



STHFT-HES Data

The staff at Sheffield Teaching Hospitals Foundation Trust (STHFT), process information about you and your health, so that you can receive the right care and treatment. STHFT has a collaboration agreement with IQVIA for the purpose of producing an enhanced dataset for use in medical research studies.

This enhanced dataset has been generated by linking STHFT data and the Hospital Episode Statistics (HES) data provided by NHS Digital (“STHFT-HES Data”). The methodology used for this linkage was created by a trusted third party using secure encryption technology to link patient records without compromising patient confidentiality. This has also been approved and executed by NHS Digital. The purpose of this linkage is to enable the development of a retrospective database study with the linked datasets. IQVIA Solutions UK Limited, STHFT and Janssen Pharmaceuticals are the data controllers of the STHFT-HES Data, and Janssen are the funders of the study. As part of GDPR, a data controller *“determines the purposes for which and the means by which personal data is processed. An entity is a joint controller when together with one or more organisations it jointly determines ‘why’ and ‘how’ personal data should be processed”*. In this case, for NHS Digital, HES data is considered to be personal data and any entity that provides input into the protocol which will use HES data needs to be added as a joint data controller as they are determining why and how the data will be used. So, in this case, this includes Janssen/Janssen, Sheffield and IQVIA as all of these entities are currently contributing to the development of the protocol.

The purpose for which STHFT-HES Data is processed and used

Pulmonary Arterial Hypertension (PAH) (a type of Pulmonary Hypertension (PH)), is a progressive and rare disease caused by narrowing or tightening (constriction) of the pulmonary arteries. There are other types of PH, including Chronic Thromboembolic Pulmonary Hypertension (CTEPH) and Sarcoidosis-Associated Pulmonary Hypertension (SAPH). Due to the complexity, late diagnosis and absence of real-world studies across all subtypes of PH (PAH, CTEPH and SAPH), there is currently a lack of understanding regarding the clinical pathway leading to diagnosis. In addition, there is also the need to further explore and study patient related outcomes associates with these diseases in the routine clinical practice.

Your de-identified information will support researchers in generating a better understanding of PAH, CTEPH and SAPH patients, in terms of characteristics of patients, clinical pathways pre-diagnosis, treatment patterns post-diagnosis, clinical outcomes and healthcare resource use (HCRU). The goal of the research is to:

- Generate real world evidence on the clinical and treatment management of patients diagnosed with PAH, CTEPH and SAPH
- Analyse the characteristics of diagnosed patients at the time of confirmed diagnosis, as the clinical pathways leading up to diagnosis and the post-diagnostic treatment patterns
- Investigate various clinical outcomes associated with PH and its subtypes, and a comparative outcomes analysis of PH treatments
- To explore the HCRU and the costs associated with the diagnosis

Your data will improve the body of knowledge around these three sub-types and further enhance the possibility of developing better clinical pathways, improving treatment patterns and informing clinical guidelines to improve patient's health and Quality of Life. It could also help us to develop new approaches to diagnosing and treating PH, including supporting the development of new drug discovery in partnership with pharmaceutical companies.

IQVIA processes the STHFT-HES Data on the basis of legitimate interests in supporting medical research and because it is necessary for the above scientific research purposes, subject always to appropriate safeguards. Technical and organisational measures are in place to ensure only non-identified data is used.

All directly identifiable details (name, address, post code, telephone numbers, NHS number, full date of birth) are removed from your information before being used for research, and all information will be checked for identifiable details by an automated process before any researchers have access.

What are your choices about how your information is used?

We will need to use information from your medical records for this research project.

This information will include your NHS number and date of birth. People will use this information to do the research or to check your records to make sure that the research is being done properly. We will keep all information about you safe and secure.

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from <https://www.sheffieldclinicalresearch.org/for-patients-public/how-is-your-information-handled-in-research/>
- by contacting Sheffield Teaching Hospitals NHS Foundation Trust: Information Governance Officer on telephone number: 0114 2265151 or email sth.infogov@nhs.net.
- by asking one of the research team

Data retention

The linked STHFT-HES Data will hold records from 2007 to 2018. For studies using patient data to be scientifically sound, all information relating to a patient's past medical events should be considered as this will influence their doctor's decision and affect their current care. Historical data on patient contact with secondary care is important because the lead up to diagnosis of many conditions, particularly rare diseases, can be complex and lengthy. In addition, longitudinal data are increasingly important in, for example, studying chronic conditions, when, a long history is required so that trends and signals can be detected, and early risk prediction tools can be designed. Availability of sufficient data and research can drive health policy changes or adoption of new guidelines for healthcare providers, thus leading to improved outcomes for patients.

IQVIA retains data in accordance with UK Medical Research Council (MRC) guidelines which recommend basic research data and related material be retained for a minimum of 10 years after the study has been completed. This is to support good research practice which requires research studies to be reproducible.

<https://mrc.ukri.org/documents/pdf/retention-framework-for-research-data-and-records/>

Security

IQVIA has implemented an Information Security Management System. IQVIA Solutions UK Limited is accredited to the ISO 27001 standard and IQVIA Ltd has an NHS approved Information Governance Toolkit (IGT) assessment and has submitted an NHS data security and protection toolkit (DSPT) assessment.

IQVIA stores the STHFT-HES Data records on secure servers located in the UK only. IQVIA have put in place appropriate security measures to prevent unauthorised access to or disclosure of the STHFT-HES Data. Access to the data is strictly controlled and limited internally to authorised personnel. External use and access are governed by data sharing agreements detailing confidentiality and the terms on which the data is shared, used, stored and accessed.

Changes to this notice

IQVIA may update this notice from time to time. IQVIA encourages you to review this notice periodically to stay informed about how IQVIA is using and protecting STHFT-HES Data. If IQVIA plans to use personal data for a new purpose, IQVIA will update the privacy information and communicate the changes to individuals before starting any new processing. Any changes to this notice take effect immediately after being posted or otherwise provided by us.

Contact details

Questions and comments regarding this notice and use of your information should be addressed as follows:

To IQVIA: **Edmund Drage** on telephone number: +44 2030755784 or email Edmund.Drage@iqvia.com or email the IQVIA EU DPO eu.dpo@iqvia.com.

To the Sheffield Teaching Hospitals NHS Foundation Trust: Information Governance Officer on telephone number: 0114 2265151 or email sth.infogov@nhs.net.

About us

The STHFT is registered at the following address 8 Beech Hill Rd, Sheffield, S10 2SB, England.

IQVIA Solutions UK Limited is part of the IQVIA Inc. group of companies serving the combined industries of health information technologies and clinical research worldwide. IQVIA specialises in the provision of products and services including medical research and analytical solutions to healthcare and life sciences organisations. In the UK, IQVIA has collected and supported the research use of non-identified patient data for over 20 years.

IQVIA is registered in England and Wales as: IQVIA Solutions UK Limited, registration number: 00634325. Our registered office is at 210 Pentonville Road, London, N1 9JY.