HAPPIER PATIENTS, FEWER DROPOUTS

The Holistic, Digital Approach to Effective Recruitment and Engagement for Clinical Trials

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With the cost per participant steadily increasing in clinical trials, [1]clinical research organizations (CROs) face a high price for losing qualified patients. Unfortunately, as we discussed in our last whitepaper - "The High Cost of Low Patient Retention: Why So Few Patients Complete Clinical Trials, and What To Do About It", a dropout rate of 30% across all clinical trials[2] has led to endless delays and wasted money. Most egregiously, it's created false impressions about new drugs and their effectiveness, inviting increased scrutiny from regulatory agencies. [3] And one of the key culprits behind this high attrition rate is poor patient engagement.[4]

Simple digital interventions have proven effective for aiding both patient recruitment and retainment.[5] These solutions help keep participants engaged and encourage greater compliance by providing more touchpoints throughout the process. This can include aspects such as programmed reminders to take a certain dose of the trial medication at a certain time, which may result in more reliable results and better health outcomes.

Ideally, CROs address problems not at any given stage of a trial, but at all stages, resulting in a comprehensive, holistic approach to patient engagement in clinical trials. As Beth Harper's "Leaky Pipe" analysis[6] demonstrates, the average clinical trial loses 90% of its participants between recruitment and completion, and there is no single leak that can be plugged to stop this from happening.

In this paper, we will examine how comprehensive digital solutions like those offered by Brillio can improve participant engagement at each stage of the clinical trial process, from marketing to the final analysis.

1 Streamlining Participant Identification and Recruitment

Problems with patient recruitment account for half of all delays in clinical trials,[7] lead to many more failing to meet accrual goals at all.[8] Issues contributing to this endemic problem include an old-fashioned approach to recruitment efforts and unnecessary barriers to patient enrollment (like consent forms that must be signed in-person at inconvenient locations).

A modern, technologically-enabled approach to recruitment provides a smoother experience for both CROs and patients, improving the patient experience from the very first step.

One possible solution is an app-based approach, utilizing a mobile recruitment app to allow patients to enroll themselves in trials for which they are eligible. An app may be trial-specific, with patients only able to self-enroll in certain trials, but could equally be rolled out to include all trials within the pharmaceutical industry, or for a group of CROs.This approach provides a quick and easy way for patients to enroll, and allows CROs to gather necessary information about self-enrolled patients through self-reported data, which can then be independently verified to determine eligibility.

Apps can also be utilized to streamline the gathering of informed consent. An eSignature enabled app is convenient for the patient, who can read through the information provided at their leisure and sign from wherever they are. This removes the strain of extraneous on-site visits, which may be especially inconvenient for patients with health issues. In their guidelines for the use of electronic informed consent (eIC), the U.S. Food and Drug Administration (FDA) acknowledged that "Electronic process may promote timely entry of any eIC data into a study database and allow for timely collection of the subject's informed consent data from remote locations."[9] The FDA also stated that the use of an interactive interface (which could include videos, pictures, or audio recordings) may "facilitate the subject's ability to retain and comprehend the information,"[9] empowering patients to make the decision that's right for them.
A more advanced option is a recruitment platform for clinical trials, enabling all the benefits noted above while providing a single, integrated solution that can be accessed by both trial physicians and participants.

A platform offers a place for all current enrolling studies to be displayed, with real-time updates about their status. When qualified subjects enroll, they can be directed easily to the nearest enrolling principal investigator (PI), who can deploy an eConsent feature to efficiently complete signup. At the same time, qualified physicians can be quickly onboarded to the study to prevent delays. By providing a direct connection between the PI and trial participants, solutions like these enable recruitment issues to be resolved faster, and for problems with enrolment criteria to be flagged as soon as they arise.

The use of a mobile platform that can be accessed by both patients and physicians has benefits far beyond recruitment alone. In fact, the use of a secure and scalable platform can facilitate the real-time entry of patient data. This allows the relevant physician to access data immediately, enabling prompt follow-up with the participant if anything seems awry.[10]

2 Reporting Health Parameters and Improving Adherence

This also benefits the patient, who can self-report data quickly, easily, and from any location, reducing the necessity for costly and inconvenient on-site monitoring.

The Internet of Things (IoT) allows for patients to access a mobile application from whichever device they are most comfortable using, which may vary drastically across different patient demographics. For example, a trial that consists primarily of millennial subjects might find that a smartphone application is most useful to patients, while older participants may prefer to use a computer. An adaptable platform can cater to the unique needs of each patient and physician who accesses it, improving the experience for all.

Digital solutions like these can also help CROs improve adherence in clinical trials. A patient who routinely forgets to follow the guidelines provided for the trial may compromise the reliability of any data obtained, since the actual effectiveness of the drug may not showcase.

Innovations in the IoT have allowed Bluetooth chips to be embedded directly into certain medical apparatus, such as inhalers and even pill containers. When connected to the patient's mobile application, regular alerts can be provided to remind participants when and how to take their dose.

The chip will then immediately capture and store information when the patient takes their dose, conveying it directly to the physicians. This way, gaps in adherence can be spotted at once and rectified, instead of waiting until the next on-site monitoring session or even the end of the trial to discover that a patient has not been compliant.

3 Providing Accurate Analytics in Real Time

One of the major benefits of incorporating digital solutions in clinical trials is the ability to immediately capture analytics, including red flags. Accurately tracking and documenting the progress of a clinical trial is vitally important for robust data to be obtained. Problems need to be flagged fast to prevent them from derailing the trial and skewing the outcome.

CROs can use electronic clinical outcome assessments (eCOAs) and electronic patient-reported outcome (ePRO) tools to collect data remotely from participants at every step of the trial. This increases the number of touchpoints available, keeping patients more engaged and offering options for physicians to check in with participants regularly.[10]

Participants can input data using study tablets at the trial site, with the principal investigator present. This data is stored in respective cloud servers, with real-time snapshots and analytics related to each patient available to the pharmaceutical company. Throughout the trial, clinical and operational metrics can be viewed in a dashboard or in the form of visual analytics, making it easy to track the progress of each participant and of the trial as a whole.

Electronic data collection (EDC) is an efficient alternative to paper case report forms (CRFs),[11] which are time-consuming to complete and may be easily damaged or misplaced. An EDC system instantaneously stores data securely, and can flag irregularities in patient data based in the parameters programmed in.[12]

The solutions discussed above are pieces of a much larger puzzle. Rather than trying to treat individual symptoms that lead to poor patient engagement, why not treat the problem at its core and provide a better patient experience through and through?

By utilizing a mobile platform that incorporates all of these digital solutions in a unified mobile platform, CROs can move participants through the clinical trial process faster, with fewer dropouts and happier patients. Since physicians can engage with the platform in a manner similar to the participants, this may encourage greater engagement within the pharmaceutical community.

With the participants' perspective and experience in mind, a platform can be developed that helps them remember to adhere to the treatment regimen and comply with requirements easily. With a personalized patient portal, participants can engage with the trial in the manner most convenient to them. They will also have the option to report data on aspects meaningful to them, like the quality of their sleep,[12] which might otherwise be neglected.

4 The Holistic Approach: A Fully Integrated Digital Solution

5 Providing Accurate Analytics in Real Time

The benefits of platforms like this include:

- Access to a larger pool of potential subjects through the platform's database.
- Participants can easily find clinical trials based on their interests.
- Fast and hassle-free enrollment, including electronic informed consent.
- Ability to incorporate interactive content to enhance understanding and enjoyment.
- Efficient verification process and automatic acknowledgment of enrolment into the system.
- Integrated patient medical histories, enabling smoother screening process.
- Ability to pay patient incentives through the platform.
- Patients receive notifications including date and the start of the trial, alerts related to the treatment regimen, and any updates to the procedure.
- Remote patient monitoring capabilities, including the ability to track adherence and compliance, vital signs, and adverse drug reaction (ADR) reporting.
- Secure and accurate tracking of patient outcomes, with EDC and Cloud synchronization.

Summary

Brillio has the capability and expertise to build holistic digital solutions that enable CROs to get the most out of every clinical trial—lowering attrition rates, reducing costs, and increasing engagement and happiness among patients. With a digital platform that can be customized to suit the individual needs and requirements of your clinical trial, you can reduce the likelihood of unnecessary dropouts, making the process easier for participants and for the physicians involved.

Sources

1. Medrio. The Top 5 Cost-Drivers in Phase I Clinical Trials. 2015.
2. National Research Council. The Prevention and Treatment of Missing Data in Clinical Trials. 2010.
3. Quintiles. Diabetes clinical trials: Planning for recruitment and retention success. 2015.
4. Walter Alexander. The Uphill Path to Successful Clinical Trials. 2013.
5. Peter Bower, et al. Interventions to improve recruitment and retention in clinical trials: A survey and workshop to assess current practice and future priorities. 2014.
6. Beth Harper. A Strategic Formula to Enhance Subject Enrollment and Retention. 2009.
7. Pharmafile. Clinical trials and their patients: The rising costs and how to stem the loss. 2016.
8. Applied Clinical Trials. Barriers to Clinical Trial Recruitment and Possible Solutions: A Stakeholder Survey. 2015.
9. U.S. Food and Drug Administration. Use of Electronic Informed Consent. 2016.
10. Clinical Leader. Accelerating Clinical Trial Patient Engagement & Retention Through Mobile Technology. 2017.
11. Clinical Leader. 5 Ways To Engage Clinical Trial Sites With Technology. 2017.
12. Glen De Vries. We should be using new digital technology to improve clinical trials. 2016.

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