

# Recommendations

## *Enabling consistent and responsible data sharing*

### Recommendation 1

Sharing genetic / genomic variants is a necessary part of clinical care and NHS service delivery. Current arrangements for sharing genetic / genomic data within the NHS are unsatisfactory: inconsistent practices are causing significant differences in patient care and are compromising quality and safety. Three elements are needed to improve, optimise and transform existing practice:

- » There is a need for **strong leadership** by the multiple responsible health organisations to demonstrate the benefits associated with data sharing, as well as the burdens and risks associated with sharing and not sharing, and to fully exploit new opportunities for building genomic capacity and services in the UK
- » **National agreement** is urgently needed in order to optimise sharing of genetic / genomic data within the NHS. All those involved need to develop a common understanding of the **legitimacy of data sharing**. We support a responsible and proportionate approach that takes account of a set of common principles to demonstrate trustworthiness. These include transparency about the purpose, risks, benefits and safeguards involved
- » **Standardised operational processes** need to be developed to achieve robust, effective and consistent sharing practices. There needs to be a **designated sustainable database or mechanism for sharing data across NHS clinical genetics / genomics services with clear governance, oversight, standards and safeguards**. A nationally accessible resource is integral to improving clinical outcomes and to supporting the effective delivery of clinical genetics / genomics services and as such should be long-term and sustainably resourced

## *Data sharing within the NHS*

### Where to share?

### Recommendation 2

A variety of approaches might be suitable for a national data sharing system: **end-users should engage early with stakeholders who are already developing systems and applications** to ensure that optimal mechanisms are developed for clinical use, including (where appropriate) interoperability with existing relevant infrastructure. If the most effective strategy to enable and promote data sharing is to build on existing knowledge and systems such as DECIPHER and adapt this for the NHS, then the principles from [Recommendation 1](#) must still apply.

## What to share?

### Recommendation 3

**As a minimum all disease causing or potentially disease causing genetic variants identified through clinical investigations should be accessible and shared.** This should be supplemented by diagnostic and phenotypic data and metadata. This data should be accessible to authorised users within the NHS (and some elements to other users subject to appropriate safeguards). (Further detail in section 2.5).

## How to share

### Recommendation 4

**Data deposition, sharing and curation are essential elements of laboratory service delivery.** These must be safeguarded by secure, efficient, robust and sustainable mechanisms and processes. A variety of tools and approaches are likely to be required, ranging from dedicated resources for data curation and sharing, to developing a collaborative framework for laboratories to share tools, experience and best practice for facilitating data sharing.

### Recommendation 5

Comprehensive, **peer reviewed, best practice guidelines for data sharing** for clinical genetics and genomics practice should be developed by laboratory scientists and relevant clinical professionals to provide consensus, establish minimum quality standards and therefore promote greater data sharing.

## Future proofing

### Recommendation 6

**Mechanisms ought to be established for sharing and managing whole genome and exome sequences and raw genomic reads,** in ways that promote the future development and improvement of clinical genomic services. These mechanisms should take account of advanced or innovative methods of data storage, processing and analytics (such as cloud computing) as well as novel approaches to consent (such as dynamic or machine readable consent).

## *Data sharing beyond the NHS*

### Recommendation 7

**Systems and legal processes need to be put in place to allow the contents of the NHS Database system (whether a consortium or dedicated database) to be shared more widely outside the NHS.** In order to address proposed legislative changes, the optimal method of establishing a firm legal basis for sharing identifiable patient data beyond the clinical care of the patient would be to seek routine appropriate consent. This will contribute to building public trust.

## *Wider considerations – achieving consistent and supported data sharing*

### **Recommendation 8**

Once a robust data sharing model has been established, through identifying a database or securing access to variant data via a federated system, **data sharing should be made more robust by mandating requirements for sharing genetic variants and monitoring compliance** through commissioning (as part of the service specifications for clinical genetics laboratory provision). These approaches should be supported by relevant commissioning bodies and professional clinical guidelines.

### **Recommendation 9**

In order to facilitate public engagement and public trust, **there needs to be a concerted effort by NHS providers and other relevant stakeholders to inform patients about how their data are used** both to support routine clinical care and for other secondary purposes (such as research, commissioning, and education and training). This could be achieved through a variety of processes including information leaflets, posters or by verbal communication.

### **Recommendation 10**

**Relevant regulatory agencies and professional groups should work together to ensure that there are harmonised appropriate approaches to evaluating and assessing health and care data use** by organisations and individuals, and that sanctions are applied in a robust and consistent manner.

### **Recommendation 11**

In developing a national consensus on data sharing the risks and harms of sharing ought to be balanced with the risks, harms and opportunity costs of not sharing data firstly within the NHS, and then also beyond NHS services. **A collaborative, multi-agency assessment of the probability of the risks of privacy breaches occurring and the impact they may have on patients, as well as the risks and impact on patients of not sharing data, is warranted.**