Mobile ePRO as a Cost-effective Method of Patient Data Capture

As digital technology plays an increasingly important part in our everyday lives, it comes as no surprise that it has a huge potential to address some of the key challenges faced by the pharmaceutical industry as well. The collection of electronic clinical outcomes assessments (eCOA, which includes patient-reported outcomes (PRO), observer-reported outcomes (ObsRO) and clinician-reported outcomes (ClinRO)) data via PDA and smartphone devices is an area of clinical research that benefits from digital technology in particular. The revolution in personal mobile adoption and advances in wireless data exchange technology now make it possible to design flexible technology solutions that align with the needs of the target patient population, rather than mandating a ‘one size fits all’ approach across all demographics. Mobile technology allows researchers to communicate with patients remotely between site visits through a medium that patients carry with them wherever they are. It provides an effective system for sending reminders to ensure timely actions such as attending clinic visits, correct drug intake, fasting, etc., while also serving as the means to communicate much more broadly with the patient, facilitating a two-way open communication channel that allows patients to respond to prompts as appropriate. Alongside this ability to engage patients, eCOA facilitates real-time data collection and, through using a mobile ePRO approach, the benefits of electronic data capture can be incorporated in a cost-effective manner.

Benefits of ePRO in Clinical Trials
The increasing popularity of mobile ePRO tools has transformed the way patients engage in clinical trials. Providing familiar technology to patient populations facilitates the collection of time-stamped data, and, as mobile technology has propagated across the globe, it serves as an ideal mechanism for communicating and collecting data from hard-to-reach patients in developing markets such as Eastern Europe, Asia Pacific, and Latin America.

Ensuring the simplicity of the data collection interface is especially crucial considering that paper diary compliance is proven to be as low as 11%1. ePRO solutions can provide a simple, effective modality to communicate and collect data and information from patients. As users are already familiar with the technology, they can navigate easily through the different steps of the data-collection process. Consequently, these tools facilitate simple, real-time, and reliable collection of data from study participants, irrespective of age or demographic.

Mobile ePRO solutions can be customised to suit the specific requirements of each trial. The assessment could consist of a series of text messages sent intermittently to a patient’s mobile phone to deliver online questionnaires, which can then be answered instantly via the mobile device. Alternatively, assessments could be delivered via an app, which is particularly useful when connecting with patients in regions with limited connectivity, as data can be stored within the app and transmitted when connection is available.

Adopting a mobile ePRO approach can be extremely cost-effective for sponsors. The flexibility to select a device that fits the required functionality allows providers to work within study budgets. Additionally, the approach can reduce support and training costs during studies themselves, as selecting a familiar device can simplify training requirements and limit the number of support queries, while the use of up-to-date devices can lead to fewer failures in the field. Applying ePRO solutions through apps can further enhance efficiencies and cost savings, for example deploying interim study updates remotely without the need to recall patients and their devices back to site.

A common misconception regarding the use of ePRO is the perceived difficulty in the deployment of validated instruments. This is because when certain instruments are used to collect primary end point data for label claims, it may be necessary to validate on the selected ePRO modality. To achieve this when using a mobile approach, the author/owner of the instrument must first approve the use of the scale using the chosen modality. Typically a usability study will then be performed to ensure patients can interact with the electronic version and then a validation study will be conducted to assess psychometric equivalence compared to existing modes of delivery. An example of such a study is the m-WOMAC Osteoarthritis Index, which was found to be valid and reliable using a simple mobile phone application and showed no statistically significant difference between mobile and paper scores2.

Technology
Medical device readings are also an important part of eCOA data. The move towards ePRO data collection and the addition of Bluetooth® technology on many devices now enables integration of medical device readings into regular ePRO collection by the patient, such as blood glucose meters and spirometers, whether it is as part of a clinical trial or in a real-world setting. Furthermore, alongside the collection of primary outcomes data, ePRO can incorporate secondary outcomes data through the passive integration with lifestyle devices (such as activity trackers, thermometers or weighing scales) which are becoming increasingly popular tools for use in clinical research.

**BYOD in Clinical Research**

Whilst many studies require a provisioned model, the BYOD (bring your own device) approach is now recognised as a viable method of engaging and collecting data from trial participants through the ability to recognise device parameters and optimise the configuration of data according to the device in use (e.g., laptop, tablet, mobile phone). BYOD offers the eCOA market true scalability with potential to service studies which would not fit into the fully-provisioned model. The growth of digital and mobile technology has resulted in many patients already owning a device that can be used during the study. Device analysis can easily be integrated into patient enrolment, and provisioning can typically be reduced to as little as 10% or 20% of study participants. In some cases, this approach has the potential to remove the need for provisioning altogether such that the patients’ own devices are employed throughout the entire study, although it is also important to appreciate some level of device provisioning is likely to be required for the foreseeable future.

**Case Study – Incorporating Patient Data Capture Using Mobile ePRO**

Trigemina’s TI-001 is a patented application of a formulation including oxytocin with a novel mode of action (MOA) as a therapy for high-frequency migraine. Following several single-dose trials in which TI-001 demonstrated promising analgesic effects, a new Phase II trial was initiated in mid-2013 to seek analgesic effects and reduction in frequency of migraine headache days in a chronic and high-frequency episodic migraine population.

The decision to use electronic patient-reported outcomes data (ePRO) was an important part of Trigemina’s clinical strategy. Migraines are not timed events. In a multi-month trial such as Trigemina’s, in which patients record their headaches round the clock, ePROs were vital components of the study protocol. Although missing data is known to be a major problem with PROs recorded on paper, Trigemina were far more concerned with data integrity. Knowing that patients are under no direct obligation to enter data on a real-time basis, and that they can wait days or even weeks and then try to recall their experience, ePRO provided the necessary assurance that data was entered by the patient at the time the migraine episode occurred.

There were a number of considerations when selecting the best approach to incorporate ePRO into the TI-001 study, a key one of which was cost. The study required provisioning of mobile devices to all patients to preserve psychometric validity and a consistent user experience across the patient population for the collection of primary endpoint data. Despite the 100% provisioning requirement, the mobile ePRO approach offered a more cost-effective solution than other alternatives, whilst providing all the necessary reassurance of experience, data security and quality.

The selection of mobile ePRO had a positive impact on the conduct of the TI-001 study, most notably through the immediate access to data it has provided for review and progression. It was not only important to monitor the progression of the study itself, but the ePRO data collected to date has shown positive results and has been a pivotal factor in securing further funding from investors. Additionally, these exciting early results have enabled Trigemina to significantly expand the study. The trial population has been increased almost threefold and sites in Australia and New Zealand have now been introduced, to meet their desire to garner data from multiple ethnic populations.

The use of mobile ePRO to collect primary endpoint data has been a pivotal factor in the progress and expansion of the TI-001 Phase II clinical trial. The deployment of this cost-effective ePRO service enabled Trigemina to review data in real time. This ability has been especially valuable as they were able to observe the exciting early results of the study and use these positive indications to secure additional funding, which in turn has facilitated the expansion of the study into two new countries.

**Conclusion**

Looking at the current landscape of the pharmaceutical industry, mobile ePRO will evidently play a large role in the drug development process through its cost-effectiveness, improved quality of patient data and the simplicity of data capture. Electronic data capture holds huge opportunities for clinical research, with the key potential to reduce the major financial burdens of running clinical trials in the long run. ePRO is increasingly being used as a means of collecting patient data across broad demographics and multiple locations in both clinical studies and healthcare programmes. The universal nature of mobile devices and the ability to select the right tool according to the type and specifications of a study makes the technology well-placed for integration into global markets.

**References**

2. Bellamy, N. et al., “Osteoarthritis Index Delivered By Mobile Phone (m-WOMAC) is valid, reliable, and responsive.” (2011), Journal of Clinical Epidemiology, 64(2) pp.182-190.

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