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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

MediTox s.r.o.
Czech Republic
e-mail: surova@meditox.eu
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CARDIOLOGY DISEASES

HUNTINGTON´S DISEASE MODEL

DIABETES / OBESITY MODEL

OPHTHALMOLOGY DISEASES

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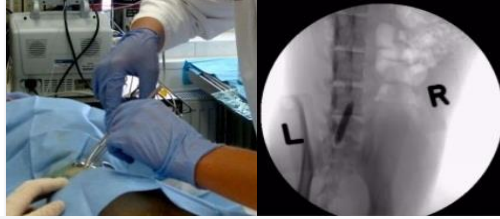
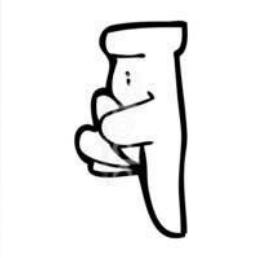


Do you know what is the main goal of preclinical toxicology?

No, it is not to prove your drug candidate/product is safe

A major objective of preclinical toxicology is to provide appropriate information for a compound to proceed safely through clinical trials to registration.



…You are inventing; we are able to move your thoughts in the right direction.
Let´s work together…

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

Sverige
Sweden
Suomi
Finland
Norge
Eesti
Estonia
Latvija
Russia
Lietuva
Lithuania
Danmark
Denmark
United
Kingdom
Ireland
Беларусь
Belarus
Nederland
Netherlands
Polska
Poland
Belgique
Belgium
Deutschland
Germany
Česká Rep
Czech Rep
Slovensko
Slovakia
Україна
Ukraine
Switzerland
Österreich
Slovenia
Moldova
Kazakhstan
France
Magyarország
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România
Romania
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Croatia
Srbija
Serbia
Italia
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Türkiye
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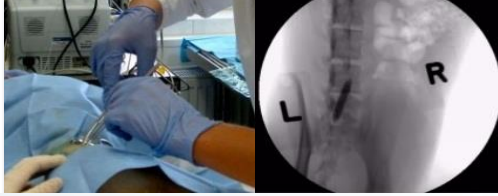

Main actvities

Comprehensive preclinical toxicological program

Human & veterinary drugs/biological, vaccines, medical device, food/feed additives

Preclinical R&D

Participation in scinetific project focused on vaccine development and regenerative medcicine (international and national grant projects)

Animal models of selected human diseases

Chronic glaucoma, influenza, osteoarthrosis, wound healing, contacts dermatitis, colitis, NASH

Laboratory animal breeding

Non-human primates, dogs

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.

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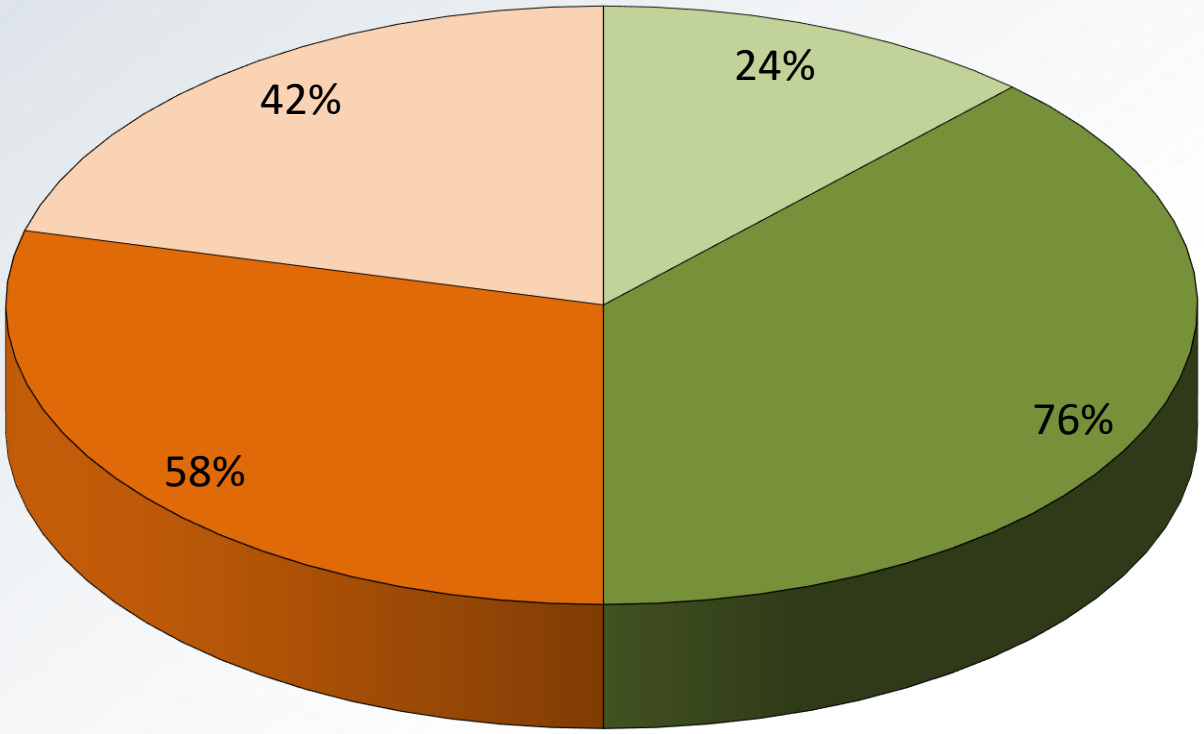
Summary information

Structure of exprimental work



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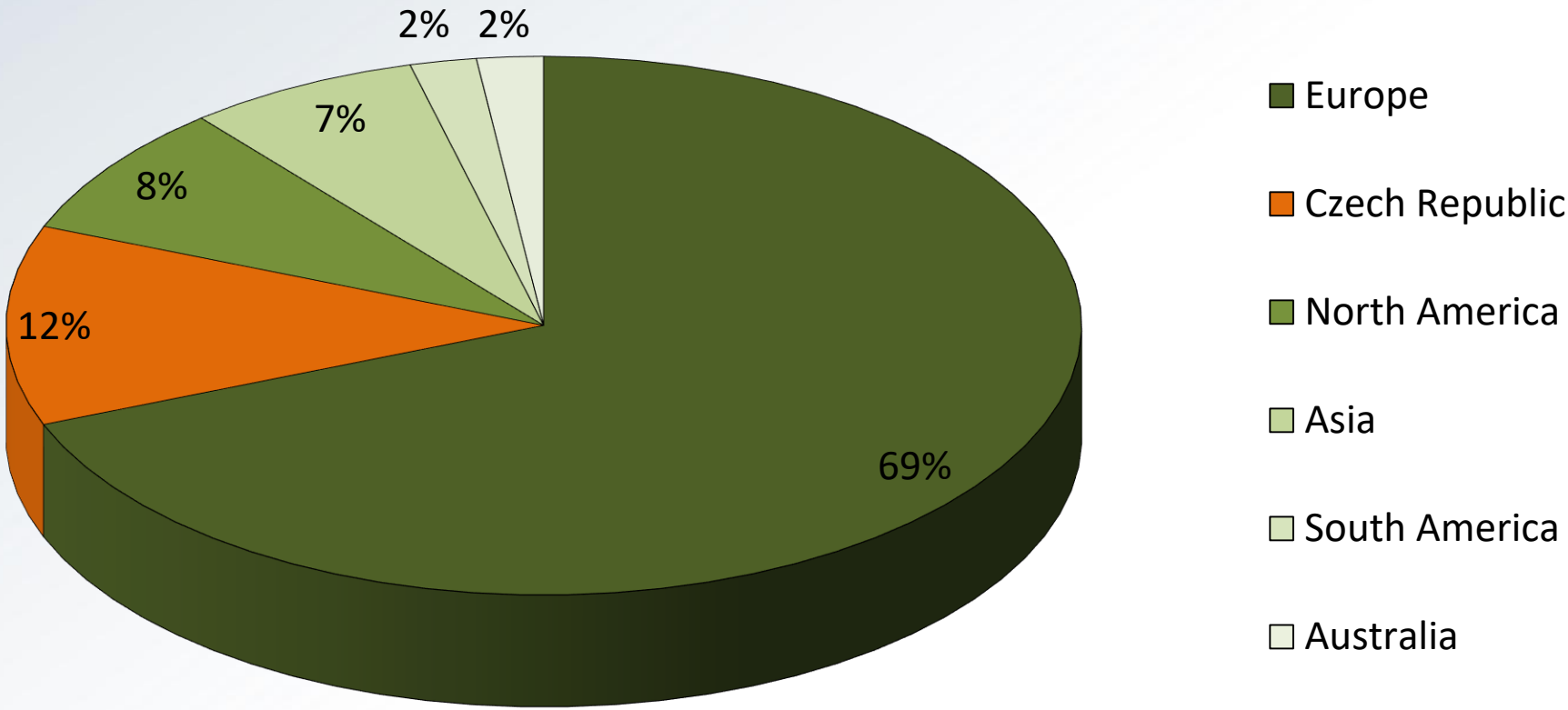
Summary information

Structure of clients



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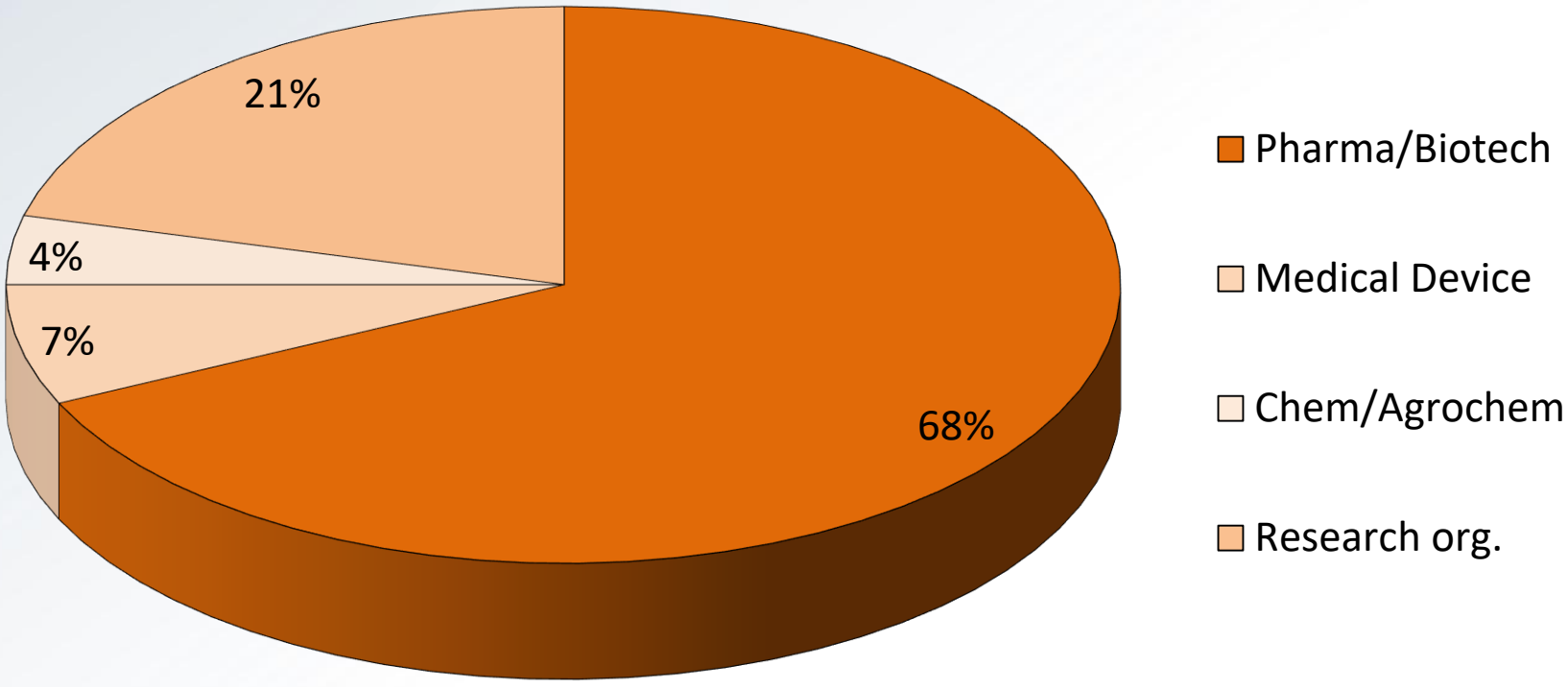
Summary information

Structure of clients



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Selected R&D projects

EUIMMUnCoV: **The European Immunotherapy Platform against 2019-NCOV**

Horizon 2020, **SC1-PHE-CORONAVIRUS-2020,**
Austria, Czech Republic, Denmark, Italy

FLUVAC **Live attenuated replication-defective influenza vaccine**

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

ANTIFLU **Innovative anti-influenza drugs exluding 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)

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Contract-based experimental services

Study type	Guideline	Test system
Genetic toxicology & cytotoxicity	ICH, OECD, FDA, ISO 10993	*In vitro*
General toxicology (acute, sub-chronic, chronic)	ICH, OECD, FDA	Rodents, non-rodents
Safety Pharmacology (CNS, CVS)	ICH, FDA	Rats, dogs
Local effects (irritability, sensitization, implantation, local tolerance)	ICH, OECD, ISO 10993	Rodents, non-rodents
Non-clinical evaluation (anticancer pharmaceuticals, vaccines, biotech-derived products, fixed combinations, etc.)	ICH	Rodents, non-rodents)
PK, TK, BA, BEQ	ICH, OECD, VICH	Rodents, non.-rodents

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Contract-based experimental services

Study type	Guideline	Test system
Target animal safety studies	VICH	Non-rodents
Biocompatibility of medical devices	ISO 10993-1, 2, 3, 5, 6, 10, 11, 12	Rodents, non-rodents
Biodistribution studies (Non-radiolabeled compounds)	ICH, OECD	Rodents

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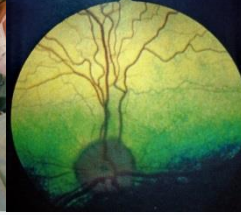


Dieases models

Chronic glaucoma (dogs)

Acute contact dermatitis (pigs)

Influenza model (ferrets)

Osteoarthrosis (guinea pigs, rabbits, dogs)

Diabetes (type II - non-human primates)

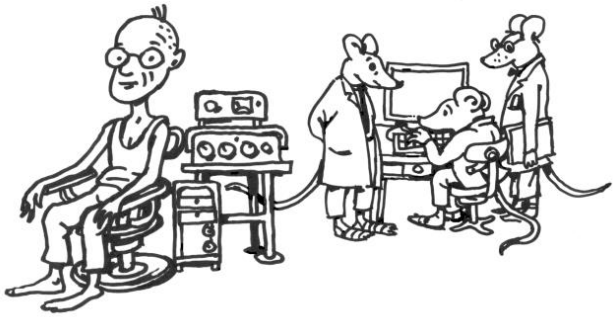
Models under development:

PhIP/DSS induced Colorectal cancer (mice)

Osteroarthrosis (rabbit)

Chronuc glaucoma (rabbit)

Colitis model (mice



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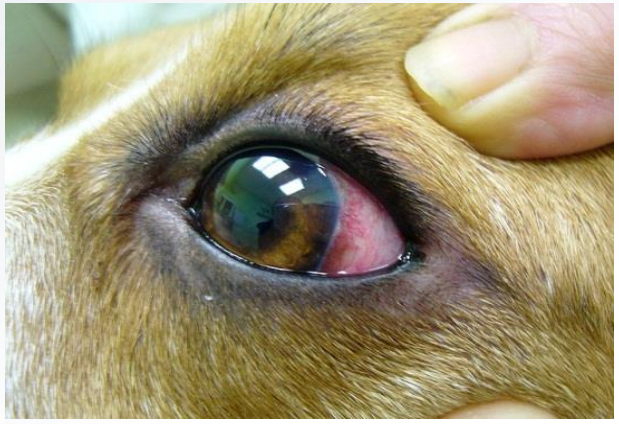
Experimental chronic glaucoma, dogs

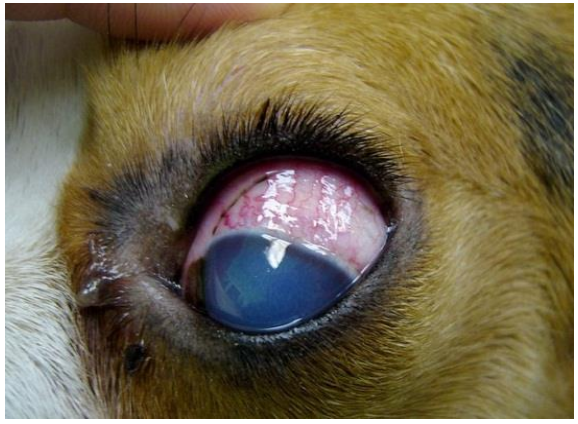
„More than 70 million people worldwide suffer from glaucoma. Glaukoma is leading cause of blindness.“

Induced by intraocular injection of chymotripsine

Revealing chracteristical clinical signs

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





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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 abnormalitires**
- **Weight loss and/or anorexia**
- **Lethargy**
- **Lymphopenia**
- **Transmission to susceptible contacts**
- **Hypercytokinemia**
- **Distribution of sialic acid in respiratory tract**

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References

Alzprotect, France
Amega Biotech, Argentina
BIOVET AD, Belgium
Celon Pharma, Poland
CONTIPRO a.s., CR
DECHRA, USA/UK
DelSiTech Ltd., Finland
EMS, Brazil
Evestra, Germany
Faraday, Inc., USA
FATRO, Italy
Immuneed, Sweden
Orexo, Sweden
Klifovet, Germany
KRKA, Slovenia
Lesaffre, France
Medicine Development, Australia
Mabion, Poland
NovoNordisk, Denmark
Olainfarm, Latvia
Oxford University, UK
Rotapharm, Italy
Sanofi Group (Zentiva)
Sunpharma, India
Triveritas, USA/UK
Vetcare Oy, Finland
Virbac, France

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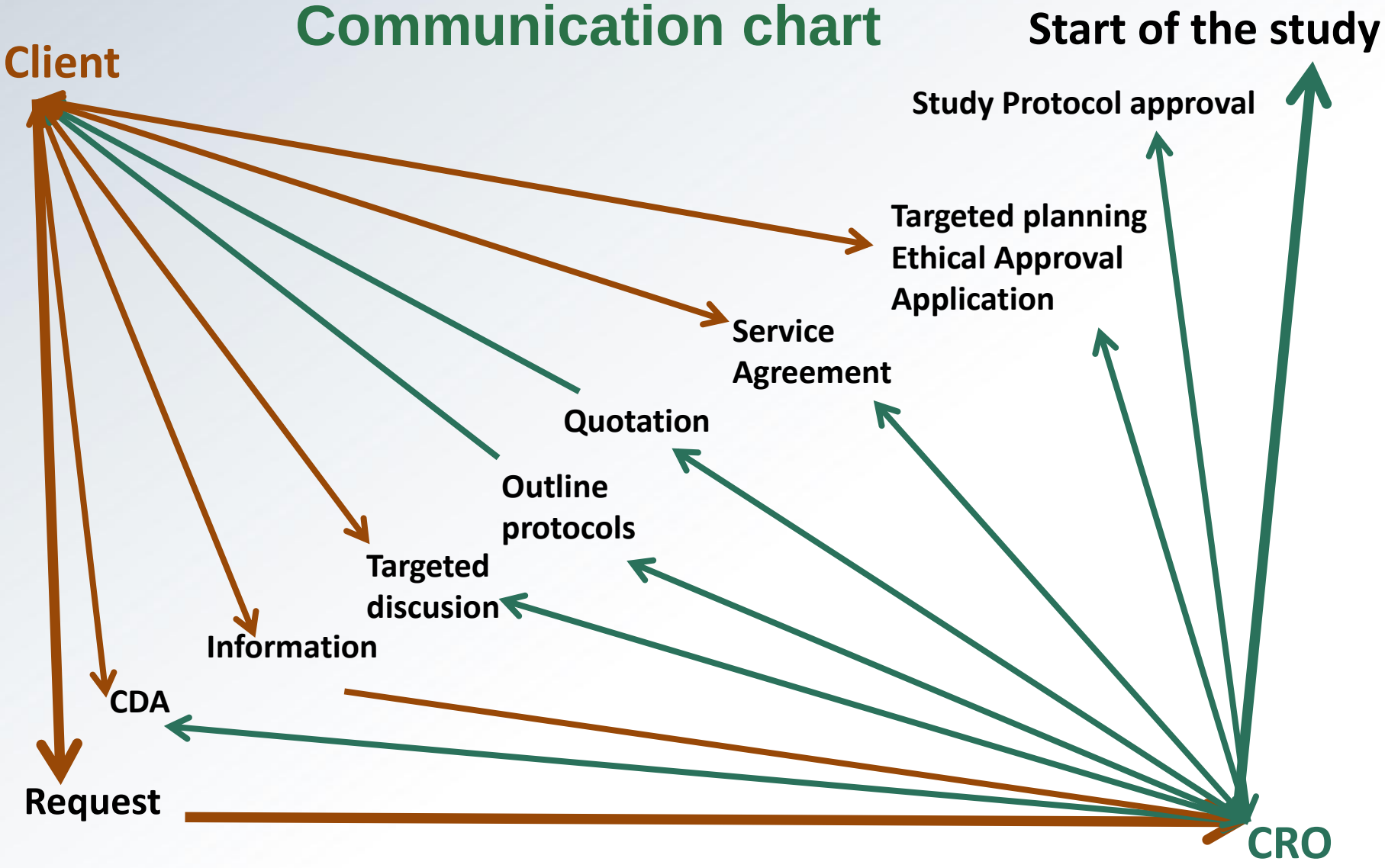
Communication chart



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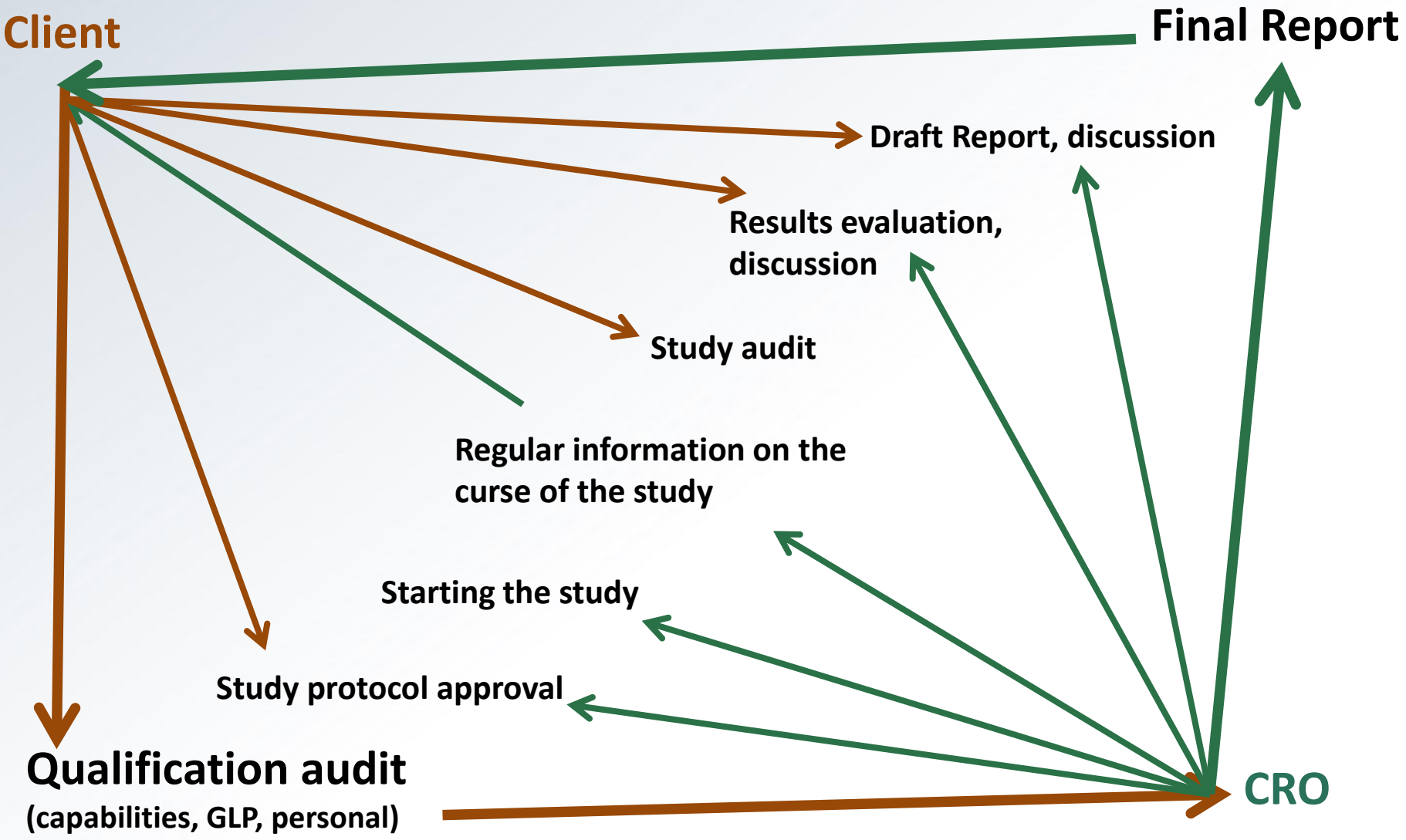
Sequence of events during the project



General service flow chart

Event	Responsibility	Approximate duration
1.RFQ	Sponsor	**N/A**
2.Proposal/Quotation	CRO	**3 – 7 days**
3.PQ assessment	Sponsor	**1 – 4 weeks, preferably as soon as possible**
4.If PQ agreed by Sponsor, preparation of Contract	CRO	**1 – 2 weeks**
5.Contract comments	Sponsor	**1 – 4 weeks, preferably as soon as possible**
5.1 TIDS available to CRO	Sponsor	**1 – 2 weeks, preferably as soon as possible after PQ/Contract approval**
5.2 TIDS comments by CRO	CRO	**3 - 5 days**
5.3 Preparation and internal approval of Application for Ethical Approval (EA)	CRO	**3 – 7 days after TIDS is completed**
6. Application for Ethical Approval assessment	State Authority (Ministry of Health)	**4 – 8 weeks (up to 40 working days), submissions are possible monthly**
6.1 Preparation of SP and discussion with Sponsor	CRO/Sponsor	**2 – 4 weeks (study plan prepared within EA approval period)**
6.2 Request for test system	CRO	**Rodents: 2 weeks - 2 months depending on strain Non-rodents 2 - 6 months Before planned start of the study, usually just after Contract is approved**
6.3 Test item delivery to the Test facility	Sponsor	**1 - 2 weeks before planned start of the study at the latest**
7. Performing of the study	CRO	**As soon as possible after getting Ethical Approval, duration depends on study type**
8. Audited Draft Report submission	CRO	**Within 4 - 8 weeks after the end of in-life phase of the study (depending on histopathology)**
8.1. Sponsor comments and discussion	Sponsor/CRO	**2 – 6 weeks**
9. Submission of Final Report	CRO	**1 – 2 weeks after Sponsor approved the Draft Report**

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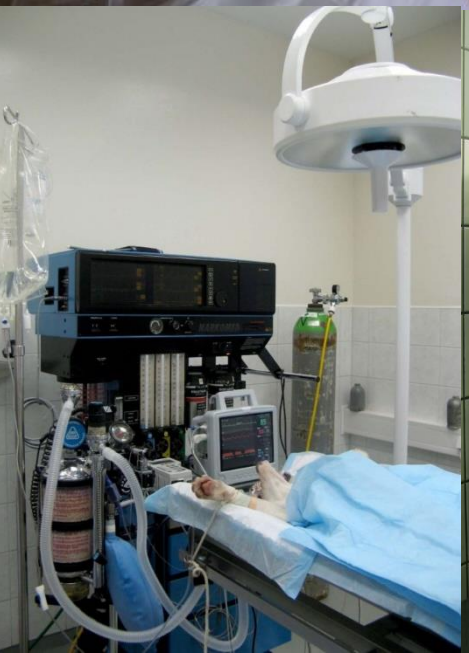

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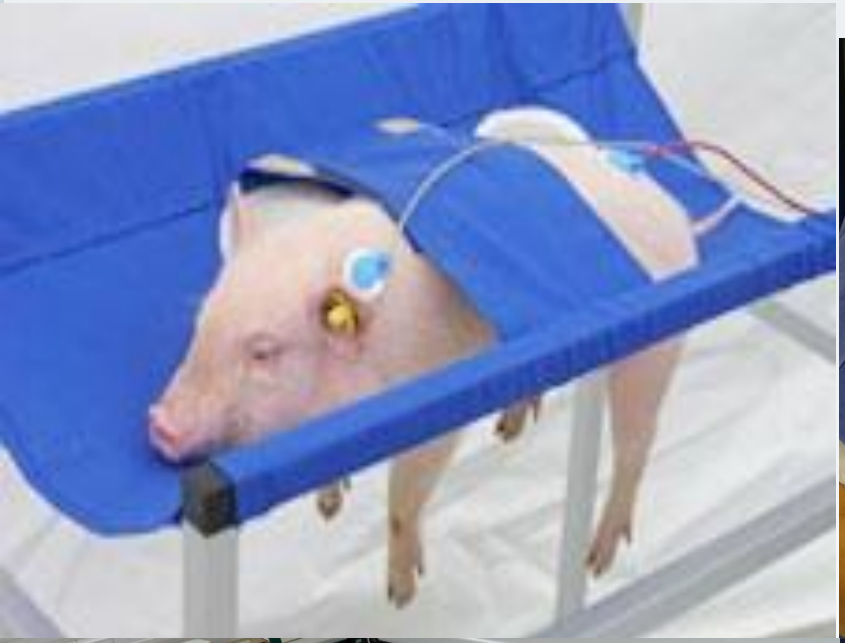

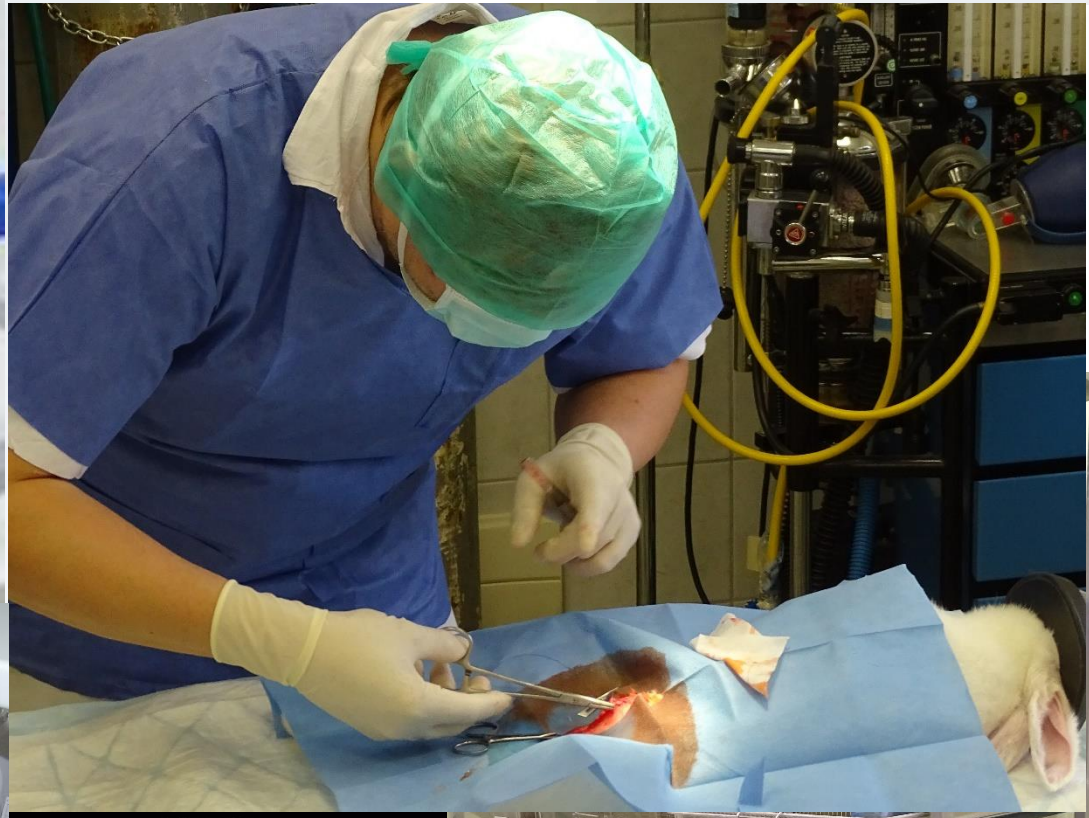

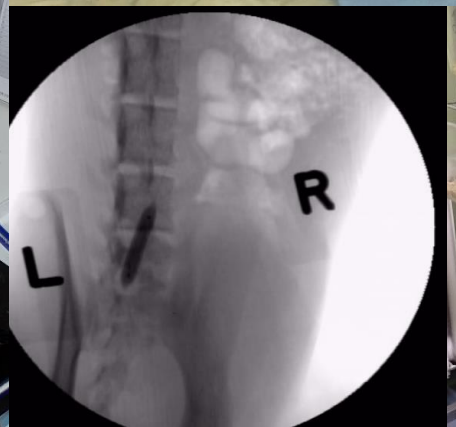

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