AstraZeneca
IMED Biotech Unit

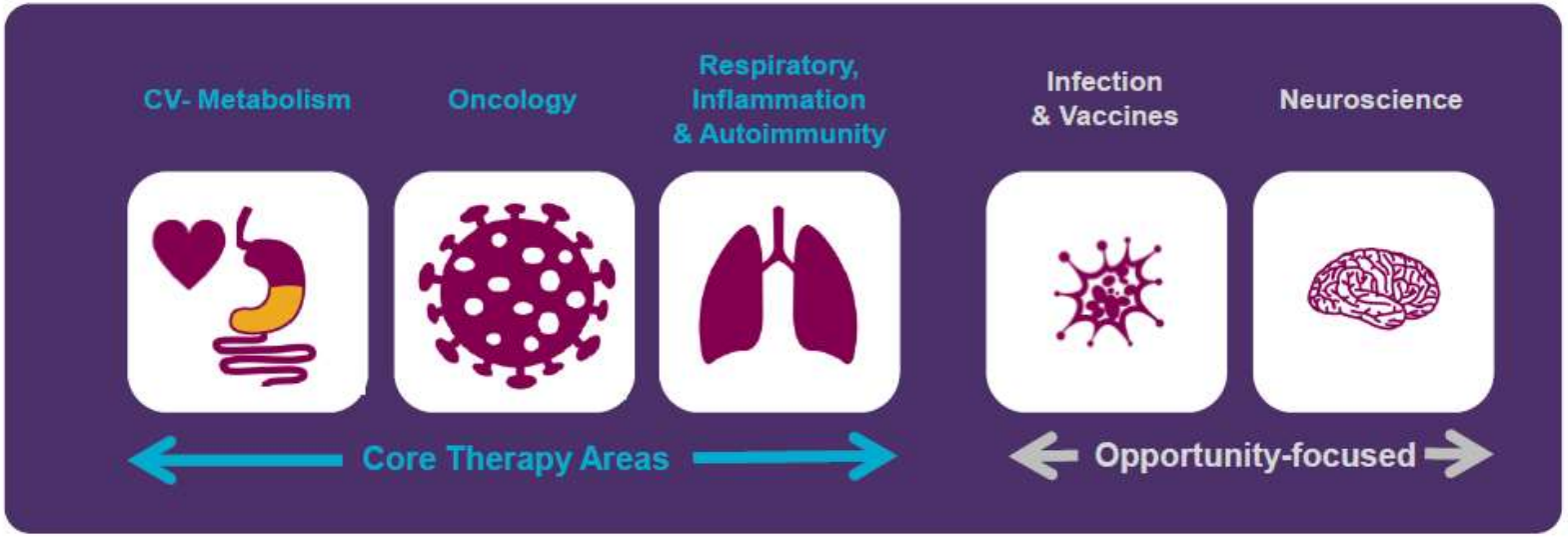
# Enhancing the interface with Industry

ESBB 2015: Satellite meeting: Coordination of biobanking in the UK

**Kirstin Goldring: Principle Scientist: HBS Strategy and Governance**

September 2015

# A focus to Medicines Development



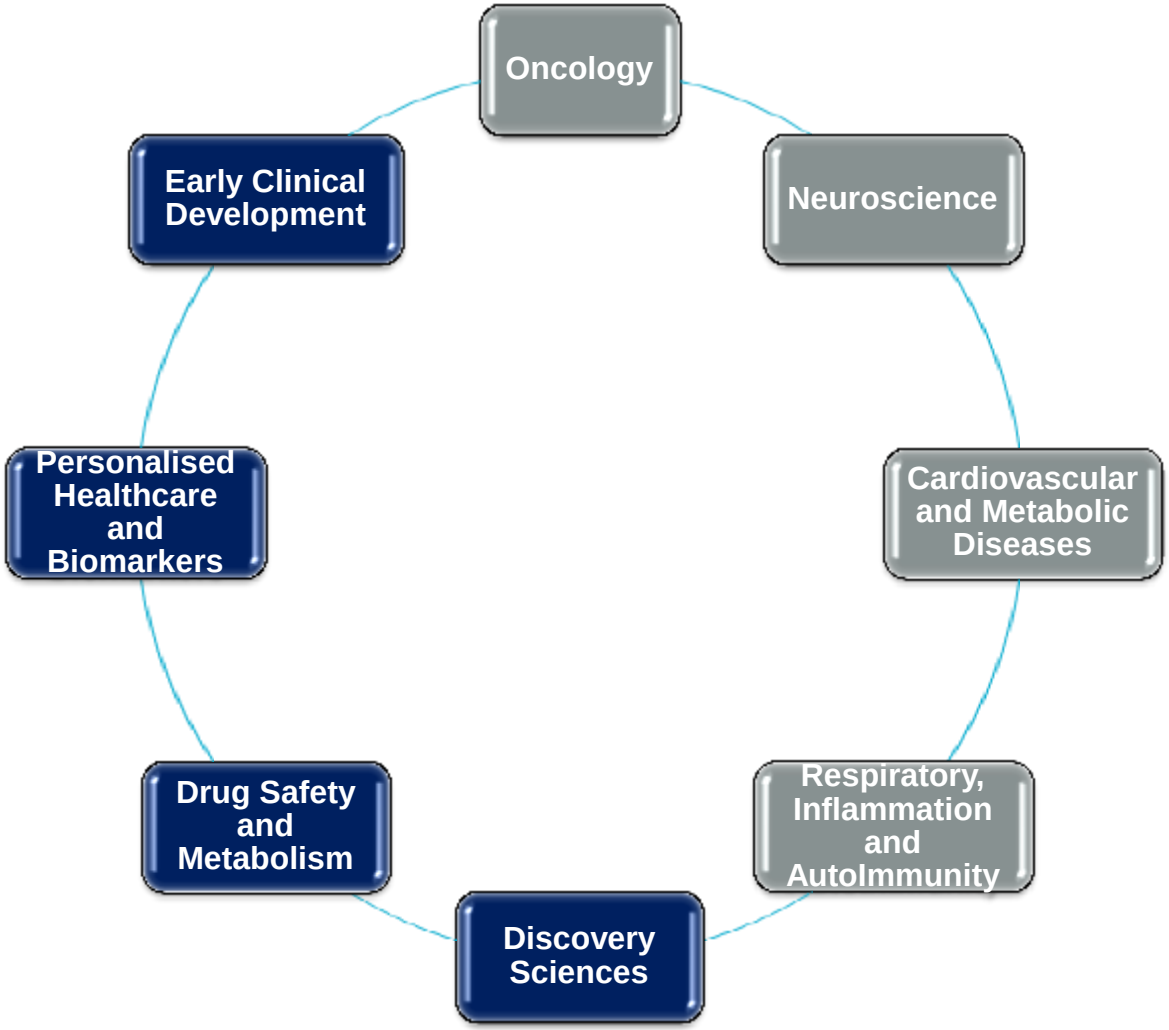

**Cancer**
7 million lives lost every year

**Asthma**
235 million sufferers today

**Heart disease**
17 million deaths every year

**Diabetes**
350 million people affected today

# Innovative Medicines and Early Development (IMED)

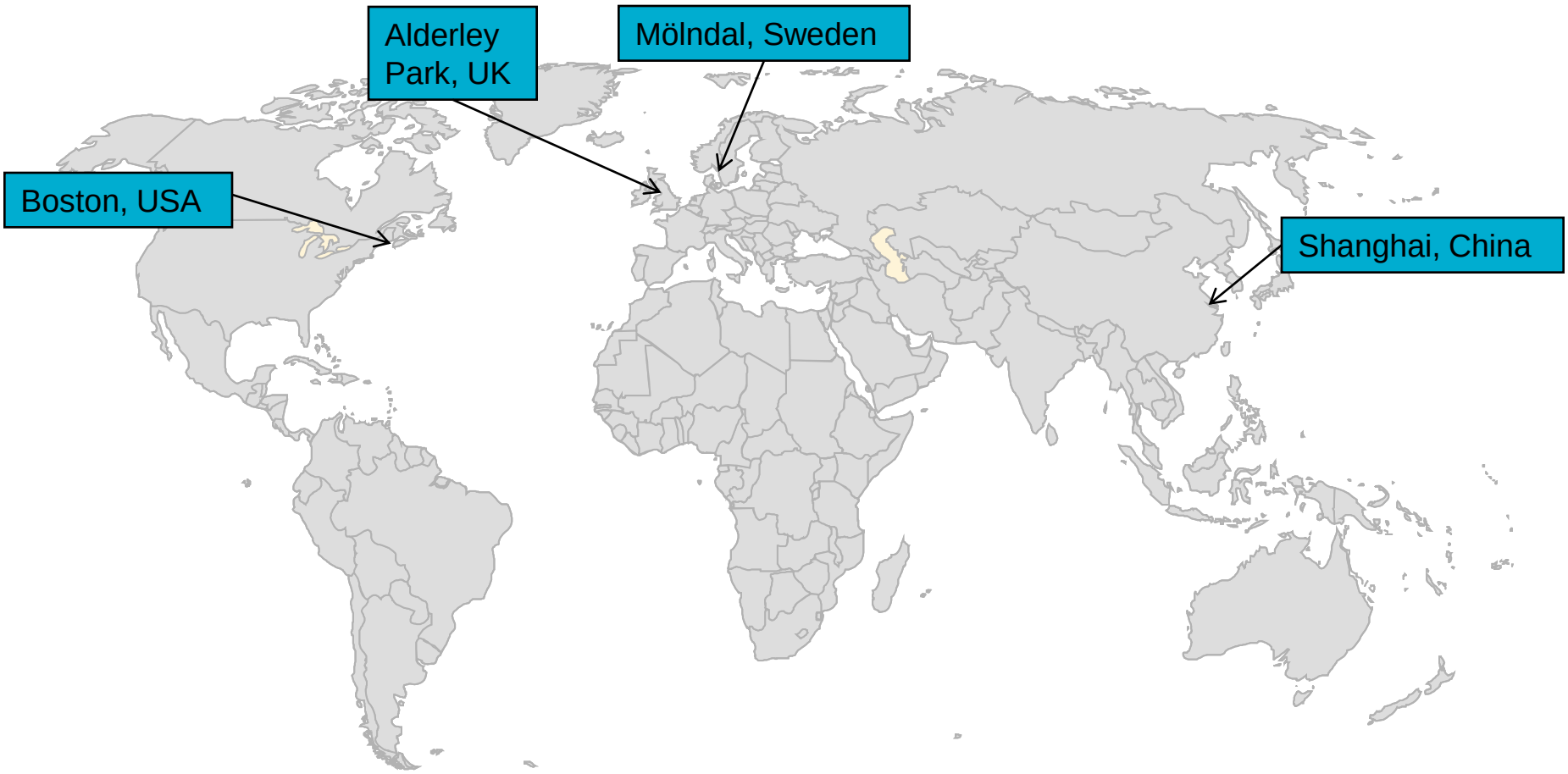


# AstraZeneca Biobank

## Vision

To collate, store and distribute annotated human biological samples (HBS), in full compliance with ethical and legal standards, to support the discovery of innovative medicines and personalised healthcare

# Global R&D sites with Biobanking capabilities




Future: UK R&D activities will relocate from Alderley Park to Cambridge

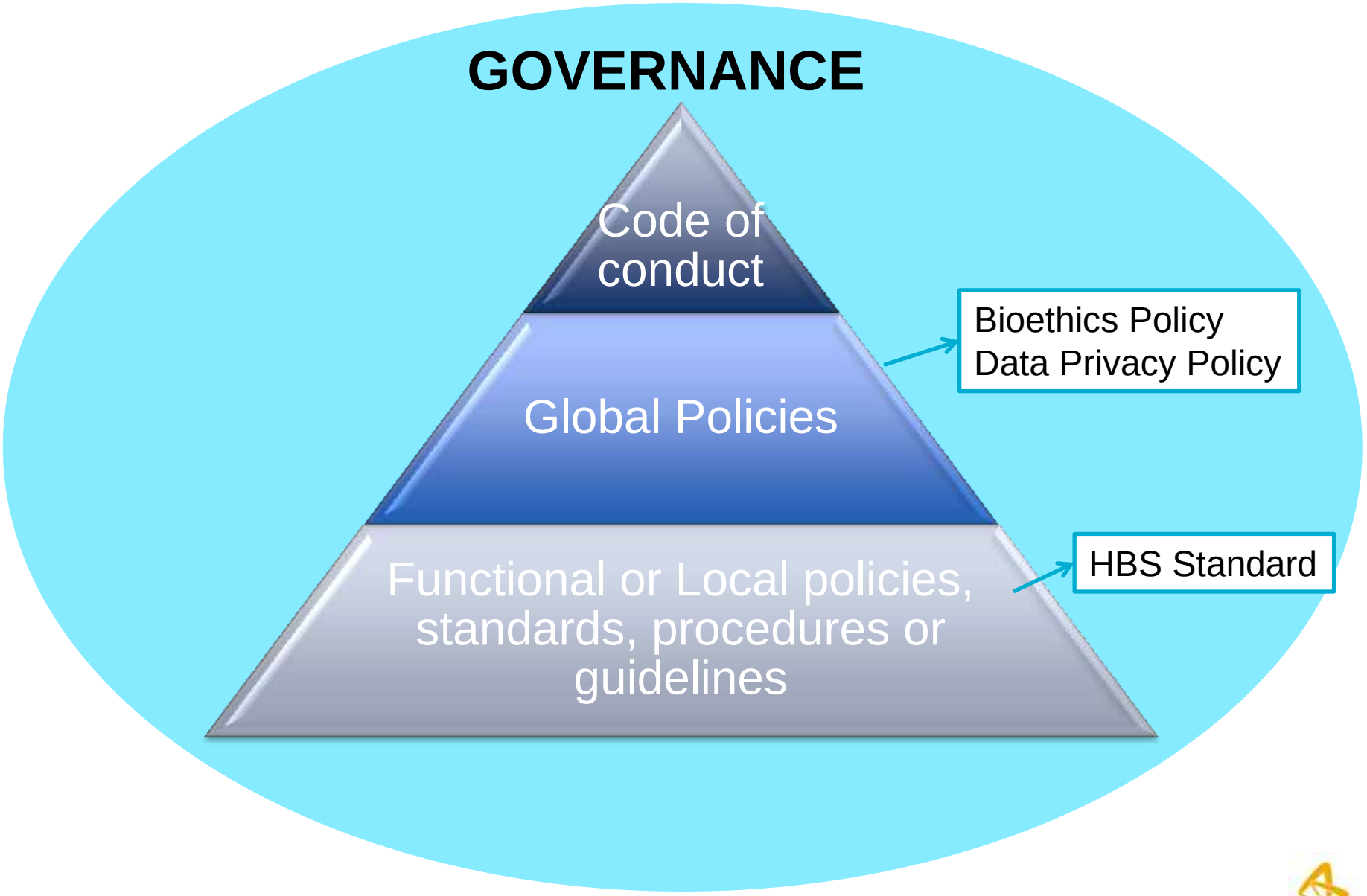
# HBS Sample Sources

# Key Considerations: Collaboration and External Sources

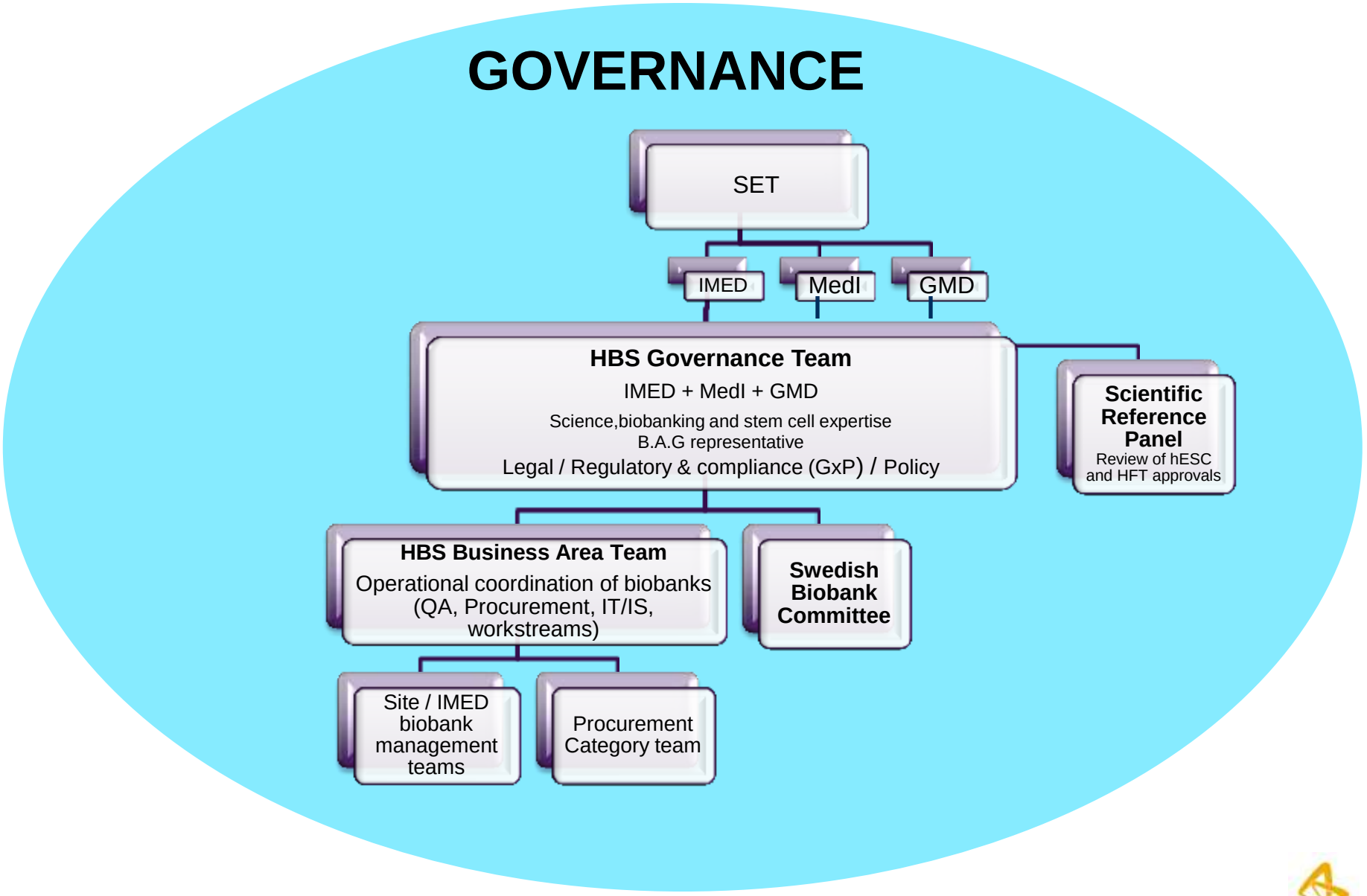
## GOVERNANCE

- VISIBILITY, VALUE, RELIABILITY
- QUALITY
- CONSENT: PATIENTS WISHES
- DATA
- COMPLIANCE

# Governance


GOVERNANCE
Code of conduct
Global Policies
Functional or Local policies, standards, procedures or guidelines
Bioethics Policy
Data Privacy Policy
HBS Standard

# Governance HBS



# Governance: HBS Standard

- Any work conducted by AstraZeneca or by a contracted 3rd party on behalf of AstraZeneca, that involves HBS, then the requirements of the Global Standard must be adhered to.
  - i.e. if a 3rd party is using HBS on behalf of AstraZeneca and has sourced HBS on our behalf – the HBS must be sourced according to the requirements of the AZ Global Standard.
- key principles for the acquisition of HBS are to ensure that only HBS Approved Suppliers are used for the supply & use of HBS, fit for purpose contracts are used and the acquisitions are channelled through the correct internal processes and responsible teams

# Governance: HBS Standard – supplier approval


**Initiate approval**

- Inform Procurement to request approval process
  - If required samples can be sourced from an approved supplier, the approved supplier will have priority

**3RPM**

- Procurement initiates **Responsible Procurement** process
  - This is to ensure AstraZeneca minimises reputational risk and is compliant with all legal and regulatory requirements. This is our commitment to the Code of Conduct and Responsible Business Plan.

**RFI**

- Procurement, supported by the BioBank, initiates **R&D Due Diligence**
  - A Request for Information (RFI) together with the Human Biological Material Supply Agreement (HBMA) will be sent to the supplier

**Assessment**

- Once all information from the supplier is received, Procurement and the BioBank will assess the RFI and associated information
- In parallel terms and conditions of the HBMA are negotiated – if changes are requested by the supplier legal approval need to be obtained

**Approval**

- Following the review of the 3RPM, the R&D Due Diligence and the HBMA, the supplier will either be approved or escalated into the HBS governance process
  - Once full approval is granted, the HBMA is signed and the supplier is updated in AIM and order can be placed

# Contract Information

## Signed Contract

- A signed contract needs to be in place for all approved HBS suppliers.
- Suppliers are expected to agree to AZ terms and conditions.

## Laws and Regulations

- We expect all our suppliers to conduct their business within applicable local and internal law, industry and business best practice and to conduct themselves in an ethical manner and with integrity similar to the standards Astra Zeneca self sets.

# HBS Due Diligence Process

## Consent

## Legal Regulatory ethics requirements

## AZ Policy and Standards

# Key Considerations

CONSENT: Donor's Wishes

- valid consent – who, voluntarily, appropriately informed, capacity
- scope of consent – may differ, generic or specific. Generic – any restrictions – commercial, research type - genetic
- duration of consent – may differ, enduring or time limit
- withdrawal of consent – at any time but implications make clear
- Donor expectations

# Key Considerations


Relevance is source country and where the samples are to be used.

# Key Considerations: Collaboration and External Sources

## GOVERNANCE

- VISIBILITY, VALUE, RELIABILITY
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- DATA
- COMPLIANCE

# Key Considerations: HBS

Industry moves fast and needs access to a wide range of sample types, formats, sample services

Don’t want to spend too much time identifying the samples we need and going through the process of approving and getting contract in place

# Key Considerations

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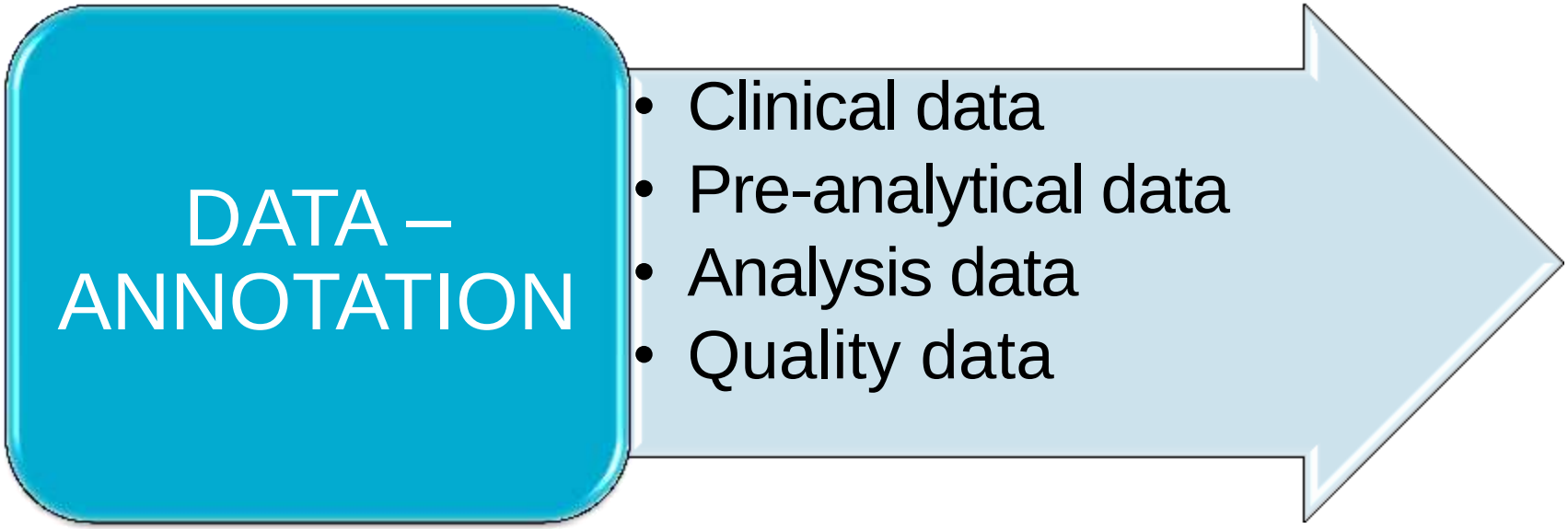
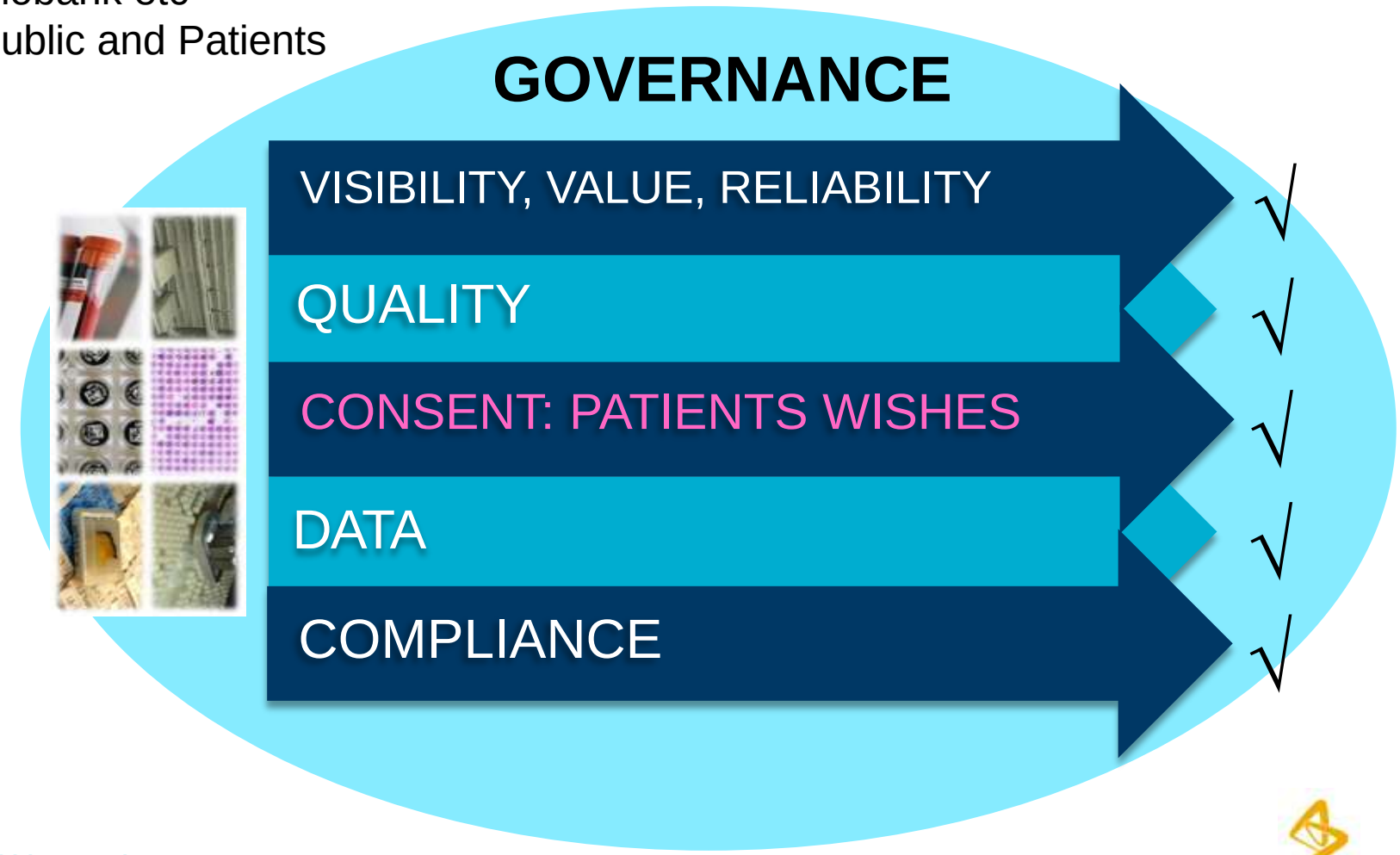


# Supporting the interface: UK

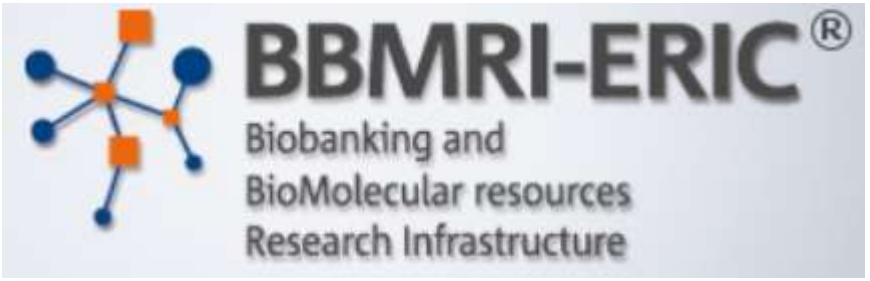
Tissue Directory and Coordination Centre

- IT
- Harmonisation
- Stakeholder Engagement
    - Biobank etc
    - Public and Patients



# Supporting the interface: EU


Tissue Directory and Coordination Centre =


**THE MISSION**

BBMRI-ERIC will increase efficacy and excellence of European bio-medical research by facilitating access to quality-defined human health/disease-relevant biological resourced through the inclusion of associated data in an efficient and ethically and legally compliant manner

Full members

| | |
|---|---|
| Kingdom of Belgium | Federal Public Planning Service Science Policy (BELSPO) |
| Czech Republic | Ministry of Education (MŠMT) |
| Federal Republic of Germany | German Federal Ministry of Education and Research (BMBF) |
| United Kingdom of Great Britain and Northern Ireland | Medical Research Council (MRC) |
| Republic of Estonia | Ministry of Education and Research of the Republic of Estonia (MER EE) |
| Hellenic Republic | Biomedical Research Foundation of the Academy of Athens (BRFAA) |
| French Republic | Institute of Health and Medical Research (INSERM) |
| Italian Republic | National Institute of Health (ISS) |
| Republic of Malta | University of Malta (UoM) |
| Kingdom of the Netherlands | The Netherlands Organisation for Health Research and Development (ZonMW) |
| Republic of Austria | Federal Ministry of Science, Research and Economy (BMWFW) |
| Republic of Finland | Ministry of Education and Culture of the Republic of Finland (OKM) |
| Kingdom of Sweden | Swedish Research Council (SRC) |

Observers

| | |
|---|---|
| Norway | Research Council of Norway |
| Republic of Poland | Ministry of Science and Higher Education of the Republic of Poland (MNiSW) |
| Switzerland | Swiss National Science Foundation (SNSF) |
| Turkey | Dokuz Eylul University of Izmir |
| IARC/WHO | International Agency for Research on Cancer/World Health Organization |

# Enhancing the interface with industry

- Many sources of samples and data, but it is important that these samples of high quality, fit for purpose, collected and curated within appropriately governed and managed frameworks and available within defined parameters and timeframes.
- Industry moves fast and needs access to a wide range of sample types, formats, sample services and associated data, in accessing these samples and resources, there is a need for confidence in not only the quality but also that samples and data are collected, processed and stored in line with the company's policies and standards.
- Visibility of what samples and services are available, as well as knowing that they can be sourced to certain standards will help enhance the interface between external sources and industry.

- The Future
    - better planning for future needs for sample and data,
    - follow up samples and data

## Confidentiality Notice