



REVOLUTIONIZING RETENTION

**DIGITALIZING PATIENT
ENGAGEMENT IN
CLINICAL TRIALS**





PATIENT RETENTION IN CLINICAL TRIALS



Patient attrition has always been a problem in clinical trial execution, and it is getting worse.

Average trial retention rates dropped from 69% in 2003 to 30% in 2013, a 56% decrease in 10 years¹.

The retention problem is a major source of increased cost and lost revenue for trial sponsors. Loss of participants leads to missing data, introducing biases and reducing the statistical power of clinical trial results. This can lead to a failure to win regulatory approval as skewed data can misestimate safety and efficacy. In the worst cases, participant attrition can force the entire trial to be cancelled.

Participant drop-out occurs due to a range of factors that can depend on the exact nature of the disease and the study population. Sometimes it occurs due to patients losing interest or facing logistical challenges (e.g. transport issues) that hinder continued participation. Often participants are lost due to a failure to adhere to trial protocols, a problem that is exacerbated in conditions like obesity,

addiction and cognitive disorders like Alzheimer's disease and schizophrenia.

Trials are also increasing in complexity - a recent study finds that the total number of procedures in phase III protocols has gone up from 110 in 2001-2005 to 187 in 2011-2015, a 70% increase². This rise in protocol complexity stems from a combination of stricter regulatory requirements and recent trends in drug development. Increasing interest in personalized medicine and specialized care means that more sponsors are developing drugs that target very specific patient demographics, such as particular ethnic groups and rare diseases. Targeting these small, hard-to-reach patient populations makes the need for effective retention strategies even more urgent.

Strategies for reducing attrition are an important component of protocol design in clinical trials³, but empirical evidence supporting the efficacy of commonly used retention programs is weak^{4,5}.

Pharmaceutical companies are in a tough spot with the retention problem. Lack of evidence for effective retention strategies, rising patient attrition, increasing trial complexity, shrinking margins - how can trial sponsors overcome this herculean challenge?

Patient-centered clinical research: Digitalizing trial participation

What is needed is a radical overhaul of the entire approach to clinical trials. Instead of being seen as “subjects” – anonymous vessels for the extraction of data – patients need to be seen as meaningful stakeholders in the clinical research process. This would encourage trial participants to feel that they have a personal stake in clinical research, increasing motivation for both enrollment and long-term adherence.

Pharmaceutical companies are embracing this patient-centered view of drug development. In 2014, Sanofi became the first Big Pharma company to appoint a Chief Patient Officer (CPO), a C-suite position that reports directly to senior management on patient issues. Other firms, including Merck, are beginning to follow suit. One of the most visible manifestations of this new approach can be seen in the increasing use of patient-reported outcome measures (PROMs) in drug development and clinical research^{6,7,8}. However, PROMs are just one dimension of patient-centricity and do not directly address the retention problem.

Pharmaceutical companies seeking models for patient-centricity can draw inspiration from consumer telecommunications, an industry which has been pioneering the use of digitalization to enhance customer engagement over the past few years.

A recent example of this can be found in the case of Rogers Communication, the largest provider of wireless communication services in Canada. Starting in 2014, they launched “Roger 3.0” – a multi-year plan to revitalize customer engagement by adapting support services to the channels where their customers already spend most of their time, e.g. Facebook, Messenger and Twitter. The approach has been astonishingly successful – Rogers has seen a 65% increase in partner channel customer satisfaction since introducing these digitalized solutions⁹.

Pharmaceutical companies trying to embrace patient-centricity could learn much from cases like “Roger 3.0”, but many are wary of drastically changing established models. Breaking from the herd, Pfizer was an early innovator in applying digitalization and mobile technology to drug development. In 2011, they carried out a “virtual”, remote clinical trial for the overactive bladder drug tolterodine¹⁰. Participants received medication reminders and answered questionnaires on mobile devices without having to physically visit sites, greatly reducing the burden of effort for both patients and investigators.

Digitalized clinical trial participation is a promising solution for addressing the retention problem in a patient-centric manner. Although some early steps have been taken in this direction, there is much room for further improvement and disruptive innovation.

Tackling patient retention through digitalized trial participation

Digitalized interfaces for trial participation would allow sponsors to apply insights gained from fields like cognitive science, behavioral economics¹¹ and anthropology to increase engagement and reduce attrition in clinical research. The scope for innovation in this area is vast, and remains largely untapped.

Disruptive innovators at the interface of telecommunication and life science are actively working on different approaches for digitalizing patient engagement in clinical trials, including:

- *Gamification of trial adherence (Behavioral science)*

Virtual incentives for successful adherence, converting tedious aspects of trial participation into game-like tasks with points and rewards¹². Even the mundane act of correctly following a medication reminder can be transformed into a game-like task, tapping into the human brain’s innate reward learning mechanisms to reinforce protocol adherence in a non-intrusive manner. More complex aspects of trial participation – automated “teach-back” using quizzes to ensure participant comprehension, entry of PROMs into digital diaries – could also be converted into game-like tasks.

- *Dynamic social engagement of companions & caregivers (Social psychology)*

Creating a virtual social environment for medical professionals, trained coaches and companion caregivers to productively and effortlessly engage with trial participants through video, voice and text. This is particularly interesting in light of research demonstrating physiological links between social support and disease outcomes¹³.



DIGITALIZATION WILL REVOLUTIONIZE PATIENT RETENTION IN CLINICAL RESEARCH

- *Narrativizing trial participation (Anthropology, interaction design)*

Using interactive animations, journey maps and visual representations to transform the trial participation process into a meaningful and personal narrative for the patient; promoting health literacy and patient engagement through accessible and emotionally authentic multimedia narratives that are tailored to specific cultural contexts and patient demographics^{14,15}.

Digitalized clinical trial participation promises to be a rich area for research and development in the coming years. Innovative solutions for clinical trial participation have the potential to bring about a radical paradigm shift in the entire research process - reducing patient attrition, streamlining data collection and increasing efficiency across the drug development cycle.

Ultimately the most effective solutions to the retention problem will not come from traditional actors in drug development, but from disruptive innovators who are able to leverage expertise in consumer telecommunications and interaction design to deliver novel end-to-end solutions for patient engagement at every step of the clinical trials process.

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CUSTOMER TESTIMONIALS



Using Trialbee's solution we have been able to reduce our workload in finding patients and matching them to clinical trials. We saved several hours of work per patient. Trialbee's pre-screening of patients is efficient and the direct



We have indeed had a great experience with Trialbee, too good in fact, which is why we'd like to stop today. The sites have a backlog of patients that they can't process fast enough.



ABOUT US

Trialbee is a software solutions company founded in 2010 and based in Malmö, Sweden.

We partner with pharmaceutical companies and CROs to digitally connect and engage stakeholders across the clinical study chain.

Our aim is to help save lives by accelerating medical research and provide innovative solutions to healthcare challenges.



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