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Modernizing drug development and ensuring global equity in the organoid revolution

Emmanuel Enoch Dzakah, Chao Ni, Xiaomin Feng, Wei Hu, Bing Zhao, Shixing Tang & Clifford Pang



Global regulatory shifts are accelerating the move from animal models to human-relevant systems like organoids and MPS. Without deliberate inclusion, Africa risks exclusion despite its high disease burden, limiting global health equity and full scientific potential.

The transition to human-relevant models in biomedical research

Animal models, though historically indispensable to biomedical research, exhibit well-documented limitations that hinder their predictive utility for human biology^{1–3}. Interspecies differences often result in poor translatability of preclinical findings, while high maintenance costs, ethical challenges, and lengthy experimental timelines contribute to the unsustainable clinical trial failure rate exceeding 90%^{4,5}. Recognizing these limitations, the US Food and Drugs Administration (FDA), through the FDA Modernization Act 2.0, enacted in 2022, explicitly authorized the use of non-animal alternatives—such as cell-based assays, organoids, and organ-on-chip systems—to support investigational new drug applications, a request for authorization from the FDA⁶. Importantly, the FDA Modernization Act 2.0 also removed the long-standing requirement for animal studies in new drug license applications⁶. To further advance this regulatory paradigm, the FDA's Roadmap to Reducing Animal Testing in Preclinical Safety Studies, released in April 2025⁷, delineated a strategic transition from reliance on animal models toward the implementation of scientifically validated New Approach Methodologies (NAMs). These NAMs encompass organ-on-a-chip systems, three-dimensional organoid models, computational modeling, and other advanced in vitro assays. The Roadmap outlines a stepwise framework aimed at substantially reducing animal-based toxicity testing within the next 3–5 years through the rigorous integration of data generated from NAMs—an approach anticipated to improve human relevance, accelerate decision-making, and significantly reduce research expenditures⁷ (Fig. 1).

This landmark policy shift, driven by both scientific validation and sustained regulatory advocacy, signifies a pivotal transformation in pre-clinical testing. Sponsors are now explicitly permitted to employ non-animal methodologies—including 3D organoids and microphysiological systems (MPS) such as organ-chips—for the assessment of drug safety and efficacy, provided that such approaches are scientifically justified and validated for their intended contexts of use.

The National Institutes of Health (NIH) has launched a major initiative to reduce the use of animals in NIH-funded research, signaling an irreversible shift in biomedical science—the era of exclusively animal-dependent drug development is drawing to a close⁸. Through the National Center for Advancing Translational Sciences, the NIH has long invested in the development and validation of non-animal technologies, including advanced organoid and microphysiological systems. Most recently, the NIH announced the award of contracts totaling \$87 million to establish the Standardized Organoid Modeling Center—a national resource dedicated to optimizing organoid protocols in real time, enhancing data accessibility, and fostering global collaboration across the research community⁹. This milestone represents a significant federal commitment to accelerating the adoption of NAMs in drug discovery and toxicology research.

In parallel, regulatory momentum is also advancing internationally. In a move analogous to the actions of the FDA and NIH, the European Commission—through its European Chemicals Industry Action Plan, submitted to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions—outlined a comprehensive roadmap for the development, validation, and regulatory integration of animal-free testing methods¹⁰. The Commission has committed to presenting a data-driven roadmap by 2026, aimed at phasing out animal testing for chemical safety assessments. The overarching goal is to collaborate closely with scientific and industrial stakeholders to promote the adoption of reliable, cost-effective, and non-animal testing strategies grounded in validated NAMs¹⁰.

Beyond the United States, Europe, and China, countries such as Japan and Singapore have also implemented national strategies supporting human-relevant experimental platforms. Japan has invested through the Japanese Agency for Medical Research and Development (AMED) programs in organ-on-chip and stem-cell-derived organoid platforms for drug safety and regenerative medicine^{11,12}, while Singapore's Agency for Science, Technology and Research (A*STAR) has integrated organoid and microphysiological systems into translational research and pharmaceutical partnerships¹³. These coordinated policy and funding frameworks have been deliberately designed to prioritize organoid technology, thereby positioning these regions as leading contributors to its global advancement.

China has established a comprehensive set of ethical guidelines for the research and application of human organoids. The new framework specifically addresses critical issues such as obtaining informed consent, protecting donor privacy, and preventing the misuse or commercialization of these biological innovations^{14–16}. These guidelines align with broader international efforts to establish ethical governance frameworks for human organoid research, particularly with respect to informed consent, data protection, and responsible application.

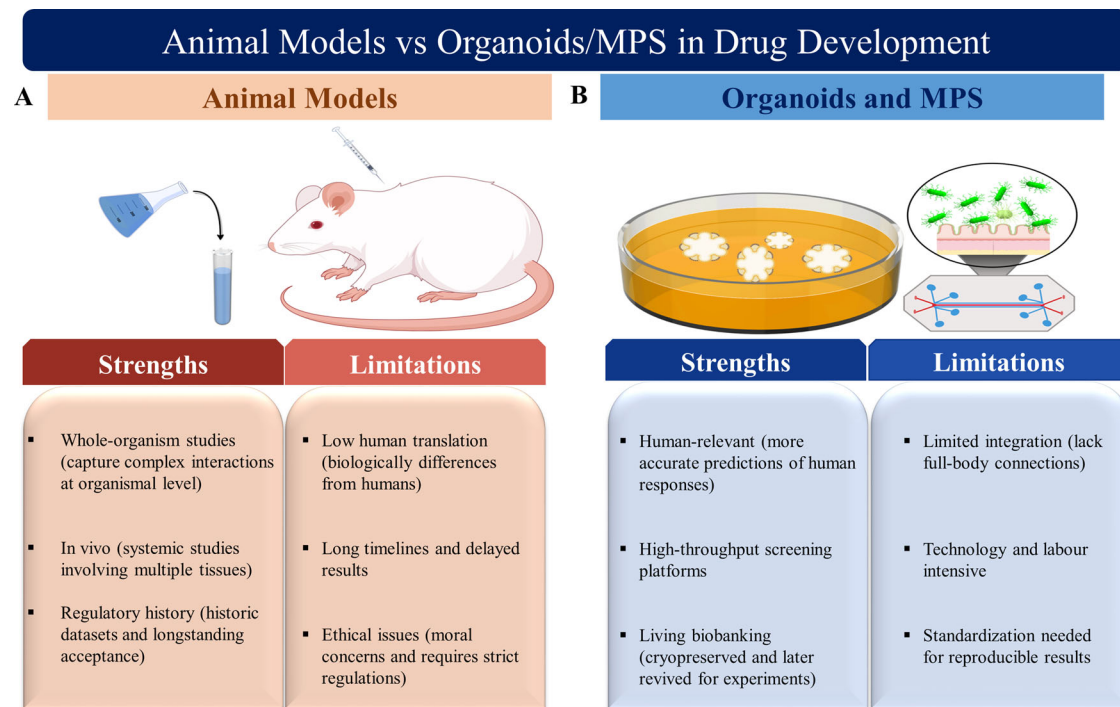


Fig. 1 | Comparison of animal models and human organoid and micro-physiological system platforms in drug development. **A** Animal models offer whole-organism context and extensive regulatory precedent but are limited by low human translatability, long experimental timelines, and ethical constraints. **B** Organoid and MPS platforms provide human-relevant biology and higher-

throughput experimental capacity, enabling improved prediction of human drug responses, while remaining constrained by limited systemic integration, technological complexity, and ongoing needs for standardization and validation. Images were drawn using Figdraw (www.figdraw.com).

Africa's stark absence and why this matters

While research hubs in the United States, the European Union, Japan, China, and Singapore continue to advance organoid and MPS development—supported by coordinated funding mechanisms, national strategies, and regulatory engagement—Africa's participation remains limited. This gap reflects a convergence of structural constraints rather than a lack of scientific interest or capability. Establishing and maintaining organoid and MPS laboratories requires sustained investment in advanced cell culture infrastructure, reliable power and water supply, high-resolution imaging platforms, and specialized reagents, all of which pose significant financial and logistical challenges for many African institutions^{17,18}. In parallel, the technical expertise required to culture complex three-dimensional organoids and operate organ-chip platforms depends on prolonged hands-on training, yet opportunities for local training or extended international placements remain scarce. Chronic underinvestment in research and development, coupled with fragmented supply chains and high import costs for specialized materials, further constrains adoption. Additionally, funding priorities—both domestic and international—often emphasize immediate public health interventions, limiting investment in enabling technologies such as organoids despite their relevance for studying infectious diseases, drug-induced toxicity, and regionally prevalent conditions.

The limited inclusion of African populations in organoid research has important scientific and translational implications. African populations harbor the greatest human genetic diversity globally, making inclusion essential for developing therapies that are broadly effective and for understanding population-specific disease mechanisms and drug responses^{19,20}. Organoids derived from African donors offer unique opportunities to study

neglected tropical diseases, infectious disease pathogenesis, genetic disorders such as sickle cell disease, and environmental or drug-related toxicities that are underrepresented in current models²¹. Also, African donors could reveal novel genotype–phenotype relationships, uncover previously uncharacterized disease mechanisms, and improve the prediction of drug efficacy and toxicity in genetically diverse populations. Furthermore, constrained access to transformative experimental platforms limits local innovation capacity and restricts the diversity of scientific perspectives contributing to global biomedical research.

A call for action to build an inclusive future

Addressing these disparities will require coordinated, long-term investment and partnership across funding agencies, governments, and research institutions (Table 1).

Targeted international partnerships. NIH, Wellcome Trust, EU programs, Belt and Road Initiative, and major pharmaceutical companies must establish equitable partnerships focused on building sustainable organoid/MPS capacity in leading African universities and institutions. This goes beyond equipment donation—it requires long-term funding for core facilities, technician training, and collaborative research projects addressing African health priorities.

South-South cooperation and regional hubs. Foster networks between African institutions and emerging leaders in organoid technology within low-income or middle-income countries, such as China, India, Brazil, and support the development of regional expertise hubs in Africa.

Table 1 | Partnership models informing capacity building for organoid and microphysiological system research

Initiative (Lead)	Primary focus	Key features	Relevance to organoid/MPS capacity building
H3Africa (NIH, Wellcome Trust)	Genomics research capacity in Africa	Africa-led funding; shared infrastructure; embedded ethics frameworks	Demonstrates how long-term, investigator-driven funding and harmonized ethical governance can support advanced human-derived biological research, including organoids ^{22–24}
Africa CDC – Pathogen Genomics Initiative (African Union)	Public health genomics	Regional reference laboratories; workforce training; continent-wide data systems	Provides a scalable model for regional hubs and centralized training applicable to organoid/MPS core facilities ²⁵ .
African BioGenome Project (Africa Union)	Biodiversity genomics	Open science; distributed networks; local ownership	Highlights the importance of Africa-led governance, open data, and networked research structures relevant to organoid biobanking and protocol sharing ^{26–28}
ASLM Laboratory Strengthening Program (Fleming Fund Projects-UK)	Clinical laboratory systems	Hands-on training; quality management; sustainability	Underscores the role of sustained technical mentorship and quality systems for reproducible organoid and MPS research ²⁹ .
China–Africa Science and Technology Partnership (Belt and Road Initiative)	Joint laboratories and technology transfer	Infrastructure development; personnel exchange; applied research	Illustrates how South–South cooperation can support infrastructure and skills transfer for advanced experimental platforms ^{30–32}

Selected international and regional initiatives illustrate transferable principles—long-term investment, workforce development, ethical governance, and regional hubs—that can inform sustainable capacity building for organoid MPS research in Africa.

Dedicated funding streams. African governments, the African Union, and global health funders such as The Global Fund or Africa Centres for Disease Control and Prevention (CDC) must allocate specific funding for advanced biomedical engineering and human cell-based model research. Leveraging initiatives like the Africa CDC’s Pathogen Genomics Initiative could integrate organoid components.

Open science and technology transfer. Promote affordable, open-source designs for organ-chip systems and facilitate technology transfer agreements that prioritize access and local manufacturing potential.

Building local capacity. Efforts must be made to integrate organoid/MPS concepts into postgraduate curricula and support extensive postdoctoral training fellowships in both African and international labs for African scientists, with binding commitments to return to Africa and build capacity.

Conclusion

The FDA and NIH have rightly accelerated the transition beyond sole reliance on animal models. Similarly, the European Union, China, as well as countries from East Asian and Southeast Asian regions have also come up with guidelines and roadmaps on the application of NAMs. However, the benefits of this revolution—more predictive, efficient, and personalized medicine—will remain inequitably distributed unless the global scientific community actively ensures Africa is not just a bystander, but a co-creator. Investing in inclusive organoid and organ-chip capabilities across Africa is a scientific and moral imperative to harness full human biological diversity, tackle neglected diseases, and build a truly global ecosystem for 21st-century drug development. Ensuring that organoid and microphysiological system research reflects global human biological diversity will be essential for maximizing the scientific validity, translational impact, and equity of next-generation drug development.

Reporting summary. Further information on research design is available in the Nature Portfolio Reporting Summary linked to this article.

Emmanuel Enoch Dzakah ^{1,2} , Chao Ni³, Xiaomin Feng^{1,2}, Wei Hu^{1,2}, Bing Zhao ^{3,4}, Shixing Tang⁵ & Clifford Pang ^{1,2} 

¹Clinical Research Centre, Guangdong Clifford Hospital, Guangzhou, China. ²Guangzhou Wellness Stem Cell Research Co., Ltd, Guangzhou, China. ³Z Lab, bioGenous BIOTECH, Shanghai, China. ⁴MOE Organoid Resource Center, Jiangxi Medical College, Nanchang University, Nanchang, China. ⁵Institute for Global Health, Southern Medical University, Guangzhou, China. ✉e-mail: edzakah@ucc.edu.gh; cpang@cliffordgroup.com.cn

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Author contributions

E.E.D., S.T., and C.P. conceived the concept and scope of the manuscript. E.E.D., X.F., and W.H. drafted the initial manuscript. E.E.D., C.N., and B.Z. curated and refined Table 1 and Fig. 1. E.E.D., S.T., and C.P. critically revised the manuscript for intellectual content. All authors reviewed and approved the final version of the manuscript.

Competing interests

The authors declare no competing interests.

Additional information

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Correspondence and requests for materials should be addressed to Emmanuel Enoch Dzakah or Clifford Pang.

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