

Precompetitive Collaborations Workshop  
Institute of Medicine Washington 22 July 2010

# Sustaining access to biospecimens

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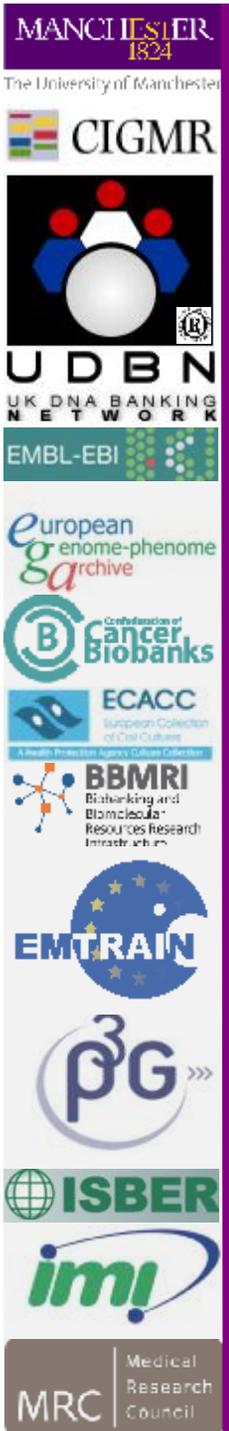
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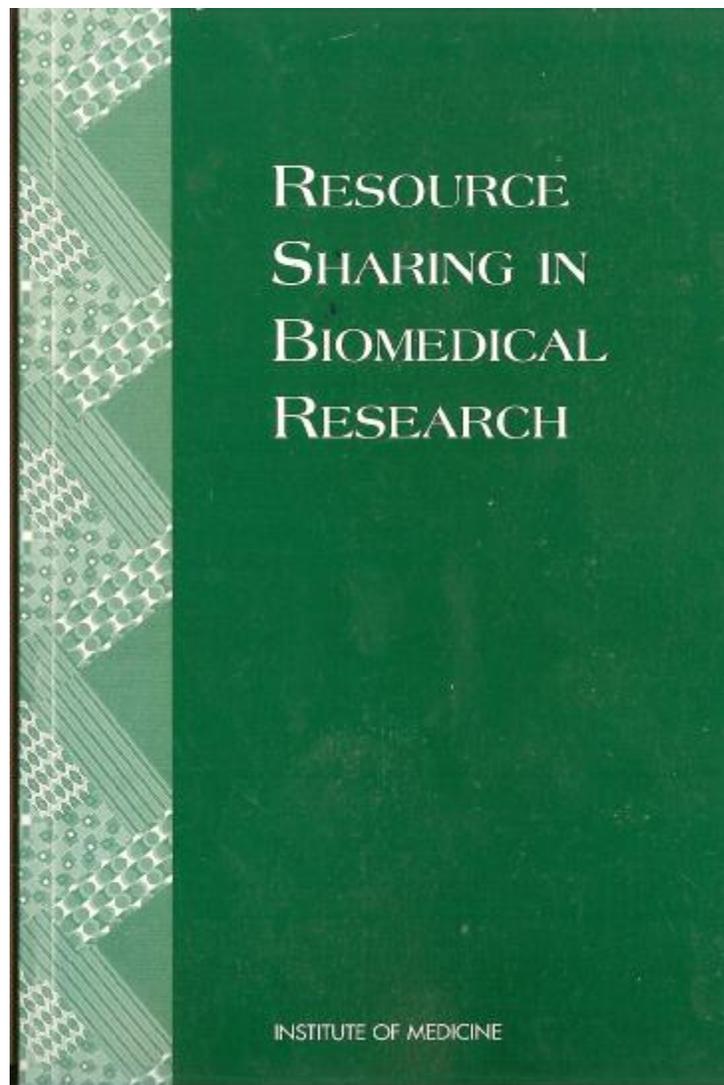


U D B N  
UK DNA BANKING  
NETWORK





# Sharing is not so easy...



Resource sharing in Biomedical research.  
Committee on Resource Sharing in Biomedical Research  
Division of Health Sciences Policy  
Editors: Berns KI, Bond EC, Manning FJ

*Report of workshop Washington DC 22-23 Jan 1996*



# UK DNA Banking Network: an infrastructure research project

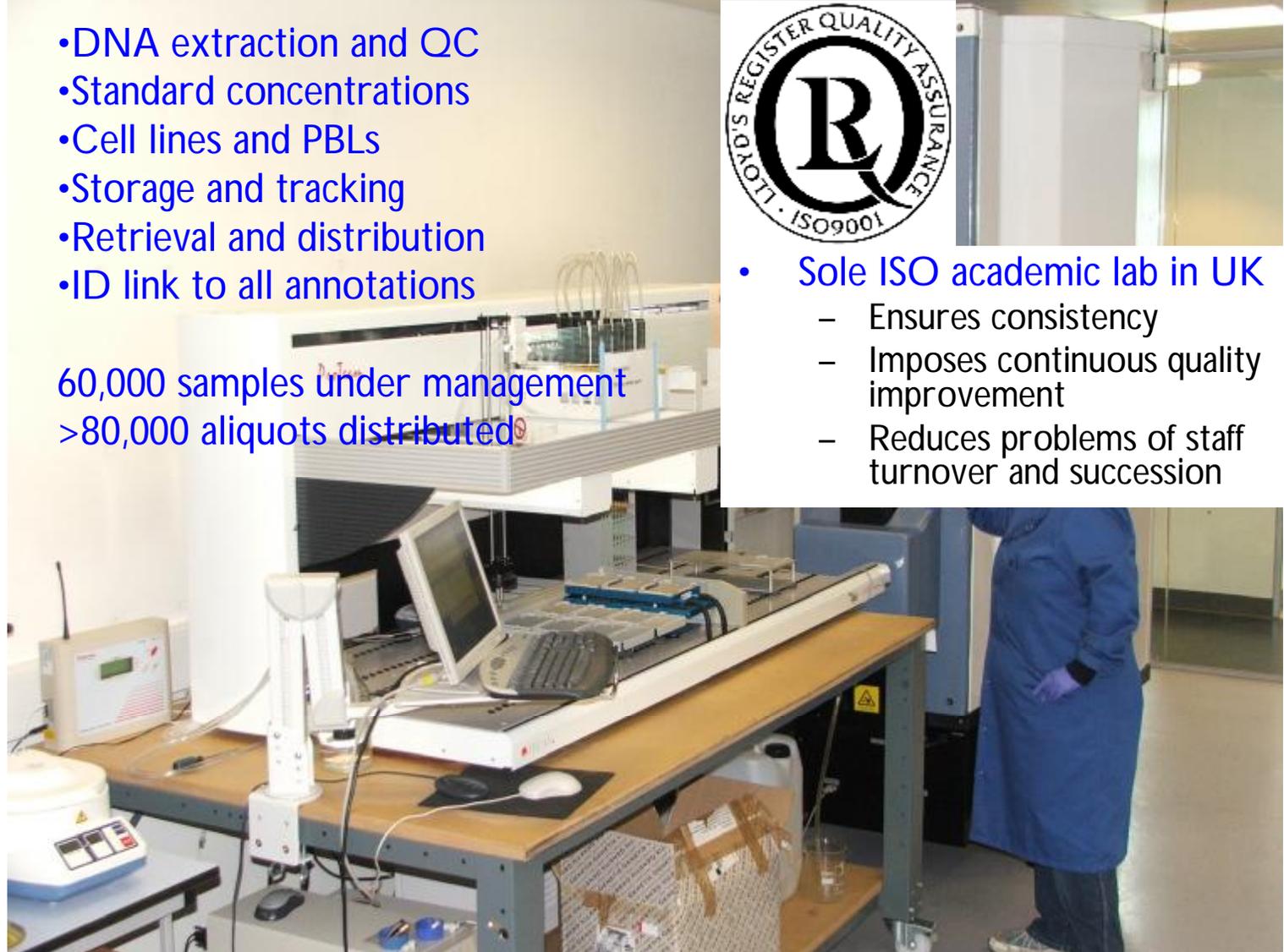


- DNA extraction and QC
- Standard concentrations
- Cell lines and PBLs
- Storage and tracking
- Retrieval and distribution
- ID link to all annotations

60,000 samples under management  
>80,000 aliquots distributed

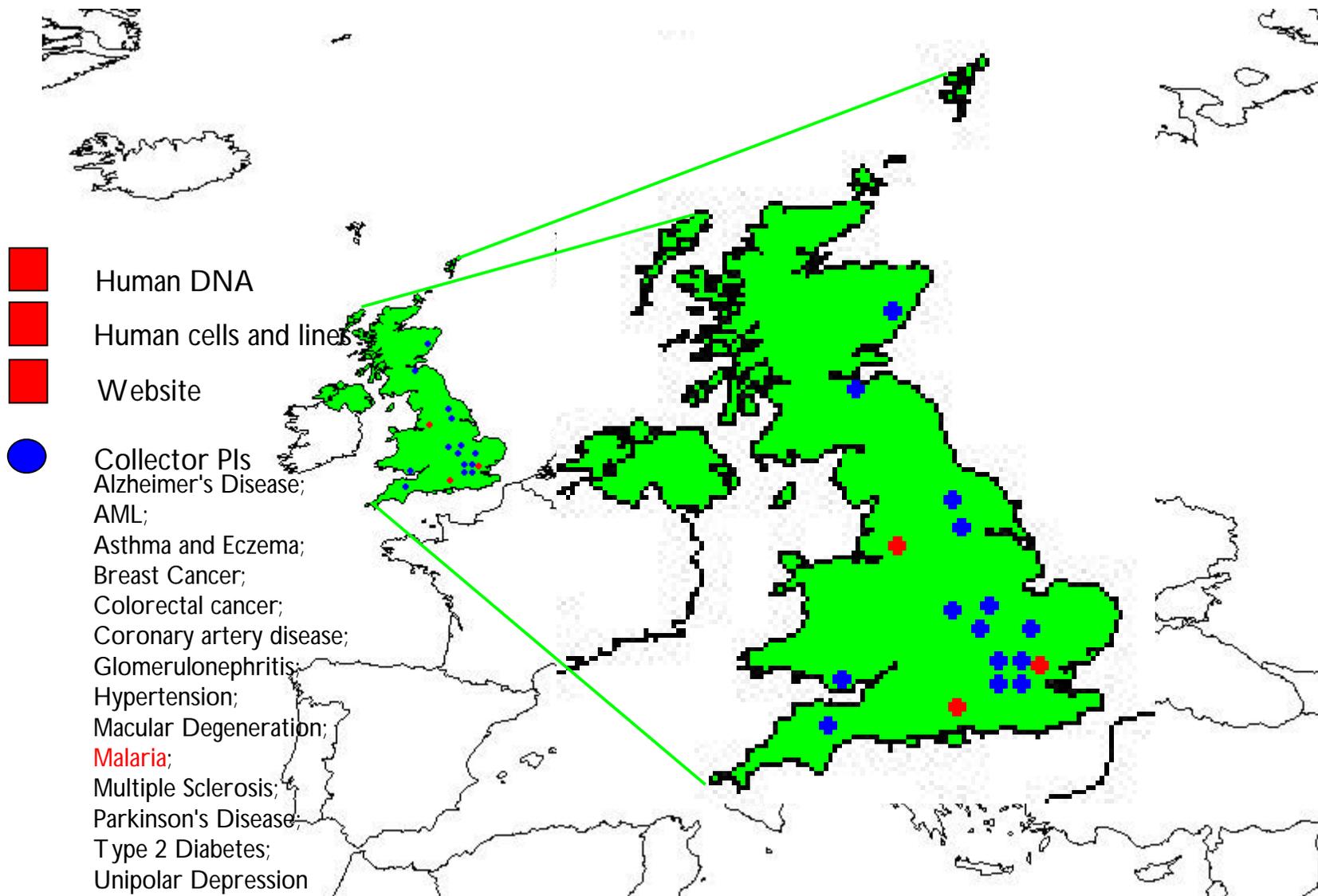


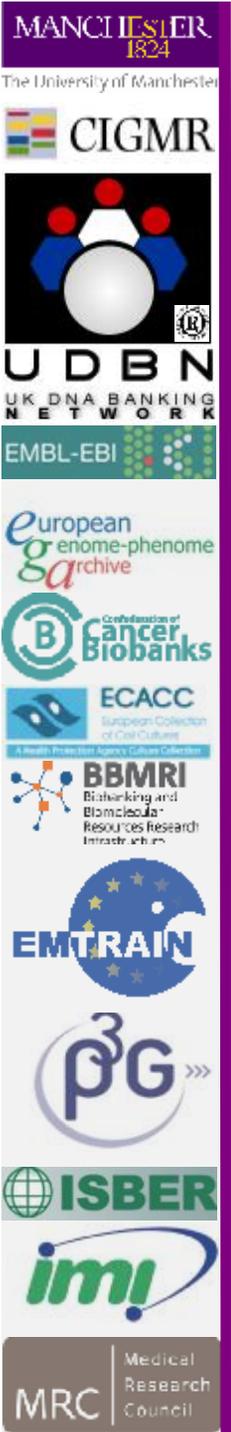
- Sole ISO academic lab in UK
  - Ensures consistency
  - Imposes continuous quality improvement
  - Reduces problems of staff turnover and succession



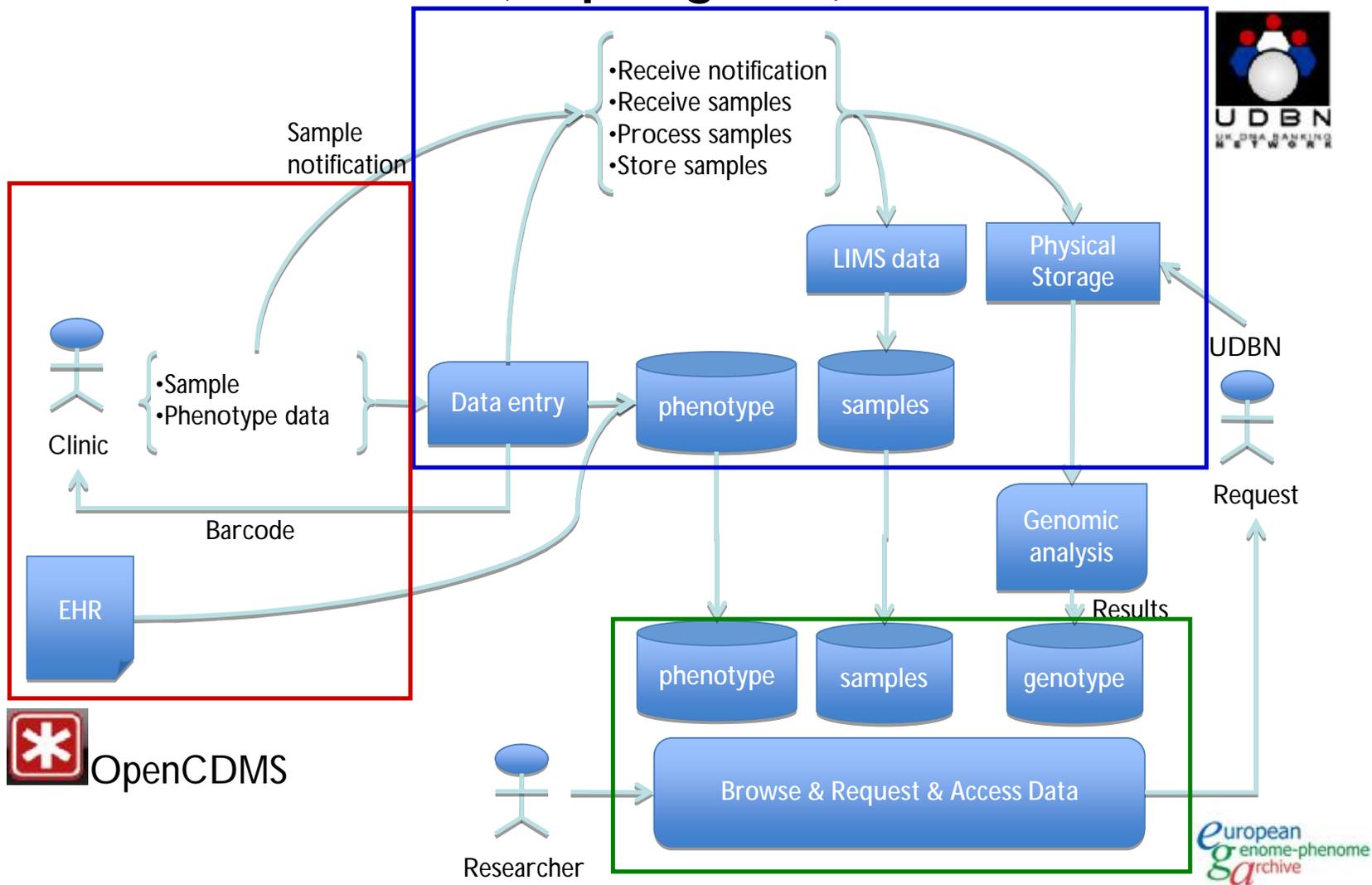


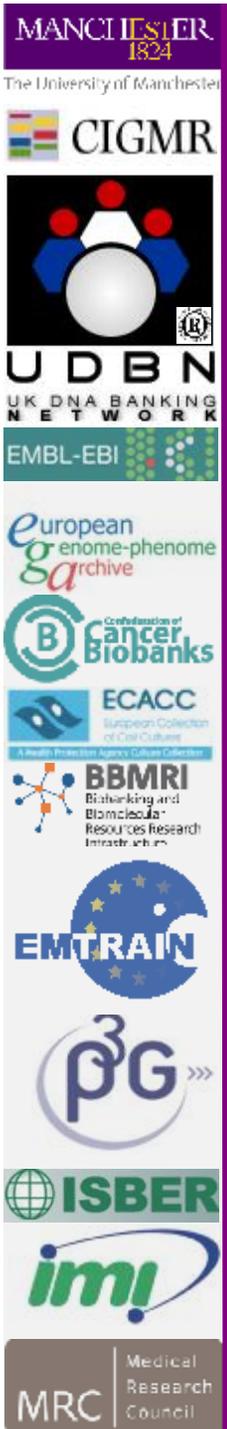
# Phase 1 UDBN: a secondary biobank for advanced sample management





# Phase 2 UDBN: advanced management of annotations (in progress)



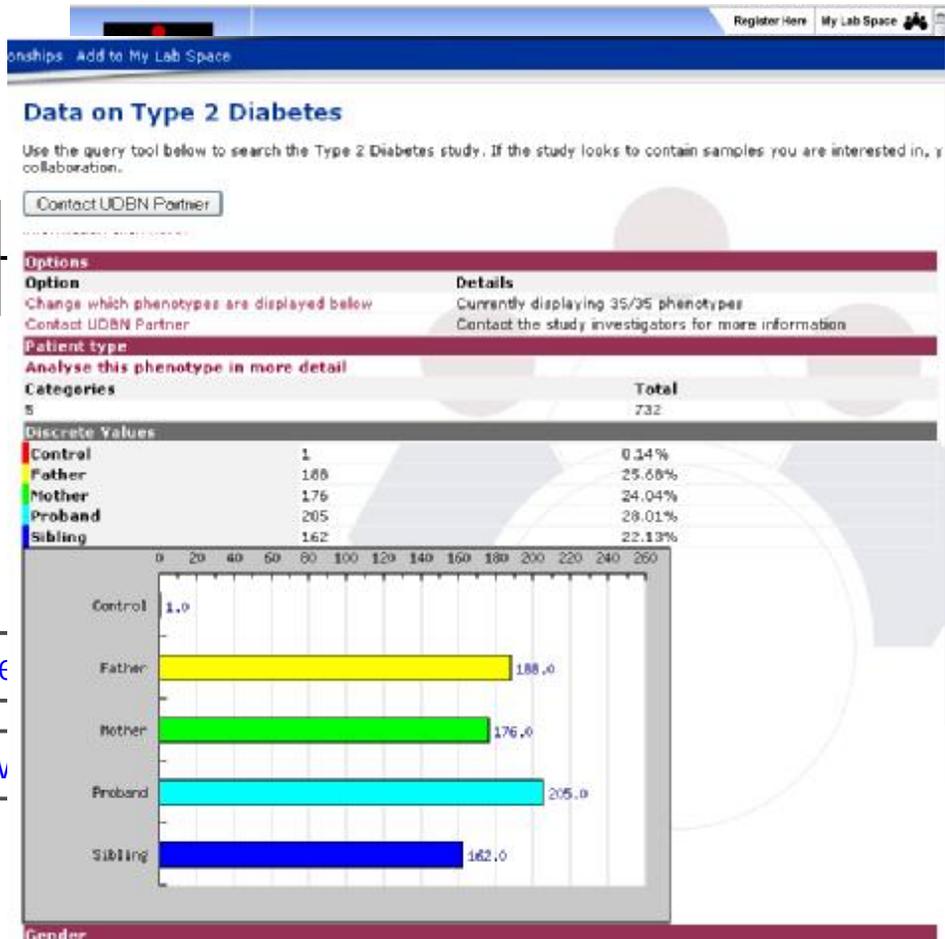
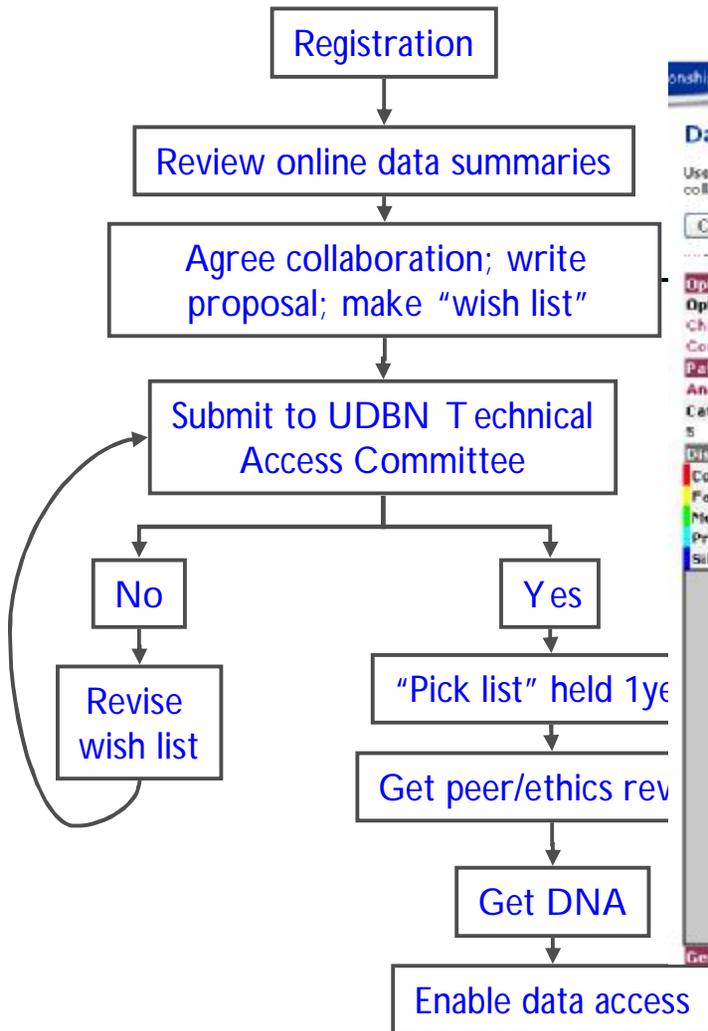


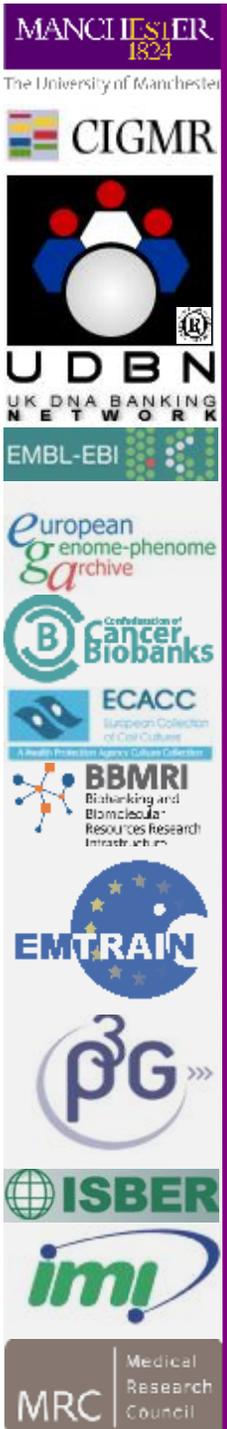
## Access policy for 'national' resources

- “All DNA collections in the Initiative are funded on the understanding that they are to be managed as shared national resources, and must be made readily available to collaborators.”
  - MRC terms of grants to collectors (2000)
- “Council now wishes to establish a network of centres with a remit to house large DNA collections. The network will be required to make these resources available to the UK scientific community.”
  - MRC instructions to UDBN in 2001
- After 2 years discussion, the network agreed that
  - access to samples should be by collaboration (as a default)
  - access to phenotype and sample availability data should be allowed to all *bona fide* researchers

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

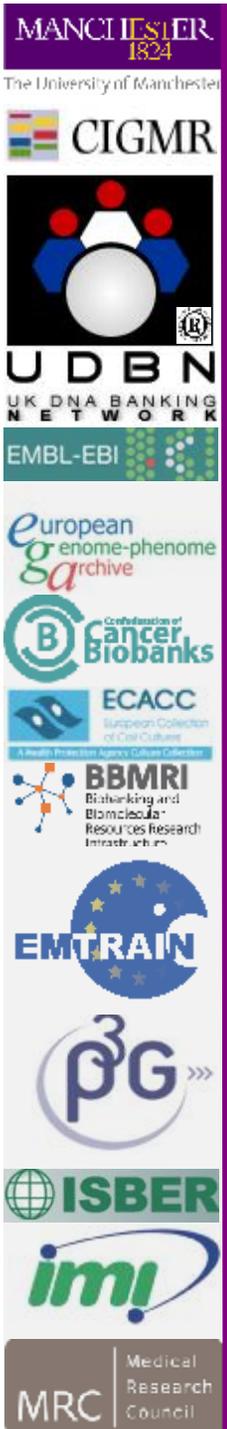
# Current access arrangements





# Questions for this session

- What are the unique issues [technical, cultural, ethical] in sharing biospecimens (and data) that need to be considered in a sharing framework?
  - “National” biomedical samples are a new concept
    - as significant as and similar to the transition from hunter-gatherer society to agriculture’s systematic husbandry of resources
  - Development of such a national resource requires and justifies seeking broad consent
  - Sharing requires
    - a chain of quality
      - resources analysed by differing groups require consistent management of quality of samples, platforms and data
    - data return
    - cross-border movement of samples and data: a global vision
    - respect for all stakeholders: “fair access”



# UDBN's 'fair access' charter

Yuille M, Dixon K, Platt A, Pullum S, Lewis D, Hall A, Ollier W. The UK DNA Banking Network: a "fair access" biobank. Cell Tissue Bank. 2009 Aug 12. Online.

- 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





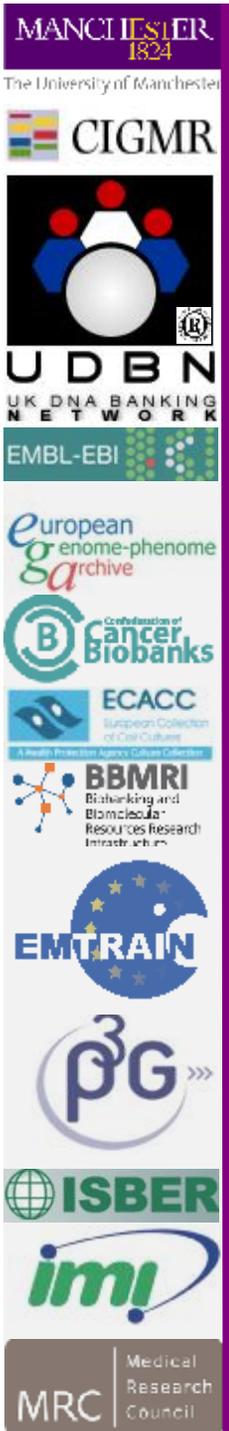
# Questions for this session

- What have you learned from your initiative that could be used to define 'best practices' for specimen and data sharing?
  - Academic biobanking adds scientific value
    - academic biobankers need default co-authorship
  - Sustainability of funding is based on adding scientific value
    - cost recovery is generally too 'lumpy'
  - Secondary biobanking (i.e. an honest broker) is essential to ensure focus on good management
  - No-one will let you manage their samples unless you do it better (ISO9001 is a minimum)
  - You can't share samples unless you have previously shared data summaries
  - There is no solution to the "depletion of sample" problem
  - Samples lose scientific value when their annotations (and related tools) become out-dated
  - A step-by-step approach is needed toward optimal sharing = transparent collaboration



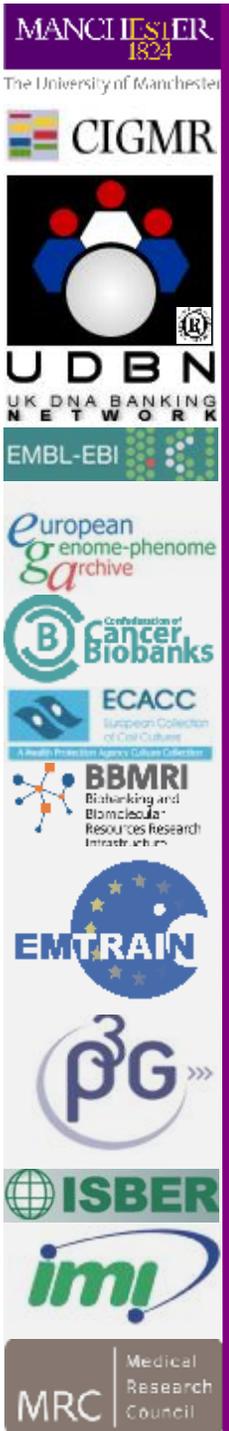
## Questions for this session

- What should motivate industry stakeholders to share specimens and data with each other and with the broader investigator community?
  - Detection of small effects in common disease or of larger effects in rare disease requires annotated samples from many sources
  - It may be unethical to refuse to share if this impedes improvements to diagnosis or treatment
  - Joint undertakings (i.e. public-private partnerships) are essential for a biological approach to drug discovery
  - Joint undertakings favour improved training for new entrants to the industry (e.g. IMI EMTRAIN)



## Questions for this session

- What incentives should or need to be in place to encourage sharing of biospecimens and data?
  - Nothing except
    - quality managed samples
    - the richest possible annotations
    - simple online access procedures
    - standard charges for “pre-competitive” research



# Questions for this session

- What key structures and/or rules do you think are required for a framework of sharing biospecimens and data?
  - Rules on sharing differ depending on
    - accrual for a prospective study (UK Biobank)
    - accrual for case-control studies
    - accrual of surplus clinical material
  - Standards for peer review
    - most UK charitable funders (including Wellcome Trust) abide by a common code
    - do industry funders need a common code?
  - Sharing is not a major technical problem. It's a cultural problem
    - Extensive (and expensive) national and international discussions, workshops, network events, collaboration promotion are essential if we are to win an understanding that we need competition between ideas – not competition for de facto control of human sample resources



# Acknowledgements

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