Improving the quality and accessibility of clinical data collection through patient engagement

It is widely recognised that putting the patient at the centre of a trial's design can significantly improve the quality and accessibility of data collection. To do this, pharmaceutical companies need to first understand patients' needs and expectations, as well as make sure that the trial participation fits into their daily lives. In short: the patient must feel engaged throughout the process. Keeping the patients engaged in the study regimes allows for capturing their data more easily, which enables adapting the system responses in order to personalise content and provide target reports and summaries to all stakeholders in the clinical research. Engagement, however, is more than simply providing reminders to the trials' participants. Patients should be supplied with the most appropriate technology and features which would not only fit seamlessly into their daily routines, but which would also make their participation in a trial more rewarding. Putting the patient at the centre of a trial's design can significantly improve the quality and accessibility of data collection during clinical research.

Improving accessibility through patient engagement

How then, to ensure that patients are put at the centre of a trial's design and are engaged throughout? Traditionally, data collection was conducted using paper diaries due to the associated hardware costs of implementing electronic solutions. However, collecting and consolidating data this way can be resource-intensive and a burden on both timescales and budget. Additionally, data analysis is near impossible due to the difficulty of re-engaging with patients and the timeframes elapsed between recording and review. The clinical research industry is increasingly adopting a more patient-centric approach which recognises that if patients are supported throughout a study, higher levels of compliance and retention can be achieved[1].

Patient engagement also goes beyond the communication plan; to truly engage patients throughout the study lifetime it is important to make their required actions as simple and non-intrusive as possible. A device inclusive approach facilitates seamless integration of clinical trial activities into the everyday lives of patients, through the flexibility to select any connected device for communication and data capture. This should be coupled with the ability to build in true mobility enabling the patients to send and receive data using different media to fit in with their lifestyle.

Listening to the patients during drug development, and partnering throughout their clinical trial experience, as well as the simplification of methods to capture and report patient data obtained during the trial, is now seen as vital to pharmaceutical R&D success. Sponsors and

clinical research organisations (CROs) have demonstrated a growing desire to simplify clinical data collection by implementing innovative solutions that provide greater access (in real time) to better quality data, in a more cost effective way[1,2] – whilst in parallel helping to facilitate continuous patient engagement for the duration of the trial[3,4].

Using mobile solutions, each study can be designed to include a relevant, tailored communication plan. This is not the future – mobile technology is now being implemented as a means of communicating directly with patients across broad demographics and multiple widespread geographic locations in clinical trials. Simplicity is the key. A single system can be used to engage with patients, collect data and enable real time data review by all stakeholders. Patient outcomes can then be integrated into a single data repository which creates standard reports for instant access. As a result physicians and sponsors can address safety risks as they occur.

Reinforcing patient engagement

The rise of electronic clinical outcome assessments (eCOA) and, specifically, electronic patient reported outcome (ePRO) tools implemented through everyday mobile technology has transformed how patients can be engaged throughout a clinical trial. Through this approach each study can be designed to include a relevant, standardised and tailored communication plan, delivered through SMS messaging, emails or in-app notifications. As such, patients can be prompted to take medication, record data and attend site visits, where previously they typically would have been left with no support between the visits. In addition, through the inclusion of timely and relevant educational and informational messages, they can be better engaged throughout the duration of the study, which not only makes trials an easier and more useful experience for the patients, but also enables researchers to collect and process fuller data quickly, accurately and reliably.

With clinical trials now commonly being conducted on a global scale, increasing efficiencies in data management is critical, and a 'device inclusive' approach can deliver return on investment through a number of avenues, facilitating patient involvement at the same time. The BYOD (Bring Your Own Device) approach offers the eCOA market true scalability and has the potential to greatly reduce the considerable cost and logistical effort of providing and maintaining traditional ePRO devices for all patients participating in clinical studies. However, provisioning may be required for example when a validated instrument is being used to assess primary outcomes, or where Bluetooth® integration with next-generation home monitoring devices is included. Irrespective of which model is used however, the device inclusive approach can ensure that the technology used to capture and disseminate clinical assessments is both practical and effective in addressing protocol requirements, and is also engaging and convenient for study participants.

A patient-centric ethos

One of the easiest ways to ensure that patients feel wanted and engaged throughout their participation in a clinical study is to simply thank them for their efforts and time. Appreciating their participation and involvement can have a substantial effect on the morale of the patient, and affect their decision on whether or not to enrol in future trials. There is also a growing drive in both the EU and US to allow clinical trial patients access to their own data, so that they can see physical evidence of their own contribution to the outcome of the trial. This could further strengthen their engagement in the study regimes and make them feel like part of the wider drug development story.

A commitment to putting patient engagement at the heart of your study ensures increased patient compliance to required activities. This has several benefits, including increased quality and accuracy of data, and the ability to meet tight deadlines and budgets. A patient-centric ethos will also increase retention, reduce lost-to-follow-up and improve clinical outcomes through improved adherence.

References

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