Science 37®

INSIGHT BRIEF

Centralize Clinical Trials with **Decentralized Clinical Trials.**

With agile and decentralized approaches, sponsors actually have more centralized command and oversight.

David Coman
Chief Executive Officer, Science 37

One of the most notable early uses of the term "decentralized clinical trials" came from the presiding FDA Commissioner, Dr. Scott Gottlieb, in a January 2019 speech, where he noted that decentralization can "help clinical trials become agile and efficient by reducing the administrative burdens on sponsors and those conducting trials, and can allow patients to receive treatments from community providers without compromising the quality of the trial or the integrity of the data being collected."[1]

Since then, the industry has rallied around the term "decentralized clinical trials" and expanded its definition to include all mobile, remote, home-based or community provider-based solutions for collecting clinical outcomes data. But why use the term *decentralized*, and what does it really refer to? The original intent was to define the inverse for the traditional clinical trial design in which the collection of data is *centralized* within one brick and mortar investigative site location.

While the term made so much sense in the context of traditional research, the irony is that the traditional model is based on a highly *decentralized* network of independent sites to collect outcomes data. Each of these investigative sites have their own processes, people and technology, to matriculate patients through the trials they are conducting on behalf of sponsors. As a result, sponsors can spend, on average, a quarter of the entire clinical trial budget conducting source data verification (SDV)[2] with oversight from clinical research associates (CRAs) to ensure protocol compliance.

If you step back from the status quo, this really doesn't feel very *centralized* at all, does it?

The term *centralization* commonly refers to the concentration of control under a single authority. With this definition, the authority in the development process presumably would be the company sponsoring the trial.

By definition, if a clinical trial sponsor were to *centralize* trial execution, it would seek to maintain control of the processes, people and technology required to execute the trial rather

[1]Gottlieb, Scott. "Breaking Down Barriers Between Clinical Trials and Clinical Care: Incorporating Real World Evidence into Regulatory Decision Making." Bipartisan Policy Center, January 28, 2019, Washington, DC.

[2]BrJ Clin Pharmacol, Impact of source data verification on data quality in clinical trials: an empirical post hoc analysis of three phase 3 randomized clinical trials, October 19, 2014

than leaving their protocols susceptible to the inherent inconsistencies and subsequent costly oversight required when using a myriad of disparate investigative sites.

Without the dependency on the traditional site network and its limited geographic catchment area, the sponsor would have the freedom to maximize the number of patients who could participate. Guided by an effective operating system, the sponsor could ensure that every investigator, nurse, and study coordinator executes by the exact same standard operating procedures and is supported by the exact same technology to ensure compliance with a protocol in an unambiguous manner. The sponsor could also require that all of its data be entered directly into a source system for real-time access to study performance, thus reducing the chances of misinformation and eliminating the need for SDV by CRAs who fly all over the world.

This centralized set of processes, people and technology is being deployed every day now by Science 37 across almost every therapeutic area, geography and trial phase. Unsurprisingly, sponsors that are centralizing these activities are achieving up to 15x faster enrollment, up to 28% greater retention and 3x the diversity in their studies, while ensuring greater compliance, less rater variability and real-time visibility to performance data. Not to mention significantly reducing patient burden.

And yet we call this *centralization* of processes, people and technology, "decentralized clinical trials." Go figure.

The Agile Clinical Trial

An important note in Dr. Gottlieb's original speech was that the deployment of these capabilities now known as *decentralization* leads to more "agility." Today, many study designs being deployed with decentralized clinical trial capabilities are a hybrid between traditional and decentralized.

Many leading sponsors are simply supplementing their traditional site networks with a virtual site, or what Science 37 refers to as a Metasite™, to generate speed of enrollment. Other trials are initiated at a traditional clinical trial site, with all follow-up visits coming from the comfort of the patient's home, to reduce patient burden and increase retention. Still others are initiated remotely, with common procedures being conducted by local community providers.

Ultimately the goal of every study is to accelerate enrollment, ensure efficiency and compliance, and generate the highest quality data. To accomplish these goals most effectively, sponsors need the flexibility to execute more agile clinical trial models. This requires an operating system with standardized processes, centralized networks of patients, investigators, nurses and coordinators, and a unifying technology that can be used on-premise and off-premise, which yields the additional benefit of enabling sponsors to be in control of their destiny.

Today, more sponsors are standardizing on the Science 37 operating system to achieve the flexibility and control required to deliver today's more agile clinical trial models and to yield all the benefits of speed, retention, diversity, lower patient burden, less rater variability and the highest quality data. To learn more visit www.science37.com.

David Coman
Chief Executive Officer

David Coman is the chief executive officer of Science 37, which makes it easier for people to participate in clinical research by connecting patients with doctors and nurses through telemedicine visits and home health screenings, then managing trial logistics from an integrated, comprehensive platform.

David came to Science 37 from ERT, where he led its data and analytics business after serving as the company's chief strategy officer. As the leader of ERT's data and analytics business, David reimagined the way the pharmaceutical industry looks at performance and risk management for clinical trials while more than doubling the company's bookings from analytics over a two-year period. In his strategy role, David spearheaded the acquisition of four companies in a 12-month period, generating more than $1 billion in enterprise value, while repositioning ERT as the market leader in clinical trial data generation.

David joined ERT from Quintiles (now IQVIA), where as chief marketing officer and founder of its Digital Patient business, he helped lead the company's growth from $2.7 billion in 2007 to $4.3 billion in 2015. It was here that David pioneered some of the industry's first decentralized clinical trials while also driving significant growth and enterprise value.

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