



# CLINICAL RESEARCH PLATFORM (CLB)

## Expertise

- Clinical project development
- Recognized Early Phases Center in oncology for adult and pediatric patients (French NCI (INCa) accreditation)
- Phase I dedicated team
- Partnerships : pharmaceutical companies, national and European collaborative groups
- Funding request
- Biostatistics
- Health economics
- QA ISO-9001 certification in 2013, renewed in 2016

## Applications

- Investigation: all phases studies
- Sponsoring: early phase trials, personalized medicine, randomized phases II and III trials
- Data-management
- Biostatistics : prognostic and predictive marker analysis, optimization of experimental plans in oncology, big data analysis and identification of prognostic biomarkers and building prognostic scores, real-world data
- Health economics : cost-effectiveness and budget impact analyses of innovations in health care

The aim of this comprehensive infrastructure is to **develop and conduct high quality clinical trials**, through strong collaborations with medical, basic and transfer research teams. Over the past 30 years, the clinical research platform has provided clinicians and researchers with **a strong support and a recognized expertise in clinical research**. More than 20% of CLB patients (i.e., about 2,000 patients per year) are included in clinical trials and more than 200 studies are conducted each year at the CLB. Clinical research is structured and professionalized with more than 80 collaborators trained in ICH-GCP and dedicated to the activity.

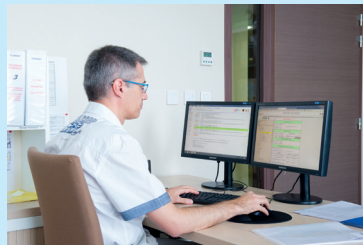
### Our expertise is recognized by partners:

#### From pharmaceutical companies (big-pharma and biotechs):

- We were selected as an immunotherapy Center of Research Excellence by Roche / Genentech (ImCore 21 CCC worldwide) and BMS (GECI network).
- More than 30 ongoing Investigator-Initiated Studies are being developed with pharmaceutical companies.

#### From French NCI and Health authority, AFNOR:

- We were selected as Data-Management Center, Early Phase center by French NCI (INCA), Clinical Research Center (French Health Office).
- We are certified ISO 9001 since 2013.



Photos: ©Marie-Laure LUCA

### Investigation activity

#### Our missions are to conduct and manage clinical studies:

- On site trial organization
- Patient recruitment
- Medical follow-up
- Investigational Medicinal Product dispensation
- Clinical data collection
- Bio-specimen collection

### Strength: Phase I Unit, Philippe Cassier, MD, PhD, Head

- Team: dedicated clinicians, clinical research nurses and clinical research associates
- 10 phase I beds, including 4-day hospital beds
- ≈ 30 ongoing trials per year, ≈ 125 patients enrolled/year
- Fast track procedure for study initiation : 30 days after internal approval (on site study review committee)
- Average time from site activation to first patient inclusion ≈ 28 days



## Access details

- CLB/CRCL researchers and clinicians
- Collaborative groups
- Industrials and academic partners
- Clinical projects at all phases

## Mention us in your publications!

To allow our platform to pursue its objectives, we need you to mention our work in your publications as follows:

**Direction de la Recherche Clinique et de l'innovation, Centre Léon Bérard, Lyon, France**

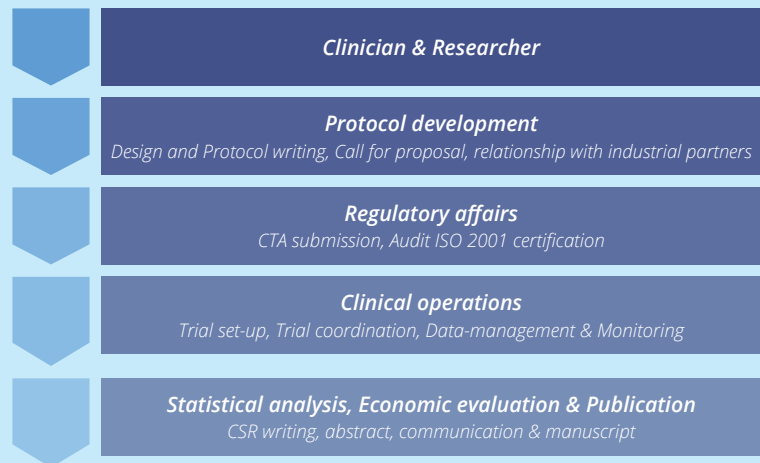


## Contacts

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## Sponsoring activity - Project workflow



### David Perol, MD

– Head

*David PEROL is the head of the Clinical Research Department of the CLB. He obtained his medical degree with a specialization in Epidemiology and Public Health. He has a methodological and statistical expertise in the field of innovative clinical trial designs in oncology.*



### Gwenaële Garin, PhD

– Head, Early Phase Unit, sponsorship

*Gwenaële Garin has a Bachelor's degree and a PhD in Molecular and Cell Biology. Within the Sponsorship unit, Gwenaële coordinates the team dedicated to early phase studies which aim is to support medical oncologists and researchers in their protocol development, study implementation /management and result valorization.*



### Sylvie Chabaud, MsC

– Head, Biostatistics and data-management

*Sylvie Chabaud, obtained her Master's degree in Analysis and Modeling of biological systems. Since 2005, she is the Head of biostatistics unit within the Clinical research platform of CLB, and is in charge of statistical analysis of phase I to III multicentric clinical trials in oncology.*



### Lionel Perrier, PhD, HDR

– Head, Innovations and strategies unit

*Lionel Perrier, obtained his PhD in Economics and his Accreditation to supervise research (HDR). Since 2015, he is the head of the Innovations and Strategies unit, member of the GATE Lyon Saint-Etienne (UMR CNRS-5824) and of the economic evaluation and public health Commission of the French National Authority for Health (HAS), he has an extensive experience in economic evaluations and project management.*

Submission form and more infos:

[www.cancer-research-lyon.com](http://www.cancer-research-lyon.com)