Genome England data access policy

MEDT32/33

Key features

- Genome sequence data
  - blood, tissue, and saliva
  - health and wellbeing
- Individual's data is not released.
- Analysed within a secure, monitored environment
- Access
  - Researchers : de-anonymised data
  - Doctors, nurses and other healthcare professionals in NHS Genomic Medicine Centres

Researchers Using data

- research users will have their research proposal approved by an independent Access Review Committee
- identity check and be employed or contracted to a registered healthcare or research organisation
- sign an electronic data access agreement

Clinicians

- will not have to sign a data access agreement
- adhere to their Trust's data governance policies

Research infrastructure

- Genomics England Clinical Interpretation Partnership (GeCIP)
  - work in domains dependent on expertise
  - cross-cutting projects
  - Approval for MSc projects is ultimately thought GeCIP

Access

- able to download anonymised results of analysis, provided that these results do not reveal the identity of any of the participants
- Direct identifiers: name and date of birth, held in a separate part of the data infrastructure
- Penalties : fne of up to £500,000 under section 55 of the Data Protection Act

http://www.genomicsengland.co.uk/the-100000-genomes-project/data/current-research/

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IG Data Access and Acceptable Uses Policy

3.0 Key Principles

1. All principles expressed in this document are based on the current version of the 100,000 Genomes Project Protocol and may be amended as the programme evolves.
2. Activity within the 100,000 Genomes Project is based on the donation of samples and associated consent for sample storage, DNA sequencing, and other analysis of the participants' tissue and clinical data for the purposes of processing by research and commercial users.
3. Genomics England will process and deliver decisions on data sharing and access requests keeping in mind the public interest, scientific utility, the corresponding consent, and wider Genomic England policies.
4. Genomics England intends to offer comprehensive access to enable leading edge outputs from analysis of the data that are expected to have both scientific research value and clinical value particular to the participants whose data is involved.
5. For each request, Genomics England will determine the appropriate cohort of genomic and associated data to make available within the approved trusted environment.
6. Data access will only be granted to users validated by Genomics England, using traceable IP addresses, who have a data-sharing contract or are approved staff of Genomics England.

shall include an independent chair, and appropriate independent experts in areas such as genomic medicine and ethics. It will receive advice and input as needed from internal committees of Genomics England such as the Ethics Advisory Committee and the Data Advisory Committee. A member of Genomics England staff will support the Committee including a Senior Information Risk Owner who may call upon the advice of a Caldicott Guardian for all data held.

11. Genomics England will process access applications and provide decisions via the independent ARC on behalf of the Genomics England Executive Board.

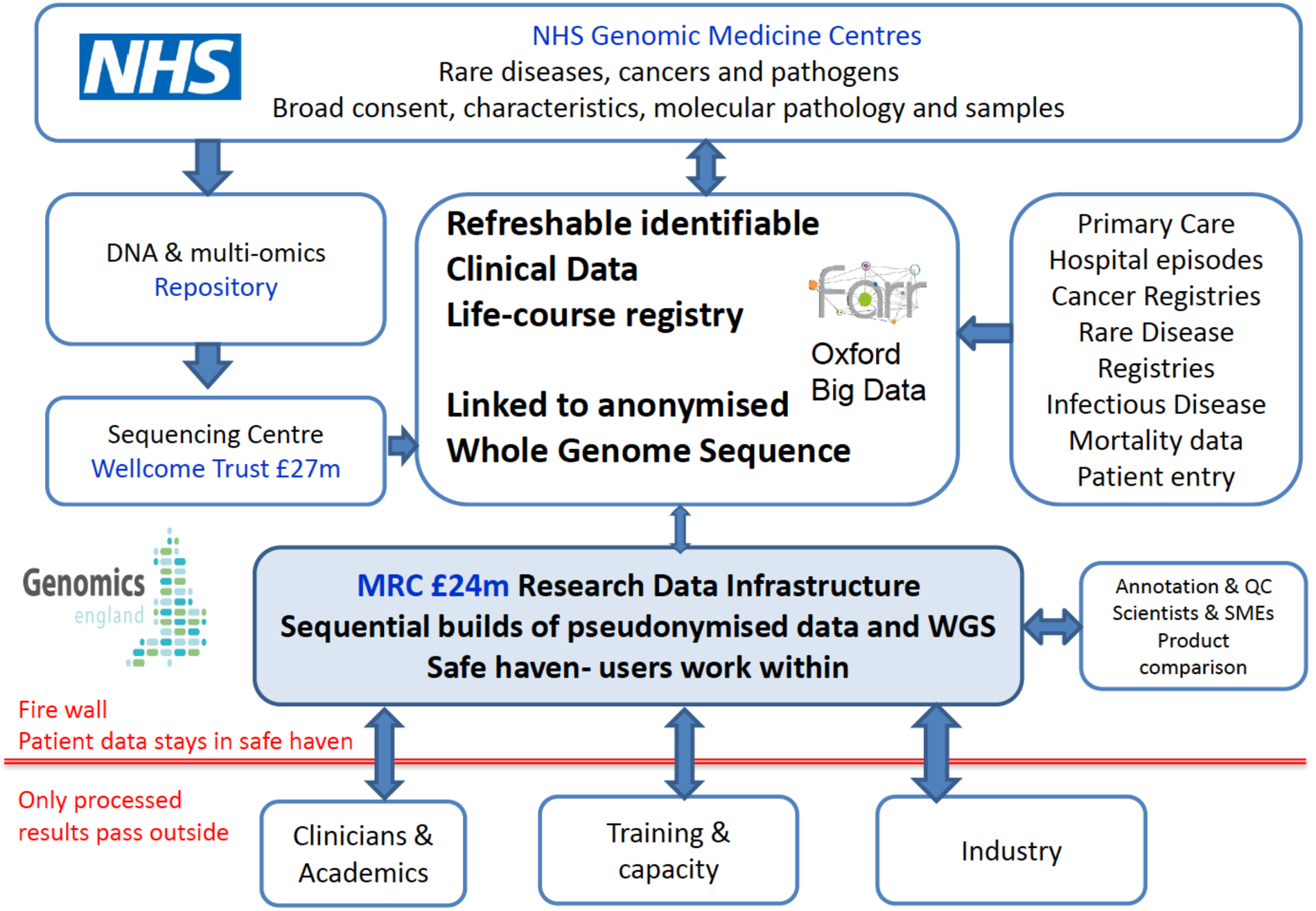
12. Genomics England will utilise best practice guidance and privacy enhancing technologies to provide de-identification of data, meet anonymisation standards, and minimise the risks of inadvertent disclosure.

13. Compliance with the policy shall be audited and verified as required. Non-compliance shall be reported to the Genomics England Programme Board and appropriate contractual and legal action taken. Actionable decisions in the case of a breach will be under the remit of the Caldicott Guardian.

14. Arrangements for archiving of the data when it is no longer required will be set out in the Genomics England Information Quality and Records Management Policy.

15. Parties will sign legally binding data access contracts with Genomics England that outline the terms of access and processing information, which includes as a breach of contract any attempts to re-identify participants.

16. Users will have a facility to introduce new data sets into the Data Centre for wider research purposes as defined in Section 8 of the Genomic England Protocol document. This data will then be subject to the same rigorous data access, sharing and acceptable uses procedure as set out in this document. Genomics England will ensure compliance with governance requirements across the pipeline regardless of data source to safeguard data confidentiality and participant privacy.


NHS
NHS Genomic Medicine Centres
Rare diseases, cancers and pathogens
Broad consent, characteristics, molecular pathology and samples
DNA & multi-omics
Repository
Sequencing Centre
Wellcome Trust £27m
Refreshable identifiable
Clinical Data
Life-course registry
Linked to anonymised
Whole Genome Sequence
Farr
Oxford
Big Data
Primary Care
Hospital episodes
Cancer Registries
Rare Disease
Registries
Infectious Disease
Mortality data
Patient entry
Genomics
england
MRC £24m Research Data Infrastructure
Sequential builds of pseudonymised data and WGS
Safe haven- users work within
Annotation & QC
Scientists & SMEs
Product
comparison
Fire wall
Patient data stays in safe haven
Only processed
results pass outside
Clinicians &
Academics
Training &
capacity
Industry

Genomics England Clinical Interpretation Partnership - GECIP

Goals

- Drive up the fidelity of clinical interpretation of genome sequencing
- Foster the use of the programme's data
- Accelerate academic/industry partnership and development of diagnostics and therapies.

Composition

- UK-led and organised into domains
- Self proposed partnership between researchers, the NHS and Trainees with skills.
- Can bring international collaborators

Expectations:

- All data generated contributes to the Genomics England Dataset and are available to all inside a GeCIP domain.
- IP owned by Genomics England but readily licensed to incentivise active collaboration
- Training workstreams

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GeCIP Domains – 1st wave

- 8 proposed domains for cancer derived from 26 submissions: ovarian, lung, breast, etc
- 14 domains for rare disease comprising 21 submissions: cardiovascular, neurological, paediatrics, etc
- 10 functional and cross cutting domains comprising 24 submissions. Population genomics, variant interpretation, education and training/primary care, etc
- 1 Ethics, Law and Social care domain comprising 13 submissions.
- Clinical Interpretation, Validation and Feedback (V&F) domain: “operations” arm of GECIP to coordinate clinical interpretation

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Generic delivery model

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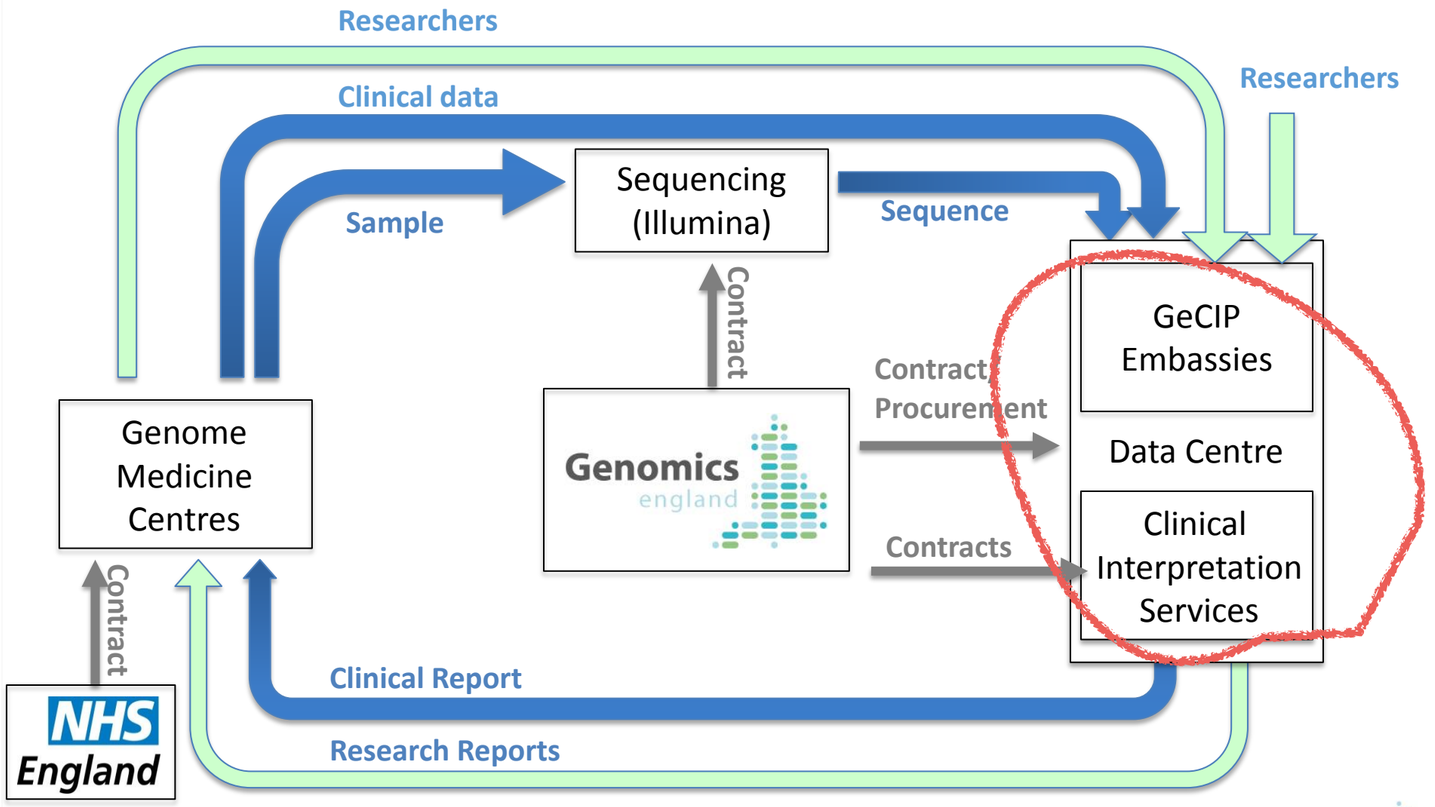
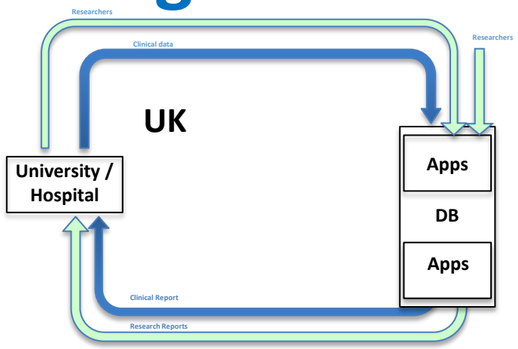
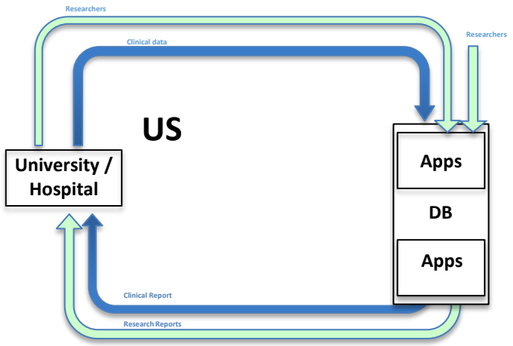
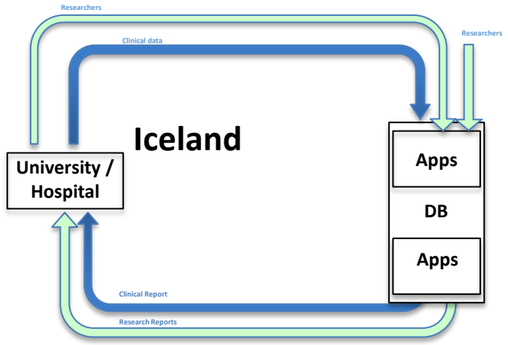
100KGP delivery model

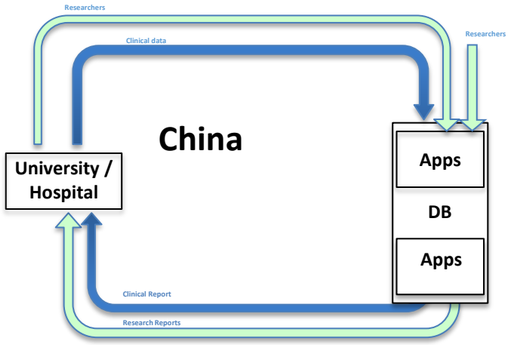


Effect of health service data living in walled gardens









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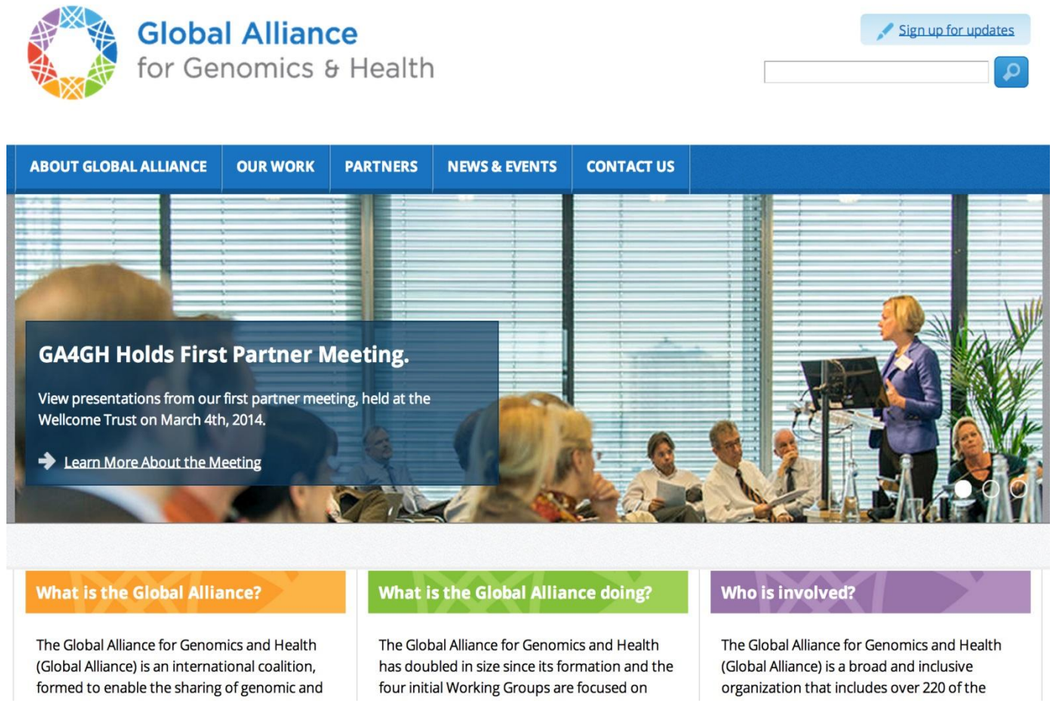
Global Alliance for Genomes and Health
http://genomicsandhealth.org/



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Gene Consortium launch partners

- AbbVie
- Alexion Pharmaceuticals
- AstraZeneca
- Biogen
- Dimension Therapeutics
- GSK
- Helomics
- Roche
- Takeda
- UCB*

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