

ICR GCP & Ethics Forum

NIHR Collaboration Across the NHS, Social Care and Research Study Teams:

NIHR Clinical Research Network Coordinating Centre Covid-19 Research Model - The Study Support Service 2021

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Let's start with why...





Your thoughts...

why do you think support for research is provided through national organisations?

We asked attendees at our recent Life Science event to share the words that come to mind when thinking about why research support is coordinated nationwide



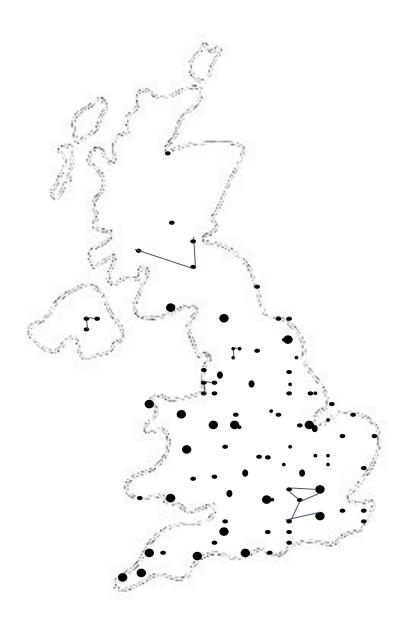
Our working themes

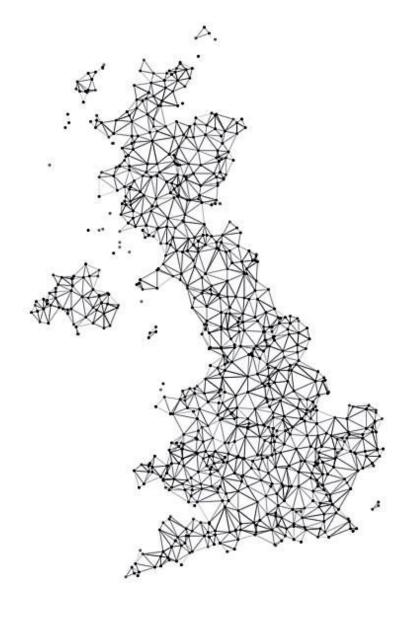
trust, visibility, inform, COOrdinate, relationships, effective, patients, learn, test, collaborate, communicate, inclusive, evolving, partnership, share, agile, People, collective, supportive, Progress, underpinning, behind-the-scenes, frontdoor, improve, specialists, vision, nationwide, engage, together



Our collective support exists to help **PLAN** PLACE & PERFORM research across the nation, for the nation









Our Structure

- Single, collective UK system-wide approach involving NIHR, Public Health England, UK Research & Innovation, HRA, MHRA and others
- Enables a complete picture of all COVID-19 Urgent Public Health Research activity across the UK
- Ensures appropriate geographical distribution of Urgent Public Health Research to maximise recruitment and minimise over-commitment of resource
- Urgent Public Health Research prioritisation by DHSC initiated expedited study set-up and delivery activities across the research system including performance oversight







The UK's system-wide approach

We are:

- One National Network covering all of England Operating across 15 geographical areas in England and 3 in the Devolved Administrations (Northern Ireland, Scotland & Wales).
- Each covering all study delivery in all therapy areas
- Comprised of one National Coordinating Centre and 15 Local Clinical Research Networks
- Including a specialty group containing key opinion leaders for all 30 therapeutic areas

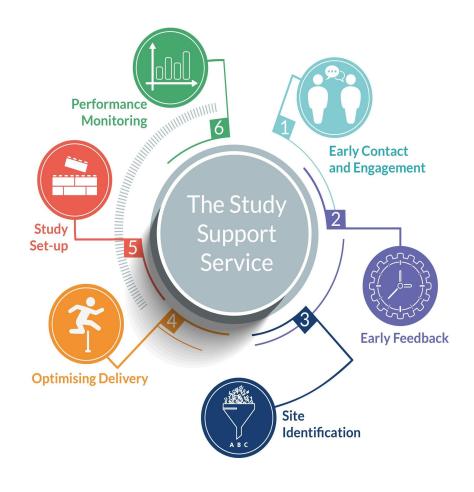






Nationwide coordination 4 of research planning, placement and performance



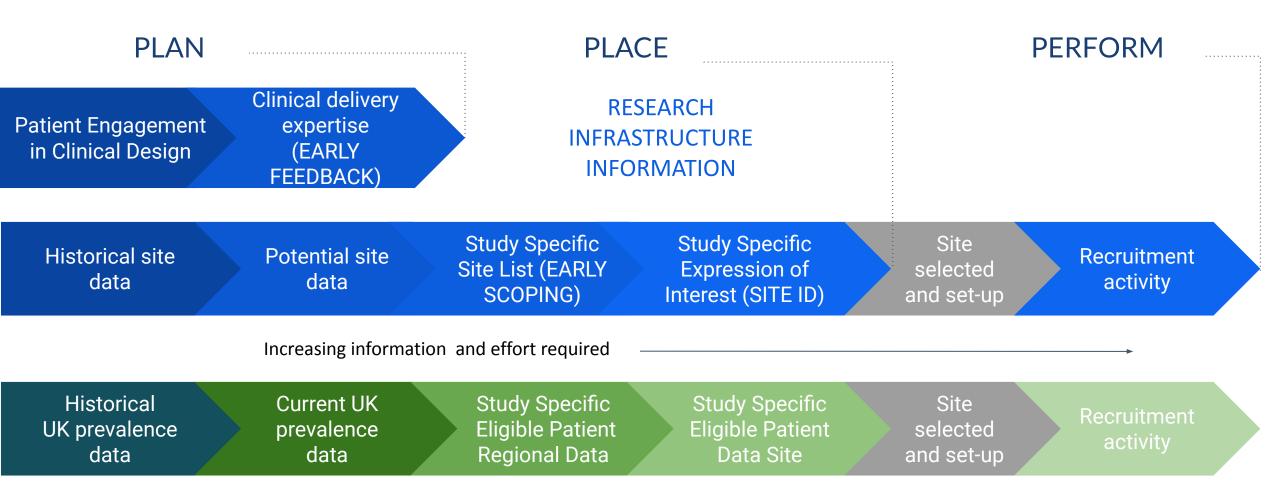








Shares and collates growing layers of information



PATIENT PREVALENCE INFORMATION



 Sites that have not yet recruited

Sites which have recruited

Bolder colour and larger circles indicate the number of studies per site

COVID-19 cases

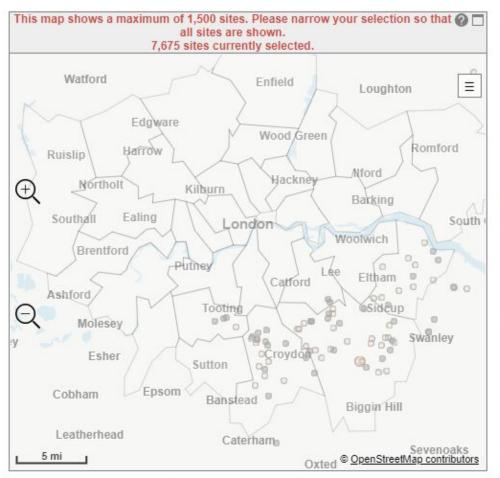
Bolder colour
- indicates a greater +
number of cases

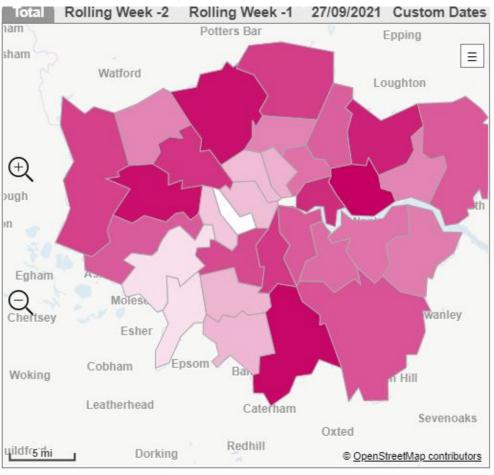
Region

East Midlands South East
East of England South West
London West Midlands
North East Yorkshire and T...
North West

Place of Death

Care home Home Hospital Elsewhere Hospice Other co...







NHS-DRIVEN

NHS driven support from the heart

PLANNING

Access to clinical expertise, patient groups, high level prevalence and costing tools

PLACEMENT

Identify interested sites across the UK and access research infrastructure intelligence



PERFORM

Nationwide infrastructure to facilitate research set-up and delivery

APPROVALS & SET-UP

Ideal path to access relevant pre-approval support provided by national specialists groups (Pharmacy, Radiation)





Nationwide coordination of NHS study approvals and site set-up





Nationwide coordination 6 to embed research within NHS provider requirements

COVID-19 Vaccines Research Delivery Programme

- Set up June 2020 UK wide model of delivery
- Regional model of collaborating sites developed to enable large scale recruitment at vaccine hubs
- Recruitment of 47,331 recruits (09.12.2021)
- 23 studies have recruited, 16 closed to recruitment; 3 studies in set up, 8 open to recruitment.
- Initial studies were large scale and recruiting unvaccinated participants
- Portfolio evolving to smaller studies such as boosters, 3rd primary dose, adolescents, pregnancy.
- NHS Vaccine Research Registry over 500,000 people have signed up



COVID-19 Vaccines Research Delivery Programme

Collaboration and communication:

- Vaccine Research Delivery Group, Operational Group and Pharmacy Group set up (UK wide representatives)
- Regional Vaccine Leads identified in each of the 18 regions (15 LCRNs; 3 Devolved Administrations)
- COVID-19 vaccine Chief Investigator group brought together to collaborate across the studies
- Planning framework developed, and regions shared their knowledge and details of arrangements
- Regular updates sent out to Regional Vaccine Leads, and they had forum to discuss progress





NIHR Collaboration Across the NHS, Social Care and Research Study Teams: CRN Yorkshire and Humber Covid-19 Research Delivery Model

Tanya Turgoose
Industry Operations Manager, CRN Yorkshire and Humber



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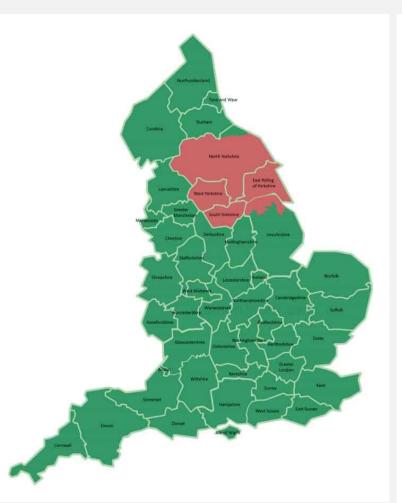


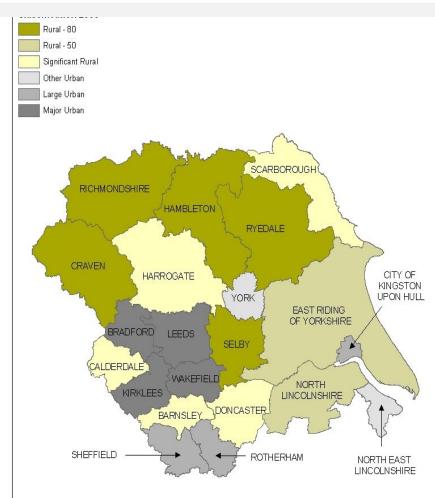




Y&H Vaccine Delivery Model - Challenges

Yorkshire & Humber system-wide approach





CRN YH Vaccine Model (Challenges)

Geographically huge

- 15,500 square kilometers
- 5 Million people (10% of the population and around the same number as the whole of scotland Scotland)
- 22 Local Authorities
- 3 ICS footprints

Regional coverage

Equity of Access

Equity of Opportunity

Scale - very high throughput needed



VTF Pump-priming Funding





To be utilised for both study support costs and non-study support costs such as space and equipment





Y&H Vaccine Delivery Model - Rotational Vaccine Hubs

Yorkshire & Humber system-wide approach

Doncaster Region

GSK/Sanot

New CRF established at a Mental Health/Community

Barnsley/Rotherham Region

- Valneva

Delivery at Acute Hospital

York City Region

- Medicago

Sportshall model at University of York

Wakefield City Region

AZ Monoclona

New CRF established at a Social Enterprise

Sheffield City Region

Oxford/AZ

Delivery at Acute Hospital CRF

Hull City Region

Oxford/AZ

Delivery at Acute Hospital

Leeds City Region

- Novavax

Sportshall model at the University of Leeds

CRN YH Vaccine Model (Rotational Hubs)

8 major vaccine hubs providing region-wide coverage

Placement on a rotational basis to ensure equity

Each hub is a city/region-wide model encompassing relevant Acute, Primary Care, CCG, council, HEI and social care partners

Each hub has working a steering group with membership from across the partners.

Hubs have offered to support one another where they are able as demand for resource shifts around the region. All hubs were supported by the CRN Y&H Agile Research Team.

BAME inclusion is a key part of the regions vaccine strategy.

Bradford City Region

- Novavax

Sports hall model at University of Bradford



A Closer Look - The Wakefield Hub





Together against COVID-19

The eight organisations which comprise the Wakefield Research partnership and helped to successfully deliver the trial are:

- · Spectrum Community Health CIC
- Mid Yorkshire Hospitals NHS Trust
- NIHR Clinical Research Network (Yorkshire and Humber)
- Wakefield Council
- · Bradford and Craven CCG
- Yorkshire Ambulance Service NHS Trust
- · Connexus Healthcare
- South West Yorkshire Partnership NHS Foundation Trust





② November 30, 2020

Cate

World-first for Wakefield as COVID-19 Antibody Trial begins

Read m



3 September 24, 2021

Categories -

Success for Wakefield Research partners at the Pharma Times Awards!

Congratulations to our partners across the Wakefield Together network, who were collectively crowned "Clinical Site Team of the Year" at the Pharma Times Awards in September! The Wakefield Research network picked up the top prize for their work co-delivering the PROVENT COVID-19 Antibody Trial in 2020. Spectrum was a key delivery partner in the PROVENT project, led [...]

Collaboration: A Model for Success



	CRN	Total RA →
1.	Yorkshire and Humber	2,821
2.	North West Coast	2,454
3.	Thames Valley and South Midlands	2,342
4.	South London	2,158
5.	North East and North Cumbria	1,728
6.	Greater Manchester	1,714
7.	West Midlands	1,633
8.	Wessex	1,375
9.	North West London	1,370
10.	West of England	1,335
11.	North Thames	1,324
12.	East Midlands	1,173
13.	Eastern	1,084
14.	South West Peninsula	992
15.	Kent, Surrey and Sussex	148



Highest recruiting region to ALL Vaccine trials



Highest recruiting region to the Oxford/AZ trial



Highest recruiting site to the Novavax trial



First Global patient recruited to AZ monoclonal antibody trial

Lasting success





Continuous collaborations



Lasting investment – two new community–based CRFs continue to be supported with additional funding from the host organisations and both have a new pipeline of research trials.



Supported by additional funding investment to develop a Direct Delivery Team (DDT) to support research delivery in the non-acute setting



