BYOD
when, why and how

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INTRODUCTION

The sudden and unprecedented global changes resulting from the COVID-19 pandemic acted as a catalyst for the digitalization of clinical trials. The Bring Your Own Device (BYOD)[1] approach has emerged from a range of patient-centered methods of collecting patients' data electronically during clinical trials.

But when, why, and how should we be implementing BYOD strategies? This white paper gathers substantial information on BYOD approaches, describing the technical options available and showing their numerous advantages for both patients and clinical trial teams. As one size does not fit all, this white paper compares specific cases where such approaches make sense and bring value with situations where such strategies would not be applicable or where the benefit would not be strong enough to justify their implementation.

CONTENTS

WHAT EXACTLY IS BYOD? AND WHAT ARE THE MAIN CHARACTERISTICS THAT MAKE IT A STRONG FEATURE FOR DECENTRALIZED TRIALS?

The BYOD approach in clinical trials is a technique whereby subjects use their own smartphone or internet-connected device to perform PRO and eDiary assessments. BYOD includes mobile phones, tablets, and computers[2].

Although this approach is not new, it has gathered momentum during the COVID-19 pandemic, as teams had to adjust data collection and processing methods when patients were not allowed or were unwilling to continue attending clinical sites.

The term 'own device' covers several aspects, and BYOD can take the shape of web-based or app-based technology.

- **The web approach** requires a permanent internet connection, and the patient uses their own device to connect to the internet, access and complete questionnaires, and submit data. This has the advantage of not requiring any download that would necessitate storage capacity on the device but has the drawback of requiring a permanent connection.

- The other option is an **app-based solution** whereby the patient downloads an application on their own device which is then used to access and complete questionnaires. In this case an internet connexion may not be always required, which can bring some level of autonomy to the patients as they may be able to complete their questionnaires in an offline mode, but this solution encompasses the risk for the data to be stored locally for a certain amount of time. This has the downside of putting at risk the timeliness of the data transfer and monitoring.

Being a solution whereby patients can use their own devices to complete ePROs and eDiaries makes BYOD an important game-changer in the clinical trial industry. BYOD brings multiple benefits for both the clinical study team and the patients.

FOR PHARMA ORGANIZATIONS,

BYOD helps to save time and reduce costs, two major aspects for pharmaceutical companies.

- **Reducing turnaround time:** With eCOA implementation comes the need to provide devices, and the logistics and turnaround time for shipment to and from sites can be extensive. Such constraints are removed with BYOD, which therefore has a positive impact on study start-up timelines and the readiness of sites to enrol patients.
- **Reducing costs:** The BYOD approach decreases the volume of provisioned devices (PDs), which is associated with significant reductions in costs associated with device leasing, shipments, connectivity, and potential replacements, yet potentially increasing the cost of support due to the multiplicity of devices used.

The lack of the need for any logistical and financial management of PDs is also of human resource value, freeing up time for clinical teams to focus on other activities

This has also the added value of reducing the carbon footprint of the solution, since no additional device is required and the logistics-associated carbon emissions are also reduced. As such, BYOD can be considered a more eco-friendly solution..

FOR PATIENTS,

familiarity with their own devices improves the likelihood of patients keeping their device with them at all times. The use of their own device means that patients may care more, which can help increase compliance. Furthermore, using their own device can improve ease of use and means that patients do not have to 'think about' the extra device, which also reduces the burden on patients.

Another advantage is that it removes the round trips to the clinical site to collect and return the PD, thus reducing the well-known clinical trial participation barriers that travel cost and travel burden represent. This, in turn, may have a positive effect on clinical trial recruitment.

As this approach also allows patients to participate in clinical trial from almost any location, it can lead to increased diversity in clinical trials, increased recruitment, and can reduce the logistics burden on clinical trial participants.

At first sight BYOD appears to be a positive and cost-effective technology, so why not implement BYOD studies more widely? BYOD brings its own set of challenges and risks that deserve to be explored, and it may not be appropriate for all studies.

IT IS NOT A ONE SIZE FITS ALL:

KEY FACTORS TO BE CONSIDERED FOR DEVELOPING A BYOD STRATEGY

Challenges for BYOD include compliance risks, technical difficulties, data security and data privacy, and patient diversity.

COMPLIANCE RISKS

Although using a familiar device and not having to think about an extra device can help to maintain a high level of compliance, the possibility of muting the device or disabling notifications could eliminate the audible notifications and reminders.

- Thus, in studies where very high level of compliance is mandatory for score calculations (e.g. score driving randomization), the study team will probably need to consider the risk of reminders that can be forced when PD solutions are used being inaudible. The option of providing a device for the screening data collection period should be considered, and the pros and cons discussed as a team according to the specifics of the patient population, the duration of the data collection period, and the criticality of the data points.

- A robust contingency plan for capturing data in the event of device loss, device failure, or if the app is deleted by the patient will also be necessary. WebCoA[3] that can be available from any type of electronic device including the patients home computer or a quickly accessible PD will probably be the back-up plans that provide the highest comparability in terms of data collection.

TECHNICAL DIFFICULTIES

Sponsor, site, and service providers must deal with a device and all the issues that come with it. If an app-based BYOD is to be used off line, the patient's device should have enough memory to store both the app and the data. Additionally, the patient may delete the app—and thus delete data—or may upgrade their phone during a data transfer, which could jeopardize data transmission to the eCOA server. The study team:

- May consider implementing an app-based BYOD study if the study is not very demanding in terms of the data collected. With a low number of questionnaires and a limited volume of eDiary data, the risk of insufficient storage space on patients' phones is reduced. This risk is even eliminated when using a solution in an online mode only. On the other hand, studies with regular visits, procedures that require the patients to attend the study site, numerous questionnaires to be completed on site, and daily diaries, may not be appropriate for a BYOD solution.

- Should also consider the study from the strategic standpoint: Is the study an exploratory trial, or a long-term pivotal trial taking place in many countries with different internet security regulations? This should be assessed as part of the risk mitigation plans.

Also, as BYOD requires dealing with a large variety of operating systems (OS), screen sizes, resolutions, storage capacities, and browsers, there can be risks of non-comparability between devices. The generation of any potential bias that could be introduced in this way should be considered and study teams may wish to try a BYOD option on a limited number of suitable devices.

- As such, proposing a hybrid solution where some patients use their own device if suitable, whilst others complete their PROs and eDiaries using the comparable provisioned device, is appropriate. This can be even more relevant in studies using scales for which equivalence demonstration would not be considered sufficient[4].

DATA SECURITY AND DATA PRIVACY

Security and privacy of patients' data is essential, but in a BYOD scenario, clinical study and other private data may coexist on the same device. The study participants are likely to have personal and sensitive data such as photos or bank information stored on their device. Some apps installed by the user for private use have the potential to automatically share data held on or accessed by the device.

- Some security controls can be implemented within the solution: opting for a web browser embedded in an App means that no clinical data are stored on the patient's device, which reduces the data privacy risk but requires patients to be online to complete their questionnaires or eDiaries. HTTPS data transfer secures data access, and encrypted data are then securely stored in the eCOA vendor data center.

- How will the team address patient concerns about protecting data privacy on their device? These are also key considerations to make when informing and training patients in a study. Data security should be addressed with clinical site staff, and it is the responsibility of the eCOA vendor and the sponsor to develop clear information material that will be used to inform the site teams. Well-informed site staff will always be in a better position to caution and inform patients.

PATIENT DIVERSITY

Although BYOD allows study patients to participate in a clinical trial from almost any location with the comfort of using their own familiar device, the downside of BYOD is that every potential patient would need to have a suitable device. Adding this to an already extensive list of inclusion criteria would not only be ethically unacceptable but it would

also narrow the study population to one that may not be representative of the real population. Also, some patients may not want another app on their device or may not want to use their own device, preferring to separate their personal and clinical trial environments.

- To prevent this potential impairment of patient diversity and recruitment, and to respect patients' preferences, study teams should consider including a PD strategy to a BYOD approach.

And the regulatory positions regarding data captured through BYOD solutions also need to be considered. The FDA and EMA are showing an increasing interest in BYOD but have not issued formal guidance regarding acceptance criteria for BYOD-captured data. Until such guidance is made available, study teams may refer to the US FDA Patient-Focused Drug Development Guidance Series for Enhancing the Incorporation of the Patient's Voice in Medical Product Development and Regulatory Decision Making[5] and the Draft guideline on computerised systems and electronic data in clinical trials (europa.eu)[6], and may plan to address their BYOD strategy with regulatory bodies as they see fit[7].

CONCLUSION

BYOD offers significant advantages for both patients and pharma organizations, and with the rapid evolution of technology, BYOD utilization will grow in near future.

However, several considerations are important before implementing a suitable BYOD strategy, which is not yet fully ready to be used as a stand-alone option.

Further work to address the BYOD approach in clinical trials is necessary to resolve remaining technical queries, reduce data privacy risks, and ensure patient diversity, before regulatory bodies issue guidance regarding acceptance criteria. Flexible approaches probably remain the wisest option while these questions are resolved, to allow clinical trials to move forward in the digital era while keeping patients safe.

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