

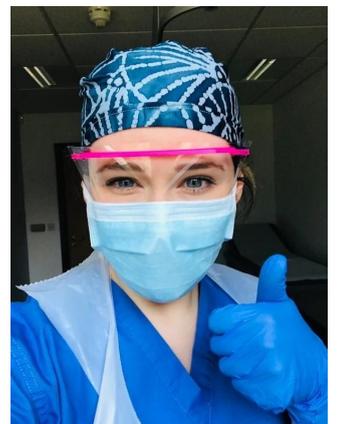
Clinical Research Network West Midlands 2020/21 Annual Report

CRN West Midlands has had one of the most challenging years yet, but right from the start we knew that research was going to be at the heart of the country's response to the pandemic, and the associated recovery. However, the year of challenges has also brought about a year of positive change; we identified that working practices that were operating well before the pandemic were no longer suitable for the current and post-COVID research world and transformation was needed. Research has never had such a high profile, and this was an opportunity for us as a region to work together to meet the health and care needs of our population, and to make research participant-centered. And we have all embraced that opportunity.

Section 1. The LCRN's contribution to three Urgent Public Health studies

Despite the difficult circumstances and pressures that our partners were under, the Network worked closely with our Partner Organisations (POs) to contribute to 43 of the most urgent pandemic-related studies in 20/21. In total, 67,675 participants were recruited from the West Midlands region to these.

Falcon Moonshot - In the advent of the second wave and the need for more Covid testing, the Network quickly responded to the call from the Department of Health & Social Care (DHSC) and rapidly set up and operationalised three 'drive through' testing sites at Birmingham Airport, Coventry and Stoke deploying four teams of staff (recruiting and consenting). The teams recruited 130 patients in less than three weeks. A system of receiving consent for our own patients was developed, which relieved the burden on the study team and significantly increased recruitment. DHSC flagged Moonshot as one of the highest priority research programmes in the UK.



The Network's informatics team was heavily involved in the national activities on [Health Informatics](#) for [PRINCIPLE](#), and undertook rapid adaptation of the study searches in line with the ongoing study amendments. This prevented pauses to recruitment and enabled patients to be continued to be offered treatment otherwise unavailable if not through the study. GP practice participation was also encouraged and facilitated, leading to the study being set up in 95 GP sites in the region, giving access to therapeutics to 427 patients. This informatics team also helped with the development of searches for other Networks on many of the phase 3 vaccine trials, even where West Midlands were not directly delivering that trial.

To ensure rural populations had equal access to vaccine studies a vaccine hub was established using a disused ward in a community hospital in Cheadle in just three weeks. Led by Midlands Partnership NHS Foundation Trust (MPFT) and using a truly collaborative approach the site successfully delivered the [Novavax](#) vaccine trial. All parts of the regional research infrastructure contributed to the successful set up of a call centre for screening and appointment booking, vaccine delivery centre, surveillance of symptomatic study participants and safety reporting. Led by a community Trust, the collaboration included neighbouring acute Trust and University staff, Using GP practices in the West Midlands to identify suitable patients resulted in the successful delivery of the study but also the huge benefits from collaborative working which will provide a blueprint for how we establish our research eco-systems detailed in our Entry Plan.

Engagement and **partnership working** were the huge successes to emerge from 20/21; from University Hospital Birmingham's recruitment of over 1,000 participants, to MPFT leading on a vaccine study with true collaboration (pictured), to using our GP practices to identify and recruit to studies.

The Pharmacy Lead convened and chaired the National Pharmacy Research Delivery Group to support the delivery of the COVID-19 vaccine studies. This collaborative national working contributed to identification and escalation of issues impacting the delivery of the studies and developed a process for undertaking risk assessments.



Section 2. Challenges recruiting to Urgent Public Health (UPH) Prioritised studies

In addition to the deployment of both clinical and non-clinical staff to support our partners with the delivery of urgent public health studies, the Network put the following measures in place to maximise recruitment:

- Set up a volunteer programme for medical/biomedical students to support recruitment. Over 200 volunteer students supported this
- Suspended all of our Research Scholars' clinical trials sessions to support urgent public health (UPH) recruitment. Many of our highest recruiting UPH Principal Investigators (PIs), who led the trials locally, were drawn from our Specialty Research Leads or our scholars
- A volunteer and PI engagement programme was set up and this enabled multiple GP returners to assist with vaccine studies, PRINCIPLE, [ISARIC](#) and [SIREN](#)
- Development of research fellow posts to support the PIs at vaccine sites without a Clinical Research Facility, and the repurposing of established research fellows to assist in these posts, enabled us to meet our targets for most of our vaccine task force trials demonstrating the effectiveness of our response
- Due to the speed in which UPH studies were developed communication from study teams was often inefficient and amendments proved resource intensive. The Study Support Service (SSS) identified a single point of contact for each study to maximise communication with the Sponsor and our POs, and to ensure consistency in service provision
- Patient eligibility was reported as an issue at some sites for a number of the studies leading to screen failures. To increase our recruitment into the [RECOVERY](#) study, two of our partner organisations completed continuous improvement projects to share interventions and understand lessons learnt ([RECOVERY: Continuous Improvement](#) and [SWBH RECOVERY: Continuous Improvement](#))
- Lack of [clinical equipoise](#) in [Recovery RS](#) was identified as a challenge and using the Chief Investigator (CI) to promote the study and participate in clinical discussions helped alleviate some of the concerns
- Launched a Covid-19 Vaccine Trials Oversight Group to coordinate the Network's response, utilising experience and knowledge of teams with both a Primary Care and Secondary Care background. The group had the regional ability to set up and deliver, at pace, urgent public health vaccine studies and also the communication of the UK Vaccine Task Force vision & objectives to the Network and our POs

- Despite significant challenges the POs in the West Midlands made an outstanding contribution to vaccine research, supported by the Network's Delivery Service Team recruiting 2,502 participants to eight vaccine trials across four sites. Recruitment targets were met or exceeded in all trials and delivered to competitive timelines. **Equity of access** was a key consideration when selecting sites and studies for the vaccination hubs, which were set up as collaborations between NHS Trusts and the Network. Army Medics provided expert advice on the set up of field hospitals to ensure the studies were delivered safely and quickly

Section 3. Workforce

Having an agile workforce in place prior to the pandemic enabled us to react quickly and effectively with rapid deployment of our staff to the highest priority areas and studies. There were a number of [workforce related initiatives](#) that, combined with the deployment, put our workforce at the centre of the response. The combination of these showed the added value a Network can have for POs and the health of the population. Additional initiatives that increased our workforce capability and demonstrated **flexibility** included:

- Creation of a [Research Assistant Development Pathway](#) to upskill non delivery staff to supplement delivery teams in administrative/data management /coordination roles
- Medical Student Volunteer Initiative (pictured) - 231 expressions of interest and 60 placements; [volunteer process & training pathway](#) shared nationally; latest stakeholder [report](#) and 'volunteers in research' [publication](#)



- Creation of a [Clinical Research Internship Programme](#) - seven interns now in post and a complementary 12 month [learning programme](#) established
- Bank Medical Locum system within Host Trust (Royal Wolverhampton NHS Trust) adapted to permit work in other POs to be indemnified and remunerated - this applied to retired returner GPs (four locum co-PIs and two volunteers), and a pharmacist
- Collaboration between organisations (NHS and Higher Education Institutions (HEIs)) to share delivery staff resources and deploying these across 'traditional' specialty boundaries (primary care/secondary care/care homes etc)
- Remote working implemented where possible (eg. vaccine call centre) to utilise shielding staff

As an **evidence-based** organisation the Network has reflected on our experiences of staff deployment and have identified lessons which will inform our workforce and organisational development strategy including:

- Employers of core staff (NHS vs HEI) had an impact on pre-existing mandatory training and ease of deployment; explore movement of staff across wider care settings as we transform our research delivery
- Nurses are more flexible to deploy but also more vulnerable to frontline redeployment; research experienced facilitators were retained within research roles; explore upskilling our facilitators to enhance agility
- Upskilling of non delivery staff to support in clinical areas in admin/data entry roles - will be maintained as part of emergency preparedness plan
- Welfare of data staff - significant unanticipated impact for staff without clinical context managing data with high mortality outcomes (ISARIC) - we implemented a point of contact, welfare drop-in sessions, and held a debrief event focussing on UPH research outcomes and wellbeing.
- Redeployment of staff in first wave to support frontline - clinical staff fatigued then straight into vaccine work; unanticipated consequences - mitigated in second wave as all retained within research roles.

Section 4. Restart and Partner organisation engagement

The Network was able to support both managed recovery studies as well as those studies that were not identified in the central managed recovery process. This balance was achieved through frequent communications, surveys, initiating new supportive collaborations between POs and proactively using a flexible workforce. It was recognised early on that POs would be differentially impacted by the pandemic and in their ability to restore clinical services and research activities. There was genuine buy-in from POs to work collaboratively and **efficiently**, a willingness to be kept informed of issues and progress, and to find collective solutions.



- The Chief Operating Officer established weekly hangout meetings for Research & Development (R&D) managers - these were very much welcomed by the POs and enabled useful discussions and sharing of best practice. Frequent informal Partnership Group meetings were also established, alternating with the formal meetings, which served to update on national and local progress, agree actions needed, and to obtain endorsement of the decisions taken in line with **good governance** principles. In depth discussions of the RESTART challenges were facilitated, and much practical and moral support provided between R&D managers, R&D directors and Network staff
- Throughout RESTART, focussed reporting and data presentations helped identify what we were trying to achieve, the balance between studies and the Network's national contributions to the initiative
- Regular Network and PO meetings also fostered a willingness to share staff between organisations and become more **responsive**, for example staff from small community healthcare Trusts supporting acute Trusts.. Having a forum to discuss staffing capacity and skills mix proved key to generating a more mobile workforce
- Using the ACROSS principles (Application to Request Network Service Support) POs were able to request additional support from the staff in the CRN flexible core team. This included clinical patient-facing nursing staff, clinical research assistants, and administration staff who could support with data collection to release the clinical staff. True partnership working was established and accepted as beneficial to all

Section 5. Patient and Public Involvement and Engagement (PPIE)

PPIE has always been a priority for the Network and the team quickly recruited the help of the Research Champions to promote research to all population groups, maximising the impact that PPIE could have on the recruitment for UPH studies, vaccine studies and the delivery of the Patient Research Experience Survey (PRES) in an **inclusive** environment.

- Research Champions were provided with information about the Covid-19 Vaccine Research Registry and asked to promote it amongst their extensive networks, increasing the numbers signed up
- The West Midlands Minority Ethnic Research Group led a [survey to collect views on COVID-19 and vaccine hesitancy](#). The survey has been published in the Trials and BMJ Open journals. Members of the CRN WM Equality, Diversity and Inclusion Research Champions Group were involved in reviewing and further refining the questions prior to the survey going live, resulting in a more friendly questionnaire
- We adapted the PRES and Research Champions programmes within the context of COVID-19. A digital only version of the survey was promoted, along with a QR code
- A PRES Response Strategy Group was established to focus on the delivery of PRES, increasing the number of responses received, resulting in 1,489 responses (target 1,200), 1,163 of which were online
- Members of the PPIE Team met regularly with the West Midlands Vaccine Project Lead and delivery teams to discuss up and coming vaccine studies and embedding the delivery of PRES in these studies
- A Google PRES dashboard was adapted to cater for the needs of all participating sites giving them access to live information about their responses which they could share with their delivery teams
- Following the suspension of the Young Persons' Steering Group due to the pandemic, it was relaunched virtually and it was an opportunity to attract new members who will now focus on how we ensure we learn the lessons from Covid and use digital tools to develop, recruit and promote research to young people
- A review of the role and purpose of The West Midlands Research Champions Forum led to a survey to update information on the numbers, skills/experiences and the need to provide a refresh/induction

Section 6. Selected non-COVID-19 LCRN achievement

- Development of the Network's Entry Plan; a co-produced programme of priority projects to ensure that we learn from the past year and continue to work collaboratively for the benefit of our population whilst promoting the research culture
- Wellbeing programmes were delivered virtually and recorded almost 3,000 attendances at 77 online sessions. Participants included Network staff, and research teams from our POs
- The Network published 19 press releases, featured 15 patient stories, contributed to 31 pieces of media coverage and through a social media campaign increased activity and followers; a staff video about their contribution to the Covid-19 effort reached 16,700 people on Facebook
- Rapid set up of remote working and supply of equipment enabled us to ensure that our teams had access to all of the IT infrastructure required, and closing smaller satellite offices reduced estates costs
- Learning from adaptations made to the SSS Team to enable efficient set up and monitoring of studies. New Hybrid Team will enable sharing of expertise and good practice between staff across the range of study support activities, with support provided by one contact from pre-funding to study closedown
- Research Scholars - The 20/21 Programme funded 19 Research Scholars based in 10 different NHS Trusts across the region. Grant income from the previous cohorts amounts to £9.5m (as of April 2021)
- [Strategic Funding Improvement and Innovation \(I&I\) Programme](#) supported delivery of research outside of the traditional NHS setting, particularly in community trusts, social care and schools

- Engagement with our POs has improved. We encouraged a regional response, whether to UPH studies or trying to restart the portfolio, enabling all of our partners to work collaboratively rather than in competition
- DaRe2THINK is a forward thinking study which was developed in the West Midlands and has adopted an innovative research design to allow large clinical trials for patient benefit to run in the NHS, using Clinical Practice Research Datalink, digital trials infrastructure, remote eConsent and data-enabled follow-up
- The West Midlands developed Associate PI scheme was expanded to support UPH recruitment across the UK. This programme is now being scaled up to include non-medical PIs including nurses and Allied Health Professionals. A project led by the Network and University of Birmingham teams is evaluating the impact of the scheme

healthcare DAta for pragmatic clinical REsearch

DaRe² | THINK

