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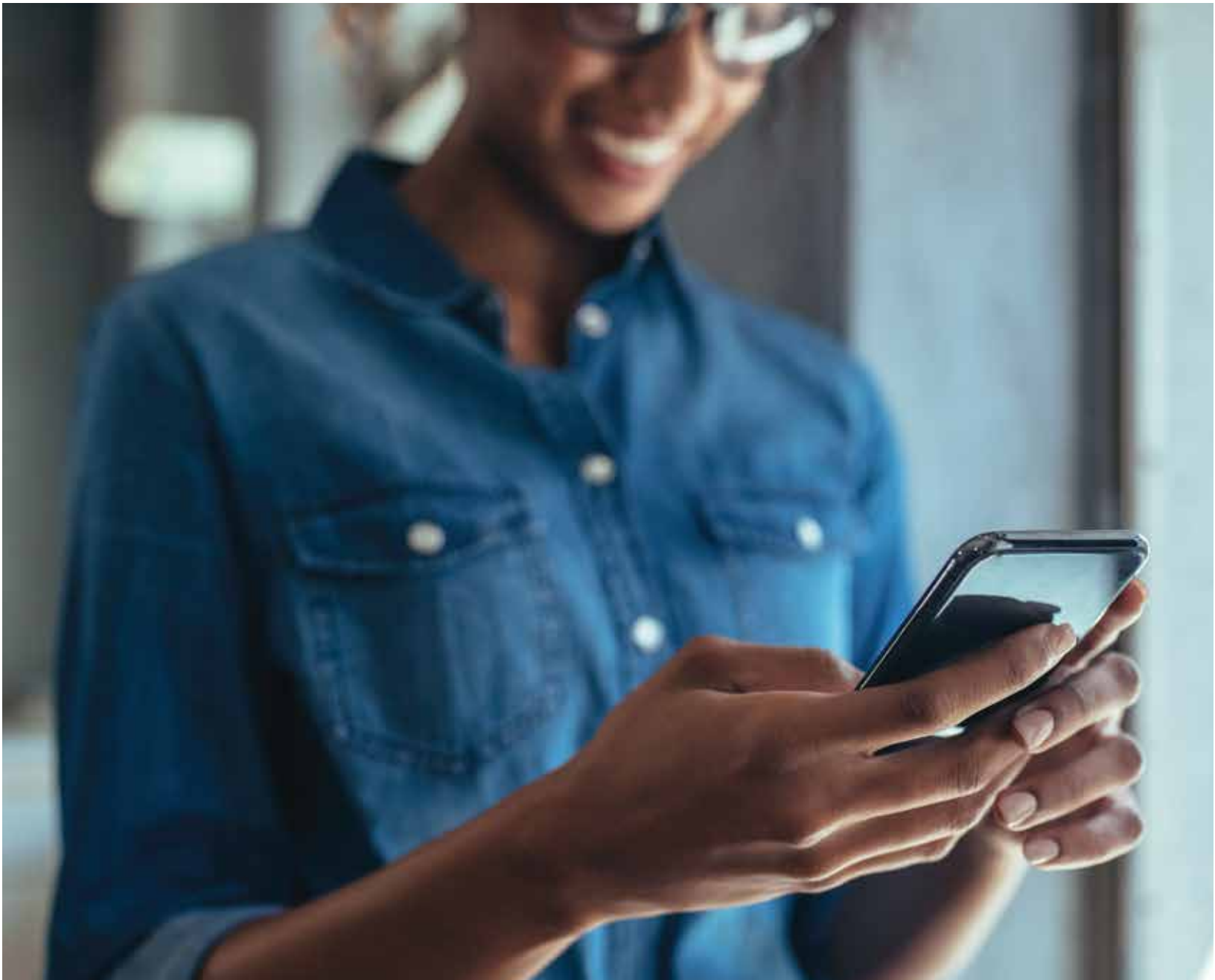
Strategies to Improve Study Retention and Patient Experience:

Patient Resources in Clinical Trials



LOW PATIENT ENGAGEMENT AND RETENTION DRIVES THE HIGH COST OF CLINICAL TRIALS

Clinical trial sponsors invest heavily in studies to provide evidence for future clinical development and earn regulatory approval for their novel therapies. While these investments are large, there is another cost that is often not highlighted—the cost to patients. Clinical study participants make many sacrifices to participate in trials. During the study, patients must manage complicated study protocols, travel logistics, recurrent study visits, and the financial costs related to their participation in these research studies. All of these factors contribute to low levels of patient retention across the pharmaceutical industry.

Poor patient engagement can expand study timelines and decrease the quality of trial data, while rapidly ballooning overall study expenses. These costs are significant, as approximately 48% of sites miss their enrollment targets, leading to delays in 80% of trials due to low recruitment . Moreover, analysis from Cutting Edge Information shows that 72% of studies run more than one month behind, with some estimating that sponsors can lose between $600,000 and $8 million for every day product development and launch is delayed . For some sponsors, patient dropouts can cost close to $36,000 per patient, and includes the added risk of needing to spend additional funds opening new study sites to bolster enrollment[3] .

One approach to address issues with recruitment and retention is moving study participants to the center of the clinical trial experience. **To do so, study sponsors must first empower study participants, moving them from mere subjects to active collaborators in the study.** One way to accomplish this is to produce high-quality informational resources, coupled with innovative delivery platforms that revolutionize how sponsors engage with patients throughout their clinical trial experience. Informational resources is a term that refers to content or information which enables patients to become knowledgeable champions of their own health. Investing in resources provides patients with a greater appreciation of how their active study participation contributes to the discovery of innovative therapies that have the potential to improve their own lives, and those of countless other patients.

Combined with the digital technologies available today, resources provide sponsors with the opportunity to re-imagine how they engage with clinical study participants. Study teams can utilize these advances to provide tailored resources to patients who want to be empowered and champion their own health. This is important, as 93% of clinical trial patients in one survey agreed that they would be "interested in helping researchers to design better trials." It is this high level of interest that creates an opportunity for sponsors to partner with their patients to advance clinical development[4] .

Patient recruitment and retention drives the high cost of clinical trials. As a result, patient resources can be leveraged throughout all phases of a study to reduce trial costs, shorten timelines, and improve the overall patient experience.

SCREENING - EDUCATING PATIENTS USING INFORMATIONAL RESOURCES

Participants usually rely on the site physicians and clinical research coordinators to first inform them of a study. These interactions are often not long enough to allow patients to get a full picture of the study and how it may impact their own disease. Study sites are juggling a multitude of responsibilities and often do not have the time to educate patients about all aspects of the study design, logistics, and mechanism of action of the therapeutic agent. For these reasons, patient referral rates to clinical trials are generally low, with only about 0.2% of patients being referred[5] . This presents an opportunity for sponsors to develop resources that increases a patient's understanding about their clinical studies. This builds upon the already high demand for health care information by patients. It is not surprising then, that before any study visit, patients are increasingly utilizing online search engines to learn more about their disease and treatments options. In the United States, for example, 80% of patients carry out online research prior to a consultation with a physician[6]. . .

To take advantage of this desire for more information during study start-up, study sponsors can develop the following types of resources:

1. Disease state information: resources about the disease, including information about etiology, incidence and prevalence, clinical presentation (signs and symptoms), prognosis, disease burden, and treatment options.

2. Drug/therapeutic information: an easy-to-understand description about the investigational therapy that focuses on the mechanism of action, available pre-clinical and clinical data to date, and anticipated risks and benefits.

3. Study eligibility criteria and informed consent: high level information about the specific inclusion and exclusion study criteria, including summaries of the informed consent and screening process, which sites are participating in the study (and where they are located), and which sites are currently enrolling.

4. Clinical study activities: information summarizing details about clinical tests and samples, number of expected study visits, expected duration of study participation, and whether any compensation for study participation is offered.

Access to a wider variety of resources provides patients with transparency on visit-related activities and a deeper understanding about why each test is being done. In order for patients to feel empowered and engaged, they must first be aware of the study; subsequently, they must be well educated about how and why the therapy may work. By providing more high-quality resources to patients, sponsors are better able to tackle issues with patient participation during screening and enrollment.

STUDY CONDUCT - ENGAGING PATIENTS USING RESOURCES

After enrolling patients in the study, the most challenging aspect of the study conduct phase is patient engagement and retention. Clinical trial dropout rates across the industry average around 30%, with adherence rates in the chronic disease therapeutic areas ranging between 43-78%[7]. This high drop-out rate is further complicated by a growing trend of more complex study designs that require more visits and procedures. These complex study designs increase the burden on trial participants, who are often not compensated for their time and other costs associated with their involvement.

So, how can sponsors ensure that patients stay engaged throughout the trial? Patient resources can help address these issues in a couple of crucial ways, including the following:

1. **Study logistic information:** resources providing visit reminders and location details.
2. **Study updates:** information highlighting results from interim and primary analyses and changes resulting from any study protocol amendments.
3. **Health suggestions:** reminders about health, diet, and overall activity.
4. **Patient timelines and milestones:** interactive reports that track individual patients' progress throughout the study visits.
5. **Safety updates:** information about adverse events associated with the investigational agent.
6. **Patient stories:** content that highlights a patient's clinical trial experience to other study participants and creates a higher level of community engagement for all participants.

Together these types of patient resources work as a critical part of any patient engagement strategy for study sponsors. They create a variety of additional touchpoints for sponsors with their patients in between study visits, serving as a tool to improve their overall trial experience and keep the trial at the forefront of their minds. Ultimately, these engagement vehicles provide yet another tool to treat patients as collaborators in completing the trial and create an even greater investment in its overall success.

STUDY CLOSURE - APPRECIATING PATIENTS USING RESOURCES

As clinical studies near their close, sponsors have another opportunity to actively engage participants. Here, it is important to show appreciation for study participation by providing patients with information about the study's progress, final results, and next steps after the trial. Resources also add value to patients as they manage their own health.

These can take on the following forms:

1. Study site highlights: summaries of any site-specific updates for patients. These can include enrollment totals, messages from site leads and research coordinators, and any other site-specific patient resources.

2. Clinical trial summaries: content that includes any interim or final results of the study, and any other potentialancillary studies associated with the trial.

3. Patient appreciation: these can include any congratulatory notes and words of encouragement for patients.

4. General wellness and nutrition information: resources educating patients about other ways to manage and cope with their disease.

5. Patient data: if allowed by protocol, the patient should be easily able to download or receive a copy of their data

The relationship between the trial sponsor and patients can continue as the therapeutic agent makes its way through the regulatory and approval process. This is a great opportunity to leverage patient resources, as over 50% of patients cite that they are not well informed of trial results after study closure[8]. This also has the added value of building a long-term relationship with patients and increases the likelihood of any possible future engagement with the sponsor and clinical studies overall.

LEVERAGING DIGITAL PATIENT ENGAGEMENT PLATFORMS TO DELIVER PATIENT RESOURCES

Perhaps one of the most groundbreaking advances in digital technologies has been the development of smartphones. Already in the United States, 13% of clinical trials utilize some form of mobile texting function. Smartphone applications are now a key part of how patients engage with their health care providers, with most large healthcare systems in the United States already utilizing phone-based applications to disseminate patient appointment reminders, laboratory results, and facilitate confidential communication between patient and physicians[9]. With the acceptance of mobile apps for healthcare, study sponsors can leverage this technology to deliver digital patient resources[10].

These apps allow sponsors to remain engaged with study participants between study visits by distributing resources relevant to the patients and study. Mobile apps are versatile and can be configured to deliver content tailored to the needs and can include text, graphics, audio and video. These apps can also enable ad-hoc communications sent through SMS texts and in-app notifications or announcements.

Conclusions. Patients are at the heart of the clinical trial. Patient resources provide a new opportunity to be more intentional about making the clinical trial experience more patient centric. By engaging with patients as partners through study screening, conduct, and closure, sponsors can use patient resources to facilitate greater collaboration, which in turn will help to quickly bring innovative healthcare solutions to address unmet medical needs.

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