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# Pushing the boundaries of in vitro technologies for drug discovery and safety

Working in partnership with biopharmaceutical companies, InSphero is developing 3D human-cell-based platforms that better predict patient response to new drugs.

The pharmaceutical industry is on the cusp of a momentous shift driven by innovation and skyrocketing drug development costs. Disruptive biotechnologies are changing how we develop new drugs and spurring increased demand for preclinical 'human' models that more closely mimic patient response to drugs earlier in R&D pipelines.

New therapeutic modalities, such as immunology drugs, CAR T cells, and gene therapies cannot be properly assessed on cell monolayers or animal models. Patient-centric drug discovery approaches require a better understanding of patient-specific physiology and population variability. High-throughput readout technologies, including next-generation sequencing, high content imaging, and multiplex assays, now enable researchers to extract valuable information about the effects and mechanism of action of drug candidates using human-cell-based 3D spheroids models as patient avatars.

InSphero, a Swiss-based biotech that collaborates with 17 of the world's top 20 pharmaceutical companies, is perfecting 3D-cell-based assay solutions and scaffold-free 3D organ-on-a-chip technologies engineered for this era of innovation.

"Technologies that accurately model patient tissues and organs are becoming a standard tool for improving the efficiency of preclinical drug assessment," said Jan Lichtenberg, InSphero co-founder and CEO.

"We are starting to see a real shift towards using human-based in vitro technologies to predict patient responses to novel compounds better and faster," Lichtenberg said. "Large biopharmaceutical companies seek not only to reduce their reliance on animal models, but also reduce overall costs of drug R&D."

## A more 'human' approach to preclinical research

InSphero's interdisciplinary team of cell biologists and bioengineers have been developing an extensive range of robust and scalable 3D in vitro technologies and research platforms since 2009. These include 3D human liver platforms for detecting drug-induced liver toxicity, as well as a growing portfolio of disease models to support discovery and development of drugs against diseases (Fig. 1).

"We have 3D discovery platforms for non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH), Type 1 and Type 2 diabetes, and various types of cancer," Lichtenberg explained. InSphero has developed proprietary protocols for recapitulating disease progression in vitro, such as inflammation and scarring in NASH for example, compressing a process that takes years in humans to less than 2 weeks.



Fig. 1 | Fostering innovation through research and technology partnerships.

InSphero's discovery and safety platforms are:

- Ideal for single and combination drug screening and 6 to 10x faster than comparable animal efficacy studies
- 2x more predictive in identifying hepatotoxic compounds (experiments and studies)<sup>1</sup>
- Produced using human primary cell models, with no artificial scaffolds and no animal cells
- Customizable to address specific disease conditions

With InSphero's organ-on-a-chip technology, researchers can simultaneously assess effects of drugs in multiple tissue types. "Up to 10 of our 3D microtissue models can be connected on a microfluidic chip to create a standardized multi-tissue network that is compatible with high-throughput workflows suitable for investigating pro-drug activation and potential systemic effects," said Lichtenberg. These organs-on-chips platforms will be invaluable tools in the study of diseases that affect multiple organ systems such as metabolic disorders<sup>2</sup>.

## Strategic partnering model drives innovation

InSphero's strategic partnering model is based on multi-tiered, custom solutions for pharma, biotech and academic organizations. "Our extensive experience with a vast array of 3D in vitro technologies means we can actively collaborate with our partners to optimize the models, assays appropriate for their experimental programs," Lichtenberg said. "We can help define endpoints or even re-design our technology so that it works with their existing screening

infrastructure, streamlining the evaluation of drug candidates or drug combinations."

Typically, biopharma partners pay an upfront fee to use InSphero technology and engage in development of tailored models, plus a fee to undertake research activities together. "We set success-based milestones, which can be as late as successfully completing a phase 2 trial, and success-based fees defined by asset value," Lichtenberg explained. "Once the final success fee is paid, our partner retains complete ownership of the IP asset."

Through these partnerships, InSphero is continually improving its 3D platforms and underlying technology while making its solutions affordable and accessible as assay-ready solutions. InSphero's unique shipping system enables it to deliver models to researchers globally for in-house studies. "We want as many people as possible to use this technology and leverage its full value," Lichtenberg said. "Our mission is to make pharmaceutical research more predictive, reduce animal testing, and accelerate the identification of the most suitable lead candidates for clinical testing."

1. Proctor, W.R. et al. *Arch. Toxicol.* **91**, 2849–2863 (2017).
2. Frey, O. et al. *Nat. Commun.* **5**, 4250 (2014).

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