



Medical
Research
Council



NHS-HE IG Group - London

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Medical Research Council, Regulatory Support Centre

Overview

- HDRUK
- NHS Digital / Research Advisory Group
- National Data Opt-Out



Health Data Research UK

Building a UK-wide capability that will enable the safe and responsible use of health-related data at scale for research and innovation

- **Data:** Longitudinal, event-based, multi-modal, curated datasets on disease sub-groups
- **Access:** Single, easy-to-use route to data
- **Scale:** High quality data with UK-wide coverage
- **Speed:** Fast response times and streamlined contracting, governance and approvals
- **Expertise:** Access to domain specialists, AI and applied analytics, phenotyping
- **Multiple purposes:** Real world data, ability to rapidly identify trial cohorts

Bringing benefits to all

- **For researchers** - faster, more accurate and less expensive research and development
- **For clinicians and patients** - identification of new medicines, treatments and technologies
- **For businesses large and small** - to better develop, test and deploy new products, devices, tools and AI technologies in health and care earlier
- **For society** - creating jobs, generating investment, improving health services

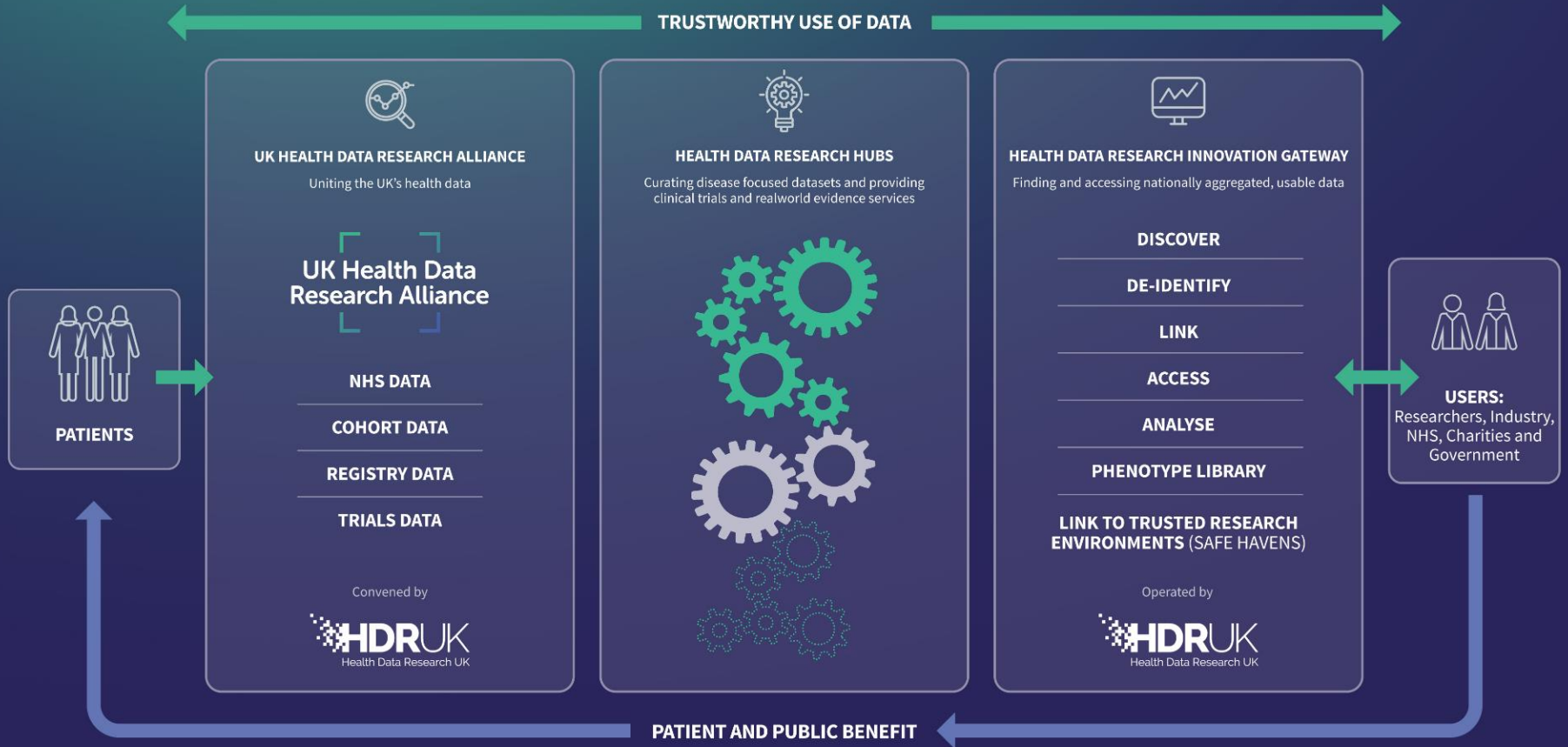




INDUSTRIAL
STRATEGY

UK Research
and Innovation

UNITING THE UK'S HEALTH DATA TO MAKE DISCOVERIES THAT IMPROVE PEOPLE'S LIVES



Health Data Research Alliance



Barts Health NHS Trust



Nottingham University Hospitals NHS Trust



University Hospitals Birmingham NHS Foundation Trust



Clinical Practice Research Datalink



Cystic Fibrosis Trust



The Brain Tumour Charity



NHS Digital



NHS England



NHS Scotland



NHS Wales



Health and Social Care Northern Ireland



NHSX



Genomics England



UK Biobank



National Institute for Health Research (NIHR) Bioresource



Public Health England



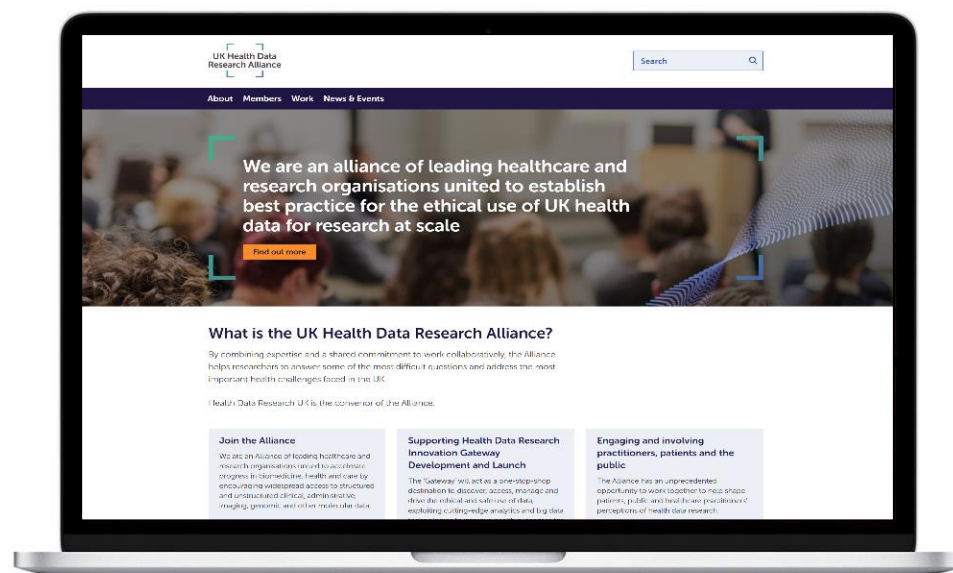
HQIP



Royal College of General Practitioners (RCGP)

Communications & Engagement

- **Build credibility** - demonstrate how the Alliance is accelerating progress in medicine and health by encouraging better access to data in a trustworthy and ethical way
- **Bring in new datasets** - make the Alliance attractive to other UK data custodians
- **Promote the assets** - showcasing the datasets available to UK industry, academia and healthcare
- **Earn confidence** - increase the trust of patients, the public and practitioners in use of health data for research and innovation



Find out more: <https://ukhealthdata.org/>

Health Data Research Alliance

- Data standards and quality
- Supporting Innovation Gateway development and launch
- Promoting participation and agreeing the terms and conditions
- Aligning approach to Trusted Research Environments
- Engaging and involving practitioners, patients and the public

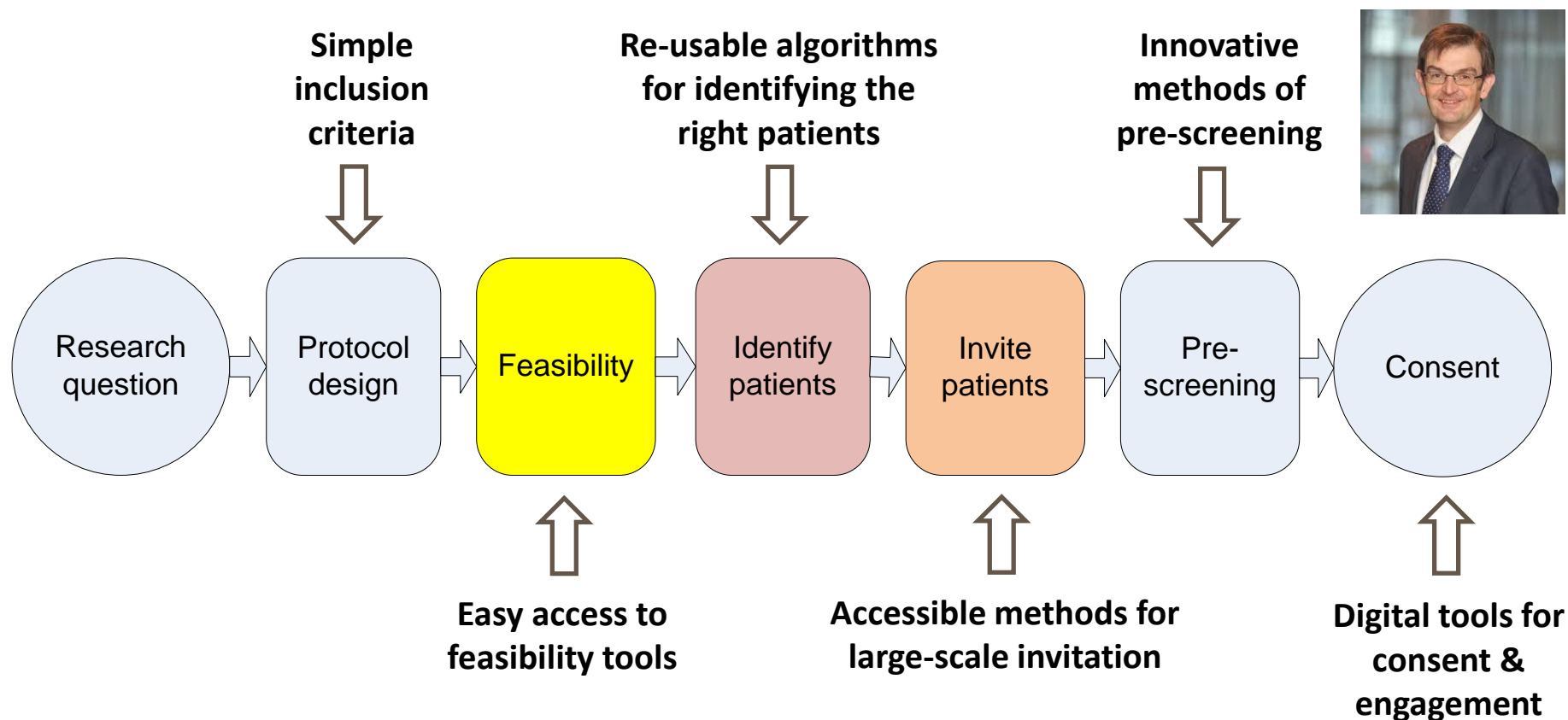
Health Data Research Hubs

- **BREATHE** Health Data Research Hub for Respiratory Health
- **DATA-CAN** Health Data Research Hub for Cancer
- **Discover-NOW** Health Data Research Hub for Real World Evidence
- **G.I. Know** Health Data Research Hub for Inflammatory Bowel Disease
- **INSIGHT** Health Data Research Hub for Eye Health
- **PIONEER** Health Data Research Hub for Acute Care
- **NHS DigiTrial** Health Data Research Hub for Clinical Trials



BETTER, FASTER, EFFICIENT
CLINICAL TRIALS

Re-imagining the recruitment pathway



National feasibility: Example ORION-4

- Simple inclusion criteria which identify relevant population and are well coded in Hospital Episode Statistics held by NHS Digital
- Feasibility analysis conducted in partnership with NHS Digital in less than 2 weeks
- Identified >1.5 million potential participants & mapped to show the acute NHS Trusts with the greatest activity
- **Web-based service now being developed with NHS Digital, NIHR Clinical Research Network and Health Data Research UK so that this approach becomes “business as usual” (launch: Sept 2019)**



Sprint Exemplar Innovation Programme

Using Routine NHS Data to Accelerate Clinical Trial Recruitment

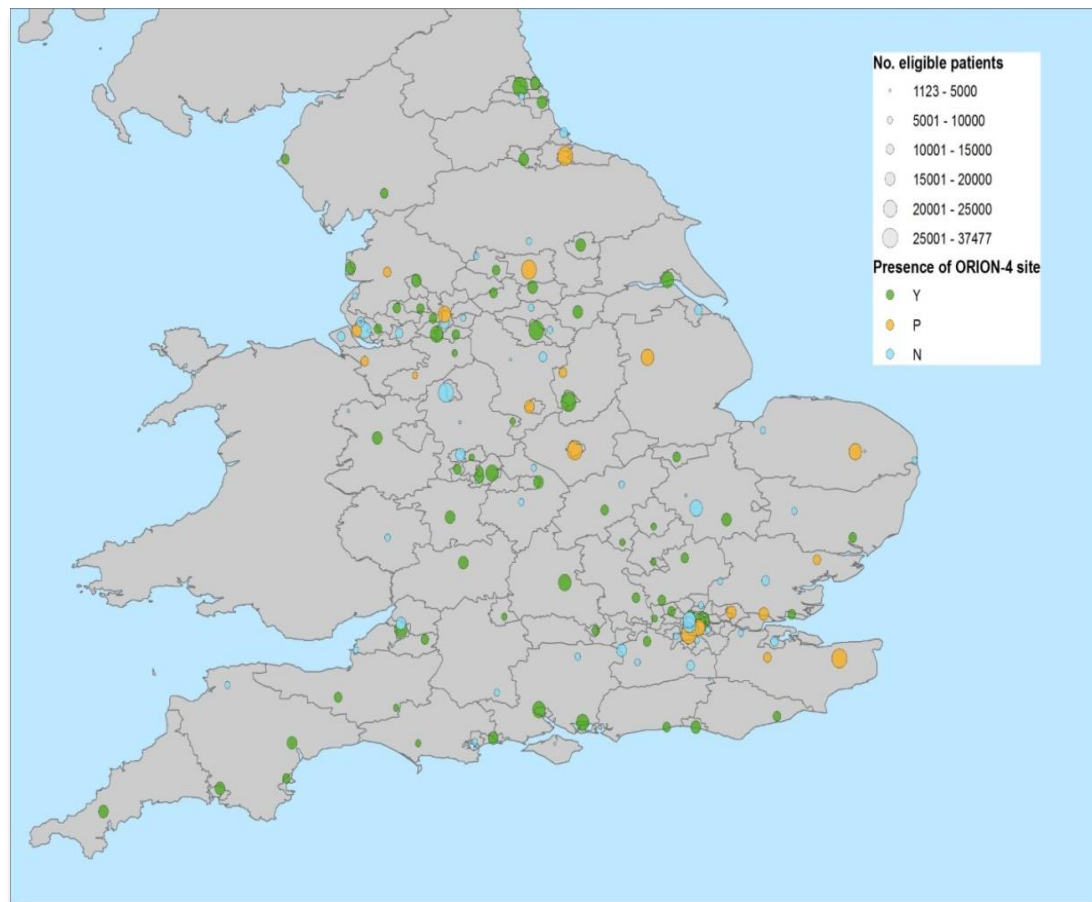
A system that uses the 'hospital episodes' information to identify potentially suitable patients from across the country who could be asked if they wish to take part in clinical trials.

National feasibility: Results for ORION-4

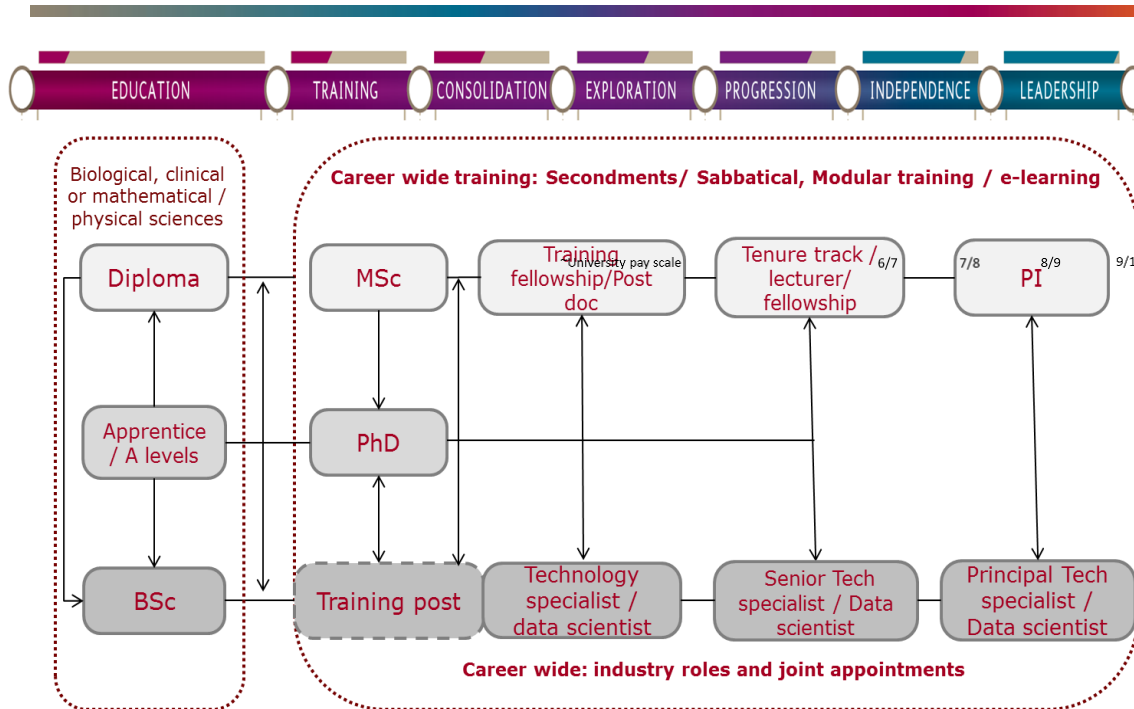
**Target: 12,000 pts with
prior MI, ischaemic stroke
or peripheral revascularization**

Patients/ hospital	Hospitals	Patients
>10,000	96	~1.5M
>15,000	54	~0.8M
>20,000	26	~0.5M

Flagging of pts



Training



- Masters
- PhD Programme in Health Data Science with the Alan Turing Institute
- Post-doctoral Fellowships
- Training at Scale

Career pathways for interdisciplinary health data scientists
Train up to 10,000 data scientists

Innovation Gateway

The Gateway is a common access point to UK health research data for accredited researchers and innovators

Innovation Gateway

- **The Gateway Portal** - requiring design and development of the front-end user experience, allowing researchers and innovators to easily search and identify relevant datasets
- **A Metadata Catalogue** - which will provide the underlying functionality to support the Gateway portal, and which will be developed through a separate process
- **Alliance data modelling and metadata loading** - which will provide the tooling and resource to enable Alliance members to undertake the necessary data modelling and metadata loading processes to enable both high value and volume datasets to be made available by Alliance members

Research Advisory Group

Research Advisory Group

The Research Advisory Group (RAG), hosted by NHS Digital, brings the research community, the third sector and NHS Digital together to advance the use and effectiveness of NHS Digital's data and services for research. The aim of RAG is to build an enduring and strategic partnership between researchers and NHS Digital. More details can be found on the RAG website

RAG Streamlining Sub-Group

- Aims to streamline access to data by removing duplication and bureaucracy in data application and research approval processes. The main streams of activity are:
- Improving the transparency of the processes required to gain research approvals and access to health data - designing tools and guidance that provide clarity about the various approval processes, how decisions are made and how applications are assessed
- Reducing duplication between approval bodies and harmonising language - simplifying data application and approval processes so that, for example, approvals from one organisation could be accepted by other organisations without the need for further review
- Developing a mutually consistent understanding of the laws, policies and guidance around the use of health data in research - helping to ensure that organisations and researchers interpret legal and policy requirements in the same way e.g. providing clarity about the role of consent in health research

RAG Streamlining Sub-Group

The RAG Streamlining Sub-Group has:

- Developed an online tool (Health Data Access Toolkit) to help researchers and research governance teams successfully navigate application processes
- Worked with The Office for National Statistics to improve the efficiency and timescales for accessing death data and thereby reducing the burden on researchers
- Reviewed and produced a variety of research-specific guidance documents about data protection and confidentiality e.g. Controllers and Processors in Health Research
- Undertaken a number of Researcher Roadshows focusing on what health data is available at NHS Digital, the developments in how to access data, now and in the future, and providing opportunities to influence NHS Digital's development plans
- Ensured application forms from all data providers / research approvers employ consistent language and interpretation of that language e.g. consent for disclosing confidential patient information
- Established communication routes to more easily deal with complex research projects involving several data providers / research approvers, reducing the burden to applicants

RAG Comms Sub-Group

- Not easy to find up-to-date information about NHS Digital (and other data providers) activities that are relevant to research
- Increasing amount of good work done, but still not visible
- Coordinated way to disseminate a consistent message and assess impact

National Data Opt-Out

National Data Opt-Out

- Allows patients in England to opt-out of their confidential patient information being used for research and planning
- Currently only data released from NHS Digital is subject to the National Data Opt-Out.
- For research, only applies if the project relies on Section 251 support from the Confidentiality Advisory Group (CAG)
- Register via GP and opt-out rate is stable around 2.75%

What's new?

- From March 2020, all publicly-funded, commissioned or coordinated health and adult social care providers in England must apply the National Data Opt-Out to research and planning
- When obtaining CPI from any health or adult social care provider in England, with Section 251 support, you may see an impact on the data that you receive
- Details at:

<https://digital.nhs.uk/services/national-data-opt-out>

National Data Opt-Out doesn't apply when

- Consent has been obtained for disclosure of the CPI, regardless of whether consent was obtained before or after the patient opted-out
- You already have the CPI i.e. when a patient opts-out, their CPI will only be removed from disclosures from that time onward
- You receive anonymous patient information, as long as no data flows rely on Section 251 support (e.g. the act of data collection and anonymising requires Section 251 support)
- The CPI is disclosed from outside the health and adult social care sector
- The CPI does not originate from England

Logistics

- National Data Opt-outs Service run by NHS Digital via MESH
- Data provider sends a list of NHS Numbers via MESH
- Receive an amended list from NHS Digital
- List contains numbers that have no National Data Opt-Out registered
- Consent?

Impact

- Nothing for the vast majority of researchers
- An impact for research that relies on Section 251
- Impact on organisations that provide data for research
- Publicity around National Data Opt-Out and ease of opt-out may impact opt-out rate

Summary

- HDRUK
- NHS Digital / RAG
- National Data Opt-Out



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For support and guidance with:

- Consent, ethics and governance;
- Confidentiality, data protection and data access;
- Translational research (e.g. medicines, devices, *in vitro* diagnostics, cell and gene therapies *etc.*)
- Human tissue; and more.

mrc.ukri.org/regulatorysupportcentre