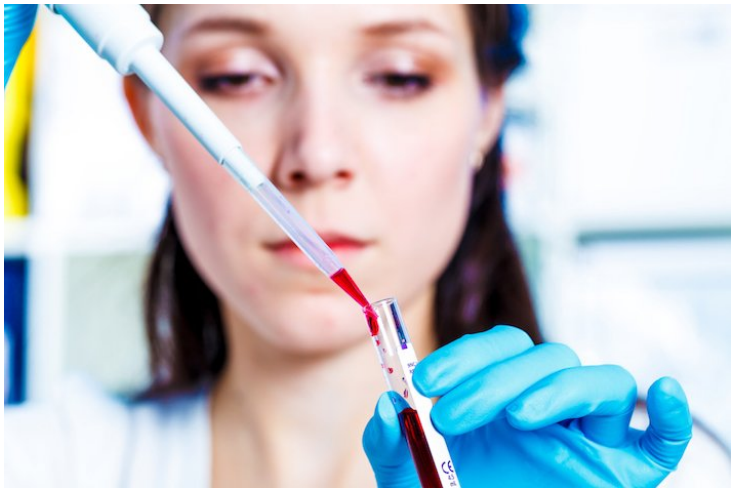
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Hetero Biopharma deploys Transcell-Quantiphi's digital animal replacement technology for drug development

16 August 2023 | News

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Hyderabad-based Hetero Biopharma has embarked on a working relationship with Transcell and Quantiphi to explore the integration of the Digital Animal Replacement Technology (DART) into its operational processes. Transcell and US-based Quantiphi have collaboratively developed an innovative solution known as DART which harnesses human Microphysiological Systems and employs artificial intelligence (AI) and machine learning-powered digital prediction models. These models are integrated into modular assays that predict safety and efficacy concerns of pharmaceuticals and biopharmaceuticals intended for human use.

One standout aspect of DART is its seamless integration into existing workflows, enhancing end-user engagement. This empowers users to assess the safety and efficacy of their assets, providing human-relevant data even before clinical trials commence and sometimes during routine batch testing stage.

Within the developmental cycle of biosimilars, a strategic approach involves a progressive evaluation of biosimilarity and efficacy equivalence. This includes the consideration of conducting animal studies when necessary and appropriate, based on remaining uncertainties. This approach aims to efficiently tailor study requirements.

DART is one of the fascinating areas that the Hyderabad-based startup Transcell is working on with an aim to replace the need for live animal testing in parts of the drug and vaccine development and manufacturing process.

The US FDA Modernization Act 2.0 marks a pivotal moment in reshaping the global pharmaceutical and biopharmaceutical industry. Additionally, the Drugs Controller General of India *(*DCGI) has granted authorisation for the use of alternative methods to animal testing, such as cell-based assays and computer models.

“We have started working with Hetero Biopharma’s young and dynamic leadership team in offering some of the non-animal DART residing modules for human cardiotoxicity and immunogenicity like key assessments. We are sure to add value in supporting their routine testing requirements within their processes and workflow – Advantage in adopting DART, which is anti-thesis to contract testing model”, says Dr S Dravida, Founder & CEO of Transcell group representing DART implementation opportunity.

Dr Bala Reddy, Director of Hetero Biopharma says “Evaluating the value of animal studies to support regulatory approval of biosimilars is becoming more and more important. In light of guidelines from various regulatory agencies that encourage alternative approaches to animal testing, innovative technologies like Transcell’s human Microphysiological Systems in combination with AI & ML-based in-silico modeling, provide opportunities to develop better and more predictive scientific tools to safeguard the environment and the health of both humans and animals.”