



A future without laboratory animals – what does it take?

Jan Lund Ottesen, VP, Laboratory Animal Science

Sif Groth Rønn, VP, Integrated Physiology Research

Novo Nordisk

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Novo Nordisk

- Global healthcare company, founded in 1923 and headquartered just outside Copenhagen, Denmark.
- Our purpose is to drive change to serious chronic diseases such as diabetes, obesity, and rare blood and rare endocrine diseases.
- We employ more than 55,000 people in 80 offices around the world, and market our products in 170 countries.



Agenda

- Introduction
- Novo Nordisk use of animals
- Micro Physiological Systems (MPS)
- A future without laboratory animals – what does it take?

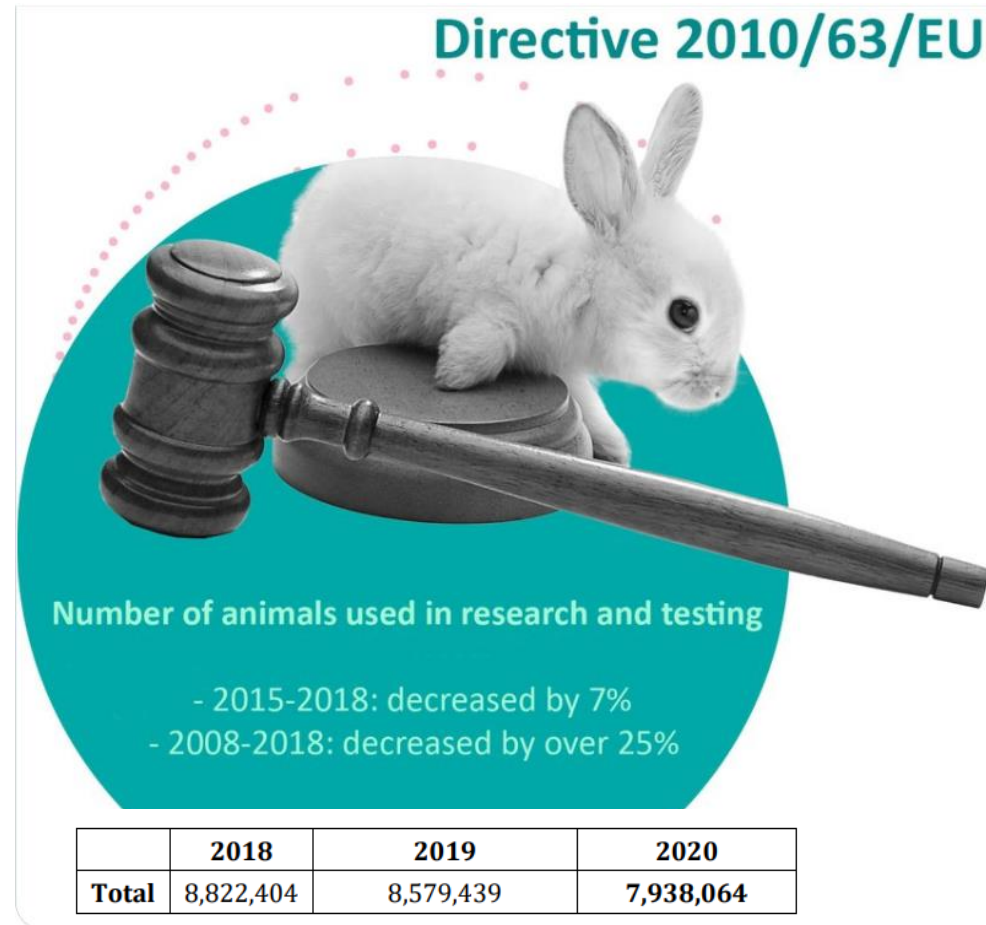
The use of animals in research is still essential for pharmaceutical companies



- To safeguard humans, it is required to provide appropriate data regarding efficacy, safety and toxicology from testing in both animals and people before the authorities can approve a new product.
- However, with the recent years progress of micro physiological systems (MPS) – and recent attention from Authorities (in both US and EU) - a future without use of animals is no longer just an unreachable future.

So what is the status (for EU) ?

ALURES – Open access EU database

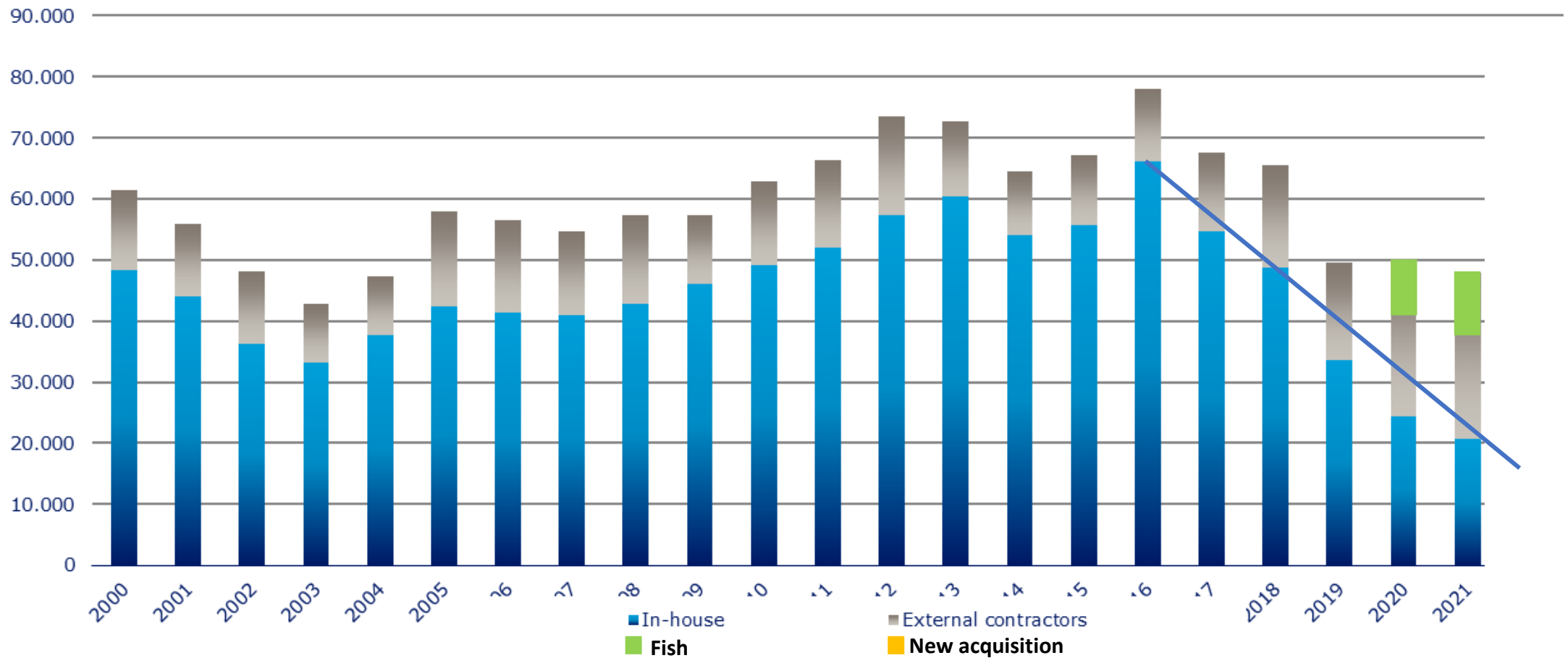


2018-2020: decreased by 10%

How is Novo Nordisk doing when it comes to reduction in number of laboratory animals?



Total number of animals purchased by Novo Nordisk and external contractors



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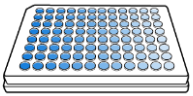
Phasing-In New Approach Methodologies

EFPIA Members
commit to the science-
based phase-in of
methods to replace
the use of animals for
scientific purposes and
the deletion of animal
tests which are
obsolete or redundant

Complex human physiology requires complex model systems



Human body consists of ~78 organs, separated by barriers such as blood-brain, intestinal, endothelial etc.



Complex physiology cannot be captured in conventional in vitro models



Large need for preclinical animal experiments to ensure safety and efficacy translation



Recent advances are beginning to enable in vitro modelling of increasing complexity – *Micro Physiological Systems*

'A Micro Physiological System is an in vitro system that realistically represents physiology of interest'



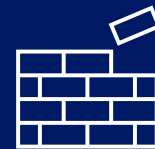
Relevant cell types / micro tissue / organ



Unidirectional steady flow

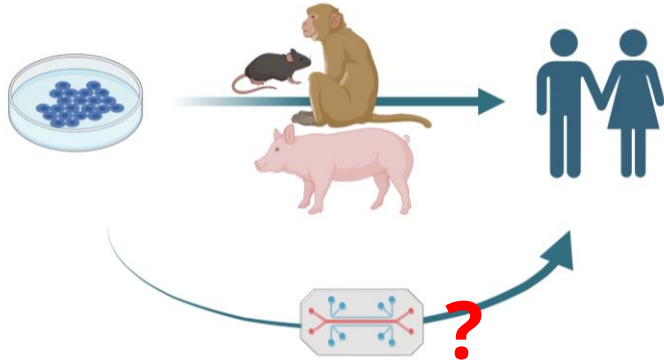


Pressure, stretch, contraction



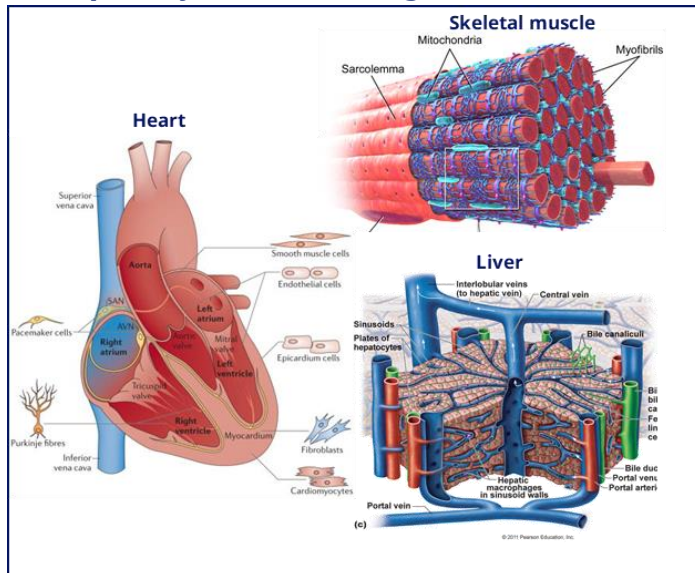
Relevant barriers that separate different compartments

Establishing *in vitro* models to mimic complex human physiology

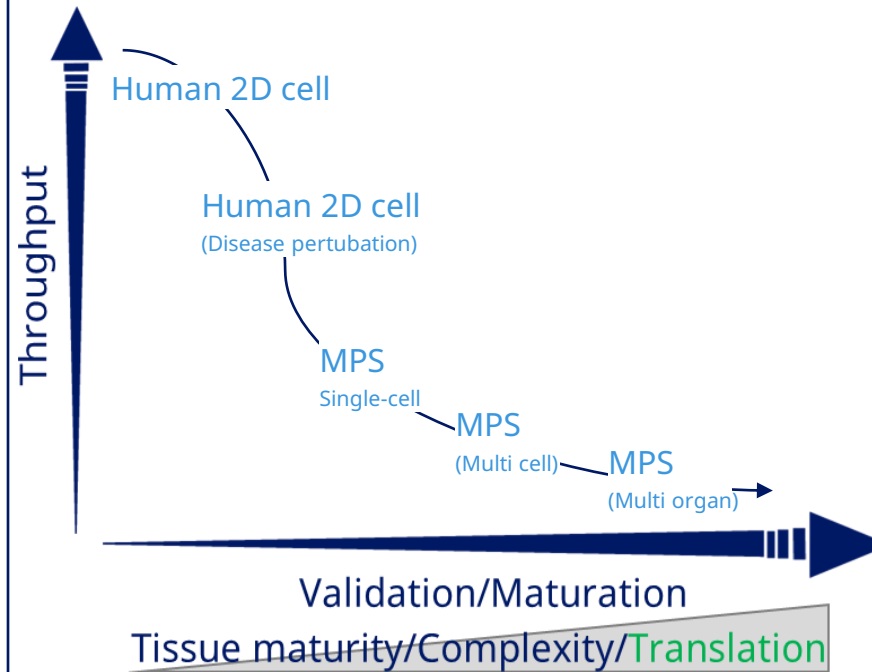


- Human physiology is **extremely complex**
- Conventional *in vitro* models can capture **select isolated** aspects
- **Massive research efforts** required to phase in MPS as alternatives to animals

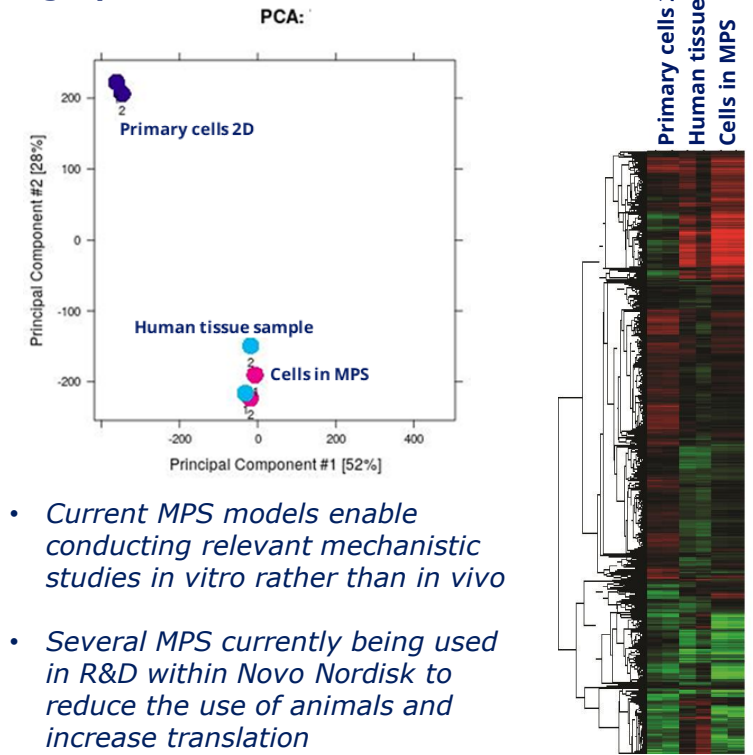
Complexity of human organs



Increased model complexity comes with lower throughput



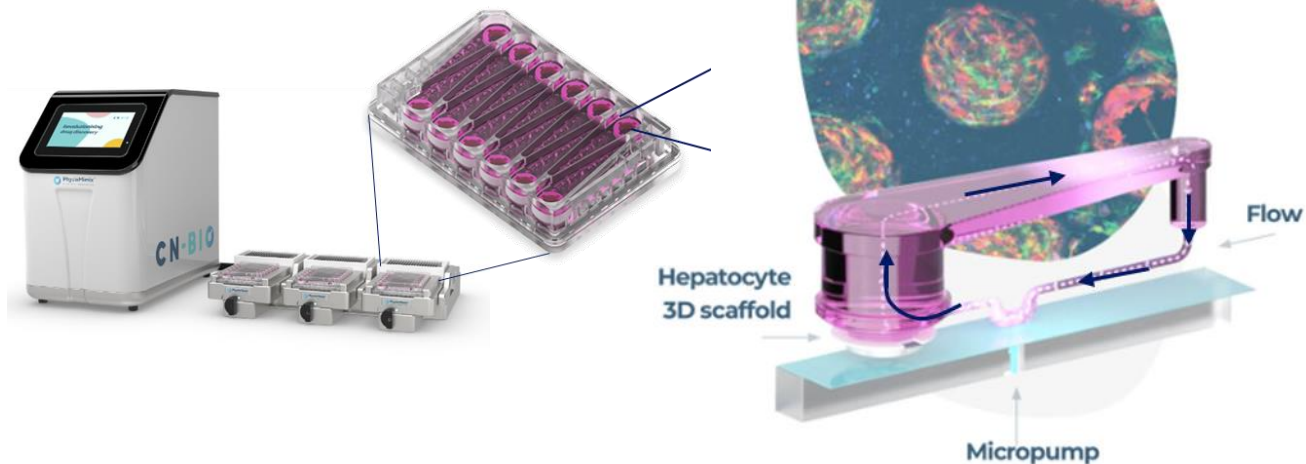
Culturing human cells (hepatocytes) in MPS can recapitulate key biological fingerprints of 'real' tissue



- Current MPS models enable conducting relevant mechanistic studies *in vitro* rather than *in vivo*
- Several MPS currently being used in R&D within Novo Nordisk to reduce the use of animals and increase translation

Current models implemented in Novo Nordisk drug discovery pipeline recapitulate hallmarks of human physiology and enable direct translation from *cell* to *human* – reducing the need for preclinical animal models

- CN Bio's multi-well PhysioMimix™ Liver-on-a-Chip (Microphysiological System MPS-LC12) using human primary hepatocytes
- Disease models to support pipeline, e.g. within insulin resistance & NASH



- Each plate/experiment contains data points equivalent of 6-12 experimental animals
- Despite increased complexity, available MPS are **still relatively simple** compared to whole body physiology
- **Massive investments and resources required** to advance field with ultimate goal to completely phase out use of animals in drug discovery

Novo Nordisk to establish MPS unit in Boston

press release

Novo Nordisk to expand R&D presence in greater Boston area

Bagsværd, Denmark, 2 March 2023 – Novo Nordisk just announced plans to expand its research and development (R&D) presence in the greater Boston metro area, creating one of its largest R&D hubs outside of Denmark. This new hub, which will leverage the company's existing presence in Lexington, Cambridge and Watertown, Massachusetts, will be home to the majority of Novo Nordisk's US-based research and development activities.

The Novo Nordisk MPS Boston is a dedicated unit committed to establishing and implementing MPS in drug discovery to advance the field and reduce animal usage



A future without laboratory animals – what does it take?

- Strategy incl. Management support
- “Artificial bottlenecks”
- Massive research efforts
- Huge investments in alternatives (e.g., MPS, in silico)
- Change of regulatory requirements



Thanks for your attention

