

## SCRS Digital Innovation Initiative

### Decentralized Trials Workstream Meeting Summary - January 2022

Progress continues to be made amongst the individual groups focusing on the data, the patient, and the site journeys. Below are summaries from the individual teams who focused this month of finalizing the starting and ending points, as well as diving into the finer details of those individual points on the journey.



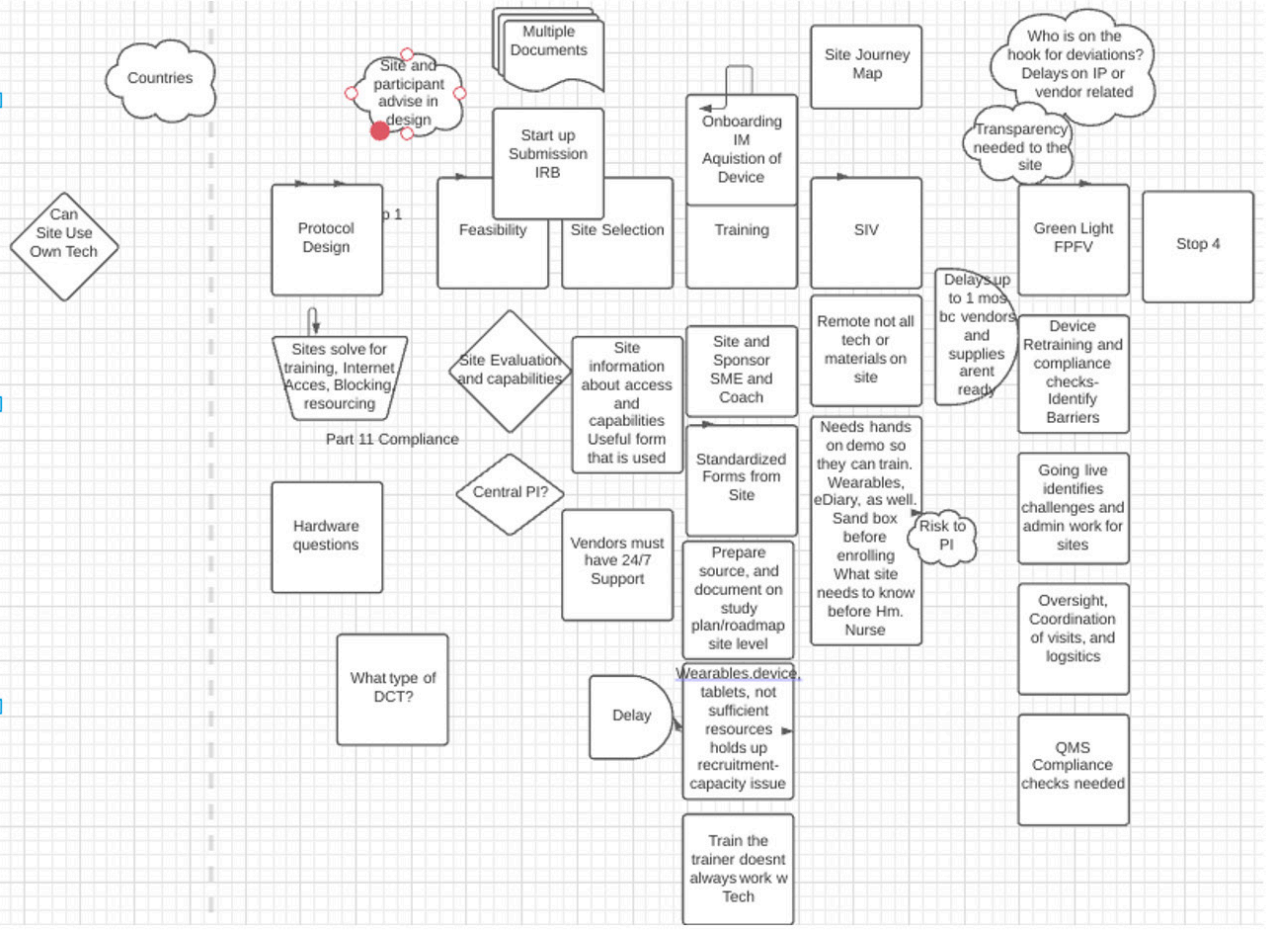
## Data

- Someone needs to be able to access the patients chart
- IRB approval needing local context review experts
- Monitoring Plan - understand the details
- PK and overnight stays - Understanding this and the details here
  - Cost Prohibiting
- Out of the box solution discovery to meet the needs of the trial
  - Patient focused - where the patient is, not where the site is.
- Sponsors and CROs - Talk to the sites about protocol design
- Patient Data vs. Study Data
  - Where Patient data is, coming from, and stored
  - How is patient data getting back to where it needs to go when its not part of a system
  - Think about use cases and what are potential scenarios
    - Internal and external patients
      - External/Community Patients - They may come from other places
        - Not Getting Care, Public/Community Health, Multi-System Patients, Virtual Patients
        - Governed by medical licenses and what they have
      - Local and state regulatory differentiation
- Diversity component - call it out as enabling through this
  - Diversity target commitments and how you will meet those
  - How you can deliver those patients
- Analysis of the systems needed

# Sites

Establish the Starting and Ending point for this Journey  
 On or around Protocol design  
 Assure focus - The site. This is for them and it needs to be focused on information they need  
 What are the key positions of this journey? Elements, considerations, points of mention  
 What do the sites need to know along the way  
 What are the "stops" along the journey?  
 After that, build out each of these "stops"  
 What does each one need to explain or portray?  
 What is the important information here?  
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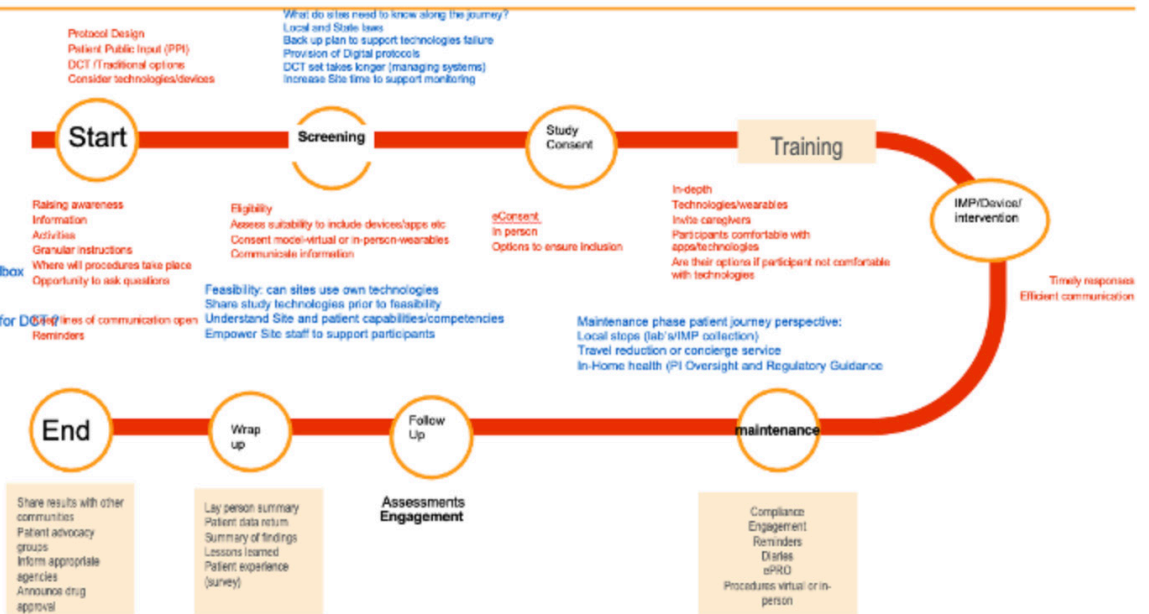
Quality concerns:  
 Where deviation come from Root Cause. Site gets dinged for things they werent responsible for.  
 Bench mark extra time it takes to implement DCTs



# Patient



- Highlights to be considered:
- Cost & Compensation (What is the cost?)
  - PI Oversight
  - Training requirements/Provide patient sandbox environment for site training
  - Applicable local & State laws
  - Resourcing studies-What skill set required for DCTs



Next meeting, the team will focus on expanding on the points of the journey in-between the starting and ending points more specifically.