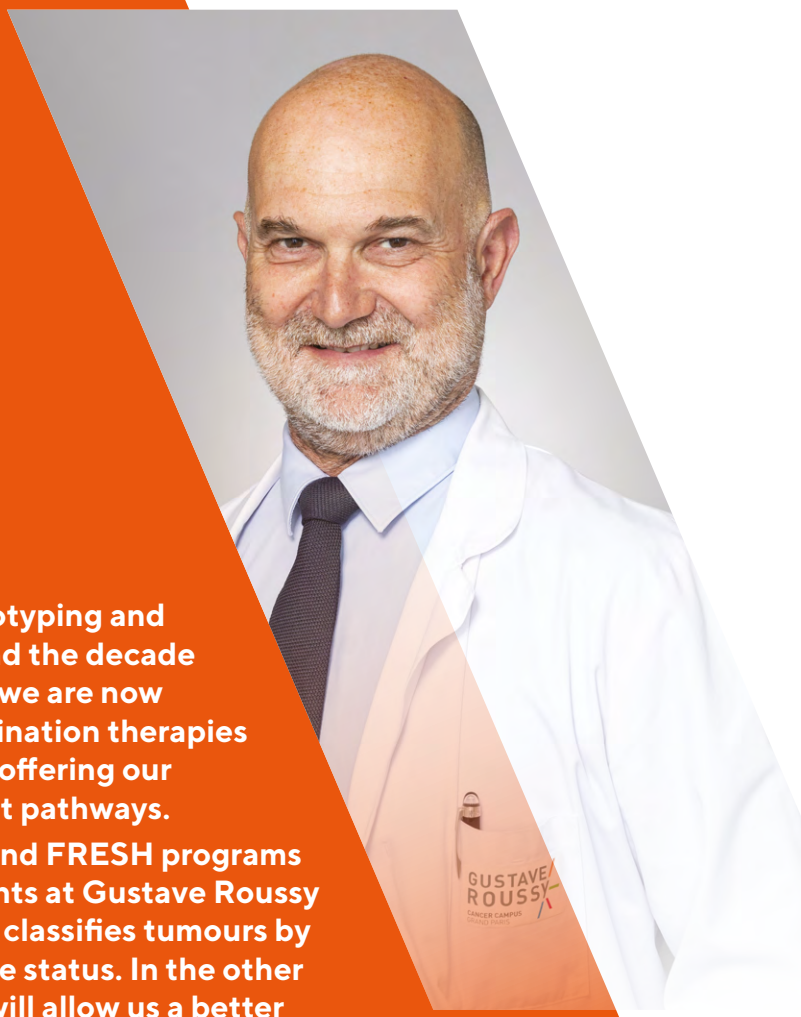
# INNOVATIVE RESEARCH AT **Gustave Roussy,** France

An exploratory clinical research platform

GUSTAVE ROUSSY
CANCER CAMPUS
GRAND PARIS

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**"Following the decade of genotyping and targeted therapies in 2000 and the decade of immuno-oncology in 2010, we are now entering the era of drug combination therapies and ultra-individualisation by offering our patients customised treatment pathways.**

**In one hand, with our PRISM and FRESH programs we want to offer to each patients at Gustave Roussy a true precision medicine that classifies tumours by biology, molecular and immune status. In the other hand, the UNLOCK program will allow us a better understanding of the mode of action of new drugs and our ambition is to better understand how medicines and our treatments work and also their resistance from early trials onward.**

**To strengthen its clinical research capabilities, Gustave Roussy has set up an unprecedented organisation dedicated to clinical research in early clinical trials in order to offer new hope and opportunity for patients."**

# Prof. Fabrice Barlesi

*CEO, Gustave Roussy*

# ALL CANCERS, ALL STAGES, ALL AGES


*"Among the numerous assets of the Clinical Research Platform, Gustave Roussy stands out through its comprehensive expertise, both scientific and clinical, across all types of cancer. Gustave Roussy's Highly Cited Researchers and Key Opinion Leaders are instrumental in the development of new therapies, from Phase I through Phase III, transforming early clinical trials (phase I and I/II) into standards of care and shaping international guidelines."*

**Prof. Laurence Albiges,**
*Head of the Medical Oncology Department*

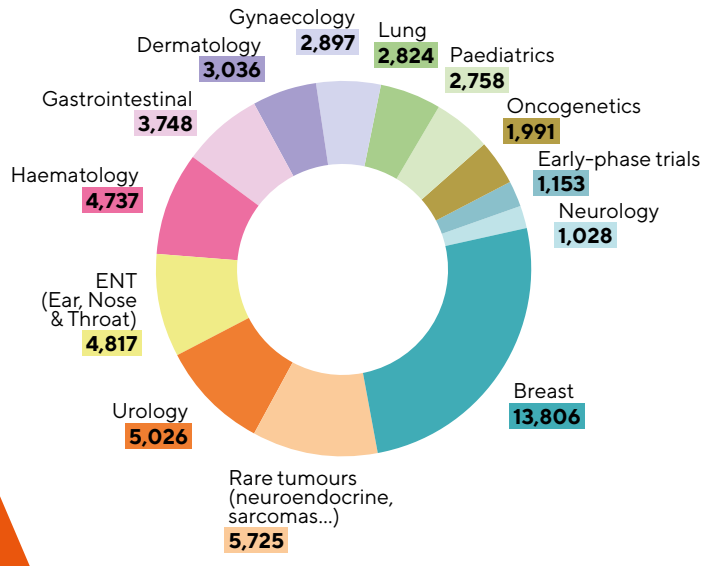
*"Our mission is to integrate clinical research activities for studies that require close monitoring and/or involve complex protocol procedures in a single, specially designated area. Our multidisciplinary clinical research platform offers greater patient safety, better quality, better capacity, and innovative early clinical trials."*

**Prof. Benjamin Besse,**
*Director of clinical research*

*"The aim of the clinical research platform is to facilitate a smooth transition from Phase 1 to Phase 3, via Phase 1/2 or Phase 2, and to support our industrial partners in the development of new therapies for patients with solid or haematological cancers, in close collaboration with the research teams at Gustave Roussy and IHU."*

**Prof. Christophe Le Tourneau,**
*Deputy Director of Clinical Research, Deputy General Director of the National Center for Precision Medicine in Oncology PRISM*

## NUMBER OF PATIENTS SEEN AT GUSTAVE ROUSSY BY CANCER TYPE (2025)




## GUSTAVE ROUSSY CARE IN NUMBERS (2025)

**600** beds

**354,000** medical consultations, including **17,000** in paediatrics

**139,000** recorded stays
(full hospitalization, day hospitalization, chemotherapy and radiotherapy sessions)

**54,300** patients monitored, including **2,700** in paediatrics

**26,490** new patients, including **587** paediatric cases

# GUSTAVE ROUSSY: A Clinical Research Success Story

*"At Gustave Roussy, we provide a seamless clinical research continuum from preclinical studies to Phases I, II and III, and market approval in better controlled timelines. Linking clinical and scientific facilities to expert's resources ensures successful management of innovative drug development outcomes."*

**Prof. Yohann Loriot**
*Medical Oncologist, Deputy Head of DITEP (Innovative Therapies and Early Trials Department), coordinator of the UNLOCK program*

## Gustave Roussy Organizational Assets

- → DITEP: Broad access to innovative molecules and multiple mechanisms of action, and clinical expertise.
- → Cutting-edge medico-scientific clinical research facilities.
- → Sequential biopsies performed in advanced interventional radiology platform.
- → High-tech biological platforms: technology-driven analysis and expert interpretation.

## Guiding Drug Development: Two examples of Successful Case Studies

### ERDAFITINIB

*"On January 19, 2024, the Food and Drug Administration approved erdafitinib (Balversa, Janssen Biotech) for adult patients with locally advanced or metastatic urothelial carcinoma (mUC) with susceptible FGFR3 genetic alterations, as determined by an FDA-approved companion diagnostic test, whose disease has progressed on or after at least one line of prior systemic therapy."*

Soon after, erdafitinib was approved by the European Medical Agency in August 2024 for the same indications. The achievement of a research "odyssey".

- → Initially developed as anti-angiogenic molecule, erdafitinib was imbalanced by its Phase I toxicity and an unclear mechanism of action as only few patients respond to the treatment.
- → Analyses of tumor biopsies in MOSCATO trial identified somatic fusion/mutation of FGFR 2/3 genes in responding patients.
- → Following the Expert Boards recommendation to Janssen, to revise the development plan of the molecule and target patients carrying these mutations. This strategy was confirmed by the phase II trial targeting patient with Urothelial carcinoma.
- → This phase II trial funded FDA conditional approval in unresectable metastatic tumor, and afterwards EMA approvals.
- → In recent phase III trials erdafitinib has been demonstrated superiority over chemotherapy in the same indication.

### DAROLUTAMIDE

This direct inhibitor of androgen receptors has been tested in phase I-III trials, mostly at Gustave Roussy. Now approved in France, darolutamide's development plan illustrates the agile continuum of Gustave Roussy's robust research platform from early-to-late clinical phases.

# CUTTING-EDGE CONTINUUM in Onco-Hematology Research

*"The AGILE phase III study illustrates the research continuum in Gustave Roussy with a first-in-class molecule, ivosidenib, an inhibitor of the IDH1 and 2 enzyme."*

**Dr. Stéphane de Botton**
*Medical Oncologist, Head of the Haematology Department*

- Somatic mutations in the gene encoding IDH1 occur in 6 to 10% of patients with acute myeloid leukemia. Mutant IDH1 catalyzes a disruption in cellular metabolism and epigenetic regulation, contributing to oncogenesis.
- The mechanism of action of ivosidenib has been explored in ex vivo preclinical cellular and animal models in Gustave Roussy collaborative biotechnical platform (Inserm Unit UMR 1170). Once the impact on mutated IDH1 cells has been demonstrated, several phase I clinical trials followed with clinical activity in selected patients with mutated acute myeloid leukemia in monotherapy or combination.

Results led FDA to approve ivosidenib for adults with relapsed or refractory IDH1-mutated acute myeloid leukemia or newly diagnosed IDH1- mutated acute myeloid leukemia who are 75 years of age or older or with coexisting conditions that preclude intensive chemotherapy.

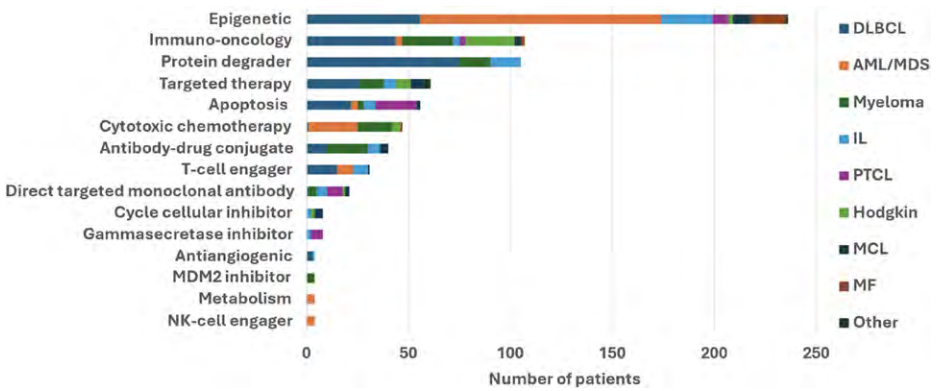
- It involved a randomized multicentric phase III trial AGILE published in NEJM (2022): median event-free survival 22.9 months (95% CI, 7.5 to could not be estimated) with ivosidenib and azacitidine and 4.1 months (95% CI, 2.7 to 6.8) with placebo and azacitidine.

## What we did

- Biomarker identification
- Mechanism of action of the molecule (Inserm preclinical platform)
- Early and late clinical trials

**Evolution of the number of patients with haematological cancer over the last 15 years**

| | 2010 | 2025 |
|---|---|---|
| **New cases** | 599 | 1,033 **+ 72,4 %** |
| **Conventionel hospitalization** | 1,230 | 986 **- 19,8 %** |
| **Active file** | 2,936 | 4,736 **+ 56,0%** |
| **Autologous BMT** | 82 | 155 **+ 61,3 %** |
| **Allogeneic BMT CAR-T cells** | 43<br>0 | 86, **+ 50,0 %**<br>31, **N/A** |
| **EDD (patients)** | 25 | 71 **+ 184,0 %** |
| **Clinical trials EDD** | 5 | 26 **+ 420,0 %** |




*Matteo Guerra, Emily Alouani, Thomas Hueso et al. Relevance, Risks, and Benefits of Early-Phases Clinical Trials Participations for Patients With Hematological Malignancies From 2008 to 2023. European Journal of Haematology, 2025; 114:89–97- https://doi.org/10.1111/ejh.14307*

# A NOVEL CLINICAL RESEARCH PLATFORM

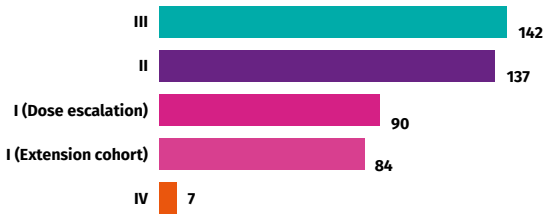
*"Our innovative clinical research platform is expanding its capacity for early-phase I and II trials, based on a strong integration with translational research teams. The objective is to access new drugs and new therapies for adult patients with solid tumors or hematological cancers."*

**Prof. Christophe Massard**
*Head of the Department of Therapeutic Innovation and Early Phase Trials (DITEP)*

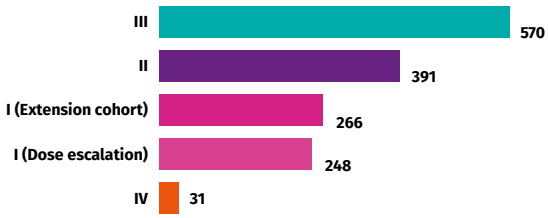
## A significant research activity

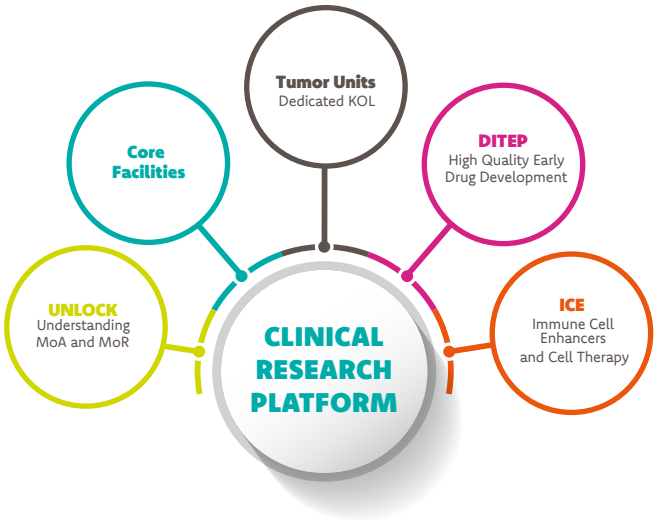
In 2025, a total of 7505 patients were enrolled in 618 clinical trials, including 466 in early-phase studies.

**2025 research distribution by phase**




**Distribution of 2025 inclusions by phase**




## Tumor biopsies

- 15 biopsies slot per week - 60 per month.
- Over 700 tumor biopsies performed in early-phase clinical trial patients in 2025.
- More than 1,000 biopsies conducted in 2025 Phase II and III trials at Gustave Roussy.

## Fast track

**OBJECTIVE**

Site initiation visit-Clinical trial protocol as soon as possible after regulatory approvals.

**ELIGIBILITY CRITERIAS**

- Phases I/First-in-Human
- Dose escalation
- CROs/responsive manufacturers
- Mutual commitment

**BENEFITS**

- Shorter lead times
- Attractiveness to developers
- Smooth and collaborative organization

SIV ASAP or in 2 weeks after Health Authority approvals

**Single contact: Aline LAGACHE, aline.lagache@gustaveroussy.fr**

**Operational Organization:**
" Fast Track " designation for all transactions
Dedicated time slots increased flexibility
Dedicated team: ARC appointed in advance
Project manager, CDP Anticipation contact

# DRUG DEVELOPMENT DEPARTMENT – DITEP

## DITEP is the largest Phase I clinical trial center in France and one of the largest in Europe, with national accreditations including ARS, CLIP², INCa, and ISO9001.

The department maintains close links with all Gustave Roussy organ-specific committees (with DITEP physicians holding dual appointments), as well as with a national network of referring oncology specialists. This structure enables innovative trials to patients with frequent cancer subtypes exhibiting specific molecular abnormalities or rare cancers with unmet medical needs.

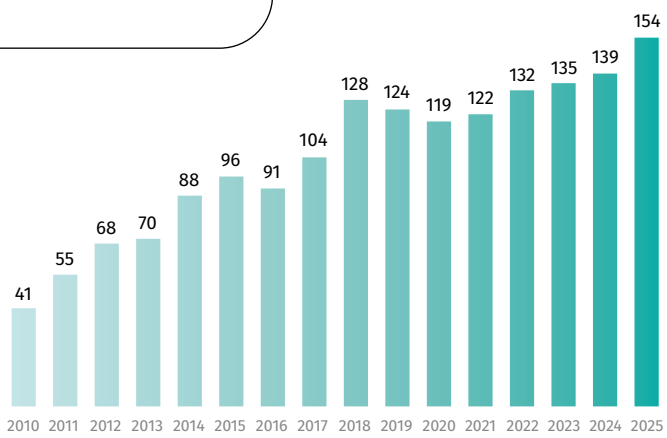
## Medical Team

The team comprises of 25 MDs/MD-PhDs with dual expertise across a wide range of specialties, including thoracic, gastro-intestinal, gynaecological, head and neck, genito-urinary, breast, central nervous system cancers, melanoma, haematology diseases, and also rare cancers such as sarcomas or neuroendrocrine tumors.

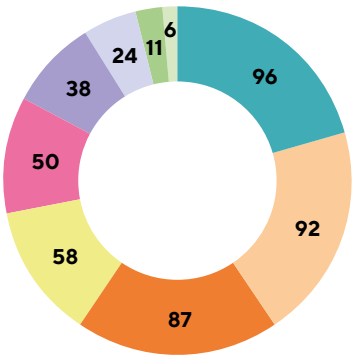
## Facilities

- → Inpatient unit: 11 single-occupancy patient beds for weekly hospitalization.
- → Outpatient day-care unit: 11 treatments chairs.
- → Dedicated clinical operations unit.
- → More than 150 early clinical trials running in 2025.

**Yearly number of ongoing early clinical trials**




**Number of patients enrolled in early clinical trials at Gustave Roussy by cancer type (2025)**




**In 2025, 466 patients with various types of cancer were treated in early-phase clinical trials.**

- Thorax
- Gynaecology
- Urology
- Haematology
- ENT (Ear, Nose & Troat)
- Breast
- Sarcomas
- Melanomas

## DITEP Main Activities and Clinical team in hematology

**FROM SEPT 2009 TO JAN 2026**

**Clinical Trials: 93**

**Not open yet: 9**

**More than 830 patiens with Haematologic diseases treated**

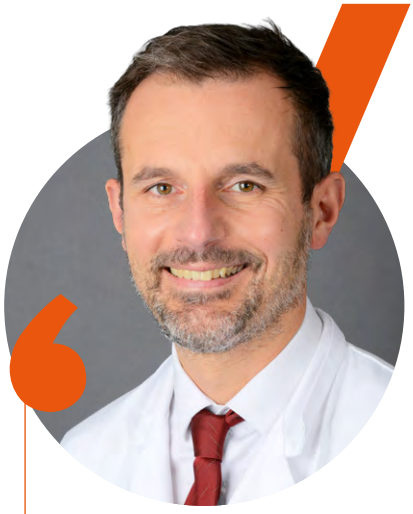
**Haematology Clinical Team**
→ Dr Vincent Ribrag

**Lymphoid malignancies**
→ Dr Jean-Marie Michot
→ Dr Thomas Hueso

**Myeloïd malignancies**
→ Dr Stéphane De Botton

A CUTTING-EDGE PLATFORM FOR RELIABLE RESULTS

# PRECISION ONCOLOGY PROGRAM

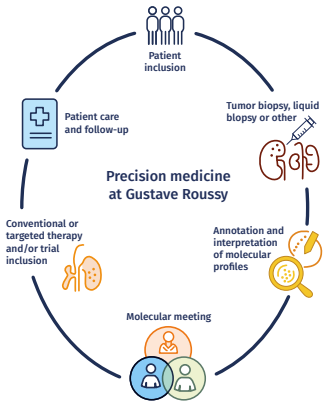


*"High-throughput tumor profiling is a cornerstone of modern oncology. By integrating tissue biopsy, liquid biopsy and expert molecular interpretation within the IHU PRISM ecosystem, we can better match each patient to the most appropriate therapeutic strategy and clinical trial."*

**Prof. Antoine ITALIANO**
*Medical Oncologist, Professor of Medicine DITEP – Phase I trials, Precision Medicine Programme*

## Genomic profiling is a cornerstone of our clinical practice, enabling therapeutic decisions and access to early-phase trials to be guided by the molecular characteristics of each tumor.

At Gustave Roussy, Prof. Antoine Italiano contributes to the development of precision medicine within DITEP and the IHU PRISM ecosystem, with a particular focus on sarcomas, rare tumors, and the integration of tissue and liquid biopsy into routine care and translational research. As Chair of the Molecular Tumor Board, he plays a central role in interpreting complex molecular findings and translating them into personalized therapeutic strategies.



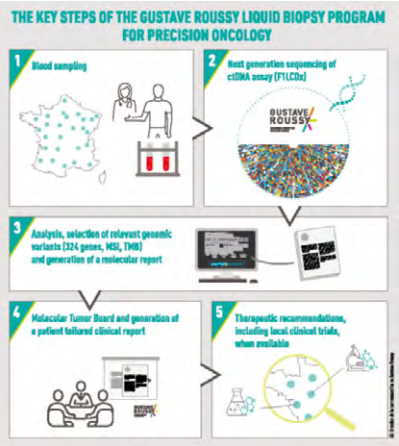

Through programs such as STING, in close interaction with FRESH for ctDNA profiling and with national genomic initiatives, patients with advanced solid tumors can access comprehensive molecular characterization, supporting state-of-the-art diagnostics and personalized treatment opportunities.

## A major institutional driver of precision oncology, integrating molecular profiling, liquid biopsy, clinical decision support and translational research.

- **High biopsy volume:** Over 6,000 image-guided tumor biopsies are performed here annually, reflecting the depth of our expertise.
- **Advanced IR Suite:** A state-of-the-art IR suite featuring three dedicated procedure rooms, including a hybrid room that combines robotic 3D angiography with a multi-detector CT-scanner enhanced by artificial intelligence, ensuring unparalleled precision.
- **Minimally Invasive Precision:** These advanced capabilities allow our specialists to obtain high-quality tissue samples from complex tumors in a real-time, image-guided, and minimally invasive manner, enhancing both patient safety and comfort.

# FRESH (French Hub for Liquid Biopsy)

**The FRESH platform is a major component of Gustave Roussy's liquid biopsy strategy and fully aligns with the missions of IHU PRISM, the national center for precision medicine in oncology. Based on ctDNA analysis from blood samples, it provides a non-invasive approach to tumor profiling, expands access to precision medicine, and supports real-time molecular monitoring for treatment selection and clinical trial orientation.**




Launched in July 2024, FRESH now operates through a national network of referring centers, with a capacity of more than 8,000 tests per year. Results are reviewed in weekly molecular tumor board meetings to translate genomic findings into personalized treatment options and clinical trial opportunities.

In its first year, the program enabled more than 5,000 patients with metastatic cancer to access genomic profiling, across more than 30 referring centers in mainland and overseas France, with an average turnaround time of 13.3 days.

# Our Validated Pioneering Research Strategy

## STING Precision Medicine Study

Lead by Prof. Antoine Italiano, the STING precision medicine study is one of the core clinical-translational pillars of our precision oncology strategy. In synergy with IHU PRISM, STING supports large-scale molecular profiling, biomarker discovery, and the identification of resistance mechanisms, while creating opportunities for translational and industrial research collaborations.

### Key Supporting Studies

- **MOSCATO-01:** Demonstrated the feasibility and clinical benefit of systematic molecular profiling in patients with limited treatment options, significantly improving outcomes through matched therapies.
- **MATCH-R:** Further showed that serial tumor biopsies at relapse can uncover resistance mechanisms and guide subsequent treatment choices.

# UNLOCK PROGRAM
## to understand mechanisms of action and resistance to innovative drugs

*"Elucidating the mechanisms of action of innovative therapies can reduce approval delay, identify optimal indications, and guide therapeutic strategies in collaboration with multidisciplinary experts. At Gustave Roussy, we offer a fully comprehensive bioclinical approach designed to streamline drug development and ensure faster access to innovation for patients."*

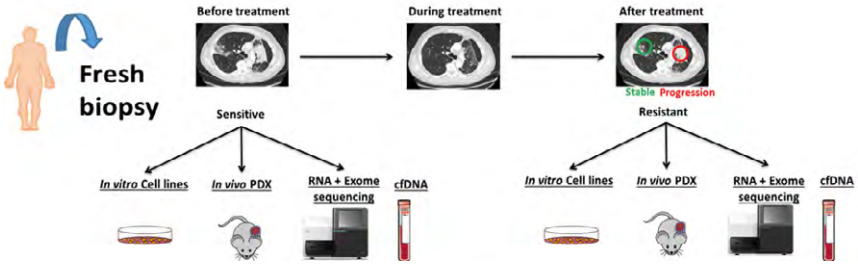
**Prof. Yohann Loriot**
*Medical Oncologist, Deputy Head of DITEP (Innovative Therapies and Early Trials Department), coordinator of the UNLOCK program*

The UNLOCK program bridges clinical and fundamental research by enrolling homogenous patient cohorts treated with innovative therapies in early-phase trials.

These patients are undergo sequential solid tumor biopsies: before treatment, during therapy, and after its completion in early phase trials.

## A Multidisciplinary Analysis by Experts

- → Radiomics, pathology, and clinical research coordination.
- → Advanced translational investigations, such as WES, RNA seq, cfDNA, scRNA seq, CTC, PDX, spatial transcriptomics, immuno-PET, cytoff...
- → Bio-informatics and data science analyses.
- → Access to national and international experts from Gustave Roussy across disciplines.



# Expected Outcomes of the UNLOCK Program in Elucidating Mechanisms of Action of Innovative Therapies

- → Identify new therapeutic targets.
- → Identify patients most likely to benefit from a treatment.
- → Design novel or unexpected treatment combinations based on solid biological knowledge.
- → Expand indications for promising therapies.
- → Accelerate patient access to innovative active molecules.

## UNLOCK scientific program

### PHASE I TRIALS

Very innovative drugs

Proof of concept
(5-10 patients)

Provide data to support phase II trial

### DEDICATED PHASE II TRIALS

Innovative drugs or recently approved drugs

Larger sample size
(50-80 patients)

Multicenter study

### INNOVATIVE DRUGS ASSESSED IN UNLOCK

| | Antibody drugs conjugates | T-cell engagers/ CAR T-cells | undruggable targets (e.g.,KRAS, TP53) | Radioligands | Epigenetic drugs |
|---|---|---|---|---|---|
| **Example of questions** | Spatial target heterogeneity Antibody trafficking | Spatial proximity of T-cells/cancer cells | Early alternative cell signaling activation | Intratumor uptake DDR activation | Clonal evolution Immune cells adaptation |
| **Example of phase II cohorts** | **DAISY trial** (NCT04132960) (F. Mosele) | **PIONEER trial** (NCT05481502) (C. Bigenwald) | **CODEBREAK trial** (NCT05481502) (M. Aldea) | **PSMA-UNLOCK** (A. Bernard) | **VENETO-UNLOCK** (S. de Botton) |

UNLOCK BY GUSTAVE ROUSSY

PRISM

UNLOCK, a flagship program of PRISM institute. PRISM institute, a large multidisciplinary national institute dedicated to the advancement and implementation of precision oncology across various types of cancer, co-founded by Gustave Roussy, INSERM, Université Paris Saclay, CentraleSupélec School of Engineering, and UNICANCER.

# THE ICE PROGRAM

*"ICE provides a clinically ready environment to accelerate the development of next-generation immunotherapies, with fast-track protocol implementation and collaborations to investigate mechanisms of action and resistance."*

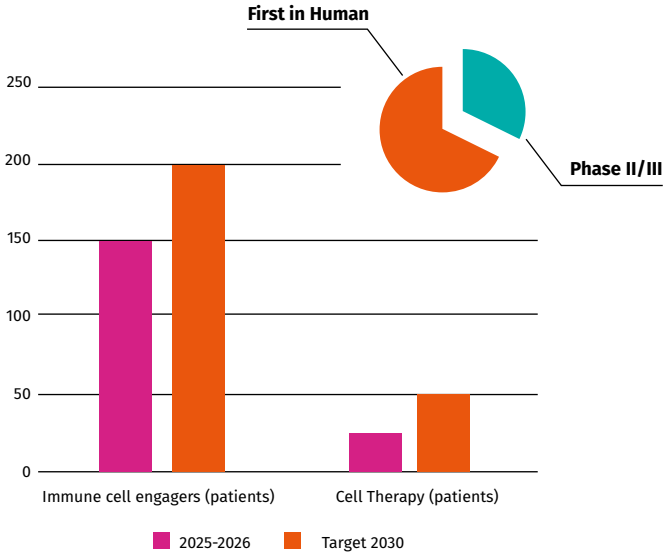
**Dr. Ronan Flippot**
*Medical Oncologist*

**Dr. François-Xavier Danlos**
*Clinical Chief, Translational Research Laboratory in Immunotherapy*

## The ICE (Immune Cell Enhancers) Program

A strategic, multidisciplinary initiative designed to support the emergence of next-generation targeted immunotherapies for both haematological malignancies and solid tumors, including notably:

- Immune cell engagers, including bispecific antibodies and other targeted immune activators.
- Cell therapies, such as CAR-T cells, tumor-infiltrating lymphocytes, and other immune cell-based compounds.




## The ICE Clinical Unit

An integrated organisational model designed to address the specific challenges of novel immunotherapies. Its expertise is grounded through the treatment of over 100 patients treated each year:

- Dedicated beds and patient pathways in the inpatient and outpatient settings.
- Refined patient care by trained physicians with dual expertise in drug development and organ-specific oncology.
- Management of immune-related toxicities (cytokine release syndrome, neurotoxicity, autoimmune manifestations) with a coordinated involvement of our mobile immunotoxicity team and intensive care department.

**NURSE NAVIGATION**
Dedicated patient pathway

**MOBILE ITOX TEAM**
Multidisciplinary toxicity evaluation and management

### ICE inpatient unit

**Immune cell enhancers for heme and solid malignancies**

Continuous patient monitoring
Dedicated nurse and medical team

**INTENSIVE CARE UNIT**
High-dose cytokines
Adverse event management

# BIOTHERIS PROGRAM

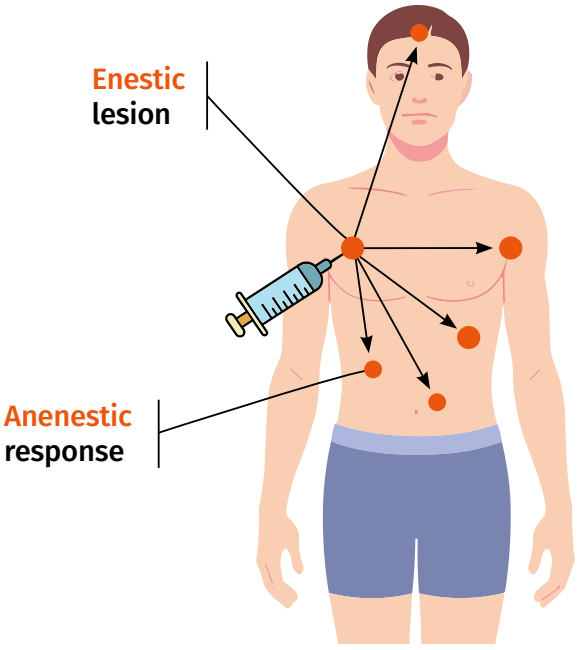
# Intratumoral Immunotherapy and Innovative Biotherapies

BIOTHERIS is a clinical investigation center dedicated to the development of innovative biotherapies, with a major focus on cancer immunotherapy. Operating under the joint supervision of Inserm, DGOS and Gustave Roussy – University Paris-Saclay, and renewed until 2030, it is a unique structure whose mission is to accelerate the evaluation and implementation of new in situ therapeutic strategies. The center conducts both industrial and academic clinical trials, with recognized expertise in the intratumoral administration of biotherapies. This approach aims to optimize local treatment efficacy while reducing systemic side effects. Clinical activities cover the entire therapeutic development pathway, from first-in-human (FIH – Phase I) studies to Phase III trials, as well as standards of care and compassionate access programs.

*"Within the BIOTHERIS, our weekly dedicated multidisciplinary tumor board is far more than a formal meeting. It is a strategic, collaborative forum where clinical teams, researchers, and interventional specialists come together to rigorously evaluate patient cases and define the most innovative, safe, and personalized therapeutic approaches. This collective intelligence is central to accelerating the development of next-generation biotherapies and ensuring that each patient benefits from cutting-edge treatment strategies."*

**Prof. Lambros TSELIKAS**
*Director of the Clinical Investigation Center BIOTHERIS, Interventional radiologist Department of Anaesthesia, Surgery and Interventional Radiology*

## Enestic (injected) vs Anenestic (non-injected)




## Research Areas

- Oncolytic viruses
- Therapeutic mRNA vaccines
- Monoclonal antibodies
- Immunomodulatory agents
- Study of intratumoral immune responses
- Innovative technologies to enhance therapeutic efficacy

## Key Figures (2017–2025)

- 30 trials conducted (2017–2025), including 24 currently running
- >1,000 injections
- 265 patients
- 285 multidisciplinary HIT-IT tumor boards

# THE DITEP Radiation Therapy Alliance in Early Phases

*"Innovative drugs rarely act through a single, universal cellular mechanism of action. Our pan-tumoral approach is built on a robust alliance with DITEP, combining radiation and clinical research expertise. We focus on the integration of immunotherapy with high tech cellular biology, leveraging our high-performance radiology platform to enable precise sequential biopsies."*

**Prof. Eric Deutsch**
*Radiation Oncologist, Head of Radiation Oncology Department, Director of the joint research unit INSERM U1030 "Molecular Radiotherapy and Therapeutic Innovations"*

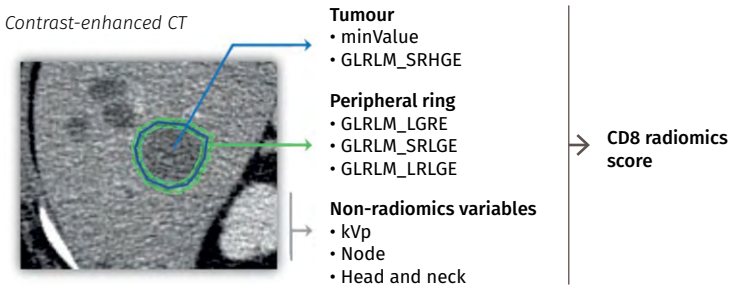
## First in Preclinical

The joint research unit Inserm U1030 "Molecular Radiotherapy and Therapeutic Innovations" has pioneered high-impact preclinical research in radiobiology, immunotherapy, biomarkers, and radiomics as applied to radiotherapy.

→ Elucidating interactions between tumors and their microenvironment leads to personalized treatment approaches that enhance efficacy.

→ Comprehensive biological ultra-characterization of patient and their tumor (immunity escaping, hypoxia, DNA repair, etc.), is performed before, during and after treatment to distinguish responders from non-responders, and shed light on resistance mechanisms.

→ Selected patients biological subgroups guide new therapeutic indications.




## Early and Late Clinical Trials

Secondary lesions in patients with advanced cancer can be precisely targeted through external radiation therapy or interventional radioligands therapy, combined, with or without immunotherapy combinations.

→ Ultra-high-dose rate radiotherapy – Flash RT.

→ Spatial fractionation.

→ Mini-beam therapy.

→ Nano-agents: use of metallic nanoparticles.

In clinical Phase I to III, patient's bio clinical clues are investigated: radiomics, liquid biopsies, blood biomarkers, tracking treatment resistance.

## Radiomics for Pathology Driven Radiotherapy

In patients with metastatic advanced cancers, genomic diversity needs an exact feature of secondary lesions. Beyond tumor biopsies, Radiomics and fine imaging play a key role in completing tumor characterization.

Deciphering cellular spatial heterogeneity with repeated CTscan and radiomics are an opportunity to develop new biomarkers:

→ Prediction of CD8 T-cells using radiomics on contrast enhanced CT scans.

→ Unique radiomic biomarker for immunotherapies validated by several studies and centers.

# INNOVATIVE RADIOLIGAND THERAPY

**PRECLINICAL AND TRANSLATIONAL RESEARCH**

- Over 30 active projects focused on radiobiology, immunotherapy, and biomarkers.
- Development of radiosensitizers, nanoparticles, and innovative protocols, including FLASH, mini-beams, spatial and fractionation.

**Clinical Trials**

- Approximately 60 ongoing clinical trials involving radiotherapy, from Phase I to phase III.
- 15 early-stage trials conducted in direct collaboration with DITEP.
- Over 400 patients enrolled annually in innovative radiotherapy protocols.

**Imaging, Radiomics and Biomarkers**

- Integration of several thousand image sets into radiomics and artificial intelligence programs.
- Systematic collection of biological samples (blood, sequential biopsies) for multi-omic analyses and monitoring of treatment resistance.

**Clinical Capacity**

- 10 treatment devices available, including VMAT/LECTA, tomotherapy, CyberKnife, and the MRI-Linac (currently in installation).
- Nearly 60,000 radiotherapy sessions delivered annually.
- Approximately 6,000 patients treated each year in the Radiotherapy Department at Gustave Roussy.

***"In 2023, we established a dedicated Phase I – First-in-Human Unit in Nuclear Medicine, in close collaboration with the DITEP. A very important milestone lead, in January 2025, the first clinical phase I inclusion of patients undergoing an experimental therapeutic radioligand. This is a ground-breaking approach for metastatic cancers."***

**Prof. Désirée Deandreis**
*Nuclear Medicine Physician, Head of the Nuclear Medicine Department*

## Radioligands Therapy from Phase I to Phase III Clinical Trials

Phase I clinical trials in radioligand therapy remain significantly underdeveloped in France and across Europe, largely due to significant organizational and regulatory constraints.

In 2024, following official authorization, the first patient, diagnosed with metastatic breast cancer, was treated with [177Lu]Lu-NeoB, a radiopharmaceutical targeting the bombes in receptor, frequently overexpressed in various cancers, including breast cancer.

This achievement was made possible thanks to the specialized infrastructure and expertise developed at Gustave Roussy. The nuclear medicine division demonstrated its capability to ensure a safe pathway for both patients and healthcare professionals, maintain laboratories capable of handling radioligands, and to conduct precise dosimetry analyses for each administration. The team successfully met these challenges by establishing a comprehensive operational framework necessary to carry out these studies.

**NUCLEAR MEDICINE CLINICAL TRIALS SCHEDULED 2024-2025:**

- 13 clinical trials planned in 1 year.
- Across Phases I, II and III.

**A DEDICATED PLATFORM WITH:**

- Radiopharmacy facility.
- Imaging facility.

**TREATMENTS**

- Over 500 treatments per year across various cancers.
- More than 10,000 PET examinations annually, utilizing standard and innovative tracers.

# ENHANCING CLINICAL RESEARCH WITH ARTIFICIAL INTELLIGENCE (AI)

*"From the Klineo solution used website for inclusion requests to the running of Phase I clinical trials, AI supports the medical team in clinical research, by enhancing patient enrollment, improving data quality and documentation, assists medical decision making, helps anticipate screen failures, and aids in deciphering therapeutic mechanisms of action (in coordination with institutional programs such as UNLOCK and ICE).*

*We are currently developing agentic AI tools designed to further accelerate patient recruitment, automate trial matching, and reduce screen failure risk through intelligent pre-screening. In rare cancers, emerging AI-driven research programs aim to improve therapeutic strategies and help identify novel targets. Additionally, MEDITWIN stands as an institutional flagship program aimed at developing a digital twin for precision oncology within Gustave Roussy."*

**Dr. Julien Vibert**
*Assistant Professor in Medical Oncology, DITEP (Drug Development Department), Researcher in Computational Oncology*

**At the crossroads of precision medicine and state-of-the-art informatics, dedicated in-house AI algorithms optimize every step of the clinical research medical workflow. New agentic AI tools are being developed to accelerate patient-trial matching and pre-screening, while a large language model (LLM) tool is being built for Gustave Roussy in collaboration with Research units. Emerging programs also explore the potential of AI in rare cancers to improve treatment pathways and identify new therapeutic targets.**

PRISM

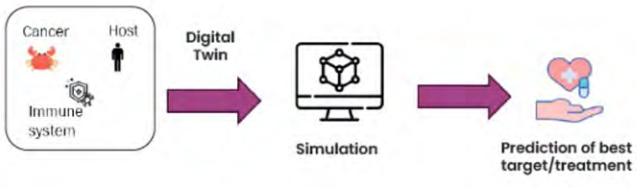
## Workflow optimization

- Extraction of data from Gustave Roussy patient files.
- Approximately 400,000 files.
- Database management, including optimization of data entry.
- Summarization of clinical notes.
- Automatic matching to clinical trials.
- Pilot mode within Klineo (website collecting nation-wide requests for clinical trials).
- Agentic AI tools under development for automated patient-trial matching and intelligent pre-screening to reduce screen failures.
- Emerging AI-driven research programs in rare cancers, exploring new therapeutic strategies and target discovery.

## MEDITWIN Program

This large-scale academic-industrial consortium, involving seven Hospital University Institutes, is dedicated to creating digital twins in oncology, cardiology and neurology. Gustave Roussy leads the Precision Medicine for Oncology initiative, in collaboration with IHU PRISM and Dassault Systèmes.

Aiming to develop a comprehensive digital twin of cancer, host and immunity, Meditwin modeling algorithms will integrate multiscale data, including clinical, biological, pathological and imaging. Trained on Gustave Roussy patient data, these models will allow in silico, personalized predictions of the most effective treatments and optimal targets for innovative drugs.



# PARTNERING WITH GUSTAVE ROUSSY to Shape the Future of Clinical Research

*"Through its industrial partnerships collaboration, Gustave Roussy provides expertise to co-develop asset strategies, while also enhancing support for innovative therapy clinical trials and delivering high-level medico-scientific guidance"*

**Dr. Edouard Dupis**
*Alliance & Partnership Manager, Clinical Research Expert*

1. CLINICAL OPERATIONS

## From Phase I to Phase III Trials, a Unique Expertise

*Direct contact with the Clinical Research Division Staff*

→ Facilitation of the Start Up Process.
→ Monthly KPIs follow up.
→ Appointment of a Single Point of Contact.

2. TRANSLATIONAL RESEARCH

## From Patient to Research and Research to Patient

Access to exploratory and translational research

→ UNLOCK and OASIS programs aiming to deciphering the mechanisms of action and resistance to innovative drug.
→ Immune Cell Enhancers (ICE) Unit expertise.

More than 25 translational research projects are ongoing in 2025 through various partnerships such as ICARUS and PIONNEER.

3. MEDICO-SCIENTIFIC COOPERATION

## From Key Opinion Leaders to Involved Clinical Teams

The interaction with Gustave Roussy's experts includes:

→ Pipeline review.
→ Education (masterclass, trainings).
→ Webinar.
→ Advisory board.

# GUSTAVE ROUSSY, the Largest Cancer Campus in Europe

Gustave Roussy Campus is a unique ecosystem dedicated to the fight against cancer in France and across Europe. Located on a single site, it brings together healthcare, research and industrial innovation, offering patients the highest quality of care combining medical expertise, precision oncology with personalized support.

The campus hosts internationally renowned teams engaged in cutting-edge research to better understand, diagnose and treat cancer. Moreover, the industrial innovation campus facilitates strong partnerships with companies and start-ups, accelerating the development of new therapies and technologies.

## Paris-Saclay Cancer Cluster in Short

→ HUB 3.0
- A campus dedicated to care
- A campus dedicated to research and teaching
- An economic development campus

→ A major € 480 million investment plan over 5 years.

→ Co-founded with Sanofi, Inserm, the Institut Polytechnique de Paris and the Université Paris-Saclay.

→ Directly connected to Paris city center, international airports, and train stations.

## 1./ Care Facilities

### Central building

### Interception building

→ Targeted prevention for people at higher risk of cancer.

→ City-hospital collaboration.

→ Development of new screening methods.

### New building dedicated to prevention, diagnosis, outpatient and international activities

→ Improved patient intake and care pathway.

→ Scheduled to open in 2029.

## 2./ Research and Teaching

### Research pavilion 1 and 2

### Molecular medicine building

### New Tertiary Building

→ Start of work: 2025 | Delivery: 2028

→ A new car park, offices and a new amphitheater with 200 spaces and 3 modular rooms that can accommodate up to 240 students.

## The future Gustave Roussy Research Center

### New research building

- May 2025: start of work
- Early 2028: official opening
- 33,000 m² - €190 millions
- Objectives: 40 to 60 research teams

## 3./ 100,000 m² Dedicated to Innovation and Economic Development

### Biocluster I

- Lab 116 by Perelis: available since October 2024
- Byos by Amundi: available since February 2025
- The Hive by Kadans: available since November 2025

### Biocluster II (Fort de la Redoute)

### Metro line openings

- Line 14: since January 2025
- Line 15: January 2027

**The creation of a real neighborhood that will host companies, healthcare and research players, in particular to enable the transformation of research products to improve the care offer for patients but also to strengthen international attractiveness.**

### CLINIC RESEARCH AT GUSTAVE ROUSSY

**350** staff

**13** clinical committees

**DITEP:** early clinical trials Departement

### PATIENTS

**7505** patients participating in a clinical study in 2025

**618** total active clinical trials in 2025

### 2025 PUBLICATIONS

**368** scientific publications linked with clinical research activities

### CONTACTS

**Prof. Benjamin Besse, MD, PhD**
*Director of Clinical Research*
benjamin.besse@gustaveroussy.fr

**Prof. Christophe le Tourneau MD, PhD**
*Deputy Director of Clinical Research at Gustave Roussy, Deputy General Director of the National Center for Precision Medicine in Oncology PRISM*
*christophe.le-tourneau@gustaveroussy.fr*

**Prof. Christophe Massard, MD, PhD**
*Head of the Department of Therapeutic Innovation and Early Stage Trials (DITEP)*
christophe.massard@gustaveroussy.fr

**Prof. Laurence Albiges, MD, PhD**
*Head of the Department of medical Oncology*
laurence.albiges@gustaveroussy.fr

**Dr. Édouard Dupis, PharmD**
*Industrial Partnerships Project Manager*
edouard.dupis@gustaveroussy.fr

**Prof. Eric Deutsch, MD, PhD**
*Head of the Radiotherapy Department*
eric.deutsch@gustaveroussy.fr

**Prof. Désirée Deandreis MD, PhD**
*Head of the Nuclear Medicine Unit*
desiree.deandreis@gustaveroussy.fr

**Prof. Yohann Loriot MD, PhD**
*Deputy Head of the DITEP, PI of UNLOCK*
yohann.loriot@gustaveroussy.fr

**Dr. Ronan Flippot, MD**
*Head of the ICE unit*
ronan.flippot@gustaveroussy.fr

GUSTAVE ROUSSY

CANCER CAMPUS
GRAND PARIS

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unicancer

Inserm

PRISM

DITEP
Drug Development Department

UNLOCK
BY GUSTAVE ROUSSY

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