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Document management

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1.0	3 September 2025	Final version for publication

Reviewers

This document must be reviewed by the following people:

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[REDACTED]	Project Owner (DHSC)	8/8/2025	v0.7
Michael Chapman	Director of Data Access and Partnerships	9/8/2025	v0.7
Louise Greenrod	Deputy Director Data Policy, Department for Health and Social Care	3/9/2025	v0.7

Glossary of Terms

Term / Abbreviation	What it stands for
DHSC	Department of Health and Social Care
Data Processor	Has the meaning given in UK GDPR being a natural or legal person, public authority, agency, or other body which processes personal data on behalf of the controller
DPS	Data Processing Services
EDI	Equality, Diversity and Inclusion
EDGE	Cloud-based clinical research management system developed by the Clinical Informatics Research Unit (CIRU), at the University of Southampton, United Kingdom under Data Processor agreements with HCOs
HCO	Health care organisations which are publicly funded health organisations in England which have been funded by NIHR to deliver clinical trials.
LSOA	Lower Layer Super Output Areas
MSOA	Middle Layer Super Output Areas
NHS England Corporate Reference Data	Reference data held by NHS England to classify, sort or better interpret data records.
NIHR	National Institute for Health and Care Research
PDS	Personal Demographics Service
RRDN	NIHR Regional Research Delivery Network

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Purpose of document

This document sets out the Specification for the Equality, Diversity and Inclusion in Health and Care Research Pilot Directions 2025 (the **Pilot Directions**) and should be read alongside them:

- [Equality, Diversity and Inclusion in Health and Care Research Pilot Directions 2025](#) issued by the Secretary of State for Health and Social Care

Introduction / Purpose of data collection

Background

Different groups of people may present with different symptoms or respond differently to an intervention due to differences in physiology or disease state. Therefore, if research fails to include a broad range of participants, results may not be applicable to the whole population affected. Only by studying the effects of an intervention in a range of groups can we be sure that the balance of risk and benefit is favourable for a given group.

Representative research demonstrates whether interventions will work in practice. Delivery of an intervention to the target populations is complex, with logistical, sociocultural, psychological, and biological differences all having an impact. Unless research has tested if an intervention can be deployed effectively to different groups, we cannot be sure that it will be successful in our health and care system.

The provision of analytics and data products around equality, diversity, and inclusion in health and care research will help research funders, researchers, and the health and care system to address these issues, and ultimately ensure their research is representative and inclusive.

Purpose

The purpose of this data collection is to understand inclusion, representation and participation in health and care research, identify variation in participation in health and care research, based on demographics, to assess and improve equality, diversity and inclusion in such research, to ultimately improve access to good quality, evidence-based health and care (**Purpose**).

The Pilot Directions will enable collection of data by NHS England from participating health care organisations (**HCOs**) providing health research study projects (including clinical trials) funded by the National Institute for Health and Care Research (**NIHR**) (these may include NHS Trusts, General Practices or organisations commissioned by these to deliver health research study functions) to support a pilot (the **EDI Pilot**) for the Purpose above. The EDI Pilot will include the development and implementation of a dashboard by NHS England (**EDI Dashboard**) and the provision of analytics and data products around EDI in health and care research to DHSC and NIHR. Data outputs will be aggregated with small numbers suppressed.

The EDI Pilot will support DHSC and NIHR to identify variation of participation in research – initially based on age, gender, geographic location and deprivation.

Note that collection and analysis of ethnicity data is not included in Phase 1 of this project but will be considered in Phase 2. Both Phase 1 and Phase 2 of the project are included in the EDI Pilot.

In summary, the purpose of Phase 1 of the EDI Pilot project includes:

- building the infrastructure for receiving data from the EDGE clinical research management system (EDGE), which is operated by the University of Southampton as the data processor for HCOs
- building the infrastructure to send aggregate data to NIHR and DHSC
- building a beta version of the aggregate EDI Dashboard
- testing and assuring the technical solution
- conducting preliminary analysis of demographic data to identify patterns of representation in clinical research
- providing proof of concept and support discovery and development of Phase 2 of the EDI Pilot

and

The purpose of Phase 2 of the EDI Pilot project includes:

- identifying the most appropriate source of ethnicity data for inclusion in the data collection
- further development of the infrastructure to include linkage to ethnicity data
- identifying other data relevant to EDI in health and care research
- discovery and development of integration of research management systems, other than EDGE, to collect data
- testing and refinement of the aggregate EDI dashboard to support its publication
- evaluation of the EDI Pilot which will inform DHSC decisions with regard to implementation of a national EDI collection and dashboard.

Data collection

Scope

NHS England will collect data relating to health research study projects (including clinical trials) in England, held by participating HCOs (the **EDI Pilot Data**).

The collection will be limited to those HCOs who have agreed to participate and who will be issued with a [data provision notice \(DPN\)](#) requiring them to provide information under section 259(1)(a) of the Health and Social Care Act 2012.

Source

Data will be collected from participating HCOs via their Data Processor, the University of Southampton, who operate the EDGE system.

The University of Southampton will submit the data via two record level csv files from its EDGE system to NHS England:

- Project file: 9 fields of data on research study projects, a full refresh each month
- Participant file: 5 fields of data which relate an individual (participant) to the research study project; this file contains personal data (NHS Number), this will be appended with a monthly update of data

The DPN will only be issued to those HCOs that have agreed to take part.

Category

The EDI Pilot Data collection comprises of the following information:

- Patient identifier which is the NHS Number of the participant.
- Additional data relating to the nature of the research (**Study**) is also collected which comprises of study related information, including:
 - Name of Study and Study identification code
 - physical/mental health or condition (as part of the 'Project_ Speciality' data item in the Project file. These are the clinical groupings by which NIHR Regional Research Delivery Network (**RRDN**) manages its portfolio of studies and is at a high level e.g., Dermatology.
 - Study funding type

Data will be collected in accordance with the technical data specification published with the EDI Pilot DPN.

Frequency

NHS England will collect the EDI Pilot Data on an ongoing monthly submission basis from the University of Southampton.

Data will be submitted on the first working day of the month and data will contain the previous month's data, based on the date an NHS Number is added.

This collection is limited to the term of the EDI Pilot and aligned with the timescale specified within the Pilot Directions.

Analysis

Data Linkage and Analysis

On receipt of the EDI Pilot Data, NHS England will sample and check the files for data which deviates from the detected norm and undertake any appropriate investigation and resolution, for example correcting any coding or detecting data item irregularities.

The EDI Pilot Data will use the NHS number to link to the Personal Demographics Service's (**PDS**) dataset to obtain further information: -

- current postcode
- date of birth
- age (derived from date of birth)
- gender (recorded in PDS as administrative gender. Provided by the General Register Office and as gender is written on the birth certificate).

This will be linked to NHS England Corporate Reference Data to obtain LSOA and MSOA geographical coding, and other derivations will be generated e.g., age. The curated dataset holds NHS Number and derived items (age, LSOA, MSOA); it does not hold the personal data from PDS (date of birth, postcode) which was used to derive these items.

Counts and small numbers will be suppressed in line with statistical standards to maintain confidentiality.

NHS England will solely process, link and analyse data with the purpose of producing the EDI Dashboard and data extracts for DHSC and NIHR as detailed in the Dissemination section below. Further analysis will be carried out by DHSC and NIHR on the aggregated small number suppressed data in the EDI Dashboard and data extracts.

Collection and/or processing of ethnicity data is out of scope of Phase 1 of this EDI Pilot project. The source and the use of the ethnicity data will be considered in Phase 2 of the project.

Consultation

Under section 258 of the Health and Social Care Act 2012, NHS England must consult with certain specified stakeholders before establishing a new collection. The following stakeholders have been consulted and may be consulted further as the EDI Pilot progresses:

- a. NHS England has consulted with the issuing organisation, DHSC, on behalf of the Secretary of State for Health and Social Care.
- b. NHS England has consulted with the prime users of the information including DHSC, NIHR and RRDNs (formerly Local Clinical Research Networks (LCRNs)).
- c. DHSC has engaged with nine NHS Trusts and all 12 LCRNs (now known as RRDNs) who have a representative role in this context.
- d. NHS England has consulted with members of the public, this involved:
 - Eight online discussion groups involving around eight people per group were held on the topics of EDI in health and care research and data collection by the NHS.
 - People representative of the target user group population were recruited, with a mix of attitudes towards the NHS and data sharing.
 - Outcome measures included attitude and opinion in terms of their non-identifiable data being collected to monitor and improve the inclusivity of health and care research participation.
 - These discussion groups were run by an external agency and held with participants who had given their informed, opt-in consent to participate in the research.

Following the EDI Pilot further consultation will be held prior to project development for Phase 2.

Advice and Guidance

NHS England has produced guidance for use by HCOs who are participating in the EDI Pilot. HCOs taking part in the EDI Pilot are responsible for ensuring their patient transparency and privacy materials are accurate and up to date, the guidance is intended to support HCOs with their review and update of any such materials.

Dissemination/Sharing

Regular Dissemination/Sharing

NHS England is directed to disseminate aggregate, small number suppressed data to:

- NIHR, who will receive monthly reports which are aggregated summaries, with small numbers suppressed.
- DHSC and NIHR, through providing access to the EDI Dashboard, which consists of aggregated summaries with small numbers suppressed. Access is subject to a registration process for a multi-factor authentication. The dashboard will be updated monthly.

Data sharing agreements will be established as required by the NHS England [Data Access Request Service \(DARS\)](#). Data will not otherwise be made available to other organisations outside of DHSC and NIHR via the DARS service during the EDI Pilot.

Publication

Data not to be published

NHS England is directed not to publish any data obtained by complying with the Pilot Directions and accordingly, will not publish data obtained by virtue of the Pilot Directions, including in aggregate form.

System Delivery Function

NHS England expects to utilise its existing systems and toolsets to meet these requirements.

Change control process

Changes to this Specification will be managed by NHS England in conjunction with DHSC to ensure such changes are aligned with the Equality, Diversity and Inclusion in Health and Care Research Pilot Directions 2025.