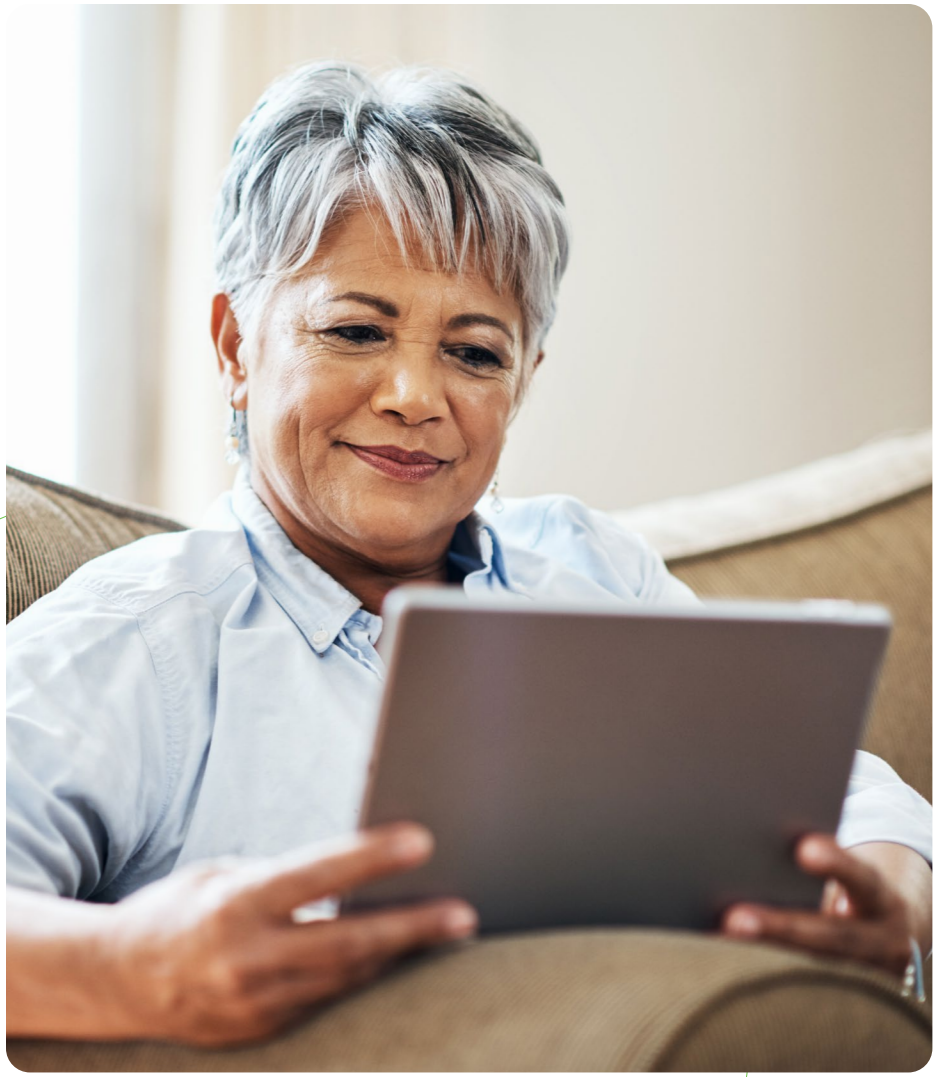
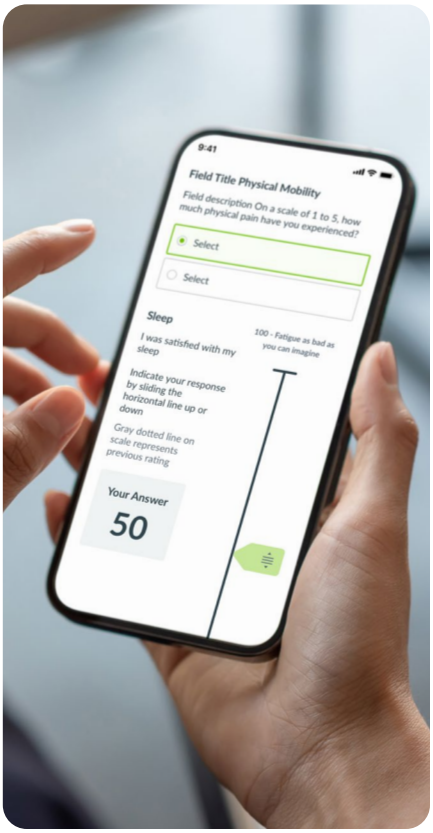
Science 37

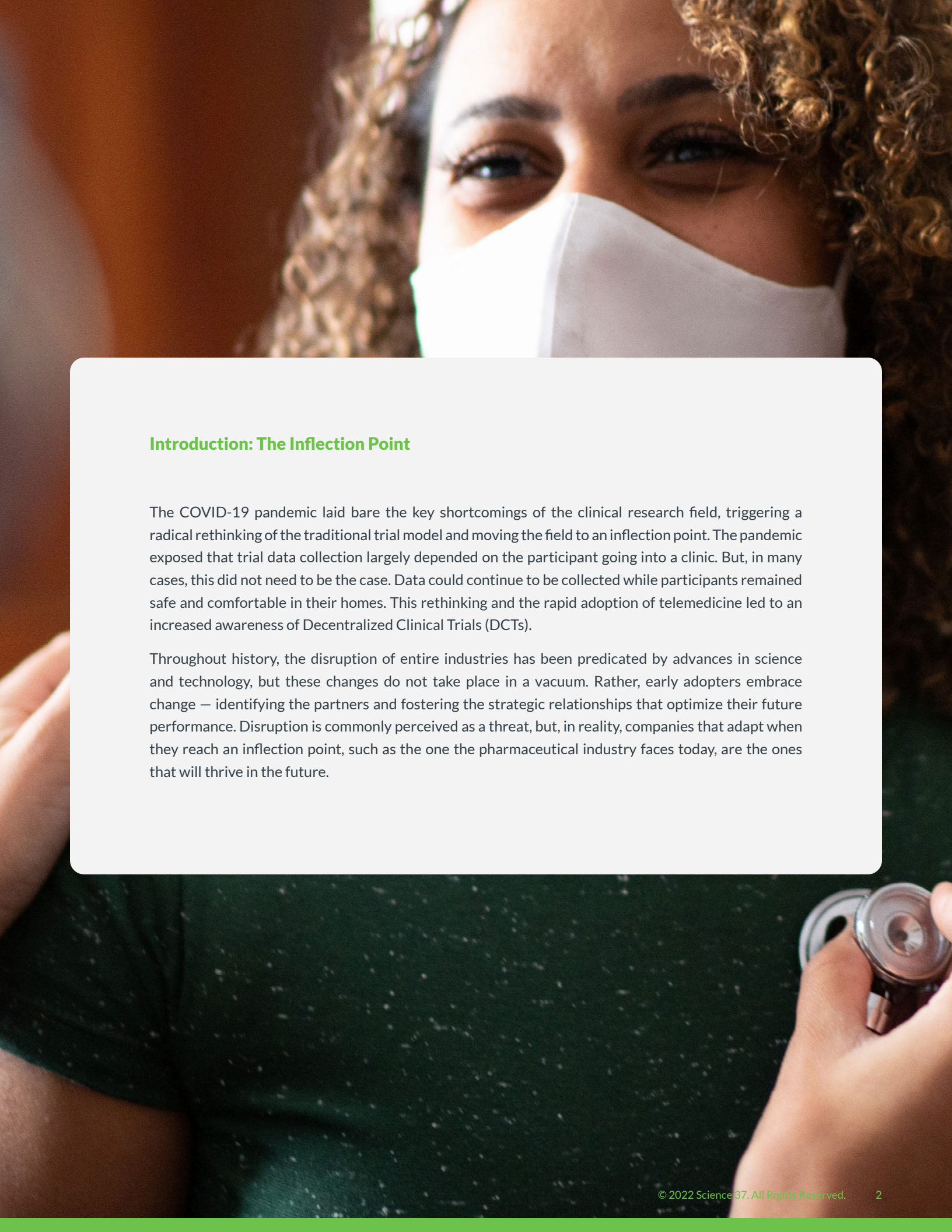
WHITE PAPER

An Executive Clinical Trial Playbook:

How Decentralized and Hybrid Trials Accelerate Research and Enable Diversity







Introduction: The Inflection Point

The COVID-19 pandemic laid bare the key shortcomings of the clinical research field, triggering a radical rethinking of the traditional trial model and moving the field to an inflection point. The pandemic exposed that trial data collection largely depended on the participant going into a clinic. But, in many cases, this did not need to be the case. Data could continue to be collected while participants remained safe and comfortable in their homes. This rethinking and the rapid adoption of telemedicine led to an increased awareness of Decentralized Clinical Trials (DCTs).

Throughout history, the disruption of entire industries has been predicated by advances in science and technology, but these changes do not take place in a vacuum. Rather, early adopters embrace change — identifying the partners and fostering the strategic relationships that optimize their future performance. Disruption is commonly perceived as a threat, but, in reality, companies that adapt when they reach an inflection point, such as the one the pharmaceutical industry faces today, are the ones that will thrive in the future.

Rethinking Clinical Trials From the Ground Up

Clinical research sponsors have always struggled with challenges to the traditional clinical trial model: only 8% of the patient population overall participates in clinical trials, along with a mere 3% of physicians. Four out of five clinical trials experience delays, with 94% of clinical trials delayed more than a month with a potential daily financial impact of more than $600,000.[1]

Reflective of the healthcare disparities amplified during the pandemic, diversity is still lacking in most clinical trials, with white patients accounting for approximately 86% of all participants globally. In the United States, black patients account for just 5% of trial participants, although they comprise 13% of the overall U.S. population. Hispanic patients account for a mere 1% of trial enrollees, despite making up 19% of the U.S. population.[2,3] This lack of representation in study data, in turn, limits clinicians' ability to understand safety and efficacy in population sub-groups.

A factor in this underrepresentation is a reliance on clinical trial sites for study delivery, which not only limits participation by geography but also demands that patients invest considerable time and cost in transportation, time off work, and possibly lost wages. These factors create retention challenges, particularly for long-running trials.

Regulators and lawmakers have sent clear signals indicating that they expect the industry to prioritize diversity in clinical research. In April 2022, the Food and Drug Administration published new draft guidance informing clinical trial sponsors that they have a responsibility to improve their efforts to recruit and enroll members of underrepresented populations. Additionally, The House of Representatives introduced the Diverse and Equitable Participation in Clinical Trials (DEPICT) Act in February of 2022, the FDA User Bill H.R. 7667 was passed by the House on June 8 has been submitted to Senate (as of June, 2022). If this legislation becomes law, it will set a higher standard for collecting and reporting data pertaining to trial participant demographics and would require sponsors to improve the equity of trial access across all racial and ethnic populations.

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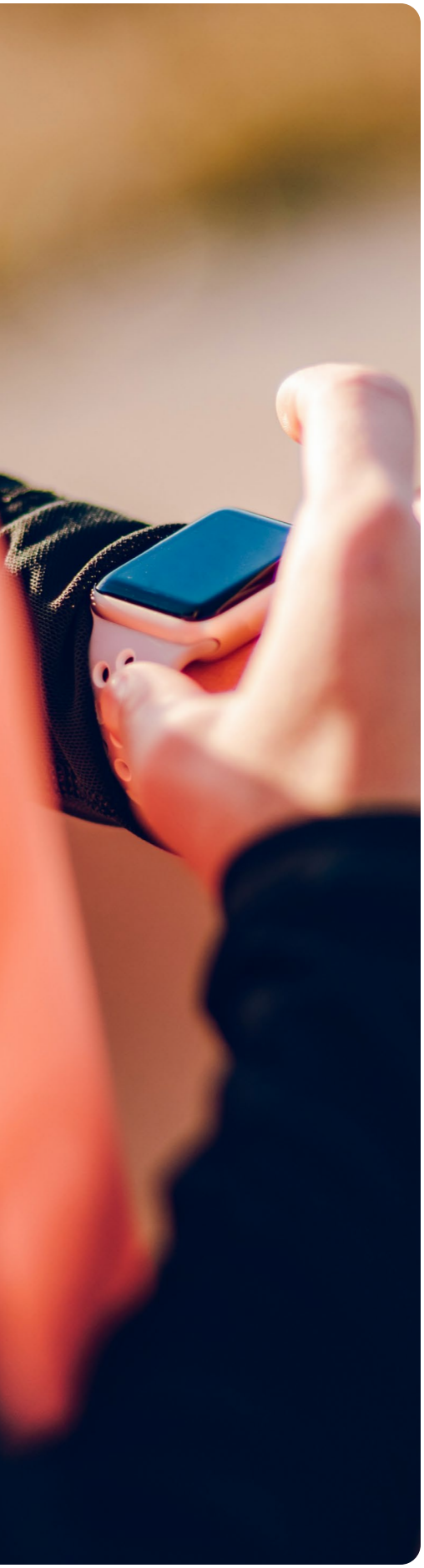


The Catalyst for Change

The widespread adoption of telemedicine, engendered by the pandemic, greatly accelerated a shift to more flexible and patient-centric processes for clinical research management. The industry became more agile, supporting trials at site, fully decentralized, or a spectrum of hybrid designs. The shift from the traditional way of managing clinical research expands patient access for rapid and diverse recruitment. It also enables the collection of high-quality, contemporaneous data: a product of unified processes and centralized coordination across telemedicine investigators, wearable devices, mobile healthcare professionals, and local providers.

The ubiquity of wearable health devices is a prime example of the disruptive influence of innovation and collaboration. As of 2019, approximately 1,400 clinical trials had been conducted with the use of a health-tracking device.[4] Kaiser Associates estimates that 70% of clinical trials will incorporate sensors by 2025. This is critical, as 99.9% of patient health-related activity occurs outside of a hospital or clinic, where sensors are the primary source of patient health-related information, according to EHR Intelligence.[4]

Demand for more data is a detriment of the traditional clinical trial model. The time and labor required to record this information increases the burden on patients and clinicians. With fitness trackers like the Fitbit and Apple Watch becoming an everyday part of millions of people's lives, modern trials are able to accurately and effortlessly collect a previously unimagined trove of data. This development has the potential to reshape key parts of clinical trial reporting, increasing access to a much wider pool of patients.

What Agile Enables: Any Patient. Anywhere.

As of June 2022, there are 17,853 active trials, with 14,764 trials recruiting studies, according to Global Data.[5] When faced with an 80% delay rate due to poor enrollment, the industry is potentially facing more than 14,000 delayed trials—not including new trials beginning in upcoming months and years. These delays are significant due to exorbitant associated costs and detrimental implications to breakthrough medicine.[6] By breaking down the physical confines, the return on investment of agile clinical trials becomes immense.

To counter these delays, visits do not necessarily have to be at a traditional brick-and-mortar site. Instead, telemedicine investigators, mobile nursing-care providers, and community clinics can be brought into the delivery model to reach patients where they are, improving recruitment velocity, compliance, and retention. The end result observed is faster enrollment, greater retention, and real-world representation.

To deliver this model, the agile paradigm must leverage clinical trial technology that coordinates study delivery across settings of care. Through unified and agile technology, sponsors can expand the geographic footprint of a traditional trial, making participation possible for the 70% of patients who live outside of a two-hour driving distance to a traditional site.

Catalyzed by the need to improve recruitment and retention, decentralized clinical trials represent a leap forward. Industry incumbents have an opportunity to embrace change via collaboration, building a new framework of relationships—leveraging technology to engage an expanded network of stakeholders in the field of clinical research. Successful pioneers know how to distill disruption down to its essence—momentum. Seizing that momentum is the imperative and the opportunity facing incumbents in the industry.

Clinical Trial Diversity

Diversity in clinical trial participation has been notoriously hard to achieve through the traditional model due to a number of reasons, including (but not limited to): geography, inequalities in access to medical care, and a lack of trust in healthcare settings outside of the local community. For example, the autoimmune disease systemic lupus erythematosus (SLE) disproportionately affects African-American women—they are three times more likely than Caucasian women to develop SLE[7]—but only 14% of participants in trials for lupus treatments are African-American women.[8]

As supported by recent FDA statements related to diversity, enrolling a representative clinical trial population is critical to evaluating whether a product is safe and effective, given the variation in response based on age, race, ethnicity, and other determinants of health that impact patient outcomes. PK studies showed that, of 86 recently approved drugs, 76 demonstrated higher concentrations in women. And, for those drugs that elicited adverse drug reactions, sex-biased drug concentrations predicted who was having the adverse reactions. Overwhelmingly, 96% of drugs with higher concentrations in women were associated with a higher incidence of adverse drug reactions in women when compared with men.[9] This was likely a result of the dosage not being optimized for women because not enough female subjects were enrolled in those studies.

Enhancing representation in clinical trials can be complicated due to the high degree of skepticism that exists among historically marginalized communities, which is justified given how they have been overlooked by the systems that are supposed to support them. There are numerous modern instances of the medical community conducting dubious or harmful activities in marginalized communities in the name of research that has reduced confidence in the establishment.

Outside of seeking investigative sites or conducting outreach directly to potential participants in areas with higher concentrations of racial and ethnic minorities, a recent Tufts study found that the diversity of site staff is also a driver of a more representative participant population. The Tufts research suggests that the more diverse the site staff, the more likely the diversity of participants. Attention to the diversity of staff—both at sites and in a virtual setting—is of utmost importance.[10]

Under-resourced groups face myriad challenges that accumulate and impact them before they even get into a doctor's office. Many underserved populations rely on other sources for health-related information and support that falls outside the orbit of the traditional site-based clinical trial model. These trusted local networks may be faith-based or exist in social settings such as bowling alleys, hair salons, or barber shops. By enabling patient preference through agile clinical trials, access is enhanced, ultimately improving trial representativeness.

Regulator Emphasis on Diversity

Moving forward, the pharmaceutical industry will face more comprehensive regulatory scrutiny over population diversity as represented among clinical trial participants. The onus will be on trial sponsors to demonstrate to regulators that there are processes and protocols in place to ensure that trials are inclusive of historically marginalized communities.

Draft guidance from the Food and Drug Administration regarding the agency's Race and Ethnicity Diversity Plan makes it clear that the industry needs to prioritize clinical trial operation that captures results representative of the intended treatment population. They will need to be able to articulate their plans to enroll and retain subjects who are members of underrepresented racial and ethnic populations and document how those goals are to be achieved.[11]

Trial sponsors will need to provide the FDA with details about how site location and access to treatment will support the recruitment and retention of diverse subjects. They will need to demonstrate what steps they are taking to reduce burdens and barriers, such as multiple language translations and mobility or transportation assistance, as well as how they are engaging with stakeholders such as community health workers and patient advocates in support of their diversity goals.

Sponsors will also have to outline their processes for data collection and analytics to ensure that trial outcomes reflect the needs, including optimal dosage and variations in clinical response, among underrepresented racial and ethnic groups.

Agile in Action for Diversity Among Other Benefits

Key to overcoming the aforementioned barriers is the diverse, human-centric approach to agile research. An agile clinical trial delivers inclusivity with community providers and entities that foster trust and deliver services to a diverse population.

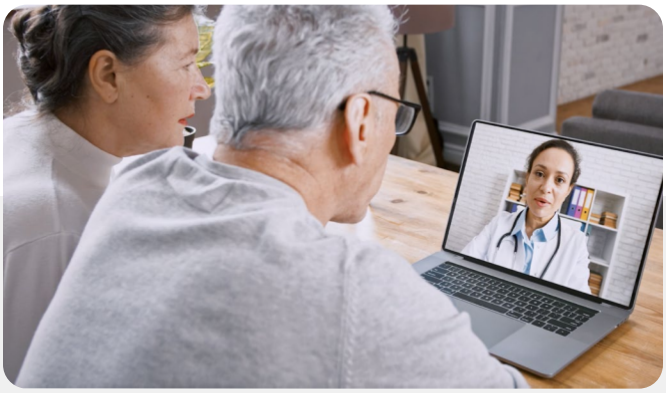
As referenced above, in the context of clinical research, agility means the ability to work multiple models of delivery for the same study including fully decentralized, at a traditional site, and hybrid, simultaneously to accommodate a wide spectrum of patient and sponsor needs.

Agile trials have rapidly become a prominent tactic for optimized clinical trial delivery. One recent survey of trial sponsor executives found that a remarkable 77% of respondents plan to conduct an agile trial within the next 12 months. By contrast, 69% reported plans to conduct a traditional site-based trial over that same time frame: the first time intent for agile rose above intent for the traditional model.[12] In addition to these metrics, discussions with both pharmaceutical companies and clinical research organizations suggest that, increasingly, protocols are being written to offer the option of decentralized or hybrid clinical trial designs, in addition to the traditional at-site model. Writing the protocol with agility in mind, even if the study begins with only at-site delivery, will avoid the need for a protocol change when a study delivered via the traditional model inevitably fails to achieve enrollment velocity and diversity targets.

While every agile trial is uniquely configured and hundreds of models exist, the industry is beginning to standardize on decentralized and hybrid approaches to support patient needs while amplifying reach. These approaches can operate independently or concurrently depending on the demands of any particular trial. The key is to build flexibility into the protocol and deploy an underlying clinical technology platform to coordinate delivery across care settings. Having both of these items will provide the optionality needed to successfully operate the agile trial.

Common Models for Agile Clinical Trials

The agile clinical trial leverages technology to facilitate the patient journey, delivering the infrastructure for coordination of care and enabling flexibility in how clinical data is collected and captured. Examples of common models that have emerged follow.



01

A Virtual Site
(Fully Decentralized Site)

In this model, sponsors supplement their traditional site network with a virtual site to accelerate patient enrollment without the need for starting up additional sites. A virtual site leverages a combination of both technology, telemedicine investigators, and home-based care, allowing for all the study activities to happen at home.

The virtual site facilitates the deployment of decentralized patient care, accelerating enrollment by eliminating the friction of geography. Telehealth functions take place in the patient's home, expanding access to potential participants that are either located too far from a traditional site or are unable to travel due to illness, work responsibilities, parental/dependent care, lack of access to transportation, or financial constraints.

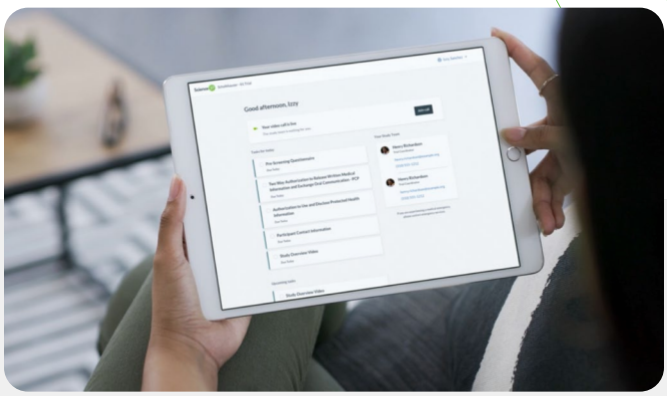
While it is recommended that the virtual site be planned as a critical component to delivering recruitment velocity, diversity, and greater patient convenience (leading to retention), this is not always the case. It is still common for sponsors to request a virtual site be set up quickly to rescue studies that are failing to meet enrollment targets.

02

Virtual Site Plus At-Home Support
for Traditional Site Participants

In this approach, traditional and virtual sites work on the same trial via home resources such as mobile nursing. For agile trials that include at-site, fully decentralized, and hybrid delivery models, we strongly recommend leveraging a single, unified technology for data capture so that all stakeholders have visibility into which visit activities have been completed as well as where, when, and by whom they are completed. This model is transformative as it streamlines recruiting, onboarding, and patient monitoring while maintaining process compliance across all trial delivery settings, enhancing data collection, speed, and quality to deliver a seamless trial experience.

The aforementioned approach is often used for trials in which sponsors need a patient-centric approach to study delivery to achieve enrollment targets with the greatest velocity while continuing to foster traditional site relationships (e.g., KOLs).



03

Community-Based Procedures

One of the most powerful tools in an agile trial toolbox is the use of community-based facilities to conduct study procedures such as diagnostic imaging. While DCTs are primarily built around virtual interactions, using local resources may be necessary to enable decentralized study conduct in trials where not all procedures and assessments can be undertaken exclusively in the home.

This model is popular for oncology trials where procedures cannot be delivered in the home and travel and long site visits are difficult for patients who suffer fatigue, nausea, and other cancer therapy-related side effects.

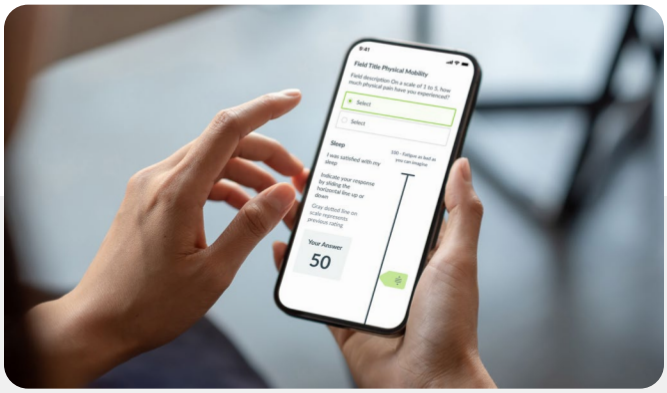
04

Site-Initiated With Remote Management

This blend of on-site and home-based healthcare allows for patients to conduct a portion of their visits remotely, decreasing the burden associated with time spent on travel and at-site. Remote visits are typically conducted through visiting nurse services and telehealth tools.

This flexible model is used across numerous therapeutic areas where only a portion of protocol visits require a site visit for procedures that are not easily delivered in the home.

While DCTs are primarily built around virtual interactions, using local resources may be necessary. The "Community-Based Procedure Model" is popular for oncology trials where certain procedures cannot be delivered at home, and travel to sites is difficult for patients who suffer fatigue, nausea, and other cancer therapy-related side effects.



05

Bring Your Own Investigator

In this model, a patient's own physician is onboarded as a sub-investigator and trained to support trial activities. The sub-investigator performs clinical duties, engaging with the unified technology platform to enter patient data, along with evidence generated by home nurses, telemedicine investigators, and participants or their caregivers.

When considering trial participation, many patients do not wish to give up the trust and comfort they have with their own physician to participate in a trial. Meanwhile, physicians often are concerned that trials take patients away from their practice, creating a climate of mutual distrust that is detrimental to initiating a referral from the managing physician for trial participation.

With this model, patients can receive care from a doctor that they know and trust, and, simultaneously, physicians are more likely to discuss trials as a care option. The benefit to the sponsor is enhanced access to patients that meet study inclusion/exclusion criteria, a particularly salient concern for sponsors of rare disease research, where targeted populations are small and often difficult to source from traditional sites that are limited by geography.

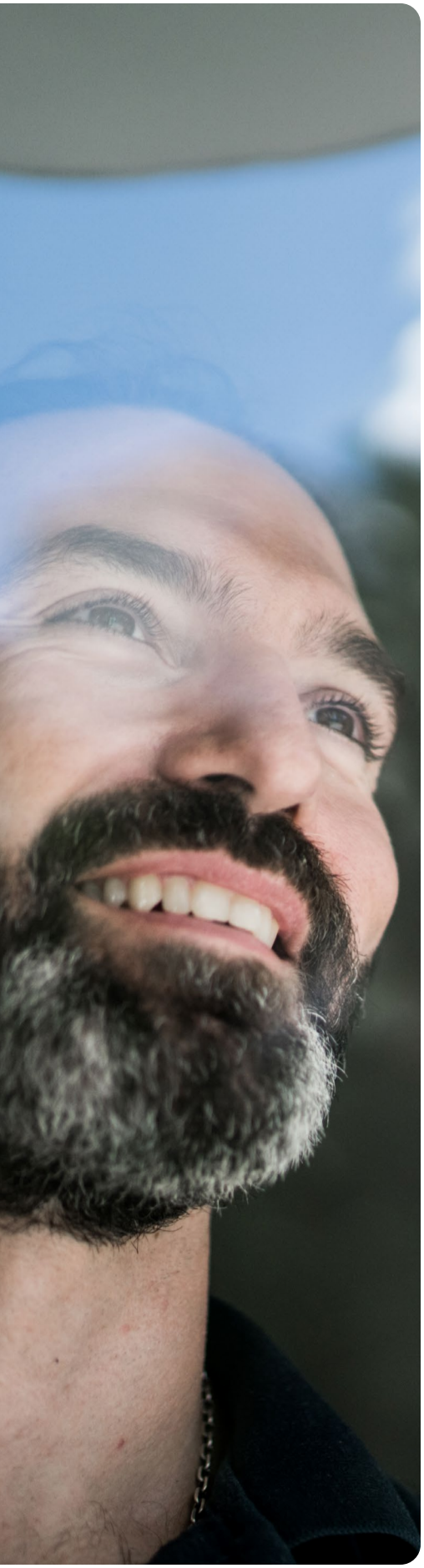
06

Long-Term Follow-Up (LTFU) Studies

This model catalyzes greater efficiency for therapeutic research by reducing patient burden and attrition, as well as eliminating the administrative and operational burdens placed on trial sites. Attrition is a constant problem with mandated observational studies, as long-term commitments can last for years, and have traditionally been viewed as unappealing for both site operators and patient populations alike.

With the LFTU model, the trial is launched at a traditional site (or via a virtual site) before transitioning to one or more virtual site-based remote modalities for follow-up observations. Patients may log self-reported data via the platform (e.g., eCOA), connected devices, work with telehealth, mobile-nursing investigators, or visit local community clinical sites for services such as blood draws or imaging as needed.

With this model, a single vendor can oversee all study elements, and sponsors access data as soon as it is collected. It also facilitates the incorporation of real world evidence (RWE) such as electronic medical records/electronic health records (EMR/EHR) into the analytical framework through patient-level "tokenization" of all data sources. The result is a rich, combined data resource that trial sponsors can use to measure and report health outcomes to clinicians, R&D teams, regulators, and other stakeholders.



Enabling Decentralized Support for a Range of Therapeutic Areas

The specific DCT solution suitable for any individual trial is dependent on a number of factors, including the safety and administration considerations of the investigational drug, the endpoints, the logistics and regulatory acceptance of performing these activities in the participant's home, the underlying medical condition and comorbidities related to the patient population, and other procedures that comprise the schedule of assessments.

From cancer diagnostic trials that incorporate biospecimen collection, imaging, and gold-standard screening modalities; to respiratory trials leveraging healthcare professionals trained to support spirometry; to CNS trials that require advanced neurological assessments in a patient's home—the agile clinical trial approach supports patients in the comfort of their homes or at a site/local clinic when preferred or necessary. For studies focusing on rare disease populations, the value is seen in the access to populations of patients, enabling enrollment regardless of their proximity to a traditional trial site.

Agile Offers Speed, Compliance, and Cost-Saving Benefits

The assumption is that integrating decentralized trial components into site-based clinical research is a hurdle. In reality, augmenting the traditional framework with hybrid elements such as telehealth and community provider participation is a monumental leap forward.

When trial sponsors prepare at the outset to incorporate a decentralized platform into their research, they can decrease their startup times by three to four months and their enrollment periods by three to six weeks. Operating at this level of efficiency can deliver between $120 million and $200 million in opportunity cost savings to sponsors.[13, 14]

Although the individual study drivers may differ, the primary areas of benefit through the implementation of an agile clinical trial are faster enrollment and high-fidelity study data—through both greater diversity and enhanced participant compliance and retention. Data from decentralized trials have shown up to 21 times faster patient enrollment when compared to traditional sites. This improvement is a result of the removal of geographic barriers—bringing the trial to the patient in a manner that is consistent with their lifestyle—offering activities in the home, at hours that extend beyond traditional site operating times (e.g., nights, holidays, and weekends).

By opening up geography, experience suggests that representativeness also grows three times greater than a traditional site model. As described above, this diversity is critical to obtaining the information clinicians need to treat all patients, including those from ethnic and socioeconomic backgrounds not typically included in traditional trials. And, with the FDA's recent draft guidance on diversity plans,[11] opening geography through the implementation of the agile clinical trial models presented above is critical to achieving data equity.

Finally, by providing the patient with multiple options for study participation (e.g., at-site, at-home, in the community), patients are more engaged with the clinical trial and more compliant in their participation. Eliminating the time required at a site (both in travel, waiting, and treatment time) is particularly important for participants who work during traditional clinic hours, especially for those who are paid on an hourly wage or those who might incur expenses associated with child or other dependent care during the day. In contrast, agility brings the trial to the participant, enabling participation in a manner more consistent with their activities of daily living.

Outside of the benefits of speed, representativeness, and compliance, it is also believed that agile clinical trials will decrease cycle times and protocol deviations during study conduct, offering further time benefits to the sponsor. From a technology perspective, for example, digitizing the visit schedule and assessments; automating the workflow for patients, investigators, nurses, and coordinators; and collecting evidence in the home all contribute to faster, more complete, and more efficient data capture. This ultimately leads to the high fidelity data required by regulatory authorities and other industry stakeholders.

By increasing the number of patients that can be recruited and retained, companies can effectively accelerate their clinical trial recruitment and product launch timelines. This more holistic spectrum of patient touch points enables companies to diversify access and promote engagement, which ultimately decreases time-to-market. This does not just save money — it saves lives.

Conclusion: The Agile Clinical Trial is No Longer the Future, it is the Now

Agile clinical trials are rapidly becoming a standard part of clinical trial delivery. Discussions with both pharmaceutical companies and clinical research organizations suggest that, increasingly, protocols are being written to offer the option of hybrid and decentralized clinical trial designs to avoid a protocol change in cases where DCT conduct was not incorporated at the time of study initiation.

The agile clinical trial has already been proven to be an effective mitigation tool throughout the COVID-19 pandemic. As we emerge from this global crisis, the operational elements relied upon during this challenging time are being widely adopted by sponsors and patients. Sponsors can see and quantify value drivers such as enhanced recruitment velocity and diversity, cost efficiencies, reduced human error, increased patient compliance, and higher retention rates. These significant and measurable improvements suggest that the industry is unlikely to turn back to delivery solely through traditional brick-and-mortar sites.

An agile trial is the way of the future, and it is available today. Outside of the benefits to sponsors, it is only through the agile clinical trial that the industry can truly deliver on the promise of a clinical trial as a care option for any patient, anywhere.

CASE STUDY

Agile in Action:
Science 37 Implements an Agile Clinical Trial for a Large Population Diagnostic Screening Study.

A biopharma company was looking to investigate how their diagnostic screening technology performed against the gold standard. The protocol required that 25,000 patients enroll. Participants were required to be between the ages of 45 and 85, at average risk for cancer, and were asked to provide a one-time blood sample before a screening procedure. The sponsor was also looking to focus on including a diverse and representative population in the trial.

Through an agile approach, Science 37 implemented a virtual site, leveraging a decentralized model with both a direct-to-patient approach along with community-based provider locations. All procedures occurred the same way they would in a traditional trial using the same collection methods, processing steps, and a central lab. For the direct to patient group, the blood draws were performed at home. Screening procedures were performed in a clinic setting by qualified gastroenterologists.

Combining both community-based providers and a direct-to-patient approach—Science 37 accelerated enrollment and retention. The agile model allowed clinical trial participants to choose the manner in which they preferred to participate in the trial, supporting patient choice.

Science 37 delivered:

- 12,000 enrolled participants
- 24.2% minority representation
- Four virtual investigators (Science 37 broadly-licensed physicians)
- 80+ community provider locations
- eConsent & eSource via Science 37 Technology Platform
- Coordination of procedure scheduling and collection of reports
- Science 37 mobile phlebotomy for in-home blood draw/processing
- “Bring Your Own Device” (BYOD)

Science 37's Metasite™ (Virtual Site) enrolled nearly 50% of the entire study with 24.2% minority representation.

The Metasite enabled recruitment and access across 49 states.

CASE STUDY

Agile in Action: Science 37 Succeeds Delivering a Hybrid Oncology Trial.

A Top 10 pharmaceutical company approached Science 37 to deliver an innovative solution to test treatment of a targeted population of participants with metastatic breast cancer from their homes. The sponsor was looking to facilitate enrollment, increase retention and minimize in-person visits.

Science 37 delivered an agile trial model involving collaboration with brick-and-mortar sites. Outside of the initial enrollment and consent visit, Science 37 handled all treatments at home to reduce patient burden. A single technology platform was used for all data capture, scheduling, and trial orchestration.

Home nursing visits included vital signs, IMP administration, and blood draws; with optional telemedicine physical exams conducted by the brick-and-mortar physicians—assisted by the nurse in the home. Trained mobile nurses provided cardiology support for advanced at-home needs. Temperature-tracked and refrigerated IMP shipments were overnighted to patients.

Science 37 worked alongside 12 brick-and-mortar sites, treating patients in 17 states. This study changed the formulation of a breast cancer treatment from infusion to subcutaneous injection, testing whether patients could get their treatments at home.

Science 37 Delivered Technology, Mobile Nursing, and Hybrid Trial Orchestration.

- A record-breaking 28-day platform build
- 1,599 home nursing visits to date
- First patient screened in June 2020, 1st visit in July 2020
- Patients treated at home every 3 weeks
- Up to 18 cycles over the course of 12.5 months
- Direct to patient IMP shipments within 24 hours (compared to a 72 hour industry standard)

How Science 37 Delivers the Agile Clinical Trial

To deliver the Agile Clinical Trial, sponsors and contract research organizations (CROs) are looking to Science 37 for unified technology and centralized networks, including patient communities, telemedicine investigators, community providers, mobile nurses, remote coordinators, and connected devices. Science 37's Unified Technology Platform enables eConsent, Telemedicine, eSource, and eCOA. It is deployed for interoperable data capture across the spectrum of connected devices to deliver superior workflow orchestration, evidence generation, and data harmonization across a comprehensive array of stakeholders.

The Science 37 Metasite™ further supports the Agile Clinical Trial, serving as a virtual site that enables patients and providers access to clinical trials no matter their geographic location. Far more than a traditional virtual site, the Metasite facilitates engagement with broadly-licensed telemedicine physicians, in-house mobile healthcare providers, and research coordinators. Patients can be recruited and enrolled from anywhere and seen in the comfort of their own homes—providing a level of convenience and flexibility beyond a traditional site or virtual site.

Science 37 delivers the flexibility to research, delivering a patient-centric approach that transforms clinical trials, enabling access to any patient, anywhere. The result is a powerful and sophisticated offering that can be uniquely configured for any clinical trial.

To learn more about how Science 37 enables decentralized, hybrid, and agile trials, visit www.science37.com.

Authors:

Ryan Brown
Senior Director, Diversity in Clinical Trials
Science 37

Ryan Brown leads Science 37's Diversity in Clinical Trials business unit and also serves as a strategic advisor to the industry's first Diversity in Clinical Trials Foundation. Ryan brings more than a decade of clinical research experience from PRA, PPD and Worldwide Clinical Trials across clinical operations, business development, and strategic commercial leadership roles. She also spent more than 15 years driving diversity and high-priority initiatives for cross-functional organizations in academia, grassroots communities and clinical research, including of CISCRP, ACRO and WOCIP (Women of Color in Pharma.)

Jonathan Cotliar
Chief Medical Officer
Science 37

As Chief Medical Officer for Science 37, Jonathan Cotliar is board-certified in both internal medicine and dermatology, and also serves as director of in-patient dermatology at Harbor-UCLA Medical Center. Jonathan specializes in complex medical dermatology with a focus on oncodermatology, including graft-versus-host disease, adverse drug reactions, and the management of cutaneous toxicities related to chemotherapy and targeted anticancer therapies. Jonathan received his B.A. from Trinity College, MD from the University of Kentucky College of Medicine, and completed his training in dermatology and internal medicine at the David Geffen School of Medicine at UCLA. While at UCLA, he completed an NIH-sponsored K30 Fellowship in translational investigation.

Elisa Cascade
Chief Product Officer
Science 37

Elisa Cascade has devoted more than 30 years to advancing clinical trial technology, direct-to-patient operations, and healthcare strategy. Throughout her career, she has been instrumental in using technology to transform clinical research to better serve stakeholders. Before joining Science 37, Elisa held a number of high-profile roles, including executive VP and product line executive for eCOA at ERT; chief product officer at DrugDev, an IQVIA Company; and VP of the digital patient unit at Quintiles. Elisa adds tremendous technological expertise and strategic prowess to Science 37's Operating System, helping the company achieve its mission of enabling universal access to clinical trials. Elisa earned an MBA at The Wharton School of the University of Pennsylvania.

Darcy Forman
Chief Delivery Officer
Science 37

As Chief Delivery Officer for Science 37, Darcy Forman has responsibility and oversight for clinical operations, service delivery, patient engagement, data management, and nursing solutions. Darcy has more than 20 years of experience bridging clinical operational expertise and strategic corporate development initiatives, with a passion for decentralized clinical trial execution. Most recently, Darcy served as the vice president of corporate development at Firma Clinical Research, where she led the identification, development, and execution of corporate development opportunities. Darcy started her career as a bench scientist at Pfizer, before transitioning into a role in the company's clinical research division. She has held various positions in clinical operations and project management at various CROs, spanning large, mid-size, and niche.

David Coman
Chief Executive Officer
Science 37

David Coman is a pioneer of Agile Clinical Trials and came to Science 37 from ERT, where he was Chief Strategy Officer and ran its Data & Analytics business. Prior to that, he was CMO at Quintiles and Founder of the Digital Patient Unit where he led the exploration of some of the first decentralized clinical trials. Earlier in his career, David held a variety of marketing leadership roles in telecommunications, including at AOL, Excel Communications, and Aerial Communications.

Suzanne Pendl
Senior Director of Medical Affairs
Science 37

As Senior Director of Medical Affairs for Science 37, Suanne Pendl provides medical, scientific, and technical insight and consultation in support of unlocking universal access to clinical research. Prior to joining Science 37, Suzanne performed original research at Cedars-Sinai Medical Center's Biomedical Imaging Research Institute, where she used functional MRI to probe the development of infant brain networks and the dynamics of adult neurological disease. Suzanne has an interdisciplinary background in biomedical science, neuroscience, and biophysics, and received her PhD in Biomedical Science from the department of Biophysics at the Medical College of Wisconsin. There she used neuroimaging techniques to uncover principles of language organization in the human brain.

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About Science 37

Science 37, Inc.'s (Nasdaq: SNCE) mission is to enable universal access to clinical research, making it easier for patients and providers to participate from anywhere. Since 2014, we've pioneered decentralized and agile clinical trial approaches and having conducted more than 125 agile clinical trials, we're helping forge the future of research. The Science 37 Operating System (OS) supports today's more agile clinical research design, enabling up to 21x faster enrollment, 28% better retention, and 3x more diverse patient population. To learn more about our solutions, and how we can help you implement Agile and Decentralized Trials, visit www.science37.com, or email science37@science37.com.

