Science 37®

The Oncology Clinical Trial Survey 2022

How Agile Clinical Trials are Impacting Oncology Research

New data sheds light on how trends in clinical trials are shaping the way oncology studies are executed

Agile Trials and Oncology

R&D spend in oncology is projected to top US$70 billion this year, accounting for almost one-third of the global clinical research budget.

At the end of 2021, a landmark Science 37 survey painted a detailed picture of the clinical trial landscape, documenting a pivotal shift in the way clinical research is executed—away from traditional, site-based studies and toward Agile (hybrid) and Fully Decentralized clinical trials.

Although the results were hardly shocking—after all, the traditional, site-based model for clinical trials is slow, costly, and inaccessible to more than 90% of the population—the data revealed, for the first time, that more sponsors and CROs were expecting to execute Agile clinical trials in 2022 than were planning to run traditional trials.

Agile clinical trials move fluidly between traditional and decentralized components, taking advantage of both models to deliver significant benefits, including universal access to patients and providers anywhere, faster enrollment, higher retention rates, increased diversity, improved patient experience, and better-quality data.

Oncology clinical trials will be high adopters of decentralized approaches in the year ahead, and with good reason.

Globally, there are currently 3,718 active clinical trials in oncology, investigating 2,160 treatments from 1,903 companies, according to Evaluate Pharma. Together, these studies deploy more than 26,000 investigators and in excess of 11,000 sites. Just over half (52%) of these are Phase 2 trials, and almost a third (31%) are Phase 3 (a further 4% are classified as Phase 2/3).

R&D spend in oncology is set to top US$70 billion this year, making it the largest research market by some distance, and accounting for almost one-third of the total drug R&D budget. Evaluate Pharma also projects that, by 2026, the number of oncology clinical trials could exceed 10,000—which is more than the combined estimates for CNS and anti-infectives!

To document likely trends in oncology clinical trials for the year ahead, Science 37 surveyed research executives at sponsor companies and CROs. This report conveys our findings.

By 2026, we could see more than 10,000 oncology clinical trials—which is more than the estimates for CNS and anti-infectives combined.

The Oncology Clinical Trial Survey

New data sheds light on how trends in clinical trials will impact the way oncology studies are executed.

Three-quarters of oncology executives (73%) are planning to run either an Agile (hybrid) or Fully Decentralized clinical trial in the next 12 months.

- Science 37 undertook a global survey of clinical research executives in the oncology space to document current dynamics and future trends in the design and execution of oncology clinical trials. The study, conducted in March and April of 2022, yielded 85 qualified, completed responses—60% of which were from biopharmaceutical sponsors, and notably, around one-third from organizations with more than US$20 billion in revenue.
- The data aligns strongly with the patterns we have seen in our other recent studies: Namely, that in oncology clinical research—much like in CNS and the overall landscape—we are witnessing a pivotal shift, away from traditional, site-based clinical trials and towards Agile (hybrid) and Fully Decentralized models.
- The big insight: Three-quarters of oncology executives (73%) are planning to run either an Agile (hybrid) or Fully Decentralized clinical trial in the next 12 months, up from just 49% in the previous 12 months. Conversely, less than two-thirds of respondents (65%) are planning to execute a traditional, site-based clinical trial in the next 12 months, down considerably from the 88% that ran a traditional trial in the previous year.
- What's keeping our respondents up at night, regarding all oncology clinical trials (including both traditional and Agile/DCTs)? The three biggest perceived challenges concern speed: Patient Recruitment (72%); Study Start-Up (55%); and Timeline/Delays (54%).
- Sponsors and CROs are planning to execute Agile trials/DCTs in the next 12 months for a wide range of oncology indications, led by Lung Cancer (with 40% of respondents planning Agile studies); Leukemia/Blood Cancers (37%); and Breast Cancer (30%).
- More than half of respondents report that they plan to include ePRO/eCOA tools (57%) and Telemedicine (54%) in their oncology clinical trial designs over next 12 months. A further 48% expect to deploy Mobile Nurses, with the same number planning to incorporate eConsent. Meanwhile, the use of Wearables and Sensors in oncology trials could grow by a staggering 113% in the coming year.
- The top three perceived benefits of using Agile/DCT tools in oncology trials are: Increased Patient Retention (which 67% of respondents ranked in their top three); Greater Patient Diversity (54%); and Faster Patient Recruitment (50%).

DCT Adoption in Oncology Clinical Trials

More respondents expect to run Agile (hybrid) or Fully Decentralized clinical trials over the next 12 months than are planning traditional studies.

We asked respondents: *Within oncology, what types of clinical trial activity has your organization done in the previous 12 months, and what does it plan to do over the next 12 months?*

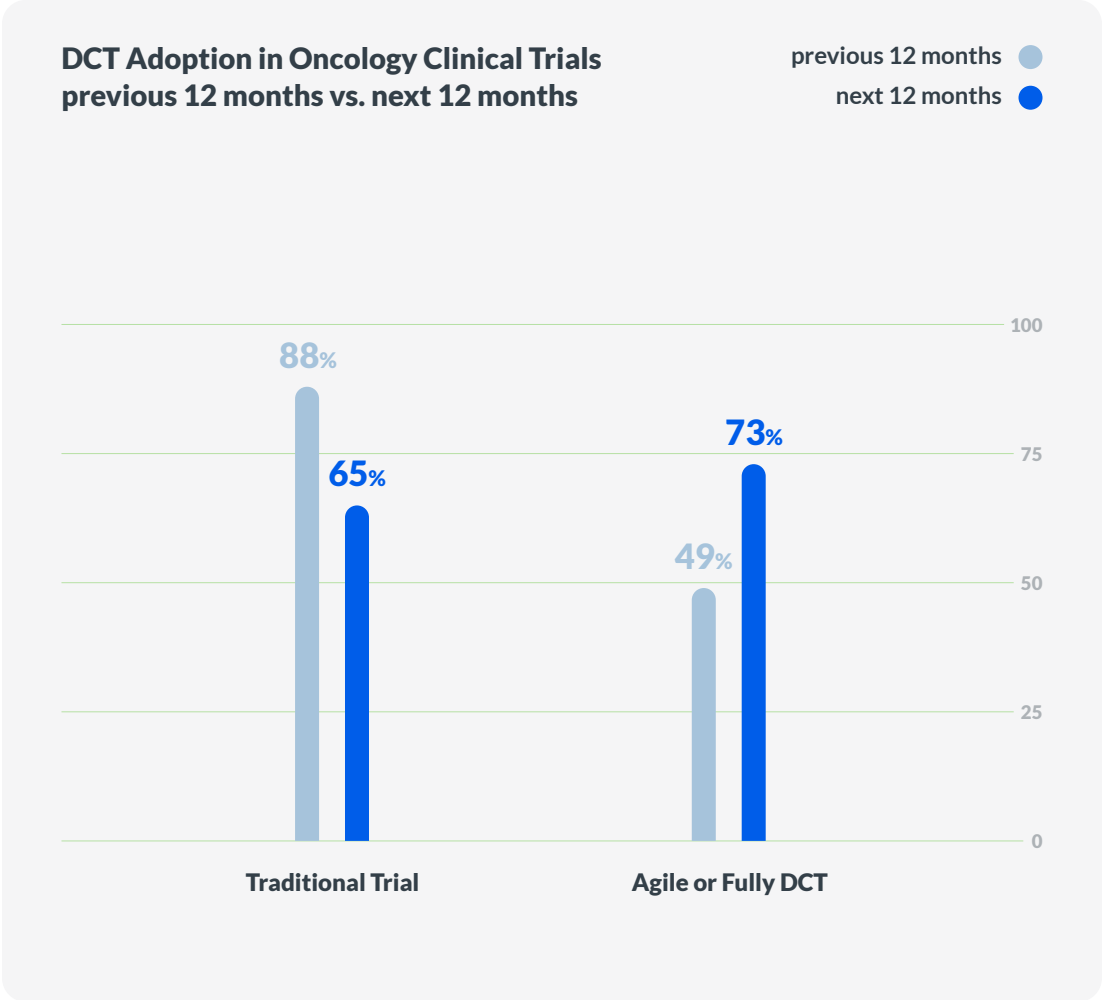
By comparing respondents' oncology clinical trial activity from the past 12 months with their planned activity for the year ahead, we can build an accurate picture of trends for the oncology research landscape.

As with our previous surveys—across all therapeutic areas, and also specifically within CNS—this new data underlines an ongoing shift away from traditional, site-based clinical trials and toward Agile (hybrid) and Fully Decentralized clinical trials (DCTs).

Almost three-quarters of oncology executives (73%) are planning to run either an Agile (hybrid) or Fully Decentralized trial in the next 12 months, up from just 49% for the previous 12 months. Conversely, less than two-thirds of respondents (65%) are planning to execute a traditional, site-based clinical trial in the next 12 months, down considerably from the 88% that ran a traditional trial in the previous year.

Less than two-thirds of respondents are planning to execute a traditional, site-based clinical trial in oncology during the next 12 months.

Fig. 1



What's Keeping Oncology Execs Up at Night

Patient Recruitment is seen as the greatest challenge in executing oncology clinical trials.

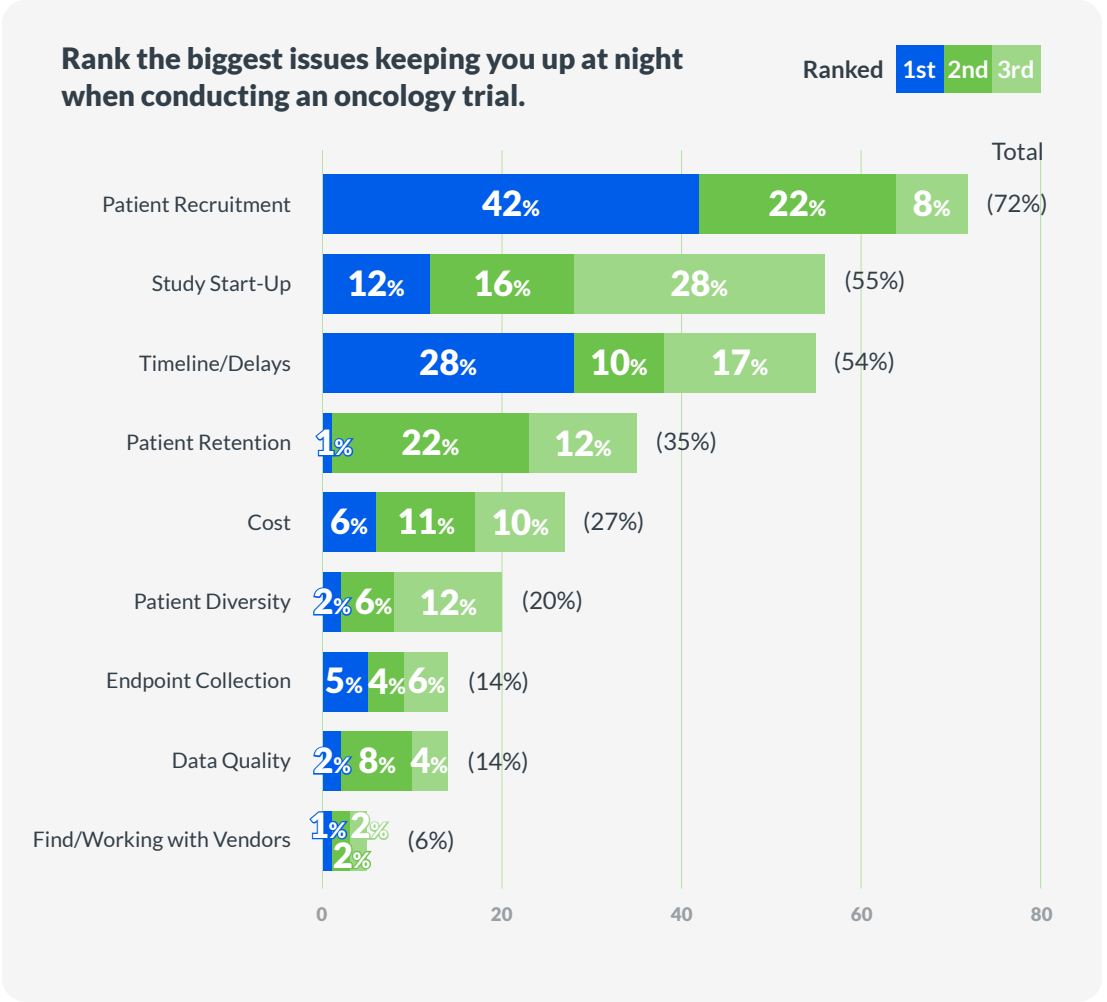
We asked respondents: *Rank the biggest issues keeping you up at night when conducting an oncology trial.* We offered nine key challenges (Fig. 2), plus the option to add Others.

The overwhelming "winner" was Patient Recruitment, which 72% of respondents placed in their top three rankings. In fact, more than four in 10 (42%) of our oncology research executives cited Patient Recruitment as their greatest overall challenge (i.e. ranked number one).

Two other challenges were top of mind: Study Start-Up and Timeline/Delays, which 55% and 54%, respectively, had placed in their top three rankings. Timeline/Delays was also the top-ranked concern overall for more than a quarter of respondents.

Collectively, these three biggest perceived challenges were significantly ahead of all the others, indicating that time is clearly of the essence when executing an oncology clinical trial. Notably, delays in getting new drugs to market can cost sponsors upwards of US$600 million a day[1].

Fig. 2



[1] Cost of Disrupted Clinical Research Due to COVID-19 Equates to $10+ Billion & Potential Study Delays, B. Wollsey, Drug Development & Delivery

Oncology Categories with DCT Components

Lung cancer, Leukemia and Breast Cancer top a wide range of planned Agile clinical trials.

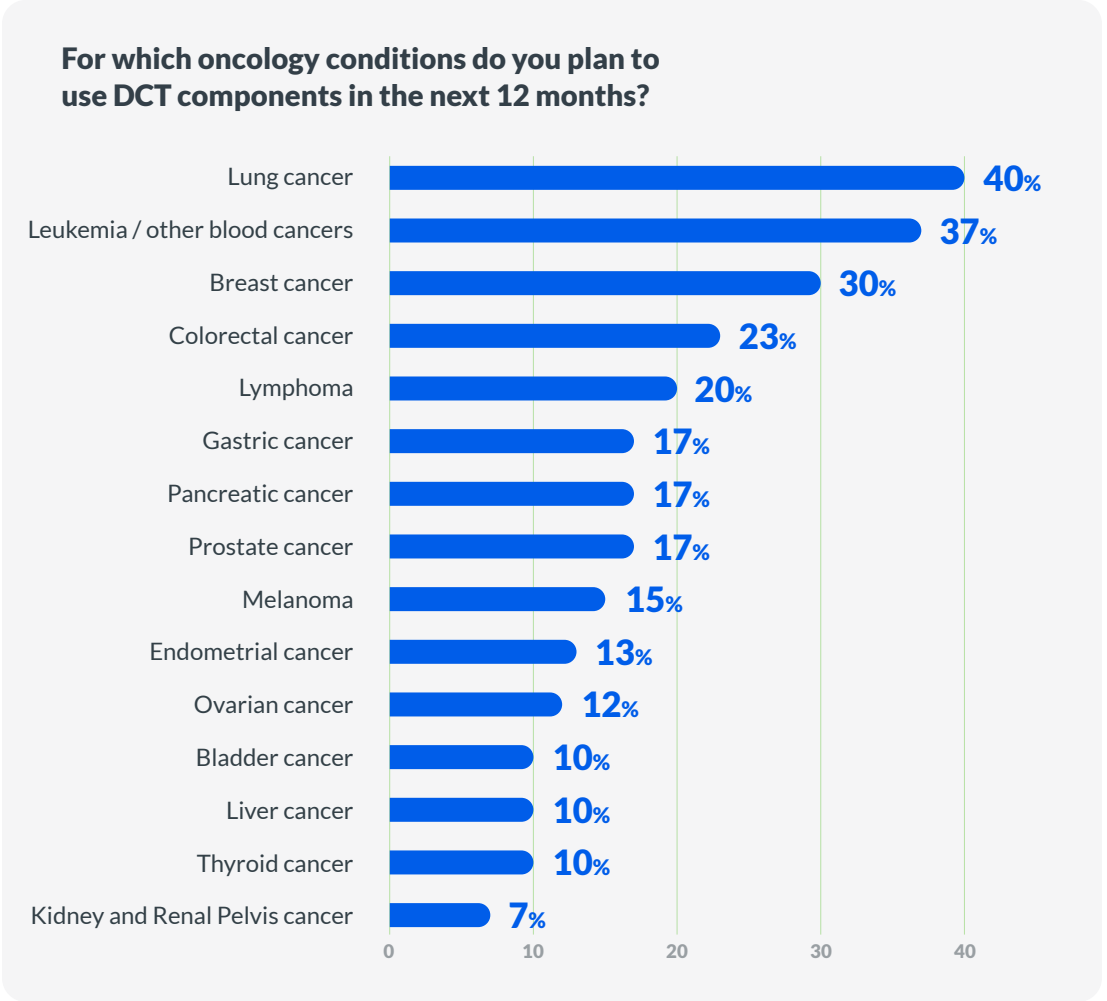
We asked respondents: ***For which oncology conditions do you plan to conduct clinical trials using Decentralized components in the next 12 months?***

Results show that, in the next 12 months, sponsors and CROs are planning to execute Agile and Fully Decentralized clinical trials across a wide range of oncology indications. Four in 10 expect to run studies in Lung Cancer, while more than a third (37%) are planning clinical trials in Leukemia/Other Blood Cancers. Completing this trio of leading indications, three in 10 respondents will execute Agile or DCTs in Breast Cancer.

The wider oncology therapeutic area, of course, comprises many different indications, and our data show that as many as 14 different cancer types will each be studied by at least 10% of our sponsor/CRO respondents, using Agile/DCT approaches, during the next 12 months.

14 cancer types will each be studied by at least 10% of respondents in the year ahead, using Agile or Fully DCT approaches.

Fig. 3



DCT Components Used in Oncology Trials

More than half of respondents plan to use ePRO/eCOA and Telemedicine this year.

We asked respondents: ***Which Agile/Decentralized components do you plan to incorporate in oncology clinical trials over the next 12 months?***

More than half of our respondents reported that they plan to include each of ePRO/eCOA tools (57%) and Telemedicine (54%) in their oncology clinical trial designs over next 12 months. While eCOA is not a new phenomenon, of course, it continues to evolve as part of the Agile clinical trial Operating System.

A further 48% expect to deploy Mobile Nurses, with the same number planning to use eConsent in the year ahead. Meanwhile, more than a third of respondents indicate that they will incorporate Metasites/Remote Sites (38%), Local Clinics (36%) and Wearables/Sensors (34%) in their oncology clinical trial designs over the next 12 months.

As for which DCT components will see the biggest increase in adoption this year within oncology (previous 12 months vs next 12 months), Wearables/Sensors is the clear leader with a sizeable increase of 113%, year over year.

Wearables/Sensors should see a huge 113% increase in adoption within oncology this year.

DCT Components Used in Oncology Trials (Cont.)

Fig. 4A

Which DCT components do you plan to use in oncology trials in the next 12 months?

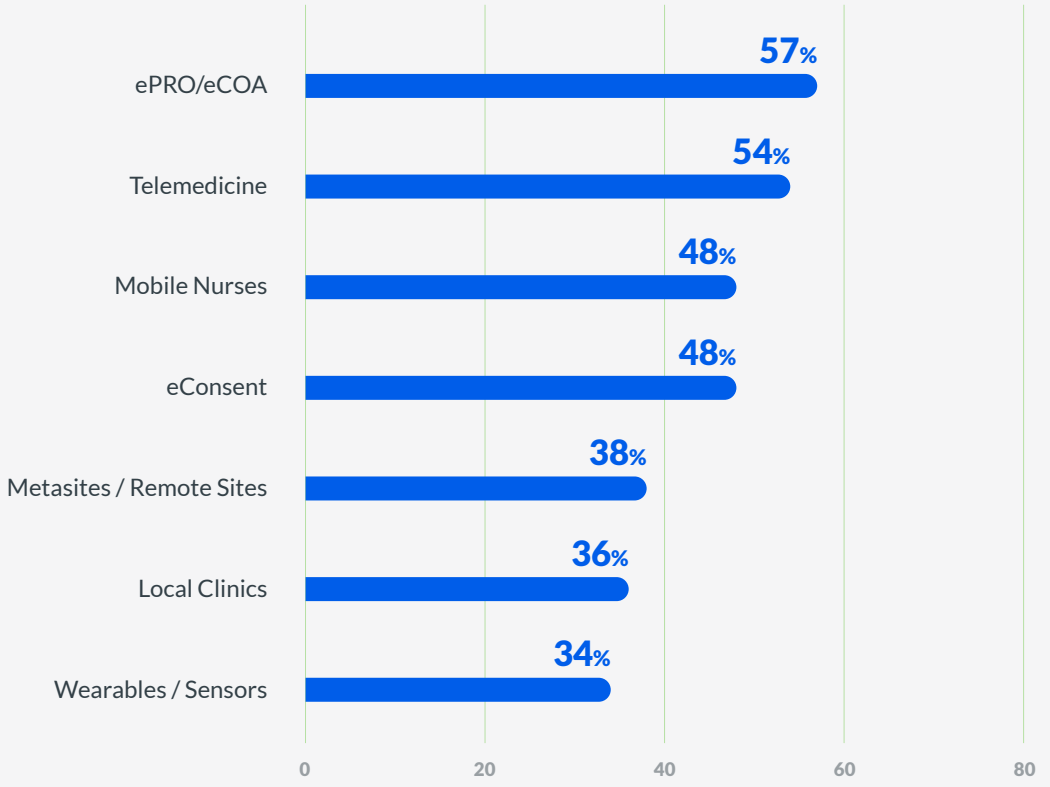
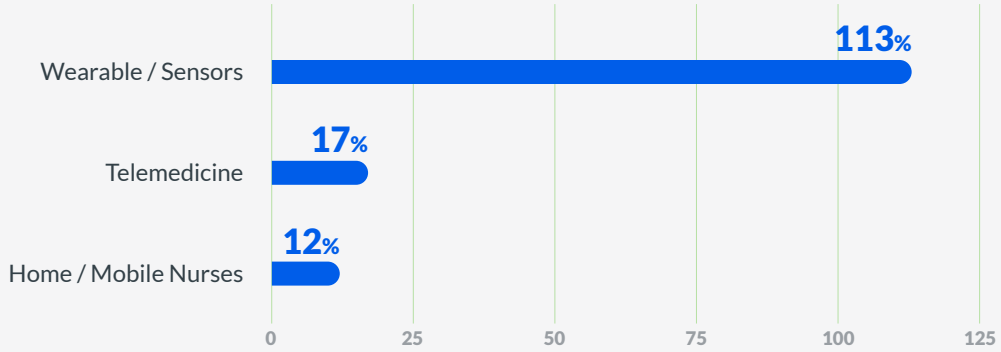


Fig. 4B

Which DCT components will see the biggest increases in adoption in the next 12 months?



Greatest Perceived Benefits of Including DCT Components in Oncology Trials

The top three ranked responses are all patient-focused benefits.

We asked respondents: *What do you, or your organization, perceive to be the greatest benefits of incorporating Agile/DCT components into your clinical trial designs for oncology therapies?*

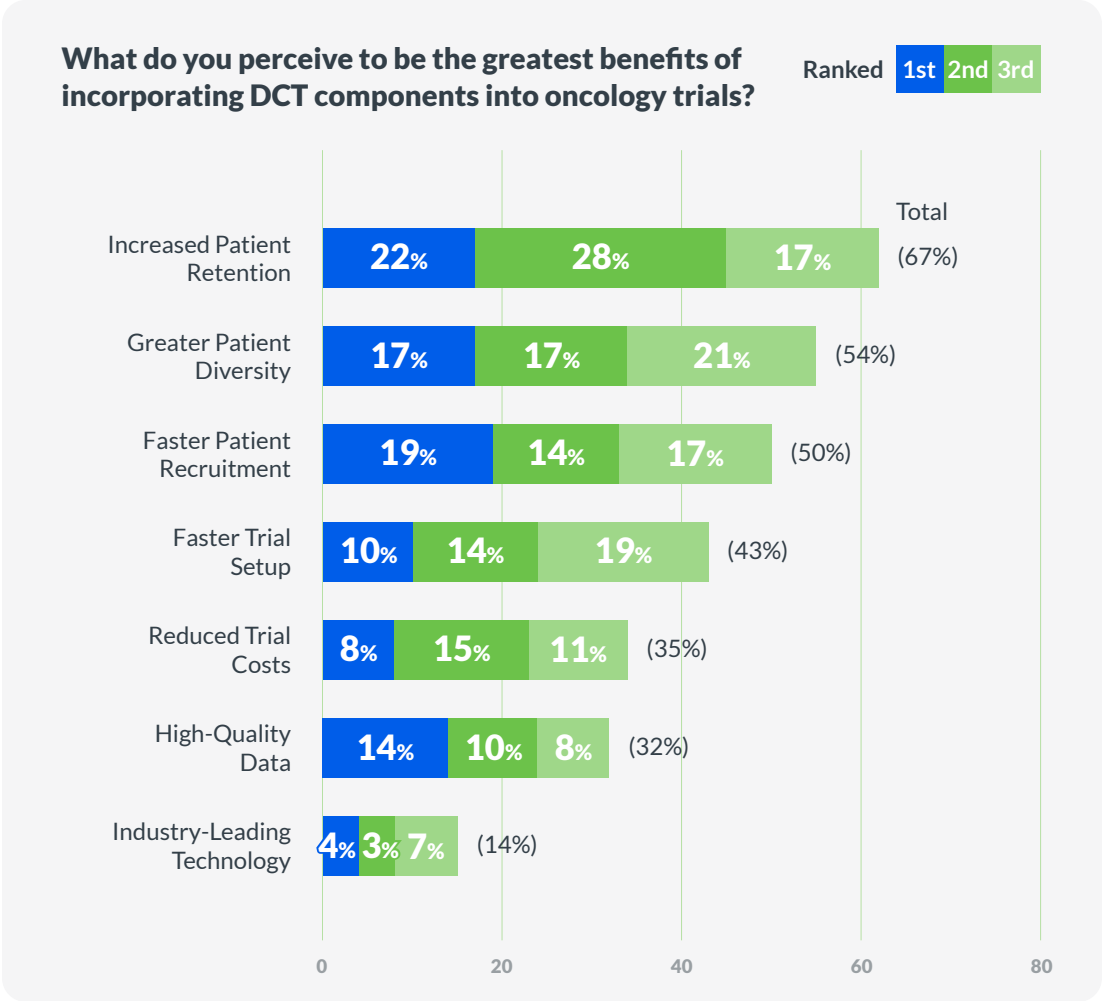
Respondents were presented with seven potential benefits of DCTs (plus the option to add Others) and were asked to rank these from biggest to smallest. To place their responses in order, we added the percentages of the top three rankings for each one (Fig. 5).

Just as we saw with our CNS survey earlier this year, the same three perceived benefits rose to the top of the standings, and by a clear margin—and each has a strong patient focus. These are: Increased Patient Retention (which 67% of respondents included in their top three rankings), Greater Patient Diversity (54% in the top three), and Faster Patient Recruitment (50%).

While it is certainly true that decentralized models lead to increased retention, improved diversity and faster recruitment, perhaps one of the greatest benefits of Agile/DCT approaches is the speed of trial setup—interestingly, less than half of respondents cited this among their top three perceived benefits, and just 10% chose it as the top benefit overall.

One of the greatest benefits of DCTs is the speed of setup, yet less than half of respondents ranked this in their top three.

Fig. 5



Viability Assessments for Using DCT Components in Oncology Trials

Almost three-quarters of respondents have conducted a DCT assessment in the past year.

We asked respondents: ***In the past 12 months, has your organization conducted a viability assessment of decentralized components for an oncology clinical trial?***

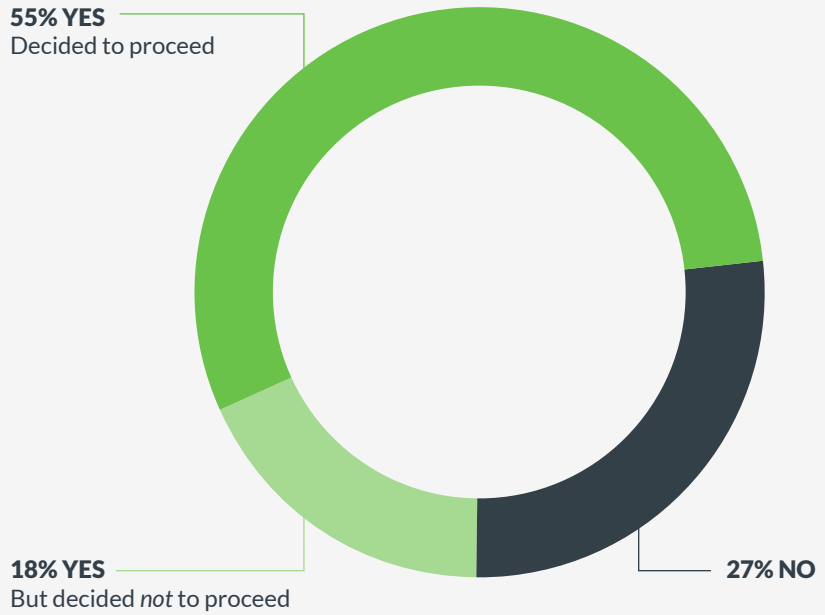
Almost three-quarters of respondents (73%) said, Yes, they had conducted a viability assessment of using Agile/DCT approaches in oncology clinical trials, with the vast majority of these deciding to proceed with using DCT components. The remainder (27%) had not performed such an assessment in the past year.

Respondents' top-ranked reasons for adopting DCTs following an assessment (Fig. 6B) mirrored their "perceived" benefits of DCT elements for oncology trials from the previous section (Fig. 5): Namely, 60% placed Increased Patient Retention in their top three rankings; next was Greater Patient Diversity (58% in top three); followed by Faster Patient Recruitment (56%). Interestingly, Recruitment was the most top-ranked response overall, with 26% ranking it number one.

The vast majority of organizations that conducted an assessment of DCTs in oncology decided to proceed with the approach.

Fig. 6A

Have you done a viability asessment for using DCT components in an oncology trial in the past 12 months?



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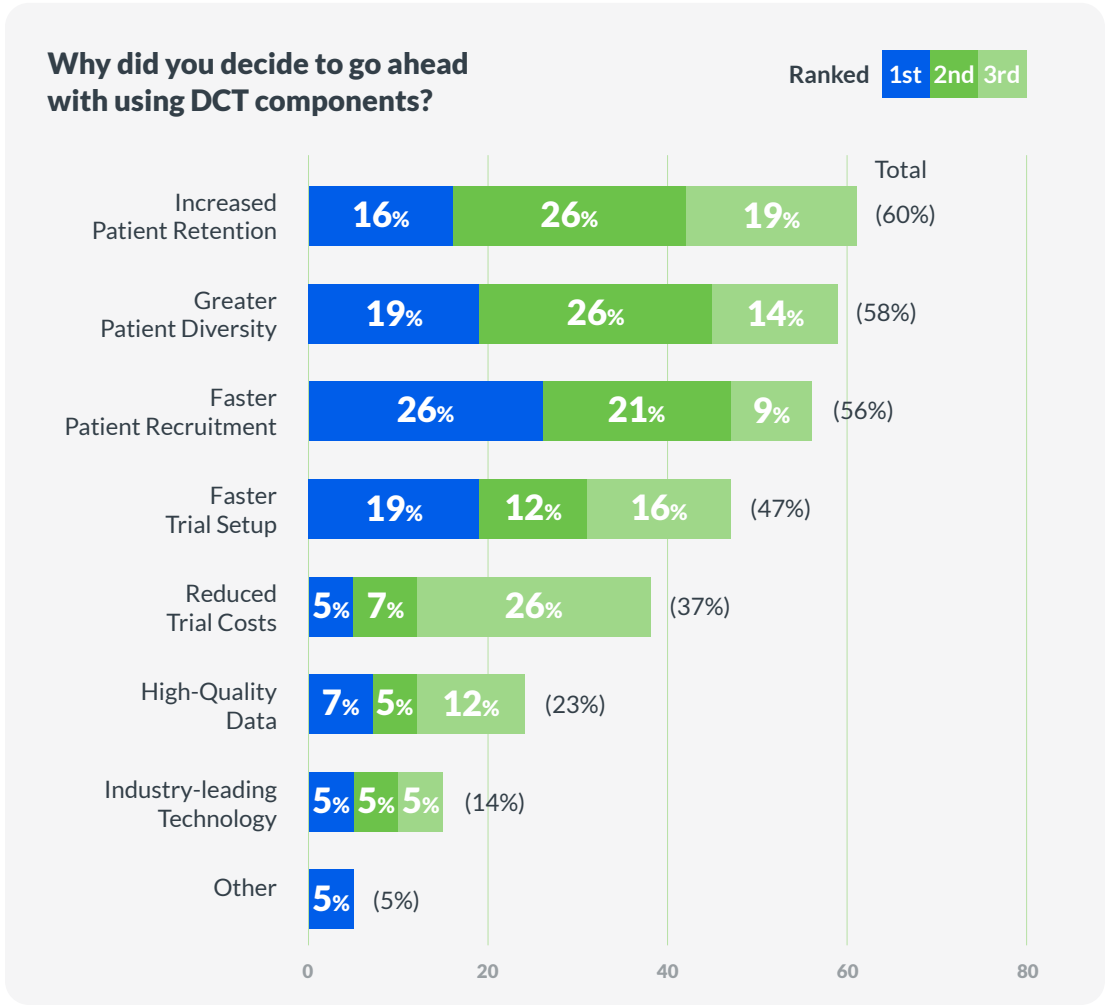
Viability Assessments for Using DCT Components in Oncology Trials (Cont.)

Fig. 6B



How Wearables and Sensors are Used in Oncology Clinical Trials

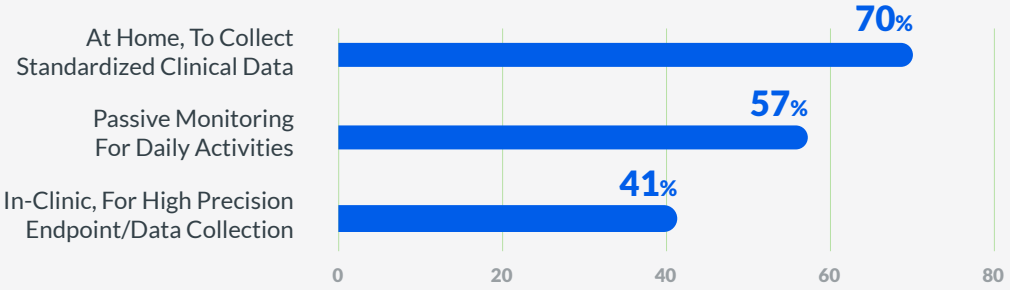
Seven out of 10 respondents who are using, or planning to use, wearables and sensors collect standardized data in patients' homes.

We asked respondents: ***How are you currently using, or plan to use, wearables and sensors in oncology studies? And, specifically, how are you using/plan to use the data generated by wearables sensors in oncology studies?***

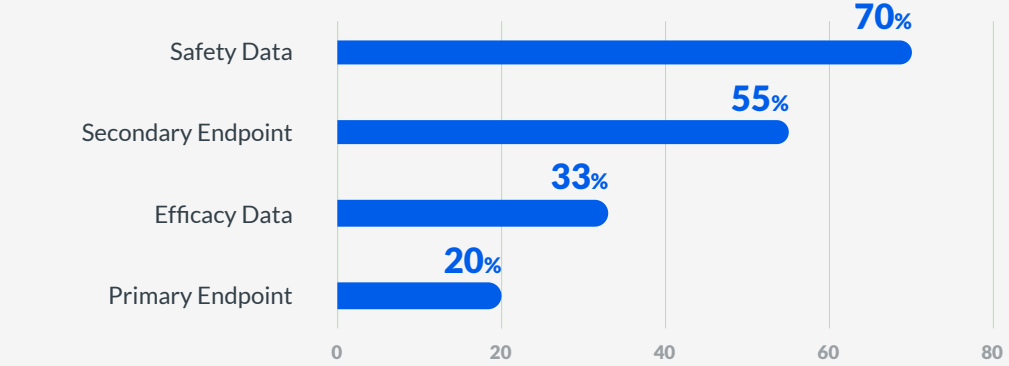
Seven out of 10 respondents reported that they use wearables/sensors in oncology clinical trials At Home To Collect Standardized Clinical Data (Fig. 7A). Almost six in 10 (57%) use them for Passive Monitoring Of Daily Activities, while a further four out of 10 deploy them In Clinic For High-Precision Endpoint/Data Collection.

As for what they do with the data, seven out of 10 said they use wearables and sensors to collect Safety Data, followed by 55%, who deploy them to generate Secondary Endpoints. A further one in three reported using them to collect Efficacy Data (which was the top response in the CNS survey), while just one in five use them to generate Primary Endpoints.

How are you using wearables/sensors in oncology studies? *Fig. 7A*



How are you using wearable/sensor data in oncology studies? *Fig. 7B*



70% of those incorporating wearables and sensors in oncology trials are using them to generate safety data.

CONCLUSION

Five Reasons for Taking an Agile Approach to an Oncology Study

This report has documented an evolving shift away from traditional, site-based clinical trials and toward Agile/Decentralized studies in the oncology space.

Here are our top 5 reasons for taking an Agile approach to an oncology clinical trial.

1 The patient-centricity of Agile trials helps all stakeholders win.

Oncology clinical research execs reported that Patient Enrollment (page 7) is what keeps them up at night. They also ranked Patient Retention, Patient Diversity and Patient Enrollment as their top perceived benefits of incorporating decentralized components into clinical trials (page 11).

Agile trials can enhance the patient experience in several key ways: They enable universal access to participation (including more diverse patients); they reduce the burden for patients; they allow sponsors to set new standards in clinical trial "customer service"; and they offer potential new treatments to more patients. Beyond enhancing the patient journey, they also make trials more accessible to providers, contribute greatly to patient enrollment, retention and diversity, and generally facilitate the acceleration of clinical research, potentially bringing new drugs to market faster. Furthermore, DCTs allow patients to bring their own providers into trials; the aim of Agile trials is not to break up these important relationships, but to nurture them.

In Science 37's experiences, decentralized approaches have produced, on average, 15x faster patient enrollment, 28% greater patient retention, and 3x more diverse patient representation. Despite the nuances of different therapeutic areas, these key benefits translate to any disease state, including oncology.

2 Regulatory bodies are increasingly embracing Agile trials.

Regulatory bodies began noting the benefits of incorporating decentralized components into clinical trials during the pandemic, and have been working to get on board with Agile clinical trials across all therapeutic areas, including oncology.

The FDA supports the idea that decentralized approaches may encourage participation for those who do not live close to study sites, and acknowledges the need to test treatments on more representative populations. In fact, the FDA recently issued draft guidance for increasing the diversity of clinical trials, which we know is a key benefit of Agile approaches, and increasingly regulatory bodies are asking for a diversity component.

For global oncology clinical trials, regulatory nuances will likely involve taking a country-by-country approach, which Science 37's regulatory experts are well-prepared to execute.

3 Agile trials enable the collection of more consistent, reliable data.

Another major benefit of Agile clinical trials is they enable the collection of higher-quality data, both from an efficacy and a safety perspective. Electronic data is associated intrinsically with greater fidelity, and so with, say, ePRO tasks like self-completion questionnaires, it is generally easier to track the timing and legitimacy of the data.

In addition, we have seen from our study results that the use of wearables and sensors is expected to explode (page 10), with seven out of 10 users deploying devices in the home to collect standardized clinical data. The same number of respondents also

Five Reasons for Taking an Agile Approach to an Oncology Study (Cont.)

said they would use wearables and sensors primarily for safety data, which, in itself, is a significant endorsement of Agile clinical trials.

4 Metasites can increase speed, reduce friction—and rescue studies.

Metasites (or virtual clinical trial sites) are a great way to consolidate patients into a central recruitment approach and may eliminate the need for deploying so many brick-and-mortar sites in oncology studies.

By their very nature, Metasites can also help reduce the burden of participation, and can even be used to rescue underperforming or delayed clinical trials, especially where patient enrollment is a concern. Science 37's research has shown that reducing reliance on physical sites can also remove friction in the clinical trial process, greatly enhancing the patient experience and subsequently increasing retention rates and the diversity of the study population.

The Agile clinical trial Operating System enables data generated by Metasites to be harmonized seamlessly with physical site data. The Metasite is effectively an enhancement, rather than a disruption, of the existing arrangement.

5 The Agile clinical trial Operating System continues to evolve.

While the potential benefits of Agile clinical trials are numerous, the model can be complex to execute, and requires a comprehensive, end-to-end platform to fully orchestrate studies that require both remote and on-premise management.

The NextGen SaaS release of Science 37's Operating System for Agile clinical trials does this seamlessly, unifying stakeholder journeys, increasing compliance, and generating the highest-quality data for Agile models.

The increase in demand for Decentralized and Agile research has led sponsors and CROs to implement numerous point-solution technologies, often resulting in disconnected processes that lead to study delays and threaten data quality. In contrast, Science 37's technology platform coordinates and unifies the stakeholder journey through every visit, with reliable, consistent data-capture to increase compliance and generate the highest-quality evidence.so that we can get new treatments to market faster and into the hands of those who need them most.

Five Reasons for Taking an Agile Approach to an Oncology Study (Cont.)

Science 37®

1. The patient-centricity of Agile trials helps all stakeholders win.

Agile clinical trials enhance the patient experience in a number of ways, and all stakeholders stand to reap the benefits.

2. Regulatory bodies are increasingly embracing Agile trials.

Agencies are backing the execution of Agile trials, particularly as it relates to the diversity of participants, as recent FDA guidance attests.

3. Agile trials enable the collection of more consistent, reliable data.

The high fidelity of electronic data means Agile trial models can generate safety and efficacy data of greater quality than traditional sites alone.

4. Metasites can increase speed, reduce friction—and rescue studies.

Metasites are effective tools for accelerating enrollment, reducing the burden of participation, and rescuing underperforming or delayed trials.

5. The Agile clinical trial Operating System continues to evolve.

It takes a comprehensive, end-to-end platform to fully orchestrate studies that require both remote and on-premise management.

APPENDIX

Methodology, Respondent Data, Author Bios, and About Science 37

APPENDIX

Methodology and Respondent Characteristics

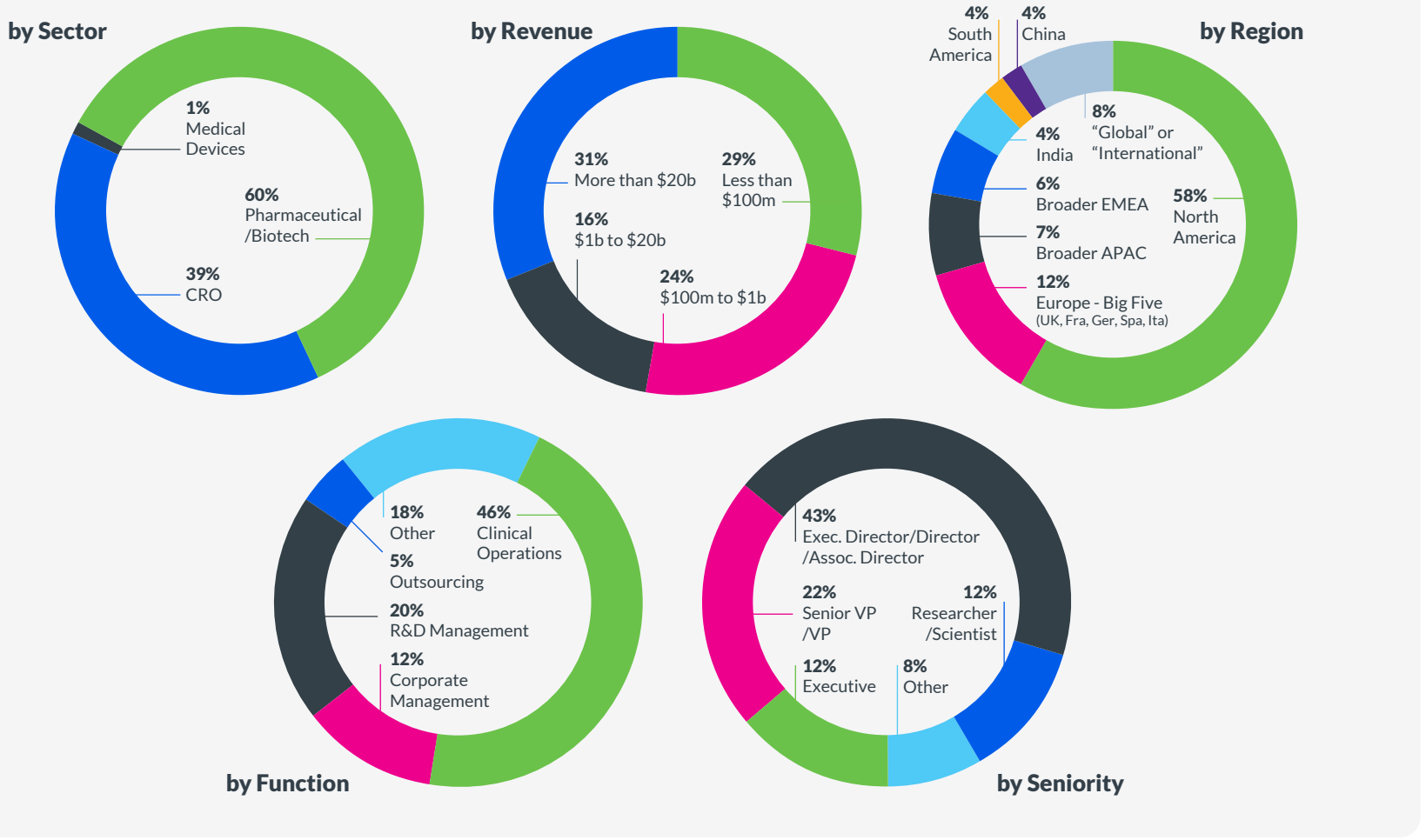
Science 37 executed this oncology survey online in March and April 2022. Respondents were targeted largely by email, with some social media promotion, and they submitted their responses to us via online questionnaires.

The questionnaires generated a "qualified" respondent sample of 85 responses.

We included only complete responses from senior executives who are either involved in sponsoring or managing clinical research within oncology, or who are planning to execute oncology clinical trials in future.

All numbers published in this report represent a percentage of the universal sample size of 85.

Response data were analyzed by Life Science Strategy Group and percentages were tested for significance at the 95% confidence level.



APPENDIX

Glossary of Terms

DCT, or Decentralized Clinical Trial

Refers to the decentralization of clinical trial operations, where technology is used to communicate with participants and collect data. Studies are executed via telemedicine and mobile/local healthcare providers, using patient-focused processes and technologies. These differ from traditional clinical trials, which are centered around (and limited by) brick-and-mortar sites.

Fully Decentralized Clinical Trial

Where the entire study is executed virtually, as a DCT, without incorporating physical sites. In a fully decentralized trial, Science 37 is the sole provider, running all study components from its technology platform—including orchestrating all of the visits and activities—and with responsibility for all patients within the study.

Agile (or Hybrid) Clinical Trial

Moves fluidly between traditional and decentralized components, taking advantage of both models to deliver significant benefits, including universal access to patients and providers, faster enrollment, higher retention rates, increased diversity, improved patient experience, and better-quality data. Numerous studies show the industry is shifting toward Agile studies, which allow patients to participate either from their homes, from sites, or a combination of home and site; meanwhile, providers can participate on- or off-premise. Agile trials require: the ability to activate any provider and any patient, regardless of premises; a network of patient communities, telemedicine investigators, mobile nurses and remote coordinators; and a flexible Operating System to navigate seamlessly between on-site and off-site.

Traditional, Site-Based Clinical Trial

Refers to the standard approach for designing and executing clinical trials, which deploys networks of brick-and-mortar sites. Each site is responsible for enrolling patients and providers, and collecting data, according to the study protocol. The traditional model is widely considered to be slow, costly and inaccessible; less than 10% of patients and providers are able to participate in these types of trials.

TA, or Therapeutic Area

A grouping of similar diseases or conditions under a generalized heading, such as Oncology, Cardiovascular or Central Nervous System (CNS).

Operating System™

A framework of solutions for executing an agile (hybrid) or fully decentralized clinical trials. Science 37's Operating System (OS) is underpinned by an end-to-end technology platform and supported by five specialized networks—patient communities, telemedicine investigators, mobile nurses, remote coordinators and connected devices—to operationalize, conduct and support studies.

Sponsor

An entity or organization that takes responsibility for executing and initiating a clinical investigation. This includes pharmaceutical, biotech, diagnostic and medical device companies; academic organizations; non-profits; and government agencies (e.g. National Institute of Health).

CRO, or Contract Research Organization

A company that provides support to pharmaceutical, biotech and medical devices companies in the form of outsourced research services.

Provider

A health professional licensed to provide healthcare diagnosis and treatment to patients. Through its global network of healthcare providers, Science 37 can identify patients and providers, based on medical criteria.

Investigator

A physician who leads the conduct of a clinical trial at a study site. A Principal Investigator (PI), has a leadership role that helps create the foundation of a successful clinical trial. And a Telemedicine Investigator is one that is recruited by Science 37, but without any affiliation to a specific site.

Mobile Nurse

Administers visits, treatments and procedures in the patient's home, as part of a clinical trial protocol. Science 37 has its own global network of trusted, consistently trained, tech-enabled mobile nurses, bringing extensive, in-home capabilities covering multiple procedures and data collection techniques.

Site

A brick-and-mortar location or facility, committed to the ethical conduct of clinical research, which produces data to enable scientific decision-making based on the safety and efficacy of investigational products.

Metasite™

A virtual site, where Science 37 acts as a study arm to supplement a network of traditional sites, orchestrating the clinical trial and taking responsibility for a portion of the total patients associated with a clinical trial. Sponsors also are able to "bring their own investigators" or BYOI, where Science 37 trains and onboards the sponsor's previously engaged investigators, or a patient's providers, to become a telemedicine investigator on a specific study.

Wearable/Sensor

A wearable is an electronic device that can be worn as an accessory, embedded in clothing, implanted in the user's body, or even tattooed on the skin. It is hands-free and can send and receive data via the internet. A sensor detects and responds to input from the physical environment, and can be deployed in clinical trials to measure a patient's biometrics, movement and other tests.

APPENDIX

About the Authors and Science 37

Drew Bustos

Chief Strategy & Marketing Officer,
Science 37

An expert on innovation, design thinking, and technology, Drew currently leads Global Strategy, Marketing, Partnerships, and External Diversity for Science 37. He is actively engaged in helping drive the adoption of innovative technologies via patient-centric approaches within the life sciences industry. He has led corporate strategy, marketing, and product management throughout his career, successfully executing aggressive growth plans.

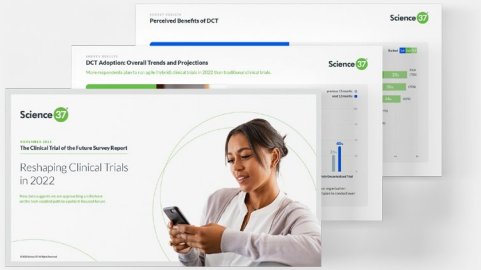
Dr. Shaalan Beg, M.D., M.S.C.S.

Vice President, Oncology
Science 37

Dr. Beg brings a wealth of clinical investigator and research expertise to spearhead Science 37's agile clinical trials program in oncology. Dr. Beg came to Science 37 from the University of Texas, Southwestern Medical Center in Dallas, TX where he served as Medical Director for the Clinical Research Office at the Simmons Comprehensive Cancer Center and held the position of Director Gastrointestinal Medical Oncology and Associate Professor of Hematology and Medical Oncology. Dr. Beg is a graduate of ASCO's Leadership Development Program and has been a member of the Pancreatic Cancer Task Force of the National Cancer Institute (NCI) GI Cancer Steering Committee.

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 and helping to accelerate the development of treatments that impact patient lives. As a pioneer of decentralized clinical trials, the Science 37 Clinical Trial Operating System (OS) supports today's more agile clinical research designs with its full-stack, end-to-end technology platform and specialized networks of patient communities, telemedicine investigators, mobile nurses, remote coordinators and connected devices. Configurable to enable any study type, the Science 37 OS enables up to 21x faster enrollment, 28% better retention and 3x more diverse patient population with industry-leading workflow orchestration, evidence generation and data harmonization. For more information, visit www.science37.com.



Recommended Reading

APRIL 2022: INSIGHT BRIEF

Decentralization: An Ethical Obligation

https://science37.co/EthicalObligationIB

MARCH 2022: REPORT

How Agile Clinical Trials are Impacting CNS Research

https://science37.co/CNSReport

FEBRUARY 2022: INSIGHT BRIEF

Decentralized Clinical Trials Are Far More… Centralized?

https://science37.co/DecentralizedClinicalTrialsIB

DECEMBER 2021: REPORT

The Clinical Trial of the Future Survey Report

https://science37.co/ClinicalTrialOfTheFuture

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