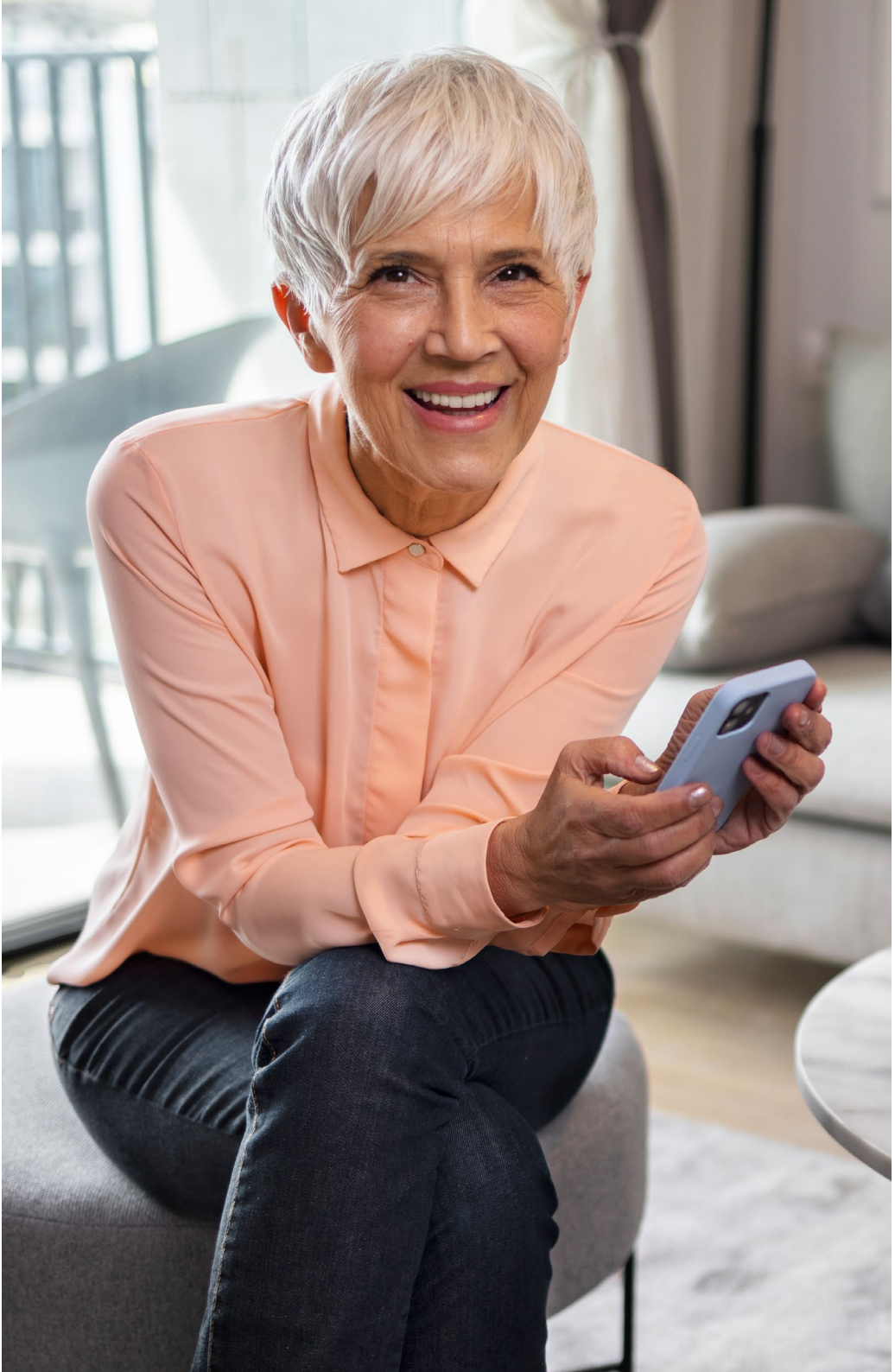


Trial Online® by Replior

Empowering Clinical Trials

The Art and Science of Patient Engagement

Replior AB 2023

The ultimate guide to patient engagement in clinical trials

In the grand landscape of modern clinical research, scientific breakthroughs and innovation are changing the way we approach patient treatment and wellbeing with clinical trials standing as the beacon of hope. However, beneath the surface of clinical trials lies a challenge that is persisting: the struggle to retain patients throughout the clinical trial journey.

Let us have a look into the strategies and solutions that can bridge the gap between clinical trials and patient retention and engagement.

Patient engagement, not just a buzzword

Patient engagement in clinical trials goes beyond recruiting individuals who will participate in the study.

Patient engagement means making an active effort to involve patients at every step of the clinical trial process. This means actively listening to their thoughts, preferences, and needs, ensuring that the trial is not only patient-centric but also profoundly meaningful. In this collaborative effort, all stakeholders in a clinical trial—be it sponsors, investigators, extended site staff, caregivers, patients, or advocacy groups—come together to design studies, recruit participants, and maintain their enthusiasm and commitment until the study's completion.

Moreover, patient engagement entails the collection and utilization of patient feedback regarding their experiences, fostering a transparent and close-knit relationship. It's a two-way street where patients aren't just passive subjects but active contributors to the clinical research process.

Why is patient engagement so crucial?

Because involving patients in the design and execution of research that directly affects them empowers them and elevates the quality of the clinical research data itself. In this light, patient engagement in clinical trials is more than a buzzword; it's a transformative approach that brings patients into the heart of medical progress.

Struggling to retain patients in your clinical trial - a deeper dive

The challenge of retaining patients in clinical trials is a multifaceted puzzle. We can dissect the primary reasons behind patient dropouts into three distinct categories: health-related factors, logistical challenges, and the overall trial experience.

Health-related challenges frequently lead to patient dropout. Disease progression and the often-daunting adverse events can significantly deter individuals from continuing their participation, especially in trials that involve frequent site visits, intricate procedures and assessments, and extensive data collection. Moreover, the financial burden of participation, including costs related to transportation, childcare, medical expenses, and time away from work, can exacerbate patient dropouts and limit the diversity of trial participants.

Yet, it's not just the clinical aspects that affect patient retention. The patient experience within a clinical trial also plays a pivotal role. A lack of clear communication, adequate support, and transparency can make patients feel disconnected, resulting in confusion, frustration, and ultimately, dropout.

Tufts CSDD Impact Report shows clinical trial dropout rate rose to **19.1%** globally in late phase trials in 2019 from a 15.3% in 2012

CNS trial dropout rates increased to **25.9%** from 19.2%

Oncology trial dropout rates grew to **19.3%** from 18.2%

Vaccine trials experienced a **12.3%** dropout rate in 2019

4 main strategies to improve patient engagement

Ensuring that patients remain engaged, informed, and empowered throughout their clinical trial journey can make an extraordinary difference. In this section, we'll explore a range of potent strategies to enhance patient engagement in clinical trials.

Clear and direct communication

Open, detailed communication is the cornerstone of patient engagement. Providing patients with comprehensive information and education about the trial's purpose, assessments, tasks, risks, and benefits, as well as keeping them updated on trial progress, is crucial. Regular feedback channels can help guide patients through trial tasks and empower them through knowledge.

Patient-centric study design

Acknowledge that clinical trials can be demanding for participants. When designing trial protocols, prioritize patient preferences and convenience when scheduling visits, tests, and treatments. Tailoring the trial to accommodate patients' needs can significantly boost engagement.

Keep a flexible model

Flexibility is key to accommodating diverse patient needs and preferences. Offering options like remote monitoring reduces the burden of frequent visits and complex procedures, increasing the likelihood of sustained participation.

04 Embrace technology

Technology acts as a bridge between convenience and engagement, offering innovative solutions to streamline the patient experience.
Here's how technology can revolutionize patient engagement:

Remote data collection

Wearable devices and mobile apps allow participants to monitor their health and collect data from the comfort of their homes as well as real-time data collection provides researchers with a more comprehensive view of participants' conditions and responses to treatment.

Virtual visits

Virtual visits enable participants to have consultations with healthcare professionals without the need for in-person appointments. This convenience reduces travel and time burdens, increasing the likelihood of sustained participation.

Wearable Devices and sensors

Wearables can track vital signs, activity levels, and even specific biomarkers. This data offers a more comprehensive understanding of participants' health trends and responses to interventions.

Real-time feedback

Participants can provide feedback and complete surveys in real time through digital platforms. This helps researchers assess participant experiences and make necessary adjustments.

Gamification features

Gamified features apps can encourage participants to adhere to treatment regimens and complete required tasks. Incorporating rewards and incentives for achieving milestones boosts motivation.

Engage your patients with Trial Online ePRO

Trial Online ePRO focuses on collecting electronically the data that is reported directly by the patients participating in clinical trials. Patients use their own digital devices or devices provisioned by Replior to directly input information about their symptoms, experiences, quality of life, and treatment-related outcomes.

Patient retention has long been a daunting challenge in clinical trials, impacting sites, sponsors, and CROs. A recent report by Biopharma Dive highlights the grim reality: 85% of clinical trials struggle to recruit sufficient patients, and a staggering 80% face delays due to recruitment issues. To compound this, high dropout rates persist as sites grapple with maintaining patient engagement throughout the study.

Trial Online ePRO is designed to incorporate gamification elements, making the patient's journey in a clinical trial more exciting and engaging. Through the ePRO app, users can track their activity and study progress, receive guiding or encouraging notifications and alerts for pending tasks, and earn badges and prizes upon completing questionnaires or eDiaries. We understand that every patient is unique. Therefore, we ensure that communication is personalized to meet each patient's specific needs. Whether it's guidance, encouragement, or relevant updates, Trial Online ePRO delivers tailored messages to enhance patient engagement and satisfaction.

"Introducing gamification with Trial Online has improved the satisfaction of our patients and therefore increased the robustness of the data base."

Diego Herrera Egea

Senior Leader, Clinical Data & Information Management,

Almirall

The power of gamification in patient engagement

Picture this: patients immersed in the world of clinical trials, completing questionnaires and diaries with the enthusiasm of a gamer conquering challenges. Sounds intriguing, isn't it?

Gamification is a technique that can be used in systems such as ePROs to create similar experiences to those we have while playing a game to motivate users and keep them engaged. During a clinical trial, patients are tasked with answering extensive questionnaires and completing diaries daily, a dreary task although crucial to gather data regarding patient's not only quality of life but also safety. And this is where gamification is a game changer.

The power of gamification lies in its ability to tap into fundamental human desires for achievement, creativity, recognition, and social interaction.

Here are the key drivers behind gamification's effectiveness:

Engagement and motivation
Capture attention and keeps individuals engaged through challenges, rewards, and progress tracking

Sense of purpose
Connect participants to a larger cause, providing a sense of meaning and significance.

Social interaction
Foster collaboration and interaction among participants, creating a sense of community.

Personalization and empowerment
Allow individuals to personalize their experience and make meaningful choices.

Feedback and progress tracking
Provide immediate feedback on performance, promoting a sense of accomplishment.

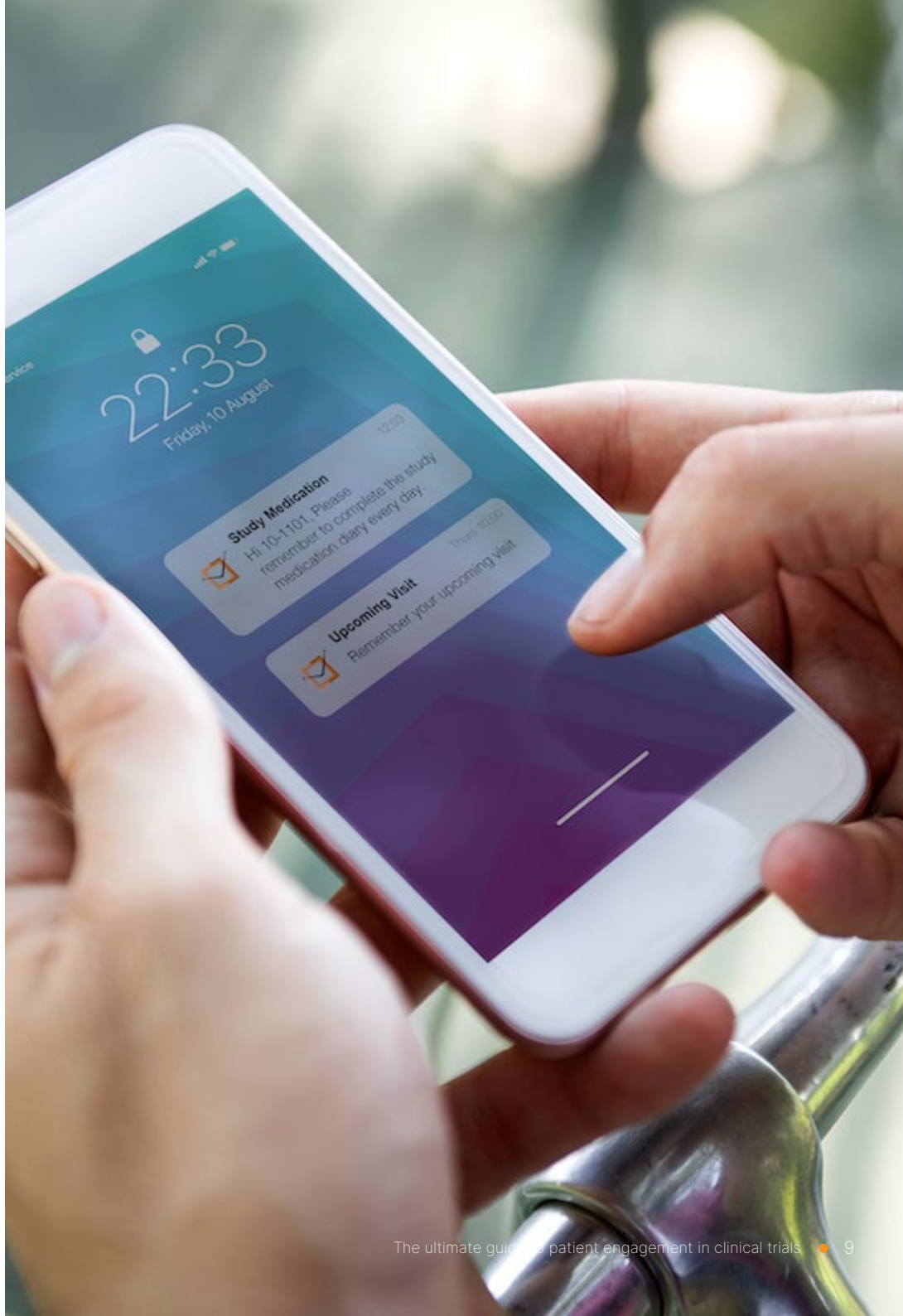
Overcoming challenges and curiosity
Incorporate elements of unpredictability and curiosity, keeping participants engaged.

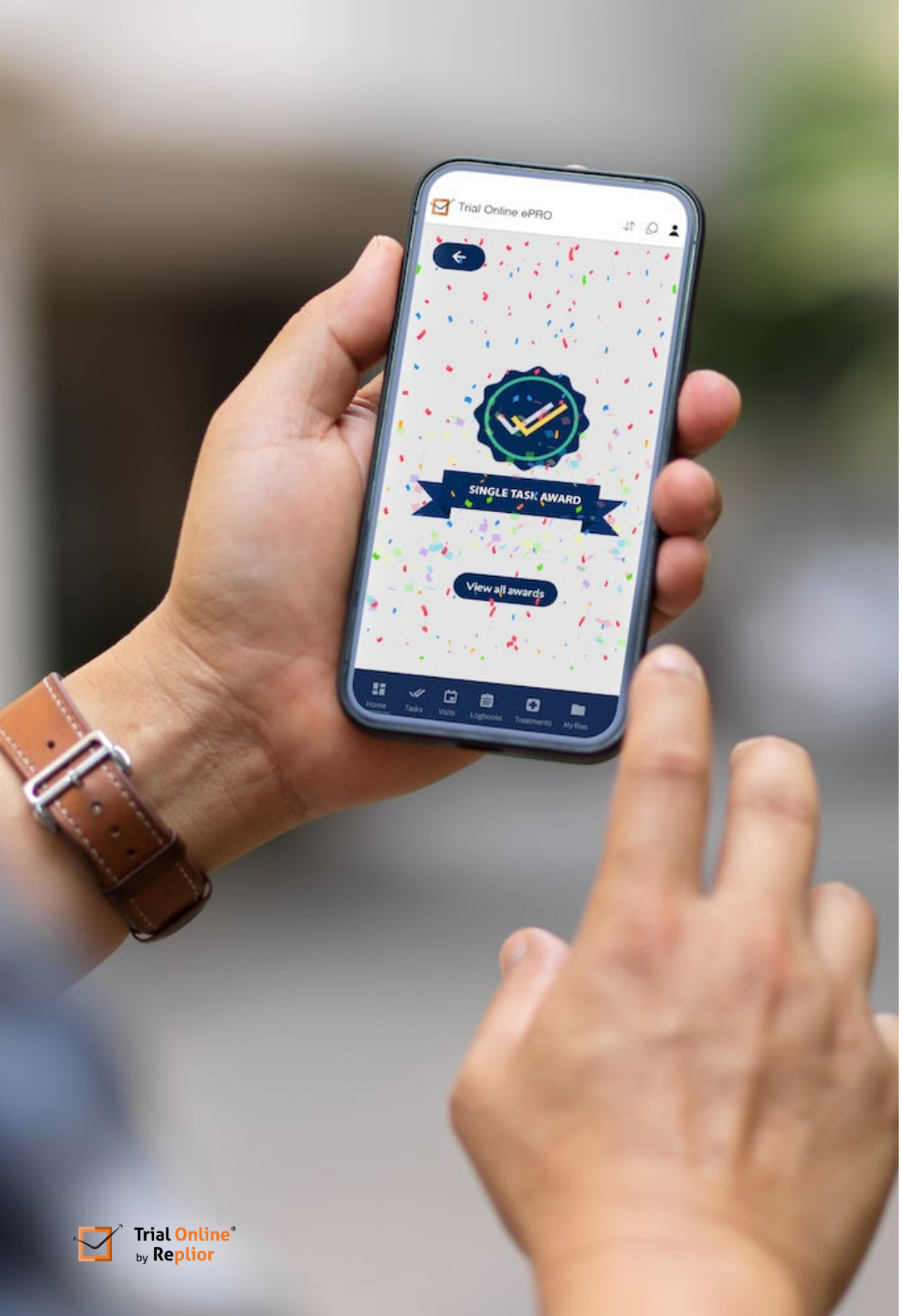
Emotional connection and enjoyment
Evoke positive emotions, making tasks more enjoyable and immersive.

How does Trial Online ePRO incorporate gamification elements?

Tailored notifications

The ePRO should allow all types of notifications to be sent to the participant's electronic device. From clinical trial protocol-related guidance to treatment instructions, and upcoming visits information. The same communication channel could be used to motivate the participant's activity in the study by sending personalized messages that guide, train and support the participant whenever needed.





Tailored awards

The ePRO tool should show appreciation for the efforts of the clinical trial participants to complete all protocol-required activities and tasks through awards, motivation is high throughout the study to provide those always required key data points.

Study progress

Participants should always see their progress status in the ePRO: time and effort invested and time and effort pending to be invested until study completion. Knowing the progress and where it stands in relation to study completion, boosts motivation.

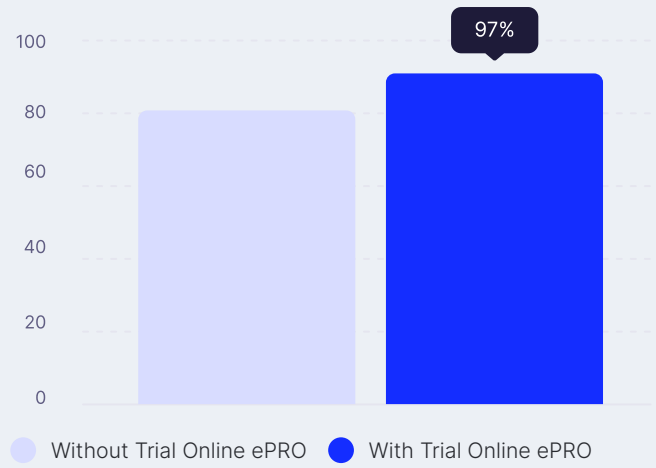
Patients play the most essential role in clinical trials and their continuous and engaged participation is crucial for regulatory approval and the generation of valuable data for understanding disorders and developing effective treatments.

Technology has provided innovative solutions to enhance the experience of the clinical trial participants, but it is equally important to ensure that patients remain engaged and appreciated throughout the study. Trial Online ePRO has embraced these three gamification elements and the results speak for themselves.

Spotlighting the results of embracing gamification

Three different clinical trials conducted by Almirall embraced gamification through Trial Online ePRO and the following results were observed:

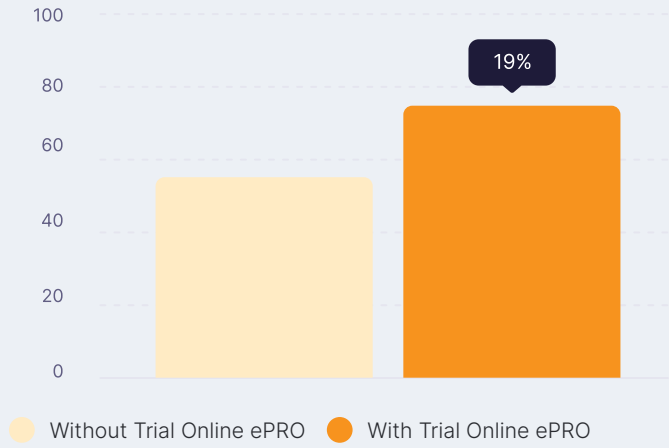
1



97% Patient retention

In a phase IV biologic study with 9 PROs to be completed at each patient visit, patient retention increased from 90% in a previous study to 97% with Trial Online ePRO.

2



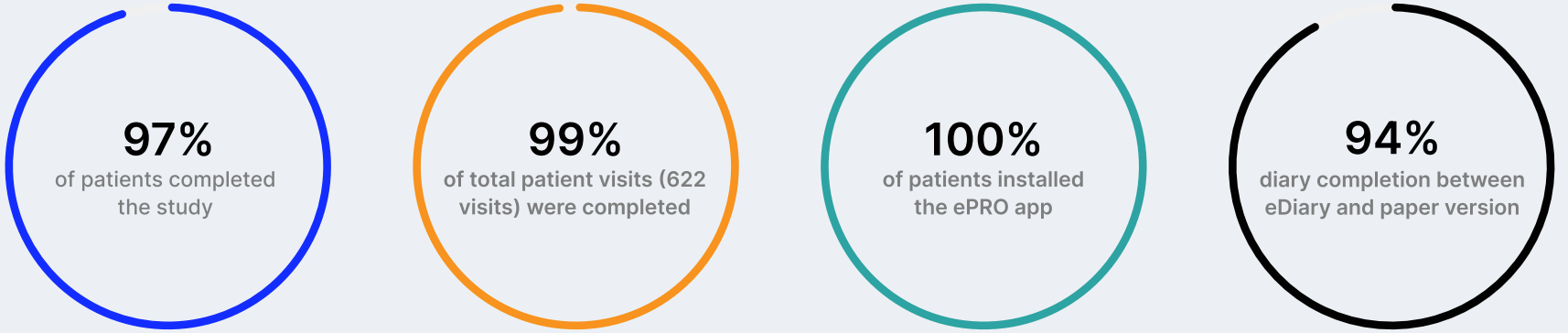
19% Increase in retention

A second 2 active treatments phase IV study with 4 PROs to be completed at each patient visit saw patient retention spike from 56% to 75% with Trial Online ePRO.

Results, continued

3

In a phase III study with an average population of 69 years old who completed their eDiary on Trial Online ePRO, having the paper diary version as back up, we observed that:



Read the Almirall Phase III case study if you'd like to know more information on the effect of Trial Online ePRO on patient engagement rates.

Future trends in patient engagement approaches

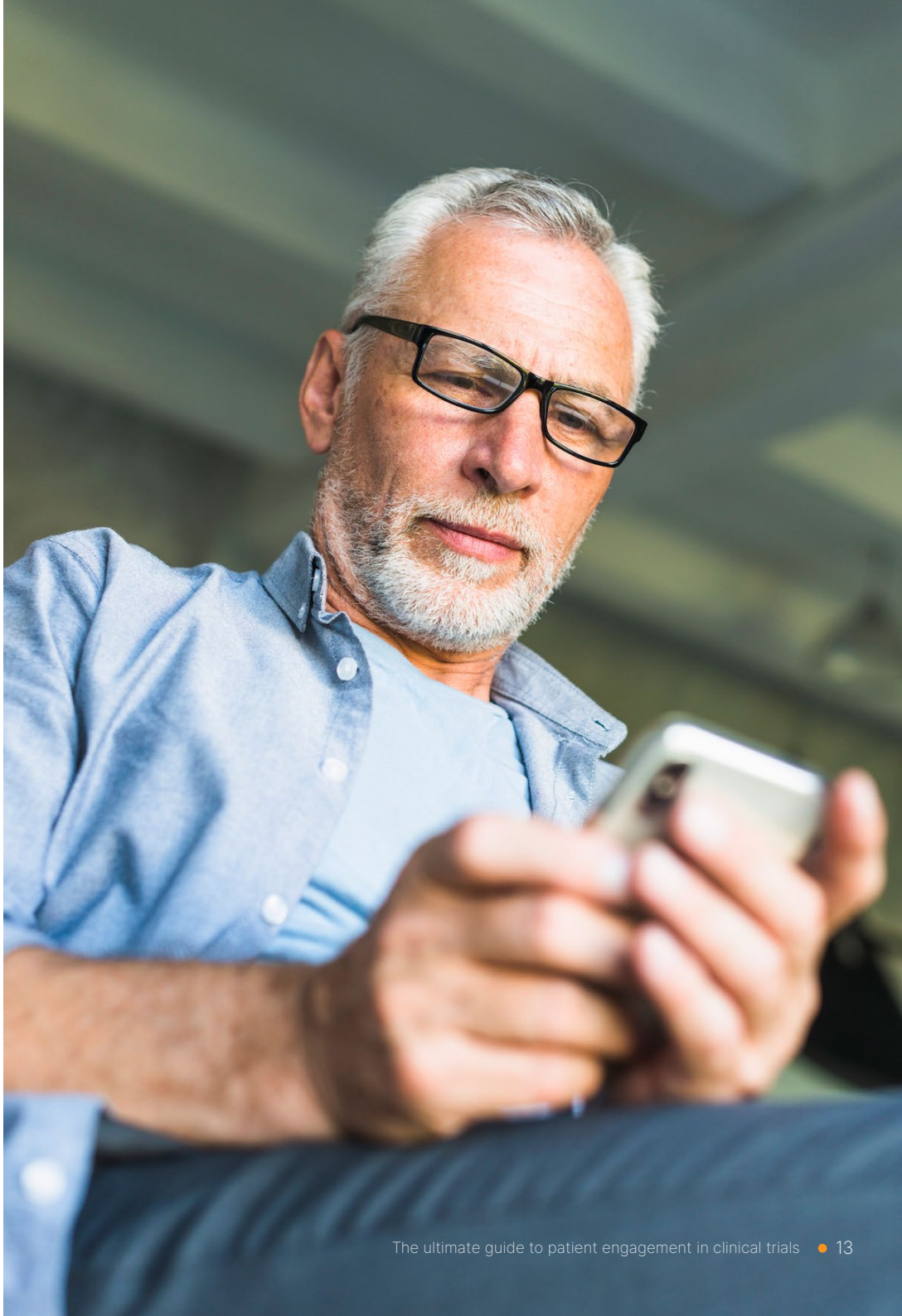
Artificial intelligence (AI)

One of the challenges in decentralized trials is collecting data from participants, which often involves completing surveys, diaries, and electronic Patient Reported Outcomes (ePRO) at home. This data entry process can be time-consuming and error-prone, leading to reduced adherence and accuracy. AI, particularly reinforcement learning, can optimize the timing and content of notifications to motivate participants and minimize unnecessary interruptions.

Additionally, AI-powered computer vision can guide participants in capturing images and videos correctly, ensuring data quality and reducing the need for retakes. In dermatology, neurological, and behavioural health trials, where image and video submissions are common, this approach can significantly improve the user experience.

In trials measuring participants' mobility, wearable sensors are traditionally used. However, AI models for temporal data analysis have the potential to reduce the number of required sensors while providing detailed movement pattern assessments. This innovation can make continuous mobility monitoring in real-life settings more feasible.

By incorporating AI into clinical trials, participants can enrol more easily, complete trials with reduced burden, and provide high-quality health assessments throughout their participation. AI has already demonstrated its value in improving user experiences in various industries and can similarly enhance the clinical trial process.



More remote data collection

Innovation has significantly enhanced the capabilities of wearable devices, which has resulted in the increased use of the technology in clinical trials. A search of the current ClinicalTrials.gov database shows more than 1,000 clinical studies that are completed or ongoing that include the words “wearable”. Wearables have been used across multiple therapeutic areas, including oncology, neuroscience and the study of respiratory and metabolic disorders. While utilizing wearables does present certain risks, such as data privacy concerns, data validation challenges, and logistical considerations, their advantages far outweigh these concerns. They offer the advantage of remote data collection, reducing the burden on both patients and clinical sites. Sponsors gain nearly real-time access to critical trial data, expediting decision-making processes. Moreover, patient recruitment and retention stand to benefit significantly from these technologies, potentially driving down data collection costs.

Cutting-edge technologies like mobile apps, wearable devices, and telehealth platforms are fundamentally transforming how patients are monitored and engaged in clinical trials. These tools enable remote monitoring, continuous data collection, and the collection of patient-reported outcomes, offering researchers a comprehensive, real-time understanding of patients’ health status. Remote monitoring not only enhances patient convenience but also reduces costs and contributes to improved participant retention in clinical trials.

Patients at the centre of clinical research

Patient-centric approaches prioritize the active participation of patients at every stage of the research journey. This involvement encompasses critical aspects like study design, participant recruitment, and data interpretation, ultimately resulting in outcomes that are more closely aligned with the needs and perspectives of patients. The deployment of patient engagement tools, including patient portals, social media platforms, and support groups, serves to empower patients, enabling them to take an active role in advancing research and influencing the future development of therapies. This collaborative approach ensures that research endeavours are not only patient-driven but also more likely to yield meaningful and impactful results.

Conclusion: Patients are and should be even more the core of clinical trials

In closing, patients are at the centre of clinical research, and their continuous and engaged participation is vital for generating valuable data and advancing medical knowledge. The strategies, technologies, and gamification elements discussed in this guide represent a roadmap to enhancing patient engagement and retention in clinical trials, ultimately driving progress in healthcare and improving patients' lives.

About us

Replior is a company providing software for clinical trials. Our suite of systems is called Trial Online and enables collection and management of data from investigators, participants and wearables in an easy and efficient way.

Trial Online supports decentralized clinical trials by enabling the trials to operate with site visits, remote visits or as a hybrid. Trial Online is the single place to collect all types of data for a clinical trial and collaborate with both trial teams and participants. The Trial Online product suite consists of EDC, ePRO, eConsent, and Virtual Visits, fulfilling all regulatory requirement.