

Please see below for a link to the webinar recording for the Trials Methodology Research Partnership:

Demystifying access to routine data

Suzanne Hartley (University of Leeds)

26 August 2021

On behalf of the Health Data Research UK

The slides are also available below.

For any queries, please contact uktmn@nottingham.ac.uk

https://www.youtube.com/watch?v=u-iacrBu_LQ

Demystifying access to routine data

Trials Methodology Research Partnership / HDRUK

Suzanne Hartley, CTRU, University of Leeds

26th August 2021

Access to data - where to start?



Demystifying access to routine data

Organisational readiness

Trial readiness

Applications

Data sharing

Data retention

Summary & future directions

Organisational readiness

Data Protection Act registration

The screenshot shows a web browser window with the URL ico.org.uk/ESDWebPages/Search. The page header features the ICO logo and the text "Data protection public register". Below the header, there is a search form with the following fields: "Registration number", "Name", "Address", and "Postcode". There are three buttons: "SEARCH REGISTER", "HELP", and "SAMPLE". Below the form, there is a section titled "Can't find what you're looking for?" with a paragraph of text and a tip. A link "Download the register of data controllers" is also present.

ico. Information Commissioner's Office

Data protection public register

Use this search to find organisations and people registered with the ICO under the Data Protection Act.

Registration number

Name

Address

Postcode

Can't find what you're looking for?
Data controllers are officially registered from the date we receive a valid form and fee, but at busy times it may take us longer to process your registration.
Domestic CCTV owners that register with the ICO are not required to publish their address, so searches based on addresses for these organisations may not return results.
Tip: Try entering information in only one search box first. If you have a query about this register you can contact us on 0303 123 4567.

[Download the register of data controllers](#)

Valid DPA registration
DPA expiring within 2 months must have a plan to renew

Registration number
Date of registration
Expiry date
Address
DPO contact details


<https://ico.org.uk/ESDWebPages/Search>

Contracts

Organisations who wish to receive and use NHS Digital's data must have a valid DSFC

Provides framework of legally binding terms and conditions

Data Sharing Framework Contract



Part 1 : Front Sheet

Contract Reference	CON-XXXXXX-XXXXX (Version 2.02)
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Introduction

A NHS Digital (as defined in Clause 1.1, Part 1 below) has a statutory function to collect, analyse, publish and disseminate certain health and social care data and may in accordance with its statutory functions from time to time share and permit others to use that data.

B Any party wishing to receive and use NHS Digital's data must first enter into this Contract and will, where the data is Personal Data, be a Controller of that Personal Data. This Contract is a framework agreement. It creates a framework of legally binding terms and conditions that will apply on each and every occasion NHS Digital agrees to share data with the Recipient (as defined in Clause 1.2, Part 1 below). NHS Digital will not share data with any party that has not entered into this Contract unless the party is a Processor acting on behalf of the Recipient, and NHS Digital has agreed to share the data with that Processor.

C Entering into this Contract does not guarantee that NHS Digital will agree to share any data with the Recipient, on any particular occasion, or for any particular purpose. Sharing of data by NHS Digital is at the absolute discretion of NHS Digital and subject to such terms and conditions as NHS Digital may impose. The terms and conditions on which NHS Digital will permit the Recipient to receive and use data on a particular occasion and for a particular purpose will be set out in a separate Data Sharing Agreement entered into between NHS Digital and the Recipient. Each Data Sharing Agreement will be subject to the terms and conditions of this Contract and will identify the specific data in question and will set out any specific terms that will apply to the sharing and use of the data by the Recipient on that occasion and for that particular purpose.

Data sharing agreements

Project specific

Specify Data to be provided

Legal basis for sharing Data

Purpose of the sharing and use of the Data

Expected benefits to health and/or social care by sharing the Data

Data transfer method


Associated DSAs

Special terms and conditions for the use or reuse of the Data

Charges payable for the Data

Signed by Controller(s)

The screenshot shows the 'Application Summary' page of the NHS Digital DARS application. It includes a table for '1: General' with fields for Request Number, Request Title, DSA Start Date, DSA End Date, and Generated by Contact Centre. Below the table is section '1a. Summary - Completed by Data Access Case Officer' with fields for Governance Path, Categories, Reason, and Agreement Type Application. A section for 'Summary of data changes' is also present, followed by '1b: Data Controller(s)' with a bullet point and fields for Data Controller, Organisation Type, Data Controller Type, and NHS Digital Framework Contract Reference.

Application Summary
DARS-NIC- 

Data Access Request Service (DARS) Application

1: General

Request Number:	Generated by Contact Centre
Request Title:	Add Study Request Title here
DSA Start Date:	Data Sharing Agreement Length – Standard 1
DSA End Date:	

1a. Summary – Completed by Data Access Case Officer

Governance Path:
Categories:
Reason:
Agreement Type Application:

Summary of data changes

1b: Data Controller(s)

- **Data Controller:**
Data Controller Standard 1b

Organisation Type:
Data Controller Type:
NHS Digital Framework Contract Reference:

Data Controller / Processor

Organisations processing personal data need to be identified as a Controller(s) and / or Processor(s) based on level of control over the purpose and means of processing personal data

Controller determines "why" and "how" personal data would be processed - does not need to access or process data

Collaborative research may involve several Controllers / Processors, and it is an **organisational responsibility** to determine who is Controller and Processor

Why is it important?

NHS Digital enter into a legally binding contract with Controller(s)

NHS Digital need to be able to enforce the contract (audit, data destruction, indemnification) against the correct organisation(s)

Risk - legal, reputational and public trust

HRA guidance suggests It is the sponsor who determines what data is collected for the research study, and acts as the controller in relation to the research data

Consider role of steering & scientific committees, collaborators, honorary contacts, staff moving institutions

Security assurances

Minimum security standards must be in place, and evidenced, to provide assurance that patient data will be safe and secure

This includes arrangements for storage, access, back-ups and disaster recovery, and destruction of data. All locations storing and processing data must be identified in your application.

Controllers and processors need a valid Data Security and Protection Toolkit (DSPT), ISO27001 or System Level Security Processes (SLSP) to evidence adequate security assurance

Data Security Protection Toolkit

Online self-assessment, measure against NDG 10 data security standards

Annual assessment – allows for alignment with current best practice

Provides a means of reporting security incidents / breaches

Requires a Senior Information Risk Officer - overall risk accountability

Includes tech & IG requirements
Check which is relevant for your organisation

NHS Digital Data Security and Protection Toolkit Register Log in

Organisation search News Help

Organisation search

Commissioner data is provided from the [Organisation Data Service](#) (where available)

Primary Sector
Commissioner

[Download results as a spreadsheet \(CSV file\)](#)

ODS	Organisation name	Latest status	Published
8E218-IRC	University of Leeds - IRC	20/21 Standards Met	30/06/2021
8E218-SEED	University of Leeds - SEED	20/21 Standards Met	29/06/2021
8KM29	University of Leeds - LASER	20/21 Standards Met	12/04/2021
ECC0010	University of Leeds - Clinical Trials Research Unit (CTRU)	20/21 Standards Met	02/06/2021
EE133839-DA C	University of Leeds - DATA-CAN	20/21 Standards Met	17/08/2021
EE133839-So M-LCMCOS	University of Leeds - School of Medicine - Legal Costs and Medical Causation in Orthopaedic Surgery	19/20 Standards Not Met	30/09/2020
TR016	PAVFIELD UNIVERSITY OF	20/21 Standards Met	10/06/2021

<https://www.dsptoolkit.nhs.uk/OrganisationSearch>

<https://www.dsptoolkit.nhs.uk/News/21-22-DSP-Toolkit-evidence-items>

Trial readiness

Data processing is lawful, fair and transparent

Legal basis is required to processing data

For public authorities, such as Universities, the most appropriate lawful bases when processing personal data and health data (defined as special category data) for the purposes of research are:

- Article 6:1(e): Specific task in the ‘public interest’ or task that has a clear basis in law, and
- Article 9:2(j): Special category data used for “Archiving in the public interest, scientific or historical research or statistical purposes”, with a basis in law.

Common Law Duty of Confidentiality

Applies to confidential information (including health related data) which is not in the public domain

Consent can be used to demonstrate compliance with CLDC

Clear that their identifiable data is being shared with NHS Digital, to link with confidential data held in their electronic health records - apply a principle of “no surprises”

Section 251 approval from the Health Research Authority (HRA) Confidentiality Advisory Group (CAG) can be used as an alternative

Fair and transparent

Research participants must be informed about how their personal data is being collected and used.

This is “**Privacy Information**” and should include information on **what their personal data will be used for** (i.e. its purpose), **how long** their personal data will be retained, **what their rights** are in terms of processing their data, **where it will be stored** and **who will have access** to the personal data, including whether their personal data will be **shared with other organisations**.

Provided in Participant Information Sheets / Informed Consent Forms, study websites, newsletters, social media, and any other information provided by health care professionals at relevant study visits.

Plan how to keep participants informed about what is happening with their data at start of your study – include in funding and approvals

Does the data meet your requirements?

Do you know what data you need?

Can the data answer your research question?

Can the data be shared for your purpose?

<https://digital.nhs.uk/services/data-access-request-service-dars/dars-products-and-services>

Does the project have sufficient time?

Application process

IGARD review / contract signatory

Lag in availability of data

Preparation of data

Project analysis (deriving outcome, analysis)

Does the project have sufficient funds?

NHS Digital charge to processing and delivering service

Application

Renewal / extensions / review

Volumes of data (per year / dataset)

Number of disseminations

Bespoke data linkage

Cohort tracing

<https://digital.nhs.uk/services/data-access-request-service-dars/data-access-request-service-dars-charges>

THE APPLICATION

Purpose

Objective

Purpose of data request

Other related projects

Details and size of cohort

Commercial purpose

Will data be shared?

Is linkage required?

Processing

Dataflow between organisations

Legal basis for each flow

Data linkage with other data sources

Which organisations will access data

How long will data be retained?

What is the geographical areas where data will be stored, processed, accessed

Outputs

Peer review publications

Conferences

Tailored summaries

Level of data

When outputs will be achieved?

Measureable Benefits

New treatments for patients with a specific condition

Updates to clinical guidelines to inform patient care

Improved information for patients

More efficient / effective use of resource

The importance of benefit

Legal requirement

Health and Social Care Act 2012 as amended by the Care Act 2014, which stipulates that NHS Digital (the HSCIC) may only disseminate information under its **general dissemination power in section 261(1)** for the purposes of the **provision of health care or adult social care** or for the **promotion of health**

Maintaining public trust and confidence

Section 5 of the Data Sharing Agreement forms NHS Digital's **Data Uses Register**

Public expectation

Research with the public overwhelmingly demonstrates that the existence of **public benefit** is regarded as an **essential condition** of the appropriate use of health and care data for purposes beyond individual care

Avoid pre-judging outcomes

“We will establish that drug X is safe so we can reassure patients....this study will lead to new guidance”

We **hope** to establish that drug X is safe **compared to similar drugs.**

We **hope** that the outputs of this study will be used to update guidelines

Write application assuming it will be in the public domain

Supporting Evidence

Protocol (all versions)

Patient Information Sheets / Consent form (all versions) –
include breakdown of patients who consented to each version

Ethics - approval / documentation

CAG – approval / documentation

Funding confirmation letter

Contracts / honorary contracts

Data Flow Diagram

Learn from others - Data Uses Register

NHS Digital's Data Uses Register (Applicant Organisations)



Select an Applicant Organisation from the list on the right, and then click the button in the bottom left corner to view the Data Sharing Agreement(s) (DSA) associated with it.

Applicant Organisation

Click on an APPLICANT ORGANISATION and then click [HERE](#) to view the DSA(s)

- Applicant Organisation
- 2020 Delivery Ltd
- 3M United Kingdom Plc
- AstraZeneca AB
- AstraZeneca UK Limited
- Bangor University
- BARNSLEY METROPOLITAN BOROUGH COUNCIL
- Barts and the London School of Medicine and Dentistry
- BARTS HEALTH NHS TRUST
- BATH AND NORTH EAST SOMERSET COUNCIL
- BIRMINGHAM CITY COUNCIL
- BIRMINGHAM WOMEN'S AND CHILDREN'S NHS FOUNDATION TRUST
- BLACKBURN WITH DARWEN BOROUGH COUNCIL
- BLACKPOOL BOROUGH COUNCIL
- BOLTON METROPOLITAN BOROUGH COUNCIL
- BRACKNELL FOREST COUNCIL
- BRIGHTON AND HOVE CITY COUNCIL
- BRISTOL CITY COUNCIL
- British Thoracic Society
- BUCKINGHAMSHIRE COUNCIL
- BUCKINGHAMSHIRE HEALTHCARE NHS TRUST
- BURY METROPOLITAN BOROUGH COUNCIL
- CAMBERLEY METROPOLITAN BOROUGH COUNCIL

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- <https://digital.nhs.uk/services/data-access-request-service-dars/data-uses-register>



Learn from others - Data Uses Register



Data Sharing Agreements



University of Leeds

Applicant Organisation

Reference Number	Application Title	DSA Start Date	DSA End Date	Data Controller(s)	Sole/Joint Data Controller	Does Sublicensing Apply	For Commercial Purposes
DARS-NIC-320074-F005D-V0.14	SHIFT Trial Participant Data MR1384	20/04/2018	27/04/2021	University of Leeds	Sole Data Controller	No	No
DARS-NIC-332338-X1N2G-v0.9	Health related quality of life and clinical outcomes following acute myocardial infarction: linked EMMACE, HES and Civil Registration Mortality Data	01/11/2020	31/10/2023	University of Leeds	Sole Data Controller	No	No
DARS-NIC-378185-P4L5Z-v0.4	Improving the safety and continuity of medicines management at care transitions (ISCOMAT): a cluster Randomised Controlled Trial	13/05/2021	12/05/2024	BRADFORD TEACHING HOSPITALS NHS FOUNDATION TRUST, University of Leeds	Joint Data Controller	No	No
DARS-NIC-378523-Y5Q9L-v0.25	Routinely collected hospital admissions data for care home residents	01/06/2017	31/05/2020	BRADFORD TEACHING HOSPITALS NHS FOUNDATION TRUST, University of Leeds	Joint Data Controller	No	No
DARS-NIC-378523-Y5Q9L-v1.2	Routinely collected hospital admissions data for care home residents	21/10/2020	20/04/2021	BRADFORD TEACHING HOSPITALS NHS FOUNDATION TRUST, University of Leeds	Joint Data Controller	No	No
DARS-NIC-402417-N9Z5W-v0.4	Enumerating the impact of COVID-19 on cancer pathways: a robust evaluation of the NHS Digital Trusted Research Environment	19/04/2021	18/04/2023	LEEDS TEACHING HOSPITALS NHS TRUST, University of Leeds	Joint Data Controller	No	No
DARS-NIC-40493-G5Y6K-v1.22	Improving the safety and continuity of medicines management at care transitions (The ISCOMAT Programme) Work Packages 1 and 2	07/12/2018	09/12/2020	BRADFORD TEACHING HOSPITALS NHS FOUNDATION TRUST, University of Leeds	Joint Data Controller	No	No
DARS-NIC-49164-R3G5K-v0.4	QuantCode: Admitted Patient Care Data	01/10/2017	30/09/2020	University of Leeds	Sole Data Controller	No	Yes

Organisation Type:

Academic

Number of Active DSAs:

10

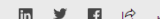
Click on a REFERENCE NUMBER and then click HERE to view the PURPOSE STATEMENTS for a DSA

Click on a REFERENCE NUMBER and then click HERE to view the DATASETS for a DSA

Click on a REFERENCE NUMBER and then click HERE to view the DATA RELEASES for a DSA

Microsoft Power BI

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Learn from others - Data Uses Register

Purpose Statements



DARS-NIC-378185-P4L5Z-v0.4

University of Leeds

Objective for Processing	Processing Activities	Expected Output	Expected Measurable Benefits	Yielded Benefits
<p>Bradford Teaching Hospitals NHS Foundation Trust and the University of Leeds are requesting to use NHS Digital data for a study entitled "Improving the Safety and Continuity Of Medicines management at Transitions of care" (ISCOMAT).</p> <p>ISCOMAT has received a favourable ethical opinion, is funded by the National Institute for Health Research (NIHR) and is performed by a public authority, Bradford Teaching Hospitals NHS Foundation Trust's and the University of Leeds' lawful bases for processing personal data and health data (defined as special category data) for the purposes of this project are:</p> <p>Article 6:1(e): Specific task in the 'public interest' or task that has a clear basis in law, and</p> <p>Article 9:2(j): Special category data used for "Archiving in the public interest, scientific or historical research or statistical purposes", with a basis in law.</p> <p>Participants consented to have their personal data shared with NHS Digital, including personal details (initials, date of birth, postcode and NHS number) to be shared with NHS Digital for this project. Participants who withdrew their consent for data collection from routine sources will not form part of this cohort for this data application. All consent documentation and subsequent amendments to it were reviewed and approved by the ISCOMAT Patient Led Steering Group.</p> <p>ISCOMAT Background and rationale: Making the use of medicines as safe and effective as possible are priorities for patients and healthcare providers. When a patient moves, for example from hospital to home, medicine problems are common and planned changes are</p>	<p>The trial statistician at the Clinical Trials Research Unit (CTRU) will provide the following identifiers: sex, date of birth, postcode and NHS number. Study ID for each participant will be provided to allow linkage of the NHS Digital data to the trial data held by the CTRU. For each participant, date of admission to hospital, and 12 month post registration will be provided. This will provide assurance that minimum data required is obtained. The data will be transferred to NHS Digital via the required secure platform.</p> <p>NHS Digital will perform an automatic cohort tracing system to search the data provided against existing electronic records to generate a set of records that belong to the cohort of 1615 trial participants. This will include linkage of data from Hospital Episode Statistics (HES) Admitted Patient Care (APC), HES Critical Care (CC), HES Outpatients, Emergency Care Data Set (ECDS), Civil Registration (Deaths) Secondary Care Cut, and the Medicines Dispensed in Primary Care (NHSBA) data.</p> <p>Opt-outs will not be applied, as all participants included in the cohort have consented for their personal data to be shared with NHS Digital to obtain information from their electronic health records, and have not withdrawn their consent for sharing of their personal data with NHS Digital for this purpose.</p> <p>NHS Digital will transfer the linked record level data to the trial statistician on one occasion. NHS Digital will return pseudonymised data linked using the CTRU supplied Study ID. On receipt of data from NHS Digital, the trial statistician will transfer the data into a secure folder prior to using in statistical software for analysis. As a first step, the trial statistician will perform data cleaning in accordance with CTRU Standard Operation</p>	<p>The main analysis is due to be completed by March 2022, with the aim to publish main trial results in late spring, early summer 2022. Results will be published in open access and peer reviewed journals, including publication via the National Institute for Health Research's own journal library, the Lancet, the British Medical Journal (BMJ) and the European Heart Journal (EHJ). Results will also be presented at relevant conferences linked to cardiology and patient safety, including the European Society of Cardiology Congress (Summer 2022).</p> <p>Longstanding and ongoing engagement with stakeholders, including both scientific and policy-making audiences will provide a direct pathway to impact for the outputs of this research.</p> <p>The Patient-Led Steering Group will inform the dissemination strategy and its members will play an active role in the format and content of academic papers (specifically patient implications) and will present at local, regional and national conferences and wider stakeholder meetings.</p> <p>Only analyses featuring aggregated data with small number suppression will appear in outputs.</p> <p>The results and outputs of the study will be further communicated via the study team's websites, social media accounts and through other public promotion of research utilising the study team's networks, including clinical networks, scientific networks and charitable organisations with heart failure and medicines safety focus.</p> <p>Lay summaries will be added to the trial website (https://www.bradford.ac.uk/iscomat/) and the trial registry will be updated (https://doi.org/10.1186/ISRCTN66212970). Summaries will also be provided to participating sites. The Use My Data citation - "This work uses</p>	<p>Heart failure affects 26 million people globally and approximately 900,000 people in the UK. With the incidence of new diagnoses of the condition increasing, the ISCOMAT trial results have the potential to inform the treatment and care of heart failure patients when especially vulnerable during a care transition. The benefits from this dissemination will not be realised for health care until the main results of the trial are published in 2022.</p> <p>The benefits focus on patient care improvement, and dissemination will be led by the trial research team, including programme management group, trial management group and trial steering committee. The results, placed in open-access peer reviewed publications, are hoped will provide an evidence base with potential to impact on clinical guidance, including National Institute for Health and Care Excellence (NICE) guidelines on heart failure and medicines related care. It is hoped that benefits for health service commissioners will include provision of evidence to support future commissioning of community pharmacy services as well as the need for more effective optimisation of heart failure treatment, with associated health benefits. The aim of this is to ensure that patient medicines management is optimised, and the burden of cardiovascular disease is reduced through preventable cardiovascular events that occur in the period after patients with heart failure are discharged from hospital. Our findings are intended to be, with modifications, transferable to other patient groups who have long-term conditions, frequent hospital readmissions and polypharmacy.</p>	<p>Yielded Benefits is not a requirement for new applications.</p>

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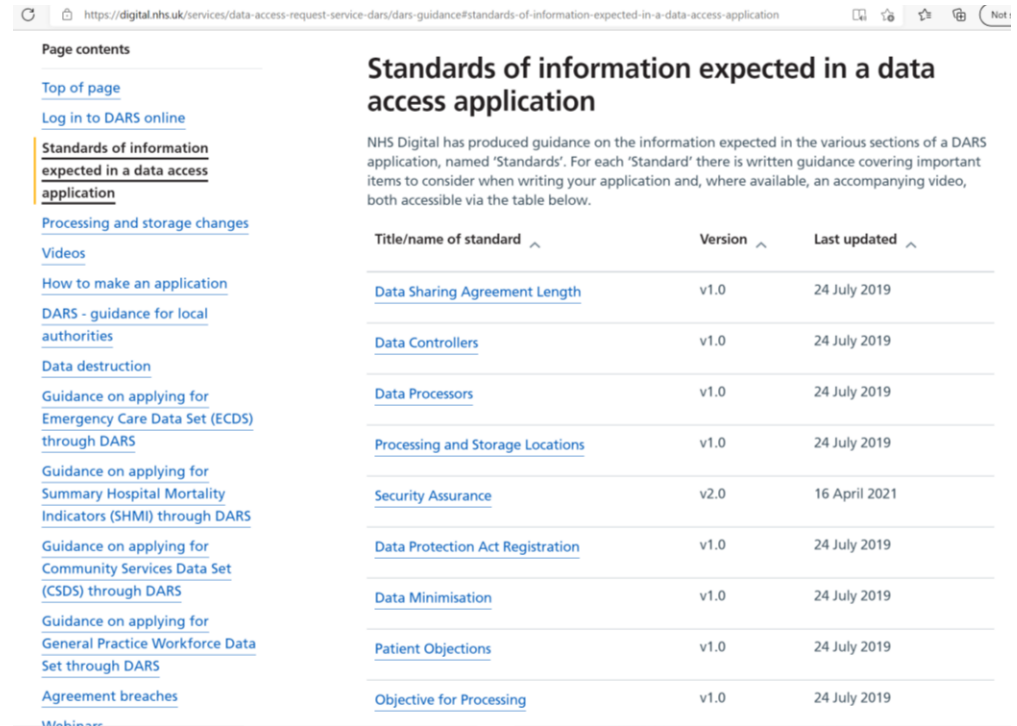
NHS Digital standards

All standards are available to the **public** on NHS Digital's website.

Every section of the Data Sharing Agreement has its **own standard** to assist with completing the DSA.

These standards are **owned by NHS Digital** and reflect prevailing law (primarily UK GDPR/DPA 2018) and policy.

They are **not** "IGARD's standards" but are the **objective "checklists"** that IGARD will have regard to.



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Standards of information expected in a data access application

NHS Digital has produced guidance on the information expected in the various sections of a DARS application, named 'Standards'. For each 'Standard' there is written guidance covering important items to consider when writing your application and, where available, an accompanying video, both accessible via the table below.

Title/name of standard ^	Version ^	Last updated ^
Data Sharing Agreement Length	v1.0	24 July 2019
Data Controllers	v1.0	24 July 2019
Data Processors	v1.0	24 July 2019
Processing and Storage Locations	v1.0	24 July 2019
Security Assurance	v2.0	16 April 2021
Data Protection Act Registration	v1.0	24 July 2019
Data Minimisation	v1.0	24 July 2019
Patient Objections	v1.0	24 July 2019
Objective for Processing	v1.0	24 July 2019

<https://digital.nhs.uk/services/data-access-request-service-dars/dars-guidance>

What might increase duration of your application

Identifiable information shared with NHS Digital

NHS Digital requirement to re-identification individuals

Data linkage, with cohort, across different datasets

Data extracts, rather than TRE

Not knowing what data you require

Onward sharing of data

Pandemic

Not providing all supporting evidence

Not having relevant contracts, security assurance, clarity on controller, inadequate privacy information

Not clear benefit to provision of health care or adult social care

Not complying with the standards

DATA SHARING AND RETENTION

Data sharing – primary use

Purpose

For safety reporting of the intervention(s) evaluated in the clinical trial

For licensing decisions of the intervention(s) evaluated in the clinical trial

To perform audit or to verify the results of the clinical trial.

To re-analyse the data to address emergent safety and validity questions, of the clinical trial

Process

Include purpose(s) in the DSA

Include details of data processors who will perform audit / re-analysis in DSA

Data Sharing – secondary use

Purpose

Secondary use, with other researchers

Process

Sub-license standard

Flow responsibilities of DSFC to the sub-licensee, via a sublicense agreement – include audit

Appropriate governance and review

Purposes of the provision of health care or adult social care or for the promotion of health

Data retention

New DSFC allows retention of data where required by Applicable Law – including Research Law

Enter into new DSA to cover retention period

5 year Archive DSA is currently available

Inform NHS Digital of any processors involved

Data Access Programme

“Ensuring NHS Digital has a simple trusted service that enables legal, timely and transparent access to data with the customers at the heart of the process”

5 workstreams:

End to End process - Map and design an end-to-end process for data access requests

Requesting access – streamline the data access process

Assurance model – requirements on what is needed to provide assurance that data can be shared

Data and technology – improve tools to deliver data

Engagement - Engage internal and external stakeholders

Summary

The landscape for access to data is complex and evolving

Work is ongoing to simplify, standardised and streamline requirements as much as possible

Applying existing standards enables researchers to complete high quality applications, and receive timely approval

Plan applications alongside other approvals

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QUESTIONS?