



Real World Data Experience

**RWD flagship programs
and research project opportunities**

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Data and Partnership department

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Summary



1. Who we are
2. Our RWD strategy
3. Our RWD flagship programs
4. Focus on ESME program



Who are we?



Local coverage of the national territory

- **18 French Comprehensive Cancer Centres (FCCCs)**: private, not-for-profit health centres, spread over **20 hospital sites** in France
- **1 affiliated member** to the GCS (health cooperation group – groupement de coopération sanitaire)



We have highly qualified and specialised teams

- **More than 21 000 professionals** committed, on a daily basis, to a permanent quest for excellence in care, research and higher education



Unicancer

- **The only French hospital federation dedicated to cancer** (among the 4 national hospital federations in France)
- Defends **the interests of the FCCCs** and manages the **National Collective Agreement**
- **1st academic sponsor of oncology clinical trials, at the European level**



More than 530 000* patients treated each year

- More than **150 000** patients hospitalised per year
- Nearly **1 130 000** consultations

* short-stay, hospitalization at home and outpatient procedures

** inpatient and outpatient procedures



Humanism

≥ 21 000 women and men committed to humanistic medicine that respects each patient



Excellence

A permanent quest for excellence on a daily basis to be at the forefront of the fight against cancer



Solidarity

Health care centres dedicated to providing a public service, accessible to all patients without exceeding fees



Innovation

FCCCs are driven by a culture of research as a source of shared progress and by the ambition to improve treatment and care for all



Our RWD strategy

How we collect RWD?



Retrospective cohorts using hospital data

- No medical intervention
- Depend on hospital information system structuration and interoperability (patient records, imaging, molecular biology,...)
- Need an appropriate investment and a good ratio between the costs for high quality data collection or structuration and the reachable use cases...

Immediate usable information



Prospective cohorts

- Prospective registration of the patients
- Possibility of prospective and systematic biobanking
- Possibility to add various PROMs / PREMs (not yet introduced in standard care)

Need sufficient follow-up before valorisation

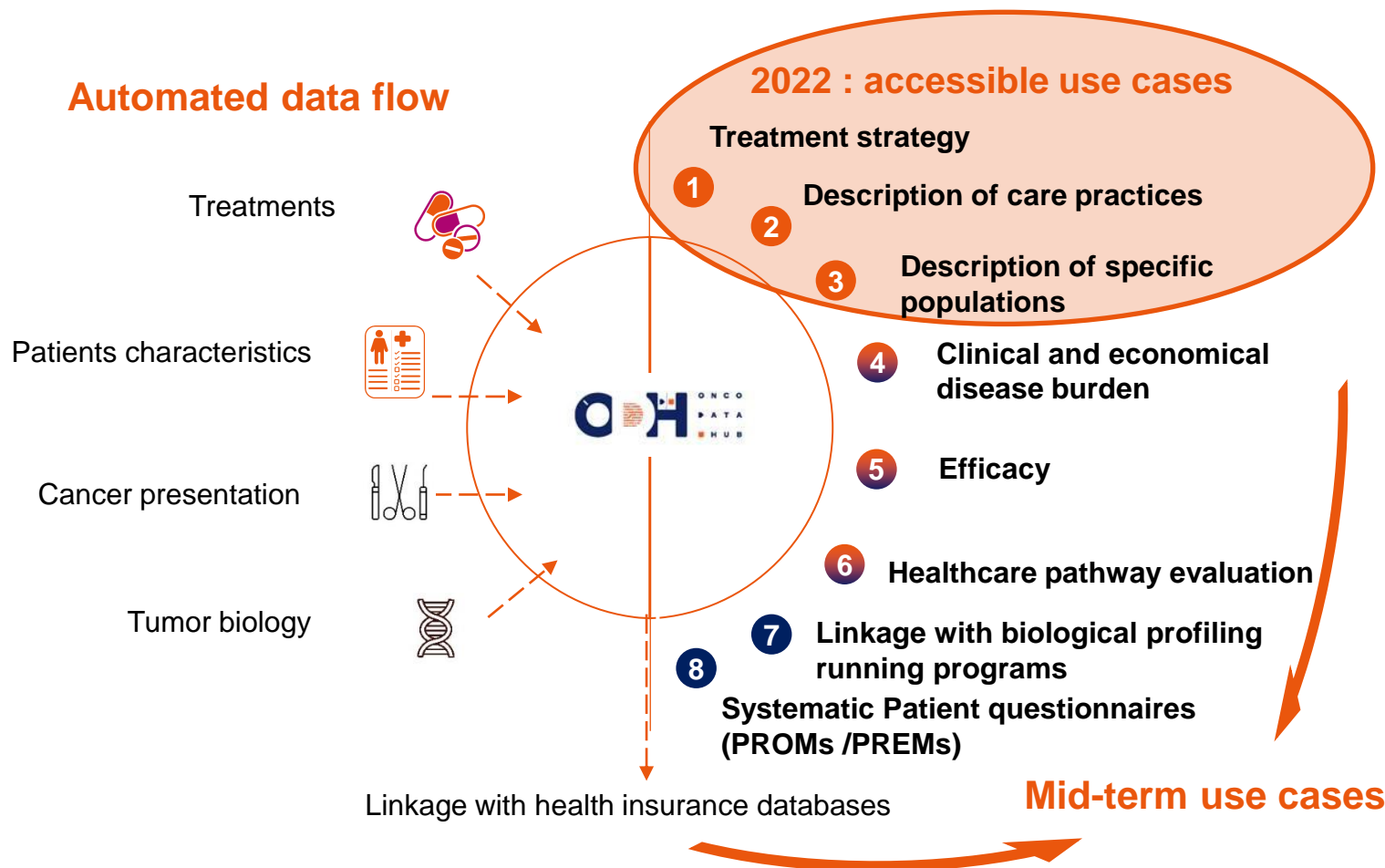




Our RWD flagship programs

ODH, the oncology drug observatory, launch in September 2021

Target 2023: 80 French private and public hospital involved

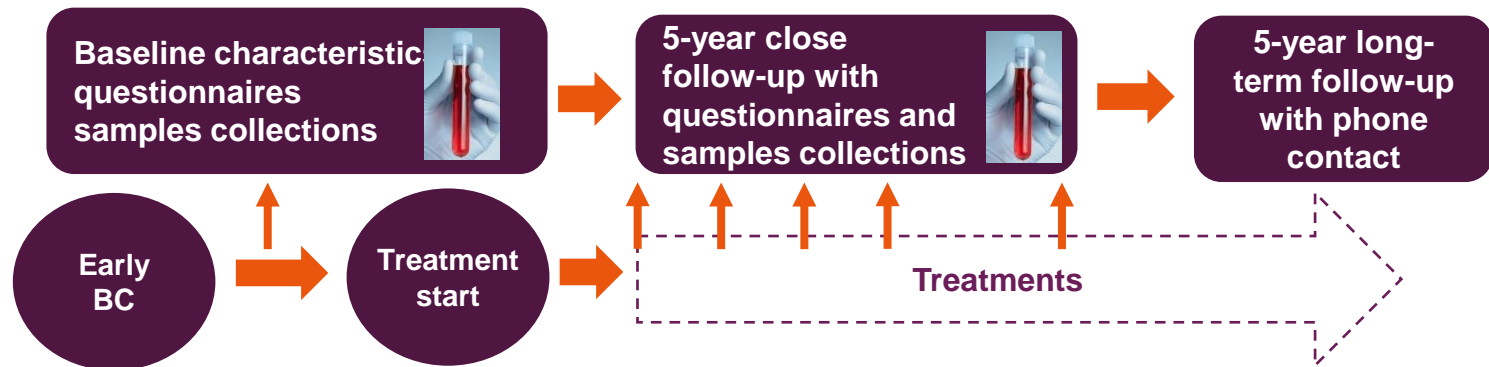


Cancer toxicities



Canto, building a cancer survivorship research program on breast cancer

Next step (2022): extension to patient exposed to innovative treatments for localized cancer (breast and lung)



Inclusions started
Feb 2012

LARGE DATABASE

LARGE BIOBANK
Blood serum plasma DNA
microbiota

ESME, retrospective data



ESME, Epidemiological Strategy and Medical Economics

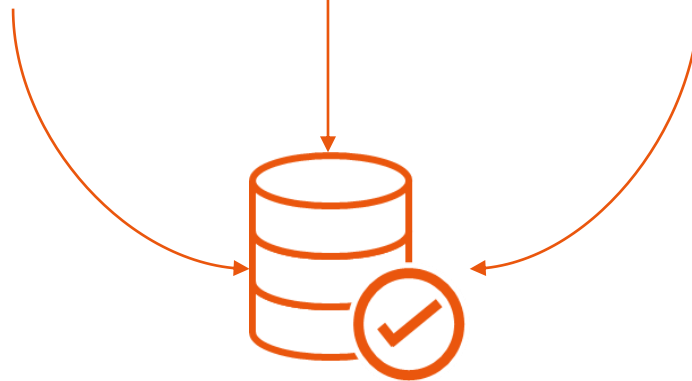
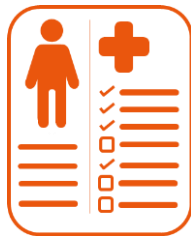
Longitudinal retrospective RWD on cancer management in oncology



Patient database

Treatment database

Hospital database



ESME data platform

Data administration using an Oracle Solution hosted by a
« Certified Personal health data hosting » provider

Patient Database (200+)

Patient data collected based on electronic health records:

- Demographics
- Disease characteristics
- Treatments
- Clinical events

Treatment Database (10+)

- *On-site pharmacy records*: Dates, cytotoxic drug, therapeutic protocol and other concomitant drugs

Hospital Database (20+)

- *Hospitalizations* (dates, diagnoses, GHS code)
- *Medical procedures* (including Radiotherapy): dates and code

The best way to answer questions

ESMÉ

- ✓ Epidemiology
- ✓ Therapeutic strategies efficacy evaluation
- ✓ Historical control arms
- ✓ Agencies pre-MA => registration
- ✓ Agencies post MA => RWD complementary data
- ✓ Artificial intelligence

ONCO DATA HUB

- ✓ Innovative treatment observatory and evaluation
- ✓ Therapeutic strategies evaluation
- ✓ Pan –tumor evaluations
- ✓ Institution and Hospital benchmark

cantoi

CANcer TOxicities

- ✓ Patient burden measure
- ✓ Treatment toxicities and patient adherence
- ✓ Identification of patients at risk
- ✓ Social impact of disease and treatment
- ✓ Predictive algorithms
- ✓ Personalisation of care
- ✓ Artificial intelligence

Digital tools for patients / physicians



Focus on ESME research program

ESME research program



From idea to data platform

Target indication



Available population



Partner support



- ▣ Health Authorities
- ▣ Academic/institutional
- ▣ Industrial

ESME project



ESME data platform



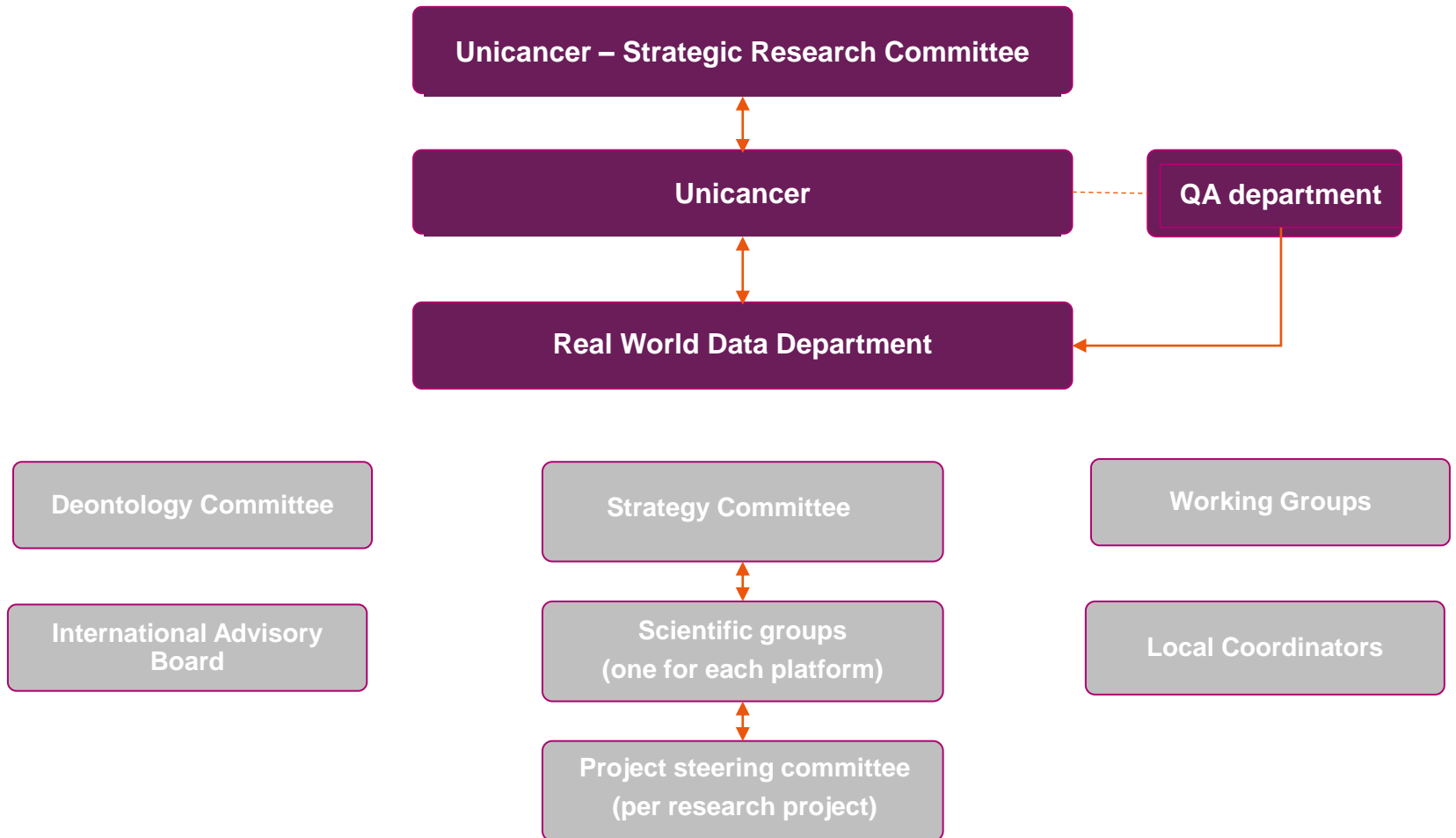
Dedicated cross-functional team:

- ▣ Central coordination
- ▣ Local coordinator(s)
- ▣ Expertise and Monitoring
- ▣ Data Protection Officer

ESME research program



Governance





Centralization of existing data from patient medical files

An independent academic RWD platform supported by private funds

○ Independent

- Independence from stakeholders
- Raw data collected without medical interpretation
- Data collection processes and data acquisition handled by an academic organisation
- Centralized data analyses (specialized analysis centres)

○ Comprehensive

- Data collected from 20 comprehensive cancer centres and other health care institutions
- Target population at each centre (standard screening process)
- Robust dataset with sufficient variables to conduct quality analysis

○ Validated

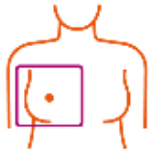
- Piloted by a committee of academic experts
- Scientific expertise for data interpretation
- Standard quality assurance processes



Provide valid statistical outputs to answer public health questions



Three data platforms so far....



ESME MBC

Adult women or men who began initial therapy* for **metastatic breast cancer**

Recruiting centres: 20 (FCCCs)

Patients: 28 000+ recruited

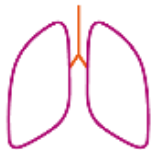


ESME OC

Adult women, who received therapy* or surgery* or who were diagnosed with **ovarian cancer**

Recruiting centres: 20 (FCCCs)

Patients: 12 000+ recruited



ESME AMLC

Adult women or men who began initial therapy* for **advanced lung cancer**, or who were diagnosed with **metastatic lung cancer**

Recruiting centres: 36 (FCCCs and other public hospitals)

Patients: 32 000+ recruited

**radiotherapy, chemotherapy, targeted therapy or hormone therapy in a participating center during the selection period*



Objectives and opportunities

Describe patient care in routine medical practice and evaluate therapies efficiency in real life setting

- Describe cancer management in France and its evolution overtime
- Provide data on innovation drug use in medical institutions
 - Before marketing authorization and in real life setting
- Describe therapeutic trends (e.g. sequence of treatment strategies)
- Provide data to support requests from health authorities
 - Medical & economic assessment of therapeutic strategies
 - Description of patient management/settings (clinical features, therapeutic management, costs) : linkage to data from the National Health Insurance Fund.
 - Description of reported outcomes
 - Description of specific population(s) (e.g. elderly patients, clinical trial participants, rare mutation profile, etc.)
 - Data modelling & extrapolation to the national population (generalisability)
 - Building of historical control arm (e.g. for comparison and/or matching)

How to collaborate?



Academic project proposals

- Open to contributing centres
- Peer review & validation by Scientific Committee
- Analysis performed by the Investigator
- Results published



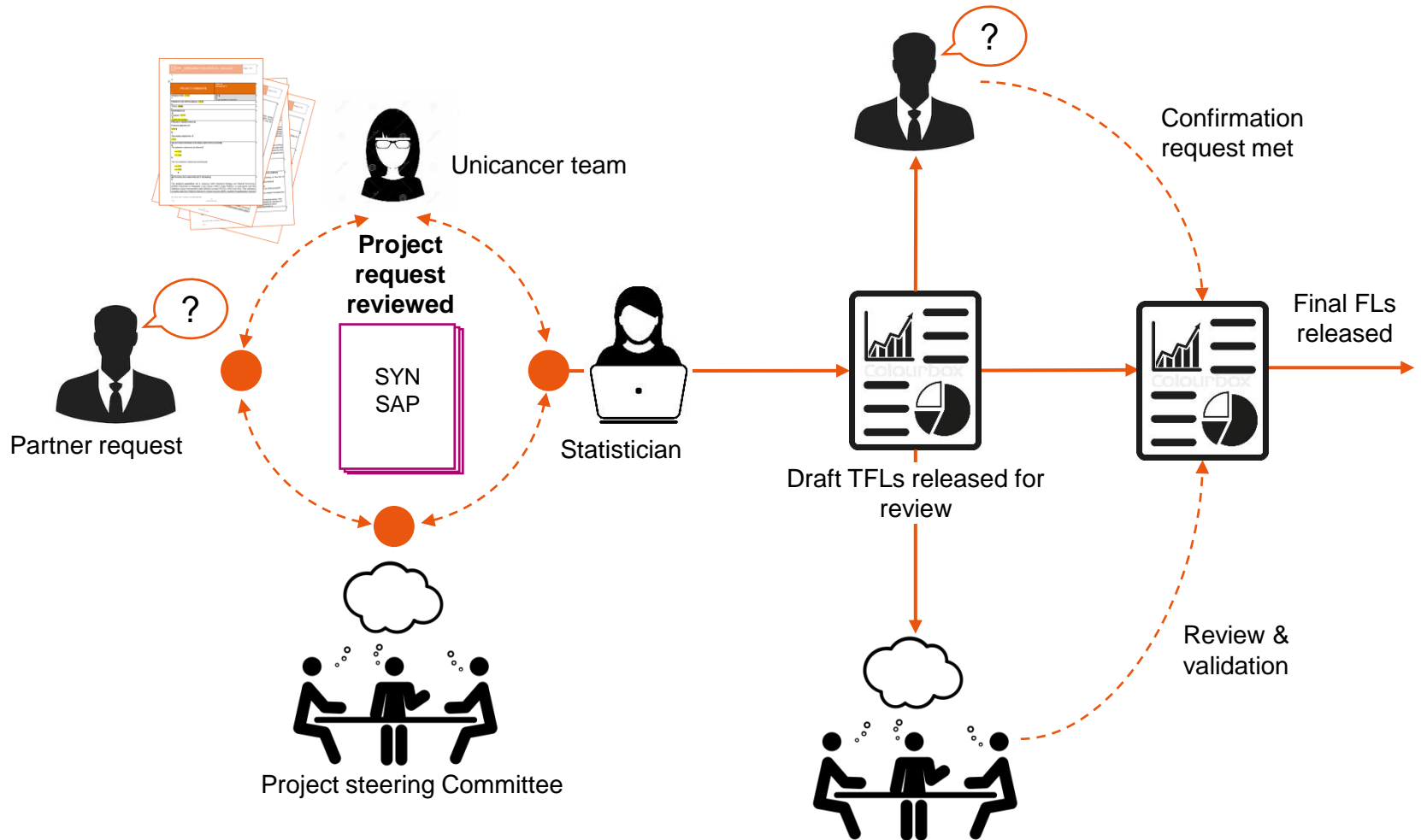
Partner request for analysis

- Defined by contract
- Subject to review & amendment by appointed Steering Committee
- Analysis performed by Unicancer
- Statistical analysis report transmitted to Partner and Health Authorities
- Results published

ESME research program



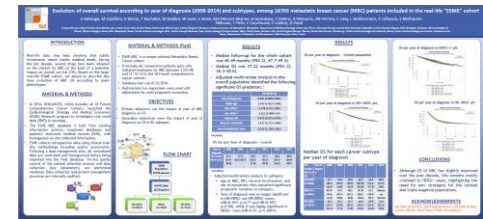
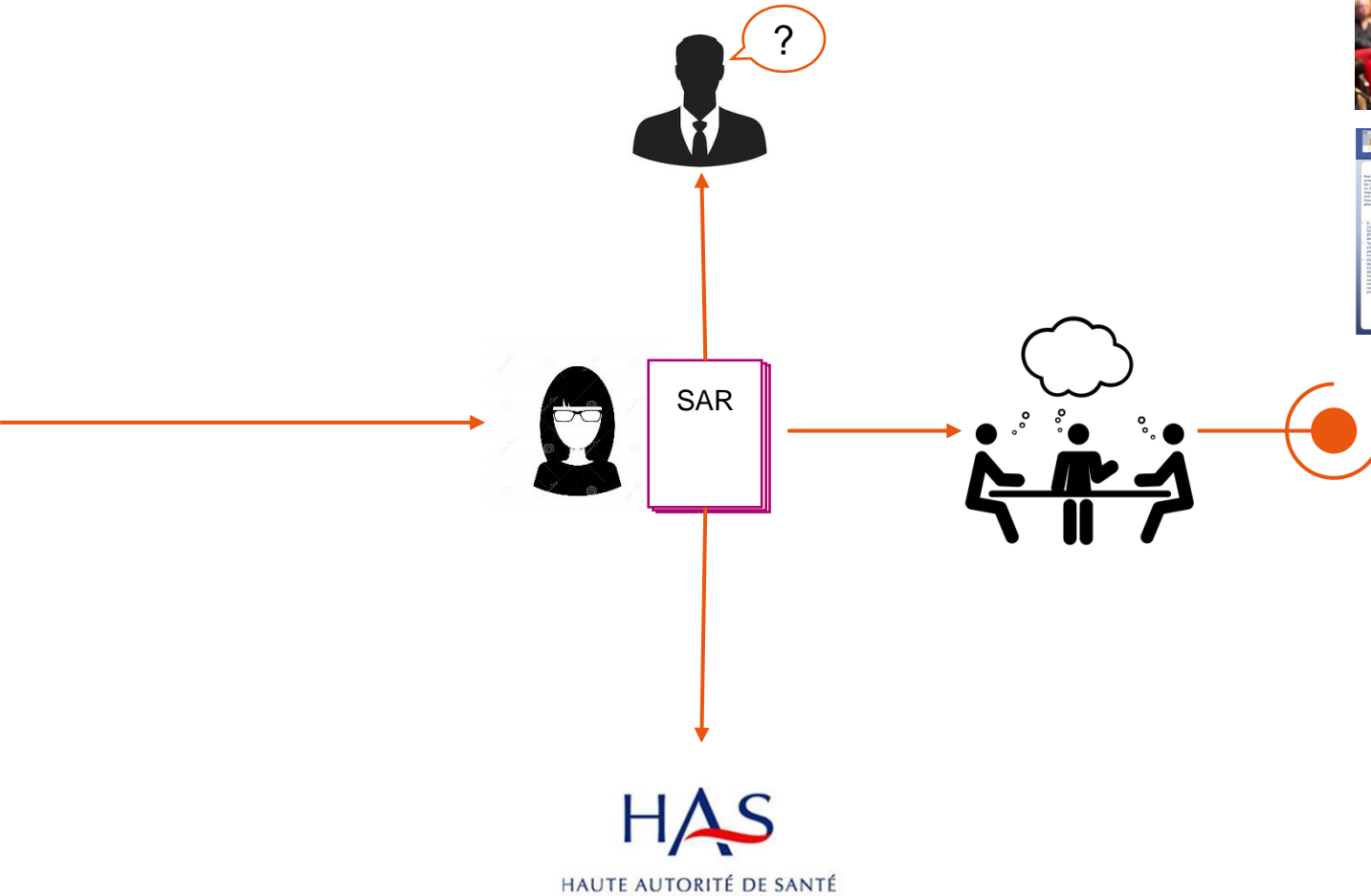
Collaboration process



ESME research program



How to collaborate?



Academic publication of results by Steering Committee



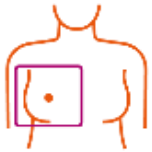
Original Research
Time trends of overall survival among metastatic breast cancer patients in the real-life ESME cohort
 Elia Gobbi¹, Maria Kraziani¹, Vincenzo Diarra¹, Thomas Bachelot¹, Estelle Bruyat¹, Marc Delisle¹, William Jacot¹, Mary Ange Moura Reynier¹, Anthony Goncalves¹, Florence Dulac¹, Anne Poincay¹, Jean Marc Ferrero¹, Christophe Levy¹, Vanessa Lengua¹, Laurence Vachonema¹, Claudia Lefevre-Posse¹, Simon Mathelin-Poirier¹, Thierry Poul¹, Lionel Uver¹, Chloéle Journaud¹, Martine Lohrman¹, Magali Laurent-Folli¹, Audrey Lady-Cheval¹, Mathieu Richard¹, Corine Courantaud¹, Christian Caillon¹, David Paul¹, Saïette Delaloge^{1*}

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ESME research program



ESME results so far...



ESME MBC

65 Projects

- 36 Ongoing
- 29 Completed

62 Communications

- 29 Publications
- 2 Oral presentations
- 31 Posters



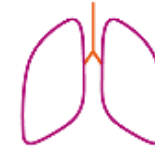
ESME OC

16 Projects

- 12 Ongoing
- 4 Completed

4 Communications

- 1 Publication
- 3 Posters



ESME AMLC

29 Projects

- 14 Ongoing
- 15 Completed

16 Communications

- 1 Publication
- 13 Posters
- 2 Oral presentation





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