

How to make a good DARS application

Date 05 July 2017

Thank you for joining the webinar and we will be starting shortly.

Please ensure that you have also dialled in on telephone number 0203-478-5289 (Meeting ID 956 436 757#).

Throughout the session you can ask questions via the chat function.

Welcome

- Introductions:
 - Catherine Day, Principal Business and Operational Delivery Administrator
 - Dave Cronin, Senior Business and Operational Delivery Manager
- How the session will run:
 - How to ask questions via chat
 - Questions after the session
 - Your feedback
- *You will be muted on joining the call but you should all be hearing us!*

Agenda

- Who are we & overview of process
- What an application must have – pre-requisites
- What makes a good application – focus on Purpose/Methods/Outputs section
- Common issues with applications
- Questions

Role of NHS Digital

Our Vision

Our vision is to harness the power of information and technology to make health and care better

What we do

We are the national information and technology partner for the health and care system.

Our team of information analysis, technology and project management experts create, deliver and manage the essential technology infrastructure, digital systems, services, products and standards upon which health and care professionals depend.

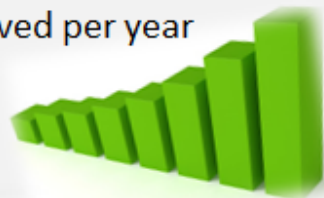
Over **500** active
agreements
managed through
DARS Online



Over **10,000**
data disseminations per
year, including HES, mental
health and PROMS



Over **1,000**
applications for data
received per year



86 monthly
data extract
customers

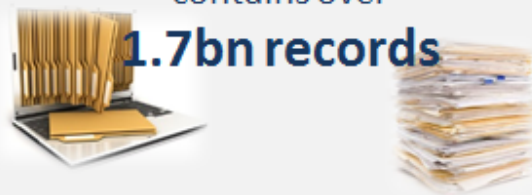


Over **1,100**
data releases for
medical research
disseminated every
year



Access to a range of
data products,
including HES which
contains over

1.7bn records



Over **230** active
medical research
studies



Customers include NHS & Social Care organisations, research, business intelligence companies and the wider life science sector – all for benefit of Health and Social Care

What an application must have...

- All applicable sections of the form filled in
- An active Data Sharing Framework Contract for all named Data Controllers
- Evidence of a legal basis for each data flow
- Security assurance for all Data Processors

Data Controller(s)

- Any organisation (or person representing an organisation) who can determine, alone or jointly, what will be done with the data should be named as a data controller
- Consider roles of committees, commissioners, funders, Principal Investigators, etc. in determining the above
- There may be multiple Data Controllers (Data Controllers in common or joint Data Controllers)

Data Processor(s)

- Name any/all organisations whose employees are accessing the data for any reason
- Include organisations providing data storage/back up facilities
- Where employees of a third party organisation have an honorary contract with a named Data Processor, their substantive employer may not need to be named as a Data Processor
 - however, we would require evidence of contractual controls regarding the conduct of the individual and an agreement with the substantive employer in respect of disciplinary proceedings in the event of a data security breach

Security Assurance

- IG Toolkit
 - Provide organisation code
- ISO 27001 Certification
 - Provide certificate – must be in date and cover the specified location(s)!
- System Level Security Policy
 - Provide relevant documents

Legal Basis

- Pseudonymised data
 - Typically data is disseminated under section 261(1) Health & Social Care Act 2012
- Identifiable data
 - Typically either:
 - Informed Participant Consent for sharing data with NHS Digital and data is disseminated under section 261(2)(c) HSCA 2012, or
 - Section 251 NHS Act 2006 support
 - May be other legal basis but applicant must provide this
- ONS data
 - Provided under Statistics & Registration Service Act 2007
 - Informed Participant Consent
 - Section 42(4) SRSA 2007
 - Approved Researcher Gateway

Mandatory Supporting Evidence

- For identifiable data
 - Evidence of favourable opinion by a Research Ethics Committee (REC) or evidence that REC review is not required
 - Any supporting documents associated with REC review – e.g. Study Protocol
 - To evidence informed consent
 - All iterations of participant information sheets and consent forms used.
 - If multiple iterations were used, provide details of what was used when and for how many participants

Mandatory Supporting Evidence

- For identifiable data
 - To evidence section 251 (NHS Act 2006) support
 - Copy of the application form submitted to HRA CAG (or predecessor)
 - Copies of all letters in response from CAG (e.g. Conditional Approval, Final Approval, Annual Reviews, amendments, etc.)
 - Evidence of Fair Processing notices
 - E.g. Participant newsletters, website notices, etc.

Purpose/Methods/Outputs

- Who/What is it for?
 - This section provides information on what data you require, why and what will be done with the data
 - This section is published if the application is approved
 - It is replicated in the Data Sharing Agreement to convey the scope of permitted use of the data
 - It needs to be clearly understood by:
 - The Data Applications team
 - The approvers within NHS Digital
 - The Independent Group Advising on the Release of Data (IGARD)
 - The public
 - Auditors
 - You

Purpose/Methods/Outputs

- DO
 - Write in plain English
 - Avoid jargon and excessive acronyms
 - Write in third person style
 - [The organisation] will use the data for its programme of research ✓
 - We will use the data for our STIX study ✗
 - Make clear unambiguous statements that are not open to interpretation
- DO NOT
 - Assume knowledge of your industry or subject matter by the reader

Purpose/Methods/Outputs

- DO
 - Focus on the data from NHS Digital for which you require access
 - The data may be the only data being used or used in conjunction with data collected from other sources
 - The use of data from NHS Digital may be the main part of the project/purpose or a component of a wider programme of work
 - Be clear about what processing, sharing of data, outputs and benefits relate to the data from NHS Digital
- DO NOT
 - Provide excessive information about the wider programme/ project/purpose that is not directly relevant to the use of the data from NHS Digital data
 - Some background information may be necessary but keep it concise

Purpose/Methods/Outputs

- The Health & Social Care Act 2012 as amended by the Care Act 2014 dictates that NHS Digital may only release data for use for the benefit of health and social care and not for solely commercial purposes
- In the Purpose/Methods/Outputs section you must explain how your proposed use of the data will benefit health and social care
- DO NOT presume it will be obvious how benefits will be achieved
 - E.g. It will not be assumed that publishing findings in a peer reviewed journal will benefit health. You need to elaborate on how doing this will logically lead to measurable benefits.

Purpose/Methods/Outputs

- Ensure you provide a clear link between:
 - the data you are requesting,
 - the objectives for requesting the data,
 - the outputs to be produced and
 - the benefits to be achieved

Objectives for Processing

- Explain why you need the data
- Explain the organisations involved and their roles
- Explain why the work is being undertaken (with reference to intended benefits to healthcare)

Processing Activities

- Describe what happens with the data
- Be clear about what data you are referring to including what identifiers are present if applicable
- At each stage of processing be clear:
 - Who has access to the data?
 - Where is the data?
 - In what form?
 - For what purpose?

Processing Activities

- Where it adds clarity, describe what will NOT happen with the data – e.g.
 - The data will not be linked with any record level data
 - The data will not be made available to any third parties other than those specified except in the form of aggregated outputs with small numbers suppressed in line with the HES Analysis Guide

Processing Activities

- Justify why the full amount of data requested is the minimum amount of data required
- Types of data minimisation include filtering to:
 - Specific individuals – e.g. individuals with specific diagnoses and/or above, below or between specific ages
 - Specific geographical areas – e.g. selected regions rather than national data
 - Specific health conditions/diagnoses – e.g. select all hospital episodes involving x diagnosis
 - Specific time periods – e.g. episodes within a 5/10/15-year timeframe

Specific Outputs Expected

- What do we mean by outputs?
 - Anything you produce after processing the data such as:
 - Reports
 - Publications
 - Presentations
 - Information to the public
 - Tools
- What do we not mean by outputs?
 - Analyses – e.g. “The outputs will be mortality outcomes after 30 days” **x**

Specific Outputs Expected

- What do we need to know about the outputs?
 - Target date for completion
 - Target audience(s)
 - Purpose of the output(s)
 - “The output will be peer reviewed journal publications..” **x**
 - “An output will be a report outlining the project’s findings which, subject to acceptance, will be published in high impact peer review journals such as the Lancet” **✓**
 - “An output will be a report of findings and recommendations to the Department for Health and NICE” **✓**

Specific Outputs Expected

- If applicable state: “All outputs will contain only data that is aggregated with small numbers suppressed in line with the HES Analysis Guide.”
- If you are amending, extending or renewing a previous Data Sharing Agreement, have any outputs already been produced?

Specific Measurable Benefits

- Explain who will do what with the outputs disseminated as described above to directly or indirectly achieve benefits to health and/or social care including:
 - What is the logical sequence of events that would need to take place in order for such benefits to be achieved including actions/decisions by third parties?
 - Why is it reasonable to expect that the expected benefits will be realised (e.g. has there been prior engagement with key decision/policy makers?)?
 - What are the actual expected benefits and how do these benefit healthcare users (e.g. cost/efficiency savings which would enable commissioners/care providers to reallocate funding to other areas of care benefitting care users; improved quality of care/reduced waiting times/improved ability of care providers to meet demand; improved survival rates; improved quality of life post-treatment/care, etc.).
 - Clarify the expected magnitude of the impact. i.e. How many care users are expected to benefit? What is the expected impact in terms of cost/efficiency savings?

Specific Measurable Benefits

- Do not presume benefits to health will be obvious
 - “Findings will be published in high impact peer review journals...” **x**
 - “Findings will be directly fed back to NHS policy makers...” **x**
- For an extension/renewal/amendment request or a request related to a long-running programme of work, specify whether any benefits have been achieved to date
- Avoid listing publications; focus on the impact of published findings to date or expected impact of planned publications

Common Issues

- Inadequate information in the 'Outputs' and 'Benefits' sections to justify release of the data for the benefit of health/social care
- Data minimisation - Insufficient justification for the amount of data requested
- Lack of clarity over roles and involvement of other organisations
- Consent materials do not provide enough clarity about the data and organisations involved; the sharing of data with NHS Digital; of participants' right to withdraw, and of the process to withdraw

Tips

- Check out our Register of Approved Data Releases at:
<http://content.digital.nhs.uk/dataregister>
- It contains copies of the 'Purpose/Methods/Output' statements of approved applications

Any Questions?



Future Webinars

How to make a DARS application – DARS Online guidance

9th August 2017

Other dates to be confirmed

How to make a good DARS application – purpose statement guidance

9th August 2017

Other dates to be confirmed

Fair Processing

Changes around access to ONS data directly

DARS Online Developments

Dates to be confirmed

LAPH Data Access – a wider understanding of the data sets available and further updates

Dates to be confirmed

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for better health and care