These tools are meant to be generalizable, based on typical roles and responsibilities in trials.
This is a set of best practices, which can be adapted to align to the operational model and processes of any study using DCT elements

Instructions

1) These tools were created with the intention to increase clarity and coordination across roles performed by different organizations and individuals using DCT elements in trials.

2) **Sponsors**: Use these tools while writing protocols including DCT elements, when identifying sites, and during study start up / conduct.

Suggested Sponsor Users: Clinical Operations Leaders, Medical Team, Site Engagement / Feasibility Team, Digital Health Team

Research Site Staff: Use these tools when considering participation in as a research site and as part of trial start up and conduct.

Suggested Site Users: Clinical Research Coordinator, Site Management / Leadership, Resource and Budget /Contract Managers

Technology and service providers: Use these tools when planning to support a specific clinical trial, and when defining what is needed to support any clinical trial.

Suggested Service Provider Users: Implementation and Delivery Leaders, Technical Support Team, Training Team

3)**Start** at the Platform Card - Answer these questions first, alone or in collaboration between sites, CROs, Sponsors and Service providers.
Check the Box for any of the DCT elements that apply in your specific clinical trial to be directed to the relevant cards.

4) Use the questions as an approach to **set clear mutual expectations** about who is doing what, what is being used, and how the DCT element impacts the study conduct and data flow.

Assumptions:

1) These tools are used in alignment to meet ICH, GCP requirements and local regulatory guidance recommendations including GDPR.
e.g. Conducting Clinical Trials With Decentralized Elements (Sept 2024)
Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations Questions and Answers (Oct 2024)

2)Any DCT technology solutions meet technical requirements for use in clinical trial conduct (CFR 11, GDPR, etc). and have been qualified for use by Sponsor

3) All DCT elements will be conducted within state laws

4) The PI will be informed when any of the DCT elements are used as part of the site's study conduct and or oversight

5) These tools were designed to for use when DCT elements are included in the protocol design, rather than when the protocol adapts to use them following study start

Recommendations:

1) As a research site, consider using these tools to better define what is needed to use DCT elements efficiently at your site.
We suggest you use these questions as the basis of a readiness assessment for each DCT element by reviewing the questions to be answered and the capabilities required. This may also help clarify to sponsors what would be needed to adopt the DCT element successfully.

2) Use the associated excel spreadsheet to align your specific study operational plan (DCT Elements, Vendor plan) and team model to a clarify roles and responsibilities in a specific study.

Key Sponsor Decisions- Digital Health Tools (DHT) and Devices

(sites should ask these questions if not provided by sponsor)

Feasilbility

- What is the DHT / Device workflow across the study visits? How is the DHT data used?
- Who provisions DHTs to Patients? (Wearabes / Sensors)
- Can patients use their own device? (BYOD approach)
- Is there financial support for patients to cover data plans / wfi access?
- Who trains patients when BYOD DHT devices are used for data capture?

Inv Meeting/ SIV

- What is the end to end plan for DHT use / data collection in the study?
- Who maanges patient costs for data plans / wifi access?
- Who confirms a patient's device meets BYOD requirements?
- Where is device data collected by visible? To whom?
- Where is Operational data collected by DHTs visible? To whom?

Key Site Questions - Digital Health Tools (DHT) and Devices

Feasilbility

- Does site provision DHT devices?
- Who trains study site staff on DHT device use?
- Who supports patient questions re DHT devices?
- Who trains patients on use of DHT devices?

Inv Meeting/ SIV

- Who ensures patients have access to Wifi/ Cellular networks?
- Who deploys a working device to a patient if a DHT device fails?
- When are patients trained on use of DHT devices?
- Who reviews data collected by DHTs for completeness?
- Who reviews data collected by DHTs for safety signals?
- Who is accountable to review data queries based on DHT data?

What capabilities will be required for this method?

- Wifi/ Cellular Acces for DHT connectivity/ data exchange
- Patient and caregiver training
- Technical support for patients/ caregivers
- Site acess to data platform if DHT data is not in clinical data set / EDC platform.

Budget/Resource Questions:

- How does this impact my study coordinator workload?
- How does this integrate to my workflows?
- What resources are available when I have questions?
- What is the tech support model/ methodology?
- What is the quality control process?
- Will this require new skills /resources

Legend

- Sponsor/CRO
- Site
- DCT Vendor
- Other Vendor

Access Instruction Sheet for use of these tools here