ANNUAL RESEARCH REPORT 21

unicancer RESEARCH

unicancer
RECHERCHE

Research is at the heart of Unicancer's action. In recent years, cancer research has proven to be a formidable field of therapeutic, technological and organisational innovation.

Pr. Jean-Yves Blay, Président d'Unicancer

Innovative by nature, the Centres in our network have always been at the forefront of the fight against cancer to improve patient care by ensuring rapid access to innovations in care and research.

Sophie Beaupère, Déléguée Générale d'Unicancer

CONTENTS

Discover more on :

About us

Leading academic clinical trial sponsor in France, Unicancer is a major stakeholder in cancer research in France and in Europe.
Its mission, to move research and treatments forward in a translational approach using health data; Its ambition, to work to serve public health and benefit all patients, with a special focus on rare cancer and cancer with poor prognosis and on specific populations, especially paediatric and geriatric.

> We have the ambition to bring French excellence in cancer to the highest level of international innovation.

Pr. Jean-Yves Blay
President

Sophie Beaupère
General Director

> We must think about the future together; this is how we will build it.

EDITORIAL

2021: a year of major progress for Unicancer

Encore bousculée par la crise sanitaire, 2021 n'en a pas moins été une année de consolidation et d'avancées majeures pour la recherche Unicancer. Forte de sa nouvelle organisation duale autour d'une direction R&D et d'une direction Données de Santé et Partenariats, notre activité de recherche a démultiplié ses efforts.
Publication de résultats prometteurs induisant des changements de pratiques, lancement d'un OncoDataHub, nouvelles recommandations dans la prise en charge de cancers de mauvais pronostic, reprise des inclusions dans les grands essais historiques… : la recherche Unicancer s'est illustrée par son dynamisme et ses succès en 2021, réaffirmant les engagements et les ambitions de notre réseau. Celles de mieux comprendre et combattre la maladie, celles de mieux soigner et accompagner les patients.

A l'image de nos Centres de Lutte contre le Cancer qui travaillent dans l'esprit « Comprehensive Cancer Center », la recherche Unicancer est à la fois experte et multidisciplinaire, globale et transverse, focalisée et ouverte. Elle s'appuie sur la force d'un réseau à taille humaine, la tradition collaborative et l'excellence de nos chercheurs-médecins, elle est agile, pragmatique, partenariale. Notre vision de la recherche est celle d'un continuum, « de la paillasse au lit du patient », du préclinique au clinique et jusqu'à la recherche sur les données en vie réelle. Ce continuum de la recherche répond au continuum de la prise en charge qui s'étend de la prévention jusqu'au post-cancer en passant par le diagnostic, la thérapie, et se conjugue désormais à l'aune de la médecine 4, 5 ou 6 P : personnalisée, prédictive, basée sur les preuves, participative, centrée sur le patient… Ce patient qui, après être devenu un acteur de son parcours de soin, devient peu à peu, et c'est la volonté des équipes Unicancer, un partenaire de la recherche. Ce patient qui, quelles que soient les mutations de sa tumeur, la rareté de son cancer, doit avoir accès à l'innovation thérapeutique.
Ce patient qui doit être suivi, accompagné après son cancer.
C'est tout l'enjeu de nos nouveaux projets de recherche, qui misent sur l'ADN circulant, le profilage moléculaire, les sciences humaines et sociales ou l'intelligence artificielle pour mieux diagnostiquer, personnaliser et prédire la réponse thérapeutique et évaluer l'impact de la maladie et des traitements sur la vie, la survie et la qualité de vie des patients. La recherche Unicancer s'est donné les moyens de relever ces défis et de répondre aux grands enjeux de l'oncologie de demain, au bénéfice des patients d'aujourd'hui.

Still shaken up by the health crisis, 2021 was nevertheless a year of consolidation and major progress for Unicancer research. Fortified by its new dual organisation with an R&D division and Health Data and Partnerships division, our research activity has multiplied.
The publication of promising results leading to changes in practices, the launch of an OncoDataHub, new recommendations for the treatment of cancer with poor prognosis, resumption of inclusions in major past trials etc., Unicancer research has distinguished itself by its dynamism and successes in 2021, reasserting the commitments and ambitions of our network.
Those of better understanding and fighting the disease, those oftreating patients more effectively and providing them with greater support.
Like our cancer centres, working true to the spirit of a Comprehensive Cancer Center, Unicancer research is both an expert and multidisciplinary, global, cross-sectoral, focussed and open programme. it is based on a human-sized network, on the collaborative work by and
excellence of our researchers, it is agile, pragmatic and partner-based. Our vision of research is that of a continuum, "from bench to bedside", from the preclinical to the clinical through to research on real-life data.
This research continuum answers to the treatment continuum which ranges from prevention, through diagnosis and treatment to the after cancer phase, which now work together with regard to 4, 5 or 6 P medicine: personalised, predictive, proof-based, participative, patient-centred…
The patient who, after becoming a stakeholder in their own healthcare pathway gradually becomes a research partner. This is what Unicancer teams want to see. The patient who, regardless of the mutations in their tumour, the rareness of their cancer, must have access to therapeutic innovation. The patient who needs to be cared for and supported after their cancer.
This is the challenge for new research projects, investing in circulating DNA, molecular profiling, human and social sciences or artificial intelligence for better diagnosing, personalising and predicting the treatment response, and evaluating the impact of the disease and treatments on patients lives, survival and quality-of-life.
Unicancer research has gathered the resources it needs to rise to these challenges and to answer to the leading issues in the oncology of the future, for the benefit of its patients today.

> Cooperation is a key factor for success, building strategic partnerships a priority.

Claire Labreveux
Director of Research and Development

EDITORIAL

2021: research is progressing but also changing

La recherche avance. Ces dernières décennies ont été marquées par des avancées et progrès majeurs en termes de compréhension des maladies cancéreuses et de survie et qualité de vie des patients. Mais la recherche évolue aussi très vite, devenant de plus en plus complexe, au fur et à mesure que les mutations permettent de définir des sous-types de tel cancer, de cibler telle population ou de suivre des malades devenus chroniques. Cette recherche ciblée, précise, à la fois rapide et au long cours, est aussi plus coûteuse et compliquée à financer, dans un environnement administratif plus lent que le rythme de la recherche et dans un contexte récent bousculé par la pandémie Covid-19.

Avec ses 120 personnes et 100 essais en cours, dont un tiers d'essais internationaux, le Département de la Recherche Clinique et Translationnelle d'Unicancer participe activement à cette dynamique. Et porte fièrement les valeurs d'excellence, d'innovation, de solidarité et d'humanité qui sont celles d'Unicancer. Alors que de nombreuses nouvelles molécules arrivent sur le marché, notre mission de recherche académique est d'en optimiser l'usage, de définir les associations, les séquences de traitement, et explorer les domaines moins couverts par la recherche pharmaceutique. En un mot, d'améliorer et de personnaliser les schémas thérapeutiques. C'est tout l'enjeu des récentes publications, présentées à l'ASCO et à l'ESMO, qui induisent des changements de pratiques ayant un impact direct sur la prise en charge des patients. C'est tout l'enjeu de nos différents projets qui ciblent des cancers rares, de mauvais pronostic, et des populations orphelines.
Cet engagement quotidien se nourrit aussi de collaborations et de transversalité : l'ouverture aux patients dont le rôle doit être grandissant et les partenariats que nous nouons avec les professionnels médicaux et paramédicaux et nos collègues internationaux. Pour bâtir, ensemble et jour après jour, ce continuum de la recherche, du fondamental à la clinique au bénéfice des patients, de chaque patient.

Research is progressing. The last decades have seen major advances and progress in terms of understanding cancerous diseases and patient survival and quality of life. But research is also rapidly changing, becoming increasingly complex, as mutations are used to define subtypes of a given cancer, to target a given population or to monitor diseases that have become chronic.
This targeted, precise, both immediate and long-term research is also more costly and complicated to fund, in an administrative environment moving at a slower pace than research, in a context recently shaken up by the COVID-19 pandemic.

With its 120 staff and 100 ongoing trials, of which one third are international trials, the Unicancer Clinical and Translational Research Department is actively participating in this growth. It stands proudly for the values of excellence, innovation, solidarity and humanity, all values of Unicancer. Whereas many molecules are arriving on the market, our academic research mission is to optimise their use, to define combinations, treatment sequences and to explore areas less covered by pharmaceutical research. In a nutshell, improving and personalising treatment regimens. Such are the issues covered in recent publications, presented at the ASCO and the ESMO, leading to changes in practices with a direct impact on patient management. This is what our various projects are faced with, targeting rare cancers, with poor prognosis and orphan populations.
This daily commitment is also driven by partnerships and work with other sectors. Opening up to patients whose role must be given more importance and partnerships we build with medical and paramedical professionals and our international colleagues. **To build together, day after day, this research continuum, from fundamental research to clinical practice, for the benefit of patients, of every patient.**

Anne-laure Martin
Director of Health Datas and Partnerships

> Health data is an integral part of health innovation.

EDITORIAL

2021: operational implementation of the Health Datas and Partnerships département

2021 saw the operational implementation of the Health Data Research Department, created in 2020 but which seals an approach initiated in 2014 with the launch of the ESMÉ (Epidemiological-Medical-Economic Strategy) programme. structured around four units and involving around sixty specialised staff, the department is now in working order, and is creating a buzz around the exploitation of health data.

These much sought after, complex and even under-exploited health data, are indeed essential as they answer to major health challenges, in oncology in particular. They refine diagnoses, personalise treatments, take the long-term disease-burden into account, and capture, assess and accelerate access to innovation.

In the field of research, health data are a permanent cross-sectoral aspect of the research chain – bench, pre-clinical, clinical…- and represent a powerful driver for-providing answers, especially in three emerging areas in which Unicancer has taken a firm stance:

- Health data are a tool for monitoring the effect of treatments after their marketing, which make this "phase 4" possible in real-life, while promoting early access to therapeutic innovations.
- The 2nd use concerns rare diseases and cancer for which molecular profiling is used to differentiate sub-types affecting a small number of patients. Whereas the health agencies' gold standard remains the randomised trial, health data are used to compile a virtual comparator arm and therefore to accelerate implementation of targeted therapy trials.
- The 3rd area of action is that of digital disease, where health data combined with artificial intelligence are used to refine the disease diagnosis and predict treatment response.

2021 was also the year in which two major programmes were launched in the department: WeShare and Onco Data Hub. In 2022, other ambitious, ground breaking projects around data interoperability and shared hosting but also AI for assisting diagnosis and prognosis, will see the day. **Again in the aim of helping to rise to the great challenges of oncology in the 21st Century using health data.**

2021 est l'année de la mise en œuvre opérationnelle du Département Recherche en Données de santé, créé en 2020 mais qui concrétise une démarche engagée dès 2014 avec le lancement du programme ESMÉ (Épidémio-Stratégie Médico-Economique). Structuré autour de quatre pôles et regroupant une soixantaine de personnel dédié, le département est désormais en ordre de marche, dans un contexte d'effervescence autour de l'exploitation des données de santé.

Ces données de santé, convoitées, complexes, et encore sous-exploitées, sont en effet essentielles car elles répondent à des enjeux majeurs en santé et en particulier en oncologie : préciser les diagnostics, personnaliser les traitements, prendre en compte le fardeau à long terme de la maladie, capter, évaluer et accélérer l'accès à l'innovation.

Dans le domaine de la recherche, les données de santé constituent une approche transversale tout au long de la chaine de la recherche – paillasse, pré-clinique, clinique…- et représentent un levier puissant pour apporter des réponses notamment dans trois domaines émergents sur lesquels Unicancer se positionne résolument :

- Les données de santé sont un outil de suivi post-AMM de l'effet des traitements, rendant possible cette fameuse « phase 4 » en vie réelle, tout en favorisant un accès précoce aux innovations thérapeutiques.
- Le 2e usage concerne les pathologies rares et les cancers dont le profilage moléculaire permet de distinguer des sous-types concernant un effectif réduit de patients. Alors que le « gold standard » des agences reste l'essai randomisé, les données de santé permettent de construire un bras comparateur virtuel et donc d'accélérer la mise en place d'essais de thérapie ciblée.
- Le 3e champ d'action est celui de la pathologie digitale, quand les données de santé combinées à l'intelligence artificielle permettent d'affiner le diagnostic anatomopathologique et de prédire la réponse au traitement.

2021 est aussi l'année du lancement des deux grands premiers programmes du Département : WeShare et Onco Data Hub. En 2022, d'autres projets ambitieux et novateurs, autour de l'interopérabilité et d'un hébergement mutualisée des données mais aussi de l'IA pour l'aide au diagnostic et pronostic, verront le jour. Avec toujours l'objectif de contribuer à répondre, à l'aide des données de santé, aux grands enjeux de la cancérologie du XXIe siècle.

UNICANCER RESEARCH PRIORITIES AND CHALLENGES

Over 2021-2022, this commitment is seen in three strategic priorities answering to the main challenges of oncology in the 21st Century:

1: UNDERSTAND AND ERADICATE CANCER

Faced with a polymorphic, progressive and sometimes so-called chronic disease, Unicancer uses an integrated and comprehensive approach. From research into risk factors through the development and evaluation of new therapies, to post-cancer mental health and welfare care, and investing especially in:

- The development of early phase trials to fast track access to innovation, especially for cancer with poor prognosis,
- Study of the benefit-risk ratio of new treatments,
- Evaluation and optimisation of treatment strategies and sequences,
- Personalisation of treatments according to the genetic and molecular profile of patients and tumours,
- Prevention and early detection of cancer especially through large cohort studies,
- Improvement of quality of life of patients by treatment de-escalation and long-term follow-up.

2: BE AT THE FOREFRONT OF KNOWLEDGE AND TECHNOLOGIES

Positioning ourselves at the front of oncology innovations requires combining scientific excellence, new paradigms and disruptive technology. Spearhead of innovation in oncology, as much in research as in care, Unicancer has taken a firm stance on:

- Circulating DNA detection techniques for improving early diagnosis, predicting treatment response, refining the prognosis and adapting supportive care,
- Collection and exploitation of health data, by launching or integrating large-scale database programmes and working on their interoperability,
- Artificial intelligence especially to support pathology.

3: MEET UNMET MEDICAL NEEDS AND MAJOR HEALTH ISSUES

Go where no one has gone before, to areas little covered by the pharmaceutical industry, looking at specific populations, especially the elderly, targeting rare cancers and cancer with poor prognosis: Unicancer dedicates a large part of its activity to rare diseases, because the medical and human challenges are significant in that area.

Beyond that, by investing in translational research and cross-analysis of data from clinical trials and real-life health data, Unicancer has been rolling out an innovative and to the purpose R&D strategy.

As a bonus, major publications hailed by the international community and changes in practices to benefit patients. Improving patient treatment and quality-of-life and answering to major health issues remains Unicancer's ambition in the years to come.

UNICANCER STRENGTHS & ASSETS

A network of 18 French Comprehensive Cancer Centers and 2 affiliates members, exclusive expertise in cancer, a culture of collaboration, integrated approach to the fight against cancer, Unicancer Research's strengths and assets can be covered in 3 points:

1: EXPERTISE AND INTEGRATION

- French network of dedicated cancer centres working on the three missions that are care, research and training
- A philosophy and organisation true to the spirit of Comprehensive Cancer Centers, leading to integrated and multidimensional management and a cross-sectoral research approach, from fundamental research to real-life data, through clinical research, with a new Data Department especially.
- Researchers with groups per therapeutic area and cross-disciplinary groups for reinforced, but shared and collegial expertise.

2: AGILITY, LEADING-EDGE TECHNOLOGIES, PRAGMATISM

- Unicancer, an expert, human-sized network with tried-and-tested and efficient networking.
- A combination of agility and pragmatism so as not to spread resources thin and to use all sources and opportunities for innovation.
- Leading-edge technical hubs for conducting innovative and ambitious projects
- ISO 9001-certified clinical research activity
- A biological resource centre in Lyon, a data centre in Montpellier
- Certified and centralised biobanks and data platforms

3: NETWORK, PARTNERSHIP AND COLLABORATION

- The coming together of site research and a network within cancer centres and research through major programmes coordinated by Unicancer R&D Departments.
- A tradition within cancer centres raised to the rank of philosophy and strongly anchored in how Unicancer operates.
- A historic leaning which is seen in terms of multidisciplinarity, but also internationally and with all types of bodies, especially public-private (pharmaceutical companies and start-ups).
- Two concrete examples:

- MATWIN (Maturation & accelerating translation with industry): innovation development centre in oncology and example of Unicancer's ambitious partner-based and translational dynamic
- EORTC (European Organization for Research and Treatment of Cancer) liaison office: a central role and recognition of Unicancer's excellence in cancer research.

PATIENT'S ROLE

THE PATIENT, KEY STAKEHOLDER IN UNICANCER RESEARCH

For some years now, 4, 5 or 6P medicine has placed the patient at the heart of healthcare strategies. Patients also are staking a claim to a place in the field of research little by little, whereby the concept of "patient expert" takes on its full meaning. A patient that is also a carer, trainer, resource who has gained knowledge of their disease and the related stakes. Initially a figure of rare or chronic diseases, the patient-expert is now a key stakeholder in the fight against cancer, and at Unicancer has a central place in the vision the institution is developing in the management of patients and cancerous diseases. From prevention to reinsertion through care and clinical research.

Stakeholder in their disease and treatment, the patient is asked to get involved in reviewing research protocols and results in liaison with Unicancer research departments. Because their viewpoint is relevant and their position and perception bring up additional issues.

In 2021, several tangible initiatives and actions on the role of the patient in research were launched or continued. They embody the drive of Unicancer researchers to work with and for patients and are among the strategic objectives for 2022.

Setting up patient committees

Even if working with patients' associations is commonplace, they are often rigid and intimidating to patients.
Unicancer would therefore like to go further and set up patient committees which would become involved in research priorities and projects. Far beyond the idea of simple consent, the aim is to involve patients in research choices, in creating trial synopses but also in building networks of patients and former patients. The objective here is also to maintain a link and to measure the impact of the chronic burden of disease and to fuel discussions on human and social sciences and health data and health data platforms.

Sharing all research results

All results from Unicancer research projects, both positive and negative, are published in peer-reviewed papers and/or presented at congresses. However these data are little accessible to the public. In 2021, the Unicancer Clinical and Translational Research Department therefore took the initiative to write summary, popularised reports on the results of clinical trials in a language and format easy to read and understand for patients.
This initiative will be continued and escalated in 2022.

EXPERT GROUPS

Unicancer provides structural support to 10 internationally recognised and multidisciplinary expert groups dedicated to designing and steering innovative clinical studies. Their goals are to offer patients access to innovative treatments, to optimise therapeutic strategies and to contribute to scientific education and dissemination in their field, notably by developing collaborative networks.

Discover more on :

TUMOR GROUPS

FRENCH BREAST CANCER INTERGROUP (UCBG)

President : Thomas Bachelot, Centre Léon Bérard, Lyon

Strategic priorities

Subtypes with poor prognosis, biology-driven strategies of therapeutic de-escalation, survivorship

GASTRO-INTESTINAL GROUP (UCGI)

President : Christelle de la Fouchardière, Centre Léon Bérard, Lyon

Strategic priorities

Innovative phase II studies, new diagnostic approaches towards personalized treatment, translational research, large randomised phase II/III studies, rare cancers

GENITOURINARY GROUP (GETUG)

President : Karim Fizazi, Gustave Roussy, Villejuif

Strategic priorities

Therapeutic strategy studies, research programmes in rare tumours, development of biological research programmes in connection with clinical projects

HEAD & NECK GROUP

President : Joël Guigay, Centre Antoine Lacassagne, Nice

Strategic priorities

Early-phase studies, rare cancers, biology-driven medicine

SARCOMA / RARE CANCERS GROUP

President : Nathalie Gaspard, Gustave Roussy, Villejuif (paediatrics) ; Jean-Yves Blay, Centre Léon Bérard, Lyon (adults)

Strategic priorities

Improvement of early management of sarcomas and other rare connective tissue tumours, translational research, biobankings

CROSS-PATHOLOGY GROUPS

IMMUNO-ONCOLOGY GROUP (IOG)

President : Frédérique Penault-Llorca, Centre Jean Perrin, Clermont-Ferrand

Strategic priorities

Cancer immunotherapy research, translational research, identification of predictors and biomarkers of extreme response or poor tolerance to immunotherapy

ONCOLOGY GERIATRICS (GERICO)

President : Loïc Mourey, Institut Universitaire du Cancer, Toulouse

Strategic priorities

Innovative clinical research in oncogeriatry, methodological adaptation of the evaluation criteria to the geriatric population, diagnostic and therapeutic rationalisation
Expertise in the evaluation and description of geriatric populations, promote the use of G-CODE developed in the framework of DIALOG (Oncogeriatric intergroup associating SOFOG), specific questions for elderly subjects, innovative methodology & adaptive phase II, Evaluation of strategies in elderly patients

PERSONALISED MEDICINE GROUP (MED PERSO)

President : Fabrice André, Gustave Roussy, Villejuif

Strategic priorities

Personalized biology-drivenmedicine, proof of concept studies, identification of predictors or biomarkers of treatment efficacy or resistance

SUPPORTIVE CARE INTERGROUP (SDS AFSOS)

President : Didier Mayeur, Centre Georges François Leclerc, Dijon

Strategic priorities

High standard clinical programmes for the evaluation of supportive cares, quality of life, cost-efficiency, humanities and social sciences.
4 strategic axes have been identified: The organization of the care pathway, Symptom management, Health Behaviour, Develop and strengthen patient trials.

TRANSLATIONAL RESEARCH AND DEVELOPMENT IN ONCOLOGY RADIATION (UNITRAD)

President : Sophia Rivera, Gustave Roussy, Villejuif

Strategic priorities

Changing practice clinical studies integrating translational research, Artificial Intelligence radiomic/Imaging, radiobiology (immunoradiotherapy /radiosensitivity/ radiopotentialisation), radiotherapy quality assurance, PROMs and real-world data, new technologies and physics innovation.

MATWIN

Maturation and Accelerating Translation With INdustry

MATWIN is a French open-innovation platform, fully-owned subsidiary of Unicancer, dedicated to supporting innovation in oncology. For more than ten years, its goal has been to help scientists and entrepreneurs evaluate and optimize opportunities to transform their research into product, for the benefit of the patient.

MATWIN main objectives are to select R&D innovative oncology projects with high technology transfer potential, drive asset identification and support the most promising ones in accelerating development and optimizing collaboration opportunities.
The process is based on a continuing partnership with major international companies working in oncology (Amgen, AstraZeneca, Boehringer Ingelheim, Bristol-Myers Squibb, Gilead, GlaxoSmithKline, MSD, Nanostring Technologies, Novartis, Pfizer, Pierre Fabre, Roche, Sanofi) willing to benefit from the attractiveness of French research in oncology.

The MATWIN's accelerator programme is open to European academic teams and startups looking forward accessing high value-added expertise and network of stakeholders to foster partnership opportunities.

In addition to this program, MATWIN has also co-organised the annual European Oncology Partnering Convention MEET2WIN since 2015. This event has proved increasingly successful and is becoming a reference meeting point to boost collaborative opportunities in the oncology field in Europe gathering each year around 300 attendees (international companies, SMEs, startups, investors, researchers,…).

Discover more on :

www.matwin.fr

contact@matwin.fr

Tel : +33 5 35 54 19 36

Discover more on :

https://matwin.fr/en/meet2win-2022/

MEET2WIN

Each year, MEET2WIN is combining conferences, workshops, projects elevator pitches and thousands of face to face meetings. A large time is dedicated to networking, and a showcase is offered for startups looking forward to fundraising via a dedicated session called OUI (Oncology Upward Investment). This specific session allows selected companies to pitch their innovative solutions in front of a review panel of 15 major European investors able to support their growth, thus offering new opportunities of development support to leverage cutting edge innovation in oncology.

A few figures from MATWIN's review (2009-2021):

- **+228** applicant projects, **+143** projects assessed by academic & industrial experts
- **+80** projects interviewed by the MATWIN International Board
- **+ 32** start-ups already created (amongst which Syndivia, PDC*line, ElyssaMed, H-Immune, Gliocure, Apmonia Therapeutics, Yukin Therapeutics…)
- **+30** collaborations with biotechs or pharmas

unicancer

2021 KEY FIGURES

20 191
PATIENTS
included in Unicancer R&D sponsored-clinical trials
of which 16753 in MyPeBS

109
ONGOING CLINICAL TRIALS
for the Unicancer R&D department,
including 50 recruiting trials

60
PUBLICATIONS
in scientific journals

83 000
PATIENTS
registered in the ESME database

247
INVESTIGATIONAL SITES INVOLVED*
(public hospitals, private clinics,
comprehensive cancer centres), including 49 Abroad

9
NEWLY INITIATED CLINICAL TRIALS

afaq iso 9001

Unicancer is **ISO 9001 certified** for its clinical research activity

** The French general practitioners, gynaecologists and radiologists who contributed to the MyPeBS recruitment in 2019 are not included in this number.*

INTERNATIONAL COLLABORATIONS

Several major trials sponsored by Unicancer are conducted at an international level, thanks to key partnerships with other academic cancer research groups, or through an extended network of collaborating university hospitals and research teams, mainly in Europe but also overseas. Unicancer, as a major European academic sponsor in oncology, seeks to gain worldwide visibility, with the ultimate goal of developing high-quality practice-changing clinical research and accelerating patients' access to innovation.

Glossary of cancer research groups and networks

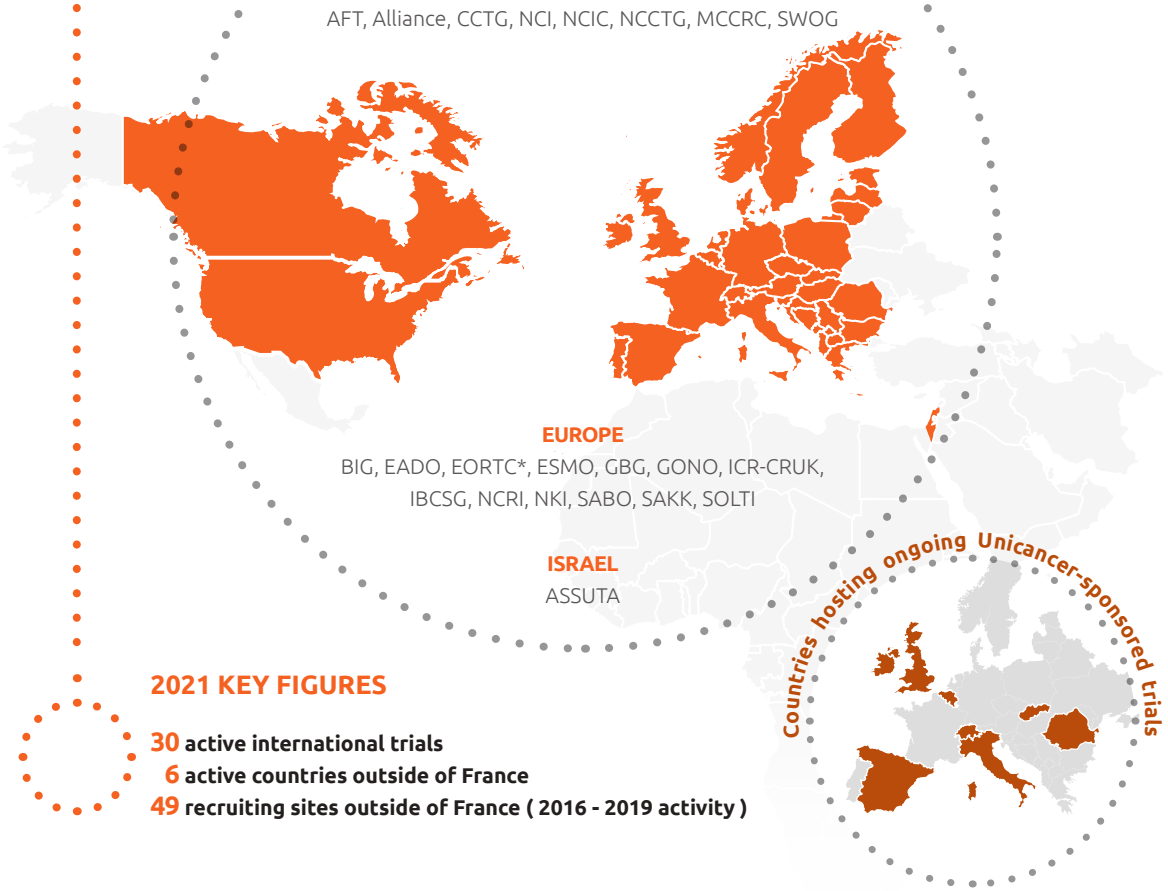
AFT: Alliance Foundation Trials in oncology
BIG: Breast International Group
CCTG: Canadian Cancer Trials Group
CRUK: Cancer Research UK
EADO: European Association of Dermato Oncology
EORTC: European Organisation for Research and Treatment of Cancer
FAGE: Federación Argentina de Gastroenterología
GBG: German Breast Group
ICR-CRUK: Institute of Cancer Research - Cancer Research UK centre
IBCSG: International Breast Cancer Study Group
GONO: Gruppo Oncologico del Nord Ovest
MCCRC: Multiprofessional Critical Care Review Course
NCCTG: North Central Cancer Treatment Group
NCI: National Cancer Institute - USA
NCIC: National Cancer Institute of Canada
NCRI: National Cancer Research Institute - UK
NKI: Netherlands Cancer Institute
SABO: Swedish Association of Breast Oncologists
SAKK: Groupe Suisse de Recherche

Unicancer's international partners

NORTH AMERICA
AFT, Alliance, CCTG, NCI, NCIC, NCCTG, MCCRC, SWOG

EUROPE
BIG, EADO, EORTC*, ESMO, GBG, GONO, ICR-CRUK, IBCSG, NCRI, NKI, SABO, SAKK, SOLTI

ISRAEL
ASSUTA



2021 KEY FIGURES

30 active international trials
6 active countries outside of France
49 recruiting sites outside of France (2016 - 2019 activity)

Clinical Research

MyPeBS, PADA-1, PEACE, Prodige-23… Code names at recent congresses, Unicancer clinical trials produced conclusive results in 2021 which were published in prestigious journals. In colon, pancreatic or prostate cancer, phase 3 trials led to new treatment recommendations. Another positive sign, after slowing of the COVID-19 pandemic, inclusions resumed especially in the international study on personalised breast cancer screening.
2021 was a significant year, marked by major results.

Discover more on :

Discover more on our clinical trials :

Clinical Trials

https://recherche.unicancer.fr/fr/fr/la-recherche-clinique/les-essais-cliniques-unicancer/

MAIN CLINICAL RESEARCH PROJECTS

CANcer TOxicities

The **CANTO** project initiated by the **UCBG expert group** and funded by the French National Research Agency (ANR), aims to quantify and predict treatment-related chronic toxicities and social impact in patients with newly diagnosed early breast cancer. It enrolled more than 12,000 women since 2012 and has now entered valorization phases of research results with some 69 ongoing academic projects and challenging self-funded developments (CANTO 2 Young with recruitment of patients under 45 years old at diagnostic and CANTO 3 INNOV with recruitment of patient treated with new standard of care). In addition, the program is developing to allow the launch of a cohort dedicated to lung cancer that should open to recruitment in 2023.

The third edition of the CANTO patient meeting was organized on 2 October 2021 by UNICANCER in 7 cities (Paris, Lyon, Caen, Nancy, Bordeaux, Lille and Reins) with also a live broadcast on an online broadcasting platform. With 213 participants, present or connected, this new edition allowed feedback and cross-discussions on the results of the CANTO study (prediction of toxicity, biomarkers, return to work, quality of life, quality of care, ...).

CANTO-GenMed: Analysis of Genome-Wide Association study.

CANTO COMPLETE: a sub-study evaluating psychological predictors of young patients' compliance to Endocrine Therapy in adjuvant setting.

CANTO Prot: Developing biologic predictors of cancer treatment toxicities, the role of inflammatory markers and adipokines in fatigue, emotional dysfunction and obesity after breast cancer.

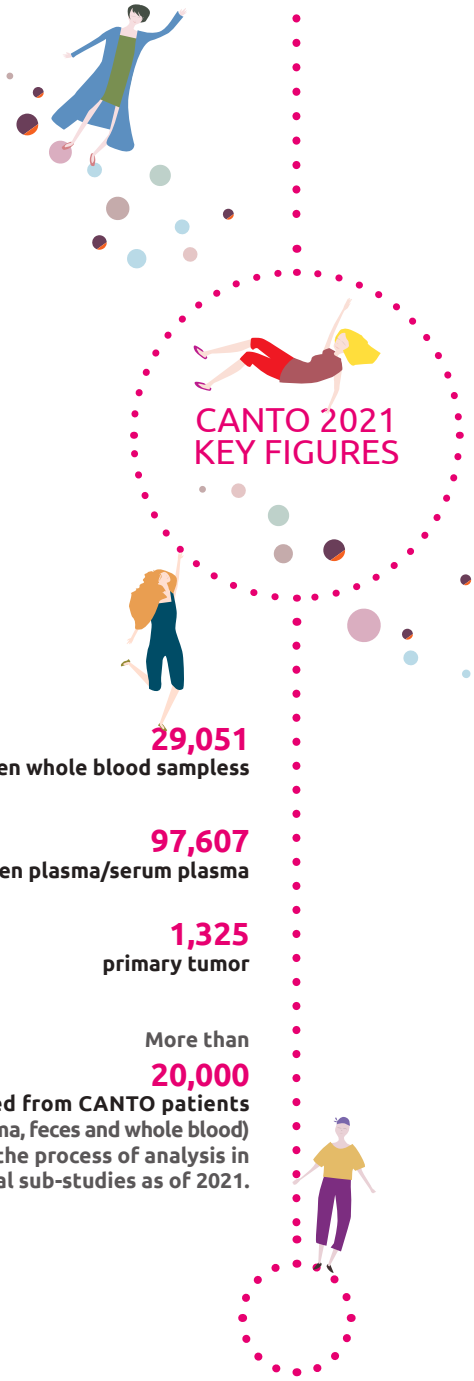
CANTO Protox breast: A study of PROteomics as predictive biomarker of toxicities in women with breast cancer.

CANTO CHIP: Prevalence of clonal hematopoiesis in breast cancer patients at diagnosis and impact on the occurrence of side effects after treatment.

Metabo-Breast: Metabolomics to predict treatment related toxicities in breast cancer patients within CANTO study.

MICROBIOTA: determining the role of microbiota in the response to chemotherapy.

MyProbe: Molecular assays to predict outcome in early breast cancer.



CANTO 2021 KEY FIGURES

29,051
frozen whole blood sampless

97,607
frozen plasma/serum plasma

1,325
primary tumor

More than
20,000
samples collected from CANTO patients (DNA, serum plasma, feces and whole blood) were in the process of analysis in 8 translational sub-studies as of 2021.

MyPeBS
Personalising
Breast Screening

My Personal Breast Screening

The MyPeBS project seeks to answer a simple yet fundamental question: should the type and frequency of breast screening be tailored to each woman's individual risk?

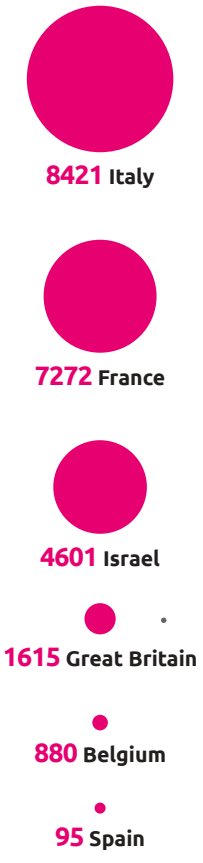
To meet such a goal, at MyPeBS's core is a multi-centre, international, randomised clinical study that aims to assess the effectiveness of a **personalised breast cancer screening**, based on each woman's individual risk of developing the disease, compared to standard screening. Overall, we hope to recruit **85,000 female volunteers** (about 20,000 in France) aged 40 to 70 years-old and without history of breast cancer, living in Italy, France, the United Kingdom, Israel, Belgium, or Spain.

Since the personal experience of women is crucial in this new approach, MyPeBS will also analyse several psycho-social aspects associated with this personalised screening and compare them to the standard screening. The ultimate ambition of MyPeBS is to provide a **more effective (better benefit/risk ratio) breast cancer screening in Europe**, while demonstrating the acceptability, practical feasibility and medico-economic viability of such an approach.

This 8-year project is coordinated by Dr Suzette Delaloge (Gustave Roussy, Villejuif) and managed by Unicancer. It involves 27 partners in 8 countries and is funded by the EU (H2020 - grant agreement nb 755394) and by the French NCI in France (PHRC 2017 research programmes).

Sponsored by Unicancer, the MyPeBS clinical trial started in July 2019 and has included **22,884 participants as of 31 December 2021**, one third of whom in France (see figure below). A total of 16,753 participants were recruited in 2021 only.

Cumulative inclusion of participants by country in the MyPeBS study as of 31/12/2021



Discover more on :

www.mypebs.eu

INCLUSIONS BY EXPERT GROUPS

Number of patients included in 2021 per Group and per institution type

-	UCBG	UNITRAD	MED PERSO	UCGI	GETUG	IOG
Public hospitals of Paris (AP-HP)	192	2	0	30	47	0
Other public hospitals (excl AP-HP)	1688	11	20	131	78	0
FCCCs	1656	103	85	158	166	0
Other private non-profit hospitals	19	0	0	36	31	0
Private clinics	341	20	3	61	65	0
City medical practice	1492	0	0	0	0	0
Foreign institutions	13399	0	0	57	11	0
TOTAL	18787	136	108	473	398	0
POURCENTAGE	93,0%	0,7%	0,5%	2,3%	2,0%	0,0%

SARCOMA	SDS	GERICO	UCH&N	UNICANCER SPECIFIC PROJECTS	TOTAL
4	0	0	11	1	287
31	15	14	22	7	2017
34	26	58	55	5	2346
0	5	0	0	0	91
0	0	1	0	0	491
0	0	0	0	0	1492
0	0	0	0	0	13467
69	46	73	88	13	20191
0,3%	0,2%	0,4%	0,4%	0,1%	

INCLUSIONS BY EXPERT GROUPS

Focus on the Unicancer network of French Comprehensive Cancer Centres (FCCCs)

-	UCBG	UNITRAD	MED PERSO	UCGI	GETUG	IOG
Léon Bérard center	59	3	1	24	6	0
Jean Perrin center	6	1	1	0	7	0
Curie Institute	552	7	5	1	4	0
Gustave Roussy	282	14	3	23	14	0
Oscar Lambret center	114	6	3	4	16	0
Francois Baclesse center	50	1	5	18	13	0
Institute of Cancer research in Western France	198	11	23	24	26	0
Bergonie Institute	67	3	3	1	24	0
Claudius Regaud Institute	27	5	6	4	3	0
Lorraine Institute of Oncology	22	2	1	3	3	0
Jean Godinot Institute	24	6	6	12	0	0
Paoli calmettes Institute	49	1	1	4	13	0
Montpellier Cancer Institute - Val d'Aurelle	4	6	0	8	4	0
Antoine Lacassagne center	34	9	8	8	12	0
Georges-François Leclerc center	72	4	12	7	6	0
Paul Strauss center	2	5	6	12	3	0
Henri Becquerel center	32	6	0	0	0	0
Eugène Marquis center	44	9	1	3	8	0
Sainte-Catherine Institute	28	4	0	2	4	0
TOTAL	1666	103	85	158	166	0
POURCENTAGE	70,7%	4,4%	3,6%	6,7%	7,0%	0,0%

SARCOMA	SDS	GERICO	UCH&N	UNICANCER SPECIFIC PROJECTS	TOTAL	POURCENTAGE
6	0	3	5	0	107	4,5%
0	0	0	0	0	15	0,6%
8	0	14	6	5	602	25,6%
10	0	0	20	0	366	15,5%
3	0	6	0	0	152	6,5%
0	9	9	0	0	105	4,5%
2	3	0	1	0	288	12,2%
2	0	2	0	0	102	4,3%
1	0	16	5	0	67	2,8%
0	0	0	4	0	35	1,5%
0	1	1	0	0	50	2,1%
1	0	0	0	0	69	2,9%
1	0	0	1	0	24	1,0%
0	0	0	5	0	76	3,2%
0	0	0	0	0	101	4,3%
0	0	0	1	0	29	1,2%
0	0	6	3	0	47	2,0%
0	13	0	0	0	78	3,3%
0	0	1	4	0	43	1,8%
34	26	58	55	5	2356	
1,4%	1,1%	2,5%	2,3%	0,2%		

INCLUSIONS BY TUMOUR LOCALISATION

Number of patients included in 2021 by tumour localisation and institution type

-	BREAST	BREAST_OF WHICH MYPEBS	BREAST_OF WHICH TUMOSPEC	DIGESTIVE	GENITO-URINARY	SARCOMA
Public hospitals of Paris (AP-HP)	9	44	141	30	47	4
Other public hospitals (excl AP-HP)	58	1250	404	136	78	31
FCCCs	650	298	826	167	166	34
Other private non-profit hospitals	6	13	0	38	31	0
Private clinics	36	263	58	61	65	0
City medical practice	0	1492	0	0	0	0
Foreign institutions	6	13393	0	57	11	0
TOTAL	765	16753	1429	489	398	69
POURCENTAGE	3,8%	83,0%	7,1%	2,4%	2,0%	0,3%

LUNG	GYNEACOLOGICAL	HEAD & NECK	MULTIPLE LOCALISATIONS	TOTAL	POURCENTAGE
0	0	11	1	287	1,4%
0	4	22	34	2017	10,0%
31	4	55	115	2346	11,6%
0	0	0	3	91	0,5%
1	0	0	7	491	2,4%
0	0	0	0	1492	7,4%
0	0	0	0	13467	66,7%
32	8	88	160	20191	
0,2%	0,0%	0,4%	0,8%		

PARAMEDICAL RESEARCH

A strong axis of the Unicancer strategic plan

At the forefront of research, Unicancer's agile model allows and encourages the implementation of paramedical research on priority themes.

Paramedical research is a decisive factor in improving treatment and organisation and is a genuine mission of the Cancer Centres (CLCC).

Thus, all the medical assistants in the CLCCs have the possibility of investing in research, benefiting from favourable conditions: adapted time, allocated means, inter-institutional synergies. The Unicancer network supports emerging professions in healthcare research (IPA , IDEC , IDES, etc.)

The emulation and inspiration generated by such projects enhance the value of staff, build team loyalty and strengthen the attractiveness of our centres of excellence, by offering them stimulating and dynamic career prospects.

To date, more than 50 paramedical research projects have been carried out or initiated. This figure illustrates the commitment of the teams, for whom constantly improving patient care is an absolute priority.

UCBG

unicancer

FRENCH BREAST CANCER INTERGROUP

Strategic priorities

Subtypes with poor prognosis, biology-driven strategies of therapeutic de-escalation, survivorship

Focus on main achievements in 2021

The result of the primary objective of the prospective phase III **PADA-1** study was presented during a plenary session at the San Antonio Breast Cancer Symposium (SABCS) by Prof François Clément Bidard (Curie Institute, Paris). PADA-1 study included 1017 women who were treated with an aromatase inhibitor plus palbociclib as first-line therapy and provided blood samples for ESR1 mutation screening at baseline, 1 month, and every 2 months thereafter. Switching from an aromatase inhibitor plus palbociclib to fulvestrant and palbociclib upon detection of ESR1 mutation allowed a doubling in median progression-free survival. This study demonstrated that, in most patients, resistance-associated mutations in the oestrogen receptor gene can be detected and targeted before tumour progression indicating the **clinical utility of monitoring ESR1 mutation in blood.**

The **UNIRAD** study, evaluating the benefit of adding everolimus to adjuvant hormone therapy in oestrogen receptor positive, HER2-negative primary breast cancer, has included more than 1,200 patients in 3 countries (France, Belgium, and United Kingdom). This study was presented by Dr Thomas Bachelot (Centre Leon Berard, Lyon) at the inaugural European Society for Medical Oncology (ESMO) Virtual Plenary programme.
The article presenting the main results has just been accepted for publication in Journal of Clinical Oncology and will be available in early 2022.

Thomas Bachelot
President

MyPeBS study has received funding from the European Union's Horizon 2020 research and innovation. This is an international study that evaluate a new breast cancer screening strategy. It investigates whether a personalised breast cancer screening could be a better option for women aged 40 to 70, compared with the current standard breast screening. The MyPeBS study involves 27 partners from 8 different countries (Belgium, United States, France, Israel, Italy, Netherlands, United Kingdom, and Spain), including many leading doctors, scientists and prestigious institutions engaged in breast cancer research and prevention. Furthermore, the implication of patient's representatives and advocates from several associations since the beginning of the MyPeBS study has been crucial. Nearly 23,000 patients have been recruited by the end of 2021!

Major perspectives for 2022

Since UCBG is represented within international organizations, our group is highly involved in major international studies either as a sponsor or partner.

In 2022 we will again be working with several international groups:

- German Breast Group (SASCIA study)
- Spanish SOLTI group (RIBOLARIS study)
- Breast International Group (DECRESCENDO study)

The UCBG will also continue to develop large international studies such as **ERASMUS** (coordinating investigator Prof Mario Campone, Institut de Cancérologie de l'Ouest, Angers/Nantes).
This is an international randomised study evaluating amcenestrant (a new selective oestrogen receptor degrader) in combination with Everolimus in patients with hormone receptor positive, HER2-negative advanced or metastatic breast cancer which progressed on or after combination of aromatase inhibitor and CDK 4/6 inhibitor treatment.
This large study will be conducted in collaboration with Spain, Germany, Belgium, and United Kingdom.

In addition, one of the major priorities of the UCBG is the development of prospective studies with treatment decisions according to circulating tumour DNA (ctDNA; such as in the PADA1 study).
Thus, the **TRAK-ER** study will investigate the potential benefits of monitoring molecular relapse with circulating tumour DNA assays in patients with oestrogen receptor-positive, HER2-negative breast cancer on adjuvant endocrine therapy.
This study is developed in collaboration with Prof Nick Turner from Royal Marsden Hospital (London). This innovating and personalized study will be launched before summer 2022.

UCGI

unicancer

GASTROINTESTINAL GROUP (UCGI)

Strategic priorities

Innovative phase II studies, new diagnostic approaches towards personalized treatment, translational research, large randomised phase II/III studies, rare cancers

Focus on main achievements in 2021

The UCGI in collaboration with the PRODIGE intergroup and the Canadian Cancer Trials Group (CCTG) conducted the **PRODIGE 24-ACCORD 24** study, funded by the French Ministry of Health and the French Cancer League. The initial results reported at ASCO 2018 have established mFOLFIRINOX as the new standard of care in adjuvant setting for patients with resected pancreatic ductal adenocarcinoma, in replacement of gemcitabine that was used for more than 10 years.

An oral presentation at the ESMO conference in September 2021 described the updated results with five-year outcomes. They confirmed the survival benefits of adjuvant mFOLFIRINOX and its status of **recommended adjuvant regimen after resected pancreatic ductal adenocarcinoma resection.**

Since 2004, no major changes were made in the treatment of locally advanced rectal cancer. Results of the **PRODIGE 23-ACCORD 23- UCGI 23** study published in the Lancet oncology in April 2021, conducted to a change in clinical practice for these patients. This phase III study sponsored by Unicancer and conducted in collaboration with the PRODIGE intergroup and the GRECCAR group was funded by the French Ministry of Health and the French Cancer League. This study evaluated the administration of neoadjuvant chemotherapy before standard preoperative chemoradiotherapy in patients with locally advanced rectal cancer (stage II or III).

Christelle de la Fouchardière
President

The results, initially presented through oral communications at ASCO and ESMO congresses in 2020, demonstrated that intensified treatment with neoadjuvant FOLFIRINOX before preoperative chemoradiotherapy was more efficient and better tolerated than adjuvant chemotherapy with improved disease-free survival and decreased neurotoxicity.
This treatment represent, with the results of the RAPIDO study, one of the **new standard of care for total neoadjuvant therapy in locally advanced rectal cancer.**

The **PRODIGE 28-UCGI 27-TIME** study is a multicentre national study sponsored by Unicancer and conducted in collaboration with the PRODIGE intergroup. The aim was to evaluate a maintenance strategy with cetuximab versus surveillance in patients with unresectable metastatic colorectal cancer RAS wild-type and with controlled disease after FOLFIRI plus cetuximab induction treatment. Few studies are available on the role of maintenance therapy after induction with anti-EGFR based chemotherapy. The primary results were presented through oral communications during ASCO GI, JFHOD, and ESMO congresses in 2021. The primary endpoint 6-month PFS was not achieved but the difference observed in terms of PFS was clinically meaningful and warrants further investigation. Updated results including overall survival are expected in 2022.

Major perspectives for 2022

Several exciting study results are expected in 2022:
- **The full PRODIGE 28-UCGI 27-TIME** results including overall survival data
- **PRODIGE 29-UCGI 26-NEOPAN** study that compared FOLFIRINOX versus gemcitabine in locally advanced non resectable pancreatic ductal adenocarcinoma
- **PRODIGE 65-UCGI 36-GEMPAX** study that evaluated a second line treatment with gemcitabine plus paclitaxel versus gemcitabine alone after failure of FOFLIRINOX in metastatic pancreatic ductal adenocarcinoma

Five new studies will be initiated in 2022:
- 2 studies evaluating immune-checkpoint inhibitors in hepatocellular carcinoma
  - **PRODIGE 64-UCGI 39-TACE 3** evaluating nivolumab in combination with TACE
  - **UCGI 41-HESTIA** evaluating tislelizumab in Child-Pugh B patients

- **PRODIGE 73-UCGI 40-LOGICAN** evaluating TASOX treatment in gastro-oesophageal cancer patients non eligible to triplet treatment
- **PRODIGE 75-UCGI 43-COBRAF**, a large prospective clinico-biological cohort of BRAF V600E mutated metastatic colorectal cancer
- **UCGI 42-TARGET-MONITO** evaluating the interest of drug monitoring for oral targeted therapies in several indications

This year is the time of a change in presidency:
Dr Christelle De La Fouchardière replacing Dr Emmanuelle Samalin as president of UCGI group and Dr Julien Edeline becoming vice-president.
We will focus our actions on improving the **involvement of young physicians** in UCGI activities, promoting **translational projects** on available biological collections, improving the **training of CRA** on sites and at Unicancer and extending our **international collaborations** with other academic groups.

Karim Fizazi
President

GETUG

unicancer

GENITOURINARY GROUP

Strategic priorities

Therapeutic strategy studies, research programmes in rare tumours, development of biological research programmes in connection with clinical projects

Focus on main achievements in 2021

GETUG is part of a transcontinental network for prostate cancer research and is a major actor of the **PEACE programme (Prostate Cancer Consortium in Europe)** developed to facilitate large academic clinical studies in prostate cancer in Europe.

In 2021, results of the European phase III study **PEACE-1** were presented at the ASCO and ESMO congresses:

- Adding abiraterone to androgen deprivation therapy plus docetaxel significantly improves radiographic progression-free survival by 2.5 years in median in men with de novo metastatic prostate cancer
- Overall Survival is improved with a **25% reduction in the risk of death**, even when 84% of metastatic castration-sensitive prostate cancer men in the control group receive at least one life-prolonging treatment (next generation androgen signalling inhibitors in 81%)
- This benefit translates in a median **lifetime gain of more than 1.5 year** for men with high-volume metastases (5.1 vs 3.5 years). Overall survival data for low volume men remain immature at this point. This also applies for the radiotherapy question
- Toxicity was as expected, with no apparent synergistic side effects from this combination

These data are practice changing: at least de novo high-volume metastatic castration-sensitive prostate cancer **men should be offered** androgen deprivation therapy plus **docetaxel plus abiraterone based on evidence that this triplet will provide 2.5 years of additional time without radiographic progression or death and 1.5 additional year of survival.**

The GETUG expert group is the international coordinator of the European phase III **PEACE-6 programme** intended for men with castration-naïve metastatic prostate cancer. As part of this programme, **PEACE-6 PRESTO** is already open to inclusions in France and will be initiated in Slovakia in 2022. This study aims to assess the efficacy of ablative radiotherapy (Stereotactic body radiation therapy applied to all oligometastases) administered to all gross tumour sites (metastases with or without the prostate) in oligometastatic hormone-sensitive prostate cancer patients. Over the 350 expected patients, 120 patients were already included.

ALBAN (Genitourinary Group) is a phase III registration study, evaluating the efficacy of atezolizumab **in addition to one year Bacillus Calmette-Guerin (BCG) bladder instillation in BCG-naive patients with high-risk non-muscle invasive bladder cancer.** Inclusion has been opened-up internationally (France, Spain, and Belgium). Over the 516 patients expected by the end of 2022, 351 patients are already included in these 3 countries.

Major perspectives for 2022

Two studies from the **PEACE-6 programme** are planned to be initiated in 2022:

PEACE-6 Vulnerable will be initiated in around 12 countries over Europe in 2022. It received financial support from BAYER and the PHRC in France.

This study aims to evaluate the efficacy of androgen deprivation therapy with or without darolutamide in de novo metastatic prostate cancer patients with vulnerable functional ability and not elected for docetaxel or androgen receptor targeted agents.

The first patient is expected to be included in the study in France by the end of March 2022.

One study dedicated to patients defined as **poor responder** by prostate-specific antigen (PSA; defined as a PSA of 0.2 ng/mL or higher after 6 to 8 months of systemic treatment initiation) and who have a poor outcome. This study is financed by AAA-Novartis and will be initiated in 7 countries in Europe in 2022.

UCH&N

unicancer

HEAD & NECK GROUP

Strategic priorities

Early-phase studies, rare cancers, biology-driven medicine

Focus on main achievements in 2021

Most ongoing clinical studies focusing on human papilloma virus (HPV)-driven oropharynx cancer aim to deescalate treatment since these cancers are mainly associated with good prognosis. In contrast, new therapeutic approaches are needed for HPV-driven oropharynx cancer patients with high risk of relapse. These patients represent a significant proportion of all HPV driven oropharynx cancer. Indeed, the presence of multiple metastases at diagnosis is extremely frequent, and nearly half of HPV-positive patients are current or former smokers. **IMMUNEBOOST-HPV** is a multicentre randomised phase II study evaluating the use of neoadjuvant nivolumab before standard chemoradiotherapy in high-risk HPV driven oropharynx cancer. Interim analysis results were presented at the ESMO conference 2021. The accrual was achieved in September 2021 and final results are expected in 2022.

The recent results of KEYNOTE-038 study conducted to a change in standard of care in recurrent and/or metastatic head and neck squamous cell carcinoma with combined positive score ≥1. Pembrolizumab is now the standard first-line treatment; however, the overall response remains low and progression-free survival short with loco-regional disease being the main cause of treatment failure. **PEMBROMETA-RT**, a phase III randomised multicentre study, proposes to evaluate the addition of a local treatment with radiotherapy to systemic treatment based on pembrolizumab in newly diagnosed metastatic head and neck squamous cell carcinoma with combined positive score ≥1. This study sponsored by Unicancer and conducted in collaboration with the French H&N intergroup included its first patient in December 2021.

Mandibular invasion is a key issue in the management of oral and oropharyngeal cancers. Primary ablative surgery followed by immediate mandibular reconstruction is an effective therapeutic option providing satisfactory oncological and functional outcomes. Until recently, reconstruction relied on intraoperative subjective evaluation of the post ablative defect and the need to use a number of imperfect manipulations to re-sculpt the bony gap. Advances in technology have allowed the use of computerised tomography data for tridimensional virtual surgery (preoperative virtual planning: PVP). Most studies evaluating PVP for mandibular reconstruction are however non-comparative, retrospective, and monocentric. The **CURVE** study proposes to evaluate the use of PVP in a prospective randomised study. This study sponsored by Unicancer was activated in April 2021 and 31 out of the 132 patients required were included as of 31 Dec 2021.

Major perspectives for 2022

The H&N will continue to **develop and sponsor innovative clinical studies** in head and neck cancer with several research axes:

- **HPV-driven oropharyngeal cancers** to propose:
  - Treatment de-escalation when possible: ongoing **PATHOS** study
  - Surveillance adaptation: **SURVEILLE-HPV** study with PHRC grant application in 2022
  - Intensive treatment for high-risk patients: **IMMUNE BOOST-HPV** study with final results expected in 2022 and **ICARE** study with PHRC grant application in 2022

- Clinical studies dedicated to:
  - **Rare cancers** such as salivary glands
  - **Specific populations such as elderly patients** (**ELAN-IMMUNE** study with PHRC grant requested in 2022)
  - **Cutting-edge questions** such as the use of preoperative virtual planning in reconstruction surgery (**CURVE** study)

Guided and supported by the Translational Steering Committee, the group will promote **translational programmes** on existing biological collections. Several large and exciting programmes are ongoing or will start in 2022 based on biological collection derived from our studies **TOPNIVO**, **IMMUNEBOOST**, **ICING**, and the salivary gland clinical studies **PACSA**, **NISCAHN**, and **AcSé NIVO**.

The H&N group will improve the **training** of CRA and data-managers working in clinical studies, promote **public awareness and prevention campaigns**, maintain inside the French H&N intergroup **collaboration with other academic groups**. Furthermore, **international collaborations** will be reinforced through the participation in H&N Cancer International Group and the conduct of studies with international partners.

Joël Guigay
President

Sarcoma Group

unicancer

SARCOMA / RARE CANCERS GROUP

Strategic priorities

Improvement of early management of sarcomas and other rare connective tissue tumours, translational research, biobankings

Focus on main achievements in 2021

In the absence of dedicated recommendations, patients aged 65 years and older currently receive doxorubicin-based chemotherapy as first-line therapy, with substantial risk of toxicity (particularly cardiac).
Metronomic oral cyclophosphamide in patients over 65 years old has shown promising activity and a favourable toxicity profile in this population. **GERICO 14** is a phase III study comparing standard doxorubicin chemotherapy with metronomic oral cyclophosphamide in 242 patients over 65 years old with normal G8 scores and left ventricular ejection fractions who are deemed suitable for anthracyclines. The study received approvals in January 2021 and is now in the recruitment phase.

Osteosarcoma is a rare tumour in adolescent whose cure rate has not improved in the last 40 years, due to a lack of innovation, particularly because of the absence of molecular classification. No targeted therapies or immunotherapy are routinely used, and access to innovation is largely insufficient.
Boost Data is a national osteosarcoma database that combines pre-clinical and clinical research data from academic research facilities. The goal is to integrate data from innovative technologies to identify osteosarcoma subclasses associated with different tumour clones and microenvironment interactions.
The ultimate clinical application is to propose specific treatments and an adapted follow-up for each osteosarcoma subclass. A consortium of 11 partners was implemented in 2021 and Unicancer is making a substantial contribution providing this database with clinical, radiological, and biological data from the **SARCOME 09-OS 2006**, **SARCOME 13-MEPACT**, and **SARCOME 12-REGOBONE studies.**

Nathalie Gaspard
President (paediatrics)

Major perspectives for 2022

Two project have been submitted to the 2021 PHRC grant application and will be initiated when funding is secured.

The international **Inter-Ewing1** study, aimed at patients of all ages diagnosed with Ewing's sarcoma.
This study currently open to inclusion in UK, is sponsored by the University of Birmingham with the support of Cancer Research UK. The remarkable effort made by European and international academics structures (more than 12 countries) to implement the Inter-Ewing1 programme should be highlighted. Questions evaluated by this study should allow for major changes in clinical practices providing innovative systemic treatment to patients with metastatic disease at diagnosis, defining optimal radiotherapy regimens, and evaluating maintenance treatment after standard chemotherapy. Unicancer is mobilised and hopes that the PHRC will support the implementation of this project which is of major importance to improve the management of these patients.

The **L-UteCIN** study, aims to demonstrate that the adjuvant treatment for patients with uterine leiomyosarcoma after initial surgery can be adapted according to the risk defined by the CINSARC signature. Sponsored by Unicancer, this study will be open at the European level to ensure the required recruitment. The French teams, in particular the coordinators Florence Duffaud and Patricia Pautier, have recognized expertise in conducting clinical studies on this rare disease.

Jean-Yves Blay
President (adults)

Immuno-Oncology Group

unicancer

IMMUNO-ONCOLOGY GROUP

Strategic priorities

Cancer immunotherapy research, translational research, identification of predictors and biomarkers of extreme response or poor tolerance to immunotherapy

Focus on main achievements in 2021

AcSé immunotherapy includes two phase II "basket" studies, launched in 2017 by Unicancer under the aegis of the INCa 'secured access' (AcSé) programme, assessing the efficacy and safety of immune checkpoints inhibitors, pembrolizumab (**AcSé Pembrolizumab** study) and nivolumab (**AcSé Nivolumab** study), in patients with specific rare metastatic or locally advanced cancers for which no other standard or experimental treatment options are available.
At the end of 2020, 603 patients have been included in 13 cohorts and most of them were on treatment or in follow-up in 2021.

MOIO study is a non-inferiority, randomised (1:1), French national multicentre phase III comparing the standard scheduling of a variety of immunotherapy regimens versus 3-monthly scheduling in adult patients with metastatic cancer in partial or complete response after 6 months of standard immunotherapy dosing (except melanoma in CR).
A total of 646 patients are expected to be included in 36 sites during a 36-month follow-up period.

Major perspectives for 2022

The immuno-oncology group promotes and develops innovative and strategic clinical studies with a strong translational component.

The IOG group strategy is to:
- Develop and evaluate therapeutic strategies involving immunotherapies
- Promote immunotherapy development in orphan indications to foster access to innovative therapies for patients with rare diseases
- Investigate biomarkers associated with immunotherapies response, in order to identify potential responders, predict treatment escape, and avoid immune-related toxicity

In 2022, immuno-oncology group seeks to:

- Build new national and international collaborations to develop its portfolio of clinical and ancillary projects.
- Develop activities of its biological task force, which is dedicated to define and coordinate a strategic programme of biological samples collection and valorisation:
  - Exploitation of existing biological collections
  - Harmonisation of collection practices across immune-oncology sponsored studies
  - Defining a network of centres of excellence for specific analyses

Frédérique Penault-Llorca
President

GERICO

unicancer

ONCOLOGY GERIATRICS

Strategic priorities

Innovative clinical research in oncogeriatry, methodological adaptation of the evaluation criteria to the geriatric population, diagnostic and therapeutic rationalisation

Expertise in the evaluation and description of geriatric populations, promote the use of G-CODE developed in the framework of DIALOG (Oncogeriatric intergroup associating SOFOG), specific questions for elderly subjects, innovative methodology & adaptive phase II, Evaluation of strategies in elderly patients

Focus on main achievements in 2021

GERICO 14 trial, a phase III study evaluating the improvement in progression-free survival of oral cyclophosphamide therapy in patients aged 65 years or older with advanced or metastatic soft tissue sarcoma compared to doxorubicin therapy, has started this year. 107 patients are expected in each arm.

Major perspectives for 2022

Results of the French UNICANCER Geriatric Oncology Group (GERICO) and Breast Group (UCBG) multicentre, randomised, phase III study **ASTER 70 - GERICO 11** are currently being analysed. The purpose of this study is to address the question of the added value of adjuvant chemotherapy to adjuvant endocrine treatment on the survival of women over 70 with oestrogen-receptor positive, HER2-negative breast carcinoma, deemed "at risk of relapse" according to genomic grade. The benefit of the chemotherapy will be weighed with the competition exerted by comorbidities on mortality.

TOUCH - GERICO 16 a phase II, multicentre, randomized study evaluating neoadjuvant palbociclib in combination with hormone therapy and HER2 blockade versus paclitaxel in combination with HER2 blockade in postmenopausal women with hormone receptor/HER2 positive early breast cancer is scheduled for analysis in 2022. This study aims to demonstrate the efficacy of treatment de-escalation, i.e. targeted therapies versus conventional treatment (chemotherapy) in order to limit adverse effects, which is particularly attractive for the elderly population. The ultimate goal is to modify elderly patients care.

APPALACHES - GERICO 18, sponsored by the EORTC, is a phase II study evaluating adjuvant palbociclib as an alternative to chemotherapy in elderly patients with high-risk ER+/HER2- early breast cancer. This study, which aims to demonstrate the effectiveness of de-escalation of chemotherapy in elderly patients, could contribute to changing practices for the benefit of patients by avoiding over-treatment and the treatment-related adverse effects.

This year, the GERICO group has strengthened its expertise and links with other tumour groups. The DIALOG intergroup has been strengthened by associating PACAN expertise to the GERICO and SOFOG partnership. On this occasion the organization was enriched by 4 working committees (Organ, Transverse, Methodological, Biology).

Loïc Mourey
President

Personalized Medicine Group

unicancer

PERSONALISED MEDICINE GROUP

Strategic priorities

Personalized biology-drivenmedicine, proof of concept studies, identification of predictors or biomarkers of treatment efficacy or resistance

Fabrice André
President

Focus on main achievements in 2021

The results of the **SAFIR02 BREAST** study initiated in 2014 were presented through oral communication at the San Antonio Breast Cancer Symposium (Texas, USA) in December 2021.
Designed as a proof of concept, this study demonstrated that giving tumour genomic profiling-based treatment to patients with metastatic breast cancer is more effective than chemotherapy as long as the treatment was chosen using validated decision support tools. The use of the ESCAT classification has confirmed a benefit of such therapies on progression-free survival for patients treated with a target-therapy combination based on a documented level of evidence (ESCAT I-II).
On the other hand, for patients treated with a target-therapy combination with low level of evidence (ESCAT >III), no difference was observed between targeted therapy and the existing chemotherapy.

The recruitment phase of the **DAISY** study ended in early 2021 with 186 metastatic breast cancer patients included. All patients were treated with trastuzumab deruxtecan, then allocated to 3 cohorts: HER2-overexpressed, HER2-low (IHC2+/FISH- and IHC1+), and HER2-null.
Results reported through a mini-oral presentation at the San Antonio Breast Cancer Symposium (Texas, USA) in late 2021 confirmed trastuzumab deruxtecan efficacy in the multi-treated HER2-overexpressed population and to a lower extend in HER2-low and null patients as well. The study has provided the opportunity to access a promising therapeutic innovation for patients without further therapeutic options.
Furthermore, the timing was perfect to fill the gap between the study initiation and the temporary authorisation to use trastuzumab deruxtecan for this cohort of patient.
DAISY also encompass an ambitious translational programme aimed at understanding trastuzumab deruxtecan mechanism of action.
This component is made possible thanks to the centres whose technicality makes possible the constitution of a rich collection of iterative biopsies. For these reasons, this model of study could be actively developed in 2022 to investigate other antibody drug conjugates.

Major perspectives for 2022

TNew interesting studies are expected for 2022:

• Following the **SAFIR** programme developed in the personalised medicine group, and after significant efforts of the French UCGI, British and Belgian digestive groups, the **SAFIR ABC10** precision medicine study should start the inclusions of patients in 2022.
800 patients with advanced biliary cancer will benefit from molecular profiling then will be offered 8 innovative targeted molecules provided by 6 industrial partners. The stakes are high in this disease with severe prognosis and limited and ineffective therapeutic alternatives to date.

• The **SAFIR03** study uses blood ctDNA analysis as a tool for early detection of resistance to CDK4/6 inhibitor in metastatic hormone receptor-positive breast cancer patients. Predicting treatment resistance allows for identification of a difficult-to-treat population for whom treatment options need to be provided as soon as possible to prevent relapse. In addition to the circulating ctDNA assay performed during treatment with a particular CDK4/6 inhibitor, the presence of PIK3CA gene mutations will be investigated in 1000 patients. This population of women will receive either alpelisib as a bypass strategy for the emergence of biological escape mechanisms, or to continue with the current treatment.

Finally, in line with the strategy validated with Unicancer's R&D steering committee, the group will developed studies to explore antibody-drug conjugates in various breast cancer types. These studies should include translational programmes to quickly determine predictors for response to treatments with these antibody-drug conjugates.

Supportive Care Group

unicancer

SUPPORTIVE CARE INTERGROUP

Strategic priorities

High standard clinical programmes for the evaluation of supportive cares, quality of life, cost-efficiency, humanities and social sciences.
4 strategic axes have been identified: The organization of the care pathway, Symptom management, Health Behaviour, Develop and strengthen patient trials.

Focus on main achievements in 2021

QUALIOR study is evaluating the feasibility and effectiveness of a standardised, supervised physical activity program at home in patients receiving oral targeted therapy for metastatic cancer. Inclusions started in 2017 and results of the first step presented at the ESMO 2021 showed that the supervised physical activity program is feasible. A publication is planned for 2022.

CyPRES, whose objective is to establish a patients consensus for research in supportive care, started in 2017 and is one of the first French studies to consult patients on their expectations for supportive care. The recruitment of patients and the completion of 2 questionnaires dedicated to the identification of supportive care (that they would have received or liked to receive), and their prioritization, respectively, allowed a first analysis of the results, presented at the AFSOS 2021 congress.

Patients were mostly women with breast cancer included post treatment. The most supportive care identified by patients were physical therapy, socio-aesthetic care, osteopathy, and reflexology.
Prioritization remains to be explored by the analysis of the patients' profiles.

RILUZOX 01 a project evaluating the therapeutic efficacy of riluzole in the prevention of oxaliplatin-induced peripheral neuropathy, proposes updated inclusion criteria with the administration of Folfox and Xelox.

Didier Mayeur
President

Major perspectives for 2022

The Netherlands Cancer Institute (NKI) **SEC-trial** is a large-scale European study with at least 1,000 expected participants, evaluating the economic impact of the disease on cancer patients. It will be initiated in France at the beginning 2022, with the contribution of Unicancer.

PROACTIF is a randomized phase II study evaluating the interest of a program combining a nutritional intervention and an individualised adapted physical activity in patients with advanced bronchial or digestive cancers in a fragile situation.

PALLU is a project of prospective, randomized study intended to show the interest of an early management in palliative care on the occasion of an unscheduled hospitalization in emergency service.

PSILONCO plans to study the use of psilocybin in existential distress in oncology.

The **ApaGaPaC** study entitled prehabilitation with adapted physical activity and nutritional support in patients with localised gastric/gastroesophageal and pancreatic adenocarcinoma undergoing preoperative chemotherapy, is part of a collaboration between the EORTC quality of life group and the EORTC digestive group.

Collaboration with Onco-addiction group.

This year, the Task Force has established links with different groups in order to strengthen multidisciplinary.
A statistician/methodologist, a medico-economist, and an expert representative of the (UCGI) Unicancer Gastro-Intestinal group have joined the SDS AFSOS.

UNITRAD

unicancer

TRANSLATIONAL RESEARCH AND DEVELOPMENT IN ONCOLOGY RADIATION

Strategic priorities

Changing practice clinical studies integrating translational research, Artificial Intelligence radiomic/Imaging, radiobiology (immunoradiotherapy /radiosensitivity/ radiopotentialisation), radiotherapy quality assurance, PROMs and real-world data, new technologies and physics innovation

Focus on main achievements in 2021

UNITRAD has increasing involvement in international studies and collaborations with the main cooperative groups abroad at the European (EORTC, EADO) as well as international (CCTG (ongoing collaboration), University of Leicester) level. UNITRAD is becoming a key international player in clinical research in the radiation oncology field.

HYPOG-01 is a non-inferiority phase III open-label, randomised, controlled multicentric study comparing hypofractioned versus standard radiotherapy in breast cancer with an indication for regional lymph node irradiation in terms of lymphedema occurrence. From September 2016 to March 2020, 1265 patients have been included in this study. First results of this study on acute toxicity were presented through an oral communication at ESMO 2021 congress.

Various ancillary studies are ongoing. A UNITRAD study on AI-driven quality assurance for delineation in radiotherapy breast clinical studies in collaboration with the start-up TheraPanacea has been set-up in 2020. **HYPOG-01** data have been used for the development of this contouring/ quality control tool. The first results for this collaborative study were presented at ESTRO 2020, ASTRO 2020, and ESTRO 2021.

BEPCOME-MB is a phase II, international, randomised, controlled, open-label, multicentric, parallel study assessing the efficacy and safety of adding upfront stereotactic radiosurgery to binimetinib-encorafenib plus pembrolizumab combination therapy in the treatment of BRAF V600 mutation-positive melanoma with brain metastasis. The recruitment of this study is planned to start in Q1 2022. The study is supported by Pierre Fabre Medicaments & MSD.

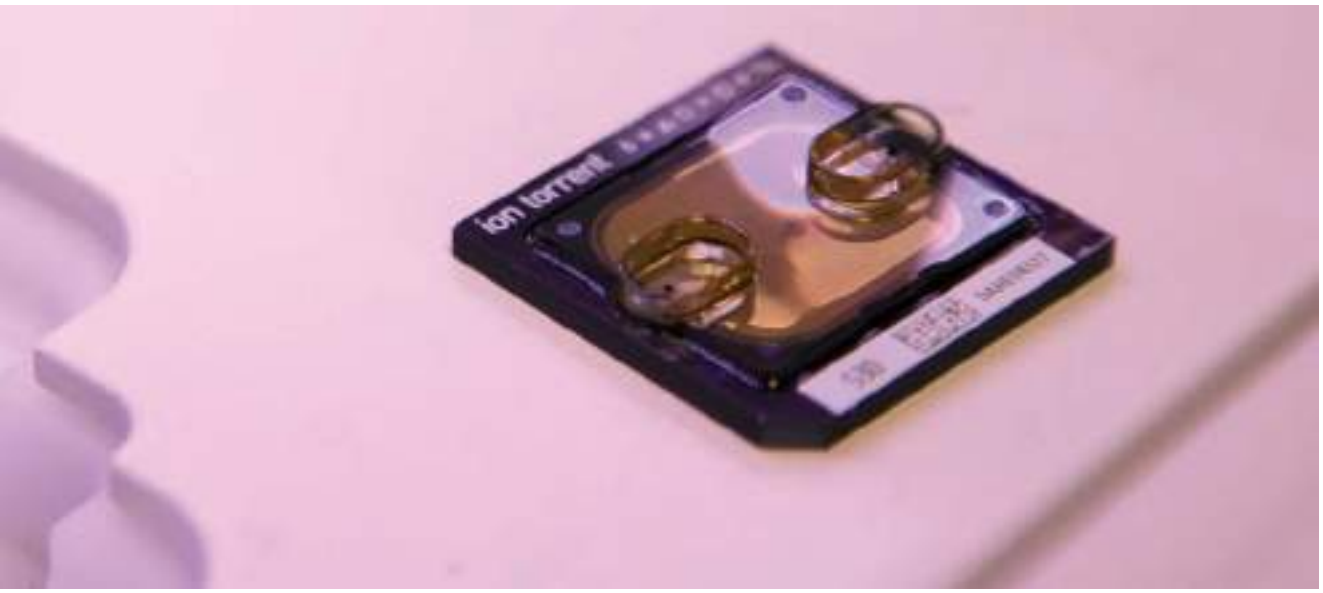
UNITRAD has been selected as the European coordinator for the North American phase III **SELECT** study. This study will evaluate the SPECT-CT Guided ELEctive Contralateral Neck Treatment in Lateralized Oropharynx Cancer.

UNITRAD has applied in 2021 for a PHRC grant to support the French part of this international study. Our letter of intent was selected with excellent scores and full proposal has been submitted.

Major perspectives for 2022

The UNITRAD main goal is to conduct changing practice clinical studies, improve and homogenize daily practice, and optimise radiotherapy quality and safety.

UNITRAD seeks to develop further collaborations with international research groups, in order to foster innovative and personalised research for the benefit of the patients, especially for those with an unmet medical need.



Indeed, in 2022, a new European project under Horizon Europe in collaboration with the University of Leicester and 8 other partners has been granted. This project will integrate data from the **HYPOG-01** study, the CANTO and REQUITE cohorts to build an artificial intelligence-based predictive model for major side effects of breast cancer radiotherapy such as arm lymphedema. This artificial intelligence-based model and its explainability will be validated in a clinical study, promoted by Unicancer and coordinated by UNITRAD, to support treatment share decision making regarding radiotherapy regimen and fractionation. This study will evaluate whether using the predictive model changes the arm lymphedema rate and impacts treatment decisions and quality-of-life. Generalisability of this predictive model for other types of toxicities and cancers will be evaluated through transfer learning techniques.

Sophia Rivera
President

EORTC

EORTC trials portfolio and recruitment status in France in 2021

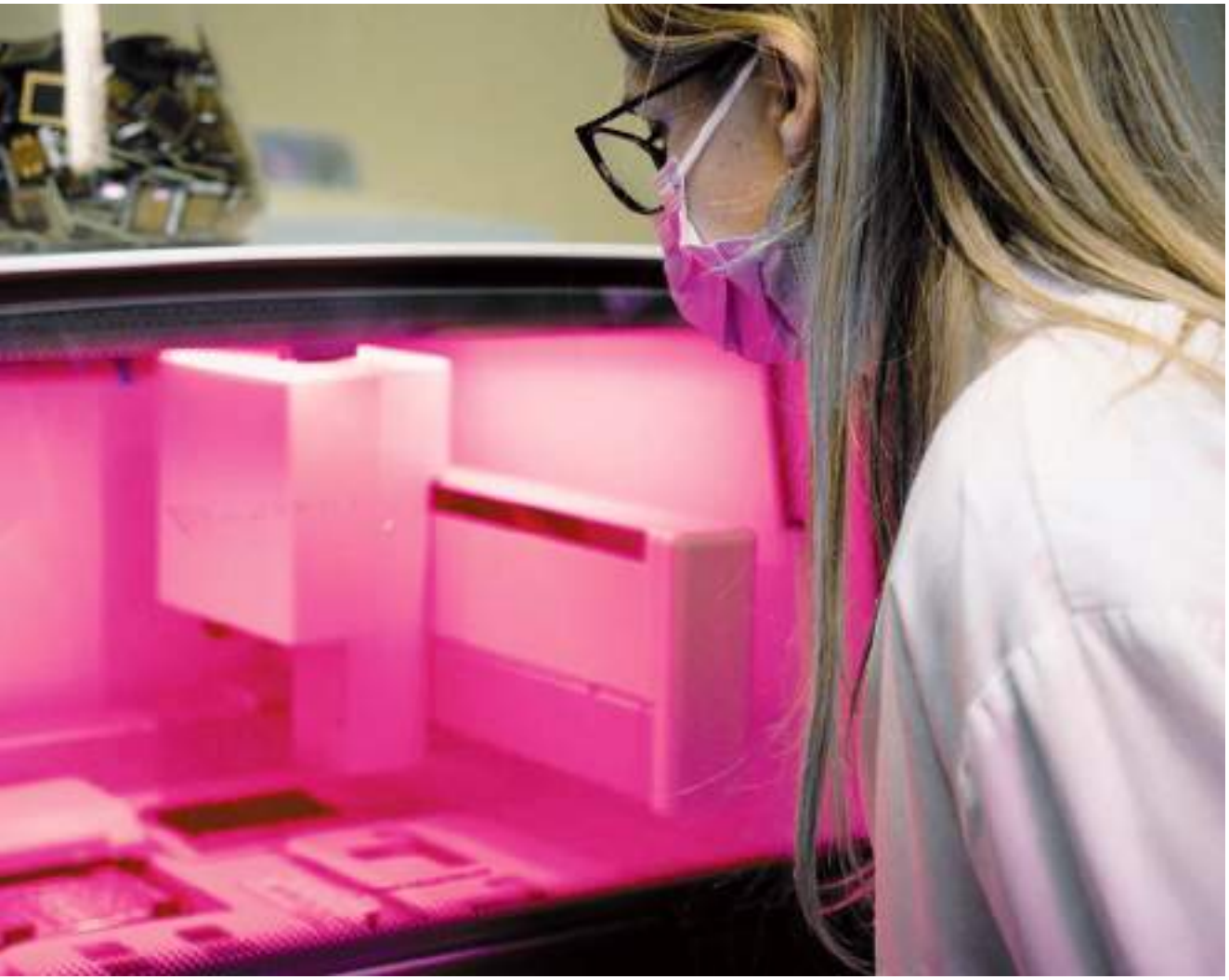
Unicancer has been the local representative of EORTC in France since 2009.
This collaboration aims to facilitate the activation of EORTC-sponsored trials in France and to stimulate the participation of the French investigational centres.

The Unicancer EORTC liaison officer ensures all regulatory and operational tasks required for site initiation and monitoring in France and is the preferred contact person of all French participating sites for all regulatory and operational questions.

In 2021, we had 5 new EORTC-sponsored trials activated and 30 studies recruiting in France.

List of EORTC studies approved in France in 2021

EORTC RESEARCH GROUP(S)	STUDY	TITLE
QLG-BCG-ROG	1617	Follow-up in Early and Locally Advanced Breast Cancer Patients
CLTF	1754 (REACH)	Study to determine the aetiology of chlormetine gel induced-skin drug reaction in early stage mycosis fungoides cutaleous T cell lymphoma (MF-CTCL)
CLTF	1820 (MOGAT)	Open-Label, phase II, Multi-Center, study of Anti-CCR4 Monoclonal Antibody (mogamulizumab) Plus Total Skin Electron Beam therapy (TSEB) in patients with stage IB-IIB Cutaneous T-Cell Lymphoma
LCG	1825 (ALKALINE)	Activity of Lorlatinib based on ALK resistance mutations on blood in ALK positive NSCLC patients previously treated with 2nd generation ALK inhibitor
All groups	1945 (OligoRARE)	Stereotactic body radiotherapy in addition to standard of care treatment in patients with rare oligometastic cancers (OligoRARE): a randomized, phase 3, open-label trial



STUDY APPROVAL DATE IN FRANCE	NATIONAL COORDINATOR IN FRANCE	NUMBER OF EXPECTED PATIENTS (FRANCE/ALL COUNTRIES)
01/07/2021	Dr Eleonor RIVIN DEL CAMPO (Hôpital Tenon, Paris)	60/830
28/10/2021	Pr Martine BAGOT (Hôpital Saint-Louis, Paris)	14/71
22/07/2021	Pr Martine BAGOT (Hôpital Saint-Louis, Paris)	5/43
17/01/2021	Dr Benjamin BESSE (Institut Gustave Roussy, Villejuif)	13/84
05/03/2021	Dr David PASQUIER (Centre Oscar Lambret, Lille)	36/200

List of EORTC studies active in France in 2021

EORTC RESEARCH GROUP(S)	STUDY	TITLE
BTG	1419	Molecular genetic, host-derived and clinical determinants of long-term survival in glioblastoma
BTG	1608 (STEAM)	Study of TG02 in Elderly Newly Diagnosed or Adult Relapsed Patients in the Anaplastic Astrocytoma or Glioblastoma: A Phase Ib Study
BTG	1635 (IWOT)	IDH mutated 1p/19q intact lower grade glioma following resection Wait Or Treat? IWOT – A phase III study.
BTG-ROG	1308 (ROAM)	Radiation versus Observation following surgical resection of Atypical Meningioma: a randomized controlled trial (The ROAM trial)
GITCG	1203 (INNOVATION)	INtegratioN of trastuzumab, with or without pertuzumab, into periOperatiVe chemotherApy of HER-2 posiTIe stOmach cancer: the INNOVATION-TRIAL
GUCG	1532 (ODM-201)	A phase 2 Randomized Open-Label Study of Oral ODM-201 vs. androgen deprivation therapy (ADT) with LHRH agonists or antagonist in Men with Hormone Naïve Prostate Cancer
GUCG-ROG	1414 (Pegasus)	Phase IIIb randomized trial comparing irradiation plus long-term adjuvant androgen deprivation with GnRH antagonist versus GnRH agonist plus flare protection in patients with very high risk localized or locally advanced prostate cancer. A joint study of the EORTC ROG and GUCG- Pegasus
HNCG	1206	A randomized phase II study to evaluate the efficacy and safety of Chemotherapy (CT) vs androgen deprivation therapy (ADT) in patients with recurrent and/or metastatic, androgen receptor (AR) expressing, salivary gland cancer (SGCs).
HNCG-ROG	1420 (Best Of)	Phase III study assessing the "best of" radiotherapy compared to the "best of" surgery (trans-oral surgery (TOS)) in patients with T1-T2, N0 oropharyngeal carcinoma
HNCG	1559 (UPSTREAM)	A pilot study of personalized biomarker-based treatment strategy or immunotherapy in patients with recurrent/metastatic squamous cell carcinoma of the head and neck "UPSTREAM"
GITCG	1707 (VESTIGE)	Adjuvant immunotherapy in patients with resected gastric cancer following preoperative chemotherapy and high risk for recurrence (N+ and/or R1)- an open label randomized controlled phase 2 study
GITCG-ROG	22114-40111 (TOP GEAR)	Trial of preoperative therapy for gastric and esophagogastric junction adenocarcinoma. A randomized phase II/III trial of preoperative chemoradiotherapy vs preoperative chemotherapy for resectable gastric cancer
LCG	1525 (NivoThym)	Single-arm, multicenter, phase II study of nivolumab in patients with type B3 thynoma and thymic carcinoma previously treated with chemotherapy
LCG-ROG	1702 (HALT)	Targeted therapy with or without dose intensified radiotherapy for oligo-progressive disease in oncogene-addicted lung tumors
LCG	1825 (ALKALINE)	Activity of Lorlatinib based on ALK resistance mutations on blood in ALK positive NSCLC patients previously treated with 2nd generation ALK inhibitor
MG	1208 (Minitub)	Minitub: Prospective registry on Sentinel Node (SN) positive melanoma patients with minimal SN tumor burden who undergo Completion Lymph Node Dissections (CLND) or Nodal Observation.
MG	1612 (EBIN)	Combination of targeted therapy (Encorrafebib and Binimetinib) followed by combination of immunotherapy (Ipilumab and Nivolumb) vs immediate combination of immunotherapy in patinets with unresectable or metastatic melanoma with BRAF V600 mutation: an EORTC phase II randomized study

STUDY APPROVAL DATE IN FRANCE	NUMBER OF INCLUDED PATIENTS AS OF DEC 31, 2021 (FRANCE/ALL COUNTRIES)
05/07/2015	122/522
16/03/2018	47/99
08/07/2019	3/18
22/08/2017	9/156
02/09/2015	28/169
07/09/2017	7/61
09/08/2017	62/300
04/02/2015	22/88
18/09/2017	1/52
24/11/2017	131/226
14/06/2019	21/138
13/11/2013	35/171
03/06/2019	23/70
07/01/2019	1/2
17/01/2021	1/24
28/04/2015	10/295
04/07/2018	160/215

List of EORTC studies active in France in 2021

EORTC RESEARCH GROUP(S)	STUDY	TITLE
STBSG	1403 (rEECur)	International Randomised Controlled Trial of Chemotherapy for the treatment of recurrent and primary refractory Ewing sarcoma.
STBSG	1809 (STRASS 2)	A randomized phase III study of neoadjuvant chemotherapy followed by surgery alone for patients with High Risk RetroPeritoneal Sarcoma
STBSG-GCG	62113-55115	A randomized double-blind phase II study evaluating the role of maintenance therapy with cabozantinib in High Grade Undifferentiated Uterine Sarcoma (HGUS) after stabilization or response to doxorubicin +/- ifosfamide following surgery or in metastatic first line treatment.
QLG-LG	1621 (SPARTA)	A Survivorship Project to understand and to improve long-Term outcomes for Acute myeloid leukemia patients (SPARTA): The SPARTA platform
All groups	1811 (E²-RADIATE)	EORTC-ESTRO RADiotherapy InfrAstrucTure for Europe
All groups	1553 (SPECTA*) RP-1759 (AYA/TYA)	Screening Cancer Patients for Efficient Clinical Trial Access Investigations on adolescent and young adults cohort within 1553-SPECTA
All groups	1553 (SPECTA*) RP-1828 (IMMUcan)	Screening Cancer Patients for Efficient Clinical Trial Access Integrated IMMUnoprofiling of large adaptive CANcer patients cohorts
All groups	1553 (SPECTA*) RP-1843 (Arcagen)	Screening Cancer Patients for Efficient Clinical Trial Access Molecular characterization of rare cancer

STUDY APPROVAL DATE IN FRANCE	NUMBER OF INCLUDED PATIENTS AS OF DEC 31, 2021 (FRANCE/ALL COUNTRIES)
10/03/2016	77/272
22/09/2020	3/25
30/01/2015	19/59
29/09/2020	18/150
11/06/2019	0/979
30/03/2017	13/100
30/03/2017	99/328
30/03/2017	246/572

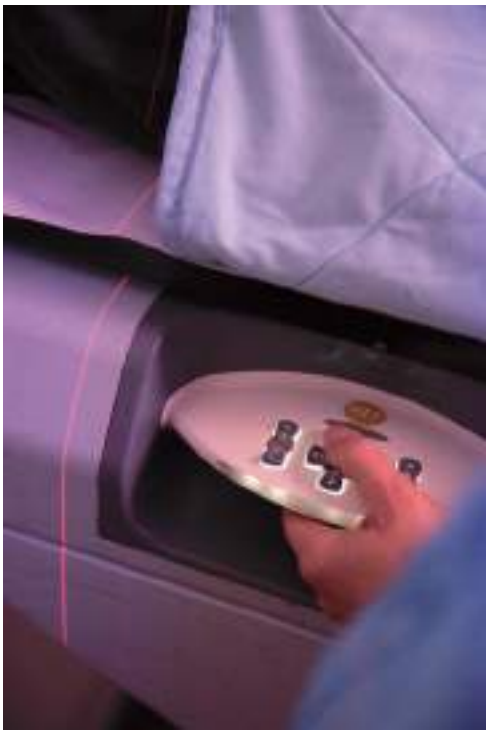
** SPECTA is a collaborative European platform that helps deliver high-quality, molecular and pathological screening across tumor types to aid patient selection into clinical trials.*

Discover more on :

https://recherche.unicancer.fr/en/unicancer-research/eortc/

Glossary

BTG: BRAIN TUMOR GROUP (EORTC BTG)
CLTF: CUTANEOUS LYMPHOMA TASK FORCE (EORTC CLTF)
GITCG: GASTROINTESTINAL TRACT CANCER GROUP (EORTC GITCG)
GUCG: GENITOURINARY CANCER GROUP (EORTC GUCG)
HNCG: HEAD&NECK CANCER GROUP (EORTC HNCG)
LCG: LUNG CANCER GROUP (EORTC LCG)
LG: LEUKEMIA GROUP (EORTC LG)
MG: MELANOMA GROUP (EORTC MG)
QLG: QUALITY OF LIFE GROUP (EORTC QLQ)
ROG: RADIATION ONCOLOGY GROUP (EORTC ROG)
STBSG: SOFT TISSUE AND BONE SARCOMA GROUP (EORTC STBSG)



Discover more on :

Translational Research

Appearing in the twentyfirst century, the concept of translational research perfectly embodies what Unicancer research is.
Collaborative, multidisciplinary research which, from “bench to bedside” according to the accepted expression, has a direct and rapid impact for patients. Studying the microbiota, defining the molecular signature of tumours, developing tests to detect relapse based on circulating DNA are some of the areas currently being explored in these ambitious translational research programmes.

TRANSLATIONAL RESEARCH

Focus on main achievements in 2021

In 2021, part of the translational research programme related to the **PEACE 1** study has been funded under the PRT-K calls for projects. For this research, led by Dr Yohann Loriot and Prof Karim Fizazi (Gustave Roussy), collected tumour from initial biopsies will be sequenced.

Analysed exomes along with immunohistochemistry assays will provide integrated phenotypic and molecular analyses of de novo metastatic castration-naïve prostate cancer. This population represents 5–10% of prostate cancer diagnoses but contributes to almost 50% of prostate cancer-related deaths.

The goals of this research are to provide insights on how to envision new strategies to improve the outcome by identifying:

- A signature of response to abiraterone acetate
- Key drivers as well as the mechanisms of aggressiveness of metastatic castration-naïve prostate cancer

Prof François-Clément Bidard (Institut Curie) proposed a translational research, called **YODA** based on the large phase III clinical trial **PADA-1**, which demonstrated the clinical utility of ESR1 mutation detection during first-line endocrine therapy for oestrogen receptor-positive, HER2-negative breast cancer. This translational research aims to further understand the biology underlying the onset of resistance mechanisms. First results on the characterisation of ESR1 mutations were presented at the AACR 2021 congress.

Major perspectives for 2022

Other ongoing flagship programmes include the **MyProbe** project (led by Prof Fabrice André, Gustave Roussy), one of the 2017 winners of the Programme d'Investissements d'Avenir operated by the Agence Nationale de la Recherche and the **ONCOBIOME** programme, an international programme led by Gustave Roussy and supported by the European Commission.

The objective of **MyProbe** is to create 3 tests to identify patients with early breast cancer of poor prognosis. Two tests will be aimed at patients with hormone receptor-positive breast cancer that does not overexpress the HER2 protein. The third prognostic test will be dedicated to patients with triple-negative breast cancer (i.e. neither hormone receptor-positive nor HER2-overexpressing). The development of these prognostic tests will allow to better adapt patient treatments, to decrease the risk of toxicities, and to reduce the costs of patient care.
Biological samples from several Unicancer adjuvant studies are used for the development of these tests.

The objective of the **ONCOBIOME** programme is to determine the relationship between intestinal microbial signatures and the incidence, prognosis, and resistance to treatment (as well as toxicity) in breast, colon, lung, and melanoma cancers. Biological samples from **CANTO** and **NIRVANA** studies will be used in this programme.

AcSé Cible the translational phase of the AcSé immunotherapy programme

The ancillary programme AcSé Cible which is part of the AcSé immunotherapy programme, proposes to take a more pragmatic approach on the question of biomarkers for immunotherapy. This programme focus on factors that may contraindicate treatment with PD-1 antagonists, allowing clinicians to identify patients for whom treatment may have an absence of effect or even a deleterious effect (e.g. toxicity without efficacy, paradoxical hyper-progression, …).

A multi-parametric analysis of the clinical, biological, and radiological characteristics of the AcSé patients treated by anti-PD-1 (nivolumab or pembrolizumab) is performed in order to identify combination of factors which strongly correlate with early failure of nivolumab or pembrolizumab therapy, as follows:

• Leverage the baseline tumour genomics & transcriptomics to identify mutations, pathways, or molecules associated to early treatments failure (WES + RNAseq on tumour samples at baseline)

• Determine the on-treatment disease kinetics for early preemptive treatment stratification upon anti-PD-1 Failure (ctDNA analysis)

• Identify features of the baseline immune tumour environment or circulating biomarkers (including anti-microbiota serum reactions) associated to an absence of clinical benefit to anti-PD1 therapy

Two hundred patients from the two AcSé studies have been pooled and are being analysed together (“discovery cohort”), regardless of the tumour type, in order to develop a signature or a combination of markers predictive of treatment failure.
The reliability of the signature in predicting clinical outcome will be tested in the 300 additional patients in the AcSé programme on top of the first 200 patients (“validation set”).

This ancillary project will provide practical clinical tools to select the prescription of these expensive treatments to patients with expected benefits while preventing patients without any hope of immunotherapy efficacy to be exposed to immune related adverse events.
Moreover, the results of this collaborative work will highlight new biological pathways responsible for primary resistance to anti-PD1 and identify potential novel therapeutic targets for cancer immunotherapy.

BIOLOGICAL RESOURCE CENTRE

The Unicancer biobank was set up in 2012 to meet the research strategy requirements by creating a collection of samples from the clinical research program. This collection was made available to all research teams to promote biological research and advances in cancer treatment.

The whole collection includes **76,124 samples**, centralised at the Unicancer Biological Resource Center (BRC) located at Léon Bérard Centre in Lyon. Samples were collected from 16,084 patients enrolled in 65 studies.
Historical collections mostly focused on breast cancer.
The collection has been enriched with 9,657 samples in 2021.

The BRC Steering Committee pursued the reflection initiated at the end of 2020 on a new global strategy to enhance the value of the existing collections and to rationalise the constitution of future collections.
Structural changes have been made to offer an immediate solution to the storage capacity challenge faced by Unicancer BRC. New premises were delivered in November 2021.

In 2021, 4,167 samples were unarchived to feed 12 translational research projects, mainly based on advanced technics of molecular biology and deep-learning medical imaging.
Although our samples collections are available for all types of institutions, they have been mainly released for academic research teams in the CLCCs.
Samples can also be made available to industrial companies involved in research partnerships.
Access to the collections is granted upon submission of a valid research project and subject to approval by the Unicancer's translational steering committee.

In order to increase the number of research projects received and to inform a broader community of research teams (universities other than CLCCs, industries, etc.), Unicancer has decided to improve its communication about the collections available. To this end, a new web portal will be made available through Unicancer website allowing the entire scientific community to access biological collection information (including the innate characteristics of the sample, the clinical parameters of the patient, and the genomic analyses already performed).

Through the **mesdonnees.unicancer.fr** website, patients treated within the network or people who have participated in a clinical trial can be informed about the re-use of their data and samples.
This dynamic website meets the requirements of the General Data Protection Regulation (GDPR).

Discover more on :

https://mesdonnees.unicancer.fr/

76,124
samples stored

in total, representing approximately
190,000
aliquots*

9,657
new entries in 2021

4,167
outputs in 2021 used in 12 research projects

** Samples represent collection timepoints: several individual biological samples (called aliquots) can be collected at one given collection timepoint (e.g.baseline or Day 1 post treatment), therefore 1 sample actually represents 1 or more aliquots.*

NUMBER OF SAMPLES BY SUBTYPE

Plasma **25813**

Basket trial **8383**

Prostate **8044**

Lung **8620**

Head & Neck **3320**

Kidney **8043**

Pancreas **5150**

Bone **3729**

Colorectal **1327**

Stomach **1951**

Stem cells **491**

Solid tumours **673**

Solid tumours **580**

SAMPLE DISTRIBUTION BY TUMOUR LOCALISATION

Breast **64 811**

Basket trial **11 803**

Prostate **4 973**

Lung **4 602**

Head & Neck **2 524**

Kidney **900**

Pancreas **891**

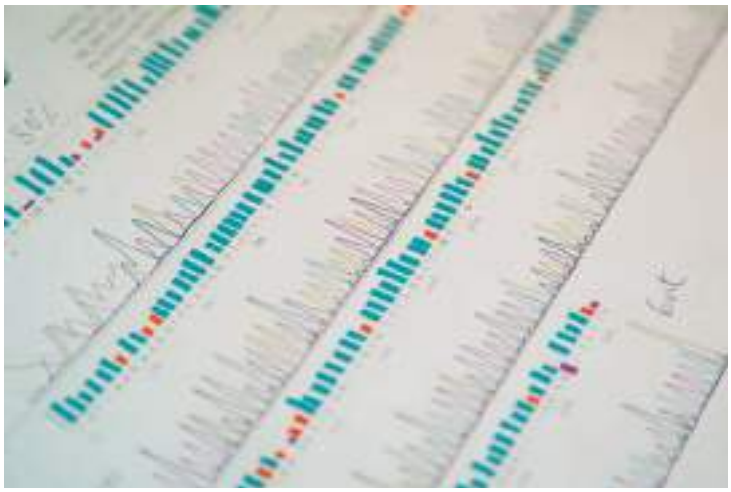
Bone **853**

Colorectal **434**

Stomach **214**

Stem cells **16**

Solid tumours **12**



Health Data Research

ESMÉ (Epidemiological-Medical-Economic Strategy) which integrated 9,000 new patients in 2021, OncoDataHub, a genuine real-life observatory of innovative medicines which already brings together 13 establishments, WeShare which monitors patients from a human and social sciences perspective. Three examples, among others, of initiatives Unicancer is rolling out around health data exploitation in the area of oncology. The new Unicancer Research Department is intended as a think tank and project kickstarter on health data, involving patients in their use and exploitation.

Discover more on :

ESMÉ

2021 KEY FIGURES

Metastatic Breast Cancer

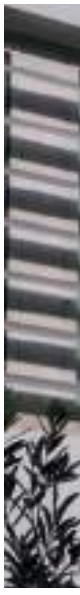
31 000
CASES SELECTED
Metastatic breast cancer database

Advanced & Metastatic Lung Cancer

38 000
CASES SELECTED
Lung cancer database

Ovarian Cancer

14 000
CASES SELECTED
Ovarian cancer database



36
PROJECTS
since the start of the ESMÉ research programme

88
COMMUNICATIONS AND PUBLICATIONS
by the end of 2021

afaq iso 9001

Unicancer is **ISO 9001 certified** for its clinical research activity

ESMÉ

The ESME research program is a French platform of longitudinal retrospective real world data on cancer management in oncology.
It is a unique platform centralizing data from patient medical files describing the therapeutic decisions and care management in routine practice.

4 objectives :

- Describe cancer management in France, and its evolution over time
- Provide data on innovative drug use in medical institutions
- Describe therapeutic trend
- Provide data to support the Health Economic Models and requirements of the Health Technology Assessment bodies

Ten or so cases of use of these retrospective data have been recorded as indirect comparators in dossiers submitted to the HAS Transparency Commission (CT).

Two partnerships have been established with international entities to use ESME databases as real world external control arms for clinical studies.

These control arms were set up with a high degree of selectivity of patient data sets based on very strict inclusion and exclusion criteria.

OncoDataHub:
The oncology drug observatory

The French oncology drug observatory to describe patient care in routine practice open to all actors across the health system.
Goal : 80 French hospitals by 2023 both non-profit and private.
2021 target : Breast and Lung cancer.
2023-2024 : potentially all indication.
A 60-variable data set automatically taken from patients' files to cover a high range of use-cases, with updated, representative and accurate data.

Objectives

- Describe cancer management in France, and its evolution over the time (multi-annual updates)
- Provide data on innovative drug use (pre-MA and real-life setting) in medical institutions
- Describe therapeutic trends (e.g. sequence of treatment strategies)
- Provide data to support the Health Economic Models and requirements of the Health Technology Assessment (HTA) bodies

Go further:

- **New cancers**
- **Broaden the data-set**
- **Linkage with other databases**
- **Facilitate data collection, interoperability, …**

TARGET : 80 HOSPITALS

2022-2023 : Implement & improve processes

JANUARY 2022 : 13 hospitals, 19 500 patients

2021 Launch

Web-based Exploitation of Social and Human sciences to Advance cancer REsearch

Unicancer, in association with a multidisciplinary consortium, is creating a new digital infrastructure: WeShare. It will enable the acceleration of research in Human and Social Sciences in the field of Quality of Life in cancer and post-cancer. Coordinated scientifically by Gustave Roussy, the objective of the WeShare platform is to identify new levers to act on the impact of cancer and its treatment on patients' quality of life.

WeShare (ANR-21-ESRE-0017) has been selected for the 2020 Equipex call for projects by the ANR (French National Research Agency) under the "Investissements d'avenir" programme and has been awarded €11M in funding.
WeShare will last 8 years. 2021 is the first year of the project setting up with an official start date at May 2021.
The ANR aid agreement was signed on September 24, 2021.
The kick-off meeting, in the presence of all partners and French National Research Agency (ANR) members, took place on October 7, 2021. A press release announcing the launch of WeShare was issued on December 7, 2021. A first Executive Committee has been scheduled for January 20, 2022.

In 2021, expected deliverables for the project between 2021 and 2029 has been defined. From a contractual point of view, the repayment agreement between Unicancer and partners have been established and governance has been validated.

Unicancer is in charge of developing the platform. In 2021, expertise and missions of each partner has been detailed and validated. The needs from partners and scientific collaborators has been carried out in order to set priority modules to be developed in 2022 : infrastructure, database, web portail, ePro, eConsent, randomization, standardized dataset.
In addition, the work relating to the creation of the WeShare website and the communication campaign with social networks relating to the launch of the website has begun.
A reflection has also been initiated regarding the dissemination of the platform at national and international level.

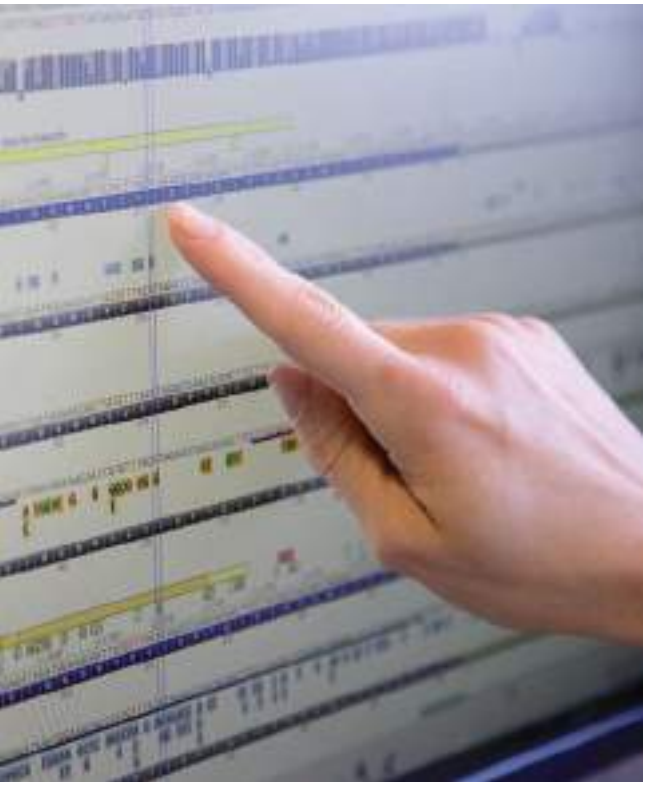
CONSORE
continuum soins recherche
unicancer

A search engine for big data in oncology

The Consore project reached some major milestones in 2021 with the implementation of 10+ innovative features such as new datasources (lab results), improvements on metastasis or oral treatments detection, statistical dashboards...

As a major achievement, two new comprehensive cancer centers joined the network : Gustave Roussy and Institut de Cancérologie de l'Ouest, raising the of Consore, a unique infrastructure in France and Europe for big data exploration in oncology, gathering now 10 comprehensive cancer centers.

The project has been involved in an important strategic partnership between UNICANCER and the Health Data Hub signed in July 2021, it's the UNIBASE project.



UNIBASE

Initiative to promote data sharing and support real-world evidence

After several months of work and talks, a convention was signed on July 2021 between UNICANCER and the Health Data Hub (HDH) to set up the UNIBASE program.

UNIBASE aims to make multicentric studies from big volumes of data from "real life", to answer to major scientific questions that could not be answered by other means. The objective is to create a dialogue between databases of reference in oncology to allow collaborative research.

We have selected pilot projects within the scope of an AMI. We need to build an infrastructure and the conditions for feasibility of these projects on all matters: legal, technical, respecting GDPR.

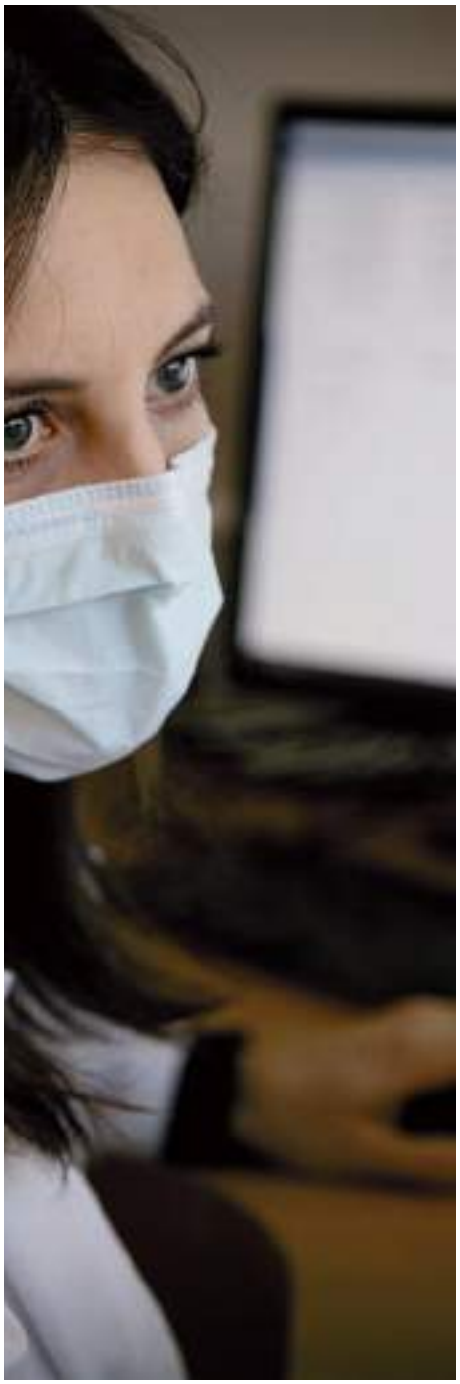
These projects will be selected by a jury and will be supported technically and financially by UNICANCER and the HDH. The criteria for the selection of these projects is to have an impact on patients' care and research in oncology with fast results. These projects will be sponsored by several CLCC candidates. We will progressively build all the tools necessary to allow more collaborative projects.

In 2022, the AMI is open to all the CLCC who will benefit from the Consore data warehouses.

Discover more on :

Research in the FCCCs'

Unicancer groups together 18 French Comprehensive Cancer Centres (FCCCs) spread across 20 hospital sites throughout France and one affiliate member.
They are private, non-profit health establishments dedicated to cancer care, research and education.
Most of the research platforms accredited by the French National Cancer Institute (INCa) are hosted in our FCCCs, thus demonstrating the excellence and innovativeness of our research in the field of precision medicine.



2021 KEY FIGURES

16%
OF THE PATIENTS
treated in the FCCCs are included in a clinical trial versus 8.5% of cancer patients in average in France

630
ACTIVE CLINICAL TRIALS
sponsored by the Unicancer network

104
NEW TRIALS
sponsored by the Unicancer network

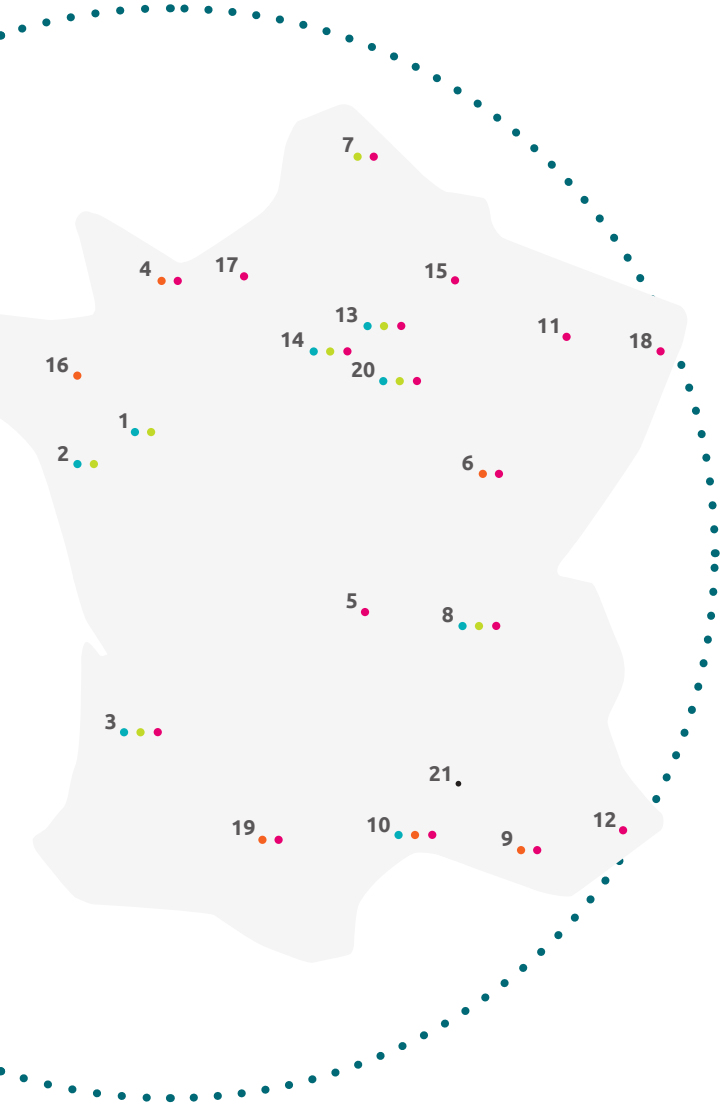
12
early phase INCa-accredited centres (CLIP2) are hosted in a FCCC, out of 19 in France

Unicancer is ISO 9001 certified for its clinical research activity

SIRIC HOSTED IN A FCCC OR INTEGRATING A FCCC:

BRIO / Bordeaux Recherche Intégrée Oncologie (Institut Bergonié, Bordeaux)
LYriCAN / Manipulating cell plasticity for innovative cancer treatment (Centre Léon Bérard, Lyon)
SIRIC ILIAD / Imaging and Longitudinal Investigations to Ameliorate Decision Making (Institut de cancérologie de l'Ouest, Angers/Nantes)
SOCRATE 2.0 / Stratified Oncology Cell DNA Repair and Tumor Elimination 2.0 (Gustave Roussy, Villejuif)
SIRIC Montpellier Cancer (Institut du Cancer de Montpellier, Montpellier)
SIRIC Curie (Institut Curie, Paris)

UNICANCER, A UNIQUE NETWORK OF EXPERT CENTRES IN FRANCE



- *SIRIC*
- *CLIP2 - adult*
- *CLIP2 - adult and paediatric*
- *Molecular genetics platform*

INSTITUT DE CANCÉROLOGIE DE L'OUEST 1 - 2
Unicancer Pays de la Loire

INSTITUT BERGONIÉ 3
Unicancer Nouvelle-Aquitaine

CENTRE JEAN PERRIN 4
Unicancer Clermont Auvergne Métropole

CENTRE FRANÇOIS BACLESSE 5
Unicancer Normandie-Caen

CENTRE GEORGES-FRANÇOIS LECLERC 6
Unicancer Bourgogne Franche-Comté

CENTRE OSCAR LAMBRET 7
Unicancer Hauts-de-France

CENTRE LÉON BÉRARD 8
Unicancer Lyon, Auvergne-Rhône-Alpes

INSTITUT PAOLI-CALMETTES 9
Unicancer Marseille

INSTITUT DU CANCER DE MONTPELLIER 10
Montpellier

INSTITUT DE CANCÉROLOGIE DE LORRAINE 11

CENTRE ANTOINE LACASSAGNE 12
Unicancer Nice

INSTITUT CURIE 13 - 14
Unicancer Paris – Saint-Cloud – Orsay

INSTITUT GODINOT 15
Unicancer Reims en Champagne

CENTRE EUGÈNE MARQUIS 16

CENTRE HENRI BECQUEREL 17
Unicancer Normandie-Rouen

ICANS 18
Unicancer Strasbourg

IUCT ONCOPOLE – INSTITUT CLAUDIUS REGAUD 19

GUSTAVE ROUSSY 20

ICAP - Sainte Catherine 21
Avignon-Provence

CLINICAL TRIALS INCLUSIONS IN THE FCCCs

FRENCH COMPREHENSITE CANCER CENTRE (FCCCS)	CITY	ACTIVE PATIENT FILE	PATIENTS INCLUDED IN A CLINICAL TRIAL	TOTAL ACTIVE TRIALS	AVERAGE NUMBER OF PATIENTS INCLUDED PER CLINICAL TRIAL	% OF PATIENTS SIGNING AN INFORMED CONSENT *
Bergonie Institute	Bordeaux	8.581	2.319	377	6,2	51%
Francois Baclesse Centre	Caen	7.637	746	169	4,4	12%
Jean Perrin Centre	Clermont	5.958	638	129	4,9	18%
Georges-François Leclerc centre	Dijon	5.349	1.806	272	6,6	36%
Oscar Lambret Centre	Lille	7.241	1.309	158	8,3	21%
Léon Bérard Centre	Lyon	11.083	1.893	380	5,0	19%
Paoli calmettes Institute	Marseille	10.611	1.264	246	5,1	14%
Montpellier Cancer Institute - Val d'Aurelle	Montpellier	7.153	1.478	198	7,5	25%
Lorraine Institute of Oncology	Nancy	5.646	639	134	4,8	12%
Institute of Cancer research in Western France	Nantes / Angers	12.440	1.296	268	4,8	17%
Antoine Lacassagne Centre	Nice	5.419	546	182	3,0	11%
Curie Institute	Paris Saint Cloud	15.243	2.410	244	9,9	17%
Jean Godinot Institute	Reims	3.809	210	78	2,7	6%
Eugène Marquis centre	Rennes	5.008	421	98	4,3	10%
Henri Becquerel centre	Rouen	5.622	340	92	3,7	6%
Paul Strauss Centre	Strasbourg	5.052	665	197	3,4	16%
Claudius Regaud Institute	Toulouse	7.629	939	256	3,7	22%
Gustave Roussy	Villejuif	13.323	4.214	475	8,9	47%
Total		142.804	23.133			22%
Mean		7.934	1.285	220	5	20%
+/- SD		3280	987	108	2	13%
median		7.197	1.102	198	5	17%
min		3.809	210	78	3	6%
max		15.243	4.214	475	10	51%

	ACADEMIC SPONSOR			INDUSTRIAL SPONSOR	
% OF THE ACTIVE PATIENT FILE INCLUDED IN A CLINICAL TRIAL	NUMBER OF PATIENTS INCLUDED	NUMBER OF ACTIVE TRIALS	% OF PATIENTS INCLUDED IN AN INSTITUTIONAL CLINICAL TRIAL	NUMBER OF PATIENTS INCLUDED	NUMBER OF ACTIVE TRIALS
27%	1986	204	86%	333	173
10%	666	125	89%	80	44
11%	493	91	77%	145	38
34%	1641	174	91%	165	98
18%	1013	110	77%	296	48
17%	1446	217	76%	447	163
12%	1102	160	87%	162	86
21%	1386	138	94%	92	60
11%	581	102	91%	58	32
10%	1091	171	84%	205	97
10%	445	116	82%	101	66
16%	2151	145	89%	259	99
6%	151	64	72%	59	14
8%	349	64	83%	72	34
6%	299	55	88%	41	37
13%	510	124	77%	155	73
12%	667	133	71%	272	123
32%	3457	166	82%	757	309
16%	19.434		84%	3.699	
15%	1.080	131	83%	206	89
8%	834	46	7%	177	71
12%	840	129	84%	159	70
6%	151	55	71%	41	14
34%	3.457	217	94%	757	309

** With the development of personalised medicine, an increasing number of clinical trials include a molecular screening as eligibility criteria. Patients who have accepted and signed an informed consent can be denied in a second step due to the negative result of the molecular screening (this representan average 62% of the patients having signed the informed consent in such trials). Such trials represent an average 35% of industrially sponsered trials and 11% of the academically sponsored trials proposed in our centres.*

GROUP	STUDY	TITLE
Groupe d'étude des tumeurs urogénitales (GETUG)	NA	Randomized Phase III Trial of Dose-dense Methotrexate, Vinblastine, Doxorubicin, and Cisplatin, or Gemcitabine and Cisplatin as Perioperative Chemotherapy for Patients with Muscle-invasive Bladder Cancer. Analysis of the GETUG/AFU V05 VESPER Trial Secondary Endpoints: Chemotherapy Toxicity and Pathological Responses
Groupe d'étude des tumeurs urogénitales (GETUG)	NA	Chemotherapy for Muscle-invasive Bladder Cancer: Impact of Cisplatin Delivery on Renal Function and Local Control Rate in the Randomized Phase III VESPER (GETUG-AFU V05) Trial
Groupe d'étude des tumeurs urogénitales (GETUG)	OLIGOPELVIS - GETUG P07	OLIGOPELVIS GETUG P07, a Multicenter Phase II Trial of Combined High-dose Salvage Radiotherapy and Hormone Therapy in Oligorecurrent Pelvic Node Relapses in Prostate Cancer
Groupe d'étude des tumeurs urogénitales (GETUG)	NA	Patient Preference Between Cabazitaxel and Docetaxel for First-line Chemotherapy in Metastatic Castration-resistant Prostate Cancer: The CABADOC Trial
Groupe Head & Neck	NA	Cetuximab, docetaxel, and cisplatin versus platinum, fluorouracil, and cetuximab as first-line treatment in patients with recurrent or metastatic head and neck squamous-cell carcinoma (GORTEC 2014-01 TPExtreme): a multicentre, open-label, randomised, phase 2 trial
Groupe Head & Neck	NA	Tumors: Oto-Rhino-Laryngology
Groupe Head & Neck	NA	Systemic treatment of metastatic squamous cell carcinoma of the head and neck: proposal for management changes
French Breast Cancer Intergroup (UCBG)	NA	The tale of TILs in breast cancer: A report from The International Immuno-Oncology Biomarker Working Group
Groupe d'étude des tumeurs urogénitales (GETUG)	GETUG-AFU17	Re: Adjuvant Radiotherapy Versus Early Salvage Radiotherapy plus Short-term Androgen Deprivation Therapy in Men with Localised Prostate Cancer After Radical Prostatectomy (GETUG-AFU 17): A Randomised, Phase 3 Trial
Groupe d'étude des tumeurs urogénitales (GETUG)	GETUG-AFU 26 NIVOREN	Primary Renal Tumour Response in Patients Treated with Nivolumab for Metastatic Renal Cell Carcinoma: Results from the GETUG-AFU 26 NIVOREN Trial
Groupe d'étude des tumeurs urogénitales (GETUG)	GETUG-AFU 26 NIVOREN	Association of AXL and PD-L1 Expression with Clinical Outcomes in Patients with Advanced Renal Cell Carcinoma Treated with PD-1 Blockade
Groupe d'étude des tumeurs urogénitales (GETUG)	GETUG-AFU 26 NIVOREN	Soluble BTN2A1 Is a Potential Prognosis Biomarker in Pre-Treated Advanced Renal Cell Carcinoma
Groupe d'étude des tumeurs urogénitales (GETUG)	GEP 03	Everolimus or sunitinib as first-line treatment of metastatic papillary renal cell carcinoma: A retrospective study of the GETUG group (Groupe d'Etude des Tumeurs Uro-Genitales)
Groupe d'étude des tumeurs urogénitales (GETUG)	GETUG-AFU19	Dose-Dense Methotrexate, Vinblastine, Doxorubicin, and Cisplatin With or Without Panitumumab in Patients With Advanced Urothelial Carcinoma: Multicenter, Randomized, French Unicancer GETUG/AFU 19 Study
Groupe Head & Neck	COPAN	Phase I trial of copanlisib, a selective PI3K inhibitor, in combination with cetuximab in patients with recurrent and/or metastatic head and neck squamous cell carcinoma.
Médecine personnalisée	PEVOsq	Combining immunotherapy with an epidrug in squamous cell carcinomas of different locations: rationale and design of the PEVO basket trial
Médecine personnalisée	GEP04 Radher	A phase II randomized study of preoperative trastuzumab alone or combined to everolimus in early HER2-positive breast cancer patients and predictive biomarkers (RADHER trial)
Médecine personnalisée	AcSé crizotinib	The Activity of Crizotinib in Chemo-Refractory MET-Amplified Esophageal and Gastric Adenocarcinomas: Results from the AcSé-Crizotinib Program

MAIN AUTHOR	REFERENCES
	Eur Urol. 2021 Feb;79(2):214-221
	Clin Genitourin Cancer. 2021 Dec;19(6):554-562
	Eur Urol. 2021 Oct;80(4):405-414
	Eur Urol. 2021 Nov 14:S0302-2838(21)02117-5
	Lancet Oncol. 2021 Apr;22(4):463-475
	Encyclopedia of Gerontology and Population Aging, D. Gu and M.E. Dupre, Editors. 2020, Springer International Publishing: Cham. p. 1-12
	Curr Opin Oncol. 2021 May 1;33(3):160-167
Khalid El Bairi	NPJ Breast Cancer 2021 Dec 1;7(1):150
Lara Rodriguez	Eur Urol. 2021 Apr;79(4):555-556
Jean Courcier	Eur Urol. 2021 Sep;80(3):325-329
Stéphane Terry	Clin Cancer Res. 2021 Dec 15;27(24):6749-6760
Emilien Billion	Front Immunol. 2021 Apr 20;12:670827
Mathilde Cancel	Eur J Cancer. 2021 Oct 4;158:1-11
Stéphane Culine	Clin Genitourin Cancer. 2021 Aug;19(4):e216-e222
Grégoire Marret	Invest New Drugs. 2021 Dec;39(6):1641-1648
E De Guillebon	ESMO Open. 2021 Jun;6(3):100106
Mario Campone	Eur J Cancer. 2021 Oct 19;158:169-180
Thomas Aparicio	Target Oncol. 2021 May;16(3):381-388

GROUP	STUDY	TITLE
Médecine personnalisée	SAFIR02-BREAST	Durvalumab compared to maintenance chemotherapy in metastatic breast cancer: the randomized phase II SAFIR02-BREAST IMMUNO trial
Médecine personnalisée	SAFIR02-BREAST	Genomic Alterations in PIK3CA-Mutated Breast Cancer Result in mTORC1 Activation and Limit the Sensitivity to PI3Kα Inhibitors
Médecine personnalisée	RUBY	Rucaparib in patients presenting a metastatic breast cancer with Homologous Recombination Deficiency, without germline BRCA1/2 mutation
Groupe sarcome	sarcome 08	Final analysis of the randomized trial on imatinib as an adjuvant in localized gastrointestinal stromal tumors (GIST) from the EORTC Soft Tissue and Bone Sarcoma Group (STBSG), the Australasian Gastro-Intestinal Trials Group (AGITG), UNICANCER, French Sarcoma Group (FSG), Italian Sarcoma Group (ISG), and Spanish Group for Research on Sarcomas (GEIS)
Groupe sarcome	Sarcome 09	Successive Osteosarcoma Relapses after the First Line O2006/Sarcome-09 Trial: What Can We Learn for Further Phase-II Trials?
Groupe sarcome	Sarcome 09	Characterization of macrophages and osteoclasts in the Osteosarcoma tumor microenvironment at diagnosis: New perspective for osteosarcoma treatment?
Groupe sarcome	REGOBONE	Efficacy and safety of regorafenib in patients with metastatic or locally advanced chondrosarcoma: Results of a non-comparative, randomised, double-blind, placebo controlled, multicentre phase II study
Groupe Soin de support	NA	Longitudinal analysis of health-related quality of life in cancer clinical trials: methods and interpretation of results
French Breast Cancer Intergroup (UCBG)	GRT02-COMET	Multimodal liquid biopsy for early monitoring and outcome prediction of first line chemotherapy in metastatic breast cancer patients
French Breast Cancer Intergroup (UCBG)	RxPonder	Postmenopausal Women with HR+/HER2– Early Breast Cancer, 1–3 Positive Nodes, and a Low Risk of Recurrence Can Safely Forego Chemotherapy
French Breast Cancer Intergroup (UCBG)	RxPonder	21-Gene Assay to Inform Chemotherapy Benefit in Node-Positive Breast Cancer
French Breast Cancer Intergroup (UCBG)	TUMOSPEC	TUMOSPEC: A Nation-Wide Study of Hereditary Breast and Ovarian Cancer Families with a Predicted Pathogenic Variant Identified through Multigene Panel Testing
French Breast Cancer Intergroup (UCBG)	MyPeBS	Validation of a new fully automated software for 2D digital mammographic breast density evaluation in predicting breast
Groupe gastro-intestinal (UCGI)	Prodige 5 - Accord 17	Joint modelling with competing risks of dropout for longitudinal analysis of health-related quality of life in cancer clinical trials
Groupe gastro-intestinal (UCGI)	UCGI23-Prodige23	Neoadjuvant chemotherapy with FOLFIRINOX and preoperative chemoradiotherapy for patients with locally advanced rectal cancer (UNICANCER-PRODIGE 23): a multicentre, randomised, open-label, phase 3 trial
Groupe gastro-intestinal (UCGI)	Prodige 7 - Accord 15	Cytoreductive surgery plus hyperthermic intraperitoneal chemotherapy versus cytoreductive surgery alone for colorectal peritoneal metastases (PRODIGE 7): a multicentre, randomised, open-label, phase 3 trial
Groupe gastro-intestinal (UCGI)	UCGI28-PANIRINOX	Association of COVID-19 Lockdown With the Tumor Burden in Patients With Newly Diagnosed Metastatic Colorectal Cancer
Groupe gastro-intestinal (UCGI)	Prodige 17 - Accord 20	Targeting HGF/c-Met Axis Decreases Circulating Regulatory T Cells Accumulation in Gastric Cancer Patients

MAIN AUTHOR	REFERENCES
Thomas Bachelot	Nat Med. 2021 Feb;27(2):250-255
Yanyan Cai	Cancer Res. 2021 May 1;81(9):2470-2480
Anne Patsouris	Eur J Cancer. 2021 Dec;159:283-295
PG Casali	Ann Oncol. 2021 Apr;32(4):533-541
Eric Thebault	Cancers (Basel). 2021 Apr 2;13(7):1683
Anne Gomez-Brouchet	Cancers (Basel). 2021 Apr 2;13(7):1683
Florence Duffaud	Eur J Cancer. 2021 Jun;150:108-118
Caroline Bascoul-Mollevi	"Qual Life Res. 2021 Jan;30(1):91-103
Amanda Bartolini Silveira	NPJ Breast Cancer. 2021 Sep 9;7(1):115
	Oncologist 2021;26 (Suppl 2):S11–S12
Kevin Kalinsky	N Engl J Med. 2021 Dec 16;385(25):2336-2347
Fabienne Lesueur	Cancers (Basel). 2021 Jul 21;13(15):3659
Paolo Giogi	Sci Rep. 2021 Oct 6;11(1):19884
Benjamin Cuer	Qual Life Res. 2021 Nov 24
Thierry Conroy	Lancet Oncol. 2021 May;22(5):702-715
François Quenet	Lancet Oncol. 2021 Feb;22(2):256-266
Alain R. Thierry	JAMA Netw Open. 2021 Sep 1;4(9):e2124483
Juliette Palie	Cancers (Basel). 2021 Nov 5;13(21):5562.

GROUP	STUDY	TITLE
Translational Research and Development of Oncolgy Radiation (UNITRAD)	STEREO-OS	Efficacy of Extracranial Stereotactic Body Radiation Therapy (SBRT) added to standard treatment in patients with solid tumors (breast, prostate and non-small cell lung cancer) with up to 3 bone-only metastases: Study protocol for a randomised phase III Tr
Translational Research and Development of Oncolgy Radiation (UNITRAD)	NIRVANA-LUNG	PD-1 iNhibitor and chemotherapy with concurrent IRradiation at VAried tumor sites in advanced Non-small cell lung cAncer: the Prospective Randomized Phase 3 NIRVANA-Lung Trial

MAIN AUTHOR	REFERENCES
Sébastien Thureau	Sébastien Thureau, Vincent Marchesi, Marie-Hélène Vieillard, Lionel Perrier, Albert Lisbona, Marianne Leheurteur, Jean Tredaniel, Stéphane Culine, Bernard Dubray, Naïma Bonnet, Bernard Asselain,Julia Salleron & Jean-Christophe Faivre
Jerome Doyen	Jérôme Doyen, Benjamin Besse, Matthieu Texier, Naima Bonnet, Antonin Levy

GROUP	STUDY	TITLE
ESMÉ - CBP	/	Biomarker Testing in Older Patients Treated for an Advanced or Metastatic Non-Squamous Non-Small-Cell Lung Cancer: The French ESME Real-Life Multicenter Cohort Experience
ESMÉ - CBP	/	Treatment strategies for unresectable locally advanced non-small cell lung cancer in the real-life ESME cohort
ESMÉ - CBP	/	A Real-World Study of Patients with Advanced Non-squamous Non-small Cell Lung Cancer with EGFR Exon 20 Insertion: Clinical Characteristics and Outcomes
ESMÉ - CSM	/	"Early locoregional breast surgery and survival in de novo metastatic breast cancer in the real-life multicenter national ESME cohort"
ESMÉ - CSM	/	Progression-free survival on endocrine therapy, before or after chemotherapy, in hormone receptor-positive HER2-negative metastatic breast cancer
ESMÉ - CSM	/	Metastatic inflammatory breast cancer: survival outcomes and prognostic factors in the national and real-life French cohort (ESME)
ESMÉ - CSM	/	Breast cancer patients treated with intrathecal therapy for leptomeningeal metastases in a large real-life database
ESMÉ - CSM	/	Evolution of overall survival and receipt of new therapies by subtype, among 20 446 metastatic breast cancer patients in the ESME cohort 2008-2017.
ESMÉ - CSM	/	De Novo Metastatic Breast Cancer in Patients with a Small Locoregional Tumour (T1-T2/N0): Characteristics and Prognosis
ESMÉ - CSM	/	Phenotypic discordance between primary and metastatic breast cancer in the large scale real-life multicenter French ESME cohort
ESMÉ - CSM	/	Addressing the issue of bias in observational studies: using instrumental variables and a quasi-randomization trial to evaluate paclitaxel plus bevacizumab versus paclitaxel as first-line treatment for HER2-negative metastatic breast cancer. An ESME resea
ESMÉ - CSM	/	Treatments and outcome in older versus younger women with HER2-positive metastatic breast cancer in the multicenter national observational ESME database
ESMÉ - CSM	/	Outcome beyond third line of chemotherapy for metastatic triple negative breast cancer in the French ESME program
ESMÉ - CSM	/	Real-life prognosis of 5 041 bone-only metastatic breast cancer patients in the multicenter national observational ESME program
ESMÉ -OVR	/	Clinicopathological characterization of a real-world multicenter cohort of endometrioid ovarian carcinoma: analysis of the French national ESME-Unicancer database
CANTO	/	Differentiation of groups of patients with cognitive complaints at breast cancer diagnosis: Results from a sub-study of the French CANTO cohort.
CANTO	/	Intestinal microbiota influences clinical outcome and side effects of early breast cancer treatment
CANTO	/	Long-term patient reported outcomes and hematologic toxicity among patients who received Granulocyte-Colony Stimulating Factors during chemotherapy for early breast cancer

MAIN AUTHOR	REFERENCES
Lamy Tina	Cancers 14, no. 1 (December 24, 2021): 92.
Girard Nicolas	Lung Cancer (Amsterdam, Netherlands) 162 (November 6, 2021): 119–27.
Chouaid Christo	Targeted Oncology 16, no. 6 (November 2021): 801–11.
Hotton Judicael	Ann Surg. 2021 Feb 1.
Corbaux Pauline	Breast Cancer Research and Treatment, October 23, 2021.
Dano Domitille	ESMO Open 2021 Aug;6(4):100220.
Carausu Marcela	ESMO Open, May 10, 2021
Grinda Thomas	ESMO Open, April 22, 2021
Gaillard Thomas	European Journal of Cancer 158 (November 2021): 181–88.
Grinda Thomas	"Breast Cancer 7, no. 1 (December 2021): 41.
Ezzalfani Monia	" PLOS ONE 16, no. 9 (September 15, 2021): e0255017.
Annonay Mylène	The Breast 60 (December 2021): 138–46.
Cabel Luc	The Breast (2021); 56:18-25.
Bertho Marion	Therapeutic Advances in Medical Oncology 13 (January 2021): 175883592098765.
De Nonneville Alexandre	Gynecologic Oncology, July 2021, S0090825821005813.
Isabelle Hardy Léger	Psychooncology. 2021 Apr;30(4):463-470
Safae Terrisse	Cell Death Differ. 2021 Sep;28(9):2778-2796
Pietro Lapidari	Breast. 2021 Jun;57:43-48

GROUP	STUDY	TITLE
CANTO	/	Effects of acyl coenzyme A binding protein (ACBP)/diazepam binding inhibitor (DBI) on body mass index
CANTO	/	The challenge of return to work after breast cancer: the role of family situation
CANTO	/	Determinants of use of oral complementary-alternative medicine among women with early breast cancer: a focus on cancer-related fatigue
CANTO	/	Unhealthy behaviors after breast cancer: capitalizing on a teachable moment to promote lifestyle improvements

MAIN AUTHOR	REFERENCES
Adrien Joseph	Cell Death Dis. 2021 Jun 9;12(6):599
Elsa Caumette	Curr Oncol. 2021 Oct 1;28(5):3866-3875
Pietro Lapidari	Breast Cancer Res Treat. 2021 Dec;190(3):517-529
Antonio Di Melglio	Cancer. 2021 Aug 1;127(15):2774-2787

GROUP	STUDY	TITLE
French Breast Cancer Intergroup (UCBG)	PADA-1	Characterization of ESR1 mutations at metastatic relapse and outcome under first line aromatase inhibitor and palbociclib in the PADA-1 trial.
French Breast Cancer Intergroup (UCBG)	PADA-1	Efficacy of AI and palbociclib in ER+ HER2- advanced breast cancer patients relapsing during adjuvant tamoxifen: An exploratory analysis of the PADA-1 trial
Groupe d'étude des tumeurs urogénitales (GETUG)	GETUG21-PEACE1	A phase 3 trial with a 2x2 factorial design of abiraterone acetate plus prednisone and/or local radiotherapy in men with de novo metastatic castration-sensitive prostate cancer: first results of PEACE-1
Groupe immuno-oncologie (GIO)	AcSé Pembrolizumab	High clinical activity of pembrolizumab in chordoma, alveolar soft part sarcoma (ASPS) and other rare sarcoma histotypes: The French AcSé pembrolizumab study from Unicancer.
Groupe immuno-oncologie (GIO)	AcSé Pembrolizumab	Benefits of pembrolizumab in progressive radioactive iodine refractory thyroid cancer: Results of the AcSé Pembrolizumab Study from Unicancer.
Médecine personnalisée	SAFIR 02-LUNG	Maintenance targeted therapy compared to standard of care (SoC) in patients (pts) with metastatic non-small cell lung cancer (NSCLC): Results from the phase II randomized UNICANCER/IFCT1301- SAFIR02-LUNG intergroup trial.
Groupe Head & Neck	Immuneboost	Interim analysis of IMMUNEBOOST-HPV: A multicenter, randomized, open label, phase II study evaluating the feasibility, and tolerance of neoadjuvant nivolumab in high-risk HPV driven oropharynx cancer.
Groupe d'étude des tumeurs urogénitales (GETUG)	GETUG-AFU 26 NIVOREN	Prognosis impact of serous metastases (SMs) in clear cell renal cell carcinoma patients in the GETUG-AFU-26 NIVOREN phase II trial.
Groupe d'oncogériatrie (GERICO)	GERICO 12	NACRE : A randomized study comparing short course radiotherapy with radiochemotherapy for locally advanced rectal cancers in the elderly—Preliminary results.
Groupe gastro-intestinal (UCGI)	PRODIGE28 - TIME	"Maintenance treatment with cetuximab versus observation in RAS wild-type metastatic colorectal cancer: results of the randomized phase 2 PRODIGE28-TIME UNICANCER study"
Groupe d'étude des tumeurs urogénitales (GETUG)	GETUG-AFU 26 NIVOREN	Safety and efficacy of nivolumab in older patients (pts) with renal cell carcinoma: Results of a sub-group analysis of the GETUG-AFU 26 NIVOREN multicenter phase II study.
Groupe d'étude des tumeurs urogénitales (GETUG)	GETUG-AFU 26 NIVOREN	Association of statins and nivolumab activity in patients with metastatic renal cell carcinoma (mRCC): Results from the phase II nivoren—GETUG AFU 26 trial.
Groupe d'étude des tumeurs urogénitales (GETUG)	GETUG21-PEACE1	PEACE1: Abiraterone acetate plus prednisone added to androgen deprivation therapy and docetaxel in men with de novo metastatic castration-sensitive prostate cancer (mCSPC): detailed analysis of radiographic progression-free survival in the PEACE-1 phase 3 trial
French Breast Cancer Intergroup (UCBG)	UNIRAD	Phase III study of everolimus or placebo in addition to adjuvant hormone therapy for high risk early breast cancer: subgroup analysis of the UCBG UNIRAD trial.
French Breast Cancer Intergroup (UCBG)	UNIRAD	Efficacy of Everolimus in Patients With HR+/HER2- High Risk Early Stage Breast Cancer
Groupe d'étude des tumeurs urogénitales (GETUG)	GETUG23-PEACE2	A randomized Phase III, factorial design, of cabazitaxel and pelvic radiotherapy in patients with localized prostate cancer and high-risk features of relapse: the PEACE 2 trial from Unicancer
Groupe d'étude des tumeurs urogénitales (GETUG)	GETUG21-PEACE1	A phase 3 trial with a 2x2 factorial design in men with de novo metastatic castration-sensitive prostate cancer: overall survival with abiraterone acetate plus prednisone in PEACE-1
Groupe d'étude des tumeurs urogénitales (GETUG)	GETUG 38 - SAKK 08/16	Darolutamide maintenance in metastatic castration resistant prostate cancer (mCRPC) previously treated with novel hormonal agents (NHA) and non-progressive disease after subsequent treatment with a taxane: A randomized double-blind placebo-controlled phase II trial (SAKK 08/16)

MAIN AUTHOR	ESTABLISHMENT MAIN AUTHOR	TYPE OF PRESENTATION
Anne Pradines	Institut Claudius Regaud	Poster
FC Bidard	Institut Curie	Poster
Karim Fizazi	Gustave Roussy	Oral
J.Y. Blay	Centre Léon Bérard	Mini oral presentation (Poster)
Sophie Leboulleux	Gustave Roussy	Poster
Benjamin Besse	Gustave Roussy	
Haitam Mirghani	non CLCC	Poster
Florian Bardet	non CLCC	Poster
Eric François	Centre Antoine Lacassagne	Oral
Valerie Boige	Gustave Roussy	Poster
Loic Mourey	Institut Claudius Regaud	Poster
E. Colomba	Gustave Roussy	Poster
Karim Fizazi	Gustave Roussy	Oral
P.H. Cottu	Institut Curie	Poster
Thomas Bachelot	Centre Léon Bérard	Oral
P. Blanchard	Gustave Roussy	Poster
K. Fizazi	Gustave Roussy	Oral
R. Cathomas	non CLCC	Mini oral session (Poster discussion)

GROUP	STUDY	TITLE
Groupe d'étude des tumeurs urogénitales (GETUG)	GETUG13	Assessment of bleomycin pulmonary toxicity in men with poor-prognosis non-seminomatous germ-cell tumors treated in the GETUG 13 phase III trial
Groupe d'étude des tumeurs urogénitales (GETUG)	GETUG AFU 26 - NIVOREN	NIVOREN GETUG-AFU 26 Translational study: Baseline peripheral cytokines predict survival in metastatic clear cell renal carcinoma (RCC) treated with nivolumab.
Groupe d'étude des tumeurs urogénitales (GETUG)	GETUG AFU 26 - NIVOREN	Antibiotic (ATB) therapy and outcome from Nivolumab (N) in metastatic Renal Cell Carcinoma (mRCC) patients (pts): Results of the GETUG-AFU 26 NIVOREN Multicentric Phase II Study
Groupe gastro-intestinal (UCGI)	PRODIGE28 - TIME	Maintenance treatment with cetuximab versus observation in RAS wild-type metastatic colorectal cancer: first results of the randomized phase 2 TIME-PRODIGE28 UNICANCER study according to RAS/BRAF status
Groupe gastro-intestinal (UCGI)	PRODIGE28 - TIME	Tumour mutation profiles and Circulating tumour cells in Metastatic Colorectal Cancer patients treated with FOLFIRI + cetuximab: A Prospective Ancillary Study of the UNICANCER PRODIGE-28 trial
Groupe gastro-intestinal (UCGI)	PRODIGE 68 UCGI 38 - SOREGATT	PRODIGE 68 - UCGI 38 - SOREGATT: A randomized phase II study comparing the sequences of regorafenib (reg) and trifluridine/tipiracil (t/t) after failure of standard therapies in patients (pts) with metastatic colorectal cancer (mCRC)
Groupe gastro-intestinal (UCGI)	Accord 24 PRODIGE 24	Unicancer PRODIGE 24/CCTG PA6 trial: Updated results of a multicenter international randomized phase III trial of adjuvant mFOLFIRINOX (mFFX) versus gemcitabine (gem) in patients (pts) with resected pancreatic ductal adenocarcinomas (PDAC)
Groupe Radiothérapie (UNITRAD)	HYPOG 01	Acute toxicity associated with a 3-week versus a standard 5-week regimen for locoregional breast radiotherapy delivered in the Unicancer HypoG-01 phase III Trial
Groupe Radiothérapie (UNITRAD)	HYPOG 01	Improvement of a deep learning based automatic delineation model using anatomical criteria
Groupe sarcome	SARCOME 12 - REGOBONE	Results of the randomized, Placebo (PL)-controlled Phase II study evaluating the efficacy and safety of Regorafenib (REGO) in patients (pts) with relapsed advanced or metastatic chordoma, on behalf of the French Sarcoma Group (FSG) and Unicancer
Groupe Soin de support	QUALIOR	Feasibility of home-based supervised physical activity (SPA) for metastatic cancer patients receiving oral targeted therapy: the AFSOS-Unicancer QUALIOR randomized phase 2 Study.
Médecine personnalisée	MOVIE	Tremelimumab (T) + durvalumab (D) combined with metronomic oral vinorelbine (MOV): results of the recurrent cervical cancer (RCC) cohort of the MOVIE study
French Breast Cancer Intergroup (UCBG)	NEOPAL CARMINA 04	Letrozole and palbociclib versus 3rd generation chemotherapy as neoadjuvant treatment in luminal breast cancer: survival results of the UNICANCER-NeoPAL study
Groupe gastro-intestinal (UCGI)	PRODIGE28 - TIME	Traitement d'entretien par cetuximab versus pause thérapeutique chez les patients atteints d'un cancer colorectal métastatique RAS sauvage : résultats de l'étude de phase 2 multicentrique PRODIGE 28 – UCGI 27 - TIME UNICANCER
French Breast Cancer Intergroup (UCBG)	PADA-1	Fulvestrant-palbociclib vs continuing aromatase inhibitor-palbociclib upon detection of circulating ESR1 mutation in HR+ HER2- metastatic breast cancer patients: Results of PADA-1, a UCBG-GINECO randomized phase 3 trial
French Breast Cancer Intergroup (UCBG)	PADA-1	First line aromatase inhibitor (AI) + palbociclib with randomized switch to fulvestrant + palbociclib upon detection of circulating ESR1 mutation in HR+ HER2- metastatic breast cancer patients: global safety results of PADA-1, a UCBG-GINECO phase III trial
French Breast Cancer Intergroup (UCBG)	PADA-1	Real time detection of ESR1 mutation in blood by droplet digital PCR in the PADA-1 trial: feasibility and cross-validation with NGS
French Breast Cancer Intergroup (UCBG)	MyPeBS	Mypebs: An international randomized study comparing personalized, risk-stratified to standard breast cancer screening in women aged 40-70

MAIN AUTHOR	ESTABLISHMENT MAIN AUTHOR	TYPE OF PRESENTATION
N. Naoun	Gustave Roussy	Poster
L. Carril Ajuria	Gustave Roussy	Poster
L. Derosa	Gustave Roussy	Mini oral presentation (Poster discussion)
V. Boige	Gustave Roussy	Poster
H. Blons	non CLCC	Mini oral presentation (Poster discussion)
M. Ducreux	Gustave Roussy	Poster
T. Conroy	Institut de Cancerologie de Lorraine	Oral
S. Rivera	Gustave Roussy	Mini oral presentation (Poster discussion)
T. Brion	Gustave Roussy	Mini oral session (Poster discussion)
F. Duffaud	non CLCC	Oral
F. Joly	Centre Henri Becquerel	Poster
J.S. Frenel	Institut de Cancerologie de l'Ouest	Poster
S. Delaloge	Gustave Roussy	Oral
V. Boige	Gustave Roussy	Oral
FC Bidard	Institut Curie	Oral
S. Delaloge	Gustave Roussy	Poster
C. Callens	Institut Curie	Poster
S. Delaloge	Gustave Roussy	

GROUP	STUDY	TITLE
French Breast Cancer Intergroup (UCBG)	RX-PONDER	Updated results from a phase 3 randomized clinical trial in participants (pts) with 1-3 positive lymph nodes (LN), hormone receptor-positive (HR+) and HER2-negative (HER2-) breast cancer (BC) with recurrence score (RS) < 25 randomized to endocrine therapy (ET) +/- chemotherapy (CT): SWOG S1007 (RxPONDER)
Médecine personnalisée	SAFIR-02-Breast	Clinical utility of genomic profiling in patients with metastatic breast cancer: Results of a randomized trial
Médecine personnalisée	DAISY	Trastuzumab deruxtecan (T-DXd) for Advanced Breast Cancer Patients (ABC), regardless HER2 status: a phase II study with Biomarkers Analysis (DAISY)
Médecine personnalisée	MOVIE	Metronomic oral vinorelbine (MOV) combined with tremelimumab (T) + durvalumab (D): Efficacy and safety results of the advanced breast cancer (ABC) patients (pts) cohort of the MOVIE study
Médecine personnalisée	ACSé Nivolumab	Nivolumab in pretreated metastatic penile squamous cell carcinoma: Results of the penile cohort from the French AcSé prospective program
French Breast Cancer Intergroup (UCBG)	UNIRAD	Prognostic value of EndoPredict test in patients screened for UNIRAD, a UCBG randomized, double blind, phase III international trial evaluating the addition of everolimus (EVE) to adjuvant hormone therapy (HT) in women with high risk HR+, HER2- early breast cancer (eBC)

MAIN AUTHOR	ESTABLISHMENT MAIN AUTHOR	TYPE OF PRESENTATION
Kevin M Kalinsky	non CLCC	Poster
F. André	Gustave Roussy	Oral
V. Dieras		Mini oral presentation (Poster discussion)
T. De la Motte	Centre Eugène Marquis	Poster
David Pouessel	Institut Claudius Regaud	Poster
F. Penault-Llorca	Centre Jean Perrin	Mini oral presentation (Poster discussion)

GROUP	STUDY	TITLE
ESMÉ - CBP	ASCO	EGFR Exon 20 insertion: Prognostic and predictive values in advanced non-small cell lung cancer, a real-world study.
CANTO	ASCO	Assessing the risk of severe post-treatment (tx) cancer-related fatigue (CRF) among breast cancer survivors (BCS) in the CANcer TOxicity (CANTO) cohort.
CANTO	Cancer Survivorship conference	Breast cancer and perceived discrimination in the workplace: a longitudinal cohort study
CANTO	Cancer Survivorship conference	Return To Work (RTW) after breast cancer: The role of working conditions (Survivorship)
ESMÉ - CBP	CPLF	Traitements de première ligne et prise en charge du cancer broncho-pulmonaire non à petites cellules avancé ou métastatique avec une mutation EGFR – Analyse de la base nationale de données de vie réelle du programme Epidémio-Stratégie Médico-Economique.
ESMÉ - CBP	CPLF	Prise en charge des patients atteints d'un cancer bronchopulmonaire à petites cellules de stade IV – Analyse de la base nationale de données de vie réelle du programme Épidémio-Stratégie Médico-Économique (ESME)
ESMÉ - CBP	CPLF	Programme épidémio-stratégie médicoéconomique : une base nationale de données de vie réelle pour mieux comprendre la prise en charge du cancer bronchopulmonaire en France
ESMÉ - CBP	ELCC	Real-world evaluation of pembrolizumab monotherapy as first-line treatment for PD-L1 positive (TPS>50%) metastatic NSCLC in France
ESMÉ - CBP	ELCC	Real-world evaluation of pembrolizumab monotherapy for previously treated PD-L1 positive (TPS>1%) advanced NSCLC in France
ESMÉ - CBP	EPICLIN	Real-world outcomes for patients with metastatic non-small cell lung cancer according to first-line treatment
ESMÉ - CBP	EPICLIN	Exploratory analyses of surrogate endpoints in metastatic non-small cell lung cancer
ESMÉ - CBP	ESMO	Molecular testing in older patients treated for an advanced or metastatic non-squamous non-small cell lung cancer
ESMÉ - CSM	ESMO	HER2-Low Metastatic Breast Cancer (MBC): Management and Prognosis of a New Breast Cancer Entity in a Real-World Setting
ESMÉ - CSM	ESMO	Prognosis and efficacy of frontline treatment for HR+ HER2- metastatic breast cancer occurring in gBRCA1/2 carriers
ESMÉ - OVR	ESMO	Real-world clinical outcomes of patients with de novo advanced high-grade epithelial ovarian cancer eligible to niraparib maintenance in France
ESMÉ - CSM	ESMO	Efficacy of Taxane Rechallenge in Early Metastatic Relapse of HER2-Negative Breast Cancer Patients Previously Treated with Taxane. " Annals of Oncology 32 (September 2021): S501–2.
CANTO	ESMO	Cognitive impairment in breast cancer patients up to 18 months after cancer treatments: the French multicentric longitudinal CANTO-Cog cohort substudy
CANTO	ESMO	Coffee and tea consumption (CTC), patient-reported (PRO), and clinical outcomes in a longitudinal study of patients (pts) with breast cancer (BC)
CANTO	ESMO	Enrolment in Clinical Trials (CT) among patients (pts) with early breast cancer (BC)

MAIN AUTHOR	ESTABLISHMENT MAIN AUTHOR	TYPE OF PRESENTATION
CHOUAID Christos	non CLCC	Poster
DI MEGLIO A.	Gustave Roussy	Mini oral presentation (Poster discussion)
RUIZ-DE-AZUA G.	Gustave Roussy	Poster
DUMAS A.	Gustave Roussy	Poster
GIRARD Nicolas	Institut Curie	Communication orale
AUDIGIER-VALETTE Clarisse	non CLCC	Poster
PEROL Maurice	Centre Léon Bérard	Poster
PEROL Maurice	Centre Léon Bérard	Poster
PEROL Maurice	Centre Léon Bérard	Poster
BELAROUSSI Yacine	Institut Bergonié	Poster
BOUTEILLER Fanny	Institut Bergonié	Poster
LAMY Tina	Gustave Roussy	Poster
FRENEL Jean-Sébastien	Institut de Cancerologie de l'Ouest	Poster
FRENEL Jean-Sébastien	Institut de Cancerologie de l'Ouest	Poster
Rodrigues Manuel	Institut Curie	Poster
VASSEUR Antoine	Institut Curie	Poster
JOLY F.	Centre François Baclesse	Poster
SOLDATO D.	Gustave Roussy	Poster
CARAUSU Marcela	Institut Curie	Poster

GROUP	STUDY	TITLE
ESMÉ - CSM	ESMO BREAST	Breast cancer patients treated with intrathecal therapy for leptomeningeal metastases: Characteristics and validation of prognostic models in a large real-life database
CANTO	ESMO BREAST	Impact of germline BRCA (gBRCA) mutation (m) status on clinical characteristics and patterns of care among women with early breast cancer (eBC): an analysis of the observational prospective CANTO cohort
ESMÉ - CBP	ESMO IO	Treatment patterns in patients with advanced non-small cell lung cancer (aNSCLC) after discontinuing an immune checkpoint inhibitor (ICI) therapy in second-line or later in Germany and France
ESMÉ - CSM	SABCS	Impact of prior adjuvant trastuzumab (aT) on clinical characteristics, patterns of recurrence and outcomes in 4145 patients with Her2 positive (HER2+) metastatic breast cancer (MBC)- Results from the French ESME UNICANCER program
ESMÉ - CSM	SABCS	Long term results with everolimus in advanced hormone receptor positive breast cancer in a multicenter national real world observational study (ESME)
ESMÉ - CSM	SABCS	Impact of hormone receptor status on clinicopathological characteristics and outcomes among HER2-positive metastatic breast cancer patients in the ESME database
CANTO	SABCS	Patterns of adjuvant endocrine therapy, discontinuations, toxicities and quality of life: Development of a model for early discontinuation using the CANTO cohort
CANTO	SABCS	Attitudes and factors influencing contraception use over time in premenopausal women with early breast cancer in the prospective CANTO study
CANTO	SABCS	Development of a clinico-bio-behavioral model for cancer-related fatigue (CRF) incorporating inflammatory biomarkers and proteomic data
CANTO	SABCS	An integrated clinical, behavioral and biological model to predict the risk of weight gain among breast cancer survivors (BCS)
CANTO	SABCS	Cancer-related cognitive impairment (CRCI) in early breast cancer (BC) survivors
CANTO	SABCS	Association between plasma-based sequential windowed acquisition mass spectrometry (SWATH-MS) and invasive disease free survival (iDFS) in HR+/HER2- early breast cancer in the CANTO cohort
CANTO	SABCS	ATTITUDE: understanding and reducing ATTrition In longiTUDinal studiEs of cancer survivors
CANTO	SABCS	CANTO-RT: the largest prospective multicenter cohort of early breast cancer patients treated with radiotherapy including full DICOM RT data
CANTO	SABCS	IMPROFIB: ImPact of Radiotherapy On Fatigue in Breast cancer survivors
ESMÉ - OVR	SFOG	Analyses des données de vie réelle des patientes traitées en première ligne pour un cancer épithélial de l'ovaire de stade avancé de haut grade, éligibles à un traitement de maintenance par niraparib en France
ESMÉ - CBP	SIOG	Real-world overview of therapeutic strategies and prognosis of older patients with advanced or metastatic non-small cell lung cancer (AM-NSCLC)
ESMÉ - CBP	SIOG	Molecular Testing in Older Patients Treated for an Advanced or Metastatic Nonsquamous Non-Small-Cell Lung Cancer

MAIN AUTHOR	ESTABLISHMENT MAIN AUTHOR	TYPE OF PRESENTATION
CARAUSU Marcela	Institut Curie	Poster
BERTAUT A.	Institut Curie	Poster
GRIESINGER Frank	non CLCC	Poster
DIERAS V.	Centre Eugène Marquis	Poster
FRANCOIS-MARTIN H.	Institut Curie	Poster
CABEL L.	Institut Curie	Poster
BALAZARD F.	Gustave Roussy	Poster
LAMBERTINI M	Gustave Roussy	Poster
DI MEGLIO A.	Gustave Roussy	Poster
SOLDATO D.	Gustave Roussy	Mini oral presentation (Poster discussion)
PRESTI D.	Gustave Roussy	Poster
DELLA NOCE A.	Gustave Roussy	Poster
LAPIDERI P.	Gustave Roussy	Poster
SARRADE T.	Gustave Roussy	Mini oral presentation (Poster discussion)
GHANNAM Y.	Gustave Roussy	Mini oral presentation (Poster discussion)
JOLY Florence	Centre François Baclesse	Poster
CABART Mathilde	Institut Bergonié	Poster & Communications orale
LAMY Tina	Gustave Roussy	Communication orale

UNICANCER

101, rue de Tolbiac
75654 Paris Cedex 13

Tél. 01 44 23 04 04
unicancer@unicancer.fr

contact@recherche.unicancer.fr

RESEARCH OFFICE

Okabé
67, avenue de Fontainebleau
94270 LE KREMLIN-BICETRE
France

CONTACTS

Research & Development Director : **Claire Labreveux** / c-labreveux@unicancer.fr
Director of Health Datas and Partnerships : **Anne Laure Martin** / al-martin@unicancer.fr
Clinical Operations Director : **Béata Juzyna** / b-juzyna@unicancer.fr

credits

Coordination : Unicancer's Development, Communication and International Relations Department

Content writing : Alexandra Foissac - VICBIOSTART

Design : www.domenicorutigliano.com

unicancer

101, rue de Tolbiac
75654 Paris Cedex 13

Tél. 01 44 23 04 04
unicancer@unicancer.fr

contact@recherche.unicancer.fr

facebook/unicancer

linkedin/company/unicancer

twitter.com/groupeunicancer

instagram.com/reseau.unicancer

www.recherche.unicancer.fr/en

Excellence and **Innovation**
in patients care