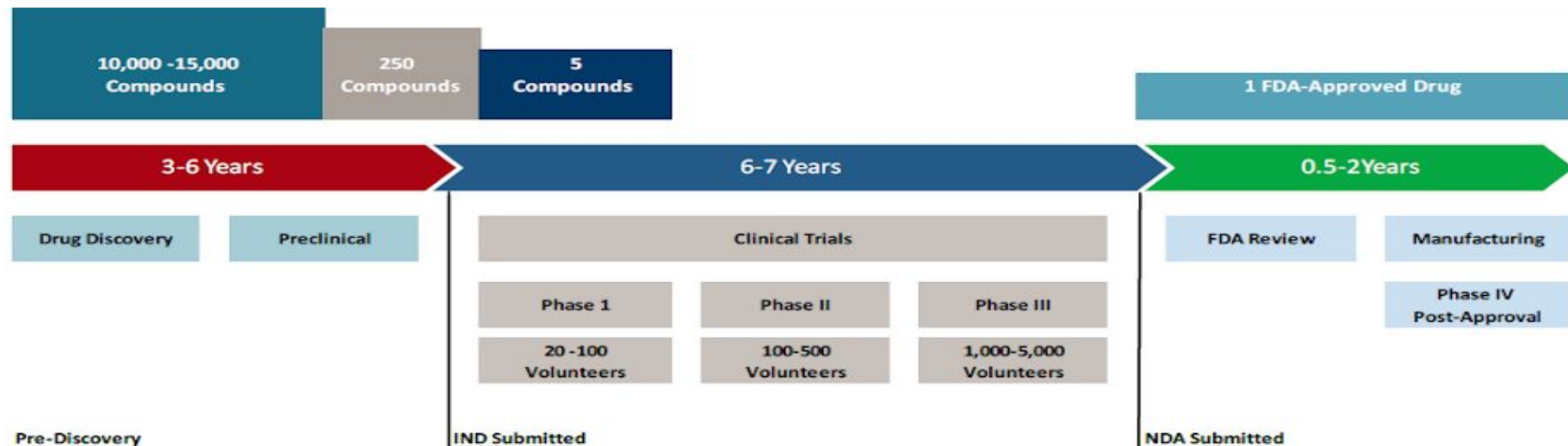


# Uso de animais em estudos pré clínicos

Luciana Cintra

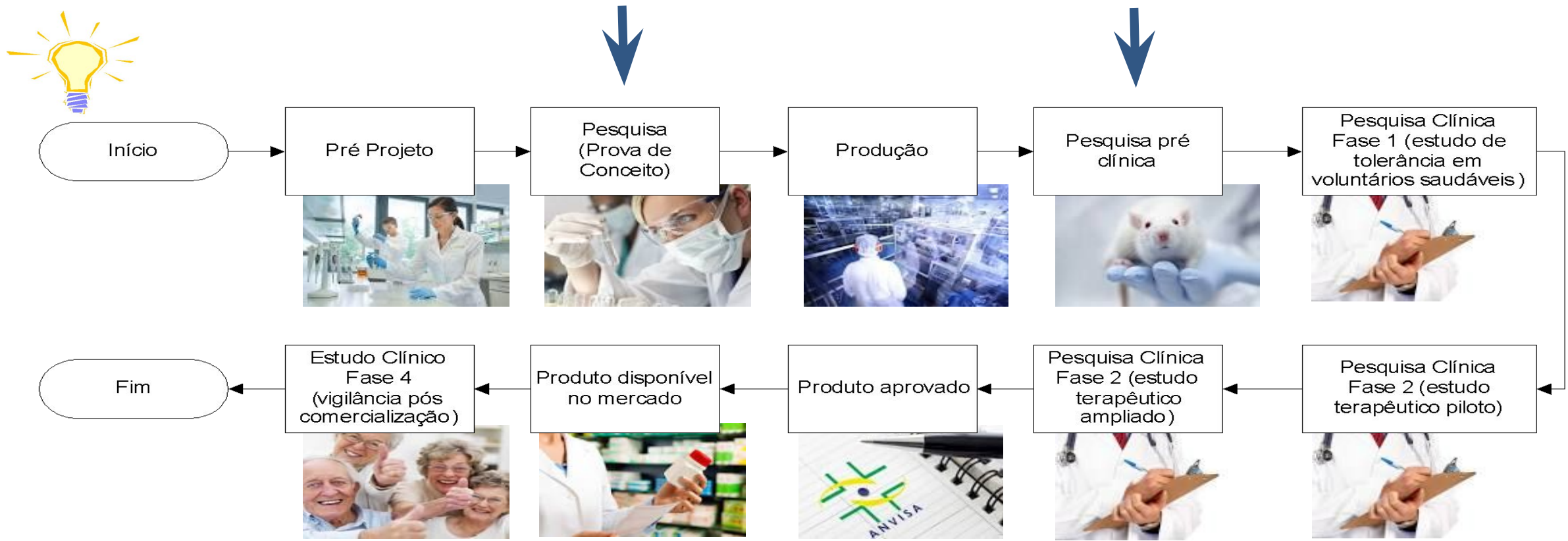


# Fases para validação de um produto na área saúde



Fonte: FDA, Credit Suisse

# O que envolve o estudo pré-clínico?



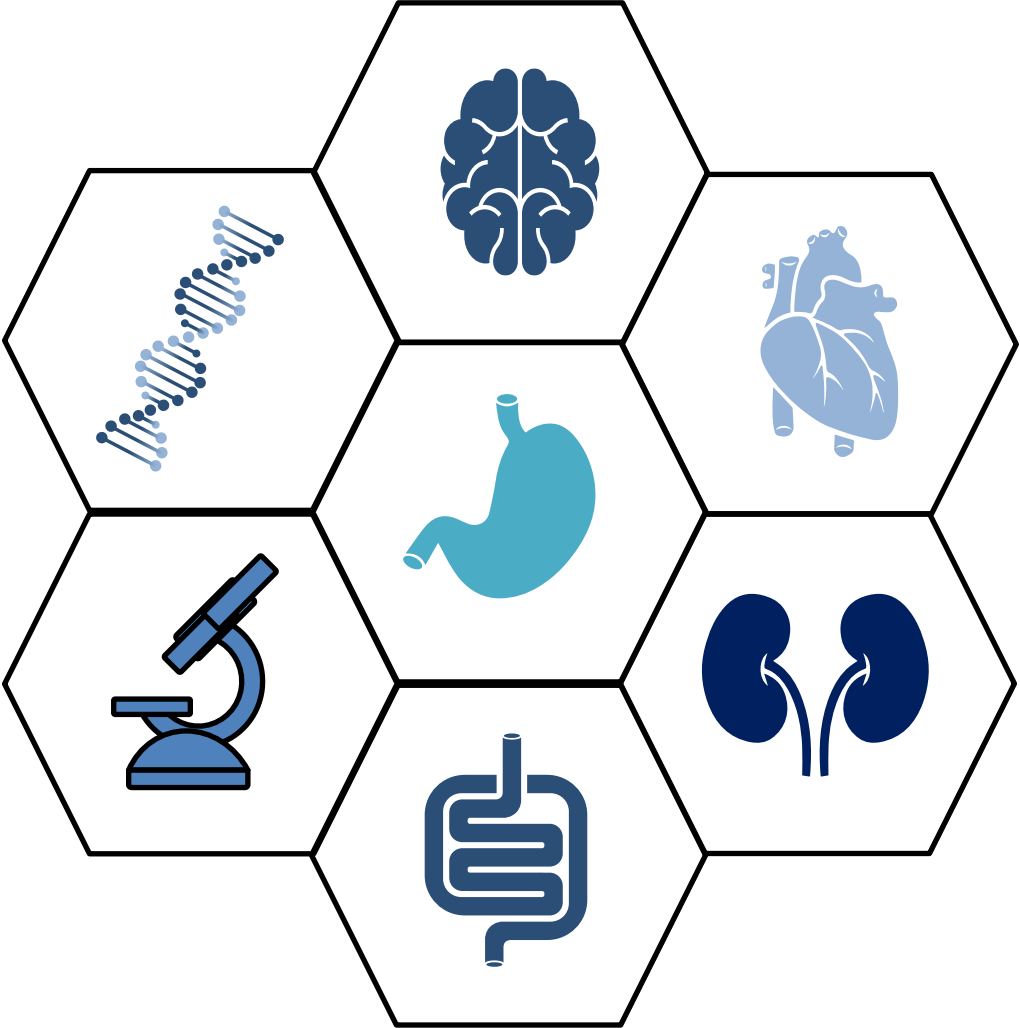
A pesquisa básica em medicamentos inclui todas as atividades necessárias para a identificação e a validação do alvo terapêutico e das moléculas candidatas. Os testes pré-clínicos, realizados em laboratório (*in vitro*) ou em animais (*in vivo*), buscam determinar se a molécula é segura e eficaz o suficiente para iniciar os testes em humanos.

BNDES Setorial 36, p.45-84. Ensaios clínicos no Brasil: competitividade internacional e desafios, 2012.

# Qual o produto a ser validado?



# Modelo a ser escolhido?



## The OECD Test Guidelines Programme

The OECD Guidelines are a unique tool for assessing the potential effects of chemicals on human health and the environment. Accepted internationally as standard methods for safety testing, the Guidelines are used by professionals in industry, academia and government involved in the testing and assessment of chemicals (industrial chemicals, pesticides, personal care products, etc.). These Guidelines are regularly updated with the assistance of thousands of national experts from OECD member countries. OECD Test Guidelines are covered by the Mutual Acceptance of Data, implying that data generated in the testing of chemicals in an OECD member country, or a partner country having adhered to the Decision, in accordance with OECD Test Guidelines and Principles of Good Laboratory Practice (GLP), be accepted in other OECD countries and partner countries having adhered to the Decision, for the purposes of assessment and other uses relating to the protection of human health and the environment.

- › [Section 1: Physical Chemical Properties](#)
- › [Section 2: Effects on Biotic Systems \(Software for TG 223\)](#)
- › [Section 3: Environmental Fate and Behaviour\\* \(Softwares for TG 305 and TG 318\)](#)
- › [Section 4: Health Effects \(Software for TG 455, TG 432 and TG 425\)](#)
- › [Section 5: Other Test Guidelines](#)

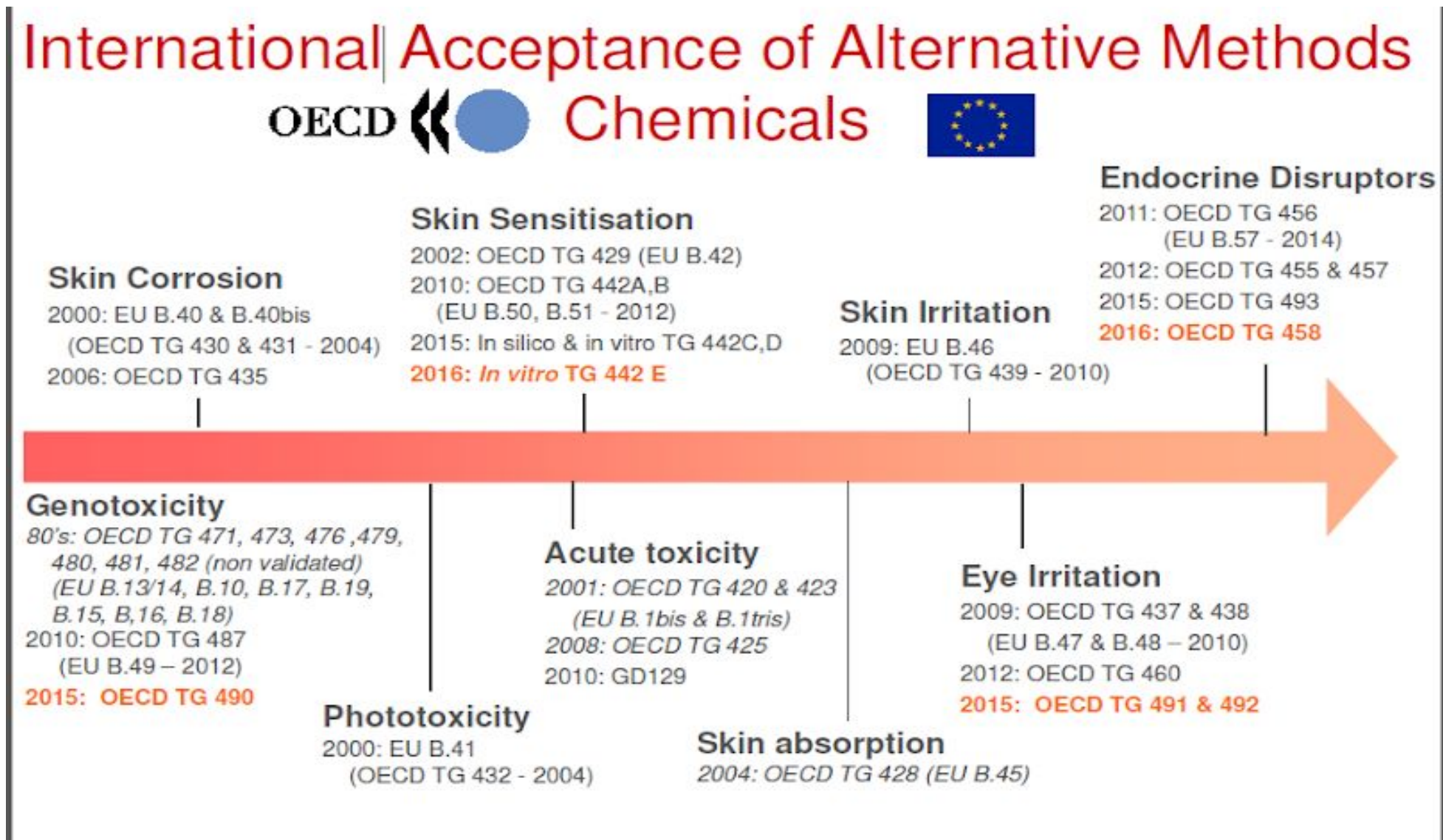


Monitoramento BPL

# Estudos de Segurança Farmacológica









Estudos	# OECD Test	OECD Guidelines for the Testing of Chemicals	Modelo
Estudos de toxicidade de dose única (aguda)	420	Acute Oral Toxicity – Fixed Dose Procedure	Ratos
Estudos de toxicidade de doses repetidas	407	Repeated Dose 28-Day Oral Toxicity Study in Rodents	Ratos
	408	Repeated Dose 90-day Oral Toxicity Study in Rodents	Camundongos
	409	Repeated Dose 90-Day Oral Toxicity Study in Non-Rodents	Mini-pigs
Estudos de toxicidade reprodutiva	421	Reproduction/Developmental Toxicity Screening Test	Ratos
Estudos de genotoxicidade (in vitro e in vivo)	471	Bacterial Reverse Mutation Test (in vitro)	S. typhimurium
	474	Mammalian Erythrocyte Micronucleus Test (in vivo)	Camundongos
Estudos de tolerância local	EMA	Guideline on non-clinical local tolerance testing of medicinal products	Ratos
Estudos de carcinogenicidade	453	Combined Chronic Toxicity/Carcinogenicity Studies	Ratos
Estudos de interesse para avaliação da segurança farmacológica		Sistema Nervoso Central	Ratos
		Sistema Cardiovascular	Coelhos
		Sistema Respiratório	Camundongos
Estudos de toxicocinética	417	Toxicokinetics	Ratos

# Métodos alternativos em estudos de segurança





# Estudios de cosméticos

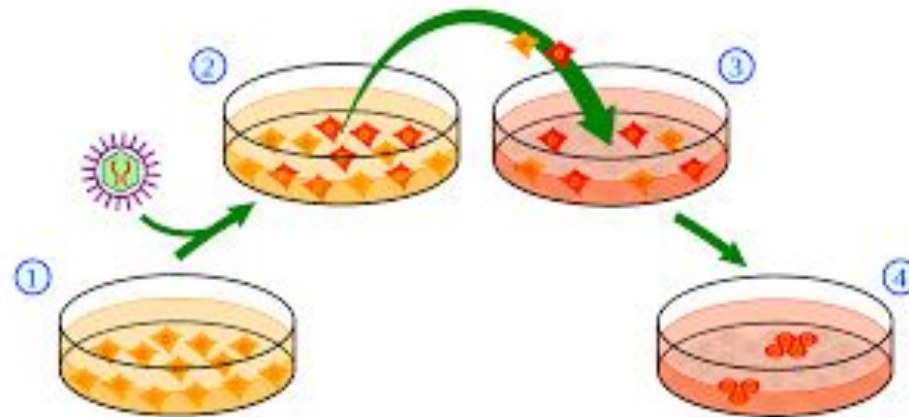
MODELS	APPLICATIONS
 T-Skin Human Full Thickness Model	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>
 SkinEthic RHE Human Epidermis	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>
 EpiSkin Human Epidermis	<input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>
 SkinEthic RHPE Pigmented Epidermis	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
 SkinEthic HCE Corneal Epithelium	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
 SkinEthic HOE Oral Epithelium	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
 SkinEthic HGE Gingival Epithelium	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
 SkinEthic HVE Vaginal Epithelium	<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

EPISKIN

3D models

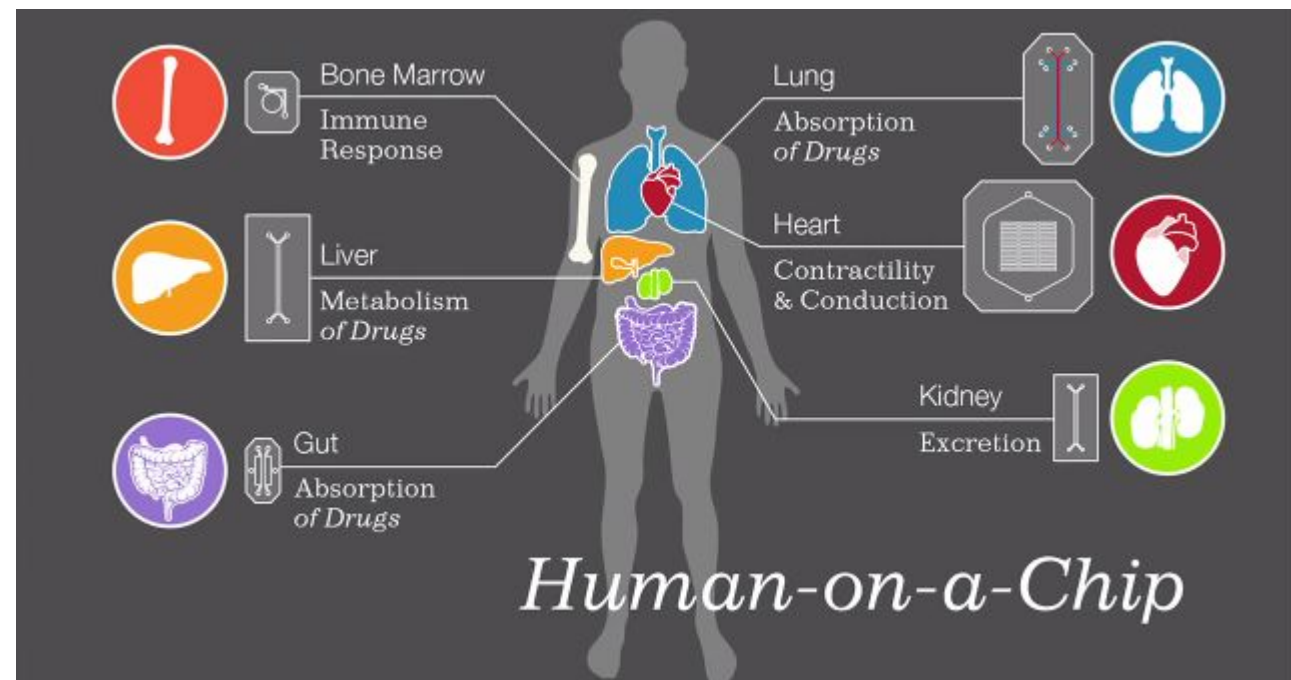
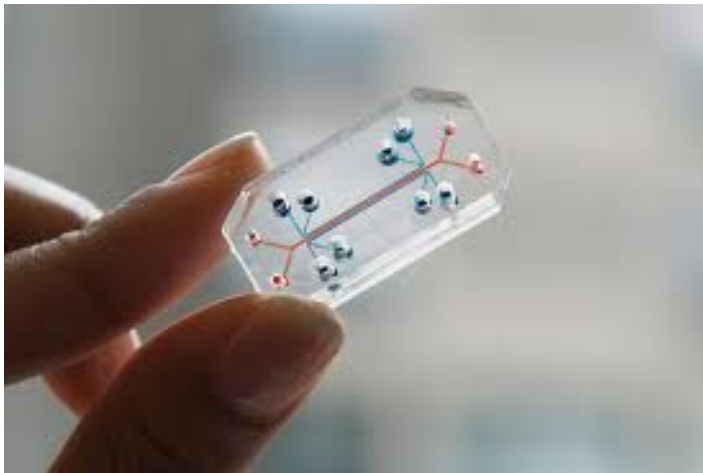
# Estudos in vitro

• **Células-tronco pluripotentes induzidas (IPSC):** estas células representam uma grande promessa para a medicina, uma vez que, tendo a capacidade de se diferenciar em qualquer tecido de um organismo adulto, dão esperança de que um dia seja possível reconstruir tecidos ou órgãos de pacientes e ainda auxiliar no desenvolvimento de fármacos para as mais diferentes moléstias humanas.



# Inovação em estudos pré-clínicos

- Human on a chip



Desafios na extrapolação de dados dos animais aos seres humanos: estudos em imunologia, sistema nervoso central e oncologia.

# Serviços disponíveis no mundo

1  
1



Are You Looking for a Preclinical CRO with Proven Cardiovascular, Neurovascular and Peripheral Vascular Experience?

We can help. Surpass has assisted hundreds of companies advance their vascular innovations through preclinical research.

**IMAVITA** is an **innovating contract research organization** proposing **preclinical services** in the **exploration of preclinical models** of human pathologies by the use of **innovating imaging techniques**.

The vision of our company is to propose to **pharmaceutical industries, biotechnology companies and other private & public laboratories**, innovating solutions in **efficacy / toxicity evaluation of active ingredients** in laboratory species by the use of non invasive imaging techniques and appropriate imaging analysis for quantitative evaluation of specific imaging biomarkers.

**IMAVITA** is actually developing the following **tools**:

- ⦿ Pre-clinical services testing in laboratory species (induction of pathologies / treatment & sampling phases)
- ⦿ Imaging techniques like SPECT/CT, CT with Single/Dual Energy CT approach, MRI, ultrasonography, etc...
- ⦿ Images exploitation and analysis for quantitative imaging



Home

About Us

Expertise

Who We Are



Pharma Models is a pre-clinical contract research organization based in eastern Massachusetts conveniently close to the Boston and Worcester metro areas.

We specialize in animal models of human diseases in the areas of [cancer research](#), [inflammatory](#)

[diseases](#), [obesity](#) and [diabetes](#). Every study we perform is a custom designed study, tailored specifically for the intended client and designed to meet specific needs. Let us design a study for you today.

Pharma Models is owned entirely by the scientists that work here and is committed to providing quality services to the pharmaceutical industry at eminently affordable prices.

Applications of Imavita services:

- ⦿ Dermatology
- ⦿ Oncology
- ⦿ Drug disposition / PK
- ⦿ Medical Devices
- ⦿ Osteo-articular
- ⦿ Cardiovascular

# Linhas de Estudos - Modelos de avaliação de eficácia *in vivo*



## Neurologia

Avaliação de memória.

Ansiedade e depressão.

Epilepsia.

Modelo de Acidente Vascular Cerebral.

- Modelo de isquemia cerebral focal e global

Modelo de doença de Parkinson induzida por 6-OHDA.



## Oncologia

Modelo de Glioblastoma cerebral.

Modelo de tumores ectópicos

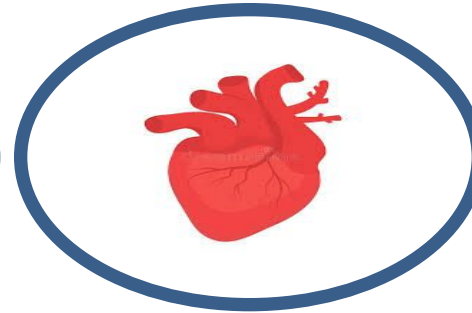
- Câncer de próstata.



## Hematologia

Modelo xenogênico de Leucemia Mielóide Aguda

Modelo xenogênico de Leucemia Mielóide Aguda



## Cardiologia

Registro de ECG e imagens cintilográficas de ventriculografia radioisotópica.

Imagens tomográficas SPECT de coração de ratos.

Modelo de infarto do miocárdio

Modelo de hipertensão arterial.



## Distúrbios metabólicos

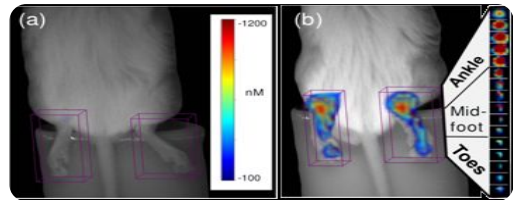
Modelo genético de obesidade e diabetes (camundongo ObOb).

Diabetes induzida pela estreptozotocina.

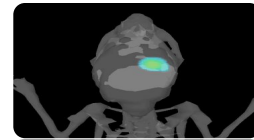
Obesidade induzida por dieta hipercalórica

Modelo genético de aterosclerose (camundongos APOE).

## AVALIAÇÃO DE PATOLOGIAS (in vivo)



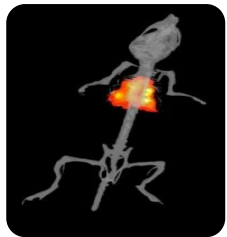
Inflammation



Neuroscience



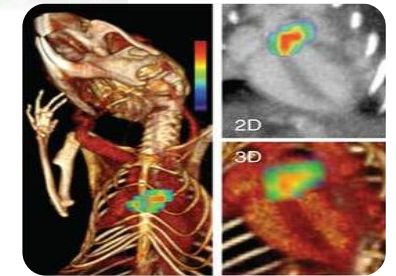
Oncology



Infectious diseases

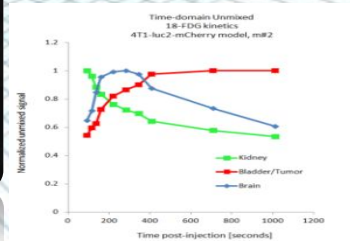
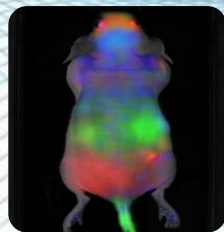


Cardiovascular

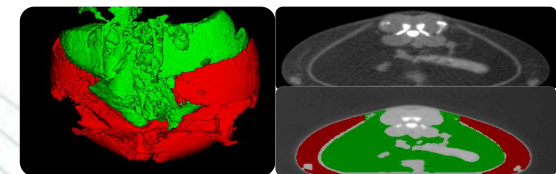
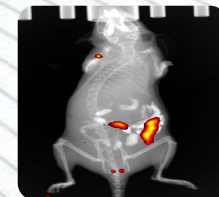


Biodistribution  
PK/PD

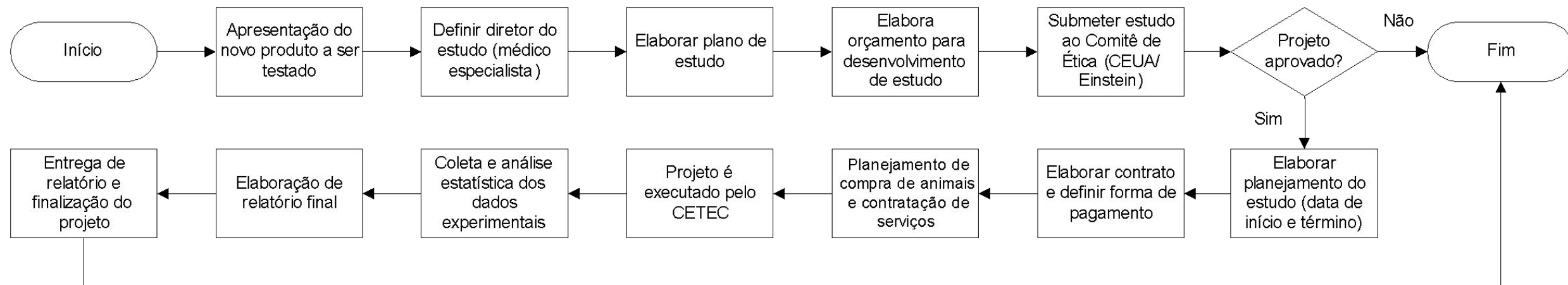
Metabolic Disorders



Gastrointestinal



# Fluxo de Serviços Contratados



OBRIGADA

[luciana.cintra@einstein.br](mailto:luciana.cintra@einstein.br)