



Clinical  
Research  
Network

# NICRN ANNUAL REPORT

## 2023 –2024



NICRN Team Christmas Lunch in King Edward Boardroom, RVH

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## Glossary

<b>Acronym</b>	<b>Definition</b>
AHP	Allied Health Professional
AMRC	Association of Medical Research Charities
AR	Annual Report
BHSCT	Belfast Health and Social Care Trust
BREXIT	British Exit
C&C	Capacity & Capability
CI	Chief Investigator
CMG	Clinical Management Group
COVID-19	Coronavirus Disease
CSG	Clinical Steering Group
DGH	District General Hospital
DOH	Department of Health
ECMC	Experimental Cancer Medicine Centre
FPFV	First Patient First Visit
GPARTS	General Practice Academic Research Training Scheme
HSC R&D	Health and Social Care Research & Development
IBD	Irritable Bowel Disease
INY	In year (1 <sup>st</sup> April 2023-31 <sup>st</sup> March 2024)
NHS	National Health Service
NHSCT	Northern Health and Social Care Trust
NI	Northern Ireland
NICRCF	Northern Ireland Cancer Research Consumer Forum
NICRF	Northern Ireland Clinical Research Facility

NICRN	Northern Ireland Clinical Research Network
NICTN	Northern Ireland Cancer Trials Network
NIHR	National Institute for Health and Care Research
NIMDTA	Northern Ireland Medical and Dental Training Agency
NICRRRG	Northern Ireland Clinical Research, Recovery, Resilience and Growth group
$P^{\wedge}$	Proportion
PHA	Public Health Agency
PI	Principle Investigator
PICU	Paediatric Intensive Care Unit
PPI	Patient and Public Involvement
QUB	Queen's University Belfast
R&D	Research & Development
RCT	Randomised Control Trial
RtT	Recruitment to Target
RVH	Royal Victoria Hospital
SEHSCT	South Eastern Health and Social Care Trust
SHSCT	South Health and Social Care Trust
T&O	Trauma and Orthopaedics
UK	United Kingdom
UKRI	UK Research and Innovation
UPH	Urgent Public Health
UU	Ulster University
WHSCT	Western Health and Social Care Trust
WTE	Whole Time Equivalent

## Director's Report of achievements / Challenges in reporting year 2023-2024

Once again the complex multi-professional team of clinicians, academics, administrators and support workers in the NICRN family are to be congratulated on delivering high quality clinical research across the whole of Northern Ireland. The annual report, as has been the case in previous years, sets out activity and achievements by individual Clinical Specialty Group. This year we have chosen to illustrate some of the clinical specialty data within the relevant sections, as opposed to in the appendices. The tabular format is recurrent throughout the report and the table below should help readers to interpret data effectively. The Northern Ireland regional Dashboard summary report has been included at the end of this section.

Table Number	Table Title	Description
1	Studies and Sites Data	The 6 data fields in this table highlight; 1- The number of active clinical specialities within a Trust. For the CSG dashboards; the number of Trusts with activity in year. For the regional dashboard this data field reflects the number of active CSGs regionally. 2- The total number of active portfolio studies undertaken within the reporting period. 3- Number of recruiting sites, across HSC. 4- Number of HSC sites at which new patients have been recruited within the reporting period. 5- Number of new studies supported within the reporting period. 6- Number of studies closed within the reporting period.
2	Screening and Recruitment in year and Cumulative Totals for Active Studies during the reporting period	Columns 1&2 highlight the number of participants screened and thereafter recruited to supported studies within the reporting period. Columns 3&4 highlight the cumulative total number of participant's screened and recruited to these studies up to 31 <sup>st</sup> March 2024.
3 (a+b)	a – Recruitment and Median Recruitment to Target (%) by Sponsorship Type (Commercial/Non-Commercial/Combined). b - Recruitment and Median Recruitment to Target (%) by Design Type (Interventional/Observational/Combined)	In both tables 3a&b the number of participants refers to the number of participants recruited in year (INy), whereas the Recruitment to Target (RtT) median figure, expressed as a %, relates to participants recruited to studies that have closed to recruitment within the reporting period.
4	Portfolio Sponsorship, Randomisation and Design Mix for Active Studies During 2023-24.	Numbers included in this table equate to the number of active studies referred to in table 1.
5	Median First Patient First Visit (FPFV), First Visit Windows (Days) and Proportion of Studies Achieving <30 Days (%) (Commercial/Non-Commercial/Combined).	Data included in this table highlights the median times taken to recruit the first patient across all active recruiting studies, and the % of those active studies which meet the FPFV UK benchmark of recruitment within 30 days of site opening.

6 (a + b)	6a NI regional data/HSC Trust data by Clinical Specialty Group. 6bNI regional data/Clinical speciality group data by HSC Trust	6a (NI regional data dashboard) This reflects the key metrics as reported across CSGs for NI.  6a (HSC Trust data dashboard) This reflects the HSC Trust key metrics as reported across CSGs.  6b (Ni regional data dashboard) This reflects the key metrics as reported across HSC Trusts for NI.  6b (Clinical speciality dashboard) This reflects the key CSG metrics as reported across HSC Trusts for NI.
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Each of the Clinical Specialty Groups have included very useful summary, key achievement and publication data in their respective sections. In those cases where publication activity by group members has been high, only some specific publications have been listed in the main body of the report with links to additional publications provided on the [NICRN website](#). Leads and NICRN team members have also, as has been the case in previous years, highlighted some good news stories relevant to each group. I have chosen to highlight in this, my reflective section, highlights that have attracted my attention and will hopefully be of interest to you the reader.

### **Building Motivation across the Sector**

Overall, and within year, 9128 patients were screened with a view to recruitment into a total of 191 active studies available across 341 sites. Twenty three percent (2078) of those screened progressed to recruitment. The fact that Screening had increased by 12% in comparison to 2022-23, whereas recruitment had dropped by 8%, is a measure of the complexity of some of the studies adopted and the staffing and resource availability challenges faced by some of the Clinical Specialty Groups. Recruitment to target across all studies has remained consistently high at 87%, and there has been a significant improvement in the First Patient First Visit median to 41 days from 70 in the preceding year. The proportion of commercial studies has increased slightly from 26% to 31% although the nature of commercial studies, which usually are competitive and recruit across multiple global sites is that recruitment numbers are much lower than those recorded in Non-Commercial studies.

None of what has been achieved could have happened without the dedicated commitment of 71 clinical research NICRN staff (44.9WTEs) appointed through R&D funding. Excluding the impact that COVID support funding had on staffing numbers last year this represents a surprisingly stable number over the last 5 years. The support team although predominantly from a nursing background includes amongst its numbers, AHPs, and clinical scientists. I am indebted to Ms Sonia McKenna and her senior management team for their support. All of the work undertaken generates data, populates databases and illustrates tables that produce the metrics against which we are judged, and ultimately provides the detail used to inform this report. My very grateful thanks go to Shane Jackson and his team in the coordinating centre for their tireless commitment to detail.

During the course of 2023-24 one of my priorities was to enhance NICRN staff collegiality and cooperation. This year's staff Conference, held at the Galgorm Hotel Ballymena (25.05.2023), was attended by over 75 clinical and support staff. Representatives from 5 of our CSGs presented results from their studies highlighting achievements and challenges. I believe that presenting to peers is important and I congratulate those who stepped up to the mark and shared their findings with us. My

aspiration is that our staff will take the opportunity to speak about the good work that they undertake to a wider audience both regionally and at appropriate scientific meetings in the UK and Ireland. Our 2 invited keynote speakers Kate Greenwood and Emma Clayton presented on “People centred Research” and “Colourful conversation, the art of communicating in a digital world”. Alison Murphy and Bernie Pearson, complimented the message Paul Biagioni and I had been presenting on the new Cluster model, by outlining how the regions Research Governance environment was changing. The closing highlight from the event was that 93% of attendees reported that the event itself was either Excellent (70%) or Very Good (23%), with very positive feedback on both local and keynote content.

Whereas the Annual NICRN staff Conference is specifically designed to motivate and enthuse clinical and support staff, my broader agenda is to build collegiality and engagement across Clinical Specialty Groups. With this in mind we in conjunction with ABPI ran the NICNs first Clinical Leads and Senior Research CI/PI Conference at the Titanic Hotel in Belfast (26.01.2024). Fifty five research attendees including HSC Research Directors, Clinical and Academic Consultants, Clinical Leads and Primary Investigators, Senior leaders from the Public Health Agency and Department of Health as well as research colleagues from Queens University, Ulster university and Centre for Public Health attended the event at which one major agenda item the Lord James O’Shaughnessy Review of Clinical Trials in the UK and the implications for NI. Professor Ian Young, Chief Scientific Advisor for NI (Department of Health) presented on the Priorities for Research in NI and the advantages of the new Department of Health research strategy currently being developed for NI. Mr Oliver Buckley Mellor, Innovation and Research Policy Manager for ABPI, presented on the short to medium term priorities for implementing the UK wide vision for clinical research and the O’Shaughnessy review. Professor Frank Kee, Director Centre for Public Health in the School of Medicine, Dentistry and Biomedical Sciences, Queens University Belfast, presented on Multi-Morbidity and the need to work together to improve care through collaborative clinical research. The final presentation of the day from Professor Mike Clarke, Director MRC Methodology Hub, (School of Medicine, Dentistry and Biomedical Sciences, Queens University Belfast) centred on Methodology in Clinical Research and Trial Design. Feedback received is that this was an important day, bringing together the research community in NI, celebrating what we do well and planning our next steps for the future. A theme of the day was, Research is not an add-on to clinical care, it is not a privilege, our patients in NI deserve access to cutting edge treatment and we will work tirelessly to ensure this for the benefit of everyone in Northern Ireland.

### **Celebrating Achievement across the Sector**

The **Cardiovascular Group** are to be congratulated on the increased screening and recruitment figures generated in 2023-24. Recruitment increased by 20%, with Belfast team recognised for its contribution to the Percutaneous Aortic Valve programme and the South Eastern team praised for speedy recruitment to cardiovascular disease detection and preventative studies.

The **Child Health Group**, that has expanded to cover new subspecialty areas, are also to be congratulated on increased screening and recruitment activity, with recruitment having increased by 91% over the course of the year. Of particular note was the fact that the team recruited the first UK patient to the FERN Monochorionic Twin Pregnancy Trial.

The **Critical Care and Perioperative Medicine Group**, that has expanded to include studies related to perioperative care, have increased both screening and recruitment activity, with recruitment having increased by 72.4% in 2023-24. A recruitment to target figure of 97% makes Critical Care and Perioperative Medicine one of the most successful NICRN Specialty Groups. Members of the team have also contributed to important study related publications in prestigious European and North

American Journals. One particular co-author, Prof Danny McAuley, is to be congratulated on having been appointed Scientific Director for the National Institute for Health Research (NIHR).

The **Diabetes Group**, which faced a number of staffing challenges this year, were able to increase screening activity although overall recruitment fell slightly. Recruitment to target (99%) and First Patient First Visit (75% commercial within 30 days) achievements were excellent. During the course of the year the Team were delighted to welcome Prof Miras on board as a clinical academic working in the WHSCT and University of Ulster. Prof Miras is leading on the SYNCHRONISE CVOT trial. Two centres in NI are contributing to that trial.

**Gastroenterology** activity was reduced this year as a result of staffing challenges including the illness of the Group Clinical Lead. All in the NICRN Group wish Dr Allen a speedy recovery and look forward to his return to the helm.

The **Mental Health Group**, led by Professors Mulholland and Leavey, has been extremely successful in attracting research funding to Northern Ireland. The impact of this can be seen from the comprehensive list of related publications and team achievements. Recruitment to studies adopted by NICRN is however low and work is being done to investigate how the group can be resourced most appropriately.

The year 2024 sees the end of an era for the **Neurodegenerative Research Group** with the retirement of Professor Peter Passmore. Peter has led on many clinical trials throughout his career, and has co-lead the NICRN Dementia group since its inception in 2008. He will be greatly missed not only by members of the Neurodegenerative team, but by the wider family of clinical researchers and support staff in NICRN. Given the nature of studies currently active, and the fact that the first phase of the NICOLA-HAP study has completed with 1037 participant interviews, screening and recruitment are down this year. It is however very encouraging to note that Prof McGuinness has secured funding for Wave 3 which the NICRN Vision Group plan to assist with.

The **Orthopaedic and Trauma Research Group** continues to grow and I am delighted with the closer cooperation that is being achieved between NICRN and the Orthopaedics TORC Group. The nature of current studies is such that although screening was increased by a factor of 4 this year recruitment was reduced by 20%. Overall recruitment to open studies sits at 265. Two new research interested consultants have joined the Group, Mr Paul Karayiannis and Mr Sam McMahon, after their time away on fellowship training. The group continue to publish widely and attract commendations internationally.

During the course of 2023-24 the **Primary Care Group** experienced very significant change with the retirement of their 3 highly experienced and longstanding research nurses (Claire Leathem, Marina Maxwell and Maeve Nesbitt). This together with successful advanced planning to align the Group with the Eastern Federation Support Unit reduced capacity for new in year activity. This innovative and exciting collaboration between the NICRN PC group and the Eastern Federation Support Unit bodes well for the future.

The **Renal Group** have been very active during 2023-24 increasing recruitment by a factor of x2.3. Many studies including the successful EMPA-KIDNEY study have run across multiple Trusts whereas others including RaDaR and ACHIEVE have or continue to achieve way above target. Belfast's commitment to the ACCESS study is regularly mentioned in the list of top monthly recruiters whereas our Southern Trust Trial team in the course of participating in NightLife were the first renal centre on the Island of Ireland to deliver nocturnal dialysis.

**The Respiratory Team** screening almost 1000 patients to recruit 165 to what are often complex studies illustrates the high level of activity generated. Amongst achievements reached this year BHSCCT have been recognised as the highest recruiting site, out of 13, for NEUROCOUGH, exceeding the original target of 100 to finish with 150 recruited patients. BHSCCT also recruited the first and last patients to the CLEAR trial, finishing as the highest recruiter out of 22 UK sites. Meanwhile the WHSCT Respiratory Research Team were the third highest recruiting site for IPF-COMFORT out of 37 recruiting sites worldwide.

With 10 active studies the **Stroke Team** increased year on year recruitment by 148% in 2023-24 with activity distributed across all 5 Trusts. Of particular note was the ESCAPE-MeVO thrombectomy trial that reached its final target and is due to close in 2024. Trial analysis and publication is eagerly awaited to help guide management in patients with M2 / M3 cerebral occlusions. The SEHSCCT Team are also to be congratulated on their commitment to the MAP-2 Pneumonia and Stroke study.

The **Vision Team** are currently working on 20 studies including 4 new studies which were opened in year. Of studies currently open 9 are commercial and 11 non commercial, 206 patients were recruited in year, a 76% increase on the previous year. In addition to routine activity the Team also successfully negotiated an MHRA inspection of the TIGER trial. Of particular note this year was the awarding of a CBE to Professor Giuliana Silvestri, clinical director for Ophthalmic Services, who has co-led the NICRN Vision group since 2008. The whole team congratulate Prof Silvestri and celebrate this very well earned award.

Understandably the work of the **COVID Delivery Team** diminished throughout the year as the long term impact of the Pandemic reduced. I am indebted to Professor Judy Bradley and Dr Peter McGuigan who led on this area of research and who retired from the lead positions during the course of the year. Those involved in the work did however continue to recruit 80 patients of 1566 screened to 6 active COVID related research studies. Recruitment ran across 5 Trusts and it is a credit to the team that RtT reached 100% overall.

The **Cancer Group**, which understandably represents a broad collective of research active clinicians and support staff, present their comprehensive data set in a variety of reports, though none are public facing the reports can be shared on request, hence the absence of their data in the appendices to this report. Led by Prof McIntosh and Dr Morris, the group consists of 70 research active oncologists, haematologists, surgeons and other senior medical and scientific specialists. In 2023-24 589 participants were recruited to a portfolio of 71 clinical trials, 23 of which had been newly adopted and progressed through set up. This constitutes a 95% increase in recruitment in comparison to the preceding year. Of particular note this year is the fact that the cancer group have been at the forefront of introducing some of the new and novel cancer vaccine clinical trials now available. Also of note are the commendations from sponsors and patient groups. Prof Coyle in particular is to be congratulated for his innovative work in pioneering translational Belfast led clinical interventions. Lastly, regarding Cancer, this collective of highly motivated individuals are to be thanked for the way in which they integrate PPI into everyday practice, something from which we can all learn.

## **Gaining a Regional Perspective of the Sector**

This is the first year that I have asked all 5 Health Trust Research and Development Clinical Directors to comment on the Regional aspect of NICRN work, and in addition presented an overview of the good work carried out within and across Trusts.

In September the **Belfast Health and Social Care Trust** saw the departure of Prof Ian Young as Director of Research and Development, this role now having passed to Dr Mark Cross the Trusts Deputy Medical Director with responsibility for Risk and Governance. All in NICRN send best wishes to Ian as he concentrates on other aspects of his research career, and thank him for his years of dedicated service to research at the BHSCT. I for one have been profoundly impacted by Prof Young's support over the last few years and could not have taken on board NICRN leadership without his guidance and support. Clinical research activity has been carried out by members of all 14 CSGs in the Belfast Trust this year. In total 1395 patients have been recruited to 139 studies, at 154 sites, 22% of which have been commercial.

Dr Minnis, in his role as Research Director at the **Northern Health and Social Care Trust** highlights much of the good work undertaken by those in the Diabetes and Mental Health teams. As work in these areas expands we in NICRN look forward to increased collaboration across a broad range of studies. [Dr Minnis's message from the Director](#) is well worth a read by those seeking to reinvigorate their commitment to and love of clinical research "Lets get curious". With 9 Clinical Specialty Groups recruiting to 35 active studies at 47 sites the NHSC NICRN team recruited 101 patients and achieved a 100% RtT figure.

Dr Donnelly, the Research Director at the **South Eastern Health and Social Care Trust** reports on the Trusts commitment to research resilience, stakeholder engagement and the recently released 5 year research strategy plan. We have enjoyed working with Dr Donnelly's team as we have tackled the challenge of adopting, and adapting to Encompass. Access to this, the regions unified electronic clinical record system, will be invaluable to clinical research teams. Dr Donnelly makes specific reference to the Gastroenterology, Stroke, Critical Care and Perioperative Medicine, Cardiology, Renal and Child Health research staff active within the Trust. With 10 active CSGs working on 37 studies across 44 sites the team in the South Eastern Trust recruited 229 patients from 1166 screened in 2023-24 and achieved a 100% RtT figure.

Dr Sharpe, the Research Director at the **Southern Health and Social Care Trust** makes reference to his team's success in the fields of Cardiology, Renal and Orthopaedics. Of particular note was staff support for the Nightlife study within which patients were the first on the island of Ireland to review nocturnal dialysis, which can have huge impact on quality of life. With 9 active CSGs working on 40 studies across 44 sites the team in the Southern Trust recruited 241 patients from 996 screened in 2023-24 and achieved a 100% RtT figure.

Prof Peace the Research Director at the **Western Health and Social Care Trust** with whom I have had the pleasure of working more closely recently, highlights the fact that closer collaboration has resulted in a 200% increase in screening and recruitment over the last year. Screening 2596 patients to recruit 112 to 42 studies delivered at 52 sites by staff engaged with 9 CSGs, helps position us well for the challenges of O'Shaughnessy.

### **My Grateful Thanks to Team**

So, to conclude 2024 has been a challenging yet exciting year within which we have reported many positive developments. Moving forward I look forward to even close collaboration

across CSGs as they evolve into Clusters, and to working with CIs, PIs, Research Fellows, Nursing staff, clinical Scientists, AHPs and support staff on new and exciting studies and opportunities that will come our way. It would also be entirely inappropriate to conclude without thanking our dedicate team of NICRN clinical and coordinating staff across all disciplines and Trusts. Without your dedication, help and commitment none of this would be possible and it would be our patients who benefit most from innovation, who would suffer. Finally, to Paul, Shane, Sonia, Louise, and Emma (who has moved on) thank you for your unwavering support and the hours of work that it has taken to produce the data that enables me to create the report.



Professor Jonathan Jackson  
NICRN Director



**Figure 1: NI Clinical Research Network: Research and Engagement Event at Titanic Belfast with our Partners ABPI. Pictured (L-R) Prof Frank Kee, Mr Oliver Buckley-Mellor, Prof Mike Clarke, Prof Jonathan Jackson, Mrs Marion Laverty and Prof Ian Young**

# NI Health and Social Care Trust Research and Development Dashboard

No. of Active CSOs	14
No. of Active Studies	191
No. of Recruitment Sites	341
No. of Sites with Recruitment (INY)	297
No. of New Studies during 23-24	42
No. of Studies closed during 23-24	51

Screened (INy*) during 23-24	Recruited during (INy*) 23-24	Screened (TOT)** as at 31/03/2024	Recruited (TOT)** as at 31/03/2024
9,128	2,078	33,214	9,277

\* INY = Activity reported over reporting period (01/04/2023 - 31/03/2024)  
 \*\* TOT = Total activity reported up to and including 31/03/2024

Commercial		Non-Commercial		Combined	
Recruited (INy) during 23-24	Median RT (%)*	Recruited (INy) during 23-24	Median RT (%)*	Recruited (INy) during 23-24	Median RT (%)*
179	80.00%	1,899	96.12%	2,078	87.06%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

Interventional		Observational		Combined	
Recruited (INy) during 23-24	Median RT (%)*	Recruited (INy) during 23-24	Median RT (%)*	Recruited (INy) during 23-24	Median RT (%)*
953	84.00%	1,125	95.83%	2,078	87.06%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

	Commercial	Non-Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	59	132	113	78	127	64
Proportion (%)	30.89%	69.11%	59.16%	40.84%	66.49%	33.51%

Commercial(56)		Non-Commercial(241)		Combined(297)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
52.5	37.50%	38.0	44.40%	41.0	43.10%

\* Metrics calculated on Active Sites with Recruitment only

List of CSGs	Recruitment (INy) during 23-24	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Recruitment to Target (%)**	Median ALL FPFV* (days)	Proportion (%) < 30 days
Cardiovascular	121	5.82%	37	10.85%	73.67%	50.0	33.33%
Child Health	151	7.27%	24	7.04%	60.00%	55.5	22.22%
COVID Delivery Team	80	3.85%	23	6.74%	100.00%	5.5	90.91%
Critical Care	538	25.89%	42	12.32%	97.50%	48.0	41.46%
Diabetes	34	1.64%	18	5.28%	99.00%	30.0	57.14%
Gastroenterology	17	0.82%	12	3.52%	75.50%	99.0	25.00%
Mental Health	28	1.35%	8	2.35%	0.00%	99.0	0.00%
Neurodegenerative	307	14.77%	5	1.47%	81.85%	41.0	33.33%
Orthopaedics	98	4.72%	11	3.23%	83.33%	30.0	55.56%
Primary Care	92	4.43%	48	14.08%	100.00%	8.5	63.04%
Renal	169	8.13%	36	10.56%	71.43%	98.0	27.27%
Respiratory Health	165	7.94%	30	8.80%	69.00%	38.0	40.00%
Stroke	72	3.46%	26	7.62%	70.83%	96.5	25.00%
Vision	206	9.91%	21	6.16%	100.00%	41.5	35.00%
Totals:	2,078	100.00%	341	100.00%	87.06%	41.0	42.76%

\* FPFV Metrics calculated on Active Studies with Recruitment only

\*\*Median RT Metrics calculated on Active Studies which have closed to recruitment

HSC Trusts	Recruitment (INy) during 23-24	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Recruitment to Target (%)**	Median ALL FPFV* (days)	% < 30 days
BHSCT	1,395	67.13%	154	45.16%	80.00%	38.0	43.41%
NHSCT	101	4.86%	47	13.78%	100.00%	35.0	48.84%
SEHSCT	229	11.02%	44	12.90%	100.00%	36.0	46.34%
SHSCT	241	11.60%	44	12.90%	100.00%	56.0	43.90%
WHSCT	112	5.39%	52	15.25%	85.33%	62.0	32.56%
Totals:	2,078	100.00%	341	100.00%	87.06%	41.0	43.10%

\* FPFV Metrics calculated on Active Studies with Recruitment only

\*\*Median RT Metrics calculated on Active Studies which have closed to recruitment

# NICRN Clinical Specialty Lead reviews of the year's activities

In this section the activity of each Clinical Specialty Group has been outlined in a format that seeks to facilitate easy access to relevant data for those interested in topic specific data. Clinical Leads, and their NICRN support staff, have provided some specialty specific background information followed by information on in year (INY) achievements, key publications and good news stories. Only a sample of publications highlighted by leads have been included in the main body of the specialty reports, additional papers having been reported in the appendices. I trust that readers will also enjoy the pictorial approach introduced in the 2022-23 report, and which we have enhanced this year. This together with the Dashboards will provide the information needed to interpret the Networks in year activity.

**Table 1: Acronyms used for NICRN Clinical Specialty Groups (CSG):**

<b>CRV</b>	Cardiovascular	<b>CHI</b>	Child Health	<b>CCA</b>	Critical Care and Perioperative Medicine
<b>DIA</b>	Diabetes	<b>GAS</b>	Gastroenterology	<b>MHT</b>	Mental Health
<b>NEU</b>	Neurodegenerative	<b>ORT</b>	Orthopaedics and Trauma	<b>PCR</b>	Primary Care
<b>REN</b>	Renal	<b>RES</b>	Respiratory Health	<b>STR</b>	Stroke
<b>VIS</b>	Vision	<b>CDT</b>	COVID Delivery Team	<b>NICTN</b>	Northern Ireland Cancer Trials Network

(Throughout the report we will refer to the NICRN clinical speciality groups (CSGs) and the above acronyms will be used throughout our tables.)

# Cardiovascular (CRV)

## Clinical Leads, Active PIs and CMG Members

<b>Cardiology Group Clinical Leads</b> Donna Fitzsimmons – QUB Patrick Donnelly - SEHSCT	<b>CMG Members</b> <b>BHSCT-</b> Colum Owens, Andrew McNeice, Conleth Murphy <b>QUB –</b> Donna Fitzsimmons <b>SEHSCT-</b> Patrick Donnelly, Bernardas Valecka <b>SHSCT-</b> Ian Menown <b>WHSCT-</b> Aaron Peace
<b>Chief and Principal Investigators (CIs &amp; PIs)</b> Colum Owens -BHSCT Andrew McNeice -BHSCT Conleth Murphy - BHSCT Lana Dixon – BHSCT Mark Spence – BHSCT Nicola Johnston – BHSCT Pascal McKeown – BHSCT Ian Menown – SHSCT Aaron Peace – WHSCT Kathryn Ryan – SEHSCT Adesh Ramsewak - WHSCT	<b>PPI Representative</b> Position Vacant

## Group Background/Summary

2023-24 represented the first year that the cardiovascular group were able to meet in person post-COVID. It proved to be a great opportunity to meet up and to allow our new team members to meet our NICRN director.

Despite significant challenges to recruitment not least due to significant personnel changes and complex research protocols the group managed to screen 2061 patients and recruited 121 patients to 31 active studies over four Trust organisations. 58% of our activity involved multicentre commercial studies and almost 80% of these were interventional. Studies were being undertaken across 4 Trusts at 37 sites.

## Key Achievements

**Belfast Trust** have been at the forefront of cardiology device innovation. Their percutaneous aortic valve programme is one of the most experienced in the United Kingdom and recently the BHF PROTECT TAVI project has been evaluating a new technique that could make this

procedure safer. The HIGHLIFE project is a novel percutaneous valve intervention for the mitral valve which if successful may develop a new minimally invasive solution for patients thought to be too high risk for conventional surgical repair or replacement of the valve. The CHIP BCS3 is attempting to make high risk percutaneous coronary intervention safer in patients with severe heart dysfunction by testing a new strategy and a novel device that reduces the amount of work the heart has to do during procedures.

**Southern Trust** continues to deliver high quality percutaneous coronary artery intervention research and were top recruiters to the DEDICATE and eUltra studies. The DEDICATE study used a new stent platform that delivered a drug that could prevent stent complications while the eULTRA trial is evaluating the very latest in coronary artery stent design.

**Western Trust** in the TRANSFORM II study have been evaluating a drug coated balloon to help improve coronary artery blockages against our current standard of care which uses drug coated stents. They also continue to test ways to minimise heart damage after a heart attack by using novel drug therapies in the IOCYTE AMI 3 and HORIZON studies.

**South Eastern Trust** continued their work in the prevention, early detection and management of coronary artery disease and heart failure. Early coronary artery disease detection was evaluated in the DISCHARGE study to which the trust was a top recruiter in the United Kingdom. They exceeded expectations and were asked to contribute further patients in the coronary artery disease prevention PREVAIL trial using a novel cholesterol lowering medication. In their heart failure work they continue as a CI site for Global Congestive Heart Failure registry which will inform our global understanding of heart failure care. They were a super-recruiter for the BHF sponsored IRONMAN study which evaluated the role of intravenous iron in the management of patients with chronic heart failure and they had the fastest first patient randomised in the VICTOR study.

## Relevant Publications

The EASTBOURNE Prospective Registry. Cortese, B, ... **MD Ian Menown**. et al. *J Am Coll Cardiol Intv*. 2023 Jul, 16 (14) 1794–1803. <https://doi.org/10.1016/j.jcin.2023.05.005>

Investigating Temporal Features of Carotid Intima-Media Thickness from Ultrasound Imaging with Recurrent Neural Networks. Jing M, ..., **Menown I**, et al. *Annu Int Conf IEEE Eng Med Biol Soc*. 2023 Jul;2023:1-4. doi: 10.1109/EMBC40787.2023.10340661. PMID: 38083237.

Effect of IV Iron on haemoglobin and clinical events according to age in patients with heart failure and iron deficiency in a randomised trial (IRONMAN)- Heart 2023 BCS Conference Paper.

Computed Tomography Versus Invasive Coronary Angiography in Patients With Diabetes and Suspected Coronary Artery Disease. Benedek T, ..., **Donnelly P**, et al. *Diabetes Care* 2023 *Diabetes Care* 2023 Nov 1;46(11):2015-2023. doi: 10.2337/dc23-0710

Impact of smoking in patients with suspected coronary artery disease in the randomised DISCHARGE trial. Mancone M, ... **Donnelly P**, et al. *European Radiology* 2023. *Eur Radiol*. 2024

## Awards/Good New Stories

**BHSCT Number 1 Recruitment Site in the UK for Cardiovascular IVUS CHIP Trial:** The NI Clinical Research Network Cardiovascular team are the Number 1 Recruiter in the UK for the IVUS CHIP Trial. The team based in the Royal Victoria Hospital, Belfast have recruited 41 patients.

**SEHSCT Cardio Team – Fastest First Patient Randomised for the MERCK VICTOR trial**

PI Dr Patrick Donnelly and the SEHSCT Research Team were congratulated for screening and randomising their first patient. As the last site to be added to the study in the UK, SEHSCT achieved the shortest amount of time between their Site Ready declarations to First Patient Randomised.



**Figure 2: (L-R) SEHSCT Cardio team: Ms Aileen Smith, Dr Bernardas Valecka and Ms Susan Regan.**

# Dashboard (Cardiovascular -CRV)

Table 1: Studies and Sites Data	
No. of Active HSC Trusts	4
No. of Active Studies	31
No. of Recruitment Sites	37
No. of Sites with Recruitment (INV)	33
No. of New Studies during 23-24	9
No. of Studies closed during 23-24	4

Table 4: Portfolio Sponsorship, Randomisation and Design Mix for Active Studies During 23-24						
	Commercial	Non-Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	18	13	21	10	24	7
Proportion (%)	58.06%	41.94%	67.74%	32.26%	77.42%	22.58%

Table 2: Screening and Recruitment In Year and also Cumulative Totals for Active Studies During 23-24			
Screened (INV)* during 23-24	Recruited during (INV)* 23-24	Screened (TOT)** as at 31/03/2024	Recruited (TOT)** as at 31/03/2024
2,061	121	3,307	804

\* INV = Activity reported over reporting period (01/04/2023 - 31/03/2024)  
 \*\* TOT = Total activity reported up to and including 31/03/2024

Table 5: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days (%) *					
Commercial(18)		Non-Commercial(15)		Combined(33)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
47.5	33.33%	87.0	33.33%	50.0	33.33%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 3a: Recruitment and Median Recruitment to Target (%)* by Sponsorship Type					
Commercial		Non-Commercial		Combined	
Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*
66	26.67%	55	81.00%	121	73.67%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

Table 6b: Clinical Specialty Group Data by HSC Trust							
List of HSC Trusts***	Recruitment (INV) during 23-24	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Recruitment to Target (%)**	Median ALL FPFV* (days)	Proportion (%) < 30 days
BHSCT	44	36.36%	13	35.14%	73.33%	25.0	50.00%
NHSCT							
SEHSCT	27	22.31%	9	24.32%	74.00%	60.5	25.00%
SHSCT	38	31.40%	8	21.62%	90.00%	45.0	28.57%
WHSCT	12	9.92%	7	18.92%		68.0	16.67%
<b>Totals:</b>	<b>121</b>	<b>100.00%</b>	<b>37</b>	<b>100.00%</b>	<b>73.67%</b>	<b>50.0</b>	<b>33.33%</b>

\* FPFV Metrics calculated on Active Sites with Recruitment only

\*\*Median RT Metrics calculated on Active Studies which have closed to recruitment

\*\*\*HSC Trust names highlighted in purple indicates which Trusts are active in the CSG portfolio

Table 3b: Recruitment and Median Recruitment to Target (%)* by Design Type					
Interventional		Observational		Combined	
Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*
73	73.33%	48	74.00%	121	73.67%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

# Child Health (CHI)

## Clinical Leads, Active PIs and CMG Members

<b>Child Health Group Clinical Leads</b> David Sweet - BHSCT Anthony McCarthy – BHSCT	<b>CMG Members</b> <b>BHSCT</b> – David Sweet, Anthony McCarthy, David Millar <b>SEHSCT</b> - Michael Magowan <b>SHSCT</b> - Alison Verner, Lesley-Ann Funston <b>WHSCT</b> - Damien Armstrong <b>NHSCT</b> - Dave Watkins
<b>Chief and Principal Investigators (CIs &amp; PIs)</b> David Sweet - BHSCT Bharathi Rao - BHSCT Julie Richardson - BHSCT Brian McCrossan - BHSCT Suzanne Lawther - BHSCT Catriona Monaghan - BHSCT Michael Magowan - SEHSCT Alison Verner - SHSCT Lesley-Ann Funston –SHSCT	<b>PPI Representative</b> Position vacant

## Group Background/Summary

CMG meetings have recently been re-convened. As new studies open and the pandemic resolves and childrens CRN remains actively engaged in seeking studies where they can provide support. Studies were undertaken across 3 Northern Irish Health Care Trusts at 21 sites, the SHSCT having achieved in excess of 100% recruitment to target. There are currently 21 active studies recruiting, with 5 others recently closed. Four new studies were opened during 2023/24. The main hurdle to opening even more studies was the slow turn around due to lack of staff in the R&D office. In 2023/24 365 paediatric patients were screened with 151 recruited into active studies. We are striving to recruit staff and studies to include all 5 Trusts.

## Key Achievements

For the first time ever in 2023/24 we achieved full nursing staff complement. This has enabled us to carry out more activity than before. Paediatric research nurses and midwives are expanding their skill set through training, for example performing sweat tests and novel pulmonary function tests used for monitoring children with cystic fibrosis. The inclusion of 2 commercial studies within the portfolio has resulted in income generation. We have also successfully expanded into more clinical areas including Paediatrics, ED, Cardiology,

Nephrology and paediatric surgery. There is now much more awareness of the Children's CRN team as a result of this.

## Relevant Publications

**OSCAR TRIAL:** Gupta S, et al. **(Trial investigator and research site for the trial)** Baby-OSCAR Collaborative Group. Trial of Selective Early Treatment of Patent Ductus Arteriosus with Ibuprofen. *N Engl J Med.* 2024 Jan 25;390(4):314-325. doi: 10.1056/NEJMoa2305582. PMID: 38265644; PMCID: PMC7615774.

**ECLIPSE TRIAL:** Lyttle MD, et al. **(Trial investigator and research site for the trial)** Paediatric Emergency Research in the United Kingdom & Ireland (PERUKI) collaborative. Levetiracetam versus phenytoin for second-line treatment of paediatric convulsive status epilepticus (ECLIPSE): a multicentre, open-label, randomised trial. *Lancet.* 2019 May 25;393(10186):2125-2134. doi: 10.1016/S0140-6736(19)30724-X. Epub 2019 Apr 17. PMID: 31005385; PMCID: PMC6551349.

There were a number of clinical trials during the Covid era now published for which our nurses were engaged in recruitment and data collection.

## Awards/Good New Stories

We are delighted that now we have moved out of the aftermath of the COVID pandemic the paediatric CRN team has become more actively engaged in opening new trials and recruiting paediatric patients into worthwhile studies.

Clinical Research Network Child Health Team Recruit the First patient to the FERN Trial  
Our Child Health Research Team, based at the Royal Jubilee Maternity Hospital, Belfast was the first site to recruit a patient to the FERN: Intervention or Expectant Management for Early Onset Selective Fetal Growth Restriction in Monochorionic Twin Pregnancy Trial.

The research team received a prize from the Study Management team at University of Liverpool for their achievement in this study.



Figure 3: Children's CRN with prize for their achievement on the Fern study.

# Dashboard (Child Health - CHI)

Table 1: Studies and Sites Data	
No. of Active HSC Trusts	3
No. of Active Studies	21
No. of Recruitment Sites	24
No. of Sites with Recruitment (INV)	18
No. of New Studies during 23-24	4
No. of Studies closed during 23-24	5

Table 4: Portfolio Sponsorship, Randomisation and Design Mix for Active Studies During 23-24						
	Commercial	Non-Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	2	19	14	7	13	8
Proportion (%)	9.52%	90.48%	66.67%	33.33%	61.90%	38.10%

Table 5: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days (%) *					
Commercial(1)		Non-Commercial(17)		Combined(18)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
42.0	0.00%	57.0	23.53%	55.5	22.22%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 2: Screening and Recruitment in Year and also Cumulative Totals for Active Studies During 23-24			
Screened (INV)* during 23-24	Recruited during (INV)* 23-24	Screened (TOT)** as at 31/03/2024	Recruited (TOT)** as at 31/03/2024
364	151	1,005	490

\* INV = Activity reported over reporting period (01/04/2023 - 31/03/2024)

\*\* TOT = Total activity reported up to and including 31/03/2024

Table 6b: Clinical Specialty Group Data by HSC Trust							
List of HSC Trusts***	Recruitment (INV) during 23-24	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Recruitment to Target (%)**	Median ALL FPFV* (days)	Proportion (%) < 30 days
BHCT	118	78.15%	19	79.17%	60.00%	52.5	28.57%
NHCT							
SEHCT	10	6.62%	1	4.17%		86.0	0.00%
SHCT	23	15.23%	4	16.67%	135.00%	70.0	0.00%
WHCT							
<b>Totals:</b>	<b>151</b>	<b>100.00%</b>	<b>24</b>	<b>100.00%</b>	<b>60.00%</b>	<b>55.5</b>	<b>22.22%</b>

\* FPFV Metrics calculated on Active Sites with Recruitment only

\*\*Median R/T Metrics calculated on Active Studies which have closed to recruitment

\*\*\*HSC Trust names highlighted in purple indicates which Trusts are active in the CSG portfolio

Table 3a: Recruitment and Median Recruitment to Target (%)* by Sponsorship Type					
Commercial		Non-Commercial		Combined	
Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)	Recruited (INV) during 23-24	Median RT (%)*
0	60.00%	151	65.00%	151	60.00%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

Table 3b: Recruitment and Median Recruitment to Target (%)* by Design Type					
Interventional		Observational		Combined	
Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*
87	50.00%	64	270.00%	151	60.00%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

# Critical Care and Perioperative Medicine (CCA)

## Clinical Leads, Active PIs and CMG Members

<b>Critical Care and Perioperative Medicine</b>	<b>CMG Members</b>
<b>Group Clinical Lead</b>	
Jon Silversides - BHSCT & QUB	<b>BHSCT</b> – Adam Glass, Danny McAuley, Jackie Green, Jon Silversides, Kiran Reddy, Michael McGinlay, Peter McGuigan, James McNamee, Chris Nutt, Ciara O’Donnell, Aisling O’Neill, Suzanna Paterson, Murali Shyamsundar, Christine Turley, Kathryn Ward, Chris Wright, Emma Bohan, Matthew Adams, Rosemary Hogg, David Johnston, Neil Cody
<b>Chief and Principal Investigators (CIs &amp; PIs)</b>	<b>NHSCT</b> – Paul Johnston, Jude Gallagher, Rebecca Gibson
Jon Silversides – BHSCT & QUB	<b>SEHSCT</b> – Chris Murray, Matthew Devine, Samantha Hagan
Danny McAuley – BHSCT & QUB	<b>SHSCT</b> – Rob Charnock, Claire Shevlin, Denise McFarland, Orla McAtasney, Michael Jones, Shiva Arava
Adam Glass – BHSCT & QUB	<b>WHSCT</b> – Adrian Donnelly, Sinead O’Kane
Peter McGuigan – BHSCT	
Chris Nutt – BHSCT	<b>PPI Representative</b>
James McNamee – BHSCT	Position vacant
Murali Shyamsundar – BHSCT	
Ciara O’Donnell – BHSCT	
David Johnston – BHSCT	
Dominic Trainor – BHSCT	
Suzanna Paterson – BHSCT	
Laura Loughlin – BHSCT	
Paul Johnston – NHSCT	
Samantha Hagan – SEHSCT	
Rob Charnock – SHSCT	
Claire Shevlin – SHSCT	
Denise McFarland – SHSCT	
Adrian Donnelly – WHSCT	
Michelle Fallon – WHSCT	
Sinead O’Kane – WHSCT	

## Group Background/Summary

The critical care and perioperative medicine specialty group continued to have high levels of activity, and to grow, particularly with expansion into perioperative studies, an area which was previously underserved. The group's portfolio consisted of 21 studies active across the 5 trusts. Of 2156 patients screened, almost 25% (538) were formally recruited, and of these 381 participated in interventional trials. Of studies closed in year 97% achieved recruitment to target. CMG meetings were held quarterly, with regular representation from 4 of 5 Trusts, as well as representative from the NICRN coordinating centre.

### Portfolio Studies

#### Studies opened during the 2023/4 reporting period:

RV study – Assessment of right ventricular contractile reserve following resection by dobutamine stress cardiac magnetic resonance. (BHSCT)

SRAVI – A speech recognition application as a communication aid for critical care patients with tracheostomies (BHSCT, WHSCT)

iREHAB – Remote multicomponent rehabilitation compared to standard care for survivors of critical illness after hospital discharge. (SEHSCT)

SIGNET - Statins in Organ Donor Management An evaluation of the benefits of a single dose of Simvastatin given to potential organ donors declared dead by neurological criteria on outcomes in organ recipients. (SHSCT)

SINFONIA – Sugammadex for prevention of post-operative pulmonary complications. (SHSCT)

#### Studies closed during the 2023/4 reporting period:

A2B - Alpha 2 agonists for sedation to produce better outcomes from critical illness. (BHSCT)

A-STOP - Antifungal stewardship opportunities with rapid tests for fungal infection in critically ill patients. (BHSCT, NHSCT, SEHSCT, SHSCT, WHSCT)

CHEST – Characterising biofilms in endotracheal tubes to direct a new strategy for preventing ventilator-associated pneumonia in critically ill adults. (BHSCT)

PHIND - Clinical Evaluation of a Point of Care (POC) assay to identify PHenotypes IN the Acute Respiratory Distress Syndrome. (BHSCT)

REALIST - Repair of Acute Respiratory Distress Syndrome by Stromal Cell Administration.(BHSCT)

SCUFFD – Feasibility of slow continuous ultrafiltration for deresuscitation in critically ill patients. (BHSCT)

SRAVI – A speech recognition application as a communication aid for critical care patients with tracheostomies. (BHSCT, WHSCT)

VACIRISS - Pneumococcal Vaccination to Accelerate Immune Recovery in Sepsis Survivors. (BHSCT)

ZANAMIVIR – Retrospective observational study to evaluate the effectiveness of treatment with Zanamivir in a cohort of ICU patients with complicated influenza infection. (BHSCT)

Studies currently in setup:

AWAKE-PRONE – Awake prone positioning in patients with acute hypoxaemic respiratory failure not due to COVID-19. Part of the CORECCT umbrella study. (BHSCT)

GUARDS – Glucocorticoids in adults with Acute Respiratory Distress Syndrome. (BHSCT, SHSCT, WHSCT)

INFINIT – Can interferon gamma prevent infection in critically ill patients at highest risk? (BHSCT)

INITIALISE – Investigation of novel and established therapies in a human intravenous lipopolysaccharide model of sepsis. (BHSCT)

RELEASE – Airways Pressure Release Ventilation v conventional ventilation. Part of the CORECCT umbrella study. (BHSCT)

SepTIC – Sepsis Trials in Critical Care. (BHSCT)

SHORTER – Comparing different antibiotic durations for the treatment of sepsis. (SEHSCT)

STPCARE - Sedation, Temperature and Pressure after Cardiac Arrest and Resuscitation. (BHSCT)

## Key Achievements

- Completed recruitment to several NI-led studies: PHIND, SRAVI, SCUFFD, CHEST, and the long-running REALIST study, a Phase 2 trial investigating mesenchymal stem cells in ARDS led by Prof Danny McAuley (QUB).
- Opened the first NICRN-adopted perioperative trial in SHSCT (SINFONIA, comparing 2 agents for reversal of neuromuscular blockade), which is led by Dr Jon Silversides (QUB).
- Continued high levels of recruitment to UK-ROX trial (comparing high versus low oxygenation targets in mechanically ventilated patients) in SEHSCT and SHSCT (PIs Dr Chris Murray and Dr Rob Charnock) with 116 and 99 patients recruited respectively
- BHSCT third highest recruiting centre in the UK, with 38 recruited, for SOS trial comparing mannitol with hypertonic saline in traumatic brain injury.
- Publication of a landmark paper from the REMAP-CAP platform trial, to which NI sites recruited patients: Simvastatin in Critically Ill Patients with Covid-19 (NEJM 2023;389:2341-54) led by Prof Danny McAuley (QUB).
- RVH second highest recruiting site for SINFONIA in UK – 61 (BHSCT total 92).
- BHSCT third highest recruiter for MARCH out of 65 sites across the UK.
- BHSCT top recruiting site for REALIST.

## Relevant Publications

The Effect of Lower Tidal Volume Ventilation Facilitated by Extracorporeal Carbon Dioxide Removal Compared With Conventional Lung Protective Ventilation on Cardiac Function. **McGuigan PJ, ..., Boyle AJ, ..., McNamee JJ, ..., McAuley DF, et al.** . Crit Care Explor. 2024 Jan 10;6(1):e1028. doi: 10.1097/CCE.0000000000001028. eCollection 2024 Jan.

Alpha 2 agonists for sedation to produce better outcomes from critical illness (A2B Trial): protocol for a multicentre phase 3 pragmatic clinical and cost-effectiveness randomised trial in the UK. Walsh TS, ... **McAuley DF**, et al. BMJ Open. 2023 Dec 10;13(12):e078645. doi: 10.1136/bmjopen-2023-078645.

Simvastatin in Critically Ill Patients with Covid-19. REMAP-CAP Investigators... **McAuley DF**. N Engl J Med. 2023 Dec 21;389(25):2341-2354. doi: 10.1056/NEJMoa2309995. Epub 2023 Oct 25.

Landiolol and Organ Failure in Patients With Septic Shock: The STRESS-L Randomized Clinical Trial. Whitehouse T, ..., **McAuley D**, et al. STRESS-L Collaborators. JAMA. 2023 Nov 7;330(17):1641-1652. doi: 10.1001/jama.2023.20134.

Intravenous Vitamin C for Patients Hospitalized With COVID-19: Two Harmonized Randomized Clinical Trials. LOVIT-COVID Investigators, on behalf of the Canadian Critical Care Trials Group, and the REMAP-CAP Investigators... **McAuley DF** et al. JAMA. 2023 Nov 14;330(18):1745-1759. doi: 10.1001/jama.2023.21407.

biomarker-guided Duration of Antibiotic treatment in hospitalised Patients with suspected Sepsis (ADAPT-Sepsis): A protocol for a multicentre randomised controlled trial. Dark P, ... , **McAuley D, et al.** R. J Intensive Care Soc. 2023 Nov;24(4):427-434. doi: 10.1177/17511437231169193. Epub 2023 Apr 25.

Initiation of continuous renal replacement therapy versus intermittent hemodialysis in critically ill patients with severe acute kidney injury: a secondary analysis of STARRT-AKI trial. Wald R, ... **McAuley DF**, et al. ; STARRT-AKI Investigators. Intensive Care Med. 2023 Nov;49(11):1305-1316. doi: 10.1007/s00134-023-07211-8. Epub 2023 Oct 10.

Mild Hypercapnia or Normocapnia after Out-of-Hospital Cardiac Arrest. Eastwood G, ... **McGuigan PJ**, et al. TAME Study Investigators. N Engl J Med. 2023 Jul 6;389(1):45-57. doi: 10.1056/NEJMoa2214552. Epub 2023 Jun 15.

Repair of Acute Respiratory Distress Syndrome in COVID-19 by Stromal Cells (REALIST-COVID Trial): A Multicenter, Randomized, Controlled Clinical Trial. Gorman EA,... **McGuigan P**, ..., **Silversides J**, ..., **McAuley DF**, et al. Am J Respir Crit Care Med. 2023 Aug 1;208(3):256-269. doi: 10.1164/rccm.202302-0297OC.

Effect of Angiotensin-Converting Enzyme Inhibitor and Angiotensin Receptor Blocker Initiation on Organ Support-Free Days in Patients Hospitalized With COVID-19: A Randomized Clinical Trial. Writing Committee for the REMAP-CAP Investigators Lawler PR,... **McAuley DF** et al. Webb SA. JAMA. 2023 Apr 11;329(14):1183-1196. doi: 10.1001/jama.2023.4480.

Other key publications and presentations have been listed in the appendices.

## Awards/Good New Stories

Prof Danny McAuley appointed Scientific Director for the National Institute for Health Research (NIHR).

Dr Jon Silversides appointed to the NIHR Health Technology Assessment prioritisation committee for hospital-based care.

Dr Peter McGuigan awarded ICC-CTN Early Career Researcher Seed Funding Award from the Irish Critical Care Trials Group.

NI Clinical Research Network Critical Care and Perioperative Medicine team, led by Dr Jon Silverside, recruited 45 patients in one month in Belfast Trust alone, demonstrating an outstanding run of recruitment this year.



**Figure 4: Pictured (L-R) Recruiting 45 patients in 1 month. Professor Jonathan Jackson congratulates Ms Jackie Green, Ms Erin Collins, Ms Christine Turley, Ms Kathryn Ward and Mr Chris Wright.**

# Dashboard (Critical Care and Perioperative Medicine - CCA)

Table 1: Studies and Sites Data	
No. of Active HSC Trusts	5
No. of Active Studies	21
No. of Recruitment Sites	42
No. of Sites with Recruitment (INV)	41
No. of New Studies during 23-24	0
No. of Studies closed during 23-24	8

Table 4: Portfolio Sponsorship, Randomisation and Design Mix for Active Studies During 23-24						
	Commercial	Non-Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	1	20	14	7	15	6
Proportion (%)	4.76%	95.24%	66.67%	33.33%	71.43%	28.57%

Table 2: Screening and Recruitment In Year and also Cumulative Totals for Active Studies During 23-24			
Screened (INV*) during 23-24	Recruited during (INV**) 23-24	Screened (TOT)** as at 31/03/2024	Recruited (TOT)** as at 31/03/2024
2,156	538	6,710	1,212

\* INV = Activity reported over reporting period (01/04/2023 - 31/03/2024)  
 \*\* TOT = Total activity reported up to and including 31/03/2024

Table 5: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days (%) *					
Commercial(1)		Non-Commercial(40)		Combined(41)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
85.0	0.00%	41.5	42.50%	48.0	41.46%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 3a: Recruitment and Median Recruitment to Target (%)* by Sponsorship Type					
Commercial		Non-Commercial		Combined	
Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*
10	100.00%	528	95.00%	538	97.50%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

Table 6b: Clinical Specialty Group Data by HSC Trust							
List of HSC Trusts***	Recruitment (INV) during 23-24	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Recruitment to Target (%)**	Median ALL FPFV* (days)	Proportion (%) < 30 days
BHSC	370	68.77%	23	54.76%	97.50%	34.0	45.45%
NHSC	0		2	4.76%	63.33%	49.5	0.00%
SEHSC	90	16.73%	5	11.90%	171.33%	71.0	40.00%
SHSC	62	11.52%	5	11.90%	115.15%	29.0	60.00%
WHSC	16	2.97%	7	16.67%	86.67%	123.0	28.57%
<b>Totals:</b>	<b>538</b>	<b>100.00%</b>	<b>42</b>	<b>100.00%</b>	<b>97.50%</b>	<b>48.0</b>	<b>41.46%</b>

\* FPFV Metrics calculated on Active Sites with Recruitment only

\*\*Median RT Metrics calculated on Active Studies which have closed to recruitment

\*\*\*HSC Trust names highlighted in purple indicates which Trusts are active in the CSG portfolio

Table 3b: Recruitment and Median Recruitment to Target (%)* by Design Type					
Interventional		Observational		Combined	
Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*
403	49.44%	135	115.58%	538	97.50%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

# Diabetes (DIA)

## Clinical Leads, Active PIs and CMG Members

<p><b>Diabetes Group Clinical Lead</b></p> <p>John Lindsay- BHSCT Alex Miras- UU &amp; WHSCT</p>	<p><b>CMG Members</b></p> <p><b>BHSCT</b> - John Lindsay, Philip Johnston, Hamish Courtney <b>NHSCT</b> – Anna Strzelecka <b>SEHSCT</b> – Ciara Mulligan <b>WHSCT</b> - Alex Miras</p>
<p><b>Chief and Principal Investigators (CIs &amp; PIs)</b></p> <p>John Lindsay-BHSCT Philip Johnston-BHSCT Hamish Courtney-BHSCT Anna Strzelecka-NHSCT Ciara Mulligan – SEHSCT Alex Miras- WHSCT &amp; UU</p>	<p><b>PPI Representatives</b></p> <p>Position Vacant</p>

## Group Background/Summary

The diabetes CMG meets every six months with regular representation across four of the five health Trusts. The portfolio includes studies in type 1 diabetes, type 2 diabetes, cardio-metabolic, metabolic bone disease and obesity management.

43% of the portfolio are industry-sponsored studies. Fifty percent of studies are randomised and interventional in design. Three new studies, adopted by the diabetes NICRN are UK-EDI for Pancreatic Cancer, UK Prospective Diabetes Study (UKPDS) Legacy Study and SYNCHRONIZE CVOT to be delivered in the Belfast, Northern and Western Trusts. Newly open for recruitment are FAME 1 Eye, SYNCHRONIZE CVOT and ADDRESS2. The Fenofibrate And Microvascular Events in Type 1 diabetes Eye (FAME 1 Eye) is evaluating the efficacy on retinopathy and safety of fenofibrate in adults with type 1 diabetes. SYNCHRONIZE CVOT is a trial testing the effect of Survodutide (BI 456906) on cardiovascular safety in people with overweight or obesity. ADDRESS-2 is a multi-centre UK collaboration aiming to improve understanding of the development and progression of type 1 diabetes and to establish a resource to facilitate type 1 diabetes research.

During 2023-24 we screened 123 patients and recruited 34 to active studies with a median first participant-first visit of 29.5 days for commercial studies and 62 days for non-commercial

studies. Overall our recruitment to target (RtT) for studies closed to recruitment was excellent at 99%.

## Key Achievements

- In BHSCT a number of trials in a wide range of research areas are underway, including FAME 1 Eye, ADDRESS 2, TOPaZ, SOUL and Pioneer Real.
- The NHSCT team are engaged in a range of cardio-metabolic and obesity studies and have been highly successful with patient recruitment during 2023-24. Ongoing studies include SYNCHRONIZE – CVOT, ADDRESS 2, Pioneer Real, SELECT LIFE, REDEFINE 2.
- We were delighted to welcome Research Nurse Natalie Hanley who is doing part-time work in Diabetes research in NHSCT.
- In WHSCT, Prof Miras is leading on the SYNCHRONIZE CVOT trial. Two centres in NI are contributing to that trial. Prof Miras is also contributing to NICRN activity through his academic studies (alpha-MSH) at Ulster University Coleraine campus.
- The SEHSCT team are engaged in two trials, ADDRESS 2 and VESALIUS/CV.

## Relevant Publications

Semaglutide and Cardiovascular Outcomes in Obesity without Diabetes. Lincoff AM, et al; **(NHSCT was a research site for the trial)**. N Engl J Med. 2023 Dec 14;389(24):2221-2232. doi: 10.1056/NEJMoa2307563. Epub 2023 Nov 11.

## Awards/Good New Stories

- In March 2024, the NHSCT Diabetes Research Team was the Highest Recruiter for ADDRESS 2 Trial.
- Professor Miras has been disseminating his research findings with wider audiences through interviews with BBC NI (radio and TV) and Radio Foyle.
- Our BHSCT Diabetes Research team organised a Diabetes Research Café morning on Thursday 1st February 2024, at the Regional Centre for Diabetes and Endocrinology, Royal Victoria Hospital.
- Congratulations to our Northern Health and Social Care Trust Diabetes Research team. Who were the 2nd highest recruiters in the UK and 1st in the UK for patients screened for the Novonordisk REDEFINE 2 research trial. The study screened 181 patients and randomised 134 in the UK.



**Figure 5: Northern Health and Social Care Trust Diabetes Research Team including research nurse Ms Moyra McMaster, PI Dr Anna Strzelecka and research nurse Natalie Hanley (REDEFINE2).**

# Dashboard (Diabetes - DIA)

Table 1: Studies and Sites Data	
No. of Active HSC Trusts	4
No. of Active Studies	12
No. of Recruitment Sites	18
No. of Sites with Recruitment (INV)	14
No. of New Studies during 23-24	3
No. of Studies closed during 23-24	3

Table 4: Portfolio Sponsorship, Randomisation and Design Mix for Active Studies During 23-24						
	Commercial	Non-Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	7	5	6	6	6	6
Proportion (%)	58.33%	41.67%	50.00%	50.00%	50.00%	50.00%

Table 2: Screening and Recruitment In Year and also Cumulative Totals for Active Studies During 23-24			
Screened (INV*) during 23-24	Recruited during (INV*) 23-24	Screened (TOT)** as at 31/03/2024	Recruited (TOT)** as at 31/03/2024
123	34	482	150

\* INV = Activity reported over reporting period (01/04/2023 - 31/03/2024)  
 \*\* TOT = Total activity reported up to and including 31/03/2024

Table 5: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days (%) *					
Commercial(8)		Non-Commercial(6)		Combined(14)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
29.5	75.00%	55.0	33.33%	30.0	57.14%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 3a: Recruitment and Median Recruitment to Target (%)* by Sponsorship Type					
Commercial		Non-Commercial		Combined	
Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)	Recruited (INV) during 23-24	Median RT (%)*
13	108.00%	21	86.67%	34	99.00%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

Table 6b: Clinical Specialty Group Data by HSC Trust							
List of HSC Trusts***	Recruitment (INV) during 23-24	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Recruitment to Target (%)**	Median ALL FPFV* (days)	Proportion (%) < 30 days
BHSC	7	20.59%	9	50.00%	80.00%	46.0	50.00%
NHSC	22	64.71%	7	38.89%	122.22%	30.0	71.43%
SEHSC	5	14.71%	1	5.56%		70.0	0.00%
SHSC							
WHSC	0	0.00%	1	5.56%			
<b>Totals:</b>	<b>34</b>	<b>100.00%</b>	<b>18</b>	<b>100.00%</b>	<b>99.00%</b>	<b>30.0</b>	<b>57.14%</b>

\* FPFV Metrics calculated on Active Sites with Recruitment only

\*\*Median RT Metrics calculated on Active Studies which have closed to recruitment

\*\*\*HSC Trust names highlighted in purple indicates which Trusts are active in the CSG portfolio

Table 3b: Recruitment and Median Recruitment to Target (%)* by Design Type					
Interventional		Observational		Combined	
Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*
12	97.33%	22	140.00%	34	99.00%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

# Gastroenterology (GAS)

## Clinical Leads, Active PIs and CMG Members

<b>Gastroenterology Group Clinical Lead</b> Patrick Allen - SEHSCT	<b>CMG Members</b> <b>BHSCT</b> -Graham Morrison, Inder Mainie <b>NHSCT</b> - Kok Diong <b>SEHSCT</b> - Patrick Allen <b>WHSCT</b> - John McGoran
<b>Chief and Principal Investigators</b> Graham Morrison - BHSCT Inder Mainie - BHSCT Kok Diong – NHSCT Patrick Allen - SEHSCT John McGoran –WHSCT	<b>PPI Representatives</b> Position Vacant

## Group Background/Summary

The Gastroenterology group has had 1 CMG in September 2023, the next CMG is planned for September 2024.

The Gastroenterology group has 11 active studies, 4 new and 3 closing in this annual reporting period. Screening 37 patients and recruiting 17.

## Key Achievements

Gastroenterology was the highest site recruiter in the UK in the real world study ‘Galocean’.

Gastroenterology has in addition been praised for their high level of data completion in the ELEVATE study

## Awards/Good New Stories

In Partnership with ABPI and Queens University Belfast Dr Inder Mainie, Consultant Gastroenterologist at the Belfast Trust, represented the specialty on the first delegate discussion panel, the topic was, “Incorporating research into routine practice.” (Figure 6)



**Figure 6: (L\_R) Professor Jonathan Jackson, Dr Pdraig Mulholland, Dr Daniel Butler, Dr Ikhlas El Karim, Dr Inder Mainie, Ms Margaret Grayson: 1<sup>st</sup> Panel in NI Clinical Research Network: Research and Engagement Event at Titanic Belfast with our Partners ABPI.**

# Dashboard (Gastroenterology - GAS)

Table 1: Studies and Sites Data	
No. of Active HSC Trusts	3
No. of Active Studies	11
No. of Recruitment Sites	12
No. of Sites with Recruitment (INV)	8
No. of New Studies during 23-24	4
No. of Studies closed during 23-24	3

Table 4: Portfolio Sponsorship, Randomisation and Design Mix for Active Studies During 23-24						
	Commercial	Non-Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	8	3	5	6	8	3
Proportion (%)	72.73%	27.27%	45.45%	54.55%	72.73%	27.27%

Table 2: Screening and Recruitment In Year and also Cumulative Totals for Active Studies During 23-24			
Screened (INV*) during 23-24	Recruited during (INV*) 23-24	Screened (TOT)** as at 31/03/2024	Recruited (TOT)** as at 31/03/2024
37	17	162	128

\* INV = Activity reported over reporting period (01/04/2023 - 31/03/2024)  
 \*\* TOT = Total activity reported up to and including 31/03/2024

Table 5: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days (%) *					
Commercial(5)		Non-Commercial(3)		Combined(8)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
171.0	0.00%	29.0	66.67%	99.0	25.00%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 3a: Recruitment and Median Recruitment to Target (%)* by Sponsorship Type					
Commercial		Non-Commercial		Combined	
Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)	Recruited (INV) during 23-24	Median RT (%)*
11	50.00%	5	140.50%	16	75.50%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

Table 6b: Clinical Specialty Group Data by HSC Trust							
List of HSC Trusts***	Recruitment (INV) during 23-24	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Recruitment to Target (%)**	Median ALL FPFV* (days)	Proportion (%) < 30 days
BHSCT	2	11.76%	6	50.00%	50.00%	177.5	25.00%
NHSCT	0	0.00%	1	8.33%			
SEHSCT	15	88.24%	5	41.67%	180.00%	37.0	25.00%
<b>Totals:</b>	<b>17</b>	<b>100.00%</b>	<b>12</b>	<b>100.00%</b>	<b>75.50%</b>	<b>99.0</b>	<b>25.00%</b>

\* FPFV Metrics calculated on Active Sites with Recruitment only

\*\*Median RT Metrics calculated on Active Studies which have closed to recruitment

\*\*\*HSC Trust names highlighted in purple indicates which Trusts are active in the CSG portfolio

Table 3b: Recruitment and Median Recruitment to Target (%)* by Design Type					
Interventional		Observational		Combined	
Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*
2	75.50%	15		17	75.50%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

# Mental Health (MTH)

## Clinical Leads, Active PIs and CMG Members

<p><b>Mental Health Group Clinical Leads</b></p> <p>Ciaran Mulholland – NHSCT, QUB &amp; UU(Hon)</p> <p>Gerry Leavey- UU</p> <p><b>Chief and Principal Investigators (CIs &amp; PIs)</b></p> <p>Ciaran Mulholland-NHSCT &amp; QUB</p> <p>Suzanne Barrett – NHSCT</p> <p>Michael Duffy – BHSCT &amp; QUB</p> <p>Kevin Dyer - NHSCT/Exeter/QUB</p>	<p><b>CMG Members</b></p> <p><b>BHSCT &amp; QUB</b> - Aidan Turkington</p> <p><b>NHSCT</b>- Ciaran Mulholland ,Suzanne Barrett</p> <p><b>SEHSCT</b> – Gary Woods</p> <p><b>SHSCT</b> – Chris Southwell</p> <p><b>WHSCT</b> - John Brady</p> <p><b>UU</b> - Gerry Leavey</p> <p><b><u>Clinical Trainee Rep</u></b></p> <p>Ursula Campbell – Junior Doctor</p> <p><b><u>PPI Representatives</u></b></p> <p>Mr Robin Kelly - PPI co-applicant for IRAS309119/Member of the PPI group for the NI Trauma Service &amp; Network</p> <p>Ms Marlyn Grant [Service User Consultant] &amp; Involvement Team, NHSCT</p>
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## Group Background/Summary

No CMG meetings in year 2023-24.

During the course of the 2023-24 year we continued work on 3 ongoing studies occurring across 8 sites.

## Key Achievements

- Professors Leavey & Mulholland have been respectively successfully running the Bamford (UU; ADRC NI) and Impact (NHSCT Regional Trauma Network; Forensic Managed-Care Network) Research Centres.
- Profs Mulholland, Dyer and Dr Duffy have been leading on an NIHR Grant “Does a Phased Approach Enhance Outcomes for Trauma-Focused Cognitive Therapy for Complex Posttraumatic Stress Disorder?” This 4 year study, due to complete in 2025,

accrued research costs funding to the tune of £2,099,422.39. This study involves a consortium of Northern Ireland Regional Trauma Network, Queen's University (Co-Cl: Dr Michael Duffy, BHSCT), Oxford University (Co-Cl: Prof. Anke Ehlers), Oxford Mental Health Trust and London Trauma. Centre. Prof Kevin Dyer and Prof Ciaran Mulholland are named applicants. 56 patients have been recruited across all 5 Trusts to date. Fifteen Independent assessors and 36 NI Therapists were trained in the protocol, improving research, and potentially future service delivery, capacity.

- Trialling of the "OSI-Grows" programme, an intervention developed and tested in NI CAMHS services (The Co-CAT RCT), continues in participating RCT delivery centres. Work arising from this study was recently presented by research centre staff from Oxford at the BABCP 52<sup>nd</sup> annual conference, along with information relating to OSCA, an Online Cognitive Therapy Intervention for Social Anxiety in Adolescents.
- Appointment of Dr. Kevin Dyer to Professorship in Clinical Psychology at QUB School of Psychology (commencing August 2024).
- Encompass NHSCT R&D Representation: Research eFCDG leading to Superuser nomination for Dr Suzanne Barrett.

### Successful Grants:

#### Professor Leavey

- **2024-2028** UK Mental Health Hub (with KCL and UK academic partners) NI Lead: ESRC £8,000,000.
- **2024- 27** Challenging Health Outcomes- Integrating Care Environments. Building community coalitions to tackle social exclusion for people with severe mental illness. Funded by the AHRC £1,890,000.
- The CHOICE project will establish and evaluate a social prescribing platform for people with severe mental illness seeks. The CRN-MH will be requested to assist in the recruitment of 300 patients in NI.

#### Professor Mulholland

- P<sup>S</sup>ychosis Ireland Structured Training and Research programme (PSI-STAR). This PSI-STAR programme is led by an All-Ireland team of clinicians and academics from the fields of psychiatry, nursing, social work, sociology, psychology and, "importantly includes an academic with lived experience of psychosis". The programme will train 5+ PhD students who will go on to be leaders in the field of psychosis and make a positive impact on people's lives. The programme is funded by the Health Research Board (Rep of Ireland) (€2, 00000) and involves Prof Ciaran Mulholland (QUB and NHSCT) and Prof Ciaran Shannon (NHSCT) and Prof Gavin Davidson (QUB).
- The DETECT Programme (**D**etecting **E**merging **T**raits of **P**sychosis in **E**ducational and **C**ommunity **C**ohorts (Mulholland and Shannon). (Small Business Research Initiative 2018-date: total approx. £350,000). One study (lead by QUB) focusing on phone usage and mental health is ongoing in phase 3.

- McCartan, Shannon, Jordan, Moore, Mulholland, Davidson & Webb. NHSCT HSC Research Fund. Green and blue spaces to support trauma-informed care. (Funding awarded 2022, £5000).
- Members of the Group have supported two successful PhD funding applications in partnership with QUB (funded via Department for the Economy and EPSRC): “Conflict-Related Sexual Violence” and “Implementing Trauma-Informed Care in Early Psychosis”.

## Relevant Publications

Adolescent mental well-being, religion and family activities: a cross-sectional study (Northern Ireland Schools and Wellbeing Study) Bamford, J., **Leavey, G.**,... et al., 22 Jun 2023, (Published online) In: *BMJ Open*. 13, 6, p. 1-8 9 p., e071999.

The influence of adverse and positive childhood experiences on young people’s mental health and experiences of self harm and suicidal ideation. Bunting, L., ...**Mulholland, C.**, et al., Jun 2023, In: *Child Abuse and Neglect*. 140, 12 p., 106159.

Bunting, L., ...**Mulholland, C.**, et al.. The influence of adverse and positive childhood experiences on young people’s mental health and experiences of self-harm and suicidal ideation, Jun 2023, In: *Child Abuse and Neglect*. 140, 12 p., 106159.

Screening children with a history of maltreatment for post-traumatic stress disorder in frontline social care organizations: a process evaluation Devaney, J., Walsh, C., Bunting, L., Best, P., Davidson, G., **Mulholland, C.**, French, D. & **Duffy, M.**, Nov 2023, In: *Child and Family Social Work*. 28, 4, p. 1225-1234 10 p.

Severe mental illness and ophthalmic health: a linked administrative data study . Ferry, F. ... **Leavey, G, et al.** 7 Jun 2023, (Published online) In: *PLoS ONE*. 18, 6, p. 1-12 13 p., e0286860.

Occupation type, family demands and mental health: analysis of linked administrative data.,Ferry, F. R., ...**Leavey, G et al.** 6 Mar 2023, (Published online) In: *Journal of Mental Health*.

Severe mental illness and ophthalmic health: A linked administrative data study. Ferry, F., ...**Leavey, G. et al.**. 2023, *PloS one*, 18(6), e0286860.

The structure of the Prodromal Questionnaire-16 (PQ-16) in a non-help-seeking youth population: Exploratory and confirmatory factor analyses study. Howie, C, ... **Mulholland, C, et al.** Nov 2023, In: *Schizophrenia research*. 261, p. 281-286 6 p.

Healthcare staff mental health trajectories during the COVID-19 pandemic: findings from the COVID-19 Staff Wellbeing Survey . Jordan, J-A., .... , **Mulholland, C. et al.** Jul 2023, In: *BJPsych Open*. 9, 4, 9 p., e112.

Assessing the clinical and cost-effectiveness of inpatient mental health rehabilitation services provided by the NHS and independent sector (ACER): protocol. Killaspy, H., ... **Leavey, G.**, et al. 6 Feb 2024, (Published online) In: BMC Psychiatry. 24, 1, p. 1-14 14 p.

Qualitative study investigating the professional and personal effects of patient suicide on general practitioners in Northern Ireland. McAnee, G.,...**Leavey, G et al.** 10 Feb 2024, In: BMJ Open. 14, 2, p. 1-9 10 p.

Physical health disparities and severe mental illness: a longitudinal comparative cohort study using hospital data in Northern Ireland. McCarter, R., ...**Leavey, G, et al.** 14 Aug 2023, (Published online) In: European psychiatry : the journal of the Association of European Psychiatrists. 66, 1, p. 1-26 26 p.

Case study 1: the Omagh Bomb, the mental health response, and the lessons learned, 01 Feb 2024, Major incidents, pandemics and mental health: the psychosocial aspects of health emergencies, incidents, disasters and disease outbreaks. **Mulholland, C.** & Duffy, M.. Williams, R., Kemp, V., Porter, K., Healing, T. & Drury, J. (eds.). Cambridge University Press, p. 252-256.

**Mulholland, C.** Ré shuaite, inchinn shuaite: ceacht ó Choimhlint Thuaisceart Éireann

**Mulholland, C.** Troubled times, troubled minds: lesson from the Northern Ireland conflict, 31 Dec 2023, Creative Brain Week: knowledge making. Campbell, D. & Kelleher, B. (eds.). Dublin: Creative Aging International, p. 10-15.

## Awards/Good New Stories

- Level 4 completion in Makaton in September with NHST with regional trainer, Grant Wetherall (S. Barrett).
- Showcase inclusion in UU Douglass Week 2024 of short film, entitled “*I Am*”, created by S Barrett and other students of Belfast Feminist Film Network, completed for certification (Summer School September - 2023 cohort).
- External representation by C Mulholland at Rol Mental Health Research Strategy Working Group 2023-24.



Figure 7: "Sign Simply" group including Suzanne Barrett (Level 4 completion in Makaton)

# Dashboard (Mental Health - MTH)

Table 1: Studies and Sites Data	
No. of Active HSC Trusts	4
No. of Active Studies	3
No. of Recruitment Sites	8
No. of Sites with Recruitment (INV)	5
No. of New Studies during 23-24	0
No. of Studies closed during 23-24	2

Table 4: Portfolio Sponsorship, Randomisation and Design Mix for Active Studies During 23-24						
	Commercial	Non-Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	1	2	1	2	2	1
Proportion (%)	33.33%	66.67%	33.33%	66.67%	66.67%	33.33%

Table 2: Screening and Recruitment In Year and also Cumulative Totals for Active Studies During 23-24			
Screened (INV*) during 23-24	Recruited during (INV*) 23-24	Screened (TOT)** as at 31/03/2024	Recruited (TOT)** as at 31/03/2024
31	28	35	32

\* INV = Activity reported over reporting period (01/04/2023 - 31/03/2024)  
 \*\* TOT = Total activity reported up to and including 31/03/2024

Table 5: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days (%) *					
Commercial(0)		Non-Commercial(5)		Combined(5)	
Median PPFV (days)	% < 30 days	Median PPFV (days)	% < 30 days	Median PPFV (days)	% < 30 days
		99.0	0.00%	99.0	0.00%

\* PPFV Metrics calculated on Active Sites with Recruitment only

Table 3a: Recruitment and Median Recruitment to Target (%)* by Sponsorship Type					
Commercial		Non-Commercial		Combined	
Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)	Recruited (INV) during 23-24	Median RT (%)*
0	0.00%	28	5.00%	28	5.00%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

Table 6b: Clinical Specialty Group Data by HSC Trust							
List of HSC Trusts***	Recruitment (INV) during 23-24	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Recruitment to Target (%)**	Median ALL PPFV* (days)	Proportion (%) < 30 days
BHSCT	3	10.71%	3	37.50%	0.00%	93.0	0.00%
NHSCT	11	39.29%	3	37.50%	5.00%	191.5	0.00%
SEHSCT	7	25.00%	1	12.50%		111.0	0.00%
SHSCT							
WHSCT	7	25.00%	1	12.50%		99.0	0.00%
<b>Totals:</b>	<b>28</b>	<b>100.00%</b>	<b>8</b>	<b>100.00%</b>	<b>0.00%</b>	<b>99.0</b>	<b>0.00%</b>

\* PPFV Metrics calculated on Active Sites with Recruitment only

\*\*Median RT Metrics calculated on Active Studies which have closed to recruitment

\*\*\*HSC Trust names highlighted in purple indicates which Trusts are active in the CSG portfolio

Table 3b: Recruitment and Median Recruitment to Target (%)* by Design Type					
Interventional		Observational		Combined	
Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*
28	0.00%	0	5.00%	28	5.00%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

# Neurodegenerative (NEU)

## Clinical Leads, Active PIs and CMG Members

<b>Neurodegenerative Group Clinical Leads</b> Bernadette McGuinness- BHSCT & QUB Peter Passmore – BHSCT & QUB (retired Jan 2024)	<b>CMG Members</b> <b>BHSCT &amp; QUB</b> – Bernadette McGuinness, Peter Passmore, Emma Cunningham, Joe Kane <b>BHSCT</b> – Maria McGrath <b>SEHSCT</b> - Jim Anderson <b>WHSCT</b> – Stephen Todd <b>QUB</b> – Carole Parsons
<b>Chief and Principal Investigators (CIs &amp; PIs)</b> Bernadette McGuinness BHSCT & QUB Peter Passmore BHSCT & QUB Emma Cunningham BHSCT & QUB Joseph Kane BHSCT & QUB	<b>PPI Representative</b> Gordon Kennedy

## Group Background/Summary

CMG did not meet 2023-24 as despite several attempts it proved impossible to agree a date when a quorum was available.

Professor Peter Passmore retired at the end of January 2024. Peter led on many clinical trials throughout his career and has co-led the NICRN Dementia group since its inception in 2008. Paula, Hazel and Elish were his faithful research nurses for many years, and he continues to inspire the research nurses that are currently involved in the network: Eileen, Patricia, Michael, Alison, Nicola. Peter has the remarkable ability to lead and collaborate effectively in everything he does. He led the Dementia CMG group with gusto, we will miss him and we wish him every best wish in his retirement.

During 2023/2024 there were five active studies within the Neurodegenerative group. The NICOLA-HCAP study completed recruitment with 1037 participant interviews and 862 informant interviews. Figures are lower for 2023-24 as 70% of the target of 1000 were recruited the previous year. The study therefore recruited to target and beyond. The Supportive Environments for Physical and Social Activity, Healthy Ageing and Cognitive Health (SPACE) study successfully recruited more than 400 participants following initial approach from the NICOLA-HCAP team.

The HCAP Clinical Validation Study is ongoing with 40 participants recruited from the Join Dementia Research platform with recruitment from Belfast Trust Memory Clinics ongoing;

with a plan to increase sample size to 120 to aid statistical power with continued input from the NICRN.

Three Lewy Body studies were active during 2023/2024, TopHat study recruiting three participants in the reporting period and is now closed to recruitment. Screening and recruitment for Neflamapimod in Patients with DLB commenced in March 2024.

Ongoing challenges with research governance approval in BHSCT have had a negative impact on activity related to NICRN. The HCAP clinical validation study took almost one year for approval to be gained and simple amendments took many months. We believe that as a result of approval challenges we are being approached by fewer pharmaceutical companies due to this reputational damage. Our group believe that when this situation is addressed and resolved we will again become an attractive site with which pharmaceutical companies can engage in order to deliver important clinical trials.

## Key Achievements

NICOLA-HCAP study completed: 1037 participant interviews and 862 informant interviews. HCAP Clinical Validation Study (CVS) ongoing.

- Two further Dementia with Lewy Bodies studies added to portfolio.
- Data from NICRN adopted studies was presented in 6 poster presentations at the Alzheimer's Association International Conference (AAIC) 2023.
- Funding received for commencement of NICOLA study Wave 3.
- Professor McGuinness accepted as member of NIHR Dementia Translational Research Network.
- Professor McGuinness member of UK Brain Health Clinic Coalition.

## Relevant Publications

The RESIST Study: Examining Cognitive Change in Rheumatoid Arthritis Patients with Mild Cognitive Impairment Being Treated with a TNF-Inhibitor Compared to a Conventional Synthetic Disease-Modifying Anti-Rheumatic Drug. Marr C, ... , **McGuinness B**, et al. *J Alzheimers Dis.* 2024;99(1):161-175. doi: 10.3233/JAD-231329. PMID: 38669538.

Northern Ireland Cohort for the Longitudinal Study of Ageing (NICOLA): health assessment protocol, participant profile and patterns of participation. Neville CE, ..., **McGuinness B** et al.. *BMC Public Health.* 2023 Mar 10;23(1):466. doi: 10.1186/s12889-023-15355-x. PMID: 36899371; PMCID: PMC9999338.

Investigating the prevalence of cognitive impairment and dementia in the Northern Ireland Cohort for the Longitudinal Study of Ageing (NICOLA): the Harmonised Cognitive Assessment

Protocol (HCAP) cross-sectional sub-study. O'Hara L, ..., **McGuinness, B**, et al. 2024 BMJ Open 2024;14:e075672. <https://doi.org/10.1136/bmjopen-2023-075672>

Muscle Strength, Excess Adiposity and Incident Cognitive Impairment in Older Northern Irish Men: Results from the PRIME-COG Study. Farsi, D..., **Passmore, P**,, ... **McGuinness, B**, et al. . Available at <http://dx.doi.org/10.2139/ssrn.4660405> (Under review).

## Awards/Good New Stories

- Professor Bernadette McGuinness and Dr Emma Cunningham appointed Principal Investigator and Clinical Lead of NICOLA study.
- The Lewy Body Society event 'A scarf for Lewy' held at the Waterfront Hall was attended by Dr Joe Kane and NICRN nurses Eileen Fox and Nicola Milligan.
- Dr Emily Bowman successfully defended her thesis, "*Investigating subphenotypes of delirium using existent research data*". Dr Bowman was supervised by Dr Emma Cunningham.
- Michael McAlinden awarded HSC R&D Pre-Doctoral Bridging Scheme award 2024.
- Michael McAlinden graduated MSc Dementia Studies (University of Stirling).
- Oral and Poster presentations on results from the NICOLA study, many of which have published abstracts, have been given at the following Conferences: - Alzheimer's Society International Conference (AAIC) 2023; British Society of Gerontology Annual Conference 2023; NICRN staff conference 2023; Irish Gerontological Society (IGS) 70<sup>th</sup> Annual and Scientific Meeting.
- We have also provided new support to the Belfast HSCT MND Research Service, funded via a small grant from the Motor Neurone Disease, MND, Association UK to Prof Karen Morrison, Dean of Education in Faculty MHLS Queen's University Belfast and Consultant Neurologist and lead of the NI Regional MND Clinic at BHSCT from Oct 2020 – March 2023. The grant provided funding for professional services support from the CRN to the BHSCT MND clinical team to upload clinical data for all those patients from 2015 onwards who had consented to have their clinical data recorded on the NI MND Database, and to then extract anonymised data from this database into a format to allow transfer to the UK National MND Patient Register. The patient data from 2015 to the present date has now been uploaded to the NI Register and extracted into an anonymised form ready for transfer to the UK National MND Register.



**Figure 8: (L-R) Mr Michael McAlinden, (Dementia Research Nurse BHSCT/QUB), Professor Peter Passmore (Professor of Ageing and Geriatric Medicine, CPH QUB/ Consultant Geriatrician, Belfast Trust), Dr Aoife Sweeney (Research Fellow, CPH QUB), Professor Bernadette McGuinness (Clinical Professor of Ageing, CPH QUB/ Consultant Geriatrician, Belfast Trust), Dr Emma Cunningham (Clinical Lecturer in Ageing, CPH QUB/ Geriatrician, Belfast Trust) and Dr Calum Marr (Research Assistant, CPH QUB ). Attending a conference.**

# Dashboard (Neurodegenerative - NEU)

Table 1: Studies and Sites Data	
No. of Active HSC Trusts	1
No. of Active Studies	5
No. of Recruitment Sites	5
No. of Sites with Recruitment (INY)	3
No. of New Studies during 23-24	3
No. of Studies closed during 23-24	1

Table 4: Portfolio Sponsorship, Randomisation and Design Mix for Active Studies During 23-24						
	Commercial	Non-Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	1	4	2	3	3	2
Proportion (%)	20.00%	80.00%	40.00%	60.00%	60.00%	40.00%

Table 2: Screening and Recruitment In Year and also Cumulative Totals for Active Studies During 23-24			
Screened (INY)* during 23-24	Recruited during (INY)* 23-24	Screened (TOT)** as at 31/03/2024	Recruited (TOT)** as at 31/03/2024
309	307	1,082	1,080

\* INY = Activity reported over reporting period (01/04/2023 - 31/03/2024)  
 \*\* TOT = Total activity reported up to and including 31/03/2024

Table 5: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days (%) *					
Commercial(0)		Non-Commercial(3)		Combined(3)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
		41.0	33.33%	41.0	33.33%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 3a: Recruitment and Median Recruitment to Target (%)* by Sponsorship Type					
Commercial		Non-Commercial		Combined	
Recruited (INY) during 23-24	Median RT (%)*	Recruited (INY) during 23-24	Median RT (%)*	Recruited (INY) during 23-24	Median RT (%)*
0		307	81.85%	307	81.85%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

Table 6a: Clinical Specialty Group Data by HSC Trust							
List of HSC Trusts***	Recruitment (INY) during 23-24	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Recruitment to Target (%)**	Median ALL FPFV* (days)	Proportion (%) < 30 days
BHSCT	307	100.00%	5	100.00%	81.85%	41.0	33.33%
NHSCT							
SEHSCT							
SHSCT							
WHSCT							
<b>Totals:</b>	<b>307</b>	<b>100.00%</b>	<b>5</b>	<b>100.00%</b>	<b>81.85%</b>	<b>41.0</b>	<b>33.33%</b>

\* FPFV Metrics calculated on Active Sites with Recruitment only

\*\*Median RT Metrics calculated on Active Studies which have closed to recruitment

\*\*\*HSC Trust names highlighted in purple indicates which Trusts are active in the CSG portfolio

Table 3b: Recruitment and Median Recruitment to Target (%)* by Design Type					
Interventional		Observational		Combined	
Recruited (INY) during 23-24	Median RT (%)*	Recruited (INY) during 23-24	Median RT (%)*	Recruited (INY) during 23-24	Median RT (%)*
3	60.00%	304	103.70%	307	81.85%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

# Orthopaedics and Trauma (ORT)

## Clinical Leads, Active PIs and CMG Members

<b>Orthopaedics &amp; Trauma Group Clinical Leads:</b> Owen Diamond - BHSCT Richard Napier - BHSCT	<b>CMG Members:</b> No CMG currently in place for Trauma and Orthopaedics.
<b>Chief and Principal Investigators (CIs &amp; PIs)</b> Owen Diamond - BHSCT Richard Napier - BHSCT Samuel Sloan - BHSCT Ciara Stevenson - BHSCT Brendan Gallagher – BHSCT Paul Magill - SHSCT Ravi Pagoti - BHSCT Ciara O'Donnell - BHSCT David Johnston - BHSCT	<b>Other T&amp;O Research Team Members:</b> David Beverland Janet Hill Roslyn Cassidy Nicola Gallagher Paul Karayiannis Sam McMahon Leeann Bryce Sharon Marks Emma Cunningham BHSCT & QUB
	<b>PPI Representatives:</b> Position Vacant

## Group Background/Summary

The Orthopaedic and Trauma (ORT) research group continues to grow and is delighted to welcome Consultants Mr Paul Karayiannis and Mr Sam McMahon back into the team after their time away on fellowship training. Paul brings an interest in Arthroplasty Research and Paediatric Trauma research and Sam is already building connections with the Oncology group and is working in collaboration with Orthopaedic Oncology on the SarcoSIGHT Study, into the management of Sarcoma.

Our group holds a unique position in that it is linked to the Trauma and Orthopaedic Research Charity (TORC), which works to promote research in Trauma and Orthopaedics across all Trusts in Northern Ireland. The group is supported with Dr Janet Hill, our Research Group Manager, Dr Nicola Gallagher who is a Post-Doc with an interest in Research methodology and Dr Roslyn Cassidy, a Post-Doc with an interest in Bio-Statistics. Leeann Bryce is our TORC Research Nurse and Sharron Marks is our NICRN Research Practitioner.

The ORT Research Group have a monthly Orthopaedic Research Committee meeting which is attended by research staff and key clinical staff. At the meeting, progress with current research studies is discussed along with the adoption/planning of future research studies.

Currently all clinical ORT trials are sponsored by other sites therefore PPI has been provided by the main site. The following studies are recruiting in ORT:

Orthopaedic Retrievals: PI Mr Napier, Opened to recruitment 01/06/2021, Recruited to date - 131

BASIS: PI Mr Sloan, Opened to recruitment 06/04/2022, Recruited to date – 23

Effect of strontium on mesenchymal stem cells from osteoporotic donors: PI Mr Diamond, Opened to recruitment 08/03/2022, Recruited to date - 30

Meteor2: PI Ms Stevenson, Opened to recruitment 07/03/2023, Recruited to date – 2

RAPSODI: PI Mr Gallagher, Opened to recruitment 23/03/2023, Recruited to date – 0

PERISCOPE: PI Mr Pagoti, Opened to recruitment 02/02/2024, Recruited to date – 0

The following studies have completed recruitment and are in follow up:

SCIENCE: PI Mr Napier, Opened to recruitment 10/09/2019, closed on Oct 2023 Recruited - 29

HUSH: PI Mr Diamond, Opened to recruitment 30/08/2022, closed on 17/11/2024 Recruited - 10

WHITE LIT: Dr O'Donnell & Dr Johnston, Opened to recruitment 1/09/2023, closed in Belfast on 14/06/2024 Recruited - 21

WHITE DUALITY: Mr Diamond, Opened to recruitment 1/07/2023, closed on 03/04/2024 Recruited - 28

The following studies are awaiting R&D approval from the BHSCT:

My Knee Plan: PI Mr Napier	G-FORCE: PI Mr Napier	SarcoSight: PI Mr McMahon
ODDSOCKS: PI Mr Napier	PICBONE: PI Mr Karayiannis	POLYFIX DCM: PI Mr Niall Eames

## Key Achievements

We now have multiple NICRN studies open across a variety of sub-specialist areas including soft tissue knee, spines, hip trauma, peri-operative delirium and revision arthroplasty.

Fruits of our first study in Orthopaedic Trauma with NIHR, the WAX study, will be published in the Lancet in June. The study examined the benefits of early weight bearing after ankle fracture surgery.

## Relevant Publications

1. Return to work and activity after rib-fixation for acute chest trauma: first application of a validated patient-reported outcomes assessment tool. Blythe A, **Cassidy R, Diamond O**,... et al. Eur J Cardiothorac Surg. 2024 Jun 3;65(6):ezae192. PMID: 38718222.
2. Reoperation risk of periprosthetic fracture after primary total hip arthroplasty using a collared

cementless or a taper-slip cemented stem.

Lynch Wong M, ..., **Bryce L, Cassidy R, ... Diamond O, Beverland D, et al.** Bone Joint J. 2024 Feb 1;106-B(2):144-150 PMID: 38425304.

3. Early surgery improves survival after femoral fractures in the elderly: A retrospective review of 502 fragility fractures. Gilmore C, ..., **Cassidy R, Diamond O, et al.** Injury. 2024 Feb;55(2):111275. PMID: 38134490.
4. Are Patients With Morbid Obesity at Increased Risk of Pulmonary Embolism or Proximal Deep Vein Thrombosis After Lower Limb Arthroplasty? A Large-database Study. Thompson R, **Cassidy R, Hill J, Bryce L, Napier R, Beverland D.** Clin Orthop Relat Res. 2024 Jan ;482(1):115-124. Epub 2023 Jul 4. PMID: 37404124.
5. The painful truth of waiting for hip and knee arthroplasty in Northern Ireland. **Karayiannis PN, ...Cassidy R, ..., Beverland D, et al.** Bone Joint J. 2023 Jul 1;105-B(7):783-794. PMID: 37399093.
6. Survivorship of 500 Cementless Total Knee Arthroplasties in Patients Under 55 Years of Age. Sheridan GA, **Cassidy RS, ..., Hill JC, Beverland DE, et al.** J Arthroplasty. 2023 May;38(5):820-823. Epub 2022 Oct 27. PMID: 36309144.
7. Is Cementless Total Knee Arthroplasty Safe in Women Over 75 Y of Age? Gibbons JP, **Cassidy RS, Bryce L, Napier RJ, ..., Beverland DE, et al.** J Arthroplasty. 2023 Apr;38(4):691-699. Epub 2022 Oct 19. PMID: 36272510.

## Awards/Good New Stories

Professor David Beverland gave the prestigious Charnley Lecture at the British Orthopaedic Association Annual Congress in Liverpool in September 2023. His presentation was entitled 'Failure is a Gift.'

An application for NIHR HTA funding has been submitted for the following study: Treatment of Toddlers Fractures: Observation Or Immobilisation (TOTs). The CI for this is Mr Nichola Nicolaou from Sheffield Children's NHS Foundation Trust and Mr Richard Napier is a co-investigator on the study. It has passed the first round of funding.

Ms Ciara Stevenson was awarded the prestigious American-British-Canadian (ABC) Travelling Fellowship in 2024. This fellowship is open to consultant orthopaedic surgeons and hasn't been awarded to someone in Northern Ireland for over 30 years so is a real accolade to N. Ireland orthopaedics. It is hoped this will enable Ciara to create long term potential partners in research with other orthopaedic centres.



Figure 9: Dr Ciara Stephenson awarded Prestigious Annual ABC Fellowship.

The British Hip Society Annual Meeting 2024 was held in Belfast in March for the first time in 21 years. Leading experts in hip surgery attended the meeting and several presentations from the local team were presented with Prof David Beverland presenting on how to enable a resource constrained NHS do more work.



**Figure 10: British Hip Society Meeting in Belfast.**

Due to the success of the SCIENCE and WAX studies, Professor Dan Perry and Professor Matt Costa (both consultant trauma and orthopaedic surgeons) have agreed to come to Belfast in October for a research seminar. This will be a great opportunity for the research team to learn from two successful researchers.

Belfast were the second best recruiting site for WHITE DUALITY and in the top 5 for WHITE LIT. The SCIENCE Study finished recruitment with Belfast being the top recruiting site, HUSH also closed to recruitment with Belfast in the top 10 recruiting sites. Belfast is currently still recruiting for the BASIS study and is the 4th best recruiting site and the METEOR2 study (2nd best recruiting site). Well done to research nurse Leeann Bryce, NICRN research coordinator Sharon Marks and the rest of the T&O research team who helped make recruitment a success for these studies.

# Dashboard (Orthopaedics and Trauma -ORT)

Table 1: Studies and Sites Data	
No. of Active HSC Trusts	2
No. of Active Studies	10
No. of Recruitment Sites	11
No. of Sites with Recruitment (INV)	9
No. of New Studies during 23-24	1
No. of Studies closed during 23-24	1

Table 4: Portfolio Sponsorship, Randomisation and Design Mix for Active Studies During 23-24						
	Commercial	Non-Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	0	10	8	2	7	3
Proportion (%)	0.00%	100.00%	80.00%	20.00%	70.00%	30.00%

Table 2: Screening and Recruitment In Year and also Cumulative Totals for Active Studies During 23-24			
Screened (INV)* during 23-24	Recruited during (INV)* 23-24	Screened (TOT)** as at 31/03/2024	Recruited (TOT)** as at 31/03/2024
567	98	875	265

\* INV = Activity reported over reporting period (01/04/2023 - 31/03/2024)  
 \*\* TOT = Total activity reported up to and including 31/03/2024

Table 5: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days (%) *					
Commercial(0)		Non-Commercial(9)		Combined(9)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
		30.0	55.56%	30.0	55.56%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 3a: Recruitment and Median Recruitment to Target (%)* by Sponsorship Type					
Commercial		Non-Commercial		Combined	
Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*
0		98	83.33%	98	83.33%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

Table 6b: Clinical Specialty Group Data by HSC Trust							
List of HSC Trusts***	Recruitment (INV) during 23-24	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Recruitment to Target (%)**	Median ALL FPFV* (days)	Proportion (%) < 30 days
BHSCT	90	91.84%	10	90.91%	83.33%	41.5	50.00%
NHSCT							
SEHSCT							
SHSCT	8	8.16%	1	9.09%		10.0	100.00%
WHSCT							
<b>Totals:</b>	<b>98</b>	<b>100.00%</b>	<b>11</b>	<b>100.00%</b>	<b>83.33%</b>	<b>30.0</b>	<b>55.56%</b>

\* FPFV Metrics calculated on Active Sites with Recruitment only

\*\*Median RT Metrics calculated on Active Studies which have closed to recruitment

\*\*\*HSC Trust names highlighted in purple indicates which Trusts are active in the CSG portfolio

Table 3b: Recruitment and Median Recruitment to Target (%)* by Design Type					
Interventional		Observational		Combined	
Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*
73	83.33%	25		98	83.33%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

## Primary Care (PCR)

### Clinical Leads, Active PIs and CMG Members

<p><b>Primary Care Group Clinical Leads</b></p> <p>Nigel Hart - QUB / BHSCT Claire Leathem - BHSCT</p> <p><b>Chief and Principal Investigators</b></p> <p>Nigel Hart - QUB &amp; BHSCT Ian Young - QUB &amp; BHSCT &amp; Department of Health (DOH) Simon Hutchinson -Ballygomartin Group Practice Gerry Burns -Duncairn Medical Practice Laura McQuillan – QUB</p> <p><b>Associate P.I.</b></p> <p>Dan Butler – General Practice Academic Research Training Scheme (GPARTS), QUB, Northern Ireland Medical and Dental Training Agency (NIMDTA)</p>	<p><b>CMG Members</b></p> <p><b>BHSCT &amp; QUB</b> - Gerry McKenna (Dentistry) <b>HSCB</b> - Emma Quinn (Pharmacy) <b>QUB</b> - Paul Best (Social Work) <b>UU:</b> Bernie Reid (Nursing), Jackie Gracey (Allied Health Professional(AHP) )</p> <p><b>PPI Representatives</b></p> <p>Position Vacant</p>
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### Group Background/Summary

Primary care had 6 active studies in the 2023-24 period, 2 closed in this reporting year. The current open portfolio consists of 1 commercial study and 5 non commercial.

Primary Care screened 95 and recruited 92 patients in 2023-24.

Studies currently on Primary Care portfolio are :

Pioneer Real (BHST, NHSCT): A Non-interventional Type-2 Diabetes Study . A multi-centre, prospective, non-interventional single-arm study investigating clinical parameters associated with the use of once-daily oral semaglutide in a real-world adult population with type 2 diabetes in the United Kingdom.Reflect (BHSCT, NHSCT, SEHSCT, SHSCT, WHSCT): A

Randomised controlled trial to Evaluate the effectiveness and cost benefit of prescribing high dose Fluoride toothpaste in preventing and treating dental Caries in high-risk older adults. The study is examining the prevention of tooth decay in adults aged 50 + using prescription-only, high dose fluoride toothpaste.

Poly Prime (NHSCT, SEHSCT, SHSCT, WHSCT): An external pilot cluster randomised controlled trial of a theory-based intervention to improve appropriate polypharmacy in older people in primary care. This pilot study aims to assess the feasibility of the PolyPrime intervention in primary care in Northern Ireland (NI) and the Republic of Ireland (ROI).

PRINCIPLE (BHSCT, NHSCT, SEHSCT, SHSCT, WHSCT): Platform Randomised trial of treatments in the Community for epidemic and Pandemic illnesses. This is an open, adaptive, platform trial to evaluate treatments suitable for use in the community for treating COVID-like-illness that might help people recover sooner and prevent hospitalisation. Walk with me two (BHSCT, SEHSCT, WHSCT): Effectiveness and cost-effectiveness of a peer-led walking programme to increase physical activity in inactive older adults. This study will examine the effectiveness and cost-effectiveness of the Walk with Me peer-led walking programme which aims to increase moderate-to-vigorous physical activity in adults aged 60 years+ living in socio-economically disadvantaged communities.

MY Diabetes and Me (BHSCT, NHSCT, SEHSCT, SHSCT, WHSCT): The clinical and cost-effectiveness of the DESMOND-ID education programme for adults with Intellectual disability and Type 2 Diabetes.

## Key Achievements

During the 2023-24 reporting period the NICRN-PC have made significant progress in developing an innovative and exciting collaboration between the NICRN PC group and the Eastern Federation Support Unit. This will facilitate and improve the recruitment of patients and GP practices involved in Primary Care Research throughout Northern Ireland.

Following on from the successful recruitment to the initial arm of the UK-Wide PANORAMIC trial, the team continued their involvement through the Paxlovid arm of the study. The NICRN-PC were the top recruiting site in the UK in May 2023.

In June 2023, Dr Laura McQuillan presented at the CHITIN (Cross-border Healthcare Intervention Trials in Ireland Network) Celebration Event on the MyCOMRADE+ Trial. The work of the NICRN-PC in the Polyprime and ACP studies was also highlighted at this event.

The decades of invaluable hard work by Research Nurses Claire Leathem, Marina Maxwell and Maeve Nesbitt were recognised upon their retirements during this period.

## Relevant Publications

Randomized controlled trial of molnupiravir SARS-CoV-2 viral and antibody response in at-risk adult outpatients. Standing, J. F, et al., ... **PANORAMIC Virology Group (NI was part of the Investigator group)** (2024). . *Nature Communications*, 15, Article 1652. <https://doi.org/10.1038/s41467-024-45641-0>

Platform adaptive trial of novel antivirals for early treatment of COVID-19 In the community (PANORAMIC): protocol for a randomised, controlled, open-label, adaptive platform trial of community novel antiviral treatment of COVID-19 in people at increased risk of more severe disease. Gbinigie, O., et al. (2023). **(NI was part of the Investigator group)** . *BMJ Open*, 13(8), Article e069176. <https://doi.org/10.1136/bmjopen-2022-069176>

## Awards/Good New Stories

NI Panoramic Hub (Primary Care) Top Recruiting Site in UK for May 2023.

Primary Care Co lead and Research Nurse, Mrs Claire Leathem retires after 40 years of Nursing, and Primary Care research nurses Marina and Maeve Nesbit.



**Figure 11: NICRN Coordination team and Primary Care team. Celebrate Primary Care and Co-Lead and Research Nurse Claire Leathem’s retirement.**

# Dashboard (Primary Care – PCR)

Table 1: Studies and Sites Data	
No. of Active HSC Trusts	5
No. of Active Studies	6
No. of Recruitment Sites	48
No. of Sites with Recruitment (INV)	46
No. of New Studies during 23-24	0
No. of Studies closed during 23-24	2

Table 4: Portfolio Sponsorship, Randomisation and Design Mix for Active Studies During 23-24						
	Commercial	Non-Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	1	5	5	1	5	1
Proportion (%)	16.67%	0.00%	83.33%	16.67%	83.33%	16.67%

Table 2: Screening and Recruitment In Year and also Cumulative Totals for Active Studies During 23-24			
Screened (INV*) during 23-24	Recruited during (INV*) 23-24	Screened (TOT)** as at 31/03/2024	Recruited (TOT)** as at 31/03/2024
95	92	581	578

\* INV = Activity reported over reporting period (01/04/2023 - 31/03/2024)

\*\* TOT = Total activity reported up to and including 31/03/2024

Table 5: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days (%) *					
Commercial(1)		Non-Commercial(45)		Combined(46)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
0.0	100.00%	9.0	62.22%	8.5	63.04%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 3a: Recruitment and Median Recruitment to Target (%) * by Sponsorship Type					
Commercial		Non-Commercial		Combined	
Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*
0	100.00%	92	100.00%	92	100.00%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

Table 6b: Clinical Specialty Group Data by HSC Trust							
List of HSC Trusts***	Recruitment (INV) during 23-24	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Recruitment to Target (%)**	Median ALL FPFV* (days)	Proportion (%) < 30 days
BHSCT	1	1.09%	5	10.42%	100.00%	138.5	50.00%
NHSCT	19	20.65%	15	31.25%	100.00%	19.0	66.67%
SEHSCT	28	30.43%	10	20.83%	100.00%	3.5	70.00%
SHSCT	0	0.00%	6	12.50%	100.00%	4.5	66.67%
WHSCT	44	47.83%	12	25.00%	100.00%	24.0	54.55%
<b>Totals:</b>	<b>92</b>	<b>100.00%</b>	<b>48</b>	<b>100.00%</b>	<b>100.00%</b>	<b>8.5</b>	<b>63.04%</b>

\* FPFV Metrics calculated on Active Sites with Recruitment only

\*\* Median RT Metrics calculated on Active Studies which have closed to recruitment

\*\*\* HSC Trust names highlighted in purple indicates which Trusts are active in the CSG portfolio

Table 3b: Recruitment and Median Recruitment to Target (%) * by Design Type					
Interventional		Observational		Combined	
Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*
92	100.00%	0	100.00%	92	100.00%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

## Renal (REN)

### Clinical Leads, Active PIs and CMG Members

<b>Renal Group Clinical Leads</b> Neal Morgan -SHSCT &QUB Christopher Hill -BHSCT &QUB  <b>Chief and Principal Investigators (CIs &amp; PIs)</b> Christopher Hill - BHSCT Stephanie Bolton -NHSCT Alastair Woodman – SEHSCT Neal Morgan – SHSCT Frank McCarroll - WHSCT	<b>CMG Members</b> <b>BHSCT</b> – Christopher Hill <b>NHSCT</b> - Stephanie Bolton <b>SEHSCT</b> - Alastair Woodman <b>SHSCT</b> - Neal Morgan <b>WHSCT</b> - Frank McCarroll  <b>PPI Representatives</b> No fixed input but involvement of patient groups (NI Kidney Research Fund and NI Kidney Patient Association) as needed
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### Group Background/Summary

Renal CMG met formally on 31<sup>st</sup> May 2023. Unfortunately there was no autumn meeting. We were actively involved in 15 studies during the 2023-24 year and adopted 4 new studies on to the network portfolio:

- APPARENT – a trial of an oral complement inhibitor, Iptacopan, in patients with membranoproliferative glomerulonephritis.
- ACORN – an investigator-led study exploring the effects on caregivers of looking after patients with advanced chronic kidney disease.
- Prepare for Kidney Care – a first of its kind NIHR-funded randomized controlled trial coordinated by the University of Bristol comparing preparation for dialysis versus preparation for conservative care Duration UTI - This is a multicentre, open label, multi-arm, randomised study with the primary aim of finding the shortest duration of effective antibiotic treatment for urinary tract infection (UTI) in women. The study aims to recruit 2,248 women presenting to primary or secondary care with a UTI. Our Renal Network team in the South-Eastern Trust is supporting the secondary care arm which seeks to recruit women with suspected kidney infection (pyelonephritis), the most severe form of UTI. Participants are randomised to one of six groups comparing durations of antibiotic treatment ranging from 4 to 14 days.

## Key Achievements

The Renal Portfolio remains broad and inclusive, recruiting patients with varied renal diseases and treatment modalities.

- Recruitment to the ACHIEVE trial across three Trusts. This trial is investigating the impact of spironolactone on cardiac outcomes in regular dialysis patients.
- Recruited to target was achieved for the ACCESs trial and the Belfast team were regularly cited as top monthly recruiters across the UK.
- Further publications from the EMPA-KIDNEY trial (see below) with ongoing post-trial follow up of patients.
- Adoption and recruitment was achieved for the following studies – ACORN, FRAIL-KT, NIGHTLife, Prepare for Kidney Care and MOODMAPS.
- Ongoing recruitment to national registry studies including UKIVAS (BHSCT opened as a recruiting site during 2023), UK Calciphylaxis Study and RaDaR (rare renal diseases registry) across Northern Ireland.
- Completion of post-trial follow-up for the NeflgArd trial (see publication list below).
- Selection of NI sites to participate in the forthcoming EASi-KIDNEY trial which is investigating the impact of a novel aldosterone synthase inhibitor on heart and kidney outcomes in patients with chronic kidney disease.

## Relevant Publications

Studies in which Investigators or NI based Centres are listed in the publications:

### *NeflgArd*

Results from part A of the multi-centre, double-blind, randomised, placebo-controlled NeflgArd trial, which evaluated targeted-release formulation of budesonide for the treatment of primary immunoglobulin A nephropathy. Barratt J et al. (**NeflgArd Trial Investigators (Renal team were part of the Investigators team)**). *Kidney Int* 2023;103:391-402.

Efficacy and safety of a targeted-release formulation of budesonide in patients with primary IgA nephropathy (NeflgArd): 2 year results from a randomised phase 3 trial. Yonghua Zou et al. (**Renal team were part of the Investigators team**). *Lancet* 2023;402:859-870.

### *EMPA-KIDNEY*

Impact of primary kidney disease on the effects of empagliflozin in patients with chronic kidney disease: secondary analyses of the EMPA-KIDNEY trial. EMPA-Kidney Collaborative Group (**Collaborator: Morgan N**) *Lancet Diabetes & Endocrinology* 2024;12:51-60.

Effects of empagliflozin on progression of chronic kidney disease: a pre specified secondary analysis from the EMPA-KIDNEY trial. EMPA-KIDNEY Collaborative Group(**Collaborator: Morgan N**). *Lancet Diabetes & Endocrinology* 2024;12:39-50.

### *FRAIL-KT*

Latest advances in frailty in kidney transplantation: a narrative review. Fergie R, Maxwell AP, Cunningham EL. *Transplantation Reviews* 2024;38 (2). doi: 10.1016/j.trre.2024.100833. Epub 2024 Jan 24. PMID: 38309184.

## Awards/Good New Stories

### *ACCess trial (Anaesthesia Choice for Creation of Arteriovenous Fistulae)*

Our Belfast trial team were consistently amongst the highest recruiting teams on a monthly basis and were recognised by the Trial Sponsor on a number of occasions for this.

### *NightLife trial*

Clinical Research Network team in Daisy Hill Hospital (SHSCT) were the first hospital in NI to take part in the NightLife study which aims to find out if Night-time dialysis improves quality of life in patients with end stage kidney disease. The NIHR funded study is led by Chief Investigator Professor James Burton (Professor of Nephrology Leicester University) and co-ordinated via the Leicester CTU.

The team at Daisy Hill got off to an impressive start, setting a new randomisation record for the study randomising 13 patients on their first day.



**Figure 12: Renal patient William Abraham is pictured with Renal team members Carolyn Hutchinson (NICRN Renal Research Nurse), Fiona Owens (Lead Nurse for Nephrology), Judi Graham (Consultant Nephrologist and Co-PI), Teresa Mc Kinley (NICRN Research Nurse) and Neal Morgan (Consultant Nephrologist and co-lead NICRN Renal Network).**

# Dashboard (Renal – REN)

Table 1: Studies and Sites Data	
No. of Active HSC Trusts	5
No. of Active Studies	15
No. of Recruitment Sites	36
No. of Sites with Recruitment (INV)	33
No. of New Studies during 23-24	4
No. of Studies closed during 23-24	3

Table 4: Portfolio Sponsorship, Randomisation and Design Mix for Active Studies During 23-24						
	Commercial	Non-Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	3	12	7	8	8	7
Proportion (%)	20.00%	80.00%	46.67%	53.33%	53.33%	46.67%

Table 2: Screening and Recruitment In Year and also Cumulative Totals for Active Studies During 23-24			
Screened (INV*) during 23-24	Recruited during (INV*) 23-24	Screened (TOT)** as at 31/03/2024	Recruited (TOT)** as at 31/03/2024
266	169	1,393	683

\* INV = Activity reported over reporting period (01/04/2023 - 31/03/2024)  
 \*\* TOT = Total activity reported up to and including 31/03/2024

Table 5: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days (%) *					
Commercial(4)		Non-Commercial(29)		Combined(33)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
158.5	0.00%	98.0	31.03%	98.0	27.27%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 3a: Recruitment and Median Recruitment to Target (%)* by Sponsorship Type					
Commercial		Non-Commercial		Combined	
Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)	Recruited (INV) during 23-24	Median RT (%)*
0	52.38%	169	75.00%	169	71.43%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

Table 6b: Clinical Specialty Group Data by HSC Trust							
List of HSC Trusts***	Recruitment (INV) during 23-24	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Recruitment to Target (%)**	Median ALL FPFV* (days)	Proportion (%) < 30 days
BHSCT	107	63.31%	8	22.22%	78.13%	93.0	14.29%
NHSCT	11	6.51%	7	19.44%	40.63%	248.0	33.33%
SEHSCT	11	6.51%	7	19.44%	75.00%	31.0	50.00%
SHSCT	30	17.75%	9	25.00%	78.13%	225.0	22.22%
WHSCT	10	5.92%	5	13.89%	30.00%	98.0	20.00%
<b>Totals:</b>	<b>169</b>	<b>100.00%</b>	<b>36</b>	<b>100.00%</b>	<b>71.43%</b>	<b>98.0</b>	<b>27.27%</b>

\* FPFV Metrics calculated on Active Sites with Recruitment only

\*\*Median RT Metrics calculated on Active Studies which have closed to recruitment

\*\*\*HSC Trust names highlighted in purple indicates which Trusts are active in the CSG portfolio

Table 3b: Recruitment and Median Recruitment to Target (%)* by Design Type					
Interventional		Observational		Combined	
Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*
33	78.13%	136	65.00%	169	71.43%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

# Respiratory Health(RES)

## Clinical Leads, Active PIs and CMG Members

<p><b>Respiratory Health Group Clinical Leads</b></p> <p>Judy Bradley – BHSCT &amp; QUB</p> <p>Lorcan McGarvey – BHSCT &amp; QUB</p> <p><b>Chief and Principal Investigators</b></p> <p>Liam Heaney – BHSCT &amp; QUB</p> <p>Damien Downey – BHSCT &amp; QUB</p> <p>Jane McDowell – BHSCT &amp; QUB</p> <p>John Lindsay - BHSCT</p> <p>Steven Caskey - BHSCT</p> <p>Nicholas Magee – BHSCT</p> <p>David McCracken - BHSCT</p> <p>Alastair Reid - BHSCT</p> <p>Julie Richardson - BHSCT</p> <p>Paul Minnis – NHSCT</p> <p>Jennifer Elder – SEHSCT</p> <p>Frederick McElwaine - SEHSCT</p> <p>Rory Convery - SHSCT</p> <p>Martin Kelly - WHSCT</p> <p>Nazia Chaudhuri – WHSCT/UU</p>	<p><b>CMG Members</b></p> <p><b>BHSCT</b> – Judy Bradley, Lorcan McGarvey, Liam Heaney, Damian Downey, John Lindsay, Claire Butler, Steven Caskey, Alastair Reid, Joe Kidney, Dermot Linden, Nicholas Magee, Julie Richardson, Brenda O’Neill</p> <p><b>NHSCT</b> – Paul Minnis</p> <p><b>SEHSCT</b> – Jennifer Elder, Frederick McElwaine</p> <p><b>SHSCT</b> – Rory Convery, Conor Hagan</p> <p><b>WHSCT</b> – Martin Kelly, Nazia Chaudhuri</p> <p><b>PPI Representatives</b></p> <p>Position Vacant</p>
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## Group Background/Summary

### Studies opened during the 2023/24 reporting period:

GREAT-2 – A phase 2 trial of Gremubamab compared to placebo in participants with bronchiectasis and chronic Pseudomonas aeruginosa infection (BHSCT).

DUPIAZA – An observational, retrospective multicentre medical record review to describe the post-authorisation early clinical experience of dupilumab in the treatment of adult severe asthma (BHSCT).

RXC007/0002 – Phase 2a study to assess the safety, Pharmacokinetics, Pharmacodynamics and Clinical Activity of Ascending Doses of RXC007 in Patients with Idiopathic Pulmonary Fibrosis (BHSCT, WHSCT).

POS-ARI-ER – Perpetual Observational Study of Acute Respiratory Infections presenting via Emergency Rooms and Other Acute Hospital Care Settings (SHSCT).

CLEAR – A 2x2 factorial randomised open label trial to determine the clinical and cost-effectiveness of hypertonic saline (HTS 6%) and carbocysteine for airway clearance versus usual care over 52 weeks in bronchiectasis (SEHSCT (PIC Site)).

FIBRONEER - A double blind, randomized, placebo-controlled trial evaluating the efficacy and safety of BI 1015550 over 52 weeks in patients with Progressive Fibrosing Interstitial Lung Disease (WHSCT).

CSL-312 – A Randomized, Double-blind, Placebo-controlled, Study to Investigate the Safety, Pharmacokinetics, and Pharmacodynamics of CSL312 in Subjects with Idiopathic Pulmonary Fibrosis (WHSCT).

CORAL – A Randomized, Double-Blind, Placebo-Controlled, Parallel, 4-Arm Dose Ranging Study of the Safety and Efficacy of NAL ER Tablets for the Treatment of Cough in Idiopathic Pulmonary Fibrosis (WHSCT).

#### **Studies closed during the 2023/24 reporting period:**

BEAT-SA – Beyond Allergic Th2 Severe Asthma (BHSCT).

DUPIAZA – An observational, retrospective multicentre medical record review to describe the post-authorisation early clinical experience of dupilumab in the treatment of adult severe asthma (BHSCT).

#### **Studies currently in setup:**

3TR-ABC – Biomarkers and mechanisms of asthma remission following treatment with dupilumab/mepolizumab/tezepelumab in adults with severe asthma (BHSCT).

ARRIVAL – Phase IIIb Study to Assess the Potential for Tezepelumab-treated Patients with Severe Asthma to Reduce Background Therapy While Sustaining Asthma Control and Clinical Remission (BHSCT).

RASPER – Randomised trial of Suction for Primary Pneumothorax Early Resolution (BHSCT).

REIMAGINE – A prospective, real-world, interventional study to evaluate the effect of mepolizumab on achieving clinical remission in participants with severe asthma (BHSCT).

TB-DILI – Reintroduction of anti-tuberculosis therapy following drug-induced liver injury (BHSCT).

AWAKE PRONE – Awake prone positioning in patients with acute hypoxaemic respiratory failure not due to COVID-19 (SHSCT).

BEACON-IPF – A randomized, double-blind, dose-ranging, placebo-controlled study to evaluate the efficacy and safety of PLN-74809 (bexotegrast) for the treatment of idiopathic pulmonary fibrosis (WHSCT). Overall, 165 patients recruited across NI to a wide range of complex, early phase interventional trials as well as observational studies; covering both adults and child health services.

## Key Achievements

- BHSCT (Liam Heaney, CI) will be lead site for two incoming commercial studies – ARRIVAL and REIMAGINE.

## Relevant Publications

Cohort profile: post-hospitalisation COVID-19 (PHOSP-COVID) study. Omer Elneima ..., **Liam G. Heaney, L. McGarvey**, et al. PHOSP-COVID Study Collaborative Group. Feb 2024, In: International Journal of Epidemiology. 53, 1, 17 p.

Consensus goals and standards for specialist cough clinics: the NEUROCOUGH international Delphi study. Woo-Jung Song ..., **Lorcan P. McGarvey, et al.** 20 Nov 2023, In: ERJ Open Research. 9, 6, 13 p., 00618.

Higher dose corticosteroids in patients admitted to hospital with COVID-19 who are hypoxic but not requiring ventilatory support (RECOVERY): a randomised, controlled, open-label, platform trial. Abdullah, A., ...**Downey, D., Linden, D., McGarvey, L.** et al., 06 May 2023, In: The Lancet. 401, 10387, p. 1499-1507 9 p.

Long COVID research: an update from the PHOSP-COVID Scientific Summit. Evans, R. A., ...**Heaney, L. G., McGarvey, L.** et al, 01 Nov 2023, In: The Lancet Respiratory Medicine. 11, 11, p. e93-e94 2 p.

Reduction of daily maintenance inhaled corticosteroids in patients with severe eosinophilic asthma treated with benralizumab (SHAMAL): a randomised, multicentre, open-label, phase 4 study. Jackson, D. J., **Heaney, L. G.**,... et al.. & SHAMAL Investigators, 20 Jan 2024, In: The Lancet. 403, 10423, p. 271-281.

Use of digital measurement of medication adherence and lung function to guide the management of uncontrolled asthma (INCA Sun): a multicentre, single-blinded, randomised clinical trial. Hale, E. M., ...**Convery, R., Heaney, L.G.**,et al.. INCA Research Team, Jul 2023, In: The Lancet. Respiratory medicine. 11, 7, p. 591-601.

Improvement in lung clearance index and chest computed tomography scores with elexacaftor/tezacaftor/ivacaftor treatment in people with cystic fibrosis aged 12 years and older – The RECOVER Trial. McNally P, ..., **Downey D**, et al. RECOVER Study Group 01 Nov 2023, In: American Journal of Respiratory and Critical Care Medicine. 208, 9, p. 917-929 13 p.

Early COPD Network (BEACON) Cohort Investigators. Structural Predictors of Lung Function Decline in Young Smokers with Normal Spirometry. Ritchie AI, ..., **McGarvey L**, et al.; Am J Respir Crit Care Med. 2024 May 15;209(10):1208-1218. doi: 10.1164/rccm.202307-1203OC.

## Awards/Good New Stories

BHSCT highest recruiting site for NEUROCOUGH, out of 13 sites, exceeding the original target of 100 to finish with 150 recruited patients.

BHSCT recruited the first and last patient for the CLEAR trial, finishing as the highest recruiter out of 22 UK sites – target of 25, 67 recruited.

Esther Ramsay and Michelle Spence from the BHSCT Respiratory Team presented a session on at a Post-Grad Respiratory Specialist Nurse seminar held in Queens University Belfast.

WHSCT Respiratory Research Team recognised for being third highest recruiting site for IPF-COMFORT out of 37 recruiting sites worldwide.



**Figure 13: Pictured (L-R): Respiratory Research team outside of the Regional Respiratory Centre in Belfast. Ms Abitha Nair, Ms Esther Ramsey and Ms Fionnuala White.**

# Dashboard (Respiratory Health- RES)

Table 1: Studies and Sites Data	
No. of Active HSC Trusts	4
No. of Active Studies	22
No. of Recruitment Sites	30
No. of Sites with Recruitment (INV)	25
No. of New Studies during 23-24	9
No. of Studies closed during 23-24	4

Table 4: Portfolio Sponsorship, Randomisation and Design Mix for Active Studies During 23-24						
	Commercial	Non-Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	8	14	12	10	14	8
Proportion (%)	36.36%	63.64%	54.55%	45.45%	63.64%	36.36%

Table 5: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days (%) *					
Commercial(7)		Non-Commercial(18)		Combined(25)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
89.0	28.57%	34.0	44.44%	38.0	40.00%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 2: Screening and Recruitment in Year and also Cumulative Totals for Active Studies During 23-24			
Screened (INV*) during 23-24	Recruited during (INV*) 23-24	Screened (TOT)** as at 31/03/2024	Recruited (TOT)** as at 31/03/2024
990	165	4,911	848

\* INV = Activity reported over reporting period (01/04/2023 - 31/03/2024)

\*\* TOT = Total activity reported up to and including 31/03/2024

Table 6b: Clinical Specialty Group Data by HSC Trust							
List of HSC Trusts***	Recruitment (INV) during 23-24	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Recruitment to Target (%)**	Median ALL FPFV* (days)	Proportion (%) < 30 days
BHSCT	92	55.76%	15	50.00%	64.00%	21.0	58.33%
NHSCT	7	4.24%	4	13.33%	0.00%	123.0	0.00%
SEHSCT							
SHSCT	54	32.73%	3	10.00%	126.67%	19.0	66.67%
WHSCT	12	7.27%	8	26.67%	100.00%	89.0	14.29%
<b>Totals:</b>	<b>165</b>	<b>100.00%</b>	<b>30</b>	<b>100.00%</b>	<b>69.00%</b>	<b>38.0</b>	<b>40.00%</b>

\* FPFV Metrics calculated on Active Sites with Recruitment only

\*\*Median RT Metrics calculated on Active Studies which have closed to recruitment

\*\*\*HSC Trust names highlighted in purple indicates which Trusts are active in the CSG portfolio

Table 3a: Recruitment and Median Recruitment to Target (%)* by Sponsorship Type					
Commercial		Non-Commercial		Combined	
Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*
26	75.00%	139	69.00%	165	69.00%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

Table 3b: Recruitment and Median Recruitment to Target (%)* by Design Type					
Interventional		Observational		Combined	
Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*
39	50.00%	126	87.06%	165	69.00%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

# Stroke (STR)

## Clinical Leads, Active PIs and CMG Members

<b>Stroke Group Clinical Leads</b> Jim McIlmoyle - BHSCT Carolee McLaughlin - BHSCT  <b>Principal Investigators (CIs &amp; PIs)</b> Cathy Patterson BHSCT Ivan Wiggam BHSCT Particia Gordon BHSCT Paul Burns BHSCT Carolee McLaughlin – BHSCT Jim McIlmoyle - BHSCT Djamil Vahidassr -NHSCT Murudappa Bhattad - NHSCT Mark Bowman – SEHSCT Michael McCormick -SHSCT Breffni Keegan - WHSCT Roisin Healy -WHSCT	<b>CMG Members:</b> <b>BHSCT</b> –Jim McIlmoyle, Carolee McLaughlin <b>NHSCT</b> – Djamil Vahidassr, Murudappa Bhattad <b>SEHSCT</b> – Mark Bowman <b>SHSCT</b> – Michael McCormick <b>WHSCT</b> - Roisin Healy, Breffni Keegan  <b>Northern Ireland Stroke Improvement Network</b> - Fiona Quigg  <b>PPI Representatives</b> Position Vacant (PPI engagement is currently under review)
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## Group Background/Summary

The Stroke speciality group continued to have good levels of research activity within the 5 Trusts. Regular CMG meetings were held quarterly which were well attended by representatives of the 5 Trusts (BHSCT, NHSCT, WHSCT, SEHSCT, SHSCT). During the course of 2023-24 we supported 10 active studies and 1 new study adopted and opened. Of 134 patients screened 72 were recruited to studies in year.

### Studies Opened during the 2023-2024 reporting period:

- CHAT Phase 3 adopted 03/07/2023 opened 01/11/2023.
- Maps opened new sites NHSCT 26/04/2023, SHSCT 30/08/2023.

### Studies Closed during the 2023-2024 reporting period:

- CONVINCENCE – colchicine for prevention of Vascular Inflammation in non-cardio-embolic stroke.
- TEMPO-2 – tenecteplase versus standard of care for minor ischaemic stroke with proven occlusion.

- ATTEST 2 alteplase – tenecteplase trial evaluation for stroke thrombolysis.
- OPTIMAS – optimal timing of anticoagulation after stroke.

#### Studies Currently Open:

- MAPS-2 – metoclopramide for avoiding pneumonia after stroke.
- TICH-3 – tranexamic acid for hyperacute spontaneous intracerebral haemorrhage.
- ESCAPE-MeVO (closed Jun2024) – endovascular treatment to improve outcomes for medium vessel occlusions.
- WATCHMANTM – assessment of the WATCHMAN device in patients unsuitable for oral anticoagulation.
- CHAT Phase 3 - Can technology optimise a Speech and language therapy service to meet the NICE guidelines for people with aphasia following a stroke in Northern Ireland?
- ENRICH AF – anticoagulation in patient with cerebral amyloid angiopathy.

#### Studies in set-up during the 2023-2024 reporting period:

- LACI-3 - the effects of isosorbide mononitrate (ISMN) and/or cilostazol to prevent long term adverse outcomes after lacunar stroke and progression cerebral small vessel disease (SVD).
- PhEAST - To assess whether Pharyngeal Electrical Stimulation (PES) is safe and effective at improving post-stroke dysphagia (PSD).

## Key Achievements

- The ESCAPE-MeVO thrombectomy trial has reached its final target and is closed to recruitment in Jun 2024. 7 patients from a total of 350 participants were recruited in Royal Victoria Hospital. The trial analysis and publication is eagerly awaited to help guide management in patients with M2 / M3 cerebral occlusions.
- SHSCT recruited OPTIMAS' 3500<sup>th</sup> participant.
- SHSCT were the 7<sup>th</sup> highest recruiter in the UK to CONVINCCE (study closed Dec2023).

## Relevant Publications

### TEMPO-2

Tenecteplase versus standard of care for minor ischaemic stroke with proven occlusion (TEMPO-2): a randomised, open label, phase 3 superiority trial. Shelagh CB, ... **Wiggam IM, et al.** [www.thelancet.com](http://www.thelancet.com) Published online May 17, 2024. Doi: 10.1016/S0140-6736(24)00921-8 3.

## Awards/Good New Stories

The MAPS-2 trial are introducing lanyard eligibility cards after SHSCT suggested that they would be helpful at our SIV. SHSCT were acknowledged in the studies newsletter.

NI Clinical Research Network Stroke Research Team recruit the 600th Patient to the MAPS-2 Clinical Trial in SEHSCT. Our SEHSCT Stroke Research team based at the Ulster Hospital have recruited their 10<sup>th</sup> patient to the MAPS-2 Trial: Metoclopramide for Avoiding Pneumonia after Stroke (a single-blind, randomised controlled trial of metoclopramide for the prevention of pneumonia in patients with dysphagia after an acute stroke.) The research team's latest recruit brings the study total recruitment to 600 patients.



Figure 14: Stroke Research Team at Ulster Hospital, SEHSCT. MAPS 2 trial.

# Dashboard (Stroke - STR)

Table 1: Studies and Sites Data	
No. of Active HSC Trusts	5
No. of Active Studies	10
No. of Recruitment Sites	26
No. of Sites with Recruitment (INV)	20
No. of New Studies during 23-24	1
No. of Studies closed during 23-24	4

Table 4: Portfolio Sponsorship, Randomisation and Design Mix for Active Studies During 23-24						
	Commercial	Non-Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	1	9	10	0	9	1
Proportion (%)	10.00%	90.00%	100.00%	0.00%	90.00%	10.00%

Table 5: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days (%) *					
Commercial(3)		Non-Commercial(17)		Combined(20)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
24.0	66.67%	121.0	17.65%	96.5	25.00%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 2: Screening and Recruitment In Year and also Cumulative Totals for Active Studies During 23-24			
Screened (INV)* during 23-24	Recruited during (INV)* 23-24	Screened (TOT)** as at 31/03/2024	Recruited (TOT)** as at 31/03/2024
134	72	764	213

\* INV = Activity reported over reporting period (01/04/2023 - 31/03/2024)  
 \*\* TOT = Total activity reported up to and including 31/03/2024

Table 6b: Clinical Specialty Group Data by HSC Trust							
List of HSC Trusts***	Recruitment (INV) during 23-24	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Recruitment to Target (%)**	Median ALL FPFV* (days)	Proportion (%) < 30 days
BHSCT	31	43.06%	9	34.62%	66.67%	58.5	25.00%
NHSCT	11	15.28%	4	15.38%	60.83%	144.5	25.00%
SEHSCT	11	15.28%	1	3.85%		14.0	100.00%
SHSCT	13	18.06%	5	19.23%	83.33%	190.5	25.00%
WHSCT	6	8.33%	7	26.92%	42.00%	356.0	0.00%
<b>Totals:</b>	<b>72</b>	<b>100.00%</b>	<b>26</b>	<b>100.00%</b>	<b>70.83%</b>	<b>96.5</b>	<b>25.00%</b>

\* FPFV Metrics calculated on Active Sites with Recruitment only

\*\*Median RtT Metrics calculated on Active Studies which have closed to recruitment

\*\*\*HSC Trust names highlighted in purple indicates which Trusts are active in the CSG portfolio

Table 3a: Recruitment and Median Recruitment to Target (%)* by Sponsorship Type					
Commercial		Non-Commercial		Combined	
Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*
25	83.33%	47	58.14%	72	70.83%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

Table 3b: Recruitment and Median Recruitment to Target (%)* by Design Type					
Interventional		Observational		Combined	
Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*
47	58.14%	25	83.33%	72	70.83%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

# Vision (VIS)

## Clinical Leads, Active PIs and CMG Members

<p><b>Vision Group Clinical Leads</b></p> <p>Jonathan Jackson -BHSCT Julie Silvestri - BHSCT &amp; QUB</p> <p><b>Chief and Principal Investigators (CIs &amp; PIs)</b></p> <p>Augusto Azuara-Blanco – BHSCT &amp; QUB Colin Willoughby – BHSCT, WHSCT &amp; UU Jonathan Jackson – BHSCT Julie Silvestri – BHSCT &amp; QUB Katheryn Saunders - UU Michael Williams – BHSCT &amp; QUB Noemi Lois – BHSCT &amp; QUB Padraig Mulholland - UU Roger Anderson – UU Ruth Hogg – QUB Tanya Moutray – BHSCT Tunde Peto – BHSCT &amp; QUB Karen Gillvray – BHSCT</p>	<p><b>CMG Members:</b></p> <p><b>BHSCT</b> - Jonathan Jackson, Karen Gillvray</p> <p><b>BHSCT &amp; QUB</b> - Augusto Azuara-Blanco, Julie Silvestri, Michael Williams, Noemi Lois, Tunde Peto</p> <p><b>UU</b> - Padraig Mulholland, Roger Anderson</p> <p><b>PPI Representatives:</b> (Position Vacant)</p>
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## Group Background/Summary

The Vision CMG met in June and November 2023 with further meeting planned for early summer 2024.

Vision’s 2023-24 portfolio consisted of 20 studies, including 5 new studies, which were opened in year. Of studies currently open 9 were commercial and 11 non commercial.

Our median FPFV metric for our combined studies was 41 days, with 35% of studies recruiting first patients within 30 days of opening. Vision screened 427 patients in 2023-24 recruiting 206, exceeding our target in the majority of studies. The REVAMP study has been running at both BHSCT and Coleraine (UU) sites, whereas the vast majority of our portfolio studies run in the BHSCT which is the region’s hub.

The Vision teams skill set includes NICRN Clinical Research Nurses, NICRN Senior Imagers, NICRN Optometrists, Sub-Investigators in addition to our CI/PIs.

In the latter half of the year the team invested considerable time preparing for an MHRA inspection for our TIGER trial.

## Key Achievements

Comino and Balaton 2, sister commercial studies that VISION participated in, completed their Primary Analysis and we received good feedback:

*Feedback from UK CSM and CSS:*

*“Please see confirmation that the Primary Analysis snapshot is now complete. I would just like to reiterate Alana's sentiment and thank you all again for your hard work, diligence and commitment in helping achieve this”*

*Feedback from the Global lead Alana:*

*“There are no amount of words that I can offer to all of you and your teams that truly represent how proud I am of this community, of the challenges we have all had to overcome over the past 2+ years and of the dedication and collaboration that this group has demonstrated- it is truly unlike any other and I thank each and every one of you for your commitment and hard work to get to where we are today!*

Dr Karen Gillvray has been appointed as the National SAS [Specialty & Associate Specialist] Doctor rep on the Academic and Research Sub Committee of the Royal College of Ophthalmologists (RCO). As part of SAS week, the RCO interviewed Karen about SAS doctors in Research. Click here for the vlog: <https://www.rcophth.ac.uk/our-work/ophthalmology-careers/resources-for-sas-doctors/>

Dr Karen Gillvray also had an article published in Eye News in January 2023 and is speaking at the RCO's National Congress meeting in Birmingham about her involvement in research, all to try and showcase SAS doctors in varied roles, and to encourage more to come forward and get involved in research.

## Relevant Publications

Detailed analysis of an enriched deep intronic ABCA4 variant in Irish Stargardt disease patients. Whelan L, ...,**Silvestri G**, et al . Sci Rep. 2023 Jun 9;13(1):9380. doi: 10.1038/s41598-023-35889.

Usher Syndrome on the Island of Ireland: A Genotype-Phenotype Review.

Stephenson KAJ, ...,**Silvestri G**, et al. Invest Ophthalmol Vis Sci. 2023 Jul 3;64(10):23. doi: 10.1167/iovs.64.10.23.PMID: 37466950 .

Athletes Perspectives of The Classification System in Alpine Skiing for Those with A Visual Impairment. Douglas S,..., **Jackson J**, et al. (2023). European Association for Sport Management Conference: Forward Thinking in Sport Management: Inclusivity, Accessibility, and Sustainability. (In Press)

Visual performance measures using a virtual reality headset to assess vision-related daily tasks in those with severely reduced vision. **Hogg RE, McConnell E, ...Jackson J**, et al. (2023) Investigative Ophthalmology & Visual Science 64 (8), 2843-2843.

What impact does reduced optotype presentation time have on VA measurements for those with Visual Impairment? Douglas S, ...**Jackson J**, et al. (2023) Investigative Ophthalmology & Visual Science 64(8), 5047-5047 .

Certification of Visual Impairment due to Diabetic Eye Disease in Northern Ireland from 2014 to 2019. Cushley LN, **Peto T**, ...,**Moutray T, Jackson AJ**, et al. (2023) Journal of Visual Impairment and Blindness 117(2)183-188.

Prevalence and phenotype associations of complement factor I mutations in geographic atrophy. Adnan H. Khan ..., **T Peto** et al. DOI: 10.1002/humu.24242 / .

Face-down positioning or posturing after pars plana vitrectomy for macula-involving rhegmatogenous retinal detachments Fung, T. H., ... **Lois, N.**, et al. T., 15 Mar 2024, In: Cochrane Database of Systematic Reviews. 2024, 3, 46 p., CD015514.

Retinal vascular regeneration. Pathak, V., ..., **Lois, N.**, et al., 09 Mar 2024, *Retinal and choroidal vascular diseases of the eye*. Chhablani, J. (ed.). Academic Press, p. 581-588.

Design and conduct of randomized clinical trials evaluating surgical innovations in ophthalmology: a systematic review. **Azuara-Blanco, A.**, ..., **Lois, N.**, et al., Apr 2023, In: American Journal of Ophthalmology. 248, p. 164-175 12 p.

Diabetic macular edema and diode subthreshold micropulse laser: A randomized double-masked noninferiority clinical trial. **Lois, N.**, ..., **Azuara-Blanco, A.**, et al. 2023, In: Ophthalmology. 130, 1, p. 14-27 14 p.

Fenofibrate for diabetic retinopathy. Kataoka, S. Y., **Lois, N.**, ... et al. 13 Jun 2023, In: Cochrane Database of Systematic Reviews. 2023, 6, CD013318.

Retinal ischaemia in diabetic retinopathy: understanding and overcoming a therapeutic challenge: understanding and overcoming a therapeutic challenge. Mohite, A. A., ... , **Lois, N.**, et al. 21 Mar 2023, In: Journal of Clinical Medicine. 12, 6, 2406.

Scleral buckle, vitrectomy, or combined surgery for inferior break retinal detachment: systematic review and meta-analysis Bonnar, J., ..., **Lois, N.**, et al. & IRB-RRD Study group, Oct 2023, In: Ophthalmology Retina. 7, 10, p. 837-847 11 p.

Structural and metabolic retinal changes associated with mild cognitive impairment in type 2 diabetes. Pedersen, F. N., ...**Lois, N.**, et al. 19 Sept 2023, (Early online date) In: Diabetes.

Subthreshold micropulse laser versus standard laser for the treatment of central-involving diabetic macular oedema with central retinal thickness of <400µ: a cost-effectiveness analysis from the DIAMONDS trial. Mistry, H., ... **Lois, N.** et al & **DIAMONDS Study Group**, 18 Oct 2023, In: BMJ Open. 13, 10, 7 p., e067684.

## Awards/Good New Stories

Research Project on adult patients living with Inherited Retinal Degenerations

August 2022 | Vol. 4 Rare disease policy newsletter. Page 3. Belfast Trust Ophthalmology Consultants and Medical Genetics colleagues (Silvestri, BHSC Vision team) <https://executive.nhs.wales/functions/networks-and-planning/rare-diseases/rare-disease-forum-newsletters/rd-newsletters/august-2022-newsletter/>. Trust research team have been able to identify about 80% + of individuals with Inherited Retinal Degenerations in Northern Ireland, genotyping 50% of these individuals and been able to provide NHS accredited confirmation to around 125 patients.

In the report: “Top ten Performing Commercially Sponsored Trials Over the past 3 Years”, on the performance NICRN’s top ten, the Vision group were listed with 4 vision studies out of 10 commercial studies and with an excellent First visit and RtT DATA.

iTRAC: Last year we successfully delivered iTRAC (NIHR-HTA funded, led by Aberdeen). Study completed and closed.

ACE: we are recruiting very well in the ACE study (NIHR-HTA funded). Belfast is the top recruiter, out of 20 sites. We are very grateful to NICRN for allowing us to over recruit. We estimate we will finish recruitment in August 2024.

TAGS: NIHR has funded a 10-year extension.

Professor Jackson FCOptom DipTp(IP)m, NICRN Director and Head of Optometry was awarded a Life Fellowship for his contribution to the Ophthalmic profession.

Professor Giuliana Silvestri Clinical Director for Ophthalmic Services and Vision research Clinical Lead, was awarded CBE for services to Ophthalmology and Eyecare in Northern Ireland.



**Figure 15: NICRN Vision Co-Lead Professor Julie Silvestri awarded CBE for services to Ophthalmology in NI. Dr Cathy Jack, Professor Julie Silvestri, Professor Usha Chakravarthy and Professor Jonathan Jackson here congratulate Professor Silvestri.**

NI Author Fredrick Gilbert Watson helps us to better understand our local history through his writing. Thanks to the TIGER study, a Vision related clinical trial, both clinical research and our local history were brought into focus and Mr Watson was able to complete his book.



**Figure 16: NICRN Vision Optometrists, Drs Lesley Doyle and Emma McConnell and Vision study patient and author Mr Fredrick G Watson.**

# Dashboard (Vision - VIS)

Table 1: Studies and Sites Data	
No. of Active HSC Trusts	1
No. of Active Studies	20
No. of Recruitment Sites	21
No. of Sites with Recruitment (INV)	20
No. of New Studies during 23-24	4
No. of Studies closed during 23-24	10

Table 4: Portfolio Sponsorship, Randomisation and Design Mix for Active Studies During 23-24						
	Commercial	Non-Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	9	11	4	16	9	11
Proportion (%)	45.00%	55.00%	20.00%	80.00%	45.00%	55.00%

Table 2: Screening and Recruitment In Year and also Cumulative Totals for Active Studies During 23-24			
Screened (INV)* during 23-24	Recruited during (INV)* 23-24	Screened (TOT)** as at 31/03/2024	Recruited (TOT)** as at 31/03/2024
429	206	2,662	424

\* INV = Activity reported over reporting period (01/04/2023 - 31/03/2024)  
 \*\* TOT = Total activity reported up to and including 31/03/2024

Table 5: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days (%) *					
Commercial(8)		Non-Commercial(12)		Combined(20)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
38.0	50.00%	41.5	25.00%	41.5	35.00%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 3a: Recruitment and Median Recruitment to Target (%)* by Sponsorship Type					
Commercial		Non-Commercial		Combined	
Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*
28	100.00%	178	123.81%	206	100.00%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

Table 6b: Clinical Specialty Group Data by HSC Trust							
List of HSC Trusts***	Recruitment (INV) during 23-24	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Recruitment to Target (%)**	Median ALL FPFV* (days)	Proportion (%) < 30 days
BHSCT	206	100.00%	21	100.00%	100.00%	41.5	35.00%
NHSCT							
SEHSCT							
SHSCT							
WHSCT							
<b>Totals:</b>	<b>206</b>	<b>100.00%</b>	<b>21</b>	<b>100.00%</b>	<b>100.00%</b>	<b>41.5</b>	<b>35.00%</b>

\* FPFV Metrics calculated on Active Sites with Recruitment only

\*\*Median RT Metrics calculated on Active Studies which have closed to recruitment

\*\*\*HSC Trust names highlighted in purple indicates which Trusts are active in the CSG portfolio

Table 3b: Recruitment and Median Recruitment to Target (%)* by Design Type					
Interventional		Observational		Combined	
Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*
18	100.00%	188	100.00%	206	100.00%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

# COVID Delivery Team (CDT)

## Clinical Leads, Active PIs and CMG Members

<b>COVID Delivery Team Group Clinical Leads</b> Judy Bradley (QUB) (resigned from post Dec 2022) Peter McGuigan (BHSCT)(resigned from post Dec 2022) <b>Chief and Principal Investigators</b> Simon Hutchinson (Ballygomartin Group Practice) Gerry Burns (Duncairn Medical Practice) Peter McGuigan (BHSCT) Dr Damian Downey (BHSCT) Joe Kidney (BHSCT) Paul Johnston (NHSCT) Paul Minnis (NHSCT) Chris Murray (SEHSCT) Jennifer Elder (SEHSCT) Rory Convery (SHSCT) Adrian Donnelly (WHSCT) Martin Kelly (WHSCT) Jon Silverside (QUB) Danny McAuley (QUB)	<b>CMG Members:</b> <b>BHSCT &amp; QUB</b> Peter McGuigan <b>QUB</b> Judy Bradley <b>NICRN</b> Paul Biagioni, Sonia McKenna, Shane Jackson  <b>PPI Representatives:</b> (Position Vacant)
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## Group Background/Summary

The establishment of a dedicated COVID-19 Delivery Team (CDT) was an output of the Northern Ireland Clinical Research Recovery, Resilience and Growth (NICRRRG) management board back in November 2021. They agreed to fund a regional dedicated team of Clinical Research nurses/AHPs and admin support to enable the delivery of nationally prioritised research studies under the banner of Urgent Public Health (UPH), whilst allowing the core network teams of CRNs/AHP to refocus their energies towards re-establishing the non-COVID portfolio.

Within Northern Ireland this team was led by Professor Judy Bradley and Dr Peter McGuigan and was made up of 9.5 Band 6 posts and a 0.5 Band 4 administrative post. Regionally the

posts were deployed across the HSC environment in the following manner: five Band 6 CRN posts, 0.5 WTE Band 6 Clinical trials pharmacist post and 0.5 WTE Band 4 admin support post in BHSCT and one Band 6 CRN posts in each of the other four HSC Trusts.

Recruitment and selection processes for these posts took longer than expected due partly to the limited, temporary nature of the posts i.e. only 18 month of secure funding. This impacted on the process by reducing the available pool of interested candidates and lengthened the process so that all posts were not filled until May 2022. However by this time the national and global urgency of COVID-19 was waning with falling infection rates and significantly reduced threat from the condition. With the much reduced activity the leads for this group were able to step down as of December 2022 and we thank them for their support throughout this period.

As part of the original agreement to fund the CDT, the NICRRRG management board had agreed that if there was a substantial reduction in COVID-19 clinical research and this new team becomes no longer needed, a reconfiguration of their roles will be agreed between the NICRN and the Management Board for the NICRRRG fund in order to maximise the contribution to recovery, resilience and growth.

The CDT therefore were redirected to support the remaining active and open COVID-19 studies and to support the specialities where indicated. This meant the CDT essentially were absorbed into the respiratory and critical care teams which were the most impacted.

## Our Experience

The network experienced a slow steady decline in COVID-19 numbers over the first 2 quarters of 2023/24. This resulted in the CDT gradually waning as other more permanent posts became available across the HSC research infrastructures. This reduced the team numbers and by the last quarter in 2023/24 we had a much reduced workforce of only 2 x 1.0 WTEs, available mainly sitting in our respiratory and critical care specialities.

This much reduced workforce has maintained a low but constant state of recruitment to the open COVID-19 studies on our portfolio. Regionally over this reporting window the NICRN CDT has maintained activity across 6 open COVID-19 studies namely, GenOMICC, RECOVERY, REMAP CAP, HEAL COVID, ICASARS and PANORAMIC. In total 1561 potential participants were screened by the CDT at over 23 actively recruiting sites across NI HSC and actively recruited 80 participants into these open studies.

Our median recruitment to target (RtT) is calculated on closed studies and the only study and site which actively closed recruitment was the HEAL COVID study within the South Eastern HSCT, due to the reduction in their CDT team as explained above. This therefore retained a relatively low RtT of 10%. However we would highlight that to achieve this the team did have to screen over 160 potential participants to get 2 consented.

No new studies were opened during the reporting period other than a new arm of REMAP CAP at our SEHSCT site. The site had a median first patient first visit (FPFV) window of 5.5 days from receiving site green light status. We would also commend the SEHSCT team in achieving the highest regional recruitment rate over the reporting period with 25 participants recruited ahead of NHSCT, BHSCT, SHSCT and WHSCT in that order.

# Dashboard (Covid Delivery Team – CDT)

Table 1: Studies and Sites Data	
No. of Active HSC Trusts	5
No. of Active Studies	6
No. of Recruitment Sites	23
No. of Sites with Recruitment (INV)	22
No. of New Studies during 23-24	0
No. of Studies closed during 23-24	2

Table 4: Portfolio Sponsorship, Randomisation and Design Mix for Active Studies During 23-24						
	Commercial	Non-Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	0	6	5	1	5	1
Proportion (%)	0.00%	100.00%	83.33%	16.67%	83.33%	16.67%

Table 2: Screening and Recruitment In Year and also Cumulative Totals for Active Studies During 23-24			
Screened (INV)* during 23-24	Recruited during (INV)* 23-24	Screened (TOT)** as at 31/03/2024	Recruited (TOT)** as at 31/03/2024
1,566	80	9,245	2,370

\* INV = Activity reported over reporting period (01/04/2023 - 31/03/2024)  
 \*\* TOT = Total activity reported up to and including 31/03/2024

Table 5: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days (%) *					
Commercial(0)		Non-Commercial(22)		Combined(22)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
		5.5	90.91%	5.5	90.91%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 3a: Recruitment and Median Recruitment to Target (%)* by Sponsorship Type					
Commercial		Non-Commercial		Combined	
Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)	Recruited (INV) during 23-24	Median RT (%)*
0	0.00%	80	100.00%	80	100.00%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

Table 6b: Clinical Specialty Group Data by HSC Trust							
List of HSC Trusts***	Recruitment (INV) during 23-24	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Recruitment to Target (%)**	Median ALL FPFV* (days)	Proportion (%) < 30 days
BHSCT	17	21.25%	8	34.78%	107.50%	4.0	100.00%
NHSCT	20	25.00%	4	17.39%	10.00%	5.5	75.00%
SEHSCT	25	31.25%	4	17.39%	72.00%	14.0	75.00%
SHSCT	13	16.25%	3	13.04%	155.00%	1.0	100.00%
WHSCT	5	6.25%	4	17.39%	0.00%	7.0	100.00%
<b>Totals:</b>	<b>80</b>	<b>100.00%</b>	<b>23</b>	<b>100.00%</b>	<b>100.00%</b>	<b>5.5</b>	<b>33.33%</b>

\* FPFV Metrics calculated on Active Sites with Recruitment only

\*\*Median RT Metrics calculated on Active Studies which have closed to recruitment

\*\*\*HSC Trust names highlighted in purple indicates which Trusts are active in the CSG portfolio

Table 3b: Recruitment and Median Recruitment to Target (%)* by Design Type					
Interventional		Observational		Combined	
Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*
43	100.00%	37		80	100.00%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

# NICTN: CANCER

## Clinical Leads, Active PIs and CMG Members

### **Leads & Active PIs**

NICTN Clinical Director: Stuart McIntosh

NICTN Operational Director: Melanie Morris

### **NICTN Executive Committee:**

NICTN Clinical Director (Co-Chair)	Stuart McIntosh
NICTN Operational Director (Co-Chair)	Melanie Morris
Clinical Oncology Lead	Joe O’Sullivan
Haematology Oncology Lead	Oonagh Sheehy
Experimental Cancer Medicine Centre Lead	Victoria Coyle
CRUK Senior Research Nurse	Ruth Boyd
NICTN Manager/Lead Nurse	Eileen Dillon
PPI representative	Aidan McCormick

### **BELFAST EXPERIMENTAL CANCER CENTER STEERING GROUP**

ECMC Clinical Lead:	Vicky Coyle
ECMC Deputy Clinical Lead:	Stuart McIntosh
ECMC Scientific Lead:	Dan Longley
ECMC Deputy Scientific Lead	Kiernan Savage
ECMC Business Lead:	Melanie Morris
ECMC CRUK Senior Research Nurse:	Ruth Boyd
ECMC PPI Rep:	Tim Kerr

The NI Cancer Research Consumer Forum (NICRCF) supports NICTN and Belfast ECMC by providing PPI input at numerous levels, including review of patient information for all new studies being considered for adoption. Membership has increased significantly this year with over 60 PPI representatives now registered with NICRCF.

## Active PIs in 2023-24

<b>PI Name</b>	<b>Job Title</b>	<b>Trust</b>	<b>Affiliation</b>	<b>Area</b>
Stuart McIntosh	Consultant Surgeon	BHSCT	QUB	Breast
Jane Hurwitz	Consultant Oncologist	BHSCT	N/A	Breast
Rhun Evans	Consultant Oncologist	BHSCT	N/A	Breast
Rosalie Douglas	Consultant Oncologist	BHSCT	N/A	Breast
Gareth Irwin	Consultant Surgeon	BHSCT	N/A	Breast
Alison Clayton	Consultant Oncologist	BHSCT	N/A	Breast
Nora Scally	Consultant Oncologist	SHSCT	N/A	Breast
Audrey Fenton	Consultant Oncologist	SHSCT	N/A	Breast
Helen Mathers	Consultant Surgeon	SHSCT	N/A	Breast
Brendan McFall	Consultant Surgeon	NHSCT	N/A	Breast
Stephen Kirk	Consultant Surgeon	SEHSCT	N/A	Breast
Janne Bingham	Consultant Surgeon	WHST	N/A	Breast
Goudarz Mazdai	Consultant Oncologist	WHST	N/A	Breast
Paul Farry	Consultant Surgeon	WHST	N/A	Breast
Hossam Abdulkhakek	Consultant Oncologist	WHST	N/A	Breast
Conor O'Neill	Consultant Oncologist	WHST	N/A	Breast/Upper GI
Nazreen Aziz	Sp Registrar	WHST	N/A	Breast
Michael Harron	Consultant Oncologist	WHST	N/A	Breast
Brendan Skelly	Consultant	WHST	N/A	Breast
Linda McLaughlin	Consultant Oncologist	WHST	N/A	Breast
Vicky Coyle	Professor in Oncology	BHSCT	QUB	Early Phase
Catherine Davidson	Consultant Oncologist	BHSCT	N/A	Early Phase
Suneil Jain	Professor in Oncology	BHSCT	QUB	GU
Joe O'Sullivan	Professor in Oncology	BHSCT	QUB	GU
Darren Mitchell	Consultant Oncologist	BHSCT	N/A	GU
Aiden Cole	Consultant Oncologist	BHSCT	QUB	GU
Jacqui Harney	Consultant Oncologist	SHSCT	N/A	GU
Darren Brady	Consultant Oncologist	WHST	N/A	GU/Lower GI
Conor McGarry	Radiotherapy Physicist	BHSCT	N/A	GU/Radiotherapy
Ian Hardy	Consultant Surgeon	BHSCT	N/A	Gynae
Joanne Millar	Consultant Oncologist	BHSCT	N/A	Gynae
Anne Drake	Consultant Oncologist	BHSCT	N/A	Gynae
Mark McComiskey	Consultant Oncologist	BHSCT	N/A	Gynae
Oonagh Sheehy	Consultant Haematologist	BHSCT	N/A	Haem

Mary Frances McMullin	Professor of Haematology	BHSCT	QUB	Haem
Claire Arnold	Consultant Haematologist	BHSCT	N/A	Haem
David Donaldson	Consultant Haematologist	BHSCT	N/A	Haem
Nick Cunningham	Consultant Haematologist	BHSCT	N/A	Haem
Sarah Lawless	Consultant Haematologist	BHSCT	N/A	Haem
Damian Finnegan	Consultant Haematologist	BHSCT	N/A	Haem
Christina Bradford	Consultant Haematologist	SHSCT	N/A	Haem
Allister Foy	Consultant Haematologist	SHSCT	N/A	Haem
Bridgin Merron	Consultant Haematologist	NHSCT	N/A	Haem
Suzanne McPherson	Consultant Haematologist	NHSCT	N/A	Haem
Aaron Niblock	Consultant Haematologist	NHSCT	N/A	Haem
Feargal McNicholl	Consultant Haematologist	WHSCT	N/A	Haem
Patrick Elder	Consultant Haematologist	WHSCT	N/A	Haem
Moulod El-Agnaf	Consultant Haematologist	SEHSCT	N/A	Haem
Keith Rooney	Consultant Oncologist	BHSCT	N/A	Head & Neck
Kirsty Taylor	Consultant Oncologist	BHSCT	N/A	Head & Neck
Richard Park	Consultant Oncologist	BHSCT	N/A	Lower GI
Grant Caddy	Consultant Gastroenterologist	SEHSCT	N/A	Lower GI
Jonathan McAleese	Consultant Oncologist	BHSCT	N/A	Lung
Lynn Campbell	Consultant Oncologist	BHSCT	N/A	Lung
David Johnston	Specialist Registrar	BHSCT	N/A	Lung
Judith Carser	Consultant Oncologist	BHSCT	N/A	Melanoma
Bode Oladipo	Consultant Oncologist	BHSCT	N/A	Melanoma
Bethany Mitchell	Consultant Haematologist	BHSCT	N/A	Paediatric
Anthony McCarthy	Consultant Paediatric Oncologist	BHSCT	N/A	Paediatric
Robert Johnston	Consultant Paediatric Oncologist	BHSCT	N/A	Paediatric
Christine Macartney	Consultant Paediatric Haematologist	BHSCT	N/A	Paediatric
Heather McCarty	Consultant Oncologist	BHSCT	N/A	Paediatric
Patricia O'Hare	Consultant Paediatric Oncologist	BHSCT	N/A	Paediatric
Amy Ritchie	Consultant in Palliative Medicine	NHSCT	N/A	Palliative Care
Caroline Forde	Consultant Medical Oncologist	BHSCT	N/A	Renal
Paul Henry	Consultant Oncologist	BHSCT	N/A	Thyroid
Martin Eatock	Consultant Oncologist	BHSCT	N/A	Upper GI
Richard Turkington	Consultant Oncologist	BHSCT	QUB	Upper GI
Claire Harrison	Consultant Oncologist	BHSCT	N/A	Upper GI
David Vass	Consultant Surgeon	BHSCT	N/A	Upper GI

## Group Background/Summary

In 2023-24, the NICTN offered a portfolio of 71 cancer clinical trials and research studies to both adult and paediatric cancer patients. Regionally, 589 participants were recruited to the available trials portfolio. 70% of trials (50) were interventional in design and accounted for 28% of overall recruitment (167). Although the overall NICTN portfolio is predominantly non-commercial in nature, commercial trial activity continues to expand, with 24% of active trials (17) sponsored by industry partners.

During the past year, 29 new cancer trials were considered for adoption following review by the multi-professional NI Cancer Clinical Trials Coordinating Committee. The trials presented spanned a number of different disease sites, with almost a quarter of new studies (7) being brought forward by the Early Phase Clinical Study Group. Other areas such as urology, haematology and gastroenterology were also well represented, with each group proposing between 5-6 new clinical trials. Twenty-six of the trials presented were interventional in nature, with 16 being commercially sponsored. Of the studies considered for adoption, 23 studies subsequently progressed through set-up.

NICTN Clinical Study Groups (CSGs) continued to meet throughout the year to oversee portfolio performance with the exception of the Lung and UGI/HPB CSGs. Due to changes in committee constitution and responsible chair, these CSGs were temporarily suspended. Reinstatement of these CSGs, alongside the introduction of additional CSGs for disease sites currently not supported (e.g. Gynae and GU) is planned for the incoming year.

## Key Achievements

- With the development of cancer vaccines being a highly publicised and exciting development in the battle against cancer, NICTN has been delighted to introduce a number of cancer vaccine studies onto their portfolio:
  - **IMCODE003:** This Roche sponsored study will evaluate auto gene cevumeran, an RNA-based cancer vaccine, in combination with atezolizumab and mFOLFIRINOX as adjuvant therapy in patients with resected pancreatic cancer. Dr Martin Eatock will assume the role of UK Chief Investigator for this study, which is scheduled to open in Belfast late 2024.
  - **AHEAD-MERIT:** Dr Kirsty Taylor is aiming to open NICTN's first BioNtech trial in autumn 2024. This trial will investigate the RNA vaccine BNT113 in combination with pembrolizumab for patients with a form of head and neck cancer.
  - **ModiFY** trial (Scancell Ltd) aims to evaluate the use of a DNA cancer vaccine in a variety of solid tumours (Dr Vicky Coyle).
- Over the past year, NICTN has continued to support investigator-led clinical trials. This '*born in Belfast, led by Belfast*' approach has seen a number of studies move from concept to execution. Two studies of note that are due to open later in 2024 are:
  - **CV6-168** (Prof V Coyle), an exciting 'first in human study' that will see a drug, the dUTPase inhibitor CV6-168 developed by a local spin-in company, CV-6 Therapeutics (NI) Ltd, be tested for safety, tolerability, pharmacokinetics and anti-tumour activity in patients with advanced malignancies.

- **ASTFOX** (Prof V Coyle) is another example of Belfast led science translating in to a clinical trial. This phase I study will assess the IAP antagonist, ASTX660 (Tolinapant), in combination with standard of care FOLFOX chemotherapy in metastatic colorectal cancer.
- NICTN has received commendation for their performance across many studies. Some examples are as follows:
  - **SABRE** (Prof S Jain - prostate) – top UK recruiting site and second top recruiting site across Europe.
  - **SMALL** (Prof S McIntosh – breast) - top UK recruiting site.
  - **MOSAICC** (Prof MF McMullin – haematology) - top UK recruiting site.
  - **PROTECTOR** (Mr I Harley – gynae) – special recognition for contribution to recruitment .
  - **STAMPEDE** (Prof J O’Sullivan) – trophy awarded for being in the top 20 UK recruiters to this practice changing trial.
- NICTN supported by NICRCF continued to champion cancer clinical trials at many events attended by MLAs, researchers, clinicians, industry, charities, PHA/DOH and the public. Examples of such events included a Cancer Research Stormont ‘drop-in’ event (Oct 23) and attendance at ‘Agreement 25’ where a session on ‘Cancer Knows No Borders’ looked at how the Good Friday Agreement helped the island of Ireland deliver international impact in cancer research and care (April 23).



Figure 17: Left, Hilary Benn, the (then) Shadow Secretary of State for NI, with NICTN and NICRF members at a Stormont Cancer Research Event, October 2023. Figure 18: Above, Dr Melanie Morris, NICTN Operational Director discusses cancer clinical trials with MLA, Paula Bradshaw.

- In September 2023, NICTN and NICRCF hosted a very successful public event in celebration of the 10-year anniversary of the NICRCF.(Figure 19: Pictured right)
- The NICRCF was awarded support from Macmillan to commission an arts project to celebrate World Cancer Day. Forum members, researchers, nurses, clinicians, and other health professionals shared their experience of what cancer meant to each of them. Their stories and emotions helped develop '**Silver Linings**' a short contemporary dance performed at the launch of the Cancer: Through our Eyes exhibition at the MAC in Feb 2024.(Figure 20)



Figure 19



Figure 20: Professional dancers and the 'Sing for Life' Choir performed 'Silver Linings'.

## Relevant Publications

Meaningful Symptomatic Change in Patients with Myelofibrosis from the SIMPLIFY Studies. Stacie Hudgens, ..., **Mary Frances McMullin, et al**: Value Health 2024 May; 27(5):607-613 Epub 2024 Feb 2. PMID: 38311180.

Fludarabine, Cytarabine, Granulocyte Colony-Stimulating Factor, and Idarubicin With Gemtuzumab Ozogamicin Improves Event-Free Survival in Younger Patients With Newly Diagnosed AML and Overall Survival in Patients With *NPM1* and *FLT3* Mutations. Russell NH, ..., **Arnold C**, et al. PORTEC Study Group. J Clin Oncol. 2024 Apr 1;42(10):1158-1168. doi: 10.1200/JCO.23.00943. Epub 2024 Jan 12. PMID: 38215358.

Capture-based targeted sequencing using a T-cell control in myeloid malignancies and idiopathic cytopenias. Pietka G, ..., **McMullin MF**, et al.. 2024 Apr; 204(4):1325-1334. doi: 10.1111/bjh.19377. Epub 2024 Mar 11. PMID: 38462984.

A phase I open-label, dose-escalation study of NUC-3373, a targeted thymidylate synthase inhibitor, in patients with advanced cancer (NuTide:301). Spiliopoulou P, ..., **Coyle VM**, et al. J Exp Clin Cancer Res. 2024 Apr 2;43(1):100. doi: 10.1186/s13046-024-03010-1. PMID: 38566164.

An objective measure of response on whole-body MRI in metastatic hormone sensitive prostate cancer treated with androgen deprivation therapy, external beam radiotherapy, and radium-223. Giacometti V, ..., **Hounsell AR, McGarry CK, O'Sullivan JM**, et al. Br J Radiol. 2024 Mar 28; 97(1156):794-802. doi: 10.1093/bjr/tqae005. PMID: 38268482.

A potential biomarker of radiosensitivity in metastatic hormone sensitive prostate cancer patients treated with combination external beam radiotherapy and radium-223. Redmond KM, **Turner PG, Cole A, Jain S**, Prise KM, **O'Sullivan JM**. Radiother Oncol. 2024 Feb; 191:110063. doi: 10.1016/j.radonc.2023.110063. Epub 2023 Dec 20. PMID: 38135185.

The MARECA (national study of management of breast cancer locoregional recurrence and oncological outcomes) study: protocol for a prospective, multicentre cohort study. Hartup SM, ..., **McIntosh SA**, et al. Int J Surg Protoc. 2024 Jan 26;28(1):20-26. doi: 10.1097/SP9.000000000000018. eCollection 2024 Mar. PMID: 38433867.

The aetiology and burden of myeloproliferative neoplasms in the United Kingdom: the Myeloproliferative neoplasmS: an In-depth case-control (MOSAICC) study protocol. Abutheraa N, ..., **McMullin MF**, et al. BMC Cancer. 2023 Dec 7;23(1):1207. doi: 10.1186/s12885-023-11483-0. PMID: 38062390.

Trimodality therapy versus perioperative chemotherapy in the management of locally advanced adenocarcinoma of the oesophagus and oesophagogastric junction (Neo-AEGIS): an open-label, randomised, phase 3 trial. Reynolds JV, ..., et al; **Neo-AEGIS Investigators and Trial Group**. Lancet Gastroenterol Hepatol. 2023 Nov; 8(11):1015-1027. doi: 10.1016/S2468-1253(23)00243-1. Epub 2023 Sep 18. PMID: 37734399.

The *JAK2<sup>V617F</sup>* mutation and the role of therapeutic agents in alleviating myeloproliferative neoplasm symptom burden. Orbell LY, ..., **McMullin MF**, et al. EJHaem. 2023 Oct 31;4(4):1071-1080. doi: 10.1002/jha2.805. eCollection 2023 Nov. PMID: 38024634.

Patient-reported Outcomes and Quality of Life in Anemic and Symptomatic Patients With Myelofibrosis: Results From the MOMENTUM Study. Ruben A Mesa, ..., **Mary Frances McMullin**, et al : Hemasphere. 2023 Oct 24;7(11):e966. PMID: 37901848.

Pathologic Lymph Node Regression After Neoadjuvant Chemotherapy Predicts Recurrence and Survival in Esophageal Adenocarcinoma: A Multicenter Study in the United Kingdom. Moore JL, ..., **Turkington RC**, et al ; Oesophageal Cancer Clinical and Molecular Stratification (OCCAMS) study group, The Guy's and St Thomas' Oesophago-gastric Research Group, and

The PROGRESS study group. J Clin Oncol. 2023 Oct 1; 41(28):4522-4534. doi: 10.1200/JCO.23.00139. Epub 2023 Jul 27. PMID: 37499209.

A randomized comparison of CPX-351 and FLAG-Ida in adverse karyotype AML and high-risk MDS: the UK NCRI AML19 trial. Othman J, ..., **Arnold C**, et al. Blood Adv. 2023 Aug 22;7(16):4539-4549. doi: 10.1182/bloodadvances.2023010276. PMID: 37171402.

Feasibility of home-based exercise training during adjuvant treatment for metastatic castrate-resistant prostate cancer patients treated with an androgen receptor pathway inhibitor (EXACT). Brown M, ...**Crawford F, Cole A, O'Sullivan JM, Jain S**, et al. Support Care Cancer. 2023 Jul 4;31(7):442. doi: 10.1007/s00520-023-07894-1. PMID: 37402060.

### **Other Key publications - High impact trial that NICTN recruited to:**

A decade of the Oesophageal Cancer Clinical and Molecular Stratification Consortium. Peters CJ ... et al; **OCCAMS Consortium**; Fitzgerald RC. Nat Med. 2024 Jan;30(1):14-16. doi: 10.1038/s41591-023-02676-y. PMID: 38114667.

Dysphagia-optimised intensity-modulated radiotherapy versus standard intensity-modulated radiotherapy in patients with head and neck cancer (DARS): a phase 3, multicentre, randomised, controlled trial. Nutting C... et al; DARS Trialist Group. Lancet Oncol. 2023 Aug; 24(8):868-880. doi: 10.1016/S1470-2045(23)00265-6. Epub 2023 Jul 6. PMID: 37423227.

Mutational signature dynamics shaping the evolution of oesophageal adenocarcinoma. Abbas S,... et al ; **OCCAMS Consortium**; Fitzgerald RC, Secrier M. Nat Commun. 2023 Jul 15;14(1):4239. doi: 10.1038/s41467-023-39957-6. PMID: 37454136.

Pembrolizumab in combination with gemcitabine and cisplatin compared with gemcitabine and cisplatin alone for patients with advanced biliary tract cancer (**KEYNOTE-966**): a randomised, double-blind, placebo-controlled, phase 3 trial. Kelley RK,... et al ; **KEYNOTE-966 Investigators**. Lancet. 2023 Jun 3; 401(10391):1853-1865. doi: 10.1016/S0140-6736(23)00727-4. Epub 2023 Apr 16. PMID: 37075781.

### **The following were presented at national/international conferences/meetings:**

#### **Oral presentations**

Breast Cancer Surgical Trials day, Royal College of Surgeons London: Two of the NICTN clinical research Nurses, Kerry Nicholls and Ruth Gibson, gave an oral presentation entitled "How research nurses can help optimise the culture of trials in your unit".

#### **Poster presentations**

European Society for Therapeutic Radiology and Oncology (ESTRO) 2023: Validation of a quality score assessing the spacer placement in patients treated with prostate SABR. Valentina Giacometti, Owen McLaughlin, Patrick Comiskey, Hannah Marshall, Orla A Houlihan, Glenn Whitten, Niamh Clark, Kevin M Prise, Alan R Hounsell, Suneil Jain, Conor K McGarry.

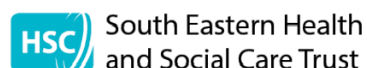
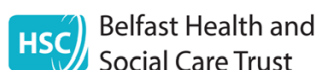
## Awards/Good New Stories

- Friends of the Cancer Centre ‘Celebrate Great Awards’ recognise those who go above and beyond for their patients. NICTN Staff **Sharon Mc Clean** (CRN) and **Gail Gilchrist** (CRR) were just some of the recipients from across the NI Cancer Centre who received this award in 2023/24.
- BHSCT Certificates of recognition were awarded across all sections of the NICTN team throughout the year.
- In March 2024, NICTN’s Clinical Research Radiographer Team alongside colleagues in the NI Cancer Centre Radiotherapy Department were shortlisted for the NI Health Care Award for their **ADVOCATE project - ADVancing radiOtherapy teChniques as A Team**.
- A NICTN Clinical Research led article on Belfast Radiotherapy developments and the role of the Clinical Research Radiographer was published on QUB website - Your Space | The Patrick G Johnston Centre for Cancer Research | Queen's University Belfast (qub.ac.uk). This was a great opportunity to highlight how trials have progressed radiotherapy treatments in Northern Ireland.
- This year NICTN continued to fundraise for the many charities that support the team deliver cancer trials:
  - In September 2023, our haematology research nurses raised £1200 for Cure Leukaemia by supporting ‘Your 14 Campaign’ by walking 14 floors of the BCH tower block for 14 days signifying that one person is diagnosed with a blood related cancer every 14 minutes.
  - In October 2023, NICTN staff raised £1600 for the Cancer Research UK Shine Appeal by joining a very illuminating 10k night walk across Belfast.

***Further information regarding all aspects of cancer trial activity can be found in the NICTN annual report 2023-24 which is available on request.***

# NI Health and Social Care Trust Research and Development Directors Reviews

In this the Regional section the activity by each Clinical Specialty Group across the 5 Health and Social Care Trusts has been outlined in a format identical to that used in the Clinical Specialty Sections. Over time each Trust will have developed its own areas of specialist research expertise and when resources are scarce it's just not possible to support 14 clinical specialty group activity across all Trusts. R&D Directors together with the Clinical Leads, and their NICRN support staff, have provided some Trust specific background information followed by information on in year achievements, key publications and good news stories. I am very grateful to all 5 Trust R&D Directors for having taken time to report on the Trust specific activity in this section and look forward to expanding on this in years to come.



# Belfast Health and Social Care Trust R&D

## Directors review

### Director, Chief and Principal Investigators

<p><b>Research Deputy Director:</b> Mark Cross <i>(Trusts Deputy Medical Director with responsibility for Risk and Governance)</i></p> <p><b>Research Manager:</b> Alison Murphy</p>	<p><b>Chief and Principal Investigators</b></p> <table><tr><td>Adam Glass</td><td>John Lindsay</td></tr><tr><td>Alastair Reid</td><td>Jon Silversides</td></tr><tr><td>Andrew McNeice</td><td>Jonathan Jackson</td></tr><tr><td>Anthony McCarthy</td><td>Joseph Kane</td></tr><tr><td>Augusto Azuara-Blanco</td><td>Judy Bradley</td></tr><tr><td>Bernadette McGuinness</td><td>Julie Richardson</td></tr><tr><td>Bharathi Rao</td><td>Julie Silvestri</td></tr><tr><td>Brian McCrossan</td><td>Karen Gillvray</td></tr><tr><td>Carolee McLaughlin</td><td>Lana Dixon</td></tr><tr><td>Cathy Patterson</td><td>Laura Loughlin</td></tr><tr><td>Catriona Monaghan</td><td>Liam Heaney</td></tr><tr><td>Chris Nutt</td><td>Lorcan McGarvey</td></tr><tr><td>Ciara O'Donnell</td><td>Mark Spence</td></tr><tr><td>Colin Willoughby</td><td>Michael Duffy</td></tr><tr><td>Colum Owens</td><td>Michael Williams</td></tr><tr><td>Conleth Murphy</td><td>Murali Shyamsundar</td></tr><tr><td>Damien Downey</td><td>Nicholas Magee</td></tr><tr><td>Danny McAuley</td><td>Nicola Johnston</td></tr><tr><td>David Johnston</td><td>Noemi Lois</td></tr><tr><td>David McCracken</td><td>Patricia Gordon</td></tr><tr><td>David Sweet</td><td>Pascal McKeown</td></tr><tr><td>Emma Cunningham</td><td>Peter McGuigan</td></tr><tr><td>Graham Morrison</td><td>Peter Passmore</td></tr><tr><td>Hamish Courtney</td><td>Philip Johnston</td></tr><tr><td>Inder Mainie</td><td>Steven Caskey</td></tr><tr><td>Ivan Wiggam</td><td>Suzanna Paterson</td></tr><tr><td>James McNamee</td><td>Suzanne Lawther</td></tr><tr><td>Jane McDowell</td><td>Tanya Moutray</td></tr><tr><td>Jim McIlmoyle</td><td>Tunde Peto</td></tr></table>	Adam Glass	John Lindsay	Alastair Reid	Jon Silversides	Andrew McNeice	Jonathan Jackson	Anthony McCarthy	Joseph Kane	Augusto Azuara-Blanco	Judy Bradley	Bernadette McGuinness	Julie Richardson	Bharathi Rao	Julie Silvestri	Brian McCrossan	Karen Gillvray	Carolee McLaughlin	Lana Dixon	Cathy Patterson	Laura Loughlin	Catriona Monaghan	Liam Heaney	Chris Nutt	Lorcan McGarvey	Ciara O'Donnell	Mark Spence	Colin Willoughby	Michael Duffy	Colum Owens	Michael Williams	Conleth Murphy	Murali Shyamsundar	Damien Downey	Nicholas Magee	Danny McAuley	Nicola Johnston	David Johnston	Noemi Lois	David McCracken	Patricia Gordon	David Sweet	Pascal McKeown	Emma Cunningham	Peter McGuigan	Graham Morrison	Peter Passmore	Hamish Courtney	Philip Johnston	Inder Mainie	Steven Caskey	Ivan Wiggam	Suzanna Paterson	James McNamee	Suzanne Lawther	Jane McDowell	Tanya Moutray	Jim McIlmoyle	Tunde Peto
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## Group Background/ Summary

During this year the BHSCT Research and Development Director Prof Ian Young retired from this post in Sept 2023. The Medical Director acknowledged the work that Prof Young had performed for a long time period leading Research and Development within the BHSCT. The Deputy Medical Director for Risk and Governance Mark Cross has supported the Research and Development Portfolio within the BHSCT since Prof Ian Young retired from his BHSCT role.

During this reporting time period the BHSCT NICRN delivered 38 research studies which have now closed. During the same reporting time period there have been an approximately equal numbers of new studies supported and delivered by the NICRN (22). Currently within the BHSCT this brings the NICRN delivery of active studies to 139. This is delivered by 14 CSGs across 154 sites. All potential research sites across BHSCT are currently involved in active study recruitment, displaying engagement across all of the complex healthcare sectors within our Trust.

Within the BHSCT, working alongside NICRN staff, there have been 4112 potential research participants screened. The NICRN staff have recruited 33.9 % of screened research participants (1395) into BHSCT studies. On behalf of the Medical Director, I would like to acknowledge and thank the NICRN staff for all this outstanding work and ensuring that our patients have been recruited into research studies. This effort by the NICRN I acknowledge will improve the outcomes for our patients within the BHSCT by ensuring there is an active culture of research and development within the organisation.

## Key Achievements, including relevant awards, good news stories etc.

NICRN staff have delivered clinical trials across a wide range of patients and service users recruited into research within the BHSCT. This year in particular just over 60 % of the clinical studies were delivered in Critical Care, Vision Science and Neurodegenerative areas. We also have shown that our children have an equitable chance of participating in clinical research.

## A message from the R&D Director

This year we have developed a closer working relationship with the leadership of the NICRN with the development of regular meetings focusing on shared vision for research and development. The NICRN has helped develop the BHSCT senior leadership perspective on research and development, meeting with Chairperson, Non-Executive Director of Trust Board,

and executive directors. NICRN working alongside the Deputy Medical Director ensures that there is an alignment of resources across, and matching our shared visions.

The BHSCT welcomes the contribution and leadership from the NICRN to effectively deliver clinical trials for our patients in a safe and well governed approach. The preparation from the NICRN during the roll out of ENCOMPASS across the region must be personally acknowledged for this significant contribution in ensuring important interfacing of digital systems and data migrations occurred.

We look forward to developing a Strategy for Research and Development for the BHSCT with the NICRN and alongside other major investment strategies including, but not limited to, the Belfast City Regional Deals.

# Dashboard – BHSCT

No. of Active CSGs	14
No. of Active Studies	139
No. of Recruitment Sites	154
No. of Sites with Recruitment (INV)	129
No. of New Studies during 23-24	22
No. of Studies closed during 23-24	38

Screened (INV)* during 23-24	Recruited during (INV)** as at 31/03/2024	Screened (TOT)** as at 31/03/2024	Recruited (TOT)** as at 31/03/2024
4,112	1,395	17,573	5,895

\* INV = Activity reported over reporting period (01/04/2023 - 31/03/2024)  
 \*\* TOT = Total activity reported up to and including 31/03/2024

Commercial		Non-Commercial		Combined	
Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*
63	73.33%	1,332	82.00%	1,395	81.00%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

Interventional		Observational		Combined	
Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*
493	68.33%	902	100.00%	1,395	81.00%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

	Commercial	Non-Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	30	109	84	55	96	43
Proportion (%)	21.58%	78.42%	60.43%	39.57%	69.06%	30.94%

Commercial(22)		Non-Commercial(107)		Combined(129)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
52.5	45.45%	37.0	42.99%	38.0	43.41%

\* Metrics calculated on Active Sites with Recruitment only

List of CSGs*	Recruitment (INV) during 23-24	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Recruitment to Target (%)**	Median ALL FPFV* (days)	Proportion (%) < 30 days
Cardiovascular	44	3.15%	13	8.44%	73.33%	25.0	50.00%
Child Health	118	8.46%	19	12.34%	60.00%	52.5	28.57%
COVID Delivery Team	17	1.22%	8	5.19%	107.50%	4.0	100.00%
Critical Care	370	26.52%	23	14.94%	97.50%	34.0	45.45%
Diabetes	7	0.50%	9	5.84%	80.00%	46.0	50.00%
Gastroenterology	2	0.14%	6	3.90%	50.00%	177.5	25.00%
Mental Health	3	0.22%	3	1.95%	0.00%	93.0	0.00%
Neurodegenerative	307	22.01%	5	3.25%	81.85%	41.0	33.33%
Orthopaedics	90	6.45%	10	6.49%	83.33%	41.5	50.00%
Primary Care	1	0.07%	5	3.25%	100.00%	138.5	50.00%
Renal	107	7.67%	8	5.19%	78.13%	93.0	14.29%
Respiratory Health	92	6.59%	15	9.74%	64.00%	21.0	58.33%
Stroke	31	2.22%	9	5.84%	66.67%	58.5	25.00%
Vision	206	14.77%	21	13.64%	100.00%	41.5	35.00%
Totals:	1,395	100.00%	154	100.00%	81.00%	38.0	43.41%

\* CSG names highlighted in purple are active within trust area  
 \*\*Median RT Metrics calculated on Active Studies which have closed to recruitment

# Northern Health and Social Care Trust R&D

## Directors review

### Director, Chief and Principal Investigators

<p><b>Research Director:</b> Paul Minnis</p> <p><b>Research Manager:</b> Frances Johnston</p>	<p><b>Chief &amp; Principal Investigators, within Trust, currently active on NICRN adopted studies.</b></p> <p>Paul Johnston Anna Strzelecka Kok Diong Stephanie Paul Minnis M Bahattad</p>
<p><b>Director of IMPACT research centre:</b> Ciaran Shannon</p>	<p><b><u>IMPACT Centre</u></b></p> <p>Ciaran Mullholland Kevin Dyer Suzanne Barrett</p>

## Group Background/ Summary

An NIHR-funded RCT (NIHR - £2,099,422.39; CI: Dr Michael Duffy (QUB)/Prof. Anke Ehlers (Oxford)) entitled Does a Phased Approach Enhance Outcomes for Trauma-Focused Cognitive Therapy (TF CT-PTSD) for Complex Posttraumatic Stress Disorder (CPTSD)? (Edge ID: 154737) opened across five NI HSC Trusts and five Trusts in England, commencing Spring 2023. Dr Suzanne Barrett, NICRN Mental Health & Impact Centre - NHSCT advised on the application and completed the consultation with the PIs to develop the protocol and IRAS application for the study from the successful grant materials in 2022, before transfer of responsibilities to the newly appointed trial managers in Autumn/Winter 2022. The research team includes Study Medical Officer: Prof. Ciaran Mulholland; Study Training Lead – Dr Kevin Dyer and NHSCT Investigator, Deborah Mairs). Recruitment following screening on 31.03.2024 was as follows: n=35 of 175 [20% of target; assumes NI is responsible for 50% of recruitment at its 5 of 10 UK sites] (BHSCT n=3 of 35; NHSCT n=11 of 35; SEHSCT n=7 of 35; SHSCT n=7 of 35; WHSCT n=7 of 35). Further info: Dr. Nina O’Neill (QUB) Email: nina.oneill@qub.ac.uk. Publication of the final protocol is anticipated in 2024.

The International Survey of Childbirth-Related Trauma UK (INTERSECT UK; CI: Prof Susan Ayers (City, UCL); Edge ID: 152173) opened on 31st March 2023 in the NHSCT Maternity services. The Local Collaborative team were listed as: S Barrett (Site Investigator for NI); S. Hamilton, C Diamond and C Mulholland. Due to challenges with the reorganisation of maternity services in NHSCT following COVID-19 pandemic, the study closed out in 2023 without recruitment.

## Key Achievements, including relevant awards, good news stories etc.

- NICRN-Mental Health completed a report entitled *Rates of common mental health disorders (CMDs) in England, Northern Ireland, Scotland and Wales (1991-2021): evidence from General Health questionnaire -12 survey data* (embargoed pending publications, but available on request to authors at the Centre). It has resulted in two planned peer-reviewed publications (submissions scheduled April 2024; June 2024 to PLOS Mental Health).
- Dr Barrett has acted as the NHSCT rep for Encompass - Research Working Group 2022-24 and represented NI in NIHR Cluster C Meetings.
- She has attended the HIRANI Innovate UK Digital Mental Health Event 2023 and the [ESTSS - Conference Summer 2023](#).
- Dr Dyer was appointed Professor of Psychology at University of Exeter.
- The IMPACT Research Centre, NHSCT will publish its report on psychological research activity within the Trust in April 2024. For further information, contact Prof. Shannon: [Ciaran.Shannon@northerntrust.hscni.net](mailto:Ciaran.Shannon@northerntrust.hscni.net).
- The Child Anxiety Treatment in the context of COVID-19 (Co-CAT) study (CI, Prof. Cresswell (Oxford); PIs Rowan/McClean&Cresswell) worked with children, parents and NHS/HSC clinicians to develop an online program that parents/carers of children with anxiety disorders work through with remote support from a CAMHS therapist. An OSI GROWS free-to-use licence has been the subject of service evaluation in RCT participating services (SEHSCT, BHSCT) throughout 2023-24. [Co-CAT \(osiresearch.org.uk\)](#); [OSI GROWS \(osiresearch.org.uk\)](#).

### Diabetes

*SYNCHRONIZE-CVOT* is a Phase 3, randomised, double-blind, parallel-group, event driven, Cardiovascular safety study with BI 456906 administered subcutaneously compared with placebo in participants with obesity or who are overweight with established Cardiovascular Disease or Chronic Kidney Disease and/or at least 2 weight related complications or risk factors for Cardiovascular Disease. The study is led by the University Hospitals of Leicester NHS Trust and Chief Investigator Dr Manish Saxena.

*Select* was also one of the top recruiting sites in the UK.

Our Diabetes Research Team based at Antrim Area Hospital recruited 3 patients within a month of opening. This is no easy task and shows the hard work and dedication of the Diabetes Research Team which consists of Research Nurses Moyra McMaster and Natalie Hanley being led by Northern Ireland's only Primary Investigator; Dr Anna Strzelecka. The team are now joint second top recruiting sites in the UK.

### **ICU/Critical Care**

*GenOMICC* Study will identify the specific genes that cause some people to be susceptible to specific infections and consequences of severe injury with the hope that identifying these genes will help to use existing treatments better and to design new treatments to help people survive critical illness.

The Northern Health and Social Care Trust (Antrim Area Hospital) were in the top 20 recruiting sites during February 2024.

### **GI**

The NHSCT were delighted to support Dr Diong Kok with a 0.2 WTE GI nurse, this resource has assisted Dr Diong in getting the Gondamar Study opened.

## **A message from the R&D Director**

It is a pleasure to report on excellent research activity within the Northern HSC in partnership with NICRN achieved in the face of limited resources and challenging circumstances. In my view research is what propels humanity forward. It's fuelled by curiosity: we get curious, ask questions, and immerse ourselves in discovering everything there is to know. Learning is thriving. Without curiosity and research, progress would slow to a halt, and our lives as we know them would be completely different. Participating in clinical research plays a pivotal role in advancing medical knowledge and improving patient care. Within the Northern HSC Trust we aim to ensure that high quality research is accessible and available to all and aspire to embed research into routine clinical care. We look forward to continuing the highly productive partnership with NICRN with the aims of doing more, better and faster.

# Dashboard – NHSCT

Table 1: Studies and Sites Data	
No. of Active CSGs	9
No. of Active Studies	35
No. of Recruitment Sites	47
No. of Sites with Recruitment (INV)	43
No. of New Studies during 23-24	4
No. of Studies closed during 23-24	8

Table 2: Screening and Recruitment In Year and also Cumulative Totals for Active Studies During 23-24			
Screened (INV)* during 23-24	Recruited during (INV)** 23-24	Screened (TOT)** as at 31/03/2024	Recruited (TOT)** as at 31/03/2024
258	101	1,861	621

\* INV = Activity reported over reporting period (01/04/2023 - 31/03/2024)  
 \*\* TOT = Total activity reported up to and including 31/03/2024

Table 3a: Recruitment and Median Recruitment to Target (%)* by Sponsorship Type					
Commercial		Non-Commercial		Combined	
Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*
25	100.00%	76	100.00%	101	100.00%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

Table 3b: Recruitment and Median Recruitment to Target (%)* by Design Type					
Interventional		Observational		Combined	
Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*	Recruited (INV) during 23-24	Median RT (%)*
61	100.00%	40	90.00%	101	100.00%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

Table 4: Portfolio Sponsorship, Randomisation and Design Mix for Active Studies During 23-24						
	Commercial	Non-Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	10	25	20	15	20	15
Proportion (%)	28.57%	71.43%	57.14%	42.86%	57.14%	42.86%

Table 5: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days (%) *					
Commercial(10)		Non-Commercial(33)		Combined(43)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
30.0	60.00%	40.0	45.45%	35.0	48.84%

\* Metrics calculated on Active Sites with Recruitment only

Table 6a: HSC Trust Data by Clinical Specialty Group							
List of CSGs*	Recruitment (INV) during 23-24	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Recruitment to Target (%)**	Median ALL FPFV* (days)	Proportion (%) < 30 days
Cardiovascular							
Child Health							
COVID Delivery Team	20	19.80%	4	8.51%	10.00%	5.5	75.00%
Critical Care	0	0.00%	2	4.26%	63.33%	49.5	0.00%
Diabetes	22	21.78%	7	14.89%	122.22%	30.0	71.43%
Gastroenterology	0	0.00%	1	2.13%			
Mental Health	11	10.89%	3	6.38%	5.00%	191.5	0.00%
Neurodegenerative							
Orthopaedics							
Primary Care	19	18.81%	15	31.91%	100.00%	19.0	66.67%
Renal	11	10.89%	7	14.89%	40.63%	248.0	33.33%
Respiratory Health	7	6.93%	4	8.51%	0.00%	123.0	0.00%
Stroke	11	10.89%	4	8.51%	60.83%	144.5	25.00%
Vision							
Totals:	101	100.00%	47	100.00%	100.00%	35.0	48.84%

\* CSG names highlighted in purple are active within trust area  
 \*\*Median RT Metrics calculated on Active Studies which have closed to recruitment

# South East Health and Social Care Trust R&D Directors review

## Director, Chief and Principal Investigators

<b>Research Director:</b> Patrick Donnelly	<b>Chief and Principal Investigators:</b> Patrick Donnelly
<b>Research Manager:</b> Stephanie Kelly	Michael Magowan
	Samantha Hagan
	Ciara Mulligan
	Patrick Allen
	Jennifer Elder
	Frederick McElwaine
	Mark Bowman
	Chris Murray

## Group Background/ Summary

The Research Development & Innovation Department SET has had a strong focus on building resilience and extending our reach within the organisation. There have been extensive stakeholder engagement meetings within the Trust and with our regional and national collaborators. The findings from these sessions will be reflected next year within our first 5-year research strategy document.

We have made significant changes to our staffing model. With ongoing support from the PHA RD and NICRN we have appointed 4 new staff members, 3 to our governance office, and one research nurse to support “conditions focused” research activity. Our new governance manager and research administrator will modernise our current operational policies and processes. Our new data administrator will facilitate greater research accountability with the development of a Trust-wide research database. This database will link with ENCOMPASS and our regional reporting platform -EDGE. Our governance department will work with this new regional team to prepare us for our new role in the delivery of timely research “capacity and capability” assessments. We have also reviewed our research nurse workforce and have adopted a team’s based approach that will increase our productivity and resilience. These new members of staff have been invaluable in helping our sister organisations in their planning for ENCOMPASS. Our NICRN Research Nurses have also been involved in the ‘Grow Your Own’ event promoting the role of NICRN Research Nurses within SEHSCT.

The number of researchers within our organisation has increased with 47 members of staff now recognised as a Principal or Chief Investigator. In keeping with our ambition to have research accessible to all our staff 59% of our research leads are medical and 41% are allied health care professionals. We are now embedded within 10 of the 14 Northern Ireland Clinical Research Network (NICRN) research speciality groups our main regional collaborator. Our partnership with NICRN has allowed us to adopt 37 studies, screen over 1166 patients and involve 229 participants in research trials. 47% of our patients have their first research visit within 30 days of recruitment.

In order to improve our research offer we have agreed a national research contract tariff that we believe is competitive nationally and should allow greater research transparency and reduce the time it takes for research adoption. We have also undertaken a pathfinder initiative with the new Research Regional Approvals service to help streamline processes with a view to this service going live next year across Northern Ireland. We were the only Trust in Northern Ireland to contribute to a National Health Research Authority project that aimed to identify ways by which access to research could be simplified for NHS staff. We were the first site in Northern Ireland to help develop and implement the new ENCOMPASS research module which embeds research within a patients electronic health care record.

## Key Achievements, including relevant awards, good news stories etc.

There have been a number of notable successes for our research teams:

Gastroenterology led by Dr Patrick Allen and Dr Tony Tham have been recognised for the highest site recruitment in the UK in the real world study ‘Galocean’. This study will advance our understanding of a novel drug in the treatment of patients with ulcerative colitis. They have also been commended for their high level of data completion in the ELEVATE study, another trial evaluating a novel drug for ulcerative colitis patients.

The Stroke team led by Dr Mark Bowman have excelled in the MAPs -2 Study which is evaluating the use of an old drug metoclopramide in patients with swallowing difficulties after a stroke. They were lauded for their rapid enrolment of 10 patients into the trial.

The Critical Care team led by Dr Matt Devine & Research Trials Nurse Sam Hagan have hosted 5 studies and were our top speciality recruiters with 90 patients enrolled. Their UK-ROX trial which is evaluating oxygen therapy in critically ill patients has been flagged as one of their most successful studies. Despite opening late they now have the highest recruitment in Northern Ireland and one of the highest recruitment sites in the UK.

The Cardiology team led by Dr Patrick Donnelly and Dr Valecka continued their work in the prevention, early detection and management of coronary artery disease and heart failure. Early coronary artery disease detection was evaluated in the DISCHARGE study to which the Trust was a top recruiter in the United Kingdom. They exceeded expectations and were asked

to contribute further patients in the coronary artery disease prevention PREVAIL trial using a novel cholesterol lowering medication. In their heart failure work they continue as a CI site for the Global Congestive Heart Failure registry which will inform our global understanding of heart failure care. They were a super-recruiter for the BHF sponsored IRONMAN study which evaluated the role of intravenous iron in the management of patients with chronic heart failure and they had the fastest first patient randomised in the VICTOR study.

The Renal group led by Dr Alistair Woodman and Dr Fred McElwaine were congratulated as the second secondary care site in the UK to open for recruitment to the DURATION study- this is an Oxford led study that is researching secondary care antibiotic effectiveness and use in women with urinary tract infections.

Our Child Health team were congratulated for excellent recruitment over two successive months for the SURFON study. This important trial is evaluating the use of surfactant in late preterm or early term infants with respiratory distress

## A message from the R&D Director

The SEHSCT will publish their research position paper this year - People, Place, Process and Pipeline. This document has highlighted the importance of NICRN in supporting research activity within our organisation. It also outlines how we will align our conditions based research priorities with the NICRN Speciality Groups. This will provide the focus for SEHSCT to engage in high quality research that is of regional significance. Working closely together with NICRN I hope that we will be able to take advantage of new commercial clinical trials opportunities, and broaden patient access to important life-changing clinical research.

# Dashboard – SEHSCT

Table 1: Studies and Sites Data	
No. of Active CSGs	10
No. of Active Studies	37
No. of Recruitment Sites	44
No. of Sites with Recruitment (INy)	41
No. of New Studies during 23-24	7
No. of Studies closed during 23-24	4

Table 4: Portfolio Sponsorship, Randomisation and Design Mix for Active Studies During 23-24						
	Commercial	Non-Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	9	28	22	15	23	14
Proportion (%)	24.32%	75.68%	59.46%	40.54%	62.16%	37.84%

Table 2: Screening and Recruitment In Year and also Cumulative Totals for Active Studies During 23-24			
Screened (INy)* during 23-24	Recruited during (INy)* 23-24	Screened (TOT)** as at 31/03/2024	Recruited (TOT)** as at 31/03/2024
1,166	229	5,174	784

\* INy = Activity reported over reporting period (01/04/2023 - 31/03/2024)  
 \*\* TOT = Total activity reported up to and including 31/03/2024

Table 5: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days (%) *					
Commercial(8)		Non-Commercial(33)		Combined(41)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
40.5	25.00%	26.0	51.52%	36.0	46.34%

\* Metrics calculated on Active Sites with Recruitment only

Table 3a: Recruitment and Median Recruitment to Target (%)* by Sponsorship Type					
Commercial		Non-Commercial		Combined	
Recruited (INy) during 23-24	Median RT (%)*	Recruited (INy) during 23-24	Median RT (%)	Recruited (INy) during 23-24	Median RT (%)*
35	39.71%	194	100.00%	229	100.00%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

Table 6a: HSC Trust Data by Clinical Specialty Group							
List of CSGs*	Recruitment (INy) during 23-24	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Recruitment to Target (%)**	Median ALL FPFV* (days)	Proportion (%) < 30 days
Cardiovascular	27	11.79%	9	20.45%	74.00%	60.5	25.00%
Child Health	10	4.37%	1	2.27%		86.0	0.00%
COVID Delivery Team	25	10.92%	4	9.09%	72.00%	14.0	75.00%
Critical Care	90	39.30%	5	11.36%	171.33%	71.0	40.00%
Diabetes	5	2.18%	1	2.27%		70.0	0.00%
Gastroenterology	15	6.55%	5	11.36%	180.00%	37.0	25.00%
Mental Health	7	3.06%	1	2.27%		111.0	0.00%
Neurodegenerative							
Orthopaedics							
Primary Care	28	12.23%	10	22.73%	100.00%	3.5	70.00%
Renal	11	4.80%	7	15.91%	75.00%	31.0	50.00%
Respiratory Health							
Stroke	11	4.80%	1	2.27%		14.0	100.00%
Vision							
<b>Totals:</b>	<b>229</b>	<b>100.00%</b>	<b>44</b>	<b>100.00%</b>	<b>100.00%</b>	<b>36.0</b>	<b>46.34%</b>

\* CSG names highlighted in purple are active within trust area  
 \*\*Median RT Metrics calculated on Active Studies which have closed to recruitment

Table 3b: Recruitment and Median Recruitment to Target (%)* by Design Type					
Interventional		Observational		Combined	
Recruited (INy) during 23-24	Median RT (%)*	Recruited (INy) during 23-24	Median RT (%)*	Recruited (INy) during 23-24	Median RT (%)*
184	100.00%	45	74.00%	229	100.00%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

# Southern Health and Social Care Trust R&D

## Directors review

### Director, Chief and Principal Investigators

<b>Research Director:</b> Peter Sharpe	<b>Chief &amp; Principal Investigators, within Trust, currently active on NICRN adopted studies:</b>
<b>Research Manager:</b> Rachelle Moore	Neal A. Morgan
	Judi Graham
	Claire Shevlin
	Rob Charnock
	Shiva Arava
	Michael Jones
	David Graham
	Lesley-Ann Funston
	Sarinda Millar
	Alison Vernor
	Michael McCormick
	Rory Convery
	Ian Menown
	Paul Magill

## Group Background/ Summary

We have a total of 40 active studies incorporating all of the clinical specialties. Most active is renal with 9 studies, 5 in both critical care medicine paediatrics and respiratory medicine with 4 in both stroke and cardiovascular medicine. This demonstrates considerable success in the Trust in recruiting to all of the clinical specialties that we engage in. Three new studies have been adopted within this defined period in cardiology, anaesthetics and stroke. The Teams set realistic targets of recruitment on all studies and have achieved this. We are proud of our performance on all NICRN adopted studies and will continue to seek to expand and grow in the coming year.

## Key Achievements, including relevant awards, good news stories etc.

We have had several key achievements during the year: In cardiovascular for the eUltra 10K trial Dr Ian Menown was named in the top 3 recruiters within 1st month of opening. In the Orthopaedic Duality Trial Southern Trust was the 6th largest recruitment site and the Nightlife study undertaken in Renal had 13 participants recruited in one day. Our Trust has consistently been a top recruiter into numerous trials over many years. We strive to continue with this success going forward. These successes are celebrated through Trust mediums. Following the COVID pandemic all study areas have grown and continue to perform well. We are committed to investing staff and resource to NICRN trials in all areas.

## A message from the R&D Director

NICRN studies are of key importance and relevance to our Trust. They form the bulk of studies that we are involved in, in several key clinical areas. Our Clinicians are highly committed to the network and fully participate in regional discussions regarding research priorities. The network facilitates excellent research through central coordination, planning and human resourcing. We are proud to consistently deliver on studies through achieving high recruitment figures and completion of studies. These studies enhance patient safety and quality outcomes throughout the Trust and allow patients to be involved in clinical trials, which is highly desirable for them, and facilitates access to new potentially highly effective treatments. The SHSCT has several established partnerships both internally and externally for example; pharmacy, information governance, laboratory services, radiology, HSC Innovations, clinical trials and research networks, universities, and industry. Working with NICRN has expanded on all of these partnerships which is greatly welcome. The future of research is through increased networking and we will continue to expand our involvement with NICRN to enable the delivery of high quality research which will greatly improve our population health and wellbeing. With resources being increasingly limited it is even more vital that working together to improve capacity and capability is achieved to an optimal level of efficiency and cost effectiveness. Work undertaken in all areas demonstrates the value that research brings, not only to the local population but also as an employer of professionals interested in undertaking research in the years to come.

# Dashboard – SHSCT

Table 1: Studies and Sites Data	
No. of Active CSGs	9
No. of Active Studies	40
No. of Recruitment Sites	44
No. of Sites with Recruitment (INV)	41
No. of New Studies during 23-24	7
No. of Studies closed during 23-24	6

Table 4: Portfolio Sponsorship, Randomisation and Design Mix for Active Studies During 23-24						
	Commercial	Non-Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	7	33	27	13	26	14
Proportion (%)	17.50%	82.50%	67.50%	32.50%	65.00%	35.00%

Table 2: Screening and Recruitment In Year and also Cumulative Totals for Active Studies During 23-24			
Screened (INV)* during 23-24	Recruited during (INV)* 23-24	Screened (TOT)** as at 31/03/2024	Recruited (TOT)** as at 31/03/2024
996	241	3,416	1,356

\* INV = Activity reported over reporting period (01/04/2023 - 31/03/2024)  
 \*\* TOT = Total activity reported up to and including 31/03/2024

Table 5: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days (%) *					
Commercial(7)		Non-Commercial(34)		Combined(41)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
69.0	28.57%	47.0	47.06%	56.0	43.90%

\* Metrics calculated on Active Sites with Recruitment only

Table 3a: Recruitment and Median Recruitment to Target (%)* by Sponsorship Type					
Commercial		Non-Commercial		Combined	
Recruited (INV) during 23-24	Median RTT (%)*	Recruited (INV) during 23-24	Median RTT (%)	Recruited (INV) during 23-24	Median RTT (%)*
34	86.67%	207	102.50%	241	100.00%

\* Median RTT Metrics calculated on Active Studies which have closed to recruitment

Table 3b: Recruitment and Median Recruitment to Target (%)* by Design Type					
Interventional		Observational		Combined	
Recruited (INV) during 23-24	Median RTT (%)*	Recruited (INV) during 23-24	Median RTT (%)*	Recruited (INV) during 23-24	Median RTT (%)*
121	100.00%	120	115.15%	241	100.00%

\* Median RTT Metrics calculated on Active Studies which have closed to recruitment

Table 6a: HSC Trust Data by Clinical Speciality Group							
List of CSGs*	Recruitment (INV) during 23-24	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Recruitment to Target (%)**	Median ALL FPFV* (days)	Proportion (%) < 30 days
Cardiovascular	38	15.77%	8	18.18%	90.00%	45.0	28.57%
Child Health	23	9.54%	4	9.09%	135.00%	70.0	0.00%
COVID Delivery Team	13	5.39%	3	6.82%	155.00%	1.0	100.00%
Critical Care	62	25.73%	5	11.36%	115.15%	29.0	60.00%
Diabetes							
Gastroenterology							
Mental Health							
Neurodegenerative							
Orthopaedics	8	3.32%	1	2.27%		10.0	100.00%
Primary Care	0	0.00%	6	13.64%	100.00%	4.5	66.67%
Renal	30	12.45%	9	20.45%	78.13%	225.0	22.22%
Respiratory Health	54	22.41%	3	6.82%	126.67%	19.0	66.67%
Stroke	13	5.39%	5	11.36%	83.33%	190.5	25.00%
Vision							
<b>Totals:</b>	<b>241</b>	<b>100.00%</b>	<b>44</b>	<b>100.00%</b>	<b>100.00%</b>	<b>56.0</b>	<b>43.90%</b>

\* CSG names highlighted in purple are active within trust area  
 \*\* Median RTT Metrics calculated on Active Studies which have closed to recruitment

# Western Health and Social Care Trust R&D Directors review

## Director, Chief and Principal Investigators

<p>Research Director: Aaron Peace</p> <p>Research Manager: Diane Mackey</p>	<p>Chief &amp; Principal Investigators, within Trust, currently active on NICRN adopted studies.</p> <p>Aaron Peace Adam Canning Adesh Ramsewak Adrian Donnelly Alex Miras Athinyaa Thiraviaraj Breffni Keegan Brendan Skelly Damien Armstrong Elizabeth Best Frank McCarroll Joe Clarke John McGornan Mark McCarron Martin Kelly Nazia Chaudhuri Oonagh McCloskey Rachael McGlinchey Colin Mulholland Conor Moran Micheal Harron Neal McAlister Sinead O’Kane Clionagh McElhinney</p>
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## Group Background/ Summary

During the course of 2023-24 we in the Western Trust were involved in 42 NICRN adopted studies, recruiting 112 patients from a screening population of 2596. This represents an increase of over 200% on screening and recruitment compared to available 2022-23 figures, with greatest recruitment in Primary Care and Critical Care.

## Key Achievements, including relevant awards, good news stories etc.

### **IPF Comfort Study - 3rd Highest Recruiter**

Respiratory Study Co-Ordinators – Kathryn Ferguson/ Valerie Mortland/Ryan Campbell & Hazel Thompson, PI – Dr Nazia Chaudhuri.

#### **Sponsor Feedback received:-**

*'I also just wanted to take the opportunity to thank you for the great work you've done on the study on our behalf. Although a couple of our other UK sites have recruited a few more subjects than you in total, you have been open for a much shorter period of time and so that, I think, makes you our best site in terms of recruitment rate.'*

### **RXC007**

Respiratory Study Co-Ordinators – Kathryn Ferguson/ Valerie Mortland/Ryan Campbell & Hazel Thompson, PI – Dr Nazia Chaudhuri.

#### **Patient Feedback received:-**

*"I wish to thank you and your team for my meeting with you and your team yesterday. Whatever the outcome of the test results I had a memorable adventure and experience. I also found the scanning staff first class in their part of the testing. I found it wonderful the way the LFT equipment was so up to date it was wonderful to hold it in my hands".*

### **Enrich AF**

Stroke Study Co-ordinator – Dónal Concannon, PI – Dr Breffni Keegan.

Target of 3 patients to be recruited onto ENRICH-AF Trial and so far have recruited 4 patients with recruitment still on-gong. Impressive recruitment by WHSCT research stroke team for a global cutting edge trial. Opened also in Altnagelvin Site with a new PI.

## A message from the R&D Director

The increased research studies and recruitment of patients post pandemic is welcomed.

I plan to meet the entire R & D staff to share the Western Trust Research and Development Strategy and to also provide and inform our aspiration to expand clinical trials in line with Lord O'Shaughnessy review and regional strategy.

# Dashboard – WHSCT

No. of Active CSGs	9
No. of Active Studies	42
No. of Recruitment Sites	52
No. of Sites with Recruitment (INY)	43
No. of New Studies during 23-24	11
No. of Studies closed during 23-24	8

Screened (INy)* during 23-24	Recruited during (INy)* 23-24	Screened (TOT)** as at 31/03/2024	Recruited (TOT)** as at 31/03/2024
2,596	112	5,190	621

\* INY = Activity reported over reporting period (01/04/2023 - 31/03/2024)  
 \*\* TOT = Total activity reported up to and including 31/03/2024

Commercial		Non-Commercial		Combined	
Recruited (INy) during 23-24	Median RT (%)*	Recruited (INy) during 23-24	Median RT (%)*	Recruited (INy) during 23-24	Median RT (%)*
22	50.00%	90	93.33%	112	85.33%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

Interventional		Observational		Combined	
Recruited (INy) during 23-24	Median RT (%)*	Recruited (INy) during 23-24	Median RT (%)*	Recruited (INy) during 23-24	Median RT (%)*
94	67.00%	18	103.33%	112	85.33%

\* Median RT Metrics calculated on Active Studies which have closed to recruitment

	Commercial	Non-Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	12	30	33	9	35	7
Proportion (%)	28.57%	71.43%	78.57%	21.43%	83.33%	16.67%

Commercial(9)		Non-Commercial(34)		Combined(43)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
85.0	11.11%	50.5	38.24%	62.0	32.56%

\* Metrics calculated on Active Sites with Recruitment only

List of CSGs*	Recruitment (INy) during 23-24	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Recruitment to Target (%)**	Median ALL FPFV* (days)	Proportion (%) < 30 days
Cardiovascular	12	10.71%	7	13.46%		68.0	16.67%
Child Health							
COVID Delivery Team	5	4.46%	4	7.69%		7.0	100.00%
Critical Care	16	14.29%	7	13.46%	86.67%	123.0	28.57%
Diabetes	0	0.00%	1	1.92%			
Gastroenterology							
Mental Health	7	6.25%	1	1.92%		99.0	0.00%
Neurodegenerative							
Orthopaedics							
Primary Care	44	39.29%	12	23.08%	100.00%	24.0	54.55%
Renal	10	8.93%	5	9.62%	30.00%	98.0	20.00%
Respiratory Health	12	10.71%	8	15.38%	100.00%	89.0	14.29%
Stroke	6	5.36%	7	13.46%	42.00%	356.0	0.00%
Vision							
Totals:	112	100.00%	52	100.00%	85.33%	62.0	32.56%

\* CSG names highlighted in purple are active within trust area  
 \*\*Median RT Metrics calculated on Active Studies which have closed to recruitment

# Staffing Update

## Staff training events

The Annual Report is an opportunity to showcase our excellent NICRN staff; how we perform against regional and national targets, and the progress we make as we learn from best practice. The maintenance of an engaged skilled and capable workforce is crucial to the effective operation of our network. Our team is comprised of skilled hard working professionals from a variety of backgrounds including Nurses, Midwives, Optometrists, Physiotherapists, Physiologists, Psychologists, Ophthalmic Imaging Specialist and Clinical Trial Assistants. We want to pay tribute to our staff who meet the challenges and pressures across our service and continue to deliver safe, compassionate, and effective care.



**Figure 21: NICRN Conference 2023**

During 2023/24 we were delighted to welcome fourteen new Coordinators and two new Clinical Trial Assistants to our network. Staff management continued to meet the work/life balance needs of our workforce by supporting our staff through significant life events. To continue to promote staff wellbeing we were pleased to enable staff requests for flexible working, throughout the Trusts, according to the appropriate policies and procedures. Sadly, this year, we said goodbye to all of our Primary Care (PC) team but wished them a long and happy retirement. We are looking forward to engaging with a 'new look' PC team in the coming year. A further seven staff unfortunately left us throughout the year but we were delighted for them as they all gained promotion within the NHS.

Thoughts from a recent joiner and leaver:

*"Recently joining the NICRN, the team in the office have been brilliant! Everyone comes from a different background of nursing and brings a diverse range of knowledge and experience. The training has been really thorough and the team have been so patient with my endless questions. Management have been so supportive and kind, it's a really lovely team to be part of."* - Emma

*“I do miss work and the people I was lucky enough to work with. I can’t believe how my life has changed in the past year. The support I’ve been afforded by the management team has been humbling.*

*Very often I’ve heard people say that Nurses are not kind to each other. This has not been my experience thankfully.*

*I wish the NICRN every success in the future.” - Marina*

One of the key successes this year has been changing our recruitment strategy to create a generic waiting list of Allied Health Professionals and Nursing staff as a responsive tool to meet the demands of our service. This approach has been relatively effective and staff have embraced the opportunity to work beyond the confines of their past experience and across CSGs. However some posts have remained harder to fill due to the perceived need for ‘specific’ skills. We continue to maintain a full workforce that meets the needs of the service and welcome and encourage feedback from all sources.

To capitalise on the current workforce’s ability to deliver, it was essential for staff management to operate strategically using the available skill mix. An opportunity to deliver the NIHR My Diabetes and Me study was presented to the network. As this study specifically recruited from the Learning Disability community we realigned our existing CRL capacity to ensure an inclusive approach since this specific interest group was not reflected in our current CSGs. Another example of collaborative working is the ongoing delivery of the FAME 1 Eye Trial. BHSC are the only European site delivering this trial and it has involved staff working across two disciplines to ensure the smooth delivery and recruitment to time and target.

Ongoing training of staff is essential in developing staff skillsets appropriate to the rapidly changing clinical research environment.

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

- Alzheimer’s Association International Conference (AAIC)
- Association of British Pharmaceutical Industry (ABPI)
- British heart Foundation Conference
- Critical Care Reviews
- Cystic Fibrosis Conference
- International Nurses’ Day
- International Clinical Trials Day
- NICRN Day
- Ophthalmic Technicians Introduction Course
- RCN International Nursing Research Conference
- RCN Clinical Research Nursing Conference
- UK Stroke Conference

Staff continuously update and maintain their statutory and mandatory training through e-learning and NICRN staff have also been supported throughout 2023-24, to attend investigators meetings across UK & Europe. We celebrated the success of two of our current staff members gaining their Master Degrees this year and the many achievements of all staff including the Certificates of Recognition received by many colleagues.

Looking forward to the coming year we have highlighted some potential areas for development. A work in progress is addressing the lack of opportunity for promotion for the clinical team. To encourage the entry into the research environment we engaged with Nursing/Midwifery and AHP students in QUB. We have introduced a new post of Clinical Trial Assistant to enhance access opportunities. To broaden the experience and upskill existing staff we will look for opportunities to collaborate with our research partners and share knowledge.



Figure 22: NICRN Staff Manager Sonia McKenna encouraging entry level to research at QUB event.

## Administrative Staff News



**Figure 23 and 24: Senior Portfolio manager, Shane Jackson and Chris Wright receiving certificates of Recognition.**

Our regional Network Portfolio Manager, Mr. Shane Jackson received a Certificate of Recognition from the BHSCT chief executive, Dr Cathy Jack, in recognition of his outstanding dedication to clinical research reporting. Shane was recognised for his flexibility and agility when answering urgent requests, his dedication to the regional reporting platform, often working under great pressure and his willingness to go above and beyond what is expected.

Over 2023/24 the HSC environment embarked on the deployment of a new clinical management tool, Encompass.

Encompass is a HSC programme creating a single digital care record for every citizen in NI engaging with HSC. It will provide patients and service users with the ability to view and update their health information online. It will also make it easier for HSC staff to view all the relevant information about their patients both in clinical and community settings.

Over this reporting period Encompass was deployed across the South Eastern HSC Trust in September of 2023. Its deployment meant that NICRN's Local Portfolio Management System, EDGE, would no longer be the appropriate repository for the relevant patient related data for our eligible study portfolio. This resulted in a huge body of work for our portfolio team in ensuring the NICRN could still access and report on our portfolio whilst enabling the HSC Trusts to deploy Encompass as efficiently as possible whilst retaining functionality for our clinical teams at site. This involved a thorough quality control audit and subsequent data cleanse of the existing participant data held in the NICRN EDGE instance. It was necessary to complete an organisational data transfer template in which all participant related data items; clinical users, forms and fields had to be verified before sign off. The work package took several weeks and involved multiple stakeholders but we are very pleased to say that the data was migrated successfully before the site went live on the 9<sup>th</sup> November 2023.

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

<b>Table 2</b>	<b>HSC Trust</b>	<b>2018/2019 WTE Deployed</b>	<b>2019/2020 WTE Deployed</b>	<b>2020/2021 WTE Deployed</b>	<b>2021/2022 WTE Deployed</b>	<b>*2022/2023 WTE Deployed</b>	<b>2023/2024 WTE Deployed</b>
	<b>BHSCT</b>	29.43	29.83	27.08	28.63	32.60	27.70
	<b>NHSCT</b>	4.85	4.00	4.50	4.50	5.50	4.00
	<b>SEHSCT</b>	5.30	3.80	4.80	3.30	4.30	3.30
	<b>SHSCT</b>	4.80	4.00	5.35	4.80	5.80	5.30
	<b>WHsCT</b>	5.00	4.50	3.85	5.35	5.65	4.60
	<b>TOTAL</b>	<b>49.38</b>	<b>46.13</b>	<b>45.58</b>	<b>46.58</b>	<b>53.85</b>	<b>44.90</b>

The figures in table 2 above show the total WTE deployed across each of the HSC Trusts over the last the last 6 years. There is relative stability across these values until 2022/23. The increase of 7 WTE relates to the temporary increase in staff from the dedicated COVID delivery team.

**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	2022/2023 WTE funded		2022/2023 WTE Staff in Post (as at 31/03/2023)		No. Staff in Post (as at 31/03/2023)	CSG	2023/2024 WTE funded		2023/2024 WTE Staff in Post (as at 31/03/2024)		No. Staff in Post (as at 31/03/2024)
	PHA funded	Non-PHA funded	PHA funded	Non-PHA funded			PHA funded	Non-PHA funded	PHA funded	Non-PHA funded	
Cardiovascular	5.30		4.05		12	Cardiovascular	5.30		4.80		12
Child Health	3.50		3.30		7	Child Health	3.50		3.06		6
Critical Care	6.30		5.90		11	Critical Care	6.05		5.35		10
Diabetes	3.50		2.50		7	Diabetes	3.50		3.00		6
Gastroenterology	1.50	0.50	1.50	0.50	4	Gastroenterology	1.50		1.00		2
Mental Health	2.00		1.00		1	Mental Health	2.00		1.00		1
Neurodegenerative	2.00	2.00	1.50	2.00	5	Neurodegenerative	2.00	2.00	2.00	1.40	5
Orthopaedics	1.00		0.50		1	Orthopaedics	1.00		0.50		1
Primary Care	2.50		2.50		3	Primary Care	2.60		1.00		0
Renal	3.80		3.30		6	Renal	3.30		3.30		7
Respiratory Health	6.00	2.50	2.80	2.00	11	Respiratory Health	6.25		5.85		9
Stroke	3.85		2.85		7	Stroke	3.80		2.90		5
Vision	3.60		2.10		5	Vision	3.60		2.40		6
COVID	9.00		8.50		12	Generic / SHSCT	0.50		0.50		1
<b>Total</b>	<b>53.85</b>	<b>5.00</b>	<b>42.30</b>	<b>4.50</b>	<b>92.00</b>	<b>Total</b>	<b>44.90</b>	<b>2.00</b>	<b>36.66</b>		<b>71</b>

\* includes B6 and B7 staff

## Portfolio metrics

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

Fundamental to the success of NICRN is the ability to deliver high quality data on time and with confidence. This underpins the integrity of our portfolio. The headline figures from this year's portfolio report would suggest sustained modest growth in most areas, using well established key metrics. The total number of active studies this year (191) is on a par with results reported over the last 5 years and indicates a return to pre-pandemic levels. Please note when reference is made to the figure 193 for "Total Number of Active Studies", this reflects on 2 studies which were delivered by 2 CSG's at the same time.

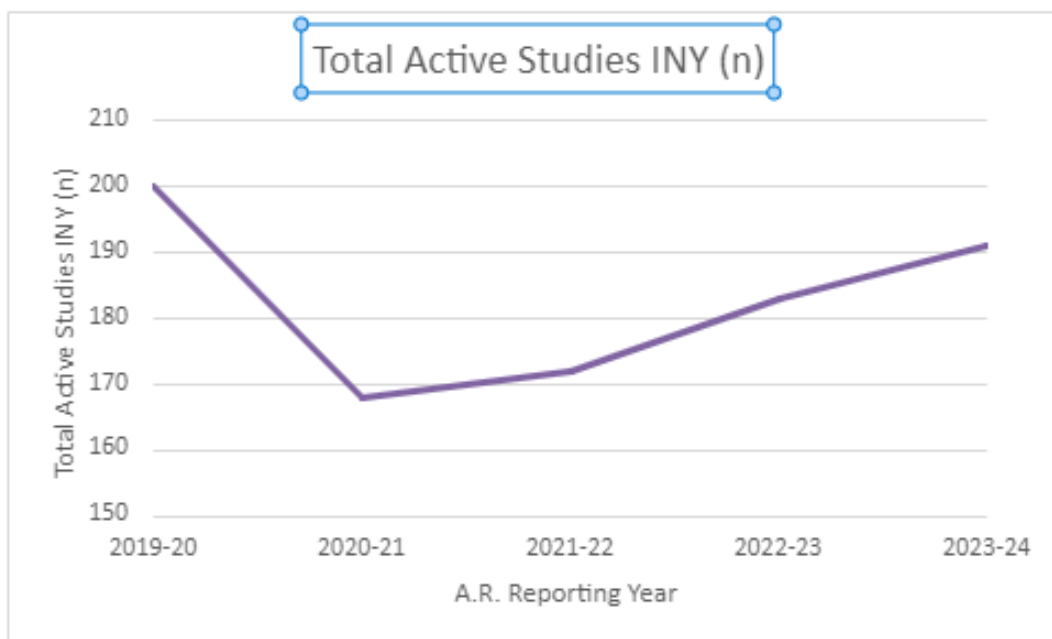
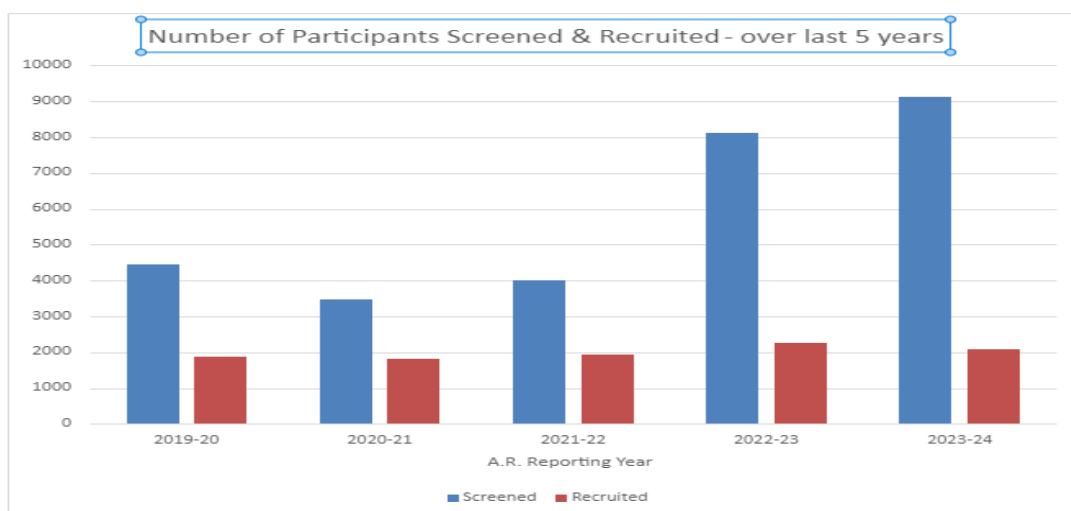


Figure 25: Total active studies for this year (191) marks a return to pre-pandemic levels.



**Figure 26: Illustrates the relative stability in recruitment figures over the last 5 years and our variability around levels of screening to achieve our recruitment targets**

All of the research activity data presented in our Annual Report comes from a local portfolio management system (EDGE). Shane Jackson and his team have worked tirelessly in partnership with our study delivery teams, and partnering organisations, to ensure the timeliness and accuracy of the research activity data which is entered into EDGE.

### **EDGE 3 goes live (May 2023)**

EDGE v2 was first deployed, as a newly released version, in NI in October 2012. In May 2023 EDGE v3 was released in the UK, having been significantly delayed by the COVID-19 pandemic. EDGE V3 represented a total root and branch upgrade, an essential redevelopment of the entire EDGE system that we had all been waiting for. The NICRN Team worked regionally within NI to collate issues and provide feedback directly to the EDGE developers based in Southampton. The local team were used to troubleshoot the new system and ensure that it was being deployed to meet the specific needs of NI as a region.

### **ENCOMPASS Clinical Management System and EDGE 3 Interface Development**

In May 2021 the possibility of linking a new clinical management system for NI called ENCOMPASS with EDGE was first discussed. It was conceived that there could be significant advantages gained by collecting the research activity data directly in the clinical management system (ENCOMPASS) and then sending it through an interface into the research portfolio management system (EDGE). This proposed interface development will be the first of its kind in the UK where a clinical management system is directly linked to a portfolio management system. Fast forward to this reporting year, when ENCOMPASS was deployed to the SEHSCT (November 2023). Shane Jackson and the coordination centre team were brought in by EDGE to provide user requirements to inform the design of the interface. This essential intervention in the development process ensured that the planned end product will be fit for purpose and meet operational needs in NI.

The tables that follow, accompanied with explanatory captions, illustrate the in year activity across all CSGs and Trusts.

**Table 4: Total number of new studies supported in year, studies closed in year and total number of active studies in year compared over the last 5 years.**

A.R. Reporting Year	In Year TOTALS		
	New Studies INY (n)	Studies Closed INY (n)	Total Active Studies INY (n)
2019-20	52	65	200
2020-21	24	59	168
2021-22	54	30	172
2022-23	43	29	183
2023-24	42	52	193

**Note:** New Studies are eligible studies which have been supported by NICRN and therefore added to the portfolio during the reporting period. Studies Closed are studies which have ended activity and have closed during the reporting period. Also please note Total Active Studies will always include all New Studies and Studies Closed but also includes all other active studies during the reporting period for example studies closed to recruitment but in follow up.

**Table 5: Total number of new studies supported in year, studies closed in year and total number of active studies in year by CSG, compared over the last 5 years.**

A.R. Reporting Year	CCA			CHI			CRV			DIA			GAS			A.R. Reporting Year
	New Studies INY (n)	Studies Closed INY (n)	Total Active Studies INY (n)	New Studies INY (n)	Studies Closed INY (n)	Total Active Studies INY (n)	New Studies INY (n)	Studies Closed INY (n)	Total Active Studies INY (n)	New Studies INY (n)	Studies Closed INY (n)	Total Active Studies INY (n)	New Studies INY (n)	Studies Closed INY (n)	Total Active Studies INY (n)	
2019-20	11	5	28	5	3	14	6	11	37	3	1	9	5	3	10	2019-20
2020-21	3	4	20	5	5	12	6	11	33	0	3	9	0	4	10	2020-21
2021-22	8	6	25	7	2	14	1	5	25	2	0	7			9	2021-22
2022-23	7	2	22	5	0	18	5	4	25	4	1	11	4	3	11	2022-23
2023-24	0	8	21	4	5	21	9	4	31	3	3	12	4	3	11	2023-24
A.R. Reporting Year	MHT			NEU			ORT			PCR			REN			A.R. Reporting Year
	New Studies INY (n)	Studies Closed INY (n)	Total Active Studies INY (n)	New Studies INY (n)	Studies Closed INY (n)	Total Active Studies INY (n)	New Studies INY (n)	Studies Closed INY (n)	Total Active Studies INY (n)	New Studies INY (n)	Studies Closed INY (n)	Total Active Studies INY (n)	New Studies INY (n)	Studies Closed INY (n)	Total Active Studies INY (n)	
2019-20	3	2	8	0	5	7				3	5	9	1	5	14	2019-20
2020-21	0	5	8	0	1	3				1	1	9	1	6	12	2020-21
2021-22	2	0	6	1	2	3	6	0	6	3	5	9			11	2021-22
2022-23	0	3	6	1	1	3	4	1	10	2	1	6	3	0	11	2022-23
2023-24	0	2	3	3	1	5	1	1	10	0	2	6	4	3	15	2023-24
A.R. Reporting Year	RES			STR			VIS			CDT			A.R. Reporting Year			
	New Studies INY (n)	Studies Closed INY (n)	Total Active Studies INY (n)	New Studies INY (n)	Studies Closed INY (n)	Total Active Studies INY (n)	New Studies INY (n)	Studies Closed INY (n)	Total Active Studies INY (n)	New Studies INY (n)	Studies Closed INY (n)	Total Active Studies INY (n)				
2019-20	6	15	32	5	3	14	4	7	18							2019-20
2020-21	4	9	21	1	4	12	3	6	19							2020-21
2021-22	12	4	25	5	2	12	7	4	20							2021-22
2022-23	2	7	22	2	2	12	4	4	20	0	0	6				2022-23
2023-24	9	4	22	1	4	10	4	10	20	0	2	6				2023-24

**Table 6: The total number of NICRN supported studies active in each HSC Trust.**

A.R. Reporting Year	Total Active Studies - In Year TOTALS					Study / Sites
	BHSCT	NHSCT	SEHSCT	SHSCT	WHSCT	
2019-20	138	37	28	44	36	283
2020-21	120	41	36	39	36	272
2021-22	130	41	37	43	35	286
2022-23	140	57	35	40	34	306
2023-24	154	47	44	44	52	341

**Note:** the numbers here describe the number of active studies running within each HSCT area. Please note that active studies can be running in several HSCT areas simultaneously

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

**Table 7: Total number and proportion (P<sup>^</sup>) of Active commercial/non-commercial studies in NICRN portfolio.**

A.R. Reporting Year	in Year Totals				Total No of Studies
	Comm		Non-Comm		
	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	
2019-20	69	34.50%	131	65.50%	<b>200</b>
2020-21	58	34.52%	110	65.48%	<b>168</b>
2021-22	49	28.49%	123	71.51%	<b>172</b>
2022-23	47	25.68%	136	74.32%	<b>183</b>
2023-24	60	31.09%	133	68.91%	<b>193</b>

**Note:** Within NICRN we have taken the approach of balancing the commercial vs non-commercial elements of our portfolio to maintain an approximate 40:60 split. This is to try and maintain a balance across the more academically sought NIHR and other Association of Medical Research Charity (AMRC) funders and the commercial sector. We note over the 2023-24 reporting period we have seen an increase in number of commercial studies and also a 5% increase in commercial proportionate share.

**Table 8: Total number and proportion (P<sup>^</sup>) of Active (interventional/observational/not specified) studies in NICRN portfolio.**

A.R. Reporting Year	In Year Totals (Study Designs)						Total No of Studies
	Interventional		Observational		Not Specified		
	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	
2019-20	143	71.50%	56	28.00%	1	0.50%	200
2020-21	120	72.73%	45	27.27%	0	0.00%	165
2021-22	115	71.43%	46	28.57%	0	0.00%	161
2022-23	126	68.85%	57	31.15%	0	0.00%	183
2023-24	128	66.32%	65	33.68%	0	0.00%	193

**Note:** This breakdown has remained relatively stable over the last 5 years, although we note a slight increase in observational studies bringing them to their highest levels over the last 5 years. Specialities are asked to balance their portfolio across observational and interventional study design to maximise the participant recruitment and engagement with research teams.

## Portfolio activity: Recruitment (Patients screened and accrued)

**Table 9: The total numbers of patients screened and recruited over the last 5 reporting years.**

A.R. Reporting Year	In Year TOTALS	
	Screened	Recruited
2019-20	4437	1868
2020-21	3463	1818
2021-22	3991	1932
2022-23	8133	2261
2023-24	9128	2078

**Note:** This table demonstrates that the amount of screening and recruitment has remained relatively stable this year when compared to last 2 years.

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

**Table 10: Total numbers recruited into Active interventional/observational/not specified studies across NICRN portfolio.**

A.R. Reporting Year	In Year Totals (Recruitment)			Total Recruitment
	Interventional	Observational	Not Specified	
2019-20	747	1121	0	1868
2020-21	1346	478	0	1824
2021-22	1302	630	0	1932
2022-23	1002	1259	0	2261
2023-24	953	1125	0	2078

**Table 11: Total numbers recruited into Active commercial and non-commercial studies across NICRN portfolio.**

A.R. Reporting Year	In Year Totals (Recruitment)		Total Recruitment
	Commercial	Non-Commercial	
2019-20	86	1782	1868
2020-21	23	1801	1824
2021-22	103	1829	1932
2022-23	80	2181	2261
2023-24	179	1899	2078

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

**Table 12: Median percentage target recruitment attained across the total NICRN study portfolio.**

A.R. Reporting Year	In Year Total Median (% RtT)
2019-20	75.16%
2020-21	80.03%
2021-22	86.34%
2022-23	87.00%
2023-24	87.06%

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 metric's 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 the last 4 years back to a regional level of 87%

in 2022-23 and this has been slightly improved to 87.06% in 2023-24 (Table 12). We have observed continued stability in our median % RtT for our observational portfolio from 100% to 96% as seen in Table 13 (range 0%-270% appendix 7). As can be seen in Table 14 the network has significantly increased the median % RtT from approximately 66% to 80% for our commercial portfolio and have maintained our median % RtT for our non-commercial portfolio at a very creditable 96%.

**Table 13: Total median % RtT in interventional/observational/not specified studies across NICRN portfolio.**

<b>Median across CSGs (RtT%)</b>			
<b>A.R. Reporting Year</b>	<b>Interventional</b>	<b>Observational</b>	<b>Not Specified</b>
<b>2019-20</b>	73.40%	89.48%	11.11%
<b>2020-21</b>	73.36%	100.00%	
<b>2021-22</b>	74.61%	96.28%	
<b>2022-23</b>	85.00%	100.00%	
<b>2023-24</b>	84.00%	95.83%	

**Table 14: Total median % RtT in commercial and non-commercial studies across NICRN portfolio.**

<b>Median across CSGs (RtT%)</b>		
<b>A.R. Reporting Year</b>	<b>Commercial</b>	<b>Non-Commercial</b>
<b>2019-20</b>	78.89%	94.90%
<b>2020-21</b>	62.61%	80.74%
<b>2021-22</b>	67.72%	80.74%
<b>2022-23</b>	65.72%	98.33%
<b>2023-24</b>	80.00%	96.12%

**Table 15: Median % recruitment to target (RtT) attained across the recruitment sites of studies at each HSC Trust.**

HSC Trust	Totals 2019-20		Totals 2020-21		Totals 2021-22		Totals 2022-23		Totals 2023-24		HSC Trust
	No. Recruitment Sites	Median % RtT	No. Recruitment Sites	Median % RtT	No. Recruitment Sites	Median % RtT	No. Recruitment Sites	Median % RtT	No. Recruitment Sites	Median % RtT	
BHSCT	138	78.71%	120	65.37%	130	81.35%	140	80.00%	154	80.00%	BHSCT
NHSCT	37	49.78%	41	89.32%	41	80.75%	57	48.33%	47	100.00%	NHSCT
SEHSCT	28	100.00%	36	75.00%	37	75.00%	35	74.61%	44	100.00%	SEHSCT
SHSCT	44	96.91%	39	80.91%	43	62.63%	40	78.13%	44	100.00%	SHSCT
WHSCT	36	85.42%	36	84.33%	35	68.13%	34	63.67%	52	85.33%	WHSCT

**Note:** The WHSCT has joined the BHSCT in now having delivered a steady state return to pre-COVID levels of median % RtT and we have observed dramatic increases in the other three HSC Trusts each delivering a median % RtT value of 100%.

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

The First Patient First Visit (FPFV) window (number of days from site opening to recruitment and first participant recruited) 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 16-18 we show the FPFV windows over the last 5 years for our commercial and non-commercial portfolios across all CSG's. Table 18 also shows what P^ of these studies achieved the <30-day window.

**Table 16: First patient first visit (FPFV) intervals expressed as median number of days for the Commercial study portfolio at each HSC Trust.**

		Commercial					
HSC Trust	All CSGs 2019-20 FPFV (days)	All CSGs 2020-21 FPFV (days)	All CSGs 2021-22 FPFV (days)	All CSGs 2022-23 FPFV (days)	All CSGs 2023-24 FPFV (days)	HSC Trust	
BHSCT	68.7	29.0	75.3	85.0	52.5	BHSCT	
NHSCT	115.8	217.0	220.5	28.5	30.0	NHSCT	
SEHSCT	36.7	40.0	39.8	40.5	40.5	SEHSCT	
SHSCT	87.3	130.8	146.5	146.5	69.0	SHSCT	
WHSCT	36.3	257.0	235.5	59.0	85.0	WHSCT	
All trusts	68.9	134.8	143.5	71.9	52.5	All trusts	

**Note:** In last year's report we committed to continue our focus in seeking to reduce the median FPFV number for the commercial portfolio and we have met this objective, over all Trusts, we have improved to a median FPFV number of 52.5 days. This improved metric being delivered while also participating in an increased number of, and proportionate share of commercial studies. Whilst this represents an improvement it is still longer than the team would wish for and will therefore remain a focus that we continue to address over 24/25, especially in relation to how the Northern Ireland HSC environment reacts to the O'Shaughnessy report.

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

		Non-Commercial					
HSC Trust	All CSGs 2019-20 FPFV (days)	All CSGs 2020-21 FPFV (days)	All CSGs 2021-22 FPFV (days)	All CSGs 2022-23 FPFV (days)	All CSGs 2023-24 FPFV (days)	HSC Trust	
BHSCT	37.3	34.8	39.7	33.5	37.0	BHSCT	
NHSCT	57.3	26.3	73.2	24.0	40.0	NHSCT	
SEHSCT	105.5	27.0	28.8	21.5	26.0	SEHSCT	
SHSCT	64.1	42.5	91.0	39.3	47.0	SHSCT	
WHSCT	74.4	21.0	86.0	31.0	50.5	WHSCT	
All trusts	67.7	30.3	63.7	29.9	38.0	All trusts	

**Note:** Last year we achieved the best FPFV data for the non-commercial section having met the national target of lower than 30 days. This year we have slipped back slightly to a sector median value of 38 days. This may be due to increased focus on the commercial sector.

**Table 18: First patient first visit (FPFV) intervals expressed as median number of days for the Non-Commercial / Commercial study portfolios, also includes Proportion (P<sup>^</sup>) of those studies achieving FPFV < 30days.**

A.R. Reporting Year	In Year Totals					
	Commercial		Non-Commercial		Combined (All Studies)	
	Median FPFV (days)	P <sup>^</sup> Studies < 30 days	Median FPFV (days)	P <sup>^</sup> Studies < 30 days	Median FPFV (days)	P <sup>^</sup> Studies < 30 days
2019-20	51.1	44.52%	46.7	50.49%	49.0	47.67%
2020-21	58.3	38.94%	50.7	48.15%	54.6	43.91%
2021-22	77.6	21.09%	60.7	48.11%	68.9	36.44%
2022-23	88.5	31.55%	55.2	52.02%	70.0	43.93%
2023-24	52.5	37.50%	38.0	44.40%	41.0	43.10%

**Note:** Table 18 shows the P<sup>^</sup> of commercial and non-commercial studies that are achieving the <30-day metric. The table shows for 2023-24 that across each sector (Commercial, Non-Commercial and Combined), we have significantly reduced the median FPFV window number and have therefore made significant progress toward the national target of <30 days. We have also noticed an increase proportion of our commercial studies achieved a FPFV window of < 30 days, rising from 31.55% (2022-23) to 37.50% (2023-24).

# Patient and Public Involvement (PPI) Engagement

Over the 2023/24 reporting period very little strategic or operational change occurred within the PPI environment. One major change proposed and being worked on over this time was the establishment of PPI at a more strategic level within the broader network structure. To date the PPI position within NICRN has been very much focused on embedding representation within the clinical management groups. However over 2023/24 we have engaged with the Directors of research and development from each of the 5 HSC Trusts alongside the director and assistant director of the HSC R&D division to develop a new governance model for the NICRN and its partners. The relationships and the positioning of PPI central to the majority of our new oversight groups is illustrated in the schematic below (Figure 27). The NICRN team would wish to thank Mrs Margaret Grayson Chair of NCI/CRUK Cancer Grand Challenges Advocacy for her invaluable input and support throughout this period.

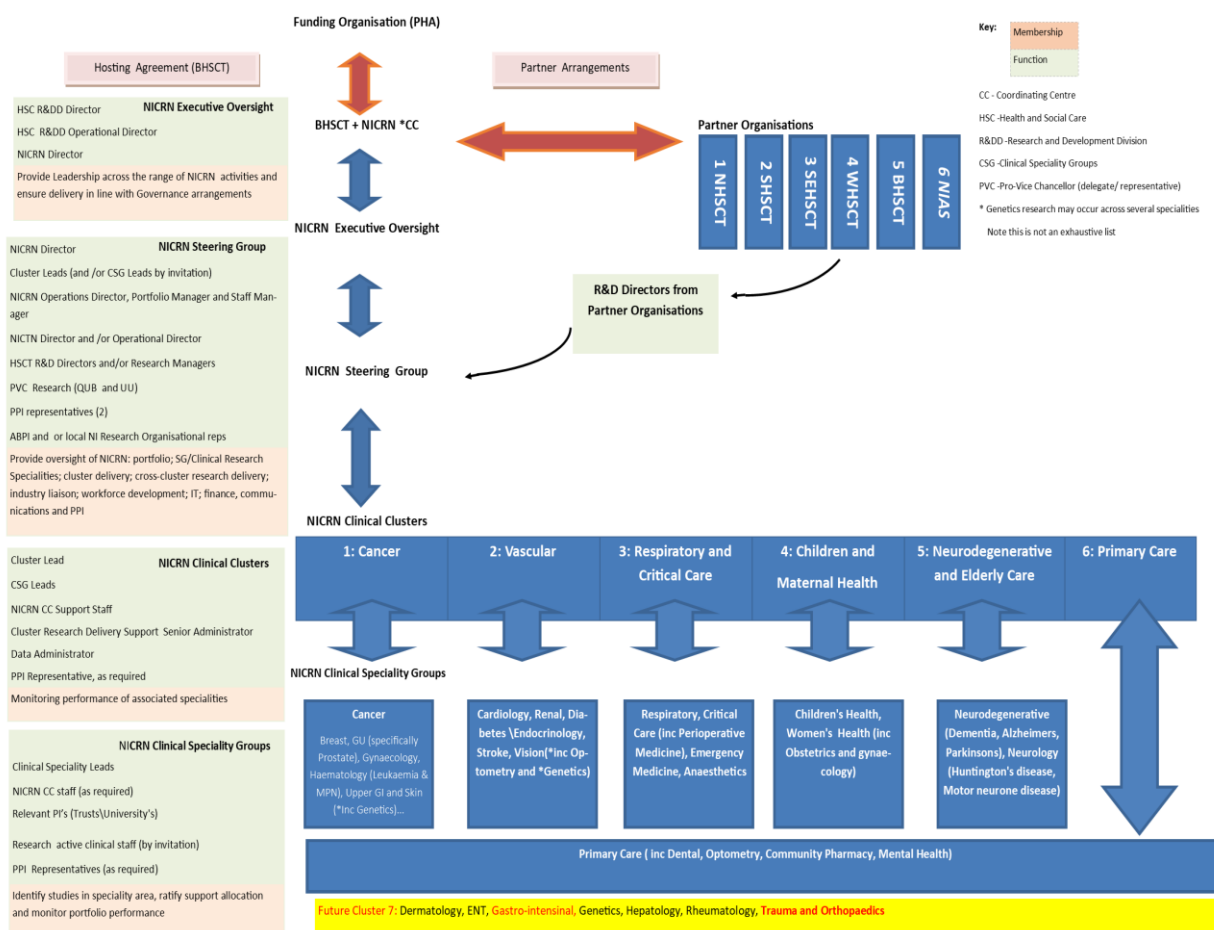


Figure 27: Illustrates the proposed new governance model across the active HSC stakeholders. As can be seen on the left we are intending to embed PPI representation at several oversight platforms.

# Appendices

## Appendix 1 - Additional data for Portfolio breakdown: Study numbers and Proportion (P^A) by funding type (commercial, non-commercial sponsorship)

A.R. Reporting Year	CRV				CHI				CCA				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	
	No of Studies	P^A(%)	No of Studies	P^A(%)	No of Studies	P^A(%)	No of Studies	P^A(%)	No of Studies	P^A(%)	No of Studies	P^A(%)	No of Studies	P^A(%)	No of Studies	P^A(%)	No of Studies	P^A(%)	No of Studies	P^A(%)	No of Studies	P^A(%)	No of Studies	P^A(%)	No of Studies	P^A(%)	No of Studies	P^A(%)
2019-20	17	45.95%	20	54.05%	2	14.29%	12	85.71%	1	3.57%	27	96.43%	5	55.56%	4	44.44%	6	60.00%	4	40.00%	2	25.00%	6	75.00%	1	14.29%	6	85.71%
2020-21	15	45.45%	18	54.55%	2	16.67%	10	83.33%	0	0.00%	20	100.00%	5	55.56%	4	44.44%	7	70.00%	3	30.00%	3	37.50%	5	62.50%	0	0.00%	3	100.00%
2021-22	11	44.00%	14	56.00%	2	14.29%	12	85.71%	1	40.00%	24	96.00%	5	71.43%	2	28.57%	5	55.56%	4	44.44%	2	33.33%	4	66.67%	0	0.00%	3	100.00%
2022-23	9	36.00%	16	64.00%	3	16.67%	15	83.33%	1	4.55%	21	95.45%	7	63.64%	4	36.36%	6	54.55%	5	45.45%	2	33.33%	4	66.67%	0	0.00%	3	100.00%
2023-24	18	58.06%	13	41.94%	2	9.52%	19	90.48%	1	4.76%	20	95.24%	7	58.33%	5	41.67%	8	72.73%	3	27.27%	1	33.33%	2	66.67%	1	20.00%	4	80.00%

A.R. Reporting Year	ORT				PCR				REN				RES				STR				VIS				CDT			
	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^A(%)	No of Studies	P^A(%)	No of Studies	P^A(%)	No of Studies	P^A(%)	No of Studies	P^A(%)	No of Studies	P^A(%)	No of Studies	P^A(%)	No of Studies	P^A(%)	No of Studies	P^A(%)	No of Studies	P^A(%)	No of Studies	P^A(%)	No of Studies	P^A(%)	No of Studies	P^A(%)	No of Studies	P^A(%)
2019-20					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					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%	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%				
2022-23	0	0.00%	10	100.00%	1	16.67%	5	83.33%	2	18.18%	9	81.82%	6	27.27%	16	72.73%	1	8.33%	11	91.67%	9	45.00%	11	55.00%	0	0.00%	6	100.00%
2023-24	0	0.00%	10	100.00%	1	16.67%	5	83.33%	3	20.00%	12	80.00%	8	36.36%	14	63.64%	1	10.00%	9	90.00%	9	45.00%	11	55.00%	0	0.00%	6	100.00%

## Appendix 2 - Additional data for Portfolio breakdown: Study numbers and Proportion (P<sup>^</sup>) by design type (observational, interventional, not specified)

A.R. Reporting Year	CRV (Study Design)						CHI (Study Design)						CCA (Study Design)						DIA (Study Design)						GAS (Study Design)					
	Int		Obs		Not Spec		Int		Obs		Not Spec		Int		Obs		Not Spec		Int		Obs		Not Spec		Int		Obs		Not Spec	
	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)
2018-19	29	76.32%	9	23.68%	0	0.00%	7	63.64%	4	36.36%	0	0.00%	13	72.22%	4	22.22%	1	5.56%	7	77.78%	2	22.22%	0	0.00%	4	50.00%	4	50.00%	0	0.00%
2019-20	29	78.38%	8	21.62%	0	0.00%	10	71.43%	4	28.57%	0	0.00%	20	74.07%	7	25.93%	0	0.00%	7	77.78%	2	22.22%	0	0.00%	7	70.00%	3	30.00%	0	0.00%
2020-21	27	81.82%	6	18.18%	0	0.00%	8	66.67%	4	33.33%	0	0.00%	15	75.00%	5	25.00%	0	0.00%	6	66.67%	3	33.33%	0	0.00%	6	60.00%	2	20.00%	0	0.00%
2021-22	21	84.00%	4	16.00%	0	0.00%	9	64.29%	5	35.71%	0	0.00%	9	64.29%	5	35.71%	0	0.00%	4	57.14%	3	42.86%	0	0.00%	8	88.89%	1	11.11%	0	0.00%
2022-23	19	76.00%	6	24.00%	0	0.00%	13	72.22%	5	27.78%	0	0.00%	15	68.18%	7	31.82%	0	0.00%	6	54.55%	5	45.45%	0	0.00%	9	81.82%	2	18.18%	0	0.00%
2023-24	24	77.42%	7	22.58%	0	0.00%	13	61.90%	8	38.10%	0	0.00%	15	71.43%	6	28.57%	0	0.00%	6	50.00%	6	50.00%	0	0.00%	8	72.73%	3	27.27%	0	0.00%

A.R. Reporting Year	MHT (Study Design)						NEU (Study Design)						ORT (Study Design)						PCR (Study Design)						REN (Study Design)					
	Int		Obs		Not Spec		Int		Obs		Not Spec		Int		Obs		Not Spec		Int		Obs		Not Spec		Int		Obs		Not Spec	
	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)
2018-19	3	50.00%	3	50.00%	0	0.00%	4	57.14%	3	42.86%	0	0.00%							6	54.55%	2	18.18%	3	27.27%	8	38.10%	13	61.90%	0	0.00%
2019-20	6	66.67%	3	33.33%	0	0.00%	4	57.14%	3	42.86%	0	0.00%							7	77.78%	1	11.11%	1	11.11%	6	42.86%	8	57.14%	0	0.00%
2020-21	5	62.50%	3	37.50%	0	0.00%	1	33.33%	2	66.67%	0	0.00%							6	75.00%	2	25.00%	0	0.00%	6	50.00%	6	50.00%	0	0.00%
2021-22	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%	7	75.51%	2	50.00%	0	0.00%	6	70.21%	5	45.45%	0	0.00%
2022-23	4	66.67%	2	33.33%	0	0.00%	2	66.67%	1	33.33%	0	0.00%	8	80.00%	2	20.00%	0	0.00%	3	50.00%	3	50.00%	0	0.00%	5	45.45%	6	54.55%	0	0.00%
2023-24	2	66.67%	1	33.33%	0	0.00%	3	60.00%	2	40.00%			7	70.00%	3	30.00%	0	0.00%	5	83.33%	1	16.67%	0	0.00%	8	53.33%	7	46.67%	0	0.00%

A.R. Reporting Year	RES (Study Design)						STR (Study Design)						VIS (Study Design)						CDT (Study Design)											
	Int		Obs		Not Spec		Int		Obs		Not Spec		Int		Obs		Not Spec		Int		Obs		Not Spec		Int		Obs		Not Spec	
	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)
2018-19	18	66.67%	9	33.33%	0	0.00%	9	75.00%	3	25.00%	0	0.00%	13	76.47%	4	23.53%	0	0.00%												
2019-20	23	71.88%	9	28.13%	0	0.00%	11	78.57%	3	21.43%	0	0.00%	13	72.22%	5	27.78%	0	0.00%												
2020-21	15	71.43%	6	28.57%	0	0.00%	10	83.33%	2	16.67%	0	0.00%	15	78.95%	4	21.05%	0	0.00%												
2021-22	17	68.00%	8	32.00%	0	0.00%	10	83.33%	2	16.67%	0	0.00%	15	75.00%	5	25.00%	0	0.00%												
2022-23	14	63.64%	8	36.36%	0	0.00%	10	83.33%	2	16.67%	0	0.00%	13	65.00%	7	35.00%	0	0.00%	5	83.33%	1	16.67%	0	0.00%						
2023-24	14	63.64%	8	36.36%			9	90.00%	1	10.00%	0	0.00%	9	45.00%	11	55.00%			5	83.33%	1	16.67%	0	0.00%						

### Appendix 3 – Additional data for Portfolio activity: Recruitment (Patients screened and accrued)

A.R. Reporting Year	CRV		CHI		CCA		DIA		GAS		MHT		NEU	
	Scr	Rec	Scr	Rec	Scr	Rec	Scr	Rec	Scr	Rec	Scr	Rec	Scr	Rec
2019-20	361	259	74	35	327	241	279	271	57	55	3	1	344	341
2020-21	57	49	153	150	2633	630	6	5	1	0	6	5	182	182
2021-22	100	90	330	92	1567	429	35	21	24	14	19	12	0	0
2022-23	221	99	138	79	1652	312	119	50	123	109	20	15	715	715
2023-24	2,061	121	364	151	2,156	538	123	34	37	17	31	28	309	307

A.R. Reporting Year	ORT		PCR		REN		RES		STR		VIS		CDT		in Year Totals	
	Scr	Rec	Scr	Rec	Scr	Rec	Scr	Rec	Scr	Rec	Scr	Rec	Scr	Rec	Screened	Recruited
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
2022-23	248	119	159	159	387	73	942	218	71	29	298	117	3040	167	8133	2261
2023-24	567	98	95	92	266	169	990	165	134	72	429	206	1,566	80	9,128	2078

## Appendix 4 – Additional data for Portfolio breakdown: Recruitment (Patients accrued by study design)

A.R. Reporting Year	CRV (recruitment)			CHI (recruitment)			CCA (recruitment)			DIA (recruitment)			NEU (recruitment)			GAS (recruitment)			MHT (recruitment)			ORT (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	Int	Obs	Not Spec
2019-20	35	224	0	12	23	0	126	115	0	43	228	0	0	341	0	2	53	0	1	0	0			
2020-21	14	35	0	26	124	0	487	143	0	5	0	0	168	14	0	0	0	0	5	0	0			
2021-22	78	12	0	31	61	0	218	211	0	0	21	0	0	0	0	2	12	0	10	2	0	39	33	0
2022-23	94	5	0	28	51	0	249	63	0	0	50	0	2	713	0	109	0	0	15	0	0	59	60	0
2023-24	73	48	0	87	64	0	403	135	0	12	22	0	3	304	0	2	15	0	28	0	0	73	25	0

A.R. Reporting Year	PCR (recruitment)			REN (recruitment)			RES (recruitment)			STR (recruitment)			VIS (recruitment)			CDT (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	Interventional	Observational	Not Specified
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	732	50	0	1	29	0	136	192	0	36	7	0	19	0	0				1302	630	0
2022-23	102	57	0	60	13	0	50	168	0	26	3	0	59	58	0	149	18	0	1002	1259	0
2023-24	92	0	0	33	136	0	39	126	0	47	25	0	18	188	0	43	37	0	953	1125	0

## Appendix 5 – Additional data for Portfolio breakdown: Recruitment (Patients accrued by funding type)

A.R. Reporting Year	CRV (recruitment)		CHI (recruitment)		CCA (recruitment)		DIA (recruitment)		GAS (recruitment)		MHT (recruitment)		NEU (recruitment)		ORT (recruitment)	
	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm
2019-20	7	252	7	28	0	241	25	246	1	54	0	1	0	341		
2020-21	12	37	0	150	0	630	6	5	0	0	0	5	0	182		
2021-22	54	36	3	89	0	429	21	0	1	13	0	12	0	0	0	72
2022-23	8	91	3	76	12	300	47	3	0	109	0	15	0	715	0	119
2023-24	66	55	0	151	10	528	13	21	11	6	0	28	0	307	0	98

A.R. Reporting Year	PCR (recruitment)		REN (recruitment)		RES (recruitment)		STR (recruitment)		VIS (recruitment)		CDT (recruitment)		in Year Totals (recruitment)	
	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Commercial	Non-Commercial
2019-20	0	145	5	104	16	110	6	57	19	203			86	1782
2020-21	0	20	0	72	4	689	0	4	1	7			23	1801
2021-22	0	782	1	29	4	324	0	43	19	0			103	1829
2022-23	1	158	0	73	0	218	0	29	9	108	0	167	80	2181
2023-24	0	92	0	169	26	139	25	47	28	178	0	80	179	1899

## Appendix 6 – Additional data for Portfolio activity: Recruitment to target (by clinical specialty group)

A.R. Reporting Year	CRV	CHI	CCA	DIA	NEU	GAS	MHT	PCR	REN	RES	STR	VIS	ORT	CDT	in Year Total Median (% RtT)
2019-20	80.00%	78.89%	70.00%	58.33%	60.00%	100.00%	29.79%	108.00%	65.40%	100.00%	71.43%	102.50%			75.16%
2020-21	80.00%	65.33%	100.00%	86.67%	100.72%	75.00%			80.06%	65.33%	71.43%	162.50%			80.03%
2021-22	75.00%	5.90%	87.78%	97.33%	85.62%	100.00%	n/a	63.33%	78.13%	87.06%	75.00%	100.00%	122.00%		86.34%
2022-23	93.50%	80.00%	76.00%	97.33%	95.14%	75.00%	85.00%	100.00%	73.21%	65.33%	87.00%	100.00%	122.00%		87.00%
2023-24	73.67%	60.00%	97.50%	99.00%	81.85%	75.50%	0.00%	100.00%	71.43%	69.00%	70.83%	100.00%	83.33%	100.00%	87.06%

## Appendix 7 – Additional data for Portfolio activity: Recruitment to target (by study design)

A.R. Reporting Year	CRV (Median % RtT)			CHI (Median % RtT)			CCA (Median % RtT)			DIA (Median % RtT)			GAS (Median % RtT)			MHT (Median % RtT)			NEU (Median % RtT)			ORT (Median % 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	Int	Obs	Not Spec	
2019-20	90.28%	87.33%		75.97%			70.83%	91.63%		58.33%			62.50%	100.00%		14.29%	29.79%		45.00%	106.67%					
2020-21	92.92%	112.26%		71.11%	32.00%		111.48%	72.73%		72.60%	92.77%		50.00%	100.00%			14.89%			100.72%					
2021-22	85.79%	177.00%		40.00%	60.00%		73.70%	193.33%		71.56%	110.00%		83.33%	100.00%		n/a	n/a	n/a	94.57%	90.83%		122.00%			
2022-23	93.50%	177.00%		70.00%	220.00%		69.44%	76.00%		86.67%	110.00%		50.00%	100.00%		85.00%			95.14%	0.00%		122.00%			
2023-24	73.33%	74.00%		50.00%	270.00%		49.44%	115.58%		97.33%	140.00%		75.50%			5.00%	0.00%		60.00%	103.70%		83.33%			

A.R. Reporting Year	PCR (Median % RtT)			REN (Median % RtT)			RES (Median % RtT)			STR (Median % RtT)			VIS (Median % RtT)			CDT (Median % RtT)			Median across CSGs(% 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
2019-20	77.78%	11.11%	11.11%	88.23%	102.82%		89.40%	80.51%		48.57%	74.91%		100.32%	153.20%					73.40%	89.48%	11.11%
2020-21	81.26%	40.00%		66.84%	107.06%		56.87%	107.06%		74.11%			143.30%	107.06%					73.36%	100.00%	
2021-22	75.51%	50.00%		70.21%	92.56%		63.33%	81.47%		65.00%			108.33%	180.00%					74.61%	96.28%	
2022-23	100.00%	100.00%		75.00%	71.43%		40.00%	100.00%		58.14%	100.00%		100.00%	100.00%					85.00%	100.00%	
2023-24	100.00%	100.00%		78.13%	65.00%		50.00%	87.06%		58.14%	83.33%		100.00%	100.00%		100.00%			84.00%	95.83%	

## Appendix 8 – Additional data for Portfolio activity: Recruitment to target (by funding type)

A.R. Reporting Year	CRV (Median % RtT)		CHI (Median % RtT)		CCA (Median % RtT)		DIA (Median % RtT)		NEU (Median % RtT)		GAS (Median % RtT)		MHT (Median % RtT)		ORT (Median % RtT)	
	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm
2019-20	80.80%	97.44%	77.78%	75.37%		82.87%	58.33%		80.00%	51.67%	33.33%	125.00%		24.62%		
2020-21	138.46%	95.76%	77.78%	54.13%		89.95%	62.11%	90.55%		80.74%	50.00%	100.00%		11.91%		
2021-22	79.24%	108.62%		46.67%		80.74%	64.00%	80.74%		92.08%	83.33%	100.00%	n/a	n/a		80.74%
2022-23	85.00%	100.00%	60.00%	150.00%		76.00%	94.00%	98.33%	0.00%	95.14%	50.00%	100.00%		92.50%		122.00%
2023-24	26.67%	81.00%	60.00%	65.00%	100.00%	95.00%	108.00%	86.67%		81.85%	50.00%	140.50%	0.00%	5.00%		83.33%

A.R. Reporting Year	PCR (Median % RtT)		REN (Median % RtT)		RES (Median % RtT)		STR (Median % RtT)		VIS (Median % RtT)		CDT (Median % RtT)		Median across CSGs (% RtT)	
	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm
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	50.00%	75.51%	71.43%	75.69%	56.89%	80.74%	47.50%	100.00%	103.33%	192.50%			67.72%	80.74%
2022-23	100.00%	100.00%	71.43%	75.00%	33.33%	75.53%	20.00%	90.00%	100.00%	125.00%			65.72%	98.33%
2023-24	100.00%	100.00%	52.38%	75.00%	75.00%	69.00%	83.33%	58.14%	100.00%	123.81%		100.00%	80.00%	96.12%

Appendix 9 – Additional data for Portfolio activity: Time from study set-up to first patient visit (by clinical specialty group and funding type)

	CRV				CHI				CCA				DIA				NEU			
	Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm	
	Median	P^	Median	P^	Median	P^	Median	P^	Median	P^	Median	P^	Median	P^	Median	P^	Median	P^	Median	P^
	FPFV (days)	Studies < 30 days	FPFV (days)	Studies < 30 days	FPFV (days)	Studies < 30 days	FPFV (days)	Studies < 30 days	FPFV (days)	Studies < 30 days	FPFV (days)	Studies < 30 days	FPFV (days)	Studies < 30 days	FPFV (days)	Studies < 30 days	FPFV (days)	Studies < 30 days	FPFV (days)	Studies < 30 days
BHSCT	3.0	66.67%	43.0	44.44%	42.0	0.00%	53	30.77%	85.0	0.00%	34.0	47.62%	45.0	50.00%	46.0	50.00%			41.0	33.33%
NHSCT											49.5	0.00%	29.5	83.33%	48.0	0.00%				
SEHSCT	37.0	40.00%	140.0	0.00%			86	0.00%			71.0	40.00%			70.0	0.00%				
SHSCT	69.0	20.00%	21.5	50.00%			70.0	0.00%			29.0	60.00%								
WHSCT	63.0	20.00%	160.0	0.00%							123.0	28.57%								

	GAS				MHT				ORT				PCR				REN			
	Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm	
	Median	P^	Median	P^	Median	P^	Median	P^	Median	P^	Median	P^	Median	P^	Median	P^	Median	P^	Median	P^
	FPFV (days)	Studies < 30 days	FPFV (days)	Studies < 30 days	FPFV (days)	Studies < 30 days	FPFV (days)	Studies < 30 days	FPFV (days)	Studies < 30 days	FPFV (days)	Studies < 30 days	FPFV (days)	Studies < 30 days	FPFV (days)	Studies < 30 days	FPFV (days)	Studies < 30 days	FPFV (days)	Studies < 30 days
BHSCT	184.0	0.00%	29.0	100.00%			93.0	0.00%			41.5	50.00%			138.5	50.00%	93.0	0.00%	92.5	16.67%
NHSCT							191.5	0.00%					0.0	100.00%	20.0	64.29%	406.0	0.00%	210.0	40.00%
SEHSCT	94.0	0.00%	29.5	50.00%			111.0	0.00%							3.5	70.00%	44.0	0.00%	26.0	60.00%
SHSCT										10	100.00%			4.5	66.67%	224.0	0.00%	236.0	25.00%	
WHSCT							99.0	0.00%							24.0	54.55%			98.0	20.00%

	RES				STR				VIS				CDT				in Year Totals (2023-24)			
	Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm	
	Median	P^	Median	P^	Median	P^	Median	P^	Median	P^	Median	P^	Median	P^	Median	P^	Median	P^	Median	P^
	FPFV (days)	Studies < 30 days	FPFV (days)	Studies < 30 days	FPFV (days)	Studies < 30 days	FPFV (days)	Studies < 30 days	FPFV (days)	Studies < 30 days	FPFV (days)	Studies < 30 days	FPFV (days)	Studies < 30 days	FPFV (days)	Studies < 30 days	FPFV (days)	Studies < 30 days	FPFV (days)	Studies < 30 days
BHSCT	21.0	100.00%	25.5	50.00%	14.0	100.00%	70.0	14.29%	38.0	50.00%	41.5	25.00%			4.0	100.00%	52.5	45.45%	37.0	42.99%
NHSCT	235.0	0.00%	94.0	0.00%	126.0	0.00%	163.0	33.33%							5.5	75.00%	30.0	60.00%	40.0	45.45%
SEHSCT							14.0	100.00%							14.0	75.00%	40.5	25.00%	26.0	51.52%
SHSCT			19.0	66.67%	24.0	100.00%	260.0	0.00%							1.0	100.00%	69.0	28.57%	47.0	47.06%
WHSCT	96.0	0.00%	48.0	33.33%			356.0	0.00%							7.0	100.00%	85.0	11.11%	50.5	38.24%