



INNOVATIVE RESEARCH

at Gustave Roussy,
France

An exploratory clinical
research platform

**GUSTAVE /
ROUSSY**
PARIS CANCER CAMPUS



"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.

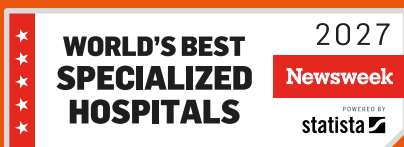
To strengthen its clinical research capabilities, Gustave Roussy has set up an unprecedented organisation dedicated to clinical research in early clinical trials in order to offer new hope and opportunity for patients."



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Prof. Fabrice Barlesi

CEO, Gustave Roussy



The leading cancer treatment center in France and Europe, and the 3rd in the world

(World's Best Specialized Hospitals 2027 Ranking, *Newsweek Magazine*)

ALL CANCERS, ALL STAGES, ALL AGES



"At Gustave Roussy, clinical research is part of the care pathway, not a parallel activity. By bringing together medical oncologists, radiation oncologists, surgeons, biologists, imaging specialists and data scientists around our patients, we can test new therapeutic concepts rapidly, identify who benefits, and move the most promising strategies from early trials to practice."

Prof. Éric Deutsch

Radiation Oncologist,
Medical Director,
Director of the joint research unit
INSERM U1355 RAMO-IT



"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

Director of Clinical Research

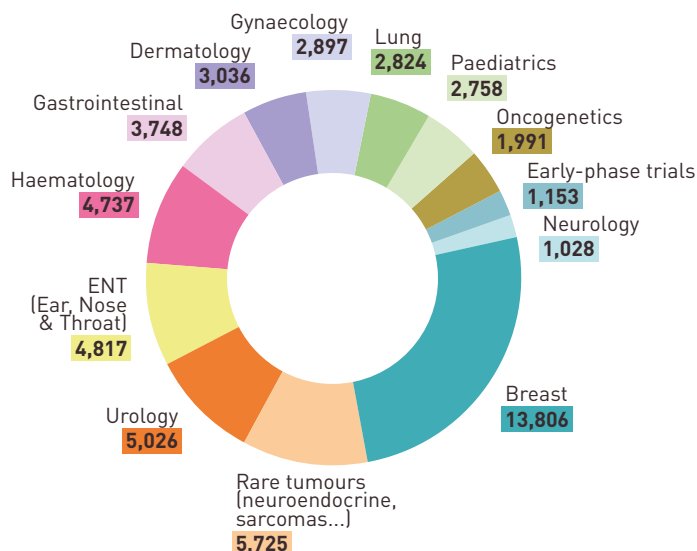


"Our mission is to integrate clinical research activities for studies that require close monitoring and/or involve complex protocol procedures in a single, specially designated area. Our multidisciplinary clinical research platform offers greater patient safety, better quality, better capacity, and innovative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

Prof. Benjamin Besse

Deputy Director of Clinical Research

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

144,000 recorded stays
(full hospitalization, day hospitalization,
chemotherapy and radiotherapy sessions)

54,000 patients monitored,
including **2,800** in paediatrics

24,000 new patients, including
581 paediatric cases

GUSTAVE ROUSSY:

A Clinical Research Success Story



Prof. Yohann Loriot

Medical Oncologist, Deputy Head of DITEP (Innovative Therapies and Early Trials Department), coordinator of the UNLOCK program

"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."

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.

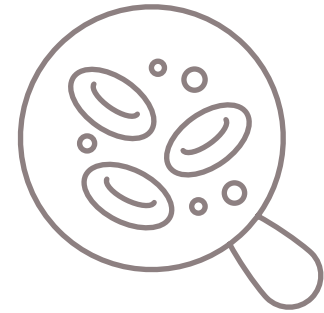
→ In recent phase III trials erdafitinib has been demonstrated superiority over chemotherapy in the same indication.

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."

Prof. 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.

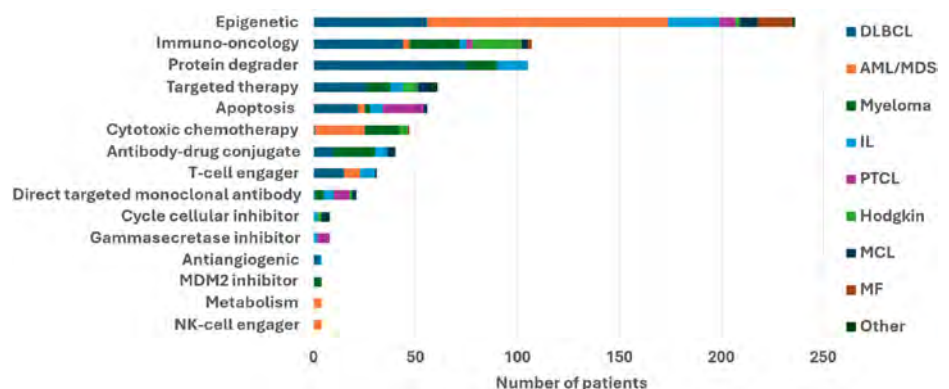
- It involved a randomized multicentric phase III trial AGILE published in NEJM (2022): median event-free survival 22.9 months (95% CI, 7.5 to could not be estimated) with ivosidenib and azacitidine and 4.1 months (95% CI, 2.7 to 6.8) with placebo and azacitidine.

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%
Conventional hospitalization	1,230	986 - 19,8%
Active file	2,936	4,736 + 56%
Autologous BMT	82	155 + 61,3%
Allogeneic BMT CAR-T cells	43 0	86, + 50% 31, N/A
EDD (patients)	25	71 + 184%
Clinical trials EDD	5	26 + 420%



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

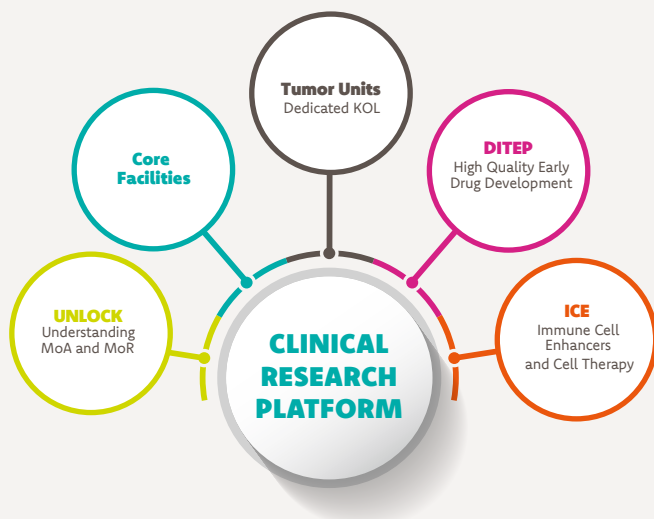
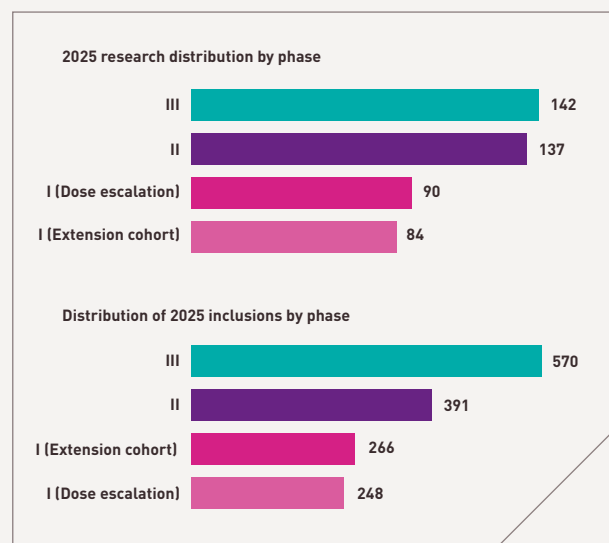


"Our innovative clinical research platform is expanding its capacity for early-phase I and II trials, based on a strong integration with translational research teams. The objective is to access new drugs and new therapies for adult patients with solid tumors or hematological cancers and make every patient,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

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

A significant research activity

In 2025, a total of 7 505 patients were enrolled in 618 clinical trials, including 466 in early-phase studies.



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.

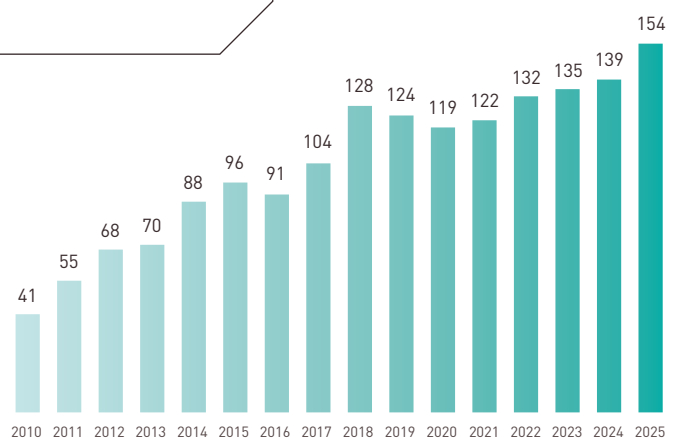
Medical Team

The team comprises of 30 MDs/MD-PhDs with dual expertise across a wide range of specialties, including thoracic, gastrointestinal, gynaecological, head and neck, genito-urinary, breast, central nervous system cancers, melanoma, haematology diseases, and also rare cancers such as sarcomas or neuroendocrine tumors.

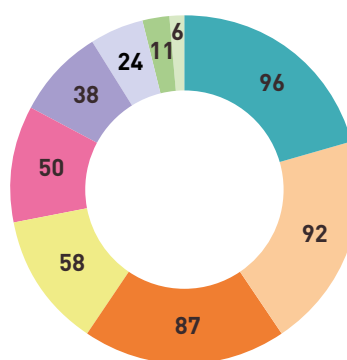
Facilities

- 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
GastroIntestinal
Urology
Haematology
ENT (Ear, Nose & Throat)
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 patients with Haematologic diseases treated



Haematology Clinical Team
• Dr Vincent Ribrag

Lymphoid malignancies
• Dr Jean-Marie Michot
• Dr Thomas Hueso

Myeloid malignancies
• Dr Stéphane De Botton

PRECISION ONCOLOGY PROGRAM

Precision medicine connects genomic and immune profiling with longitudinal monitoring and early-phase trials.

At Gustave Roussy, Prof. Antoine Italiano leads the Precision Medicine Program and chairs the Molecular Tumor Board. Working across DITEP, IHU PRISM and the sarcoma team, he integrates tissue and plasma profiling with early-phase trials to guide treatment for patients with advanced solid tumors and rare cancers.

The program extends precision medicine beyond baseline genomic matching. It connects molecular and immune selection before treatment with serial ctDNA and MRD monitoring, then pairs tissue, blood and spatial analyses at resistance.



"Precision oncology should combine tissue and liquid biopsy, expert molecular interpretation, serial ctDNA monitoring and spatial biology to guide treatment, assess efficacy early and understand resistance."

Prof. Antoine Italiano

MD, PhD - Head, Precision Medicine Program - DITEP
Early-Phase Trials - Sarcoma Team - IHU PRISM - Chair,
Molecular Tumor Board

FRESH (French Hub for Liquid Biopsy)

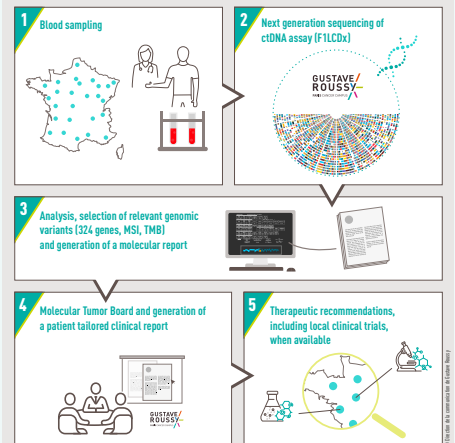


The FRESH platform translates liquid biopsy into routine clinical decision-making at scale. Integrated with IHU PRISM and weekly Molecular Tumor Boards, it provides ctDNA profiling for treatment selection, trial orientation and longitudinal monitoring through a national referral network.

Launched in July 2024, FRESH operates through a national network of referring centers and has capacity for more than 8,000 tests per year. Weekly Molecular Tumor Boards translate genomic findings into treatment recommendations and trial opportunities.

The program has already provided genomic profiling for more than 12,000 patients across over 30 centers in mainland and overseas France, with an average turnaround time of 12.3 days.

THE KEY STEPS OF THE GUSTAVE ROUSSY LIQUID BIOPSY PROGRAM FOR PRECISION ONCOLOGY



A precision oncology Continuum

- **SELECT**
Tissue and plasma profiling interpreted by the Molecular Tumor Board
- **MONITOR**
Serial ctDNA and MRD assessment during treatment
- **UNDERSTAND**
Paired biopsies and spatial analyses at resistance

Supported by more than 6,000 image-guided tumor biopsies each year.

Precision medicine accross solid tumors including sarcomas and other rare cancers

STING Precision Medicine Study

Led by Prof. Antoine Italiano, STING links deep clinical annotation with paired tumor, germline and serial plasma profiling in approximately 12,000 patients treated in early-phase trials. The collection includes more than 20,000 biospecimens, with cfDNA obtained at baseline and early during treatment. STING supports biomarker discovery, early molecular-response assessment and the analysis of resistance mechanisms.

Sarcoma precision oncology

Rare tumors and sarcomas require a dedicated precision oncology approach. At Gustave Roussy, expert diagnosis is combined with genomic, immune and spatial characterization to refine tumor classification, identify therapeutic vulnerabilities and guide treatment. Sarcomas are a major focus of this program, which links specialized care with translational research and early-phase drug development in diseases where evidence and treatment options remain limited.

WINDOW OF OPPORTUNITY TRIALS – UNLOCK PROGRAM

Early biological insights to guide therapeutic development

THE PREOPERATIVE WINDOW

Window-of-opportunity trials use a short, protocol-defined treatment period before surgery or standard neoadjuvant therapy to investigate drug effects while the primary tumour remains in place.

Paired tumour samples and serial blood collection provide complementary insights into changes in tumour biology, the immune microenvironment and systemic responses. These studies can reveal early biological activity even when changes in tumour size are limited, helping to understand how a treatment acts and which mechanisms may contribute to sensitivity or early adaptation.

BUILDING ON EXPERIENCE IN PREOPERATIVE BREAST CANCER RESEARCH

Gustave Roussy's experience in preoperative breast cancer studies, ranging from endocrine therapy and immunotherapy, provides a foundation for investigating different therapeutic mechanisms within a coordinated clinical-translational framework.

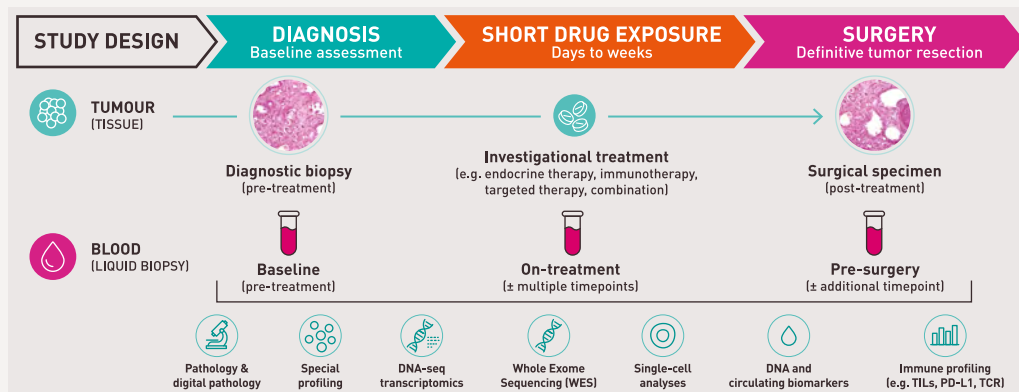
The ambition is to build on this experience to study novel agents and biologically informed combinations, with sampling strategies and analytical approaches tailored to each scientific question.



"The value of the preoperative window lies not only in collecting samples before and after treatment, but in integrating clinical context, biospecimen quality and biological interpretation."

Dr Joana M. Ribeiro
Medical Oncologist,
Breast Cancer Specialist

PAIRED TISSUE AND BLOOD SAMPLING



Analytical approaches are selected and adapted to the scientific objectives of each study, with additional assays incorporated according to biospecimen suitability and technical feasibility.

IMMUNOTHERAPY

EXAMPLE OF QUESTIONS:

How does PD-L1 blockade reshape the tumour immune microenvironment?

ENDOCRINE THERAPY

EXAMPLE OF QUESTIONS:

Can an oral SERD achieve antiproliferative activity without ovarian function suppression?

Immune activation
Tumour-immune spatial organisation
Early sensitivity and resistance
Antiproliferative activity
Role of ovarian suppression
Biomarkers of endocrine response

EXAMPLE OF STUDIES:

POP-DURVA
Durvalumab
Early triple-negative breast cancer

EXAMPLE OF QUESTIONS:

POP-ELA
Elacestrant ± ovarian function suppression
Premenopausal ER+/HER2- breast cancer
Illustrative studies within a question-driven preoperative research platform.

FROM BIOLOGICAL SIGNAL TO CLINICAL DEVELOPMENT

The aim is to translate early biological observations into testable hypotheses: identifying candidate biomarkers, informing patient selection and rational combinations, and guiding the design of subsequent clinical trials.

UNLOCK
BY GUSTAVE ROUSSY

PRISM
National Institute
for Precision Oncology

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 (Department of Therapeutic Innovation and Early Phase Trials), coordinator of the UNLOCK program

Dr. Maria Fernanda Mosele

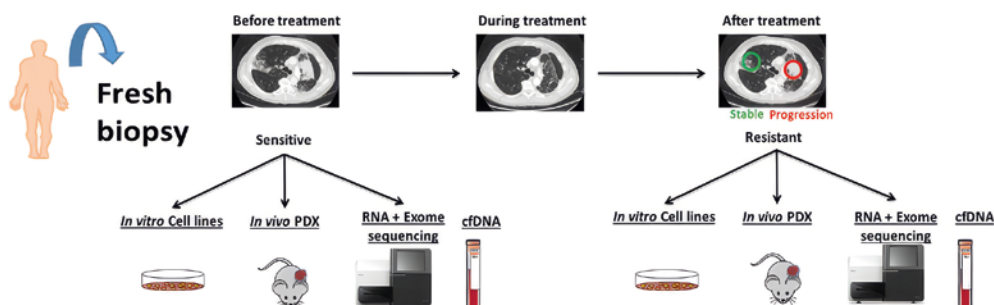
Medical oncologist, researcher in breast cancer, Department of Therapeutic Innovation and Early Phase Trials (DITEP)

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

These patients 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.
- Bio-informatics and data science analyses.
- Advanced translational investigations, such as WES, RNA seq, cfDNA, scRNA seq, CTC, PDX, spatial transcriptomics, immuno-PET, cytoff...
- 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
National Institute
for Precision Oncology

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.

IMMUNE CELL ENHANCERS PROGRAM



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

Dr. François-Xavier Danlos

Clinical Chief, drug development department

Dr. Cristina Castilla-Llorente

Medical Oncologist,
Head of cell therapies program

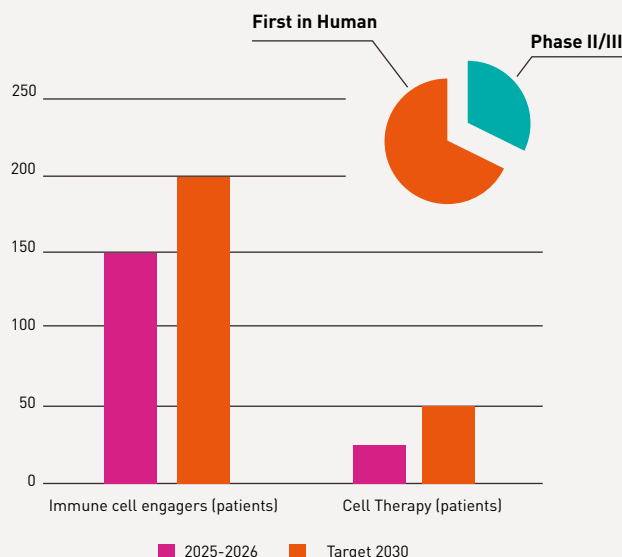
Dr. Ronan Flippot

Medical Oncologist

Immune Cell Enhancers (ICE) program

A strategic, multidisciplinary initiative designed to support the emergence of next-generation targeted immunotherapies for both haematological malignancies and solid tumors, from phase 1 studies to standard of care therapies, including :

- 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



COORDINATION TEAM

Dedicated patient pathways in Gustave Roussy



ICE INPATIENT UNIT

CELL THERAPY UNIT

Immune cell enhancers for heme & solid malignancies
Continuous patient monitoring
Identified nurses and medical team
Multidisciplinary toxicity evaluation and management
High-dose cytokines / Adverse event management

INTENSIVE CARE UNIT

MOBILE ITOX UNIT

The ICE Clinical Coordination

An 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 & hematology
- Management of immune-related toxicities (cytokine release syndrome, neurotoxicity, autoimmune manifestations) with a coordinated involvement of our mobile immunotoxicity team and intensive care

The ICE Clinical Interactions

Ongoing works to increase knowledges about ICE therapies locally and in our communities to improve patient's care, clinical research & scientific discoveries.

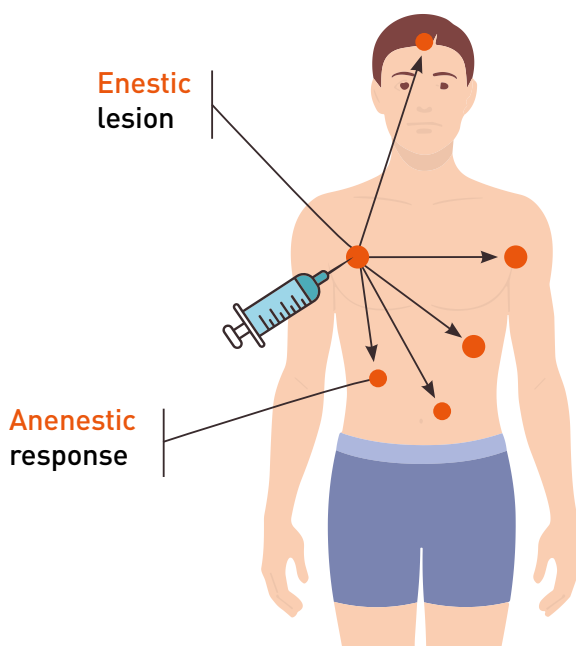
- Internal lectures for physician and nurses
- Research multidisciplinary seminars «Immune Interaction»
- MasterClass with industrial partners (Ipsen, Amgen, etc)

BIOOTHERIS PROGRAM

Intratumoral Immunotherapy and Innovative Biotherapies

BIOOTHERIS 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.

Enestic (injected) vs Anenestic (non-injected)



"Within the BIOOTHERIS, 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 BIOOTHERIS, Interventional radiologist
Department of Anaesthesia, Surgery and Interventional Radiology

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

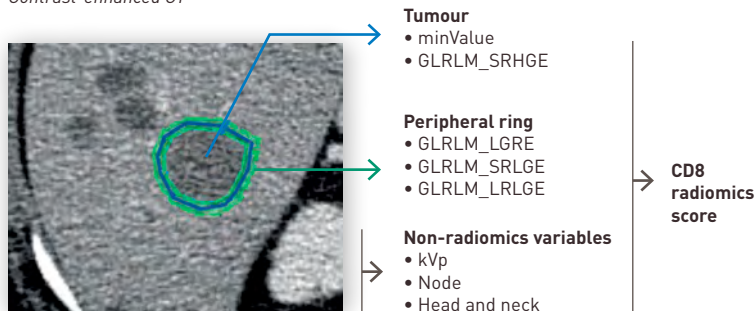
RADIO^{IO}THERAPY:

From innovation to new standards of care

Radio-Immunotherapy and Systemic Treatment Combination

Gustave Roussy has developed an integrated radio-immunotherapy strategy built on close collaboration between radiation oncology, translational research, and the Department of Drug Development and Early Phase Trials (DITEP). Our programs investigate synergies between radiotherapy, immunotherapies, targeted therapies, and radioligand treatments to enhance antitumor efficacy, overcome resistance mechanisms, and identify new therapeutic indications.

Contrast-enhanced CT



"Radiotherapy is becoming a platform for therapeutic innovation, not only a local treatment. By combining precise irradiation, tumor and immune biology, novel technologies such as FLASH and SFRT, and targeted alpha therapies through our DART platform, we aim to move rapidly from mechanistic research to biomarker-driven clinical trials and new standards of care."

Prof. Éric Deutsch

Radiation Oncologist,
Medical Director,
Director of the joint research unit
INSERM U1355 RAMO-IT

Prof. Sofia Rivera

Head of radiation department

FLASH Radiotherapy, UHDR and Spatially Fractionated Radiotherapy (SFRT)

As a pioneer in next-generation radiation technologies, Gustave Roussy develops and evaluates innovative approaches including ultra-high dose rate (UHDR) FLASH radiotherapy, Spatially Fractionated Radiotherapy (SFRT), and minibeam therapy. These breakthrough technologies aim to improve the therapeutic index by increasing tumor control while reducing normal tissue toxicity, paving the way for new standards of cancer care.

Multimodal Biomarkers and Imaging

Leveraging the combined expertise of Inserm Unit U1355, advanced imaging, and radiomics, Gustave Roussy develops multimodal biomarkers integrating imaging data, liquid biopsies, genomic profiling, and biological parameters. This dynamic characterization of tumors before, during, and after treatment enables the identification of responders, the monitoring of resistance mechanisms, and the acceleration of personalized therapeutic strategies.

Leveraging the combined expertise of Inserm Unit U1355, advanced imaging, and radiomics, Gustave Roussy develops multimodal biomarkers integrating imaging data, liquid biopsies, genomic profiling, and biological parameters. This dynamic characterization of tumors before, during, and after treatment enables the identification of responders, the monitoring of resistance mechanisms, and the acceleration of personalized therapeutic strategies.

INNOVATIVE RADIOLIGAND THERAPY

PRECLINICAL AND TRANSLATIONAL RESEARCH

→ DART platform (Development of Alpha Radiation Therapy for Revolution in Cancer Treatment) integrated within the Paris Saclay Cancer Cluster (PSCC) ecosystem dedicated to the development of alpha therapies in radioligand therapy and radiation oncology, from preclinical proof of concept to clinical trials.

Clinical Trials

→ Approximately 20 ongoing clinical trials, from Phase I to phase III.
→ More than 10 early-stage trials conducted in collaboration with DITEP.

Imaging, Radiomics and Biomarkers

→ Integration of several thousand image sets into radiomics and artificial intelligence programs.
→ Personalized Dosimetry program
→ Systematic collection of biological samples (blood, sequential biopsies) for multi-omic analyses and monitoring of treatment resistance, including collaboration with UNLOCK program.

Clinical Capacity

→ 2 digital PET/CT
→ 2 gamma cameras (including whole body CZT technology)
→ 4 protected rooms and 5 outpatients facilities for radioligand therapy
→ On site radioligand labelling
→ More than 15 radionuclides authorized



"Radioligand therapy (RLT) is transforming cancer care, particularly in endocrine and prostate cancers, with proven benefits for patients. A new generation of RLT is emerging, driven by novel molecular targets, new radiopharmaceuticals and innovative radionuclides. Yet, Phase I clinical trials remain underdeveloped in France and Europe."

Prof. Désirée Deandreis

Nuclear Medicine Physician,
Head of the Nuclear Medicine Department,
DART platform coordinator

Prof. Jérémie Calais

Nuclear Medicine Physician,
Paris-Saclay

Radioligands Therapy from Phase I to Phase III Clinical Trials

In 2024, following regulatory authorization, the first patient was treated at Gustave Roussy in a phase I with innovative radioligand for metastatic breast cancer. This first-in-human development was made possible by the specialized infrastructure and multidisciplinary expertise established at Gustave Roussy, enabling safe patient pathways, radiopharmaceutical handling, radiation protection and individualized dosimetry.

Gustave Roussy is also developing the DART platform (Development of Alpha Radiation therapy for Revolution in cancer Treatment) dedicated to targeted alpha therapies, bringing together radiochemistry, preclinical development, dosimetry, imaging and early clinical trials.

The objective is to accelerate the translation of alpha-emitting radiopharmaceuticals from proof-of-concept to clinical development and to explore their combination with external beam radiotherapy and systemic therapies. Through this platform, Gustave Roussy aims to create a fully integrated environment that supports the development, evaluation and clinical implementation of next-generation radiopharmaceuticals, strengthening its leadership in innovative and personalized radiation-based cancer treatments.

This ambitious research and development program also strengthens the attractiveness of Gustave Roussy, bringing talents and key opinion leader to the team from United States.

NUCLEAR MEDICINE CLINICAL TRIALS SCHEDULED 2024-2025:

→ 20 clinical trials planned in 1 year.
→ Across Phases I, II and III.

A DEDICATED PLATFORM WITH:

→ Radiopharmacy facility.
→ PET-SPECT Imaging facility.
→ DART platform for alpha therapy.

TREATMENTS

→ Over 600 treatments per year with radioligands across various cancers.
→ More than 10,000 PET examinations annually, utilizing standard and innovative tracers.
→ More than 2,000 SPECT/CT performed every year.

ENHANCING CLINICAL RESEARCH WITH ARTIFICIAL INTELLIGENCE (AI)



“From the Klineo website used for inclusion requests to the conduct of phase I trials, AI supports the medical team at every step of clinical research: patient enrollment, data quality and documentation, medical decision making, anticipation of screen failures, and the deciphering of therapeutic mechanisms of action in coordination with programs such as UNLOCK and ICE. Through IHU PRISM, we run a joint research program with CentraleSupélec on AI for oncology: multimodal representations of patients combining clinical, molecular, pathology and imaging data; agentic AI for rare cancers and molecular tumor boards; AI for digital pathology and radiomics; and AI-based structuration of hospital records at cohort scale. MEDITWIN remains our institutional flagship program for a digital twin in precision oncology. In parallel, our teams use cutting-edge bioinformatics and AI to profile large cohorts of patient samples with single-cell and spatial multi-omics technologies, which is where new targets and resistance mechanisms are identified.»

Dr. Julien Vibert

Assistant Professor in Medical Oncology, DITEP (Department of Therapeutic Innovation and Early Phase Trials), Researcher in Computational Oncology, IHU Prism

Dr. Mihaela Aldea

Medical Oncologist, Department of Therapeutic Innovation and Early Phase Trials (DITEP), Gustave Roussy

Emerging programs also explore the potential of AI in rare cancers to improve treatment pathways and identify new therapeutic targets, in close collaboration with CentraleSupélec School of Engineering within the IHU PRISM ecosystem.

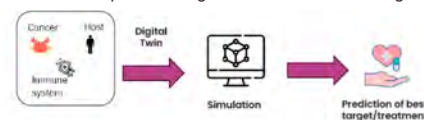


Workflow optimization

- Extraction and management of data from approximately 400,000 Gustave Roussy patient 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.
- AI-based structuration of unstructured hospital records, feeding the GOLDEN curated clinical database.
- LUCC, a multicenter lung cancer cohort in which AI extraction of clinical variables was validated against trained clinical research professionals [Aldea et al., Annals of Oncology 2026].
- AI applied to digital pathology and radiomics, on both trial and routine-care cohorts.
- 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.



Profiling patient cohorts at spatial resolution. Gustave Roussy combines cutting-edge bioinformatics and AI with single-cell and spatial multi-omics to profile large cohorts of patient samples. Within UNLOCK and dedicated rare-cancer atlases, these data map tumor and immune cell states in situ and help identify new targets and mechanisms of resistance.

ARCANE and the PRISM–CentraleSupélec axis

Within IHU PRISM, co-founded by Gustave Roussy, INSERM, Université Paris-Saclay, CentraleSupélec and UNICANCER, clinicians and engineers develop AI tools on Gustave Roussy data: multimodal patient representations, agentic AI, computational pathology, radiomics, and large-scale data structuration.

ARCANE, a neuro-symbolic AI agent designed to support molecular tumor boards in sarcomas and other rare cancers, is the first of these tools to enter institutional evaluation, with medical device software certification as the target.

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. Édouard Dupis
Alliance & Partnership Manager,
Clinical Research Expert



"Valorisation extends the life of a clinical trial: turning clinical and biological data into publications, ancillary studies and translational research - from bench to bedside and back - and making every industry partnership a lasting scientific collaboration."

Dr. Arnaud Bayle
Head of Valorisation and Partnerships,
Clinical Research Department

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.

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.

More than 25 translational
research projects are ongoing
in 2026 through various
partnerships such as ICARUS
and PIONNEER.

More than 10 preferred
clinical operations
partnerships in 2026

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.



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

- Improved patient intake and care pathway.
- Scheduled to open in 2029.

1. Care Facilities

Central building Interception building

- Targeted prevention for people at higher risk of cancer.
- City-hospital collaboration.
- Development of new screening methods.

2. Research and Teaching

Research pavilion 1 and 2 Molecular medicine building New Tertiary Building

- Start of work: 2025 | Delivery: 2029
- 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: June 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
Département

PATIENTS

7 505

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

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