

SPECTArare as an innovative model of combining clinical research and care in an ERN

Denis Lacombe, MD, MSc
EORTC, Director General
Brussels, Belgium

Contents

- The changing clinical research pathway
- How this affects rare tumors?
- SPECTA model
- Impact on infrastructure and partnerships

European Organization for Research and Treatment of Cancer (EORTC)

- Private and not for profit organization created in 1962
- Main mission: promote and conduct research to improve cancer care
- Core activity: conduct clinical trials
 - International
 - Multidisciplinary
 - Develop new treatments
 - Define new standards of care
 - Large academic trials
- Track records in rare tumors



Henri Tagnon, Co-founder of EORTC

EORTC 2015

- > 187,600 patients in the databases
- > 24,000 patients being followed-up
- > 4,125 collaborators (clinicians, pathologists, researchers,....)
- > 632 institutions in the network
- >175 members in the HQ staff
- > 1600 publications with EORTC in the title (pubmed)
- 442 publications in 2012-2014
- 34 different countries
- 44 trials open to patient entry, 207 active trials
- 21 groups/task forces

The changing clinical research pathway

From trials “designed to learn” to real life situation



Early clinical trials (R&D)

- Biology / imaging driven
- Integrated TR
- Screening platforms
- Collection of high quality data from various sources

Pivotal trials

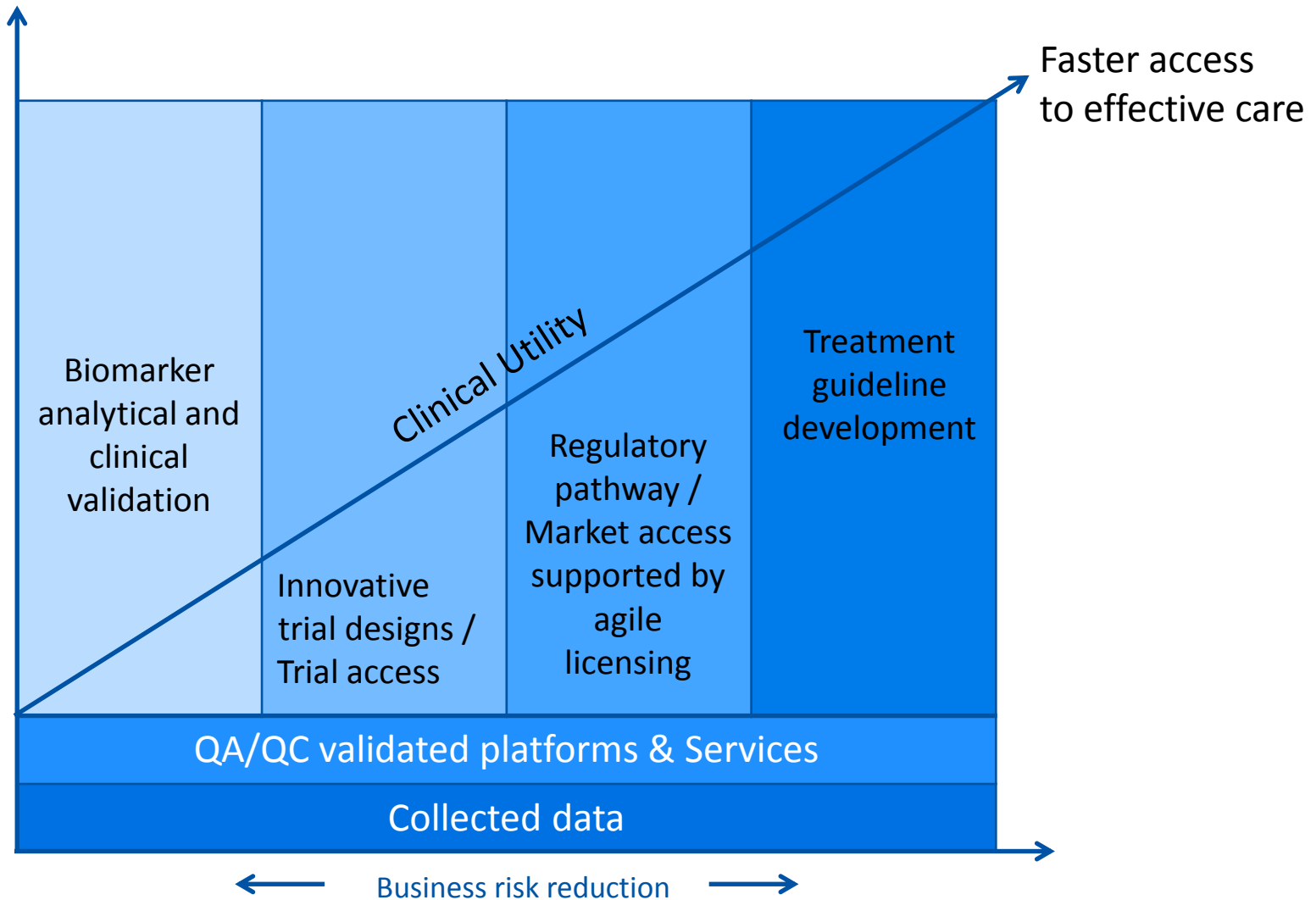
- Highly targeted
- Large differences

Population-based studies

- Real world data
- Quality of life
- Health economics
- HTA
- Pragmatic trials

Burock et al. Eur.J.Cancer (2013), <http://dx.doi.org/10.1016/j.ejca,2013.05.016>

Towards a big data driven Healthcare



How this affect clinical development
in rare tumors?

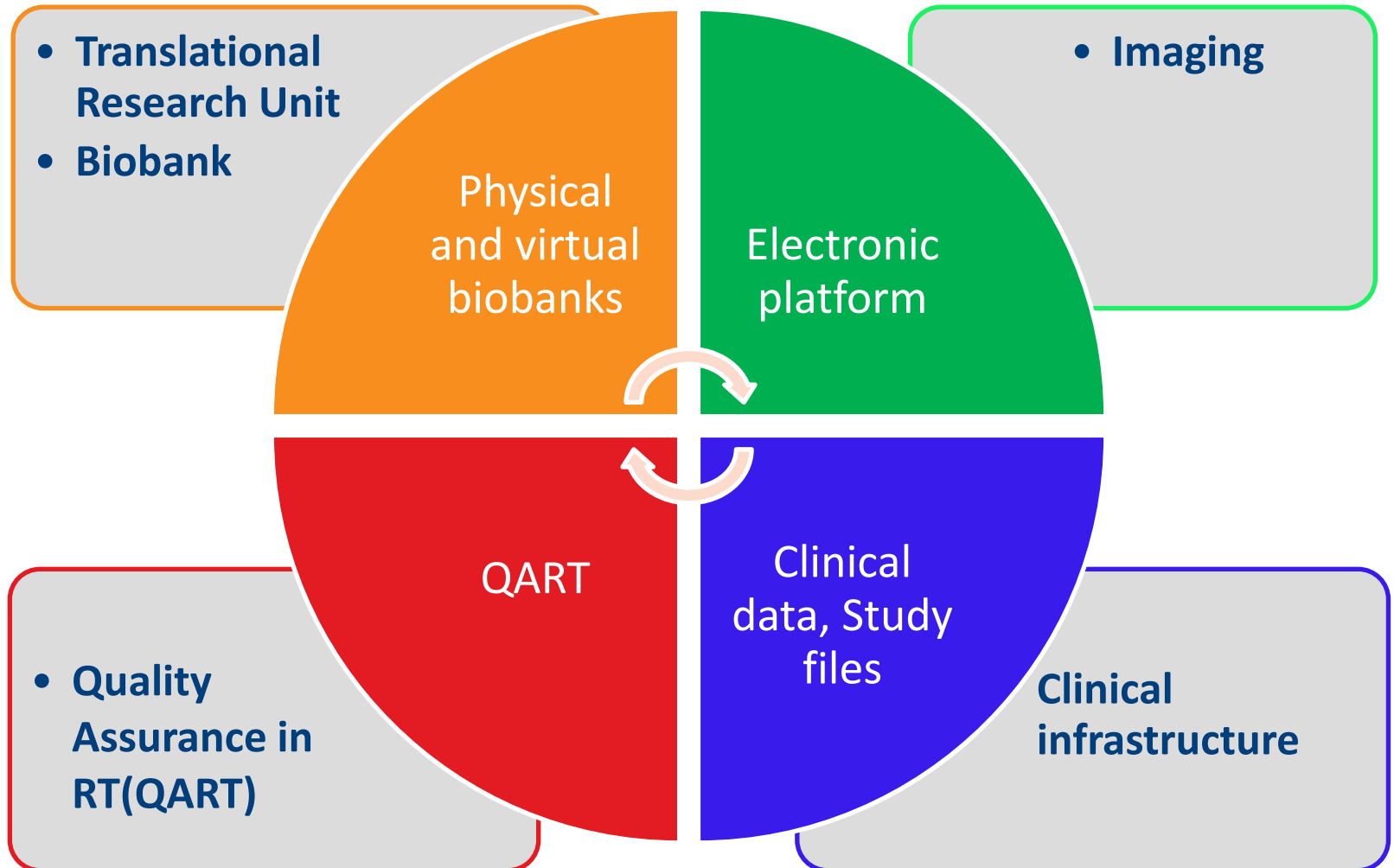
Selected challenges for clinical development in rare tumors

- Clinical trial designs
 - Identifying the most relevant question
 - Community wide endorsed control arm
 - Lack of robust existing data
 - Confusing diagnostic at the pathology level
 - Poorly documented biology
- Operational level
 - Recruitment capacities
 - Number of sites
 - Inadequate regulatory framework



High quality QA programs are required
Integration of research and care is mandatory

EORTC Infrastructure to support new generation clinical trials



New leading models for new forms of research

- To overcome:
 - Patient access to fore front research
 - Complexity and costs of TR based clinical trials



Shared infrastructure across rare entities

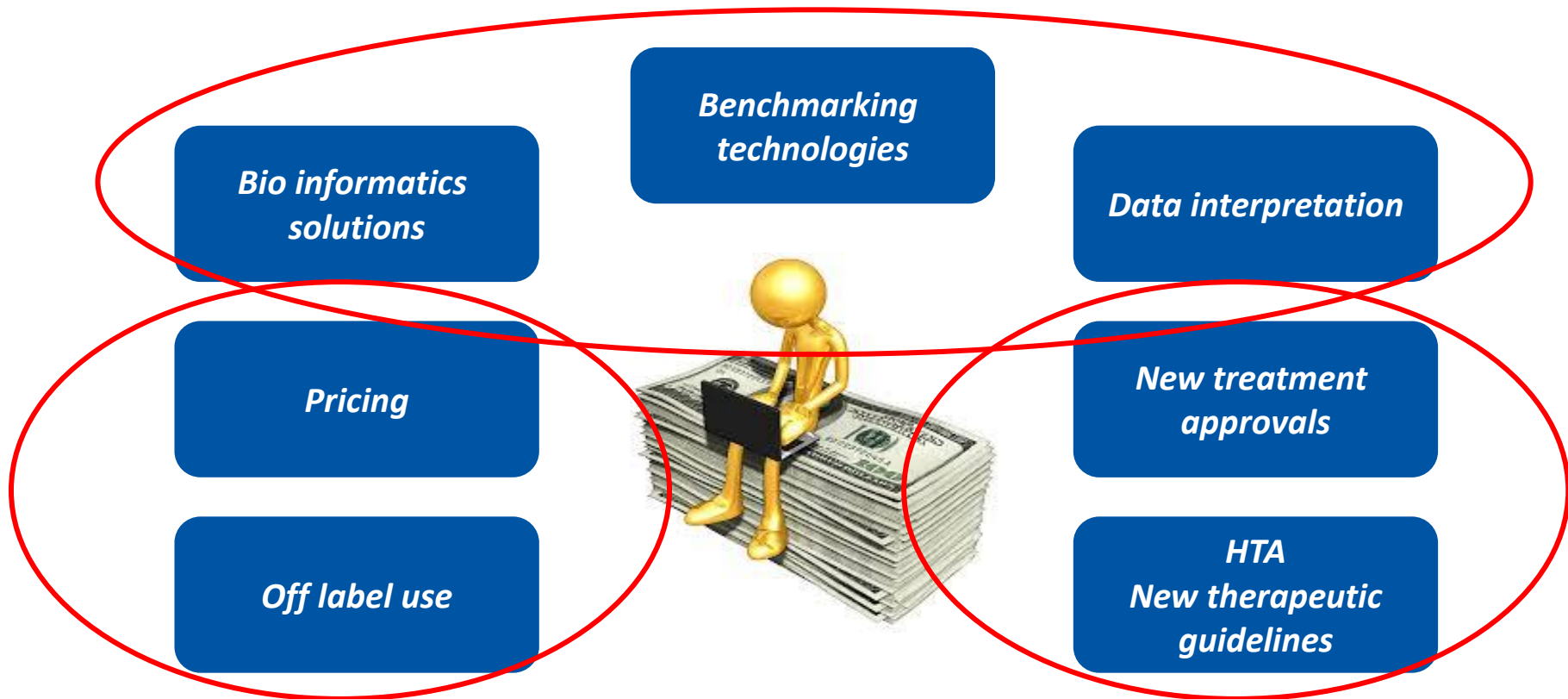
- To set up new models of partnerships
 - industry
 - academia
 - patients
 - payers/regulators



Explore new routes for treatment access/ off label

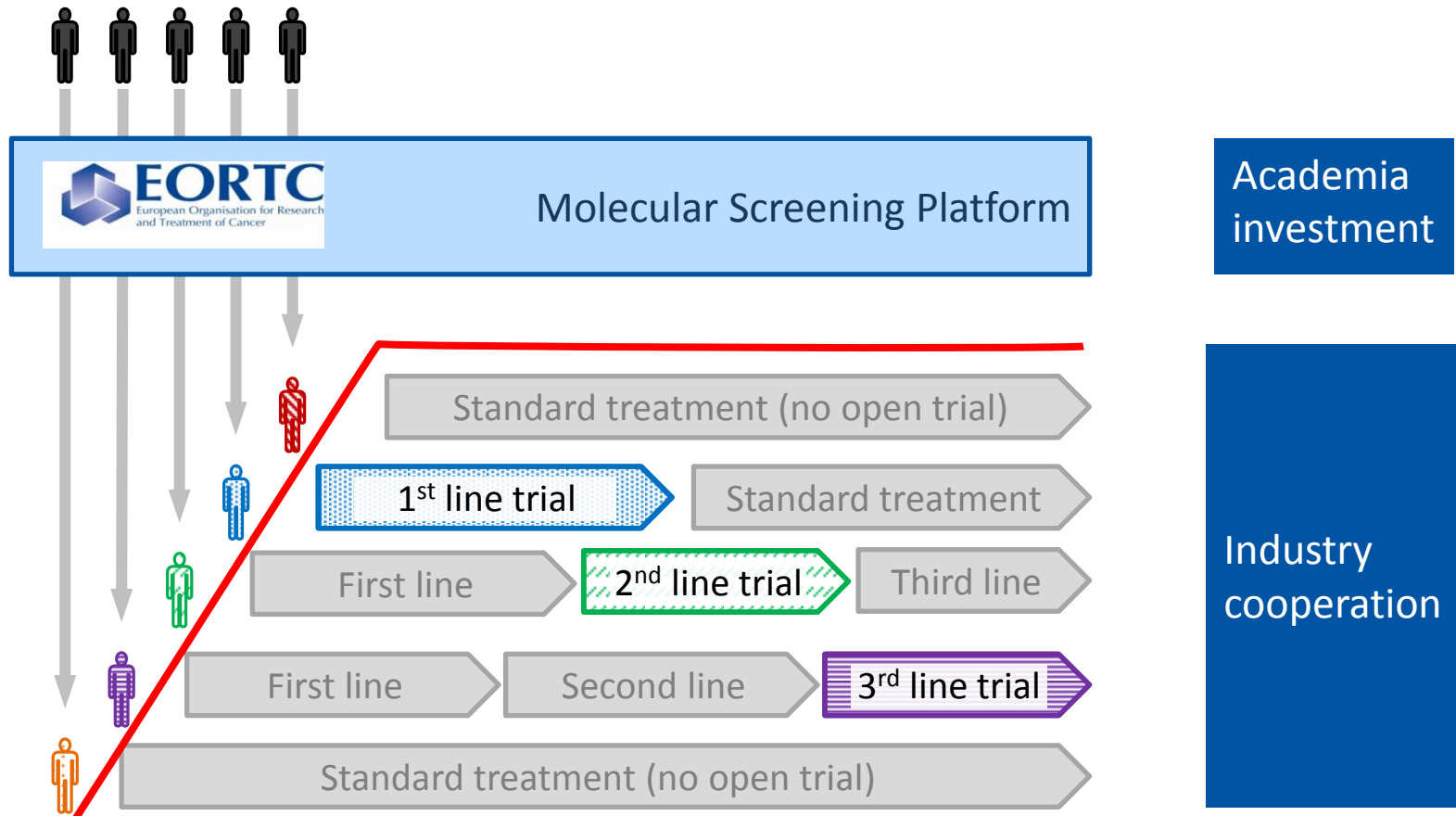
Some of the issues...

EU capacity for clinical research requires supra national standardization and interoperability



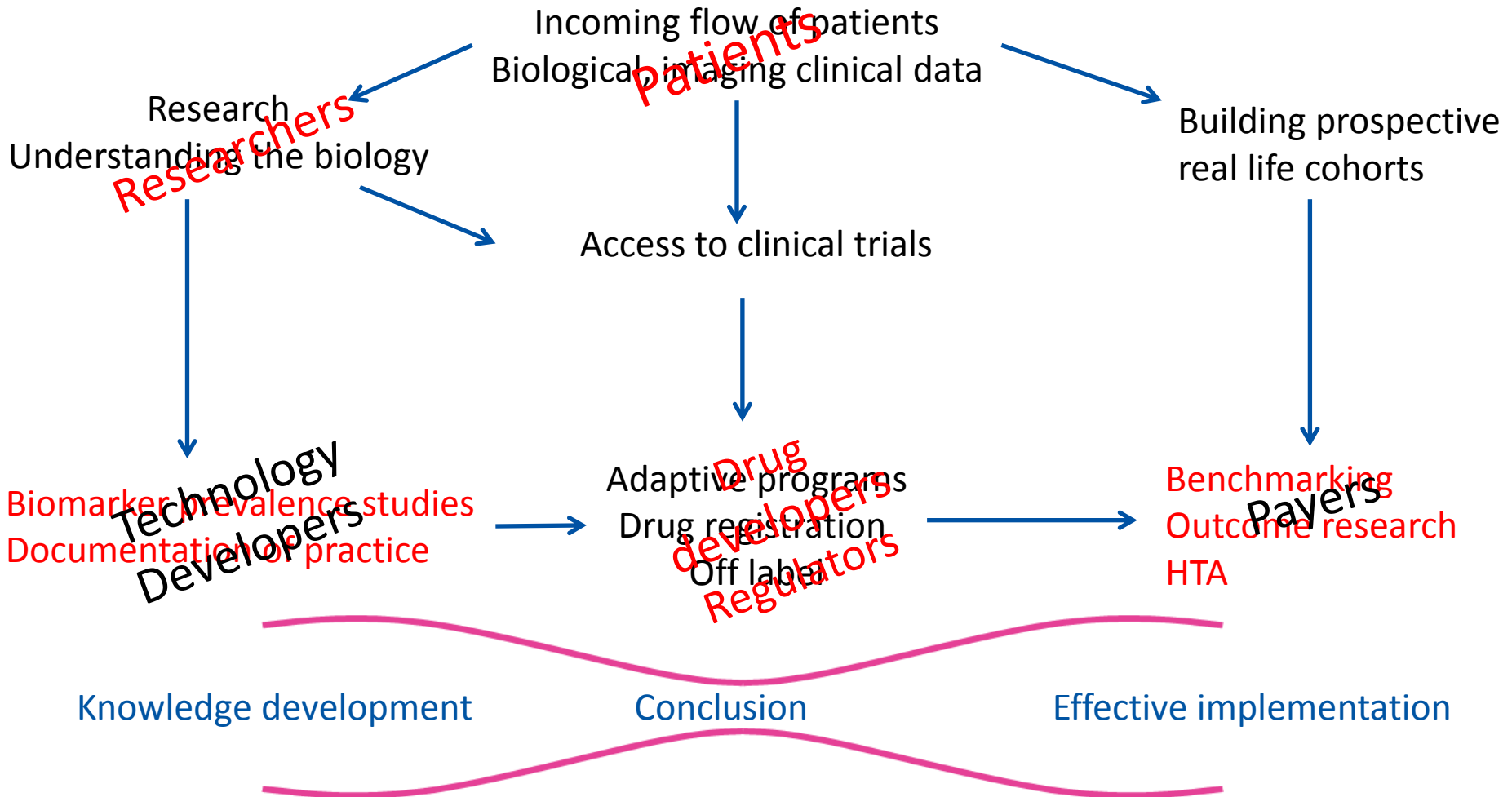
The SPECTA collaborative platform

Knowledge development



A prospective and longitudinal clinically annotated biobank

Therapeutic innovation through infrastructure and new partnerships



Towards disruptive therapeutic progress

- Convergence of disciplines: genomics, imaging, proteomics, metabolomics...
- Emergence of bio-informatic algorithms
- Alignment of stakeholders: patients, industry, researchers, regulators, payers..

Will lead to:

- New classification of diseases
- Referral expert networks needed to access to rapidly evolving knowledge, access to emerging data and treatment decision processes

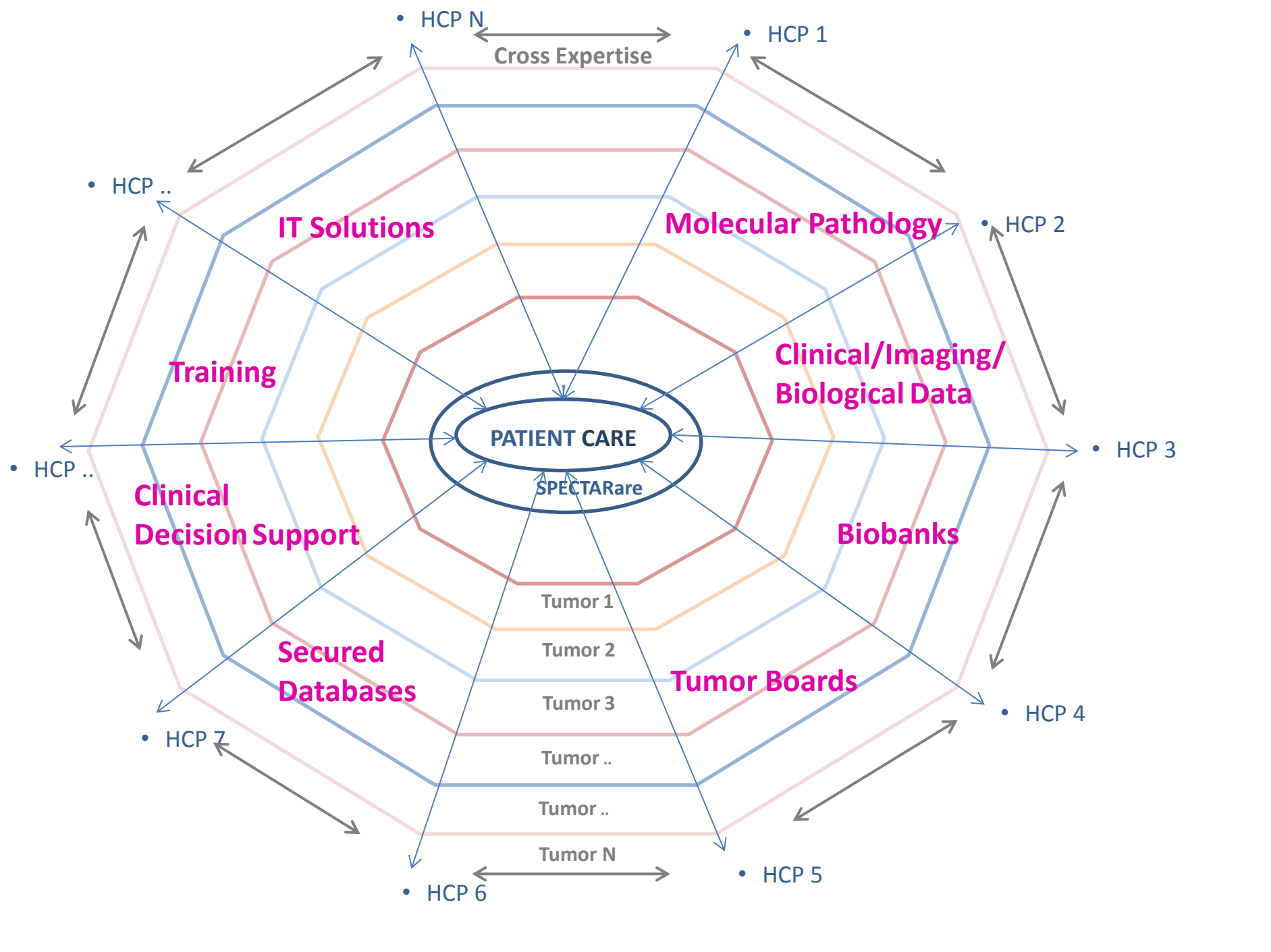
SPECTArare as a support for ERN

(already piloted for frequent tumors in more than 800 pts/24 sites/9 countries)

- SPECTArare will address more than 10 rare tumors as a start
- SPECTArare matches most of the 6 criteria for networks
 - Knowledge, expertise to diagnose and follow up patients
 - EORTC has demonstrated evidence of good outcomes
 - Multidisciplinarity
 - Capacity to implement QC and outcome measures
 - Research
 - Collaborate with multiple centers and networks
- Parameters to be optimized for the “care ‘ dimension
 - Specific training and teaching
 - Communication between HCP

A plea for European Reference/ Research Network for rare tumors

- Do not dissociate research and care
- Allow medical judgement by specialists but maximise cross expertise through joined research infrastructure such as SPECTA
- ERN is an opportunity to build top level HCP supported by fore front infrastructure such as SPECTArare.
- Such network is needed taking all contributions available from all stakeholders along shared strategies



www.eortc.org/ibcd2015
#IBCD2015

Innovation and Biomarkers in Cancer Drug Development (IBCD)

A Joint Meeting by EORTC, NCI, EMA and AACR

*3 - 4 December 2015
Brussels, Belgium*

