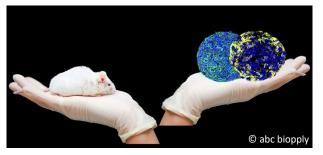


FDA no longer has to require animal testing for new drugs

The year 2023 is starting with positive news after the U.S. Congress passed the FDA Modernization Act 2.0, which removes the requirement for animal testing in drug development.

10.01.2023 The landmark achievement allows the FDA to consider non-animal cutting-edge testing methods as alternative or supportive tests for preclinical studies. The decision paves the way to finally allowing the use of data generated from new alternative methods (NAMs), such as multi-organ systems or OrganOnAChip models, for evaluating the safety and efficacy of drugs.



Although the <u>existing literature</u> demonstrates the unreliability of animal studies in terms of poor predictability of outcomes in humans in a variety of disease areas, the demand for evidence-based medicine has nevertheless made animal modeling the gold standard over the last decades. FDA's chief scientist Namandjé Bumpus says the agency is therefore in favour of trying to move away from animal testing—when other approaches are ready. *"We support alternative methods that are backed by science and provide the necessary data showing whether products are safe and effective. We continue to encourage developers working on alternative methods to present their work to the FDA." She also notes that the agency requested and received \$5 million this year to launch <u>an FDA-wide program</u> to develop methods to replace, reduce, and refine animal testing (read full article...)*

Over the last decade, abc biopply has pioneered a unique portfolio of 3D multi-organoid *in chip* assays that perfectly mimicries the physiological microenvironment. The proprietary technology enables the easy and reliable generation of quantitative datasets permitting powerful and predictive statistics. The assays and the related CRO services support pharmaceutical and biotech companies to de-risk their drug development processes. With this development abc biopply has successfully boosted the relevance of purely *in vitro* testing to the *ex vivo* level.

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