

Key Sponsor Decisions - Platform

(Sites: Ensure each question is answered by Sponsor)

Feasibility

How many technology platforms or systems will be used for the DCT elements of the study?

What is the draft workflow and vendor plan for DCT methods across the study visits? (e.g eConsent, eCOA, etc)

Is there a single portal for sites to access all the technology? ie one platform for all vendors and sites to use for the study?

Can sites use their own technology platforms? For which elements?

What is the data flow and transfer plan across the platforms / DCT data collection tools?

Inv Meeting / SIV

How many technology vendors will sites be expected to work with to use decentralized elements?

Do your vendors have the capability to integrate site technology with vendor tech platforms? e.g scheduling

What is the support strategy for each DCT / Technology Vendor? What are the hours and languages offered by the support team(s)?

How many tech platforms will study participants be expected to use for decentralized elements?

Key Site Questions - Platform

Feasibility

Can site use any of their qualified / validated DCT providers?

CONFIRM: How many tech platforms will study participants be expected to use for decentralized elements?

Where will data need to be entered manually? How many platforms will be used?

How will participant PII be protected per local law and who will have access to it?

Inv Meeting / SIV

What is the site responsibility for onboarding vendors involved in the DCT elements of the study?

Who is responsible to train the sites?

Who is responsible for supporting the site and the patient for each technology platform?

Who trains the study participants on the use of DCT tools / technologies?

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

Which DCT elements will be used?

- Direct to Patient Shipment (IMP and Supplies)
- eConsent
- ePros / eCOA
- Home Health Care
- Remote Biospecimen Collection
- Telemedicine Visits
- Digital Health Technologies (DHTs)
- Digital Patient Recruitment/ Engagement

Legend

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

Access Instructions to use these tools here