

Enabling Innovation & Technology Organisations in Life Sciences



GALILEO
RESEARCH

Your R&D Team Extension

Pharmaceutical

- ▶ *In silico* Predictions
- ▶ *In vitro* and *in vivo* Pharmacology
- ▶ *In vitro* and *in vivo* ADME
 - Biological Barriers Permeability
 - Stability
 - Binding
 - CYP₄₅₀ interactions
 - Pharmacokinetic
- ▶ *In vitro* and *in vivo* Toxicology
 - Single and Repeated Systemic Toxicity with toxicokinetics
 - Genotoxicity
 - Reproductive Toxicity
 - Local Tolerance
 - Cytotoxicity
 - Immunotoxicity

Pharmaceutical

- ▶ Molecular Analysis
 - mechanisms of action
 - target identification
 - protein expression
 - gene expression
- ▶ Sensitization (Mouse Local Lymph Node Assay)
- ▶ Regulatory toxicology (GLP compliant)
- ▶ Management and Planning of the non-clinical phase
- ▶ Regulatory Support
 - CTD
 - Expert Report
 - PDE

Medical Devices

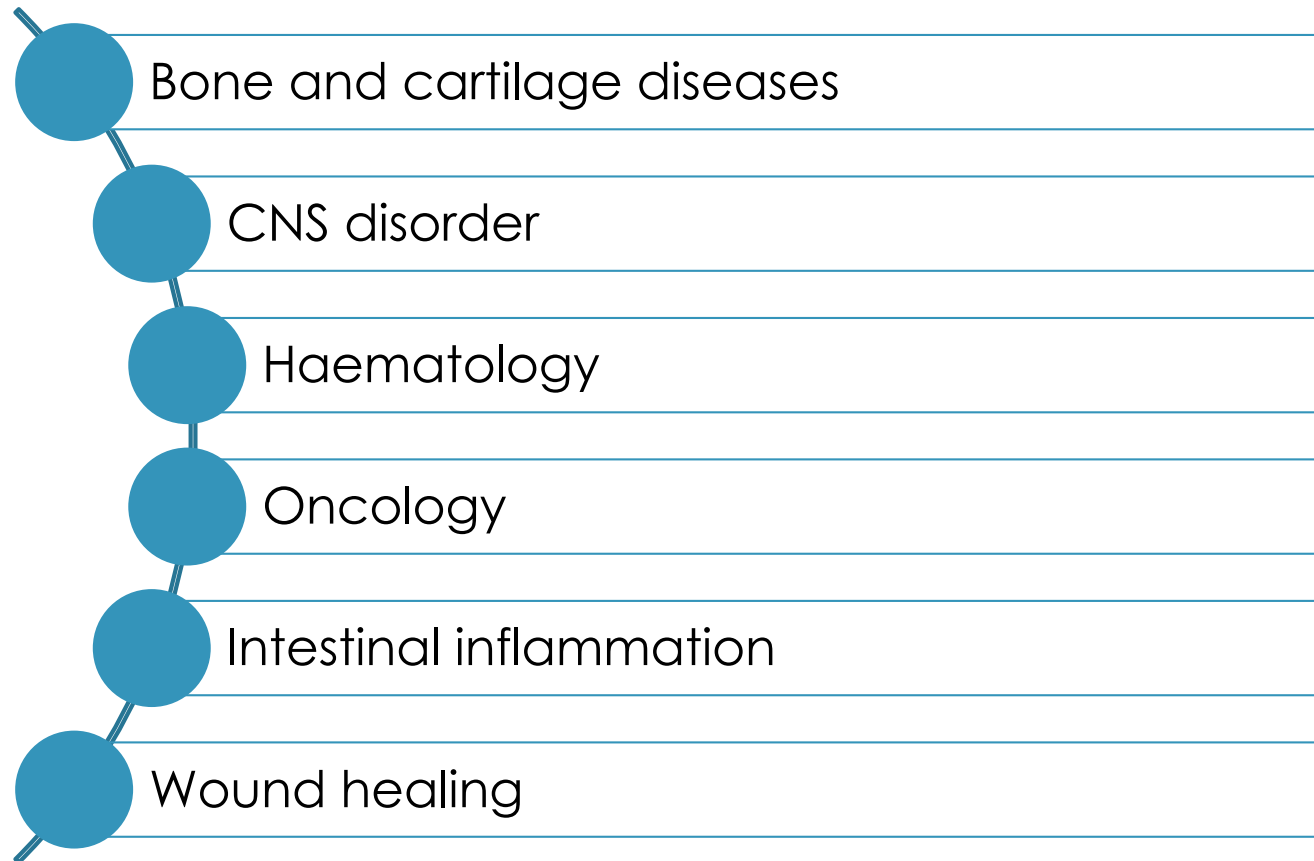
Biocompatibility Plan, Testing (GLP) and Report according to ISO 10993-1 series within a Risk Management Process

- ▶ Genotoxicity
- ▶ Reproductive and developmental toxicity
- ▶ In vitro cytotoxicity
- ▶ Implant toxicity (clinically relevant implantation site)
- ▶ Bio-Degradation
- ▶ Irritation and skin sensitization
- ▶ Systemic Toxicity
- ▶ Sample preparation
- ▶ Toxicokinetic
- ▶ Immunotoxicology

Novel food, Food supplements and Botanicals

- ▶ *In vitro* and *in vivo* Potential Benefits Assessment
- ▶ *In vitro* and *in vivo* Safety Assessment
- ▶ *In silico* Prediction
- ▶ Regulatory *in vivo* Toxicological Data collection to support approval from EFSA - including genotoxicity, information on absorption, distribution, metabolism and excretion (ADME)

Key Therapeutic Areas



A History of Success

- ▶ Hyaluronic acid platform
- ▶ Implanted Medical Devices (bio-polimers)
- ▶ Botanicals
- ▶ Molecular biology
- ▶ Novel food
- ▶ 3D-reconstructed human tissues in vitro
 - Irritation
 - Absorption
 - Efficacy
 - Histology
 - Immunohistochemistry



Close to 100% regulatory submission compliance

Thank You!



Your R&D Team Extension

