

Principles for analysis and use of health data by ABPI members



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abpi 

Key summary

PRINCIPLE

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We will be transparent about the purpose of our health data access

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We will ensure that contractual arrangements to access health data will be clear and will return fair value to the system

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We will actively promote Patient and Public Involvement and Engagement (PPIE) in health data projects

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We will ensure that insights arising from the health data analysis we conduct will be appropriately shared across the health system for the benefit of patients and other researchers, as agreed with the data custodian

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05

We support robust health data privacy protections and will ensure compliance with all prevailing laws and regulations as they evolve

About the ABPI

The ABPI exists to make the UK the best place in the world to research, develop and use new medicines and vaccines. We represent companies of all sizes which invest in discovering the medicines of the future.

Our members supply cutting edge treatments improve and save the lives of millions of people.

We work in partnership with Government the NHS so patients can get treatments faster and the NHS can plan much it spends on medicines.

Every day, we partner with organisations the life sciences community and beyond transform lives across the UK.



○ What is Health Data?

The Data Protection Act 2018 defines 'data concerning health' as personal data relating to the physical or mental health of an individual, including the provision of health care services, which reveals information about their health status.

'NHS health data' is data produced by the NHS in the process of care delivery, including genomic data.

'Data custodians' are the organisations that have the legal right to grant access to health data.

○ About the principles

Using health and genomic data can accelerate understanding of disease, improve efficiency of healthcare services and support the discovery, development and evaluation of new medicines. UK health data has exceptional potential to advance these goals, as the NHS routinely collects and stores data on health services, treatments and outcomes across the country.

This document sets out principles that ABPI members will adhere to when analysing and using NHS health data. These will complement the governance processes established by the data custodians.

It is intended that these principles, and our members' commitment to them, will underpin our work to generate and maintain public trust in the research-based biopharmaceutical industry's use of health data for research purposes.

In developing these principles, the ABPI has sought feedback widely through a public consultation and several deep dive interviews with individuals from patient representative groups, researchers from academia, industry and charity sectors, government and the NHS.

■ In These principles are intended to complement the Department for Health and Social Care's Five Guiding Principles as set out in the publication "[Creating the right framework to realise the benefits for patients and the NHS where data underpins innovation](#)", as well as adhering to all other legal and regulatory requirements.

We will be transparent about the purpose of our health data access

We will be clear and open about what company researchers aim to do with health data, how the data will be analysed, what the expected research benefits are and how risk will be managed. We will take steps to ensure this information is easily accessible to the public.

- Analysis of health data can move the complex process of research, discovery, development and deployment of new medicines forward at all stages. For example:
 - Understanding disease processes and progression, identifying which patients respond best to different approaches and interventions, and defining current unmet need
 - Identifying new biological targets, and designing new medicinal interventions
 - Stratifying and selecting the right patients for clinical trials to develop new medicines
 - Supporting delivery of precision medicines to the right patients
 - Assessing the performance and cost effectiveness of medicines in routine clinical practice, and identifying indicators of variable response
 - Analysing and refining patient pathways to ensure the best patient outcomes for different patient groups, and to support equality of access to these pathways

All data analysis projects conducted by ABPI members will be described in a short abstract, covering aims, approach, anticipated benefits the research will deliver to all parties (e.g. industry, patients, the public and the NHS). Abstracts will additionally describe potential risks, steps taken to minimise those risks, and patient/public involvement in development of the project.

Information will be provided in plain language, will be made available in accessible formats and will not include commercially sensitive information. Abstracts will be publicised by, for example, posting on a public database or website hosted by the data custodian and/or the researching organisation.



We will ensure that contractual arrangements to access health data will be clear and will return fair value to the system

Agreements with data custodians will be designed to return 'fair value' as agreed by all relevant parties. Agreements will describe how they contribute to the sustainability of the system (including recognising the costs associated with collecting, validating, curating, storing and providing access to the data). Agreements will also recognise taxpayer investment in the UK's data infrastructure and services and the need to deliver an appropriate balance of commercial and public benefit, regardless of whether the outcomes of individual projects are successful in delivering their original research aims or not.

- Projects analysing health datasets are hugely varied and can include:
 - a single analysis at a point in time
 - regular follow-up at specified intervals to explore trends
 - analysis of linked datasets through partnership with a custodian to explore detailed understanding of disease over time
 - The costs associated with collecting, curating and managing the data vary, depending upon the scale, detail and duration of follow-up. It will be important that the researchers and data custodians can efficiently reach a common understanding of project goals, agree proportionate levels of access to deliver on projects, the

legal basis for data use and analysis, and the arrangements for how data users return fair value to the system.

A summary of this agreement will be publicly available, including:

- The type of commercial model (e.g., fee for service, license of data, shared benefit/risk) excluding pricing
- The rights of patients to withdraw consent for their data to be used (opt out)
- Explicit parameters for use of the health data, including how the data will be anonymised and how long the data will be retained
- Where and how the data will be processed and analysed and how access will be controlled)

PRINCIPLE

03

We will actively promote Patient and Public Involvement and Engagement (PPIE) in health data projects

We will actively promote effective and meaningful involvement of patient/public representatives at an early stage in the design and approval of health data projects, both within their organisations and when projects are reviewed by data custodians.

- Data custodians have a responsibility for building public trust and confidence in data partnerships. Key to this is involving patient and public representatives in reviewing applications from data 'users' – those who wish to research and analyse their datasets. We consider that patients and the public are invaluable partners across a wide range of data analysis projects, supporting research, discovery, development and evaluation of medicines, and improved treatment pathways.

As PPIE becomes increasingly embedded in the overall design of development programmes for new medicines, involvement of patients in the design of relevant data projects should become increasingly routine. Clarity in demonstrating how such PPIE has taken place will help ensure projects are accepted first time by data custodian review panels. Effective PPIE should include robust measures to ensure diversity and inclusion, such as accessibility for people living with a range of health conditions.



We will ensure that insights arising from the health data analysis we conduct will be appropriately shared across the health system for the benefit of patients and other researchers, as agreed with the data custodian.

- The publication of the results from analysis of NHS data has the potential to significantly address health inequalities, improve patient pathways and contribute to NHS efficiency. We therefore commit to publicise insights through, for example, peer reviewed journals, website summaries, conference presentations and submissions to regulatory bodies.

In line with the Department for Health and Social Care's five [Guiding Principles](#) for creating the right framework to realise the benefits of health data, companies will not 'buy' or 'own' specific NHS datasets (i.e. become a data custodian) at the expense of these datasets being readily available to other researchers.



PRINCIPLE
05

We support robust health data privacy protections and will ensure compliance with all prevailing laws and regulations as they evolve

All projects and arrangements will adhere to national level legal, regulatory, privacy and security obligations, in line with long-established requirements and practice.

- All researchers will collaborate fully with data custodians to ensure that all analyses of health datasets are conducted within current national laws, privacy and security requirements and regulations, with appropriate regard to relevant global legal codes. We will keep pace with evolving requirements, demonstrating leadership and commitment to strengthening accountability and best practice.

Compliance with patients' rights to choose how their data is used is central to building trust in health data research. The NHS offers patients the opportunity to opt out of data re-use. We support the right of patients to opt out and will consult with data controllers to ensure that no datasets analysed include data from patients who have opted out.





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