Going further, innovating together

R&D UNICANCER
Annual Report
2016

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Presentation and organisation

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.

Acteur majeur de la cancérologie française, UNICANCER regroupe les 20 Centres de lutte contre la cancérologie (CLCC), établissements de santé privés à but non lucratif exclusivement dédiés aux soins, à la recherche et à l'enseignement en cancérologie. R&D UNICANCER en tant que promoteur académique, travaille en direct avec les unités de recherche des CLCC et d'autres établissements de santé (CHU, CH, cliniques) en France et à l'international. R&D UNICANCER a pour mission la mise en œuvre de la stratégie globale de recherche menée par UNICANCER et est notamment chargé :

- 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 les connaissances sur le cancer pour un transfert rapide des innovations au lit du patient et une amélioration continue de sa prise en charge.

Editorials

Key programmes and significant results in 2016

By Alexander Eggermont,
UNICANCER Vice President responsible for research,
and Christian Cailliot, R&D UNICANCER Director

In 2016, some 5,400 patients were included (compared to 5,000 in 2015) in around forty open clinical trials conducted at a total of 270 sites, in France and beyond (20% of sites outside France). Ten new clinical trials were launched in 2016, including: ULTIMATE (UCBG), PANIRINOX (UCGI), EXPRESS (MedPerso), NIVOREN-GETUG 25 / GETUG 27 (GETUG) and COPANLISIB / EORTC 1206 (UCH&N), as well as the first two studies conducted by the UNITRAD group, created in 2015.

This increase in activity led to the reinforcement of R&D UNICANCER teams and the rationalisation of their working methods, both in order to meet the expertise needs of FCCC (French Comprehensive Cancer Centres) and to maintain and boost the appeal of R&D UNICANCER to research structures in France and internationally.

In addition, this year the real-world data platform known as the ESME programme (Epidemiology and Medico-Economic Strategy), launched a project focusing on ovarian cancers, following the project concerning metastatic breast cancer opened in 2014. In 2017, the ESME programme is expected to be extended to lung cancer and opened up to include other health institutions than FCCC.

One of the highlights of 2016 was the growth in joint projects with other French cancer research players; firstly in gastrointestinal oncology (official collaboration between UNICANCER UCGI, the FFCD (French-language Cancerology Federation) and GERCOR (multi-disciplinary cooperative group in the field of oncology), and secondly in head and neck cancers, between UNICANCER, UCH&N, GORTEC (group for head and neck oncology and radiotherapy), GETTEC (head and neck tumours study group) and GERCOR. The five UNICANCER tumour groups are now part of the intergroups recognised by INCa (French National Cancer Institute).

In addition, the links between R&D UNICANCER and its long-standing charitable partners – the Ligue Nationale contre le cancer (French Ligue Against Cancer) and the ARC Foundation – led to the launch of 3 trials in 2016, of major importance to patients in terms of equality of access to new therapies and the development of knowledge in the field of precision medicine: the two AcSé immunotherapy studies and the Express project (study of exceptional responders to targeted therapies).

Review of 2016 and outlook for 2017

By Patrice Viens,
UNICANCER President

2016 was a year of renewed growth in activities for R&D UNICANCER and cooperation with all the other health stakeholders involved in the fight against cancer – national and international, public and private, research scientists and clinicians, institutions and charities – and, of course, with patient associations. In addition to continuing to increase our professionalism and pool our resources in order to optimise the service we provide to CLCCs, R&D UNICANCER ambitions for 2017 include continuing to develop strategic academic research, in particular via the launch of new thematic groups, such as the immuno-oncology group, and seeking new alliances and collaborations, including with international groups. Everything we do must focus on our main strategic objective: to launch innovative and ambitious projects targeting the rapid transfer of "breakthrough" innovations to routine care, for the benefit of patients.

Christian Cailliot,
Director of R&D UNICANCER

Alexander Eggermont,
Vice-Président of UNICANCER
Research Representative

Éditoriaux

Programmes phares et résultats notables de l'année 2016

Par Alexander Eggermont, vice-président d'UNICANCER en charge de la recherche, et Christian Cailliot, directeur de R&D UNICANCER

En 2016, près de 5 400 patients ont été inclus (contre 5 000 en 2015) dans une quarantaine d'essais cliniques ouverts dans 270 centres au total situés en France et à l'étranger (pour 20 % d'entre eux). Dix nouveaux essais cliniques ont été lancés en 2016 dont : ULTIMATE (UCBG), PANIRINOX (UCGI), EXPRESS (MedPerso), NIVOREN-GETUG 25/GETUG 27 (GETUG), COPANLISIB/EORTC 1206 (UCH&N), mais aussi les deux premières études du groupe UNITRAD créé en 2015.

Pour répondre à cette augmentation de l'activité, les équipes de R&D UNICANCER ont été renforcées et les modes de fonctionnement rationalisés afin de répondre aux besoins d'expertise des CLCC, mais aussi afin de conserver et renforcer l'attractivité de R&D UNICANCER vis-à-vis des structures de recherche en France comme à l'étranger.

Par ailleurs, cette année également, la plateforme de données de vraie vie appelée programme ESME (Épidémiologie et Stratégie Médico-Économique) a lancé un projet dans les cancers de l'ovaire, après le cancer du sein métastatique ouvert en 2014. En 2017, le programme ESME devrait s'étendre au poumon et s'ouvrir aux établissements de santé hors CLCC.

Un des faits marquants de 2016 est le rapprochement avec d'autres acteurs français de la recherche en cancérologie ; d'une part en cancérologie digestive – rapprochement officialisé entre UNICANCER UCGI, la FFCD (Fédération francophone de cancérologie digestive) et le GERCOR (Groupe coopérateur multidisciplinaire en oncologie –, d'autre part dans les cancers ORL entre UNICANCER, UCH&N, le GORTEC (Groupe oncologie radiothérapie tête et cou), le GETTEC (Groupe d'étude des tumeurs de la tête et du cou) et le GERCOR. Désormais, les cinq groupes tumeurs d'UNICANCER s'inscrivent dans les intergroupes reconnus par l'INCa.

Par ailleurs, les liens de R&D UNICANCER avec ses deux partenaires caritatifs historiques – la Ligue nationale contre le cancer et la Fondation ARC – ont abouti en 2016 au lancement de trois essais majeurs pour les patients en termes d'égalité d'accès aux nouvelles thérapies et de développement des connaissances en médecine de précision : les deux études AcSé immunothérapie, et le projet Express (étude des répondeurs exceptionnels aux thérapies ciblées).

Bilan 2016 et perspectives 2017

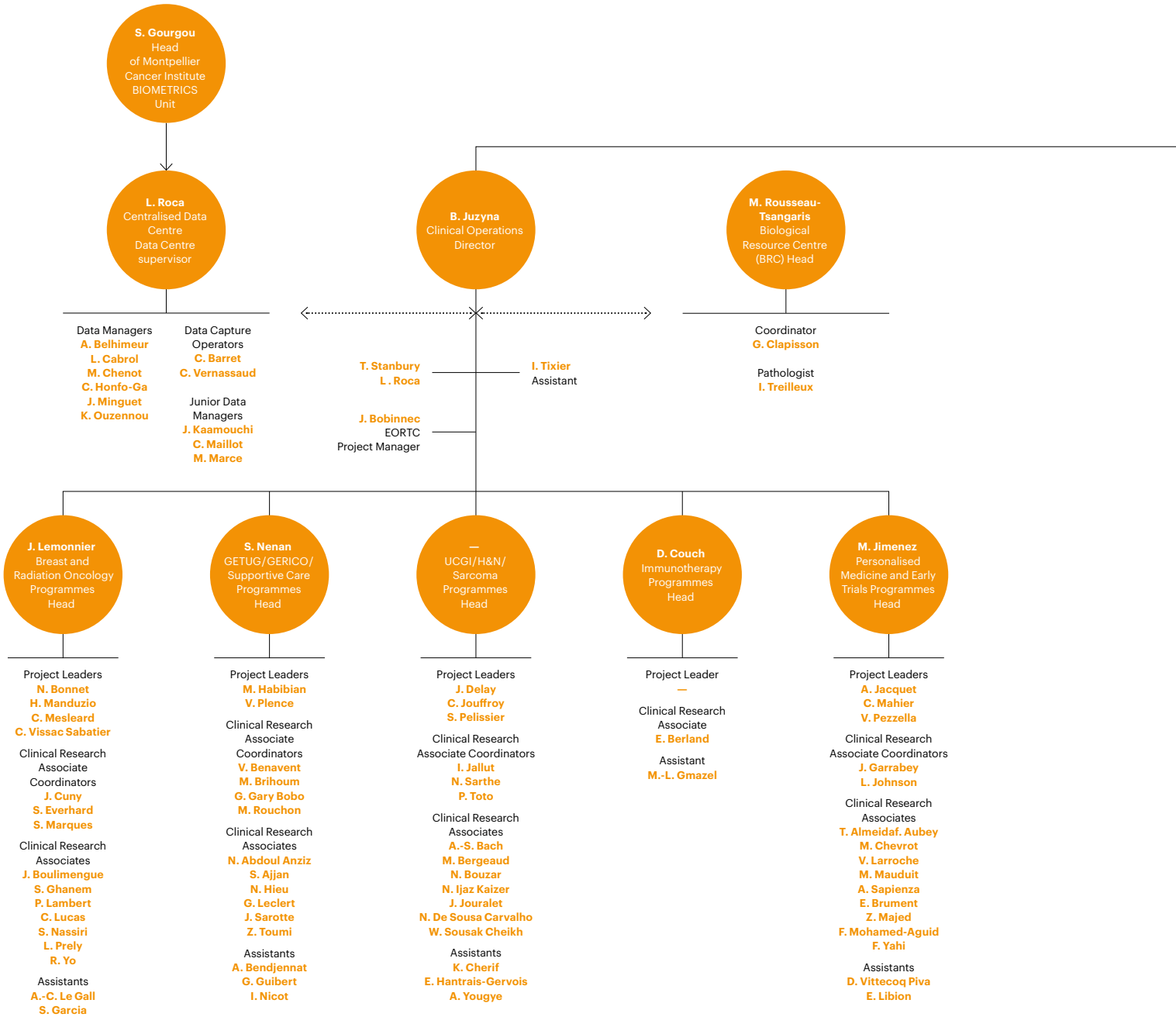
Par Patrice Viens, président d'UNICANCER

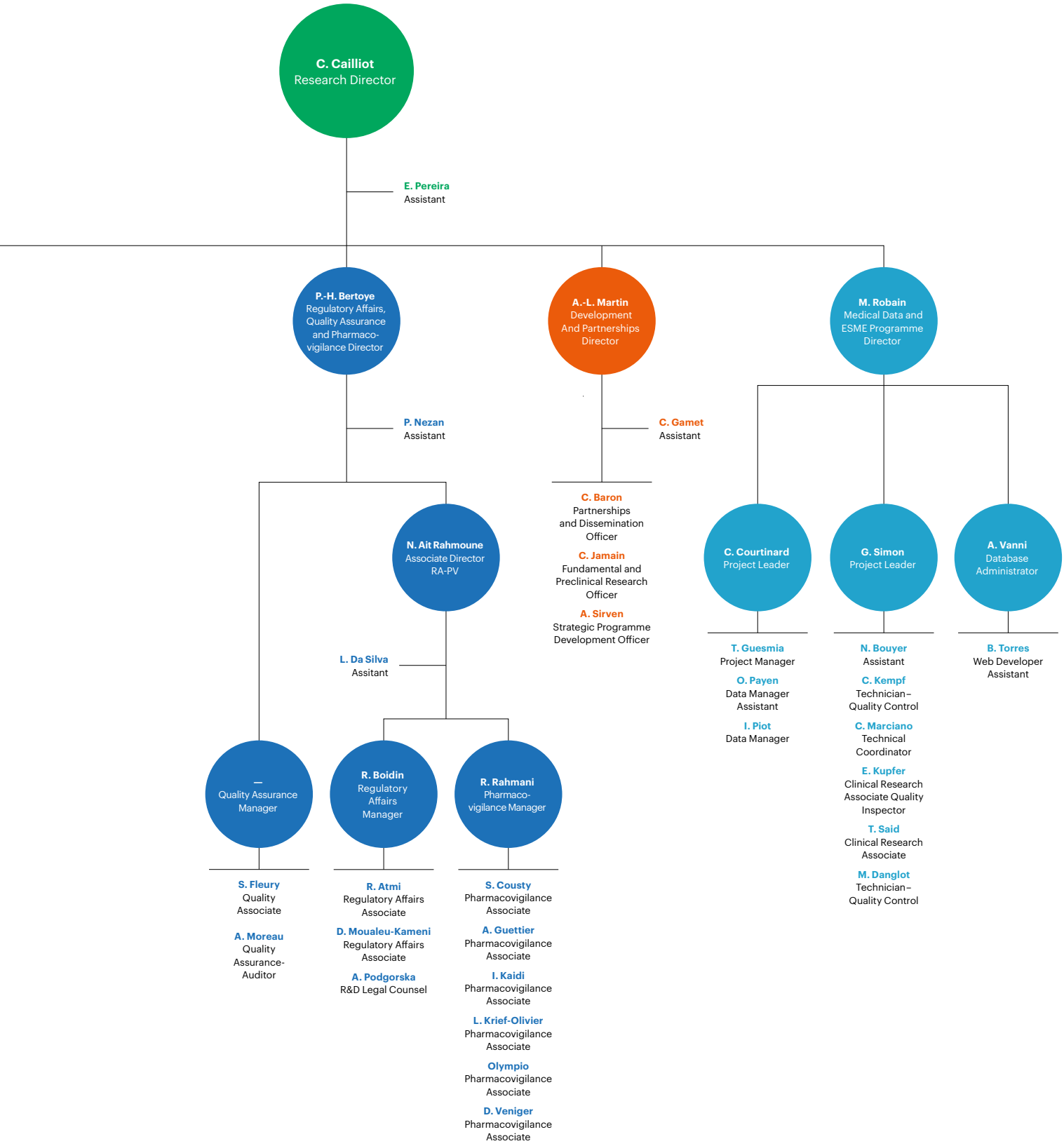
L'année 2016 a été placée sous le signe de la croissance renouvelée de l'activité de R&D UNICANCER et de la coopération avec tous les acteurs en santé impliqués dans le cancer, qu'ils soient nationaux ou internationaux, publics ou privés, chercheurs ou cliniciens, institutionnels ou caritatifs, et bien entendu avec les associations de patients. Les aspirations de R&D UNICANCER pour 2017 sont, outre continuer à se professionnaliser et mutualiser nos ressources pour servir toujours mieux les CLCC, de continuer à développer une recherche stratégique académique, notamment *via* le lancement de nouveaux groupes thématiques comme l'immuno-oncologie, et de trouver de nouvelles alliances et collaborations y compris avec des groupes internationaux. Tout doit nécessairement converger vers notre axe stratégique majeur : le lancement de projets novateurs et ambitieux avec en ligne de mire la transposition rapide d'innovations "de rupture" vers les soins courants, et cela au bénéfice des patients.

Patrice Viens,
UNICANCER's President

Organisational chart

On March 9th, 2017.




C. Cailliot
Research Director
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Regulatory Affairs, Quality Assurance and Pharmaco-vigilance Director
A.-L. Martin
Development And Partnerships Director
M. Robain
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C. Jamain
Fundamental and Preclinical Research Officer
A. Sirven
Strategic Programme Development Officer
N. Ait Rahmoune
Associate Director RA-PV
L. Da Silva
Assitant
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R. Boidin
Regulatory Affairs Manager
R. Rahmani
Pharmaco-vigilance Manager
S. Fleury
Quality Associate
A. Moreau
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Regulatory Affairs Associate
D. Moualeu-Kameni
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C. Marciano
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E. Kupfer
Clinical Research Associate Quality Inspector
T. Said
Clinical Research Associate
M. Danglot
Technician–Quality Control
B. Torres
Web Developer Assistant

R&D resources and organisation

FCCC
A unique national network of 20 FCCC, which are private non-profit hospitals dedicated to fighting cancer through a threefold mission: care, research and education.

Technical platforms
Access to state-of-the-art technical platforms within the FCCC, fully equipped for molecular screening, translational research, bioinformatics, etc.

Expert groups*
Internationally recognised scientific and medical expertise provided by cooperative groups of top level clinicians and scientists, all oriented towards research excellence and innovation for the benefit of the patients.

ESME
A department devoted to Real World Data research in Epidemiological Strategy and Medical Economics.

Clinical operations
An in-house clinical operations department of highly skilled, dedicated teams, allowing customised partnerships: R&D UNICANCER can act as a full sponsor or a preferred partner in collaborative researches.

A unique network
A powerful network of scientific collaborations with other cancer cooperative groups at national and international level, as well as with stakeholders from the public and private sectors. R&D UNICANCER hosts the French liaison office of the European Organisation for Research and Treatment of Cancer (EORTC).

Biobank&Data centre
A centralised biobank and an FDA compliant centralised data centre.

MATWIN
A unit for maturation&accelerating translation with Industry.

*Expert groups

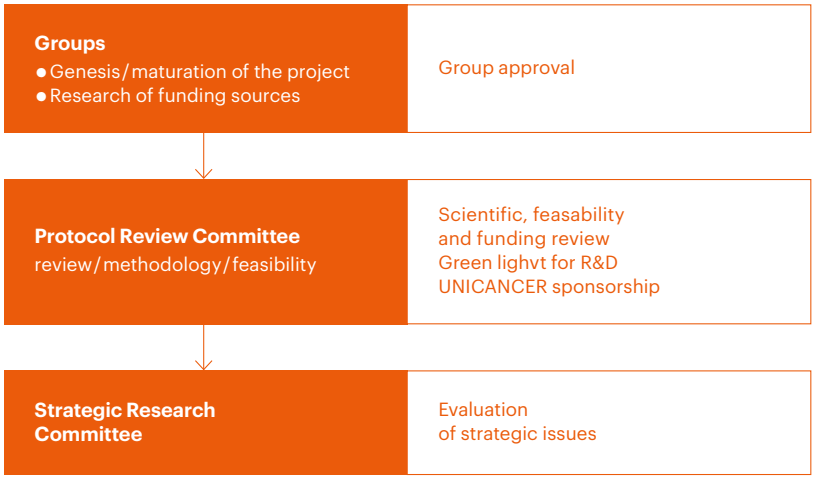
Tumour groups
- French Breast Cancer Intergroup UNICANCER (UCBG)
- UNICANCER Gastrointestinal Group (UCGI)
- UNICANCER Genitourinary Group (GETUG)
- UNICANCER Head and Neck Group (UCH&N)
- UNICANCER Sarcoma Group

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

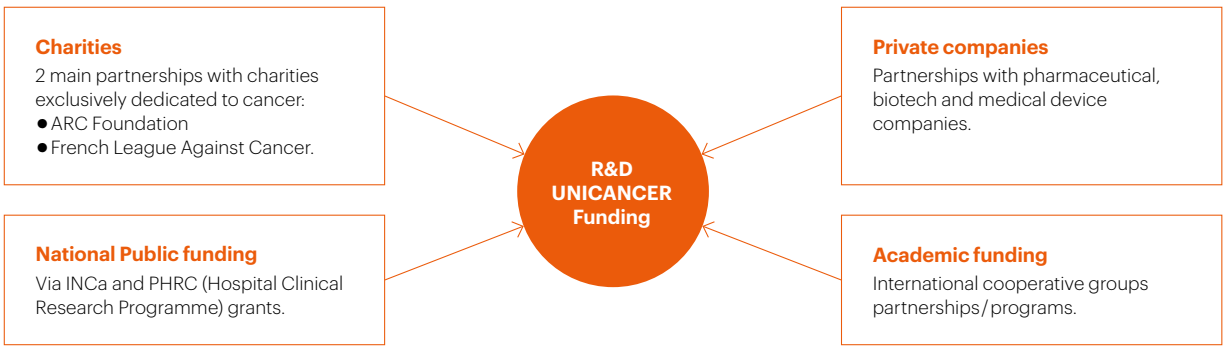
Transversal groups
- Clinical Pharmacology and Oncology Group (GPCO)
- Genetic and Cancer Group (GGC)
- Cancer Biostatistics Group
- Group of Evaluation of Immunohistochemical Prognostic Factors in Breast Cancer (GEFPICS)
- Prevention of Infections in Cardiology Group (GPIC)

Decision process

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



Funding model



2016 clinical activity

R&D UNICANCER, the leading French academic clinical research organisation in oncology.

Major results

● **Clinical research activity:** Compared to the year 2015, the year 2016 was marked by an increase in most of R&D UNICANCER's clinical research activities' indicators, notably: +57% and +33% in the number of studies submitted to and accepted by the R&D UNICANCER Protocol Review Committee, respectively; +42% in the number of newly initiated clinical trials; +18% in the overall number of ongoing clinical trials; +6% in the total number of patients included in R&D sponsored-clinical trials (see appendix).

● **The scientific output** recorded a remarkable increase as well compared to the year 2015, with almost 50% more articles published in international scientific journals, and twice as many oral communications and posters presented at international congresses – of which 3 times more were accepted at the ASCO congress (see following pages). Of note amongst these publications, one original article was published in the *New England Journal of Medicine* by F. Cardoso and colleagues which demonstrated the clinical utility of the addition of the 70 – gene signature (MammaPrint) to standard clinical-pathological criteria in selecting early – stage breast cancer patients for adjuvant chemotherapy (the international MINDACT study) for which R&D UNICANCER was co-sponsor and has recruited through the active role of the UNICANCER Breast Group (UCBG) one third (> 2,000) of the patients.

● **French hospital clinical research programmes (PHRC-K) 2016:** Four projects were accepted in the course of the PHRC-K campaign (see p. 9). Their respective goals illustrate the diversity of the research topics that are of interest to the UNICANCER expert groups (see table following). In addition, one translational project was accepted as part of the French translational public research funding programme (PRT-K) 2016 campaign, which proposes to study the safety of nivolumab in patients with metastatic renal cell carcinoma.

● **New studies:** 10 studies were initiated in 2016 (see table p. 10), of which the first two trials developed by the Translational Research and Development in Radiation Oncology Group (UNITRAD).

● **ESME Programme:** This year, the ESME (Epidemiological Strategy and Medical Economics) programme initiated a new project in ovarian cancers and run the feasability of a third one in lung cancer.

5,400
Patients included in R&D sponsored-clinical trials

76
Ongoing clinical trials, including 40 in recruitment phase

10
Newly initiated clinical trials

270
Investigator sites involved (public and private hospitals, comprehensive cancer centres), including 60 located in 8 other countries

29
Publications in scientific journals, including 1 in the *New England Journal of Medicine* and 3 in the *Lancet Oncology*

61
Communications of which 18 were at ASCO, 8 at ESMO and 8 at SABCS

62,000
Samples stored in the Biological Resource Centre

140
R&D UNICANCER team: including the Centralised Data Centre and the Biological Resource Centre

From protocol review to public research funding

30
Clinical studies reviewed by UNICANCER Protocol Review Committee in 2016

16
Clinical studies accepted (16 are still to be reviewed)

11
Full projects submitted to the 2016 French hospital clinical research programme (PHRC-K)

4
Projects accepted for funding

4
Letters of intent submitted to the 2016 French translational public research funding programme (PRTK)

1
Project accepted for funding

French hospital clinical research and translational programmes accepted during the 2016 campaign

PHRC-K

Expert group	Short title	Study coordinator	Study title
GEP	MOVIE	A. Gonçalves, Institut Paoli-Calmettes, Marseille	A phase II basket trial evaluating a combination of Metronomic oral vinorelbine plus anti-PD1/PDL1 immunotherapy in patients with advanced solid tumors.
GETUG	PEACE 5	P. Blanchard, Gustave Roussy, Villejuif	Phase III randomized controlled trial of local ablative treatment of metastases in patients with oligometastatic hormone-naïve prostate cancer.
SARCOMA	MEPACT SARCOME 13	N. Gaspar, Gustave Roussy, Villejuif	Randomized Phase 2 trial of mepact combined with post-operative chemotherapy for newly diagnosed high risk osteosarcoma (metastatic or localized disease with poor histologic response).
Supportive care	RILUZOX-01	D. Pezet, University Hospital, Clermont Ferrand	Effectiveness assessment of riluzole in the prevention of oxaliplatin-induced peripheral neuropathy: A phase II randomized study of the UNICANCER-AFSOS Supportive Care Intergroup.

PRT-K

Expert group	Short title	Study Coordinator	Study title
GETUG	NIVOREN	L. Albiges, Gustave Roussy, Villejuif	A Phase II Safety Trial of Nivolumab in Patients with Metastatic Renal Cell Carcinoma Who Have Progressed During or After Prior Systemic Anti-Angiogenic Regimen.

Clinical trials opened in 2016

Expert group	Internal reference	Study title	Study coor-dinator	Expected number of patients	Phase	France (F)/ Inter-national (I)	Study activation date
GETUG	UC-0160/ 1506	GETUG 26– NIVOREN A Phase II Safety Trial of Nivolumab (BMS-936558) in Subjects with Advanced or Metastatic Renal Cell Carcinoma Who Have Progressed During or After Receiving one prior systemic anti-angiogenic regimen.	L. Albiges	300	II	F	01/01/16
GETUG	UC-0160/ 1406	GETUG 25– MEGACEP Evaluation of Lymphadenectomy and Chemotherapy TIP (paclitaxel, ifosfamide and cisplatine) on Inguinal Lymph Nodes in Squamous Cell Carcinoma of the Penis.	J. Rigaud	78	II	F	01/04/16
UCH&N	UC-0130/ 1507	ORL 06– COPANLISIB Phase Ib/II trial of Copanlisib in combination with cetuximab in recurrent or metastatic HNSCC harboring a PI3KCA mutation or PTEN loss.	C. Letourneau	32	Ib/II	F	01/05/16
PERSO MED	UC-0105/ 1508	GMP07– EXPRESS Molecular characterization of patients with solid tumors who presented an exceptional response to targeted therapies.	C. Ferté, F. André	264	cohort	F	22/06/16
UCH&N	UC-1030/ 1601	ORL 07– EORTC 1206 A randomized phase II study to evaluate the efficacy and safety of chemotherapy (CT) versus androgen deprivation therapy (ADT) in patients with recurrent and/or metastatic, androgen receptor (AR) expressing, salivary gland cancer (SGCs).	F. Rolland	152	II	I	01/07/16
UNITRAD	UC-0107/ 1604	RAD01– HYPOG-01 Multicenter randomized phase III trial comparing hypofractioned versus standard radiotherapy in breast cancer with an indication for regional lymph node irradiation in terms of lymphedema occurrence.	S. Rivera	1,012	III	F	06/09/16
GETUG	UC-1260/ 1509	GETUG 27– TIGER A Randomized Phase III Trial Comparing Conventional-Dose Chemotherapy Using Paclitaxel, Ifosfamide, and Cisplatin (TIP) with High-Dose Chemotherapy Using Mobilizing Paclitaxel Plus Ifosfamide Followed by High-Dose Carboplatin and Etoposide (TI-CE) as First Salvage Treatment in Relapsed or Refractory Germ Cell Tumors.	A. Fléchon	50	III	I	01/10/16
UCBG	UC-0140/ 1606	CARMINA 05– ULTIMATE A phase II trial testing durvalumab combined with endocrine therapy in patients with ER+/her2– breast cancer eligible for neoadjuvant endocrine therapy and who present CD8+ T cell infiltration after 4–6 weeks exposure to immune-attractant.	F. André	240	II	I	13/12/16
UCGI	UC-0110/ 1608	UCGI 28– PANIRINOX Phase II randomized study comparing FOLFIRINOX +Panitumumab versus mFOLFOX6 +Panitumumab in metastatic colorectal cancer patients stratified by RAS and B-RAF status from circulating DNA analysis.	T. Mazard	209	II	F	20/12/16
UNITRAD	UC-0107/ 1603	RAD03– STEREO-OS Extracranial Stereotactic Body Radiation Therapy (SBRT) added to standard treatment versus standard treatment alone in solid tumors patients with between 1 and 3 bone-only metastases.	S. Thureau, J.-C. Faivre	196	III	F	22/12/16

New R&D UNICANCER flagship programmes

● **EXPRESS (Personalised medicine group):** Initiated in 2016 and supported by the ARC foundation, this cohort study aims to identify genetic characteristics unique to patients presenting an unexpected and exceptional response to targeted therapy approved in France. The response of almost 300 patients presenting with diverse solid tumours will be analysed in 6 (so far) separate multi-drug cohorts according to tumour type: advanced or metastatic breast, lung, colorectal, ovarian cancer, renal cell carcinoma and melanoma.

Coordinator: Charles Ferté, Gustave Roussy

● **AcSé Immunotherapy (Immuno-Oncology group):** These phase II "basket" studies , led by UNICANCER under the auspices of INCa with the support of the French League Against Cancer, give secure access to anti-PD-1 for patients with rare cancers. The first enrolled patient is expected in 2017. Two products will be evaluated: nivolumab (250 patients expected, 5 cohorts) and pembrolizumab (300 patients expected, 6 cohorts). The study objective is to assess the treatment efficacy and safety in each cohort and to determine the predictive factors of response.

Coordinator: Jean-Charles Soria, Gustave Roussy

● **HYPOG-01 (UNITRAD group):** This multicentre, randomized phase III trial comparing hypofractioned versus standard radiotherapy in breast cancer with an indication for regional lymph node irradiation in terms of lymphedema occurrence is expected to include more than 1,000 patients.

Coordinator: Sofia Rivera, Gustave Roussy

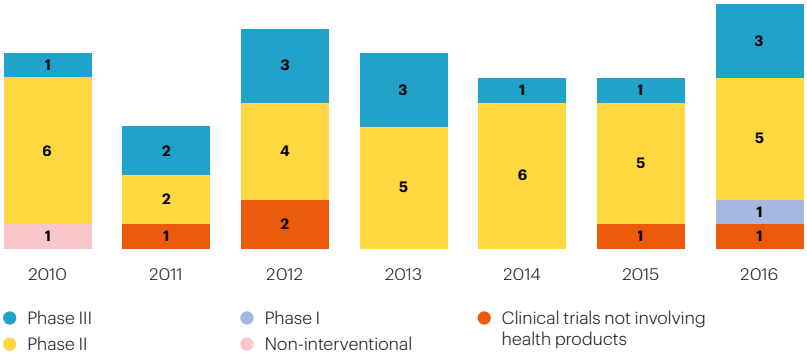
A major translational ancillary research programme has been developed alongside this study, with the aim to develop a multiparametric model to identify predictors of normo- or hypofractionated loco-regional radiotherapy induced toxicity.

Clinical research activity: evolution over the years

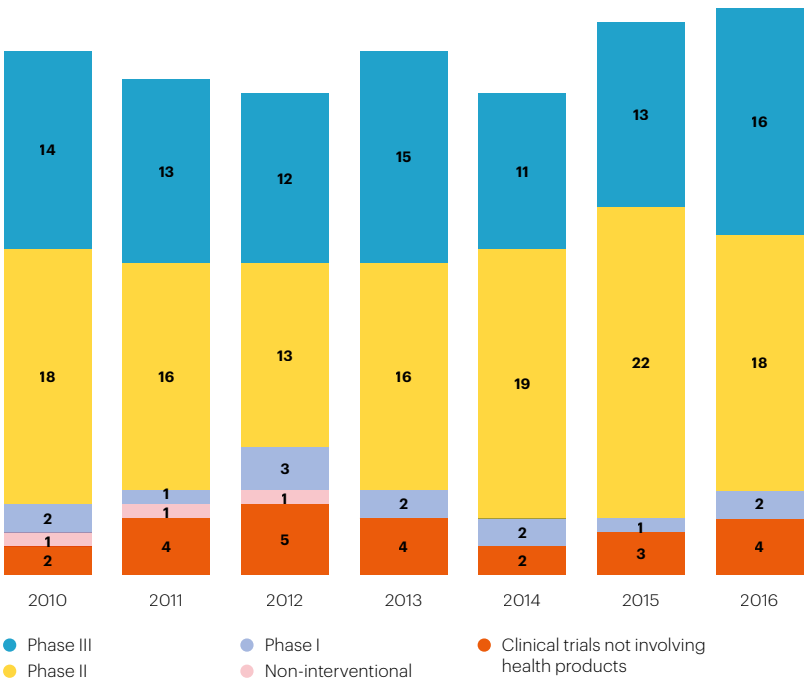
Evolution of inclusions in R&D UNICANCER clinical research

Number of patients enrolled per year

Number of new trials per year and per phase

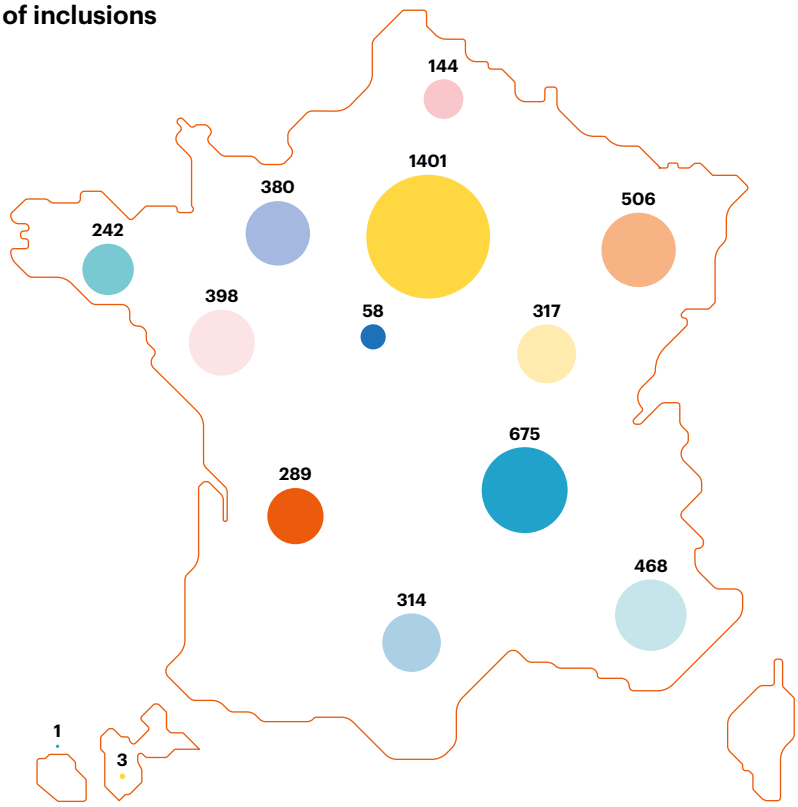


Number of active trials per year and per phase



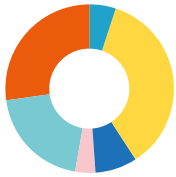
Inclusions by cancer localisation, by institution type and by geographical area

Geographical distribution of inclusions



Proportion of recruiting sites by type of institution

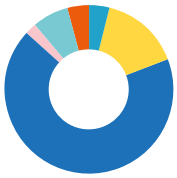
(*N*= 218 institutions overall)



- 5% Public Hospitals of Paris (AP-HP)
- 36% Public Hospitals (excl. AP-HP)
- 8% FCCC
- 4% Other Private Non-profit Hospitals
- 20% Private Clinics
- 27% Foreign Institutions

Patients' accrual share by type of institution

(*N*= 5,392 patients overall)

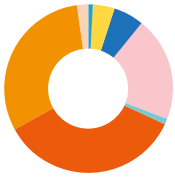


- 4% Public Hospitals of Paris (AP-HP)
- 15% Public Hospitals (excl. AP-HP)
- 67% FCCC
- 2% Other Private Non-profit Hospitals
- 7% Private Clinics
- 4% Foreign Institutions

Total number of patients included by localisation and by institution type

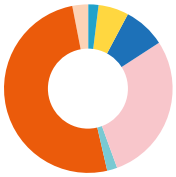
Type of Health Institution	Ovarian	Lung	Digestive	Genito-urinary	Sarcoma	Breast	Of which CANTO	Multiple localisa-tions	Total	%
Public Hospitals of Paris (AP-HP)	9	7	14	75	3	121	72	12	241	4%
Public Hospitals (excl. AP-HP)	12	109	130	229	3	268	11	60	811	15%
FCCC	39	97	77	527	42	2,813	1,600	39	3,634	67%
Other Private Non-profit Hospitals	–	–	14	19	–	76	10	9	118	2%
Other Private Hospitals	–	–	49	121	–	219	2	3	392	7%
Foreign Institutions	1	–	14	94	–	87	–	–	196	4%
Total	**61**	**213**	**298**	**1,065**	**48**	**3,584**	**1,695**	**123**	**5,392**	–

Distribution of included patients by cancer localisation



- 1% Ovarian
- 4% Bronchopulmonary
- 6% Digestive
- 20% Genitourinary
- 1% Sarcoma
- 35% Breast without CANTO
- 31% Breast with CANTO
- 2% Multiple localisations

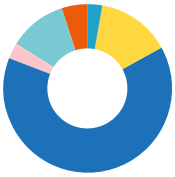
Distribution of included patients by cancer localisation without CANTO cohort



- 2% Ovarian
- 6% Bronchopulmonary
- 8% Digestive
- 29% Genitourinary
- 1% Sarcoma
- 51% Breast without CANTO
- 3% Multiple localisations

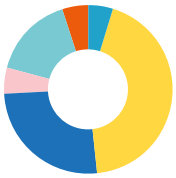
Patients' accrual share by type of institution for the three main localisations

Breast (without CANTO)



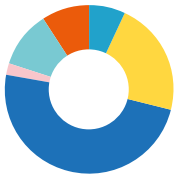
- 3% Public Hospitals of Paris (AP-HP)
- 14% Public Hospitals (excl. AP-HP)
- 64% FCCC
- 3% Other Private Non-profit Hospitals
- 11% Private Clinics
- 5% Foreign Institutions

Digestive



- 5% Public Hospitals of Paris (AP-HP)
- 44% Public Hospitals (excl. AP-HP)
- 26% FCCC
- 5% Other Private Non-profit Hospitals
- 16% Private Clinics
- 5% Foreign Institutions

Genitourinary



- 7% Public Hospitals of Paris (AP-HP)
- 22% Public Hospitals (excl. AP-HP)
- 49% FCCC
- 2% Other Private Non-profit Hospitals
- 11% Private Clinics
- 9% Foreign Institutions

Contribution of institutions by localisation and by institution type

Type of Health Institution	Digestive	%	Genito-urinary	%	Breast without Canto	%
Public Hospitals of Paris (AP-HP)	14	5%	75	7%	49	3%
Public Hospitals (excl. AP-HP)	130	44%	229	22%	257	14%
FCCC	77	26%	527	49%	1,213	64%
Other Private Non-profit Hospitals	14	5%	19	2%	66	3%
Other Private Hospitals	49	16%	121	11%	217	11%
Foreign Institutions	14	5%	94	9%	87	5%
Total	298		1,065		1,889	

International collaborations

R&D UNICANCER expert groups have developed strong collaborations with several major actors in academic research in oncology: two main collaborations can be highlighted for 2016.

- UCBG is group leader for international trials conducted under the umbrella of the Breast International Group (BIG) (e.g. ULTIMATE trial launched in December 2016);
- A new collaborative trial, IROCAS, has been developed by UCGI in collaboration with Canadian experts. This phase III trial comparing mFOLFIRINOX to mFOLFOX in adjuvant treatment of colon cancer is funded by the PHRC-K 2015 and will be activated in early 2017.

Three large phase III trials sponsored by UNICANCER under the lead of a UNICANCER Groups are currently recruiting.

- UNIRAD – PACS 11: a trial evaluating the benefit of everolimus in women with poor prognosis primary breast cancer. Collaboration between UCBG/CR-UK/Belgian investigators group.
- PEACE 1: a phase III study in patients with metastatic hormone-naïve prostate cancer. Collaboration between GETUG, EORTC and hospitals in 15 countries.
- PEACE 2: a phase III trial in patients with localised prostate cancer and high-risk features of relapse. Collaboration between GETUG and a network of hospitals in 8 different countries.

Further discussions are ongoing for a general partnership with NCIC (whole cancer localisations) as well as with Cancer Research-UK (mainly in radiation therapy and personalised medicine). The contribution of the UNICANCER French Breast Intergroup (UCBG) to the success of the **recently published MINDACT trial** (Cardoso et al.; N Engl J Med. 2016 Aug 25;375(8):717-29.) should be noted: one third of the global inclusions of patients were done by the UCBG investigators (i.e. >2,000 patients over 3 years)

EORTC liaison office

- UNICANCER is the local representative of EORTC in France. A partnership agreement was signed in 2009. This collaboration aims to facilitate the activation of the EORTC sponsored-trials in France from a regulatory point of view, and to facilitate and stimulate the participation of the French investigational centres. The liaison officers are ensuring regulatory and operational tasks for site initiation and monitoring. They are the preferred contact for all questions regarding the EORTC sponsored trials.
- In 2016, 3 new trials were activated in France by the liaison office and 20 trials were recruiting (see below and p.15).

EORTC trials portfolio and recruitment status in France in 2016

List of studies approved in France in 2016

EORTC Research Group(s)	EORTC Study number (acronym)	Study title	Study approuval date in France
LCG	1205	EORTC randomized phase II study of pleurectomy/decortication (P/D) preceded or followed by chemotherapy in patients with early stage malignant pleural mesothelioma.	19/09/2016
GITCG	1317	Phase II study of cabozantinib in patients with metastatic gastrointestinal stromal tumor (GIST) who progressed during neoadjuvant, adjuvant or palliative therapy with imatinib and sunitinib.	10/11/2016
GITCG-IG	1527 (DREAM)	Diffusion-Weighted Magnetic Resonance Imaging Assessment of Liver Metastasis and Improve Surgical Planning.	27/12/2016

LEXICON

BTG: Brain Tumor Group (EORTC BTG)

BCG: Breast Cancer Group (EORTC BCG)

CLG: Children Leukemia Group (EORTC CLG)

ENTF: Endocrine Task Force (EORTC ENTF)

ETF: Cancer In Elderly Task Force (EORTC ETF)

GCG: Gynecological Cancer Group (EORTC GCG)

GITCG: Gastrointestinal Tract Cancer Group (EORTC GITCG)

IG: Imaging Group (EORTC IG)

LCG: Lung Cancer Group (EORTC LCG)

LG: Leukemia Group (EORTC LG)

MG: Melanoma Group (EORTC MG)

NOCI: Network Of Core Institutions (EORTC NOCI)

List of EORTC studies active in France in 2016

EORTC Research Group(s)	EORTC Study number (acronym)	Study title	Study start date	Number of French patients included in 2016/total number of patients randomised
BTG	1320	Trabectedin for recurrent grade II or III meningioma: a randomized phase II study of the EORTC Brain Tumor Group.	10/07/2015	16/82
CLG	58051	International collaborative treatment protocol for infants under one year with acute lymphoblastic or biphenotypic leukemia.	07/01/2008 Recruitment suspended	2/97
CLG	58081	Translational research – observational study for identification of new possible prognostic factors and future therapeutic targets in children with acute lymphoblastic leukaemia (ALL).	19/05/2011	231/1,171
ENTF	1209	A phase II study exploring the safety and efficacy of BIBF1120 as second line therapy for patients with either differentiated or medullary thyroid cancer progressing after first line therapy.	28/04/2014	3/96
ETF-BCG	75111 – 10114	Pertuzumab + trastuzumab (PH) versus PH plus metronomic chemotherapy (PHM) in the elderly HER2+ metastatic breast cancer population who may continue on T-DM1 alone following disease progression while on PH/PHM: an open-label multicentre randomized phase II selection trial of the EORTC Elderly Task Force and Breast Cancer Group.	18/06/2013 Recruitment closed on: 12/05/2016	1/80
GITCG	1203 (INNOVA-TION)	Integration of trastuzumab, with or without pertuzumab, into perioperative chemotherapy of HER-2 positive stomach cancer: the INNOVATION-TRIAL.	02/29/2015	6/22
GITCG-ROG	22114 – 40111 (TOP GEAR)	Trial of preoperative therapy for gastric and esophagogastric junction adenocarcinoma. A randomized phase II/II trial of preoperative chemoradiotherapy vs preoperative chemotherapy for resectable gastric cancer (TOP GEAR).	13/11/2013	6/349
IG-GITCG	1423	Evaluation of diffusion weighted imaging – MRI in patients with resectable liver metastases from colorectal cancer treated with fluoropyrimidine-based chemotherapy as preoperative treatment.	12/11/2015	3/26
LCG	08111 ETOP5-12 (SPLENDOUR)	A randomized, open-label phase III trial evaluating the addition of denosumab to standard first-line anticancer treatment in advanced NSCLC.	11/12/2014	7/451
LG-ETF	1301 (AML21)	10-day decitabine versus conventional chemotherapy ("3+7") followed by allografting in AML patients ≥60 years: a randomized phase III study of the EORTC Leukemia Group, CELG, GIMEMA and German MDS Study Group.	20/11/2014	20/243
MG	1208 (Minitub)	Minitub: Prospective registry on Sentinel Node (SN) positive melanoma patients with minimal SN tumor burden who undergo Completion Lymph Node Dissections (CLND) or Nodal Observation.	28/04/2015	1/85
MG	18081	Adjuvant peginterferon alpha-2b for 2 years vs Observation in patients with an ulcerated primary cutaneous melanoma with T(2-4)bN0M0: a randomized phase III trial of the EORTC Melanoma Group.	23/10/2012	4/112
NOCI	90101 (CREATE)	Cross-tumoral Phase 2 clinical trial exploring crizotinib (PF-02341066) in patients with advanced tumors induced by causal alterations of ALK and/or MET.	27/08/2012	4/139
NOCI-BCG	90091-10093 (Treat CTC)	Trastuzumab in HER2-negative Early breast cancer as Adjuvant Treatment for Circulating Tumor Cells (CTC).	26/04/2013 Recruitment closed on: 03/10/2016	25/63
ROG-LCG	22113-08113 (LUNGTECH)	Stereotactic ablative radiotherapy (SABR) of inoperable centrally located NSCLC.	27/11/2014	2/23
ROG-HNCG	1219 (DAHANCA-29)	A blind randomized multicenter study of accelerated fractionated chemo-radiotherapy with or without the hypoxic cell radiosensitizer nimorazole (Nimoral), using a 15-gene signature for hypoxia in the treatment of HPV/p16 negative squamous cell carcinoma of the head and neck. (DAHANCA-29).	27/05/2014	14/159
STBSG	1321 (ALT-GIST)	A randomized phase II trial of imatinib alternating with regorafenib compared to imatinib alone for the first line treatment of advanced gastrointestinal stromal tumour (GIST).	02/03/2016	5/51
STBSG	1403 (rEECur)	International Randomized Controlled Trial of Chemotherapy for the treatment of recurrent and primary refractory Ewing sarcoma.	10/03/2016	17/104
STBSG-ROG	62092-22092 (STRASS)	A phase III randomized study of preoperative radiotherapy plus surgery versus surgery alone for patients with Retroperitoneal sarcomas (RPS)– STRASS.	16/01/2012	19/266
STBSG-GCG	62113-55115 (IRCI 006/HGUS)	A randomized double-blind phase II study evaluating the role of maintenance therapy with cabozantinib in High Grade Undifferentiated Uterine Sarcoma (HGUS) after stabilization or response to doxorubicin +/– ifosfamide following surgery or in metastatic first line treatment.	30/01/2015	5/5

Expert groups

To fulfil its objectives, R&D UNICANCER works closely with **17 internationally recognised groups of experts** and provides the necessary support structure for efficient project management. R&D UNICANCER expert groups are multidisciplinary groups **focused on developing and steering innovative clinical studies.** Their goals are to optimise treatment strategies and to contribute to scientific education and dissemination in their field, through participation in conferences and publications. **The French National Cancer Institute (INCa) has granted its quality label to four UNICANCER expert groups,** thus acknowledging their operating capability and excellence.

● **News in the experts groups:** Created in 2016, the **UNICANCER Immuno-Oncology Group** is the newest of the UNICANCER expert groups and **already has a dozen studies involving immune checkpoint inhibitors,** in particular the AcSé immunotherapy programme (see the box "Acsé immunotherapy" p.10). At the end of 2016, the **UNICANCER head and neck group** joined the GORTEC, the GETTEC and the GERCOR cooperative groups within the head and neck intergroup, which is accredited by the French National Cancer Institute (INCa). **The UNICANCER Genitourinary group** (GETUG) launched on 31 March and 1 April 2016 its first education and research thematic symposium, which gathered more than 100 clinicians and researchers interested in conducting clinical and translational research in the genitourinary area. This event was the opportunity for the GETUG to lay the foundation stone for a scientific collaboration with other European cooperative groups in the field of genitourinary oncology, through the organisation of a roundtable with EORTC, SAKK (Switzerland) and SOGUG (Spain). A few months later, on 28 June 2016, the **GERICO group** also organised, within the INCa-accredited GERICO-UCOG (DIALOG) cooperative intergroup, its **first symposium on research in geriatric oncology,** which was quite successful, with the participation of 80 medical oncologists and geriatricians interested in the specificities of the clinical research conducted in the elderly population. Finally, the **UNICANCER Gastrointestinal group** (UCGI) organised on 28 January 2016 the second edition of its ABCD course (**Accelerated course on the Biology of the Cancer of the Digestive tract**), with the support of the PRODIGE Intergroup: approximately 170 attendees could benefit from this symposium, the objective of which is to diffuse knowledge and increase the attractiveness of clinical research among the French medical centres and encourage emulation among young research oncologists.

It happened in 2016

● The 10,000th patient with breast cancer was included in the CANTO cohort study

● The ESME-metastatic breast cancer project reached 17,000 included patients

● At the end of 2016, 200 patients had been included in the AcSé crizotinib study and 140 in the AcSé vemurafenib study

● Eighteen months after the study started, almost 1,100 patients have been screened in the SAFIR-02 breast and lung trials, meeting the enrolment objectives set for 2016; an amendment will allow the screening of 1,000 additional patients in the SAFIR-02 breast trial.

UNICANCER tumour groups

All UNICANCER tumour groups share common goals:

- to evaluate existing and new therapeutic strategies,
- to improve patient prognosis and quality of life via personalised treatments,
- to develop innovative approaches to cancer treatment, and
- to identify predictors of treatment response, resistance and toxicity.

To achieve these goals, the UNICANCER tumour groups develop strategic clinical research programmes with a **strong translational component** relying on systematic centralised banking of biological samples. These clinical studies involve research units and cutting-edge technical platforms within the 20 French Comprehensive Cancer Centers (FCCC), **as well as a large number of public and private hospitals in France.** All the UNICANCER tumour groups are moving towards international trials thanks to **various partnerships with other cooperative groups and strong collaborations with industry.**

French Breast Cancer Intergroup (UCBG)*

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

Genitourinary Group (GETUG)*

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

Gastrointestinal Group (UCGI)

President: Dr David Malka,
Gustave Roussy, Villejuif
Collaborations: • French / EU level: FFCD and GERCOR within the PRODIGE intergroup / EORTC – • International level: NCI of Canada / Canadian Cancer Trials Group
Strategic priorities: Translational research / innovative studies / improvement of therapeutic strategies in adjuvantand metastatic setting

Sarcoma Group*

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

Head and neck Group (UCH&N)

President: Pr Joël Guigay,
Antoine Lacassagne Centre, Nice
Collaborations: • French / EU level: GORTEC, GETTEC, GERCOR within the head and neck intergroup / EORTC
Strategic priorities: Early-phase studies / rare cancers / biology driven medicine

*INCa accredited-group

LEXICON

AFSOS: French Association of Supportive Care in Cancer

AFU: French Association of Urology

BIG: Breast International Group

CeRePP: Research Group on Prostate Cancer and Urologic Tumors

EBMT: European Society for Blood and Marrow Transplantation

EORTC: European Organisation for Research and Treatment of Cancer

FFCD: French group of Digestive Oncology

GBG: German Breast Group

GENMED: Laboratory of Excellence in Medical Genomics

GERCOR: Multidisciplinary Cooperative Group in Oncology

GETTEC: French head and neck cancer Study Group

GORTEC: Cooperative Group of Radiation Therapy for head and neck Cancer

Go-AJA: Adolescents and Young Adults Onco-haematology Group

INCa: French National Cancer Institute

INTERSARC: Network of Cooperative Groups in the Field of Sarcoma

MCCRC: Mayo Clinic Cancer Research Consortium

SAKK: Swiss Group for Clinical Cancer Research

SWOG: SouthWest Oncology Group

UK NCRN: UK National Cancer Research Network

UNICANCER cross-pathology groups and programmes

Oncogeriatrics Group (GERICO)*

The UNICANCER Oncogeriatrics Group forms, together with the UCOG oncogeriatric coordination units, the DIALOG intergroup, which is accredited by the French NCI. It brings together oncologists, geriatricians, radiotherapists, surgeons, biostatisticians and pharmacologists, all working towards promoting clinical research and innovation in oncogeriatry and tailoring clinical trials for the elderly population by adapting methodological approaches and rationalising diagnostic and treatments.

President: Dr Étienne Brain,
Curie Institute – René Huguenin Hospital, Saint-Cloud

Personalised Medicine Programme

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

President: Pr Fabrice André,
Gustave Roussy, Villejuif

Early Phase Group (GEP)

The UNICANCER Early Phase Group has become an important player in France, acknowledged by academic and industrial partners for the quality of its phase Ib and phase II trials. This cross-disciplinary group has successfully developed early-phase trials in cancers of the upper airway and digestive tract, as well as in breast, kidney and prostate cancers. The group is committed to providing patients with early access to innovative treatments by designing increasingly complex trials according to the latest methodologies and research developed in the area of precision medicine.

President: Dr Thomas Bachelot,
Léon Bérard Centre, Lyon

Supportive Care Intergroup

The UNICANCER-AFSOS Supportive Care Intergroup has set itself the ambitious goal of designing and conducting high-standards clinical programmes using the most up-to-date and optimal methodology available and including the evaluation of quality of life and, whenever possible, a cost-efficiency analysis. Building a bridge with humanities and social sciences has also become an important ambition of this group, which has recently welcomed new members coming from the area.

President: Pr Ivan Krakowski,
Bergonié Institute, Bordeaux

Translational Research and Development in Radiation Oncology Group (UNITRAD)

The goal of the UNICANCER Translational Research and Development in Radiation Oncology Group is to promote innovative and/or strategic radiotherapy research programmes and to develop collaborative networks. Its experts work on numerous topics such as brachytherapy, imaging, modelling and radiomics, radiobiology and radio-potentiation, ionising radiation, quality assurance, methodology and pediatrics.

President: Pr David Azria,
Montpellier Cancer Institute, Montpellier

Immuno-Oncology Group

Established in 2016, the UNICANCER Immuno-Oncology Group is the newest of UNICANCER's expert groups. It embodies UNICANCER's strong desire to be a major player in cancer immunotherapy research. Bringing together renowned researchers and clinicians from the areas of immunology and oncology, this group offers a framework for cross-fertilization. A dozen clinical and translational studies involving immune checkpoint inhibitors are already under preparation, in particular the AcSé studies with nivolumab and pembrolizumab, led under the auspices of INCa.

President: Pr Frédérique Penault-Llorca,
Jean Perrin Centre, Clermont-Ferrand

Epidemiological Strategy and Medical Economics

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

President of the Scientific Committee:
Dr David Perol, Léon Bérard Centre, Lyon

UNICANCER transversal groups

Clinical Pharmacology and Oncology Group (GPCO)

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

President: Pr Joseph Ciccolini,
School of Pharmacy of Marseille,
Aix-Marseille University

Genetic and Cancer Group (GGC)

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

President: Dr Catherine Noguès,
Paoli-Calmettes Institute, Marseille

Cancer Biostatistics Group

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

President: Pr Stefan Michiels,
Gustave Roussy, Villejuif

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

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

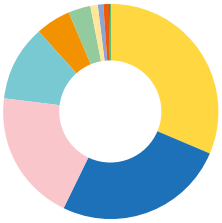
President: Dr Magali Lacroix-triki,
Gustave Roussy, Villejuif

Prevention of Infections in Cardiology Group (GPIC)

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

President: Dr Pierre Berger,
Paoli-Calmettes Institute, Marseille

*INCa accredited-group



Distribution of included patients by UNICANCER group

- UCBG-CANTO only (1,695)
- UCBG without CANTO (1,397)
- GETUG (1,063)
- MED PERSO (621)
- UCGI (282)
- GERICO (172)
- FEDEGYN (61)
- GEP (40)
- SARCOMA (48)
- UNITRAD (13)

Inclusions per Group

Type of Health Institution	FEDEGYN	GEP	GERICO	GETUG	PERSO MED	SARCOMA	UCBG	Of which CANTO	UCGI	UNITRAD	Total
Public Hospitals of Paris (AP-HP)	9	–	2	75	19	3	119	72	14	–	241
Public Hospitals (excl. AP-HP)	12	3	42	229	188	3	210	11	124	–	811
FCCC	39	37	91	525	399	42	2,414	1,600	74	13	3,634
Other private hospitals	–	–	5	19	12	–	68	10	14	–	118
Private Institutions	–	–	18	121	3	–	208	2	42	–	392
Foreign Institutions	1	–	14	94	–	–	73	–	14	–	196
Total	**61**	**40**	**172**	**1,063**	**621**	**48**	**3,092**	**1,695**	**282**	**13**	**5,392**

Focus on FCCC

Institution name	FEDEGYN	GEP	GERICO	GETUG	PERSO Med	SARCOMA	UCBG	Of which CANTO	UCGI	UNITRAD	Overall total
Antoine Lacassagne Centre	0	0	5	35	13	2	34	0	10	–	99
Eugène Marquis Centre	–	2	3	46	20	2	69	62	0	–	142
François Baclesse Centre	1	3	6	30	18	0	160	84	4	–	222
Georges-François Leclerc Centre	0	0	3	23	26	2	196	173	0	–	250
Henri Becquerel Centre	0	0	7	2	4	0	139	106	–	–	152
Jean Perrin Centre	1	6	8	14	4	1	162	85	–	–	196
Léon Bérard Centre	6	0	1	61	54	3	153	110	8	–	286
Oscar Lambret Centre	8	0	3	1	7	2	63	31	1	–	85
Paul Strauss Centre	0	6	1	0	0	0	17	2	6	–	30
Gustave Roussy	1	2	14	91	78	4	305	190	10	13	518
Bergonié Institute	1	0	1	19	12	7	75	46	1	–	116
Claudius Régaud Institute	1	0	1	44	30	5	71	27	0	–	152
Curie Institute	0	0	22	2	43	4	483	297	0	–	554
Lorraine Institute of Oncology (Alexis Vautrin Centre)	5	0	1	25	1	2	197	172	13	–	244
Institute of Cancer Research in Western France	4	11	7	58	52	2	102	63	17	–	253
Jean Godinot Institute	0	0	2	1	0	0	152	126	1	–	156
Paoli-Calmettes Institute	5	0	0	62	31	5	25	24	2	–	130
Montpellier Cancer Institute–Val d'Aurelle	6	7	6	11	6	1	11	2	1	–	49
Overall Total	**39**	**37**	**91**	**525**	**399**	**42**	**2,414**	**1,600**	**74**	**13**	**3,634**

2016 publications

Group	Study	Title	Authors	Reference
ESME	ESME CSM	Paclitaxel plus bevacizumab or paclitaxel as first-line treatment for HER2-negative metastatic breast cancer in a multicenter national observational study.	S. Delaloge, D. Pérol, C. Courtinard, E. Brain, B. Asselain, T. Bachelot, M. Debled, V. Dieras, M. Campone, C. Levy, W. Jacot, V. Lorgis, C. Veyret, F. Dalenc, J.-M. Ferrero, L. Uwer, P. Kerbrat, A. Goncalves, M.-A. Mouret-Reynier, T. Petit, C. Jouannaud, L. Vanlemmens, G. Chenuc, T. Guesmia, M. Robain, C. Cailliot	Ann Oncol. 2016 Sep. 27(9):1725-32
ESME	ESME CSM	Routinely collected data may usefully supplement randomized controlled data on treatment effects for mortality.	D. Pérol, M. Robain, S. Delaloge, C. Cailliot	BMJ. 2016 Dec. 16; 355:i6745
ESME	ESME CSM	Reply to 'The potential and perils of observational studies' by M. Buyse et al.	S. Delaloge, D. Pérol, M. Robain, C. Cailliot	Ann Oncol. 2016 Nov. 9
ESME	ESME CSM	UNICANCER ESME Program: how to use real world data to build a new research model in oncology (article in French).	C. Cailliot, G. Simon, C. Baron, C. Courtinard, M. Robain	Innovations & Théra-peutiques en Oncologie 2016 2(4):164-166
GEP	GEP07/ PACIFIK	Phase I, Dose-Escalation Trial of Pazopanib in Combination with Cisplatin in Patients with advanced Solid Tumors: A UNICANCER Study.	V. Diéras, T. Bachelot, M. Campone, N. Isambert, F. Joly, C. Le Tourneau, P. Cassier, E. Bompas, P. Fumoleau, S. Noal, C. Orsini, M. Jimenez, D.-C. Imbs, E. Chatelut	Oncol Ther. 2016 4:211.
GEP	GEP07/ PACIFIK	Pharmacokinetic interaction between pazopanib and cisplatin regimen.	D.-C. Imbs, V. Diéras, T. Bachelot, M. Campone, N. Isambert, F. Joly, M. Jimenez, T. Lafont, E. Chatelut	Cancer Chemother Pharmacol. 2016 Feb. 77(2):385-92
GEP	GEP03/ SUPAP	How to report toxicity associated with targeted therapies?	B. Cabarrou, J.-M. Boher, E. Bogart, E. Tresch-Bruneel, N. Penel, A. Ravaud, B. Escudier, C. Mahier Ait-Oukhatar, J.-P. Delord, H. Roché, T. Filleron	Ann Oncol. 2016 Aug. 27(8):1633-8
GETUG	GETUG 12	Outcome According to Elective Pelvic Radiation Therapy in Patients With High-Risk Localized Prostate Cancer: A Secondary Analysis of the GETUG 12 Phase 3 Rando-mized Trial.	P. Blanchard, L. Faivre, F. Lesaunier, N. Salem, N. Mesgouez-Nebout, E. Deniau-Alexandre, F. Rolland, J.-M. Ferrero, N. Houédé, L. Mourey, C. Théodore, I. Krakowski, J.-F. Berdah, M. Baciuchka, B. Laguerre, J.-L. Davin, M. Habibian, S. Culine, A. Laplanche, K. Fizazi	Int J Radiat Oncol Biol Phys. 2016 Jan. 1; 94(1):85-92
GETUG	GETUG 16	Salvage radiotherapy with or without short-term hormone therapy for rising prostate-specific antigen concentration after radical prostatectomy (GETUG-AFU 16): a rando-mized, multicentre, open-label phase 3 trial.	C. Carrie, A. Hasbini, G. de Laroche, 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. Créhange, N. Barbier, M. Habibian, C. Ferlay, P. Fourneret, A. Ruffion, S. Dussart	Lancet Oncol. 2016 Jun. 17(6):747-56
GGC	GENESIS	GENESIS: A French national resource to study the missing heritability of breast cancer.	O.-M. Sinilnikova, M.-G. Dondon, S. Eon-Marchais, F. Damiola, L. Barjhoux, M. Marcou, C. Verny-Pierre, V. Sornin, L. Toulemonde, J. Beauvallet, D. Le Gal, N. Mebirouk, M. Belotti, O. Caron, M. Gauthier-Villars, I. Coupier, B. Buecher, A. Lortholary, C. Dugast, P. Gesta, J.-P. Fricker, C. Noguès, L. Faivre, E. Luporsi, P. Berthet, C. Delnatte, V. Bonadona, C.-M. Maugard, P. Pujol, C. Lasset, M. Longy, Y.-J. Bignon, C. Adenis, L. Venat-Bouvet, L. Demange, H. Dreyfus, M. Frenay, L. Gladieff, I. Mortemousque, S. Audebert-Bellanger, F. Soubrier, S. Giraud, S. Lejeune-Dumoulin, A. Chevrier, J.-M. Limacher, J. Chiesa, A. Fajac, A. Floquet, F. Eisinger, J. Tinat, C. Colas, S. Fert-Ferrer, C. Penet, T. Frebourg, M.-A. Collonge-Rame, E. Barouk-Simonet, V. Layet, D. Leroux, O. Cohen-Haguenauer, F. Prieur, E. Mouret-Fourme, F. Cornélis, P. Jonveaux, O. Bera, E. Cavaciuti, A. Tardivon, F. Lesueur, S. Mazoyer, D. Stoppa-Lyonnet, N. Andrieu	BMC Cancer 2016 16:13
GGC	GENESIS	Mutation screening of MIR146A/B and BRCA1/2 3'UTRs in the GENESIS study.	A.-I. Garcia, M. Buisson , F. Damiola, C. Tessereau, L. Barjhoux, C. Verny-Pierre, V. Sornin, M.-G. Dondon, S. Eon-Marchais, GENESIS investigators, O. Caron, M. Gautier-Villars, I. Coupier, B. Buecher, P. Vennin, M. Belotti, A. Lortholary, P. Gesta, C. Dugast, C. Noguès, J.-P. Fricker, L. Faivre, D. Stoppa-Lyonnet, N. Andrieu, O.-M. Sinilnikova, S. Mazoyer	Eur J Hum Genet. 2016 Aug. 24(9):1324-9
GPCO		Prevention of fluoropyrimidine toxicity: do we still have to try our patient's luck?	R. Danesi, M. Del Re, J. Ciccolini, J.-H. Schellens, M. Schwab, R.-H. Van Schaik, A.-B. Van Kuilenburg	Ann Oncol. 2016 Sep. 29
PERSO MED	SAFIR01/ SAFIR02	Improving the Performance of Somatic Mutation Identification by Recovering Circulating Tumor DNA Mutations.	Y. Fu, C. Jovelet, T. Filleron, M. Pedrero, N. Motté, Y. Boursin, Y. Luo, C. Massard, M. Campone, C. Levy, V. Diéras, T. Bachelot, J. Garrabey, J.-C. Soria, L. Lacroix, F. André, C. Lefebvre	Cancer Res. 2016 Oct. 15; 76(20):5954-5961
PERSO MED	EXPRESS	Analysing patients presenting an exception-al and unexpected response in oncology: recent initiatives (article in French).	C. Ferté, O. Delattre, P. Laurent-Puig, J.-C. Soria, C. Caux, J.-Y. Pierga, C. Lebbé, L. Mortier, F. Barlési, T. Bachelot, A. Leary, I. Treilleux, T. Mazard, V. Boige, J.-S. Frenel, A. Gonçalves, O. Tredan, L. Albigès, T. Filleron, V. Pezzella, M. Jimenez, F. André	ITO. 2016 Jun. 2(3) :135-140
PERSO MED	AcSé	Equal access to innovative therapies and precision cancer care.	A. Buzyn, J.-Y. Blay, N. Hoog-Labouret, M. Jimenez, F. Nowak, M.-C. Deley, D. Pérol, C. Cailliot, J. Raynaud, G. Vassal	Nat Rev Clin Oncol. 2016 Jun. 13(6):385-93

Group	Study	Title	Authors	Reference
PERSO MED	SAFIR02	Mutational profile of metastatic breast cancers: a retrospective analysis.	C. Lefebvre, T. Bachelot, T. Filleron, M. Pedrero, M. Campone, J.-C. Soria, C. Massard, C. Lévy, M. Arnedos, M. Lacroix-Triki, J. Garrabey, Y. Boursin, M. Deloger, Y. Fu, F. Commo, V. Scott, L. Lacroix, M.-V. Dieci, M. Kamal, V. Diéras, A. Gonçalves, J.-M. Ferrerro, G. Romieu, L. Vanlemmens, M.-A. Mouret Reynier, J.-C. Théry, F. Le Du, S. Guiu, F. Dalenc, G. Clapisson, H. Bonnefoi, M. Jimenez, C. Le Tourneau, F. André	PLoS Med. 2016 Dec. 27; 13(12)
R&D UNICANCER	–	What specifications for a centre or network of excellence in clinical research?	V. Diebolt, M. Lang, F. Thoby; participants of the Giens XXXI round-table N°5	Thérapie 2016 71, 51-57
R&D UNICANCER	ConSoRe	The ConSoRe project supports the implementation of big data in oncology (article in French).	P. Heudel, A. Livartowski, P. Arveux, E. Willm, C. Jamain	Bull Cancer. 2016 Nov. 103(11):949-95
SARCOMA	Sarcome 09 (OS2006)	Zoledronate in combination with chemotherapy and surgery to treat osteosarcoma (OS2006): a randomized, multicentre, open-label, phase 3 trial.	S. Piperno-Neumann, M.-C. Le Deley, F. Rédini, H. Pacquement, P. Marec-Bérard, P. Petit, H. Brisse, C. Lervat, J.-C. Gentet, N. Entz-Werlé, A. Italiano, N. Corradini, E. Bompas, N. Penel, M.-D. Tabone, A. Gomez-Brouchet, J.-M. Guinebretière, E. Mascard, F. Gouin, A. Chevance, N. Bonnet, J.-Y. Blay, L. Brugières; Sarcoma Group of UNICANCER; French Society of Pediatric Oncology (SFCE); French Sarcoma Group (GSF-GETO)	Lancet Oncol. 2016 Aug. 17(8):1070-80
SARCOMA	Several studies, including Sarcoma 09 (OS2006)	The ENCCA-WP7/EuroSarc/EEC/PROVABES/EURAMOS 3rd European Bone Sarcoma Networking Meeting/Joint Workshop of EU Bone Sarcoma Translational Research Networks; Vienna, Austria, September 24–25, 2015. Workshop Report.	L. Kager, J. Whelan, U. Dirksen, B. Hassan, J. Anninga, L. Bennister, J.-V. Bovée, B. Brennan, J.-M. Broto, L. Brugières, A.-M. Cleton-Jansen, C. Copland, A. Dutour, F. Fagioli, S. Ferrari, M. Fiocco, E. Fleuren, N. Gaspar, H. Gelderblom, C. Gerrand, J. Gerß, O. Gonzato, W. Van der Graaf, S. Hecker-Nolting, D. Herrero-Martín, S. Klco-Brosius, H. Kovar, R. Ladenstein, C. Lancia, M.-C. Le Deley, M.-G. McCabe, M. Metzler, O. Myklebost, M. Nathrath, P. Picci, J. Potratz, F. Redini, G.-H. Richter, D. Reinke, P. Rutkowski, K. Scotlandi, S. Strauss, D. Thomas, O.-M. Tirado, F. Tirode, G. Vassal, S.-S. Bielack	Clin Sarcoma Res. 2016 Mar. 16; 6:3
UCBG	RTS01-Young Boost	Factors associated with patient-reported cosmetic outcome in the Young Boost Breast Trial.	P.J.A.M. Brouwers, E. van Werkhoven, H. Bartelink, A. Fourquet, C. Lemanski, J. van Loon, John H. Maduro, N.-S. Russell, L.J.E.E. Scheijmans, D.A.X. Schinagl, A.-H. Westenberg, P. Poortmans and L.J. Boersma, on behalf of the Young Boost Trial research group	Radiother Oncol. 2016 Jul. 120(1):107-13
UCBG	UCBG	Breast cancer screening: On our way to the future (article in French).	S. Delaloge, T. Bachelot, F.-C. Bidard, M. Espie, E. Brain, H. Bonnefoi, J. Gligorov, F. Dalenc, A.-C. Hardy-Bessard, D. Azria, J.-P. Jacquin, J. Lemonnier, W. Jacot, A. Goncalves, C. Coutant, G. Ganem, T. Petit, F. Penault-Lorca, M. Debled, M. Campone, C. Levy, B. Coudert, A. Lortholary, L. Venat-Bouvet, J. Grenier, H. Bourgeois, B. Asselain, J. Arvis, M. Castro, A. Tardivon, D.-G. Cox, P. Arveux, C. Balleyguier, F. André, R. Rouzier; Intergroupe national de recherche sur le cancer du sein UNICANCER (UCBG)	Bull Cancer 2016 Jul. 26
UCBG	PACS07	70-Gene Signature as an Aid to Treatment Decisions in Early-Stage Breast Cancer.	F. Cardoso, L.-J. Van't Veer, J. Bogaerts, L. Slaets, G. Viale, S. Delaloge, J.-Y. Pierga, E. Brain, S. Causeret, M. DeLorenzi, A.-M. Glas, V. Golfinopoulos, T. Goulioti, S. Knox, E. Matos, B. Meulemans, P.-A. Neijenhuis, U. Nitz, R. Passalacqua, P. Ravdin, I.-T. Rubio, M. Saghatchian, T.-J. Smilde, C. Sotiriou, L. Stork, C. Straehle, G. Thomas, A.-M. Thompson, J.-M. Van Der Hoeven, P. Vuylsteke, R. Bernards, K. Tryfonidis, E. Rutgers, M. Piccart; MINDACT Investigators	N Engl J Med. 2016 Aug. 25; 375(8):717-29.
UCBG	AMA	A phase II trial of abiraterone acetate plus prednisone in patients with triple-negative androgen receptor positive locally advanced or metastatic breast cancer (UCBG 12-1).	H. Bonnefoi, T. Grellety, O. Tredan, M. Saghatchian, F. Dalenc, A. Mailliez, T. L'Haridon, P. Cottu, S. Abadie-Lacourtoisie, B. You, M. Mousseau, J. Dauba, F. Del Piano, I. Desmoulins, F. Coussy, N. Madranges, J. Grenier, FC. Bidard, C. Proudhon, G. MacGrogan, C. Orsini, M. Pulido, A. Gonçalves	Ann Oncol. 0:1–6, 2016
UCBG	CANTO	A Systematic Evaluation of Blood Serum and Plasma Pre-Analytics for Metabolomics Cohort Studies.	E. Jobard, O. Trédan, D. Postoly, F. André, A.-L. Martin, B. Elena-Herrmann, S. Boyault	Int J Mol Sci. 2016, 17, 2035
UCBG	PACS09	Bevacizumab plus neoadjuvant chemotherapy in patients with HER2-negative inflammatory breast cancer (BEVERLY-1): a multicentre, single-arm, phase 2 study.	F. Bertucci, M. Fekih, A. Autret, T. Petit, F. Dalenc, C. Levy, G. Romieu, J. Bonneterre, J.-M. Ferrero, P. Kerbrat, P. Soulie, M.-A. Mouret-Reynier, T. Bachelot, F. Lerebours, J.-C. Eymard, M. Deblock, A. Lortholary, A.-C. Hardy-Bessard, P. Barthelemy, H. Bonnefoi, E. Charafe-Jauffret, F.-C. Bidard, P. Viens, J. Lemonnier, J.-Y. Pierga	Lancet Oncol. 2016 May 17(5):600-11
UCBG	CARMINA02	Randomized phase 2 neoadjuvant trial evaluating anastrozole and fulvestrant efficacy for postmenopausal, estrogen receptor-positive, human epidermal growth factor receptor 2-negative breast cancer patients: Results of the UNICANCER CARMINA 02 French trial (UCBG 0609).	F. Lerebours, S. Rivera, M.-A. Mouret-Reynier, S. Alran, L. Venat-Bouvet, P. Kerbrat, R. Salmon, V. Becette, C. Bourgier, P. Cherel, V. Boussion, C. Balleyguier, F. Thibault, S. Lavau-Denes, JM. Nabholz, B. Sigal, M. Trassard, MC. Mathieu, AL. Martin, J. Lemonnier, E. Mouret-Fourme	Cancer. 2016 Oct. 122(19):3032-40
UCGI	–	An assessment of the benefit-risk balance of FOLFIRINOX in metastatic pancreatic adenocarcinoma.	J. Péron, P. Roy, T. Conroy, F. Desseigne, M. Ychou, S. Gourgou-Bourgade, T. Stanbury, L. Roche, B. Ozenne, M. Buyse	Oncotarget. 2016 Dec. 13; 7(50):82953-82960
UCGI	ACCORD 11	Applying the longitudinal model from item response theory to assess 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. 2016 Jul. 36(5):615-28

Clinical operations

2016 projects, past and close future...
R&D UNICANCER aims to develop, conduct and coordinate international and translational clinical research. R&D UNICANCER is recognised in Europe as a leader in oncology and its goals are to improve the standard of cancer treatment for patients and ultimately increase survival and quality of life.

R&D UNICANCER promotes innovative research and implements strategies for prevention of all types of cancer. It is always looking for new and better solutions to improve the survival and lives of patients. Rare cancer types are included as well as marginalised groups such as the elderly, whilst also focusing on immunology and radiotherapy. Due to the increasingly complex and changing nature of clinical research, the clinical operations department restructured its organisation in 2016. It is now capable of setting up and managing large and complex studies and is in the process of certification for the quality of its activities. Furthermore a variety of software packages (CTMS, CS MONITOR and Export Online) are also being finalised and will soon be operational.

Tumour biology continues to expand at a great speed. R&D UNICANCER follows the identification of molecular alterations and targets them in order to find the best drugs for its patients. Indeed, R&D UNICANCER was the pioneer regarding these innovative studies, e.g. AcSé crizotinib et vemurafenib studies.

R&D UNICANCER is widely recognised as a leader in cancer trials and the number of patients participating in its studies has significantly increased since 2016. In order to achieve its strategy, R&D UNICANCER mobilises a broad network of clinical and medical scientists spread across 218 centres worldwide (159 in France and 59 abroad). End of 2016, R&D UNICANCER was conducting 76 studies, 40 in recruitment stage. R&D UNICANCER launched 10 studies in 2016 and established the immuno-oncology group. The visibility of R&D UNICANCER continues to progress through 50% more publications in international scientific journals and twice as many communications in international cancer congresses.

In 2017 R&D UNICANCER wants to accelerate and develop more ambitious projects focusing on immunology and personalised medicine. In addition, R&D UNICANCER aims to increase the number of international studies and develop its academic network.

Centralised Data-Centre
The partnership signed in 2011 between R&D UNICANCER and Montpellier Cancer Institute, which hosts the data-centre, has been renewed for 6 years through 2023.

A future objective is to implement e-CRF for all new trials. Processes and standards were adapted in 2016 to manage this change.

The data-centre has been in the process of quality certification since 2015. The final audit before certification will occur in June 2017.

Biological Resource Centre (BRC)

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

Some 71,000 biological samples (fixed and frozen tumour samples, complete blood and derivative products, DNA, RNA, etc.) have been banked in total so far. In 2016, 13,100 samples were collected prospectively.

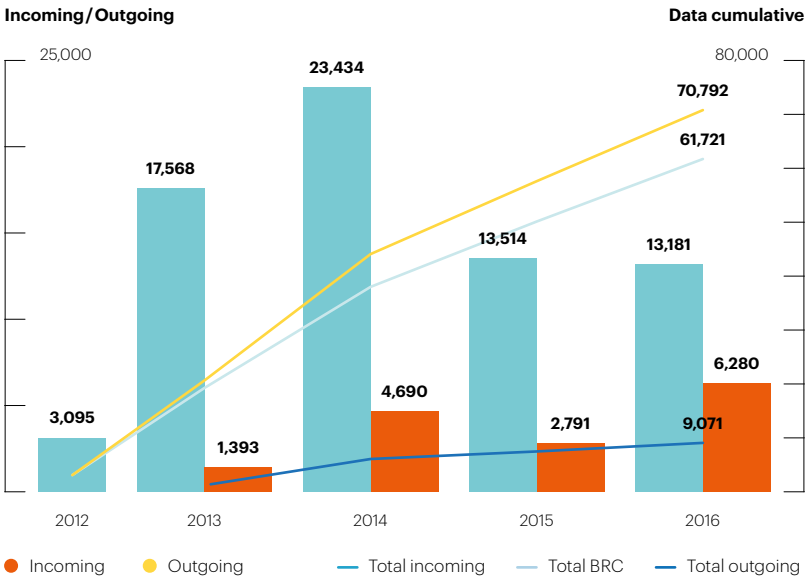
This centralisation guarantees the correct storage of the samples and ensures that they are rapidly available to research teams. The samples can be accessed following submission of a research project to R&D UNICANCER and validation of the project by a biological steering committee.

Since the activity was launched in 2012, around 20 research projects have been set up reusing biological samples archived in UNICANCER's biobank. Although the majority of these studies are still ongoing and the results are not yet available, some of them have already produced results of interest to cancer research communities and clinicians.

This is the case for the results published in 2015 by S. Ladoire et al. (Autophagy. 2015; 11(10): 1878-90. doi: 10.1080/15548627.2015.1082022), for example, which demonstrated that HMGB1 and LC3B can be considered to be predictive markers of breast cancer, especially in patients with a poor prognosis.

The development of biobanks requires the elaboration of large-scale approaches for monitoring biological sample quality and compliance with standard protocols. A systematic evaluation was published by UNICANCER's biobank team this year in the *International journal of Molecular Science* (E. Jobard et al., Int. J. Mol. Sci. 2016, 17, 2035; doi:10.3390/ijms17122035).

Evolution of entries and outputs samples



Regulatory affairs, pharmaco-vigilance, quality assurance

Ensuring quality and safety in clinical trials.

Regulatory, Legal and Pharmaceutical Affairs
In 2016, the new role of the Regulatory, Legal and Pharmaceutical Affairs unit as a legal support was successfully implemented in collaboration with the Department of Development and Partnership.

In addition to responding to daily queries, the unit actively participated in the development of regulatory texts relating to the new French regulation (Loi Jardé) on research involving human subjects, through consultations and working groups.

With respect to the protection of personal data, the unit is working towards the application of the General Data Protection Regulation. To this end, it has initiated a privacy impact assessment on R&D UNICANCER's research activities. This is a first step in shifting from an administrative compliance approach towards a system in which data protection is integrated by design and by default.

The unit also published guidelines and interpretation bulletins for the use of operational teams and provided training on the ever evolving regulatory framework with a focus on the new French and European clinical trials regulations.

Quality assurance
The Quality Assurance (QA) unit focuses on enhancing the quality level of activities led by R&D UNICANCER. 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 (Epidemio Strategy and Medical Economics) programme, as well as to French Comprehensive Cancer Centers (FCCC).

The support provided includes
- development of an efficient quality management system by creating and updating the relevant documentation governing R&D UNICANCER activities, in order to adapt to technical advances and new regulations;
- organisation and conduct of audits (sponsor site, trial documentation, investigational sites and suppliers); and
- provision of staff training on the main topics related to clinical trials and on any newly introduced documentation or tools.

In 2016, **the ISO 9001 certification project** for R&D UNICANCER activities and associated key supporting activities was launched in order to reinforce the quality assurance policy. All teams were involved and coordinated by the QA unit in order to construct a quality management system (via 12 processes and 95 activities) in compliance with ISO 9001 standard. The ISO 9001 certification project for French Comprehensive Cancer Centers (FCCC) launched in 2015 was continued in 2016 and 7 FCCC are certified so far. A joint IT communication platform was also created on the UNICANCER extranet and currently has 69 contributors. The purpose of this platform is to exchange regulatory texts, guidance and information on quality, regulatory and pharmaceutical topics (160 documents shared so far).

12
Newly authorised studies

55
Substantial amendments including 16 trials sponsored by FCCC

4
Initial authorisations in new countries

Pharmacovigilance

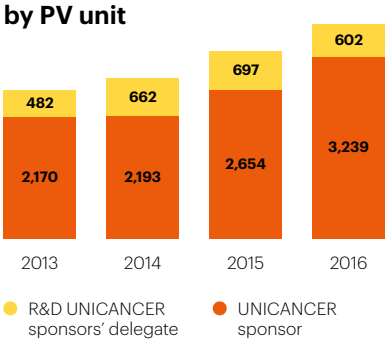
The Pharmacovilance (PV) unit plays a key role in the conduct of clinical trials. Indeed, patient safety is paramount in the conduct of clinical studies. By participating in the internal review committee, this department reviews the protocols from their conception in order to check the adequacy of the vigilance provisions to the study protocol and the specificities of each study. The PV unit is also involved throughout the research, by managing the pharmacovigilance cases (serious adverse events or SAEs) and participating in meetings where the patients' safety is discussed, such as data review meetings, for which the PV department produces an overview of safety cases reported throughout the concerned study. This step is part of the overall monitoring of studies, as well as the production of annual safety reports. Indeed, once a year and for each clinical trial, an annual safety report (ASR or DSUR for Development Safety Update Report) is produced by the PV department. The purpose of this document is to briefly describe any new safety information relevant to the clinical trial concerned and to assess the safety of the patients participating in this trial. This document serves as a link between the sponsor (R&D UNICANCER) and the French Medicine Agency (ANSM) concerning the safety of clinical trials. The PV unit is a major point of contact for ANSM regarding the safety of patients included in the various clinical studies, as it is for the competent authorities of each state in which a clinical trial promoted by UNICANCER is conducted.

The UNICANCER PV unit is also in charge of the pharmacovigilance/vigilance responsibilities on behalf of the French Comprehensive Cancer Centers (FCCC) that request it.

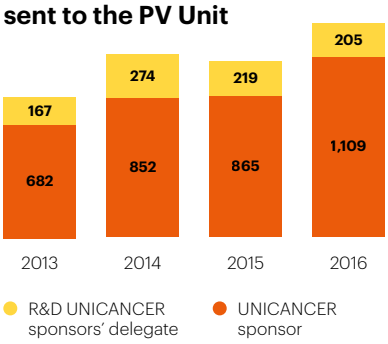
The regulatory changes that occurred at the end of 2016 imposed more vigilance constraints on all sponsors of clinical trials. The vigilance department took these changes into account and is in the process of updating its internal procedures for SAEs management to meet these new requirements. The setting up of a system for monitoring the SAE cases that may occur during closed days that would allow expedited reporting of all SAEs is also being considered, within the framework of a mutualised approach with the FCCC.

Two years ago, the PV unit acquired a new PV database, which will allow adaptation to all potential future international modifications in terms of transmission format of PV cases to the competent authorities. Important work was done in 2016 to ensure that all SAEs were imported to this new database, along with an import quality check. Another tool is under development and will enable electronic transmission of SAEs: this should ease the work of the investigating centres as well as that of the PV department. The development of this tool is expected for the second half of 2017. It will be made available to all centres that delegate vigilance to R&D UNICANCER.

Number of notifications (including follow-up) managed by PV unit



Number of SAEs sent to the PV Unit



Epidemiological Strategy and Medical Economics

Harnessing real-life data in oncology to improve patient care.

Presentation

In 2014, R&D UNICANCER launched the Epidemiological Strategy and Medical Economics (ESME) programme to centralise real-world patient data in oncology. The database is managed by R&D UNICANCER with a dedicated team assigned to the programme. It integrates data from three main sources: the patient electronic file, containing data from non-structured sources (e.g. medical records); pharmacy records, with data on all anti-cancer treatments delivered by the FCCC; and a systematic database (French programme for medicalisation of information systems) containing data on hospitalisation. The programme is today funded by four industrial partners (Roche, Pierre Fabre, Pfizer and AstraZeneca) and should be joined soon by other partners.

Database analyses may be requested either through calls for project proposals (academic requests) or by our industrial partners. The analyses, performed by R&D UNICANCER or by selected FCCC biostatistics departments, allow the description of the patient medical care provided, measuring the efficiency of therapeutic strategies and/or health products. The ESME Research Programme also responds to the various healthcare institution objectives from the "Plan Cancer", 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 registration/re-registration.

The ESME Scientific Committee (CSE) ensures the applicable scientific rules are followed and evaluates the analysis requests in compliance with defined eligibility criteria and scientific pertinence. Created in 2016, the ESME Independent Ethics Committee manages conflicts of interest. Finally, the ESME International Advisory Board reviews key international communication and reinforces international academic cooperation.

ESME projects

The programme's first project involves the construction of a large real-life database on patients with metastatic breast cancer (MBC), one of the leading causes of cancer-related mortality among women. By the end of 2016, clinical and therapeutic data were centralised for 17,000 patients initially treated in one of 20 FCCC between 2008 and 2014 for their metastatic disease. The first scientific communications were published in 2016; new communications and publications are planned in 2017.

The second ESME programme was prepared during the second semester of 2016. We are expecting 12,000 selected patients in 2019 to be treated for an ovarian cancer in the FCCC. We are discussing the possibility of involving other cancer healthcare establishments.

The feasibility phase for a new project dedicated to non-small cell lung cancer is in process. We are especially discussing the participation of non FCCC centres (public and private health establishments) in this project.

For all academic requests to the ESME database, we have begun to specialise 4 FCCC biometry departments to analyse these complex databases. Dedicated biometric teams should be able to respond more efficiently to all requests.

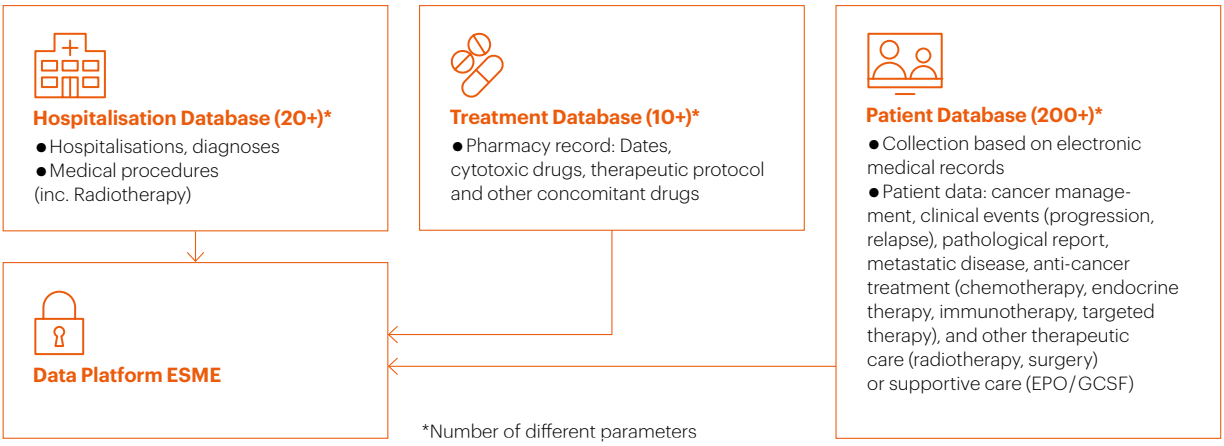
Perspective

We are discussing the next ESME projects for 2017 and 2018, especially in metastatic colorectal cancer and metastatic prostatic cancers, and are considering the capability to improve a specific ESME for immunotherapy. We are initiating collaboration with the French National Cancer Institute to extrapolate ESME data based on the global Cancer Database (external validity). We are also planning the potential linkage to the SNIIRAM data (Public Reimbursement Health Insurance Data) in order to match data obtained outside the French Comprehensive Cancer Centers.

Governance of the ESME research programme

Management of data collection and interrogation on ESME database

ESME Data Platform: Specifications



*Number of different parameters

ESME data platform: independent program management

Academics requests on ESME MBC (Metastatic Breast Cancer) database

2016–04	Étude de la survie globale en fonction de l'âge au diagnostic du cancer du sein métastatique.
2016–06	Projet BIOMETASEIN – Étude comparative des profils phénotypiques des métastases *versus* tumeurs primitives et détermination des facteurs prédisant le recours à une biopsie des métastases.
2016–07	Impact des définitions des critères d'évaluation (événements) sur les analyses de survie de la population des patients pris en charge pour un cancer du sein métastatique entre 2008 et 2013 dans les FCCC en France.
2016–08	ESME-VOLUTION: Description of the evolution of overall survival after a diagnosis of metastatic breast cancer (overall and among subtypes) across a 5 year period, and study of the potential determinants of the evolutions observed, in the national ESME database.
2016–09	CinéBreast – Determinants and impact on survival of tumor growth kinetics of breast cancer.
2016–10	Efficacité de l'Etoposide (VP-16) oral dans les cancers du sein métastatiques.
2016–13	Description des stratégies thérapeutiques et du pronostic des cancers du sein triple négatifs.
2016–14	Intérêt de la chimiothérapie dans la prise en charge initial des cancers du sein luminaux.
2016–16	De l'importance du traitement loco-régional de la tumeur primitive sur la survie, chez les patientes ayant d'emblée un carcinome mammaire de stade IV, à l'aire des traitements systémiques ciblés.
2016–18	Survie globale de la population métastatique HER2+ de novo/rechute et caractérisation de la présentation métastatique.
2016–19	Patients atteints de cancer du sein métastatique avec les récepteurs hormonaux positifs et un long avantage clinique par la thérapie hormonale seule: analyse d'une grande cohorte de patients français.
2016–20	Évaluation de l'intérêt des hormonothérapies successives dans la prise en charge initial des cancers du sein luminaux.

Development and partnerships

Optimising collaborations to foster innovation.

The research sponsored by R&D UNICANCER stems from a desire to
- bring together the broader scientific community by promoting themes of interest in terms of public health and patient access to innovation; and
- develop collaborations with the key players in research in France and abroad via partnerships focusing on specific themes or framework agreements.

At the national level, our collaboration with other actors in the field of oncology research is underscored by the fact that the five UNICANCER tumour groups are now members of multi-group collaborative networks accredited by the French National Cancer Institute (INCa). Indeed, 2016 was notable for the **conclusion of alliances between UNICANCER and the main research groups in digestive oncology** (FFCD and GERCOR) **and in head and neck cancers** (GORTEC, GETTEC and GERCOR). **Our historic partnerships with the ARC Foundation and French League Against Cancer have grown** through their support of three new trials: the Express study, and the two AcSé immunotherapy projects developed under the aegis of INCa, who have once more conferred their trust in the R&D operational organisation. These trials are of major interest for patients in terms of equal access to new treatments and for the researchers in terms of increased understanding of precision therapy.

The constant improvement of R&D UNICANCER in terms of mutualised operational capacity and the development of our research portfolio have allowed us to capitalise on a level of competence and credibility in discussions with our industrial partners to develop **new collaboration paradigms which combine scientific and operational expertise with a capacity to mobilise research networks.**

Our collections of biological samples amassed from the various R&D sponsored trials are of major interest for the validation of prognostic factors for different treatments. It is in this context that framework agreements with the pharmaceutical companies are expected in 2017. The French Comprehensive Cancer Centers can also provide expertise in fields other than medicine, such as radiotherapy, making us an attractive partner to institutions such as Cancer Research UK and various private companies.

Finally for 2016, in addition to the **extension of the ESME programme** to include two additional indications (ovarian and lung cancer) thanks to the confidence of a new partner, AstraZeneca, it is important to underline **the signature of a partnership agreement** between UNICANCER and the "labex" GENMED (CEA, CEPH) to genotype the samples collected as part of the CANTO cohort funded by ANR (National Research Agency). This represents more than 10,000 blood samples from women with breast cancer, which will be analysed over the next 2 years in an attempt to identify predictive genetic markers of response to treatment and treatment related toxicity.

- **MAP conference:** Our strong partnership with Cancer Research UK (CRUK) and the European Society for Medical Oncology (ESMO) led to the organisation of the second edition of the Molecular Analysis for Personalised Medecine (MAP) international conference, launched on the initiative of UNICANCER under the scientific leadership of Fabrice André, Jean-Charles Soria and Charles Swanton. It was held in September 2016 at the Business Design Center in the heart of London, and gathered about 400 clinicians and researchers. This year, the founders were happy to welcome the ARC foundation as an associate scientific partner for a multi-year duration.

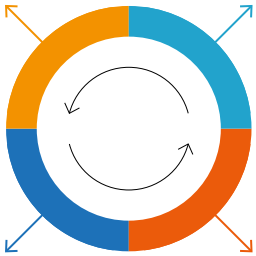
Principal remit of the development and partnerships department

Development of parnerships and strategic alliances

- Definition of partnerships strategy
- Institutional collaborations
- Academic intergroup collaborations
- Industrial and academic research collaborations
- Public – private partnerships
- European collaborations

Pooling of resources and processes

- Strategic advice for pooling clinical research activities
- FCCC advocacy on clinical research funding and policy
- Scientific intelligence on calls for Projects
- Technical support for projects submissions
- Coordination / management of research consortiums



Promotion of research activities

- Institutional representation of R&D UNICANCER
- Management and financing of expert groups' scientific symposia
- Development of R&D UNICANCER external communication
- Developement of research activity measurement tools

Development of research activities

- Implementation of new research axes, in particular via incubation of new expert groups
- Technical and organisational assistance to expert groups, e.g. for projects priming, management and financing / experts networking to facilitate bridges between fundamental-translational-clinical research / scientific animation
- Conception of internal calls for proposals (transversal and clinical research)
- Benchmarking

LEXICON

FFCD: French group of Digestive Oncology

GERCOR: Multi-disciplinary Cooperative Group in Oncology

GORTEC: Cooperative Group of Radiation Therapy for head and neck Cancer

GETTEC: French head and neck cancer Study Group

CEA: The French Alternative Energies and Atomic Energy Commission

CEPH: Human Polymorphism Study Center

Research in the FCCC

Key 2016 figures

Clinical research in the FCCC

- 15,1% of the patients treated in the FCCC are included in a clinical trial versus 8.5% of cancer patients on average in France
- Almost 500 active clinical trials over all
- 51% of the French hospital clinical research programmes in the field of cancer are granted to the FCCC

FCCC scientific publications*

- Ranked 5th in the number of publications in the oncology field, worldwide
- FCCC contributed 1/3 of the French publications in the field of cancer
- 24% of FCCC articles are published in the 10% most cited journals in the world

***Publications:** 2010–2015

Number of patients included in a clinical trial in 2016 per FCCC

French Comprehensive Cancer Centre (FCCC)	Town	Active patient files	Patients included in a clinical trial	Total active trials	Average N° of patients included/ active trials	% of the active patient file included in a clinical trial	Academic sponsor			Pharmaceutical industry sponsor	
							N° of patients included	N° of open trials	%patients included in an institutional clinical trial	N° of patients included	N° of open trials
Bergonié Institute	Bordeaux	6,206	1,598	224	7	25.7%	916	81	57.3%	682	81
François Baclesse Centre	Caen	6,550	925	166	6	14.1%	869	45	93.9%	56	45
Jean Perrin Centre	Clermont	4,652	497	84	6	10.7%	468	20	94.2%	29	20
Georges-François Leclerc Centre	Dijon	4,444	973	209	5	21.9%	836	65	85.9%	137	65
Oscar Lambret Centre	Lille	6,492	755	177	4	11.6%	640	44	84.8%	115	44
Léon Bérard Centre	Lyon	9,427	1,869	209	9	19.8%	1,338	84	71.6%	531	84
Paoli-Calmettes Institute	Marseille	8,468	1,348	224	6	15.9%	1,202	81	89.2%	146	81
Montpellier Cancer Institute – Val d'Aurelle	Montpellier	6,238	1,022	127	8	16.4%	941	38	92.1%	81	38
Lorraine Institute of Oncology	Nancy	4,512	517	125	4	11.5%	502	22	97.1%	15	22
Institute of Cancer Research in Western France (P. Papin/ R. Gauducheau)	Nantes Angers	10,716	1,034	254	4	9.6%	877	92	84.8%	157	92
Antoine Lacassagne Centre	Nice	5,139	585	144	4	11.4%	440	38	75.2%	145	38
Curie Institute	Paris Saint Cloud	12,850	1,393	190	7	10.8%	1,268	67	91.0%	125	67
Jean Godinot Institute	Reims	3,096	243	49	5	7.8%	217	11	89.3%	26	11
Eugène Marquis Centre	Rennes	4,713	447	93	5	9.5%	318	37	71.1%	129	37
Henri Becquerel Centre	Rouen	4,648	584	125	5	12.6%	521	35	89.2%	63	35
Paul Strauss Centre	Strasbourg	3,758	187	69	3	5.0%	143	16	76.5%	44	16
Claudius Regaud Institute	Toulouse	6,138	917	182	5	14.9%	603	80	65.8%	314	80
Gustave Roussy Institute	Villejuif	11,809	3,215	353	9	27.2%	2,295	221	71.4%	920	221
Total		**119,856**	**18,109**	–	–	**15.1%**	**14,394**		**79.5%**	**3,715**	–
Mean/FCCC		6659	1,006	167	6	14.3%	800	60	82.2%	206	60
+/– SD		2,846	717	75	2	6.0%	510	48	11.3%	251	48
Median		6,172	921	172	5	12.1%	738	45	85.4%	127	45
Min		3,096	187	49	3	5.0%	143	11	57.3%	15	11
Max		12,850	3,215	353	9	27.2%	2,295	221	97.1%	920	221

Appendices

R&D UNICANCER portfolio of trials in active phase (under recruitment) in 2016

Localisation	Study title	Study coordinator	Phase	Number of included patients	Expert group(s)
Breast cancer – Metastatic stage – Predictive factors for the response	GRT 02 – COMET Cohort study of prospective validation of predictive factors and biological imaging of response to bevacizumab (Avastin®) in combination with weekly paclitaxel chemotherapy in first line treatment patients with metastatic breast cancer.	J.-Y. Pierga	Cohort	510	UCBG
Breast cancer – Locally advanced stage	CADUSEIME 03 – SAKK – PERNETTA A randomized phase II trial of pertuzumab in combination with trastuzumab with or without chemotherapy, both followed by T-DM1 in case of progression, in patients with HER2-positive advanced breast cancer.	H. Bonnefoi	II	208	UCBG
Breast cancer – Localized stage	CANTO A cohort to quantify and to predict treatment related chronic toxicities in patients with non-metastatic breast cancer.	F. André	Cohort	10,000	UCBG
Breast Cancer – Non metastatic stage – ER+/Her2 – with poor prognosis	PACS 11 – UNIRAD Randomized, double-blind, multicentric phase III trial evaluating the safety and benefit of adding everolimus to adjuvant hormone therapy in women with poor prognosis, ER+ and HER2 – primary breast cancer who remain free of disease after receiving 3 years of adjuvant hormone therapy.	T. Bachelot, F. André	III	1,984	UCBG
Breast Cancer-luminal – Neoadjuvant	CARMINA 04 – NEOPAL Open-label, randomized, multicenter, international, parallel exploratory phase II study, comparing 3 FEC-3 docetaxel chemotherapy to letrozole +palbociclib combination as neoadjuvant treatment of stage II-IIIA PAM 50 defined luminal breast cancer, in postmenopausal women.	P. Cottu, S. Delaloge	II	132	UCBG
Breast Cancer – Localized stage	PACS 12 – RxPonder A phase III, randomized clinical trial of standard adjuvant endocrine therapy +/– chemotherapy in patients with 1–3 positive nodes, hormone receptor-positive and HER2-negative breast cancer with recurrence score (RS) of 25 or less. RxPONDER: A clinical trial Rx for positive node, endocrine responsive breast cancer.	S. Delaloge	III	1,000 in France (5,000 in total)	UCBG
Breast – HR positive, HER2 negative – Primary – with high relapse risk after neoadjuvant chemotherapy	PACS 13 – PENELOPEB Phase III study evaluating palbociclib (PD-0332991), a Cyclin-Dependent Kinase (CDK) 4/6 Inhibitor in patients with hormone-receptor-positive, HER2 – normal primary breast cancer with high relapse risk after neoadjuvant chemotherapy.	H. Bonnefoi	III	80 in France (800 in total)	UCBG
Breast cancer – ER+, HER2–	PACS 14 – 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.	F. Penault-Llorca, S. Delaloge	Cohort	200	UCBG
Breast cancer – ER positive/HER2 negative – Eligible for neoadjuvant endocrine therapy – TIL+	CARMINA 05 – ULTIMATE A phase II trial testing durvalumab combined with endocrine therapy in patients with ER+/HER2 – breast cancer eligible for neoadjuvant endocrine therapy and who present CD8 +T cell infiltration after 4–6 weeks exposure to immune-attractant.	F. André	II	240	UCBG
Breast cancer – Neoadjuvant treatment – HER2 positive	GEP 13 – NEOTOP Neoadjuvant phase II trial combining (3 FEC 100 followed by 3 docetaxel associated with trastuzumab plus pertuzumab) or (6 docetaxel, carboplatin associated with trastuzumab plus pertuzumab] according to TOP2A status in patients with operable, HER2-positive breast cancer. Identification of pathological Complete Response (pCR) predictive factors.	M.-A. Mouret-Reynier	II	90	GEP/UCBG

Localisation	Study title	Study coordinator	Phase	Number of included patients	Expert group(s)
Breast cancer – Adjuvant stting – ER(+)/HER2(–) – Elderly population	GERICO 11 – PACS 10 – ASTER 70s Adjuvant systemic treatment for oestrogen-receptor (ER)-positive HER2-negative breast carcinoma in women over 70 according to genomic grade index (GGI): chemotherapy +endocrine treatment versus endocrine treatment. A French UNICANCER Geriatric Oncology Group (GERICO) and Breast Group (UCBG) phase III multicentre trial.	E Brain	III	2,000 included for 1,080 randomized	GERICO/ UCBG
Breast cancer – Metastatic stage	GMP06 – RUBY A single arm, open-label, phase II study to assess the efficacy of rucaparib in metastatic breast cancer patients with a BRCAness genomic.	A. Patsouris	II	41	PERSO MED
Breast cancer – Metastatic stage	GMP 03 – SAFIR 02-BREAST Evaluation of the efficacy of high throughput genome analysis as a therapeutic decision tool for patients with metastatic breast cancer.	F. André	II	460 patients screened for 240 patients treated	PERSO MED/ UCBG
Breast cancer – Neoadjuvant setting – HER2+	GMP 05 – SAFIR-TOR Neoadjuvant phase II trial combining [3 FEC 100 followed by 3 docetaxel associated with trastuzumab plus pertuzumab] or [6 docetaxel, carboplatin associated with trastuzumab plus pertuzumab] according to TOP2A status in patients with T1c operable, HER2-positive breast cancer.	T. Bachelot	II	150	PERSO MED/ UCBG
Breast cancer – Indication for regional lymph node irradiation	RAD01 – HYPOG-01 Multicenter randomized phase III trial comparing hypofractioned versus standard radiotherapy in breast cancer with an indication for regional lymph node irradiation in terms of lymphedema occurrence.	S. Rivera	III	1,012	UNITRAD
Ovarian cancer – Relapse stage	FEDEGYN 02 – CHIPOR A phase III randomized study evaluating Hyperthermic Intra-Peritoneal Chemotherapy (HIPEC) in the treatment of relapse ovarian cancer.	J.-M. Classe	III	444	FEDEGYN
Pancreatic cancer – Non metastatic stage – Adjuvant treatment – Surgical resection	PRODIGE 24 – ACCORD 24 Multicentric randomized phase III trial comparing adjuvant chemotherapy with gemcitabine versus 5-fluorouracil, leucovorin, irinotecan and oxaliplatin (mFolfirinox) in patients with resected pancreatic adenocarcinoma.	T. Conroy	III	490	UCGI
Pancreatic Cancer – Locally advanced stage	PRODIGE 29 – UCGI 26 – NEOPAN A Randomized phase III trial comparing chemotherapy with folfirinox to gemcitabine in locally advanced pancreatic carcinoma.	M. Ducreux	III	170	UCGI
Rectal cancer – Locally advanced stage – Neoadjuvant treatment	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.	T. Conroy	III	460	UCGI
Rectal cancer – Locally advanced stage – Neoadjuvant treatment	GERICO 12 – NACRE A Phase III Study Evaluating Two Neoadjuvant Treatments Radio-chemotherapy (5 Weeks – 50 Gy + Capecitabine) and Radiotherapy (1 week – 25 Gy) in Patient Over 75 With Locally Advanced Rectal Carcinoma.	E. François	III	420	GERICO/ UCGI
Colorectal cancer – Metastatic stage	PRODIGE 28 – UCGI 27 – TIME Randomized phase II study of first-line FOLFIRI plus cetuximab for 8 cycles followed by either single-agent cetuximab as maintenance therapy or observation in patients with wild-type KRAS and NRAS metastatic colorectal cancer.	V. Boige	II	168	UCGI
Colorectal cancer – Metastatic stage	UCGI 28 – PANIRINOX Phase II randomized study comparing FOLFIRINOX + Panitumumab versus mFOLFOX6 + Panitumumab in metastatic colorectal cancer patients stratified by RAS and B-RAF status from circulating DNA analysis.	T. Mazard	II	209	UCGI
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) vs delayed radiotherapy until biochemical relapse associated with hormonal therapy of LH-RH analogue (decapeptyl® LP) in patients with operable prostate cancer pT3 R1 pN0 or pNx at intermediate risk.	P. Richaud	III	718	GETUG
Prostate cancer – Adjuvant setting	AFU – GETUG 20 Phase III randomized study to evaluate the benefit of adjuvant hormonal treatment with leuprorelin acetate (eligard® 45mg) for 24 months after radical prostatectomy in patients with high risk of recurrence.	S. Culine	III	700	GETUG

Localisation	Study title	Study coor-dinator	Phase	Number of included patients	Expert group(s)
Prostate cancer – Metastatic stage	AFU-GETUG 21 – PEACE1 A 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.	K. Fizazi	III	916	GETUG
Prostate cancer – Localized stage – High risk of recurrence	GETUG-AFU 23 – PEACE 2 A randomized phase III factorial design of cabazitaxel and pelvic radiotherapy in patients with localized prostate cancer and high-risk features of relapse.	K. Fizazi	III	1,048	GETUG
Prostate cancer – Biological relapse	GEP 12 – CARLHA Safety and efficacy radiotherapy combined with a 6-months LH-RH agonist and abiraterone hormone therapy treatment in biochemically-relapsing prostate cancer following surgery.	S. Supiot	I/II	37-43	GEP
Collecting Duct Carcinoma – Metastatic stage	GETUG-AFU 24 – BEVABEL Prospective phase II study of gemcitabine plus platinium salt in combination with bevacizumab (avastin®) for metastatic collecting duct carcinoma.	N. Pécuchet	II	41	GETUG
Renal Cell Carcinoma – Advanced or metastatic stage	GETUG-AFU 26 – NIVOREN A Phase II Safety Trial of Nivolumab (BMS-936558) in Subjects with Advanced or Metastatic Renal Cell Carcinoma Who Have Progressed During or After Receiving one prior systemic anti-angiogenic regimen.	L. Albiges	II	300	GETUG
Germ Cell tumors: testicular, mediastinal and retroperitoneal	GETUG-AFU 27 – TIGER A Randomized Phase III Trial Comparing Conventional-Dose Chemotherapy Using Paclitaxel, Ifosfamide, and Cisplatin (TIP) with High-Dose Chemotherapy Using Mobilizing Paclitaxel Plus Ifosfamide Followed by High-Dose Carboplatin and Etopo-side (TI-CE) as First Salvage Treatment in Relapsed or Refractory Germ Cell Tumors.	A. Fléchon	III	50	GETUG
Penile cancer – Metastatic lymph node involvement	GETUG-AFU 25 – MEGACEP Evaluation of Lymphadenectomy and Chemotherapy TIP (paclitaxel, ifosfamide and cisplatine) on Inguinal Lymph Nodes in Squamous Cell Carcinoma of the Penis.	J. Rigaud	II	78	GETUG
Uterine or Soft Tissue Leiomyosarcomas – Metastatic or relapse stage	SARCOME 11 – LMS 03 Phase II multicenter study to determine the efficacy of gemcitabine with pazopanib as second line treatment in patients with metastatic or relapsed uterine or soft tissue leiomyosarcomas.	P. Pautier	II	94	SARCOMA
Bone Sarcomas – Metastatic stage	SARCOME 12 – REGOBONE Randomized phase II, placebo-controlled, multicenter study evaluating efficacy and safety of regorafenib in patients with metastatic bone sarcomas.	F. Duffaud	II	132	SARCOMA
Head and neck squamous cell carcinoma – Metastatic stage	ORL 06 – COPAN Phase Ib/II trial of copanlisib in combination with cetuximab in recurrent or metastatic HNSCC harboring a PI3KCA mutation or PTEN loss.	C. Letourneau	Ib/II	32	UCH&N
Salivary gland cancer – Recurrent and/or metastatic – Androgen receptor positive	ORL 07 – EORTC 1206 A randomized phase II study to evaluate the efficacy and safety of chemotherapy versus androgen deprivation therapy in patients with recurrent and/or metastatic, androgen receptor expressing, salivary gland cancer.	F. Rolland	II	152	UCH&N
Non-Small Cell Lung Cancer – Metastatic stage	GMP 04 – SAFIR 02 LUNG Intergroup study UNICANCER 0105-1305/IFCT 1301 Evaluation of the efficacy of high throughput genome analysis as a therapeutic decision tool for patients with metastatic non small cell lung cancer.	J.-C. Soria	II	650 patients screened for 230 patients treated	PERSO MED
Multiple localisations – Metastatic stage	RAD 03 – STEREO-OS Extracranial Stereotactic Body Radiation Therapy (SBRT) added to standard treatment versus standard treatment alone in solid tumors patients with between 1 and 3 bone-only metastases.	S. Thureau, J.-C. Faivre	III	196	UNITRAD
Multiple localisations – Metastatic stage	ACSE CRIZOTINIB Secured access to crizotinib for patients with tumors harboring a genomic alteration on one of the biological targets of the drug.	G. Vassal	II	500	PERSO MED
Multiple localisations – Metastatic or unresectable locally advanced	ACSE VEMURAFENIB Secured access to vemurafenib for patients with tumors harboring BRAF genomic alterations.	J.-Y. Blay	II	500	PERSO MED
Multiple localisations – Metastatic stage	GMP07 – EXPRESS Molecular characterization of patients with solid tumors who presented an exceptional response to targeted therapies.	C. Ferté, F. André	Cohort	264	PERSO MED

Portfolio of trials in follow-up phase in 2016

Localisation	Study Title	Study coor-dinator	Phase	Number of included patients	Expert group(s)
Breast Cancer – Prevention	PREV 01 – MAP 3 A phase III randomized study of exemestane vs placebo in post-menopausal women at increased risk of developing breast cancer.	P. Pujol	III	19	UCBG
Breast cancer – BRCA mutations – Prevention	ONCO 03 – LIBER Prevention of breast cancer by letrozole in post-menopausal women carrying a BRCA1/BRCA2 mutation	P. Pujol	Prevention	170	UCBG
Breast cancer – Localized stage – Neoadjuvant treatment	CARMINA 02 – NIMFEA A randomized multicenter phase II study identifying hormone sensitivity profiles and evaluating the efficacy of anastrozole and fulvestrant in the neo-adjuvant treatment of operable breast cancer in postmenopausal women	F. Lerebours	II	116	UCBG
Breast Cancer – Non-metastatic lymph node-positive	PACS 01 A phase III study evaluating the benefit of docetaxel given sequentially with FEC 100 chemotherapy treatment in axillary lymph node-positive early breast cancer	H. Roché	III	1999	UCBG
Breast cancer – Non-metastatic stage with positive lymph nodes	PACS 04 Randomized and multicentric opened phase III study evaluating the concomitant administration of docetaxel 75 mg/m² and epirubicine 75 mg/m² versus FEC 100 in non metastatic with positive lymphatic nodes breast cancer subjects, and the sequential addition of herceptin In (HER2+++) and (HER2++ and FISH+) subjects	M. Spielmann	III	3010	UCBG
Breast cancer – Non-metastatic stage	PACS 05 Phase III randomized study of adjuvant fluourouracil, epirubicin and cyclophosphamide, in women with stage I breast cancer	P. Kerbrat	III	1500	UCBG
Breast Cancer – Non-metastatic stage – Genomic signature	PACS 07 – MINDACT (Microarray In Node-negative and 1 to 3 positive lymph node Disease may Avoid ChemoTherapy): A prospective, randomized study comparing the 70-gene signature with the common clinical-pathological criteria in selecting patients for adjuvant chemotherapy in breast cancer with 0 to 3 positive nodes.	S. Delaloge	–	2066	UCBG
Breast cancer – Non-metastatic stage – Poor prognosis	PACS 08 – TaVix Randomized open label multicentric phase III trial evaluating the benefit of sequential regimen associating FEC100 and ixabepilone in adjuvant treatment of non metastatic, poor prognosis breast cancer defined as triple-negative tumor (HER2 negative – ER negative – PR negative) or (HER2 negative and PR negative) tumor in node positive or node negative patients.	M. Campone	III	762	UCBG
Breast Cancer – Non-metastatic stage	RTS 01 – YOUNG BOOST Radiation dose intensity study in breast cancer in young women: a randomized phase III trial of additional dose to the tumor bed	A. Fourquet	III	712	UCBG
Breast cancer – Non-metastatic stage – Low risk of local recurrence	RTS 02 – SHARE Phase III multicentric trial comparing accelerated partial breast irradiation (APBI) versus standard or hypofractionated whole breast irradiation in low risk of local recurrence of breast cancer	Y. Belkacemi	III	914	UCBG
Breast Cancer – HER2 Inflammatory	PACS 09 – BEVERLY 1 Phase II Study Evaluating the Efficacy and Tolerance of Bevacizumab (Avastin) in HER2 – Inflammatory Breast Cancer	P. Viens	II	100	UCBG
Breast cancer – Ductal carcinoma	IBIS II Adjuvant tamoxifen compared with anastrozole in treating post-menopausal women with ductal carcinoma in situ (IBIS-II DCIS)	C. Levy	III	426	UCBG
Breast cancer – Locally advanced or metastatic stage	CADUSEIME 02 – AMA A 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	H. Bonnefoi	II	34	UCBG
Breast – Non-metastatic stage – HER-2 positive	GEP 04 – RADHER A phase II, randomized, multi-center study, assessing value of adding RAD001 to trastuzumab as preoperative therapy of HER-2 positive primary breast cancer amenable to surgery	M. Campone	II	82	GEP/UCBG

Localisation	Study Title	Study coor-dinator	Phase	Number of included patients	Expert group(s)
Endometrial cancer– Advanced stage	FEDEGYN 01– PORTEC 3 Randomized phase III trial comparing concurrent chemoradiation and adjuvant chemotherapy with pelvic radiation alone in high risk and advanced stage endometrial carcinoma: PORTEC-3.	C. Haie-Meder	III	67	FEDEGYN
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)	Pr V. Beckendorf	III	306	GETUG
Prostate Cancer– Locally advanced or high risk of relapse	GETUG 12 Phase III randomized study of adjuvant hormonal therapy with and without docetaxel and estramustine in patients with advanced prostate cancer or with a high risk of relapse	K. Fizazi	III	413	GETUG
Prostate cancer– 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	B. Dubray	III	378	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	C. Carrie	III	743	GETUG
Prostate cancer– Unfavorable group	GETUG-AFU 18 Phase III study comparing irradiation at a dose of 80 Gy to irradiation at 70 Gy in unfavorable prostate cancers associated with prolonged hormonal therapy	C. Hennequin	III	505	GETUG
Prostate cancer– localized stage– Detectable PSA	GETUG-AFU 22 A multicenter randomized phase II study comparing the efficiency of a HT concomitant with RT vs RT alone in the salvage of patients with a detectable PSA after prostatectomy	S. Guérif	II	125	GETUG
Colorectal cancer– Peritoneal carninomatosis	ACCORD 15– PRODIGE 07 Phase III study evaluating the uise of systemic chemotherapy and ChemoHyperthemia Intraperitoneal Preoperatively (CHIP) and after maximum resection of peritoneal carcinomatosis originating with colorectal cancer	F. Quenet	III	265	UCGI
Colorectal cancer– Metastatic stage– liver metastases	ACCORD 21– PRODIGE 14 (METHEP) Phase II multicentric randomized trial, evaluating the best protocol of chemotherapy, associated with targeted therapy according to the tumor KRAS status, in metastatic colorectal cancer (CCRM) patients with initially non-resectable hepatic metastases	M. Ychou	II	256	UCGI
Colorectal cancer– Metastatic stage– wtKRAS	ACCORD 22– PRODIGE 18 Phase II, multicentric randomized trial, evaluating the efficacy of fluoropyrimidine-based standard chemotherapy, associated to either cetuximab or bevacizumab, in KRAS wild-type metastatic colorectal cancer patients with progressive disease after receiving first-line treatment with bevacizumab	J. Bennouna	II	133	UCGI
Colorectal cancer– Metastatic stage– wtKRAS	UCGI 25 A multicentric randomized phase II trial evaluating dual targeting of the EGFR using the combination of cetuximab and afatinib versus cetuximab alone in patients with chemotherapy refractory wtKRAS metastatic colorectal cancer	J. Bennouna	II	75	UCGI
Bladder cancer– Advanced stage	GETUG-AFU 19 Intensified methotrexate, vinblastine, doxorubicin and cisplatin (MVAC-I) with or without panitumumab as first-line treatment of advanced urothelial carcinoma in patients without H-Ras nor K-Ras mutations. Randomized phase II study.	S. Culine	II	113	GETUG
Non-seminomatous Germ Cell tumours– Poor prognostic	GETUG 13 A risk-adapted strategy of the use of dose-dense chemotherapy in patients with poor-prognosis disseminated non-seminomatous germ cell tumors	K. Fizazi	III	263	GETUG
Biliary tract cancers– Non metastatic stage– Surgical resection	ACCORD 18– PRODIGE 12 Phase III multicenter randomized study comparing the effect of adjuvant chemotherapy for six months with gemcitabine-oxaliplatin 85 mg/m² (GEMOX 85) to observation in patients who underwent surgery for cancer of the bile ducts	E. Boucher	III	196	UCGI
Gastroesophageal cancer– Locally advanced or metastatic stage	ACCORD 20– PRODIGE 17– MEGA MEGA (Met or EGFR inhibition in Gastroesophageal Adenocarcinoma): FOLFOX alone or in combination with AMG 102 or panitumumab as first-line treatment in patients with advanced gastroesophageal adenocarcinoma FNCLCC-FFCD-AGEO PRODIGE 17-ACCORD 20 Randomized phase II trial	D. Malka	II	162	UCGI

Localisation	Study Title	Study coor-dinator	Phase	Number of included patients	Expert group(s)
GIST – Localized stage – High and intermediate risk	SARCOME 08 – EORTC 62024 Intermediate and high risk localized, completely resected, gastrointestinal stromal tumors (GIST) expressing KIT receptor : a controlled randomized trial on adjuvant imatinib mesylate (Glivec) versus no further therapy after complete surgery.	A. Lecesne	III	266	SARCOMA
Head and neck Squamous Cell Carcinoma – Non metastatic – Preoperative treatment	GEP 11 – PREDICTOR Multi-centric randomized phase II study of pre-operative afatinib (BIBW2992) aiming at identifying predictive and pharmacodynamic biomarkers of biological activity and efficacy in untreated non-metastatic head and neck squamous cell carcinoma patients	C. Letourneau	II	61	GEP / UCH&N
Lingual carcinoma	ORL 01 – HPV ORO Evaluation of the frequency of Human Papilloma Virus infections in tonsillar and basal lingual carcinomas.	H. Mirghani	II	302	UCH&N
Salivary gland cancer – Relapse or metastatic stage	ORL 02 – PACSA Phase II study of pazopanib in patients with recurrent and / or metastatic salivary gland carcinoma of the head and neck	J. Guigay	II	72	UCH&N
Ewing sarcoma	SARCOME 01 – EURO EWING 99 Treatment protocol for Ewing tumors : including a medico economic evaluation	N. Gaspar	I-II	1,135	SARCOMA
Osteosarcoma	SARCOME 09 – OS 2006 Intergroup Study (SFCE / GSF-GETO) OS2006 – Zoledronate osteo-sarcoma – treatment protocol for osteosarcoma of the child, adoles-cent and adult including: A randomized trial and biological studies	L. Brugières	III	653	SARCOMA
Multiple localisations – Advanced stage	GEP 07 – PACIFIK An open label dose escalation and pharmacokinetic phase I study with pazopanib in combination with cisplatin (CDDP) every three weeks in patients with advanced solid tumors.	V. Dieras	I	38	GEP

Communications

Group	Study	Congress	Title	Authors	Type of presentation
ESME	ESME CSM	EPICLIN	Plateforme de données de vie réelle ESME. Constitution d'une liste de sélection exhaustive multi-source.	T. Guesmia, M. Robain, D. Perol, B. Favier, D. Berchery, D. Cauchois, I. Piot, O. Payen, C. Courtinard, A. Doly, A. Guizard, A. Loeb, G. Perrocheaux, M. Mons, M. Velten, G. Simon	Oral presentation
ESME	ESME CSM	ASCO 2016	Overall survival of patients with HER2-negative metastatic breast cancer treated with a first-line paclitaxel with or without bevacizumab in real-life setting: Results of a multicenter national observational study.	S. Delaloge, D. Pérol, E. Brain, B. Asselain, T. Denis Bachelot, M. Debled, V. Dieras, M. Campone, C. Levy, W. Jacot, V. Lorgis, C. Veyret, F. Dalenc, J.-M. Ferrero, L. Uwer, A. Goncalves, I. Piot, G. Simon, M. Robain, C. Cailliot	Poster Discussion
ESME	ESME CSM	SABCS 2016	Real-life activity of oral vinorelbine in metastatic breast cancer patients in the UNICANCER ESME database.	P.-E. Heudel, M. Saghatchian, D. Parent, N. Madranges, C. Levy, F. Dalenc, M. Ung, L. Uwer, W. Jacot, P. Augereau, A. Mailliez, C. Lefeuvre, M. Campone, M.-P. Sablin, M.-A. Mouret-Reynier, M. Leheurteur, J.-C Eymard, T. Petit, J.-M. Ferrero, B. Coudert, A. Goncalves, C. Cailliot, G. Simon, D. Perol	Poster presentation
FEDEGYN	FEDEGYN 02– CHIPOR	PSOGI 2016	Multicentric, randomized, phase II trial evaluating Hyperthermic Intra-Peritoneal Chemotherapy (HIPEC) in the treatment of relapse ovarian cancer	J.-M. Classe	Oral discussion
GEP	GEP04/ RADHER	ASCO 2016	Predictive value of intratumoral signaling and immune infiltrate for response to pre-operative (PO) trastuzumab (T) vs trastuzumab + everolimus (T+E) in patients (pts) with primary breast cancer (PBC): UNICANCER RADHER trial results.	M. Campone, I. Treilleux, J. Salleron, M. Arnedos, Q. Wang, S. Delaloge, D. Loussouarn, J. Bonneterre, M. Lion, C. Mahier Ait-Oukhatar, X. Paoletti, M. Rios, V. Diéras, M. Jimenez, J.-L. Merlin, T. Bachelot	Poster presentation Abstract n°11620
GERICO	GERICO 11	PSOGI 2016	ASTER 70s ou Traitement adjuvant systémique du cancer du sein avec récepteurs aux oestrogènes-positifs et HER2-négatif de la femme de plus de 70 ans en fonction du grade génomique (GG).	F. Coussy, O. Mir, E. Bourbouloux, S. Kirscher, O. Rigal, J.-M. Ferrero, D. Allouache, P. Cottu, G. Romieu, E. Blot, M. Aude-Savoye, X. Durando, F. Duhoux, L. Venat, E. Malaurie, C. Lefeuvre, L. Jean-Canon, M. Lacroix-Triki, F. Rollot, F. Hermitte, C. Orsini, C. Dubot, F. Bonnetain, E. Brain	Poster presentation
GERICO	GERICO 11	SIOG 2016	ASTER 70S or optimal adjuvant treatment for women over 70 with luminal breast cancer: a GERICO/UNICANCER phase III trial.	F. Coussy, O. Mir, E. Bourbouloux, S. Kirscher, O. Rigal, J.-M. Ferrero, D. Allouache, P. Cottu, G. Romieu, E. Blot, A.-M. Savoye, X. Durand, F. Duhoux, L. Venat-Bouvet, E. Malaurie, C. Lefeuvre, J.-L. Canon, M. Lacroix-Triki, F. Rollot, F. Hermitte, C. Orsini, C. Dubot, F. Bonnetain, E. G. C. Brain	Poster presentation abstract SIOG-ABS-1362
GERICO	GERICO 10	SIOG 2016	Final results of gerico 10 getug p03 trial evaluating feasibility of docetaxel in vulnerable or frail elderly (75+) patients with metastatic castration resistant prostate cancer.	M. Loic, I. Latorzeff, N. Houede, J. Meunier, F. Priou, M. Gravis-Gwenaëlle, E. Carola, C. Orsini, T. Filleron	Poster presentation abstract SIOG16-ABS-1336
GETUG	ICECaP	ASCO 2016	Disease free survival (DFS) is a surrogate for Overall Survival (OS) in Localized Prostate Cancer (CaP).	C. Sweeney, W. Xie, M. M. Regan, M. Nakabayashi, M. E. Buyse, N. W. Clarke, L. Collette, J. J. Dignam, K. Fizazi, M. Habibian, S. Halabi, P. W. Kantoff, W. R. Parulekar, H. M. Sandler, O. Sartor, H. R. Soule, M. Robert Sydes, B. F. Tombal, S. G. Williams	Accepted poster discussion
GETUG	GETUG 13	ASCO 2016	Mature results of the GETUG 13 phase III trial in poor-prognosis germ-cell tumors (GCT).	K. Fizazi, A. Flechon, G. Le Teuff, J. Mardiak, L.-C. Pagliaro, L. Geoffrois, P. Kerbrat, C. Chevreau, R. Delva, F. Rolland, C. Theodore, G. Roubaud, G. Gravis, J.-C. Eymard, J.-P. Malhaire, C. Linassier, M. Habibian, M. Reckova, C. Logothetis, S. Culine	Oral presentation abstract n°4504
GETUG	GETUG 14	ASCO 2016	Does short-term androgen depletion add to high dose radiotherapy (80 Gy) in localized intermediate risk prostate cancer? Final analysis of GETUG 14 randomized trial.	B.-M. Dubray, J. Salleron, S. Gilles Guerif, E. Le Prise, A. Reynaud-Bougnoux, J.-M. Hannoun-Levi, T. Dat Nguyen, C. Hennequin, J. Cretin, M. Fayolle-Campana, J.-L. Lagrange, J.-M. Bachaud, D. Azria, A. Grangirard, P. Pommier, J.-M. Simon, M. Habibian, P. Bey, V. Beckendorf	Poster discussion abstract n°5021
GETUG	GETUG 15	ASCO 2016	Efficacy and tolerance of treatments received beyond progression in men with metastatic hormone-naïve prostate cancer treated with androgen deprivation therapy (ADT) with or without docetaxel in the GETUG-AFU 15 phase III trial.	P. Lavaud, G. Gravis, C. Legoupil, F. Joly, S. Oudard, F. Priou, L. Mourey, M. Soulie, I. Latorzeff, R. Delva, I. Krakowski, B. Laguerre, C. Theodore, J. M. Ferrero, P. Beuzeboc, M. Habibian, S. Foulon, J. M. Boher, G. Tergemina-Clain, K. Fizazi	Poster presentation abstract n°5080
GETUG	ICECaP	ESMO 2016	Metastasis free survival (MFS) is a surrogate for Overall Survival (OS) in Localized Prostate Cancer (CaP).	W. Xie, C. Sweeney, M. Regan, M. Nakabayashi, M. Buyse, N. Clarke, L. Collette, J. Dignam, K. Fizazi, M. Habibian et al	Oral presentation
GETUG	GETUG 12	ESMO 2016	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. Houédé, L. Mourey, C. Theodore, I. Krakowski, J.-F. Berdah, M. Baciuchka, B. Laguerre, J.-L. Davin, M. Habibian, S. Culine, A. Laplanche, K. Fizazi	Poster discussion

Group	Study	Congress	Title	Authors	Type of presentation
GETUG	GETUG 12	ESMO 2016	Modelling relapse in patients with high-risk localized prostate cancer treated randomly in the GETUG 12 phase III trial reveals two populations of relapsing patients.	C. Vicier, 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. Flechon, S. Oudard, M. Habibian, S. Culine, K. Fizazi	Poster presentation
GETUG	GETUG 15	ESMO 2016	How should we treat castration-resistant prostate cancer patients who have received androgen deprivation therapy (ADT) plus docetaxel upfront for hormone-sensitive disease? Mature analysis of the GETUG-AFU 15 phase III trial.	P. Lavaud, G. Gravis, C. Legoupil, S. Foulon, F. Joly, S. Oudard, F. Priou, M. Soulié, L. Mourey, I. Latorzeff, R. Delva, I. Krakowski, B. Laguerre, C. Theodore, J.-M. Ferrero, P. Beuzeboc, M. Habibian, J.-M. Boher, G. Tergemina-Clain,K. Fizazi	Poster presentation
GETUG	GETUG 15	ESMO 2016	Clinical outcome of new metastatic hormone sensitive metastatic prostate (nmHSPC) cancer in real life population, in monocentric study. Comparison with nmHSPC patients included in the GETUG 15 study.	M. Guerin, P. 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 presentation
GETUG	GETUG14	SFRO 2016	Suppression androgénique courte et radio-thérapie à haute dose (80 Gy) pour cancer prostatique de risque intermédiaire: analyse finale de l'essai randomisé GETUG 14.	B. Dubray, J. Salleron, S. Guerif, É. Le Prisé, A. Reynaud-Bougnoux, J. Hannoun-Lévi, T. Nguyen, C. Hennequin, J. Cretin, M. Fayolle-Campana, J. Lagrange, J. Bachaud, D. Azria	Oral presentation
GGC	GENESIS	8e assises de génétique humaine et médicale	Une ressource française unique pour étudier l'héritabilité manquante du cancer du sein: description de la population de l'étude GENESIS.	O.-M. Sinilnikova, S. Eon-Marchais, M.-G. Dondon, F. Damiola, L. Barjhoux, M. Marcou, C. Verny-Pierre, V. Sornin, L. Toulemonde, J. Beauvallet, D. Le Gal, N. Mebirouk, M. Belotti, O. Caron, M. Gauthier-Villars, I. Coupier, B. Buecher, A. Lortholary, C. Dugast, P. Gesta, J.-P. Fricker, C. Nogues, L. Faivre, E. Luporsi, P. Berthet, C. Delnatte, V. Bonadona, C.-M. Maugard, P. Pujol, C. Lasset, M. Longy, Y.-J. Bignon, C. Adenis, L. Venat-Bouvet, L. Demange, H. Dreyfus, M. Frenay, L. Gladieff, I. Mortemousque, S. Audebert-Bellanger, F. Soubrier, S. Giraud, S. Lejeune-Dumoulin, A. Chevrier, J.-M. Limacher, J. Chiesa, A. Fajac, A. Floquet, F. Eisinger, J. Tinat, C. Colas, S. Fert-Ferrer, C. Penet, T. Frebourg, M.-A. Collonge-Rame, E. Barouk-Simonet, V. Layet, D. Leroux, O. Cohen-Haguenauer, F. Prieur, E. Mouret-Fourme, F. Cornelis, P. Jonveaux, O. Bera, E. Cavaciuti, F. Lesueur, S. Mazoyer, D. Stoppa-Lyonnet, N. Andrieu	Poster presentation
GGC	GENESIS	8e assises de génétique humaine et médicale	Impact des facteurs de la reproduction sur l'association entre les gènes de la régulation des œstrogènes et le risque de cancer du sein: une stratégie pour l'étude GENESIS.	J. Coignard, C. Lonjou, M.-G. Dondon, S. Eon-Marchais, F. Damiola, L. Barjhoux, M. Marcou, C. Verny-Pierre, V. Sornin, L. Toulemonde, J. Beauvallet, D. Le Gal, N. Mebirouk, M. Belotti, O. Caron, M. Gauthier-Villars, I. Coupier, B. Buecher, A. Lortholary, C. Dugast, P. Gesta, J.-P. Fricker, C. Nogues, L. Faivre, E. Luporsi, P. Berthet, C. Delnatte, V. Bonadona, C.-M. Maugard, P. Pujol, C. Lasset, M. Longy, Y.-J. Bignon, C. Adenis, L. Venat-Bouvet, L. Demange, H. Dreyfus, M. Frenay, L. Gladieff, I. Mortemousque, S. Audebert-Bellanger, F. Soubrier, S. Giraud, S. Lejeune-Dumoulin, A. Chevrier, J.-M. Limacher, J. Chiesa, A. Fajac, A. Floquet, F. Eisinger, J. Tinat, C. Colas, S. Fert-Ferrer, C. Penet, T. Frebourg, M.-A. Collonge-Rame, E. Barouk-Simonet, V. Layet, D. Leroux, O. Cohen-Haguenauer, F. Prieur, E. Mouret-Fourme, F. Cornelis, P. Jonveaux, O. Bera, E. Cavaciuti, S. Mazoyer, O.-M . Sinilnikova, F. Lesueur, D. Stoppa-Lyonnet, N. Andrieu	Poster presentation
GGC	OFELy	8e assises de génétique humaine et médicale	Observatoire Français pour l'Étude du syndrome de Lynch OFELy: base clinico-biologique nationale et ressources biologiques dédiées à la recherche sur le syndrome de Lynch.	C. Lasset, S. Grandjouan, G. Perkins, P. Faure, C. Colas, O. Caron, F. Desseigne, J. Tinat, Y.-J. Bignon, D. Leroux, L. Faivre, B. Buecher, M.-A. Collonge-Rame, S. Fert-Ferrer, J.-P. Fricker, C. Nogues, P. Gesta, S. Giraud, I. Coupier, S. Audebert Bellanger, F. Prieur, C. Maugard, H. Dreyfus, A. Lortholary, S. Lejeune-Dumoulin, V. Mari, P. Pujol, O. Bera, M. Longy, J.-C. Saurin, S. Baert Desurmont, E. Pleynet Hagay Sobol, P. Laurent-Puig, T. Frebourg, UNICANCER, Genetics Group GGC	Poster presentation
GGC	OFELy	8e assises de génétique humaine et médicale	Cancer du sein chez l'homme à propos de quatorze patients reçus en consultation d'oncogénétique de 2012 à 2015.	B. Porquet, A.-M Birot, E. Mouret-Fourme, C. Senechal, C. Nogues	–
GGC	GENESIS	8e assises de génétique humaine et médicale	Recherche de nouveaux facteurs génétiques prédisposant au cancer du sein dans l'étude GENESIS-iCOGS: apport de la biologie des systèmes.	C. Lonjou, M.-G. Dondon, S. Eon-Marchais, F. Damiola, L. Barjhoux, M. Marcou, C. Verny-Pierre, V. Sornin, L. Toulemonde, J. Beauvallet, D. Le Gal, N. Mebirouk, J. Coignard, M. Belotti, O. Caron,M. Gauthier-Villars, I. Coupier, B. Buecher, A. Lortholary, C. Dugast, P. Gesta, JP. Fricker, C. Noguès, L. Faivre, E. Luporsi, P. Berthet, C. Delnatte, V. Bonadona, C. M Maugard, P. Pujol, C. Lasset, M. Longy, Y.-J. Bignon, C. Adenis, L. Venat-Bouvet, L. Demange, H. Dreyfus, M. Frenay, L. Gladieff, I. Mortemousque, S. Audebert-Bellanger, F. Soubrier, S. Giraud, S. Lejeune-Dumoulin, A. Chevrier, J.-M. Limacher, J. Chiesa, A. Fajac, A. Floquet, F. Eisinger, J. Tinat, C. Colas, S. Fert-Ferrer, C. Penet, T. Frebourg, MA. Collonge-Rame, E. Barouk-Simonet, V. Layet, D. Leroux, O. Cohen-Haguenauer, F. Prieur, E. Mouret-Fourme, F. Cornelis, P. Jonveaux, O. Bera, E. Cavaciuti, E. Barillot, S. Mazoyer, O. Sinilnikova, D. Stoppa-Lyonnet, N. Andrieu, F. Lesueur	Oral presentation

Group	Study	Congress	Title	Authors	Type of presentation
GGC	TUMOSPEC	8e assises de génétique humaine et médicale	Détermination du spectre tumoral, de la pénétrance et de l'utilité clinique des mutations constitutionnellesdans les nouveaux gènes de prédisposition aux cancers du sein et de l'ovaire: l'étude TUMOSPEC.	O. Caron , S. Eon-Marchais, F. Coulet, C. Colas , C. Delnatte, A. fajac, C. Houdayer, C. Lasset, M. Longy, D. Stoppa-Lyonnet, D. Vaur, C. Nogues, F. Lesueur, N. Andrieu	Poster presentation
GGC	–	8e assises de génétique humaine et médicale	Validation et mise en place du criblage somatique des gènes BRCA1/2 dans les adénocarcinomes séreux de haut grade de l'ovaire en vue d'un traitement par un inhibiteur de PARP1.	C. Benoist, E. Hua, A. Briaux, V. Moncoutier, C. Callens, M. Piccot, C. Nogues, A. Vincent-Salomon, D. Stoppa-Lyonnet, C. Houdayer, I. Bieche, E. Rouleau	–
PERSO MED	SAFIR02	SABCS 2016	High-throughput genome analysis and therapeutic decision for patients with HER2-negative metastatic breast cancer: first feasibility and molecular results of the randomized phase II study SAFIR02 BREAST (UCBG– 0105/1304).	A.Gonçalves, T. Bachelot, A. Lusque, M. Arnedos, M. Campone, Ivan Bièche, Ludovic Lacroix, G.Pierron, Florence Dalenc, T. Filleron, M.-P Sablin, M.Jimenez, J.-M Ferrero, C. Lefeuvre Plesse, H. Bonnefoi, V. Attignon, I. Soubeyran, P. Jezequel, F. Commo, F. André	Poster discussion
PERSO MED	SAFIR02	Hopital Expo 2016	La médecine de précision pour TOUS par la validation de l'utilisation de l'analyse du génome tumoral comme outil de décision thérapeutique.	C. Audigier-Valette, J.-C. Soria, F. Barlesi	Poster presentation
PERSO MED	AcSe crizotinib	ASCO 2016	Crizotinib in children and adolescents with advanced ROS1, MET or ALK-rearranged cancer: results of the AcSé phase II trial.	G. Vassal, L. Faivre, B. Geoerger, D. Plantaz, A. Auvrignon, C. Coze, N. Aladjidi, A. Verschuur, C. Icher, O. Minckes, N. Sirvent, G. Schleiermacher, N. Auger, E. Lonchamp, C. Mahier-Aït Oukhatar, M.-C. Le Deley, M. Jimenez, N. Hoog Labouret	Oral presentation (Clinical Science Symposium)
PERSO MED	AcSe crizotinib	SIOP2016	Efficacy of crizotinib in ALK+, MET+ or ROS1+ advanced pediatric malignancies: results of the AcSé phase II trial.	G. Vassal, L. Faivre, B. Geoerger, D. Plantaz, A. Auvrignon, C. Coze, N. Aladjidi, A. Verschuur, C. Icher, O. Minckes, N. Sirvent, G. Schleiermacher, N. Auger, E. Lonchamp, C. Mahier Ait Oukhatar, M.C. Le Deley, M. Jimenez, N. Hoog Labouret	Oral presentation
PERSO MED	AcSé vemurafenib	ASCO2016	Biomarker-driven access to vemurafenib in BRAF positive cancers: second study of the French National AcSé Programme.	J.-Y. Blay, N. Hoog Labouret, C. Cropet, J. Mazières, F. Nowak, I. Bièche, X. Troussard, E. Lonchamp, J. Charles, S. Dalle, E. Maubec, S. Leboulleux, D. Malka, B. Arnulf, A. Fléchon, I. Ray-Coquard, D. Pérol, V. Pezzella, M. Jimenez, Agnès Buzyn	Poster presentation
PERSO MED	AcSé vemurafenib	ESMO 2016	Vemurafenib (VM) in non-melanoma V600 and non-V600 BRAF mutated cancers: first results of the ACSE trial.	J.-Y. Blay, J. Mazières, D. Pérol, F. Barlesi, D. Moro-Sibilot, G. Quere, J. Trédaniel, X. Troussard, S. Leboulleux, D. Malka, A. Fléchon, C. Linassier, I. Ray-Coquard, B. Arnulf, Ivan Bièche, G. Ferretti, F. Nowak, M. Jimenez, N. Hoog-Labouret, A. Buzyn	Poster presentation
PERSO MED	AcSé vemurafenib	ESMO 2016	Lower risk of Cutaneous squamous cell carcinomas (cSCCs) induced by vemurafenib (V) in non-melanoma patients.	E. Maubec, A. Levy, C. Cropet, J. Mazières, X. Troussard, S. Leboulleux, D. Malka, M. Dinulescu, F. Granel-Brocard, D. Le Goupil, F. Truchetet, S. Dalle, M.-T. Leccia, N. Hoog-Labouret, GCC, M. Jimenez, B. Busser, J. Charles, J.-Y. Blay	Poster presentation
PERSO MED	AcSé vemurafenib	Journées de Dermatologie de Paris 2016 (JDP)	Carcinomes épidermoïdes cutanés (CE) induits par le Vemurafenib (Vemu) chez les patients atteints de tumeurs non mélanocytaires.	E. Maubec, A. Levy, C. Cropet, J. Mazières, X. Troussard, S. Leboulleux, D. Malka, M. Dinulescu, F. Granel-Brocard, D. Le Goupil, F. Truchete, S. Dalle, M.-T. Leccia, N. Hoog-Labouret, GCC, M. Jimenez, B. Busser, J. Charles, J.-Y. Blay	Poster presentation
PERSO MED	AcSé vemurafenib	WCLC 2016	Vemurafenib in patients with non-small cell lung cancer (NSCLC) harboring BRAF mutation. Preliminary results of the AcSé trial.	J. Mazieres, C. Cropet, F. Barlesi, P.J. Souquet, V. Avrillon, B. Coudert, J. Le Treut, F. Orsini Piocelle, G. Quere, E. Fabre, J. Tredaniel, M. Wislez, O. Huillard, E. Dansin, D. Moro-Sibilot, H. Blons, G. Ferretti, E. Lonchamp, N. Hoog-Labouret, V. Pezzella, C. Mahier, Aït Oukhatar, J.-Y. Blay	Poster presentation
UCBG	TransPACS 08	Carrefour Pathologie	Analyse globale de l'environnement immunitaire des cancers du sein triple négatif de l'essai multicentrique UNICANCER-PACS08.	E. Lardenois, I. Treilleux, M. Campone, M. Lacroix-Triki, A. Colombe, L. Odeyer, Christine Caux, C. Couillault, B. Dubois, J. Mussard, J. Valladeau-Guilemond, Mc. Michallet, S. Chabaud, E. Lavergne, A. Lardy-Cleaud, F. Andre, J. Lemonnier, N. Bendriss-Vermare, C. Caux	Oral presentation
UCBG	AMA	EBCC 10	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 and A. Goncalves	Poster presentation
PERSO MED	AcSé vemurafenib	ASCO2016	Biomarker-driven access to vemurafenib in BRAF positive cancers: second study of the French National AcSé Program.	J.-Y. Blay, N. Hoog Labouret, C. Cropet, J. Mazières, F. Nowak, I. Bièche, X. Troussard, E. Lonchamp, J. Charles, S. Dalle, E. Maubec, S. Leboulleux, D. Malka, B. Arnulf, A. Fléchon, I. Ray-Coquard, D. Pérol, V. Pezzella, M. Jimenez, . Buzyn	Poster presentation
PERSO MED	AcSé vemurafenib	ESMO 2016	Vemurafenib (VM) in non-melanoma V600 and non-V600 BRAF mutated cancers: first results of the ACSE trial.	J.-Y. Blay, J. Mazières, D. Pérol, F. Barlesi, D. Moro-Sibilot, G. Quere, J. Trédaniel, X. Troussard, S. Leboulleux, D. Malka, A. Fléchon, C. Linassier, I. Ray-Coquard, B. Arnulf, Ivan Bièche, G. Ferretti, F. Nowak, M. Jimenez, N. Hoog-Labouret, A. Buzyn	Poster presentation

Group	Study	Congress	Title	Authors	Type of presentation
PERSO MED	AcSé vemurafenib	ESMO 2016	Lower risk of Cutaneous squamous cell carcinomas (cSCCs) induced by vemurafenib (V) in non-melanoma patients.	E. Maubec, A. Levy, C. Cropet, J. Mazières, X. Troussard, S. Leboulleux, D. Malka, M. Dinulescu, F. Granel-Brocard, D. Le Goupil, F. Truchetet, S. Dalle, M.-T. Leccia, N. Hoog-Labouret, GCC, M. Jimenez, B. Busser, J. Charles, J.-Y. Blay	Poster presentation
PERSO MED	AcSé vemurafenib	Journées de Dermatologie de Paris 2016 (JDP)	Carcinomes épidermoïdes cutanés (CE) induits par le Vemurafenib (Vemu) chez les patients atteints de tumeurs non mélanocytaires.	E. Maubec, A. Levy, C. Cropet, J. Mazières, X. Troussard, S. Leboulleux, D. Malka, M. Dinulescu, F. Granel-Brocard, D. Le Goupil, F. Truchete, S. Dalle, M-T Leccia, N. Hoog-Labouret, GCC, M. Jimenez, B. Busser, J. Charles, J.-Y. Blay	Poster presentation
PERSO MED	AcSé vemurafenib	WCLC 2016	Vemurafenib in patients with non-small cell lung cancer (NSCLC) harboring BRAF mutation. Preliminary results of the AcSé trial.	J. Mazieres, C. Cropet, F. Barlesi, P.-J. Souquet, V. Avrillon, B. Coudert, J. Le Treut, F. Orsini Piocelle, G. Quere, E. Fabre, J. Tredaniel, M. Wislez, O. Huillard, E. Dansin, D. Moro-Sibilot, H. Blons, G. Ferretti, E. Lonchamp, N. Hoog-Labouret, V. Pezzella, C. Mahier-Aït Oukhatar, J.-Y. Blay	Poster presentation
UCBG	TransPACS 08	Carrefour Pathologie	Analyse globale de l'environnement immunitaire des cancers du sein triple négatif de l'essai multicentrique UNICANCER-PACS08.	E. Lardenois, I. Treilleux, M. Campone, M. Lacroix-Triki, A. Colombe, L. Odeyer, Christine Caux, C. Couillault, B. Dubois, J. Mussard, J. Valladeau-Guilemond, Mc. Michallet, S. Chabaud, E. Lavergne, A. Lardy-Cleaud, F. Andre, J. Lemonnier, N. Bendriss-Vermare, C. Caux	Oral presentation
UCBG	AMA	EBCC 10	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 and A. Goncalves	Poster presentation
UCBG	PACS 09	ISMRC	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 multicentre phase II trials of neoadjuvant chemotherapy combined with bevacizumab (BEVERLY 1&2 studies).	F. C. Bidard, J. Y. Pierga, 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, C. Proudhon, J. Lemonnier, P. Viens	Oral presentation
UCBG	PACS14 Adendom	SABCS	UCBG 2-14: A prospective multicenter non-randomized trial evaluating the effect of EndoPredict® (EPclin) clinico-genomic test on treatment decision making among patients with intermediate clinical risk.	F. Penault Lorca, F. Kwiatkovski, J. Grenier, C. Levy, M. Leheurteur, L. Uwer, O. Derbel, A. Le Rol, J.-P. Jacquin, C. Jouannaud, N. Quenel-Tueux, V. Girre, C. Foa, E. Guardiola, A. Lortholary, S. Catala, J. Lemonnier, S. Delaloge	Poster presentation
UCBG	CARMINA02	SABCS	Predictive value of FDG-PET/CT after neoadjuvant endocrine treatment in breast cancer.	S. Boughdad, L. Champion, V. Becette, P. Cherel, E. Fourme, V. Edeline, J. Lemonnier, F. Lerebours, J.-L. Alberini	Poster presentation
UCBG	CARMINA02	SABCS	Genomic analysis to evaluate response to neoadjuvant anastrozole and fulvestrant in post-menopausal ER-positive HER2-negative breast cancer patients included in the UCBG CARMINA02 trial.	C. Callens, N. Bessoltane, C. Ngo, W. Chemlali, V. Becette, V. Bernard, O. Delattre, J. Lemonnier, M.-A. Mouret-Reynier, F. André, I. Bièche, F. Lerebours	Poster presentation
UCBG	TransPACS04	SABCS	Prognostic and predictive values of High Endothelial Venules (HEV) and tumor infiltrating CD8+ lymphocytes (CD8) in tumors of patients included in the adjuvant PACS04 trial: HEV is predictive of outcome for HER2+ tumors exposed to trastuzumab.	H. Roché, F. Lafouresse, T. Filleron, R. Laffont, V. Maisongrosse, M. Pichery, S. Le Guellec, F. Penault-Llorca, J. Lemonnier, M. Lacroix-Triki, J.-P. Girard	Poster presentation
UCBG	COMET	SABCS	Circulating tumor cells (CTC) and endothelial cells (CEC) prognostic value in HER2 negative metastatic breast cancer patients treated with first line weekly paclitaxel and bevacizumab: first results of a prospective cohort from the French Breast Cancer InterGroup UNICANCER (UCBG): COMET study.	J.-Y. Pierga, O. Tredan, M. Chevrier, C. Dubot, V. Lorgis, G. Romieu, A. Goncalves, M. Debled, C. Levy, Jean-M. Ferrero, C. Jouannaud, E. Luporsi, M.-A. Mouret-Reynier, F. Dalenc, F. Berger, J. Lemonnier, C. Proudhon, F.-C. Bidard	Poster presentation
UCBG	PACS07–MINDACT	SABCS	Can Surrogate Pathological Subtyping Replace Molecular Subtyping? Outcome Results from the MINDACT Trial.	F. Cardoso, L. Slaets, F. de Snoo, J. Bogaerts, L.-J. van't Veer, J. Emiel Rutgers, J. Martine Piccart-Gebhart, L. Stork-Sloots, L. Russo, P. Dell'Orto, G. Viale	Poster Discussion PD7-01
PD7-01	ACCORD 12–PRODIGE 2	ASCO 2016	PRODIGE 2 phase III trial neoadjuvant in rectal cancer: quality of life and results at 5 years.	P.-L. Etienne, E. Francois, S. Gourgou, M. Jarlier, D. Azria, P. Rouanet, T. Conroy, O. Bouche, L. Mineur, V. Vendrely, J. Doyen, J.-F. Seitz, T. Stanbury, J.-P. Gerard	Poster presentation
UCGI	ACCORD 20–PRODIGE 17	ASCO 2016	Prognostic value of circulating tumor cells in advanced gastroesophageal adenocarcinomas in the randomized trial PRODIGE 17– MEGA (UNICANCER GI-AGEO).	S. Pernot, C. Badoual, M. Terme, F. Castan, E. Marcheteau, O. Bouche, J. Bennouna, E. Francois, F. Ghiringhelli, C. De La Fouchardiere, E. Samalin, J.-B. Bachet, C. Borg, M. Ducreux, A. Cazes, T. Stanbury, S. Gourgou, D. Malka, J. Taieb	Poster presentation

Group	Study	Congress	Title	Authors	Type of presentation
UCGI	ACCORD 20 – PRODIGE 17	ASCO 2016	Peripheral natural killer cells are a prognostic factor in advanced oesogastric adenocarcinoma and are associated with intestinal types in the randomized trial PRODIGE17 – ACCORD20 (UNICANCER GI).	M. Terme, S. Pernot, E. Marcheteau, F. Castan, O. Bouche, J. Bennouna, E. Francois, F. Ghiringhelli, V. Boige, C. De La Fouchardiere, E. Samalin, J.-B. Bachet, C. Borg, T. Stanbury, S. Gourgou, D. Malka, J. Taieb	Poster presentation abstract n°4061
UCGI	ACCORD 20 – PRODIGE 17	ASCO 2016	Prognostic value of circulating tumor cells in advanced gastroesophageal adenocarcinomas in the randomized trial PRODIGE 17 – MEGA (UNICANCER GI-AGEO).	S. Pernot, C. Badoual, M. Terme, F. Castan, E. Marcheteau, O. Bouche, J. Bennouna, E. Francois, F. Ghiringhelli, C. De La Fouchardiere, E. Samalin, J.-B. Bachet, C. Borg, M. Ducreux, A. Cazes, T. Stanbury, S. Gourgou, D. Malka, J. Taieb	Poster presentation
UCGI	ACCORD 20 – PRODIGE 17	ASCO 2016	Peripheral natural killer cells are a prognostic factor in advanced oesogastric adenocarcinoma and are associated with intestinal types in the randomized trial PRODIGE17 – ACCORD20 (UNICANCER GI).	M. Terme, S. Pernot, E. Marcheteau, F. Castan, O. Bouche, J. Bennouna, E. Francois, F. Ghiringhelli, V. Boige, Christelle De La Fouchardiere, E. Samalin, J. Baptiste Bachet, C. Borg, T. Stanbury, S. Gourgou, D. Malka, J. Taieb	Poster presentation abstract n°4061
UCGI	ACCORD 21 – PRODIGE 14	ASCO 2016	FOLFIRINOX combined to targeted therapy according RAS status for colorectal cancer patients with liver metastases initially non-resectable: A phase II randomized Study – Prodige 14 – ACCORD 21 (METHEP-2), a UNICANCER GI trial.	M. Ychou, M. Rivoire, S. Thezenas, R. Guimbaud, F. Ghiringhelli, A. Mercier-Blas, L. Mineur, E. Francois, F. Khemissa, D. Moussata, Y. Becouarn, P. Houyau, T. Aparicio, R. Adam, M.-P. Galais, F. Audemar, E. Assenat, T. Stanbury, O. Bouche	Poster discussion abstract n°3512
UCGI	ACCORD 22 – PRODIGE 18	ASCO 2016	Bevacizumab or cetuximab plus chemotherapy after progression with bevacizumab plus chemotherapy in patients with wtKRAS metastatic colorectal cancer: A randomized phase II study (Prodige 18 – UNICANCER GI).	S. Hiret, C. Borg, A. Bertaut, O. Bouche, A. Adenis, G. Deplanque, E. Francois, T. Conroy, F. Ghiringhelli, G. Des Guetz, J.-F. Seitz, P. Artru, T. Stanbury, M.-G. Denis, J. Bennouna	Poster discussion abstract n°3514
UCGI	UCGI 25	ASCO 2016	A multi-centric randomized phase II trial evaluating dual targeting of the EGFR with cetuximab and afatinib versus cetuximab alone in patients with chemotherapy refractory wtKRAS metastatic colorectal cancer (UCGI 25: A UNICANCER trial).	H. Senellart, E. Samalin, F. Castan, C. Borg, A. Adenis, C. De La Fouchardiere, D. Malka, V. Guerin-Meyer, E. Francois, M. Ben Abdelghani, E. Boucher, T. Andre, F. Ghiringhelli, A. Lievre, T. Stanbury, Jaafar Bennouna	Poster presentation Abstract n°3537
H&N	PACSA – ORL02	ASCO 2016	PACSA: Phase II study of pazopanib in patients with progressive recurrent or metastatic (R/M) salivary gland carcinoma (SGC).	J. Guigay, J. Fayette, C. Even, D. Cupissol, F. Rolland, F. Peyrade, B. Laguerre, C. Le Tourneau, S. Zanetta, L. Bozec Le Moal, C. Borel, P. Do, L. Digue, J. Delaye, A. Auperin, F. Bidault, V. Costes, L. Faivre	Poster presentation abstract n°6086
H&N	PACSA – ORL02	ESMO 2016	Pazopanib in patients with progressive or metastatic (R/M) salivary gland carcinoma (SGC): further evaluation of efficacy including tumor growth rates (TGR) analysis. H&N UNICANCER Group, PACSA trial with the REFCOR.	J. Guigay, F. Bidault, J. Fayette, C. Even, D. Cupissol, F. Rolland, F. Peyrade, B. Laguerre, C. Le Tourneau, S. Zanetta, L. Bozec Le Moal, C. Borel, L. Digue, J. Delaye, S. Diffetocq, V. Costes, A. Auperin, L. Faivre	Poster presentation
SARCOMA	EuroEwing99 (Sarcome 01)	ASCO 2016	Efficacy of Busulfan-Melphalan high dose chemotherapy consolidation in localized high-risk Ewing sarcoma: Results of EURO-E.W.I.N.G 99 R2Loc randomized trial.	J. Whelan, M.-C. Le Deley, U. Dirksen, I. Robert Judson, S. Douglas Hawkins, H. Van Den Berg, R. Ladenstein, J. Kruseova, A. Ranft, S. Amler, N. Gaspar, V. Laurence, G. Le Teuff, P. Marec-Berard, B. Brennan, K. Wheatley, B. Morland, S. Marreaud, H. Juergens, Odile Oberlin	Oral presentation
SARCOMA	EuroEwing99 (Sarcome 01)	ASCO 2016	Comparison of VAI standard chemotherapy & whole lung irradiation and Busulfan-Melphalan high dose chemotherapy in Ewing sarcoma (EwS) patients with pulmonary metastases: Results of EURO-E.W.I.N.G. 99 R2pulm randomized trial.	U. Dirksen, M.-C. Le Deley, Bernadette Brennan, Ian Robert Judson, Mark L. Bernstein, Richard Greg Gorlick, Neyssa Marina, Richard B. Womer, Nathalie Cozic, Nathalie Gaspar, Gwenael Le Teuff, Perrine Marec-Berard, Andreas Faldum, Michael Paulussen, Herbert Juergens, Lars Hjorth, Keith Wheatley, Mark D. Krailo, Jeremy Whelan, Douglas S. Hawkins	Oral presentation
SARCOMA	EuroEwing99 (Sarcome 01)	CTOS 2016	Busulfan-Melphalan with blood stem cell rescue (BuMel) for high risk localized Ewing Sarcoma (ES): results of R2Loc randomized study.	J. Whelan, M.-C. Le Deley, U. Dirksen, N. Gaspar, I. Judson, B. Brennan, A. Ranft, J. Hardes, P. Marec-Berard, M. Paulussen, G. Le Teuff, I. Lewis, A. Craft, H. Juergens, O. Oberlin	Poster
SARCOMA	EuroEwing99 (Sarcome 01)	EMSOS 2016	Ewing sarcoma of the head and neck: local treatment evaluation of the French population of Euro-Ewing99.	J. Bouaoud, S. Bolle, S. Temam, K. Belhous, L. Galmiche, F. Kolb, Q. Quassemyar, F. Bidault, V. Couloigner, N. Cozic, MC Le Deley, N. Kadlub, N. Gaspar	Oral presentation
SARCOMA	Sarcome 09 (OS2006)	EMSOS 2016	Local relapse in patients treated in the French OS2006 study: incidence, risk factors and outcome.	E. Mascard, L. Brugieres, B. Valery Ocean, F. Chotel, F. Gouin, P. Anract, P. Mary, A. Gomez-Brouchet, C. Bouvier, F. Larousserie, J.-L. Jouve, C. Glorion, J. Salles de Gauzy, J.-M. Guinebretière, G. de Pinieux, P. Marec Berard, J.-Y. Blay, H. Pacquement, S. Piperno-Neumann, M.-C. Le Deley	Oral presentation

Group	Study	Congress	Title	Authors	Type of presentation
SARCOMA	Sarcome 09 (OS2006)	SIOP 2016	Results of Methotrexate-Etoposide-Ifosfamide based regimen in osteosarcoma patients included in the French OS2006 study.	L. Brugières, B.-V. Occéan, H. Pacquement, C. Lervat, P. Marec-Bérard, J.-C. Gentet, N. Corradini, N. Entz-Werlé, M.-D Tabone, L. Saumet, M.-P. Castex, E. Bombas, C. Schmitt, H. Brisse, P. Petit, E. Mascard, F. Chotel, J.-M. Guinebretiere, S. Piperno-Neumann, N Gaspar, M.-C. Le Deley	Oral presentation
SARCOMA	Sarcome 09 (OS2006)	SIOP 2016	Local relapse in patients treated in the French OS2006 study: incidence, risk factors and outcome.	E. Mascard, L. Brugières, B. Occéan, F. Chotel, F. Gouin, P. Anract, P. Mary, A. Gomez-Brouchet, C. Bouvier, F. Larousserie, J.-L. Jouve, C. Glorion, J. Salles de Gauzy, J.-M. Guinebretière, G. de Pinieux, P. Marec Berard, J.-Y. Blay, H. Pacquement, S. Piperno-Neumann, MC Le Deley	Oral presentation
SARCOMA	Sarcome 09 (OS2006)	SIOP 2016	Osteosarcoma with several bone localisations at diagnosis: experience of the OS2006 study.	C. Lervat, L. Brugières, B.-V. Occéan, P. Marec-Bérard, N. Corradini, N. Entz-Werlé, J.-C. Gentet, H. Pacquement, L. Mansuy, M.-D. Tabone, S. Piperno-Neumann, M.-C. Le Deley	Poster presentation
SARCOMA	Sarcome 09 (OS2006)	CTOS 2016	Results of Methotrexate-Etoposide-Ifosfamide based regimen in osteosarcomas patients included in the French OS2006/ Sarcome-09 study.	L. Brugières, B.-V. Occéan, H. Pacquement, C. Lervat, P. Marec-Bérard, J.-C. Gentet, N. Corradini, N. Entz-Werlé, M.-D. Tabone, L. Saumet, M.-P. Castex, E. Bombas, C. Schmitt, H. Brisse, P. Petit, E. Mascard, F. Chotel, J.-M. Guinebretiere, S. Piperno-Neumann, N Gaspar, M.-C. Le Deley	Poster presentation
SARCOMA	Sarcome 09 (OS2006)	CTOS 2016	Comparison of Methotrexate-Etoposide-Ifosfamide and API-AI based regimen in 18-25yr osteosarcoma patients included in the French OS2006/Sarcome-09 study.	V. Laurence, L. Brugières, B.-V. Occéan, N. Gaspar, E. Bombas, J.-Y. Blay, D. Cupissol, N. Penel, C. Lervat, P. Kerbrat, A. Italiano, C. Mahier, M.-C. Le Deley, S. Piperno-Neumann, P. Marec-Bérard	Poster presentation
SARCOMA	Sarcome 09 (OS2006)	CTOS 2016	Results of API-AI based regimen in Osteosarcoma patients in the French OS2006/ Sarcome-09 study.	S. Piperno-Neumann, B.-V. Occéan, J.-Y. Blay, D. Cupissol, N. Penel, P. Marec-Bérard, A. Italiano, E. Bompas, O. Collard, A. Le Cesne, M. Rios, P. Kerbrat, M. Jimenez, L. Brugières, M.-C. Le Deley	Poster presentation
SARCOMA	Sarcome 09 (OS2006)	CTOS 2016	Impact of Zoledronic acid on children growth: results of the OS2006 randomized trial.	A. Chevance, L. Brugières, P. Marec-Bérard, H. Pacquement, C. Lervat, J.-C. Gentet, N. Entz-Werlé, N. Corradini, M.-D. Tabone, V. Gaveikaite, K. Buffard, F. Rédini, S. Piperno-Neumann, M.-C. Le Deley	Poster presentation

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