

GLP Certificate holder

MEDITOX

MEDITOX
since April 2013 new name of
Bio Test

www.meditox.eu

PRECLINICAL RESEARCH AND DEVELOPMENT

cardiology, diabetes, neurology,
vaccines, ophthalmology

COMPREHENSIVE PRECLINICAL TOXICOLOGICAL PROGRAM

human and veterinary drugs, biological,
medical devices, REACH

ANIMAL MODELS OF SELECTED HUMAN DISEASES

CVS, neurodegenerative, ophthalmic, diabetes



ACCREDITED BREEDING FACILITY FOR LABORATORY ANIMALS

non-human primates, dogs, rodents



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www.meditox.eu



CARDIOLOGY DISEASES

HUNTINGTON'S DISEASE MODEL

DIABETES / OBESITY MODEL

OPHTHALMOLOGY DISEASES

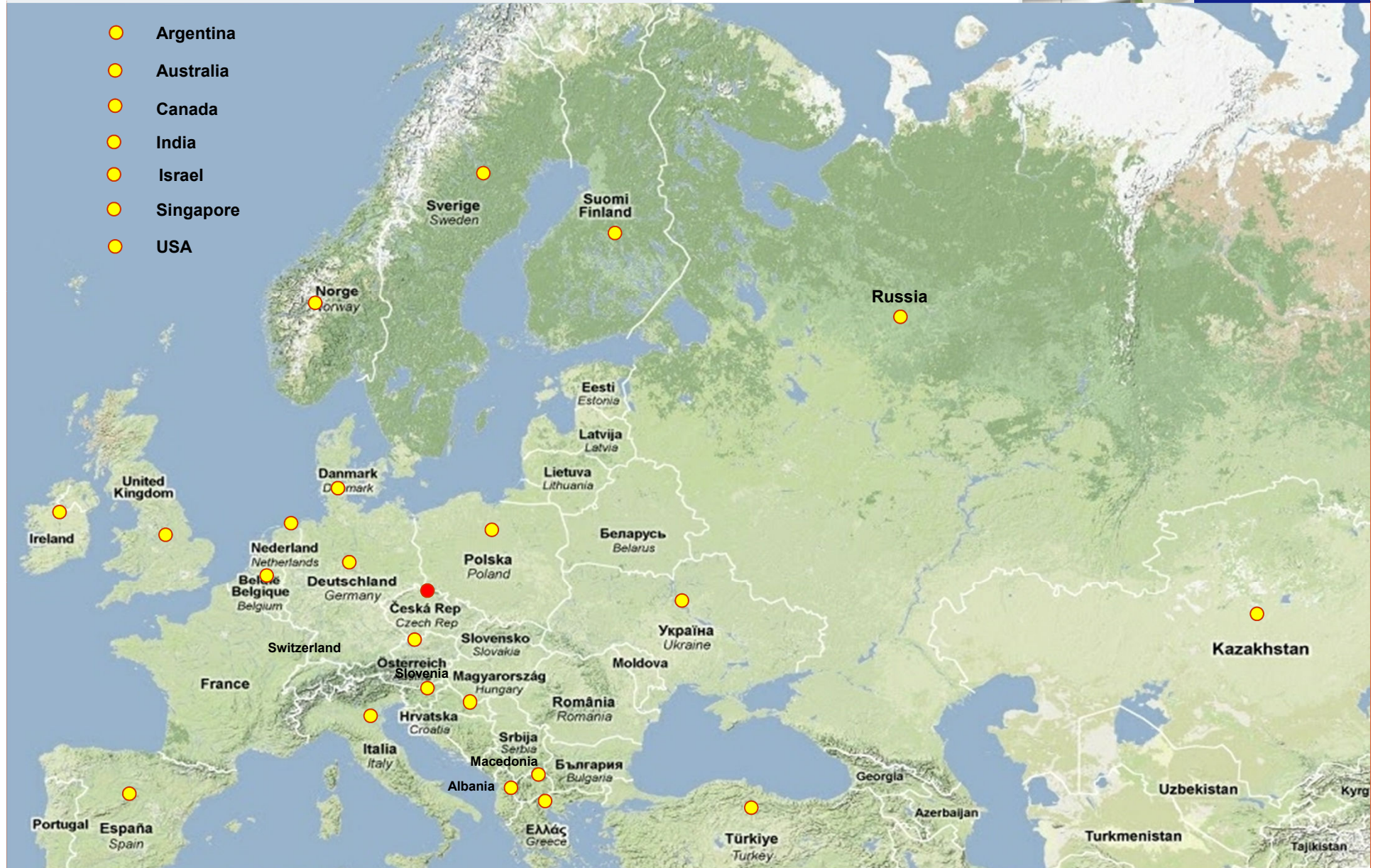


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per aspera ad astra



- Argentina
- Australia
- Canada
- India
- Israel
- Singapore
- USA





History

1951: Research Institute for Pharmacy and Biochemistry, Prague
250 drugs (29 original substances)
Pelentan, Kebuzon, Dosulepin, Metipranolol
Full chain of drug development

1999: Privatization and splitting off RIPB into several private companies - BioTest s.r.o. (branch of pre-clinical toxicology)

April 1, 2013: Change the brand to MediTox s.r.o.

www.meditox.eu



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MediTox celebrates **15 years** since its founding in 2014.

We would like to thank all our partners and clients around the world as well as all of employees who, through hard work and motivation contribute to the continuing development of the company. Let us wish the company a lot of achievements and many satisfied clients in the following years.



Main activities

Preclinical R&D

Cardiovascular disorders, diabetes, preclinical vaccine development
neurodegenerative diseases, ophthalmic diseases

Comprehensive toxicological program

Human & veterinary pharmaceuticals/biological, food additives, medical
devices (PHARM) chemicals & agrochemicals (REACH)

Animal models of selected human diseases

Experimental IM, glaucoma, diabetes type II, chronic SCI, arthrosis

Laboratory animal breeding

Non-human primates, dogs, rodents

Certification

Good Laboratory Practice Certificate OECD GLP

[C(97)186 Final] Pharmaceuticals, medical devices and food additives
(PHARMA)

Good Laboratory Practice Certificate OECD GLP [C(97)186 Final]

Chemicals, agrochemicals (REACH)

Authorization for Using of Experimental Animals

The Central Committee for Animal Protection of the Ministry of Agriculture

Authorization for Breeding of Experimental Animals

The Central Committee for Animal Protection of the Ministry of Agriculture

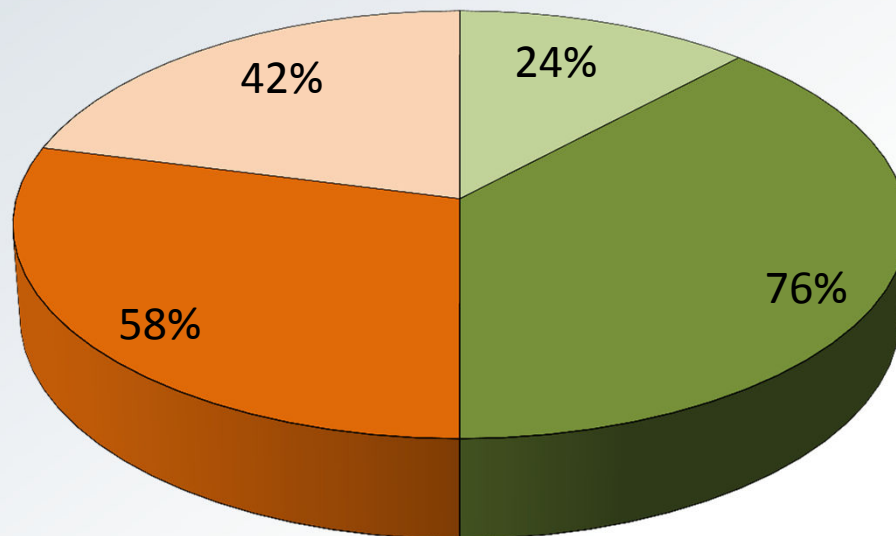
Approval for handling with GMO in compliance with Act

No. 153/2000 Coll.



Summary information

Structure of experimental work



■ R&D activities

■ Contract-based activities

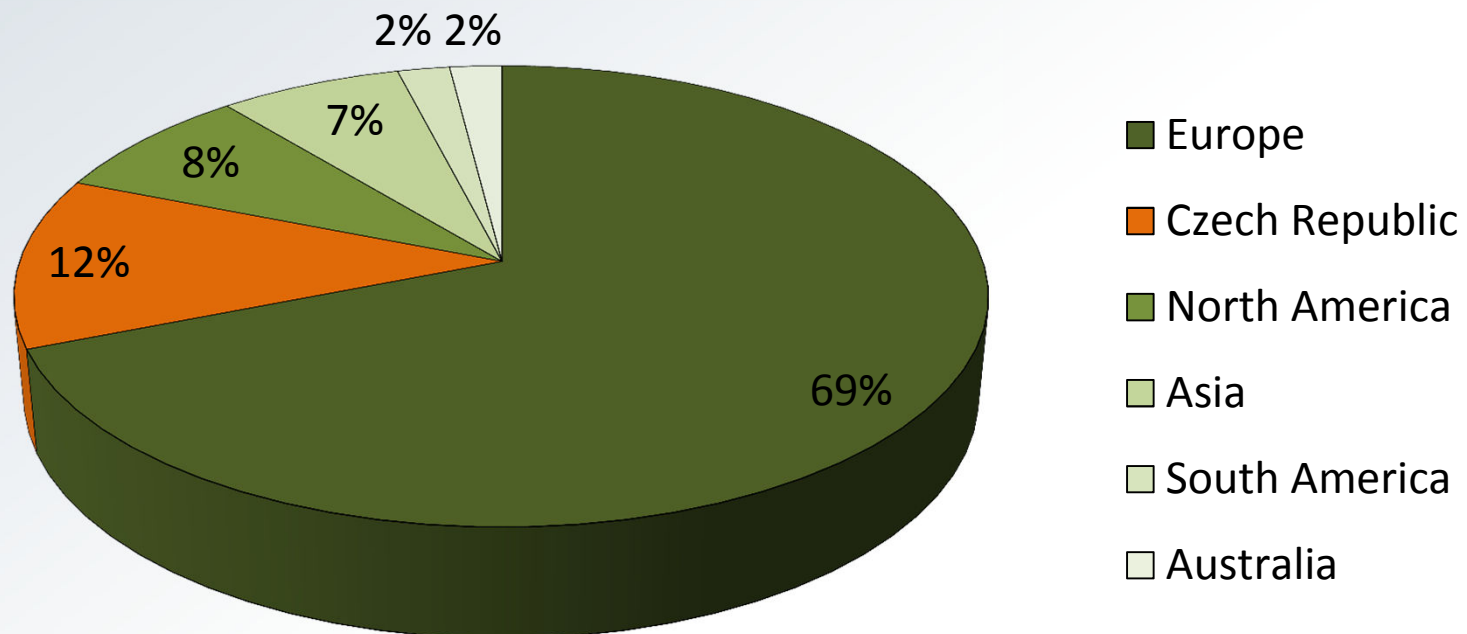
■ GLP-compliant

■ Non-GLP



Summary information

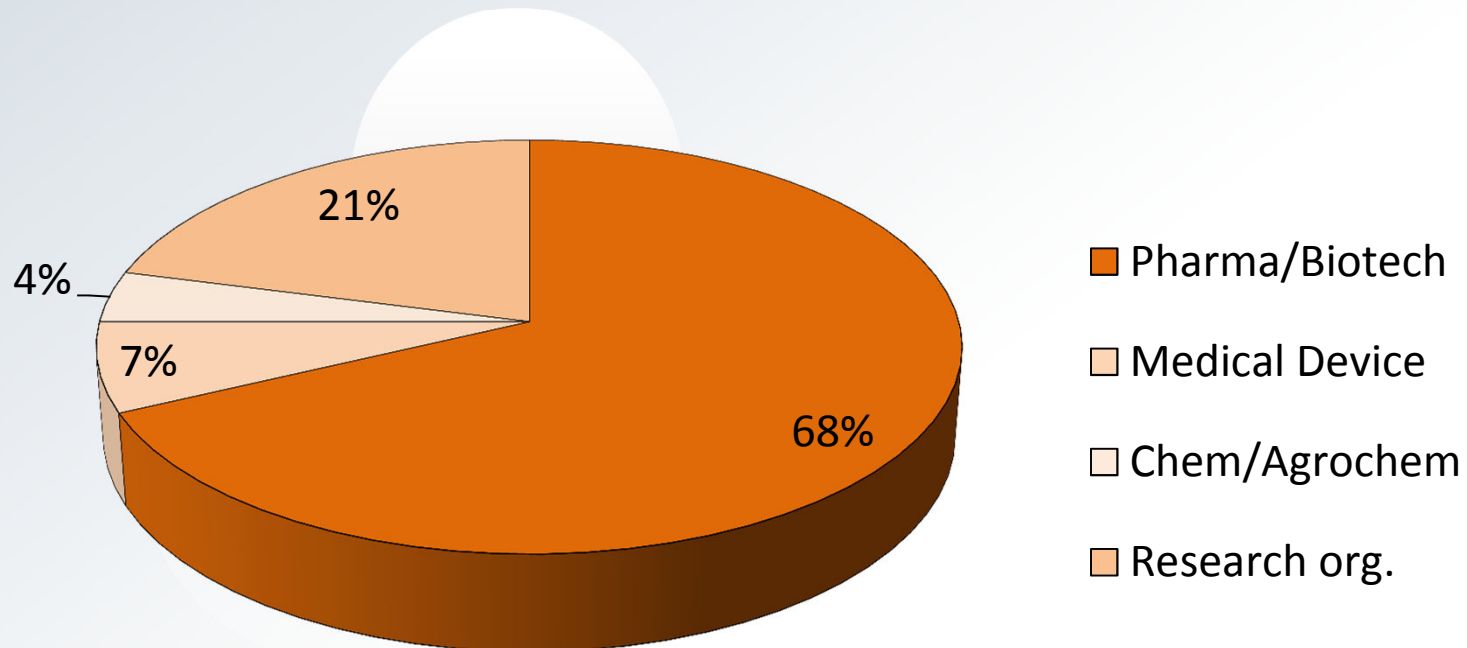
Structure of clients





Summary information

Structure of clients





Selected R&D projects - international

FLUVAC

Live attenuated replication-defective influenza vaccine

Austria (AGBT), Germany, Russia, Slovenia, Czech Republic

ANTIFLU

Innovative anti-influenza drugs excluding viral escape

Denmark, France, Germany (MPI), Hungary, Israel, United Kingdom, Czech Republic

OSTEOGROW

Novel morphogenetic protein-6 biocompatible carrier device

Austria, Bosnia and Herzegovina, Croatia (UZ), Czech Republic, Sweden

MOTIF

Micorbicide optimization through innovative formulation for vaginal and rectal delivery

Czech Republic, France, Italy, United Kingdom (KCL)

HELICOVAXOR

Development of an oral Helicobacter Pylori vaccine

Belgium, Czech Republic, France, Switzerland, United Kingdom (ICL)

Selected R&D projects - international

UNIVAC

**A „Universal“ influenza vaccine though synthetic,
dendritic cell-targeted, self-replicating RNA Vaccines**

Czech Republic, Finland, France, Germany, Norway, Russia, UK, Switzerland

MuleVaClin

**Clinical studies on a multivalent vaccine for human visceral
leishmaniasis**

Czech Republic, Italy, Spain, Switzerland



R&D projects under preparation

Horizon 2020

RESCUE

A new therapy against alcohol use disorders

Czech Republic, France, Italy, Switzerland

Vacc2020

Development of scalable manufacturing processes and GMP manufacture for non-replicating vaccine vectors of simian adenovirus and poxvirus origin carrying synthetic pathogen-derived transgenes

Czech Republic, Germany, United Kingdom (Oxford Univ), USA



Selected R&D projects - national

ODDC

Original Drug Development Center

IOCB AS CR, ICT, IEM AS CR, Institut of Physiology AS CR, Apigenex s.r.o., MediTox s.r.o., Quinta-Analytica s.r.o.

BIOMEDTEST

Biomedical models of traumatic spinal cord injury and neurodegenerative diseases in miniature pigs for testing of new therapeutic approaches

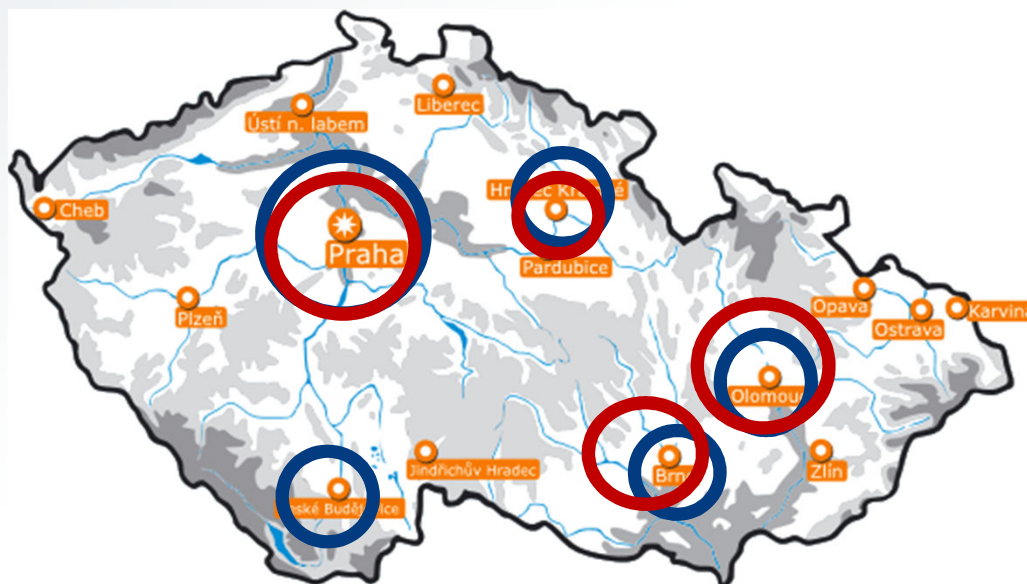
Institut of Animal Physiology & Genetics AS CR, MediTox s.r.o.



Collaboration within professional associations

CzechBio Association of Czech biotech companies

MedChemBio Cluster of Medicinal Chemistry and Chemical Biology





Participation in professional events

CPHI/ICSE 2014 (St. Petersburg, Russia , April 16 – 17, 2014)

IATI BioMed 2014 (Tel Aviv, Israel, May 20 – 22, 2014)

BIO International Convention 2014 (San Diego, USA, June 23 – 26, 2014)

CPHI/ICSE South America 2014 (Sao Paulo, Brazil , August 5 – 7, 2014)

CPHI/ICSE Worldwide 2014 (Paris, France, October 7 – 9, 2014)

BIO-Europe 2014 (Frankfurt, Germany, November 10 – 11, 2014)



Contract-based experimental services

Pre-clinical evaluation of biotech-derived products

rodents, non-rodents

Non-clinical implantation studies

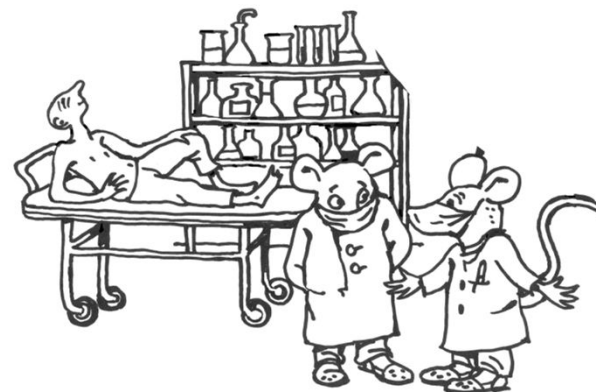
rodents, non-rodents

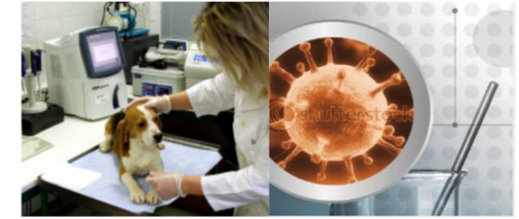
Biocompatibility and irritability & sensitization

rodents, non-rodents

Local tolerance studies (dermal,

rodents, non-rodents





Contract-based experimental services

Genetic toxicology & cytotoxicity

in vitro (bacteria, mammalian cells), *in vivo* (rodents)

General toxicology

rodents, non-rodents

Non-clinical safety

rodents, non-rodents

Safety Pharmacology, CVS

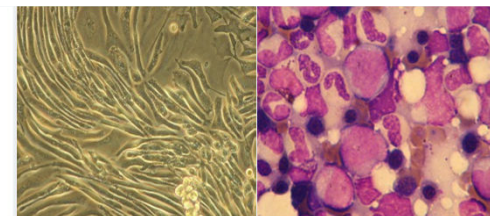
dogs

Immunogenicity/Immunotoxicity

rodents, non-rodents

**Non-clinical evaluation
of anticancer pharmaceuticals**

rodents, non-rodents



Contract-based experimental services

Toxicity to reproduction

Rodents

Screening reproduction toxicity

Prenatal developmental toxicity

One- and two-generation toxicity

Combined reproduction/toxicity studies

Carcinogenicity

Rodents

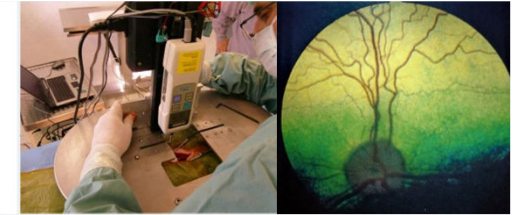
Carcinogenicity (including DRF)

Combined toxicity/carcinogenicity studies

Biodistribution studies

Rodents, non-rodents

Non-radiolabeled compounds



Animal models of selected human diseases

Diabetes (type II - non-human primates, type I – rats)

Chronic glaucoma (dogs)

Experimental myocardial infarct (dogs, minipigs)

Chronic traumatic spinal cord injury (minipigs)

Acute contact dermatitis (minipigs)

Influenza model (ferrets)



Models under development

Diabetes (dogs, mini pigs)

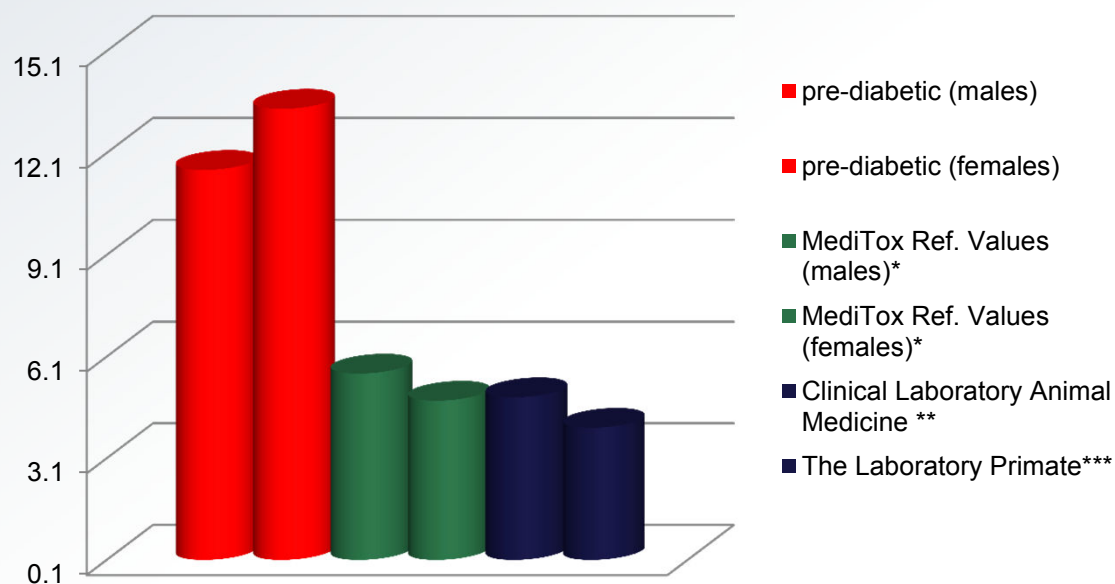
Arthritis (rats)

Enterocolitis (rats)



Experimental model of diabetes, rhesus monkeys

- Most common in older, obese animals
- Period of obesity-associated insulin resistance initially with compensatory insulin secretion
- Pathological changes in pancreatic islets similar to those seen in human
- Changes in plasma lipid and lipoprotein concentrations and lipoprotein composition

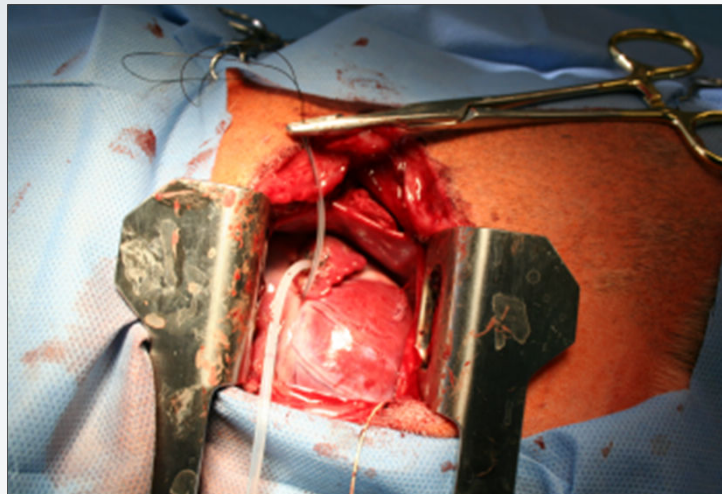




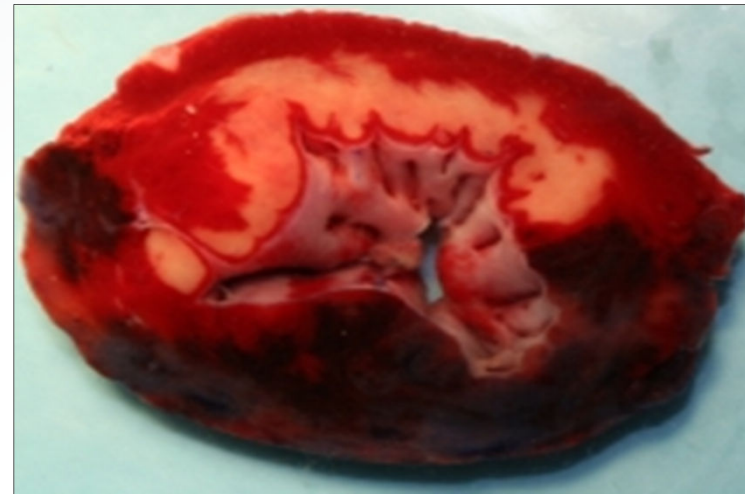
Experimental model of myocardial infarction, dog

- Left ventricular dysfunction induced by by ligation of the left coronary artery (myocardial ischemia) followed by heart reperfusion.
- Morphometric analysis of area at risk and area of infarction performed using Coomassie blue

Arteria coronaria occlusion
90-minute ischemia following 5-hour re-perfusion

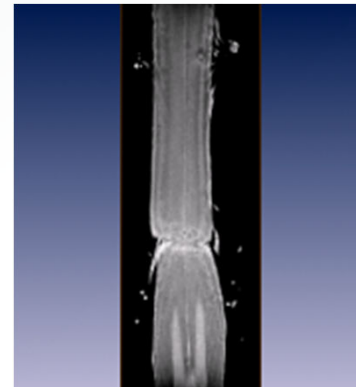
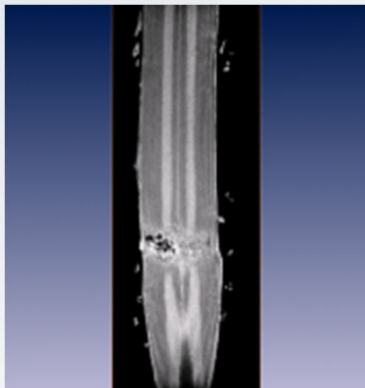


Myocardial section (Coomassie blue injected into *arteria coronaria*):
Dark blue – intact myocardium
Red – ischemia zone
White - infarctation zone



Chronic traumatic spinal cord injury model, pig

- Computer-managed device providing **strictly repeatable spinal cord injury**, either in the **thoracic** or **lumbal** region
- All essential reflexes (feeding, urination and defecation) preserved
- Long lasting survival of paraplegic animals





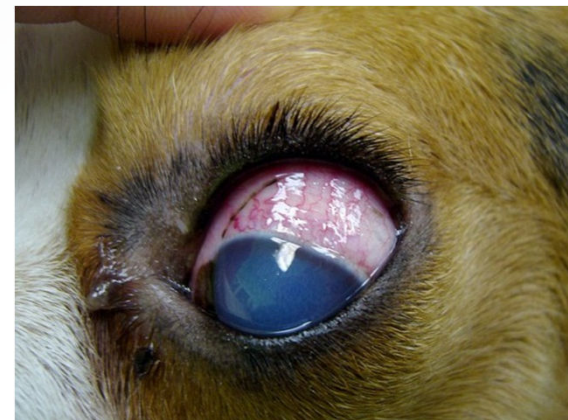
Experimental chronic glaucoma, dogs

„More than 70 million people worldwide suffer from glaucoma. Glaucoma is leading cause of blindness.“

Induced by intraocular injection of chymotrypsine

Revealing characteristic clinical signs

- elevation of IOP
- corneal opacity
- dilated episcleral blood vessels at the corneal edge
- reduced or absent pupillary reflex
- uveitis.





Ferret model for safety and efficacy of influenza therapy

Ferrets (*Mustela putoria*) emulate numerous clinical features associated with human disease; this is especially the case with regard to influenza

Clinical and clinical laboratory features shared by humans and ferret model following virus infection

- Fever
- Nasal secretion
- Coughing
- Serum abnormalities
- Weight loss and/or anorexia
- Lethargy
- Lymphopenia
- Transmission to susceptible contacts
- Hypercytokinemia
- Distribution of sialic acid in respiratory tract





Breeding of laboratory animals

Rodents

Rats (Wistar:Han, SPF quality)

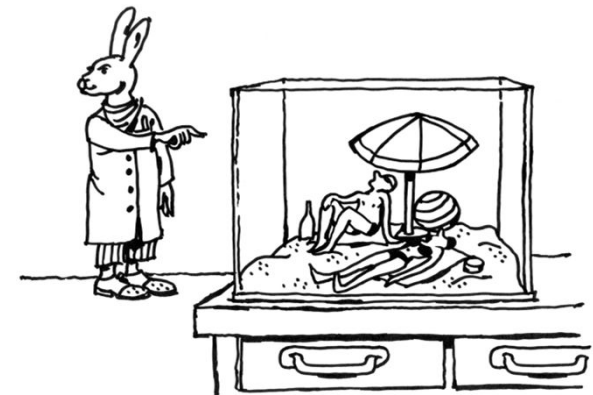
Mice (NMRI, SPF quality)

Guinea pigs (*Cavia aperea f. porcellus*, monitored quality)

Non-rodents

Rhesus macaques (*Macaca mulatta*, monitored quality)

Beagle dogs (monitored quality)



References

AGINKO AG, Switzerland

Amega Biotech, Argentina

Apeiron Biologics, Austria

Baxter Biosciences, Austria

BIOVET, Belgium

Dechra Veterinary Products, UK

Fusion Pharm, Russia

Gelesis Inc., USA

HUVE Pharma, Belgium

Immune System Key, Israel

JSC Pharmstandard, Russia

King's College London, UK

KRKA, Croatia

Lesaffre, France

Lupin Pharma, India

Mabion, Poland

Max-Planck Inst. of Inf. Biol. Germany

Midatech, Switzerland

NovoNordisk, Denmark

OCT Clinical Trials, USA

Oncos Therapeutics, Finland

Panacea Biotech, India

Pharmathen, Greece

Sanofi Group (Zentiva)

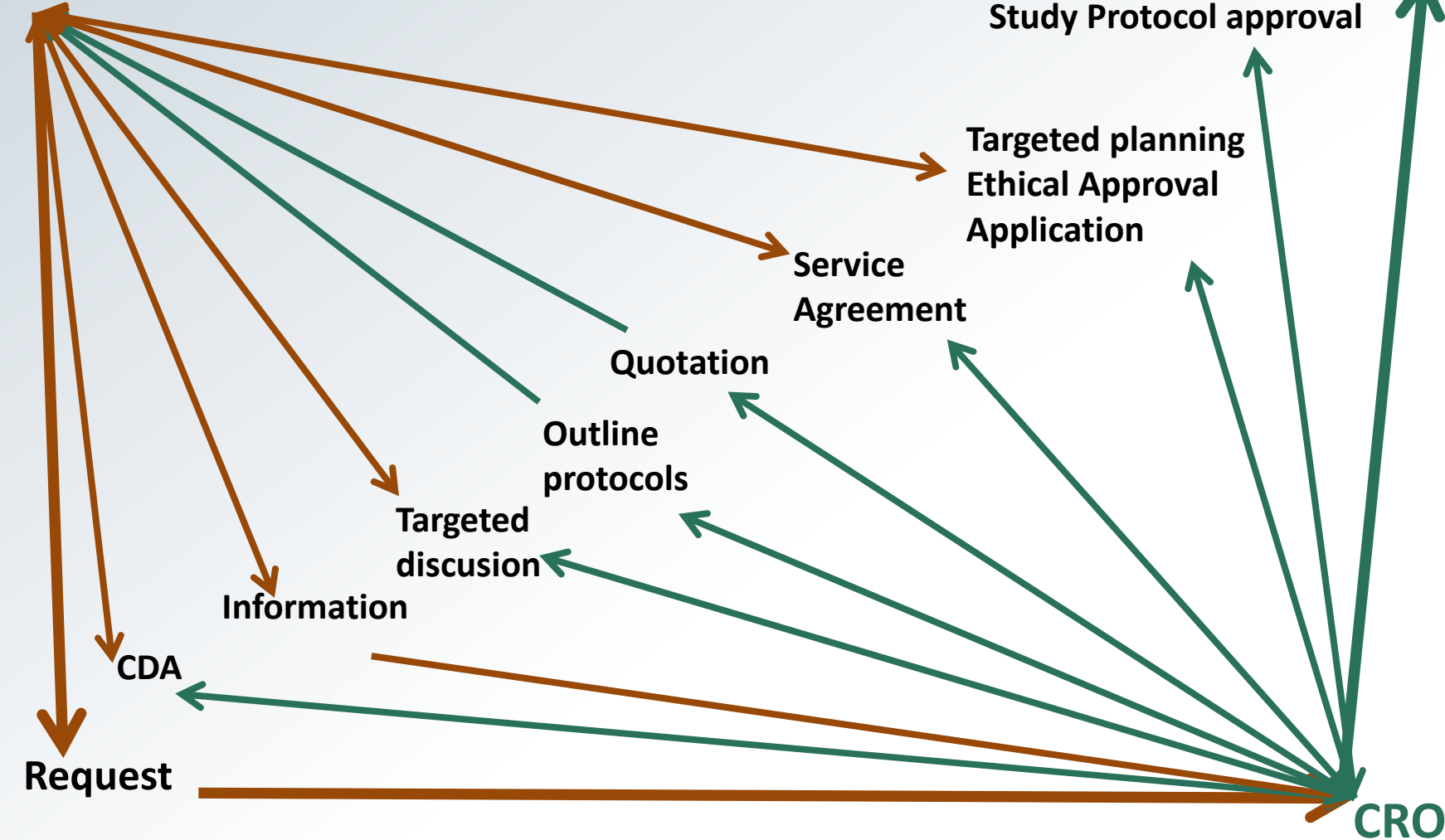
Sun Pharmaceuticals, India

Vetcare Oy, Finland and more...

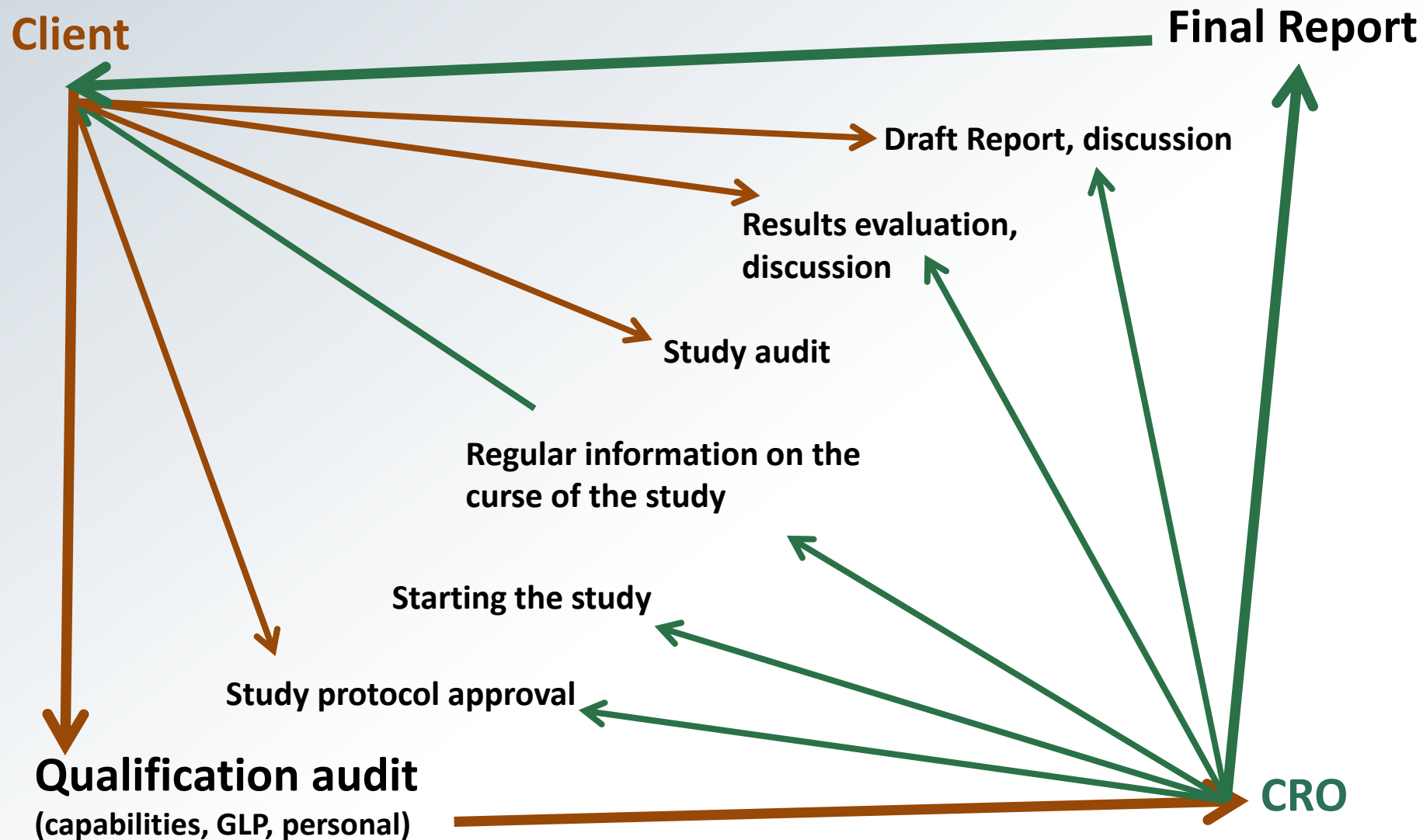
Communication chart

Start of the study

Client



Sequence of events during the project



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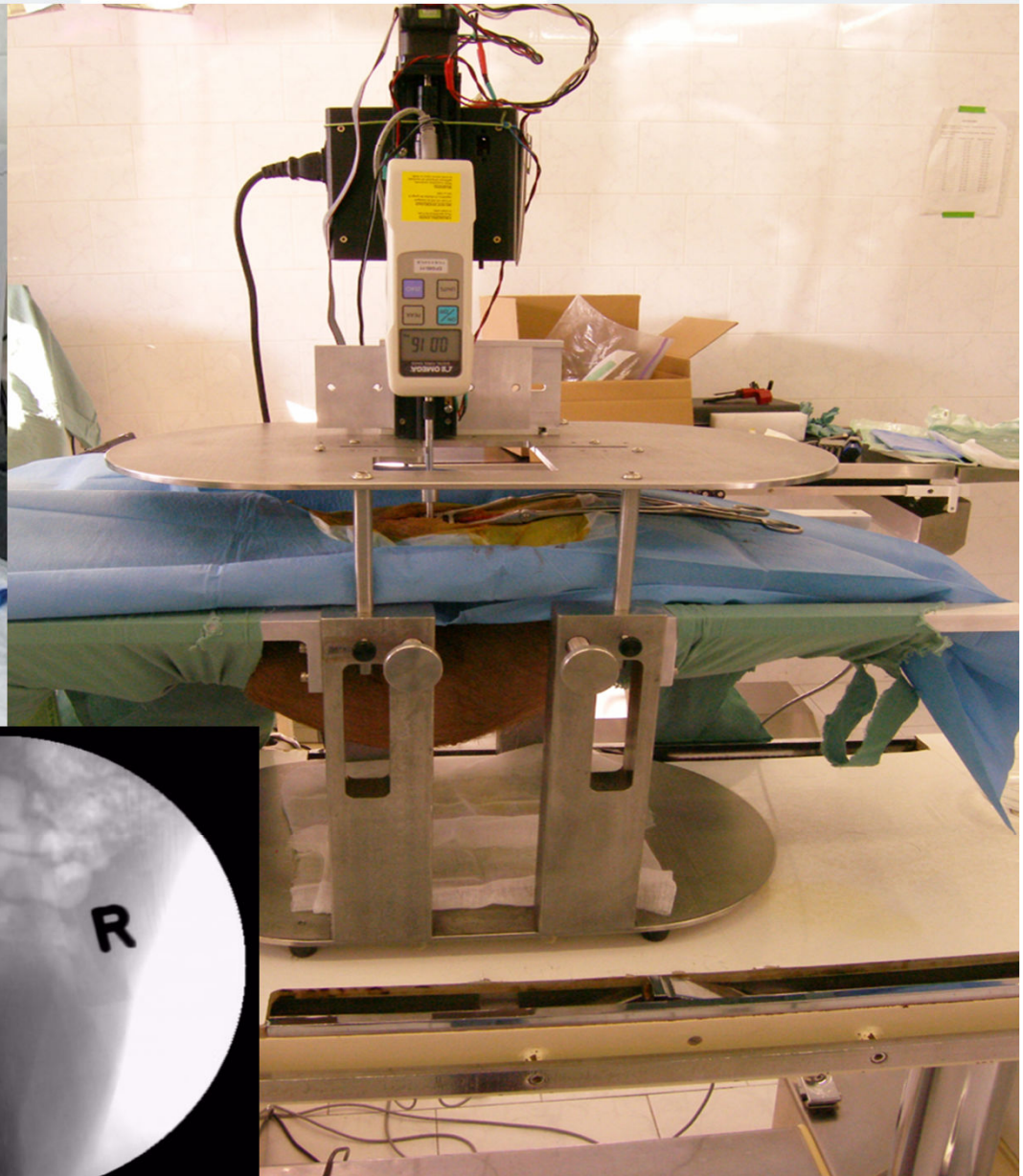
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Celebrate with us the 15-year anniversary

MEDITOX

15 years

5 %

We decided to donate **5%** of each order in 2014 for support of projects of your choice:

- a) support preclinical development by 5% price reduction
- b) support social projects (Médecins Sans Frontières (MSF), SOS Children's Villages, Hospital Clowns) by contribution of 5% of the order sum.

Let us know your choice.



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