

SCRS Digital Innovation Initiative

Decentralized Trials Workstream Meeting Summary - March 2021

Work continues in the Decentralized Clinical Trial (DCT) workstream as they focus on and develop the deliverables portion of the recommendations and best practices of decentralized trials for sites.

Progress from the previous meeting was first presented and discussed. This was summarized around the roadmap sites can follow and what the components of a DCT are. Much of the discussion on this recap was focused around operationalizing DCTs at the site level and how the incorporation of different prospective – the site, the patient, and the data were important. The question that should be answered by the reader is – What is the best way for my site to approach this to be successful?

The team brought up points around how we want to include sites who not only have no experience with DCTs, but also those that have limited or minimal experience and need to enhance their practice. Another major consideration here is establishing the minimums a site should consider when it comes to implementing DCT elements. There was also discussion around how at this time, there is no intention to disqualify a site who has not or does not intend to be DCT enabled but this qualification may be on the horizon. This being a concern of sites and worth intentionally addressing as part of our purpose. It was mentioned that being aligned on the needs of the sites among sponsors and CROs to help this process along. Also a core understanding for our development work.



When it comes to components of a DCT, through conversation we learned that there isn't an acute awareness of the struggle's sites have. There exist challenges that surround policy and regulatory decisions or impacts that sites need to be aware of. The group came to the conclusion that it may be helpful to have as an interim outcome an overview of the challenges and struggles that sites face when it comes to DCTs, so we have a better picture of what to address. SCRS will take this feedback and consider implementing a formal sub-project focused on this area.



Finally, the group spent some time discussing how to visually represent the work mentioned above. Consensus was something of a "subway map" that allowed a logical progression of a journey, with different routes and paths depending on needs. Speaking to previous points around minimum requirements, having a hierarchy type chart for components also plays into this map.