

ILMERAC

Update on an International Qualification Study on Organs-on-a-Chip

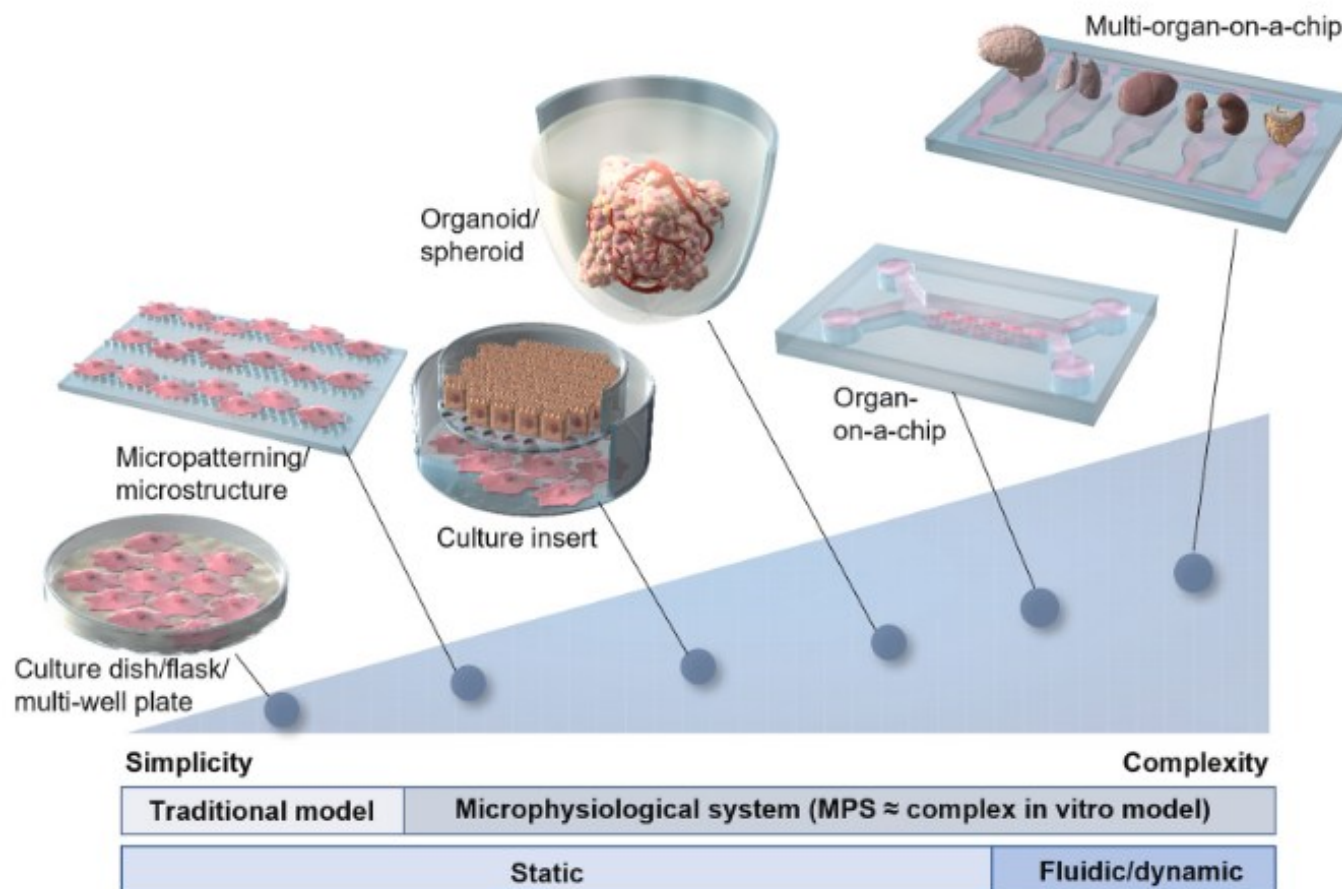
7 OCTOBER 2026, ONLINE

Dr. Denise Bloch, ILMERAC Co-Chair

German Federal Institute for Risk Assessment (BfR)

Advantages

- Greater predictive capacity in drug screening compared to animal models
- Interconnected
- Extracellular matrix



Harriot AD, Ward CW, Kim DH. Microphysiological systems to advance human pathophysiology and translational medicine. *J Appl Physiol* (1985). 2024 Nov 1;137(5):1494-1501. doi: 10.1152/jappphysiol.00087.2024.

Kimura, H., Nishikawa, M., Kutsuzawa, N., Tokito, F., Kobayashi, T., Kurniawan, D. A., ... & Sakai, Y. (2025). Advancements in Microphysiological systems: Exploring organoids and organ-on-a-chip technologies in drug development-focus on pharmacokinetics related organs. *Drug Metabolism and Pharmacokinetics*, 60, 101046.

Overall

- Gain regulatory experience with OoC
- Work towards qualification

First study

Phase I

- Derive inter-laboratory variability for a two-organ commercial chip

Phase II

- Provide case studies for qualification



Korea Institute of
Toxicology



JRC



US FDA



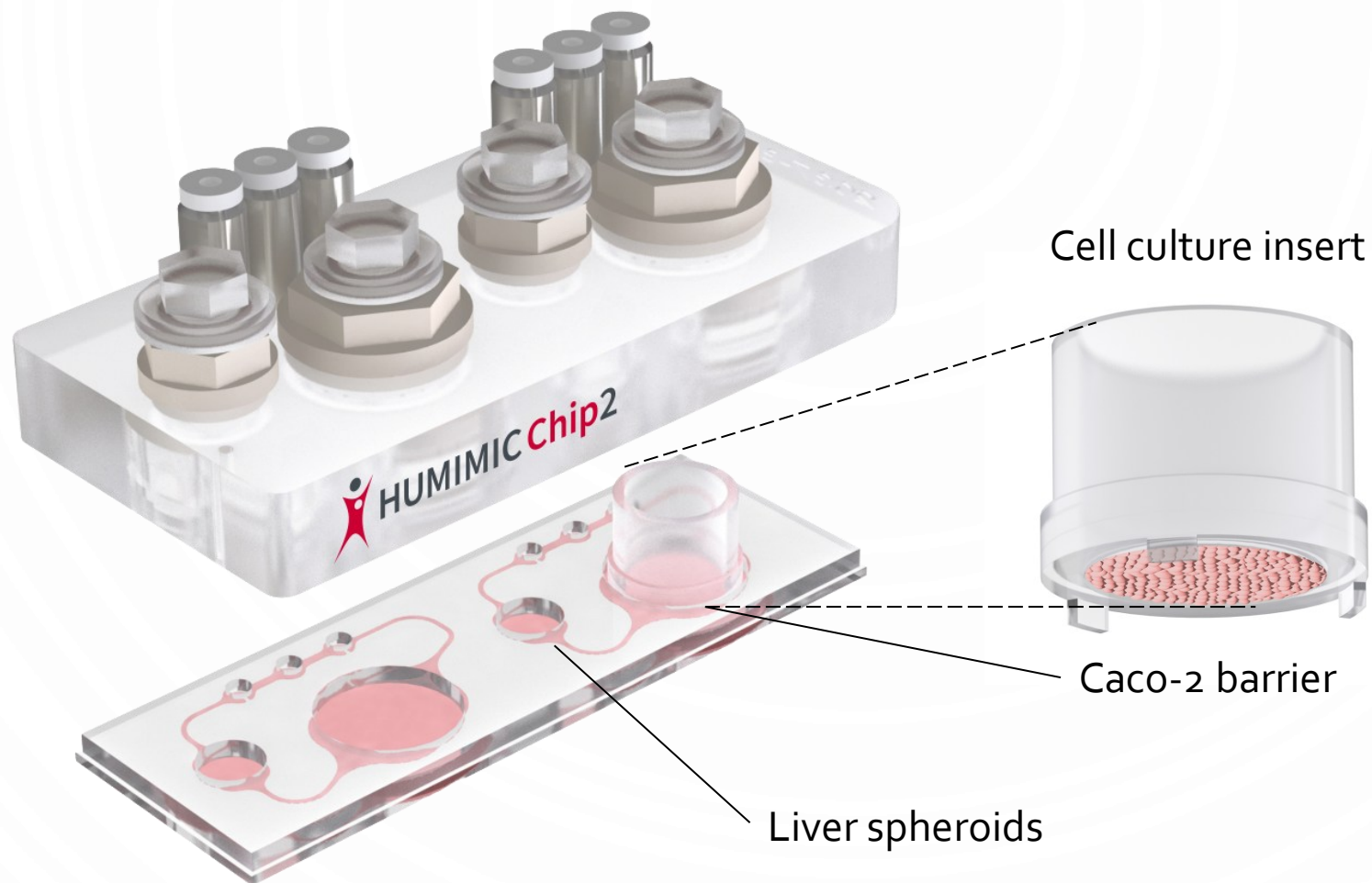
DE BfR



DESIGN



ILMERAC
International Liaison Group on
Methods for Risk Assessment
of Chemicals in Food and Feed

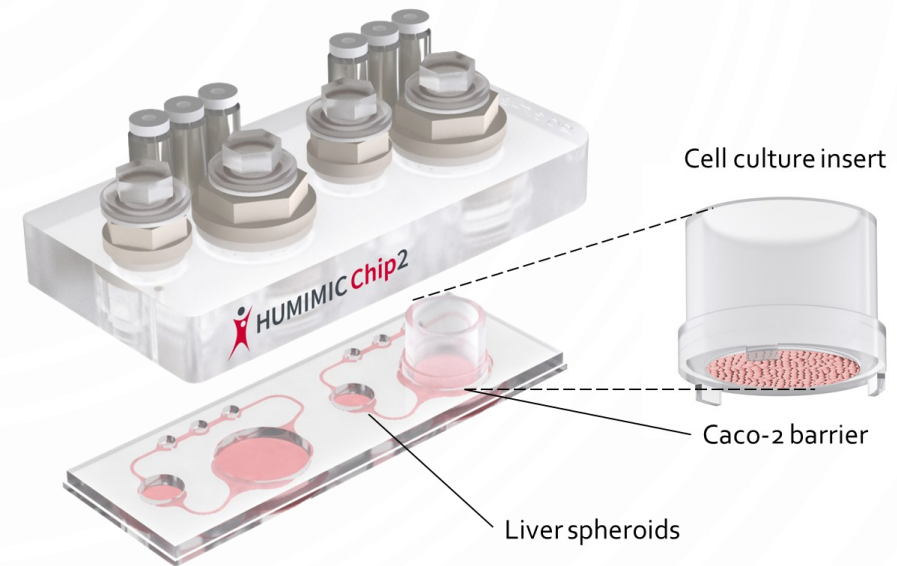


PHASE I

- Set up test system in all partner laboratories
- Comparative testing of shared test substances

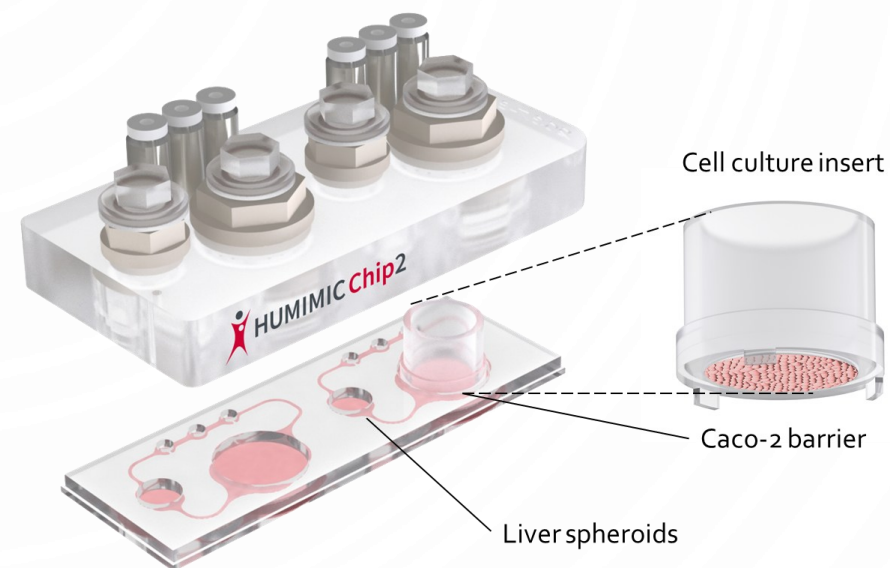
Timeline

- ✓ Test system
- ✓ Partners
- ✓ Finalise SOP
- ✓ Organise resources
- SOP training (Sep '26 & Apr '27)
- Test substance selection
- Endpoints and assays
- Analytics
- Conduct parallel testing



PHASE II

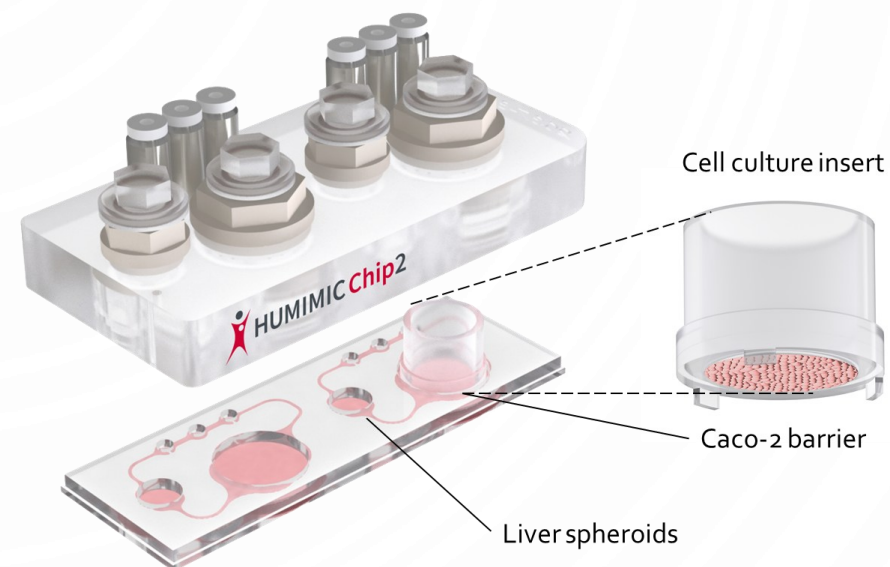
- Apply test system to address regulatory challenges and data gaps
 - Food supplements (e.g. green tea extract, curcumin)
 - Pesticide mixtures



- Work towards improvement of inter-laboratory variability
- Provide a qualification plan

Needs

- Support international collaboration and ILMERAC as a vital platform for exchange and a driver for innovation
- Join ILMERAC
- Nominate interested partners for OoC qualification from your institutions



WHO WE ARE



MEMBER 21 Members

OBSERVER 12 Observers

BfR Scientific Secretariat

➤ 4 more institutions currently considering membership



WHAT WE DO

Working groups

→ NAMs

→ Mixtures

→ Evidence integration

Output

→ Expert Dialogues

→ Perspective papers

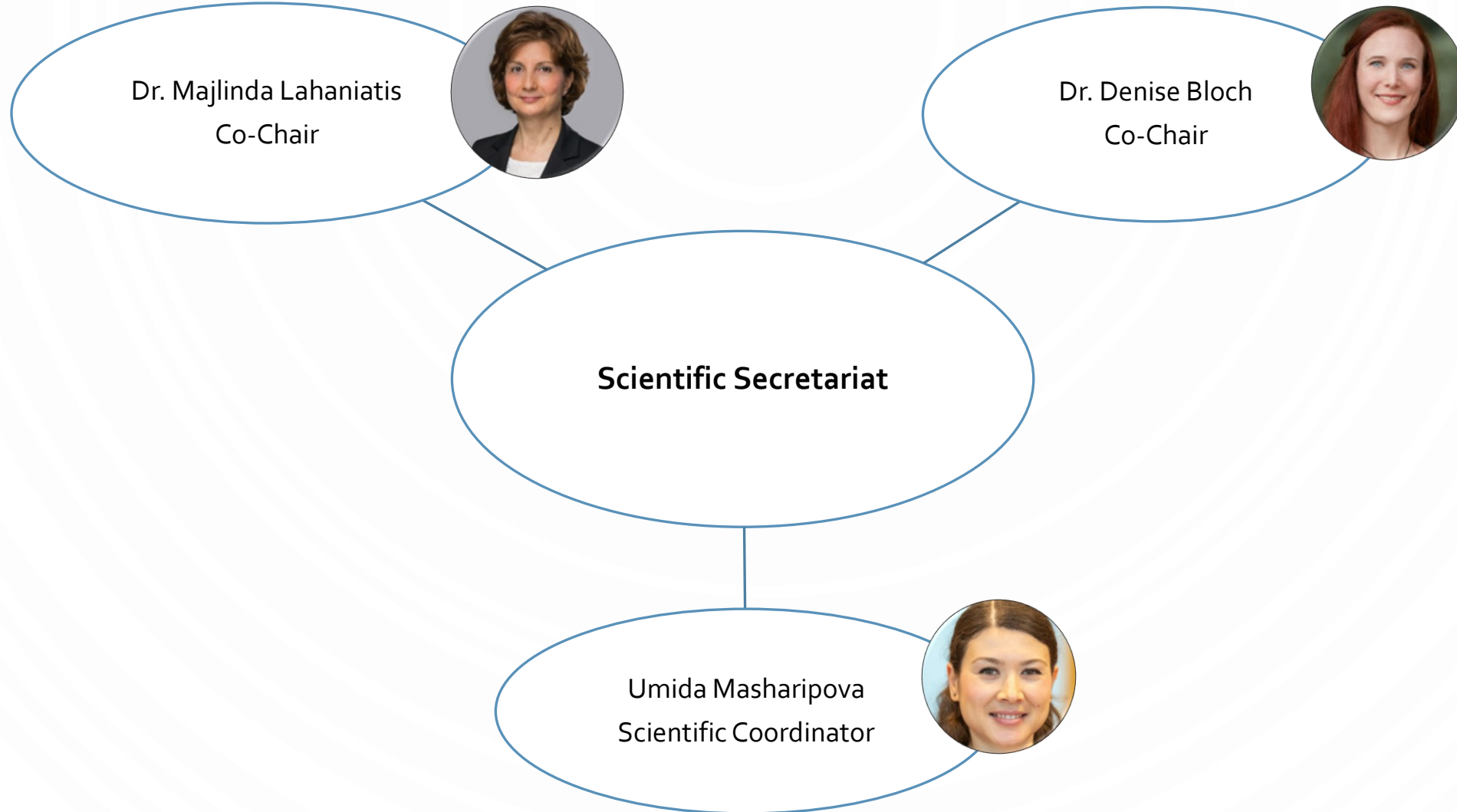
EFSA ADVISORY FORUM | ONLINE | DR DENISE BLOCH



ILMERAC

Connecting global expertise
to safeguard human health

ILMERAC TEAM AT BFR



Any Questions? Let's connect!

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