



SCRS Digital Innovation Initiative

Connected Devices Workstream Meeting Summary - December 2021

Work has finally begun on the true heart of the best practices and recommendations publication for sites for their use of connected devices. The team spent the majority of the meeting discussing the starting point and ending point as it pertains to connected devices at the site level. Answering the question, where does the first touch point start and when is the final touch point at the site level.



Below is a summary of the discussed points:

Starting point – When the site gets a protocol and it specifies the devices they are going to use.

- Do we need to think about something TA or country specific?
- When we provide them advisory information, we can give them use cases so they can understand how to use these
- Why don't sites collaborate? Sponsors want uniformity so having different things from different sites. Consistent data is important
- Advising to site to be asking and knowing what vendors are being used
 - Maybe it's at start-up, IM, SIVs, etc. that this information is discovered
 - Sites - Do this so you can effectively budget and contract
- Obligations on trainings for said devices
- Analyzing the package that comes for the device
 - What needs and burden exists
 - What is the support - capabilities that exist
- What is the mechanism, level of assistance
- Start-up time for me to review this with my patients

How to incorporate use cases and layering on levels of complexity



Ending Point

- When we ship the device back and when we get the consolidated data
- We can sometimes go into portals, PDFs, we don't usually send drives.
- Reconciliation of the device
- What happens to your device and the data
- LTF and Early Term patients - the Process there???
- BYOD and how to reconcile that.
 - Patients that want to keep their data?
 - Access to portals
- Who's responsibility is it to retain the data and assure access?
 - Sometimes 25 years

Continued discussion will occur around these two major milestones on the trial journey at subsequent meetings. We will also then shift attention to developing the "stops" along the way as they pertain to major steps in the incorporation and use of connected devices at the trial level.