

Data Provision Notice

NHS DigiTrials Recruitment Service



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Background

The Health and Social Care Act 2012 (the Act) gives NHS England statutory powers, under section 259(1)(a), to require data from health or social care bodies, or organisations that provide publicly funded health or adult social care in England, where it has been directed to establish an information system by the Secretary of State for Health and Social Care, and to request data under section 259(1)(b) from all other organisations.

The data, as specified by NHS England in this published Data Provision Notice, is required to support a direction from the Secretary of State for Health and Social Care to NHS England. Therefore, organisations that are in scope of the notice are legally required, under section 259(5) of the Act, to provide the data in the form and manner specified below.

Purpose

The purpose is to enhance the support for health and life sciences research by implementing and operating the NHS DigiTrials Recruitment Service (the Service). The Service will:

- Aim to enhance the efficiency and effectiveness of clinical trial recruitment across the UK by identifying appropriate cohorts to be invited to take part in research, using data which has already been collected by NHS England;
- Collect, analyse and link data required to support requesting organisations in the use of the Service; and
- Enable the use of data obtained as part of delivering the Service, including through analysis and linkage of data, to support service delivery management, monitoring and improvement.

Benefits

Benefits to Health and Social Care

The NHS DigiTrials Recruitment Service delivers a range of strategic and operational benefits by providing the DigiTrials team-controlled access to high quality data for the purpose of clinical trials. Most notably, use of the Recruitment Service aims to:

- Enhance opportunities for the widest possible group of individuals to participate in vital clinical research to address large scale public health risks.
- Improve the diversity of research cohorts such that those who are offered the opportunity take part in research, become more representative of the population.
- Support faster participant recruitment to find answers more quickly to important clinical questions.
- Reduce the cost of running clinical trials and other important research. This will provide particular benefit for publicly funded studies such as those which ran during the COVID-19 global pandemic.

- Reduce the burden of trial administration and data collection from front line clinicians and healthcare settings.
- Support a thriving UK life sciences research sector by reducing the costs of running trials and attracting more research to the UK.
- Ultimately improve NHS services and access to evidence-based diagnostics, vaccines and treatments for the wider population.

Legal basis for collection, analysis, publication and dissemination

NHS England has been directed by the Secretary of State for Health and Social Care under section 254 of the Health and Social Care Act 2012; to establish and operate a system for the collection and analysis of the information specified for this service. The direction and accompanying requirements specification are published on the NHS England website:

<https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/directionsanddata-provision-notices/secretary-of-state-directions/nhs-digitrials-recruitmentservicedirections-2026/nhs-digitrials-recruitment-service-directions-2026>

- Health and Social Care Organisations using the DigiTrials Recruitment Service

This information is required by NHS England under section 259(1)(a) of the Health and Social Care Act 2012. Health and Social Care Organisations using the DigiTrials Recruitment Service are required under section 259(1)(a) to comply with the requirement and must provide information to NHS England in the form, manner and period specified in this Data Provision Notice.

- All Other Organisations using the DigiTrials Recruitment Service

This information is required by NHS England under section 259(1)(b) of the Health and Social Care Act 2012. All Other Organisations using the DigiTrials Recruitment Service are requested to provide information to NHS England in the form, manner and period specified in this Data Provision Notice.

However, under section 259(2)(b), where an Other Organisation is using the DigiTrials Recruitment Service and the research/study is publicly funded, organisations are required under section 259(1)(a) to comply with the requirement and must provide information to NHS England in the form, manner and period specified in this Data Provision Notice.

In line with section 259(5) of the Act, all organisations in scope, in England, must comply with the requirement and provide information to NHS England in the form, manner and period specified in this Data Provision Notice.

This Notice is issued in accordance with the procedure published as part of an NHS England duty under section 259(8).

Persons consulted

A variety of stakeholders have been engaged to support developing various aspects of the Service Directions, including:

- NHS England & NHS DigiTrials SMEs (Subject Matter Expert) – for example Data Applications, Data Onboarding, Data Engineering and Technical Teams, Legal, Privacy, Transparency and Trust teams (Information Governance), Commercial and Business Development Teams, Clinical, Cyber Security and NHS App Teams and the Personal Demographics Service Team
- Health Ministers
- Department of Health and Social Care
- Confidentiality Advisory Group (CAG)
- Requestions Organisations
- National Cyber Security Centre (NCSC)
- NHS England Advisory Group for Data (AGD)
- NHS England Data Access Service (DAS)
- NHS Co-Development Panel (Public & Patient Involvement and Engagement) • External Public & Patient Involvement and Engagement

Following receipt of a direction to establish a system to collect NHS DigiTrials Recruitment Service, NHS England has, as required under section 258 of the Health and Social Care Act 2012, consulted with the following persons:

- Department of Health and Social Care, as directing organisation

Scope of the collection

Under section 259(1)(a) of the Health and Social Care Act 2012, this Notice is served in accordance with the procedure published as part of the NHS England duty under section 259(8) on the following persons:

- All Health and Social Care Organisations using the NHS DigiTrials Recruitment Service

Under section 259(1)(b) of the Health and Social Care Act 2012, this Notice is served in accordance with the procedure published as part of the NHS England duty under section 259(8) on the following persons:

- All other Organisations using the NHS DigiTrials Recruitment Service

Under section 259(5) of the Health and Social Care Act 2012 the organisation types specified above must comply with the Form, Manner and Period requirements below.

Form & Manner of the collection

Data will be collected from all customers of the NHS DigiTrials Recruitment Service. This data will be in a standardised automated csv template and will be provided by email. The data will be returned via Secure Electronic File Transfer (SEFT). A submission guidance pack is provided at the point of contact with the Recruitment Service.

Period of the collection

Collections will be required at a minimum of every two weeks.

Burden of the collection

Steps taken by NHS England to minimise the burden of collection

NHS England has a statutory duty under section 253(2) of the Act to seek to minimise the burden it imposes on others, in support of its obligation under 265(3) of the Act, NHS England has an assessment process to validate and challenge the level of burden incurred through introducing new information standards, collections and extractions.

This process is carried out by the Data Governance, Assurance, and Testing team (DGAT) which assures burden assessment evidence as part of the overarching Data Alliance Board (DAB) approval process. The DAB, acting under authority of the Secretary of State, oversees the assurance, approval and publication of information standards and data collections for the health and social care system in England.

In this case no burden assessment is required. All data collected will be from the organisations using the DigiTrials Recruitment Service and agreed upon at the point of entering into contract with them.