

Advancing Mobile Data Capture in Clinical Trials

The last decade has seen the emergence of a new player in the completion of clinical outcome assessments (COAs): electronic data collection. This method of capturing information directly from patients is proving to be an ever-more valuable tool for sponsors, sites and patients themselves, facilitated by the global growth of mobile technology. It has created a new, more efficient way to access patients and provides an ideal platform for capturing assessment data, commonly known as patient-reported outcomes (PRO).

At its core, mobile technology is able to support the diaries, scales and questionnaires required for capturing electronic PROs (ePROs) during trials. However, the advantage mobile ePRO holds over paper and other types of ePRO devices lies in the provision of a simple intuitive interface for patients, that facilitates the two-way communication vital in keeping patients engaged. For example, educational and motivational content can be delivered via messaging and in-app notifications throughout a patient's participation in a clinical trial.

The barriers to the use of mobile ePRO have been broken down through the incorporation of data security measures to protect patient data, the validation of a wide range of instruments from paper entry to mobile, and the reassurance of regulatory acceptability – both through public statements such as the comment from the FDA that the “BYOD (Bring Your Own Device) approach does not contravene 21 CFR Part 11”¹ and, perhaps more substantially, the use of mobile ePRO to collect primary outcomes data in numerous product approvals in Europe and the USA.

This shift away from ePRO device provisioning towards an approach where patients are able to use their own mobile devices has caused much debate within the healthcare industry. There has been the mistaken belief that when introducing BYOD into a protocol, enrolment of patients with a specific type of device is the **only** option. That approach would be offering choice in the same way that Henry Ford did to the choice of colour for his Model T car – you can bring any device to this study, as long as it's an Android with Ice Cream version 12.2 OS – an approach which would seriously limit study eligibility criteria.

The reality of BYOD in clinical trials is very different. The provision of ePRO solutions for BYOD trials almost always introduces an element of provisioning in pre-approval studies. The key is to be able to identify the specifications of the patient's device and ascertain whether it meets the requirements for the individual study. If not, then a suitable device can be provisioned – a flexible provisioning approach. The provisioning rate for such studies is decreasing year-on-year as the uptake of more advanced mobile technology increases: in the US

almost ¾ of adults over 65 now own a mobile phone². In pre-approval studies we are seeing rates anywhere from around 50% provisioned down to as low as 10%, depending on the study population. This provides two significant benefits: not only does it enable the patient to use their own device, the one they personally selected from all available options; but it significantly reduces the cost and logistical complexity of device provisioning for sponsors.

A decade ago, no-one could have predicted just how far mobile technology would advance and how it would become such an integral part of daily life for people around the world. Mobile eCOA has now been proven to be a highly beneficial and versatile option for data capture in clinical trials. Evidence shows that this modern, more efficient method of data collection has significantly improved PROs and has been used – both through a provisioning and a BYOD approach – to collect primary outcomes data in Europe and US drug approvals.

The industry continues to escalate its adoption of mobile ePRO, which is now expected to become the standard approach to collecting self-reported clinical data.

References

1. Panel session at MCT Congress 2014
2. <http://www.pewinternet.org/data-trend/mobile/cell-phone-and-smartphone-ownership-demographics/>



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