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

APPLY

Challenge-based SME support

#04 Development and validation of a human gut–liver MPS to profile oral bioavailability and distinguish intestinal versus hepatic first-pass metabolism

OBJECTIVE

Create and validate a human gut–liver microphysiological system (MPS) that supports oral dosing into the gut compartment with subsequent transfer to shared circulation for hepatic metabolism. The system should be capable of measuring parent and metabolite concentration over time in gut-only, liver-only, and combined configurations, distinguishing intestinal and hepatic first-pass effects and supporting oral bioavailability prediction. This challenge addresses a critical innovation gap in oral bioavailability prediction: the limited ability of conventional in vitro models to disentangle intestinal and hepatic first-pass metabolism within a human-relevant, integrated system.

Required capabilities

- Primary-cell gut and human hepatocyte or liver co-culture capability in MPS
- Multi-compartment PK sampling with LC/MS
- Evidence of maintained intestinal and liver function in shared circulation media
- Delivery within 6–9 months (≥ 2 probe compounds and reproducibility runs)

EXPECTED DELIVERABLE

Indicative duration: 6 – 9 months

- Establishment of a physiologically relevant human gut-liver architecture & flow
- Functional qualification of gut barrier (maintain tight junction integrity and consistent transport across the membrane during dosing and circulation) and intestinal / liver metabolic competence (e.g., CYP3A, CES, UGT)
- Integrated PK-like dataset with at least one CYP3A probe and one additional compound reproducibility assessment
- Interpretation framework for gut vs liver contribution; (optional) in vitro-in vivo extrapolation (IVIVE) and/or physiological-based pharmacokinetic (PBPK)-ready parameter package.

LONG-TERM COLLABORATION POTENTIAL

Subject to scientific and strategic alignment

If the platform meets the defined performance and reproducibility criteria for these overarching contexts of use, there is interest to expand to additional ADME/DMPK applications (e.g., broader enzyme/transporter interplay, DDI mechanistic studies), consistent with the broader industry direction for qualified MPS use.

CANDIDATE SELECTION

Initial eligibility check by MPR. Final selection by the challenge provider.

Completion of EDUCATE	Core Module
Company status	SME under EU criteria; > 50 employees preferred
Maximum number of supported companies	1 – 2
Minimum required TRL	Platform demonstrated in-house with at least one barrier tissue and one metabolic tissue ready for integration and qualification
Confidentiality NDA/ CDA required	Yes

Selection by the challenge provider based on fit, relevance, readiness and innovation potential.

Additional selection criteria

Geographic area	SME from across EU are welcome. SMEs from Interreg NEW are prioritized, particularly partner regions

APPLICATION

Application directly via the STEP4NAMs Moodle platform

https://step4nams.moodlecloud.com/

Scan the QR code to learn more about the STEP4NAMs training programme

SUPPORT

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