

SCRS Digital Innovation Initiative

Workstream Meeting - January 2021

Both of the Digital Innovation Initiative workstreams are heading into 2021 with a renewed vigor and focus on the importance of both decentralized trials and connected devices. The teams kicked off the first meeting of the year beginning to work on the bulk of their best practices resource deliverables. We will continue this momentum through the next several meetings as we sort out the best ways to produce the deliverables originally agreed upon as part of the scope of work.

The decentralized trials team tackled the decentralized trial roadmap and components of a DCT aspects of their deliverables. The roadmap will act as a guide for sites as they traverse the path of implementation of various virtual trial elements on their clinical trials and the group indicated that this process really starts with an understanding of protocol design. Much of this will center around a process flow and how this process generally is executed, incorporating not only the site journey but also the patient journey and data flow. When discussing this and the components, the group agreed that there is a significant amount of variability here as DCTs reside on a spectrum depending on the trial. The team also agreed that how these things are operationalized and how they affect the patient flow is what will be critical to the sites that absorb this information.

Following a similar process, the connected devices workgroup focused initially on the guidance for incorporating connected devices as well as the considerations necessary when working with these tools. These guidance's will help drive insights into best practices and help remove some of the secular concerns that exist with connected devices. Much of what will advise this work will be where these devices are coming from – the site themselves or the sponsor. This affects capabilities as well as what components of this guidance apply. The focus of these areas will be how these flows and considerations will allow sites to empower patients through effective implementation and education of the use of these tools. How these tools can be used and what elements affect their use is going to be a major focus of these areas.

The teams will continue to focus and refine these aspects as well as the other deliverables and constraints as we move through Q1 and Q2 of 2021. While a daunting and large task, these groups are up to the challenge of producing something that will truly help sites navigate these technologies.

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