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 - Platform

(Sites: Ensure each question is answered by Sponsor)

Feasilbility

- 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

Feasilbility

- 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

Key Sponsor Decisions- Training
(sites should ask these questions if not provided by sponsor)

Feasilbility

- 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)?

Feasilbility

- 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

Feasilbility

- 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 elemetns.

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

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
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- DCT Vendor
- Other Vendor

Access Instruction Sheet for use of these tools here

Key Sponsor Decisions- eConsent

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

Feasilbility

Can sites use their own eConsent solutions?

Please explain the end to end workflow for use of eConsent.

1. Who sets up the patient?
2. Who manages amendments?
3. How is remote consent managed?

How is the site supported when end-users have questions?

What are the support team's hours, languages and response times?

Feasilbility

What is the eConsent workflow when a paper copy of the ICF is signed? (Upload capability?)

Inv Meeting/ SIV

How will the site staff eConsent training be completed and documented?

How will sites be provided a copy of the signed ICF for long-term archiving?

Clarify the minimum device hardware and software requirements for eConsent.
I.e. Phone model and software

Key Site Questions - eConsent

Feasilbility

Is consent managed remotely? If so, what is the workflow?

Will eConsent tool allow for source documentation notes within platform, or will site need to document notes separately?

Does the eConsent tool use video or other media to support the consent process?

Inv Meeting / SIV

Is the site responsible to confirm that the patient's device meets minimum eConsent platform requirements?

What capabilities will be required for this method?

- Internet connection
- For eConsent Platform:
ICH, 21 CFR 11, GDPR, and all requirements for audit capability
- Method to verify participant ID (e.g. telemedicine or other approach)

Budget/Resource Questions:

- How does this impact my study coordinator workload?
- How will this impact study start up?
-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

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- Other Vendor

Access Instructions to use these tools here

Key Sponsor Decisions- Direct to Patient Medication (IMP) Delivery

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

Feasilbility

- Is Direct to Patient shipment of IMP used in this study?
- What is the workflow for DTP shipments? What is the end to end process?
- If DTP is used is delivery from site to patient or depot to patient?
- Is the courier/ delivery service provider familiar with clinical trial requirements? (PII protection, documentation).
- Are supplies sent direct to patient? e.g. Kits, medication admin supplies, devices?

Inv Meeting / SIV

- How and where is drug accountability managed?
- How are patients trained on storage and administration of IMP?
- What role does the patient play in IMP drug accountability?
- How is the patient trained about IMP drug accountability?

Inv Meeting / SIV

- How is temperature control of IMP monitored? During shiptment? After delivery?
- Where is temperature excursion data monitored and by whom?
- How are temperature excursions managed? (Process and communication)
- Who is accountable to manage temp excursions?
- What is the support model for sites? for Patients>

Key Site Questions - Direct to Patient Medication (IMP) Delivery

Feasilbility

- How are patients trained on the IMP shipment and receipt processes?
- How are patients trained on the shipment and receipt processes for any other supplies?
- What is Site's role in the IMP chain of custody?
- What is expected of the pharmacy at my site?

Inv Meeting / SIV

- What training materials are available for sites / patients on IMP DTP shipments?
- How are shipments scheduled?
- How is PII protected across the shipment / delivery process?
- How is IMP delivery confirmed? To Patient / By Patient?
- How is operational data re shipments managed? Who resolves issues?

What capabilities will be required for this method?

- Depot for supplies
- Clear triggers to ensure materials reach patient by required time.
- Integration to IRT
- Cloud based shipment tracking / receipt confirmation
- Temperature tracking and excursion reporting
- Drug accountability and destruction processes
- PII protection for patient info with DTP shipment.

Budget/Resource Questions:

- How is billing for the IMP determined?
- Are medication diaries (eDiaries) used?
- How will this impact study start up?
- 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

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- DCT Vendor
- Other Vendor

Access Instructions for use of these tools here

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

Feasilbility

- What is the workflow for DTP shipments? What is the planned end to end process?
- Is DTP fit for purpose, considering supplies saftey 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

Feasilbility

- 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/ equiptment?
- 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 to use these tools here

Key Sponsor Decisions- ePRO/eCOA

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

Feasilbility

- What is the overall workflow for eCOA / ePRO in the study for sites and patients??
- Can sites choose their own eCOA / ePRO platform and vendor?
- What is required to collect ePROs/ eCOAs based on assessments/ scales used. (e.g. home health HCP, Video)
- Does ePRO/eCOA have or need video upload capabilities?

Feasilbility

- Are all eCOA/s ePROs collected using Sponsor-defined technology?
- Can site use their own video visit platform for video assessments?
- What are requirements for patient's devices? Is Sponsor provisioning?

Inv Meeting/ SIV

- Who trains Site satff on eCOA/ ePRO platform / Tools?
- Who acquires scales to be used in ePRO/eCOA?

Key Site Questions - ePRO and eCOA

Inv Meeting/ SIV

- Has my site worked with this vendor before?
- Which roles and how many people need to be trained on eCOA / ePRO platform/ tools?
- Who trains patients?
- Who reviews data? Where is data stored/ reviewed?

Inv Meeting/ SIV

- Do I understand the workflow and team roles to conduct ePRO / eCOA?
- Are there home health visits where ePRO/eCOA is performed? Are site personnel involved?
- Who creates patient training mateirals?
- Who provides tech support for patients?
- Who confirms patient's tech device meets the eCOA / ePRO requirements?

What capabilities will be required for this method?

- Smart phone or provisioned devices for participants?
- Video visits for any scales / assessments?

Budget/Resource Questions:

- How does this impact my study coordinator workload?
- What is required of my staff outside of normal activities?
- Are some of the remote visit activities performed by other personnel than my site?
- Can I use my own platform for video visits?
- 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

Key Sponsor Decisions- Patient Recruitment / Engagement
(sites should ask these questions if not provided by sponsor)

Feasilbility

- What is the patient engagement workflow, from awareness through study completion? Which Platforms are planned?
- Where are decentralized elements that intersect with patient engagement outlined in the study documents?
- Are there multiple locations for patient recruitment in the study?
  Are they physical or remote?
- Will sites be expected to recruit outside the site practice?

Inv Meeting/ SIV

- Who manages patient payments and using which reimbursement tools?
- What is the patient engagement workflow, from awareness through study completion? Which Platforms are planned?

Key Site Questions - Pt Recruitment / Engagement

Feasilbility

- Is the online screening tool provided through a vendor?
- Who is accountable to oversee patient eligibility for digitially recruited patients?
- Are there special patient communication / engagement needs that will require extra site time?

Inv Meeting/ SIV

- Who follows up with patients to complete on-line screening and enrollment?
- Who directs the patient to the on-line screening tool?
- What is the expectation of sites to manage patient screening and enrollment?
- Who manages payments to patients directly?

Inv Meeting/ SIV

- What is expected of sites to manage patient communication / engagement?

What capabilities will be required for this method?

- Internet/ Cellular Access for participants and sites
- Clear handoff from anyone doing pre-screening to screening
- A process to obtain medical records from an external site / location
- Access to a tracker / dashboard to manage / see the patient flow

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

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- Site
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- Other Vendor

Access Instructions to use these tools here

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

Key Sponsor Decisions- Biospecimen Collection
(sites should ask these questions if not provided by sponsor)

Feasilbility

- What is the planned workflow for biospecimen collection? Are any central labs / imaging facilities planned?
- Can patients have biospecimens / images collected at local lab facilities?

Inv Meeting/ SIV

- Are there specific vendors/ providers that may be used?
- How is payment to for these services managed? Is this a pass through from sites?

Key Site Questions - Biospecimen Collection

Inv Meeting/ SIV

- Who schedules appointments for the patient at the local faciliity?
- if a procedure needs to be rescheduled or repeated, who manages this?

Inv Meeting/ SIV

- Who enters data from the biospecimen collection? Where is it entered?
- Where is the operational data from the visits visible? to whom?
- Where are the clinical results from the visits visible? To whom?

What capabilities will be required for this method?
- Is this a platform where data is already reviewed as part of clinical care?
- Credentialing and access requirements?

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 Instruction Sheet for use of these tools here