Devices (smartphones and tablets) in DCTs

Introduction

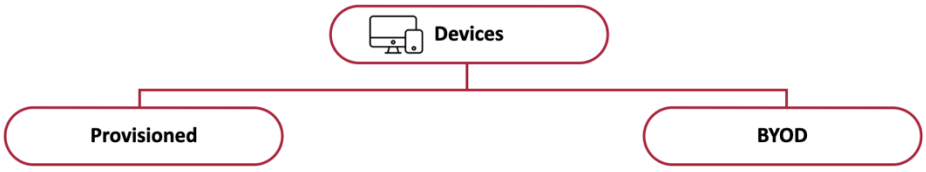
Smartphones and tablets (here, collectively termed “devices”) can be configured either as Bring Your Own Device (BYOD) or provisioned devices. They are often used in DCTs to help participants, investigators, sites, and sponsors collect data. Devices can be vehicles for participant data collection through electronic patient-reported outcomes (ePROs), observer-reported outcomes (ObsRO), and other eCOAs (electronic clinical outcome assessment). These assessments are usually deployed using applications downloaded onto the device.

Note that some studies involve investigation of the application or software itself, which raises questions of risk and benefit for the IRB/EC. For instance, a study may involve an app for the assessment of cognition. While this app may be part of a DCT and loaded onto a device, the IRB/EC will wish to review additional potential safety and other issues than those described here.

This document covers only non-investigational devices (smartphones and tablets) devices as objects in common use, deployed for the purpose of conducting the DCT; for information about wearables, connected devices, and applications, see the Connected Sensors section.

IRBs should understand which types of devices (provisioned or BYOD) are being used.

Differences between categories of Mobile Devices



- Provided by sponsor or investigator
- Technical training and help often necessary
- Internet access and cellular data plans provided
- Terms of Use to be reviewed
- Data access and confidentiality provisions important
- Consequences/process for loss or failure to return (if applicable)
- Regional considerations (e.g., inducement in some countries)

- Typically provided by participant
- Device assessment for study
- Confirmation of security & confidentiality of data transfer
- Incremental cellular data plan may be necessary

BYOD devices

Although some sponsors are hesitant to allow participants to bring their own device (BYOD), some participants may prefer to use their own device in a clinical trial. BYOD can offer benefits such as improved data collection as owners are generally comfortable and experienced using their own devices.

Considerations for IRBs

- Equity and equitable access
    - For example, if a smartphone is required, for those who do not have their own device will one be provided? Does that decision have implications for the equitable selection of participants?
    - Provisioned devices ought to be considered if the BYOD device or data plan/Wi-Fi availability is inadequate. The decision to provide devices to participants unable to BYOD helps to ensure equity, as everyone would have equal opportunity and access.
- A minimal set of requirements for the BYOD hardware and software should be predefined, and a clear list of such requirements, written in plain language, should be made available to the investigator, study team, and participant. The requirements should define the compatible make/models and operating systems of devices.
    - Sponsors should consider how to update provisioned and BYOD devices to maintain current versions of software.
- Each participant's device should be assessed to ensure that the BYOD device meets the minimum device requirements to run the trial apps. Older models, for example, may no longer be supported or may not work well for this purpose.
- The cellular data plan must accommodate data collection and transfer needs in the trial or be augmented by the study team or sponsor. If the data plan will not be reimbursed, the informed consent process and document should alert prospective participants to the likely costs that will be incurred.
- Security and confidentiality for data transfer should be ascertained and confirmed, with particular attention to sensitive or health information.
- It should be understood if the application accesses information from other applications on the device and if there are risks associated with that additional information.
- Informed consent considerations for BYOD:
    - Costs associated with data plans/WIFI essential to trial data submission must be disclosed. Supplemental data plans should be provided if needed.
    - Trial participants must consent to the use of their own device during the clinical trial.

Provisioned devices

Provisioned devices are devices provided by the sponsor or institution, and provide a more controlled, standardized data capture platform than BYOD. Thus, investigators and sponsors should define whether all participants will be given a provisioned device or only those who do not have an adequate personal device along with the implications this may have for participant selection.

Considerations for IRBs/ECs

- The IRB/EC should review the plan for reporting and replacing a device lost, damaged or stolen. While rare exceptions may exist, the participants should not incur penalties for losing provisioned devices. Particular attention should be paid to any proposed penalty (e.g., covering replacement costs, withdrawal from the study) that will be imposed upon the participant.
- Any change to the study to add a penalty or cost for a lost, damaged, or stolen device should be considered a change to the research and require IRB/EC review and approval.
- Sponsors and/or investigators should ensure that a provisioned device can be tracked, and that the tracking functionality is active only upon notification of loss.
- Sponsors and/or investigators should ensure PHI and clinical trial data are encrypted at rest and in transit and be able to lock and wipe the device remotely.
- If a device is lost or stolen, the device should be remotely accessed and wiped to remove all information.
- The provision of a replacement device need not be reported to the IRB/EC.
- Any possibility of disclosure of PHI through lost or stolen data should be reported to the IRB/EC and to any covered entities as a potential HIPAA violation, as applicable.
- The IRB/EC should anticipate that the type of provisioned device will vary by region.
- Data collected and transmitted automatically should be available to both the investigator and the sponsor (i.e., to verify that data was not modified)
- Informed consent for provisioned devices should include the following information:
    - Costs associated with associated data plans, if any.
    - Instructions in the event that a device is lost, damaged, or stolen.
    - Information on who will provide replacement device(s) and limitations in the number of replacement devices, as applicable
    - Description of the process a trial participant will follow if a device is lost, damaged, or stolen. Optimally, there should be no penalties for lost, damaged, or stolen devices. If any penalties (e.g., financial reimbursement, removal from study) are proposed, the penalty should be explained in the informed consent process and documented in the consent form. Penalties should be non-punitive and reasonable based on the depreciated value of the device.
    - Disposition of the device at the end of the study:
        - Whether the device be returned to the sponsor and the method for return, such as participant return to study site or pre-paid return shipping label provided.

- Whether the participant can keep the de-commissioned device at the end of trial. If the participant retains the device, depreciation of the device should be calculated and documented so that the participant incurs no tax consequence.

Device logistics and cost

- Sponsors rarely handle the logistics of their own devices, and either buy the device outright or lease it from a technology partner.
- When the device is a required tool for trial participation, participants should be provided with appropriately administered and documented instructions to use the device properly.
- Trial participants should have access to a Helpdesk (see helpdesk tool) device troubleshooting.
- Cost considerations:
    - IRBs/ECs may wish to consider the cost of the device in their deliberations, particularly if possession of the device may subject the participant to risk of harm (e.g., in some settings, possession of the device will expose the person to privacy risks or risk of theft).
    - IRBs/ECs may wish to consider situations where the participants are allowed to retain the device after the trial, and whether the possibility of retention is an appropriate incentive to participate in the trial. In that context, the depreciated value of the device at the end of the trial should be considered.