

The Nonclinical Innovation and Patient Safety Initiative (NIPSI): Supporting Human-Based Nonclinical Approaches Through Advances in Regulation, Policy, Science, Education and Training

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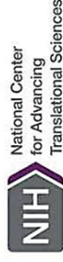
Background

The integration of modern and state-of-the-art approaches to assessing drug safety and efficacy in humans is necessary to improve nonclinical testing. The Nonclinical Innovation and Patient Safety Initiative (NIPSI) is a broad group of drug development stakeholders working to improve the human relevance of nonclinical testing through advances in science, law, policy, education and training. Participants met in-person in Jan 2017, Mar 2017 and Mar 2018, then published recommendations for advancing human-based approaches and began collaborating to implement the recommendations.

A Review of Recent NDAs

Using [accessdata.gov](https://accessdata.fda.gov), we reviewed original new drug applications (NDA), searching pharmacology and nonclinical reviews for new molecular entities by month from Jan 2016 – Dec 2018 to determine whether any NDAs included data from organ/tissue chips or MPS. We searched the terms: tissue chip, organ chip, human on a chip, microphysiological system, 3D tissue model and organ model. **We found that none of the NDAs submitted to FDA from Jan 2016 – Dec 2018 contained data from organ/tissue chips or MPS.** These results, along with other NDA reviews that found little or no use of human-based approaches in regulatory submissions, reflect the need to support integration and training of new tests.

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Recommendations

Participants identified scientific, legal, regulatory, policy, educational and training opportunities that should be addressed. Recommendations include the following calls to action:

- **Modify regulations and guidance** that mandate the use of in vivo animal tests
- **Establish a pathway for FDA acceptance** of in vitro and in silico approaches
- **Increase funding** for development of human-based approaches
- Support implementation of existing initiatives that aim to improve nonclinical approaches such as the **FDA's Predictive Toxicology Roadmap**
- Support assessment activities that **incorporate human data**
- **Increase access to high-quality human cells and tissues** for research
- Create a central hub to **communicate existing training, funding and educational opportunities** in human-based regulatory science/new approaches
- Develop additional **training and educational opportunities** in human-based nonclinical approaches

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Representatives from these institutions have contributed to the initiative. Identification here does not indicate official agency or institutional policy.