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CLINICAL STUDIES

NEW OPPORTUNITIES FOR SUCCESSFUL CLINICAL STUDIES

WHITE PAPER

CONTENTS

The challenge of recruiting suitable patients into clinical trials has always been a significant obstacle to drug and medical device development programs. The difficulty of generating evidence delays the introduction of new medical interventions and entails high costs. In a new Covid-19 context, the pharmaceutical industry is facing unprecedented pressure. With the global population of people with multiple chronic diseases increasing (now estimated at one in three adults), the need and urgency to address the challenges of effectively enlisting and engaging patient cohorts is a critical issue for the evolution of medical care.

> **A key objective** is to address **R&D cost structures** and improve the **efficiency** and **effectiveness** of the clinical development process. I**mproving patient recruitment, engagement and retention** is an essential component. The pharmaceutical industry is at the center of a **digital revolution** that will transform the healthcare ecosystem.

By implementing patient path-focused strategies, trial centers may be able to implement a simpler model of care. New technologies, such as Digital Health platforms and social media, are designed precisely to help patients connect with doctors so that they can more easily and quickly access information and services according to innovative and sustainable care models.

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STRATEGIES FOR PATIENT RECRUITMENT AND RETENTION

The best recruitment and retention strategies for clinical trials focus on the patient perspective. To be successful, a reliable program must be developed using a range of awareness and education methods designed to reach patients quickly and efficiently, providing them with the information they need for their care choices. This article examines the challenges and initiatives successfully implemented in the most recent studies.

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CHALLENGES OF **CLINICAL TRIAL PATIENT RECRUITMENT**

$900,000
on average spent on patient recruitment and retention

up to $8 million/day
in lost sales due to delays in patient recruitment

50% of clinical trials fail to recruit enough patients during the planned recruitment period

40% of patient dropout rate in longitudinal trials

THE CHALLENGES OF RESEARCH

Randomized controlled trials (RCTs) are widely accepted as the gold standard for evaluating new therapies. Recruitment is often slower or more difficult than expected, and many studies fail to reach the expected sample size within the timeframe and with dedicated study funding. If the target number of patients is not reached, the results will usually be less reliable. If the recruitment period is to be extended, costs usually increase and the application of the results in clinical practice is delayed.

As an example, a study on multiple sclerosis recently published in **the journal JAMA**[1] was partially compromised by a much slower recruitment than expected, with the need to reduce the number of patients enrolled (in accordance with the regulatory agency FDA). From a statistical point of view, this variation reduces the reliability of the results and requires specific analyzes to analyze the bias introduced by the differences in the number of patients enrolled, which was very low (<3 patients) in 30% of the centers involved.

CURRENT ISSUES ***IN CLINICAL TRIALS***

Of no less importance is the discomfort for the patient represented by the burden that many studies entail, such as frequent visits, invasive procedures and the distances to travel to reach the center, for which the patient is discouraged to participate.

Hospitals conducting clinical trials are often plagued by high staff turnover and limited by inefficient infrastructure. As a result, center staff are often overburdened and forced to prioritize multiple patient-facing tasks, resulting in a potential loss of study candidates and / or an increase in patients leaving the trial before its conclusion.

ECONOMIC IMPACT

Biopharmaceutical companies spend an average of nearly $ 900,000 on patient recruitment and adherence while developing a new drug. Despite this investment, nearly 50% of clinical trials fail to recruit a sufficient number of subjects during the expected period. Delays in patient recruitment can dramatically postpone time to market, resulting in revenue losses that are estimated to be up to $ 8 million per day in lost sales. Adding to these problems are patient dropout rates, which can reach 40% in longitudinal studies.

DECENTRALIZED STUDIES

Decentralized clinical trials (DCTs), where clinical trial data is collected through sensors or remote monitoring devices brought by the patient without the need to visit a clinical center, can offer many benefits to pharmaceutical companies, including

cost savings, better patient recruitment and retention, and better data quality.

Prior to the Covid-19 pandemic, significant information existed on the benefits of DCTs, but only a few pilot projects used these technologies, as companies were disincentivated by regulatory uncertainties, the need for upfront investments in sensors and products, and the limited functionality of available technologies. Today, DCTs have proved a lifesaver to restart clinical trials that were interrupted during the pandemic. Furthermore, recent technological advances, the proliferation of wearables and the push by the FDA to adopt DCTs after the Covid-19 case have made the DCT landscape ripe for a breakthrough.

The main benefit of decentralized clinical trials is the opportunity to improve the patient experience. But the remote model has reduced in-person interactions. Insufficient communication from sites and sponsors is often at the root of the current challenges in recruiting and enrolling patients in clinical trials. Human touch, an important psychological aspect in health care, is lacking in this model. Added to this is the burden of learning about new products and technologies. All of these factors create a general sense of discomfort and disengagement among patients, creating further acceptance problems for clinical trials. However, the most recent studies, such as those described below, show how these barriers can be overcome.

THE SEARCH FOR THE FUTURE

A recent study has shown how decentralized studies, even large ones, can broaden access to trials and reduce the risk of exposure for patients and staff. The **DeTAP study**[2](Decentralized Trial in Afib Patients), conducted entirely during the Covid-19 pandemic, integrated a number of digital technologies, including paired home sensors, into a 100% virtual experimentation experience in patients with atrial fibrillation (AF) in anticoagulation. The study recruited 100 participants over 26 days (traditional recruitment: 6 patients over 2 weeks; social media: 94 patients over 12 days). Moreover, there was an over-recruitment with over 200 suitable candidates on the waiting list. All key study completion metrics showed high compliance: telemedicine visit (91%); patient questionnaires (85%); completion of the ECG and blood pressure measurement by sensors (90%).

In the summer of 2021, the National Institute of Health (NIH), alog with other US government agencies, launched Operation Warp Speed. The goal was to accelerate the development, production and distribution of medical countermeasures for Covid-19. Interested persons have entered a register on a website, equipped with security protections. Clinical study staff used the registry to contact and select potential study volunteers. The program achieved the recruitment of 600,000 volunteers in the first 6 weeks, a group that represented a wide variety of demographics and enrolled in multiple Phase III studies on Covid-19.

These results indicate that virtualization of enrolling and conducting large, pivotal-scale clinical trials is now possible.

USE OF THE WEB AND SOCIAL NETWORKS

In the United States in recent years, researchers have expanded traditional methods, such as newspaper, radio or television advertising, flyers and bus signs, with **social media**[3] strategies to accelerate recruitment. In Europe, traditional methods of patient recruitment include leaflets and posters distributed in hospitals and / or general practitioners' offices. The material can be used only after approval by the competent Ethics Committee.

Social media can be a useful tool for patient recruitment due to its ability to target personalized messages to specific patients. Additionally, several social media platforms have a higher percentage of users from minority groups (for example, African American use of Twitter), making it easier to enlist different ethnic groups.

The use of the web and social networks to recruit patients in recent years has grown a lot in the United States, making it possible to reach the target population with a speed certainly superior to traditional recruitment methods: reaching patients on social media, for example through the numerous groups in which patients share their experience, united by a pathology or a therapy, allows you to interact with the patients themselves and provide information on the study.

INVOLVEMENT OF DOCTORS AND PATIENTS

Sending newsletters to participating centers and organizing meetings with the main players involved in clinical trials represent an excellent opportunity to share information and progress on enrollment - which is often competitive - at individual centers. This can be a stimulus for slower enrollment centers. Organizing webinars and seminars between the various experimental centers and patient associations to allow participating patients to intervene directly on the problems of the studies can increase the chances of enrollment, given the increasingly important role of patients in the success of clinical trials.

Involve doctors in the area or in the clinics, which patients turn to in the first instance. General practitioners generally do not have the potential to enroll patients for clinical trials, but they care about their patients and are available to report clinical trials when appropriate. To increase the chances of enrolling new patients in the clinical trial, it is useful to consider the relationship between the patient and the general practitioner; a simple and concise communication to the doctor, using digital engagement systems, allows to transmit the salient but exhaustive information on the study, trace the reading and plan subsequent communications based on the results obtained in terms of contacts with new potential patients.

HOW TO APPLY THE NEW MODELS

To deliver a superior patient experience and reap the maximum benefit from new technologies and models for conducting studies, companies and individuals involved in the study need to be aware of clinical trial enrollment challenges that could be a major obstacle. A deeper analysis of the main challenges, specific to each study, is critical for companies to develop effective measures for patient engagement and retention.

ABOUT MEDITRIAL

Meditrial is a leading, full services Clinical Research Organization (CRO) focused on the needs of the medical device industry. We are proud to serve the most innovative life sciences companies in the world.

Meditrial is renowned as the go-to partner by pharma and medical device companies developing breakthrough devices that require a clearly defined strategic path to first-in-man and pivotal clinical studies.

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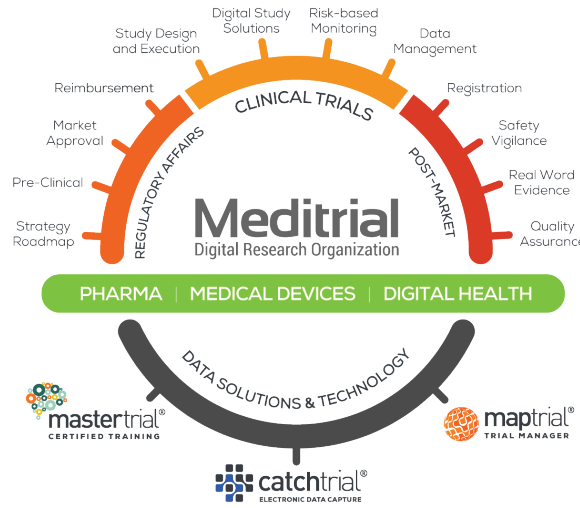

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