Customer Loyalty

Recent advances have proven successful in keeping participants engaged in clinical studies, but have neglected to consider two other important stakeholders – namely sponsors and CROs. What can they gain by implementing such technologies?

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at Exco InTouch

Engagement has been established as a key concept in clinical trials over the past decade. The trend has delivered significant benefits for participants who, rather than being unconnected from the study between site visits, now engage in a continual technology-enabled dialogue with their trial. Yet, having implemented systems that improve the patient experience, the industry has overlooked the potential for engagement technologies to benefit two other key stakeholders: sponsors and CROs.

Sponsors and CROs have first-hand experience of the value of these technologies. The rise of mobile devices has enabled them both to oversee a major transformation in the relationship between clinical studies and the participants they enrol. In the past, this connection has been relatively distant. Once a patient signed up to take part in a trial, their interactions with the study were limited to occasional site visits. Between visits, participants were expected to continue to comply with the study protocol and were given varying levels of support and encouragement to help them with this sometimes onerous task.

Over time, even well-intentioned patients can start forgetting to take their medication, missing site visits or may eventually drop out of the study altogether. The inability of a trial to retain participants marks a failure to maintain the enthusiasm that drove individuals to enrol in the study in the first place. In 2016, there is no excuse for not taking steps to keep subjects engaged in a trial, and keep them aware of the importance of their contribution. Since the rise of SMS text messaging and, subsequently, in-app notifications, studies have had access to technology capable of supporting a continual dialogue with patients.

Sponsors and CROs use messaging, as well as the additional features available on smartphones, to make it as simple as possible for patients to commit to – and stay committed to – a clinical trial. While technology has facilitated these advances, it has also created further challenges – notably by dramatically increasing the volume and variety of data sponsors and CROs need to manage. Clinical studies now accrue data on site performance, compliance and multiple other metrics.

These data are potentially very valuable for sponsors and CROs and, therefore, the clinical trials they oversee. They can yield insights that can improve the performance of an active study, or deliver lessons that enable sponsors and CROs to design better trials in the future. However, the sheer scale of

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the datasets can make it difficult to uncover such insights and lessons without committing excessive time and resources.

Technology has simplified patients' relationships with clinical studies. Now, there is an opportunity to do the same for sponsors and CROs.

What is Needed

The challenge facing sponsors and CROs is one shared by companies in multiple industries today. Organisations in every sector can – and are – tracking a wider range of metrics with greater precision than ever before. What is needed are technologies that can intelligently connect and handle the large datasets generated by these activities. Currently, the ability of CROs, for example, to derive insights that improve the performance of an active clinical trial is hindered by the fact that data are siloed within each module of a study, making it hard to monitor overall performance.

As a first step, sponsor and CRO engagement technologies must pull down unnecessary silos, enabling each type of organisation to access all of the data they are permitted to see. While such a system would remove some of the barriers currently obstructing the data-to-insight workflow, it would still leave sponsors and CROs to shoulder the burden of organising and making sense of the information. Instead of just having access to a mass of raw data, sponsors and CROs need tools that can sift through and package the information in a way that is meaningful to their operations.

This entails going beyond simply gathering and storing data. The next generation of clinical trial tools must also process and analyse the information in a way that yields meaningful insights and easy-to-understand reporting. Even today, this is far from trivial. Clinical studies are complex operations with multiple data inputs and types of end user, each of whom needs access to different information to do their jobs effectively. In some situations, the details staff are permitted to access are limited by regulations, adding an extra layer of complexity for technological solutions to consider.

As such, the ideal system would distinguish between different types of data and user, and adjust its response and output accordingly. By tailoring the display to the permission level of each user, it will be possible to ensure individuals never see information they are not authorised to view. This has the added benefit of making it easy for users to access the data that are of most relevance to their job functions. The idea can even be taken a step further: instead of making users log on to check for updates, a well-designed system would issue targeted alerts whenever data, analyses and reports of relevance are available.

How Sponsors Can Benefit

Patients already benefit from systems that alert them to upcoming site visits and other information relating to their participation in a study. Translating this approach to sponsors will spread the advantages more broadly. The specifics of how to carry this out are tied to the position of sponsors in the trial process. Sites oversee patients; CROs oversee sites; and sponsors oversee the whole operation. As such, sponsors require a macro-level view of the trial's performance to carry out their jobs.

Specifically, sponsors need quick and straightforward ways of monitoring the status and progress of their clinical research programmes on global, regional and national levels. Currently, clinical trials are generating these data, but technological shortcomings are rendering the insights they contain somewhat inaccessible to sponsors. Opening up the data to them will yield multiple benefits. For example, a sponsor that can easily pull up data on enrolment and compliance, and compare them to targets set at the start of the study will have more productive progress reviews with their CROs.

This workflow is underpinned by access to real time data analyses on the status of a clinical trial. For this to work, the system must be able to pull in data as they are generated and, importantly, very quickly analyse the information and package it in way that delivers meaningful insights to sponsors. Without such a rapid system for analysing and visualising metrics and key performance indicators, sponsors will struggle to respond to issues quickly enough to have a tangible impact on the running of their clinical trials.

What CROs Stand to Gain

The data demands of CROs differ from those of sponsors. While sponsors will benefit most from a macro-level overview of a study, the position of CROs in the process makes more granular data of greater use to them. It is normally CROs, not sponsors, that contract with sites. As such, it is CROs that need data – preferably packaged into an easily digestible form – on how a clinical trial is performing on a site-by-site basis. Real time access to such data can make the difference between a study hitting its timelines and falling behind.

For CROs, the criticality of the data derives from their ability to support decisions that alter the performance of a study. If a CRO can identify which sites are struggling to enrol patients early in a clinical trial, it can initiate training programmes and other support actions intended to bring certain centres up to speed before they start to affect the timely completion of the study. In parallel, a CRO can spot high-performing sites, learn what tactics are working for them and transfer the lessons to other centres. This approach to site management is a better use of CRO resources.

These immediate, targeted benefits are complemented by longer-term, broader gains. As well as giving CROs a way to view the performance of individual studies, technology can provide an overview of the collective status of multiple clinical trials. Such a view provides a snapshot of the overall health of the activities being overseen by a CRO. Retrospective analyses of these activities, both at a study and CRO-wide level, can uncover learnings that enable CROs to improve the design of future trials. This can cut the time it takes to set up a study, and reduce the risk of problems arising once it is live.

Integrated Engagement

The technological framework outlined above can end the uneven distribution of the benefits that are unlocked by clinical trial engagement technologies. Over the past decade, patients have, quite rightly, been the focus of trial engagement initiatives. Prior to the emergence of mobile engagement tools, it is patients who were arguably the most unconnected from studies, despite them being the focus of the whole process. With mobile devices bridging the gap between participants and clinical trials, the sector is on a path that will lead to studies becoming ever-more attuned to the needs of patients.

Now, there is scope to expand engagement activities to improve the clinical trial experience for other groups. Like patients, sponsors, CROs and sites can all benefit from being given the information they need, when they need it. This information already exists. What was previously lacking was a way to collate, organise, analyse and visualise the data in ways that meet the unique needs of each set of organisations. This technological gap has recently been addressed, positioning the clinical trial sector to gain from the efficient flow of data to those who need it most.

Once such technology takes root, it will make the current system – in which sponsors, CROs and sites are cut off from the insights they need to make decisions – appear as outmoded as the pre-patient engagement era appears to us today. The downstream consequences of this advance for all groups involved in clinical trials are likely to be significant.

About the author

Dr Chris Watson has a PhD in Behavioural Neuropharmacology and is an experienced Product Strategist with 18 years' experience in the delivery of business- and consumer-based solutions, the last eight of which have been focused in the clinical technology industry. He has an extensive knowledge of product and software development processes and is responsible for implementing mobile product strategy at Exco InTouch.

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