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ANIMALS IN SCIENCE

Supporting Replacement in Academia

BARNEY REED

European Commission

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Available languages: English

Commission acts to accelerate phasing out of animal testing in response to a European Citizens' Initiative

FDA Announces Plan to Phase Out Animal Testing Requirement for Monoclonal Antibodies and Other Drugs

For Immediate Release: April 10, 2025

Today, the U.S. Food and Drug Administration is taking a groundbreaking step to advance public health by replacing animal testing in the development of monoclonal antibody therapies and other drugs with more effective, human-relevant methods. The new approach is designed to improve drug safety and accelerate the evaluation process, while reducing animal experimentation, lowering research and development (R&D) costs, and ultimately, drug prices.

Recent technological progress and policy momentum

efpia
European Federation of Pharmaceutical Industries and Associations

EFPIA Recommendations on Phasing Out Animal Testing for Chemical Safety Assessments

JUNE 2025


MERCK COMPANY EXPERTISE RESEARCH NEWS & MEDIA CAREERS INVESTORS

SUSTAINABILITY BUSINESS ETHICS ANIMAL ETHICS

THE MERCK APPROACH FOR A ROADMAP TO PHASE OUT ANIMAL TESTING

Roadmap means that the right things need to be done first, not that we can solve everything today.

SHARE

World Health Organization

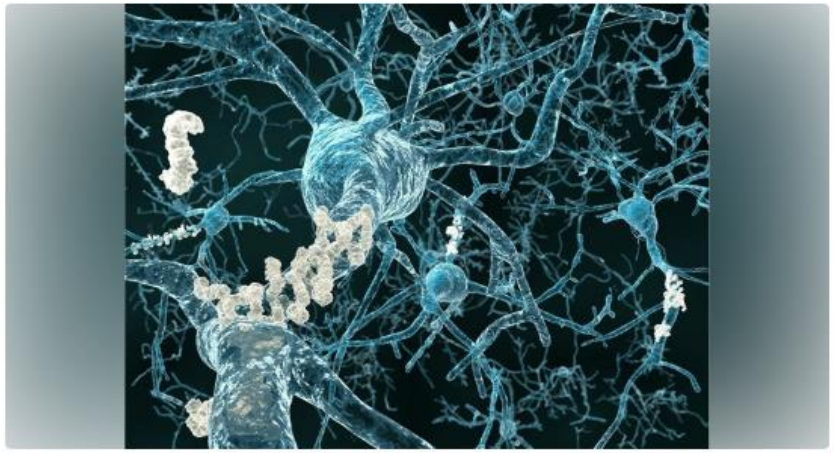
WHO: DRAFT VERSION
ENGLISH ONLY

Guidelines on the phasing out of animal tests for the quality control of biological products

"The Government will take steps to place the UK at the forefront of an alternative methods revolution and we believe that scientific advances make the prospects for change better than they have ever been"

Neural organoids offer insight into mechanisms of dementia

5mo • 1 min read



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Article | Open access | Published: 04 June 2024

Using organ-on-a-chip technology to study haemorrhagic activities of snake venoms on endothelial tubules

Mátyás A. Bittenbinder, Flavio Bonanini, Dorota Kurek, Paul Vulto, Jeroen Kool & Freek J. Vonk

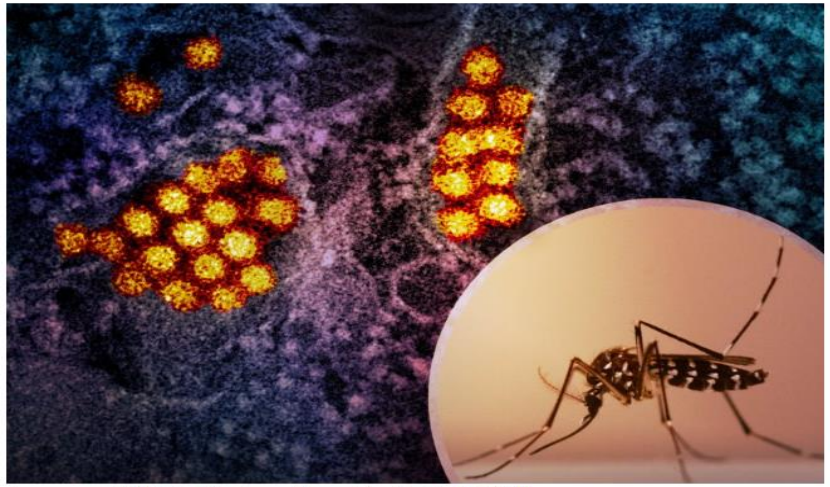
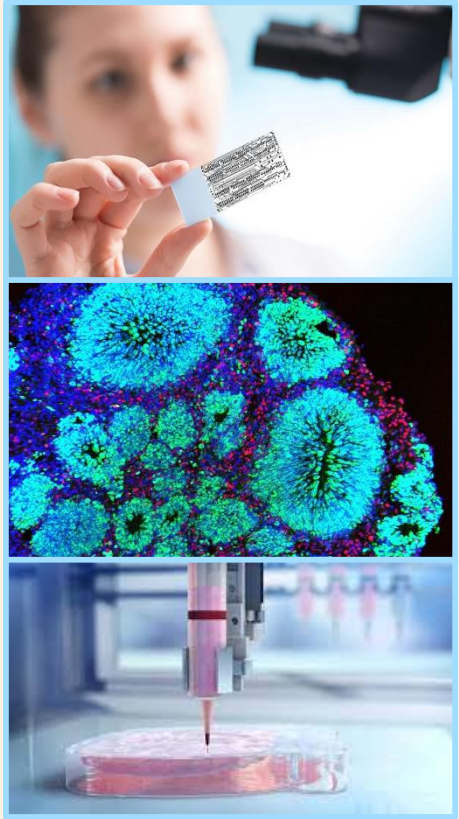


Image source: NIAID, Aedes Mosquito and Dengue Virus Particles, (CC BY 2.0)

News • Mechanopathology

'Dengue-on-a-chip' to study infection mechanisms

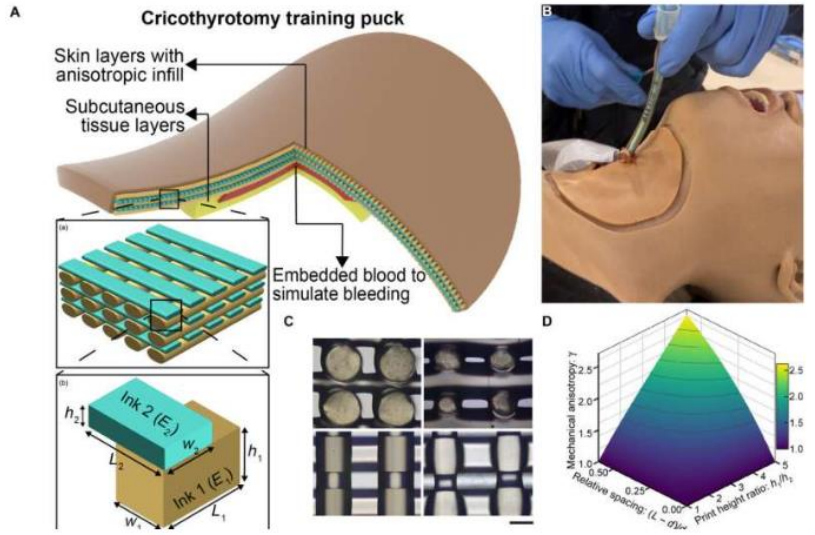
Researchers at Leiden University have created a unique model that mimics how disease develops after a dengue infection. This 'dengue-on-a-chip' model helps them study the virus more effectively.

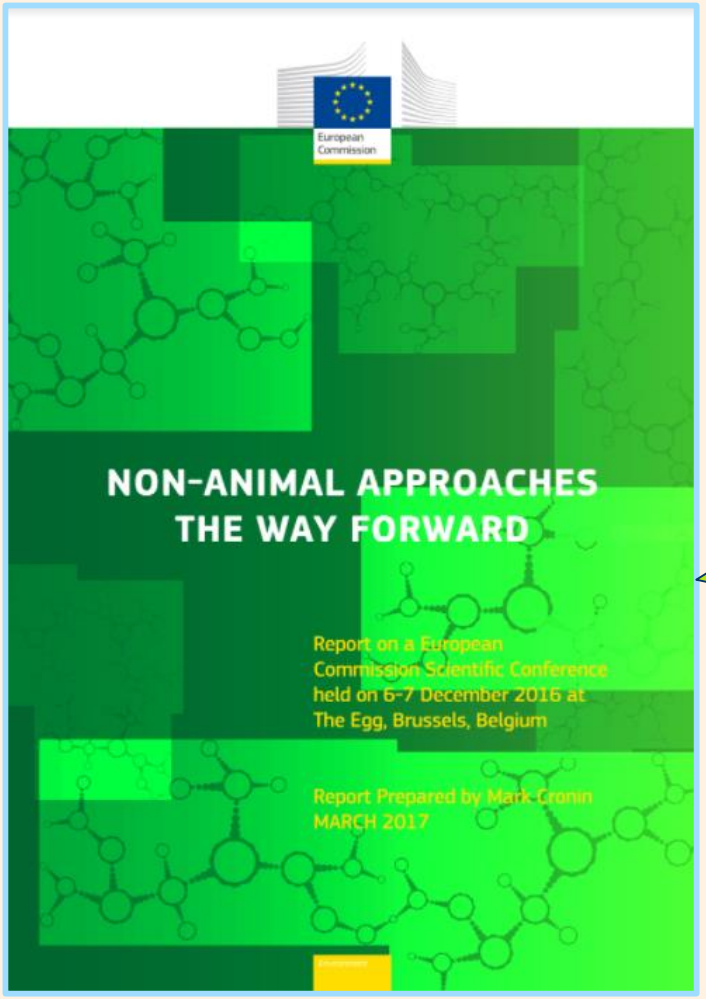


3D-printed tissue brings new realism to medical training

by University of Minnesota

edited by Gaby Clark, reviewed by Robert Egan · Editors' notes





*"…**new technologies will not implement themselves**, neither will the obstacles to their implementation be resolved automatically."*

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https://ec.europa.eu/environment/chemicals/lab_animals/3r/pdf/scientific_conference/non_animal_approaches_conference_report.pdf

"scientific practices do not change through the development of new technologies alone […] ***support for scientists needs to be put in place in order to accelerate this transition****"*

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54%

of animal use for scientific purposes in the UK takes place in universities or medical schools

Latest available data.
Source: Home Office 2020.

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Image credit: istockphoto.com/fotografixx

Some key features of academia…

- has been described* as having "***scientific inertia***" and "***lock-in***" around the use of animals in research
- traditional methods passed on
- animal models often taught as a 'gold standard'
- drivers and rewards of behaviour reinforce animal use
- lack of 'value' placed on development and use of NATs/NAMs
- insufficient inter-disciplinary collaboration
- lack of support for changes in career direction

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* e.g. Lohse (2021)

*"In general, there appears to be **a tendency to use the model that is available rather than the best model for the question** and this approach can lead to poor reproducibility and translation. In addition, risk aversion means researchers tend to use the same model, '**stick to what they know**', as changing models is perceived to be difficult due to validation concerns and associated costs, risk of failure, and funding insecurities."*

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www.ukri.org/wp-content/uploads/2022/03/final-5040-JS-Publishing-Models-Report-A4_CB_v8.pdf

Words that researchers would use to describe research culture

Survey, n = 2839 – research community, UK and international.

Wellcome 2020

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https://wellcome.org/reports/what-researchers-think-about-research-culture

Our project:

Exploring social and cultural barriers to the uptake and acceptance of non-animal methods in academia

Dr Renelle McGlacken

Including:

- How do researchers make **choices** about which models and methods to use?
- What are the key considerations, **motivators** or **concerns**?
- How do researchers view the **role and potential of non-animal models** and methods?

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- Convened stakeholder group for input to our proposed plan, and again afterwards to discuss the findings around the **key drivers** and **barriers** to the wider use of non-animal approaches in academia.

- Seek to provide clear ideas and **recommendations** for:

  academic institutions, **funders**, **professional bodies**, **publishers**, **governments**, **people in different roles** (e.g. AWBs, scientists) and others to help to **overcome the barriers**

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- **32 in-depth semi-structured interviews** with researchers using animals
  (PhD, early, mid, and late career)

- Gathering **insights into decision-making** around methods and models, and how academia may shape **awareness** of, **confidence** in, and **enthusiasm** towards non-animal approaches.

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Findings - 11 main 'themes'

Awareness of NAMs

Knowledge, expertise and skills

Funding

Access to NAMs

Career progression

Institutional commitment to replacing animals

Training in NAMs

Disciplinary silos e.g. those developing or using NAMs vs animal models

Established nature of animal models

Perceived limitations of NAMs

Perceptions of NAMs as 'complementary' methods

Examples

Use of particular research models can lead to a person developing specific skills, professional status and interests, which can then be hard to move away from

*"**There's a lot of inertia,** […and when you have] a long history of working together, then you do get that, almost kind of peer pressure. There's just a lot of momentum there for one group to [then] say, "Actually, we're going to stop using this mouse and we're going to start using something else," because then that almost **cuts them off from their support network that they've built for themselves**…"*

Participant 18, Group leader, Biochemistry, Mid-career

Image by starline on Freepik

"I don't know that it's necessarily people not wanting to move away… [but] that ***people become more comfortable and more expert in one area, and then don't want to have to try and re-learn that in another model****.*

Participant 29, First-year PhD student, Neuroscience

"You can move into new areas ***but it gets increasingly difficult because you have a track record that you get funded on the basis of****… if you don't have a track record in a new area, how are you going to get the funding?"*

Participant 30, Professor, Cancer Biology, Late-career

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The ‘pressure to publish’ intensifies this

“I would say that’s probably the biggest driver because there’s such a high pressure to publish, and publish in good journals, and get the next grant. ***That makes more risky work, like using a brand-new model to do something, much, much harder to get people to uptake that, because they can’t afford the risk****.”*

Participant 13, Associate Professor, Immunology, Mid-career

*“****you have to take it in vivo****, otherwise you're not going to get published.”*

Participant 26, Research Assistant, Immunology, Early-career

Early career researchers may think that employers are less likely to offer them a job using methods they did not have experience with

"I think, if I had a CV that was entirely animal work and then kind of pivoted and was like, "Oh, I don't want to do this anymore, I want to replace animals", I think practically, it's so different that […] ***it would be quite a hard pivot to go from one to the other*** *[…] I think that's because I mostly know people that have either really done animal [or NAMs].* ***I don't know anyone that's, kind of, weaved between the two****… the impression that I've got from others is* ***that you go one way or you go the other****."*

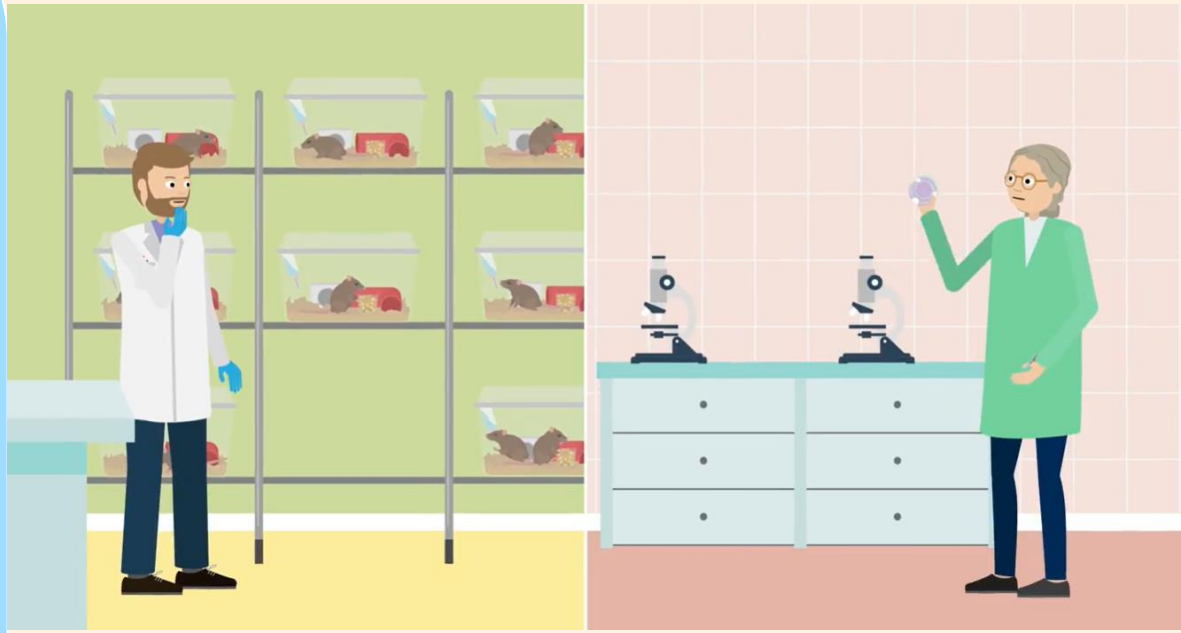
Participant 27, Final-year PhD student, Biochemistry

Image by pch.vector on Freepik

There is often insufficient challenge of whether and how animals are used, and implementation of the 3Rs

"I don't think I knew when I was deciding on the PhD project, maybe what it would entail. But […] the PI had already worked with this model before and someone else in the lab trained me on it. ***I would say I never really had a discussion on like, does it have to be an animal?"***

Participant 22, Postdoctoral Research Assistant, Neuroimmunology, Early-career



*“What I felt is that it’s a tick box exercise to be completely honest… **basically being able to say in the licence why that** [animal use] **can't be replaced and let me say my research is super important, which it isn't necessarily**.”*

Participant 24, Final year PhD student, Psychology and Biosciences

Image by rawpixel.com on Freepik

Non-animal methods may be viewed as 'risky' due to concerns they may quickly become outdated or obsolete

"if you train somebody to work with a mouse, a fish, a fly, whatever, in 10 years' time they're still probably going to be able to do that […]. Whereas ***with organoids you could spend a year training somebody and then a completely new system comes out that actually makes what you've done somewhat redundant…"***

Participant 18, Group leader, Biochemistry, Mid-career

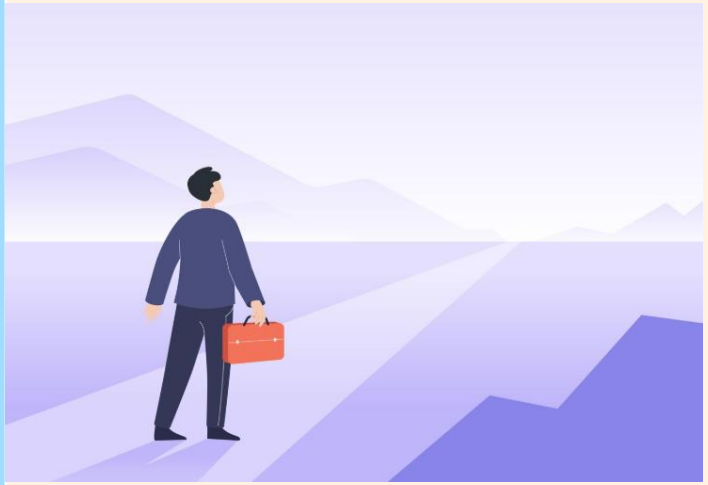


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Image by pch.vector on Freepik

The lack of professional training programmes, associated infrastructure and support systems, may impact on researchers' confidence in being able to set up and run non-animal methods in their lab

"the training that you get when you're learning to work with animals is taking place in a context of a very professionalised service with people who have been doing it for years and absolutely know what they're doing, whereas the training that you're going to get in organoids might be you go and visit the lab of another researcher for a couple of weeks and you shadow a PhD student who's been doing it for six months, because the postdoc doesn't have time and you don't get really the same level of training. Through nobody's fault, it's just that ***that infrastructure isn't there****."*

Participant 18, Group leader, Biochemistry, Mid-career

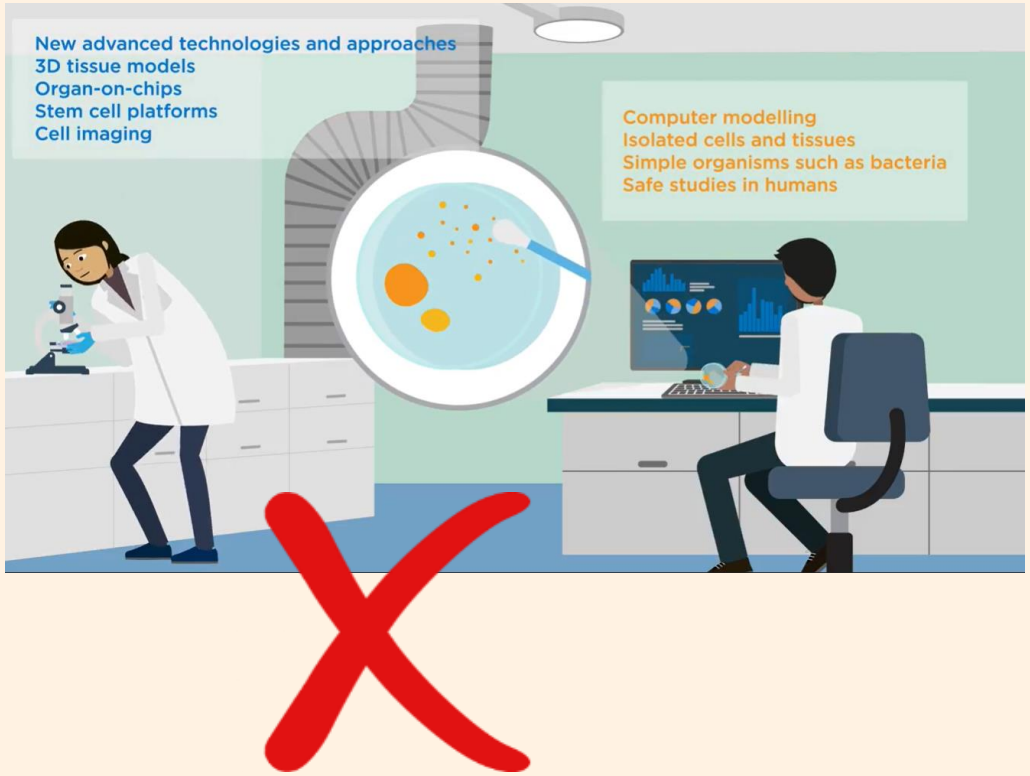
Talking about non-animal methods without also providing access to relevant training programmes, may mean researchers struggle to see how they could be use in their own research

"I think [the institution is] limited in what they can really find in terms of training or anything like that […]. In terms of the replacement side of things […] ***we're just given information about how to access other information that's already out there****."*

Participant 13, Associate Professor, Immunology, Mid-career

Replacement doesn't really seem like a tangible thing that I can really implement *[…] it seems like this […] thing that we tack on the end of the 3Rs that* ***I don't think anybody necessarily thinks about seriously or spends a good amount of time thinking about.***"

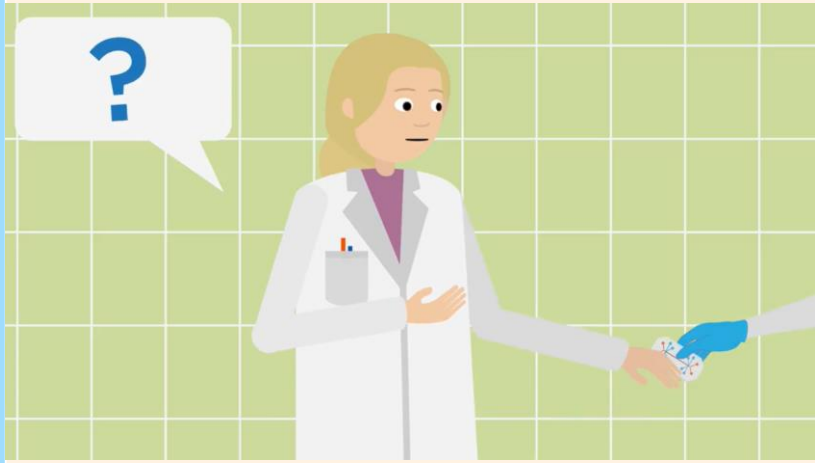
Participant 31, Post-doctoral Research Assistant, Cardiovascular science



Awareness-raising around non-animal methods is most valuable if it communicates the purposes they can serve, the benefits they offer and the opportunities surrounding them

"My understanding of replacement models isn't very good at all, and I don't feel like visualisation of that, or accessibility of that, has been something that's been advertised during my research career, for sure. ***I'm aware that these exist out there somewhere, but I don't know where they are or how much they cost or where they might be beneficial*** *over and above that."*

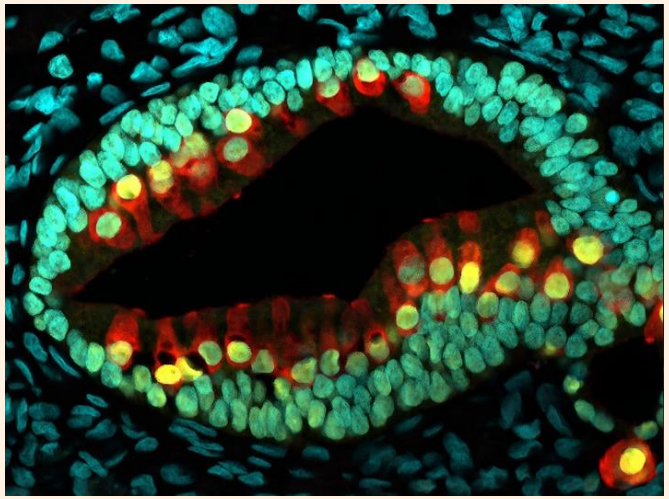
Participant 31, Post-doctoral Research Assistant, Cardiovascular science



Funding grants usually do not enable the flexibility needed to pick up other skills, or use other methods alongside the defined research plan

"I have big chunks of my current grant which are all for animal work… ***I can't really just go and start spending that on organoids because I have a student who says, "Actually that's what I want to do instead."***

Participant 13, Associate Professor, Immunology, Mid-career



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Short-term funding grants can especially raise barriers for researchers to picking up on new methodological developments

"most of these people are being hired for two or three years to do a specific piece of work on a grant, so ***there just isn't time to train them in something that their group isn't doing. If they were supported for five years and they had a year and a half to just pick up new skills before they actually started doing anything productive it might be a different question,*** *but there just isn't the time for most people."*

Participant 18, Group Leader, Biochemistry

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Image by juicy_fish on Freepik

There is limited communication between users of animals, and users of non-animal methods

*"Because **we are all in silos** in our own building, we are **not really talking with each other**.."*

Participant 08, Senior Lecturer, Toxicology, Late-career

*"If [NAMs] researchers were to… say, "Look. I have this new model. Look what I can do, and look what I can answer. **Come and work with us**," I think that would just be much more attractive […], **it moves from being pretty much purely informational, for informational purposes, to an opportunity and opportunities of generating data for publications, etc**."*

Participant 31, Post-doctoral Research Assistant, Cardiovascular science

Newer non-animal methods are not yet as 'established' as animal models

"…[if] the data that you build up over a long career is in one particular model, let's say a mouse, and you want to compare new results to what you've done before, then ***you either have to redo everything in the non-animal system or you just do this one experiment in a mouse****"*

Participant 18, Group leader, Biochemistry, Mid-career

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There are perceptions and concerns about the upfront costs associated with some of the more advanced non-animal methods

*"**Organoid** specifically, I have to say, is another **extremely expensive thing to do, so it's not for everybody**, […] a handful of labs have the financial muscle to run these studies"*

Participant 28, Postdoctoral Fellow, Biochemistry, Early-career

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Although universities do not themselves drive *how* research should be done, they could help 'de-risk' researchers changing practice

"I think if you talk to senior people, they would say that they were committed, but I don't see on the ground the investment… ***I don't see that there's the level of investments that would be happening from an institution that was really genuinely ambitious about reducing animal use".***

Participant 18, Group Leader, Biochemistry, Mid-career

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Image by macrovector on Freepik

"I think more infrastructure would be really helpful for me… I have a very small lab [...] so, if I were to hire somebody to do a project on organoids that would be actually a very big part of what was going on in my lab, just by virtue of it being like 50% of the full-time staff. And that means that ***it then becomes a huge risk for me if we can't get systems up and running properly****, if we can't get the training, all of that kind of stuff. So, I would be much more open to it, and I already am, like, I would like to be using some NAMs for some of our research, but I would say* ***the main thing limiting me is that kind of institutional support that takes away some of the risk****."*

Participant 18, Group Leader, Biochemistry, Mid-career

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Summary

Awareness of NAMs

- Researchers need to know **what kinds of NAMs are available**, be informed about their **advantages and limitations**, and understand their specific **purposes and applications**.

- Information-sharing around NAMs should be connected to **opportunities for accessing training, funding, and building networks and collaborations**.

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Confidence in NAMs

- Need to provide **training** to researchers in the set-up, use of, and analysis of data from, NAMs.
- This includes access to **help to facilitate the use of NAMs**, with support on troubleshooting, and guidance on wider aspects such as how to cost projects involving NAMs or where and how to publish papers with data from NAMs.
- More support from **funders** (and institutions) **for infrastructure** is needed, to help ‘de-risk’ a move to using a new model.
- Ensure and promote the feasibility of **career paths** in scientific research within academia that do not involve animal use.

Enthusiasm for NAMs

- The value of NAMs needs to be promoted by **funding bodies** and **professional scientific societies**, who can provide incentives for their use.

- Initiatives to promote the uptake of NAMs have to play into **established systems of reward and recognition** within academia.

- Closer **communication is needed between those developing NAMs and those using animal models**, with support to enable those developing and working with NAMs to showcase these to *in vivo* researchers and communities, while also gaining further understanding of their specific needs and the research questions they are trying to answer.

Going forwards…

In your institution

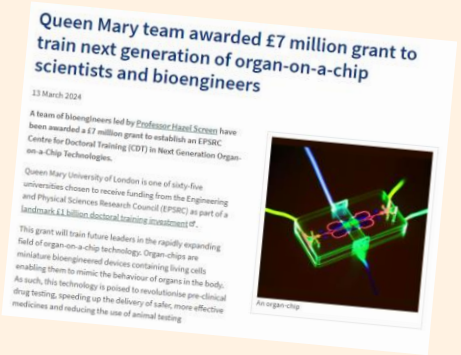
- **Speak to the scientists** to <u>understand their perspectives</u>, concerns and needs.
- **Ensure you are staying up-to-date with developments** - both at a macro level, and in the specific areas relevant to the research being done at your establishment.
- Have '**supporting replacement**' as a **strategic ambition** and **Animal Welfare Body objective** - and be able to *demonstrate* annual actions being taken to support scientists transition to non-animal methods

  e.g. task specific personnel with ensuring the flow of information into and around the institution, facilitate collaborations, increase access to training opportunities, and infrastructure.

Article 27.1(b) of the Directive requires that the Animal Welfare Body "***advise the staff on the application of the requirement of replacement****, reduction and refinement, and* ***keep it informed of technical and scientific developments concerning the application of that requirement****".*

Funding bodies

- Review **structures and processes of funding programmes** to see if/how they are acting as barriers to people changing approaches.
- Reflect on own awareness and training in non-animal technologies and ensure representation of people with appropriate knowledge of these in the **design of funding schemes** and **grant panels** reviewing applications.
- Make explicit that proposals, and requests for additional money, are welcomed from scientists for **upskilling** in NAMs.
- Make resources available so that **parallel studies** can be run to compare information gained from NAMs with animal studies - to build understanding and confidence in the methods.
- Invest in **doctoral training schools and 'skills labs'** for broadening base of NAMs expertise, and in widening access to human cell and tissue biobanks.



Queen Mary team awarded £7 million grant to train next generation of organ-on-a-chip scientists and bioengineers

13 March 2024

A team of bioengineers led by Professor Hazel Screen have been awarded a £7 million grant to establish an EPSRC Centre for Doctoral Training (CDT) in Next Generation Organ-on-a-Chip Technologies.

Queen Mary University of London is one of sixty-five universities chosen to receive funding from the Engineering and Physical Sciences Research Council (EPSRC) as part of a landmark £1 billion doctoral training investment.

This grant will train future leaders in the rapidly expanding field of organ-on-a-chip technology. Organ-chips are miniature bioengineered devices containing living cells enabling them to mimic the behaviour of organs in the body. As such, this technology is poised to revolutionise pre-clinical drug testing, speeding up the delivery of safer, more effective medicines and reducing the use of animal testing

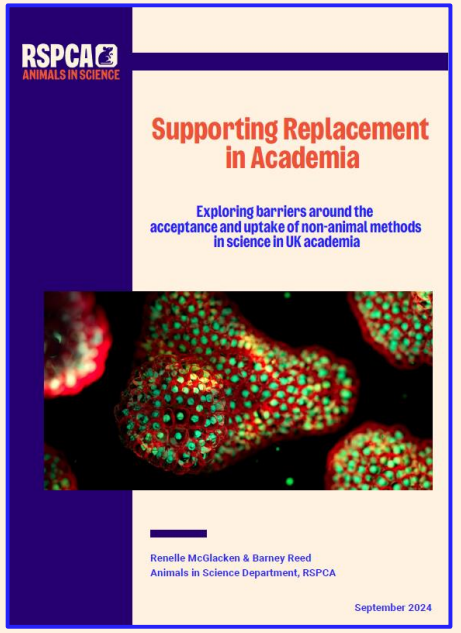
An organ-chip

Professional and learned societies

- Include specific themes and sessions at **conferences** that invite people developing and using new approaches that could potentially replace the use of animals to **share expertise** and highlight opportunities for collaborations.
- Consider having a **sub-committee on NAMs policy** - in the same way there might be one for animal science.
- Review the guidelines given to **journal editors and reviewers** to avoid unnecessary asks ‘for *in vivo* data’, and share the rationale for this with peer community.

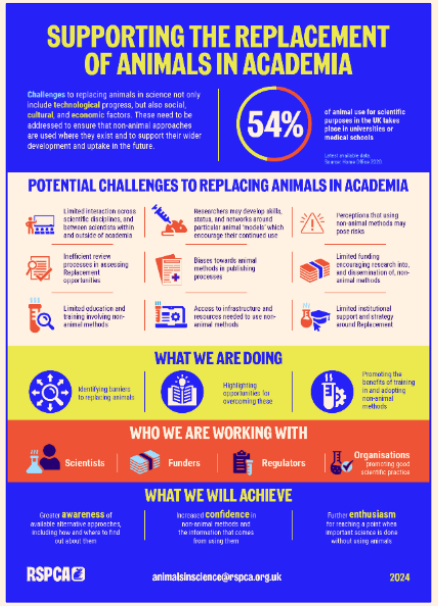
Image from Freepik

For more information



Read the full report

https://tinyurl.com/SupportingReplacement2024



See our project infographic

https://tinyurl.com/SupportingReplacementGraphic

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