Bayer's use of digital twins in clinical trials

Clinical trials are the foundation for the development of medical, surgical, or behavioural interventions for patients. They are the primary way in which the safety and effectiveness of new treatments or medical devices are evaluated. Recent technological advances, such as digital twins, have the potential to revolutionize how we run clinical trials.

Digital twins are virtual recreations of a person, organ or tissue. They can simulate biological processes to:

- *Obtain information or efficacy of a treatment*
- *Investigate potential drug-drug interactions*
- *Refine dosing*

Digital twins speed up and improve clinical research.

Computer modelling is changing the way we conduct clinical trials

Bayer has been active in this space for more than 20 years, developing new simulation technologies which are run in parallel with conventional clinical trials. Simulations are then used to refine dosing and inform early treatment development (i.e. identify new targets).

Bayer has used digital twin technology to:

Run simulations to inform dose selection for an anticoagulant medication

Bayer has used digital twin technology to run simulations to inform dose selection for an anticoagulant medication. The data was almost perfectly in line with the results and allowed Bayer to confirm the adequacy of the selected doses. This meant that patients had a lower risk of strokes, heart attacks, thromboses and other undesired side effects.

Predict the level of blood glucose to inform insulin dosing

Bayer has also developed virtual diabetes twins to predict the level of blood glucose that successfully informed insulin dosing. This technology has been instrumental in developing treatments to slow the progression of chronic kidney disease (CKD) and lowers the risk of cardiovascular complications in adults with CKD in type 2 diabetes.

Replace control arms in some clinical trials

Bayer has also used digital twins to create virtual trial arms or "external control arms", which can replace control/placebo arms in some clinical trials. This can help fill evidence gaps e.g., where an RCT (randomized control trial) is not feasible or ethically sound, in addition to reducing costs, overall development time and/or trial recruitment time.

Accelerate and scale quantum chemistry calculations

Bayer is further accelerating research by applying high-performance computing power. Therefore, Bayer is collaborating with Google Cloud to use their high-speed processors to run cutting-edge machine learning models and computationally intensive workloads so as to help accelerate and scale Bayer's quantum chemistry calculations.

Barriers to digital twin implementation in clinical trials

Lack of reliable access to good-quality data

Serious lack of standardization of healthcare data and fragmented interpretations of existing data protection rules such as the GDPR.

Lack of technical data availability

No global robust databases that represent the diversity and richness of information theoretically available across the world.

Lack of harmonized regulatory guidelines

The requirements for acceptance of evidence generated via computer models must be further developed and refined and regulatory guidance harmonized.

Bayer shares knowledge of the digital twin technology on open source platform

In recognition of the potential of this technology and the impact it can have on healthcare, Bayer developed an open source/open science platform “Open Systems Pharmacology”.

The open-source/ open-science platform aims to increase and share knowledge of the digital twins technology. Sharing information of this technology shall help to foster the regulators’ acceptance of evidence generated via data-driven modeling and simulation.

// *The platform provides the necessary **software and tutorials on how to set up digital twins in pharmaceuticals and the life sciences***

// *The tools are **available and free** to be used by **competitors, research institutes and regulatory agencies***