

Regulatory Science Panel Discussion

**Identifying Best Practices and Use of Brain Organoids,
Ensuring Patient Safety and Public Trust**

October 3, 2024

Future4Care

**HOW ALTERNATIVES TO ANIMAL
MODELS CAN SHAPE THE FUTURE OF
BIOMEDICAL RESEARCH**

Emeline Gougeon, Strategy Director

Dr Lilas Courtot, Scientific Director



PRO ANIMA SCIENTIFIC COMMITTEE

A PIONEERING AND UNIQUE NGO IN FRANCE

Created in 1989

Under the honorary presidency of Professor Théodore Monod (1989 - 1999)



Pr Théodore Monod

"I prefer ignorance, despite my tireless curiosity, to the acquisition of knowledge that I know was only obtained through the suffering of a living being."

Christiane Laupie-Koechlin

"With technological progress and the advances of scientific knowledge, it is possible to do things differently and better than with animal testing"



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Goals

Contribute to better evaluation of drugs and chemical substances for health and the environment thanks to innovative methods without the use of animals



Missions

Promote, finance and gain scientific and regulatory recognition for non-animal methods and technologies

MULTI-LEVEL ACTIONS



RAISE AWARENESS



CITIZENS, SCIENTISTS, REGULATORS,
POLITICAL AND ECONOMIC ACTORS

FINANCE



NON-ANIMAL RESEARCH WITH
THE DESCROIX-VERNIER
ETHICSCIENCE PRIZE



PUBLISH



SCIENCES, ISSUES, HEALTH
The only French journal dedicated
to non-animal research



FOSTER DIALOGUE



KEY PLAYERS IN THE SECTOR
Industries, researchers, regulators



citizens, media, public
authorities, economic actors,
researchers/scientists



HEALTH AND THE PHARMACEUTICAL INDUSTRY: LIMITED BY AN OBSOLETE MODEL



>10 MILLIONS / YR

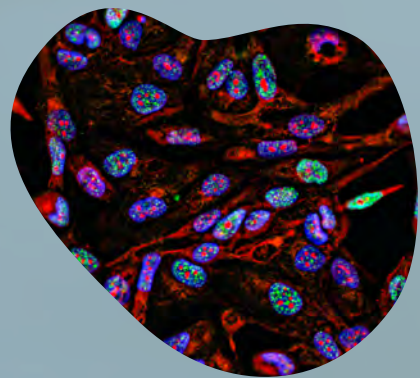


~2 MILLIONS / YR

Results are difficult to transfer and reproduce

Failure rate between 80 and 99%

THE HEAVY RELIANCE ON ANIMALS



Basic research (~40%)

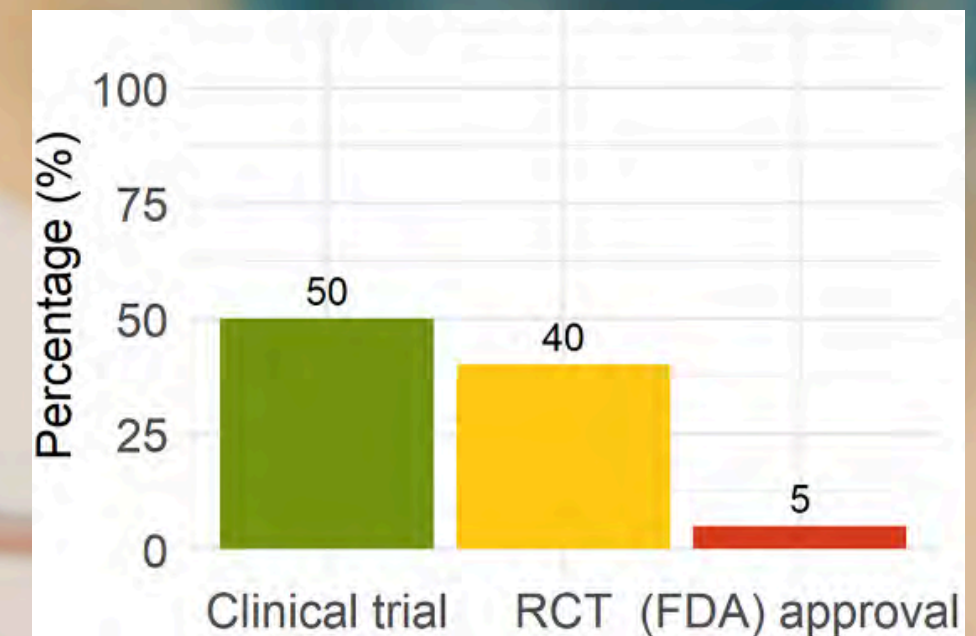


Applied research (~30%)



Regulatory and toxicology (<30%)

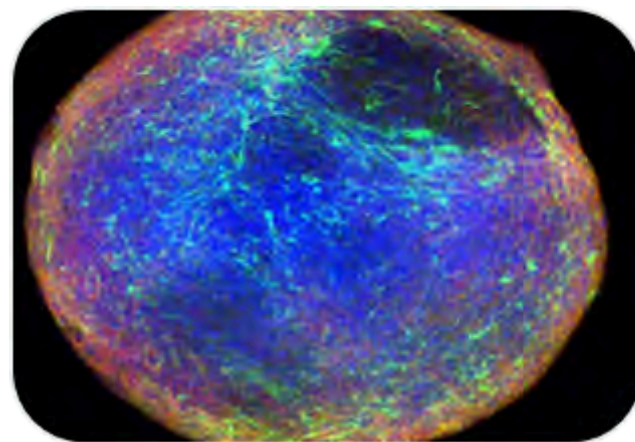
10-15 years for a drug to be approved (~\$2.6 billion)



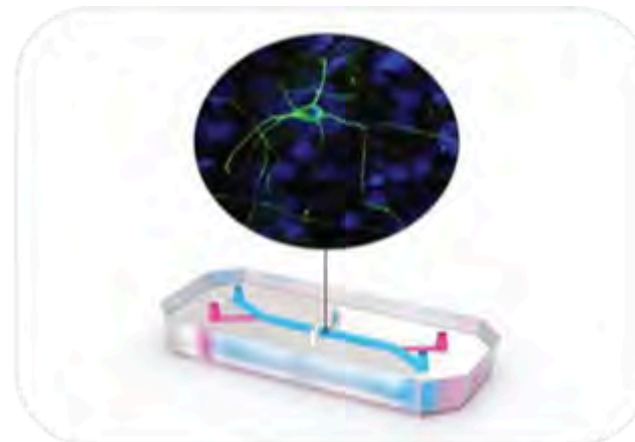
Source: Ineichen BV, et al., PLoS Biol (2024)

Sources : circabc.europa.eu
enseignementsup-recherche.gouv.fr

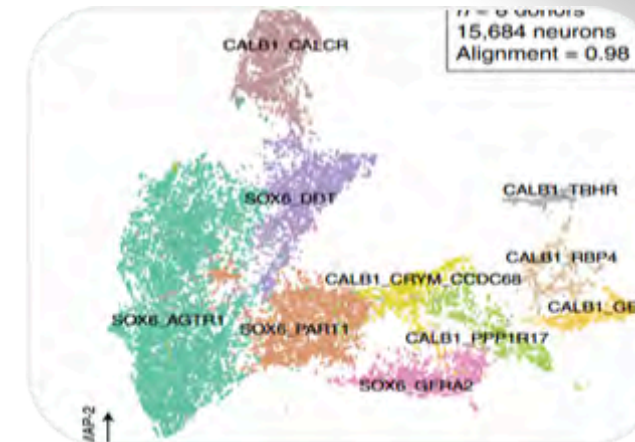
NEW NON-ANIMAL METHODS: PROMISING ALTERNATIVES



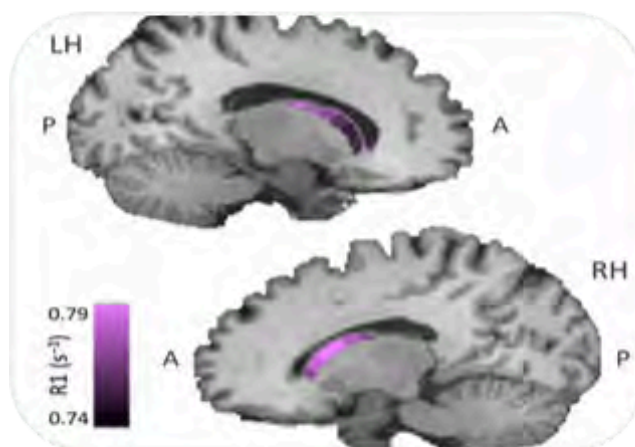
3D organoids



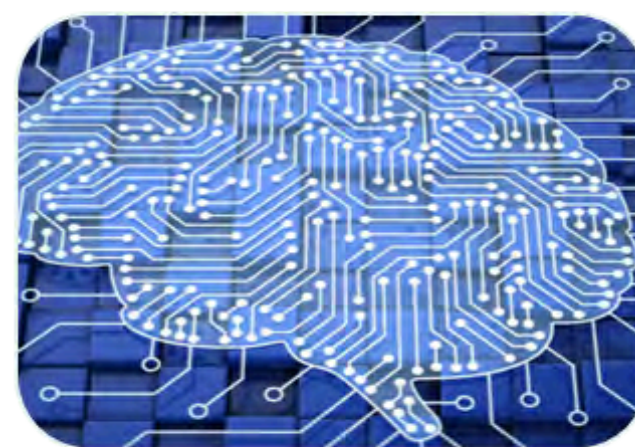
OoC



Single-cell
Multi-omics



Advanced
imaging



AI, Machine
Learning



3D-printed
organs

Better predictability, efficiency,
and reproducibility

Save time and money

Benefit for patients



NON-ANIMAL METHODS: AN INTERNATIONAL MOVEMENT

FDA Modernisation Act 2.0 & 3.0

US



NAMs can be used instead of animal studies for drug development and approval.

Roadmap

European Commission



Replacing the use of animals in next-generation chemical risk assessment.

Transition centre

The Netherland

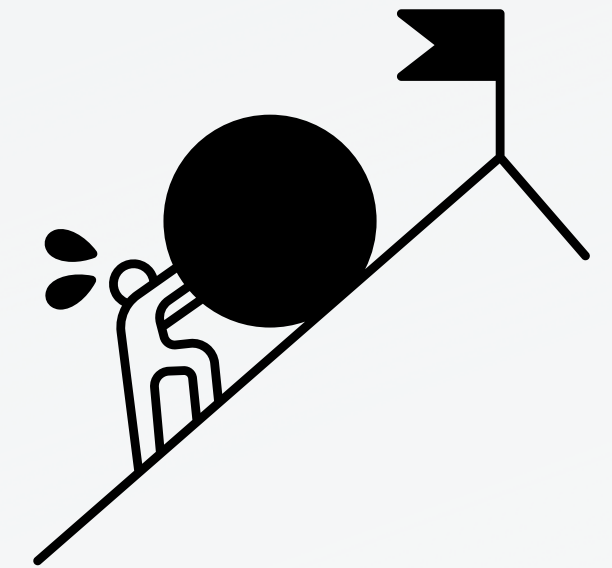


Dutch National Growth Fund invests 124,5 million in transition to animal-free innovation

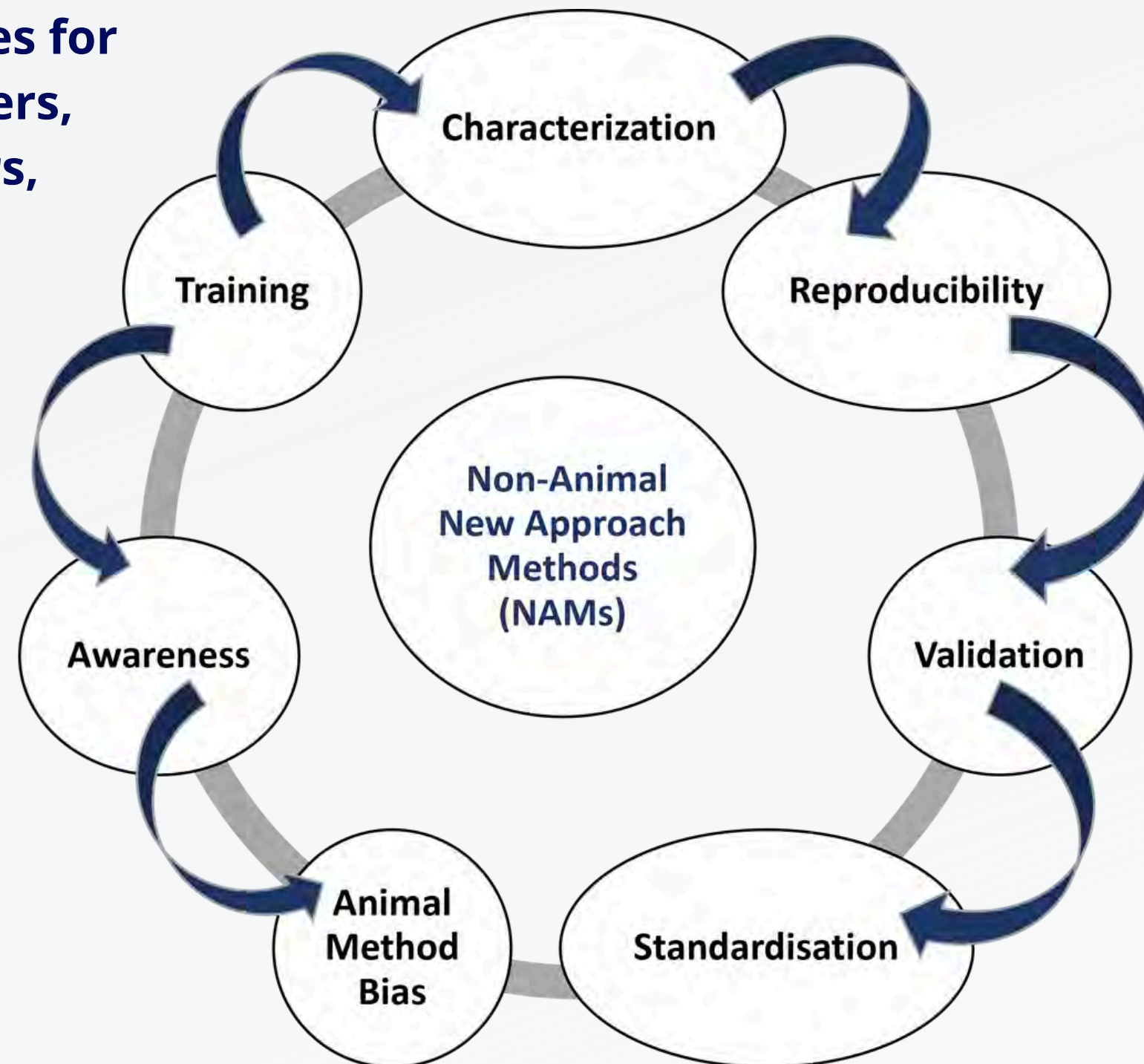
“ The Netherlands is setting the stage for transition science, but The Netherlands cannot achieve the change alone, as regulations usually work on a global scale.

Prof. Merel Ritskes-Hoitinga ”

NAMS CHALLENGES: EXPERTS & GENERAL PUBLIC



Challenges for
researchers,
regulators,

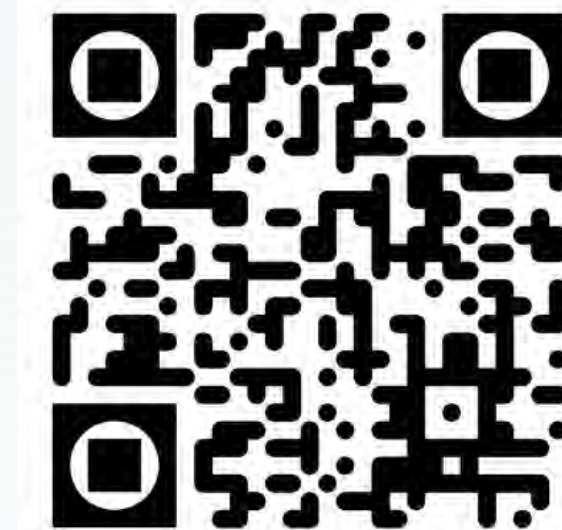


Patient trust and
Public awareness

How to communicate with the general public?
Role of researchers and the media



Round table on October 4, 2024
From 5 p.m. to 7 p.m.



Join us!



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with the FRM




Innovateur pour sauver



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