Northern Ireland Clinical Research Network Annual Report

2021/2022

Contents

Director's Report (Executive summary) of achievements / challenges in reporting year

Those of us who work within the NICRN family, whether Clinical Leads, PIs, Clinical Research staff or managerial/administrative support staff, do so because we believe that clinical research is essential if we are to better understand disease processes and, as a result, develop new tests, treatments and interventions. Our steadfast belief that this is the case is what has enabled us to meet the challenges posed by COVID-19 and indeed exploit opportunities arising from the pandemic. As I personally reflect on the opportunities and challenges presented in the last year (2021-22), the three words that come to mind are resilience, recovery and growth. The NICRN staff, numbering 65 (tables 2, 3 & appendix 1) during the course of 2021-22, are a hugely resilient group of individuals who demonstrated flexibility throughout the pandemic as they adjusted work patterns and processes in such a way as to help and support colleagues delivering both clinical and research care to patients, some of whom were very unwell. As we began to emerge from the pandemic staff enthusiastically took on board the challenge of managing research recovery. The evidence supporting this has been the fact that almost 2000 patients have been recruited to, or remain in active follow up, in almost 180 studies. Recruitment to Target (RtT) figures achieved during the challenging year in question have also been very encouraging (86%). So too has been the Team's ability to service a significant proportion of commercially driven studies (30%) when challenges nationally have been restricting this type of activity. These figures, which are comparable with those recorded pre COVID-19, provide evidence that as we move into 2022-23 growth is a very realistic aspiration. The teams' achievements in this regard are indeed testimony to the values engrained within the service as seeded and nourished by the service's recently retired Director, Dr Maurice O'Kane. As 2021-22 draws to a close we send Maurice our very best regards and thanks for having led us throughout the last 5 years.

As we entered the 20-21 year, one NICRN aspiration was to increase Clinical Specialty Group(CSG) collegiality through the introduction of Clusters, each incorporating related disease areas. The aim of the Cluster delivery model was to increase efficiency of working, facilitate collaboration between existing CSGs and to enable support for disease areas that fell outside existing CSGs. The Covid-19 pandemic impacted our ability to do this to the extent that this objective has been put on hold and is to be re-evaluated during the course of 2022/23. In similar fashion, Clinical Management Group (CMG), the NICRN Steering Group and indeed Personal and Public Involvement (PPI) in NICRN activity will all be reviewed in the incoming year and decisions made with regards the way forward will be informed by lessons learned during the course of the pandemic.

The sections which follow highlight the outcome achievements and delivery challenges faced by each of the 14 CMG groups. Some found that COVID increased capacity to engage in evidence-based research, whereas others found that the challenges resulted in a pausing of activity. Each group has highlighted a few of their main achievements. Particular attention should be paid to those highlighted by Primary Care, Respiratory Health and Critical Care. Critical Care increased recruitment by 87% during this challenging period and Team members have contributed to important peer reviewed publications. Regarding Primary Care, particular attention needs to be paid to the teams' achievements in the PANORAMIC study and to the leadership example shown by the clinical leads. In a similar vein, the COVID related activity of the Respiratory team has been second to none and the portfolio activity in this area has been exceptional. The Renal Teams EMPA-KIDNEY study in addition illustrates the positive impact that research can have on everyday clinical care whereas the Diabetes Team have embraced all island health and wellbeing collaborative opportunities. The work of the Mental Health Team has positioned them nicely to tackle the mental health challenges arising out of COVID, whereas we have welcomed Orthopaedics to the NICRN as a group who have an extensive research portfolio that will align nicely with NICRN

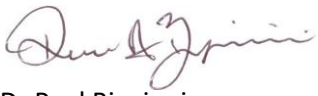
priorities. The Cardiovascular, Gastroenterology, Neurodegenerative and Children's groups which were very significantly impacted by COVID service changes saw less activity during the course of 21-22, but these groups are now increasing activity as restrictions are lifted. Both Stroke and Vision Groups continue current studies whilst setting in place processes to support new studies arising post COVID. Summary data covering portfolio activity has been included in tables 4-19 at the end of this report. More detailed information can be found in appendices 2-10. Results from the NI Cancer Trials Network (NICTN), which is recognised as an independent cluster will appear in a separate report although a brief summary of opportunities and challenges has been included within this report.

So, to conclude I am delighted to have taken up the challenge of building on Maurice's good work and am grateful to him for having established such active and enthusiastic clinical management groups. I am also privileged to have inherited such an enthusiastic team of committed staff both at the clinical research interface and in the administrative support office. As we move into a new year, I look forward to working not only with our current cohort of staff, PIs and research active clinicians, but to working with research partners across all Trusts, our two Universities and the Pharmaceutical Industries both locally, nationally and indeed Internationally.

Adj Prof Jonathan Jackson

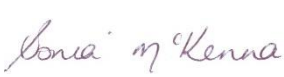
NICRN Director

And the senior management team:



Dr Paul Biagioni

NICRN General Manager



Sonia McKenna

NICRN Senior Staff Manager

Shane Jackson

NICRN Senior Portfolio Manager

Background (A Challenging Year)

2021-22 was in effect a year of transition, where hospital and community sites set in place plans to resume normal pre-COVID-19 services. Patient flow pathways were reviewed, and outpatient clinics were reinstated, though at much-reduced capacity. The impact of this was that, NICRN staff could more easily access hospital patients, GP (General Practitioner) primary care referrals increased, and virtual clinics increased patient contact opportunities.

Whereas funding for Network activity remained stable and staffing resilience was good throughout the reporting year, COVID-19 routinely impacted on our day-to-day staffing capacity.

A review of overall activity confirms relative stability with regards the total numbers of studies adopted, open and recruiting, across all HSC (Health and Social Care) Trusts, when compared to previous years. Recruitment, when considered both in terms of design and funder, remained stable at around 1900 participants in the 2021-22 year.

Within the BHSCT, which understandably is the most active Trust with regards to clinical research, figures show a slight increase in total number of studies open to recruitment over the reporting period. This may relate to two factors; broader engagement with Urgent Public Health (UPH) studies which were strategically important, prioritized by national networks; and faster reestablishment of patient referral pathways. As BHSCT is a regional centre for many clinical services such as endocrinology, paediatrics, ophthalmology etc. these services were under greater service pressures to restart so patient pathways were opened to recruitment quicker where risk allowed.

Unsurprisingly the critical care and respiratory health specialities showed an increase in studies opened and recruiting during the reporting period. This highlights the excellent research being undertaken on the impact of COVID-19 on our population, as reflected in the focus of the recruitment strategies for the Urgent Public Health (UPH) studies. Many of the UPH studies were focussed broadly on the different stages of disease progression. This allowed for a more efficient review of participant eligibility across a range of open studies.

Regarding the types of studies adopted within NICRN, the 2021-22 portfolio maintained design stability around interventional versus observational studies (70%:30% respectively). The breakdown of commercial to non-commercial studies show subtle change, reflecting a reduction in the numbers of commercial studies observed over the pandemic. The balance shifted from a pre COVID-19, 60:40 split for non-commercial vs commercial to a 70:30 split, respectively.

Overall, the screening to recruitment rate remained fixed at a ratio of 2:1. This represents efficiency in participant identification and excellent triaging strategies, compared to 2017-18. This directly impacts on our capacity, as in the past, we found that staff were burdened with reviewing a variety of different potential patient pathways to find eligible participants. With more ICT systems and refined patient pathways being available and used we are able to focus our staff attention better toward delivery rather than set up.

Over 2021-22 the NICRN team were able to maintain a relatively high median Recruitment to Target (RtT) value of 86% for the full portfolio. Whilst this was short of our national target of 90% it represents a significant achievement for the network teams whilst having to deliver their portfolios under very challenging clinical conditions. This result should however be viewed within the context of the wider range of observed RtT figures, ranging from 5.9%-120%. This clearly shows that large discrepancies in patient access were observed over sites throughout the year and whilst some studies/groups were more successful in identifying and recruiting participants, others, were not. This could be due to local patient flow challenges i.e., no face-to-face clinics, lack of searchable ICT databases etc

First Patient, First Visit (FPFV) timeframes are an important metric for many stakeholders, especially our commercial partners. It is a good measure of a sites readiness to recruit and its underlying capability. Wherever possible the Network endeavours to have as short a FPFV window as possible. Nationally we try to achieve a 30-day window from approval to getting our first participant recruited. Over this reporting period the median number of days across all sites for both our commercial and non-commercial portfolios ranged between 28.8 days up to 200 days +. These figures are unsustainable, and the network will have to concentrate our efforts in reducing these to a tolerable and practical level as a matter of urgency.

As has been reported previously, the NICRN has been moving towards a cluster-based system for our CSGs to operate within. This model was proposed to try and make efficiencies, in line with our scale, across the supporting infrastructure for the CSGs. The development of this model has understandably stalled over the last two reporting years. The intention was to bring our partners for Northern Ireland Cancer Trial Network into cluster 1 and to share common activities such as annual reporting as well as staffing resources and administrative support. This has not been achievable within this reporting period but with the recruitment of a new director we would hope to refocus attention of this project and build NICTN as the cluster 1 CSG. This will mean that as of 22-23 NICRN annual reporting will include the full coverage of NI specialities in a single report.

Table 1 Acronyms used for NICRN Clinical speciality groups (CSG)

CCA	Critical Care	**MHT**	Mental Health	**REN**	Renal
CHI	Child Health	**NEU**	Neurodegenerative	**RES**	Respiratory Health
CRV	Cardiovascular	**NICTN**	NI Clinical Trials Network	**STR**	Stroke
DIA	Diabetes	**ORT**	Orthopaedics	**VIS**	Vision
GAS	Gastroenterology	**PCR**	Primary Care		

Throughout the report we will refer to the NICRN clinical speciality groups (CSG's) and the above acronyms will be used throughout our tables. Across NI, we now have established specialities including NICTN, to these have been added the COVID-19 delivery team, which will provide support for studies designed to address challenges arising from the pandemic.

NICRN Clinical Speciality Lead reviews of the year's activities

Cardiovascular group (CRV):

Clinical leads

Professor Donna Fitzsimons, QUB

Dr Patrick Donnelly, SEHSCT

Active PIs

Johnston, Dr Nicola, BHSCT

McCann, Dr Conor, BHSCT

McKeown, Prof Pascal, QUB

McNeice, Dr Andrew, BHSCT

Murphy, Dr Conleth, BHSCT

Owens, Dr Colum, BHSCT

Spence, Dr Mark, BHSCT

Lyons, Dr Kristopher, NHSCT

Bowman, Dr Mark, SEHSCT

Donnelly, Dr Patrick, SEHSCT

Menown, Dr Ian, SHSCT

Peace, Dr Aaron, WHSCT

Ramsewak, Dr Adesh, WHSCT

The cardiovascular group has resumed research recruitment across all sites and at the recent CMG the team discussed a range of strategies by which to develop its communication and performance post-pandemic.

The BHSCT has more than doubled projected recruitment (n=44 patients) to the British Heart Foundation "Protect TAVI" study that seeks to find optimal treatment to reduce the risk of stroke after trans-aortic valve implantation.

Two Trusts (SHSCT & BHSCT) are recruiting well to the ABILITY study that seeks to test two different types of stents in patients with diabetes.

Child Health (CHI):

Clinical leads

Dr Anthony McCarthy, BHSCT

Dr David Sweet, BHSCT

Active PIs

Bailie, Dr Carolyn, BHSCT	Convery, Dr Mairead, BHSCT
Downey, Dr Damian, BHSCT	Hill, Mr Chris, BHSCT
McCrossan, Dr Brian, BHSCT	McLoone, Dr Eibhlin, BHSCT
O'Kane, Dr Donal, BHSCT	Richardson, Dr Julie, BHSCT
Sweet, Dr David, BHSCT	Funston, Dr Lesley Anne, SHSCT

The Child Health Clinical Management Group have had a quiet period during the COVID-19 pandemic as most research activity was paused or stopped to enable research teams to focus on COVID-19 related studies. The 2 Clinical Leads have however continued to meet regularly with the nursing team. The majority of Clinical Trials in the Paediatric Portfolio are national multi-centre randomised controlled trials.

During the course of 21-22 the Child Health CSG had 11 open studies, 9 on the Royal site and 2 in the Southern Trust. Across all open studies 235 subjects have been screened and 215 entered into the trials. Most studies are below projected recruitment targets, and this is because of suspension of activity because of COVID-19. Two studies (BESS and ASSERVO) involve seasonal bronchiolitis and it is anticipated that recruitment for these trials will increase as we move into winter months. The team are also to be congratulated on getting KD-Caap established on the RVH site as this is one of only three studies coming from the Pan-European C4C network which has just started. Important peer reviewed publications include;

Bell JL, Gupta S, Juszczak E, Hardy P, Linsell L. Baby-OSCAR: Outcome after Selective early treatment for Closure of patent ductus ARteriosus in preterm babies-a statistical analysis plan for short-term outcomes. Trials. 2021 May 26;22(1):368. doi: 10.1186/s13063-021-05324-3. Erratum in: Trials. 2021 Sep 9;22(1):609. PMID: 34039414; PMCID: PMC8157743.

Sweet DG, Turner M, Straňák Z, Plavka R, Clarke P, Stenson B, Singer D, Goelz R, Fabbri L, Varoli G, Piccinno A, Santoro D, Del Buono D, Speer CP. A first-in-human clinical study of a new SP-B and SP-C enriched synthetic surfactant (CHF5633) in preterm babies with respiratory distress syndrome: two-year outcomes. J Matern Fetal Neonatal Med. 2022 Dec;35(24):4739-4742. doi: 10.1080/14767058.2020.1863363. Epub 2020 Dec 20. PMID: 33345663.

As the service emerges from the COVID-19 pandemic it is hoped that the team will develop expertise and capacity that will facilitate recruitment to more commercial studies, and that activity will take place at additional sites across NI.

Critical Care (CCA):

Clinical leads

Dr Jon Silversides, BHSCT

Dr Peter McGuigan, BHSCT

Active PIs

McAuley, Prof Danny, BHSCT

Shyamsundar, Dr Murali, BHSCT

McNamee, Dr James, BHSCT

Nutt, Dr Chris, BHSCT

Charnock, Dr Rob, SHSCT

Devine, Dr Matt, SEHSCT

Johnston, Dr Paul, NHSCT

Silversides, Dr Jon, BHSCT

McGuigan, Dr Peter, BHSCT

Laughlin, Dr Laura, BHSCT

McMullan, Prof Ronan, BHSCT

Trinder, Dr John, SEHSCT

Donnelly, Dr Adrian, WHSCT

During the course of 2021-22 there were 18 trials open or in active follow up. In response to the COVID-19 pandemic, all five trusts took part in the major platform trials investigating treatments for COVID-19; (REMAP-CAP and RECOVERY), recruiting nearly 200 patients to REMAP-CAP. As we have emerged from the COVID-19 pandemic, trusts have rebuilt and taken on other NIHR (National Institute for Health Research) prioritised studies, for example ICU-ROX which is investigating oxygenation targets on ICU (Intensive care unit).

Within the BHSCT alone the critical care team have successfully recruited 616 patients to the research studies currently open or in active follow up. This represents an 87% increase in recruitment over a 12-month period and equates to approximately 1 in 8 of all admissions to critical care. Recruitment has now expanded to both the RVH and BCH sites.

The success of the critical care team is reflected in a number of national firsts and publications in peer reviewed journals. For example, the team achieved a world first in delivering mesenchymal stem cells to a COVID-19 patient as part of the REALIST-COVID trial. The group also recruited the first patients nationally to antiviral and statin treatments being tested in the REMAP-CAP trial. Of particular note is the fact that Prof McAuley co-led the RECOVERY-RS trial, the largest trial of respiratory support in COVID-19. A number of CMG members also sit on domain-specific working groups for statins, convalescent plasma and cysteamine as part of the REMAP-CAP trial.

A selected list of the group's publications in high impact factor peer reviewed journals include:

Heath PT, et al. Safety and Efficacy of NVX-CoV2373 COVID-19 Vaccine. New England Journal of Medicine. 2021 Sep 23;385(13):1172–83.

Writing Committee for the REMAP-CAP Investigators. Effect of Convalescent Plasma on Organ Support–Free Days in Critically Ill Patients With COVID-19: A Randomized Clinical Trial. JAMA. 2021;326(17):1690–1702.

Silversides JA, et al. Feasibility of conservative fluid administration and deresuscitation compared with usual care in critical illness: the Role of Active Deresuscitation After Resuscitation-2 (RADAR-2) randomised clinical trial. Intensive Care Med. 2022 Feb 1;48(2):190–200.

McNamee JJ, et al. Effect of Lower Tidal Volume Ventilation Facilitated by Extracorporeal Carbon Dioxide Removal vs Standard Care Ventilation on 90-Day Mortality in Patients With Acute Hypoxemic Respiratory Failure: The REST Randomized Clinical Trial. JAMA. 2021;326(11):1013–1023.

Gorman E, et al. Repair of acute respiratory distress syndrome by stromal cell administration (REALIST) trial: A phase 1 trial. eClinicalMedicine. 2021 Nov 1; 41:101167.
Dankiewicz J, et al. Hypothermia versus Normothermia after Out-of-Hospital Cardiac Arrest. New England Journal of Medicine. 2021 Jun 17;384(24):2283–94.

Diabetes (DIA):

Clinical lead

Dr John R Lindsay, BHSCT

Active PIs

Courtney, Dr Hamish, BHSCT

Lindsay, Dr John, BHSCT

Thiraviaraj, Dr Athinyaa, WHSCT

Johnston, Dr Philip, BHSCT

Strzelecka, Dr Anna, NHSCT

The Diabetes team, has achieved a number of important highlights over the last 12 months, despite the COVID-19 related challenges faced in 2021-22;

The team were for example able to continue follow up for both the TOPAZ (multicentre RCT investigating the use of Teriparatide and Zoledronic acid in Osteogenesis Imperfecta) and the SOUL (multicentre RCT of oral Semaglutide cardiovascular outcomes trial in patients with type 2 diabetes) studies, throughout the pandemic.

They have also adopted, on to the portfolio, the PIONEER REAL study. This is a non-interventional study on the diagnosis and treatment of Type 2 diabetes in daily routine practice with oral semaglutide. Recruitment to this study commenced in late 2021.

Seeking to develop a broader collaborative research portfolio the Team have joined a new all Ireland initiative: DCCT-N-I (Diabetes Collaborative Clinical Trial-Network-Ireland). This collaboration aims to improve health and wellbeing for all patients with Diabetes, through research and the development of an active portfolio of ambitious multicentre trials on the island of Ireland.

Gastroenterology (GAS):

Clinical lead

Dr Patrick Allen, SEHSCT

Active PIs

Mainie, Dr Inder, BHSCT

Morrison, Dr Graham, BHSCT

Agnew, Dr Paul, SEHSCT

Allen, Dr Patrick, SEHSCT

As was the case with other study groups the GAS network functioned at reduced capacity during the COVID-19 pandemic. This was mainly due to reallocation of network nursing staff. This has led to reduced research output consequentially, similar to how other UK sites have been affected.

The GI group has currently five open studies, with three new studies in set up. In total 4 out of the 8 studies are commercially supported/sponsored. Activity and input to the group stretches across all 5 Trusts.

Adopted studies included a combination of Upper GI (cancer and screening) and inflammatory bowel disease studies.

As the group develops it is hoped that additional research activity will commence at BHSCT and SEHSCT sites and that this will represent a balance of commercial and non-commercial studies.

Mental Health (MHT):

Clinical leads

Professor Ciaran Mulholland, NHSCT

Professor Gerard Leavey, UU

Active PIs

Rowan, Dr Val, BHSCT

Turkington, Dr Aidan, BHSCT

McAuley, Dr Judy, NHSCT

Mulholland, Prof Ciaran, NHSCT

The mental health group have been successful in continuing to work on a number of studies some of which have resulted in important peer reviewed publications.

Recruitment to the CHITIN (Cross border Healthcare Intervention Trials in Ireland Network) WORTH trial study, which involved collaboration between UU and the NHSCT closed at 100% recruitment to target. This cross-border study examined the feasibility of a walking intervention in low-density/rural settings for the treatment of patients with severe mental illness (SMI). Publications arising from this study include: the study protocol and preliminary results from the study.

> *McDonough, S. M., Howes, S. C., et al "A study protocol for a randomised controlled feasibility trial of an intervention to increase activity and reduce sedentary behaviour in people with severe mental illness: Walking fOR Health (WORtH) Study" 15 Nov 2021, (E-pub ahead of print) In: Pilot and Feasibility Studies. 7, 1, p. 1-10 10 p., 205.*

> *Howes, S., Atkinson, A., Brady, J., Carroll, B., Clarke, M., Mike, C., Dillon, M., Donnelly, A., Kerr, H., McArdle, D., McAuley, J., McDonough, C. M., McMahon, M., Murphy, M. H., Niven, A., O'Neill, T., Tully, M., Williams, J., Wilson, I. & McDonough, S.Supporting participants with severe mental illness and associated cognitive deficits to engage in physical activity and sedentary behaviour research. 18 May 2022, (Accepted/In press) p. 822. 2 p.*

Collaborative activity was further enhanced by the adoption and launch of recruitment to the CO-CAT study which involved partnering with Oxford University, the BHSCT, the SEHSCT and the Ulster University. This study focused on parent-led Online Support and Intervention ("OSI") for the treatment of anxiety in children in the context of the COVID-19 pandemic. As a result of the outcome data from this study the team will now explore free licence use for "OSI Grows" and the transfer of administrative privileges to the platform for one year as part of their QI (Quality Improvement) initiatives following closeout of recruitment to the RCT.

Members of the Mental Health team, throughout 2021-22, have also been providing consultation advice to the QUB School of Psychology who are partnering with other national groups looking at research governance approvals across the four nations. The NICRN Mental Health team also provided input on research design, methodology and protocol training to a heavily funded UKRI (UK Research and Innovation) study group.

Neurodegenerative/Dementia (NEU):

Clinical leads

Professor Bernadette McGuinness, QUB

Professor Peter Passmore, QUB

Active PIs

Beverland, Prof David, BHSCT

McGuinness, Prof Bernadette, QUB

Mennagh, Dr Gary, NHSCT

The COVID-19 pandemic has had a huge influence on dementia related studies in the last year. This is partly due to the fact that many subjects have to be seen in person and often need to attend hospital or be visited at home. Nevertheless, the portfolio has been quite healthy in terms of the number of studies supported and the number of participants recruited. Examples of studies running during 2021-22 are:

The HCAP study: An NIA funded study which examines the harmonisation of cognitive assessments. From 1000 anticipated participants we have 257 completed interviews and 67 interviews scheduled.

The SPACE study: This is an ESRC funded study. From 257 HCAP participants we have 108 sets of completed data. The conversion rate from HCAP to SPACE sits at 55%, which is what had initially been anticipated when calculating study power.

The RESIST study: Funded by the Alzheimer's society, this study involved recruiting people with rheumatoid arthritis to examine the effects of inflammation and use of immunotherapies on cognition. Recruitment and follow-up have now been completed although there was a large attrition rate due to COVID-19 restrictions. A Paper detailing results of screening data is currently under review with BMC Psychiatry.

The Post-Operative Delirium study:(ARUK funded), The study is following up a cohort of patients who had elective hip or knee surgery at Musgrave Park. 172 participants have been followed up from the 312 who originally took part in the post-operative delirium study.

NI Cancer Trials Network (NICTN)

Clinical Leads

Clinical Director – Mr Stuart McIntosh, BHSCT

Operational Director – Dr Melanie Morris, BHSCT

Active PI's

Breast:

McIntosh, Mr Stuart, BHSCT
Hurwitz, Dr Jane, BHSCT
Douglas, Dr Rosalie, BHSCT
McFall, Mr Brendan, NHSCT
Kirk, Mr Stephen, SEHSCT
Fenton, Dr Audrey, SHSCT
Salman, Ms Reem, SHSCT
Mazdai, Dr Goudarz, WHSCT
Farry, Dr Paul, WHSCT

Colorectal:

Coyle, Prof Vicky, BHSCT
Park, Dr Richard, BHSCT
Brooks, Dr Jason, BHSCT
Conkey, Dr David, NHSCT
Caddy, Dr Grant, SEHSCT
Harte, Dr Robert, SHSCT
Brady, Dr Darren, WHSCT

Urology:

O'Sullivan, Prof Joe, BHSCT
Jain, Prof Suneil, BHSCT
Mitchell, Dr Darren, BHSCT & WHSCT
McAleese, Dr Jonathan, NHSCT
Harney, Dr Jacqui, SEHSCT
Carser, Dr Judith, SHSCT
Mullholland, Mr Colin, WHSCT

Lung:

James, Dr Jackie, BHSCT
Scullin, Dr Paula, BHSCT
Eakin, Dr Ruth, BHSCT
McAleese, Dr Jonathan, BHSCT
Johnston, Dr David, BHSCT

Gynae:

Drake, Dr Anne, BHSCT
Millar, Dr Joanne, BHSCT
Harley, Mr Ian, BHSCT
McKenna, Dr Sarah, BHSCT

Lymphoma & Myeloma:

Sheehy, Dr Oonagh, BHSCT
Lawless, Dr Sarah, BHSCT
Bradford, Dr Christine, SHSCT
McNicholl, Dr Fearghal, WHSCT

Paediatrics:

McCarthy, Dr Anthony, BHSCT
Johnston, Dr Robert, BHSCT
Macartney, Dr Christine, BHSCT

GI (upper):

Turkington, Dr Richard, BHSCT
Harrison, Dr Claire, BHSCT
Eatock, Dr Martin, BHSCT

Skin:

Oladipo, Dr Bode, BHSCT
Carser, Dr Judith, BHSCT

Head and Neck:

Houghton, Dr Fionnuala, BHSCT
Rooney, Dr Keith, BHSCT

Hepatobiliary & Pancreatic:

Turkington, Dr Richard, BHSCT
Eatock, Dr Martin, BHSCT

Leukaemia & MPN:

McMullin, Prof Mary Frances, BHSCT
Arnold, Dr Claire, BHSCT

Thyroid:

Houghton, Dr Fionnuala, BHSCT
Henry, Dr Paul, BHSCT

Neuro-oncology:

Flannery, Dr Tom, BHSCT

Sarcoma:

Johnston, Dr Robert, BHSCT

During 2021-22, the NI Cancer Trials Network (NICRN Cluster 1) offered a portfolio of 90 cancer clinical trials and research studies to both adult and paediatric cancer patients in Northern Ireland, with 21 new trials being adopted and commencing set-up. The successful restart of the portfolio was down to a coordinated effort of a dedicated team, working in a risk assessed manner to support the safe delivery of trials, whilst being sensitive to service pressures.

Despite the ongoing challenges posed by the pandemic, 369 cancer patients were recruited to the regional trials' portfolio, with 107 patients participating in an interventional trial. Although our focus on reactivation of trials was to offer treatment trials, with 70% (n: 63) of the active portfolio being interventional in design, they accounted for only 29% of overall recruitment (107 participants). This reduction in interventional trial activity was not only a direct result of the service and staffing challenges faced during the pandemic but was also down to the fact that cancer trials are becoming much more targeted, thus reducing the potential number of patients eligible for each trial.

The cancer trials portfolio supported by the NICTN continues to be a mix of commercial and non-commercial studies, alongside locally developed studies led by our clinical academics. This year the NICTN, through its Research Management Service continued to support two investigator-led studies offering novel treatments in prostate cancer:

ADRRAD - Neo-adjuvant Androgen Deprivation Therapy, Pelvic Radiotherapy and RADium-223 for new presentation T1-4 N0/1 M1B adenocarcinoma of prostate.

SPORT - A Randomised Feasibility Study Evaluating Stereotactic PrOstate RadioTherapy in High-Risk Localised Prostate Cancer with or without Elective Nodal Irradiation. Of note, the SPORT study has informed the development of a multicentre study phase III randomised trial of 5 fraction prostate SBRT versus 5 fraction prostate and pelvic nodal SBRT (PACE- Nodes) which is now in set-up in Belfast.

The NICTN continues to work in partnership with the NI Cancer Research Consumer Forum (NICRCF) which continued to meet to provide PPI support, albeit virtually, throughout the year. After 10 years of loyal service Mrs Margaret Grayson stepped down from her role as NICRCF chair, graciously handing over the reins to Mr Aidan McCormick who took up the role in September 2021.

The public interest in clinical trials has presented new opportunities to researchers. As Northern Ireland looks to support the recovery, resilience and growth of clinical research, NICTN has used its own experiences to work with the wider research community to help reshape how research could be managed and delivered in the future. In tandem, NICTN has contributed to the development of the new 10-year Cancer Strategy for NI launched in March 2022 and are extremely encouraged that increased access to cancer trials, and the need for a Cancer Research Strategy for NI have been highlighted as key actions.

This year has undoubtedly brought with it challenges like no other and it is therefore more important than ever to thank our dedicated staff and investigators for all that they have done. This report covers the work of the whole team, with everyone playing an equally important role. Together they have worked tirelessly across the network, despite uncertainty, to continue caring for our cancer patients and importantly each other.

(Note: A detailed NICTN annual report covering regional activity is available).

Orthopaedics (ORT):

Clinical lead

Dr Owen Diamond, BHSCT

Active PIs

Diamond, Mr Owen, BHSCT

Napier, Mr Richard, BHSCT

Sloan, Mr Samuel, BHSCT

Trauma and Orthopaedics (T&O) research was introduced as a new speciality group to the Northern Ireland Clinical Research Network in April 2021. Since then, it has been exciting to see the T&O portfolio grow and develop. One particular highlight relates to the Trauma and Orthopaedic Research Teams attendance at the 10th NIHR OTS (Orthopaedic Trauma Society) Musculoskeletal Annual Trauma Meeting, in Southampton, on 15th June 2022. At this meeting, the team collected awards for having achieved 'Top Recruiter to the SCIENCE study in 2021' for the Royal Belfast Hospital for Sick Children and 'Best Effort in 2021' for the Royal Victoria Belfast's participant in NIHR Oxford Trauma clinical trials.

Studies adopted by the T&O NICRN Team in 2021/2022 included:

The WAX study: A multi-centre RCT comparing Early Weight-bearing (2 wks post-op) Vs Delayed Weight-bearing following ankle fracture (6 wks post-op). This study is now in following up, recruitment having ended in Oct 2021. The RVH Team are to be congratulated on having been the 2nd highest recruiting site for this study, despite joining the study after many other sites.

The SCIENCE study: A multi-centre RCT, recruiting throughout the UK, Australia and New Zealand, compares operative fixation vs non-operative treatment for medial epicondyle fractures of the humerus in children. In this case the RBHSCT Team are currently the top recruiting site for this study.

Orthopaedic Retrievals: Recruitment commenced in June 2021. Despite the challenges that the elective orthopaedic service has faced as a result of the pandemic, with a reduction in surgeries taking place, we are delighted to see that the team have now recruited over 50 patients to this study.

The BASIS study: This important study has been designed to compare night-time versus full-time bracing in adolescent idio-pathic scoliosis. Currently night-time braces are not available on the NHS in the UK due to lack of high-quality evidence. Families have however reported that they would prefer the night-time brace over the full-time brace. This high-quality multi-centre randomised controlled trial (RCT), which was adopted in the 2021-22 year, seeks to address the lack of evidence, and has now commenced recruitment.

The Strontium Study: This study is a collaboration involving both QUB and T&O research staff. The study team are investigating the differences in the response of cells from osteoporotic patients to healthy donors. Strontium has been shown to encourage new bone healing and this research hopes to lead to the development of a new type of fixation which encourages new bone growth and decreased loosening, while fractures heal. Whilst adopted in 2021-22 recruitment to the study has now commenced.

Primary Care (PCR):

Clinical leads

Professor Nigel Hart, QUB

Mrs Claire Leathem, BHSCT

Active PIs

Hutchinson, Dr Simon, Ballygomartin Group Practice

McNally, Dr Damien, Ormeau Clinical Trials Limited, Belfast

Mulholland, Dr Conor, Notting Hill Medical Practice

Kernohan, Dr Ian, Old School Surgery

Troughton, Dr Alison, Waterside Medical Practice

Burns, Dr Gerry, Duncairn Medical Practice

Hughes, Prof Carmel, QUB

Murphy, Prof Andrew, NUIG

The Primary Care team have had a very busy and productive 2021-22. There have been many positive moments, the biggest of which has been overcoming the challenges and barriers associated with facilitating NI participation in the PANORAMIC Trial [*Platform Adaptive trial of NOvel Antivirals for early treatMent of COVID-19 In the Community*]. Northern Ireland, utilising a Central Hub and spoke model, exceeded their pro-rata four-nation recruitment targets. This resulted in 1,020 NI participants, from 319 NI GP practices having been recruited to the Molnupiravir arm of the study over Q3 and Q4 of 2021/22. The team are currently meeting the next challenge of setting up the Paxlovid arm of PANORAMIC whilst completing the longer-term outcomes and follow up for Molnupiravir .

Other highlights occurring in the 2021-22 period, and some of the related outputs are:

Having been able to continue follow up for two CHITIN [Cross-border Healthcare Intervention Trials in Ireland Network] studies.

- POLYPRIME, an RCT intervention to improve appropriate polypharmacy in older people in primary care.
- MyComrade+, an RCT complex intervention of a multi-morbidity medication collaborative review, with General Medical Practitioners (GMPs) and General Practice Pharmacists (GPPs).

Both these trials had no-cost study extensions granted allowing the PCR team to complete participant data collection, a process that involved travelling across NI to 14 GP practices.

The team have also been able to adopt academic dental studies (SENIOR & TOPIC Trials) through collaboration with colleagues in Wales and QUB. These are NIHR funded multi-centre cluster RCT trials to address issues of the oral health of care-home residents. Previous research has shown residents suffer much poorer oral health

compared to those living in the community. These are the first adopted community dental studies taking place in nursing homes as opposed to Dental Clinics.

Walk with Me, an NIHR funded study lead by Prof Mark Tully UU, examining the efficacy and cost-effectiveness of a peer-led walking programme to increase physical activity in inactive older adults, has also been adopted by the Team. This study was delayed due to COVID-19, but it is envisaged that it will recruit 300 participants from NI.

Papers published from PCR adopted studies:

GARFIELD AF Trial [closed] an International Registry of Atrial Fibrillation published four papers in the journals: Blood advances, European Heart Journal-Quality of Care & Clinical Outcomes, The American Journal of Medicine and the British Journal of General Practice.

HEAT Trial [closed] The UK Helicobacter Eradication Aspirin Trial have published two papers in Trials and the British Medical Journal.

Polyprime Study [closed] [Cross-Border, Chitin Funded] published two papers in: Pilot and feasibility studies, and Trials.

Anticipatory Care Planning Intervention Study [Cross-Border, Chitin Funded] published three papers in the journals PloS one, BMC health services research and Pilot and feasibility studies

PRINCIPLE Trial [paused] [COVID-19] published two papers in The Lancet.

MY COMRADE Study [closed] [Cross-Border, Chitin Funded] published a paper in the journal Pilot and feasibility studies.

Renal (REN):

Clinical leads

Dr Chris Hill, BHSCT

Dr Neal Morgan, SHSCT

Active PIs

Hanko, Dr Jennifer, BHSCT	Hill, Dr Christopher, BHSCT
Maxwell, Prof Peter, BHSCT	Bolton, Dr Stephanie, NHSCT
Harron, Dr Camille, NHSCT	Quinn, Dr Michael, NHSCT
Woodman, Dr Alastair, SEHSCT	Harty, Dr John, SHSCT
Morgan, Dr Neal, SHSCT	Kuan, Dr Ying, WHSCT
McCarroll, Dr Frank, WHSCT	

The Renal team, despite the COVID-19 related challenges faced in 2021-22, has achieved a number of important highlights over the 12-month period:

Encouragingly the renal team have been able to continue to follow up patients recruited to the EMPA-KIDNEY study throughout the pandemic. This is a multicentre RCT study investigating the use of empagliflozin in CKD (chronic kidney disease). – The trial was stopped early this year as an interim analysis has shown a positive result from intervention. All renal units in Northern Ireland recruited patients to this study.

The team has also adopted our first ever vascular access in haemodialysis trial. In this study, which has recruited 30 participants already this year, the team is investigating the impact of different anaesthetic techniques at the time of fistula creation.

An additional adoption, on to the portfolio, had been the ACHIEVE study investigating whether low-dose spironolactone reduces the incidence of cardiovascular events in dialysis patients. This is a multi-centre randomised controlled trial which will recruit patients from three NI renal units – Belfast City Hospital, Daisy Hill Hospital and the Ulster Hospital.

Given the challenges faced the Renal team have had less opportunity to develop their CMG during the year in question and this in-turn has impacted on PPI involvement. Patient involvement and lesion has however been helped through Dr Morgan's voluntary input as a medical advisor to a local kidney charity – Northern Ireland Kidney Research Fund.

Respiratory Health Group (RES):

Clinical leads

Professor Judy Bradley, Queens University Belfast

Professor Lorcan McGarvey, Queens University Belfast

Active PIs:

Bradley, Prof Judy, QUB	Downey, Prof Damian, BHSCT
Heaney, Prof Liam, QUB	Kidney, Dr Joe, QUB
Magee, Dr Nicholas, BHSCT	McAuley, Prof Danny, QUB
McGarvey, Prof Lorcan, QUB	Reid, Dr Alastair, BHSCT
Minnis, Dr Paul, NHSCT	Convery, Dr Rory, SHSCT
Kelly, Dr Martin, WHSCT	

In working collaboratively with other NHS organisations and research institutions this group has played an important role in delivering studies targeted at the rapid development of new treatments for COVID-19 patients, and in building and sharing knowledge of COVID-19. Of the many studies adopted by the Group (RECOVERY-RS, Heal- Covid, CAR-CF, P-HOSP-COVID Study, NOVAVAX -, Recovery, CLEAR, NEuroCOUGH, PROSPECT, Gefapixant), the following are particularly important:

RECOVERY-RS

As the impact of the COVID-19 pandemic increased it became clear that the UK was facing a shortage of both equipment and trained staff to operate ventilators and that it was crucial to find effective, alternative ways to treat patients. This trial, designed to address this challenge, opened in Belfast in April 2020, and it has resulted in the recruitment of 4,000 patients across the UK to help identify new solutions for patients with COVID-19.

The trial found that significantly fewer patients treated with continuous positive airway pressure (CPAP) compared with conventional oxygen therapy required invasive mechanical ventilation or died. These findings have directly impacted national and international practice, with immediate changes made across the NHS. Complimentary work has also been undertaken in the international RECOVERY trial to which NI recruited 859 of 47,619 participants across 198 active sites.

To learn more about RECOVERY-RS & RECOVERY - *https://www.nihr.ac.uk/news/recovery-rs-trial-finds-continuous-positive-airway-pressure-cpap-reduces-need-for-invasive-ventilation-in-hospitalised-COVID-19-patients/* - *https://www.recoverytrial.net*

Heal-Covid

The national, multi-centre 'HElping to Alleviate the Longer-term consequences of COVID-19' study, opened in Sept 2021. It was established to identify treatments that may be beneficial for people discharged from hospital after recovering from COVID-19, thus reducing re-admittance and further complications. The team in NI, working across 4 sites, have recruited 42 of 1,122 participants across the UKs 105 sites.

To learn more about this trial - https://heal-covid.net/about/

CAR-CF

This international consortium study 'COVID-19 Antibody Response in Cystic Fibrosis', involving 14 European countries, Canada and the USA, has been successfully adopted by the NI Group. The study explores the level of antibodies to SARS-CoV-2 after vaccination or after infection, and how they change over time in people with cystic fibrosis. Recruitment to both adult and paediatric arms of the study are running to plan.

To find out more about CAR-CF - https://www.ecfs.eu/ctn/projects/car-cf

P-HOSP-COVID Study

PHOSP COVID is a consortium of leading researchers and clinicians from across the UK working together to understand and improve long-term health outcomes for patients who have been in hospital with confirmed or suspected COVID-19. This is a national study actively involving 83 open sites within the UK. The NICRN respiratory health group was in the top 5 for recruitment. The Belfast team was personally recognised by Dr Cathy Jack for their outstanding recruitment records.

Find out more about P-HOSP - *https://phosp.org/*

NOVAVAX

A number of sites across the UK hosted this vaccine trial, which is the largest double-blind, placebo-controlled COVID-19 vaccine trial to be undertaken in the UK to date. Over 500 participants were recruited across Northern Ireland. The new vaccine "Novavax" was shown to be 89.3% effective and it is being used world-wide in the fight against COVID-19. The successful delivery of the Novavax vaccine study was most definitely a NI team effort and acknowledgment should be accredited to the NI Clinical Research Facility (NICRF) for accommodating the trial, NICRN Primary care staff for their support and indeed each HSC Trust who supported by allowing the redirection of staff to cover the very busy rota. It truly was a regional study.

To learn more about the NOVAVAX trial - *https://www.nihr.ac.uk/news/nihr-welcomes-uk-approval-of-the-novavax-covid-19-vaccine/29617*

The NICRN (Respiratory health) team have also worked quickly to ensure continued delivery of the portfolio of non-COVID-19 studies. A number of studies including CLEAR, which recruited well in NI, were transitioned to remote delivery during the pandemic. Regular communication within the team aided delivery and smooth transition back to face-to-face visits.

Although the respiratory health group have been central to the delivery of most of the NI COVID-19 studies along with their colleagues in critical care, they have maintained, where capacity has allowed, the delivery of some of the higher prioritised non-COVID studies. Two important examples are, NEuroCOUGH (NEw Understanding in the tReatment Of COUGH study) and Gefapixant, the latter of which resulted in an important peer reviewed publication. (McGarvey LP et al; COUGH-1 and COUGH-2 Investigators. Efficacy and safety of gefapixant, a P2X3 receptor antagonist, in refractory chronic cough and unexplained chronic cough (COUGH-1 and COUGH-2): results from two double-blind, randomised, parallel-group, placebo-controlled, phase 3 trials. Lancet. 2022 Mar 5;399(10328):909-923)

In addition to running many successful studies the respiratory group have availed of development opportunities over the past year including participation in the project management of the NICRN Induction Programme, and coordinator attendance at the RCN Clinical Research Nursing Conference 2022: Back to the future: Moving clinical research nursing forward in both 2021 and 2022.

Stroke (STR):

Clinical leads

Dr Patricia Fearon, BHSCT

Mrs Carolee McLaughlin, BHSCT

Active PIs

Fearon, Dr Patricia, BHSCT	Gordon, Dr Patricia, BHSCT
Kerr, Dr Enda, BHSCT	McIlmoyle, Dr Jim, BHSCT
McLaughlin, Mrs Carolee, BHSCT	Owens, Dr Colum, BHSCT
Wiggam, Dr Ivan, BHSCT	O'Neill, Louise, NHSCT
Vahidassr, Dr Djamil, NHSCT	Bowman, Dr Mark, SEHSCT
McCormick, Dr Michael, SHSCT	Taggart, Wendy, SHSCT
Best, Dr Elizabeth, WHSCT	Keegan, Dr Breffni, WHSCT

Encouragingly, the Stroke Team have been able to continue follow up of patients recruited to the CONVINCE study (multicentre RCT investigating role of colchicine in stroke secondary prevention) throughout the pandemic across 4 trusts. It is also encouraging to note that all studies on the portfolio prior to the pandemic, are now recruiting again.

One notable success has been that during the course of 2021-22 the Stroke Team, successfully opened the SWIFT-direct study (multicentre RCT) within the regional thrombectomy centre in Belfast. This study compared bridging IV (Intravenous) thrombolysis and mechanical thrombectomy (standard care) with direct mechanical thrombectomy (intervention). Participating centres needed to be able to provide exemplary hyperacute care, recruiting patients within strict timeframes. The Belfast Team were one of only two sites selected to participate across the UK. Our first patient was recruited on the first day the trial opened, the fastest recruiting site globally, with Belfast promoted globally on Twitter by the trial sponsor.

The Team have also adopted a number of new studies onto the portfolio including; TICH 3 (tranexamic acid for ICH within 6 hours); OPTIMAS (optimal timing of initiation of OAC for AF after ischaemic stroke); PREPARE (qualitative analysis of palliative care for stroke patients) and CHATS-2 (community rehabilitation study for dysphasic patients using tailor made specific therapy apps in phase 2 SBRI) across a variety of stroke services regionally.

Vision (VIS):

Clinical Leads

Prof. Julie Silvestri, BHSCT/QUB

Adj Prof. Jonathan Jackson, BHSCT

Active PIs

Blanco-Azuara, Prof Augusto, QUB

Lois, Prof Noemi, QUB

Moutray, Dr Tanya, BHSCT

Jackson, Adj Prof Jonathan, BHSCT

Peto, Prof Tunde, QUB

Silvestri, Prof Julie, BHSCT/QUB

Williams, Dr Michael, BHSCT

The Vision Team faced both COVID-19-related and significant staff turnover challenges during the course of 2021-2022. As a result, team members had to adapt their roles to take on responsibilities normally considered outside of their usual skill set. In addition, some members of the vision NICRN team provided sessions in support of the pandemic where skills were translatable. Despite these challenges, the team continued to recruit and deliver over the 12-month period. Notable highlights from the team's portfolio include:

The RHINE study was a Phase III, multi-centre RCT investigating the use of Faricimab to treat patients with diabetic macular oedema. Positive results from this study have led to this treatment being licenced and made available to patients on the NHS.

Towards the end of 2021, the Mag-Vue study received the green light from R&D governance and recruitment commenced in early 2022. This is a novel single site study investigating the efficacy and safety of an intraocular magnifier in advanced macular disease. The study also incorporates an added novel approach trialling a contact lens incorporating a small magnification central button lens, to act as a simulator for the intraocular implant.

The team succeeded in adding the CANBERRA study to the portfolio. This is a RCT investigating the safety of different doses of a cannabinoid derivative on patients with moderate diabetic retinopathy.

In addition to the selection of intervention studies adopted by the team, a dry eye observational study (MTHDLGY0010) was adopted as one of the first Optometry led NICRN Vision studies. The team have worked exceptionally hard to set in place processes which maximised our chances of recruiting to target.

The Vision team which adapted exceptionally well to the challenges imposed by COVID-19, look forward to adopting a new portfolio of studies in 2022, many in partnership with other leading institutes both nationally and wider afield.

Major developments in reporting year

Staffing

One of the main challenges over the reporting period was managing staff under unpredictable and ever-changing conditions within the HSC environment. Following a busy 20-21 many staff were emotionally and physically exhausted. This was especially noticeable in areas such as critical care where clinical teams were under sizable clinical pressures.

The NICRN engaged with trust management to review potential interventions where staff could rotate out of clinical rota to a research post for a short, fixed time period. These discussions are continuing as the plan provides positive benefits across all stakeholders. They also enabled more active discussion between clinical and research infrastructure to focus attention on more collaborative management interventions and shared awareness of stakeholders' priorities.

Another persistent challenge over the course of the year was redeployment requests to ease clinical pressures, however on engagement with nursing and medical directors we found a sympathetic approach and generally avoided impacting on research capacity. However, where redeployment was unavoidable, we did observe how the limited capacity was fragile to this challenge. Staff resilience is an observed risk which needs addressing in the future. Our workforce remained relatively stable as compared to pre-COVID-19 levels with 46.6 WTE shared over 65 staff across all 5 HSC trusts as shown in (Table 2).

Over the reporting period the clinical environment was significantly impacted by corporate social distancing measures. Research requirements were not a priority and as such the network lost many of its longer-term accommodations. This was observed across many services and BHSCT network infrastructure was impacted the hardest.

The management team engaged with the Belfast Trust Estates Department but due to social distancing impacting significantly across all clinical services we could not secure research accommodation internal to Trust. BHSCT has had a long and productive relationship with Queens University, Belfast with many shared accommodation blocks. The NICRN senior management worked with the support of Professor Stuart Elborn and Professor Judy Bradley to secure a large office accommodation block adjacent to the Belfast City Hospital site within Dunluce Health Centre. This has been a fruitful collaboration and is continuing to develop with full handover planned for Q1 of 2022-23. This will give a great deal of flexibility in staff development and team building and will path find some shared challenges for future collaborative working practices across academia and clinical infrastructure.

Table 3 illustrates the number of staff in post fulfilling the WTE funded allocation. As we can appreciate the network is a very dynamic organisation which continually is balancing our service against a relatively fixed capacity and the workforce's experience of work life balance. Although the service was significantly affected by the many organisational demands experienced over the reporting period, we managed to maintain a relatively fixed level of support.

Specialities including critical care, diabetes and vision were exceptions to the normal staff changeover experience in 21-22 due to resignations and changeover of staff, hence higher number of staff in post as shown in table 3.

Table 2: The Whole Time Equivalent (WTE) funded by HSC R&DD and deployed across each HSC Trust.

HSC Trust	2017/2018 WTE Deployed	2018/2019 WTE Deployed	2019/2020 WTE Deployed	2020/2021 WTE Deployed	2021/2022 WTE Deployed
BHSCT	**28.63**	29.43	29.83	27.08	28.63
WHSCT	**5.00**	5.00	4.50	3.85	5.35
NHSCT	**3.85**	4.85	4.00	4.50	4.50
SEHSCT	**4.80**	5.30	3.80	4.80	3.30
SHSCT	**3.03**	4.80	4.00	5.35	4.80
TOTAL	**45.31**	**49.38**	**46.13**	**45.58**	**46.58**

Table 3: WTE positions funded by HSC R&DD and by income/capacity across each NICRN CSG and the actual number of staff these WTE relate to in post.

CSG	2021/2022 WTE funded		2021/2022 WTE Staff in Post		No. Staff in Post
	PHA funded	Non-PHA funded	PHA funded	Non-PHA funded	
Cardiovascular	5.50	-	4.30	-	**6**
Child Health	3.50	-	3.00	-	5
Critical Care	7.30	-	3.30	-	9
Diabetes	3.53	-	1.50	-	5
Gastroenterology	2.00	0.50	2.50	1.00	5
Mental Health	1.50	-	1.00	-	1
Neurodegenerative	2.00	2.00	1.00	2.00	4
Orthopaedics	1.00	-	0.50	-	1
Primary Care	2.50	-	1.50	-	3
Renal	3.80	-	3.30	-	7
Respiratory Health	6.00	1.00	6.00	1.00	8
Stroke	3.85	-	2.00	-	5
Vision	4.10	-	2.10	-	6
Total	**46.58**	**3.50**	**32.00**	**4.00**	**65.00**

The staffing breakdown across CSG's shows a wide range in staff deployed from only 1 staff member covering the activities in our mental health and orthopaedic groups up to 8-9 for the respiratory health and critical care groups. This reflects activity and staffing demands of their respective portfolios.

Staff training events

Ongoing training of staff is essential in developing staff skillsets appropriate to the rapidly changing clinical research environment. Locally delivered staff training events in 2021-22 included:

- Celebration to mark International Nurses Day 12th May 2021.
- International Clinical Trials Day 20th May 2021.
- Demonstrating Self-Awareness 15th Nov 2021.
- Data Protection Training 15th Nov 2021.
- Research Finance Training 3rd Dec 2021.
- Values Workshop 12th Jan 2022.
- Edge & IT training (Ongoing)

NICRN staff also attended a range of national symposia, workshops and conferences:

- Inaugural Clinical Research Conference 29th April 2021
- NIHR Research Nurse International Video 8th April 2021
- RCN International Nursing Research Conference 7th - 9th Sept 2021.
- RCN Clinical Research Nursing Conference 24th March 2022

Staff continuously update and maintain their statutory and mandatory training through e learning.

All NICRN staff have also been supported throughout 2021-22, to attend investigators meetings across UK & Europe.

A huge ongoing achievement throughout 2021-22, led by NICRN staff managers, has been the updating of the NICRN Induction Pack which involved representation and participation of present staff from each of the five Trusts across the region.

Portfolio activity: Study numbers (new, open, recruiting)

Overall, the number of active, open studies has remained relatively unchanged at 172 over the reporting period as shown in table 4. When we relate this stability to the annual recruitment as shown in table 10, we see that the network has also been stable in recruitment figures at approx. 1900 recruited participants across the full portfolio in 21/22. Though marginal, the difference year on year suggests a return to pre-pandemic levels of activity. (Data relating to NICTN activity will appear in a separate report and is not included in the following tables).

Table 4: Total number of new, open and recruiting network supported studies per year across full portfolio.

In Year Totals	Year
203	**2017-18**
185	**2018-19**
200	**2019-20**
168	**2020-21**
172	**2021-22**

Portfolio activity: Study numbers by speciality group and Trust (new, open, recruiting)

Table 5: Total numbers of open, active studies by clinical speciality.

A.R. year	CCA	CHI	CRV	DIA	GAS	MHT
2017-18	24	19	35	10	6	5
2018-19	18	11	38	9	8	6
2019-20	28	14	37	9	10	8
2020-21	20	12	33	9	10	8
2021-22	25	14	25	7	9	6

Table 6: Total numbers of open, active studies by clinical speciality (cont.).

A.R. year	NEU	ORT	PCR	REN	RES	STR	VIS
2017-18	8	N/A	7	21	27	17	24
2018-19	7	N/A	11	21	27	12	17
2019-20	7	N/A	9	14	32	14	18
2020-21	3	N/A	9	12	21	12	19
2021-22	3	6	9	11	25	12	20

Tables 5 and 6 show the total number of open and actively recruiting studies across all NICRN clinical specialities. Both respiratory health and critical care groups showed a moderate and expected increase in study numbers as compared to 2020-21. With these 2 groups accounting for 29% of the total NI portfolio in 2021-22.

The only major reduction was observed in our cardiovascular group who had a 24% reduction on 2020-21 portfolio, much of which was attributed to local staffing challenges across the cardiothoracic services at all sites. The rest of the specialities remained relatively stable or experienced minor reductions in their portfolios. Our orthopaedic group was newly established in 2021-22 and established a very productive non-commercial portfolio in their initial year.

Table 7: The total number of NICRN supported studies active in each HSC (Health and Social Care) Trust.

	Totals 2017-18	Totals 2018-19	Totals 2019-20	Totals 2020-21	Totals 2021-22
H&SC Trust	**No. Active Studies**	**No. Active Studies**	**No. Active Studies**	**No. Active Studies**	**No. Active Studies**
BHSCT	135	125	138	120	130
NHSCT	41	40	37	41	41
SEHSCT	37	32	28	36	37
SHSCT	39	44	44	39	43
WHSCT	45	37	36	36	35
Study/Sites	297	278	283	272	286

Table 7, clearly shows that for the portfolio of NICRN supported studies, the BHSCT is the principal site for research activity across NI on a scale of approximately 4:1. Over 2021-22, we observed an 8% increase in the BHSCT and a 10% increase in the SHSCT portfolios as compared to the other HSC Trusts. These increases were in line with a moderate steady return to pre-pandemic levels of 201-20.

Portfolio breakdown: Study numbers by funding type (commercial, non-commercial sponsorship)

The network has always tried to maintain a balance across the portfolio, so the staffing resource is available across high quality, nationally important public funded studies and equally high quality commercially funded studies. Each speciality is tasked with supporting a commercial: non-commercial portfolio split of approximately 40%:60%. As can be seen from table 8 the general change in focus towards prioritising our staffing capacity for Urgent Public Health (UPH) studies and the reduction in the commercial sector pipeline over this reporting period resulted in a general change to a 30%:70% split across our local portfolio. Commercial engagement was also impacted by the national prioritization of the vaccine work and UPH focus for all national networks. Over the reporting period we observed a 15% decrease in the number of commercial studies and an 11% increase in non-commercial studies as compared to same reporting period in the previous year (Table 8).

Table 8: Total number and roportion (P^) of commercial/non-commercial studies in NICRN portfolio.

Commercial		Non-Commercial		A.R. year
No of Studies	**P^ (%)**	**No of Studies**	**P^ (%)**	
72	35.47%	131	64.53%	**2017-18**
67	36.22%	118	63.78%	**2018-19**
69	34.50%	131	65.50%	**2019-20**
58	34.52%	110	65.48%	**2020-21**
49	28.49%	123	71.51%	**2021-22**

N.B. Proportional % are expressed on a row by row basis

Portfolio breakdown: Study numbers by design type (observational, interventional, not specified)

The balance of interventional and observational studies included in the NICRN portfolio over this year was stable as compared to previous years (table 9). With interventional studies accounting for just over 71% and observational studies of just under 29%.

Table 9: Total number and proportion of (interventional/observational/not specified) studies in NICRN portfolio.

Annual Reporting Year	In Year Totals (Study Design)					
	Interventional		Observational		Not Spec	
	No of Studies	**P^ (%)**	**No of Studies**	**P^ (%)**	**No of Studies**	**P^ (%)**
2018-19	**121**	65.41%	**60**	32.43%	**4**	2.16%
2019-20	**143**	71.50%	**56**	28.00%	**1**	0.50%
2020-21	**120**	72.73%	**45**	27.27%	**0**	0.00%
2021-22	**115**	71.43%	**46**	28.57%	**0**	0.00%

N.B. Proportional % are expressed on a row by row basis

These parameters are recorded for information purposes only. The data is not used as a metric against which specialty activity is measured. The number of studies has shown a reduction overall as compared to pre-pandemic levels but the relative proportion of interventional: observational studies across the portfolio has remained relatively stable at approximately 70:30 ratio.

Portfolio activity: Recruitment (Patients screened and accrued)

Table 10: The total numbers of patients screened and recruited over the last 5 reporting years.

In Year Totals		
Screened	**Recruited**	**A.R. Year**
5570	1532	**2017-18**
8931	2115	**2018-19**
4437	1868	**2019-20**
3463	1818	**2020-21**
3991	1932	**2021-22**

Following a concerted effort to minimise the screen to recruitment ratio back in 2017/18 we have modified our local screening processes to make efficiencies in our local screening processes. The organisational burden across some sites was time consuming and inefficient. Table 10 clearly shows our actions have reduced the ratio from almost 4:1 down to a more efficient 2:1 which we have maintained over the last 3 reporting years. This stability aids assessment of capacity in our internal Capacity and Capability (C&C) review process when confirming study support.

Portfolio breakdown: Recruitment (Patients accrued by study design and funding type)

In terms of participants recruited, 2021-22 was relatively successful with the second highest recruitment total over the previous 5 years (table 10). With these increases principally attributed to the open, commercially funded and observational studies (tables 11 & 12)

Table 11: Total numbers recruited into interventional/observational/not specified studies across NICRN portfolio.

In Year Totals (recruitment)			
Interventional	**Observational**	**Not Spec**	**A.R. Year**
1022	1067	26	**2018-19**
747	1121	0	**2019-20**
1346	472	0	**2020-21**
1302	630	0	**2021-22**

Table 12: Total numbers recruited into commercial and non-commercial studies across NICRN portfolio.

In Year Totals (recruitment)		
Commercial	**Non-Commercial**	**A.R. Year**
113	2002	**2018-19**
86	1782	**2019-20**
23	1801	**2020-21**
103	1829	**2021-22**

Portfolio activity: Recruitment to target (by study design and funding type)

Achieving high levels of recruitment to target (RtT) is one of the main objectives of the network. As a service we are fully appreciative of this metrics importance and its role in supporting commercial investment and assurance of our capabilities to our partners. To this end we embed the aim of reaching a 90% RtT when assessing our capacity to deliver on target. Following a significant reduction in our median RtT in 2019/20 we have seen a steady state increase in the median RtT metric over last 24 months back to a level of 86% of our studies making their recruitment target as contracted (table 13). As might have been expected with the reduction in focus on the commercial portfolio this action resulted in a slight reduction, in our median percentage RtT for commercially sponsored studies as compared to 2019-20 (table 15). Likewise, we observed a significant increase in our Median percentage RtT for our observational portfolio from 87% to 100% as seen in table 14 (range 40%-193% appendix 8). Our Median percentage RtT for our non-commercially sponsored portfolio has stabilised at 80.74% over 2020-21 and 2021-22 (range 46-192% appendix 9).

Table 13: Median percentage target recruitment attained across the total NICRN study portfolio.

in Year Total Median Recruitment to Target (RtT)	A.R. Year
91.67%	**2017-18**
91.95%	**2018-19**
75.16%	**2019-20**
80.03%	**2020-21**
86.34%	**2021-22**

Table 14: Total median % RtT in interventional/observational/not specified studies across NICRN portfolio.

Median across CSGs (% RtT)			
Interventional	**Observational**	**Not Spec**	**A.R. Year**
83.33%	97.05%	145.83%	**2018-19**
70.83%	87.33%	11.11%	**2019-20**
74.11%	96.39%		**2020-21**
75.51%	100.00%		**2021-22**

Table 15: Total median % RtT in commercial and non-commercial studies across NICRN portfolio.

Median across CSGs (% RtT)		
Commercial	**Non-Commercial**	**A.R. Year**
85.00%	84.07%	**2018-19**
78.89%	94.90%	**2019-20**
62.61%	80.74%	**2020-21**
67.72%	80.74%	**2021-22**

Table 16: Median % recruitment to target (RtT) attained across the recruitment sites of studies at each HSC Trust.

	Totals 2018-19		Totals 2019-20		Totals 2020-21		Totals 2021-22	
	No. Active Studies	Median % RtT	No. Active Studies	Median % RtT	No. Active Studies	Median % RtT	No. Active Studies	Median % RtT
BHSCT	125	82.02%	138	78.71%	120	65.37%	130	81.35%
NHSCT	40	80.40%	37	49.78%	41	89.32%	41	80.75%
SEHSCT	32	107.22	28	100.00	36	75.00%	37	75.00%
SHSCT	44	71.84%	44	96.91%	39	80.91%	43	62.63%
WHSCT	37	78.91%	36	85.42%	36	84.33%	35	68.13%

Table 16 above shows the median of each groups mean percentage RtT. The table shows a major reduction in % RtT from 20/21, which most likely reflects on the impact of COVID-19 on our ability to deliver to time and target. Also, this year's data 21/22 does not suggest a recovery to pre-pandemic levels for this metric even though numbers of studies appear to be recovering. This is an area of concern and will need addressed going forward.

Portfolio activity: Time from study set-up to first patient visit

The First Patient First Visit (FPFV) window (number of days from site approval until first participant) is a key metric for the NICRN. We aim to meet an FPFV window of less than 30 days across our new studies as this metric is often cited and used by stakeholders in determining a sites ability to set up quickly and reflects on delivery teams systems and capabilities. Across tables 17-19 we show the FPFV windows over last 5 years for our commercial and non-commercial portfolios across all CSG's. Table 19 also shows what proportion of these studies achieved the <30-day window.

No HSC site achieved the 30-day window in 2021-22 for commercial study set up times. The sites ranged from medians of 39.8 days in the SEHSCT up to 235.5 days in the WHSCT for commercially sponsored studies. The non-commercial portfolio was much improved, and the NI sites ranged from a median of 28.8 days again for the SEHSCT up to 91 days for the SHSCT. Whilst the figures for the non-commercial portfolio are much better than the commercial portfolio, the results are still well out with national expectations and need addressing as a matter of urgency as they carry a significant risk of impacting on potential future collaborations.

Table 19 shows the proportion of the commercial and non-commercial studies that are achieving the <30-day metric. The table shows that for the commercial portfolio, across all sites and CSGs less than 25% of our studies achieve the 30-day target and only 48% achieved the target for the non-commercial portfolio.

Table 17: First patient first visit (FPFV) intervals expressed as median number of days for the Commercial study portfolio at each HSC Trust.

	Commercial				
	All CSGs 2017-18 FPFV (days)	All CSGs 2018-19 FPFV (days)	All CSGs 2019-20 FPFV (days)	All CSGs 2020-21 FPFV (days)	All CSGs 2021-22 FPFV (days)
BHSCT	55.0	63.9	68.7	29.0	75.3
NHSCT	37.3	176.8	115.8	217.0	220.5
SEHSCT	37.5	47.0	36.7	40.0	39.8
SHSCT	37.5	95.3	87.3	130.8	146.5
WHSCT	19.0	22.0	36.3	257.0	235.5
All trusts	37.3	81.0	68.9	134.8	143.5

Table 18: First patient first visit (FPFV) intervals expressed as median number of days for the Non-Commercial study portfolio at each HSC Trust.

	Non-Commercial				
	All SGs 2017-18 FPFV (days)	All SGs 2018-19 FPFV (days)	All SGs 2019-20 FPFV (days)	All SGs 2020-21 FPFV (days)	All SGs 2021-22 FPFV (days)
BHSCT	25.5	42.5	37.3	34.8	39.7
NHSCT	46.5	90.4	57.3	26.3	73.2
SEHSCT	27.5	172.3	105.5	27.0	28.8
SHSCT	42.5	56.5	64.1	42.5	91.0
WHSCT	21.0	131.4	74.4	21.0	86.0
All trusts	32.6	98.6	67.7	30.3	63.7

Table 19: First patient first visit (FPFV) intervals expressed as median number of days for the Non-Commercial / Commercial study portfolios, also includes Proportion (P^) of those studies achieving FPFV < 30days

In Year Totals				
Commercial		Non-Commercial		
Median FPFV (days)	P^ Studies < 30 days	Median FPFV (days)	P^ Studies < 30 days	A.R. Year
56.3	33.13%	34.6	46.70%	**2017-18**
60.6	38.51%	46.7	47.00%	**2018-19**
51.1	44.52%	46.7	50.49%	**2019-20**
58.3	38.94%	50.7	48.15%	**2020-21**
77.6	21.09%	60.7	48.11%	**2021-22**

NICTN steering committee and future strategy

The NICRN steering committee was last convened in December 2018, before the COVID-19 pandemic. Challenges around dates/quorum etc. did not allow the group to meet in 2019 and with the advent of the pandemic this action became less important to the pressurised operational challenges faced by the network.

With the resignation of our director in December 2021 the network maintained a holding pattern until such times as a new director could be appointed. It is anticipated that the new director (appointed May 2022) will convene the new steering committee as soon as feasibly possible.

This may well be a timely action as within NI there are significant new and novel local governance initiatives being introduced which will impact on our service and therefore it would be advantageous to have a steering committee's lead on these regional changes.

PPI engagement

Throughout 2021-22, engagement with our Clinical Management Groups and their respective PPI representatives has been lacking. This is due to operational and physical restriction that both NI government and HSC directives placed on our service. As we transition out of COVID -19 we aim to re-establish our clinical management groups and will endeavour to embed PPI where this expertise will be of highest impact.

Appendices

Appendix 1 – Additional data for Staffing levels for previous reporting periods.

	2019/2020 WTE Funded*		2019/2020 WTE Staff in Post*		2020/2021 WTE Funded		2020/2021 WTE Staff in Post		
	PHA funded	Non-PHA funded	PHA funded	Non-PHA funded	PHA funded	Non-PHA funded	PHA funded	Non-PHA funded	Staff in Post
Cardiovascular	5.50	0.00	6	3	5.50		4.30		6
Child Health	2.50	0.80	5	0	3.50		3.00		5
Critical Care	7.80	0.50	7.5	2.5	6.80		6.80		9
Diabetes	3.53	0.00	4	0	3.53				5
Gastroenterology	2.50	1.00	4.5	1.5	2.50	1.00	2.50	1.00	6
Mental Health	1.50	0.00	2	0	1.50		1.00		1
Neurodegenerative	2.50	2.00	3	2	2.00	2.00	1.50	2.00	5
Orthopaedics									
Primary Care	2.50	0.00	3	0	2.50		2.50		3
Renal	3.30	0.00	6	0	3.80		3.80		7
Respiratory Health	6.00	2.00	8	1	6.00	1.00	6.00	1.00	8
Stroke	3.50	0.00	7	0	3.85		2.00		5
Vision	5.00	0.00	7	0	4.10		4.10		6
Total	**46.13**	**6.30**	**63**	**10**	**45.58**	**4.00**	**37.50**	**4.00**	**66**

* Where the number of 'Non-PHA Funded' staff in Column 5, exceeds the 'Non-PHA Funded' staff in Column 3, additional staff funding will have come from an external source, or non-core NHS funding stream.

Appendix 2 – Additional data for Portfolio breakdown: Study numbers by funding type (commercial, non-commercial sponsorship)

A.R. Year	CCA				CHI				CRV				DIA				GAS				MHT			
	Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm	
	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)
2018-19	1	5.56%	17	94.44%	1	9.09%	10	90.91%	19	50.00%	19	50.00%	6	66.67%	3	33.33%	4	50.00%	4	50.00%	2	33.33%	4	66.67%
2019-20	1	3.57%	27	96.43%	2	14.29%	12	85.71%	17	45.95%	20	54.05%	5	55.56%	4	44.44%	6	60.00%	4	40.00%	2	25.00%	6	75.00%
2020-21	0	0.00%	20	100.00%	2	16.67%	10	83.33%	15	45.45%	18	54.55%	5	55.56%	4	44.44%	7	70.00%	3	30.00%	3	37.50%	5	62.50%
2021-22	1	40.00%	24	96.00%	2	14.29%	12	85.71%	11	44.00%	14	56.00%	5	71.43%	2	28.57%	5	55.56%	4	44.44%	2	33.33%	4	66.67%

A.R. Year	ORT				NEU				PCR				REN				RES				STR				VIS			
	Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm	
	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)
2018-19					3	42.86%	4	57.14%	4	36.36%	7	63.64%	4	19.05%	17	80.95%	14	51.85%	13	48.15%	4	33.33%	8	66.67%	5	29.41%	12	70.59%
2019-20					1	14.29%	6	85.71%	2	22.22%	7	77.78%	4	28.57%	10	71.43%	17	53.13%	15	46.88%	3	21.43%	11	78.57%	9	50.00%	9	50.00%
2020-21					0	0.00%	3	100.00%	1	11.11%	8	88.89%	4	33.33%	8	66.67%	11	52.38%	10	47.62%	2	16.67%	10	83.33%	8	42.11%	11	57.89%
2021-22	0	0.00%	6	100.00%	0	0.00%	3	100.00%	1	11.11%	8	88.89%	2	18.18%	9	81.82%	7	28.00%	18	72.00%	2	16.67%	10	83.33%	11	55.00%	9	45.00%

Appendix 3 – Additional data for Portfolio breakdown: Study numbers and Proportion by design type (observational, interventional, not specified)

A.R. Year	CCA (Study Design)						CHI (Study Design)						CRV (Study Design)						DIA (Study Design)					
	Int		Obs		Not Spec		Int		Obs		Not Spec		Int		Obs		Not Spec		Int		Obs		Not Spec	
	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)	No of Studie	P^(%)	No of Studies	P^(%)	No of Studie	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)
2018-19	13	72.22%	4	22.22%	1	5.56%	7	63.64%	4	36.36%	0	0.00%	29	76.32%	9	23.68%	0	0.00%	7	77.78%	2	22.22%	0	0.00%
2019-20	20	74.07%	7	25.93%	0	0.00%	10	71.43%	4	28.57%	0	0.00%	29	78.38%	8	21.62%	0	0.00%	7	77.78%	2	22.22%	0	0.00%
2020-21	15	75.00%	5	25.00%	0	0.00%	8	66.67%	4	33.33%	0	0.00%	27	81.82%	6	18.18%	0	0.00%	6	66.67%	3	33.33%	0	0.00%
2021-22	9	64.29%	5	35.71%	0	0.00%	9	64.29%	5	35.71%	0	0.00%	21	84.00%	4	16.00%	0	0.00%	4	57.14%	3	42.86%	0	0.00%

A.R. Year	GAS (Study Design)						MHT (Study Design)						NEU (Study Design)						ORT (Study Design)					
	Int		Obs		Not Spec		Int		Obs		Not Spec		Int		Obs		Not Spec		Int		Obs		Not Spec	
	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)	No of Studie	P^(%)	No of Studies	P^(%)	No of Studie	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)
2018-19	4	50.00%	4	50.00%	0	0.00%	3	50.00%	3	50.00%	0	0.00%	4	57.14%	3	42.86%	0	0.00%						
2019-20	7	70.00%	3	30.00%	0	0.00%	6	66.67%	3	33.33%	0	0.00%	4	57.14%	3	42.86%	0	0.00%						
2020-21	6	60.00%	2	20.00%	0	0.00%	5	62.50%	3	37.50%	0	0.00%	1	33.33%	2	66.67%	0	0.00%						
2021-22	8	88.89%	1	11.11%	0	0.00%	3	50.00%	3	50.00%	0	n/a	1	33.33%	2	66.67%	0	0.00%	5	83.33%	1	16.67%	0	0.00%

A.R. Year	PCR (Study Design)						REN (Study Design)						RES (Study Design)						STR (Study Design)					
	Int		Obs		Not Spec		Int		Obs		Not Spec		Int		Obs		Not Spec		Int		Obs		Not Spec	
	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)	No of Studie	P^(%)	No of Studies	P^(%)	No of Studie	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)
2018-19	6	54.55%	2	18.18%	3	27.27%	8	38.10%	13	61.90%	0	0.00%	18	66.67%	9	33.33%	0	0.00%	9	75.00%	3	25.00%	0	0.00%
2019-20	7	77.78%	1	11.11%	1	11.11%	6	42.86%	8	57.14%	0	0.00%	23	71.88%	9	28.13%	0	0.00%	11	78.57%	3	21.43%	0	0.00%
2020-21	6	75.00%	2	25.00%	0	0.00%	6	50.00%	6	50.00%	0	0.00%	15	71.43%	6	28.57%	0	0.00%	10	83.33%	2	16.67%	0	0.00%
2021-22	7	75.51%	2	50.00%	0	0.00%	6	70.21%	5	45.45%	0	0.00%	17	68.00%	8	32.00%	0	0.00%	10	83.33%	2	16.67%	0	0.00%

A.R. Year	VIS (Study Design)					
	Int		Obs		Not Spec	
	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)
2018-19	13	76.47%	4	23.53%	0	0.00%
2019-20	13	72.22%	5	27.78%	0	0.00%
2020-21	15	78.95%	4	21.05%	0	0.00%
2021-22	15	75.00%	5	25.00%	0	0.00%

Appendix 4 – Additional data for Portfolio activity: Recruitment (Patients screened and accrued)

A.R. Year	CCA		CHI		CRV		DIA		NEU		GAS		MHT	
	Scr	Rec	Scr	Rec	Scr	Rec	Scr	Rec	Scr	Rec	Scr	Rec	Scr	Rec
2018-19	2057	201	133	65	521	243	341	43	551	276	45	28	15	13
2019-20	327	241	74	35	361	259	279	271	344	341	57	55	3	1
2020-21	2633	630	153	150	57	49	6	5	182	182	1	0	6	5
2021-22	1567	429	330	92	100	90	35	21	0	0	24	14	19	12

A.R. Year	ORT		PCR		REN		RES		STR		VIS		in Year Totals	
	Scr	Rec	Scr	Rec	Scr	Rec	Scr	Rec	Scr	Rec	Scr	Rec	Scr	Rec
2018-19			459	317	456	181	1322	234	411	214	2620	300	8931	2115
2019-20			2242	145	184	109	176	126	77	63	313	222	4437	1868
2020-21			20	20	100	72	287	693	10	4	8	8	3463	1818
2021-22	152	72	782	782	46	30	709	328	193	43	34	19	3991	1932

Appendix 5 – Additional data for Portfolio breakdown: Recruitment (Patients accrued by study design)

A.R. Year	CCA (recruitment)			CHI (recruitment)			CRV (recruitment)			DIA (recruitment)			NEU (recruitment)			GAS (recruitment)			MHT (recruitment)		
	Int	Obs	Not Spec	Int	Obs	Not Spec	Int	Obs	Not Spec	Int	Obs	Not Spec	Int	Obs	Not Spec	Int	Obs	Not Spec	Int	Obs	Not Spec
2018-19	93	85	23	13	52	0	157	86	0	21	22	0	5	271	0	4	24	0	11	2	0
2019-20	126	115	0	12	23	0	35	224	0	43	228	0	0	341	0	2	53	0	1	0	0
2020-21	487	143	0	26	124	0	14	35	0	5	0	0	168	14	0	0	0	0	5	0	0
2021-22	218	211	0	31	61	0	78	12	0	0	21	0	0	0	0	2	12	0	10	2	0

A.R. Year	ORT (recruitment)			PCR (recruitment)			REN (recruitment)			RES (recruitment)			STR (recruitment)			VIS (recruitment)			in Year Totals (recruitment)		
	Int	Obs	Not Spec	Int	Obs	Not Spec	Int	Obs	Not Spec	Int	Obs	Not Spec	Int	Obs	Not Spec	Int	Obs	Not Spec	Int	Obs	Not Spec
2018-19				314	0	3	17	164	0	104	130	0	12	202	0	271	29	0	1022	1067	26
2019-20				145	0	0	66	43	0	54	72	0	63	0	0	200	22	0	747	1121	0
2020-21				20	0	0	45	27	0	564	129	0	4	0	0	8	0	0	1346	472	0
2021-22	39	33	0	732	50	0	1	29	0	136	192	0	36	7	0	19	0	0	1302	630	0

Appendix 6 – Additional data for Portfolio breakdown: Recruitment (Patients accrued by funding type)

A.R. Year	CCA (recruitment)		CHI (recruitment)		CRV (recruitment)		DIA (recruitment)		GAS (recruitment)		MHT (recruitment)		NEU (recruitment)		A.R. Year
	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	
2018-19	0	201	0	65	53	190	8	35	4	24	0	13	2	274	**2018-19**
2019-20	0	241	7	28	7	252	25	246	1	54	0	1	0	341	**2019-20**
2020-21	0	630	0	150	12	37	6	5	0	0	0	5	0	182	**2020-21**
2021-22	0	429	3	89	54	36	21	0	1	13	0	12	0	0	**2021-22**

A.R. Year	ORT (recruitment)		PCR (recruitment)		REN (recruitment)		RES (recruitment)		STR (recruitment)		VIS (recruitment)		in Yr Totals (recruitment)		A.R. Year
	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	
2018-19			0	317	8	173	26	208	4	210	8	292	113	2002	**2018-19**
2019-20			0	145	5	104	16	110	6	57	19	203	86	1782	**2019-20**
2020-21			0	20	0	72	4	689	0	4	1	7	23	1801	**2020-21**
2021-22	0	72	0	782	1	29	4	324	0	43	19	0	103	1829	**2021-22**

Appendix 7 – Additional data for Portfolio activity: Recruitment to target (by clinical specialty group)

A.R. Year	CCA	CHI	CRV	DIA	GAS	MHT	NEU	ORT	PCR	REN	RES	STR	VIS	in Yr Total Median RtT	A.R. Year
2018-19	81.46%	94.74%	100.00%	89.17%	100.00%	12.70%	60.00%		103.00%	75.00%	100.00%	45.00%	102.50%	91.95%	**2018-19**
2019-20	70.00%	78.89%	80.00%	58.33%	100.00%	29.79%	60.00%		108.00%	65.40%	100.00%	71.43%	102.50%	75.16%	**2019-20**
2020-21	100.00%	65.33%	80.00%	86.67%	75.00%		100.72%			80.06%	65.33%	71.43%	162.50%	80.03%	**2020-21**
2021-22	87.78%	5.90%	75.00%	97.33%	100.00%	n/a	85.62%	122.00%	63.33%	78.13%	87.06%	75.00%	100.00%	86.34%	**2021-22**

Appendix 8 – Additional data for Portfolio activity: Recruitment to target (by study design)

A.R. Year	CCA (Mean % RtT)			CHI (Mean % RtT)			CRV (Mean % RtT)			DIA (Mean % RtT)			GAS (Mean % RtT)			MHT (Mean % RtT)			NEU (Mean % RtT)		
	Int	Obs	Not Spec	Int	Obs	Not Spec	Int	Obs	Not Spec	Int	Obs	Not Spec	Int	Obs	Not Spec	Int	Obs	Not Spec	Int	Obs	Not Spec
2018-19	56.05%	200.00%	191.67%	86.53%	94.74%		93.72%	99.37%		85.21%			83.33%	90.00%		26.19%	11.20%		55.00%	101.67%	
2019-20	70.83%	91.63%		75.97%			90.28%	87.33%		58.33%			62.50%	100.00%		14.29%	29.79%		45.00%	106.67%	
2020-21	111.48%	72.73%		71.11%	32.00%		92.92%	112.26%		72.60%	92.77%		50.00%	100.00%			14.89%			100.72%	
2021-22	73.70%	193.33%		40.00%	60.00%		85.79%	177.00%		71.56%	110.00%		83.33%	100.00%		n/a	n/a	n/a	94.57%	90.83%	

A.R. Year	ORT (Mean % RtT)			PCR (Mean % RtT)			REN (Mean % RtT)			RES (Mean % RtT)			STR (Mean % RtT)			VIS (Mean % RtT)			Median across SGs(% RtT)		
	Int	Obs	Not Spec	Int	Obs	Not Spec	Int	Obs	Not Spec	Int	Obs	Not Spec	Int	Obs	Not Spec	Int	Obs	Not Spec	Int	Obs	Not Spec
2018-19				103.00%	211.00%	100.00%	60.92%	76.94%		88.72%	87.03%		51.02%	74.91%		96.13%	151.50%		83.33%	97.05%	145.83%
2019-20				77.78%	11.11%	11.11%	88.23%	102.82%		89.40%	80.51%		48.57%	74.91%		100.32%	153.20%		70.83%	87.33%	11.11%
2020-21				81.26%	40.00%		66.84%	107.06%		56.87%	107.06%		74.11%			143.30%	107.06%		74.11%	96.39%	
2021-22	122.00%			75.51%	50.00%		70.21%	92.56%		63.33%	81.47%		65.00%			108.33%	180.00%		75.51%	100.00%	

Appendix 9 – Additional data for Portfolio activity: Recruitment to target (by funding type)

A.R. Year	CCA (Mean % RtT)		CHI (Mean % RtT)		CRV (Mean % RtT)		DIA (Mean % RtT)		GAS (Mean % RtT)		MHT (Mean % RtT)		NEU (Mean % RtT)	
	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm
2018-19		81.46%		88.17%	100.77%	89.10%	85.00%	86.67%	103.33%	75.00%		18.70%	80.00%	60.42%
2019-20		82.87%	77.78%	75.37%	80.80%	97.44%	58.33%		33.33%	125.00%		24.62%	80.00%	51.67%
2020-21		89.95%	77.78%	54.13%	138.46%	95.76%	62.11%	90.55%	50.00%	100.00%		11.91%		80.74%
2021-22		80.74%		46.67%	79.24%	108.62%	64.00%	80.74%	83.33%	100.00%	n/a	n/a		92.08%

A.R. Year	ORT (Mean % RtT)		PCR (Mean % RtT)		REN (Mean % RtT)		RES (Mean % RtT)		STR (Mean % RtT)		VIS (Mean % RtT)		Median across SGs(% RtT)	
	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm
2018-19			101.00%	119.00%	83.33%	71.21%	76.28%	101.23%	29.56%	70.46%	85.33%	124.34%	85.00%	84.07%
2019-20			62.50%	100.10%	133.33%	94.90%	81.56%	102.45%	28.86%	91.39%	84.08%	166.03%	78.89%	94.90%
2020-21			50.00%	79.60%	50.00%	80.74%	62.61%	73.69%	75.00%	55.36%	88.89%	80.74%	62.61%	80.74%
2021-22		80.74%	50.00%	75.51%	71.43%	75.69%	56.89%	80.74%	47.50%	100.00%	103.33%	192.50%	67.72%	80.74%

Appendix 10 – Additional data for Portfolio activity: Time from study set-up to first patient visit (by clinical specialty group and funding type)

	CCA				CHI				CRV				DIA				GAS				MHT				NEU			
	Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm	
A.R. Year	Median FPFV (days)	P^ Studies < 30 days	Median FPFV (days)	P^ Studies < 30 days	Median FPFV (days)	P^ Studies < 30 days	Median FPFV (days)	P^ Studies < 30 days	Median FPFV (days)	P^ Studies < 30 days	Median FPFV (days)	P^ Studies < 30 days	Median FPFV (days)	P^ Studies < 30 days	Median FPFV (days)	P^ Studies < 30 days	Median FPFV (days)	P^ Studies < 30 days	Median FPFV (days)	P^ Studies < 30 days	Median FPFV (days)	P^ Studies < 30 days	Median FPFV (days)	P^ Studies < 30 days	Median FPFV (days)	P^ Studies < 30 days	Median FPFV (days)	P^ Studies < 30 days
2018-19			55.5	37.50%	0	100.00%	58	37.50%	40	43.48%	31.5	50.00%	52	25.00%	41.5	50.00%	85	0.00%	27	66.67%			68	40.00%	164	0.00%	78	14.29%
2019-20			18.5	59.09%	0	100.00%	58	37.50%	40	36.84%	20	55.00%	36	33.33%	41.5	50.00%	108.5	0.00%	143	33.33%			71	40.00%	164	0.00%	78	0.00%
2020-21			12	75.00%	0	100.00%	63	33.33%	44.5	35.71%	31.5	50.00%	36	33.33%	41.5	50.00%	132	0.00%	78.5	50.00%			145	50.00%			34	33.33%
2021-22			8	66.67%	42	0.00%	70	25.00%	40	27.27%	38	46.67%	38.5	25.00%	41.5	50.00%	171	0.00%	15.5	100.00%			285	33.33%			42	33.33%

	ORT				PCR				REN				RES				STR				VIS				in Year Totals			
	Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm	
A.R. Year	Median FPFV (days)	P^ Studies < 30 days	Median FPFV (days)	P^ Studies < 30 days	Median FPFV (days)	P^ Studies < 30 days	Median FPFV (days)	P^ Studies < 30 days	Median FPFV (days)	P^ Studies < 30 days	Median FPFV (days)	P^ Studies < 30 days	Median FPFV (days)	P^ Studies < 30 days	Median FPFV (days)	P^ Studies < 30 days	Median FPFV (days)	P^ Studies < 30 days	Median FPFV (days)	P^ Studies < 30 days	Median FPFV (days)	P^ Studies < 30 days	Median FPFV (days)	P^ Studies < 30 days	Avg Median FPFV (days)	Avg P^ Studies < 30 days	Avg Median FPFV (days)	Avg P^ Studies < 30 days
2018-19					30	75.00%	22	75.00%	114	16.67%	46	42.50%	38.5	50.00%	27	58.82%	42.5	25.00%	85	33.33%	39.5	50.00%	20.5	58.33%	60.6	38.51%	46.7	47.00%
2019-20					27	92.86%	20	100.00%	77	0.00%	29	50.00%	28	58.33%	20	61.54%	2	66.67%	42	44.44%	28	57.14%	19.5	75.00%	51.1	44.52%	46.7	50.49%
2020-21					29	50.00%	29	16.36%	146	0.00%	68	39.13%	28	71.43%	16	70.59%	81.5	0.00%	70.5	30.00%	28	60.00%	19	80.00%	58.3	38.94%	50.7	48.15%
2021-22			30	60.00%	29	50.00%	20.5	59.26%	158.5	0.00%	82	25.00%	64	50.00%	16.5	61.11%	81.5	0.00%	52.5	40.00%	73.5	37.50%	88	25.00%	77.6	21.09%	60.7	48.11%

Appendix 11 – Acronyms / Glossary List.

Acronym	Definition
BHSCT	Belfast Health and Social Care Trust
NHSCT	Northern Health and Social Care Trust
SEHSCT	South Eastern Health and Social Care Trust
SHSCT	Southern Health and Social Care Trust
WHSCT	Western Health and Social Care Trust
AR	Annual Report
C+C	Capacity + Capability
CMG	Clinical Management Group
COVID-19	Coronavirus Disease
CSG	Clinical Specialty Group
FPFV	First Patient First Visit
GP / GMP	General Practitioner / General Medical Practitioner
GPP	General Practice Pharmacist
HSC	Health and Social Care
HSC R&D	Health and Social Care Research & Development
P^	Proportion
PHA	Public Health Agency
PI	Principle Investigator
PPI	Personal and Public Involvement
QI	Quality Improvement
QUB	Queen's University Belfast
NHS	National Health Service
NI	Northern Ireland
NICRCF	Northern Ireland Cancer Research Consumer Forum
NICRF	Northern Ireland Clinical Research Facility
NICRN	Northern Ireland Clincal Research Network
NICTN	Northern Ireland Cancer Trials Network
NIHR	National Institute for Health and Care Research
R&D	Research & Development
RCT	Randomised Control Trial
RtT	Recruitment to Target
T&O	Trauma and Orthopaedics
UK	United Kingdom
UKRI	UK Research and Innovation
UPH	Urgent Public Health
UU	Ulster University
WTE	Whole Time Equivalent