SAFETY ASSESSMENT

- Fully-integrated, science-driven development approach with pharmaceutical background
- State-of-the-Art quality systems with impeccable regulatory inspection history
- Diverse, dynamic team of expert scientists capable of handling projects of any complexity
- Tailored studies and programs based on specific client needs
- Solutions-based approach to problem solving

AREA OF EXPERTISE

- Toxidology and Pathology
  - Investigative and Regulatory studies
  - Rodents, dogs and NHPs facilities
  - Immunotoxicology
  - Biomarkers
  - Standard and advanced pathology read-outs

- Genetic Toxicology
  - Ames testing
  - Chromosome aberration test
  - In vitro and in vivo micronucleus test

- Abuse Liability Testing
  - Consultation
  - Behavioural studies

- Safety Pharmacology
  - Cardiovascular
  - CNS
  - Respiratory

  Gastro Intestinal Tract
Evotec provides drug discovery and development solutions by applying scientific excellence, outstanding service and a team of some of the foremost scientific professionals in the industry. We tailor studies and programs based on specific client needs, maintaining an interdisciplinary attitude.

Working within a strong regulatory environment, our scientific teams provide the assurance of client-centred project management, consistent lead times, close working relationships with customers.

**TOXICOLOGY CORE CAPABILITIES**
- Rodent, rabbit, dog and primate facilities – AAALAC accredited
- Investigative and clinical-enabling studies, custom-designed for your molecule/indication
- Expertise in multiple routes of administration
- Biomarker identification by means of standard and specialised clinical pathology
- Multiple modalities: NCE, NBE, gene therapy/viral vectors, mAb, cell therapy

**SAFETY PHARMACOLOGY (GLP)**
- Cardiovascular
  - Telemetry in conscious and freely-moving rodents, dogs, and non-human primates
  - Consolidated neurocardiovascular evaluation study available in dog
  - Cardiac safety *in vitro* panel including hERG, hNav1.5, hCav 1.2 in automated and manual patch clamp electrophysiology platforms
- CNS
  - Functional observation battery in rodents, dogs and non human primates
- Respiratory
  - Whole-body plethysmography in rodents

**Abuse Liability Assessment**
- 8-factor analysis
- ICH-compliant GLP package:
  - Self-administration
  - Drug discrimination
  - Physical dependence/withdrawal
- Inclusion of safety pharmacology endpoints in toxicology studies for appropriate indications

**GENETIC TOXICOLOGY (GLP)**
- Ames test
- Chromosome aberration test:
  - *In vitro* Human Lymphocytes (HPLA) assay
  - *In vitro* and *in vivo* micronucleus assay

**ADDITIONAL CAPABILITIES**
- Expertise in bioanalytical method development and GLP validation for both small and large molecules
- Broad skillset in pharmacokinetics and drug metabolism
- Immunoassays, Immunogenicity testing and Immunotoxicology assays