



BioRegio STERN is a partner in the EU's NAMWISE project

# New methods for reliable evaluation of chemicals and pharmaceuticals

(Stuttgart) – BioRegio STERN Management GmbH is a German partner in the European NAMWISE (New Approach Methodologies Within Integrated Safety & Efficacy evaluation of chemicals and pharmaceuticals) project, which is coordinated by the French Institut National de l'Environment Industriel et des Risques – INERIS. There are a total of 18 partners from eight countries involved in the project, and their aim is to introduce and integrate new methods (New Approach Methodologies, NAMs) to assess the safety and efficacy of chemicals and pharmaceuticals while avoiding animal testing. The project is funded by the European Framework Programme for Research and Innovation (Horizon Europe), and is set to run for 30 months. The kick-off meeting was held in Chantilly, France, on 4 and 5 February.

The project partners – an international, multidisciplinary consortium of scientists, NAM developers, and industry and regulatory experts – will drive forward the introduction of new methods for evaluating the safety and efficacy of chemicals and pharmaceuticals. At the beginning of February, the 18 partners from eight countries met in Chantilly, France, for the kick-off meeting and, under the leadership of INERIS, discussed the schedule for the 30 months of the project. Among other things, the existing NAMs are to be mapped and their legal implementation evaluated, case studies on the effective use of NAMs are to be developed, and the validation and standardisation requirements for NAMs are to be analysed. Numerous measures, such as communication and training, are designed to promote the acceptance and implementation of innovative methods, especially alternatives to animal testing, and define the legal frameworks. The project excludes NAMs that use data and models based on vertebrates, and concentrates on in vitro approaches (including organoids and organ-on-chips), in silico methods, Adverse Outcome Pathways (AOP) and Integrated Approaches to Testing and Assessment (IATA).



The NAMWISE project was launched on 1 December 2024 and is due to end on 31 May 2027. It is funded by the European Framework Programme for Research and Innovation (Horizon Europe). Its findings will be incorporated into the European Commission schedule. The project brings together 18 partners from eight countries, has a total budget of 2,242,838.75 euros, and will achieve its targets with an EU subsidy of 1,977,390 euros, which has been applied for. BioRegio STERN Management GmbH is receiving a 100 percent subsidy of 70,000 euros.

Dr. Margot Jehle is Project Lead at BioRegio STERN Management GmbH and is responsible for various NAMWISE work packages. "We will survey European scientists and entrepreneurs to gather their opinions about NAMs, and will support the evaluation of the legal implementation of NAMs. In addition, we are helping design a workshop to bring regulatory authorities, industry and researchers together round a single table. BioRegio STERN Management GmbH's primary contribution to the project is its expertise in terms of communication and cooperation between completely different players."

# The 18 NAMWISE project partners

## **Research and technology organisations:** 4

- Institut National de l'Environnement Industriel et des Risques INERIS (France)
- Instituto de Salud Carlos III (Spain)
- AIT Austrian Institute of Technology GmbH (Austria)
- Institut National de la Santé et de la Recherche Médicale (France)

## SMEs (small and medium-sized enterprises): 6

- Institute of Evidence-Based Toxicology (Germany)
- aQuaTox-Solutions GmbH (Switzerland)
- Altertox (Belgium)
- CEHTRA SAS (France)
- Watchfrog (France)
- Netri (France)

# Associations/organisations: 4

- Association Lyon Biopôle (France)
- Axelera Association Chimie-Environnement Lyon et Rhône-Alpes (France)
- BioRegio STERN Management GmbH (Germany)
- Pepper Plateforme public-privé pour la pré-validation des méthodes de



caractérisation des perturbateurs endocriniens (France)

#### Industry: 2

- Sanofi-Aventis Groupe (France)
- Charles River Laboratories Den Bosch BV (Netherlands)

## Governmental organisations: 1

• Umweltbundesamt Gesellschaft mit beschränkter Haftung – UBA GmbH (Austria)

#### Universities: 1

• The University of Birmingham (United Kingdom)

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## About BioRegio STERN Management GmbH:

BioRegio STERN Management GmbH promotes economic development in the life sciences industry, helping to strengthen the region as a business location by supporting innovations and start-up companies in the public interest. It is the main point of contact for company founders and entrepreneurs in the Stuttgart and Neckar-Alb regions, including the cities of Tübingen and Reutlingen. The STERN BioRegion is one of the largest and most successful bioregions in Germany. Its unique selling points include a mix of biotech and medtech companies that is outstanding in Germany and regional clusters in the fields of automation technology and mechanical and plant engineering.

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