R&D ANNUAL REPORT 2018

HUMAN FIRST

INNOVATION

EXCELLENCE

SOLIDARITY

unicancer

Summary

Editorials

CLAIRE LABREVEUX, DIRECTOR OF RESEARCH AND DEVELOPMENT

The continuous growth inspired in recent years by my predecessor Christian Cailliot has paved the way for innovative, complex and ambitious lines of research. My action is entirely in line with the continuity and consolidation of these axes, which give our organisation its status as a pioneer and its position as the leading European academic promoter of clinical trials in oncology.

In keeping with the ambitions of the Cancer Plan and in particular the plan to renew organised breast cancer screening, the MyPeBS study, funded by the European Horizon 2020 programme, aims to assess an earlier and more personalised screening approach based on individual risk factors. This question is important at a time when organized screening reaches only one woman in two and when personalized care and patient support guide the construction of all research programs and the provision of cancer care.

In July 2018, the inclusion of the first patient in the CHECK'UP study aiming to identify, in real-life conditions, the predictive markers of the response to immunotherapy, marks the launch of an innovative and essential study to better prescribe immunotherapies.

The ESMÉ program, with nearly 40 analytical projects implemented in 3 pathologies in all FCCCs and some University Hospital Centres and Hospital Centres, 20 communications in international congresses and the very first publications, is recognized today as a cutting-edge initiative providing high-quality information for epidemiological data and the evaluation of therapeutic strategies.

Throughout this year, our teams have invested to continue, in a dynamic of continuous improvement, to optimize our organization, increase our skills and implement performance indicators which will allow us to better control our activity.
At the same time, achieving the ISO 9001 certification at the end of the year, for all clinical research, signifies international recognition for the level of excellence of the research carried out collectively by the network as well as the effectiveness of our structure.

Our model of networking the competencies of FCCCs and their technical platforms has notably fostered the emergence of our Personalized Medicine Program, along with the development of SAFIR programs and numerous initiatives from centres focused on molecular screening (MOSCATO, SHIVA, PROFILER...). This unique breeding ground combines cutting-edge technology with expert excellence, advances knowledge in precision medicine and has led to the recognition of the quality of our teams' work by the highly prestigious journal Nature.

Finally, considerable work has been done with relation to the legal framework established by the General Data Protection Regulation (GDPR), the complexity of the practical modalities and the conditions of research, which are a major issue in international competition.

At the heart of this dynamic, the values promoted by Unicancer remain more than ever the key-words: excellence, humanism, solidarity, innovation are illustrated in the concrete examples to be discovered in this report.

PATRICE VIENS, PRESIDENT OF UNICANCER

The figures are sufficient to reflect the dynamic progress of our clinical research activity, but 2018 will also have been an exceptional year for the visibility and recognition of Unicancer on the international scene, with real advances for patients and outstanding scientific communications of which we are proud.

The results of the French-Canadian PRODIGE 24-PA-6 study, in particular, were presented orally at ASCO[1] last June and published in the New England Journal of Medicine[2] in December. This study shows a significant decrease in the rate of recurrence in patients taking Folfirinox after pancreatic surgery and imposes the protocol as the new therapeutic standard for adjuvant chemotherapy in these patients. This is a significant step forward that opens up new horizons in the treatment of a cancer that has so far had a bleak prognosis.

Also presented at the ASCO Congress in 2018, the results of the AcSé-crizotinib study show that crizotinib can be effective in cancers other than those for which it is authorised, such as lung cancers with a ROS1 mutation or MET alteration and large cell anaplastic lymphomas in children and adults. These findings have already led to a first extension of the indication for non-small cell lung cancer mutated ROS1 and further extensions of the indications are envisaged.

These examples perfectly reflect the basis and substance of our mission: to foster the emergence of innovation and develop access to rapid innovation, with diagnostic processes which are accessible and available to all, regardless of the modes and places of care.

Finally, I would like to pay tribute to the work of the teams involved in the MyPeBS project who, in an unusual context, were able to deal brilliantly with the implementation difficulties linked to the questioning of practices in the very sensitive area of screening, and to overcome the technical obstacles linked to the international scale of the trial.

These successes reinforce the leading position of Unicancer's R&D in academic clinical cancer research, to which the solid and long-term development of local and international collaborations that we strive to continually establish contributes.

ALEXANDER EGGERMONT, VICE PRESIDENT OF UNICANCER, IN CHARGE OF RESEARCH

Recent discoveries in cancer hold great hopes for all, but also many challenges, including the secure sharing and ethical use of real-life data. These data are a vital source of information for optimizing care and also for defining future health policies.

Our mission cannot be achieved without innovation, which is based on the proper use of these data. Let us hope that the politicians and the legislators, who are rightly looking after it, will be able to deploy it, particularly in the new research areas of Artificial Intelligence and e-health.

Supported by a very high-level healthcare organization where everyone can access the best path available for their pathology, we will work tirelessly to bring out coordinated research forces in order to facilitate the sharing and dissemination of knowledge.

All the disciplines and skills in our network are working hand in hand, pushing the boundaries, to meet these challenges, improve patient care and move forward together towards our goal of defeating cancer.

1. Unicancer GI PRODIGE 24/CCTG PA.6 trial: A multicentre international randomized phase III trial of adjuvant mFOLFIRINOX versus gemcitabine (gem) in patients with resected pancreatic ductal adenocarcinomas. Présentation orale de Pr Thierry Conroy –Institut de Cancérologie de Lorraine, Nancy - Session: Gastrointestinal (Noncolorectal) Cancer. Abstract n° LBA4001: http://abstracts.asco.org/214/AbstView_214_218335.html
2. N Engl J Med. 2018 Dec 20 ;379(25):2395-2406. doi: 10.1056/NEJMoa1809775. FOLFIRINOX or Gemcitabine as Adjuvant Therapy for Pancreatic Cancer.

Éditoriaux

CLAIRE LABREVEUX, DIRECTRICE DE LA RECHERCHE ET DU DÉVELOPPEMENT

La croissance continue insufflée ces dernières années par mon prédécesseur Christian Cailliot a ouvert la voie à des pistes de recherche innovantes, complexes et ambitieuses. Mon action s'inscrit toute entière dans la continuité et la consolidation de ces axes, qui confèrent à notre organisation son statut de pionnier et sa position de premier promoteur académique européen d'essais cliniques en oncologie.

Faisant écho aux ambitions du Plan Cancer et particulièrement au plan de rénovation du dépistage organisé du cancer du sein, l'étude MyPeBS financée par le programme européen Horizon 2020 vise à évaluer une approche de dépistage plus précoce et personnalisée en fonction de facteurs de risques individuels. Cette question est majeure à l'heure où le dépistage organisé n'atteint qu'une femme sur deux et où la personnalisation de l'accompagnement préside à la construction de tous les programmes de recherche et de l'offre de soin en cancérologie.

En juillet 2018, l'inclusion du premier patient dans l'étude CHECK'UP, pour mettre en lumière dans les conditions de la vie réelle, les marqueurs prédictifs de la réponse à l'immunothérapie, marque le coup d'envoi d'une étude inédite et essentielle pour mieux prescrire les immunothérapies.

Le programme ESMÉ, déployé dans 3 pathologies dans l'ensemble des CLCC et certains CHU et CH, est aujourd'hui, avec près de 40 projets d'analyse, 20 communications dans les congrès internationaux et les premières publications, reconnu comme une initiative d'avant-garde d'une grande qualité informative en termes épidémiologiques et pour l'évaluation des stratégies thérapeutiques.

Tout au long de cette année, nos équipes se sont investies pour poursuivre, dans une dynamique d'amélioration continue, une optimisation de notre organisation, augmentation des compétences et la mise en œuvre d'indicateurs de performance permettant de mieux maîtriser notre activité.

Parallèlement, l'obtention en fin d'année de la certification ISO 9001 pour l'ensemble de la recherche clinique signe la reconnaissance, à l'échelle internationale, du niveau d'excellence de la recherche déployée collectivement par le réseau et de l'efficacité de notre structuration.

Le modèle de mise en réseau des compétences des CLCC et de leurs plateaux techniques a notamment favorisé l'émergence de notre programme de médecine personnalisée, avec le développement des programmes SAFIR et de nombreuses initiatives des Centres axées sur le screening moléculaire (MOSCATO, SHIVA, PROFILER…). Ce terreau unique qui allie technologie de pointe et excellence des experts, fait progresser la connaissance en médecine de précision et a conduit à la reconnaissance de la qualité du travail de nos équipes par la très prestigieuse revue Nature.

Enfin, un travail considérable a été accompli relativement au cadre juridique posé par le règlement général sur la protection des données (RGPD), à la complexité des modalités pratiques et des conditions de la recherche, qui sont un enjeu majeur dans la compétition internationale.

Au cœur de cette dynamique, les valeurs portées par Unicancer restent plus que jamais les maîtres-mots : excellence, humanisme, solidarité, innovation s'illustrent dans les exemples concrets à découvrir dans ce rapport.

PATRICE VIENS, PRÉSIDENT D'UNICANCER

Si les chiffres suffisent à traduire la dynamique de progrès de notre activité de recherche clinique, 2018 aura été également une année d'exception pour la visibilité et la reconnaissance d'Unicancer sur la scène internationale, avec de réelles avancées pour les patients et des communications scientifiques marquantes dont nous sommes fiers.

Les résultats de l'étude franco-canadienne PRODIGE 24-PA-6, notamment, ont fait l'objet d'une communication orale à l'ASCO[1] en juin dernier et d'une publication dans le New England Journal of Medicine[2] en décembre. Cette étude montre une diminution significative du taux de récidive chez les patients sous traitement par Folfirinox après chirurgie du pancréas et impose le protocole comme le nouveau standard thérapeutique de chimiothérapie adjuvante chez ces patients. C'est une avancée significative qui ouvre de nouveaux horizons dans le traitement d'un cancer jusqu'ici de sombre pronostic.

Egalement présentés au congrès de l'ASCO en 2018, les résultats de l'étude AcSé-crizotinib montrent que le crizotinib peut avoir une efficacité dans d'autres types de cancers que ceux pour lesquels il est autorisé, tels que les cancers du poumon avec une mutation ROS1 ou une altération MET et les lymphomes anaplasiques à grandes cellules de l'enfant et de l'adulte. Ces constats ont déjà conduit à une première extension d'indication pour le cancer du poumon non à petites cellules muté ROS1 et d'autres extensions d'indications sont envisagées.

Ces exemples reflètent parfaitement ce qui depuis toujours sous-tend notre mission : favoriser l'émergence de l'innovation et développer un accès à l'innovation rapide, avec des processus de diagnostic accessibles et disponibles pour tous, quels que soient les modes et les lieux de prise en charge.

Je voudrais enfin saluer le travail des équipes impliquées dans le projet MyPeBS qui, dans un contexte inhabituel, ont su faire face avec brio aux difficultés de mise en œuvre liées au questionnement des pratiques dans le domaine très sensible du dépistage, et surmonter les obstacles techniques liés à l'ampleur internationale de l'essai.

Ces succès confortent le positionnement de premier plan de la R&D d'Unicancer dans la recherche clinique académique en cancérologie, auquel contribue notamment le développement solide et pérenne des collaborations locales et internationales que nous nous efforçons d'instaurer continuellement.

ALEXANDER EGGERMONT, VICE-PRÉSIDENT D'UNICANCER, EN CHARGE DE LA RECHERCHE

Les découvertes récentes en cancérologie sont porteuses de grands espoirs pour tous, mais aussi de nombreux défis, parmi lesquels le partage sécurisé et l'utilisation éthique des données de vie réelle. Ces données représentent une source d'information capitale pour optimiser les soins mais aussi pour définir les futures politiques de santé.

Notre mission ne peut s'accomplir sans privilégier l'innovation, qui repose sur le bon usage de ces données. Gageons que le politique et le législateur, qui y veillent à juste titre, sauront en permettre le déploiement, notamment dans les nouveaux territoires de la recherche que sont l'Intelligence Artificielle et la e-santé.

Soutenus par une organisation des soins de très haut niveau où chacun peut accéder au meilleur parcours disponible pour sa pathologie, nous n'aurons de cesse d'œuvrer à faire émerger des forces coordonnées de recherche afin de faciliter le partage et la diffusion des connaissances.

Toutes les disciplines et compétences de notre réseau travaillent main dans la main, en repoussant les frontières, pour relever ces défis, améliorer la prise en charge des patients et avancer ensemble vers notre objectif : vaincre le cancer.

Our research priorities

Unicancer, a major French player in oncology, groups together the 18 French Comprehensive Cancer Centres (FCCCs) spread across 20 hospital sites throughout France. They are private, non-profit health establishments exclusively dedicated to care, research and education in cancer.
Unicancer's technical and scientific network, its expert groups and integrated structure offer R&D department ways to develop ambitious and innovative research projects in oncology.

The acceleration of therapeutic innovation, a key element in improving patient management, implies new challenges that require defining priority developments in terms of scientific organisation. Unicancer's R&D takes a particular interest to stay at the forefront of cancer research by placing innovation at the heart of its mission to support the development of new therapeutics and focusing its research on three main themes to which it wishes to give priority.

NICHE-ORIENTED RESEARCH STRATEGIES

Unicancer's R&D has chosen to promote studies in areas of research insufficiently or not currently covered by pharmaceutical industry, in particular:

- rare tumors (orphan pathologies)
- cancers affecting orphan populations (paediatric and geriatric cancers)
- treatments requiring specific expertise in robotic assisted surgery or innovative technologies for radiation therapy

SUSTAINED DYNAMICS OF PRECISION MEDICINE

The emphasis is on:

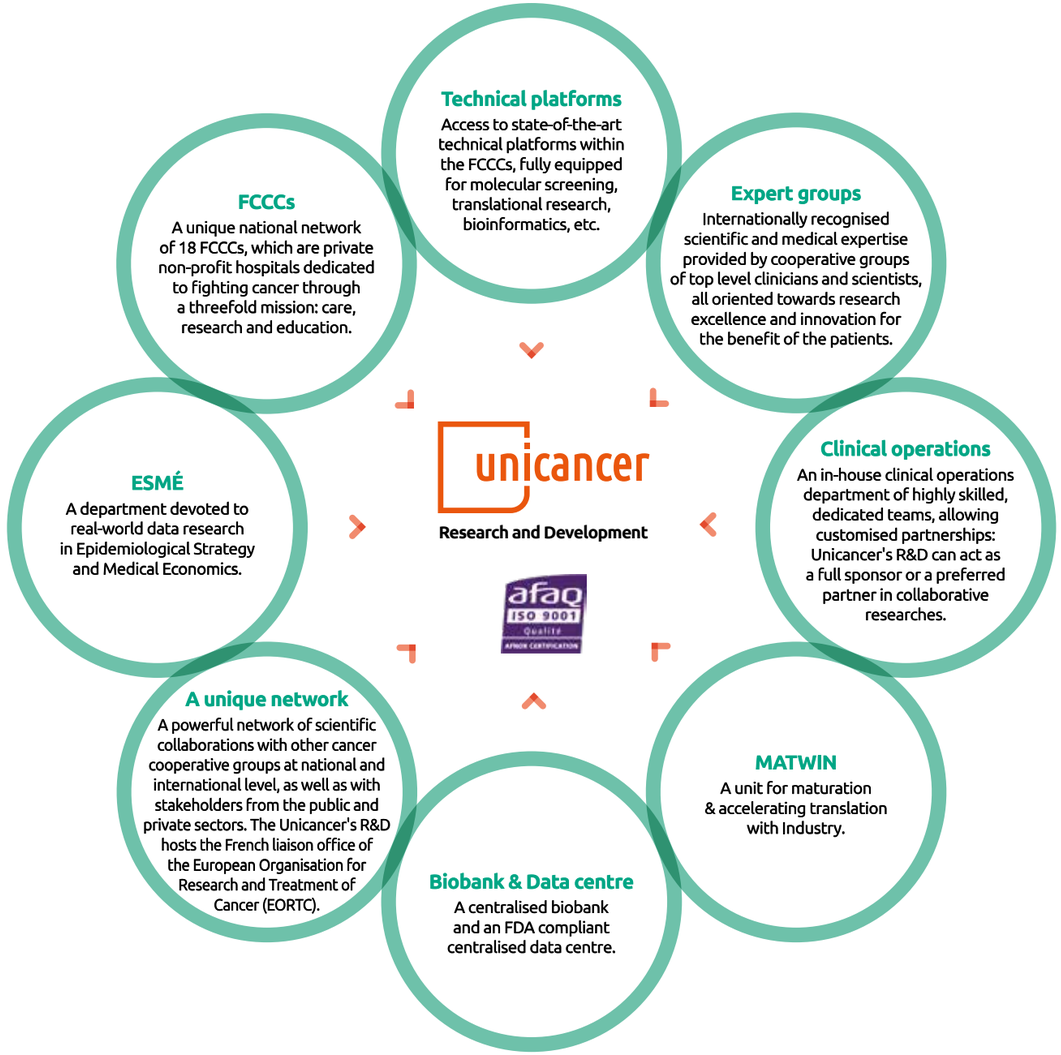
- improve cancer treatments knowledge and understanding the impact of genetics on tumor processes through the activities of the personalized medicine and immuno-oncology research groups,
- research on real-life data, both through prospective cohorts (CANTO cohort) and through data from care institutions (ESMÉ programme),
- prevention (the European MyPeBS program),
- translational research, with a strategy of partnerships to develop consortia bringing together several research units and teams around major joint projects (ONCOBIOME, MyProbe). In support, a systematic "banking" of samples (tumors, blood samples) collected in clinical trials and kept at the BRC (Biological Resources Centre) aims to set up future translational research programs, which will make it possible to propose new targeted therapies to patients.

THE PATIENT AT THE HEART OF THE RESEARCH

Several large trials aimed at improving treatment strategies are conducted in breast cancer, urological cancers and digestive cancers. They have a dual vocation:

- to improve the management of sub-populations with severe prognosis
- to promote therapeutic de-escalation and preserve the quality of life of patients with a better prognosis by avoiding unnecessary treatments

Our strenghts



Highlights

Key figures

6,328
PATIENTS INCLUDED IN UNICANCER SPONSORED-CLINICAL TRIALS

90
ONGOING CLINICAL TRIALS, INCLUDING 54 IN RECRUITMENT PHASE

ISO 9001
QUALITY CERTIFICATION

15
NEWLY INITIATED CLINICAL TRIALS

202
INVESTIGATIONAL SITES INVOLVED (PUBLIC HOSPITALS, PRIVATE CLINICS, COMPREHENSIVE CANCER CENTRES), INCLUDING 37 ABROAD

26
PUBLICATIONS IN SCIENTIFIC JOURNALS

MORE THAN
47,000
PATIENTS REGISTERED IN THE ESMÉ DATABASE

Expert groups

Unicancer provides structural support to 11 internationally recognised and multidisciplinary expert groups that focus on designing and conducting innovative clinical studies. The French National Cancer Institute (INCa) has labelled six of these expert groups, recognising their outstanding quality of work and expertise.

FRENCH BREAST CANCER INTERGROUP (UCBG)

For the **French Breast Cancer Intergroup (UCBG)**, 2018 marked the end of the inclusions in the **CANTO** (CANcer TOxicities) cohort, launched in 2012, whose objective is to quantify and prevent the side effects of treatments for localized breast cancer thus improving patient's quality of life. The CANTO database comprises data from 12,000 women. Currently, 20 research projects are underway based on these data. The preliminary results from CANTO COMPLETE, the first serum-based study to measure non-compliance of adjuvant hormone therapy in pre-menopausal patients, were presented at the **ESMO** congress on October 19, 2018.

UNICANCER GASTROINTESTINAL GROUP (UCGI)

The **Unicancer Gastrointestinal Group (UCGI)** in collaboration with the FFCD (Fédération Francophone de Cancérologie Digestive) and the Canadian Cancer Trials Group (CCTG) conducted the **PRODIGE 24** study, funded by the French Ministry of Health and the French Cancer League. The study results were initially presented orally at the **ASCO** conference in June 2018 and subsequently published in **The New England Journal of Medicine** on December 20, 2018. For more than 10 years, gemcitabine had been the standard adjuvant therapy after curative surgery, in patients with pancreatic ductal adenocarcinoma (the most common form of pancreatic cancer). In the **PRODIGE 24** study, patients treated with mFolfirinox showed a 50% reduction in disease recurrence and a significantly better survival rate three years after surgery, compared with those treated with gemcitabine. These results have established mFolfirinox as standard adjuvant chemotherapy for patients with pancreatic ductal adenocarcinoma.

On January 25, 2018, the UCGI group organised the fourth edition of the ABCD (Accelerated Biological Course in Digestive cancer). The ABCD precedes the annual FFCD digestive cancer conference. The objective of this two-day event is to disseminate knowledge, increase the attractiveness of clinical research in French medical centres, and encourage the emulation of young oncology researchers.

SARCOMA GROUP (UC SARCOMA)

In 2018, the results of the REGOBONE phase II randomised study, conducted by the **Sarcoma Group**, confirmed the interest of regorafenib, with an acceptable level of toxicity, for treating metastatic osteosarcoma patients without a curative treatment option. These results were presented at the **ASCO** conference in June 2018. Further confirmatory trials are required. Simultaneously, the randomised phase II study (Sarcoma 12/OS2016) evaluated the efficacy of mifamurtide (MEPACT) combined with post-operative chemotherapy in patients with high-grade osteosarcoma at high risk of relapse. A clinical-biological database available to researchers is expected in 2019.

IMMUNO-ONCOLOGY GROUP (GIO)

The AcSé immuno studies (part of the INCa AcSé program), conducted by the **Immuno-Oncology Group**, aims to provide patients, without any treatments options, secure access to off-label targeted therapies. The **AcSé-pembrolizumab** and **AcSé-nivolumab** trials aim to provide patients with rare cancers access to pembrolizumab and nivolumab. For each trial, patients were enrolled in six disease cohorts. In 2018, the AcSé-nivolumab MSI and the AcSé-pembrolizumab rare sarcoma cohorts completed enrolment. The initial results from these cohorts are expected in 2019.

GENITOURINARY GROUP (GETUG)

The third edition of the **GETUG** (Genitourinary Group) education and research symposium was held on March 30, 2018. This event is intended for clinical medical oncologists, radiation oncologists, urologists and researchers. It aims to identify clinical and translational projects that can be developed by the group. In this edition, the symposium specifically addressed the role of immunotherapy for genitourinary tumours and oligo-metastatic prostate cancer.

UNICANCER TUMOUR GROUPS

French Breast Cancer Intergroup (UCBG)*
Presidents: Suzette DELALOGE, Gustave Roussy, Villejuif; Thomas BACHELOT, Centre Léon Bérard, Lyon

Genitourinary Group (GETUG)*
President: Karim FIZAZI, Gustave Roussy, Villejuif

Gastrointestinal Group (UCGI)*
President: Emmanuelle SAMALIN, Institut du Cancer de Montpellier, Montpellier

Sarcoma Group (UC Sarcoma)*
President: Jean-Yves BLAY, Centre Léon Bérard, Lyon

Head & Neck Group (UCH&N)*
President: Joël GUIGAY, Centre Antoine Lacassagne, Nice

UNICANCER CROSS-PATHOLOGY GROUPS

Oncogeriatrics Group (GERICO)*
President: Loic MOUREY, IUCT Oncopole, Toulouse

Personalised Medicine Program
President: Fabrice ANDRE, Gustave Roussy, Villejuif

Early Phase Group (GEP)
President: Thomas BACHELOT, Centre Léon Bérard, Lyon

Supportive Care Intergroup
Presidents: Ivan KRAKOWSKI, Institut Bergonié, Bordeaux; Florence Joly, Centre François Baclesse, Caen

Translational Research and Development in Radiation Oncology (UNITRAD)
President: Sofia RIVERA, Gustave Roussy, Villejuif

Immuno-Oncology Group
President: Frédérique Penault-Llorca, Centre Jean PERRIN, Clermont-Ferrand

* INCa accredited-group

International collaborations

Major trials promoted by Unicancer are conducted on the international level, thanks to key partnerships with other academic organisations or through an extended network of university hospitals and research teams in Europe, but also overseas. These collaborations aim to increase the visibility of Unicancer's R&D in oncology worldwide and give us the opportunity to develop partnerships with major charities and public or private stakeholders in oncology research.

MyPeBS The **MyPeBS** project illustrates perfectly the capacity of Unicancer and its experts to develop ambitious programs based on international collaborations. This project of unprecedented scale, is implemented by some 24 partner organisations located in Italy, France, Israel, Belgium, the United Kingdom, the Netherlands and the United States, and is based on a network of several hundred investigators and research centres. 85,000 women will be enrolled over 2.5 years. The MyPeBS study received funding from the European Union under the Horizon 2020 research and innovation programme in 2017. Coordinated by Unicancer, this study aims to assess the effectiveness of a risk-based breast cancer screening strategy (using clinical risk scores and polymorphisms) compared to standard screening (according to the current national guidelines in each participating country) in detecting stage 2 or higher breast cancers.

The expert groups' commitment to leadership in international trials calls for expanding cooperations. Notably, because breast cancer is a major research topic for Unicancer, the French Breast Cancer Intergroup **(UCBG)** is working with many partners, including the **German Breast group (GBG)** for the PENELOPE study, the **ICR-CRUK (Institute of Cancer Research-Cancer Research UK)** for the UNIRAD trial and the Swiss **SAKK** group for the PERNETTA study, the **BIG** (Breast International Group) for the ULTIMATE study, which has been deployed in several European countries with the **GBG** (Germany), **SOLTI** (Spain) and **SABO** (Sweden). Collaborations have also been developed with the **SWOG** Cancer Research Network for the RxPONDER study and the **American Alliance Foundation Trials (AFT)** for the PATINA study.

In 2018, a first partnership with the **European Association of Dermato Oncology (EADO)** was implemented, as part of a trial co-built with the cross-pathology Group **UNITRAD** (Translational Research and development in Radiation Oncology).

The recent release in the New England Journal of Medicine represents the achievement of a six-year collaboration with the **NCIC - CCTG** (National Cancer Institute of Canada-Canadian Cancer Trials Group) in the co-sponsorship with the **UCGI** expert group of a clinical trial conducted in pancreatic cancers. In 2018, a formal agreement was signed between CCTG and Unicancer that aims to share research projects at an early stage of development to systematically explore the possibilities to collaborate on research projects on both Canadian and French territories, regardless of the location of organs, and for the co-promotion of studies.

EORTC The same process of project sharing and mutual scientific recognition has also been concluded with the **European Organization for Research and Treatment of Cancer (EORTC)**. The R&D of Unicancer has been host to the liaison office of the EORTC since 2009. Most patients enrolled in trials promoted by EORTC come from Unicancer group healthcare institutions or expert groups. The purpose of the liaison office is to increase the participation of the FCCCs and more generally of French hospitals in the EORTC studies, to take charge of the regulatory procedures, to facilitate the implementation of the trials in France and to be the privileged contact point of the French investigators on issues related to collaboration procedures with the EORTC.

MAP **International collaborations contribute to develop knowledge and researchers' interactions in the field of precision medicine.** The **MAP** (Molecular Analysis for Personalized therapy) **conference** was reiterated in September 2018 in Paris. This one-of-a-kind meeting designed by a faculty of highly influential key opinion leaders is the place to network with the leading academic representatives working in personalized medicine for cancer patients. MAP is a joint initiative of Cancer Research UK, Unicancer and ESMO (European Society for Medical Oncology) and aims to provide oncologists with expert guidance on interpreting genomic alterations to design tailored treatment programs for their patients.

Translational research

Translational research applies knowledge from basic biology and clinical trials to techniques and tools that address critical medical needs. As a relatively new research discipline, translational research incorporates aspects of both basic science and clinical research, requiring skills and resources that are not readily available in a basic laboratory or clinical setting.

Unicancer's R&D strategy in this domain is to support the development of cooperative research projects that benefit from the following elements:

1. Unicancer owns a large portfolio of academic clinical studies for which there is significant clinical hindsight. These studies also include several large cohorts of patients for whom omics analyses were performed (SAFIRs, CANTO).
2. The creation of a single biological samples collection for all Unicancer studies makes it possible to promote biological research on large retrospective cohorts.
3. A network of research laboratories through FCCCs (biology, bioinformatics).

Thus, Unicancer's portfolio provides a unique opportunity to design new translational research projects based on available biological samples annotated by robust clinical data. The annotated samples can be accessed following submission of a research project to Unicancer's R&D and after methodologic and scientific validation of the project by the experts of the Unicancer steering committee. For example, the MyProbe project aggregates data and samples from 8 clinical trials (PACSs, SAFIRs and CANTO trials) and was funded by the ANR as part of the 3rd RHU call for proposals. The goal of MyProbe is to develop molecular classifiers to identify breast cancer patients with a high risk of relapse after a conventional therapy. The project began in January 2018 and aims to develop and validate three new molecular tests.
The collaboration between multiple research entities and Unicancer is well illustrated by the recent research conducted as part of the **Unicancer Personalized Medicine Program**: the collaboration between Unicancer and several FCCCs and other research hospitals and organisations (Institut Paoli-Calmettes, Institut de cancérologie de l'Ouest (ICO), Centre Léon Bérard, Centre Eugène Marquis, Institut Bergonié, Institut Claudius Regaud, Institut Curie and Gustave Roussy), the French National Institute for Health and Medical Research (INSERM), the French National Centre for Scientific Research (CNRS) and the University Hospital of Basel permitted the whole exome sequencing of 599 metastatic breast cancers in order to identify new candidate targets and better stratify patients eligible for innovative therapies. The analyses were conducted on biopsies collected during the SAFIR01, SAFIR02, PERMED, MOSCATO, MATCHR and SHIVA trials and compared to primitive tumor genome. The results of this ambitious project have been published in an article entitled "Genomic Characterization of metastatic breast cancers" in the journal Nature.

However, the accumulation of generated data (omics, imaging) raises new challenges regarding the ability to access and analyse these huge volumes of information. In order to meet these challenges, Unicancer is participating in several initiatives to improve the valorisation of existing data. In particular, Unicancer participates in the OSIRIS group to promote interoperability and data sharing. Unicancer is also exploring ways to improve access to data through the implementation of tools such as cBioPortal to facilitate data visualisation.

Real-world data

Real-world data is a routinely collected data relating to patient health status and the delivery of health care. It may be derived from a variety of sources such as billing activities, electronic health records or product and disease registries. This data collected outside interventional studies, reflects patients experience during their therapeutic management.

In oncology, these data are an indispensable complement to clinical trials in order to establish the benefit-risk ratio and the level of performance of treatments under real conditions of use.

Initiated in 2014, the ESMÉ program is an academic initiative led by Unicancer's R&D, conducted in various reference institutions in cancer management in France. The aim is to build up a repository of data on cancer in order to carry out real-world studies, in particular to make better use of the various drugs and to better understand the determinants of the therapeutic strategies defined for cancer patients in day-to-day care. Indeed, this information, specific to each patient, contributes to the therapeutic choice and the "real-life" effectiveness of a therapy. By mastering the role of these parameters and the associations between them, it is possible to propose the most suitable treatment for each patient, by reconstructing data in increasingly smaller populations.

Three databases have been built in the ESMÉ Real world program to date, respectively focused on **metastatic breast cancer, ovarian cancer or advanced and metastatic lung cancer**.

ESMÉ Real-life program is now recognized by health assessment agencies as a valuable source of information to guide decision-making throughout the life cycle of a therapy.

KEY FIGURES

Metastatic Breast Cancer
23,000
CASES SELECTED

Ovarian Cancer
8,000
CASES SELECTED

Advanced & Metastatic Lung Cancer
17,000
CASES SELECTED

47,000
CASES AVAILABLE IN THE THREE ESMÉ DATABASES

UP TO
8
YEARS OF LONGITUDINAL FOLLOW-UP

26
COMMUNICATIONS AND PUBLICATIONS IN MAJOR INTERNATIONAL CONGRESSES

MATWIN

Maturation and **A**ccelerating **T**ranslation **W**ith **In**dustry

www.matwin.fr

MATWIN is a wholly owned subsidiary of Unicancer which leads a national program supporting early innovation in oncology, where the risks, before preclinical proof of concept, remain high and may deter investors.

The main objectives are to assess and support innovative projects with transfer potential either originating in Academia or start-ups, with the view of fostering early collaborations. The process is based on a partnership with 15 international laboratories (Amgen, AstraZeneca, Boehringer Ingelheim, Bristol-Myers Squibb, Celgene, Genomic Health, Gilead, GlaxoSmithKline, Janssen, Nanostring Technologies, Novartis, Pfizer, Pierre Fabre, Roche, Sanofi) who are delighted to mutualize through MATWIN a sourcing platform of French prefiltered innovative projects in oncology.

MATWIN's call for proposals is permanently open. According to their specific needs, applicants (academics or start-ups) may benefit from one or more steps of the program:

- 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 potential label from a unique European International Board, made up of academic key opinion leaders from the major European Cancer Institutes as well as International decision-makers from the R&D Global Oncology of MATWIN's partners.

Since 2015, MATWIN has also organised, simultaneously with its Board meeting, an international partnering convention called Meet2Win entirely dedicated to open innovation and collaborative research in oncology. This event has proved increasingly successful over the years and is becoming a reference meeting point for partnerships in oncology innovation in France, gathering since the first edition more than 1,000 participants and more than 3,000 B2B meetings.

Combining each year conferences, workshops, project elevator pitches, more than 1,000 B2B meetings, with a large timeframe dedicated to networking, MEET2WIN now also offers a showcase for start-ups looking for 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, artificial intelligence/software, etc.) thereby offering new opportunities of development support to leverage deep tech innovation in oncology.

APPLICANT PROJECT TYPES	
Academic teams	**50%**
INSERM, CNRS	*70%*
Universities, hospitals, CCC, etc.	*30%*
Start-ups	**50%**

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

A FEW FIGURES FROM MATWIN'S REVIEW (2012-2018)

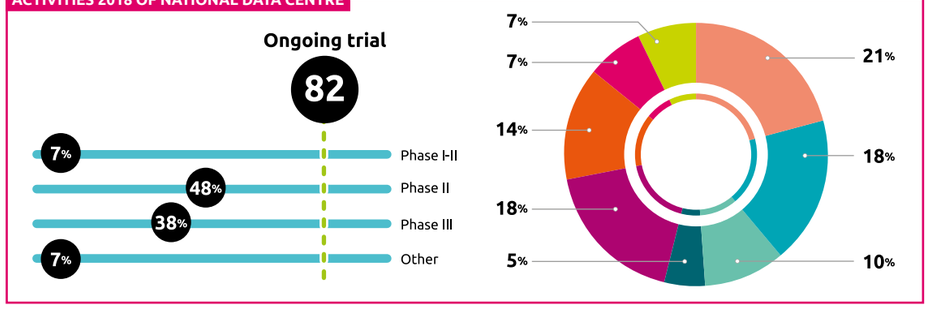
- **+200 applicant projects, +400 academic and industrial assessments**
- **+50 projects interviewed by the MATWIN International Board**
- **20 start-up creations (amongst which Syndivia, PDC*line, ElyssaMed, H-Immune, Gliocure, Phostin…)**
- **10 to 15 projects already transferred to industry**

Clinical research activity

Clinical trials actived in 2018

EXPERT GROUP(S)	SHORT TITLE	STUDY TITLE	STUDY COORDINATOR	PHASE	NUMBER OF EXPECTED PATIENTS	STUDY ACTIVATION DATE
GEP	GEP 15 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	20/06/2018
GETUG	GETUG-AFU 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	30/11/2018
GETUG	GETUG-AFU 30 BLADDER ART	Adjuvant radiotherapy in patients with pathological high-risk bladder cancer: A randomized multicentre phase II study	P. Sargos	II	109	27/03/2018
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	10/12/2018
GETUG	GETUG AFU 34 SAKK PROMET	Multicentre, Randomized Phase II Trial of Salvage Radiotherapy +/- Metformin for Patients with Prostate Cancer after Prostatectomy	S. Supiot	II	40 (FRA) 170 (INT)	21/06/2018
GETUG	GETUG-AFU 31 STEREO-Re-PRO	Phase I/II evaluating the efficacy of Repeat Stereotactic Radiation in Patients With Intraprostatic Tumor Recurrence (STEREO-RE-PRO)	D. Pasquier	I/II	47	11/06/2018
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	06/12/2018
GIO	CHECK'UP	Prospective cohort study to identify the predictive factors of response to PD-1 or PD-L1 antagonists	F. Penault-Llorca	cohorte	670	06/04/2018
PERSONALISED MEDICINE PROGRAM	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	09/01/2018
SUPPORTIVE CARE INTERGROUP	CYPRES	Consensus patients for research in supportive care	A. Annota	NA	1,000	04/12/2018
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	25/09/2018
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	17/01/2018
UCGI	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	25/07/2018
UC SARCOMA	SARCOME 13 MEPACT	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 et S. Piperno-Neumann	II	390	06/09/2018
UNITRAD	NIRVANA-LUNG	PD-(L)1 iNhibitors with concurrent IRadiation at VAried tumour sites in advanced Non-small cell lung cAncer	J. Doyen	III	510	19/11/2018

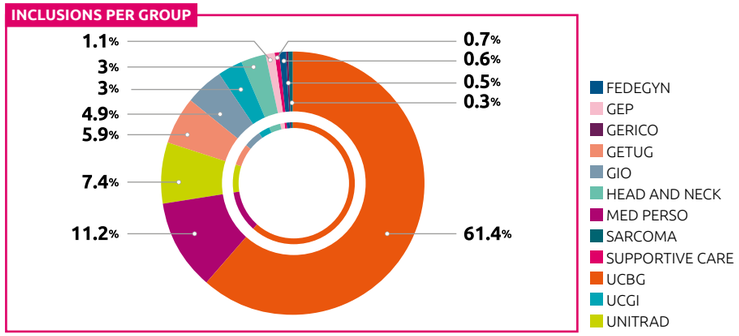
ACTIVITIES 2018 OF NATIONAL DATA CENTRE



Inclusions per expert group / Focus on FCCCs

	FEDEGYN	GEP	GERICO	GETUG	GIO	HEAD AND NECK	MED PERSO	SARCOMA	SUPPORTIVE CARE	UCBG	UCGI	UNITRAD	TOTAL
Public Hospitals of Paris (AP-HP)	1		1	11	28	3	12			21	6		83
Foreign institutions	3			63						47	24		137
FCCCs	15	62	12	155	201	102	524	17	26	2,721	50	427	4,312
Other private non-profit hospitals				11	3	14	5		5	70	18		126
Private intitutions		5	3	76	1	14	13		1	344	27	18	502
Public hospitals (excl. AP-HP)	17	4	15	57	75	54	153	5	10	684	68	26	1,168
Total	**36**	**71**	**31**	**373**	**308**	**187**	**707**	**22**	**42**	**3,887**	**193**	**471**	**6,328**

INCLUSIONS PER GROUP

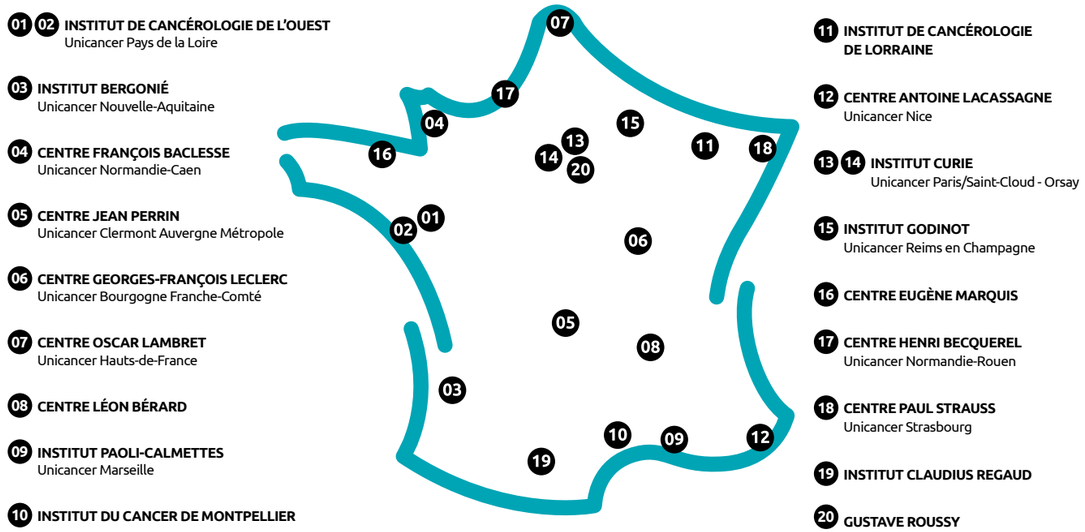


FOCUS ON FCCCs

	FEDEGYN	GEP	GERICO	GETUG	GIO	HEAD AND NECK	MED PERSO	SARCOMA	SUPPORTIVE CARE	UCBG	UCGI	UNITRAD	TOTAL
Centre Antoine Lacassagne				3	10	10	11	2		110	6	12	164
Institut Bergonié		1		26	9		32			141		8	217
Institut Claudius Regaud	1			9	15	4	30	1		80		5	145
Institut Curie					18	17	95	3		1,055	4	83	1,275
Centre Eugène Marquis		16	3	6	3	3	22	2	15	116	2	43	231
Centre François Baclesse	2	10	1	15	6	4	8		10	77	1	4	138
Centre Georges-François Leclerc		4		4	7	6	1			203	4	14	243
Institut Godinot		1	2	5	2	2				41		19	72
Gustave Roussy			1	23	39	22	83	4		303	8	42	525
Centre Henri Becquerel					1		3			102		26	132
Centre Jean PERRIN		9		1	8		23			49		2	92
Centre Léon Bérard	2	3	2	14	35	18	78	3		101	3	59	318
Institut de cancérologie de Lorraine	2			4	4	2	7			92	1	32	144
Institut du Cancer de Montpellier			1	5	7	6	15			12	9	8	63
Centre Oscar Lambret	1			1	14	5	6			1	1	15	44
Institut Paoli-Calmettes	2	1	2	14	10		22			23	3	12	89
Centre Paul Strauss		3			3	1	7			55	4	22	95
Institut de cancérologie de l'Ouest	5	14		25	10	2	81	2	1	160	4	21	325
Total	**15**	**62**	**12**	**155**	**201**	**102**	**524**	**17**	**26**	**2,721**	**50**	**427**	**4,312**

Research in the FCCCs

18 French Comprehensive Cancer Centres*,
private, non-profit health establishments
spread across 20 hospital sites throughout France.



KEY FIGURES

15.2%
OF THE PATIENTS TREATED IN THE FCCCs ARE INCLUDED IN A CLINICAL TRIAL VERSUS 8.5% OF CANCER PATIENTS ON AVERAGE IN FRANCE

590
ACTIVE CLINICAL TRIALS SPONSORED BY THE UNICANCER NETWORK

117
NEW TRIALS SPONSORED BY THE UNICANCER NETWORK

12
FCCCs ARE EARLY PHASE CENTRES ACCREDITED BY THE FRENCH NATIONAL CANCER INSTITUTE (CLIP²)

6
FCCCs HOST INTEGRATED CANCER RESEARCH SITES ACCREDITED BY THE FRENCH NATIONAL CANCER INSTITUTE (SIRIC)

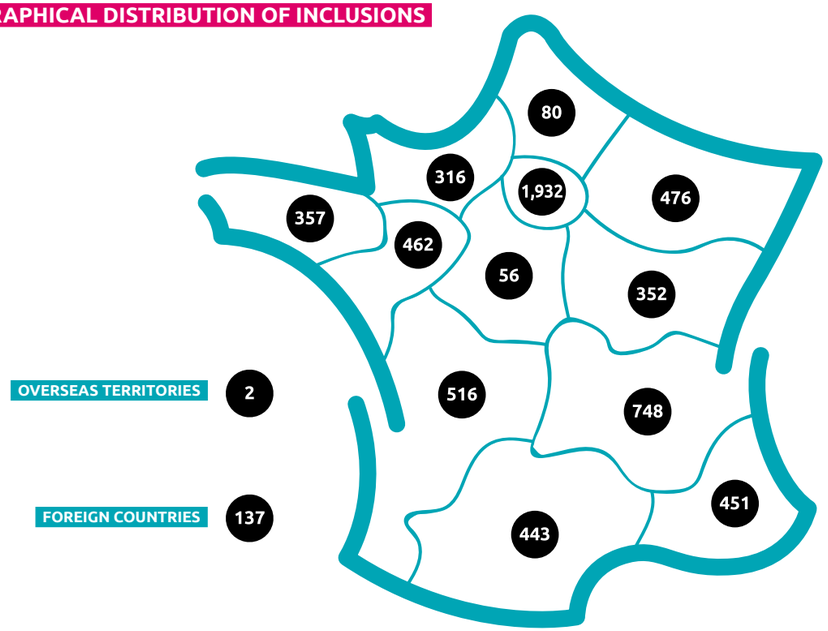
*sorted in alphabetical order by city

FRENCH COMPREHENSITE CANCER CENTRE (FCCCs)	VILLE	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**	% PATIENTS INCLUDED IN A CLINICAL TRIAL	ACADEMIC SPONSOR			INDUSTRIAL SPONSOR	
								NUMBER OF PATIENTS INCLUDED	NUMBER OF ACTIVE TRIALS	% OF PATIENTS INCLUDED IN AN INSTITUTIONAL CLINICAL TRIAL	NUMBER OF PATIENTS INCLUDED	NUMBER OF ACTIVE TRIALS
Institut de cancérologie de l'Ouest Unicancer Pays de la Loire	**Angers Nantes**	11,171	963	266	3.6	11.1%	8.6%	775	175	80%	188	91
Institut Bergonié Unicancer Nouvelle-Aquitaine	**Bordeaux**	6,665	1,328	223	6.0	35.8%	19.9%	1,095	127	82%	233	96
Centre François Baclesse Unicancer Normandie-Caen	**Caen**	6,887	534	166	3.2	8.6%	7.8%	454	123	85%	80	43
Centre Jean PERRIN Unicancer Clermont Auvergne Métropole	**Clermont-Ferrand**	5,017	337	105	3.2	9.3%	6.7%	275	79	82%	62	26
Centre Georges-François Leclerc Unicancer Bourgogne Franche-Comté	**Dijon**	4,591	1,028	251	4.1	24.8%	22.4%	936	168	91%	92	83
Centre Oscar Lambret Unicancer Hauts-de-France	**Lille**	6,676	808	148	5.5	13.2%	12.1%	603	109	75%	205	39
Centre Léon Bérard	**Lyon**	9,880	1,863	323	5.8	24.7%	18.9%	1,530	198	82%	333	125
Institut Paoli-Calmettes Unicancer Marseille	**Marseille**	9,217	1,267	232	5.5	14.2%	13.7%	1,085	150	86%	182	82
Institut du Cancer de Montpellier	**Montpellier**	6,560	1,321	172	7.7	23.5%	20.1%	1,133	125	86%	188	47
Institut de cancérologie de Lorraine	**Nancy**	4,757	507	119	4.3	11.1%	10.7%	455	97	90%	52	22
Centre Antoine Lacassagne Unicancer Nice	**Nice**	5,428	461	146	3.2	10.4%	8.5%	365	101	79%	96	45
Institut Curie Unicancer Paris/Saint-Cloud - Orsay	**Paris/ Saint-Cloud**	13,880	2,398	195	12.3	18.6%	17.3%	2,128	121	89%	270	74
Institut Godinot Unicancer Reims en Champagne	**Reims**	3,617	252	68	3.7	7.1%	7.0%	239	56	95%	13	12
Centre Eugène Marquis	**Rennes**	4,795	563	117	4.8	14.4%	11.7%	456	70	81%	107	47
Centre Henri Becquerel Unicancer Normandie-Rouen	**Rouen**	4,992	521	121	4.3	10.5%	10.4%	469	90	90%	52	31
Centre Paul Strauss Unicancer Strasbourg	**Strasbourg**	3,662	389	98	4.0	11.7%	10.6%	367	78	94%	22	20
Institut Claudius Regaud	**Toulouse**	6,863	1,190	203	5.9	24.1%	17.3%	923	116	78%	267	87
Gustave Roussy	**Villejuif**	12,280	3,585	397	9.0	33.5%	29.2%	2,759	145	77%	826	252
Total		**126,938**	**19,315**			**18.4%**	**15.2%**	**16,047**		**83%**	**3,268**	
Mean		7,052	1,073	186	5	17%	14%	892	118	84%	182	68
+/- SD		3,019	847	85	2	9%	6%	676	38	6%	186	56
median		6,613	886	169	5	14%	12%	689	119	82%	145	47
min		3,617	252	68	3	7%	7%	239	56	75%	13	12
max		13,880	3,585	397	12	36%	29%	2,759	198	95%	826	252

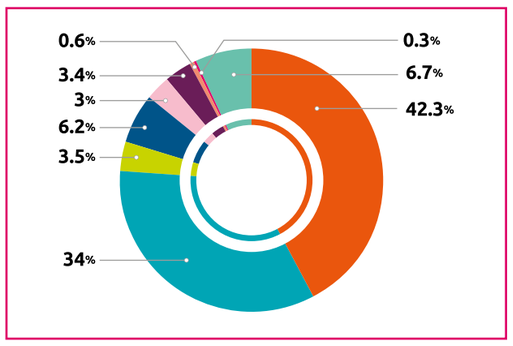
* With the development of personalised medicine, an increasing number of clinical trials include a molecular screening as eligibility criteria. Patients who have accepted and signed an informed consent can be denied in a second step due to the negative result of the molecular screening (this represent 70% of the patients having signed the informed consent in such trials). Such trials represent an average 35% of industrially sponsored trials and 11% of the academically sponsored trials proposed in our centres.

Inclusions by geographical area and cancer localisation

GEOGRAPHICAL DISTRIBUTION OF INCLUSIONS



INCLUSIONS BY CANCER LOCALISATION

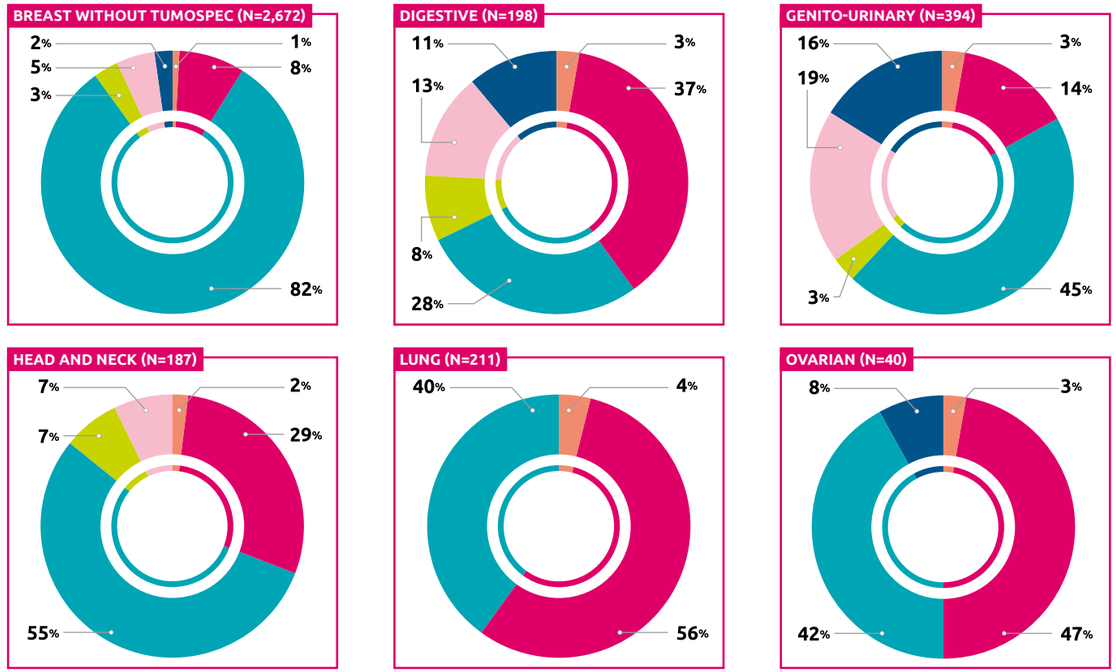


* Tumospec: specific study in breast and ovarian cancer (Cancer and Genetic Group)

Inclusions by institution type

TOTAL NUMBER OF PATIENTS INCLUDED BY LOCALISATION AND INSTITUTION TYPE

	BREAST	OF WHICH TUMOSPEC	DIGESTIVE	GENITO-URINARY	HEAD & NECK	LUNG	OVARIAN	SARCOMA	MULTIPLE LOCALISATIONS	TOTAL
Public hospitals of Paris	21		7	11	3	8	1		32	83
Other public hospitals (excl AP-HP)	733	520	83	57	54	119	17	5	100	1,168
FCCCs	3,593	1,390	62	177	102	86	15	17	260	4,312
Other private non-profit hospitals	75	6	18	11	14				8	126
Private clinics	361	238	30	76	14				21	502
Foreign institutions	47		24	63			3			137
Total	**4,830**	**2,154**	**224**	**395**	**187**	**213**	**36**	**22**	**421**	**6,328**



EORTC liaison office

Unicancer is the local representative of EORTC in France. A partnership agreement was signed in 2009. This collaboration aims to facilitate the activation of the EORTC sponsored trials in France form a regulatory point of view, and to facilitate and stimulate the participation of the French investigational centres. The liaison officers are ensuring regulatory and operational tasks for site initation and monitoring. It is the preferred contact of the French sites for all operational questions. They are the preferred contact for all questions regarding the EORTC sponsored trials.

In 2018, 8 new trials were activated in France by the liaison office and 24 trials were recruiting.

EORTC TRIALS PORTFOLIO AND RECRUITMENT STATUS IN FRANCE IN 2018

LIST OF STUDIES APPROVED IN FRANCE IN 2018

EORTC RESEARCH GROUP(S)	EORTC STUDY NUMBER (ACRONYM)	STUDY TITLE	DATE STUDY APPROVED IN FRANCE	NATIONAL COORDINATOR IN FRANCE	TOTAL NUMBER OF EXPECTED PATIENTS RANDOMIZED (FRANCE/ ALL COUNTRIES)
BTG	1608	Study of TG02 in Elderly Newly Diagnosed or Adult Relapsed Patients with Anaplastic Astrocytoma or Glioblastoma: A Phase Ib Study	16/03/2018	Dr E. Le Rhun (CHU Lille)	21/81
BTG	1709	A phase III trial of marizomib in combination with standard temozolomide-based radiochemotherapy versus standard temozolomide-based radiochemotherapy alone in patients with newly diagnosed glioblastoma	10/07/2018	Dr E. Le Rhun (CHU Lille)	74/750
CLTF	1652 (PARCT)	Phase II trial of atezolizumab (anti-PD-L1) in the treatment of stage IIb-IV mycosis fungoides/ sezary syndrome patients relapsed/ refractory after a previous systemic treatment	26/09/2018	Pr M. Bagot (Hôpital St-Louis, Paris)	3/29
ETF-BTG	1745 (APPALACHES)	A phase II study of Adjuvant PALbociclib as an Alternative to Chemotherapy in Elderly patientS with high-risk ER+/HER2- early breast cancer	28/11/2018	Dr E. Brain (Institut Curie, St-Cloud)	50/366
GITCG	1560 (ILOC)	Phase II of immunotherapy plus local tumor ablation (RFA or stereotactic radiotherapy) in patients with colorectal cancer liver metastases	27/03/2018	Pr S. Evrard (Institut Bergonié, Bordeaux)	11/70
IG	1658 (IMAGE ILD)	Qualification of imaging methods to assess cancer drug induced interstitial lung disease	13/04/2018	Dr L. Greillier (Hôpital Nord, Marseille)	12/70
MG	1612 (EBIN)	Combination of targeted therapy (encorafenib and binimetinib) followed by combination of immunotherapy (ipilimumab and nivolumab) vs immediate combination of immunotherapy on patients with unresectable or metastatic melanoma with BRAF V600 mutation: an EORTC randomized phase II study	04/07/2018	Pr C. Robert (Gustave Roussy)	114/270
ROG-GITCG	1714 (CRUCIAL)	Phase II trial in inoperable oesophageal cancer evaluating the feasibility of the combination of definitive chemoradiation with the immune checkpoint blockers Nivolumab +/- Ipilimumab	16/10/2018	Dr E. Deutsch (Gustave Roussy)	46/130

BTG: Brain Tumor Group (EORTC BTG)
BCG: Breast Cancer Group (EORTC BCG)
CLG: Children Leukemia Group (EORTC CLG)
CLTF: Cutaneous Lymphoma Task Force (EORTC CLTF)
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: Genito-Urinary Cancer Group (EORTC GUCG)

LIST OF EORTC STUDIES ACTIVE IN FRANCE IN 2018

EORTC RESEARCH GROUP(S)	EORTC STUDY NUMBER (ACRONYM)	STUDY TITLE	DATE STUDY APPROVED IN FRANCE	NUMBER OF PATIENTS INCLUDED/TOTAL NUMBER OF PATIENTS RANDOMIZED (FRANCE)
BTG	1419	Molecular genetic, host-derived and clinical determinants of long-term survival in glioblastoma	05/07/2015	77/367
BTG-ROG	1308	Radiation versus Observation following surgical resection of Atypical Meningioma: a randomized controlled trial (The ROAM trial)	22/08/2017	1/47
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	6/69
GITCG	1409 (CLIMB)	A prospective Colorectal Liver Metastasis Database with Integrated Quality Assurance program	11/05/2015	43/217
GUCG-ROG	1414 (Degarelix)	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	12/38
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	6/44
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	34/54
GITCG	1527 (DREAM)	Diffusion-Weighted Magnetic REsonance Imaging Assessment of Liver Metastasis and Improve Surgical Planning	27/12/2016	12/35
GITCG	40CRC (SPECTAcolor)	Screening Platform of the EORTC for Clinical Trials in Advanced Colorectal cancer "SPECTAcolor"	03/07/2013	16/1097
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	20/445
LCG-PBG	1335 (SPECTAlung)	SPECTAlung: Screening Patients with Thoracic Tumors for Efficient Clinical Trial Access	22/05/2015	88/603
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	25/601
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	27/33
LCG	1613 (APPLE)	APPLE trial: Feasibility and activity of AZD9291 (osimertinib) treatment on Positive Plasma T790M in EGFR mutant NSCLC patients	20/07/2017	31/58
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	54/495
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	7/169
STBSG	1202	Randomised phase II trial of cabazitaxel or prolonged infusional ifosfamide in metastatic or recurrent de-differentiated liposarcoma.	07/08/2014	4/28
STBSG	1317 (CaboGIST)	Phase II study of cabozantinib in patients with metastatic gastrointestinal stromal tumor (GIST) who progressed during neoadjuvant, adjuvant or palliative therapy with imatinib and sunitinib	10/11/2016	20/50
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	160/541
STBSG	1403 (rEECur)	International Randomised Controlled Trial of Chemotherapy for the treatment of recurrent and primary refractory Ewing sarcoma.	10/03/2016	55/263
STBSG	1447	Maintenance therapy with trabectedin versus observation after first line treatment with doxorubicin of patients with advanced or metastatic soft tissue sarcoma.	24/08/2017	10/13
STBSG	1506	A phase II multicentre 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	11/38
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	8/20
All groups	1553 (SPECTA)	SPECTA: Screening Cancer Patients for Efficient Clinical Trial Access	30/03/2017	1/8

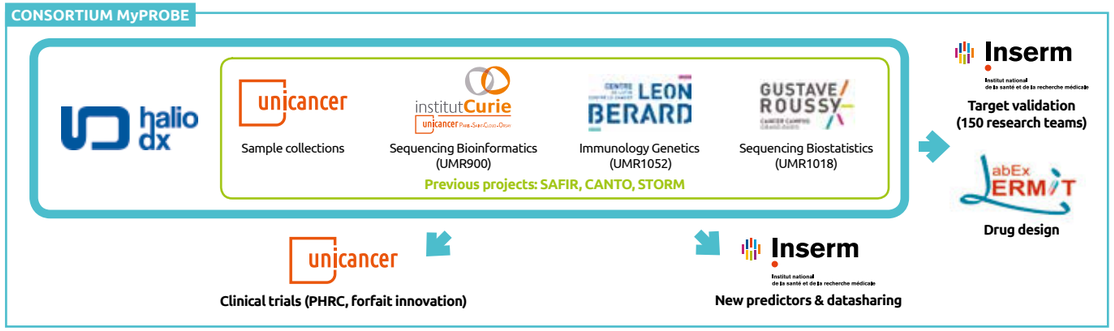
HNCG: Head and Neck Cancer Group (EORTC HNCG)
IG: Imaging Group (EORTC IG)
LCG: Lung Cancer Group (EORTC LCG)
LG: Leukemia Group (EORTC LG)
MG: Melanoma Group (EORTC MG)
NOCI: Network Of Core Institutions (EORTC NOCI)
PBG: PathoBiology Group (EORTC PBG)
ROG: Radiation Oncology Group (EORTC ROG)
STBSG: Soft Tissue and Bone Sarcoma Group (EORTC STBSG)

Translational research activity

Translational projects activated in 2018

MyProbe: Molecular assaYs to PRedict Outcome in early Breast cancEr

The objective of the MyProbe project is to identify early-breast cancer patients who have high risk of metastatic breast cancer relapse after conventional treatment.
Within the 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 promoted by Unicancer (PACSs, SAFIRs, CANTO). An innovative biomarker company - HalioDx - is also involved.
The expected impact of this ambitious project, initiated in January 2018, is to reduce the use of heavy treatments for patients, achieve savings on innovative treatments and avoid toxicities.



CHECK'UP

Promoted by the Unicancer Immuno-Oncology Group (GIO) and funded by the ARC Foundation, the CHECK'UP multicentre prospective study aims to assess patients' response to anti-PD1 and anti-PDL1 immunotherapies in real life to determine for which patients they will be effective and for which they will not.
Three cohorts are planned (melanoma, metastatic lung and head and neck cancer) but the study may evolve with the arrival of new molecules and change in the treatments. In each of these cohorts, a set of data (tumor characteristics, family history...) collected under real-life conditions and immunological, proteomic, immunogenetic data generated thanks to a large biobanking of tissue, blood/serum and feces will be analyzed by an algorithm to identify biomarkers predictive of response to immunotherapy. The CHECK'UP study is the only study that aims to aggregate all currently available biomarkers to respond to a major clinical issue, which is to improve the prescription of immunotherapies. A specific follow-up of aged patients will also be organised to answer questions concerning the interest of immunotherapies in this specific population.
It was launched in 2018 for a duration of 7 years with a target of 465 patients included; the first was included in July 2018.

UNICANCER PARTNER OF THE ONCOBIOME PROJECT

The contribution of microbiota to the regulation of human physiology and its impact on health is a rapidly developing field. Meta-genomics has led to a precise characterization of the intestinal ecosystem and has shown that its structuring and perturbations influence our immune system. As a result, the microbiome appears to be a diagnostic, even prognostic, tool of major interest in cancers.

The ONCOBIOME project, coordinated by the Gustave Roussy, was selected in 2018 as part of the European Horizon 2020 research and development funding programme. It will start in 2019, with the aim of identifying characteristic changes in the microbiota (or microbial signatures) associated with an increased risk of developing cancer, the prognosis of the disease, a patient's response to treatment, or the appearance of toxicities in patients undergoing treatment.

Through functional meta-genomics, this project will improve our understanding of the mechanisms by which the microbiota interacts with our cells in the regulation of metabolism, immunity and oncogenesis, and develop companion tests that predict the occurrence or progression of cancer.

Unicancer is partner of the ONCOBIOME consortium. It communication has given access to the data and sample collections of 3 of its trials (CANTO, CHECK'UP and Nirvana lung), and coordinates the communication work-package at the international level.

TRANSLATIONAL RESEARCH ACTIVITY

Biological Resource Centre (BRC)

The Unicancer Biological Resource Centre was established in 2012 and is housed at the Centre Léon Bérard in Lyon. It was set up to meet the requirements of Unicancer's R&D strategy by creating a collection of clinical research programme samples in order to promote biological research and advances in the field of cancer treatment.

To date, more than 46,000 biological samples are stored, issuing mainly from breast cancer patients (34,000 samples), but also from prostate, lung, head & neck and kidney cancers. Different types of samples are stored, like FFPE material, frozen samples, total blood, plasma, serum or derived products (DNA, RNA, slices). In 2018, 8,500 new samples were collected prospectively.

This centralisation guarantees the correct storage of the samples and ensures that they are rapidly available to research teams. The samples can be accessed following the submission of a research project to Unicancer's R&D and the validation of the project by a biological steering committee. At this time, around 12,000 samples have been unarchived to conduct translational research. Since the activity was launched in 2012, several research projects have been set up reusing biological samples archived in Unicancer's biobank and four of those were accepted through calls for proposals (ANR, Foundation ARC, INCa). These projects have focused mainly on the identification of predictive biomarkers for breast cancer relapse and on the development of new predictive molecular signatures.

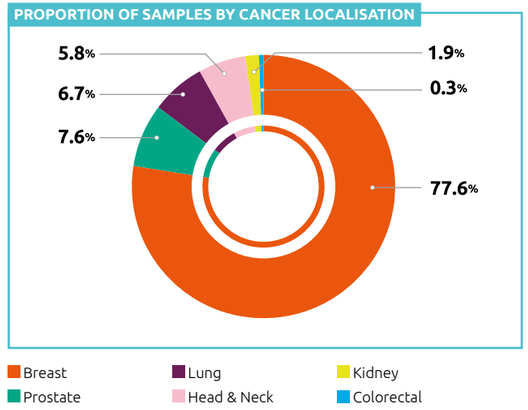
The design of new research projects requires enhanced communication about the available collections. To meet this objective, Unicancer is setting up new informative tools to show precisely what material is available, in terms of sample characteristics, but also related to the clinical parameters of the related disease and the genomic analyses already performed.

KEY FIGURE

8,560

ENTRIES AND 1,619 OUTPUTS
SAMPLES IN 2018

PROPORTION OF SAMPLES BY CANCER LOCALISATION



Real-world data

Epidemiological Strategy and Medical Economics (ESMÉ)

For each pathology, the ESMÉ warehouse integrates validated data from different information sources generated by healthcare professionals when diagnosing, caring for or monitoring patients. These data, collected retrospectively and updated annually, are natively or secondarily structured after a systematic review of the diagnostic, pathological, biological, clinical and therapeutic components for the selected patients.

The ESMÉ program benefits from the financial support of several industrial partners: Roche, Pierre Fabre, Pfizer, AstraZeneca, MSD and, since 2018, Daichi Sankyo and Esai. Other partnerships are being discussed at a global level on ambitious international projects especially in the field of lung cancer.
The industrial partners are not involved in the choice of parameters, neither in the selection of patients, nor in the analyses carried out. The individual data are centralized only within the specialized biometrics units involved in all analyses of projects carried out by the FCCCs in order to ensure consistent analyses and concordant results.

The aim is to further knowledge in order to improve cancer management and to provide complementary elements to those of RCTs (randomized clinical trials), which are useful for healthcare decision-making.

Available to the scientific and medical community, the warehouse now includes the validated data of 50,000 patients who have given rise to nearly 40 research projects carried out under the supervision of one of the scientific committees of the ESMÉ programme.

The ESMÉ platform also makes it possible to systematically transmit to the French health authorities independent information for the re-evaluation dossiers of medicinal products which are submitted to them.

ESMÉ RESEARCH PROJECTS

The first project focused on metastatic breast cancer. At the end of 2018, the therapeutic and clinical data of 23,000 patients treated in FCCCs between 2008 and 2016 were centralized.
This project has already been the subject of some twenty papers in various international congresses (ASCO, ESMO, SABCS), four of which were published in 2018.

The ovary platform was launched in 2017. At the end of 2018, approximately 8,000 patients had been selected from the target of 14,000 expected by the end of 2019. An initial analysis was carried out, the results of which were used by the health authorities in their assessment mission.

The third platform, dedicated to locally advanced or metastatic lung cancer, has been deployed in FCCCs, but also in several other healthcare facilities. By the end of 2018, it already had about 17,000 patients. The target of 21,000 patients by 2023 will be far exceeded.

The first analyses were carried out for the partner laboratories. A first communication was held at the European Lung Cancer Congress (ELCC) in Geneva in April 2019. The call for academic projects was launched in 2018.

GOVERNANCE

The Scientific Committee, headed by Prof. David Perol, was restructured at the end of 2017 to retain only a strategic role.
The scientific mission is now divided between three subcommittees, each dedicated to a pathology:

- a committee on metastatic breast cancer, chaired by Suzette Delaloge,
- a committee on lung cancer, chaired by Maurice Pérol,
- a committee on ovarian cancer, co-chaired by Manuel Rodriguez and Jean-Marc Classe.

PERSPECTIVE

ESMÉ data have been solicited as part of a major ongoing project with an American laboratory to reconstruct a historical arm for comparison with patients in a phase II study, the results of which will soon be submitted to the FDA (Food & Drug Administration) for marketing approval of a product currently under development.

In order to get as close as possible to the requirements of the FDA, and to increase the credibility of the ESMÉ data acquisition tool, a vast project of compliance with the American Standard 21CFR Part 11 (relating to the security of data collection and storage by means of an optimal and exhaustive use of Electronic technologies), has been initiated.

GOVERNANCE AND SUPERVISORY BODIES OF THE ESMÉ RESEARCH PROGRAMME

DECISION LEVEL	OPERATIONAL LEVEL	SUPERVISORY LEVEL		
FCCCs Directors	Real-World Data Department	Scientific Committee **Prof. David Perol**		
Strategy Research Committee	Centre coordinators	Breast Cancer Committee **Suzette Delaloge**	Ovarian Cancer Committee **Manuel Rodriguez** **Jean-Marc Classe**	Lung Cancer Committee **Maurice Perol**
Unicancer's R&D Director **World-Data Department**	Working groups	Independent Ethics Committee		
	QA/Regulatory Affairs Department	International Advisory Board		

PUBLICATIONS OF THE ESMÉ GROUP

TITLE	AUTHORS	REFERENCES
Time trends of overall survival among metastatic breast cancer patients in the real-life ESMÉ cohort	E. Gobbini, M. Ezzalfani, V. Dieras, T. Bachelot, E. Brain, M. Debled, W. Jacot, M-A. Mouret-Reynier, A. Goncalves, F. Dalenc, A. Patsouris, J-M. Ferrero, C. Levy , V. Lorgis, L. Vanlemmens, C. Lefeuvre-Plesse, S. Mathoulin-Pelissier, T. Petit , Lionel Uwer, C. Jouannaud, M. Leheurteur, M. Lacroix-Triki, A. Lardy Cleaud, M. Robain, C. Courtinard, C. Cailliot, D. Perol and S. Delaloge.	European Journal of Cancer 96 (2018): 17-24
Oral etoposide in heavily pre-treated metastatic breast cancer: results from the ESMÉ cohort and comparison with other chemotherapy regimens	L. Cabel, M. Carton, B. Cheaib, J-Y. Pierga, F. Dalenc, A. Mailliez, C. Levy, W. Jacot, M. Debled, M. Leheurteur, I. Desmoulins, C. Lefeuvre, A. Gonçalves, L. Uwer, J-M. Ferrero, J-C. Eymard, T. Petit, M-A. Mouret-Reynier, G. Perrocheau, I. Piot, D. Pérol, G. Simon and F. Lerebours.	Breast Cancer Research and Treatment 173.2 (2019): 397-406
Endocrine therapy or chemotherapy as first-line therapy in hormone receptorepositive HER2-negative metastatic breast cancer patients	E. Jacquet, A. Lardy-Cléaud, B. Pistilli, S. Franck, P. Cottu, S. Delaloge, M. Debled, L. Vanlemmens, M. Leheurteur, A-V. Guizard, L. Laborde, L. Uwer, W. Jacot, D. Berchery, I. Desmoulins, J-M. Ferrero, G. Perrocheau, C. Courtinard, E. Brain, S. Chabaud, M. Robain and T. Bachelot.	European Journal of Cancer 95 (2018): 93-101
Survival Impact of Locoregional Treatment of the Primary Tumor in De Novo Metastatic Breast Cancers in a Large Multicentric Cohort Study: A Propensity Score-Matched Analysis Elvire	E. Pons-Tostivint, Y. Kirova, A. Lusque, M. Campone, J. Geffrelot, C. Mazouni, A. Mailliez, D. Pasquier, N. Madranges, N. Firmin, A. Crouzet, A. Goncalves, C. Jankowski, T. De La Motte Rouge, N. Pouget, B. de La Lande, D. Mouttet-Boizat, J-M. Ferrero, L. Uwer, J-C. Eymard, M-A. Mouret-Reynier, T. Petit, M. Robain, T. Filleron, C. Cailliot and F. Dalenc.	Annals of surgical oncology 26.2 (2019): 356-365

Shared activity

Regulatory, legal affairs, pharmacovigilance, quality assurance

REGULATORY AND PHARMACEUTICAL AFFAIRS

The regulatory and Pharmaceutical affairs department has a triple objective of clinical trial safety, compliance with regulations and support for Comprehensive Cancer Centres (CCCs).

Beyond the regulatory follow-up of clinical trials (initial clinical trial and amendment submissions to France's and Foreign Competent Authorities), the Regulatory and Pharmaceutical Affairs unit ensures the legal and regulatory compliance of all the R&D Department of Unicancer activity.

Priority has been given to the compliance of the processing of personal data and its impact on the implementation and conduct of searches, within the framework of the European Data Protection Regulation (DPR) which came into force in May 2018.
In this context, Romain Boidin, appointed DPO (Data Protection Officer), has taken charge of:

- the development of the internal policy for the protection of personal data,
- the coordination of the internal unit and the Federation's Working Group on data protection,
- the conformity of data protection with the regulations,
- the exchanges with private, institutional and public authorities on data protection and the evolution of the legal and regulatory framework.

The implementation of the MyPeBS study in particular, an international multi-centre trial sensitive to a large number of specificities outside the reference methodologies (optimization and personalization of prevention, involvement of health insurance and screening centres, extension of the target population...) required original and unusual work on the part of the teams. All administrative authorizations have been obtained; validation of the CNIL (French data protection agency) is expected in 2019.

Some points still require clarification to ensure a common framework for trials at both methodological and legal levels throughout the EU. A two-pronged approach was adopted, aiming on the one hand at harmonising the interpretation of texts within Unicancer and the Centres, and on the other hand at reaching out to partners facing the same problems in order to raise a single voice with the authorities.

With the intensification of research based on data, the department is preparing for important work on Big Data and Artificial Intelligence.

LEGAL AFFAIRS AND CONTRACTS

The legal entity ensures the conformity of contracts and agreements for partnerships, clinical trials or studies, and biological samples and provides legal support to all the teams of the R&D Department, in the drafting, management and negotiation of any kind of contracts (partnerships, collaborations, confidentiality, research services, biological samples and data transfers, clinical research, etc.).

An electronic contract management is being implemented, in order to ensure centralised structured filing and electronic archiving of all these contracts.

PHARMACOVIGILANCE (PV)

The PV unit plays a major role in the implementation and conduct of clinical trials, the responsibility of this unit is to ensure that the benefit / risk ratio is and remains favorable. Representatives of this unit participate in all the meetings where trial safety is reported and discussed with the experts.

The PV Unit is responsible for the management and reporting of Serious Adverse Events (SAEs) notified by the investigators to the competent authorities as required. Another mission of this unit is to prepare, for each clinical trial, an annual safety report (development safety update report for clinical trials on medicinal products). This report is a summary of the safety levels observed in the previous year.

The unit also takes charge of the PV duties on behalf of other non-commercial sponsors (FCCCs, academic groups or hospitals).

In 2015 the PV database was changed in order to better meet regulatory requirements. In a continuous improvement of the system, an electronic system was developed for the SAEs reporting from site to the PV Unit. This tool will facilitate the work of both investigators and the pharmacovigilance unit by specifically formatting the data to allow faster integration to the database and better dissemination of the information. It will be made available to all sponsors that delegate their pharmacovigilance to R&D Department of Unicancer later in 2019.

QUALITY ASSURANCE (QA)

The QA unit provides support to enhance the quality of all activities led by Unicancer's R&D. It has piloted the Quality Management System (QMS) in accordance with ISO 9001. Initiated at national level in 2015, this project has brought together all the CCCs and R&D Department of Unicancer around a common and coordinated project. The means and skills of all were used in a concerted quality approach, with the pooling and complementarity of resources on a national level. The unit provided support for the Centres throughout their certification procedures; by the end of the year, all had obtained the certification (3 of those in 2018).

A QA manager joined the R&D team, providing additional capacity to allow work to continue, so that ISO9001 certification was obtained on October 1, 2018.

All members of the internal quality audit team were trained to the standard in 2018.

Therefore clinical research was also certified for the entire network, attesting to the recognition of its high level of quality in clinical research, both for patients, investigators, academic and industrial partners.

Unicancer's R&D, as all FCCCs, obtained the ISO 9001 quality certification for its research activities:

- **effective structure of the clinical research carried out**
- **high quality of our clinical research capacity for patients, doctors, academical and industrial partners**
- **strength of our many research branches all working under the same common values of our network: humanity, the pursuit of excellence, solidarity and innovation.**

Appendices

Portfolio of trials in active in phase 2018

LOCALISATION	EXPERT GROUP(S)	SHORT TITLE	STUDY TITLE	STUDY COORDINATOR	PHASE	NUMBER OF EXPECTED PATIENTS
Bladder Cancer	GETUG	GETUG-AFU 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
Bladder Cancer	GETUG	GETUG-AFU 30 BLADDER ART	Adjuvant radiotherapy in patients with pathological high-risk bladder cancer: A randomized multicentre phase II study	P. Sargos	II	109
Bladder Cancer	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
Bone Sarcomas - Metastatic stage	SARCOMA	SARCOME 12 - REGOBONE	Randomized phase II, placebo-controlled, multicentre study evaluating efficacy and safety of regorafenib in patients with metastatic bone sarcomas	F. Duffaud	II	132
Breast and ovarian cancer	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
Breast cancer - ER positive/her2 negative- eligible for neoadjuvant endocrine therapy - TIL +	UCBG	CARMINA 05 -ULTIMATE	A phase II trial testing durvalumab combined with endocrine therapy in patients with ER+/her2- breast cancer eligible for neoadjuvant endocrine therapy and who present CD8+ T cell infiltration after 4-6 weeks exposure to immune-attractant.	F. André	II	240
Breast cancer - Metastatic stage	PERSO MED	GMP06 - RUBY	A single arm, open-label, phase II study to assess the efficacy of rucaparib in metastatic breast cancer patients with a BRCAness genomic	A. Patsouris	II	41
Breast cancer - Localized stage	UCBG	CANTO	A cohort to quantify and to predict treatment related chronic toxicities in patients with non-metastatic breast cancer	F. André	Cohort	10,000
Breast cancer- Metastatic stage	PERSO MED / UCBG	GMP 03 - 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	460 patients screened for 240 patients treated
Breast cancer - Neoadjuvant treatment - HER2 positive	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	90
Breast Cancer - Non metastatic stage - ER+/ Her2 - with poor prognosis	UCBG	PACS 11 - 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 F. André	III	1,984
Breast cancer - Neoadjuvant setting - HER2+	PERSO MED / UCBG	GMP 05 - SAFIR-TOR	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 T1c operable, HER2-positive breast cancer	T. Bachelot	II	150
Breast cancer - indication for regional lymph node irradiation	UNITRAD	RAD01-HYPOG-01	Multicentre randomized phase III trial comparing hypofractioned versus standard radiotherapy in breast cancer with an indication for regional lymph node irradiation in terms of lymphedema occurrence	S. Rivera	III	1,012
Breast Cancer - Locally advanced or metastatic stage	GEP/UCBG	GEP 14 - LEECAP	Dose-escalation phase I multicentric trial, evaluation the combination of LEE011 and capecitabine in locally advanced or metastatic breast cancer HER2 negative	T. Bachelot	I	52
Breast cancer - Metastatic Stage	UCBG	PADA-1	Randomized, open label, miltcentric 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	800
Breast Cancer - Triple negative stage	PERSO MED	GMP08 - TRACER X	Tracking triple-negative breast cancer evolution through therapy	M. Arnedos	cohort	250
Breast Cancer Locally advanced	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 Cancer Metastatic stage	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 Cancer Metastatic stage	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
Collecting Duct Carcinoma - Metastatic stage	GETUG	GETUG-AFU 24 - BEVABEL	Prospective phase II study of gemcitabine plus platinium salt in combination with bevacizumab (avastin®) for metastatic collecting duct carcinoma	N. Pécuchet	II	41
Colorectal cancer - Metastatic stage	UCGI	PRODIGE 28 - UCGI 27 - 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	168
Colorectal cancer - Metastatic stage	UCGI	UCGI 28 - PANIRINOX	Phase II randomized study comparing FOLFIRINOX + Panitumumab versus mFOLFOX6 + Panitumumab in metastatic colorectal cancer patients stratified by RAS and B-RAF status from circulating DNA analysis.	T. Mazard	II	209
Colorectal Cancer - Adjuvant setting	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 Cancer- indication for stereostatic body radiation	UNITRAD/UCGI	RAD02 - OLIVER	Oligometastases of the LIVer treated with chemotherapy with or without Extracranial Stereotactic Body Radiation Therapy in patients with colorectal cancer	S. Servagi	III	210
Colorectal Cancer Metastatic stage	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
Germ Cell tumors: testicular, mediastinal and retroperitoneal	GETUG	GETUG-AFU 27 - 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	50
Head & Neck squamous cell carcinoma - metastatic stage	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	250

LOCALISATION	EXPERT GROUP(S)	SHORT TITLE	STUDY TITLE	STUDY COORDINATOR	PHASE	NUMBER OF EXPECTED PATIENTS
Head & Neck squamous cell carcinoma - metastatic stage	UCH&N	ORL 06 - COPAN	Phase Ib/II trial of copanlisib in combination with cetuximab in recurrent or metastatic HNSCC harboring a PI3KCA mutation or PTEN loss	C. Letourneau	Ib/II	32
Lung cancer Melanome	GIO	CHECK'UP	Prospective cohort study to identify the predictive factors of response to PD-1 or PD-L1 antagonists	F. Penault-Llorca	cohorte	670
Lung cancer NSCLC	UNITRAD	NIRVANA-LUNG	PD-(L)1 iNhibitors with concurrent IRadiation at VAried tumour sites in advanced Non-small cell lung cAncer	J. Doyen	III	510
Multiple localisations	SCI	CYPRES	Consensus patients for research in supportive care	A. Annota	NA	1,000
Multiple Localisations	IOG	IMM01 - AcSé Nivolumab	Secured access to nivolumab for adult patients with selected rare cancer types	A. Marabelle	II	300
Multiple Localisations	IOG	IMM02 - AcSé Pembrolizumab	Secured access to pembrolizumab for adult patients with selected rare cancer types	C. Massard	II	350
Multiple localisations - Metastatic or unresecable locally advanced	PERSO MED	AcSé VEMURAFENIB	Secured access to vemurafenib for patients with tumors harboring BRAF genomic alterations	J-Y. Blay	II	500
Multiple localisations - Metastatic stage	PERSO MED	GMP07 - EXPRESS	Molecular characterization of patients with solid tumors who presented an exceptional response to targeted therapies	C. Ferté, F. André	Cohort	264
Multiple localisations - Metastatic stage	UNITRAD	RAD 03 - 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, J-C. Faivre	III	196
Multiple localisations - Metastatic stage	PERSO MED	AcSé CRIZOTINIB	Secured access to crizotinib for patients with tumors harboring a genomic alteration on one of the biological targets of the drug	G. Vassal	II	500
Mutiple localisations Metastatic stage	SCI	QUALIOR	Feasibility and Efficacy of Supervised Home-based Standard Physical Exercise Program in Patients Receiving Oral Therapy for Metastatic cancer	F. Joly	II-III	312
Non Small Cell Lung Cancer - Metastatic stage	PERSO MED	GMP 04 - SAFIR 02 LUNG	Intergroup study Unicancer 0105-1305 /IFCT 1301 Evaluation of the efficacy of high throughput genome analysis as a therapeutic decision tool for patients with metastatic non small cell lung cancer	J-C. Soria	II	650 patients screened for 230 patients treated
Osteosarcoma	SARCOME	SARCOME 13 - MEPACT	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 et S. Piperno-Neumann	II	390
Ovarian cancer - Relapse stage	FEDEGYN	FEDEGYN 02 - CHIPOR	A phase III randomized study evaluating Hyperthermic Intra-Peritoneal Chemotherapy (HIPEC) in the treatment of relapse ovarian cancer	J-M. Classe	III	444
Pancreatic Cancer - Locally advanced stage	UCGI	PRODIGE 29 - UCGI 26 - NEOPAN	A Randomized phase III trial comparing chemotherapy with folfirinox to gemcitabine in locally advanced pancreatic carcinoma	M. Ducreux	III	170
Penile cancer - Metastatic lymph node involvement	GETUG	GETUG-AFU 25 - MEGACEP	Evaluation of Lymphadenectomy and Chemotherapy TIP (paclitaxel, ifosfamide and cisplatine) on Inguinal Lymph Nodes in Squamous Cell Carcinoma of the Penis	J. Rigaud	II	78
Prostate Cancer	GETUG	GETUG AFU 34 SAKK PROMET	Multicentre, Randomized Phase II Trial of Salvage Radiotherapy +/- Metformin for Patients with Prostate Cancer after Prostatectomy	S. Supiot	II	40 (FRA) 170 (INT)
Prostate Cancer	GETUG	GETUG-AFU 31 STEREO-Re-PRO	Phase I/II evaluant l'efficacité d'une irradiation stereotaxique chez des patients en recidive tumorale intraprostatique apres RT externe	D. Pasquier	I/II	47
Prostate Cancer	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 cancer - Metastatic stage	GETUG	AFU-GETUG 21 - PEACE1	A prospective randomised phase III study of androgen deprivation therapy ± local radiotherapy with or without abiraterone acetate and prednisone in patients with metastatic hormone-naïve prostate cancer.	K. Fizazi	III	916

LOCALISATION	EXPERT GROUP(S)	SHORT TITLE	STUDY TITLE	STUDY COORDINATOR	PHASE	NUMBER OF EXPECTED PATIENTS
Prostate cancer- localized stage - High risk of recurrence	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 Cancer Metastatic stage	GETUG	GETUG AFU 29 - PEACE 3 - EORTC 1333	A Randomized multicentre 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.	Y. Loriot	III	75
Rectal cancer - Locally advanced stage - Neoadjuvant treatment	GERICO / UCGI	GERICO 12 - NACRE	A Phase III Study Evaluating Two Neoadjuvant Treatments Radiochemotherapy (5 Weeks - 50Gy+Capecitabine) and Radiotherapy (1week - 25Gy) in Patient Over 75 With Locally Advanced Rectal Carcinoma	E. François	III	420
Salivary gland cancer - Metastatic stage	UCH&N	ORL 08 - NISCAHN	A Phase II, Multicentre, Non Randomized, Open Label Study of Nivolumab In Recurrent and/or Metastatic Salivary Gland Carcinoma of the Head and Neck	J. Fayette	II	92
Salivary gland cancer - recurrent and/or metastatic - androgen receptor positive	UCH&N	ORL 07 - EORTC 1206	A randomized phase II study to evaluate the efficacy and safety of chemotherapy versus androgen deprivation therapy in patients with recurrent and/or metastatic, androgen receptor expressing, salivary gland cancer	F. Rolland	II	152
Solid Tumors	GEP	GEP 15 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
Prostate cancer - Biological relapse	GEP	GEP 12 - CARLHA	Safety and efficacy radiotherapy combined with a 6-months LH-RH agonist and abiraterone hormone therapy treatment in biochemically-relapsing prostate cancer following surgery	S. Supiot	I/II	43

Portfolio of trials in follow-up phase in 2018

LOCALISATION	EXPERT GROUP(S)	SHORT TITLE	STUDY TITLE	STUDY COORDINA-TOR	PHASE	NUMBER OF INCLUDED PATIENTS
Biliary tract cancers - Non metastatic stage - Surgical resection	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	E. Boucher	III	196
Bladder cancer - Advanced stage	GETUG	GETUG-AFU 19	Intensified methotrexate, vinblastine, doxorubicin and cisplatin (MVAC-I) with or without panitumumab as first-line treatment of advanced urothelial carcinoma in patients without H-Ras nor K-Ras mutations. Randomised phase II study.	S. Culine	II	113
Breast cancer - BRCA mutations - Prevention	UCBG	ONCO 03 - LIBER	Prevention of breast cancer by letrozole in post-menopausal women carrying a BRCA1/BRCA2 mutation	P. Pujol	Prevention	170
Breast Cancer - Localized stage	UCBG	PACS 12 - RxPonder	A phase III, randomized clinical trial of standard adjuvant endocrine therapy +/- chemotherapy in patients with 1-3 positive nodes, hormone receptor-positive and HER2-negative breast cancer with recurrence score (RS) of 25 or less. RxPONDER: A clinical trial Rx for positive node, endocrine responsive breast cancer	S. Delaloge	III	1,000 in France (5,000 in total)
Breast cancer - Locally advanced stage	UCBG	CADUSEIME 03 - SAKK - PERNETTA	A randomized phase II trial of pertuzumab in combination with trastuzumab with or without chemotherapy, both followed by T-DM1 in case of progression, in patients with HER2-positive advanced breast cancer	H. Bonnefoi	II	119
Breast cancer - Metastatic stage - Predictive factors for the response	UCBG	GRT 02 - 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 Cancer - Non metastatic stage	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	689
Breast Cancer - Non metastatic stage - Genomic signature	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	-	2,066
Breast cancer - Non metastatic stage - low risk of local recurrence	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	970
Breast Cancer - HER2 Inflammatory	UCBG	PACS 09 - BEVERLY 1	Phase II Study Evaluating the Efficacy and Tolerance of Bevacizumab (Avastin) in HER2- Inflammatory Breast Cancer	P. Viens	II	100
Breast cancer - Adjuvant setting - ER (+) / HER2 (-) - Elderly population	GERICO / UCBG	GERICO 11 - PACS 10 - ASTER 70s	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 randomized
Breast Cancer - Luminal - Neoadjuvant	UCBG	CARMINA 04 - NEOPAL	Open-label, randomized, multicentre, international, parallel exploratory phase II study, comparing 3 FEC-3 docetaxel chemotherapy to letrozole + palbociclib combination as neoadjuvant treatment of stage II-IIIA PAM 50 defined luminal breast cancer, in postmenopausal women	P. Cottu S. Delaloge	II	125
Breast cancer- Non-metastatic stage - Poor prognosis	UCBG	PACS 08 - TaVix	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 cancer- Ductal carcinoma	UCBG	IBIS II	Adjuvant tamoxifen compared with anastrozole in treating postmenopausal women with ductal carcinoma in situ (IBIS-II DCIS)	C. Levy	III	426
Colorectal cancer - metastatic stage - liver metastases	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
Colorectal cancer - Metastatic stage - wtKRAS	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 cancer- Peritoneal carninomatosis	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
Endometrial cancer - Advanced stage	FEDEGYN	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. Haie-Meder	III	63
Ewing sarcoma	SARCOMA	SARCOME 01 - EURO EWING 99	Treatment protocol for Ewing tumors: including a medico economic evaluation	N. Gaspar	I-II	1,135
GIST - Localized stage - High and intermediate risk	SARCOMA	SARCOME 08 - EORTC 62024	Intermediate and high risk localized, completely resected, gastrointestinal stromal tumors (GIST) expressing KIT receptor: a controlled randomised trial on adjuvant imatinib mesylate (Glivec) versus no further therapy after complete surgery.	A. Lecesne	III	266
Lingual carcinoma	UCH&N	ORL 01 - HPV ORO	Evaluation of the frequency of Human Papilloma Virus infections in tonsillar and basal lingual carcinomas.	H. Mirghani	II	302
Non-seminomatous Germ Cell tumors - Poor prognostic	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	K. Fizazi	III	203
Osteosarcoma	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
Pancreatic cancer - Non metastatic stage - adjuvant treatment - surgical resection	UCGI	PRODIGE 24 - ACCORD 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
Prostate cancer - Biological relapse	GETUG	GETUG-AFU 16 PRRAP	Phase III randomized study of adjuvant radiotherapy with versus without concurrent goserelin in patients who have undergone surgery for recurrent or refractory prostate cancer	C. Carrie	III	743
Prostate cancer - Localized stage	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 cancer - Localized stage - Detectable PSA	GETUG	GETUG-AFU 22	A multicentre randomised phase II study comparing the efficiency of a HT concomitant with RT vs RT alone in the salvage of patients with a detectable PSA after prostatectomy	S. Guérif	II	125
Prostate Cancer - Locally advanced or high risk of relapse	GETUG	GETUG 12	Phase III randomized study of adjuvant hormonal therapy with and without docetaxel and estramustine in patients with advanced prostate cancer or with a high risk of relapse	K. Fizazi	III	413
Prostate cancer - Unfavorable group	GETUG	GETUG-AFU 18	Phase III study comparing irradiation at a dose of 80 Gy to irradiation at 70 Gy in unfavorable prostate cancers associated with prolonged hormonal therapy	C. Hennequin	III	505
Prostate cancer - Localized stage	GETUG	GETUG 06	Conformational, curative radiotherapy for prostate cancer (NO, N-): Phase III multicentre study of the contribution to survival without clinical or biological change with a dose variation of 15% (80 Gy vs 70 Gy)	Pr V. Beckendorf	III	306
Prostate cancer - Localized stage - Intermediate prognostic	GETUG	GETUG 14	Multicentre randomized trial assessing the efficacy of a short neoadjuvant and concomitant hormone therapy to an exclusive curative conformational radiotherapy of localized prostate cancer with intermediate prognosis	B. Dubray	III	378
Salivary gland cancer - Relapse or metastatic stage	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
Uterine or Soft Tissue Leiomyosarcomas - Metastatic or relapse stage	SARCOMA	SARCOME 11 - LMS 03	Phase II multicentre study to determine the efficacy of gemcitabine with pazopanib as second line treatment in patients with metastatic or relapsed uterine or soft tissue leiomyosarcomas	P. Pautier	II	106
Breast Cancer - HR positive, HER2 negative	UCBG	PACS 13 - PENELOPE B	Phase III study evaluating palbociclib (PD-0332991), a Cyclin-Dependent Kinase (CDK) 4/6 Inhibitor in patients with hormone-receptor- positive, HER2- normal primary breast cancer with high relapse risk after neoadjuvant chemotherapy	H. Bonnefoi	III	121
Prostate cancer - adjuvant setting	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.	S. Culine	III	325
Rectal cancer - Locally advanced stage - Neoadjuvant treatment	UCGI	PRODIGE 23 - UCGI 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
Renal Cell Carcinoma - Advanced or metastatic stage	GETUG	GETUG-AFU 26 - NIVOREN	A Phase II Safety Trial of Nivolumab (BMS-936558) in Subjects with Advanced or Metastatic Renal Cell Carcinoma Who Have Progressed During or After Receiving one prior systemic	L. Albiges	II	730

Publications

GROUP	STUDY	TITLE	MAIN AUTHOR	REFERENCES
GERICO (oncogeriatric)		Multidisciplinary development of the Geriatric Core Dataset for clinical research in older patients with cancer: A French initiative with international survey.	E. Paillaud *et al.*	European Journal of Cancer 103 (2018): 61-68
GETUG (urogenital)	GETUG 15	Anticancer Activity and Tolerance of Treatments Received Beyond Progression in Men Treated Upfront with Androgen Deprivation Therapy With or Without Docetaxel for Metastatic Castration-naïve Prostate Cancer in the GETUG-AFU 15 Phase 3 Trial.	P. Lavaud *et al.*	European urology 73.5 (2018): 696-703.
GETUG (urogenital)	GETUG 15	Burden of Metastatic Castrate Naive Prostate Cancer Patients, to Identify Men More Likely to Benefit from Early Docetaxel: Further Analyses of CHAARTED and GETUG-AFU15 Studies.	G. Gravis *et al.*	European urology 73.6 (2018): 847-855.
GETUG (urogenital)	GETUG 15	Impact of Patient- and Clinician-Reported Cumulative Toxicity on Quality of Life in Patients With Metastatic Castration-Naïve Prostate Cancer.	Schuurhuizen CSEW *et al.*	Journal of the National Comprehensive Cancer Network 16.12 (2018): 1481-1488.
GEP (early phase)	CARLHA-GEP12	Combined abiraterone acetate plus prednisone, salvage prostate bed radiotherapy and LH-RH agonists (CARLHA-GEP12) in biochemically-relapsing prostate cancer patients following prostatectomy: A phase I study of the GETUG/GEP.	S. Supiot *et al.*	Oncotarget 9.31 (2018): 22147.
UC Sarcoma	SARCOME 09 OS2006	Results of Methotrexate-Etoposide-Ifosfamide based regimen (M-EI) in osteosarcoma patients included in the French OS2006/Sarcome-09 study.	N. Gaspar *et al.*	European Journal of Cancer 88 (2018): 57-66.
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 *et al.*	The Lancet Oncology 20.1 (2019): 120-133.
UC Sarcoma	SARCOME 09 OS2006	A Pharmacokinetic and Pharmacogenetic Analysis of Osteosarcoma Patients Treated With High-Dose Methotrexate: Data From the OS2006/Sarcoma-09 Trial.	G. Lui *et al.*	The Journal of Clinical Pharmacology 58.12 (2018): 1541-1549.
UC Sarcoma	EE99 / SARCOME 01	Ewing's Sarcoma of the Head and Neck: Margins are not just for surgeons.	J. Bouaoud *et al.*	Cancer medicine 7.12 (2018): 5879-5888.
UC Sarcoma	EE99 / SARCOME 01	High-Dose Chemotherapy and Blood Autologous Stem-Cell Rescue Compared With Standard Chemotherapy in Localized High-Risk Ewing Sarcoma: Results of Euro-E.W.I.N.G.99 and Ewing-2008	J. Whelan *et al.*	Journal of Clinical Oncology 36.31 (2018): 3110.
UCGI (gastro-intestinal)	ACCORD 03	Prognostic factors of colostomy free survival in patients presenting with locally advanced anal canal carcinoma: A pooled analysis of two prospective trials (KANAL 2 and ACCORD 03).	J-C. Faivre *et al.*	Radiotherapy and Oncology 129.3 (2018): 463-470.
UCGI (gastro-intestinal)	UCGI 29 Prodige 52	Rationale and Design of the IROCAS Study: Multicentre, 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. Bennouna *et al.*	Clinical colorectal cancer 18.1 (2019): e69-e73.
UCGI (gastro-intestinal)	ACCORD 24-PRODIGE 24	FOLFIRINOX or Gemcitabine as Adjuvant Therapy for Pancreatic Cancer.	T. Conroy *et al.*	New England Journal of Medicine 379.25 (2018): 2395-2406.
UCBG (breast)	PACS08	UCBG 2-08: 5-year efficacy results from the Unicancer-PACS08 randomised phase III trial of adjuvant treatment with FEC100 and then either docetaxel or ixabepilone in patients with early-stage, poor prognosis breast cancer.	M. Campone *et al.*	European Journal of Cancer 103 (2018): 184-194.
UCBG (breast)	PACS01	The 21-gene Recurrence Score® assay predicts distant recurrence in lymph node-positive, hormone receptor-positive, breast cancer patients treated with adjuvant sequential epirubicin- and docetaxel-based or epirubicin-based chemotherapy (PACS-01 Trial)	F. Penault-Llorca *et al.*	BMC cancer 18.1 (2018): 526.
UCBG (breast)	NeoPal	Letrozole and palbociclib versus chemotherapy as neoadjuvant therapy of high-risk luminal breast cancer.	P. Cottu *et al.*	Annals of Oncology 29.12 (2018): 2334-2340.
UCBG (breast)	CARMINA02	Molecular profiling of hormone receptor-positive, HER2-negative breast cancers from patients treated with neoadjuvant endocrine therapy in the CARMINA 02 trial (UCBG-0609)	X. Liang *et al.*	Journal of hematology & oncology 11.1 (2018): 124.
GGC (genetic)		Recommandations françaises du Groupe Génétique et Cancer pour l'analyse en panel de gènes dans les prédispositions héréditaires au cancer du sein ou de l'ovaire	J. Moretta *et al.*	Bulletin du Cancer 105.10 (2018): 907-917.
GGC (genetic)		Efficacy of Anthracycline/taxane based neoadjuvant chemotherapy on Triple-Negative Breast Cancer in BRCA1 / BRCA2 mutation carriers.	L. Bignon *et al.*	The breast journal 24.3 (2018): 269-277.
GGC (genetic)		The Influence of Number and Timing of Pregnancies on Breast Cancer Risk in Women with BRCA1 and BRCA2 mutations	M-B. Terry *et al.*	JNCI cancer spectrum 2.4 (2019): pky078.

GROUP	STUDY	TITLE	MAIN AUTHOR	REFERENCES
GGC (genetic)		GEMO, a national resource to study genetic modifiers of breast and ovarian cancer risk in BRCA1 and BRCA2 pathogenic variant carriers	F. Lesueur *et al.*	Frontiers in oncology 8 (2018): 490.
GGC (genetic)		Oral contraceptive use and breast cancer risk: retrospective and prospective analyses from a BRCA1 and BRCA2 mutation carrier cohort study	Lieske H. Schrijver *et al.*	JNCI Cancer Spectrum 2.2 (2018): pky023.
ESMÉ (real-world data)		Time trends of overall survival among metastatic breast cancer patients in the real-life ESMÉ cohort	E. Gobbini *et al.*	European Journal of Cancer 96 (2018): 17-24.
ESMÉ (real-world data)		Oral etoposide in heavily pre-treated metastatic breast cancer: results from the ESMÉ cohort and comparison with other chemotherapy regimens	L. Cabel *et al.*	Breast Cancer Research and Treatment 173.2 (2019): 397-406.
ESMÉ (real-world data)		Endocrine therapy or chemotherapy as first-line therapy in hormone receptorepositive HER2-negative metastatic breast cancer patients	E. Jacquet *et al.*	European Journal of Cancer 95 (2018): 93-101.
ESMÉ (real-world data)		Survival Impact of Locoregional Treatment of the Primary Tumor in De Novo Metastatic Breast Cancers in a Large Multicentric Cohort Study: A Propensity Score-Matched Analysis Elvire	E. Pons-Tostivint *et al.*	Annals of surgical oncology 26.2 (2019): 356-365.

Communications

GROUP	STUDY	CONGRESS	TITLE	AUTHORS	TYPE OF PRESENTATION
UCGI (gastro-intestinal)	Accord21 PRODIGE14-METHEP2	ASCO	Induction chemotherapy (CT) with FOLFIRINOX or FOLFOX/FOLFIRI, plus cetuximab (CET) or bevacizumab (BEV) (by RAS status), in patients (pts) with primarily unresectable colorectal liver metastases (CRLM): Results of the randomized Unicancer PRODIGE 14-ACCORD 21 (METHEP-2) trial	M. Ychou *et al.*	Poster Session
UCGI (gastro-intestinal)	Accord21 PRODIGE14-METHEP2	ASCO	FOLFIRINOX plus cetuximab (CET) or bevacizumab (BEV) in patients (pts) with initially unresectable colorectal liver metastases (CRLM) with BRAF mutated (mut) tumors: A subgroup analysis of the Unicancer PRODIGE 14-ACCORD 21 (METHEP2) trial.	E. Lopez-Crapez *et al.*	Poster Session
Personalised Medicine Program	AcSé crizotinib	ASCO	The activity of crizotinib in chemo-refractory MET-amplified esogastric adenocarcinomas: results from the AcSé-crizotinib program.	T. Aparicio *et al.*	Poster Session
Personalised Medicine Program	AcSé crizotinib	ASCO	Biomarker-driven access to crizotinib in ALK, MET or ROS1 positive (+) malignancies in adults and children: the French national AcSé Program	G. Vassal *et al.*	Oral Session
UCBG (breast)	PADA-1	ASCO	PADA-1: a randomized, open label, multicentric phase III trial to evaluate the safety and efficacy of palbociclib in combination with hormone therapy driven by circulating DNA ESR1 mutation monitoring in ER-positive, HER2-negative metastatic breast cancer patients	F-C. Bidard *et al.*	Poster Session
Personalised Medicine Program	RUBY	ASCO	An open-label, phase II study of rucaparib, a PARP inhibitor, in HER2- metastatic breast cancer patients with high genomic loss of heterozygosity.	A. Patsouris *et al.*	Poster Session
UC Sarcoma	SARCOME 12 / REGOBONE	ASCO	Results of randomized, Placebo (PL)-controlled Phase II study evaluating efficacy and safety of regorafenib (REG) in patients (pts) with metastatic Osteosarcoma (metOS), on behalf of the French Sarcoma Group (FSG) and Unicancer.	F. Duffaud *et al.*	Oral Session
UCGI (gastro-intestinal)	UCGI 29 PRODIGE 52 - IROCAS	ASCO	A multicentre, international, randomized phase III 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. Bennouna *et al.*	Poster Session

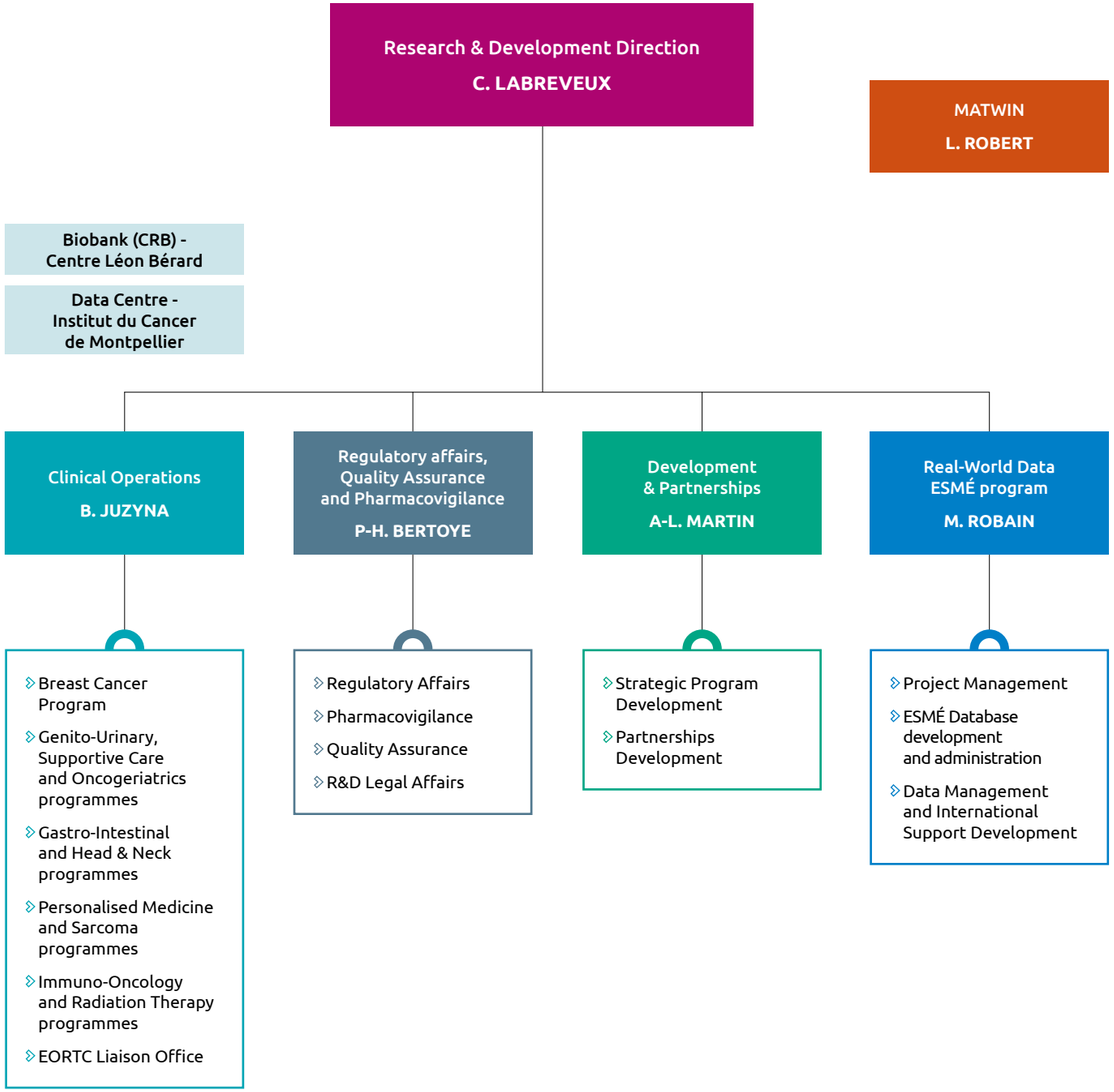
GROUP	STUDY	CONGRESS	TITLE	AUTHORS	TYPE OF PRESENTATION
GETUG (urogenital)	GETUG-AFU 26 NIVOREN	ASCO GU	Safety and efficacy of nivolumab in metastatic renal cell carcinoma (mRCC): Results from the NIVOREN GETUG-AFU 26 study.	L. Albiges *et al.*	General Session
ESMÉ (real-world data)	ESMÉ CBP	CPLF	Programme Epidémio-Stratégie Médico-Economique: une base nationale de données de vie réelle pour mieux comprendre la prise en charge du Cancer Broncho-pulmonaire en France.	M. Robain *et al.*	Poster Session
UCBG (breast)	CARMINA02	EBCC	5-years relapse-free survival and predictive factors identification in HR-positive HER2-negative breast cancer patients treated with anastrozole or fulvestrant neoadjuvant endocrine therapy: Pooled analysis of the CARMINA02 and HORGEN phase II trials	F. Lerebours *et al.*	Poster Session
ESMÉ (real-world data)	ESMÉ CSM	EBCC	Outcomes of 9800 metastatic luminal HER2-negative breast cancer patients in the French national real-life Unicancer ESMÉ-breast cohort	E. Chamorey *et al.*	Poster Session
UCBG (breast)	PACS14 Adendom	EBCC	Shared decision of adjuvant chemotherapy including a genomic test: 1 year patients reported outcomes in a multicentre, national clinical trial (UCBG-2-14).	S. Lefevre *et al.*	Oral Session
UCBG (breast)	CARMINA02	EPICLIN	5-years RFS and prognostic factors study in HR-positive HER2-negative breast cancer patients treated with neoadjuvant endocrine therapy: Pooled analysis of two phase II trials.	F. Lerebours *et al.*	Poster Session
ESMÉ (real-world data)	ESMÉ	EPICLIN	Addressing the issue of bias in observational studies: Instrumental variable & Quasi-trial in ESMÉ Research program	M. Ezzalfani *et al.*	Poster Session
ESMÉ (real-world data)	ESMÉ CSM	EPICLIN	Construction et évaluation d'un substitut de l'indice fonctionnel ECOG (PS), mesure de l'état de santé général du patient au diagnostic du cancer du sein métastatique	C. Courtinard *et al.*	Poster Session
ESMÉ (real-world data)	ESMÉ CSM	EPICLIN	Construction de paramètres d'extrapolation des résultats statistiques de la cohorte ESMÉ Sein métastatique – Reconstruction d'une cohorte de patients traités pour un cancer du sein métastatique dans un CLCC à partir de la cohorte Cancer de l'INCa	C. Courtinard *et al.*	Poster Session
ESMÉ (real-world data)	ESMÉ CSM	EPICLIN	Utilisation du score de propension : application aux données ESMÉ, pour évaluer l'activité de l'Eribuline en pratique réelle chez les patients atteints d'un cancer du sein métastatique	J. Fraisse *et al.*	Oral Session
GETUG (urogenital)	AXIPAP	ESMO	Efficacy and safety of axitinib in metastatic papillary renal carcinoma (mPRC): results of a GETUG multicentre phase II trial (Axipap)	S. Negrier *et al.*	Poster Session

GROUP	STUDY	CONGRESS	TITLE	AUTHORS	TYPE OF PRESENTATION
UCBG (breast)	CANTO	ESMO	Overweight, obesity and weight gain after breast cancer (BC): a prospective clinical study	A. Di Meglio *et al.*	Poster Session
UCBG (breast)	CANTO	ESMO	Weight loss, physical and psychological patient reported outcomes (PROs) among obese patients (pts) with early breast cancer (BC)	A. Di Meglio *et al.*	Poster Session
UCBG (breast)	CANTO	ESMO	Serum assessment of non-adherence to adjuvant endocrine therapy (ET) among premenopausal patients in the prospective multicentre CANTO cohort	B. Pistilli *et al.*	Oral Session
UCBG (breast)	CANTO	ESMO	Breast Cancer (BC) related fatigue: a longitudinal investigation of its prevalence, domains and correlates	I. Vaz Luis *et al.*	Poster Session
UCBG (breast)	CANTO	ESMO	Physical Activity (PA) and patterns of Quality of Life (QOL) after adjuvant chemotherapy (CT) for breast cancer (BC)	A. Di Meglio *et al.*	Poster Session
UCBG (breast)	CANTO	ESMO	Neuropathy and health behaviors in cancer survivors treated with chemotherapy.	M. Matias *et al.*	Poster Session
ESMÉ (real-world data)	ESMÉ CSM	ESMO	Impact of breast cancer molecular subtypes on the occurrence, kinetics and prognosis of central nervous system metastases in a large multicentre cohort	A. Darlix *et al.*	Poster Session
ESMÉ (real-world data)	ESMÉ CSM	ESMO	Management and outcome of metastatic breast cancer in men in the national multicentre observational ESMÉ program.	J. Sirieix *et al.*	Poster Session
GETUG (urogenital)	GETU 12	ESMO	Updated results of GETUG-12, a phase 3 trial of docetaxel-based chemotherapy in high-risk localized prostate cancer, with a 12-year follow-up	K. Fizazi *et al.*	Oral Session
GETUG (urogenital)	GETUG-AFU 26 NIVOREN	ESMO	Brain metastases response to nivolumab in patients with renal cell carcinoma (RCC): prospective analysis from the GETUG-AFU 26 (NIVOREN) trial	R. Flippot *et al.*	Poster Session
UCHN (head and neck)	ORL 09 - TOPNIVO	ESMO	TOPNIVO - 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): first results on behalf of the Unicancer H&N group and the GORTEC.	C. Even *et al.*	Poster Session
UCBG (breast)	PERNETTA	ESMO	PERNETTA – A none comparative randomized open label phase II trial of 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): (SAKK 22/10 / Unicancer UC-0140/1207)	J. Huober *et al.*	Poster Session

GROUP	STUDY	CONGRESS	TITLE	AUTHORS	TYPE OF PRESENTATION
UCBG (breast)	START	ESMO	A randomized phase II study in patients with triple negative, androgen receptor positive locally recurrent (unresectable) or metastatic breast cancer treated with darolutamide or capecitabine (UCBG-306)	H. Bonnefoi *et al.*	Poster Session
UCGI (gastro-intestinal)	UCGI 28 - PANIRINOX	ESMO	The UCGI 28 PANIRINOX trial - a randomized phase II study assessing Panitumumab + FOLFIRINOX or mFOLFOX6 in RAS and BRAF wild type metastatic colorectal cancer patients (mCRC) selected from circulating DNA analysis	T. Mazard *et al.*	Poster Session
UCGI (gastro-intestinal)	UCGI26 PRODIGE29-NEOPAN	ESMO	PRODIGE 29 - UCGI 26 - NEOPAN: - A Randomised trial of chemotherapy with Folfirinox or gemcitabine in locally advanced pancreatic carcinoma	M. Ducreux *et al.*	Poster Session
UCGI (gastro-intestinal)	UCGI 34 - PROSCORE	ESMO GI	UCGI 34 - PROSCORE: A prospective study assessing whether Immunoscore® Colon test impacts the choice of adjuvant chemotherapy, in a multidisciplinary meeting, for treating non-metastatic colon cancer patients after curative-intent surgery	D. Malka *et al.*	Poster Session Abstract
GIO (immuno-oncology)	AcSé Immunotherapy	ESMO I/O	AcSé immunotherapy trials: anti-PD-1 therapy for adult patients with selected rare cancer types	A. Marabelle *et al.*	Poster Session
GIO (immuno-oncology)	CHECK'UP	ESMO I/O	CHECK'UP: A prospective cohort study to identify predictive factors of response and mechanisms of resistance to PD-1 and PD-L1 antagonists	F. Penault-Llorca *et al.*	Poster Session
UNITRAD (radiation therapy)	HYPOG01	ESTRO	Implementing contouring guidelines can be achieved by online learning through a dummy run	L. Levy *et al.*	Poster Session
UCBG (breast)	GRT02-COMET	EUROMAR	Predicting clinical benefits of combined bevacizumab and paclitaxel therapy for HER-2 negative metastatic breast cancer: a serum NMR metabolomics investigation	E. Jobard *et al.*	Poster Session
UCBG (breast)	CANTO	ICCTF	Cognitive impairment in breast cancer patients before surgery?	I. Léger *et al.*	Poster Session
UCBG (breast)	CANTO	MASCC	Cognitive impairment in breast cancer patients before surgery?	I. Léger *et al.*	Poster Session
UCBG (breast)	CANTO	SABCS	Association Between Exercise and Pathological Complete Response in Patients Receiving Neoadjuvant Chemotherapy for Operable Breast Cancer: Results from the CANTO Study	J-L. Baker *et al.*	Poster Session
ESMÉ (real-world data)	ESMÉ CSM	SABCS	Phenotypic discordance between primary and metastatic breast cancer (MBC) in a large scale real-life multicentre French cohort	S. Lefèvre *et al.*	Poster Session

GROUP	STUDY	CONGRESS	TITLE	AUTHORS	TYPE OF PRESENTATION
ESMÉ (real-world data)	ESMÉ CSM	SABCS	Metastatic inflammatory breast cancer: clinical features and outcomes in the national, multicentric, real-life ESMÉ cohort	A. Monneur *et al.*	Poster Session
ESMÉ (real-world data)	ESMÉ CSM	SABCS	Early locoregional breast surgery improves overall and progression-free survival in oligometastatic breast cancer	J. Hotton (ICL) *et al.*	Poster Session
UCBG (breast)	GRT02 - COMET	SABCS	Circulating tumor DNA (ctDNA) and Circulating Tumor Cells (CTC) predictive value in HER2 negative metastatic breast cancer (MBC) patients treated with first line weekly paclitaxel and bevacizumab: results of a prospective cohort from the French Breast Cancer InterGroup Unicancer (UCBG): COMET study	J-Y. Pierga *et al.*	Poster Session
UCBG (breast)	NeoPAL	SABCS	TILs variations, proliferative response and PEPI scores in patients with luminal breast cancer receiving neoadjuvant letrozole-palbociclib or chemotherapy: an extended analysis of the NEOPAL trial	A. Vincent-Salomon *et al.*	Poster Session
UCBG (breast)	PADA-1	SABCS	Circulating ESR1 mutation detection rate and early decrease under first line aromatase inhibitor and palbociclib in the PADA-1 trial	F-C. Bidard *et al.*	Poster Session
Personalised Medicine Program	SAFIR 01	SABCS	Genomic characterisation of metastatic breast cancer	F. André *et al.*	Oral session
Personalised Medicine Program	AcSé Vému	SFH	Intérêt du Vemurafenib chez les patients atteints d'une leucémie à tricholeucocytes (HCL): résultats de l'étude de phase II AcSé Vemurafenib	X. Troussard *et al.*	Oral session
GGC (genetic)		BRCA Symposium	Familial breast cancer and DNA repair genes: insights into known and novel susceptibility genes from the GENESIS study	E. Girard *et al.*	Abstract
GGC (genetic)		Assises de Génétique Humaine et Médicale	Recommandation française du Groupe Génétique et Cancer pour l'analyse en panel de gènes dans le cadre de la prédisposition héréditaire au cancer du sein ou de l'ovaire – Quels gènes analyser ? Pour quelle utilité clinique?	J. Moretta Serra *et al.*	Oral Session Abstract
GGC (genetic)		Assises de Génétique Humaine et Médicale	Evaluation de l'intérêt de l'IRM corps entier pour la détection précoce des cancers chez les sujets porteurs de mutation constitutionnelle de TP53 dans le cadre d'un syndrome de Li-Fraumeni: résultats étude LIFSCREEN.	O. Caron *et al.*	Oral Session
GGC (genetic)		Assises de Génétique Humaine et Médicale	Rôle des gènes de la réparation de l'ADN dans la prédisposition génétique aux cancers du sein et implication pour les tests génétiques: résultats de l'étude cas-témoins GENESIS.	E. Girard *et al.*	Abstract

Organisation chart



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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.

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