

Session 4 speaker:

Advancing clinical translation: An automated platform for massively scalable preclinical human testing

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Dr. Anthony Bahinski is Chief Technology Officer at Vivodyne, where he leads the translation of Vivodyne's automated platform for massively scalable safety and efficacy testing on lifelike lab-grown human tissues to pharmaceutical and regulatory partners. Prior to joining Vivodyne, he served as the Global Head of Safety Pharmacology at GlaxoSmithKline. Dr. Bahinski's career spans academic research and large Pharma, with more than 20 years' experience in the pharmaceutical industry. He served as Lead Senior Staff Scientist on the Advanced Technology Team at Harvard's Wyss Institute, leading DARPA, and FDA collaborative efforts in development of organ chip systems. Dr. Bahinski has served on several advisory boards and is currently member of the Science Board of the US FDA, and formerly of the US EPA Board of Scientific Counselors (BOSC), Industrial Advisory Board for Dutch Research Council awarded SMART Organ on Chip (OoC) project and European ORgan-on-Chip In Development (ORCHID) Advisory Board. He is a member of the Editorial Board of the journals Applied In Vitro Toxicology and Frontiers in Pharmacology of Ion Channels and Channelopathies. He has served on Peer Review Panels at the NIH, US EPA, and NCI SBIR. Dr. Bahinski is author/co-author of over 40 publications including peer-reviewed articles and book chapters.

Short abstract

Over the last decade, New Alternative Methods (NAMs) such as human organs-on-chips have been developed to overcome the clinical translation shortcomings and ethical issues associated with animal experimentation. However, current approaches are harshly limited by low throughput, lack of reproducibility and intensive manual labor. These issues limit their use to specific niches within preclinical efficacy and safety screening cascades and prevented their widespread adoption and implementation by the pharmaceutical industry. To address these issues, we developed a high-throughput platform infrastructure with end-to-end robotic automation for the seeding, cultivation, dosing, imaging, and multi-omic analysis of thousands of independent, functional, self-organizing, vascularized 3D human tissue models in parallel. As an example, we present an integrative bioengineering strategy to develop a vascularized, microphysiological human bone marrow model that leverages the ability of adult stem cells to self-organize into a complex, specialized microenvironment of human hematopoietic stem/progenitor cells (HSPCs). The microengineered niche reconstitutes key characteristics of native human bone marrow. Treatment with clinically relevant concentrations of FDA approved anticancer drugs demonstrated concentration-dependent induction of erythropenia, neutropenia and thrombocytopenia predictive of clinical human results. The fully automated platform has the capability to cultivate multiple different human organ tissue models for the evaluation of pharmaceutical agents. In summary, the platform supports the high-throughput interrogation of complex in vitro models that faithfully recapitulate complex human phenotype and function, while also providing robotic reproducibility and walk-away automation to a formerly artisanal, effort-intensive process.