EBE-EFPIA Satellite Group On Biobanks

Objectives and Activities
Oliver Karch, Kirstin Goldring, Lotte Glück, Anthony Chadwick, Audrey Wolf on behalf of the group
About EBE-EFPIA

About EBE
European Biopharmaceutical Enterprises (EBE) represents the voice of biopharmaceutical companies of all sizes in Europe and is a specialised group within the European Federation of Pharmaceutical Industries and Associations (EFPIA). Established in 2000, EBE is recognised as the leading biopharmaceutical association in Europe.

About EFPIA
The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the pharmaceutical industry operating in Europe. EFPIA is the voice on the EU scene of 1,900 companies committed to researching, developing and bringing to patients new medicines that will improve health and the quality of life around the world.

Partnering with Research, e.g. IMI – Innovative Medicines Initiative
The Innovative Medicines Initiative (IMI) is Europe's largest public-private initiative aiming to speed up the development of better and safer medicines for patients. IMI supports collaborative research projects and builds networks of industrial and academic experts in order to boost pharmaceutical innovation in Europe. IMI is a joint undertaking between the European Union and the pharmaceutical industry association EFPIA.
Objectives of the Satellite Group on Biobanks

MISSION
The aim of the Satellite Group on Biobanks is to ensure that the needs of biopharmaceutical companies in biobanking are met. The group is therefore collaborating and aligning with relevant experts and initiatives across Europe and internationally, such as BBMRI-ERIC, ISBER Pharma working group, TransCelerate

OBJECTIVES

✓ Drive and contribute to relevant working groups e.g. ESBB Translate, IMI (Innovative Medicine Initiative) projects, e.g. BD4BO, DO-IT WP4

✓ Foster dialogue with Academic and Commercial Biobanks

✓ Map current environment and identify opportunities, e.g. harmonization of sample reuse

✓ Develop industry position on biobanking

✓ Advocate the industry position towards key stakeholders

✓ Act as the voice of the client (of a biobank)
Topics of the Satellite Group on Biobanks

The group is working towards harmonization of biosample practices, particularly with a focus on

- Compliance to legislations
- Consent and transparency to patients / donors regarding biosample usage
- Respect of patient confidentiality (GDPR)
- Quality control of collection and storage
- Data annotation
- Biosample exchange between all parties (Biobank/Pharma/CRO/Academia)

Focus is on harmonization and implementation across enterprises
Impact HBS Lifecycle

Collection Source
- Clinical Trials
- Staff
- Vendors / Suppliers

Disposal
- Return to Donor / Biobank
- Incineration
- Respectful
- MTA / SLA

Transport
- Import and Export of HBS
- Return to Donor / Biobank
- MTA / SLA

Use
- Informed Consent
- Sample Identity
- Protection of Privacy / Confidentiality
- Labelling
- Ethics Approval of Research
- Protocol / SOW / MTA

Storage
- Biorepository
- Informed Consent
- MTA / SLA
- Storage Period
- HBS Security / Integrity

Further / Future use
- Bioinformatics
- Biorepository
- Amendment
- Informed Consent
- MTA / SLA

HARMONISATION Activities Impacted
Clinical Study Use Case: Biosample’s Journey through the Enterprises

Sample annotation phase

- Management of ICF obligations
- Access to local ICFs
- Access to preanalytic information

ICF documentation
Reconciliation
Logistic
Sample inventory

Central Lab
Analytical Lab

Sample processing

Biorepository

Sample query / retrieval phase

- Sample tracking
- ICF obligations
- Consistency of sample inventories
- Governance
- Oversight

Consolidated Inventory & New samples

Sample destruction

Sample re-use

Sample return

Harmonized MTAs, DTAs, ICF obligations (Patient choices + Policies of Institutional Review Boards) to

- Enable smooth sample exchange
- Structured querying of samples
Co-Development of Companion Diagnostics

The regulatory focus may change towards samples and quality of the samples (e.g. well documented pre-analytics)

1. Analytical Validation
   - Demonstrate reliability of assay
     - Influenced by pre-analytics, -treatment
     - Intend to diagnose population

2. Assessment in Clinical Trial
   - Test correlation of assay result with clinical outcome
     - Exploratory
     - Determination of cut-off value

3. Validation in Clinical Trial
   - Demonstrate correlation of assay result with clinical outcome
     - Investigational Device Exemption (IDE) required in case of significant risk

4. Bridging Study
   - Demonstrate comparability to assay used in trial
     - If assay changes after pivotal trial
     - Requires spare samples from pivotal trial

→ Industry needs to complement sample collection e.g. by biomarker negative population, repurposing of diagnostic samples
→ There is a need for searchable catalogs for this material
Please Join Us

Representation from a number of Biopharmaceutical companies

✓ Abbvie
✓ AstraZeneca
✓ Bayer
✓ Boehringer-Ingleheim
✓ Covance
✓ Merck
✓ MSD
✓ Janssen

Write an Email to Audrey.Wolf@efpia.eu