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

Valid DPA registration

DPA expiring within 2 months must have a plan to renew

### Data protection public register

**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:

- Domestic CCTV owners that register with the ICO are not required to publish their address, so searches based on addresses for:
- 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

**Download the register of data controllers**

**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 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)
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

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?

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
<table>
<thead>
<tr>
<th>Purpose</th>
<th>Objective</th>
<th>Processing</th>
<th>Outputs</th>
<th>Measureable Benefits</th>
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<tr>
<td></td>
<td>Purpose of data request</td>
<td>Dataflow between organisations</td>
<td>Peer review publications</td>
<td>New treatments for patients with a specific condition</td>
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<td></td>
<td>Other related projects</td>
<td>Legal basis for each flow</td>
<td>Conferences</td>
<td>Updates to clinical guidelines to inform patient care</td>
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<tr>
<td></td>
<td>Details and size of cohort</td>
<td>Data linkage with other data sources</td>
<td>Tailored summaries</td>
<td>Improved information for patients</td>
</tr>
<tr>
<td></td>
<td>Commercial purpose</td>
<td>Which organisations will access data</td>
<td>Level of data</td>
<td>More efficient / effective use of resource</td>
</tr>
<tr>
<td></td>
<td>Will data be shared?</td>
<td>How long will data be retained?</td>
<td>When outputs will be achieved?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Is linkage required?</td>
<td>What is the geographical areas where data will</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>be stored, processed, accessed</td>
<td></td>
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</tr>
</tbody>
</table>

**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

### Learn from others - Data Uses Register

#### Data Sharing Agreements

**Applicant Organisation:** University of Leeds

<table>
<thead>
<tr>
<th>Reference Number</th>
<th>Application Title</th>
<th>DSA Start Date</th>
<th>DSA End Date</th>
<th>Data Controller(s)</th>
<th>Solo/Joint Data Controller</th>
<th>Data Sub-Licensing Apply</th>
<th>For Commercial Purposes</th>
</tr>
</thead>
<tbody>
<tr>
<td>DARS-NIC-32207-F1950C05-V0.14</td>
<td>Improving the safety and continuity of medicines management at care transitions (ISCOMAT); a cluster Randomised Controlled Trial</td>
<td>20/04/2018</td>
<td>21/04/2019</td>
<td>University of Leeds</td>
<td>Solo Data Controller</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>DARS-NIC-332338-X1N2G-v0.9</td>
<td>Health related quality of life and clinical outcomes following acute myocardial infarction: linked EMMACE HES and Civil Registration Mortality Data</td>
<td>01/11/2020</td>
<td>31/10/2023</td>
<td>University of Leeds</td>
<td>Solo Data Controller</td>
<td>No</td>
<td>No</td>
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<tr>
<td>DARS-NIC-378115-P4L5Z-v0.9</td>
<td>Improving the safety and continuity of medicines management at care transitions (ISCOMAT); a cluster Randomised Controlled Trial</td>
<td>13/05/2021</td>
<td>12/05/2024</td>
<td>Bradford Teaching Hospitals NHS Foundation Trust, University of Leeds</td>
<td>Joint Data Controller</td>
<td>No</td>
<td>No</td>
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<tr>
<td>DARS-NIC-378523-Y5Q9L-v0.25</td>
<td>Routinely collected hospital admissions data for care home residents</td>
<td>01/06/2017</td>
<td>31/05/2020</td>
<td>Bradford Teaching Hospitals NHS Foundation Trust, University of Leeds</td>
<td>Joint Data Controller</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>DARS-NIC-378523-Y5Q9L-v1.2</td>
<td>Routinely collected hospital admissions data for care home residents</td>
<td>21/10/2020</td>
<td>20/04/2021</td>
<td>Bradford Teaching Hospitals NHS Foundation Trust, University of Leeds</td>
<td>Joint Data Controller</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>DARS-NIC-402417-M6Z5W-v0.4</td>
<td>Enumerating the impact of COVID-19 on cancer pathways: a robust evaluation of the NHS Digital Trusted Research Environment</td>
<td>10/04/2021</td>
<td>16/04/2023</td>
<td>Leeds Teaching Hospitals NHS Trust, University of Leeds</td>
<td>Joint Data Controller</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>DARS-NIC-404035-S5Y6Kv1.22</td>
<td>Improving the safety and continuity of medicines management at care transitions (The ISCOMAT Programme): Work Packages 1 and 2</td>
<td>07/12/2018</td>
<td>09/12/2020</td>
<td>Bradford Teaching Hospitals NHS Foundation Trust, University of Leeds</td>
<td>Joint Data Controller</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>DARS-NIC-49184-R3G9K-v0.4</td>
<td>QuantCode: Admitted Patient Care Data</td>
<td>01/10/2017</td>
<td>30/06/2020</td>
<td>University of Leeds</td>
<td>Solo Data Controller</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

- **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.
Learn from others - Data Uses Register

<table>
<thead>
<tr>
<th>Purpose Statements</th>
</tr>
</thead>
</table>

**DARS-NIC-378185-P4L5Z-v0.4**

**Objective for Processing**
- 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 Medical Management at Transitions of Care" (ISCOMAT).
- ISCOMAT has received a favourable ethical opinion, a funded by the National Institute for Health Research (NIHR) and is performed by a public authority. Bradford Teaching Hospital 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:
  - Article 6(1)(e): Specific task in the public interest, scientific or historical research or scientific purposes, with a basis in law.
  - Article 9(2)(j): Special category data used for "achieving the public interest, scientific or historical research or educational purposes", with a basis in law.

**Processing Activities**
- 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 the cohort for this data application.
- Consent documentation and subsequent amendments to it were reviewed and approved by the ISCOMAT Patient Led Steering Group.

**Expected Benefits**
- Heart failure affects 2.6 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 realized for health care until the main results of the trial are published in 2022.
- 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 guideline, 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 estimation of heart failure treatment, with associated health benefits. The aim of this is to ensure that patient management is optimized, 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.

**Yielded Benefits**
- Yarded Benefits is not a requirement for new applications.
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.

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

<table>
<thead>
<tr>
<th>Purpose</th>
<th>Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Secondary use, with other researchers</td>
<td>Sub-license standard</td>
</tr>
<tr>
<td></td>
<td>Flow responsibilities of DSFC to the sub-licensee, via a sublicense agreement – include audit</td>
</tr>
<tr>
<td></td>
<td>Appropriate governance and review</td>
</tr>
<tr>
<td></td>
<td>Purposes of the provision of health care or adult social care or for the promotion of health</td>
</tr>
</tbody>
</table>
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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Dr Macey Murray  macey.murray@ucl.ac.uk

QUESTIONS?