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Re: Comments on the Draft Application Guidelines, Application Form, and Implementation Framework for the “PIONEER Program” to Promote Research and Application of New Approach Methodologies in Drug Development

Dear Drs. Sun and Yin:

On behalf of Hong Kong-based People for the Ethical Treatment of Animals (PETA) Asia—PETA entities represent more than 10.4 million members and supporters worldwide—we respectfully submit these comments on the Center for Drug Evaluation's (CDE) proposed Propel Innovation and Operation of NAMs to Enhance Efficiency in R&D (PIONEER) Program,¹ which seeks to promote the research and application of New Approach Methodologies (NAMs) in drug development.

The PIONEER Program is an important step toward modernizing drug development and nonclinical testing, one that should be supported and expanded. To best achieve its goals, leadership should ensure that NAMs are prioritized as the first choice in research and nonclinical testing, that NAMs are defined as only those derived from humans and human data, and that their advancement accompanies a dramatic reduction and planned transition away from the use of animals.

These additions, along with the recommendations provided at the end of this letter, will ensure that the program improves research quality and demonstrates China's position as a world leader in innovative, superior research and testing methods that will benefit human health and the environment.

PETA U.S.'s [Research Modernization NOW](#)² outlines a roadmap for optimizing investment in research and testing to cure and prevent disease—by ending funding for strategies that don't work and investing in evidence-based methodologies that are relevant to humans. When replacement of animal use is the primary focus, NAMs will improve human relevance, increase efficiency, and reduce uncertainty caused by interspecies differences.

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We are encouraged by the CDE's definition of NAMs as innovative methods or strategies that do not rely on traditional animal tests and are oriented toward human biological relevance, including computational, chemical, *in vitro* approaches such as organoids and organ chips, *ex vivo* methods, and structured combinations of such methods, and

encourage the CDE to exclude “lowly developed animals” from the definition of NAMs to ensure human relevance. We appreciate the efforts of the CDE in creating a constructive platform through which drug developers, NAM developers, and regulators can discuss intended uses, validation plans, and regulatory application of NAM evidence.³

Science Supports a Transition to Human-Relevant Methods

In addition to ethical concerns, modern science demonstrates that experiments on animals fail to yield effective treatments or cures for human disease, including the top killers in China. Reliance on animal studies diverts funds from more promising areas of research and delays the development of effective drugs and treatments, limiting our ability to protect human health and the environment. For example, 100% of HIV vaccines,^{4,5} and new drugs for stroke,^{6,7} and sepsis,⁸ fail in human clinical trials. 95% of **all** new drugs fail in human clinical trials,⁹ and 90% of basic research fails to lead to human health advances within 20 years.¹⁰ An estimated 89% of preclinical experiments are not reproducible,¹¹ and 81% of the time, animal tests fail to detect the potential side effects of drugs in humans.¹²

By contrast, innovative, human biology-based research methods, such as organoids, organs-on-chips, and other advanced *in vitro* models, 3D printing, ‘omics techniques, and advanced computer modeling, use human biology directly. These reasons are why NAMs are gaining global momentum to replace animal use (Appendix A). As the CDE has recognized, NAMs can improve accuracy in extrapolating nonclinical results to humans.

Chinese innovation can lead the way to a cruelty-free future. Public sentiment in China (and globally) is increasingly opposed to animal suffering. By leading in developing international roadmaps and data, the CDE can set moral as well as scientific leadership.

Recommendations

We encourage the CDE to build on the PIONEER Program's promise by committing to a clear, time-bound phase-out of experiments on animals. We recommend the following:

1. Adopt the [Research Modernization NOW](#) strategy:
 - Phase out the use of animals in research areas where evidence has shown animals to be poor models of human disease, and using them has impeded progress.
 - Conduct systematic reviews of the efficacy of animal use to identify additional areas in which non-animal methods are available and/or animal use has failed to protect human health and the environment, and can, therefore, be ended.

- Redirect funds from animal studies to reliable, non-animal methods.
 - Implement a harm-benefit analysis system for animal studies that includes an ethical perspective and consideration of lifelong harm inflicted on animals.
 - Work with organizations and agencies globally to harmonize and promote international acceptance of non-animal testing methods for regulatory testing requirements. In this vein, the CDE should consider NAMs that have been accepted by other regulatory agencies, as a way to save time and resources.
 - Educate the scientific community about the benefits of non-animal approaches and train scientists to use them.
2. Additionally, the following would help the PIONEER Program meet its goals:
- Make replacement the central program objective.
 - Mandate human-based methods as the first choice for applicants.
 - Validate NAMs against human biology and real-world data, rather than concordance with less predictive animal data.
 - Revise regulations to accept NAMs and update technical guidelines to explicitly allow NAM data in place of animal tests.
 - Offer expedited review for submissions that reduce animal use.
 - Require applicants in the PIONEER Program to report animal use and progress in adopting NAMs.
 - Invest in NAM research and infrastructure to develop, validate, and widely share these technologies throughout China.
 - Engage stakeholders, including ethicists and animal protection organizations.
 - Publicly report on the program's progress.

By aligning the PIONEER Program with these best practices, China can accelerate 21st-century science. We ask that the CDE put forth the goal of a future free of experiments on animals and an evidence-based plan for getting there. We respectfully submit these comments and look forward to collaborating on a roadmap that promotes innovation *and* compassion.

Thank you for your consideration.

Yours sincerely,



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Appendix A

Roadmaps from the EU, UK, US, and Canada

As you know, regulators around the world are adopting plans to replace animal experimentation. Notably, the European Commission just published its *Roadmap towards phasing out animal testing* (June 2026) covering industrial chemicals, pharmaceuticals, and more.¹³ This roadmap builds on EU law (Directive 2010/63/EU),¹⁴ which mandates that animal use be phased out “as soon as scientifically possible.”¹⁵ It includes more than 30 actions to replace experiments on animals with human-relevant methods. Similarly, the United Kingdom unveiled an ambitious strategy (November 2025) to “phase out animal tests as alternative methods come on stream.”¹⁶ That strategy commits to concrete targets (e.g., ending all animal tests for skin/eye irritation by the end of 2026, and reducing dog/primate use in pharmacokinetics by 2030), supported by dedicated funding (£75 million) and by cross-government collaboration. U.K. animal welfare groups welcomed this “clear ambition towards eliminating animal use.”¹⁷

The U.S. FDA has taken similar steps. In April 2025, the FDA announced a plan to phase out certain animal testing requirements for new drugs.¹⁸ Former Commissioner Makary called this a “major step toward ending the use of laboratory animals in drug testing,” noting that thousands of animals could be spared each year as agencies adopt AI and human cell-based tests. The FDA’s roadmap encourages drug developers to submit NAM data (computer models, organoids, organ-on-chips) in place of animal-based studies, promising faster reviews and incentives.¹⁹

In April 2025, the U.S. National Institutes of Health (NIH) announced a plan to move funding away from animal experimentation and toward cutting-edge non-animal research methods.²⁰ NIH’s plan adopts several recommendations from PETA U.S.’s [Research Modernization NOW](#), including expanding funding, training, and infrastructure for non-animal methods. In September, 2025, NIH launched the Standardized Organoid Modeling Center, a national resource for human organoid models,²¹ and in June, 2026, announced the creation of the Office of Research Innovation, Validation, and Application (ORIVA), to speed the development and use of human-based research technologies across the agency.²²

In January 2026, the EPA reaffirmed its commitment to eliminating animal tests²³ and, in June, updated its list of non-animal methods for chemical assessment and launched a new program for stakeholders to nominate methods to the list.²⁴ The EPA’s renewed focus on non-animal methods reflects the agency’s long-standing position and the significant scientific and technological progress that now allows for more reliable, human-relevant testing approaches.

In Canada, the federal government in 2025 released a “Strategy to replace, reduce or refine vertebrate animal testing” under chemical safety laws.²⁵ This strategy – following Canada’s 2023 ban on cosmetics animal tests – sets a goal to end animal toxicity testing by 2035 (as pledged by the government). It outlines pillars for integrating NAMs (AI models, human cells, and tissues, etc.) into risk assessment. Environmental and Health Canada emphasize that NAMs “often outperform traditional animal methods” – predicting outcomes more accurately, faster, and at lower cost.²⁶

These examples show that clear, time-bound roadmaps are practical and achievable. CDE has the opportunity to build on this momentum by developing a roadmap tailored to China's scientific strengths, regulatory priorities, and leadership in biomedical innovation. We encourage the PIONEER Program to include mandatory milestones to phase out specific categories of animal tests (e.g. cosmetics, safety pharmacology, toxicokinetics) and replace them with NAMs, beginning with areas where animal use is no longer scientifically necessary or where accepted non-animal methods are already available. Early targets (e.g. ending cosmetic safety animal tests immediately, discontinuing the use of poorly predictive species) would signal China's commitment to advancing more reliable, human-relevant science. Such a roadmap would position China as a global leader in modern regulatory science while contributing to the shared international goal of replacing animal tests with approaches grounded in human biology.

¹ National Medical Products Administration, Center for Drug Evaluation. CDE launches the "Pioneer Program" for New Approach Methodologies (NAMs) in nonclinical research and evaluation. Published July 24, 2026. Accessed July 30, 2026.

<https://www.cde.org.cn/main/news/viewInfoCommon/84bd78d4d9d2a28cca032d13f7aa66a>

² PETA U.S. Research Modernization NOW. 2026. www.science.peta.org

³ National Medical Products Administration, Center for Drug Evaluation. Pioneer Program for New Approach Methodologies (NAMs) in Nonclinical Drug Research and Evaluation (先锋计划). Published July 2026. Accessed July 30, 2026.

<https://www.cde.org.cn/main/att/download/38354907bcb042c14468295d8b1a8d3f>

⁴ Bailey J. An assessment of the role of chimpanzees in AIDS vaccine research. *Altern Lab Anim*. 2008;36(4):381-428.

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⁵ Is there a vaccine to prevent HIV? HIV.gov. Updated February 25, 2026. Accessed July 31, 2026. <https://www.hiv.gov/hiv-basics/hiv-prevention/potential-future-options/hiv-vaccines>

⁶ O'Collins VE, Macleod MR, Donnan GA, Horky LL, van der Worp BH, Howells DW. 1,026 experimental treatments in acute stroke. *Ann Neurol*. 2006;59(3):467-477. doi:10.1002/ana.20741

⁷ Roth S, Liesz A. Stroke research at the crossroads—where are we heading? *Swiss Med Wkly*. 2016;146:w14329.

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⁸ National Advisory General Medical Sciences Council Working Group on Sepsis. Final Report. Published May 17, 2019. Accessed July 31, 2026. <https://www.nigms.nih.gov/sites/nigms/files/migrated/nagmsc-working-group-sepsis-report.pdf>

⁹ National Center for Advancing Translational Sciences (NCATS). New Therapeutic Uses. Updated November 5, 2024. Accessed July 31, 2026. <https://ncats.nih.gov/research/research-activities/ntu>

¹⁰ Contopoulos-Ioannidis DG, Ntzani E, Ioannidis JP. Translation of highly promising basic science research into clinical applications. *Am J Med*. 2003;114(6):477-484. doi:10.1016/S0002-9343(03)00013-5

¹¹ Freedman LP, Cockburn IM, Simcoe TS. The economics of reproducibility in preclinical research. *PLoS Biol*. 2015;13(6):e1002165.

doi:10.1371/journal.pbio.1002626

¹² van Meer PJ, Kooijman M, Gispens-de Wied CC, Moors EH, Schellekens H. The ability of animal studies to detect serious post marketing adverse events is limited. *Regul Toxicol Pharmacol*. 2012;64(3):345-349. doi:10.1016/j.yrtph.2012.09.002

¹³ European Commission. Roadmap to phase out animal testing for chemical safety. Press Release No. IP/26/1214; June 1, 2026. Available at: https://ec.europa.eu/commission/presscorner/detail/en/ip_26_1214. Accessed July 30, 2026.

¹⁴ European Parliament and Council of the European Union. Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes. *Off J Eur Union*. 2010;L276:33-79.

¹⁵ *Ibid*.

¹⁶ Department for Science, Innovation and Technology; Department for Environment, Food & Rural Affairs; Home Office. Animal testing to be phased out faster as UK unveils roadmap for alternative methods. GOV.UK. Published November 11, 2025. Accessed July 31, 2026.

<https://www.gov.uk/government/news/animal-testing-to-be-phased-out-faster-as-uk-unveils-roadmap-for-alternative-methods>

¹⁷ *Ibid*.

¹⁸ U.S. Food and Drug Administration. FDA announces plan to phase out animal testing requirement for monoclonal antibodies and other drugs. FDA.gov. April 10, 2025. Accessed July 31, 2026. <https://www.fda.gov/news-events/press-announcements/fda-announces-plan-phase-out-animal-testing-requirement-monoclonal-antibodies-and-other-drugs>

¹⁹ U.S. Food and Drug Administration. Roadmap to Reducing Animal Testing in Preclinical Safety Studies. Silver Spring, MD: FDA; 2024. Available at: <https://www.fda.gov/media/186092/download?attachment>. Accessed July 30, 2026.

²⁰ National Institutes of Health. NIH to prioritize human-based research technologies. NIH.gov. April 29, 2025. Accessed July 31, 2026. <https://www.nih.gov/news-events/news-releases/nih-prioritize-human-based-research-technologies>

²¹ National Institutes of Health. NIH establishes nation's first dedicated organoid development center to reduce reliance on animal modeling. NIH.gov. September 25, 2025. Accessed July 31, 2026. <https://www.nih.gov/news-events/news-releases/nih-establishes-nations-first-dedicated-organoid-development-center-reduce-reliance-animal-modeling>

²² National Institutes of Health. NIH launches new office to advance human-based research and reduce animal use. Published June 15, 2026. Accessed August 3, 2026. <https://www.nih.gov/news-events/news-releases/nih-launches-new-office-advance-human-based-research-reduce-animal-use>

²³ United States Environmental Protection Agency. Administrator Zeldin gets EPA back on track to eliminate animal testing after Biden admin halted phase out. EPA.gov. January 22, 2026. Accessed July 31, 2026. <https://www.epa.gov/newsreleases/administrator-zeldin-gets-epa-back-track-eliminate-animal-testing-after-biden-admin>

²⁴ United States Environmental Protection Agency. Trump EPA Takes New Action to Eliminate Animal Testing. EPA.gov. Published June 2, 2026. Accessed July 31, 2026. <https://www.epa.gov/newsreleases/trump-epa-takes-new-action-eliminate-animal-testing>

²⁵ Environment and Climate Change Canada; Health Canada. Strategy to Replace, Reduce or Refine Vertebrate Animal Testing Under the Canadian Environmental Protection Act, 1999 (CEPA). Government of Canada. Published July 2025. Accessed July 31, 2026. <https://www.canada.ca/en/environment-climate-change/services/canadian-environmental-protection-act-registry/implementing-modernized-cepa/strategy-replace-reduce-refine-vertebrate-animal-testing.html>

²⁶ *Ibid.*