GOING FURTHER
INNOVATING TOGETHER

UNICANCER
R&D ANNUAL REPORT 2017

unicancer

SUMMARY

03 Presentation

04 Editorials

06 Organisation chart

08 Resources and organisation

09 Decision process and funding model

10 MATWIN

11 2017 key figures and majors results

12 New flagship programmes

15 Clinical research activity: evolution over the years

16 Inclusions by cancer, localisation, institution type and geographical area

18 International collaborations and EORTC liaison office

20 Epidemiological strategy and medical economics

22 News in the expert groups

25 Inclusions per group / focus on FCCCs

26 Publications

28 Clinical operations

29 From protocol review to national public research funding

30 Centralised national data center

31 Biological resource centre (BRC)

32 Regulatory affairs, pharmacovigilance, Quality Assurance

34 Development and partnerships

36 Research in the FCCCs

37 Portfolio of trials in active phase in 2017

40 Portfolio of trials in follow-up phase in 2017

43 Communications

49 Contacts, follow us

PRESENTATION

Acteur majeur de la cancérologie française, Unicancer regroupe les 18 Centres de lutte contre le cancer (CLCC), répartis sur 20 sites hospitaliers. Ce sont des établissements de santé privés à but non lucratif exclusivement dédiés aux soins, à la recherche et à l'enseignement en cancérologie.
Unicancer en tant que promoteur académique, travaille en direct avec les unités de recherche des CLCC et d'autres établissements de santé (CHU, CH, cliniques) en France et à l'international.
La direction de la recherche et du développement a pour mission la mise en œuvre de la stratégie globale de recherche menée par Unicancer et est notamment chargée :

- de contribuer au développement de la recherche clinique en oncologie en France et à l'international ;
- de se concentrer sur des questions scientifiques dans des domaines insuffisamment couverts par l'industrie (cancers rares, chirurgie, radiothérapie, épidémiologie, etc.) et de faciliter l'accès des patients à l'innovation (recherche translationnelle et essais précoces) afin d'améliorer leur prise en charge ;
- de développer des partenariats, publics comme privés, et de coopérer avec tous les acteurs de la recherche ;
- de faciliter et de promouvoir la recherche préclinique et fondamentale réalisée dans les CLCC ;
- d'accompagner les équipes de recherche des CLCC et de mutualiser des activités support telles que les affaires réglementaires, la pharmacovigilance, l'assurance-qualité et la veille des appels à projets.

Le principal objectif de la R&D d'Unicancer est de faire progresser les connaissances sur le cancer pour un transfert rapide des innovations au lit du patient et une amélioration continue de sa prise en charge.

Unicancer, a major French player in oncology, groups together the 18 French Comprehensive Cancer Centers (FCCCs), at 20 hospital sites throughout France. They are private, non-profit health establishments exclusively dedicated to care, research and education in cancer.
Unicancer's R&D is the driving force of Unicancer's research and, as an academic sponsor, it works directly with the research units of the FCCCs and other health establishments (university hospitals, public hospitals and private clinics) in France and abroad. The mission of the direction of research and development is to implement Unicancer's global research strategy and, as such, its task is namely to:

- contribute to the development of clinical research in oncology in France and abroad;
- focus on scientific issues insufficiently covered by the pharmaceutical industry (rare cancers, surgery, radiation, epidemiology, etc.) and facilitate patient access to innovation (translational research and early trials) to improve their care;
- develop public and private partnerships and cooperate with all the stakeholders of research;
- facilitate and promote the preclinical and basic research carried out in the FCCCs;
- accompany the research teams of the FCCCs and mutualise support activities such as regulatory affairs, pharmacovigilance, quality assurance and monitoring of calls for projects.

The primary objective of Unicancer's R&D is to help increase knowledge about cancer for the rapid transfer of innovations to the patient's bedside and continuous improvement of patient care.

EDITORIALS

CHRISTIAN CAILLIOT,
HEAD OF RESEARCH AND DEVELOPMENT
CLAIRE LABREVEUX,
SCIENTIFIC DIRECTOR, DEPUTY DIRECTOR OF RESEARCH & DEVELOPMENT

Beyond its clinical research activity, research and development at Unicancer took another considerable leap forward this year, a decisive step in its growth with the launch of three notably ambitious projects:

- The **MyPeBS projec**t, financed under the European H2020 programme, which aims to optimise breast cancer screening practices using personalised screening based on individual risk factors;
- The **Check'Up study**, a national clinical-biological prospective cohort aiming to identify predictive response factors and resistance to immunotherapies as well as predisposing factors for the development of induced toxicities;
- Finally, the development of the **ESME Lung/ Immunology** RWD database (real-world data).

Each of these projects showcases a significant expansion of both the activity and attractiveness of R&D, in both the magnitude and the financial investment that they represent. They are made possible by the confidence of our partners who are committed to supporting these complex projects that require rigorous quality management.

The projects became feasible thanks to extensive cooperation with the FCCCs experts, Unicancer's enlarged international status and its ability to provide both human resources and dedicated expertise.

The creation and momentum of the new expert Group in Immuno-Oncology and the growing number of alliances and scientific partnerships with international groups (EORTC, NCIC, CRUK, SAKK, IBCSG, BIG…), is part of an integrated and dynamic approach to innovation and research with the intention of maintaining Unicancer's international position.

In July, the R&D department recruited Dr Claire Labreveux to help rise to the challenge. She brings her double experience of clinical research, both in hospital and industrial situations, to her new position as Scientific Director Deputy Director of Research and Development.

With the aim of optimising and pooling resources to better help the Centres in their constant quest for innovation and improvement of therapeutic strategies for better living conditions and longer life expectancy, 2017 has also seen a number of changes; The restructuring of clinical activities around research hubs ; The creation of a network of CRA mobilised in function of requirements to optimise the use of resources; stronger Regulatory Affairs, Quality Assurance and Pharmacovigilance, to guarantee patient safety and the quality of collected data; and finally, the assembly of all the teams on one single site in Kremlin Bicêtre (Paris, France).

These few examples serve to illustrate the impetus of Unicancer R&D, which relies on the implication of all its teams. The full scope of the 2017 projects remains to be discovered in this document. Please read on!

PATRICE VIENS,
PRESIDENT OF UNICANCER

Research and development activities at Unicancer have been in constant expansion over recent years, even so, 2017 will be remembered for its great steps forward, both in the quality and quantity of ambitious projects initiated this year.

The cooperation and complementarity between the Centres, the close ties between study fields, the incessant increase in clinical trial subjects, as well as the alliance of education and research combine to create a unique source of expertise which allows Unicancer to explore the emerging areas of innovation and experimentation involved in the future of cancer care.
Unicancer R&D is taking an active part in fundamental ongoing research in oncology - in the field of genomics and immunotherapy - but also in radiotherapy, through early screening and real-world data.

This progress has led the way to decisive international cooperation and unprecedented research perspectives, which confirm Unicancer's position as Europe's leading academic promoter in oncology.

This recognition is the fruit of a strategy based on the quest for both excellence and innovation.

Equal access to quality healthcare has always been one of the founding values at Unicancer. A value which has been furthered by the activities of R&D Unicancer this year by increasing the access of patients to Unicancer sponsored clinical trials whatever the origin of the patient (Public hospitals, private clinics or FCCCs).

ALEXANDER EGGERMONT,
VICE PRESIDENT OF UNICANCER IN CHARGE OF RESEARCH

The world of oncology is currently witness to an unprecedented revolution. Following the rise of targeted therapies, immunotherapy has emerged into the therapeutic landscape and for the first time ever, we have the ability to treat resistant metastatic cancers. But this is only the beginning, there is still much more left to discover and understand. The entire strategy of Unicancer R&D is directed towards a comprehensive approach to research, with the ultimate goal of furthering our expertise.

CHRISTIAN CAILLIOT

CLAIRE LABREVEUX

PATRICE VIENS

ALEXANDER EGGERMONT

ÉDITORIAUX

CHRISTIAN CAILLIOT,
DIRECTEUR DE LA RECHERCHE ET DU DÉVELOPPEMENT
CLAIRE LABREVEUX,
DIRECTRICE SCIENTIFIQUE ET DIRECTRICE ADJOINTE

Au-delà de l'activité de recherche clinique, la direction de la recherche et du développement d'Unicancer (R&D) franchit cette année encore, une étape décisive de sa croissance avec notamment le déploiement de 3 projets ambitieux :

- le projet **MyPeBS**, financé dans le cadre du programme européen H2020, qui vise à optimiser les pratiques de dépistage du cancer du sein en Europe par une personnalisation du dépistage en fonction du risque individuel ;
- l'étude **Check'Up**, cohorte clinico-biologique prospective nationale visant à identifier des facteurs prédictifs de réponse et d'échappement aux immunothérapies ainsi que les facteurs de prédisposition de toxicités induites par ces traitements ;
- et enfin, le développement de la plateforme de données en vie réelle **ESME poumon / immunologie**.

Ils témoignent par leur portée, leur taille, et l'investissement financier qu'ils représentent, d'une progression significative de l'activité et de l'attractivité de la R&D, tout comme la confiance renouvelée des partenaires qui s'engagent et soutiennent ces projets complexes nécessitant rigueur et qualité de gestion.

Ces projets ont été réalisables grâce à une importante collaboration avec les experts des Centres de lutte contre le cancer, à **l'accroissement de la visibilité** de la R&D d'Unicancer sur la scène internationale et à sa capacité à disposer de ressources humaines et de compétences dédiées.

La création puis la montée en puissance du nouveau Groupe d'experts en Immuno-Oncologie, et la multiplication des alliances et collaborations scientifiques avec des groupes étrangers (EORTC, NCIC, CRUK, SAKK, IBCSG, BIG…), s'inscrivent dans la **dynamique de recherche intégrée et d'innovation** voulue par la direction et sa volonté d'asseoir son positionnement au niveau international.

Pour relever le challenge, la direction de la R&D s'est adjointe en juillet de la double expérience en recherche clinique, à la fois hospitalière et industrielle, du Dr Claire Labreveux, en qualité de directrice scientifique et adjointe de la direction.

La réorganisation des activités cliniques autour de pôles de recherche, l'optimisation des ressources avec la création d'un pool d'ARC, mobilisés en fonction des besoins ; le renforcement des affaires règlementaires, de l'assurance qualité et de la pharmacovigilance, garantes de la sécurité des patients et de la qualité des données générées d'une part, et la réunion de l'ensemble des équipes au Kremlin Bicêtre d'autre part, attestent de la volonté de la direction d'optimiser et de mutualiser les ressources pour toujours **mieux accompagner les Centres** dans leur recherche permanente d'innovation et d'optimisation des stratégies thérapeutiques en vue d'augmenter la durée et la qualité de vie des patients.

Ces quelques exemples illustrent le dynamisme de la R&D d'Unicancer, qui repose sur l'investissement des équipes. L'étendue des projets menés en 2017 est à découvrir dans ce document, bonne lecture !

PATRICE VIENS,
PRÉSIDENT D'UNICANCER

Si les activités de recherche et développement d'Unicancer connaissent une croissance régulière depuis plusieurs années, 2017 restera marquée par un grand pas en avant sur les plans quantitatif et qualitatif, qu'illustrent les projets ambitieux initiés cette année.

La collaboration et la complémentarité des Centres, avec le rapprochement des disciplines, la constante augmentation des inclusions dans les essais et l'alliance entre l'enseignement et la recherche, constituent une source d'expertise unique sur laquelle Unicancer s'appuie pour investir les terrains d'innovation et d'expérimentation de la cancérologie de demain. La R&D d'Unicancer participe activement aux avancées capitales qui se préparent en cancérologie, portées par la génomique et l'immunothérapie, mais aussi par la radiothérapie, le dépistage précoce et les données en vie réelle.

Cette progression a ouvert la voie à des coopérations internationales décisives et à des perspectives de recherche inédites, qui confirment sa position de promoteur académique leader en Europe.

Cette reconnaissance est le fruit d'une stratégie fondée sur la quête de l'excellence et l'innovation. Avec le renforcement de la participation aux essais cliniques de communautés de patients issus d'établissements hors CLCC (CHU, CHG), l'activité de recherche et développement d'Unicancer contribue également à la mise en application d'une autre de ses valeurs socles : l'égal accès de tous à des soins de qualité.

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

Le monde de la cancérologie vit une révolution sans précédent. Après l'essor des thérapies ciblées, l'immunothérapie s'est imposée dans l'arsenal thérapeutique avec, pour la première fois, la possibilité de traiter des cancers métastatiques résistants. Mais nous n'en sommes qu'au début, il y a encore tant à découvrir et comprendre. Toute la stratégie de la R&D Unicancer tend vers une approche intégrée de la recherche pour atteindre ce but ultime : contribuer à l'émergence de la connaissance.

ORGANISATION CHART

ON MARCH 20TH, 2018

C. LABREVEUX
Scientific Director
Deputy Director of Research and Development

A. MAUDUIT
Assistant

C. CAILLIOT
Research and Development Director

MATWIN
L. Robert
CEO

E. PEREIRA
Assistant

B. JUZYNA
Clinical Operations Director

I. TIXIER
Assistant

J. BOBINNEC
EORTC Liaison Officer

T. STANBURY
Medical Writer

P. TOTO
Data Management Programmer

V. LOUNAS
Medical Writer

J. LEMONNIER
Breast and Radiotherapy Clinical Programmes Manager

Project Managers :
N. BONNET
H. MANDUZIO
C. VISSAC SABATIER
S. EVERHARD

Clinical Research Associate Coordinators :
J. CUNY
S. MARQUES
S. BADACHE
M. ROUCHON

Assistants:
S. GARCIA
AC. LE GALL

S. NENAN LE FICHER
GETUG/GERICO/ Supportive care Programmes Manager

Project Managers:
V. PLENCE FAUROUX
Y. BADRONE
S. PELISSIER
F. TANTOT

Clinical Research Associate Coordinators:
V. BENAVENT
M. BRIHOUM
G. GARY BOBO

Assistants :
E. HANTRAIS GERVOIS
N. DANCOISNE
G. GUIBERT

C. JOUFFROY
UCGI/H&N/Sarcoma Clinical Programmes Manager

Project Managers:
V. PEZZELLA
J. DELAYE
N. LACHAUX

Clinical Research Associate Coordinators:
M. BERGEAUD
N. SARTHE
N. DE SOUSA
I. JALLUT

Assistants :
S. DRARIS
K. CHERIF

D. COUCH
Immuno-oncology Clinical Programmes Manager

Project Managers:
C. SIMON

Clinical Research Associate Coordinators:
S. GHANEM

Assistant :
M.L. GMAZEL

M. JIMENEZ
Personalised Medicine Clinical Programmes Manager

Project Managers:
A. JACQUET
C. MAHIER
F. LEGRAND

Clinical Research Associate Coordinators:
J. GARRABEY
C. COULOMB
L. JOHNSON

Assistants :
F. FAROOQ
E. LIBION

Translational Research Project Manager/BRC:
E. LONCHAMP

My PEBS Project Manager:
C. BARON

CRA Manager:
C. MESLEARD

Clinical Research Associates:
S. AJJAN
J. SAROTTE
B. SOLDA
FZ. TOUMI
M. ADAMS
N. IJAZ-QAISER
A. BENDJENNAT
V. SCHARTNER
S. TROCHU
TKD. VO-BOURGAIS
S. GHANEM
S. NASSIRI
R. YO
G. BAGOE
J. BOULI-MENGUE
M. CHAOUCH
P. LAMBERT
G. PHOTHIRATH
A. POITOU
AS. BACH
S. BARNAT
N. FRAYSSINET
W. SOUSAK CHEIKH
E. BERLAND
O. QUEREL
T. ALMEIDA-ROQUE
F. AUBEY
S. AUNEAU
SI. BENYAGOUB
M. BOUZINA
E. BRUMENT
E. HOAREAU
M. HUSLEAG
A. KADI HANIFI
Z. MAJED
G. MANSOURI
M. MAUDUIT
N. IJAZ QAISER
G. KACI

N. AIT RAHMOUNE
Regulatory Affairs and Pharmacovigilance Deputy Director

L. Da SILVA
Assistant

PH. BERTOYE
Regulatory affairs, Quality Assurance and Pharmacovigilance Director

P. NEZAN
Assistant

R. BOIDIN
Regulatory Affairs Manager/DPO

R. ATMI
Regulatory Affairs Officer

D. MOUALEU-KAMENI
Regulatory Affairs Officer

A. PEPION
Legal Counsel intern

-
Personal Data Protection Project Officer

R. RAHMANI
Pharmacovigilance Physician Manager

S. COUSTY
Pharmacovigilance Officer

I. KAIDI
Pharmacovigilance Officer

L. KRIEF-OLIVIER
Pharmacovigilance Officer

OLYMPIO
Pharmacovigilance Officer

D. VENIGER
Pharmacovigilance Officer

A. GUETTIER
Pharmacovigilance Officer

D. RIBAULT
Quality Assurance Manager

A. MOREAU
Quality Assurance - Auditor

S. FLEURY
Quality Officer

A. PODGORSKA
Legal Expert/ DDP Contract

AL. MARTIN
Development and Partnerships Director

C. GAMET
Assistant

Partnerships and Dissemination Manager

C. JAMAIN
Fundamental and Preclinical Research Manager

A. SIRVEN
Strategic Programme Development Manager

M. ROBAIN
Head of Real World Data

G. SIMON
Associate Director, ESME studies Manager

T. GUESMIA
Medical Projects Manager

C. COURTINARD
Manager of Data management Operations, International support development

N. BOUYER
Project assistant

I. PIOT
Data Manager

O. PAYEN
Data Manager

O. VILLACROIX
Data manager

P. JOUANY
Projects Operations Manager

M. CHEVROT
Technical Coordinator

C. MARCIANO
Technical Coordinator

P. DANGLOT
Regional Clinical Studies Technician – Quality Control

E. KUPFER
Local Clinical Studies Technicians

T. SAID
Local Clinical Studies Technicians

A. VANNI
e-CRF Developments Project Manager and ESME Database Administrator

J. PAREDES
Web Developer
Project Manager ESME Database Administrator

B. TORRES
Programmer

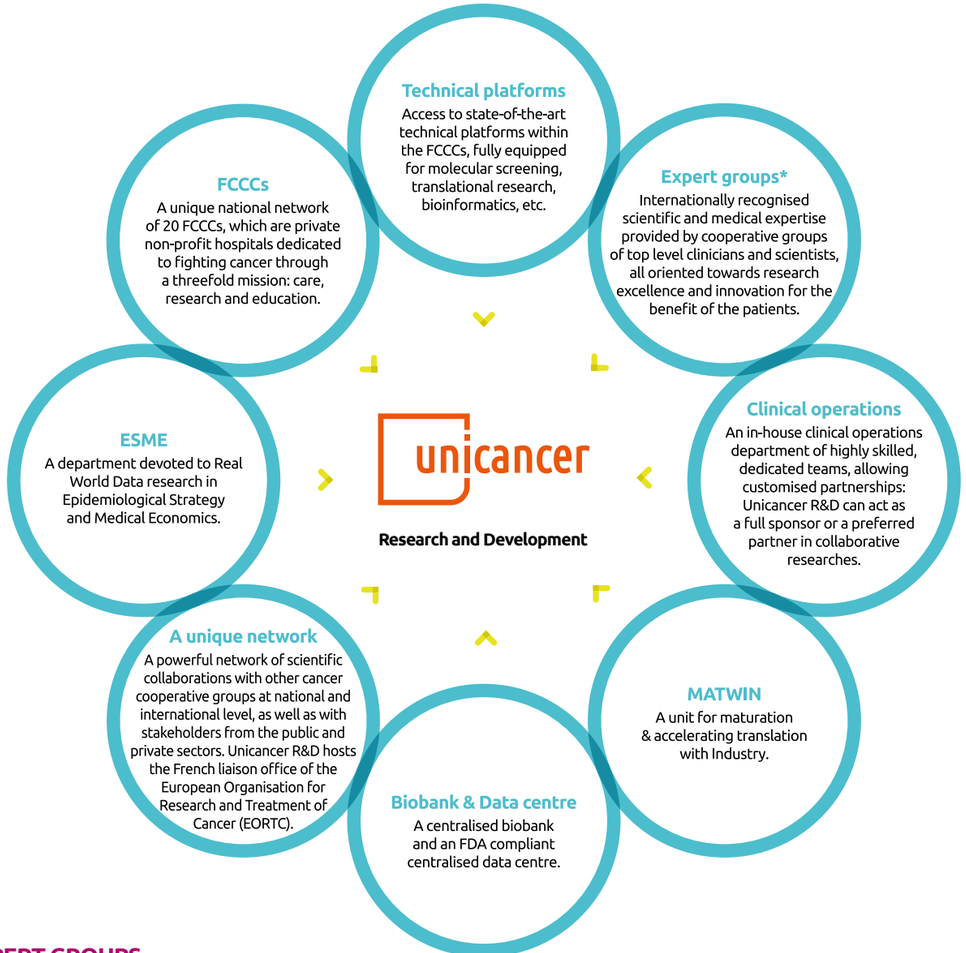
Clinical Operations Department

Regulatory affairs, Quality Assurance and Pharmacovigilance Department

Development and Partnerships Department

Real World Data Departement

RESOURCES AND ORGANISATION



*EXPERT GROUPS

Tumour groups

- French Breast Cancer Intergroup (UCBG)
- Gastrointestinal Group (UCGI)
- GenitourinaryGroup (GETUG)
- Head and Neck Group (UCH&N)
- Sarcoma Group

Cross pathology groups and programmes

- Geriatrics Group (GERICO)
- Personalised Medicine Programme
- Early Phase Group (GEP)
- Supportive Care Intergroup
- Radiation Therapy Group (UNITRAD)
- Epidemio Strategy and Medical Economics (ESME) Programme
- Immuno-oncology Group

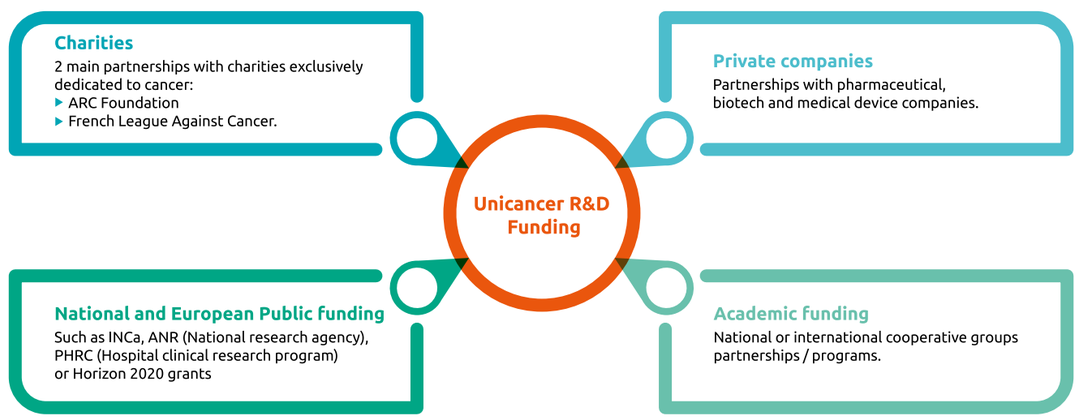
Transversal groups

- Clinical Pharmacology and Oncology Group (GPCO)
- Genetic and Cancer Group (GGC)
- Onco-biostatistics Group
- Group of Evaluation of Immunohistochemical Prognostic Factors in Breast Cancer (GEFPICS)
- Prevention of Infections in Cancerology Group (GPIC)

DECISION PROCESS

The research projects undertaken by the research and development direction at Unicancer are first subjected to a validation process where the decisions are made by decision-making bodies.

FUNDING MODEL



MATWIN

MATURATION AND ACCELERATING TRANSLATION WITH INDUSTRY

MATWIN is a fully-owned subsidiary of Unicancer which leads a national programme 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 coming from Academia or start-ups, with the view of fostering early collaborations. The process is based on a partnership with international laboratories (AstraZeneca, Boehringer Ingelheim, Bristol-Myers Squibb, Celgene, Genomic Health, GlaxoSmithKline, Janssen, Nanostring Technologies, Novartis, Pfizer, Pierre Fabre, Roche, Sanofi) willing to benefit from the appeal of French research 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 several steps of the programme:

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

Since 2015, MATWIN has also organised simultaneously with the Board meeting an international partnering convention called MEET2WIN entirely dedicated to open innovation and collaborative research in oncology. This event has proved increasingly successful over the years and is becoming a reference meeting point for partnerships in oncology innovation in France, gathering more than 800 participants and more than 2.300 B2B meetings.

In 2017, the International Board was joined by two large Biotech companies, specialised in the development of cancer diagnostic tools, Genomic Health and NanoString Technologies, making the programme even more attractive.

For the first time, MATWIN also invited representatives of venture capital funds to allow them identify projects of interest and possibly financially support their development.

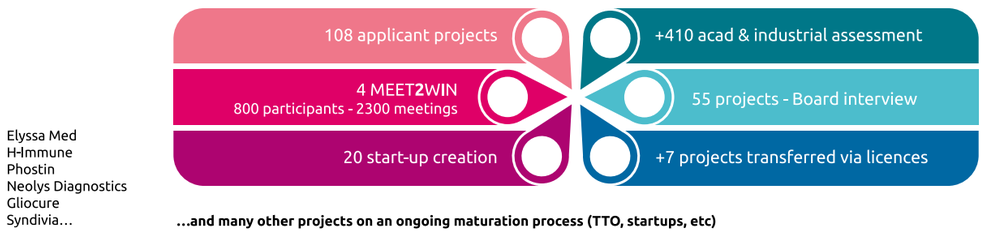
A few figures from MATWIN's review (2009-2017) :

- 108 applicant projects, +400 academic and industrial assessments
- 57 projects interviewed by the MATWIN International Board
- 20 start-up creations (amongst which Syndivia, ElyssaMed, H-Immune, Phostin, Gliocure…)
- +7 projects already transferred via licences

The next step will be the expansion of the programme into new growth areas, possibly digital innovation and artificial intelligence in oncology.

APPLICANT PROJECT TYPES	
Therapy, including	71%
Immunotherapies	20%
Small molecule drugs	19%
Diagnostic/prognosis/biomarkers	23%
Other (e-health, medical devices)	6%

A POSITIVE REVIEW ! 2009-2017



…and many other projects on an ongoing maturation process (TTO, startups, etc)

2017 KEY FIGURES AND MAJORS RESULTS

4987
PATIENTS INCLUDED IN R&D SPONSORED-CLINICAL TRIALS

86
ONGOING CLINICAL TRIALS, INCLUDING **44** IN RECRUITMENT PHASE

11
NEWLY INITIATED CLINICAL TRIALS **+ 2** TRANSLATIONNAL PROGRAMMES

1
PROJECT GRANTED BY THE EUROPEAN **H2020** PROGRAMME.

216
INVESTIGATIONAL SITES INVOLVED (PUBLIC HOSPITALS, PRIVATE CLINICS, COMPREHENSIVE CANCER CENTRES), INCLUDING **52** LOCATED IN 8 OTHER COUNTRIES

25
PUBLICATIONS IN SCIENTIFIC JOURNALS, INCLUDING 1 IN THE *NEW ENGLAND JOURNAL OF MEDICINE*

40
COMMUNICATIONS OF WHICH **14** WERE AT ASCO, **9** AT ESMO AND **11** AT SABCS

30 000
PATIENTS REGISTRED IN THE ESME PROGRAMME OF WHICH 10 000 IN THE NEW ESME PROJECTS LAUNCHED IN 2017

CANTO

CANTO: A cohort to quantify and to predict treatment related chronic toxicities and social impact in patients with non-metastatic breast cancer. Coordinator: F. André. Number of planned inclusions: 12,000

As of December 31, 2017, 11 239 women are included in the CANTO cohort.

The data base is now mature for a first set of patients and open to research projects via dedicated calls for proposal . Some twenty projects have been approved after scientific review. Major scientific aims such as neuropsychological impact, medico-economic impact, return to work, adherence to care plans, microbiota and physical activity are investigated through these first set of projects.

In 2017, the first symposium entirely dedicated to patients took place in Paris, thanks to the departmental committees of the "Ligue Nationale contre le cancer" (French League against cancer). Preliminary results of the ongoing studies were presented to the assembly. This symposium was massively supported by the women volunteers to participate to the CANTO cohort and hospital staffs involved in the project.

The first scientific communications have been released in 2 major congresses for oncology research (ASCO and SABCS).

SABCS	CANTOCHEM: analysis of chemotherapy practice and early side effects in the 6090 first patients from the prospective CANTO cohort	P. Cottu, Y. Amar, B. Pistilli, H. Bonsang-Kitzis, A. Lesur, F. Lerebours, L. Vanlemmens, O. Tredan, C. Levy, C. Jouannaud, M. Fournier, P. Soulie, O. Rigal, S. Giacchetti, A. Arnaud, O. Arsene, A. Savignoni, C. Mesleard, F. Andre and P. Arveux	Poster #P6-12-18
ASCO	Unicancer : prospective cohort study of treatment related chronic toxicities in patients (pts) with localized breast cancer (BC) (CANTO).	I. M. Vaz Duarte Luis, P. H. Cottu, C. Mesleard, A-L. Martin, A. Dumas, S. Dauchy, O. Tredan, C. Levy, J. Adnet, M. Rousseau-Tsangaris, F. Andre, P. Arveux	Poster #PS10125

EUROEWING 99

The international EE99 trial launched in 2000 was designed to address several questions of which the assessment of consolidation high-dose chemotherapy with busulfan-melphalan for patients with localised high-risk Ewing sarcoma. With proven survival benefits, without excessive toxicity, busulfan-melphalan is now standard chemotherapy in this setting Patients and clinicians can now benefit from robust evidence of the value of this treatment.

ACSÉ VEMURAFENIB

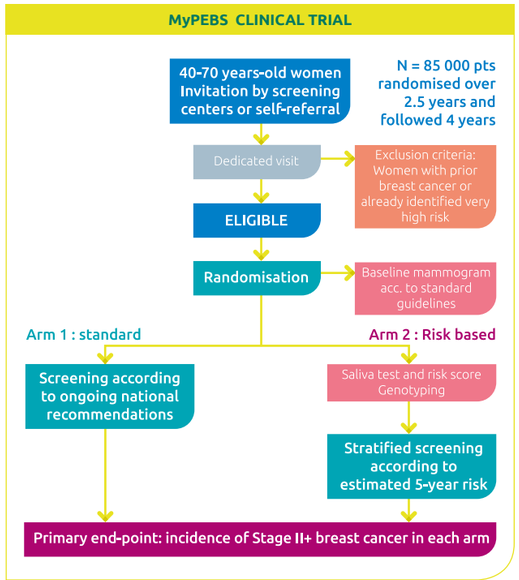
Final results of the AcSé vemurafenib cohort of patients presenting advanced Hairy Cell Leukemia (HCL) show the high efficacy of vemurafenib in refractory HCL and the feasibility of this treatment (need of cutaneous care but no hematological toxicities). After a 4-months follow-up, the best overall response was complete in 6/10 patients and partial in 4.

NEW FLAGSHIP PROGRAMMES

MyPeBS project: towards personalising breast cancer screening

Today, age is the only variable considered by breast cancer (BC) screening initiatives worldwide to determine when and how often women should be invited for a mammogram. But each woman has her own risk of developing BC, depending on her personal and family medical history, genetic factors, breast density, etc. What if personalising breast screening using an individual level of risk was more efficient in reducing the frequency of invasive breast cancer than the current age-based only screening strategy?
In 2017, Unicancer obtained an EU grant for MyPeBS, an 8-year international clinical research project that will compare in 85,000 women aged 40 to 70 from 5 countries, a personalized BC risk-based strategy to the standard local screening strategy. Unicancer is the Project Coordinator and the trial sponsor.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 755394.



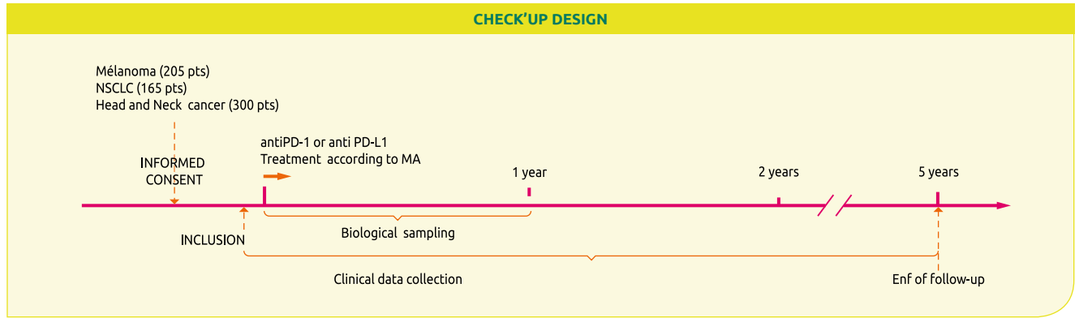
CHECK'UP

In 2017, Unicancer launched CHECK'UP, the largest prospective cohort in France aiming at identifying a predictive signature of response to immunotherapies (specifically PD-1/PD-L1 checkpoint inhibitors) as well as evaluating the risk factors for treatment-related toxicity, the long-term effects of treatment and the economic impact of these treatments in a real-life setting.
CHECK'UP is coordinated by Pr Frédérique Penault-Llorca (Centre Jean Perrin) and Pr Gilles Vassal (Gustave Roussy), and entirely financed by the ARC foundation.
This study will be activated in 2017 and will collect data and biological samples (biopsies, blood, microbiota) from a total of 670 patients treated with anti-PD-1 or anti-PD-L1 therapies with marketing authorisation (MA) in France. Each patient will be followed for a total of 5 years.

Three cohorts of patients will be enrolled, according to their indication:

- Patients with non-resectable or metastatic melanoma;
- Patients with non-small cell lung cancer without prior treatment;
- Patients with head & neck squamous cell carcinoma that is recurrent or progressing following chemotherapy*.

The number of cohorts and accepted drugs may evolve during the course of the study if new marketed authorisations are granted.



*Recruitment to this cohort will begin once the price of nivolumab has been fixed by the HAS.

AcSé immunotherapy

In 2017, under the aegis of the INCa 'secured access' (AcSé) programme, Unicancer launched AcSé Immunotherapy – twin trials aimed at evaluating anti-PD1 therapies (nivolumab and pembrolizumab) in 650 patients with specific rare cancers.

Scientific coordination is provided by Dr Aurélien Marabelle and Dr Christophe Massard of the Drug Development Department (DITEP) at Gustave Roussy, with the support of the INCa rare cancer network groups. The French National Cancer Institute (INCa), the "Ligue Nationale contre le cancer" (French League against cancer) and our industrial partners (Bristol-Myers Squibb and MSD France) provide treatments and financial support.

Esme

In 2017 a second data platform on ovarian cancer was launched within the FCCCs. At the end of the year, 6 000 patients had already been selected, aiming 14 000 cases collected by 2019.
By the end of the year 2017 , a third data platform, dedicated to advanced or metastatic lung cancer, has been set up within the network of FCCCs centres and hospital centres, with a total of 7 000 patients available in the database by December. The aim is to get a national cover of the lung cancer management with the involvement of 20 health institutions outside the FCCCs network for more than 26 000 patients expected by 2023.

CLINICAL TRIALS ACTIVATED IN 2017

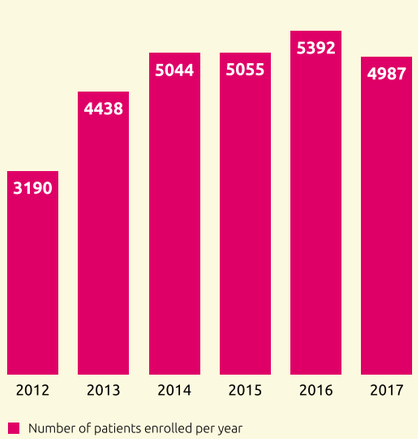
EXPERT GROUP	INTERNAL REFERENCE	SHORT TITLE	STUDY TITLE	STUDY COORDI-NATOR	EXPECTED NUMBER OF PATIENTS	PHASE	FRANCE (F) /INTERNA-TIONAL (I)	STUDY ACTIVATION DATE
GETUG	Eudract 2014-001787-38	GETUG-AFU 29 - PEACE 3/EORTC 1333	A Randomized multicenter phase III trial comparing enzalutamide *vs.* a combination of Ra223 and enzalutamide in asymptomatic or mildly symptomatic castration resistant prostate cancer patients metastatic to bone. PEACE III	Y. Loriot	75 (France only)	III	I	13/10/2017
IOG	UC-0105/1611	AcSé Nivolumab	Secured access to nivolumab for adult patients with selected rare cancer types	A. Marabelle	300	II	F	25/04/2017
GIO	UC-0105/1612	AcSé pem-brolizumab	Secured access to pembrolizumab for adult patients with selected rare cancer types	C. Massard	350	II	F	23/05/2017
PERSO MED	UC-0105/1614	TRACERX	Tracking triple-negative breast cancer evolution through therapy	M. Arnedos	250	cohort	F	14/04/2017
SUPPORTIVE CARE	UC-0106/1510	QUALIOR	Feasibility and Efficacy of Supervised Home-based Standard Physical Exercise Programme in Patients Receiving Oral Therapy for Metastatic cancer	F. Joly	312	II-III	F	21/06/2017
UCBG	UC-0140/1615	PADA-1	Randomized, open label, milticentric 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	800	III	F	22/03/2017
UCBG	UC-0104/1605	TUMOSPEC	Investigation of tumour spectrum, penetrance and clinical utility of germline mutations in new breast and ovarian cancer susceptibility genes	O. Caron	500	cohort	F	21/09/2017
UCGI	UC-0110/1609	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	640	III	I	02/02/2017
UCH&N	UC 0130/1619	NISCAHN-ORL08	A Phase II, Multicenter, Non Randomized, Open Label Study of Nivolumab In Recurrent and/or Metastatic Salivary Gland Carcinoma of the Head and Neck	J. Fayette	92	II	F	09/03/2017
UCH&N	UC-0130/1703	TOPNIVO-ORL09	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	250	II	F	07/07/2017
UNITRAD	UC-0107/1602	OLIVER	Oligometastases of the LIVer treated with chemotherapy with or without Extracranial Stereotactic Body Radiation Therapy in patients with colorectal cancer	S. Servagi	210	III	F	14/12/2017

TRANSLATIONNAL PROJECTS ACTIVATED IN 2017

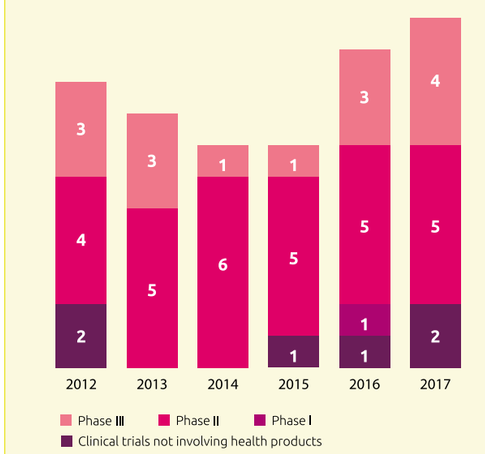
EXPERT GROUP	SHORT TITLE	PROJECT TITLE	PROJECT COORDINATOR	ACTIVATION DATE
MED PERSO	SAFIVA	From primary tumors to metastasis – Study of spatial and temporal heterogeneity in breast cancer – The SAFIVA project	M. Lacroix-Tricki	08/06/2017
UCBG	MyPROBE	Molecular assaYs to PRedict Outcome in early Breast cancEr	F. André	15/12/2017

CLINICAL RESEARCH ACTIVITY: EVOLUTION OVER THE YEARS

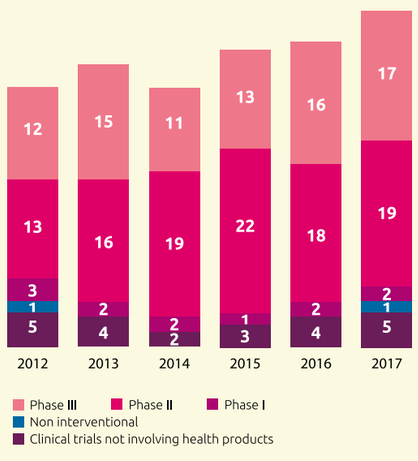
NUMBER OF PATIENTS ENROLLED PER YEAR



NUMBER OF NEW TRIALS PER YEAR AND PER PHASE

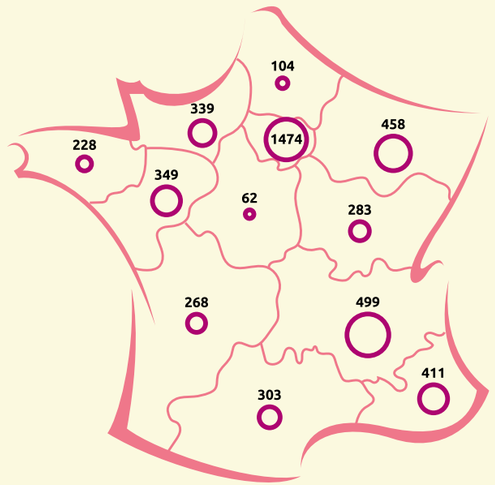


NUMBER OF RECRUITING TRIALS PER YEAR AND PER PHASE

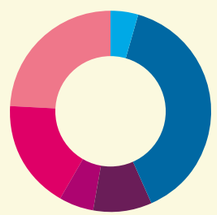


INCLUSIONS BY CANCER, LOCALISATION, INSTITUTION TYPE AND GEOGRAPHICAL AREA

GEOGRAPHICAL DISTRIBUTION OF INCLUSIONS IN FRANCE (N=4778)

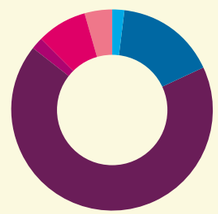


PROPORTION OF RECRUITING SITES BY TYPE OF INSTITUTION



- 5% Public hospitals of Paris (AP-HP)
- 39% Other public hospitals (excl. AP-HP)
- 9% FCCCs
- 6% Other private non-profit hospitals
- 18% Private Clinics
- 24% Foreign Institutions

PATIENTS' ACCRUAL SHARED BY TYPE OF INSTITUTION



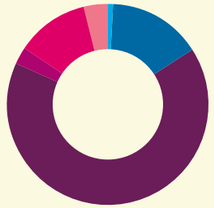
- 2% Public hospitals of Paris (AP-HP)
- 16% Other public hospitals (excl. AP-HP)
- 68% FCCCs
- 2% Other private non-profit hospitals
- 8% Private Clinics
- 4% Foreign Institutions

TOTAL NUMBER OF PATIENTS INCLUDED BY LOCALISATION AND BY INSTITUTION TYPE

	BREAST	OF WHICH CANTO	DIGESTIVE	GENITO -URINARY	HEAD & NECK	LUNG	OVARIAN	SARCOMA	MULTIPLE LOCALISATIONS	TOTAL
Public hospitals of Paris (AP-HP)	19		6	29	4	7	4	4	27	100
Other public hospitals (excl. AP-HP)	305		99	120	64	136	11	2	65	802
FCCCs	2546	1209	61	250	246	95	20	24	126	3368
Other private non-profit hospitals	54		15	22	3				6	100
Private Clinics	235		32	114	5				22	408
Foreign Institutions	77		1	128			3			209
Total	**3236**	**1209**	**214**	**663**	**322**	**238**	**38**	**30**	**246**	**4987**

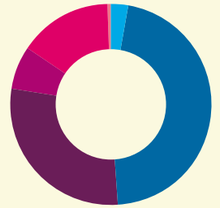
PATIENTS' ACCRUAL SHARE BY TYPE OF INSTITUTION FOR THE MAIN LOCALISATION

BREAST (WITHOUT CANTO, N=2027)



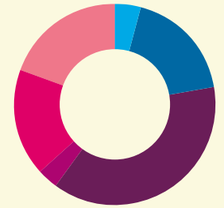
- 1% Public hospitals of Paris (AP-HP)
- 15% Other public hospitals (excl. AP-HP)
- 66% FCCCs
- 3% Other private non-profit hospitals
- 12% Private Clinics
- 4% Foreign Institutions

DIGESTIVE (N=214)



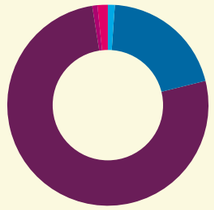
- 3% Public hospitals of Paris (AP-HP)
- 46% Other public hospitals (excl. AP-HP)
- 29% FCCCs
- 7% Other private non-profit hospitals
- 15% Private Clinics
- 0% Foreign Institutions

GENITO-URINARY (N=663)



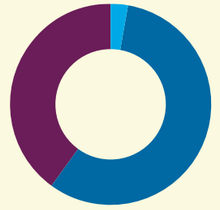
- 4% Public hospitals of Paris (AP-HP)
- 18% Other public hospitals (excl. AP-HP)
- 38% FCCCs
- 3% Other private non-profit hospitals
- 17% Private Clinics
- 19% Foreign Institutions

HEAD AND NECK (N=322)



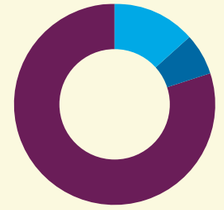
- 1% Public hospitals of Paris (AP-HP)
- 20% Other public hospitals (excl. AP-HP)
- 76% FCCCs
- 1% Other private non-profit hospitals
- 2% Private Clinics

LUNG (N=238)



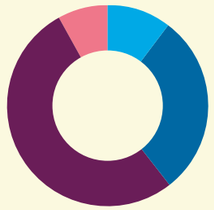
- 3% Public hospitals of Paris (AP-HP)
- 57% Other public hospitals (excl. AP-HP)
- 40% FCCCs

SARCOMA (N=30)



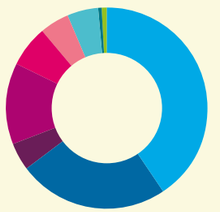
- 13% Public hospitals of Paris (AP-HP)
- 7% Other public hospitals (excl. AP-HP)
- 80% FCCCs

OVARIAN (N=38)



- 11% Public hospitals of Paris (AP-HP)
- 29% Other public hospitals (excl. AP-HP)
- 53% FCCCs
- 8% Foreign Institutions

DISTRIBUTION OF INCLUDED PATIENTS BY CANCER LOCALISATION



- 40% Breast without canto
- 24% CANTO (Breast)
- 4% Digestive
- 13% Genito-urinary
- 6% Head & Neck
- 5% Lung
- 5% Multiple localisations
- 1% Ovarian
- 1% Sarcoma

INTERNATIONAL COLLABORATIONS

Over the years, the Unicancer expert groups developed strong collaborations with several major actors in academic research in oncology. 11 of the current 44 trials currently in progress are the result of an international collaboration for the development of the scientific project or the cooperation in the recruitment of patients, together with scientific partnerships in the results analysis or conduct of the translational programmes associated to the biological collections associated to the trials.

Let's underline for 2017:

- the success of the MyPeBS project to the H2020 call (see page 12). This project results in the collaboration of 24 international partners coordinated by Unicancer.
- **the publication of the final results of the MINDACT-PACS 07 trial were the contribution of the French network of investigational sites represents a third of the recruitment.**
- The signature of a Memorandum of understanding with the NCI-C-CCTG for the systematic evaluation of possible collaborations in any topic of research
- The launch of two collaborative trials:
  - the IROCAS trial, developed by UCGI (iunder the umbrella of the French PRODIGE intergroup) in collaboration with Canadian experts. This phase III trial comparing mFOLFIRINOX to mFOLFOX in adjuvant treatment of colon cancer is funded by the PHRC-K 2015 in France and by the NCI-C in Canada.
  - the GETUG-AFU 29 - PEACE 3/EORTC 1333 trial conducted under the umbrella of the EORTC and the GETUG group. (A Randomized multicenter phase III trial comparing enzalutamide vs. a combination of Ra223 and enzalutamide in asymptomatic or mildly symptomatic castration resistant prostate cancer patients metastatic to bone).
- **The progress of 3 large phase III trials sponsored by Unicancer under the lead of a Unicancer Group:**
  - UNIRAD – PACS 11: a trial evaluating the benefit of everolimus in women with poor prognosis primary breast cancer. Collaboration between UCBG / CRUK / Belgian investigators group.
  - PEACE 1: a phase III study in patients with metastatic hormone-naïve prostate cancer. Collaboration between GETUG, EORTC and hospitals in 15 countries.
  - PEACE 2: a phase III trial in patients with localised prostate cancer and high-risk features of relapse.

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 from 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 initiation 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 2017, 10 new trials were activated in France by the liaison office and 23 trials were recruiting (see below and p. 19).

EORTC TRIALS PORTFOLIO AND RECRUITMENT STATUS IN FRANCE IN 2017

List of studies approved in France in 2017

EORTC RESEARCH GROUP(S)	EORTC STUDY NUMBER (ACRONYM)	STUDY TITLE	DATE STUDY APPROVED IN FRANCE
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
LCG	1613 (APPLE)	APPLE trial: Feasibility and activity of AZD9291 (osimertinib) treatment on Positive Plasma T790M in EGFR mutant NSCLC patients	20/07/2017
ROG-BTG	1308	Radiation *versus* Observation following surgical resection of Atypical Meningioma: a randomized controlled trial (The ROAM trial)	22/08/2017
ROG-GUCG	1414	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
GUCG	1532	A phase 2 Randomized Open-Label Study of Oral ODM-201 *vs.* androgen deprivation therapy (ADT) with LHRH agonists or antagonist in Men with Hormone Naïve Prostate Cancer	07/09/2017
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
HNCG	1559	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
HNCG-ROG	1420	Phase III study assessing the "best of" radiotherapy compared to the "best of" surgery (trans-oral surgery (TOS)) in patients with T1-T2, N0 oropharyngeal carcinoma	18/09/2017
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
STBSG	1506	A phase II multicenter study comparing the efficacy of the oral angiogenesis inhibitor nintedanib with the intravenous cytotoxic compound ifosfamide for treatment of patients with advanced metastatic soft tissue sarcoma after failure of systemic non-oxazaphosporine-based first line chemotherapy for inoperable disease "ANITA"	04/05/2017

List of EORTC studies active in France in 2017

EORTC RESEARCH GROUP(S)	EORTC STUDY NUMBER (ACRONYM)	STUDY TITLE	STUDY START DATE	NUMBER OF FRENCH PATIENTS INCLUDED IN 2017/TOTAL NUMBER OF PATIENTS RANDOMISED
BTG	1320	Trabectedin for recurrent grade II or III meningioma: a randomized phase II study of the EORTC Brain Tumor Group	10/07/2015 Recruitment closed on: 20/07/2017	23/90
BTG	1419	Molecular genetic, host-derived and clinical determinants of long-term survival in glioblastoma	05/07/2015	34/241
CLG	58051	International collaborative treatment protocol for infants under one year with acute lymphoblastic or biphenotypic leukemia	07/01/2008 Recruitment suspended	72/97
CLG	58081	Translational research - observational study for identification of new possible prognostic factors and future therapeutic targets in children with acute lymphoblastic leukaemia (ALL).	19/05/2011	839/1201
ENTF	1209	A phase II study exploring the safety and efficacy of BIBF1120 as second line therapy for patients with either differentiated or medullary thyroid cancer progressing after first line therapy.	28/04/2014	33/98
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	4/47
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	6/13
GITG	1527 (DREAM)	Diffusion-Weighted Magnetic REsonance Imaging Assessment of Liver Metastasis and Improve Surgical Planning	27/12/2016	0/0
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	15/374
IG-GITCG	1423	Evaluation of diffusion weighted imaging -MRI in patients with resectable liver metastases from colorectal cancer treated with fluoropyrimidine-based chemotherapy as preoperative treatment	12/11/2015 Recruitment closed on: 30/04/2017	5/27
LCG	8111 (ETOP5-12 (SPLENDOUR)	A randomised, open-label phase III trial evaluating the addition of denosumab to standard first-line anticancer treatment in advanced NSCLC.	11/12/2014	63/490
LCG	1205	ORTC randomized phase II study of pleurectomy/ decortication (P/D) preceded or followed by chemotherapy in patients with early stage malignant pleural mesothelioma	19/09/2016	0/10
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	18/447
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	43/331
NOCI	90101 (CREATE)	Cross-tumoral Phase 2 clinical trial exploring crizotinib (PF-02341066) in patients with advanced tumors induced by causal alterations of ALK and/or MET ("CREATE").	27/08/2012 Recruitment closed on : 04/07/2017	20/141
ROG-LCG	22113-08113 (LUNGTECH)	Stereotactic ablative radiotherapy (SABR) of inoperable centrally located NSCLC.	27/11/2014	2/31
ROG-HNCG	1219 (DAHANCA-29)	A blind randomized multicenter study of accelerated fractionated chemo-radiotherapy with or without the hypoxic cell radiosensitizer nimorazole (Nimoral), using a 15-gene signature for hypoxia in the treatment of HPV/p16 negative squamous cell carcinoma of the head and neck. (DAHANCA-29).	27/05/2014	66/185
STBSG	1202	Randomised phase II trial of cabazitaxel or prolonged infusional ifosfamide in metastatic or recurrent de-differentiated liposarcoma.	07/08/2014	1/10
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	6/13
STBSG	1321 (ALT-GIST)	A randomised phase II trial of imatinib alternating with regorafenib compared to imatinib alone for the first line treatment of advanced gastrointestinal stromal tumour (GIST).	02/03/2016	17/72
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	108/383
STBSG	1403 (rEECur)	International Randomised Controlled Trial of Chemotherapy for the treatment of recurrent and primary refractory Ewing sarcoma.	10/03/2016	40/181
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	5/8

BTG : Brain Tumor Group (EORTC BTG)
BCG : Breast Cancer Group (EORTC BCG)
CLG : Children Leukemia Group (EORTC CLG)
ENTF : Endocrine Task Force (EORTC ENTF)
ETF : Cancer In Elderly Task Force (EORTC ETF)
GCG : Gynecological Cancer Group (EORTC GCG)
GITCG : Gastrointestinal Tract Cancer Group (EORTC GITCG)
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)

EPIDEMIOLOGICAL STRATEGY AND MEDICAL ECONOMICS

The Epidemiological Strategy and Medical Economics (ESME Research programme) was created in 2014 to centralise existing real-world data in oncology. It integrates data from three main sources: the patient electronic health records (EHR), pharmacy records, and a hospital-stay database (French programme for medicalisation).

It provides independent, high quality aggregated data, available for analysis by the scientific and medical community or industrial partners, its principle aims are to describe current standard therapeutic strategies and treatment lines, and assess available therapeutic strategies based on reported outcomes.

The ESME research programme responds to the various objectives from the Plan Cancer, in particular those which reinforce the Health economics mission with regard to therapeutic strategies, prescription and healthcare, and the evaluation of anti-cancer medication and their registration or re-evaluation.

The ESME Research programme was financially supported by four industrial partners: Roche, Pierre Fabre, Pfizer and AstraZeneca. MSD officially joined in 2017. Discussions are currently underway with other partners such as Esai in France and others, notably in the USA which should be finalised in 2018.

ESME RESEARCH PROJECTS

The first project was related to the medical care of patients suffering from Metastatic Breast Cancer (MBC). By the end of 2017, clinical and therapeutic data were centralised for 20 000 patients treated in the FCCCs between 2008 and 2015. This project has already been the subject of 12 oral or poster communications throughout 2017, in various international congresses (ASCO, ESMO, SABCS). Two of them are expected to be published in 2018.
In 2017 a second data platform on ovarian cancer was launched with the FCCCs. At the end of the year, 6 000 patients had already been selected, aiming 14 000 cases collected by 2019.

A third data platform, dedicated to locally-advanced or metastatic lung cancer, is currently being set up within the network of FCCCs centres but also inside other public hospitals, with a total of 7 000 patients already selected in December 2017. The aim is to involve, in time, 20 healthcare establishments outside the FCCCs. 26 000 patients are expected by 2023.

Four statistical reports have already been issued to the Health Authorities for authorisations and may be cited as reference in reports from the Transparency Commission.
ESME methodology has now become a reference in the reports published by the French authorities (France's drug regulator ANSM, France's Transparency Commission, National Health Insurance Fund).

The coordination of the four specialised biometric units involved in complex database analysis ensures consistency across analyses and results.

GOVERNANCE

The ESME research programme has been monitored until now by three boards:

- The Scientific Committee which ensures compliance with the ethical and scientific rules of use and interpretation of the collected data, it also determines if the requests for analysis meet the defined criteria and can be considered eligible.
- The Deontology Committee, which manages any conflict of interest with experts involved.
- The International Advisory Board, whose role is to review key international communication and reinforce international academic cooperation.

With the extension of the programme to two new indications, the Scientific Committee has been restructured. It is now focused only on a strategic mission. The scientific direction of the programme has been divided between three subcommittees, each dedicated to one specific pathology. This new organisation will enter in force in 2018.

PROSPECTS

In order to anticipate possible data linkage with other national databases, notably those of the French SNDS- Système National des Données de Santé (which compiles the healthcare data collected by the public healthcare system), an update of the ESME databases was initiated in June 2017 to further personalise and secure access conditions.

A partnership with the French National Cancer Institute (INCa), was undertaken in 2016 aiming at extrapolating ESME data nationwide. The first communication resulting from this partnership is expected in 2018 at the French Conference of Clinical Epidemiology (EPICLIN).

GOVERNANCE AND SUPERVISORY BODIES OF THE ESME RESEARCH PROGRAMME

DECISION LEVEL	OPERATIONAL LEVEL	SUPERVISORY LEVEL		
FCCCs General Directions	Real-World Data Department	Scientific Sub-committees		
Strategic Research Committee	Site coordinators	Breast Cancer subcommittee	Ovarian Cancer subcommittee	Lung Cancer subcommittee
R&D Unicancer Direction	Working groups	Independent Deontology Committee		
	QA/Regulatory Affairs Department	International Advisory Board		

ACADEMICS REQUESTS ADDRESSED ON ESME MBC (METASTATIC BREAST CANCER)

2017-01	ESME-SNC : Central nervous system metastases incidence, kinetics, prognosis and treatments in breast cancer: a multicenter national observational study based on the ESME cohort (2008-20132014)
2017-02	Evaluation of the efficacy of eribulin in patients with metastatic breast cancer in real life setting
2017-04	Evaluation of the efficacy of TDM-1 in HER2 positive metastatic breast cancer patients in real life setting
2017-06	Metastatic inflammatory breast cancer: clinical features and outcomes

CONTRIBUTIONS OF THE ESME MBC DATABASE

REFERENCES	INSTITUTION / PUBLICATION
Compte rendu de séance du 28/03/2017 - Réunion du Comité Technique de Pharmacovigilance - CT01201703 - Enquête de pharmacovigilance Docétaxel	ANSM (French competent authority
Report : "Les données de vie réelle, un enjeu majeur pour la qualité des soins et la régulation du système de santé. L'exemple du médicament - Bernard Bégaud, Dominique Polton, Franck Von Lennep"	Health ministry
Requests for post-registration studies (PRS), patients follow-up in actual practice: changes in the role of databases	Thérapie journal

NEWS IN THE EXPERT GROUPS

To fulfil its objectives, Unicancer works closely with **17 internationally recognised groups of experts** and provides the necessary support structure for efficient project management. 11 of the Unicancer expert groups are multidisciplinary groups **focused on developing and steering innovative clinical studies**. Their goals are to optimise treatment strategies, to improve treatment in orphan populations and rare cancers, to improve knowledge in the field of cancer biological mechanisms and cancer treatments and to contribute to scientific education and dissemination in their field, through participation in conferences and publications. **The French National Cancer Institute (INCa) has granted its quality label to six Unicancer expert groups**, thus acknowledging their operating capability and excellence.

Created in 2016, the **Unicancer Immuno-Oncology Group (GIO)** is the newest of the Unicancer expert groups and **already supervise a dozen studies involving immune checkpoint inhibitors**, in particular the AcSé immunotherapy programme (see the box “Acsé immunotherapy” p. 10). At the end of 2017 a challenging programme aiming to address translational questions concerning the mechanisms of immunotherapies was launched: the CHECK’UP cohort entirely supported by the ARC foundation.
Unicancer head and neck group (UCHN) signed a partnership with the GORTEC in order to reinforce research operational and scientific capabilities in this field by a close cooperation between the two groups for the promotion of clinical trials and translational programmes.
The radiation therapy group (UNITRAD) was missioned by the Unicancer research strategic committee to explore and facilitate the development of a quality control platform for radiotherapy (RT) to improve the quality of results obtained in this field. Thanks to the contribution of radiotherapists and physicians, this platform is today operational and accessible for all the RT clinical programmes promoted by the FCCCs, Unicancer and other cooperative groups conducting trials in partnership with the Unicancer experts groups.
The Unicancer Genitourinary group (GETUG) launched in March its second education and research thematic symposium, which gathered more than 100 clinicians and young researchers interested in conducting clinical and translational research in the genitourinary area.
On 13 December 2017, the **group for Onco-geriatrics (GERICO)** also organised, within the INCa-accredited GERICO-UCOG (DIALOG) cooperative intergroup, its **third symposium on research in geriatric oncology**, which was successful, with the participation of 80 medical oncologists and geriatricians interested in the specificities of the clinical research conducted in the elderly population. The next edition will be held on 12 December 2018. The **Unicancer Gastrointestinal group** (UCGI) organised on 26 January 2017 the third edition of its ABCD course **(Accelerated course on the Biology of the Cancer of the Digestive tract)**, with the support of the PRODIGE Intergroup: approximately 150 attendees could benefit from this symposium, the objective of which is to diffuse knowledge and increase the attractiveness of clinical research among the French medical centres and encourage emulation among young research oncologists.

UNICANCER TUMOUR GROUPS

All Unicancer tumour groups share common goals:
- to evaluate existing and new therapeutic strategies
- to improve patient prognosis and quality of life through personalised treatments
- to develop innovative approaches to cancer treatment
- to identify predictors of treatment response, resistance and toxicity.

To achieve these goals, the Unicancer tumour groups develop **strategic clinical research programmes with a strong translational component** that relies upon a systematic centralised banking of biological samples. These clinical studies involve the FCCCs’ units and platforms as well as a large number of public and private hospitals in France. All Unicancer tumour groups are moving towards **international clinical trials** thanks to **various partnerships** with other cooperative groups and strong collaborations with industry.

French Breast Cancer Intergroup (UCBG)*

President: Dr Suzette DELALOGE, Gustave Roussy, Villejuif
Collaborations
French / EU level: INCa / GENMED / European academic groups (UK NCRN, SAKK, GBG) / European intergroups (BIG, EORTC)
International level: SWOG, MCCRC
Strategic priorities: Subtypes with poor prognosis / biology-driven strategies of therapeutic de-escalation / long-term follow-up data

Genitourinary Group (GETUG)*

President: Prof. Stéphane CULINE, Saint-Louis Hospital, Paris
Collaborations
French / EU level: AFU / CeRePP / GERICO / AFSOS / EORTC / PEACE (Prostate Consortium in Europe) / EBMT
International level: Various key hospitals leaders in the genitourinary field
Strategic priorities: biobanking / proof of concept studies / therapeutic strategies evaluation / real-life data / medical economics

Gastrointestinal Group (UCGI)*

President: Dr David MALKA, Gustave Roussy, Paris
Collaborations
French / EU level: FFCD & GERCOR within the PRODIGE intergroup / EORTC
International level: NCI of Canada / Canadian Cancer Trials Group (CCTG)
Strategic priorities: translational research / innovative studies / improvement of therapeutic

Sarcoma Group*

President: Prof. Jean-Yves BLAY, Léon Bérard Centre, Lyon
Collaborations
French / EU level: INCa / GSF-GETO French Sarcoma Group / Go-AJA / INTERSARC / EORTC / EuroEwing consortium / Patient Advocacy Groups
Strategic priorities: improvement of initial management of sarcomas and rare connective tissue tumours / biobanking / translational research

Head & Neck Group (UCH&N)*

President: Prof. Joël GUIGAY, Antoine Lacassagne Centre, Nice
Collaborations
French / EU level: GORTEC, GETTEC, GERCOR within the head & neck intergroup / EORTC
Strategic priorities: early-phase studies / rare cancers / biology-driven medicine

*INCa accredited-group

LEXICON

AFSOS: French Association of Supportive care in cancer
AFU: French Association of Urology
BIG: Breast International Group
CeRePP: Research group on prostate cancer and urologic tumours
EBMT: European Society for Blood and Marrow Transplantation
EORTC: European Organisation for Research and Treatment of Cancer
FFCD: French group of Digestive Oncology
GBG: German Breast Group
GENMED: Laboratory of Excellence in MEDical GENomics
GERCOR: Multidisciplinary Cooperative Group in Oncology
GETTEC: French Head & Neck cancer Study Group
GORTEC: Cooperative Group of Radiation therapy for head and neck cancer
Go-AJA: Adolescents and Young Adults onco-haematology Group
INCa: French National Cancer Institute
INTERSARC: French network of Cooperative Groups in the field of sarcoma
MCCRC: Mayo Clinic Cancer Research Consortium
SAKK: Swiss Group for Clinical Cancer Research
SWOG: SouthWest Oncology Group
UK NCRN: UK National Cancer Research Network

UNICANCER CROSS-PATHOLOGY GROUPS

Oncogeriatrics Group (GERICO)*

The **Unicancer Oncogeriatrics Group** forms, together with the UCOG oncogeriatric coordination units, the DIALOG intergroup, which is accredited by INCa. It brings together oncologists, geriatricians, radiotherapists, surgeons, biostatisticians and pharmacologists, all working towards promoting clinical research and innovation in oncogeriatry and tailoring clinical trials for the elderly population by adapting methodological approaches and rationalising diagnostics and treatments.
President: Dr Étienne BRAIN, Curie Institute – René Huguenin Hospital, Saint-Cloud

Early Phase Group (GEP)

The **Unicancer Early Phase Group** has become an important player in France, acknowledged by academic and industrial partners for the quality of its phase I and phase II trials. It is committed to providing patients with early access to innovative treatments by designing increasingly complex trials according to the latest methodologies and research developed in the area of precision medicine.
President: Dr Thomas BACHELOT, Léon Bérard Centre, Lyon

Translational Research and Development in Radiation Oncology (UNITRAD)

The **Unicancer Translational Research and Development in Radiation Oncology Group**’s goal is to promote innovative and strategic radiotherapy research programmes, and to develop collaborative networks. Its experts work on numerous of topics such as brachytherapy, imaging, modelling and radiomics, radiobiology and radiopotentiation, ionising radiation, quality assurance and methodology.
President: Prof. David AZRIA, Montpellier Cancer Institute, Montpellier

Immuno-Oncology Group (GIO)

Established in 2016, the **Unicancer Immuno-Oncology Group** embodies Unicancer’s strong desire to be a major player in cancer immunotherapy research. Bringing together renowned researchers and clinicians from the areas of immunology and oncology, this group offers a framework for cross-fertilisation and a dozen clinical and translational studies involving immune checkpoint inhibitors are already underway.
President: Prof. Frédérique Penault-Llorca, Jean Perrin Centre, Clermont-Ferrand

Personalised Medicine Programme

The **Unicancer Personalised Medicine Programme** develops multidrug predictors to enable the selection of the most effective treatments for individual patients. This multidisciplinary group of experts in biology-driven medicine develops programmes aimed at: proof of concept for personalised treatments, identification of predictors of sensitivity or resistance to therapy, identification of biomarkers of relapse or extreme responses and validation of therapeutic decision algorithms based on biological tests. Cross-pathology trials are developed in close collaboration with several tumour-specific groups in France.
President: Prof. Fabrice ANDRÉ, Gustave Roussy, Villejuif

Supportive Care Intergroup

The **Unicancer-AFSOS Supportive Care Intergroup** has set itself the ambitious goal to design and conduct high-standards clinical programmes using the most up-to-date and optimal methodology available, including the evaluation of quality of life and, whenever possible, a cost-efficiency analysis. Building a bridge with humanities and social sciences has also become key to this group.
President: Prof. Ivan KRAKOWSKI, Bergonié Institute, Bordeaux

Epidemiological Strategy and Medical Economics

Launched in 2014, the Unicancer ESME Programme is the first independent French academic database of "real-life" data in oncology, centralising all longitudinal data available in routine practice. Its aim is to describe the use of cancer treatments and assess the therapeutic strategies. These data can be made available to the scientific community,the pharmaceutical industry and the French health authorities. Two initial programmes are already ongoing, in breast and ovarian cancers, and a third is in preparation in lung cancer.
President of the Scientific Committee: Dr David Perol, Léon Bérard Centre, Lyon

UNICANCER TRANSVERSAL GROUPS

Clinical Pharmacology and Oncology Group (GPCO)

The Clinical Pharmacology and Oncology Group was established over 30 years ago and brings together a great number of actors concerned with the pharmacology of anticancer medications in France: researchers, biologists and clinicians coming from the FCCCs as well as from other hospital and university research structures. In particular, the GPCO focuses on the pharmacokinetic, the pharmacodynamic and the pharmacogenetic profile of anticancer agents (cytotoxics, targeted therapies, biotherapies, and immunotherapies).
President: Pr Joseph Ciccolini, School of Pharmacy of Marseille, Aix-Marseille University

Genetic and Cancer Group (GGC)

Since its creation in 1991, the Genetic and Cancer Group (GGC) has evaluated the genetic risk of cancer within families, created management guidelines for populations with specific risks and their relatives and ensured their dissemination in France, and conducted clinical, biological and epidemiological research in the field of genetic predisposition to cancers. This group also coordinates at a national level the evaluation of projects concerning standard practice.
President: Dr Catherine Noguès, Paoli-Calmettes Institute, Marseille

Cancer Biostatistics Group

The Cancer Biostatistics Group is composed of about 90 biostatisticians and epidemiologists working in the FCCCs. This group plays an important role in the design and valorisation of clinical research projects initiated by FCCCs or other cooperative groups, from protocol to publication. Several members of the group are also referent statisticians for the Unicancer expert groups. The group also conducts its own methodological research, animated by taskforces (phase I, endpoints, biomarkers, etc.). Finally, it is very active in dissemination, with members participating in a great number of conferences on specific topics.
President: Pr Stefan Michiels, Gustave Roussy, Villejuif

Group for the Evaluation of Immuno-histochemical Prognostic Factors in Breast Cancer (GEFPICS)

GEFPICS is an international group which brings together about 40 breast cancer pathologists and cytogeneticists, coming from Comprehensive Cancer Centres as well as public and university hospitals and private laboratories located in France, Belgium, Switzerland and Canada. Logistically supported by Unicancer, this group elaborates or updates nationwide practices / guidelines in breast pathology which are regularly published and develops its own translational and clinical research projects. The group is also involved in the AFAQAP quality programme.
President: Dr Magali Lacroix-Triki, Gustave Roussy, Villejuif

Prevention of Infections in Cardiology Group (GPIC)

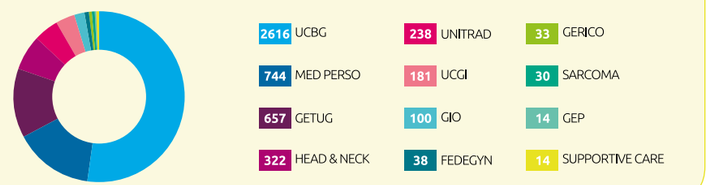
GPIC is an inter-FCCCs collaborative group established in 2007 to include the fight against health-care associated infections in the global care of the patient. It is open to all members of the FCCCs operational hygiene teams. The objective of the GPIC is to share competence and experience to more effectively diminish health-care-associated infections in the FCCCs and to improve the prevention, diagnosis and treatment of these infections. Defining common strategies as well as choosing common indicators is part of the GPIC's missions.
President: Dr Pierre Berger, Paoli-Calmettes Institute, Marseille

INCLUSIONS PER GROUP / FOCUS ON FCCCs

DISTRIBUTION OF INCLUDED PATIENTS BY UNICANCER GROUP

	FEDEGYN	GEP	GERICO	GETUG	GIO	HEAD & NECK	MED PERSO	SARCOMA	SUPPOR-TIVE CARE	UCBG	*OF WHICH CANTO*	UCGI	UNITRAD	TOTAL
Public Hospitals of Paris (AP-HP)	4			29	16	4	18	4		18		6	1	100
Foreign institutions	3			128						77		1		209
FCCCs	20	14	9	244	69	246	436	24	10	2020	*1209*	52	224	3368
Other private non-profit hospitals				22		3	4		2	54		15		100
Private institutions			6	114		5	22			230		26	5	408
Public hospitals (excl. AP-HP)	11		18	120	15	64	264	2	2	217		81	8	802
Total	**38**	**14**	**33**	**657**	**100**	**322**	**744**	**30**	**14**	**2616**	***1209***	**181**	**238**	**4987**

INCLUSIONS PER GROUP



FOCUS ON FCCCs

	FEDEGYN	GEP	GERICO	GETUG	GIO	HEAD & NECK	MED PERSO	SARCOMA	SUPPORTIVE CARE	UCBG	UCGI	UNITRAD	TOTAL
Eugène Marquis Centre			2	14		7	17	1	7	23		20	91
Antoine Lacassagne Centre			2	8	4	24	17			42	8		105
Léon Bérard Centre	1	2	2	27	10	38	35	3		125	3	33	279
Jean Perrin Centre				1	2	6	13			26			48
Curie Institute				6	3	15	60	3		450		35	572
Georges-Francois Leclerc Centre				10		30	3	2		170	1	15	231
Gustave Roussy			2	35	18	37	87	5		477	17	60	738
Oscar Lambret Centre	1				6	16	5	3		20	1	1	53
Paul Strauss Centre					2		1			11	4	30	48
Francois Baclesse Centre	1	2		23	1	7	11		3	122	4		174
Henri Becquerel Centre							9			136			145
Institute Of Cancer Research In Western France	11	10		36	8	18	48	1		39	7	11	189
Bergonie Institute				22	2		14	2		32		8	80
Claudius Regaud Institute				27	9	5	39	2		62			144
Lorraine Institute Of Cancerology (Alexis Vautrin Centre)	4			7	2	19	17			154	1	7	211
Jean Godinot Institute						7				101			108
Paoli Calmettes Institute				23	2		50	1		26	1		103
Montpellier Cancer Institute - Val D'aurelle	2		1	5		17	10	1		4	5	4	49
Total	**20**	**14**	**9**	**244**	**69**	**246**	**436**	**24**	**10**	**2020**	**52**	**224**	**3368**

PUBLICATIONS

GROUP	STUDY	TITLE	AUTHORS	REFERENCES	LIEN PUBMED
ESMÉ	ESME CSM	Triple-NOTE (Triple Negative OuTcome in ESME). Large recent real-world prognostic data on Triple Negative metastatic breast cancers (mTNBC)	MP. Sablin, C. Tchokothe, D. Loirat, T. Bachelot, E. Fourme, M . Carton, M-S. Mokdad-Adi, D. Berchery, C. Levy, W. Jacot, F. Penault-LLorca, A. Goncalves, L. Vanlemmens, J-C. Eymard, M. Campone, G. Simon, M. Robain, C. Cailliot, C. Le Tourneau, F. Ricci	Journal of Clinical Oncology. 2017 Jun	http://ascopubs.org/doi/abs/10.1200/JCO.2017.35.15_suppl.e12592
GGC	GGC	Development and validation of an ELISA method for the quantification of nivolumab in plasma from non-small-cell lung cancer patients	A. Puszkiel, G. Noé, P. Boudou-Rouquette, C-L. Cossec, J. Arrondeau, J-S. Giraud, A. Thomas-Schoemann, J. Alexandre, M. Vidal, F. Goldwasser, B. Blanchet	J Pharm Biomed Anal. 2017 May 30;139:30-36	https://www.ncbi.nlm.nih.gov/pubmed/28260630
GGC	GGC	Pharmacogenetics of anti-cancer drugs: State of the art and implementation - recommendations of the French National Network of Pharmacogenetics	S. Quaranta, F. Thomas	Therapie. 2017 Apr;72(2):205-215	https://www.ncbi.nlm.nih.gov/pubmed/28262261
GGC	GGC	A simple and rapid LC-MS/MS method for therapeutic drug monitoring of cetuximab: a GPCO-Unicancer proof of concept study in head-and-neck cancer patients.	F. Becher, J. Ciccolini, D-C. Imbs, C. Marin, C. Fournel, C. Dupuis, N. Fakhry, B. Pourroy, A. Ghettas, A. Pruvost, C. Junot, F. Duffaud, B. Lacarelle, S. Salas	Sci Rep. 2017 Jun 2;7(1):2714.	https://www.ncbi.nlm.nih.gov/pubmed/28578404
GGC	GGC	Prevention of fluoropyrimidine toxicity: do we still have to try our patient's luck?	R. Danesi, M. Del Re, J. Ciccolini, J-H-M. Schellens, M. Schwab, R-H-N. van Schaik, A-B-P. van Kuilenburg	Ann Oncol. 2017 Jan 1;28(1):183	https://www.ncbi.nlm.nih.gov/pubmed/27687313
GERICO	OSAGE	Chemoradiation in elderly esophageal cancer patients : rationale and design of a phase I/II multicenter study (OSAGE).	S. Servagi Vernat, G. Créhange, F. Bonnetain, C. Mertens, E. Brain, J-F. Bosset	BMC Cancer. 2017 Jul 13;17(1):483. doi: 10.1186/s12885-017-3465-4.	https://www.ncbi.nlm.nih.gov/pubmed/?term=Chemoradiation+in+elderly+esophageal+cancer+patients%3A++rationale+and+design+of+a+phase+I%2FII+multicenter++study+(OSAGE)
GETUG	GETUG 13	Patterns of relapse in poor-prognosis germ-cell tumours in the GETUG 13 trial: Implications for assessment of brain metastases	Y. Loriot, L. Pagliaro, A. Fléchon, J. Mardiak, L. Geoffrois, P. Kerbrat, C. Chevreau, R. Delva, F. Rolland, C. Theodore, G. Roubaud, G. Gravis, J-C. Eymard, J-P. Malhaire, C. Linassier, M. Habibian, A-L. Martin, F. Journeau, M. Reckova, C. Logothetis, A. Laplanche, G. Le Teuff, S. Culine, K. Fizazi	Eur J Cancer. 2017 Dec;87:140-146. doi: 10.1016/j.ejca.2017.09.029	https://www.ncbi.nlm.nih.gov/pubmed/29149760?dopt=Abstract
GETUG	GETUG 15	Q-TWiST analysis of patients with metastatic castrate naive prostate cancer treated by androgen deprivation therapy with or without docetaxel in the randomised phase III GETUG-AFU 15 trial.	P. Marino, P. Sfumato, F. Joly, K. Fizazi, S. Oudard, S. Culine, M. Habibian, J-M. Boher, G. Gravis	Eur J Cancer. 2017 Oct;84:27-33. doi: 10.1016/j.ejca.2017.07.008	https://www.ncbi.nlm.nih.gov/pubmed/28780479?dopt=Abstract
GETUG	GETUG 15	A randomized controlled trial of metastases-directed treatment in patients with metastatic prostate cancer using stereotactic body irradiation: A GETUG-AFU trial.	P. Blanchard, S. Foulon, G. Louvel, M. Habibian, K. Fizazi	Cancer Radiother. 2017 Oct;21(6-7):491-494. doi: 10.1016/j	https://www.ncbi.nlm.nih.gov/pubmed/28869198
GETUG	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, G. Gravis, S. Foulon, et al.	Eur Urol. 2017 Oct 23. pii: S0302-2838(17)30791-1. doi: 10.1016/j.eururo.2017.09.022	https://www.ncbi.nlm.nih.gov/pubmed/29074061?dopt=Abstract
UCH&N	ORL 03	Cabazitaxel in recurrent/metastatic squamous cell carcinoma of the head and neck: phase II Unicancer trial ORL03.	J. Fayette, J. Guigay, C-L. Tourneau, M. Degardin, F. Peyrade, E-M. Neidhardt, M-P. Sablin, C. Even, F. Orlandini, B. Juzyna, C. Bellera	Oncotarget. 2017 Mar 4;8(31):51830-51839. doi: 10.18632/oncotarget.15901. eCollection 2017 Aug 1. PMID: 28881692	https://www.ncbi.nlm.nih.gov/pubmed/28881692
GEP	GEP 04-RADHER	Longitudinal serum metabolomics evaluation of trastuzumab and everolimus combination as pre-operative treatment for HER-2 positive breast cancer patients.	E. Jobard, O. Trédan, T. Bachelot, A-M. Vigneron, C-M. Aït-Oukhatar, M. Arnedos, M. Rios, J. Bonneterre, V. Diéras, M. Jimenez, J-L. Merlin, M. Campone, B. Elena-Herrmann	Oncotarget. 2017 Jun 28;8(48):83570-83584. doi: 10.18632/oncotarget.18784	https://www.ncbi.nlm.nih.gov/pubmed/29137365?dopt=Abstract
PERSO MED	AcSé crizotinib	Genomic diagnostics leading to the identification of a TFG-ROS1 fusion in a child with possible atypical meningioma;	M. Rossing, C. Westmose Yde, A. Sehested, O. Østrup, D. Scheie, V. Dangouloff-Ros, B. Geoerger, G. Vassal, K. Nysom	Cancer Genetics 2017; 212-213 (2017) : 32–37	https://www.ncbi.nlm.nih.gov/pubmed/28449809
Sarcome	OS2006/ Sarcome 09	Results of Methotrexate-Etoposide-Ifosfamide based regimen (M-EI) in osteosarcoma patients included in the French OS2006/Sarcome-09 study.	N. Gaspar, B-V. Occean, H. Pasquement, E. Bompas, C. Bouvier, H. J Brisse, M-P. Castex, N. Cheurfa, N. Corradini, J. Delaye, et al.	Eur J Cancer. 2018 Jan;88:57-66. doi: 10.1016/j.ejca.2017.09.036. Epub 2017 Nov 28.	https://www.ncbi.nlm.nih.gov/pubmed/29190507
Sarcome	OS2006/ Sarcome 09	CD163-positive tumor-associated macrophages and CD8-positive cytotoxic lymphocytes are powerful diagnostic markers for the therapeutic stratification of osteosarcoma patients: An immunohistochemical analysis of the biopsies fromthe French OS2006 phase 3 trial.	A. Gomez-Brouchet, C. Illac, J. Gilhodes, C. Bouvier, S. Aubert, J-M. Guinebretiere, B. Marie, F. Larousserie, N. Entz-Werlé, G. de Pinieux, T. Filleron, V. Minard, V. Minville, E. Mascard, F. Gouin, M. Jimenez, M-C. Ledeley, S. Piperno-Neumann, L. Brugieres, F. Rédini	Oncoimmunology. 2017 Aug 24;6(9):e1331193. doi: 10.1080/2162402X.2017.1331193. eCollection 2017.	https://www.ncbi.nlm.nih.gov/pubmed/28932633
Sarcome	OS2006/ Sarcome 09	Prognostic impact of blood and urinary angiogenic factor levels at diagnosis and during treatment in patients with osteosarcoma: a prospective study.	M-D. Tabone, L. Brugières, S. Piperno-Neumann, M-A. Selva, P. Marec-Bérard, H. Pacquement, C. Lervat, N. Corradini, J-C. Gentet, R.Couderc, A. Chevance, C. Mahier-Ait Oukhatar, N. Entz-Werle, J-Y. Blay, M-C. Le Deley	BMC Cancer. 2017; 17: 419. doi: 10.1186/s12885-017-3409-z	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5473001/
Supportive Care Group	QUALIOR	QUALIOR Study: the Feasibility and Efficacy of a Home based Standardised Adapted Physical Activity Programme of Patients Receiving Oral Targeted Therapy for Metastatic Cancer Randomised, Phases II–III Unicancer–AFSOS Supportive Care Intergroup Study	F. Joly, C. Orsini, F. Bonnetain	Oncologie. Vol 19, N 1-2, Janvier-Février 2017: 16-20. doi:10.1007/s10269-017-2678-4	https://onco.revuesonline.com/articles/lvonco/abs/2017/01/lvonco191p16/lvonco191p16.html
Supportive Care Group	FARADI	L'essai FARADI: efficacité et tolérance du citrate de fentanyl dans les accès douloureux induits lors des examens diagnostiques ou thérapeutiques chez des patients souffrant de cancer	L. Labreze, M. Pulido, I. Krakowski	Oncologie Vol 19, N 1-2, Janvier-Février 2017: 26-31. doi: 10,1007/s10269-017-2680-6	https://onco.revuesonline.com/articles/lvonco/abs/2017/01/lvonco191p26/lvonco191p26.html
UCBG	PACS06	Optimal duration of adjuvant chemotherapy for high-risk node negative (N-) breast cancer patients: 6-year results of the prospective randomized multicenter phase III Unicancer-PACS 05 Trial.	P. Kerbrat, I. Desmoulins, L. Roca, C. Levy, A. Lortholary, A. Marre, R. Delva, M. Rios, P. Viens, É. Brain, D. Serin, M. Edel, M. Debled, M. Campone, M-A. Mourret-Reynier, T. Bachelot, M-J. Foucher-Goudier, B. Asselain, J. Lemonnier, A-L. Martin, H. Roché	Eur J Cancer. 2017 Jul;79:166-175.	https://www.ncbi.nlm.nih.gov/pubmed/28501763?dopt=Abstract
UCBG	PACS 09	Circulating Tumour Cells and pathological complete response: independent prognostic factors in inflammatory breast cancer in a pooled analysis of two multicentre phase II trials (BEVERLY 1 & 2) of neoadjuvant chemotherapy combined with bevacizumab.	J-Y. Pierga, F-C. Bidard, A. Auret, et al.	Ann Oncol. 2017 Jan 1;28(1):103-109.	https://www.ncbi.nlm.nih.gov/pubmed/28177480?dopt=Abstract
UCBG	PACS01 PACS04 PACS06	20-Year Risks of Breast-Cancer Recurrence after Stopping Endocrine Therapy at 5 Years.	H. Pan, R. Gray, J. Braybrooke, C. Davies, C. Taylor, P. McGale, R. Peto, K-I. Pritchard, J. Bergh, M. Dowsett, and D-F. Hayes, for the EBCTCG	N Engl J Med 2017;377:1836-46.	http://www.nejm.org/doi/10.1056/NEJMoa1701830
UCGI	ACCORD 11 -PRODIGE 4	Retrospective analysis of CA19-9 decrease in patients with metastatic pancreatic carcinoma treated with FOLFIRINOX or Gemcitabine in a randomized phase III study (ACCORD11/PRODIGE4).	M. Robert, M. Jarlier, S. Gourgou, F. Desseigne, M. Ychou, O. Bouché, B. Juzyna, T. Conroy, J. Bennouna	Oncology 2017;93:367-376 doi:10.1159/000477850	https://www.ncbi.nlm.nih.gov/pubmed/28982109
UCGI	ACCORD 12 -PRODIGE 2	Late toxicities and clinical outcome at 5 years of the ACCORD 12/0405-PRODIGE 02 trial comparing two neoadjuvant chemoradiotherapy regimens for intermediate-risk rectal cancer.	D. Azria, J. Doyen, M. Jarlier, I. Martel-Lafay, C. Hennequin, P. Etienne, V. Vendrely, E. François, G. de La Roche, O. Bouché, X. Mirabel, B. Denis, L. Mineur, J. Berdah, M. Mahé, Y. Bécouarn, O. Dupuis, G. Lledo, J. Seitz, L. Bedenne, S. Gourgou-Bourgade, B. Juzyna, T.Conroy, J. Gérard	Ann Oncol. 2017 Oct 1;28(10):2436-2442. doi: 10.1093	https://www.ncbi.nlm.nih.gov/pubmed/28961836?dopt=Abstract
UCGI	ACCORD 17 -PRODIGE 5	Health-related quality of life results from the PRODIGE 5/ACCORD 17 randomised trial of FOLFOX *versus* fluorouracilecisplatin regimen in oesophageal cancer.	C. Bascoul-Mollevi, S. Gourgou, M-P. Galais, J-L. Raoul, O. Bouché, J-Y. Douillard, A. Adenis, P-L. Etienne, B. Juzyna, L. Bedenne, T. Conroy	Eur J Cancer. 2017 Oct;84:239-249	https://www.ncbi.nlm.nih.gov/pubmed/?term=Health-related+quality+of+life+results+from+the+PRODIGE+5%2FACCORD+17+randomised+trial+of+FOLFOX+versus+fluorouracilecisplatin+regimen+in+oesophageal+cancer
UCGI	PRODIGE 17 -ACCORD 20	Dynamic evaluation of circulating tumour cells in patients with advanced gastric and oesogastric junction adenocarcinoma: Prognostic value and early assessment of therapeutic effects.	S. Pernot, C. Badoual, M. Terme, F. Castan, A. Cazes, O. Bouche, J. Bennouna, E. Francois, F. Ghiringhelli, C. De La Fouchardiere, E. Samalin, J-B. Bachet, C. Borg, M. Ducreux, E. Marcheteau, T. Stanbury, S. Gourgou, D. Malka, J. Taieb	Eur J Cancer. 2017 Jul;79:15-22. doi: 10.1016/j.ejca.2017.03.036. Epub 2017 Apr 26.	https://www.ncbi.nlm.nih.gov/pubmed/28456090

CLINICAL OPERATIONS

The Clinical Operations department, in association with the Regulatory Affairs, Pharmacovigilance & Quality Assurance Department as well as the Development and Partnerships Department, guarantees both project development, and data monitoring in the respect of Good Clinical Practice guidelines.

In 2017, a restructuring process was initiated in the department in three strategic areas. The following actions were performed with the objective to improve both production quality and efficiency:

- The designation of programme managers, whose mission is to help the promotion and the development of R&D Unicancer groups of experts in a highly competitive environment,
- The creation of a network of CRA-Clinical Research Associates supervised and coordinated by a CRA manager, whose objective is to homogenise the CRA activities across the Unicancer project teams and ensure greater adaptability of the resources in each therapeutic area. Continuous training (e-learning), sharing of practical experience and individual support are the three main component of the coaching provided to the CRA.
- The introduction and expansion of technologies such as Clickview to optimise the characterization and use of samples stored in the Biological Resource Centre (BRC), the use of the e-CRF (e-Case Report Form) for all clinical trials.
- The characterisation of a specific team dedicated to the development and management of translational programmes and Biological Resource Centre central management.

The Unicancer's R&D mobilises a network of 216 research centres worldwide (52 centres outside of France) and currently counts 84 ongoing trials (13 launched in 2017 and 44 at the recruitment stage). At the end of 2017, 4897 patients had been included, and 7 additional projects have been granted by the PHRC (health ministry funding programme).

Unicancer continues to reinforce its position as one of the leaders at a European level, notably by developing its collaboration with other international academic groups:

- The European Organization for Research and Treatment of Cancer (EORTC) collaborates with the Head & Neck group (UCHN), the Genitourinary group (GETUG) and the Onco-geriatrics group (GERICO)
- The Swiss Group for Clinical Cancer Research (SAKK) with The GETUG
- The Canadian Cancer Trials Group (CCTG) with The Gastrointestinal Group (UCGI).
- the French Breast Cancer Intergroup UCBG is group leader of 6 international projects currently recruiting

Ambitious projects were launched in 2017 such as MyPeBs for which Unicancer has obtained a European funding (call for project H2020). This programme is aiming at assessing a new personalised Breast Cancer screening strategy at a large scale. Five countries are involved in this programme.

The development of the Immuno-Oncology Group (GIO) embodies Unicancer's desire to maintain its position as a research leader in cancer immunotherapy. In 2017, the GIO launched the AcSé immunotherapy programme for treating rare cancers and the Check'Up cohort study. The group is also planning to develop Immuno-biology and X-ray imaging task forces.

PERSPECTIVES

The department's primary objectives for 2018 are:

- To increase its productivity by expanding the e-learning to the entire operational team
- To develop skills and competence enhancement (coaching, mentoring new arrivals, professional standard references…)
- To develop and implement tools for remote data control (CTMS, CDMS, CSMonitor, ExportOnLine) intending to facilitate and improve CRA project management

FROM PROTOCOL REVIEW TO NATIONAL PUBLIC RESEARCH FUNDING

29
CLINICAL STUDIES REVIEWED BY UNICANCER PROTOCOL REVIEW COMMITTEE (PRC) IN 2017

17
CLINICAL STUDIES APPROVED FOR UNICANCER DEVELOPMENT AND SPONSORSHIP

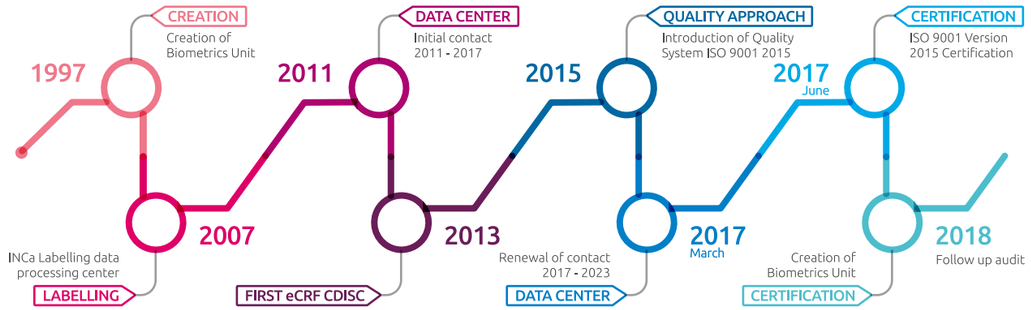
14
PROJECTS SUBMITTED TO THE 2017 FRENCH HOSPITAL RESEARCH PROGRAMME (13 PHRC-K AND 1 PRME-K) (FRENCH HOSPITAL MEDICO-ECONOMIC RESEARCH PROGRAMME) -> 7 PHRC-K ACCEPTED

FRENCH HOSPITAL RESEARCH PROGRAMMES APPROVED DURING THE 2017 CALL FOR PROPOSAL

EXPERT GROUP	SHORT TITLE	STUDY TITLE	STUDY COORDINATOR	INSTITUTION	REFERENCE
UNITRAD	NIRVANA-LUNG	NIRVANA-lung: Nivolumab with concurrent IRradiation at VAried tumor sites in advanced Non smAll cell lung cancer	J. Doyen	Antoine Lacassagne Center	PHRC-K17-134
UNITRAD	ROMANCE	ROMANCE: Phase III trial of omission of whole-breast radiotherapy following breast-conserving surgery in patients with very low risk ductal carcinoma in situ of the breast	A. Fourquet	Curie Institut	PHRC-K17-146
UCBG	My PeBS	(My Personal Breast Screening) Comparaison randomisée du dépistage standard *versus* celui stratifié par le risque des femmes en Europe âgées de 40 à 74 ans	S. Delaloge	Gustave Roussy	PHRC-K17-154
UCGI	GEMPAX	Randomized phase III trial to evaluate the association of gemcitabine plus paclitaxel vs gemcitabine in second line treatment after FOLFIRINOX treatment failure.	C. De La Fouchardière	Léon Berard Center	PHRC-K17-106
H&N	IMMUNEBOOST HPV	Neoadjuvant PDLI/PDI blockade in high risk HPV+ oropharyngeal cancer randomized phase II trial	H. Mirghani	Gustave Roussy	PHRC-K17-145
UCGI	LUNA	Liver resection with Unresectable pulmonary Nodules from colorectal Adenocarcinoma	S. Evrard	Bergonie Institut	PHRC-K17-167
GERICO	GERICO 14/ SARCOME	Randomized phase III study of oral cyclophosphamide *versus* doxorubicin in patients ≥65 years old with advanced or metastatic soft tissue sarcoma (STS): a Unicancer/GERICO multicentre trial.	O. Mir	Gustave Roussy	PHRC-K17-162

CENTRALISED NATIONAL DATA CENTER

HISTORY AND KEY DATES OF BIOMETRICS UNIT



National Data Center (NDC) since 2011, the Biometrics unit of Montpellier Cancer Institute headed by Sophie Gourgou hosts and manages clinical trials data from Unicancer R&D sponsored trials. the NDC uses the CDISC SDTM format for the conception of the trial data-bases, allowing the inter-operability of the different data-bases through a homogeneous, standardized and international data format.
The data management is performed using EnnovClinical software, compliant to 21CFRpart11. Implementation has been validated by a QI/QO/QP/QFDA protocol.
Since 2016, data of new studies are all collected via eCRF.

The NDC performs the design of the eCRF and randomizations programmes. From documentation (data management plan, validation plan and data review) to the programming of consistency tests and monthly clinical data listings, data management encompasses data capture, the management of queries and the coding of medical data using the MedDRA standard as well as reconciliation between clinical database and pharmacovigilance database. The transition to eCRF influenced new practices, online consistency testing, user profile management, automated alerts, electronic medical signatures, as well as many new tools requiring changes in processes and standards.

This year's progress

Involved in a quality system since 2015 with the validation of all business processes, The NDC obtained in 2017 the ISO9001 CERTIFICATION focusing customer satisfaction and continuous improvement as the major goals for its activity.
In this same context, numerous data managers obtained the EnnovClinical Certification V7.5.40.

As of December 2017, the NDC manages 72 ongoing clinical trials (international phase III trials as well as early phase trials or phase II trials with a high level of complexity : multi-cohort trials as the AcSé projects) . This activity is possible thanks to a team of 14 people (10 data managers, 3 data capturing operators, 1 coordinator). 38 new projects were initiated, of which 13 were launched this year.

DATA CENTER ACTIVITY FOR UNICANCER 2017

In a context of new clinical approaches (personalized medicine, immunology), new technical approaches or processes are developed (as regular import of external data, development of iRECIST).

BIOLOGICAL RESOURCE CENTRE (BRC)

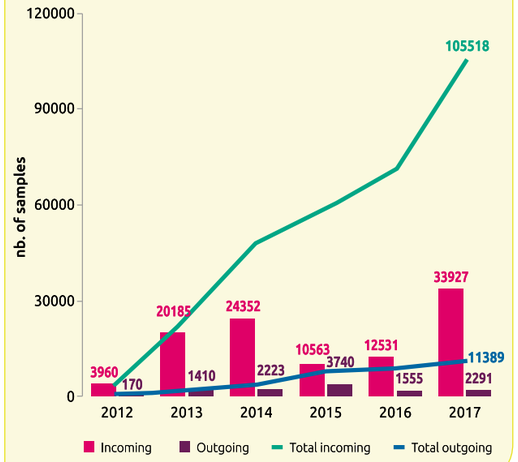
Since it was established in 2012, the Unicancer Biological Resource Centre has been housed at the Léon Bérard Centre in Lyon. It was set up to meet the requirements of Unicancer strategy by creating a collection of clinical research programme samples in order to promote biological research and advances in the field of cancer treatment.

Some 106,000 biological samples have been banked in total so far, arising mainly from patients with a breast cancer (84,600 samples), but also from lung, kidney and prostate cancer. Different types of samples are stored, like FFPE material, frozen samples, total blood, plasma, serum or derived products (DNA, RNA, slices). In 2017, 33,700 samples were collected prospectively.

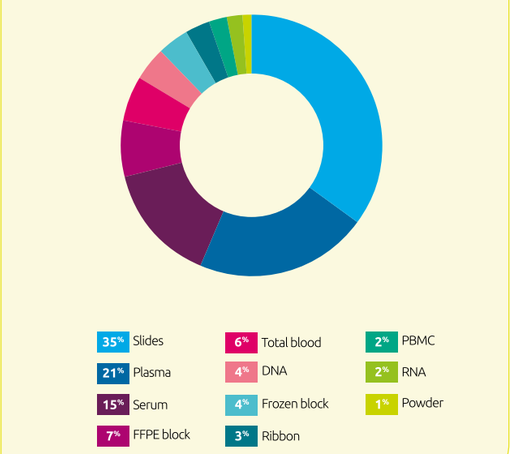
This centralisation guarantees the correct storage of the samples and ensures that they are rapidly available to research teams. The samples can be accessed following submission of a research project to Unicancer and validation of the project by a biological steering committee. Since the activity was launched in 2012, 21 research projects have been set up reusing biological samples archived in Unicancer's biobank. Four of them were granted in calls for proposals (ANR, Fondation ARC, INCa). These projects focuses mainly on identification of biomarkers predictive of breast cancer relapse and on development of new predictive molecular signatures. At this time, among 12,000 samples were unarchived to conduct translational research.

The design of new research projects needs to enhance the communication about the collections available. To meet this objective Unicancer is setting up new tools to allow researchers to interrogate the biobank's catalogue. This tool will allow knowing precisely what material is available regarding characteristics of the sample by itself but also regarding some relevant clinical and biological parameters of the related disease.

EVOLUTION OF ENTRIES AND OUTPUTS OF SAMPLES



TYPE OF SAMPLES BANKED



REGULATORY AFFAIRS, PHARMACOVIGILANCE, QUALITY ASSURANCE

REGULATORY, LEGAL AND PHARMACEUTICAL AFFAIRS

Beyond the regulatory follow-up of clinical trials (initial clinical trial and amendment submissions to France's Competent Authority ANSM), the Regulatory, Legal and Pharmaceutical Affairs unit ensures the legal and regulatory compliance of all the Unicancer R&D activity. The legal entity ensures the conformity of contracts and agreements dedicated to partnerships, clinical trials and studies, and biological samples.

In 2017, the unit has been preparing the application of the new General Data Protection Regulations (GDPR) which will enter in force in May 2018.

In this context, a DPO (Data Protection Officer) was appointed, his office will begin in early 2018. He will be in charge of:

- Management and development of the internal data protection policy.
- Coordination of both the internal task force and the FCCCs inclusive work group on data protection
- Drafting of practical guidelines on both patient information and data research.
- Liaison with public and private partners, as well as with national authorities, on data protection and the evolution of the legal and regulatory frameworks.

The recruitment of a regulatory specialist in biobanks has further strengthened the team.

The unit also published a number of guidance documents on the proper interpretation of new regulatory provisions directed towards operational teams.

QUALITY ASSURANCE

The Quality Assurance (QA) unit focuses on enhancing the quality of all activities led by R&D Unicancer. The QA department provides support to internal development structures including the Clinical Operations Department, the Department in charge of Clinical data, the ESME (Epidemio Strategy and Medical Economics) programme, as well as to all the French Comprehensive Cancer Centres (FCCCs).

Its activities are:

- implementing a Quality Management System (QMS) in compliance with ISO 9001: 2015 standards. This QMS is built in order to optimise and harmonise practices in line with standards and regulations applicable to each type of activities. This system is about to get certified (Q4-2018) according to ISO 9001 standards.

By entering in this ISO 9001 certification process, the R&D at Unicancer has modeled all its actions through processes each comprising several activities. Each process is conducted, monitored and regularly reviewed by pilots.

Thus, the entire Unicancer R&D staff is involved in continual quality improvement involves, which is relayed and embodied by the ISO 9001 pilots, and coordinated by the Quality Assurance unit.

- providing support for the Centres throughout their certification procedures. At the end of the year, 15 centres had already obtained certification (8 of those in 2017). Only three Centres were still awaiting their certification, planned in the first trimester 2018.
- Organising audits on clinical trials sponsored by Unicancer, (trial documentation, investigational sites). This year the QA unit notably brought its expertise to the Algerian cancer centres' audit programme, as a part of a partnership to implement the Algerian strategy for cancer control (see: Development and partnerships p. 34).
- Initiating training programmes in function of evolutions.

Collaborative work with the Comprehensive centres in regard to clinical research was strengthened this year, with:

- The enrichment of the joint IT communication platform, created in 2016 (86 contributors and 238 shared documents to date).
- An intensification of meetings held within the different FCCCs, increased to 2 to 3 per year, with an objective of 4 per year in 2018.
- A videoconference training session about the new regulations, available to all Centres.

Finally, there is a project to constitute working groups on policy documents which is currently underway, to further the cohesion between FCCCs in the field of clinical research.

PHARMACOVIGILANCE

The Pharmacovigilance (PV) unit plays an essential role in the conduct of clinical trials. The PV department participates in all the internal review committees and ensures that the level of vigilance provided is in adequation with the trial specifications.

The PV department is also responsible for managing any serious adverse events (SAE) which may occur during a clinical trial. It is involved in all discussions related to patient safety. For each trial, a safety report including all the relevant information to assess the safety of the participating patients is produced annually for transmission to the ANSM or the competent authorities of the country in which the trial is conducted.

Due to the regulatory changes that occurred at the end of 2016, the vigilance department has updated its internal procedure for SAE management, with the goal of reducing delays for SAE reporting. The new procedure will also allow the rapid evaluation of any adverse event which could be considered a SUSAR (Suspected Unexpected Serious Adverse Reaction) which will significantly accelerate reporting to the authorities.

The PV unit also takes charge of the PV responsibilities on behalf of the FCCCs which request it. A partnership established in December 2017 between Unicancer Head & Neck and the GORTEC (French Head & Neck Oncology and Radiotherapy Group) aims to share and mutualise sponsorship activities in the field of head and neck cancers. The Unicancer pharmacovigilance unit is well recognised by our partners as an efficient operational structure able to manage pharmacovigilance issues for complex trials. Therefore, the partnership anticipates that all vigilance activities will be performed by Unicancer independently of the designation of the legal sponsor.

The Pharmacovigilance database is designed to be adaptable to any future regulatory evolutions.
In time, it will also be able to provide clinical test tolerance reports.

Finally, a new electronic SAE declaration procedure is currently under implementation. This new tool will simplify the process both for the FCCCs and the PV unit by specifically formatting data to allow faster integration to the database and therefore better dissemination of information.
This tool will be available to all the FCCCs that delegate their Pharmacovigilance to Unicancer later in 2018.

DEVELOPMENT AND PARTNERSHIPS

The Development and Partnership department intervenes upstream of research projects. Its principal missions are to promote research, to foster mutualisation between the different FCCCs and to promote R&D Unicancer's visibility in the field of Oncology.

In that capacity, the department brings its support to:

- **The FCCCs**, notably in the procedures of response to calls for tender.

In 2017 Unicancer achieved great success with the selection of its MyPeBS (My Personal Breast Screening) project in the H2020 call for projects. Financed by the European Union, this project will include 5 countries in a comparative study between a new personal risk-stratified breast screening strategy and the standard strategy, with a potential to modify it. It will be launched in october 2018.

At the end of 2017, 8 studies had been submitted to calls for projects launched by Horizon 2020 and ERA-NET (European Research Schemes), or ANR (National Research Agency) and the RHU (University Hospital Research Centres).

- **Research groups**, with the development of financial and academic structuring partnerships and the promotion of their expertise.

Two academic research intergroups of international scale have been formed this year: The Unicancer- FFCD- Gercor intergroup which is specialised in digestive cancers, and the Unicancer Head & Neck-GORTEC intergroup specialised in ENT cancers. These two intergroups have been labelled by the French National Cancer Institute (INCa).

A memorandum of understanding was also signed between Unicancer and the NCIC CTG (National Cancer Institute of Canada - Cancer Trials Group) for research collaboration on all projects coming from Unicancer or the NCIC.

In March 2017, the CANTO-CANcerTOxicities study (a study of susceptibility to treatment-related toxicities in a cohort of 12000 patients suffering from non-metastatic breast cancer) received a highly favourable opinion from the international jury of the Commission, during their mid-term evaluation.

New financial partnerships, notably with AstraZeneca and MSD have allowed the development of two new data platforms within the framework of the ESME (Epidemiological Strategy and Medical Economics) research programme.

The teaching and research days organised by the genitourinary group GETUG, and the digestive oncology group UCGI, were respectively reiterated in 2017 for the third and fourth times, as was the MAP conference (Molecular Analysis for Personalised Therapy), a joint initiative of Cancer Research UK, Unicancer and ESMO aiming to provide oncologists with expert guidance on interpreting genomic alterations to design tailored treatment programmes.

- **The development of research**

Research activity has made a strong impact this year, with:

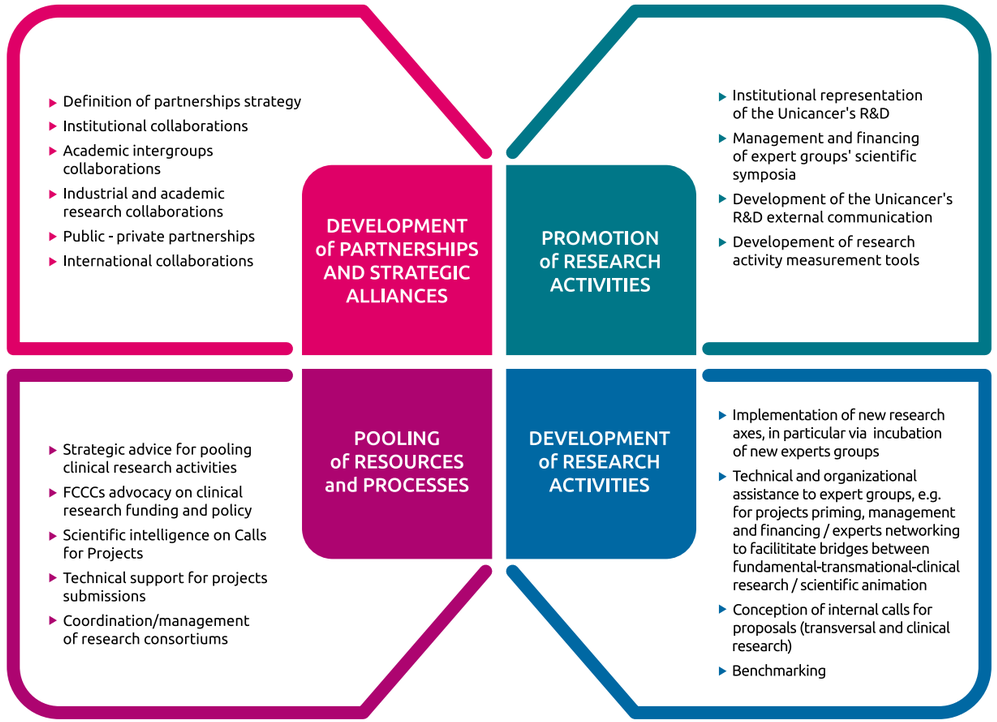
- The continued impetus of the group of UNITRAD Radiotherapy experts: 5 research projects financed by the PHRC (Hospital Clinical Research Programme) in 2017, and a radiotherapy Quality-Control platform aimed at academic research.
- The conduct by the Immuno-Oncology Group of the AcSe Immunotherapy projects (a study of immune checkpoints inhibitors in patients with rare cancers and identified alterations of target genes), and the Check'Up cohort project (aiming to identify predictive factors of response to immunotherapies).

These two projects, essential for patients - in terms of equal access to treatment, and for research – in terms of development of the precision medicine, reaffirm the implication of both the 'ARC foundation' and the "Ligue Nationale contre le cancer" (French League against cancer) alongside Unicancer.

- The feasibility study for the creation of a research group for oncology surgery.

Finally, in october 2017, as a part of the implementation of the Algerian national cancer plan, Unicancer and AstraZeneca signed a partnership project in the field of clinical trials under the aegis of the Algerian ministry of Health.

PRINCIPAL REMIT OF DEVELOPMENT & PARTNERSHIPS DEPARTMENT



UNICANCER IN MULTIPARTNERSHIP CALLS FOR PROPOSAL

UNICANCER ROLE	CALL FOR PROPOSAL	APPROVAL	ACRONYM	SCIENTIFIC COORDINATOR
Coordinating partner / trial sponsor	H2020	2017	MyPEBS	Suzette Delaloge (Gustave Roussy)
Partner	RHU	2016	Lumière	Laurence Zitvogel (Gustave Roussy)
Partner	RHU	2017	MyPROBE	Fabrice André (Gustave Roussy)
Partner	ERA-NET FLAG-ERA	2016	IT-FoC	Nora Benhabiles (CEA)
Technical assistance	ERA-NET Transcan	2016	Immunoglio	François Ghiringhelli (CGFL)

RESEARCH IN THE FCCCs

KEY 2017 FIGURES

Clinical research in the FCCCs

15,1%
OF THE PATIENTS TREATED IN THE FCCCs ARE INCLUDED IN A CLINICAL TRIAL *VERSUS* 8.5% OF CANCER PATIENTS ON AVERAGE IN FRANCE

569
ACTIVE CLINICAL TRIALS SPONSORED BY THE UNICANCER NETWORK

51,3%
OF THE FRENCH HOSPITAL CLINICAL RESEARCH PROGRAMMES IN THE FIELD OF CANCER ARE GRANTED TO THE FCCCs

FCCCs scientific publications*

RANKED 5TH IN THE NUMBER OF PUBLICATIONS IN THE ONCOLOGY FIELD, WORLDWIDE

FCCCs CONTRIBUTED 1/3 OF THE FRENCH PUBLICATIONS IN THE FIELD OF CANCER

24% OF FCCCs ARTICLES ARE PUBLISHED IN THE 10% MOST CITED JOURNALS IN THE WORLD

FRENCH COMPREHENSIVE CANCER CENTRE (FCCCs)	TOWN	Active patient file	Patients included in a clinical trial	total active trials	Average number of patients included per clinical trial	% of the active patient file included in a clinical trial	ACADEMIC SPONSOR			PHARMACEUTICAL INDUSTRY SPONSOR	
							Number of patients included	Number of active trials	% of patients included in an institutional clinical trial	Number of patients included	Number of active trials
Bergonie Institute	Bordeaux	6 380	2 026	221	9,2	31,8%	955	145	47%	1 071	76
Francois Baclesse Centre	Caen	6 676	556	156	3,6	8,3%	478	114	86%	78	42
Jean perrin Centre	Clermont	4 842	392	98	4,0	8,1%	323	75	82%	69	23
Georges-François Leclerc centre	Dijon	4 493	1 172	222	5,3	26,1%	1 046	152	89%	126	70
Oscar Lambret Centre	Lille	6 337	778	174	4,5	12,3%	670	130	86%	108	44
Léon Bérard Centre	Lyon	9 625	1 884	215	8,8	19,6%	1 502	131	80%	382	84
Paoli calmettes Institute	Marseille	8 813	1 480	225	6,6	16,8%	1 230	144	83%	250	81
Montpellier Cancer Institute - Val d'Aurelle	Montpellier	6 414	976	157	6,2	15,2%	872	116	89%	104	41
Lorraine Institute of Oncology	Nancy	4 690	557	74	7,5	11,9%	532	67	96%	25	7
Institute of Cancer research in Western France	Nantes Angers	10 904	954	246	3,9	8,7%	782	168	82%	172	78
Antoine Lacassagne Centre	Nice	5 395	410	159	2,6	7,6%	309	105	75%	101	54
Curie Institute	Paris Saint-Cloud	13 464	1 666	197	8,5	12,4%	1 456	125	87%	210	72
Jean Godinot Institute	Reims	3 219	211	65	3,2	6,6%	200	54	95%	11	11
Eugène Marquis centre	Rennes	4 670	377	108	3,5	8,1%	258	68	68%	119	40
Henri Becquerel centre	Rouen	4 689	511	107	4,8	10,9%	482	75	94%	29	32
Paul Strauss Centre	Strasbourg	3 896	203	100	2,0	5,2%	175	74	86%	28	26
Claudius Regaud Institute	Toulouse	6 696	859	195	4,4	12,8%	580	114	68%	279	81
Gustave Roussy	Villejuif	11 964	3 617	364	9,9	30,2%	2 888	140	80%	729	224
Total		**123 167**	**18 629**			**15,1%**	**14 738**		**79,1%**	**3 891**	
Mean		**6 843**	**1 035**	**171**	**5**	**14,0%**	**819**	**111**	**81,9%**	**216**	**60**
+/- SD		**2 934**	**855**	**74**	**2**	**8,0%**	**660**	**34**	**11,8%**	**274**	**48**
median		**6 359**	**819**	**167**	**5**	**12,1%**	**625**	**115**	**84,5%**	**114**	**49**
min		**3 219**	**203**	**65**	**2**	**5,2%**	**175**	**54**	**47,1%**	**11**	**7**
max		**13 464**	**3 617**	**364**	**10**	**31,8%**	**2 888**	**168**	**95,5%**	**1 071**	**224**

*Publications :2010-2015

PORTFOLIO OF TRIALS IN ACTIVE PHASE IN 2017

LOCALISATION	STUDY TITLE	STUDY COORDINATOR	PHASE	NUMBER OF EXPECTED PATIENTS	EXPERT GROUP(S)
Bone Sarcomas - Metastatic stage	SARCOME 12 - REGOBONE Randomized phase II, placebo-controlled, multicenter study evaluating efficacy and safety of regorafenib in patients with metastatic bone sarcomas	F. Duffaud	II	132	SARCOMA
Breast Cancer - HR positive, HER2 negative	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	80 in France (800 in total)	UCBG
Breast and ovarian cancer	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	UCBG
Breast Cancer - Triple negative stage	GMP08 - TRACER X Tracking triple-negative breast cancer evolution through therapy	M. Arnedos	cohort	250	PERSO MED
Breast cancer - ER positive/her2 negative- eligible for neoadjuvant endocrine therapy - TIL +	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	UCBG
Breast cancer - Localised stage	CANTO A cohort to quantify and to predict treatment related chronic toxicities in patients with non-metastatic breast cancer	F. André	Cohort	10 000	UCBG
Breast cancer - Neoadjuvant treatment - HER2 positive	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	GEP / UCBG
Breast Cancer - Non metastatic stage - ER+/ Her2 - with poor prognosis	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	1984	UCBG
Breast Cancer - Localised stage	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	1000 in France (5000 in total)	UCBG
Breast cancer - Metastatic stage	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	PERSO MED
Breast cancer- Metastatic stage	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	PERSO MED / UCBG
Breast cancer - Neoadjuvant setting - HER2+	GMP 05 - SAFIR-TOR Identification of the molecular alterations associated with resistance to endocrine therapy and impacting treatment with mTOR inhibitor of HR+ metastatic breast cancer in post-menopausal women.	T. Bachelot	II	150	PERSO MED / UCBG
Breast cancer - indication for regional lymph node irradiation	RAD01-HYPOG-01 Multicenter 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	1012	UNITRAD

LOCALISATION	STUDY TITLE	STUDY COORDINATOR	PHASE	NUMBER OF EXPECTED PATIENTS	EXPERT GROUP(S)
Breast Cancer - Locally advanced or metastatic stage	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	GEP/UCBG
Breast cancer - Metastatic Stage	PADA-1 Randomized, open label, milticentric 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	UCBG
Collecting Duct Carcinoma - Metastatic stage	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	GETUG
Colorectal cancer - Metastatic stage	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	UCGI
Colorectal cancer - Metastatic stage	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	UCGI
Colorectal Cancer - Adjuvant setting	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	UCGI
Colorectal Cancer- indication for stereostatic body radiation	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	UNITRAD/ UCGI
Germ Cell tumors: testicular, mediastinal and retroperitoneal	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	GETUG
Head & Neck squamous cell carcinoma - metastatic stage	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	UCH&N
Head & Neck squamous cell carcinoma - metastatic stage	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	UCH&N
Multiple Localisations	IMM01 - ACSé Nivolumab Secured access to nivolumab for adult patients with selected rare cancer types	A. Marabelle	II	300	IOG
Multiple Localisations	IMM02 - ACSé Pembrolizumab Secured access to pembrolizumab for adult patients with selected rare cancer types	C. Massard	II	350	IOG
Multiple localisations - Metastatic or unresecable locally advanced	AcSé VEMURAFENIB Secured access to vemurafenib for patients with tumors harboring BRAF genomic alterations	J-Y. Blay	II	500	PERSO MED
Multiple localisations - Metastatic stage	GMP07 - EXPRESS Molecular characterization of patients with solid tumors who presented an exceptional response to targeted therapies	C. Ferté, F. André	Cohort	264	PERSO MED
Multiple localisations - Metastatic stage	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	UNITRAD
Multiple localisations - Metastatic stage	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	PERSO MED
Mutiple localisations Metastatic stage	QUALIOR Feasibility and Efficacy of Supervised Home-based Standard Physical Exercise Programme in Patients Receiving Oral Therapy for Metastatic cancer	F. Joly	II-III	312	SCI
Non Small Cell Lung Cancer - Metastatic stage	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	F. Barlesi, B. Besse	II	650 patients screened for 230 patients treated	PERSO MED

LOCALISATION	STUDY TITLE	STUDY COORDINATOR	PHASE	NUMBER OF EXPECTED PATIENTS	EXPERT GROUP(S)
Ovarian cancer - Relapse stage	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	FEDEGYN
Pancreatic Cancer - Locally advanced stage	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	UCGI
Penile cancer - Metastatic lymph node involvement	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	GETUG
Prostate cancer - adjuvant setting	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	700	GETUG
Prostate cancer - Metastatic stage	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	GETUG
Prostate cancer - Biological relapse	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	37-43	GEP
Prostate cancer- localised stage - High risk of recurrence	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	1048	GETUG
Prostate Cancer Metastatic stage	GETUG AFU29 - PEACE 3 - EORTC 1333 A Randomized multicenter phase III trial comparing enzalutamide *vs.* a combination of Ra223 and enzalutamide in asymptomatic or mildly symptomatic castration resistant prostate cancer patients metastatic to bone. PEACE III	Y. Loriot	III	75	GETUG
Rectal cancer - Locally advanced stage - Neoadjuvant treatment	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	460	UCGI
Rectal cancer - Locally advanced stage - Neoadjuvant treatment	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	GERICO / UCGI
Renal Cell Carcinoma - Advanced or metastatic stage	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	300	GETUG
Salivary gland cancer - Metastatic stage	ORL 08 - NISCAHN A Phase II, Multicenter, Non Randomized, Open Label Study of Nivolumab In Recurrent and/or Metastatic Salivary Gland Carcinoma of the Head and Neck	J. Fayette	II	92	UCH&N
Salivary gland cancer - recurrent and/or metastatic - androgen receptor positive	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	UCH&N

PORTFOLIO OF TRIALS IN FOLLOW-UP PHASE IN 2017

LOCALISATION	STUDY TITLE	STUDY COORDINATOR	PHASE	NUMBER OF INCLUDED PATIENTS	TUMOR GROUP
Biliary tract cancers - Non metastatic stage - Surgical resection	ACCORD 18 - PRODIGE 12 Phase III multicenter 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	UCGI
Bladder cancer - Advanced stage	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	GETUG
Breast cancer - BRCA mutations - Prevention	ONCO 03 - LIBER Prevention of breast cancer by letrozole in post-menopausal women carrying a BRCA1/BRCA2 mutation	P. Pujol	Prevention	170	UCBG
Breast cancer - Localised stage - Neoadjuvant treatment	CARMINA 02 - NIMFEA A randomized multicenter phase II study identifying hormone sensitivity profiles and evaluating the efficacy of anastrozole and fulvestrant in the neo-adjuvant treatment of operable breast cancer in postmenopausal women	F. Lerebours	II	116	UCBG
Breast cancer - Locally advanced or metastatic	CADUSEIME 02 - AMA A phase II trial evalutating Abiraterone in molecular apocrine locally advanced or metastatic breast cancer (AMA)	H. Bonnefoi A. Gonçalves	II	31	UCBG
Breast cancer - Locally advanced stage	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	208	UCBG
Breast cancer - Metastatic stage - Predictive factors for the response	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	UCBG
Breast Cancer - Neoadjuvant treatment	FLT01 Interest of Positron Emission Tomography with 3'-deoxy-3 '- [18F] fluoro-thymidine ([18F] -FLT) for evaluation of the response to neoadjuvant chemotherapy of breast cancer	O. Couturier	HPS	68	UCBG
Breast cancer - Non metastatic stage	PACS 05 Phase III randomized study of adjuvant fluourouracil, epirubicin and cyclophosphamide, in women with stage I breast cancer	P. Kerbrat	III	1500	UCBG
Breast Cancer - Non metastatic stage	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	712	UCBG
Breast Cancer - Non metastatic stage - Genomic signature	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	-	2066	UCBG
Breast cancer - Non metastatic stage - low risk of local recurrence	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	914	UCBG
Breast Cancer - HER2 Inflammatory	PACS 09 - BEVERLY 1 Phase II Study Evaluating the Efficacy and Tolerance of Bevacizumab (Avastin) in HER2- Inflammatory Breast Cancer	P. Viens	II	100	UCBG
Breast cancer - Adjuvant setting - ER (+) / HER2 (-) - Elderly population	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	2000 included for 1080 randomized	GERICO / UCBG
Breast Cancer - Luminal - Neoadjuvant	CARMINA 04 - NEOPAL Open-label, randomized, multicenter, 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	132	UCBG
Breast cancer- Non metastatic stage withpositive lymph nodes	PACS 04 Randomized and multicentric opened phase III study evaluating the concomitant administration of docetaxel 75 mg/m² and epirubicine 75 mg/m² *versus* FEC 100 in non metastatic with positive lymphatic nodes breast cancer subjects, and the sequential addition of herceptin In (HER2+++) and (HER2++ and FISH+) subjects	M. Spielmann	III	3010	UCBG
Breast cancer- Non-metastatic stage - Poor prognosis	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	UCBG
Breast cancer- Ductal carcinoma	IBIS II Adjuvant tamoxifen compared with anastrozole in treating postmenopausal women with ductal carcinoma in situ (IBIS-II DCIS)	C. Levy	III	426	UCBG
Breast Cancer- Non metastatic lymph node-positive	PACS 01 A phase III study evaluating the benefit of docetaxel given sequentially with FEC 100 chemotherapy treatment in axillary lymph node-positive early breast cancer	H. Roché	III	1999	UCBG
Colorectal cancer - metastatic stage - liver metastases	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	UCGI
Colorectal cancer - Metastatic stage - wtKRAS	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	133	UCGI
Colorectal cancer - Metastatic stage - wtKRAS	UCGI 25 A multicentric randomized phase II trial evaluating dual targeting of the EGFR using the combination of cetuximab and afatinib *versus* cetuximab alone in patients with chemotherapy refractory wtKRAS metastatic colorectal cancer	J. Bennouna	II	75	UCGI
Colorectal cancer- Peritoneal carninomatosis	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	265	UCGI
Endometrial cancer - Advanced stage	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	67	FEDEGYN
Ewing sarcoma	SARCOME 01 - EURO EWING 99 Treatment protocol for Ewing tumors : including a medico economic evaluation	N. Gaspar	I-II	1135	SARCOMA
Gastroesophageal cancer - Locally advanced or metastatic stage	ACCORD 20 - PRODIGE 17 - MEGA MEGA (Met or EGFR inhibition in Gastroesophageal Adenocarcinoma): FOLFOX alone or in combination with AMG 102 or panitumumab as first-line treatment in patients with advanced gastroesophageal adenocarcinoma FNCLCC-FFCD-AGEO PRODIGE 17-ACCORD 20 Randomized phase II trial	D. Malka	II	162	UCGI
GIST - Localised stage - High and intermediate risk	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	SARCOMA
Head and Neck Squamous Cell Carcinoma - Non metastatic - Preoperative treatment	GEP 11 - PREDICTOR Multi-centric randomized phase II study of pre-operative afatinib (BIBW2992) aiming at identifying predictive and pharmacodynamic biomarkers of biological activity and efficacy in untreated non-metastatic head and neck squamous cell carcinoma patients	C. Letourneau	II	61	GEP / UCH&N
Lingual carcinoma	ORL 01 - HPV ORO Evaluation of the frequency of Human Papilloma Virus infections in tonsillar and basal lingual carcinomas.	H. Mirghani	II	302	UCH&N

LOCALISATION	STUDY TITLE	STUDY COORDINATOR	PHASE	NUMBER OF INCLUDED PATIENTS	TUMOR GROUP
Multiple localisations - Advanced stage	GEP 07 - PACIFIK An open label dose escalation and pharmacokinetic phase I study with pazopanib in combination with cisplatin (CDDP) every three weeks in patients with advanced solid tumors.	V. Dieras	I	38	GEP
Non-seminomatous Germ Cell tumors - Poor prognostic	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	263	GETUG
Osteosarcoma	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	SARCOMA
Pancreatic cancer - Non metastatic stage - adjuvant treatment - surgical resection	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	490	UCGI
Prostate cancer - Biological relapse	GETUG 16 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	GETUG
Prostate cancer - Localised stage	GETUG-AFU 17 Randomized, multicenter 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	718	GETUG
Prostate cancer - Localised stage - Detectable PSA	GETUG-AFU 22 A multicenter 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	GETUG
Prostate Cancer - Locally advanced or high risk of relapse	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	GETUG
Prostate cancer - Unfavorable group	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	GETUG
Prostate cancer - Localised stage	GETUG 06 Conformational, curative radiotherapy for prostate cancer (NO, N-) : Phase III multicenter 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	GETUG
Prostate cancer - Localised stage - Intermediate prognostic	GETUG 14 Multicenter 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	GETUG
Salivary gland cancer - Relapse or metastatic stage	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	72	UCH&N
Uterine or Soft Tissue Leiomyosarcomas - Metastatic or relapse stage	SARCOME 11 - LMS 03 Phase II multicenter 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	94	SARCOMA

COMMUNICATIONS

GROUP	STUDY	CONGRESS	TITLE	AUTHORS	PRESENTATION TYPE	LIEN ABSTRACT
ESME	ESME	ASCO	Assessment of multiple endocrine therapies for metastatic breast cancer in a multicenter national observational study.	O. Le Saux, A. Lardy-Cleaud, S. Frank, P-H. Cottu, B. Pistilli, M. Debled, L. Vanlemmens, M. Leheurteur, A-V. Guizard, L. Laborde, L. Uwer, V. D'hondt, D. Berchery, V. Lorgis, J-M. Ferrero, G. Perrocheau, C. Courtinard, S. Chabaud, M. Robain, T. D. Bachelot	Poster Abstract #1052	http://ascopubs.org/doi/abs/10.1200/JCO.2017.35.15_suppl.1052
ESME	ESME	ASCO	Evolution of overall survival according to year of diagnosis (2008-2014) and subtypes, among 16703 metastatic breast cancer (MBC) patients included in the real-life "ESME" cohort.	S. Delaloge, M. Ezzalfani, V. Dieras, T. Bachelot, M. Debled, W. Jacot, E. Brain, M-A. Mouret-Reynier, A. Goncalves, F. Dalenc, A. Patsouris, J-M. Ferrero, C. Levy, L. Vanlemnens, C. Lefeuvre, S. Mathoulin-Pellissier, T. Petit, C. Courtinard, C. Cailliot, D. Perol	poster Abstract #1078	http://ascopubs.org/doi/abs/10.1200/JCO.2017.35.15_suppl.1078#
ESME	ESME	EPICLIN	Données de vraie vie en oncologie. Méthodologie de constitution d'une plateforme de données exhaustive.	T. Guesmia, C. Courtinard, F. Bachelot, M. Mons, A. Jaffré, A-V. Guizard, J-P. Bleuse, P. Arveux, E. Chamorey, M. Breton, L. Laborde, D. Parent, D. Pérol, M. Robain.	communication Orale	http://www.em-consulte.com/article/1120567/article/donnees-de-vraie-vie-en-oncologie-methodologie-de-#
ESME	ESME	ESMO	Use of Everolimus in advanced hormone receptor positive metastatic breast cancer in a multicenter national observational study.	P. Cottu, A. Lardy-Cléaud, S. Frank, O. Le Saux, S. Chabaud, D. Parent, B. Pistilli, M. Debled, A. Mailliez, C. Veyret, T. Petit, L. Uwer, S. Guiu, M. Ung, E. Chamorey, P. Arveux, T. Guesmia, P. Augereau, G. Simon, T. Bachelot	Poster abstract #266P	http://oncologypro.esmo.org/Meeting-Resources/ESMO-2017-Congress/Use-of-Everolimus-in-Advanced-hormone-receptor-positive-metastatic-breast-cancer-in-a-multicenter-national-observational-study
ESME	ESME	ESMO	Survival of patients with aromatase inhibitors sensitive HR+/HER2 - metastatic breast cancer treated with a first-line endocrine therapy or chemotherapy in a multicenter national observational study.	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, B. Coudert, J-M. Ferrero, G. Perrocheau, M-A. Mouret-Reynier, D. Parent, V. Diéras, M. Velten, C. Courtinard, S. Chabaud, M. Robain, T. Bachelot	Poster abstract #265P	http://oncologypro.esmo.org/Meeting-Resources/ESMO-2017-Congress/Survival-of-patients-with-aromatase-inhibitors-sensitive-HR-HER2-metastatic-breast-cancer-treated-with-a-first-line-endocrine-therapy-or-chemotherapy-in-a-multicenter-national-observational-study
ESME	ESME	ESMO	FICHE-YOUNG: FIrst-line treatment CHoicE in hormone receptor positive (HR+)/ HER2- negative metastatic breast cancer patients (MBC) ≤45 years old. A large observational multicenter cohort survival analysis.	B. Pistilli, A. Lardy-Cléaud, E. Jacquet, S. Delaloge, P. Cottu, M. Debled, L. Vanlemmens, M. Leheurteur, F. Divanon, A. Gonçalves, C. Laurent, B. Coudert, E. Chamorey, L. Campion, M-A. Mouret-Reynier, M. Breton, T. Petit, G. Simon, C. Cailliot, T. Bachelot	Poster abstract #280P	http://oncologypro.esmo.org/Meeting-Resources/ESMO-2017-Congress/FICHE-YOUNG-FIrst-line-treatment-CHoicE-in-hormone-receptor-positive-HR-HER2-negative-metastatic-breast-cancer-patients-MBC-45-years-old.-A-large-observational-multicenter-cohort-survival-analysis
ESME	ESME	SABCS	Impact of age at diagnostic of metastatic breast cancer on overall survival in the real-life "ESME" cohort.	S. Frank, C. Tchokothe, M. Carton, E. Mouret-Fourme, C. Dubot, M. Campone, B. Pistilli, F. Dalenc, A. Mailliez, C. Levy, W. Jacot, M. Debled, M. Leheurteur, B. Coudert, C. Lefeuvre, A. Gonçalves, L. Uwer, J-M. Ferrero, J-C. Eymard, T. Petit, M-A. Mouret-Reynier, T. Guesmia, T. Bachelot, M. Robain, P. Cottu	Poster P6-08-10	https://www.abstracts2view.com/sabcs/view.php?nu=SABCS17L_251
ESME	ESME	SABCS	Impact of loco-regional treatment (LRT) on overall-survival (OS) in patients with de novo metastatic breast cancer (MBC): results of the French ESME multicenter national observational programme.	E. Pons-Tostivint, Y. Kirova, A. Lusque, M. Campone , C. Levy, S. Delaloge, A. Mailliez, M. Debled, W. Jacot, M. Leheurteur, A. Gonçalves, B. Coudert, C. Lefeuvre, T. Bachelot, J-M.Ferrero, L. Uwer, J-C. Eymard, M-A. Mouret-Reynier, T. Petit, N. Pouget, B. de La Lande, D. Berchery, M. Robain, T. Filleron, C. Cailliot, F. Dalenc	Poster p1-14-02	https://www.abstracts2view.com/sabcs/view.php?nu=SABCS17L_977

GROUP	STUDY	CONGRESS	TITLE	AUTHORS	PRESENTATION TYPE	LIEN ABSTRACT
ESME	ESME	SABCS	Oral etoposide (VP-16) in heavily pre-treated metastatic breast cancer: a multicenter national observational study.	F. Lerebours, M. Carton, J. Bacrie, J-Y. Pierga, R. Rouzier, M. Saghatchian, F. Dalenc, A. Mailliez, C. Levy, W. Jacot, M. Debled, M. Leheurteur, B. Coudert, C. Lefeuvre, A. Gonçalves, L. Uwer, J-M. Ferrero, J-C. Eymard, T. Petit, M-A. Mouret-Reynier, I. Piot, G. Perrocheau, C. Cailliot, D. Perol	Poster p6-14-06	https://www.abstracts2view.com/sabcs/view.php?nu=SABCS17L_925
ESME	ESME	SABCS	Real-life activity of eribulin among metastatic breast cancer patients in the multicenter national observational ESME programme	W. Jacot, P-E. Heudel, J. Fraisse, S. Gourgou, S. Guiu, F. Dalenc, B. Pistilli, M. Campone, C. Levy, M. Debled, M. Leheurteur, M. Chaix, C. Lefeuvre, A. Goncalves, L. Uwer, J-M. Ferrero, J-C. Eymard, T. Petit, M-A. Mouret-Reynier, C. Courtinard, P. Cottu, M. Robain, A. Mailliez	Poster p6-14-02	https://www.abstracts2view.com/sabcs/view.php?nu=SABCS17L_711
GEP / GETUG	GEP12 CARLHA	ASCO GU	Combined Abiraterone, salvage prostate bed Radiotherapy and LH-RH Agonists (CARLHA) in biochemically-relapsing prostate cancer patients following prostatectomy: a phase I study of the GETUG/GEP.	S. Supiot, L. Campion, P. Pommier, M. Dore, S. Racadot, E. Rio, G. Milano, C. Mahier - Ait Oukhatar, C. Carrie	Poster Abstract #45	https://meetinglibrary.asco.org/record/140441/abstract
GEP / UCH&N	GEP 11-PREDICTOR	ASCO	PREDICTOR (Unicancer GEP11): Randomized phase II study of preoperative afatinib in untreated head and neck squamous cell carcinoma (HNSCC) patients.	C. Le Tourneau, J-P. Delord, G. Dolivet, O. Malard, J. Fayette, O. Capitain, C. Even, C. Hoffmann, S. Vergez, L. Geoffrois, F. Rolland, P. Zrounba, L. Laccourreye, J. Guigay, I. Bièche, J. Klijianenko, N. Aide, V. Bénavant, J. Gal, S. Temam	communication Orale Abstract #6021	https://meetinglibrary.asco.org/results/GEP11;page=1
GETUG	GETUG	ASCO	The benefit of combining docetaxel to androgen deprivation therapy in localized and metastatic castration-sensitive prostate cancer as predicted by ERG status: An analysis of two GETUG phase III trials.	S. Rajpar, A. Carmel, Z. Merabet, P. Vielh, S. Foulon, F. Lesaunier, R. Delva, F. Rolland, F. Priou, J-M. Ferrero, N. Houede, L. Mourey, C. Theodore, I. Krakowski, L. Faivre, M. Habibian, S. Culine, A. Chauchereau, G. Gravis, K. Fizazi	Poster discussion Abstract #5012	https://meetinglibrary.asco.org/record/144574/abstract
GETUG	GETUG-AFU26-NIVOREN	ASCO	Efficacy and safety of nivolumab in patients with metastatic renal cell carcinoma (mRCC) and brain metastases: preliminary results from the GETUG-AFU 26 (Nivoren) study.	L. Albiges, R. Flippot, J. Arfi-Rouche, C. Caramella, F. Ruatta, L. Derosa, G. Louvel, P. Maroun, A. Bossi, B. Escudier	Poster Abstract #4563	http://ascopubs.org/action/doSearch?field1=AllField&text1=+GETUG-AFU+26+%28Nivoren%29+study&Ppub=&Ppub=&AfterYear=&BeforeYear=
GETUG	GETUG-AFU19	ASCO GU	Results of the GETUG-AFU 19 trial: A randomized phase II study of dose dense Methotrexate, Vinblastine, Doxorubicin and Cisplatin (dd-MVAC) with or without anti-Epidermal Growth Factor Receptor (EGF-R) monoclonal antibody panitumumab (PANI) in advanced transitional cell carcinoma (ATCC);	S. Culine, A. Fléchon, G. Gravis, G. Roubaud, Y. Loriot, F. Joly, P. Barthélémy, E. Assaf, H. Mahammedi, P. Beuzeboc, S. Van Hulst, F. Rolland, A. Guillot, M. Gross-Goupil, D. Kayat, S. Tartas, M. Deblock, M. Habibian, S. Thezenas, Y. Allory.	Poster Abstract #307	http://ascopubs.org/action/doSearch?field1=AllField&text1=+GETUG-AFU+19&Ppub=&Ppub=&AfterYear=&BeforeYear=
GETUG	GETUG-AFU 22	ASCO GU	The acute toxicity results of the GETUG-AFU 22 study: a multicenter randomized phase II trial comparing the efficacy of a short hormone therapy in combination with radiotherapy to radiotherapy alone as a salvage treatment for patients with detectable PSA after radical prostatectomy .	S. Guerif, I. Latorzeff, L. Roca, N. Allouache, S. Supiot, E. Lagneau, P. Richaud, E. Deniaud-Alexandre, P. Ronchin, A. Benyoucef, L. Cartier, H. Hamidou, A. Hasbini, G. Créhange, P. Pommier, G. De Laroche, M. Habibian, E. Gross, P. Fourneret, L. Salomon.	Poster Abstract #16	https://meetinglibrary.asco.org/record/140433/abstract
GETUG	GETUG-AFU 15	ASCO GU	Burden of Metastatic Hormone Sensitive Prostate Cancer Identifies Men More Likely to Benefit from Early Docetaxel.	G. Gravis, J-M. Boher, Y. Chen, G. Liu, K. Fizazi, M. Carducci, S. Oudard, R. Dipaola, F. Joly, D.Jarrard, M. Soulié, M. Eisenberger, M. Habibian, R. Dreicer, N-J. Vogelzang, M. Hussain, M. Kohli, J. Garcia, J. Picus, C. Sweeney	Poster Abstract #136	https://meetinglibrary.asco.org/record/140466/abstract

GROUP	STUDY	CONGRESS	TITLE	AUTHORS	PRESENTATION TYPE	LIEN ABSTRACT
PERSO MED	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: RUBY	A. Patsouris, C. Vicier, W. Gouraud, M. Jimenez, V. Pezzella, I. Bieche, C. Callens, A. Loehr, L. Campion, F. Andre	Poster abstract #TPS1117	http://ascopubs.org/doi/abs/10.1200/JCO.2017.35.15_suppl.TPS1117#affiliationsContainer
PERSO MED	SAFIR02 Breast	ABC4 Lisbonne	Characteristics of the metastatic breast cancer population with PIK3CA mutation in the randomized phase II study SAFIR02 BREAST (UCBG- 0105/1304)	C. Lefeuvre-Plesse, A. Lusque, I. Bièche, L. Lacroix, M. Arnedos, M. Campone, A. Gonçalves, F. Le Du, A. Jacquet, H. Bonnefoi, V. Attignon, M-P. Sablin, I. Soubeyran, P. Jezequel, N. Isambert, C. Levy, J-M. Ferrero, T. Filleron, T. Bachelot, F. André	Poster Abstract #BP67	https://www.sciencedirect.com/science/article/pii/S0960977617306860
PERSO MED	SAFIR02 Breast + RUBY	SABCS 2017	Mutational processes, genome evolution, and outcome in metastatic breast cancers	A. Patsouris, T. Filleron, A. Jacquet, A. Gonçalves , V. Pezzella, H. Bonnefoi, C. Le Tourneau, T. Bachelot, C. Lefebvre, Y. Fu, M. Jimenez, F. André	Spotlight poster discussion Abstract #PD1-08	http://www.abstracts2view.com/sabcs/view.php?nu=SABCS17L_1466
PERSO MED	AcSé crizotinib	ASH	Crizotinib in advanced ALK+ Anaplastic Large Cell Lymphoma in children and adults: results of the AcSé phase II trial.	L. Brugières, R. Houot, N. Cozic, C. De La Fouchardière, F. Morschhauser, P. Brice, N. Arakelyan, A. Auvrignon, N. Aladjidi, B. Kolb, A. Delmer, L. Blanc, A. Pagnier, J. Arfi-Rouche, A-S. Cottereau, C. Mahier-Aït Oukhatar, N. Hoog Labouret, G. Vassal	Poster	www.bloodjournal.org/content/130/Suppl_1/2831
PERSO MED	AcSé vemurafenib	ASH	Vemurafenib in Advanced Patients with Hairy Cell Leukemia (HCL): Results of the Acsé Phase II Trial.	X. Troussard, L. Montané, M. Tiab, C. Chaleteix, I. Grulois, C. Lindet, D. Legoupil, F. Kohser, D. Pannier, F. Maloisel, P. Bories, C. AIT Oukhatar, N. Hoog Labouret and J-Y. Blay.	Communication orale	www.bloodjournal.org/content/130/Suppl_1/156
Sarcome	SARCOME 11	ESMO	Results of the LMS03 phase II study evaluating gemcitabine combined with pazopanib as a 2nd-line treatment for metastatic/relapsed leiomyosarcomas (uterine or soft tissue) after failure of anthracyclinebased chemotherapy: the Unicancer SARCOME 11 study.	P. Pautier, N. Penel, I. Ray-Coquard, A. Italiano, E. Bompas, C. Delcambre, J-O. Bay, F. Bertucci, J. Delaye, C. Chevreau, D. Cupissol, L. Bozec Le Moal, J-C. Eymard, A. Thyss, N. Isambert, C. Guillemet, M. Rios, S. Piperno-Neumann, G. Chenuc, F. Duffaud	poster	http://oncologypro.esmo.org/Meeting-Resources/ESMO-2017-Congress/Results-of-the-LMS03-phase-II-study-evaluating-gemcitabine-combined-with-pazopanib-as-a-2nd-line-treatment-for-metastatic-relapsed-leiomyosarcomas-uterine-or-soft-tissue-after-failure-of-anthracycline-based-chemotherapy-the-Unicancer-SARCOME-11-study
Supportive care Group	QUALIOR	ASCO	A phase II-III, multicenter, randomized, open study evaluating the feasibility and efficacy of a supervised home-based standard physical exercise programme, for metastatic cancer patients receiving oral targeted therapy: The Unicancer SdS 01 QUALIOR study, ID-RCB: 2015-A01922-47 - NCT03169075	F. Joly, L. Vanlemmens, J-M. Descotes, S. Abadie-Lacourtoisie, C. Boiron, C. Garnier-Tixidre, V. Girre, C. Helissey, N. Houede, C. Lefeuvre-Plesse, B. Mastroianni, N. Meneveau, S. Oudard, V. Plence, F. Priou, S. Salas, L. Stefani, A. Zannetti, F. Bonnetain, I. Krakowski	Trial in progress Abstract # TPS10126	https://meetinglibrary.asco.org/record/153071
UCBG	PACS07-MINDACT	ASCO	Standard anthracycline-based *vs.* Docetaxel-Capecitabine in early breast cancer: results from the chemotherapy randomization (R-C) of EORTC 10041/ BIG 3-04 MINDACT phase III trial.	F. Cardoso, M. Piccart, E. Rutgers, S. Litière, L. J. van 't Veer, G. Viale, J-Y. Pierga, F. Bootsma van den Berkmortel, E. Brain, P. Gomez, T. Goulioti, S. Knox, E. Luporsi, U. Nitz, I-T. Rubio, L. Stork, P. Vuylsteke, K. Tryfonidis, J. Bogaerts, S. Delaloge	Poster Discussion Abstract #516	https://meetinglibrary.asco.org/record/145545/abstract
UCBG	GRT02-COMET	ASCO	Pharmacogenetics revisits bevacizumab in breast cancer patients – An ancillary analysis of the UCBG trial COMET, a French multicentric prospective study from R&D Unicancer.	G. Milano, J-Y. Pierga, J. Gal, L. Llorca, C. Dubot, G. Romieu, I. Desmoulins, E. Brain, A. Goncalves, J-M. Ferrero, P-H. Cottu, M. Debled, O. Tredan, E. Chamorey, M. C. Merlano, J. Lemonnier, M-C. Etienne-Grimaldi	Poster Abstract #1079	https://meetinglibrary.asco.org/record/144908
UCBG	CANTO	ASCO	Unicancer : prospective cohort study of treatment related chronic toxicities in patients (pts) with localized breast cancer (BC) (CANTO).	I. M. Vaz Duarte Luis, P-H. Cottu, C. Mesleard, A-L. Martin, A. Dumas, S. Dauchy, O. Tredan, C. Levy, J. Adnet, M. Rousseau-Tsangaris, F. Andre, P. Arveux	Poster Abstract #TPS10125	https://meetinglibrary.asco.org/record/153339/abstract

GROUP	STUDY	CONGRESS	TITLE	AUTHORS	PRESENTATION TYPE	LIEN ABSTRACT
UCBG	PACS07-MINDACT	ESMO	Not all small, node- negative (T1a-b N0) breast cancers are similar: Outcome results from an EORTC 10041/ BIG 3-04 MINDACT trial substudy.	K. Tryfonidis, C. Poncet, L. Slaets, G. Viale, F. Snoo, K. Aalders, L. van' t Veer, E. Rutgers, M. Piccart, J. Bogaerts and F. Cardoso	communication Orale Abstract #500	http://oncologypro.esmo.org/Meeting-Resources/ESMO-2017-Congress/Not-all-small-node-negative-pT1abN0-breast-cancers-are-similar-Outcome-results-from-an-EORTC-10041-BIG-3-04-MINDACT-trial-substudy
UCBG	NeoPAL	ESMO	Letrozole and palbociclib as neoadjuvant treatment in luminal breast cancer. Results of the Unicancer-NeoPal study.	P. Cottu, V. D'Hondt, S. Dureau, F. Lerebours, I. Desmoulins, P. Heudel, F. Duhoux, C. Levy, M-A. Mouret Reynier, F. Dalenc, M. Campone, C. Jouannaud, L. Venat-Bouvet, S. Nguyen, J-M. Ferrero, J-L. Canon, J. Grenier, A. Vincent-Salomon, J. Lemonnier, S. Delaloge	communication Orale Abstract #LBA9	http://oncologypro.esmo.org/Meeting-Resources/ESMO-2017-Congress/Letrozole-and-palbociclib-versus-3rd-generation-chemotherapy-as-neoadjuvant-treatment-of-luminal-breast-cancer.-Results-of-the-Unicancer-NeoPAL-study
UCBG	PACS04-05	SABCS	MAAT: Menses after Adjuvant Treatment. Prediction of menses recovery after chemotherapy for early breast cancer (BC) by using a nomogram model in Unicancer PACS04 and PACS05 trials.	B. Pistilli, C. Mazouni, A. Zingarello, M. Faron, M. Saghatchian, M. Grynberg, M. Spielmann, H. Roché, B. Coudert, T. Bachelot, M. Campone, C. Levy, A. Gonçalves, A. Lesur, C. Veyret, L. Vanlemmens, J. Lemonnier, S. Delaloge	Poster discussion Abstract #PD7-06	https://www.abstracts2view.com/sabcs/view.php?nu=SABCS17L_600
UCBG	PACS04	SABCS	Overtime distribution and predictors of local recurrences (LRs) in patients with hormone receptor positive (HR+) and node positive (N+) breast cancers (BCs): 10 -year follow-up analysis of Unicancer-PACS 01 and PACS04 trials.	B. Pistilli, T. Filleron, C. Mazouni, M. Lacroix-Triki, S. Rivera, B. Coudert, D. Serin, J-L. Canon , M. Campone, A. Gonçalves, C. Levy, P. Cottu, T. Petit, J-C. Eymard, M. Debled, T. Bachelot, H. Roché, L. Roca, J. Lemonnier, S. Delaloge	Poster Abstract #p1-07-07	https://www.abstracts2view.com/sabcs/view.php?nu=SABCS17L_626
UCBG	CANTO	SABCS	CANTOCHEM: analysis of chemotherapy practice and early side effects in the 6090 first patients from the prospective CANTO cohort	P. Cottu, Y. Amar, B. Pistilli, H. Bonsang-Kitzis, A. Lesur, F. Lerebours, L. Vanlemmens, O. Tredan, C. Levy, C. Jouannaud, M. Fournier, P. Soulie, O. Rigal, S. Giacchetti, A. Arnaud, O. Arsene, A. Savignoni, C. Mesleard, F. Andre and P. Arveux	Poster Abstract #P6-12-18	https://www.abstracts2view.com/sabcs/view.php?nu=SABCS17L_1189
UCBG	CANTO	ICCTF	Cognitive impairment in breast cancer patients before surgery ?	I. Léger, M. Lange, I. Licaj, S. Rajpar, O. Rigal, J. Le Fel, C. Lévy, A. Capel, C. Coutant, J. Meyer, F. Lerebours, J. Pettrucci, L. Vanlemmens, M. Brion, M. Campone, P. Soulié, M. Blain, L. Tron, A-L. Martin, C. Mesleard, J. Adnet, F. André, S. Dauchy, F. Joly	Abstract	
UCBG	GRT02-COMET	SABCS	Heterogeneity and variability of human epidermal growth factor receptor 2 (HER2) expression on Circulating Tumor Cells (CTC) in HER2 negative metastatic breast cancer patients treated with first line weekly paclitaxel and bevacizumab in a prospective cohort from the French Breast Cancer InterGroup Unicancer (UCBG): COMET study.	J-Y. Pierga, C. Proudon, O. Tredan, C. Decraene, C. Dubot, V. Lorgis, W. Jacot, A. Goncalves, M. Debled, C. Levy, J-M. Ferrero, C. Jouannaud, E. Luporsi, M-A. Mouret-Reynier, F. Dalenc, J. Lemonnier, F. Berger and F-C. Bidard	Poster Abstract #P2-01-02	https://www.abstracts2view.com/sabcs/view.php?nu=SABCS17L_1307
UCBG	PACS04	SABCS	FGFR1 / ZNF217 copy numbers and outcome in patients with node positive, HR+/Her2- early breast cancer: A genomic analysis of PACS04 trial	F. Andre, F. Penault Llorca, D. Carene, H. Roche, S. Delaloge, L. Lacroix, V. Scott, C. Richon, M. Lacroix-Ticrit, J. Lemonnier, S. Michiels	Poster Discussion Abstract #PD4-10	https://www.abstracts2view.com/sabcs/view.php?nu=SABCS17L_1137
UCBG	PACS07-MINDACT	SABCS	MammaPrint is cost-effective compared to clinical risk assessment in early stage breast cancer.	V. P. Retèl, M. A. Joore, L. van 't Veer, F. Cardoso, M. Piccart, E. Rutgers, K. Tryfonidis, C. Poncet, Wim H. van Harten	P4-12-01	https://www.abstracts2view.com/sabcs/view.php?nu=SABCS17L_829
UCBG	PACS07-MINDACT	SABCS	Young age and the risk of disease recurrence as assessed by the 70-gene signature – an analysis from the EORTC 10041/BIG 03-04 MINDACT trial.	K. Aalders, E. Genbrugge, C. Poncet, A. Kuijer, B. Pistilli, M. Piccart, K. Tryfonidis, T. van Dalen, F. Cardoso, L. van 't Veer, E. Rutgers	P1-07-08	https://www.abstracts2view.com/sabcs/view.php?nu=SABCS17L_806

GROUP	STUDY	CONGRESS	TITLE	AUTHORS	PRESENTATION TYPE	LIEN ABSTRACT
UCGI	PRODIGE18-ACCORD 22	ESMO	Bevacizumab (Bev) or cetuximab (Cet) plus chemotherapy after progression with bevacizumab plus chemotherapy in patients with wild-type (WT) KRAS metastatic colorectal cancer (mCRC): final analysis of a randomized, multicenter, phase II study (PRODIGE 18).	J. Bennouna, S. Hiret, C. Borg, A. Bertaut, O. Bouche, G. Deplanque, E. Francois, T. Conroy, F. Ghiringhelli, G. Des Guetz, J-F. Seitz, P. Artru, T. Stanbury, M. G. Denis, A. Adenis	Communication orale Abstract #4770	http://oncologypro.esmo.org/Meeting-Resources/ESMO-2017-Congress/Bevacizumab-Bev-or-cetuximab-Cet-plus-chemotherapy-after-progression-with-bevacizumab-plus-chemotherapy-in-patients-with-wild-type-WT-KRAS-metastatic-colorectal-cancer-mCRC-final-analysis-of-a-French-randomized-multicenter-phase-II-study-PRODI
UCGI	PRODIGE 12-ACCORD 18	ESMO	Adjuvant GEMOX for biliary tract cancer: updated relapse-free survival and first overall survival results of the randomized PRODIGE 12-ACCORD 18 (Unicancer GI) phase III trial.	J. Edeline, F. Bonnetain, J-M. Phelip, J. Watelet, P. Hammel, J-P. Joly, M. Benabdelghani, O. Rosmorduc, K. Bouhier-Leporrier, J-L. Jouve, R. Faroux, V. Guerin Meyer, E. Assenat, J-F. Seitz, D. Malka, C. Louvet, A. Bertaut, B. Juzyna, T. Stanbury, E. Boucher	Communication orale Abstract #LBA29	http://oncologypro.esmo.org/Meeting-Resources/ESMO-2017-Congress/Adjuvant-GEMOX-for-biliary-tract-cancer-updated-relapse-free-survival-and-first-overall-survival-results-of-the-randomized-PRODIGE-12-ACCORD-18-Unicancer-GI-phase-III-trial
UCGI	ACCORD 12-PRODIGE 2	ESMO	Impact of Immune response-associated gene Polymorphisms on tumor response in Rectal Cancer Patients Treated with capecitabine +/- oxaliplatine and Radiation in the ACCORD-12/PRODIGE-2 phase III trial.	V. Boige, C. Mollevi, N. Chaput, S. Gourgou, D. Azria, J-F. Seitz, L. Bigot, B. Juzyna, I. Miran, J-P. Gérard, P. Laurent-Puig.	Poster Abstract #560P	http://oncologypro.esmo.org/Meeting-Resources/ESMO-2017-Congress/Impact-of-Immune-response-associated-gene-Polymorphisms-on-tumor-response-in-Rectal-Cancer-Patients-Treated-with-capecitabine-oxaliplatine-and-Radiation-in-the-ACCORD-12-PRODIGE-2-phase-III-trial

CONTACTS

RESEARCH DIRECTOR
Christian Cailliot
c-cailliot@unicancer.fr

SCIENTIFIC DIRECTOR
DEPUTY DIRECTOR OF RESEARCH & DEVELOPMENT
Claire Labreveux
c-labreveux@unicancer.fr

CLINICAL OPERATIONS DIRECTOR
Béata Juzyna
b-juzyna@unicancer.fr

HEAD OF REAL WORLD DATA
Mathieu Robain
m-robain@unicancer.fr

REGULATORY AFFAIRS; QUALITY ASSURANCE
AND PHARMACOVIGILANCE DIRECTOR
Pierre-Henri Bertoye
ph-bertoye@unicancer.fr

DEVELOPMENT AND PARTNERSHIPS DIRECTOR
Anne-Laure Martin
al-martin@unicancer.fr

UNICANCER
101, rue de Tolbiac
75654 PARIS CEDEX 13
France
R&D OFFICE
Okabé - 67, avenue de Fontainebleau
94270 LE KREMLIN-BICETRE

FOLLOW US

Website
www.unicancer.fr/en

Twitter
@groupeunicancer

Facebook
facebook.com/unicancer

LinkedIn
linkedin.com/company/unicancer

GRAPHIC DESIGN AND REALISATION
Charlotte Moreau
www.charlotte-moreau.fr

ICONOGRAPHY
Photo credits : Unicancer/Julie Bourges,
DR Paoli-Calmettes Institute, Frederic Stucin/La Compagny.

JOURNALIST
Sylvie Favier

FRONT AND BACK COVER GRAPHIC DESIGN
AND REALISATION
CIMAYA
www.cimaya.fr

INNOVATION
HUMAN FIRST
EXCELLENCY
SOLIDARITY

Follow us

www.unicancer.fr/en

facebook.com/unicancer
linkedin.com/company/unicancer
twitter.com/groupeunicancer

unicancer

101, rue de Tolbiac
75654 Paris Cedex 13
France
+ 33 (0) 1 44 23 04 04
www.unicancer.fr/en