Short Communication

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American Journal of Pharmacology and Pharmacotherapeutics

2021
Vol 9. No. S(2)

Evolving Paradigms of Drug Discovery and Development: A new paradigm shift using 3D Bio-printed tools as translational models of efficacy and safety

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Citation: Subrahmanyam Vangala, et al., Evolving Paradigms of Drug Discovery and Development: A new paradigm shift using 3D Bio-printed tools as translational models of efficacy and safety. American Journal of Pharmacology and Pharmacotherapeutics.2022, 9:2.

Abstract

Currently, animal models are used along with a limited in vitro human models to predict the first-in-human safe dose and estimating the ideal clinical efficacious dose. Nevertheless, clinical attrition rates following IND nomination is very high (75% or higher depending on therapeutic area) with $2.5 billion cost for one drug to reach the market. Animal efficacy and toxicity models are poorly predictive of clinical efficacy and safety, therefore, requiring novel alternate models.

In the last two decades, there is extensive interest in building 3D human models those mimic human physiology and pharmacology, for effective clinical translation and for rational clinical trial design. Two major factors those impact drug disposition in humans are drug metabolism and drug transport. The drug metabolizing enzymes (DME) and drug transporters (DT) of humans are functionally different from animal equivalents and thus contribute to variation in drug pharmacokinetics (PK) from animals to humans and associated efficacy and safety predictions in humans. Additionally, human DME and DT have intra-ethnic and inter-ethnic polymorphic differences as well as can be modulated by environment and life style factors. In many cases the disease state, in particular, inflammatory mediators down-regulate the gene expressions of both DME and DT. Drug-drug interactions, where poly pharmacy of geriatric patients is associated with serious and fatal adverse events or modifying efficacy has been another serious post-marketing issue and major cause of withdrawal of drugs from market (or black-box warnings limiting their use). 3D human models can retain these properties of DME and DT, therefore, next generation models to predict human PK, efficacy and toxicity as well as for rational clinical trial design should be based on human models rather than animal models. The author will walk through the paradigm shifts in drug discovery and development, and need for human derived models to bridge the translational gaps.

Received: January 24, 2022; **Accepted:** January 28, 2022; **Published:** February 08, 2022

Biography

Subrahmanyam Vangala is currently CEO & Founder of Reagene Biosciences Pvt Ltd. Bangalore, India. He is an experienced leader in pharmaceutical drug discovery and regulatory development with nearly 30 years of industrial research experience in American Cyanamid/Wyeth, Purdue Pharma, Johnson & Johnson PRD, SHIRE Human Genetic Therapies, Sai Advantium (Sai Life) and Advinus therapeutics (Eurofin Advinus). He contributed eensively for several IND filings early drug discovery and preclinical development including clinical pharmacology. Some of the molecules he contributed for approved by US-FDA and are on the market. In his current role, the company is building various human 3D bio printed platforms for translational drug discovery research. He received his PhD from Memorial University, Canada and postdoctoral training at University of Colorado, Boulder and University of California, Berkeley. In 2019, He received prestigious Promising Entrepreneurs of India award from Economic Times of India.

