Science 37

INSIGHT BRIEF

Long-Term Follow-Up Studies Get Agile.

How decentralized clinical study approaches can optimize delivery of LTFUs

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The pandemic proved that decentralized clinical studies (DCSs) not only lower the burden of participation for patients, they can also help sponsors accelerate recruiting, increase diversity, improve safety, and accelerate the capture of clinical data.

These technology-enabled research models became essential tools for the rapid development of COVID-19 vaccines. By allowing patients to participate in studies using telehealth, electronic data collection, and other virtual research tools, sponsors were able to recruit tens of thousands of patients in a matter of weeks, and maintain their safety while speeding access to early study results.

With or without the pandemic, DCS approaches are here to stay. Science 37's recent survey of sponsors and CROs suggests the industry has reached a pivotal point in the way clinical studies are carried out. More respondents (77%) are planning to conduct an agile clinical study (a hybrid model featuring a mix of traditional and DCS approaches) in the next 12 months than are planning to execute a traditional, site-based study (69%), the study reveals. This is a major swing from the previous 12 months, when 92% of the same sample ran a traditional study and only 59% ran an agile study.

The success of these agile clinical studies has given sponsors impetus to determine where else decentralized research models can be used to reduce patient burden and accelerate data collection. One area where it has huge potential — and with a relatively low barrier to entry — is real-world, observational studies such as long-term follow-up studies (LTFUs).

Low-hanging fruit

LTFUs can be the bane of a sponsor's research portfolio. Usually mandated by regulatory bodies, these observational studies — which can last for a decade or more — require sponsors to monitor patients in the real world to validate the long-term safety and effectiveness of a treatment, per regulatory requirements. At annual or biannual visits, patients answer a litany of questions, fill out a survey, and report on their general health as it relates to the study's endpoints.

It is tedious work for sites, which generally prefer to work on more leading-edge studies that generate higher rates of revenue. And because the studies tend to go on for several years, attrition is a constant problem.

Because the patients in these studies aren't seeking treatment benefits from an experimental drug, their dedication to long-term participation can be quite fragile. And even if these appointments only occur once or twice a year, they can require four or more hours to travel to and from a site to complete an appointment.

As the study participants age and likely change their work or living circumstances, attending these appointments becomes

less of a priority. And should they, say, move to another city, sponsors would need to cover their travel costs to attend appointments, which could turn a simple site visit into a multiday event, adding cost and burden for everyone involved.

As a result, research suggests LTFUs see average drop-out rates as high as 30% to 70% before they are completed. This high rate of attrition can cause gaps in the data and biased results, which could negatively impact outcomes.

WHY CHOOSE DCSs FOR LTFUs?

Agile clinical study approaches can address all of these challenges. When sponsors adopt a DCS or agile model for a LTFU, the burden for sites, sponsors and patients dissipates almost immediately, and retention rates become easier to maintain.

Benefits for patients: Using a DCS, much or all of the data collection required for the LTFU can be completed virtually, via online questionnaires, e-consent forms, electronic patient-reported outcomes (ePROs), and telehealth visits, if necessary. An agile clinical study model transforms the LTFU experience from a multi-hour on-site visit, to an occasional 10-minute survey that can be completed from anywhere that has an internet connection. It weaves the study into patients' lives, making participation a minor distraction rather than a half-day event.

And, if a blood draw or other clinical test is required, these can be performed by a visiting nurse or phlebotomist at the participant's home, eliminating the need for site visits altogether.

This ease of use can have a powerful impact on retention for these studies. Data from Science 37 across all studies show that DCS approaches deliver, on average, 15x faster enrollment, 28% greater retention, and a three times more diverse patient population.

Benefits for sponsors: DCS components in an agile model can significantly reduce the administrative burden of managing sites and running LTFUs. In traditional studies, a sponsor often needs to partner with multiple sites across regions, each of which may only manage a handful of patients. Many sites are wary of signing up for LTFUs, which can make it difficult for sponsors to secure enough partners. And when they do, sites may deploy different technologies, transcription timelines, and other approaches that make oversight more complicated.

Using a DCS model, sponsors can funnel all of the patients through a single vendor. This makes it easier to launch and manage a study, oversee the data, and build a strong relationship with the vendor and the study participants.

Companies like Science 37 amplify that value proposition, providing patients with a dedicated portal where they can access study information and paperwork, set alerts, and complete appointment documents. Sponsors can then access all of those results as they are posted, which creates a consistent near-real-time flow of data.

And should the sponsor have any concerns about the study or the data, they have a single point of contact for a quick resolution.

Benefits for sites: Because much, if not all, of the data are collected remotely, decentralized studies require less time on the part of site staff. Patients can submit the required data with little or no interaction with investigators, and because the data is digital, it is instantly captured in the study database with no additional transcription or medical coding required. This allows sites and clinicians to continue with the patient's standard of care while easing the burden to collect additional research focused data endpoints.

If the study can be conducted entirely online, which is common with LTFUs, a single vendor can oversee all of the study elements and stay engaged with patients, regardless of their locations or life-changing events.

The combination of fewer sites and decentralized data collection adds to a more streamlined and efficient study design, which can reduce long-term costs, and improve the experience for everyone involved.

Science 37 continually collects patient feedback from all its agile clinical studies, and among the hundreds of recent comments, one patient noted, "The study was so easy to participate in and the people who I interacted with were very helpful, respectful and knowledgeable" (Jan. 7, 2022). Another was enamored by the quality of the in-home treatment: "Everyone was so very nice! Loved the RN that came to draw the blood!" (Jan. 25, 2022). Meanwhile, a third participant focused on the greater good of the research, remarking that the agile study was "super easy" and that "I hope that it provides the information needed to offer less invasive screening options for people to assess for colon cancer" (Jan. 18, 2022).

Best practices for decentralized LTFUs

LTFUs are an ideal environment for sponsors to verify the reliability, viability, and ease of use of DCSs in a relatively low-risk environment. The data-collection process is minimal, most LTFUs require few or no physical interventions, and the low burden to patients makes them far more attractive than traditional, site-based approaches. But to get the most value from these study models, sponsors need to plan ahead.

1. Pick a vendor.

A successful agile clinical study requires a blend of clinical and technical expertise. Sponsors need to be confident that the DCS partner they choose has the experience to recruit patients, manage their interactions, and safely and reliably collect all of the necessary data in line with regulatory requirements. While many vendors have run LTFUs, few have experience hosting these studies using a DCS model.

2. Start recruiting.

One of the keys to success for any LFTU is getting patients signed on as early as possible. As soon as sponsors know they will need to run an LTFU, they need to think about who will participate in the study and how they will be recruited.

Sponsors often wait to recruit for LTFUs until the end of a phase 3 study, or post-approval. But that can cause them to lose out on the engagement patients have with the research, which makes recruiting more time-consuming and difficult to complete.

"The study was so easy to participate in and the people who I interacted with were very helpful, respectful and knowledgeable."

Patient feedback from Jan. 7, 2022

The ideal time to recruit for an LFTU is when patients are just beginning phase 3 study participation. At this point, they are excited about the research, and the impact it could have on their own life and the lives of other patients with the same conditions; they are committed to the clinical research journey and are optimistic about study participation.

In this first appointment, which may occur on-site or virtually, sponsors are encouraged to talk to patients about the LTFU opportunity, and why participation is so important. They walk them through what's involved, including the cadence of data collection, the time commitment, and the goals of the study. If patients show an interest, they can sign up for the study at that time, complete virtual informed consent paperwork, and receive log-in information for the LTFU platform where the study will be conducted.

This whole exchange, which can be completed in 30 minutes or less, maximizes participation in the LTFU, and proactively sets the stage for a warm hand-off to the next phase of research.

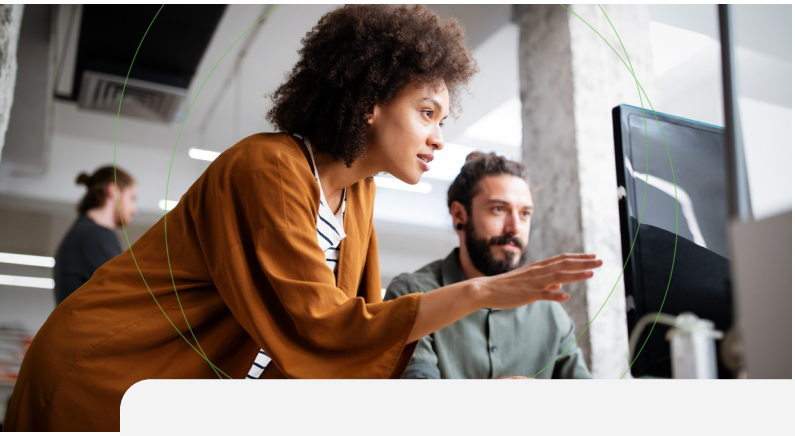
3. Promote the benefits of DCSs

When recruiting patients for an agile LTFU, sponsors need to talk up the ease of use and other benefits of decentralized approaches. Highlighting the minimal time commitment (often as little as 10 minutes, twice a year), the patient-centric technology that can be accessed from any device, and the willingness of the sponsor to send healthcare providers to patients' homes, even if they move abroad, ensures participants have an accurate perception of what the study entails. Promoting the low burden of participation, in combination with the value they can provide to the larger patient community, can make the decision to sign up for an LTFU pretty easy.

The future of research

While DCSs — and especially agile studies — are becoming a permanent part of the clinical study environment, some sponsors are still wary of running clinical research using virtual tools.

LTFUs offer a low-risk environment to test the waters of decentralized approaches, while addressing the challenges of time, cost and retention that these studies historically face. They can be launched quickly, and provide a space for sponsors to test the technology and demonstrate success. These early projects can lay the groundwork for future of agile clinical studies, giving stakeholders the confidence they need to embrace these new research models.



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Gordon leads the Real-World Evidence (RWE) division at Science 37. He has worked in the real-world evidence space for over 25 years in research, product development, study design, strategic development, and global operations. Gordon has direct experience with health plans/IDNs, pharmacy/PBMs, provider networks, associations, and academic institutions.

Gordon was the past ISPOR co-chair for classifications of retrospective databases, past member for scientific journals, and has numerous publications/posters/presentations in real-world evidence across multiple indications. His undergraduate degree (Mathematics/Actuarial Science) and Master's degree (Statistics) are from Southwest Missouri State University.

Why Science 37

The increasing adoption of technology, mobile devices, wearables, and other biosensors – combined with recent advances in digital and advanced analytics – is making real-world evidence (RWE) more readily available to enable better design and conduct of clinical trials in healthcare settings. The Science 37 Operating System™ connects the patient with the physician investigator and Science 37 study team to collect RWE, making us ideally suited to tackle the industry's biggest issue – the inability of patients to participate.

Science 37 focuses on ensuring our tailored model is aligned with the customer's objectives and primary endpoints to meet or exceed expectations, no matter what the specific design. Our direct engagement with patients opens up a host of pathways for real-world data that can drive your RWE plan and implementation much earlier.

To learn more about how Science 37 empowers real-world evidence, visit www.science37.com.

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