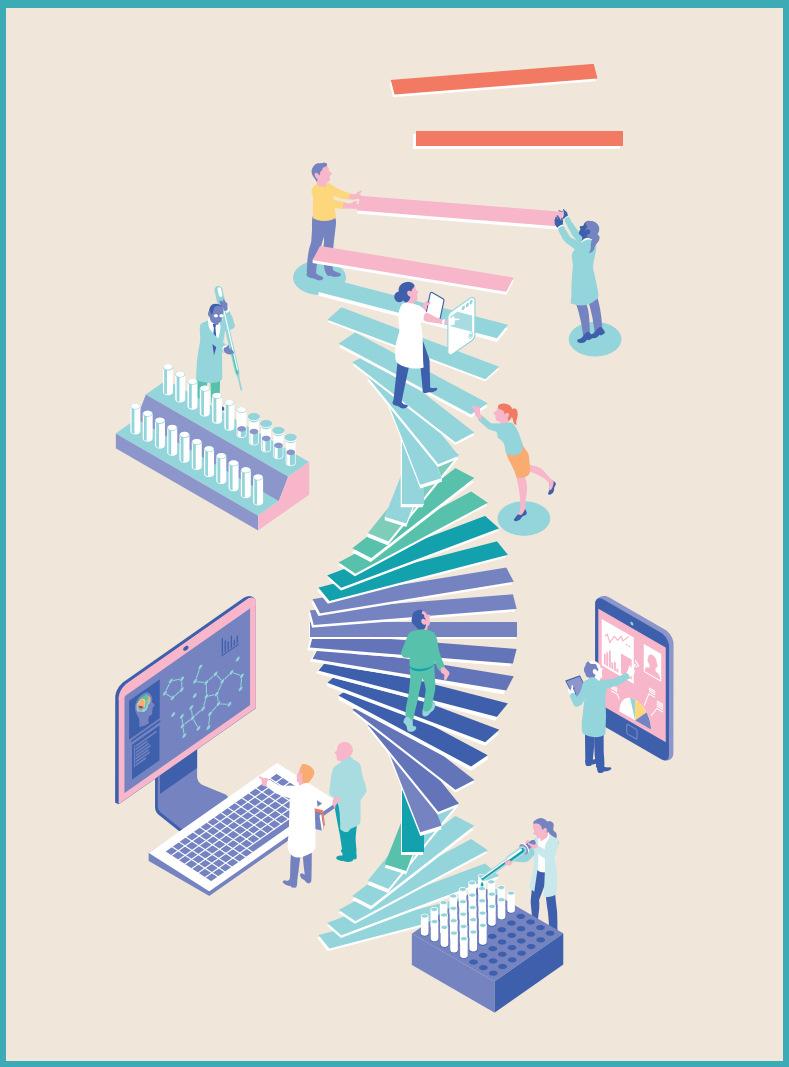


R&D UNICANCER
Activity report
2015

Going further, innovating together

UNICANCER R&D

Summary

Presentation

UNICANCER, a major French player in oncology, groups together 20 French Comprehensive Cancer Centers (FCCC). They are private, non-profit health establishments exclusively dedicated to care, research and education in cancer.

UNICANCER's R&D department is the driving force of UNICANCER's research and, as an academic sponsor, it works directly with the research units of the FCCC and other health establishments (university hospitals, hospitals and clinics) in France and abroad.

The mission of R&D UNICANCER 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 Centers;
– accompany the research teams of the FCCC and mutualize support activities such as regulatory affairs, pharmacovigilance, quality assurance and monitoring of calls for projects.

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

Présentation

Acteur majeur de la cancérologie française, UNICANCER regroupe les 20 Centres de lutte contre le cancer (CLCC), établissements de santé privés à but non lucratif exclusivement dédiés aux soins, à la recherche et à l'enseignement en cancérologie.

Fer de lance de la recherche d'UNICANCER, la direction de la recherche R&D UNICANCER, 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.

R&D UNICANCER 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 Centres ;
– 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 R&D UNICANCER est de faire progresser la connaissance sur le cancer pour un transfert rapide des innovations au lit du patient et une amélioration continue de sa prise en charge.

Presentation

“For R&D UNICANCER, the scientific department of UNICANCER, 2015 marked a new stage in its development with emblematic and original research programs.”

“Pour R&D UNICANCER, direction scientifique d’UNICANCER, l’année 2015 marque une nouvelle étape dans son développement, avec la réalisation de programmes de recherche emblématiques et innovants.”

Pr. Patrice Viens
UNICANCER’s President

Innovation serving patients

Continue to innovate, always at the patients' service

Today, R&D UNICANCER is the first national academic clinical research structure in France, in accordance with the objective set by my predecessor, Professor Josy Reiffers, to whom I wish to pay tribute. UNICANCER president from 2010 to 2015, he will be remembered for his visionary analysis of the stakes around cancer and his repeated calls for innovation in the organization of the care and of the structures dedicated to fighting cancer. His aim was to preserve and promote the model of the French Comprehensive Cancer Centers (FCCC), based on management of the patient without extra billing, on a continuum of care, research and training and on a multidisciplinary approach regardless of the location of the tumor.

Elected President of UNICANCER in December 2015, I wish to continue this work, which has advanced in recent years, and propel R&D UNICANCER and the FCCC as accelerators for the conception and diffusion of innovations.

For R&D UNICANCER, the scientific department of UNICANCER, 2015 marked a new stage in its development with emblematic and original research programs including:
– the intensification of research projects involving precision medicine and target identification: these studies are often on a national scope and carried out in conjunction with industrialists, owners of new molecules, but also with the public institutions which support us or which generate their own projects that they then entrust to us;
– the initiation of seven new clinical trials including three for the French Breast Cancer Intergroup (UCBG);
– the strengthening of the radiotherapy activity with the creation of the UNITRAD group (UNICANCER group of Translational Research and Development in Radiation Oncology), whose objective is to develop innovative research on ionizing radiation: three projects were in fact selected by the by the French National Cancer Institute (INCa) during the 2015 PHRC-K campaign;
– the obtainment of eight PHRC (Hospital Clinical Research Programs): 12 dossiers were submitted out of 15 initial letters of intention;
– the first R&D UNICANCER call for projects, piloted with the UNICANCER Breast Intergroup and supported by a €1.2 million grant from Pfizer and the setting up of an independent jury.

I would like to emphasize that, in addition to the industrial partners who have chosen to follow R&D UNICANCER, two major charitable organizations also renewed their support to us in 2015, the French Cancer League and the ARC Foundation. The challenge for 2016 will be, among others, to open up more to other partnerships, invent new forms of collaboration, and create new networks structured around innovations.

Continuer d'innover, toujours au service des patients

R&D UNICANCER est aujourd'hui la première structure académique nationale de recherche clinique dans le cancer en France, selon l'objectif que s'était fixé mon prédécesseur, le Professeur Josy Reiffers, à qui je souhaite ici rendre hommage. Président d'UNICANCER de 2010 à 2015, il aura marqué les esprits, par sa lecture visionnaire des enjeux du cancer et ses appels répétés à un effort d'innovation dans l'organisation des soins et des structures de lutte contre le cancer. Son objectif était de préserver et de promouvoir le modèle des CLCC, fondé sur une prise en charge du patient sans dépassement d'honoraires, sur le continuum recherche-soins-formation et sur la pluridisciplinarité, quelle que soit la localisation des tumeurs.

Élu Président d'UNICANCER en décembre 2015, je souhaite poursuivre ce travail impulsé ces dernières années et propulser R&D UNICANCER et les CLCC en tant qu'accélérateurs de la mise en place et de la diffusion des innovations.

Pour R&D UNICANCER, direction scientifique d'UNICANCER, l'année 2015 marque une nouvelle étape dans son développement, avec la réalisation de programmes de recherche emblématiques et innovants parmi lesquels :
– l'intensification des projets de recherche impliquant la médecine de précision et l'identification des cibles : ces essais sont souvent de portée nationale et en relation avec les industriels, propriétaires des nouvelles molécules, mais aussi avec les institutions publiques qui nous soutiennent ou qui génèrent elles-mêmes des projets qu'elles nous confient ensuite ;
– le lancement de sept nouveaux essais cliniques activés dont trois pour le French breast cancer intergroup (UCBG) ;
– le renforcement de l'activité radiothérapie avec la création du groupe UNITRAD (UNICANCER group of Translational Research and Development in RADiation Oncology), dont l'objectif est de développer une recherche innovante sur les rayons ionisants : trois projets ont d'ailleurs été retenus par l'Institut national du cancer (INCa) lors de la campagne des PHRC-K 2015 ;
– l'obtention de huit PHRC sur les quinze lettres d'intention initiales ;
– le premier appel à projets R&D UNICANCER piloté avec l'Intergroupe Sein UNICANCER a pu être conduit grâce à une dotation du laboratoire Pfizer de 1,2 million d'euros et par la mise en place d'un jury indépendant.

Je tiens enfin à souligner, outre les partenaires industriels qui font le choix de suivre R&D UNICANCER, la confiance renouvelée en 2015 de deux grands acteurs caritatifs que sont la Ligue contre le cancer et la Fondation ARC. L'enjeu pour 2016 sera, entre autres, de nous ouvrir encore plus à d'autres partenariats, inventer de nouvelles modalités de collaboration, et créer de nouveaux réseaux structurés autour des innovations.

"R&D UNICANCER is coordinating the certification process and accompanying the FCCC while at the same time undertaking the actions required for certification of its own activities."

Alexander Eggermont
Vice-President of UNICANCER, Research Representative and President of the Research Strategic Committee

Strengthen collaboration with the French Comprehensive Cancer Centers

The collaboration between the UNICANCER R&D teams and the FCCC has enabled the implementation of many projects, including in 2015:
– the rolling out of the ISO 9001 certification of the clinical research activities of R&D UNICANCER and the FCCC: R&D UNICANCER is coordinating the certification process and accompanying the FCCC while at the same time undertaking the actions required for certification of its own activities (clinical operations, pharmacovigilance, regulatory activities, data-management, quality assurance), with a view to finalization in 2017—three Centers were already certified in 2014 (Léon Bérard Center, Paoli-Calmettes Institute, Claudius Regaud Institute) and two others were certified in 2015 (Georges-François Leclerc Center, Lorraine Institute of Oncology);
– the development of the ESME Program, which is proof of the close cooperation between the UNICANCER scientific board of directors and the teams of the Centers: the project, initiated in 2014 in metastatic breast cancer, made it possible to group together clinical and therapeutic data from more than 14,000 patients from the FCCC, making ESME Europe's largest source of real life information in this area (extension of this program to ovarian cancer, lung cancer and new immunotherapies is currently under study);
– the mutualization of activities such as regulatory affairs, pharmacovigilance, and audits, has been notably reinforced, for example with information being shared on regulations, the pooling of procedures and tools, and temporary assistance being given on technical/regulatory issues.

Renforcer la collaboration avec les Centres de lutte contre le cancer

La collaboration entre les équipes de R&D UNICANCER et les CLCC a permis la mise en place de nombreux projets, avec notamment en 2015 :
– le déploiement de la certification ISO 9001 des activités de recherche clinique de R&D UNICANCER et des CLCC: R&D UNICANCER accompagne et coordonne le processus de certification de l'ensemble des CLCC et réalise les actions nécessaires en vue d'obtenir la certification de ses propres activités (opérations cliniques, pharmacovigilance, activités réglementaires, data-management, assurance qualité), ceci à l'horizon 2017— à ce jour, cinq Centres ont déjà été certifiés dont deux en 2015 ;
– le développement du programme ESMÉ, preuve d'une collaboration étroite entre la direction scientifique d'UNICANCER et les équipes des Centres : le projet, initié en 2014 dans le cancer du sein métastatique, a permis de regrouper des données cliniques et thérapeutiques de plus de 14 000 patientes des CLCC, ce qui fait déjà d'ESMÉ la plus importante source européenne d'information en vie réelle dans ce domaine (l'extension de ce programme au cancer de l'ovaire, au cancer du poumon et aux nouvelles immunothérapies est actuellement à l'étude) ;
– le renforcement de la mutualisation des activités telles que les affaires règlementaires, la pharmacovigilance, les audits, est notable, avec par exemple l'information sur la réglementation, la mutualisation de procédures et d'outils, et l'aide ponctuelle sur des questions technico-réglementaires.

Collaboration and mutualization serving research

"Two major ambitions of the department for today and the coming years."

Christian Cailliot
Director of R&D
UNICANCER

Confirmation of the development of two key axes in 2015 and future years: immunotherapy and the internationalization of research

R&D UNICANCER pays tribute to Professor Josy Reiffers, who passed away on September 21st 2015, victim of the disease which UNICANCER is focusing all its energy on eliminating. A great boss and an undisputed leader in research, he helped develop R&D UNICANCER which is now the first national academic cancer clinical research structure, as he liked to say. 2015 once again reflected the growth of R&D UNICANCER, and the two major ambitions of the department for today and the coming years are to:
– get involved in and develop cancer immunotherapy research projects, with the creation of a focus group of experts in the field: the department actually anticipated this revolution very nicely as no less than ten immunotherapy projects involving checkpoint inhibitors are currently being developed, some of which have already been started. The SAFIR02 trial now allows patients who cannot be treated with targeted therapies to be treated with durvalumab. Soon, the start of the ULTIMATE trial (UCBG), the AcSé rare tumors programs (Medperso), or the NIVOREN study (GETUG) begun in 2015, will truly mark the deployment of this therapeutic strategy;
– "Internationalize" research through projects with consortiums and European academic structures: the success of the MAP Congress (Molecular Analysis for Personalized therapy) demonstrates the strong position of the department's expert teams in international research in highly innovative research areas.

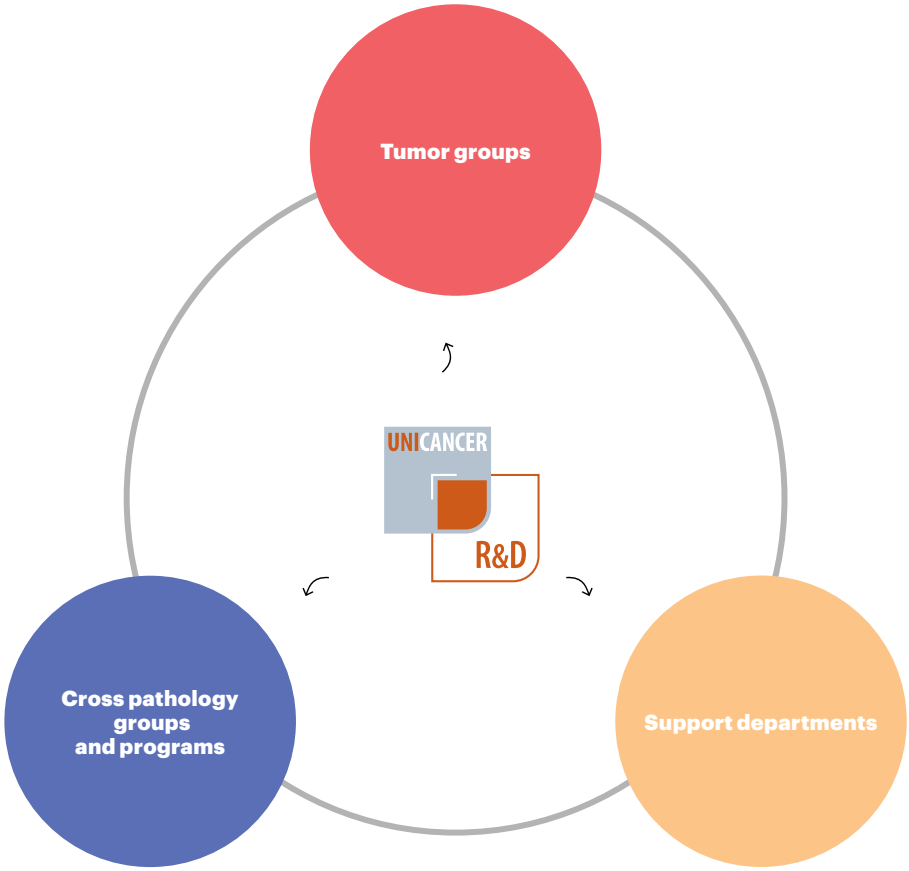
In 2016, the R&D UNICANCER department will continue its professionalization and will carry on seeking to improve the quality of its clinical trials. 2016 will also be a year of essential reorganization for the department's teams, and developments in research processes should enable them to achieve their ultimate goal: to progress in the fight against cancer.

Assurer le développement de deux axes phares pour 2015 et les années à venir : l'immunothérapie et l'internationalisation de la recherche

R&D UNICANCER rend hommage au Professeur Josy Reiffers, qui nous a quittés le 21 septembre 2015, victime de la pathologie que nous mettons tous nos efforts à éliminer/faire reculer.
Formidable patron et leader incontesté pour la recherche, il a permis de pouvoir développer R&D UNICANCER, actuellement première structure académique nationale de recherche clinique dans le cancer, comme il se plaisait à le dire. Cette année 2015 est encore une fois le reflet de l'essor de R&D UNICANCER, avec deux ambitions notables pour aujourd'hui et ces prochaines années :
– l'implication et le développement de projets de recherche dans le domaine de l'immunothérapie du cancer, avec la création d'un groupe de réflexion composé d'experts du domaine : nous avons assez bien anticipé cette révolution puisqu'à l'heure actuelle pas moins de dix projets d'immunothérapie impliquant les *check points* inhibiteurs sont en cours de préparation, dont certains ont déjà été démarrés. L'essai SAFIR02 permet dorénavant le traitement par le durvalumab chez des patients qui ne peuvent bénéficier de thérapies ciblées. Bientôt, le démarrage de l'essai ULTIMATE (UCBG), des programmes AcSé tumeurs rare (Medperso), ou bien encore l'étude NIVOREN (GETUG) débutée en 2015, vont véritablement marquer le déploiement de cette stratégie thérapeutique ;
– « L'internationalisation » de la recherche au travers de projets avec des consortiums et des structures académiques européennes : le succès du congrès MAP (Molecular Analysis for Personalised therapy) témoigne du positionnement fort de nos équipes d'experts dans la recherche internationale sur des axes de recherche particulièrement innovants.

L'année 2016 aura pour objectif la poursuite de notre professionnalisation et la recherche permanente de l'amélioration de la qualité de nos essais cliniques. 2016 devra également permettre la réorganisation nécessaire des équipes et l'évolution des process de recherche afin d'atteindre l'objectif ultime : progresser dans la lutte contre le cancer.

Exploration of new cancer research fields



Tumor groups

- French Breast Cancer Intergroup UNICANCER (UCBG)
- UNICANCER Gastro-Intestinal Group (UCGI)
- UNICANCER Urogenital Group (GETUG)
- UNICANCER Head & Neck Group
- UNICANCER Sarcoma Group

Cross pathology groups and programs

- Geriatrics Group (GERICO)
- Personalized Medicine Program
- Early Phase Group (GEP)
- Supportive Care Intergroup
- Radiation Therapy Group (UNITRAD)
- Epidemio Strategy and Medical Economics (ESME) Program

Support departments

- Regulatory Affairs and Pharmacovigilance
- Quality Assurance
- Centralized Data Center
- Centralized Biobank
- Basic and Preclinical Research

To fulfill its objective, R&D UNICANCER works closely with its groups of experts and provides them the necessary support structure to allow efficient project management.

Organization

The research projects undertaken by R&D UNICANCER are first subjected to a validation process where the decisions are made by decision-making bodies:

Groups – Formulation/maturation of the project – Seeking of funds	**Approval of the Group**
↓	
Protocol Review Committee (PRC) Review of scientific & methodological aspects/feasibility/funding	**UNICANCER Implementation agreement (Sponsoring)**
↓	
Strategic Research Committee (SRC)	**Assessment of the strategic aspects**

+5,000
patients included in clinical trials conducted in France and abroad

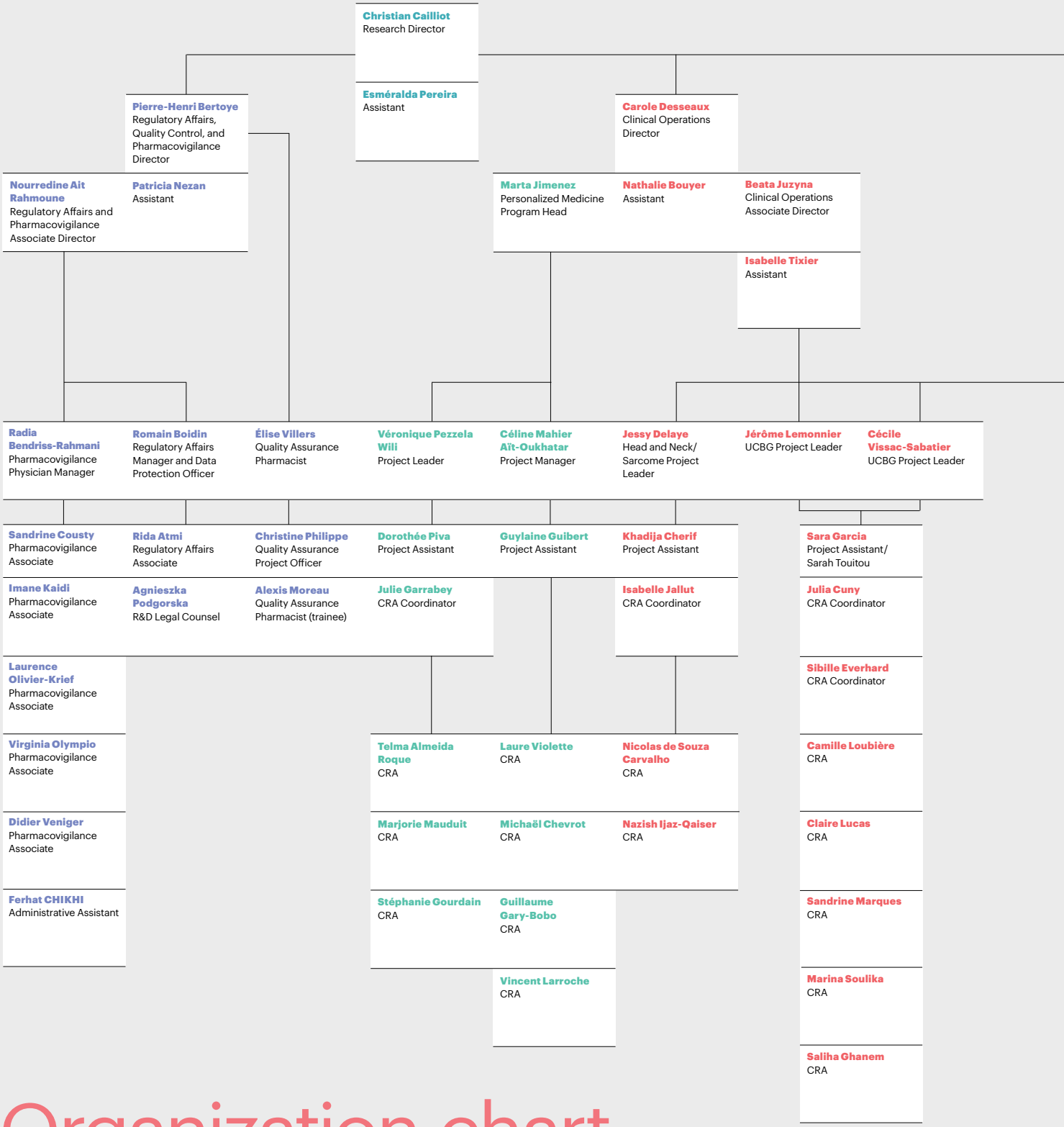
7
newly initiated clinical trials

+250
French and international centers participating in these studies (university hospitals/general hospitals, private hospitals and FCCC)

10
immunotherapy projects involving checkpoint inhibitors currently being prepared

17
publications listed in international scientific journals

23
communications presented at congresses



Organization chart

On March 31st, 2016

Anne-Laure Martin
Development and Partnerships Director

Aude Sirven
Strategic Program Development Head

Corinne Gamet
Assistant

Camille Baron
Partnerships and Dissemination Officer

Christophe Jamain
Fundamental and Preclinical Research Supervisor

Mathieu Robain
Medical Data and ESME Program Director

Alexandre Vanni
Project Leader

Gaëtane Simon
Project Leader

Coralie Courtinard
Project Leader

Irwin Piot
Data Manager

Charlène Legendre
CRA Coordinator

Tahar Guesmia
Project Manager

Olivier Payen
Data Manager Assistant

Élodie Kupfer
CRA Quality Inspector

Toihiri Saïd
CRA

Muriel Habibian
GETUG Project Leader

Christine Orsini
GERICO/Supportive Care Project Leader

Sandra Pelissier
UCGI Project Leader

Claire Jouffroy
UCGI-FEDEGYN Project Leader

Christel Mesléard
CRB Centralized BRC/ CANTO Project Manager

Justine Bobinnec
EORTC Project Manager

Naïma Bonnet
UNITRAD Project Leader

Trevor Stanbury
Project Leader

Amina Bendjennat
Project Assistant

Isabelle Nicot
Project Assistant

Angèle Yougye
Project Assistant

Estelle Hantrais Gervois
Project Assistant

Anne-Chantal Le Gall
Project Assistant

Hélène Manduzio
CRA Coordinator

Valérie Bénavent
CRA Coordinator

Nathalie Sarthe
CRA Coordinator

Myriam Rouchon
CRA Coordinator

Meryem Brihoum
CRA Coordinator

Patrick Toto
CRA Coordinator

Anne-Sophie Gross
CRA

Pauline Grégoire
CRA

Nadia Bouzar
CRA

Laurette Prely
CRA

Naïssa Abdoul Anziz
CRA

Zohra Toumi
CRA

Marie Bergeaud
CRA

Fabienne Lamort
CRA

Evelia Audisio
CRA

Camille Jouanny
CRA

Charlotte Cernon
CRA

Wafa Sousak-Cheikh
CRA

Bringing value to research and imagining a new type of partnerships

"The year 2015 was marked by an increased visibility of our ongoing research efforts and experts groups."

Increasing visibility of expert groups

In the recent years, a number of medical expertise groups developed within the framework of R&D UNICANCER have come forth as front-line players in national and international research in oncology. Since the years 2013 and 2014, R&D UNICANCER has become a key operator in research oncology in France. Its activity is widely recognized by public institutions and health authorities. The French National Cancer Institute (INCa) in France has granted its quality label to four main experts groups of R&D UNICANCER, thus acknowledging their operating capability and excellence. The year 2015 was marked by an increased visibility of our ongoing research efforts and of experts groups with the success of the first occurrence of the Molecular Analysis for Personalized Medecine (MAP) symposium that was held in Paris. This symposium, that was created on the initiative of UNICANCER in partnership with Cancer Research UK and ESMO, attests to the strong positioning of our teams of experts in innovating domains of international research. Beside the MAP international conference, R&D UNICANCER experts groups have launched several theme-day meetings in partnership with other actors of cancer research in France. For instance, we can cite the first ABCD class (Accelerated course on the Biology of the Cancer of the Digestive tract) organized by the gastro-instestinal expertise group (UNICANCER GI), as well as the research lecture days of the GETUG group. The objective is to diffuse knowledge and increase the attractiveness of clinical research among the French medical centers and encourage emulation among the young research oncologists. In parallel, an other incentive for UNICANCER was to start an association with John Libbey Publishing for the publication of Innovations & Thérapeutiques en Oncologie (*ITO*), a journal published in French with a multidisciplinary scope aimed at dealing with all aspects from research to palliative cares to respond to the needs of the young clinical practitioners and researchers.

Developping large-scale research programs

In 2015, many ongoing discussions took place with our public, private and institutional partners with the aim of developing research collaborations both in the clinical and translational research domains. Results from these endeavors should allow the development of large-scale research programs. R&D UNICANCER has acquired the human resource and competence necessary to develop and conduct scientific projects within the framework of international research consortia and bring adequate support to the teams operating in the research centers with the implementation of European projects. Seven projects are being currently developed within the framework of the H2020 research program.

Keeping confidence of historic partners

Finally, we are also pleased to benefit from the renewed trust from the French Cancer League and the ARC Foundation, two non-profit organizations that subsidize cancer research and with which we are developing long-term partnerships on shared axes of research. We are recognized as well by private profit pharmaceutical enterprises, such as Pfizer, that dare enter a new type of partnership in which financial support is granted to the development of institutional research projects without allowing the financing industry to exert any decision filter on the projects selected.

+400

participants at the MAP symposium (Molecular Analysis for Personalized Medicine), with the support of 13 industrial partners

In 2015, seven new studies were activated, with five of them initiated or developed in collaboration with UCBG. The total number of patients included in UNICANCER sponsored trials was similar to the previous year with 5,055 patients included in 2015 versus 5,044 in 2014.

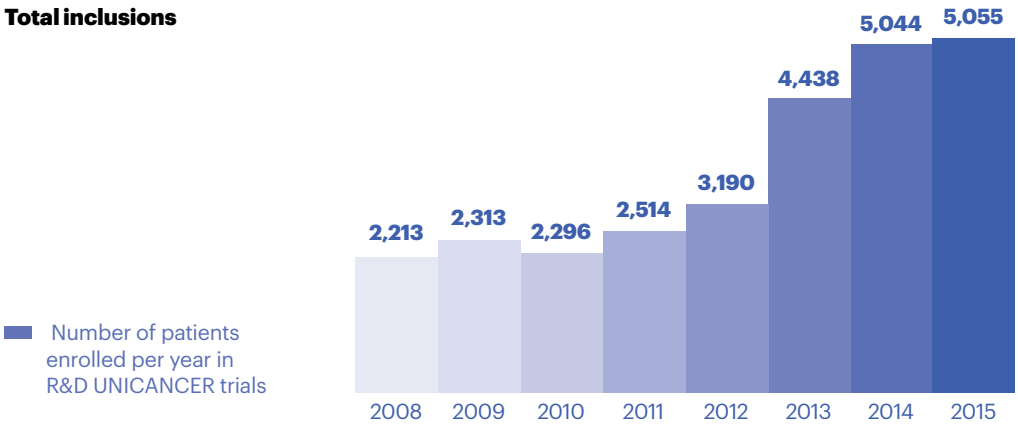
UNICANCER is now carrying out 70 clinical trials—39 of them actively recruiting during 2015—leading to more and more publications (17) and oral communications (11).
But 2015 was also a year of transition which generated activities not reflected in these numbers: changes in the design of trials (with more phase II/adaptative type trials in preparation), the emergence of immuno-oncology projects (and the approval of the durvalumab arm in the SAFIR02 trial), and the creation of a new research group in radiation oncology: UNITRAD (UNICANCER group of Translational Research and Development in Radiation Oncology) whose goal is to develop innovative research in the field of ionizing radiation.
The PHRC 2015 campaign clearly projects an increase in the near future activity with eight projects accepted.

Clinical trials actived in 2015

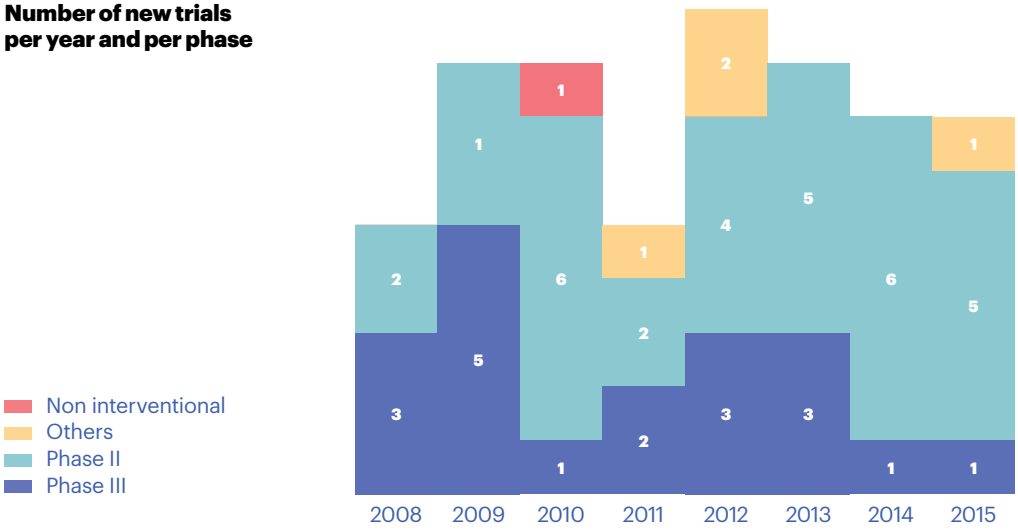
Clinical trials opened in 2015

Tumor group	Internal reference	Abridged Title	EudraCT N° or ANSM Ref.	Title of study	Expected number of patients	Phase	France (F)/ International (I)	Study activation date
UCBG	UC-0140/1404	CARMINA 04-NEOPAL	2014-002560-33	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	180	2	I	02/02/15
UCBG	UC-0140/1308	PACS 12 / RX-PONDER	2013-A01153-42	Randomized, phase III trial comparing standard adjuvant hormone therapy +/- chemotherapy in female patients with localized 1-3 N+, RH+ and Her2- breast cancer with recurrence score of 25 or less according to Oncotype DX™	600	3	I	02/13/15
UCGI	UC-0110/1405	UCGI 26/ NEOPAN	2014-003510-82	Randomized, phase III trial comparing chemotherapy with Folfirinox regimen with gemcitabine to treat locally advanced pancreas carcinoma	170	2	F	02/06/15
GERICO	UC-0103/1503	GERICO 12/ NACRE	2015-A01365-44	Phase III study evaluating two neoadjuvant treatments, radiochemotherapy (five weeks – 50 Gy+capecitabine) and radiotherapy (one week – 25 Gy) in patients over 75 with locally advanced rectal adenocarcinoma, PRODIGE-GERICO-GRECCAR study	420	3	F	12/01/15
MEDPERSO	UC-0105/1403	GMP 05-SAFIRTOR	2014-A00704-43	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	150	2	F	04/21/15
UCBG	UC-0140/1505	ADENDOM	2015-A00528-41	Prospective multicenter study assessing EndoPredict® (EPclin) genomic test impact on shared decision of adjuvant chemotherapy in patients with ER-positive, Her2-negative early breast cancer with uncertainty on the indication of chemotherapy using standard assessments	200	cohort	F	01/05/15
MEDPERSO	UC-0105/1501	GMP 06-RUBY	2015-000580-14	Single arm, open-label, phase II study to assess the efficacy of rucaparib in metastatic breast cancer patients with a BRCAness genomic	41	2	F	11/05/15

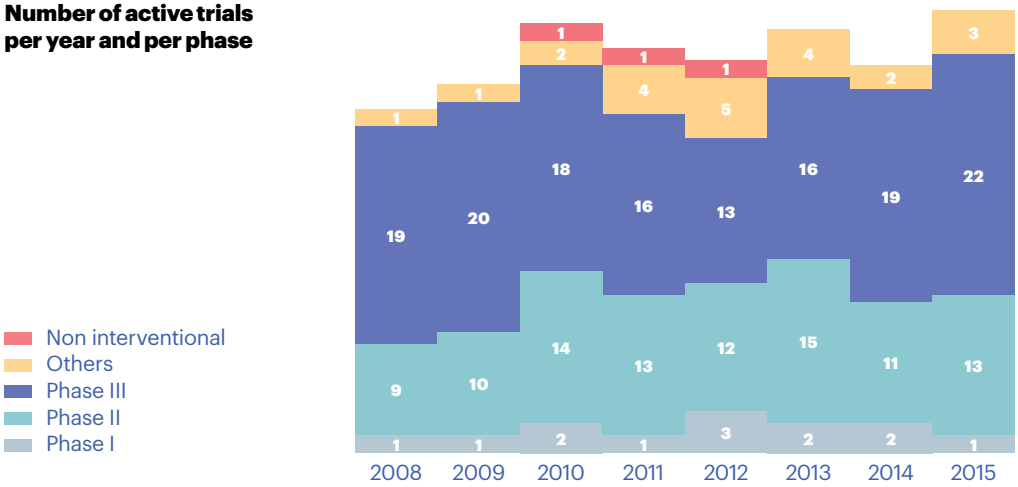
Total inclusions



Number of new trials per year and per phase



Number of active trials per year and per phase



Activated sites in 2015

UNICANCER continues its growth in Europe with 20% of sites opened abroad in 2015 (versus 15% in 2014 and 6,7% in 2013). The number of participating sites was stable for the Parisian Public Healthcare system (AP-HP*) but increased slightly for private and public hospitals with 23% and 44% of active sites, respectively.

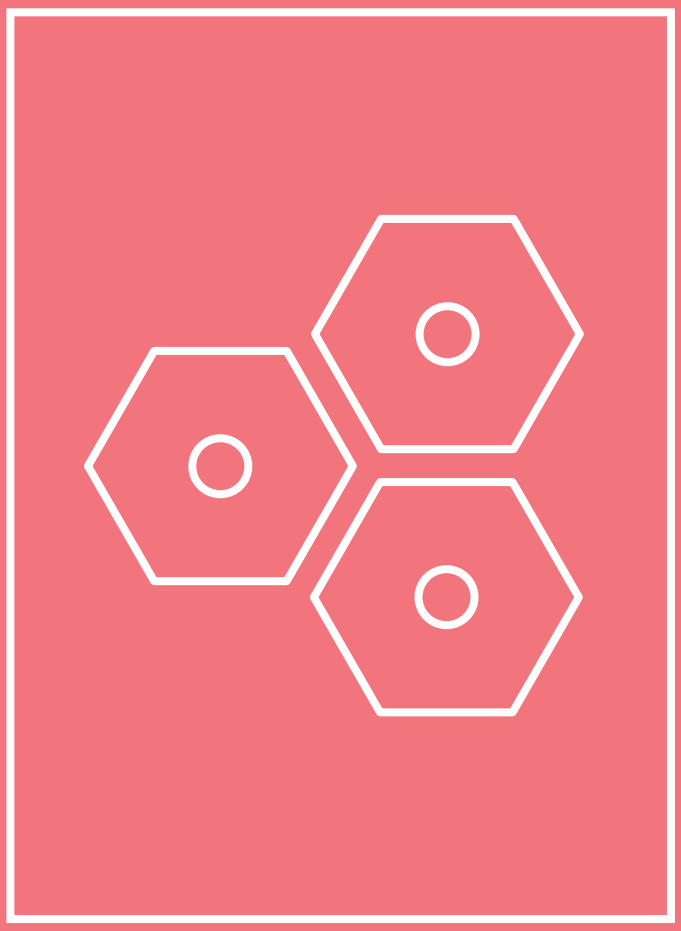
*The Assistance publique – Hôpitaux de Paris (AP-HP) is the public hospital system (*établissement public de santé*) of the city of Paris.

TYPE OF HEALTH INSTITUTION	Number of Centers		FEDEGYN	GEP	GERICO	GETUG	UCGI	SAR-COMA	UCBG	*of which Canto CANTO*	HEAD & NECK	MED PERSO
Parisian Public Healthcare (AP-HP)	18	7%	2	0	1	5	8	2	3	*1*	0	5
International Centers	51	20%	1	0	12	19	16	0	6	*0*	0	0
FCCC	18	7%	9	10	18	16	11	14	18	*18*	6	17
Private Hospitals	58	23%	0	0	10	27	15	0	20	*1*	0	6
Public Hospitals	112	44%	4	2	17	28	35	19	27	*2*	0	43
Overall total	**257**	**100%**	**16**	**12**	**58**	**95**	**85**	**35**	**74**	**22**	**6**	**71**

Total number of patients included per Tumor group

Accrual has been maintained in 2015 even though ten studies reached their recruitment targets and were stopped. The inclusions are still led by UCBG (with half of total enrolment). However, the MedPerso, GERICO and GETUG group each realized 10% of the total recruitment. The CANTO cohort represents 44% of the enrolled patients. Of note, the active participation of non-FCCC sites in the trials sponsored by UNICANCER was confirmed with 27% of patients being enrolled in private or public hospitals (versus 20% in 2014).

TYPE OF HEALTH INSTITUTION	FEDEGYN	GERICO	GETUG	UCGI	SARCOMA	UCBG	*of which CANTO*	HEAD & NECK	MED PERSO	GEP	TOTAL
Parisian Public Healthcare (AP-HP)	6	3	16	30	10	62	*49*	0	75	0	**203**
International Centers	2	54	66	37	0	10	*0*	0	0	0	**169**
FCCC	20	321	161	113	102	2,585	*2,109*	9	353	30	**3,694**
Private Establishments	0	54	115	43	0	102	*30*	0	8	0	**321**
Public Hospitals	17	91	101	130	50	132	*11*	0	144	3	**668**
Overall total	**45**	**523**	**459**	**353**	**162**	**2,891**	***2,199***	**9**	**580**	**33**	**5,055**
% of group participation	1%	10%	9%	7%	3%	57%	*44%*	0%	11%	1%	
% of FCCC participation	44%	61%	35%	32%	63%	89%	*96%*	100%	61%	91%	



Tumor groups

French Breast Cancer Intergroup — UNICANCER (UCBG)

To develop strategic research programs in breast cancer

Presentation

The French Breast Cancer Intergroup — UNICANCER (UCBG) is accredited by the French National Cancer Institute (INCa) since late 2013. It brings together over 100 institutions and follows the strategy developed within its Scientific and Strategic Committee (CS3), composed of oncologists from different specialties. The main topics developed by the CS3 are based on strategic plans (de-escalation based on biomarkers, precision medicine including immunological markers, clinical studies on the elderly, preoperative settings, survivorship, etc.), more and more headed up towards international trials. UCBG becomes a key player in the field of international clinical research on breast cancer.

Goals

Our goal is to focus on scientific questions about breast cancer and to conduct clinical studies, both national and international with the participation of all the cooperative network. The group also ensures that the clinical trials are conducted properly according to scientific and operational best standards.

Medical Oncologist
Suzette DELALOGE
Head of Breast Cancer Intergroup, Gustave Roussy Institute, Villejuif
suzette.delaloge@gustaveroussy.fr

Project Leaders
Jérôme LEMONNIER
+33 (0)1 71 93 67 02
j-lemonnier@unicancer.fr

Cécile VISSAC-SABATIER
+33 (0)1 73 79 77 58
c-vissac@unicancer.fr

Project leader
Christel MESLEARD
+33 (0)1 44 23 55 51
c-mesleard@unicancer.fr

Clinical Research Coordinators
Julia CUNY
+33 (0)1 44 23 04 75
j-cuny@unicancer.fr

Sibille EVERHARD
+33 (0)1 73 77 54 33
s-everhard@unicancer.fr

Clinical Research Associates
Camille LOUBIERE
+ 33 (0)1 76 64 78 03
c-loubiere@unicancer.fr

Claire LUCAS
+33 (0)1 73 77 54 34
c-lucas@unicancer.fr

Sandrine MARQUES
+33 (0)1 73 79 73 03
s-marques@unicancer.fr

Marina SOULIKA
+33 (0)1 73 79 77 51
m-soulika@unicancer.fr

Saliha GHANEM
+33 (0)1 80 50 12 98
s-ghanem@unicancer.fr

Project Assistant
Sara GARCIA
+33 (0)1 44 23 04 65
s-garcia@unicancer.fr

French breast cancer intergroup UNICANCER
UCBG

Events

UCBG held two general meetings which took place on May 25th at UNICANCER offices and on October 3rd at Maison de la Chimie (Paris). The purposes of these meetings were to inform, to promote and to discuss about the clinical projects conducted within the intergroup.

Significant results

Several significant milestones can be highlighted for the year 2015, among them:

- a growing international visibility of the UCBG: the intergroup was involved in an average of two to three international clinical trials per year, but in 2015, our participation has doubled (including three out of seven trials for which UNICANCER is the sponsor and UCBG the project initiator, and two additional trials developed under the hospices of the UCBG, in precision medicine;
- an oral presentation at the ASCO meeting of the results regarding the strong independent prognostic value of circulating tumor cells and complete pathological response in inflammatory breast cancer (BEVERLY studies);
- The creation of a website dedicated to the UCBG activities: **www.ucbgbreastcancer.org**

Collaborative studies, on going in 2015

Study Title	Study coordinator	Phase	Study start date	Number of active sites	Number of expected patients	Number of patients included (12/31/2015)	Study status (12/31/2015)
GRT02-COMET Cohort study of prospective validation of predictive factors and biological imaging of response to bevacizumab (Avastin®), in combination with weekly paclitaxel chemotherapy, in first-line treatment for patients with metastatic breast cancer	Pr. Jean-Yves PIERGA	cohort	01/30/10	18	510	505	Recruiting
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	Pr. Hervé BONNEFOI	III	07/03/15	11	80 in France (800 in total)	17	Recruiting
OLYMPIA Randomized, double-blind, parallel group, placebo-controlled multicenter Phase III study to assess the efficacy and safety of olaparib versus placebo, as adjuvant treatment in patients with germline BRCA1/2 mutations and high risk HER2 negative primary breast cancer who have completed definitive local treatment and neoadjuvant or adjuvant chemotherapy	Pr. Hervé BONNEFOI	III	x	2	1,320	170 selected; 19 randomized	Recruiting
APHINITY Prospective, randomized, multicenter, multinational, double-blind placebo controlled comparison of chemotherapy plus trastuzumab and placebo given for a total of one year, versus chemotherapy plus trastuzumab and pertuzumab given for a total of one year, as adjuvant therapy in patients with operable HER2-positive primary breast cancer	Pr. Hervé BONNEFOI	III	Dec. 11	40	4,800	4,800	Follow-up

Scientific and strategic comittee (CS3)

DELALOGE
Suzette
Gustave Roussy Institute

BONNEFOI
Hervé
Bergonié Institute

ANDRÉ
Fabrice
Gustave Roussy Institute

BACHELOT
Thomas
Léon Bérard Center

ESPIE
Marc
Saint-Louis Hospital

ASSELAIN
Bernard
Non affiliated

BARRANGER
Emmanuel
Antoine Lacassagne Center

BOURGEOIS
Hugues
Jean Bernard Center

BRAIN
Etienne
Curie Institute, Saint-Cloud

CAMPONE
Mario
ICO-René Gaudducheau Center

CANON
Jean-Luc
Charleroi Grand Hospital

COUDERT
Bruno
Georges-François Leclerc Center

COUTANT
Charles
Georges-François Leclerc Center

DALENC
Florence
Claudius Regaud Institute

DESSEAUX
Carole
UNICANCER

DIÉRAS
Véronique
Curie Institute,Paris

GANEM
Gérard
Jean Bernard Center

GIACCHETTI
Sylvie
Saint-Louis Hospital

GLIGOROV
Joseph
Tenon Hospital

GONÇALVES
Anthony
Paoli-Calmettes Institute

GRENIER
Julien
Sainte-Catherine Institute

HARDY
Anne-Claire
Armorican Clinic of Radiology

JACOT
William
Montpellier Cancer Institute (ICM) – Val d'Aurelle

JACQUIN
Jean-Philippe
Lucien Neuwirth Cancer Institute

LEMONNIER
Jérome
UNICANCER

LÉVY
Christelle
François Baclesse Center

LORTHOLARY
Alain
Catherine de Sienne Center

MARTIN
Anne-Laure
UNICANCER

PETIT
Thierry
Paul Strauss Center

PIERGA
Jean-Yves
Curie Institute, Paris

TUBIANA
Nicole
Limoges University Hospital

VENAT-BOUVET
Laurence
Limoges University Hospital

ROUZIER
Roman
Curie Institute

AZRIA
David
Montpellier Cancer Institute (ICM) – Val d'Aurelle

PENAULT-LORCA
Frédérique
Jean Perrin Center

ARVIS
Johanna
Patient Representative

CASTRO
Martine
Patient Representative

Studies

Study Title	Study coordinator	Phase	Study start date	Number of active sites	Number of expected patients	Number of patients included (12/31/2015)	Study status (12/31/2015)
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: clinical trial Rx for positive node, endocrine responsive breast cancer	Dr. Suzette DELALOGE	III	04/15/15	29	1,000 in France (5,000 in total)	196 selected; 113 randomized	Recruiting
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	Dr. Paul COTTU Dr. Suzette DELALOGE	II	02/02/15	20	132	44 in total - France: 40 - Belgium: 4	Recruiting
CADUSEIME03- PERNETTA 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	Pr. Hervé BONNEFOI	II	10/30/13	16	208	209 in total - France: 118 - Switzerland: 75 - Holland: 13 - Germany: 3	Recruiting
PACS11- 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- Profimary breast cancer, who remain free of disease after receiving three years of adjuvant hormone therapy	Dr. Thomas BACHELOT Pr. Fabrice ANDRÉ	III	03/31/13	38	1,984	278 in total - France : 267 - Belgium: 5 - UK: 6	Recruiting
CANTO Cohort to quantify and to predict treatment related chronic toxicities in patients with non-metastatic breast cancer	Pr. Fabrice ANDRÉ	cohort	03/20/12	24	10,000	8,335	Recruiting
ADENDOM Prospective multicenter study assessing EndoPredict® (EPclin) genomic test impact on shared decision of adjuvant chemotherapy, in patients with ER-positive, Her2-negative early breast cancer with uncertainty on the indication of chemotherapy using standard assessments	Pr. Frédérique PENAULT-LLORCA Dr. Suzette DELALOGE	HPS	12/01/15	2	200	5	Recruiting
CADUSEIME02-AMA Phase II trial evaluating the activity of abiraterone acetate plus prednisone in patients with a molecular apocrine HER2-negative locally advanced or metastatic breast cancer	Pr. Hervé BONNEFOI	II	06/26/13	27	31	31	Follow-up
RTS02-SHARE Phase III, multicentric trial comparing Accelerated Partial Breast Irradiation (APBI) versus standard or hypofractionated whole breast irradiation in low risk of local recurrence of breast cancer	Pr. Yazid BELKACEMI Pr. Eric LARTIGAU Dr. Céline BOURGIER	III	10/20/10	34	800	914	Follow-up
PREV01 MAP3 Phase III, randomised, study of exemestane vs placebo in post-menopausal women at increased risk of developing breast cancer	Pr. Pascal PUJOL	III	Sept. 09	6	300	4,560 of which 19 recruited in France	Follow-up
PACS09 - Beverly 1 Phase II study evaluating the efficacy and tolerance of bevacizumab (Avastin) in HER2- inflammatory breast cancer	Pr. Patrice VIENS	II	12/17/08	21	100	100	Follow-up
RTS01: YOUNG BOOST Radiation dose intensity study in breast cancer in young women: randomized, phase III trial of additional dose to the tumor bed	Dr. Alain FOURQUET	III	Oct. 08	13	710	2,423 of which 712 recruited in France	Follow-up
ONCO03/LIBER Prevention of breast cancer by letrozole in post-menopausal women carrying a BRCA1/BRCA2 mutation	Pr. Pascal PUJOL	Prevention	Feb. 08	35	382	386 170 recruited	Follow-up
CARMINA02 - NIMFEA 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 menopausal women	Dr. Florence LEREBOURS	II	Oct. 07	6	116	116	Follow-up
PACS08 - Tavlx 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	Dr. Mario CAMPONE	III	09/24/07	58	2,500	2,500 762 recruited	Follow-up

Study Title	Study coordinator	Phase	Study start date	Number of active sites	Number of expected patients	Number of patients included (12/31/2015)	Study status (12/31/2015)
PACS07 - MINDACT Prospective, randomized study comparing the 70-gene signature with the common clinical-pathological criteria in selecting patients for adjuvant chemotherapy in breast cancer with zero to three positive nodes	Dr. Suzette DELALOGE	III	03/21/07	22	2,066	6,600 of which 2,066 recruited in France	Follow-up
IBIS II Adjuvant tamoxifen compared with anastrozole in treating post-menopausal women with ductal carcinoma *in situ* (IBIS-II DCIS)	Dr. Christelle LEVY	III	05/11/04	27	450	2,980 of which 726 recruited in France	Follow-up
PACS05 Phase III, randomized study of adjuvant fluourouracil, epirubicin and cyclophosphamide, in women with stage I breast cancer	Pr. Pierre KERBRAT Dr. Alain LORTHOLARY	III	Sept. 02	60	1,512	1,500	Follow-up
PACS04 Randomized, 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	Pr. Marc SPIELMANN	III	Feb. 01	82	3,000	3,010	Follow-up
PACS01 Phase III study evaluating the benefit of docetaxel given sequentially with FEC100 chemotherapy treatment in axillary lymph node-positive early breast cancer patients	Pr. Henri ROCHE	III	June 97	43	2,000	1,999	Follow-up

The inclusions by type of establishment in 2015

UCBG

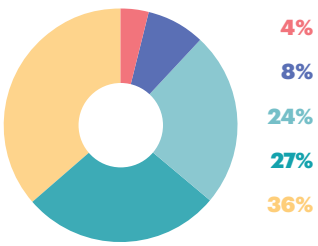
TYPE OF ESTABLISHMENT	Number of sites	Number of patients included
Parisian Public Healthcare (AP-HP)	3	62
International Centers	6	10
FCCC	18	2,585
Private Hospitals	20	102
Public Hospitals	27	132
Overall total	**74**	**2,891**

Of which CANTO

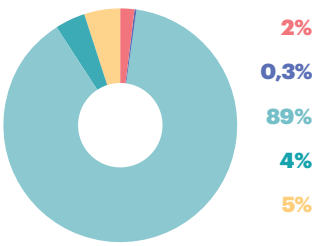
TYPE OF ESTABLISHMENT	Number of sites	Number of patients included
Parisian Public Healthcare (AP-HP)	1	49
International Centers	0	0
FCCC	18	2,109
Private Hospitals	1	30
Public Hospitals	2	11
Overall total	**22**	**2,199**

UCBG

% of centers opened

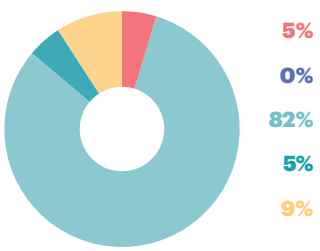


% of inclusions

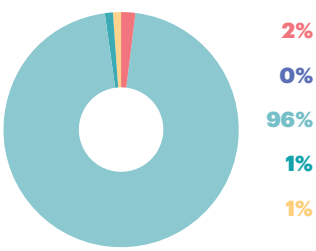


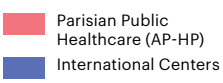
Of which CANTO

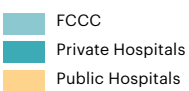
% of centers opened



% of inclusions







UNICANCER Gastro-Intestinal Group (UCGI)

Developing and promoting clinical trials in gastro-intestinal cancers

Presentation

At the end of 2015, Dr. David Malka succeeded Pr. Jafaar Bennounna as the President of UCGI, with Dr. Emmanuelle Samalin replacing Dr. Malka as the Vice-President of the group.

UCGI group is a dynamic group dealing with a diverse range of cancers within the gastro-intestinal system. The group collaborates with all the major players in France, including the FCCC, public hospitals and other private institutions. UCGI continues to collaborate internationally and hopes to be able to increase its international presence within the coming years.

UCGI successfully received funding from the INCa for two projects (IROCAS and SULTAN-01) and is in discussion with several industrial partners for the funding of a number of important projects.

Goals

The mission of the UCGI group is to promote and develop clinical trials in digestive cancers. UCGI collaborates with the French Federation of Digestive Oncology (FFCD) within the intergroup Prodige. The integration of the GERCOR into the Prodige intergroup is currently under discussion. This important alliance brings together the main French academic players in the field of digestive cancers, ensuring that solutions to major challenges in this domain can be addressed by this unified alliance.

President
Dr. David MALKA
Gustave Roussy Institute, Paris

Vice-President
Dr. Emmanuelle SAMALIN
Montpellier Cancer Institute

Project Leaders
Claire JOUFFROY
+33 (0)1 71 93 63 66
c-jouffroy@unicancer.fr

Sandra PELISSISER
+33 (0)1 44 23 55 68
s-pelissier@unicancer.fr

Project Assistant
Angèle YOUGYE
+33 (0)1 80 50 12 97
a-yougye@unicancer.fr

Clinical Research Coordinators
Nathalie SARTHE
+33 (0)1 76 64 78 02
n-sarthe@unicancer.fr

Patrick TOTO
+33 (0)1 71 93 63 69
p-toto@unicancer.fr

Clinical Research Associates
Camille JOUANNY
+33 (0)1 44 23 55 75
c-jouanny@unicancer.fr

Marie BERGEAUD
+33 (0)1 73 77 54 38
m-bergeaud@unicancer.fr

Nadia BOUZAR
+33 (0)1 71 93 67 01
n-bouzar@unicancer.fr

Wafa CHEICK
+33 (0)1 44 23 55 80
w-cheick@unicancer.fr

Events

In 2015, the UCGI group organized two main events. The first being the «ABCD class» (Accelerated course on the Biology of the Cancer of the Digestive tract) focusing on the biological aspects of digestive cancers and linked to the well-established "Scientific Days" organized by the FFCD, making this event a collaborative effort within Prodige. Furthermore, UCGI organized a two-day meeting (ARCADI) to provide information concerning our clinical trials and the corresponding pathologies; specifically organized for Clinical Research Associates (CRA) dedicated to UCGI projects. Our objective was to improve the knowledge concerning the various pathologies and, in so doing so, improving the quality of our research. This event was attended by 40 CRA from R&D UNICANCER, the FCCC and other sites collaborating in our trials. These events were successful and we hope they will become important annual events.

Significant results

In terms of clinical trials, 2015 was an important year with the final analysis of Prodige 17-Accord 20 (MEGA) and the end of the inclusion phases for Prodige 18-Accord 22, Prodige 14-Accord 21, and UCGI 25. A poster concerning Prodige 17-Accord 20 was presented at ASCO 2015 and the publication of the final results is expected in 2016. The analysis of the five-year follow-up of Prodige 2-Accord 12 concerning patients with resectable cancer of the rectum was performed with the results expected in 2016.

UCGI Studies

Study Title	Study coordinator	Phase	Study start date	Number of active sites	Number of expected patients	Number of patients included (12/31/2015)	Study status (12/31/2015)
PRODIGE 29 - UCGI 26 - NEOPAN Randomized, Phase III trial comparing chemotherapy with folfirinox to gemcitabine in locally advanced pancreatic carcinoma»	Pr. Michel DUCREUX	III	03/30/15	11	170	12	Recruiting
PRODIGE 28 - UCGI 27 - TIME Randomized, phase II study of first-line FOLFIRI plus cetuximab for eight cycles, followed by either single-agent cetuximab as maintenance therapy or observation, in patients with wild-type KRAS and NRAS metastatic colorectal cancer	Dr. Valérie BOIGE	II	01/15/14	21	168	38	Recruiting
PRODIGE 23 - UCGI 23 Randomized, phase III study comparing preoperative chemo-radiotherapy alone versus neoadjuvant chemotherapy with Folfirinox regimen followed by preoperative chemoradiotherapy, for patients with resectable locally advanced rectal cancer	Pr. Thierry CONROY	III	06/05/12	33	460	290	Recruiting
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	Pr. Thierry CONROY	III	04/03/12	77 of which 19 in Canada	490	394	Recruiting
UCGI 25 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	Pr. Jaafar BENNOUNA	II	11/05/12	14	75	75	Follow-up
PRODIGE 14 - ACCORD 21 (METHEP) Multicentric, randomized, phase II 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	Pr. Marc YCHOU	II	02/09/11	31	256	256	Follow-up
PRODIGE 18 - ACCORD 22 Multicentric, randomized, phase II 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	Pr. Jaafar BENNOUNA	II	12/15/10	25	133	133	Follow-up
PRODIGE 17 - ACCORD 20 (MEGA) Randomized, phase II trial evaluating 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	Dr. David MALKA	II	11/30/10	29	165	162	Follow-up
PRODIGE 12 - ACCORD 18 Multicenter, randomized, phase III 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	Dr. Eveline BOUCHER	III	09/22/09	33	196	196	Follow-up
PRODIGE 07 - ACCORD 15 Phase III study evaluating the use of systemic chemotherapy and chemohyperthemia intraperitoneal preoperatively (CHIP) and after maximum resection of peritoneal carcinomatosis originating with colorectal cancer	Dr. François QUENET	III	02/04/08	17	264	265	Follow-up
PRODIGE 02 - ACCORD 12 Randomized, phase III trial comparing in a preoperative schedule the result of two concurrent chemoradiation schemes (45 Gy + capecitabine vs 50 Gy + capecitabine - oxaliplatin) on the rate of sterilization of the operative specimen in resectable rectal carcinomas T3-4 No-2 Mo	Pr. Jean-Pierre GERARD	III	09/14/05	56	590	598	Follow-up

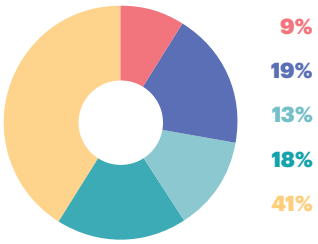
The inclusions by type of establishment in 2015

UCGI

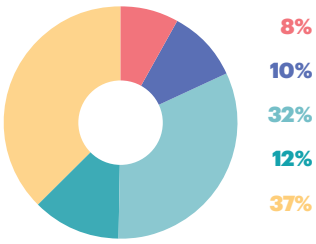
TYPE OF ESTABLISHMENT	Number of sites	Number of patients included
Parisian Public Healthcare (AP-HP)	8	30
International Centers	16	37
FCCC	11	113
Private Hospitals	15	43
Public Hospitals	35	130
Overall total	85	353

UCGI

% of centers opened



% of inclusions



FEDEGYN

Since 2011 the clinical trials initiated by the FEDEGYN group have been coordinated by UCGI project team. The European clinical trial CHIPOR: investigating the use of hyperthermic intraperitoneal chemotherapy in relapsed ovarian cancer continues to include patients in France, Belgium and Spain, with sites in Italy expected to be initiated in 2016.
The advancement of the CHIPOR trial was presented at the 2015 ESGO conference in Nice, France.

FEDEGYN Studies

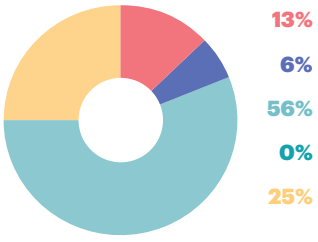
Study Title	Study coordinator	Phase	Study start date	Number of active sites	Number of expected patients	Number of patients included (12/31/2015)	Study status (12/31/2015)
FEDEGYN 02 - CHIPOR Multicentric, randomized, phase II trial evaluating Hyperthermic Intra-Peritoneal Chemotherapy (HIPEC) in the treatment of relapse ovarian cancer	Pr. Jean-Marc CLASSE	III	05/15/11	23	444 International	190 (of which 3 in Spain and 2 in Belgium)	Recruiting
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	In France : Dr. Christine HAIE MEDER	III	01/18/10	16	686 International	67 in France	Follow-up

FEDEGYN

TYPE OF ESTABLISHMENT	Number of sites	Number of patients included
Parisian Public Healthcare (AP-HP)	2	6
International Centers	1	2
FCCC	9	20
Private Hospitals	0	0
Public Hospitals	4	17
Overall total	16	45

FEDEGYN

% of centers opened



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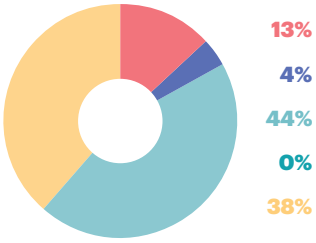
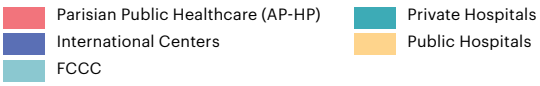




UNICANCER Urogenital Group (GETUG)

The sole French academic group which aims to develop clinical trials in onco-urology

Presentation

GETUG, with Pr. Stéphane Culine (Saint-Louis Hospital) as President, is a multidisciplinary group which get together more than a hundred physicians (oncologists, radiotherapists and urologists) since 1994. More recently, pathologists and methodologists have joined the group to reinforce the impact of the GETUG, already known at the international level. The GETUG as well as the French Association of Urology (AFU) are involved since 2015 in a French cooperating group in onco-urology labeled by the INCa.

Goals

The first objective of the GETUG is to develop clinical trials in the field of onco-urology to improve treatments and medical knowledge in prostate, kidney, urinary tract and external genital organs cancers.

Another of the most important objectives for the GETUG members is to actively participate to the high level of the onco-urological scientific knowledge thanks to the involvement in international congresses and publications.

President
Pr. Stéphane CULINE
+33 (0)1 49 81 45 24
stephane.culine@aphp.fr

Project Leaders
Muriel HABIBIAN
+33 (0)1 76 64 78 07
m-habibian@uncancer.fr

Claire JOUFFROY (PEACE1)
+33 (0)1 71 93 63 66
c-jourffroy@unicancer.fr

Project Assistants
Amina BENDJENNAT
+33 (0)1 44 23 55 73
a-bendjennat@unicancer.fr

Angèle YOUGYE (PEACE1)
+33 (0)1 80 50 12 97
a-yougye@unicancer.fr

Clinical Research Coordinators
Hélène MANDUZIO
+33 (0)6 18 38 96 26
h-manduzio@unicancer.fr

Meryem BRIHOUM
+33 (0)1 80 50 12 95
m-brihoum@unicancer.fr

Patrick TOTO (PEACE1)
+33 (0)1 71 93 63 69
p-toto@unicancer.fr

Clinical Research Associates
Naïssa ABDOUL ANZIZ
+33 (0)6 21 10 62 22
n-abdoul-anziz@unicancer.fr

Mélanie DOS SANTOS
+33 (0)6 68 32 23 98
m-dossantos@unicancer.fr

Mickaël DOS SANTOS
+33 (0)6 08 48 16 40
m-dos-santos@unicancer.fr

Leïla CAPET
+33 (0)7 76 07 15 10
l-capet@unicancer.fr

Basma AMDOUNI
+33 (0)7 76 00 72 11
b-amdouni@unicancer.fr

Anne-Sophie GROSS
+33 (0)6 34 20 37 72
as-gross@unicancer.fr

Events

This year was marked by the first session of training specifically dedicated to the sites CRA who are keys in the organization of the clinical trials. These two days, which aim was to develop the knowledge on the GETUG trials managed in the sites, were performed by the coordinators of clinical trials themselves as specialists of the pathology.

This year was also particularly rich in terms of participation of the GETUG on international congress — ASCO-GU, ASCO and ASTRO — with four oral presentations and two posters.

Significant results

Among the oral presentations in congress, the results of the trial GETUG-AFU 16, which focused on short androgen deprivation therapy combined with radiotherapy as salvage treatment for biological relapse after radical prostatectomy, have been presented at ASCO.
The trial showed that salvage radiotherapy combined with limited androgen deprivation therapy improves the five-year progression free survival rate compared to radiotherapy alone. The results of overall survival are now expected.
It must be noticed as well the first inclusions of patients in the trial GETUG-AFU 24 BEVABEL. The trial concerns metastatic carcinoma of the collecting ducts of the kidney, a very rare tumor of very poor prognosis. It is hoped that this trial will provide a standard of care for this disease.

Studies

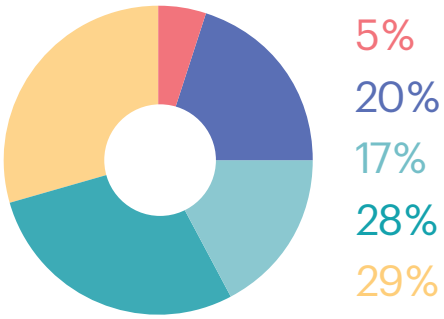
Study Title	Study coordinator	Phase	Study start date	Number of active sites	Number of expected patients	Number of patients included (12/31/2015)	Study status (12/31/2015)
GETUG-AFU 24 BEVABEL Prospective phase II study of gemcitabine plus platinium salt in combination with bevacizumab (Avastin®) for metastatic collecting duct carcinoma	Dr. Nicolas PÉCUCHET	II	12/15/14	15	41	5	Recruiting
AFU-GETUG 21/PEACE1 Randomized, prospective phase III study of androgen deprivation therapy ± local radiotherapy with or without abiraterone acetate and prednisone in patients with metastatic hormone-naïve prostate cancer	Pr. Karim FIZAZI	III	11/12/13	65	916	313	Recruiting
GETUG-AFU 23/PEACE 2 Randomized, phase III factorial design of cabazitaxel and pelvic radiotherapy in patients with localized prostate cancer and high-risk features of relapse	Pr. Karim FIZAZI	III	09/16/13	64	1,048	171	Recruiting
AFU-GETUG 20 Randomized, phase III 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	Pr. Stéphane CULINE	III	06/07/11	54	700	248	Recruiting
GETUG-AFU 17 Randomized, multicenter study comparing the immediate adjuvant radiotherapy associate with hormonal therapy of LH-RH analogue (Decapeptyl® LP) versus 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	Dr. Pierre RICHAUD	III	12/12/07	48	718	398	Recruiting
GETUG-AFU 22 Randomized, multicenter, phase II study comparing the efficiency of a HT concomitant with RT versus RT alone in the salvage of patients with a detectable PSA after prostatectomy	Dr. Stéphane GUERIF	II	12/14/12	22	122	125	Follow-up
GETUG-AFU 19 Randomized, phase II study of 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	Pr. Stéphane CULINE	II	09/27/10	19	105	113	Follow-up
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	Pr. Christophe HENNEQUIN	III	04/22/09	32	500	505	Follow-up
GETUG 16 Randomized, phase III study of adjuvant radiotherapy with versus without concurrent goserelin in patients who have undergone surgery for recurrent or refractory prostate cancer	Dr. Christian CARRIE	III	09/27/06	41	738	743	Follow-up
GETUG 13 Risk-adapted strategy of the use of dose-dense chemotherapy in patients with poor-prognosis disseminated non-seminomatous germ cell tumors	Pr. Karim FIZAZI	III	11/07/03	28	260	263	Follow-up

Study Title	Study coordinator	Phase	Study start date	Number of active sites	Number of expected patients	Number of patients included (12/31/2015)	Study status (12/31/2015)
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	Pr. Bernard DUBRAY	III	07/24/03	20	450	378	Follow-up
GETUG 12 Randomized, phase III study of adjuvant hormonal therapy with and without docetaxel and estramustine, in patients with advanced prostate cancer or with a high risk of relapse	Pr. Karim FIZAZI	III	11/13/02	35	400	413	Follow-up
GETUG 06 Conformational, curative ratiotherapy for prostate cancer (NO, N-): multicenter, phase III study of the contribution to survival without clinical or biological change with a dose variation of 15% (80 Gy vs 70 Gy)	Dr. Véronique BECKENDORF	III	08/01/99	19	250	306	Follow-up

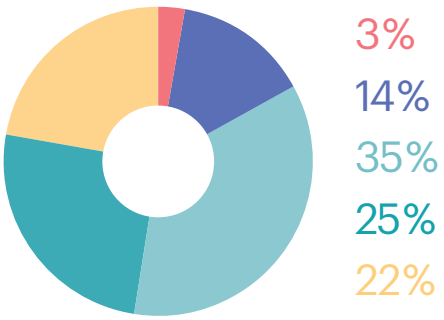
The inclusions by type of establishment in 2015

TYPE OF ESTABLISHMENT	Number of sites	Number of patients included
Parisian Public Healthcare (AP-HP)	5	16
International Centers	19	66
FCCC	16	161
Private Hospitals	27	115
Public Hospitals	28	101
Overall total	**95**	**459**

% of centers opened



% of inclusions



Parisian Public Healthcare (AP-HP)
International Centers
FCCC
Private Hospitals
Public Hospitals

UNICANCER Head & Neck Group

To foster and develop innovating phase I-II trials in Head and Neck tumors

Presentation

The UNICANCER Head & Neck (H&N) group was initially set up 25 years ago and then restructured in 2009. In September 2015, Pr. Joël Guigay, Antoine Lacassagne Center's General Director (Nice), was re-elected as President of the Group, and the UNICANCER projects team was partially renewed between September 2015 (new Projects Manager) and early January 2016 (new CRA coordinator and CRA). 2015 and even more 2016 are challenging years for the Group, with two new early trials being set up (ORL06 and ORL07) and six new projects, all led by young and enthusiastic investigators, submitted to national academic calls for proposals.

Goals

H&N group's objectives can be summarized around three main actions:

- to develop strong relationships with other national or international academic collaborating groups (GORTEC, EORTC, etc.);
- to demonstrate its ability and capacity in developing early phase I-II trials;
- to teach and train relevant stakeholders working on our trials in France.

Events

In November 2015, H&N group organized its first training course for staff working on our studies. Over two days, senior physicians and statistician kindly offered their time, experience and deep knowledge.
This meeting was a success and a great opportunity for everyone to learn and discuss around major and hot topics such as immunotherapy and best therapeutic approaches.

Significant results

In 2015, the recruitment in the PACSA trial (conducted by Pr. Joël Guigay, Nice), a multicenter single arm phase II study, assessing the anti-tumor activity of pazopanib in patients with progressive recurrent or metastatic salivary glands carcinoma, ended and the primary endpoint (six months progression-free Survival rate) was analyzed at the end of the year. The positive results, submitted for ASCO congress in 2016, led us in building a randomized phase III trial assessing the pazopanib as monotherapy versus chemotherapy as per Investigator's choice (PHRC 2016).

2015 was also an important year for the phase II ORL03 study conducted by Dr. Jérôme Fayette (Lyon): results were indeed presented orally at the ESMO Congress in September and a publication is currently being written for submission to the Lancet Oncology.

President
Pr. Joël GUIGAY
Antoine Lacassagne Center, Nice
+33 (0)4 92 03 15 01
joel.guigay@nice.unicancer.fr

Board members
Vice-President
Dr. Gilles DOLIVET
Lorraine Institute of Oncology, Nancy
+33 (0)3 83 59 84 46
g.dolivet@nancy.unicancer.fr

Group Secretary
Dr. Jérôme FAYETTE
Léon Bérard Center, Lyon
+33 (0)4 78 78 51 03
jerome.fayette@lyon.unicancer.fr

Projet Leader
Jessy DELAYE
+33 (0)1 44 23 55 77
j-delaye@unicancer.fr

Project Assistant
Khadija CHERIF
+33 (0)1 73 77 54 35
k-cherif@unicancer.fr

Clinical Research Coordinator
Isabelle JALLUT
+33 (0)1 44 23 04 11
i-jallut@unicancer.fr

Clinical Research Associates
Nazish IJAZ-QAISER
+33 (0)1 73 77 54 32
n-ijazqaiser@unicancer.fr

Nicolas DE SOUSA CARVALHO
+33 (0)1 71 93 67 09
n-de-sousa@unicancer.fr

The inclusions by type of establishment in 2015

TYPE OF ESTABLISHMENT	Number of sites	Number of patients included
Parisian Public Healthcare (AP-HP)	0	0
International Centers	0	0
FCCC	6	9
Private Hospitals	0	0
Public Hospitals	0	0
Overall total	6	9

% of centers opened

100%

% of inclusions

100%

Studies

Study Title	Study coordinator	Phase	Study start date	Number of active sites	Number of expected patients	Number of patients included (12/31/2015)	Study status (12/31/2015)
ORL 02- PACSA Phase II study of pazopanib in patients with recurrent and/or metastatic salivary gland carcinoma of the head and neck	Pr. Joël GUIGAY, Antoine Lacassagne Center	II	07/03/13	15	63	72	Follow-up
ORL 01 - HPV ORO Evaluation of the frequency of human papilloma virus infections in tonsillar and basal lingual carcinomas	Dr. Haïtham MIRGHANI, Gustave Roussy Institute	II	12/02/10	15	300	302	Follow-up

UNICANCER Sarcoma Group

A key player bringing together national and international partner groups

Presentation

The UNICANCER Sarcoma group started in 1999 thanks to strong relationships with the French Sarcoma Group (GSF) and the French Society of Childhood Cancer (SFCE), enabling France to be a major stakeholder in international trials such as EuroEwing99 with 30% of the total inclusions performed in France. Since 1999, 12 studies have been initiated and conducted by the Sarcoma Group, enrolling more than 2,000 patients. All these projects include complex translational research studies to develop a better understanding and more in depth knowledge of biological mechanisms, and to characterize biomarkers that could predict efficacy and response to anticancer treatments. Since 2013, investigators from the Sarcoma Group are involved in the UNICANCER Personalized Medicine Group sponsoring AcSé trials (AcSé-Crizotinib and AcSé-Vémurafénib).

Goals

As a member of the Intersarc Intergroup, UNICANCER Sarcoma Group has a double objective: to improve patients' prognoses and quality of life thanks to tailored treatments, and to evaluate new treatments such as protein-kinase inhibitors in these rare tumors. EuroJOSS and RMS trials, in which the UNICANCER Sarcoma Group are involved, are good examples of the strong collaboration that exists between major national and international intergroups, including adult and pediatric sarcoma groups.

Events

In 2015, patient registration of two historically important trials in the group stopped: in July 2015 for the EuroEwing99 trial (Sarcome 01) due to the start of recruitment in the EuroEwing12 study, and in December 2015 for the OS2006 trial (Sarcome 09). In total these trials registered around 1,800 patients. Patients are still in the follow-up period and biological samples are still being collected for the translational research.

Significant results

The results of the OS2006 randomized trial are currently being reviewed by the Lancet Oncology for publication. This phase III study was conducted to determine whether zoledronate in combination with chemo-therapy, as compared with chemotherapy alone, improves event-free survival in patients with newly diagnosed osteosarcoma. The results indicate that zoledronate did not improve the event-free survival, the good histological response rate or the overall survival for these patients.

President
Pr. Jean-Yves BLAY
Adults coordinator
Léon Bérard Center
jean-yves.blay@lyon.unicancer.fr

Vice-President
Dr. Nathalie GASPAR
Pediatrics coordinator
Gustave Roussy Institute
nathalie.gaspar@gustaveroussy.fr

Project Leader
Jessy DELAYE
+33 (0)1 44 23 55 77
j-delaye@unicancer.fr

Project Assistant
Khadija CHERIF
+33 (0)1 73 77 54 35
k-cherif@unicancer.fr

Cinical Research Coordinator
Isabelle JALLUT
+33 (0)1 44 23 04 11
i-jallut@unicancer.fr

Cinical Research Associates
Nazish IJAZ-QAISER
+33 (0)1 73 77 54 32
n-ijazqaiser@unicancer.fr

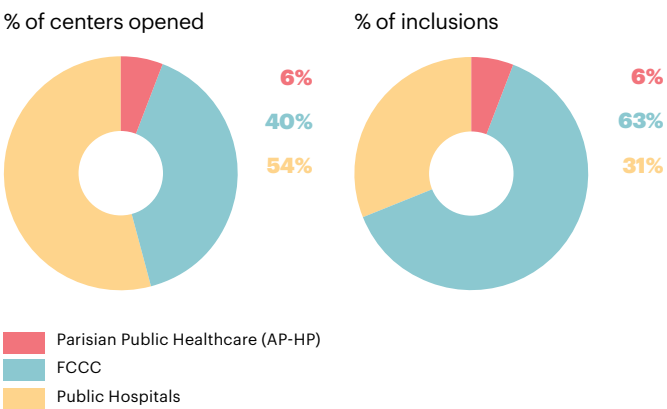
Nicolas DE SOUSA CARVALHO
+33 (0)1 71 93 67 09
n-de-sousa@unicancer.fr

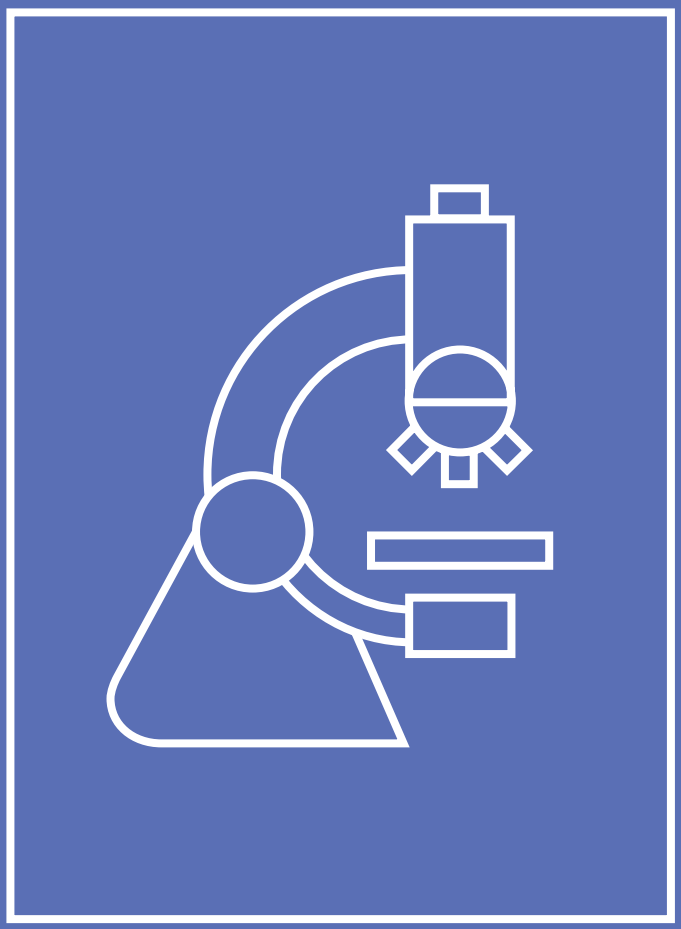
Studies

Study Title	Study coordinator	Phase	Study start date	Number of active sites	Number of expected patients	Number of patients included (12/31/2015)	Study status (12/31/2015)
SARCOME 12 REGOBONE Randomized, placebo-controlled, multicenter, phase II study evaluating efficacy and safety of regorafenib in patients with metastatic bone sarcomas	Pr. Florence DUFFAUD, La Timone	II	09/11/14	17	132	54	Recruiting
SARCOME 11 - LMS 03 Multicenter, phase II study to determine the efficacy of gemcitabine with pazopanib as second-line treatment in patients with metastatic or relapsed uterine or soft tissue leiomyosarcomas	Dr. Patricia PAUTIER, Gustave Roussy Institute	II	10/10/11	18	94	89	Recruiting
SARCOME 09 OS 2006 Intergroup Study (SFCE/GSF-GETO) OS2006 - Zoledronate osteosarcoma - treatment protocol for osteosarcoma of the child , adolescent and adult including: randomized trial and biological studies	Dr. Laurence BRUGIÈRES (Children), Gustave Roussy Institute Dr. Sophie PIPERNO-NEUMANN (Adults) Curie Institute, Paris	III	03/19/07	49	470	653	Follow-up
SARCOME 08 - EORTC 62024 Intermediate and high risk localized, completely resected, gastrointestinal stromal tumors (GIST) expressing KIT receptor: controlled, randomised trial on adjuvant imatinib mesylate (Glivec) versus no further therapy after complete surgery	Dr. Axel LECESNE, Gustave Roussy Institute	III	04/20/05	33	300	266	Follow-up
SARCOME 01 - EURO EWING Treatment protocol for Ewing tumors: including a medico economic evaluation	Dr. Nathalie GASPAR, Gustave Roussy Institute	I-II	08/02/99	42	1,261	1,135	Follow-up

The inclusions by type of establishment in 2015

TYPE OF ESTABLISHMENT	Number of sites	Number of patients included
Parisian Public Healthcare (AP-HP)	2	10
International Centers	0	0
FCCC	14	102
Private Hospitals	0	0
Public Hospitals	19	50
Overall total	**35**	**162**





Cross pathology groups and programs

Geriatrics Group (GERICO)

UNICANCER group dedicated to geriatric oncology

Presentation

The GERICO group, created in 2002, is a multidisciplinary group which includes a variety of medical experts, medical oncologists, geriatricians, radiotherapists, surgeons, biostatisticians and pharmacologists, all working towards improve cancer treatment for the elderly.

Goals

The GERICO group is dedicated to clinical research in oncology specifically for elderly patients. With the support of the operational platform for clinical research at R&D UNICANCER, the group focuses on clinical studies investigating tailored treatments for the elderly, or allowing these patients access to innovative diagnostic tests.

Events

An annual general meeting was organized in September to discuss major topics concerning elderly patients and supportive care. In 2015, the group has actively worked to develop studies for which UNICANCER is the sponsor in the following three domains:

- first-line chemotherapy for HER2-negative metastatic breast cancer (MBC) in elderly women (≥70) with an impaired G8: a UNICANCER/GERICO randomized, multicentre, phase II/III program based on initial dose adjustment and impact on health-related quality of life (HRQoL) score deterioration-free survival;
- randomized, phase III study of oral cyclophosphamide vs doxorubicin in patients ≥65 years old with advanced or metastatic soft tissue sarcoma (STS);
- phase III study evaluating the effectiveness and the impact on health-related quality of life (HRQoL) of two palliative radiotherapy schedules (multi-fraction versus one fraction regimen) in cancer patients aged 70 and older, with non-complicated bone metastasis.

DIALOG (GERICO-UCOG) *Dialogue intergroupe pour la personnalisation de la prise en charge en onco-gériatrie*

President: Pierre Soubeyran, Bergonié Institute, Bordeaux.

DIALOG is a cooperative group, labelled by the French National Cancer Institute (INCa) in 2014 with the following objectives: to organize and structure national collaborations (GERICO, UCOG—*Unités pilotes de coordination en onco-gériatrie*—and SoFOG), to prioritize cancer clinical research in the elderly population, to facilitate access for the elderly, to promote clinical research and innovation throughout the national territory, to collaborate with other cooperative groups in clinical research, and to organize international collaborations.

Significant results

The GERICO12 study was launched in 2015. This study is financed by a PHRC and by the French Cancer League. This study involves 420 elderly patients and investigates the most appropriate neoadjuvant radio(chemo)therapy in patients over 75 with locally advanced rectal carcinoma. This trial is a collaboration between UNICANCER GERICO and the intergroup Prodige which includes UNICANCER GI (Gastro-Intestinal), the FFCD and GERCOR.

President
Dr. Étienne BRAIN
Curie Institute - René Huguenin Hospital, Saint-Cloud
etienne.brain@curie.fr

Project Leader
Christine ORSINI
+33 (0)1 71 93 67 07
c-orsini@unicancer.fr

Project Assistant
Isabelle NICOT
+33 (0)1 71 93 67 07
i-nicot@unicancer.fr

Clinical Research Coordinator
Valérie BENAVENT
+33 (0)1 71 93 63 65
v-benavent@unicancer.fr

Clinical Research Associates
Fatima-Zohra TOUMI
+33 (0)1 44 23 55 72
z-toumi@unicancer.fr

Evelia AUDISIO
01 44 23 55 69
e-audisio@unicancer.fr

Pauline GRÉGOIRE
+33 (0)1 44 23 55 82
p-grégoire@unicancer.fr

Board Members
Dr. Étienne BRAIN
(Medical oncologist)
Curie Institute - René Huguenin Hospital, Saint-Cloud
etienne.brain@curie.fr

Dr. Cécile MERTENS
(Geriatrician)
Bergonié Institute, Bordeaux
c.mertens@bordeaux.unicancer.fr

Dr. Loïc MOUREY
(Medical oncologist)
University Cancer Institute Toulouse –Oncopole, Toulouse
mourey.loic@iuct-oncopole.fr

Dr. Valérie QUIPOURT
(Geriatrician)
Dijon University Hospital, Dijon
valerie.quipourt@chu-dijon.fr

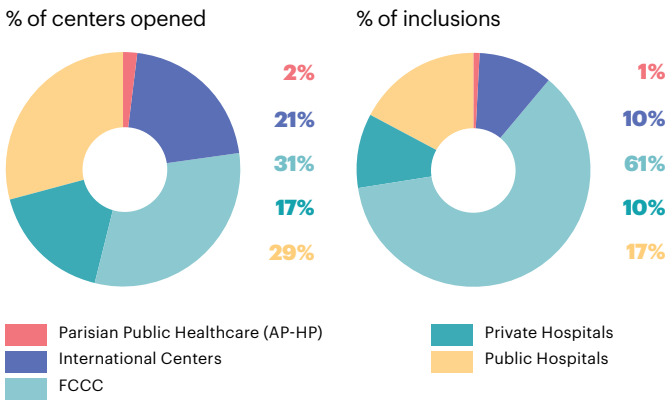
Dr. Catherine TERRET
(Medical oncologist)
Léon Bérard Center, Lyon
catherine.terret@lyon.unicancer.fr

Studies

Study Title	Study coordinator	Phase	Study start date	Number of active sites	Number of expected patients	Number of patients included (12/31/2015)	Study status (12/31/2015)
GERICO 12 (UCGI) Phase III study evaluating two neoadjuvant treatments radiochemotherapy (five weeks – 50 Gy+capecitabine) and radiotherapy (one week – 25 Gy) in patient over 75 with locally advanced rectal carcinoma	Dr. Eric FRANÇOIS – Antoine Lacassagne Center – Nice	III	12/01/15		420		Recruiting
GERICO 11 (UCBG) Adjuvant systemic treatment for (ER)-positive HER2-negative breast carcinoma in women over 70 according to genomic grade (GG): chemotherapy + endocrine treatment versus endocrine treatment (ASTER 70s)	Dr. Etienne BRAIN – Curie Institute, Saint-Cloud	III	04/12/12	59 (France) 12 (Belgium)	2,000 Included patients (1,080 randomized)	1,833 included patients (984 randomized)	Recruiting
GERICO-labelled trial Trial of a simplified geriatric evaluation carried out by oncologists before oncologic treatment with radiotherapy or chemotherapy in subjects over 70 with an inoperable epidermoid cancer of the head and neck	Dr. Joël GUIGAY – Antoine Lacassagne Center – Nice Coordinator GERICO: Dr. Cécile MERTENS – Bergonié Institute - Bordeaux	Current healthcare			800		Recruiting
GERICO 10 (GETUG) Feasibility of a chemotherapy with docetaxel-prednisone for castration-resistant metastatic prostate cancer elderly patients	Dr. Loïc Mourey - University Cancer Institute Toulouse – Oncopole Toulouse	Randomized Phase 2	12/09/10	21	144 max	66	Final analysis

The inclusions by type of establishment in 2015

TYPE OF ESTABLISHMENT	Number of sites	Number of patients included
Parisian Public Healthcare (AP-HP)	1	3
International Centers	12	54
FCCC	18	321
Private Hospitals	10	54
Public Hospitals	17	91
Overall total	**58**	**523**



Personalized Medicine Program

Conducting programs in precision medicine, and to identify and develop innovative research in this domain

Presentation

Both highly strategic for UNICANCER and attractive for experts in a multitude of domains, the research in personalized medicine has all the characteristics to mobilize not only the community of researchers and practitioners in the French Comprehensive Cancer Centers (FCCC), but also those in all health institutions. It is for this reason that this group was created in 2013 by the initiative of Pr. Fabrice André, the President of the group.

Goals

The group has set the ambitious goal of developing a multidrug predictor for selecting the most effective treatment for patients. For this, the group is structured around several work packages to implement a number of different strategies, including: the identification of sensitivity or resistance biomarkers to therapy, relapse or extreme responses biomarkers, or the development and validation of therapeutic decision algorithms based on biological tests.

Events

In 2015 the SAFIR02 Breast and Lung studies (evaluation of the efficacy of high throughput genome analysis as a therapeutic decision tool for patients with metastatic non-small cell lung cancer or breast cancer) successfully integrated a new drug to the eight targeted drugs already available. This drug, durvalumab (MEDI4736) is a PD-L1 inhibitor developed by AstraZeneca. Oncologists have high expectation for this immunotherapy and hope to be able to treat the very first patients as of January 2016. Patients who cannot benefit from a targeted therapy will be offered immunotherapy. This is a significant evolution for patients, as well as a demonstration of the capability of complex studies to integrate innovation when available.

The 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) is a biomarker study that was initiated this year. SAFIR-TOR is part of an integrated program that aims to offer different therapeutic opportunities to patients who have obtained a genomic profile of their tumor. Accordingly, SAFIR-TOR and SAFIR02 are connected and patients could participate in one study to another depending on the more relevant medical option for them.

Significant results

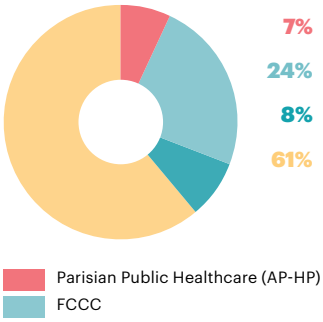
Acsé Crizotinib study is a secured access to crizotinib for patients with tumors harboring a genomic alteration on one of the biological targets of the drug.

The final results of crizotinib's activity in ROS1 translocated and C-MET amplificated NSCLC were presented in September during the IASLC World lung cancer conference (Denver). Crizotinib was well tolerated and achieved a robust treatment response rate in ROS1-positive NSCLC (ORR=69% [IC 95%: 52; 84]). The response and survival in ROS1-positive NSCLC was comparable to these observed in ALK positive NSCLC. Furthermore, crizotinib showed interesting activity in MET amplified NSCLC (ORR = 32% [IC 95%: 9; 45]). These results demonstrate that nationwide biomarker-driven access to crizotinib for patients with ROS1 or c-MET-positive malignancy is feasible and emphasizes the importance of integrating ROS1 in routine biomarkers screening.

The inclusions by type of establishment in 2015

TYPE OF ESTABLISHMENT	Number of sites	Number of patients included
Parisian Public Healthcare (AP-HP)	5	75
International Centers	0	0
FCCC	17	353
Private Hospitals	6	8
Public Hospitals	43	144
Overall total	71	580

% of centers opened



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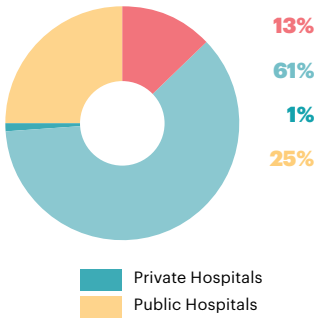


Studies

Study Title	Study coordinator	Phase	Study start date	Number of active sites	Number of expected patients	Number of patients included (12/31/2015)	Study status (12/31/2015)
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	Thomas BACHELOT	II	04/21/15	6 sites open 4 sites active	150	24	Recruiting
GMP 02 - ACSE CRIZOTINIB Secured access to crizotinib for patients with tumors harboring a genomic alteration on one of the biological targets of the drug	Jean-Yves BLAY	II	10/01/14	87 sites open 39 sites active	500	63	Recruiting
GMP 03 - SAFIR 02 / BREAST Evaluation of the efficacy of high throughput genome analysis as a thera-peutic decision tool for patients with metastatic breast cancer	Fabrice ANDRÉ	II	03/24/14	17 sites open 17 sites active	460 patients screened for 240 treated patients	366 patients included (49 randomized)	Recruiting
GMP 04 - Intergroup study UNICANCER 0105-1305 / IFCT 1301 SAFIR 02 / LUNG Evaluation of the efficacy of high throughput genome analysis as a therapeutic decision tool for patients with metastatic non-small cell lung cancer	Jean-Charles SORIA	II	03/10/14	26 sites opens 23 sites active	650 patients screened for 230 treated patients	330 patients included (47 randomized)	Recruiting
GMP 01 - ACSE CRIZOTINIB Secured access to crizotinib for patients with tumors harboring a genomic alteration on one of the biological targets of the drug	Gilles VASSAL	II	07/23/13	177 sites open 68 sites active	500	153	Recruiting
GRT 01 - SAFIR01 High throughput technologies to drive breast cancer patients to specific phase I/II trials of targeted agents	Fabrice ANDRÉ	II	05/17/11	17 sites open 17 sites active	400	423	Follow-up

President
Pr. Fabrice ANDRÉ
Gustave Roussy Institute, Villejuif

Vice-President
Pr. Mario CAMPONE
Institute of Cancer Research in Western France, Nantes

Program Head
Marta JIMENEZ
+33 (0)1 44 23 55 58
m-jimenez@unicancer.fr

Project Managers
Céline MAHIER AÏT-OUKHATAR
+33 (0)1 44 23 55 84
c-mahier@unicancer.fr

Stéphanie HERVÉ
Keyrus Pharma for UNICANCER
+33 (0)1 71 93 63 64
s-hervé@unicancer.fr

Véronica PEZZELLA
+33 (0)1 44 23 04 77
v-pezzella@unicancer.fr

Clnical Research Coordinators
Julie GARRABEY
+33 (0)1 44 23 04 14
j-garrabey@unicancer.fr

Laëtitia JOHNSON
TFS for UNICANCER
+33 (0)1 44 23 04 14
l-johnson@unicancer.fr

Clnical Research Associates
Guillaume GARY-BOBO
+33 (0)1 71 93 67 08
g-gary-bobo@unicancer.fr

Michaël CHEVROT
+33 (0)1 71 93 61 61
m-chevrot@unicancer.fr

Marjorie MAUDUIT
+33 (0)1 73 79 77 54
m-mauduit@unicancer.fr

Laure VIOLETTE
+33 (0)1 73 79 77 59
l-violette@unicancer.fr

Vincent LARROCHE
+33 (0)1 73 79 77 55
v-larroche@unicancer.fr
Stéphanie GOURDAIN
+33 (0)1 73 79 73 02
s-gourdain@unicancer.fr

Telma ALMEIDA ROQUE
+33 (0)1 80 50 12 92
t-roque@unicancer.fr

Project Assistants
Dorothée PIVA
+33 (0)1 44 23 04 68
d-piva@unicancer.fr

Guylaine GUIBERT
+33 (0)1 73 79 73 04
g-guibert@unicancer.fr

Early Phase Group (GEP)

Innovation for patients

Presentation

Over the years, the UNICANCER Early Phase Group has established itself as an important player recognized by academic and industrial partners for the quality of its trials. The objective of diversification of explored pathologies explored and the cross-disciplinarities of the group has been consolidated by the development of projects in cancers of the upper airway and digestive tract, as well as breast, kidney and prostate cancer studies. These projects have been conducted in collaboration with the UNICANCER tumor group concerned.

Goals

The GEP supports the development of personalized medicine trials. In a context where access to therapeutic innovation for the FCCC and for patients is of utmost importance, the development of personalized medicine brings new challenges to overcome. To maintain its commitment to innovation and make accessible breakthrough therapies within the FCCC, the trials to be led by GEP are becoming increasingly technical and complex. These trials will be designed according to the new methodologies and research developed by precision medicine.

Events

GEP13 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. For this original neoadjuvant study in HER2+ breast cancer patients, several limiting factors for the recruitment were identified during this year. Tumor size limited to 1-2cm (T1c), associated with a HR-negative status were amongst the more important constraints to accrual. As a consequence, an amendment was submitted to enlarge the study population to include T2, T3 and T4a tumors, and with HR-negative status only limited to T1c tumors. Since the implementation of this modification, the recruitment has improved from eight patients included in 2015 to eight additional patients included in the first two months of 2016.

Significant results

The GEP 11 PREDICTOR study: multicentric, 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.

Even though it is difficult to recruit patients for pre-operative trials, the objective of including 60 patients was reached in three and a half years. The group once again showed its capacity to reach its target. The biomarker analyses and first results are expected in 2016.

President
Mario CAMPONE
Institute of Cancer Research in Western France, Nantes

Vice-President
Thomas BACHELOT
Léon Bérard Center, Lyon

Secretary
Nicolas ISAMBERT
Georges-François Leclerc Center, Dijon

Program Head
Marta JIMENEZ
+33 (0)1 44 23 55 58
m-jimenez@unicancer.fr

Project Leader
Christine ORSINI
+33 (0)1 71 93 67 07
c-orsini@unicancer.fr

Project Manager
Céline MAHIER
AÏT-OUKHATAR
+33 (0)1 44 23 55 84
c-mahier@unicancer.fr

Clnical Research Coordinator
Valérie BENAVENT
+33 (0)1 71 93 63 65
v-benavent@unicancer.fr

Clnical Research Associates
Guillaume GARY-BOBO
+33 (0)1 71 93 67 08
g-gary-bobo@unicancer.fr

Evelia AUDISIO
+33 (0)1 73 77 54 41
e-audisio@unicancer.fr

Fatima-Zohra TOUMI
+33 (0)1 44 23 55 72
z-toumi@unicancer.fr

Project Assistants
Linda MARTIN
+33 (0)1 73 79 73 09
l-martin@unicancer.fr

Guylaine GUIBERT
+33 (0)1 73 79 73 04
g-guibert@unicancer.fr

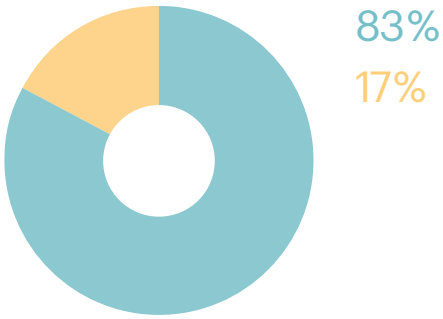
Studies

Study Title	Study coordinator	Phase	Study start date	Number of active sites	Number of expected patients	Number of patients included (12/31/2015)	Study status (12/31/2015)
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	Marie-Ange MOURET-REYNIER	II	12/05/14	11 sites opens 3 sites active	90	8	Recruiting
GEP 12 - CARLHA Safety and efficacy radiotherapy combined with a six-months LH-RH agonist and abiraterone hormone therapy treatment in biochemically-relapsing prostate cancer following surgery	Stéphane SUPIOT	I	09/21/12	2 sites open 2 sites active	37-43	16	Recruiting
GEP 07 PACIFIK 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	Véronique DIÉRAS	I	06/11/10	5 sites opens 5 sites active	N/A	35	Follow-up
GMP 06 RUBY Single arm, open-label, phase II study to assess the efficacy of rucaparib in metastatic breast cancer patients with a BRCAness genomic		II	11/05/15		41		Initiation

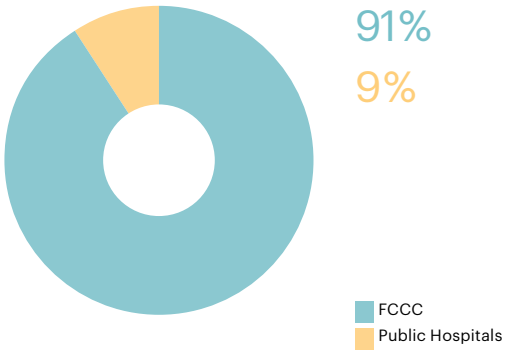
The inclusions by type of establishment in 2015

TYPE OF ESTABLISHMENT	Number of sites	Number of patients included
Parisian Public Healthcare (AP-HP)	0	0
International Centers	0	0
FCCC	10	30
Private Hospitals	0	0
Public Hospitals	2	3
Overall total	**12**	**33**

% of centers opened



% of inclusions



Supportive Care Intergroup

An intergroup dedicated to clinical research in oncology and supportive care

Presentation

The UNICANCER-AFSOS Intergroup was created in November 2013 from the partnership between AFSOS (Association Francophone pour les Soins Oncologiques de Support) and UNICANCER with the support of the French Cancer League and Hospira, an industrial partner.

Goals

The aim of the intergroup is to develop research programs dealing with supportive care for cancer patients, using the most up-to-date and optimal methodology available. The studies conducted by the intergroup are designed with highest standards, integrating the evaluation of the quality of life, and (if possible) a medico-economic component.

Events

The annual general meeting for the intergroup was held in February 2015 followed by a Search-session set up during the AFSOS Congress in October. The groups third call for projects was organized in December 2015: 32 projects were received and are currently under review for UNICANCER sponsoring, illustrating the dynamic nature of the group. In 2015, the group actively worked on identifying those methodologies and endpoints most appropriate for the field of supportive care. A other working group was dedicated to developing a research in order to, identify and prioritize supportive cares considered important for patients (CyPRES) Finally, three studies were elaborated in 2015 and should be initiated early in 2016:

- QUALIOR, Feasibility and effectiveness of a standardized exercise program at home in patients receiving oral targeted therapy for metastatic cancer;
- FARADI, Efficacy and safety of fentanyl citrate for pain induced during diagnostic or therapeutic examinations in patients with cancer;
- RILUZOX, Effectiveness assessment of riluzole in the prevention of oxaliplatin-induced peripheral neuropathy.

President
Pr. Ivan KRAKOWSKI
Bergonié Institute, Bordeaux
i.krakowski@bordeaux.unicancer.fr

Project Leader
Christine ORSINI
+33 (0)1 71 93 67 07
c-orsini@unicancer.fr

Project Assistant
Linda MARTIN
+33 (0)1 71 93 67 07
l-martin@unicancer.fr

Clinical Research Coordinator
Valérie BENAVENT
+33 (0)1 71 93 63 65
v-benavent@unicancer.fr

Clinical Research Associates
Fatima-Zohra TOUMI
+33 (0)1 44 23 55 72
z-toumi@unicancer.fr

Evelia AUDISIO
+33 (0)1 44 23 55 69
e-audisio@unicancer.fr

Pauline GRÉGOIRE
+33 (0)1 44 23 55 82
p-grégoire@unicancer.fr

Board members
Pr. Ivan KRAKOWSKI
(President)
Bergonié Institute, Bordeaux
i.krakowski@bordeaux.unicancer.fr

Pr. Florence JOLY
(Vice-President)
François Baclesse Center, Caen
f.joly@baclesse.unicancer.fr

Pr. Franck BONNETAIN
(Secretary)
Besançon University Hospital, Besançon
franck.bonnetain@univ-fcomte.fr

UNICANCER Group of Translational Research and Development in Radiation Oncology (UNITRAD)

To promote and develop an innovative radiotherapy research program

Presentation

UNITRAD (UNICANCER Group of Translational Research and Development in Radiation Oncology), was created in 2014 following interest shown in this initiative by the radiologists in the FCCC.

The UNITRAD group is supervised by a steering committee and is composed by eight working groups: brachytherapy, imaging, physical and technological development, modeling and radiomics, radiobiology and radio-potentiation, quality assurance, human and social sciences (SHS), and methodology.

Goals

UNITRAD's missions are to:

- develop strategic guidance, and stimulate and organize innovative research programs in the field of ionizing radiation;
- provide a committee of experts to evaluate and discuss study proposals;
- stimulate interactions with different actors involved in ionizing radiation research and facilitate the creation of collaborative networks (including research groups, research laboratories, and investigators in clinical research within UNICANCER and internationally).

Significant milestone

The The INCa has agreed to provide funding for three out of the four clinical trials submitted for evaluation in 2015:

- HYPO-G01: 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:
  - the Stereo Os trial investigating Extracranial Stereotactic Body Radiation Therapy (SBRT) versus standard treatment in solid tumors patients with ≤3 bone-only metastasis;
- the OLIVER trial dealing with Oligometastases of the LIVer treated with chemotherapy with or without Extracranial stereotactic body Radiation Therapy in patients with breast or colorectal cancer.

The obtention of this funding illustrates the dynamic nature of the group and the importance of radiation therapy in cancer research in France. We expect these trials to be initiated in 2016.

President
Pr. David AZRIA
Montpellier Cancer Institute (ICM), Montpellier
david.azria@icm.unicancer.fr

Vice-President
Pr. Marc-André MAHÉ
ICO site René Gaudducheau,Nantes

Project Leader
Naïma BONNET
+33 (0)1 85 34 33 74
n-bonnet@unicancer.fr

Project Assistant
Anne-Chantal LE GALL
+33 (0)1 44 23 04 13
ac-legall@unicancer.fr

Epidemio Strategy and Medical Economics (ESME) Program

Presentation

The Data Platform ESME, created in 2014 as an initiative of R&D UNICANCER and the FCCC, is the first French "real-life" database in oncology centralizing all data available in routine practice and
made available to the scientific Community (call for projects). The first project is related to medical care of patients suffering from metastatic breast cancer (MBC). By the end of 2015, clinical and therapeutic data were populated for more than 14,000 patients initially treated in one of 18 FCCC between 2008 and 2013 for their metastatic disease. Centralizing data means standardization of data structure including a systematic output to each participating center for its own contribution. The MBC component of the program is today funded by our three industrial partners (Roche, Pierre Fabre and Pfizer) and should be soon joined by other partners. Annual updates are planned and will allow the selection of new cases, as well as update data from the ones initially selected.

The collected data is a picture of the current clinical practice in all of the 18 FCCC without any influence on the doctor-patient relationship. Any analysis requested are performed completely independently by R&D UNICANCER after being reviewed by the ESME Scientific Committee. Analysis may be requested either by a call for projects proposal process, or by our institutional or industrial partners. These analysis allow the description of the provided patient medical care, measuring the efficiency of therapeutic strategies and/or health products. Within the boundaries of the Cancer Plan, the ESME Research Program also responds to the various healthcare institution objectives, in particular those reinforcing the medico-economic mission with respect to therapeutic strategies, prescriptions and healthcare, but also medico-economic evaluation of anticancer medication and their (re-)registration.

Three committees have been established in the ESME Research Program with their principal objectives listed below:

The ESME Scientific Committee (CSE):
- ensure the applicable scientific rules;
- evaluate the analysis requests in compliance with defined eligibility criteria and the scientific pertinence;
- manages the call for projects proposals and the database requests.

The ESME Independent Ethics Committee to manage the conflicts of interest (2016):
- suggest recommandations that may improve the system in general and prevent conflict of interest risks;
- provides an opinion on individual or particular situations;
- gives an opinion concerning potential collaborations with private partners.

The ESME International Advisory Board (2016):
- reviews for key international communication;
- has a consultative opinion on the scientific coherence of the program;
- formulates recommendations on the methodology;
- reinforces international academic cooperation.

Significant milestone

To develop the strategy for the ESME Program, a number of possibilities are under discussion at the end of 2015:

- extending to other partners and other therapeutic domains;
- planning the potential linkage to the SNIIRAM data (Public Health Insurance reimbursement data) in order to extrapolate and match data obtained outside of the FCCCC (external validity);
- providing a secured data server dedicated to accepted projects proposals for which the analysis will be performed under the responsibility of project owner.

Prospect status

2015 focused on data collection, data management and analysis activities of real-life data concerning the medical care provided for patients with metastatic breast cancer. 34,000 potential patients were identified, validated data has been collected on a 14,000 patients panel treated in all the FCCC in compliance with expectations.

The ESME Research Program thus provides access to more than 14,000 patients' medical files allowing Centers and all potential partners to ask scientific questions or requests which may result in publications under the Scientific Committee. The first two analysis reports have been performed and communicated to our partners and health institutions. The first scientific communications are expected in 2016. In addition, an initial call for projects proposal, for the FCCC, has also been initiated to allow physicians/researchers access to all the ESME data to answer scientific questions.

President of the Scientific Committee
Dr. David PEROL
+33 (0)4 78 78 28 79
david.perol@lyon.unicancer.fr

Medical Data Director
Dr. Mathieu ROBAIN
+33 (0)1 44 23 55 52
m-robain@unicancer.fr

Assistant
Esméralda PEREIRA
+33 (0)1 44 23 04 03
e-pereira@unicancer.fr

Project Leaders
Coralie COURTINARD
+33 (0)1 85 34 33 72
c-courtinard@unicancer.fr

Gaëtane SIMON
+33 (0)1 73 79 73 00
g-simon@unicancer.fr

Project Manager
Tahar GUESMIA
+33 (0)1 73 79 73 01
t-guesmia@unicancer.fr

Clinical Research Coordinator
Charlène LEGENDRE
+33 (0)1 80 50 15 91
c-legendre@unicancer.fr

Clinical Research Associate/ Quality Inspector
Elodie KUPFER
+33 (0)1 80 50 15 92
e-kupfer@unicancer.fr

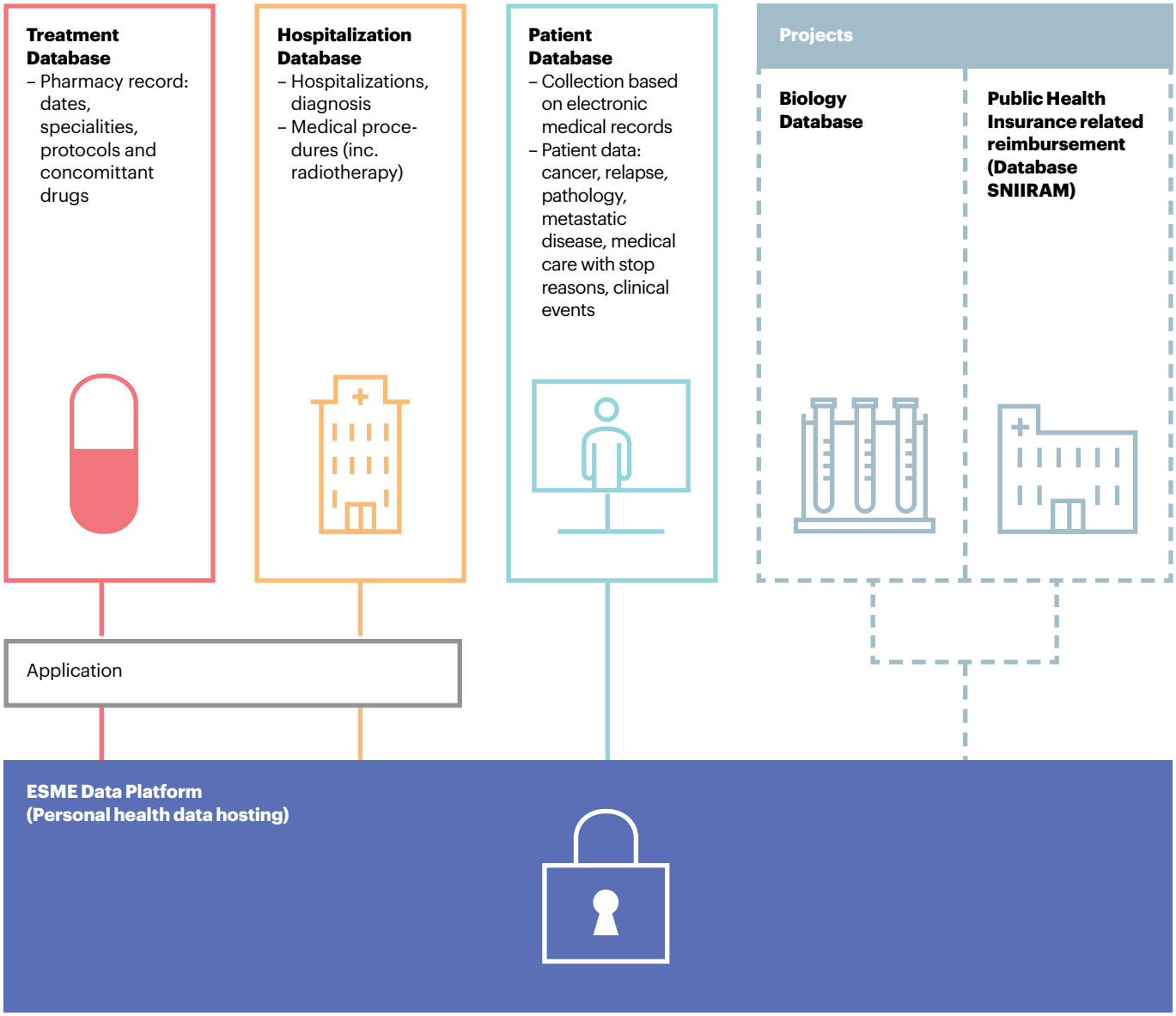
Clinical Research Associate
Toihiri SAID
+33 (0)1 80 50 15 93
t-said@unicancer.fr

Project Leader
Alexandre VANNI
+33 (0)1 71 93 61 63
a-vanni@unicancer.fr

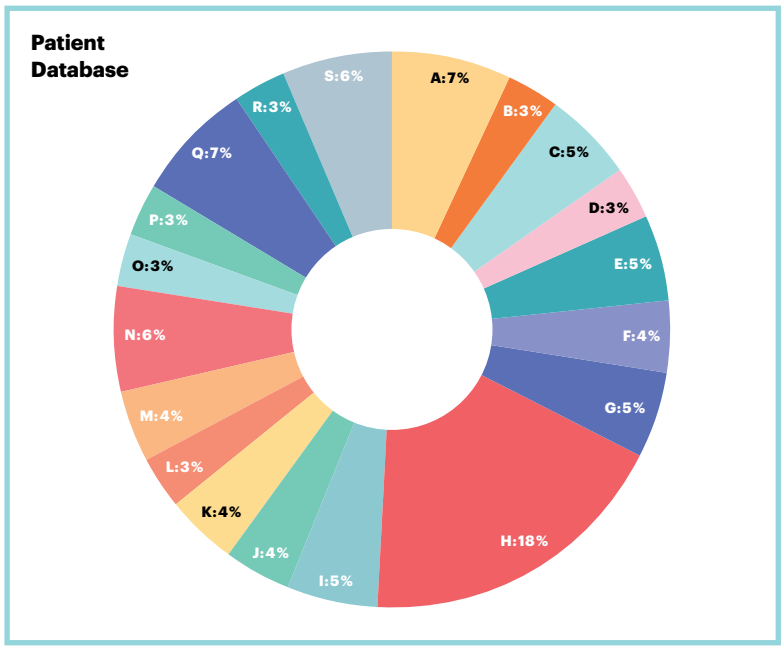
Data Manager
Irwin PIOT
+33 (0)1 44 23 55 87
i-piot@@unicancer.fr

Data Manager Assistant
Olivier PAYEN
+33 (0)1 85 34 33 77
o-payen@unicancer.fr

ESME Data Platform



Distribution of the selected patient's validated data across FCCC



Treatment Database

87%

Hospitalization Database

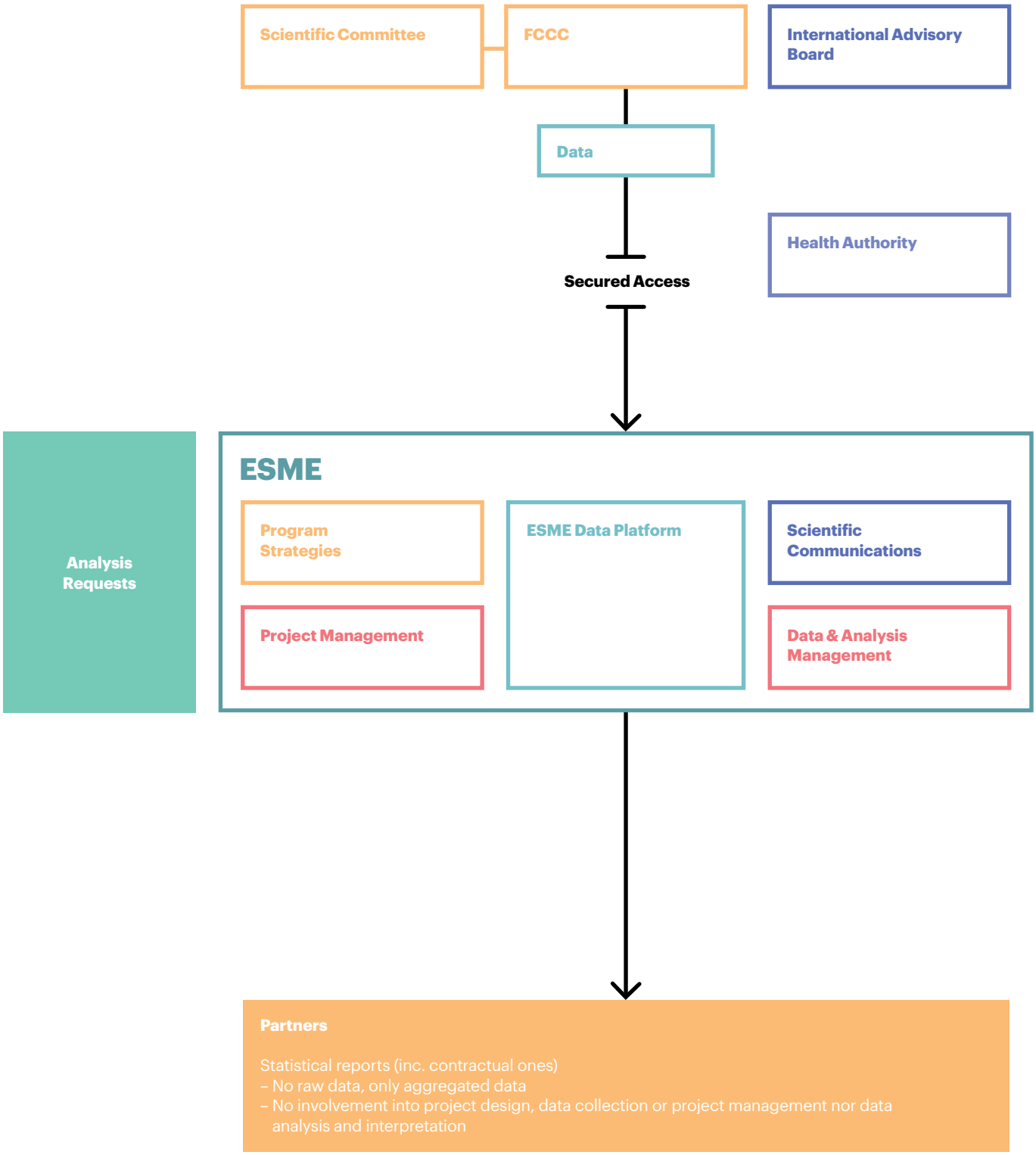
73%

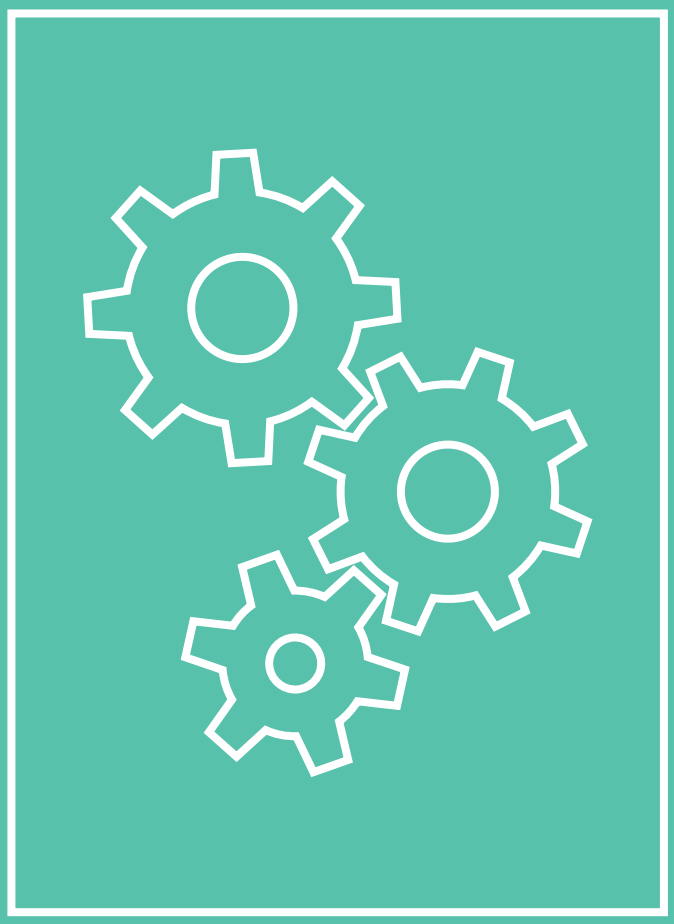
of which 13% of patients without hospitalization;
of which 27% of patients without treatment dispensed by the FCCC pharmacy.

Gouvernance of ESME Research Program

Executive Level	Operationnal Level	Supporting committee
UNICANCER — Bureau	Real-Life Data — ESME Research Program Department	Independent Ethics Committee
R&D UNICANCER — Strategic and Research Committee	Centers Coordinators	Scientific Committee
R&D UNICANCER — Director RWD Department — Head	Working Groups	International Advisory Board (IAB)
	Quality Assurance Department	

ESME Data Platform: Independent Program Management





Support departments

Regulatory Affairs and Pharmacovigilance

Regulatory Affairs

The Regulatory Affairs department plays a major role in the management of the scientific research conducted by UNICANCER. In this respect, this department guarantees that the different activities, sponsored by the structure, are performed in accordance with the laws and regulations applicable to research. This department also plays a role in assisting and advising the different UNICANCER groups. Its activity begins well in advance of the initiation of the projects, continuing throughout the lifetime of the research up until the termination. The supporting of the groups equally concerns the assistance with respect to different themes related to scientific research, including interventional and non-interventional biomedical research. This support takes the form of recommendations in terms of ethics, data management, or any other issues that may arise during project management.

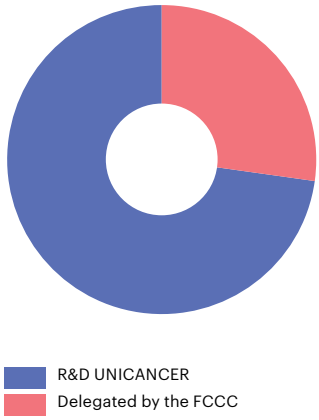
Results

The Regulatory Affairs department plays an important role in the training of the UNICANCER teams; in 2015 three training sessions were organized by the department: the new European regulations for clinical trials, the pharmaceutical aspects of clinical trials, and Good Clinical Practice.

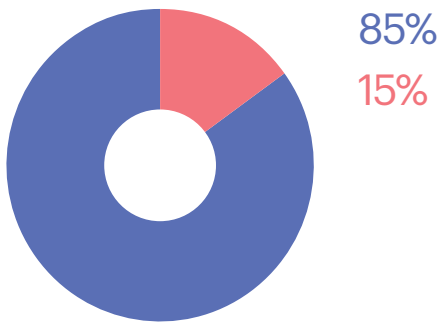
Eight new clinical trials sponsored by R&D UNICANCER were submitted and approved in France; at the same time six trials were submitted and authorized in other European countries (Germany, Belgium, Italy and Romania). In parallel, three study authorizations were obtained for the French Comprehensive Cancer Centers (FCCC). The department also dealt with modifications to trials still recruiting, this concerned 139 amendments of which 118 concerned R&D UNICANCER sponsored trials and 21 trials for which the FCCC delegated this responsibility.

The distribution between the activities related to R&D UNICANCER trials and those delegated are shown in the following graph:

New requests for clinical trial authorizations, distribution between R&D UNICANCER and delegation by the FCCC



Amendments submitted, distribution between R&D UNICANCER and those delegated by the FCCC



Regulatory Affairs, Quality Control and Pharmacovigilance Director
Pierre-Henri BERTOYE
+33 (0) 1 73 79 73 08
ph-bertoye@unicancer.fr

Regulatory Affairs and Pharmacovigilance Associate Director
Nourredine AIT RAHMOUNE
+33 (0) 1 71 93 67 04
n.ait-rahmoune@unicancer.fr

Regulatory Affairs, Quality Assurance and Pharmacovigilance Assistant
Patricia NEZAN
+33 (0)1 44 23 04 15
p-nezan@unicancer.fr

Pharmacovigilance Physician Manager
Dr. Radia RAHMANI
+33 (0) 1 44 23 04 16
r-rahmani@unicancer.fr

Pharmacovigilance Associates
Sandrine COUSTY
+33 (0) 1 44 23 55 53
s-cousty@unicancer.fr

Virginia OLYMPIO
+33 (0) 1 44 23 55 86
v-olympio@unicancer.fr

Laurence OLIVIER-KRIEF
+33 (0) 1 44 23 55 63
l-krief@unicancer.fr

Didier VENIGER
+33 (0) 1 44 23 04 73
d-veniger@unicancer.fr

Imane KAIDI
+33 (0) 1 44 23 55 86
i-kaidi@unicancer.fr

Regulatory Affairs Manager and Data Protection Officer
Romain BOIDIN
+33 (0) 1 73 79 77 52
r-boidin@unicancer.fr

R&D Legal Counsel
Agnieszka PODGORSKA
+33 (0)1 80 50 15 96
a-podgorska@unicancer.fr

Regulatory Affairs Associates
Rida ATMI
+33 (0) 1 44 23 04 79
r-atmi@unicancer.fr

Vigilance

The vigilance is a key activity in the management of clinical trials. The surveillance of the security of the patients included in clinical trials is the responsibility of the sponsor and is ensured for the duration of the trials by the pharmacovigilance (PV) department. This is a crucial mission in the management of clinical trials. The PV department participates in all meetings concerning the safety of the patients included in the trials sponsored by UNICANCER.

This department is implicated in the design of the clinical trial protocols since the pharmacovigilance procedures appear in this document to assist the investigators with the declaration of serious adverse events (SAE). The intervention continues throughout the clinical trials, since all the SAE received by the PV department are entered into the dedicated database and also evaluated by the pharmacovigilance physician. Their evaluation is swiftly performed since certain notification require a so called immediate declaration to the competent authorities, ethics committees and other concerned investigators. These events requiring immediate declaration (within 7 to 15 days) are those considered unexpected with regards to the reference document (investigator's brochure or summary of product characteristics).

In order to give the project teams an up-to-date view of the vigilance of the studies, the PV department transfers a monthly table summarizing all the SAE received and can also alert when events could induce a change in the benefit-risk ratio for the research.

Furthermore, for each trial an Annual Safety Report is prepared by the PV department in collaboration with the project team for transmission to the competent authorities and ethics committees. This document gives a ruling concerning the tolerance of the research and indicates whether the benefit-risk ratio remains favorable.

In 2015, a part of the activity of the pharmacovigilance department was dedicated to trials sponsored by the FCCC for which this service was delegated. The department adapts to the requirements of the FCCC. The delegation of the pharmacovigilance can be complete, in other words the management of all the SAE, or only those serious adverse reactions that are unexpected.

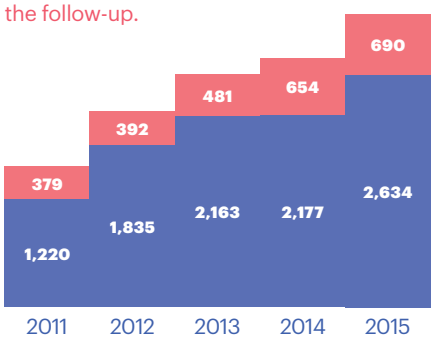
Assessment for 2015

The pharmacovigilance activity is in evolution with respect to previous years, with an increase of more than 17% in terms of notifications (including SAE and follow-ups).

More than 100 studies are in progress (current recruiting or in follow-up) which require pharmacovigilance activities. For each of these an Annual Safety Report is prepared; for studies implemented as of 2014 these reports are at present in the form of a DSUR (Development Safety Update Report), a format meeting international requirements. This essential document contains substantial information since it collects all data concerning patients' safety. Almost 100 Annual Safety Reports were prepared in 2015.

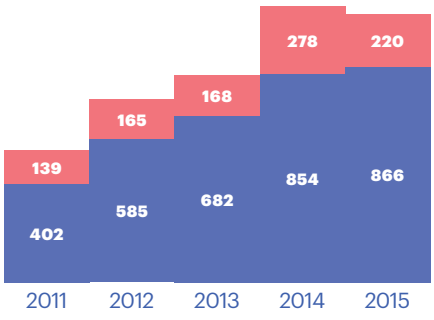
Notifications

The graph below represents the variation in the nofications to the Pharmacovigilance department since 2011. The notifications include the initial SAE declarations and the follow-up.



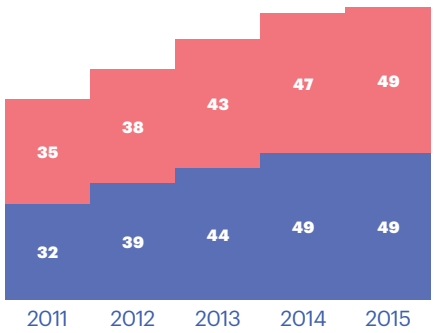
Serious Adverse Events

The graph below represents the variation in the notification of serious adverse events to the Pharmacovigilance department since 2011.



Annual Safety Reports

The graph below shows the variation in the number of Annual Safety Reports prepared since 2011.



R&D UNICANCER
Delegated by the FCCC

Quality Assurance

Presentation

In 2015, UNICANCER intensified its quality assurance policy in the fields of biomedical research, real life studies and collection of biological samples, to build up these activities and increase data quality.

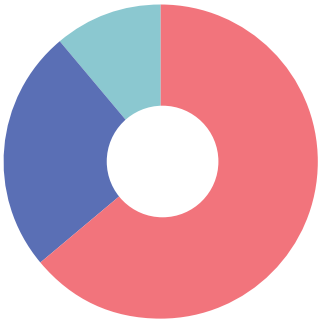
The Quality Assurance department provides support to internal development structures including the Clinical Operations department and the department in charge of Clinical Data and the ESME program, as well as to the FCCC. The team was considerably strengthened by the arrival in February 2015 of a Quality Assurance Pharmacist-Auditor and in September 2015 of a Quality Assurance Pharmacist trainee, and by the time dedicated to this activity by the Executive Assistant.

The activities of the department include:
- the revision of the QA documentation system;
- pre-qualification system and trial audits and the implementation of preventive and corrective actions;
- staff training through training tutorials and meetings on the sharing of new procedures, methods and tools;
- implementation and use of a risk-based approach, which began with monitoring being adapted according to the risk level of the trial;
- ISO 9001 certification of the Centers: three centers are now certified (Léon Bérard Center, Paoli-Calmettes Institute, Claudius Regaud Institute) and 2 centers (Georges-François Leclerc Center, Lorraine Institute of Oncology) were certified in 2015;
- initiation of the ISO 9001 certification process for R&D UNICANCER, with the selection of a service provider for the coordination and official launch of the initiative in February 2016.

Deployment of the internationally recognized ISO 9001 quality approach, as the keystone for the other research quality improvement activities in the centers and R&D UNICANCER, will guarantee a high level of quality and safety for all—patients, doctors, academic and private partners—in the carrying out of our clinical trials. This quality improvement effort has benefited from the participation of Roche.

Significant milestone
5 Centers already ISO 9001-certified

2015 : 14 audits



Quality Control, Regulatory Affairs and Pharmacovigilance Director
Pierre-Henri BERTOYE
+33 (0)1 73 79 73 08
ph-bertoye@unicancer.fr

Quality Assurance Pharmacist-auditor
Elise VILLERS
+33 (0)1 71 93 61 64
e-villers@unicancer.fr

Quality Assurance Project Officer
Christine PHILIPPE
+33 (0)1 44 23 04 72
c-philippe@unicancer.fr

Quality Assurance Pharmacist (trainee)
Alexis MOREAU
+33 (0)1 85 34 31 06
a-moreau@unicancer.fr

Assistant
Patricia NEZAN
+33 (0)1 44 23 04 15
p-nezan@unicancer.fr

Data Center

Presentation

In 2011, R&D UNICANCER decided to entrust the management of data for all its biomedical research to the data center of Val d'Aurelle, part of the Montpellier Cancer Institute (ICM). The unit of Biometry, coordinated by Sophie Gourgou under the direction of Dr. Jean-Pierre Bleuse, has developed with at present more than ten people dedicated to the data management of R&D UNICANCER clinical trials.

The past years have been marked by the qualification of the Data Management systems and the development of the electronic Case Report Form (eCRF). In 2015, the data center's focus was on improving performance by initially upgrading the eCRF software used (Clinsight V7.5) and consequently simplifying both the CRF preparation process and CRF contents. The interface between the data center and clinical operations has also been strengthened with regular management meetings and early involvement of the Data Center team in clinical trial setting process.

In parallel, the ISO 9001 certification has entered into an active phase with an audit by the consultants in June 2015, followed in November by the launch of the working groups. These working groups will meet throughout 2016 to formalize all processes by the end of the year; with the certification expected in June 2017.

President/
Data Center Supervisor
Lise ROCA
Lise.roca@icm.unicancer.fr
+33 (0)4 67 61 30 88

Data Managers
Marina CHENOT
Marina.chenot@icm.
unicancer.fr
+33 (0)4 67 61 45 84

Lætitia CABROL
laetitia.cabrol@icm.
unicancer.fr
+33 (0)4 67 61 85 92

Amel BELHIMER
amel.belhimer@icm.
unicancer.fr
+33 (0)4 67 61 45 59

Julien FRAISSE
julien.fraisse@icm.
unicancer.fr
+33 (0)4 67 61 30 30

Johanna MINGUET
johanna.minguet@icm.
unicancer.fr
+33 (0)4 67 61 45 58

Camille BRIAND
camille.briand@icm.
unicancer.fr
+33 (0)4 67 61 30 27

Khadija OUZENOU
Khadija.ouzenou@icm.
unicancer.fr
+33 (0)4 67 61 30 27

Entry Assistants
Julie-Marine PAUL
julie-marine.paul@icm.
unicancer.fr
+33 (0)4 67 61 24 52

Candy BARRET
candy.barret@icm.
unicancer.fr
+33 (0)4 67 61 24 52

Biometrics Unity Officer
Sophie GOURGOU
sophie.gourgou@icm.
unicancer.fr
+33 (0)4 67 61 37 75

Data Center referent
Lise ROCA
Lise.roca@icm.unicancer.fr
+33 (0)4 67 61 30 88

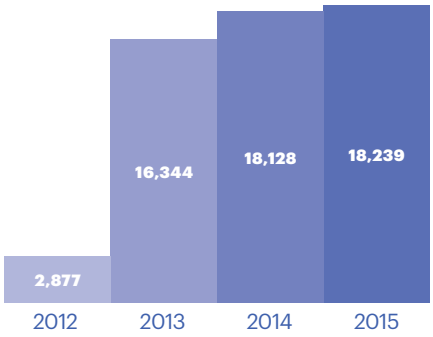
Administration
ctdcancer@icm.unicancer.fr
+33 (0)4 67 61 45 48

Biological Resource Center (BRC)

Presentation

The UNICANCER Biological Resource Center (BRC) is localized at the Léon Bérard Center in Lyon and has been structured to respond to the strategy of R&D UNICANCER to create a collection of samples for all clinical research programs, and to develop programs to valorize these collections. After an open call for tender, the BRC was selected and a partnership agreement was signed in 2012. Approximately 55,000 biological samples (FFPE tumor blocks, frozen tumor, PBMC, plasma, complete blood, serum, DNA, RNA, slides, powders) have been collected since the start of this active, including 15,000 samples collected prospectively in 2015.

Yearly banking (samples/year)



This centralization guarantees the correct conservation of the samples and allows them to be rapidly available when required. The samples are available for research teams through project proposals or by responding to calls for projects by the biological steering committees for UNICANCER trials. The objective of these committees is to ensure that these precious samples are used correctly within rigorous and pertinent research projects for the advancement of medicine and science. Since 2012, approximately 20 projects have been accepted by these committees, with more than 7,000 samples made available to research teams.

In the next step, within its advisory mission for R&D UNICANCER, the BRC of Léon Bérard Center will need to reflect upon new techniques for storage, this within the need of optimizing the cost of research and in particular concerning those biopsy samples currently conserved in liquid nitrogen storage containers. An *ad hoc* committee will be constituted in 2016 for this purpose. The BRC will also be involved in a more general reflection concerning the strategy for the use and valorization of the biological samples.

Scientific Coordinator for PGEB
(Platform for the management of biological resources)
Gilles CLAPISSON
+33 (0)4 69 16 66 38
gilles.clapisson@lyon.unicancer.fr

Team Managers
Séverine MARTINEZ
severine.martinez@lyon.unicancer.fr

Régis PARRIN
regis.parrin@lyon.unicancer.fr

Julie COULOMB
julie.coulomb@lyon.unicancer.fr

Delphine JURY
delphine.jury@lyon.unicancer.fr

Aurélie AMBLOT
aurelie.amblot@lyon.unicancer.fr

BRC Project Manager
Christel MESLEARD
+33 (0)1 44 23 55 51

UNICANCER Group

Research in the FCCC

Each year an inventory is organized in the French Comprehensive Cancer Centers (FCCC) to follow the progression of inclusions in clinical trials. Since 2006, the inventory has used three indicators for monitoring clinical research activity in the FCCC:

- Indicator 1: percentage of hospitalized patients included in a clinical trial;
- Indicator 2: percentage of patients included in an institutional trial;
- Indicator 3: percentage of patients included in a pharmaceutical industry trial.

From the time of the first inventory, the inclusions increased significantly up to 2014. In 2015, a slight decrease was noted (-3.8%) compared to 2014, which was the year in which the largest number of inclusions was observed in the FCCC.

If the three indicators are considered, the first indicator reached 16.6% in 2015, showing a slight decline compared to 2014, a very fruitful year in terms of inclusions.

Indicators 2 and 3 showed a sharp increase in inclusions in pharmaceutical industry trials (+12.5%) and, in parallel, a slight decrease in inclusions in institutional trials (-7%). Nonetheless, institutional trial inclusions still account for the largest share compared to pharmaceutical industry trial inclusions (respectively 82.5% and 17.5%).

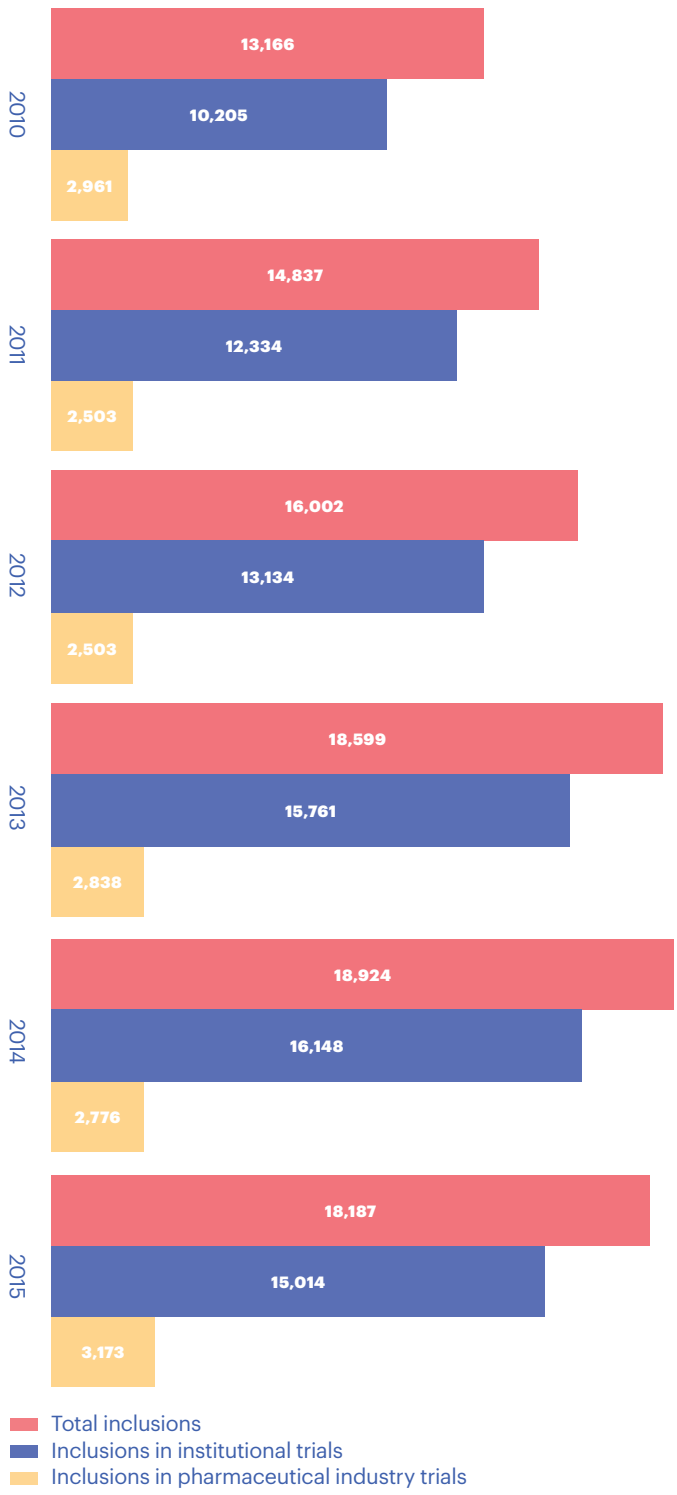
The FCCC continue to be the first recruiters in clinical trials sponsored by UNICANCER.

16,6%
of hospitalized patients included in a clinical trial

82,5%
of patients included in an institutional trial

17,5%
of patients included in a pharmaceutical industry trial

Number of patients included in FCCC per year



The biannual meetings of the heads of the clinical research units of the FCCC

The two meetings of the heads of the clinical research units of the FCCC were held in February and July 2015.

Like each year, the usual topics were discussed, i.e. the activity report of the previous year and regulatory developments. Among other topics, the single contract was also discussed.

The ISO 9001 certification process was also examined. As a reminder, the FCCC that have not yet been certified have begun the process leading to certification. UNICANCER is coordinating and supporting the FCCC in this.

Governmental Hospital Program for Clinical Research (PHRC)

Following the national call for cancer projects, 16 FCCC projects were selected; six centers are implicated as shown below:

Gustave Roussy Institute	11
Montpellier Cancer Institute (ICM) - Val d'Aurelle	1
François Baclesse Center	1
Lorraine Institute of Oncology	1
Antoine Lacassagne Center	1
Oscar Lambret Center	1

Number of patients included in a clinical trial in 2015 per FCCC

French Comprehensive Cancer Centers (FCCC)	Town	Active patients files (source: hospital activity database - PMSI)	Total patients included in a clinical trial	Total open trials	Total patients/ open trials	% patients hospitalized and included in a clinical trial	Academic Sponsor			Pharmaceutical industry Sponsor	
							Number patients included	Number open trials	% patients included in an institutional clinical trial	Number patients included	Number open trials
Gustave Roussy Institute	Villejuif	10,745	3,454	316	10.93	32.15%	2,662	123	77.07%	792	193
Léon Bérard Center	Lyon	8,473	1,870	193	9.69	22.07%	1,565	125	83.69%	305	73
Montpellier Cancer Institute - Val d'Aurelle	Montpellier	6,111	1,220	101	12.08	19.96%	1,144	70	93.77%	76	31
Georges-François Leclerc Center	Dijon	3,997	791	195	4.06	19.79%	676	133	85.46%	115	62
Bergonié Institute	Bordeaux	5,808	1,041	206	5.05	17.92%	545	129	52.35%	496	77
Paoli-Calmettes Institute	Marseille	7,050	1,174	239	4.91	16.65%	1,025	167	87.31%	149	72
Curie Institute	Paris/Saint-Cloud	11,625	1,804	189	9.54	15.52%	1,658	131	91.91%	146	58
Oscar Lambret Center	Lille	6,072	901	189	4.77	14.84%	797	143	88.46%	104	46
Institute of Cancer Research in Western France (P. Papin/R. Gauducheau)	Angers/ Nantes	9,745	1,445	226	6.39	14.83%	1,198	136	82.91%	247	90
Antoine Lacassagne Center	Nice	4,711	671	180	3.73	14.24%	591	146	88.08%	80	34
Henri Becquerel Center	Rouen	4,300	596	135	4.41	13.86%	537	86	90.10%	59	49
Lorraine Institute of Oncology	Nancy	4,274	547	124	4.41	12.80%	535	104	97.81%	12	20
Jean Godinot Institute	Reims	2,755	332	65	5.11	12.05%	215	55	64.76%	117	10
François Baclesse Center	Caen	5,937	707	145	4.88	11.91%	637	108	90.10%	70	37
Jean Perrin Center	Clermont-Ferrand	4,300	459	83	5.53	10.67%	425	63	92.59%	34	20
Institut Claudius Regaud	Toulouse	5,649	586	161	3.64	10.37%	431	93	73.55%	155	68
Paul Strauss Center	Strasbourg	3,577	358	104	3.44	10.01%	216	79	60.34%	142	25
Eugène Marquis Center	Rennes	4,326	231	83	2.78	5.34%	157	55	67.97%	74	28
TOTAL		109,414	18,187			16.62%	15,014		82.55%	3,173	
Mean/FCCC		6,079	1,010	163	6	15.28%	834	108	81.57%	176	55
+/-SD		2,463	754	63	3	5.70%	613	33	12.44%	186	40
Median		5,729	749	171	5	14.54%	614	116	86.38%	116	48
MIN		2,755	231	65	3	5.34%	157	55	52.35%	12	10
MAX		11,625	3,454	316	12	32.15%	2,662	167	97.81%	792	193

Active patients' files = number of patients with cancer having been hospitalized or having had a hospital session during the year*

* Main diagnosis (DP), Related diagnosis (DR) according to the INCa algorithm and/or for which the chemotherapy or radiation codes were found.

Clinical Pharmacology and Oncology Group (GPCO)

Federate the national actors concerned with the pharmacology of anticancer medications

Presentation

The Clinical Pharmacology and Oncology Group (GPCO), is well established with more than 30 years of existence, and federates all national actors implicated in fundamental, translational and clinical research. In particular, the GPCO focuses on the pharmacokinetic, the pharmacodynamic, and the pharmacogenetic of anticancer agents (cytotoxics, targeted therapies, biotherapies, and immunotherapies).

The GPCO also groups researchers, biologists and clinicians from the French Comprehensive Cancer Centers, public hospitals, universities and other public establishments dealing with scientific and technological research. It is also open to student-researchers and to members of the pharmaceutical industry with common research interests.

Goals

- Federate the actors implicated in fundamental, translational, and clinical research on anticancer medications.
- Participate in the transfer of knowledge within the clinical pharmacology of cancer domain.
- Publish new evidence concerning the pharmacological surveillance of drugs.
- Establish clinical trials on the proper use of anticancer drugs and the reduction of drug related toxicities.

Significant results

This year, the GPCO also participated in the organization of the PAMM-EORTC Group congress held in Marseille.

The GPCO, with other national learned societies (STP group of the French Federation of Clinical Pharmacology, National Network of Pharmacogenetics), is also a major contributer in terms of publications of evidence concerning the therapeutic pharmacological surveillance of anticancer medications. The group is also participating in the current discussions about revising the nomenclature for biological acts in France.

With its strong network of laboratory partners throughout France, the GPCO has initiated a series of clinical projects already funded (PHRC, ANSM) or currently being reviewed (submitted to Horizon 2020), centered around the proper usage of anticancer drugs and the reduction of drug-related toxicities.

In 2016, the GPCO also initiated two new working groups open to any partners desiring to acquire an expertise; one concerns the pharmacokinetics of therapeutic monoclonal antibodies and the other the therapeutic surveillance of oral targeted therapies.

Effectively, the GPCO has as its mission the diffusion of scientific knowledge and technology free of rights, to improve therapeutic practices in the anticancer drug domain and thus providing better healthcare for cancer patients.

Events

The GPCO organizes an annual scientific event that each year is attended by more than 200 participants. This event also permits the validation of the continuous professional development program (DPC).

This year, the event was held in Tours and had as its theme “Metabolomics and its application in oncology”. Emerging discipline in drug evaluation and the research of biomarkers in pharmacology, the conceptual aspects of the metabolomic approach were presented by the orators and during two practical workshops.

President
Joseph CICCOLINI
School of Pharmacy
of Marseille, Aix-Marseille
University (AMU)
joseph.ciccolini@univ-amu.fr

Board members
Nicolas ANDRÉ
Marseille University Hospital
nicolas.andre@ap-hm.fr

Alexandre EVRARD
Institute of Cancer Research
of Montpellier (IRCM)
alexandre.evrard@
univ-montp1.fr

Angelo PACI
Gustave Roussy Institute
angelo.paci@gustaveroussy.fr

Bernard ROYER
Besançon University Hospital
broyer@chu-besancon.fr

Fabienne THOMAS
Toulouse University Institute
– Oncopole – Claudius
Régaud
thomas.fabienne@
iuct-oncopole.fr

Contact at UNICANCER
Christophe JAMAIN
Tél. : +33 (0)1 44 23 04 76
c-jamain@unicancer.fr

Genetic and Cancer Group (GGC)

Presentation

Since its creation, in 1991, the Genetic and Cancer Group (GGC) evaluates the genetic risk of cancer within families, elaborate health care for them and contributes to the increase in knowledge concerning the genetic predisposition of patients to cancers.

Goals

- Ensure the elaboration, organization, installation and diffusion of good practices concerning health care of patients and their families.
- Coordinate at a national level the evaluation of projects concerning standard practices; and clinical, biological, and epidemiological research.

Significant results

The year 2015 was marked by a new organization of the GGC meetings to facilitate the exchange between practitioners and to increase the reactivity of the group. This has allowed an opinion to be given concerning the place of the gene PALB2 in the diagnosis of the hereditary predisposition to breast cancer and concerning the organization of rapid logistics for theranostic. The group's high productivity in terms of research is also to be highlighted.

With an annual plenary meeting open to all the members of the GGC (210 members to date) and two to three meetings for the practitioners (50 participants per meeting), the group is increasingly more efficient in terms of organization of clinical practice, as well as its dynamic research. This development has occurred within the context of a substantial increase in activity with fewer resources.

The group continues to invest in onco-genetic epidemiological studies (cohort GENEPSO and GEMO for persons carrying the BRCA-mutated gene; GENESIS for the research of new genes with an increased risk for breast cancer, COVAR project to validate the variants VUS of the BRCA gene; OFELy observatory for Lynch Syndrome) and to working on international consortia (cohort IBCCS, consortium CIMBA), with a total of 11 publications in 2015 of which two concerned SHS (ancillary project within the GENEPSO cohort) and three linked to the GENESIS study. To date, more than 3,000 persons carrying the BRCA1/2 mutations are included in GENEPSO and will be followed for a minimum of ten years. The OFELy observatory contained, at the end of 2015, 813 families that are carriers of a mutation of a MMR gene. In 2015, the inclusions were completed for the LIFSCREEN study (use of total body MRIs in Li-Fraumeni syndrome), the follow-up phase was continued for women included in the LIBER study (testing an anti-aromatase in prevention of breast cancer in women with a mutated BRCA gene), and the financing was obtained for the TUMOSPEC project, dealing with the estimation of the tumor risk of new genes with predisposition to breast or ovarian cancer in the panel analyzed by Next-Generation Sequencing (NGS), project to be initiated in 2016.

Administration
ggc@unicancer.fr

President
Catherine NOGUÈS
Curie Institute - Paris/Saint-Cloud
+33 (0)1 47 11 15 01
catherine.nogues@curie.fr

Secretaries
Christine LASSET
Léon Bérard Center, Lyon
+33 (0)4 78 78 27 52
christine.lasset@lyon.unicancer.fr

Catherine DUGAST
Eugène Marquis Center, Rennes
+33 (0)2 99 25 31 40
c.dugast@rennes.unicancer.fr

Pascaline BERTHET
François Baclesse Center, Caen
+33 (0)2 31 45 51 65
p.berthet@baclesse.fr

Pascal PUJOL
Arnaud de Villeneuve Hospital, Montpellier
+33 (0)4 67 33 07 04
p-pujol@chu-montpellier.fr

Cancer Biostatistics Group

Presentation

The Cancer Biostatistics Group is composed by around 90 members working in the FCCC. It plays an important role in the conception and valorization of clinical research projects from protocols to publications. Several members of the group are the referent statisticians for the organ groups at UNICANCER and a member is part of the UNICANCER protocol review committee. The group, which meets twice a year during winter and at spring, reunites methodologists, biostatisticians and epidemiologists within and beyond the Centers.

Events

In 2015, the winter meeting — with 35 participants — was held in Paris where common projects and internal procedures of the group were discussed. The spring or annual statisticians meeting, which is jointly organized with EPICLIN (Francophone Conference of Clinical Epidemiology) took place from the 20 to 22nd of May 2015 in Montpellier. The 2015 edition was a tremendous success with more than 200 participants and a rich program, with international speakers on topics such as Bayesian methods for clinical trials, health economics of stratified medicine, pharmaco-epidemiology and big data, and offering a platform for clinical research for less developed countries. The 2016 edition will be held in Strasbourg. Methodological seminars are held annually in the different Centers and the group organizes courses and workshop in biostatistics, health economics and data management (e.g. a workshop on meta-analysis was organized in 2015). The group also conducts its own methodological research, animated by taskforces (phase I, endpoints, biomarkers, etc) essentially in the context of labelled research environments by Universities, INSERM and INCa. This research leads each year to numerous publications as first or last authors and to the supervisions of Master, PhD and postdoctoral students. Most of the research programs use data generated by the FCCC or cooperative groups; and contributes to the valorization of completed clinical trials.

President
Stefan MICHIELS
stefan.michiels@gustaveroussy.fr

Vice-President
Sophie GOURGOU
sophie.gourgou@icm.unicancer.fr

Vice-President
Xavier PAOLETTI
xavier.paoletti@gustaveroussy.fr

Group for the Evaluation of Immunohistochemical Prognostic Factors in Breast Cancer (GEFPICS)

Presentation

The GEFPICS group brings together pathologists and cytogeneticists experienced in breast pathology, from institutions (FCCC, public and university hospitals, private laboratories) all over France, Belgium (Liège and Gosselies), Switzerland (Lausanne), and Canada (Québec). Supported by UNICANCER, the group (40 members) meets twice a year not only to share experience and best practices in breast pathology (regularly published in guidelines from the GEFPICS), but also to brainstorm translational research studies or clinical trials. The GEFPICS group has published several updated guidelines on HER2 scoring and for the pre-analytical stage for biomarker assessment in breast cancer (Ann Pathol 2014). The group is also involved in the AFAQAP quality program.

Significant milestone

Several projects were initiated by the end of 2015: a national retrospective database for equivocal HER2 cases, retrospective study on chromosome 17 monosomy, and a study on tumor infiltrating lymphocytes assessment following the international published guidelines. Finally, the GEFPICS group provides strong support for development and completion of the pathology part of UNICANCER clinical trials (central collection construction and review, protocol writing, and breast pathology expertise).

GEFPICS coordinating pathologist
Dr. Magali LACROIX-TRIKI, MD PhD, Pathology Department, Gustave Roussy Institute, Villejuif
Magali.lacroix-triki@gustaveroussy.fr

Prevention of Infections in Cardiology Group (GPIC)

Presentation

The GPIC is a multicenter collaborative group, established in 2007 to integrate the combat against health care associated infections within the global care of the patient. It is open to all of the operational hygiene teams in the FCCC: hygiene practitioners, microbiologists, hygiene nurses, bio-hygienist technicians, infectious diseases specialists, risk-management quality controllers and coordinators of the risk associated with health care. The dynamism of the GPIC is based on the diversity of its members in terms of area of interest and profession.

Goals

The objective of the GPIC is to unite competence and experience to more effectively diminish health care associated infections in FCCC patients and to improve the diagnosis and treatment of these infections. Defining common prevention strategies, diagnostics and therapies, as well as choosing indicators is part of the GPIC objectives.

Significant milestone

In 2015, four meetings "Hygiene and prevention of risk of infection" brought together 66 members from the 17 FCCC. The principal work focused on the evaluation of occupational practices concerning surgical site infections and prosthetic breast surgery, with the objective of identifying the specific risk factors for breast reconstruction in the oncology context and the interest in identifying/decolonizing of Staphylococcus aureus. The participation of nine FCCC allowed the development of a cohort of 1,013 patients. A clinical research project "Surgical site infections and prosthetic breast surgery" was presented to UNICANCER's Strategic Research Committee. The GPIC participates in the formal consensus of experts "protective isolation" of the French Society for Hospital Hygiene (D. Vanjak).

PROPIAS, the national program for the prevention of infections associated with health care, was published in June 2015: the GPIC contributed to the work piloted by the DGOS (French General Directorate on Health Care Services) (P. Berger and B. Tequi). The GPIC's work on the correct use of antibiotics consisted of three meetings in 2015, a training workshop on the epidemiological surveil-lance and treatment strategy for difficult Staphylococcus aureus, opened to non-GPIC members. All the FCCC participated in the collection of data concerning the antibiotics consumed, allowing the comparison by type of activity for 2013 and 2014.

Administration
gpic@unicancer.fr

President
Pierre BERGER
Paoli-Calmettes Institute, Marseille

Secretary
Brigitte TEQUI
Institute of Cancer Research in Western France, Angers-Nantes

Board Members
Martine SIMON
Léon Bérard Center, Lyon

Dominique VANJAK
Curie Institute, Paris/ Saint-Cloud

R&D UNICANCER
Christophe JAMAIN

Appendices

Table of upgraded trials

Localization	Study Title	Phase	Status on the 12/31/2015	Tumor group
Breast cancer – Metastatic setting	**GRT 01 - SAFIR 01** High throughput technologies to drive breast cancer patients to specific phase I/II trials of targeted agents (SAFIR01)	II	Follow-up	UCGB
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	Cohort	Inclusion	UCGB
Breast cancer – Ductal carcinoma	**IBIS II** Adjuvant tamoxifen compared with anastrozole in treating post-menopausal women with ductal carcinoma in situ (IBIS-II DCIS)	III	Follow-up	UCGB
Breast cancer – Locally advanced or metastatic stage	**CADUSEIME 02 - AMA** Phase II trial evaluating the activity of abiraterone acetate plus prednisone in patients with a molecular apocrine HER2-negative locally advanced or metastatic breast cancer	II	Follow-up	UCGB
Breast cancer – Locally advanced stage	**CADUSEIME 03 - SAKK - PERNETTA** 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	II	Inclusion	UCGB
Breast cancer – Localized stage	**CANTO** Cohort to quantify and to predict treatment related chronic toxicities in patients with non-metastatic breast cancer	Cohort	Inclusion	UCGB
Breast cancer – Localized stage – Neoadjuvant treatment	**CARMINA 02 - NIMFEA** Randomized multicenter phase II study identifying hormone sensitivity profiles and evaluating the efficacy of anastrozole and fulvestrant in the neoadjuvant treatment of operable breast cancer in post-menopausal women	II	Follow-up	UCGB
Breast cancer – BRCA mutations – Prevention	**ONCO 03 - LIBER** Prevention of breast cancer by letrozole in post-menopausal women carrying a BRCA1/BRCA2 mutation	Prevention	Follow-up	UCGB
Breast Cancer – Non metastatic lymph node-positive	**PACS 01** Phase III study evaluating the benefit of docetaxel given sequentially with FEC 100 chemotherapy treatment in axillary lymph node-positive early breast cancer	III	Follow-up	UCGB
Breast cancer – Non metastatic stage with positive lymph nodes	**PACS 04** Randomized, 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	III	Follow-up	UCGB
Breast cancer – Non metastatic stage	**PACS 05** Phase III randomized study of adjuvant fluourouracil, epirubicin and cyclophosphamide, in women with stage I breast cancer	III	Follow-up	UCGB
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): 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	-	Follow-up	UCGB
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.	III	Follow-up	UCGB
Inflammatory Breast Cancer	**PACS 09 - BEVERLY 1** Phase II study evaluating the efficacy and tolerance of bevacizumab (Avastin®) in HER2- inflammatory breast cancer	II	Follow-up	UCGB
Breast Cancer – Non metastatic stage – ER+/Her2 – with poor prognostic	**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 three years of adjuvant hormone therapy	III	Inclusion	UCGB
Breast Cancer – Prevention	**PREV 01 - MAP 3** A phase III randomised study of exemestane versus placebo in post-menopausal women at increased risk of developing breast cancer	III	Follow-up	UCGB
Breast Cancer – Non metastatic stage	**RTS 01 - YOUNG BOOST** Radiation dose intensity study in breast cancer in young women: randomized phase III trial of additional dose to the tumor bed	III	Follow-up	UCGB
Breast cancer – Non metastatic stage – low risk of local recurrence	**RTS 02 - SHARE** Multicentric, phase III trial comparing accelerated partial breast irradiation (APBI) versus standard or hypofractionated whole breast irradiation in low risk of local recurrence of breast cancer	III	Follow-up	UCGB

Localization	Study Title	Phase	Status on the 03/31/2015	Tumor group
Breast Cancer – Luminal - Neoadjuvant	**NEOPAL-CARMINA 04** 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 post-menopausal women	II	Inclusion	UCGB
Breast Cancer – Localized stage	**PACS 12 / RX-PONDER** 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: clinical trial Rx for positive node, endocrine responsive breast cancer	III	Inclusion	UCGB
Breast cancer – ER+, HER2-	**PACS 14 - ADENDOM** Prospective multicenter study assessing EndoPredict® (EPclin) genomic test impact on shared decision of adjuvant chemo-therapy in patients with ER-positive, Her2-negative early breast cancer with uncertainty on the indication of chemotherapy using standard assessments	Cohort	Inclusion	UCGB
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	III	Follow-up	FEDEGYN
Ovarian cancer – Relapse stage	**FEDEGYN 02 - CHIPOR** Phase III randomized study evaluating Hyperthermic Intra-Peritoneal Chemotherapy (HIPEC) in the treatment of relapse ovarian cancer	III	Inclusion	FEDEGYN
Rectal Cancer – Neoadjuvant treatment	**ACCORD 12** Randomized, phase III trial comparing in a preoperative schedule the result of two concurrent chemoradiation schemes (45 Gy + capecitabine vs 50 Gy + capecitabine - oxaliplatin) on the rate of sterilization of the operative specimen in resectable rectal carcinomas T3-4 N0-2 M0	III	Study completed	UCGI
Cancer colorectal – 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	III	Follow-up	UCGI
Biliary tract cancers – Non metastatic stage – Surgical resection	**ACCORD 18 - PRODIGE 12** Randomized, multicenter, phase III study comparing the effect of adjuvant chemotherapy for six months with gemcita-bine-oxaliplatin 85 mg/m2 (GEMOX 85) to observation in patients who underwent surgery for cancer of the bile ducts	III	Follow-up	UCGI
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	II	Follow-up	UCGI
Colorectal cancer – metastatic stage – Liver metastases	**ACCORD 21 - PRODIGE 14 (METHEP)** Randomized, multicentric, phase II 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	II	Follow-up	UCGI
Colorectal cancer – Metastatic stage – wtKRAS	**ACCORD 22 - PRODIGE 18** Randomized, multicentric, phase II 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	II	Follow-up	UCGI
Rectal cancer – Locally advanced stage – Neoadjuvant treatment	**UCGI 23 - PRODIGE 23** Randomized, phase III study comparing preoperative chemoradiotherapy alone versus neoadjuvant chemotherapy with folfirinox regimen followed by preoperative chemoradiotherapy for patients with resectable locally advanced rectal cancer	III	Inclusion	UCGI
Pancreatic cancer – Non metastatic stage – Adjuvant treatment – Surgical resection	**ACCORD 24 - PRODIGE 24** Randomized, multicentric, phase III trial comparing adjuvant chemotherapy with gemcitabine versus 5-fluorouracil, leucovorin, irinotecan and oxaliplatin (mFolfirinox) in patients with resected pancreatic adenocarcinoma	III	Inclusion	UCGI
Colorectal cancer – Metastatic stage – wtKRAS	**UCGI 25** Randomized, multicentric, 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	II	Follow-up	UCGI
Colorectal cancer – Metastatic stage – wtRAS	**PRODIGE 28 - UCGI 27 (TIME)** Randomized phase II study of first-line FOLFIRI plus cetuximab for eight cycles followed by either single-agent cetuximab as maintenance therapy or observation in patients with wild-type KRAS and NRAS metastatic colorectal cancer	II	Inclusion	UCGI
Pancreatic Cancers – Locally advanced stage	**PRODIGE 29 - UCGI 26 (NEOPAN)** Randomized phase III trial comparing chemotherapy with folfirinox to gemcitabine in locally advanced pancreatic carcinoma	III	Inclusion	UCGI

Localization	Study Title	Phase	Status on the 03/31/2015	Tumor group
Multiple localisations – Advanced stage	**GEP 07 - PACIFIK** Open-label, dose escalation, pharmacokinetic, phase I study with pazopanib in combination with cisplatin (CDDP) every three weeks in patients with advanced solid tumors	I	Follow-up	GEP
Head and Neck squamous cell carcinoma – Non metastatic – Preoperative treatment	**GEP 11 - PREDICTOR** Randomized, multicentric, phase II study of preoperative 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	II	Follow-up	GEP
Prostate cancer – Biological relapse	**GEP 12 - CARLHA** Safety and efficacy radiotherapy combined with a six-months LH-RH agonist and abiraterone hormone therapy treatment in biochemically-relapsing prostate cancer following surgery	I/II	Inclusion	GEP
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	II	Inclusion	GEP
Breast cancer – Adjuvant treatment – 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 French UNICANCER Geriatric Oncology Group (GERICO) and Breast Group (UCBG) phase III multicentre trial	III	Inclusion	GERICO
Rectal cancer – Neoadjuvant treatment	**GERICO 12 (UCGI)** Phase III study evaluating two neoadjuvant treatments radiochemotherapy (five weeks - 50gy+capecitabine) and radiotherapy (one week - 25gy) in patient over 75 with locally advanced rectal carcinoma	III	Inclusion	GERICO
Head and neck squamous cell carcinoma	**ELAN ONCOVAL (GORTEC)** Epidermoid cancer of the head and neck GERICO-labelled trial. Trial of a simplified geriatric evaluation carried out by oncologists before oncologic treatment with radiotherapy or chemotherapy in subjects over 70 with an inoperable epidermoid cancer of the head and neck.	Cohort	Inclusion	GERICO
Prostate cancer – localized 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)	III	Follow-up	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	III	Follow-up	GETUG
Non-seminomatous germ cell tumors – Poor prognostic	**GETUG 13** Risk-adapted strategy of the use of dose-dense chemotherapy in patients with poor-prognosis disseminated non-seminomatous germ cell tumors	III	Follow-up	GETUG
Prostate cancer – Localized 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	III	Follow-up	GETUG
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	III	Follow-up	GETUG
Prostate cancer – Localized stage	**GETUG-AFU 17** Randomized, multicenter study comparing the immediate adjuvant radiotherapy associate with hormonal therapy of LH-RH analogue (decapeptyl® LP) versus 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	III	Inclusion	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	III	Follow-up	GETUG
Bladder cancer – Advanced stage	**GETUG-AFU 19** Randomized, phase II study of 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	II	Follow-up	GETUG
Prostate cancer – Localized stage – High risk of recurrence	**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.	III	Inclusion	GETUG
Prostate cancer – Metastatic stage	**AFU-GETUG 21/PEACE1** Prospective randomized phase III study of androgen deprivation therapy ± local radiotherapy with or without abiraterone acetate and prednisone in patients with metastatic hormone-naïve prostate cancer.	III	Inclusion	GETUG

Localization	Study Title	Phase	Status on the 03/31/2015	Tumor group
Prostate cancer – Localized stage – Detectable PSA	**GETUG-AFU 22** Randomized, multicenter, phase II study comparing the efficiency of a HT concomitant with RT versus RT alone in the salvage of patients with a detectable PSA after prostatectomy	II	Follow-up	GETUG
Prostate cancer – Localized stage – High risk of recurrence	**GETUG-AFU 23/PEACE 2** Randomized phase III factorial design of cabazitaxel and pelvic radiotherapy in patients with localized prostate cancer and high-risk features of relapse	III	Inclusion	GETUG
Metastatic Collecting Duct Carcinoma	**GETUG-AFU 24 BEVABEL** Prospective phase II study of gemcitabine plus platinium salt in combination with bevacizumab (Avastin®) for metastatic collecting duct carcinoma	II	Inclusion	GETUG
Tonsillar and basal lingual carcinomas	**ORL 01 - HPV ORO** Evaluation of the frequency of Human Papilloma Virus infections in tonsillar and basal lingual carcinomas	II	Follow-up	Head&Neck group
Salivary gland cancer – Relapse or metastatic stage	**ORL02 - PACSA** Phase II study of pazopanib in patients with recurrent and/or metastatic salivary gland carcinoma of the head and neck	II	Follow-up	Head&Neck group
Multiple localizations – Metastatic stade	**ACSE CRIZOTINIB** Secured access to crizotinib for patients with tumors harboring a genomic alteration on one of the biological targets of the drug	II	Inclusion	MED PERSO
Multiple locations – Metastatic or unresctable locally advanced	**ACSE VEMURAFENIB** Secured access to vemurafenib for patients with tumors harboring BRAF genomic alterations	II	Inclusion	MED PERSO
Breast cancer – Metastatic stage	**SAFIR 02 / BREAST** Evaluation of the efficacy of high throughput genome analysis as a therapeutic decision tool for patients with metastatic breast cancer	II	Inclusion	MED PERSO
Non small cell lung cancer – Metastatic stage	**SAFIR 02 / LUNG** Evaluation of the efficacy of high throughput genome analysis as a therapeutic decision tool for patients with metastatic non small cell lung cancer	II	Inclusion	MED PERSO
Breast cancer metastatic	**SAFIRTOR** Neoadjuvant phase II trial combining [3 FEC 100 followed by 3 docetaxel associated with trastuzumab plus pertuzumab] or [6 docetaxel, carboplatin associated with trastuzumab plus pertuzumab] according to TOP2A status in patients with T1c operable, HER2-positive breast cancer	II	Inclusion	MED PERSO
Breast cancer metastatic	**RUBY** Single arm, open-label, phase II study to assess the efficacy of rucaparib in metastatic breast cancer patients with a BRCAness genomic	II	Inclusion	MED PERSO
Breast cancer metastatic	**SARCOME 01 - EURO EWING** Treatment protocol for Ewing tumors : including a medico economic evaluation	I-II	Follow-up	SARCOME
Breast cancer metastatic	**SARCOME 09 - OS 2006** Intergroup Study (SFCE/GSF-GETO) OS2006 - Zoledronate osteosarcoma - treatment protocol for osteosarcoma of the child , adolescent and adult including: randomized trial and biological studies	III	Follow-up	SARCOME
GIST - Localized stage – High and intermediate risk	**SARCOME 08 - EORTC 62024** Intermediate and high risk localized, completely resected, gastro-intestinal stromal tumors (GIST) expressing KIT receptor: controlled, randomised trial on adjuvant imatinib mesylate (Glivec) versus no further therapy after complete surgery	III	Follow-up	SARCOME
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	II	Inclusion	SARCOME
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	II	Inclusion	SARCOME

Communications R&D UNICANCER

Group	Study	Congress	Title	Authors	Type of presentation
UCBG	CARMINA03	SNMMI	Early metabolic response assessment to neoadjuvant endocrine treatment in ER+, HER2- breast cancer: comparison to the morphological and pathological response.	S. Boughdad, L. Champion, V. Becette, P. Cherel, E. Fourme, V. Edeline, J. Lemonnier, F. Lerebours, J.-L. Alberini	Poster
UCBG	PACS09	AACR	Circulating Tumor Cells (CTC) but not Circulating Endothelial Cells (CEC) are independent prognostic factors in neoadjuvant chemotherapy combined with bevacizumab in HER2 negative inflammatory breast cancer (IBC) in multicentre phase II trial BEVERLY1	J.-Y. Pierga, F.-C. Bidard, A. Autret, F. Andre, T. Petit, F. Dalenc, C. Levy, W. Jacot, J. Bonneterre, J.-M. Ferrero, P. Kerbrat, J. Lemonnier, F. Bertucci, P. Viens	Poster
UCBG	PACS09	ASCO	Circulating Tumor Cells (CTC) and pathological complete response (pCR) are strong independent prognostic factors in inflammatory breast cancer (IBC) in a pooled analysis of two multicenter phase II trials of neoadjuvant chemotherapy combined with bevacizumab (BEVERLY 1/2 studies)	J. Y. Pierga, F. C. Bidard, A. Autret, T. Petit, F. Andre, F. Dalenc, C. Levy, J. M. Ferrero, G. Romieu, J. Bonneterre, F. Lerebours, T. Bachelot, P. Kerbrat, E. Charafe-Jauffret, J. Lemonnier, P. Viens	Oral presentation
UCBG	PACS 08	SABCS	UCBG intergroup: three-years efficacy results of the UNICANCER-PACS08 trial including poor-prognosis patients treated with docetaxel or ixabepilone in adjuvant setting	M. Campone, M. Lacroix-Triki, L. Roca, M. Spielmann, H. Wildiers, P. Cottu, P. Kerbrat, C. Levy, F. Mayer, T. Bachelot, T. Winston, J.-C. Eymard, L. Uwer, J.-P. Machiels, D. Verhoeven, D. Jaubert, T. Facchini, H. Orfeuvre, J.-L. Canon, B. Asselain, J. Lemonnier, H. Roché	Poster
UCBG	IBIS 2	SABCS	Anastrozole versus tamoxifen for the prevention of loco-regional and contralateral breast cancer in post-menopausal women with locally excised Ductal Carcinoma In-Situ (IBIS-II DCIS)	J. F. Forbes, I. Sestak, A. Howell, B. Bonanni, N. Bundred, C. Levy, G. von Minckwitz, P. Neven, M. Stierer, C. Holcombe, R. E. Coleman, L. Jones, I. Ellis, J. Cuzick	Oral presentation
UCBG	AMA	EBCC	Results of a phase II trial of abiraterone acetate plus prednisone in patients with a molecular apocrine HER2-negative locally advanced or metastatic breast cancer (UCBG 2012-1)	T. Grellety, H. Bonnefoi, O. Tredan, F. Dalenc, P. Cottu, A. Mailliez, M. Saghatchian, S. Abadie-Lacourtoisie, T. L'Haridon, F. Del Piano, I. Desmoulins, F. Coussy, J. Dauba, J. Grenier, M.Mousseau, G. MacGrogan, C. Orsini, M. Pulido A. Goncalves	
GETUG	GETUG-AFU 15	ASCO Genitourinary Cancers Symposium (February 26-28, 2015)	Androgen deprivation therapy (ADT) plus docetaxel (D) versus ADT alone for hormone-naïve metastatic prostate cancer (PCa): long-term analysis of the GETUG-AFU 15 phase III trial	G. Gravis, J-M. Boher, F. Joly, S. Oudard, L. Albiges, F. Priou, I. Latorzeff, R. Delva, I. Krakowski, B. Laguerre , F . Rolland, C. Théodore, G. Deplanque, J-M. Ferrero, D. Pouessel, L. Mourey, P. Beuzeboc, M. Habibian, M. Soulie K. Fizazi	Oral presentation
GETUG	GETUG-AFU 15	ESMO 2015	Clinical outcome of newly diagnosed metastatic hormone sensitive prostate cancer (HSPC), in real life, population from a single center: comparison with newly diagnosed metastatic HSPC patients included in the GETUG-AFU 15 trial	M. Guerin, Sfumato, J.-M. Boher, N. Salem, S. Dermeche, J. Thomassin, K. Fizazi, F. Joly, S. Oudard, M. Habibian, S. Culine, J. Walz, G. Gravis	Poster
GETUG	GETUG-AFU 16	ASCO Annual Meeting (May 29 - June 2nd, 2015)	Interest of short hormonotherapy (HT) associated with radiotherapy (RT) as salvage treatment for biological relapse (BR) after radical prostatectomy (RP): results of the GETUG-AFU 16 phase III randomized trial	C. Carrie, A. Hasbini, G. Delaroche, M. Habibian, P. Richaud, S. Guerif, I. Latorzeff, S. Supiot, M. Bosset, J. L. Lagrange, V. Beckendorf, F. Lesaunier, B. Dubray, J. P. Wagner, T. D. N'guyen, J. P. Suchaud, G. Crehange, N. Barbier, A. Ruffion, S. Dussart	Oral presentation
GETUG	GETUG 01	Annual Meeting October 18-21st	Is there a role for pelvic irradiation in localized prostate adenocarcinoma? final results of the GETUG 01 randomized study	P. Pommier, S. Chabaud, J. L. Lagrange, P. Richaud, E. Le Prise, J. P. Wagner, M. H. Hay, V. Beckendorf, J. P. Suchaud, V. Bernier, D. Perol, C. Carrie	Oral presentation
GETUG	GETUG-AFU 18	ASTRO	Randomized phase III trial of dose escalation (80 vs 70 Gy) in high-risk prostate cancers combined with long-term androgen deprivation – GETUG-AFU 18 trial- Acute and one-year toxicities	C. Hennequin, P. Richaud, L.Roca, M. Silva, I. Latorzeff, V. Beckendorf, C. Carrie, A. Benyoucef, A. Hasbini, S. Supiot, P. Ronchin, T. Wachter, D. Azria, P.E. Cailleux, L.Cormier, M. Habibian, G. Delaroche	Oral presentation
GETUG	GETUG 15	ESMO	Androgen-deprivation therapy plus docetaxel versus androgen-deprivation therapy alone in metastatic non-castrate prostate cancer: impact of metastatic burden and long-term survival analysis of the randomized phase III GETUG-AFU 15 trial	G.Gravis, J-M.Boher, F.Joly, S.Oudard, L.Albiges, F.Priou, I.Latorzeff, R.Delva, I.Krakowski, B.Laguerre , F .Rolland, C.Théodore, G.Deplanque, J-M .Ferrero, D.Pouessel, L.Mourey, P.Beuzeboc, M.Habibian, M.Soulie and K.Fizazi	Poster
GERICO	GERICO 11	SIOG	Aster 70s or optimal adjuvant treatment for women over 70 with luminal breast cancer : a UNICANCER phase III trial	F. Coussy, E. Bourbouloux, O. Mir, O. Rigal, S. Kirscher, J.-M. Ferrero, E. Blot, D. Allouache, H. Cure, P., Cottu , G. Romieu, E. Malaurie, N. Tubiana-Mathieu, C. Lefeuvre, F. Duhoux, M. Lacroix-Triki, F. Rollot, G. Rochette de Lempdes, H. Peyro-Saint-Paul, C. Orsini, C. Dubot, F. Bonnetain, E. Brain	Poster

Group	Study	Congress	Title	Authors	Type of presentation
MED PERSO	ACSé-crizotinib	WCLC	Activity of crizotinib in MET amplified NSCLC: Preliminary results of the AcSé trial.	D. Moro-Sibilot, M.C. Le Deley, G. Zalcman, S. Bota, R. Sabatier, P.J. Souquet, L. Favier, M. Poudenx, P. Bombaron, C. Audigier-Valette, P. Bernard, P. Foucher, N. Girard, J.-P. Merlio, L. Arnould, G. Ferretti, T. Mortier, E. Lonchamp, G. Vassal, C. Mahier - Ait Oukhatar	Oral presentation
MED PERSO	ACSé-crizotinib	ASCO	Activity of crizotinib in relapsed MET amplified malignancies: Results of the French AcSé Program	G. Vassal, MC Le Deley, C. Tournigand, T. Aparicio, I.Ray-Coquard, L. Taillandier, B. Escudier, B. You, A. Gonçalves, C. Lombard-Bohas, J.F. Seitz, T. André, J.P. Merlio, L. Arnould, G. Ferretti, Y. Menu, T. Mortier, E. Lonchamp, C. Mahier-Aït-Oukhatar, D. Moro-Sibilot	Poster
MED PERSO	ACSé-crizotinib	WCLC	Crizotinib in patients with ROS1 NSCLC: preliminary results of the AcSé trial	D. Moro-Sibilot, L. Faivre, G. Zalcman, M. Perol, J. Mazières, F. Barlesi, J. Otto, I. Monnet, A. Cortot, M. Wislez, H. Léna, P.J. Souquet, S. Lantuejoul, I. Rouquette, A. McLeer-Florin, G. Ferretti, N. Hoog-Labouret, F. Nowak, M. Jimenez, G. Vassal	Oral presentation
MED PERSO	ACSé-crizotinib	ASCO	Crizotinib in patients with advanced ROS1-rearranged non small cell lung cancer (NSCLC): preliminary results of the ACSé phase II trial	D. Moro-Sibilot, L. Faivre, G. Zalcman, M. Pérol, F. Barlesi, J. Otto, I. Monnet, A. B. Cortot, M. Wislez, H. Lena, J. Mazières, X. Durando, S. Lantuejoul, I. Rouquette, A. McLeer Florin, G. Ferretti, N. Hoog Labouret, F. Nowak, M. Jimenez, G. Vassal	Poster
MED PERSO	ACSé Crizo	ECCO-ESMO	Biomarker-driven access to crizotinib In ALK, MET or ROS1 positive malignancies in adults and children: the French AcSé Program	G. Vassal, D. Moro Sibilot, M.-C. Le Deley, N. Hoog-Labouret, F. Nowak, M. Jimenez, C. Tournigand, R. Houot, D. Malka, T. Aparicio, B. Escudier, I. Ray Coquard, Y. Godbert, L. Taillandier, I. Bièche, S. Lantuejoul, G. Ferretti, Y. Menu, J.-Y. Blay, A. Buzyn	Oral presentation
HEAD& NECK	ORL 03	ESMO	Cabazitaxel in patients with refractory recurrent or metastatic (R/M) squamous cell carcinoma of the head and neck (SCCHN): final results of phase II Trial ORL 03 UNICANCER	J. Fayette, J. Guigay, C. Le Tourneau, M. Degardin, F. Peyrade, F. Orlandini, K. Buffard, C. Bellera	Oral presentation
UCBG	CARMINA02	SNMMI	Early metabolic response assessment to neoadjuvant endocrine treatment in ER+, HER2- breast cancer: comparison to the morphological and pathological response.	S. Boughdad, L. Champion, V. Becette, P. Cherel, E. Fourme, V. Edeline, J. Lemonnier, F. Lerebours, J.-L. Alberini	Poster
GEP	GEP04- RADHER	36th EORTC-PAMM Winter Meeting	ALTERATION OF THE TUMOR SIGNALING PATTERN IN HER2-POSITIVE BREAST CANCER TREATED BY PREOPERATIVE TRASTUZUMAB - EVEROLIMUS	M. Lion, J. Wong, T. Bachelot, F. André, I. Treilleux, D. Loussouarn, J. Bonneterre, M. Rios, V. Diéras, M. Jimenez, A. Leroux, M. Campone, J.-L. Merlin	Oral presentation
FEDEGYN	CHIPOR	ESGO 2015	Hyperthermic intraperitonela chemotherapy (HIPEC), a promising treatment for relapsed intraperitoneal ovarian cancer –CHIPOR, an ongoing phase III, european multicentric randomized trial	J.-M. Classe, L. Campion, P. Meeus, F. Quenet, E. Leblanc, G. Lorimier, G. Ferron, G. Houvenaeghel, S. Gouy, F. Marchal, B. Baranger, F. Lecuru, M. Pocard, F. Guyon, S. Durand-Fontainer, J. José Torrent, T. Stanbury, O. Glehen	Poster
UCGI	Prodige 17- Accord 20 (MEGA)	ASCO 2015	Folfox alone or combined to rilotumumab or panitumumab as first-line treatment in patients (PTS) with advanced gastroesophageal adenocarcinoma (AGEA): an open-label, randomized phase II trial (Prodige 17 Accord 20 MEGA)	D. Malka, F. Castan, E. François, O. Bouché, J. Bennouna, F. Ghiringhelli, C. De La Fouchardière, C. Borg, E. Samalin, J.-B. Bachet, J.-L. Raoul, F. Cvitkovic, L. Miglianico, L. Bengrine-Lefèvre, L. Dahan, C. Lécaille, T. Aparicio, H. Perrier, S. Gourgou, J. Taïeb	Poster

Publications R&D UNICANCER

Group	Study	Title	Authors	Reference
UCBG	PEGASE07	UNICANCER-PEGASE 07 study: a randomized phase 3 trial evaluating post-operative docetaxel-5FU regimen after neoadjuvant high-dose chemotherapy for treatment of inflammatory breast cancer	A. Gonçalves, J.-Y. Pierga, J.-M. Ferrero, M.-A. Mouret-Reynier, T. Bachelot, R. Delva, M. Fabbro, M. Janvier, Pr. J.-P. Lotz, C. Linassier, N. Dohollou, J.-C. Eymard, B. Leduc, J.Genève, A.-L. Martin, J.-M. Boher, P. Viens, H. Roché	Ann Oncol. 2015 Aug;26(8):1692-7
UCBG	PACS08	Co-expression of androgen receptor and FOXA1 in non-metastatic triple-negative breast cancer: ancillary study from UNICANCER-PACS08 multicenter trial	S. Guiu, C. Charon-Barra, D. Vernerey, P. Fumoleau, M. Campone, M. Spielmann, H. Roché, C. Mesleard, L. Arnould, J. Lemonnier, M. Lacroix-Triki	Future Oncol. 2015;11(16):2283-97
UCBG	IBIS II	Anastrozole versus tamoxifen for the prevention of loco-regional and contralateral breast cancer in post-menopausal women with locally excised Ductal Carcinoma In-Situ (IBIS-II DCIS)	J. F. Forbes, I. Sestak, A. Howell, B. Bonanni, N. Bundred, C. Levy, G. von Minckwitz, W. Eiermann, P. Neven, M. Stierer, C. Holcombe, R. E. Coleman, L. Jones, I. Ellis, J. Cuzick on behalf of the IBIS-II Investigators (listed in Appendix)	Lancet 2015 Dec 11. pii: S0140-6736(15)01129-0
UCBG	TransPACS01-04	Combined evaluation of lc3b puncta and hmgb1 expression predicts residual risk of relapse after adjuvant chemotherapy in breast cancer.	S. Ladoire, F. Penault-Llorca, L. Senovilla, C. Dalban, D. Enot, C. Locher, N. Prada, V. Poirier-Colame, K. Chaba, L. Arnould, F. Ghiringhelli, P. Fumoleau, M. Spielmann, S. Delaloge, M. Laure Poillot, P. Arveux, A. Goubar, F. Andre, L. Zitvogel & G. Kroemer	Autophagy. 2015 Oct 3;11(10): 1878-90.
UCBG	CANTO	Validation of the French translation-adaptation of the impact of cancer questionnaire version 2 (IOCv2) in a breast cancer survivor population	M. Blanchin,corresponding author S. Dauchy, A. Cano, A. Brédart, N. K. Aaronson, and J.-B. Hardouin	Health Qual Life Outcomes. 2015; 13: 110. Published online 2015 Jul 29. doi: 10.1186/s12955-015-0301-x
GETUG	GETUG 12	Androgen-deprivation therapy plus docetaxel versus androgen-deprivation therapy alone in metastatic non-castrate prostate cancer: long-term survival analysis of the randomized phase III GETUG-AFU 15 trial	K. Fizazi, L. Faivre, F. Lesaunier, R. Delva, G. Gravis, F.Rolland, F. Priou, J.-M. Ferrero, N. Houede, L. Mourey, C. Theodore, I. Krakowski, J.-F. Berdah, M. Baciuchka, B. Laguerre, A. Fléchon, A. Ravaud, I. Cojean-Zelek, S. Oudard, J.-L. Labourey, P. Chinet-Charrot, E. Legouffe, J.-L. Lagrange, C. Linassier, G. Deplanque, P. Beuzeboc, J.-L.Davin, A.-L. Martin, M. Habibian, A. Laplanche, S. Culine	The Lancet Oncology. 2015, May 29; S1470 pp.1-8
GETUG	GETUG 12	Outcome according to elective pelvic radiotherapy in patients with high-risk localized prostate cancer: a secondary analysis of the GETUG 12 phase III randomized trial	P. Blanchard, L. Faivre, F. Lesaunier, N. Salem, N. Mesgouez-Nebout, E. Deniau-Alexandre, F. Rolland, J.-M.Ferrero, N. Houede, L. Mourey, C. Theodore, I. Krakowski, J.-F. Berdah, M. Baciuchka, B. Laguerre, J.-L. Davin, M. Habibian, S. Culine, A. Laplanche, K. Fizazi	Int J Radiation Oncol Biol Phys (2015) XX,XX, p.1-8 (printing)
GETUG	GETUG 15	Androgen-deprivation therapy plus docetaxel versus androgen-deprivation therapy alone in non-castrate metastatic prostate cancer: long-term survival analysis of the randomized phase III GETUG-AFU 15 trial	G. Gravis, J-M. Boher, F. Joly, S. Oudard, L. Albiges, F. Priou, I. Latorzeff, R. Delva, I. Krakowski, B. Laguerre , F. Rolland, C. Théodore, G. Deplanque, J-M. Ferrero, D. Pouessel, L.Mourey, P. Beuzeboc, M. Habibian, M. Soulie and K. Fizazi	European Urology 2015
GETUG	GEP 03 SUPAP	First-line treatment with sunitinib for type 1 and type 2 locally advanced or metastatic papillary renal cell carcinoma: a phase II study (SUPAP) by the French Genitourinary Group (GETUG)	A. Ravaud, S. Oudard, M. De Fromont, C. Chevreau, G. Gravis, S. Zanetta, C. Theodore, M. Jimenez, E. Sevin, B. Laguerre, F. Rolland, M. Ouali, S. Culine, B. Escudier	Ann Oncol. 2015 Jun;26(6):1123-8
GETUG		Definition of lymph node areas for radiotherapy of prostate cancer: a critical literature review by the French Genito-Urinary Group and the French Association of Urology (GETUG-AFU)	P. Sargos, S. Guerif, I. Latorzeff, C. Hennequin, P. Pommier, J.L. Lagrange, G. Créhange, O. Chapet, R. de Crevoisier, D. Azria, S. Supiot, M. Habibian, M. Soulié, P. Richaud	Cancer Treat Rev. 2015 Dec;41(10):814-20
GETUG		Prognostic factors for survival in noncastrate metastatic prostate cancer: validation of the glass model and development of a novel simplified prognostic model	G. Gravis, J.M. Boher, K. Fizazi, F. Joly, F. Priou, P. Marino, I. Latorzeff, R. Delva, I. Krakowski, B. Laguerre, J. Walz, F. Rolland, C. Théodore, G. Deplanque, J.M. Ferrero, D. Pouessel, L. Mourey, P. Beuzeboc, S. Zanetta, M. Habibian, J.F. Berdah, J. Dauba, M. Baciuchka, C. Platini, C. Linassier, J.L. Labourey, J.P. Machiels, C. El Kouri, A. Ravaud, E. Suc, J.C. Eymard, A. Hasbini, G. Bousquet, M. Soulie, S. Oudard	Eur Urol. 2015 Aug;68(2):196-204
SARCOME	SARCOME 01 EUROEWING	Impact of gender on efficacy and acute toxicity of alkylating agent-based chemotherapy in Ewing sarcoma: secondary analysis of the Euro-Ewing99-R1 trial	H. van den Berg, M. Paulussen, G. Le Teuff , I. Judson, H. Gelderblom, U. Dirksen, B. Brennan, J. Whelan, R. Lydia Ladenstein, P. Marec-Berard, J. Kruseova, L. Hjorth, T. Kuhne, B. Brichard, K. Wheatley, A. Craft, H. Juergens, N. Gaspar, M.-C. Le Deley	European Journal of Cancer (2015) Nov;51(16):2453-64

Group	Study	Title	Authors	Reference
UCGI	Accord 16	Low response rate after cetuximab combined with conventional chemoradiotherapy in patients with locally advanced anal cancer: long-term results of the UNICANCER ACCORD 16 phase II trial	A. Levy, D. Azria, J.P. Pignon, A. Delarochefordiere, I. Martel-Lafay, E. Rio, D. Malka, T. Conroy, L. Miglianico, Y. Becouarn, K. Malekzadeh, J. Leclercq, B. Juzyna, P. Ezra, C. Lemanski, E. Deutsch	Radiother Oncol. 2015 Mar;114(3):415-6. doi: 10.1016/j.radonc.2015.02.008. Epub 2015 Mar 11.
UCGI	ACCORD 12	Clinical complete response (CCR) after neoadjuvant chemoradiotherapy and conservative treatment in rectal cancer: findings from the ACCORD 12/PRODIGE 2 randomized trial	J.P. Gérard, E. Chamorey, S. Gourgou-Bourgade, K. Benezery, G. de Laroche, M.A. Mahé, V. Boige, B. Juzyna	Radiother Oncol. 2015 May;115(2):246-52. doi: 10.1016/j.radonc.2015.04.003. Epub 2015 Apr 24.
UCGI	ACCORD 11	Applying the longitudinal model from item response theory to assess the health-related quality of life in the PRODIGE 4/ACCORD 11 randomized trial	A. Barbieri, A. Anota, T. Conroy, S. Gourgou-Bourgade, B. Juzyna, F. Bonnetain, C. Lavergne, C. Bascoul-Mollevi	Med Decis Making. 2015 Dec 18. pii: 0272989X15621883. [Epub ahead of print]
MED PERSO	ACSé CRIZO	Equal access to innovative therapies and precision cancer care	A. Buzyn, J.Y. BLAY, N. Hoog-Labouret, M. Jimenez, F. Nowak, M.-C. Le Deley, D. Perol, C. Cailliot, J. Raynaud, G. Vassal	NRCO
MED PERSO	SAFIR01	Impact of centralization on a CGH-based genomic profiles for precision medicine in oncology	F. Commo, C. Ferté, J.C. Soria, S.H. Friend, F. André, J. Guinney	Ann Oncol. 2015 Mar;26(3):582-8. doi: 10.1093/annonc/mdu582. Epub 2014 Dec 23.

Inclusions per Group and per Center

The main contributor, in terms of recruitment, to UNICANCER clinical trials remains the Gustave Roussy Institute —with almost 20% of the enrolled patients—followed by the Curie Institute (13%). It should be noted that the participation of the FCCC in the Precison Medecine Programs has reached 10% in two years.

Establishment name	FEDEGYN	GEP	GERICO	GETUG	UCGI	SARCOMA	UCBG	*of which CANTO*	HEAD & NECK	MED PERSO	Overall total
Antoine Lacassagne Center		0	21	4	17	1	20	*7*	1	7	**71**
Eugène Marquis Center			13	6	0	0	9	*5*	0	10	**38**
François Baclesse Center	1	2	19	11	2	6	128	*85*	0	13	**182**
Georges-François Leclerc Center		0	5	8	0	1	243	*211*	0	11	**268**
Henri Becquerel Center			17	5		1	164	*140*		5	**192**
Jean Perrin Center	0	4	24	7		2	79	*72*	0	3	**119**
Léon Bérard Center	2	0	8	16	8	25	201	*161*	2	52	**314**
Oscar Lambret Center	2		9	1	9	12	178	*137*	0	18	**229**
Paul Strauss Center		2	13	0	9	0	19	*18*	0	2	**45**
Gustave Roussy Institute	0	7	52	27	16	22	437	*373*	1	87	**649**
Bergonié Institute	1	0	10	16	2	3	89	*69*		25	**146**
Claudis Regaud Institute	2	2	4	11	0	2	88	*41*		19	**128**
Curie Institute	0	2	65	9	0	18	341	*289*	3	29	**467**
Institute of Cancer Research in Western France	2	7	1	2	3	5	179	*172*	1	44	**244**
Lorraine Institute of Oncology (Alexis Vautrin Center)	6	2	24	24	32	0	126	*107*	0	1	**215**
Jean Godinot Institute	0		7	0	0	0	147	*118*	0	0	**154**
Paoli-Calmettes Institute	3		14	12	7	1	43	*40*		22	**102**
Montpellier Cancer Institute– Val d'Aurelle	1	2	15	2	8	3	94	*64*	1	5	**131**
Overall total	**20**	**30**	**321**	**161**	**113**	**102**	**2,585**	***2,109***	**9**	**353**	**3,694**

Contacts

Research Director
Christian Cailliot
c-cailliot@unicancer.fr

Clinical Operations Director
Carole Desseaux
c-desseaux@unicancer.fr

Medical Data and ESME Program Director
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
www.unicancer.fr

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