

## SCRS Digital Innovation Initiative

### Decentralized Trials Workstream Meeting Summary - November 2021

Work has begun amongst the teams on the journeys that are key to the success of decentralized trials – data, the patient, and the site. The three teams spent this first meeting in breakout groups focusing on the starting point and ending point of their respective journey, using this as the boundaries in which subsequent meetings would be spent filling in the various points in between. Below are summaries of the individual groups work.



## Data

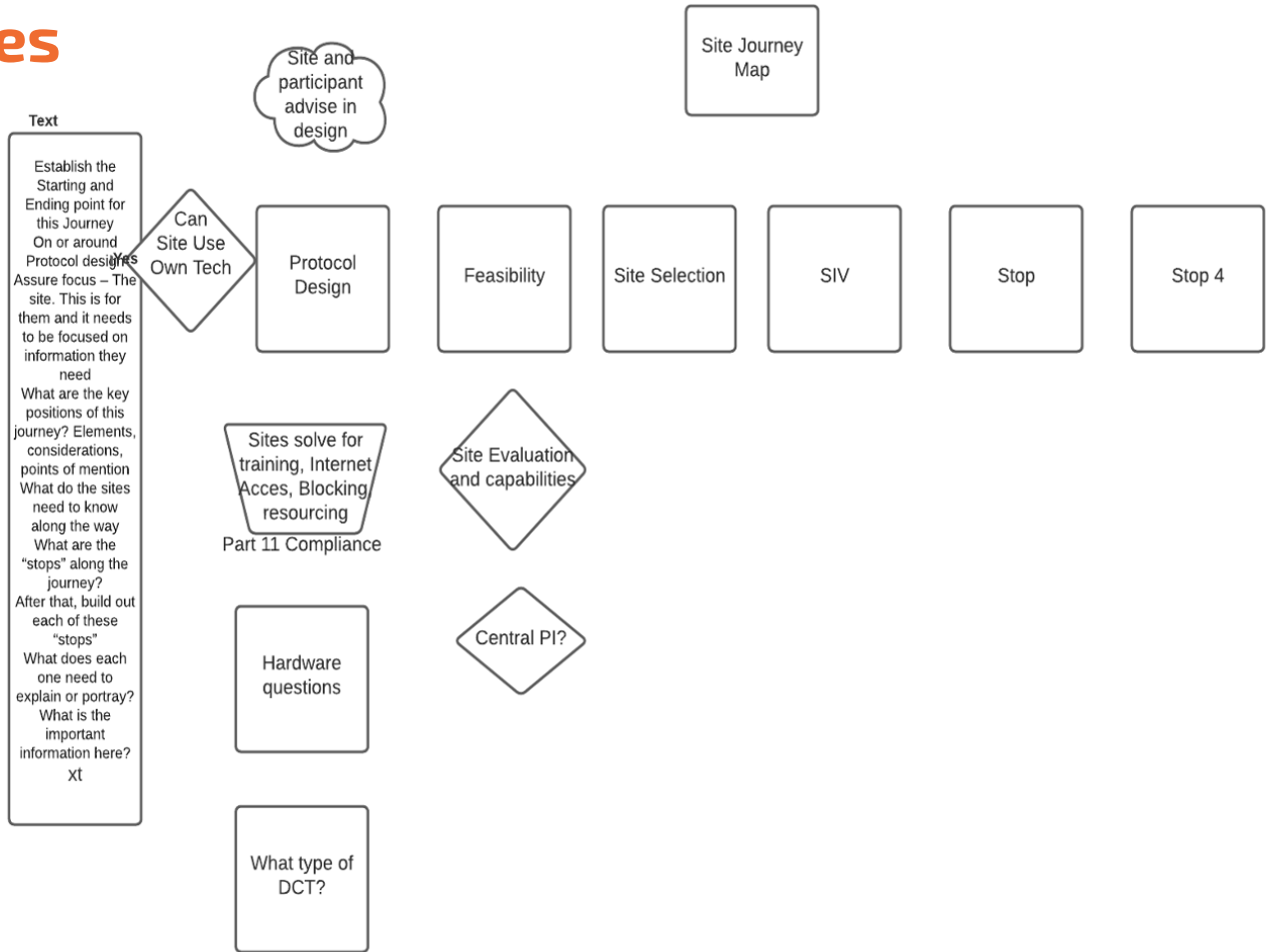
### Starting Point

- Important to discern between the patient data and study data.
  - Patient data should be gathered for medical history purposes and to be used during feasibility.
- Analysis of the systems needed and available to perform feasibility and start-up tasks through a solutions evaluation
- Understanding of regulatory needs, including local and state laws
  - What are they and how they are assessed
- How systems might be integrated and what this process would look like from a flow prospective
- Communication of challenges that arise during the protocol and solutions evaluation back to the sponsor/CRO
- Assess what data is necessary and what is considered non-essential
- Devices – what those devices physically are, how they collect data, storage and support

### Ending Point

- Understanding laws surrounding timelines for data retention
- How and where data is stored
- Withdrawing consent – what that process is
- Format in which data is received
- Transmission of data – what that looks like and in what format

# Sites



# Patient

