SCRS Digital Innovation Initiative

Connected Devices Workstream Meeting Summary – March 2021

The Connected Devices workstream continues to make great strides as they embark on completing the second phase of the best practices and recommendations publication. During this meeting the team recapped the discussion around the guidance and how that takes shape, as well as what the considerations are when working with connected devices. They then spent time diving further into each of these two areas before talking briefly about the discussion points that should be included.

The guidance will be based on standards and best practices, in addition to key things to avoid. This guidance will be advising using CD's as fully integrated tools and how to allow flexibility. It was important to address where the data is going in addition to how sites interpret the "package" of resources that are provided and ultimately how it is used. Discussion ensued on how important it is for sites to have something to come awaywith, and where they can best put their resources. We emphasized the importance of understanding the flow of data and how that data is secured.

We began our recent considerations discussion reviewing how the consent process is affected, how we empower patients, security of data, and focusing on data flow. This led to a discussion around resourcing and how the site should be spending their time with these tools. Also, what reimbursement needs to look like, and the costs sites should be assessing. Much of this discussion centered around how we should be advising a mindset adjustment at the site level.

Finally, the team spent some time discussing how we address what the touch points are between the sites and sponsors. How we communicate the necessary training and who is responsible for this training is considered a major point in this topic of discussion.

The next session will see the team determining what the specific discussion points should be, at the site level, as well as summarizing the points made previously as we work to finalize many of these sections. We will continue to move through Phase 2 and towards completion.