

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

Feasibility

What is the workflow for DTP shipments? What is the planned end to end process?

Is DTP fit for purpose, considering supplies safety and storage profile?

What supplies are being shipped directly to the patient? (Equipment, scales, test materials, etc?)

Are supplies shipped DTP from site to patient? or from depot to patient?

Inv Meeting/ SIV

Where is the shipment data visible and to whom?

What is the 'supply accountability' process? Where is this tracked and by whom?

Key Site Questions - DTP Shipments

Feasibility

What is the role of the site in the chain custody of the shipment contents?

Inv Meeting/ SIV

How are shipments scheduled?

What training materials are available for sites and patients on DTP shipments?

Who trains patients on use of shipment contents? Is follow up expected by sites about patient use of supplies/ equipment?

How is operational data re shipments managed? Who resolves issues?

Inv Meeting/ SIV

How is PII protected across the shipment / delivery process?

How is temp control monitored (If needed)?

Who is accountable to manage temp excursions?

How is delivery confirmed? By site? By Patient?

What capabilities will be required for this method?

- Portal access for supply shipment / accountability / excursion management?

- PII protection between site and shipment service provider.

Budget/Resource Questions:

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

Legend

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

Access Instructions for use of this tool here