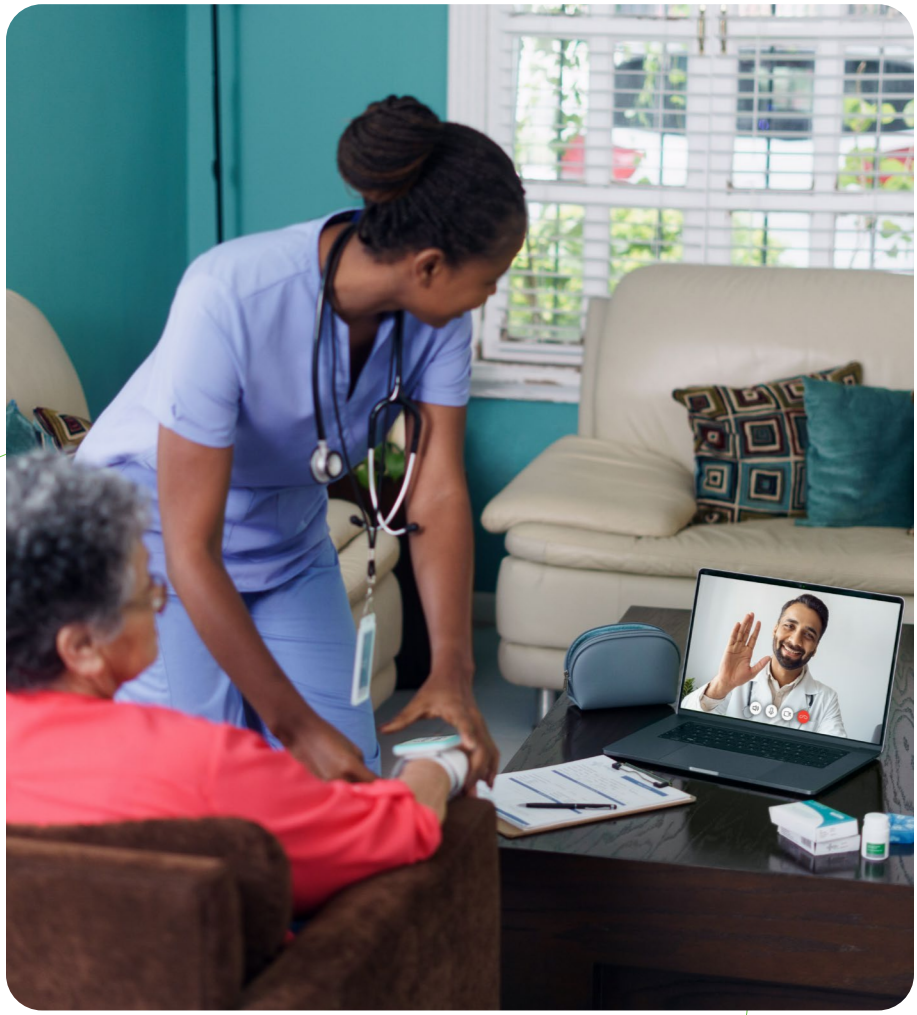
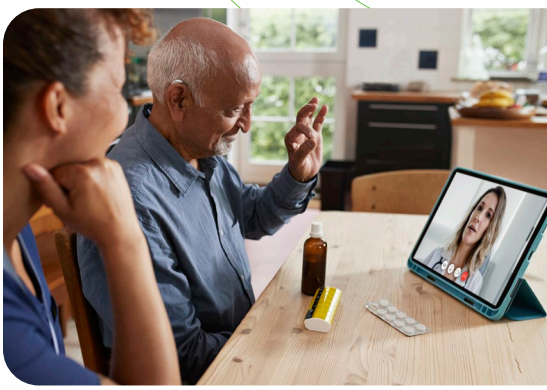
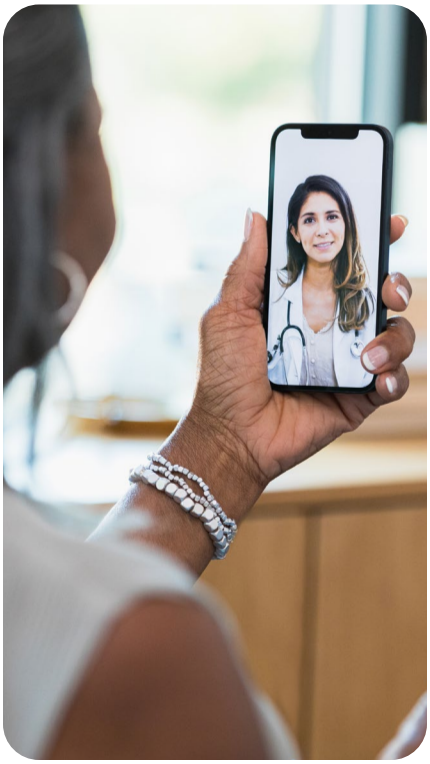
Science 37

THE FUTURE OF CLINICAL TRIALS | 2023

A Survey-Based Exploration of Biopharma's Shifting Landscape and the Crucial Role of Direct-to-Patient Trials.







Key Findings

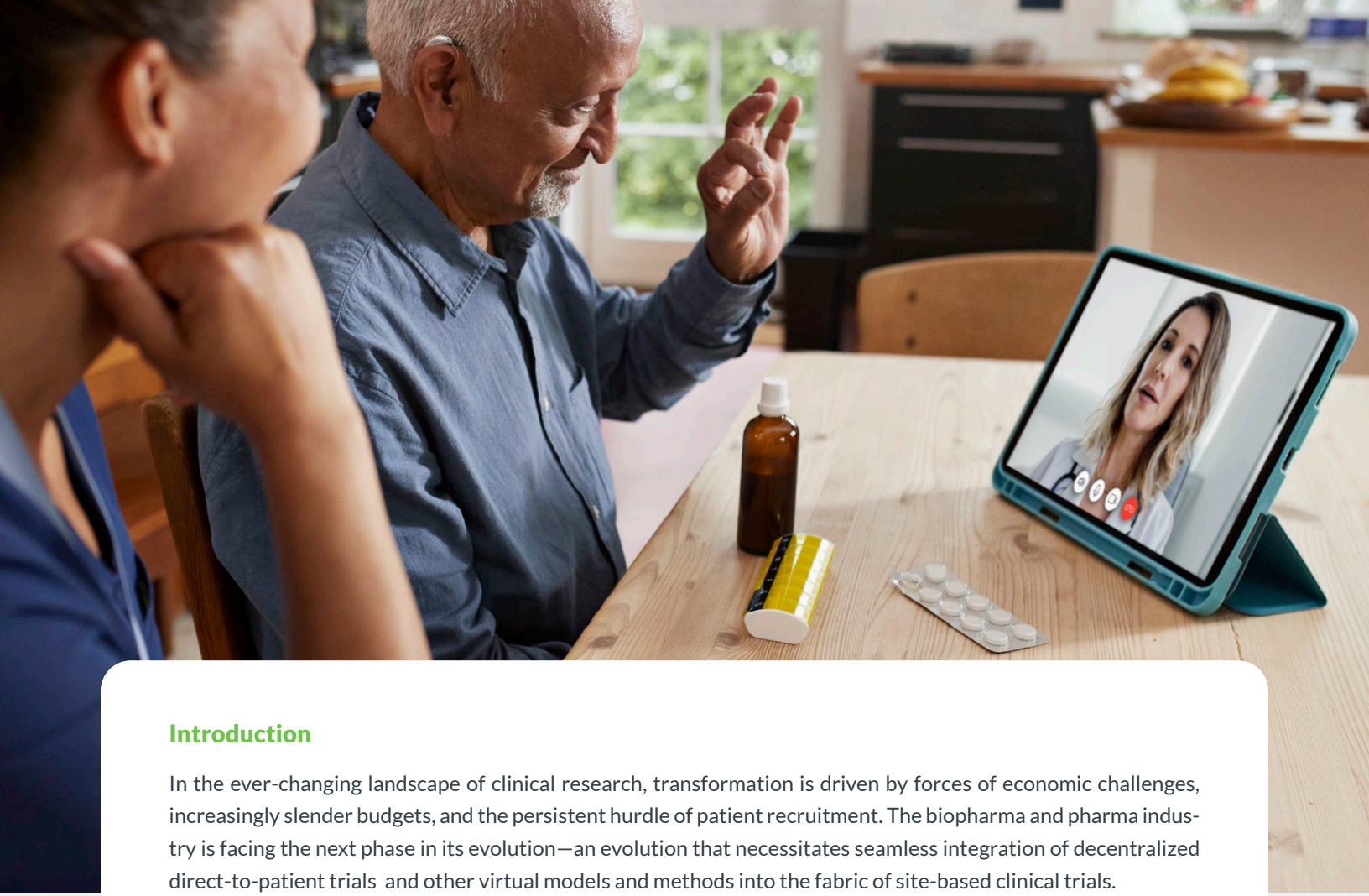
TIMELINES/DELAYS are the most pressing issue keeping biopharma executives up at night. Individually, more respondents chose **PATIENT RECRUITMENT** as their #1 concern, with 23% placing this challenge ahead of all others.

Well over half of the respondents selected **COST** as one of their top three benefits of decentralized approaches, and more than one in five perceived cost reduction as DCT's biggest overall benefit. This contrasts starkly with this survey's findings from 2022, where COST was perceived as a top-three benefit by only 17% of respondents (dead last), and fewer than one in ten perceived it as the greatest benefit.

Almost four out of ten respondents placed **financial pressures** among their top three concerns, compared with only 30% in 2022.

REDUCED PATIENT BURDEN is widely perceived to be the greatest benefit of decentralized and hybrid approaches, with two-thirds (66%) of respondents perceiving it as one of the top three benefits.

One in four respondents chose **LACK OF IN-HOUSE CAPABILITY** as the biggest challenge of incorporating DCT into trial designs, with nearly half (47%) placing it in their top three.



Introduction

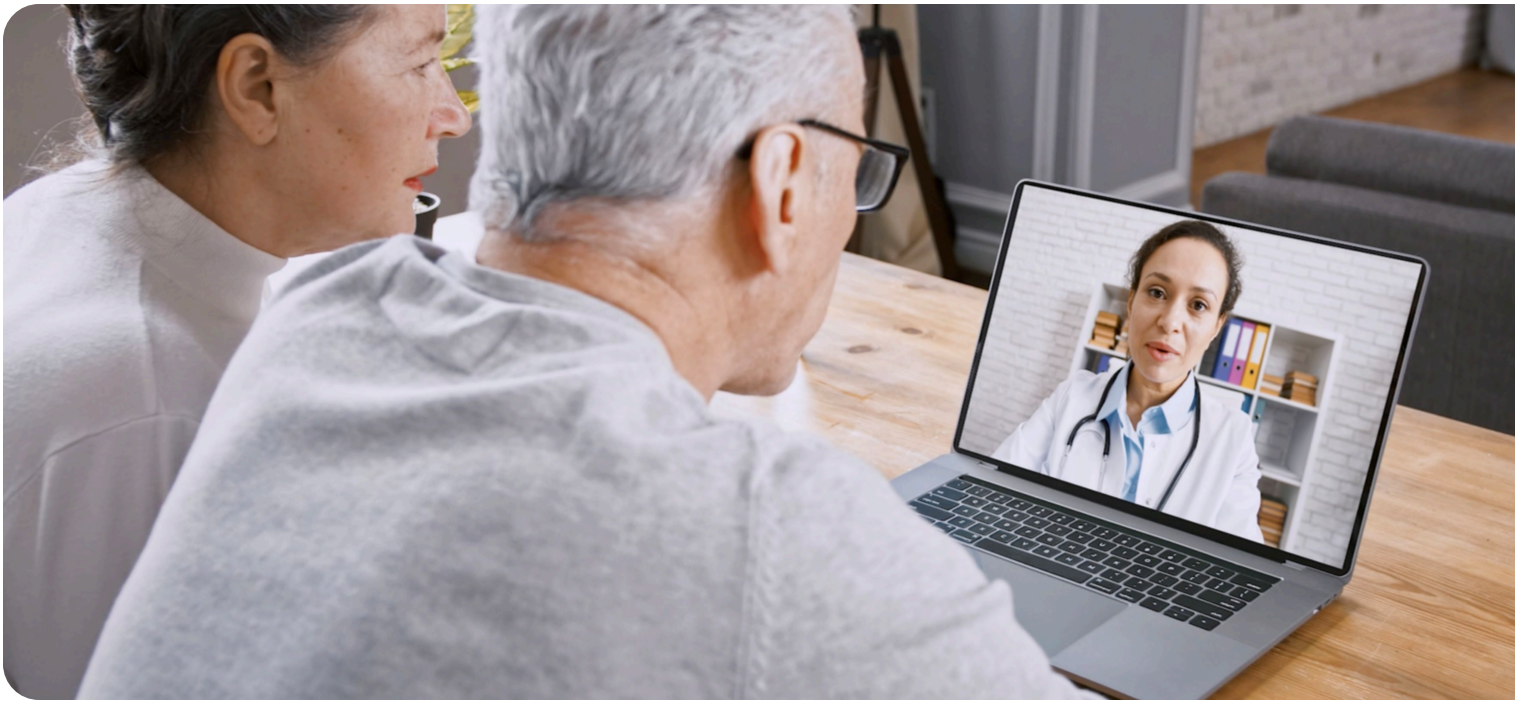
In the ever-changing landscape of clinical research, transformation is driven by forces of economic challenges, increasingly slender budgets, and the persistent hurdle of patient recruitment. The biopharma and pharma industry is facing the next phase in its evolution—an evolution that necessitates seamless integration of decentralized direct-to-patient trials and other virtual models and methods into the fabric of site-based clinical trials.

This report presents findings of a Science 37 survey of clinical trial executives across all therapeutic areas to help document the shift in the way clinical research is executed. Science 37 conducted this survey online in the late summer of 2023. Respondents were targeted largely by email, and they submitted their responses via online questionnaires. The questionnaires generated a "qualified" survey sample of 101 respondents from senior executives who are involved in sponsoring or managing clinical trials. Our mission in this report is clear—to shed light on the critical industry issues that drive this evolution and to help illuminate the path forward.

Amidst the financial constraints that permeate the industry, cost management has become an increasing worry for biopharma executives. Clinical development budgets have gotten thinner, prompting a heightened need for innovative solutions to expand patient access, elevate the patient experience, and accelerate development timelines. Data from this survey illuminates the perceived potential for decentralized clinical trials to strike this delicate balance, offering insights into how cost reduction, though not the sole factor, can indeed be a beneficial outcome of integrating virtual approaches into clinical research.

In the journey toward patient-centric innovation and fiscal responsibility, the industry is slowly but surely shifting. Our survey data reveals a notable increase in the utilization of direct-to-patient trials (including DCT and hybrid approaches). It also shows increased concerns about trial costs and the perceived potential of decentralized clinical trial models and methods to control them. But this is a journey marked by incremental progress, a conscious evolution, not a sudden revolution.

This report is your guide—a roadmap to navigate the challenges, seize the opportunities, and foster a transformative evolution that embraces change without disrupting the foundations of site-based clinical trials.



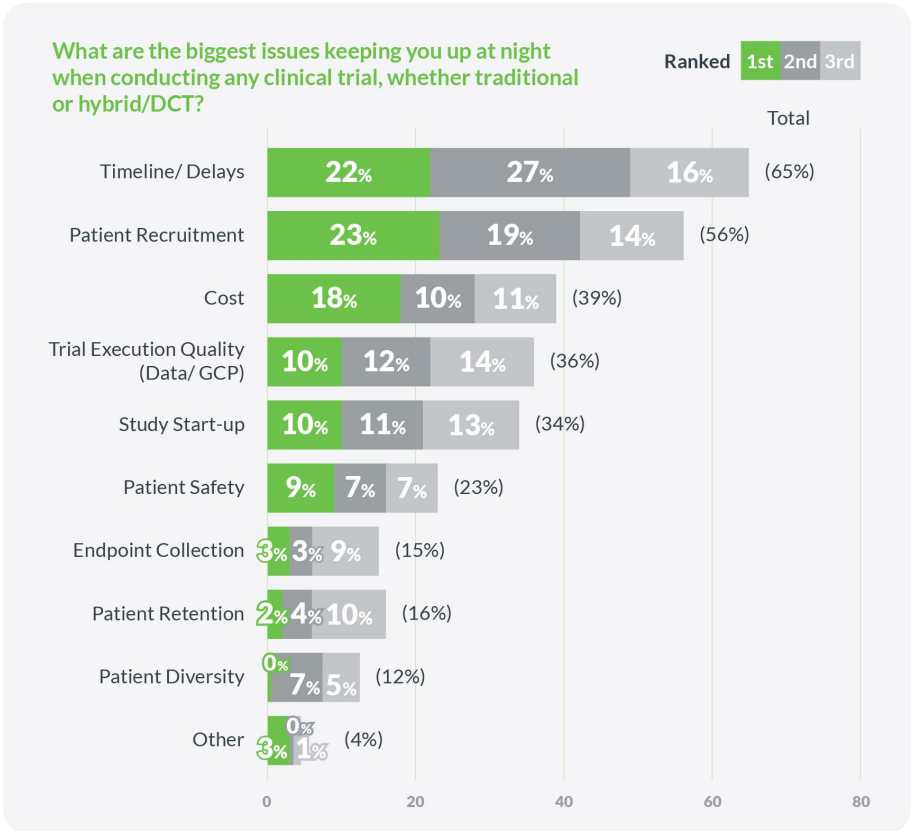
What's Most Worrisome About Clinical Development?

We asked survey respondents to rank the biggest issues keeping them up at night when conducting any clinical trial, whether traditional, DCT, or hybrid. We offered nine key challenges, plus the option to add others.

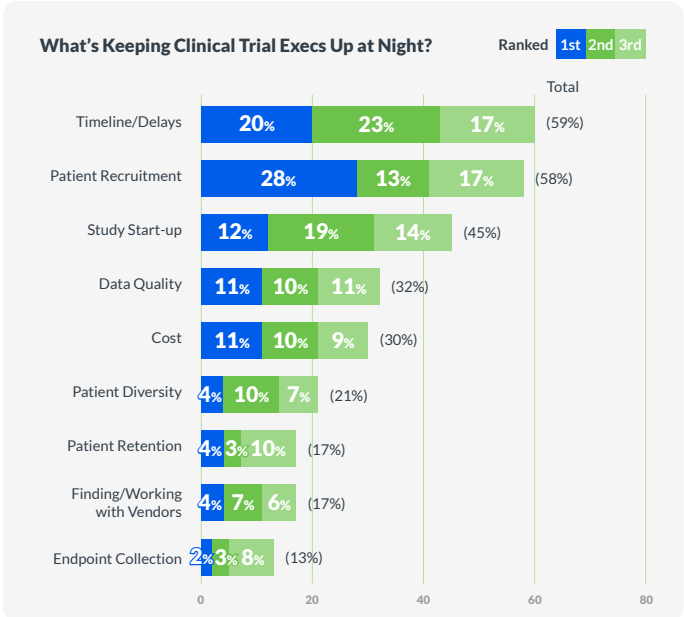
Similar to what we have seen in previous years, TIMELINES/DELAYS is the most pressing issue keeping biopharma execs at night with almost two-thirds of respondents selecting it as one of their top three choices. Individually, more respondents chose PATIENT RECRUITMENT as their #1 concern, with 23% placing this challenge ahead of all others.

Notably, respondents to this year's survey reported worrying more about COST than in previous studies, with almost four out of ten placing financial pressures among their top three concerns, compared with only 30% in 2022.

These data underscore the enduring challenges that have long plagued the biopharmaceutical industry: patient enrollment, efficiency in trial completion, and cost containment remain the perennial concerns that keep industry leaders awake at night. What sets this year apart is a heightened focus on trial COSTS, with a significant uptick in respondents expressing financial pressures as a top concern.



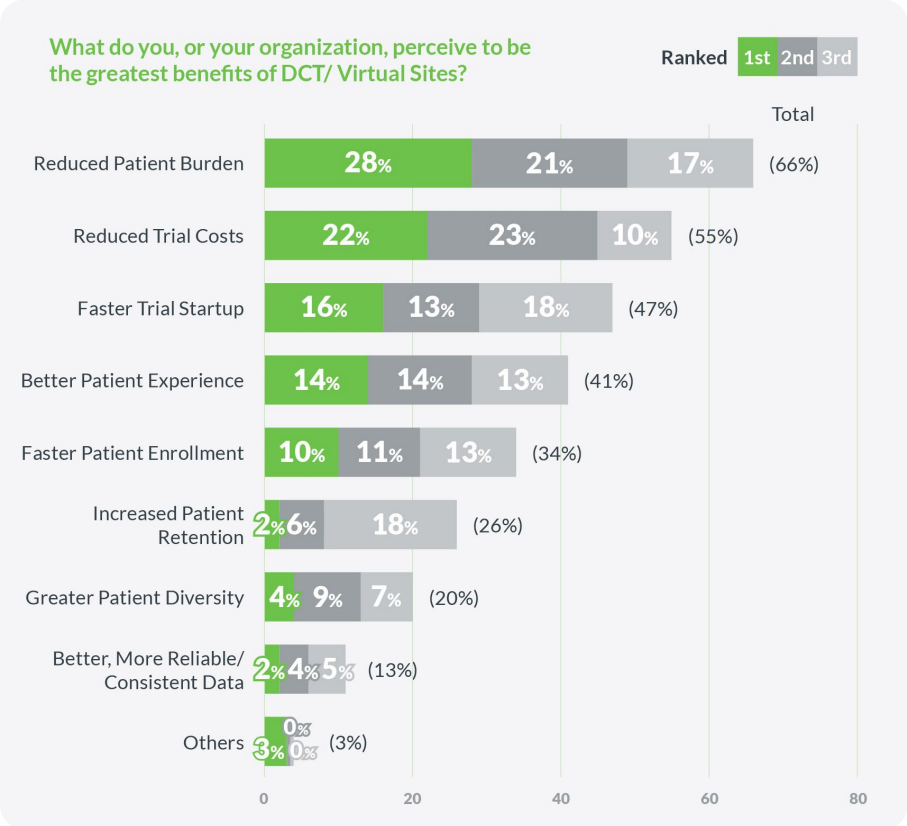
Results from Science 37 Survey, 2022.



Can Direct-to-Patient Trials Help?

Within this landscape, direct-to-patient tools, technologies, and expertise are increasingly being applied across clinical research to help expedite the development of new therapies. But to what end? We asked biopharma execs what they perceive to be the greatest benefits of incorporating DCT/hybrid approaches into clinical trials. Respondents were presented with nine potential benefits of DCTs (plus the option to add others) and were asked to rank these from greatest benefit to the least.

As we've seen consistently since the start of this survey in 2021, REDUCED PATIENT BURDEN is widely perceived to be the greatest benefit of decentralized and hybrid approaches, with two-thirds (66%) of respondents perceiving it as one of the top three benefits.



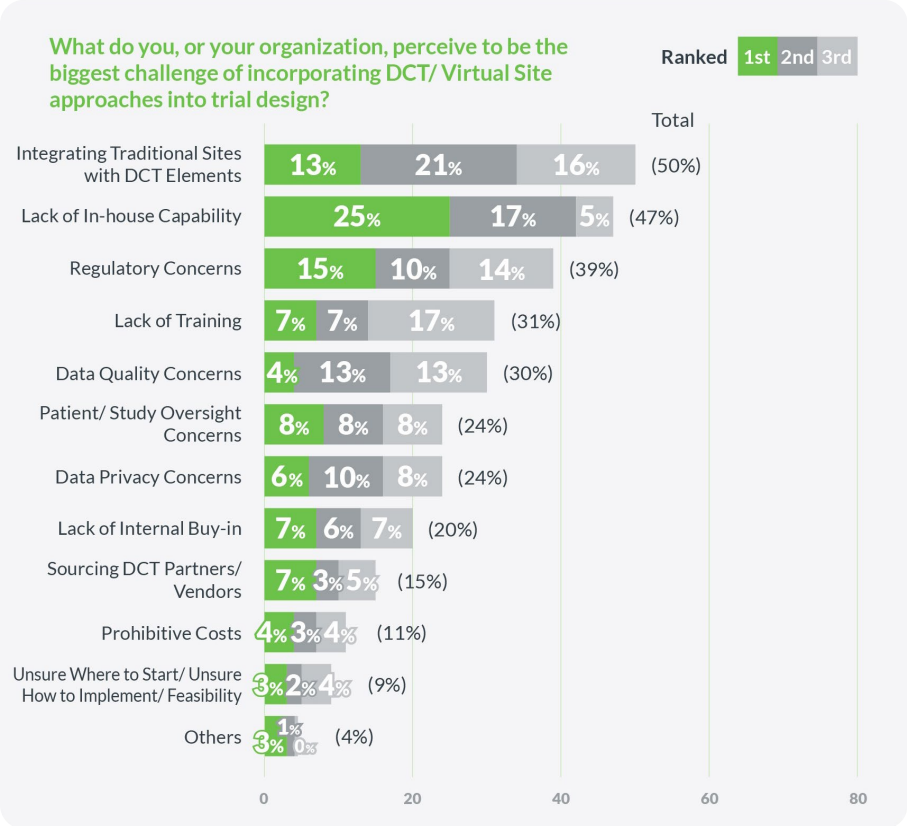
The most striking findings concern COST, with 55% of respondents selecting COST as one of their top three benefits of decentralized approaches, and more than one in five perceiving cost reduction as DCT's biggest overall benefit. This contrasts starkly with this survey's findings from 2022, where COST was perceived as a top-three benefit by only 17% of respondents (dead last), and fewer than one in ten perceived it as the greatest benefit.

This data underscores the assessment that biopharma executives find themselves at a unique crossroads, where concerns about cost are on the rise while the potential benefits of decentralized and hybrid approaches shine brightly. This paradigm shift aligns with the industry's growing realization that decentralized models and methods offer a strategic avenue to not only improve patient recruitment but reduce overall trial costs as well. When viewed in context with what is keeping biopharma execs up at night, we see a convergence of heightened cost concerns and the recognition of cost containment as a benefit of integrating decentralized methods into clinical research.

What are the Roadblocks to Wider Direct-to-Patient Trial Adoption?

To balance out biopharma executives' perceptions of the benefits of incorporating decentralized approaches into clinical trial designs, we also asked what they perceived as the biggest challenges. As with the previous question, respondents were presented with nine potential challenges of DCTs (plus the option to add others) and were asked to rank these from the biggest challenge to the smallest. To order their selections, we again took the sum of the top three rankings for each response.

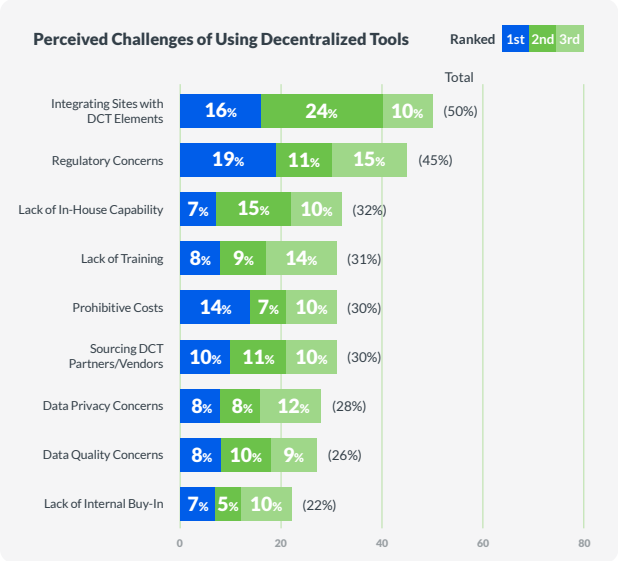
In a major shift from 2022, one in four respondents chose LACK OF IN-HOUSE CAPABILITY as the biggest challenge of incorporating DCT into trial designs, with nearly half (47%) placing it in their top three. Compared with only 7% saying this was the top perceived challenge in our 2022 survey, these findings underscore the industry's struggle to fully integrate DCT technologies into traditional clinical trial protocols—whether with a vendor or without.



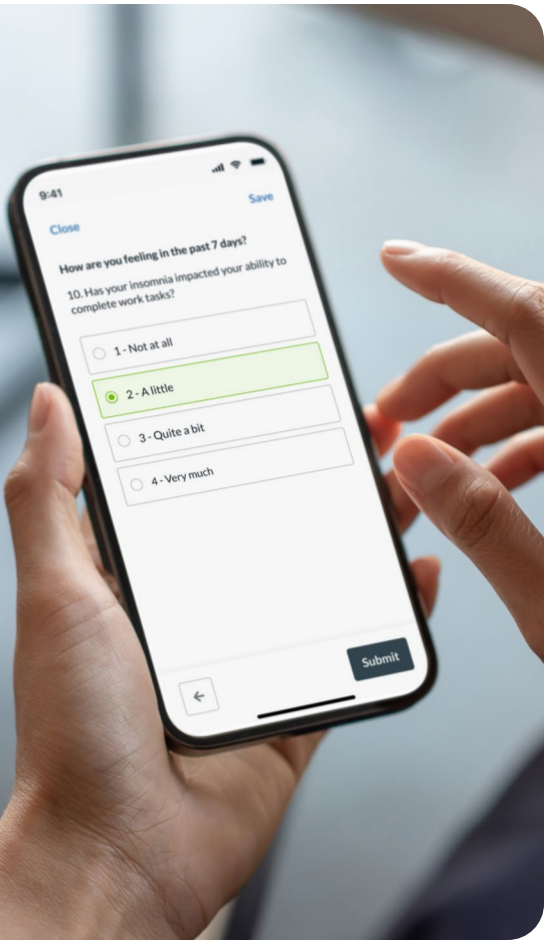
Results from Science 37 Survey, 2022.

Indeed, INTEGRATING TRADITIONAL SITES WITH DCT ELEMENTS was again chosen by half of those surveyed as being in their top three perceived challenges, perhaps indicating that although decentralized approaches are seen as beneficial to the patient experience—and could potentially reduce trial costs—biopharma is still struggling to implement DCT technology and tools effectively.

Survey respondents also showed less concern about PROHIBITIVE COSTS than they have previously, with only 4% saying it was the most challenging aspect of incorporating DCT approaches into clinical designs, and only 11% including it in their top three. By contrast, more than 14% of respondents to our 2022 survey selected PROHIBITIVE COSTS as the biggest challenge (second overall), with almost a third placing it among their top three.



These findings underscore the industry's ongoing struggle to seamlessly embed DCT technologies into conventional clinical trial protocols and further emphasize the persistent challenge of integrating traditional sites with DCT elements, a concern echoed by half of those surveyed. This shifting perspective highlights a growing industry realization that the benefits of DCT integration outweigh the associated costs, indicative of a pragmatic approach to evolving the clinical research landscape.

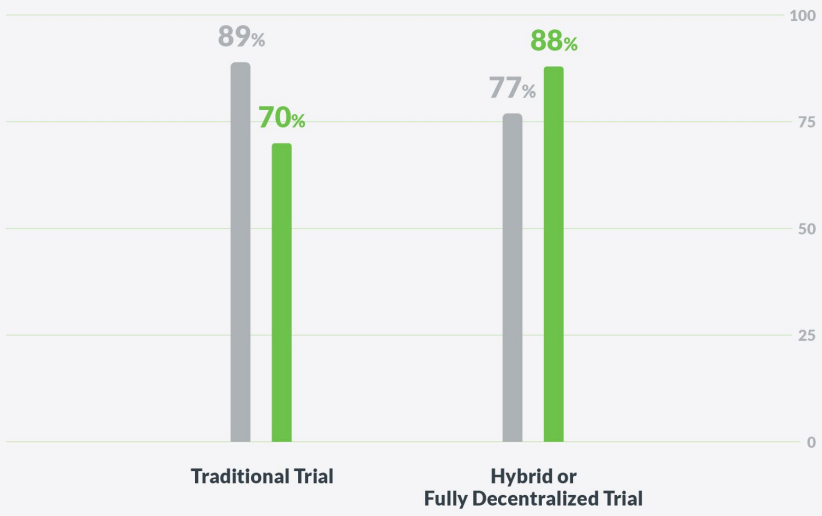


A Shift in Direct-to-Patient Approaches to Clinical Research

As revealed by our survey data, there has been a remarkable increase over the past year in both the planning and execution of hybrid and decentralized trials. Almost nine out of ten (88%) of respondents reported planning a hybrid or decentralized trial for the next 12 months, compared to only 69% who anticipated doing so in 2022. An opposing shift is seen in traditional trials, with only 70% expecting to conduct a traditional trial in the next year, as opposed to 89% who conducted one in the previous year.

Lastly, there is a notable development in completely virtual trials, with more than one in four respondents planning to conduct a fully decentralized trial within the next 12 months. This signifies a growing exploration of cutting-edge, fully decentralized models that have the potential to reduce trial timelines and improve the patient experience considerably.

What TYPES of clinical trial activity has your organization conducted in the previous 12 months, and what does it plan to conduct over the next 12 months?



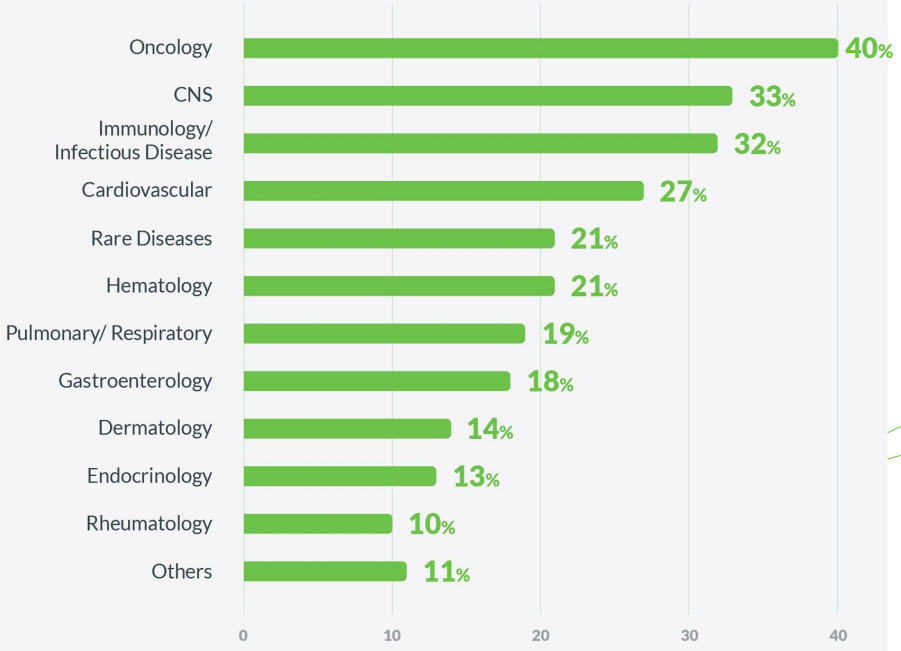
Adoption by Therapeutic Area

To get a sense of where and how decentralized clinical trial models and methods are being applied, we asked survey respondents for which therapeutic areas they have conducted or plan to conduct a clinical trial comprising one or more decentralized components.

Unsurprisingly—and consistent with previous years' data—ONCOLOGY is expected to have the most activity, as 40% of survey respondents said they planned to conduct a cancer trial with decentralized components in the coming year.

More broadly, we continue to see an incremental uptick across almost all therapeutic areas in the number of trials including DCT components, indicating an increasing familiarity with specific technologies as well as the conditions for which a virtual or hybrid model is most appropriate.

For which THERAPEUTIC AREAS have you conducted, and/or plan to conduct, clinical trials comprising one or more DCT components?



Use of Specific Tools that Enable Direct-to-Patient Conduct

We see a similar uptick in the planned use of specific DCT tools. We asked survey respondents to tell us which DCT components they deployed recently and/or plan to use in the coming year. We offered nine different tools, and they could choose as many as they wished.

ECONSENT remains the most widely applied tool, with 58% saying they plan to use it in the next 12 months, up from only 44% who said they used it in the previous year. Similar increases were seen for every tool (except EPRO/ECOA), with a notable jump in the number of survey respondents planning to use WEARABLES/SENSORS: less than a quarter reported using these tools in the previous year, yet four out of ten plan to do so next year.

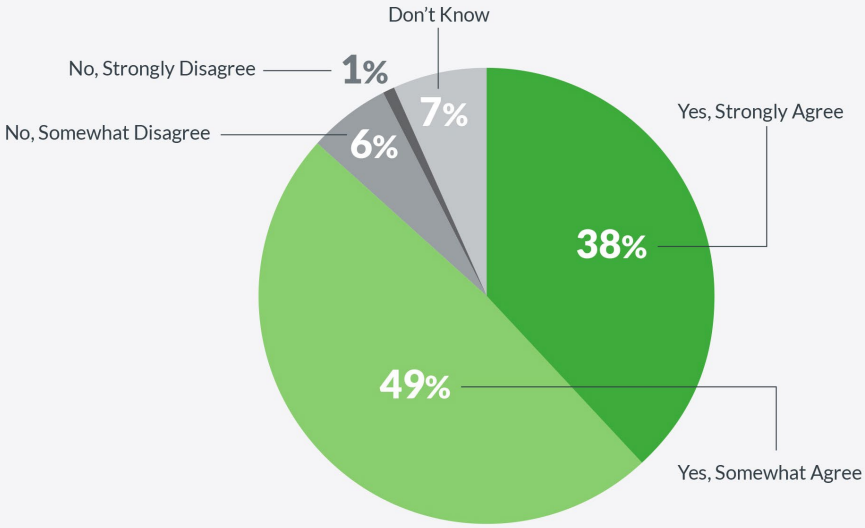
Impact on Diversity Initiatives

Lastly, as regulators and lawmakers expect the clinical research industry to prioritize diversity among trial participants, we asked respondents if they felt decentralized/hybrid models enable greater diversity in clinical trials. Our findings show that almost nine out of ten execs report that DCT/hybrid models enable greater diversity, with 38% saying they STRONGLY AGREE with the sentiment.

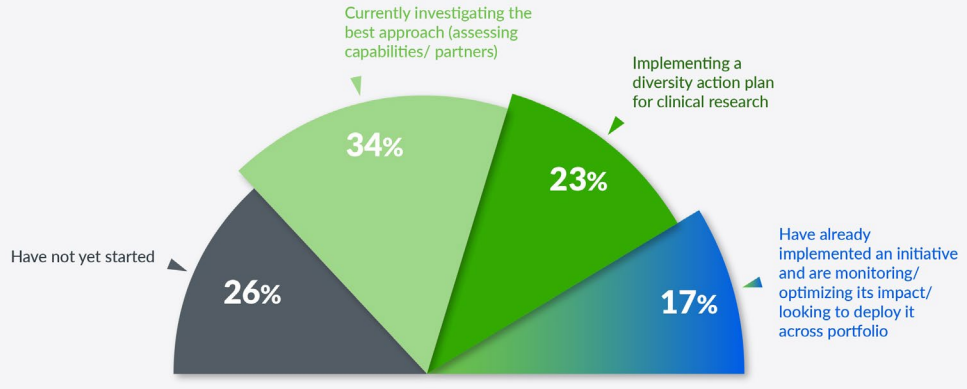
However, despite the feeling that decentralized models and methods can help with clinical trial diversity, our survey also shows that biopharma has been slow to adopt and incorporate enterprise-wide diversity initiatives for clinical trials.

When asked whether they agreed with a statement about their organization's progress in executing a diversity initiative, a whopping 60% of respondents have either NOT YET STARTED (26%) or are CURRENTLY INVESTIGATING THE BEST APPROACH (34%). Less than one in five (17%) report having ALREADY IMPLEMENTED AN INITIATIVE, indicating that there's more work to be done to improve diversity among clinical trial participants.

Do you think decentralized/hybrid models enable greater diversity in clinical trials?



Which of the following statements best describes your progress to date in executing a diversity initiative for clinical trials?

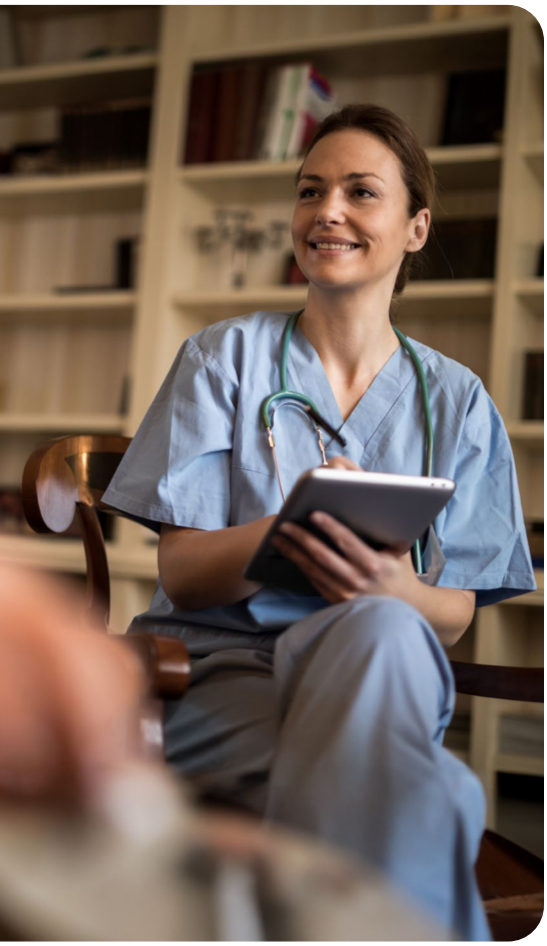


Conclusion

In the ever-evolving landscape of clinical research, the challenges faced by biopharma executives are diverse and demanding, with patient recruitment, clinical trial timelines, and cost management ranking high among their concerns. Our journey through the data and insights provided in this report has uncovered a shifting paradigm in the industry's perception of direct-to-patient approaches to clinical research.

As observed, the landscape of clinical research is marked by incremental progress, not sudden, dramatic changes. Patient recruitment, a long-standing challenge, continues to be a worry, but the industry is now recognizing the potential for change and the benefits of reduced patient burden that direct-to-patient approaches can offer. Significantly, clinical trial cost has emerged as a top concern in the minds of biopharma executives, signaling a growing realization that innovative solutions are needed to address budget constraints while improving the patient experience.

However, while the potential for DCT and hybrid trials to address the concerns of patient recruitment and cost containment is evident, there's a roadblock that must be acknowledged: sponsors and CROs often lack in-house capabilities to execute decentralized trials. Biopharma executives are struggling to fully integrate DCT technologies into traditional clinical trial protocols, highlighting the need for expertise and experience in this transformative journey.



Direct-to-patient sites, such as the Science 37 Metasite™ offer myriad advantages, enhancing the patient experience by providing universal access, reducing patient burden, and expanding the reach of innovative treatments. These approaches are instrumental in increasing patient enrollment, improving retention, and fostering diversity, ultimately accelerating the pace of clinical research and expediting drug development.

It's important to note that direct-to-patient trials do not aim to sever the important patient-provider relationship but, instead, nurture it. Virtual sites help to facilitate a seamless transition between traditional sites and decentralized components, optimizing methodologies and tools for the benefit of patients, providers, and sponsors. For instance, the Science 37 Metasite can consolidate patients, enhance recruitment strategies, and rescue underperforming trials to reduce the burden on physical sites. These methods help to streamline the clinical trial process, enhancing the patient experience, increasing retention, and ensuring a more diverse representation.

Furthermore, data generated by virtual sites can seamlessly integrate with physical site data through the Science 37 Unified Platform. The Metasite complements existing arrangements, enhancing the clinical trial landscape rather than disrupting it.

In conclusion, the journey toward direct-to-patient trials, is one of conscious evolution, driven by the industry's growing recognition of the benefits they can bring. It's a path that acknowledges the persistent challenges of patient recruitment, timely execution, and fiscal responsibility, while also embracing the potential for change. As the industry moves progressively towards direct-to-patient approaches, there is a need for strategic guidance and expertise to ensure that the promises of cost reduction and improved patient experiences are fully realized.

Authors:

Dr. Jonathan Cotliar
Chief Medical Officer
Science 37

Jonathan Cotliar is the Chief Medical Officer for Science 37. He previously served as Vice President of Medical Affairs, where he contributed as an investigator on a number of virtual clinical trials in addition to his work in support of business development and regulatory strategy.

Jonathan is board-certified in both internal medicine and dermatology. He serves as Director of Inpatient Dermatology at Harbor-UCLA Medical Center, with previous full-time faculty appointments at the David Geffen School of Medicine at UCLA, Northwestern University Feinberg School of Medicine, and City of Hope National Medical Center, where he was Chief of the Division of Dermatology. 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.

Darcy Forman
Chief Delivery Officer
Science 37

Darcy Forman is the Chief Delivery Officer for Science 37, where she has responsibility and oversight for clinical operations service delivery, including patient engagement, clinical operations, 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 innovative and decentralized clinical trial execution.

Most recently, Darcy served as the Vice President of Corporate Development at Firma Clinical Research, where she had oversight and leadership responsibility for the identification, development, and execution of corporate development opportunities, including the evaluation of Firma corporate strategies and strategic planning. Darcy started her career at Pfizer as a bench scientist before transitioning into a role in the company's clinical research division. She continued her career with ascending clinical operations and project management positions at various CROs spanning large, mid-size, and niche.

About Science 37

Science 37 Holdings, Inc.'s (Nasdaq: SNCE) mission is to accelerate clinical research by enabling universal trial access for patients. Through our Metasite™ we reach an expanded population beyond the traditional site, delivering on our goal of clinical research that works for everyone—with greater patient diversity. Patients gain the flexibility to participate from the comfort of their own homes, at their local community provider, or at a traditional site when needed. Our Metasite is powered by a proprietary technology platform with in-house medical and operational experts that drive uniform study orchestration, enabling greater compliance and high-quality data. To learn more, visit www.science37.com, or email science37@science37.com.

