Your R&D Team

GALILEO
RESEARCH

Contract Research Organization

We are focused on providing fast and efficient support in customers' drug development.

Galileo Research srl is a private R&D company established in July 2011 as a spin-off of the R&D Division of Abiogen Pharma.
The Research Centre is organized in three specialized departments (**Biotechnology**, **Pharmacology** and **Toxicology**), in the 2500 m2 plant and equipped with advanced instruments and technologies.

CERTIFICATIONS

The Testing Facility works in compliance with Good Laboratories Practices (GLP) and has been GLP certified by the Italian Ministry of Health since 1992. The last GLP certificate was issued by the Italian Ministry of Health on 09/05/2023.

ANIMAL WELFARE

Galileo Research is strongly committed to the implementation of the 3Rs (Reduction, Refinement and Replacement) and already offers a list of validated alternative methods that replace animal use or, at least, reduce it. When the use of animals is unavoidable, Galileo Research is authorized by the Italian Ministry of Health to carry out studies in rodents (Authorization n. 09/2023-UT of 19/01/2023).

GALILEO
RESEARCH
Contract Research Organization

Advancing Healthcare Intelligence through open and innovative approaches.

Galileo Research is a non-clinical contract research organization (CRO) that provides experience, knowledge, and the skills required to fastly and effectively put drugs, medical devices, supplements and cosmetics on the market.

Our solutions meet global regulatory requirements and include studies on **toxicology, biocompatibility, efficacy/performance and mechanisms of action.**

With over 30 years of experience in conducting GLP-compliant studies, our scientists work as members of your team, helping you expedite your research goals.

GALILEO
RESEARCH
Contract Research Organization

Fields of application

Drug discovery and development

DRUGS

Galileo helps Pharmaceutical Companies design the best strategy to select the lead drug candidate (small molecules, biopharmaceuticals and ATMPs), thus effectively accelerating the development of new medicines and reducing attrition rate.

Biological evaluation

MEDICAL DEVICES

Review and evaluation of existing data and the selection of potential additional tests to guarantee the safety of the product.

Food safety evaluation

FOOD&FOOD SUPPLEMENTS

Design and validation of in vitro and in vivo experimental methodologies suitable to identify the effects of the product; selection of substances with nutritional or physiological effect to be added to foods and food supplements.

In vitro testing

COSMETICS

Galileo can help to proof product safety and efficacy and ensure its conformity to regulations with specific in vitro testing.

GALILEO RESEARCH

Contract Research Organization

Wide network of excellence and multidisciplinary collaborations.

Galileo Research supports **discovery and development** with a complete range of non-clinical studies.

Our expertise offered in regulatory submissions and knowledgeable strategic skills in planning non-clinical testing programmes can **reduce attrition rate and speed up the process.**

Based in Tuscany, surrounded by top Universities and the National Council of Research (CNR), Galileo Research boasts a wide network of excellence and multidisciplinary collaborations that result in creating knowledge to **answer the customer's needs** and building a **best-in-class non-clinical service business** through open and innovative approaches to discovery and development.

GALILEO
RESEARCH
Contract Research Organization

The close collaboration between our scientists and yours guarantees a rewarding and fruitful working relationship. Our project management is based on transparency with regular project reporting as frequently as requested.

Dr. Silvia Trasciatti
Chief Scientific Officer | Galileo Research

Biography and Pubblications

Silvia Trasciatti graduated in Biological Sciences at University of Pisa, has a specialization degree in Biotechnology from the University of Milano, a Master in Nutritional Science from the University of Firenze and a Master Degree in Business Economics and Management from the University of Pisa. She began her scientific career at the CNR (National Council of Research), then moved on to the Italian pharmaceutical companies Istituto Gentili then Abiogen Pharma, where she was actively involved in the development of new molecular entities, started a fruitful collaboration with universities and research institutes and was also involved in licensing, business development and strategic planning. In 2011 she became Chief Scientific Officer (CSO) of Galileo Research.
Silvia Trasciatti has a broad experience in pharmacology, toxicology and molecular biology, as well as, knowledge of GLP, GCP and international regulations for drug, medical device and novel food approval. Her scientific expertise ranges from bone and cartilage diseases, immunology, monoclonal antibodies, cancer immunotherapy, ATMPs. Silvia has 14 patents, has brought 15 projects to clinical Phases and has obtained 6 substantial research grants from the Italian government.

GALILEO RESEARCH
Contract Research Organization

DRUG DISCOVERY AND DEVELOPMENT

DRUGS

Preclinical research is a vital phase of drug discovery and development, designed to identify a lead candidate from several hits; Galileo helps customers design the best strategy to select the lead drug candidate, thus effectively accelerating the development of new medicines and reducing attrition rate. We offer a full range of studies and bioanalytical services, providing powerful tools and rigorous solutions for preclinical drug development of therapeutic candidates, advance lead compounds towards first-in-human trials, and support for ongoing clinical development:

- ADMET screening, to select optimal candidates for clinical success
- Pharmacology, to predict biological effect of new therapeutic entities
- Pharmacokinetics and metabolism, to evaluate PK parameters
- Acute toxicology in rodents, to predict likely target organ toxicity and help with dose selection for initial repeated dose toxicity tests
- Dose range finding and maximum tolerated dose in rodents, to establish initial safety facilitating subsequent regulatory toxicity studies
- Repat-Dose toxicity in rodents, to ensure robust safety testing data needed to support the advancement of your development program

In support of human clinical trials and marketing authorization approval, Galileo Research offers a full battery of toxicity studies for the regulatory development of small drugs, as well as biologics and advanced therapies, in compliance with Good Laboratory Practice (GLP), ICH and OECD guidelines.

GALILEO RESEARCH

Contract Research Organization

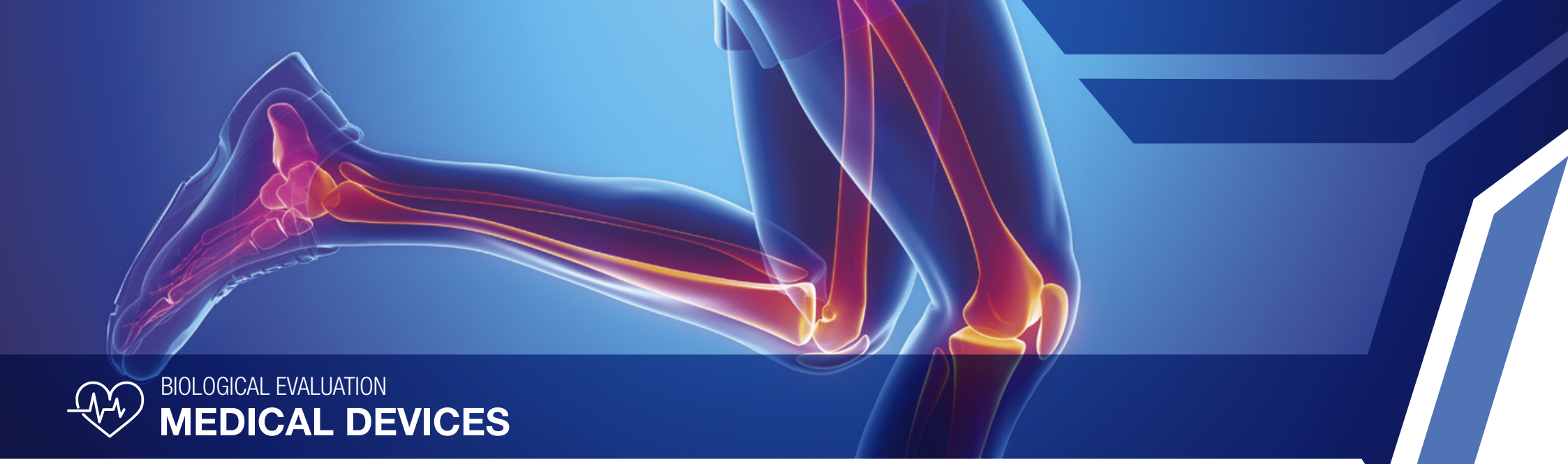
DRUG DISCOVERY AND DEVELOPMENT

DRUGS

GENOTOXICITY	• Ames' Test • Mouse Lymphoma Assay • In Vivo Micronucleus Test • HGPRT Mutations in V79 Cells • Chromosomal Aberrations In Vitro
TOXICOLOGY	Single dose Toxicity in Rodents (various routes of administration) • Fixed Dose Method • Up-and-down Procedure • Toxic classic method Repeated Dose Toxicity in Rodents (various routes of administration) • 28-Day Toxicity in Rodents, including recovery, toxicokinetic • 90-Day Toxicity in Rodents, including recovery, toxicokinetic • 6-Month Toxicity in Rodents, including recovery, toxicokinetic Reproductive and developmental toxicity • Embryo-Foetal Develpment in Rats • Reproduction Toxicity in Rats • Immunotoxicity • Local tolerance
PHARMACOLOGY	• Pharmacokinetic and Metabolism in vitro and in vivo • Pharmacodynamics in vitro and in vivo models of diseases available to study the efficacy of drugs including: bone and cartilage pathologies (osteoporosis, osteoarthritis), oncology, brain ischemia, mood disorders, dermatological diseases skeletal muscle diseases, gastro-intestinal diseases. Galileo Research can design and validate customized model systems to evaluate efficacy and potency of drugs. • Studies on the mechanism of action, through advanced technologies that include gene expression analysis, qRT-PCR, in situ hybridization, immunohistochemistry and more...).

GALILEO RESEARCH

Contract Research Organization



BIOLOGICAL EVALUATION

MEDICAL DEVICES

Biological evaluation of medical devices is a complex process that represents a part of the overall development of a product. It consists in the review and evaluation of existing data and the selection of potential additional tests to guarantee the safety of the product.

Galileo Research can drive the nonclinical development of your medical device by preparing the Biological Evaluation Plan (BEP) according to ISO 10993-1, performing the additional tests and releasing the Biological Evaluation Report (BER).

Tests are done according to the most recent version of ISO 10993 standards and OECD requirements and in compliance with GLP.

GALILEO RESEARCH

Contract Research Organization

BIOLOGICAL EVALUATION

MEDICAL DEVICES

In vitro cytotoxicity L929 murine fibroblast (Direct contact and after extraction)
Genotoxicity
Irritation on reconstructed human tissues in vitro
Local effects after implantation in vivo
Degradation
Systemic toxicity in vivo
Reproductive and developmental toxicity
Skin sensitization (Mouse Local Lymph Node Assay)
Toxicokinetic
Immunotoxicology
In vitro absorption by quali-quantitative evaluation of penetration of MD components through reconstructed human tissues (skin, corneal epithelium, vaginal mucosa, oral mucosa and gingival epithelium)

GALILEO RESEARCH

Contract Research Organization

FOOD SAFETY EVALUATION

FOOD&FOOD SUPPLEMENTS

Potential benefits and safety of dietary supplements need to be assessed by scientifically validated means, in the context of Regulation (EC) 2015/2283 on novel foods. Toxicological data, including genotoxicity, information on absorption, distribution, metabolism and excretion (ADME) need to be collected to support approval from the competent Authorities.

Demonstration of health claims typically depends on various research approaches from basic in vitro research on the mechanisms of action to animal and human studies. Depending on the claim, Galileo Research can help to design and validate in vitro and in vivo experimental methodologies suitable to identify the effects of the product and help in the selection of substances with nutritional or physiological effect to be added to foods and food supplements.

GALILEO RESEARCH

Contract Research Organization

FOOD SAFETY EVALUATION

FOOD&FOOD SUPPLEMENTS

Novel food development can be supported by the following studies:

- Genotoxicity
- Reproductive and developmental toxicity
- Single- and repeated-dose toxicity and toxicokinetic
- Pharmacokinetic and Metabolism
- Simulated digestion and absorption in vitro
- In vitro toxicity and efficacy of food supplements

GALILEO RESEARCH

Contract Research Organization

IN VITRO TESTING

COSMETICS

The industry of personal care and cosmetics is in continuous innovation and development. New formulations must be tested for quality, safety and effectiveness.

Galileo research can help to proof product safety and efficacy and ensure its conformity to regulations with specific in vitro testing.

GALILEO RESEARCH

Contract Research Organization

BIOLOGICAL EVALUATION

MEDICAL DEVICES

SAFETY TESTING

- In vitro dermal irritation test
- In vitro ocular irritation test
- In vitro dermal sensitization test based on the human cell line activation assay
- Genotoxicity
- In vitro dermal corrosion test
- In vitro ocular corrosion test

PERFORMANCE TESTING

- Anti-aging effect: inhibition of ROS production or ROS scavenging, synthesis of collagen, GAGs, hyaluronic acid, cell proliferation, elastase inhibition In vitro ocular irritation test
- Whitening effect: inhibition of tyrosinase
- Skin absorption by quali-quantitative evaluation of penetration
- Corneal absorption by quali-quantitative evaluation of penetration
- Vaginal absorption by quali-quantitative evaluation of penetration
- Oral/Gingival absorption by quali-quantitative evaluation of penetration

GALILEO RESEARCH

Contract Research Organization

GALILEO
RESEARCH

Contract Research Organization

Galileo Research Srl

Via Paradiso 6, 56019
Vecchiano (Pisa) - Italy
Tel. +39 050 3154401
Fax +39 050 803338
info@galileoresearch.it
www.galileoresearch.it