Sponsors and CROs: Closing the Technological Gap in Clinical Trials

Engagement has recently been established as a key concept within clinical trials. This trend has delivered a multitude of benefits for participants, who, rather than being unconnected from the trial between site visits, now engage in a continual technology-enabled dialogue with their study. However, the industry has overlooked the potential for engagement technologies to benefit two other key stakeholders: sponsors and CROs.

These stakeholders have first-hand experience of the value of these technologies. Previously, interactions were limited to occasional site visits, with patients receiving varying levels of support or encouragement in between. Even well-intentioned patients forget to take their medication, and drop out of studies because of a failure to maintain the enthusiasm that initially drives them to enrol. However, the rise of SMS text messaging – and subsequently in-app notifications – has enabled continual dialogue, and mobile devices have enabled sponsors and CROs to oversee a transformation in the relationship between clinical trials and participants.

Conversely, the use of these technologies has meant that the amount of data these other stakeholders need to manage has increased – data which are potentially very valuable and can yield insights that improve the performance of an active trial and show where improvements might lie.

Breaking Down Silos, Creating Insights

Organisations in every sector are tracking a wider range of metrics than ever before, so what is needed are technologies that can intelligently connect and handle large datasets. Currently, the ability of CROs to derive insights that improve the performance of an active trial is hindered by the fact that data are siloed within each module of a study, making overall performance monitoring difficult.

Technologies must pull down unnecessary silos, making it possible for each type of organisation to access all of the data it is permitted to see. This new type of system would remove barriers that obstruct data-to-insight workflow, and provide sponsors and CROs with the tools that can sort and package information in a meaningful way. The next generation of clinical trial tools must handle information in a way that yields easy-to-understand insights through real-time data.

Clinical trials are complex operations, and each end user needs access to different information. Sometimes access to details is limited by regulation, making things even more complex. An ideal system would differentiate between types of data and user, adjusting its response and output accordingly. By tailoring the display to a user's permission level, unauthorised access to data would be prevented. This would also allow users to access data relevant to their jobs. Moreover, a well-designed system would issue targeted alerts whenever data, analyses and reports are available.

How Sponsors can Benefit

Patients already benefit from systems which alert them to information relevant to the study they're participating in. The specifics of how to extend these types of benefits to sponsors are tied to their position within the trial process. Sites oversee patients; CROs oversee sites; and sponsors oversee everything, meaning sponsors need a macro-level view of a trial's, or multiple trials', performance.

Specifically, sponsors need quick, straightforward ways of monitoring their clinical research programmes. Currently, clinical trials are generating these data but technological shortcomings are rendering the insights they contain inaccessible to sponsors. Opening up the data will yield multiple benefits. If a sponsor can pull up data on enrolment and compliance and compare them to targets they will have more productive progress reviews with CROs.

This workflow is underpinned by access to real-time data analyses on the status of a clinical trial. The system must pull in data as they are generated and very quickly analyse and package information in a meaningful way. Without such a rapid system, sponsors will struggle to respond to issues quickly enough to have an impact on the running of clinical trials.

What CROs Stand to Gain

Granular data are more useful to CROs than macro-level overviews. It is normally CROs that contract with sites. As such, CROs need easily-digestible data on how a clinical trial is performing on a site-by-site basis. Real-time access to these data can determine whether or not a study falls behind.

For CROs, the criticality of the data derives from their ability to support performance-altering decisions. If a CRO can identify which sites are struggling to enrol patients early on, it can initiate support actions to bring centres up to speed. A CRO can also spot high-performing sites, learn what's working there, and transfer the lessons accordingly.

These immediate, targeted benefits are complemented by longer-term gains. Technology can also provide an overview of multiple clinical trials, giving a snapshot of the overall health of the activities being overseen by a CRO. Retrospective analyses of these activities can uncover learnings that enable CROs to improve the design of future trials. This can save time and reduce the risk of problems arising once a trial is live.

The Value of Integrated Engagement

This technological framework has the potential to end the uneven distribution of benefits unlocked by clinical trial engagement technologies. Lately, patients have rightly been the focus of trial engagement initiatives with the use of mobile devices leading to studies becoming ever-more attuned to patient needs.

Like patients, sponsors, CROs and sites can all benefit from these advances. Information already exists – what was lacking was a way to organise and analyse data that met the unique needs of organisations. This technological gap has now been addressed and soon the current system will appear as outmoded as the pre-patient engagement era appears to us today.

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