

Virtual human organs in clinical trials

Sumeet Subhedar, Covance by Labcorp

ABSTRACT

Today, technology has already shown its promising outcomes in different fields, and is making its way in the field of drug development (data collection and analysis). But the recent pandemic has brought the world on its knees and there was an urgent need for an effective vaccine/antivirals in fast and cost effective way. We do have a solution available today, but does it mark a beginning of wide usage of a technology: Virtual organs/body replication using computer simulation? In simple words, computer simulation is replacing actual humans with computer human. Developing a tool focusing on different data collection points that are important for any drug research, example demographics, will be a challenge, but seems to be an achievable task in upcoming years. This paper will focus on certain aspects that can be visualized if virtual organs or humans take over actual humans.

“Virtual” is one of the prime word that has been recognized globally, during the pandemic, to solve some or the other issue. And the best part being, we as humans have adapted it so fast that it seems to be a possibility to adapt the “Virtual patients/organs” as well. But, there are pros and cons for every new technology we apply, that too, on the data which is dealing with human life. Theoretically, it appears like a cake walk, but whether advancing technology is the solution for speedy and cost effective drug development OR a traditional human touch is also required.

INTRODUCTION

Our body is a blend of 11 different systems which work within and across each other so as to maintain the equilibrium for smooth functioning. Any issues or entry of a foreign body within us triggers a series of reaction by the respective system to maintain the equilibrium. Considering such a complex system, any new drug cannot be directly tested on humans and requires a pre-clinical, regulated animal testing and respective regulatory approvals.

Technology has already shown and kept its footprint in different fields viz. aeronautics, automobiles, electronics, pharmaceuticals and healthcare etc. and is advancing its steps in clinical trials, drug research and analysis. Consider it being used to design the complex human body which can be part of clinical trial, instead of actual human volunteers, which can be helpful for fulfilling certain common features during drug development, in click of a button:

- Safety
- ADME (Pharmacokinetics)
- Bioequivalence
- Metabolite reaction and excretion
- Toxicology

This computer simulation and visualization method for creating virtual body/organs will act as a boon for any drug research company for identifying the performing and non performing drugs through a quick safety and efficacy assessment and will speed up data collection and analysis.

POTENTIAL

Decentralized clinical trial is one of the most emerging methods to conduct a trial and has an advantage of providing comfort and most importantly focusing on the safety of subjects/patients. It has its own set of pros and cons, but follows similar kind of setup of traditional clinical trials.

To mimic the complex human body system, below points needs to be taken care:

- Modelling: Mapping elements of biological system
- Simulation: Showing body adapting over time under given stimuli
- Visualization: Representing results in graphical form or other image.

This tool can then provide the clinicians, investigators or doctors a scope to understand the drug effect on the complex human structure for a better healthcare. For example, HeartFlow Analysis, which mimics and creates a personal dynamic color coded 3D heart model based on CT images of patient's heart which shows actual blood flow within the blood vessels and narrowing or blockages on blood flow.

This model helps:

- a) Doctors in identifying/diagnosing the severity and scale of Coronary Heart Disease(CAD), rather than going for an invasive angiogram and then deciding the mode of action to be taken.
- b) Respective patients, who can be shown and explained about their heart conditions and necessary medication or personalized therapy which can be taken.

On similar lines, it would be an advantage of having a tool or model showing the drug and target specific receptor interaction at molecular level with computer simulation. To get such results it is time consuming method wherein the site has to check for an actual or side effects in traditional clinical trial. The benefits seem to be reasonable, wherein different approaches, methods, suggestions or recommendations for a drug action or medical device performance can be achieved for a most effective or viable option. To add on, we can expect a synergistic result, keeping in mind the technology and the experience of the clinical or investigators put on table which could help in making robust decision at every critical step. Further, the tool could also provide some insights or predication on the future body reaction/chronic effects or study the PK characteristics (ADME), especially the metabolite affecting any other body organs or any other adverse reaction that can happen over time.

We do have approved medical devices or computer based diagnostics which are helpful in identifying potential risk or stages of certain medical conditions/indications, there is always a need for a fast and effective treatment. The current pandemic has opened up different channels and approaches, virtually, on how to tackle a situation in an efficient way to achieve the target. The virtual bodies/organs could play a major role in COVID-19 trials, in identifying a potential vaccine candidate at the initial stage that is working effectively among different demographics and ethnic people. It has definitely opened the doors to consider it as a viable option for a cost effective, faster and flexible clinical trials.

ACCESSIBILITY AND RISK

Data is the new oil, and considering clinical trial and human body system, the tool modelling, simulating it and then visualization is always a challenge. Accessing such a huge medical data base, and providing entry channels to the tool will again require lot of advances and testing on the robustness and reliability of it.

Though the idea of virtual body/organs seems to be quite practicable, but lot of ground level work has to be done and accomplished including medical database (ranging from different demographics, ethnicity etc.), human anatomical database, human physiological database, computer modelling, mathematical algorithms, regulatory requirements and so on, which is humongous but achievable task in near future.

Availability of new technology, 4G/5G spectrum, can further help in enhancing this task and will play a major role in clinical trials including virtual bodies, providing us a real time data, faster data collection, analysis and regulatory submissions. More data will help in creating a stronger and varied data base for modelling purpose thus helping in robust safety and efficacy analysis.

As we see this happening on computers/servers, confidential, crucial and critical data being transferred globally deciding the fate of the drug under trail, it involves lots of risk which has to be taken care of on an

ongoing basis. We can say, with more data comes more responsibilities. Technology has and will always be an advantage, but lot of effort also runs in parallel to maintain it as an advantage for human survival.

CONCLUSION

Considering the human adaption to constantly changing demographics, food habits, climatic conditions, global warming etc., a thought that comes in my mind, are the virtual bodies/organs the best solution or will we still stick to the traditional approach of humans in clinical trial. On the other hand, the pandemic has changed the whole perception of going virtual and keep things in progress, it is actually considering virtual bodies/organs to be a part of clinical trials in near future, rather than just keeping it as a thought. To sum it up, there are still lot of things happening and new ideas might still come up to balance out the technological, scientific, regulatory, human body, real world data and data collection in clinical trials for a safe and effective drug approval and safety of patients.

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CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

Sumeet Subhedar
Covance, Bangalore
sumeet.subhedar@covance.com