Chapter 1
Advanced Technologies in Clinical Research and Drug Development

N. L. Swathi
https://orcid.org/0000-0002-3695-0732
Jawaharlal Nehru Technological University, Anantapur, India

Achukutla Kumar
Indian Council of Medical Research, India

ABSTRACT

This chapter explores the synergistic potential of decentralized trials, gene editing (e.g., CRISPR-Cas9), and the integration of artificial intelligence (AI) and machine learning (ML) in clinical trials and drug development. Decentralized trials enhance diversity and expedite timelines, while gene editing ensures precision in treating genetic diseases, necessitating robust ethical guidelines. AI and ML streamline processes, improving efficiency from patient recruitment to data analysis. Digital biomarkers and real-time monitoring systems provide rich data streams. This confluence marks a transformative era, promoting patient-centric research, accelerating innovation, and optimizing trial design. Ethical and regulatory challenges require careful navigation. Integrating digital biomarkers and continuous monitoring will enhance data quality. This synergy holds promise for personalized medicine and improved outcomes, emphasizing the need for stakeholders to balance innovation with ethical responsibility for optimal healthcare advancement.

INTRODUCTION

Clinical trials are essential for advancing medical understanding and enhancing patient care. They are crucial for assessing the security and effectiveness of novel therapies, interventions, or regulations (Kiley et al., 2017). However carrying out clinical trials can be difficult for a variety of reasons, including difficulties with recruiting participants, organizational obstacles, and methodological problems (Schmitt,

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2002). Clinical trials are increasingly using qualitative research to address more general research questions that quantitative methods by themselves cannot address (Elliott et al., 2017). Researchers can better understand the challenges of recruitment and informed consent in clinical trials with the aid of qualitative research, which sheds light on participants' perspectives and behaviors (Elliott et al., 2017).

The investigation of obstacles to minority recruitment in cancer clinical trials is also made possible (Jackson, 2020). According to one study (Briel et al., 2021), randomized controlled trials (RCTs) are frequently halted or revised as a result of poor recruitment. Narrow eligibility criteria, investigator sponsorship, increased workload for patients and recruiters, dated control interventions, and the launch of RCTs later than those with good recruitment are all factors that contribute to poor recruitment (Briel et al., 2021). Clinical trials can only be carried out successfully with the help of research coordinators. They are in charge of several duties, including patient registration and randomization, recruitment follow-up, case report form completion, collaboration with other stakeholders like Clinical Research Associates (CRAs), reporting of serious adverse events, handling investigator files, and preparing sites for audits (Rico-Villademoros et al., 2004).

Thus, technology now plays a role in reducing these concerns by combining technology with clinical research. Dentistry is one industry where cutting-edge technologies have had a significant impact. A narrative review of three-dimensional printed complete dentures was done by Anadioti et al. in 2020 (Anadioti et al., 2020). The successful fabrication of removable dental prostheses using CAD/CAM technologies was discovered to be a result of recent advancements in digital dentistry. However, they pointed out that in the available literature, milled dentures have received more attention than 3D-printed ones. Garbayo et al. (2020) reviewed developments in cancer treatment and regenerative medicine using nanomedicine and drug delivery technologies (Garbayo et al., 2020) in the field of drug delivery systems and nanomedicine. They emphasized how chemotherapeutic drugs can have their biodistribution and target site accumulation altered by nanomedicine, which lowers their toxicity.

The ability of drug delivery systems to deliver therapeutic proteins and peptides in a controlled manner while preventing their deterioration was also covered. The authors gave illustrations of anticancer drug-loaded nanoparticles that had demonstrated effectiveness in preclinical settings. Another area where advanced technologies have been utilized is in the field of RNA interference (RNAi) therapeutics.(Weng et al., 2019) provided an overview of the cutting-edge biotechnological development of RNAi therapeutics (Weng et al., 2019). They discussed the approval of Alnylam Pharmaceuticals' RNA interference drug ONPATTROTM as a treatment for hereditary forms of transthyretin-mediated amyloidosis. They emphasized how this approval has created new opportunities for the creation and application of RNAi therapeutics in several diseases.

Clinical trials use a variety of cutting-edge technologies, not just biomaterials and drug delivery systems. As part of the BRAIN Initiative, Litvina et al. (2019) talked about cutting-edge resources and tools for neuroscience research (Litvina et al., 2019). They emphasized how technological developments like deep learning and spectral flow cytometry are opening up new perspectives on Brain circuit function and allowing researchers to create ground-breaking treatments for neurological diseases. The difficulties in conventional clinical trials have also been addressed by the emergence of innovative trial designs. Innovative human trial designs that have produced notable therapeutic compounds were reviewed by Chen et al. (2020) (Chen & Qi, 2020). They discussed expedited clinical trial modes that aim to improve efficiency and reduce costs while maintaining rigorous scientific standards. They comprise master protocols, platform trials, basket trials, and adaptive trial designs.