

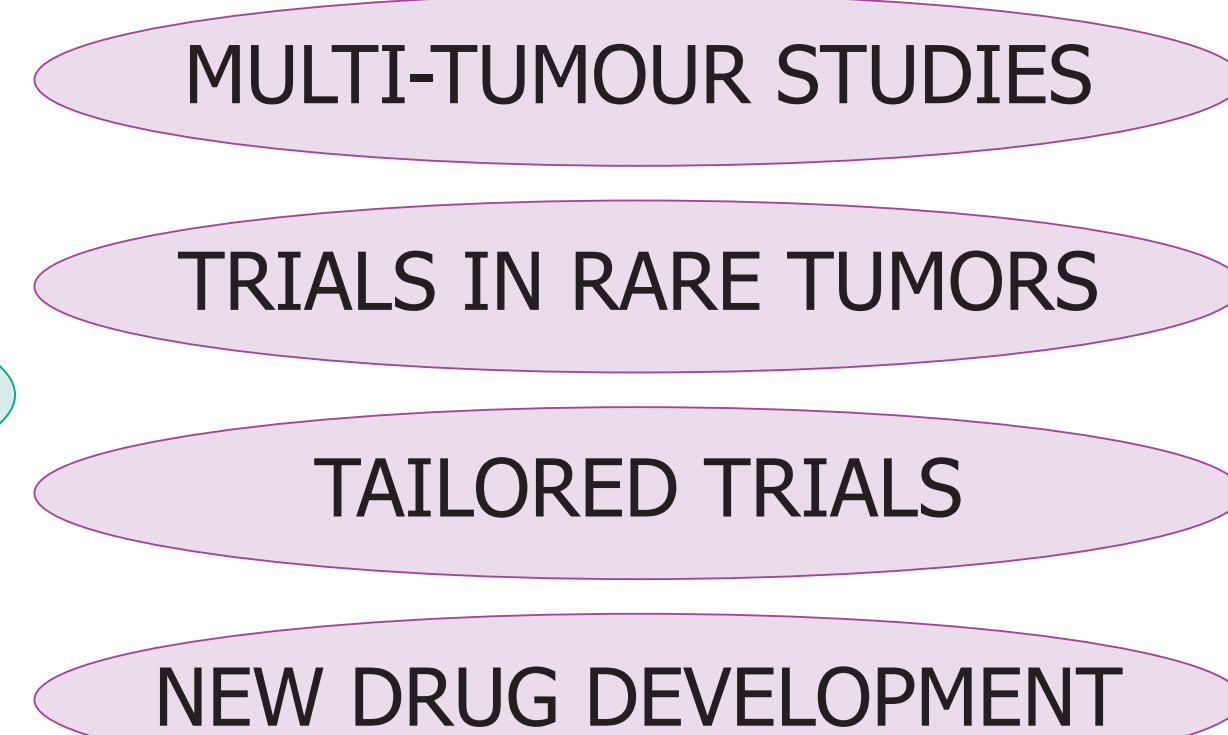
INTRODUCTION

Main mission To develop, conduct and stimulate translational and clinical research in Europe to improve cancer care

EORTC today

- Network of 300 institutions in 30 countries
- More than 2,500 collaborators (scientists and clinical investigators)
- 6,500 patients are treated each year according to EORTC protocols
- 50,000 patients in follow-up
- 30 trials open to patient entry
- EORTC databases contain high quality clinical and follow-up data for all the patients enrolled into EORTC clinical trials

Core activity



International & multidisciplinary

- Biologically driven trial design
- Strong TR component
- Network of excellence: Disease Oriented Groups, TRD, NOCI
- A central database with high quality clinical data
- IT infrastructure and virtual microscopy facility

Access to human biological materials (HBM) in both sufficient quantity and quality is one of the major bottlenecks hindering successful bench to bedside translation.

BACKGROUND

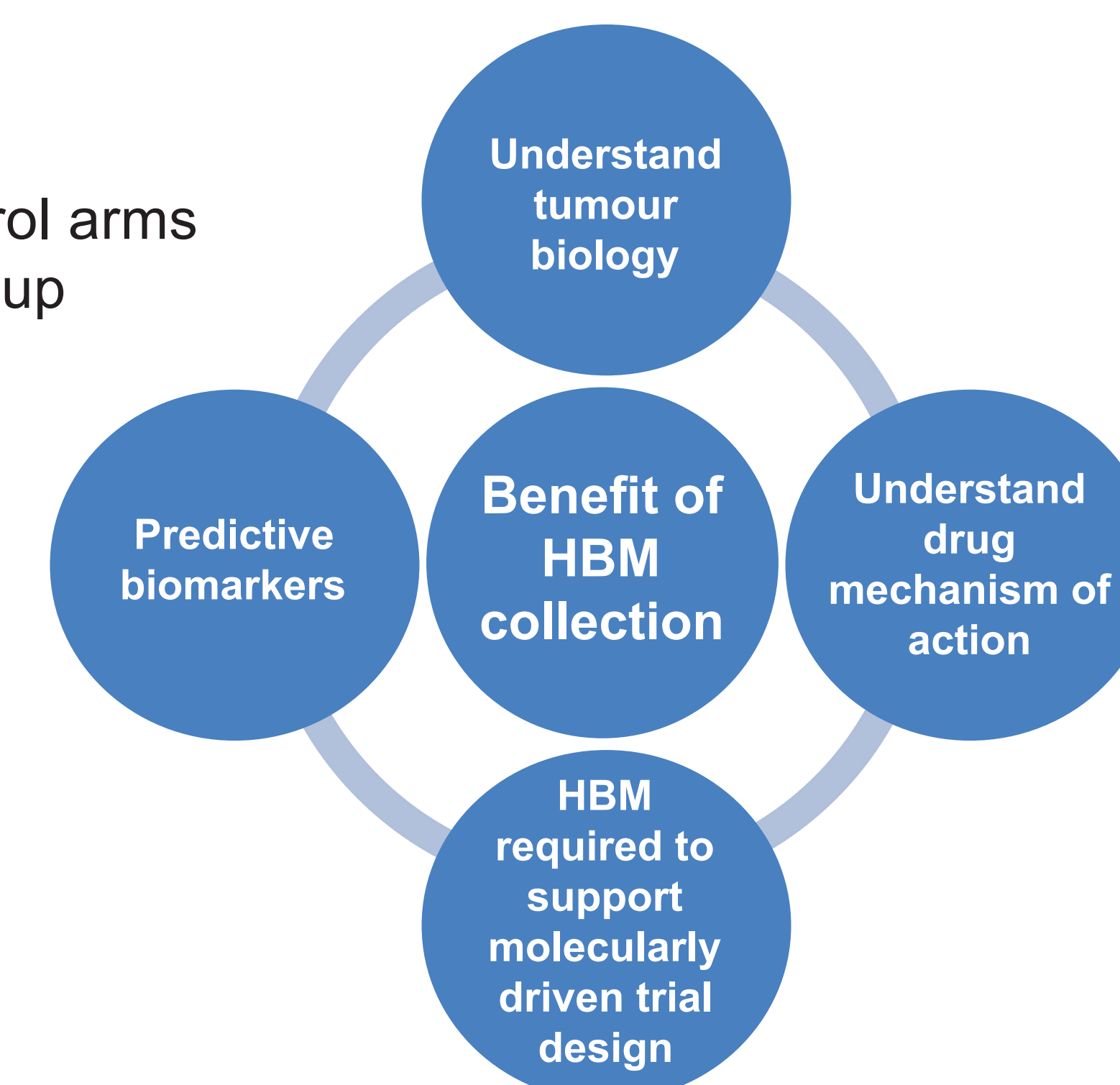
What is Biobanking?

Organized collections of HBM e.g. tumor tissue, blood and derivatives such as RNA and DNA, with associated data (clinical data and HBM quality information).

Biobanks are established to store and supply HBM for future research objectives. Biobanks include the infrastructure in which the collection is stored as well as the organizational structure.

Why collect HBM in clinical trials?

- Large, homogenous patient populations; treatment with new drugs; treatment & control arms
- High quality data & long term clinical follow-up

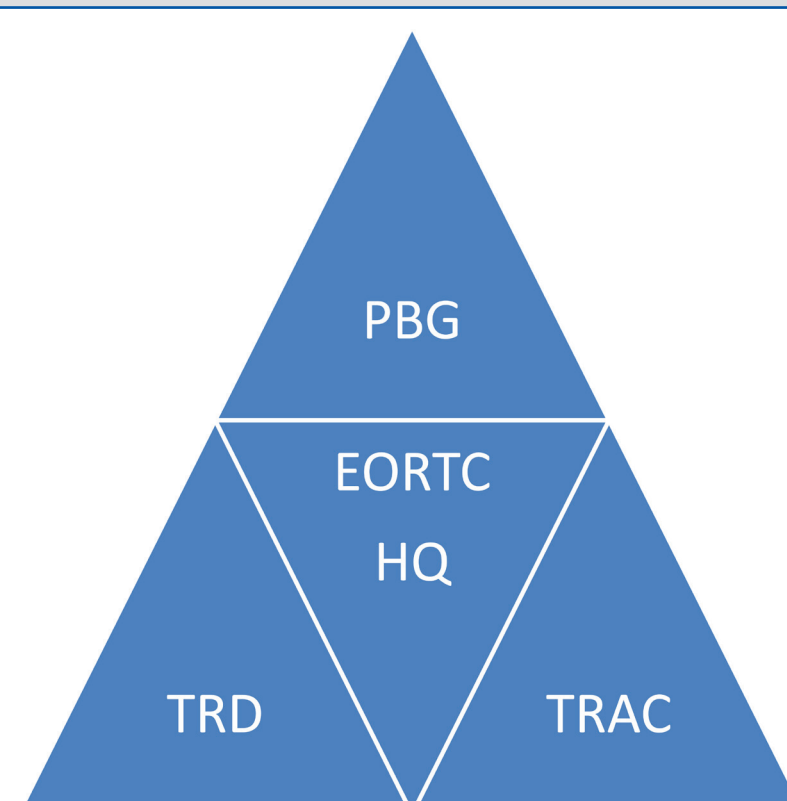


Biobanking is a key component of modern clinical cancer research for which EORTC has given a high priority

AIMS

Why a policy for HBM collection in biobanks?

- ▶ Changing research environment
- ▶ Need for adequate sample size
- ▶ Retrospective HBM access (increasing importance)
- ▶ Need to meet quality requirements for HBM
- ▶ Increasing prevalence of 'biobanking' legislation
- ▶ Complex European legislative landscape



Policy Core Principles

- ▶ Custodianship: entity initiating the HBM collection and centralization
- ▶ Ethical principles
- ▶ Confidentiality and data protection
- ▶ Access to HBM
- ▶ Promote best practice & QA in biobanking
- ▶ Logistics (traceability of HBM)
- ▶ HBM collection & storage protocols developed prospectively
- ▶ Distribution of research results and publications

EORTC BIOBANK NETWORK

- Biobanking at EORTC has been developed via a strategy of sequential pilot projects based on the expertise of the EORTC groups and HQ e.g. TUBAFROST and CHEMORES European Frame Work Programme (FP) projects.
- Quality assured biobank infrastructures via an EORTC "quality label" for sites that wish to store HBM.
- Build on existing infrastructures and expertise in the network but also provides expertise and support to de novo establishment of group biobanks

* EORTC QA

EORTC

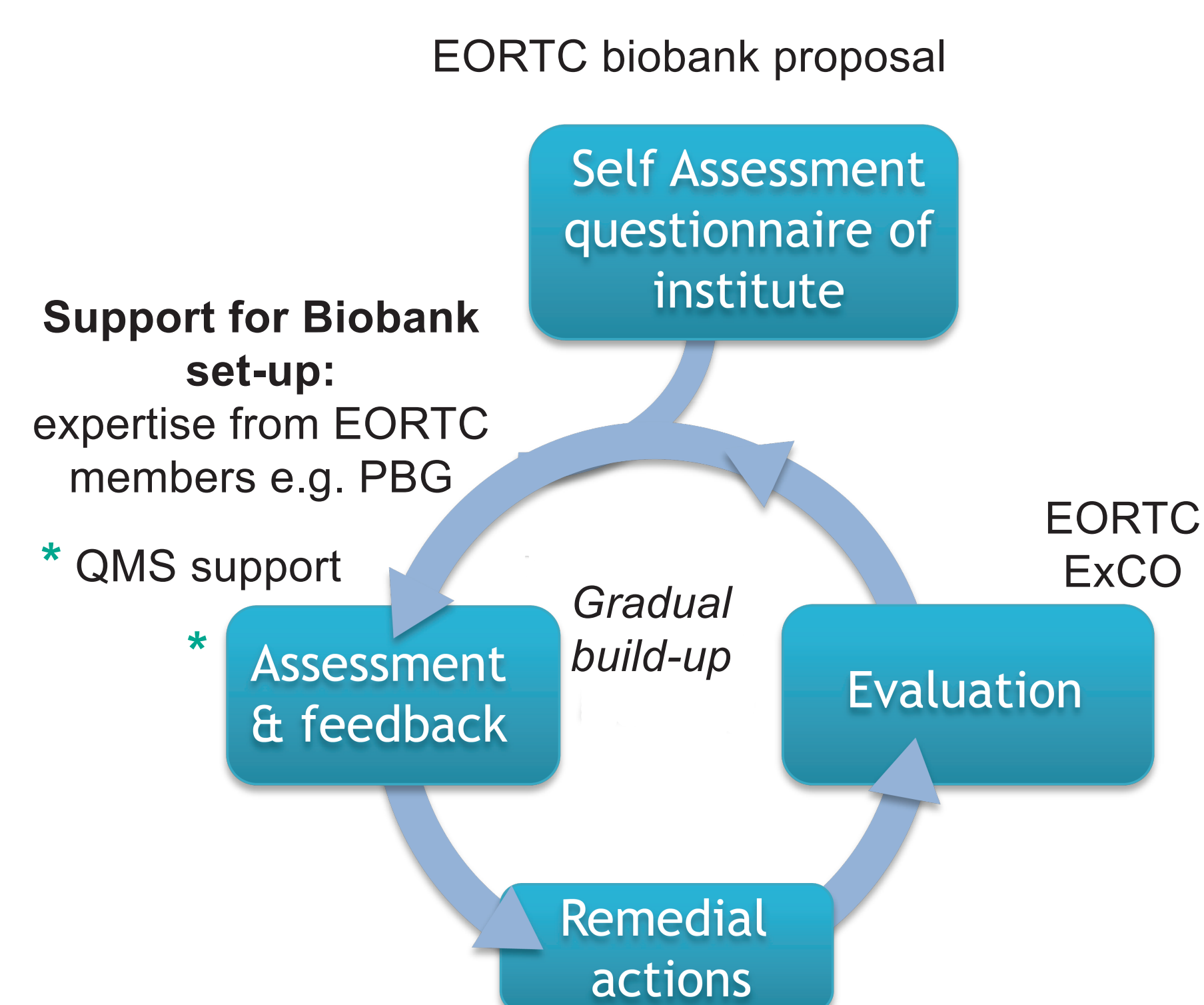
Independent Service Provider

- Potential breakthrough trials
- Key strategic trials
- Pharma

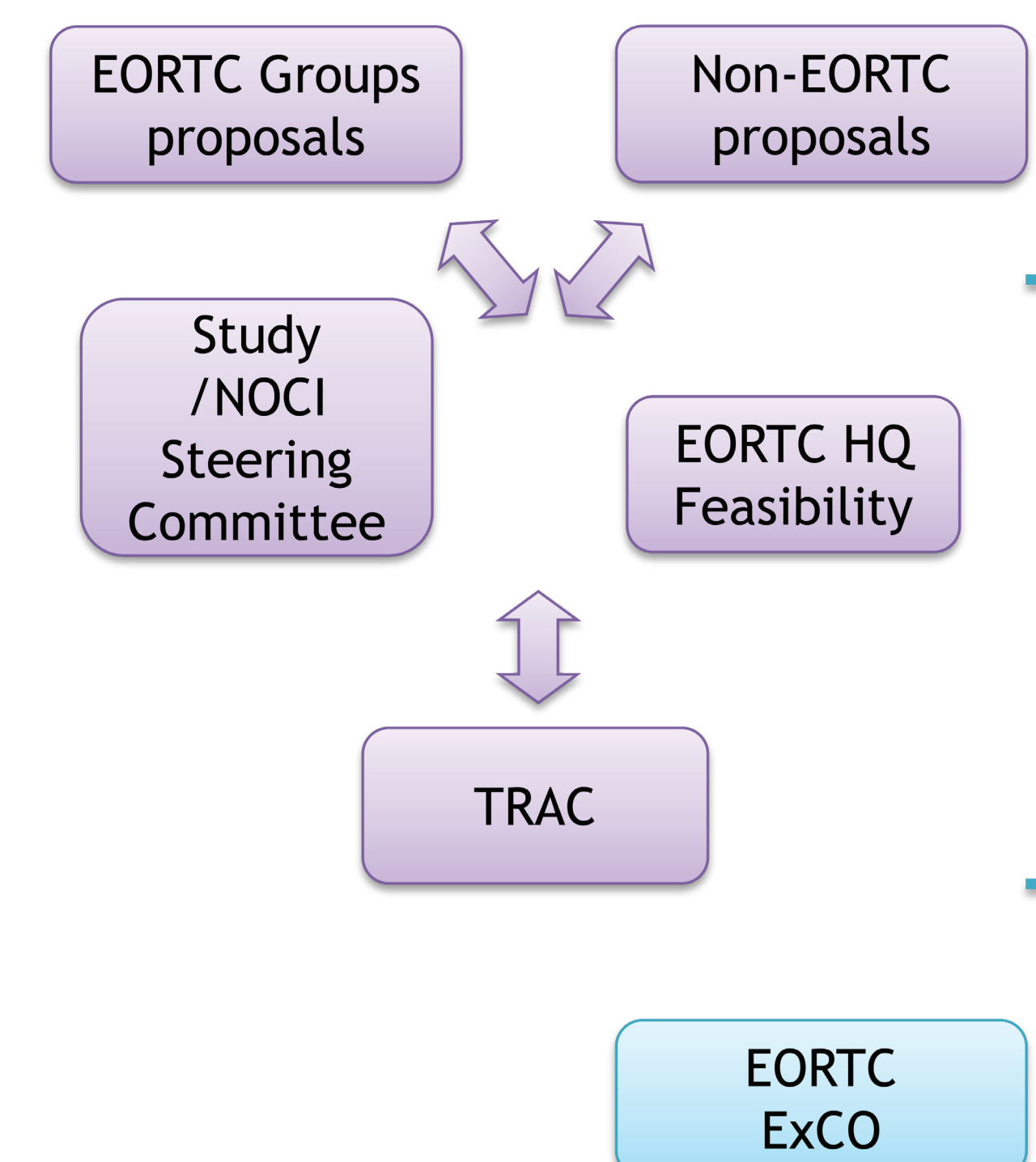
Group Biobank

- At well established sites
- Investigator led studies
- Specific expertise for specialized HBM collection

ACTIVATION OF BIOBANKS



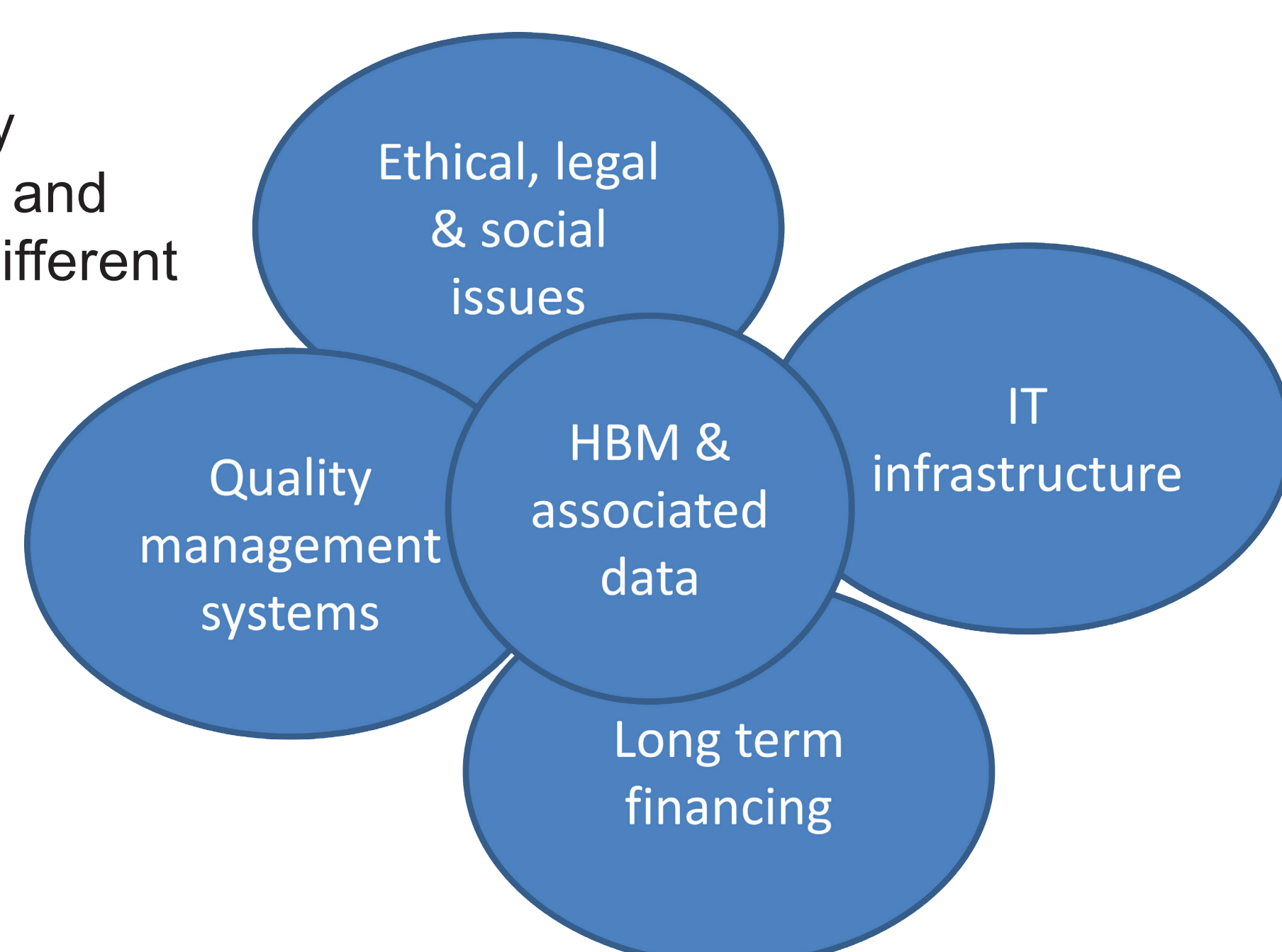
ACCESS TO HBM



CHALLENGES

A sustainable concept for ethical, legal and financial frameworks underpinning a quality driven network infrastructure for biobanking

- Integrating international standards for quality management in cancer research biobanking and best practice-based standard protocols for different types of HBM collection
- Regulatory & operational aspects within an international environment
- Standardization of HBM collection/storage (QA/QC)
- Regulatory obstacles
- Country-specific protectionism
- Logistical challenges



THE FUTURE: A MULTI-MODALITY PATIENT DATABASE

Combining:

- HBM collection initiatives
- Prospective collection of key quality data on the HBM
- High quality clinical and quality of life databases
- Radiotherapy database
- Imaging database
- Images of tissue (virtual microscopy)

These resources, in toto, will add further dimensions to the analysis of endpoints in clinical trials.

