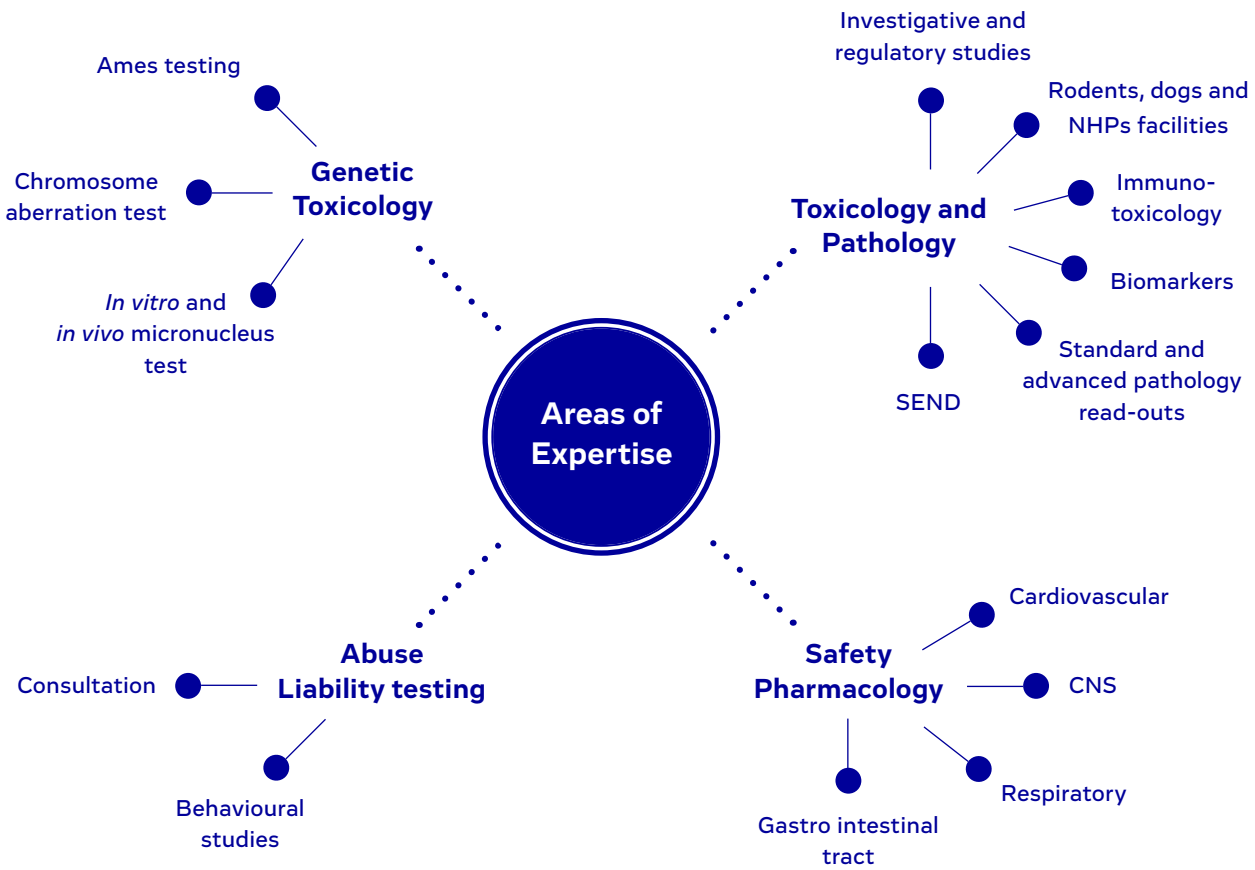
evotec

#RESEARCHNEVERSTOPS

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



Evotec's safety assessment offers a full range of capabilities from exploratory programmes to fully GLP-compliant toxicology studies with the aim to establish the toxicological profile of new compounds or to extend the known profiles of existing ones (new indications, new formulations, new routes of administration).

The team includes dedicated and experienced study directors with project-leadership expertise to design and manage studies up to the timely delivery of the final report.

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
- Expertise in different blood sampling including microsampling from small and large animals
- Advanced surgical research facility
- 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
- Pathology services
- Scientific and strategic consulting
- Specialized statistical analysis
- Generation of SEND dataset for all studies using internal data capture systems