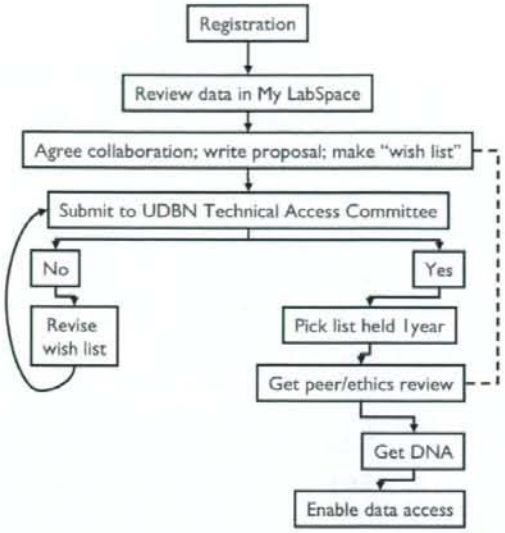
Overview of access



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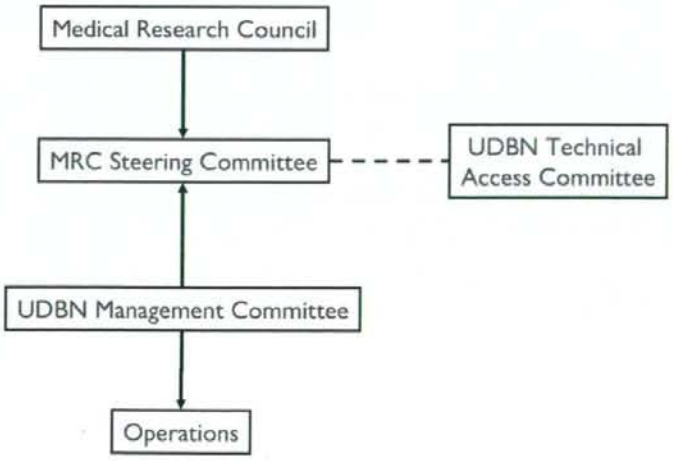
UDBN Technical Access Committee



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Registration

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Registration

- The Registered User agrees
  - To use data only for the advancement of medical research.
  - To preserve the confidentiality of data and metadata.
  - Not to give access to data. UDBN can inspect user's data security.
  - To acknowledge UDBN in any publication.
- UDBN establishes *bona fides* of applicant
  - Confirms email address
  - Confirms employer is a legitimate research organisation

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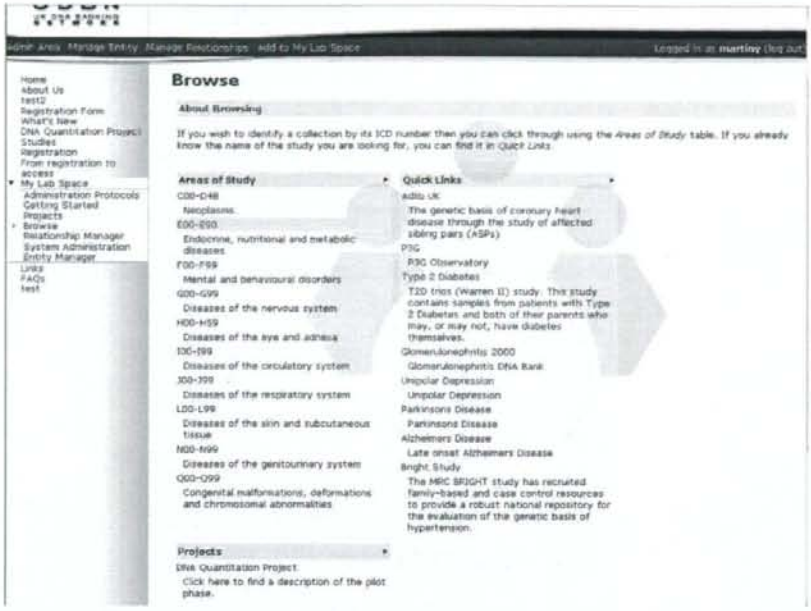
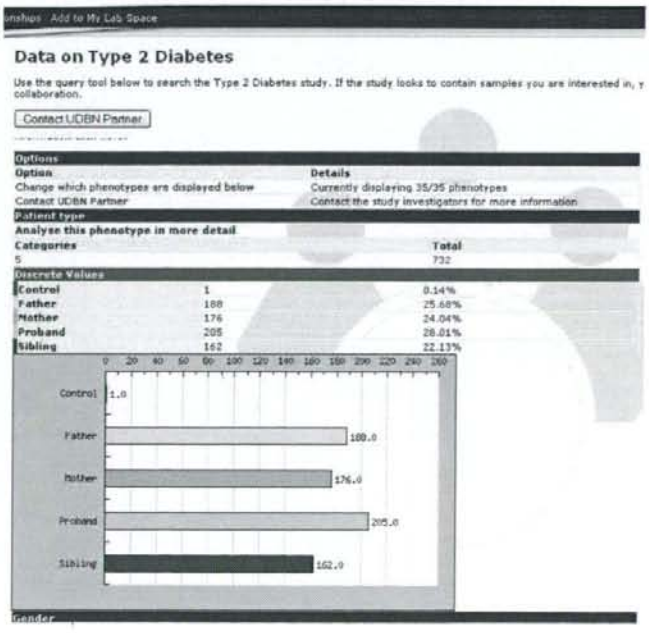
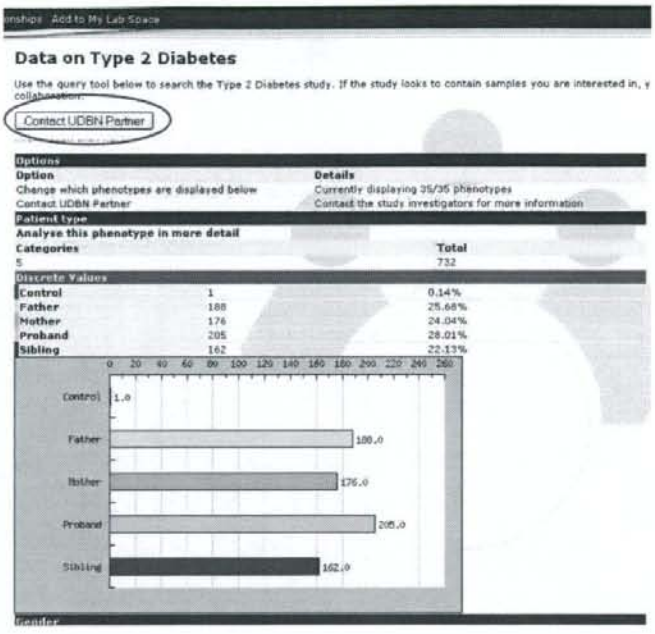
Browse the collections…



Browse the data…



...and contact the collectors



The Technical Access Committee decides if ...

- The platform (s) is appropriate for the tests.
- There is no other platform available that uses significantly less DNA.
- The out-sourced genotyper is reputable.
- The amount of DNA/sample requested matches the amount of DNA/sample required.
- The requested concentration of DNA is reasonable for the platform.
- The test(s) can be performed with comparable reliability on cell line DNA or on WGA-DNA as on blood-derived DNA
- Less than 20% of the tests on the samples requested have not been performed or submitted for approval previously.
- The plan for data access is reasonable.
- The peer review processes of the funder are acceptable.

Terms and conditions of release of DNA

- The Recipient is a registered user of the UDBN website and will:
  - Not sell DNA or use for profit or any other commercial gain
  - Only use DNA for previously specified tests
  - Give UDBN access to all the data within 10 days of the date of publication
  - Agree that UDBN will publish summary data via the website
  - Acknowledge UDBN

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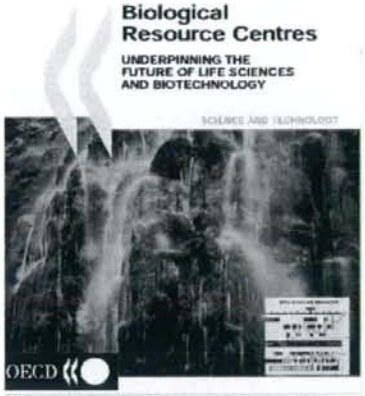
The growth of biobanking

- Global policy context: OECD
- If BRCs are to underpin the future of life sciences and biotechnology, then we need to establish:
  - National BRCs
  - An accreditation system based on scientifically acceptable objective international criteria
  - International linkages
  - Internationally co-ordinated and harmonised operational parameters
  - A global BRC network
    - Paris, 2001



Organisation for Economic Cooperation and Development
Task Force Chair: Hideaki Sugawara

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Global biobank harmonisation

P3G Public Population Project in Genomics

- The aims of P3G are to:
  - Foster collaboration between biobanks
  - Optimize the design, set up and research activities of population-based biobanks
  - Promote harmonisation
  - Facilitate transfer of knowledge and provide training

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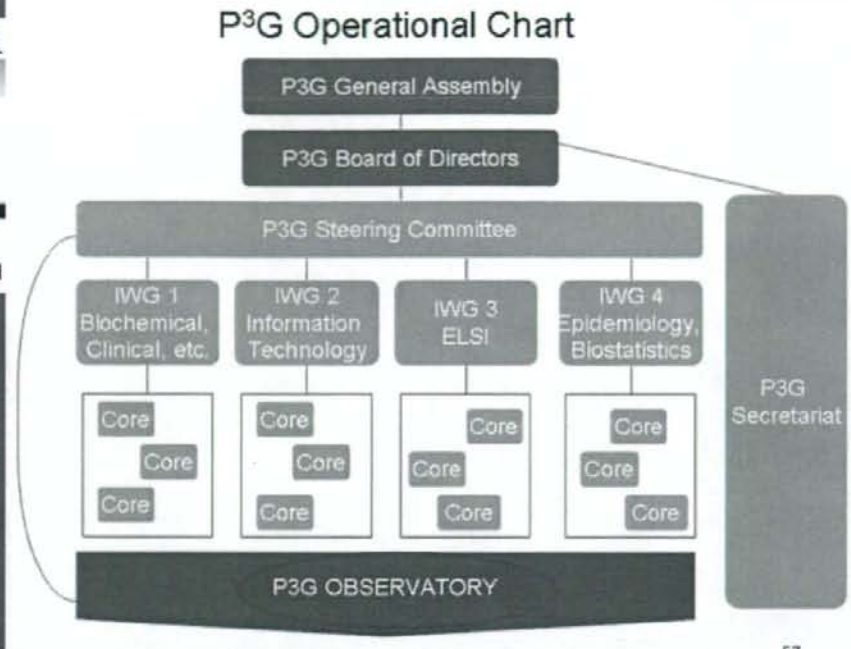

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P3G Observatory

- Study Catalogue
  - A catalogue of 91 large population-based studies around the world
  - Plus comparison tools

- Questionnaire Catalogue
  - A catalogue of 17 selected cross sectional questionnaires
  - Plus comparison tools

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European infrastructure development

- European Roadmap for Research Infrastructures
  - Expensive facilities
  - Data links
  - Resource sharing
  - Projected budget: €27 billion
- Areas of research
  - Biomedical and life sciences
  - Social sciences and humanities
  - Environmental sciences
  - Computer science
  - Energy
  - Material sciences
  - Astronomy and particle physics

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Biobanking and Biomolecular Resources Infrastructure (BBMRI)

- Preparatory phase funded Feb 2008
- Aim of preparatory phase
  - To prepare contracts between institutions and funders for "a pan-European and broadly accessible network of existing and de novo biobanks and biomolecular resources"

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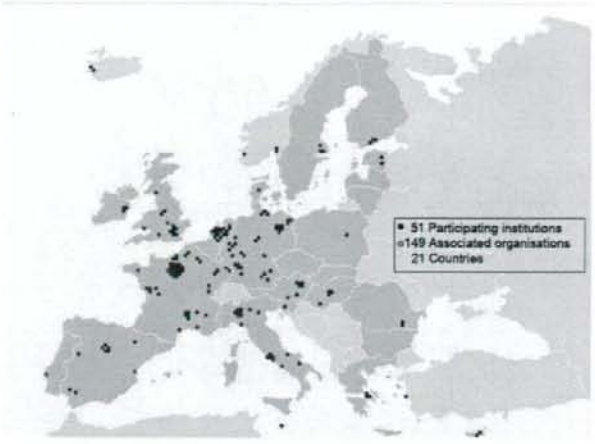
CIGMR

UDBN

BBMRI

BBMRI participants



- Statutory funders from 10 EU states
- 40 institutions with substantial resources

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UDBN

BBMRI

Current available resources

Biobank format	Number of biobanks	Number of samples
Population based	36	2.4m
Disease oriented	67	10m
Other	1	1500
Total	**104**	**12.5m**

Total current investment	€340m
Total approved investment	€138m
Anticipated BBMRI infrastructure investment	€170m

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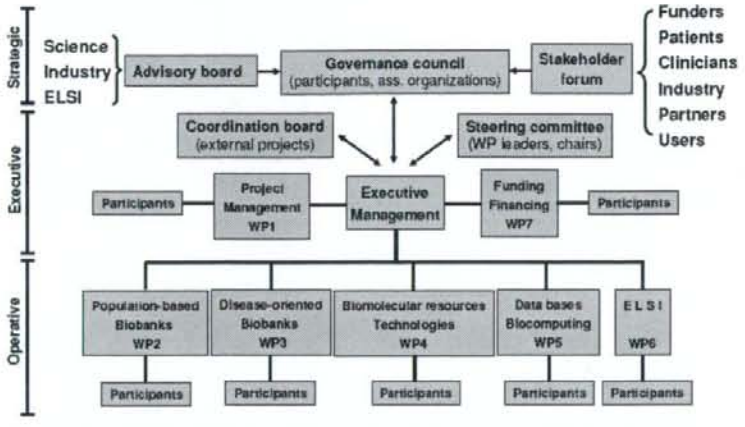
Preparing BBMRI



- N.B. Advisory Board is international: its aim is to ensure harmonised standards worldwide

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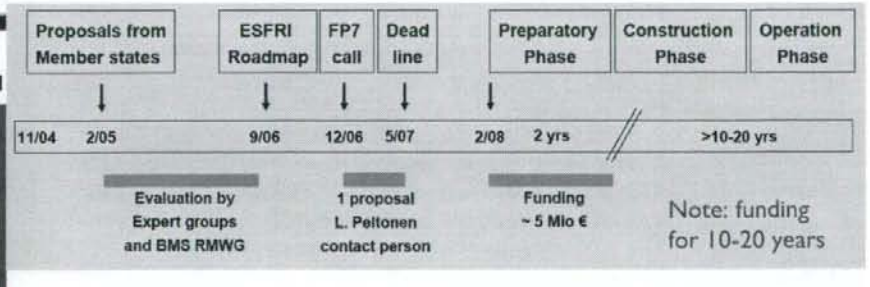
BBMRI timetable



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Timetable details

- Evaluate existing resources and solutions
- Identify open issues

Concept for:
- Integration of existing resources
- Integration of future resources
- Process standardisation, certification
- Access rules
- Incentives and benefits
- International exchange of samples and data

Operations concept

Financial plan

Contracts

Implement-ation plan

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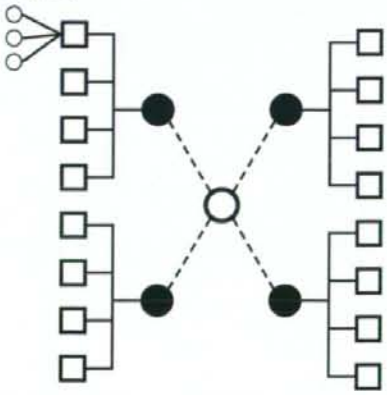
What will the BBMRI network look like?



Associated partners, hospitals, universities, service providers	Domains (biobanks, biomolecular resources, tech centres)	Hubs (resource-based, geographically-based)	Virtual hub	Samples and data	Data

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BBMRI in the UK

RESEARCH COUNCILS UK

- Research Councils UK has adopted the European Roadmap for research infrastructures as part of the creation of the European Research Area
- BBMRI is a 'planned facility' named in the Large Facilities Roadmap of RCUK

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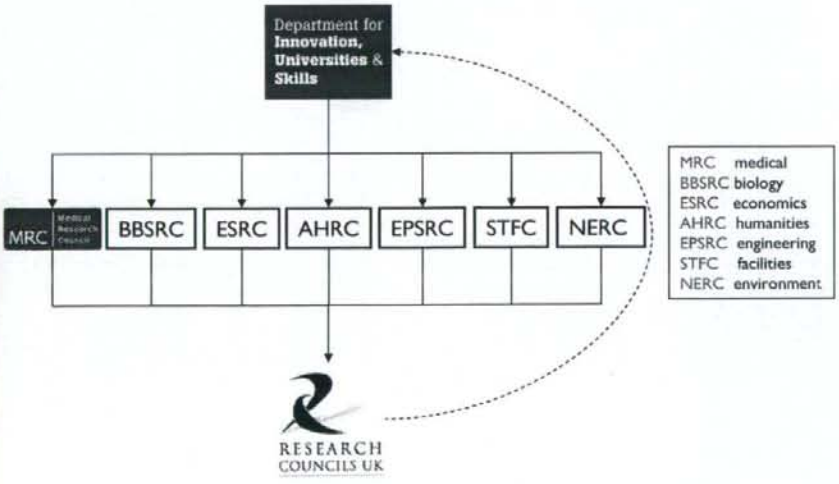
What is RCUK?

simplified



RCUK is responsible for production of a Large Facilities Roadmap

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DIUS supports Large Facilities

- Large Facilities Capital Fund
  - £100m (= ¥200m) p.a. support for Research Councils' investments that "could not be sensibly accommodated" from within Research Council budgets.
  - Used to help pay capital costs
- Work has started to develop the scientific and business case for UK BBMRI
- This will then allow
  - Short-listing by MRC
  - Prioritisation by RCUK
  - Consideration by government
  - Agreement by government and RCUK
  - Approval by minister

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A development strategy

- Fund first things first
- Prepare for the infrastructure
- Call for infrastructure proposals
- Build the infrastructure
- Fund the infrastructure
- Pathfinder projects
- 'Fair access' principles

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Fund first things first

- Post-genomic molecular epidemiology requires the efficient accrual, proper management and seamless integration of very large numbers of samples and datasets
  - This is the 'cutting edge' of the science today
  - The primary weakness (loss of statistical power) in large genome wide association studies has arisen from
    - Poor quality samples
    - Poor quality sample management
      - Inadequate phenotyping can also contribute
  - This loss of power will increase risk of failure when we want to look for more subtle genetic effects
    - We shall be forced to start accrual all over again
  - But many investigators will lobby primarily for 'cutting edge' technology
    - There is evidence that cutting edge genotyping technologies are delivered better by industrial enterprises than academic institutions
- Fund management separately from accrual
  - Management requires expertise in logistics and laboratory methods
  - Accrual requires epidemiological and clinical expertise
- This means building the management infrastructure first
  - In the UK, accrual was funded first causing delay, conflict and confusion

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Prepare for the infrastructure

- Preparatory Phase
  - Funder organises national workshops to
    - explain the vision for national biobanking infrastructure to
      - overcome the fragmentation of national resources
      - meet the challenges of post-genomic molecular epidemiology
    - examine issues of ownership, sharing, security
  - Funder establishes an international committee to facilitate
    - OECD vision of global harmonisation, standardisation and integration
    - increased cohesion of the national research communities
  - Funder develops 'fair access' principles
  - Funder promotes harmonisation and standardisation with other relevant funders
    - Complex projects may have >1 source of funding

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Call for infrastructure proposals

- Preparatory Phase
  - Funder issues call for proposals to host the infrastructure
  - Select applicants with experience in
    1. service provision
    2. large-scale infrastructure management
    3. web-based data networks
    4. laboratory methods research
    5. genetics, epidemiology, cell culture
  - Do not accept commercial applicants
    - problems of public trust and engagement
    - but public-private partnerships may address these problems

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Build the infrastructure

- Construction Phase by selected applicant
  - Policy development
    - Hold regular networking events nationwide
    - Work with stakeholders to seek to undertake management of legacy collections
    - Make policy recommendations on consent, privacy, public engagement, access
    - Implement pathfinder collection projects that
  - Infrastructure development
    - Develop web-based accrual project management software
    - Develop web-based access mechanisms
    - Identify / create a suitable common data centre
    - Develop central consent and IPR management
    - Implement high throughput sample processing (DNA extraction; serum aliquotting; quantitation, storage, retrieval)
    - Second site storage to guard against catastrophic loss
    - Establish sample replenishment methods
    - Gain ISO accreditation for sample and data management
    - Identify research needs for sample and data management methods
  - Pilot operations
    - Work closely with pathfinder projects
    - Identify and harmonise with genotypers etc
    - Propose cost recovery mechanisms

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Fund the infrastructure

- Rolling funding mechanism is needed
  - First phase: can the applicant meet the targets?
  - Second phase: provide secure long-term funding to re-assure collectors
  - Biobanking as part of the national research infrastructure development programme

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Pathfinder projects

- As soon as the infrastructure has been funded, issue a call for proposals
  - for new collections
  - to investigate high-impact health problems
  - with evidence of international cooperation / collaboration
  - with novel conditions of grant
    - Patient (subject) gifts sample to funder
    - Patient gives informed general consent
    - Accrual should focus on improving phenotype data
      - Use standard questions where possible
      - Use data standards (HL7 / SNOMED)
    - Collection is a "shared scientific resource"
    - Make resource available after publication
    - On-time completion of pathfinder deliverables will lead to a tailored call for genotyping etc.

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Funding to analyse a resource

- Investigator agrees
  - To use a genotyper etc approved by the biobanking infrastructure
  - That genotyping data will go directly from genotyper to common database
  - That all versions of data will be stored there
  - That third party *bona fide* potential collaborators will have access to summary data at time of publication

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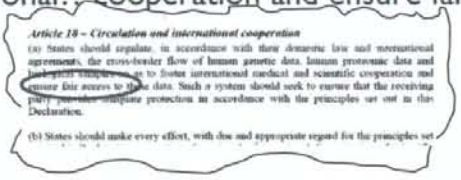
UDBN's 'fair access' principles

- Based on 2003 UNESCO International Declaration on Human Genetic Data
  - Article 18 : Circulation and International Cooperation
    - States should regulate the cross-border flow of data and samples "so as to foster international cooperation and ensure fair access"



Article 18 – Circulation and international cooperation

(a) States should regulate, in accordance with their domestic law and international agreements, the cross-border flow of human genetic data, human proteomic data and biological samples so as to foster international medical and scientific cooperation and ensure fair access to these data. Such a system should seek to ensure that the receiving party provides adequate protection in accordance with the principles set out in this Declaration.

(b) States should make every effort, with due and appropriate regard for the principles set

UDBN's 'fair access' principles

- Fair to the subject
  - Privacy and confidentiality
  - Ethical use of samples and data
  - Consent management: national open methods to permit effective withdrawal of consent
  - Public engagement: understanding and goal-setting
- Fair to the collector
  - Right to first access
- Fair to the recipient
  - Collaboration management: ensure transparency
  - Access to usable published / unpublished data
  - Long term availability of sample: stock control
  - Minimum of administration
- Fair to collector's and investigator's institution
  - IPR management: long term tracking of samples and data

The critical advantage of access via collaboration is that it corresponds to existing practices which are self-monitoring and which we know work well

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Challenges in biobanking I

- Commitment to infrastructure
  - Researchers minimise their requests for infrastructure. This blocks development of biobanking and negates its advantages.
- Recognition of biobanking work
  - There are no incentives to become a biobanker.
- Career structures
  - There is no career structure for staff.
- Research on biobanking
  - Biobanking research = laboratory methods research. This is a low priority relative to the development of new methods.
  - Cutting costs of accrual and management is key to progress.
- Culture of research
  - Biobanking implies sharing of resource. This is foreign to biomedical resources – though not to biomolecular resources.
- Public education and engagement
  - For large scale biobanking, consent is not enough. Active engagement of the public is required. To achieve this, the public (not just politicians) must understand the science and help sets its goals. This may allow the introduction of presumed concent.

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Challenges in biobanking 2

- Laws restricting consent and collaboration
  - Transnational aggregation of resources is impeded by differing national laws. These need to be re-examined globally.
- Funders
  - Networking means linking resources that are each supported by different funders. That funding must be standardised.
- Electronic Health Record
  - Implementation of eHR for all UK citizens + sample banking = radical new study designs become possible
- Personalised medicine
  - The patient becomes explicitly an experimental subject
  - Consent to treatment = consent to research = a need for population banking

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Thank you