SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

The Signal

Trial Optimization as the Focus for Decentralized Methods

Decentralized trials (DCT) tend to be associated with reduced site visits, but a more useful perspective is optimization – optimizing the way clinical trials are run, and how clinical evidence is collected. This needs to be accomplished with speed, accuracy, and a focus on ensuring an empathetic patient experience.

Decentralizing aspects of a clinical trial through enabling certain procedures and assessments to be conducted away from a site is one important tactic of trial optimization, with an emphasis on collecting the right data at the right time, using the right solutions in the right setting. Thoughtful, optimized trial design should consider the number of activities conducted at required site visits and how the visit experience can be simplified for both patients and sites by migrating certain elements to be conducted remotely. This will sometimes, but not always, lead to fewer site visits – however, it will always lead to a simpler experience for all participants.

Benefits of Decentralized Methods and Signant's 6 S's

Signant understands that all trials, including DCTs, rely on accurate and reliable safety and efficacy data regardless of how or where they are conducted. By leveraging decentralized methods, sponsors and study teams can:

- **Optimize how clinical evidence is collected –** This requires the thoughtful application of comprehensive technology solutions along with clinical science expertise and support, independent of the setting where the trial is being conducted.
- **Deliver a more empathetic patient experience –** A patient-focused approach should be embedded in everything from your protocol design to how your eCOA tools are designed. Signant leverages our technology to enable more remotely administered assessments and procedures, reduce the need to visit sites for medication provision, and maintain patient engagement with the site, all to reduce burdens while maintaining the site-patient relationship.
- **Ensure speed and accuracy –** Our full-featured eCOA solution includes design features that will help you build studies up to 40%-60% faster without sacrificing data quality. Its intuitive interface makes it easy to collaborate on and review designs in process, reducing time spent at user acceptance testing so that your trial can launch efficiently. Plus, the platform's built-in patient reminders will help ensure accurate assessment completion on time.

- **Enable operation at scale –** In order to run a successful DCT, sponsors need a clinical solutions partner like Signant that has extensive global reach with available project teams in all time zones, complete with the global architecture and infrastructure to facilitate trials anywhere around the world.

Did you know that the concept of DCT is actually not new, despite recent growing trends fueled by the COVID-19 pandemic? For over 20 years, Signant Health has been implementing leading technologies to facilitate remote trial conduct. We accomplish this by leveraging full-featured solutions along with 6 S's for DCT success:

1. **Solution –** End-to-end software solutions such as eCOA, eConsent, and RTSM that optimize evidence generation, trial operation, and the patient experience from enrollment through trial closeout, leaving no surprise capability gaps.

2. **Scale –** As mentioned previously, Signant has the infrastructure and support teams in place to support any global trial and help you reach patients wherever they are located.

3. **Science –** Our team of over 50 in-house clinicians oversee all aspects of trial design and conduct to ensure we deliver successfully on decentralization while maintaining outcome measure reliability and accuracy. They can help your study team enable different measurement settings and approaches, as well as ensure ongoing data quality monitoring.

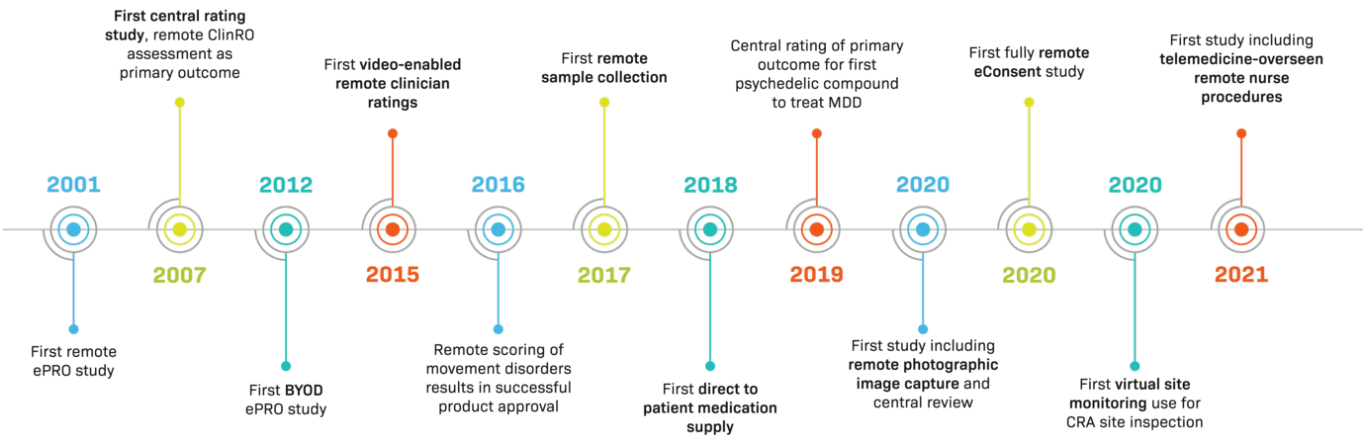
4. **Supplies –** Our DCT suite includes our integrated, comprehensive randomization and trial supply management (RTSM) solution to enable remote supply chain management, including direct-to-patient medication provision with full, last-mile traceability.

5. **Service –** Signant is prepared to implement our DCT solutions through a single experienced global project delivery team supported by vital accompanying services, including in-house provisioning and logistics, COA scale and license management, and a 24/7 local language, patient-facing help desk.

6. **Source data aggregation –** Our data aggregation and intelligence platform addresses the challenge of increasing numbers of data sources by facilitating rapid data consolidation from all sources, which helps enable a 360-degree data review for actionable insights, RBQM, and proper data management.

Signant's Direct DCT experience

Our rich heritage of DCT experience includes many success stories from our 20+ years of enabling remote ratings for complex ClinROs by phone and video, providing central rating services, conducting remote electronic informed consent, and managing direct-to-patient medication provision, amongst others. View these on the timeline shown below and access more details about any of the key items, including case studies that highlight our eClinRO and eConsent solutions, at the link here.



The Cornerstone of DCT success

When sponsors discuss DCT, they are often referencing eCOA, which is then combined with other enabling components to simplify participation such as eConsent, patient engagement, telemedicine, and direct-to-patient medication supply. Simply put, eCOA is the cornerstone – it represents the patient-facing solution that collects clinical evidence to derive crucial endpoints, so a robust and reliable solution is essential for trial success.

That's why Signant's eCOA is built on 4 pillars of success that go beyond just reliable technology. To learn more about those 4 S's, view our resources here and contact us to connect with our renown eCOA science experts.

Conclusion

As trials continue to increasingly leverage decentralized methods, our industry should approach decentralization as just one way we can optimize future trials. While it is important to reduce site visits, we must also think about how to optimize every aspect of remote conduct to ensure trials collect clinical evidence of the highest quality while continuing to simplify the patient and site experience. With the right solutions, support, science, and service from partners like Signant, we are confident that the DCT adoption curve will continue to grow.
