# FDA to phase out animal testing, accelerating shift to organ chips and AI in drug development



In a significant move that could reshape drug development, the US Food and Drug Administration (FDA) announced plans to phase out animal testing over the next three to five years, signalling a shift towards alternative preclinical testing methods such as organ chips, organoids, and computer simulations. The agency intends to start with monoclonal antibodies and eventually extend this approach to all drugs, potentially accelerating reviews for studies employing these alternatives.

This initiative represents a pivotal moment for the pharmaceutical industry and biotechnology firms that develop non-animal testing technologies. Jim Corbett, CEO of Emulate—a company specialising in organ chips originally developed by Don Ingber’s team at Harvard University’s Wyss Institute for Biologically Inspired Engineering—has recently experienced a surge in interest from potential clients and investors following the FDA’s announcement.

Emulate’s organ chips, which are small devices resembling thumb drives, contain hollow channels lined with living human cells sourced from patients or stem cells. These channels mimic the functional tissue interfaces of organs. For instance, their liver chip combines hepatocytes and capillary cells to replicate liver function. A 2022 study cited by the FDA demonstrated this chip’s capability to accurately identify 87% of hepatotoxic drugs that cause liver injury in patients.

“This is a clear and deliberate shift,” Corbett said, reflecting on the FDA’s stance. Tomasz Kostrzewski, chief scientific officer at CN Bio, another organ-chip developer, described the move as a “key watershed, historic moment,” stating that it is a clear signal the FDA is fully committed to moving away from animal testing within a three to five-year window.

For decades, animal testing has been the cornerstone of preclinical safety assessment in drug development. Mice, rats, dogs, and nonhuman primates have been widely used to predict a drug’s safety and efficacy in humans. However, animal testing faces challenges including ethical concerns, high maintenance costs, and limited predictive accuracy for human outcomes. Notably, approximately 90% of drug candidates that pass animal testing ultimately fail in clinical trials due to differences between species.

Alif Saleh, CEO of AxoSim, a company that develops brain organoids, emphasised the limitations of animal models for neurological research. “The human brain is incredibly complex... Animals just don’t have a brain that’s representative, quite frankly, of anything close to a human brain,” he said, highlighting the need for better human-relevant models. AxoSim grows miniature brain organoids from human neurological cells, which have shown promise in detecting neurotoxicity with considerable specificity.

Pharmaceutical companies have begun incorporating these alternatives into their testing regimes. Moderna, for example, uses Emulate’s organ chips to screen lipid nanoparticles for safety, while Hesperos collaborates with multiple pharma firms including Sanofi and AstraZeneca to assess drug candidates in diseases such as neurodegeneration. Several compounds screened in this manner are advancing through clinical trials.

The future of drug testing will likely involve a combination of human-on-chip models, organoids, and artificial intelligence-driven simulations. Corbett noted that in silico models will “have a place at the table,” and Tina Morrison, vice president of scientific strategy at EQTY and former FDA adviser, supported integrating organ chips with computational surrogates for comprehensive assessment. Thomas Hartung of Johns Hopkins University’s Center for Alternatives to Animal Testing advocated for organoid models complemented by AI to address complex functions typically studied in nonhuman primates.

Despite advances, challenges remain in replacing animal testing, particularly in ensuring the safety and reliability of new models. An anonymous former FDA official expressed concern that premature adoption could lead to patient harm and setbacks. James Hickman, chief scientist at Hesperos, underscored the high stakes, saying, “If you fail on safety, people get really upset. That could set the field back years.”

One technical hurdle is modelling complex systemic effects, including immune responses and off-target toxicities. To address this, researchers incorporate immune cells into organ chips or conduct parallel tests with multiple organ models. Ingber’s lab has developed a “human body on a chip” linking about 15 organ chips to simulate drug pharmacokinetics and dynamics, potentially enhancing clinical trial design.

Funding for the transition away from animal testing is crucial but faces obstacles. Although the FDA Modernization Act 2.0 and 3.0 have bolstered legal support for non-animal methods, they have not provided dedicated funding. Moreover, budget cuts and administrative issues have led to delays in some research projects. Ingber reported stop-work orders on two organ-chip projects, attributing these partly to political conflicts.

AxoSim’s Saleh believes smaller biotech firms will adapt quickest to new testing methods due to their focus and flexibility, whereas larger pharmaceutical firms, while slower to change, possess the resources to integrate alternatives gradually. A significant challenge lies with clinical research organisations (CROs), which traditionally rely heavily on animal testing and may be resistant to change due to established revenue models. Kostrzewski noted CROs’ reluctance to move away from conventional assays, despite industry shifts.

Following the FDA announcement, Charles River Laboratories, a major CRO specialising in animal trials, saw its stock drop sharply but indicated a pivot toward “humanized platforms” including tumoroids, cell assays, and AI. Other CROs are similarly expanding beyond animal testing, presenting new opportunities for organ-chip companies like CN Bio.

The FDA’s plan to reduce animal testing signifies a transformative period in drug development, driven by scientific innovation and evolving regulatory perspectives. Industries involved in organ-chip technology, organoids, and computational modelling stand at the forefront of this transition as efforts continue to validate and implement these new approaches.

Source: [Noah Wire Services](https://www.noahwire.com)

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