

Key Sponsor Decisions- Training

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

Feasibility

How many technologies or other DCT provider offerings will sites need to be trained on?

Is the training on-demand with a training credential (e.g. similar to EDC)?

Who needs to complete training at the site? (PI, SC, pharmacist, other?)

What format does each tech/ DCT provider use for training? e.g. video (duration?), in-app instructions, power point)?

Feasibility

In what format is training given?

Inv meeting, self-training, Webex meeting?

What is the estimated total time the site needs to spend on training activities prior to site activation?

Is there a visit by visit infographic showing what is used, when and by who? (both patient and site staff)?

Inv Meeting / SIV

How are the patients trained on each DCT component?

How many DCT elements/ technology platforms will each patient need to be trained to use?

Key Site Questions - Training

Feasibility

What is the site's role to train study participants on any DCT Elements and study-specific devices as part of the study start-up and study visits?

What roles need to be trained on the technology? Are there specific qualifications needed?

Inv Meeting / SIV

What training materials are available for direct-to-patient shipments? (IMP, equipment, other)

Are instructions sent to patients with DTP shipments? Or do sites share them with patients?

Inv Meeting / SIV

What training materials are available for training the patient on each DCT element?

What is the support model for site staff for each DCT element?

What is the support model for patients in the study for each DCT element and any study-specific device needs? What in-country support is used?

What is the escalation plan for support services if problems occur?

What capabilities will be required for this method?

- Access to platform or other site for training.
- Clear understanding of who will need to be trained on which elements.

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 to use these tools here