

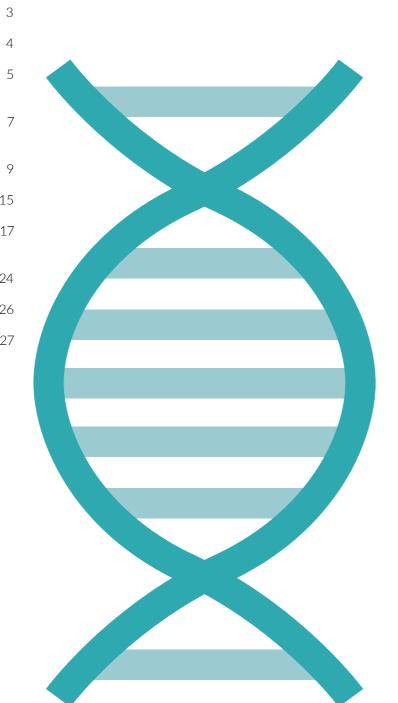


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### Foreword

Statement from Amy Barratt, Research Delivery Manager, NIHR Clinical Research Network, Greater Manchester.

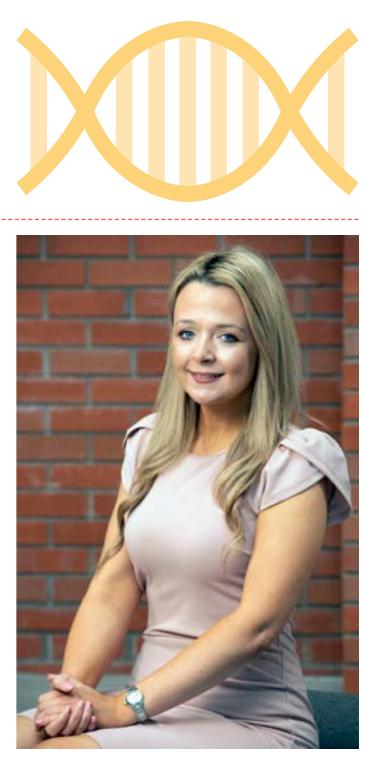
"Since 2014, the NIHR Clinical Research Network Greater Manchester community has significantly advanced life sciences research delivery, fostering transformation through collaboration, that improves health and care outcomes for our local communities, and has made a significant contribution to UKPLC.

We have effectively partnered with the life sciences sector, supporting commercial research that provides people living in East Cheshire, East Lancashire and Greater Manchester with increased opportunities to take part in research studies that are most relevant to them and their health and care needs. With our shared strategic vision, joint working and collegiate leadership, CRN Greater Manchester has provided an exemplary model for delivering research together across health, care, commercial and academic expertise; co-creating with local communities and people with lived experience; and experienced health and care staff working across a diverse range of settings and specialty areas. This united approach over the last 10 years with life science organisations has contributed to better health and care outcomes.

I am incredibly proud of the dedication of our Research Delivery sites and staff who continue to work extremely hard across our life sciences portfolios. I would like to recognise and thank the people who have volunteered their time and commitment to participate in these studies, the many colleagues we have worked with across life sciences industry organisations over the last 10 years; the success and achievements you read in this report would not have been possible without you. We will continue to build on these successes in the North West Regional Research Delivery Network ensuring an effective, inclusive, and efficient research delivery system for the future".

#### Amy Barratt

Research Delivery Manager, NIHR Clinical Research Network, Greater Manchester.



### Our 10 years in numbers:



Total participants in commercial research – **44, 256** (highest in the United Kingdom)



An average of **12 participants** recruited to commercial studies, per working day over 10 years



Total number of commercial studies recruiting in the last 10 years – **1,803** 



Over **60** notable **1st recruits**, Global, European, UK first recruits – **23 global**, **7 European** and **33 UK** firsts



Local average set up times – **51 days** compared with a national average of 117 days



Percentage of commercial recruitment to time and target – **84%** (highest in England)



Number of recruits to medtech studies – **137 recruiting studies** with **11,191 participants** 



Top recruiting region with **467 studies**, nationally and internationally.



Growing number of Investigators in our region. Currently **1,165** active Principal Investigators and over 190 Chief Investigators, which is an increase from 34 in 2012 – 2013.

## Why is Commercial Research Important?

Commercial research in health and care is important because it leads to better, faster, and more effective treatments and technologies, improved outcomes and quality of life for everyone. It also supports the economy and addresses unmet clinical needs, making health and care services more accessible and efficient.

### How we have helped to bring more Life Sciences opportunities to our communities

Life Sciences Industry seek collaborations with delivery sites that offer:

- Speed and Efficiency Rapid approval and setup processes for commercial activity are crucial. Rapid approval and setup processes allow for more time to engage and enrol local people into commercial research studies, so it's important we have established efficient and effective coordination of our site and study start up.
- Standardised and Streamlined Processes A comprehensive and mandatory national approach to contracting and costing is essential to eliminate delays and inconsistencies. This has been an important milestone as it has enabled us to work more efficiently and provide more access to our communities.
- **Equality, Diversity and Inclusion** By working with the life sciences industry across research programmes, we have ensured that research benefits everyone, has reduced health disparities and has fostered a more equitable health and care system.
- **Community Engagement and Recruitment** Efficient systems for participant recruitment and engagement are critical. We have established common approaches for contacting people about research, have enhanced participation rates and have ensured diverse involvement of our communities in studies.
- Collaboration and Resolution Strong collaboration between health and care providers, academic institutions, and the industry is vital. We have formed a dedicated support team and business unit that focus on research delivery and continue to help expedite processes and ensure high-quality outcomes.
- Transformation and Modernisation Adoption of workforce models, delivery transformation and decentralised models are key to improving research experiences and through this work we have made it easier for local people to participate. Digital technologies and mobile research units are highly valued and are significant areas of regional growth.

### Our commitment to reducing study set up times

CRN Greater Manchester has been a standout region in terms of the delivery and setup times for commercial research. CRN Greater Manchester has made notable strides in reducing setup times and enhancing research delivery efficiency.

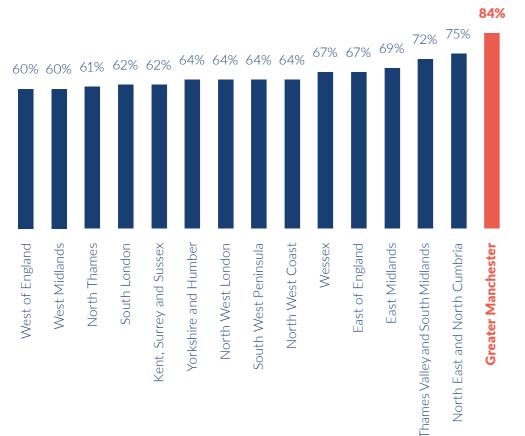
CRN Greater Manchester has consistently outperformed national averages in study setup. Since 2019, the regional site start-up timelines have been reduced to an average of 51 days, compared to the national median of over 117 days for commercial study start up. CRN Greater Manchester has worked closely with Life Sciences Industry and our local Partner Organisations to ensure a smooth study set up ensuring an exceptional experience. A fast and effective study start up is essential for cost efficiencies, patient access, and speed to market.

### Our promise to delivering on time and to target

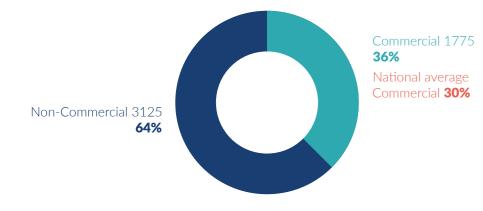
Delivery of commercial studies has been a strong focus in CRN Greater Manchester. The recruitment to time and target across commercial studies in CRN Greater Manchester delivery sites averaged 84% over the last 10 years. This is notably higher than the next best regional average of 75% across the same time period and was also significantly higher than the national average of 60%. We reached a peak of 91% in 2015/16 and are the only network to average a 10-year 'green' rating in achieving the expected target of at least 80% of commercial research study sites recruiting to target and on time.

Over the last decade, we recruited over **44,000** participants to **1,775** commercial studies. This represented **36%** of our regional research portfolio and was above the national average.





#### CRN Greater Manchester -Studies recruited Commercial vs Non-Commercial



### Our CRN Greater Manchester dedicated Industry business unit

Life sciences industry seeks an environment that minimises delays, reduces administrative burden, leverages technology for efficiency, ensures ongoing engagement, and supports strong collaborative frameworks.

Over 10 years ago CRN Greater Manchester began implementing dedicated staff roles for Commercial research being placed in the region, but also to ensure more business opportunities were available to local people. This has been a critical part of the Commercial delivery success.

CRN Greater Manchester's dedicated life sciences industry team have worked directly with our local delivery sites to maintain and develop our study delivery and future growth. The team has worked closely with the sites from early feasibility, attending site selection visits and site invitation visits through to study recruitment and ongoing retention, this is reflected on our experience and performance data over the past 10 years.

Here's an overview of the importance of various individual roles which have all played a vital part to ensure the best performance across CRN Greater Manchester:

- Business Development Manager Has been responsible for driving the growth and success of the region's commercial study portfolio. The staff working in this role are to be thanked for supporting the identification of new business opportunities, fostering relationships with industry customers, and supporting the strategic objectives of the national network in our local health and care system.
- Industry Operations Manager Has been a pivotal position in leading and managing the ongoing collaboration between CRN Greater Manchester and industry partners for identified research programmes across East Cheshire, East Lancashire and Greater Manchester. The people who have held this position are to be congratulated on their commitment to the successful and consistent delivery of Commercial research, with particular thanks to their effective negotiation and resolutions skills that have been particularly impactful both locally and nationally.

Industry Facilitators These dedicated staff in CRN Greater Manchester serve as a key intermediary between the network, delivery sites and industry partners. This role has been pivotal in facilitating the efficient execution of commercial research by ensuring seamless communication, coordination, and support throughout the study lifecycle. The people who have contributed to these roles over the last 10 years are to be commended for their quick responses, proactive approach and embedding a culture of learning between organisations and workforce groups. The focus and impact of these roles has also enhanced the delivery of non-commercial research studies.

Each role in this bespoke infrastructure has performed specific and vital functions which together have driven the successful delivery of Commercial studies. From strategic oversight and business development, to data management and delivery oversight the synergy of these roles ensures that all studies in the region have been given every possible effort to succeed and deliver impact for local people. The collaboration and integration of these roles have been an essential part of the achievements across CRN Greater Manchester and continue to provide foundations for the future.



### Lord O'Shaughnessy Review praise

Commercial clinical trials in the UK: the Lord O'Shaughnessy review was commissioned by the UK government and published in May 2023, aimed to revitalise the commercial clinical trials sector in the UK. The review made 27 recommendations to address key challenges and improve the environment for commercial studies. These included both immediate actions and longer-term strategies.

CRN Greater Manchester was highlighted in the report as an example of best practice for commercial research delivery. The report recognised the regional strong infrastructure, collaborative environment, and efficient processes, which together had seen the local system emerge as a hub for commercial research and was positioned as a leader for future growth.

In his review published in 2023, Lord O'Shaughnessy, said CRN Greater Manchester had "bucked the trend" as national participation in commercially sponsored trials had fallen by 36%, but in CRN Greater Manchester it had risen by 19%.

The review described how we were ahead of the national average times for study setup, which "accelerated regional site start up timelines to an average of 51 days, in comparison to the national median for commercial study set-up of over 117 days".

"The O'Shaughnessy Review is crucial for revitalising the UK's commercial clinical trials sector by streamlining approval processes, improving national contracting approaches, enhancing patient engagement, and securing significant investment to re-establish the UK as a global leader in life sciences research. We are proud of the way the staff and partners have worked together and we are grateful for the community engagement and participation."

Professor Martin Gibson, Co-Clinical Director, NIHR Clinical Research Network, Greater Manchester.



keynote speaker at the Great North Research Conference in Manchester in November 2023.

### **Commercial Engagement and key Commercial Partnerships**

Life Sciences Industry partnerships and CRN Greater Manchester foster a collaborative environment that drives health and care transformation, boosts the economy, improves research efficiency, and addresses critical health challenges. These collaborations are essential for maintaining the region's status as a leader for life sciences health and care research.

#### Statement from Kat Dutton, Business Development Manager:

"Over the last 10 years, CRN Greater Manchester has partnered with Clinical Research Organisations (CROs), pharma, biotech and medtech organisations, as well as study solution providers.

This work has taken place across a multitude of settings to deliver commercial contract research across the NIHR CRN portfolio, including a significant contribution to Urgent Public Health studies during the Covid19 pandemic.

These partnerships have been integral to helping support CRN Greater Manchester's shared system ambition to provide inclusivity and equity of research access to our population, as well as relevant research opportunities to promote health and economic prosperity in our region.

The dedication and commitment of our Research Delivery Sites to these research studies has provided exceptional experiences to both our research participants and our commercial partners.

The future of the North West Regional Research Delivery Network is an exciting opportunity to build on these existing partnerships and develop in emerging areas to ensure we continue to innovate and provide cutting edge treatments, preventions and diagnostic options to the North West region and UK PLC".







(I to r) James Connolly, Lauren Tough, Sarah Fallon, Tanya Turgoose and Kat Dutton, representatives from the four Northern Local Clinical Research Networks.

### **Northern Diamond**

We are part of the Northern Diamond, a collaborative across the North of England which seeks to strengthen health and care research opportunities. This business approach sees us work closely with our colleagues and Research Delivery sites across CRN North West Coast, CRN Yorkshire and Humber, and CRN North East and North Cumbria. This alliance is about ensuring we see the North as a collective research destination, recognising our shared strength to increase the capability and capacity for research delivery opportunity through study placement and shared expertise, intelligence, and assets. This collaboration helps us to support and improve the health and care of the northern population and transfer knowledge.

### Partnerships with Industry

Industry collaboration with the health and care system works in research because it accelerates innovation, provides necessary resources, enhances expertise, improves clinical trial efficiency, addresses unmet clinical needs, and ensures the global distribution of life-saving treatments. These partnerships create a powerful synergy that drives progress and ultimately improves patient outcomes.

During our 10 years as CRN Greater Manchester, we have collaborated with many global Clinical Research Organisations (CRO) and pharma organisations that have supported our local values, of delivering relevant research, inclusive involvement, and exceptional experiences. These collaborative relationships gave access to new investigators and research delivery sites and boosted established delivery site's portfolios.

### **IQVIA Northern Prime Site**

In 2019, along with our colleagues at CRN Yorkshire and Humber, we supported the creation of the IQVIA Northern Prime Site. This is a partnership between NIHR and IQVIA, the global health technology and human data science company focused on the delivery of lifechanging clinical research. The relationship brought together NHS research-ready hospitals across the two regions and enabled a significant increase in clinical trials and real world evidence studies in the North.

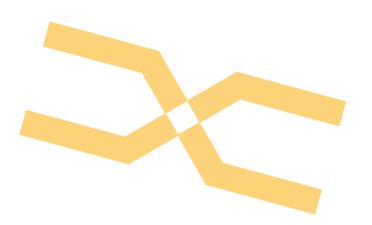
Since its inception, the number of IQVIA studies delivered across both regions has risen by 70% and the number of participants has increased 45%. In 2023, the Northern Prime had the fastest contracting times across all the Europe, Middle East, and Africa (EMEA) Prime Sites, with a median of 31 days compared to the overall EMEA median of 92.5 days. The Northern Prime also contributed the highest percentage of participants recruited in 2023 with 20% of IQVIA UK participant recruitment coming from the Northern Prime Site. The Delivery Sites involved benefited from an alignment of processes, early sight of new study opportunities and joint governance and support from both the local CRNs and IQVIA. This partnership also allowed some of the less research active sites to increase their commercial portfolio and take advantage of all the advice, support and growth that this partnership offered. Sue Crawford, Northern Prime Director, has previously said: "Our relationships with the CRN Greater Manchester industry team members and the responsiveness of this team are very valuable. They are always ready to step up when needed."



### PPD

In 2017, CRN Greater Manchester became the first PPD 'Select' site in England. PPD provides comprehensive drug development, laboratory and lifecycle services to customers across pharmaceutical, biotechnology, medical device, academic and government entities. This partnership has enabled us to increase our commercial portfolio in a number of our District General Hospitals, including those in Wrightington, Wigan and Leigh Teaching Hospitals NHS Foundation Trust and the former Pennine Acute Hospitals NHS Trust, providing access to more research opportunities for our participants closer to home. During the pandemic, our partnership was fundamental in the placement of key Covid-19 treatment studies and our relationship enabled us to trial innovative delivery methods to deliver vaccine studies seamlessly in out-of-hospital settings. As a result, we were the highest recruiting region to a high profile vaccine study. 2023 saw our most successful year to date in terms of the number of new PPD studies activated, number of new sites selected and the number of active studies in the region.







CRN Greater Manchester Industry Facilitators Paula Taylor and Naomi Charlton (left) and Business Development Manager Kat Dutton (right) welcome members of the Medpace team.

### Medpace

In 2017, we strengthened our partnership with the CRO Medpace. Medpace helps biotechs accelerate the development of their medical therapeutics with a full breadth of services and collaborative model. We were one of the first organisations to join their prestigious "Flagship Programme" and a certified centre of excellence when the programme was first launched. We have built a strong network of key delivery sites in a number of rare disease conditions, strengthening our portfolio of opportunities for participants in a number of key therapeutic areas. As a result, we have seen a rapid increase in the number of Medpace studies, growing by 171% from 2017/18 to the end of 2023/24. One key performance indicator of a Flagship site, is rapid recruitment and we are proud to have been the highest UK recruiting site to 4 studies in the last financial year. In addition to increasing our portfolio, one of our partner organisations has been named as one of the top two preferred sites for review among the Flagship sites in the UK. Manchester University NHS Foundation Trust is a stand out site as it is well organised, has a high number of contributing patients in the area and provides a very speedy turnaround time. This highlights our commitment to inclusive involvement in our research portfolio.

Tonia Koutsoukou, Site Relationship Manager, has confirmed: "Our collaboration with CRN Greater Manchester has been absolutely fantastic, having developed a mutually beneficial relationship with the region to be able to bring more studies to the region and provide access to novel treatments for patients across Manchester. At Medpace, inclusivity in participation to our trials is very important to us and CRN Greater Manchester as well as Trusts across Manchester have been trusted partners in helping us achieve this goal. Thank you for the ongoing collaboration, it has been an absolute pleasure working with the team and we look forward to everything we can achieve together as part of our partnership in the future." Clinical Research Network Greater Manchester



Delivery team staff from Manchester University NHS Foundation Trust with hampers provided by Syneos as part of their sponsorship of our Evening of Excellence awards ceremony in 2021.

#### Syneos

Syneos Health is a leading fully integrated biopharmaceutical solutions organisation built to accelerate customer success. Syneos Health translates unique clinical, medical affairs and commercial insights into outcomes to address modern market realities. Greater Manchester has a long-standing relationship with Syneos Health and became a Network partner in 2021: "Syneos Health is committed to building lasting and productive partnerships with our sites. Working with Greater Manchester supports our dedication to high-quality clinical trials, patient access and enhancing our global strategy in an ever-changing market," said Adrienne Bush, Director Global Site Partnership Solutions, Syneos Health.

### **Pfizer INSPIRE**

Pfizer is an organisation which works directly with health care professionals to study how medicines work, including designing and learning more about medicines and treatment approaches through clinical trials both before and after a medicine is approved for use by patients. Originating as part of the Pfizer INSPIRE programme, in 2015/16, CRN Greater Manchester and Pfizer were able to share expert knowledge and experience of Commercial research, to help bring more studies to CRN Greater Manchester and the wider UK in order to deliver the best results for patients in the NHS. Our collaboration has been valuable and Debbie Mitchell, Site Care Partner, has noted: "CRN Greater Manchester's Industry Team's support is so valuable, from help with site identification and feasibility to select the correct sites from the start through to follow up on recruitment activity with open sites. The team are also excellent at providing updates on CRN GM's latest initiatives to support the decentralisation and diversity and inclusivity of Clinical Trials".

Parexel

Parexel is an organisation providing the full range of Phase I to IV clinical development services to help lifesaving treatments reach patients faster. CRN Greater Manchester has a strategic partnership with Parexel as an Alliance site which has enabled the East Cheshire. East Lancashire and Greater Manchester population early opportunities for new research opportunities. Our relationship and regular engagement has seen our sites deliver swift study set up - 12% faster than other UK NHS sites and greater enrollment to Parexel studies than other UK sites. Andrew Boden. Associate Director. Site Alliance (Therapeutic Networks) has noted: "CRN Greater Manchester has been a valued Parexel Site Alliance member since 2016. Over the years it has brought opportunities for new research to the people of Greater Manchester. Our relationship and regular engagement has been the cornerstone of the partnership. Whether it be a phone call or an on site visit, it has always been a pleasure!"



Andrew Boden from Parexel (left) presents the Inclusive Involvement Excellence award, sponsored by Parexel, to Stephanie Shoop-Worrall at the 2023 Greater Manchester Health and Care Research Awards, with Professor Martin Gibson (right), CRN Greater Manchester Co-Clinical Director.



Members of the CRN Greater Manchester team and wider network with representatives from Sanofi.

#### Sanofi's first UK premier site

We entered into a landmark partnership with global pharmaceutical company Sanofi in 2018 as we became their first **UK Premier Site**. This created a mutually beneficial environment; closely linking the cutting-edge clinical trials sponsored by Sanofi with our network of R&D experts and research centres in primary and secondary care. This has evolved to include a number of 'Partner' sites within the region and has enabled us to increase the commercial research portfolio at some of our local hospitals, for example Tameside's respiratory team, and within Primary Care services.

### Small Medium Enterprises (SMEs)

Over the last 10 years, we have supported local SMEs in their ambition to deliver research in our area. This process has been refined and has resulted in the formation of a 'SME forum' in collaboration with local GM stakeholders, including representatives from the Integrated Care System, Health Innovation Manchester, and three local universities as well as locally hosted NIHR infrastructure. This forum was formed to reduce the duplication of discussions in the region and give industry access to the relevant partner for their product. Many of the SMEs we have engaged with highlighted that they were "very satisfied" with the experience they had received and that the "direct support with all stakeholders involved" had been most valuable. As a result, in the past 10 years we have supported 137 MedTech studies in the region, with 11,052 participants recruited.

### Collaboration with GlaxoSmithKline (GSK)

GSK is a global biopharma company with a purpose to unite science, technology and talent to get ahead of disease together. The Salford Lung Study was a groundbreaking respiratory study sponsored by GSK and considered the first of its kind globally, a large real-world trial, carried out across a patient population within a single geographical setting. It was the world's first digitally-enhanced Randomised Controlled Trial, which focused on how participants interact with their medication. Eight CRN Greater Manchester health and care organisations collaborated on the project to enrol 8,000 local participants from 80 GPs and 130 community pharmacies. Dr Sue Collier, GSK Head of Medical Operations for the Salford Lung Study, said: "The Network was crucial in developing relationships with the practices, getting them on board, explaining what's involved, providing Good Clinical Practice Training, and advising on the delivery of the study in this real-world setting. Without the support of the CRN at a local level, this study would never have happened."



Stakeholders gather for the launch of the Salford Lung Study, including our then Primary Care Specialty Lead Dr Sheila McCorkindale (centre).



### **First-of-its-kind Commercial** conference promotes the North

We hosted the first ever Great North Research Conference for the life sciences and med tech industries in partnership with our fellow northern CRNs. The two-day conference in Manchester marketed the North as a cooperative and consolidated, prime destination for commercial research, emphasising our research strengths and disease burden challenges and brought together partners from across the UK. Over 450 delegates attended the famous Concorde Centre and 95% rated their experience as good or excellent. In a unique feature, all delegates had the opportunity to be part of research and over 70 people took part in studies. Keynote speaker Lord James O'Shaughnessy, who led the governmentcommissioned UK review of commercial clinical trials, said: "There is so much great practice in the North, the outstanding growth in commercial trials in CRN Greater Manchester, the focus on digital innovation in CRN Yorkshire and Humber, the primary care research strengths in CRN North West Coast, and the excellence in MedTech in CRN North East and North Cumbria. to name a few. There is lots of inspiration for the whole country."



### **Experiences from Life Sciences Industry Partners**

Each year, we ask our Life Sciences Industry stakeholders to tell us what they think of the service they received from our dedicated CRN Greater Manchester Industry team. The survey is shared with all of our contacts in areas such as pharmaceuticals, CROs, SMEs and medtech. Last year, 100% of respondents were completely satisfied with their enhanced experience. Industry stakeholders frequently commented on our relationship management and engagement expertise.

Albert Labs is a pharmaceutical company focused on natural neurological therapies to treat the immediate, unmet needs of the ever-worsening mental health crisis. Albert Labs said: "CRN Greater Manchester's local insight, immediate understanding of the research goals and needs, together with the immediacy of action to help Albert Labs advance discussions with key clinicians and local decision makers was outstanding!"



**CRN Greater Manchester core team colleagues** in discussion in our Citylabs 1.0 office on Manchester's Oxford Road Campus.

Clinerion is the worldwide leader in medical data informatics, radically improving efficiency in patient search and identification, increasing effectiveness in clinical research and accelerating the process of drug development to ensure an earlier availability of medicines. Clineron said: "They are very cooperative and professional in trying to find solutions for any kind of problem."

Amgen is a pioneer in the science of using living cells to make biologic medicines. They aim to invent the processes and tools that built the global biotech industry-turning it into a leading source of therapies for patients. Amgen said: "The collaboration we have established between Amgen and CRN Greater Manchester has led to improvements in the running of studies and relationships with our key delivery sites. The relationship has enabled us to resolve issues which would have otherwise caused significant challenges and delays with clinical trials in our portfolio."

## **Enhancing Delivery using digital solutions**

### Virtual tours

Through strategic development across local districts, we developed a series of virtual tours of delivery sites in our network to support remote site selection and to promote assets and facilities in the region. This included a tour of our bespoke research van, which is a mobile research unit designed to deliver clinical research in the community and increase access for local people. These tours are cost-effective and time saving for both the site and Life Sciences Industry customers. One delivery site estimated a saving of £97,000 in staff time in under a year by using this facility to reduce the time taken to provide 121 tours for customers and stakeholders. Future digital enhancements will include access to an enhanced-reality platform, whereby the Life Sciences Industry can 'visit' our facilities in a more immersive experience.





### Locally developed tools to aid local delivery

Research for the Future is a North West innovation which has supported researchers to involve, engage and recruit the right people to participate in their research. It has helped find local people for a wide range of research involvement and engagement opportunities including grant applications, clinical trials and other patient and public involvement and engagement opportunities. Since its formation in 2011, over 12,500 people have registered and consented to be approached about research opportunities, and it has supported over 250 studies to recruit to a range of research opportunities. Research for the Future has collaborated with NWEH to support patient and public involvement and engagement (PPIE) for commercial-contract research, facilitating focus groups for research sponsors and their regulatory commitments.

FARSITE was developed in collaboration with North West eHealth to promote the usability of the local feasibility to assist and potentially boost recruitment within the region. The feasibility tool has contributed to the delivery of research, providing early feedback, early engagement and recruitment of patients into studies. Engagement work with stakeholders, such as NHS and Life Sciences Industry partners, was carried out to understand the use of the feasibility tool and the added benefits. The use of the Farsite tool has supported amendments to the eligibility criteria for a number of commercial-contract research studies based on real-world evidence.

### App boosts commercial trial efficiency

The National Contract Value Review (NCVR). is the new UK-wide standardised approach to costing and contracting for commercial contract research. The Lord O'Shaughnessy UK independent review of commercial studies recommended that it should be 'radically expanded'. CRN Greater Manchester developed an app to enable proactive study resource monitoring for NVCR. This innovation has helped set up times, sponsor experience and reduce business development risk at a regional and national level. In Primary Care, our engagement resulted in our network having the highest number of committed practices choosing to proactively join NVCR in the UK.

### Automation of the site identification service which saves over a month of staff time per year

The identification of suitable delivery sites for commercial trials can be time-consuming and delays studies getting up-and-running. CRN Greater Manchester transformed the local site identification process with the use of the Site IdenTification Support App (SISTA). This enables sites to receive a pre-populated site identification form which saves around 25 business days per year across Greater Manchester as well as increased data quality and consistency of expressions of interest submitted to companies. Subsequently, research opportunities are being made available to our population in a timely manner and studies are placed and delivered in the best way.



### Locally developed Initiatives to strengthen delivery

Teams working in collaboration across Greater Manchester helps to improve research capacity as well as further develop efficiencies in research delivery; sharing expertise and working together to create solutions. Thereby enabling participants to have wider access to health and care research opportunities.

### **Business Development and Marketing Champions**

CRN Greater Manchester launched a Business Development Champions programme to identify motivated colleagues from the regional research community. Seven champions were selected to represent their organisations to enhance commercial development opportunities. They are working with CRN Greater Manchester and the Life Sciences Industry representatives to develop stronger relationships and explore new ways to meet local community needs.



### **Vital Vaccine Delivery**

Messenger RNA (Moderna) is not new technology, but is discovering new ways to use it to treat and prevent illnesses and diseases. Biontech are an organisation who are committed to improving the health of people worldwide with our fundamental research and our work in the area of development of immunotherapies utilising the full potential of the immune system to fight cancer, infectious diseases and other serious diseases.

The UK government has established partnerships with Moderna and BioNTech to give UK sites the opportunity to deliver respiratory, infection and cancer vaccine studies over the next 10 years.

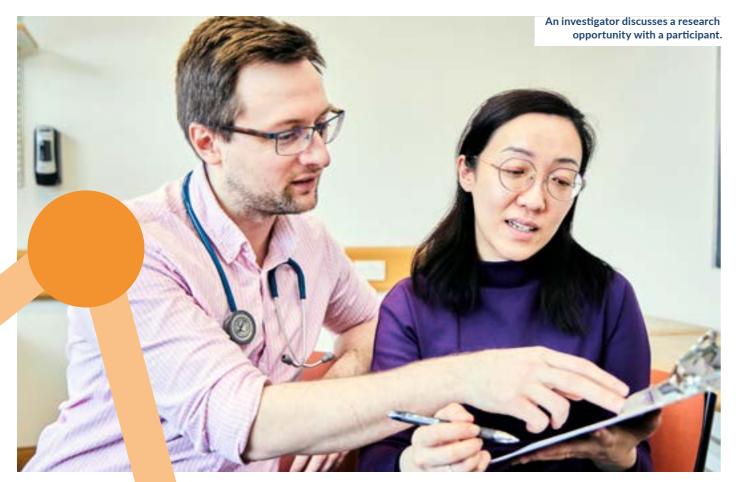
In response, CRN Greater Manchester established a regional vaccine group designed to identify sites and settings with the capability and capacity to set up such studies efficiently, recruit to time and target and provide an exceptional experience. We are exploring opportunities to use a hub and spoke delivery model and proposing to use a mobile workforce model to complete study activity across the CRN Greater Manchester and offer equity of access to our local community. In addition, a pharmacy subgroup has been formed to develop a centralised regional approach to setting up and delivering trials. It focuses on resolving bottlenecks and creating innovative approaches across all specialties and settings. Their efforts have streamlined processes and garnered national recognition for th



Greater Manchester Matron, prepares to deliver a vaccine trial.

national recognition for their contributions to improving clinical research delivery across support service areas.

By embracing these decentralised clinical trials, CRN Greater Manchester enhances its capacity to conduct research efficiently while improving recruitment and retention. These innovative approaches contribute to advancing research delivery and ultimately improving health and care outcomes for the local population and beyond.



### Wider access for Oncology Participants

Initially. The Christie NHS Foundation Trust's Outreach project was established with focus on delivering Breast Cancer trials in satellite centres, ultimately to increase the equality of late phase clinical trials access across CRN Greater Manchester. The vast majority of Oncology studies were set up and delivered through The Christie's main site, which sits within South Manchester. With the assistance of The Christie research teams, and other local sites such as Royal Albert Edward Infirmary and the Royal Oldham Hospital, the people of East Cheshire have benefited from increased and life saving access to early phase studies using The Christie@ site as a hub and spoke delivery model. The project has vastly expanded across the UK and has increased its collaboration with a host of other Commercial Sponsors.

Premier Research Group is dedicated to helping biotech, specialty pharma, and device innovators transform life-changing ideas and breakthrough science into new medical treatments. Erin Pike, Clinical Research Associate from Premier Research Group Limited, a Clinical Research Organisation managing monarchE, the first study delivered via the CRN Greater Manchester Oncology outreach collaboration, said: "The team have been a breath of fresh air to work with. They worked tirelessly to identify patients and their determination to ensure patients were able to access the trial at their local site as opposed to having to travel to Manchester, the closest alternative, was nothing short of inspiring".

### Developing the future care for people living with Mental Health conditions

Mental health Trusts collaborate with one another to secure first Commercial Clinical Trials of Investigational Medicinal Products: Pennine Care has secured their first commercial trial looking at a new antipsychotic medication, running as a joint venture with Greater Manchester Mental Health NHS Foundation Trust. Combined investment from Pennine Care and the CRN Greater Manchester has enabled commercial studies to run at Pennine Care, placing them in a strong position to increase their commercial portfolio and serve their communities most in need.

### Advancing Cancer Care and Treatments

### The Christie has contributed to practise changing research for common cancer

**types:** In the last 10 years The Christie has recruited the most cancer participants in England to commercial studies, recruiting over 3,200 to around 650 commercial studies. They have recruited to CAPitello-291, DeLLphi-301 and Combi-V that changed clinical practice for breast, lung and melanoma patients. This really was groundbreaking research which will impact future generations.



Dignitaries and staff gather for the grand opening of Wrightington, Wigan and Leigh Teaching Hospitals NHS Foundation Trust's research hub in Ashton-in-Makerfield

### Improving access for people living in Wrightington Wigan and Leigh (WWL)

WWL have worked within the local community to improve the future of research delivery in the area and to ensure that patients have access to trials closer to home by creating a 'hub' which is a specialist centre for the delivery of clinical trials. You can take a look around the new WWL community hub via our new **3D walkaround tour**.

WWL has also made an outstanding contribution to the Oncology Outreach Project in collaboration with The Christie, which has led to a wider selection of research opportunities for local people with the most need.



Scan to tour Wrightington, Wigan and Leigh Teaching Hospitals NHS Foundation Trust's research hub.



### Improving access for people living in Bury, Rochdale, **Oldham and Salford**

#### **Consultant Neurologist presented with Exceptional Experience award for life saving**

research : Dr Adrian Parry-Jones was part of research which saved the life of a patient named John, who was admitted to hospital with a severe stroke. The catheter placed in John's brain crucially reduced the amount of bleeding and, ultimately, allowed him more precious time with his family. Sadly, John died 18 months later from an unrelated illness, but for the rest of his life, he and his wife Jean spoke of their gratitude for this invaluable research opportunity. This example shows how Adrian went above and beyond for John and how he's remained in touch with his family.



Special Award for Exceptional Experience at the 2022 Greater Manchester Health and Care Research Awards.

### **Commercial research growth** has allowed patients to participate in a variety of research opportunities in a range of therapeutic areas

East Cheshire has worked to increase their commercial portfolio. While the vast majority of their activity is made up of academic research. East Cheshire has supported the recruitment of 11 commercial studies, providing an opportunity for 111 of their patients to participate in commercial research over the last decade. The growth of commercial research has allowed patients at Macclesfield District General Hospital access to novel therapies and treatments in Paediatrics, Oncology, Cardiovascular, Stroke, Respiratory and Ophthalmology.

### Metabolic and endocrine: First UK patient treated with pioneering gene therapy

The first patient in the UK was treated in CRN Greater Manchester with a pioneering new investigational gene therapy designed to treat the debilitating genetic disorder Gaucher disease. They had access to the one-off treatment as part of a study which represented a major milestone for the inherited condition, which causes harmful substances to build up in cells that then accumulate in various organs. It is hoped this could stop disease progression, improve outcomes, and free people from lifelong treatment, none of which currently work for everyone.

#### **Enabling access for communities** living in East Lancashire

East Lancashire Hospitals NHS Trust is a specialist centre for urological cancer and has delivered many noteworthy clinical trials in this area which have been of benefit to people in CRN Greater Manchester.

In 2024, they celebrated two global first recruits in quick succession to Ultra Long and Alpha Long, both are cardiac stent trials. This is an outstanding contribution to research, and shows the dedication of the delivery teams.

### at Fairfield General Hospital in Bury.



### Highest recruiting Trust in Gastroenterology studies:

The Northern Care Alliance was the highest recruiting Trust of more than 100 sites involved in recruiting patients to NIHR portfolio gastroenterology studies. Between April 2022 and March 2023, more than 1,100 patients took part in IBD research.

### **Commitment to Mental Health Services**

Commercial research brought to prisons in Greater Manchester: Greater Manchester Mental Health NHS Foundation has collaborated with non-NHS stakeholders such as prisons and secure units to enable commercial research opportunities in areas such as substance misuse. Collaboration with these organisations further emphasises the NIHR's long-term commitment to social care research.

### Delivering for North, South and Central Manchester communities

The first patient has been recruited to a new device study which aims to improve dialysis treatment by preventing side effects for

**kidney disease patients:** Cora Nolan, 57, from Wythenshawe, Manchester, was the first person to take part in the study. Cora, said: "When I was first asked if I wanted to take part in this research study, I just thought 'you never know, it might help someone in the future' and I wanted to give it a go." Principal Investigator on the study, Dr Leonard Ebah who is also a Consultant Nephrologist and Medical Director at Manchester Royal Infirmary, said: "Excess inflammation has been linked to the primary causes of premature death in patients on dialysis. This approach aims to tackle this and eventually improve patient outcomes."

### Royal Manchester Children's Hospital is one of five Libmedly® qualified treatment centres in

**Europe:** St Mary's and Royal Manchester Children's Hospital were instrumental in establishing the UK as a Metachromatic Leukodystrophy/Libmedly qualified treatment centre. A 19 month old baby girl named Teddi, was the first child in the UK to receive life saving therapy in February 2023. Professor Robert Wynn, Paediatric Bone Marrow Transplant Programme director, said many of his young transplant patients have genetic diseases and that using gene therapies will be "transformative". **St Mary's participates in groundbreaking Iysosomal storage disease study:** Infants diagnosed with Gaucher disease have a life expectancy

of five to eight years. Professor Simon Jones was the only investigator outside of the United States and engaged with clinicians nationally and internationally to ensure all potentially eligible participants were considered. As a result, the team were able to provide potentially life saving gene therapy to a baby boy from Turkey.

### Manchester Royal Eye Hospital and MedTech collaboration changes clinical practice:

Mr Leon Au, consultant ophthalmologist specialising in minimally invasive glaucoma surgery, successfully collaborated with Ivantis Incorporated – manufacturer of the Hydrus® Microstent. The Hydrus Microstent® is now used in practice as standard of care.

### Supporting residents of Stockport to access Commercial research

**Vaccine research success over the years:** A true CRN Greater Manchester collaboration led by Stockport: This successful high throughput delivery model, saw over 750 healthy volunteers take part in a study testing the safety and effectiveness of a Covid-19 vaccine developed by US biotechnology company Novavax, now one of the vaccines used in the national booster programme.

This working model was then used for the COV-BOOST trial, where ~150 more healthy volunteers in the region were involved in evaluating Covid-19 vaccine boosters, to see which doses, type and combinations worked best for immunity. This trial directly informed the development of the national UK Covid-19 booster immunisation programme.

### Boosting Bolton's Commercial offer

Bolton NHS Foundation Trust has been named the highest recruiting Trust in the country for an innovative study which used a urine test to support the diagnosis of womb cancers. The study aims to determine whether looking at a protein found in urine could help diagnose womb cancer as an additional diagnostic test alongside scans, biopsies and blood tests that are currently available.



Professor Andy Ustianowski, CRN Greater Manchester Co-Clinical Director, presentes the Special Award for Relevant Research to the FIND-IT study team from Tameside and Glossop Integrated Care NHS Foundation Trust at the 2023 Greater Manchester Health and Care Research Awards.

### Transforming Tameside and Glossop through Life Sciences Industry Partnerships

#### Tameside pioneers the FIND IT study to diagnose 20% of undiagnosed patients with Diabetes or Pre diabetes: Tameside A&F

staff designed and conducted a simple blood test to discover if patients had undiagnosed diabetes or pre-diabetes. Professor Edward Jude, Chief Investigator, said that "the study has demonstrated the high prevalence of undiagnosed diabetes amongst patients attending A&E in a busy district general hospital." The study has also attracted interest from NHS England, which is considering rolling out a screening programme to identify diabetes/pre-diabetes at an early stage.

#### Tameside is the first site in CRN Greater Manchester to contribute to the 'Born and

**Bred in' study:** The study is gathering data from pregnant women and their children to improve the health and well-being of people in the local area. The study has generated interest from public health and other organisations and will lead to the development of further research studies soon.

Principal Investigator, Margaret Cooper, said: "This is a great opportunity for the Trust to work collaboratively and form new linkages with local authorities and the Integrated Care Systems, to look at our local health deprivations and to develop new evidence to support the provision of services tailored to the needs of our specific population."

### Primary Care

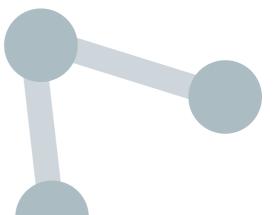
CRN Greater Manchester are proud of colleagues that have delivered Commercial research in Primary Care, Social Care and in Non-NHS settings. Life Sciences Industry partners worked with us to introduce a higher level of inclusion across non hospital settings.

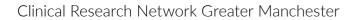
We have formed a successful partnership with AstraZeneca, supporting research sites to improve outcomes for people living with COPD and asthma, and continue to build on existing partnerships and relationships. We have seen a noticeable increase in the number of Primary Care sites engaged in Commercial research and the number of studies open across different districts in our region.

This has contributed towards our record number of participants in Primary Care research. In 2023/24, this was our most successful year yet, with 6,074 commerical recruits; a ranking of nine out of 15 local CRNs.

Over the course of 10 years, 28% of our GP practices have recruited to commercial studies. Our delivery sites have recruited to 58 individual commercial studies over a range of 19 different specialty areas, with an overall recruitment of 14,806 participants in 10 years.

In addition, 33 of our practices have signed up to the National Contract Value Review (NCVR) to improve study set-up times and increase our involvement in the commercial portfolio.







trial, which focused on Meningitis B, in schools and colleges.

### **CRN Greater Manchester Research Delivery Sites Collaboratives**

Collaboration in clinical research enhances the quality, efficiency, and impact of studies. By pooling resources, expertise, and perspectives, collaborative efforts can overcome the inherent challenges of clinical research, leading to more robust and generalizable findings, faster development of new treatments, and ultimately, better health outcomes for patients worldwide.

### **Recognising Excellence and collaborations**

The PharmaTimes Bronze Award recognizes excellence in clinical research and is part of the broader Clinical Researcher of the Year competition. This competition is designed to acknowledge and reward outstanding talent among clinical researchers globally, offering categories that cover a wide range of roles and experience levels. We were shortlisted in the category for Clinical Site Team of the Year and won the bronze award after impressing judges with our ability to adapt our successful pandemic initiatives to enhance delivery of non-Covid-19 research programmes. The initiatives included recruitment sessions in the community, at weekends, and aboard our Research Van - to deliver non-COVID research.

The collaboration involving the NIHR CRN Greater Manchester **Research Van** involves partnerships with local health and care providers, research institutions, community organisations, and potentially pharmaceutical companies or other sponsors of clinical trials. These collaborations aim to enhance the reach and impact of clinical research by bringing studies directly to diverse communities within East Cheshire, East Lancashire and Greater Manchester. Through these collaborations, the NIHR CRN Greater Manchester Research Van aims to promote inclusivity in clinical research, improve outcomes, and contribute valuable data to advance health and care.



### Increasing capacity across children's research

CRN Greater Manchester collaborated to deliver infant vaccine study: We recruited over 300 babies to The Hospitalised Respiratory Syncytial Virus Monclonal Antibody Prevention (HARMONIE) Study. Respiratory Syncytial Virus is the most common cause of chest infections in children, estimated to account for 45,000 GP appointments, 29,000 hospitalisations and 80 deaths in the UK per year. The study sponsor published data to show a single dose of Nirsevimab reduced RSV hospitalisations by 83%, severe chest infection hospitalisations by 76% and all chest infections by 58%.

In 2022/23, gene therapy highlights include the first gene therapy study in Fabry Disease within the Northern Care Alliance NHS Foundation Trust and the first child in the **UK** receiving life-saving gene therapy treatment as a result of rigorous clinical trial testing at Royal Manchester Children's Hospital.



part in the HARMONIE study which showed the effectiveness of a medication for RSV in infants.

### World leading diagnostic testing

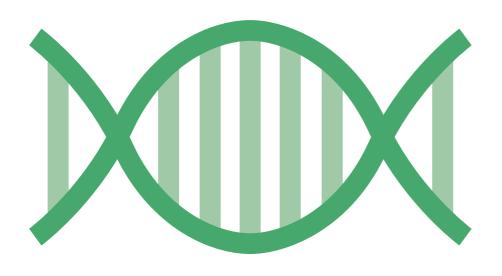
Diagnostic testing remains an important part of CRN Greater Manchester's research portfolio and as the home of graphene. University of Manchester is collaborating with a graphene electronic specialist and Northern universities to develop a world-first to identify patients who need antibiotics within minutes. Manchester University Hospitals NHS Foundation Trust has collaborated with MedTech organisation genedrive PLC and The University of Manchester to develop the **world's first genetic test** to prevent hearing loss in babies administered with the antibiotic Gentamicin. These diagnostic developments will not only impact on the people in need by targeting the most accurate antibiotic in a timely manner but will also have huge cost saving implications for the care system. Stephen Powis, NHS National Medical Director said: "Through world-class innovation, the NHS is delivering cutting edge treatments to save and improve patients' lives as well as delivering on the commitments of the NHS Long Term Plan."

### Improving research access to people with rare conditions

The renowned Manchester Centre for Neuro Sciences team has successfully delivered a programme of research into Amyotrophic Lateral Sclerosis (ALS) in the last financial year. Participants were recruited and supported this important work, looking at an alternative treatment to the current standard treatment option, where it has been shown to have a modest impact on survival.

### Expediting start up for communities living in Bolton

A collaboration between two local hospitals, St Mary's Hospital, the Chief Investigator site, and Royal Bolton Hospital, has been testing an innovative urine test for the diagnosis of endometrial cancer. This potential diagnostic test will allow the swifter and much less invasive diagnosis of this cancer in women. Royal Bolton Hospital is the 4th highest recruiting site to this study, having enrolled over 150 participants.



### Conclusion

To conclude, the delivery of commercial research in CRN Greater Manchester has been marked by exceptional achievements and continuous progress. Our commitment to efficiency, collaboration, and innovation has established us as a premier destination for cutting-edge research. The dedication and expertise of our research teams, coupled with strong partnerships across the industry, have enabled us to consistently meet and exceed the expectations of the life sciences industry.

As we look to the future, we remain steadfast in our pursuit of excellence in commercial study delivery. By fostering a supportive and dynamic research environment, we will continue to attract high-profile studies, contribute to the development of groundbreaking therapies, and improve healthcare outcomes for people locally and globally.





### Statement from Sarah Fallon, Chief Operating Officer, NIHR Clinical Research Network Greater Manchester

"I am immensely proud of the outstanding achievements of everyone who has worked across CRN Greater Manchester to support and enable our Commercial portfolio. Our network's dedication to advancing health and care, fostering strong partnerships with industry customers, and working together, has positioned us as a leader in this space.

Over the past 10 years, CRN Greater Manchester delivery sites have consistently demonstrated excellence in accelerating the setup and delivery of Commercial studies. The commitment to efficiency, transformation, and collaboration has not only streamlined research processes but also significantly contributed to the rapid development of new therapies and treatments. These efforts have undoubtedly changed peoples lives and influenced the future of health and care services.

Our success in commercial delivery is a testament to the hard work and expertise of our core team, dedicated commercial business unit, researchers, organisation and specialty leaders, site delivery staff, public contributors, coordination and administrative colleagues, and support services and functions. These people have all worked together with our life sciences industry customers to learn, develop and excel. I would like to personally thank everyone who has contributed and worked hard to deliver relevant research, made involvement inclusive, and provided exceptional experiences.

CRN Greater Manchester has shown great skill in managing complex studies, recruiting diverse populations, and ensuring high-quality delivery. These efforts have been instrumental in attracting high-profile commercial studies to East Cheshire, East Lancashire and Greater Manchester, thereby enhancing our region's reputation as



a hub for cutting-edge research delivery. However this has only been made possible through the continued support of our communities, and the precious gift of their time. So I would like to finish my reflections by thanking each of the **43,619** local people who chose to participate in the **1,775** Commercial research studies that have taken place across our delivery sites in the last 10 years.

Looking ahead, we remain committed to maintaining our high standards and further enhancing our commercial research portfolio. We will continue to prioritise community-centric approaches, and innovative delivery to ensure that our contributions to research studies have a meaningful impact on health and care outcomes.

I extend my heartfelt gratitude to everyone involved in the CRN Greater Manchester commercial portfolio for their continuous delivery efforts. The dedication and passion for advancing our health and care services are truly exemplary.

Together, we will continue to make strides in research delivery, improving lives and shaping the future of health and care together within the new NIHR Northwest Regional Research Delivery Network.

#### Sarah Fallon

Chief Operating Officer NIHR Clinical Research Network Greater Manchester

### **Contact us**

For all enquiries about how we can support you to set up and deliver research in NHS, Public Health and Social Care settings in Greater Manchester, East Cheshire and East Lancashire, email our single point of contact address: **researchsupport.crngm@nihr.ac.uk** 

You can also find out more by:

- Visiting our website https://local.nihr.ac.uk/lcrn/greater-manchester/
- Following us on social media: X: x.com/NIHRCRN\_gman and LinkedIn: linkedin.com/company/nihr-clinical-research-network-greater-manchester

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