

# Your Full-Spectrum Toxicity Testing Partner.



Full rodent and non-rodent toxicity testing for medicinal products (small molecular entities, biologicals, biotherapeutics, ATMPs), medical device, chemicals, and food products.

## TOXICOLOGY

### General Toxicology

Characterize systemic toxicity, target organs and dose-response relationships to support informed decisions

- Single - and Repeated dose toxicity
- Acute toxicology (7-14 days)
- Subacute toxicology (28 days)
- Subchronic toxicology (90 days)
- Chronic toxicology ( $\geq$  180 days)

## STUDY DESIGN & REGULATORY SUPPORT

- Species selection
- Dose selection
- Study design consultation
- Regulatory strategy support
- GLP study planning
- Protocol development

## ADDITIONAL TESTING

### Selected Methods

Mechanism-driven immune safety tailored to the biology, mode of action and regulatory requirements of your therapeutic

#### In vivo

- Murine local lymph node assay (LLNA)
- Delayed-type hypersensitivity (DTH)
- Tests for anaphylaxis (ASA/ACA/PCA)

#### Ex vivo / In vitro

- Cytokine release
- Complement activity
- T-cell activation marker
- Mixed lymphocyte reactions (MLR)
- Cytotoxic T-lymphocyte reaction

#### Immunogenicity

- Anti-drug antibodies (ADA)
- Serological antibody titer determination / isotype distribution

## IMMUNOTOXICOLOGY & IMMUNOGENICITY

### Standard Toxicity with Immune

#### Parameters

Evaluate adverse effects of pharmaceuticals on the immune system according to CH S6/S8

#### Descriptive:

- Hematology, including bone marrow plus immunophenotyping of leucocytes and lymphocyte subsets
- Clinical chemistry
- Organ/tissue gross pathology and enhanced histopathology

#### Functional:

##### Innate cell activity

- NK cell activity
- Macrophage function

##### Humoral and cellular responses to antigen

- T cell dependent antibody response (TDAR)
- T-cell proliferation

#### Host resistance

- Resistance to tumor cells

Note: These are exemplary assays only. The selection of assays always depends on the type of product.

## ADMINISTRATION ROUTES

- Enteral (per os, rectal, drinking water/ dietary admixture)
- Parenteral (intravenous, intraperitoneal, subcutaneous, intradermal, intracutaneous, intramuscular, implantation)
- CNS/Intracranial (intracerebroventricular)
- Topical/Local (mucosal, intranasal)

## SPECIALISED SAFETY STUDIES

### Tailored Safety Assessments

Tailored safety assessments aligned with the biology, modality and the regulatory pathway of your candidate

- Cytotoxic T-lymphocyte reaction
- Immunogenicity
  - Anti-drug antibody (ADA) assay
  - Serological antibody titer determination/isotype distribution
- Developmental and Reproductive Toxicity (DART)
  - (Combined) repeated dose toxicity screening tests
  - Embryo-fetal development
  - One or more generation reproduction toxicity
  - Extended one generation reproductive toxicity
- Endocrine Disruptors (in vivo)
- Carcinogenicity
  - Also combined with chronic toxicity
- Customized studies for biologicals & ATMPs
  - Immunodeficient models
  - Humanized mice (transgenic, stem cell engrafted)
  - Evaluation of animal models for relevance



Full Website Overview

## Therapeutic Types

- Medical Device - ISO
- Chemical - OECD
- Food Safety Testing - EFSA
- Biological Products - EMA / FDA
- ATMPs - EMA / FDA
- Pharmaceuticals - EMA / FDA

## YOUR SCIENTIFIC PARTNER

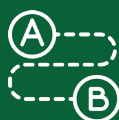


### STRATEGY BEFORE EXECUTION

The right study starts with the right strategy. InnoSer works with you to define the most appropriate models, endpoints, dose levels and study designs before execution begins.

#### Our scientific approach helps you

- Select the right model and study design
- Define meaningful and regulatory-relevant endpoints
- Identify potential challenges before study initiation
- Connect translational findings with safety assessment
- Generate data that supports the next development decision



### NONCLINICAL PROGRESS WITHOUT COMPLICATIONS

InnoSer is a specialist preclinical CRO helping you make better development decisions through direct access to scientific experts, rapid decision-making and continuity throughout the study.

#### From study strategy to regulatory-ready data, we bring scientific expertise directly to your programme:

- Direct access to study directors and scientific experts
- Fast answers and rapid decision-making
- Scientific continuity from planning through reporting
- Study strategies designed around your development objectives
- Translational and safety expertise under one scientific team
- Transparent collaboration and visibility throughout the study

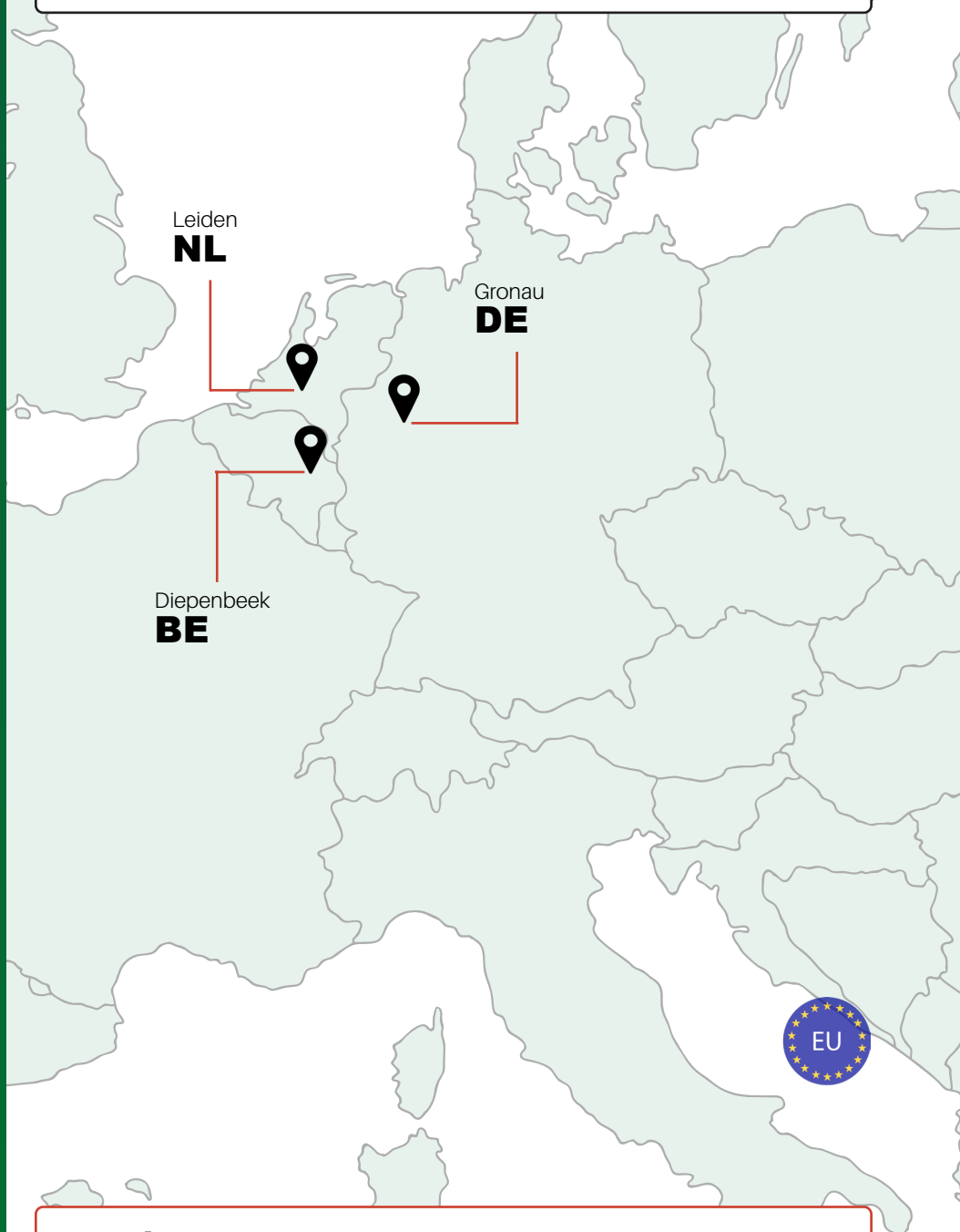


### CONTINUITY THROUGH EVERY STAGE

Scientific insight should not get lost between handovers. At InnoSer, the same scientific team remains involved throughout planning, execution, interpretation and reporting.

## EUROPEAN EXPERTISE, GLOBAL REGULATORY PERSPECTIVE.

InnoSer supports sponsors worldwide with nonclinical expertise aligned with European and international regulatory expectations, including EMA and FDA requirements.



## LET'S DISCUSS YOUR PROGRAMME

Speak directly with our scientific team to discuss your study objectives, model requirements or nonclinical development strategy.