RESEARCH ANNUAL REPORT 2020

HUMAN FIRST INNOVATION

EXCELLENCE SOLIDARITY

unicancer

table of contents

about us

highlights

clinical research activity

translational research activity

real-world data

research in the FCCCs

appendices

about us

Editorials

Jean-Yves Blay
PRESIDENT

Sophie Beaupère
GENERAL DIRECTOR

Alors que la crise sanitaire a amplifié la complexité des travaux de recherche, nous tenons à saluer le professionnalisme et l'engagement des équipes d'Unicancer et des CLCC, qui ont fait preuve d'une capacité d'adaptation exceptionnelle pour maintenir la recherche et l'innovation au cœur de nos actions. **Le principal enseignement de cette année singulière est la nécessité d'une recherche innovante, fluide et pertinente. Ce constat a conforté Unicancer dans sa volonté de faire évoluer l'organisation de sa Recherche, synonyme d'excellence en France et à l'international, en la structurant autour de deux piliers majeurs :**

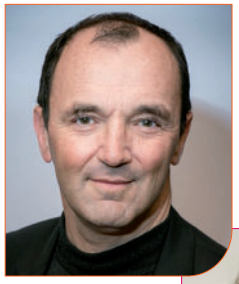
- **Une direction R&D** qui œuvre pour assurer le continuum recherche fondamentale, clinique et translationnelle, avec un recentrage de ses activités sur les programmes structurants et la valorisation des bases de données
- **Une direction data et partenariats**, créée en 2020, qui concrétise la place majeure et l'engagement d'Unicancer dans le traitement des données de santé.

Ces nouvelles orientations permettront à la Recherche Unicancer de conserver sa position de leader tout en s'inscrivant dans le cadre de la politique nationale : Ségur de la Santé, Stratégie décennale de lutte contre le cancer.

Capitalisant sur ces bases solides, forts des initiatives amorcées en 2020, nos efforts seront guidés par les principes que nous défendons depuis toujours, leviers essentiels de notre stratégie :

- Intensifier la prévention et le dépistage
- Améliorer la qualité de vie des patients, en développant des approches participatives et des outils de suivi
- Multiplier les programmes de recherche dans les cancers à pronostic défavorable (notamment le pancréas, le poumon et les cancers rares)
- Développer l'intelligence artificielle et des data sciences

Nous avons l'ambition de porter l'excellence française en cancérologie au plus haut niveau de l'innovation internationale. C'est ensemble que nous devons penser l'avenir ; c'est ensemble que nous le bâtirons.



Whilst the health crisis has increased the complexity of research, we would like to acknowledge the professionalism and commitment of the Unicancer and the FCCCs teams, who have demonstrated their exceptional adaptability maintaining research and innovation at the heart of our actions.
The principal lesson to retain from this highly singular year is the need for innovative, fluid and relevant research. This observation has reinforced Unicancer's desire to evolve the organization of its Research, synonymous with excellence in France and internationally, by structuring it around two major pillars:

- ***An R&D department*** *that works to ensure the fundamental, clinical and translational research continuum, with a refocusing of its activities on structuring programs and the valorisation of databases*
- ***A data and partnerships department****, created in 2020, which consolidates the strong role and commitment of Unicancer in the treatment of health data.*

These new orientations will allow Unicancer Research to maintain its leading position while being in line with the French national policy: the agreements reached within the consultation of all those involved in care provision (Ségur de la Santé), the government's ten-year strategy to fight cancer.

Building on these solid foundations and based on the initiatives launched in 2020, our efforts will be guided by the principles that we have always defended. The essential levers of our strategy are:

- *To augment prevention and screening*
- *To improve the quality of life of patients, by developing participatory approaches and monitoring tools*
- *To increase the number of research programs towards cancers with poor prognosis (including pancreatic and rare cancers)*
- *To develop artificial intelligence and data sciences*

We have the ambition to bring French excellence in cancer to the highest level of international innovation. We must think about the future together; this is how we will build it.

Editorials

Anne-Laure Martin

DIRECTOR OF HEALTH DATAS AND PARTNERSHIPS

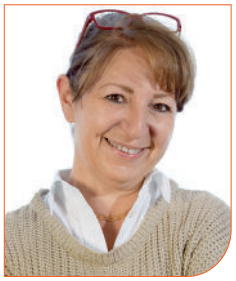
Les données de santé sous-tendent la médecine connectée et personnalisée et font partie intégrante de l'innovation en santé. Les données de vraie vie, issues de la pratique clinique de routine, complètent les données collectées dans le cadre expérimental.

Cet enjeu majeur des données de santé s'est traduit par la création cette année d'une direction des données de santé en oncologie, avec l'objectif d'assurer un continuum entre la recherche clinique et translationnelle, gérée par la R&D, et l'exploitation innovante des données de vie réelle, coordonnée par cette nouvelle Direction. A la clé, une seule et même ambition : insuffler de la connaissance pour prévenir et traiter les cancers le plus efficacement possible.

Cette initiative fait écho aux politiques nationales visant à dynamiser la constitution d'entrepôts de données, le déploiement d'infrastructures partagées pour agréger et analyser ces données, et l'essor des start-ups de l'intelligence artificielle appliquée à la santé avec, en ligne de mire, les retentissements décisifs attendus en matière de recherche pour une médecine personnalisée accessible à tous et les gains d'efficience pour notre système de santé.

Le projet EquipEx WeShare, sélectionné pour être financé dans le cadre du programme d'investissement d'avenir de l'ANR, incarne pleinement cette volonté. Mise à la disposition de tous les acteurs en cancérologie, cette plateforme nationale de recherche intégrée et dynamique facilitera l'acquisition de nouvelles sources de données centrées autour du patient et permettra de donner une nouvelle impulsion à une recherche transformatrice sur le cancer, en intégrant la dimension patient au cœur de l'évaluation de leur prise en charge.

Clés de voûte de l'excellence de notre recherche et de notre compétitivité au niveau international, ces programmes qui s'appuient sur les données de santé connaîtront à n'en pas douter une forte accélération dans l'année à venir, que nous espérons tous plus favorable que celle qui s'achève.



Health data underpins connected and personalised medicine and is an integral part of health innovation. Real-life data, derived from routine clinical practice, complements the data collected in the experimental setting.

This major challenge of health data has resulted this year in the creation of the Oncology Health Data Department, with the aim of ensuring a continuum between clinical and translational research, managed by R&D, as well as the innovative exploitation of real-life data, coordinated by this new Department. In the end, both share the same ambition to diffuse knowledge to prevent and treat cancers as effectively as possible.

This initiative is in line with the national policies aimed at boosting the establishment of data warehouses, the deployment of shared infrastructures to aggregate and analyse this data, combined with the rise of AI start-ups applied to health. As a result, major positive impacts are expected in terms of research for personalized medicine accessible to all and the efficiency of our healthcare system.

The EquipEx WeShare project, selected for funding under the ANR's Investment for the Future programme, fully embodies this desire. This dynamic, national, integrated research platform will be made available to all stakeholders in cancer, it will facilitate the acquisition of new patient-centred data sources and give new impetus to transformative cancer research, by better integrating the patients in the evaluation of their care.

As the cornerstone of our research excellence and international competitiveness, these data-driven programs will undoubtedly accelerate over the coming year, one which we all hope will be more favourable than the last.

Editorials

Claire Labreveux

DIRECTOR OF RESEARCH AND DEVELOPMENT

Cette année, la convergence des contraintes liées à la crise sanitaire et aux bouleversements règlementaires liés au Brexit a mobilisé toutes les énergies, nous obligeant à revoir à la fois l'organisation de la recherche et les calendriers.

Une phase de renouvellement à laquelle nos équipes se sont admirablement adaptées pour que nos activités de recherche se poursuivent dans les meilleures conditions pour tous.

Ainsi les recrutements dans le cadre de l'étude clinique internationale MyPeBS, qui évalue les avantages d'une approche de dépistage basée sur l'estimation du risque individuel de chaque femme de développer un cancer du sein par rapport au dépistage standard en vigueur, ont pu reprendre après une suspension de 6 mois due au COVID dans l'ensemble des cinq pays participants, auxquels l'Espagne s'est ajoutée cette année.

A l'issue d'une évaluation très favorable de l'IGAS soulignant l'intérêt majeur de la cohorte en termes de santé publique, et de l'ANR concernant son apport scientifique, le ministère de la recherche a octroyé des financements complémentaires qui permis de reprendre les inclusions en vue d'enrichir CANTO avec des femmes jeunes, chez lesquelles l'impact sociétal de la maladie et de ses traitements est le plus fort. Le conventionnement et le financement de l'ANR ont été reconduits pour une nouvelle période de 4 ans. Véritable infrastructure de collecte de données, CANTO occupe une place capitale dans le paysage de l'innovation et de la personnalisation des traitements, à la jonction entre la recherche clinique et translationnelle traditionnelle, et la recherche sur les données de vie réelle.

L'ADN tumoral circulant et les développements technologiques récents de détection dans le sang constituent également une perspective prometteuse en termes de diagnostic, de prise en charge et de suivi.

Fidèles à notre conviction que la coopération est un facteur clé de succès, nos équipes continuent de construire des partenariats stratégiques en s'appuyant sur des collaborations internationales ouvrant la voie à une ère pleine de promesses.

This year, the convergence of constraints related to the health crisis and the regulatory upheavals related to Brexit have mobilized all energies, forcing us to review both the organization of research and the schedules.

It has been a phase of renovation to which our teams have adapted admirably so that our research activities could continue in the best conditions for all.

Recruitment for the international clinical study MyPeBS, which evaluates the advantages of a screening approach based on the estimation of each woman's individual risk of developing breast cancer compared to the standard screening in force, was able to resume after a 6-month suspension due to COVID in all five participating countries, to which Spain was added this year.

Following a very favourable evaluation by IGAS[1] underlining the major interest of the cohort in terms of public health, and of the ANR[2] concerning its scientific contribution, the Ministry of Research has granted additional funding. This has allowed us to resume inclusions to enrich the CANTO study with younger women, in whom the societal impact of the disease and its treatments is the strongest. The agreement and the ANR funding have been renewed for a further period of 4 years. As a true data collection infrastructure, CANTO is at the forefront on the landscape for innovation and personalized treatment, at the crossroads between traditional clinical research, translational research and real-life data research.

Circulating tumour DNA (ctDNA) and the recent developments of detection technology in blood samples also provide promising prospects for diagnosis, treatment and follow-up.

True to our belief that cooperation is a key factor for success, our teams continue to build strategic partnerships based on international collaborations paving the way for an era holding great promise.

(1) French Government Agency for Social Affairs
(2) French National Agency for Research

Our research priorities

With a portfolio of 100 active clinical studies, Unicancer is now the leading academic sponsor in oncology in France and one of the main ones in Europe. Unicancer also leads a growing number of significant projects in the field of clinical research and medical data, for which it has dedicated increasing human resources and budget in the past recent years. Unicancer seeks to develop further collaborations with international research groups, in order to foster innovative and personalized research for the benefit of the patients, especially where there is an unmet medical need.

NICHE-ORIENTED RESEARCH, where the pharma industry is less involved, are at the heart of Unicancer academic priorities, with a focus on

- Rare tumours where there is no or too little therapeutic options
- Cancers affecting orphan populations (e.g. pediatric or geriatric)

CHANGING PRACTICE AND THERAPEUTIC STRATEGY STUDIES (e.g. PEACE programme in prostate cancer, ACCORD 11 and PRODIGE 24 trials in pancreatic cancer, treatment de-escalation studies)

EVALUATING INNOVATIVE THERAPIES while offering early access to innovative therapies for rare cancer patients (e.g. AcSé - immunotherapy programmes)

MAINTAINING RESEARCH ON PRECISION MEDICINE as a priority, especially through molecular screening programmes, using the most up-to-date scientific and technical advances, e.g. circulating DNA or Artificial Intelligence

CONDUCTING RESEARCH ON REAL-LIFE DATA, both through prospective cohorts (CANTO study) and through data from care institutions (ESME programme)

UNDERSTANDING THE MECHANISMS OF TREATMENT-RELATED TOXICITIES AND/OR RESISTANCE through translational research using tissue and blood samples collected and centralized in our biobank (e.g. CHECK'UP)

DEVELOPING RESEARCH IN PREVENTION MEDICINE, in order to contribute to the development of the "4P medicine" (i.e., predictive, preventive, personalized and participatory) in an overall effort to transform healthcare (e.g. MyPeBS study – evaluating a personalized breast screening strategy).

PATIENTS ARE AT THE HEART OF OUR RESEARCH

Several Unicancer large trials notably in breast, urological and digestive cancers are ongoing with the aim to:

- Improve the management of sub-populations with severe prognosis
- Promote de-escalation, e.g. dosage of radiotherapy (dose and/or frequency or radiations) or anticancer drugs (targeted therapy, chemotherapy, immunotherapy), to preserve or improve the patients' quality of life
- Enable early and equitable access to innovative therapies, especially for patients with rare cancers.

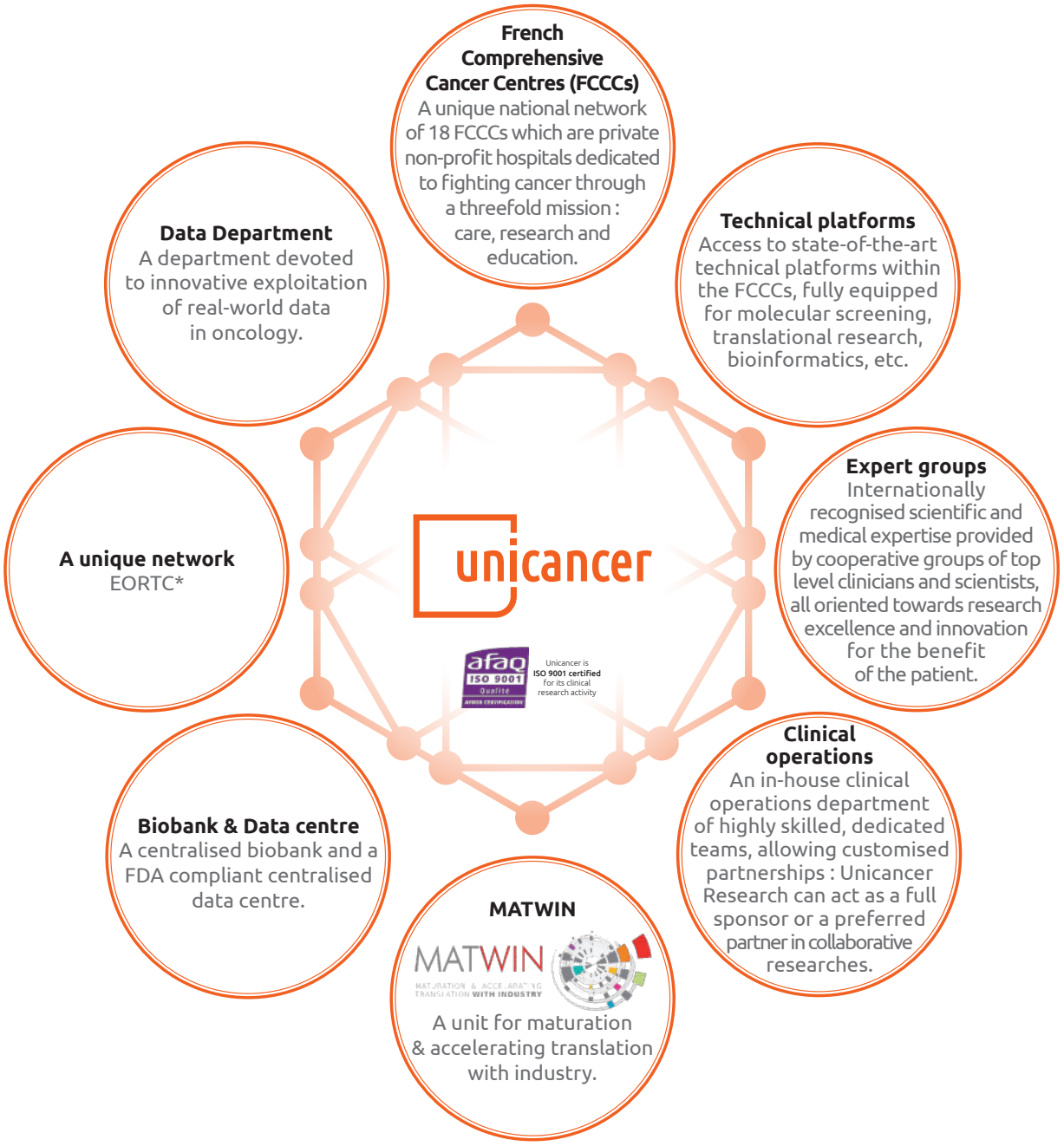
ABOUT OUR CHARITY PARTNERS

We are in close long-term partnerships on shared axes of research with the French Cancer League and the ARC Foundation, two non-profit organisations that subsidise cancer research.

FONDATION ARC POUR LA RECHERCHE SUR LE CANCER
Reconnue d'utilité publique

LA LIGUE CONTRE LE CANCER

Our Strengths



* A powerful network of scientific collaborations with other cancer cooperative groups at national and international level, as well as with stakeholders from the public and private sectors. The Unicancer's Research hosts the French liaison office of the European Organisation for Research and Treatment of Cancer (EORTC).

Our 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.
The French National Cancer Institute (INCa) has accredited six of them, thus acknowledging their excellence in research and operating capabilities.

TUMOUR 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

Genitourinary Group (GETUG) *
President : Karim Fizazi, Gustave Roussy, Villejuif
Strategic priorities: therapeutic strategy trials, research programmes in rare tumours, development of biological research programmes in connection with clinical projects

Gastrointestinal Group (UCGI) *
President : Emmanuelle Samalin
Institut du cancer, Montpellier
Strategic priorities: innovative phase II studies, new diagnostic approaches towards personalized treatment, translational research, large randomized phase II/III studies, rare cancers

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

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

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

Translational Research and Development in Oncology Radiation (UNITRAD)
President : Sophia Rivera, Gustave Roussy, Villejuif
Strategic priorities: translational research, imaging, modelling and radiomics, brachytherapy, radiobiology and radio-potentiation, quality assurance, methodology

Oncology Geriatrics (DIALOG) *
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 rationalization

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

Unicancer provides access to clinical data and biological samples to develop translational research

Unicancer, as an academic sponsor of clinical trials, has a large structured database collected prospectively in multiple indications and pathologies. In order to accelerate the development of knowledge in oncology, to increase the interface between basic and clinical research (translational research), Unicancer provides researchers and clinicians, from any institution, with access to data for their projects of interest.

Any clinician or researcher wishing to use clinical data and/or biological samples in the context of a specific research project can contact Unicancer which, as the person in charge of the data warehouse and the biological collection, will ensure the proper use of the data in compliance with the information given to patients beforehand.
The numerous ancillary researches supported by clinical trials have allowed Unicancer to build up a collection of biological samples that can be associated with clinical data and thus allow reuse for research purposes, while respecting the current regulations.

highlights

2020 Key Figures

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

Patient-centered strategy

For many years, Unicancer has been working to identify ways to improve the cancer care offer. Patients' experiential knowledge and information are at the heart of this approach. New initiatives in favour of "connected and active" patients ensure that we are one step ahead.

UNICANCER'S COMMITMENT TO TRANSPARENCY

With the launch of the **"My Health Data" website** (https://mesdonnees.unicancer.fr), patients treated within the network or included in a clinical trial sponsored by Unicancer or one of the FCCCs can access all information relating to the re-use of their personal data collected in one of these settings.

Although patients are obviously notified of the possible use of their data and biological samples for research purposes prior to their treatment or participation in a clinical trial, it is not always possible to anticipate research opportunities. It is therefore in the interests of transparency that this site provides patients with additional information and updates on the re-use of their data.
This website meets the requirements of the reference methodology dedicated to research on biological data and samples issued by the French data protection authority (CNIL) and guarantees the compliance of Unicancer's research with the regulations.

The "My health data" website is the first dynamic patient information website launched by a French academic research organisation. A reflection is underway to broaden access outside the Unicancer network.

VALUING PATIENTS' EXPERIENCES

In October 2020, Unicancer signed a partnership with the French Institute for Patient Experience (IFEP), with the aim of strengthening the integration of FCCC patients in the organisation of their care pathway and in strategic decision-making that concerns them.

The aim of this collaboration is to reaffirm the patient experience as a lever for improving care and to bring out innovative practices through ongoing international monitoring, experience sharing, participation in thematic working groups or conferences and webinars.

A dedicated working group has been created to support concrete actions carried out within the FCCC network.

Patient-centered strategy

Personalised prevention and care are two major areas of Unicancer.
But nothing is possible without patient engagement, as shown by the different views reported below.

MyPeBS
Personalising Breast Screening

With an accrual target of 85,000 female volunteers, MyPeBS (My Personal Breast Screening) is a huge unique international project funded by the European Commision. It investigates whether a personalised risk-based screening strategy could be a better option than standard screening for women aged 40 to 70.

Dr Suzette Delaloge, medical oncologist at Gustave Roussy and international PI of the MyPeBS study:

"More and more women are being cured of breast cancer, but the incidence is increasing exponentially. Far too many still die of it every year. And even if the increase in life expectancy favours the development of cancers, breast cancer does not only affect older women.
Organised screening has proved its worth, the question is whether we can do better. Until now, the only criterion used worldwide to invite women to have a mammogram is age. But not all women are the same. MyPeBS considers that each woman is unique, that some have more risk factors than others, based on genetic factors, breast density or personal and family history.
If we can define each woman's individual risk of developing breast cancer in the future and design tailor-made surveillance for each woman according to that risk, then screening will be even more effective and accurate in the future. Women who join MyPeBS are helping to advance science. They are personally contributing to the improvement of breast cancer screening, not only for their own benefit, but also for that of their friends, sisters, daughters and future generations."

canto
CANcerTOxicities

CANTO is a prospective cohort study of the chronic toxicities associated with treatments in patients with localised breast cancer. It aims to evaluate their social and economic impact to improve women's quality of life. This year, thanks to the renewal of public and private funding, new inclusions of young working women will make it possible to evaluate the psycho-social impact of the disease in this specific population.

"I joined the CANTO protocol primarily because I was determined to continue working and hoped to gain knowledge that would help me cope with the side effects. I also didn't want to give up my favourite sport (horse riding).
And this is exactly what happened: I am very grateful to my referral nurse who gave me valuable advice. I learned many tricks to relieve the pain linked to the treatments, which in my case were very numerous and diverse (successively chemotherapy, mastectomy, radiotherapy, immunotherapy, hormone therapy, reconstruction surgery) over five years. I particularly appreciated being invited to the CANTO symposiums and I will return even though the treatments have now been completed, because some discomforts remain, such as treatment-induced neuropathy, and are still a concern. It is an opportunity to gather an update and useful information, to exchange with health professionals and other patients... and to see that many face the same difficulties! I highly recommend this experience to all cancer patients".

S., 56-year-old, enrolled in 2015

« I knew when I joined the study that the benefit would not be for me. Several women in my family have already had breast cancer; I did it for my daughter, who attended several CANTO conferences with me, and of course for the generations to come. I have personally suffered a lot from the alteration of my body image with treatments - hair loss, damaged nails, breast removal. I want to believe that my involvement contributes to build the knowledge base on how to avoid this.
I also underwent a lot of side effects - nausea, burning, fatigue – at different stages of my treatment. I make a point of describing them extensively in the questionnaire booklets. The time I spend on them is not a constraint, I even think that it should be compulsory! Otherwise, how can we make progress?
Finally, I would specifically like to thank my referral nurse and all the teams involved in the protocol for the quality of our discussions and their great warmth and kindness which are an unvaluable support at a time when, with the disease, friendships are changing, sorting out your life becomes necessary..."

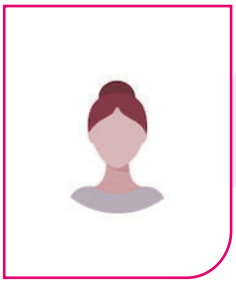
S., 50-year-old, enrolled in 2017

Patient-centered strategy

For over 20 years, Unicancer has submitted its informed consent forms for approval by the Patients' Committee of the National Cancer League. Patient representatives have progressively been invited to join expert groups and share their experience and expertise. They are involved in discussions on ethical and methodological issues that may influence the determination of endpoints for clinical trials.

PATIENT-EXPERTS AS KEY PLAYERS IN RESEARCH

The Patients' Committee was born in 1998 from a joint initiative of Unicancer and La Ligue contre le cancer (National Cancer League) and has now become a key partner for clinical trial sponsors.
A daring project at the time, aiming to make the patients active partners, by merging their own knowledge and experience of the disease with medical knowledge, with a view to reducing the burden of the study procedures for future enrolled patients.



Marie Lanta, in charge of information for patients and their relatives at the National Cancer League, was one of the first reviewers involved in the process:

" **The very first objective** of this Committee was to review the information note that accompanies the study protocols, before patients give their consent to enter a clinical trial. It was essential to propose improvements to make this note clear and accessible about the constraints of the study and the treatment's side effects. This partnership really took off a few years later, when the improvement of information on clinical trials and its review by the Patients' Committee was first included in the National Cancer Plan. From then on, many pharma companies joined us. This was the first major step of our development.

The second major step is the co-construction of clinical trials. Only patients can play an active upstream role in identifying potential obstacles that might lead patients not to participate in a clinical trial. It is therefore a rich and fruitful collaboration for both parties. For the patients involved, there is a real benefit on a human, intellectual and psychological level. Most continue their mission for years. Within the scientific community, the patient is once for all a recognised and legitimate voice: sponsors who have once used the Committee have never backed down afterwards. Very recently, we set up video conferences including European patients and sponsors, where representatives from each country could share information on a given disease area. This user-friendly format was an immediate success. **The third major step** is to ensure the disclosure of the global clinical trial results to participating patients. This is a necessary step to provide meaningful information to patients and the question at stake is trust and transparency in clinical trials."

THE PATIENTS' COMMITTEE IS NOW CONSULTED BY MANY ACADEMIC AND INDUSTRIAL SPONSORS.

With **189** protocols reviewed this year (2020) and **130** active members benefiting from regular training, the Patient Committee plans to recruit new patients to cope with the exponential increase in its activity.

189 protocols

130 active members

Clinical Research

The COVID-19 pandemic obviously had an immediate impact on clinical research activity and practices. However, the commitment of Unicancer's expert groups to pursue a sustained research effort, in support of innovation as the key value of the FCCC network, has made this year a most promising year.

KEY RESEARCH RESULTS AND PUBLICATIONS

• The CANTO analysis is beginning to produce major results for the management of early breast cancer patients. Several communications were presented during international meeting such as ESMO and the description of non-adherence to tamoxifen hormotherapy has been published in the Journal of Clinical Oncology in June 2020.

• Results of studies of the AcSé-immunotherapy program were presented at the ESMO meeting:
- In the presentation entitled "High activity of Nivolumab in patients with pathogenic exonucleasic domain POLE (edPOLE) mutated Mismatch Repair proficient (MMRp) advanced tumors", nivolumab conferred promising benefits to edPOLE mutated MMRp advanced colorectal cancer patients with specific mutations.
- In the presentation entitled "High clinical benefit rates of pembrolizumab in very rare sarcoma histotypes: First results of the AcSé Pembrolizumab study", pembrolizumab showed high levels of prolonged activity in patients with selected subtypes of rare sarcomas.

• An exploratory analysis of the **PADA-1** trial on the prognostic impact of ESR1 mutations in ER+ HER2- metastatic breast cancer patients prior treated with first line aromatase Inhibitor and palbociclib was selected for oral presentation at the ASCO meeting. These results could lead to a personalisation of hormone therapy according to the initial mutation status.

• **MyPeBS** consortium participates in the European Collaborative on Personalized Early Detection and Prevention of Breast Cancer (ENVISION) network. the members of this network identified research areas requiring development to enable evidence-based personalized interventions that might improve the benefits and reduce the harms of existing breast cancer screening and prevention programmes. Priorities are highlighted in a paper published in Nat Rev Clin Oncol. (2020; 17(11): 687–705).

• Results of the **GETUG-AFU 17** study, published in Lancet Oncology, suggest taht a policy of early salvage radiotherapy in patients with localized prostate cancer after radical prostatectomy could spare men from overtreatment with radiotherapy and the associated adverse events.

• The UNITRAD's study AI-driven quality insurance for delineation in radiotherapy breast clinical trials concluded that an anatomically preserving ensemble neural network retrained on high quality contours coming from a multi-center clinical trial could lead to the development of a clinical acceptable control delineation tool. These results were presented at both ESTRO and ASTRO meetings.

SCIENTIFIC EVENTS

A Scientific Advisory Board meeting was held per video in March during which the programmes of the Breast Cancer and Personalised Medicine Groups, were presented. In its conclusions, which were particularly complimentary of all the programmes, the scientific advisors were notably impressed by:

- **The innovative research initiatives and the willingness to address unmet clinical needs.**
- **The collaborations initiated with other researchers in France and around the world.**
- **The high productivity of projects and that to come.**
- **The new approaches to personalised medicine, molecular markers of recurrent diseases and breast cancer prevention.**

MAJOR ONGOING PROJECTS

FLAGSHIP STUDIES INVOLVING INTERNATIONAL COLLABORATIONS/ MAJOR PARTNERSHIPS AGREEMENTS

MyPeBS
Personalising Breast Screening

The international randomised MyPeBS (My Personal Breast Screening) study (UCBG) is an EU-funded H2020 project coordinated by Unicancer, involving 27 international partners in 8 countries. It 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. The trial has been opened in 5 of the recruiting countries (France, Italy, Israel, Belgium and UK) and has recruited more than 6,000 women aged 40 to 70 so far, out of the 85,000 expected overall. Spain is expected to join the accrual force in 2021.
MyPeBS is a major study that could lead to the issuing of new harmonised recommendations for breast cancer screening in Europe.

ALBAN (Genitourinary Group GETUG) **is a phase III trial registration study, evaluating the efficacy of atezolizumab in patients with high-risk non-muscle invasive bladder cancer after BCG** (bacillus Calmette-Guerin) **treatment.** Enrollment has been opened up internationally and a total of 614 patients are expected to be included during a 2-year follow-up period.

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

The AcSé immunotherapy studies (Immuno-Oncology Group), **aims to investigate the efficacy of pembrolizumab and nivolumab immune checkpoints inhibitors in patients with specific rare cancers.** 13 cohorts have now been set up. A total of 650 treatment-refractory patients are expected in these studies by 2021.

canto
CANcer TOxicities

The CANTO (CANcer TOxicities) project (UCBG) aims to quantify and predict treatment-related chronic toxicities and social impact in patients with newly diagnosed early breast cancer. The renewal of Pfizer's financial support in metastatic breast cancer has enabled to re-open the trial for patient enrollment, particularly young women. This is a very promising continuation of CANTO as it has previously been shown that persistent post-treatment toxicities have a major impact on the social and professional activities of women under 45.

FLAGSHIP UCBG ctDNA PROGRAMMES (PERSONALISED MEDICINE)

The PADA1 (Metastatic Breast Cancer) study is conducted in collaboration with the Arcagy-Gineco Intergroup. It **is a randomized, open label, multicentric phase III trial to evaluate the safety and efficacy of palbociclib in combination with hormonotherapy driven by circulating DNA ESR1 mutation monitoring in estrogen receptor-positive, HER-2 negative metastatic breast cancer patients.**

The cTRAK-ER (adjuvant Breast Cancer) **study is a randomized trial of early detection of molecular relapse with circulating tumour DNA tracking and treatment with palbociclib plus fulvestrant versus standard endocrine therapy in patients with ER positive HER2 negative breast cancer.** 40 centres, half of them in the UK, are participating in this study.

MAJOR RESEARCH PERSPECTIVES

GETUG

unicancer

The GETUG expert group is the international coordinator of the European phase 3 PEACE-6 trial, being designed to identify the oncogenic drivers of de novo metastatic prostate cancer, based on assessment of ADT/darolutamide combination efficacy. The study is intended for men with castration-naïve metastatic prostate cancer from the Prostate Cancer Consortium in Europe (PEACE), favouring cross-border cooperation.

UCGI

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In hepatocellular carcinoma (HCC), the 3rd leading cause of death worldwide, transarterial embolization/ chemoembolization (TAE/TACE) is the first-line treatment. This treatment results in a massive release of tumour antigen and 'danger' signals suggesting that a combination with immunotherapy (nivolumab) is appropriate.
The UCGI Group's PRODIGE 64-TACE 3 study, in collaboration with Clatterbridge Cancer Centre and the NHS Foundation (UK) is a phase III randomised trial of nivolumab in combination with TACE/TAE for patients with intermediate stage HCC.

UCBG

unicancer

Two large studies are being implemented by the UCBG Intergroup, in collaboration with European partners:

- DECRESCENDO, a de-escalation study in collaboration with the Bordet Institute and the Breast International Group (Belgium) involving an estimated 1065 patients with confirmed invasive, unilateral, HER2-positive, ER-negative/ PR-negative node-negative early breast cancer, candidates to receive neoadjuvant therapy.
- The SASCIA study, in collaboration with the GBG German group, evaluating an antibody drug conjugate in primary HER2-negative breast cancer patients with high relapse risk after standard neoadjuvant treatment.

Sarcoma Group

unicancer

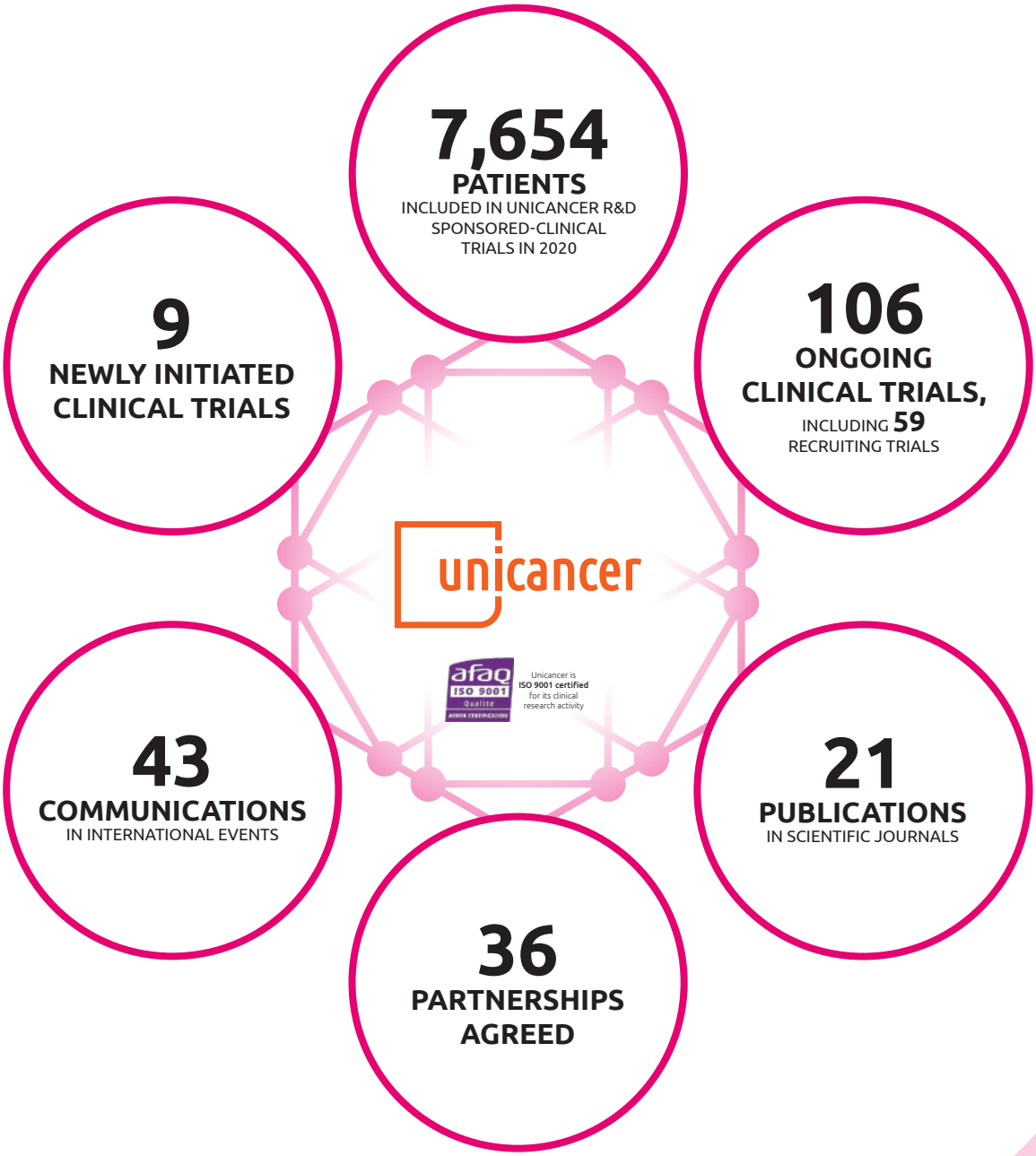
One third of patients with soft tissue sarcoma are 65 years or older. With age, co-morbidities increase in number and severity, which makes it necessary to prioritise the pathologies to be treated and
conditions the prognosis of the cancer.
The GERICO 14-Sarcoma-Elderly study, is a phase III study conducted by the Sarcoma Group integrating a comprehensive geriatric assessment (CGA) for a patient population defined using the dataset
recommended by the Geriatric Oncology Intergroup.
It aims to compare the reference chemotherapy treatment (doxorubicin), which carries a substantial risk of cardiac toxicity, with metronomic oral
cyclophosphamide, which has a favorable toxicity profile in elderly patients.
This study is being initiated in the FCCCs; the first patient is expected next year.

Immuno-Oncology Group

unicancer

The rising cost of cancer care in the era of immunotherapy is a major concern for payers around the world, especially as standard immunotherapy (IO) treatment is sometimes toxic or ineffective. A project initiated by the Immuno-oncology Group, the MOIO study is a randomised Phase III trial of IO by checkpoint inhibitors versus reduced dose intensity of IO in patients with metastatic cancer in response after 6 months of standard IO. If the hypothesis of non-inferiority in progression-free survival (PFS) with a reduced dose intensity of IO is verified, this could replace standard treatment, with a reduction in treatment costs and toxicity, leading to an improvement in patients' quality of life.

Clinical Research Key Figures



Translational Research

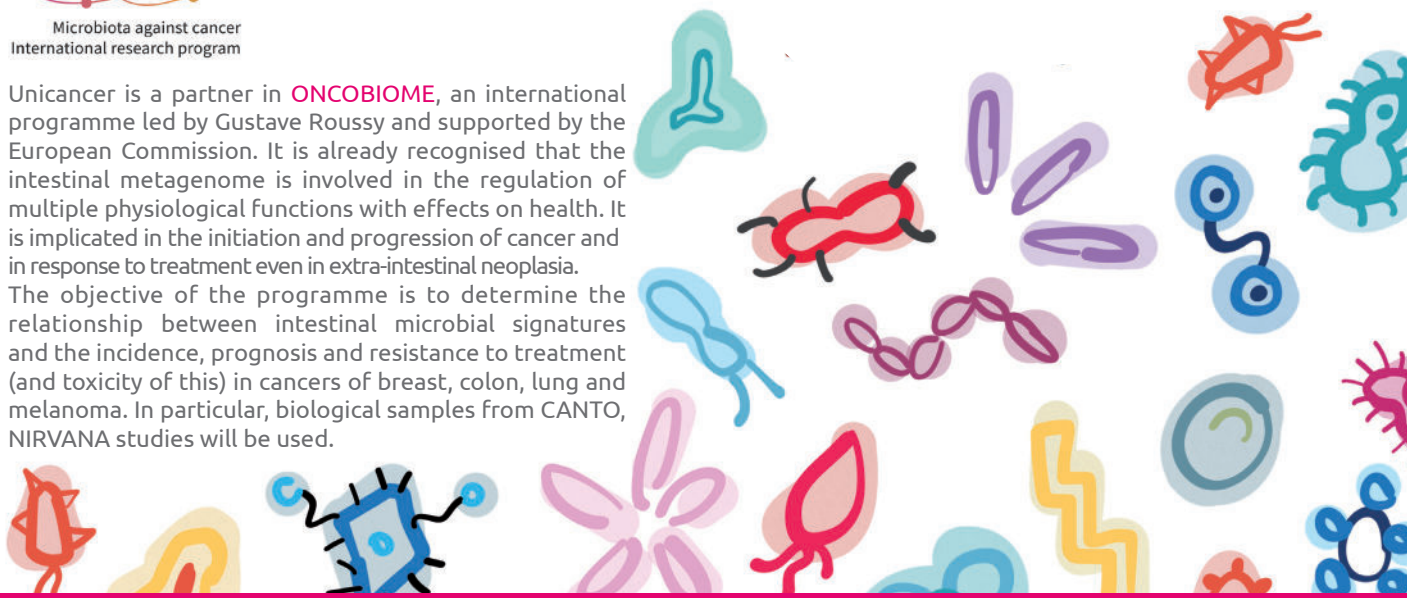
Based on close collaboration between physicians and researchers and on the use of human samples and sophisticated technological platforms, translational research has a strategic role in accelerating the application of scientific innovations for better patient care. Thus, all clinical trials sponsored by Unicancer include the collection of biological samples (mainly tumor and blood samples)" with the aim to foster translational research programmes.

2020 KEY FACTS

The RHU MyProbe (led by Pr. Fabrice André, Gustave Roussy) is one of the 2017 winners of the Programme d'Investissements d'Avenir (PIA) operated by the Agence Nationale de la Recherche (ANR). The MyPROBE consortium, composed of leading academic cancer centres and an innovative biomarker company, forms a multidisciplinary team with research, clinical and biotechnology expertise.
The objective is to create 3 tests to identify patients with early breast cancer of poor prognosis. Two tests will be aimed at patients with hormone-sensitive (HR+) breast cancer that does not overexpress the Her2 protein (Her2-).
The third prognostic test will be dedicated to patients with triple-negative breast cancer (TNBC), i.e. that is neither hormone-sensitive nor Her2-overexpressing.
The development of these prognostic tests will allow to better adapt the treatment of patients, to decrease the risk of toxicities and to reduce the costs of patient care.

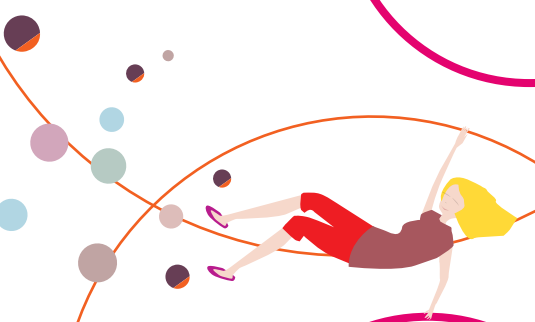
ONCOBIOME
Microbiota against cancer
International research program

Unicancer is a partner in ONCOBIOME, an international programme led by Gustave Roussy and supported by the European Commission. It is already recognised that the intestinal metagenome is involved in the regulation of multiple physiological functions with effects on health. It is implicated in the initiation and progression of cancer and in response to treatment even in extra-intestinal neoplasia.
The objective of the programme is to determine the relationship between intestinal microbial signatures and the incidence, prognosis and resistance to treatment (and toxicity of this) in cancers of breast, colon, lung and melanoma. In particular, biological samples from CANTO, NIRVANA studies will be used.



27,600
FROZEN WHOLE BLOOD SAMPLES

92,700
FROZEN PLASMA/ SERUM PLASMA



19,300
SAMPLES COLLECTED
FROM CANTO PATIENTS (DNA, SERUM PLASMA, FECES AND WHOLE BLOOD) WERE IN THE PROCESS OF ANALYSIS IN 7 TRANSLATIONAL SUB-STUDIES AS OF 2020.

canto
CANcer TOxicities

CANTO: a clinical database unique in the world, associated with more than 19,000 biological samples collected. Several research projects in major scientific areas are currently underway: metabolomics, proteomics, clonal haematopoiesis, sequencing. Using Genome-Wide Association Data a paper describing the prediction of Breast Cancer Treatment–Induced Fatigue by machine Learning has been published in JNCI Cancer Spectrum. In addition, thanks to serum collection, Pistilli et al have reported in 2020 the rate of biochemical nonadherence to adjuvant tamoxifen using serum assessment. This study identified a worryingly high proportion of patients, one in six, who were nonadherent to therapy at only 1 year after treatment prescription. These major findings highlight the need to develop targeted interventions to manage adherence to endocrine therapy.

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

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.

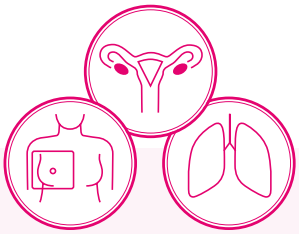
Department Health Data

Convinced of the potential of real-world data (RWD) for French and international research, Unicancer has made the collection and use of this data a priority, which led to the creation of a Department Health Data in May 2020. Real-world data are used to assess the efficacy and side effects of cancer treatments after registration trials. In oncology, RWD is a decision-support tool for use in regulatory decision-making, drug design and clinical practice guidelines. Since 2014, Unicancer has focused on the intelligent use of data via the ESMÉ (Epidemiological Strategy and Medical Economics) initiative, which is the largest European well-recognized platform for real-life data in oncology.

THREE NEW INNOVATIVE PROJECTS HAVE BEEN AGREED AND WILL BE IMPLEMENTED IN 2021:

• **The WeShare project**, based on strategic alliances, is a dynamic, integrated, patient-centered national research platform that will provide to cancer researchers and institutions technological tools for transformative research that now includes social and human sciences components.
This project has been selected to be financed by the Investments for the Future programme of the ANR (France's project-based funding agency for research).
• Based on data from Roche's PRM (Personalized Reimbursement Models) and Unicancer's ESME programmes, the **ODH-Onco Data Hub project**, aims to automate data collection, with a view to integrating new establishments and extending the collection to all cancers in the future.
• **The Impact Covid19 project**, funded by the ANR, will study the impact of delayed diagnosis or treatment on the life expectancy of patients with poor prognosis cancers, based on retrospective data collection.

ESMÉ : EPIDEMIOLOGICAL STRATEGY AND MEDICAL ECONOMICS



It includes data from patients in three areas: metastatic breast cancer (MBC), ovarian cancer (OC) and advanced or metastatic lung cancer (AMLC).

- DATABASES COMPLIANCE WITH REGULATIONS (GDPR)

The ESMÉ warehouse opens up opportunities for secure sharing with other data sources and warehouses in France data useful for patients and decision-makers. Consequently, a growing number of hospitals outside the Unicancer network uses the ESMÉ databases.
In 2020, Unicancer was granted by the French Data protection Authority (CNIL) a permanent authorization to waive the obligation to provide information for the implementation of scientific research projects conducted on the data in the ESMÉ warehouse.

- SCIENTIFIC PRODUCTION

Since the start of ESMÉ programme, the academic researchers involved have produced **52 international communications or publications**. Among the most notable this year:
• The study "Clinical Outcome of patients with isolated brain progression on first line Pertuzumab and Trastuzumab treatment for HER2 positive metastatic breast cancer in a real life cohort", selected for oral presentation at the 2020 ASCO meeting.
• The study "Molecular screening in locally advanced and metastatic non-small cell lung cancer in the elderly: state of practice in France", presented in an e-poster session at the 2020 congress of the SoFOG (French learned society dedicated to geriatric oncology).

At the end of 2020, the ESME platforms had a total of **56** ongoing projects:

• ESME MBC: **57** projects submitted; **31** in progress

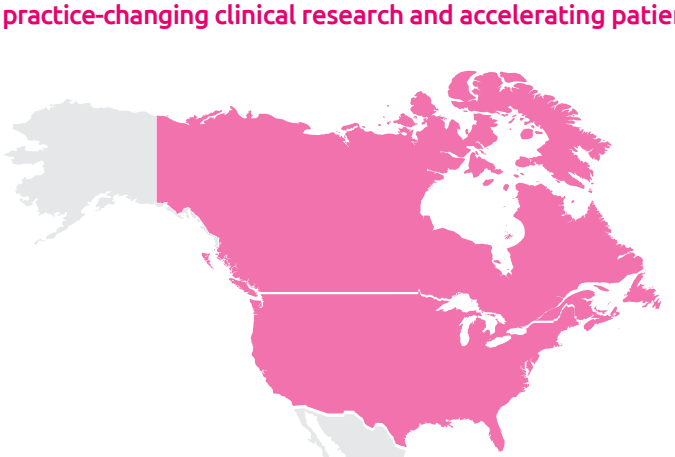
• ESME OC: **12** projects submitted; **9** in progress

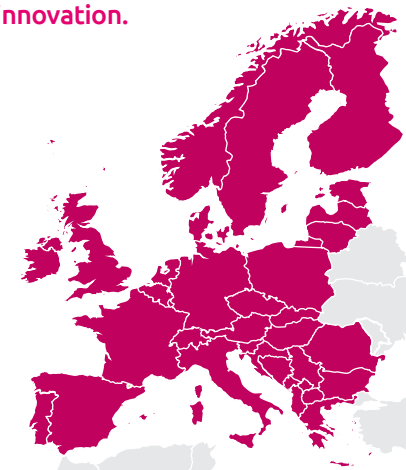
• ASME AMLC: **19** projects submitted; **16** in progress

ESME Key Figures

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.





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

COUNTRIES HOSTING ONGOING UNICANCER-SPONSORED TRIALS

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

KEY FIGURES

36 active international trials
11 active countries outside of France
86 recruiting sites outside of France (2016-2019 activity)

MATWIN

Maturation and Accelerating Translation With Industry

www.matwin.fr

Contact : contact@matwin.fr

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 /Celgene, Exact Sciences, Gilead, GlaxoSmithKline, Nanostring Technologies, Novartis, Pfizer, Pierre Fabre, Roche, Sanofi) willing to benefit from the attractiveness of French research in oncology.

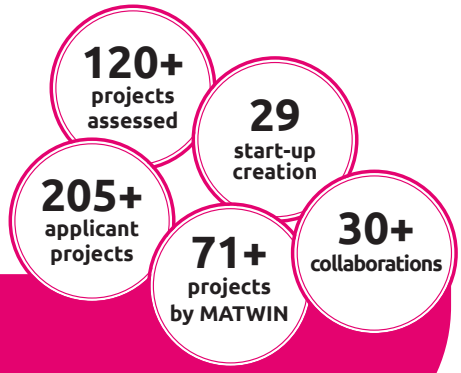
MATWIN's call for proposals is permanently open to European academic teams or startups. According to their specific needs, applicants may benefit from one or several steps of the program:

- Access to assessment by 15-20 key international industrial and academic opinion leaders from the global oncology R&D department of MATWIN's partners and EU renowned research centres
- Personalised coaching to help optimising the project structuring and its industry-oriented R&D development plan,
- Access to a network of partners (major groups, biotechs, investors) looking for collaborations

In addition to its accelerator 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, technology transfer offices…).

MEET2WIN Oncology Partnering Convention

Each year, MEET2WIN is combining conferences, workshops, projects elevator pitches and thousands of face to face B2B 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.



+205 applicant projects, **+120** projects assessed by academic & industrial experts

+71 projects interviewed by the MATWIN International Board

29 start-up creation (amongst which Syndivia, PDC*line, ElyssaMed, H-Immune, Gliocure, Apmonia Therapeutics, Yukin Therapeutics…)

+30 collaborations with biotechs or pharmas

AMGEN · Boehringer Ingelheim · GILEAD · Kite · Pfizer · SANOFI · AstraZeneca · GSK GlaxoSmithKline · nanoString · Bristol Myers Squibb · EXACT SCIENCES · NOVARTIS · Pierre Fabre · Roche

clinical research activity

Clinical trials activated in 2020

SHORT TITLE	STUDY TITLE	EXPERT GROUP	STUDY COORDINATOR	PHASE	TUMOUR LOCALISATION(S)	NUMBER OF EXPECTED PATIENTS	ACTIVATION DATE
ORL 12 - ICING	A phase II trial assessing Bintrafusp alfa, a bifunctional fusion protein targeting TGF-β and PD-L1, in a pre-operative setting for resectable and untreated head and neck squamous cell carcinoma	UC&N	C. HOFFMAN	II	Head & Neck	59	22/09/20
ORL 11 -PATHOS	A multicentre, randomised , open label phase III trial to assess de-escalation of Post-Operative adjuvant treatment for HPV-positive tumours	UC&N	H. MIRGHANI	III	Head & Neck	150	10/09/20
RILUZOX-01	Effectiveness assessment of riluzole in the prevention of oxaliplatin-induced peripheral neuropathy: A phase II randomized study of the UNICANCER-AFSOS Supportive Care Intergroup.	SDS	D. PEZET	III	Colorectal	210	08/09/20
AMBRE	Open-label, randomized, multicenter, phase III study, comparing standard chemotherapy to Endocrine Therapy + Abemaciclib combination as initial metastatic treatment among patients with visceral metastasis of ER+ Her2- breast cancer, high burden disease	UCBG	V. DIERAS	III	Breast	378	09/03/20
POLAR	A phase III open-label, multicenter, randomized trial of adjuvant palbociclib in combination with endocrine therapy versus endocrine therapy alone for patients with hormone receptor positive, HER2-negative resected locoregional recurrence of breast cancer	UCBG	B. PISTILLI	III	Breast	200	06/01/20
PRODIGE 68 - UCGI 38 SOREGATT	A randomized, phase II study to compare the regorafenib-trifluridine/tipiracil versus trifluridine/ tipiracil-regorafenib sequences beyond second-line therapy in patients with metastatic colorectal cancer	UCGI	M. DUCREUX	II	Colorectal	340	20/10/20
PEVOsq	Basket phase II trial evaluating the efficacy of a combination of pembrolizumab and vorinostat in patients with advanced and/or recurrent squamous cell carcinoma	MED PERSO	C. LE TOURNEAU	II	Anus; Penis; Lung; Head and Neck; Uterus; Vulva	111	01/10/20
GEFPICS IHC4	Retrospective study assessing the concordance of the IHC4 score performed in local pathology laboratory or in a central laboratory to a molecular gold standard test Endopredict in breast cancer infiltrating RH+ HER2-	UCBG	J. Haudebourg		Breast	155	17/02/20
EVIDENCE	Serodiagnostic COVID-19 in oncology	TRANSL	F.C. BIDARD	HPS	Anus; Germ cells; Brain; HCC; Colorectal; Stomach; Ewing; Liver; Salivary glands; Esophagus; Bone; Ovary; Pancreas; Skin; Penis; Peritoneal; Lung; Prostate; Rectum; Kidney; Breast; Head and neck; Soft tissue; NET; Solid tumours; Urothelial; Uterus; Bladder; Biliary tract; Vulva	620	25/05/20

Inclusions by expert groups

Number of patients included in 2020 per Group and per institution type

	UCBG	UNITRAD	MED PERSO	UCGI	GETUG	IOG	SARCOMA	SDS	GERICO	UCH&N	UNICANCER specific projects	Total
Public hospitals of Paris (AP-HP)	50	4	3	16	32	7	1			6	142	261
Other public hospitals (excl AP-HP)	957	17	30	128	75	26	6	20	13			1,272
FCCCs	1,151	124	283	176	120	71	10	10	26	21	48	2,040
Oher private non-profit hospitals	71	4	2	27	27	2						133
Private clinics	320	24	7	30	72							453
City medical practice	1,341											1,341
Foreign institutions	2,095			47	12							2,154
TOTAL	5,985	173	325	424	338	106	17	30	39	27	190	7,654
POURCENTAGE	78,2%	2,3%	4,2%	5,5%	4,4%	1,4%	0,2%	0,4%	0,5%	0,4%	2,5%	

Inclusions by expert groups

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

	UCBG	UNITRAD	MED PERSO	UCGI	GETUG	IOG	SARCOMA	SDS	GERICO	UCH&N	UNICANCER specific projects	Total
EUGÈNE MARQUIS CENTRE	60	2	23	2	5	1	1	6				100
ANTOINE LACASSAGNE CENTRE	33	9	33	14	7	2				1		99
LÉON BÉRARD CENTRE	18	10	28	27	8	7	3			2		103
JEAN PERRIN CENTRE	12	1	8		3	3					25	52
MARIE CURIE INSTITUTE	427	13	36	6	0	2	2	0	15	0	23	524
GEORGES-FRANÇOIS LECLERC C.	23	5	18	21	9		1					77
GUSTAVE ROUSSY CENTRE	112	24	30	20	13	17	2			13		231
OSCAR LAMBRET CENTRE	67	4	4	2	7	6			5			95
PAUL STRAUSS CENTRE	26	5	3	2								36
FRANCOIS BACLESSE CENTRE	18	4	19	4	7	2		4	2			60
HENRI BECQUEREL CENTRE	3	11	0			3						14
INSTITUTE OF CANCER RESEARCH IN WESTERN FRANCE	113	3	31	27	27	10	0	0	0	2	0	206
BERGONIE INSTITUTE CENTRE	96	4	14	4	9	3	1		2			139
CLAUDIUS REGAUD INSTITUTE	57	6	4		12	2			2	2		87
LORRAINE INSTITUTE OFONCOLOGY	2	12	4	2	3	2				1		26
JEAN GODINOT INSTITUTE	21	5	3	16	1	3						48
PAOLI CALMETTES INSTITUTE	53	4	25	15	8	8						108
MONTPELLIER CANCER INSTITUTE VAL D'AURELLE	10	2	0	14	1							35
TOTAL	1,151	124	283	176	120	71	10	10	26	21	48	2,040

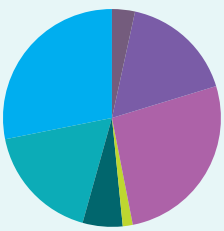
Inclusions by tumour localisation

Number of patients included in 2020 by tumour localisation and institution type

	Breast	of which Tumospec	of which MyPeBS	Digestive	Genito-urinary	Sarcoma	Lung	Gyneacological	Head & Neck	Multiple localisations	Total
Public hospitals of Paris (AP-HP)	6	39	7	16	32	1	2	0	6	152	261
Other public hospitals (excl AP-HP)	76	324	601	119	75	6	2	12	0	57	1,272
FCCCs	499	816	125	159	120	10	19	21	21	250	2,040
Other private non-profit hospitals	6	13	54	27	27	0	2	0	0	4	133
Private clinics	21	50	258	29	72	0	4	1	0	18	453
City medical practice	0	0	1,341	0	0	0	0	0	0	0	1,341
Foreign institutions	6	0	2,089	47	12	0	0	0	0	0	2,154
TOTAL	614	1,242	4,475	397	338	17	29	34	27	481	7,654

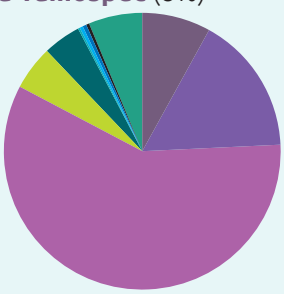
INCLUSIONS BY INSTITUTION TYPE

- **Public hospitals of Paris (AP-HP)** (3,4%)
- **Other public hospitals (excl AP-HP)** (16,9%)
- **FCCCs** (26,6%)`
- **Other private non-profit hospitals** (1,5%)
- **Private clinics** (5,9%)
- **City medical practice** (17,5%)
- **Foreign institutions** (28,1%)



INCLUSIONS BY TUMOUR LOCALISATION

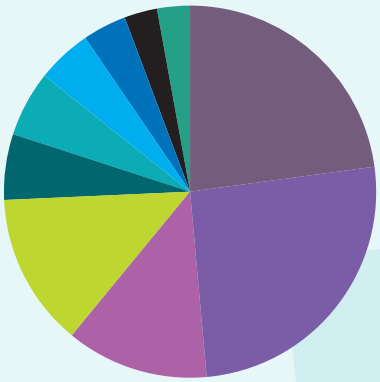
- **Breast without MyPeBS and Tumospec** (8%)
- **Breast - Tumospec** (16%)
- **Breast - MyPeBS** (58%)
- **Digestive** (5%)
- **Genito-urinary** (4%)
- **Sarcoma** (0,2%)
- **Lung** (0,4%)
- **Gyneacological** (0,4%)
- **Head & Neck** (0,4%)
- **Multiple localisations** (6%)



Ongoing trials

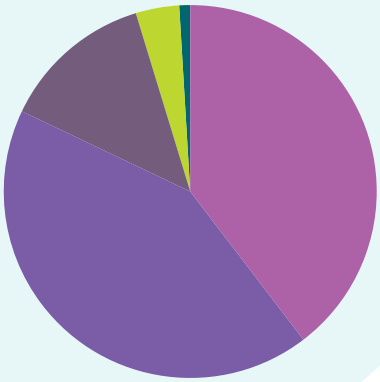
NUMBER OF ONGOING TRIALS PER GROUP

- GETUG (24)
- UCBG (27)
- UCGI (13)
- MED PERSO (14)
- UCH&N (6)
- UNITRAD (6)
- SARCOMA (5)
- GERICO (4)
- IOG (3)
- SDS (3)



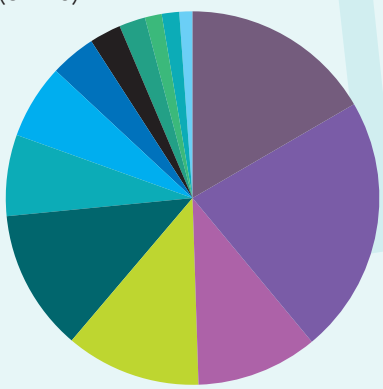
DISTRIBUTION OF ONGOING TRIALS PER PHASE

- Phase I (1)
- Phase I/II (4)
- Phase II (42)
- Phase III (45)
- Other (e.g. cohort) (14)



TOTAL NUMBER OF INCLUSIONS PER GROUP IN ONGOING TRIALS

- UCBG (w/o C, T and M) (8.926)
- CANTO (C) (12.012)
- TUMOSPEC (T) (5.649)
- MyPeBS (M) (6.291)
- GETUG (6.581)
- MED PERSO (3.780)
- UCGI (3.466)
- SARCOMA (2.119)
- UNITRAD (1.470)
- GERICO (1.223)
- SDS (782)
- IOG (812)
- UCH&N (613)



EORTC liaison office

The future of cancer therapy

Unicancer is the local representative of EORTC in France. A partnership agreement was signed with EORTC in 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.

KEY FIGURES

In 2020, **4** new EORTC-sponsored trials have been activated in France and **31** studies were recruiting.

4 new trials

31 studies

List of EORTC studies approved in France in 2020

EORTC Research Group(s)	EORTC Study number (acronym)	STUDY TITLE	Study approval date in France	National Coordinator in France	Number of expected patients (France/All countries)
LCG	08112 (NEMO)	Nintedanib as maintenance treatment of malignant pleural mesothelioma (NEMO): a double-blind randomized phase II of the EORTC Lung Cancer Group	26/02/2020	Dr Matteo GIAJ LEVRA (CHU Grenoble)	30/116
STBSG	1762 (REDUCE)	Reduced dose-density of denosumab for maintenance therapy of unresectable giant cell tumor of bone: a multicenter phase II study "REDUCE"	05/05/2020	Dr Christine CHEVREAU (Institut Claudius Regaud, Toulouse)	23/100
STBSG	1809 (STRASS 2)	A randomized phase III study of neoadjuvant chemotherapy followed by surgery alone for patients with High Risk RetroPeritoneal Sarcoma (STRASS 2)	22/09/2020	Dr Sylvie BONVALOT (Institut Curie, Paris)	35/250
QLG-LG	1621 (SPARTA)	A Survivorship Project to understand and to improve long-Term outcomes for Acute myeloid leukemia patients (SPARTA): The SPARTA platform	29/09/2020	Dr Thomas XAVIER (CHU Lyon)	25/343

GLOSSARY
BTG : BRAIN TUMOR GROUP (EORTC BTG)
CLTF : CUTANEOUS LYMPHOMA TASK FORCE (EORTC CLTF)
GCG : GYNECOLOGICAL CANCER GROUP (EORTC GCG)
GITCG : GASTROINTESTINAL TRACT CANCER GROUP (EORTC GITCG)
GUCG : GENITOURINARY CANCER GROUP (EORTC GUCG)
GCG : GYNECOLOGICAL CANCER GROUP (EORTC GCG)
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)

List of EORTC studies active in France in 2020

EORTC Research Group(s)	EORTC Study number (acronym)	STUDY TITLE	Study approval date in France	Number of expected patients (France/All countries)
BTG	1419	Molecular genetic, host-derived and clinical determinants of long-term survival in glioblastoma	05/07/2015	113/477
BTG	1608 (STEAM)	Study of TG02 in Elderly Newly Diagnosed or Adult Relapsed Patients in the Anaplastic Astrocytoma or Glioblastoma: A Phase Ib Study	16/03/2018	44/91
BTG	1635 (IWOT)	IDH mutated 1p/19q intact lower grade glioma following resection Wait Or Treat? IWOT – A phase III study.	08/07/2019	1/1
BTG	1709 (MIRAGE)	A phase III trial of marizomib in combination with standard temozolomide-based radiochemotherapy versus standard temozolomide-based radiochemotherapy alone in patients newly diagnosis glioblastoma	10/07/2018	109/746
BTG-ROG	1308 (ROAM)	Radiation versus Observation following surgical resection of Atypical Meningioma: a randomized controlled trial (The ROAM trial)	22/08/2017	8/123
CLTF	1652 (PARCT)	Phase II trial of atezolizumab (anti-PD-L1) in the treatment of stage IIb-IV myociss fungoides/sezary syndrome patients relapse/refractory after a previous systemic treatment	26/09/2018	5/26
GITCG	1203 (INNOVATION)	INtegratioN of trastuzumab, with or without pertuzumab, into periOperatiVe chemotherApy of HER-2 posiTIe stOmach cancer: the INNOVATION-TRIAL	02/09/2015	18/120
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	07/09/2017	5/46
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	09/08/2017	39/170
GCG	1508	A phase II study of the anti-PDL1 antibody atezolizumab, bevacizumab and acetylsalicylic acid to investigate safety and efficacy of this combination in recurrent platinum-resistant ovarian, fallopian tube or primary peritoneal adenocarcinoma	13/06/2017	20/122
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).	04/02/2015	15/68
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	18/09/2017	1/28
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"	24/11/2017	103/166
GITCG	1527 (DREAM)	Diffusion-Weighted Magnetic REsonance Imaging Assessment of Liver Metastasis and Improve Surgical Planning	27/12/2016	26/96
GITCG	1560 (ILOC)	Phase II of immunotherapy plus local tumor ablation in patients with metastatic colorectal cancer	27/03/2018	4/20
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	14/06/2019	1/51
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 (TOP GEAR).	13/11/2013	30/560
GITCG-ROG	1714 (CRUCIAL)	Phase II trial in inoperable oesophageal cancer evaluationg the feasibility of the combination of definitive chemoradiation with the immune checkpoint blockers Nivolumab +/- Ipilimumab	27/08/2018	8/8

EORTC Research Group(s)	EORTC Study number (acronym)	STUDY TITLE	Study approval date in France	Number of expected patients (France/All countries)
LCG	1416 (PEARLS)	A randomized, phase 3 trial with anti-PD-1 monoclonal antibody pembrolizumab (MK-3475) versus placebo for patients with early stage NSCLC after resection and completion of standard adjuvant therapy.	10/11/2015	Confidential/1380
LCG	1525 (NivoThym)	Single-arm, multicenter, phase II study of nivolumab in patients with type B3 thynoma and thymic carcinoma previously treated with chemotherapy	03/06/2019	12/55
LCG	1613 (APPLE)	APPLE trial: Feasibility and activity of AZD9291 (osimertinib) treatment on Positive Plasma T790M in EGFR mutant NSCLC patients	20/07/2017	63/156
LCG-ROG	1702 (HALT)	Targeted therapy with or without dose intensified radiotherapy for oligo-progressive disease in oncogene-addicted lung tumors	07/01/2019	1/25
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.	28/04/2015	10/265
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	04/07/2018	83/98
STBSG	1403 (rEECur)	International Randomised Controlled Trial of Chemotherapy for the treatment of recurrent and primary refractory Ewing sarcoma.	10/03/2016	75/462
STBSG	1506 (ANITA)	A phase II multicenter study comparing the efficacy of the oral angiogenesis inhibitor nintedanib with the intravenous cytotoxic compound ifosfamide for treatment of patients with advanced metastatic soft tissue sarcoma after failure of systemic non-oxazaphosporine-based first line chemotherapy for inoperable disease "ANITA"	04/05/2017	17/80
STBSG-GCG	62113-55115 (IRCI 006/HGUS)	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.	30/01/2015	17/42
All groups	1811 (E^2-RADIATE)	EORTC-ESTRO RADiotherapy InfrAstrucTure for Europe	11/06/2019	0/309
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	30/03/2017	7/77
All groups	1553 (SPECTA*) RP-1828 (IMMUcan)	Screening Cancer Patients for Efficient Clinical Trial Access Integrated IMMUnoprofiling of large adaptive CANcer patients cohorts	30/03/2017	59/141
All groups	1553 (SPECTA*) RP-1843 (Arcagen)	Screening Cancer Patients for Efficient Clinical Trial Access Molecular characterization of rare cancer	30/03/2017	113/268

* 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.

SPECTA program web site: https://www.eortc.org/specta/

translational research activity

Main Translational Research Projects

Unicancer has a large database of structured data collected prospectively in multiple indications and pathologies. In order to accelerate the development of knowledge in oncology and to promote translational research, Unicancer opens its data and samples to researchers and clinicians from any institution for their projects of interest.

All new projects are evaluated by a committee of experts appointed by Unicancer, which may issue recommendations on methodological or scientific aspects before final approval. The Research teams analyse the logistical and regulatory feasibility, particularly with regard to prior information to patients.

ONGOING MAJOR PROJECT

The **AcSé Cible** programme is part of the AcSé immunotherapy programme, aiming to allow off-label access to anti-PD1 (nivolumab or pembrolizumab) for patients with rare cancers, based on the tumour biological profile.
With regards to the state of the art, **the AcSé Cible programme is an original approach which aims to identify negative predictive biomarkers for patients treated with anti-PD-1 immunotherapies.**

Seminal discoveries have already been made, leading to define priority areas for research:

- Tumour immune contexture;
- Patients' microbiome activation of immune responses (in particular, possible modulating effect of the gut microbiota on checkpoint inhibitors);
- Circulating tumour and immune cell dynamics;
- Inter-individual variability of anti-PD1 pharmacokinetic/pharmacodynamic behaviour and relationship with response;
- Hyper-progression biological mechanisms through cancer routine imaging data.

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.

Indeed, PD-1 antibodies have shown to be effective in the treatment of a range of tumour types (melanoma, non-small cell lung cancer, head and neck squamous cell carcinoma, renal cancer, urothelial cancer, Hodgkin's disease) but many patients develop primary or acquired resistance to immunotherapy.

This study aims to provide the oncology community with clinical tools enabling them to select patients who may actually benefit for anti-PD(L)-1 therapies, to avoid exposing non-responder patients to immune-related adverse events, and to limit prescriptions of such expensive treatments to patients with expected clinical benefits.

Based on multi-centric analysis of the clinical, biological (blood and formalin-fixed biopsy samples) and radiological characteristics of patients treated with anti-PD1 (), researchers seek to identify factors which strongly correlate with early resistance to nivolumab or pembrolizumab therapy, in order to develop signatures predictive of treatment failure.

Biological Resource Centre

Unicancer's biobank was set up in 2012 to meet the requirements of Research's strategy by creating a collection of clinical research program samples to promote biological research and advances in cancer treatment. In spite of COVID and lockdowns, the activity of the Biological Research Centre (BRC) did not slow down in 2020.

The whole collection includes **72,737 samples,** centralised at the Léon Bérard Centre and made available to the research teams. Samples are coming from 16,398 patients enrolled in a total of 63 studies. Historical collections are mostly focused on breast cancer. **14,398 new samples entered the collection in 2020.** New types of biological samples such as faeces and saliva are also being collected, with the advent of new research programmes.

In 2020, 3,396 samples were unarchived to feed 12 translational research projects, mainly focused on the development of predictive molecular signatures. Most of these have been made available to academic research teams in the CLCCs. Samples can also be made available to industrial companies involved in research partnerships. Access to the collection is granted on submission of a valid research project and subject to acceptance by Unicancer's biological steering committee.

The design of new research projects requires enhanced communication about the available collections. To this end, **QlikView is a data visualisation tool which facilitates the identification of samples of interest and improves the traceability of data and sample flows.**

This tool allows them to know exactly what material is available, both in terms of the innate characteristics of the sample and the clinical parameters of the disease concerned and the genomic analyses performed.

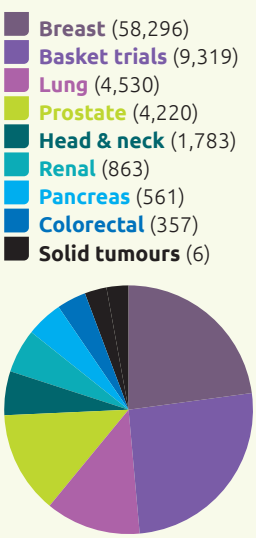
In order to facilitate queries on specific subtypes of the population, the development of a new link to clinical data available in genomic analysis platforms has been initiated in collaboration with the Data Department and should be finalised next year.

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 or samples. The opening of this site meets the requirements of the General Data Protection Regulation (GDPR).

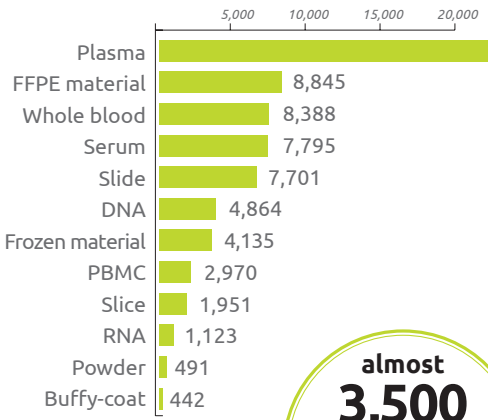
Finally, a list of available collections will also soon be available to the FCCCs, project leaders and the entire scientific community via a space dedicated to biological collections on the Unicancer website.

At the end of 2020, the BRC Steering Committee initiated a reflection on a new global strategy for the use of samples, in order to enhance the value of existing collections and to rationalise the constitution of future collections.

SAMPLE DISTRIBUTION BY TUMOUR LOCALISATION



NUMBER OF SAMPLES BY SUBTYPE



more than **70,000** samples stored in total

almost **15,000** new entries in 2020

almost **3,500** outputs in 2020 used in 12 research projects

representing approximately **170,000** aliquots*

** 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.*

real world data

Epidemiological Strategy and Medical Economics (ESME)

ESMÉ
unicancer

Initiated in 2014, the ESME research programme, is a French platform of real-world data (RWD) on cancer management in oncology. It centralizes existing longitudinal retrospective RWD, and makes them available to the scientific and medical community for analysis and as high quality aggregated reports to the pharma industry.
Data contributors include the Unicancer network of French Comprehensive Cancer Centres (FCCCs) and public or private hospitals across France. It relies on three integrated poles of expertise: information systems development, data validation and scientific project management.

The ESME data platform includes data from different information sources generated by healthcare professionals, patient and hospital data (see chart).

It is supported by major industrial partners: Pfizer (whose support in metastatic breast cancer was renewed this year for 3 years), Roche, AstraZeneca, MSD, Daiichi Sankyo, Esai, BMS (as the coordinator of the IO-Optimise international partnering programme for immunotherapy treatment optimization in advanced or metastatic lung cancer, in which Unicancer is involved), and since 2020 GSK (in ovarian cancer), Janssen and Amgen (both in advanced or metastatic lung cancer).

Under the IO-Optimise programme, an evaluation of the ESME retrospective data and the prospective data of the Crisp database of the German academic group AIO, in terms of content, interoperability and capacity to be reconciled, is currently underway with a view to a scientific collaboration on new research projects.

Other partnerships are under discussion.

THE ESME DATA ARE USED TO :

- **describe cancer management in France as well as current standard therapeutic strategies/treatment lines and therapeutic trends,**
- **provide data on innovative drug use in medical institutions for market access filing and real-life settings,**
- **support Health Economic Models and requirements from Health Authorities.**

ESME RESEARCH PROJECTS

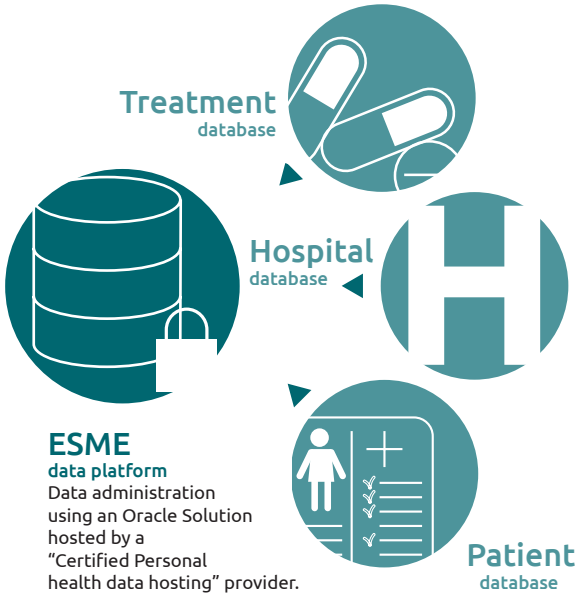
Three data platforms respectively focus on:

Metastatic Breast Cancer (26,216 patients selected from FCCCs at the end of 2020) aiming to help standardize the management of MBC and improve patient care.

Advanced and metastatic lung cancer (26,816 patients selected from FCCCs and other healthcare facilities at the end of 20209), aiming to describe the evolution of medical care for patients treated for an advanced or metastatic lung cancer and evaluate the impact of new therapies, especially immunotherapies, on disease treatments.

Ovarian Cancer (10,495 patients selected from FCCCs at the end of 2020), aiming to describe clinical characteristics, treatment pattern and clinical outcomes in adult women diagnosed with Platinum Sensitive Relapse (PSR) advanced epithelial relapsed ovarian, fallopian tube or primary peritoneal cancer.

INFORMATION SOURCES OF THE ESME DATA PLATFORM



ESME GOVERNANCE

The ESME research programme is developed by the Health Data Department, headed by Anne-Laure Martin.
Three bodies monitor the ESME research programme: the Strategic Committee (associated with three dedicated Scientific Groups, see below), the Deontology Committee and the International Advisory Board.
The main roles of the Strategic Committee, headed by David Perol, are to evaluate any ancillary projects in compliance with defined criteria and scientific pertinence and to monitor all the validated ancillary projects. It includes three Scientific Groups, each dedicated to one pathological area:

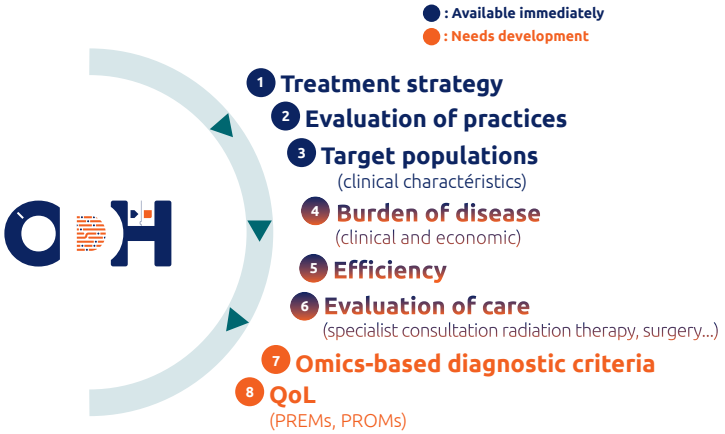
- **A group on metastatic breast cancer, chaired by Suzette Delaloge**
- **A group on ovarian cancer, co-chaired by Laurence Gladieff and Jean-Marc Classe**
- **A group on lung cancer co-chaired by Maurice Perol, Nicolas Girard and Clarisse Audigier-Valette**

The ESME Deontology Committee monitors any conflicts of interest related to experts involved in the programme, provides recommendations for conflict prevention and opinions on individual/particular situations and collaborations with private partners.
The ESME International Advisory Board has a consultative role with regard to coherence of the scientific program and reviews key international communications, formulates recommendations for publication rules or methodology and reinforces international academic cooperation.
ESME databases are fully compliant with the American Standard 21 CFR part11, relating to optimal use of electronic technologies for the security of data collection and storage.

ODH : Onco Data Hub

ODH project is the result of a partnership between Roche and Unicancer aimed at setting up a national oncology drug observatory.

The ODH is the first French public-private structure expected to address use cases that meet the needs of RWD/ RWE for studies on the management and use of health products to improve cancer patient care. It is designed to allow access to and reconciliation with the databases of other public or private entities (e.g., SNDS - National Health Data System).



Target users :
- Academics
- Pharmas
- Centres (contributors)
- Institutions : HAS (France's Health Authority), CEPS (government's Economic Committee for Healthcare Products)

THIS PROJECT IS BASED ON:

- Data on the use of therapeutic products from Roche's current PRM data set (Personalised Reimbursement Models)
- A large panel of centres representative of the care provided
- Having developed collection and visualisation tools
- Data used in treatment strategies development, in medical practice studies and in the monitoring of treatment prescriptions (dashboards)

- Data from clinical care available in the Unicancer's ESME programmes
- Deep, clinical, disease-representative databases,
- Recognised scientific publications,
- Use in medical research: description of populations/sub-populations, survival/progression-free survival data, comparative studies and clinical trials

THE DATA SET WILL CONSTITUTE A COMPREHENSIVE CATALOGUE OF USES THAT WILL ALLOW TO:
- address a number of needs via a single platform ("one-stop-shop"),
- benefit from validated methodologies and increased acceptability by institutions,
- have quality, informative and representative data on cancer care,
- automate and reiterate requests at different levels (prescriptions, therapeutic strategies, survival)
- carry out research projects on therapeutic strategies (particularly on the place iof innovative therapies)
- evaluate the therapeutic innovation of drugs using recognised and robust real-life data

DATABASE DEVELOPEMENT AND MANAGEMENT

CLINICAL TRIAL ORGANISATION

PATIENT ENGAGEMENT

ADDITIONAL MODULES

CORE PLATFORM

HUMAN AND SOCIAL SCIENCES

weSHARE

Cancer survivors now continue to live longer and better lives.

This has opened up new fields of research on the reduction of medical and social risks associated with cancer and cancer treatments, requiring the integration of the research in social and human sciences (economic, psychological and sociological data) into classical oncology research.

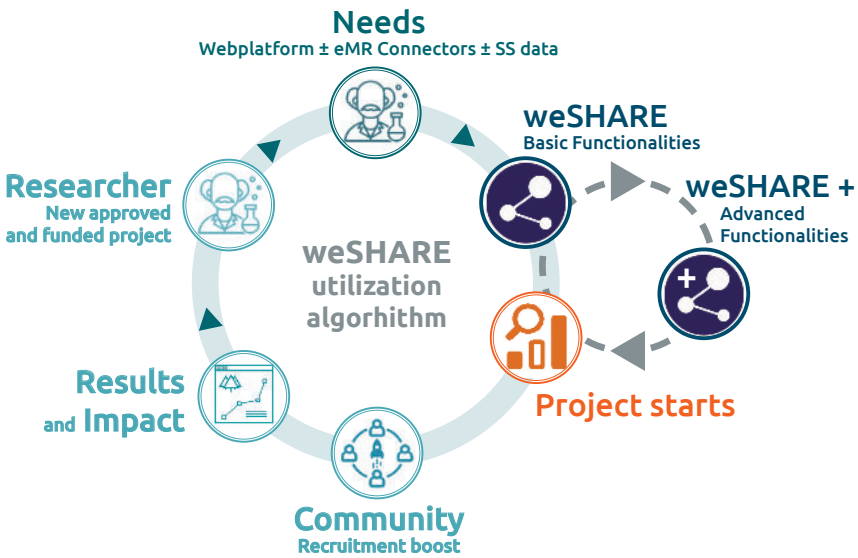
To this end, Unicancer is developing the weSHARE project, in cooperation with three FCCCs (Gustave Roussy, François Baclesse, Léon Bérard), the Ecole Polytechnique, the Seintinelles association and the national Quality of Life and Cancer platform.

weSHARE is a patient-focused integrated dynamic web structure that will serve all cancer researchers and centres. It will centralise technological tools to streamline cancer research that includes strong social and human sciences components.

By creating greater synergy between disciplines and data from the different fields of knowledge, weSHARE is ultimately expected to become:

- **an accelerator** for identifying research questions, translating knowledge into action for the benefit of patients, and disseminating evidence to guide health policy,
- **an incubator** for innovative studies,
- **a powerful catalyst** for a new generation of research.

weSHARE was one of the highest ranked projects selected to be funded by the French National Agency for Research (ANR) as part of its Investments for the Future programme, with an estimated grant of nearly 11 million euros. It is expected to be launched in June 2021.



research in the FCCCs

Inclusions in the FCCCs' network

Unicancer groups together 18 French Comprehensive Cancer Centres (FCCCs) spread across 20 hospital sites throughout France. 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.

UNICANCER, A UNIQUE NETWORK OF EXPERT CENTRES IN FRANCE

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

3 **INSTITUT BERGONIÉ** • • •
Unicancer Nouvelle-Aquitaine

4 **CENTRE FRANÇOIS BACLESSE** • •
Unicancer Normandie-Caen

5 **CENTRE JEAN PERRIN** •
Unicancer Clermont Auvergne Métropole

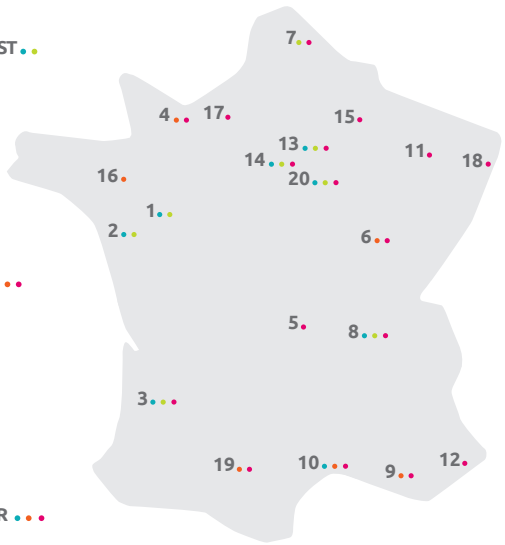
6 **CENTRE GEORGES-FRANÇOIS LECLERC** • •
Unicancer Bourgogne Franche-Comté

7 **CENTRE OSCAR LAMBRET** • •
Unicancer Hauts-de-France

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

9 **INSTITUT PAOLI-CALMETTES** • •
Unicancer Marseille

10 **INSTITUT DU CANCER DE MONTPELLIER** • • •
Montpellier



11 **INSTITUT DE CANCÉROLOGIE DE LORRAINE** •

12 **CENTRE ANTOINE LACASSAGNE** •
Unicancer Nice

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

15 **INSTITUT GODINOT** •
Unicancer Reims en Champagne

16 **CENTRE EUGÈNE MARQUIS** •

17 **CENTRE HENRI BECQUEREL** •
Unicancer Normandie-Rouen

18 **ICANS** •
Unicancer Strasbourg

19 **IUCT ONCOPOLE – INSTITUT CLAUDIUS REGAUD** • •

20 **GUSTAVE ROUSSY** • • •

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

• SIRIC: INCa-accredited, integrated sites for translational and innovative research in oncology

• CLIP: INCa-accredited early phase clinical trial centres

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)

Key figures

14% **of the patients** — 14% of the patients treated in the FCCCs are included in a clinical trial versus 8.5% of cancer patients in average in France

603 **active clinical trials** — 603 active clinical trials sponsored by the Unicancer network

99 **new trials** — 99 new trials sponsored by the Unicancer network

56% **of the national funding** — 56% of the national funding for oncology clinical research programmes ('PHRC-K') has been allocated to Unicancer

52% **of the national funding** — 52% of the national funding for oncology translational programmes ('PRTK') has been allocated to Unicancer

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

19 **INCa -accredited** — 19 INCa-accredited cancer molecular genetics platforms are hosted in a FCCC, out of 28 in France

6 **INCa -accredited** — 6 INCa-accredited, integrated sites for translational and innovative research in oncology (SIRIC) are hosted in a FCCC, out of 8 in France

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 *	% of the active patient le included in a clinical trial	ACADEMIC SPONSOR			INDUSTRIAL SPONSOR	
								Number of patients included	Number of active trials	% of patients included in an institutional clinical trial	Number of patients included	Number of active trials
Bergonie Institute	Bordeaux	7,247	1,492	322	4,6	4,6	20,6%	1,317	185	88%	175	137
Francois Baclesse Centre	Caen	7,340	493	177	2,8	2,8	6,7%	411	125	83%	82	52
Jean Perrin Centre	Clermont	5,342	934	131	7,1	7,1	17,5%	877	93	94%	57	38
Georges-François Leclerc Centre	Dijon	4,969	732	216	3,4	3,4	14,7%	596	144	81%	136	72
Oscar Lambret Centre	Lille	6,958	1,248	176	7,1	7,1	17,9%	1,047	125	84%	201	51
Léon Bérard Centre	Lyon	10,277	1,608	312	5,2	5,2	15,6%	1,308	182	81%	300	130
Paoli calmettes Institute	Marseille	10,045	949	218	4,4	4,4	9,4%	756	116	80%	193	102
Montpellier Cancer Institute - Val d'Aurelle	Montpellier	6,706	1,329	197	6,7	6,7	19,8%	1,206	141	91%	123	56
Lorraine Institute of Oncology	Nancy	5,288	769	126	6,1	6,1	14,5%	743	105	97%	26	21
Institute of Cancer research in Western France	Nantes Angers	11,839	1,273	254	5,0	5,0	10,8%	1,088	164	85%	185	90
Antoine Lacassagne Centre	Nice	5,412	852	164	5,2	5,2	15,7%	781	112	92%	71	52
Curie Institute	Paris Saint Cloud	14,167	1,761	223	7,9	7,9	12,4%	1,522	134	86%	239	89
Jean Godinot Institute	Reims	3,662	235	77	3,1	3,1	6,4%	196	67	83%	39	10
Eugène Marquis Centre	Rennes	4,889	343	126	2,7	2,7	7,0%	253	93	74%	90	33
Henri Becquerel Centre	Rouen	5,197	273	94	2,9	2,9	5,3%	232	71	85%	41	23
ICANS	Strasbourg	4,588	533	159	3,4	3,4	11,6%	446	114	84%	87	45
Claudius Regaud Institute	Toulouse	7,208	997	228	4,4	4,4	13,8%	758	128	76%	239	100
Gustave Roussy	Villejuif	13,212	2,943	432	6,8	29	22%	2,399	161	82%	544	271
Total		**134,346**	**18,764**			**17%**	**14%**	**15,936**		**85%**	**2,828**	
Mean		7,464	1,042	202	5	17%	13%	885	126	85%	157	76
+/- SD		3,133	658	88	2	9%	5%	548	34	6%	125	61
median		6,832	942	187	5	15%	14%	770	125	84%	130	54
min		3,662	235	77	3	5%	5%	196	67	74%	26	10
max		14,167	2,943	432	8	38%	22%	2,399	185	97%	544	271

* 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.

appendices

Trials in active phase in 2020

Tumour Localisation(S)	EXPERT GROUP(S)	STUDY SHORT TITLE	Study title	Study Coordinator	Phase	Number of expected patients
Anus;Penis; Lung;Head &Neck; Uterus;Vulva	MED PERSO	PEVOsq	Basket phase II trial evaluating the efficacy of a combination of pembrolizumab and vorinostat in patients with advanced and/or recurrent squamous cell carcinoma	Christophe LE TOURNEAU	II	111
Bladder	GETUG	GETUG-AFU 30 BLADDER ART	Adjuvant radiotherapy in patients with pathological high-risk bladder cancer: A randomized multicentre phase II study: Bladder-ART study	Paul SARGOS	II	109
Bladder	GETUG	GETUG-AFU 35 BLADDER SPARING	Phase II study of concomitant and maintenance anti-PDL1 treatment with atezolizumab after chemoradiotherapy for muscle-infiltrating bladder cancer patients not eligible for radical cystectomy: Bladder Sparing	Christophe HENNEQUIN	II	77
Bladder	GETUG	AFU-GETUG 37 - ALBAN	An open label, randomized, phase III trial, evaluating efficacy of Atezolizumab in addition to one year BCG (Bacillus CaLmette-Guerin) bladder instillation in BCG-naive patients with high-risk non-muscle invasive Bladder cANcer	Morgan ROUPRET	III	516
Bone	SARCOME	SARCOME 12/ REGOBONE	A Randomized Phase II, placebo-controlled , multicenter study evaluating efficacy and safety of regorafenib in patients with metastatic bone sarcomas	Florence DUFFAUD	II	179
Bone	SARCOME	MEPACT/ SARCOME 13	Randomised Phase 2 trial of mepact combined with post-operative chemotherapy for newly diagnosed high risk osteosarcoma (metastatic or localized disease with poor histologic response)	Nathalie GASPAR	II	390
Breast	UNITRAD	HYPOG 01	Multicenter randomized phase III trial comparing hypo-fractioned versus standard radiotherapy in breast cancer with an indication for regional lymph node irradiation in terms of lymphedema occurrence	Sofia RIVERA	III	1265
Breast	UCBG	UNIRAD	Randomised, double-blind, multicentre phase III trial evaluating the safety and benefit of adding everolimus to adjuvant hormone therapy in women with high risk of relapse, ER+ and HER2- primary breast cancer who remain free of disease	Thomas BACHELOT	III	1984
Breast	MED PERSO	TRACER-X	Tracking triple-negative breast cancer evolution through therapy	Monica ARNEDOS	Cohort	250
Breast	MED PERSO	SAFIR PI3K	SAFIRPI3K: a phase II randomized trial testing Alpelisib as maintenance therapy in patients with PIK3CA mutated advanced breast cancer	Anthony GONCALVES	II	31
Breast	UNITRAD	ROMANCE	ROMANCE: Prospective study of omission of whole-breast radiotherapy following breast-conserving surgery in patients with very low risk ductal carcinoma in situ of the breast	Alain FOURQUET	II	666
Breast	GERICO	GERICO 16 -TOUCH	Phase II open-label, multicenter, randomized trial of neoadjuvant palbociclib in combination with hormonal therapy and HER2 blockade versus paclitaxel in combination with HER2 blockade for elderly patients with hormone receptor positive/HER2 positive early breast cancer -Dr Etienne Brain	Etienne BRAIN	II	40/144
Breast	GERICO	GERICO 18- Appalaches	Adjuvant palbociclib as an alternative to chemotherapy for older patients with high risk luminal early breast cancer – Dr Etienne Brain	Etienne BRAIN	II	
Breast	UCBG	TUMOSPEC	Détermination du spectre tumoral, évaluation de la pénétrance et de l'utilité clinique des mutations constitutionnelles de nouveaux gènes de prédisposition aux cancers du sein et de l'ovaire	Olivier CARON	Cohort	500
Breast	UCBG	CANTO	A cohort to quantify and to predict treatment related chronic toxicities in patients with non-metastatic breast cancer	Fabrice ANDRE	Cohort	13250
Breast	UCBG	MyPeBS	MyPeBS - (Personalizing Breast Screening)International Randomized Study Comparing personalized, Risk-Stratified to Standard Breast Cancer Screening In Women Aged 40-70	Corinne BALLEYGUIER	Cohort	85 000
Breast	UCBG	START	A randomized phase 2 study in patients with triple-negative, androgen receptor positive locally recurrent (unresectable) or metastatic breast cancer treated with darolutamide or capecitabine	Hervé BONNEFOI	II	90
Breast	UCBG	IMpassion030	A PHASE III, MULTICENTER, RANDOMIZED, OPEN-LABEL STUDY COMPARING ATEZOLIZUMAB (ANTI–PD-L1 ANTIBODY) IN COMBINATION WITH STANDARD ADJUVANT ANTHRACYCLINE/TAXANE-BASED CHEMOTHERAPY VERSUS CHEMOTHERAPY ALONE IN PATIENTS WITH OPERABLE TRIPLE-NEGATIVE BREAST CANCER	William JACOT	III	2300
Breast	UCBG	PATINA	A Randomized, Open Label, Phase III Trial to Evaluate the Efficacy and Safety of Palbociclib + Anti-HER2 therapy + Endocrine therapy vs. Anti-HER2 therapy + Endocrine therapy after induction treatment for Hormone Receptor Positive (HR+)/HER2-Positive Metastatic Breast Cancer	Joseph GLIGOROV	III	150

Tumour Localisation(S)	EXPERT GROUP(S)	STUDY SHORT TITLE	Study title	Study Coordinator	Phase	Number of expected patients
Breast	MUCBG	DOLAF	DOLAF- An international multicenter phase I/II trial of Durvalumab plus OLAparib plus Fulvestrant in metastatic or locally advanced ER-positive, HER2-negative breast cancer patients selected using criteria that predict sensitivity to olaparib.	Severine GUIU	I/II	158
Breast	UCBG	PALATINE	Optimized combined locoregional and systemic treatments for de novo, treatment naive, stage IV ER+, HER2- breast cancer patients	Delphine HEQUET	II	200
Breast	UCBG	AMBRE	Open-label, randomized, multicenter, phase III study, comparing standard chemotherapy to Endocrine Therapy + Abemaciclib combination as initial metastatic treatment among patients with visceral metastasis of ER+ Her2- breast cancer, high burden disease	Véronique DIERAS	III	378
Breast	UCBG	POLAR	A phase III open-label, multicenter, randomized trial of adjuvant palbociclib in combination with endocrine therapy versus endocrine therapy alone for patients with hormone receptor positive, HER2-negative resected locoregional recurrence of breast cancer	Barabra PISTILLI	III	200
Breast	GEP	GEP 14 LEECAP	Dose-escalation, Phase I Multicentric Trial, evaluating the combination of LEE011 and capecitabine in locally advanced or metastatic breast cancer HER2 negative	Thomas BACHELOT	I	52
Breast	MED PERSO	DAISY	Phase 2, Open label Study of DS-8201a, an Anti-HER2-Antibody Drug Conjugate (ADC) for advanced BreaSt Cancer patients, with biomarkers analysis to characterize response/resistance to therapY	Véronique DIERAS	II	162
Colorectal	SDS	RILUZOX-01	Effectiveness assessment of riluzole in the prevention of oxaliplatin-induced peripheral neuropathy: A phase II randomized study of the UNICANCER-AFSOS Supportive Care Intergroup.	Denis PEZET	III	210
Colorectal	UCGI	UCGI 28 - PANIRINOX	Phase II randomized study comparing FOLFIRINOX + Panitumumab versus FOLFOX + Panitumumab in metastatic colorectal cancer patients selected by RAS and B-RAF status from circulating DNA analysis.	Thibault MAZARD	II	209
Colorectal	UCGI	UCGI 29 / PRODIGE 52 - IROCAS	A Phase III, Randomised, international trial comparing mFOLFIRINOX triplet chemotherapy to mFOLFOX for high-risk stage III colon cancer in adjuvant setting	Jaafar BENNOUNA	III	640
Colorectal	UCGI	UCGI 30 - PRODIGE 53 - SULTAN	A randomized phase II study comparing treatment intensification with hepatic arterial infusion chemotherapy plus systemic chemotherapy to systemic chemotherapy alone in patients with liver-only colorectal metastases considered still non resectable after at least two months of systemic induction chemotherapy: SULTAN (improving SUrgery of Liver metastases: a Trial of the Arterial chemotherapy Network)	Valérie BOIGE	II	140
Colorectal	UCGI	PRODIGE 68 - UCGI 38 SOREGATT	A randomized, phase II study to compare the regorafenib-trifluridine/tipiracil versus trifluridine/tipiracil-regorafenib sequences beyond second-line therapy in patients with metastatic colorectal cancer	Michel DUCREUX	II	340
Colorectal;Ovaire; Melanoma;Lung; Kidney;Breast	MED PERSO	EXPRESS	Molecular characterization of patients with solid tumors who presented an exceptional response to targeted therapies	Olivia LE SAUX	Cohort	264
Esophagus	UCGI	PRODIGE 67 - UCGI 33- ARION	Association of Radiochemotherapy and Immunotherapy for the treatment of unresectable Oesophageal caNcer: a comparative randomized phase II trial	Anouchka MODESTO	II	120
Gastric	UCGI	PRODIGE 58 - UCGI 35 REGIRI	A randomized phase II trial assessing Regorafenib (Stivarga®) in combination with irinotecan in metastatic gastric cancer patients as 2nd line treatment	Emmanuelle SAMALIN	II	154
Germ cells	GETUG	TIGER GETUG AFU-27 / ALLIANCE A031102	A randomized phase III Trial comparing conventional-dose chemotherapy using PACLITAXEL, IFOSFAMIDE, and CISPLATIN (TIP) with high-dose chemotherapy using mobilizing PACLITAXEL PLUS IFOSFAMIDE followed by high-dose CARBOPLATIN AND ETOPOSIDE (TI-CE) as first	Aude FLECHON	III	40
Germ cells	GETUG	QUALI-TESTIS-ETUDE ANCILLAIRE GETUG 13	Strategy adapted to the prognosis for the use of dosedense chemotherapy in patients with disseminated non-seminomatous germ tumors of poor prognosis: phase III trial	Florence JOLY	III	95
Head & Neck	HEAD & NECK	ORL 07 - EORTC 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)	Lisa LICITRA	II	40
Head & Neck	HEAD & NECK	ORL 12 -ICING	A phase II trial assessing Bintrafusp alfa, a bifunctional fusion protein targeting TGF-β and PD-L1, in a pre-operative setting for resectable and untreated head and neck squamous cell carcinoma	Caroline HOFFMAN	II	59
Head & Neck	HEAD & NECK	ORL 10 - IM-MUNEBOOST HPV	A multicenter, randomized, open label, phase II study evaluating the feasibility and tolerance of nivolumab neoadjuvant immunotherapy in high risk HPV driven Oropharynx Cancer.	Haitham MIRGHANI	II	61

Tumour Localisation(S)	EXPERT GROUP(S)	STUDY SHORT TITLE	Study title	Study Coordinator	Phase	Number of expected patients
Head & Neck	HEAD & NECK	ORL 11 - PATHOS	A multicentre, randomised , open label phase III trial to assess de-escalation of Post-Operative adjuvant treatment for HPV-positive tumours	Haitham MIRGHANI	III	150
Lung	UNITRAD	NIRVANA-LUNG	PD-1 INHIBITOR AND CHEMOTHERAPY WITH CONCURRENT IRRADIATION AT VARIED TUMOUR SITES IN ADVANCED NON SMALL CELL LUNG CANCER	Jerôme DOYEN	III	515
Lung	UNITRAD	NIRVANA- ONCOBIOME	ONCOBIOME: Exploitation of research results and the potential for application of the human microbiome in prediction, prevention and personalised treatment of disease.		Cohort	100
Lung; Head & Neck	GIO	CHECK'UP	Prospective cohort study to identify the predictive factors of response to PD-1 or PD-L1 antagonists	Frédérique PENAULT-LLORCA	Cohort	465
Lung; Prostate; Breast	UNITRAD	STEREO-OS	Extracranial Stereotactic Body Radiation Therapy (SBRT) added to standard treatment versus standard treatment alone in solid tumors patients with between 1 and 3 bone-only metastases	Sebastien THUREAU	III	196
Melanoma;Penis; Kidney;Head & Neck	GIO	AcSé Nivolumab	Secured access to nivolumab for adult patients with selected rare cancer types	Aurelien MARABELLE	II	300
Multiple organs	TRANSL	EVIDENCE	Serodiagnostic COVID-19 in oncology	Francois-Clément BIDARD	HPS	620
Ovary	UCGI	CHIPOR	Randomized phase III study evaluating hyperthermic intraperitoneal chemotherapy in the treatment of ovarian cancer relapse	Jean-Marc CLASSE	III	404
Ovary;TNE	GIO	AcSé Pembro-lizumab	Secured access to pembrolizumab for patients with selected rare cancer types	Christophe MASSARD	II	350
Pancreatic	UCGI	UCGI 26 / PRODIGE 29 / NEOPAN	Randomised, phase III study comparing chemotherapy under the Folfirinox protocol to gemcitabine in treatment of locally advanced pancreatic cancer.	Michel DUCREUX	III	170
Pancreatic	UCGI	PRODIGE 65 - UCGI 36-GEMPAX	A Phase III randomized study evaluating gemcitabine and paclitaxel versus gemcitabine alone after FOLFIRINOX failure or intolerance in Metastatic Pancreatic Ductal Adenocarcinoma	Christelle DE LA FOUCHARDIERE	III	210
Penis	GETUG	AFU-GETUG 25 MEGACEP	Prospective Phase II Study Evaluating a Multimodal Care of Inguinal Node Metastasis in Squamous Cell Carcinoma of the Penis by Bilateral Lymphadenectomy and Chemotherapy TIP	Jérôme RIGAUD	II	37
Prostate	GETUG	GETUG-AFU 28_TACTIK	PERSONALIZED TREATMENT OF METASTATIC CASTRATE-RESISTANT PROSTATE CANCER PATIENTS ACCORDING TO CIRCULATING TUMOR CELLS KINETIC DURING CHEMOTHERAPY	Stéphane CULINE	II	396
Prostate	GETUG	GETUG-AFU 34_PROMET	PROMET - Multicenter, Randomized Phase II Trial of Salvage Radiotherapy +/- Metformin for Patients with Prostate Cancer after Prostatectomy	Stéphane SUPIOT	II	106
Prostate	GETUG	PEACE 2 / GETUG-AFU 23	A randomized Phase III, factorial design, of cabazitaxel and pelvic radiotherapy in patients with localized prostate cancer and high-risk features of relapse	Karim FIZAZI	III	1048
Prostate	GETUG	PEACE 3 GETUG-AFU 29	A Randomized multicenter phase III trial comparing enzalutamide vs. a combination of Ra223 and enzalutamide in asymptomatic or mildly symptomatic castration resistant prostate cancer patients metastatic to bone. PEACE III	Yohann LORIOT	III	75
Prostate	GETUG	GETUG-AFU 31_STEREO-RE-PRO	PHASE I/II MULTI-CENTER STUDY EVALUATING THE EFFICACY OF REPEAT STEREOTACTIC RADIATION IN PATIENTS WITH INTRAPROSTATIC TUMOR RECURRENCE AFTER EXTERNAL RADIATION THERAPY.	David PASQUIER	I/II	47
Prostate	GETUG	GETUG-AFU 36 PRESTO	Prostate-cancer treatment using Stereotactic Radiotherapy for Oligometastases ablation in Hormone-naive patients - a GETUG-AFU Phase III randomized controlled trial	Pierre BLANCHARD	III	350
Prostate	GETUG	GETUG-AFU 33_CARLHA 2	AN OPEN LABEL, RANDOMIZED, PHASE III STUDY EVALUATING THE EFFICACY OF A COMBINATION OF APALUTAMIDE WITH RADIOTHERAPY AND LHRH AGONIST IN HIGH-RISK POST-PROSTATECTOMY BIOCHEMICALLY RELAPSED PROSTATE CANCER PATIENTS	Stéphane SUPIOT	III	490
Prostate;Breast; Head & Neck; Uterus	MED PERSO	MOVIE	A phase I/II basket trial evaluating a combinaition of Metronomic oral vinorelbine plus antiPD1/PDL1 immunotherapy in patients with advanced solid tumors	Anthony GONCALVES	I/II	159
Solid Tumours	SDS	QUALIOR	Feasibility and efficacy of standardized APA in patients receiving oral therapy for metastatic cancer	Florence JOLY	HPS	256

Trials in follow-up phase in 2020

Tumour Localisation(S)	EXPERT GROUP(S)	STUDY SHORT TITLE	Study title	Study Coordinator	Phase	Number of expected patients
Bone	SARCOME	SARCOME 09/ OS 2006	Intergroup Study (SFCE/GSF-GETO) OS2006 - Zoledronate Osteosarcoma Treatment Protocol for osteosarcoma of the child , adolescent and adult including: A randomized trial and biological studies	Laurence BRUGIERES	III	653
Breast	UCBG	PACS08	Randomized, open label, multicentric phase III trial evaluating the benefit of a sequential regimen associating FEC100 and Ixabepilone in adjuvant treatment of non metastatic, poor prognosis breast cancer defined as triple-negative tumor [HER2 negative - ER negative - PR negative] or [HER2 negative and PR negative] tumor; in node positive or node negative patients	Mario CAMPONE	III	762
Breast	UCBG	PERNETTA	Trastuzumab (T) and pertuzumab (P) compared to trastuzumab pertuzumab combined with chemotherapy (C) both followed by T-DM1 in case of progression– a randomized phase 2 trial.	Hervé BONNEFOI	II	119
Breast	MED PERSO	SAFIR-TOR	Identification of the molecular alterations associated with resistance to endocrine therapy and impacting treatment with mTOR inhibitor of HR+ metastatic breast cancer in post-menopausal women	Thomas BACHELOT	Cohorte	150
Breast	GERICO	GERICO 11	Adjuvant systemic treatment for oestrogen-receptor (ER)-positive HER2-negative breast carcinoma in women over 70 according to genomic grade index (GGI): chemotherapy + endocrine treatment versus endocrine treatment. A French Unicancer Geriatric Oncology Group (GERICO) and Breast Group (UCBG) phase III multicentre trial	Etienne BRAIN	III	1089
Breast	UCBG	PACS07 MINDACT	MINDACT (Microarray In Node-negative and 1 to 3 positive lymph node Disease may Avoid ChemoTherapy): A prospective, randomized study comparing the 70-gene signature with the common clinical-pathological criteria in selecting patients for adjuvant chemotherapy in breast cancer with 0 to 3 positive nodes.	Suzette DELALOGE	III	2066
Breast	UCBG	IBIS II	ESSAI INTERNATIONAL, RANDOMISÉ, EN DOUBLE AVEUGLE, CONTRÔLÉ, COMPARANT LE TAMOXIFÈNE À L'ANASTROZOLE CHEZ LES FEMMES MÉNOPAUSÉES OPÉRÉES D'UN CARCINOME CANALAIRE IN SITU DU SEIN	Christelle LEVY	III	426
Breast	UCBG	ONCO03 LIBER	Prevention of breast cancer by letrozole in post-menopausal women carrying a BRCA1/BRCA2 mutation	Pascal PUJOL	III	170
Breast	UCBG	RTS 01 - Young Boost	Radiation dose intensity study in breast cancer in young women: a randomized phase III trial of additional dose to the tumor bed	Alain FOURQUET	III	726
Breast	UCBG	RTS02-SHARE	Phase III multicentric trial comparing accelerated partial breast irradiation (APBI) versus standard or hypofractionated whole breast irradiation in low risk of local recurrence of breast cancer	Yazid BELKACEMI	III	1006
Breast	UCBG	GRT02-COMET	Cohort study of prospective validation of predictive factors and biological imaging of response to bevacizumab (Avastin®) in combination with weekly paclitaxel chemotherapy in first line treatment patients with metastatic breast cancer	Jean-Yves PIERGA	Cohorte	510
Breast	UCBG	NeoPAL	A randomized phase II Study of Neoadjuvant Letrozole + Palbociclib versus sequential chemotherapy in Post-Menopausal Women with stage II-IIIA Luminal B Breast Cancer	Paul-Henri COTTU	II	125
Breast	UCBG	Olympia	A randomised, double-blind, parallel group, placebo-controlled multi-centre Phase III study to assess the efficacy and safety of olaparib versus placebo as adjuvant therapy in BRCA mutated high-risk HER2-negative primary breast cancer patients who have completed definitive local and systemic neoadjuvant/adjuvant treatment	Suzette DELALOGE	III	101
Breast	UCBG	PADA-1	Randomized, open label, multicentric phase III trial to evaluate the safety and efficacy of palbociclib in combination with hormone therapy driven by circulating DNA ESR1 mutation monitoring in estrogen receptor-positive, HER2-negative metastatic breast cancer patients	Francois-Clément BIDARD	III	1017
Breast	UCBG	PENELOPE	Phase III study evaluating palbociclib (PD-0332991), a Cyclin-Dependent Kinase (CDK) 4/6 Inhibitor in patients with hormone-receptor-positive, HER2-normal primary breast cancer with high relapse risk after neoadjuvant chemotherapy	Hervé BONNEFOI	III	121

Tumour Localisation(S)	EXPERT GROUP(S)	STUDY SHORT TITLE	Study title	Study Coordinator	Phase	Number of expected patients
Breast	UCBG	RxPONDER	InEtude de phase III randomisée comparant une hormonothérapie adjuvante standard +/- chimiothérapie chez des patientes atteintes de cancer du sein localisé avec 1-3 N+, RH+ et Her2- dont le score de rechute selon Oncotype DX™ est inférieur ou égal à 25	Suzette DELALOGE	III	1520
Breast	UCBG	TREAT-CTC	TRastuzumab in HER2-negative Early breast cancer as Adjuvant Treatment for Circulating Tumor Cells (CTC)	Jean-Yves PIERGA	II	
Breast	UCBG	ULTIMATE	ULTIMATE trial: UnLock The IMmune cells ATtraction in ER+ breast cancers	Fabrice ANDRE	II	61
Breast	GEP	GEP 13/NEOTOP	Neoadjuvant phase II trial combining [3 FEC 100 followed by 3 docetaxel associated with trastuzumab plus pertuzumab] or [6 docetaxel, carboplatin associated with trastuzumab plus pertuzumab] according to TOP2A status in patients with operable, HER2-positive breast cancer. Identification of pathological Complete Response (pCR) predictive factor	Marie-Ange MOURET-REYNIER	II	86
Breast	UNITRAD	THERAPANACEA	AI-driven quality insurance for delineation in radiotherapy breast clinical trials	Sofia RIVERA	HPS	1020
Breast	UCBG	GEFPICS IHC4	Retrospective study assessing the concordance of the IHC4 score performed in local pathology laboratory or in a central laboratory to a molecular gold standard test Endopredict in breast cancer infiltrating RH+ HER2-	Juliette Haudebourg		0
Breast	MED PERSO	SAFIR 02 BREAST	Evaluation of the efficacy of high throughput genome analysis as a therapeutic decision tool for patients with metastatic breast cancer	Fabrice ANDRE	II	1462
Colorectal	SDS	GERICO 12	Phase III study evaluating two neoadjuvant treatments, radiochemotherapy 5 weeks - 50Gy + Capecitabine) and radiotherapy (1 week - 25Gy), in patients over 75 years of age with locally advanced rectal adenocarcinoma. PRODIGE-GERICO-GRECCAR study	Eric FRANCOIS	III	103
Colorectal	UCGI	UCGI 23 / PRODIGE 23	Randomized phase III study comparing preoperative chemoradiotherapy alone versus neoadjuvant chemotherapy with folfirinox regimen followed by preoperative chemoradio-therapy for patients with resectable locally advanced rectal cancer	Thierry CONROY	III	461
Colorectal	UCGI	UCGI 27 / PRODIGE 28 / TIME	Randomized phase II study of first-line FOLFIRI plus cetuximab for 8 cycles followed by either single-agent cetuximab as maintenance therapy or observation in patients with wild-type KRAS and NRAS metastatic colorectal cancer	Valérie BOIGE	II	214
Ewing	SARCOME	SARCOME 01/ EUROEWING 99	Ewing's tumor treatment protocol: randomized trials with comparison of consolidation chemotherapy including a medico-economic evaluation	Nathalie GASPAR	II	1135
Germ celles	GETUG	GETUG 13	A RISK-ADAPTED STRATEGY OF THE USE OF DOSE-DENSE CHEMOTHERAPY IN PATIENTS WITH POOR-PROGNOSIS DISSEMINATED NON-SEMINOMATOUS GERM CELL TUMORS: A PHASE III TRIAL	Karim FIZAZI	III	203
Head & Neck	HEAD & NECK	ORL 08 - NISCAHN	A Phase II, Multicenter, Non Randomized, Open Label Study of Nivolumab In Recurrent and/or Metastatic Salivary Gland Carcinoma of the Head and Neck	Jérôme FAYETTE	II	98
Head & Neck	HEAD & NECK	ORL 09 - TOP-NIVO	A Safety study of Nivolumab in Patients with Recurrent and/or Metastatic Platinum-refractory Squamous Cell Carcinoma of the Head and Neck (SCCHN)	Caroline EVEN	II	351
Kidney	GETUG	GETUG-AFU 24	Prospective phase II study of Gemcitabine plus platinium salt in combination with bevacizumab (Avastin®) for metastatic collecting duct carcinoma.	Constance THIBAULT	II	36
Kidney	GETUG	GETUG-AFU 26 / NIVOREN	A Phase II Safety Trial of Nivolumab in Patients with Metastatic Renal Cell Carcinoma Who Have Progressed During or A fter Prior Systemic Anti-Angiogenic Regimen	Bernard ESCUDIER	II	729

Tumour Localisation(S)	EXPERT GROUP(S)	STUDY SHORT TITLE	Study title	Study Coordinator	Phase	Number of expected patients
Lung	MED PERSO	SAFIR02-LUNG	Evaluation of the efficacy of high throughput genome analysis as a therapeutic decision tool for patients with metastatic non-small cell lung cancer.	Fabrice BARLESI	II	999
Pancreatic	UCGI	ACCORD 24 / PRODIGE 24	Multicentric randomized phase III trial comparing adjuvant chemotherapy with emcitabine versus 5-fluorouracil, leucovorin, irinotecan and oxaliplatin (mFolfirinox) in patients with resected pancreatic adenocarcinoma	Thierry CONROY	III	493
Prostate	GETUG	GETUG 12 PRRAP	Phase 3 trial, comparing combined hormonal and chemotherapy treatment (docetaxel and estramustin) with hormonal treatment alone, in a neo-adjuvant situation of prostate cancer that is locally advanced or at high risk of relapse.	Karim FIZAZI	III	413
Prostate	GETUG	GETUG-AFU 16	Randomised multi-centre study comparing the efficacy of short hormone therapy with Zoladex® concomitant to radiotherapy, versus radiotherapy alone, in treatment against prostate cancer biochemical recurrence after surgery.	Christian CARRIE	III	743
Prostate	GETUG	GETUG-AFU 17	Randomized multicentric trial comparing an immediate adjuvant radiotherapy associated with short hormonotherapy by LH-RH (Décapeptyl® LP) analogue vs a delayed radiotherapy started at the biochemical relapse associated with short hormonotherapy by LH-RH (Décapeptyl® LP) analog in patients operated for a prostate cancer type pT3 R1 pN0 ou pNX, intermediate risk.	Pierre RICHAUD	III	424
Prostate	GETUG	GETUG-AFU 18	Randomized trial (GETUG 18) of dose escalation (80 vs 70 Gy) in high-risk prostate cancers combined with long-term androgen deprivation	Christophe HENNEQUIN	III	505
Prostate	GETUG	AFU-GETUG 20	Phase III randomised study to evaluate the benefit of adjuvant hormonal treatment with leuprorelin acetate (eligard® 45mg) for 24 months after radical prostatectomy in patients with high risk of recurrence.	François ROZET	III	325
Prostate	GETUG	GETUG 21/ PEACE1	A prospective randomised phase III study of androgen deprivation therapy with docetaxel with or without local radiotherapy with or without abiraterone acetate and prednisone in patients with metastatic hormone-naïve prostate cancer.	Karim FIZAZI	III	1173
Prostate	GETUG	GETUG-AFU 22	A multicenter randomized phase II trial comparing the efficacy of a short hormone therapy in combination with radiotherapy to radiotherapy alone as a salvage treatment for patients with detectable PSA after radical prostatectomy.	Stéphane GUERIF	II	125
Prostate	GETUG	GETUG-AFU 38 SAKK 08/16	ODM-201 maintenance therapy in patients with metastatic castration resistant prostate cancer (mCRPC) previously treated with one novel hormonal agent first line and non-progressive disease after second line treatment with a taxane: A multicenter randomize	Guilhem ROUBAUD	II	6
Prostate	GEP	GEP 12 - CARLHA	Safety and efficacy of radiotherapy combined with a 6-month LH-RH agonist and abiraterone hormone therapy treatment in biochemically-relapsing prostate cancer following surgery.	Stéphane SUPIOT	I/II	47
Solid tumours	SDS	CYPRES	Consensus patients pour des recherches en soins de support	Amélie ANOTA	HPS	631
Solid tumours	MED PERSO	ACSE CRIZO	Secured access to crizotinib for patients with tumors harboring a genomic alteration on one of the biological targets of the drug	Gilles VASSAL	II	246
Solid tumours	MED PERSO	ACSE VEMU	Secured access to vemurafenib for patients with tumors harboring BRAF genomic alterations	Jean-Yves BLAY	II	216
Uterus	UCGI	PORTEC 3	Randomized phase III trial comparing concurrent chemoradiation and adjuvant chemotherapy with pelvic radiation alone in high risk and advanced stage endometrial carcinoma	Christine HAIER-MEDER	III	63
	SARCOME	SARCOME 08	Intermediate and high risk localized, completely resected, gastrointestinal stromal tumors (GIST) expressing KIT receptor: a controlled randomized trial on adjuvant Imatinib mesylate (Glivec) versus no further therapy after complete surgery			266

2020 Publications

Group	Study	Study title	First Author	References
UCBG	RTS 01 - Young Boost	A case-control study to identify molecular risk factors for local recurrence in young breast cancer patients		Radiotherapy and Oncology 156 (2021) 127–135
GETUG	GETUG-AFU 17	Adjuvant or early salvage radiotherapy for the treatment of localised and locally advanced prostate cancer: a prospectively planned systematic review and meta-analysis of aggregate data	Vale Clare	
GETUG	GETUG-AFU 17	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	SARGOS Paul	Lancet Oncol 2020; 21: 1341–52
UCBG	PACS04	Association between FGFR1 copy numbers, MAP3K1 mutations, and survival in axillary node-positive, hormone receptor-positive, and HER2-negative early breast cancer in the PACS04 and METABRIC studies.	CARENE Dimitri	Breast Cancer Res Treat. 2020 Jan; 179(2):387-401.
UCBG	CANTO	Body weight and return to work among survivors of early-stage breast cancer	Di MEGLIO Antonio	ESMO Open. 2020 Nov;5(6):e000908
UCBG	CANTO	Changes in weight, physical and psychosocial patient-reported outcomes among obese women receiving treatment for early-stage breast cancer: A nationwide clinical study	Di MEGLIO Antonio	Breast 2020 Aug;52:23-32.
UCBG	ADENDOM	Decision of adjuvant chemotherapy in intermediate risk luminal breast cancer patients: A prospective multicenter trial assessing the clinical and psychological impact of EndoPredict® (EPclin) use (UCBG 2-14).	PENAULT-LLORCA Frédérique	Breast. 2019 Nov 14; 49:132-140.
UCBG		Differentiation of groups of patients with cognitive complaints at breast cancer diagnosis: Results from a sub-study of the French CANTO cohort	HARDY-LEGER Isabelle	"Psychooncology . 2020 Oct 14. doi: 10.1002/ pon.5572"
UCBG	CARMINA 02	Early Metabolic Response of Breast Cancer to Neoadjuvant Endocrine Therapy: Comparison to Morphological and Pathological Response	BOUGHDAD Sarah	Cancer Imaging. 2020 Jan 28;20(1):11.
GETUG	GETUG-AFU 17	étude de phase III randomisée comparant la radiothérapie adjuvante à la radiothérapie de rattrapage précoce, combinées à l'hormonothérapie courte, pour les patients présentant un cancer de la prostate traité par prostatectomie radicale	SARGOS Paul	2020 Nov; 30(13):733-734
SDS		Feasibility and efficacy of a supervised home-based physical exercise program for metastatic cancer patients receiving oral targeted therapy: study protocol for the phase II/III - UNICANCER SdS 01 QUALIOR trial		Joly et al. BMC Cancer (2020) 20:975
UCBG	CANTO	Impact of Breast Cancer Treatment and its Physical and Psychological Late Effects on Employment – Results of a Multicenter Prospective Cohort Study (CANTO)	DUMAS Agnes	J Clin Oncol. 2020 Mar 1;38(7):734-743.
MED PERSO	SAFIR 02 BREAST	Outcome and molecular landscape of patients with PIK3CA-mutated metastatic breast cancer	Mosele Fernanda	Ann Oncol. 2020 Mar;31(3):377-386.
UCBG	CARMINA 02	Predictive Factors of 5-year Relapse-Free Survival in HR+/HER2- Breast Cancer Patients Treated With Neoadjuvant Endocrine Therapy: Pooled Analysis of Two Phase 2 Trials	LEREBOURS Florence	Br J Cancer. 2020 Mar;122(6):759-765.
UCBG	GRT02-COMET	Prognostic value of CEC count in metastatic breast cancer patients treated with bevacizumab and chemotherapy: a prospective validation study.	VASSEUR Antoine	Angiogenesis. 2020 May;23(2):193-202
UCBG		Serum detection of non-adherence to adjuvant tamoxifen and breast cancer recurrence risk		J Clin Oncol . 2020 Aug 20;38(24):2762-2772.
MED PERSO		Somatic and Germline BRCA 1 and 2 Mutations in Advanced NSCLC From the SAFIR02-Lung Trial.		JTO CRR vol 1 No3:1-11
UCBG	PACS07 MINDACT	Standard Anthracycline Based Versus Docetaxel-Capecitabine in Early High Clinical and/or Genomic Risk Breast Cancer in the EORTC 10041/BIG 3-04 MINDACT Phase III Trial	DELALOGE Suzette	J Clin Oncol. 2020 Apr 10;38(11):1186-1197
UCBG	PACS07 MINDACT	Standard Anthracycline-based versus Docetaxel-Capecitabine in early high clinical and/or genomic risk breast cancer in the EORTC 10041/ BIG 3-04 MINDACT phase III trial	DELALOGE Suzette	J Clin Oncol. 2020 Apr 10;38(11):1186-1197
UCGI		Treatment intensification with hepatic arterial infusion chemotherapy in patients with liver-only colorectal metastases still unresectable after systemic induction chemotherapy – a randomized phase II study -- SULTAN UCGI 30/PRODIGE 53 (NCT03164655)- stud		J Clin Oncol. 2020 Apr 10; 38(11):1186-1197
UCBG	GRT02-COMET	VEGF related germinal polymorphisms may identify a subgroup of breast cancer patients with favorable outcome under Bevacizumab-based therapy – A message from COMET, a French Unicancer multicentric study	GAL Jocelyn	(2020) 20:74
UCBG	MyPeBS	Personalized early detection and prevention of breast cancer: ENVISION consensus statement.	Nora Pashayan	Nat Rev Clin Oncol.2020Nov;17(11):687-705. doi: 10.1038/s41571-020-0388-9. Epub 2020 Jun 18. PMID: 32555420

2020 Communications

Group	Study	CONGRESS	Study title	First Author	Type of presentation
GETUG	GETUG-AFU 24	ESMO	A prospective phase II study of Gemcitabine + platinum salt in combination with bevacizumab for kidney metastatic medullary and collecting duct carcinoma (GETUG-AFU 24, BEVABEL trial)	JOLY florence	Poster session
UNITRAD	HYPOG 01	ESTRO	AI-driven quality insurance for delineation in radiotherapy breast clinical trials	RIVERA Sofia	Poster session
UCBG	CANTO	ESMO	Breast cancer and perceived discrimination in the workplace: A longitudinal cohort study		Poster session
UCBG	DOLAF	SABCS	DOLAF- An international multicenter phase II trial of Durvalumab (MEDI4736) plus OLAparib plus Fulvestrant in metastatic or locally advanced ER-positive, HER2-negative breast cancer patients selected using criteria that predict sensitivity to olaparib (UC	GUIU Severine	Poster session
UNITRAD	STEREO-OS	ESTRO	Dummy Run for bone SBRT in french multicentric study	THUREAU Sebastien	Poster session
MED PERSO	SAFIR02-LUNG	ESMO	Durvalumab (D) compared to maintenance chemotherapy (SoC) in patients (pst) with metastatic non-small cell lung cancer (NSCLC): Results from the randomized SAFIR02 LUNG-IMMUNO trial	BARLESI Fabrice	Poster session
UCBG	PADA-1	ESMO	ESR1 mutations and outcomes in BRCA1/2 or PALB2 germline mutation carriers receiving first line aromatase inhibitor + palbociclib (AI+P) for metastatic breast cancer (MBC) in the PADA-1 trial.		Poster session
UCBG	START	SABCS	First efficacy results of a 2-stage Simon's design randomised phase 2 of darolutamide or capecitabine in patients with triple-negative, androgen receptor positive advanced breast cancer (UCBG06-3)	BONNEFOI Hervé	Poster session
GIO		ASH	First results of the AcSé Pembrolizumab Phase II in the Primary CNS Lymphoma (PCNSL) cohort	HOANG-XUAN Khê	Poster session
UCBG	ONCO03 LIBER	ASCO	Five-year letrozole versus placebo in BRCA1/2 germline mutations carriers: Final results of LIBER, a double-blind randomized phase III breast cancer prevention trial.	PUJOL Pascal	Poster session
UNITRAD	STEREO-OS	ASTRO	French randomized phase III study between: Standard Treatment with or without SBRT in Solid Tumors Patients with Between 1 and 3 Bone-only Metastases (STEREO-OS)	THUREAU Sebastien	Poster session
HEAD & NECK		ESMO	Germinal immunogenetics and response to Nivolumab in recurrent/metastatic head and neck squamous cell carcinoma patients: TOPNIVO ancillary study		Poster session
UNITRAD	HYPOG 01	ASTRO	Improving radiotherapy workflow through implementation of delineation guidelines & AI-based annotation		Poster session
UCGI	ACCORD 18 / PRODIGE 12	ESMO	Individual patient data meta-analysis of adjuvant gemcitabine-based chemotherapy for biliary tract cancer: combined analysis of the BCAT and PRODIGE-12 studies	EDELINE Julien	Poster session
GETUG	GETUG-AFU 26 / NIVOREN	ASCO GU	Is body mass index (BMI) associated with favorable outcomes in metastatic renal cell carcinoma (mRCC) treated with nivolumab? An ancillary study of the NIVOREN-GETUG AFU-26 trial.	FLECHON Aude	Poster session
GETUG	GETUG-AFU 26 / NIVOREN	ESMO	Kidney ccRCC Immune Classification (KIC) enhances the predictive value of T effector (Teff) and angiogenesis (Angio) signatures in response to Nivolumab (N)	VANO Yann	Poster session
GETUG	GETUG-AFU 22	ASCO GU	Late toxicity and quality of life from GETUG-AFU 22 study	LATORZEFF Igor	Poster session
MED PERSO		ESMO	Metronomic oral vinorelbine (MOV) combined with tremelimumab (T) + durvalumab (D) in advanced solid tumors (AST): dose finding results.		Poster session
MED PERSO		ESMO	Metronomic oral vinorelbine (MOV) combined with tremelimumab (T) + durvalumab (D): efficacy and safetypreliminary results of the advanced breast cancer (ABC) patients (pts) cohort of the MOVIE study.		Poster session
GIO	AcSé Nivolu-mab	ASCO GU	Nivolumab in metastatic non-clear cell renal cell carcinoma: first results of the AcSe prospective study	ALBIGES Laurence	Poster session
GETUG	GETUG-AFU 26 / NIVOREN	ASCO GU	NIVOREN GETUG-AFU 26 translational study: Association of PD-1, AXL, and PBRM-1 with outcomes in patients (pts) with metastatic clear cell renal cell carcinoma (mccRCC) treated with nivolumab (N).	VANO Yann	Poster session
UCGI	PRODIGE 65 - UCGI 36-GEMPAX	ESMO	PRODIGE 65 - UCGI 36 - GEMPAX: A Phase III randomized study evaluating gemcitabine and paclitaxel versus gemcitabine alone after FOLFIRINOX failure or intolerance in Metastatic Pancreatic Ductal Adenocarcinoma	DE LA FOUCHARDIERE Christelle	Poster session

Group	Study	CONGRESS	Study title	First Author	Type of presentation
UCBG	CANTO	ASCO	Social disparities in access to innovation and treatment delivery in early breast cancer (BC) patients (pts) with universal health care coverage	MENVIELLE Gwenn	Poster session
UCBG	CANTO	ASCO	The mechanisms of social disparities in return to work (RTW) after early breast cancer (BC)	MENVIELLE Gwenn	Poster session
GETUG	GETUG-AFU 26 / NIVOREN	ASCO GU	Validation of the lung immune prognostic index (LIPI) in patients with metastatic renal cell carcinoma treated with nivolumab in the GETUG-AFU 26 NIVOREN trial.	Lavaud Pernelle	Poster session
GETUG	GERICO 06	ASCO GU	Vefora, GETUG-AFU V06 study: Randomized multicenter phase II/III trial of fractionated cisplatin (CI)/gemcitabine (G) or carboplatin (CA)/g in patients (pts) with advanced urothelial cancer (UC) with impaired renal function (IRF): Results of a planned int	MOUREY Loic	Poster session
MED PERSO	ACSE VEMU	ESMO	Vemurafenib in non melanoma V600 and non V600 BRAF mutated cancers: results of the ACSE basket trial.		Poster session
UCBG	NeoPAL	Ann Oncol	Letrozole and palbociclib versus chemotherapy as neoadjuvant therapy of high-risk luminal breast cancer.	COTTU Paul-Henri	Poster-discussion
GETUG	GETUG-AFU 17	ASTRO	A Phase III Randomised Trial comparing adjuvant versus early salvage Radiotherapy combined with short term androgen deprivation therapy following a Radical Prostatectomy: First results of the GETUG-AFU 17 study [NCT00667069]	SARGOS Paul	Oral session
GIO		JDP	AcSé Nivolumab : résultats préliminaires pour le carcinome baso-cellulaire avancé	VERON Marie	Oral session
GIO		JDP	AcSé Nivolumab : résultats préliminaires pour le carcinome trichoblastique	TOULEMONDE Elise	Oral session
UNITRAD	UNI-DATA	SFRO	Capture, restitution et exploitation multicentrique des données de vie réelle en radiothérapie.	CLAVIER Jean-Baptiste	Oral session
GIO	AcSé Nivolumab	ESMO	High activity of Nivolumab in patients with pathogenic exonucleasic domain POLE (edPOLE) mutated Mismatch Repair proficient (MMRp) advanced tumors	ROUSSEAU Benoit	Oral session
UCBG	CANTO	ESMO	Longitudinal Evaluation of Serum Assessed Non-Adherence to Tamoxifen (TAM) among Premenopausal Patients (pts) in the prospective multicenter CANTO cohort		Oral session
UCBG	CANTO	ESMO	Long-term patient reported outcomes (PRO) and hematologic toxicity among patients (pts) who received Granulocyte-Colony Stimulating Factors (G-CSF) during chemotherapy (CT) for early breast cancer (EBC)"		Oral session
UCBG	PACS07 MINDACT	ASCO	MINDACT: Long-term results of the large prospective trial testing the 70-gene signature MammPrint as guidance for adjuvant chemotherapy in breast cancer patients		Oral session
HEAD & NECK	ORL 09 - TOPNIVO	ESMO	ORL09 - TOPNIVO - A safety study of nivolumab in patients with recurrent and/or metastatic platinium-refractory squamous cell carcinoma of the head and neck (R/M SCCHN): final analysis, on behalf of the Unicancer H&N group and the GORTEC.	EVEN Caroline	Oral session
UCBG	GRT02-COMET	AACR	Predictive and prognostic value of circulating tumor DNA (ctDNA) compared to circulating tumor cells (CTC) in a prospective cohort of metastatic breast cancer patients : the UCBG COMET trial	PIERGA Jean-Yves	Oral session
UCBG	PADA-1	ASCO	Prognostic impact of ESR1 mutations in ER+ HER2- MBC patients prior treated with first line AI and palbociclib: An exploratory analysis of the PADA-1 trial.	BIDARD	Oral session
GETUG	"PRRAP GETUG-AFU 16"	SFRO	Quel est l'impact d'une hormonothérapie associée à la radiothérapie de la loge sur la qualité de vie des personnes âgées ? Une analyse en sous-groupe de l'essai GETUG-AFU 16		Oral session
SARCOME	SARCOME 12/ REGOBONE	ESMO	RESULTS OF THE RANDOMIZED, PLACEBO (PLA)-CONTROLLED PHASE II STUDY EVALUATING THE EFFICACY AND SAFETY OF REGORAFENIB (REGO) IN PATIENTS (PTS) WITH METASTATIC RELAPSED EWING SARCOMA, ON BEHALF OF THE FRENCH SARCOMA GROUP (FSG) AND UNICANCER	DUFFAUD Florence	Oral session
UCGI		ASCO	Total neoadjuvant therapy with mFOLFIRINOX versus preoperative chemoradiation in patients with locally advanced rectal cancer: Final results of PRODIGE 23 phase III trial, a UNICANCER GI trial.		Oral session
UCBG	CANTO	ESMO Breast	Use of physical activity (PA) and supportive care (SC) among patients (pts) with early breast cancer (BC) reporting cancer-related fatigue (CRF)	Di MEGLIO Antonio	Oral session
UCBG	RTS 01 - Young Boost	Radiother Oncol	A case-control study to identify molecular risk factors for local recurrence in young breast cancer patients		Publication

2020 ESME Publications

Study title	Authors	References
IMPACT OF BODY MASS INDEX ON OVERALL SURVIVAL IN PATIENTS WITH METASTATIC BREAST CANCER	Carton M, Dieras V, Heudel P-E, Brain E, D'Hondt V, et al.	The Breast. 2020 Dec 1;55:16–24.
PALLIATIVE CARE DELIVERY ACCORDING TO AGE IN 12,000 WOMEN WITH METASTATIC BREAST CANCER: ANALYSIS IN THE MULTICENTRE ESME-MBC COHORT 2008–2016.	Sabathe C, Delaloge S, Galvin A, Patsouris A, Levy C, et al.	European Journal of Cancer. 2020 Sep 1; 137:240–9.
IMPACT OF AGE AT DIAGNOSIS OF METASTATIC BREAST CANCER ON OVERALL SURVIVAL IN THE REAL-LIFE ESME METASTATIC BREAST CANCER COHORT.	Carton M, Dubot C, Campone M, Pistilli B, Dalenc F, et al.	The Breast. 2020 Aug;52:50–7.
REAL-WORLD EVALUATION OF ORAL VINORELBINE IN THE TREATMENT OF METASTATIC BREAST CANCER: AN ESME-MBC STUDY.	Delaloge S, Parent D, Madranges N, Levy C, Dalenc F, et al.	Anticancer Res. 2020 Jul;40(7):3905–13.
RADIATION THERAPY TO THE PRIMARY TUMOR FOR DE NOVO METASTATIC BREAST CANCER AND OVERALL SURVIVAL IN A RETROSPECTIVE MULTICENTER COHORT ANALYSIS.	Kirova Y, Lusque A, Campone M, Geffrelot J, Rivera S, et al.	Radiotherapy and Oncology. 2020 Apr;145:109–16.
CONTEMPORARY OUTCOMES OF METASTATIC BREAST CANCER AMONG 22,000 WOMEN FROM THE MULTICENTRE ESME COHORT 2008-2016.	Antoine A, Bachelot T, Lardy-Cleaud A, Dieras V, Brain E, et al.	Eur J Cancer. 2020 Apr;129:60–70.
TREATMENT AND OUTCOMES IN PATIENTS WITH CENTRAL NERVOUS SYSTEM METASTASES FROM BREAST CANCER IN THE REAL-LIFE ESME MBC COHORT.	Darlix A, Louvel G, Fraisse J, Jacot W, Brain E, et al.	European Journal of Cancer. 2020 Jan;125:22–30.
MANAGEMENT AND OUTCOME OF MALE METASTATIC BREAST CANCER IN THE NATIONAL MULTICENTER OBSERVATIONAL RESEARCH PROGRAM EPIDEMIOLOGICAL STRATEGY AND MEDICAL ECONOMICS (ESME).	Julien Fraisse, Simone Mathoulin-Pelissier, Marianne Leheurteur, Laurence Vanlemmens, Christelle Jouannaud et al.	Therapeutic Advances in Medical Oncology; 2020, Vol. 12: 1–13

2020 ESME Communications

Study	Congress	Study title	Main Author	Authors
ESME CSM	EPICLIN	Facteurs d'accès aux prises en charge palliatives interdisciplinaires des patients atteints de cancer du sein métastatique de la cohorte ESME-CSM : analyse préliminaire	M. Frasca	M. Frasca, M. Abiven, M. Pulido, G. Perrocheau, AV. Guizard, MA. Mouret-Reynier, P. Arveux, M. Cucchi, T. Bachelot, L. Laborde, V. Perotin, C. Laurent, L. Campion, E. Chamorey, C. Bouleuc, C. Bouleuc, M. Breton, A. Loeb., M. Velten, M. Mons, D. Berchery, M. Chevrot, C. Courtinard, S. Mathoulin-Pelissier
ESME CSM	ASCO	Clinical Outcome of patients with isolated brain progression on first line Pertuzumab and Trastuzumab treatment for HER2 positive metastatic breast cancer in a real life cohort	COLLET Laëtitia	Lauriane Eberst, Julien Fraisse, Marc Debled, Christelle Levy, Marie A nge Mouret Reynier, Isabelle Desmoulins, Anthony Goncalves, Mario Campone, Jean Marc Ferrero, Etienne Brain, Veronique Dieras, Thierry Petit, Gaetane Simon, Marianne Leheurteur, Florence Dalenc, Laurence Vanlemmens, Amelie Darlix, Monica Arnedos, Thomas Bachelot
ESME CSM	EBCC	Contemporary picture of metastatic breast cancer: characteristics and outcomes of 22000 women from the ESME cohort 2008-2016	DELUCHE Elise	Alison ANTOINE, Thomas BACHELOT, Audrey LARDY-CLEAUD, Veronique DIERAS, Etienne BRAIN, William JACOT, Anthony GONCALVES, Florence DALENC, Anne patsouris, Simone Mathoulin-Pelissier, Coralie courtinard, David PEROL, Mathieu ROBAIN, Suzette DELALOGE
ESME CSM	ESMO	Progression free survival of patients with HR+/HER2- metastatic breast cancer treated with endocrine therapy, before or after chemotherapy in a multicenter national observational study	CORBAUX Pauline	A. Lardy-Cléaud, M. Alexandre, M. Fontanilles, C. Levy, A. Viansone, A. Mailliez, M. Debled, A. Gonçalves, C. Lefeuvre, F. Lerebours, J-M. Ferrero, J-C. Eymard, M-A. Mouret-Reynier, T. Petit, J-S. Frenel, E. Pons-Tostivint, C. Courtinard, M. Chaix, T. Bachelot
ESME CSM	ESMO	Clinicopathological characteristics and prognosis of breast cancer patients with isolated central nervous system metastases in the multicenter ESME database	CARAUSU Marcela	M. Carton, L. Cabel, A. Patsouris, C. Levy, B. Verret, A. Mailliez, M. Debled, A. Gonçalves, I. Desmoulins, I. Lecouillard, T. Bachelot, J-M. Ferrero, J-C. Eymard, M-A. Mouret-Reynier, M. Chevrot, E. Pons-Tostivint, L. Uwer, A. Darlix, L.Bozec
ESME CSM	ESMO	Contemporary picture of metastatic breast cancer: characteristics and outcomes of 22000 women from the ESME cohort 2008-2016	DELUCHE Elise	Alison ANTOINE, Thomas BACHELOT, Audrey LARDY-CLEAUD, Veronique DIERAS, Etienne BRAIN, William JACOT , Anthony GONCALVES, Florence DALENC, Anne patsouris, Simone Mathoulin-Pelissier, Coralie courtinard, David PEROL, Mathieu ROBAIN, Suzette DELALOGE
ESME CSM	ESMO	Real-life management and prognosis of young women (≤ 40 yo) with de novo metastatic breast cancer in the multicenter national observational ESME program.	FRANCOIS Amélie	A. Lusque, C. Levy, B.Pistili, E. Brain, D. Pasquier, M. Debled, JC.Thery, A. Gonçalves, I. Desmoulins, T. De La Motte Rouge, C.Faure, J-M. Ferrero, J-C. Eymard, M-A. Mouret-Reynier, T. Petit, O. Payen, L. Uwer, S.Guiu, J-S. Frenel
ESME CSM	Autres	Palliative care delivery according to age among metastatic breast cancer patients. ESME-MBC cohort	FRASCA Matthieu	Courtinard C, Bouleuc C, Levy C, Mourey-Reynier M-A, Bachelot T, Goncalves A, Perotin V, Eymard J-C, Mathoulin-Pelissier S
ESME CP	SOFOG	Screening moléculaire dans le cancer broncho pulmonaire non à petites cellules localement avancé et métastatique du sujet âgé : état des pratiques en France	LAMY Tina	Cabarrou B, Quantin X, Schneider S, Bringuier M, Robain M, Planchard D, Besse B, Baldini C

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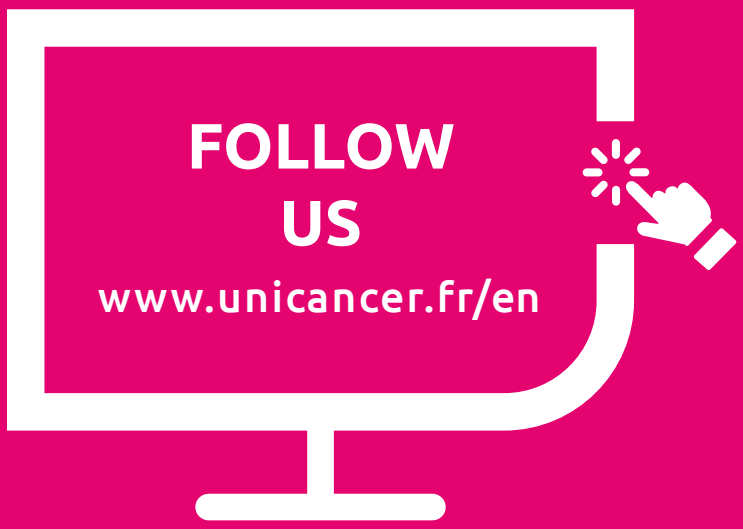

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