

Unicancer, a research and patient care Network



The poster features a background image of a Parisian river scene with a bridge and trees. At the top left is the Institut Curie logo. The main title is in large blue capital letters. To the right, the OECI logo is displayed, followed by its full name and a list of associated organizations.

institutCurie

**HOW TO ESTABLISH
PATIENT-CENTRED QUALITY
STANDARDS FOR VARIOUS TYPES
OF CANCER NETWORKS**

*Paris
April 19th 2018*

OECI
Organisation
of European
Cancer Institutes

An initiative under the
OECI Accreditation and Designation
Working Group

In collaboration with:
Institut Marie Curie

Under the auspices of:
Rare Cancers of the Adult Joint Action
(JARC)

Innovative Partnership for Action
Against Cancer (iPAAC)



Dr Pierre-Henri BERTOYE, Head Regulatory Affairs, Vigilances and QA





Unicancer, a research and patient care Network

Presentation focussed on clinical research

Contents:

- 1. Organization and Networks**
- 2. Clinical Research: quality through cooperation and mutualization**
 - 2.1. Involvement of expertise**
 - 2.2. Concentrations of services**
 - 2.3. Cooperation on methods and Practices**

In summary...



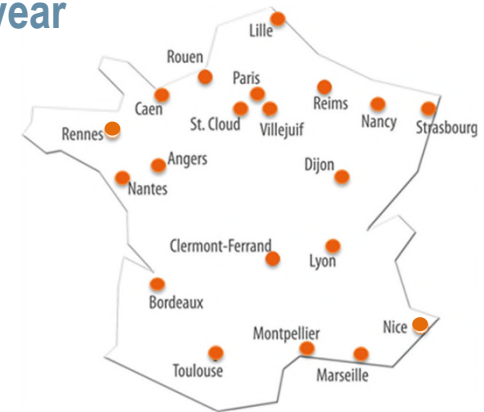


Unicancer, a research and patient care Network

1. Organization and Networks

A model in France based on the care-research-care continuum

- A national network **20 French Cancer Centers (FCCCs)** :
 - Private nonprofit hospitals, with a public service mission
 - Threefold mission: **care, research, education**
 - 19,000 employees and **135,000 patients** hospitalized per year
- Integrated management of **many types of cancer**:
 - Mainly solid tumors (with 1/3 of breast cancer patients in France)
 - Rare cancers
 - Complex situations / advanced cancers



UNICANCER is one of the largest cancer care and research organisations in Europe



5

FCCCs
are INCa-certified
integrated cancerology
research sites (SIRIC)
out of 8 in France

15

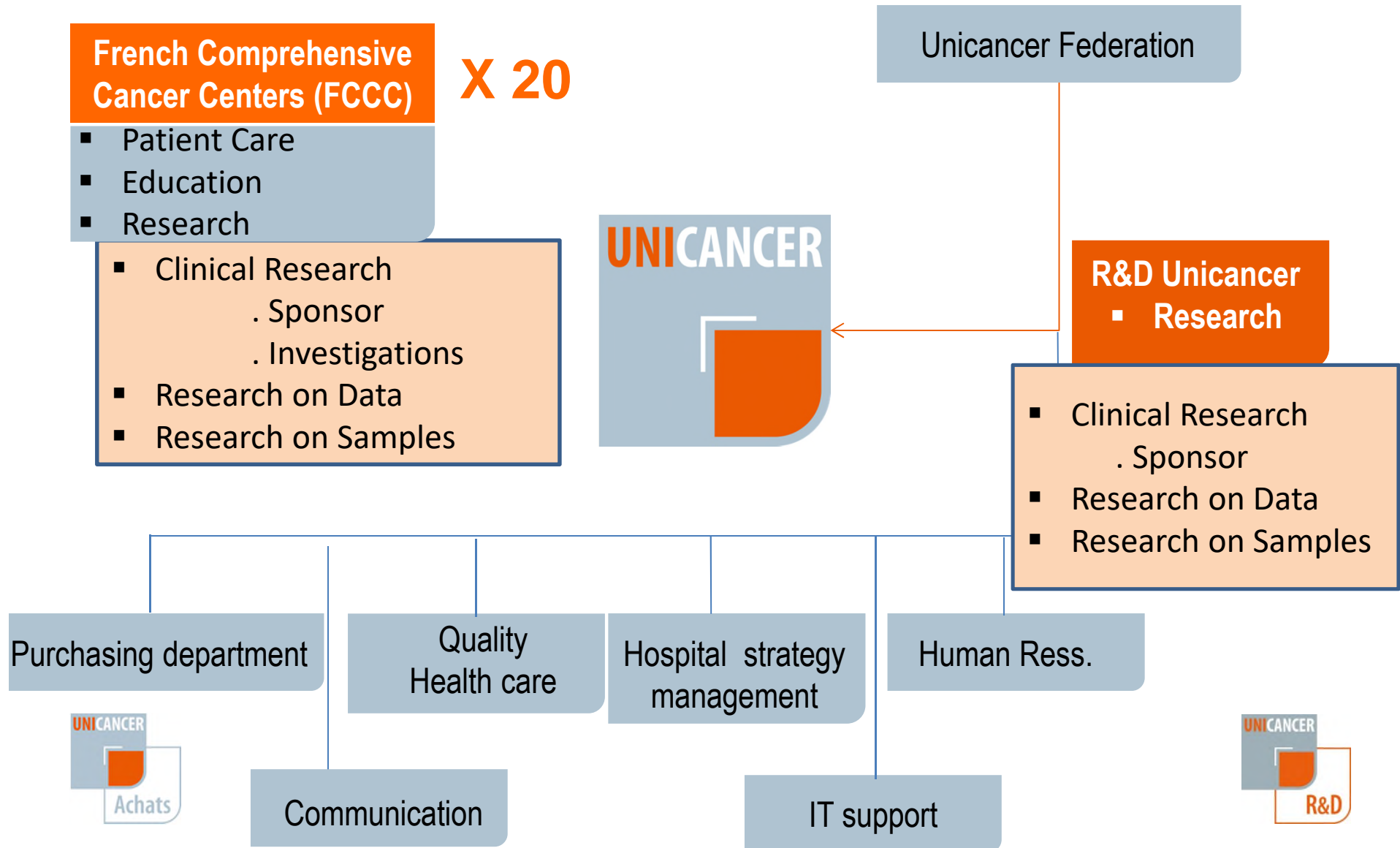
FCCCs are
INCa-certified
Molecular biology
platforms

12

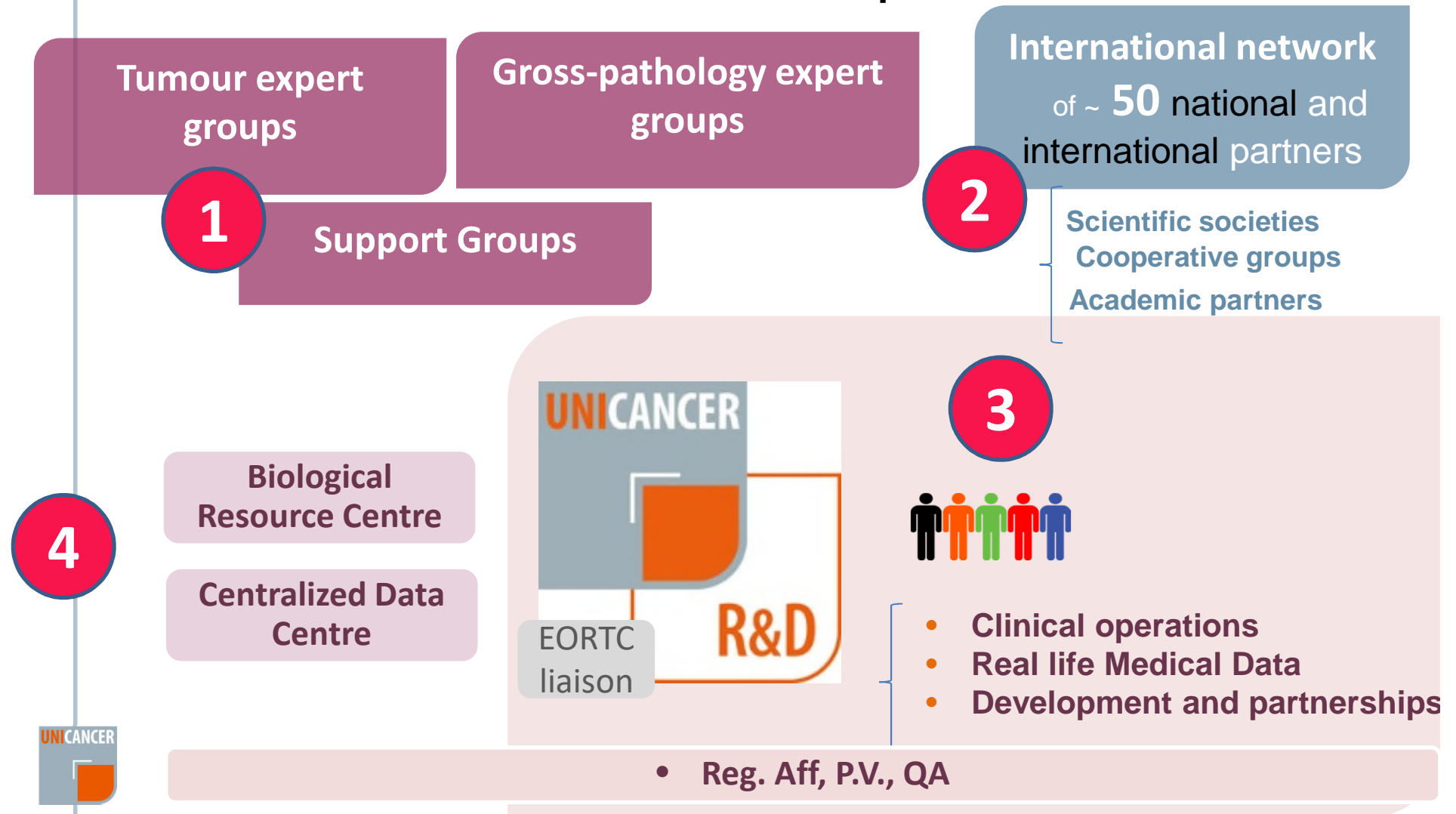
FCCCs
are INCa-certified
early-phase clinical trial
Centres (CLIP²),
out of 16 in France



Unicancer Organization: Health and Research



R&D Unicancer: network of expertise and resources, for the benefit of the patients



The UNICANCER Expert Groups



THE UNICANCER GROUP

PATIENTS

HEALTHCARE PROFESSIONALS

THE UNICANCER RESEARCH

- ▶ **R&D UNICANCER**
 - Expert groups
 - The CANTO Study
 - The tumour bank
 - The EORTC Liaison Office
 - Real world data
 - R&D UNICANCER publications
- ▶ Research in the French Comprehensive Cancer Centers

CAREERS AND TRAINING

NEWS

YOU ARE ▼

Patients

Being treated in a
Comprehensive Cancer
Center

UN

Find out more about us



Home » The UNICANCER research » R&D UNICANCER » Expert groups

Expert groups

UNICANCER expert groups are multidisciplinary groups focused on developing and steering innovative clinical studies.

Their goals are:

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



To achieve these goals, the UNICANCER tumour groups develop strategic clinical research programs with a strong translational component that relies upon a systematic centralised banking of biological samples. These clinical studies involve the FCCCs' units and platforms as well as a large number of public and private hospitals in France.

These groups 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.

UNICANCER tumour groups

French Breast Cancer Intergroup (UCBG)*

Genitourinary Group (GETUG)*

Gastrointestinal Group (UCGI)

Sarcoma Group*

Head & Neck Group (UCH&N)

UNICANCER cross-pathology groups

Oncogeriatrics Group (GERICO)*

Personalized Medicine Programme

Early Phase Group (GEP)

Supportive Care Intergroup

Translational Research and Development in
Radiation Oncology (UNITRAD)

Immuno-Oncology Group

Real World Data Group

The UNICANCER Groups, a large network of experts

1

Tumour Groups

French Breast Cancer Intergroup (UCBG)
Dr S. Delaloge / FCCC Villejuif

Gastro-Intestinal Group (UCGI)
Dr D. Malka / FCCC Villejuif

Genito-urinary Group (GETUG)
Pr S. Culine / AP-HP Paris

Head & Neck Group (UC HN)
Pr J. Guigay / FCCC Nice

Sarcoma Group (UC Sarcoma)
Pr J-Y. Blay / FCCC Lyon

Cross pathology Groups

Personalized Medicine
Pr F. André / FCCC Villejuif

Early Phase (GEP)
Dr T. Bachelot / FCCC Lyon

Onco-Immunology
Pr F. Penault-Llorca / FCCC Clermont-Ferrand

Oncogeriatrics (GERICO)
Dr E. Brain / FCCC St Cloud

Supportive Care and Social sciences & humanities
Pr I. Krakowski / FCCC Bordeaux

Radiation oncology (UNITRAD)
Pr D. Azria / FCCC Montpellier

Epidemiology Strategy Medical Economics (ESME)
Dr D. Perol / FCCC Lyon

Support Groups

Clinical Pharmacology and Oncology (GPCO)
Pr J. Ciccolini / Aix Marseille University

Evaluation of Immunohistochemical Prognostic Factors in BC (GEFPICS)
Dr M. Lacroix-Triki / FCCC Villejuif

Prevention of Infections in Oncology (GPIC)
Dr P. Berger / FCCC Marseille

Genetics and cancer (GGC)
Dr C. Noguès / FCCC Marseille

Statistics
Pr S. Michiels / FCCC Villejuif

All Groups are open to non-FCCC experts



Acknowledged by INCa as the key scientific group for the considered oncology domain

R&D Unicancer: National partners

2

FCCC

Public and
private hospitals

Academic
institutions

Inserm, CNRS,
Labex GENMED

Charities



Cooperative
groups

ex. IFCT, FFCD,
GERCOR,
GORTEC,
GSF-GETO,
SFCE, FFCD

ANSM
INCa
HAS

Health
agencies

Scientific
societies

ex. SFC,
AFSSOS,
AFU,

Biotech and
Pharmaceutical
companies



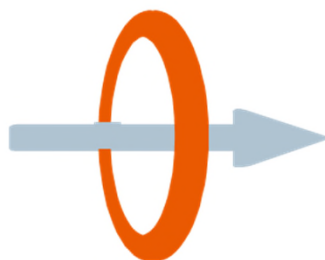
R&D Unicancer: international partners



2

Liaison Office

EORTC



**European
Cooperative
Groups**

BIG,
EORTC groups,
GBG,
SAKK

**US Cooperative
Groups**

NCI network ,
NCCTG/MCCRC,
SWOG

14 recruiting countries,

Belgium, Canada, Denmark, Ireland,
Israel, Italy, France (85% of sites↓),
Germany, Greece, The Netherlands,
Poland, Spain, Switzerland, United
Kingdom ...

**Biotech and
Pharmaceutical
companies**

**Public and
private hospitals**



R&D UNICANCER,

140 people, full sponsoring capabilities



3

■ Clinical Trial operations team, structured with 5 expert poles

- Close interaction with cooperative groups
- 18 Clinical Project Managers
- 46 CRAs m

■ Real World Data

■ Development an

Internal shared re

■ Regulatory Aff

ISO 9001
Certification in
progress

- **93 active trials,**
 - 41 in inclusion phase
 - 52 in FU phase
- **270 trial sites, 67/270 abroad**
- **4898 patients included in 2017**

4

External shared re

■ Biological Res

■ Centralized Data





Unicancer, a research and patient care Network

2. Research: quality through cooperation and mutualization

Unicancer, a research and patient care Network

Quality through cooperation and mutualization



CTTI RECOMMENDATIONS: QUALITY BY DESIGN

June 2015

1. Create a culture that values and rewards **critical thinking and open dialogue** about quality, and that goes beyond sole reliance on tools and checklists.
2. **Focus** effort on **activities that are essential to the credibility** of the study outcomes.
3. Involve the **broad range of stakeholders in protocol development** and discussions around study quality
4. **Prospectively identify and periodically review** the critical to quality factors.





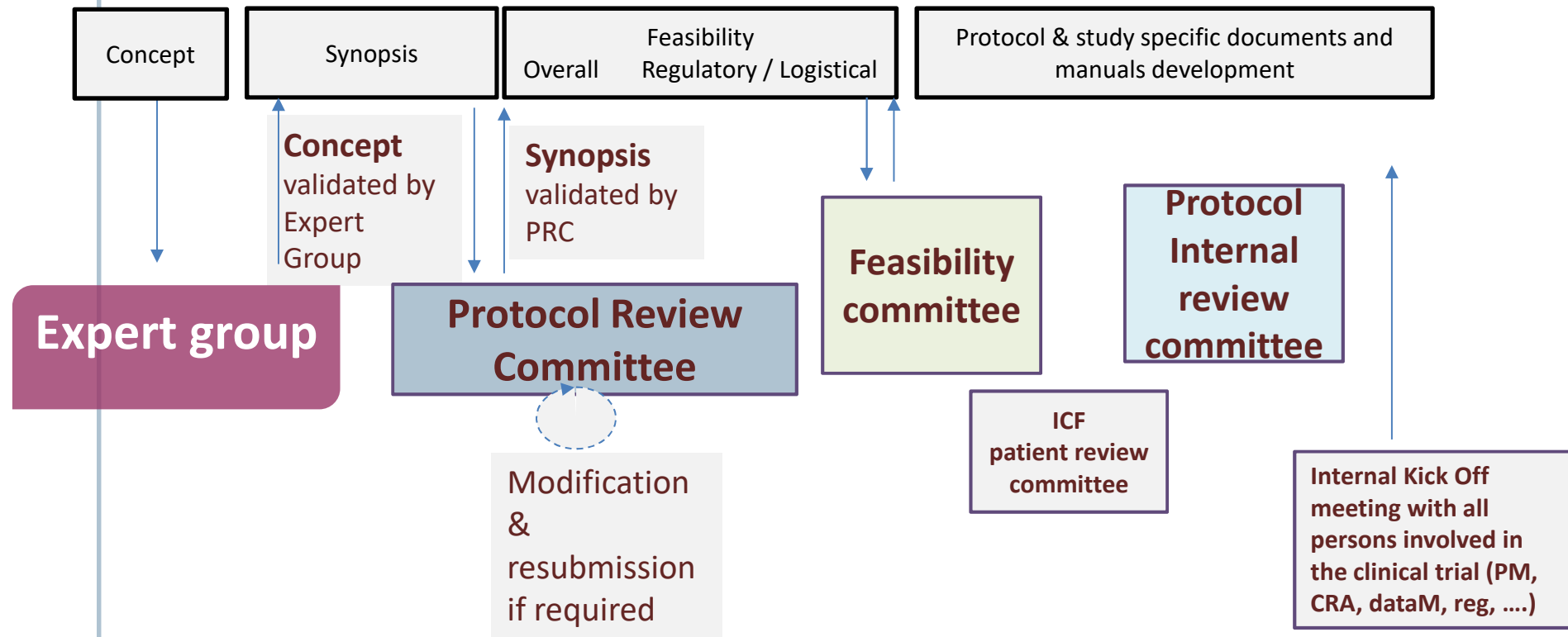
Unicancer, a research and patient care Network

2. Research: quality through cooperation and mutualization

2.1. Involvement of expertise in protocol concept, development and conduct

R&D UNICANCER

Clinical Trial: **From concept to implementation** Review process and Quality measures

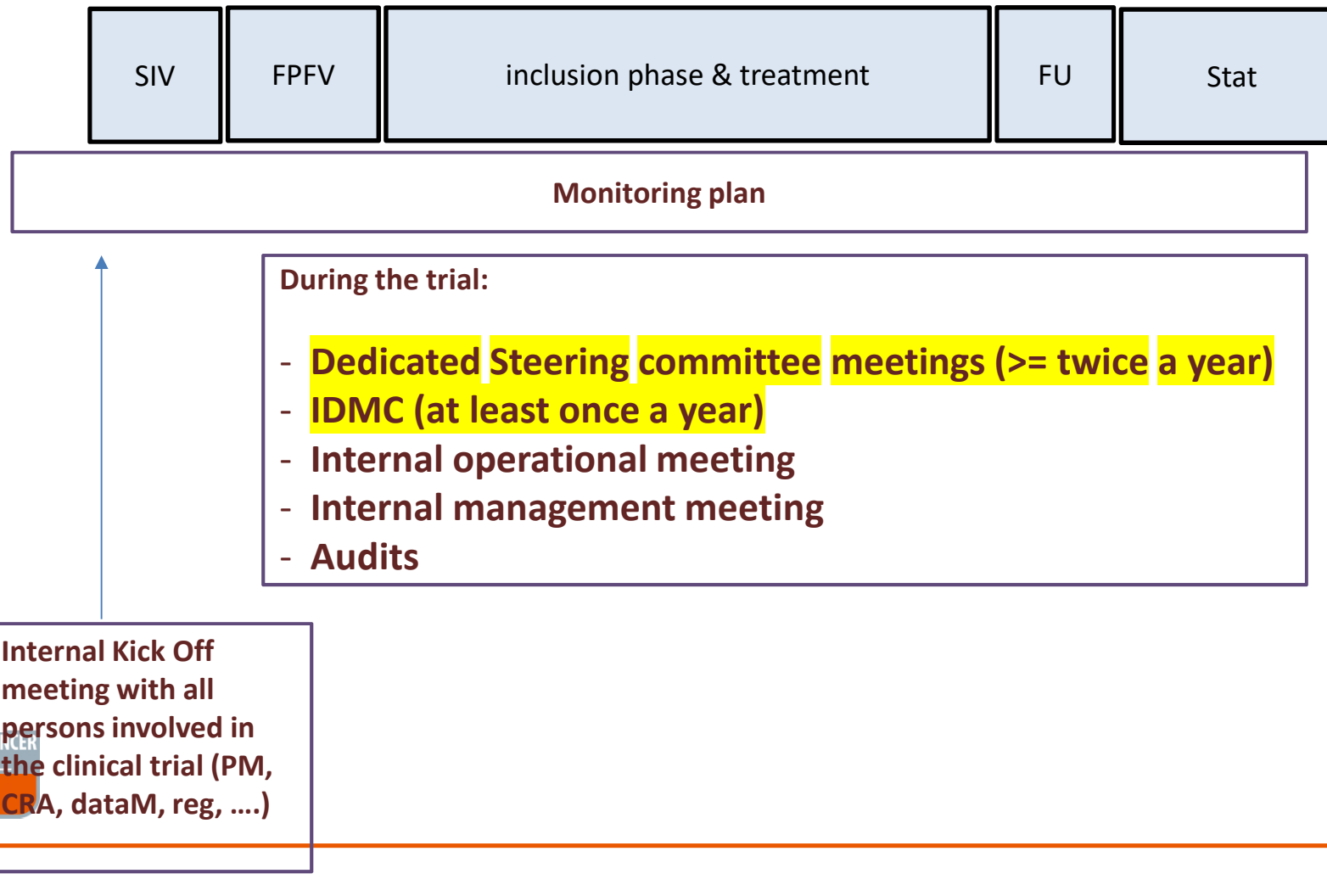


Protocol Review Committee (PRC): duties

- Scientific review of all the projects submitted by the Expert Groups
- Identification and approval of the projects to be sponsored by R&D according to :
 - Clinical scientific interest
 - Interest of translational research
 - Study feasibility
- Other criteria to be taken into consideration:
 - Financial support
 - R&D UNICANCER human resources
- Other tasks: global scientific advice

R&D UNICANCER

Clinical Trial: **Conduct and termination** **Review process and Quality measures**



R&D Unicancer International trials governance

The Steering Committee, a strategic role

Missions

- Trial design
- Trial follow-up and surveillance (safety)
- Amendments (as needed)
- Promoting translational research
- Access to trial data (and access rules definition)
- Access to biobank (and access rules definition)
- Publication rules
- Scientific dissemination (call for proposals, industrial partnerships)

Composition

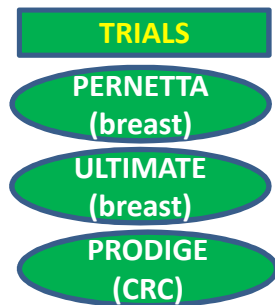
- If applicable, Members of each national group
- Sponsor representative
- Referent pathologist
- Referent biostatistician
- Ad hoc experts (appointed by the Intergroup)

Code of ethics

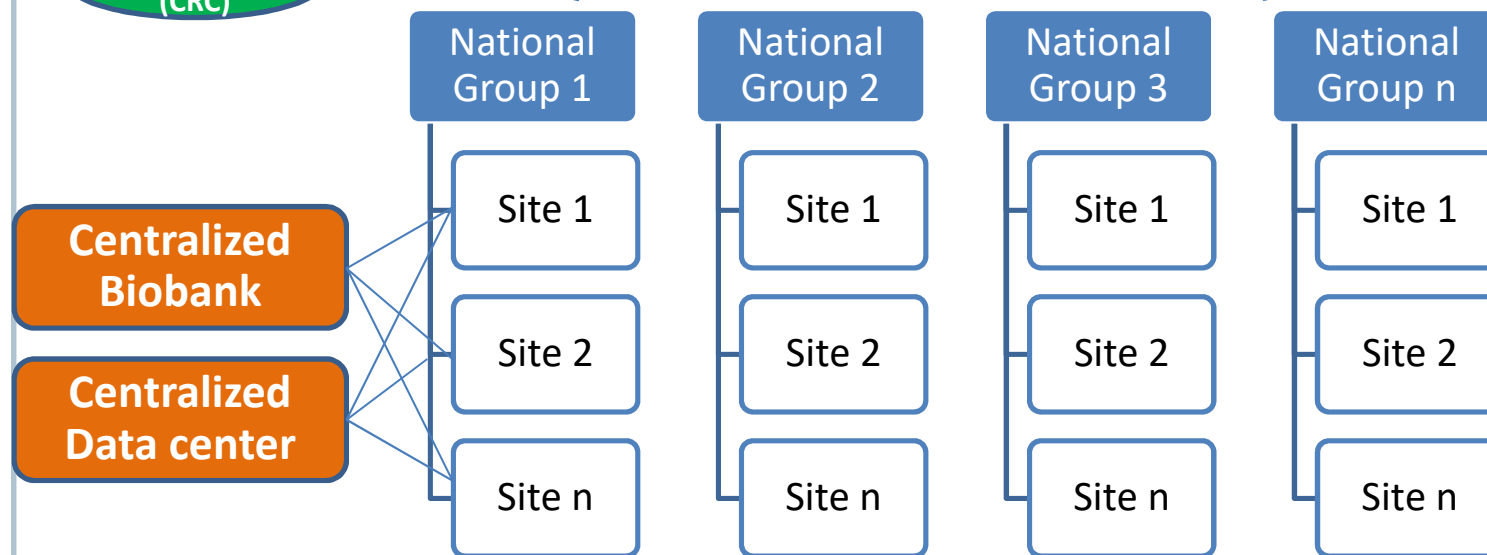
- Promoting patients quick access to innovation
- Ensuring fair access to data and biological samples
- Ensuring research and results consistency / avoiding redundancy

R&D Unicancer: Trial oversight with international partners

Intergroup collaboration model



- Fundings
- Regulatory submission
- Insurance
- Sites feasibility
- Trial management
- DM & data analysis



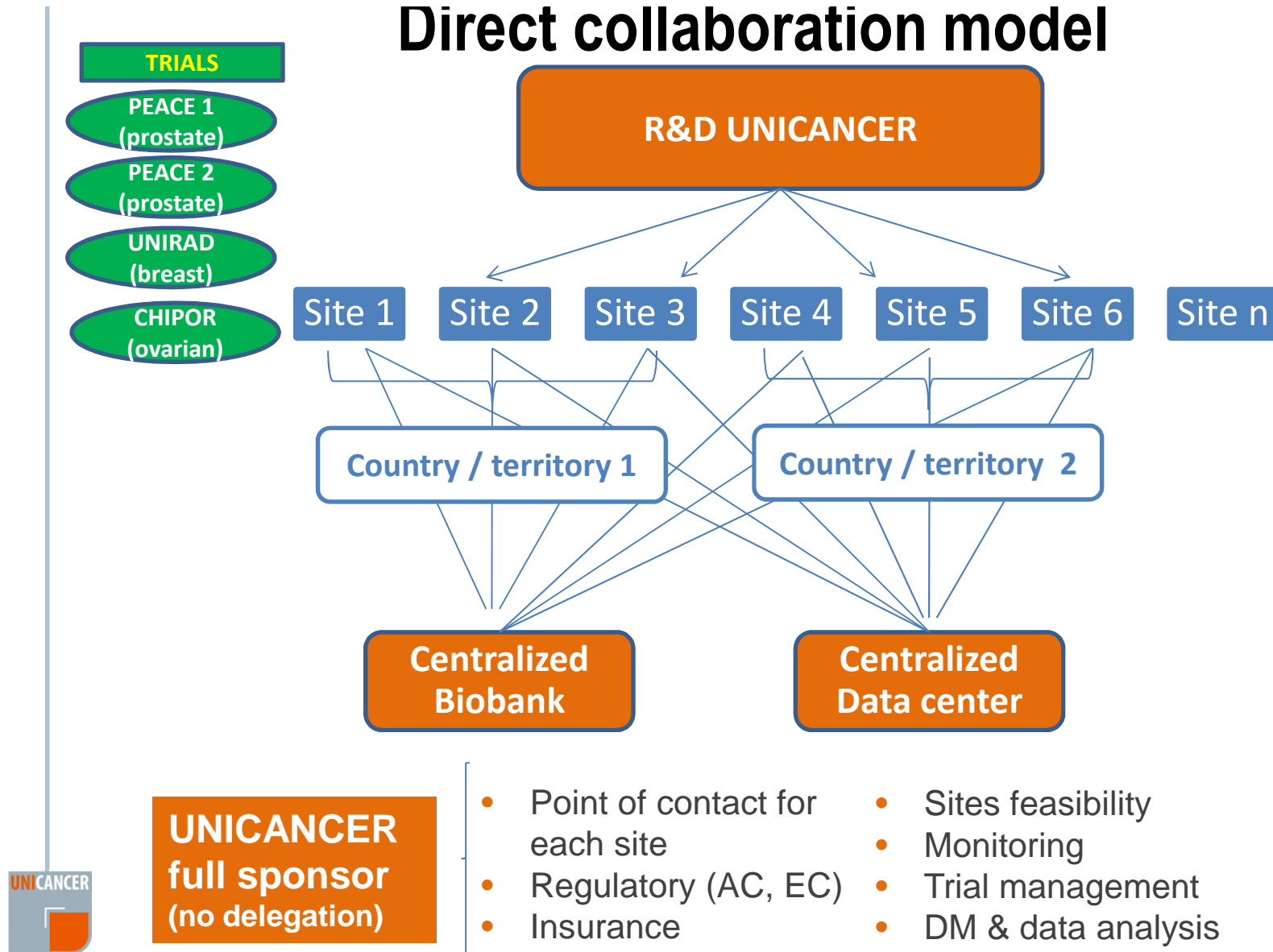
National Groups :

- Delegated sponsor
- Investigator sites contact point
- Depending on feasibility, Unicancer can delegate to each national group
 - Drafting of contracts with sites
 - Monitoring
 - Ethic Committee submission
 - Recruitment follow-up



R&D Unicancer: Trial oversight with international partners

Direct collaboration model



Unicancer, a research and patient care Network

2. Research: quality through cooperation and mutualization

2.2. Concentration of Services by RD Unicancer: Centers of Excellence (CoE)

- Centralized Data Centre (FCCC Montpellier)
- Biological Resource Centre (FCCC Lyon)
- Quality insurance, **regulatory** and **PV Dept**

Concentration of Services by RD Unicancer

■ Centralized Data Centre (FCCC Montpellier)

- 12 data managers
- C-DISC SDTM, INCa-certified



ISO 9001



Concentration of Services by RD Unicancer

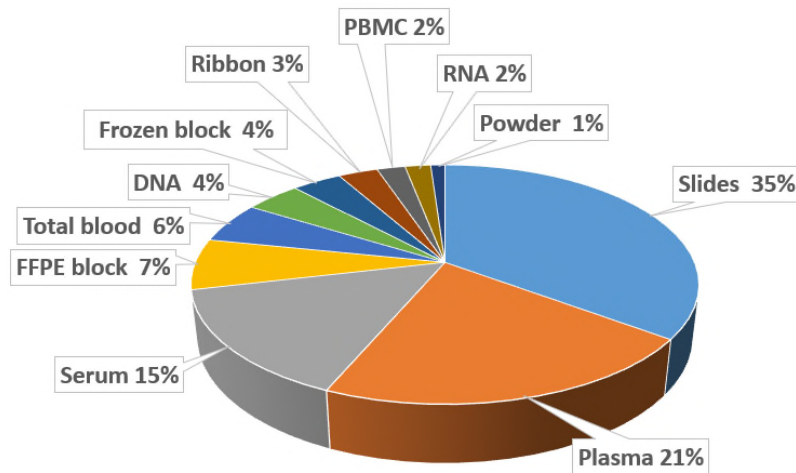
■ Biological Resource Centre (FCCC Lyon)

- 94 503 samples stored (2017)
- ISO 9001 certified (AFNOR NF S96-900)

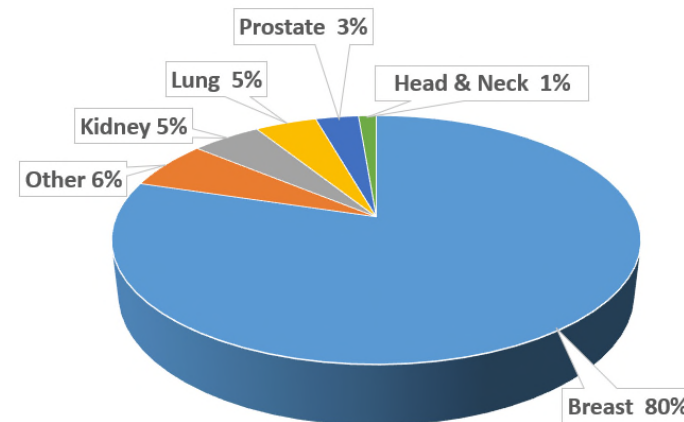


ISO 9001
NF S96-900

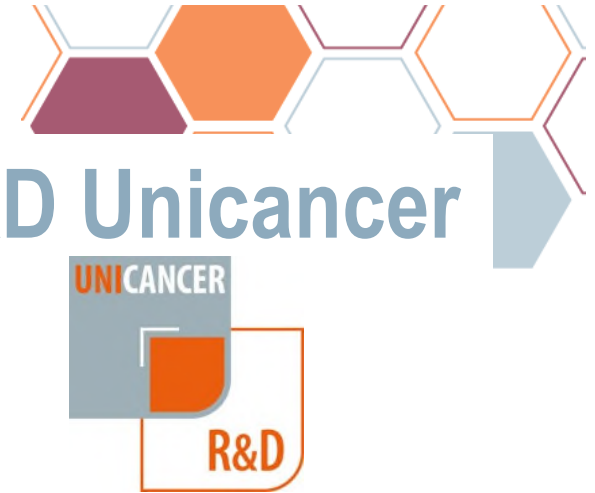
Type of samples banked



Type of cancer



Concentration of Services by RD Unicancer



■ Pharmacovigilance

■ Management of vigilance for all clinical trials sponsored by RD Unicancer

■ Management of vigilance for clinical trials sponsored by FCCC (7 centers)

2017: 85 projects managed (73 with full delegation and 12 with partial delegation (periodic safety))

■ Management of vigilance for non Unicancer institutions / cooperative group : 3





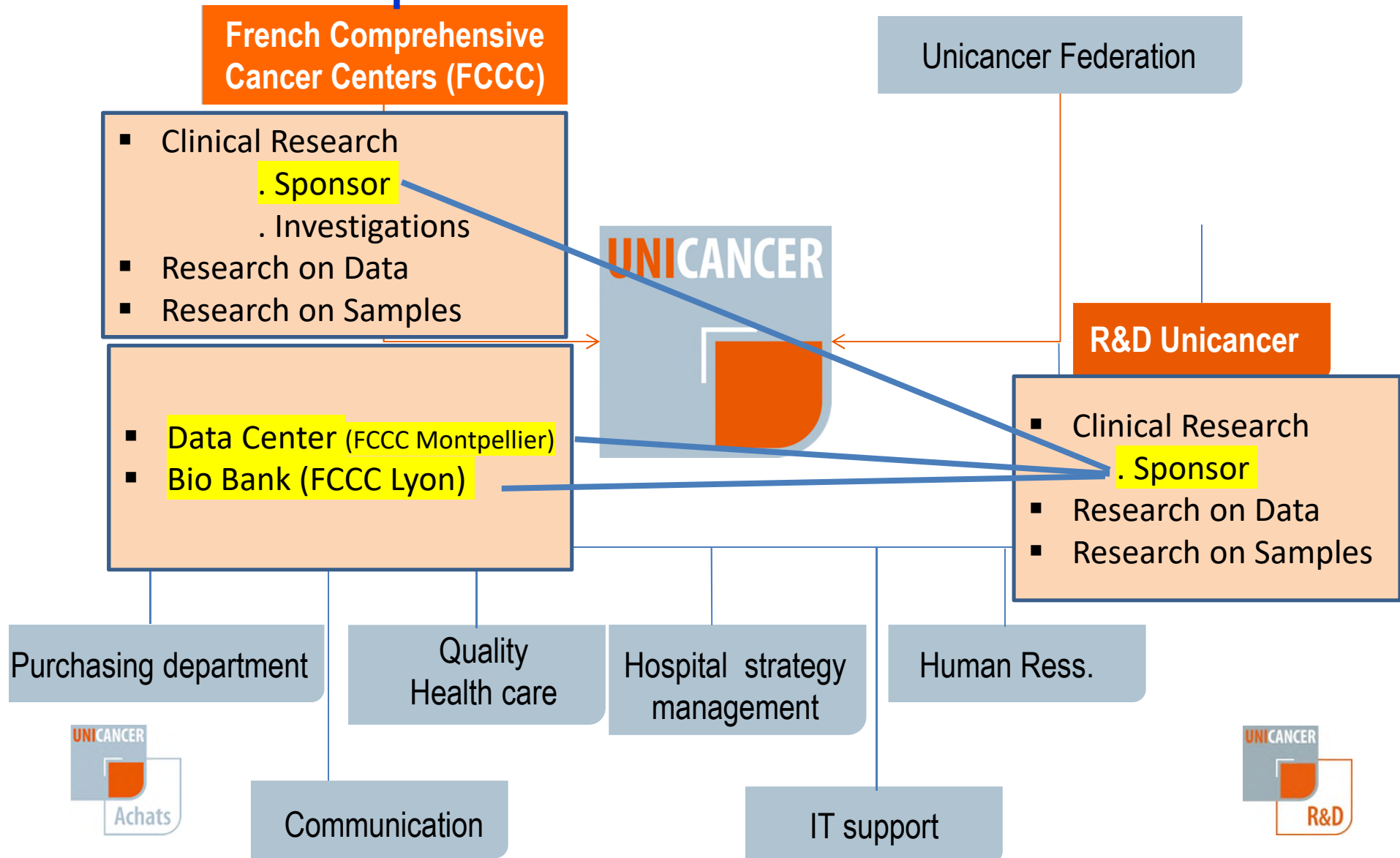
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2. Research: quality through cooperation and mutualization

2.3. Cooperation on Methods and Practices between FCCC and R&D Unicancer



Sponsor entities in the Network





Cooperation and mutualization: Methods and practices

Between sponsor entities

■ Common understanding of Regulations

- Main changes at National, European and ICH levels: clinical trials, Data protection
 - Trainings on regulations and categorization of researches
 - Clarification documents
 - Questions / answers

■ Harmonization of Practices

- Exchanges on practices: Risk based approach...
- Clarification documents: Site implementation and monitoring, vigilance...
- Common Training kits development

■ Electronic tools : E-CRFs, E-TMF, Remote monitoring, CTMS

■ Practical supports

- 4 meetings / Y
- Information / document sharing: dedicated platform
- Working groups



Cooperation and mutualization: Methods and practices

Between sponsor entities: ISO 9001 Certification

■ FCCC

- All Sponsor entities ISO 9001 certified (2 certificates pending),
- 3 certified before 2015,
- Common initiative for 17 centres ,
- Granting, Coordination and Mutualisation enhanced through R&D Unicancer

■ R&D Unicancer

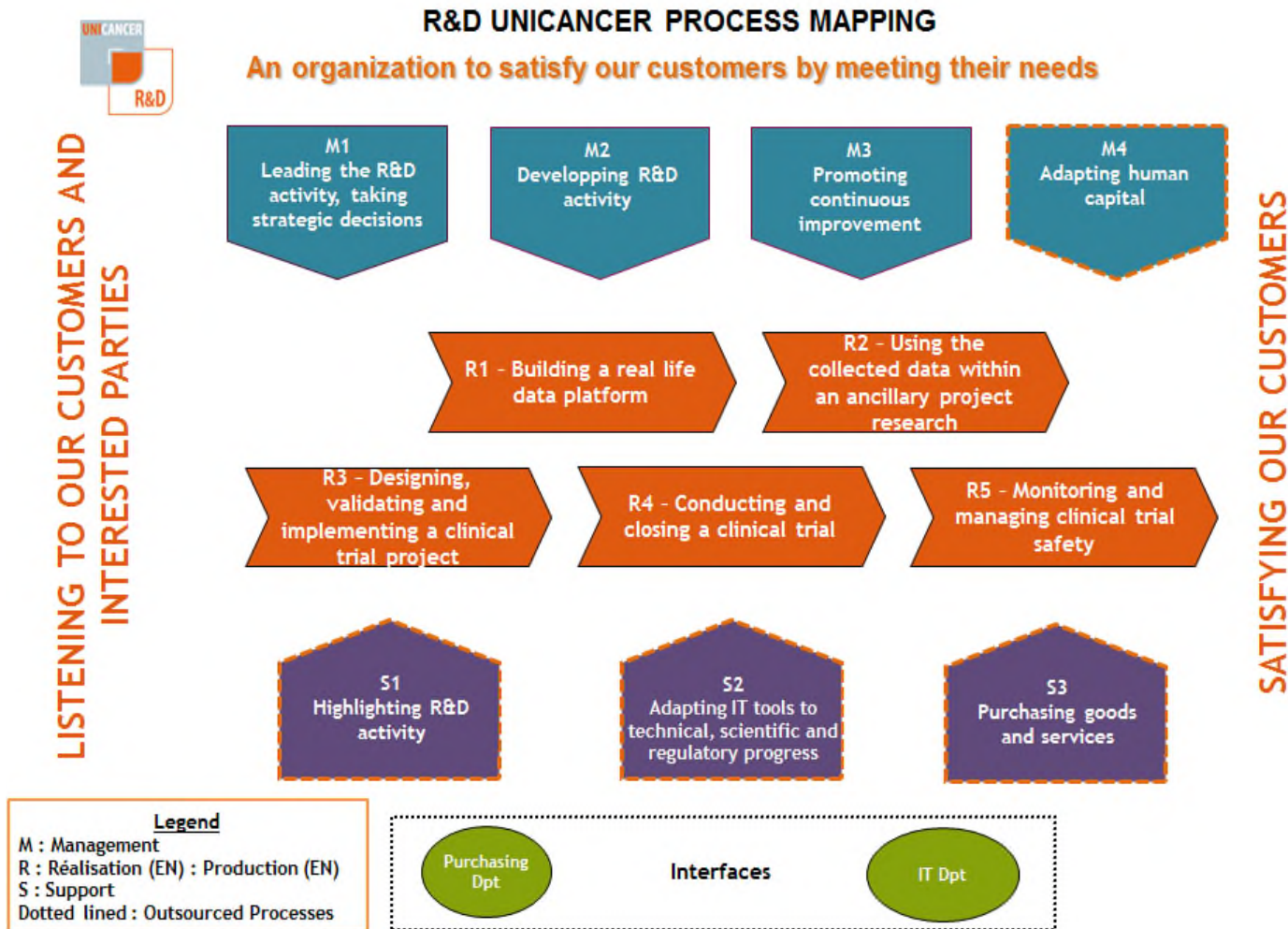
- Certification process ongoing, planned October 2018

■ Practical supports

- Same development tools, same consultant
- 11 meetings
- Information / document sharing: dedicated platform
- Bilateral cooperation between FCCCs

Cooperation and mutualization: Methods and practices

ISO 9001 Certification, R&D Unicancer



Unicancer, a research and patient care Network

In summary...

Taking advantage of and strengthen a **large Network of care, research and education** centers

- ➔ Involvement of expertise in protocol concept, development and conduct
- ➔ Designation of CoE shared between FCCC and R&D Unicancer
- ➔ Cooperation on Methods and Practices between 'same job' entities

Implies common objectives, common will and a strong QMS development

Unicancer, a research and patient care Network

Thank you



Dr Pierre-Henri BERTOYE, Head Regulatory Affairs, Vigilances and QA





Unicancer, a research and patient care Network

FCCC Figures

UNICANCER

Research in the FCCCs: 2016 key figures



..... CLINICAL RESEARCH IN THE FCCCs.....

17%

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

Approximately

500

active
clinical trials

51%

of the French hospital
clinical research
programs in the field of
cancer are granted to
the FCCCs

..... FCCCs' SCIENTIFIC PUBLICATIONS

Ranked **5th**

In the number of
publications in the
oncology field,
worldwide

FCCCs contributed

to **1/3**

of the **French**
publications* in the
field of cancer

24%

of FCCCs articles
are published in the
10% most cited
journals in the world



* Publications : 2010-2015 period



Unicancer, a research and patient care Network

Some Key programs



R&D UNICANCER **flagship programs**



Patient access to innovative drugs

2011

SAFIR

To assess the efficacy of high throughput genome analysis as a therapeutic decision tool for patients with metastatic breast cancer or metastatic non-small cell lung cancer.

Phase II “umbrella” studies

> 1000 patients included, 8 targeted drugs so far

Coordinators :

Breast: F. André, GR
Lung: JC Soria, GR

2013

AcSé



To give secure access to targeted therapies for patients with tumours harbouring the corresponding molecular signature.

Phase II “basket” studies

- 200 patients included in the Crizotinib study
- 140 patients included in the Vemurafenib study

Coordinators :

AcSé Crizotinib: G. Vassal, GR
AcSé Vemurafenib: JY Blay, CLB

Large cohort studies

2012

CANTO



To quantify and predict treatment related chronic toxicities in patients with non-metastatic breast cancer.

Long term prospective cohort study
>10,000 patients included so far

Coordinator : Pr F. André, GR

2014

ESMÉ

1st independent academic “real life” database in oncology, centralising all longitudinal data available in routine practice in France. Its aim is to describe the use of cancer treatments and assess the therapeutic strategies.

Data available for : scientific community, pharmaceutical industry and French MoH.

2014: MBC → > 17000 patients

2016: ovarian cancer

2017+: lung

Future?: CRC, prostate, immunotherapy

R&D UNICANCER: new flagship programs



2016



EXPRESS

To determine the genetic characteristics of the patients presenting an unexpected and exceptional response to a targeted therapy approved in France.

→ **Recruitment objective: to include 300 patients** presenting with diverse solid tumours. Patients will be analysed in 6 (so far) separate multi-drug cohorts according to tumour type: advanced or metastatic breast, lung, colorectal, ovarian cancer, a renal cell carcinoma or melanoma.

Coordinator :
Charles Ferté, Gustave Roussy

2017



AcSé immuno

To give secure access to anti-PD-1 for patients with rare cancers

Objective: to assess the treatment efficacy and safety in each cohort, and to determine the predictive factors of response.

Phase II “basket” studies

→ **Recruitment objectives:**

AcSé nivolumab : 3000 patients, 6 cohorts

AcSé pembrolizumab : 300 patients, 6 cohorts

Coordinator :

Jean-Charles Soria, Gustave Roussy



R&D UNICANCER: international trials



Conduct large international therapeutic strategy trials

2013

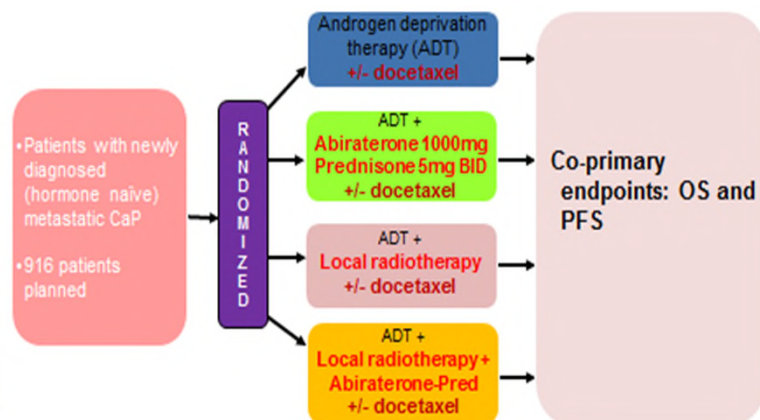
PEACE 1

2013 PHRC*

Efficacy of abiraterone associated to androgen deprivation therapy (+/- Docetaxel), with or without local radiotherapy in hormone naive metastatic prostate cancer

916 expected patients, in 9 countries

Coordinator: Pr Karim Fizazi



2016

IROCAS

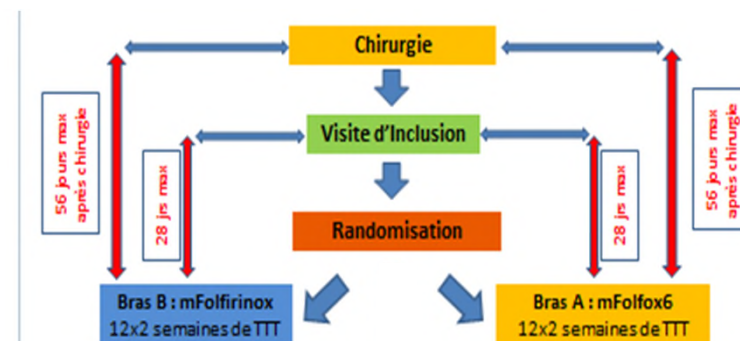
2015 PHRC*

Irinotecan and Oxaliplatin (mFOLFIRINOX and mFOLFOX) as adjuvant therapy in colorectal cancer.

640 expected patients

France / Canada

Coordinator : Pr Jaafar Bennouna



*PHRC= French hospital clinical research program (public grant)