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BYOD: Consumer Mobile Devices in Clinical Research

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Smart phones, watches, tablets and other consumer mobile devices can be used in clinical studies to collect pain, mobility, physiology, quality of life, and other data. Consumer mobile devices offer benefits like familiarity to the study participants and reduced cost to the study sponsor, especially when study participants already own the devices. However, a variety of issues must be addressed.

What is a Mobile Device?

The FDA addressed the use of mobile *medical* devices in a February 9, 2015, guidance, *Mobile Medical Applications Guidance for Industry and Food and Drug Administration Staff.* However, the FDA does not have regulatory authority over the use of mobile *non-medical* devices. As a result, study sponsors cannot rely on FDA guidance for the use of such devices in clinical studies.

While the FDA does not define the term "mobile," the above guidance states:

> Many mobile apps are not medical devices (meaning such mobile apps do not meet the definition of a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)), and FDA does not regulate them.
>
> A [medical] device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory that is:
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> - recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
> - intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
> - intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o) [of the FD&C Act].

In addition, the FDA "Device — Not a Device" webpage (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051521.htm) can help determine whether a specific device meets the definition of a medical device.

While certain medical applications could be used on a laptop or smart phone, neither stand-alone device meets the FDA's definition of a mobile medical device.

Whose Device Do We Use?

The term "bring your own device" (BYOD) refers to the use of the study participants' mobile devices. In addition to the general-purpose types of devices mentioned above, consumer-

owned prescription and over-the-counter monitoring (and treatment) devices, such as cardiac defibrillators and glucose meters, can also collect and report data.

Table 1 presents advantages and disadvantages of using BYOD devices in clinical studies:

Table 1. BYOD Pros and Cons

BYOD Pros	BYOD Cons
Cost savings, since the devices are already available Time savings in purchasing and provisioning Reduced or no learning curve for study staff and participants Convenience, since participants do not have to manage another device A greater sense of empowerment and control, which can boost participant morale	Might need to support multiple types and versions of devices Potential for inconsistent data parameters (e.g., units of measure) Lack of data security Potential HIPAA violations Potential loss of data integrity Potential challenges in collecting data from devices Lack of or need to redefine "source documentation" at site level

Once the Sponsor has determined that a device it wishes to use in a study is not a regulated medical device, it can follow a five-step process to determine if a BYOD device is appropriate for that particular study:

Step 1. Determine roughly what data could be collected by mobile devices.

Step 2. Identify the type of devices to be considered for use.

Step 3. Determine whether the subject, sponsor and/or investigative site will provide devices.

Step 4. Identify the suitability, advantages and disadvantages of the device(s) for the study. Categorize each advantage/disadvantage, including risk levels. Ask the following questions:

- What will the data be used for, e.g., safety, efficacy or both?
- How does the study phase affect the risk of using the device?
- Will the data relate to primary, secondary or tertiary endpoints?
- What data characteristics are required, e.g., precision, accuracy, frequency and completeness?
- How will the data be transferred, e.g., wireless or wired upload?
- Can the device encrypt data for storage and transfer?
- How will the incoming data be incorporated into the study database and subject's research files?
- What would the impact be if data were incorrect, never captured, or lost?
- Can data from different device types and versions be harmonized?
- If a potential participant is required to provide but does not already have a suitable device, will one be provided, or will that person be excluded from the study?
- If a potential participant cannot use the device, e.g., because of poor Internet connectivity, is there a back-up option?
- What technical support will be provided to participants, and what will that support entail?

- Where will the use of personal devices be documented within the study files: data management plan, protocol, etc.?
- If the device requires a prescription, what brand/make/model(s) can be used?
- Does the device actually perform correctly in a trial run?
- Will study personnel be able to access the study participants' non-study private information?
- What policies, procedures and processes will support data integrity and confidentiality?
- What happens if a personal device is lost, destroyed or stops functioning? What is the back-up plan?
- Will the study population be comfortable using the device in the study? (Consultation with a representative sample of potential study participants might yield insights, e.g., that a potential subject only has access to an employer-provided device, which should not be used in a study.)
- How will participants and site personnel be trained?
- How will data quality be verified? Will there be a positive control?
- Where, how and for how long will original, raw data be stored?
- Can data be inspected and audited?
- What are the financial and time costs and benefits?

Step 5. Make and document a "go/no-go" risk-based decision based on all the pros and cons.

Step 6. After a "go" decision has been made:

- Create a plan for reducing or eliminating any disadvantages.
- Incorporate device usage within study documentation as appropriate, e.g., in the protocol, monitoring plan, study manual of operations, and data entry instructions.
- Develop and execute a training program for site personnel and participants.
- Implement a quality control program.
- And, in conclusion, keep the following requirements in mind:
    - Conduct the risk assessment prior to implementation.
    - Securely encrypt data on both wired and wireless devices.
    - Adopt strict authentication and password policies at every connection point.
    - Implement an effective data management plan for data acquisition, storage and transfer.
    - Prepare a data breach response and contingency plan.

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