

Digitalization of clinical trials

How new technologies enhance the future of health care



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Medical care has improved dramatically in recent decades, leading to a better quality of life for patients and their relatives. However, biopharma companies admit that there is still progress to be made with regard to the clinical trial process, particularly in terms of high Research and Development (R&D) costs, risk of failure, and reliability of data due to archaic procedures. It would seem that the current way of conducting clinical trials is nearing an end. As the world progresses to a more digitalized era, clinical trials are driven by the adoption of new technologies, which quickly accelerate the digital transformation of their processes.



The pharmaceutical industry has supported the rise of new perspectives and approaches related to clinical trials since the 1990s. Over the past thirty years, clinical trials have undergone a substantial redesign with the introduction of process and cost optimization strategies such as Business Process Outsourcing (BPO) or risk-based monitoring¹. Nevertheless, none of the initiatives have resulted in a noticeable change, despite the substantial investments made to reduce cost and time inefficiencies in clinical trials.

As stated by the World Health Organization (WHO)², many health care systems in Europe face huge challenges when they consider introducing a new drug to the market. High costs and risks as well as time-consuming protocols reduce the efficiency of the whole drug development process. Clinical trials constitute an important part of the drug development lifecycle and rely on accurate and sufficient

data for the validation of the study and of the new drug. Since clinical trials take a long time and depend on the continuous monitoring of many participants, the digitalization of data collection could significantly improve the process and bring about efficiency gains.

Today, more than 30,000^{3,4} clinical studies recruit patients in Europe alone, with some requiring thousands of participants, all of whom need to fulfil a precise set of criteria in order to participate. Most clinical trials currently rely on archaic, paper-based data collection and require that participants regularly visit the trial sites in hospitals or research centers. From participant recruitment, to data collection, to adherence, the early stages of clinical trials are full of logistical challenges and inefficiencies. This causes delays in most trials and leads to billions of euro and countless hours spent each year validating new drugs, devices, and medical interventions⁵. ➔

1 Clinical trials at a digital inflection point, Wipro, 2016

2 Access to new medicines in Europe: technical review of policies initiatives and opportunities for collaboration and research, World Health Organization, 2015

3 <https://www.clinicaltrialsregister.eu/ctr-search/trial/2017-003847-39/LT>

4 http://www.who.int/research-observatory/monitoring/processes/clinical_trials_1/en/

5 Luxembourg towards a smart nation: providing the keys to unlock our country's potential, Deloitte Luxembourg, 2018

Considering the current state of data collection and the resulting data quality, adjustments to the process are cumbersome.

Therefore, the situation is clear; clinical trials require major changes to their processes to evolve in order to reach a point where they embrace the digitalized era. Before covering the impacts digitalization could bring to clinical trials, this article will first look at the different reasons that strengthen the case for change.

Quality of data

As mentioned, paper-based data collection represents a major issue for the accuracy and quality of data generated in clinical trials. The complexity of the trial process requires patients to not only be available at predefined times for data collection, but also to be physically present at the trial center or at the hospital to complete patient surveys known as patient-reported outcomes (PRO). Several studies⁶ found that patients' replies to surveys are often delayed or they do not reply at all. This whole approach mainly leads to a loss in terms of data quality. The systematization of data collection should be favored, requiring the standardization and digitalization of the collection process.

Flexibility of the process

The clinical trial process is quite rigid and does not allow for much flexibility⁷. Indeed, strict protocols and procedures need to be followed and changes are tedious to implement. Hence, changes can only be made when trial sponsors are well informed about the current results and can make decisions based on timely access to relevant data. Considering the current state of data collection and the resulting data quality, adjustments to the process are cumbersome. The problem also appears when it comes to the collection of data by the different collection centers acting on behalf of the trial sponsors. These centers may use different approaches to collect data and the lack of a standardized approach may result in difficulties for the trial sponsors to exploit the data collected. Therefore, it appears obvious that new technologies provide the opportunity to improve the efficiency of the clinical trial process management by tackling the lack of standardization and continuity in the collection, exchange, treatment, and storage of data throughout the process.

Patient adherence

One of the major issues faced today when it comes to clinical trials is patient adherence. 85 percent of clinical trials fail to retain enough patients⁸. In order to achieve relevant results to pursue the drug development process and justify their market launch, the commitment of patients during the trial process needs to be ensured. Nevertheless, several studies show a 30 percent dropout rate across all clinical trials. The lack of patient involvement results in poor patient retention along the process and often leads to unusable data and high investment losses. The main reasons⁹ for dropping out are, among others, inconvenient schedule or location, intensity of the process, and misunderstanding of the expectations and side effects¹⁰.

Nowadays, pharmaceutical companies are under pressure to bring increasingly targeted solutions and medicines to the market. The issues faced during drug development, including clinical trials, highlight the need to focus on innovative solutions in order to reduce costs and increase trial efficiency. The



digital transformation of clinical trials will require a thorough reassessment of current regulations pertaining to personal data management. This will surely have a positive impact on the delivery time to launch therapeutic innovations on the market, while relying on data collected directly during the patients' daily lives¹¹.

In order to tackle the issues faced during the clinical trial process, the main actors in drug development have decided to work together to meet the requirements to expedite the digitalization of trials. In 2012, several global pharmaceutical companies joined forces to form the non-profit organization TransCelerate BioPharma, with the purpose of investigating how digital technology can be leveraged to improve clinical trials¹². With the same ambition, the US Food and Drug Administration (FDA) recently started working on new regulations and guidance to define the groundwork for advances in digital health and to facilitate the incorporation of digital therapeutics into drug development and clinical trials¹³.

To ensure the efficiency of clinical trials based on these new perspectives, an innovative strategy called patient-centricity has recently emerged. Patient-centricity relies on clinical trials focused on the patient in order to better respond to their needs and ensure their commitment throughout the clinical trial process¹⁴. However, the main goal of patient-centricity is the empowerment of patients in order to attract, involve, and retain them. In particular, patient-centricity aims to engage patients to lead them to become active partners by incorporating their points of view and considerations into the trial process, thereby increasing patient retention and reducing trial failures.

Capitalizing on new technologies, sponsors of clinical trials such as Sanofi and Pfizer have aligned their business development strategies and designed new apps and wearables that not only enhance the collection of data, but also improve direct communication with patients, making it possible to adjust the study on a timely basis. With apps and wearables directly connected to the patient's phone, clinical trials can now have access to data based

on the patient's daily behaviors. Data is also more accurate and better reflects the reality of patients' lives. Indeed, instead of going to a clinical center where trials are conducted in an extraordinary environment, a drug's effects can now be tested by patients from their homes and collected directly through their digital devices, creating a whole new clinical trial ecosystem¹⁵ where the data collected is more reliable.

However, digital devices not only improve the quality of data collected, they also facilitate the diversification of the population tested in order to reflect the demographic diversity that drugs need to cover.

Embracing the digital era, sponsors involved in digital trials refer to four main benefits of digitalization¹⁶:

01. Cost-reduction by 50 percent per participant compared with current on-site clinical trials
02. Increased recruitment rate and diversification by making trial participation more convenient
03. Increased data collection on participants, since longer time spans can be monitored (up to 75 times more)
04. Increased data quality based on participant's natural environment instead of on-site-collected data

Conclusion

New technologies have drastically changed the way in which clinical trials are being conducted. Recent initiatives from global healthcare companies and governments demonstrate their willingness to catch up with current developments in the approach to performing clinical trials, which is dominated by the digitalization of process and data collection. Facing pressure in terms of costs and risks, big pharma companies now count on the adoption of digitalization to increase the efficiency of clinical trials and provide the market with targeted drugs that respond to the ever-increasing complexity of patient needs. Nevertheless, progress is still required to ensure that the relevant stakeholders work together to support the incorporation of digital technologies in the clinical trial process. ●

- 6 Current practices in patient-reported outcome (PRO) data collection in clinical trials: a cross-sectional survey of UK trial staff and management, Kyte D, Ives J, Draper H, et al., BMJ Open, 2016
- 7 Clinical trials: how technology is driving digitisation, Cambridge consultants, 2018
- 8 Global Clinical Trials for Alzheimer's Disease: Design, Implementation, and Standardization, Menghis Bairu, Michael Weiner, 2013
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- 12 In-Depth: the rise of the digital clinical trial, Dave Muoio, 2017
- 13 FDA Releases New Digital Health Draft Guidance Documents, Moe Alsumidaie, 2017
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- 15 The Digital Clinical Trial: An Ecosystem View, Edetek, Peter Smilansky, Tom Guinter & Monique Garrett, 2018
- 16 Software-Enabled Clinical Trials, Andy Coravos, 2018