





"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



"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

From cancer prevention to survivorship, Gustave Roussy provides end-to-end management of the patient pathway across all tumor types with a high level of care, integrating clinical research and access to innovation for patients with every tumor type.

The Clinical Research Platform ensures a continuum from preclinical research to drug approval:

- · Large and diverse patient population, including pediatric patients, adolescents, young adults, and geriatric oncology.
- Drug development support at every step with international KOLs across all tumor types and hematological malignancies.
- DITEP for early drug development (Phases I and I/II).
- DMO (Medical Oncology Department), Radiation therapy Department, Surgery Department and Hematology Department for later-phase drug development (Phases II and III).

GUSTAVE ROUSSY CARE IN NUMBERS

600 beds

277,092 medical consultations, including 16,838 in pediatrics

137,986 recorded stays (full hospitalization, day hospitalization, chemotherapy and radiotherapy sessions)

52,257 patients monitored, including 2,644 in pediatrics

24,000 new patients, including 472 pediatric cases

19,118 hospitalized patients

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 antiangiogenic molecule, erdafitinib was imbalanced by its Phase I toxicity and an unclear mechanism of action as only few patients respond to the treatment.

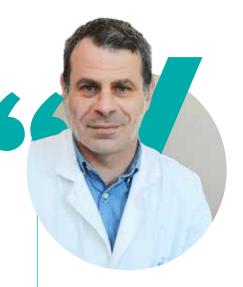
- → Analyses of tumor biopsies in MOSCATO trial identified somatic fusion/mutation of FGFR 2/3 genes in responding patients.
- → Following the Expert Boards recommendation to Janssen, to revise the development plan of the molecule and target patients carrying these mutations. This strategy was confirmed 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.



n 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 Hematology Department

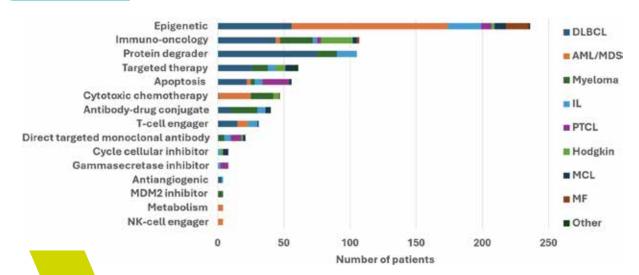
- → Somatic mutations in the gene encoding IDH1 occur in 6 to 10% of patients with acute myeloid leukemia. Mutant IDH1 catalyzes a disruption in cellular metabolism and epigenetic regulation. contributing to oncogenesis.
- → The mechanism of action of ivosidenib has been explored in ex vivo preclinical 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



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

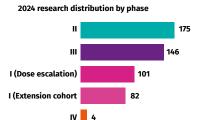
Head of the Department of Therapeutic Innovation and Early Phase Trials (DITEP)

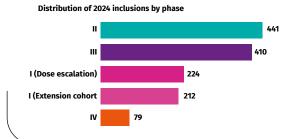
Core Facilities CLINICAL RESEARCH PLATFORM Tumor Units Dedicated KOL DITEP High Quality Early Drug Development CLINICAL RESEARCH and Cell Therapy



A significant research activity

In 2024, a total of 6115 patients were enrolled in clinical trials, including 423 in early-phase studies.





Extensive Expertise in Drug Development

- → Inhibitors of different molecular targets, immune modulators, as well as epigenetic and metabolic regulators.
- → Development of innovative non-drug strategies, including radiation therapy, nuclear medicine and advanced surgical techniques.
- → Unique expertise in intra-tumoral therapies.

Tumor biopsies

- \rightarrow 15 biopsies slot per week 60 per month.
- → Over 700 tumor biopsies performed in earlyphase clinical trial patients in 2024.
- → More than 1,000 biopsies conducted in Phase II and III trials at Gustave Roussy.

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.

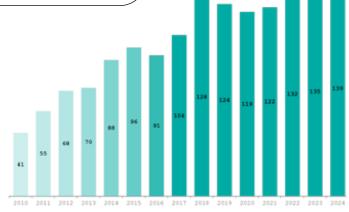
The department maintains close links with all Gustave Roussy organ-specific committees (with DITEP physicians holding dual appointments), as well as with a national network of referring oncology specialists. This structure enables innovative trials to patients with frequent cancer subtypes exhibiting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

Medical Team

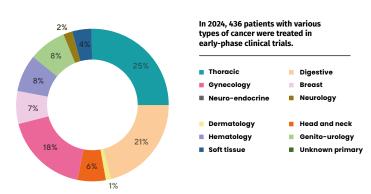
The team comprises of 25 MDs/MD-PhDs with dual expertise across a wide range of specialties, including thoracic, gastrointestinal, gynecological, head and neck, genito-urinary, breast, central nervous system cancers, melanoma, hematology diseases, and also rare cancers such as sarcomas or neuroendrocrine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

Facilities

- → Inpatient unit: 11 single-occupancy patient beds for weekly hospitalization.
- → Outpatient day-care unit: 11 treatments chairs.
- → Dedicated clinical operations unit.
- → Almost 140 early clinical trials running in 2024.



Yearly number of ongoing early clinical trials



DITEP Main Activities and Clinical team in hematology

FROM SEPT 2015 TO AUG 2025

Clinical Trials: 79

→ Epigenetics: 16

→ IO drugs: 20

→ ADC: 6

→ Signaling: 33

→ Various: 4

Open to inclusion: 15

Still active: 23

Not open yet: 4

More than 800 NHL included

Hematology Clinical Team

→ Dr Vincent Ribrag

Lymphoid malignancies

- → Dr Jean-Marie Michot
- → Dr Thomas Hueso

Myeloïd malignancies

→ Dr Stéphane De Botton

PRECISION ONCOLOGY PROGRAM



"High throughput tumor profiling, as part of a true "bench to bedside" approach, is an integral part of our clinical workflow. It ensures that therapeutic decisions and early clinical trial inclusion are guided by each patient's unique tumor genetics."

Prof. Antoine ITALIANO

Head of the new Precision Medicine program at Gustave Roussy

Genomic profiling is central to our clinical practice, enabling therapeutic decisions and early-phase trial inclusion to be guided by the molecular characteristics of each tumor.

All patients with advanced solid tumors undergo comprehensive in-house next-generation sequencing (NGS) through the STING precision medicine study (Coordinating Investigator: Prof. Antoine Italiano), to identify actionable genetic alterations.

The precision medicine team operates in partnership with the FRESH platform (central hub for ctDNA profiling) and the French national

genomics program (SEQUOIA), ensuring state-of-the-art diagnostic capabilities.



One of the largest Interventional Radiology (IR) department in France

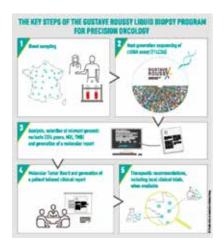
- → High biopsy volume: Over 6,000 image-guided tumor biopsies are performed here annually, reflecting the depth of our expertise.
- → Advanced IR Suite: A state-of-the-art IR suite featuring three dedicated procedure rooms, including a hybrid room that combines robotic 3D angiography with a multi-detector 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 enables tumor profiling via circulating tumor DNA (ctDNA) analysis from blood samples, offering a non-invasive alternative for patients unable to undergo tissue biopsy or those requiring real-time monitoring during early-phase clinical trials.



With over 7,000 ctDNA analyses performed annually, FRESH ranks among the most comprehensive liquid biopsy initiatives worldwide. The program benefits from an exclusive on-site implementation of the FDA-approved FoundationOne® Liquid CDx assay (324 genes), developed in collaboration with Roche/ Foundation Medicine.

All genomic data (tissue and liquid) are reviewed by our Molecular Tumor Board chaired by Prof. Antoine Italiano, and composed of specialists from every oncology subspecialty.

In the majority of cases, actionable alterations are identified, enabling personalized therapies or clinical trial enrollment. Additionally, the STING study has enrolled over 10,000 patients in just three years, creating a vast clinico-genomic database designed to identify real-time biomarkers of treatment response and resistance PRISM Portal is now running for inclusion.

Our Validated Pioneering Research Strategy

STING Precision Medicine Study

Led by Prof. Antoine Italiano, the STING program offers a comprehensive in-house NGS for patients with advanced cancers. It has led to significant breakthroughs in precision oncology, including the elucidation of resistance mechanisms and the demonstration of the clinical utility of large-panel ctDNA sequencing, the establishment of tumor fraction as a robust prognostic biomarker, the validation of ctDNA as a reliable surrogate of tumor burden. STING provides an invaluable resource to establish research partnerships with industrial partners, fostering translational collaborations that accelerate innovation in precision oncology.

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

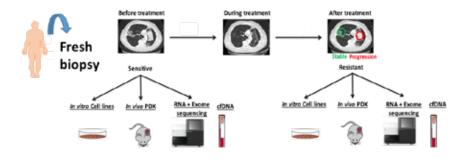
Medical Oncologist, Deputy Head of DITEP (Innovative Therapies and Early Trials Department), coordinator of the UNLOCK program

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 1 TRIALS

Very innovative drugs

Proof of concept (5-10 patients)

Provide data to support phase 2 trial

DEDICATED PHASE 2 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 2 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)





THE ICE PROGRAM

Immune Cell Enhancers and Next Generation Immunotherapies



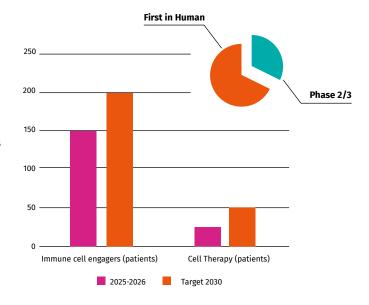
"ICE provides a clinically ready environment to accelerate the development of next-generation immunotherapies, with fast-track protocol implementation and collaborations to investigate mechanisms of action and resistance."

Dr. Ronan FlippotMedical Oncologist, Head
of the ICE Clinical Unit

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 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

Figure 1. ICE clinical unit organization and patient enrollment

The ICE Ecosystem

A wide range of experts working in close synergy: physicians, pharmacists, data scientists, biologists, and regulatory specialists.

The scientific program relies on specialised platforms for immune monitoring, pharmacology, and biomarker tracking (efficacy and toxicity), all of which are essential in early-phase (I/II) trials (Fig 2.). A regulatory support tailored to novel immunotherapy modalities including assistance with first-in-human trial applications.

FIRST-IN CLASS DRUG

Scientific Questions

Mechanisms of Action Mechanisms of Resistance

LONGITUDINAL TISSUE AND PERIPHERAL SAMPLING

GUSTAVE ROUSSY PLATFORMS AND TECHNOLOGIES (AMMICA)

SCIENTIFIC EXPERTISE AND COLLABORATIONS

TUMOR AND MICROENVIRONMENT LANDSCAPE

IMMUNE DYNAMICS

Circulating Immune cells subtypes, clonality and funtionality Soluble factors and

inflammatory blomarkers Spatial based proteomics and transcriptomics

EPIGENETIC DETERMINANTS OF RESPONSE

Chromatin remodelling and immune cell phenotypes

TARGET EXPRESSION

Tissue and circulating target expression, colocalization

Live immune and tumor cell interactome

LIVE IMMUNE AND TUMOR CELL INTERACTOME

EX-VIVO TUMOR EXPLANTS

Activation, migration and cytotoxicity upon treatment exposure

IMMUNE AND TUMOR CELL MODELS

Complex patient-derived organoïds, evaluation of immune engagement

DIGITAL TOOLS

RADIOMICS

Image-based prediction of tumor and immune phenotype

DIGITAL TWIN

Multilayered predictors of drug activity

Figure 2. ICE ancillary output for tailored scientific collaborations

THE DITEP

Radiation Therapy Alliance in Early Phases

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.

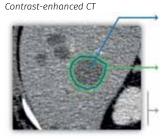
- → Elucidating interactions between tumors and their microenvironment leads to personalized treatment approaches that enhance efficacy.
- → Comprehensive biological ultra-characterization of patient and their tumor (immunity escaping, hypoxia, DNA repair, etc.), is performed before, during and after treatment to distinguish responders from non-responders, and shed light on resistance mechanisms.
- → Selected patients biological subgroups guide new therapeutic indications.



"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"



Tumour

- · minValue
- GLRLM_SRHGE

Peripheral ring • GLRLM_LGRE

- GLRLM_SRLGE
- GLRLM LRLGE
- Non-radiomics variables
- kVp
- Node
- Head and neck

CD8 radiomics

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.

NNOVATIV RADIOLIGAND 'HERAP'



"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.

PRECLINICAL AND TRANSLATIONAL RESEARCH

- → Over 30 active projects focused on radiobiology, immunotherapy, and biomarkers.
- → Development of radiosensitizers. nanoparticles, and innovative protocols, including FLASH, minibeams, 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

- → Ten 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.

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).

Additionally, MEDITWIN stands as an institutional flagship program aimed at developing a digital twin for precision oncology within Gustave Roussy."

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. For example, a large language model (LLM) tool is being developed for Gustave Roussy in collaboration with Research units.



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 nationwide requests for clinical trials).

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



"Gustave Roussy industrial privileged partnership offers three adaptable options, for an adaptable co-designed asset choice, providing the most convenient service at the best quality for innovative therapies clinical trials."

Dr. Edouard Dupis

Alliance Partnership Project 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.

TRANSLATIONAL RESEARCH

From Patient to Research and Research to Patient

Translational Project: *ICARUS, PIONNEER*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 2024 through various partnerships.

(3) MEDICO-SCIENTIFIC COOPERATION

From Key Opinion Leaders to Involved Clinical Teams

The interaction with Gustave Roussy's experts includes on demand:

- → 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.



- → 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.
- \rightarrow Development of new screening methods.



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

- → Improved patient intake and care pathway.
- \rightarrow 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: delivered in November 2025

Biocluster II (Fort de la Redoute)

Metro line openings

→ Line 14: since January 2025

→ Line 15: September 2026

"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 our patients but also to strengthen our international attractiveness.

CLINIC RESEARCH AT GUSTAVE ROUSSY

350 staff

clinical committees

DITEP: early clinical trials Departement

PATIENTS

6,115 patients participating in a clinical

study in 2024

586 total active clinical trials in 2024

2024 PUBLICATIONS

368

scientific publications linked with clinical research activities

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