Decentralized Clinical Trials Are Far More…**Centralized?**

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It's official: Since former FDA Commissioner Scott Gottlieb included the term decentralized clinical trials in a January 2019 speech about incorporating real-world evidence into regulatory decision making,[1] we're all now referring to trials that use mobile, remote or home-based solutions to collect data directly from patients as Decentralized Clinical Trials (DCTs). It makes sense, right? From the perspective of, it's always been done that way; when we introduce new processes and technology to collect data directly from the patient rather than through *centralized* site locations, we would logically classify this activity as *decentralized*.

Here's the irony though: The traditional clinical trial relies on a highly decentralized network of independent clinical trial sites, each with their own processes, people and technology, to matriculate patients through the trials that they are conducting on behalf of sponsors. As a result, sponsors are left to the mercy of these institutions to ensure they are effective and compliant to their protocol designs. And only the oversight from costly clinical research associates (CRAs) ensures that their protocols are managed appropriately. If you step back from the status quo, this really doesn't feel very *centralized* at all, right?

What if you were able to insert more control versus the traditional quilt-work of disparate clinical trial sites? That is to say, what if you could *centralize* your processes, people and technology to yield better performance? You wouldn't leave your study up for interpretation by independent clinical trial sites to translate your protocol into their systems, would you?

[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.

You'd invite all qualifying patients to participate, regardless of geographical restrictions inherent in traditional clinical trial site recruiting. You'd ensure that every coordinator, nurse, and investigator is armed with the exact same standard operating procedures and technology to ensure that the protocol is unambiguous, and compliance is consistently enforced, without requiring CRAs to fly around the world for oversight. And you'd require that your data is directly entered into the source system to make source data verification redundant and provide greater data accessibility.

Unsurprisingly, by directly targeting patients from anywhere; ensuring consistent processes, people, and technology; and directly capturing data, sponsors 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 a significantly better patient experience.

You'd probably call the application of all these unifying performance and control measures, which are yielding significantly better results, "centralization." Yet, it's these exact ideals that perfectly describe what we all call "Decentralized Clinical Trials" today. Go figure.

Beyond Decentralized Clinical Trials

You'll typically see Science 37 reference the term Agile Clinical Trials™. This term not only encompasses decentralized clinical trial designs, but it also includes the flexibility to add traditional clinical trial sites and non-traditional community providers into the mix as an extension to the DCT design. It's important to note that to properly yield all the positive benefits as noted above, both the traditional and non-traditional providers need to follow the centralized trial design that can only be achieved via the unifying technology, standardized processes and centralized networks available only through Science 37's Agile Clinical Trial Operating System™.