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The Role of Innovative Clinical Trials in Novel Drug Development

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Abstract

Traditionally, a randomized clinical trial (RCT) is known to be the mainstream for novel drug development and a pipeline for therapeutic and safety evaluation of any drug candidate before entering into the market. Unfortunately, it takes tedious and complex protocols that consume huge amounts of resources, and time. Therefore, this poses the limitation in the trial, including the short study period, recruiting a small number of participants, and lack of funding by the sponsors, which in turn expedites the safety and efficacy failure, as well as the chances of several adverse drug events following the market feedback. Thanks to the recent innovation in clinical trial space that allows the flexible modifications of RCT, which consist of the evaluation of human pharmacokinetic bioequivalence, the inclusion of phase 0 stage, and adoption of "master protocol" in clinical trial design among others. The aforesaid strategies bring about the study flexibility and upper potential solutions to the inherent limitations of RCTs. This research survey in-depth literature on the specific research keywords in the recognized global scientific databases like PubMed, Elsevier, Science Direct, Google Scholar, et al. More so, we focus on highlighting the recent strategies adopt in designing the innovative clinical trials along with their associated benefit and perspectives.

Biography:

Ibrahim Aminu Shehu is a young scientist of 28 years old, an indigenous citizen of Kano State, Nigeria, who currently pursuing a Masters Degree in Pharmaceutical Sciences specialized in Drug Design and Development at Sharda University, Greater Noida, India. He is a licensed Pharmacist (Reg. No. 025144), and a member of the Pharmaceutical Society of Nigeria (PSN). He has 3 years of working experience in hospital and community pharmacy. He is a founder of HabibaMed Pharmaceuticals. Ibrahim has 3 publications in reputable journals with 2 accepted abstracts while 5 manuscripts were under some journal consideration. Moreover, he is currently executing two projects aiming to be concluded before the year ending.

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