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Digital Twin – A Revolution In Clinical Trials

Unlocking the potential of Digital Twin in Revolutionizing Healthcare

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Abstract: Digital twins (DT) are essentially virtual digital counterparts for patients, reflecting their physiological and anatomical uniqueness. The concept builds on the convergence of computer science, mathematics, engineering, and the life sciences, and its transition into pharmaceutical research has been groundbreaking. The digital replica allows researchers to observe the patient in real-time while simulating and predicting the clinical outcome for the patient in a clinical trial. Integrating machine-learning models with electronic health records, data linkage, and DNA sequencing enables the creation of a DT of patients in clinical trials. The potential benefits of DT in the setting of a clinical trial are predicting personal responses, less reliance on animal and human trials, speeding up drug development, precision, and personalization. The technology has been successfully employed in trials on Diabetes and Musculoskeletal diseases. The use of Digital Twin in a clinical trial is yet to be fully revealed. The study strives to establish the significance of Digital Twin in trials and how it can significantly enhance research.

***Index Terms*- Digital Twin, Clinical Trial, Personalization, Technology**

I. INTRODUCTION

Digital Twin (DT), a new revolution in healthcare is a virtual analogue of a biological system. DT portrays their biological, functional, and structural uniqueness (1). A Digital Twin is a replication of a biological system, such as a cell, an organ, or an individual which allows researchers to monitor the patient instantaneously while projecting the various clinical outcomes for the patient in a clinical trial (2). A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes (3). It is an advanced model designed to mirror the natural system, evaluate its conduct, and provide predictive discernment, and is being swiftly embraced by healthcare (2, 4). The integration of Digital Twin in clinical trials is yet to be fully discovered but is inevitable due to its ability to reflect the hierarchical nature of human systems (5). With technological evolution and ethical considerations, they are a tool for optimizing clinical trial designs, marking a trend towards more efficient and personalized drug development processes.

II. EVOLUTION OF DIGITAL TWINS

Digital Twin have been invariably incorporated into various fields such as automotive, construction, manufacturing, and aerospace and is in conception in healthcare, with a particular focus on research (6). It was initially adopted in 1960 as the NASA space program used it to stimulate a spacecraft and debug flight issues and was successfully utilized in the Apollo 13 mission. It succeeded when it brought back the spacecraft and astronauts safely to Earth. This led to the development of the term Digital twin in 2005 by Michael Grieves (7, 8). Following this, in 2010 NASA and John Vickers utilized DT in product cycle management (7).

III. THE TRANSITION INTO HEALTHCARE

The field of healthcare was not late to the trend and now Digital Twin has begun to emerge in the fields of Precision medicine, Personalization, and Wellness (7). The introduction of the digital twin holds the potential for transforming the nature and conduct of trials and improving therapeutic developments (9). The need for Digital Twin is accelerated by the gap between real and virtual models and thus the authenticity of the data prediction and inconsistency of the data secured from the use of Electronic Health Records in Clinical trials (10). Its use in Clinical Trials is justified by PROCOVA (Prognostic Covariate Adjustment) used for deriving the prognostic score of a patient's AI-generated DT method and is qualified by the European Medicine Agency and US Food and Drug Administration (11). The Digital Twin technology has reached its epitome in the establishment of DT Centres such as Swedish Digital Twin Consortia, Human Digital Twin One Planet Research Centre, and The Digital Twins for Health Consortium (7). Twin group offers DT for members to achieve sustainable weight loss and freedom from chronic metabolic conditions like obesity, pre-diabetes, and type 2 diabetes for a healthier, happier life (12).

IV. DEVELOPMENT OF DIGITAL TWIN

Digital Twin is constructed with AI and machine-learning models and includes a combination of Electronic Health Records, data linkages, and DNA sequencing. It is made of components such as a Physical entity, a virtual replica, and a connection. It is essential to establish an ever-evolving connection between the living system and the digital system to enable a bi-directional impact. The complexity of Digital Twin traverses from microscopic to macroscopic scales and over the course of lives. A Digital Twin should possess features such as Individualized, Interconnected, Interactive, Informative, and Impactful (5Is) (7). The Digital Twin constitutes the following elements which are inevitable in the functioning of a digital twin. An array of the data collected is used for the development of digital twins by 3D Based Model Engineering to portray the patient's characteristics. The DT encompasses a wide array of Sensors and Actuators to collect physical data from physical counterparts and to convert it to digital representation. The data from the sensors in the digital counterpart is stored in Cloud infrastructure which is capable of providing information in an updated and interactive manner. The data collected is analyzed and interpreted with the help of Artificial Intelligence. The incorporation of AI is also useful in decision-making and trend identification. The Digital Twin platform is built to observe and interact with Digital Twin and is stored in cloud platforms, web, and mobile applications. Since digital platforms are prone to the risk of a data breach, well and efficient security systems are established (13).

V. POTENTIAL OF DIGITAL TWIN IN CLINICAL TRIAL

- Individualized treatment on personalized twin and the ability to recreate a condition numerous times to target the right treatment (2, 14).
- Since the twin creates a digital counterpart of the subjects, it can aid patient recruitment. It can also contribute to being the control arm of the trial. It is particularly beneficial in the study of rare diseases where recruitment is in bottleneck condition (2).
- Its use in control arms is proven by use in conducting pilot studies before the actual trial commences. The twin can be employed in the planning, conducting, implementation, and forecasting outcomes of Clinical trials (14, 15).
- We cannot fail to address the potential of Digital Twin in reducing the time and costs needed for a clinical trial. The DT can be used to analyze a broad range of hypotheses with a single, accurate comprehensive, updated model. There is a strong possibility that digital twins may lead to shorter clinical trial timelines, which could be reduced by six months or one year, according to Fisher (9, 16).

- Real-time information and discernment are provided by the Digital Twin and allow optimize the inputs by providing continuous data information. Problems as they arise can be sorted by effective strategies (17, 16).
- It is technically capable of storing, modifying, and providing visual and digital imaging of the biological system even to microscopic levels such as the cells or nuclei thereby increasing the efficiency of the trial (5).

VI. CHALLENGES

- It is difficult to address gaps in modeling to replicate the natural system. Novel approaches must be developed to include all the essential clinical characteristics (18, 19).
- Collection modalities for obtaining patient data is a challenge in developing countries as they are in the initial stages of Electronic Health Records. Even in the updated areas, we confront issues with data drift, changing standards of care, and novel diagnostics (11, 17).
- Development of data analytics for model amendments from updated data and solving problems in calibration.
- Dealing with issues of cyber security to protect data as required by the ethical guidelines (11).
- Validating the processes to avoid discriminatory outcomes of research from algorithms with inherent or acquired bias (19).

VII. EXAMPLES

Digital Twin technologies in Clinical trials have been demonstrated by the following trials done in conjunction with DT as obtained from Clinicaltrials.gov.

Precision treatment for patients with type 2 diabetes- (NCT05181449)

Strength training for musculoskeletal injuries and diseases- (NCT04849923)

Evaluation of Digital Twins in Insulin Delivery and Meal Prediction Algorithms- (NCT04203823)

Evaluation of digital twins in giving personalized dietary advice by predicting postprandial responses- (NCT05313594) (20).

Digital families have already been used in more than 500 submissions to the Food and Drug Administration (FDA) and the FDA has brought out papers exploring the use of digital twins in medical research (5).

VIII. CONCLUSION

Digital twin technologies are the breakthrough in the field of Clinical research with their ability to elevate the outcome and requisite hours to complete a clinical trial. The trend, though novice in healthcare, has significantly impacted the fields it was involved in. The ethical and social aspects along with complexity and novelty make it challenging to come to terms with. However, in reality, Digital Twin is the future and the future is not too far.

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