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Requirements Specification for NHS DigiTrials Recruitment Service Directions 2026

Document management

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Reviewers

This document has been reviewed by the following people:

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Glossary of Terms

Term / Abbreviation	**What it stands for**
DHSC	Department of Health and Social Care
DPS	Data Processing Services
FRF	Find, Recruit, Follow-Up
DARS	Data Access Request Service

Document Control:

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Purpose of document

This document sets out the requirements for the NHS DigiTrials Recruitment Service and should be read alongside the:

- NHS DigiTrials Recruitment Service Directions 2026 dated given by the Secretary of State for Health and Social Care (Direction).

Introduction / Purpose of Service

Introduction

The NHS DigiTrials Recruitment Service (the Service) is an innovative, direct-to-participant recruitment model designed to enhance the efficiency and effectiveness of clinical trial recruitment across the UK. Developed in collaboration with researchers and grounded in strong public and patient engagement, the Service leverages routinely collected NHS health data to identify and contact potential participants for approved clinical research studies.

The Service compliments existing recruitment methods by offering a streamlined, data-driven approach that reduces the time, effort, and cost associated with participant recruitment. Following the success of a pilot of the Service under the Pilot NHS DigiTrials[1], the decision was made to transition this service into business as usual under these directions.

The Service processes personal and special category data to identify individuals who may be eligible to be invited to participate in health research studies. Although the Service is primarily aimed at organisations conducting clinical trials (Requesting Organisations) it is recognised that the Service may also benefit wider healthcare research. Throughout this document the term ‘clinical trial’, ‘trial’ and ‘trialist’ are used for simplicity, but it should be noted that the Service may be used to support any clinical research that meets the definition of clinical research as set out in the UK Policy Framework for Health and Social Care Research[2] and as overseen by the Health Research Authority.

Purpose

The purpose of the Service is to enable NHS England to develop and operate the Service. The Service will:

- Aim to enhance the efficiency and effectiveness of clinical trial recruitment across the UK by identifying appropriate lists of cohorts to be invited to take part in research. Leading to an increase in the availability of high-quality treatments and improved NHS Services to the UK population
- 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 to Health and Social Care

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[1] https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/directions-and-data-provision-notices/secretary-of-state-directions/pilot-nhs-digitrials-recruitment-support-services-directions-2021

[2] UK Policy Framework for Health and Social Care Research - Health Research Authority (hra.nhs.uk)

The 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.

Data Processing necessary to deliver the NHS DigiTrials Recruitment Service

Scope

The scope of the processing required to provide the Service will consist of the following:

- Review and assessment of requests received from Requesting Organisations wishing to use the Service
- Ongoing development of a patient-centric data model using data already held within NHS England and, where provided by the Requesting Organisation, by data linkage
- Creation of cohorts in line with the relevant inclusion and exclusion criteria provided by the Requesting Organisation
- Sending contact details for the purposes of invitations, this could either be NHS England's communications provider, the Requesting Organisation, or an external provider on behalf of the requesting organisation
- Onboarding of new datasets to deliver the Service where required to support requests
- Creation of a non-contact list where participants have expressed an objection to receiving invitations to participate in research/trials
- Creation of reports and management information relating to the request based on cohort creation and information provided by the requesting organisation
- Creation of Service evaluation information

More detailed information regarding scope of the processing activities is set out below.

Where a requesting organisation has previously used the Service under the Pilot NHS DigiTrials Recruitment Support Service Direction, they will continue to be supported under this Direction.

Analysis and Linkage

NHS England will undertake analysis and linkage of data already held by NHS England to enable delivery of the Service.

The onboarding of NHS England held data to be used by the Service will be subject to the following onboarding governance process and held within a controlled DigiTrials data environment (patient-centric data model).

Governance process for onboarding datasets

When the Service onboards additional existing NHS England held Datasets into its patient-centric data model, this model is designed to organise data around individuals rather than healthcare providers and allows the Service to build a more complete and accurate picture of each patient’s healthcare journey. All data onboarding is carried out under strict governance controls to ensure privacy, security and compliance with NHS England standards. A Task and Finish group reporting to the DigiTrials Programme Board will be created to understand and consider any adverse impact for the patients identified in the dataset, and ensure these impacts are mitigated as much as possible.

Each Task and Finish group will be made up from a range of NHS England Subject Matter Experts (SMEs) and could consist of:

- Privacy Transparent and Trust Representatives
- Caldicott Guardian Representative
- Dataset Information Asset Owner
- Behavioural Science Representatives
- Clinical Informatic Specialists
- Technology and Data Engineering Teams
- DigiTrials Operations Team
- Policy/Strategy Leads
- Approved Health Professionals.

This multidisciplinary input ensures that legal, clinical, ethical, technical, and operational considerations are fully addressed during dataset onboarding. Data Protection Impact Assessments will be updated and re-approved to reflect additional datasets onboarded, as part of the Task and Finish Group work.

Invitations to take part

The Service processes personal and special category data to identify individuals who may be eligible to be invited to participate in health research studies. The data subjects are typically members of the public in England, and the specific cohort is determined based on clinical and demographic inclusion/exclusion criteria provided by the Requesting Organisation (e.g., cancer patients, individuals with specific conditions, or members of the general population). The invitations could be sent using a variety of communication methods such as a letter or SMS, as well as incorporating follow-up reminders. The communication method used, and use of reminders will both be detailed in either a Data Capture form linked to the Data Access Request Service (DARS) platform or a Data Sharing Agreement.

An automated data pipeline is used to interrogate onboarded national datasets (for which NHS England is the data controller), and any other data collected where a legal basis exists, to identify a list of potentially eligible individuals, where a national dataset is not precluded from use for research purposes.

Requesting Organisations may send the Service lists of people who have already signed up to take part, to avoid re-invitation. This will only be done where Requesting Organisation consent materials clearly allow data to be processed in this way.

Although the pipeline analyses and links multiple datasets to determine eligibility, it only outputs the minimum necessary contact information required for the method of invitation. For example:

- For postal invitations: name and address.
- For SMS invitations: name and mobile number.

Before any invitations are issued, the data pipeline applies standard exclusions such as removing individuals who are deceased, in the military, in prison, or flagged with an S-flag (sensitivity flag). Requesting organisations may send NHS England lists of people who have already signed up to take part, to avoid re-invitation. This will only be done where there is a supporting legal basis in place, i.e. where patients have consented.

Once the list of potentially eligible individuals is finalised the contact information will be outputted in accordance with the Data Capture form or Data Sharing Agreement.

All data processing relating to the sending of invitations by a trial, other than through the Digitrials Recruitment Service, will be supported by a clear legal basis e.g. the trial may be supported by an approval under section 251 of the NHS Act 2006 or patient consent as well as in all cases, an appropriate legal basis under the UK General Data Protection Regulation (UK GDPR) and Data Protection Act 2018.

The output from the Service would then be used in one of the following scenarios:

- to send out the invitations on behalf of the requesting organisation as part of the Recruitment Service. The NHS Numbers of the potentially eligible individuals are sent to the NHS Notify Service.
- to send out the invitations on behalf of the requesting organisation as part of the Recruitment Service. The required contact details of the potentially eligible individuals are sent to the NHSE contracted 3rd party supplier.
- A Requesting Organisation requests the Service to send the contact details to their own 3rd party provider, who will send out the invitations on behalf of the organisations. This processing would require the organisation to obtain a section 251 from the Health Research Authority under the National Health Service Act 2006, if they did not already have this in place for the purpose of the research/trial.
- A Requesting Organisation requests the Service to send the contact details back to them to send out the invitations themselves. This processing would require the organisation to obtain a section 251 from the Health Research Authority under the National Health Service Act 2006.

Additionally, aggregate reports are produced for the requesting organisation, showing the actual number of invites sent out by demographic, compared to what was requested. The Service also uses data to support service delivery management, monitoring and improvement.

Data Quality

As part of our quality assurance process, the Service includes a small group of internal team members whose contact details are used solely for data quality checks. For each batch of invitations prepared for dispatch, two individuals are randomly selected from this group, and their contact details are added to the invitation file. The contact details that are used are limited to the method of communication for the batch. E.g. For postal invitations: name and address and for SMS invitations: name and mobile number.

This allows the Service to receive an identical copy of the communication that members of the public receive. By doing so, the team can verify the accuracy, formatting, and content of the invitations, and quickly identify and resolve any issues or inconsistencies before the next batch is sent. This process helps ensure the integrity and reliability of the Service while maintaining high standards of data quality and user experience.

Collection of Invitation Uptake and Monitoring

To evaluate the effectiveness of recruitment efforts, the Service will request feedback from trials about individuals who have signed up to participate in their studies. This feedback typically includes either a unique reference number or a combination of NHS Number and Date of Birth, full details can be found in Appendix A.

We use this information to cross-check against the list of individuals invited, enabling the Service to:

- Assess recruitment effectiveness – Understand how well the invitations are contributing to the trial’s recruitment targets.
- Monitor and manage invitation frequency – Recording sign-ups to help prevent over-inviting individuals to multiple studies, supporting fair and ethical recruitment practices.
- Evaluate Behavioural Science Interventions – Where a Study Within A Trial (SWAT) is conducted, and different invitation formats or messages are tested (e.g., with behavioural nudges), this feedback allows us to measure the impact of each approach and refine future communications accordingly.

Provision of this feedback data will be collected under section 259 of the Health and Social Care Act 2012. This will ensure that NHSE can build continuous improvement of the Service and ensures that invitation strategies are evidence-based and participant-friendly.

Collection from Research Registries

To enhance the efficiency and effectiveness of participant recruitment, the Service may receive data from research registries where the participants of the research registry have provided their consent to the operator of the research registry for their data to be shared with NHS England. These registries may be managed by, for example, the National Institute for Health and Care Research (NIHR) or other organisations, only where a lawful basis to share data with NHS England exists and is confirmed by the Service. The data items used can vary depending on the registry that is used. Details of the data items which may be provided will be recorded in the Data Capture form and in a Data Sharing Agreement are included in Appendix A.

The data from these registries typically includes individuals who have proactively expressed an interest in taking part in research. By prioritising invitations to these individuals, we can:

- Target those most likely to respond positively to an invitation.
- Accelerate the recruitment process by reaching engaged participants first.

- Reduce the number of invitations required to meet recruitment targets, thereby lowering overall costs and improving resource efficiency.

This targeted approach supports more timely and cost-effective delivery of research studies while respecting individuals' preferences and interests in participating in health research.

Internal Access

It is also anticipated that data obtained under this Direction may be analysed under the NHS England De-Identified Data Analytics and Publication Directions 2023 (Data Analytics Direction). Any analysis under the Data Analytics Direction will only occur where approved in accordance with Information Governance procedures and controls, including where required in accordance with the statutory guidance issued under s274A of the 2012 Act, and advice from the NHS England Advisory Group for Data.

NHS England may also analyse the Information in accordance with the Life Sciences Directions 2019, where this has been approved.

Consultation

Ongoing consultation has taken place throughout the pilot of the NHS DigiTrials Recruitment Support Services, details of which can be found in the supporting requirements specification for the Pilot NHS DigiTrials Recruitment Support Services 2021. The Service will continue to seek ongoing consultation through Public & Patient Involvement and Engagement (PPIE) and Subject Matter Experts.

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

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

Dissemination/Sharing

Regular Dissemination/Sharing

When a Requesting Organisation wishes to use the Service invitations can be sent by the Service itself, or by the Requesting Organisation.

Where the Service is sending out invitations on behalf of the requesting organisation, this will be done by NHS England. No sharing or dissemination of data takes place to the requesting organisation which means that a Data Sharing Agreement will not be required. The requirements and eligibility criteria of the trial are captured in a Data Capture form linked to the NHS England Data Access Service platform.

Where a requesting organisation requests NHS England to send them the cohort contact data to send their own invitations, this will be done using the standard Data Access Service (DAS) process. They will need to enter into an overarching Data Sharing Framework Contract (DSFC) and Data Sharing Agreement (DSA) and this forms the basis for the ongoing relationship with NHS England. It outlines expectations for governance, security standards, retention and destruction of data as well as NHS England audit rights. Further information on the DAS Service process can be found at Data Access Request Service (DARS)

The request to access data is subject to approval via NHS England's Data Access Service (DAS) and uses a Data Sharing Agreement (DSA) which documents:

- The data that is required
- The purpose of accessing the data
- The legal basis supporting the use of the data
- How data minimisation will be applied
- How the organisation is funded
- Any commercial aspects that need recording
- The different processing activities required
- What outputs will be produced
- What the expected benefits will be
- How the organisation is being transparent with the request to access data.

The organisation applies to Service following (or sometimes in parallel with) an application to a Research Ethics Committee (REC), where they must get a Favourable Opinion. In some circumstances they may also need to apply to the Health Research Authority (HRA) with support from the Confidentiality Advisory Group (CAG).

Once the requesting organisation has all the relevant approvals, the application for data access is progressed through the NHS England Data Access Governance process.

Where a Data Sharing Agreement is required the Service may seek the advice of AGD on specific elements of data sharing, and only where the Service feels advice is needed.

NHS England will provide aggregate summary reports to Requesting Organisations, regarding the service provided to them by the Service.

Any other data access requests for dissemination must be via the established end to end DAS[3] process or in line with NHS England safe haven processes for release of aggregate or anonymised data. These are in line with the statutory guidance on the protection of patient data[4]

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[3] Data Access Service (DAS)

[4] NHS England's protection of patient data - GOV.UK (www.gov.uk)

Publication

Published Data

Data will be published in accordance with NHS England's duty to publish under s260(1) of the 2012 Act, unless it falls within a description of s260(2) of the 2012 Act.

NHS England will not publish any identifiable data it obtains by complying with the Directions, publication will be limited to anonymous statistical data (with small numbers suppressed).

Change control process

Changes to this Specification will be managed by NHS England in conjunction with the DHSC to ensure such changes are aligned with the NHS DigiTrials Recruitment Service Directions 2026.

Appendix A – Table of categories of data processed by the NHS DigiTrials Recruitment Service

Data Categories	Processed	Justification
Name	Yes	Requirement for invitation personalisation
Address	Yes	Requirement for invitation personalisation
Postcode	Yes	Requirement for invitation personalisation
DOB	Yes	Requirement for Analysis and Linkage
Age	Yes	Requirement for Inclusion/Exclusion Criteria
Sex	Yes	Requirement for Inclusion/Exclusion Criteria
Marital Status	No	
Gender	No	
Living Habits	No	
Professional Training / Awards / Education	No	
Income / Financial / Tax situation / Financial affairs	No	
Email Address	Yes	Requirement for sending email Invitations
Physical Description	No	
General Identifier e.g. NHS No	Yes	Requirement for Analysis and Linkage
GP Practice	Yes	Requirement for Inclusion/Exclusion Criteria
Home Phone Number	No	
Online Identifier e.g. IP Address/Event Logs	No	
Website Cookies	No	
Mobile Phone / Device No / IMEI No	Yes	Requirement for sending SMS Invitations
Location Data (Travel / GPS / GSM Data)	No	
Device MAC Address (Wireless Network Interface)	No	
Banking information e.g. account number, sort code, card information	No	
Criminal convictions / alleged offences / outcomes /	No	

proceedings / sentences		
Return to sender file extract, including GUID, APS Unique ID, contact information and return reason code		NHSE mailing providers are instructed to return a regular file extract to NHS England for letters which could not be delivered to the recipient. This contains: • GUID – NHS England's Unique ID • Family Name • Given Name • Address Lines 1-5 • Postcode • Letter Template • Return Reason code 1. APS Unique ID NHS England will use this information in accordance with its statutory functions to maintain GP patient lists and ensure that the contact information for the patient held in the Personal Demographics Service (PDS) is accurate and up to date.
Physical / Mental Health or Condition	Yes	Requirement for Inclusion/Exclusion Criteria
Sexual Life / Orientation	No	Note: While this is not collected or processed as part of the Recruitment Support Service, this could be implied or inferred.
Religion or Other Beliefs	No	
Trade Union membership	No	
Racial / Ethnic Origin	Yes	Requirement for Inclusion/Exclusion Criteria
Biometric Data (Fingerprints / Facial Recognition)	No	
Genetic Data	No	