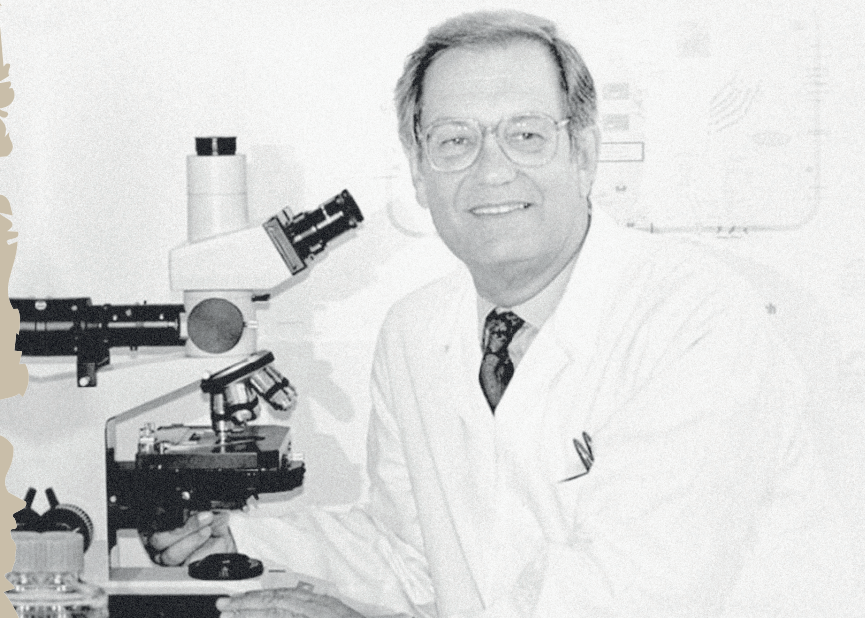


# FONDAZIONE GIANNI BONADONNA

---

SUPPORTING PARTNER

PRADA Group





**Luca Gianni, MD**

President

Gianni Bonadonna Foundation, Milan



**Diego Tosi, MD PhD**

Scientific Coordinator

Gianni Bonadonna Foundation, Milan  
Early Clinical Trial Unit, ICM, Montpellier

## BRIEF HISTORY

**Fondazione Gianni Bonadonna (FGB) was promoted in 2015 by Fondazione Michelangelo with Gruppo Prada as supporting partner to:**

- △ foster innovation and progress in cancer research
- △ widen cancer treatment options with focus on early-stage drug development

**FGB Headquarters are sited in Milan (Italy):**

- △ Luca Gianni MD is the President
- △ Diego Tosi MD is the Scientific Coordinator

**In 2017, FGB was recognized as a national foundation according to Italian law.**

## MISSION AND GOALS

The main aim of FGB is **to promote clinical therapeutic innovation in oncology** by:

- △ integrating preclinical, translational and clinical research
- △ acting as a hub for the academia and pharmaceutical industry
- △ promoting advanced courses and fellowships to train new generations of physicians in clinical and translational oncology

## FACILITIES AND EXPERTISE

FGB counts on **key facilities and expertise to:**

- △ scout for innovation in clinical oncology
- △ move pre-clinical opportunities to clinic (CTA/IND/IMPD)
- △ design and conduct phase I clinical trials
- △ interact with regulatory authorities worldwide
- △ deal with different research proposals including cellular therapies
- △ partner with research laboratories and conduct translational studies

# SCOUTING FOR NEW DRUG ENTITIES

FGB **conducts scouting for new oncology drugs**, through:

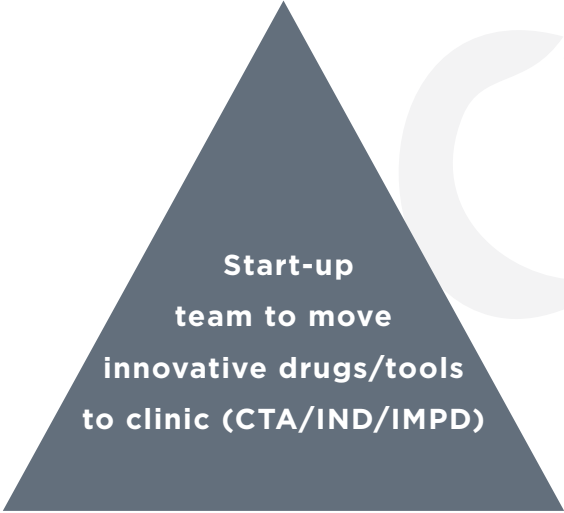
- △ assessment of patented or to-be-patented new entities from academic research laboratories;
- △ partnerships with small pharmaceutical biotechnology companies
- △ Conduct/design laboratory studies to re-purpose existing drugs from other indication or non oncology field

**Scouting and  
partnering for  
innovation in drugs,  
assays and devices**

# PRECLINICAL INDUSTRIAL DEVELOPMENT

The **FGB-associated biotechnology startup team** is able to provide:

- △ support in rising seed funding and early clinical development funding
- △ know-how for assembling CTA/IND/IMPD package for phase I trial in accordance with international regulatory requirements
- △ management of industrial production process, including **GMP products**
- △ submission of CTA/IND/IMPD package to Health Authorities
- △ legal support for **intellectual property management**



**Start-up  
team to move  
innovative drugs/tools  
to clinic (CTA/IND/IMPD)**



# CONCERTED RESEARCH INSTITUTE

- △ To promote and conduct the research activities, FGB has launched a **Concerted Research Institute (CRI)**
- △ CRI conducts innovative **independent oncology research** by coordinating clinical and preclinical scientists from **a small core group of cancer centers in Europe**
- △ **A broader clinical network** can join the core network whenever large cohorts of patients are needed to conduct/complete trial(s)

**Concerted Research  
Institute to design,  
conduct and report  
early phase  
clinical trials**

# CLINICAL OPERATIONS MANAGEMENT

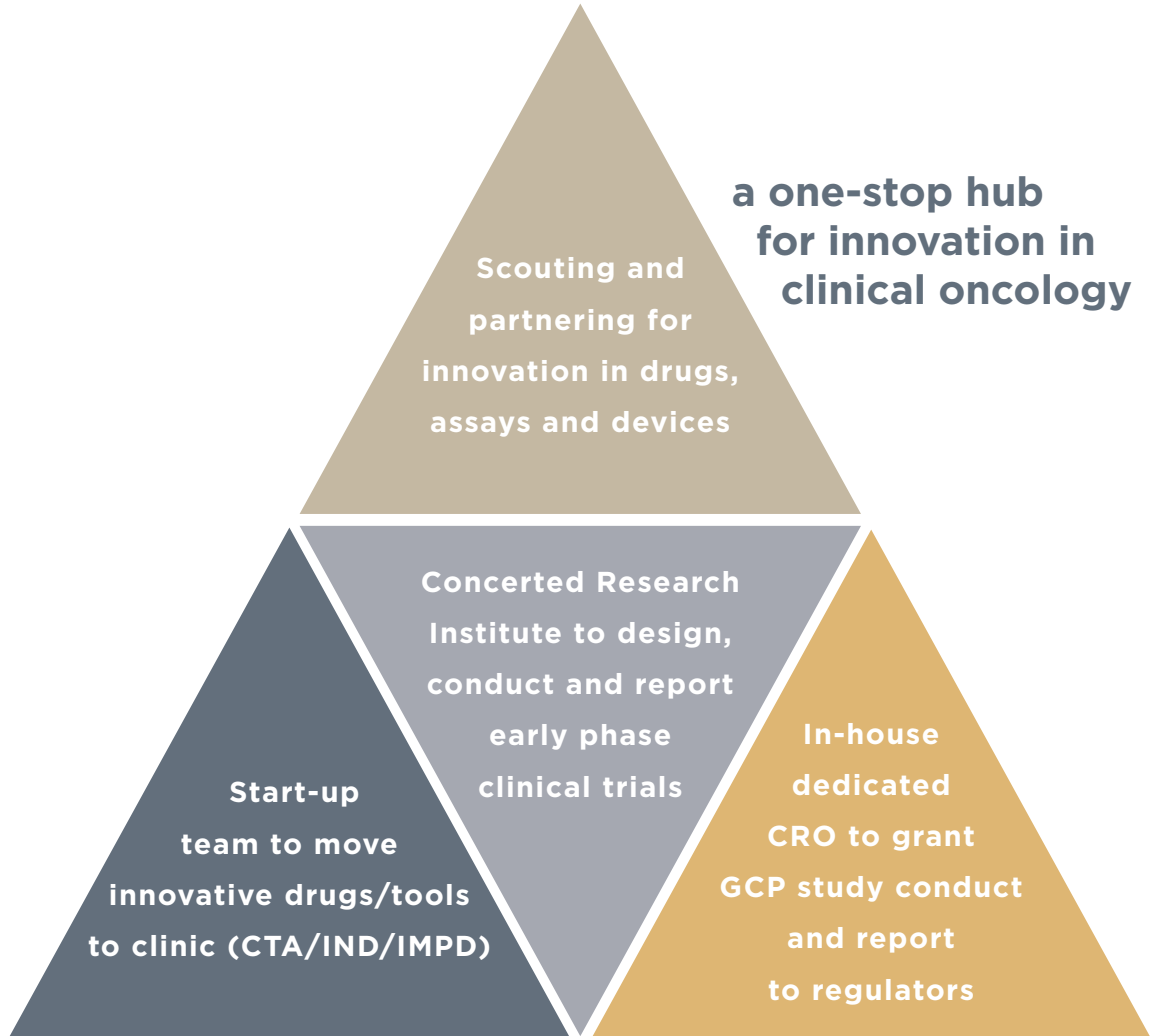
Clinical Operations of **FGB** and of the **CRI** are conducted by **Michelangelo Tech**, a certified **Clinical Research Organization (CRO)** owned by **Fondazione Michelangelo**, which:



- △ has decades-long experience in conducting phase I to III clinical trials
- △ provides all types of service for the implementation and conduct of clinical trials approved by the Boards of the Foundations
- △ works exclusively for studies promoted or approved by FGB and Fondazione Michelangelo

In-house  
dedicated  
CRO to grant  
GCP study conduct  
and report  
to regulators

## FGB AT A GLANCE







## PRADA Group

SUPPORTING PARTNER

Legal and operative office:

Via Agostino Bertani, 14 - 20154 Milan - ITALY

Fiscal code: 97777290152

Tel. +39 02 870864.20

Fax +39 02 87086449

E-mail: [segreteria@fgb-inst.org](mailto:segreteria@fgb-inst.org)

[www.fondazionebonadonna.org](http://www.fondazionebonadonna.org)