



Laura Schnackenberg, PhD

Revolutionizing Drug Testing

Arkansas Researcher's Breakthroughs in Organs-on-a-Chip Technology

Dr. Schnackenberg is on a mission to explore how new technologies can detect signs of drug toxicity and disease. She leads the Division of Systems Biology at the National Center for Toxicological Research (NCTR), an FDA research center, overseeing a group of scientists using diverse tools to address FDA-relevant regulatory questions.

One part of her team is working to explain the mechanisms behind drug-induced liver damage and learn why individuals respond differently to cancer drugs. Her team also works on developing tools that can quickly find harmful bacteria, viruses, and other contaminants. They use cutting-edge technology to discover specific indicators, called biomarkers, which can help identify diseases or the effects of drugs.

One of the team's overarching goals is to create better ways to test drugs in the lab that mimic how our bodies work and predict how safe and effective new drugs will be before they are approved for people. Dr. Schnackenberg's work is crucial for advancing our understanding of drug effects and enhancing drug safety.

The Challenge

Traditional animal testing has been instrumental in understanding how drugs work. Still, it often fails to accurately predict human responses because of the differences in physiology and metabolism between animals and humans. Moreover, ethical concerns surrounding animal testing have prompted a shift towards the use of new alternative methods (NAMs).

One promising alternative is organs-on-a-chip technology, which involves creating miniature models of human organs that mimic their functions. These systems aim to provide a more accurate representation of human biology and reduce the reliance on animal testing.

However, transitioning from animal models to organs-on-a-chip platforms poses several challenges. One challenge is validating their reliability and accuracy. Additionally, identifying the appropriate contexts of use for these systems and establishing their predictive capabilities are essential steps in gaining regulatory acceptance. While regulatory agencies such as the FDA are open to exploring NAMs, comprehensive data demonstrating the efficacy and safety of these systems is needed.

The Solution

Dr. Schnackenberg and her team's pioneering work in developing and validating organs-on-a-chip technology provides a promising solution. By utilizing chips based on human-derived cells, their research ensures a more accurate representation of human biology than animal models. This approach addresses the limitations of traditional models by offering greater predictability of human responses to drugs.

Dr. Schnackenberg and her team employ rigorous experimental methods to validate the reliability and accuracy of organs-on-a-chip platforms. They conduct extensive preclinical studies using these models, systematically comparing their performance with traditional animal models. By collecting comprehensive data on drug responses, toxicity profiles, and metabolic processes, they demonstrate the efficacy and safety of organs-on-a-chip technology for drug testing purposes.

Dr. Schnackenberg and her team collaborate closely with other FDA Centers and Offices to ensure that their research addresses critical regulatory issues. By providing evidence of the predictive capabilities and clinical relevance of organs-on-a-chip platforms, they are helping to facilitate their acceptance and integration into the drug development process. Dr. Schnackenberg's research heralds a new era of more effective and ethically sound drug testing practices.

Next Steps

Dr. Schnackenberg and her team will continue to drive innovation in methods that can be used in drug development to better identify the potential for toxicity, paving the way for safer and more effective medications. One of their primary focuses is continuing the development of the liver chip. Validation is the next significant step in this process, involving testing across different types of equipment and platforms that are commonly used in hospitals, laboratories, and research institutions to make sure the tools work effectively in real-world settings. Generating preclinical data (using lab models before testing on human subjects) can also help inform decisions about the most predictive platform for specific applications. Collaboration is also a key component of these efforts. Comparing findings with other institutions doing similar work will allow Dr. Schnackenberg's team to validate their own findings.

Dr. Schnackenberg and her team's research also holds immense potential for personalized medicine, as their research has demonstrated that patient-specific cell lines can identify populations that respond to a drug either negatively or positively. By leveraging patient-specific cell lines and advanced analytical techniques, they aim to uncover the underlying factors contributing to differential medication responses among individuals. This information would provide a foundation for tailored treatment strategies in the future. With a focus on validation and collaboration, Dr. Schnackenberg and her team pave the way for safer and more effective medications, improving patient outcomes and advancing the field of drug testing.

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