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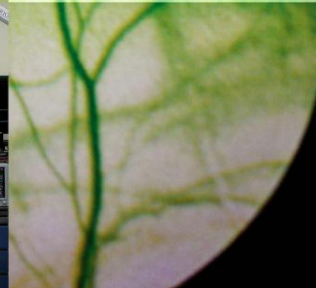
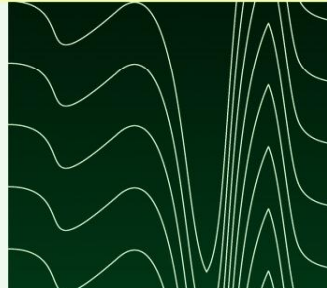
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■ **Pre-clinical research and development**
(CVS disorders, diabetes, anti-flu vaccines, oncology)

■ **Comprehensive toxicological service**
(human and veterinary pharmaceuticals, medical devices)

■ **Customized immunization and antibody production**

■ **Accredited breeding facility**
(macaques, dogs, ferrets, etc.)



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Huntington's diseases models

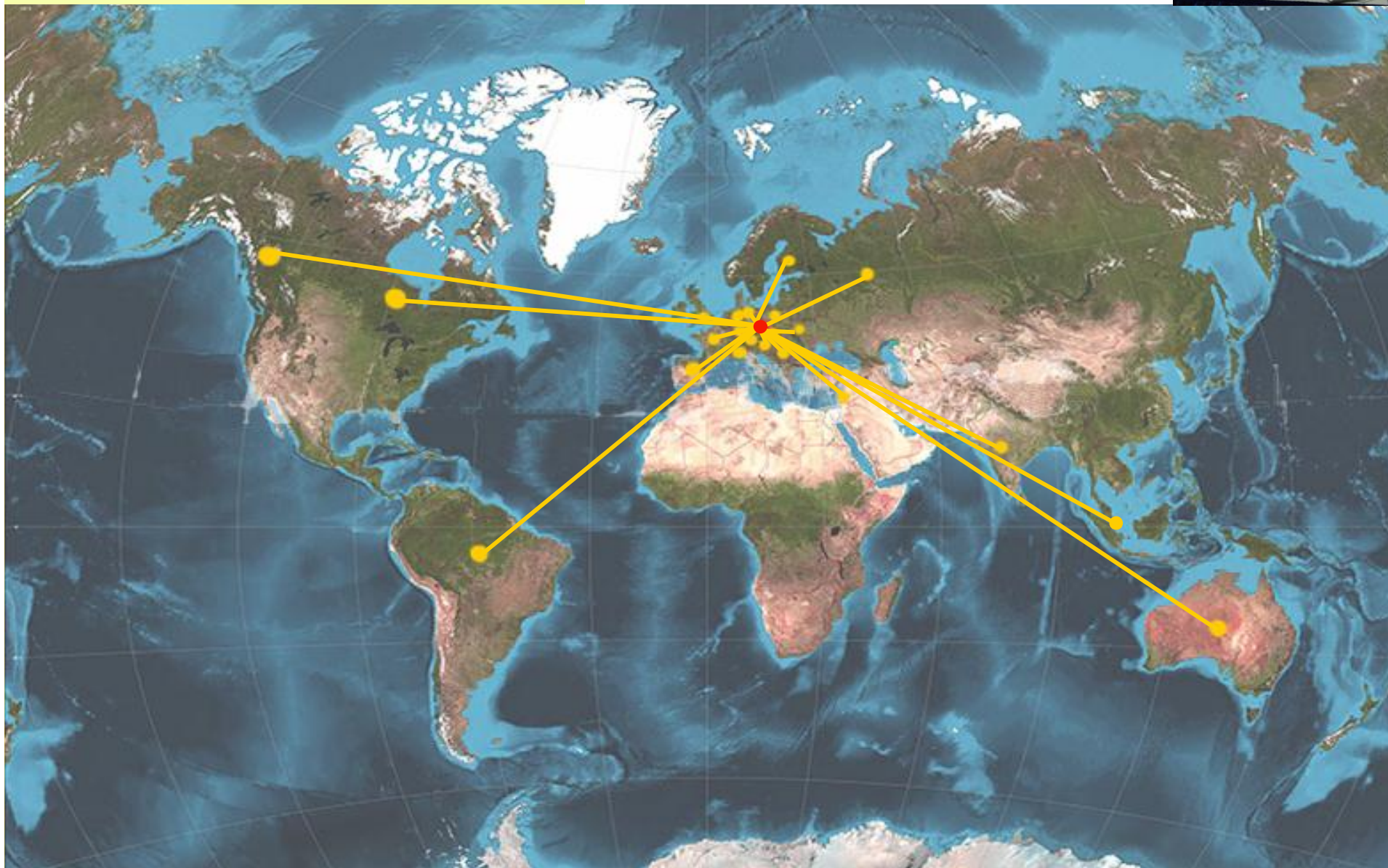
Hemodynamic laboratory

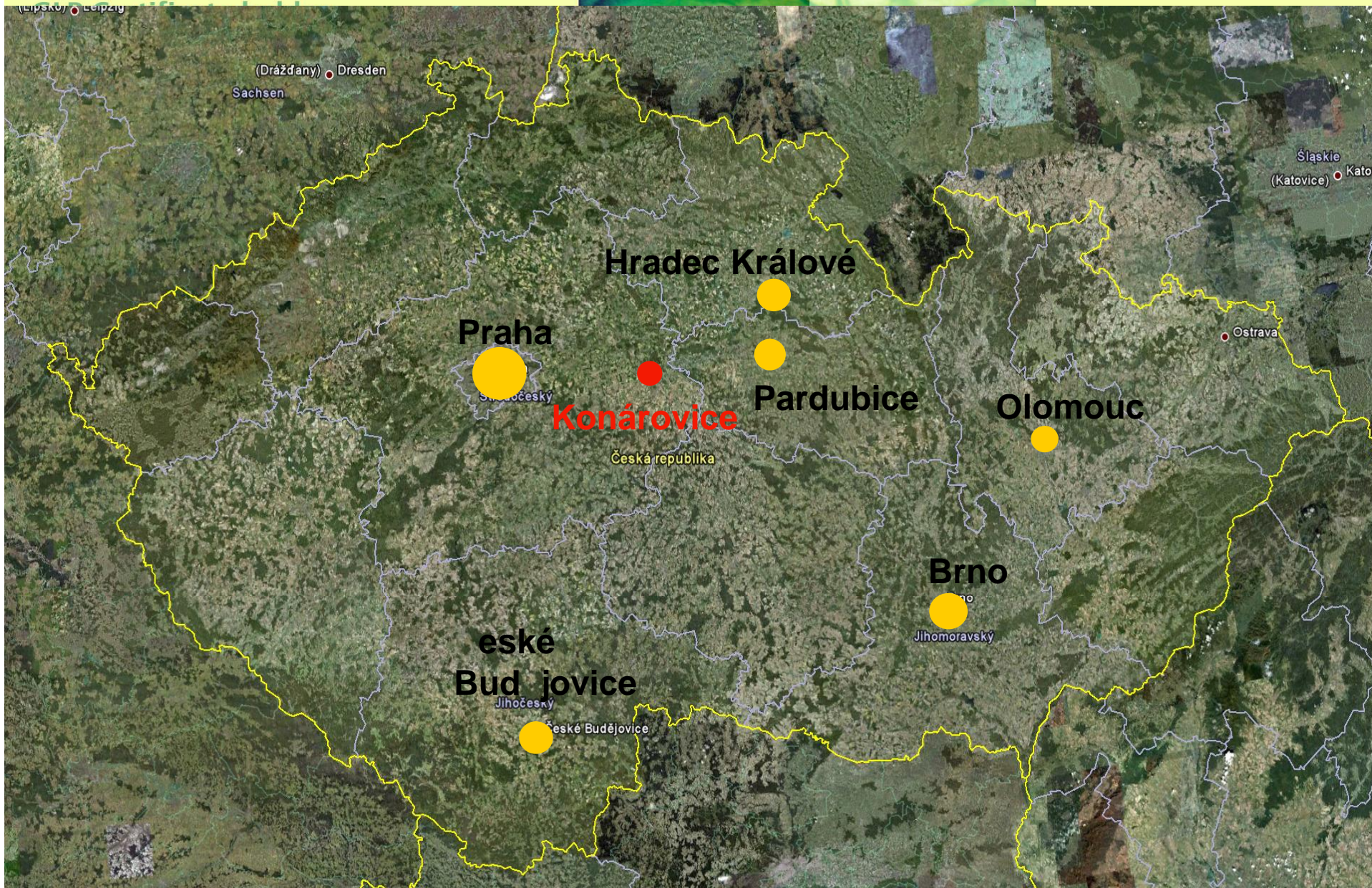
Hereditary melanoma model





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History

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



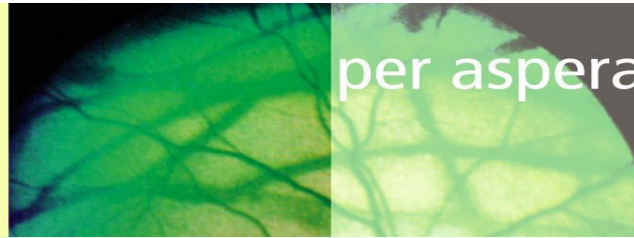
1999: Privatization and splitting off RIPB into several private companies

BioTest s.r.o. (branch of pre-clinical toxicology)

Quinta-Analytica s.r.o.

REaD VÚFB s.r.o.

VÚFB (Zentiva)



Main Activities

Preclinical R&D

Cardiovascular disorders, diabetes, oncology, antiinfluenza vaccines, neurodegenerative diseases

Comprehensive Toxicological Program (Pharma, REACH)

Human & veterinary pharmaceuticals/biologicals, chemicals & agrochemicals

Laboratory Animals Production

Non-human primates, dogs, ferrets, rodents

Certification

Good Laboratory Practice Certificate OECD GLP [C(97)186 Final]
Pharmaceuticals, medical devices and food additives

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 CR

Authorization for Breeding of Experimental Animals
The Central Committee for Animal Protection of the Ministry of Agriculture CR

Approval for handling with GMO
in compliance with Act No. 153/2000 Coll.

Summary Information

Structure of Experimental Work:

R&D activities:	25 %
Contract based activities:	75 %
GLP:	56 %
Non-GLP:	44 %

Staff Structure:

Total:	54
University:	16
High sch.:	14

Structure of Clients

Czech Republic:	10 %
Europe:	63 %
Asia:	11 %
North America:	11 %
Australia:	5 %

Pharma & Biotech:	72 %
Chem/Agrochem:	10 %
Research Org.	18 %



The best specialist are keen on to work with us



R&D: Approved Projects - international

Framework Program 6 and 7:

SARS/FLU VACCINE: Development of a combined influenza/SARS vaccine (Austria, Germany, Slovenia, Russia, Czech Republic)

CHIMERIC VACCINES: Development of Influenza deINS1 virus as a vector for foreign antigens (Austria, Germany, Slovenia, Russia, Czech Republic)

FLUVAC: Live attenuated replication-defective influenza vaccine (Austria, Germany, Russia, Slovenia, Czech Republic)

H5 VACCINE: Immunogenicity and protective efficacy of intranasal deINS1/H5N1 influenza vaccine (Austria, Germany, Russia, UK, Czech Republic)

ANTIFLU: Innovative anti-influenza drugs excluding viral escape (Denmark, France, Germany, Hungary, Israel, United Kingdom, Czech Republic)



R&D: Upcoming projects - international

OSTEOGROW: Novel bone morphogenetic protein-6 biocompatible carrier device for bone regeneration (Austria, Bosnia and Herzegovina, Croatia, Czech Republic, Sweden)

RENOPROTECT: Characterization of BMP1-3 structure, function and mechanism of action: Development of new regenerative tools for treating patients with a chronic kidney disease (Croatia, Czech Republic, Italy, Slovenia, Switzerland, United Kingdom)

NERVECONDUIT: Development of novel biofunctionalised nerve conduits for application in regenerative medicine (Czech Republic, Denmark, France, Greece, Poland, Slovenia, Spain, Switzerland, United Kingdom)

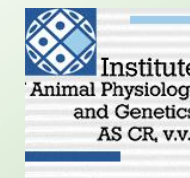
R&D: Approved Projects - national

Technology Agency of The Czech Republic:



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

(Instit of Animal Physiology & Genetics CAS, BioTest s.r.o.)



Collaboration within associations and clusters:

CzechBio Ě Association of Czech biotechnology companies



MedChemBio Cluster Ě Cluster of Medicinal Chemistry and Chemical Biology





R&D : Collaborative Advanced Projects

Experimental models of myocardial infarction (dogs)

Vascular re-stenosis (non human primates)

Liver ischemia/reperfusion injury (non human primates)

Diabetes model type I (rodents) and II (rhesus monkeys)

Hereditary melanoma model in miniature pigs (the MeLiM strain)*

Neurodegenerative diseases (Huntingdon´s diseases models in miniature pig)*

Chronic traumatic spinal cord injury and stem cell therapy model (miniature pig)*

* Projects conducted in cooperation with the Institute of Animal Physiology and Genetics CAS



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Experimental models of myocardial infarction (beagle dog)

The occurrence of left ventricular dysfunction shortly following the onset of a myocardial infarction is mimicked by ligation of the left coronary artery which producing myocardial ischemia followed by heart reperfusion.

At the end of reperfusion, morphometric analysis of area at risk and area of infarction was performed using computerized program and the infarct size was determined by the weight of infarct over the weight of area at risk.

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

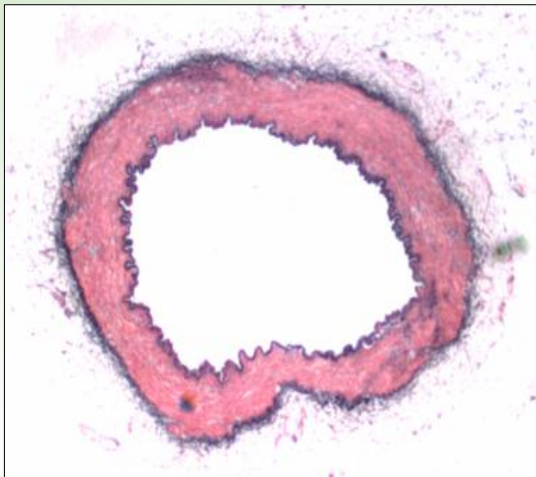


Myocardial section (Coomassie blue injected into *arteria coronaria*):
Dark blue . intact myocardium
Red . ischemia zone
White - infarctation zone



Vascular balloon injury model in rhesus monkeys

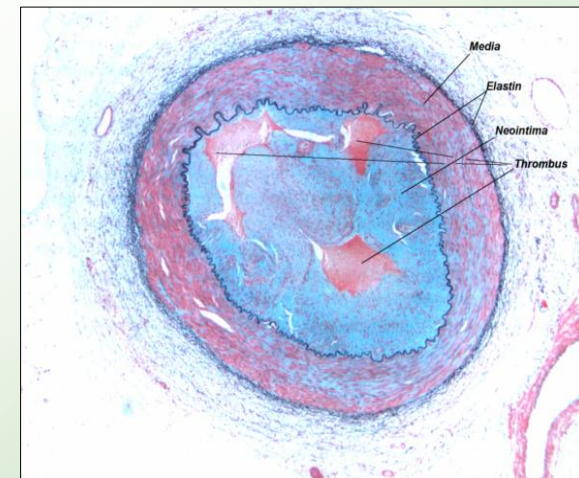
Balloon angioplasty is a common intervention for the treatment of blood vessel stenosis, particularly of the coronary vasculature. Similar procedure was used for repeated iliac artery occlusion. Inflated balloon causes significant trauma to the vascular endothelium, which is evidenced by an immediate loss of endothelial-dependent relaxation, and is itself associated with a concomitant induction of smooth muscle cell proliferation and neo-intima formation.



Non-injured iliac artery



The balloon catheter placement



Iliac artery after balloon injury

Hereditary melanoma model in miniature pigs (the MeLiM strain)



Melanomas are visually recognizable as black-pigmented lesions on the skin



Chronic traumatic spinal cord injury and stem cell therapy model, pig

Computer-managed device has been developed providing **strictly repeatable spinal cord injury**, either in the **thoracal** or **lumbal region**, allowing the long lasting survival of paraplegic animals.

All essential reflexes (feeding, urination and defecation) are in function, so no infectious complications exist under laboratory conditions

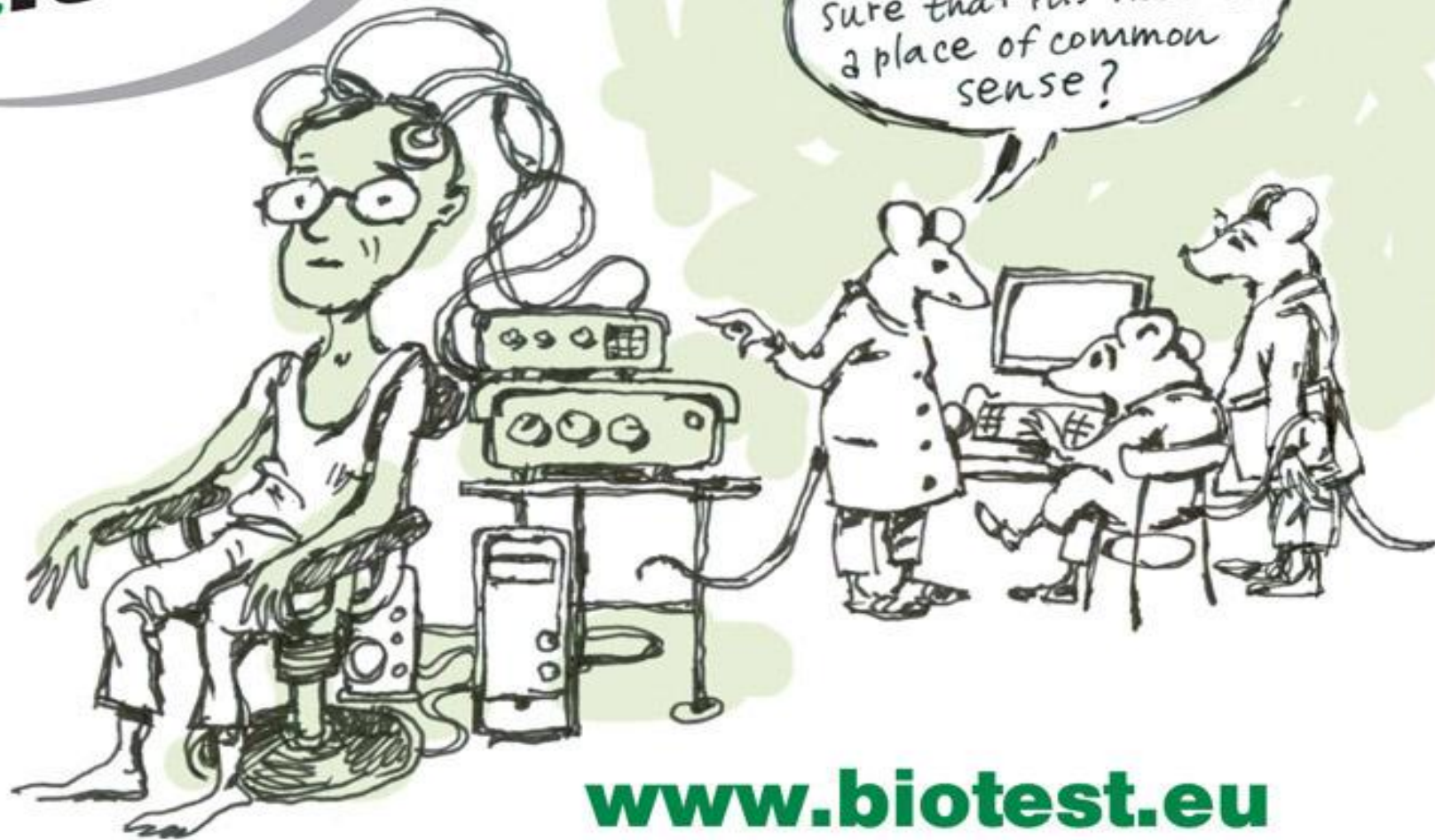
The model is ready to use for:

stem cell therapy

pharmacological approaches to a long-lasting treatment of paraplegia.



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Contract-based Experimental Services

General Toxicology & Pharmacology

Acute toxicity studies, rodents

Skin/Eye irritability, Skin sensitization, rabbits, guinea pigs

Sensitization (LLNA), mice

MTD/DRF studies, rodents, non rodents

Sub-acute, Sub-chronic and Chronic toxicity studies, rodents, non rodents

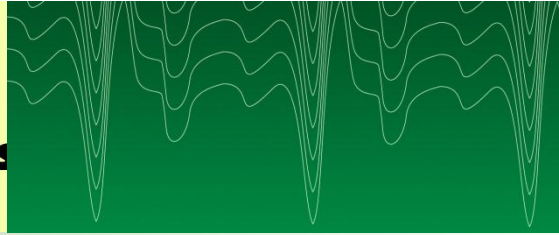
TK/PK/BQ/BEQ studies, rodents, non rodents

Non-clinical safety and Local tolerance studies, rodents, non rodents

Safety pharmacology studies, rodents, non rodents

Immunogenicity/Immunotoxicity studies, rodents, non rodents

Neurotoxicity studies, rodents



Contract-based Experimental Services

Genetic Toxicology

***Salmonella typhimurium* + *E. coli* reverse mutation test**

Cytotoxicity *in vitro* (MTT, XTT)

Mammalian micronucleus test *in vitro*

Mammalian erythrocyte micronucleus test *in vivo*

Chromosomal aberration test *in vitro*

Gene mutation test *in vitro* Æ Mouse Lymphoma Assay



Contract-based Experimental Services

Reproduction Toxicology

Prenatal developmental toxicity

One- and two-generation reproduction toxicity

Combined RD and reproduction/developmental toxicity

Carcinogenicity

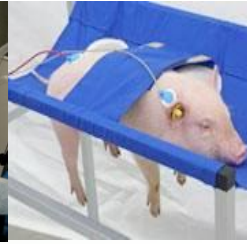
Combined RD and carcinogenicity study

Carcinogenicity study

Anti-tumor effectiveness

Antitumor effect in vitro (specific tumor cell lines)

Antitumor effect in vivo (transplanted tumors, SCID, Nu/nu)



Contract-based Experimental Services

Special animal models

Chronic traumatic spinal cord injury model in miniature pigs*

Hereditary melanoma model in miniature pigs*

Arthrosis model in beagle dogs

Rheumatoid arthritis model (AIA) in rats

Collagen-induced arthritis model (CIA) in rats

Balloon vascular injury model in non human primates

Liver ischemia/reperfusion injury model in beagle dogs

Experimental infarction model in beagle dogs

- * Projects conducted in cooperation with the Institute of Animal Physiology and Genetics CAS



Animal Breeding Facility

Rhesus macaques (*Macaca mulatta*), monitored quality

Beagle dogs, monitored quality

Ferrets (*Mustela putorius*)

Guinea pigs (*Cavia aperea f. porcellus*)

Rats (Wistar:Han), SPF quality

References

Affiris, Austria

Archimedes Pharma, UK

Avir Green Hills Biotechnology,
Austria

Baxter Biosciences, Austria

Cosmo Technologies, Ireland

Dafra Pharmaceuticals, Belgium

Gelesis, USA

Ikaria Inc., USA

Immune systém Key, Israel

Lupin Pharma, India

Medicine Development, Australia

Max-Planck Institut of

Immunobiology, Germany

Midatech, Switzerland

Neurotune, Switzerland

NovoNordisk, Denmark

Oncos Pharmaceuticals, Finland

Pasteur Institut, France

Pharmasafe, Switzerland

Ranbaxy Ltd., India

Rottapharm, Italy

S*BIO, Singapore

Sun Pharmaceuticals, India

Univ of Zagreb, Croatia

Univ of Lille, France

University Clinics Basel

Varleigh Ltd., UK

VetCare Oy, Finland,

and moreõ



We regularly attend the most important events

Bio-Europe Spring (Milano, March 14 . 16, 2011)

Czech Technology Days in Boston (March 23 . 24, 2011)

ChinaBIO Partenring Forum (Beijing, May 12 . 13, 2011)

BioForum (ýód , May 11 . 12, 2011)

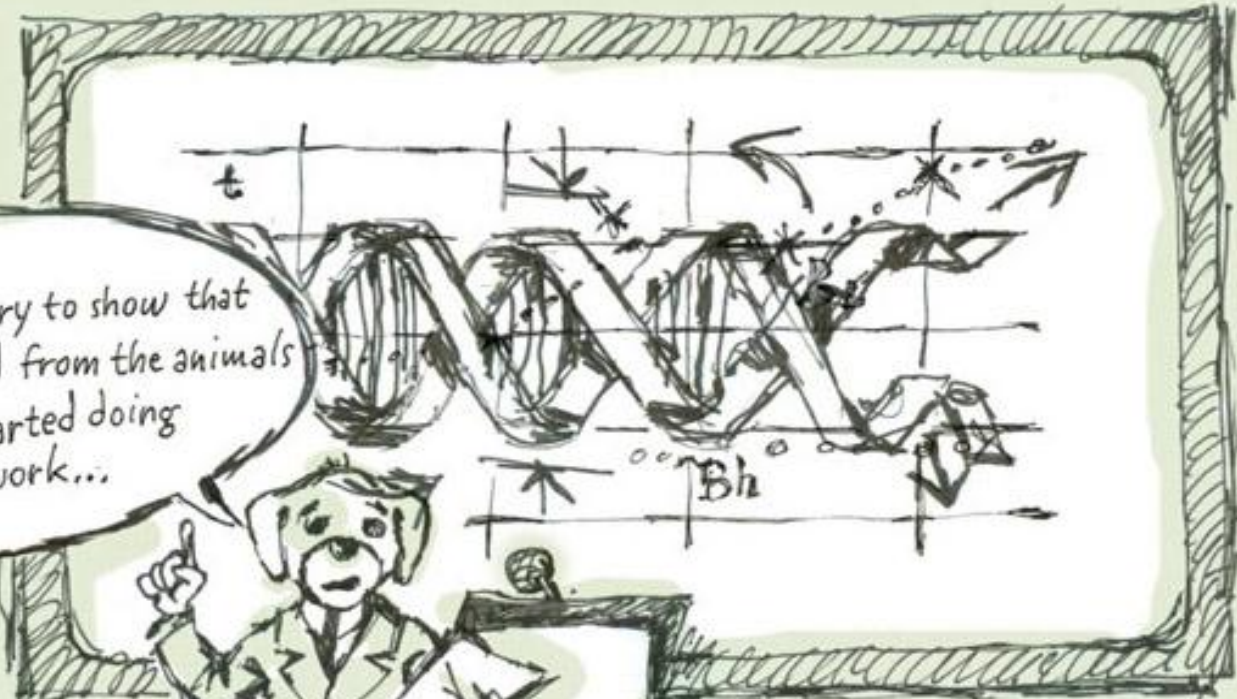
BIO International Convention (Washington DC, June 27 . 30, 2011)

CPh/ICSE (Frankfurt, October 25 . 27, 2011)

BIO-Europe (D sseldorf, October 31 . November 2, 2011)



In my lecture, I will try to show that the man distinguished from the animals only when he started doing unnecessary work...

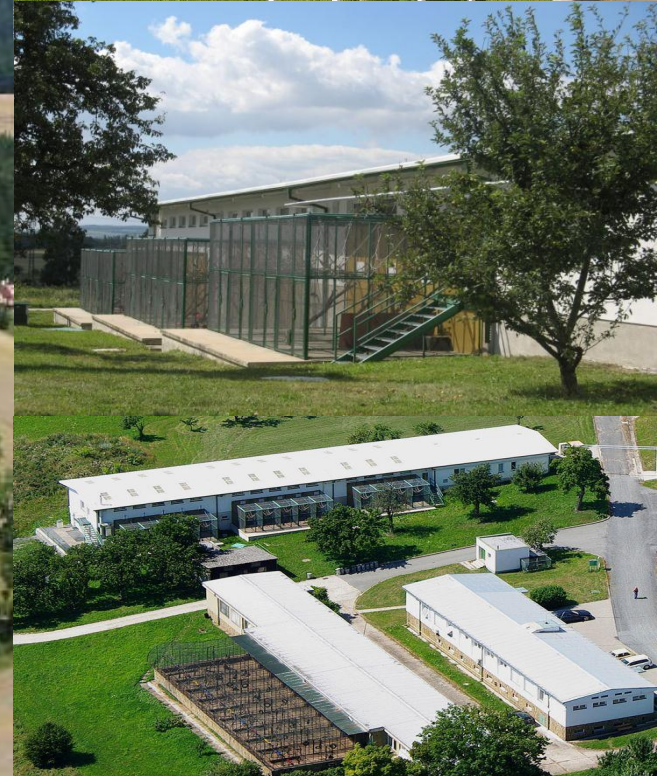
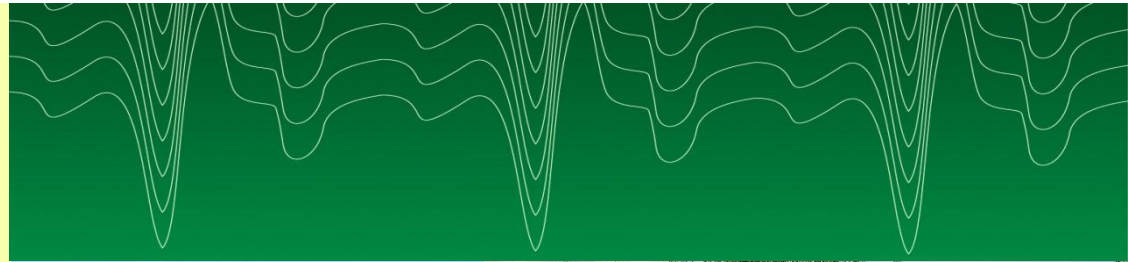


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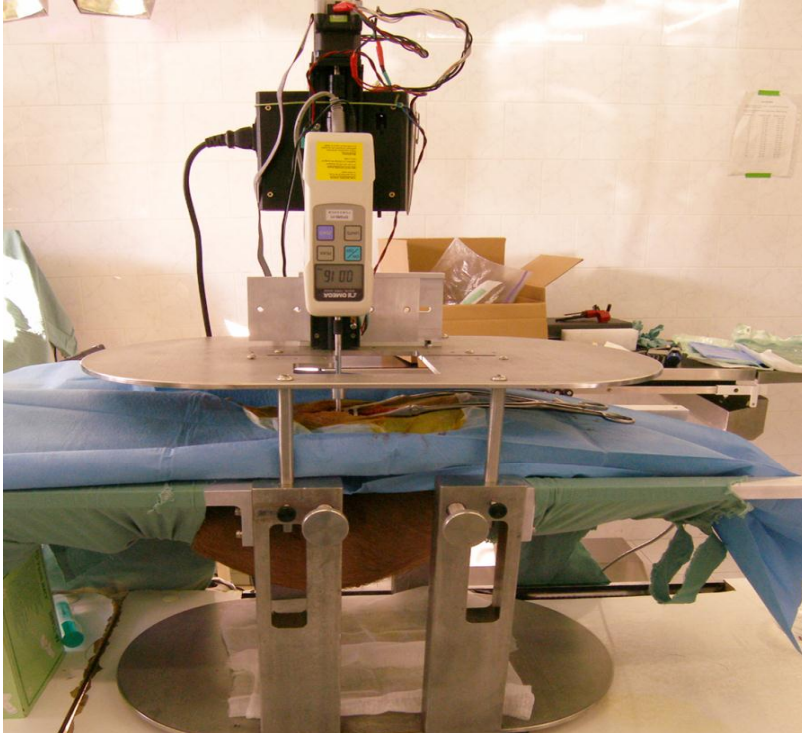
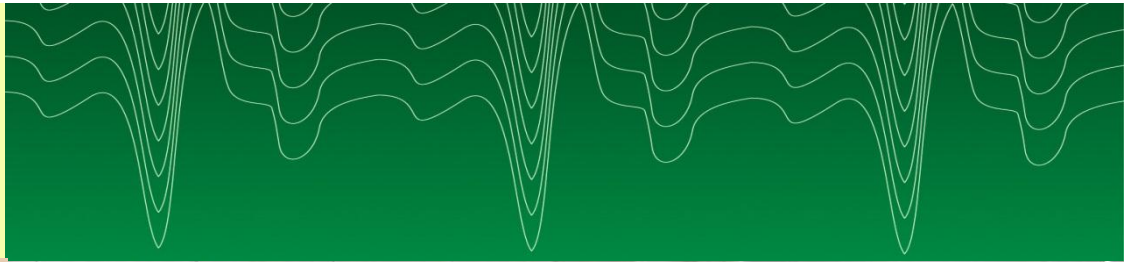
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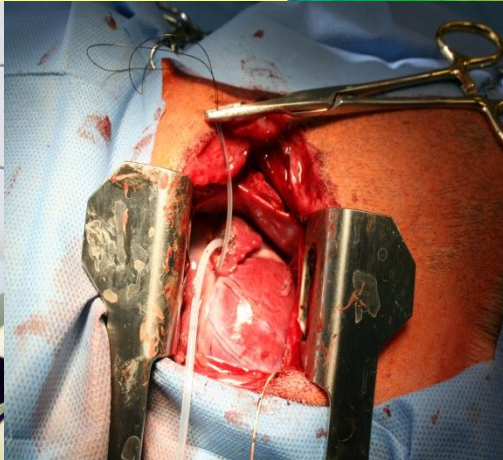
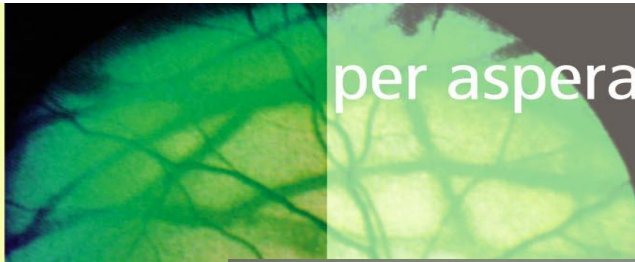
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