Streamlining Microfluidic Device Development through an Open-Source Compendium

Regul8ors

Sergio Garcia, Salome Ghvinephadze, Emily Reitz, Shivali Vashisht

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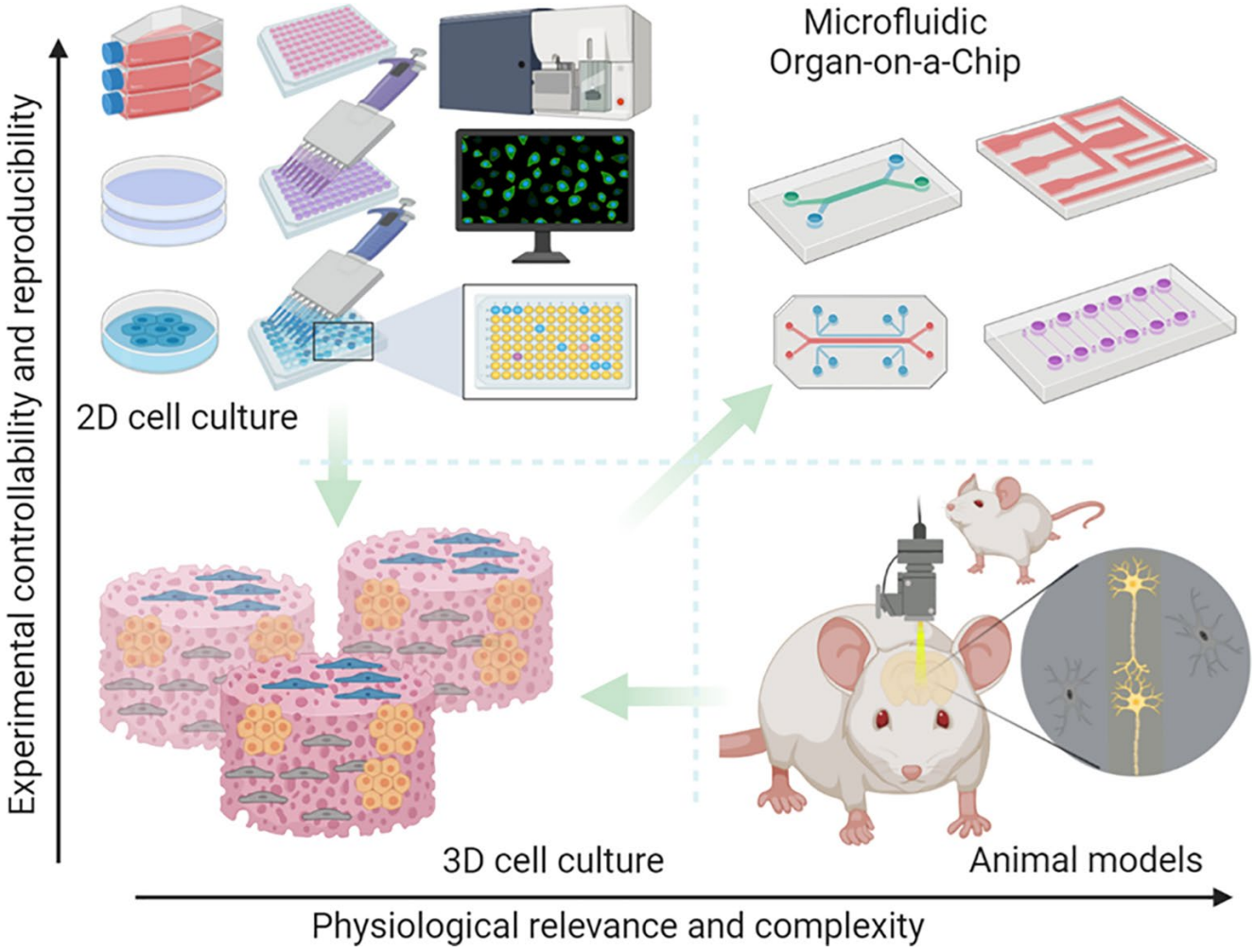
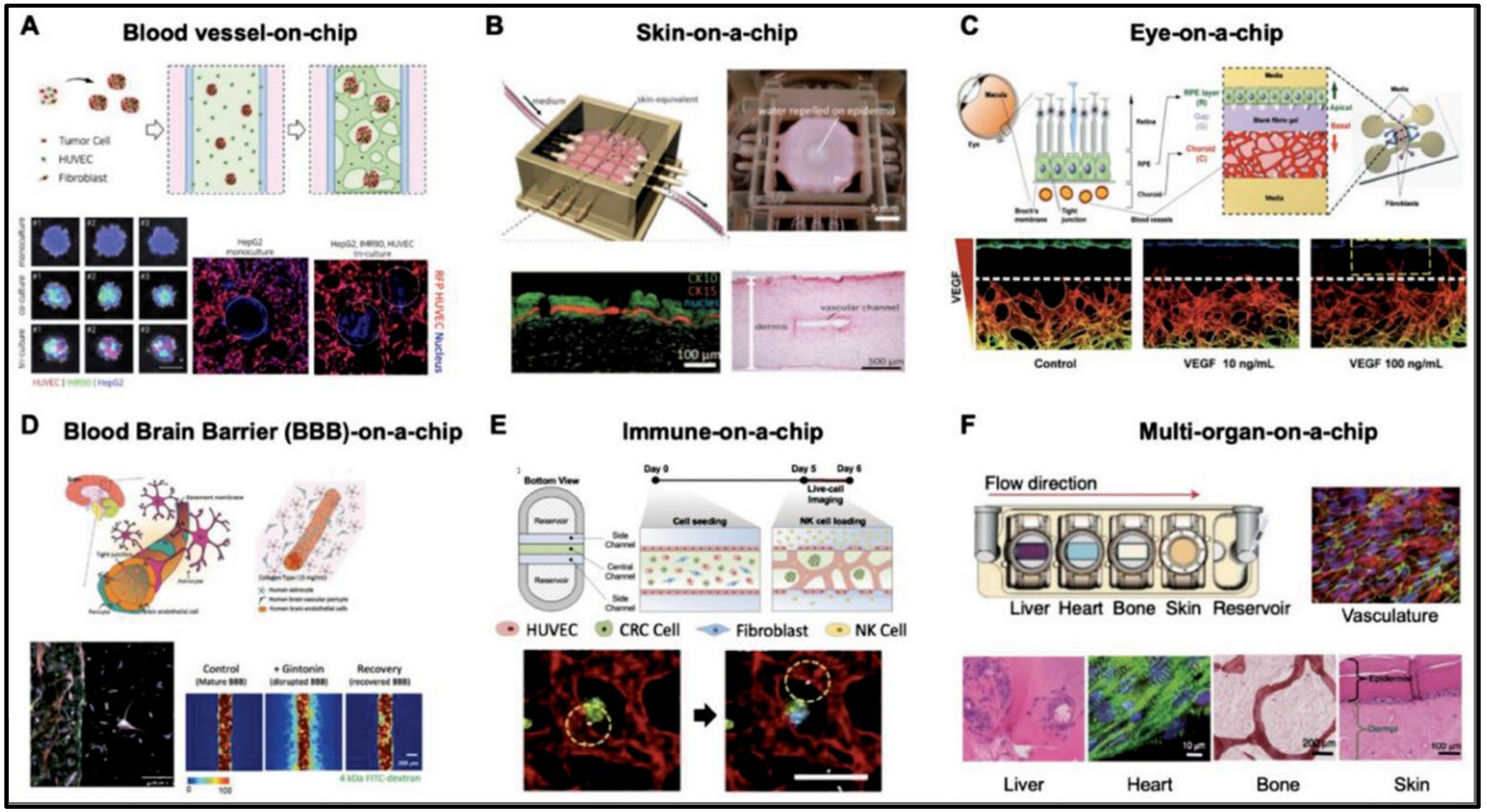
Current Non-clinical Testing Platforms



Ma, C. et al. *Trends Pharmacol Sci,* 2021

Organ-on-Chip to Model Human Tissues

Microphysiological systems (MPS) are designed to mimic physiologically relevant functions of human tissues and can be more predictive than current *in vitro* and *in vivo* animal models[1]



[2]

[1] Baran, S. W. et al. *ALTEX - Alternatives to animal experimentation,* 2022
[2] Ko, J. et al. *Adv. Healthcare Mater.,* 2024

FDA Focus Area

Novel Technologies to Improve Predictivity of Non-clinical Studies and Replace, Reduce, and Refine Reliance on Animal Testing

Regulatory Significance of Alternative Testing Methods in Numbers:

There has been a **400%** increase in medical device submissions that utilize microfluidics between 2013-2018

U.S. Food and Drug Administration. Microfluidics Program: Research on Microfluidics-Based Medical Devices

Current Regulations

- **No specific FDA-recognized standards**
- The microfluidics program of CDRH actively engages in research and standardization efforts
- Since 2023: a collaboration between the FDA and the NCATS to advance MPS technologies

U.S. Food and Drug Administration. Memorandum of Understanding 225-23-003

The Microfluidics Program Activity

Target Areas

- Preclinical testing protocols
- Materials and microfluidic device manufacturing processes
- *In vitro* models representing common microfluidic device applications
- Impact of Microfluidic failure modes on device performance

Gaps

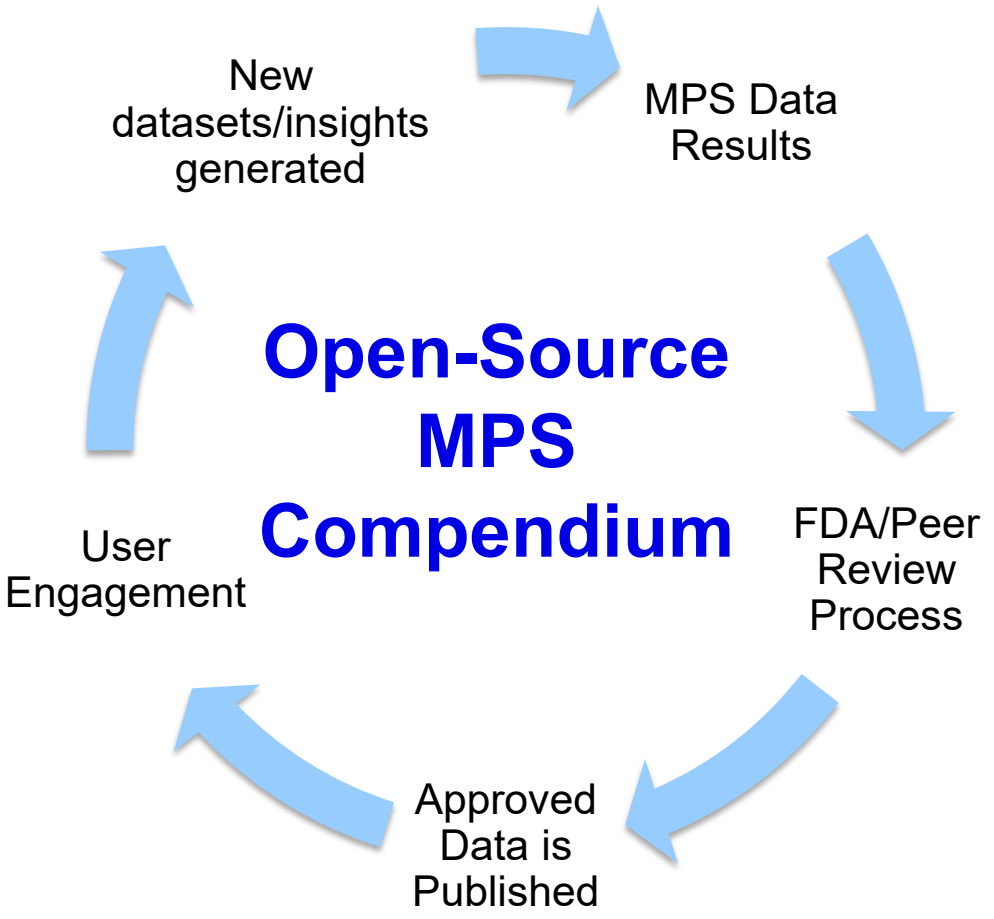
- Lack of understanding of performance failures
- Reliance on costly clinical data
- Challenges in translating research devices to commercial products
- "One size fits all" does not apply

U.S. Food and Drug Administration. Microfluidics Program: Research on Microfluidics-Based Medical Devices

Proposed Solution from Regul8ors

- **A Shared Compendium for MPS devices**
  - Advancing <u>expedited regulatory pathways</u> for Diagnostic MPS Devices

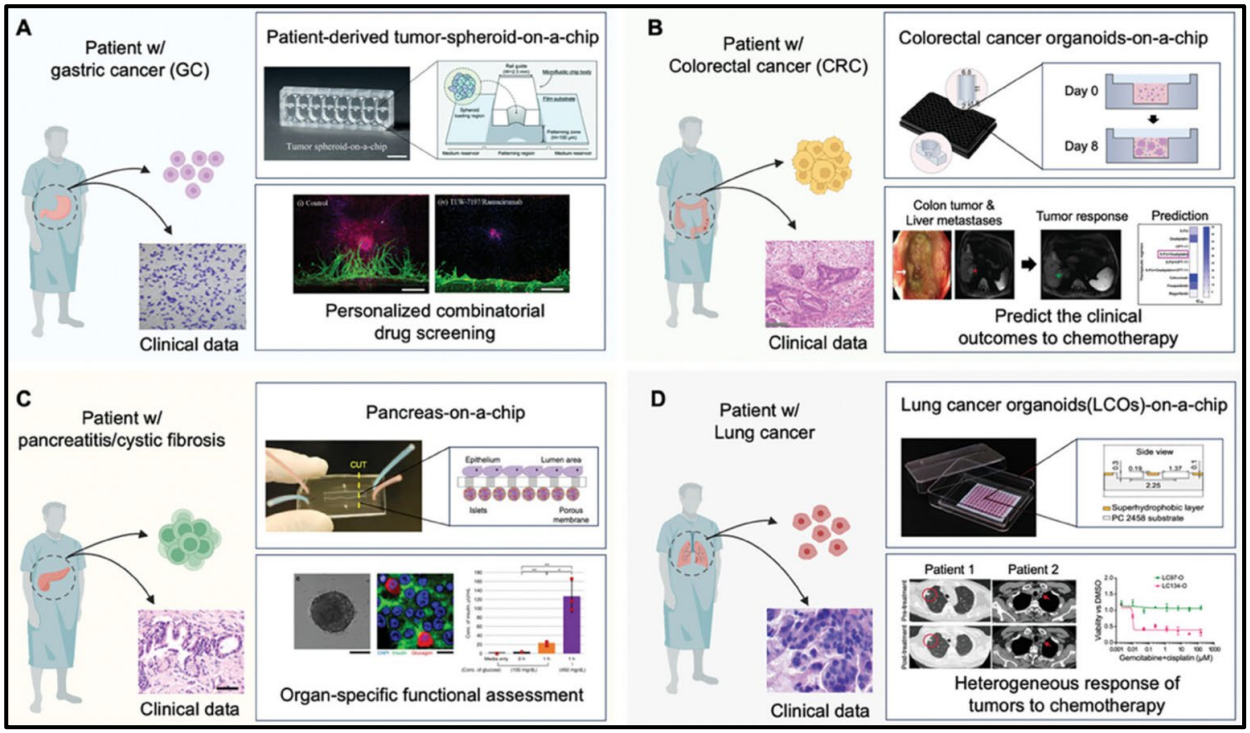
Regulatory Science Solution



KEY FEATURES

- Login-Based
- Standard operating procedures
- Curated Datasets
- Performance Benchmarks
- Case Studies
- Regulatory Guidance
- Community Features
- Cross-Disease Models

MPS Compendium Streamlines Discovery



Cross-Disciplinary Collaboration

FDA Standardization

Transparency

Reproducibility

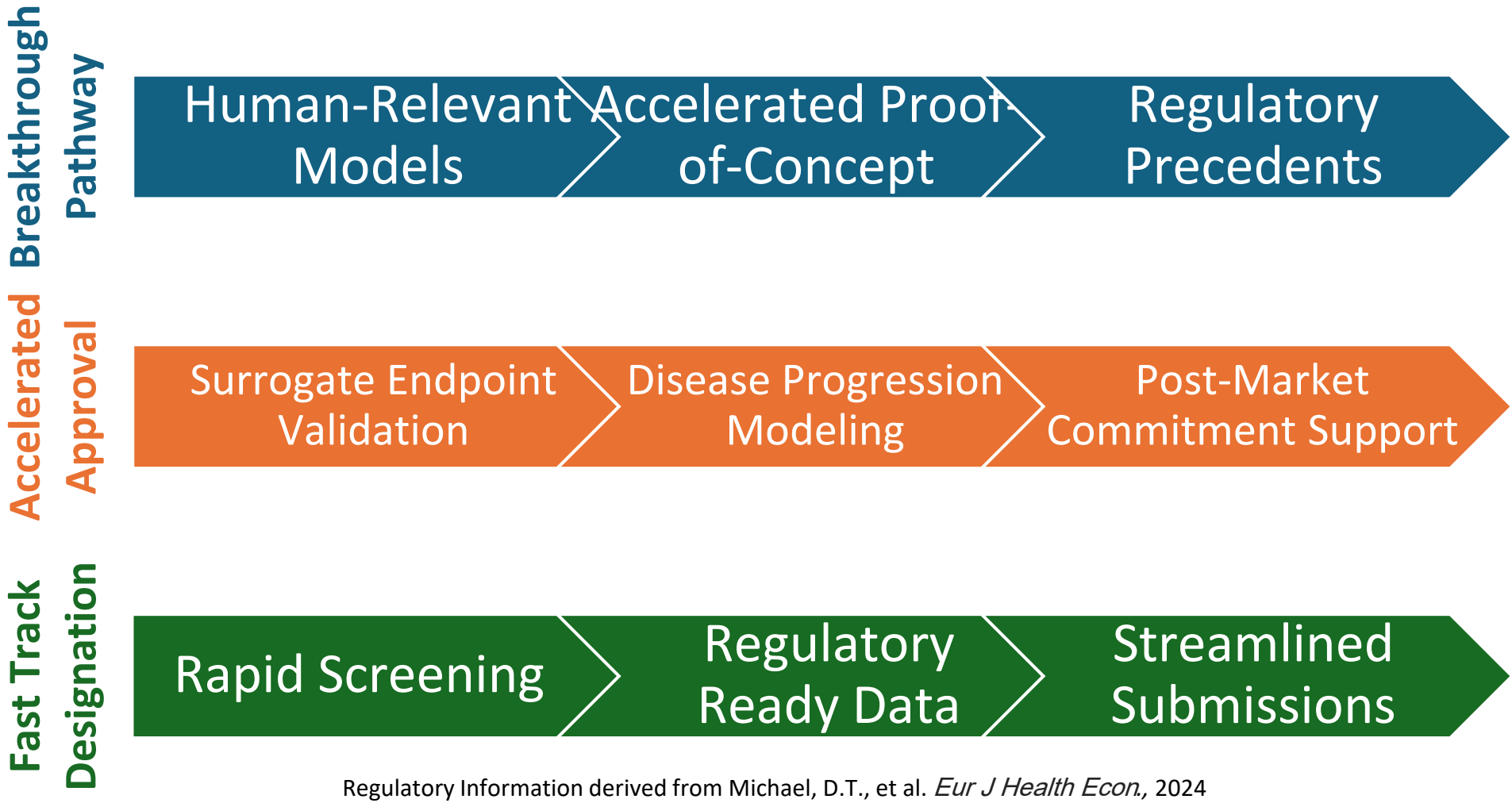
Personalized Medicine

Accelerates Adoption of MPS Approaches in Regulatory Practice

MPS can be paired with human samples and enable disease diagnostics

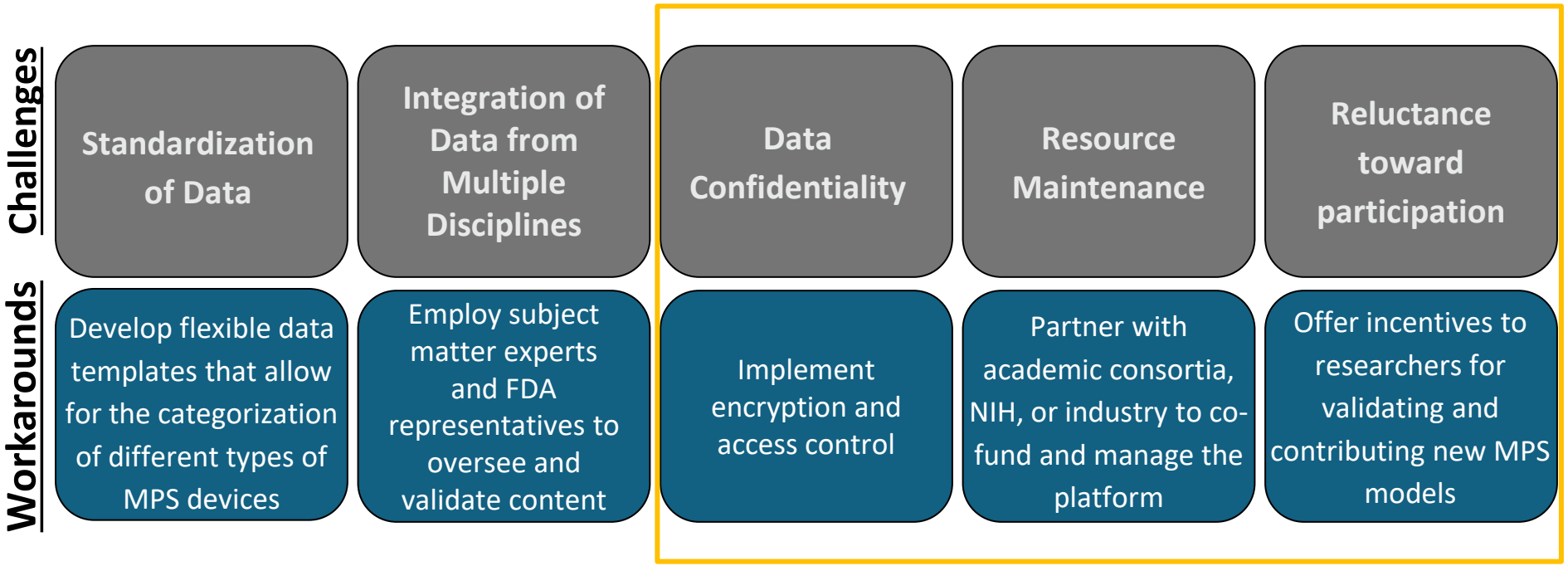
Ko, J. et al. *Adv. Healthcare Mater.*, 2024

MPS Compendium could significantly support pathways like **Breakthrough Therapy Designation**, **Accelerated Approval**, and **Fast Track Designation** by enhancing the preclinical and translational stages of product development



Regulatory Information derived from Michael, D.T., et al. *Eur J Health Econ.,* 2024

Compendium challenges and workarounds



Summary

Focus Area

Novel Technologies to Improve Predictivity of Non-clinical Studies and Replace, Reduce, and Refine Reliance on Animal Testing

Main Challenge

No specific FDA-recognized standards for microfluidic devices

Proposed Solution

Open-Source MPS Compendium

Regulatory Impact

Accelerating the incorporation of microfluidic devices in diagnostics

Thank You!

References:

Ma, C. et al. *Trends Pharmacol Sci*, 2021.

Baran, S. W. et al. *ALTEX - Alternatives to Animal Experimentation*, 2022.
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U.S. Food and Drug Administration. Microfluidics Program: Research on Microfluidics-Based Medical Devices. [Accessed December 3, 2024]. Available at: https://www.fda.gov/medical-devices/medical-device-regulatory-science-research-programs-conducted-osel/microfluidics-program-research-microfluidics-based-medical-devices#:~:text=Microfluidics%20Program%3A%20Research%20on%20Microfluidics%2DBased%20Medical%20Devices,-Subscribe%20to%20Email&text=The%20Microfluidics%20Program%20in%20the,that%20are%20safe%20and%20effective.

U.S. Food and Drug Administration. Memorandum of Understanding 225-23-003. [Accessed December 3, 2024]. Available at: https://www.fda.gov/about-fda/domestic-mous/mou-225-23-003

Michael, D. T., et al. *Eur J Health Econ*, 2024.