LB Research® srl

International clinical trials management

since 2008

Contract Research Organization full services

Company profile

LB Research® srl
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Share Capital: € 100.000,00 (Fully paid)
Web site: www.lbresearch.it

LB Research® srl – Cantù (CO) - Italy

General Information

Founders and Owners

Flavio Lietti: President and BD Director
Flavia Baruzzi: Scientific Director
Nicoletta Belotto: Head of Clinical Operations

Annual Revenue

≥ € 4.500.000,00

Share Capital and Investments

€ 100.000,00 (fully paid-up capital)

LB invests the 8 % of its total revenue in Quality,

Personnel training (10/year) and Technology innovation

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Mission

To be an ideal partner and provide adequate resources and expertise to local and multinational Pharmaceutical Companies sharing their goals in the management of all types of clinical trials (Pharmacological, Observational, Registry, with Medical Devices and Food supplements), working in synergy from the contract finalization until the delivery of results

LB Research® Organization Chart

- President
  Scientific Director
  Head of Clinical Operations
  - Auditor
  - Quality Assurance Manager
  - Quality Assurance Senior
  - Quality Assurance
  - Data Protection Officer
  - Privacy Manager
  - Finance & Administrative Officer
  - General Service Officer
    - Backup Operators
    - IT Manager
    - IT Specialist
  - Project Managers
    - Clinical Monitors
    - Clinical Trial Assistant
    - Medical Writer
    - Medical Monitor
  - Data Management Coordinator
    - Data Managers
      - Data Entry Operators
    - Statistician
      - Statistician Back up

LB Research® staff

- **Board of Directors** 3
- **Project Managers** 12
- **CTAs** 5
- **Quality Assurance Dept** 3 (1 Consultant)
- **Privacy Dept** 2 (1 Consultants)
- **Finance & Accountability** 2
- **Data Manager** 5
- **Statisticians** 3 (1 Consultant)
- **Medical Writers** 2 (Consultants)
- **Information Technology** 2 (Consultants)

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Our Customers

Local and Multinational Pharmaceutical Companies and Scientific Communities

Repeated Business

80% of total turnover

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Clinical Trials

- **Pharmacological** (Phase II, III, IV, PAES, PASS) (40%)
- **Medical Devices** (35 %)
- **Observational and Registry** (20%)
- **Food supplements** (5%)

Main therapeutic areas experience

- Onco-Hematology
- Immunology
- Rheumatology
- Cardiovascular
- Gastroenterology
- Uro-andro-ginecology
- Dermatology
- Neuro-Psychiatry
- Orthopedics
- Diabetology
- Virology/Infectious diseases
- Ophtalmology
- Aesthetic medicine
- Transplants
- Pneumology
- Rare Diseases

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Clinical trial activities

- **Sites selection and feasibility**
- **Protocol and Synopsis development**
- **ICF and GP letter preparation**
- **Preparation and Application to CA/CEC CTIS submission for drug studies**
- **Preparation of documents and submission/notification to CAs for MD studies**
- **Center file, Investigator file and Trial Master file preparation (eTMF if requested)**
- **Amendment development and submission or notification**
- **E-CRF LB development (or Paper CRF)**
- **e-PRO (Patient reported outcomes)**
- **CDISC Standards (ADaM data set and SDTM standards)**
- **Project Management and site management**
- **On site and off site monitoring**
- **Remote monitoring**
- **Medical Monitoring**
- **Data Management and Statistical Activities**
- **Clinical Study report**
- **Paper/Abstract/Poster**

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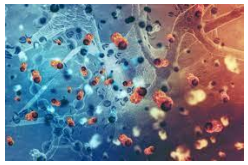
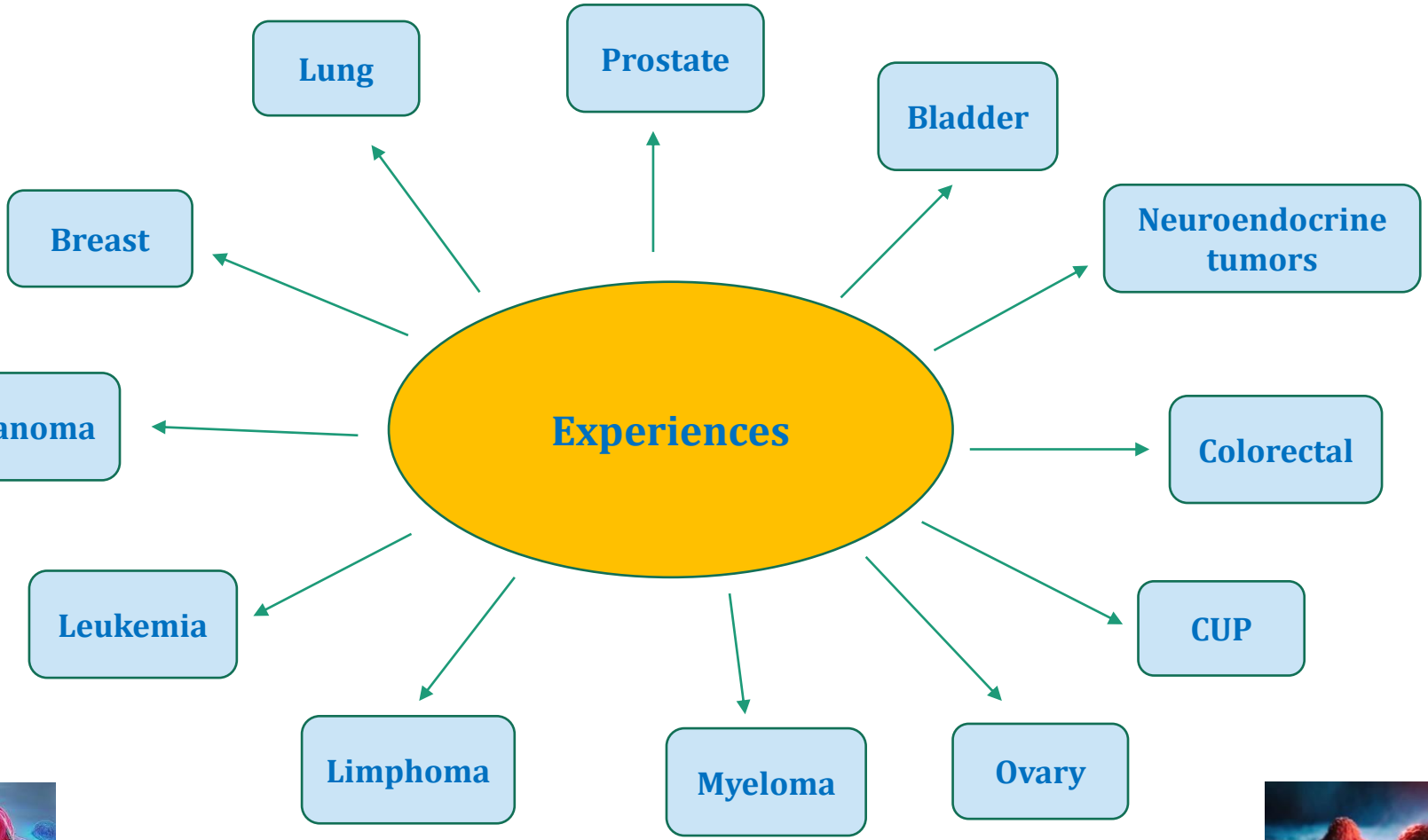
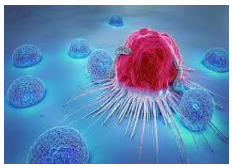


Onco-Hematology expertise





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International Clinical Trials

Countries involved in our Clinical Trials

- Germany
- Spain
- Hungary
- France
- The Netherlands
- Portugal
- Belgium
- Romania
- Latvia
- Georgia
- UK
- Russia
- Turkey
- Slovakia
- Czech Rep.
- Greece
- Poland

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Clinical Trials with General Practitioners (GPs)

LB Research has managed
about 20 GPs trials
(Pharmacological, Observational,
with Medical Devices and Food supplements)

LB organizes, in agreement with local Competent Authorities, free GCP courses for GPs

Other services

- **Virtual clinical trials**
- **Narrative Medicine**
- **Patient Associations involvement**
- **Ecs fees and Patients grants payment**
- **Pre-clinical studies (Partnership with Galileo Research – Vecchiano – Pisa)**
- **Video-Telemedicine**
- **Drug Management**
- **Pharmacoeconomy**

LB Research® Electronic CRF

FDA compliant – GAMP 5 Validated

(Platform Actide® - Nubilaria srl)

- **Data Base design, set up and validation**
- **Data Management plan**
- **Edit check implementation and validation**
- **E-PROs**
- **Standard on line reports**
- **E-CRF user guide**
- **Accounts (Sites, Sponsor and CRO credentials)**
- **Help-Desk (on working days)**

eCOA

(Electronic Clinical Outcome Assessment)

A web-based module to capture **ePRO (electronic Patient Reported Outcomes)**, **eObsRO (electronic Observer Reported Outcome)**, **eClinRO (electronic Clinical Reported Outcomes)** and **ePerfO (electronic Performance Outcomes)** data within the same database of the eCRF with the convenience of using patient's own device

A fully featured mobile EDC solution:

- Login with username and password (or PIN), face-detection and fingerprint
- Responsive design capable to automatically adapt its content to any device
- Upload images and files from both the device camera and internal file system
- Deliver on-device notifications
- Multilingual interface
- Data stored directly in the eCRF database

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e-CRF

(Finalization Timelines)

Protocol
(Final version)

→ **50-55 working days**

e-CRF go live
(GAMP 5 validation included)

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Electronic TMF

A secure and practical access point for TMF study documentation, supporting all essential document processes and reducing TMF management timelines, costs and risks

Complete eTMF system for your studies:

- **Online h24x7x365**
- **Drug Information Association (DIA) TMF Reference Model natively compliant**
- **Automatic backups**
- **Complete, compliant and clear audit trail**
- **Placeholders**
- **Unlimited number of releases per document**
- **Tags**
- **Standard and customized reports**

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Artificial Intelligence

in clinical trials

MACHINE LEARNING, DEEP LEARNING AND FOUNDATION MODELS

FOR THE MANAGEMENT OF CLINICAL TRIALS

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Experimental *Sites*

About 500 sites

(Italy and Europe)

Site references

Site enrollment performances

Audits by Pharmaceutical Companies and Competent Authority Inspections

System Audits

about 3/year

In house AIFA inspection

September 2015

Site Inspections

AIFA, FDA, Swissmedic and SUKL (Slovak Agency)

No critical findings highlighted

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nubilaria ACTide

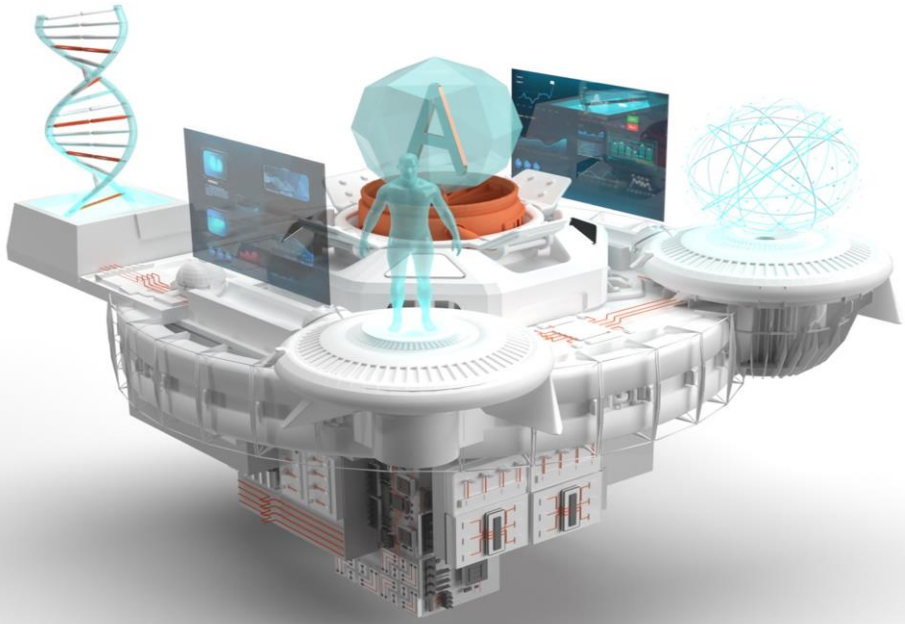
Partnership LB Research®- Nubilaria (Information Technology Company)

eClinical solutions

Nubilaria is a private eClinical IT company certified for GCP, ISO 9001 and ISO 27001 for information security

Design, development and management of:

- **Data Management Solutions and innovative ICT Services under strictly regualted policies**
- **Business Intelligence Systems**
- **Data Manipulation Systems**
- **Data-Entry Advanced Interfaces**
- **Data Repositories Consolidation and Normalization**
- **Geographically distributed Data Management Systems**
- **Mobile Data Management Applications**



Partnership LB Research®- Galileo Research for Non–Clinical testing

Galileo Research is a private R&D company certified for Good Laboratories Practices and ISO 9001, authorized for research and regulatory studies on rodents
***In vitro* and *in vivo* research protocols can be customized based on scientific, technical and regulatory needs**

- **Pharmaceuticals - Drug discovery screening, Regulatory Toxicology and Pharmacokinetics (GLP)**
- **Medical devices - Biological Evaluation Plan, Biocompatibility testing, Biological Evaluation Report**
- **Food & food supplements - Potential benefit and Safety of dietary supplement assessment**
- **Cosmetics - product Safety and Efficacy ensuring conformity to regulations with *in vitro* testing**

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Why should you work with LB ?

Strengths

Founders experience (35 years average)

Staff experience (18 years average)

Dedicated team (for the whole study duration)

Expertise in many therapeutic areas

Availability - Flexibility - Confidentiality

High Quality of Services

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Thank you for your attention

Any questions ?

Flavio Lietti
Founder and President