# Workshop: Use of routine data in trials

Presenters and their contact details:


| | | |
|---|---|---|
| Fiona Lugg-Widger | Cardiff University | LuggFV@cardiff.ac.uk |
| Suzanne Hartley | University of Leeds | S.Hartley@leeds.ac.uk |
| Louise Dunn | NHS Digital | data.applications@nhsdigital.nhs.uk |


Link from the ICO regarding defining a data controller and processor as discussed in the meeting:
https://ico.org.uk/media/for-organisations/documents/1546/data-controllers-and-data-processors-dp-guidance.pdf

# Introduction to routine data

*"Each person in the world creates a Book of Life. This Book starts with birth and ends with death. Its pages are made up of the records of the principal events in life...Record linkage is the name given to the process of assembling the pages of this Book into a volume"*

Dr. Halbert Dunn 1946

**Routine Data**

Information that has been collected routinely for day to day administrative purposes

**Linked Data**

Data linkage brings together information from two different records that are believed to belong to the same person

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# Introduction to routine data

Cardiff University – Centre for Trials Research
Prifysgol Caerdydd – Canolfan Ymchwil Treialon

Cancer trials utilising ONS death data:

**FRAGMATIC**

**FOLFERA**

**AML-15**

**AML-16**

**SCOPE 1**

**SCALOP**

## Centre for Trials Research

### Building Blocks trial

Evaluation of FNP in England
***F**amily **N**urse **P**artnership*

### Building Blocks: 2-6

Longer term consequences of the FNP programme using routine data

### FNP Scotland

Evaluation of FNP in Scotland

### POOL

Establishing the safety of waterbirth for mothers and babies

## Division of Population Medicine Collaborations

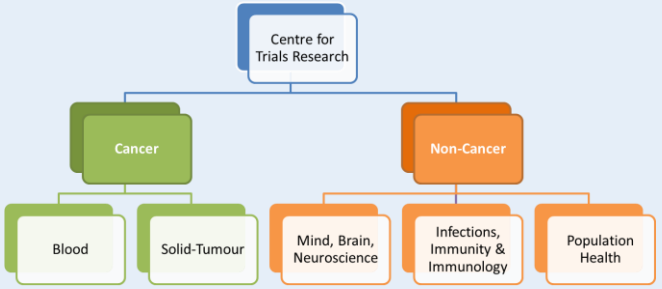
### LUCI Study

Long term follow-up of children with UTI using routine data

### HealthWise Wales

Doeth am Iechyd Cymru HealthWise Wales

Welsh national cohort using prospectively collected data linked with NHS records

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# Introduction to routine data

*Local Health Board data – Radiology*

*Health data in **England** (Inpatient, Outpatient & Emergency care)*

*UK mortality data*

***Dept. of Health:** Abortion statistics team*

Clinical Practice Research Datalink (**CPRD**) – *GP data in the **UK***

Secure Anonymised Information Linkage – *Health & Education data in **Wales***

**National Pupil Database** - *Education and Social Care data in **England***

EuroKing & **NNRD** National Neonatal Research Dataset – ***UK** Maternity & neonatal data*

**eDRIS** electronic Data Research and Innovation Service – *Health data in **Scotland***

**EAS** – *Education and Social Care data in **Scotland***

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# BENEFITS TO USING ROUTINE DATA

- Data is already available
- Reduces burden on participant | research nurse | GP
- Objective assessments

**But…..**

# Introduction to routine data


Building Blocks: 2-6

Longer term consequences of the FNP programme using routine data

## Study aim

To determine the effectiveness of the FNP programme in reducing objectively measured **medium-term maltreatment outcomes** when compared to usually provided health and social care alone using **routine data**.

**Study Design:** Data linkage study with an additional 4 year follow up

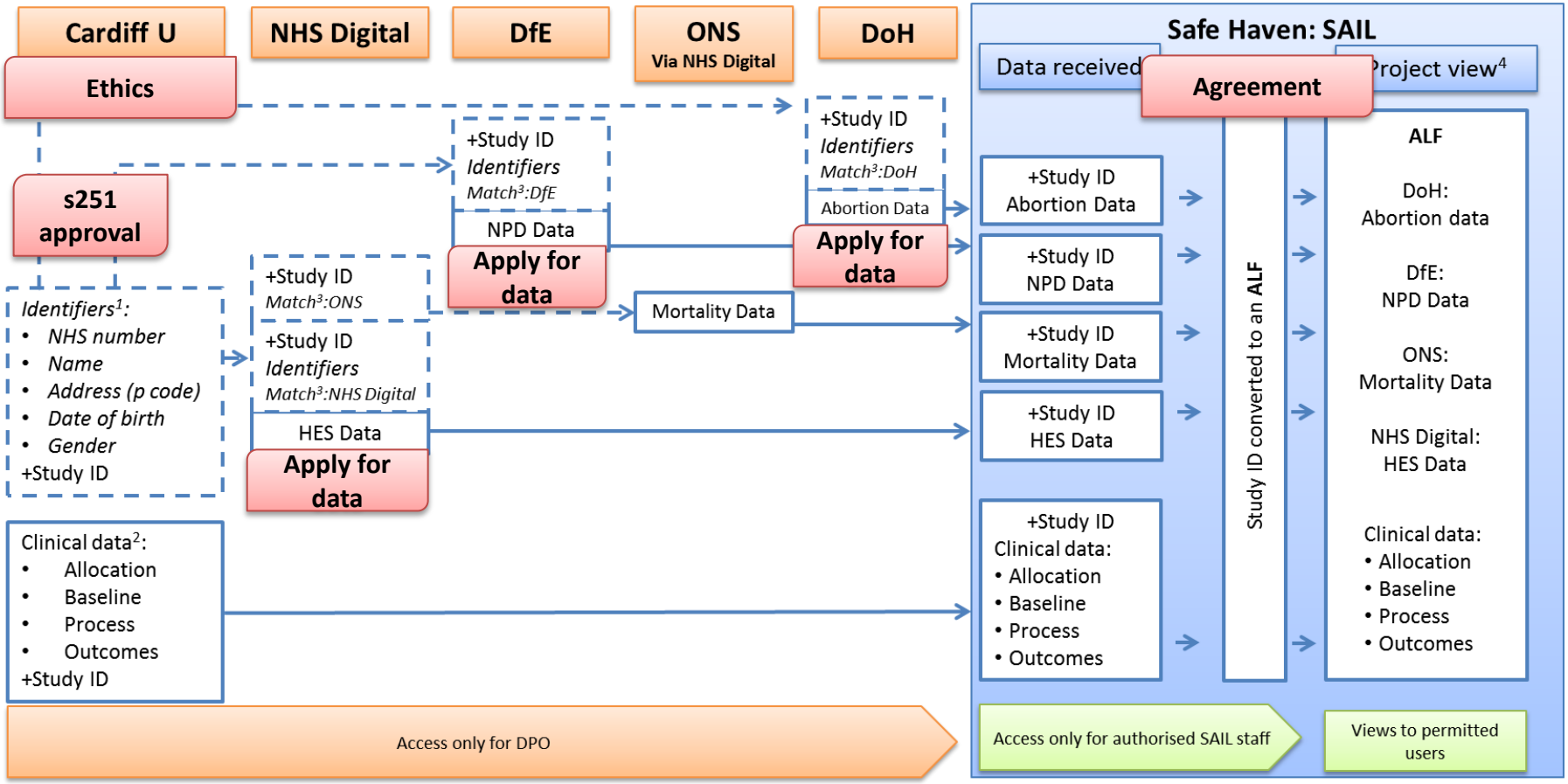
**Participants:** n=1,563 mothers/children exiting BB1 trial

**Outcomes:**

- Objective and associated measures of maltreatment
- Intermediate FNP programme outcomes
- Child health, developmental & educational outcomes

Lugg-Widger FV et al. 2017. Assessing the medium-term impact of a home-visiting programme on child maltreatment in England: protocol for a routine data linkage study. *BMJ Open, 7(7) e015728.*

# Introduction to routine data




- *Sensitive person identifiable information*
- +Study ID converted to **ALF**
- **ALF: Anonymised Linking Field**

DPO: Data Providing Organisation
*Identifiers*: i.e. specifically for linkage
SAIL: Secure Anonymised Information Linkage

1 De-identification and Standardisation (DIAS) applied (e.g. date of birth to week of birth)
2 Hosted on SAIL secure platform
3 Information Centres confirm matching of BB/NHS/ONS/DfE identifiers

Building Blocks: 2-6
Longer term consequences of the FNP programme using routine data

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National Institute for Health Research

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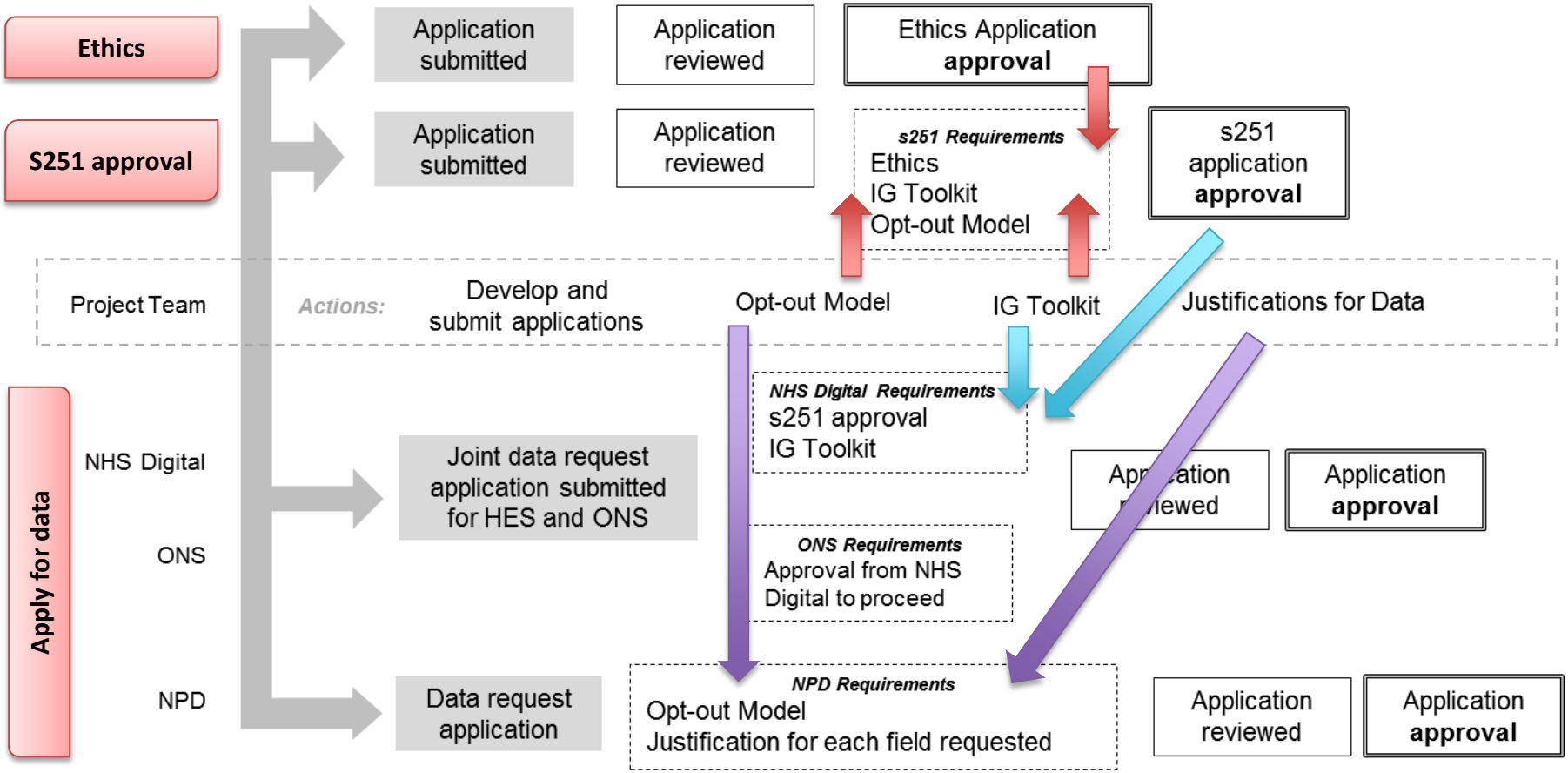


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Building Blocks: 2-6
Longer term consequences of the FNP programme using routine data

NHS National Institute for Health Research

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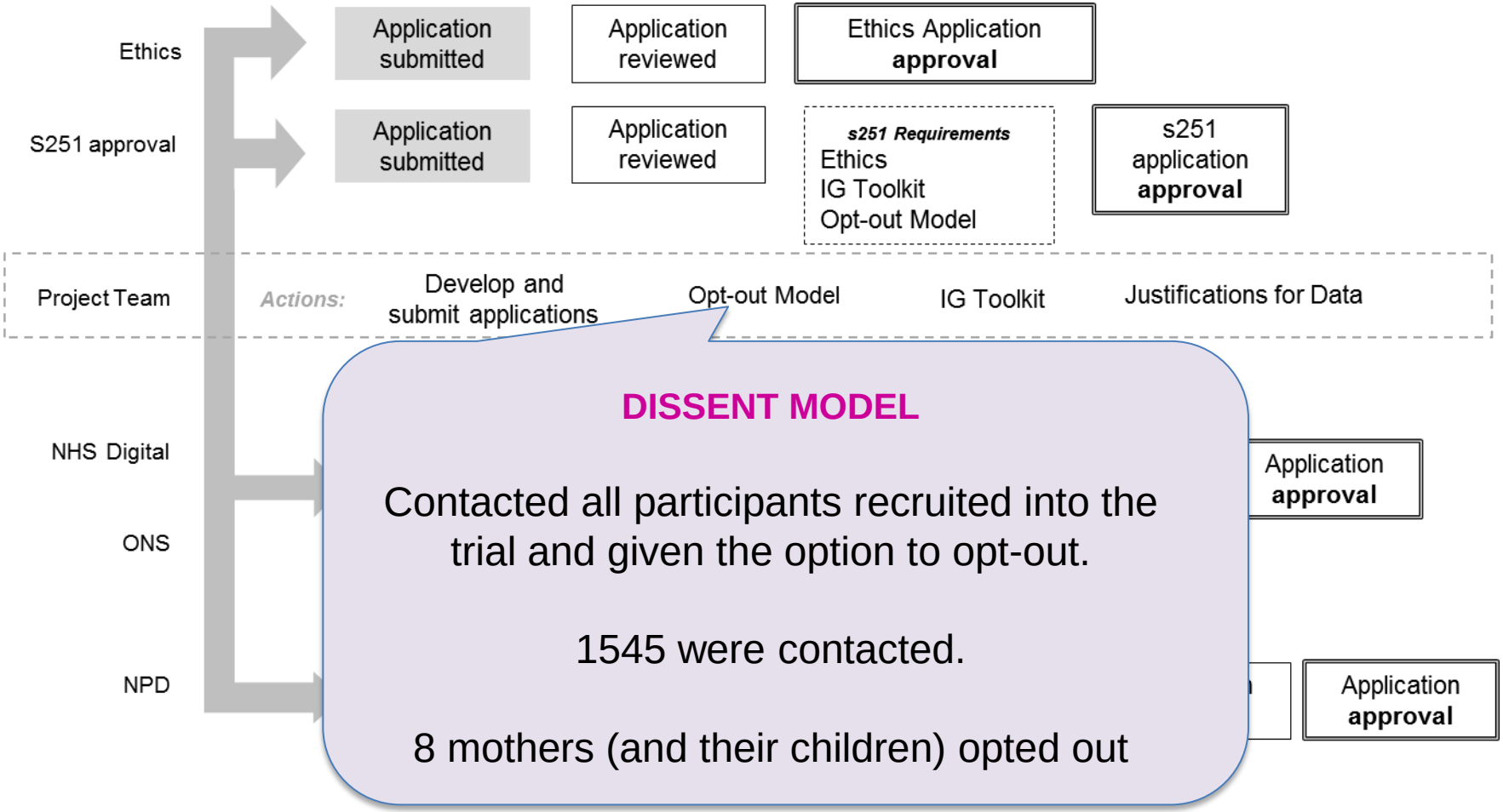


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Building Blocks: 2-6
Longer term consequences of the FNP programme using routine data

National Institute for Health Research

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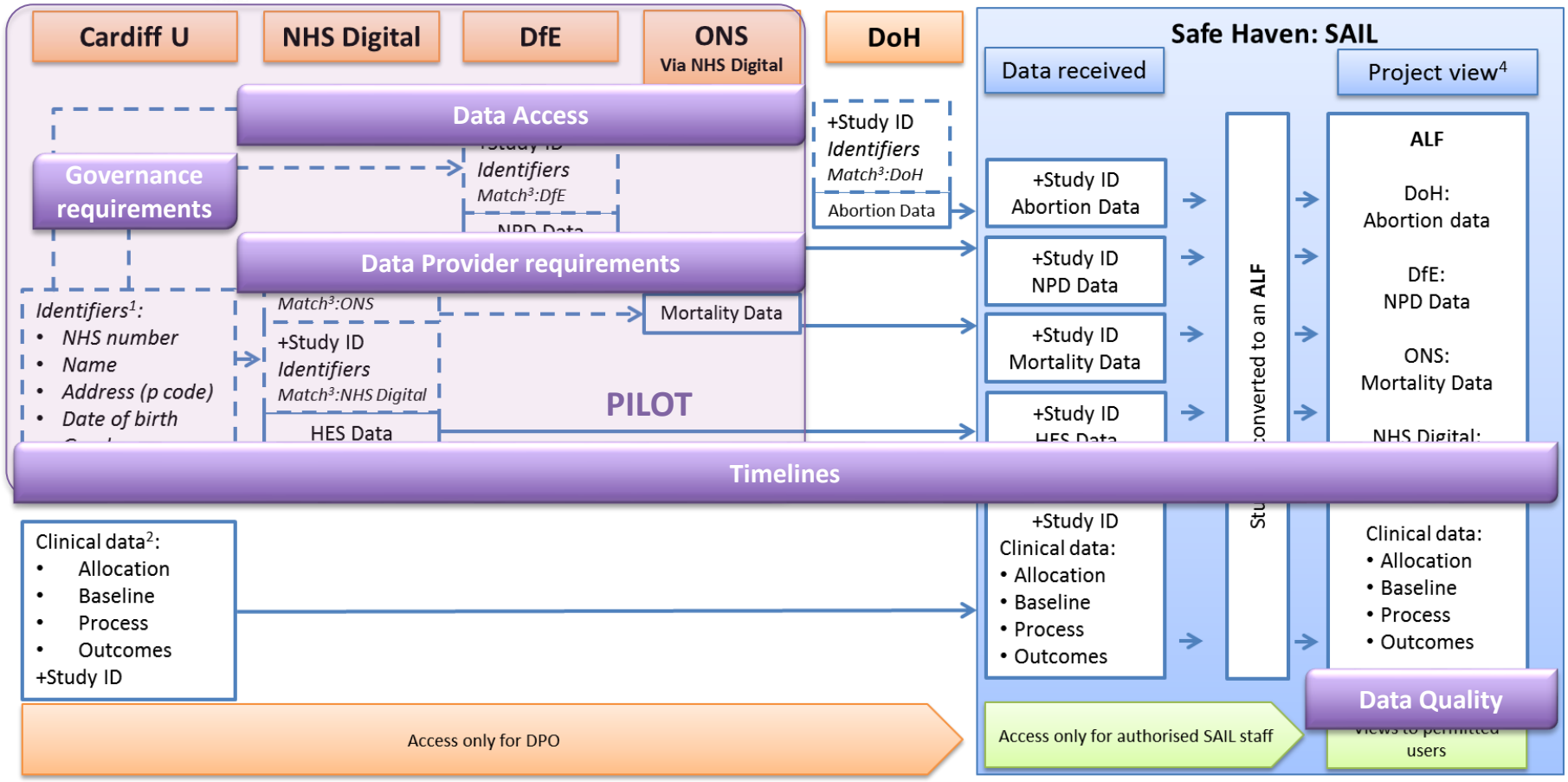


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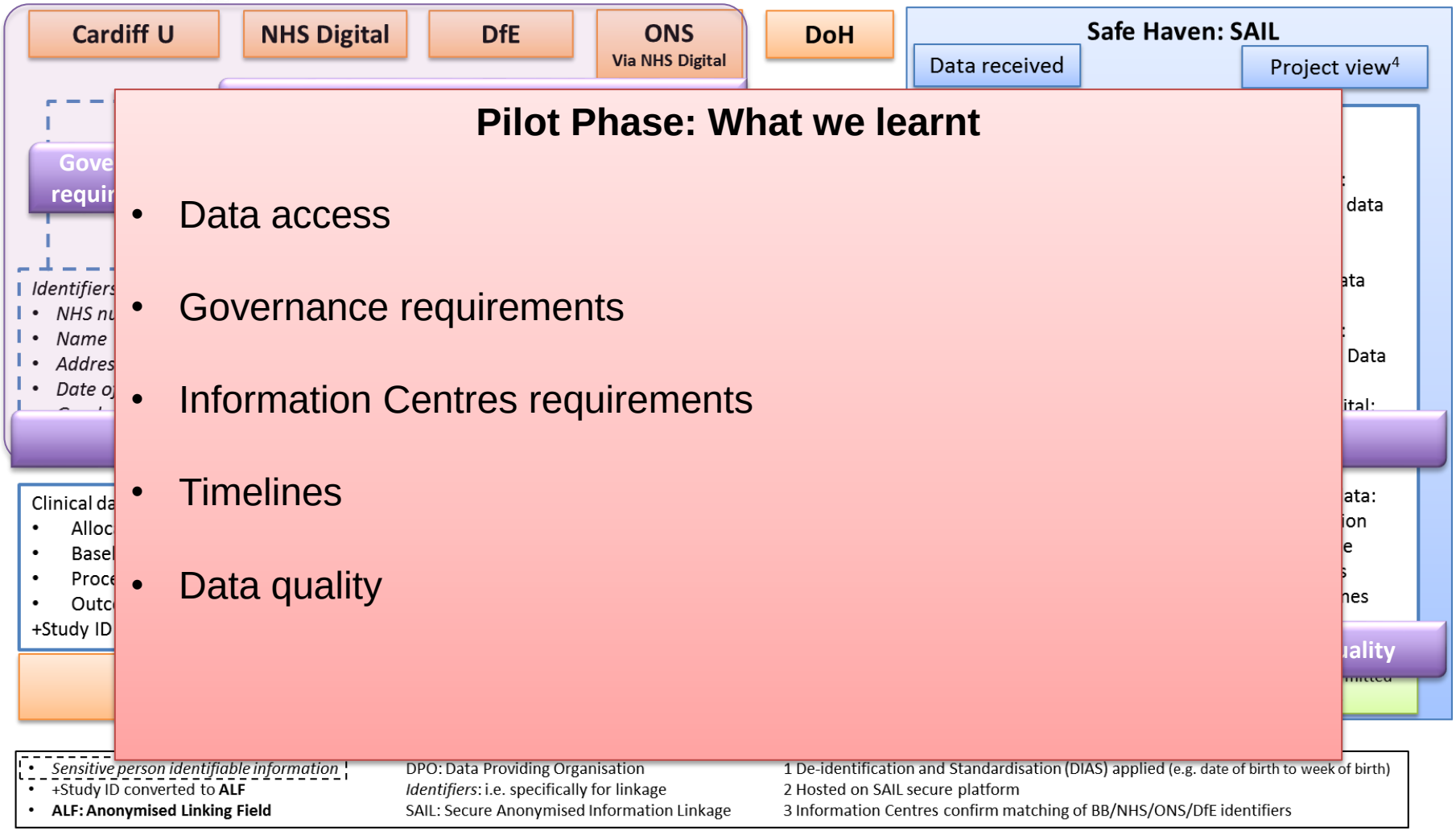
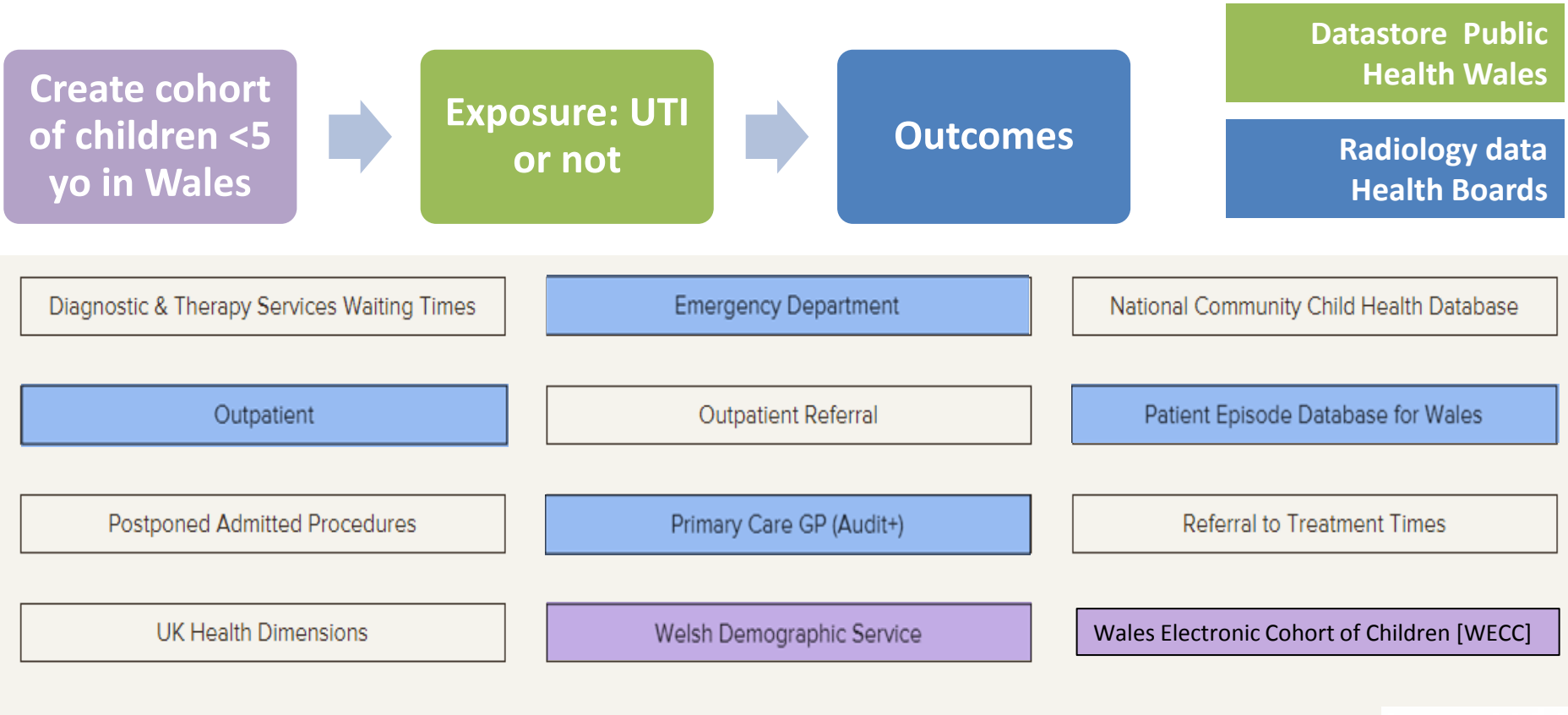



Lugg-Widger FV et al. 2018. Assessing the impact of specialist home visiting upon maltreatment in England: a feasibility study of data linkage from a public health trial to routine health and social care data. *Pilot and feasibility studies, 4(1), p.98.*

# Introduction to routine data

**Research Question 1**: Does childhood UTI (Urinary Tract Infection) lead to renal scarring and other long term-complications in **routinely sampled** children?

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LUCI Study
Long term follow-up of children with UTI using routine data

**Research Question 2:** Are outcomes different for children with a childhood UTI identified through routine sampling compared to systematic sampling ?

Create cohort

SAIL Databank

tastore Public Health Wales

spital Episode ics NHS Digital

Radiology data Health Boards

Study data

## What we learnt

- Definitions take time
- Roles of staff are different
- Data applications / providers differ

s251 approval

Ethics

Compare with DUTY & EURICA participants


LUCI Study

Long term follow-up of children with UTI using routine data

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# Recommendations

| Theme | Challenge | Resolution/Addressed how | Risk[1] |
|---|---|---|---|
| 1. Data application process | Adapting to changes over time | Be aware of any changes by signing up to newsletters, email distribution lists. | Project |
| | Length of application process | Start discussions with data providers early on, factor in timelines at the funding application stage. | Project |
| | Different application requirements for difference centres | Resource this period of time appropriately and learn from other researchers. | Project |
| 2. Project timelines | Unpredictability | Start discussions with data providers early on to be aware of additional delays. | Project |
| 3. Dependencies and considerations related to consent | Ensuring Fair processing over long term | Consider using other methods of communication such as websites and seek data provider input early on to discuss acceptable options. | Project |
| | Comprehendible vs. comprehensive | Ensure documentation receives review from a lay representative and seek data provider input early on. Emphasis should be on it being understood. Formally test adequacy where possible. | Project |
| 4. Information Governance | Differences across providers | ISO 27001 certification; Consider use of data safe havens to securely hold the data for the project. Appropriately resource time to implement the DSP Toolkit. Ensure stakeholders in the broader organisation (e.g. outside of the applying department) are involved in planning / consultation. | Project & Organisation |
| 5. Contractual | Compliance with numerous Data Providers' contractual requirements | Development of standard operating procedures intrinsic to the department to address requirement. | Project & Organisation |
| | Long-term data retention | Appropriately cost studies to enable long-term retention. Seek input from data providers. | Project & Organisation |
| | Oversight of all requirements from all providers | Employ/fund a member of staff to take responsibility for ensuring policies and procedures in the department have consideration for all contractual requirements. | Organisation |

1. Communication (with data providers, newsletters, twitter, publications)
2. Be realistic about timelines
3. Think about consent / fair processing as early as possible
4. Get your organisation ready
5. Review contracts, assess against your processes, consider the costs and request support

Lugg-Widger et al. 2018. Challenges in accessing routinely collected data from multiple providers in the UK for primary studies: Managing the morass. IJPDS. *3 (3)*

Clinical Trials Research Unit


University of Leeds

**UKTMN**

# Goal of this Session

By the end of this session, you will have gained an understanding of

- Organisation requirements to receive data
- Project requirements to get your application ready

And hopefully:

- Improve the quality (and speed) of an application to receive data from NHS Digital

# Organisational – Define the data controller

## Data Controller

a) The natural or legal person, public authority, agency or any other body;

b) which alone or **jointly** with others;

c) determines the purposes and means of the processing of personal data.

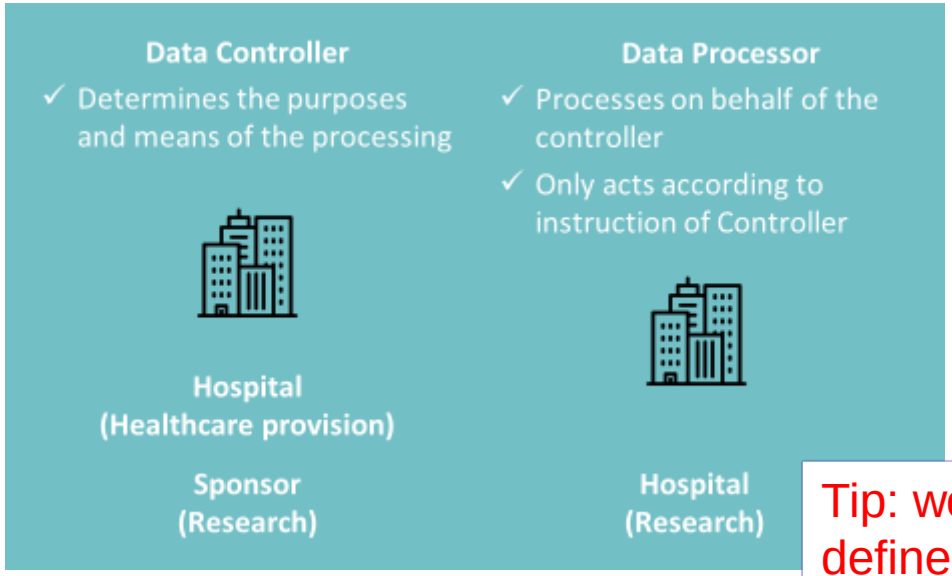
d) Several organisations can work as joint data controllers to make decisions on **why** and **how** the personal data is processed.

## Data processor

a) Processed data on behalf of the data controller

b) Only acts according to the instruction of the data controller

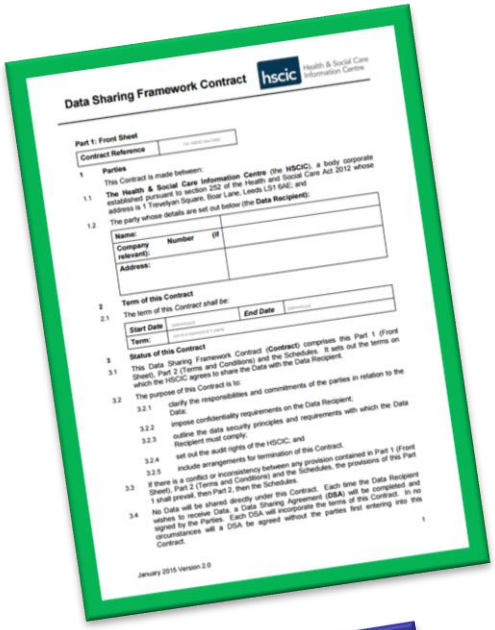
# Data controller vs Data Processor




Tip: work with your collaborators to define the Data Controller and document this in the application form.

Check the collaboration agreement for clarity on roles and responsibilities. This should have improved post-GDPR!

# Data Sharing Framework Contracts


Data Sharing Framework Contract

hscic Health & Social Care Information Centre

Part 1: Front Sheet

Contract Reference

1 Parties

1.1 This Contract is made between:

The Health & Social Care Information Centre (the HSCIC), a body corporate established pursuant to section 252 of the Health and Social Care Act 2012 whose address is 1 Trevelyan Square, Boar Lane, Leeds LS1 6AE; and

1.2 The party whose details are set out below (the Data Recipient):

Name:

Company number (if relevant):

Address:

2 Term of this Contract

2.1 The term of this Contract shall be:

Start Date

End Date

Term:

3 Status of this Contract

3.1 This Data Sharing Framework Contract (Contract) comprises this Part 1 (Front Sheet), Part 2 (Terms and Conditions) and the Schedules. It sets out the terms on which the HSCIC agrees to share the Data with the Data Recipient.

3.2 The purpose of this Contract is to:

3.2.1 clarify the responsibilities and commitments of the parties in relation to the Data;

3.2.2 impose confidentiality requirements on the Data Recipient;

3.2.3 outline the data security principles and requirements with which the Data Recipient must comply;

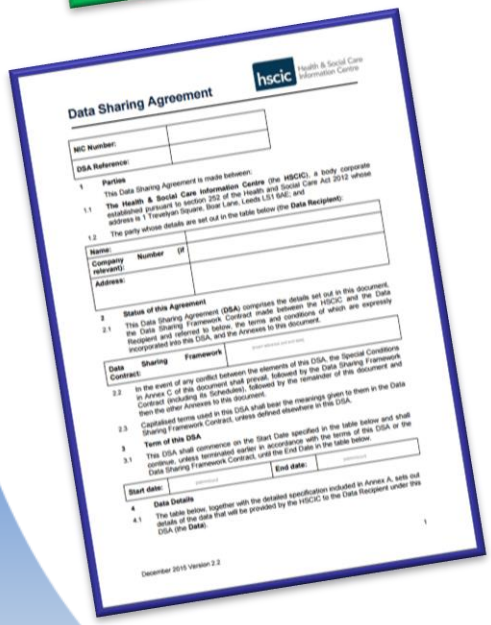
3.2.4 set out the audit rights of the HSCIC; and

3.2.5 include arrangements for termination of this Contract.

3.3 If there is a conflict or inconsistency between any provision contained in Part 1 (Front Sheet), Part 2 (Terms and Conditions) and the Schedules, the provisions of this Part 1 shall prevail, then Part 2, then the Schedules.

3.4 No Data will be shared directly under this Contract. Each time the Data Recipient wishes to receive Data, a Data Sharing Agreement (DSA) will be completed and signed by the Parties. Each DSA will incorporate the terms of this Contract. In no circumstances will a DSA be agreed without the parties first entering into this Contract.

January 2015 Version 2.0


Data Sharing Agreement

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NIC Number:

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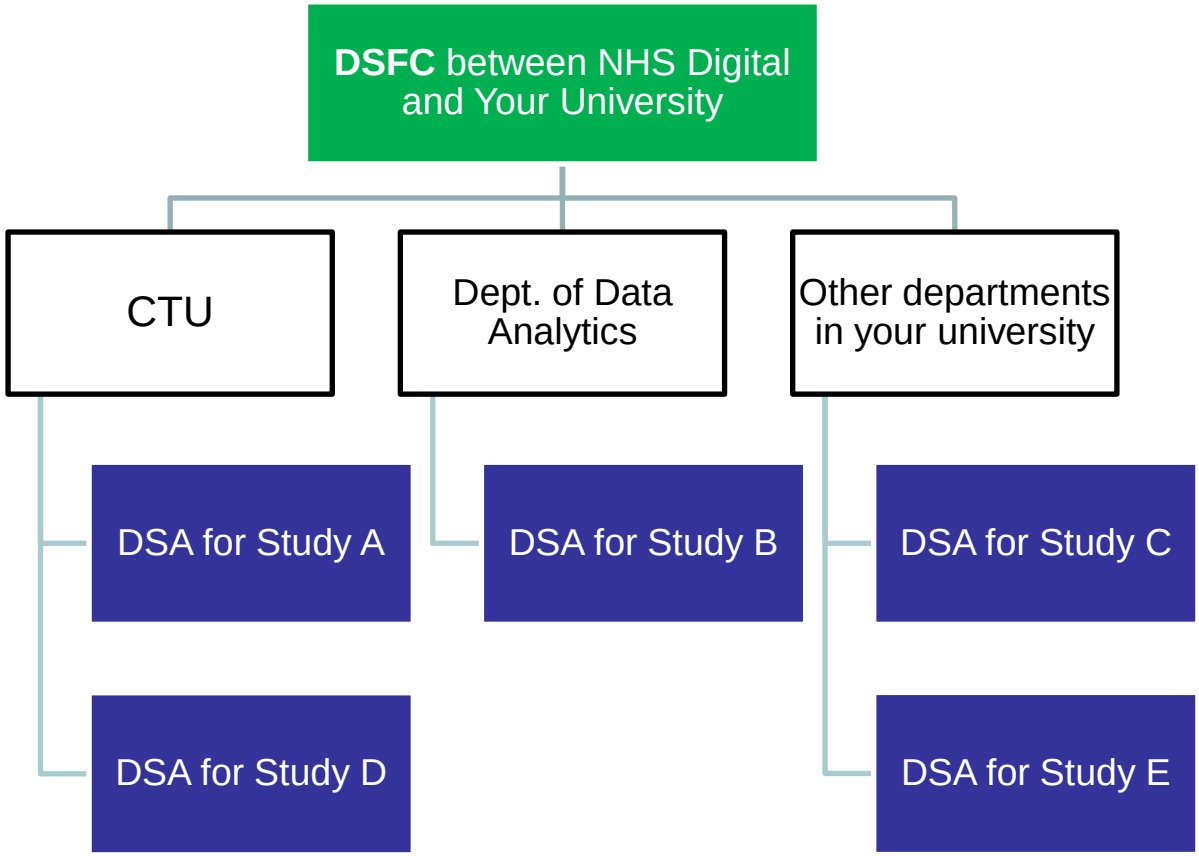
Start date:

End date:

4 Data Details

4.1 The table below, together with the detailed specification included in Annex A, sets out details of the data that will be provided by the HSCIC to the Data Recipient under this DSA (the Data):

December 2015 Version 2.2

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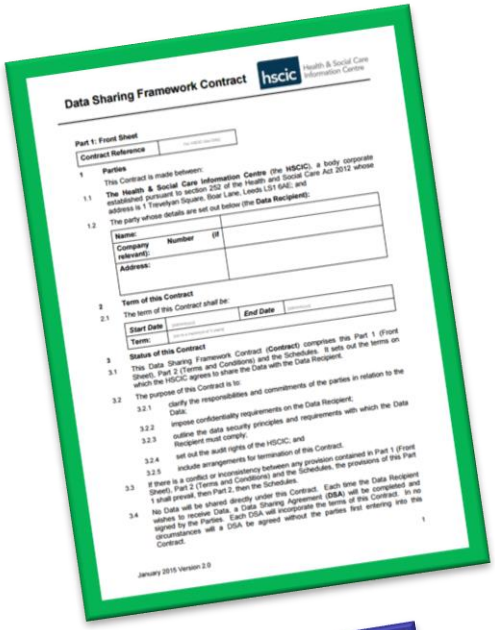
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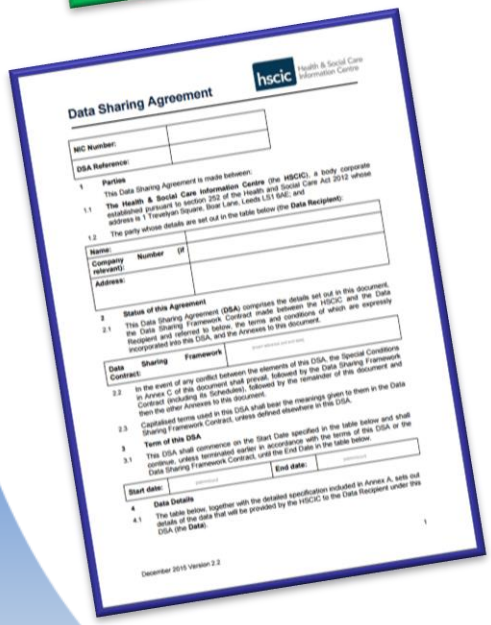
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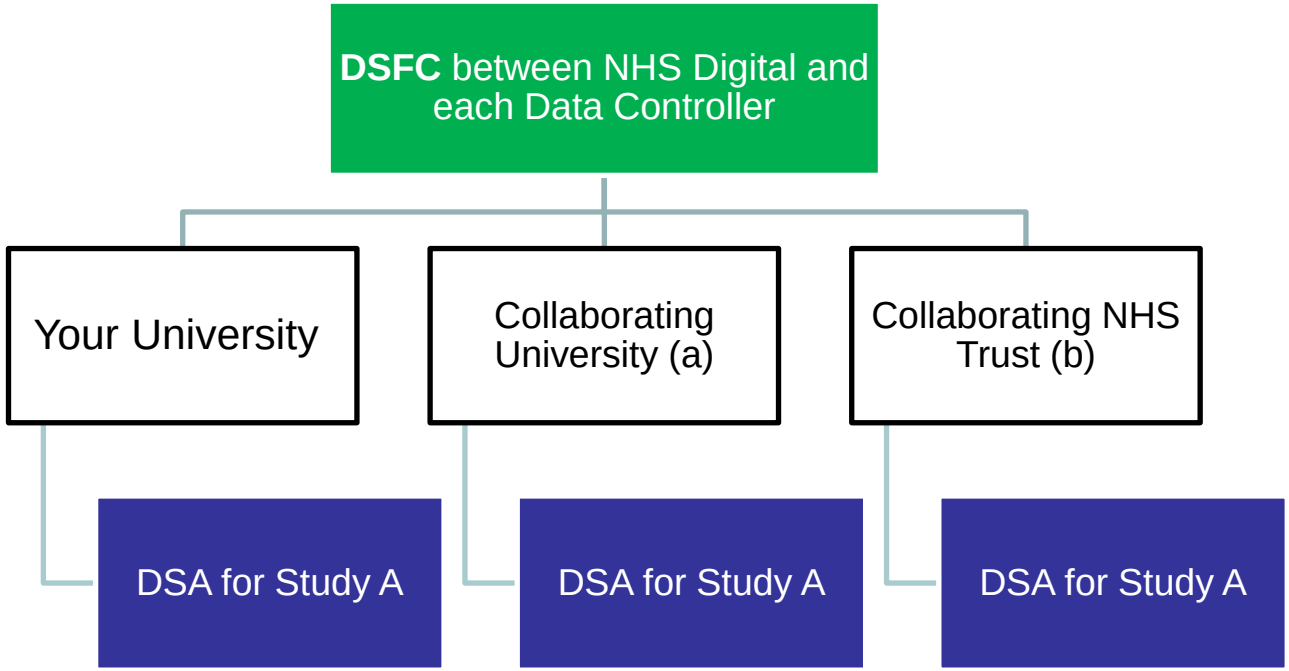


Tip: find out from your contracts team who is responsible for signing these contracts and give advanced notification of your intention to apply to NHS Digital for data.

Tip: Joint data controllers needs to have signed up to the same version of the DSFC.

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# Organisation – security assurances

- Technical security measures are needed to ensure the patient data is safe and secure.
- Arrangements for storage, access, back-ups and disaster recovery, and destruction of data.
- This is in addition to the Data Security and Protection (DSP) Toolkit (Information Governance Toolkit / System Level Security Policy).

Tip: find out from your IS team who has this responsibility for IS security arrangements within your organisation and give advanced notification of your intention to apply to NHS Digital for data.

# Organisational - Lawful basis for processing data

**Article 6**

e. Task in the public interest

**Article 9**

j. Archiving in the public interest, scientific or historical research or statistical purposes

- Public bodies, such as Universities, are paid for from the public purse to undertake tasks which are considered to be in the public interest.
- Public bodies can rely on Task in the Public interest when processing personal data for the purpose of health research.
- Document justification eg. public research purposes established by University Charter.

# Organisational - Safeguards for health research

# Project level – considerations for patient information

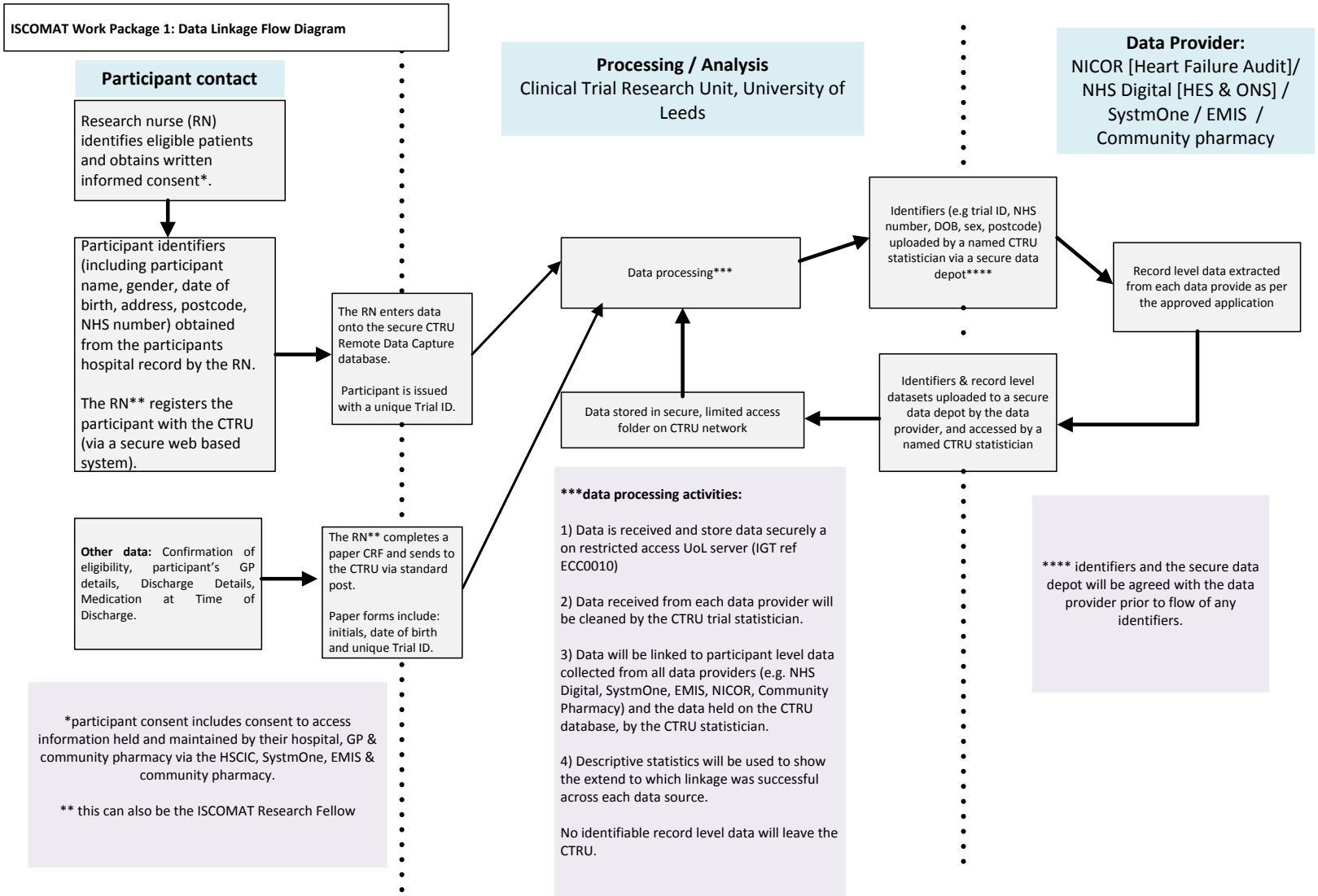
- Privacy notice
- Data Controller
- Categories of personal data
- Where data is collected from (i.e. source of data)
- Purposes of processing
- Sharing
- Subjects rights in respect of the processing
- How to withdraw
- How to complain / data protection officer

Tip: keep communication routes open – newsletters, websites – to facilitate contact with participants about how their personal data is processed.

# Project level – Data flow

- Know the data items required and how these will answer your research question
- Detail data processing activities from the point of receipt to destruction.
- Describe the role of collaborators – the why and how
- Describe intention to link data from NHS Digital with data from other sources, including the data collected direct from the hospital records, or from a patient, or another data provider.
- Detail in patient information that personal data will be shared with NHS Digital (or other data providers) to obtain information from electronic health records, or intent to share anonymised data for secondary research
- Detail in patient information what “rights” a patient has in the how their personal data is handled for example, what happens to their data if they decide they no longer want to take part in the study and who do they inform.
-

# Example data flow

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# Project level – benefit

- Demonstrate a benefit to health and social care
  - What is the problem?
  - Why is the research important in terms of improving the health of the public and/or to patients and the NHS?
  - Why is the research needed now?

Tip: This may have been included in your funding application

# Project – output

What is your expected output / impact?

- Maximise impact amongst all stakeholders – patient groups, clinical teams, service providers and commissioners
- Academic: presentations, journal publications – target journals?
- Systematic reviews / Cochrane Guidelines
- Clinical Practice / policy > evidence based practice
- When will the impact be achieved?

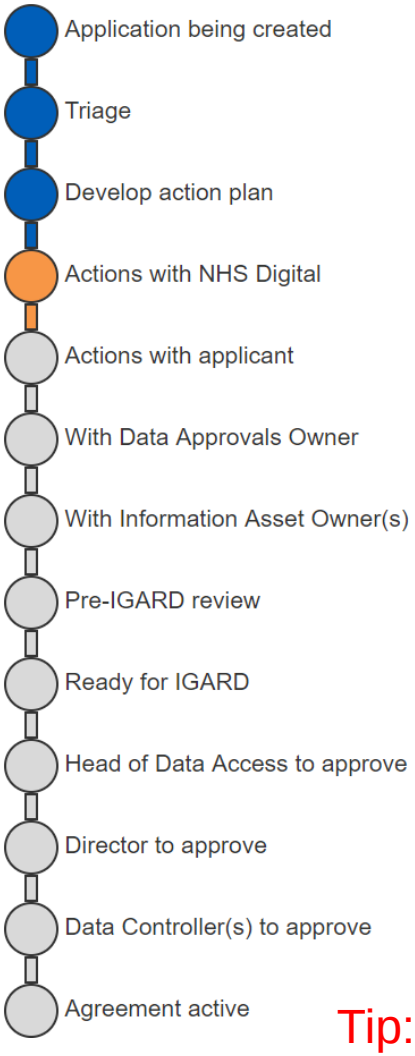
Tip: This may have been included in your funding application

# Project level – main cost drivers

- Costs will vary per application
- Depend on number of datasets, number of years of data, number of disseminations, linkage
- How long you will retain the data

Tip: Contact NHS Digital at the grant application stage (or as soon as you know about the application!) to get an estimate of costs, and give early notification of the data access request.

# Project level – timelines




- Timeline will vary depending on content of application and organisational readiness.
- NHS Digital are committed to a 60 Day Service Level Agreement
- Data Approvals Owner and Case Officer assigned to each request and support request from receipt to IGARD review.
- IGARD meet weekly
- Minutes from IGARD meetings, detailing the decisions for each data requests, are published and provide useful information on common issues with data access requests, and how these can be avoided or resolved.

Tip: Contact NHS Digital as soon as possible to give early notification of the access request.

## **Scenario 1:** *Data Sources*

| | |
|---|---|
| Primary Outcome | NHS Digital – HES – Inpatient (Admitted patient care)<br>SAIL – Inpatient dataset |
| Secondary Outcomes | NHS Digital:<br>HES – Inpatient (Admitted patient care); Mortality data<br><br>SAIL: Inpatient dataset; Key stage 1 & 2 datasets<br><br>NPD: Key stage 1 & 2<br><br>ONS: Mortality data<br><br>QoL: Not possible |

## **Scenario 2:** *Data Sources*

| | |
|---|---|
| Primary Outcome | NHS Digital: Mortality data, Rehospitalisation<br>ONS: Mortality data<br>National Institute of Cardiovascular Outcomes (NICOR): Rehospitalisation |
| Secondary Outcomes | National Institute of Cardiovascular Outcomes (NICOR)<br>CPRD: 25% of population<br>THIN: 5.7% of population<br>TPP / EMIS<br>APOLLO: 50% GP coverage from all 4 key software providers<br>NHS Digital: Future datasets<br><br>Patient understanding / satisfaction: not possible |

## Costs

| | |
|---|---|
| Staff costs | Data access application: TM<br>Data cleaning: DM / Statistician<br>Analysis: Statistician<br>Data agreement renewal: TM<br>Linking datasets: DM / DA / Statistician |
| Data Access | Scenario1 - NHSD: Inpatient, Outpatient & A&E, Mortality (4 x 2ys x £300) + £1030 + £930 + £2060 + VAT<br>SAIL: £1000 + 2days + 3days(x6) |
| Non-staff costs | Archiving of NSHD data<br>High performance computer (if needed)<br>Software<br>Safe haven (if needed) |

## Timelines

- Data Application writing
- Organisation-level requirements
- Consent / Participant information: Review by data provider, ethics, PPI
- Application review and approval (data providers)
- Defining the extract
- Data extract provided
- Data cleaning
- Data analysis
- Data interpretation