R&D UNICANCER
Oncology Research

R&D UNICANCER

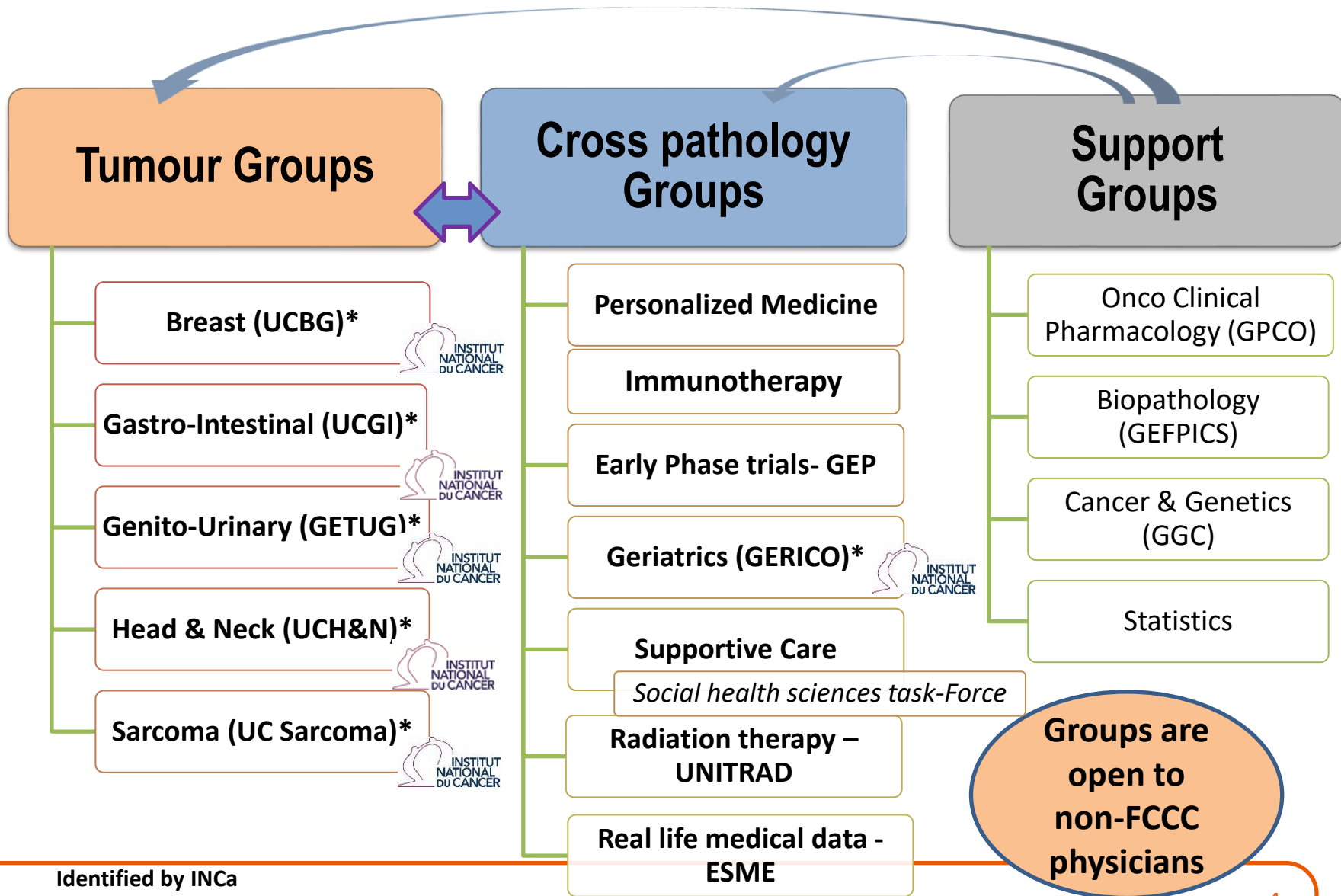**A national academic sponsor dedicated to clinical research in oncology**

Our missions:

- **Promote and accelerate Clinical Research in Oncology, especially in areas insufficiently covered by pharma**
- **Facilitate patient access to Innovation for a better care**
- **Encourage Translational Research and increase cancer knowledge**

UNICANCER
R&D

R&D UNICANCER

- **More than 150 people fully dedicated to clinical trials and real life data operations and management**

- **Tumor bank with 25,000 new samples per year (Lyon)**

- **Centralized Data Center –C-DISC SDTM, INCa-certified and FDA compliant (Montpellier)**

- **French liaison office for EORTC (European Organization for Research and Treatment of Cancer)**

The UNICANCER Groups, a large network of experts

Tumour Groups

- Breast (UCBG)*
- Gastro-Intestinal (UCGI)*
- Genito-Urinary (GETUG)*
- Head & Neck (UCH&N)*
- Sarcoma (UC Sarcoma)*

Cross pathology Groups

- Personalized Medicine
- Immunotherapy
- Early Phase trials- GEP
- Geriatrics (GERICO)*
- Supportive Care
  - *Social health sciences task-Force*
- Radiation therapy – UNITRAD
- Real life medical data - ESME

Support Groups

- Onco Clinical Pharmacology (GPCO)
- Biopathology (GEFPICS)
- Cancer & Genetics (GGC)
- Statistics

Groups are open to non-FCCC physicians

Identified by INCa as the key scientific groups for the specific oncology domain

*ESME: EpidemioStrategy Medical Economics

4

R&D UNICANCER: Funding model

Charities

2 main partnerships with charities exclusively dedicated to cancer

Private companies

Partnerships with pharmaceutical, biotech and medical device companies

R&D UNICANCER Funding

National Public funding

Via INCa and PHRC (Hospital Clinical Research Program) call for projects

Academic funding

International cooperative groups partnerships/programs

R&D UNICANCER: Strategic orientations (1)

Covering unmet needs
- Rare cancers
- Orphan populations
- Surgery, Radiotherapy

Evaluation of diagnostic or therapeutic strategies to improve patients survival and QoL

Evaluating the interest and efficacy of biology driven medicine
- Promoting large programs of molecular screening
- Developing proof of concept programs
- Improving knowledge on disease and treatments
- Offering patients early access to new therapies

R&D UNICANCER: Strategic orientations (2)

- **Promoting Immunotherapy Research**
  - Offering early access to rare / orphan cancers (**Acsé**)
  - Understanding the mechanisms of treatment toxicities and resistance (**Check'Up**)

- **Generating Real Life Data Programs**
  - **Retrospective real life database** : the **E.S.M.E*** program
    ⇨ 1st project in 2014 in metastatic breast cancer
  - **Prospective cohorts** with biological material collection
    ⇨ e.g. **CANTO** : long term toxicities of cancer treatment (non metastatic breast cancer)

* *Epidemiological-Strategy-and-Medical-Economics*

R&D UNICANCER
2017 key figures

13
New trials
=> **1 H2020**

86
clinical trials in progress, incl **44** in active phase

150
highly-qualified dedicated employeees

30 000
Patients in the ESME program

216
Investigator sites involved in France and abroad

≈ 5000
patients enrolled each year

UNICANCER
R&D

R&D Unicancer **national** partners

200 Public and private hospitals

70 Academic institutions — e.g. Inserm CNRS

Charities

Cooperative groups — e.g. IFCT, FFCD, GERCOR, GSF-GETO, SFCE

Scientific societies — e.g. SFC, AFSSOS, AFU, FFCD

ANSM INCa, HAS — Health agencies

Biotech and Pharmaceutical companies

R&D Unicancer **International** partners

European Coop Groups

BIG, GBG, NCRI groups
Cancer research UK
EORTC groups
SAKK…

Liaison Office   **EORTC**

North American Coop Groups

NCI network , NCIC
NCCTG/MCCRC
SWOG

→ Reg. clinical trials, R&D Unicancer can act as :
- Sponsor
- Delegate sponsor
- Partner (liaison)

R&D Unicancer **Flagship** Programs

- Acse

- Phase III international trials (PEACE1, IROCAS)

- Genomic trials (SAFIR02)

- Cohorts (Canto, EXPRESS, Check up)

- ESME

2013

AcSé thérapies ciblées

Accès sécurisé à des thérapies innovantes pour des patients avec une tumeur porteuse d'une anomalie génomique cible de la molécule.

Essais de phase II "basket"

> 180 sites ouverts
> 300 patients inclus

Programme AcSé 2013-2017

INSTITUT NATIONAL DU CANCER

	AcSé crizotinib	AcSé vemurafenib
1	ALK, MET, RON, ROS1	BRAF V600
	10,000 – 18,000 patients 14,000 – 25,000 tests	
Diagnostic moléculaire	28 INCa Plateformes de génétique moléculaire	28 INCa Plateformes de génétique moléculaire
2	PI : G. Vassal autorisations – mai 2013 1er patient – aout 2013	PI : JY Blay autorisations – juillet 2014 1er patient – octobre 2014
Essai clinique phase II	16 cohortes, 465 patients 5 ans d'inclusion Durée totale de l'essai 5-6 ans	11 cohortes, 500 patients 5 ans d'inclusion Durée totale de l'essai 5-6 ans
	Promoteur Jusqu'à 250 centres investigateurs	Promoteur Jusqu'à 250 centres investigateurs

FONDATION ARC POUR LA RECHERCHE SUR LE CANCER
Reconnue d'utilité publique

2017

INSTITUT NATIONAL DU CANCER

■AcSé immunothérapie

Secured Access to anti-PD-1.

Essais de phase II "basket"
Cancers rares

Coordonnateur :
Pr JC Soria

AcSé Nivolumab	
250 patients	
5 cohorts (20-50 pts / cohort):	
• Non-clear RCC	B. ESCUDIER
• Rare head and neck cancer	F. JANOT
• Rare skin cancer	L. MORTIER
• Cancers with MSI (except CRC)	C. TOURNIGAND
• Penile cancer	D. POUESSEL

AcSé Pembrolizumab	
300 patients	
6 cohorts (20-50 pts / cohort):	
• Rare sarcomas	J.Y. BLAY
• Rare ovarian cancers	I. RAY COQUARD
• PCNSL	K. HOANG-XUAN
• Rare thyroid cancers	M. SCHLUMBERGER
• Rare malignant neuro-endocrine cancers	P. NICCOLI
• Germ-cell-cancers	C. MASSARD

	2016	2017	2018	2019	2020	2021	2022	2023
Submission:								
Site Initiation:								
Patient enrolment:								
Treatment & followup:								
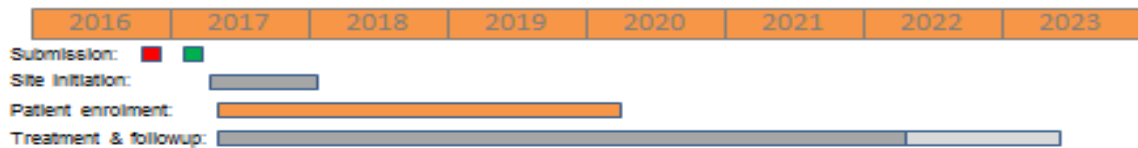
Event	Date
ANSM & EC submission	AcSé Nivolumab: 15 Dec 2016 AcSé Pembrolizumab: 21 Dec 2016
ANSM & EC approval	Feb/Mar 2017
First SIV	Mar 2017
FPI	Mar 2017
First interim analysis	Q4 2017 / Q1 2018
LPI	Mar 2020
LPLV	2023

UNICANCER R&D

LA LIGUE CONTRE LE CANCER

2014
ESMÉ

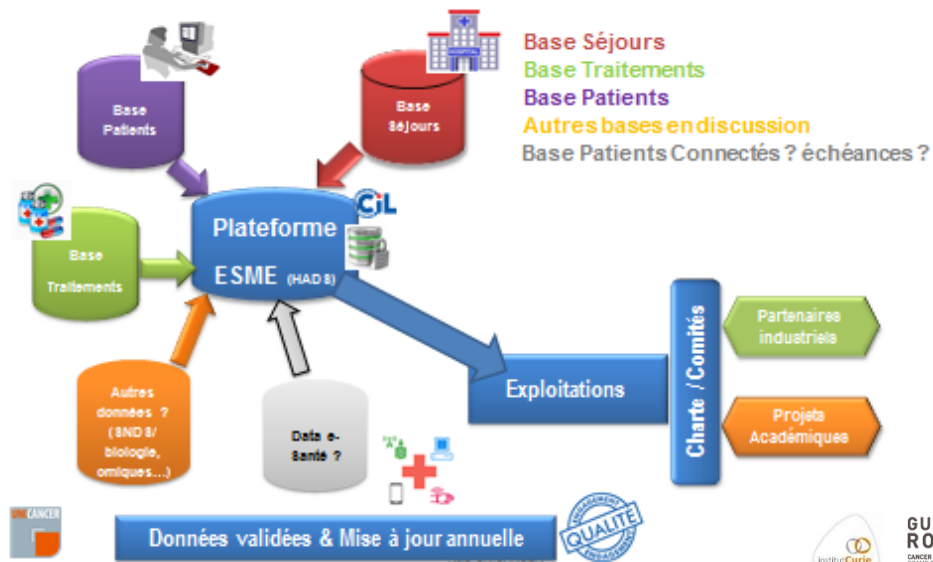Real life databases describing patient treatment and its socioeconomical impact at large scale**..

Data available for scientific reports, French Health authorities, industrial partners…

2014: MBC -> 20 000 pts
2016 : ovarian cancers -> 5 000 pts
2017: lung cancers-> 16 000 pts

Patients

Partenaires ESME

Roche   Pierre Fabre   MSD

Pfizer   AstraZeneca   EISAI

- **ESME MBC : 23,000 cases (female /male) / 27,000 expected**
- **ESME OC: 6,800 female cases, 14,000 expected**
- **ESME Poumon CLCC et hors CLCC : 12.000 cases (female /male) / 30,000 expected**
- **Next ESME data platforms : metastatic Kidney Cancer, Colorectal cancer, Prostate,…)**
- **Other activities in progress :**
    - **Involvment of other health centers (outside the FCCC network)**
    - **Partnership with the French NCI (INCa) : data modeling for generalisability of ESME results at national level**
    - **Access to primary care data /Other pratices (institutional partnership to match with SNDS data)**
    - **Oncology RWD used as historical arm for phase II/III trials**
    - **Artificial intelligence, linkage with existing Data Warehouse, international academic cooperation…**

Automate « data abstraction » in all health centers for patients diagnosed with cancer
Populate data from other sources (biology, e-Health, …)

Original Research

Time trends of overall survival among metastatic breast cancer patients in the real-life ESME cohort

Elisa Gobbini [a], Monia Ezzalfani [b], Véronique Dieras [c],
Thomas Bachelot [d], Etienne Brain [c], Marc Debled [e], William Jacot [f],
Marie Ange Mouret-Reynier [g], Anthony Goncalves [h], Florence Dalenc [i],
Anne Patsouris [j], Jean Marc Ferrero [k], Christelle Levy [l],
Veronique Lorgis [m], Laurence Vanlemmens [n], Claudia Lefeuvre-Plesse [o],
Simone Mathoulin-Pelissier [p], Thierry Petit [q], Lionel Uwer [r],
Christelle Jouannaud [s], Marianne Leheurteur [t], Magali Lacroix-Triki [u],
Audrey Lardy Cleaud [b], Mathieu Robain [v], Coralie Courtinard [v],
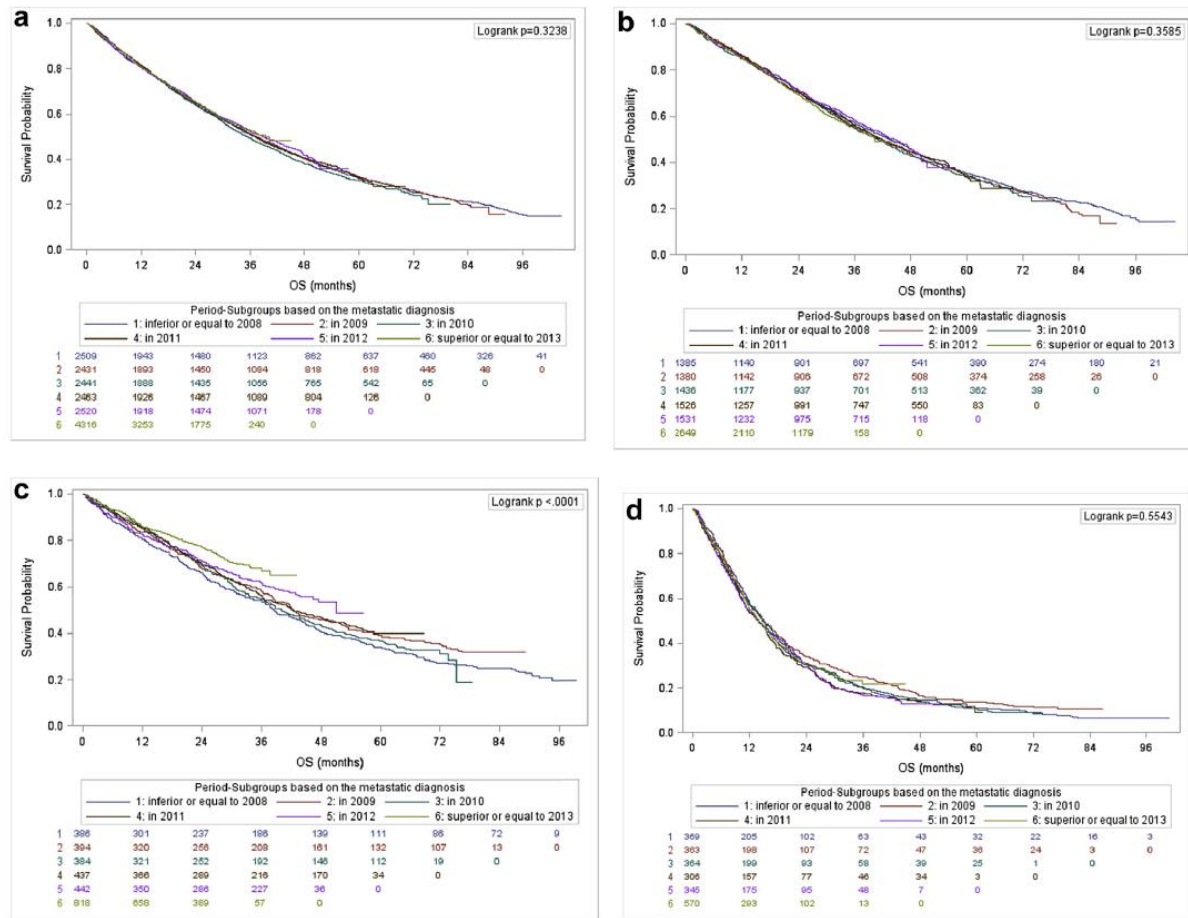Christian Cailliot [v], David Perol [b], Suzette Delaloge [a,*]

Fig. 2. Overall survival in the whole cohort of patients and in each subcohort by year of metastatic diagnosis. a. Overall survival of the whole cohort by year of diagnosis. b. Overall survival in the HR+ HER2− MBC subcohort by year of diagnosis. c. Overall survival in the HER2+ MBC subcohort by year of diagnosis. d. Overall survival in the HR− HER2− MBC subcohort by year of diagnosis. HR, hormone receptor; MBC, metastatic breast cancer; OS, overall survival.

Ongoing data platform and next steps (Sep-2018)

- **ESME MBC : 23,000 cases (female /male) / 27,000 expected**
- **ESME OC: 6,800 female cases, 14,000 expected**
- **ESME Poumon CLCC et hors CLCC : 12.000 cases (female /male) / 30,000 expected**
- **Next ESME data platforms : metastatic Kidney Cancer, Colorectal cancer, Prostate,…)**
- **Other activities in progress :**
  - **Involvment of other health centers (outside the FCCC network)**
  - **Partnership with the French NCI (INCa) : data modeling for generalisability of ESME results at national level**
  - **Access to primary care data /Other pratices (institutional partnership to match with SNDS data)**
  - **Oncology RWD used as historical arm for phase II/III trials**
  - **Artificial intelligence, linkage with existing Data Warehouse, international academic cooperation…**

Automate « data abstraction » in all health centers for patients diagnosed with cancer

Populate data from other sources (biology, e-Health, …)

NETSARC, RREPS and CONTICABASE

Origine géographique des patients discutés en RCP Sarcome dans les centres du réseau Netsarc

Auteur : Yohan Fayet, géographe, Centre Léon Bérard
Source : Base de données Netsarc-ResOs (2014)

NetSarc-ResOs
Réseaux de référence Cliniques
Sarcomes - GIST - Desmoïdes - Tumeurs osseuses rares

Sarcoma Database

L'ANSM suspend les essais masitinib promus par AB Science. Le GSF-GETO recommande imatinib ou sunitinib en remplacement.

🏠 Home   👤 Account request   🔒 Reset password   ❶ Help & Infos   🎓 Education   🔧 Tools   Login

Welcome to NetSarc-ResOs

NetSarc is the French clinical reference network for soft tissue and visceral sarcomas, implemented in 2010 and approved by the INCa in 2014 (28 centers). NetSarc's RCP list.

ResOs is the French reference network for bone sarcoma and rare bone tumours, implemented in 2013 (14 centers). ResOs's RCP list.

This site gathers clinical data from patients discussed on sarcoma multidisciplinary committees (RCP) in NetSarc-ResOs centres.

These 2 networks work jointly with the French sarcoma pathological reference network (RRePS) which insures a second expert pathological review of every suspected cases.

The very structure of these networks and the automatic study of each case of sarcoma in specialized RCP improve and homogenize the management of patients with sarcomas in France, especially by making access to clinical protocols and to innovative therapeutics for all patients easier.
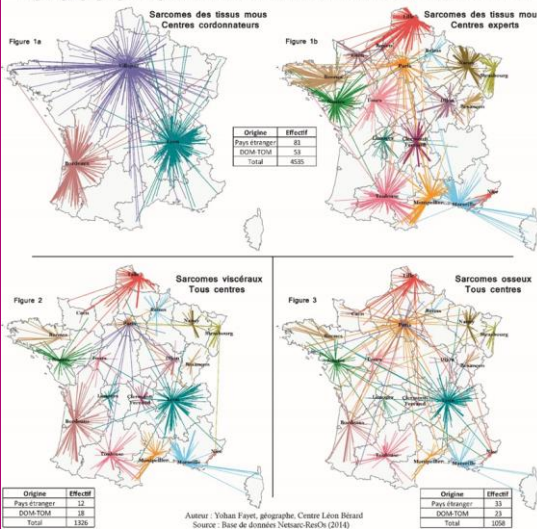
Content overview

- Patients : 49477
- Primary tumours : 49737
- RCPs : 116384
- Trial inclusions : 3225

Last change on 27/09/2018 17:17:00 by pervieux.
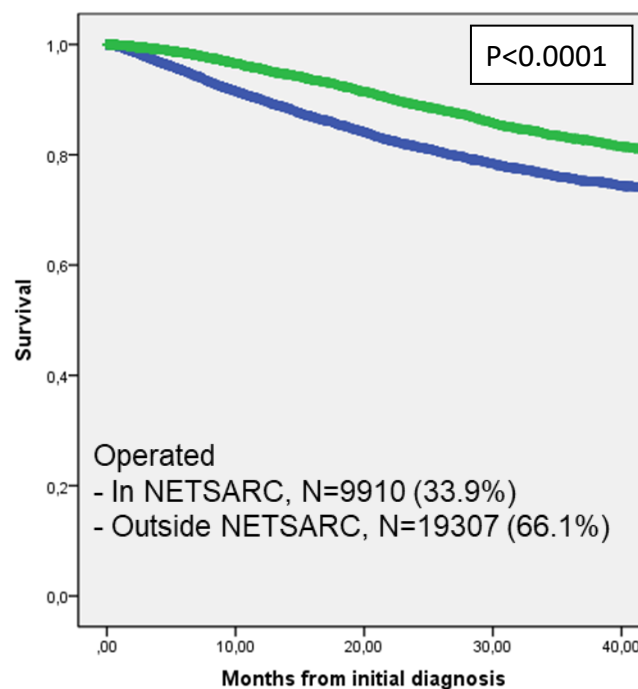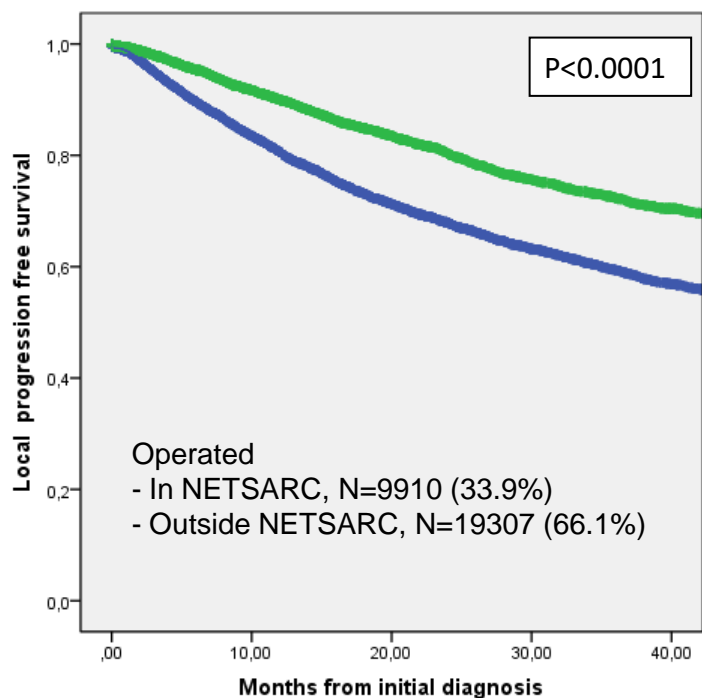
Copyright © 2018   Version : 4.0.1

unicancer

LRFS & OS : incident sarcoma patient population in France since 01/01/2010

N=29217 patients with sarcomas

P<0.0001

Operated
- In NETSARC, N=9910 (33.9%)
- Outside NETSARC, N=19307 (66.1%)

P<0.0001

Operated
- In NETSARC, N=9910 (33.9%)
- Outside NETSARC, N=19307 (66.1%)

unicancer

LRFS & OS : incident patient population
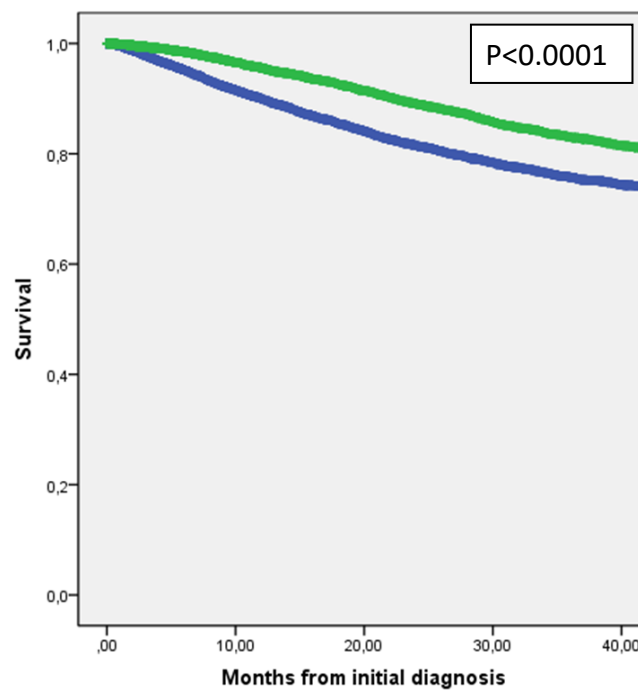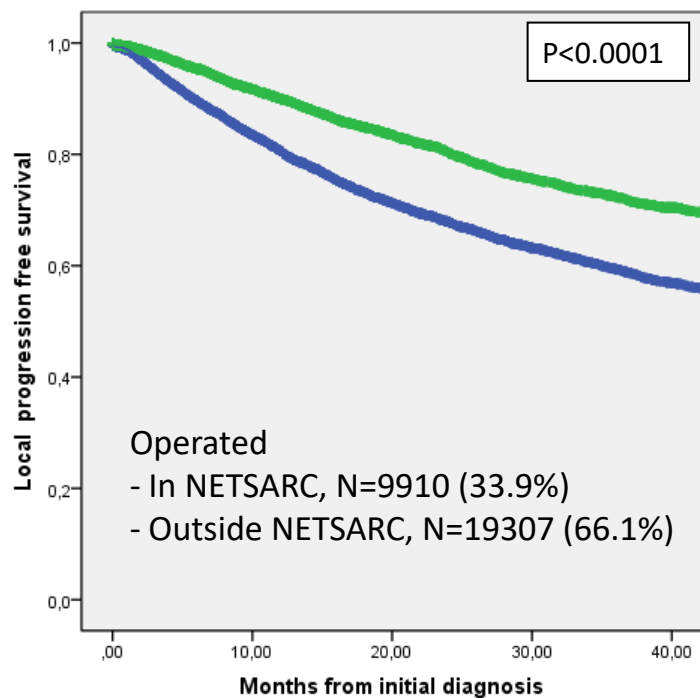
P<0.0001

Operated
- In NETSARC, N=9910 (33.9%)
- Outside NETSARC, N=19307 (66.1%)

P<0.0001

EURACAN

RARE SOLID ADULT CANCERS