GLP Certificate holder

MEDITOX

per aspera ad astra

www.meditox.eu

CARDIOLOGY DISEASES

HUNTINGTON´S DISEASE MODEL

DIABETES / OBESITY MODEL

OPHTHALMOLOGY DISEASES

PRECLINICAL RESEARCH AND DEVELOPMENT

COMPREHENSIVE PRECLINICAL TOXICOLOGICAL PROGRAM

ANIMAL MODELS OF SELECTED HUMAN DISEASES

ACCREDITED BREEDING FACILITY FOR LABORATORY ANIMALS

MediTox s.r.o.

MEDITOX

per aspera ad astra

MediTox is a private independent CRO offering special taylored services with the emphasis on competitive price, flexibility, high quality and scientific standards.

Preclinical R&D

Comprehensive TOX/Safety program

Disease models


Argentina
Australia
Canada
India
Israel
Singapore
USA
Sverige
Sweden
Suomi
Finland
Norge
Norway
Eesti
Estonia
Latvija
Latvia
Lietuva
Lithuania
Danmark
Denmark
United
Kingdom
Ireland
Беларусь
Belarus
Nederland
Netherlands
Polska
Poland
België
Belgique
Belgium
Deutschland
Germany
Česká Rep
Czech Rep
Slovensko
Slovakia
Україна
Ukraine
Kazakhstan
Österreich
Austria
Moldova
France
Switzerland
Magyarország
Hungary
Slovenia
Hrvatska
Croatia
România
Romania
Srbija
Serbia
Italia
Italy
Македония
Bulgaria
Macedonia
Georgia
Uzbekistan
Azerbaijan
Portugal
España
Spain
Ελλάς
Greece
Türkiye
Turkey
Turkmenistan
Tajikistan

MEDITOX

per aspera ad astra

Good Laboratory Practice Certificate OECD GLP [C(97)186 Final]
Last re-inspection: September 2022

Authorization to Use Experimental Animals
Valid for: 2020 - 2025

Authorization to Breed Experimental Animals
Valid for: 2020 - 2025

Authorization to Handle GMO
in compliance with Act No. 153/2000 Coll.

Institution´s Animal Welfare Assurance
approved by **National Institute of Health, Office of Laboratory Animal Welfare (USA),** Valid for: 2020 - 2025

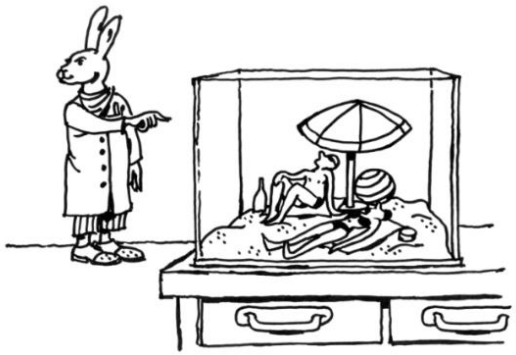
Crédit Impôt Recherche (CIR) accreditation
Valid for 2021 - 2023

Experimental premises available – animal housing

Conventional
Mice, rats, hamsters, guinea pigs, rabbits, ferrets, cats, dogs
Mini pigs/pigs, NHP

Barrier
Mice, rats, hamsters, Guinea pigs, rabbits, ferrets

BSL II
Mice, rats, hamsters, guinea pigs, rabbits, ferrets



Experimental premises available - laboratories

- Fully equipped surgical operating room for conducting studies requiring surgery, X-ray imaging
- Lab of toxicology (ophthalmoscopy, electrocardiography, clinical observation)
- Lab of clinical pathology (hematology, serum chemistry, urinalysis)
- Lab of pathology & histopathology
- Application formulation unit

Quality assurance

- QA unit, Archives

Test systems available

Non-rodents species:
Rabbits, dogs, ferrets, cats, pigs/mini pigs, NHP

Rodent species:
Mice, rats, hamsters, guinea pigs

In vitro:
Bacteria (S. tph, E. Coli), mammalian cells (human lymphocytes, erythrocytes, murine fibroblasts, etc.)

Adminstration routes available

Oral (capsules, tablets, esophageal gavage, gastric gavage)

Buccal, rectal, vaginal

Dermal, sub-cutaneous, intra-cutaneous

Intra-nasal, intra-tracheal

Ocular, intra-vitreal

Intra-articular

Intra-venous, intra-cardial, intra-peritoneal, intra-muscular

Implantation (bone, muscle, subcutis)

Inhalation (nose-only exposure)

MEDITOX

per aspera ad astra

Human medicine area

Early preclinical developemnt

Solubility (water, DMSO, FaSSIF)

Permeability (PAMPA, Caco2 A→B

Fraction unbound in plasma

Half-life (plasma, liver microsomes)

Cytochrom P agonists/antagonists)

AhR Activator

CAR agonist/inhibitor, PXR agonist

CSTO1 inhibitor

ALDH1A1 inhibitor

Cytotoxicity (2D/3D), genotoxicity hERG inhibitor

MEDITOX

per aspera ad astra

Human medicine area

Preclinical development

General toxicology/non-clinical safety, EMA, ICH, OECD TG

MTD/DRF, pilot, POC studies

Acute (SD) studies

Repeated dose studies (7 days – 12 months)

Genetic toxicology, EMA, ICH, OECD TG, ISO 10993

Gene mutation in bacteria (Ames test)

Mammalian cells chromosome aberration test (in vitro, in vivo)

Mammalian cells micronucleus test (in vitro, in vivo)

Comet assay

Mouse Lmphoma Assay, (L5178Y, mutation TK)

Cytotoxicity test

MEDITOX

per aspera ad astra

Human medicine area

Local effects, EMA, ICH, OECD TG, ISO 10993

Skin irritation (in vitro, in vivo)

Eye irritation (in vitro, in vivo)

Skin sensitization in vivo (LLNA)

Skin sensitization in vitro (DPRA, Keratinosens, h-CLAT)

Non-clinical local tolerance (mucosal, ocular, local tolerance after implantation to muscle, subcutis and bone)

Safety pharmacology, EMA, ICH

Central nervous system (modified Irwin test, body temperature)

Cardiovascular system (ECG, heart rate, blood pressure, hERG)

Respiratory system (Head-out plethysmography)

PK/TK/BA, Biodistribution, EMA, ICH, OECD TG

MEDITOX

per aspera ad astra

Human medicine area

Efficacy, EMA, ICH

Anti-viral efficacy/immunogenicity

Anti-glaucoma efficacy

Non-clinical safety, EMA, ICH

Nonclinical evaluation of the potential for delayed ventricular repolarization

Non-clinical safety studies for the conduct of human clinical trials for pharmaceuticals

Preclinical safety evaluation of biotechnology-derived products

Preclinical pharmacological and toxicological testing of vaccines

Nonclinical evaluation for anticancer pharmaceuticals

MEDITOX

per aspera ad astra

Human medicine area

Toxicity to reproduction, ICH, OECD TG

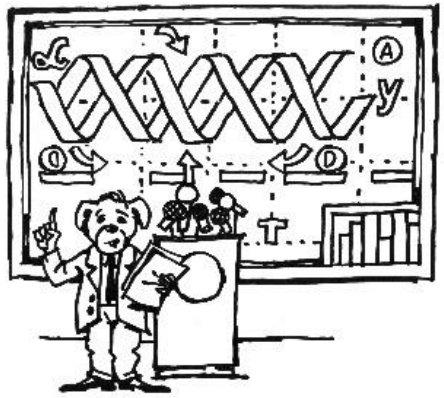
Embryo-Foetal Developmental Study (rats, rabbits, DRF, main study)

Prenatal developmental study (rats, rabbits, DRF, main study)

Carcinogenicity, ICH, OECD TG

Repeated dose 2-year carcinogenicity study in rats

Repeated dose 6-month carcinogenicity study in transgenic mouse (B6C3F1, ICR or Balb/c mice)



Veterinary medicine area

Safety studies, **VICH, EMA**

Target animal safety studies

Bio-equivalence studies

Immersion/Wash-out study

Wipe test

Feed/food additives testing, **EFSA, VICH**

Palatability

Safety studies

Efficacy

Medical device area

Medical device biocompatibility, ISO 10993

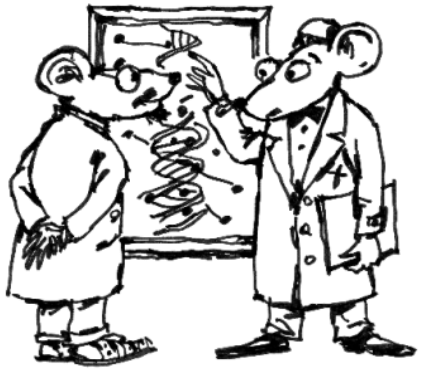
Genetic toxicity

Cytotoxicity

Irritation and skin sensitization

Systemic toxicity

Local and systemic tolerance after implantation (subcutis, muscle, bone)



Disease models

Available models:

Chronic glaucoma, dog

Human influenza, ferret

Osteoarthritis (CLT), dog

Models under development

Chronic glaucoma, rabbit

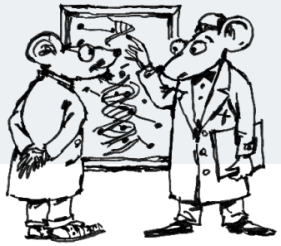
Osteoarthritis, rabbit

Periodontitis, dog

Permetrhin intoxication therapy, cat

MEDITOX

per aspera ad astra



Participation in R&D projects

FLUVAC: Live attenuated replication-defective influenza vaccine

Austria, Germany, Russia, Slovenia, Czech Republic

ANTIFLU: Innovative anti-influenza drugs exluding viral escape

Denmark, France, Germany, Hungary, Israel, United Kingdom, Czech Republic

OSTEOGROW: Novel morphogenetic protein-6 biocompatible carrier device

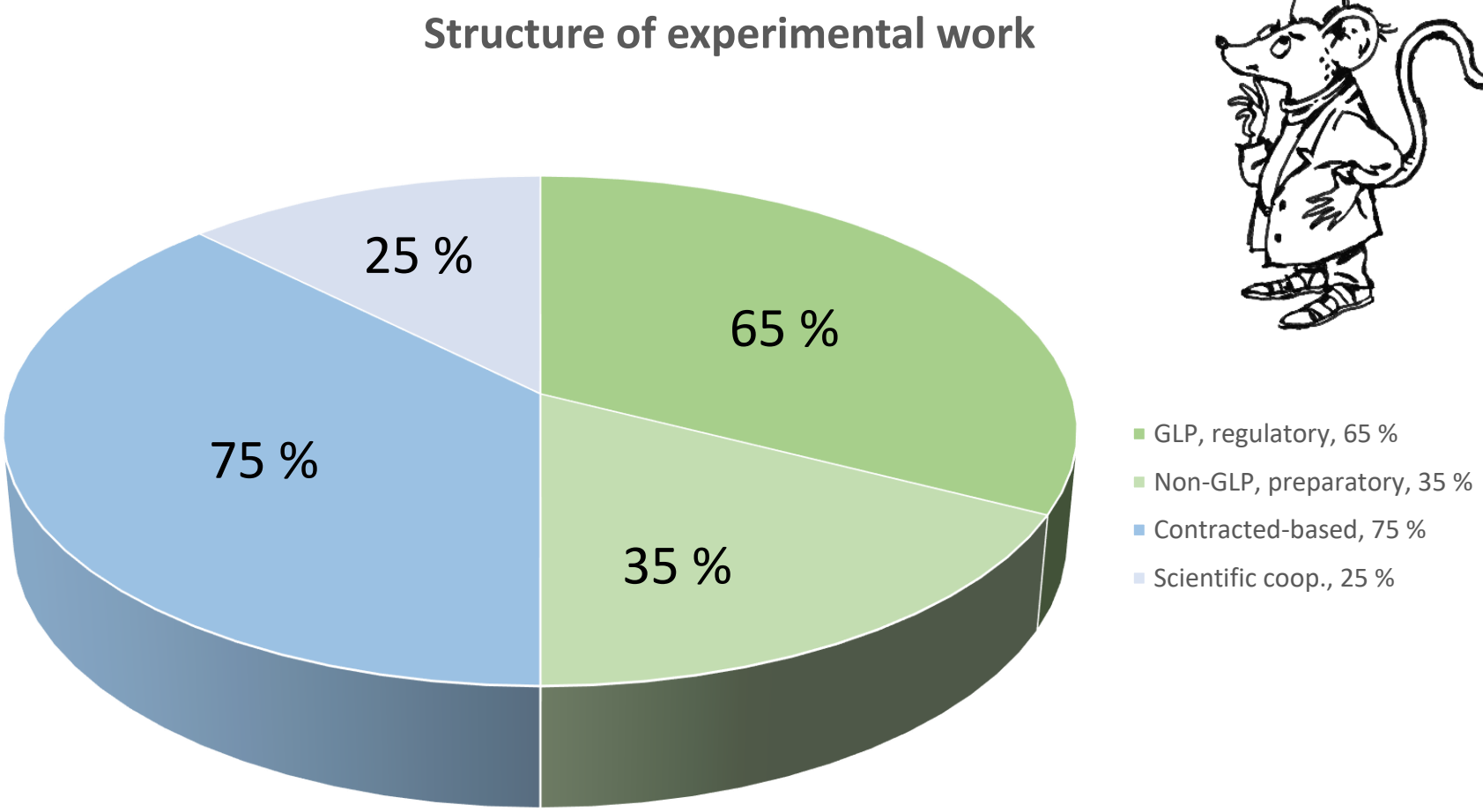
Austria, Bosnia and Herzegovina, Croatia, Czech Republic, Sweden

FLUniversal: Intranasal, rapid acting universal influenza vaccine

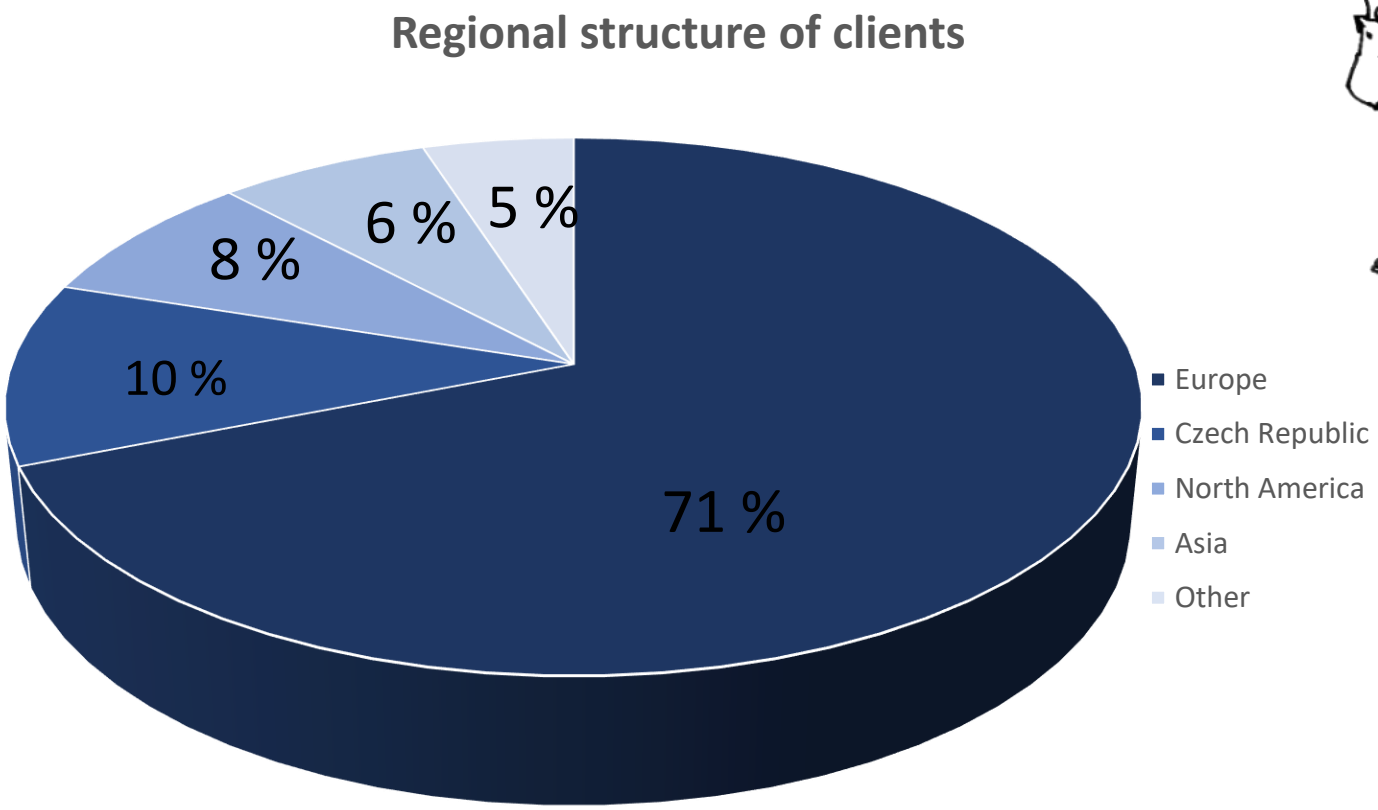
Austria, Denmark, Czech Republic, Denmark, Hungary, Italy, UK, The Netherlands

Project approved in May 2023

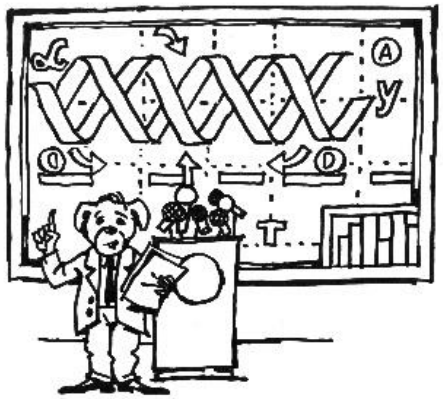
A bit of statistics…

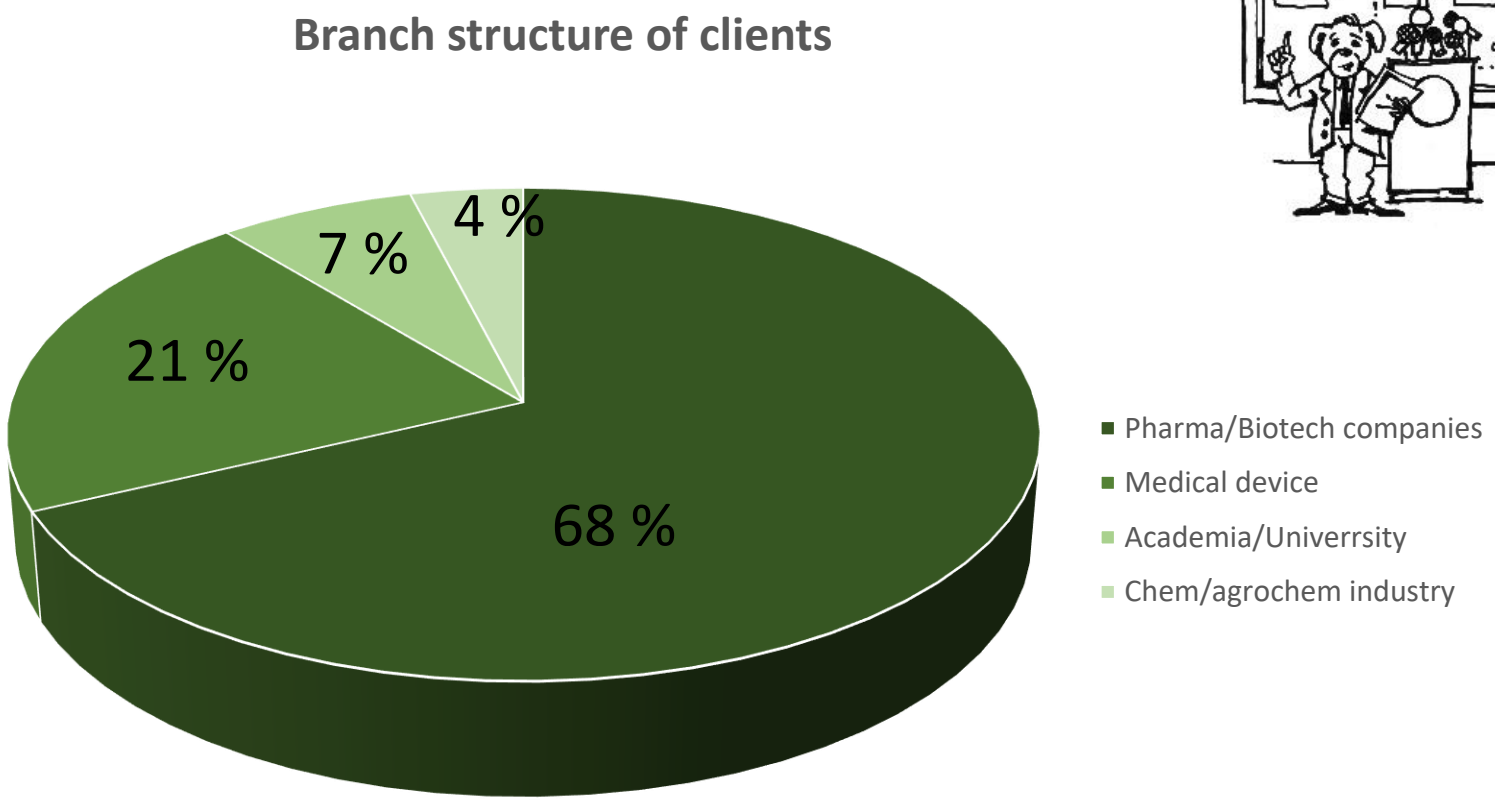


A bit of statistics…



A bit of statistics…





MEDITOX

per aspera ad astra

Selection of references

Artialis, Belgium
Bioceltix, Poland
California Univ, USA
Celon Pharma, Poland
CR. HANSEN, Denmark
Cromepharma, UK
Dicot, Sweden
DÔMES Pharma, France
EirGen Pharma, Ireland
Faraday, Inc., USA
FATRO, Italy
Gelesis Inc, USA
Herantis, Finland
HUVE Pharma, Belgium
INEB, Portugal
Kancera S.A., Sweden
Klifovet, Germany
KRKA, Slovenia
Leiden University Medical Centre, NL
Lesaffre, France
Lupin Pharma, India
Mount Sinai School of Medicine, USA
Nicox, Italy
Olainfarm, Latvia
Pharmathen, Greece
Polpharma, Poland
Regivet, The Netherlands
Rontis, Greece
Royal College of Surgeons in Ireland, Ireland
Sunpharma, India
Triveritas, UK
VetBiobank, France
Vetcare Oy, Finland
Virbac, France, …

General service flow chart

Event	Responsibility	Approximate duration
1.RFQ	Sponsor	**N/A**
2.Proposal/Quotation	CRO	**3 – 7 days**
3.PQ assessment	Sponsor	**2 – 4 weeks**
4.If PQ agreed by Sponsor, preparation of Contract	CRO	**1 – 2 weeks**
5.Contract comments	Sponsor	**2 – 4 weeks**
5.1 TIDS available to CRO	Sponsor	**1 – 2 weeks after PQ/Contract approval**
5.2 TIDS comments by CRO	CRO	**1 week**
5.3 Preparation and internal approval of Application for Ethical Approval (EA)	CRO	**1 week after TIDS is completed**
6. Application for Ethical Approval assessment	State Authority (Ministry of Health)	**12 weeks from the submission**
6.1 Preparation of SP and discussion with Sponsor	CRO/Sponsor	**2 – 4 weeks**
6.2 Request for test system	CRO	**Rodents: 6 – 12 weeks** **Non-rodents 3 - 8 months before planned study start, usually just after Contract is approved**
6.3 Test item delivery	Sponsor	**1 - 2 weeks before planned study start**
7. Study performance	CRO	**Start as soon as possible after getting Ethical Approval, duration depends on study type**
8. Audited Draft Report submission	CRO	**Within 4 – 12 weeks (depending on study type)**
8.1. Sponsor comments and discussion	Sponsor/CRO	**Preferably as soon as possible**
9. Submission of Final Report	CRO	**2 weeks after Sponsor approved the Draft Report**

MEDITOX

per aspera ad astra

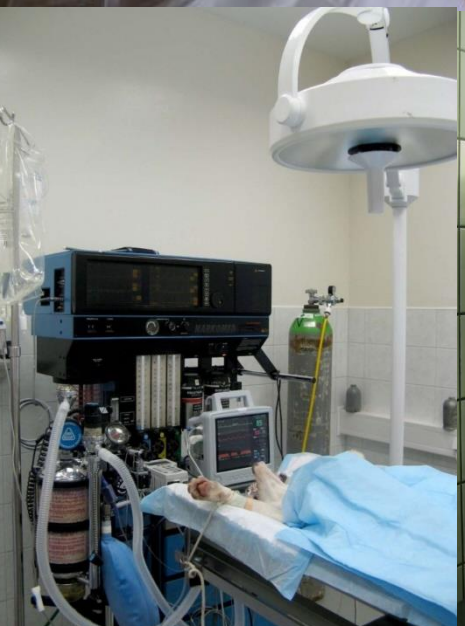
MEDITOX

per aspera ad astra

MEDITOX

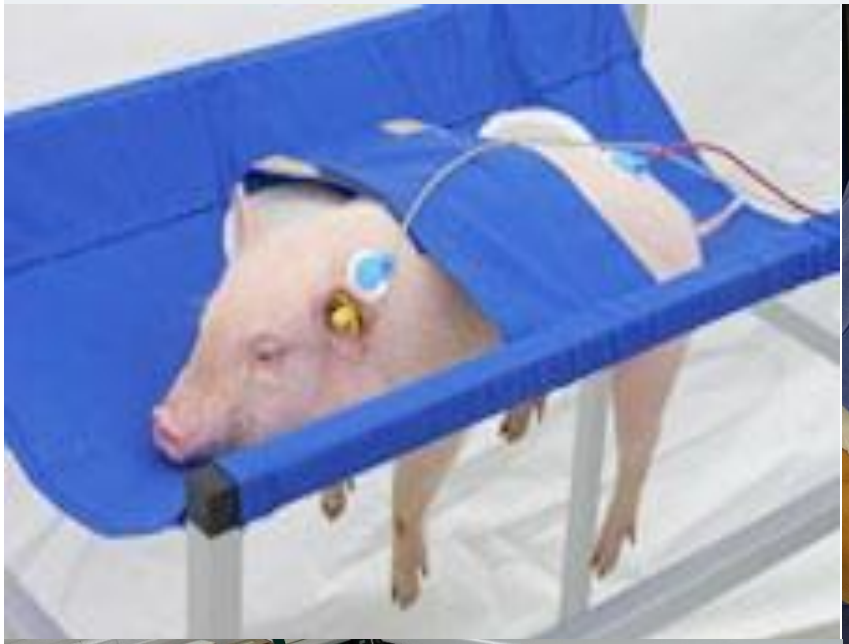
per aspera ad astra

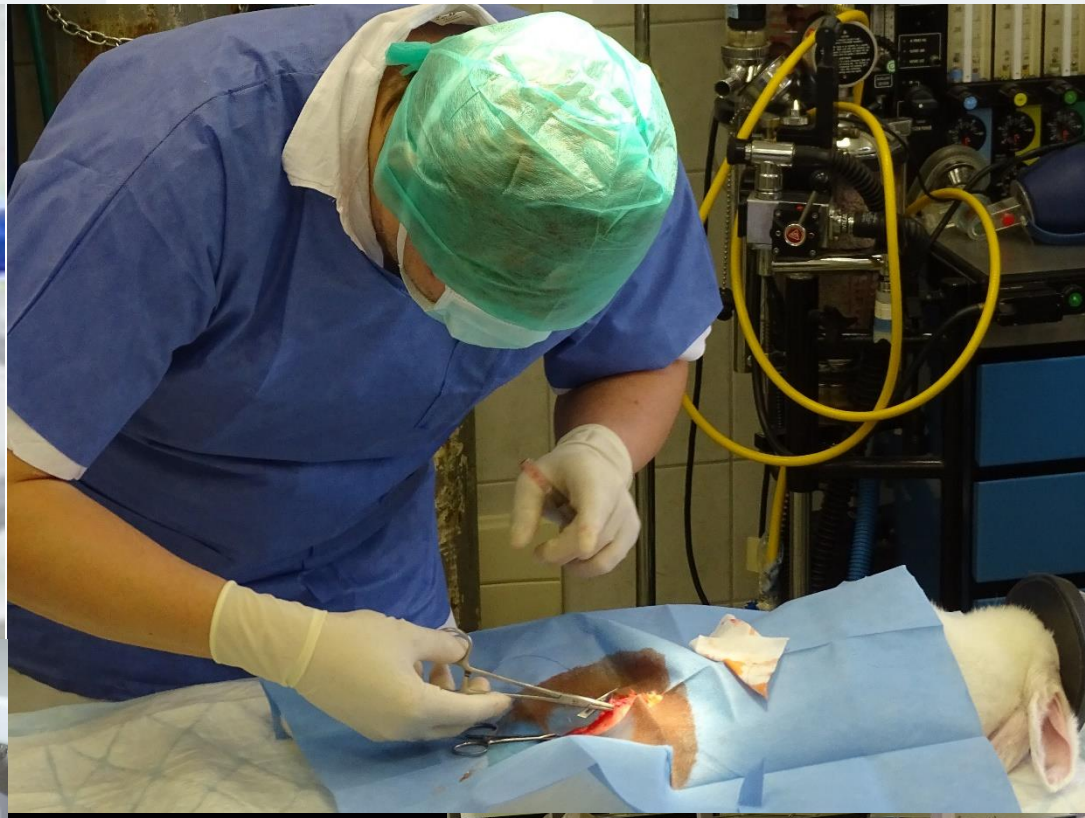


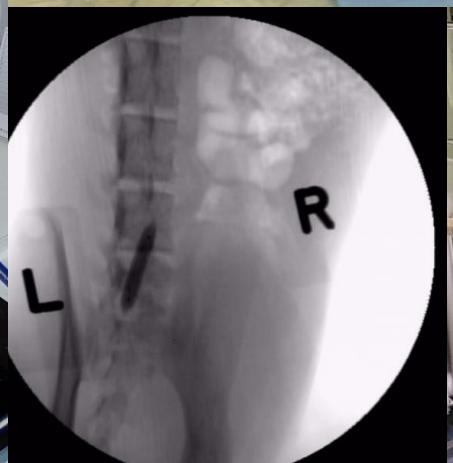




MediTox

per aspera ad astra

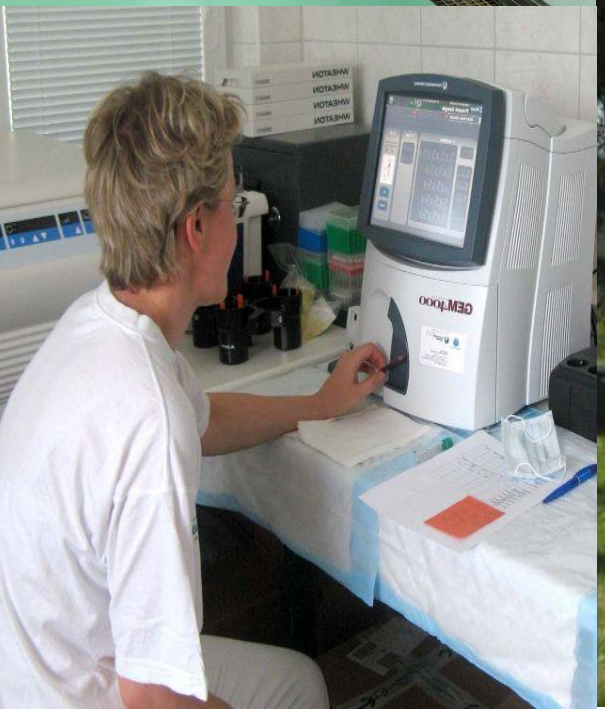






MEDITOX

per aspera ad astra



per aspera ad astra

GLP Certificate holder

MEDITOX

PRECLINICAL RESEARCH AND DEVELOPMENT

COMPREHENSIVE PRECLINICAL TOXICOLOGICAL PROGRAM

ANIMAL MODELS OF SELECTED HUMAN DISEASES

ACCREDITED BREEDING FACILITY FOR LABORATORY ANIMALS

www.meditox.eu

CARDIOLOGY DISEASES

HUNTINGTON´S DISEASE MODEL

DIABETES / OBESITY MODEL

OPHTHALMOLOGY DISEASES

Thank you for attention