BIOBANKING TO SUPPORT EORTC CLINICAL STUDIES

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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

- Biobanking is a key component of modern clinical cancer research for which EORTC has given a high priority
- Access to human biological materials (HBM) in both sufficient quantity and quality is one of the major bottlenecks hindering successful bench to bedside translation

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

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 CHEMOTHER 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

Keystone EORTC

Independent Service Provider

Group Biobank

→ Potential breakthrough trials
→ Key strategic trials
→ Pharma

EORTC

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

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

BACKGROUND

What is biobanking?
Organized collections of HBM e.g. tumor tissue, blood and derivates 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

Access to HBM

Support for Biobank set-up:
Expertise from EORTC members e.g. PBG

OMS support
Gradual build-up
Self Assessment questionnaire of Institute
EORTC ExCo
Gradual build-up
Evaluation
Remedial actions

ACTIVATION OF BIOBANKS

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.

THE FUTURE: A MULTI-MODALITY PATIENT DATABASE

Clinical trials
Biobanking
Images
Pathology
Translational Research

Poster design: Stephanie Hendrapskis, EORTC Communications Office, Brussels, Belgium

HBM = Human Biological Material, EORTC HQ = EORTC Headquarters, PBG = EORTC Pathobiology Group, TRAC = EORTC Translational Research Advisory Committee, TRD = EORTC Translational Research Division, QA = Quality Assurance, EORTC ExCo = EORTC Executive Committee, NOCI = Network Of Core Institutions, QMS = Quality Management Systems