



Introducing the NHS DigiTrials Service

Key contact details:

To discuss any aspect of the NHS DigiTrials service you can contact the enquiry team via phone 0300 303 5678 or email enquiries@nhsdigital.nhs.uk

What is NHS DigiTrials?

NHS DigiTrials is a service aimed to help clinical trials progress more easily at every stage, using data that NHS England already collects from health and care organisations across England. NHS DigiTrials offers a service that will make the data for trial follow-up available for linkage to clinical trial data, in one place, meaning better understanding of longer term outcomes of new treatments, improving healthcare across the country.

NHS DigiTrials is a relatively new service (started in 2019) powered by NHS Digital to support clinical trials, with the ultimate aim of improving NHS services and access to evidence based diagnostics, vaccines and treatments to improve the health of patients. It was developed and supported by a diverse panel, representing the voice of patients and the public.

Whilst NHS DigiTrials is a new service, it has already supported over 72 research studies, sent around 23.8 million invitations, and helped recruit over 1.2 million study participants.

Available services on offer from NHS DigiTrials:

Feasibility: Fully anonymised and aggregated data will be processed to improve the assessment of clinical trial feasibility and provide rapid insights into potential participant numbers, supporting improved planning and locating of clinical trials in the UK.

Recruitment: Identifiable patient data will be processed for approved research. The aim of this service is to deploy data analysis and linkage to provide data to research projects in the form of lists of potential participants who meet the inclusion criteria for the purpose of inviting them to join the trial, encouraging research participation and thus representation. NHS DigiTrials handle the entire process from outreach to engagement.

Communication: This service will process the identifiable patient data of participants who have consented to receive ongoing communication and information about the trial, improving retention and study outcomes.

Outcomes: Identifiable patient data will be processed to support research team's information about the impact of an intervention or to support long-term follow up of research participants.

The application process:

The data is under strict controls and will only be made available and shared with *approved* researchers, if it is relevant, lawful and used to benefit patient care, all of which will be assessed during the approval process.

Applications for the NHS DigiTrials service will follow the NHS Digital DARS application process. Applications must be made via the DARS online portal, with the required information and supporting documentation. <u>DARS documents and guidance can be accessed here</u>.

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ARC Data Hub Resource





Once your application has been submitted you will be allocated a case officer who will review your application and if necessary schedule an appointment to discuss anything outstanding that must be completed for your application to progress.

DARS undergo stringent review by staff and independent groups against published criteria. The application is reviewed by the Independent Group Advising on the Release of Data (IGARD). The panel consists of independent specialists and lay members of the public. If GP data is also included in the application an additional review is completed by the Professional Advisory Group (PAG). The application process is expected to take approximately 30 working days.

Getting the data after approval:

The data will be shared and stored safely and securely within a Secure Data Environment, adhering to robust governance, data protection requirements and information security.

Costs:

NHS DigiTrials offers multiple services, which researchers can choose based on the needs of the trial. Each service will have a cost applied, example charges range from £2,000 (for self-service) to £6,800 (for managed support). Charges are likely to be tailored to each clinical trial based on needs and will be discussed upon request.

Further information about charges for the different NHS DigiTrials services <u>can be found</u> here.

Additional information:

To read more about NHS DigiTrials and explore trials / projects it's already supported, check out our recent blog post about the service on the ARC KSS Data Science Hub.

End of document.

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