PRECLINICAL REGULATORY SAFETY STUDIES

avantdrug offers preclinical studies of your product under development for regulatory approval:

avantdrug is the preclinical studies area of Creatio, dedicated to the validation of new technologies and healthcare products under development for their regulatory approval.

With extensive experience in the field, our skilled professionals provide private and public sector clients with a wide range of preclinical studies conducted under high quality standards, ISO 9001:2015 and/or GLP quality standards, as well as technical and scientific advisory services.

avantdrug aims to become the foremost preclinical research center of its kind, setting a benchmark for preclinical studies that promote the timely and cost-effective launch of innovative, safe and effective products for the benefit of the society.

TOXICITY STUDIES

✓ Toxicity *in vitro*:

- *In vitro* skin irritation & corrosion tests (OECD 431 & 435, 429, ECVAM DB-ALM 47)
- Balb/c 3T3 cell phototoxicity assay (OECD 432)
- *In vitro* cytotoxitity tests (HepG2, A549, 3T3, Caco-2) (INVITTOX 17 & 64)
- Cytotoxiticy in primary hepatocytes of rats & other species (INVITTOX 20)
- Cell transformation assay (CTA) (ENV/JM/MONO(2015)18)
- Screening assay for different cell types
- Phototoxicity assay (OECD 432)

✓ Reproduction & developmental toxicity:

- Fertility
- Reproduction/developmental toxicity screening (OECD 421)
- Embryonic stem cell test *in vitro* (ECVAM DB-ALM 113)
- Repeat-dose toxicity study combined with reproduction/ developmental toxicity screening test (OECD 422)
- Prenatal development (OECD 414)
- 1- and 2-generation reproduction toxicity study (OECD 415 & 416)

ADME, PK & PK/PD STUDIES

- Absorption, distribution, metabolism & excretion (ADME) studies
- Pharmacokinetic (PK) studies: lineality, bioavailabity & bioequivalence
- Pharmacokinetic/pharmacodymanic relationship studies
- Kinetic studies of new forms of dosage and local tolerance
- Toxicokinetic evaluation

CLINICAL PATHOLOGY

- Histopathology service for necropsy, histological processes, and evaluation
- Hematological & biochemical determinations
- Histochemical & immunohistochemical determination in tissues
- Coagulation profiles

✓ Genotoxicity:

- Bacterial reverse mutation assay (Ames) (OECD 471)
- *In vitro* mammalian cell gene mutation test (OECD 476)
- *In vitro* and *in vivo* micronuclei assay (OECD 487 & 474)
- *In vitro* and *in vivo* Comet assay (OECD 489)

✓ Local tolerance:

- Acute local tolerance & repeat-dose study
- Local lymph sensitivity assay (OECD TG 442A)
- *In vitro* skin sensitization & absorption test (OECD TG 442E, OECD 406 & 428)

✓ Toxicity *in vivo* & carcinogenicity:

- Acute toxicity studies (OECD 402, 404, 405, 420, 423 & 425)
- Repeat-dose toxicity (OECD 407, 408, 409, 410, 411 & 452)
- Carcinogenicity assay (OECD 451) combined with chronic toxicity (OECD 453)
- Behavior evaluation

OTHER STUDIES

- Medical device toxicology studies (ISO 10993)
- Cosmetic efficacy studies
- Microbiology studies
- Palatability studies
- Bacterial endotoxin determination
- *In vitro* neurotoxicology studies using human models
- *In vitro* non-animal methodology studies

INTEGRATED SERVICES

- Risk assessment study
- Regulatory requirements assessment
- Optimal procedure design to reduce cost and timings
- Expert & risk assessment reports
- Scientific & technical advice
- Support with documentation for regulatory authorities

Production and validation center of advanced therapies
UNIVERSITAT DE BARCELONA

We ensure all projects are compliant with applicable UNE-EN-ISO 9001:2015 and/or GLP guidelines, and the Creatio Quality System.