yprime | eCOA

Device Strategy for eCOA: BYOD or Provisioned?

Mark Maietta, President, YPrime

The COVID-19 pandemic created a watershed moment in the drug development industry, accelerating further exploration into the use of advanced digital technologies for decentralized, virtual, and patient-centric trials. Collecting clinical outcome assessment data electronically from patients is one tool that provides significant benefits by enhancing clinical trial efficiency, minimizing patient and site burden, and improving patient compliance. There are also significant complexities with planning and implementing an effective electronic clinical outcome assessment (eCOA) solution that delivers all the possible benefits and a sponsor's device strategy plays a critical role in the success of a clinical study. Which device is better for collecting eCOA—a patient's own device, known as bring your own device (BYOD), or a vendor provisioned device (PD)?

The short answer is, "It depends." There are questions we can ask and answer that can help guide sponsors toward one strategy or another based on the protocol, patient needs, risks, and risk mitigation. By asking the right questions, and understanding and preparing for all the variables, a sponsor can successfully implement the modality that increases patient compliance while minimizing missing data and risks to data integrity throughout the life of a study, even a long-term study.

Perceived Benefits and Risks of BYOD and Provisioned Devices

The reason we say "perceived" is because these benefits or risks may be based on misconceptions or outdated information. Many of the perceived benefits may be relative—for example, sponsors may reduce costs in inventory management, while increasing their spend in technical support. Many of the perceived risks can be mitigated if addressed proactively.

	PERCEIVED BENEFITS	PERCEIVED RISKS
BYOD 	• Reduce costs for the sponsor (data plans, shipping, lost or unreturned devices, inventory management) • Reduce burdens on study sites (training, technical support) • Reduce burden on patients (No need to carry an additional device, requires less technical support—subject is already familiar with navigating their own device)	• Security is more complicated to ensure (data storage, data transfer, privacy, user authentication) • Loss or theft of device • Patient replaces their phone • Patient perceptions over data privacy • No control over device capacity, OS updates, widgets, or other apps that may impact the sponsor's study app
PROVISIONED 	• Device designed exclusively for eCOA data collection (full operating system control, full control of user's experience) • Standardized platform for data collection, reducing variability in data • Reminders/alarms cannot be disabled by users • Can be easily replaced, preventing loss of data and data integrity • Can be remotely accessed for technical support	• Inconvenient to carry second device • Site burden for providing training and technical support • Barriers to initial and re-supply shipments to sites (time to ship, clear customs, and additional costs to import devices) • Can I get more devices if we add to the study in the future and how quickly are those devices available

Figure 1: Perceived Benefits and Risks of BYOD and Provisioned Devices

What is the regulatory guidance on BYOD or PD?

Both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) support remote patient research and the use of electronic tools to collect patient data. The FDA is currently developing four new methodological Patient-Focused Drug Development (PFDD) guidance documents for industry that incorporates the patient experience into drug development. The FDA acknowledges the increasing interest in BYOD and has sought comments on the use of BYOD technology but has not issued formal guidance. The FDA has stated that sponsors need to reduce variations in instrument format and functionality by using a single platform during clinical trials[1].

In June 2020, EMA issued a document highlighting some of the key points to consider to successfully qualify digital technology-based methodologies, including eCOA, that are intended to support approval of medicinal products. In it, they acknowledge that digital technologies are becoming part of the conduct of clinical trials and address many of the questions that arise around ensuring the reliability and validity of data captured digitally[2].

Plan for Success

Determining which modality—BYOD or provisioned—is the better solution for your specific study requires asking the right questions.

Primary or secondary endpoints?

Primary or secondary endpoints? Will the subject require reminders or notifications to complete questionnaires throughout the day? If so, what happens if a subject chooses to turn off notifications on their own device? How critical are these notifications? What is your back up plan?

Exploratory or pivotal trial?

Is this a short-term exploratory trial, or a long-term pivotal trial that will take place over the course of several years in multiple countries across the globe? How much lead time is required and what are the import/export regulations and processes for getting provisioned devices into/out of each country? What are the regional or country-specific mobile or internet security regulations and infrastructure that will impact a BYOD strategy? What happens when the subject gets a new device and the screen size changes?

Which therapeutic area?

Will patients have to complete questionnaires throughout the day (i.e., event-based diaries like those included in IBS or overactive bladder studies) or only at the end of the day? Will the subject have issues with downloading or updating an app, as in the case of patients with neurological impairments? What impact will carrying two devices have on patient compliance or retention? How often will a patient use the device? Where will they use the device? Will a caregiver use the device?

Needs and preferences of patient population?

Will patients be excluded because they do not own a smartphone or tablet? Can the patient's device accommodate another app? What if the patient just does not want another app on their device—does that automatically exclude them from the study? How will you address patient concerns about protecting data privacy on their device?

Regulatory agencies recommend engaging with them early in the process of formulating an eCOA and device strategy for a particular study.

If a sponsor chooses the **BYOD strategy**, a detailed plan may include, among other things:

- Security
- Whether subjects will access questionnaires over a web browser or an app that is downloaded onto the device
- App compatibility with operating systems

What data will be accessed from the subject's device

- Contingency plans for capturing data in the event of device loss or failure, connectivity issues, or if the app is deleted
- Data availability to the investigator and regulatory agency
- Data monitoring plan
- Subject training

If a sponsor chooses the **PD strategy**, the plan may include such factors as:

- Appropriate marking on devices for import/export
- Ensuring sufficient supply in case a sponsor decides to add patients/sites/countries many months into the study
- Determining how many extra devices will be needed to replace broken/lost devices

Another worthwhile exercise is to gain patient insight into technology preferences for reporting outcomes data specific to their disease state, and circumstances that may impact their compliance and retention. Study-specific insight can be gained during the protocol drafting stage by interviewing patients from that disease cohort to establish which modality might be most beneficial to that patient population. Broader insight on digital technologies in general can be gained through patient advocacy groups and focus groups to influence the direction of patient-reported outcomes data.

Advanced digital technology has the potential to revolutionize the entire clinical trial industry. It takes specialized expertise and experience to plan for and execute the best eCOA and device strategy to maximize efficiency and cost effectiveness.

---

[1] US FDA: FDA Patient-Focused Drug Development Guidance Series for Enhancing the Incorporation of the Patient's Voice in Medical Product Development and Regulatory Decision Making. 18Jun2020.
https://www.fda.gov/drugs/development-approval-process-drugs/fda-patient-focused-drug-development-guidance-series-enhancing-incorporation-patients-voice-medical

[2] EMA: Questions and Answers: Qualification of digital technology-based methodologies to support approval of medicinal products. 1Jun2020.
https://www.ema.europa.eu/en/documents/other/questions-answers-qualification-digital-technology-based-methodologies-support-approval-medicinal_en.pdf