



## #03 Development and validation of a multi-organ, multi-species single assay capable of evaluating drug-induced phospholipidosis (DIPL)



### OBJECTIVE

The objective of this challenge is to establish a robust, multi-organ and multi-species in vitro assessment platform for Drug-Induced Phospholipidosis (DIPL).

While single-cell-line assays provide useful early screening information, they lack the organ and species specificity required for definitive risk assessment. Therefore, this challenge aims to identify service providers capable of delivering comprehensive cellular models of phospholipidosis, covering:

- Multiple human organ-relevant cell types (liver, lung, heart)
- Cells from toxicologically relevant non-clinical species (rat, dog, minipig and eventually monkey NHP)

The intent is to enable a more translational, mechanistic and comparative evaluation of compound-induced phospholipidosis across species, supporting risk assessment and derisking strategies in drug discovery.



### EXPECTED DELIVERABLE

*Indicative duration: 6 - 9 months*

Providers should propose a validated cellular assay for DIPL, covering the organ and species panel described on the left.

Expected readout include:

- **Max fold change:** Maximal signal amplitude relative to baseline or untreated control.
- **% vs positive control:** R relative potency or efficacy compared to a known phospholipidosis inducer.
- **Cell loss IC<sub>50</sub>:** Concentration leading to 50% cytotoxicity.
- **Lysosomal trapping IC<sub>50</sub>:** Concentration required to induce lysosomal accumulation, using imaging or dye-based methods.
- **Phospholipidosis EC<sub>50</sub>:** Concentration at which 50% of maximal phospholipid accumulation is observed.



### 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, and depending on phys/chem properties of chemical series in a given project, a sustained collaboration could allow integration of DIPL assessment into early project stages, supporting prospective derisking, reducing late attrition risk, and improving translational toxicology predictions.



### CANDIDATE SELECTION

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



Completion of EDUCATE

Core Module



Company status

SME under EU criteria



Maximum number of supported companies

1 - 3



Minimum required TRL

Proof-of-Concept validation



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 NWE 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



[step4nams@bioregio-stern.de](mailto:step4nams@bioregio-stern.de)



[Step4nams.nweurope.eu](https://step4nams.nweurope.eu)