Interreg North-West Europe
Co-funded by the European Union
STEP4NAMs

APPLY

Challenge-based SME support

#07 Organ-on-chip–based human intestinal toxicity assessment

EXPECTED DELIVERABLE

Indicative duration: 6 – 9 months

Development and qualification of a human-relevant intestinal organ-on-chip (OoC) model to assess drug-induced intestinal toxicity in an early, predictive, and mechanistically informative manner, as an alternative or complement to animal studies. The model should reproduce key structural and functional features of the human intestinal epithelium (e.g. polarized barrier, flow, mechanical cues, epithelial–endothelial crosstalk where relevant) and enable quantitative assessment of intestinal safety liabilities.

LONG-TERM COLLABORATION POTENTIAL

Subject to scientific and strategic alignment

Conventional 2D cell cultures and animal models often fail to fully predict human-relevant intestinal responses, particularly for barrier dysfunction, inflammation, transporter-mediated effects, and chronic or low-grade injury. Recent literature demonstrates that intestinal organ-on-chip systems, incorporating dynamic flow and physiologically relevant architecture, improve the prediction of drug-induced epithelial damage, barrier disruption, inflammatory responses, and recovery mechanisms. While existing commercial platforms (e.g. gut-on-chip technologies such as those proposed by Mimetas) can serve as a technical reference, the challenge is not limited to a single provider and should be grounded primarily in state-of-the-art scientific literature and more importantly demonstrated biological relevance.

Readouts should allow both functional and mechanistic interpretation and may include:

- Barrier integrity: TEER, permeability assays (e.g. dextran), tight junction organization
- Cell viability and injury: live/dead markers, cytotoxicity, apoptosis/necrosis markers
- Morphological and phenotypic analysis
- Inflammatory and stress responses: cytokine/chemokine release, stress pathway activation
- Multi-parametric imaging and/or omics-based endpoints, if feasible

The assay should support testing of proprietary and reference compounds with known intestinal liability to benchmark sensitivity and translational relevance. For Ipsen, the value of this initiative is to co-build organ-on-chip models with technology providers and CROs, strengthen internal expertise, and, critically, build confidence in these models by validating their biological relevance. Today, there is a clear gap in available NAMs for intestinal toxicity, while strategies are more established for other organ systems. This creates a strong need to define and qualify human-relevant intestinal toxicity models that can be applied early for risk identification and mechanistic understanding.

CANDIDATE SELECTION

Initial eligibility check by MPR. Final selection by the challenge provider based on fir, relevance, readiness and innovation potential

Minimum required Technology Readiness Level (TRL)

- Demonstrated experience with intestinal organ-on-chip or advanced microphysiological systems
- Human intestinal cell culture (primary cells, organoids, or iPSC-derived systems)
- Microfluidic or OoC platform enabling flow and barrier formation
- Quantitative functional readouts
- Data analysis and interpretation aligned with toxicology use cases

Relevant Information

- Preference for partners with demonstrated experience translating OoC data into safety decision-making
- Willingness to align model development with regulatory and industrial expectations for NAM adoption.
- Partners must ensure compliance with ethical sourcing of human derived materials (e.g. organoids, iPSCs) and provide appropriate documentation when required.

Additional selection criteria

- Ability to benchmark against reference compounds

Geographic area	SME from across EU are welcome. SMEs from Interreg NEW are prioritized, particularly partner regions
Completion of EDUCATE	Core Module
Company status	SME under EU criteria
Maximum number of supported companies	1 – 3
Confidentiality: NDA/ CDA required	Not necessarily

APPLICATION

Directly via the STEP4NAMs Moodle platform

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