**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- Home Health Care**
(sites should ask these questions if not provided by sponsor)

**Feasilbility**

What's the overall workflow for home nursing?
Which visits, which assessments?

Is in-home / mobile nursing an option in this study? If so, can patients decide to use it on a visit to visit basis?

Has a central in home nursing supplier been selected?

If in-home nursing is used, can it be managed by the site's preferred home nursing process / supplier?

**Inv Meeting/ SIV**

What is the window for patients to decide on home health before the visit date?

## Key Site Questions - Home Health Care

**Feasilbility**

How is data collected from the in-home visit? Is an eSource platform used?

Is there any need for telephone / telemedicine link to the in-home nurse during the visit?

**Inv Meeting/ SIV**

Is there any specific safety monitoring expected for in-home collected data?

How is the nurse connected with the site staff? What process is in place to ensure the PI / staff approve the individual?

How are in-home visits scheduled? by whom? Is this automated? How long prior to the visit must they be scrheudled?

**Inv Meeting/ SIV**

Who provisions in specific supplies and to whom (Patient, site, HCP?)

Where is operational data visible? To whom?

Where is assessment data visible? To whom?

What is the data management process for queries?

**What capabilities will be required for this method?**

- Confirm access to telemedicine (if needed)

- Access to wifi / cellular data

- Confirm PI readiness to oversee home health nurse /HCP for the study

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

**Legend**

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

Access Instructions to use these tools here