White Paper

Patient-Centricity by Design

Improving patient engagement and retention while reducing burden with scalable, adaptable decentralized trials

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Introduction

The COVID-19 pandemic has redefined the relationship between patients, technology and clinical research. When healthcare centers shut down, sponsors relied on decentralized clinical trial (DCT) models to keep patients and staff safe, while continuing to move research forward. In making this transition they discovered additional benefits of DCTs that take patient preferences and needs into consideration and include connected devices to drive greater efficiency and engagement.

This virtual approach to clinical research made it possible to rapidly ramp up trials for COVID-19 vaccines and treatments, and to engage thousands of remote patients through a combination of technology and human support. That speed was key to getting these lifesaving interventions to market.

These trials helped the industry get more comfortable with the idea of using DCT approaches – including remote patient engagement, connected devices and specialized DCT study team roles – for future clinical trials. They also underscored the need for more intentional patient-centricity to keep patients engaged in the trial experience.

A human touch in a remote trial

Early research shows patients like the idea of DCTs as a clinical research option because they eliminate much of the burden of trial participation. For example, 67% of patients who prefer remote or virtual options chose them because they were convenient and safe, according to a April 2021 global patient research survey led by IQVIA.

Data also show that patients are eager to be a part of clinical research. A 2019 CISCRP survey found 79% of people who have never participated in a trial are open to the opportunity.[1] Though they have expectations about what that experience should involve. The majority (81%) want to know all the risks and benefits before agreeing to participate, 83% expect access to their data, and 52% want appointment reminders, digital calendars and other interactions to help them manage the experience.[2]

IQVIA worked on five COVID-19 vaccine trials that were able to recruit more than 115,000 patients in 14 countries in less than six months using DCT models.

The pandemic reinforced DCT acceptability among trial participants. Consumers became more accustomed to digital interactions with healthcare professionals during the lockdowns, and they expect these tools to be part of their future healthcare interactions.

That's good news for sponsors interested in using DCTs for clinical research. However, they need to be thoughtful about the balance of technology and human interactions. Even in a fully remote trial, many patients will still need occasional support from a real person to help them navigate the technology and treatment experience, answer questions, or provide assurances. Sponsors that want to leverage the benefits of DCTs must consider how they will personalize the DCT experience if they they're going to keep future patients engaged.

Three elements of patient-centricity

IQVIA worked closely with sponsors through the pandemic to identify and address patient-centricity needs in their studies and find innovative ways to make those engagements easier and more fulfilling. We used those insights to build a three-pronged strategy that informs every DCT trial design.

1. **Incorporate the patient voice into the research, trial designs and outreach.** We use patient and advocate feedback throughout every trial to inform planning and to vet every decision. Including that patient perspective ensures we reduce barriers that otherwise limit participation and introduce tools and support that provide patients with the best possible experience.

2. **Elevate the focus on patient engagement.** We make elements of patient-centricity a measure of trial success, which causes design teams, recruiters and site staff to prioritize these goals. Tracking patient-centricity as a measure of success was particularly helpful in achieving diverse representation in COVID-19 trials.

3. **Leverage flexible DCT approaches.** DCTs are not a one-size-fits-all solution. They have to be built around the need of the patient population, taking into account their mobility, technology capability, fears, access to treatment centers, and medical conditions. We build our trials around these factors, leveraging technology and innovative designs to meet every patient population's needs.

Amplifying the patient voice

Using patient data in trial design is the key to creating a patient-centric DCT experience. But becoming patient-centric requires more than hosting a patient focus group or conducting a survey – though that can be part of it. It's about collecting data from many sources to understand the broad experiences within a patient population managing a similar disease or treatment, then using those insights to build a trial approach that best supports patients, their caregivers, families and event communities.

Data can come from various real-world sources, including electronic medical records, prescription data, social media feeds, advocate interviews and community interactions.

By analyzing this data, sponsors can learn the best way to engage the entire patient community – including undiagnosed patients, and what technologies, services and support they will need to ensure a positive DCT experience.

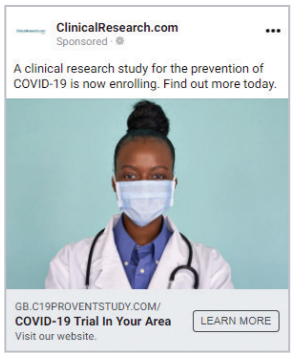
Once they have a trial plan in place, sponsors can use the data to determine where to recruit the right patients, what channels are likely to engage the target patient community, and what messaging is most likely to resonate.

Does your message resonate?

With the right data, analytics technologies and AI algorithms, sponsors can generate precise insights from patient data that can dramatically impact on recruiting results.

IQVIA's patient outreach and marketing teams use analytics technology to market test every ad, so they can identify the messages, images and calls to action that generate the most desired outcomes. Through this process, we often find that even small changes can generate measurable improvements.

For example, the ad below was tested using multiple messages.



The first option focused on the COVID-19 trial occurring in the patient's area, with a website to visit. The second version (left) shared that "a clinical research study for the prevention of COVID-19," occurring in their area, with the website. The response rate to the second message increased 56% over the first.

This kind of profound difference happens all the time when we compare messaging. It demonstrates why measuring the messaging performance while ads are in-flight is critical to driving the effectiveness of any campaign's outreach.

IS A DCT THE RIGHT CHOICE FOR YOUR TRIAL?

The pandemic proved that DCTs work for many studies, but it's not right for every trial. When deciding whether DCT is a suitable approach – and whether you want to be fully decentralized or to use a hybrid model – ask yourself these five questions:

1. **Is the indication within a well-defined patient pathway?** That pathway can include conditions that affect adults with high clinical stability or patients that can't quickly get to a trial site.
2. **Does the investigational product have a well-known safety profile?** It's rare to conduct Phase I studies using a DCT model. Sponsors should also be clear on any potential adverse events and determine how they will identify and address them in a DCT environment.
3. **Can endpoints be assessed via telemedicine or electronically without overburdening patients?** Requiring daily reports or cumbersome devices can affect retention.
4. **Can in-person tests, scans and treatments be conducted via home visits or by their local physician?** This can reduce patient burden while addressing the need for in-person care.
5. **Does the regulatory environment support DCT elements in the chosen countries?** Acceptance of DCTs is evolving across the globe, so it's essential to know it will meet regulations when designing the trial. IQVIA's DCT team tracks these trends closely and partners with our country heads and customers to ensure every DCT meets all local requirements.

Everyday engagement

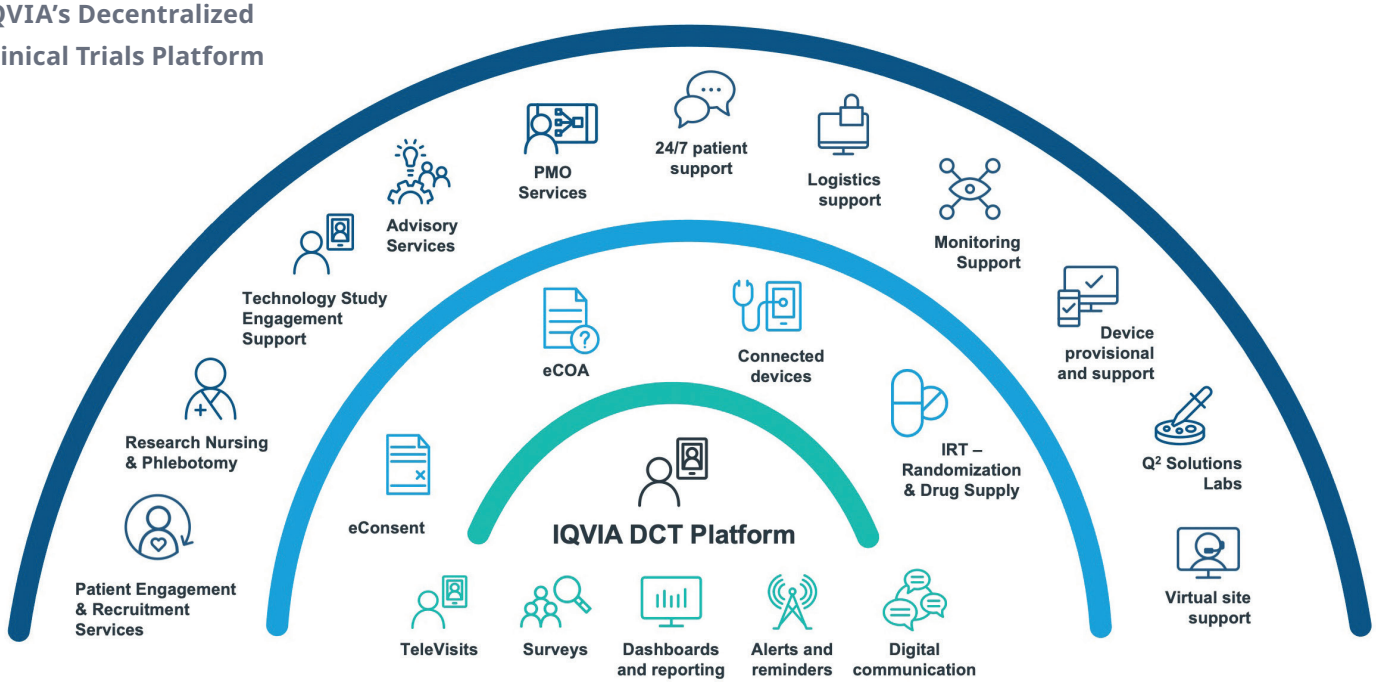
While DCTs eliminate many of the burdens that commonly cause attrition, including excessive and travel and time commitments, it's essential for patients to feel emotionally connected to the trial. That connectivity can be achieved through a constellation of small choices that together create an engaging and supportive DCT experience:

- **Use technologies familiar to the patient that can be easily integrated into their daily routine.** Allowing patients to use their own devices is a popular way to remove adoption barriers while cutting trial costs. If a trial requires additional technology, such as heart rate or actigraphy monitors, choose portable options with automated data streaming, and ship them directly to patients' homes to avoid delays.
- **Provide a central online portal for a streamlined digital experience.** Ideally, all-digital patient interactions will occur through a single platform, where patients can access all of their e-consent forms, e-diaries, telehealth links, chat features, appointment calendars, alerts and personal data. It should be easy for them to get information and interact with the clinical team.

IQVIA's Decentralized Clinical Trials Platform offers all these features in a single easy to use environment. It also provides sponsors and investigators access to a central data repository, data dashboards and analytics tools for instant access to real-time results.

- **Use language patients understand.** Be clear, concise and practical in how you communicate with patients about the trial and how you provide directions. Avoid overly complex or scientific explanations, and communicate in their preferred language whenever possible.
- **Give patients easy access to human support.** While some patients will easily navigate DCT technology, others will need real-life assistance in setting appointments, troubleshooting technology, and otherwise navigating the experience. Having an actual human being to talk to is particularly important during early interactions when patients are unfamiliar with the trial process. Providing that added assistant through a helpline and/or virtual concierge will make them feel supported and valued, and help prevent early attrition.

IQVIA's Decentralized Clinical Trials Platform



- **Bring the trial to them.** Most DCTs require some face-to-face human interactions. While that may include site visits, it can also involve drug delivery services and home health nurses and phlebotomists who visit patients' homes to oversee tests, blood draws and treatments. These direct-to-the-patient services reduce the burden of participation, can lower infection risks, and show patients they are a valued part of the process.

Be strategic

DCTs work for many study types, but every trial will require a unique design to deliver the greatest benefits to patients, investigators, and sponsors. We encourage sponsors to make these choices at the outset of trial planning and to work with partners who have experience running DCTs and adapt every trial to their patients' needs. This ensures that sponsors will get the most significant traction with their target population and that patients have an engaging experience. In the best scenarios, these patients may even become advocates for clinical research, sharing their positive experiences within their communities, which can help change the way patients view these opportunities in the future.

ACCELERATE DATA COLLECTION WITH CONNECTIONS THAT COUNT

A connected devices platform built specifically for clinical trials removes limits to traditional clinical research by fostering new possibilities for integrated novel endpoints, digital biomarkers and evidence generation.

A technology-enabled trial designed around accelerated data collection delivers more meaningful results in less time while delivering a better experience for sites, sponsors and patients.

References

1. The Center for Information and Study on Clinical Research Participation (CISCRP). Perceptions and Insights Study: Deciding to Participate. 2019. https://www.ciscrp.org/wp-content/uploads/2019/12/Deciding-to-Participate-04DEC-1.pdf

2. Dietrich J, Alivojvodic J, Seliverstov I, Metcalf M, Jakee K. Improving Information Exchange with Clinical Trials Participants: A Proposal for Industry. Therapeutic Innovation & Regulatory Science 2017, Vol. 51(5) 542-550.

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