ESME Research Program

EPIDEMIOLOGICAL STRATEGY and MEDICAL ECONOMICS

Academic Real-world Data Platform

R&D Unicancer
UNICANCER, a Healthcare Cooperation Consortium

**French Comprehensive Cancer Centers (FCCC)**
- A national network of 20 private non-profit hospitals
- > 120,000 patients/y
- > 17% of patients are included in 250 clinical trials vs 8.5% in France

**R&D UNICANCER**
- A mutualised Research Entity
- National leader in clinical research in oncology – acknowledged by French authorities
- 140+ trials since 1994, 33,000+ patients included
- 200+ sites involved in R&D Unicancer-sponsored research

**Recognized expert Groups**
- 15 Expert Groups
  - Tumours
  - Cross pathologies
  - Support groups
- 4 Groups accredited by the French National Cancer Institute (NCI), INCa

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100+ people dedicated exclusively to clinical trials operations and management

Tumor bank: 15,000+ new samples/year (Lyon)

Centralized Data center – Database C-DISC INCa* labelled – FDA certified (Montpellier)

French liaison Office for EORTC (European Organization for Research and Treatment of Cancer)

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**MATWIN**
- L Robert

**Strategic Alliance & Development**
- AL Martin, PharmD

**Clinical Operations**
- C. Desseaux, PhD

**Epidemiology**
- Real World Data
  - M. Robain, MD, PhD

**Compliance, PV & Regulatory Affairs**
- PH Bertoye, MD

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* Maturation & Accelerating Translation With INdustry
Data in oncology

Clinical trial Data
- Limited ‘protocol-generated’ sample (*calibrated population*)
- ‘Controlled’ treatment (artificial compliance)
- Designed to assess
  - Safety
  - Efficacy
- Short-term endpoints: PFS, TTP, RR, ...
- ...

Real world data
- Large real world population
- Treatment prescribed in real life
- Designed to describe
  - Toxicities of interest
  - Efficiency
- Long-term endpoints: OS

Sources of RW Data
Real-world data can also be categorized by type of data source. Our Task Force defined six such sources:
1) supplements to traditional registration RCTs; 2) large simple trials (also called practical clinical trials);
3) registries; 4) administrative data; 5) health surveys; and 6) electronic health records (EHRs) and medical chart reviews.

Observational data
Big data

Unicancer ESME database
What is ESME?

ESME is a French platform of longitudinal retrospective real world data on cancer management in oncology.

Centralisation of existing data within Unicancer Group:

- Comprehensive data with 20 cancer centers
- W/O Intervention on physician’s patients files completion
- Independance from all stakeholders
- Relies on academic group of experts
- Highest quality standards

RWD in oncology = ESME Research Program

Unicancer ESME database
An idea:
- Type of cancer
- Therapeutic domain

From:
- Health Authorities
- Academic/institutional
- Industrial

A dedicated cross-functional Team:
- Central coordination
- Local coordinator (1 by hospital)
- Expertise and Monitoring
- Data Protection Officer

ESME: from an idea to the data Platform

ESME project

ESME Data Platform

- Analysis Request via call for application
- Communication

Unicancer ESME database
ESME Data Platform : Specifications

Hospitalization Database (20+)
- Hospitalizations, diagnoses,
- Medical procedures (inc. Radiotherapy)

Treatment Database (10+)
- Pharmacy record : Dates, cytotoxic drugs, therapeutic protocol and other concomitant drugs

Patient Database (200+)
- Collection based on Electronic medical records
- Patient data : cancer management, Clinical events (progression, relapse), pathological report, metastatic disease, anti-cancer treatment (chemotherapy, endocrine therapy, immunotherapy, targeted therapy), and other therapeutic care (radiotherapy, surgery) or supportive care (EPO/GCSF)

Hosting in « Certified Personal health data hosting » provider

Unicancer ESME database
Patient Database (200+ parameters)

Diagnostic de la tumeur primitive
(ant traitement de la métastase)

Date du diagnostic :
10/09/2007

Côté :
Droit ☑

Classification TNM clinique :

Si cancer du sein controlatéral (non synchrone), date :

Y a-t-il eu une Rechute avant maladie métastatique :
Oui ☑

Y a-t-il au moins une histologie disponible :
Oui ☑

Y a-t-il eu une Chimiothérapie ou thérapie ciblée injectable administrée :
Oui ☑

Y a-t-il eu une Chimiothérapie ou thérapie ciblée orale administrée :
Oui ☑

Y a-t-il eu une Radiothérapie réalisée :
Oui ☑

Y a-t-il eu une Hormonothérapie administrée :
Oui ☑
First ESME Project: *Metastatic Breast Cancer Data platform*

Academic Real-world Data Platform

R&D Unicancer
Selection criteria:

- First therapeutic care (chemotherapy, targeted therapy, endocrine therapy or radiotherapy) of the metastatic Breast Cancer (including de novo MBC)
- In a FCCC (Unicancer Group)
- Between 2008 and 2013
- Adult population (male and female)
Goal: Identify patient initially treated for their metastatic breast cancer (MBC) in each FCCC between 2008 and 2013

- Diagnostic Codes (ICD10): C50, C77 (w/o C77.3), C78 & C79
- Data on MBC diagnostic
  - Keys words in local information on system
  - Local Cancer database
  - Multidisciplinary care team meeting minutes
  - Other (medical appointment, …)
Selection criteria:
- First therapeutic care of the MBC
- In a FCCC
- Between 2008 et 2013
- Adult population

Reasons for non selection:
- Therapeutic care initiated < 2008
- Therapeutic care “outside FCCC”
- Other

Step 2: Centralisation of data

Data Platform
ESME MBC

34,484 IDENTIFIED CASES

Selection validated locally

14,022 SELECTED CASES

Quality Review Visit for 18% of non selected cases and 11% for selected cases
mBC Data Platform 2008-2013

Patient Database

Hospitalization Database

Treatment Database

Patient selection period

Patient selection follow-up

Unicancer ESME database
Real world Data Platform ESME : Generate a comprehensive selection list using multi-source approach

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RWD, a powerful tool raising many questions

- ESME RWD: Within Unicancer Group (academic research organization), aim is to provide independent data to the scientific community ≠ decision (evidence assessment agency)

- Comparative effectiveness analyses may be undertaken on RWD with high level of quality (≠ provide proof of treatment efficacy)

- Complementary to clinical trial data (CTD) but not sufficient to drive decision? The impact of such data on decision process is being experienced.

- What should be done in the assessment is different between CTD and RWD? How RWD will impact medical practice and may improve patient care and cancer management in such case?

- What are the limits of RWD? Appropriate statistical considerations? Other ways to ensure robustness of the results (ie. instrumental variables?)
ESME, an evolving platform

- Extending the ESME program to **other cancer types**, not only metastatic but **also primary** disease
  - Ovarian cancer,
  - Lung cancer,
  - Kidney …

- Creating an ESME program for marketed **immunotherapies**
- Adding **biological data** (e.g. blood or biopsies results)
- … basically ESME is destined to incrementally evolve along with science and medical innovations, as well as with each request from industrial or institutional partners
ESME, long term goals

- **Aim:**
  - To become the largest compilation of real world data on cancer patients in France
  - To give France a leading position in analyzing Real World Data oncology data

- **Program expansion... towards capturing all cancer patients in France?**
  - Modelling project with the French NCI to extrapolate the results obtained with FCCCs data to the whole French population
  - Expansion project beyond the FCCC Network (University Hospitals, General Hospitals, Private Medical Centers...)

Unicancer ESME database
Thank you so much!

Coordinators in each FCCC

Scientific Committee
  Dr David Pérol

International Advisory Board (IAB)
  Dr Christian Kempf

Deontolgy Committee
  (Pr Grunfeld)

Real World data Department - R&D Unicancer

Unicancer ESME database
ESME Partners

Health Authorities interested in knowing methodology and results of the ESME Research Program Initiative