Navigating Health Care Systems Data for Clinical Trials

British Heart Foundation Data Science Centre
Led by Health Data Research UK

How do we access the data & other considerations?

Provider Application Processes

NHS England – Data Access Request Service (DARS)
Link to Main Page: https://digital.nhs.uk/services/data-access-request-service-dars
Application Page/Process : https ://digital.nhs.uk/services/data-access-request-service-dars/data-access-request-service-dars-process
Review Process:
When applying via DARS for data you will be assigned a case officer who will complete an initial review of the application and provide feedback. Once the application is accepted, the application will be reviewed by the Independent Group Advising on the release of data (IGARD), further information about IGARD can be found here https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/independent-group-advising-on-the-release-of-data. It is important to review the Standards of information required in an application as these are the items specifically considered by IGARD https://digital.nhs.uk/services/data-access-request-service-dars/dars-guidance.

NHS England - DigiTrials
Link to Main Page: https://digital.nhs.uk/services/nhs-digitrials
Application Page/Process: NHS Digi-trials, like DARS, is run by NHS England. Digi-trials is a data service delivery partner and so would work with the trial team as a partner providing feasibility assessments and possible patient identification. The application process starts with a feasibility assessment, https://digital.nhs.uk/services/nhs-digitrials#how-to-get-data-from-nhs-digitrials-for-your-research
Review Process: NHS Digi-trials approvals also require review by the Independent Group Advising on the release of data (IGARD), further information about IGARD can be found here https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/independent-group-advising-on-the-release-of-data. It is important to review the Standards of information required in an application as these are the items specifically considered by IGARD https://digital.nhs.uk/services/data-access-request-service-dars/dars-guidance.

Public Health Scotland – Electronic Data Research and Innovation Service (eDRIS)
Link to Main Page: https://www.informationgovernance.scot.nhs.uk/pbpphsc/
Application Page/Process: An initial enquiry form should be completed from the above link.
Review Process: The application is called a Public Benefit and Privacy Panel for Health and Social Care (HSC-PBPP) form. When applying to eDRIS you will be assigned a research coordinator. The research coordinator will review the application and ensure all documentation is in place – this will include Information Governance training, DPIA, Ethics approval etc. The HSC-PBPP will then be reviewed by an HSC-PBPP manager, Tier 1 panel or Tier 2 panel. The Tier 2 panel full committee will include relevant Caldicott Guardians. This will depend on the complexity of the request. Find more information about the panel review structure here.

NICOR/Healthcare Improvement Partnership (HQIP)
Link to Main Page: https://www.nicor.org.uk/
Application Page/Process: The data controller for NICOR is now NHS England and the data is hosted by NHS Arden and Greater East Midlands Commissioning Support Unit (Arden and GEM). Contact nicor.auditenquiries@nhs.net

NHSCR
Link to Main Page: https://www.nrscotland.gov.uk/statistics-and-data/nhs-central-register/how-to-use-the-register-for-medical-research/how-to-apply
Application Page/Process: Initial enquiries and application submission email to dg.nhscr-scotland-medical-research@nhs.scot
Review Process: NHS CR also use the Public Benefit and Privacy Panel for Health and Social Care (HSC-PBPP) process managed via eDRIS as above (Public Health Scotland)

Digital Health and Care Wales

Link to Main Page: https://dhcw.nhs.wales/
Application Page/Process: https://dhcw.nhs.wales/information-services/health-intelligence/bespoke-data-requests/
Review Process: Please contact DHCW.Info@wales.nhs.uk for information.

Confidentiality Advisory Group - England and Wales only

A trial may be required to apply to the Confidentiality Advisory Group (CAG) if applying to access confidential patient information for a compelling scientific reason without explicit consent in England and Wales. However, it is worth noting, even with patient consent you may require CAG approval if the organisation which holds the data you wish to access decides the consent statement is insufficient to meet approvals.
Further information on CAG is available from the HRA: https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/confidentiality-advisory-group/
A similar function to the confidentiality advisory group is undertaken by the Public Benefit and Privacy Panel for Health and Social Care (HSC-PBPP) in Scotland and in Northern Ireland the legislation equivalent to Section 251 is the Health and Social Care (Control of Data Processing) Act (Northern Ireland) 2016.

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Data Protection Impact Assessments (DPIA) - UK Wide

What is a Data Protection Impact Assessment (DPIA)?

A DPIA is a process to help you identify and minimise any data protection risks for a project or in this case, clinical trial. DPIAs are also a legal requirement where the processing of personal data is likely to result in a high risk for individuals. DPIAs for the processing of personal data that is undertaken for the purpose of research is the responsibility of the clinical trial sponsor.

How do I know if I need to complete a DPIA?

The Information Commissioners Office (ICO) has checklists available which help trial teams to consider if a DPIA is needed.

It is of note that there are three criteria within the activities which are deemed more likely to be high risk that may impact clinical trials:

- Sensitive data or data of a highly personal nature.
- Data processed on a large scale – *note,* this can mean processing a lot of data about one person so does necessarily refer only to large trials.
- Matching or combining datasets.

Read more about high risk activities here.

To help identify the data processor and data controller (usually the trial sponsor), the MRC Regulatory Support Centre in collaboration with the HRA, Edris, NHS Digital and CPRD have produced 'Current thinking on Controllers and Processors in health research'.

The general advice from the Information Commissioners Office is 'If in If in any doubt, we would always recommend that you do a DPIA to ensure compliance and encourage best practice.'

Who reviews my DPIA?

Your organisations Data Protection officer should review the DPIA if you have one, you should also involve information security staff, any data processors and legal advisers where relevant. You are required to contact the Information Commissioners Office if you are unable to take steps to mitigate any identified high risks.

https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/data-protection-impact-assessments-dpias/do-we-need-to-consult-the-ico/#do1

Information Standards

SNOMEDCT, ICD-10 and OPCS-4 are all "Information Standards", they are complementary but serve different purposes.

SNOMED-CT is used by clinicians to record information in the patients EHR at the point of care. This can include more granular information such as symptoms which can be shared across healthcare settings prior to a diagnosis.

ICD-10 (International Statistical Classification of Diseases and Related Health Problems 10th Revision) is an alphanumeric classification system. The ICD-10 is used to classify ***diseases, injuries and causes of death***.

OPCS-4 (OPCS Classification of Interventions and Procedures 4, 2021) is an alphanumeric classification system of *interventions and procedures* undertaken in the National Health Service (NHS) reflecting current clinical practice.

ICD-O-3 (International Classification of Diseases for Oncology, 3rd Edition) is used in cancer registries for coding the site (topography) and the histology (morphology) of neoplasms, usually obtained from a pathology report.

Data Integrity

One of the key issues for clinical triallists planning to use healthcare systems data is uncertainty around how regulators view this data. Dr Macey Murray has led a project with the 'Healthcare systems data for clinical trials group' - Use of NHS Digital datasets as trial data in the UK: a position paper. The project has focused on two important NHS Digital datasets - the Hospital Episode Statistics Admitted Patient Care dataset and the Civil Registration of Deaths dataset. The team have assessed the data integrity for these datasets demonstrating the data flow and documentation in place for each.
Based on the findings from this project, the team have shown that HES APC and CRD datasets satisfy the assessment criteria that demonstrate they are reliable transcribed copies of the original source data. Read the full paper here.
This work on data integrity is essential for increasing the use of healthcare systems data withing clinical trials and is work being continued for other datasets with HDRUK.
The team also make some helpful recommendations about documenting the use of this data within the Trial Master File (TMF) – and have produced a helpful template for the TMF Routine Dataset Justification Template**.**

Data retention and sharing – Considerations

Data Retention

Regulatory requirements mandate that clinical trial data is stored for a prolonged period of time. Historically there have been some challenges retaining routinely-collected data for this length due to data providers mandating short periods in contracts.
Providers are now aware of the challenges and will usually work to ensure agreements provided allow for appropriate data retention. This may include a Trial teams should review contracts to make sure their trial requirements are adequately documented before agreements are signed.

Data Sharing

Onward ethical and secure data sharing for data re-use projects is rapidly becoming best practice for clinical trials, with an aim to maximise the benefits of the research for patients, the public and the health and care system. However, there are a number of logistical challenges with sharing data – differing regulatory frameworks between countries, differing standards (for example, CDISC/DASH, OMOP.) and possibly selecting a platform to allow data sharing. The MRC Clinical Trials Unit (CTU) at UCL published a paper 'Sharing data from clinical trials: the rationale for a controlled access approach' with suggested guiding principles for data sharing, and UKCRC Registered CTU sets out 'Considerations for a Participant Data Sharing SOP'. Ensuring routine data can be used in onward data sharing projects is a key consideration before signing agreements.

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Support from the BHF Data Science Centre

This area will be expanded to highlight materials supporting access to healthcare systems data produced by members of the clinical trials community.
Please get in touch: bhfdsc@hdruk.ac.uk if you would like to talk to us about:

1. Accessing health systems data for cardiovascular or diabetes trials
2. Developing a data utility comparison (DUCk) – a form of SWAT ('Study within a trial') that would allow assessment of healthcare systems data to traditional data collection
3. Sharing your experiences with others

Support materials

Dr Macey Murrays webinar on 'Assessing data provenance and integrity of NHS Digital datasets for clinical trials'
'Demystifying access to routine data' – Suzanne Hartley (Trials Methodology Research Partnership / HDRUK) talks about Organisational and Trial readiness, Applications, Data sharing and Data retention.
Guidance for Good Randomised Clinical Trials – a useful guide laying out key principles of RCTs. Section 4 discusses making optimal use of pre-existing resources