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

Elizabeth Baker, Esq., Pharmaceutical Policy Program Director, Physicians Committee for Responsible Medicine

Baker, E, et al. Advancing nonclinical innovation and safety in pharmaceutical testing. Drug Discov Today. 2018; S1359-6646(18)30264-2

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, 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.

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

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

Contact

Email ebaker@pcrm.org for more information.

PhDPosters.com