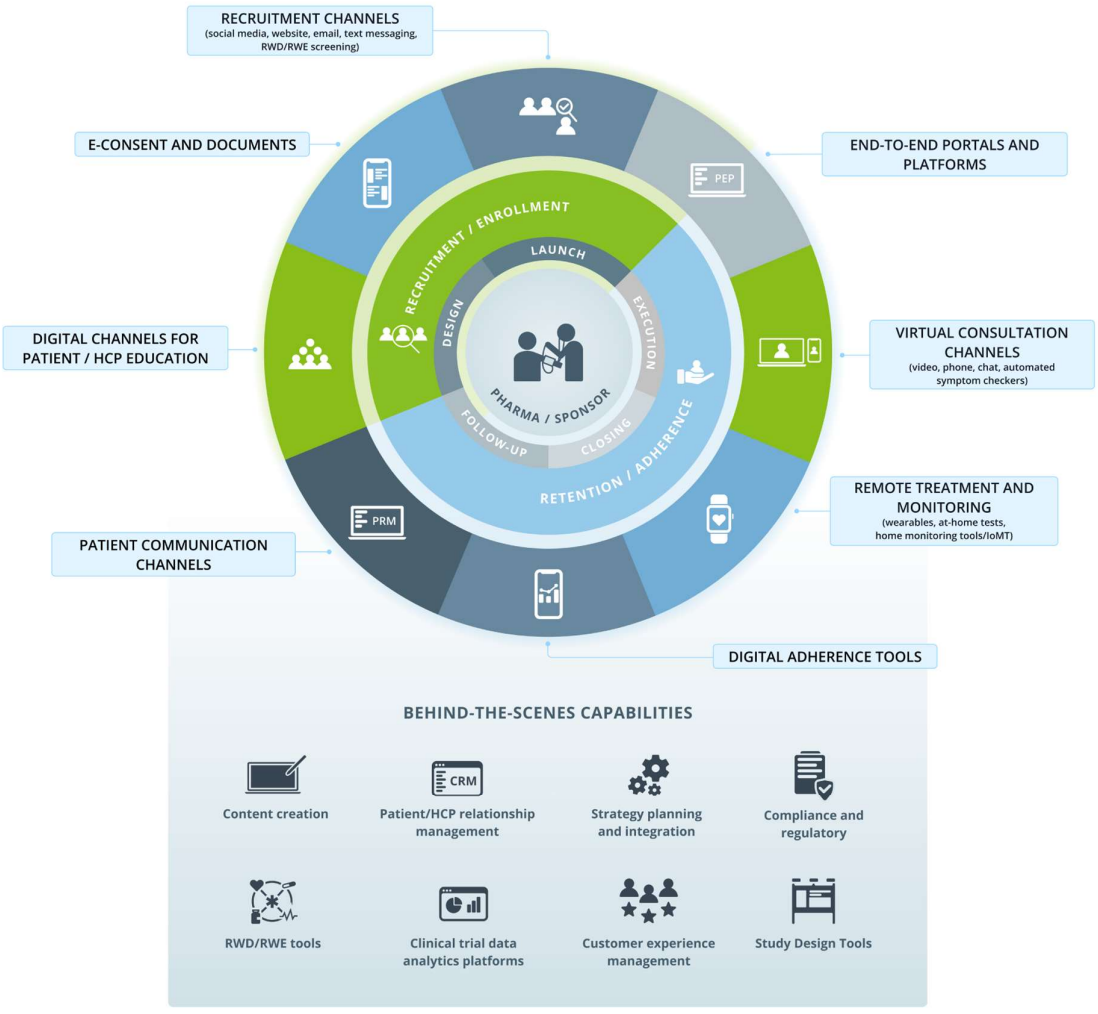
- **Reducing drug development cycle times and operational costs.** The two largest sources of clinical trial costs are the operational costs of recruiting participants and supporting the many clinic visits required over the course of a trial.[7] In 15% to 20% of cases, companies are unable to enroll a sufficient number of participants; half of all trials are delayed due to this problem, which results in losses estimated at $600,000 to $8 million per day. Consultation costs have also a significant impact on the industry—but these can be dramatically reduced by the adoption of digital approaches such as remote monitoring and virtual consultations. When hospital visits are critical, solutions involving digital integrations—such as commuting assistance via Uber—are also promising.

- **Increasing the rate of drug approvals.** The approval of one extra drug candidate in the research pipeline can improve a pharma firm's R&D productivity, boost its margin by up to $1 billion, and enable it to offer better pricing options to benefit patients.[8] While about 70% of drug candidates fail because the clinical study can't reproduce the levels of safety and efficacy seen in preclinical tests, the remaining 30% fail for reasons other than the clinical worth of the drug, including insufficient patient recruitment, high dropout rates, and data inconsistencies due to poor adherence to research protocols.[9]

THE KEY CAPABILITIES THAT PRODUCE CLINICAL TRIAL EXCELLENCE

To be approved for market, drug candidates must be tested in three phases. Phase I trials test for safety on healthy people; Phase II trials test for efficacy on small patient cohorts; and Phase III trials test larger patient cohorts. Each trial proceeds in five stages: 1) design (defining participant inclusion/exclusion criteria, endpoints, and biomarkers); 2) launch (selecting the site and identifying, recruiting, and enrolling potential participants); 3) execution (treating and monitoring patients); 4) closing (analyzing the data and submitting reports on safety and efficacy outcomes); and 5) follow-up (supporting patients post-trial and assessing the longer-term effect of therapeutics) (see Figure 2). Several types of digital capabilities can support patient touchpoints in all stages. Clinical trial organizations should focus on on-stage capabilities for processes that directly affect patients, including recruitment and retention, and behind-the-scenes capabilities for those that do not need a direct patient interface.

Figure 2: *Digital capabilities for clinical trials*



On-Stage Digital Capabilities For Patient Recruitment And Retention

On-stage capabilities are patient-facing and make touchpoints come alive by delivering patient experiences directly. Typically, the better firms deploy and use these, the better the experiences are. Success is defined by improving patient recruitment and retention throughout the trial journey. These capabilities include:

Recruitment and enrollment

- **Digital recruitment.** These are business practices for recruiting participants via digital channels. They include advertising the clinical trial via social media, websites, email, text messaging, digital banners, web and mobile apps, third-party platforms, online communities, patient advocacy groups, prescreening tools, and digital concierges (researcher-led and automated chatbots).

- **Digital enrollment/eConsent and documents.** These are business enrollment practices, such as eConsent, that provide patient consent information in electronic form. This can include multimedia components such as images, audio, video, diagrams, reports, chatbots, callout boxes, and digital signatures that aid the consent process. It may also include resources for exchanging information with researchers, clinicians, and other patients.

- **Digital clinical trial education.** Digital education programs support patients and HCPs by providing detailed information on the pathology, adverse effects, trial rationale, and timeline via websites, apps, social media, emails, webinars, and digital lectures.

Retention and adherence

- **Virtual consultation.** Virtual medical consultation methods for treatment and symptom checking include voice and video calls, text messaging and chat apps, and automated symptom checkers. These significantly reduce the need for both patients and doctors to travel, significantly improving the logistics of conducting the trial.

- **Remote monitoring.** This is the practice of capturing clinically relevant patient data from mobile phones, wearables, implanted and in-home sensor technology, and at-home diagnostic kits. It enables continuous remote monitoring of biomarkers and other vital signs to better understand drug performance, respond faster to crises, improve research data quality, and reduce the need to travel to a clinical site.

- **Medication adherence.** These are business practices dedicated to helping patients (continue to) take the medication as prescribed; they include treatment monitoring platforms, electronic alerts and chatbot reminders, electronic dispensers, ingestible sensors, mobile and web apps, and ePRO. Digital reporting of medical adherence also makes trial operations more efficient by automatically removing nonadherent patients from trial data reporting.

- **Patient communication.** Communication channels with trial participants to assess trial progress and patient experiences in real time include digital tools for patient/HCP surveys, internet forums, patient groups, social media, and automated chatbots and communication systems.

- **End-to-end portals and platforms.** These are single platforms or portals integrating all patient recruitment, retention, and adherence approaches and databases for an end-to-end digital trial such as virtual trial platforms and patient experience/engagement platforms.

Behind-The-Scenes Digital Capabilities

While not patient-facing, capabilities that leverage the power of data, such as data analytics platforms, RWD/RWE sources, and proprietary and third-party databases, are crucial to improving patient experiences. Clinical trial organizations should make it a priority to consolidate these digital capabilities, which are also important for capturing information and insights from ongoing trials in real time and optimizing content and decision-making to ensure successful, on-time study outcomes. These capabilities include:

- **Digital study design and launch.** This is the digital approach to aspects of trial design like defining criteria for endpoints, biomarkers, and participant inclusion or exclusion. Digital design can leverage web or mobile apps for patient and HCP surveys to optimize protocols (including segmentation and behavioral analysis), smart tools for inclusion/exclusion, electronic case report forms, and tools for site selection and randomization. Digital can support key aspects of study design such as disease landscaping, new drug indications, protocol optimization, trial simulation, and synthetic control arms.

- **Content creation and scientific writing and reporting.** These are the business practices related to creating and managing relevant and valuable information to attract, engage, and serve customers and other stakeholders. For clinical trials, the focus is on content for digital interactions among all participants, including research organizations, HCPs, patients, regulatory bodies, and institutional review boards (IRBs).

- **Customer relationship management.** Customer relationship management (CRM) is a method for managing a company's interactions with current and future trial stakeholders including investigator sites, contract research organizations, HCPs, and patients. It often involves using technology to organize, automate, and synchronize communications and provide technical support.

- **Strategy planning and integration.** Strategy planning is the process of determining what digital capabilities are required for trial planning and execution. It often starts by orchestrating the patient journey from a trial perspective and then works backward to arrive at preferred digital capabilities.

- **Customer experience management.** This is the practices that clinical trial teams use to optimize experiences throughout a trial. It involves understanding the specific needs of participants, creating and improving specific touchpoints and materials, and measuring overall participant satisfaction.

- **Compliance and regulatory.** These are digital business practices for regulatory submission, labeling, and IRB approval, including the screening of new requirements and protocols. Examples include intelligent planning platforms and predictive querying tools.

- **RWD/RWE databases and platforms.** These participant databases collect records and information on patient health from sources like EHRs, insurance claims, and lab and pharmacy databases. In addition to supporting patient and HCP outreach, they can be embedded into platforms to support study design, including synthetic control arms databases; smart tools for site selection and inclusion and exclusion criteria; recruitment channels; safety prediction patterns and trial simulations; and patient and HCP support for adherence and retention.

- **Clinical trial data analytics platforms.** These data platforms include clinical trial management and electronic data capture systems. Analytics is typically used to derive insights about the patients themselves; suggest improvements for study design, recruitment, and patient engagement during the trial; and gain insight into performance against overall objectives.

RECOMMENDATIONS

ASSESS DIGITAL MATURITY AND TAILOR DIGITAL STRATEGY TO TRANSFORM TRIALS

Aligning the interests of the industry with its customers has always been a key concept of commercial operations—and it's now becoming urgent for clinical operations. Today, drug development outcomes are limited by traditional touchpoints. Clinical trial organizations need to take an agile capability-building approach to assess the various needs of their trials, enable digital touchpoints, and respond flexibly. To achieve digital excellence in clinical trials:

- **Define the long-term ambition.** To transform the experiences of patients in clinical trials, begin by establishing a long-term vision for what the experience needs to be and what value it needs to create for business and patient alike. Whether the goal is improving patient engagement, optimizing the research pipeline, reducing costs and timelines, accelerating digital transformation by enabling fully virtual and decentralized studies—or some combination thereof—investments, timelines, and focus will only be effective if underpinned by a clear ambition.

- **Assess the current maturity in digital excellence for clinical trials.** An accurate understanding of today's tech stack, the level of adoption by trial teams, and drivers related to the availability and adoption of digital technology are vital inputs into the capability roadmap. The roadmap objectives are determined by your ambition; the maturity assessment allows you to understand the capability gap you need to fill. In-depth analysis of the cost drivers determines how quickly the organization can create new capabilities.

- **Design a digital capability roadmap aligned with the research pipeline.** While not all trials require the same capabilities, it's essential to have a well-run catalogue of digital capabilities for clinical trials that is easy to set up, centrally available, and cost-effective and which gives teams clear usage guidelines. The team that builds the overall capability needs to align the roadmap with the overall research program as well as today's portfolio and the future pipeline. More and more, we also see that they need to have the business acumen to be the change agent to shift the culture and imbue the organization with a digital mindset. Our interviews indicate that clinical trial organizations base their tech choices on specific disease-related factors and geographical location; this influences how they roll out new capabilities.

- **Align your internal skills, talent acquisition, and knowledge to (new) digital technologies.** As part of your digital capability roadmap, focus on developing people and acquire talent experienced in the use of new technologies. Companies that don't emphasize capacity-building will find that the digital capabilities they've purchased will remain unused shiny toys. Ongoing research suggests that firms need to create a strong learning and development foundation; make capabilities easy to deploy; and ensure that the overall organization gives employees the space, time, and resources to bring new, innovative digital initiatives to clinical trials.

Methodology

The results presented in the report, including the list and definition of clinical trial digital capabilities, are based in part on a series of semistructured interviews with eight key internal and external stakeholders at the senior vice president level from midsize and large pharmaceutical companies. We asked interviewees how they define digital maturity; what the current state of digital transformation and patient experience is at their organizations; what digital tools and capabilities they use; and what digital strategy they think will be successful in improving the outcomes of clinical trials.

Related Research

- "The DT Clinical Trial Digital Tracker," 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.

Sudip Sinha

Sudip Sinha is vice president for digital CRO at Indegene. He is a senior management professional (Six Sigma Black Belt certified) with twenty-four years of experience in healthcare leadership for pharmaceutical multinationals (Novartis, AstraZeneca, and Merck) and with contract research organizations (Quintiles and others).

Sudip has organized, managed, directed, and monitored a large number of Phase I to IV clinical studies (involving cross-functional teams) as per ICH GCP-applicable regulatory guidelines in the therapeutic areas of cardiovascular disease, endocrinology, gastrointestinal disorders, infectious diseases, internal medicine, neurology, nephrology, oncology, psychiatry, pain management, respiratory, and vaccines in various roles and capacities in the Asia Pacific, US, and European markets.

Sudip has managed and overseen the global quality assurance function, hosting FDA, EMA, TGA, sFDA, and DCGI inspections and ensuring compliance at the site and country level. As a global and country P&L head, he has exhibited strengths in effectively ideating, incubating, and propagating growth and harmonized teamwork across global, regional, and multi-country teams.

Prior to his work with Indegene, Sudip successfully deconstructed complex situations into streamlined process workflows, increasing the revenue, reducing the cycle times, and improving the productivity and profitability of the organizations he worked in.

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 Associates, 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: David B. Fogel, "Factors associated with clinical trials that fail and opportunities for improving the likelihood of success: A review", *Contemporary Clinical Trials Communications,* August 7, 2018 (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6092479/).

[3] Source: "Insights from Engaged Patients: An Analysis of the Fourth Annual Survey", Inspire, February 2019 (https://corp.inspire.com/resource/fourth-annual-survey/).

[4] Source: Eric Delente, "Improve Patient Comprehension and Retention with eConsent", Applied Clinical Trials, February 9, 2017 (https://www.appliedclinicaltrialsonline.com/view/improve-patient-comprehension-and-retention-econsent).

[5] Source: Eva Isaksson, Per Wester, Ann Charlotte Laska, Per Näsman, and Eric Lundström, "Identifying important barriers to recruitment of patients in randomised clinical studies using a questionnaire for study personnel", *Trials,* October 30, 2019 (https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-019-3737-1).

[6] Source: Alasdair Breckenridge, Jeffrey K. Aronson, Terrence F. Blaschke, Dan Hartman, Carl C. Peck, and Bernard Vrijens, "Poor medication adherence in clinical trials: consequences and solutions", *Nature,* February 3, 2017 (https://www.nature.com/articles/nrd.2017.1).

[7] 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).

[8] 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).

[9] Source: "Insights from Engaged Patients: An Analysis of the Fourth Annual Survey", Inspire, February 2019 (https://corp.inspire.com/resource/fourth-annual-survey/).