

# InSphero and FDA's NCTR Publish the Largest Benchmarking Study on Early-stage Liver Toxicity Using 3D Liver Microtissues

*InSphero's 3D liver microtissues predicted liver toxicity with 80% accuracy in a study with 152 drugs, advancing human-based safety testing.*

ZÜRICH, SWITZERLAND, November 25, 2024 /EINPresswire.com/ -- [InSphero](https://www.insphero.com), the global leader in 3D cell culture technology, and scientists from the U.S. Food and Drug Administration's (FDA) [National Center for Toxicological Research](https://www.fda.gov/oc/nctr) (NCTR) have published the largest-ever benchmarking study on liver toxicology using 3D InSight™ Human Liver Microtissues. The study tested the hepatotoxicity of 152 FDA-approved drugs, providing compelling evidence that this high-throughput safety platform can play a crucial role in early-stage drug safety testing, potentially reducing attrition rates. Most notably, 3D liver microtissues

correctly flagged 80% of the compounds that were later withdrawn due to liver safety concerns. The peer-reviewed paper, published in [Toxicological Sciences](https://www.txicology.com), the official journal of the Society of Toxicology, marks a significant advancement in predicting drug-induced liver injury (DILI), a major cause of development discontinuation. InSphero's 3D InSight™ Human Liver Microtissues are unique in combining hepatocytes from ten individuals with other important liver cell types to recapitulate the physiology accurately. This results in a market-leading predictivity: 80% of the withdrawn drugs were correctly classified as toxic, while 89% of the safe drugs were labelled accurately, too. The results highlight the unprecedented predictive accuracy, particularly for liver-toxic drugs targeting the nervous system with an impressive 90% success rate.

"Our work with the FDA's NCTR is a breakthrough in liver toxicology research and sets a new industry standard," said Dr. Jan Lichtenberg, CEO and Co-founder of InSphero. "The 152 FDA-



approved compounds used for this study had all undergone classical preclinical and clinical safety testing, including studies in animals. Despite this, some compounds were later withdrawn due to liver safety concerns. We were able to correctly flag 80% of these withdrawn compounds using a cost-efficient, highly biologically relevant, and fast in vitro assay. This provides a promising path to reducing attrition and improving safety testing in the future.”

Driving Industry Transformation with Human-Based Safety Testing

As the FDA Modernization Act 2.0 encourages a shift toward human-based in vitro testing, this study solidifies InSphero’s 3D InSight™ Human Liver Microtissues as a cornerstone technology for modern safety assessment. By providing accurate data early in the drug discovery process, InSphero’s platform reduces reliance on animal testing and directs resources towards safer, more effective drug candidates.

“Our 3D InSight™ Liver Safety Platform integrates biological accuracy with the cost-efficiency and automation-readiness that industrial applications demand,” said Dr. Madhu Nag, Chief Scientific Officer at InSphero. “We’re enabling drug developers to make informed decisions earlier in the

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*Dr. Jan Lichtenberg, CEO and Co-founder, InSphero*

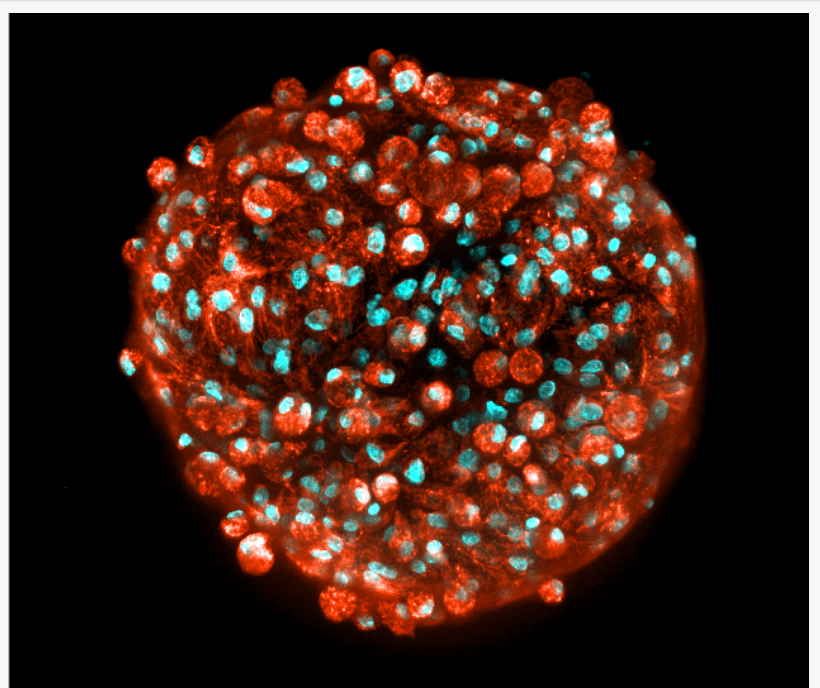
development process with a profound impact on reducing late-stage failures and accelerating the delivery of safer drugs to market.”

Unmatched Economic and Predictive Impact

The combination of predictive accuracy and scalability is poised to deliver significant economic advantages. By flagging hepatotoxic compounds earlier, drug developers could save millions in preclinical costs while improving R&D productivity and compound safety. This study also demonstrates the reproducibility of InSphero’s liver model,

ensuring reliability at scale.

“Human liver microtissues offer a highly physiological model with the same throughput as traditional 2D cell cultures, but with far greater biological relevance,” said Dr. Bruno Filippi, Vice-



3D InSight™ Human Liver Microtissues

**inSphero**

InSphero logo

President of Liver Safety at InSphero. "This positions our platform as a powerful tool for early-stage safety testing, helping drug developers identify toxic compounds before costly animal trials or clinical studies, leading to significant cost savings."

For more information on InSphero's 3D InSight™ Liver Safety Solutions or to access the InSphero/FDA peer-reviewed publication, please visit InSphero website.

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