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

TERMS OF REFERENCE

3R CENTER TÜBINGEN

Pilot II Multi-Site functional Validation of Organ-on-Chip Models

Introduction

This pilot project aims to functionally validate pre-established Organ-on-Chip (OoC) systems through a multi-site ring trial involving pharmaceutical partners. By evaluating the systems' functionality, long-term stability and predictive accuracy using both known and blinded compounds, the study seeks to build robust, reproducible data to support the broader acceptance of OoC technologies as alternatives to animal testing.

Purpose and scope

Aligned with the objectives of the STEP4NAMs project, this pilot study intends to increase stakeholder confidence, particularly among pharmaceutical companies and SMEs, in the reliability and relevance of OoC systems. The goal is to identify and disseminate best practices while contributing directly to the development of training materials and the NAM Validation Manual. The study will involve 2–5 pharmaceutical partners and focus on generating evidence supporting the reproducibility and predictive value of these advanced models across multiple sites.

Approach and methodology

The study will be conducted in three key phases across a minimum of three sites:

1. Assessment of basic functionality and long-term stability of two OoC models
2. Evaluation of dose-response relationships using six well-characterized (known) compounds.
3. Validation of predictive accuracy using six blinded compounds provided by pharma partners.

Test compound selection will follow national guidelines and be coordinated with the SAB and pharma stakeholders. A public call will identify suitable pharma partners, supported by Business Support and Cluster Organizations. All study protocols will be standardized to manage inter-site variability and results will be used to develop open-access best practice materials.

Pre-requisite for participation

Participating (pharmaceutical) companies should have prior experience with OoC systems.

- Companies as end users must be willing to conduct in-house testing.
- Companies as technology providers may submit their NAMs for testing.

All participants must commit to following the standardized testing protocols and contribute to data sharing in a confidential and anonymized manner where needed.