ePRO data collection

Decision-Making for the Adoption of a Bring Your Own Device Strategy

Kayentis

INTRODUCTION

Electronic devices have been systematically provided to participants to report Patient Reported Outcome (PRO) data in clinical trials and electronic Patient Reported Outcomes (ePRO) data collection methods have evolved over time. The current desire to reduce participant burden and drug development costs, combined with improved technology, has led to increasing interest in having study participants use their own devices ('bring your own device' or BYOD) to collect PRO data.

However, the uptake of BYOD technologies remains low despite significant interest from industry in their development. The lack of clear regulatory guidance on BYOD approaches has created a vicious circle: clinical teams are not encouraged to pioneer clinical trials submissions using BYOD-collected data, which limits publications on BYOD success stories, meaning that cautious clinical trial teams are not prompted to take the plunge and broadly adopt BYOD options.

What does the industry need to make a step forward and implement BYOD strategies? How can confidence grow so that study participants can benefit from the comfort of using their own device to collect PRO data? This white paper sets explicit expectations as to what BYOD strategies bring as well as the associated risk, and proposes structured help to support successful BYOD strategy decision-making processes and implementation.

CONTENTS

DRAW CLEAR EXPECTATIONS:

WHAT ARE THE TRUE BENEFITS OF IMPLEMENTING A BYOD STRATEGY?

As the number of data collection methods grows significantly, having a clear understanding of the value of each of them becomes necessary to set clear expectations for all clinical trials stakeholders. Having a range of solutions available to capture ePRO data is advantageous only if those who choose and use these tools clearly know what to expect from each one.

Regarding BYOD, the value is based on several aspects.

CONVENIENCE

- The BYOD approach is becoming an increasingly viable option for large-scale, interventional trials, as it is expected patients will find it easier to use their own smartphone than an unknown provisioned device (PD)[1]. Having only one device is perceived as less burdensome to patients, who find it a relief not to have to remember to bring an extra device everywhere, especially during demanding studies where eDiaries must be completed every day.

- Chronic disease patients and study participants already have a lot to remember on a daily basis. They must undergo several recurrent procedures, attend multiple study visits, and regularly complete numerous questionnaires. If we can bring them some comfort by offering options to decrease the volume of supplementary material to take care of and use, we should do it.

- Another advantage of BYOD use is the removal of trips to the clinical site to collect and return the PD, alleviating a well-known barrier to clinical trial participation, ie, travel costs and burden.

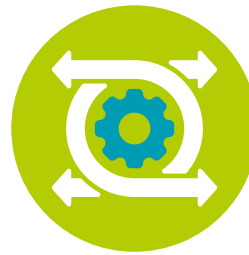
- As this approach also allows patients to participate in clinical trials from almost any location, it can lead to increased diversity and increased recruitment in clinical trials, by expanding access to much more remote areas[2].

COMPLIANCE

- It is expected that study patients would be less likely to forget their own device, which they are accustomed to carry with them routinely, than a separate PD. As such, although confirmation of this hypothesis is lacking in the scientific literature, it is expected that the BYOD option would improve study compliance. Not only are patients less likely to forget their own device, they are also potentially more inclined to pay careful attention to reminders from their own device than those from a PD.

- A reminder notification or sound that is unfamiliar on a PD is more likely to be missed or ignored, particularly when the PD has been safely stored and potentially forgotten, whereas those on a regularly checked smartphone are more likely to be addressed in a timely manner.

- In addition, it is important to note that it is possible to ensure that the presentation of PRO items is consistent regardless of the device type used. A growing body of evidence supports measurement comparability between paper and a variety of electronic formats, underlining the hypothesis that small presentational or format changes between devices have little to no impact on the integrity of PRO data[3].



FLEXIBILITY

- Patients can reduce their travel burden by using their own smartphone. When the solution is as simple as downloading a free App from public stores and linking the phone to the study by a QR code, the necessity for study site visits can be reduced. A simple and well-designed user manual can be enough to support the study participant. And if the smartphone is lost or broken, a web back-up solution can be used on the patient's own computer, so that again, travelling to the study site to get a spare PD is not necessarily needed even in the event of BYOD failure.

- Ultimately, what BYOD brings are alternatives and more choice. As clinical research evolves and expands, the integration of numerous technologies, bringing more choice to patients, has become a prominent approach. The adoption of patient-centric approaches encompasses many factors, including better flexibility for study patients, the ability for patients to adapt data collection to their own preferences, and mirroring lifestyle technologies that patients are now accustomed to using routinely.

UNDERSTANDING THE CHALLENGES OF BYOD:

WHAT DO WE NEED TO PAY ATTENTION TO?

Despite numerous advantages, opting for a BYOD solution also includes some risks that must be clearly understood so that relevant mitigations can be anticipated.

DATA STORAGE CONSTRAINTS

- Implementing a BYOD strategy means patients use their own device, in their own way. Even with the best imaginable app and the clearest training material, it is not possible to control the storage capacity of patients' own phones. And so the choice of a BYOD strategy inevitably includes a risk regarding data storage.
- If the option considered is to use an app-based BYOD, the patient's device should have enough memory to store both the app and the data but there remains a risk that the patient may delete the app and/or the study data, or may upgrade their phone during a data transfer, any of which could jeopardize data transmission to the eCOA server.

This risk can be mitigated with a web approach solution, whereby no space is required for download and collected data are continually transmitted, eliminating the risk of data loss.

DATA SECURITY CHALLENGES

- In a BYOD study, private data and data from the clinical study may coexist on the same device. Study participants are likely to have personal and sensitive data such as photos or bank information stored on their device, and some apps installed by the user for private use have the potential to automatically share data held on or accessed by the device. As such, complete separation between clinical study data and other types of data may not be guaranteed, and as BYOD becomes more prevalent, so does the need to discuss its security challenges.

  Adequate protection through relevant software installation is necessary to enforce security policies to ensure that clinical study data on the device are secure. Opting for an online solution can also contribute to mitigating this risk.

Guaranteeing the relevant level of security will not only protect the privacy of the patients and the security of the data, but it will also help promote the adoption of BYOD solutions if patients feel confident regarding their personal data security.

SMARTPHONE AVAILABILITY VERIFICATIONS

- According to Statista, in 2023, the current number of smartphone users in the world is 6.92 billion, meaning 86.29% of the world's population owns a smartphone[4]. This figure is considerably higher than 2016, when only 3.67 billion users (49.40%) were reported.

- Despite these figures, there are still countries in the world with vast populations and low smartphone adoption[4] (eg, India, where only 31.8% of its population of 1.38 billion own a smartphone). This should be a consideration when envisioning a BYOD strategy. When it is planned that the study will include countries with low smartphone penetration, alternatives will be necessary to avoid the undesirable and unethical situation of being incapable of enrolling patients due to smartphone availability.

The BYOD approach addresses many clinical trial concerns but has its own limitations that should also be considered. Researchers need to make informed decisions when choosing methods to collect eCOA data and must have the keys to understand when the BYOD option is the most appropriate method.

CHOOSE A RELEVANT BYOD STRATEGY:

WHEN DOES IT MAKE SENSE?

Given how eCOA technologies have evolved, both BYOD and PD methods will generally work for any eCOA study; however, there are situations where one or the other may be preferred. By checking key criteria, clinical teams will proceed through an informed decision-making process.

STUDY DESIGN CRITERIA

Not every protocol will be suitable for a BYOD study:

- **Considering the volume of data to be collected:** with the data storage risk that coexists when a native app solution is chosen, study teams launching research that involves very large volumes of data might opt for a PD solution, or may need to verify that the planned BYOD option is a web-based solution that allows for collected data not to be stored in the device.

- **Considering the type of endpoints:** although BYOD solutions are generally very reliable, there are situations where data collection might not be possible (eg, smartphone lost or broken, technology failure). With any electronic data collection strategy, back-up solutions are generally provided routinely as a complement to the primary eCOA mode to cover these situations; PDs or WebCOA are also made available as best practice in BYOD studies, which are generally implemented in a hybrid mode. However, a clinical team with little experience of BYOD or having opted for a native app solution may prefer to not choose a BYOD solution when the data to be collected will be used to calculate the study primary endpoint.

- **Considering the frequency of the ePRO and eDiary assessments:**
  - In a scenario where eCOA administrations are very frequent (eg, daily eDiary data collection for several months), the value of using their own device will be high for patients: they can benefit from highly customizable reminder alerts or notifications and will not have to carry multiple devices every day.
  - Alternatively, a BYOD option for a study with very few and far-apart ePROs (eg, patients completing an ePRO every 3 months) can also be very beneficial, as it will significantly reduce the risks of forgetting, losing, or leaving the PD uncharged.
  - On the other hand, for a study with weekly or monthly assessments, both BYOD and PD options should work equally well.

- **Considering study timelines:** long studies may particularly benefit from a BYOD approach: carrying multiple devices for years is likely to be be perceived as annoying by study patients and the simplicity offered by a BYOD option will be particularly important long term, whilst the burden of having two devices could be perceived as more manageable for a limited amount of time.

PATIENT POPULATION CRITERIA

Similarly, the patient population characteristics must be checked, as not all patients will behave the same way for various eCOA data collection approaches, and here more than anywhere else, flexibility will be paramount to study success:

- **Considering patient age ranges:**
  - despite a lack of scientific evidence that studies recruiting elderly populations are not the best fit for BYOD studies, it is possible that elderly patients, not having grown up during the era of smartphone technologies, might be more cautious regarding data privacy and potentially more reluctant to use their own device (if they have one).
  - On the other hand, younger adults, and particularly adolescents, being frequent users of mobile technology, might immediately perceive the value of completing their questionnaires on their own device. And so in these latter populations, the BYOD option shows potential as a strategy for improving self-management and adherence to protocol requirements.

- **Having your sites consider patients' lifestyles and preferences:** even when opting for a BYOD study, the recommended approach will be to implement the study in a hybrid mode, so that the option to fall back to a PD to meet the patients' preferences is always possible.

- For patients who are very comfortable with technology, who travel frequently, or who are particularly resistant to the burden of multiplying tools and systems, the most suitable option will be to complete their ePROs and eDiaries on their own device.
- For patients who are more reluctant regarding potential data privacy challenges or who may not feel comfortable with completing their questionnaire on their own device, then the fall back to a PD will be more appropriate.

Although this criterion cannot be checked at the time of BYOD approach decision making, this must happen at the time the study site staff have the preliminary discussions with the potential study patients.

Of note, a recent qualitative study[5] conducted by PRO Consortium and eCOA Consortium to compare participants' experience using a PD versus their own smartphone demonstrated that participants' experience of completing PRO measures was consistent across both PD and BYOD, with a preference for one of the device types being evenly split.
The absence of a strong preference for either PD or BYOD approaches reflects the high variability in patients' lifestyles and preferences, and it is unlikely that a one-size-fits-all approach will be appropriate. As giving flexibility to study patients will allow them to manage their preferences, offering the option of using their own smartphone but being able to default back to a PD to accommodate those who do not own a suitable smartphone or choose not to use their own device is likely to be the wisest strategy.

GEOGRAPHICAL CONSTRAINTS

Even if digital technology seems to have spread throughout the world, with over 11 billion mobile connections existing worldwide (which exceeds the current world population of approximately 8 billion) there are still parts of the world where implementing a BYOD strategy might not be ideal.

- **Considering the study country list:** it is possible that downloading an app to access the BYOD solution might be problematic. For instance, regulations in China do not allow apps to be downloaded from the Google store, and so a BYOD option is only possible on iOS via the Apple store and would only be possible on Android via alternative stores. Also, as the rates of smartphone saturation are considerably lower in countries outside North America, Europe and South Korea, it seems reasonable for clinical teams to weigh up the pros and cons regarding the suitability of BYOD approaches in such countries.

- **Considering the patients' home location:** it will be important for site staff to understand where patients live and to have some visibility on their connectivity coverage. Despite the considerable penetration rates mentioned above, it can still be possible that some patients have limited coverage and alternative data collection strategies may be necessary to ensure that these patients can remain compliant with their data collection requirements.

CONCLUSION

Offering study participants the option of using their own devices to collect PRO data in a BYOD approach is increasingly capturing interest in clinical trials. BYOD strategies bring significant value including improved convenience for patients, and are expected to be accompanied by better compliance. However, but beside their numerous advantages, BYOD approaches include some challenges. Relevant considerations ahead of time include verifying that the study design, the patient population, and the geographical constraints do not create a study environment that becomes less favorable to implementing a BYOD strategy. Also, implementing the clinical trial in a hybrid strategy, together with an appropriate back-up plan for data collection, will create efficient safeguards for clinical teams opting out of a BYOD approach. Ultimately, using a BYOD option remains a clinical team's informed choice, and should be considered when it makes sense.

BIBLIOGRAPHY

1 https://pubmed.ncbi.nlm.nih.gov/35949223/

2 https://kayentis.com/technological-ways-to-make-clinical-trials-really-global/

3 https://jpro.springeropen.com/articles/10.1186/s41687-022-00521-3#ref-CR1

4 https://www.bankmycell.com/blog/how-many-phones-are-in-the-world#part-1

5 https://jpro.springeropen.com/articles/10.1186/s41687-022-00492-5

Estelle Haenel

Kayentis Chief Medical Officer

Kayentis