

White Paper

Unlocking the Potential of Decentralized Clinical Trials

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Introduction

The concept of a Decentralized Clinical Trial (DCT) has been around in the industry for a number of years, since Pfizer conducted the first “virtual” trial in June 2011. But DCTs have finally started to move out of paralysis in pilots and have increasingly become a more mainstream consideration since the COVID-19 pandemic. A DCT is simply a trial that has activities conducted remotely, such as in participants’ homes, yet the reality of achieving this has not been simple at all. DCTs were discussed extensively at recent conferences including CNS and Clinical Trials Europe, and it was clear that all industry stakeholders are keen to stay abreast of this evolving field and continue driving the change to ensure full adoption.

As this white paper shows, the number of trials with decentralized attributes has been gradually increasing over time, but despite this rise, we are still in the very early stages of adapting trial design strategies to better fit around the new digital world. Based on Citeline’s validated methodology for assignment of DCT classification, the proportion of studies incorporating decentralized elements remains very low. Citeline’s proprietary data suggests this was only 3.4% for trials that started in 2022 and were reported to date in the public domain.

This paper explores the current DCT landscape and its evolution over time, as well as the key advantages of incorporating decentralized attributes and how barriers to their inclusion can be overcome. The narrative is supported by data and analysis from Citeline’s gold-standard clinical trials intelligence solution, Trialtrove, and validated by Citeline’s industry leading customer network.



Trends in DCT Design

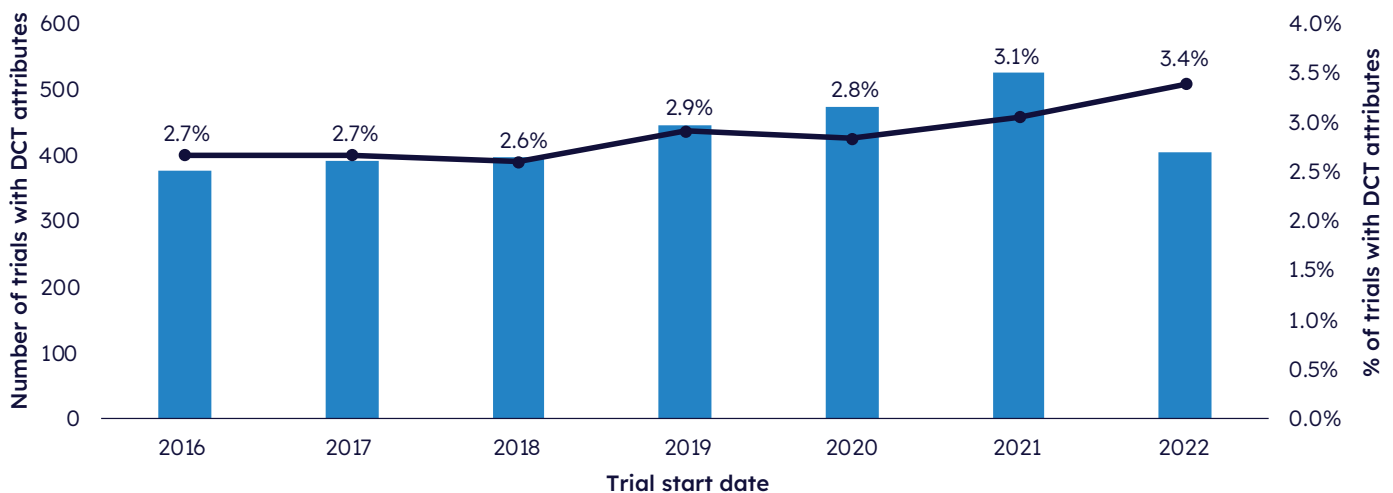
The exact characteristics that a trial needs to display to be considered a DCT is a subject of active debate. The Decentralized Trials & Research Alliance (DTRA) suggests a DCT is a clinical trial utilizing technology, processes, and/or services that create the opportunity to reduce or eliminate the need for participants to physically visit a traditional research site, and as such decentralization can be considered a spectrum.¹

To reflect this spectrum, Citeline has created an extensive dictionary of DCT-related terms based on the content observed across clinical trials in Trialtrave and supported by internal and publicly available references. This dictionary is used in the mining of relevant text fields within Trialtrave for the presence of DCT attributes. This allows the creation of a DCT filter, which reflects the currently available, publicly disclosed information included in Trialtrave. DCT-related terms are aggregated across five key categories

designed to provide views into specific sectors/elements of the DCT landscape. These comprise: Telemedicine/Telehealth, Wearables/Sensors (used remotely), Personal Devices/Apps (used remotely), Home Visits, and Electronic Consent.

Interestingly, the actual incorporation of DCT attributes is not in line with the extensive attention decentralized trial designs are receiving. The number of trials incorporating one or more DCT element has increased slightly from 376 trials starting in 2016 to 526 trials starting in 2021 (Figure 1); however, the vast majority of trials still do not incorporate DCT attributes, or at least there is no easily accessible public disclosure of this. It should be noted that certain DCT elements are less likely to be described in sources like trial registry postings and might only be described in full protocol documents. That said, adoption appears to be low, despite the potential advantages to sponsors and patients that have been widely communicated.

Figure 1: Trials incorporating DCT attributes over the last seven years



Source: Trialtrave, February 2023

Please note, Trialtrave captures data as it becomes available in the public domain. As such, the number of trials in Trialtrave with a start date of 2022, for instance, is likely to increase over time as more data is made available.

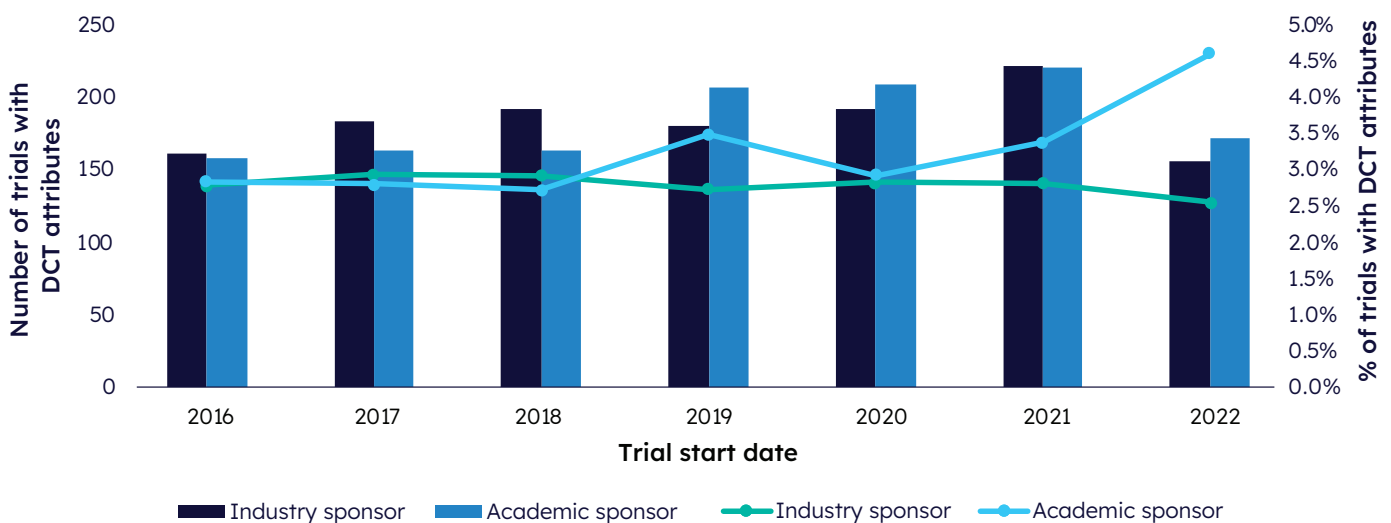
1. DTRA (2022) Glossary. Available from: <https://www.dtra.org/1a-glossary#letter-D> [Accessed 02 February 2023].

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Both industry and academic sponsors have been investing in DCTs, as shown in Figure 2. The percentage of industry-sponsored trials incorporating DCT attributes has remained relatively stable over the last seven years, fluctuating between 2.5% and 2.9%. This contrasts the uptake in academia, which rose from 2.8% in 2016 to 4.5% in 2022. It is therefore DCTs in the non-commercial setting that are driving the increase in trials with associated DCT attributes. One possible contributor to this trend is the greater capacity

for flexibility among academic sponsors, compared to large biotech or pharmaceutical companies. Industry sponsors typically have complex operating models which limit the use of unvalidated tools such as novel electronic clinical outcome assessments, and they are more likely to run pivotal trials for registration requiring compliance suitable for submissions to regulators. Academic groups are more likely to conduct smaller early-phase or late-phase post-marketing studies, and these inherently allow for greater adaptability.

Figure 2: Sponsor type for trials incorporating DCT attributes over the last seven years



Source: Trialtrrove, February 2023

Please note, Trialtrrove captures data as it becomes available in the public domain. As such, the number of trials in Trialtrrove with a start date of 2022, for instance, are likely to increase over time as more data is made available. In addition, a single trial may be associated with both an industry and academic sponsor.

Among the industry sponsor subset, certain companies are embracing this new approach to trial design more than others. Pfizer, Novartis, and Takeda emerge as the three companies with the most ongoing and planned trials with DCT attributes. Interestingly, Merck and Bristol Myers Squibb rank second and third in their

total number of ongoing and planned trials, and yet they do not sit within the top 10 sponsors for trials with DCT attributes (Table 1). This may indicate a more cautious approach to new clinical technologies, but these companies are also heavily concentrated in oncology, where decentralization is less mature.

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Table 1. Top 10 sponsors, by number of studies, for all ongoing and planned trials

Ranking	Trials with DCT attributes	All trials
1	Pfizer	AstraZeneca
2	Novartis	Merck & Co
3	Takeda	Bristol Myers Squibb
4	AstraZeneca	Roche
5	Roche	Pfizer
6	Eli Lilly	Novartis
7	Sanofi	Jiangsu Hengrui Pharmaceuticals
8	Johnson & Johnson	Johnson & Johnson
9	AbbVie	Sanofi
10	GSK	AbbVie

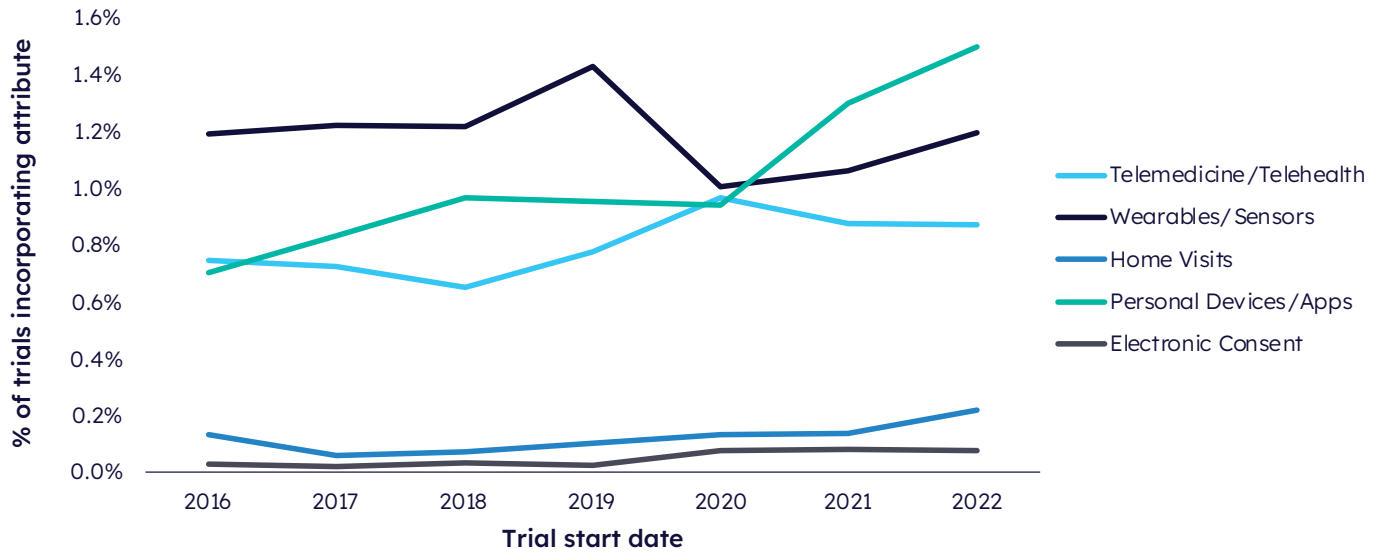
Source: Trialtruve, February 2023

With regards to the key attribute categories associated with DCTs, Personal Devices/Apps lead the way in terms of current adoption within clinical trials (Figure 3). Inclusion increased from 0.7% in 2016 to 1.5% in 2022, which is the highest inclusion rate of all assessed DCT attributes. In 2018 and 2019, smoking cessation was associated with the most trials incorporating Personal Devices/Apps; however, the pandemic quickly changed that, and COVID-19 became the top indication in 2020 and 2021, accounting for 37% and 28% of trials incorporating Personal Devices/Apps respectively. Use of Telemedicine/Telehealth was also affected by the pandemic. 119 trials that started in 2019 incorporated Telemedicine/Telehealth, and this jumped to 161 in 2020, of these 59 were for COVID-19.

The inclusion of Wearables/Sensors has remained more constant, hovering at slightly over 1%. Type 1 and type 2 diabetes trials dominated this category, owing largely to use of at-home continuous glucose monitoring. The percentage of trials incorporating home visits remained consistently low between 2016 and 2022, tracking at approximately 0.1%. It may be that their inclusion is not being fully represented in registries and other key publicly available sources that our Trialtruve analysts mine, but it is also likely that there are considerable operational barriers to uptake and that the pandemic did not help in that respect. Inclusion of electronic consent has also remained low, despite having a low technological hurdle, and may also be under-reported.

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Figure 3: Percentage of clinical trials incorporating various DCT attributes over the last seven years

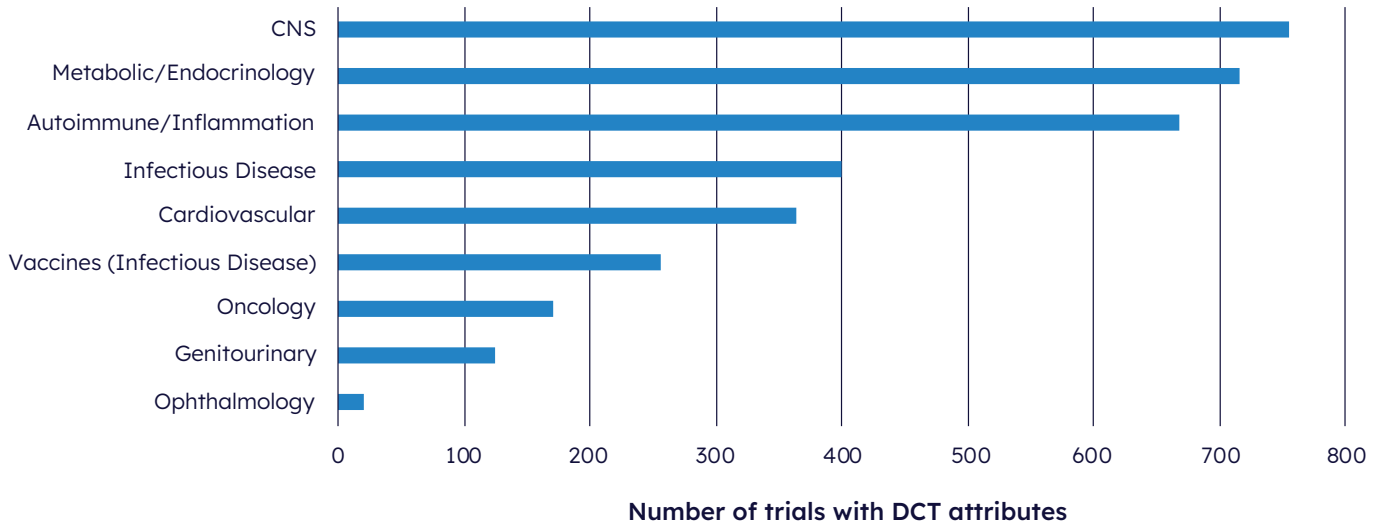


Source: Trialtrove, February 2023

Together, the three therapeutic areas of CNS, Metabolic/Endocrinology, and Autoimmune/Inflammation are associated with a large proportion (68%) of the trials that have DCT attributes (Figure 4). DCT attributes have been incorporated into trials for a wide range of CNS indications such as nociceptive and neuropathic pain, insomnia, multiple sclerosis, Alzheimer’s disease, migraine, and depression. The range of DCT attributes for this therapeutic area is also broad and includes electronic diaries, mobile devices, actigraphy, and telephone interviews to name but a few. DCT attribute inclusion in the Metabolic/Endocrinology therapeutic area is being driven by use of continuous glucose monitoring which involves a wearable/implant for type 1 and type 2 diabetes, while inclusion of DCT attributes in Autoimmune/Inflammation trials is largely attributable to the use of electronic diaries in asthma and COPD.

The therapeutic areas associated with the least trials with DCT attributes include Ophthalmology and Genitourinary, although of course, these therapeutic areas are also associated with fewer trials overall. The low positioning of Oncology, with just a 5.4% overall share, is also notable considering that almost four in 10 new trials are investigating cancer therapeutics. This speaks to the challenges of decentralization in trials with complex inclusion criteria and protocols relying heavily on in-person infusions and clinical assessments. However, to some extent this figure masks the extent to which oncology trials adopted DCT attributes throughout the pandemic due to the critical nature of the therapies for late-stage cancer patients. Sponsors had to quickly pivot to home nursing, remote patient outcomes collection, and direct IMP shipment to patient homes.

Figure 4: Therapeutic area representation among industry-sponsored trials with DCT attributes

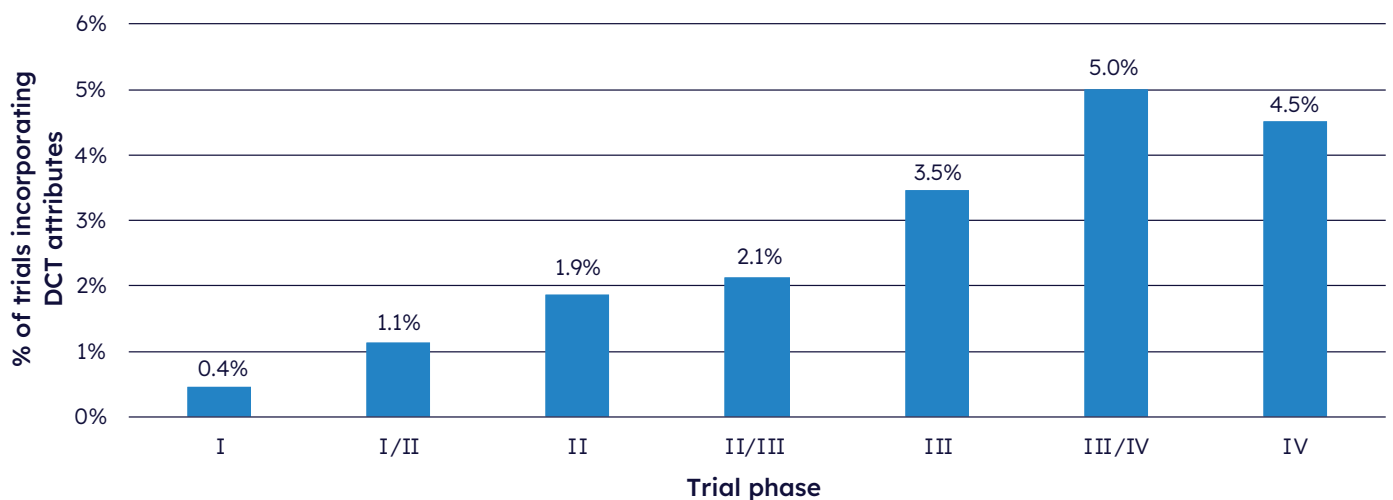


Source: Trialtrove, February 2023

With regards to trial phase, sponsors are most likely to include DCT attributes in later-stage trials, in particular Phase IV trials (Figure 5). The main objectives of a Phase IV study are to check the drug’s performance in real-life scenarios, to study the long-term risks and benefits of using the drug, and to discover any rare side effects. This results in these trials

being typically longer in length, which makes the need to continually visit the study site a greater burden. Furthermore, as regulatory data submission requirements are less prescriptive for post-marketing studies, due to the nature of monitoring real-world surveillance, there is more scope for the trial sponsor to be enabled with digital endpoints that are not yet validated.

Figure 5: Percentage of industry-sponsored trials incorporating DCT attributes by phase



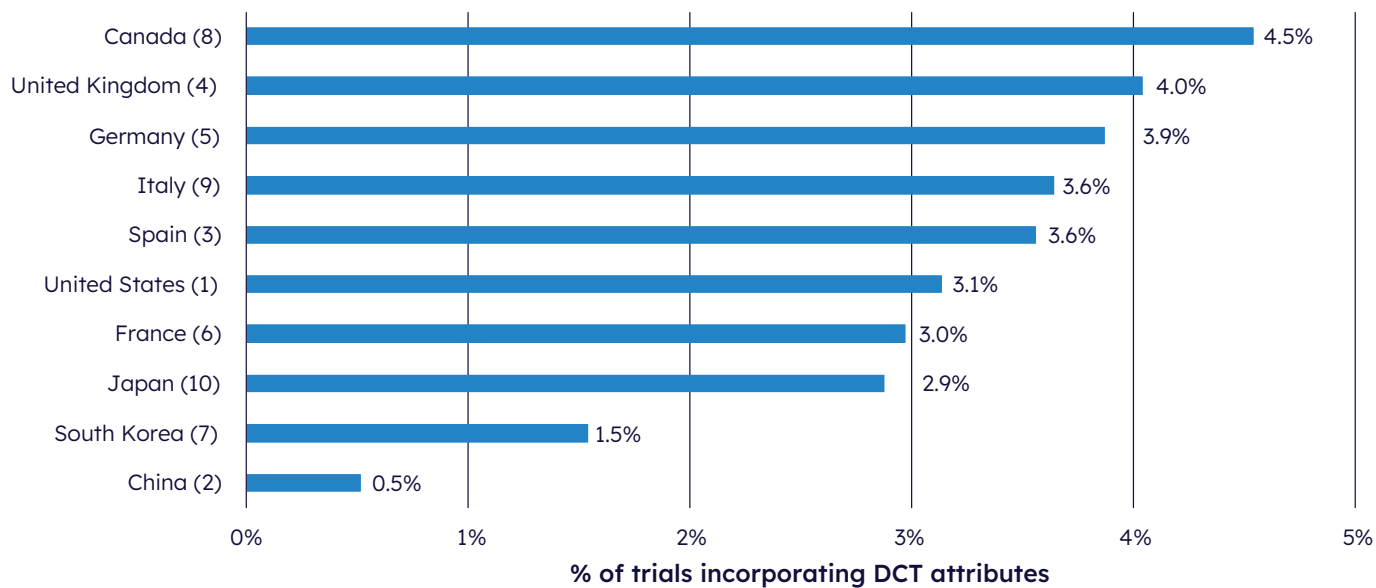
Source: Trialtrove, February 2023

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When looking at the geographical landscape of trials with DCT attributes, it is clear that there are regional differences (Figure 6). Asian countries, including China, South Korea, and even Japan, are lagging behind and have been more resistant to pivot towards novel

trial designs. Panelists at the Clinical Trials Europe conference discussed how regulatory authorities in these markets are less open to new approaches and this creates a lack of harmonization which is a challenge for sponsors planning global clinical trials.

Figure 6: Percentage of ongoing or planned industry-sponsored clinical trials incorporating DCT attributes by country.



Source: Trialtrove, February 2023

Note: For the countries with the highest number of trials. Each country has been assigned a number which reflects its ranking based on the total number of ongoing or planned trials.

Why Incorporate DCT Attributes?

The proponents of decentralization point towards numerous ways in which the adoption of technology improves the clinical trial process. Here we summarize the key benefits to DCT attribute inclusion.

Greater patient flexibility

Traveling to a study site is a major barrier to clinical trial participation. The traditional model in which patients must typically attend multiple on-site appointments is burdensome and can heavily interrupt patients' daily activities.

Wendi Lau, Senior Director of Clinical Development Operations at AbbVie, explained, "We need to make trials fit around lives rather than lives fit around trials" during her plenary presentation at Clinical Trials Europe in November 2022.

The DCT approach is fundamentally patient-centric, using virtual tools like wearable technical devices and telemedicine to conduct remote visits and monitor data, allowing for increased flexibility and convenience of participation.

Improved patient acquisition and retention

DCTs have the potential to decrease the burden that trial participation places on patients, by requiring fewer or no site visits. Many are hopeful that this will contribute not only to higher enrollment, but also to higher patient retention.

In a study conducted by Citeline and Rare Patient Voice regarding patients' attitudes towards clinical research, almost half of all patients who had not participated in a clinical

trial said this was because they were unable to find a nearby trial location.² This was by far the greatest limiting factor, more so than inclusion/exclusion criteria and uncertainty around the clinical trial process. If DCTs can help to solve problems associated with the proximity of available studies, then gains in patient recruitment and retention can be rapidly realized.

More diverse trial sets

The DCT model is especially helpful for patients who do not live near a clinical trial site, have mobility issues, or have cultural preferences that prevent them from taking part in a traditional clinical trial.

A 2022 Tufts CSDD Impact Report found that more than half of pivotal trials supporting EU Commission approval underrepresent non-white racial identities by more than 20%.³ The ability to collect a more diverse data set will increase external validity and ensure minority groups are not underrepresented.

"Unfortunately, for a lot of people, underrepresentation of some groups wasn't brought up much prior to the pandemic even though race has been an issue from almost the



2. Citeline (2021) Patient Perspectives on Clinical Trial Participation. Available from: <https://pharmaintelligence.informa.com/resources/product-content/2021/07/22/16/07/patient-perspectives-on-clinical-trial-participation-report> [Accessed 16 January 2023].

3. Tufts (2022) In Europe, Demographic Under-Representation in Clinical Trials Persists. Available from: <https://csdd.tufts.edu/impact-reports> [Accessed 11 January 2023].

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onset of clinical research,” LaShell Robinson, Head of Diversity and Inclusion in Clinical Trials at Takeda, told In Vivo.⁴

DCT approaches have the ability to enable identification of patients nationally, through leveraging digital recruitment strategies, and engage patients through online ads, social media, and interaction with patient advocacy groups. Sponsors can use these tools to tailor their message to the desired demographic.

Robin Sutherland, Vice President of Human Resources and Clinical Operations at Renovia shared her company’s experience of a virtual clinical trial in gynecology in a presentation at Clinical Trials Europe. Renovia successfully used a targeted zip code approach to increase uptake in minority groups in their remote women’s health study to evaluate the efficacy of an at-home digital device for the treatment of urinary incontinence.

Science done better

The DCT approach gives sponsors the opportunity to think about study designs differently and to improve upon their current approach for data collection. A more flexible design also supports “optionality” of methods for patient participation and in turn improves retention, in addition to faster recruitment.

“We shouldn’t try to replicate the same kind of protocol in this new setting. This new way of doing research allows us to measure things better and have deeper and more continuous insight into the patient’s life and health,” said Kai Langel, Senior Director of Strategy and Innovation, Global Regulatory Policy and Intelligence, Janssen R&D, during a Clinical Trials Europe panel session.

For instance, patients with depression have historically been evaluated using a weekly MADRS or HAM-D score. This rating scale is notoriously subjective to administer and is prone to fluctuations that lower the reliability of any measure at a single time point. But with the introduction of new approaches, sponsors have the potential to better capture the range of symptoms that patients experience with more frequent at-home monitoring.

Smaller trials

Incorporating DCT attributes should enable the collection of better data and enable researchers to see differences between study groups more easily. Ultimately it could reduce the number of patients needed in each study arm via innovative methods such a synthetic placebo arm, or more traditionally as it reduces dropouts and therefore improves the statistical power of the study design.

Lisa Moneymaker, Senior Vice President of Clinical Operations Technologies at Medidata, told Medtech Insight, “With the data that we have in-house, we can extrapolate an entire arm of a study that is totally synthetic and doesn’t require a patient to enroll against a placebo or standard of care. This will have the greatest impact on patients suffering from serious conditions. Often times it’s not about curing patients, it’s about extending their quality of life”.⁵

4. In Vivo (2022) Available from: <https://invivo.pharmaintelligence.informa.com/IV146746/Racial-And-Ethnic-Diversity-In-Clinical-Trials-A-Social-And-Scientific-Imperative> [Accessed 11 January 2023].

5. Medtech Insight (2022). Available from: <https://medtech.pharmaintelligence.informa.com/MT145819/Decentralized-Trials-Are-Here-To-Stay-What-Challenges-Do-They-Face> [Accessed 11 January 2023].

Challenges for Decentralization

Despite seeing an increase in trials incorporating DCT attributes in certain pockets of the industry, sponsors don't always take the opportunity to incorporate decentralized elements into clinical trial design. There are still barriers that need to be broken down in order to fully embrace the opportunity that DCTs offer, which we investigate further here.

Oversight

Healthcare is typically managed via a series of a face-to-face interactions with healthcare professionals, and the paradigm for clinical trials is based upon this experience. Stakeholders across the industry are concerned by the lack of perceived oversight with DCTs and there is a lack of trust in results that come out of what seems to be a less controlled environment. However, it is important to emphasize that while oversight may look different, it is not completely lost, and that when face-to-face contact is required it should be maintained. That being said, it should still be possible to look for opportunities to increase flexibility to benefit patients, whether that be through telemedicine/voice calls, visits outside of a clinic setting, or use of local healthcare services.

Regulators

In order to support the push towards harmonization, EU regulators have recently published their much-awaited perspectives on the use of decentralized elements in clinical trials undertaken in the EU/European Economic Area.⁶ The recommendation paper, published on 14 December 2022, is a joint initiative of the European Medicines Agency, the European Commission, and the EU Heads of Medicines Agencies.

The paper will help trial sponsors and other stakeholders navigate the EU's complex landscape relating to DCTs. Crucially, it includes an appendix on whether certain decentralized elements – such as electronic informed consent, delivery of the investigational medicinal product, conducting trial-related procedures at home, and trial monitoring – are permitted in different EU member states.

The FDA issued draft guidance in December 2021 on digital health technologies for remote data acquisition in clinical investigations, but further guidance on decentralized trials is needed.⁷ Even with this guidance in place, regulatory success will still be dependent on planning early, keeping track of evolving local requirements and initiating discussions with regulatory authorities to seek feedback.

The regulatory review process is often presented as a bottleneck, but Lada Leyens, Senior Regulatory Program Director at Roche, thinks regulators are increasingly open to new and well-thought-through trial designs. She believes presenting a considered approach is key to convincing regulators that sponsors are able



6. European Commission (2022) Recommendation paper on decentralized elements in clinical trials. Available from: https://health.ec.europa.eu/latest-updates/recommendation-paper-decentralised-elements-clinical-trials-2022-12-14_en [Accessed 11 January 2023].

7. FDA (2021) Digital Health Technologies for Remote Data Acquisition in Clinical Investigations. Available from: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/digital-health-technologies-remote-data-acquisition-clinical-investigations> [Accessed 11 January 2023].

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to manage data integrity and risks associated with patient safety no matter how a trial is conducted.

“Let me burst a myth. I always hear regulators are the bottleneck, regulators are not open. Actually they are very open to well-designed and well-thought-through designs that are fit for answering the scientific question and that fit within the framework of Good Clinical Practice,” said Leyens during a Clinical Trials Europe panel discussion.

Cost

The implementation of decentralized attributes – going above and beyond traditional study design approaches to reduce patient burden – is likely to add to overall study costs in the first instance. However, it is important to look beyond this to future opportunities. Ultimately, trials should recruit faster with access to a wider population, and this will get the medicine to patients quicker, assuming the clinical program is a success. The cost/benefit of DCTs is dependent upon clinical efficiency and improving R&D productivity.

“Over time as these opportunities become more and more embedded as a way of working, it’s likely sponsors will lose patients because they will be competing against trials that are offering more flexibility to patients,” said Wendi Lau during her plenary presentation at Clinical Trials Europe.

Compliance

There has been concern that there may be a lack of compliance when you remove the oversight of having to go to the physician. However, compliance is a challenge regardless of how a trial is implemented, and compliance should not be harder to manage with decentralized approaches. Use of connected devices that collect data automatically, rather than having to rely on the completion of paper or electronic diaries, has the potential to increase compliance, and notifications or reminders can be used to encourage compliant practices.

Asking patients to remember their symptoms over a two-week period is much less accurate than collecting data at home in a continuous manner. Patients may also be subject to white coat syndrome for blood pressure measurements, and this could bias the data and ultimately result in it being less consistent and accurate than what could be collected at home.

Re-imagining the trial design paradigm also presents the opportunity to reduce trial complexity which hinders compliance. Many elements of study design are nice-to-have, but not essential. This is an opportunity for sponsors to strip back this complexity and instead focus on patient-centricity.

Patients

Not all patients want to have healthcare administered outside of a clinic or a traditional healthcare setting, and so it is important to design trials that are as flexible as possible within the realms of what is trying to be achieved. One size doesn’t fit all, and decentralization may present a barrier for the participation of certain patient demographics. For example, protocols for clinical trials that enroll elderly patients must be mindful of potential technological requirements for study participants such as smartphones. Similarly, a fully remote trial experience may be less engaging for patients with conditions that benefit from human interaction with healthcare providers.

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The site perspective

A survey of 340 site professionals conducted by the Society for Clinical Research Sites (SCRS) in 2020 reported that respondents' primary concerns regarding DCTs included patient safety and study quality.⁸

More recently, a survey undertaken by the US-based Association of Clinical Research Professionals (ACRP) published in November 2022 showed that research sites and clinical research professionals are facing an increased burden in delivering DCTs.⁹

To support greater uptake, the ACRP said it was important to involve all trial stakeholders in decision-making from the start, rather than having 'solutions' imposed on the sites. The ACRP also recommended sites have more flexibility in managing third-party vendors and controlling budgets.

It will be important for sponsors to not alienate study sites as they will be reluctant to offer DCT options to patients unless they think this approach meets safety and quality requirements and will reduce their burdens.

Technology

DCTs are closely aligned to digital use of apps, eConsent, eDiaries, ePROs, sensors, etc. This technology is essential to monitor patients and gather patients without limits on geography. There has been a movement towards collecting data digitally, but further progress still needs to be made.

Currently, a big challenge for sites, particularly those running large numbers of studies, is the volume of devices and new technology that they

are expected to become familiar with. There is no consistency in the approach taken by different sponsors, and the management of the technology used in DCTs has become logistically complex. Challenges often arise in relation to storage and training.

Some sites already have services available for use as part of their organization such as telemedicine, electronic informed consent, home healthcare services, and travel arrangements, and it will be important to make use of these and to avoid the use of multiple devices for participants and sites where possible.

Data security

Data breaches regularly make the headlines across all industries, leading to valid concerns around data security and privacy. A key question all organizations face is how to best protect people's data and how to manage multi-party privacy consent.

"We don't just have to provide information on data security and privacy to the regulatory authorities but to the patients themselves. Where is your data going to and from at any given point? Who could have access to it? How are we safeguarding that? How do we qualify vendors if they are holding it? Who is a controller? Who is a user? It becomes very, very complicated," commented Rebecca Jackson, Senior Manager of Novel Trial Modalities and Innovation at Janssen, during a panel session at Clinical Trials Europe.

Critically, it will be important to treat patients as partners and to communicate the role of data collection in developing new and effective treatments.

8. SCRS (2022) Impact Assessment of Decentralized Clinical Trials (DCT). Available from: <https://myscrs.org/press/press-releases/scrs-and-virtual-release-white-paper-on-the-impact-of-decentralized-trials/> [Accessed 8 February 2023].

9. ACRP (2022) Delivering on the Promise of Decentralized Trials: Unexpected Perspectives from Clinical Research Professionals. Available from: <https://acrpnnet.org/delivering-on-the-promise-of-decentralized-trials-unexpected-perspectives-from-clinical-research-professionals/> [Accessed 11 January 2023].

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24/7 data collection

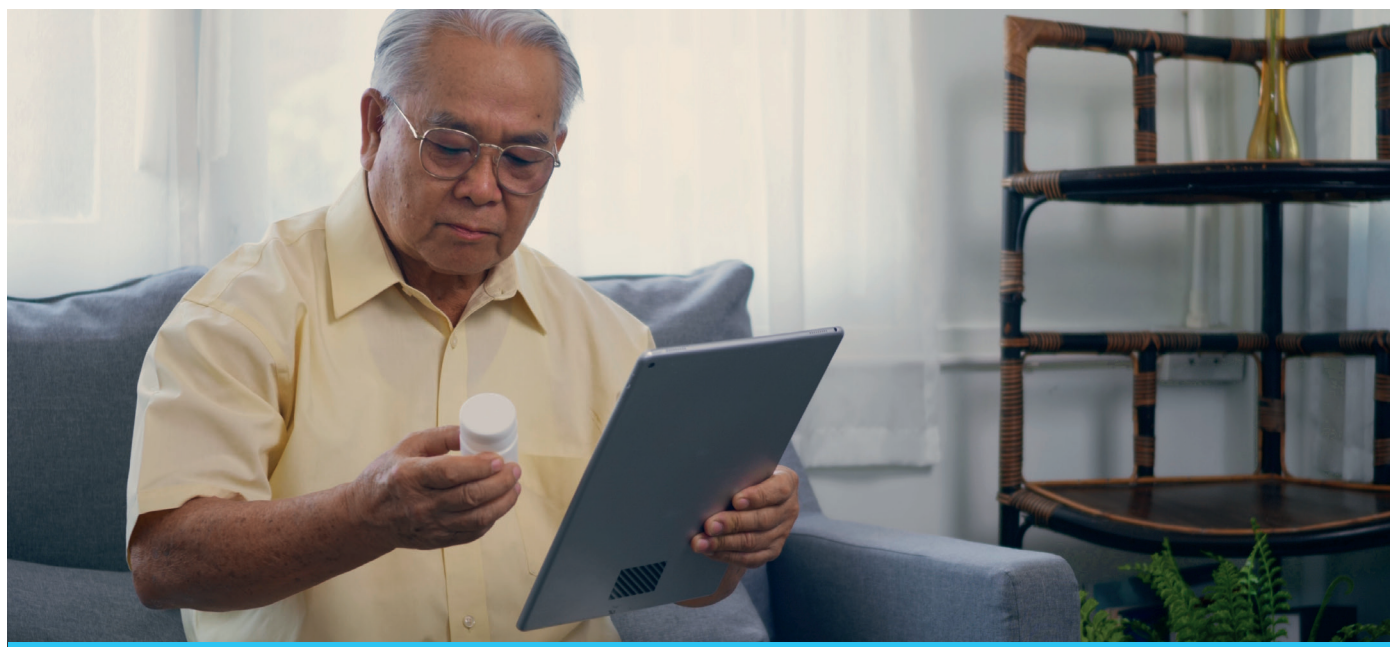
With the incorporation of DCT attributes there is the potential, in some instances, for data to be collected in real-time, but does this mean that it also needs to be monitored in real-time, and will there be an expectation among patients that their data is monitored for signs of an emergency? There has been concern among

study investigators who rightly “clock off” at the end of their shifts that they will be expected to shoulder this burden. Clearly this is not feasible, and realistic expectations around the frequency with which data can be reviewed will need to be set. But there may be opportunities to use tools such as machine learning to monitor and flag concerning data.

Key Takeaways

Incorporating DCT attributes offers a patient-centric approach, addressing various patient needs that often go unmet in traditional designs. These trial designs also have the potential to benefit sponsors by accelerating clinical development, enabling more representative patient access, and developing a stronger evidence package than traditional trials.

However, right now, the adoption of DCT elements is very low. Citeline’s proprietary data suggests it was only 3.4% for trials that started in 2022 and were reported to date in the public domain, and uptake among industrial sponsors is particularly low. Clearly, there is a long way to go, and continued communication and demonstration of the benefits of DCTs, and flexibility in overcoming the hurdles to their implementation, is required. Hype from CROs will only take us so far, now it will be necessary to prove the benefits instead of just talking about them.



Meet the Authors

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Anna is a Managing Consultant in the Citeline/Evaluate Consulting and Analytics team, a team which specializes in pharmaceutical and healthcare consultancy. Within her role Anna answers key asset, portfolio, and corporate strategy-related business questions.

Prior to joining the Consulting and Analytics team, Anna was an analyst at Citeline's Pharmaprojects. Here, she expertly curated the drug development database, provided research support to clients, and produced custom analytics projects, transforming clinical study data and drug data into actionable insights.



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Susan has been with Citeline since 2004, where she has assumed various roles including early development of Trialtrove's oncology content, managing Citeline's custom analytics/consulting services, and driving key product enhancements. She currently serves as Trialtrove Director for the CNS, Autoimmune/Inflammation and Ophthalmology therapeutic areas.



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