# FDA phase-out of animal testing accelerates adoption of organ chips in drug development



In recent weeks, the organ-chip industry has seen a surge in interest following a significant policy announcement by the US Food and Drug Administration (FDA) in early April. The FDA revealed plans to phase out the use of animal testing, which has been a foundational aspect of preclinical drug safety testing for decades, in favour of alternative technologies. These alternatives include organ chips—an innovation pioneered at Harvard University’s Wyss Institute for Biologically Inspired Engineering and developed commercially by companies like Emulate.

Jim Corbett, CEO of Emulate, has reported an increase in inquiries from potential clients and investors eager to support the start-up. Emulate’s organ chips, which are thumb-drive-sized devices containing hollow channels lined with living human cells, replicate key tissue interfaces to emulate organ functions such as the liver’s. One liver chip demonstrated an 87% success rate in identifying hepatotoxic drugs in a 2022 study cited by the FDA. The agency’s roadmap entails making animal studies an exception within a 3–5-year timeframe, beginning with monoclonal antibodies and expanding to all drugs. The FDA is even expected to expedite reviews for studies employing non-animal methods.

Tomasz Kostrzewski, Chief Scientific Officer at organ-chip developer CN Bio, described the FDA’s announcement as “a key watershed, historic moment,” recognising the agency's firm commitment to move away from animal models in drug development.

Animal testing, often involving rats, mice, dogs, and nonhuman primates, has long functioned as the primary method for assessing drug safety and efficacy. However, its limitations are increasingly acknowledged. Ethical concerns persist alongside practical drawbacks, such as high maintenance costs and poor predictability of human responses. Approximately 90% of drugs that pass animal testing fail during human clinical trials, highlighting the potential mismatch.

Alif Saleh, CEO of AxoSim, which develops brain organoids, emphasised the complexity of the human brain and questioned the credibility of animal brains as predictive models for neurological drug responses. AxoSim cultivates miniature human brain-like structures from neurological cells to model human brain development and function. Takeda Pharmaceuticals has successfully employed AxoSim’s microbrains to predict neurotoxicity with high specificity, quoting research published in Altex in 2022.

Several pharmaceutical companies, including Moderna, Sanofi, AstraZeneca, Argenx, and Apellis Pharmaceuticals, have started integrating organ chips and other non-animal alternatives into their drug screening processes. Emulate, in partnership with Moderna, screens lipid nanoparticles using organ chips, and Hesperos, another organ-chip developer, is actively involved in neurodegenerative disease research with multiple drug candidates progressing into clinical trials.

Going forward, drug development is expected to involve a combination of tools including organ chips, organoids, artificial intelligence (AI), and computer simulations. Corbett indicated that AI and in silico models will have an important role alongside biological models, a view supported by Tina Morrison of the start-up EQTY and Thomas Hartung from the Johns Hopkins University Center for Alternatives to Animal Testing. Hartung highlighted the potential of combining AI with organoids and stressed the importance of including immune system components within models, given the role of inflammation in disease and toxicity.

Despite promise, significant challenges remain. Replacing animal models requires robust safety assurances, as premature adoption could lead to dangerous trial outcomes and set back progress. James Hickman, Chief Scientist at Hesperos, warned that safety failures would provoke significant backlash.

Drug effects can extend beyond the target organ to other systems such as the immune or liver systems, which means that multi-organ models or interconnected organ chips are necessary for comprehensive testing. Don Ingber’s team at the Wyss Institute developed a “human body on a chip” system linking about 15 organ chips to mimic pharmacokinetics and drug impact across the body.

Funding issues have complicated development efforts. Former FDA officials and industry leaders highlight the need for government support and public-private partnerships. The FDA Modernization Act 2.0, enacted in 2022, allows the agency to consider data from alternatives like organ chips but did not increase funding to support their development. Further legislative efforts, such as the FDA Modernization Act 3.0 introduced in 2023, aim to compel the FDA to implement these policies but face uncertain prospects. Additionally, some projects have faced interruptions amid broader institutional challenges at Harvard University and contract pauses related to the Trump administration's funding policies.

The transition to non-animal testing models is expected to proceed fastest in the biotechnology sector, which tends to be more agile and focused, according to Saleh. Large pharmaceutical companies, although slower to change, possess substantial resources and have begun adopting alternatives. The continued integration of these technologies depends in part on the role of contract research organisations (CROs), which have traditionally relied heavily on animal studies. Kostrzewski observed resistance among CROs due to entrenched practices and financial incentives.

Following the FDA announcement, shares of Charles River Laboratories, a major CRO specialised in animal trials, fell sharply. The company is now reportedly diversifying into “humanized platforms” incorporating tumoroids, cell assays, and AI. Other CROs are also slowly expanding their portfolios to include non-animal testing options, reflecting shifting industry dynamics.

The shift away from animal testing, signalled strongly by the FDA’s announcement, is expected to reshape drug development. The organ-chip and organoid fields, along with computational methods, are positioned to play increasing roles, though challenges in validation, trust, and funding remain significant.

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

## Bibliography

1. <https://www.axios.com/2025/04/17/animal-testing-alternatives-drug-development> - This article discusses the FDA's decision to phase out animal testing in drug development, highlighting the role of organ-on-a-chip technology and other alternatives in this transition.
2. <https://www.reuters.com/world/us/us-fda-phase-out-animal-testing-drug-development-2025-04-10/> - Reuters reports on the FDA's announcement to replace animal testing with human-relevant methods, including AI-based models and laboratory-engineered human organ-like structures, aiming to enhance drug safety and reduce costs.
3. <https://www.optometryadvisor.com/news/fda-announces-plan-to-phase-out-some-animal-testing/> - This article details the FDA's shift away from animal testing in drug development, favoring human-relevant methods such as computer modeling, AI, and lab-grown human organoids to test drug safety.
4. <https://www.wired.com/story/the-us-just-greenlit-high-tech-alternatives-to-animal-testing/> - WIRED discusses the FDA Modernization Act 2.0, which allows drugmakers to use alternatives like microfluidic chips and miniature tissue models, reducing reliance on animal testing.
5. <https://www.livescience.com/is-fda-new-animal-testing-policy-safe> - Live Science examines the FDA's move to review data from non-animal tests, including lab-grown tissues and computer models, and the potential safety implications of this policy change.
6. <https://medcitynews.com/2025/04/fda-animal-testing-phase-out-preclinical-research-biologics-mabs-tgn1412/> - MedCity News reports on the FDA's phase-out of animal testing, starting with biologic drugs like monoclonal antibodies, and the encouragement of alternatives such as organoids and organ-on-a-chip systems.
7. <https://news.google.com/rss/articles/CBMiogFBVV95cUxNZ1paN21qWDdJdl9BYXR4RFdFSVVLVzNDaV9teGlrRnF2S3RKZUdzdjBXc3F2N1IzdG94cV8xdF91YThoY0JyMEtsYmNHSDVfVDhha01Lc0c3TFlDZGJqOEppcnBSZFFfTzBBTjFzWktrR3BuRzdnc2lrX2puOS1nZkdfU2pfWmhtVmF2WDA0TWxxUklCcjl5Tzk2Ti1PTEYySHc?oc=5&hl=en-US&gl=US&ceid=US:en> - Please view link - unable to able to access data