



Clinical  
Research  
Network

# NICRN ANNUAL REPORT 2024-2025



This tapestry was created using tablecloths that contained the round table discussion thoughts/doodles from participants at the NICRCF facilitated public Workshop 'Your Cancer Care and Cancer Research' 20 Feb 2025. The art piece was created by Beth McComish, Belfast Trust, Arts Care Artist in Residence.

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## Glossary

Acronym	Definition		
AHP	Allied Health Professional	NICTN	Northern Ireland Cancer Trials Network
AMRC	Association of Medical Research Charities	NIHR	National Institute for Health and Care Research
AR	Annual Report	NIMDTA	Northern Ireland Medical and Dental Training Agency
BHSCT	Belfast Health and Social Care Trust	NICRRRG	Northern Ireland Clinical Research, Recovery, Resilience and Growth group
BREXIT	British Exit	P <sup>^</sup>	Proportion
C&C	Capacity & Capability	PHA	Public Health Agency
CRDC	Commercial Research Delivery Centre	PI	Principle Investigator
CI	Chief Investigator	PICU	Paediatric Intensive Care Unit
CMG	Clinical Management Group	PPI	Patient and Public Involvement
COVID-19	Coronavirus Disease	QUB	Queen's University Belfast
CSG	Clinical Speciality Group	R&D	Research & Development
DGH	District General Hospital	RCT	Randomised Control Trial
DOH	Department of Health	RDD	Research and Development Division
ECMC	Experimental Cancer Medicine Centre	RtT	Recruitment to Target
EDGE	EDGE is a cloud-based clinical research portfolio management system	RtTT	Recruitment to Time & Target
FPFV	First Patient First Visit	RVH	Royal Victoria Hospital
GPARTS	General Practice Academic Research Training Scheme	SEHSCT	South Eastern Health and Social Care Trust
HSC R&D	Health and Social Care Research & Development	SHSCT	South Health and Social Care Trust
IBD	Irritable Bowel Disease	T&O	Trauma and Orthopaedics
INY	Occurring within reporting period (1st April 2024-31st March 2025)	TOT	Total number of participants reported as at 31 <sup>st</sup> March 2025 for all studies active within in the reporting year period.
LPMS	Local Portfolio Management System	UK	United Kingdom
NHS	National Health Service	UKRI	UK Research and Innovation
NHSCT	Northern Health and Social Care Trust	UPH	Urgent Public Health
NI	Northern Ireland	UU	Ulster University
NICRCF	Northern Ireland Cancer Research Consumer Forum	VPAG	Voluntary Scheme for Branded Medicines Pricing, Access and Growth
NICRF	Northern Ireland Clinical Research Facility	WHSCT	Western Health and Social Care Trust
NICRN	Northern Ireland Clinical Research Network	WTE	Whole Time Equivalent

## Director's Report of achievements / Challenges in reporting year 2024-2025



**Figure 1: Dr Paul Biagioni and Professor Jonathan Jackson conversing at the annual NICRN staff event.**

The reporting year 2024-25 has been a very challenging year, my 3<sup>rd</sup> as Director, for NICRN. Regionally the task of introducing the electronic care record system (Encompass/Epic) across all 5 Trusts has had a major impact on the number of patients seen across services. As a result the number of patients available to engage with clinical research was significantly reduced. The amount of training required to successfully implement the new system has also been intense and all categories and grades of staff, whether clinical or administrative, have needed to prioritise time for this. This in turn has impacted on the time and attention available to staff to drive clinical research projects forward. However, the long term benefit of having easy access to epidemiologically rich, regional clinical data, in a single databank will, when we all become more proficient at utilising it, be invaluable for clinical research. Coupled with the technological challenges we faced this year, there have been challenges associated with processing Clinical Research Governance in a timely manner, particularly in the BHSCT. Under the watch of Dr Cross, investment has been made in the BHSCT Research Office, processes and procedures are now being put in place that should ensure improved turnaround times as demand grows. On this front things look encouraging. Despite all of this I am greatly reassured and relieved to report that across the breadth of the NICRN, Clinical Leads, PIs, CIs, Clinical Researchers, Clinical support staff and administrative staff have collectively been able to match recruitment to that of last year.

This year's annual report, as has been the case in previous years, sets out activity and achievements by individual Clinical Specialty Group, although next year CSG reports will be batched under broader "Cluster Groupings". Individual CSG reports, and indeed Trust reports, will be illustrated and data presented in the standardised tabular format (Dashboards) introduced last year. The Table, at the end of this section, which includes several layout modifications, should help readers interpret data effectively. The Northern Ireland Dashboard summary Table has also been included at the end of this section.

## **A Regional Perspective**

Of 8162 patients screened in year, 2226 were recruited to 267 active studies. This represents consistently steady recruitment growth of 22% over a 5 year period. The number of active studies increased by 39% (267), whereas the number of recruitment sites increased by 15% (395), in comparison to 2023-2024. Changes in study adoption, screening and recruitment, recorded year on year, have to be viewed in light of the complexity of new interventional and commercial studies available to us. The regional median recruitment to target (RtT) figure, which relates to studies closed to recruitment within year, and is across all studies, has remained consistently high at 82%. The overall median recruitment to time and target (RtTT) figure, which relates to open studies and those in follow up, included in dashboards for the first time this year, is also fairly good at 78%. The median regional first patient first visit (FPFV) figure has remained stable at 43 days having improved from 70 in the preceding year. Despite the challenges faced in year the proportion of studies having recruited first patients within 30 days has remained stable at 40.4%. Disappointingly the proportion of commercial studies has dropped back to 18% from what had been a significant improvement last year. The dashboard, included at the end of this section, provides regional oversight of all summated

data. It also presents, in Tables 6a & 6b, activity by both Trusts and CSGs, which I trust the reader will find interesting.

Achievement could not have been reached without the dedicated commitment of 71 clinical research staff (41.8 WTEs) appointed through R&D funding. These numbers exclude both Cancer and Primary Care specialities as these groupings are funded directly via their own spending agreements with HSCRDD. Staffing numbers across NICRN & NICTN have remained surprisingly stable over the last 5 years. The support team although predominantly from a nursing background includes amongst its numbers, Midwives, Optometrists, Physiotherapists, Psychologists, Ophthalmic Imaging Specialist and Clinical Trial Assistants. Throughout the year we encourage staff to attend and participate in a wide range of professional, specialty and subject specific training events and conferences. Details regarding some of the training events and conferences attended can be found in the staffing section at the end of this report. I am indebted to Sonia McKenna and her team for their support throughout the year. All of the work undertaken generates data, populates databases and illustrates tables that produce the metrics against which we are judged. This data ultimately provides the detail used to inform this, and indeed other reports. My very grateful thanks go to Shane Jackson and his team in the coordinating centre for their tireless commitment to detail.

## Celebrating CSG Achievement.

The **Cardiovascular Group** are to be congratulated on having increased recruitment by 89% in comparison to 2023-24. During the year in question the Group were engaged in 37 active studies with increased recruitment in the SEHSCT, SHSCT & WHSCT areas. Also of note is the small increase in commercially funded research. RtT & RtTT figures vary across Trusts but generally sit at between 75% and 100%. Congratulations from all of us in NICRN to co-lead Prof Donna Fitzsimmons (OBE), an award highlighting her commitment to healthcare and education services. The **Children's Group** although having recruited fewer patients to studies within year have increased the numbers of children in studies that are either open to recruitment, or in active follow up, by 15%. Collectively the Group have achieved an overall RtT figure of 112%. Achieving a relatively even 50/50 split between observational/interventional and randomised/non-randomised trials the Group hope to attract commercial trials as they grow. Of particular note was the fact that the team have been recognised as the 3<sup>rd</sup> highest UK recruiters to the FERN Monochorionic Twin Pregnancy Trial. The **Critical Care and Perioperative Medicine Group** are to be congratulated on having added 5 new studies to the portfolio within year. The team have successfully increased screening and recruitment activity by 83% and 77% respectively. REMAPCAP is an example of a study, open across 4 Trusts that has screened almost 2000 individuals to secure 215 subjects, and recruited way above target. Research active members of the group have contributed to an extensive range of quality publications listing group members as leads, senior authors and contributory co-authors. Principal investigators have in addition recently secured in excess of £8m worth of NIHR grants which highlight the potential this group has for growth in the future. Prof McAuley and Dr Silverside have, on the basis of their reputations in their respective fields, been appointed to National research leadership roles. Recruitment

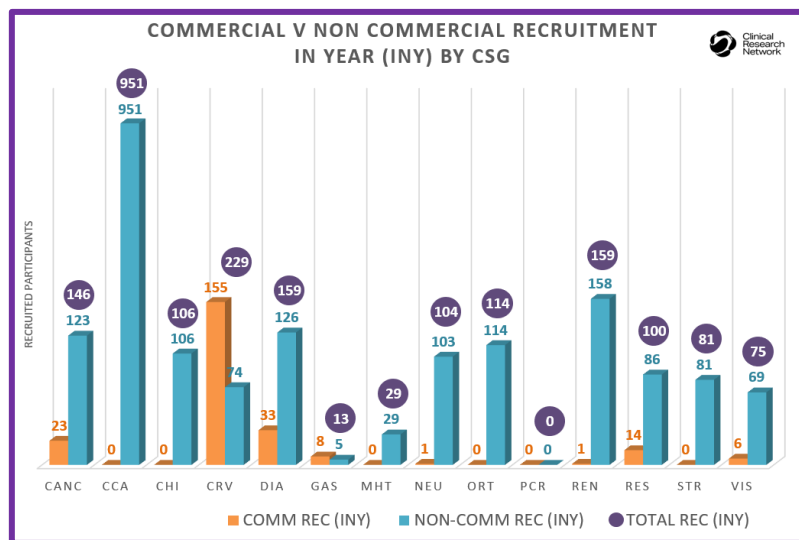
to Target and Recruitment to Time & Target figures continue to exceed the 90% figure making Critical Care and Perioperative Medicine one of the most successful NICRN Specialty Groups. Particular note should be taken of the fact that increased activity has been recorded across all Trusts. The **Diabetes Group**, under the leadership of Prof Alex Miras and the newly appointed co-lead Dr Philip Johnston, have increased both screening and recruitment activity by factors of x2 and x5 respectively. Activity, almost 40% of which is commercial, is now recorded against all 5 Trusts. Of note is the work of Dr Strzelecka in the NHSCT who has consistently achieved targets across a combination of 5 commercial and non-commercial studies. Recruitment to target and Recruitment to Time & Target figures continue to sit close to 90%. Of particular note and placing the group in a healthy position for further development, has been the award of a substantial (£10m) grant for UU (PEACEPLUS) to evaluate obesity in community. The **Gastroenterology Group** continued to face ongoing staffing challenges during the course of 2024-25. Dr Allen, who had been unwell during the course of the year stepped aside from leadership and this position was recently filled by Dr Inder Maine. No new studies were adopted within year and activity was restricted to follow up studies in 3 Trusts, and to setting things in place to build on previous important studies targeted at the early detection of Barretts Oesophageal cancer. Poor RtT, RtTT and FPFV figures reported reflect the challenges faced although under Dr Maine's leadership plans are in place to address this issues in the incoming year. The **Mental Health Group**, led by Professors Mulholland and Leavey, was unable to attract new studies in the year in question and activity, although restricted to 1 active study that recruited 29 subjects, occurred across all 5 Trusts. Poor RtT, RtTT and FPFV figures reported reflect the challenges faced by this group and plans are in place to address these issues. The **Neurodegenerative Research Group** continues to rebuild following last years retirement of Professor Peter Passmore. Whereas screening and recruitment numbers are reduced in comparison to last year, and activity is restricted to 1 Trust, the RtT and RtTT figures are approaching 90%. The HCAP Clinical Validation study which achieved a 1:1 screening to recruitment ratio continued to recruit well. Encouragingly as of Dec 2024 the NICOLA study, which is the largest study on ageing in NI, has now recommenced as Wave 3. With 61 individuals recruited in its first year we anticipate that NICOLAS recommencement will help address many of the challenges faced in 2023-24. The **Trauma and Orthopaedic Research Group** continues to grow and work in parallel with the Trauma and Orthopaedic Research Charity (TORC). Although current activity is restricted to the BHSCT, opportunities to involve research active clinicians from other Trusts are being explored. Whereas in year recruitment to studies is reduced, recruitment to all currently open studies is high at 318. Recruitment to Target for those studies which are closed and in follow up exceeds 100%. At present there are no commercial studies in the NICRN orthopaedic portfolio. The group continue to publish widely and attract commendations internationally. During the course of 2024-25 the **Primary Care Group** experienced significant change as Group management changed from within the BHSCT to the Eastern Federation Support Unit. This involved considerable alterations to management and planning with the result that it was not possible to recruit to studies during the year in question. The total recruitment figure (1268) for REFLECT, PRINCIPLE & PANORAMIC reflect the excellent engagement in studies opened in previous years, now closed to recruitment and in follow up. Under Prof Harts dynamic leadership, and with investment from VPAG, plans and facilities are

now in place to move forward regionally over the next 2 years. The **Renal Group** have continued to be very active during 2024-25, screening 257 individuals to secure 140 new recruits, to 9 open studies covering all 5 Trusts. Results from the EMPA-KIDNEY study which recruited 104 patients in NI, and has now closed, continue to appear in such prestigious publications as Lancet & NEJM. RaDaR (open) and ACHIEVE (in follow up) continue to achieve above target. The adoption of several commercial studies over the next 12 months should increase commercial activity in this group, which has been very successful in attracting interventional and randomised trials which constitute 2/3 of its portfolio. Although overall portfolio activity reported by the **Respiratory Group** reduced this year, the total numbers of patients screened (8428) and recruited (1946) to 32 active studies, open or in follow up, reflect the huge commitment this group makes to clinical trial research in NI. RtT, RtTT sit consistently in or close to 90% across the 3 most active Trusts. The Given the profile of the Respiratory Group and the successful history of having delivered on a very broad range of studies my hope is that in the new era the proportion of commercial activity adopted can be increased. The **Stroke Group** have once again increased year on year recruitment to open studies (81) with activity distributed across all 5 Trusts. RtT and RtTT figures for studies in follow up consistently reach the 90-100% level. Dr McCormick (SHSCT) and the team have had their contribution to clinical research recognised at the UK Stroke Forum where they were recognised as a high recruitment group for the OPTIMAS study. Further credit is due to this Group for their commitment to holding multidisciplinary CMG cross Trust meetings throughout the year. The **Vision Group** as was the case with several other groups, faced significant issues with staffing this year and as a result there was a reduction in the number of patients recruited to a smaller number of studies. They also were required to invest time hosting an MHRA GCP inspection of Prof Lois's successful TIGER study. Belfast has also been congratulated on having been the highest recruiter to the ACE study and the results from the DIAMOND & EMERALD studies have been incorporated into NICE Guidelines on Diabetic Retinoscopy. The RtT figure overall remains high at 123%. Staffing issues have now been resolved and the future looks more promising. This is the first year that I have been in a position to report specifically on the metrics available from the **Cancer Group**, which is a semi-autonomous group within NICRN. The group, led by Prof McIntosh and Dr Morris, consists of 60 research active Oncologists, Haematologists, Surgeons and other Senior Medical & Scientific Specialists and associated support staff. The Cancer Group have led the way regarding PPI involvement in clinical research. Of particular importance is the role the NI Cancer Research Consumer Forum (NICRCF) plays in supporting NICTN and the Belfast ECMC, by providing PPI input at numerous levels. Funding for research activity within the group is from multiple sources which creates its own scheduling challenges around the collection and reporting of outcomes to each funder. This also impacts on the specialities activity, operationally as a lack of security around soft funded posts can be a challenge in retaining staff between funding rounds. In 2024-25 only 146 participants were recruited, to a portfolio of 62 active clinical trials, with an additional 707 patients in follow up. Over time the number of patients recruited to studies has diminished, a consequence of the increasing complexity of many interventional trials. It is not possible to deliver these complex trials across all centers in NI. We, as a service, are significantly impacted by the necessity of bringing all our more highly complex studies through the BHSCT and any process or capacity bottlenecks within that

service reduce our overall potential to establish and deliver a fuller portfolio. A positive from this is that 78% of studies adopted are now interventional, and 30% of these are commercial. In total 19 studies had been newly adopted in year and progressed to set up. Of the 13 subspecialty groups serviced the most active research subgroups are in Leukaemia, Breast and Paediatric. Whereas activity within the BHSCT accounts for 2/3 of activity, approximately equal numbers of patients were recruited to studies running in the SHSCT, NHSCT and WHSCT.

### Taking a Trust Wide View.

This is the second year that I have asked all 5 Health and Social Care Trust, Research and Development Clinical Directors, to comment on the regional aspect of NICRN work. Historically the **Belfast Health and Social Care Trust**, accounts for approximately 80% of NICRN supported Clinical Trials Research portfolio activity. This is carried out by clinical leads, principal investigators and members of 13 CSGs. In total 837 patients have been recruited to one of 202 active studies. The 40% reduction in numbers of new recruits to studies, as outlined previously, can largely be accounted for by challenges associated with the introduction of the Encompass/Edge electronic clinical record program and managing the Research Governance components of capacity. Only 20% of studies are commercial, a figure that should rise as the new Voluntary Scheme for Branded Medicines Pricing, Access and Growth (VPAG) initiative takes off (Figure1).



**Figure 1: Commercial vs Non Commercial recruitment in year by CSG.**

N.B. The CCA (951) bar scale has been compressed to preserve the overall differentiation of the bars in the graph

Although numbers vary widely from study to study, RtT and RtTT figures consistently sit at between 75% and 90%. NICRN greatly appreciate the support offered at these challenging times from Dr Cross and Ms Alison Murphy and look forward to working with the broader BHSCT Research Governance team in 2025-26. Dr Minnis, in his role as Research Director highlights some of the good work undertaken by those in the **Northern Health and Social Care Trust**. Recruitment to 38 studies, 7 of which have opened in year, across 9 CSGs has remained stable over the last 12 months although RtT and RtTT figures vary considerably across studies. In the NHSCT section Dr Minnis highlights important developments that have

occurred within Trust and commends the Critical Care and Perioperative Medicine team for their on going commitments and the ICU team for recruiting the first patient in NI to the MS-POP-I intensive care study. As was the case in Belfast 20% of studies adopted are commercial. Dr Donnelly, the Research Director at the **South Eastern Health and Social Care Trust** reports on a very significant x3.5 increase in recruitment (808) to a range of studies undertaken by staff in the Trust. An amazing 609 patients were recruited to a Critical Care and perioperative medicine survey study undertaken within Trust. As was the case in other Trusts the majority of study RtT and RtTT figures sit within the 75% to 85% value and 18% of studies are commercial. Dr Donnelly in his report highlights successes in the Stroke, ICU, Respiratory, Nephrology, Child Health and Cardiology teams and in particular draws attention to the number of studies that have achieved national commendations and First in NI or UK recruitment. The research nurse team at SEHSCT supported all 4 Trusts with research ENCOMPASS integration, and for this I am truly grateful. I would like to take this opportunity to thank Dr Sharpe, the recently retired Research Director at the **Southern Health and Social Care Trust**, for his help and support with NICRN related work in the Trust. As we move into 2025-26 I would also like to welcome Prof Campbell to her new position as R&D Director and I am grateful to her for completing this years SHSCT review. With 10 active CSGs working on 44 studies the team in the Southern Trust recruited 329 patients a 36% increase on 2023-24. Overall the RtT and RtTT figures were 96%. Prof Peace the Research Director at the **Western Health and Social Care Trust** last year highlighted the fact that closer collaboration has resulted in a 200% increase in most metrics. Numbers have dropped slightly this year with 87 patients recruited to 42 studies delivered by staff engaged with 8 CMGs.

**With a Thankful Heart**, So as I conclude with reflections on activity and achievements in the 2024-25 year, having acknowledged the challenges imposed by the introduction of Encompass/Edge and the reorganisation of Clinical Research Governance in the BHSCT, I believe we are well positioned for the challenges we will face in 2025-26. Foremost of these will be the successful implementation of VPAG as we strive to increase commercially funded clinical trials research in Northern Ireland. Progress will also be made on the formation of Cluster Groups and the involvement of PPI at a more strategic level. In the incoming year I look forward to closer 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. Once again I am very grateful to our dedicated team of NICRN clinical and coordinating staff across all disciplines and Trusts. Without your dedication, help and commitment none of the work we undertake would be possible. Finally, to Paul, Shane, Sonia and Louise, thank you for your unwavering support and the hours of work that it has taken to produce the data that enables me to create this report.



Professor Jonathan Jackson (NICRN Director)

Table Number	Table Title	Description
1	Studies and Sites Data	The 7 data fields in this Table highlight; <ul style="list-style-type: none"> <li>The number of active CSGs, by Region &amp; Trust respectively, in the Region and Trust dashboards, within the reporting period. (In the case of the CSG dashboards this relates to the number of active Trusts within the reporting period)</li> <li>Number of active studies, across HSC/Trusts and CSGs respectively.</li> <li>Number of recruiting sites (locations) which have opened to recruitment, i.e. at which new participants could have been recruited, by HSC/Trusts &amp; CSGs respectively, within the reporting period. Please note the same study may be open to recruitment at multiple locations across NI and even within a single HSC trust area.</li> <li>The number of Sites, within the reporting period (INY), at which participants have been recruited by HSC/Trusts &amp; CSG respectively.</li> <li>The number of Sites, at which participants have been recruited to active studies, (TOT) by HSC/Trusts &amp; CSG respectively.</li> <li>The number of New Studies which opened to recruitment in year, by HSC, Trust &amp; CSGs respectively.</li> <li>Number of studies closed, by HSC/Trust &amp; CSGs respectively, within the reporting period.</li> </ul>
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 (INY). Columns 3&4 highlight the cumulative total number of participant's screened and recruited to these studies up to and including 31 <sup>st</sup> March 2025. (TOT).
3	Portfolio Sponsorship, Randomisation and Design Mix for Active Studies During 2024-25	Numbers included in this Table equate to the number of active studies referred to in table 1.
4 (a + b)	a – Recruitment, Median Recruitment to Target (%) and Median Recruitment to Time & Target (%) by Sponsorship Type (Commercial/Non-Commercial/Combined). b – Recruitment, Median Recruitment to Target (%) and Median Recruitment to Time & Target (%) by Design Type (Interventional/Observational/Combined)	In both tables 4a&b the number of participants refers to the number of participants recruited in year (INY). The Recruitment to Target (RT) median figure, expressed as a %, relates to participants recruited to studies that have closed to recruitment within the reporting period. The recruitment to Time and Target figure expressed as a % relates to all studies active within year.
5 (a + b)	Median First Participant First Visit Windows (FPFV), (Days) and Proportion of Studies Achieving <30 Days (%) 5a - (Commercial/Non-Commercial/Combined) 5b - (Interventional/ Observational / Combined)	Data included in these table highlight 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 open to recruitment date.
6 (a + b) [NI Dashboards]	6a – NI Regional data by HSC Trust for individual CSGs 6b - NI Regional by Clinical Specialty Group	6a NI Regional data dashboards. This reflects the NI Regional data as reported across Trusts (excluding Primary Care). 6b NI Regional data dashboards. This reflects the key metrics as reported across the CSGs for NI.
6 (a + b) [HSC Trust Dashboards]	6a – Clinical Specialty Group data by HSC Trust 6b - HSC Trust Data by Clinical Specialty Group	6a This reflects the CSG data as reported across the Trusts. 6b This reflects the key metrics as reported across the CSGs for Trusts (On the Trust specific Dashboards).
6 (a) [CSG Dashboards]	6a – Clinical Specialty Group data by HSC Trust.	6a This reflects the CSG data as reported across the Trusts.
6 (b) [CANCER Dashboards]	6b Clinical Specialty Data by Multi-Disciplinary Team	6b This reflects the key metrics as reported across the Multi-Disciplinary Teams for CANCER.

**Table 1: Definition of tables within Dashboards.**

# NI Health and Social Care Trust Research and Development Dashboard

Category	Value
No. of Active CSGs	14
No. of Active Studies	268
No. of Recruitment Sites	398
No. of Sites with Recruitment (INy)	174
No. of Sites with Recruitment (TOT)	309
No. of New Studies during 24-25	48
No. of Studies closed during 24-25	45

Screened (INy) during 24-25	Recruited during (INy) 24-25	Screened (TOT)** as at 31/03/2025	Recruited (TOT)** as at 31/03/2025
8,162	2,266	33,336	9,645

\* INy = Activity reported over reporting period (01/04/2024 - 31/03/2025)  
 \*\* TOT = Total activity reported up to and including 31/03/2025

	Commercial	Non-Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	47	221	159	109	178	90
Proportion (%)	17.54%	82.46%	59.33%	40.67%	66.42%	33.58%

Commercial		Non-Commercial			Combined			
Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**
241	83.33%	50.00%	2,025	80.00%	83.31%	2,266	81.00%	78.13%

\* Median RtT Metrics calculated on Active Studies which have closed to recruitment in year  
 \*\* Median RtTT Metrics calculated on all active studies in year

Interventional			Observational			Combined		
Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**
773	80.00%	71.64%	1,493	83.33%	90.18%	2,266	81.00%	78.13%

\* Median RtT Metrics calculated on Active Studies which have closed to recruitment in year  
 \*\* Median RtTT Metrics calculated on all active studies in year

List of HSC Trusts*	Recruitment (INy) during 24-25	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Rec to Target (%)**	Median Rec to Time & Target (%)***	Median ALL FPFV**** (days)	Proportion (%) < 30 days
BHSCT	901	39.76%	212	54.50%	80.00%	76.00%	36.0	44.38%
NHSCT	101	4.46%	38	9.77%	67.50%	90.00%	49.5	34.62%
SEHSCT	808	35.66%	44	11.31%	75.00%	88.89%	42.0	40.54%
SHSCT	329	14.52%	44	11.31%	96.25%	96.25%	56.5	36.84%
WHSCT	127	5.60%	51	13.11%	76.67%	68.47%	83.0	17.95%
<b>Totals:</b>	<b>2,266</b>	<b>100.00%</b>	<b>389</b>	<b>100.00%</b>	<b>81.00%</b>	<b>80.00%</b>	<b>45.5</b>	<b>38.93%</b>

\* HSC Trust names highlighted in purple indicates which Trusts are active in the CSG portfolio  
 \*\* Median RtT Metrics calculated on Active Studies which have closed to recruitment in year  
 \*\*\* Median RtTT Metrics calculated on all active studies in year  
 \*\*\*\* FPFV Metrics calculated on Active Sites with Recruitment only

# NI Health and Social Care Trust Research and Development Dashboard (cont'd)

Table 5a: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Commercial(60)		Non-Commercial(249)		Combined(309)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
41.0	36.67%	46.0	40.96%	43.0	40.13%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 5b: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Interventional(213)		Observational(96)		Combined(309)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
53.0	35.68%	30.5	50.00%	43.0	40.13%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 6b: NI Regional Data by Clinical Specialty Group								
List of CSGs*	Recruitment (INV) during 24-25	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Rec to Target (%)**	Median Rec to Time & Target (%)***	Median ALL FPFV**** (days)	Proportion (%) < 30 days
Cancer	146	6.44%	73	18.34%	66.33%	63.83%	63.0	32.20%
Cardiovascular	229	10.11%	44	11.06%	80.00%	74.00%	43.0	41.18%
Child Health	106	4.68%	25	6.28%	112.00%	50.00%	57.0	26.32%
Critical Care	951	41.97%	57	14.32%	91.34%	92.50%	31.0	48.89%
Diabetes	159	7.02%	23	5.78%	86.67%	91.67%	35.0	47.37%
Gastroenterology	13	0.57%	11	2.76%	10.00%	5.00%	54.5	16.67%
Mental Health	29	1.28%	8	2.01%	41.65%	41.65%	92.0	0.00%
Neurodegenerative	104	4.59%	7	1.76%		83.80%	39.0	20.00%
Orthopaedics	114	5.03%	13	3.27%	117.09%	100.42%	29.0	63.64%
Primary Care	0	0.00%	9	2.26%	115.00%	50.00%	7.0	88.89%
Renal	159	7.02%	39	9.80%	76.56%	80.00%	65.0	35.48%
Respiratory Health	100	4.41%	49	12.31%	100.00%	86.53%	21.0	54.05%
Stroke	81	3.57%	24	6.03%	79.17%	100.00%	121.0	23.08%
Vision	75	3.31%	16	4.02%	123.81%	90.19%	71.0	27.27%
<b>Totals:</b>	<b>2,266</b>	<b>100.00%</b>	<b>398</b>	<b>100.00%</b>	<b>81.00%</b>	<b>78.13%</b>	<b>43.0</b>	<b>40.13%</b>

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

In this section, the layout of which is similar to that adopted last year, the activity of each Clinical Specialty Group has been set out in such a way as to facilitate easy access to relevant data. Clinical Leads, and their NICRN support staff, have provided specialty specific background information followed by information on in year (INY) achievements, key publications and good news stories. Only a sample of other publications highlighted by leads have been included in the main body of the specialty reports, additional papers having been reported in the appendices. Pictorial illustrations have once again been included to highlight Group activity.

**Table 2: 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>CANC</b>	Northern Ireland Cancer Trials Network	<b>CDT</b>	Covid Delivery Team (2021-2024)

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

## Group Background/Summary

It has been a busy year for the Cardiovascular Group with recruitment up by around 90% from 121 patients last year, to 229 in 2024-25. In addition, a massive 1824 patients were screened for study participation by only 4.8 WTE team members. It is gratifying to note that recruitment to target also improved from 73% last year to 80% in 2024-25. The portfolio remains balanced, with 20 commercial studies and 17 non-commercial. Of these, 24 were randomised controlled trials and 13 were non-randomised controlled trials. The majority 26 were interventional, while a further 10 were observational in design. The median time from first patient, first visit was 43 days, with 40% of studies achieving this in the target region of less than 30 days. At the CMG held in March this year, 11 members were in attendance and 10 apologies were

received. The group noted the need for more regular meetings and interest was expressed in recruiting a PPI representative to the group.

The team was particularly proud to see significant dissemination of their work through presentations at international and national conferences and many high quality publications with several prizes awarded. There was a slight reduction in number of cardiovascular studies adopted in year for which the nature of studies available, access to patient cohorts, protracted approval timelines and capacity challenges all played a part.

## Key Achievements

In November 2024 Donna Fitzsimons the Co- Clinical Lead was awarded an OBE for services to Healthcare and Education. The award was presented at a ceremony in Windsor Castle(Figure 2a).

Dr Menown's team eUltra 10K were within the top 10 for global recruitment in this novel stent design study.

Prof Donnelly and Dr Valecka achieved a significant milestone by surpassing their recruitment target in the PREVAIL study. They were also asked by the PREVAIL team to become a super-recruitment site to help ensure that global recruitment could be completed as planned. The Euro-Aspire study team commended the research team for recruitment and data entry and again asked the site to be a super-recruiter due to challenges in achieving their broader UK recruitment goals(Figure 2b).

The Queen's University study team were delighted when SEHSCT & BHSCT reached their recruitment target in half the time expected for the CABIN study.

Dr Gemma Caughers was a finalist in the ESC Cardiovascular Nursing & Allied Professionals 2025 New Investigator Award (Figure 2c), disseminating results of her PhD and the CABIN study. She has also been invited to present these findings at the Irish Cardiac Society Annual Meeting in Killarney (Oct 2025).

Prof Donna Fitzsimons presented the Florence Nightingale Lecture at the ESC Congress in Madrid, entitled "Don't miss a beat": Why advocacy is an opportunity and responsibility for all healthcare professionals.

Earlier this year Ms Caroline Brown retired from her position as a Clinical Trials Nurse in Belfast Trust. Caroline has been a great colleague and made an excellent contribution to our team. We wish her a healthy and happy retirement.

Prof Pascal McKeown is planned to deliver a lecture at the Royal Victoria Hospital Annual Oration entitled 'De Motu Cordis'. The Chief Medical Officer, Professor Sir Michael McBride and recently appointed Chief Executive of BHSCT, Ms Jennifer Welsh, will be invited to be in the audience along with medical students from QUB and Ulster University and many colleagues of Prof McKeown.

## Relevant Publications

Effect of correcting iron deficiency on the risk of serious infection in heart failure: Insights from the IRONMAN trial. Foley PW, Kalra PR, Cleland JGF, Petrie MC, Kalra PA, Squire I, **Campbell P**, Chapman C, **Donnelly P**, Graham F, Hannah A, Lang NN, Matthews I, Leslie SJ, Pellicori P, Piper S, Ray R, Savage HO, Spencer C, Walsh J, Wong YK, Ford I; on behalf of the IRONMAN Study Group. Eur J Heart Fail. 2024

Impact of SGLT2 inhibition on markers of reverse cardiac remodelling in heart failure: Systematic review and meta-analysis. Savage P, Watson C, Coburn J, Cox B, Shahmohammadi M, Grieve D, **Dixon L**. ESC Heart Fail. 2024

An insight into healthcare professionals' perspectives on discussing implantable cardioverter defibrillator deactivation. Hill L, Cassidy L, **Dixon L**, **Fitzsimons D**, Thylen I, Jaarsma T. Eur J Cardiovasc Nurs. 2024

Impact of Anatomical and Viability-Guided Completeness of Revascularization on Clinical Outcomes in Ischemic Cardiomyopathy. Ezad SM, McEntegart M, Dodd M, Didagelos M, Sidik N, Li Kam Wa M, Morgan HP, Pavlidis A, Weerackody R, Walsh SJ, Spratt JC, Strange J, Ludman P, Chiribiri A, Clayton T, Petrie MC, O'Kane P, Perera D; **REVIVED-BCIS2 Investigators**. J Am Coll Cardiol. 2024

What do patients want from a digital device that supports heart failure self-management? McCune C, McNulty A, Tonry C, **Fitzsimons D**, Thompson DR, Watson JA, Watson CJ, **Dixon L**, Hill L. Patient Educ Couns. 2024

Effect of PCI on Health Status in Ischemic Left Ventricular Dysfunction: Insights From REVIVED-BCIS2. Ryan M, Taylor D, Dodd M, Spertus JA, Kosiborod MN, Shaukat A, Docherty KF, Clayton T, Perera D, Petrie MC; **REVIVED-BCIS2 Investigators**. JACC Heart Fail. 2024

SGLT2 Inhibition in Heart Failure: Clues to Cardiac Effects? Savage P, **Dixon L**, Grieve D, Watson C. Cardiol Rev. 2024

Intravenous iron for heart failure, iron deficiency definitions, and clinical response: the IRONMAN trial. John G.F. Cleland, Philip A. Kalra, Pierpaolo Pellicori, Fraser J. Graham, Paul W.X. Foley, Iain B. et al on behalf of the **IRONMAN Study group**. European Heart Journal (2024)

Percutaneous Revascularization for Ischemic Left Ventricular Dysfunction: Cost-Effectiveness Analysis of the REVIVED-BCIS2 Trial. Chivardi C, Morgan H, Sculpher MJ, Clayton T, Evans R, Dodd M, Petrie M, Rinaldi CA, O'Kane P, Brown L, Perera D, Saramago P; **REVIVED-BCIS2 Investigators**. Circ Cardiovasc Qual Outcomes. 2024

McCune C, McNulty A, Tonry C, **Fitzsimons D**, Thompson {David R.}, Watson {Jenny A.}, et al. What do patients want from a digital device that supports heart failure self-management? Patient Educ Couns. 2024

Neumann A, Steiner B, Verket M, Kanna {Niveditha Daneeza Dinesh}, Hill L, McNulty A, et al. Patients expectations and experiences with the usage of a self-care application for heart failure: A qualitative interview study. Digit Health. 2024 Nov;10.

Creighton L, **Caughers G**, Mitchell G, McMahon J, **Fitzsimons D**. Educational interventions for the modifiable risk factors of cardiovascular disease in pre-registration nursing: a scoping review. In 2024. Available from: <https://www.elsevier.com/en-gb/events/conferences/all/international-nurse-education-conference>

Szymański P, Cosentino F, **Fitzsimons D**, Traykov V, Aboyans V, Bueno H, et al. Stronger together: The impact of joint advocacy efforts for European Union and National Cardiovascular Health Plans. Kardiol Pol. 2024

Hill L, Cassidy L, **Dixon L**, **Fitzsimons D**, Thylen I, Jaarsma T. An insight into healthcare professionals' perspectives on discussing implantable cardioverter defibrillator deactivation. European Journal of Cardiovascular Nursing. 2024

Thompson G, **Caughers G**, **Bradley J**, **Donnelly P**, Mooney M, **Fitzsimons D**. The feasibility of delivering cardiac brief intervention to patients following ST-elevation myocardial infarction: protocol for a pilot randomised controlled trial. PLoS One. 2024

Creighton L, **Caughers G**, Mitchell G, Thompson G, Simms L, McHale S, et al. Heart health champions: how to develop student nurses as role models for cardiovascular health. In 2024. Available from: <https://www.escardio.org/Congresses-Events/ACNAP-Congress>

Creighton L, **Caughers G**, **Fitzsimons D**. Evaluation of a digital educational resource, ASMOSUS, to enhance cardiovascular disease knowledge and lifestyle behaviour change for first year nursing students: a mixed-methods study. In 2024.

Peters R, {Brown Wilson} C, McCutcheon K, Higgins G, Carlisle S, Kerr H, et al. Patient and Carer Education Partnership Forum (PCEP) Annual Report 2022 - 2023. Sept 2022- Aug 2023. 2024.

The DISCHARGE Trial group including **Donnelly P** (2024) Age and computed tomography and invasive coronary angiography in stable chest pain. JAMA Cardiol 9;4; 346-356 doi:10.1001/jamacardio.2024.0001

Biavati F, Saba L, Boussoussou M, **Donnelly P** et al (2024) Coronary artery calcium score predicts major adverse cardiac events in stable chest pain. Radiology <https://doi.org/10.1148/radiol.231557>

Lee P, Petrie M, **Donnelly P** (2024) Efficacy of IV ferric derisomaltose in hospitalised and outpatient settings: insights from ironman trial. BMJ 2024 110, 3 Abstract 137

**Fitzsimons D**, Cosentino F, Linde C et al (2025) Delivering a European Union Cardiovascular Health Plan: From building momentum to political action European Heart Journal 46;39,3819-3822

## Awards/Good New Stories

See further information in the achievements section above



Figure 2a: Prof Donna Fitzsimons awarded OBE



Figure 2b: SEHCT Cardiology Research Team and Dr Bernardas Valecka



Figure 2c: Dr Gemma Caughers, a finalist in the ESC Cardiovascular Nursing & Allied Professionals 2025 New Investigator Award.

# Dashboard (Cardiovascular - CRV)

Table 1: Studies and Sites Data	
No. of Active HSC Trusts	4
No. of Active Studies	37
No. of Recruitment Sites	44
No. of Sites with Recruitment (IN Y)	16
No. of Sites with Recruitment (TOT)	37
No. of New Studies during 24-25	4
No. of Studies closed during 24-25	6

Table 2: Screening and Recruitment In Year and also Cumulative Totals for Active Studies During 24-25			
Screened (IN Y*) during 24-25	Recruited during (IN Y*) 24-25	Screened (TOT)** as at 31/03/2025	Recruited (TOT)** as at 31/03/2025
1,824	229	5,120	1,029

\* IN Y = Activity reported over reporting period (01/04/2024 - 31/03/2025)  
 \*\* TOT = Total activity reported up to and including 31/03/2025

Table 3: Portfolio Sponsorship, Randomisation and Design Mix for Active Studies During 24-25						
	Commercial	Non - Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	20	17	24	13	26	10
Proportion (%)	54.05%	45.95%	64.86%	35.14%	72.22%	27.78%

Table 4a: Recruitment, Median Recruitment to Target (%)* and Median Recruitment to Time & Target (%)** by Sponsorship Type								
Commercial			Non-Commercial			Combined		
Recruited (IN Y) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (IN Y) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (IN Y) during 24-25	Median RtT (%)*	Median RtTT (%)**
155	80.00%	76.67%	74	80.00%	77.00%	229	80.00%	74.00%

\* Median RtT Metrics calculated on Active Studies which have closed to recruitment in year  
 \*\* Median RtTT Metrics calculated on all active studies in year

Table 4b: Recruitment, Median Recruitment to Target (%)* and Median Recruitment to Time & Target (%)** by Design Type								
Interventional			Observational			Combined		
Recruited (IN Y) during 24-25	Median RtT (%)*	Median RtTT (%)	Recruited (IN Y) during 24-25	Median RtT (%)	Median RtTT (%)	Recruited (IN Y) during 24-25	Median RtT (%)*	Median RtTT (%)
69	80.00%	73.33%	160	74.00%	87.00%	229	80.00%	74.00%

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

## Dashboard (Cardiovascular – CRV cont'd)

Table 5a: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Commercial(19)		Non-Commercial(18)		Combined(37)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
43.0	36.84%	40.5	44.44%	43.0	40.54%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 5b: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Interventional(27)		Observational(10)		Combined(37)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
43.0	37.04%	34.0	50.00%	43.0	40.54%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 6a: Clinical Specialty Group Data by HSC Trust								
List of HSC Trusts*	Recruitment (INY) during 24-25	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Rec to Target (%)**	Median Rec to Time & Target (%)***	Median ALL FPFV**** (days)	Proportion (%) < 30 days
<b>BHSCT</b>	40	17.47%	18	40.91%	76.67%	73.33%	6.5	57.14%
<b>NHSCT</b>	0	0.00%	0	0.00%				
<b>SEHSCT</b>	43	18.78%	10	22.73%	87.00%	100.00%	43.0	44.44%
<b>SHSCT</b>	70	30.57%	7	15.91%	97.50%	97.50%	41.5	33.33%
<b>WHSCT</b>	76	33.19%	9	20.45%	45.00%	46.36%	77.5	12.50%
<b>Totals:</b>	229	100.00%	44	100.00%	80.00%	74.00%	43.0	40.54%

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

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

\*\*\* Median RtTT Metrics calculated on all active studies in year

\*\*\*\* FPFV Metrics calculated on Active Sites with Recruitment only

# Child Health (CHI)

## Clinical Leads, Active PIs and CMG Members

<p><b>Child Health Group Clinical Leads</b></p> <p>David Sweet - BHSCT</p> <p>Anthony McCarthy – BHSCT</p> <p><b>Chief and Principal Investigators (CIs &amp; PIs)</b></p> <p>David Sweet - BHSCT (Neonates)</p> <p>Bharathi Rao - BHSCT (neonates)</p> <p>Karen Keown – BHSCT (Paeds CF)</p> <p>Adam Reynolds – BHSCT (Neonates)</p> <p>Julie Richardson - BHSCT (PICU)</p> <p>Emma McCartney – BHSCT (Cleft palate service)</p> <p>Eilish O’Connor – BHSCT (Cleft palate service)</p> <p>Frank Casey – UUJ (Paeds Cardiology)</p> <p>Thomas Waterfield – QUB (Paeds ED)</p> <p>Grace McCall – BHSCT (Paed Nephrology)</p> <p>Lynne Spiers – BHSCT (Paeds ID)</p> <p>Brian McCrossan - BHSCT (Paeds Cardiology)</p> <p>Suzanne Lawther - BHSCT (Paeds Surgery)</p> <p>Catriona Monaghan - BHSCT (O&amp;G)</p> <p>Noina Abid – BHSCT (Paeds Endocrinology)</p> <p>Michael Magowan - SEHSCT (Paeds)</p> <p>Alison Verner - SHSCT (Neonates)</p> <p>Fionnula Sayers –BHSCT (Paeds Ortho)</p> <p>Laura Jenkins – BHSCT (Paeds CF)</p> <p>Sarindra Millar – Southern (Paeds Diabetes)</p> <p>Lesley Ann Funston – Southern (Paeds)</p> <p>David Graham – Southern (Paeds)</p>	<p><b>CMG Members</b></p> <p><b>BHSCT</b> – David Sweet, Anthony McCarthy</p> <p><b>SEHSCT</b> - Michael Magowan</p> <p><b>SHSCT</b> - Alison Verner</p> <p><b>WHSCT</b> – Position unfilled</p> <p><b>NHSCT</b>- Dave Watkins</p> <p><b>PPI Representative</b></p> <p>Position vacant</p>
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## Group Background/Summary

The Child Health CMG met in March with a follow up meeting planned for June 2025. This year 7 studies were completed and closed. With recruitment to target averaging at 112%, 559 children and infants were recruited into trials which were either open or in follow up, across Northern Ireland. Recruitment is still running across three Trusts, with ongoing difficulties in

getting engagement from the Northern and Western Trusts, who at present do not have nursing support on-site. A further five studies were closed to recruitment and in follow up, with recruitment in Surf on, Dolphin and BESS all recruiting above target. There are 10 studies still open and actively recruiting, three having opened this year with a further two in site set up. The main barrier at present remains the slow turnaround of approvals to get studies started because of delays at R&D office.

## Key Achievements

- The availability of a full nursing staff complement has enabled us to carry out more activity than ever before. We have one commercial study in the paediatric portfolio and another in the pipeline
- We are covering more specialties than ever before, including cardiology, nephrology, infectious disease, paed ED, neonatology and PICU

## Relevant Publications

1. Eleftheriou D, Moraes YC, **Purvis C**, ... Brogan P et al. Multi-centre, randomised, open-label, blinded endpoint assessed, trial of corticosteroids plus intravenous immunoglobulin (IVIG) and aspirin, versus IVIG and aspirin for prevention of coronary artery aneurysms (CAA) in Kawasaki disease (KD): the KD CAA prevention (KD-CAAP) trial protocol. *Trials*. 2023 Jan 26;24(1):60. doi: 10.1186/s13063-022-07051-9. PMID: 36703139; PMCID: PMC9879235.
2. Al-Najjar N, ..., Pal DK et al. Changing Agendas on Sleep, Treatment and Learning in Epilepsy (CASTLE) Sleep-E: a protocol for a randomised controlled trial comparing an online behavioural sleep intervention with standard care in children with Rolandic epilepsy. *BMJ Open*. 2023 Mar 10;13(3):e065769. doi: 10.1136/bmjopen-2022-065769. PMID: 36898757; PMCID: PMC10008377. **Part of Castle Sleep-E study team: PI Dr Lesley Anne Funston**

## Awards/Good New Stories

1. Royal Maternity Hospital 3<sup>rd</sup> was the highest recruiter for the FERN trial.
2. The neoGASTRIC study has recruited 18 of an anticipated 60 participants in the first two months of opening. This study closes in March 2026.
3. The Gastric PICU study has recruited 19 of an anticipated 20 participants so far, with 3 months still to go.
4. The successful Surf on study achieved 122% recruited to target whereas DOLFIN recruited 133% to target.
5. Professor Frank Casey celebrating with his research participant for the SCOUT HCM- A Study of Mavacamten in adolescent participants with hypertrophic cardiomyopathy.
6. The Childrens team plan to also go to the Paediatric Critical Care Conference in Belfast in September year 2025,



**Figure 3: Professor Frank Casey with his research participant for SCOUT HCM Study alongside the NICRN Children`s clinical research nurses, and cardiac investigations team in the Heart Centre RBHS**

# Dashboard (Child Health – CHI)

Table 1: Studies and Sites Data	
No. of Active HSC Trusts	3
No. of Active Studies	23
No. of Recruitment Sites	25
No. of Sites with Recruitment (INy)	13
No. of Sites with Recruitment (TOT)	19
No. of New Studies during 24-25	3
No. of Studies closed during 24-25	7

Table 2: Screening and Recruitment In Year and also Cumulative Totals for Active Studies During 24-25			
Screened (INy*) during 24-25	Recruited during (INy*) 24-25	Screened (TOT)** as at 31/03/2025	Recruited (TOT)** as at 31/03/2025
317	106	1,149	559

\* INy = Activity reported over reporting period (01/04/2024 - 31/03/2025)  
 \*\* TOT = Total activity reported up to and including 31/03/2025

Table 3: Portfolio Sponsorship, Randomisation and Design Mix for Active Studies During 24-25						
	Commercial	Non-Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	1	22	13	10	12	11
Proportion (%)	4.35%	95.65%	56.52%	43.48%	52.17%	47.83%

Table 4a: Recruitment, Median Recruitment to Target (%)* and Median Recruitment to Time & Target (%)** by Sponsorship Type								
Commercial			Non-Commercial			Combined		
Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**
0		0.00%	106	112.00%	67.55%	106	112.00%	50.00%

\* Median RtT Metrics calculated on Active Studies which have closed to recruitment in year  
 \*\* Median RtTT Metrics calculated on all active studies in year

Table 4b: Recruitment, Median Recruitment to Target (%)* and Median Recruitment to Time & Target (%)** by Design Type								
Interventional			Observational			Combined		
Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)	Recruited (INy) during 24-25	Median RtT (%)	Median RtTT (%)	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)
56	117.11%	81.00%	50	50.00%	50.00%	106	112.00%	50.00%

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

## Dashboard (Child Health – CHI cont'd)

Table 5a: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Commercial(1)		Non-Commercial(18)		Combined(19)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
13.0	100.00%	61.5	22.22%	57.0	26.32%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 5b: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Interventional(12)		Observational(7)		Combined(19)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
57.0	33.33%	70.0	14.29%	57.0	26.32%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 6a: Clinical Specialty Group Data by HSC Trust								
List of HSC Trusts*	Recruitment (INY) during 24-25	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Rec to Target (%)**	Median Rec to Time & Target (%)***	Median ALL FPFV**** (days)	Proportion (%) < 30 days
<b>BHSCT</b>	83	78.30%	19	76.00%	81.00%	50.00%	53.5	35.71%
<b>NHSCT</b>	0	0.00%	0	0.00%				
<b>SEHSCT</b>	4	3.77%	1	4.00%	125.00%	125.00%	86.0	0.00%
<b>SHSCT</b>	19	17.92%	5	20.00%	135.00%	50.00%	126.0	0.00%
<b>WHSCT</b>	0	0.00%	0	0.00%				
<b>Totals:</b>	106	100.00%	25	100.00%	112.00%	50.00%	57.0	26.32%

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

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

\*\*\* Median RtTT Metrics calculated on all active studies in year

\*\*\*\* FPFV Metrics calculated on Active Sites with Recruitment only

# Critical Care and Perioperative Medicine (CCA)

## Clinical Leads, Active PIs and CMG Members

<b>Critical Care and Perioperative Medicine Group Clinical Lead</b> Jon Silversides - BHSCT & QUB	<b>CMG Members</b>
<b>Chief and Principal Investigators (CIs &amp; PIs)</b> Jon Silversides – BHSCT & QUB Danny McAuley – BHSCT & QUB Adam Glass – BHSCT & QUB Peter McGuigan – BHSCT & QUB Chris Nutt – BHSCT James McNamee – BHSCT Murali Shyamsundar – BHSCT David Johnston – BHSCT Dominic Trainor – BHSCT Paul Johnston – NHSCT Samantha Hagan – SEHSCT Rob Charnock – SHSCT Shiva Arava - SHSCT Denise McFarland – SHSCT Adrian Donnelly – WHSCT	<b>BHSCT</b> – Adam Glass, Danny McAuley, Jon Silversides, Michael McGinlay, Peter McGuigan, James McNamee, Chris Nutt, David Johnston, Murali Shyamsundar, Christine Turley, Kathryn Ward, Chris Wright, Emma Bohan, Rosemary Hogg, Andrew Boyle. <b>NHSCT</b> – Paul Johnston, Nathan Galloway <b>SEHSCT</b> – Chris Murray, Samantha Hagan. <b>SHSCT</b> – Rob Charnock, Denise McFarland, Orla McAtasney, Michael Jones, Shiva Arava <b>WHSCT</b> – Adrian Donnelly, Sinead O’Kane.  <b>PPI Representative</b> Position vacant

## Group Background/Summary

The critical care and perioperative medicine specialty group continued to demonstrate good levels of activity, mainly investigator led, NIHR-funded studies. While the headline figure (overall number of patients recruited) increased from the previous year, this was driven largely by a single observational study which accounted for nearly two thirds of total recruitment. Excluding this study, however, there was a sharp downturn in numbers of patients recruited compared with 2023-4 (40% decrease in recruitment to randomised trials). Contributory factors to this downturn included (1) a number of high-recruiting trials reaching

the end of recruitment in-year, (2) delays in obtaining R&D approvals for new studies to open in Belfast HSCT, and (3) increasing complexity of trials e.g. multi-arm, multi-stage designs with several randomisations and a much greater time commitment for research teams. The latter is not well-captured by accrual figures and will continue to be an issue for both sites and investigators.

The group's portfolio consisted of 57 studies active across the 5 trusts. Of 3941 patients screened, 24% (951) were recruited, and of these 236 participated in interventional trials. Of studies closed in year, recruitment achieved was 92.5% to time and target. Belfast HSCT were invariably among the top recruiting sites nationally for NIHR trials (e.g. MARCH, SINFONIA, SOS). CMG meetings were held quarterly, with regular representation from 4 of 5 Trusts, as well as representatives from the NICRN coordinating centre.

The group continue to explore ways to utilise EPIC to facilitate screening, communication, and data collection for research trials. As a group, we are conscious of the lack of commercial activity, reflecting in part a relative dearth of industry studies in this space but also a full portfolio of NIHR-funded investigator-initiated studies. This is something the group is keen to address. We are also keen to continue expansion of our small but growing portfolio of perioperative studies.

## Key Achievements

Several trials were completed during 2024-5. UK-ROX was a very large (16,500 patient) comparative effectiveness RCT comparing a conservative versus a liberal oxygen target for mechanically ventilated, critically ill adults. SEHSCT, SHSCT and WHSCT contributed 258 patients in total. This trial was presented at the *Critical Care Reviews* meeting in Belfast. UK-ROX showed a neutral effect and was presented at the *Critical Care Reviews* meeting in Belfast and published in *JAMA*. Other completed studies included SRAVI, an HSC R&D fellowship-funded clinical trial investigating a novel communication device for patients with tracheostomies (BHSCT and WHSCT); an observational perioperative study of right ventricular function (BHSCT); and VitDalize, a randomised, placebo-controlled trial of Vitamin D in critically ill vitamin-deficient adults (BHSCT). The SEHSCT team enrolled 615 patients in UnCorkED, an observational study investigating delays in admission from ED to wards and the impact of 'corridor care'.

Several new trials were opened: GUARDS (steroids in ARDS) in BHSCT and SHSCT; and SHORTER (short course antibiotics versus usual care in critically ill adults) in SHSCT. INFINIT (BHSCT) is a complex Phase 2 trial of Interferon-gamma to prevent infection in functionally immune compromised patients, and SepTIC (BHSCT) is a Phase 3 RCT investigating 3 interventions for treatment of sepsis – a novel PCR-based diagnostic; conservative fluid management including deresuscitation; and, in the most severely ill patients, GM-CSF.

The *Critical Care Reviews* meeting, held annually in Belfast each year and now also in Melbourne, was the platform for presentation of several studies to which the NICRN Critical Care and Perioperative Medicine team contributed. These trials included A2B (comparing dexmedetomidine, clonidine and propofol sedation), published in JAMA, and VACIRISS (Vaccination for immune recovery following sepsis).

## Relevant Publications

Biomarker-Guided Antibiotic Duration for Hospitalized Patients With Suspected Sepsis: The ADAPT-Sepsis Randomized Clinical Trial. Dark P, ... **McAuley DF**, ... **McNamee J**... et al .ADAPT-Sepsis Collaborators. JAMA 2025;333(8):682-693.

Evaluation of Plasma Biomarkers to Understand the Biology and Heterogeneity of Treatment Effect in Lower Tidal Volume Ventilation Facilitated by Extracorporeal CO<sub>2</sub> Removal in Acute Hypoxemic Respiratory Failure: A Secondary Analysis of the REST Trial. Boyle AJ, Reddy K ... **McNamee JJ**, **McAuley DF**, **O'Kane CM** et al.

Magnetic resonance imaging in comatose adults resuscitated after out-of-hospital cardiac arrest: A posthoc study of the Targeted Therapeutic Mild Hypercapnia after Resuscitated Cardiac Arrest trial. Eastwood GM, ... **McGuigan P**, ... Bellomo R et al; TAME trial investigators. Aust Crit Care. 2025 Mar;38(2):101130.

Drug therapy versus placebo or usual care for comatose survivors of cardiac arrest; a systematic review with meta-analysis. **McGuigan PJ**, ... **McAuley DF** et al. Resuscitation 205, 2024, 110431

Sedation, temperature and pressure after cardiac arrest and resuscitation-The STEPCARE trial: A statistical analysis plan. Kamp CB, ... **McGuigan PJ**, ... Jakobsen JC et al. Acta Anaesthesiol Scand. 2025 May;69(5):e70033.

Standardizing nomenclature in regional anesthesia: an ASRA-ESRA Delphi consensus study of upper and lower limb nerve blocks. El-Boghdadly K, ... **Hogg RMG**, ... Elkassabany NM et al. Reg Anesth Pain Med. 2024 Nov 4;49(11):782-792

Neurological injury following peripheral nerve blocks: a narrative review of estimates of risks and the influence of ultrasound guidance. Lemke E, **Johnston DF**, ... Sondekoppam RV et al. Reg Anesth Pain Med. 2024;49(2):122-132.

Physiologic determinants of near-infrared spectroscopy-derived cerebral and tissue oxygen saturation measurements in critically ill patients. Cody N, ... Quinn G, O'Neill, A, **Ward, K**, McCann J, **McAuley DF**. & **Silversides JA** et al. Critical Care Explorations. 6, 5, 9 p., e1094.

A New Global Definition of Acute Respiratory Distress Syndrome. Matthay MA, ... **McAuley DF**, ... Wick KD et al. Am J Respir Crit Care Med. 2024 Jan 1;209(1):37-47.

Dexmedetomidine- or Clonidine-Based Sedation Compared With Propofol in Critically Ill Patients: The A2B Randomized Clinical Trial. Walsh TS, ... **McAuley DF**, ... Weir CJ et al; A2B Trial Investigators. JAMA. 2025 Jul 1;334(1):32-45.

Effect of simvastatin on postoperative complications in patients undergoing one-lung ventilation during surgery: the Prevention HARP-2 randomised controlled trial. Glass A, ... **Silversides J**, ... **McAuley DF**, **Shyamsundar M** et al. Thorax. 2025 Jul 8:thorax-2025-223072.

Effectiveness of mucoactives (carbocysteine and hypertonic saline) in addition to usual airway clearance management with usual airway clearance management alone in acute respiratory failure (MARCH): study protocol for a multi-centre 2x2 factorial, randomised, controlled, open-label, Phase 3, pragmatic, clinical and cost-effectiveness trial with internal pilot. **Connolly B**, ... **Shyamsundar M**, ... **McAuley DF** et al. NIHR Open Res. 2025 Apr 10;5:30.

### Key presentations

Critical Care Canada Forum. November 2024. Prof DF McAuley

- Precision medicine in ARDS: it's coming!
- Pharmacologic Management of ARDS.
- Testing Less Injurious Ventilation Post-REST.
- The REALIST trial.

ECOS–TCS International Congress. June 2024. Prof DF McAuley.

- Latest results from the REST trial.

Society of Critical Care Medicine. February 2025. Dr J Silversides

- What goes up must come down: When to De-Resuscitate the Septic Patient.

## Awards/Good New Stories

Prof Danny McAuley was appointed to the National Institute of Health and Care's Board as Scientific Director for NIHR programmes.

Dr Jon Silversides was appointed to the NIHR HTA programme prioritisation committee for hospital-based care, and to lead the Royal College of Anaesthetists' Research leaders programme.

Major grant funding included:

NIHR/MRC EME programme £5,954,762

Precision medicine Adaptive Network platform Trial in Hypoxemic acute respiratory failure (PANTHER). Prof Danny McAuley CI

NIHR/MRC EME Advanced Fellowships £2,412,950

A phase 2 randomised clinical trial to evaluate the efficacy of anakinra in patients with the acute respiratory distress syndrome (AnakARDS). Dr Andrew Boyle CI. NICRN CC team in Belfast 2<sup>nd</sup> highest recruiters in the UK for SOS trial.



**Figure 4: Critical Care and Perioperative Medicine Belfast team celebrate 2nd highest recruiters in the UK to the SOS trial**

# Dashboard (Critical Care and Perioperative Medicine - CCA)

Table 1: Studies and Sites Data	
No. of Active HSC Trusts	5
No. of Active Studies	29
No. of Recruitment Sites	57
No. of Sites with Recruitment (INy)	35
No. of Sites with Recruitment (TOT)	45
No. of New Studies during 24-25	5
No. of Studies closed during 24-25	7

Table 2: Screening and Recruitment In Year and also Cumulative Totals for Active Studies During 24-25			
Screened (INy*) during 24-25	Recruited during (INy*) 24-25	Screened (TOT)** as at 31/03/2025	Recruited (TOT)** as at 31/03/2025
3,941	951	10,964	2,198

\* INy = Activity reported over reporting period (01/04/2024 - 31/03/2025)  
 \*\* TOT = Total activity reported up to and including 31/03/2025

Table 3: Portfolio Sponsorship, Randomisation and Design Mix for Active Studies During 24-25						
	Commercial	Non-Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	0	29	22	7	22	7
Proportion (%)	0.00%	100.00%	75.86%	24.14%	75.86%	24.14%

Table 4a: Recruitment, Median Recruitment to Target (%)* and Median Recruitment to Time & Target (%)** by Sponsorship Type								
Commercial			Non-Commercial			Combined		
Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**
0			951	91.34%	92.50%	951	91.34%	92.50%

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

\*\* Median RtTT Metrics calculated on all active studies in year

Table 4b: Recruitment, Median Recruitment to Target (%)* and Median Recruitment to Time & Target (%)** by Design Type								
Interventional			Observational			Combined		
Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)	Recruited (INy) during 24-25	Median RtT (%)	Median RtTT (%)	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)
236	92.50%	92.24%	715	90.18%	110.00%	951	91.34%	92.50%

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

## Dashboard (Critical Care and Perioperative Medicine – CCA cont'd)

Table 5a: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Commercial(0)		Non-Commercial(45)		Combined(45)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
		31.0	48.89%	31.0	48.89%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 5b: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Interventional(28)		Observational(17)		Combined(45)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
37.0	46.43%	29.0	52.94%	31.0	48.89%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 6a: Clinical Specialty Group Data by HSC Trust								
List of HSC Trusts*	Recruitment (INY) during 24-25	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Rec to Target (%)**	Median Rec to Time & Target (%)***	Median ALL FPFV**** (days)	Proportion (%) < 30 days
<b>BHSCT</b>	175	18.40%	27	47.37%	95.09%	98.14%	20.0	55.00%
<b>NHSCT</b>	18	1.89%	5	8.77%	120.00%	120.00%	7.0	66.67%
<b>SEHSCT</b>	690	72.56%	9	15.79%	231.67%	118.70%	51.0	37.50%
<b>SHSCT</b>	52	5.47%	6	10.53%	69.58%	87.55%	42.5	50.00%
<b>WHSCT</b>	16	1.68%	10	17.54%	55.00%	68.47%	92.5	37.50%
<b>Totals:</b>	951	100.00%	57	100.00%	91.34%	92.50%	31.0	48.89%

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

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

\*\*\* Median RtTT Metrics calculated on all active studies in year

\*\*\*\* FPFV Metrics calculated on Active Sites with Recruitment only

# Diabetes (DIA)

## Clinical Leads, Active PIs and CMG Members

<p><b>Diabetes Group Clinical Lead</b></p> <p>Alex Miras- UU &amp; WHSCT</p> <p>Philip Johnston - BHSCT</p> <p><b>Chief and Principal Investigators (CIs &amp; PIs)</b></p> <p>John Lindsay-BHSCT</p> <p>Philip Johnston-BHSCT</p> <p>Hamish Courtney-BHSCT</p> <p>Danny McWilliams, BHSCT</p> <p>Ailish Nugent, BHSCT</p> <p>Ben Loughrey, BHSCT</p> <p>Teresa Greene, BHSCT</p> <p>Anna Strzelecka-NHSCT</p> <p>Rhona Brennan, NHSCT</p> <p>Ciara Mulligan – SEHSCT</p> <p>Barbara Tate, SEHSCT</p> <p>Maureen Roberts, SHSCT</p> <p>Clionagh McElhinney, WHSCT</p> <p>Alex Miras- WHSCT &amp; UU</p>	<p><b>CMG Members</b></p> <p><b>BHSCT</b> - Philip Johnston</p> <p><b>NHSCT</b> – Anna Strzelecka</p> <p><b>SEHSCT</b> – Ciara Mulligan</p> <p><b>WHSCT</b> - Alex Miras</p> <p><b>PPI Representatives</b></p> <p>Position Vacant</p>
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## Group Background/Summary

The diabetes CMG meets every four-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.

There are a total of 13 active studies undertaken across all 5 trusts. Slightly more than half of all studies were interventional and randomised design. 38% of the portfolio studies are industry-sponsored. Of 268 patients screened a total of 159 participants were recruited to

studies. This represents a 2 fold increase in screening and a 5 fold increase in recruitment compared to 2023-24. The combined median first participant-first visit was 35 days. Overall the recruitment to target (RtT) and recruitment to time and target (RtTT) figures were excellent at 86% and 92%. Two new studies were adopted by the diabetes NICRN.

## Key Achievements

The Diabetes team have successfully contributed to the following studies during the reporting year:

### BHSCT

- SOUL complete: 5 recruited and a recent publication in NEJM below
- FAME-1 EYE: 11 recruited-recruitment now closed-target 11
- UK-EDI: 21 recruited-recruitment now closed-target 20
- TOPAZ: 13 recruited-now closed for recruitment
- MY DIABETES AND ME: 33 recruited target 36-still open
- ADDRESS 2: 15 recruited now closed for recruitment

### NHSCT

- Address 2: recruited 17 patients, recruitment ongoing. Initial target was 6
- Poseidon: recruited 21 patients, target was 8
- Synchronize: CVOT recruited 9, target was 8.
- Redefine 2: recruited 11, target was 8-10

### WHST

- Synchronise trial: 4 patients recruited

## Relevant Publications

McGuire DK et al, for **the SOUL Study Group**. Oral Semaglutide and Cardiovascular Outcomes in High-Risk Type 2 Diabetes. N Engl J Med 2025;392:2001-2012.

A Retrospective, Non-Interventional, Chart Review Study of the Effectiveness of FreeStyle Libre in Adults with Type 2 Diabetes, **Poster presented at ATTD**

Advances in Therapy: **PIONEER REAL UK**: A Multi-Centre, Prospective, Real-World Study of Once-Daily Oral Semaglutide Use in Adults with Type 2 Diabetes | Advances in Therapy (springer.com)

A Multi-Centre, Prospective, Real-World Study of Once-Daily Oral Semaglutide Use in Adults with Type 2 Diabetes - PubMed (nih.gov)

## Awards/Good New Stories

Ulster University has been awarded €10 million by the PEACEPLUS programme to setup and evaluate the first obesity services in primary care. The PEACETIME project will be led by Prof Alex Miras and run 2025-2029.

The WHSCT has been selected as a clinical trial site of excellence by Boehringer Ingelheim in recognition of patient feedback and retention rates.

Dr Philip Johnston has been appointed the new Diabetes Group Clinical co-lead, replacing Dr John Lindsay who has been critical to the continued success of the group over the last 6 years (Figure 5a). We wish Dr John Lindsay our very best and thank him for having led the group since 2019.



Figure 5a: NICRN Diabetes Clinical Lead changeover



Figure 5b: NHSCT team trip to the CaReMeLo Conference in Warsaw

# Dashboard (Diabetes - DIA)

Table 1: Studies and Sites Data	
No. of Active HSC Trusts	5
No. of Active Studies	13
No. of Recruitment Sites	23
No. of Sites with Recruitment (INy)	12
No. of Sites with Recruitment (TOT)	19
No. of New Studies during 24-25	4
No. of Studies closed during 24-25	2

Table 2: Screening and Recruitment In Year and also Cumulative Totals for Active Studies During 24-25			
Screened (INy*) during 24-25	Recruited during (INy*) 24-25	Screened (TOT)** as at 31/03/2025	Recruited (TOT)** as at 31/03/2025
268	159	628	318

\* INy = Activity reported over reporting period (01/04/2024 - 31/03/2025)  
 \*\* TOT = Total activity reported up to and including 31/03/2025

Table 3: Portfolio Sponsorship, Randomisation and Design Mix for Active Studies During 24-25						
	Commercial	Non-Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	5	8	7	5	7	6
Proportion (%)	38.46%	61.54%	53.85%	46.15%	53.85%	46.15%

Table 4a: Recruitment, Median Recruitment to Target (%)* and Median Recruitment to Time & Target (%)** by Sponsorship Type								
Commercial			Non-Commercial			Combined		
Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**
33	90.00%	101.25%	126	54.33%	91.67%	159	86.67%	91.67%

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

\*\* Median RtTT Metrics calculated on all active studies in year

Table 4b: Recruitment, Median Recruitment to Target (%)* and Median Recruitment to Time & Target (%)** by Design Type								
Interventional			Observational			Combined		
Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RtT (%)	Median RtTT (%)	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)
103	56.67%	88.89%	56	90.00%	105.83%	159	86.67%	91.67%

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

# Dashboard (Diabetes – DIA cont'd)

Table 5a: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Commercial(6)		Non-Commercial(13)		Combined(19)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
32.0	50.00%	36.0	46.15%	35.0	47.37%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 5b: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Interventional(11)		Observational(8)		Combined(19)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
36.0	36.36%	29.5	62.50%	35.0	47.37%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 6a: Clinical Specialty Group Data by HSC Trust								
List of HSC Trusts*	Recruitment (INY) during 24-25	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Rec to Target (%)**	Median Rec to Time & Target (%)***	Median ALL FPFV**** (days)	Proportion (%) < 30 days
<b>BHSCT</b>	74	46.54%	12	52.17%	22.00%	89.17%	28.5	62.50%
<b>NHSCT</b>	33	20.75%	6	26.09%	112.50%	110.42%	32.5	50.00%
<b>SEHSCT</b>	8	5.03%	2	8.70%		50.27%	121.0	50.00%
<b>SHSCT</b>	40	25.16%	1	4.35%		111.11%	158.0	0.00%
<b>WHSCT</b>	4	2.52%	2	8.70%	26.67%	49.44%	44.0	0.00%
<b>Totals:</b>	159	100.00%	23	100.00%	86.67%	91.67%	35.0	47.37%

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

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

\*\*\* Median RtTT Metrics calculated on all active studies in year

\*\*\*\* FPFV Metrics calculated on Active Sites with Recruitment only

# Gastroenterology (GAS)

## Clinical Leads, Active PIs and CMG Members

<b>Gastroenterology Group Clinical Lead</b> Inder Mainie – BHSCT	<b>CMG Members</b> <b>BHSCT</b> -Graham Morrison, Inder Mainie, Leah Gilroy <b>NHSCT</b> - Kok Diong <b>SEHSCT</b> - Patrick Allen <b>WHST</b> - John McGoran
<b>Chief and Principal Investigators</b> Inder Mainie – BHSCT Graham Morrison – BHSCT Leah Gilroy – BHSCT Patrick Allen – SEHSCT TCK Tham – SEHSCT Darragh McCullagh - - SEHSCT Diong KOK – NHSCT John McGoran – WHST Mumtaz Hussain – SHSCT	<b>PPI Representatives</b> Position Vacant

## Group Background/Summary

Dr I Mainie was appointed the Gastroenterology Group Clinical Lead in 2025. CMG meetings are planned for the Summer and Autumn of 2025.

There are currently 10 active studies, 5 of which are running in the Belfast Trust, one in Upper GI eosinophilic oesophagitis, The Celtic capsule study will be looking at Service improvement as an initiative and follow up to the BEST 4 trial.

From 2009, Belfast Trust has participated in the BOSS trial. This is a randomised controlled trial of surveillance vs no surveillance for patients with Barrett’s Oesophagus: BOSS (Barrett’s Oesophagus Surveillance Study). The study completed in 2024.

13 patients were recruited to this landmark study and the paper was published in the number one impact journal, Gastroenterology 2025.

In 2024-25, we screened over 1100 patients for the Delta project (Project DELTA - integrated diagnostic solution for EarLy deTection of oesophageal cAncer) investigating the use of the capsule sponge in Barrett’s and Reflux symptoms. We achieved target by recruiting 104 patients in the Belfast trust, 93 in the Western trust, 47 in the Northern trust and 13 in the

Southern trust. Posters on this work were presented at UEGW 2024 and BSG 2024. A paper on this study was recently published in the Lancet.

The Celtic Capsule Sponge (SBRI study) was another capsule sponge study looking at Service Improvement Initiative. 46 patients were recruited in the Belfast trust and 49 in the Western trust. A poster was submitted to UEGW 2025 and a paper is currently being drafted.

The Cendakimab efficacy and safety in adult and adolescent patients with eosinophilic esophagitis - CC-93538-EE trial was also adopted by the group. One patient was recruited to this biologic study. The study is now in follow-up phase in the Belfast trust. An oral Presentation (abstract) was submitted at UEGW 2025.

### Commercial

**BEST4** - This is a prospective cohort study to evaluate whether a Capsule sponge and a clinically applicable biomarker panel could be used as part of a surveillance programme to risk stratify patients with Barrett's Oesophagus and inform management protocols. Participants joining the trial from cohort 2 will receive the capsule sponge test at baseline just before their scheduled standard of care surveillance endoscopy on the same day. – 105 patients are to be recruited in 2025/2026

**DUET UC** - A Phase 2b Randomized, Double-blind, Active- and Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Efficacy and Safety of Induction and Maintenance Combination Therapy with Guselkumab and Golimumab in Participants with Moderately to Severely Active Ulcerative Colitis. One patient was recruited to this biologic study, which is now in follow up phase in the Belfast Trust.

**MAP Study** - *Mycobacterium avium* subsp. *paratuberculosis* (MAP) has long been linked with Crohn's disease, although its precise role in the disease remains uncertain; largely due to the lack of diagnostics with sufficient speed, detection sensitivity and quantitative ability to detect the bacterium. A recently developed novel one-day phage-based method (RAPIDvMAP assay, Queen's University Belfast and Rapid-Myco Technologies Ltd) for detecting viable MAP in blood theoretically offers these test attributes, but test validation is needed. This feasibility study will: (1) provide information on the suitability of the novel phage-based RAPIDvMAP assay as a rapid diagnostic to detect systemic MAP infection in humans, and (2) provide new information on the prevalence of systemic MAP infection in a cohort of NI Crohn's patients. 250 patients are to be recruited by December 2025 and recruitment is in process.

**CLUES UC** - Casting Light on Urgency and Effectiveness of an Advanced Therapy in Ulcerative Colitis (CLUES-UC): An Observational Study of Mirikizumab in Adults with Moderately to Severely Active Ulcerative Colitis. Two participants are anticipated in the coming year.

**MK8690** - A Phase 2a Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of MK-8690 in Adults with Moderately to Severely Active Ulcerative Colitis. This study is awaiting site selectio. Two participants are anticipated in the coming year.

Real-world effectiveness and safety of filgotinib with and without concomitant therapies in patients with Ulcerative Colitis: an interim analysis of the prospective, observational

GALOCLEAN study. A total of 15 patients were recruited in the SE trust. An abstract has been published in the *Journal of Crohn's and Colitis* Jan 2025.

GONDOMAR study in the Northern trust and South Eastern trust. GOals, Needs and Determinants Of Multimodal therapy in periAnal cRohn's Fistula. Two patients have been recruited to the Northern trust and 11 recruited in the SE trust. This study is in follow-up.

ELEVATE UC clinical trials, which investigated the efficacy and safety of etrasimod, a drug for moderately to severely active ulcerative colitis (UC). Nine patients recruited in the SE trust and are in follow-up.

Observational study of upadacitinib in ulcerative colitis (PROFUNDUS) – One patient has been recruited in the SE trust and is in follow-up.

## Key Achievements

### Publications:

Development and validation of a multivariable risk factor questionnaire to detect oesophageal cancer in 2-week wait patients. *Clin Res Hepatol Gastroenterol*. 2023 Mar;47(3):102087. doi: 10.1016/j.clinre.2023.102087. Epub 2023 Jan 18. Study was completed in early 2023.

Using saliva epigenetic data to develop and validate a multivariable predictor of esophageal cancer status. Timothy C Stone, ..., **Inder Mainie**, ..., **Helen Graham**, **Fiona Gregg**,... and Peter Milverton...et al, *Epigenomics*. 2024 Jan;16(2):109-125. doi: 10.2217/epi-2023-0248. Epub 2024 Jan 16.

Barrett's Oesophagus Surveillance Versus Endoscopy at Need Study (BOSS): A Randomized Controlled Trial. *Gastroenterology*. 2025 April. **Part of the Boss trial team.**

Biomarker risk stratification with capsule sponge in the surveillance of Barrett's oesophagus: prospective evaluation of UK real-world implementation. *Lancet* 2025 Jul 19;406(10500):271-282. **Part of the DELTA consortium.**

## Awards/Good New Stories

Dr Inder Main appointed new Gastroenterology group clinical lead in 2025.

SEHSCT Gastro Research team, led by Dr Tony Tham and Dr Patrick Allen (Consultant Gastroenterologists) have exceeded their expected recruitment and are the highest enroller site in the UK to this informative real world study **GALOCLEAN**: A prospective, non-interventional multi-country cohort study of the effectiveness and safety of filgotinib in adult

patients with moderately to severely active ulcerative colitis. The study aims to recruit 600 patients across 10 countries in Europe and the UK.



**Figure 6: Dr Tony Tham and SEHSCT Gastro Research Team Highest recruited to the Galocean trial.**

# Dashboard (Gastroenterology - GAS)

Table 1: Studies and Sites Data	
No. of Active HSC Trusts	3
No. of Active Studies	10
No. of Recruitment Sites	11
No. of Sites with Recruitment (IN Y)	3
No. of Sites with Recruitment (TOT)	6
No. of New Studies during 24-25	0
No. of Studies closed during 24-25	1

Table 2: Screening and Recruitment In Year and also Cumulative Totals for Active Studies During 24-25			
Screened (IN Y*) during 24-25	Recruited during (IN Y*) 24-25	Screened (TOT)** as at 31/03/2025	Recruited (TOT)** as at 31/03/2025
21	13	74	37

\* IN Y = Activity reported over reporting period (01/04/2024 - 31/03/2025)  
 \*\* TOT = Total activity reported up to and including 31/03/2025

Table 3: Portfolio Sponsorship, Randomisation and Design Mix for Active Studies During 24-25						
	Commercial	Non-Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	7	3	3	7	6	4
Proportion (%)	70.00%	30.00%	30.00%	70.00%	60.00%	40.00%

Table 4a: Recruitment, Median Recruitment to Target (%)* and Median Recruitment to Time & Target (%)** by Sponsorship Type								
Commercial			Non-Commercial			Combined		
Recruited (IN Y) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (IN Y) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (IN Y) during 24-25	Median RtT (%)*	Median RtTT (%)**
8	5.00%	0.00%	5	180.00%	100.00%	13	10.00%	5.00%

\* Median RtT Metrics calculated on Active Studies which have closed to recruitment in year  
 \*\* Median RtTT Metrics calculated on all active studies in year

Table 4b: Recruitment, Median Recruitment to Target (%)* and Median Recruitment to Time & Target (%)** by Design Type								
Interventional			Observational			Combined		
Recruited (IN Y) during 24-25	Median RtT (%)*	Median RtTT (%)	Recruited (IN Y) during 24-25	Median RtT (%)	Median RtTT (%)	Recruited (IN Y) during 24-25	Median RtT (%)*	Median RtTT (%)
1	90.00%	0.00%	12	10.00%	10.00%	13	10.00%	5.00%

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

## Dashboard (Gastroenterology – GAS cont'd)

Table 5a: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Commercial(4)		Non-Commercial(2)		Combined(6)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
111.5	0.00%	29.5	50.00%	54.5	16.67%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 5b: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Interventional(3)		Observational(3)		Combined(6)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
67.0	33.33%	42.0	0.00%	54.5	16.67%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 6a: Clinical Specialty Group Data by HSC Trust								
List of HSC Trusts*	Recruitment (INY) during 24-25	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Rec to Target (%)**	Median Rec to Time & Target (%)***	Median ALL FPFV**** (days)	Proportion (%) < 30 days
BHSCT	1	7.69%	5	45.45%	0.00%	0.00%	125.5	0.00%
NHSCT	0	0.00%	1	9.09%	0.00%	0.00%		
SEHSCT	12	92.31%	5	45.45%	95.00%	100.00%	37.0	25.00%
SHSCT								
WHSCT								
<b>Totals:</b>	13	100.00%	11	100.00%	10.00%	5.00%	54.5	16.67%

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

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

\*\*\* Median RtT Metrics calculated on all active studies in year

\*\*\*\* FPFV Metrics calculated on Active Sites with Recruitment only

Please note NHSCT Recruitment (INY) should read 3 participants recruited (GONDOMAR Study) in reporting year (July 2024 [2], August 2024 [1]), but this was not recorded in EDGE before data cut.

# 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) Gerry Leavey- UU</p> <p><b>Chief and Principal Investigators (CIs &amp; PIs)</b></p> <p>Ciaran Mulholland-NHSCT &amp; QUB Suzanne Barrett – NHSCT Michael Duffy – BHSCT &amp; QUB Kevin Dyer - NHSCT/Exeter/QUB</p>	<p><b>CMG Members</b></p> <p><b>BHSCT &amp; QUB</b> - Aidan Turkington <b>NHSCT</b>- Ciaran Mulholland , Suzanne Barrett <b>SEHSCT</b> – Gary Woods <b>SHSCT</b> – Chris Southwell <b>WHSCT</b> - John Brady <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 Ms Marlyn Grant [Service User Consultant] &amp; Involvement Team, NHSCT</p>
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## Group Background/Summary

Studies opened/Current Portfolio [Mental Health/Maternity] in 2025

**RESPIRE I** The impact of maternal pollution exposure on pregnancy outcomes. Study (Chief Investigator Lucy Higgins University of Manchester, Manchester University NHS Trust, with Prof Duncan McVicar, QUB and Northern HSC Trust NICRN Researcher staff Dr Suzanne Barrett and Ms. Sharon O’Neill with Dr David Morgan [Consultant - Obs & Gynae]). Recruiting in Ballymena, Antrim and Whiteabbey Maternity Booking Clinics; commenced recruitment in June 2025. Recruitment effort at Impact Research Centre to continue until April 2026. Recruitment on 30/09/2025 – n=11 (37% of target n=30).

***Does a Phased Approach Enhance Outcomes for Trauma-Focused Cognitive Therapy for Complex Posttraumatic Stress Disorder (CPTSD)?*** is a randomised control trial that compared the delivery of *Trauma Focussed Cognitive Therapy* (TF-CT) with and without a phased

element. In one group, the treatment involved the immediate provision of the **CT-PTSD protocol** (i.e. up to 24 sessions of TF-CT), which was adapted individually to each patient, and in the other group CT-PTSD (i.e. up to 16 sessions of TF-CT) was provided after 8 sessions of compassionate resilience training (phased CT-PTSD). The study considered whether both approaches work equally well or whether there are advantages in providing a phased approach, or a non-phased approach for some groups of patients.

Recruitment and trialling of **PHASE CPTSD** study (NIHR funded - Total research costs £2.1million) opened in the lead service in Northern HSC Trust in April 2023 and opened in Belfast, South Eastern, Southern and Western HSC Trust services in Summer 2023, with the final participant randomised to treatment in NHST in August 2024. Follow-up assessments of participants continued into 2025. After treatment, patients were followed up to 52 weeks from randomisation i.e. six months follow-up from the end of standard treatment for the majority of participants. **Recruiting services** included **IAPT Services in England** and **Specialist Trauma Services in England and Northern Ireland**.

Joint Chief Investigators were: Dr Michael Duffy [QUB – for Northern Ireland (5 sites)] and Prof. Anke Ehlers [Uni of Oxford – for English sites (n=5)].

Publication of the PHASE-CPTSD protocol can be found here: [ISRCTN13869856 PROTOCOL V4 14Jan25.pdf](#)

(Recruitment Target n = 350 (100%); Achieved by close - n=107 (37%))

- NHST : 57% (n= 20) of target (n=35) successfully recruited and randomised.
- BHST : 8.5% (n=3) of target (n=35) successfully recruited and randomised.
- SEHST : 31.5% (n=11) of target (n=35) successfully recruited and randomised.
- WHST : 37% (n=13) of target (n=35) successfully recruited and randomised.
- SHST : 26% (n=9) of target (n=35) successfully recruited and randomised.

Fifteen Independent assessors and 36 NI Therapists were trained in the protocol (UK total 74), improving research, and potentially future service delivery, capacity.

## Key Achievements (Including Good News Stories)

- Visiting Scholar in CPH, QUB in September 2025 [Barrett]
- Leaders in Partnership Programme [PHA] Intake 2025 [Barrett]
- Invited reviewer – Psychosis Journal [Barrett]
- Encompass Superuser for Research, with Edge data migration responsibilities in NHST during Encompass roll-out [Barrett]
- Appointed Deep Dive Reviewer for Makaton Charity [Barrett]

## Conferences attended

- NICRN Conference October 2024 NHSCT (team presentation) Suzanne Barrett  
Research in a Changing Environment: A Perspective from Team North
- HIRANI Health Tech Spring Conference 2025 – Titanic Belfast (S. Barrett attended)
- Health Studies User Conference 2025 (S. Barrett; platform (paper) presentation) -  
Organised by the UK Data Service in collaboration with UCL and the National Centre  
for Social Research

Topic/Abstract Title - Rates of common mental health disorders (CMDs) in Northern Ireland, England, Scotland and Wales (1991-2022): Evidence from General Health Questionnaire -12 survey data *Suzanne Barrett, Northern HSC Trust, and Michael Duffy (2,3), Ryan McIlwaine (1,3), and Ciaran C. Mulholland (1,3,4)* Affiliations: 1 Impact Research Centre, Northern HSC Trust; 2 Belfast HSC Trust; 3 Queens University Belfast 4 Northern Ireland Clinical Research Network

Topic/Abstract Title - OPEN LABEL RANDOMISED CONTROLLED TRIAL: efficacy, acceptability and safety of clinician-led remote tDCS + biometric monitoring compared to TAU + BM in (c) posttraumatic stress disorder.

Barrett Suzanne L., Mulholland Ciaran C. with NI Regional Trauma Network

## Relevant Publications

### Papers & Publications (2024-25)

Davidson, G., Bunting, L., McCartan, C., Grant, A., McBride, O., **Mulholland, C.**, Nolan, E., Schubotz, D., Cameron, J., & Shevlin, M. (2024). Parental physical activity, parental mental health, children's physical activity and children's mental health. *Frontiers in psychiatry*, 15, Article 1405783.

Grant, A., McCartan, C., Davidson, G., Bunting, L., Cameron, J., McBride, O., **Mulholland, C.**, Murphy, J., Nolan, E., Schubotz, D., & Shevlin, M. (2024). Prevalence and risk factors of parental mental health problems: a cross-sectional study. *International Journal of Mental Health Nursing*, 33(6), 2090-2101.

Walsh, C., Bunting, L., Davidson, G., Doherty, N., McCartan, C., **Mulholland, C.**, & Shevlin, M. (2025). The prevalence and impact of adverse childhood experiences in Northern Ireland. *The Executive Programme on Paramilitarism and Organised Crime*.

ISRCTN13869856\_PROTOCOL\_V4\_14Jan25.pdf

A qualitative exploration of the impact of educational social fields on mental health help-seeking in post-primary schools in Northern Ireland  
Waterhouse-Bradley, B., Corry, D. & **Leavey, G.**, 31 Jan 2025, In: *Sociology of Health & Illness*. 47, 1, p. 1-20 20 p., e13825.

Research output: Contribution to journal › Article › peer-review

A systematic review of sport-based adolescent mental health awareness programmes  
Sullivan, N., Breslin, G., McLaughlin, M., Shannon, S., **Leavey, G.** & Dempster, M., 27 Mar 2025, (Published online) In: *PLoS One* . 20, 3, p. 1-23 23 p., e0315315.

Research output: Contribution to journal › Article › peer-review

COVID-19 open data: An ecological study and international collaboration examining pandemic trends in Northern Periphery arctic countries

O’Callaghan, M. E., Casey, M., Pearl, D., Hickey, O., Fosse, A., Sigurðsson, S. E., Savage, D. W., Vehviläinen-Julkunen, K., Bykachev, K., Parviainen, A., Parker, H., Condell, J., **Leavey, G.**, Hart, N., Weihe, P., Petersen, M. S. & Glynn, L., 30 Jun 2025, In: *Health Informatics Journal*. 31, 2, p. 1-17 17 p.

Cross-agency working when conducting a pragmatic RCT for older victims of crime: our experiences and lessons learned

Serfaty, M., Satchell, J., Laycock, G. K., Brewin, C. R., Buszewicz, M., **Leavey, G.**, Drennan, V. M., Cooke, J. & Kessel, A., 15 Jan 2025, In: *Trials*. 26, 1, p. 1-9 9 p., 17.

Research output: Contribution to journal › Comment/debate › peer-review

Does change in area-level deprivation, change health outcomes? A latent class growth analysis of population data

Ferry, F. R., McDowell, R., Rosato, M., Murphy, J. & **Leavey, G.**, 30 Sept 2025, In: *SSM - Population Health*. 31, p. 1-34 34 p., 101826.

Research output: Contribution to journal › Article › peer-review

Book: *The Role of Trust in Mental Health. Vulnerability and Trust-Building in Theory and Practice*. By **Gerard Leavey**. Routledge. ISBN 9781032353876

Studies in the pipeline

- IRAS358804 - tDCS with Biomonitoring in (C) PTSD in NHS/HSC – Update Sham tDCS device now offered as placebo arm (Barrett/Mulholland with Flow Neuroscience/Shimmersense/Philia Labs and Regional Trauma Network)
- CHOICE Study (Prof. Gerry Leavey; Kate Fallon UU)
- University of Dundee CI [C. Hitch?], Claire McCartan and Regional Trauma Network – questionnaire study - **Pain After Traumatic Incidents or Events during Northern Ireland's Troubles (PATIENT Study)**
- IRAS341178 - Incidence, Prevalence and Experience of SMI “DD” during SAOR-2 implementation (in Northern HSC Trust) [**InPrExDD–SAOR2**] (Estler Project/NHSCT) – query to go ahead outstanding/QI work ongoing

- NIFEPS DPIA - This multicentre epidemiologically robust study received ethical approval from REC [RVH] on 17th December 2002 [Application No.292/02]. [see documentation attached] The follow-on work outlined herein aimed to achieve the following by December 2025:

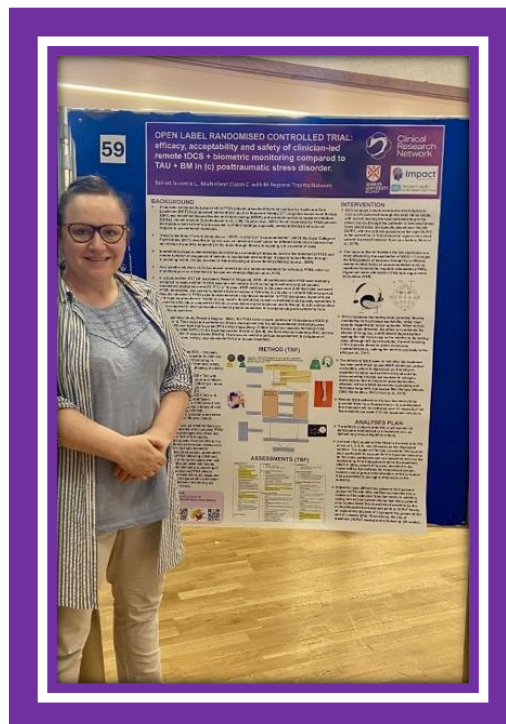
(a) publish a methods paper (to obtain an associated DOI) describing the NIFEPS project in full and the data storage and sharing arrangements planned, and in use, to obtain access to the original study data;

(b) Develop a variable dictionary to accompany the NIFEPS ACCESS Database currently in storage;

(c) Complete application paperwork and share data (MRI, cognitive and clinical data) from this longitudinal research study held in storage in the NHSC with named collaborators in the UK [Psy-ShareD\*] for the purpose of the development of AI analyses methods of scans, and

(d) have the project and variables added to searchable platforms, for example, The Catalogue of Mental Health Measures and/or The Atlas of Longitudinal Datasets.

\*The Psy-ShareD collaborative group aims to build a sustainable 'free-to-access', well-documented and well-supported structural MRI data repository, utilising pre-existing MRI scans across psychosis illness/risk stages and in control participants, and include within the database linked clinical, cognitive, and demographic data. It will manage and promote the Psy-ShareD database to ensure wide global uptake by researchers across all career stages and develop and employ state-of-the-art methods to harmonise and standardise structural MRI, clinical and cognitive datasets. Once established, the group will use Psy-ShareD to conduct and publish a proof-of-principle study addressing a current knowledge gap in the schizophrenia/psychosis MRI literature.



**Figure 7: Neuroscience Ireland Conference 2025, QUB S. Barrett poster presentation**

# Dashboard (Mental Health - MTH)

Table 1: Studies and Sites Data	
No. of Active HSC Trusts	5
No. of Active Studies	1
No. of Recruitment Sites	8
No. of Sites with Recruitment (IN Y)	5
No. of Sites with Recruitment (TOT)	7
No. of New Studies during 24-25	0
No. of Studies closed during 24-25	0

Table 2: Screening and Recruitment In Year and also Cumulative Totals for Active Studies During 24-25			
Screened (IN Y*) during 24-25	Recruited during (IN Y*) 24-25	Screened (TOT)** as at 31/03/2025	Recruited (TOT)** as at 31/03/2025
29	29	68	64

\* IN Y = Activity reported over reporting period (01/04/2024 - 31/03/2025)

\*\* TOT = Total activity reported up to and including 31/03/2025

Table 3: Portfolio Sponsorship, Randomisation and Design Mix for Active Studies During 24-25						
	Commercial	Non - Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	0	1	0	1	1	0
Proportion (%)	0.00%	100.00%	0.00%	100.00%	100.00%	0.00%

Table 4a: Recruitment, Median Recruitment to Target (%)* and Median Recruitment to Time & Target (%)** by Sponsorship Type								
Commercial			Non-Commercial			Combined		
Recruited (IN Y) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (IN Y) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (IN Y) during 24-25	Median RtT (%)*	Median RtTT (%)**
0			29	41.65%	41.65%	29	41.65%	41.65%

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

\*\* Median RtTT Metrics calculated on all active studies in year

Table 4b: Recruitment, Median Recruitment to Target (%)* and Median Recruitment to Time & Target (%)** by Design Type								
Interventional			Observational			Combined		
Recruited (IN Y) during 24-25	Median RtT (%)*	Median RtTT (%)	Recruited (IN Y) during 24-25	Median RtT (%)	Median RtTT (%)	Recruited (IN Y) during 24-25	Median RtT (%)*	Median RtTT (%)
29	41.65%	41.65%	0			29	41.65%	41.65%

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

## Dashboard (Mental Health – MTH cont'd)

Table 5a: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Commercial(0)		Non-Commercial(7)		Combined(7)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
		92.0	0.00%	92.0	0.00%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 5b: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Interventional(7)		Observational(0)		Combined(7)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
92.0	0.00%			92.0	0.00%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 6a: Clinical Specialty Group Data by HSC Trust								
List of HSC Trusts*	Recruitment (INy) during 24-25	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Rec to Target (%)**	Median Rec to Time & Target (%)***	Median ALL FPFV**** (days)	Proportion (%) < 30 days
<b>BHSCT</b>	0	0.00%	1	12.50%	25.00%	25.00%	92.0	0.00%
<b>NHSCT</b>	9	31.03%	1	12.50%	57.14%	57.14%	93.0	0.00%
<b>SEHSCT</b>	12	41.38%	4	50.00%	36.71%	36.71%	123.0	0.00%
<b>SHSCT</b>	2	6.90%	1	12.50%	60.00%	60.00%	57.0	0.00%
<b>WHSCT</b>	6	20.69%	1	12.50%	37.14%	37.14%	83.0	0.00%
<b>Totals:</b>	29	100.00%	8	100.00%	41.65%	41.65%	92.0	0.00%

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

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

\*\*\* Median RtTT Metrics calculated on all active studies in year

\*\*\*\* FPFV Metrics calculated on Active Sites with Recruitment only

# Neurodegenerative (NEU)

## Clinical Leads, Active PIs and CMG Members

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

## Group Background/Summary

The CMG did not meet in 2024-25 due to staffing issues.

During 2024/2025 there were four active and ongoing studies within the Neurodegenerative group, and one new study being adopted. The NICOLA study (Northern Ireland Cohort for the Longitudinal Study of Ageing) is the largest study of ageing in Northern Ireland and is now currently on Wave 3. It began offering repeat health assessments in December 2024, collecting up to date data and samples.

## Key Achievements

The COBALT trial COMBining memantine and cholinesterase inhibitors in Lewy body dementia Treatment has successfully begun and has recruited two participants up to 31 March 2025.

The RewinD-LD study, successfully retained a participant though out the study and into the extension phase. Top line results from RewinDLB were reported at the International LBD Conference in January 2025: "Efficacy and safety results of the RewinDLB phase 2b clinical trial of neflamapimod in dementia with Lewy bodies".

The TOPHAT study after a pause in 2024 successfully reopened to recruitment in Jan 2025, although further screening for this study has been slow. Having already recruited three participants into this study we are hopeful of reaching our target of five.

We are delighted to report that the HCAP Clinical Validation Study, which has been reported on previously, achieved 1037 participants.

## Relevant Publications

Marr, C., McDowell, B., Holmes, C., Edwards, C. J., Cardwell, C., McHenry, M., Meenagh, G., Teeling, J. L., & **McGuinness, B.** 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. *Journal of Alzheimer's Disease*. 2024;99(1):161-175. doi: 10.3233/JAD-231329. PMID: 38669538.

O'Hara L, Neville C, Marr C, **McAlinden M**, Kee F, Weir D, **McGuinness B**. 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 substudy. *BMJ Open*. 2024 Jan 31;14(1):e075672. doi: 10.1136/bmjopen-2023-075672. PMID: 38296305; PMCID: PMC10831431.

Investigating Syndemic Effects of Air Pollution and Physical Inactivity on Cognitive Decline in Older Adults. Küçükali H, Garcia L, Avila-Palencia I, Wang R, Mullineaux S, Kee F, **McGuinness B**, Hunter RF. *J Phys Act Health*. 2025 Jul 23:1-7. doi: 10.1123/jpah.2024-0756. Online ahead of print. PMID: 40701185

Identifying subphenotypes of patients undergoing post-operative delirium assessment. Bowman EML, **McAuley DF**, **McGuinness B**, **Passmore AP**, **Beverland D**, Zetterberg H, Schott JM, Heslegrave A, Veleva E, Laban R, Sweeney A, **Cunningham EL**. *Alzheimers Dement*. 2025 Jul;21(7):e70516. doi:10.1002/alz.70516. PMID: 40667953

Low hand grip strength is associated with increased risk of cognitive impairment in older men, including men with probable sarcopenic obesity: results from the Northern Ireland PRIME-COG cohort. Farsi DN, McKay GJ, Linden GJ, **McAlinden M**, Teeling J, **Passmore P**, Holmes C, Patterson CC, **McGuinness B**, McEvoy CT. *Gerontology*. 2025 Jul 11:1-20. doi: 10.1159/000547314. Online ahead of print. PMID: 40652923

Tooth loss, diet quality, and cognitive decline: A 15-year longitudinal study. Winning L, Logan D, McEvoy CT, Farsi D, McKay GJ, Patterson CC, **Passmore P**, Holmes C, Linden GJ, **McGuinness B**. *J Nutr Health Aging*. 2025 Jun 27;29(9):100620. doi: 10.1016/j.jnha.2025.100620. Online ahead of print. PMID: 40580824

Remarkable concordance in associations between epigenetic clocks and health behaviors across three countries. Klopach ET, Hernandez B, Potter C, Faul JD, Hill C, Smyth L, Mitchell C, McCrory C, Kenny RA, McKnight AJ, **McGuinness B**, Crimmins EM. *Soc Sci Med*. 2025 Sep;381:118287. doi: 10.1016/j.socscimed.2025.118287. Epub 2025 May 30. PMID: 40532495

UK Longitudinal Linkage Collaboration (UK LLC): The National Trusted Research Environment for Longitudinal Research. Boyd A, Evans KM, Turner EL, et al inc **McGuinness B** *Int J Popul Data Sci*. 2025 Feb 17;10(1):2468. doi: 10.23889/ijpds.v10i1.2468. eCollection 2025. PMID: 40129687

Epigenetic Clocks Relate to 4 Age-related Health Outcomes Similarly Across 3 Countries. Crimmins EM, Hernandez B, Potter C, Kim JK, Higgins-Chen A, Kenny RA, O'Halloran AM,

**McGuinness B**, Smyth LJ, Hill C, Fiorito G, Faul J, McKnight AJ, McCrory C. J Gerontol A Biol Sci Med Sci. 2025 Jun 10;80(7):glaf036. doi: 10.1093/gerona/036. PMID: 40091605

A systematic review of associations between the environment, DNA methylation, and cognition. Glover S, Illyuk J, Hill C, **McGuinness B**, McKnight AJ, Hunter RF. Environ Epigenet. 2024 Dec 16;11(1):dvae027. doi: 10.1093/eep/dvae027. eCollection 2025. PMID: 39882510

Cohort profile: DNA methylation in the Northern Ireland Cohort for the Longitudinal Study of Ageing (NICOLA) - recruitment and participant characteristics. Potter C, Hill C, Smyth LJ, Neville C, Scott A, Kee F, **McGuinness B**, McKnight A. BMJ Open. 2024 Sep 13;14(9):e085652. doi: 10.1136/bmjopen-2024-085652. PMID: 39277204

## Awards/Good New Stories

In September 2024, staff members of the NICRN Neurodegenerative team were able to attend the Dementia: Caring for Today, Planning for Tomorrow conference held in Queens University.

Michael McAlinden has successfully taken up the role of NICRN Staff management. He will be a big loss to the neurodegenerative nursing team (Figure 8a).

We welcome to the NICRN Neurodegenerative research team, Clinical Research Occupational Therapist Sharon Marks (Figure 8b).



**Figure 8a: New members of Staff Management team Michael McAlinden and with fellow Staff**

**Manager Samantha LaRoche**

**Manager Samantha LaRoche**



**Figure 8b: New addition to the Neurodegenerative team Sharon Marks welcomed by Eileen Fox**

# Dashboard (Neurodegenerative - NEU)

Table 1: Studies and Sites Data	
No. of Active HSC Trusts	1
No. of Active Studies	7
No. of Recruitment Sites	7
No. of Sites with Recruitment (INy)	4
No. of Sites with Recruitment (TOT)	5
No. of New Studies during 24-25	1
No. of Studies closed during 24-25	0

Table 2: Screening and Recruitment In Year and also Cumulative Totals for Active Studies During 24-25			
Screened (INy*) during 24-25	Recruited during (INy*) 24-25	Screened (TOT)** as at 31/03/2025	Recruited (TOT)** as at 31/03/2025
109	104	181	174

\* INy = Activity reported over reporting period (01/04/2024 - 31/03/2025)  
 \*\* TOT = Total activity reported up to and including 31/03/2025

Table 3: Portfolio Sponsorship, Randomisation and Design Mix for Active Studies During 24-25						
	Commercial	Non - Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	1	6	3	4	3	4
Proportion (%)	14.29%	85.71%	42.86%	57.14%	42.86%	57.14%

Table 4a: Recruitment, Median Recruitment to Target (%)* and Median Recruitment to Time & Target (%)** by Sponsorship Type								
Commercial			Non-Commercial			Combined		
Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**
1		33.33%	103		91.67%	104		83.80%

\* Median RtT Metrics calculated on Active Studies which have closed to recruitment in year  
 \*\* Median RtTT Metrics calculated on all active studies in year

Table 4b: Recruitment, Median Recruitment to Target (%)* and Median Recruitment to Time & Target (%)** by Design Type								
Interventional			Observational			Combined		
Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)	Recruited (INy) during 24-25	Median RtT (%)	Median RtTT (%)	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)
3		83.80%	101		141.34%	104		83.80%

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

## Dashboard (Neurodegenerative – NEU cont'd)

Table 5a: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Commercial(1)		Non-Commercial(4)		Combined(5)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
39.0	0.00%	39.0	25.00%	39.0	20.00%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 5b: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Interventional(3)		Observational(2)		Combined(5)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
39.0	0.00%	23.0	50.00%	39.0	20.00%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 6a: Clinical Specialty Group Data by HSC Trust								
List of HSC Trusts*	Recruitment (INY) during 24-25	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Rec to Target (%)**	Median Rec to Time & Target (%)***	Median ALL FPFV**** (days)	Proportion (%) < 30 days
<b>BHSCT</b>	104	100.00%	7	100.00%		83.80%	39.0	20.00%
<b>NHSCT</b>	0	0.00%	0	0.00%				
<b>SEHSCT</b>	0	0.00%	0	0.00%				
<b>SHSCT</b>	0	0.00%	0	0.00%				
<b>WHSCT</b>	0	0.00%	0	0.00%				
<b>Totals:</b>	104	100.00%	7	100.00%		83.80%	39.0	20.00%

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

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

\*\*\* Median RtT Metrics calculated on all active studies in year

\*\*\*\* FPFV Metrics calculated on Active Sites with Recruitment only

# Orthopaedics and Trauma (ORT)

## Clinical Leads, Active PIs and CMG Members

<p><b>Orthopaedics &amp; Trauma Group Clinical Leads:</b></p> <p>Owen Diamond - BHSCT Richard Napier - BHSCT</p> <p><b>Chief and Principal Investigators (CIs &amp; PIs)</b></p> <p>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 Paul Karayiannis - BHSCT</p>	<p><b>CMG Members:</b></p> <p>Orthopaedic and Trauma group activity is very localised to the BHSCT and as such the group works very closely with the highly successful Trauma &amp; Orthopaedic Research Charity (TORC). As leading members of the TORC management group our leads utilise the TORC platform as their clinical speciality Management group decision making body re the makeup of their portfolio.</p> <p><b>Other T&amp;O Research Team Members:</b></p> <p>David Beverland, BHSCT Janet Hill, BHSCT Roslyn Cassidy, BHSCT Nicola Gallagher, BHSCT Sam McMahan, BHSCT CRN Leeann Bryce, BHSCT Sharon Marks, BHSCT Emma Cunningham, BHSCT &amp; QUB John Wong, BHSCT &amp; UU</p> <p><b>PPI Representatives:</b></p> <p>Position Vacant</p>
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## Group Background/Summary

The Trauma and Orthopaedics Research Group, TORG, is linked to Trauma and Orthopaedics Research Charity (TORC), which works to promote research in trauma and orthopaedics across all Trusts in Northern Ireland. The group is supported by Dr Janet Hill, Research Group Manager, Dr Nicola Gallagher, 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 the TORC Research Nurse and Sharron Marks is the NICRN Research Practitioner.

TORC has monthly Orthopaedic Research Committee meetings which are 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 studies.

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

Orthopaedic Retrievals: PI Mr Napier, opened to recruitment 01/06/2021, recruited this year - 41

BASIS: PI Mr Sloan, opened to recruitment 06/04/2022, recruited this year – 4

Meteor2: PI Ms Stevenson, opened to recruitment 07/03/2023, recruited this year - 4

RAPSODI: PI Mr Gallagher, opened to recruitment 23/03/2023, recruited this year – 1

PERISCOPE: PI Mr Pagoti, opened to recruitment 02/02/24, recruited this year – 10

WHITE LIT: PIs Dr O'Donnell & Dr Johnston, opened to recruitment 1/09/2023, closed in Belfast on 14/06/2024, recruited this year – 9

MY KNEE PLAN: PI Mr Napier – opened to recruitment 29/07/24, closed on 31/07/24, recruited: 28

PICBONE: PI Mr Karayiannis, – opened to recruitment 10/09/24, closed on 04/12/24, recruited: 13

## Key Achievements

- Ms Ciara Stevenson travelled on the prestigious American-British-Canadian (ABC) Fellowship in 2024. This fellowship is open to consultant orthopaedic surgeons and hadn't been awarded to someone in Northern Ireland for over 30 years. This is a real accolade to N. Ireland orthopaedics. Ciara had a successful trip and it has opened the door for future research collaborations with international orthopaedic centres. As a result of this, the 2025 ABC travelling fellows will travel to Belfast as part of their fellowship.
- Mr Owen Diamond has been awarded the Rothman-Ranawat travelling fellowship which will take place in November-December of 2025 for 4-5 weeks throughout the United States and Canada, and will culminate at the Current Concepts in Joint Replacement conference. Again this experience will be invaluable for Mr Diamond and will ultimately benefit the wider group.
- TORC held a research day in October 2024. It was well attended by clinical staff, students and local university staff. Invited speakers included Prof Matt Costa, Prof Dan Perry, Prof John Wong, Mr Faichra Rowan and Mr Gerry Sheridan, all consultant trauma and orthopaedic surgeons, who spoke about their experiences in research. The conference feedback was very positive.
- Catherine Gilmore, orthopaedic trainee, presented and won a best abstract prize at the Association for Simulated Practice in Healthcare (ASPiH) conference in Edinburgh, November 2024 for her work on transforming learning in trauma and orthopaedics using 3D printing in a next generation simulation model with real time intra-operative radiographic feedback.

## Relevant Publications

1. Early versus delayed weight-bearing following operatively treated ankle fracture (WAX): a non-inferiority, multicentre, randomised controlled trial.  
Bretherton CP, Achten J, Jogarah V, Petrou S, Peckham N, Achana F, Appelbe D, Kearney R, Claireux H, Bell P, Griffin XL; **WAX Investigators**. *Lancet*. 2024 Jun 29;403(10446):2787-2797. doi: 10.1016/S0140-6736(24)00710-4. Epub 2024 Jun 4. PMID: 38848738
2. The risk of complications after hip fracture.  
Goh EL, Png ME, Metcalfe D, Achten J, Appelbe D, Griffin XL, Cook JA, Costa ML; **WHiTE Investigators**; *Bone Joint J*. 2025 Mar 1;107-B(3):362-367. doi: 10.1302/0301-620X.107B3.BJJ-2024-0858.R1. PMID: 40020726

### Other key publications, which highlight Individual and Group achievements and profiles

- 1) Novel radiographic stem version predictor from anterior-posterior radiographs.  
Denton O, Madden-McKee C, Dunne N, O'Connor J, Hill J, **Beverland D**, Lennon A. *Clin Biomech (Bristol)*. 2025 Mar;123:106465. doi: 10.1016/j.clinbiomech.2025.106465. PMID: 39983284 Free article.
- 2) The third gap - The forgotten space in total knee arthroplasty.  
Brown W, **Gallagher N**, Roberts D, **Napier R**, Barrett D, **Beverland D**. *Knee*. 2025 Jan;52:164-170. doi: 10.1016/j.knee.2024.10.011. PMID: 39580977
- 3) Long-term follow-up of ceramic-on-metal total hip arthroplasty.  
Baker G, Hill J, O'Neill F, McChesney J, **Stevenson M**, **Beverland D**. *Bone Jt Open*. 2024 Nov 5;5(11):971-976. doi: 10.1302/2633-1462.511.BJO-2024-0087.R1. PMID: 39496282.
- 4) Long term follow up of 257 consecutive cementless Oxford medial compartment knee arthroplasties at a non-designer centre.  
**Karayiannis P**, Cassidy R, Dobie I, **Beverland D**. *Knee*. 2024 Aug;49:201-209. doi: 10.1016/j.knee.2024.07.001. PMID: 39043015.
- 5) Socioeconomic deprivation is associated with worse health-related quality of life and greater opioid analgesia use while waiting for hip and knee arthroplasty.  
**Gallagher N**, Cassidy R, **Karayiannis P**, Scott CEH, **Beverland D**. *Bone Jt Open*. 2024 May 24;5(5):444-451. doi: 10.1302/2633-1462.55.BJO-2024-0046.R1. PMID: 38783792
- 6) 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**, McManus K. *Eur J Cardiothorac Surg*. 2024 Jun 3;65(6):ezae192. doi: 10.1093/ejcts/ezae192. PMID: 38718222
- 7) Functional outcome and risk of non-union for 5th metatarsal base fractures.  
Toner E, McCaughey P, Peace C, Cassidy R, **Bryce L**, **Diamond O**. *Eur J Orthop Surg Traumatol*. 2024 May;34(4):2171-2177. doi: 10.1007/s00590-024-03921-x. PMID: 38570341.

## Awards/Good New Stories

- Mr Diamond has been invited onto steering committee for UK trial of aspirin vs LMWH in hip fracture patients.
- Mr Diamond has been invited to sit on the National Speciality Group Meeting for Trauma and Emergency Care.
- Professor John Wong is now part of TORG. Prof Wong was a consultant foot and ankle surgeon at AAH and now divides his time between teaching at the University of Ulster and assisting in foot and ankle research in BHSCT. This is the first foot and ankle surgeon to join the group so will strengthen the group's research capacity.
- TORC sponsored study, Can the use of Virtual Reality improve total knee arthroplasty outcomes? Opened and the team recruited its first patient in October 2024. While this is not NICRN research it is part of the group's research portfolio.
- There has been good conference attendance at local, national and international conferences from the team this year showcasing the group's research outputs. Of note members attended the following conferences: the American Academy of Orthopaedic Surgery Annual Meeting, the British Hip Society Annual Scientific Meeting, the British Orthopaedics Association Annual Congress, the Great Debate, the British Orthopaedic Research Society Annual Meeting and the Irish Orthopaedic Association Annual Meeting.
- TORC has refurbished a dedicated space in Musgrave Park Hospital. The TORC Training and Education Hub is now able to facilitate meetings, training and seminars, allow a quiet space to work in addition to providing a focal point in the hospital to meet and more importantly grow our research capacity.
- Dr Owen Diamond is the PI for DUALITY. The study recruited 26 patients. The RVH site got a special mention in the WHITE PLATFORM Newsletter for May 2024 for being the second highest recruiter for the study. Second only to the Royal Cornwall Hospital



**Figure 9: Professor Jonathan Jackson, Ms Sharon Marks, Dr Daryl McAuley and Dr Owen Diamond Celebrating 2<sup>nd</sup> highest recruited in May for the Duality trial.**

# Dashboard (Orthopaedics and Trauma - ORT)

Table 1: Studies and Sites Data	
No. of Active HSC Trusts	2
No. of Active Studies	12
No. of Recruitment Sites	13
No. of Sites with Recruitment (INy)	7
No. of Sites with Recruitment (TOT)	11
No. of New Studies during 24-25	2
No. of Studies closed during 24-25	2

Table 2: Screening and Recruitment In Year and also Cumulative Totals for Active Studies During 24-25			
Screened (INy*) during 24-25	Recruited during (INy*) 24-25	Screened (TOT)** as at 31/03/2025	Recruited (TOT)** as at 31/03/2025
241	114	1,023	363

\* INy = Activity reported over reporting period (01/04/2024 - 31/03/2025)  
 \*\* TOT = Total activity reported up to and including 31/03/2025

Table 3: Portfolio Sponsorship, Randomisation and Design Mix for Active Studies During 24-25						
	Commercial	Non - Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	0	12	9	3	7	5
Proportion (%)	0.00%	100.00%	75.00%	25.00%	58.33%	41.67%

Table 4a: Recruitment, Median Recruitment to Target (%)* and Median Recruitment to Time & Target (%)** by Sponsorship Type								
Commercial			Non-Commercial			Combined		
Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**
0			114	117.09%	100.42%	114	117.09%	100.42%

\* Median RtT Metrics calculated on Active Studies which have closed to recruitment in year  
 \*\* Median RtTT Metrics calculated on all active studies in year

Table 4b: Recruitment, Median Recruitment to Target (%)* and Median Recruitment to Time & Target (%)** by Design Type								
Interventional			Observational			Combined		
Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)	Recruited (INy) during 24-25	Median RtT (%)	Median RtTT (%)	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)
17	117.09%	100.83%	97	98.90%	98.90%	114	117.09%	100.42%

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

## Dashboard (Orthopaedics and Trauma – ORT cont'd)

Table 5a: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Commercial(0)		Non-Commercial(11)		Combined(11)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
		29.0	63.64%	29.0	63.64%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 5b: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Interventional(7)		Observational(4)		Combined(11)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
30.0	57.14%	12.5	75.00%	29.0	63.64%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 6a: Clinical Specialty Group Data by HSC Trust								
List of HSC Trusts*	Recruitment (INy) during 24-25	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Rec to Target (%)**	Median Rec to Time & Target (%)***	Median ALL FPFV**** (days)	Proportion (%) < 30 days
<b>BHSCT</b>	114	100.00%	12	92.31%	116.00%	100.00%	29.5	60.00%
<b>NHSCT</b>	0	0.00%	0	0.00%				
<b>SEHSCT</b>	0	0.00%	0	0.00%				
<b>SHSCT</b>	0	0.00%	1	7.69%	133.33%	133.33%	10.0	100.00%
<b>WHSCT</b>	0	0.00%	0	0.00%				
<b>Totals:</b>	114	100.00%	13	100.00%	117.09%	100.42%	29.0	63.64%

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

\*\* Median Rtt Metrics calculated on Active Studies which have closed to recruitment in year

\*\*\* Median Rtt Metrics calculated on all active studies in year

\*\*\*\* FPFV Metrics calculated on Active Sites with Recruitment only

## Primary Care (PCR)

### Clinical Leads, Active PIs and CMG Members

<p><b>Primary Care Lead:</b> Nigel Hart</p> <p><b>Federation Lead:</b> Laura McQuillan</p> <p><b>Lead Nurse Manager:</b> Patricia Quinn</p> <p><b>Research Nursing team:</b> Kirsten Ross Marian Chindedza + 1 other starting October 2025</p> <p><b>Recruitment in-process:</b></p> <ul style="list-style-type: none"><li>• 1 * Project Manager</li><li>• 2 * Research Pharmacists</li><li>• 4 * Clinical Leads, 1 at each Federation Support Unit-</li></ul>	<p><b>CMG Members (Full list)</b> In the process of being re-established</p> <p><b>PPI Representatives</b> Not yet established</p>
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## Group Background/Summary

The Primary Care group of the NICRN is on the journey to being re-established within the Eastern Federation Support Unit (eFSU). There are 17 GP Federations in Northern Ireland; these are voluntary collaboratives of GP Practices co-located within a geographical area, initially established on a national average 100k patient population (the population of NI has however grown since 2015). The 17 Federations are supported administratively by Federation Support Units of which there are 4 across the region – East, West, North & South. The Eastern Federation Support Unit is the largest of these, providing support for 8 GP Federations.

Over the last 18 months, since the retirements of the PC Nursing Team, we have embarked upon re-establishing the PC Network in the Eastern Federation Support Unit (eFSU) but with a regional focus. Patricia Quinn was appointed in January 2025 as our lead nurse manager .

Completing the utilisation of the core R&D Capital Resource Levy funds for the PC group of NICRN we have appointed two further Band 6 Nurses, one currently in post and the second commencing in the very near future..

Being in receipt of a time-limited (4 years) capacity-building investment fund for commercial research development, provided by the Association of the British Pharmaceutical Industry's Voluntary Scheme for Branded Medicines (VPAG) Scheme and administered through the Commercial Research Delivery Centre initiative of PHA R&D we will shortly be interviewing for 2 additional nurses, pharmacists, locality-based clinical leads and a project manager.

In year we have adopted two studies and have ambitions to adopt many more; this however depends on a viable pipeline of suitable studies coming to Northern Ireland.

## Key Achievements

1. IID3 Study – Observational study for Infectious intestinal disease, University of Oxford.
  - Two primary practices have been recruited and patient recruitment will commence in the summer of 2025.
2. ECRAID - Observational study for acute respiratory infection in the community, University of Oxford.

Recruitment to this study will commence in 2025

## Relevant Publications

**Evans P, Tonner E, Williamson JD, Dolman M, Chambers E, Crawshaw SE, Yu LM.** The PANORAMIC study of COVID-19 treatments in primary care: a review and learning exercise. *NIHR Open Research.* 2024 Aug 8. doi: [10.3310/nihropenres.1115237.1](https://doi.org/10.3310/nihropenres.1115237.1)

### **PANORAMIC Trial Team.**

Cost-utility analysis of molnupiravir plus usual care versus usual care alone as early treatment for community-based adults with COVID-19 and increased risk of adverse outcomes in the UK PANORAMIC trial. *Br J Gen Pract.* 2024 Jan 16;BJGP.2023.0444. doi: [10.3399/BJGP.2023.0444](https://doi.org/10.3399/BJGP.2023.0444)

### **PANORAMIC Trial Team.**

Virological impact of molnupiravir on SARS-CoV-2 viral load and immune response: interim findings from a UK community-based randomized trial. Forthcoming 2025.  
Preprint available via: [PANORAMIC Trial Results](#)

## Awards/Good New Stories

As the result of collaborative work involving NICRN, HSC R&D and the team in Primary care the Primary Care group of the NICRN has been re-established within the Eastern Federation Support Unit (eFSU).



**Figure 10: Primary Care Eastern Federation team: Kirsten Ross, Patricia Quin, Erin Collins, Nigel Hart and Marion Chindedza.**

# Dashboard (Primary Care – PCR)

Table 1: Studies and Sites Data	
No. of Active HSC Trusts	2
No. of Active Studies	2
No. of Recruitment Sites	9
No. of Sites with Recruitment (INy)	9
No. of New Studies during 24-25	0
No. of Studies closed during 24-25	1

Table 2: Screening and Recruitment In Year and also Cumulative Totals for Active Studies During 24-25			
Screened (INy*) during 24-25	Recruited during (INy*) 24-25	Screened (TOT)** as at 31/03/2025	Recruited (TOT)** as at 31/03/2025
0	0	813	813

\* INy = Activity reported over reporting period (01/04/2024 - 31/03/2025)  
 \*\* TOT = Total activity reported up to and including 31/03/2025

Table 3: Portfolio Sponsorship, Randomisation and Design Mix for Active Studies During 24-25						
	Commercial	Non-Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	0	2	2	0	2	0
Proportion (%)	0.00%	100.00%	100.00%	0.00%	100.00%	0.00%

Table 4a: Recruitment, Median Recruitment to Target (%)* and Median Recruitment to Time & Target (%)** by Sponsorship Type								
Commercial			Non-Commercial			Combined		
Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**
0			0	115.00%	50.00%	0	115.00%	50.00%

\* Median RtT Metrics calculated on Active Studies which have closed to recruitment in year  
 \*\* Median RtTT Metrics calculated on all active studies in year

Table 4b: Recruitment, Median Recruitment to Target (%)* and Median Recruitment to Time & Target (%)** by Design Type								
Interventional			Observational			Combined		
Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)	Recruited (INy) during 24-25	Median RtT (%)	Median RtTT (%)	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)
0	115.00%	50.00%	0			0	115.00%	50.00%

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

## Dashboard (Primary Care – PCR cont'd)

Table 5a: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Commercial(0)		Non-Commercial(9)		Combined(9)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
		7.0	88.89%	7.0	88.89%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 5b: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Interventional(9)		Observational(0)		Combined(9)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
7.0	88.89%			7.0	88.89%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 6a: Clinical Specialty Group Data by HSC Trust								
List of HSC CGs*	Recruitment (INY) during 24-25	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Rec to Target (%)**	Median Rec to Time & Target (%)***	Median ALL FPFV**** (days)	Proportion (%) < 30 days
<b>BCG</b>	0		3	33.33%	115.00%	115.00%	3.0	100.00%
<b>NCG</b>	0		6	66.67%		41.67%	7.5	83.33%
<b>SECG</b>	0		0	0.00%				
<b>SCG</b>	0		0	0.00%				
<b>WCG</b>	0		0	0.00%				
<b>Totals:</b>	0	0.00%	9	100.00%	115.00%	50.00%	7.0	88.89%

\* Commissioning Group names highlighted in purple indicates which CGs are active in the CSG portfolio

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

\*\*\* Median RtTT Metrics calculated on all active studies in year

\*\*\*\* FPFV Metrics calculated on Active Sites with Recruitment only

# 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

The CMG met on 3<sup>rd</sup> September 2024, 21<sup>st</sup> January 2025 and 31<sup>st</sup> May 2025. We adopted the following new studies on to the portfolio in 2024-2025:

- EASI-KIDNEY – a trial of Vicadrostat (an aldosterone synthase inhibitor) in persons with chronic kidney disease.
- IMPEDE-PKD – an NIHR funded trial of metformin in patients with polycystic kidney disease.
- PAVE-2 – an NIHR trial investigating the effects of Paclitaxel or Sirolimus coated balloons in arteriovenous fistulae used for haemodialysis. (At site selection)
- POSIBL6 – a trial of Clazakizumab in haemodialysis patients.
- RAINIER – a trial of Povetacicept in patients with IgA Nephropathy.

## Key Achievements

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

In the last year, we have made significant efforts to broaden the scope of the Renal CMG’s activities even further. In doing so, we have adopted studies which recruited persons at every stage of the kidney disease journey from chronic kidney disease, through to dialysis and transplantation.

- Successful recruitment across three Trusts (Belfast, Southern and South Eastern) to the ACHIEVE trial investigating the impact of low dose Spironolactone on cardiovascular outcomes in persons on dialysis. This trial was presented (with simultaneous publication) at the European Renal Association meeting in Vienna in 2025.
- Successful recruitment to target and completion of FRAIL-KT, an investigator-led study exploring the impact of frailty on kidney transplant outcomes.
- All Trusts participating in two large multinational clinical trials (EASi-KIDNEY and IMPEDE-PKD).
- Inclusion of a trial investigating a radiological procedure which is of great relevance to persons requiring haemodialysis (PAVE-2).
- Participation in the trial of a new weight loss drug which specifically includes persons with chronic kidney disease. This trial is a joint collaboration between the Renal and Endocrine CMGs.

## Relevant Publications

### *EMPA-KIDNEY*

The EMPA-KIDNEY **Collaborative Group**. Effects of empagliflozin on progression of chronic kidney disease: a prespecified secondary analysis from the EMPA-KIDNEY trial. *Lancet Diabetes Endocrinol.* 2024 Jan;12(1):39-50.

The EMPA-KIDNEY **Collaborative Group**. Impact of primary kidney disease on the effects of empagliflozin in patients with chronic kidney disease: secondary analyses of the EMPA-KIDNEY trial. *Lancet Diabetes Endocrinol.* 2024 Jan;12(1):51-60.

Zhou et al. Effects of empagliflozin on quality of life and healthcare use and costs in chronic kidney disease: a health economic analysis of the EMPA-KIDNEY trial. *eClinicalMedicine* 85;103338.

The EMPA-KIDNEY **Collaborative Group**. Long-Term Effects of Empagliflozin in Patients with Chronic Kidney Disease. *N Engl J Med* 2025;392:777-787.

Fergie et al. Duke activity status index is not predictive of outcomes after kidney transplantation: a retrospective observational study. *BMC Nephrol.* 2025 Jul 4;26(1):349.

Carswell et al. A qualitative exploration of caregiver experiences of conservatively managed kidney failure: the ACORN study. *BMC Nephrol.* 2025 Jul 1;26(1):303.

## Awards/Good New Stories

Renal NICRN nurses teamed up with the rest of our renal colleagues for World Kidney Day. To promote kidney health, kidney donation, kidney research and generally educating the public about all things Renal March 2025



Figure 11: World Kidney Day NICKN Renal Stand with CRN Nina Bleakley and Hugh Murtagh.

# Dashboard (Renal – REN)

Table 1: Studies and Sites Data	
No. of Active HSC Trusts	5
No. of Active Studies	18
No. of Recruitment Sites	39
No. of Sites with Recruitment (INy)	11
No. of Sites with Recruitment (TOT)	31
No. of New Studies during 24-25	4
No. of Studies closed during 24-25	4

Table 2: Screening and Recruitment In Year and also Cumulative Totals for Active Studies During 24-25			
Screened (INy*) during 24-25	Recruited during (INy*) 24-25	Screened (TOT)** as at 31/03/2025	Recruited (TOT)** as at 31/03/2025
276	159	1,668	835

\* INy = Activity reported over reporting period (01/04/2024 - 31/03/2025)

\*\* TOT = Total activity reported up to and including 31/03/2025

Table 3: Portfolio Sponsorship, Randomisation and Design Mix for Active Studies During 24-25						
	Commercial	Non-Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	4	14	11	7	12	6
Proportion (%)	22.22%	77.78%	61.11%	38.89%	66.67%	33.33%

Table 4a: Recruitment, Median Recruitment to Target (%)* and Median Recruitment to Time & Target (%)** by Sponsorship Type								
Commercial			Non-Commercial			Combined		
Recruited (INy) during 24-25	Median RTT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RTT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RTT (%)*	Median RtTT (%)**
1		0.00%	158	76.56%	94.73%	159	76.56%	80.00%

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

\*\* Median RtTT Metrics calculated on all active studies in year

Table 4b: Recruitment, Median Recruitment to Target (%)* and Median Recruitment to Time & Target (%)** by Design Type								
Interventional			Observational			Combined		
Recruited (INy) during 24-25	Median RTT (%)*	Median RtTT (%)	Recruited (INy) during 24-25	Median RTT (%)	Median RtTT (%)	Recruited (INy) during 24-25	Median RTT (%)*	Median RtTT (%)
31	78.13%	66.67%	128	65.00%	125.00%	159	76.56%	80.00%

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

## Dashboard (Renal – REN cont'd)

Table 5a: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Commercial(1)		Non-Commercial(30)		Combined(31)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
43.0	0.00%	78.5	36.67%	65.0	35.48%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 5b: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Interventional(15)		Observational(16)		Combined(31)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
113.0	20.00%	34.0	50.00%	65.0	35.48%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 6a: Clinical Specialty Group Data by HSC Trust								
List of HSC Trusts*	Recruitment (INY) during 24-25	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Rec to Target (%)**	Median Rec to Time & Target (%)***	Median ALL FPFV**** (days)	Proportion (%) < 30 days
<b>BHSCT</b>	95	59.75%	11	28.21%	82.00%	78.13%	103.0	28.57%
<b>NHSCT</b>	3	1.89%	7	17.95%	50.31%	60.00%	210.0	40.00%
<b>SEHSCT</b>	19	11.95%	7	17.95%	90.83%	106.67%	27.0	66.67%
<b>SHSCT</b>	41	25.79%	9	23.08%	75.73%	100.00%	186.5	25.00%
<b>WHSCT</b>	1	0.63%	5	12.82%	21.88%	166.67%	43.0	20.00%
<b>Totals:</b>	159	100.00%	39	100.00%	76.56%	80.00%	65.0	35.48%

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

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

\*\*\* Median RtTT Metrics calculated on all active studies in year

\*\*\*\* FPFV Metrics calculated on Active Sites with Recruitment only



Total in-year recruitment fell from 165 to 100 participants and this is reflective of slow study start up times rather than an inability to recruit patients to our portfolio. Despite lower in-year accrual, performance indicators show strong operational health and readiness for continued growth. Recruitment and delivery depend on a small, skilled workforce especially in some Trusts e.g. NHSCT and SHSCT. With six study closures and three new openings, strengthening industry and academic engagement will be key to maintaining future portfolio momentum. We need targeted action on recruitment balance, workforce capacity, and pipeline development, but the Group is well positioned to build on its success and deliver even greater research impact in 2025–26.

## Key Achievements

- **Portfolio Growth:**

Active studies increased from 22 to 32 (+45%), with recruiting sites rising from 30 to 49. All five HSC Trusts are now engaged in respiratory research, extending reach and equity of access. A number of these studies are shared with or led by the NICRF and this collaboration increases our capacity to deliver a wide range of studies.

- **Improved Efficiency:**

Median First Participant First Visit (FPFV) reduced from 38 days to 21 days since last year, and over half of all studies (54%) now open within 30 days. This was a particular target of the groups as an effort to counteract slow set up times with a focused target to recruit patients as soon as possible after C & C obtained.

- **Regional Collaboration:**

The Southern HSC Trust (SHSCT) was the leading recruiting site, contributing 68% of in-year accrual. Other Trusts did focus on earlier phase higher intensity studies that tend to have lower target recruitments.

## Relevant Publications

Cho PSP, Birring SS, McDowell C, ... **McGarvey L** et al.. The NEuroCOUGH Chronic Cough Registry: a protocol for a pan-European observational study. ERJ Open Res. 2025 Sep 22;11(5):00289-2025.

Coley K, John C, Ghose J, Shepherd DJ, Shrine N, Izquierdo AG, Kanoni S, Magavern EF, Packer R, **McGarvey L** et al. Genomics of chronic dry cough unravels neurological pathways. Eur Respir J. 2025; 66(3):2402341.

Kum E, Guyatt GH, Abdulqawi R, Dicipinigaitis P, Dupont L, Field SK, French CL, Gibson PG, Irwin RS, Johnston F, **McGarvey L** et al. The McMaster Cough Severity Questionnaire (MCSQ): a cough severity instrument for patients with refractory chronic cough. Eur Respir J. 2025;65(2):2401565.

Jones M, Cahn A, **Chaudhuri N**, Clark AB, Forrest I, Hammond M, Jones S, Maher TM, Parfrey H, Raghu G, Simpson AJ, Smith JA, Spencer LG, Thickett D, Vale L, Wahed S, Ward C, Wilson AM. The effectiveness and risks of Treating people with Idiopathic Pulmonary fibrosis with the Addition of Lansoprazole (TIPAL): study

protocol for a randomised placebo-controlled multicentre clinical trial. *BMJ Open*. 2025 Feb 5;15(2):e088604. doi: 10.1136/bmjopen-2024-088604. PMID: 39909521; PMCID: PMC11800218.

## Awards/Good New Stories

- First UK site to recruit to “A randomised, Double-Blind, Placebo Controlled, Two-Part Study to Evaluate the Efficacy, Safety, Tolerability and Pharmacokinetics of a Repeat Dose of Inhaled ETD001 in People with Cystic Fibrosis”
- Two of our Respiratory Research Nurse’s attended the ECF Conference in Glasgow June 2024
- Five members of our team attended the Delivering Clinical Trials. From Protocol to Patient.

Dr Jane McDowell started a joint clinical academic appointment at Queen's university and as an honorary respiratory consultant in the Belfast Trust in August 2024. Her disease area is asthma where she has an interest in the mechanism of asthma exacerbations, burden of corticosteroid comorbidity in severe asthma and the contribution of non-eosinophilic immunopathology in severe asthma.

Over the course of this year she has been awarded her first investigator grant from asthma lung UK, has started supervising 2 PhD students and one MPhil student. She contributes nationally on the British Thoracic Society Scientific Advisory Board for asthma, on the editorial board for *Therapeutic Advances in Respiratory Diseases* and as a member of the UK severe asthma registry network. Jane has an eagerness for patient voice inclusion and has established an asthma patient engagement group in Belfast. She has enjoyed working alongside the Clinical research network and University Floor staff to deliver industry and academic clinical trials in Northern Ireland in the knowledge that research is crucial for delivery of best patient care and is a core investment for healthcare institutions.

Jane McDowell Abstracts and Contributions at conferences

2024:\* (Washington): American College of Rheumatology (ACR) Convergence conference

Poster ‘ A patient-focused programme for using steroids wisely’

2024: (Belfast): Clinical Academics in Training, Academy of Medical Sciences Conference\*

Poster presentation ‘Longitudinal assessment of GC toxicity in biologics treated severe asthma’.

2024 (Vienna): European Respiratory Conference, ERS\*

Oral presentation ‘Sputum proteomics shows association between asthma duration and NETosis’

Jane McDowell invited speaker

Speaker 7th Respiratory tract infections conference: Asthma, immunology and infection (February 2025)

Key speaker at annual Cancer Focus NI event, Respiratory health: Asthma and Vaping (Dunsilly, Belfast) December 2024

British Thoracic Society Symposium Chair November 2024 (London)

Irish Thoracic Society: all Ireland registrar teaching (Derry, Nov 2024): Asthma: the taming of the T2...and all the rest

AZ: Asthma precision medicine November NI (Belfast)

Limbic: ERS through a UK lens webinar (September 2024)

GSK summer NEXUS London (July 2024)

Asthma UK Centre for Applied Research (AUKAR) webinar (July 2024)

Dr Dermot Linden

"The NICRN's successful delivery of the RedX RXC007 phase 2 clinical trial of Zelasudil in idiopathic pulmonary fibrosis (IPF) represents an important milestone for ILD research in Northern Ireland. This achievement demonstrates the growing capacity of our clinical trials infrastructure to deliver complex, high-quality studies with excellent recruitment. Importantly, this also establishes a strong foundation for our patients to be able to access novel ILD therapies and the continued expansion of the respiratory clinical trials portfolio across Northern Ireland".

Research and Development would like to convey their congratulations to both Kathryn Ferguson (NICRN Study Co-Ordinator) and Hazel Thompson (NICRN Study Support Officer) in completing the ARTP Spirometry Certification. This certification is the only nationally recognised certification in the performance and interpretation of spirometry, and consequently Kathryn & Hazel are the only two entrants onto the Spirometry National Register within WHSCT, which is supported by the Care Quality Commission

Both Kathryn and Hazel are currently actively involved in respiratory research involving CTIMPs, non-CTIMPs, and other investigator-led studies within commercial, academic and public sectors.



**Figure 12: Congratulations to Kathryn Ferguson and Hazel Thompson on completing the ARTP Spirometry Certification**

# Dashboard (Respiratory Health - RES)

Table 1: Studies and Sites Data	
No. of Active HSC Trusts	5
No. of Active Studies	32
No. of Recruitment Sites	49
No. of Sites with Recruitment (IN Y)	12
No. of Sites with Recruitment (TOT)	37
No. of New Studies during 24-25	3
No. of Studies closed during 24-25	6

Table 2: Screening and Recruitment In Year and also Cumulative Totals for Active Studies During 24-25			
Screened (IN Y*) during 24-25	Recruited during (IN Y*) 24-25	Screened (TOT)** as at 31/03/2025	Recruited (TOT)** as at 31/03/2025
497	100	8,428	1,946

\* IN Y = Activity reported over reporting period (01/04/2024 - 31/03/2025)

\*\* TOT = Total activity reported up to and including 31/03/2025

Table 3: Portfolio Sponsorship, Randomisation and Design Mix for Active Studies During 24-25						
	Commercial	Non - Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	9	23	19	13	21	11
Proportion (%)	28.13%	71.88%	59.38%	40.63%	65.63%	34.38%

Table 4a: Recruitment, Median Recruitment to Target (%)* and Median Recruitment to Time & Target (%)** by Sponsorship Type								
Commercial			Non-Commercial			Combined		
Recruited (IN Y) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (IN Y) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (IN Y) during 24-25	Median RtT (%)*	Median RtTT (%)**
14	120.00%	75.00%	86	87.06%	86.53%	100	100.00%	86.53%

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

\*\* Median RtTT Metrics calculated on all active studies in year

Table 4b: Recruitment, Median Recruitment to Target (%)* and Median Recruitment to Time & Target (%)** by Design Type								
Interventional			Observational			Combined		
Recruited (IN Y) during 24-25	Median RtT (%)*	Median RtTT (%)	Recruited (IN Y) during 24-25	Median RtT (%)	Median RtTT (%)	Recruited (IN Y) during 24-25	Median RtT (%)*	Median RtTT (%)
27	100.00%	93.75%	73	80.53%	74.00%	100	100.00%	86.53%

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

# Dashboard (Respiratory Health - RES cont'd)

Table 5a: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Commercial(9)		Non-Commercial(28)		Combined(37)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
57.0	44.44%	19.5	57.14%	21.0	54.05%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 5b: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Interventional(29)		Observational(8)		Combined(37)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
28.0	51.72%	15.5	62.50%	21.0	54.05%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 6a: Clinical Specialty Group Data by HSC Trust								
List of HSC Trusts*	Recruitment (INy) during 24-25	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Rec to Target (%)**	Median Rec to Time & Target (%)***	Median ALL FPFV**** (days)	Proportion (%) < 30 days
<b>BHSCT</b>	16	16.00%	23	46.94%	80.53%	64.00%	20.0	70.59%
<b>NHSCT</b>	11	11.00%	9	18.37%	80.00%	97.03%	88.0	20.00%
<b>SEHCT</b>	0	0.00%	2	4.08%	10.00%	10.00%	88.0	0.00%
<b>SHSCT</b>	68	68.00%	6	12.24%	140.83%	121.26%	7.0	83.33%
<b>WHSCT</b>	5	5.00%	9	18.37%	120.00%	115.11%	59.0	25.00%
<b>Totals:</b>	100	100.00%	49	100.00%	100.00%	86.53%	21.0	54.05%

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

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

\*\*\* Median RtT Metrics calculated on all active studies in year

\*\*\*\* FPFV Metrics calculated on Active Sites with Recruitment only

# Stroke (STR)

## Clinical Leads, Active PIs and CMG Members

<b>Stroke Group Clinical Leads</b> Jim McIlmoyle - BHSCT Carolee McLaughlin - BHSCT	<b>CMG Members:</b> <b>BHSCT</b> –Jim McIlmoyle, Carolee McLaughlin <b>NHSCT</b> –Murudappa Bhattad <b>SEHSCT</b> – Mark Bowman <b>SHSCT</b> – Michael McCormick <b>WHSCT</b> - Roisin Healy, Breffni Keegan
<b>Principal Investigators (CIs &amp; PIs)</b> Cathy Patterson BHSCT Ivan Wiggam BHSCT Patricia Gordon BHSCT Paul Burns BHSCT Gerallt Roberts 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>Northern Ireland Stroke Improvement Network</b> - Fiona Quigg  <b>PPI Representatives</b> A.S – CLASP trial

## Group Background/Summary

The Stroke Specialty Group continued to demonstrate strong levels of research activity across the five Trusts during 2024–2025. CMG meetings were held quarterly and were well attended by representatives from all five Trusts, including Research Nurses / Coordinators and Principal Investigators (PIs). Notably, each Trust now has an identified PI, representing an improvement on the previous year.

Over the course of the year, the group supported eight active studies 2 in setup (Pheast and LACI 3) and 6 which were open or in follow up (TICH-3, MAPS-2, ESCAPE-MeVO, SMART, CHAT Phase 3 and ENRICH AF), the majority of which were multicentre. Of those, two new studies—SMART and LACI-3—were adopted. Recruitment performance was highly successful, with targets achieved and in some cases exceeded, across open studies including MAPS-2, TICH-3,

and ENRICH AF. The Southern Trust also received recognition, winning a prize at the UK Stroke Forum 2024 for being the highest recruiting site in the OPTIMAS study in N. Ireland. Number of studies closed was 2 (CHATS and ENRICH AF)

The group maintained strong engagement with other Research Coordinators, including participation in national and local initiatives to raise awareness of stroke research.

## Key Achievements

**Regular Collaboration:** Quarterly CMG meetings and strengthened connections across all five Trusts, fostering collaboration between Research Coordinators and PIs.

**Regional and National Links:** Enhanced engagement between Northern Ireland and UK research networks, supporting identification of potential new studies.

**Study Development:** Significant progress in the PHEAST study, which is now close to initiation. Regionally set-up is in progress for LACI-3, SMART with 5 other studies having expressions of interest submitted.

**International Collaboration:** Success of the ESCAPE-MeVO study from Calgary, with the RVH (P.I. Dr Paul Burns) being the only UK site selected. The trial was stopped early as the planned interim analysis suggested lack of clinical benefit.

**Recruitment Success:** Targets achieved or exceeded across multiple studies. Recognition of the Southern Trust as the highest regional recruiting site for the OPTIMAS study (P.I. Dr Michael McCormick) at the UK Stroke Forum. MAPS-2 at UHD (P.I. Dr Mark Bowman) rapidly reached target which was then doubled. They are well on their way to meeting their revised target.

**Recruitment Success:** Targets achieved or exceeded across multiple studies, including recognition of the Southern Trust as the highest recruiting site for the OPTIMUS study at the UK Stroke Forum.

**New Opportunities:** eight EOI / potential new studies identified for the upcoming year, strengthening the research pipeline.

**Workforce Development:** In the Belfast Trust we welcomed Kate Vernon-Kelly who was successfully recruited to a research co-ordinator post, supporting the delivery and sustainability of stroke research at RVH.

## Relevant Publications

Endovascular Treatment of Stroke due to Medium Vessel Occlusion. NEnglJMed, Goyal et. Al. – pg. 1-26, DOI: 10.1056/NEJMoa2411668 Site PI: **Paul Burns** MB BCh FRCR

Contributors: **Sharon Nelson BSc, Érin Collins MSc, Kerry Courtney BSc**, Chidiogo Okechukwu **MSc, Eileen Fox BSc**, Enda Kerr MBChB, **Patricia Gordon** MB BCh BaO, **Ivan Wiggam** MB BCh BaO, FRCP, **Cathy Patterson** MB BCh BaO, FRCP, Ian Rennie MB BCh BaO, Peter Flynn MB BCh BaO FRCR, Sean O'Reilly MB, BCh BAO, FRCR, EDNI, **Patricia Fearon MB**, BCh BAO, Christine O'Connor MBChB, **Gerallt Roberts** MBChB DCSM FRCP, Graham Smyth MB BCh BaO FRCR,

Karen McGuire(Adams) MBChB MRCP, **Jim McIlmoyle** MB BCH BaO, Louise Alexander MB BCH BaO

Tenecteplase versus alteplase for acute stroke within 4.5 h of onset (ATTEST-2): a randomised, parallel group, open-label trial, Muir et. al., **Ivan Wiggam**....www.thelancet.com, Lancet Neurol 2024; 23: 1087–96.

Kelly et al. Long-term colchicine for the prevention of vascular recurrent events in non-cardioembolic stroke (CONVINCE): a randomised controlled trial. The Lancet. July 2024 (404) Pg 125-133. DOI: [https://doi.org/10.1016/S0140-6736\(24\)00968-1](https://doi.org/10.1016/S0140-6736(24)00968-1). PI: **Dr. Patricia Gordon**.

Optimal timing of anticoagulation after acute ischaemic stroke with atrial fibrillation (OPTIMAS): a multicentre, blinded-endpoint, phase 4, randomised controlled trial, Werring et. al, Lancet 2024; 404: 1731–41. **Michael McCormick, Michael Magee, Grainne Tallon, Denise McFarland, Denise Cosgrove, Jim McIlmoyle, Patricia Fearon, Kerry Courtney**.

CHATS phase 3 (**Carolee McLaughlin**) disseminated regionally at NI Stroke research conference Sept 2024 and to DOH and PHA as a solution to meet intensity of therapy for aphasic patients (RCP stroke guidelines).

## Awards/Good New Stories

The Research Coordinators and Nurses have been active throughout 2024–2025, contributing to both research delivery and the wider visibility of stroke research across Northern Ireland. Key achievements include:

Carolee McLaughlin has been part of the MAPS register of use of Pharyngeal Electrical Stimulation in patients with acute/sub-acute Post-Stroke Dysphagia since 2014. This study evaluates its clinical utility in a multicentre registry. Gwenllian Wilkinson, BMedSci;<sup>1,2</sup> Carolee McLaughlin, MSc;<sup>3</sup> Habib Rehman, MD, FRCP;<sup>4</sup> Shaheen Hamdy, MD, PhD;<sup>5</sup> Philip M Bath, DSc FMedSci <sup>1,2</sup>

- Red4Research Day (Sept 2024): Nurses promoted visibility and engagement in stroke research at a regional level.
- Belfast Marathon (May 2024): Our research staff (Carolee McLaughlin, Érin Collins and Jim McIlmoyle) ran as part of 3 teams taking part from the Stroke Unit staff. Carolee's team beat Érin and Jim's team by 45 seconds! This event raised significant funds for research and equipment within the stroke unit.
- Stroke Prevention Awareness Stand (January 2025): Research nurses engaged with the public in the foyer of RVH, raising the profile of the Clinical Research Network within the community.
- UK Stroke Forum (Dec 2024): Research Nurses / Coordinators from each Trust attended in Liverpool, networking nationally and regionally, and exploring opportunities for upcoming studies in 2025.

- Northern Ireland Multidisciplinary Association of Stroke Teams (September 2024): Research activity was showcased, highlighting the breadth of stroke research taking place regionally.

Collaborative Working: Monthly meetings between research nurses and research coordinators supported relationship-building across the Trusts, strengthened learning, and promoted study delivery to expand the research portfolio.



Figure 13a: NI Clinical Research

Network Stroke Team recruit the 1500<sup>th</sup> Patient to the MAPS-2 Clinical Trial in BHSCT.



Figure 13b: Red4Research Day Sept 2025

# Dashboard (Stroke - STR)

Table 1: Studies and Sites Data	
No. of Active HSC Trusts	5
No. of Active Studies	8
No. of Recruitment Sites	24
No. of Sites with Recruitment (INy)	10
No. of Sites with Recruitment (TOT)	13
No. of New Studies during 24-25	2
No. of Studies closed during 24-25	2

Table 2: Screening and Recruitment In Year and also Cumulative Totals for Active Studies During 24-25			
Screened (INy*) during 24-25	Recruited during (INy*) 24-25	Screened (TOT)** as at 31/03/2025	Recruited (TOT)** as at 31/03/2025
309	81	442	158

\* INy = Activity reported over reporting period (01/04/2024 - 31/03/2025)

\*\* TOT = Total activity reported up to and including 31/03/2025

Table 3: Portfolio Sponsorship, Randomisation and Design Mix for Active Studies During 24-25						
	Commercial	Non-Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	1	7	7	1	6	2
Proportion (%)	12.50%	87.50%	87.50%	12.50%	75.00%	25.00%

Table 4a: Recruitment, Median Recruitment to Target (%)* and Median Recruitment to Time & Target (%)** by Sponsorship Type								
Commercial			Non-Commercial			Combined		
Recruited (INy) during 24-25	Median RrT (%)*	Median RrTT (%)**	Recruited (INy) during 24-25	Median RrT (%)*	Median RrTT (%)**	Recruited (INy) during 24-25	Median RrT (%)*	Median RrTT (%)**
0	83.33%	83.33%	81	70.00%	106.27%	81	79.17%	100.00%

\* Median RrT Metrics calculated on Active Studies which have closed to recruitment in year

\*\* Median RrTT Metrics calculated on all active studies in year

Table 4b: Recruitment, Median Recruitment to Target (%)* and Median Recruitment to Time & Target (%)** by Design Type								
Interventional			Observational			Combined		
Recruited (INy) during 24-25	Median RrT (%)*	Median RrTT (%)**	Recruited (INy) during 24-25	Median RrT (%)*	Median RrTT (%)**	Recruited (INy) during 24-25	Median RrT (%)*	Median RrTT (%)**
81	70.00%	125.16%	0	83.33%	75.00%	81	79.17%	100.00%

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

## Dashboard (Stroke – STR cont'd)

Table 5a: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Commercial(3)		Non-Commercial(10)		Combined(13)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
20.0	66.67%	133.5	10.00%	121.0	23.08%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 5b: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Interventional(10)		Observational(3)		Combined(13)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
133.5	10.00%	20.0	66.67%	121.0	23.08%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 6a: Clinical Specialty Group Data by HSC Trust								
List of HSC Trusts*	Recruitment (INY) during 24-25	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Rec to Target (%)**	Median Rec to Time & Target (%)***	Median ALL FPFV**** (days)	Proportion (%) < 30 days
<b>BHSCT</b>	24	29.63%	6	25.00%	80.83%	102.10%	59.5	25.00%
<b>NHSCT</b>	10	12.35%	5	20.83%	75.00%	87.50%	163.0	0.00%
<b>SEHSCT</b>	20	24.69%	2	8.33%		137.78%	14.0	100.00%
<b>SHSCT</b>	24	29.63%	5	20.83%	83.33%	112.91%	35.0	33.33%
<b>WHSCT</b>	3	3.70%	6	25.00%	83.33%	76.31%	358.0	0.00%
<b>Totals:</b>	81	100.00%	24	100.00%	79.17%	100.00%	121.0	23.08%

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

\*\* Median Rtt Metrics calculated on Active Studies which have closed to recruitment in year

\*\*\* Median RttT Metrics calculated on all active studies in year

\*\*\*\* FPFV Metrics calculated on Active Sites with Recruitment only

# 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

Vision’s 2024-25 portfolio consisted of 15 studies, including 1 new study, which was open in year. Of studies currently open, 5 were commercial and 10 non-commercial. Due to the nature of studies carried out in year both screening and recruitment were reduced with 117 screened to recruit 75 participants.

Our median FPFV metric for our combined studies was 71.0 days, with 27.% of studies recruiting first patients within 30 days of opening.

## Key Achievements

Staff within the Vision group have had a very busy year. Although recruitment and study numbers are down on last year this has been the result of a number of staffing and governance issues. The Group are however very happy to report on the following achievements.

- Having completed a successful MHRA GCP inspection for the TIGER study.
- Results of the DIAMONDS and EMERALD studies lead by Prof Noemi Lois as CI have been incorporated into NICE draft guidance for Managing and Monitoring Diabetic Retinopathy(<https://www.nice.org.uk/guidance/ng242/documents/economic-report>)
- Prof Noemi Lois was awarded two large NIHR grants, each in excess of £2 million.
  - DAME <https://www.fundingawards.nihr.ac.uk/award/NIHR157427>
  - COMBAT <https://www.fundingawards.nihr.ac.uk/award/NIHR161891>
- Belfast was the highest recruiting site for Augusto Azuara-Blanco's ACE trial
- Faricimab received NICE approval for the treatment of macular oedema secondary to branch and central retinal vein occlusion following the results of the 2 commercial trials COMINO and BALATON studies which were led in the BHSC by CI Prof Michael Williams.

## Relevant Publications

King, A.J., Hudson, J., **Azuara-Blanco, A.** et al., (2024) Evaluating primary treatment for people with advanced glaucoma: five-year results of the Treatment of Advanced Glaucoma Study. *Ophthalmology*, 131(7), p759-770.

Stewart C, Wu H, Alagappan U, **Azuara-Blanco A**, King AJ, Tatham AJ, et al. (2024) Feasibility of in-home monitoring for people with glaucoma: the I-TRAC mixed-methods study. *Health Technol Assess*,28(44). <https://doi.org/10.3310/GTWD6802>

Shabaninejad H, Homer T, Kernohan A. **Azuara-Blanco, A.** et al. (2024) Is primary trabeculectomy cost-effective for patients with advanced primary open angle glaucoma? Results from the Treatment of Advanced Glaucoma Study economic model *British Journal of Ophthalmology*,108:1210-1215.

Wu H, Hernández R, Crabb DP, ... **Azuara-Blanco, A.** et al. (2024) Patient preferences for ocular hypertension monitoring: a discrete choice experiment. *BMJ Open Ophthalmology*, 9:e001639. <https://doi.org/10.1136/bmjophth-2024-001639>

Douglas SM, Kitchin PJ, **Jackson AJ**, Barrett BT, Little JA (2024). "Athletes' Perspectives of the Classification System in Para Alpine Skiing for Those With Visual Impairment". Adapted Physical Activity Quarterly,41(3) Pg 402-419 <https://doi.org/10.1123/apaq.2023-0076>

Breen H, McLoone E, **Jackson J** (2024). "Case Report of a Child with Harlequin Syndrome and Nance-Horan Syndrome". *Austin Journal of Clinical Ophthalmology* 10(9) (In Press).

Cushley LN, Leonard-Hawkhead B, **Jackson AJ**, Peto T (2025). "Global Certification of Visual Impairment Registries: A scoping Review". *ACTA Ophthalmology* 103(1) Pg 7-15. doi: 10.1111/aos.16763

Cushley LN, Mo M, Tunde P, **Jackson AJ**. (2024 Dec). "The impact of COVID-19 on people with a visual impairment in NI: A Sensory Support View". *Int J of Environ Res Public Health* 21(12) Pg 1701 doi: 10.3390/ijerph21121701

Moore N, Cushley L, Wright D, McCann R, **Moutray T, Peto T, Azuara-Blanco A, Jackson AJ**, (2025). "Associations between certification of visual impairment (CVI) and socioeconomic deprivation: a study using data from the regional Northern Ireland sight impairment certification database". *BMJ Open Ophthalmol* 10(1):e001868. Doi: 10.1136/bmjophth-2024-001868

Ridgeway AR, ...**G Silvestri** et al. (2024). Novel Splice-Altering Variants in the CHM and CACNA1F Genes Causative of X-Linked Choroideremia and Cone Dystrophy. *Genes (Basel)* 16(1):25. doi: 10.3390/genes16010025

### **MONARCH Study**

Burton B...**Hogg R...Peto T** et al. (2024). Acceptability of Home Monitoring for Neovascular Age-Related Macular Degeneration Reactivation: A Qualitative Study. *Stud Health Technol Inform* 315: 425-429. doi: 10.3233/SHTI240182

**Hogg R...Peto T** et al. (2024). Home-monitoring Vision Tests to Detect Active Neovascular Age-Related Macular Degeneration. *JAMA Ophthalmol* 142(6):512-520. doi: 10.1001/jamaophthalmol.2024.0918.

**Hogg RE...Peto T** et al. (2024). Home-monitoring for neovascular age-related macular degeneration in older adults within the UK: the MONARCH diagnostic accuracy study. *Health Technol Assess* 28(32):1-136. doi: 10.3310/CYRA9912

### **RHINE Study**

Agostini h...**Peto T** et al. (2024). Faricimab for neovascular age-related macular degeneration and diabetic macular edema: from preclinical studies to phase 3 outcomes. *Graefes Arch Clin Exp Ophthalmol* 262(11):3437-3451. doi: 10.1007/s00417-024-06531-9

### **FASTBAT Study**

Gale RP...**Peto T** et al. (2024). Improved Structure and Function in Early-Detected Second-Eye Neovascular Age-Related Macular Degeneration: FASTBAT/Early Detection of Neovascular Age-Related Macular Degeneration Report 1. *Ophthalmol Retina* 8(6):545-552. doi: 10.1016/j.oret.2023.12.012

Others publications from Vision CI and PI's (full listing can be viewed in supplement document upon request):

- Cushley LN, McCann R, Moutray T, **Silvestri G, Peto T, Jackson AJ** (2025). Trends in Adult Visual Impairment Certification in Northern Ireland: A 10-Year Analysis. *Ophthalmic Epidemiol* 28:1-8. doi: 10.1080/09286586.2025.2483697
- Daka Q, Neziri B, Lindner E, **Azuara Blanco A.** (2024). Metformin in Glaucoma Treatment. *J Glaucoma* 33(6): 387-393. doi: 10.1097/IJG.0000000000002387
- Bourne RRA.....**Azuara-Blanco A.....Mulholland PJ** et al. (2024). The UK clinical eye research strategy: refreshing research priorities for clinical eye research in the UK. *Eye (Lond)* 38(10): 1947-1957. doi: 10.1038/s41433-024-03049-6.
- Hui BTK, Yeong JL, **Peto T, Willoughby CE.** (2024). Glucagon-like Peptide 1 Receptor Agonist use and the effect on diabetic retinopathy: An uncertain relationship. *Peptides* 178:171240. doi: 10.1016/j.peptides.2024.171240
- **McConnell EL....Saunders KJ** et al. (2025). Inter-Examiner and Inter-Instrument Agreement of the Myopia Master with the IOL Master 700 and NVisionK 5001 in Myopic Children. *Children (Basel)* 12(2):121. doi: 10.3390/children12020121
- Naderi-Meshkin H, **Lois N** et al. (2024). Unveiling impaired vascular function and cellular heterogeneity in diabetic donor-derived vascular organoids. *Stem Cells* 42(9):791-808. doi: 10.1093/stmcls/sxae043
- Jindal A...**PJ Mulholland** et al. (2024). An evaluation of optometric advanced skills within a tertiary based setting. *Eye (Lond)* 38(7):1276-1282. doi: 10.1038/s41433-023-02880-7.
- **Anderson RS** et al. (2025). Expert CONsensus on Visual Evaluation in Retinal disease management: the CONVERGE study. *Br J Ophthalmol* 109(2): 228-236.
- Farashi S...**Hogg R** et al. (2024). Genetic Risk of Reticular Pseudodrusen in Age-Related Macular Degeneration: HTRA1/IncRNA BX842242.1 dominates, with no evidence for Complement Cascade involvement. *medRxiv* 28: 2024.09.26.24314339. doi: 10.1101/2024.09.26.24314339
- Jackson TL...**Peto T** et al. (2024). Stereotactic radiotherapy for neovascular age-related macular degeneration (STAR): a pivotal, randomised, double-masked, sham-controlled device trial. *Lancet* 404(10447):44-54. doi: 10.1016/S0140-6736(24)00687-1

### **Key Conferences, at which members of the CMG have presented data from NICRN Studies at National or International Conferences.**

- Results from the REVAMP study (led by Ulster University) was presented at the Association for Research in Vision and Ophthalmology international conference in Seattle, USA and the Imaging and Perimetry Society Conference in Cardiff, UK.

## **Awards/Good New Stories**

- Professor Julie Silvestri (co-lead for NICRN Vision) received the Commander of the Order of the British Empire (CBE) medal for services to Ophthalmology and Eyecare

in Northern Ireland which was awarded at Windsor Castle (Figure 14a) (<https://nicrn.hscni.net/professor-giuliana-silvestri-receives-cbe-medal-at-windsor-castle/>)



**Figure 14a: Professor Juile Silvestri receives CBE**

- At the Royal College of Ophthalmologists Annual Congress in May 2024, Professor Lois was awarded the Royal College of Surgeons of Edinburgh King James IV Professorship. Up to five academics are presented with the Professorship annually, the most senior academic award made by the College that recognises a substantial body of work by an individual. This honour recognises Professor Lois' dedication to her field and specifically celebrates the advancements she made as Chief Investigator of DIAMONDS clinical trial. (<https://europe.opthalmologytimes.com/view/professor-noemi-lois-awarded-edinburgh-king-james-iv-professorship-retina-royal-college-of-surgeons>)
- Drs Shelley Black, Lesley Doyle and Emma McConnell successfully completed their Independent Prescribing for Optometrists qualification awarded by the College of Optometrists (Figure 14b).



**Figure 14b: Dr Shelley Black presenting at the annual NICRN Staff event**

# Dashboard (Vision - VIS)

Table 1: Median First Participant, First Visit Windows (days) and Proportion of	
No. of Active HSC Trusts	2
No. of Active Studies	15
No. of Recruitment Sites	16
No. of Sites with Recruitment (INy)	7
Median First Participant, First Visit Windows (days) and	
No. of New Studies during 24-25	1
No. of Studies closed during 24-25	3

Table 2: Screening and Recruitment In Year and also Cumulative Totals for Active Studies During 24-25			
Screened (INy*) during 24-25	Recruited during (INy*) 24-25	Screened (TOT)** as at 31/03/2025	Recruited (TOT)** as at 31/03/2025
117	75	1,612	306

\* INY = Activity reported over reporting period (01/04/2024 - 31/03/2025)  
 \*\* TOT = Total activity reported up to and including 31/03/2025

Table 3: Portfolio Sponsorship, Randomisation and Design Mix for Active Studies During 24-25						
			Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	5	10	3	12	5	10
Proportion (%)	33.33%	66.67%	20.00%	80.00%	33.33%	66.67%

Table 4a: Recruitment, Median Recruitment to Target (%)* and Median Recruitment to Time & Target (%)** by Sponsorship Type								
Commercial			Non-Commercial			Combined		
Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**
6	85.71%	84.25%	69	145.24%	97.33%	75	123.81%	90.19%

\* Median RtT Metrics calculated on Active Studies which have closed to recruitment in year  
 \*\* Median RtTT Metrics calculated on all active studies in year

Table 4b: Recruitment, Median Recruitment to Target (%)* and Median Recruitment to Time & Target (%)** by Design Type								
Interventional			Observational			Combined		
Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)	Recruited (INy) during 24-25	Median RtT (%)	Median RtTT (%)	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)
7	123.81%	82.78%	68	141.19%	94.66%	75	123.81%	90.19%

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

## Dashboard (Vision – VIS cont'd)

Table 5a: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Commercial(3)		Non-Commercial(8)		Combined(11)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
71.0	33.33%	55.0	25.00%	71.0	27.27%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 5b: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Interventional(4)		Observational(7)		Combined(11)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
86.5	0.00%	36.0	42.86%	71.0	27.27%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 6a: Clinical Specialty Group Data by HSC Trust								
List of HSC Trusts*	Recruitment (INy) during 24-25	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Rec to Target (%)**	Median Rec to Time & Target (%)***	Median ALL FPFV**** (days)	Proportion (%) < 30 days
BHSCT	75	100.00%	15	93.75%	123.81%	85.71%	53.5	30.00%
NHSCT	0	0.00%	1	6.25%		128.57%	92.0	0.00%
SHSCT	0	0.00%	0	0.00%				
WHSCT	0	0.00%	0	0.00%				
<b>Totals:</b>	75	100.00%	16	100.00%	123.81%	90.19%	71.0	27.27%

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

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

\*\*\* Median RtTT Metrics calculated on all active studies in year

\*\*\*\* FPFV Metrics calculated on Active Sites with Recruitment only

# 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:	Kiernan Savage
ECMC Deputy Scientific Lead	Dan Longley
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. There are currently over 60 PPI representatives now registered with NICRCF. Further detail on the work of the NICRCF is detailed in the **Personal and Public Involvement (PPI) and Engagement** section of the NICTN report.

## Active PIs in 2024-25

(PIs with studies actively recruiting or in follow up only)

<u>PI Name</u>	<u>Job Title</u>	<u>Trust</u>	<u>Affiliation</u>	<u>Area</u>
Prof Stuart McIntosh	Consultant Surgeon	BHSCT	QUB	Breast
Dr Jane Hurwitz	Consultant Oncologist	BHSCT	N/A	Breast
Dr Jackie Clarke	Consultant Oncologist	BHSCT	N/A	Breast
Dr Rosalie Douglas	Consultant Oncologist	BHSCT /NHSCT	N/A	Breast
Mr Gareth Irwin	Consultant Surgeon	BHSCT	N/A	Breast
Dr Nora Scally	Consultant Oncologist	SHSCT	N/A	Breast
Mr Stephen Kirk	Consultant Surgeon	SEHSCT	N/A	Breast
Mr Brendan McFall	Consultant Surgeon	NHSCT	N/A	Breast
Dr Audrey Fenton	Consultant Oncologist	SHSCT	N/A	Breast
Dr Therese McCartney	Consultant Oncologist	SHSCT	N/A	Breast
Dr Goudarz Mazdai	Consultant Oncologist	WHSCT	N/A	Breast
Dr Conor O'Neill	Consultant Oncologist	WHSCT	N/A	Breast
Dr Linda McLaughlin	Consultant Oncologist	WHSCT	N/A	Breast
Dr Paul Farry	Consultant Surgeon	WHSCT	N/A	Breast
Mr Michael Harron	Consultant Surgeon	WHSCT	N/A	Breast
Dr Helen Mathers	Consultant Surgeon	SHSCT	N/A	Breast
Dr Hossam Abdulkhalek	Consultant Oncologist	WHSCT	N/A	Breast
Mr Brendan Skelly	Consultant Surgeon	WHSCT	N/A	Breast
Prof Vicky Coyle	Professor in Oncology	BHSCT	QUB	Early Phase
Dr Catherine Davidson	Consultant Oncologist	BHSCT	N/A	Early Phase
Prof Suneil Jain	Professor in Oncology	BHSCT	QUB	GU
Prof Joe O'Sullivan	Professor in Oncology	BHSCT	QUB	GU
Dr Darren Mitchell	Consultant Oncologist	BHSCT	N/A	GU
Dr Aidan Cole	Consultant Oncologist	BHSCT	QUB	GU
Dr Caroline Forde	Consultant Oncologist	BHSCT	N/A	GU
Dr Jacqui Harney	Consultant Oncologist	SHSCT	N/A	GU
Dr Jonathan McAleese	Consultant Oncologist	NHSCT	N/A	GU
Dr Judith Carser	Consultant Oncologist	SHSCT	N/A	GU
Dr Conor McGarry	Radiotherapy Physics	BHSCT	N/A	Radiotherapy
Mr Ian Harley	Consultant Surgeon	BHSCT	N/A	Gynae
Dr Joanne Millar	Consultant Oncologist	BHSCT	N/A	Gynae
Dr Anne Drake	Consultant Oncologist	BHSCT	N/A	Gynae
Dr Oonagh Sheehy	Consultant Haematologist	BHSCT	N/A	Lymphoma & myeloma
Prof MF McMullin	Consultant Haematology	BHSCT	QUB	Leukaemia & MPN

Dr Claire Arnold	Consultant Haematologist	BHSCT	N/A	Leukaemia & MPN
Dr David Donaldson	Consultant Haematologist	BHSCT	N/A	Lymphoma & myeloma
Dr Nick Cunningham	Consultant Haematologist	BHSCT	N/A	Leukaemia & MPN
Dr Sarah Lawless	Consultant Haematologist	BHSCT	N/A	Lymphoma & myeloma
Dr Christina Bradford	Consultant Haematologist	SHSCT	N/A	Lymphoma & myeloma
Dr Patrick Elder	Consultant Haematologist	WHSCT	N/A	Lymphoma & myeloma
Dr Allister Foy	Consultant Haematologist	SHSCT	N/A	Leukaemia & MPN
Dr Rachel McCormick	Consultant Haematologist	SEHSCT	N/A	Lymphoma & myeloma
Dr Fearghal McNicholl	Consultant Haematologist	WHSCT	N/A	Lymphoma & myeloma
Dr Bridgin Merron	Consultant Haematologist	NHSCT	N/A	Leukaemia & MPN
Dr Keith Rooney	Consultant Oncologist	BHSCT	N/A	Head & Neck
Dr Kirsty Taylor	Consultant Oncologist	BHSCT	N/A	Head & Neck
Dr Lynn Campbell	Consultant Oncologist	BHSCT	N/A	Lung
Prof Jackie James	Molecular Pathologist	BHSCT	QUB	Lung
Dr Raafat Malek	Consultant Oncologist	WHSCT	N/A	Lung
Dr Bode Oladipo	Consultant Oncologist	BHSCT	N/A	Melanoma
Dr Bethany Mitchell	Consultant Haematologist	BHSCT	N/A	Paediatric
Dr Anthony McCarthy	Consultant Oncologist	BHSCT	N/A	Paediatric
Dr Robert Johnston	Consultant Oncologist	BHSCT	N/A	Paediatric
Dr Christine McCartney	Consultant Haematologist	BHSCT	N/A	Paediatric
Dr Heather McCarty	Consultant Oncologist	BHSCT	N/A	Paediatric
Dr Paul Henry	Consultant Oncologist	BHSCT	N/A	Thyroid
Dr Martin Eatock	Consultant Oncologist	BHSCT	N/A	Upper GI
Prof Richard Turkington	Consultant Oncologist	BHSCT	QUB	Upper GI
Dr Claire Harrison	Consultant Clinical Oncologist	BHSCT	N/A	Upper GI

## Group Background/Summary

Over the past year, a portfolio of 62 cancer clinical trials and other adopted clinical research studies were available to cancer patients in Northern Ireland (NI). Belfast HSC Trust offered a portfolio of 56 studies with the other four Trusts offering 2-9 studies. 75.8% (n: 47) of the portfolio was made up of interventional trials and accounted for 52% of overall recruitment (76 participants), which demonstrates a significant shift back to interventional trials being the main focus of NICTN activity. Increasing interventional trial participation has been a strategically important objective for NICTN. It is this access to interventional studies, which allows patients across NI access to novel treatments, and consequently helps to drive up the standard of care for cancer patients across the region.

In total, 247 participants were approached about participating in a research study, with 153 consenting patients actively screened for potential trial participation. Subsequently, 146

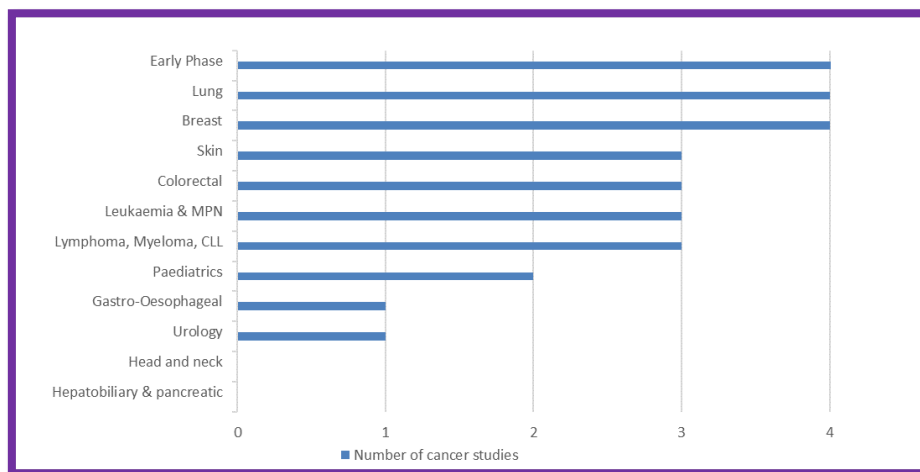
patients were recruited to the regional trials portfolio, with 76 patients participating in an interventional trial. A further 707 participants remained on follow-up at the end of this reporting period, which amounts to a significant and often unrecognized workload for both the clinical and administrative teams.

As in previous years, the mainstay of regional activity was delivered in Belfast with 68.5% of overall network recruitment being reported by Belfast HSC Trust. This again reflects the higher staffing levels available to support trial set-up and delivery, the available HSC service support for research, as well as the geographical centralisation of many cancer services.

The increasing complexity of many interventional trials means that it is not possible to deliver every trial across all centres in NI. Instead, Trusts can either seek approval to act as ‘Patient Identification Centres,’ or patients can be medically referred to Belfast (or the applicable Trust) for potential trial participation. This mechanism allows us to offer patients from across NI the opportunity to access cancer trials no matter where they live. However, where capacity allows us to support the safe delivery of appropriate trials in the Trusts out with Belfast, these trials are opened locally. A summary of portfolio activity is available on request.

### ***Study adoption and set-up***

During the past year, 29 new cancer trials were considered for adoption following review at the multi-professional NI Cancer Clinical Trials Coordinating Committee (Figure 15a). The adopted trials spanned a number of different disease sites with 24 of the trials adopted being interventional in nature, again reflecting our emphasis on trials that offer patient access to new treatment options.



***Figure 15a: Number of studies adopted per disease site***

It is recognised that the volume of studies that can be safely adopted and supported by the NICTN is dependent on a number of interlinked parameters. These include the intensity and complexity of the active trials portfolio (including studies that are open to recruitment and, importantly, also those that are in follow-up, which have a significant associated workload for the team), staff capacity to run multiple trials, availability of a local PI and lastly HSC service support. More recently, however, delays in obtaining approval to open trials have been particularly challenging. Over this reporting period, we opened 19 new studies with 20 studies closing to recruitment during the same period.

### Recruitment Activity per Disease Site 2024-25

Recruitment to cancer clinical trials is dependent not only on having the right portfolio available at the right time, but importantly the portfolio needs to be equally attractive to both the patient and clinical team. Disease site-specific recruitment is dictated by whether a trial is available, whether clinics and the relevant services can support a clinical trial and whether suitable patients are willing to participate.

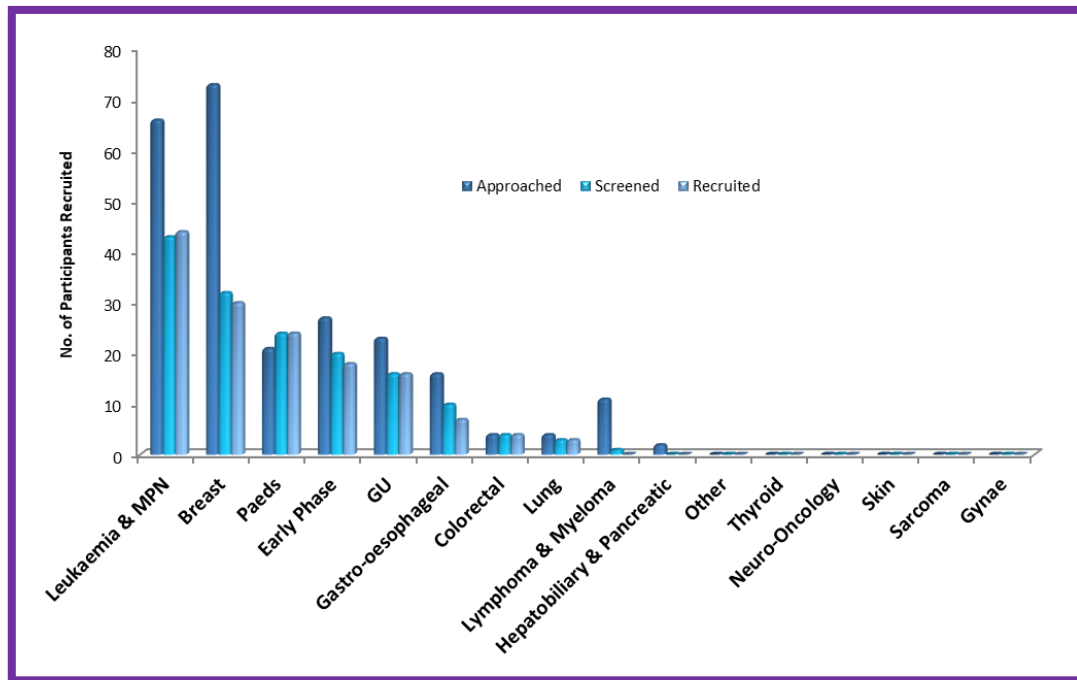


Figure 15b: Recruitment per disease site for 2024-25

Over the course of 2024-25, delays in opening new trials had a major impact on overall recruitment and unfortunately, for some disease sites there were no trials to offer our patients. That said, when disease sites had trials available they performed well (Figure 15b). Of note, both the breast and leukemia trials portfolio recruited steadily to both interventional and non-interventional trials and our early phase portfolio recruited to available trial slots when eligible patients were identified.

This year the paediatric team benefited from the opening of a number of new trials, which was reflected in an increase in recruitment activity. It is anticipated that activity will further increase as the portfolio expands with further studies set to open soon.

Activity in areas of unmet need continues to be addressed. The melanoma portfolio has several new trials in set-up and we were delighted to open the first personalised cancer vaccine study in Northern Ireland in pancreatic cancer under the leadership of Dr Martin Eatock, who is also the UK Chief Investigator for this study. We are also exploring how we can support more brain tumour trials and are currently in discussion about a number of glioblastoma trials that we would like to run here in Belfast. Lastly, we are excited to be

working with the Trauma and Orthopaedic Team on a number of surgical sarcoma trials, which will undoubtedly benefit patients from across the region.

## Key Achievements

- With the development of cancer vaccines being a highly publicised and exciting development in the battle against cancer, NICTN is delighted to have **opened** a number of cancer vaccine studies this year:
  - **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 is UK Chief Investigator. Our first patient has been recruited and manufacture of a personalised vaccine successful.
  - **ModiFY** (Scancell Ltd) is evaluating the use of a DNA cancer vaccine in a variety of solid tumours and has recruited steadily in Belfast since opening in December 2024, under the leadership of Prof Vicky Coyle as local PI.
  - **AHEAD-MERIT**: NICTN's first BioNtech trial is investigating the RNA vaccine BNT113 in combination with pembrolizumab for patients with a form of head and neck cancer. It was initially delayed in opening due to the impact of the EU IVDR (Regulation (EU) 2017/746), but is now scheduled to open locally mid-2025, following the approval of a clinical performance study application. [Over the past year, NICTN has worked closely with HSC R&D and colleagues in MHRA to provide guidance on the new regulatory requirements – a worthwhile activity that will undoubtedly benefit the wider research community].

NICTN hopes to attract more cancer vaccine studies to NI in the near future. Dr Melanie Morris (NICTN Operational Director) is an active member of both the UK Cancer Vaccine Delivery Group and the UK Cancer Vaccine Research Forum, where upcoming studies are reviewed and operational issues discussed, including the implementation of the Vaccine Innovation Pathway, which is being explored as a potential delivery pathway here in NI.

- 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. Of note, **CV6-168** (Prof V Coyle), an exciting 'first in human study' testing the dUTPase inhibitor CV6-168 developed by a local spin-in company, CV-6 Therapeutics (NI) Ltd. opened in August 2024, and continues to recruit on time and on target.
- NICTN has received commendation for their performance across many studies. Some examples are as follows:
  - **SARONG** (Prof R Turkington – GI) - highest UK recruiter March 2025
  - **UKP3BEP** (Dr Oladipo - GCT) - joint 2<sup>nd</sup> highest UK recruiter in 2024
  - **MITHRIDATE** (Prof MF McMullin - Haem) – 3<sup>rd</sup> highest UK recruiter January 2025
  - **SMALL** (Prof S McIntosh – Breast) – 4<sup>th</sup> highest UK recruiter since opening
- NICTN hosted a very successful Sponsor audit of the SABRE study, 25-27 September, 2024. The auditors stated that we should be very proud of our *'awesome team'* who were *'gracious hosts and very accommodating!'* There were only a few very minor points raised, which highlighted the fantastic work of our QA Manager, Dr Rebecca Gallagher and our Clinical Research Radiographer Team.

- Lead Clinical Research Radiographer Stacey Conway published her MSc, 'A single centre service evaluation of patients' experiences participating in radiotherapy clinical trials during and post COVID-19 in Northern Ireland. UK' in the Radiotherapy Journal.
- On 17 June 2024, NICTN were delighted to show case their work to both the Chair of the Belfast HSC Trust, Mr Ciaran Mulgrew (Figure 15c) and the Non-Executive Director, Professor Catherine Ross (Figure 15d). A number of PIs presented their trial activity and NICTN staff had an opportunity to discuss their research directly with Mr Mulgrew and Professor Ross during a poster session at what was a very successful and well received event.



Figure 15c



Figure 15d

- NICTN PI, Professor Suneil Jain met King Charles III at Ulster University's Cancer Research Centre in Coleraine during a visit in March 2025. In attendance were NICRCF members, Ann McBrien and Tim Kerr, who shared their own experience of cancer with His Majesty. Another research area highlighted during the visit was that of Sonotarg Ltd, who are actively working with NICTN on a proof of principle study, due to open next year.
- NICTN contributed to many local, regional and national initiatives. Just some examples are as follows:
  - NICTN staff, Melanie Morris and Ruth Boyd attended the HSC R&D Division Strategy Review Workshop, Clayton Hotel, Belfast, 12 September 2024
  - Jane Cousins and Oonagh Stewart presented at the Prostate Center of Excellence Event in October 2024, providing an update on NICTN radiotherapy clinical trial activity.
  - Ruth Boyd, Michael Hanna, Rebecca Gallagher attended the AI Project event at Riddell Hall, 21 November 2024. Ruth was a break-out round table Q&A session co-facilitator at this event
  - Research Radiographers Grace Totten and Lynn McCourt represented NICTN at a Head and Neck awareness day at Dunadry Hotel, 19 November 2024.
  - NICTN Operational Director (Dr Melanie Morris) and the Clinical Research Radiographer Team met Dr Matt Hobbs (Prostate Cancer UK Director), 6 February 2025, to discuss prostate cancer trial activity in Belfast.

- The NW Cancer Centre and WHSCT R&D, supported by NICTN and NICRCF, hosted a public event to showcase (Fig 15e) the cancer research activity happening in the Western Trust (15 October 2024)
- Dr Melanie Morris (accompanied by Prof Ian Young and Dr Anthony McCartney)) met with NI Minister for Health, Mr Mike Nesbitt and a local cancer charity to discuss paediatric cancer trials, with a particular focus on the challenges encountered and the potential solutions that could facilitate the delivery of more trials locally (22 November 2024).



Figure 15e

- NICTN staff are members of many national groups contributing to various works streams, including for example: National Costing Value Review, Specialist Interest Groups (e.g. Research Radiographers UK), ECMC Nursing Steering Group, ECMC Center Business Leads Forum and ECMC Early Phase Nurses and Haematology Groups. Throughout the year Melanie Morris alongside Ruth Boyd and Paul Biagioni represented NI on the UK Sustainable and Supported Research Workforce Group, co-ordinated by DHSC.
- NICTN and NICRCF worked closely with Cancer Trials Ireland and the All Island Cancer Research Institute on several ‘all-island’ work streams including protocol development and cancer research landscape analysis, with attendance at for example ‘Cancer Knows No Borders’, QUB, April 2025.

## Relevant Publications

### Molecular, clinical, and therapeutic determinants of outcome in NPM1-mutated AML.

Jad Othman<sup>1,2,3</sup>, Nicola Potter<sup>1</sup>, Adam Ivey<sup>4</sup>, Yanis Tazi<sup>5</sup>, Elli Papaemmanuil<sup>5</sup>, Jelena Jovanovic<sup>1</sup>, Sylvie D Freeman<sup>6</sup>, Amanda Gilkes<sup>7</sup>, Rosemary Gale<sup>8</sup>, Tanya Rapoz-D'Silva<sup>8</sup>, Manohursingh Runglall<sup>1,2</sup>, Michelle Kleeman<sup>9</sup>, Pawan Dhama<sup>9</sup>, Ian Thomas<sup>10</sup>, Sean Johnson<sup>10</sup>, Joanna Canham<sup>10</sup>, Jamie Cavenagh<sup>11</sup>, Panagiotis Kottaridis<sup>12</sup>, **Claire Arnold**<sup>13</sup>, Hans Beier Ommen<sup>14</sup>, Ulrik Malthe Overgaard<sup>15</sup>, Mike Dennis<sup>16</sup>, Alan Burnett<sup>17</sup>, Charlotte Wilhelm-Benartzi<sup>10</sup>, Brian Huntly<sup>18</sup>, Nigel H Russell<sup>2</sup>, Richard Dillon<sup>1,2</sup> *Blood*. 2024 Aug 15;144(7):714-728. doi: 10.1182/blood.2024024310. PMID: 38691678

### Postinduction molecular MRD identifies patients with NPM1 AML who benefit from allogeneic transplant in first remission.

Jad Othman<sup>1,2,3</sup>, Nicola Potter<sup>1</sup>, Adam Ivey<sup>4</sup>, Jelena Jovanovic<sup>1</sup>, Manohursingh Runglall<sup>1,2</sup>, Sylvie D Freeman<sup>5</sup>, Amanda Gilkes<sup>6</sup>, Ian Thomas<sup>7</sup>, Sean Johnson<sup>7</sup>, Joanna Canham<sup>7</sup>, Jamie Cavenagh<sup>8</sup>, Panagiotis Kottaridis<sup>9</sup>, **Claire Arnold**<sup>10</sup>, Hans Beier Ommen<sup>11</sup>, Ulrik Malthe Overgaard<sup>12</sup>, Mike Dennis<sup>13</sup>, Alan Burnett<sup>14</sup>, Charlotte Wilhelm-Benartzi<sup>7</sup>, Richard Dillon<sup>1,2</sup>, Nigel H Russell<sup>2</sup> *Blood*. 2024 May 9;143(19):1931-1936. doi: 10.1182/blood.2023023096. PMID: 38364112

Impact of BCR::ABL1 single nucleotide variants on asciminib efficacy Andrew J Innes<sup>#12</sup>, Chloe Hayden<sup>#3</sup>, Victoria Orovboni<sup>3</sup>, Simone Claudiani<sup>45</sup>, Fiona Fernando<sup>45</sup>, Afzal Khan<sup>45</sup>, David Rees<sup>6</sup>, Jennifer Byrne<sup>7</sup>, Paolo Gallipoli<sup>8</sup>, Sebastian Francis<sup>9</sup>, Mhairi Copland<sup>10</sup>, Gillian Horne<sup>10</sup>, Manoj Raghavan<sup>11</sup>, **Claire Arnold**<sup>12</sup>, Angela Collins<sup>13</sup>, Tanya Cranfield<sup>14</sup>, Nicholas Cunningham<sup>12</sup>, Akila Danga<sup>15</sup>, Peter Forsyth<sup>16</sup>, Rebecca Frewin<sup>17</sup>, Paula Garland<sup>18</sup>, Guy Hannah<sup>19</sup>, Daniele Avenoso<sup>19</sup>, Sandra Hassan<sup>20</sup>, Brian J P Huntly<sup>21</sup>, Jissan Husain<sup>22</sup>, Sudhakaran Makkuni<sup>23</sup>, Kate Rothwell<sup>24</sup>, Jamshid Khorashad<sup>425</sup>, Jane F Apperley<sup>45</sup>, Dragana Milojkovic<sup>45</sup>. *Leukemia*. 2024 Nov;38(11):2443-2455. doi: 10.1038/s41375-024-02411-7. Epub 2024 Sep 17. PMID: 39300220

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### **Appendix 1**

Other Key publications: High impact trials that NICTN trials recruited to, are available in an additional supplement document available on request.

### **Appendix 2**

Information on papers, posters and key presentations at national/international conferences/meetings can be seen in the additional supplement document available on request.

## **Awards/Good New Stories**

- Friends of the Cancer Centre ‘Celebrate Great Awards’ recognise those who go above and beyond for their patients. NICTN Staff **Ruth Boyd** (CRUK Senior Research Nurse), **Eileen Dillon** (NICTN Manager) and **Jo McAllister** (Clinical Trial Practitioner) were just some of the recipients from across the NI Cancer Centre who received this award in 2024/25.
- BHSCT Certificates of Recognition were awarded across all sections of the NICTN team throughout the year.
- In October 2024, the NICTN Clinical Research Radiographer Team, alongside our radiotherapy colleagues in the NI Cancer Centre, celebrated success at the Advancing Healthcare Awards hosted at Stormont Hotel in October, for their work on developing a specific research clinic (FAST) to support prostate biopsy and insertion of fiducial markers. The ‘FAST Clinic Team’ was awarded ‘**Best Collaboration**’ and was also named ‘**Overall AHA Winner 2024**’ (Figure 15f) for their **ADVancing radiOtherapy teChniques as A TEam!**



**Figure 15f**

This year NICTN continued to fundraise for the many charities that support the team deliver cancer trials:

- In May 2024, Jill Orr (NICTN Data Manager) raised £915 for CRUK Race for Life at Stormont (Figure 15f).
- On 19th September, NICTN staff supported Cure Leukaemia by running alongside CEO James McLoughlin on his ‘Run the Nations’, which involved running 16 stages and 224 miles (Figure 15h). The tour started in Belfast, with NICTN Manager Eileen Dillon completing the entire 14 mile run!



**Figure 15f**



**Figure 15h**



**Figure 15i**

- An NICTN sponsored static cycle on 20th August 2024 raised just over £3000 for Friends the Cancer Centre, the main charity funding nine NICTN staff (Figure i).

### Personal and Public Involvement (PPI) and Engagement

2024-25 was another year of effective involvement and engagement for NICTN/Belfast ECMC. A particular objective this year was to increase outreach and inclusion in alignment with the wider objectives of the University of Oxford Centre for Research Equity Northern Ireland Partnership Manifesto (2024).

The NI Cancer Research Consumer Forum (NICRCF) grew in number with the addition of eight new members (Figure 15j). Four scheduled meetings of the NICRCF were held and five additional meetings of the, now established, NICRCF Head and Neck Cancer (HNC) subgroup, took place. Each group held one on-line meeting per year, to reduce travel/aid regional access. There were several e-mailed PPI opportunities and ad hoc meetings as research project needs arose.

The Head and Neck Cancer Subgroup was delighted to be featured in the NI Cancer Network News CNS Special Edition, March 2025.

### The Personal and Public Involvement in cancer research

The input of patients and members of the public with lived experience makes research for CNSs more relevant and can ensure it addresses the things that matter most to people.

PPI also makes research more accessible and improves the quality of the research being conducted.

Furthermore, as much research is publicly funded there is a need to ensure transparency on how the work is conducted. With this in mind, the Head and Neck Cancer sub-group of the Northern Ireland Cancer Research Consumers Forum was formed in October 2023.

The group has since met with several researchers and provided PPI input to various projects in related fields. Sub-group members have spoken at public events, including the Cancer Focus Day for Head and Neck Cancer patients and their relatives. Members of the Head and Neck PPI group have also facilitated patient experience sessions for CNSs and dietitians through the HSC Clinical Education Centre.

Co-Chair David Rodgers commented, "Being part of the group has been stimulating and encouraging as we are involved in shaping and communicating with a network of researchers whose exciting work will ultimately improve the care of individuals who will, unfortunately, suffer the same conditions as we have. The feedback we have received from researchers has been overwhelmingly positive, demonstrating an appreciation for the group's contributions and validating the initiative taken in setting up the group."



**Figure 15 j**



Figure 15 k

#### NICRCF meeting June 2024

NICTN and Belfast ECMC (Figure 15K) continue to work with patient advocate partners, embedding their PPI role within NICTN/ECMC research management processes:

- NICTN Executive Committee membership
- Breast Cancer, Haematology and Children's Cancer Clinical Study Group meeting membership
- Belfast ECMC Steering Committee and Operational Group membership
- NICTN/Belfast ECMC study portfolio adoption meeting review/attendance

With the support of an HSC R&D PPI Small Grant, some members of the NICRCF were enabled to join with counterparts working with Cancer Trials Ireland in a productive two-day education and networking event held at the Royal College of Surgeons in Ireland, Dublin, 25/26 September 2024. Once again, the benefits of peer connection was evident. As a result of networking, the following month, there was co-presentation of the all-island study Pro-ACT: Patient-led Research On sexual experience After prostate Cancer Treatment at the Belfast QUB ProEx conference.

Following last year's successful project '**Cancer Through Our Eyes**', the NICRCF members again applied for a Macmillan project grant, this year with the theme 'Close the Cancer Care Gap'. This proposal had multiple elements alongside NICTN/Belfast ECMC planned activities:

- Training for NICRCF members in Health Inequalities – delivered on-line by the Community Development and Health Network, 18<sup>th</sup> December 2024.
- Education session on equality in research for NICRCF members and NICTN/Belfast ECMC staff, delivered by Dr Karen Beattie, Head of the Office of Research Ethics Committees Northern Ireland (ORECNI), 16 January 2025.
- Outreach activity with Adolescents and Young Adults – Research session as part of the 'Life After Cancer - Want The Facts' Workshop event facilitated by Simon Darby,

**Young Lives vs Cancer**, the MAC, 19 January 2025(Figure 15L). A report on this session was produced and co-developed pieces of art have been created for display.



- **Figure 15 L** Following a successful connection with the Chinese Welfare Association, initiated by Tim Kerr, Belfast ECMC PPI representative, a PGJCCR lab tour with interpreter was organised and was well evaluated, 20 January 2025.
- Public Workshop – **Your Cancer Care & Cancer Research**, Clayton Hotel, 20 February 2025. This was undertaken in collaboration with NICRCF, Gráinne Murphy, Belfast Trust Community Involvement PPI team and Arts Care Belfast Trust Artist in Residence, Beth McComish. Table facilitation was led by NICRCF members and representatives from HSC R&D. Data is collated for a report and an art work inspired by the event, utilising tablecloths used for note-taking during the event has been produced for display (see below). This work has led to other future collaborative initiatives as an effective approach in outreach.



**Figure 15M**

Other public engagement over this reporting period included the NICTN/North West Cancer Centre Showcase at Altnagelvin Hospital, 15 October, 2024. After many events in Belfast our objective is to commence a programme to widen awareness of clinical research and PPI within NI(Figure 15M). This was a successful event and useful collaboration, again, positively evaluated.

This year no activity was undertaken for International Clinical Trials Day due to the guidance issued by NIHR/HSC R&D regarding dates coinciding with the Infected Blood Inquiry Report.

Prof Vicky Coyle delivered the Belfast Trust Health Lecture for Feile an Phobail, Belfast 6 August 2024.

Members of the NICRCF HNC Subgroup worked with researchers on a Science Festival activity at PGJCCR, '**Microbes and Medicine**', 15.02.2025, which was also linked with a schools education activity.

NICRCF members supported PPI education for PhD students in QUB, UU and MSc Psychology students at QUB. NICRCF members who were involved in the Precision Medicine Centre of Excellence and Sonrai AI in cancer pathology project, were heavily involved in shaping and contributing to the public event 'AI and Cancer Diagnostics', Riddell Hall, QUB, 21 November24(Figure 15N).



Figure 15N

NICRCF members were also involved in planning and sessions/posters for the Irish Association of Cancer Research annual conference, early career researcher day, held this year at the Europa Hotel, Belfast, 05 March 2025.

NICTN also continues to support HSC R&D '**Building Research Partnerships**', as core PPI training for NICRCF members. This year Ruth Boyd, NICTN CRUK Senior Research Nurse and PPI Professional Lead is also a member of the NI CRRG PPI and Priority Setting Sub-Group.

Supported by an HSC R&D PPI Small Grant, two members of the NICRCF were facilitated to attend the **VOICE** (Science for Patient Advocates – Vision On Information, Confidence and Engagement) a 5-day course at St. Bart's, London, September 2024. Tim Kerr and Ann McBrien reported that 'this was one of the most informative and far-reaching courses' they had attended.

NICRCF have continued to work with the Department of Health in regards to the NI Cancer Research Strategy, participating in a hybrid meeting with DoH representatives 4 December 2024 and individual written comments were also submitted.

We remain indebted to the PPI volunteers for their enthusiasm and dedication. Special mention also to Mr Aidan McCormick, NICRCF Chair, and Dr David Rodgers, HNC Subgroup Co-Chair, for their support, commitment and leadership.

This report is unable to fully reflect the extent of involvement of individual NICRCF members and the impact they have on cancer research in NI. Fuller evidence will be reported in a PPI specific report.

# Dashboard (NICTN – Cancer)

No. of Active HSC Trusts	5
No. of Active Studies	62
No. of Recruitment Sites	73
No. of Sites with Recruitment (INy)	39
No. of Sites with Recruitment (TOT)	59
No. of New Studies during 24-25	19
No. of Studies closed during 24-25	26

Screened (INy)* during 24-25	Recruited during (INy)* 24-25	Screened (TOT)** as at 31/03/2025	Recruited (TOT)** as at 31/03/2025
213	146	1,166	845

\*INy = Activity reported over reporting period (01/04/2024 - 31/03/2025)  
 \*\*TOT = Total activity reported up to and including 31/03/2025

	Commercial	Non-Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	18	44	36	26	47	15
Proportion (%)	29.03%	70.97%	58.06%	41.94%	75.81%	24.19%

Commercial			Non-Commercial			Combined		
Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**
23	40.00%	29.61%	123	80.00%	67.56%	146	66.33%	63.83%

\* Median RtT Metrics calculated on Active Studies which have closed to recruitment in year  
 \*\* Median RtTT Metrics calculated on all active studies in year

Interventional			Observational			Combined		
Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**
113	66.67%	62.07%	33	60.00%	65.59%	146	66.33%	63.83%

\* Median RtT Metrics calculated on Active Studies which have closed to recruitment in year  
 \*\* Median RtTT Metrics calculated on all active studies in year

List of HSC Trusts*	Recruitment (INy) during 24-25	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Rec to Target (%)**	Median Rec to Time & Target (%)***	Median ALL FPFV**** (days)	Proportion (%) < 30 days
BHSCT	100	68.49%	56	76.71%	66.00%	66.00%	57.0	35.42%
NHSCT	17	11.64%	3	4.11%	20.00%	20.00%	37.0	50.00%
SEHSCT	0	0.00%	2	2.74%	75.00%	75.00%	29.0	50.00%
SHSCT	13	8.90%	3	4.11%	120.00%	10.00%	210.5	0.00%
WHSCT	16	10.96%	9	12.33%	100.00%	55.42%	233.0	0.00%
<b>Totals:</b>	<b>146</b>	<b>100.00%</b>	<b>73</b>	<b>100.00%</b>	<b>66.33%</b>	<b>63.83%</b>	<b>63.0</b>	<b>32.20%</b>

\* HSC Trust names highlighted in purple indicates which Trusts are active in the CSG portfolio  
 \*\* Median RtT Metrics calculated on Active Studies which have closed to recruitment in year  
 \*\*\* Median RtTT Metrics calculated on all active studies in year  
 \*\*\*\* FPFV Metrics calculated on Active Sites with Recruitment only

# Dashboard (NICTN – Cancer cont'd)

Table 5a: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days (%) *					
Commercial(13)		Non-Commercial(46)		Combined(59)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
38.0	30.77%	64.5	32.61%	63.0	32.20%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 5b: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days (%) *					
Interventional(48)		Observational(11)		Combined(59)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
73.0	27.08%	29.0	54.55%	63.0	32.20%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 6b: Clinical Specialty Group Data by Multi Disciplinary Team								
List of MDT SGs*	Recruitment (INY) during 24-25	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Rec to Target (%)**	Median Rec to Time & Target (%)***	Median ALL FPFV**** (days)	Proportion (%) < 30 days
Breast	30	20.55%	18	24.66%	75.00%	60.86%	89.0	23.08%
Colorectal	4	2.74%	1	1.37%	N/A	47.88%	5.0	100.00%
Early Phase	18	12.33%	10	13.70%	66.67%	46.59%	78.0	14.29%
Gynae	0	0.00%	1	1.37%	N/A	N/A	95.0	0.00%
Head and Neck	0	0.00%	1	1.37%	N/A	N/A	126.0	0.00%
Hepatobiliary and pancreatic	0	0.00%	2	2.74%	80.00%	72.79%	62.0	0.00%
Leukaemia	44	30.14%	10	13.70%	83.00%	78.23%	157.0	10.00%
Lung	3	2.05%	3	4.11%	20.00%	20.00%	87.5	50.00%
Lymphoma	0	0.00%	5	6.85%	28.33%	0.00%	8.0	100.00%
Not allocated	0	0.00%	1	1.37%	N/A	80.22%	89.0	0.00%
Oesophago-gastric	7	4.79%	3	4.11%	N/A	76.00%	12.0	66.67%
Paediatric	24	16.44%	9	12.33%	100.00%	98.23%	29.0	57.14%
Urology	16	10.96%	9	12.33%	78.00%	78.39%	34.0	37.50%
<b>Totals:</b>	<b>146</b>	<b>100.00%</b>	<b>73</b>	<b>100.00%</b>	<b>66.33%</b>	<b>63.83%</b>	<b>63.0</b>	<b>32.20%</b>

\* MDT names highlighted in purple indicates which MDTs are active in the CSG portfolio

\*\* Median Rtt Metrics calculated on Active Studies which have closed to recruitment in year

\*\*\* Median Rtt Metrics calculated on all active studies in year

\*\*\*\* FPFV Metrics calculated on Active Sites with Recruitment only

# 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. Each Trust has developed its own areas of specialist research expertise and, with limited resources, may not have been able to support all 14 clinical specialty groups. 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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Graham Morrison	Peter Passmore																																																										
Hamish Courtney	Philip Johnston																																																										
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Ivan Wiggam	Suzanna Paterson																																																										
James McNamee	Suzanne Lawther																																																										
Jane McDowell	Tanya Moutray																																																										
Jim McIlmoyle	Tunde Peto																																																										

## Group Background/ Summary

The Deputy Medical Director for Risk and Governance, Dr Mark Cross, continues to provide valuable support for NICRN, and we as a team are indebted to him for including NICRN as an integral component of the R&D service. This will be particularly important as Dr Cross seeks to increase the visibility of clinical research across the BHSCT.

During this reporting time period NICRN staff employed in the BHSCT participated in 204 active studies, opened 32 new studies and successfully closed 28 research studies. Activity was recorded in 13 CSGs and across 97 sites.

In total 3776 research participants were screened and 901 recruited to active studies. This represents a 9% reduction in screening activity and a 35% reduction in recruitment. A finding that, as indicated previously, resulted from a number of challenges linked to the introduction of a Trust wide electronic clinical records system (Encompass) and complex issues associated with research governance workload. It is reassuring to note that with investment currently being made to staffing in the research office these challenges will be addressed in the incoming year. Of particular importance has been the appointment of Karen Johnston as Co-Director for Medical Workforce, Education, Research and Development. Her appointment will strengthen the position of Research and Development within the Trust and ensure that this work is central to core Trust business. Within the Belfast Trust RtT and RtTT figures are really very good at 80% and 76% respectively. In similar fashion the median FPFV figure (36 days) is best in region as is the percentage of first patients recruited within 30 days of study opening (44%).

## Looking ahead

The close relationship developed over time with members of the NICRN team has been invaluable during the course of this challenging year as we introduced Encompass to the Trust and achieved integration of Encompass and EDGE in the research environment. This integration will bear fruit, not only in the BHSCT but regionally, in subsequent years. The BHSCT welcomes the contribution and leadership from the NICRN to deliver effectively clinical trials for our patients in a safe and well governed approach.

# Dashboard – BHSCT

No. of Active CSGs	13
No. of Active Studies	204
No. of Recruitment Sites	212
No. of Sites with Recruitment (INy)	97
No. of Sites with Recruitment (TOT)	160
No. of New Studies during 24-25	32
No. of Studies closed during 24-25	28

Screened (INy)* during 24-25	Recruited during (INy)* 24-25	Screened (TOT)** as at 31/03/2025	Recruited (TOT)** as at 31/03/2025
3,776	901	16,689	4,822

\* INy = Activity reported over reporting period (01/04/2024 – 31/03/2025)  
 \*\* TOT = Total activity reported up to and including 31/03/2025

	Commercial	Non-Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	39	165	120	84	138	66
Proportion (%)	19.12%	80.88%	58.82%	41.18%	67.65%	32.35%

Commercial			Non-Commercial			Combined		
Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**
33	66.67%	28.13%	868	82.00%	83.56%	901	80.00%	76.00%

\* Median RtT Metrics calculated on Active Studies which have closed to recruitment in year  
 \*\* Median RtTT Metrics calculated on all active studies in year

Interventional			Observational			Combined		
Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**
384	77.63%	73.14%	517	87.06%	85.41%	901	80.00%	76.00%

\* Median RtT Metrics calculated on Active Studies which have closed to recruitment in year  
 \*\* Median RtTT Metrics calculated on all active studies in year

List of HSC Trusts*	Recruitment (INy) during 24-25	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Rec to Target (%)**	Median Rec to Time & Target (%)***	Median ALL FPFV**** (days)	Proportion (%) < 30 days
<b>BHSCT</b>	901	100.00%	212	100.00%	80.00%	76.00%	36.0	44.38%
NHSCT	0	0.00%						
SEHSCT	0	0.00%						
SHSCT	0	0.00%						
WHSCT	0	0.00%						
<b>Totals:</b>	901	100.00%	212	100.00%	80.00%	76.00%	36.0	44.38%

\* HSC Trust names highlighted in purple indicates which Trusts are active in the CSG portfolio  
 \*\* Median RtT Metrics calculated on Active Studies which have closed to recruitment in year  
 \*\*\* Median RtTT Metrics calculated on all active studies in year  
 \*\*\*\* FPFV Metrics calculated on Active Sites with Recruitment only

# Dashboard – BHSCT cont'd

Table 5a: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Commercial(26)		Non-Commercial(134)		Combined(160)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
34.0	46.15%	37.0	44.03%	36.0	44.38%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 5b: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Interventional(112)		Observational(48)		Combined(160)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
44.5	41.07%	29.5	52.08%	36.0	44.38%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 6b: HSC Trust Data by Clinical Specialty Group								
List of CSGs*	Recruitment (INV) during 24-25	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Rec to Target (%)**	Median Rec to Time & Target (%)***	Median ALL FPFV**** (days)	Proportion (%) < 30 days
Cancer	100	11.10%	56	26.42%	66.00%	66.00%	57.0	35.42%
Cardiovascular	40	4.44%	18	8.49%	76.67%	73.33%	6.5	57.14%
Child Health	83	9.21%	19	8.96%	81.00%	50.00%	53.5	35.71%
Critical Care	175	19.42%	27	12.74%	95.09%	98.14%	20.0	55.00%
Diabetes	74	8.21%	12	5.66%	22.00%	89.17%	28.5	62.50%
Gastroenterology	1	0.11%	5	2.36%	0.00%	0.00%	125.5	0.00%
Mental Health	0	0.00%	1	0.47%	25.00%	25.00%	92.0	0.00%
Neurodegenerative	104	11.54%	7	3.30%		83.80%	39.0	20.00%
Orthopaedics	114	12.65%	12	5.66%	116.00%	100.00%	29.5	60.00%
Renal	95	10.54%	11	5.19%	82.00%	78.13%	103.0	28.57%
Respiratory Health	16	1.78%	23	10.85%	80.53%	64.00%	20.0	70.59%
Stroke	24	2.66%	6	2.83%	80.83%	102.10%	59.5	25.00%
Vision	75	8.32%	15	7.08%	123.81%	85.71%	53.5	30.00%
<b>Totals:</b>	<b>901</b>	<b>100.00%</b>	<b>212</b>	<b>100.00%</b>	<b>80.00%</b>	<b>76.00%</b>	<b>36.0</b>	<b>44.38%</b>

\* MDT names highlighted in purple indicates which MDTs are active in the CSG portfolio

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

\*\*\* Median RtT Metrics calculated on all active studies in year

\*\*\*\* FPFV Metrics calculated on Active Sites with Recruitment only

# Northern Health and Social Care Trust R&D

## Directors review

### Director, Chief and Principal Investigators

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

### Group Background/ Summary

At present we have a large portfolio of trials, 38 in total covering Renal, Diabetes, Intensive Care, Gastroenterology, Stroke, Respiratory Medicine and Mental Health. There are an additional 7 trials opening in the immediate future. Established research areas including Renal, Diabetes and Respiratory Medicine continue to recruit exceptionally well and are overachieving initial targets.

Stroke and ICU trial recruitment has benefited from local reinvestment of closed trial income to support PI research activity.

The GI team have performed exceptional well, initially under supported, and are continuing to develop research interest with participation in an inpatient Inflammatory Bowel Disease trial.

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

Key achievements include the exceptional recruitment figures in the established research areas of Diabetes, Renal and Respiratory medicine in face of limited resource.

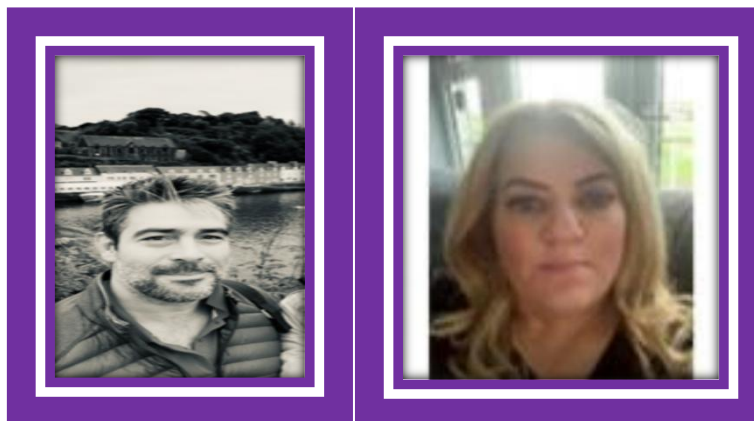
Intensive Care Medicine have successfully recovered following a downturn in activity after the SARS-CoV-2 pandemic through reorganisation of network resources and investment in PI research activity. They have recruited the first patient in NI to the MS-POP-I and continue to support an expanding portfolio of studies.

Respiratory Medicine continues to grow covering sub specialities of Pulmonary Infection, COPD and Interstitial Lung Disease. Dr Minnis has received a highly competitive funding award for Research time from the Northern Ireland Clinical Research Resilience and Growth Scheme. We have had the opportunity to enrol and support 2 trainee doctors in the associate PI Scheme. This provides practical experience for health and care professionals starting their research career and assists in further embedding a culture of research.

Within Mental Health there have been multiple publications and Dr Barret is a visiting scholar in CPH and QUB.

## 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. Proactive engagement in Research activity improves local patient care, tests new treatments, understands local health needs, and informs service delivery and policy. Conducting research ensures findings are relevant to the community, which can lead to earlier diagnoses, better treatments, and a more efficient use of resources. 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. Funding from additional sources including local reinvestment, the NI Research Resilience and Growth group and VPAG has helped pump prime new research areas and support ongoing activity in established groups. We look forward to continuing the highly productive partnership with NICRN with the aims of doing more, better and faster.



**Figure 17a and Figure 17b: R&D Director Dr Paul Minnis NHSCT and NHSCT Research and Governance Manager Frances Johnston.**

# Dashboard – NHSCT

Table 1: Studies and Sites Data	
No. of Active CSGs	9
No. of Active Studies	38
No. of Recruitment Sites	38
No. of Sites with Recruitment (IN Y)	12
No. of Sites with Recruitment (TOT)	26
No. of New Studies during 24-25	7
No. of Studies closed during 24-25	7

Table 2: Screening and Recruitment In Year and also Cumulative Totals for Active Studies During 24-25			
Screened (IN Y)* during 24-25	Recruited during (IN Y)* 24-25	Screened (TOT)** as at 31/03/2025	Recruited (TOT)** as at 31/03/2025
179	101	1,747	573

\* IN Y = Activity reported over reporting period (01/04/2024 – 31/03/2025)  
 \*\* TOT = Total activity reported up to and including 31/03/2025

Table 3: Portfolio Sponsorship, Randomisation and Design Mix for Active Studies During 24-25						
	Commercial	Non-Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	8	30	22	16	23	15
Proportion (%)	21.05%	78.95%	57.89%	42.11%	60.53%	39.47%

Table 4a: Recruitment, Median Recruitment to Target (%)* and Median Recruitment to Time & Target (%)** by Sponsorship Type								
Commercial			Non-Commercial			Combined		
Recruited (IN Y) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (IN Y) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (IN Y) during 24-25	Median RtT (%)*	Median RtTT (%)**
29	112.50%	112.50%	72	40.63%	60.54%	101	67.50%	90.00%

\* Median RtT Metrics calculated on Active Studies which have closed to recruitment in year  
 \*\* Median RtTT Metrics calculated on all active studies in year

Table 4b: Recruitment, Median Recruitment to Target (%)* and Median Recruitment to Time & Target (%)** by Design Type								
Interventional			Observational			Combined		
Recruited (IN Y) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (IN Y) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (IN Y) during 24-25	Median RtT (%)*	Median RtTT (%)**
55	48.88%	61.09%	46	82.50%	95.00%	101	67.50%	90.00%

\* Median RtT Metrics calculated on Active Studies which have closed to recruitment in year  
 \*\* Median RtTT Metrics calculated on all active studies in year

Table 6a: Clinical Specialty Group Data by HSC Trust								
List of HSC Trusts*	Recruitment (IN Y) during 24-25	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Rec to Target (%)**	Median Rec to Time & Target (%)***	Median ALL PPFV**** (days)	Proportion (%) < 30 days
BHSCT	0	0.00%						
NHSCT	101	100.00%	38	100.00%	67.50%	90.00%	49.5	34.62%
SEHSCT	0	0.00%						
SHSCT	0	0.00%						
WHSCT	0	0.00%						
<b>Totals:</b>	<b>101</b>	<b>100.00%</b>	<b>38</b>	<b>100.00%</b>	<b>67.50%</b>	<b>90.00%</b>	<b>49.5</b>	<b>34.62%</b>

\* HSC Trust names highlighted in purple indicates which Trusts are active in the CSG portfolio  
 \*\* Median RtT Metrics calculated on Active Studies which have closed to recruitment in year  
 \*\*\* Median RtTT Metrics calculated on all active studies in year  
 \*\*\*\* PPFV Metrics calculated on Active Sites with Recruitment only

## Dashboard – NHSCT cont'd

Table 5a: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Commercial(6)		Non-Commercial(20)		Combined(26)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
32.5	50.00%	58.0	30.00%	49.5	34.62%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 5b: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Interventional(15)		Observational(11)		Combined(26)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
88.0	26.67%	48.0	45.45%	49.5	34.62%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 6b: HSC Trust Data by Clinical Specialty Group								
List of CSGs*	Recruitment (INY) during 24-25	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Rec to Target (%)**	Median Rec to Time & Target (%)***	Median ALL FPFV**** (days)	Proportion (%) < 30 days
Cancer	17	16.83%	3	7.89%	20.00%	20.00%	37.0	50.00%
Cardiovascular								
Child Health								
Critical Care	18	17.82%	5	13.16%	120.00%	120.00%	7.0	66.67%
Diabetes	33	32.67%	6	15.79%	112.50%	110.42%	32.5	50.00%
Gastroenterology	0	0.00%	1	2.63%		0.00%		
Mental Health	9	8.91%	1	2.63%	57.14%	57.14%	93.0	0.00%
Neurodegenerative								
Orthopaedics								
Renal	3	2.97%	7	18.42%	50.31%	60.00%	210.0	40.00%
Respiratory Health	11	10.89%	9	23.68%	10.00%	44.06%	88.0	20.00%
Stroke	10	9.90%	5	13.16%	75.00%	87.50%	163.0	0.00%
Vision	0	0.00%	1	2.63%		128.57%	92.0	0.00%
<b>Totals:</b>	<b>101</b>	<b>100.00%</b>	<b>38</b>	<b>100.00%</b>	<b>67.50%</b>	<b>90.00%</b>	<b>49.5</b>	<b>34.62%</b>

\* CSG names highlighted in purple indicates which MDTs are active in the CSG portfolio

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

\*\*\* Median RtT Metrics calculated on all active studies in year

\*\*\*\* FPFV Metrics calculated on Active Sites with Recruitment only

Please note Gastroenterology Recruitment (INY) should read 3 participants recruited (GONDOMAR Study) in reporting year (July 2024 [2], August 2024 [1]), but this was not recorded in EDGE before data cut.

# South Eastern 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	Paul Agnew
	Michael Magowan
	Ciara Mulligan
	Patrick Allen
	Jennifer Elder
	Frederick McElwaine
	Mark Bowman
	Chris Murray
	Alison McKenna
	Tony Tham
	Bernardas Valecka
	Alastair Woodman

## Group Background/ Summary

We have placed our emphasis on building resilience within our workforce and improving our research offer. Through our improving research awareness sessions we were delighted to see through attendance and conversation that there was great interest in taking part in research within our organisation. This has translated into greater active engagement in clinical research activity. This support translated into the adoption of 38 NICRN research studies. Studies came from 9 of the networks speciality groups portfolio. 13 clinical investigators were responsible for the set up and delivery of these trials that were identified as “mattering most” for our patients and clinical services. 1381 patients took part in NICRN studies open and in follow up.

With the support of our Trust, NICRN and PHA R&D Division, we have been working towards the delivery of the *Our People, Place, Process & Pipeline* position paper. A recurrent theme from our stakeholders was to identify a dedicated space for clinical trials delivery. This would allow us to build research capacity within our organisation. The Research Oversight Group made this a priority and with their support we have secured a dedicated site within the Ulster Hospital. We hope to secure funding from the VPAG investment fund to help deliver this centre and open it to patients and researchers next year.

We have invested in our staff. Our research nurse workforce has expanded, and we have introduced new job roles. These new staff members and the simultaneous improvement in our research processes have enhanced our capability and research productivity. Our wider

research family has grown with over 75 staff members now recognised as a Principal or Chief Investigator up from 47 in our last annual report. These researchers are reflective of our broader multidisciplinary clinical team with 49 physicians and a further 26 staff from our nursing and allied health disciplines which we believe is a great strength to our research offer. We hope this increase in staff actively participating in research will translate into greater engagement with the opportunities that the NICRN portfolio could offer them.

Another strategic priority for the group is to improve dissemination of our research findings. 110 research publications, presentations, review articles and poster presentations were returned to us this year.

#### Important Publications this year

- Intravenous iron for heart failure, iron deficiency definitions, and clinical response: the Ironman trial. European Heart Journal
- Efficacy of IV ferric derimaltose in hospitalised and outpatient settings: insights from ironman trial. BMJ
- Effect of correcting iron deficiency on the risk of serious infection in heart failure: Insights from the IRONMAN trial. European Journal Of Heart Failure
- Assessing disease control in inflammatory bowel disease: a real world cross-sectional study in the UK (PODCAST-IBD). Taylor & Francis Online
- In patients with stable chest pain, does computed tomography (CT) provide comparable long-term health-related quality of life (QOL) benefits and chest pain reduction compared with invasive coronary angiography (ICA)?. JAMA Cardiology
- Vericiguat in patients with chronic heart failure and reduced ejection fraction (VICTOR): a double-blind, placebo controlled, randomised, phase 3 trial. LANCET
- The UK ROX study. Conservative Oxygen Therapy in Mechanically Ventilated Critically Ill Adult Patients. JAMA
- CABIN. The feasibility of delivering cardiac brief intervention to patients following ST-elevation myocardial infarction: Protocol for a pilot randomised controlled trial. Pubmed

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

Our Gastroenterology team led by Dr Patrick Allen and Dr Tony Tham have exceeded their expected recruitment on both Galocean and Gondomar studies. They were lauded for having the highest enrollment in the UK. GALOCEAN was a prospective, non-interventional multi-country cohort study of the effectiveness and safety of filgotinib in adult patients with moderately to severely active ulcerative colitis. The team have also received excellent feedback from the monitoring team for Abivax on the quality and accuracy of their site files and data entry.

The Nephrology team led by Dr Alastair Woodman recruited the first patient in NI to the Easi-Kidney study which is running across all 5 HSC Trusts supported by NICRN. They have been commended for their data entry and query resolution. The team worked closely with BSO and the Easi-Kidney team to resolve emerging integration IT issues with ENCOMPASS ensuring other sites in NI did not encounter the same challenges when they came online. The team

successfully recruited to time and target for the Achieve study and they recently published their results which have demonstrated that the use of sprinolactone did not significantly reduce the risk of CV death or HF hospitalisation in patients undergoing dialysis.

Dr Jennifer Elder from the Respiratory team is in the process of opening a new study Preside which is tackling the very challenging issue of antimicrobial resistance in patients with chronic lung disease. This is particularly important for our patients many of whom have high co-morbidity and results could directly influence their care. This will also be the first dedicated respiratory trial to be launched in SET.

Dr Mark Bowman who leads our Stroke team continues to recruit well to the MAP-2 study. He is hopeful that this study will prevent death and pneumonia in patients who present with acute stroke. Stroke is the second most common cause of death worldwide and the foremost cause of complex disability in the UK. Dr Bowman is currently expanding his Stroke portfolio with the support of the network with numerous studies due to come online next year.

Our ICU team, led by Dr Chris Murray & Research Nurse Sam Hagan have continued to excel in their recruitment for the Genomicc study which is studying the DNA of critically ill patients to help find new treatments for covid, sepsis, influenza and other critical illness. The team are a top recruiter to this study and are also delivering 6 other clinical trials. This is truly an ICU group effort where the clinical team help our staff to identify eligible participants, deliver interventions and collect data, which allows ICU research studies to run 24/7. This is a remarkable achievement and we wish to highlight their dedication, and commitment to advancing patient care at a time when their clinical service is stretched.

A similar theme of growth and collaboration has occurred within Women & Child Health, a relatively new research area within the Trust. Despite being a new team, they are already involved in 4 studies with their landmark study ObsUK recruiting 297 participants to date. This study aims to improve the management of excessive bleeding during and after childbirth. Dr Magowan is also leading on the Surf on study. This was a first for our site – this is a study in preterm babies where their lung development is incomplete at the time of delivery. This affects their chances of survival. The team are hoping that reduced complications and increased survival in this vulnerable group may improve by giving them surfactant which can make breathing easier. These studies have required the engagement of the wider team not least because they are an example of how research can become a core clinical activity.

The Cardiology team led by Dr Patrick Donnelly and Dr Bernardas Valecka have achieved a significant milestone by surpassing their recruitment target in the PREVAIL study. They were also asked by the Prevail team to become a super-recruitment site to help ensure that global recruitment could be completed as planned. The Euro-Apsire study team commended the research team for recruitment and data entry and again asked if our site could super-recruit due to challenges in achieving their broader UK recruitment goals. The Queens University study team were delighted when SET reached their recruitment target in half the time expected for the CABIN study. This is an important study with positive feedback from patients- one patient took the time to contact to SET management regarding the NICRN cardiac research nurse describing her as *'so caring and compassionate and listened to how I was feeling and what was concerning me. She went above and beyond to try and find a resolution*

– I can't thank her enough for this'. This is an example of the dedication of our staff but also the impact that research has on our patients

The research nurse team at SEHSCT supported all 4 Trusts with the research ENCOMPASS integration. They received positive feedback from the wider NICRN teams for their training days. This was invaluable for our NI teams and made the transition onto the new system easier.

## A message from the R&D Director

Thanks to our collaboration with NICRN we have been able to increase our research offer, with almost 3500 patients screened and recruiting just under 50%. Our community are engaged, and we have greater interest from our clinical teams. Working with the Trust, PHA RD Division and the NICRN we hope to be successful in attracting funds that will allow us to complete our new clinical trials centre which will provide research visibility and a dedicated space where more NICRN portfolio trials could be delivered.

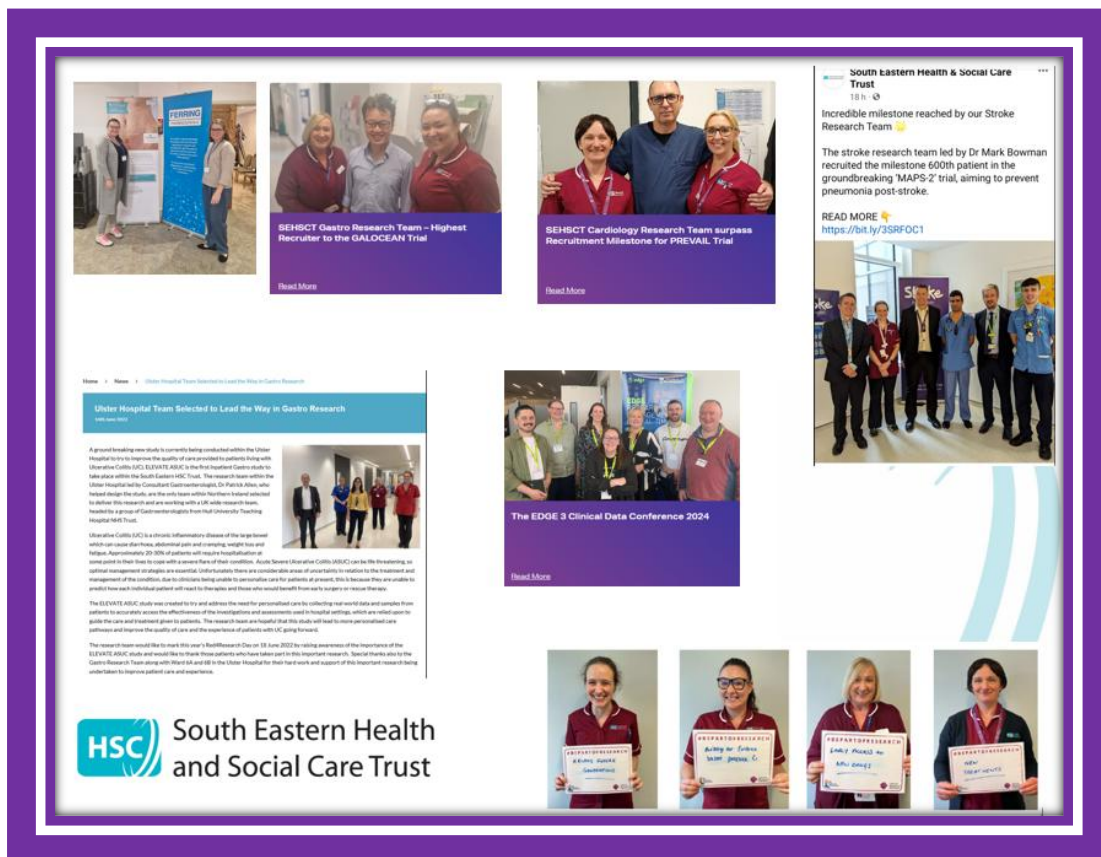


Figure 18: SHSCT image collage of several research teams (Cardiology, Gastro, Stroke) with several staff showing their “be part of research messages”.

# Dashboard – SEHSCT

No. of Active CSGs		10
No. of Active Studies		38
No. of Recruitment Sites		44
No. of Sites with Recruitment (INy)		21
No. of Sites with Recruitment (TOT)		37
No. of New Studies during 24-25		6
No. of Studies closed during 24-25		7

Screened (INy) during 24-25	Recruited during (INy) 24-25	Screened (TOT)** as at 31/03/2025	Recruited (TOT)** as at 31/03/2025
1,371	808	3,384	1,381

\* INy = Activity reported over reporting period (01/04/2024 – 31/03/2025)  
 \*\* TOT = Total activity reported up to and including 31/03/2025

	Commercial	Non-Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	7	31	20	18	22	16
Proportion (%)	18.42%	81.58%	52.63%	47.37%	57.89%	42.11%

Commercial			Non-Commercial			Combined		
Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**
23	75.00%	50.00%	785	75.00%	94.44%	808	75.00%	88.89%

\* Median RtT Metrics calculated on Active Studies which have closed to recruitment in year  
 \*\* Median RtTT Metrics calculated on all active studies in year

Interventional			Observational			Combined		
Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**
117	87.50%	73.03%	691	74.00%	100.00%	808	75.00%	88.89%

\* Median RtT Metrics calculated on Active Studies which have closed to recruitment in year  
 \*\* Median RtTT Metrics calculated on all active studies in year

List of HSC Trusts*	Recruitment (INy) during 24-25	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Rec to Target (%)**	Median Rec to Time & Target (%)***	Median ALL FPFV**** (days)	Proportion (%) < 30 days
BHSCT	0	0.00%						
NHSCT	0	0.00%						
SEHSCT	808	100.00%	44	100.00%	75.00%	88.89%	42.0	40.54%
SHSCT	0	0.00%						
WHSCT	0	0.00%						
<b>Totals:</b>	<b>808</b>	<b>100.00%</b>	<b>44</b>	<b>100.00%</b>	<b>75.00%</b>	<b>88.89%</b>	<b>42.0</b>	<b>40.54%</b>

\* HSC Trust names highlighted in purple indicates which Trusts are active in the CSG portfolio  
 \*\* Median RtT Metrics calculated on Active Studies which have closed to recruitment in year  
 \*\*\* Median RtTT Metrics calculated on all active studies in year  
 \*\*\*\* FPFV Metrics calculated on Active Sites with Recruitment only

## Dashboard – SEHSCT cont'd

Table 5a: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Commercial(7)		Non-Commercial(30)		Combined(37)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
32.0	42.86%	47.5	40.00%	42.0	40.54%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 5b: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Interventional(21)		Observational(16)		Combined(37)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
53.0	38.10%	31.5	43.75%	42.0	40.54%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 6b: HSC Trust Data by Clinical Specialty Group								
List of CSGs*	Recruitment (INy) during 24-25	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Rec to Target (%)**	Median Rec to Time & Target (%)***	Median ALL FPFV**** (days)	Proportion (%) < 30 days
Cancer	0	0.00%	2	4.65%	75.00%	75.00%	29.0	50.00%
Cardiovascular	43	5.32%	10	23.26%	87.00%	100.00%	43.0	44.44%
Child Health	4	0.50%	1	2.33%	125.00%	125.00%	86.0	0.00%
Critical Care	690	85.40%	9	20.93%	231.67%	118.70%	51.0	37.50%
Diabetes	8	0.99%	2	4.65%		50.27%	121.0	50.00%
Gastroenterology	12	1.49%	5	11.63%	95.00%	100.00%	37.0	25.00%
Mental Health	12	1.49%	4	9.30%	36.71%	36.71%	123.0	0.00%
Neurodegenerative								
Orthopaedics								
Renal	19	2.35%	7	16.28%	90.83%	106.67%	27.0	66.67%
Respiratory Health	0	0.00%	1	2.33%	10.00%	10.00%	88.0	0.00%
Stroke	20	2.48%	2	4.65%		137.78%	14.0	100.00%
Vision								
<b>Totals:</b>	<b>808</b>	<b>100.00%</b>	<b>43</b>	<b>100.00%</b>	<b>75.00%</b>	<b>88.89%</b>	<b>42.0</b>	<b>40.54%</b>

\* CSG names highlighted in purple indicates which MDTs are active in the CSG portfolio

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

\*\*\* Median RtTT Metrics calculated on all active studies in year

\*\*\*\* FPFV Metrics calculated on Active Sites with Recruitment only

# Southern Health and Social Care Trust R&D

## Directors review

### Director, Chief and Principal Investigators

<b>Research Director:</b> Patricia Campbell	<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 Sarinda Millar Alison Vernor Michael McCormick Rory Convery Ian Menown Paul Magill

## Group Background/ Summary

We have a total of 44 active studies incorporating almost all clinical specialties. Most active is renal with 9 studies, however, cardiovascular has 7, critical care and perioperative medicine have 6, respiratory medicine also has 6, and paediatrics and stroke have 5 currently open. We are also expanding and growing with research in new areas such as Orthopaedics. Our activity demonstrates considerable success in the Trust in recruiting to all clinical specialties that we engage in. Recruitment to time and target was > 96%. The Teams set realistic targets of recruitment on all studies. We are proud of our performance on all NICRN adopted studies and will continue to seek to expand and grow in the coming year. Seven new studies have been adopted within this defined period in respiratory, renal, stroke and paediatrics which is an increase of over 100% from last year's report. Given the increase in capacity and capability at SHSCT we envisage an upward trajectory in activity going forward. The opening of the new Commercial Research Delivery Centre is planned for 2026.

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

We have several key achievements during the year. In cardiovascular the eUltra 10K trial Dr Ian Menown was named in the top 3 recruiters within 1st month of opening and again in April 2024. Ongoing participation in the GenOMICC study - the largest study of its kind anywhere in the world, to date has identified 49 genetic variants underlying critical COVID-19. This study has now extended its inclusion criteria to neonatal and should be open within 2025/2026. Furthermore, SHSCT were the most successful site across HSC on recruitment to RECOVERY trial, Respiratory. They were also the 3rd highest recruiters in the UK to the Clear study and recently published outcomes in the New England Journal of Medicine. In renal medicine medication was licensed and introduced into standard of care resulting in kidney function preservation for several years. 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. We continue to grow and perform well. We are committed to investing staff and resource to NICRN trials in all areas.

## A message from the R&D Director

2025 sees a new era for R&D across the entirety of the region, and for our Trust in particular, as I take up the role as new medical director for R&D. It is with great enthusiasm I look forward to ever-improving the collaborative work that we undertake with the NICRN, where we can all share learning and progress together, ensuring we deliver effectively on the new R&D delivery model across the NI infrastructure.

NICRN studies remain central to the research portfolio of our trust across many key clinical areas, particularly critical care perioperative medicine and respiratory, followed by cardiovascular and renal. Our clinical experts in each of the arenas remain committed to network studies, and appreciate the central planning, resourcing and co-ordination of the NICRN required to allow us to achieve success in network trials, and ultimately results in improved access and care for the patients of our Trust locality. Working collaboratively with the NICRN has strengthened key partnerships within our trust and beyond to allow for our growth and expansion.

Future priorities for our group include increasing the visibility of us as an R&D centre of excellence, expansion of our networking outreach, and of our working together across the territory. While we are proud of our recruitment-to-target metrics, it is clear that we have work to do on our times to PPFV. We continue to enquire as to whether this is a capacity issue or an administrative issue with documentation of 'green light'? Similarly we wish for a

definitive presence of each Trust clinical speciality R&D lead on the clinical management group meetings, and to ensure that resource allocation across the region mirrors activity.

May our continued working in collaboration create increased capability and growth of our R&D reputations.



**Figure 19: Patricia Campbell new Research and Development director for SHSCT**

# Dashboard – SHSCT

Table 1: Studies and Sites Data	
No. of Active CSGs	10
No. of Active Studies	44
No. of Recruitment Sites	44
No. of Sites with Recruitment (INY)	22
No. of Sites with Recruitment (TOT)	38
No. of New Studies during 24-25	6
No. of Studies closed during 24-25	13

Table 2: Screening and Recruitment In Year and also Cumulative Totals for Active Studies During 24-25			
Screened (INY*) during 24-25	Recruited during (INY*) 24-25	Screened (TOT)** as at 31/03/2025	Recruited (TOT)** as at 31/03/2025
795	329	3,887	1,522

\* INY = Activity reported over reporting period (01/04/2024 - 31/03/2025)  
 \*\* TOT = Total activity reported up to and including 31/03/2025

Table 3: Portfolio Sponsorship, Randomisation and Design Mix for Active Studies During 24-25						
	Commercial	Non-Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	6	38	28	16	29	15
Proportion (%)	13.64%	86.36%	63.64%	36.36%	65.91%	34.09%

Table 4a: Recruitment, Median Recruitment to Target (%)* and Median Recruitment to Time & Target (%)** by Sponsorship Type								
Commercial			Non-Commercial			Combined		
Recruited (INY) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INY) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INY) during 24-25	Median RtT (%)*	Median RtTT (%)**
71	90.00%	86.59%	258	105.00%	101.05%	329	96.25%	96.25%

\* Median RtT Metrics calculated on Active Studies which have closed to recruitment in year  
 \*\* Median RtTT Metrics calculated on all active studies in year

Table 4b: Recruitment, Median Recruitment to Target (%)* and Median Recruitment to Time & Target (%)** by Design Type								
Interventional			Observational			Combined		
Recruited (INY) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INY) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INY) during 24-25	Median RtT (%)*	Median RtTT (%)**
139	102.50%	90.00%	190	58.10%	115.85%	329	96.25%	96.25%

\* Median RtT Metrics calculated on Active Studies which have closed to recruitment in year  
 \*\* Median RtTT Metrics calculated on all active studies in year

Table 6a: Clinical Specialty Group Data by HSC Trust								
List of HSC Trusts*	Recruitment (INY) during 24-25	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Rec to Target (%)**	Median Rec to Time & Target (%)***	Median ALL PPFV**** (days)	Proportion (%) < 30 days
BHSCT	0	0.00%						
NHSCT	0	0.00%						
SEHSCT	0	0.00%						
SHSCT	329	100.00%	44	100.00%	96.25%	96.25%	56.5	36.84%
WHSCT	0	0.00%						
<b>Totals:</b>	<b>329</b>	<b>100.00%</b>	<b>44</b>	<b>100.00%</b>	<b>96.25%</b>	<b>96.25%</b>	<b>56.5</b>	<b>36.84%</b>

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

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

\*\*\* Median RtTT Metrics calculated on all active studies in year

\*\*\*\* PPFV Metrics calculated on Active Sites with Recruitment only

# Dashboard – SHSCT

Table 5a: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Commercial(6)		Non-Commercial(32)		Combined(38)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
32.5	50.00%	57.0	34.38%	56.5	36.84%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 5b: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Interventional(25)		Observational(13)		Combined(38)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
57.0	28.00%	29.0	53.85%	56.5	36.84%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 6b: HSC Trust Data by Clinical Specialty Group								
List of CSGs*	Recruitment (INY) during 24-25	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Rec to Target (%)**	Median Rec to Time & Target (%)***	Median ALL FPFV**** (days)	Proportion (%) < 30 days
Cancer	13	3.95%	3	6.82%	120.00%	10.00%	210.5	0.00%
Cardiovascular	70	21.28%	7	15.91%	97.50%	97.50%	41.5	33.33%
Child Health	19	5.78%	5	11.36%	135.00%	50.00%	126.0	0.00%
Critical Care	52	15.81%	6	13.64%	69.58%	87.55%	42.5	50.00%
Diabetes	40	12.16%	1	2.27%		111.11%	158.0	0.00%
Gastroenterology								
Mental Health	2	0.61%	1	2.27%	60.00%	60.00%	57.0	0.00%
Neurodegenerative								
Orthopaedics	0	0.00%	1	2.27%	133.33%	133.33%	10.0	100.00%
Renal	41	12.46%	9	20.45%	75.73%	100.00%	186.5	25.00%
Respiratory Health	68	20.67%	6	13.64%	140.83%	121.26%	7.0	83.33%
Stroke	24	7.29%	5	11.36%	83.33%	112.91%	35.0	33.33%
Vision								
<b>Totals:</b>	<b>329</b>	<b>100.00%</b>	<b>44</b>	<b>100.00%</b>	<b>96.25%</b>	<b>96.25%</b>	<b>56.5</b>	<b>36.84%</b>

\* CSG names highlighted in purple indicates which MDTs are active in the CSG portfolio

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

\*\*\* Median RtT Metrics calculated on all active studies in year

\*\*\*\* FPFV Metrics calculated on Active Sites with Recruitment only

# Western Health and Social Care Trust R&D

## Directors review

### Director, Chief and Principal Investigators

<p><b>Research Director:</b> Aaron Peace</p> <p><b>Research Manager:</b> Diane Mackey</p>	<p><b>Chief &amp; Principal Investigators, within Trust, currently active on NICRN adopted studies.</b></p> <p>Aaron Peace</p> <p>Jack Andrews</p> <p>Adam Canning</p> <p>Paul Farry</p> <p>Micheal Harron</p> <p>Gerges Demian</p> <p>Conor O'Neill</p> <p>Goudarz Mazdai</p> <p>Ahmed Bedair</p> <p>Raafat Malek</p> <p>Patrick Elder</p> <p>Hossam Abdulkhalek</p> <p>Adrian Donnelly</p> <p>Neal McAlister</p> <p>Alexander Webber</p> <p>Lisa Clarke</p> <p>Sinead O'Kane</p> <p>Rachael McGlinchey</p> <p>Alex Miras</p> <p>Nazia Chaudhuri</p> <p>Martin Kelly</p> <p>Kathryn Ferguson</p> <p>Clionagh McElhinney</p> <p>Frank McCarroll</p> <p>Conor Moran</p> <p>Oonagh McCloskey</p> <p>Brefanni Keegan</p>
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## Good News Stories & Key Achievements.

The ENRICH AF Trial is being led at SWAH by Principal Investigator Dr Breffini Keegan along with Donal Concannon (Stroke Clinical Research Nurse) and Sheila Grimes (Stroke Specialist Nurse). ENRICH AF target was 3 patients to be recruited onto the Trial. The team have recruited 4 patients in 2024 with recruitment still on-gong. Impressive recruitment by WHSCT research stroke team for a global cutting edge acknowledged in ENRICH AF newsletter.

In June 2024 Western Health and Social Care Trust Research and Development Department opened their first obesity trial in the Trust led by Principal Investigator Professor Miras whereby patients were screened and recruited at our dedicated obesity clinic room based at C-TRIC with all the necessary equipment for obesity studies.

WHSCT R & D plan to run a showcasing Cancer Clinical trials event in September 2025 at C-TRIC. This will involve PPI speakers, guest speakers from Cancer Charities, NICTN and Principal Investigators within WHSCT.

## A message from the R&D Director

WHSCT have faced challenges within 2024-2025 with staffing sick-leave, retirement and maternity leave covers, and have undergone recruitment of research nurses and study support officers. This ultimately took time and effort by all our research staff to train new staff to the level which is required for them to take part in WHSCT portfolio commercial and non-commercial research studies.

There have also been many challenges with IRMER delayed sign off which still exists, alongside pharmacy capacity and additional services capacities which we have addressed throughout 2024/2025.



**Figure 20: WHSCT teams spreading the awareness of research on Clinical trials day.**

# Dashboard – WHSCT

No. of Active CSGs	8
No. of Active Studies	47
No. of Recruitment Sites	51
No. of Sites with Recruitment (INy)	22
No. of Sites with Recruitment (TOT)	39
No. of New Studies during 24-25	5
No. of Studies closed during 24-25	8

Screened (INy)* during 24-25	Recruited during (INy)* 24-25	Screened (TOT)** as at 31/03/2025	Recruited (TOT)** as at 31/03/2025
2,041	127	6,816	534

\* INy = Activity reported over reporting period (01/04/2024 – 31/03/2025)  
 \*\* TOT = Total activity reported up to and including 31/03/2025

	Commercial	Non-Commercial	Randomised	Non-Randomised	Interventional	Observational
No. of Active Studies	14	33	37	10	40	7
Proportion (%)	29.79%	70.21%	78.72%	21.28%	85.11%	14.89%

Commercial			Non-Commercial			Combined		
Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**
85	65.00%	63.33%	42	76.67%	72.22%	127	76.67%	68.47%

\* Median RtT Metrics calculated on Active Studies which have closed to recruitment in year  
 \*\* Median RtTT Metrics calculated on all active studies in year

Interventional			Observational			Combined		
Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**	Recruited (INy) during 24-25	Median RtT (%)*	Median RtTT (%)**
78	65.00%	56.54%	49	76.67%	120.00%	127	76.67%	68.47%

\* Median RtT Metrics calculated on Active Studies which have closed to recruitment in year  
 \*\* Median RtTT Metrics calculated on all active studies in year

List of HSC Trusts*	Recruitment (INy) during 24-25	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Rec to Target (%)**	Median Rec to Time & Target (%)***	Median ALL FFPV**** (days)	Proportion (%) < 30 days
BHSCT	0	0.00%						
NHSCT	0	0.00%						
SEHSCT	0	0.00%						
SHSCT	0	0.00%						
WHSCT	127	100.00%	51	100.00%	76.67%	68.47%	83.0	17.95%
Totals:	127	100.00%	51	100.00%	76.67%	68.47%	83.0	17.95%

\* HSC Trust names highlighted in purple indicates which Trusts are active in the CSG portfolio  
 \*\* Median RtT Metrics calculated on Active Studies which have closed to recruitment in year  
 \*\*\* Median RtTT Metrics calculated on all active studies in year  
 \*\*\*\* FFPV Metrics calculated on Active Sites with Recruitment only

# Dashboard – WHSC

Table 5a: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Commercial(15)		Non-Commercial(24)		Combined(39)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
63.0	6.67%	87.5	25.00%	83.0	17.95%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 5b: Median First Participant, First Visit Windows (days) and Proportion of Studies Achieving < 30 days target (%) *					
Interventional(31)		Observational(8)		Combined(39)	
Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days	Median FPFV (days)	% < 30 days
116.0	9.68%	36.0	50.00%	83.0	17.95%

\* FPFV Metrics calculated on Active Sites with Recruitment only

Table 6b: HSC Trust Data by Clinical Specialty Group								
List of CSGs*	Recruitment (INV) during 24-25	Proportion Share (%)	No. of Recruitment Sites	Proportion Share (%)	Median Rec to Target (%)**	Median Rec to Time & Target (%)**	Median ALL FPFV**** (days)	Proportion (%) < 30 days
Cancer	16	12.60%	9	17.65%	100.00%	55.42%	233.0	0.00%
Cardiovascular	76	59.84%	9	17.65%	45.00%	46.36%	63.0	14.29%
Child Health								
Critical Care	16	12.60%	10	19.61%	55.00%	68.47%	92.5	37.50%
Diabetes	4	3.15%	2	3.92%	26.67%	49.44%	44.0	0.00%
Gastroenterology								
Mental Health	6	4.72%	1	1.96%	37.14%	37.14%	83.0	0.00%
Neurodegenerative								
Orthopaedics								
Renal	1	0.79%	5	9.80%	21.88%	166.67%	43.0	20.00%
Respiratory Health	5	3.94%	9	17.65%	120.00%	115.11%	59.0	25.00%
Stroke	3	2.36%	6	11.76%	83.33%	76.31%	358.0	0.00%
Vision								
<b>Totals:</b>	<b>127</b>	<b>100.00%</b>	<b>51</b>	<b>100.00%</b>	<b>76.67%</b>	<b>68.47%</b>	<b>83.0</b>	<b>17.95%</b>

\* CSG names highlighted in purple indicates which MDTs are active in the CSG portfolio

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

\*\*\* Median RTT Metrics calculated on all active studies in year

\*\*\*\* FPFV Metrics calculated on Active Sites with Recruitment only

# NICRN Staffing and Portfolio Team Reports

In this staffing section, the report highlights detail of the staff cohort within the NICRN family as appointed to CSGs and across all 5 Trusts. The tables provide detail on the numbers of staff allocated to specific CSGs and Trusts, and information on the work of the portfolio coordinating team. The illustrations and accompanying text tells our story in a more personal way and again I congratulate the teams on the commitment they show to this important work.



Figure 21a Regional NICRN Staff Conference images QUB

## Staffing Update

The Annual Report is an opportunity to highlight 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. Throughout the year we encourage staff to attend and participate in a wide range of profession, specialty and subject specific training events and conferences. Our team is comprised of skilled hard-working professionals from a variety of backgrounds including Nurses, Midwives, Optometrists, Physiotherapists, 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. The subsections below outline some of the training, conference and good news highlights.

### Staff training & Conference attendances

#### Dementia Conference September 2024



Dr Emma Cunningham, a Senior Clinical Lecturer within the Ageing Research Interest Forum, delivered her presentation titled “*Dementia Research in Northern Ireland - A Snapshot*” at the second annual **Dementia: Caring for Today, Planning for Tomorrow** conference at Queen’s University Belfast on 20th September 2024. Dr Cunningham seen here with some of the team discussed ongoing studies that will yield evidence on biomarkers of dementia-causing diseases in Northern Ireland.

**Figure 21b**

#### ECFS – European Cystic Fibrosis Society Conference June 2024



Clinical research nurses Daniela Fernandes and Bernadette King represented the Network when attending the ECFS Conference.

**Figure 21c**

*“We both found it to be a very valuable, informative and well organised training day. The sessions provided an excellent balance between scientific updates, for example CF drug’s in pipeline during the morning session followed by practical discussions, and networking among site coordinators across Europe. The presentations were clear and relevant, and included interactive workshops - worksheets, LCI and audit discussion. It was an engaging and motivating experience that strengthened the connections with the CTN community and reinforced a shared commitment to improving clinical trial quality and patient outcomes”.*

## **RCN Conference September 2024, Northumbria University, Newcastle upon Tyne**

Seven of our regional NICRN staff attended the Royal College of Nursing, International Nursing Research Conference on September 10<sup>th</sup> – 12<sup>th</sup>, 2024. Conference highlights included a range of key note speakers with presentations from Professor Carl May, Professor Roxanne Crosby-Nwaobi, and Professor Rhonda Wilson. Topics included health policy, clinical effectiveness, patient perspectives, and serving the needs of hard to reach, and under-served populations with a focus on innovative study design and a greater commitment to inclusivity. However, key populations continue to be under-represented and under-served in our research and the main theme was to explore ‘Inclusivity in nurse research’ which links in with the current strategy:

The RCN Nursing Research Strategy (2024 – 2027) aims to be ambitious in transforming the cultures of research with the following aims:

- To promote the voice and visibility of nurses in research
- To harness recognition for the roles and value nurses have in research awareness, engagement, inclusion, delivery and leadership
- To support and inspire future generations and careers to be research and evidence centred.



**Figure 21d**

‘The conference covered many areas and I found particularly interesting was the talks on decentralization of trials – the challenges of such studies and overcoming them; and also the talk on the importance of including patients in the design and planning of studies’.

CRN Vicki Addell **SEHSCT**

‘The RCN IRC 2024 was the first conference I’ve ever attended. I came away with an appreciation and new found respect for my colleagues within the clinical research field.’

CRN Nathan Galloway **NHSCT**

‘I learnt that TYA don’t have the same access to trials, especially cancer trials, Teens and young adults below the legal age of consent are excluded, and pharmaceutical companies are not willing to spend monies to overcome this hurdle at present’.

CRN Fiona Gregg **BHSCT**

‘Attending the RCN International Nursing Conference was a great opportunity to meet and share our experiences with other Research nurses and to hear how far research has developed over the years’.

CRN Julie Elder **SHSCT**

## **Regional NICRN Staff Conference QUB October 2024**

On the 3<sup>rd</sup> October 2024 the Northern Ireland Clinical Research Network welcomed our staff from across Northern Ireland to our annual staff conference, held in Riddle Hall, Queen's University Belfast. This year's conference focused on 'Yesterday, Today & Tomorrow, 'Juggling Commercial and Non-Commercial Research and 'We can achieve more together,' NICRN clustering and the New Governance model. The event drew attendees regionally from across our five Health and Social Care Trusts, featured over eighteen speakers, and recognised the ground-breaking research undertaken in the Northern Ireland Clinical Research Network.

Throughout the day, research industry leaders from the PHA, BHSCT, and HSCNI, clinical professionals, principals investigators and Patient and Public Involvement gathered to explore the future of research with impactful discussions on the introduction of Encompass and integration of the Edge platform, initiatives in priority setting partnerships, and the importance of providing a platform to receive the valuable understanding of clinical trials from a patient's perspective.

The afternoon focused on a regional perspective celebrating the success and learning across our teams showcasing the IPF Comfort Study & WHSCT Respiratory Research Team, SHSCT Optimising Recruitment: Road 'MAPS-2' Success, BHSCT Respiratory: Data Protection: challenges we have encountered this year. NICRN staff were also supported by the BHSCT Well-being services, highlighting and signposting services to enhance wellness amongst our colleagues.

Coffee, networking and breakout table discussions enabled meaningful connections through dedicated networking and feedback sessions with a focus on what have NICRN done well, what could be better and priorities moving forward.

The insights, shared experiences and connections formed at this year's conference provided an opportunity to reflect on the year and will help drive continued growth and innovation.



Figure 21e

### **Regional NICRN Stroke Team attend UK Stroke Forum 2024**

Members of the NICRN Stroke team attend the UK Stroke Forum in Liverpool 3-5<sup>th</sup> December 2024 (Clare McGoldrick - NHSCT, Denise Cosgrove & Denise McFarland - SHSCT, Érin Collins - BHSCT and Vicki Adell – SEHSCT). Over 3-day the team had the opportunity to meet with central Stroke trial teams from various other UK hospitals, watch demonstrations of new devices, and listen to talks on ongoing or upcoming research trials. Some of these trials have already been adopted by the NICRN and are open to recruitment in Northern Ireland’s acute hospitals. The Stroke Research Co-ordinators agreed *‘It was great to see how Stroke survivors both in the acute and post-acute phases of their stroke can benefit from ongoing research in the area of Stroke care’*.

### **Queen’s University Belfast, ‘Patient to Protocol’ short course**

The QUB ‘Protocol to Patient’ short course, covers the key considerations for planning and delivering clinical trials. The course provides the information and skills needed to take a study protocol and deliver the trial safely and effectively to participants. Our NICRN staff are offered fully funded places via the Department for the Economy Skill Up Fund. Uptake on the course amongst our NICRN staff has been strong and feedback positive:

*“The QUB research course was very informative and resourceful. Not only did I learn from attending each of the lectures but also the course material has given me a resource that I can refer to at any time and through further reading gain a much greater depth of understanding. I would highly recommend it for any member of staff working in research”.*

*“The protocol to patient module was extremely useful in providing information from the planning stage to delivery of clinical trials. It offered a good balance of theoretical information, talks from relevant speakers and interactive group work to consolidate learning. The handouts provided are a useful resource to refer back to”.*

*“This course was a mix of face-to-face training, self-directed study and an exam. This was a great course for me to understand the correct pathway of research development and delivering the clinical trials. It helps me to understand how the protocol develops, the process, the approval committees, the tool for CTIMP and non-CTIMP and why it is essential to follow*

*the correct procedure to ensure the research is conducted correctly and ethically. Overall, this course has enlightened me, and I would certainly recommend it to any staff interested in learning about clinical research”.*

*“Participating in a short research course allowed me to gain a thorough understanding of the clinical research process and Good Clinical Practice (GCP) guidelines, emphasising patient advocacy, compliance with research ethics, and consent procedures. It also highlighted the importance of prioritising participants' rights, safety, and well-being above the research trial itself. Furthermore, the course helped improve my critical thinking skills, which I hope to apply to advance my career and build confidence”.*

NICRN staff also 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
  - Cardiology – CRG Heart Health Conference
  - Clinical Research: Patient Safety & Value with Prof Mike Clarke
  - Critical Care Reviews
  - International Nurses’ Day
  - International Clinical Trials Day
  - Ophthalmic Technicians Introduction Course

NICRN clinical staff have continuous professional development requirements to maintain their professional registrations. Their statutory and mandatory training requirements utilize the following departments to maintain individual needs for their respective professional registration bodies; Learn HSCNI, NIHR and the Clinical Education Centre. NICRN staff have also been supported throughout 2024-25, to attend conferences and investigators meetings across UK & Europe.

**Table 3a: The Whole Time Equivalent (WTE) funded by HSC R&DD and deployed across each HSC Trust. WTE include separate NICTN staffing in brackets.**

HSC Trust	2018/2019 WTE Deployed	2019/2020 WTE Deployed	2020/2021 WTE Deployed	2021/2022 WTE Deployed	2022/2023 WTE Deployed	2023/2024 WTE Deployed	2024/2025 WTE Deployed
BHSCT NICRN (NICTN)	29.43 (17.54)	29.83 (16.44)	27.08 (16.94)	28.63 (17.74)	32.60 (17.74)	27.70 (17.78)	24.60 (16.46)
NHSCT NICRN (NICTN)	4.85 (1)	4.00 (1)	4.50 (1)	4.50 (1)	5.50 (1)	4.00 (0.2)	4.00 (1)
SEHSCT NICRN (NICTN)	5.30 (1)	3.80 (1)	4.80 (1)	3.30 (1)	4.30 (1)	3.30 (1)	3.30(1)
SHSCT NICRN (NICTN)	4.80 (1)	4.00 (1)	5.35 (1)	4.80 (1)	5.80(1)	5.30 (1)	5.30 (1)
WHSCT NICRN (NICTN)	5.00 (0.8)	4.50 (0.8)	3.85 (1)	5.35 (1)	5.65 (1)	4.60 (0.8)	4.60 (1)
<b>TOTAL NICRN (NICTN)</b>	<b>49.38 (21.34)</b>	<b>46.13 (20.24)</b>	<b>45.58 (20.94)</b>	<b>46.58 (21.74)</b>	<b>53.85 (21.74)</b>	<b>44.90 (20.78)</b>	<b>41.80 (20.46)</b>

**Table 3b: 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. NICTN staffing is now included\* (2023-24, 2024-2025). Primary care WTE are left out of 24/25 figures due to management now being responsibility of NI GP Federation.**

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)	CSG	2024/2025 WTE funded		2024/2025 WTE Staff in Post (as at .31/03/2025)		No. Staff in Post (as at 31/03/2025)
	PHA funded	Non-PHA funded	PHA funded	Non-PHA funded			PHA funded	Non-PHA funded	PHA funded	Non-PHA funded			PHA funded	Non-PHA funded	PHA funded	Non-PHA funded	
Cancer	-	-	-	-	-	Cancer	22.12	25.68	20.78	25.68	55	Cancer	22.12	26.05	20.36	26.05	55
Cardiovascular	5.30		4.05		12	Cardiovascular	5.30		4.80		12	Cardiovascular	5.30		4.80		12
Child Health	3.50		3.30		7	Child Health	3.50		3.06		6	Child Health	3.50		3.50		6
Critical Care	6.30		5.90		11	Critical Care	6.05		5.35		10	Critical Care	6.05		6.30		10
Diabetes	3.50		2.50		7	Diabetes	3.50		3.00		6	Diabetes	3.50	0.60	3.50	0.60	5
Gastroenterology	1.50	0.50	1.50	0.50	4	Gastroenterology	1.50		1.00		2	Gastroenterology	1.50		1.25		2
Mental Health	2.00		1.00		1	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	Neurodegenerative	2.00	2.00	1.25	1.20	4
Orthopaedics	1.00		0.50		1	Orthopaedics	1.00		0.50		1	Orthopaedics	1.00		1.00		1
Primary Care	2.50		2.50		3	Primary Care	2.60		1.00		0	Primary Care			0.00		0
Renal	3.80		3.30		6	Renal	3.30		3.30		7	Renal	3.30		3.05		7
Respiratory Health	6.00	2.50	2.80	2.00	11	Respiratory Health	6.25		5.85		9	Respiratory Health	6.25		6.00		9
Stroke	3.85		2.85		7	Stroke	3.80		2.90		5	Stroke	3.80		3.10		6
Vision	3.60		2.10		5	Vision	3.60		2.40		6	Vision	3.10		2.15		8
COVID	9.00		8.50		12	Generic / SHSCT	0.50		0.50		1	Generic / SHSCT	0.50		0.50		
<b>Total NICRN</b>	<b>53.85</b>	<b>5.00</b>	<b>42.30</b>	<b>4.50</b>	<b>92.00</b>	<b>Total * NICRN (NICRN +NICTN)</b>	<b>44.90 (67.02)</b>	<b>2.00 (27.68)</b>	<b>36.66 (57.44)</b>	<b>1.4 (27.08)</b>	<b>71.00 (126.0)</b>	<b>Total * NICRN (NICRN +NICTN)</b>	<b>41.80 (63.92)</b>	<b>2.60 (28.65)</b>	<b>37.40 (57.76)</b>	<b>1.80 (27.85)</b>	<b>71 (126)</b>

\*Total figures in brackets include NICTN staffing.

## Administrative Staff News

The administrative team has been relatively stable over the reporting period. With the most significant change being the resignation of our communications officer in July. This had been held by Mrs Emma Byrne, whose enthusiasm and diligence will be a significant loss to the service.



Figure 22a: Mrs Emma Byrne and members of the NICRN administration team looking forward to their Encompass training.



Figure 22b: NICRN admin staff from across the Trusts and Senior Portfolio manager Shane Jackson at Annual Edge conference.



**Figure 22c: NICRN Admin team from across the trusts and Senior Portfolio manager Shane Jackson, Senior Staff manager Sonia McKenna, Senior Operations manager Paul Biagioni and NICRN Director Jonathan Jackson at NICRN annual event**

Unfortunately, the service does not have the necessary funding to align the network comm position to the standard pay scales within this field outside of HSC. Refilling at the funded banding level will mean our positions are more likely short lived until staff have accumulated the knowledge and move on to higher banded positions either internal to HSC communications or to other sectors. To address this loss of function we have engaged with the Trust R&D director to develop plans for a more Trust wide communications position, potentially embedded into the Trust communications department, supporting all BHSCT R&D infrastructure needs. This discussion is supported in principle by the Trust and is progressing slowly. One addition to the Admin Team in January 25 was Mr Dermot Ryder, who came into NICRN under Cluster 2. Dermot brings with him a lifetimes experience of working within the highly regulated environment of HMRC and we are all benefiting from his attention to detail.

We have also developed the admin support function for our clusters and have allocated teams to each cluster.

The band 5 cluster support officer positions are now filled and operational for our vascular cluster, supported by Ms Louise Scullion and Mr Dermot Ryder, and our Critical Care & perioperative medicine/Respiratory Health Cluster, supported by Mr Chris Wright and by band 4 admin officers Ms Fionnuala White and Mrs Ciara Forsythe. The remaining clusters of Children and Women's Health, Neurodegenerative/Ageing and our Primary Care Clusters will be recruited to over the next reporting year.

The role of the band 5 position is to support the specialities (CSGs) within the cluster by providing administrative support for collating, monitoring and reporting, on study feasibility and expressions of interest. The role includes liaising with each specialities staff management team to ensure CSG meetings are supported, minutes and outcomes appropriately cascaded

to relevant parties. In this way we aim to ensure that capacity and capability document sets are submitted, managed and progressed through the Trust procedure in a timely and monitored fashion, through to green light for study recruitment.

Within the staff management team we have allocated a dedicated position for administrative support in the form of Mrs Roisin Adams. She has been very active in supporting the teams service through orchestration of staff training events, supporting the teams 1-2-1 meetings for all staff, office management, admin support to the senior management team and a multitude of other actions needed by this very active service.

Our portfolio management team headed up by Mr Shane Jackson and supported by Mr Rahim Byrne have had an extremely challenging time over the reporting period with the regional deployment of the patient management Epic/Encompass system. The local challenge was to develop and define the working relationships between the clinical patient management system and our LPMS. Our team was the first globally to drive forward the necessary engagements between the developers of the two systems, to ensure both were aligned in terms of their operational aspects. We are very proud of Mr Jacksons role in leading this collaboration and feel that HSC will benefit greatly from this Network led initiative. The collaboration will enable more real-time recruitment data and facilitate a real overview of the regional eligible portfolio for HSC. Presently the only recruitment data recorded as standard practice within HSC was via the Networks. Trust, non-network studies did not have their recruitment data available for regional reporting. With this deployment and alignment, we now have a unique opportunity to capture, monitor and report on the full NI portfolio. This however needs appropriate resourcing to allow full functionality across HSC Trusts, HSC RDD, CRDC, NICRF and any other stakeholders with responsibilities on reporting their activity.

## 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. For this year's report we have included the NICTN portfolio data. This means that when considering any data representations which compare data points over the last five years: **2020-21, 2021-22, 2022-23 and 2023-24 will be NICRN only, and 2024-25 will be NICRN/CTN combined data.** The total number of active studies this year (268) on the face of it suggests a significant increase. This number includes NICTN (62). The underlying trend is however an increase year on year since 2020-21 (Figure 23a). Whereas the total number of patients screened, which is very study type dependant, is slightly less than last year, the number of patients recruited to studies is the highest it has been over the last 5 years (Figure 23b).

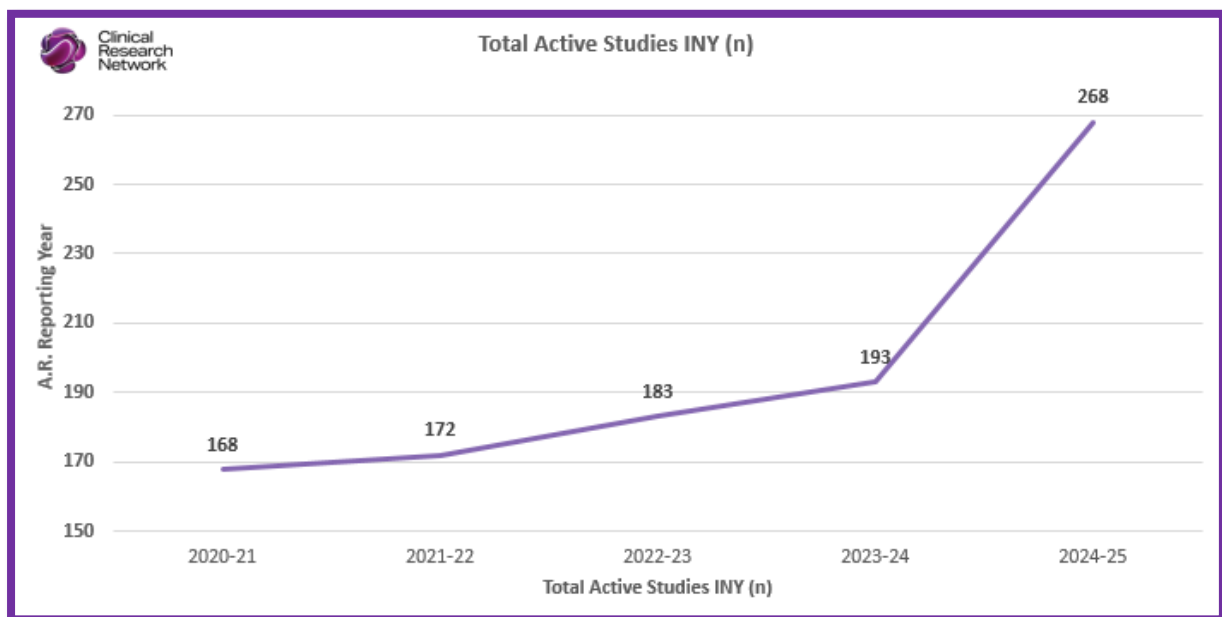
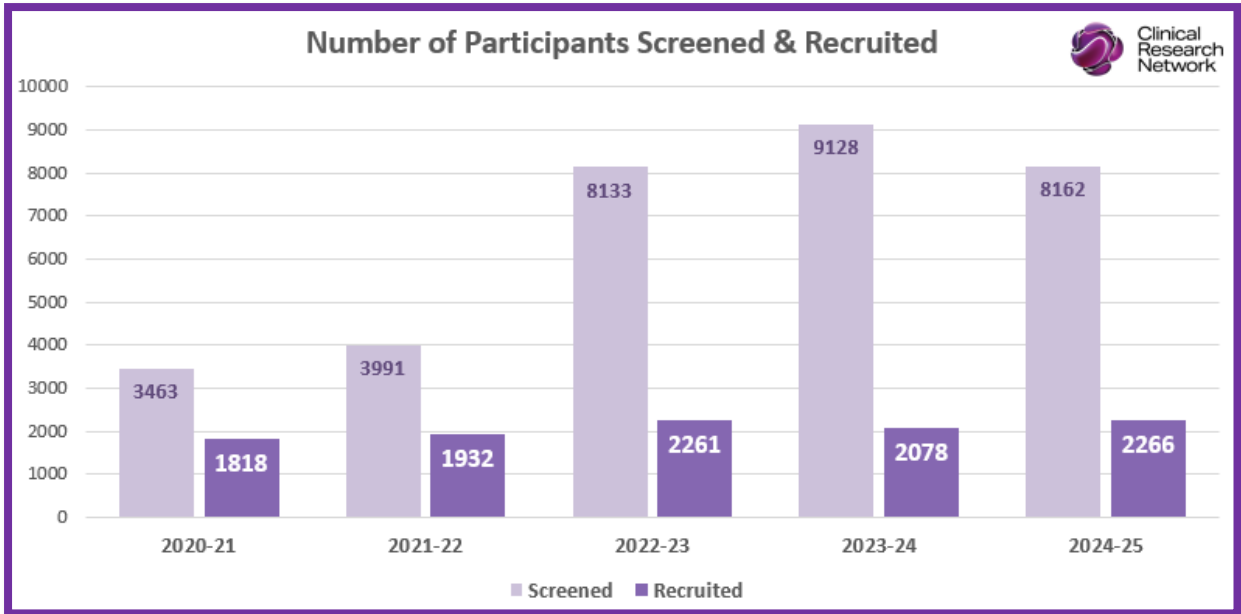


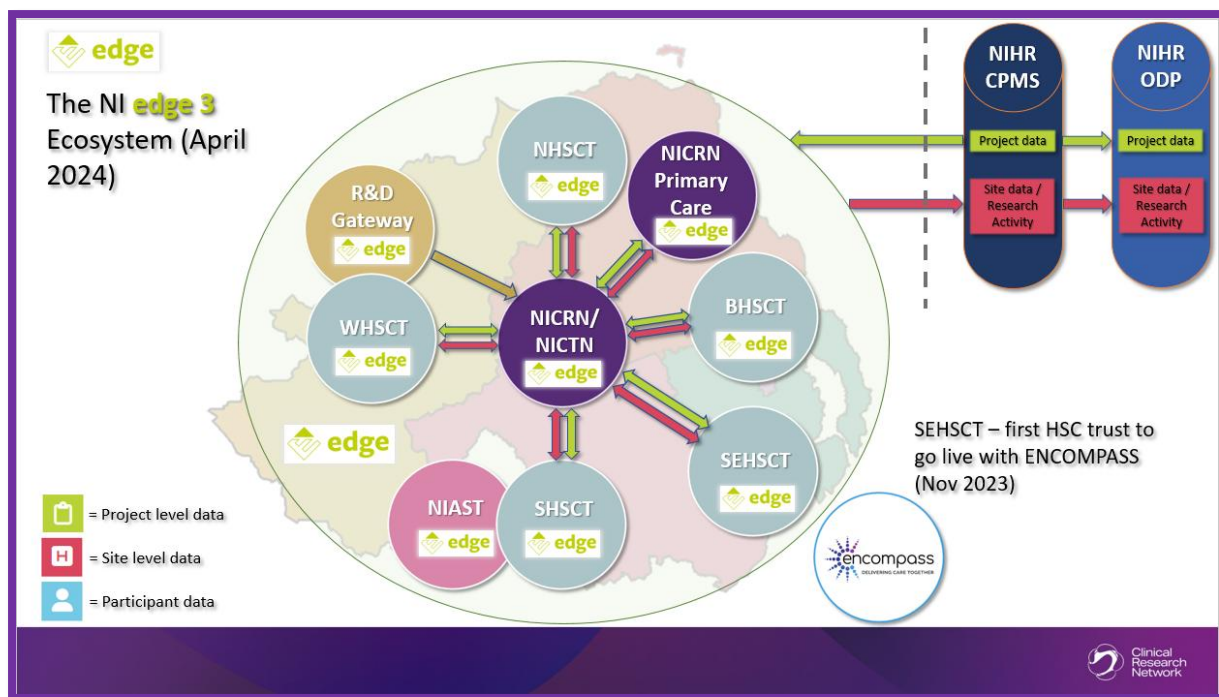
Figure 23a: Total active studies INY



**Figure 23b: Number of Participants Screened and Recruited**

### The EDGE – ENCOMPASS Systems Interface

In last year’s annual report we described the preparatory steps necessary to accommodate the deployment of a single clinical management system called ENCOMPASS, across the regional healthcare infrastructure. The first HSC trust deployment – SEHSCT had taken place in November 2023. In parallel to this regional roll out, the PHA RDD had commissioned the development of a systems interface, which would allow the exchanging of research related data between our own regional local portfolio management system (LPMS) called EDGE and ENCOMPASS. The significant advantage of such a connection would mean that clinical research staff could capture all their research activity in the clinical system and this would then flow into EDGE and then onwards onto national systems. After several months of limited progress towards developing the interface Shane Jackson (NICRN Senior Portfolio Manager) was asked by the EDGE team to consult on the EDGE – ENCOMPASS/EPIC developers working group.



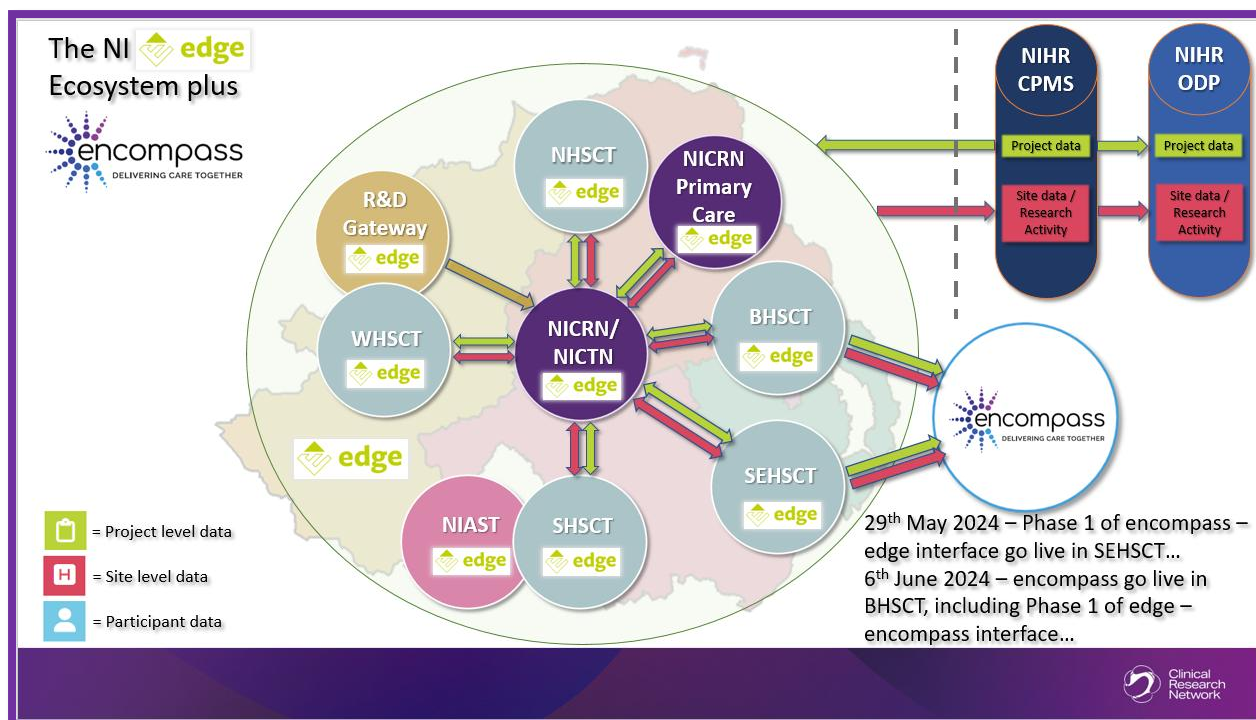
**Figure 23c: The portfolio management landscape as of April 2024**

The above diagram (Fig 23c) represents the systems infrastructure as at the beginning of April 2024. The EDGE infrastructure existed as a network of collaborating instances of EDGE whereby project and site level data is shared. Also of note is that project data can be updated from the UK national central portfolio management system (CPMS) while site Capability & Capacity (C&C) data and aggregated research activity data is pushed from EDGE into CPMS for onward reporting in the Open Data Platform (ODP). At this point in time ENCOMPASS was only operational in the SEHST and was not connected to EDGE.

Throughout the course of 2024-2025 the plan was to develop the EDGE – ENCOMPASS interface in three phases:

**PHASE 1 –**

To push project and recruitment site information from EDGE into ENCOMPASS (see Fig 28).



**Figure 23d: The portfolio management landscape in mid-June 2024**

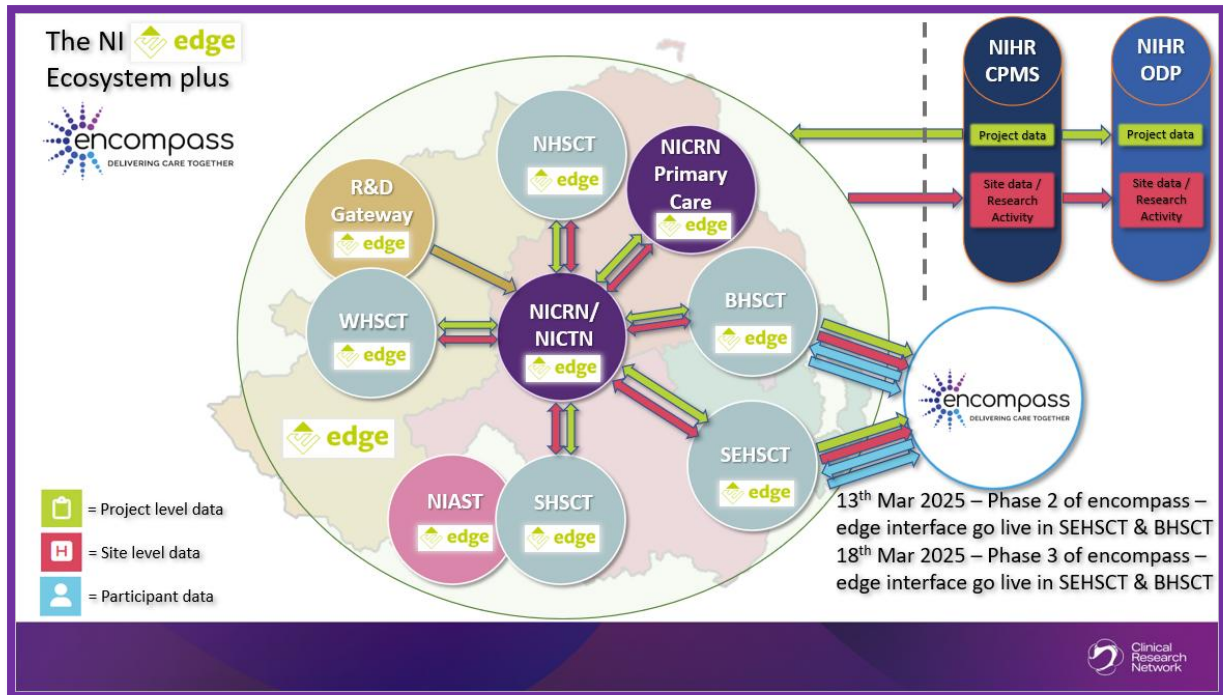
Phase 1 was operationalised for the SEHSCT and the BHSCT on 29<sup>th</sup> May 2024. The implications of this were that we could prime the ENCOMPASS research module with the BHSCT project and recruitment site information a week before ENCOMPASS was scheduled to go live in the BHSCT on 6<sup>th</sup> June. Having implemented Phase 1 of the interface meant that HSC Trust Research Offices could select the Project > Recruitment Site definitions in EDGE which were to be sent to ENCOMPASS. Having created the Study>Site definitions in ENCOMPASS, clinical research teams could then associate themselves to their studies and as a result they would be able to screen for participants, consent/recruit their participants and manage their participants through the protocol pathway all on ENCOMPASS. Another significant benefit of the system – was that all participants with active statuses on a research study in ENCOMPASS would generate a ‘Research Participant’ flag, which would appear in the participants clinical record and therefore be visible to other clinical colleagues accessing the record. However at this time users still had to manually record the research activity in EDGE to ensure regional and national reporting.

### **PHASES 2&3 –**

To push and pull participant research activity information between EDGE and ENCOMPASS (see Fig. 23e)

Following delivery of Phase 1 we then embarked upon the task of agreeing which data items were going to be exchanged and how they would map between the systems. There were many months of meetings, system testing and refining of specs. A significant ongoing

challenge throughout the development process was ensuring that both systems were essentially being manually maintained by the clinical research teams. We needed to ensure that the datasets were as close as possible so that when the interface was switched on the volume of data updates would be manageable.



**Figure 23e: The portfolio management landscape as by end of March 2025**

Then on 13<sup>th</sup> March 2025 we switched on Phase 2 of the interface for BHSCT & SEHSCT. Phase 2 of the systems interface delivered participant demographics and research activity data being sent from ENCOMPASS to EDGE. Our portfolio management team worked with Trust colleagues to work through any specific data issues which had failed to send at switch on. The following week Phase 3 was switched on for BHSCT & SEHSCT. Phase 3 of the systems interface meant that updates to research activity data could be sent from EDGE to ENCOMPASS.

With all 3 Phases of the systems interface in place for BHSCT & SEHSCT we finally have an integrated system whereby clinical research users can manage their research participants entirely in ENCOMPASS and the research activity data generated will be instantly transmitted to EDGE. This should mean the timeliness and completeness of the research activity data being captured in EDGE should be much improved.

**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.**

In Year TOTALS			
	New Studies INY (n)	Studies Closed INY (n)	Total Active Studies INY (n)
2020-21	24	59	168
2021-22	54	30	172
2022-23	43	29	183
2023-24	42	52	193
2024-25	48	67	268

**Note:** New Studies are eligible studies which have been supported/adopted by NICRN/CTN and have opened to recruitment 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.**

CANC			CCA			CHI			CRV			DIA		
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)
			3	4	20	5	5	12	6	11	33	0	3	9
			8	6	25	7	2	14	1	5	25	2	0	7
			7	2	22	5	0	18	5	4	25	4	1	11
			0	8	21	4	5	21	9	4	31	3	3	12
19	26	62	5	7	29	3	7	23	4	6	37	4	2	13

GAS			MHT			NEU			ORT			PCR		
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)
0	4	10	0	5	8	0	1	3				1	1	9
			2	0	6	1	2	3	6	0	6	3	5	9
4	3	11	0	3	6	1	1	3	4	1	10	2	1	6
4	3	11	0	2	3	3	1	5	1	1	10	0	2	6
0	1	10	0	0	1	1	0	7	2	2	12	0	1	2

REN			RES			STR			VIS		
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)
1	6	12	4	9	21	1	4	12	3	6	19
			12	4	25	5	2	12	7	4	20
3	0	11	2	7	22	2	2	12	4	4	20
4	3	15	9	4	22	1	4	10	4	10	20
4	4	18	3	6	32	2	2	8	1	3	15

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

Total Active Study / Sites - In Year TOTALS						
	BHSCT	NHSCT	SEHSCT	SHSCT	WHSCT	Study / Sites
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
2024-25	212	38	44	44	51	389

**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.**

	in Year Totals			
	Comm		Non-Comm	
	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)
2020-21	58	34.52%	110	65.48%
2021-22	49	28.49%	123	71.51%
2022-23	47	25.68%	136	74.32%
2023-24	60	31.09%	133	68.91%
2024-25	47	17.54%	221	82.46%

**Note:** Within NICRN we have historically 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. The 2024-25 data would suggest that there have been significant challenges in securing commercially sponsored research into HSC NI. While the overall number of active studies has increased, they were mostly non-commercial.

**Table 8: Total number and proportion (P<sup>^</sup>) of Active (interventional/observational) studies in NICRN portfolio.**

	In Year Totals (Study Design)			
	Int		Obs	
	No of Studies	P <sup>^</sup> (%)	No of Studies	P <sup>^</sup> (%)
2020-21	120	72.73%	45	27.27%
2021-22	115	71.43%	46	28.57%
2022-23	126	68.85%	57	31.15%
2023-24	128	66.32%	65	33.68%
2024-25	178	66.42%	90	33.58%

**Note:** The mix of interventional and observational studies remains stable, as it has been 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.**

	In Year TOTALS	
	Screened	Recruited
2020-21	3463	1818
2021-22	3991	1932
2022-23	8133	2261
2023-24	9128	2078
2024-25	8162	2266

**Note:** This table demonstrates that the amount of screening has remained relatively stable over the last 2 years, whereas recruitment has remained stable over a 5 year period.

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

**Table 10: Total numbers recruited into Active interventional/observational studies across NICRN portfolio.**

	In Year Totals (Recruitment)		Total Recruitment
	Interventional	Observational	
2020-21	1346	478	1824
2021-22	1302	630	1932
2022-23	1002	1259	2261
2023-24	953	1125	2078
2024-25	537	1729	2266

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

	In Year Totals (Recruitment)		Total Recruitment
	Commercial	Non-Commercial	
2020-21	23	1801	1824
2021-22	103	1829	1932
2022-23	80	2181	2261
2023-24	179	1899	2078
2024-25	241	2025	2266

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

Achieving high levels of recruitment to target (RtT) is one of the main objectives of the Network. This metric is importance in attracting commercial investment. Although we have not quite succeeded in achieving our 90% RtT target, we have achieved in excess of 80% in each of the previous 4 years (Table 12). Table 14 highlights the fact that the median % RtT for our commercial portfolio has increased year on year to 83%. The non-commercial figure matches this at 80%. The interventional/observational trend is similar (Table 13). This is the first year that we have been in a position to report on RtTT data.

**Table 12: Median percentage target recruitment and Median percentage recruitment to time and target attained across the total NICRN/CTN study portfolio.**

	In Year Total Median (% RtT)	In Year Total Median (% RtTT)
2020-21	80.03%	
2021-22	86.34%	
2022-23	87.00%	
2023-24	87.06%	
2024-25	81.00%	78.13%

**Table 13: Total median % RtT and Total median % RtTT in interventional/observational studies across NICRN portfolio.**

	Median across CSGs (RtT%)		Median across CSGs (RtTT%)	
	Interventional	Observational	Interventional	Observational
2020-21	73.36%	100.00%		
2021-22	74.61%	96.28%		
2022-23	85.00%	100.00%		
2023-24	84.00%	95.83%		
2024-25	80.00%	83.33%	71.64%	90.18%

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

	Median across CSGs (RtT%)		Median across CSGs (RtTT%)	
	Commercial	Non-Commercial	Commercial	Non-Commercial
2020-21	62.61%	80.74%		
2021-22	67.72%	80.74%		
2022-23	65.72%	98.33%		
2023-24	80.00%	96.12%		
2024-25	83.33%	80.00%	50.00%	83.31%

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

	Totals 2020-21		Totals 2021-22		Totals 2022-23		Totals 2023-24		Totals 2024-25	
	No. Recruitment Sites	Median % RT	No. Recruitment Sites	Median % RT	No. Recruitment Sites	Median % RT	No. Recruitment Sites	Median % RT	No. Recruitment Sites	Median % RT
BHSCT	120	65.37%	130	81.35%	140	80.00%	154	80.00%	212	80.00%
NHSCT	41	89.32%	41	80.75%	57	48.33%	47	100.00%	38	67.50%
SEHSCT	36	75.00%	37	75.00%	35	74.61%	44	100.00%	44	75.00%
SHSCT	39	80.91%	43	62.63%	40	78.13%	44	100.00%	44	96.25%
WHSC	36	84.33%	35	68.13%	34	63.67%	52	85.33%	51	76.67%

**Note:** BHSCT and SHSCT have continued to maintain a stable RtT whereas the other three HSC trusts have dropped back slightly on last years figures.

## 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 of first participant) is a key metric for the NICRN. We aim to meet an FPFV window of less than 30 days across our new studies as this metric is often cited and used by stakeholders in determining a sites ability to set up quickly and reflects on delivery teams systems and capabilities. Across tables 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				
	All CSGs 2020-21 FPFV (days)	All CSGs 2021-22 FPFV (days)	All CSGs 2022-23 FPFV (days)	All CSGs 2023-24 FPFV (days)	All CSGs 2024-25 FPFV (days)
BHSCT	29.0	75.3	85.0	52.5	34.0
NHSCT	217.0	220.5	28.5	30.0	32.5
SEHSCT	40.0	39.8	40.5	40.5	32.0
SHSCT	130.8	146.5	146.5	69.0	32.5
WHSC	257.0	235.5	59.0	85.0	63.0
All trusts	134.8	143.5	71.9	52.5	41.0

**Note:** In last year’s report we committed to continue our focus in seeking to reduce the median FPFV number for the commercial portfolio. We have met this objective in all but one Trust, which dropped by only 2 days. The overall median FPFV number of 41 days has encouragingly improved consistently over 5 years.

**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				
	All CSGs 2020-21 FPFV (days)	All CSGs 2021-22 FPFV (days)	All CSGs 2022-23 FPFV (days)	All CSGs 2023-24 FPFV (days)	All CSGs 2024-25 FPFV (days)
BHSCT	34.8	39.7	33.5	37.0	37.0
NHSCT	26.3	73.2	24.0	40.0	58.0
SEHSCT	27.0	28.8	21.5	26.0	47.5
SHSCT	42.5	91.0	39.3	47.0	57.0
WHSCT	21.0	86.0	31.0	50.5	87.5
All trusts	30.3	63.7	29.9	38.0	46.0

**Note:** This year, in the non-commercial sector, we have slipped back slightly to a sector median value of 46 days. This may be due to an increased focus on the commercial sector as this is the first time the commercial sector FPFV median value (41) is lower than that of the non-commercial sector FPFV median value (46).

**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.**

	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
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%
2024-25	41.0	36.67%	46.0	40.96%	43.0	40.13%

**Note:** Table 18 shows the P^ of commercial and non-commercial studies that are achieving the <30-day metric. The Table shows that for 2024-25, in the Commercial sector, we have significantly reduced the median FPFV window number and have therefore made significant progress toward the national target of <30 days. The proportion of our commercial studies achieved a FPFV window of < 30 days, remains stable at 37%.

## Patient and Public Involvement (PPI) Engagement

Patient and public involvement is central to the development and direction of the NI portfolio. As such we have developed our operational framework to include PPI representation in our steering group. It is envisaged that individuals will be invited to participate in the NICRN Steering group during the course of the incoming year. This will provide appropriately high level input to portfolio management. Each CSG is encouraged to, where resource is available, build specialty specific PPI representation into the CSG management group. With the introduction of the Cluster concept this year, CSGs have been encouraged to explore whether PPI involvement should be focused at Cluster or Specialty level and to consider creative ways of securing involvement. We are utilising the vast experience of our colleagues in NICTN to help develop the skill sets of potential PPI representatives identified by the CSGs, and where we have gaps we will endeavour to use the regional services of the Public Involvement Enhancing Research NI (PIER NI) platform to find suitable advisors.



Figure 27: Margaret Grayson PIER NI platform representative for the annual NICRN Staff event

# 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	CANC				CRV				CHI				CCA				DIA				GAS				MHT							
	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(%)				
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%				
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%				
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%				
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%				
2024-25	18	29.03%	44	70.97%	18	51.43%	17	48.57%	1	4.35%	22	95.65%	0	0.00%	29	100.00%	5	38.46%	8	61.54%	7	70.00%	3	30.00%	0	0.00%	1	100.00%				

A.R. Reporting Year	NEU				ORT				PCR				REN				RES				STR				VIS							
	Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm					
	No of Studies	P^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(%)				
2020-21	0	0.00%	3	100.00%					1	11.11%	8	88.89%	4	33.33%	8	66.67%	11	52.38%	10	47.62%	2	16.67%	10	83.33%	8	42.11%	11	57.89%				
2021-22	0	0.00%	3	100.00%	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%	3	100.00%	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%				
2023-24	1	20.00%	4	80.00%	0	0.00%	10	100.00%	1	16.67%	5	0.00%	3	20.00%	12	80.00%	8	36.36%	14	63.64%	1	10.00%	9	90.00%	9	45.00%	11	55.00%				
2024-25	1	14.29%	6	85.71%	0	0.00%	12	100.00%	0	0.00%	2	100.00%	4	22.22%	14	77.78%	9	28.13%	23	71.88%	1	12.50%	7	87.50%	5	33.33%	10	66.67%				

A.R. Reporting Year	CDT			
	Comm		Non-Comm	
	No of Studies	P^A(%)	No of Studies	P^A(%)
2020-21				
2021-22				
2022-23	0	0.00%	6	100.00%
2023-24	0	0.00%	6	100.00%
2024-25				



## Appendix 2 - Additional data for Portfolio breakdown: Study numbers and Proportion (P<sup>^</sup>) by design type (observational / interventional)



A.R. Reporting Year	CANC (Study Design)				CRV (Study Design)				CHI (Study Design)				CCA (Study Design)				DIA (Study Design)			
	Int		Obs		Int		Obs		Int		Obs		Int		Obs		Int		Obs	
	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> (%)
2020-21					27	81.82%	6	18.18%	8	66.67%	4	33.33%	15	75.00%	5	25.00%	6	66.67%	3	33.33%
2021-22					21	84.00%	4	16.00%	9	64.29%	5	35.71%	9	64.29%	5	35.71%	4	57.14%	3	42.86%
2022-23					19	76.00%	6	24.00%	13	72.22%	5	27.78%	15	68.18%	7	31.82%	6	54.55%	5	45.45%
2023-24					24	77.42%	7	22.58%	13	61.90%	8	38.10%	15	71.43%	6	28.57%	6	50.00%	6	50.00%
2024-25	47	75.81%	15	24.19%	26	74.29%	9	25.71%	12	52.17%	11	47.83%	22	75.86%	7	24.14%	7	53.85%	6	46.15%

A.R. Reporting Year	GAS (Study Design)				MHT (Study Design)				NEU (Study Design)				ORT (Study Design)				PCR (Study Design)			
	Int		Obs		Int		Obs		Int		Obs		Int		Obs		Int		Obs	
	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> (%)
2020-21	6	60.00%	2	20.00%	5	62.50%	3	37.50%	1	33.33%	2	66.67%					6	75.00%	2	25.00%
2021-22	8	88.89%	1	11.11%	3	50.00%	3	50.00%	1	33.33%	2	66.67%	5	83.33%	1	16.67%	7	75.51%	2	50.00%
2022-23	9	81.82%	2	18.18%	4	66.67%	2	33.33%	2	66.67%	1	33.33%	8	80.00%	2	20.00%	3	50.00%	3	50.00%
2023-24	8	72.73%	3	27.27%	2	66.67%	1	33.33%	3	60.00%	2	40.00%	7	70.00%	3	30.00%	5	83.33%	1	16.67%
2024-25	6	60.00%	4	40.00%	1	100.00%	0	0.00%	3	42.86%	4	57.14%	7	58.33%	5	41.67%	2	100.00%	0	0.00%

A.R. Reporting Year	REN (Study Design)				RES (Study Design)				STR (Study Design)				VIS (Study Design)				CDT (Study Design)			
	Int		Obs		Int		Obs		Int		Obs		Int		Obs		Int		Obs	
	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> (%)
2020-21	6	50.00%	6	50.00%	15	71.43%	6	28.57%	10	83.33%	2	16.67%	15	78.95%	4	21.05%				
2021-22	6	70.21%	5	45.45%	17	68.00%	8	32.00%	10	83.33%	2	16.67%	15	75.00%	5	25.00%				
2022-23	5	45.45%	6	54.55%	14	63.64%	8	36.36%	10	83.33%	2	16.67%	13	65.00%	7	35.00%	5	83.33%	1	16.67%
2023-24	8	53.33%	7	46.67%	14	63.64%	8	36.36%	9	90.00%	1	10.00%	9	45.00%	11	55.00%	5	83.33%	1	16.67%
2024-25	12	66.67%	6	33.33%	21	65.63%	11	34.38%	6	75.00%	2	25.00%	5	33.33%	10	66.67%				

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



A.R. Reporting Year	CANC		CRV		CHI		CCA		DIA		GAS		MHT		NEU	
	Scr	Rec	Scr	Rec	Scr	Rec	Scr	Rec	Scr	Rec	Scr	Rec	Scr	Rec	Scr	Rec
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			2061	121	364	151	2156	538	123	34	37	17	31	28	309	307
2024-25	213	146	1039	189	317	106	3941	951	268	159	21	13	29	29	109	104

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
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	1566	80	9128	2078
2024-25	241	114	0	0	276	159	497	100	309	81	117	75			7377	2226

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

A.R. Reporting Year	CANC (recruitment)		CRV (recruitment)		CHI (recruitment)		CCA (recruitment)		DIA (recruitment)		NEU (recruitment)		GAS (recruitment)		MHT (recruitment)	
	Int	Obs	Int	Obs	Int	Obs	Int	Obs	Int	Obs	Int	Obs	Int	Obs	Int	Obs
2020-21			14	35	26	124	487	143	5	0	168	14	0	0	5	0
2021-22			78	12	31	61	218	211	0	21	0	0	2	12	10	2
2022-23			94	5	28	51	249	63	0	50	2	713	109	0	15	0
2023-24			73	48	87	64	403	135	12	22	3	304	2	15	28	0
2024-25	113	33	67	122	56	50	236	715	103	56	3	101	1	12	29	0



A.R. Reporting Year	ORT (recruitment)		PCR (recruitment)		REN (recruitment)		RES (recruitment)		STR (recruitment)		VIS (recruitment)		CDT (recruitment)		in Year Totals (recruitment)	
	Int	Obs	Int	Obs	Int	Obs	Int	Obs	Int	Obs	Int	Obs	Int	Obs	Interventional	Observational
2020-21			20	0	45	27	564	129	4	0	8	0			1346	472
2021-22	39	33	732	50	1	29	136	192	36	7	19	0			1302	630
2022-23	59	60	102	57	60	13	50	168	26	3	59	58	149	18	1002	1259
2023-24	73	25	92	0	33	136	39	126	47	25	18	188	43	37	953	1125
2024-25	17	97	0	0	31	128	27	73	81	0	7	68			771	1455

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

A.R. Reporting Year	CANC (recruitment)		CRV (recruitment)		CHI (recruitment)		CCA (recruitment)		DIA (recruitment)		GAS (recruitment)		MHT (recruitment)		NEU (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
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
2022-23			8	91	3	76	12	300	47	3	0	109	0	15	0	715
2023-24			66	55	0	151	10	528	13	21	11	6	0	28	0	307
2024-25	23	123	115	74	0	106	0	951	33	126	8	5	0	29	1	103



A.R. Reporting Year	ORT (recruitment)		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	Comm	Non-Comm	Commercial	Non-Commercial
2020-21			0	20	0	72	4	689	0	4	1	7			23	1801
2021-22	0	72	0	782	1	29	4	324	0	43	19	0			103	1829
2022-23	0	119	1	158	0	73	0	218	0	29	9	108	0	167	80	2181
2023-24	0	98	0	92	0	169	26	139	25	47	28	178	0	80	179	1899
2024-25	0	114	0	0	1	158	14	86	0	81	6	69			201	2025

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



A.R. Reporting Year	CANC	CRV	CHI	CCA	DIA	NEU	GAS	MHT	PCR	REN	RES	STR	VIS	ORT	CDT	in Year Total Median (% RtT)
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%
2024-25	66.33%	80.00%	112.00%	91.34%	86.67%	104.00%	10.00%	41.65%	115.00%	76.56%	100.00%	79.17%	123.81%	117.09%		81.00%

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

A.R. Reporting Year	CANC (Median % RtT)		CRV (Median % RtT)		CHI (Median % RtT)		CCA (Median % RtT)		DIA (Median % RtT)		GAS (Median % RtT)		MHT (Median % RtT)		NEU (Median % RtT)	
	Int	Obs	Int	Obs	Int	Obs	Int	Obs	Int	Obs	Int	Obs	Int	Obs	Int	Obs
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	94.57%	90.83%
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%
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%
2024-25	66.67%	60.00%	81.00%	74.00%	117.11%	50.00%	92.50%	90.18%	56.67%	90.00%	90.00%	10.00%	41.65%			



A.R. Reporting Year	ORT (Median % RtT)		PCR (Median % RtT)		REN (Median % RtT)		RES (Median % RtT)		STR (Median % RtT)		VIS (Median % RtT)		CDT (Median % RtT)		Median across CSGs(% RtT)	
	Int	Obs	Int	Obs	Int	Obs	Int	Obs	Int	Obs	Int	Obs	Int	Obs	Int	Obs
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	122.00%		75.51%	50.00%	70.21%	92.56%	63.33%	81.47%	65.00%		108.33%	180.00%			74.61%	96.28%
2022-23	122.00%		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	83.33%		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%
2024-25	117.09%		115.00%		78.13%	65.00%	100.00%	80.53%	70.00%	83.33%	123.81%	141.19%			80.00%	83.33%

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

A.R. Reporting Year	CANC (Median % RTT)		CRV (Median % RTT)		CHI (Median % RTT)		CCA (Median % RTT)		DIA (Median % RTT)		NEU (Median % RTT)		GAS (Median % RTT)		MHT (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
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
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%
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%
2024-25	40.00%	80.00%	79.17%	80.00%		112.00%		91.34%	90.00%	54.33%			5.00%	180.00%		41.65%



A.R. Reporting Year	ORT (Median % RTT)		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	Comm	Non-Comm
2020-21			50.00%	79.60%	50.00%	80.74%	62.61%	73.69%	75.00%	55.36%	88.89%	80.74%			62.61%	80.74%
2021-22		80.74%	50.00%	75.51%	71.43%	75.69%	56.89%	80.74%	47.50%	100.00%	103.33%	192.50%			67.72%	80.74%
2022-23		122.00%	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		83.33%	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%
2024-25		117.09%		115.00%		76.56%	120.00%	87.06%	83.33%	70.00%	85.71%	145.24%			83.33%	80.00%

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



	CANC				CRV				CHI				CCA				DIA			
	Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm	
	Median FPFV (days)	P^A Studies < 30 days	Median FPFV (days)	P^A Studies < 30 days	Median FPFV (days)	P^A Studies < 30 days	Median FPFV (days)	P^A Studies < 30 days	Median FPFV (days)	P^A Studies < 30 days	Median FPFV (days)	P^A Studies < 30 days	Median FPFV (days)	P^A Studies < 30 days	Median FPFV (days)	P^A Studies < 30 days	Median FPFV (days)	P^A Studies < 30 days	Median FPFV (days)	P^A Studies < 30 days
BHSCT	35.0	36.36%	63.0	35.14%	3.0	66.67%	7	54.55%	13.0	100.00%	54.0	30.77%			20.0	55.00%	48	0.00%	27.0	71.43%
NHSCT			37.0	50.00%											7.0	66.67%	25	75.00%	32.5	0.00%
SEHSCT			29.0	50.00%	29	60.00%	113.5	25.00%			86.0	0.00%			51.0	37.50%			121	50.00%
SHSCT			210.5	0.00%	57	25.00%	21.5	50.00%			126.0	0.00%			42.5	50.00%			158	0.00%
WHSCT	239.5	0.00%	189.0	0.00%	63	14.29%	160	0.00%							92.5	37.50%	35	0.00%	53	0.00%

	NEU				GAS				MHT				ORT				PCR			
	Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm	
	Median FPFV (days)	P^A Studies < 30 days	Median FPFV (days)	P^A Studies < 30 days	Median FPFV (days)	P^A Studies < 30 days	Median FPFV (days)	P^A Studies < 30 days	Median FPFV (days)	P^A Studies < 30 days	Median FPFV (days)	P^A Studies < 30 days	Median FPFV (days)	P^A Studies < 30 days	Median FPFV (days)	P^A Studies < 30 days	Median FPFV (days)	P^A Studies < 30 days	Median FPFV (days)	P^A Studies < 30 days
BHSCT	39.0	0.00%	39.0	25.00%	125.5	0.00%					92	0.00%			29.5	60.00%			3.0	100.00%
NHSCT											93	0.00%							7.5	83.33%
SEHSCT					94	0.00%	29.5	50.00%			123	0.00%								
SHSCT											57	0.00%			10.0	100.00%				
WHSCT											83	0.00%								

	REN				RES				STR				VIS				in Year Totals (2024-25)			
	Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm	
	Median FPFV (days)	P^A Studies < 30 days	Median FPFV (days)	P^A Studies < 30 days	Median FPFV (days)	P^A Studies < 30 days	Median FPFV (days)	P^A Studies < 30 days	Median FPFV (days)	P^A Studies < 30 days	Median FPFV (days)	P^A Studies < 30 days	Median FPFV (days)	P^A Studies < 30 days	Median FPFV (days)	P^A Studies < 30 days	Median FPFV (days)	P^A Studies < 30 days	Median FPFV (days)	P^A Studies < 30 days
BHSCT			103.0	28.57%	20.0	100.00%	16.0	64.29%	14.0	100.00%	72	0.00%	71	33.33%	36.0	28.57%	35.0	36.36%	36.0	35.14%
NHSCT			210.0	40.00%	207.0	0.00%	76.5	25.00%	124	0.00%	233	0.00%			92.0	0.00%	124.0	0.00%	76.5	25.00%
SEHSCT			27.0	66.67%			88.0	0.00%			1400.00%	100.00%					29.0	30.00%	68.5	43.75%
SHSCT			186.5	25.00%	13.0	100.00%	1.0	80.00%	20	100.00%	78	0.00%					20.0	100.00%	78.0	12.50%
WHSCT	43.0	0.00%	64.0	25.00%	84.5	0.00%	29.0	50.00%			358	0.00%					63.0	0.00%	87.8	0.00%