R&D ANNUAL REPORT 2019

unicancer

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CLAIRE LABREVEUX, DIRECTOR OF RESEARCH AND DEVELOPMENT

Technological advances and the emergence of new therapeutic approaches are accelerating from year to year; with them the prospect of extraordinary progress to our knowledge of cancers and the need to adjust our practices to these changes.
With the launch of outstanding projects, the strengthening of immunotherapy research, the expansion of the use of real-life data, the internal response to the orientations defined by our research strategy, etc., this will have been a most fruitful year.

In particular, a decisive step was taken in the European **MyPeBS** project, evaluating a new method of breast cancer screening based on individual risk, with the **start of the recruitment in France and abroad**.

CHECK'UP, a programme of Unicancer and the ARC Foundation, aimed at identifying the predictive factors of response and escape to immunotherapies, has been expanded, with the **opening of a sub-study specifically dedicated to the geriatric population**.

The **ESME** real-life data platforms have gained double national and international recognition this year, with the **acquisition of research warehouse status** offering data from about 55,000 patients with three clinical indications (breast, ovary, lung), and providing analytical data in metastatic breast cancer to health agencies outside Europe.

We continued the **AcSé Nivolumab** and **AcSé Pembrolizumab** trials, with support from the National Cancer League. These trials, aimed at providing patients suffering from rare cancers with safe access to immunotherapies, and at establishing their effectiveness, are a part of the world's pioneering AcSé programme conducted under the aegis of the French national cancer institute (INCa). Their **first results delivered this year were presented at the ASCO and ESMO congresses**.

As a witness to **Unicancer's growing R&D influence on the international scene**, the year was particularly rich in scientific publications – 40 in total including 1 in the prestigious journal Nature – as well as in communications during international congresses : 53, of which 11 were oral presentations.

Such successes would not have been possible without the resource restructuring undertaken by Unicancer's R&D. I particularly commend the long term investment of all the R&D teams, which enabled the **confirmation of the ISO 9001 certification of the activity** (both in the clinical research and real-life data sectors), the completion of projects of international scope, as well as the preparation of complex application files for calls for proposals of interest, for the benefit of the Centres.

Strengthened by **new collaborations initiated this year with European cooperative groups**, notably in Italy and Spain, the Unicancer's R&D is already working on broader alliances in Argentina, Australia and New Zealand.
Tomorrow will see the launch of new international programmes, but also the active participation of patients in research, and the development of more modern tools for trial management and data retention is under consideration.

With one constant: the mobilization of the entire network in a common action, **sharing the same desire for excellence, humanity and solidarity**.

JEAN-YVES BLAY, PRESIDENT OF UNICANCER

The recurring emergence of new research challenges has set the stage for an increasingly collaborative way of working and involves pushing boundaries.
In this respect, **Unicancer's organisational model of R&D, as a complement to the Integrated Support developed by the Centres**, as well as the numerous collaborations with non-networked research actors, have proved their effectiveness, both in France and in Europe.
We are committed to continuing to develop this model, perpetuating the orientations given by my predecessor. As major strategic projects are beginning to take shape, I would like to thank Patrice Viens for his many initiatives, particularly in oncological immunotherapy with the creation of a dedicated group of experts as well as in the field of real-life data with the creation of the ESME programme, which have paved the way for major advances in new research territories and stimulated strong and sustained growth in R&D.
Three key areas of progress, on which we are making efforts, stem from this impulsion.

Promoting better linkage between Unicancer's R&D activities and those carried out individually by each of the Centres is a first priority. At a time when personalized medicine, because of the fragmentation of pathologies, requires that we **optimize the coordination and complementarity of means and actions**, choosing cooperative practices really is a necessity. To support this, a reinforced R&D communication strategy will help to **increase the visibility of the network, its challenges and added value**, as well as the dissemination of individual or collective progress.

At the same time, **reaffirming our objectives and positioning** in terms of research priorities is fundamental. We will continue to support the advancement of key issues such as precision medicine, long-term toxicity monitoring, real-life studies, etc. Beyond that, we are putting all our expertise and energy into **developing prevention-related programmes**, like MyPeBS, personalized medicine application projects such as AcSé and SAFIR programmes, networking and exploitation of real-life data, and finally **co-developing programmes based on the exploitation of Artificial Intelligence**, through partnerships with digital start-ups, like the recent cooperation agreement with the start-up Therapanacea in onco-radiotherapy.

Finally, **making calls for proposals a strategic axis of development** is an essential step to establish the competitiveness and legitimacy of Unicancer's R&D in the light of the general trends that are revolutionizing the world of research. Increasing the capacity of R&D to qualify for highly selective calls for proposals under the aegis of public entities – INCa, NRA, PRT-K, etc.– and further, within the framework of European or international cooperation projects, paves the way for a greater degree of latitude towards the **establishment of consortia and large-scale research projects** in sectors of vital importance for the future.

These issues are representative of an overall dynamic that can meet our goal of **deploying on a daily basis the innovations that will make up tomorrow's cancer care**.
Making this accessible to all and ensuring fair access to quality care for all patients is a public health issue, it is also the foundation of our mission.

CLAIRE LABREVEUX, DIRECTRICE DE LA RECHERCHE ET DU DEVELOPPEMENT

Les progrès technologiques et l'émergence de nouvelles approches thérapeutiques s'accélèrent d'année en année ; avec eux la perspective d'extraordinaires avancées dans la connaissance des cancers et la nécessité d'ajuster nos pratiques à ces bouleversements. Avec le lancement de projets hors norme, le renforcement des recherches en immunothérapie, l'élargissement de l'utilisation des données de vie réelle, la réponse interne aux orientations définies par notre stratégie de recherche… c'est une année féconde qui vient de s'achever.

Notamment, une étape décisive a été franchie dans le projet européen **MyPeBS**, évaluant un nouveau mode de dépistage du cancer du sein en fonction du risque individuel, avec le **lancement du recrutement en France et à l'étranger**.

CHECK'UP, programme d'Unicancer et de la Fondation ARC, visant à identifier les facteurs prédictifs de réponse et d'échappement aux immunothérapies, a été élargi, avec l'**ouverture d'une sous-étude spécifiquement dédiée à la population gériatrique**.

Les plateformes de données de vie réelle **ESME** ont obtenu cette année une double reconnaissance nationale et internationale, avec l'**acquisition du statut d'entrepôt** offrant à la recherche les données d'environ 55 000 patients dans trois indications (sein, ovaire, poumon), et la mise à disposition de données d'analyses dans le cancer du sein métastatique à des agences de santé hors d'Europe.

La poursuite des essais **AcSé Nivolumab** et **AcSé Pembrolizumab**, grâce au soutien de la Ligue nationale contre le cancer : faisant partie du programme AcSé, pionnier dans le monde et conduit sous l'égide de l'INCa, ces essais visant à offrir aux patients atteints de cancers rares un accès sécurisé aux immunothérapies et à établir leur efficacité, ont livré cette année leurs **premiers résultats, présentés lors des congrès de l'ASCO et de l'ESMO**.

Témoin du **rayonnement croissant de la R&D d'Unicancer sur la scène internationale**, l'année a été particulièrement riche en publications scientifiques – 40 au total dont 1 dans la prestigieuse revue Nature –, et en communications dans des congrès internationaux – 53 dont 11 présentations orales.

De tels succès n'auraient pas existé sans l'effort de structuration des ressources engagé par la R&D d'Unicancer. Je salue tout particulièrement le long investissement de l'ensemble des équipes de la R&D qui a permis la **confirmation de la certification ISO 9001 de l'activité** (tant dans le secteur de la recherche clinique que dans celui des données de vie réelle) et l'aboutissement de projets d'envergure internationale, ainsi que le montage de dossiers complexes de candidature aux appels à projets d'intérêt, pour le bénéfice des Centres.

Fort de **nouvelles collaborations initiées cette année avec des groupes coopérateurs européens**, notamment en Italie et en Espagne, la R&D d'Unicancer œuvre d'ores et déjà à des alliances plus larges en Argentine, en Australie et en Nouvelle-Zélande. Demain verra ainsi le lancement de nouveaux programmes internationaux, mais également la participation active des patients dans la recherche, et le développement d'outils plus modernes de gestion des essais et de conservation des données est à l'étude.

Avec une constante : la mobilisation du réseau tout entier dans une action commune et le **partage d'une même volonté d'excellence, d'humanité et de solidarité**.

JEAN-YVES BLAY, PRESIDENT D'UNICANCER

L'émergence récurrente des nouveaux défis qui s'imposent à la recherche a posé les jalons d'un mode de travail de plus en plus collaboratif et implique de repousser les frontières.
A cet égard, le **modèle organisationnel de la R&D d'Unicancer, complémentaire de la prise en charge intégrée développée par les Centres**, ainsi que les nombreuses collaborations avec des acteurs de la recherche hors réseau, ont fait la preuve de leur efficacité, en France comme en Europe.
Nous avons à cœur de continuer à développer ce modèle, en perpétuant les orientations impulsées par mon prédécesseur. Alors que s'amorce la concrétisation de grands chantiers stratégiques, je remercie vivement Patrice Viens pour ses nombreuses initiatives, notamment en immunothérapie oncologique avec la création d'un groupe d'experts dédié ainsi que dans le domaine des données de vie réelle avec la création du programme ESME, qui ont préparé le terrain à des avancées capitales dans des territoires de recherche nouveaux et impulsé à la R&D une croissance forte et soutenue.
Trois axes de progrès déterminants, sur lesquels nous faisons porter l'effort, procèdent de cette volonté.

Favoriser une meilleure articulation entre les actions conduites par la R&D d'Unicancer et celles menées individuellement par chacun des Centres est une première priorité. A un moment où la médecine personnalisée notamment, avec la fragmentation des pathologies, exige d'**optimiser la coordination et la complémentarité des moyens et des actions**, le parti pris de pratiques coopératives s'impose comme une nécessité. A l'appui, une stratégie renforcée de la communication portée par la R&D doit contribuer à **augmenter la visibilité du réseau, de ses enjeux et de sa valeur ajoutée**, et la diffusion des avancées individuelles ou collectives.

En parallèle, **réaffirmer nos objectifs et notre positionnement** en termes de priorités de recherche est fondamental. Nous soutiendrons sans relâche la marche en avant sur les questions saillantes telles que la médecine de précision, le suivi des toxicités à long terme, les études en vraie vie… Au-delà, nous mettons toute notre compétence et notre énergie à **développer les programmes liés à la prévention**, à l'instar de MyPeBS, les projets d'application de la médecine personnalisée tels que les programmes AcSé et SAFIR, la mise en réseau et l'exploitation des données de vie réelle, et enfin à **co-développer des programmes fondés sur l'exploitation de l'intelligence artificielle**, en partenariat avec des start-ups du digital, à l'instar du récent accord de coopération avec la start-up Therapanacea en onco-radiothérapie.

Enfin, **faire des appels à projets un axe stratégique de développement** est une démarche primordiale pour asseoir la compétitivité et la légitimité de la R&D d'Unicancer au regard des grandes orientations qui révolutionnent le monde de la recherche. Accroître la capacité de la R&D à se qualifier dans le cadre d'appels à projets très sélectifs sous l'égide d'entités publiques – INCa, ANR, PRT-K... –, et plus encore, dans le cadre de projets de coopération européenne ou internationale, ouvre la voie à de nouvelles marges de manœuvre, à l'**établissement de consortiums et de projets de recherche à grande échelle** dans des secteurs d'avenir.

Ces enjeux constituent une dynamique d'ensemble capable de porter notre ambition de **déployer au quotidien l'innovation qui fera la cancérologie de demain**.
La rendre accessible à tous et assurer une qualité des soins équitable pour tous les patients est un enjeu de santé publique, c'est aussi le fondement de notre mission.

Our research priorities

With a portfolio of 100 active clinical studies, Unicancer's R&D is now the leading academic sponsor in oncology in France and one of the main ones in Europe. Unicancer's R&D 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's R&D 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's R&D 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

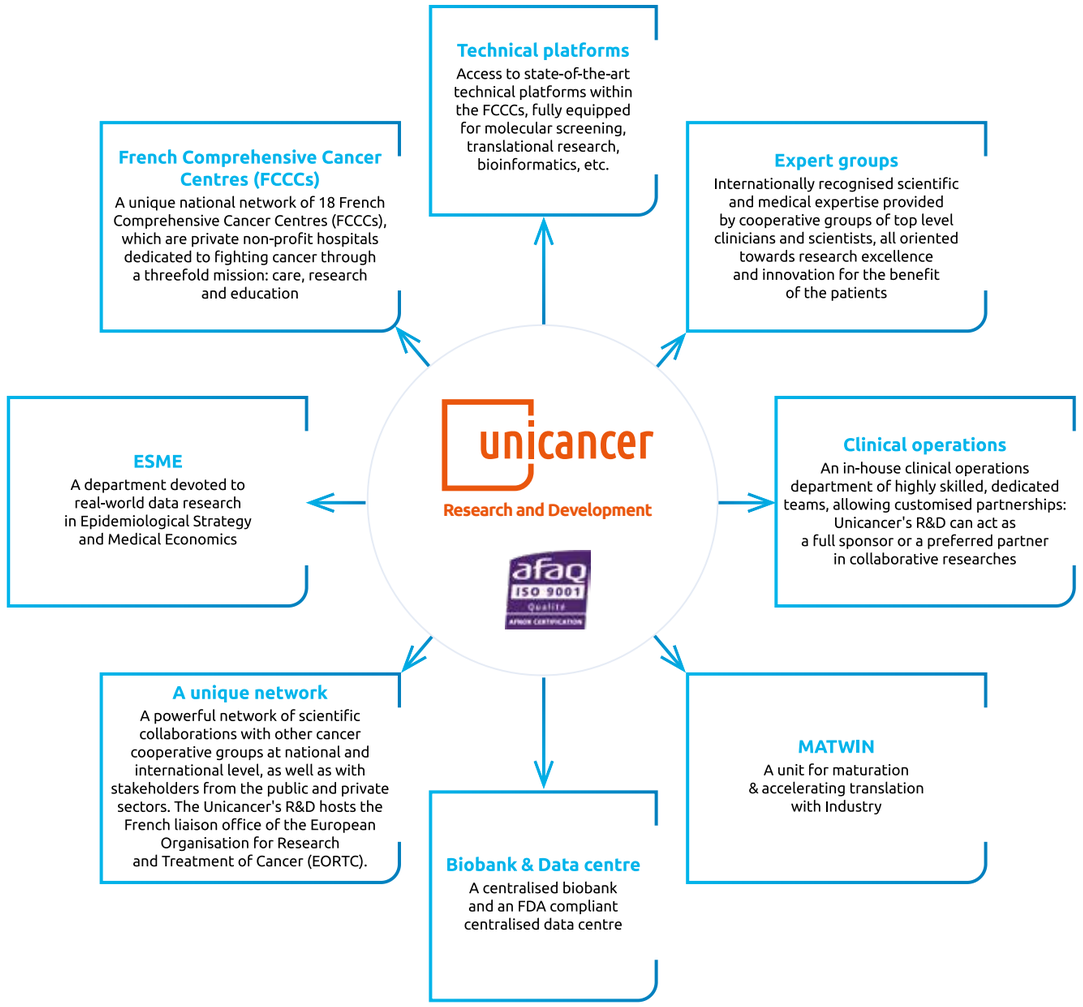
Several Unicancer large trials notably in breast, urological and digestive cancers are ongoing with the aim to:

- 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.

Our strengths



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.

UNICANCER 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 de Montpellier, 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 (UCH&N)*

President: Joël GUIGAY, Centre Antoine Lacassagne, Nice

Strategic priorities: early-phase studies, rare cancers, biology-driven medicine

Sarcoma Group (UC Sarcoma)*

Presidents: 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, biobanking

UNICANCER CROSS-PATHOLOGY GROUPS

Personalised Medicine Group (Med Perso)

President: Fabrice ANDRE, Gustave Roussy, Villejuif

Strategic priorities: personalized biology-driven medicine, 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 Radiation Oncology (UNITRAD)

President: Sofia RIVERA, Gustave Roussy, Villejuif

Strategic priorities: translational research, imaging, modelling and radiomics, brachytherapy, radiobiology and radio-potentiation, quality assurance, methodology

Oncogeriatrics Intergroup (GERICO)*

President: Loïc MOUREY, IUCT Oncopole – Institut Claudius Regaud, 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)

Presidents: Ivan KRAKOWSKI, Institut Bergonié, Bordeaux; Florence JOLY, Centre François Baclesse, Caen

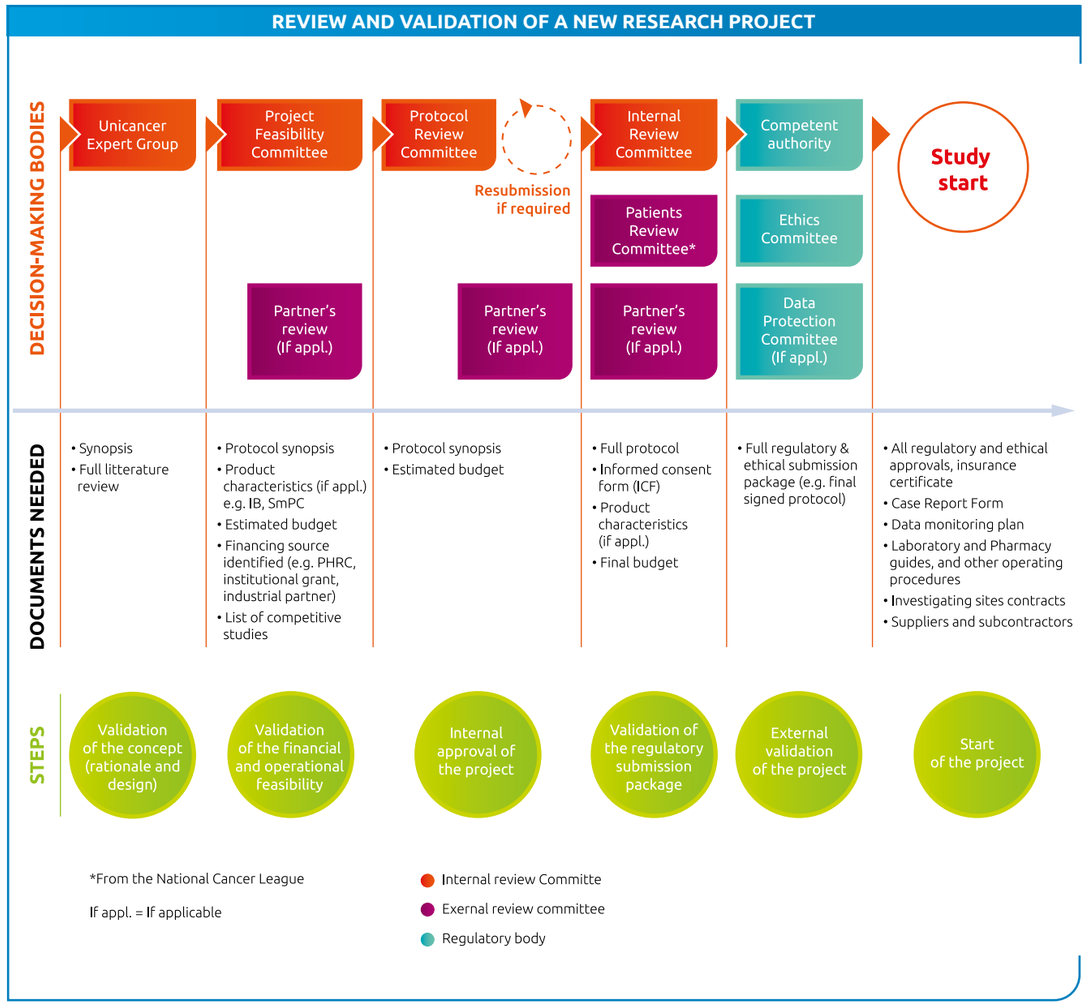
Strategic priorities: high standard clinical programmes for the evaluation of supportive cares, quality of life, cost-efficiency, humanities and social sciences

* INCa accredited-group

Our decisional process

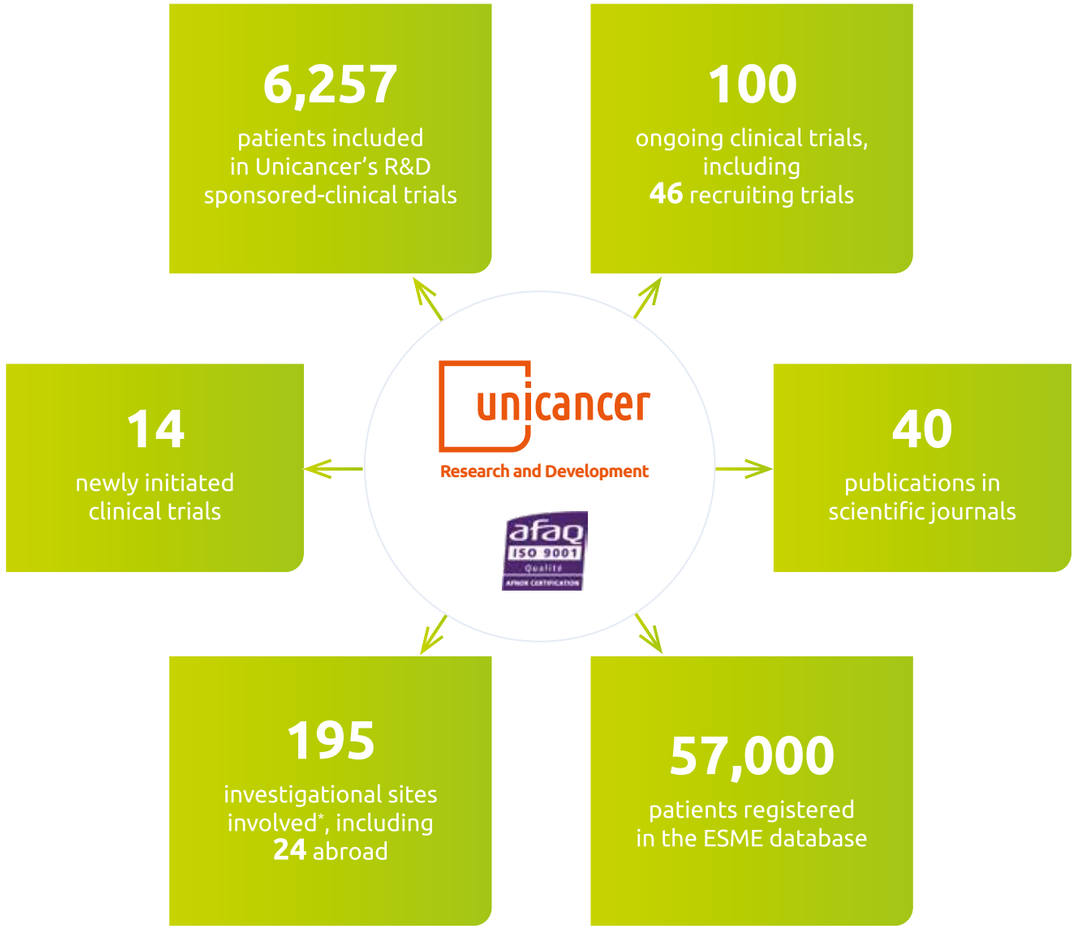
From the design of a research project to its operational implementation by Unicancer's teams, several steps take place to verify the project's scientific relevance and its operational and financial feasibility, as well as its compliance with good clinical practice and regulatory, ethical and data protection requirements. This process involves various review and validation committees, both internal and external to Unicancer, as well as institutional, academic and industrial partners where applicable. This procedure applies to all clinical studies for which Unicancer is sponsor, legal representative or national coordinator.

REVIEW AND VALIDATION OF A NEW RESEARCH PROJECT



Highlights

2019 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

The renewed efforts of Unicancer to reach an optimal structuration in 2019 echoes the continuous improvement of the quality of its research for the benefit of the patients suffering from cancer. For instance, the close monitoring of Health Security Environment non-compliances was reinforced to ensure a maximum security for patients enrolled in our studies. Furthermore, in 2019, Unicancer launched the 'My Health Data' website, designed to offer complete transparency to patients regarding the re-use of their personal data for research purposes.

MY HEALTH DATA WEBSITE: TOWARDS MORE TRANSPARENCY

As part of the legal reinforcement of individual rights and Data protection accountability (GDPR - General Data Protection Regulation), the launch in November 2019 of the Unicancer 'My Health Data' website (https://mesdonnees.unicancer.fr) is a major breakthrough related to the re-use of personal data for scientific research purposes. This is indeed the **first and only dynamic patient information website** ever launched by French academic research organisations enabling patients to obtain information on the re-use of their personal data, including re-use of their biological samples.

When a patient has received care in a FCCC or has been included in a Unicancer clinical trial, personal data are collected. Further use of these data is pertinent for research to make progress in the fight against cancer. However, not all research possibilities can be anticipated at the moment patients provide consent to hospitals for the use of their personal data, and it is sometimes very complicated, if not impossible, to go back to patients to get them re-consent for the re-use of their data for research. This is why the French Data Protection Authority (CNIL) authorised research organisations to set up a dynamic information medium to which patients can refer if they wish to obtain updated information on the re-use of their personal data.

The website allows patients to access the information by selecting the hospital where they received treatment, their tumour localisation, their period of care, their participation to a clinical study (if applicable). It then displays corresponding results and, in case of positive match, various information on the research project(s) using their data (research title and goal, entity responsible for data treatment, categories of data used, etc.).

This site is exclusively informative and anonymous (no patients' personal data is accessible). In compliance with current regulations, a contact form allows patients to exercise their right of opposition, rectification, limitation or erasure of all or part of their personal data held by Unicancer (of note, according to a specific legal provision, this right may be refused to them, in the case of studies of "major and irreplaceable public interest").

With the launch of the My Health Data' website, Unicancer meets a double objective: complete transparency towards patients and acceleration of the implementation of research projects by ensuring a priori their compliance with regulations.

PATIENT-EXPERTS PLAY A KEY ROLE IN OUR RESEARCH

Since the early 2000s, Unicancer has been submitting all the informed consent notes of its new protocols to the Patient Committee of the National Cancer League, for their review on ethical aspects and comprehensibility. Since 2012, patients' representatives are gradually joining each of the Unicancer Expert Groups to share their experience and expertise. Patients are associated in discussions on several topics like ethics and methodology, and can enrich the point of view of the clinicians for the determination of patients oriented evaluation criteria in our researches.

Clinical research

Clinical research activity is based on the collective excellence and strength of the Unicancer expert groups, in support of innovation as a key value of the network. 2019 was a prolific year for both ongoing and new programmes, as shown below.

KEY RESEARCH RESULTS AND PUBLICATIONS

Metastatic or recurrent chondrosarcoma has an overall bad prognosis; therapeutic options are therefore strongly expected. The **Regobone** study (Sarcoma Group) brought demonstration of regorafenib interest in patients after failure of prior chemotherapy, with significant delayed disease progression. These results were published in the **Lancet Oncology** medical journal in January 2019 and presented at the **ESMO** 2019 Congress in Barcelona.

In the **SAFIR02** Breast trial (Personalised Medicine Group) conducted in patients with triple-negative breast cancer, durvalumab (PD-L1 antagonist) as maintenance therapy has shown to improve overall survival outcomes compared to chemotherapy. The benefit is observed regardless of PD-L1 expression levels, opening perspectives for therapeutic approaches that could yield effective results with immunotherapy in this hard-to-treat disease. Exploratory analysis from the immunotherapy arms of the **SAFIR02** trial were presented at the 2019 **San Antonio Breast Cancer Symposium** (SABCS).

Six abstracts related to different investigational areas of the **CANTO** study (French Breast Cancer Intergroup) were selected for oral and poster presentations at the 2019 **ASCO** annual meeting.

The **AcSé immunotherapy** studies (Immuno-Oncology Group), launched in 2017 to investigate the efficacy of pembrolizumab and nivolumab immune checkpoints inhibitors (ICI) in patients with specific rare cancers have enrolled a total of 517 patients with almost 100 hospitals involved in these researches. Results concerning two cohorts have been presented at the 2019 **ESMO congress**, showing favourable outcome of these ICI in metastatic/refractory MSI-H non-colorectal cancer with nivolumab and in very rare sarcoma histotypes with pembrolizumab.

MAJOR PROJECTS LAUNCHED

In July, the first participant was enrolled in the international randomised MyPeBS (My Personal Breast Screening) study. This 8-year EU-funded H2020 project (grant agreement nb 755394), coordinated by Dr Suzette Delaloge (Gustave Roussy, Villejuif) and hosted by the French Breast Cancer Intergroup, involves 28 international partners in 7 countries and is led by Unicancer's R&D.
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. Overall, 85,000 women volunteers from 5 recruiting countries (France, Italy, UK, Belgium and Israel), aged 40 to 70 and without prior breast cancer, are expected to participate (20,000 in France). **MyPeBS is a major study that could lead to the issuing of harmonised recommendations for breast cancer screening in Europe.**

The **DAISY** study (Personalised Medicine Group) is a highly expected multicentre, open-label phase II trial assessing the efficacy of DS-8201a in patients with **metastatic breast cancer**, regardless of their HER2 status, after all standard options have been exhausted. DS-8201a is a HER2-targeting therapy with nonclinical and clinical evidence of high specificity. Its mechanisms of action predict a sensitivity of tumors previously refractory to TDM-1 treatment and it could be therefore a promising treatment for patients. The **Food and Drug Administration (FDA) already granted an accelerated approval** for DS-8201 in the USA by the end of December.

SCIENTIFIC EVENTS

For the fourth consecutive year, the Genitourinary Group **research symposium** (106 attendees) was held on 29 September 2019 in Paris, the objective being to encourage the emergence of projects developed by or in cooperation with the GETUG.

The fifth edition of **ABCD (Accelerated Biological course in Digestive Cancer)** organised by the Gastrointestinal Group took place on 25 January 2019 in Paris with 132 attendees. It aims to increase France's attractiveness for clinical research and young researchers.

The **MAP (Molecular Analysis for Precision)** leading European Congress in precision medicine for cancer patients was held in Paris on 7-11 November 2019 and hosted 450 participants. Alongside CRUK and ESMO, Unicancer has been involved in this initiative since its inception, providing expert guidance interpreting genomic alterations to design personalised treatments for patients.

MAJOR RESEARCH PERSPECTIVES

The **CANTO (CANcer TOxicities)** project initiated by the **French Breast Cancer Intergroup** and funded by the French National Research Agency (ANR), aims to quantify and predict treatment-related chronic toxicities and social impact in patients with newly diagnosed early breast cancer. It enrolled more than 12,000 women between 2012 and 2018 and has now entered valorization phases of research results with some 40 ongoing academic projects and challenging self-funded developments (see examples of translational studies p.15). A very important and promising continuation of CANTO will be the enrichment of the cohort of women under 45 years of age ("CANTO-2 Young"), starting in 2020. Indeed, it has been shown in a first analysis conducted among these women that persistent post-treatment toxicities have a major impact on their social and professional activities.
In 2019, the CANTO project received recognition from France's research and innovation bodies at both scientific and operational levels: ANR agreed to **an extension of € 3.9 million to support the CANTO cohort for 5 additional years**.

The **Genitourinary Group** is the international coordinator of the European phase 3 **PEACE-6** trial, 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.

In patients with advanced or recurrent Squamous Cell Carcinoma of various tumour locations, the **PEVO basket trial** (**Personalised Medicine Group**) aims to assess treatment with combined immunotherapy and epigenetic drug, and to explore response biomarkers. This original study led by the Institut Curie involves 5 European research groups including Unicancer's R&D and integrates a large number of biological and clinical data from different sources that will be used to improve data collection/management and develop an **AI-based tool for patient inclusion** in clinical trials.

KEY FIGURES

6,257 patients included in Unicancer's R&D sponsored-clinical trials in 2019

100 ongoing clinical trials, including **46** recruiting trials

14 newly initiated clinical trials

195 investigational sites involved (public hospitals, private clinics, comprehensive cancer centres), including **24** abroad

26 publications in scientific journals

42 communications in international congresses, including **11** oral presentations and **7** poster discussions

Unicancer is ISO 9001 certified for its clinical research activity

Translational research

Through a large portfolio of academic clinical studies, a unique collection of biological samples, and a close network of research labs, Unicancer's R&D supports the development of cooperative research projects, offering invaluable tools that are used to address very specific research questions and design large-scale translational projects.

2019 KEY FACTS

A major event in 2019 is the launch of the **CHECK'UP Elderly** study. CHECK'UP is a programme funded by the ARC foundation which mainly aims to prospectively identify predictive factors of response and mechanisms of resistance to approved immunotherapies in patients with lung cancer and head & neck carcinoma. CHECK'UP Elderly focuses on the patients aged 70 and older, in order to evaluate how ageing may affect response to treatment with anti-PD1/PD-L1 inhibitors, as well as the toxicity profile and quality of life of this specific population under anti-PD1/PD-L1. With this view, geriatric parameters (social assistance, functional status, physical performance, nutritional status) will be combined to the analysis of biological and clinical data.

Another remarkable event is the publication in the prestigious journal **Nature** of the "***Genomic characterization of metastatic breast cancers***" study in August 2019. This study evidenced that genomic alterations are acquired during the evolution of cancers from their early to late stages, and that the genomic landscape of early cancers is not representative of that of advanced disease. It included more than 600 patients from precision medicine clinical trials sponsored by the Unicancer's network (SAFIR-01, SAFIR-02, MOSCATO, SHIVA, PERMED-01, MATCH-R).

The Head & Neck expert group has established a **translational research Steering Committee**, which is expected to bring new opportunities for project development in translational medicine, starting with the setting up of ancillary studies to Unicancer clinical trials such as the **TOPNIVO ancillary study** (see below).

Finally, the **ONCOBIOME** EU-funded programme aiming to define intestinal microbiome signatures associated with cancer was launched early 2019, in which Unicancer is involved as a leading partner for results dissemination, and a provider of samples in the lung cancer cohorts.

RESEARCH PERSPECTIVES: FOCUSING ON RESISTANCE TO CANCER IMMUNOTHERAPY

AcSéCible: identify predictive factors of resistance to nivolumab and pembrolizumab

The aim of the AcSé "immunotherapy and rare cancers" programme is to allow off-label access to these anti-PD1 for patients with rare cancers, based on the tumour's biological profile. The AcSéCible programme will rely on the ancillary analysis of tumour and blood material collected from about 500 of these patients, with the hope to identify a biomarker that would predict treatment resistance and thus avoid expensive unnecessary and sometimes toxic treatments for the patients concerned.

TOPNIVO ancillary study: identify mechanisms of resistance to nivolumab in Head and Neck cancer

In this ancillary study, we will assess at baseline and after nivolumab administration:
- The expression of PD-L1,
- The amount of tumour infiltrating lymphocytes,
- The tumour phenotype.

Germline polymorphisms involved in the immune response will also be evaluated and correlated with CD8+ T cell infiltration.

KEY FIGURES FOR CANTO (CANcer Toxicities study) BIOBANK

26,000 frozen whole blood samples

91,000 frozen plasma/serum samples

17,000 samples collected from CANTO patients (DNA, serum, plasma, feces and whole blood) were used in **5 translational sub-studies** as of 2019:

- **CANTO CHIP:** prevalence of clonal hematopoiesis in breast cancer patients at diagnosis and impact on the occurrence of side effects after treatment;
- **MyProbe:** Molecular assays to Predict outcome in early breast cancer;
- **CANTO COMPLETE:** a sub-study evaluating psychological predictors of young patients' compliance to Endocrine Therapy in adjuvant setting;
- **MICROBIOTA:** determining the role of microbiota in the response to chemotherapy;
- **CANTO-GenMed:** Analysis of Genome-Wide Association Study.

Real-world data

Real-world data (RWD) are defined as routinely collected data relating to patient health status and/or the delivery of health care. These data come from a variety of sources such as billing activities, electronic health records, product and disease registries. Collected outside interventional studies, RWD reflect patients experience throughout therapy.

Real-world data are used to generate real-world evidence (RWE), which means clinical evidence about usage and potential benefits or risks of a medicinal product derived from analysis of RWD.

In oncology, the use of RWD is expanding as a decision-support tool for use in regulatory decision-making, in the R&D of medicinal products and in the development of clinical practice guidelines.

Initiated in 2014, the Unicancer ESME (Epidemiological Strategy and Medical Economics) initiative is a platform of longitudinal RWD on cancer management, including three databases focused on breast, ovarian and lung cancers (see p. 30). Health assessment agencies recognize the ESME real-world programme as a valuable source of information to guide decision-making throughout the life cycle of a therapy.

ESME RESEARCH DATABASES COMPLY WITH THE EUROPEAN GENERAL DATA PROTECTION REGULATION (GDPR)

In 2019, the French Data Protection Authority (CNIL) **granted the ESME platforms a "Data warehouse status", allowing the massively collected data - 57,000+ cases overall - to be re-used for multiple research projects.** This authorization opens up opportunities for sharing with other data sources and warehouses in France data useful for patients as well as for decision-makers (e.g. identification of data according to specific objectives). It is also a **guarantee of trust between all the stakeholders who supply and use the warehouse**, as highly secured access to data is only granted to statisticians involved in the ancillary projects to generate aggregated results, and the raw data cannot be extracted from the database. A growing number of hospitals outside the Unicancer network, e.g. public university hospitals, uses the ESME databases.

RESEARCH PROJECTS

In 2019, Unicancer launched the **first academic calls for proposals to exploit the ovarian and lung cancer dataset**. Among the ancillary projects submitted, six were accepted in ovarian cancer and nine in lung cancer. Added to the 16 newly activated projects in metastatic breast cancer, the number of new research projects validated in 2019 was 31.

SCIENTIFIC PRODUCTION

To date, **the academic researchers involved in ESME programmes** (see publications list p.31) **have produced more than 30 international communications or publications**. Among the most notable this year :

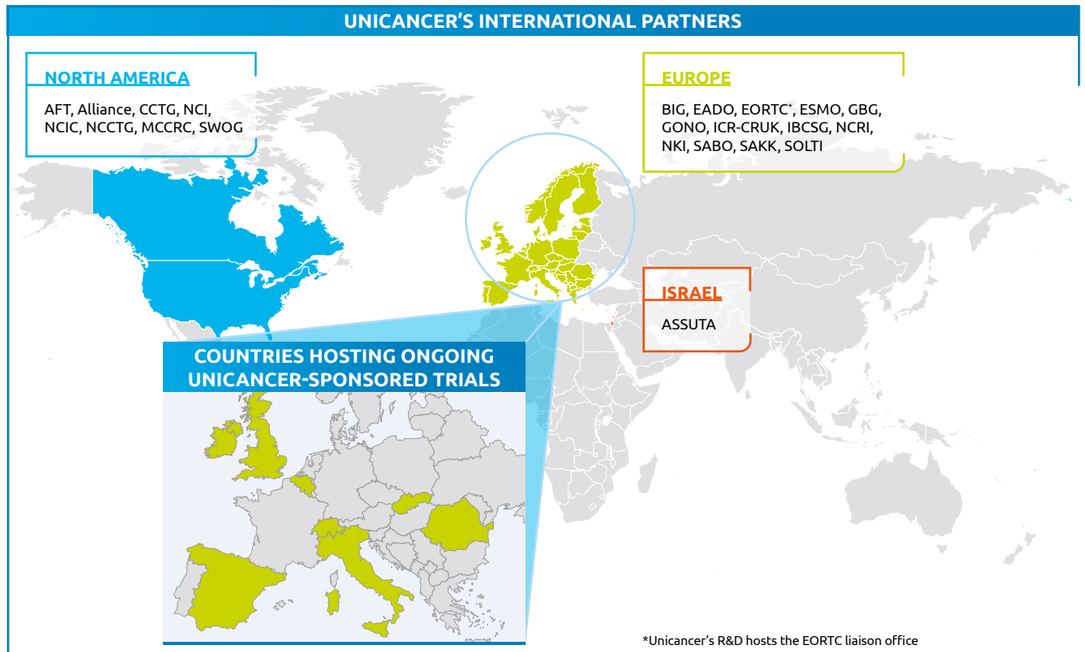
- The first poster accepted in an international congress, was presented in April 2019 and got the "Best Poster Award" in the category "Locally Advanced NSCLC" at the European Lung Cancer Congress (ELCC): *"Real-world treatment patterns, clinical practice and outcomes for locally advanced, non-resectable non-small lung cancer from the French ESME Lung database"*.
- The study *"Treatment and outcomes in patients with central nervous system metastases from breast cancer in the real-life ESME MBC cohort"* was published in December 2019 in the European Journal of Cancer.
- The study *"Contemporary outcomes of metastatic breast cancer among 22,000 women from the multicentre ESME cohort 2008-2016"*, was accepted at the end of 2019 for publication in the European Journal of Cancer and presentation at the European Breast Cancer Conference (EBCC) in 2020

KEY FIGURES

- Metastatic Breast Cancer: **24,000** cases selected
- Advanced & Metastatic Lung Cancer: **23,000** cases selected
- Ovarian Cancer: **10,000** cases selected
- **9** years of longitudinal follow-up
- **80** projects since the start of the ESME research programme
- **14** communications and publications in 2019

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 R&D hosts the EORTC liaison office

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 Clinique sur le Cancer
SOLTI: Spain Academic Research Group
SWOG: Southwest Oncology Group - USA

KEY FIGURES

- **25** 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

As a fully-owned subsidiary of Unicancer, MATWIN is leading since ten years a French accelerator programme strictly dedicated to the support of early innovation in oncology, where the risks remain high and may deter investors.

The main objectives are to assess and support innovative projects with transfer potential coming from either Academia or start-ups, with the view of fostering early collaborations. The process is based on a partnership with 14 international laboratories (Amgen, AstraZeneca, Boehringer Ingelheim, Bristol-Myers Squibb, Exact Sciences, Gilead, GlaxoSmithKline, Janssen, 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. According to their specific needs, applicants may benefit from one or several steps of the programme:

- Double international assessment by academic and industrial experts whose feedback is entirely passed on to the project holders and their associated technology transfer structures,
- Personalised coaching to optimise the structuring and industrial focus of the project,
- Access to MATWIN partners' network (major groups, biotech, investors) with a possible label from the MATWIN International Board (unique in Europe), made up of academic key opinion leaders from major European Cancer Institutes and International decision-makers from the R&D Global Oncology of MATWIN's partners.

Since 2015, MATWIN has also organised simultaneously with the Board meeting an international partnering convention called MEET2WIN entirely dedicated to open innovation and collaborative research in oncology. This event has proved increasingly successful and is becoming a reference meeting point for partnerships in oncology innovation in Europe, gathering more than 1,500 participants and generating more than 3,500 B2B meetings.

Each year, MEET2WIN is combining conferences, workshops, projects elevator pitches and more than 1,000 B2B meetings. A large time is dedicated to networking, and a showcase is offered for start-ups looking forward to fundraising via a dedicated session called **OUI** (**O**ncology **U**pward **I**nvestment). This specific session allows 10 companies to pitch their innovative solutions in front of an expert jury of European investors able to support their growth. Each sector may be represented (therapy, diagnostic, digital, eHealth, AI/software, etc.) offering new opportunities of development support to leverage deep tech innovation in oncology.

www.matwin.fr
Contact: contact@matwin.fr

KEY FIGURES FROM MATWIN'S REVIEW (2009-2019)

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

60+ projects interviewed by the MATWIN International Board

29 already created start-ups (amongst which Syndivia, PDC'line, ElyssaMed, H-Immune, Gliocure, Apmonia Therapeutics, Seekyo, Yukin Therapeutics etc.)

20+ projects already collaborated with industry

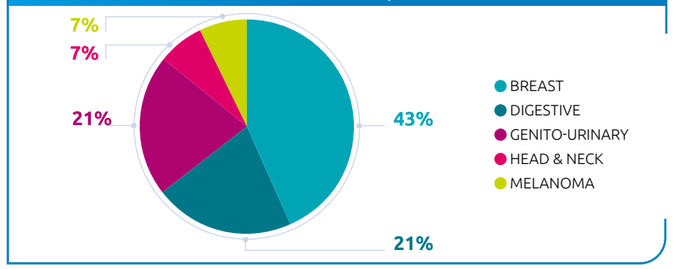
Clinical research activity

Clinical trials activated in 2019

UNICANCER'S R&D CLINICAL TRIALS ACTIVATED IN 2019

SHORT TITLE	STUDY TITLE	EXPERT GROUP	STUDY COORDINATOR	PHASE	TUMOUR LOCALISATION(S)	NUMBER OF EXPECTED PATIENTS	ACTIVATION DATE
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	UCGI	E. Samalin	II	Gastric	154	30/01/2019
PRODIGE 67/ UCGI 33 - ARION	Association of Radiochemotherapy and Immunotherapy for the treatment of unresectable Oesophageal caNcer: a comparative randomized phase II trial	UCGI	A. Modesto	II	Oesophageal	120	19/03/2019
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	UNITRAD	A. Fourquet	II	Breast	666	28/03/2019
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	UCGI		III	Pancreatic	210	23/05/2019
ORL 10 - IMMUNEBOOST 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	UCH&N	H. Mirghani	II	Head & neck	61	06/06/2019
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.	UCBG	S. Guiu	I/II	Breast	158	14/06/2019
MyPeBS	MyPeBS (My Personal Breast Screening) - International randomized study comparing personalized, risk-stratified to standard breast cancer screening in women aged 40-70	UCBG	S. Delaloge	Cohort	Breast	85,000	16/07/2019
BECOME-MB	Phase 2 randomised trial testing the addition of stereotactic radiosurgery to binimetinib and encorafenib in comparison with binimetinib and encorafenib alone in patients with BRAFV600 mutation-positive melanoma with brain metastasis	UNITRAD	P. Saiag	II	Melanoma	150	11/09/2019
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	GERICO	E. Brain	II	Breast	144	08/10/2019
PALATINE	Optimized combined locoregional and systemic treatments for de novo, treatment naive, stage IV ER+, HER2- breast cancer patients	UCBG	D. Hequet	II	Breast	200	09/10/2019
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	MED PERSO	V. Dieras	II	Breast	162	15/10/2019
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	GETUG	S. Supiot	III	Prostate	490	02/12/2019
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	GETUG	P. Blanchard	III	Prostate	350	10/12/2019
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 randomized study	GETUG	G. Roubaud	II	Prostate	40	17/12/2019

NUMBER OF TRIALS ACTIVATED IN 2019, BY TUMOUR LOCALISATION

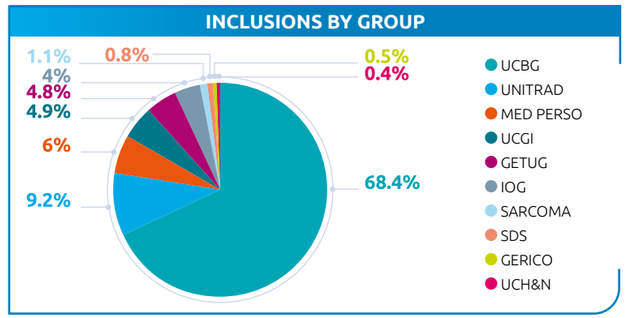


Inclusions by expert group

NUMBER OF PATIENTS INCLUDED IN 2019 BY GROUP AND INSTITUTION TYPE

	UCBG	GETUG	UCGI	UCH&N	UC SARCOMA	MED PERSO	IOG	UNITRAD	GERICO	SDS	TOTAL
Public hospitals of Paris (AP-HP)	18	22	10	4	5		18	6	3		86
Other public hospitals (excl. AP-HP)	759	46	78	1	22	70	50	37	10	22	1,095
FCCCs	1,894	115	122	18	40	296	182	475	14	25	3,181
Other private non-profit hospitals	100	29	25			6		6			166
Army hospitals		7				1				5	13
Private clinics	295	49	28			5	1	51	2		431
City medical practice	1,060										1,060
Foreign institutions	154	30	41								225
Total	**4,280**	**298**	**304**	**23**	**67**	**378**	**251**	**575**	**29**	**52**	**6,257**

INCLUSIONS BY GROUP



FOCUS ON THE UNICANCER NETWORK OF FRENCH COMPREHENSIVE CANCER CENTRES (FCCCs)

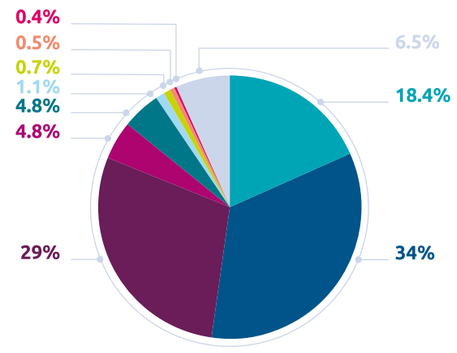
FCCC / UNICANCER EXPERT GROUP	UCBG	GETUG	UCGI	UCH&N	UC SARCOMA	MED PERSO	IOG	UNITRAD	GERICO	SDS	TOTAL
Institut de cancérologie de l'Ouest	149	30	19	3	5	32	20	23	0	0	281
Institut Bergonié	84	6	0		0	13	1	7	0		111
Centre François Baclesse	15	3	1	0	0	1	13	17	0	11	61
Centre Jean Perrin	23	1	0	0	0	19	5	5	0		53
Centre Georges-François Leclerc	58	1	8	0	0	9	22	18	0		116
Centre Oscar Lambret	16	4	2	0	4	1	6	30	0		63
Centre Léon Bérard	22	17	24	0	11	49	16	45	1		185
Institut Paoli-Calmettes	92	9	16		0	35	15	21	0		188
Institut du Cancer de Montpellier	2	1	13	0	1	16	12	2	1		48
Institut de cancérologie de Lorraine	0	2	1	0	0	1	3	38	0		45
Centre Antoine Lacassagne	49	1	13	0	1	9	10	51	2		136
Institut Curie	653	0	1	1	7	15	15	58	6	0	756
Institut Godinot	174	1	4	0	0	3	3	26	0		211
Centre Eugène Marquis	111	6	2	0	1	27	10	34	4	14	209
Centre Henri Becquerel	5	0	0	1	0	0	1	17	0		24
ICANS – Centre Paul Strauss	148	0	3	0	0	0	0	24	0		175
IUCT Oncopole – Institut Claudius Regaud	61	18	6	3	3	28	1	4	0		124
Gustave Roussy	232	15	9	10	7	38	29	55	0		395
Total	**1,894**	**115**	**122**	**18**	**40**	**296**	**182**	**475**	**14**	**25**	**3,181**

Inclusions by tumour localisation

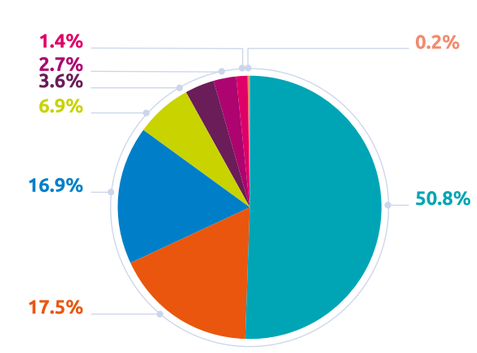
NUMBER OF PATIENTS INCLUDED IN 2019 BY TUMOUR LOCALISATION AND INSTITUTION TYPE

	BREAST	*OF WHICH TUMOSPEC*	*OF WHICH MyPeBS*	DIGESTIVE	GENITO-URINARY	SARCOMA	LUNG	GYNEACO-LOGICAL	HEAD & NECK	MULTIPLE LOCALISATIONS	TOTAL
FCCCs	2,598	*1,537*	154	114	115	40	29	16	18	251	3,181
Other public hospitals (excl. AP-HP)	827	*482*	209	79	46	22	1	9	1	110	1,095
City medical practice	1,060		1,060								1,060
Private clinics	326	*88*	182	30	49		10			16	431
Foreign institutions	154		127	38	30			3			225
Other private non-profit hospitals	107	*5*	82	25	29		3			2	166
Public hospitals of Paris (AP-HP)	23	*15*	2	12	22	5		1	4	19	86
Army hospitals					7					6	13
Total	**5,095**	***2,127***	***1,816***	**298**	**298**	**67**	**43**	**29**	**23**	**404**	**6,257**

INCLUSIONS BY TUMOUR LOCALISATION

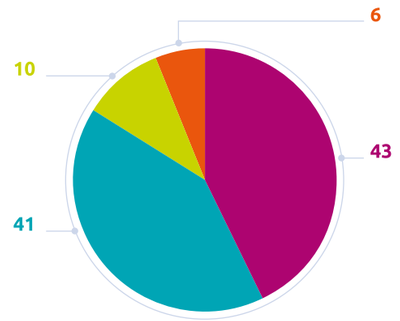


INCLUSIONS BY INSTITUTION TYPE

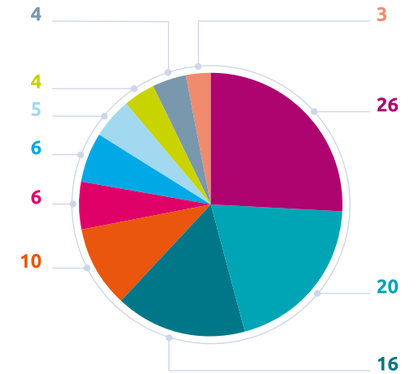


Ongoing trials

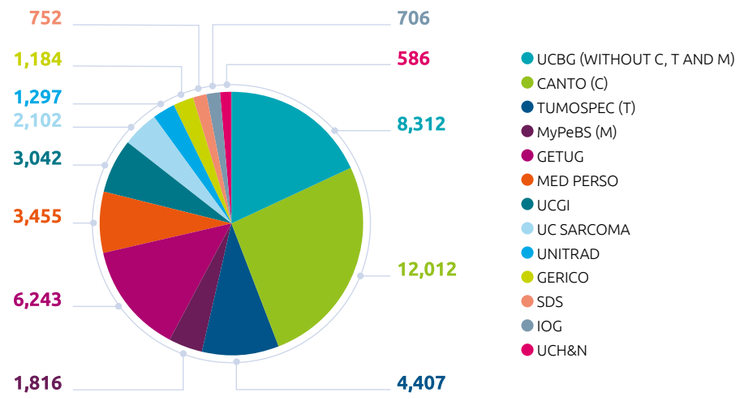
DISTRIBUTION OF ONGOING TRIALS PER PHASE



NUMBER OF ONGOING TRIALS PER GROUP



TOTAL NUMBER OF INCLUSIONS PER GROUP IN ONGOING TRIALS



EORTC liaison office

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

5 new EORTC-sponsored trials have been activated in France in 2019

35 studies were recruiting in France in 2019

EORTC TRIALS PORTFOLIO AND RECRUITMENT STATUS IN FRANCE IN 2019

List of EORTC studies approved in France in 2019

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-ROG	1702 (HALT)	Targeted therapy with or without dose intensified radiotherapy for oligo-progressive disease in oncogene-addicted lung tumors	07/01/2019	C. Le Pechoux (Gustave Roussy)	15/110
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	N. Girard (Institut Curie)	20/80
ROG	1811 (E²-RADIATE)	EORTC-ESTRO RADiotherapy InfrAstrucTure for Europe	11/06/2019	B. De Bari (CHRU Besançon)	21/81
GITCG	1707 (VESTIGE)	Adjuvant immunotherapy in patients with resected gastric cancer following preoperative chemotherapy with high risk for recurrence (N+ and/or R1): an open label randomized controlled phase 2-study	14/06/2019	V. Boige (Gustave Roussy)	25/240
BTG	1635 (IWOT)	IDH mutated 1p/19q intact lower grade glioma following resection Wait Or Treat? IWOT – A phase III study.	08/07/2019	E. Le Rhun (CHU Lille)	74/750

List of EORTC studies active in France in 2019

EORTC RESEARCH GROUP(S)	EORTC STUDY NUMBER (ACRONYM)	STUDY TITLE	STUDY APPROVAL DATE IN FRANCE	NUMBER OF INCLUDED PATIENTS AS OF DEC 31,2019 (FRANCE/ALL COUNTRIES)
BTG	1419	Molecular genetic, host-derived and clinical determinants of long-term survival in glioblastoma	05/07/2015	106/448
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	5/6
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	69/388
BTG-ROG	1308 (ROAM)	Radiation *versus* Observation following surgical resection of Atypical Meningioma: a randomized controlled trial (The ROAM trial)	22/08/2017	6/102
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	11/97

List of EORTC studies active in France in 2019 (con't)

EORTC RESEARCH GROUP(S)	EORTC STUDY NUMBER (ACRONYM)	STUDY TITLE	STUDY APPROVAL DATE IN FRANCE	NUMBER OF INCLUDED PATIENTS AS OF DEC 31,2019 (FRANCE/ALL COUNTRIES)
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	3/30
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	26/105
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	15/101
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	11/56
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	1/20
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	65/106
GITCG	1527 (DREAM)	Diffusion-Weighted Magnetic REsonance Imaging Assessment of Liver Metastasis and Improve Surgical Planning	27/12/2016	17/67
GITCG	1560 (ILOC)	Phase II of immunotherapy plus local tumor ablation in patients with metastatic colorectal cancer	27/03/2018	1/3
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	26/511
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	2/2
LCG-PBG	1335 (SPECTAlung)	SPECTAlung: Screening Patients with Thoracic Tumors for Efficient Clinical Trial Access	22/05/2015	80/532
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	1417 (REACTION)	REACTION: A phase II study of etoposide and cis/carboplatin with or without pembrolizumab in untreated extensive small cell lung cancer	07/08/2017	92/123
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	2/39
LCG	1613 (APPLE)	APPLE trial: Feasibility and activity of AZD9291 (osimertinib) treatment on Positive Plasma T790M in EGFR mutant NSCLC patients	20/07/2017	57/136
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
LG-ETF	1301 (AML21)	10-day decitabine *versus* conventional chemotherapy ("3+7") followed by allografting in AML patients ≥ 60 years: a randomized phase III study of the EORTC Leukemia Group, CELG, GIMEMA and German MDS Study Group	20/11/2014	62/606
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	9/215
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: anEORTC phase II randomized study	04/07/2018	39/43
STBSG	1402 (EE2012)	International Randomised Controlled Trial for the Treatment of Newly Diagnosed Ewing's Sarcoma Family of Tumours – Euro Ewing 2012	23/05/2016	195/640
STBSG	1403 (rEECur)	International Randomised Controlled Trial of Chemotherapy for the treatment of recurrent and primary refractory Ewing sarcoma	10/03/2016	71/347
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	17/76
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	12/32
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	2/22
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	10/15
All groups	1553 (SPECTA*) RP-1843 (Arcagen)	Screening Cancer Patients for Efficient Clinical Trial Access Molecular characterization of rare cancer	30/03/2017	5/15

*__SPECTA:__ SPECTA is a collaborative European platform that helps deliver high-quality molecular and pathological screening across tumour types to aid patient selection into clinical trials. SPECTA is a programme website: https://www.eortc.org/specta/

GLOSSARY

BTG: Brain Tumor Group (EORTC BTG)
BCG: Breast Cancer Group (EORTC BCG)
CLG: Children Leukemia Group (EORTC CLG)
ENTF: ENdocrine Task Force (EORTC ENTF)
ETF: cancer in Elderly Task Force (EORTC ETF)
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)
IG: Imaging Group (EORTC IG)
LCG: Lung Cancer Group (EORTC LCG)
LG: Leukemia Group (EORTC LG)
MG: Melanoma Group (EORTC MG)
NOCI: Network Of Core Institutions (EORTC NOCI)
ROG: Radiation Oncology Group (EORTC ROG)
STBSG: Soft Tissue and Bone Sarcoma Group (EORTC STBSG)

Translational research activity

Main translational research projects

Based on the use of human samples and sophisticated technological platforms, translational research aims to improve patient treatment and researchers' understanding of cancer. Unicancer's R&D Department offers researchers access to valuable resources centralized in its biobank and to the data of its trials, with the aim to foster innovative translational research projects. In 2019, Unicancer launched notably two new translational projects funded by the French cancer institute (PRT-K programmes).

MAJOR PROJECTS (PRT-K) ACTIVATED IN 2019

MOSAPAC

In patients with pancreatic ductal adenocarcinoma, the combinations of gemcitabine and nab-paclitaxel or folfirinox were recently shown to be superior to standard chemotherapies.

Mutations in DNA repair genes lead to homologous recombination deficiency and a potential extreme sensitivity to platinum-based therapies. However, there is no biomarker for personalized medicine development. Using the results of the PRODIGE 24 clinical trial, the MOSAPAC project (PRT-K19-131) aims to define prognostic and predictive RNA signatures validated on routine samples in a large retrospective cohort.

YODA

ESR1 mutations are the most prevalent targetable mechanisms of acquired resistance in oncology, leading to ligand-independent activation of oestrogen receptor and resistance to oestrogen deprivation. These mutations are detectable in 40% of ER+ metastatic breast cancer patients resistant to aromatase inhibitors. The PADA-1 trial allowed tracking the occurrence of ESR1 mutations in circulating tumour DNA (ctDNA) in patients treated with palbociclib and aromatase inhibitors. The YODA project (PRT-K19-110) now aims to assess the impacts of ESR1 mutations, to characterize the mechanisms of late resistance to first-line treatment and to assess the epigenetic landscape of the tumour.

ONGOING MAJOR PROJECTS

MyProbe: Molecular assaYs to PRedictOutcome in early Breast cancer

The goal of MyProbe is to develop molecular classifiers to identify patients with high risk of relapse after a conventional therapy for breast cancer and thus reduce the use of costly and cumbersome additional treatments for patients with a low risk. Within the ANR's RHU-funded MyProbe consortium, six translational research teams from Gustave Roussy, Centre Léon Bérard and Institut Curie, in collaboration with research units in biostatistics and bioinformatics, will develop and validate molecular prognostic tests based on samples from 8 clinical trials, of which 3 sponsored by Unicancer (PACSs, SAFIR, CANTO). An innovative biomarker company - HalioDx - is also involved.

The main objectives of MyProbe is to develop 3 predictive signatures in breast cancer:

- A genomic signature for luminous cancers with a high risk of relapse, using exome sequencing, comparative genomic hybridization (CGH) and genome-wide association study (GWAS),
- A test based on circulating tumour DNA (ctDNA) for early detection of relapse,
- An immune response signature specific to triple negative breast cancers: RNA analyses (RNAseq and Nanostring test) for the training set of the analysis were completed in 2019.

SAFIVA: understanding tumour genome complexity and intra-tumour heterogeneity

A large collection of metastatic breast cancer samples was built from the SAFIR and SHIVA, 2 French trials sponsored by Unicancer and Institut Curie. After conducting whole-exome sequencing, it was hypothesized that genomic alterations in those specimens might pre-exist in minority sub-clonal populations of the matched primary breast cancer tumours. A collection of 150 paired primitive and metastatic tumour samples was built in 2019 to explore this hypothesis. Whole exome sequencing and RNA sequencing is being performed for all matched tumours, as well as ultra-deep sequencing analysis of primary tumours from patients whose metastasis has an ESR1 gene mutation, with the goal to identify minority sub-clones with this mutation. Deep learning-based analysis of the digitized slides to identify possible correlations between morphological and genomic profiles. SAFIVA analyses are funded by the ARC foundation.

NIVOREN GETUG-AFU 26 translational programme: characterizing immune cell populations

The NIVOREN GETUG-AFU 26 study assessed the safety and efficacy of nivolumab in metastatic clear cell renal cell carcinoma (mccRCC) patients who failed prior anti-angiogenic therapies. Results from the PRT-K funded translational programme aiming at characterizing immune cell populations in and around the tumour by immunohistochemistry contributed to correlate outcome on nivolumab and tumour immune environment. Indeed, it showed that highest CD8 density at the invasive margin and PD-L1 expression by ³1% tumour cells or immune cells is associated with worse overall survival in patients with mccRCC receiving nivolumab.

Biological Resource Centre

Unicancer's biobank was set up in 2012 to meet the requirements of Unicancer's R&D strategy by creating a collection of clinical research programme samples to promote biological research and advances in cancer treatment. Centralization at the Centre Léon Bérard in Lyon ensures correct storage conditions of the samples and their rapid availability to research teams.

The whole collection includes 59,000 samples (except CANTO cohort samples), coming from 14,000 patients enrolled in a total of 51 studies. Historical collections, mostly focused on breast cancer, have been diversified. 9,500 new samples entered the collection in 2019, amongst these, for the first time, samples from pancreatic cancer patients (see figure below).
New types of biological samples are also being collected, with the advent of programmes dedicated to studying the microbiota, e.g. feces in CHECK'UP (see figure below).

Since 2012, some 12,700 samples have been unarchived to feed 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 FCCCs. 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 R&D biological steering committee.

The design of new research projects requires enhanced communication about the available collections. To this end, a data visualization tool was implemented in 2019, thus facilitating the identification of samples of interest and improving the traceability of data and sample flows. This tool enables researchers to know precisely what material is available regarding both innate characteristics of the sample and clinical parameters of the related disease and genomic analyses performed. Simultaneously, Unicancer launched a website dedicated to patient information on the reuse of their data and biological samples (mesdonnees.unicancer.fr, see p.12).

In 2019, two major translational research programmes in oncology (PRT-K) were funded by France's National Cancer Institute (INCa) with the aim to contribute developing biology-driven personalized treatments (see p.27):
- **MOSAPAC**, an ancillary study to the PRODIGE 24/ACCORD 24 clinical trial in pancreatic ductal adenocarcinoma,
- **YODA**, an ancillary translational study to the PADA-1 trial in hormone receptor-positive, HER2-negative metastatic breast cancer patients.

KEY FIGURES

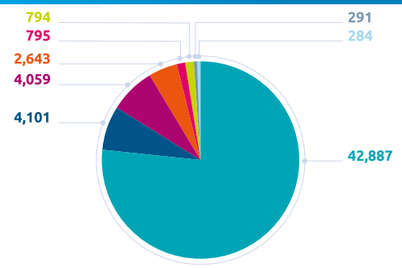
59,000 samples stored in total, representing approximately **145,000** aliquots*

9,500 new entries in 2019

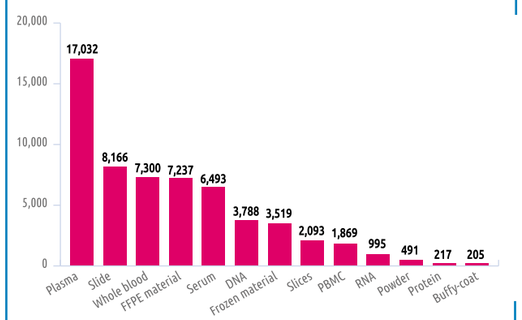
1,900 outputs in 2019, used in **10** research projects

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

SAMPLE DISTRIBUTION BY TUMOUR LOCALISATION



NUMBER OF SAMPLES BY SUBTYPE



Real-world data

Epidemiological Strategy and Medical Economics (ESME)

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 research programme serves strategic goals such as:

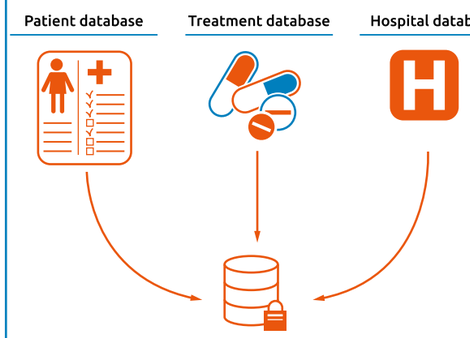
- To describe cancer management in France (updated annually),
- To describe current standard therapeutic strategies/treatment lines and therapeutic trends,
- To provide data on innovative drug use in medical institutions for market access filing and real-life settings,
- To provide data to support Health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

The ESME data platform includes data from different information sources generated by healthcare professionals: patient data collected from electronic health records, treatment data from on-site pharmacy records and hospital invoicing data from hospitalizations and medical procedures (see chart).

It is supported by major industrial partners: Roche, Pfizer, AstraZeneca, MSD, Daiichi Sankyo, Esai, and since 2019, 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. IO-Optimise will generate insights on the evolving lung cancers landscape aimed to complement clinical trial evidence and to improve patient outcomes and aid in the selection of cost-effective therapies that best meet patients' expectations.

Other partnerships are under discussion.

INFORMATION SOURCES OF THE ESME DATA PLATFORM



ESME RESEARCH PROJECTS

Three data platforms respectively focus on:

- **Metastatic Breast Cancer** (24,000 patients selected from FCCCs at the end of 2019) aiming to help standardize the management of MBC and improve patient care
- **Advanced and metastatic lung cancer** (23,000 patients selected from FCCCs and other healthcare facilities at the end of 2019), 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** (10,000 patients selected from FCCCs at the end of 2019), 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

ESME GOVERNANCE

Three bodies monitor the ESME research programme: the Strategic Committee (associated with 3 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 programme and reviews key international communications, formulates recommendations for publication rules or methodology and reinforces international academic cooperation.

ESME DATABASES ARE FULLY 21 CFR PART 11-COMPLIANT

Procedures for compliance with the American Standard 21 CFR part 11, relating to optimal use of electronic technologies for the security of data collection and storage, were completed in 2019, which is another guarantee of trust about real-life data acquisition and admissibility in studies.

ESME publications in 2019

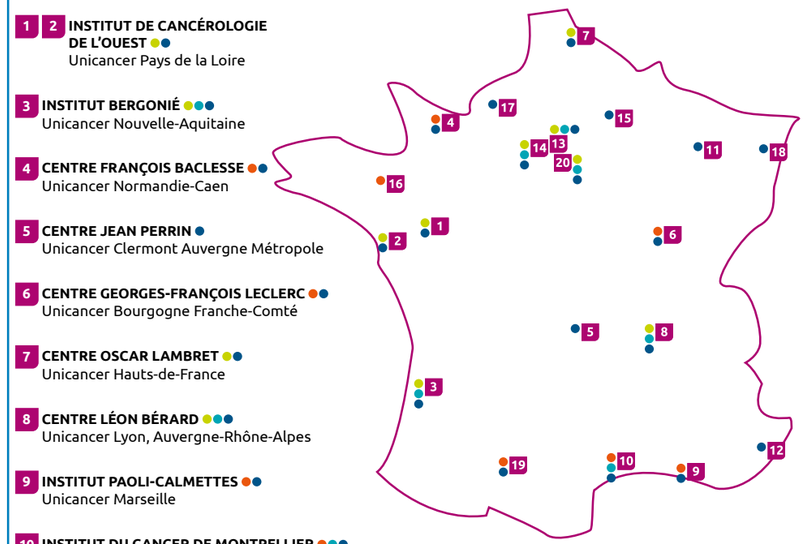
Title	Authors	References
Treatment and outcomes in patients with central nervous system metastases from breast cancer in the real-life ESME MBC cohort	D. Pasquier *et al.*	Eur J Cancer Oxf Engl 1990. 2019 Dec 10; 125: 22-30
Impact of breast cancer molecular subtypes on the incidence, kinetics and prognosis of central nervous system metastases in a large multicentre real-life cohort	A. Darlix *et al.*	Br J Cancer. 2019 Nov 13
CinéBreast-factors influencing the time to first metastatic recurrence in breast cancer: Analysis of real-life data from the French ESME MBC database	P. Gougis *et al.*	Breast. 2019 Oct 19; 49: 17-24
Cost-effectiveness of bevacizumab plus paclitaxel ***versus*** paclitaxel for the first-line treatment of HER2-negative metastatic breast cancer in specialist oncology centers in France	A. Petitjean *et al.*	BMC Cancer. 2019 Feb 11; 19(1): 140
Assessment of the efficacy of successive endocrine therapies in hormone receptor-positive and HER2-negative metastatic breast cancer: a real-life multicentre national study	O. Le Saux *et al.*	Eur J Cancer. 2019 Sep; 118: 131-141
The ongoing French metastatic breast cancer (MBC) cohort: the example-based methodology of the Epidemiological Strategy and Medical Economics (ESME)	D. Perol *et al.*	BMJ Open. 2019; 9: e023568-e023568
Real-life activity of eribulin mesylate among metastatic breast cancer patients in the multicenter national observational ESME program	W. Jacot *et al.*	Int J Cancer. 14 mai 2019; ijc.32402

Research in the FCCCs

Research 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



- **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:

- **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)
- **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)

Unicancer is ISO 9001 certified for its clinical research activity

Inclusions in the FCCCs

Clinical trials inclusions in the FCCCs

FRENCH COMPREHENSIVE CANCER CENTRE (FCCC)	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 FILE INCLUDED IN A CLINICAL TRIAL	ACADEMIC SPONSOR			INDUSTRIAL SPONSOR	
								NUMBER OF PATIENTS INCLUDED	NUMBER OF ACTIVE TRIALS	% OF PATIENTS INCLUDED IN AN INSTI-TUTIONAL CLINICAL TRIAL	NUMBER OF PATIENTS INCLUDED	NUMBER OF ACTIVE TRIALS
Institut de Cancérologie de l'Ouest	**Angers/ Nantes**	11,770	991	266	3.7	*11%*	8.4%	772	175	78%	219	91
Institut Bergonié	**Bordeaux**	7,067	1,842	273	6.7	*43%*	26.1%	1,363	154	74%	479	119
Centre François Baclesse	**Caen**	7,136	392	166	2.4	*6%*	5.5%	314	125	80%	78	41
Centre Jean Perrin	**Clermont-Ferrand**	5,222	331	101	3.3	*17%*	6.3%	247	64	75%	84	37
Centre Georges-François Leclerc	**Dijon**	4,664	951	224	4.2	*24%*	20.4%	757	144	80%	194	80
Centre Oscar Lambret	**Lille**	6,863	1,166	144	8.1	*17%*	17.0%	713	92	61%	453	52
Centre Léon Bérard	**Lyon**	10,350	2,021	375	5.4	*23%*	19.5%	1,581	236	78%	440	139
Institut Paoli-Calmettes	**Marseille**	9,822	1,367	233	5.9	*15%*	13.9%	1,066	152	78%	301	81
Institut du Cancer de Montpellier	**Montpellier**	6,921	1,572	198	7.9	*29%*	22.7%	1,430	144	91%	142	54
Institut de Cancérologie de Lorraine	**Nancy**	5,173	850	133	6.4	*17%*	16.4%	605	107	71%	245	26
Centre Antoine Lacassagne	**Nice**	5,594	702	160	4.4	*15%*	12.5%	580	108	83%	122	52
Institut Curie	**Paris/Saint-Cloud**	14,592	2,113	223	9.5	*16%*	14.5%	1,799	131	85%	314	92
Institut Godinot	**Reims**	3,696	437	71	6.2	*13%*	11.8%	421	59	96%	16	12
Centre Eugène Marquis	**Rennes**	4,907	578	105	5.5	*14%*	11.8%	440	59	76%	138	46
Centre Henri Becquerel	**Rouen**	5,150	534	128	4.2	*11%*	10.4%	455	99	85%	79	29
ICANS – Centre Paul Strauss	**Strasbourg**	3,651	415	103	4.0	*12%*	11.4%	400	84	96%	15	19
IUCT Oncopole – Institut Claudius Regaud	**Toulouse**	7,178	1,100	216	5.1	*26%*	15.3%	880	133	80%	220	83
Gustave Roussy	**Villejuif**	12,643	3,022	444	6.8	*29%*	23.9%	2,258	151	75%	764	293
Total		**132,399**	**20,384**			***19%***	**15.4%**	**16,081**		**79%**	**4,303**	
Mean		7,356	1,132	198	6	*19%*	14.9%	893	123	80%	239	75
+/- SD		3,191	738	98	2	*9%*	5.9%	572	45	9%	194	65
Median		6,892	971	182	5	*16%*	14.2%	735	128	79%	207	53
Min		3,651	331	71	2	*6%*	5.5%	247	59	61%	15	12
Max		14,592	3,022	444	9	*43%*	26.1%	2,258	236	96%	764	293

* 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 represent an average 62% of the patients having signed the informed consent in such trials). Such trials represent an average 35% of industry sponsored trials and 11% of the academic sponsored trials proposed in the FCCCs.

KEY FIGURES

15.4% of the patients treated in the FCCCs are included in a clinical trial *versus* 8.5% of cancer patients on average in France

688 active clinical trials sponsored by the Unicancer network

105 new trials sponsored by the Unicancer network

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

50% of the national funding for oncology translational programmes ('PRTK') has been allocated to Unicancer

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

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

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

Appendices

Trials in active phase in 2019

TUMOUR LOCALISATION(S)	EXPERT GROUP(S)	STUDY SHORT TITLE	STUDY TITLE	STUDY COORDINATOR	PHASE	NUMBER OF EXPECTED PATIENTS
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	P. 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	C. 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	M. Roupret	III	614
Bone sarcoma	SARCOMA	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)	N. Gaspar	II	390
Bone sarcoma	SARCOMA	SARCOME 12 / REGOBONE	A Randomized Phase II, placebo-controlled, multicenter study evaluating efficacy and safety of regorafenib in patients with metastatic bone sarcomas	F. Duffaud	II	159
Breast	GEP / UCBG	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	T. Bachelot	I	52
Breast	GERICO	GERICO 18- APPALACHES	Adjuvant palbociclib as an alternative to chemotherapy for older patients with high risk luminal early breast cancer	E. Brain	II	50
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	E. Brain	II	144
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	V. Diéras	II	162
Breast	MED PERSO	SAFIR PI3K	SAFIRPI3K: a phase II randomized trial testing Alpelisib as maintenance therapy in patients with PIK3CA mutated advanced breast cancer	A. Goncalves	II	90
Breast	MED PERSO	TRACER-X	Tracking triple-negative breast cancer evolution through therapy	M. Arnedos	Cohort	250
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	J. Gligorov	III	150
Breast	UCBG	MyPeBS	MyPeBS (My Personal Breast Screening) - International randomized study comparing personalized, risk-stratified to standard breast cancer screening in women aged 40-70	S. Delaloge	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	H. Bonnefoi	II	90
Breast	UCBG	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	S. 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	D. Héquet	II	200
Breast	UCBG	UNIRAD	Randomized, double-blind, multicentric phase III trial evaluating the safety and benefit of adding everolimus to adjuvant hormone therapy in women with poor prognosis, ER+ and HER2- primary breast cancer who remain free of disease after receiving 3 years of adjuvant hormone therapy	T. Bachelot	III	1,984
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	S. Rivera	III	1,265
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	A. Fourquet	II	666
Breast and Ovary	UCBG	ONCO 04 - TUMOSPEC	Investigation of tumour spectrum, penetrance and clinical utility of germline mutations in new breast and ovarian cancer susceptibility genes	O. Caron	Cohort	500
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)	V. Boige	II	140
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	T. 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	J. Bennouna	III	640
Colorectal, Ovary, Melanoma, Lung, Kidney, Breast	MED PERSO	EXPRESS	Molecular characterization of patients with solid tumors who presented an exceptional response to targeted therapies	O. Le Saux	Cohort	264

TUMOUR LOCALISATION(S)	EXPERT GROUP(S)	STUDY SHORT TITLE	STUDY TITLE	STUDY COORDINATOR	PHASE	NUMBER OF EXPECTED PATIENTS
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	E. Samalin	II	154
Germ cells	GETUG	GETUG AFU-27 / ALLIANCE A031102 TIGER	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 Salvage Treatment in Relapsed or Refractory Germ Cell Tumors	A. Fléchon	III	40
Germ cells	SDS	QUALI-TESTIS	Ancillary study of GETUG 13 (Strategy adapted to the prognosis for the use of dose-dense chemotherapy in patients with disseminated non-seminomatous germ tumors of poor prognosis: phase III trial)	F. Joly	III	130
Head & Neck	UCH&N	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)	L. Licitra	II	40
Head & Neck	UCH&N	ORL 10 - IMMUNEBOOST 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	H. Mirghani	II	61
Lung	UNITRAD	NIRVANA-LUNG	PD-(L)1 inhibitors with concurrent irradiation at varied tumour sites in advanced non small cell lung cancer	J. Doyen	III	510
Lung, Head and Neck	GIO	CHECK'UP	Prospective cohort study to identify the predictive factors of response to PD-1 or PD-L1 antagonists	F. 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	S. Thureau	III	196
Melanoma	UNITRAD	BECOME-MB	Phase 2 randomised trial testing the addition of stereotactic radiosurgery to binimetinib and encorafenib in comparison with binimetinib and encorafenib alone in patients with BRAFV600 mutation-positive melanoma with brain metastasis	P. Saiag	II	150
Melanoma, Penis, Kidney, Head & Neck	GIO	AcSé Nivolumab	Secured access to nivolumab for adult patients with selected rare cancer types	A. Marabelle	II	300
Oesophageal	UCGI	PRODIGE 67 - UCGI 33- ARION	Association of Radiochemotherapy and Immunotherapy for the treatment of unresectable Oesophageal caNcer: a comparative randomized phase II trial	A. Modesto	II	120
Ovary	FEDEGYN / UCGI	FEDEGYN 02 - CHIPOR	Randomized phase III study evaluating hyperthermic intraperitoneal chemotherapy in the treatment of ovarian cancer relapse	J-M. Classe	III	444
Ovary, Head & Neck	GIO	AcSé Pembrolizumab	Secured access to pembrolizumab for patients with selected rare cancer types	C. Massard	II	350
Pancreatic	UCGI	UCGI 26 / PRODIGE 29 - NEOPAN	A Randomized phase III trial comparing chemotherapy with folfirinox to gemcitabine in locally advanced pancreatic carcinoma	M. Ducreux	III	170

TUMOUR LOCALISATION(S)	EXPERT GROUP(S)	STUDY SHORT TITLE	STUDY TITLE	STUDY COORDINATOR	PHASE	NUMBER OF EXPECTED PATIENTS
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	C. De La Fouchardière	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	J. Rigaud	II	37
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	S. Supiot	III	490
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 randomized study	G. Roubaud	II	40
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	P. Blanchard	III	350
Prostate	GETUG	GETUG-AFU 28 TACTIK	Personalized treatment of metastatic castrate-resistant prostate cancer patients according to circulating tumor cells kinetic during chemotherapy	S. Culine	II	396
Prostate	GETUG	GETUG-AFU 23 PEACE 2	A randomized Phase III, factorial design, of cabazitaxel and pelvic radiotherapy in patients with localized prostate cancer and high-risk features of relapse	K. Fizazi	III	1,048
Prostate	GETUG	GETUG-AFU 29-EORTC 1333 PEACE 3	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	Y. Loriot	III	75
Prostate	GETUG	GETUG-AFU 34 PROMET	PROMET - Multicenter, Randomized Phase II Trial of Salvage Radiotherapy +/- Metformin for Patients with Prostate Cancer after Prostatectomy	A. Dal Pra	II	106
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 occurrence after external radiation therapy	D. Pasquier	I/II	47
Prostate, Breast, Head & Neck, Uterus	GEP / GIO	MOVIE	A phase I/II basket trial evaluating a combinaition of Metronomic oral vinorelbine plus antiPD1/PDL1 immunotherapy in patients with advanced solid tumors	A. Goncalves	I/II	159
Solid tumours	SDS	QUALIOR	Feasibility and efficacy of standardized APA in patients receiving oral therapy for metastatic cancer	F. Joly	HPS	120

Trials in follow-up phase in 2019

TUMOUR LOCALISATION(S)	EXPERT GROUP(S)	STUDY SHORT TITLE	STUDY TITLE	STUDY COORDINATOR	PHASE	NUMBER OF INCLUDED PATIENTS
Biliary tract	UCGI	ACCORD 18 / PRODIGE 12	Phase III multicentre randomized study comparing the effect of adjuvant chemotherapy for six months with gemcitabine-oxaliplatin 85 mg/m2 (GEMOX 85) to observation in patients who underwent surgery for cancer of the bile ducts	J. Edeline	III	196
Bone sarcoma	SARCOMA	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	L. Brugières	III	653
Breast	GEP / UCBG	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 factors	M-A. Mouret-Reynier	II	86
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	E. Brain	III	1,089
Breast	MED PERSO	RUBY	A phase II study to assess the efficacy of rucaparib in metastatic breast cancer patients with a BRCAness genomic signature	A. Patsouris	II	41
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	T. Bachelot	Cohort	150
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	F. André	II	1,462
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	P-H. Cottu	II	125
Breast	UCBG	ULTIMATE	ULTIMATE trial: UnLock The IMmune cells ATtraction in ER+ breast cancers	F. André	II	61
Breast	UCBG	CANTO	A cohort to quantify and to predict treatment related chronic toxicities in patients with non-metastatic breast cancer	F. André	Cohort	12,012
Breast	UCBG	PADA-1	Randomized, open label, multicentric phase III trial comparing the efficacy and safety of PALBOCICLIB PLUS FULVESTRANT ***versus*** PALBOCICLIB PLUS LETROZOLE in hormone receptor-positive, HER2-NEGATIVE metastatic breast cancer patients receiving LETROZOLE and PALBOCICLIB and who display detectable ESR1 mutations in circulating tumor DNA	F-C. Bidard	III	1,012
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	J-Y. Pierga	Cohort	510
Breast	UCBG	PACS 08	Randomized open label multicentric phase III trial evaluating the benefit of 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	M. Campone	III	762
Breast	UCBG	IBIS II	International randomized double-blind controlled trial comparing adjuvant Tamoxifen with Anastrozole in treating postmenopausal women with Ductal Carcinoma In Situ	C. Levy	III	426
Breast	UCBG	ONCO 03 LIBER	Prevention of breast cancer by letrozole in post-menopausal women carrying a BRCA1/BRCA2 mutation	P. 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	A. Fourquet	III	726
Breast	UCBG	RTS 02 - 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	Y. Belkacemi	III	1,006
Breast	UCBG	PACS 07 - 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	S. Delaloge	III	2,066
Colorectal	UCGI	ACCORD 22 / PRODIGE 18	Phase II, multicentric randomized trial, evaluating the efficacy of fluoropyrimidine-based standard chemotherapy, associated to either cetuximab or bevacizumab, in KRAS wild-type metastatic colorectal cancer patients with progressive disease after receiving first-line treatment with bevacizumab	J. Bennouna	II	132
Colorectal	GERICO	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	E. François	III	84
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	V. Boige	II	214
Colorectal	UCGI	UCGI 23 / PRODIGE 23	Randomized phase III study comparing preoperative chemoradiotherapy alone ***versus*** neoadjuvant chemotherapy with folfirinox regimen followed by preoperative chemoradiotherapy for patients with resectable locally advanced rectal cancer	T. Conroy	III	461
Colorectal	UCGI	ACCORD 21 / PRODIGE 14 (METHEP)	Phase II multicentric randomized trial, evaluating the best protocol of chemotherapy, associated with targeted therapy according to the tumor KRAS status, in metastatic colorectal cancer (CCRM) patients with initially non-resectable hepatic metastases	M. Ychou	II	256
Bone sarcoma	SARCOMA	SARCOME 01 / EUROEWING 99	Ewing's tumor treatment protocol: randomized trials with comparison of consolidation chemotherapy including a medico-economic evaluation	N. Gaspar	II	1,135
Germ cells	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	K. Fizazi	III	203
Head & Neck	UCH&N	ORL 02 - PACSA	Phase II study of pazopanib in patients with recurrent and /or metastatic salivary gland carcinoma of the head and neck	J. Guigay	II	77
Head & Neck	UCH&N	ORL 06 - COPAN	Phase Ib/II trial of copanlisib, a selective PI3K inhibitor, in combination with cetuximab in patients with recurrent and/ or metastatic (R/M) head and neck squamous cell carcinoma (HNSCC)	C. Le Tourneau	I/II	11
Head & Neck	UCH&N	ORL 09 - TOPNIVO	A Safety study of Nivolumab in Patients with Recurrent and/or Metastatic Platinum-refractory Squamous Cell Carcinoma of the Head and Neck (SCCHN)	C. Even	II	351
Head & Neck	UCH&N	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	J. Fayette	II	98
Kidney	GETUG	GETUG-AFU 24	Prospective phase II study of Gemcitabine plus platinium salt in combination with bevacizumab (Avastin®) for metastatic collecting duct carcinoma	C. 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 After Prior Systemic Anti-Angiogenic Regimen	B. Escudier	II	729
Lung	MED PERSO	SAFIR 02 LUNG	Evaluation of the efficacy of high throughput genome analysis as a therapeutic decision tool for patients with metastatic non-small cell lung cancer	F. Barlesi	II	999

TUMOUR LOCALISATION(S)	EXPERT GROUP(S)	STUDY SHORT TITLE	STUDY TITLE	STUDY COORDINATOR	PHASE	NUMBER OF INCLUDED PATIENTS
Pancreatic	UCGI	ACCORD 24 / PRODIGE 24	Multicentric randomized phase III trial comparing adjuvant chemotherapy with gemcitabine ***versus*** 5-fluorouracil, leucovorin, irinotecan and oxaliplatin (mFolfirinox) in patients with resected pancreatic adenocarcinoma	T. Conroy	III	493
Peritoneal	UCGI	ACCORD 15 / PRODIGE 07	Phase III study evaluating the uise of systemic chemotherapy and ChemoHyperthemia Intraperitoneal Preoperatively (CHIP) and after maximum resection of peritoneal carcinomatosis originating with colorectal cancer	F. Quenet	III	264
Prostate	GEP / GETUG	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	S. Supiot	I/II	47
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	S. Guérif	II	125
Prostate	GETUG	GETUG 06	Conformal curative radiotherapy of cancer located in the prostate (N0, N-): A multicentric phase III study of the contribution to survival without biological or clinical evolution of a dose increase of 15% (80 Gy ***VERSUS*** 70 Gy)	V. Beckendorf	III	306
Prostate	GETUG	GETUG 12	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	K. Fizazi	III	413
Prostate	GETUG	GETUG 14	Multicentric randomized study evaluating the efficacy of a short hormone therapy prior to and concomitant with an exclusive conformal radiotherapy with curative aim for cancer localized to the prostate with intermediate prognosis	B. Dubray	III	378
Prostate	GETUG	GETUG-AFU 16 PRRAP	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	C. Carrie	III	743
Prostate	GETUG	GETUG-AFU 17	Randomized, multicentre study comparing the immediate adjuvant radiotherapy associate with hormonal therapy of LH-RH analogue (decapeptyl® LP) ***vs*** delayed radiotherapy until biochemical relapse associated with hormonal therapy of LH-RH analogue (decapeptyl® LP) in patients with operable prostate cancer pT3 R1 pN0 or pNx at intermediate risk	P. 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	C. 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	F. Rozet	III	325
Prostate	GETUG	GETUG-AFU 21 PEACE 1	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	K. Fizazi	III	1,173
Soft tissue sarcoma	SARCOMA	SARCOME 11 / LMS03	Multicentric phase II study evaluating the efficacy of Gemcitabine in combination with Pazopanib as a second-line treatment for uterine leiomyosarcomas or metastatic or relapsed soft tissue carcinoma	P. Pautier	II	106
Solid tumours	MED PERSO	ACSE VEMU	Secured access to vemurafenib for patients with tumors harboring BRAF genomic alterations	J-Y. Blay	II	216
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	G. Vassal	II	246
Solid tumours	SDS	CYPRES	Patients Consensus for Supportive Care Research	A. Anota	HPS	631
Uterus	FEDEGYN / UCGI	FEDEGYN 01 -PORTEC 3	Randomized phase III trial comparing concurrent chemoradiation and adjuvant chemotherapy with pelvic radiation alone in high risk and advanced stage endometrial carcinoma: PORTEC-3	C. Haier-Meder	III	63

2019 publications

GROUP	STUDY	TITLE	FIRST AUTHOR	REFERENCES
UCBG (breast)	CANTO	Differential impact of endocrine therapy and chemotherapy on quality of life of breast cancer survivors: a prospective patient reported outcomes (PRO) analysis	A-R. Ferreira	Ann Oncol. 2019 Oct 8
UCBG (breast)	CANTO	Association of body mass index and cardiotoxicity related to anthracyclines and trastuzumab in early breast cancer: a multicenter, prospective cohort study	E. Kaboré	PLoS Med. 2019 Dec 23; 16(12): e1002989
UCBG (breast)	CANTO	Impact of Breast Cancer Treatment and its Physical and Psychological Late Effects on Employment – Results of a Multicenter Prospective Cohort Study (CANTO)	A. Dumas	J Clin Oncol. 2019 Dec 13: JCO1901726
UCBG (breast)	PACS04	Association between FGFR1 copy numbers, MAP3K1 mutations and distant metastasis in axillary node-positive, hormone receptor-positive and HER2-negative early breast cancer in the PACS04 and METABRIC Studies	D. Carene	Breast Cancer Res Treat. 2019 Oct 16
UCBG (breast)	PACS04	Disease-free survival as a surrogate for overall survival in adjuvant therapy of HER-2-positive, early breast cancer	E-D. Saad	Lancet Oncol. 2019 Mar; 20(3): 361-370
UCBG (breast)	PACS04 PACS05	Individualized Prediction of Menses Recovery After Chemotherapy for Early-stage Breast Cancer: A Nomogram Developed From Unicancer PACS04 and PACS05 Trials	B. Pistilli	Clin Breast Cancer. 2019 Feb; 19(1): 63-70
UCBG (breast)	PACS04	UCBG 2-04: Long-term results of the PACS 04 trial evaluating adjuvant epirubicin plus docetaxel in node-positive breast cancer and trastuzumab in the human epidermal growth factor receptor 2-positive subgroup	V. D'Hondt	Eur J Cancer. 2019 Nov; 122: 91-100
UCBG (breast)	TRANSPACS04	Tumor-Infiltrating Lymphocytes and Prognosis: A Pooled Individual Patient Analysis of Early-Stage Triple-Negative Breast Cancers	L. Sherene	J Clin Oncol. 2019 Jan 16: JCO1801010
UCBG (breast)	TRANSPACS08	Identification of three subtypes of triple-negative breast cancer with potential therapeutic implications	P. Jezequel	Breast Cancer Res. 2019 May 17; 21(1): 65
UCBG (breast)	TRANSPACS08	Regulation of Senescence Escape by the TSP1-CD47 Pathway Following Chemotherapy Treatment	J. Guillon	Cell Death Dis. 2019 Mar; 10(3): 199 Epub 2019 Feb 27
GETUG (urogenital)	GETUG-AFU 16	Short-term androgen deprivation therapy combined with radiotherapy as salvage treatment after radical prostatectomy for prostate cancer (GETUG-AFU 16): a 112-month follow-up of a phase 3, randomised trial	C. Carrie	Lancet Oncol. 2019 Oct 16
GETUG (urogenital)	GETUG-AFU 26 - NIVOREN	Vitiligo adverse event observed in a patient with complete response after nivolumab for metastatic renal cell carcinoma	E. Billon	Front. Oncol., 09 October 2019
GETUG (urogenital)	GETUG-AFU 26 - NIVOREN	Safety and Efficacy of Nivolumab in Brain Metastases From Renal Cell Carcinoma: Results of the GETUG-AFU 26 NIVOREN Multicenter Phase II Study	R. Flippot	J Clin Oncol. 2019 Aug 10; 37(23): 2008-2016

GROUP	STUDY	TITLE	FIRST AUTHOR	REFERENCES
GETUG (urogenital)	GETUG-AFU 31 - STEREO REPRO	GETUG-AFU 31: a phase I/II multicentre study evaluating the safety and efficacy of salvage stereotactic radiation in patients with intraprostatic tumour recurrence after external radiation therapy-study protocol	D. Pasquier	BMJ Open. 2019 Aug 2; 9(8): e026666
UCGI (gastrointestinal)	ACCORD 18 - PRODIGE 12	Gemcitabine and Oxaliplatin Chemotherapy or Surveillance in Resected Biliary Tract Cancer (PRODIGE 12-ACCORD 18-Unicancer GI): A Randomized Phase III Study	J. Edeline	J Clin Oncol. 2019 Feb 1: JCO1800050
UCGI (gastrointestinal)	ACCORD 20 - PRODIGE 17	FOLFOX alone or combined with rilotumumab or panitumumab as first-line treatment for patients with advanced gastroesophageal adenocarcinoma (PRODIGE 17-ACCORD 20-MEGA): a randomised, open-label, three-arm phase II trial	D. Malka	Eur J Cancer. 2019 Jul; 115: 97-106
UCGI (gastrointestinal)	ACCORD-12/PRODIGE-2	Impact of single-nucleotide polymorphisms in DNA repair pathway genes on response to chemoradiotherapy in rectal cancer patients: Results from ACCORD-12/PRODIGE-2 phase III trial	V. Boige	Int J Cancer. 2019 Dec 1; 145(11): 3163-3172 Epub 2019 May 31
UCGI (gastrointestinal)	ACCORD 21 - PRODIGE 14	Circulating Tumor Cells and Circulating Tumor DNA Detection in Potentially Resectable Metastatic Colorectal Cancer: A Prospective Ancillary Study to the Unicancer Prodige-14 Trial	F-C. Bidard	Cells. 2019 May 28; 8(6)
UCGI (gastrointestinal)	UCGI 29 IROCAS - PRODIGE 52	Rationale and Design of the IROCAS Study: Multicenter, International, Randomized Phase 3 Trial Comparing Adjuvant Modified (m) FOLFIRINOX to mFOLFOX6 in Patients With High-Risk Stage III (pT4 and/or N2) Colon Cancer-A Unicancer GI-PRODIGE Trial	J. Benounna	Clin Colorectal Cancer. 2019 Mar; 18(1): e69-e73 Epub 2018 Oct 19
UCGI (gastrointestinal)	ACCORD 22 - PRODIGE 18	Continuation of Bevacizumab ***vs*** Cetuximab Plus Chemotherapy After First Progression in KRAS Wild-Type Metastatic Colorectal Cancer: The Unicancer PRODIGE18 Randomized Clinical Trial	J. Bennouna	JAMA Oncol. 2019 Jan 1; 5(1): 83-90
UCHN (Head & Neck)	HPV-ORO - ORL-01	Prevalence and characteristics of HPV-driven oropharyngeal cancer in France	H. Mirghnai	Cancer Epidemiol. 2019 Aug; 61: 89-94 Epub 2019 May 31
UC Sarcoma	SARCOME 12- REGOBONE	Efficacy and safety of regorafenib in adult patients with metastatic osteosarcoma: a non-comparative, randomised, double-blind, placebo-controlled, phase 2 study	F. Duffaud	Lancet Oncol. 2019 Jan; 20(1): 120-133
UC Personalised medicine	SAFIR	Genomic characterization of metastatic breast cancers	F. Bertucci	Nature. 2019 Aug; 572(7767): E7
UC Personalised medicine	AcSé VEMURAFEMIB	Persistent response to vemurafenib in metastatic ameloblastoma with BRAF mutation: a case report	M. Broudic-Guibert	Journal of Medical Case Reports (2019) 13:245
UC Personalised medicine	AcSé CRIZOTINIB	Crizotinib in c-MET- or ROS1-positive NSCLC: results of the AcSé phase II trial	D. Morot-Sibilot	Ann Oncol. 2019 Dec 1; 30(12): 1985-1991
UC Personalised medicine	SAFIR01-SAFIR02-RUBY	Genomic expertise in action: molecular tumour boards and decision-making in precision oncology	P. Bourret	Sociol Health Illn. 2019 Jun 13

GROUP	STUDY	TITLE	FIRST AUTHOR	REFERENCES
GGC (Oncogenetics)	GENEPSO	Alcohol consumption, cigarette smoking, and risk of breast cancer for BRCA1 and BRCA2 mutation carriers: results from The BRCA1 and BRCA2 Cohort Consortium	H. Li	Cancer Epidemiol Biomarkers Prev. 2020 Feb; 29(2): 368-378 Epub 2019 Dec 2
GGC (Oncogenetics)	N/A	Parental disclosure of positive BRCA1/2 mutation status to children 10 years after genetic testing	J. Troian	Psychology, Health & Medicine (CPHM) Article ID: CPHM 1659981
GGC (Oncogenetics)	N/A	Uptake of genetic counseling among adult children of BRCA1/2 mutation carriers in France	F-B. Gauna Christaldo	Psycho-Oncology 2019; 1-7
GGC (Oncogenetics)	GENESIS	Familial breast cancer and DNA repair genes: insights into known and novel susceptibility genes from the GENESIS study, and implications for multigene panel testing	E. Girard	International Journal of Cancer 2019; 144: 1962-1974
GGC (Oncogenetics)	N/A	Cancer Risks associated with germline PALB2 pathogenic variants : an international study of 524 families	X. Yang	J Clin Oncol 38; 2019
GGC (Oncogenetics)	N/A	Combining Homologous Recombination and Phosphopeptide-binding Data to Predict the Impact of BRCA1 BRCT Variants on Cancer Risk	A. Petitalot	Mol Cancer Research 2019, 17: 54-69
GPCO (clinical oncopharmacology)	N/A	Dihydropyrimidine dehydrogenase deficiency screening for management of patients receiving a fluoropyrimidine: Results of two national practice surveys addressed to clinicians and biologists	M-A. Loriot	Bull Cancer. 2019 Sep; 106(9): 759-775
ESME (real-world data)	ESME MBC	Treatment and outcomes in patients with central nervous system metastases from breast cancer in the real-life ESME MBC cohort	D. Pasquier	Eur J Cancer Oxf Engl 1990. 2019 Dec 10; 125: 22–30
ESME (real-world data)	ESME MBC	Impact of breast cancer molecular subtypes on the incidence, kinetics and prognosis of central nervous system metastases in a large multicentre real-life cohort	A. Darlix	Br J Cancer. 2019 Nov 13
ESME (real-world data)	ESME MBC	CinéBreast-factors influencing the time to first metastatic recurrence in breast cancer: Analysis of real-life data from the French ESME MBC database	P. Gougis	Breast. 2019 Oct 19; 49: 17-24
ESME (real-world data)	ESME MBC	Cost-effectiveness of bevacizumab plus paclitaxel ***versus*** paclitaxel for the first-line treatment of HER2-negative metastatic breast cancer in specialist oncology centers in France	A. Petitjean	BMC Cancer. 2019 Feb 11; 19(1): 140
ESME (real-world data)	ESME MBC	Assessment of the efficacy of successive endocrine therapies in hormone receptor-positive and HER2-negative metastatic breast cancer: a real-life multicentre national study	O. Le Saux	Eur J Cancer. 2019 Sep; 118: 131-141
ESME (real-world data)	ESME MBC	The ongoing French metastatic breast cancer (MBC) cohort: the example-based methodology of the Epidemiological Strategy and Medical Economics (ESME)	D. Perol	BMJ Open. 2019; 9: e023568-e023568
ESME (real-world data)	ESME MBC	Real-life activity of eribulin mesylate among metastatic breast cancer patients in the multicenter national observational ESME program	W. Jacot	Int J Cancer. 2019 May 14; ijc.32402

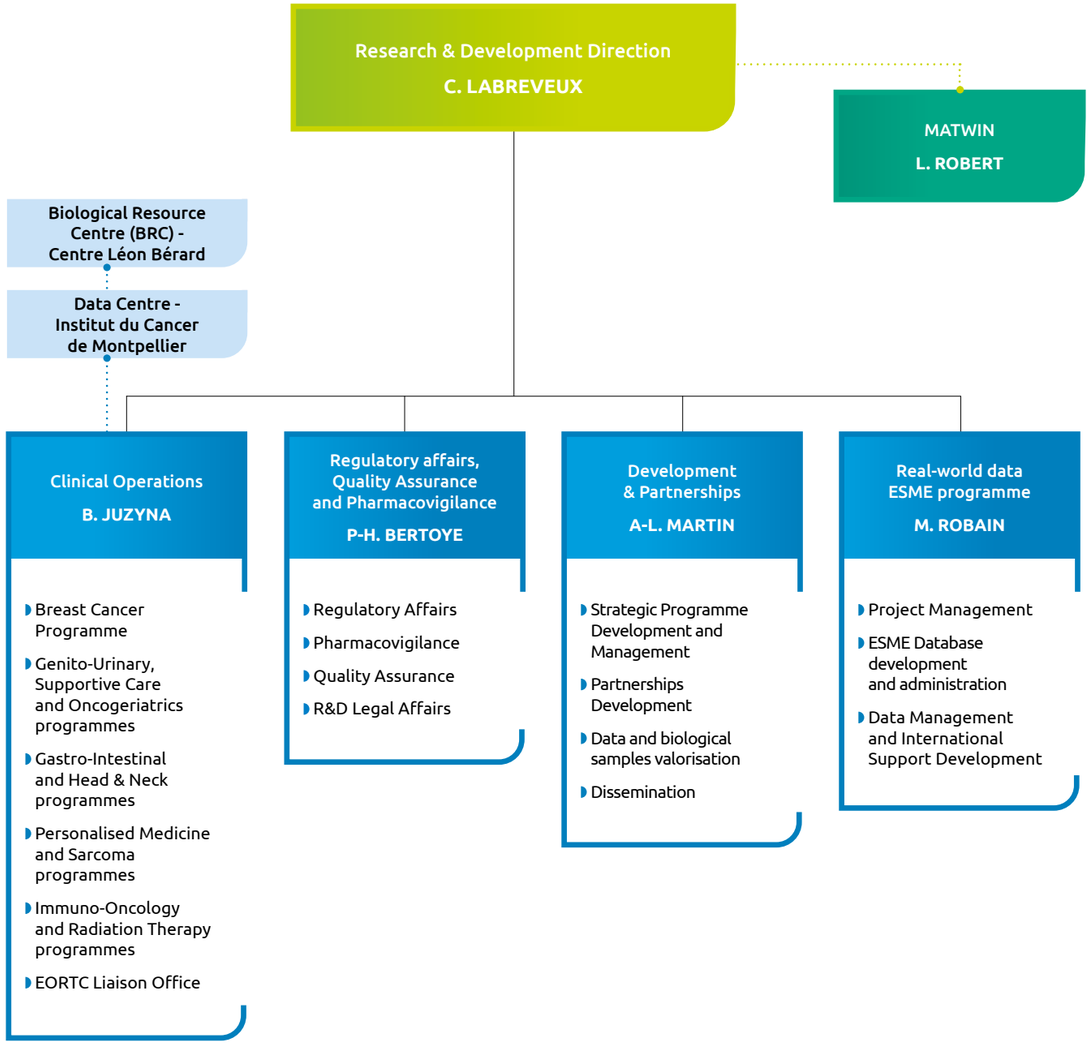
2019 communications

GROUP	STUDY	CONGRESS	TITLE	FIRST AUTHOR	TYPE OF PRESENTATION
UCBG (breast)	CANTO	ASCO	High temporal variability of clinical side effects with and without adjuvant chemotherapy in 4684 early breast cancer patients in the CANTO trial	P. Cottu	Poster session
UCBG (breast)	CANTO	ASCO	Cognitive impairment in breast cancer patients before surgery? Results of a subgroup of the French CANTO cohort	M. Lange	Poster session
UCBG (breast)	CANTO	ASCO	Return to work after breast cancer: comprehensive longitudinal analyses of its determinants	A. Dumas	Poster session
UCBG (breast)	CANTO	ASCO	Prediction of Treatment (tx)-Induced Fatigue in Breast Cancer (BC) patients (pts) using Machine Learning on Genome Wide Association (GWAS) Data in the prospective CANTO cohort	L. Sangkyu	Oral session
UCBG (breast)	CANTO	ASCO	Differential impact of endocrine therapy (ET) and chemotherapy (CT) on quality of life (QoL) of 4262 breast cancer (BC) survivors: a prospective patient reported outcomes (PRO) analysis	R. Arlindo	Poster discussion
UCBG (breast)	CANTO	ASCO	Impact of overweight, obesity and post-treatment weight changes on occupational reintegration of breast cancer (BC) survivors	A. Di Meglio	Poster session
UCBG (breast)	GRT02-COMET	ASCO	Multimodality liquid biopsy for early monitoring and outcome prediction in first line metastatic HER2 negative breast cancer: final results of the prospective cohort from the French Breast Cancer InterGroup Unicancer (UCBG): COMET study	J-Y. Pierga	Poster discussion
UCBG (breast)	MyPeBS	Congrès du collège des humanités médicales (Colhum)	De la concertation citoyenne et professionnelle sur le dépistage du cancer du sein à l'implication des SHS dans un essai clinique de dépistage stratifié du cancer du sein	S. De Montgolfier	Oral session
UCBG (breast)	CANTO	ESMO	Baseline quality of life (QoL) and chemotherapy related toxicities (CRT) in localized breast cancer (BC) patients (pts): The French multicentric prospective CANTO cohort study	I. Licaj	Poster session
UCBG (breast)	PACS04	ESMO	Long-term results of the PACS 04 trial evaluating adjuvant Epirubicin plus Docetaxel in node-positive breast cancer and Trastuzumab in the HER2-positive subgroup	V. D'Hondt	Poster discussion
UCBG (breast)	PADA-1	ESMO	Emergence of ESR1 mutation in cell-free DNA during first line aromatase inhibitor and palbociclib: an exploratory analysis of the PADA-1 trial	F.C. Bidard	Poster discussion
UCBG (breast)	CANTO	ESMO BREAST	Impact of tamoxifen (TAM) serum concentration on side effects among premenopausal patients (pts) with early breast cancer (BC) in the prospective multicenter CANTO cohort	A-R. Ferreira	Oral session
UCBG (breast)	PERNETTA	ESMO BREAST	Pertuzumab (P) + trastuzumab (T) with or without chemotherapy both followed by T-DM1 in case of progression in patients with HER2-positive metastatic breast cancer (MBC) - The PERNETTA trial (SAKK 22/10), a randomized open label phase II study (SAKK, Unicancer, BOOG)	J. Huober	Oral session
UCBG (breast)	CANTO	European public Heath Conference (EPH)	Employment two years after breast cancer diagnosis: the role of household characteristics. Evidence from the CANTO cohort	E. Caumette	Oral session
UCBG (breast)	CANTO	SABCS	Health related quality of life at the end of acute treatments for early stage breast cancer patients	O. Billa	Poster session
UCBG (breast)	CANTO	SABCS	Impact of chemotherapy on the health related quality of life among elderly patients with localized breast cancer: Findings from the prospective CANTO cohort	S. Dabakuyo	Poster session
UCBG (breast)	CANTO	SABCS	Lifestyle changes after breast cancer: A prospective study among 8580 women	A. Dimeglio	Poster session
UCBG (breast)	PADA-1	SABCS	Clinical and biological efficacy of first line AI and palbociclib in ER+ HER2- MBC with detectable circulating ESR1mutation prior to treatment initiation	F-C. Bidard	Poster session
GETUG (urogenital)	GETUG-AFU 37 ALBAN	ASCO	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 nonmuscle invasive bladder cancer (AFU-GETUG 37)	M. Roupret	Poster session
GETUG (urogenital)	GETUG-AFU 16	ASCO	Interest of short hormonotherapy (HT) associated with radiotherapy (RT) as salvage treatment for metastatic free survival (MFS) after radical prostatectomy (RP): Update at 9 years of the GETUG-AFU 16 phase III randomized trial (NCT00423475)	C. Carrie	Poster session
GETUG (urogenital)	GETUG 22	ASTRO	Late toxicity and quality of life from GETUG-AFU 22 study: a multicenter randomized phase II trial comparing 6 months of DEGARELIX in combination with radiotherapy to radiotherapy alone as a salvage treatment for patients with detectable PSA after radical prostatectomy	I. Latorzeff	Poster discussion
GETUG (urogenital)	GETUG 17-ARTISTIC	ESMO	Adjuvant or salvage radiotherapy for the treatment of localised prostate cancer? A prospectively planned aggregate data meta-analysis (133)	C-L. Vale	Oral session
GETUG (urogenital)	GETUG 26-NIROVEN	ESMO	NIVOREN GETUG-AFU 26 translational study: CD8 infiltration and PD-L1 expression are associated with outcome in patients (pts) with metastatic clear cell renal cell carcinoma (mccRCC) treated with nivolumab (N)	Y. Vano	Poster session

GROUP	STUDY	CONGRESS	TITLE	FIRST AUTHOR	TYPE OF PRESENTATION
GETUG (urogenital)	NIROVEN	ESMO	Fresh blood Immune cell monitoring in patients treated with nivolumab in the GETUG-AFU26 NIVOREN study: association with toxicity and treatment outcome	A. Desnoyer	Poster discussion
UCGI (gastro-intestinal)	PRODIGE 53-UCGI 30 SULTAN	ASCO	PRODIGE 53-UCGI 30 (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	V. Boige	Poster session
UCGI (gastro-intestinal)	PRODIGE 67-UCGI33-ARION	ESMO	PRODIGE67_UCGI33 ARION: Association of Radiochemotherapy and Immunotherapy for the treatment of unresectable Oesophageal reatment of unresectable Oesophageal caNcer: A comparative randomized phase II trial	R. Guimbaud	Poster session
UCGI (gastro-intestinal)	REGIRI	ESMO GI	Regorafenib combined with irinotecan as second-line treatment in patients with metastatic gastro-oesophageal adenocarcinomas: A randomized phase 2 trial (PRODIGE 58 – UCGI 35 – REGIRI)	E. Samalin	Poster Trial in progress
UCGI (gastro-intestinal)	PRODIGE 24 - ACCORD 24	JFHOD	Essai multicentrique international contrôlé et randomisé de phase III adjuvant comparant le mFOLFIRINOX à la gemcitabine (gem) chez des patients présentant un adénocarcinome pancréatique réséqué (Essai PRODIGE 24-Unicancer GI / NCIC PA.6)	J-B. Bachet	Plenary session
UCGI (gastro-intestinal)	PRODIGE 7 - ACCORD 15	JFHOD	La chimio-hyperthermie intra-péritonéale per-opératoire (CHIP) dans le traitement de la carcinose péritonéale d'origine colorectale : une étude multicentrique française de phase III randomisée, PRODIGE7	F. Quenet	Oral session
UCHN (Head & Neck)	NISCAHN-ORL08	ASCO	NISCAHN: A Phase II, multicenter nonrandomized trial aiming at evaluating Nivolumab (N) in two cohorts of patients (pts) with recurrent/metastatic (R/M) salivary gland carcinoma of the head and neck (SGCHN), on behalf of the Unicancer Head & Neck Group	J. Fayette	Poster session
UCHN (Head & Neck)	TOPNIVO-ORL09	ASCO	A safety study of nivolumab in patients with recurrent and/or metastatic platinum-refractory squamous cell carcinoma of the head and neck (R/M SCCHN): Interim analysis on 199 patients—The TOPNIVO study on behalf of the GORTEC and the Unicancer Head & Neck Group	C. Even	Poster session
UC Sarcoma	SARCOME 12 / REGOBONE	ESMO	Results of the randomized, Placebo (PL)-controlled Phase II study evaluating the efficacy and safety of Regorafenib (REG) in patients (pts) with locally advanced (LA) or metastatic relapsed Chondrosarcoma (CS), on behalf of the French Sarcoma Group (FSG) and Unicancer	F. Duffaud	Oral session
Med Perso (personalised medicine)	SAFIR02 Breast	AACR	Natural history and outcome of patients presenting a metastatic breast cancer with PIK3CA mutation	F. Mosele	Poster session
Med Perso (personalised medicine)	EXPRESS	ASCO	EXPRESS study - A Multicenter, Prospective Trial In Progress Exploring The Association Between Low Level Of Genomic Alteration And Exceptional And Unexpected Response To Targeted Therapies In Patients With Solid Tumors	O. Le Saux	Poster session
Med Perso (personalised medicine)	SAFIR-TOR	ASCO	mTORC1 activation assessed in metastatic sample to predict outcome in patients with metastatic breast cancer treated with everolimus-exemestan: Results from the SAFIRTOR study	T. Bachelot	Poster discussion
Med Perso (personalised medicine)	AcSé VEMURAFENIB	ESMO	Circulating tumor DNA analysis depicts potential mechanisms of resistance to BRAF-targeted therapies in BRAF-mutant non-small cell lung cancer	S. Ortiz-Cuaran	Poster session
Med Perso (personalised medicine)	SAFIR02 Breast	ESMO	Detection of PIK3CA mutation by circulating DNA during chemotherapy: A tool to identify hard-to-treat metastatic breast cancers	F. Mosele	Poster session
Med Perso (personalised medicine)	SAFIR02 Breast	ESMO Breast	Outcome and mutational landscape of patients with PIK3CA-mutated metastatic breast cancer (mBC)	F. Mosele	Oral session
Med Perso (personalised medicine)	SAFIR02-IMMUNO	SABCS	GS3-02. Durvalumab compared to maintenance chemotherapy in patients with metastatic breast cancer: Results from phase II randomized trial SAFIR02-IMMUNO	F. Dalenc	Oral session
Med Perso (personalised medicine)	AcSé VEMURAFENIB	WCLC 2019	Circulating tumor DNA analysis depicts potential mechanisms of resistance to BRAF-targeted therapies in BRAF-mutant non-small cell lung cancer	S. Ortiz-Cuaran	Oral session
GIO (immuno-oncology)	AcSé NIVOLUMAB	ESMO	High level of activity of Nivolumab anti-PD-1 immunotherapy and favorable outcome in metastatic/ refractory MSI-H non-colorectal cancer: Results of the MSI cohort from the French AcSé program	C. Tournigand	Poster session
GIO (immuno-oncology)	AcSé PEMBROLIZUMAB	ESMO	High clinical benefit rates of pembrolizumab in very rare sarcoma histotypes: first results of the AcSé Pembrolizumab study	J-Y. Blay	Poster session
GGC (genetics)	N/A	EHTG	National recommendations of the French Genetics Cancer Group - Unicancer on the modalities of multi-gene panel analyses in hereditary predispositions to tumours of the digestive tract	C. Colas	Oral session
GGC (genetics)	N/A	JFHOD	Recommandations nationales du Groupe Génétique et Cancer-Unicancer sur les modalités d'analyses en panels multi-gènes dans les prédispositions héréditaires aux tumeurs du tube digestif	M. Dhooge	Poster session
GGC (genetics)	TUMOSPEC	SABCS	Feasibility of a nation-wide family-based study to assess cancer risks in families with a predicted pathogenic variant identified through hereditary breast and ovary multi-gene panel testing: The TUMOSPEC study	O. Caron	Poster session
GGC (genetics)	N/A	SFSPM	Prédisposition héréditaire aux cancers du sein et de l'ovaire : impact clinique des recherches de mutation en panels multigènes actuellement analysés en France	J. Moretta	Oral session
GPCO (clinical oncopharmacology)	N/A	IFCC- EFLM	Prevention of severe toxicity of Fluoropyrimifines-based chemotherapy due to DPD deficiency : external quality evaluation of Uracil and Dyhydrouracil measurements in plasma	F. Thomas	Poster session

GROUP	STUDY	CONGRESS	TITLE	FIRST AUTHOR	TYPE OF PRESENTATION
GPCO (clinical oncopharmacology)	N/A	EQALM	External quality evaluation of Uracil and Dyhydrouracil measurements in plasma for prevention of severe toxicity of Fluoropyrimifines-based chemotherapy due to DPD deficiency	F. Thomas	Poster session
GPCO (clinical oncopharmacology)	N/A	ESMO	FUSAFE individual patient data meta-analysis to assess the performance of dihydropyrimidine dehydrogenase gene polymorphisms for predicting grade 4-5 fluoropyrimidine toxicity	M-C. Etienne-Grimaldi	Poster session
ESME (real-world data)	ESME MBC	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	Poster
ESME (real-world data)	ESME OVR	ESGO	Natural history of patients with BRCA-mutated high grade epithelial ovarian cancer (HGEOC) before the era of PARP inhibitors maintenance in 1st line treatment	C. Roméo	Poster
ESME (real-world data)	ESME MBC	ESMO	Prognostic impact of Body Mass Index (BMI) on overall survival in patients with metastatic breast cancer	K. Saleh	Poster
ESME (real-world data)	ESME MBC	SABCS	Impact of bone-only metastatic breast cancer on outcome in a real-life setting: a comprehensive analysis of 5,041 women from the ESME database	M. Bertho	Poster
ESME (real-world data)	ESME MBC	SABCS	Treatments and outcome in older ***versus*** younger women with HER2-positive metastatic breast cancer in the multicenter national observational ESME database	M. Annonay	Poster
ESME (real-world data)	ESME MBC	SABCS	Prediction of PFS and OS under third and fourth line chemotherapy among metastatic triple-negative breast cancer patients in the national multicenter ESME Metastatic Breast Cancer cohort	L. Cabel	Poster
ESME (real-world data)	ESME NSCLC	ELCC	Real-world treatment patterns, clinical practice and outcomes for locally advanced, non resectable, non-small cell lung cancer from the French ESME Lung database	N. Girard	Poster

Organisational chart



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