

PRESS RELEASE

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NIHR launches new National Patient Recruitment Centres for late phase commercial clinical research

The NIHR has today (12 November) launched five new National Patient Recruitment Centres (NPRCs) to enable more late phase commercial clinical research to be delivered within the NHS and make it easier for people to take part in studies.

Located at NHS hospital sites across England, the five regionally based NPRCs are funded through a £7m investment as part of the Government's Life Sciences Industrial Strategy and Sector Deal 2 - a series of measures to strengthen the UK environment for clinical research.

The NPRCs are managed by and funded through the National Institute for Health Research (NIHR), and run locally by NHS trusts. They are the first NIHR-funded research infrastructure wholly dedicated to delivering commercial research.

The new research centres are designed to make it quicker and easier for life science companies to deliver late-phase clinical research at scale and pace through the NHS. In turn, they will increase the number of commercial studies that can be delivered within the UK - benefiting patients who will gain earlier access to innovative new treatments and diagnostics, as well as the NHS and wider economy by attracting additional investment from the global life science industry.

To optimise the speed and consistency which commercial studies can be delivered through the NHS, each centre is equipped with purpose-designed facilities, clinical expertise and ready access to NHS support services including pharmacy, radiology, and pathology. These dedicated resources - together with a collaborative operating model focussed on close partnership working with local hospitals and primary and community health providers across each region - will enable expedited set up and delivery of late phase commercial studies at a rate and scale not previously achievable within the NHS.

Innovation minister Lord Bethell said:

"More patients will be able to access cutting edge treatment and diagnostics, so they can lead happier, healthier lives, by increasing commercial studies in the UK and enabling a wider range of participants to take part in clinical research.

"These centres will go a long way in providing vital evidence to help us move towards a more nuanced understanding of Covid-19 risk and how it impacts different members of the population, including through high profile vaccine studies. The centres will go on to improve treatments and diagnostics in a range of common chronic health conditions."

NPRCs: A new approach to commercial research delivery

The new centres are spread across England with a wide geographical catchment area to increase opportunities and make it easier for people in regions across the country to take part in studies and potentially benefit from innovation through clinical research.

The NPRCs specialise in recruiting non-hospitalised patients with common chronic health conditions - such as asthma, type 2 diabetes, and cardiovascular disease - conditions commonly managed by primary and community health services. Through the use of innovative recruitment strategies, alongside close collaboration with local and regional primary and community care providers, the centres will extend the reach of recruitment beyond hospitals and specialist clinics - enabling a wider cohort of participants and patients to take part in and benefit from late-phase research.

The centres will also play a pivotal role in delivering and helping people take part in vital commercial Covid-19 vaccine studies. The Novavax Phase 3 Covid-19 vaccine trial is already underway at three of the NPRCs - in the North West,

South West, and in Yorkshire and Humber - with a significant number of participants already recruited to the study through the new research centres. Other high-profile vaccine studies are also set to be confirmed for delivery through the NPRCs over the coming months.

The five National Patient Recruitment Centres, which are now operational and recruiting participants to studies, are based within the following NHS trusts:

- PRC: Blackpool - Blackpool Teaching Hospitals NHS Foundation Trust
- PRC: Bradford - Bradford Teaching Hospitals NHS Foundation Trust
- PRC: Exeter - Royal Devon and Exeter NHS Foundation Trust
- PRC: Newcastle - The Newcastle upon Tyne Hospitals NHS Foundation Trust
- PRC: Leicester - University Hospitals of Leicester NHS Trust

The NPRCs operate through a franchise-like model - an evolution in the way commercial research is delivered through the NHS. All five centres provide a uniform approach to research delivery which enable companies to benefit from the same level of dedicated facilities and staff at each location - resulting in quicker, easier, more consistent delivery of studies. To further increase the speed and efficiency by which studies can be set up, costed and contracted for delivery within the NHS, all five NPRCs also adhere to the new national contract value review process which uses standardised costing and contracting processes and uniquely, operate a single costing model which requires just one costing negotiation for all five centres, with minimal local variation.

Dr William van't Hoff, Chief Executive of the NIHR Clinical Research Network said: "The new National Patient Recruitment Centres will significantly increase our capacity and capability to support the delivery of late-phase commercial research through the NHS. By offering a streamlined, consistent and collaborative approach to study set-up and delivery, the centres will also make it quicker and easier for the life science industry to bring late phase studies to the UK and run these at pace and scale across our NHS.

"Most important of all, the centres will play a key role in helping people across the length and breadth of the country to take part in and benefit from innovative treatments through late phase commercial research - including the latest Covid-19 vaccines. With Covid-19 infections rising significantly across the UK, coinciding with an increasing number of vaccines ready to move into late phase trials, the launch of these new research centres will prove a timely and valuable asset in our urgent research response to the pandemic."

Innovative recruitment strategies to improve research delivery

The NPRCs use innovative and proactive recruitment strategies to reach out into the local community and empower patients to take part in research. An example of innovation within this area is already underway at the Patient Recruitment Centre in Newcastle, which is running one of the UK's first virtual interventional commercial clinical trials - utilising digital technology to enable participants to take part in studies remotely, from the comfort of their own homes, rather than by routinely attending clinical settings.

The RELIEVE IBS-D study is testing a new treatment for IBS with diarrhoea (IBS-D) and members of the public have been invited to take part in the study through the PRC via a consent for contact registry and digital media campaign.

The PRC: Newcastle team registered their first patient just three days after launching the virtual study, with 81 participants consented from the site after only seven weeks - roughly twice the rate achieved by 28 UK sites using traditional face-to-face processes. This demonstrates the effectiveness of virtual trials, which allow recruitment without geographical exclusion.

Professor Yan Yiannakou, PRC: Newcastle Clinical Director, said: "We're very pleased with the progress of the RELIEVE IBS-D study. It has demonstrated that there is a real demand to deliver studies virtually and to allow people to take part from the comfort of their own home.

"As we recruit more participants to the study, we can learn from the systems we have in place for future virtual studies at the PRC, which can help us to reach a wider community more effectively."

ENDS

National Patient Recruitment Centres - case studies

Pioneering virtual trials through the new National Patient Recruitment Centres

The Patient Recruitment Centre: Newcastle is delivering one of the UK's first virtual interventional commercial clinical trials - recruiting patients from the comfort of their own homes as well as hospital settings. Since it launched, the centre has been overwhelmed by the response from patients suffering with Irritable Bowel Syndrome (IBS), who have come forward in droves to participate in the study.

The RELIEVE IBS-D trial is testing a new treatment for IBS with diarrhoea (IBS-D) and members of the public have been invited to take part in the study via a consent for contact registry and digital media campaign. The ContactME-IBS patient registry has been used to recruit participants, before a two week screening process is used to confirm eligibility and randomise patients to different arms of the study.

It took the PRC: Newcastle team just three days after launching the virtual study to register their first patient, with 81 participants consented from the site after only seven weeks; roughly twice the rate achieved by 28 UK sites using traditional face-to-face processes. This demonstrates the effectiveness of virtual trials, which allow recruitment without geographical exclusion.

The study is the UK's first virtual clinical trial into IBS and consists of four video call appointments and a two minute daily diary, with participants receiving free Enterosgel drug-free treatment in the post.

Professor Yan Yiannakou, PRC: Newcastle Clinical Director, said: "We're very pleased with the progress of the RELIEVE IBS-D study. It has demonstrated that there is a real demand to deliver studies virtually and to allow people to take part from the comfort of their own home.

"As we recruit more participants to the study, we can learn from the systems we have in place for future virtual studies at the PRC, which can help us to reach a wider community more effectively."

Hazel Forsyth, Senior Research Nurse at the PRC: Newcastle, said: "It's just the start of the virtual trial journey and it has been great to have been involved from its inception."

The study offers participants a safe, easy and professional way to get involved in ground-breaking research, without having to travel to hospital sites during the COVID-19 pandemic.

One participant recruited through PRC: Newcastle, explained: "The team really put me at ease and have regularly checked up on me either by phone or through a web call. It has made the whole experience so much easier.

"The fact that it's virtual means there is no need to travel far in order to speak with the staff, which is useful as a student. The delivery of the product was very quick and efficient."

"Being able to do this research study virtually meant I was able to participate with ease. I didn't need to travel anywhere and it was able to be done within my own home and time," added another participant.

To find out more about the study, visit the RELIEVE IBS-D study site and the [ContactME-IBS registry](#).

Novavax phase 3 vaccine trial: Christopher's story

Trial volunteer Chris, an engineer from South West England, was one of the first participants to take part in the Novavax phase 3 Covid-19 vaccine study through the Patient Recruitment Centre in Exeter.

After attending the PRC to receive his first dose as part of the Novavax study, Chris said: "I am pleased to say that I have just now completed my first visit to the trial study hospital today. I was welcomed by friendly and knowledgeable medical research staff. The purpose and nature of the study had already been explained in the emailed patient information sheet, but all the staff were pleased to be able to explain it all again and answer any questions that I had. It was very reassuring. I was given a comprehensive physical screening and medical history review by a team of doctors and nurses. This included being taught how to do my own swab sampling. A blood sample was taken as the

first of several that will be used to assess my response to the vaccine. Finally, the actual vaccine was given to me in the form of an injection in my upper arm.

“While the staff looked after me to ensure that I did not have an unexpected reaction to the injection, I was instructed how to download the study symptoms tracker application. Obviously, I hope that I don’t get any symptoms, but I am reassured that I have a lot of people looking after my health and wellbeing over the next year.

“So, now I am looking forward to my next visit in three weeks, when I will receive my second dose of the vaccine. Then there will be further follow-up visits to give more blood samples so that the study can find out if my body is producing antibodies against the virus should I ever become infected. I am so proud to be part of this study. I feel that I am finally able to take part in our global community’s fight back against the virus.

Notes to editors

National Institute for Health Research (NIHR)

The National Institute for Health Research (NIHR) is the nation's largest funder of health and care research. The NIHR:

- Funds, supports and delivers high quality research that benefits the NHS, public health and social care
- Engages and involves patients, carers and the public in order to improve the reach, quality and impact of research
- Attracts, trains and supports the best researchers to tackle the complex health and care challenges of the future
- Invests in world-class infrastructure and a skilled delivery workforce to translate discoveries into improved treatments and services
- Partners with other public funders, charities and industry to maximise the value of research to patients and the economy

The NIHR was established in 2006 to improve the health and wealth of the nation through research, and is funded by the Department of Health and Social Care. In addition to its national role, the NIHR supports applied health research for the direct and primary benefit of people in low- and middle-income countries, using UK aid from the UK government. www.nihr.ac.uk

NIHR National Patient Recruitment Centres (NPRCS)

All five NIHR National PRCs are now operational, with a national virtual launch event taking place on 12 November 2020.

Further information on this national initiative can be found at: <https://www.nihr.ac.uk/explore-nihr/support/national-patient-recruitment-centres.htm>