



Clinical
Research
Network

NICRN Annual Report

2022 –2023



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¹ Dr David Sweet, clinical co-lead for NICRN Children's Health Group, pays touching tribute to Belfast trust babies participating in ASSERVO clinical trial, presenting each baby in the trial with a hand painted portrait of Paddington Bear.

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Glossary

<i>Acronym</i>	<i>Definition</i>		
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 [^]	Proportion
C&C	Capacity & Capability	PHA	Public Health Agency
CI	Chief Investigator	PI	Principle Investigator
CMG	Clinical Management Group	PICU	Paediatric Intensive Care Unit
COVID-19	Coronavirus Disease	PPI	Patient and Public Involvement
CSG	Clinical Steering Group	QUB	Queen's University Belfast
DGH	District General Hospital	R&D	Research & Development
DOH	Department of Health	RCT	Randomised Control Trial
ECMC	Experimental Cancer Medicine Centre	RtT	Recruitment to 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
NHS	National Health Service	UK	United Kingdom
NHSCT	Northern Health and Social Care Trust	UKRI	UK Research and Innovation
NI	Northern Ireland	UPH	Urgent Public Health
NICRCF	Northern Ireland Cancer Research Consumer Forum	UU	Ulster University
NICRF	Northern Ireland Clinical Research Facility	WHSCT	Western Health and Social Care Trust
NICRN	Northern Ireland Clinical Research Network	WTE	Whole Time Equivalent

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

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

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

Director's Report of achievements / challenges in reporting year 2022-2023

As a Northern Ireland Clinical Research Network (NICRN) family of Clinical Leads, PIs, Clinical Research staff and managerial/administrative support staff we believe that clinical research is essential if we are to better understand disease processes and, as a result, develop new tests, treatments and interventions. I in my role as director continue, in this my second year at the helm, to be thankful for the quality of the clinical and managerial support team within NICRN. The contribution that they made to clinical research in Northern Ireland was very apparent at the 2022-23 staff Conference which took place at Galgorm Manor in May 2022. In the executive summary I have chosen to share some reflections on this year's clinical activity against the background of activity that created the foundations on which we build.

This year Shane Jackson, NI Portfolio manager, and I have taken the opportunity to analyse and review NICRN activity data within current year, against the background of 5 years activity data recorded both pre and post the onset of Coronavirus -19(COVID-19). COVID-19, and actions required to mitigate against its effects, have had a profound impact on the Health and Social Care Trust Northern Ireland (HSCNI) clinical and academic workload, which in turn has created considerable challenges for those delivering NICRN activity. Despite this, and across all groups, excluding cancer, 183 studies were either open to recruitment or in active follow up during the course of 2022-2023. This figure is virtually identical to that recorded in 2018-2019, and has fluctuated by less than +/- 12% over a 5 year period. Across all 14 Clinical Specialty Groups (CSGs) the average new study adoption rate in 2022-23 was 3.1 (range 0-7) whereas the average number of active studies in recruitment or follow up was 13.1 (range 3-25). Regarding the 6 NI HSCTs, 140 studies (46%) were active across Belfast Health and Social Care Trust (BHSCT) sites whilst between 34 (11%) and 57 (18%) studies utilized sites in the other HSCT areas. Slightly more than two thirds of studies active during the current year (69%) were interventional studies, a proportion (P[^]) that has again remained very consistent over the last 5 years. It is particularly encouraging to note that overall recruitment to NICRN adopted studies this year (2261) represents a 17% increase when compared to 2021-2022 recruitment, and even more encouraging to see that this represents a 21% increase when compared to 2019-2020 pre COVID-19 recruitment. Particularly strong growth recorded since the initial impact of COVID-19 was noted within the Neurodegenerative, Gastroenterology, Diabetes and Vision groups. During the course of 2022-23, 8 of the 14 CSGs recruited in excess of 100 new patient's to a wide variety of studies (CCA, GAS, NEU, ORT, PCR, RES, VIS, CDT). Screening activity, which is a prerequisite to successful recruitment, has also demonstrated a very significant increase (103%) in activity over a 3 year period (8133 in current year). A notable success, that applies across virtually all CSGs, is the fact that our overall Recruitment

to Target (RtT) now sits at 87%. Of those groups undertaking observational studies (11), 8 achieved or exceeded 100% RtT (CRV, CHI, DIA, GAS, PCR, RES, STR, VIS). The interventional figure of 7 from 12 active groups achieving 75% or more RtT reflects greater challenges in this area and is a challenge that we need to address as we move forward. Regarding the relative numbers of patients recruited to Interventional (1002) vs observational (1259) studies in 2022-2023, this figure has returned to the 2018-2019 level, following a peak in interventional studies adopted during the COVID-19 recovery period. Of all active studies undertaken this year 26% (47) were classified as commercial and 74% (136) non-commercial. The former are often subject to competitive recruitment across multiple national and international sites with the result that agreed recruitment targets for sites in Northern Ireland are usually low. Our commercial portfolio was also hit hard by the COVID-19 pandemic as our scale meant the network needed to pivot staffing resource and focus our service on the delivery of the Urgent Public Health (UPH) programme and vaccine studies. Also as we transitioned out of the pandemic, Northern Ireland had a unique challenge within the UK as the impact of British Exit (BREXIT) and more specifically the NI Protocol became very apparent, with real and perceived difficulties supplying Investigational Medicinal Products (IMP). Whilst we cannot give an evidenced figure on our lost business, anecdotally we can cite that several potential studies have had significant delay in starting or were withdrawn/declined in full. This is reflected in the overall comparative recruitment numbers, Commercial (80), Non Commercial (2181). An ongoing challenge for all of us within NICRN will be to increase our commercial activity in line with many of the challenges outlined in the recently published O'Shaughnessy report ². An additional challenge will be to improve the P[^] of studies, both commercial and non-commercial, achieving a First Patient First Visit (FPFV) attendance target of within 30 days of a study going live, from the current value of 50%, to a figure approaching 66%. With the exception of FPFV during the 18 month period following the onset of COVID-19, this figure has remained relatively static over a 5 year period.

Our oncology speciality, led by Dr Melanie Morris , Dr Stuart McIntosh and their team continue to successfully transition back to more normal business as they regrow their portfolio following the COVID-19 pandemic. Over the reporting period they adopted twenty nine new studies covering a multitude of disease sites with their breast cancer clinical study group accounting for a quarter of submissions (n=8). Other areas included early phase, lung, urology and dermatology. Overall a portfolio of 88 open studies provided research opportunities to both adult and paediatric participants with a total of 302 participants being recruited over the reporting period. I would highlight and congratulate the group on successfully securing funding of £1.7 million for the continued support of the Experimental Cancer Medicine Centre (ECMC) for the next five years.

² [Commercial clinical trials in the UK: the Lord O'Shaughnessy review - final report - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/94444/Commercial-clinical-trials-in-the-UK-the-Lord-O'Shaughnessy-review-final-report-2020.pdf)

The NICRN clinical trials staff cohort in 2022-2023, managed by Ms Sonia McKenna, consisted of a group of committed and enthusiastic research nurses (82), Clinical Research: Optometrists(3), Midwives(2), Respiratory Sleep Physiologist (1), Ophthalmic Imaging Specialist (1), Psychologist(1) and Physiotherapists(2). (Tables 2, 3 & Appendix 1). The clinical team are supported by the central coordinating centre administrative team (5 management and 7 band 4 administrative assistants) operationally led by Mr Shane Jackson and supported by Mrs Ciara McKenna. The administrative team is centrally located in the NICRN co-ordinating centre to facilitate effective use of the limited resource and to ensure our teams have a broad and adaptive experience base enabling their ability to move between clinical specialities and the more operational actions needed to run the co-ordinating centre functions.

The last 2 years have proved very difficult for all HSC staff. Our clinical research nurse teams do however deserve special recognition for how they managed the highly dynamic and demanding working environment. Staff were emotionally and physically exhausted from 18 months of intensive pressures. Thankfully with the financial support of the Northern Ireland Clinical Research Recovery, Resilience and Growth (NICRRRG) task force we had successfully recruited an additional 9 Whole Time Equivalent (WTE) Clinical research nurses to temporarily augment our existing teams alongside a clinical trials pharmacist and some administrative support. Also with the additional challenges presented from social distancing measures we had found that accommodation was one of our major challenges. Thankfully with the support of the Belfast Health and Social Care Trust (BHSCT) and Queens University Belfast (QUB) the NICRN was able to secure dedicated staff accommodation within the Dunluce Health Centre, situated on the Lisburn road adjacent to the Belfast City Hospital (BCH) site. This offered both office accommodation for our staff management team and shared space for our research staff to work collaboratively providing access to high quality meeting facilities. I would personally like to thank Professor Judy Bradley and Professor Stuart Elborn (QUB) for their role in securing this site which has transformed our staffing operations. It was also with great pleasure that we hosted a visit by the NI Health Minister, Mr Robert Swann, who thanked our Primary Care team for their efforts in delivering the PANORAMIC platform trial within NI. Finally with the reduction in social distancing measures over 2022-23 it was great to finally arrange our first face to face training event for all staff in May 2022. This was a very positive event with our teams coming together for the first time in over 12 months. It also gave the full team the opportunity to say thank you and farewell to our outgoing director Dr Maurice O’Kane and welcome and provided me with an opportunity to meet the whole team.

The process of emerging out of the COVID-19 pandemic has allowed us to concentrate on supporting CSGs and fostering collegiality which I believe will progress further through the establishment of Clinical Cluster Groups (CCGs), each incorporating related disease areas. The aim of the Cluster delivery model is to increase efficiency of working, facilitate collaboration

between existing CSGs and to enable support for disease areas that fell outside existing CSGs. Much has been done this year to set the road map in place for Clinical Management Groups (CMGs), Clinical Cluster Groups (CCGs), an NICRN Steering Group and indeed broader Personal and Public Involvement (PPI) in NICRN activity. This has been undertaken whilst liaising closely with partner organisations at Trust and University level and indeed whilst supporting the work of the Northern Ireland Research Recovery, Resilience and Growth Group (NIRRRG).

In forthcoming years, we look forward to opportunities that will arise through the exciting development of a Belfast City Deal. City deals are bespoke funding packages to enable cities and their surrounding regions to maximise strengths and tackle economic challenges. The Belfast City Deal will provide approximately £1bn of investment for the Belfast region over the next 5 years. A proportion of the overall investment will be targeted at establishing an Institute for Research Excellence in Advanced Clinical Healthcare (IREACH). This is a hugely positive advancement for the Belfast region and as the largest clinical trials delivery platform, the NICRN is keen to be central to this exciting opportunity.

The sections that follow highlight the outcome achievements and delivery challenges faced by each of the 15 CSGs including the Northern Ireland Clinical Trials Network (NICTN). Some groups are very experienced and include large numbers of very active CIs and PIs, others manage extremely well with limited resources. Each group has highlighted a few of their main achievements. Good news stories reported include the fact that the Cardiovascular team have achieved excellent recruitment to target across a total of 25 open studies. The Children's team who currently are managing 310 active study participants are to be congratulated for having built on the legacy of Professor Henry Halliday, as illustrated in Figure 2. The Critical Care team have been awarded the BHSCT Chairman's Innovation award for their contribution to clinical research whereas the core strengths of the Diabetes team have been enhanced through the inclusion of newly arrived Professor Alex Miras into the CMG.

I would also thank the NICRN children's and Neurodegenerative staff for their continued support on an ad hoc basis for the SIREN study within BHSCT.

To conclude I am delighted, after having been in post for almost 18 months, to be able to reflect on a productive and exciting year in NICRN. In particular I would wish to thank clinical leads for their support throughout the year, the NICRN clinical and coordinating team's staff for their enthusiastic commitment to continually strive for improvement in the clinical research sphere, and to my senior management team led by Dr Paul Biagioni. Thanks also to colleagues in each of the Trust R&D offices and their R&D directors who have made utilizing NICRN as a regional resource possible.



A handwritten signature in blue ink, appearing to read 'J. Jackson', with the name 'J. J. JACKSON' printed in blue capital letters directly beneath it.

Professor Jonathan Jackson
NICRN Director

NICRN Clinical Specialty Lead reviews of the year's activities

Cardiovascular (CRV)

Clinical Leads, Active PIs and Clinical Management Group (CMG) Members

Cardiology Group Clinical Leads Donna Fitzsimmons – QUB Patrick Donnelly - SEHSCT Chief and Principal Investigators (CIs & PIs) Colum Owens -BHSCT Andrew McNeice -BHSCT Conleth Murphy - BHSCT Ian Menown – SHSCT Aaron Peace – WHSCT	CMG Members BHSCT- Colum Owens, Andrew McNeice, Conleth Murphy QUB – Donna Fitzsimmons SEHSCT- Patrick Donnelly SHSCT- Ian Menown WHSCT- Aaron Peace PPI Representative Position Vacant
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Group Background/Summary

During the course of the 2022-2023 year the cardiovascular group adopted 3 important studies (**Optimal Study, IVUS CHIP, CHIP BCIS3**) and continued to recruit into 2 existing studies (**Protect TAVI, Highlife**). Drs Murphy, McNeice and Owens continued to manage 154 patients in follow up in 7 studies (**Ability DM study, October Study, Sapien 3 Ultra, Noble Study, Ischaemia, ASAP TOO, and PROCTOR Study**).

Key Achievements

- Recruitment for Protect **TAVI** has been very successful at the RVH site. This is a large study with over 4000 patient recruited across the UK. The RVH team have surpassed the initial target of 40 patients having now more than doubled initial anticipated recruitment numbers (70). We await approval to increase our numbers again, with an anticipated new target of 85 patients. At the study investigator meeting in London November 2022 Belfast was selected to perform the live case for the UK conference.
- Recruitment for **IVUS CHIP** has also been very successful with monthly recruitment of 3-4 patients.

Relevant Publications

The team would wish to highlight Dr Simon Walsh's contribution to the publication of results from the the **SYNTAX II** longitudinal coronary revascularisation study, that recruited at BCH/RVH sites. [Clinical outcomes of state-of-the-art percutaneous coronary revascularization in patients with *de novo* three vessel disease: 1-year results of the **SYNTAX II** study: Javier E..., Simon Walsh, et al. *European Heart Journal*, Volume 38, Issue 42, 07 November 2017, Pages 3124-3134, <https://doi.org/10.1093/eurheartj/ehx512>]

Awards/Good New Stories

The Cardiovascular Team have received recognition, within the study newsletter, for timely completion of data input and transfer of imaging for the **Optimal Study**.



Figure 1 SEHSCT Cardiovascular Team **Ms Aileen Smith and Ms Susan Regan presenting on their site's activity** at the NI Clinical Research network Staff Conference

Child Health (CHI)

Clinical Leads, Active PIs and CMG Members

Child Health Group Clinical Leads	CMG Members
David Sweet - BHSCT Anthony McCarthy – BHSCT	BHSCT – David Sweet, Anthony McCarthy, Bharathi Rao, Chris Hill, Julie Richardson, Brian McCrossan, Suzanne Lawther, David Marshall, Fionnuala Sayers, Eibhlin McCloone, Catriona Monaghan, Eilish O'Connor
Chief and Principal Investigators	SEHSCT - Michael Magowan
David Sweet - BHSCT	SHSCT - Alison Verner, Lesley-Ann Funston
Bharathi Rao - BHSCT	
Chris Hill - BHSCT	
Julie Richardson - BHSCT	
Brian McCrossan - BHSCT	
Suzanne Lawther - BHSCT	
David Marshall - BHSCT	
Fionnuala Sayers - BHSCT	
Eibhlin McCloone - BHSCT	
Catriona Monaghan - BHSCT	
Eilish O'Connor -BHSCT	
Carolyn Baile - BHSCT	
Michael Magowan - SEHSCT	
Alison Verner - SHSCT	
Lesley-Ann Funston –SHSCT	
	PPI Representative
	Position vacant

Group Background/Summary

Due to COVID-19 restrictions, CMG meetings were curtailed during last 2 years. The last formal face-to-face CMG was in 2019. The group have however continued to meet with the children's team informally on a regular basis to discuss ongoing trials. This year we managed to open **SurfON** at two District General Hospital (DGH) sites as well two new surgical studies (**DOLFIN & CONTRACT-2**). We also support two new studies run by paediatric Allied Health Professionals (**Speech disorder/ cleft palate & the Dolphin-2 trial**). In total 340 participants have been enrolled to studies that were active during the reporting period. Actual

recruitment to active studies in year was 79 participants (see Appendix 4). In the three studies closed to recruitment but in follow up we achieved a median RtT of 80% (range 60% – 220%) despite the difficulties experienced during COVID-19. We have continued to filter trials via National Institute for Health and Care Research (NIHR) to relevant specialists. Some have taken up the challenge and become PI's. Some could not recruit as the Children's studies often involve extremely rare diseases. Others do not feel they have the time to commit to research along with their busy clinical jobs.

Key Achievements

- New studies including the **DOLFIN** trial remain open despite the Children's team being very small.
- Two surgeons are now engaged as PIs in national studies for the first time.
- Paediatric Intensive Care Unit (PICU) is now very committed to recruiting children to relevant intensive care studies. At present recruiting for **BESS** and **RECOVERY** and considering a new trial on value of Gastric residual measurement.
- One industry trial has now closed, but feedback on ability of children's teams to complete data collection is of a high standard. Recruited to 60% of projected despite COVID-19.
- A -80 degree freezer and centrifuge has now been installed and is operating in the children's haematology laboratory.
- **SurfON** with 24 recruits is the 4th best recruiter out of 43 UK sites! This study is now also open in SEHSC & SHSC Trusts.

Studies currently open to recruitment include (**ASSERVO**, **SurfON**, **TRIALNET 18**, **KD – CAAP**, **DOLFIN**, **FERN**, **BESS**, **CASTLES**). New studies in set up include (**DOLPHIN & CONTRACT-2**) with an additional 4 to 5 studies pending.

Relevant Publications

CURONEB Study Group. A Randomized, Controlled Trial to Investigate the Efficacy of Nebulized Poractant Alfa in Premature Babies with Respiratory Distress Syndrome. *J Pediatr.* Dani C ...**Sweet D** et al; 2022 Jul;246:40-47.e5. doi: 10.1016/j.jpeds.2022.02.054. Epub 2022 Mar 5. PMID: 35257740.

A first-in-human clinical study of a new SP-B and SP-C enriched synthetic surfactant (CHF5633) in preterm babies with respiratory distress syndrome: two-year outcomes. **Sweet DG** ...et al. *J Matern Fetal Neonatal Med.* 2022 Dec; 35(24):4739-4742. doi: 10.1080/14767058.2020.1863363. Epub 2020 Dec 20. PMID: 33345663.

Awards/Good New Stories

Over the course of the year the group have submitted several Good News stories to the CRN hub including our final visit after 515 days of a baby enrolled in a randomised trial of human monoclonal RSV immunoglobulin, our BHSCT Research team, were awarded Champion status by the **SurfON** Trial and this led to a wider story about the niece of the legendary Professor Henry Halliday (Father of Surfactant Therapy in Europe) being recruited into a clinical trial of surfactant.



Figure 2 BHSCT Child Health Team Dr David Sweet, Ms Angela Abbate and Ms Eileen Killen with ASSERVO Study Participant and Parents

Critical Care (CCA)

Clinical Leads, Active PIs and CMG Members

<p>Critical Care Group Clinical Lead</p> <p>Jon Silversides - BHSCT & QUB</p> <p>Chief and Principal Investigators</p> <p>Peter McGuigan – BHSCT</p> <p>Chris Nutt – BHSCT</p> <p>James McNamee – BHSCT</p> <p>Murali Shyamsundar – BHSCT</p> <p>Ciara O'Donnell – BHSCT</p> <p>David Johnston – BHSCT</p> <p>Dominic Trainor – BHSCT</p> <p>Suzanna Paterson – BHSCT</p> <p>Kathryn Ward – BHSCT (NICRN)</p> <p>Jon Silversides – BHSCT & QUB</p> <p>Danny McAuley – BHSCT & QUB</p> <p>Adam Glass – BHSCT & QUB</p> <p>Paul Johnston – NHSCT</p> <p>Matthew Devine – SEHSCT</p> <p>Samantha Hagan – SEHSCT (NICRN)</p> <p>Rob Charnock – SHSCT</p> <p>Claire Shevlin – SHSCT</p> <p>Denise McFarland – SHSCT (NICRN)</p> <p>Adrian Donnelly – WHSCT</p> <p>Michelle Fallon – WHSCT (NICRN)</p> <p>Sinead O'Kane – WHSCT (NICRN)</p> <p>Laura Sherrard – QUB</p>	<p>CMG Members</p> <p>BHSCT –Adam Glass, Danny McAuley, Jon Silversides, Kiran Reddy, Michael McGinley, Peter McGuigan, James McNamee, Neil Cody, Chris Nutt, Ciara O'Donnell, Suzanna Paterson, Ross McMullan, Murali Shyamsundar.</p> <p>NHSCT – Paul Johnston,</p> <p>SEHSCT – Matthew Devine, John Trinder, Chris Murray</p> <p>SHSCT – Rob Charnock, Claire Shevlin</p> <p>WHSCT – Adrian Donnelly, Michelle Fallon</p> <p>PPI Representatives</p> <p>Position Vacant</p>
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Group Background/Summary

Of particular note is the fact that CMG meetings have been held quarterly, with regular representation from every Trust, as well as support staff from the NICRN coordinating centre. Average attendance at CMGs is 13-15 depending on clinical responsibilities, with all Trusts normally having at least one representative and there is always NICRN coordinating centre attendance.

During the course of the last year 9 new studies opened to recruitment: **BIGPAK-2** – Biomarker guided intervention to prevent acute kidney injury after major surgery. (BHSCT), **CHEST** - Characterising biofilms in endotracheal tubes to direct a new strategy for preventing ventilator-associated pneumonia in critically ill adults. (BHSCT), **iREHAB** – Remote multicomponent rehabilitation compared to standard care for survivors of critical illness after hospital discharge. (SHSCT & WHSCT), **MARCH** – Mucoactives in acute respiratory failure: Carbocisteine and Hypertonic Saline. (NHSCT & WHSCT), **SCUFFD** – Feasibility of slow continuous ultrafiltration for deresuscitation in critically ill patients. (BHSCT), **SINFONIA** – Sugammadex for prevention of post-operative pulmonary complications. (BHSCT), **SRAVI** – A speech recognition application as a communication aid for critical care patients with tracheostomies (WHSCT), **UK-ROX** – Evaluating the clinical and cost-effectiveness of a conservative approach to oxygen therapy for invasively ventilated adults in intensive care. (SEHSCT, SHSCT), **ZANAMIVIR** – Retrospective observational study to evaluate the effectiveness of treatment with Zanamivir in a cohort of ICU patients with complicated influenza infection. (BHSCT)

Six additional studies are in setup (**A2B** – Alpha 2 agonists for sedation (SEHSCT), **GenOMICC** - Genetics of susceptibility and mortality in critical care. (SEHSCT), **INITIALISE** – Investigation of novel and established therapies in a human intravenous lipopolysaccharide model of sepsis. (BHSCT), **iREHAB** – Remote multicomponent rehabilitation compared to standard care for survivors of critical illness after hospital discharge. (BHSCT & SEHSCT), **RV study** – Assessment of right ventricular contractile reserve following resection by dobutamine stress cardiac magnetic resonance. (BHSCT), **SRAVI** – A speech recognition application as a communication aid for critical care patients with tracheostomies. (BHSCT)

In total 312 patients were recruited across 22 active studies during the course of 2022-2023. Of these 249 were recruited to interventional trials.

Key Achievements

- With agreement of CMG, expansion of remit into perioperative medicine with involvement in 3 ongoing perioperative trials. This has resulted in a 50% increase in monthly patient recruitment numbers in BHSCT.

- **A-STOP** (NI-led diagnostic study) which is now closed to recruitment, recruited 87 patients, 120% of anticipated target.
- **MARCH** – (NI-led interventional study) BHSCT has been the third highest recruiting site nationally.
- **PHIND** – (NI-led observational study) the team has achieved joint top recruiting in the UK.
- **SINFONIA** (NI Led interventional study) – open to recruitment on 10/2/23 and has recruited 15 patients by 31/3/23.

Relevant Publications

- GWAS and meta-analysis identifies 49 genetic variants underlying critical COVID-19. Pairo-Castineira E... **McAuley D** et al. *Nature*. 2023 May 17. doi: 10.1038/s41586-023-06034-3.
- Repair of Acute Respiratory Distress Syndrome in COVID-19 by Stromal Cells (REALIST-COVID Trial): A Multicentre, Randomised, Controlled Trial. Gorman EA, McGuigan P, **Silversides J, McAuley DF ...et al.** *Am J Respir Crit Care Med*. 2023 May 8. doi: 10.1164/rccm.202302-0297OC.
- Effect of Angiotensin-Converting Enzyme Inhibitor and Angiotensin Receptor Blocker Initiation on Organ Support-Free Days in Patients Hospitalized With COVID-19: A Randomized Clinical Trial. Writing Committee for the REMAP-CAP Investigators... **McAuley DF** et al. *JAMA*. 2023 Apr 11; 329(14):1183-1196. doi: 10.1001/jama.2023.4480
- Long-term (180-Day) Outcomes in Critically Ill Patients With COVID-19 in the REMAP-CAP Randomized Clinical Trial. Writing Committee for the REMAP-CAP Investigators... **McAuley DF** et al. *JAMA*. 2023 Jan 3; 329(1):39-51. doi: 10.1001/jama.2022.23257.
- Acute hypoxemic respiratory failure after treatment with lower tidal volume ventilation facilitated by extracorporeal carbon dioxide removal: long-term outcomes from the REST randomised trial. Boyle AJ, **McNamee JJ, McAuley DF et al.** *Thorax*. 2022 Oct 5;thoraxjnl-2022-218874. doi: 10.1136/thorax-2022-218874.
- Effect of Antiplatelet Therapy on Survival and Organ Support-Free Days in Critically Ill Patients with COVID-19: A Randomized Clinical Trial. REMAP-CAP Writing Committee for the REMAP-CAP Investigators... **McAuley DF** et al. *JAMA*. 2022 Apr 5; 327(13):1247-1259. doi: 10.1001/jama.2022.2910.
- Whole-genome sequencing reveals host factors underlying critical COVID-19. Kousathanas A... **McAuley D** et al. *Nature*. 2022 Jul; 607(7917):97-103. doi: 10.1038/s41586-022-04576-6.
- Aspirin as a Treatment for ARDS: A Randomized, Placebo-Controlled Clinical Trial. Toner P, **McNamee JJ, Nutt C, Johnston P, Trinder J, McAuley DF,... et al.** *Chest*. 2022 May; 161(5):1275-1284. doi: 10.1016/j.chest.2021.11.006.

Awards/Good New Stories

The Critical Care Team were awarded first place in the 'Acute Innovations' category at the Belfast Trust Chairman's Awards. This was in recognition of our contribution to the recruitment of 139 patients to the **REMAP-CAP** study during the COVID-19 pandemic waves of 2020/21.

The Critical Care research team in BHSCT was recognised by the NICRN Director for their outstanding work in the recruitment of 24 patients across 11 studies in a one-month period.

Dr Peter McGuigan (former Group Co-Lead) was awarded an "Established Clinician Award" by NIHR/Faculty of Intensive Care Medicine for his outstanding contribution to delivery of critical care research through the NICRN (May 2022).



Figure 3 BHSCT Critical Care Team were awarded first place at the BHSCT Chairman's Awards for Acute Innovation of the year

Diabetes (DIA)

Clinical Leads, Active PIs and CMG Members

Diabetes Group Clinical Lead John Lindsay- BHSCT	CMG Members BHSCT - John Lindsay, Philip Johnston, Hamish Courtney NHSCT – Anna Strzelecka SEHSCT – Ciara Mulligan WHSC - Alex Miras
Chief and Principal Investigators John Lindsay-BHSCT Philip Johnston-BHSCT Hamish Courtney-BHSCT Anna Strzelecka-NHSCT Ciara Mulligan – SEHSCT Alex Miras- WHSC & UU	PPI Representatives Position Vacant

Group Background/Summary

The diabetes CMG meets every six months with regular representation across four of the five health Trusts. The portfolio includes studies in type 1, type 2 diabetes, cardio-metabolic and obesity management. Sixty three percent of the portfolio are industry-sponsored studies. Fifty five percent of studies are randomised and interventional in design. Four new studies, adopted by the diabetes NICRN, and delivered in the Belfast and Northern Health and Social Care Trust (NHSCT), are open for recruitment: **(ADDRESS-2, SELECT LIFE, REFER-UK and REDFINE 2)**. **ADDRESS-2** is a multi-centre UK collaboration aiming to improve understanding of the development and progression of type 1 diabetes and to establish a resource to facilitate type 1 diabetes research. **SELECT LIFE** aims to study the long-term impact of anti-obesity medication. **REFER-UK** is a retrospective, non-Interventional, chart review study of the effectiveness of FreeStyle Libre in adults with Type 2 Diabetes. **REDFINE 2** aims to examine the efficacy and safety of a combined weekly obesity preparation, Cagrilintide and Semaglutide, in participants with overweight or obesity and type 2 diabetes.

During 2022-23 we recruited 50 patients (see Appendix 4) to active studies with a median first participant-first visit of 28.5 days for commercial studies and 48 days for non-commercial studies.

Key Achievements

- We are collaborating with Imperial College London to participate in the **ADDRESS-2** trial.

- We were delighted to welcome Prof Alex Miras as a joint appointment at Ulster University, and WHSCT, and look forward to expanding our portfolio of obesity trials in Northern Ireland.
- The NHSCT team are engaged in a range of cardio-metabolic and obesity studies and have been highly successful with patient recruitment during 2022-23.
- We continue to have an interest in aspects of metabolic bone health. The **TOPAZ** study of Osteogenesis Imperfecta, an international multi-centre trial continues at Musgrave Park Hospital.
- The NHSCT team have expanded the portfolio to examine the effectiveness of new technology with flash glucose monitoring in type 2 diabetes.
- Recruitment for **PIONEER REAL** study, a study of oral GLP-1 agents, was highly successful against a backdrop of COVID recovery, and is now in follow up

Relevant Publications

Semaglutide for cardiovascular event reduction in people with overweight or obesity: SELECT study baseline characteristics. Lingvay I, et al. Obesity (Silver Spring). 2023; 31(1): 111-122. doi:10.1002/oby.23621

Awards/Good New Stories

The NHSCT, Diabetes Research team were the Joint highest recruiter in UK, for the Pioneer Real trial (see Figure 4)



Figure 4 NHSCT Diabetes Research Team Ms Moyra McMaster and Dr Anna Strzelecka, whom we would like to congratulate as they were the joint highest recruiting site in the UK for the Pioneer Real Trial, which is an amazing result considering their limited capacity of only 0.5 WTE CRN support.

Gastroenterology (GAS)

Clinical Leads, Active PIs and CMG Members

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

Group Background/Summary

At present there are 11 studies active in the Gastroenterology Research Network team. Four were still in setup, four are still open to recruitment whereas 3 are now closed having completed follow up. In the past year 4 new studies have been added to the portfolio. The commercial vs non commercial ratio is 55% to 45 %, respectively. At the end of this years reporting period 152 patients were being managed within currently active portfolio studies and of these most had been recruited to the Barretts cytosponge trial (n=101 BHSCT). 109 patients were recruited during the reporting period (see Appendix 6). A priority for 2023-2024 will be to boost interest and recruitment to research in some of the Trusts not currently research active in this area.

Key Achievements

- The Gastroenterology group have been heavily involved in the non commercial UK centred cytoposponge study. This involves the non surgical detection of dysplastic Barretts. The development of this new investigative procedure makes detection easier for patients, and the process also improves cost effectivety. Team members in both WHSCT and BHSCT are currently recruting to this study.
- We would like to acknowledge the great work of the WHSCT and BHSCT NICRN teams in fast-tracking the delivery of this UK wide trial. Both sites have achieved their respective targets within the given timeframes.

- The group have an active Irritable Bowel Disease (IBD) portfolio in both BHSCT and SEHSCT. The aim is to treat refractory patients with novel agents that are not currently available in the National Health Service (NHS).
- The **ELEVATE UC** study is an important UK study on the optimal management of sick IBD patients. The SEHSCT is one of the largest recruitment sites in the UK. The Group await final data analysis which will be presented at international meetings, and likely precipitate publication in a high impact journal.

Relevant Publications

Dr Allen will be presenting on the Optimal Management of Acute Colitis at the British Society of Gastroenterology meeting in June 23. The presentation will include material from the **ELEVATE UC** protocols.

The Importance of high –quality big data in the application of AI in IBD. Ashton , ... **Allen** et al . Frontline Gastroenterology. 2022. PMID: 37056322 PMCID: PMC10086732 (available on 2023-11-17) DOI: 10.1136/flgastro-2022-102342

Awards/Good New Stories

As cited above the WHSCT and BHSCT, GI Research teams exceeded their target for the **DELTA** study and in the course of delivering this study they identified a participant with an early cancer diagnosis. This could of course have been a life threatening situation and without the efforts of the NICRN teams and our PI's this could have resulted in a very different outcome for this individual. (See Figure 5)



Figure 5 Shows the Cytosponge kit as utilised in the DELTA study.

Mental Health (MTH)

Clinical Leads, Active PIs and CMG Members

Mental Health Group Clinical Leads Ciaran Mulholland - NHSCT & QUB Gerry Leavey- UU Chief and Principal Investigators Aidan Turkington – BHSCT & QUB Ciaran Mulholland-NHSCT & QUB Suzanne Barrett – NHSCT Gary Woods - SEHSCT Chris Southwell -SHSCT John Brady – WHSCT Gerry Leavey-UU	CMG Members BHSCT & QUB - Aidan Turkington NHSCT- Ciaran Mulholland ,Suzanne Barrett SEHSCT – Gary Woods SHSCT – Chris Southwell WHSCT - John Brady UU - Gerry Leavey <u>Clinical Trainee Rep</u> Ursula Campbell – Junior Doctor <u>PPI Representatives</u> Variable – Trust PPI Representatives
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Group Background/Summary

The CMG currently aims to meet at least twice per year. There have however been no CMGs since the announcement of the COVID-19 pandemic. There have been two attempts to convene CMGs in Spring 2023 however a common date of convenience has eluded the organisers and membership due to competing workload.

Key Achievements

- Recruitment to the **CHITIN** funded **The Walking fOR Health: The WORTH trial** (Edge ID: 113815; CI: Suzanne McDonough (UU)) closed out on 31/08/2022 (End of study - 31/12/2022) with n = 25 patients recruited. Northern HSC Trust achieved 100% [n=15] of its recruitment target (PI: Dr Judith McAuley) while WHSCT (PI: Dr John Brady) achieved 66.67% of its target [n=10].
- NICRN Mental Health staff member Dr Suzanne Barrett was also seconded to the Belfast HSC Trust and South Eastern HSC Trust in 2022/23 to assist with the setting up and research auditing of **The Child Anxiety Treatment in the context of COVID-19** (Edge ID: 136376) following an approach for site ID to Prof Gerry Leavey (Ulster University). The CI, Prof Cathy Cresswell (Oxford) worked with children, parents and NHS/HSC clinicians to develop an online program (the OSI platform) that parents/carers of children with anxiety disorders work through with remote support

from a CAMHS therapist. Recruitment closed on 30/07/2022. CAMHS services reported recruitment of n=9 (90%) in BHSCT CAMHS (PI Val Rowan/Caroline McClean) and n=8 (80%) in SEHSCT (PI – Margaret Cresswell). An OSI GROWS free-to-use licence is presently the subject of Service Evaluation in participating services.

- An NIHR-funded RCT (CI: Dr Michael Duffy (QUB)/Prof Anke Ehlers (Oxford)) entitled ***Does a Phased Approach Enhance Outcomes for Trauma-Focused Cognitive Therapy (CT-PTSD) for Complex Posttraumatic Stress Disorder (CPTSD)?*** (Edge ID: 154737) is scheduled to open across five NI HSC Trusts and five Trusts in England in 2023. Dr Suzanne Barrett conducted a consultation with the co-CIs to develop a finalised protocol and IRAS application in 2022. The research team includes Study Medical Officer: Prof Ciaran Mulholland (NICRN Co-Lead, NHSCT) and Study Training Lead – Dr Kevin Dyer (Consultant Psychiatrist, NHSCT). Further information regarding the study can be obtained from the NI study manager (appointed Autumn 2022), Dr Nina O'Neill (QUB) Email: nina.oneill@gub.ac.uk
- The **International Survey of Childbirth-Related Trauma UK (INTERSECT UK)**; CI: [Prof Susan Ayers \(City, UCL\)](#); Edge ID: 152173) will open on 31st March 2023 in Northern HSC Trust Maternity services and run until the end of July 2023. The Local Collaborative team are listed as: S Barrett (Site Investigator for NI. Contact: Suzanne.Barrett@northerntrust.hscni.net); S. Hamilton (Consultant Midwife – AAH. Contact: Shona.Hamilton@northerntrust.hscni.net), C Diamond (Maternity Services Lead NHSCT) and C Mulholland (NICRN Co-Lead & Consultant Psychiatrist, NHSCT).
- NICRN Mental Health (SB) has also worked on the development of Encompass (research work stream) in 2022/23

Relevant Publications

Supporting participants with severe mental illness and associated cognitive deficits to engage in physical activity and sedentary behaviour research. *Howes, S ...Brady, J., et al.*. 18 May 2022). 822. <https://pure.ulster.ac.uk/en/publications>

An updated systematic review of interventions to increase awareness of mental health and well-being in athletes, coaches, officials and parents (Breslin, G.... **Leavey, G.** et al) (2022). *Systematic Reviews*, 11, [99]. <https://doi.org/10.1186/s13643-022-01932-5>

Prevalence and risk factors of mood and anxiety disorders in children and young people: Findings from the Northern Ireland Youth Wellbeing Survey. (Bunting L,, **Mulholland, C.** et al) (2022) *Clinical Child Psychology and Psychiatry*. 27(3):686-700. <https://doi.org/10.1177/13591045221089841>

Associations between parental bonding, social isolation and loneliness: do associations persist in later life and is isolation a mediator between parental bonding and

loneliness? (Burns, A.,... **Leavey, G.** et al.)(2022). *BMC Psychology*, 10(1), 1-9.
[152]. <https://doi.org/10.1186/s40359-022-00855-z>

Prevalence and Risk Factors of Psychiatric Symptoms among Older People in England during the COVID-19 Pandemic: a Latent Class Analysis (Curran, E., ...**Leavey, G.** et al) (2022). . *International Journal of Mental Health and Addiction*, 1 – 13 .
<https://doi.org/10.1007/s11469-022-00820-2>

Screening Tools for Mental Disorders Among Female Refugees: a Systematic Review (Donnelly, O., & **Leavey, G.**)(2022).. *Journal of Child and Adolescent Trauma*, 15(2), 209-219. <https://doi.org/10.1007/s40653-021-00375-9>

Mind the gap: an administrative data analysis of dental treatment outcomes and severe mental illness.(Ferry, F. R., ... & **Leavey, G.** et al)(2022). *Journal of Mental Health*, 1-7. <https://doi.org/10.1080/09638237.2022.2069722>

Longitudinal Associations Between Athletes' Psychological Needs and Burnout Across a Competitive Season: A Latent Difference Score Analysis. (Shannon, S. ,... **Leavey, G.**, et al). 2022. *Journal of Sport and Exercise Psychology*, 44, 240-250
<https://doi.org/10.1123/jsep.2021-0250>

Impact of COVID-19 on mental health research: is this the breaking point? (Sparasci, O., **Mulholland, C.**, et al). (2022)*The British Journal of Psychiatry*, 220 (5), 254 – 256. <https://doi.org/10.1192/bjp.2022.8>

Mental health difficulties among professional footballers: (**Woods G.**, et al.) (2022) A narrative review. *Sports Psychiatry*. 2022; 1(2):57–69.

Awards/Good New Stories

Dr Chris Southwell - TrOn learning module on behalf of Royal College of Psychiatry - See: [TrOn – Neuroreceptors \(rcpsych.ac.uk\)](https://www.rcpsych.ac.uk/neuroreceptors)

Impact Research Centre Conference, NHSCT (held 22nd February 2023) opened by Mental Health Champion for NI, Prof. Siobhan O'Neill.

Prof Ciaran Mulholland – appointed to scientific committee of 17th biennial conference of the European Society for Traumatic Stress Studies 2023. <https://www.estss2023.com/scientific-committee/Ciaran-Mulholland>



Figure 6 NHSCT Mental Health Research Coordinator Ms Suzanne Barrett with Co-CAT Research Colleagues at the NICRN training day.

Neurodegenerative (NEU)

Clinical Leads, Active PIs and CMG Members

Neurodegenerative Group Clinical Leads	CMG Members
Bernadette McGuinness- BHSCT & QUB Peter Passmore – BHSCT & QUB	BHSCT & QUB – Bernadette McGuinness, Peter Passmore, Emma Cunningham, Joe Kane
Chief and Principal Investigators Bernadette McGuinness BHSCT & QUB Peter Passmore BHSCT & QUB Emma Cunningham BHSCT & QUB Joseph Kane BHSCT & QUB	BHSCT – Maria McGrath SEHSCT - Jim Anderson WHST – Stephen Todd QUB – Carole Parsons
	PPI Representative Gordon Kennedy

Group Background/Summary

The CMG has not met since the onset of COVID-19. There have however been discussion around the need to restart regular meetings and it is anticipated that CMG meetings should recommence in 2023-2024. There are three ongoing studies within the Neurodegenerative Group. (**HCAP** 1000 participants have been recruited and cognitively assessed, NICRN input to the PostOperative **Delirium** study has been completed with 172 telephone interviews and 139 face-to-face study visits, completed, The **TOPHAT** Trial of Ondansetron as a Parkinson's Hallucinations Treatment study has commenced recruitment)

Key Achievements

- Target achieved in largest study.
- Nurses trained in study assessments.
- Studies in Lewy Body dementia added to portfolio.
- 3 feasibility requests which have been completed and site selection details awaited.

Relevant Publications

Exposure to the troubles in Northern Ireland, memory functioning, and social activity engagement: results from NICOLA. Eur J (Ageing., ..., **McGuinness B**, et al.) . 2022 Feb 10; 19(4):1099-1109. doi: 10.1007/s10433-022-00683-5. PMID: 36506685; PMCID: PMC9729674.

Prevalence of cognitive impairment in patients with rheumatoid arthritis: a cross sectional study. (McDowell B, ...**McGuinness B** et al). BMC Psychiatry. 2022 Dec 9; 22(1):777. doi: 10.1186/s12888-022-04417-w. PMID: 36494656; PMCID: PMC9733399.

Factors influencing resilience to postoperative delirium in adults undergoing elective orthopaedic surgery. (Bowman EML, ...**McGuinness B, Passmore AP, , Cunningham EL**. et al.). Br J Surg. 2022 Sep 9; 109(10):908-911. doi: 10.1093/bjs/znac197. PubMed PMID: 35707934.

The Northern Ireland Cohort for the Longitudinal Study of Ageing (NICOLA): The Harmonised Cognitive Assessment Protocol (HCAP) Sub-Study. (Leeanne O'Hara,..., **Bernadette McGuinness**. et al) Submitted BMJ Open *BMC Public Health* **23**, 466 (2023). <https://doi.org/10.1186/s12889-023-15355-x>

Abstracts presented Alzheimer's Association International Conference San Diego, USA, July-August 2022:

Preoperative Cerebrospinal Fluid and Plasma Markers of Inflammation and Neurodegeneration Predict Mortality Eight Years Later in an Observational Cohort Study of Postoperative delirium in an Older Elective Arthroplasty Population. Sweeney, A.M., **Passmore, A. P.**, Beverland, D., **McGuinness, B.**, McAuley, D. F., Mawhinney, T., O'Brien, S., Schott, J. M., Heslegrave, A., Zetterberg, H. & **Cunningham, E. L.**

Awards/Good New Stories

Emily Bowman awarded 1st prize for her presentation to the QUB School of Medicine Postgraduate Research Forum March 2023

Emma Cunningham invited onto editorial board of new Delirium and Delirium Communications Journals 2022

Emma Cunningham published an invited editorial in the Journal Neurology, Neurosurgery and Psychiatry 2022

Emma Cunningham elected secretary of the European Delirium Association (2022) and chair of the Alzheimer's Association Perioperative Cognition and Delirium Professional Interest Area .



Figure 7 Neurodegenerative Coordinator Micahel McAlinden and NI Clinical Research Network Director, Professor Jonathan Jackson

Orthopaedics and Trauma (ORT)

Clinical Leads, Active PIs and CMG Members

Orthopaedics & Trauma Group Clinical Leads: Owen Diamond - BHSCT Richard Napier - BHSCT Chief and Principal Investigators Owen Diamond - BHSCT Richard Napier - BHSCT Samuel Sloan - BHSCT Ciara Stevenson - BHSCT Brendan Gallagher – BHSCT Paul Magill - SHSCT	CMG Members: No CMG currently in place for Trauma and Orthopaedics. PPI Representatives: Position Vacant
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Group Background/Summary

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

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

Orthopaedic Retrievals: PI Mr Napier, Opened to recruitment 01/06/2021, Recruited to date - 101

SCIENCE: PI Mr Napier, Opened to recruitment 10/09/2019, Recruited to date - 24

HUSH: PI Mr Diamond, Opened to recruitment 30/08/2022, Recruited to date - 8

BASIS: PI Mr Sloan, Opened to recruitment 06/04/2022, Recruited to date – 12

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

Meteor2: PI Ms Stevenson, Opened to recruitment 07/03/2023, Recruited to date - 0

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

Going forward, the team will be taking part in the University of Oxford led World Hip Trauma Evaluation (**WHiTE**) Study Part 10 (Lidocaine Intravenous Trial, PIs: Dr Ciara O'Donnell & Dr David Johnston) and Part 12 (Dual mobility versus standard articulation total hip replacement in the treatment of older adults with a hip fracture, PI: Mr Owen Diamond) once local approval is through. In addition the Team are currently seeking permission for **G-FORCE**: A RCT comparing gait in fixed or rotating cementless total knee arthroplasties (PI: Mr Richard Napier). This is a single centre study which is funded by DePuy Synthes and the Trauma and Orthopaedic Research Charity and will be sponsored by the BHSCT. The study has used the Primary Joint Patient Liaison Group to provide PPI. The Team will also be seeking approval for **FANTA**: Fracture ANkle Tourniquet Assessment study: a RCT also sponsored by the BHSCT. Funding for this will be applied for from the capacity fund which has specific funding for trauma research.

Key Achievements

- RBHSC received a certificate to acknowledge that they were the top recruiting site for the **SCIENCE** study in 2022.
- Leeann Bryce won best research nurse for the **SCIENCE** Study in 2022.
- £150,000 of funding DePuy Synthes awarded to the ORT Research Group for the **G-FORCE** study.

Relevant Publications

Feasibility of achieving Elective Care Framework targets for total hip arthroplasty and total knee arthroplasty in Northern Ireland. Mayne AIW, ..., **Magill P**, et al. *Open*. 2022 Apr;3(4):302-306.

A conservative approach to dislocation following total hip arthroplasty: a review of 8606 hips. Ogonda L, Cassidy RS, **Beverland DE**. *Hip Int*. 2022 May; 32(3):291-297.

The Influence of Orthopaedic Surgery on Circulating Metabolite Levels, and their Associations with the Incidence of Postoperative Delirium. Jung M, Pan X,... **Passmore AP, McGuinness B, Beverland D**, et al.. *Metabolites*. 2022 Jul 1;12(7):616

Using tranexamic acid for an additional 24 hours postoperatively in hip and knee arthroplasty saves money: a cost analysis from the TRAC-24 randomized control trial. Karayiannis PN, **Bryce L**, ..., **Beverland D**, et al. *Bone Jt Open*. 2022 Jul;3(7):536-542.

Factors influencing resilience to postoperative delirium in adults undergoing elective orthopaedic surgery. Bowman EML, ..., **McGuinness B, Passmore AP, Beverland D**, et al. *Br J Surg*. 2022 Sep 9;109(10):908-911.

Cup placement in primary total hip arthroplasty: how to get it right without navigation or robotics. Meermans G, ..., **Beverland D et al**. *EFORT Open Rev*. 2022 May 31;7(6):365-374.

Decision regret after primary hip and knee replacement surgery. Cassidy RS, ...**Beverland DE**, et al. *Orthop Sci*. 2023 Jan; 28(1):167-172.

Awards/Good New Stories

British Orthopaedic Association Annual Meeting September 2022: 'Best of the Best' presentation for 'The feasibility of achieving elective care framework targets for total hip arthroplasty and total knee arthroplasty in Northern Ireland.' AIW Mayne, RS Cassidy, **P Magill**, BJ Mockford, DA Acton, MG McAlinden.

British Hip Society Annual Scientific Meeting March 2023: Best Poster Presentation for 'A ten year review of instability characteristics in 10,525 hip arthroplasty patients in Musgrave Park Hospital, Belfast.' M Robinson, M Lynch Wong, **L Bryce**, R Cassidy, J Hill, **O Diamond**, **D Beverland**.

British Hip Society Annual Scientific Meeting March 2023: Highly commended Poster Presentation for 'Long term follow up of the Ceramic on Metal Total Hip Replacement.' G Baker, J Hill, F O'Neill, N Gallagher, J McChesney, **M Stevenson**, **D Beverland**.

Outstanding Achievement for the NI Clinical Research Network Team at the NIHR OTS Musculoskeletal Annual Trauma Meeting 2022, winning two awards. Orthopaedic clinical Research Nurse Leeann Bryce was also named "Best Research Nurse for SCIENCE Study for 2022." The Royal Belfast Hospital for Sick Children team were also awarded a certificate for 'Top Recruiter for SCIENCE in 2022'. (See Figure 12)



Figure 8 BHSCT Trauma and Orthopaedic Research Nurse Ms Leeann Bryce at the NIHR OTS Musculoskeletal annual trauma meeting

Primary Care (PCR)

Clinical Leads, Active PIs and CMG Members

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

As clinical research continues to reshape as we move out of COVID-19 the Primary Care team held its first 2022-23 CMG, attended by 6 members, in March 2023.

Primary Care adopted 2 new studies in the reporting period (**Walk with Me 2** Study recruited to date 102 and **My Diabetes & Me** recruited to date 6) and opened the new Paxlovid arm of the **PANORAMIC** trial recruited to date 12. The **TOPIC** Dental Study is in set up.

Key Achievements

The work of the trial team based at the Northern Ireland Clinical Research Network (NICRN) in Belfast was praised: “PANORAMIC has been the fastest recruiting clinical trial on record in the UK and people in Northern Ireland have responded enthusiastically to take part in this research, exceeding the numbers that would have been expected given our population size”.

Relevant Publications:

An external pilot cluster randomised controlled trial (RCT) of a theory-based intervention to improve appropriate polypharmacy in older people in primary care (PolyPrime). Pilot Feasibility Study .Rankin A, ... **Leathem C, Maxwell M**, et al. 2022 Sep 10;8(1):203. doi: 10.1186/s40814-022-01161-6. PMID: 36088445; PMCID: PMC9463515.

Molnupiravir Plus Usual Care Versus Usual Care Alone as Early Treatment for Adults with COVID-19 at Increased Risk of Adverse Outcomes (PANORAMIC): Preliminary Analysis from the United Kingdom Randomised, Controlled Open-Label, Platform Adaptive Trial. Prof Christopher C Butler, ... **Professor Nigel Hart, Dr Dan Butler** et al. *The Lancet*, volume 401, (10373), pp 281-293, January 2023.

Detail of Key Conferences:

NICRN Conference Event, Galgorm Hotel, 26 May '22. CL.

Association University Departments of General Practice Ireland (AUDGPI) Galway 03-04 March '23. NH.

Awards/Good New Stories

January 2023 NICRN PC was the 2nd highest recruiter for the Paxlovid arm of PANORAMIC Trial in the UK.



Figure 9 BHSCT Primary Care Research Team, Mr Yogesh Parajuli, Mrs Claire Leathem, Dr Laura McQuillan, Ms Maeve Nesbitt and Mr Seamus Mailey celebrating their recruitment for Panoramac

Renal (REN)

Clinical Leads, Active PIs and CMG Members

Renal Group Clinical Leads Neal Morgan -SHSCT &QUB Christopher Hill -BHSCT &QUB Chief and Principal Investigators Christopher Hill - BHSCT Stephanie Bolton -NHST Alastair Woodman – SEHSCT Neal Morgan – SHSCT Frank McCarroll - WHSCT	CMG Members BHSCT – Christopher Hill NHSCT - Stephanie Bolton SEHSCT - Alastair Woodman SHSCT - Neal Morgan WHSCT - Frank McCarroll PPI Representatives 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

CMG meetings formally restarted in 2022 following the pandemic. Two CMGs were held during reporting period (July and November).

Key Achievements

The Renal Portfolio remains broad and inclusive, recruiting patients (450 in total as at end of reporting period) with varied renal diseases and treatment modalities.

- Adoption of the **ACHIEVE** trial, looking at the impact of spironolactone in heart failure outcomes on dialysis patients and recruiting in three participating sites.
- Excellent recruitment to the **ACCESS** trial.
- Completion of **EMPA-KIDNEY** trial and commencement of post-trial observational follow-up study. **EMPA-KIDNEY** represented the highest recruitment figures ever attempted for a NI renal study involving patients across Northern Ireland with results published in the New England Journal of Medicine.
- Adoption of an investigator-led PhD research study focussed on the impact of frailty on kidney transplant outcomes (Dr Ruth Fergie).
- Adoption of QUB investigator-led study (**ACORN**) in NHSC & WHSC Trusts, exploring the caregiver experiences of conservatively managed end-stage kidney disease to inform development of a psychosocial intervention.

- Adoption of the **Prepare for Kidney Care** study in NHSCT, WHSCT & SHSCT, the first RCT in patients approaching end stage renal disease comparing preparing for responsive management vs preparing for renal dialysis.
- Adoption of the **NIGHTLife** study in SHSCT investigating the effects on quality of life of nocturnal in-centre haemodialysis compared to standard daytime dialysis care.
- Adoption of the **MOODMAPS** study in SHSCT, evaluating the identification and management of depression in people living with advance kidney disease across different UK renal services in a mixed methods study
- Ongoing recruitment to national registry studies including **UKIVAS** (vasculitis registry), and **UK Calciphylaxis Study** and **RaDaR** (rare renal diseases registry) across Northern Ireland.

Relevant Publications

Results from part A of the NeflgArd trial were published in *Kidney International* (Jonathan Barratt and NeflgArd Trial Investigators. Results from part A of the multi-center, double-blind, randomized, placebo-controlled NeflgArd trial, which evaluated targeted-release formulation of budesonide for the treatment of primary immunoglobulin A nephropathy, *Kidney Int* 2023; 103:391-402). BHSCT was a collaborator and Local Clinical Centre PI: **Professor Peter Maxwell** (BHSCT).

EMPA KIDNEY study was presented at the American Society of Nephrology meeting in November 2022 and published in the *New England Journal of Medicine* (The EMPA-KIDNEY Collaborative Group [Executive Committee: Colin Baigent (co-Chair), Martin J. Landray (co-Chair)]. Empagliflozin in patients with chronic kidney disease, *N Engl J Med* 2023;388:117-127.) NI collaborators and Local Clinical Centres PIs: **Dr Christopher Hill** (BHSCT), **Dr Stephanie Bolton** (NHSCT), **Dr Neal Morgan** (SHSCT), **Dr Alastair Woodman** (SEHSCT) and **Dr Frank McCarroll** (WHSCT).

Stop-Ace Study was presented at the American Society of Nephrology meeting in November 2022 and published in the *New England Journal of Medicine* for the STOP ACEi Trial Investigators. Renin–Angiotensin System Inhibition in Advanced Chronic Kidney Disease, (Sunil Bhandari et al.) *N Engl J Med* 2022; 387:2021-2032). NI Collaborators and Local Clinical Centres PIs: **Dr Stephanie Bolton** (NHSCT), **Dr Neal Morgan** (SHSCT) and **Dr Frank McCarroll** (WHSCT).

Awards/Good New Stories

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

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

NightLife trial

Our SHSCT trial team in the course of participating in NightLife were the first renal centre on the Island of Ireland to deliver nocturnal dialysis and set a randomisation record for the study randomising 13 participants in 1 day. (See figure 9)



Figure 10 SHSCT Renal Research Team including Ms Teresa McKinley and Dr Neal Morgan with NightLife Study Participant

Respiratory Health(RES)

Clinical Leads, Active PIs and CMG Members

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

CMG meeting held annually in January to set out priorities for the coming year, with regular representation from every Trust, as well as the NICRN coordinating centre.

Studies opened during the last year

BEAT-Severe Asthma - This is a platform trial with two parallel group, randomised double blind, placebo controlled, cohorts in participants with severe asthma. (BHSCT)

CF-STORM - A randomised open label trial to assess change in respiratory function for people with cystic fibrosis (pwCF) established on triple combination therapy (Kaftrio™) after rationalisation of nebulised mucoactive therapies. (BHSCT)

IPF COMFORT – A double-blind, randomised, placebo controlled, two period cross-over study with an open label extension to evaluate the efficacy and safety of orvepitant in chronic cough in patients with idiopathic pulmonary fibrosis. (NHSCT, WHSCT)

PROSPECT - Prospective data collection on clinical, radiological and patient reported outcomes after pleural intervention. (BHSCT)

TIPAL - The effectiveness and risks of Treating people with Idiopathic Pulmonary fibrosis with the Addition of Lansoprazole. (NHSCT)

Recruitment figures

208 patients recruited across NI to a wide range of complex, early phase interventional trials as well as observational studies; covering both adults and childrens service.

Adopted and in-setup

CLEAR – A 2x2 factorial randomised open label trial to determine the clinical and cost-effectiveness of hypertonic saline (HTS 6%) and carbocysteine for airway clearance versus usual care over 52 weeks in bronchiectasis. BHSCT and WHSCT were the principal recruiting sites with SEHSCT acting as a Participant Identification Centre (PIC) **DUPIAZA** – Real-world experience of dupilumab for the treatment of severe asthma in the United Kingdom.

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

IPF COMFORT – A double-blind, randomised, placebo controlled, two period cross-over study with an open label extension to evaluate the efficacy and safety of orvepitant in chronic cough in patients with idiopathic pulmonary fibrosis. (SEHSCT (PIC Site))

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

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

Key Achievements

- Belfast City Hospital (BCH) is the top recruiting site for the **CLEAR** study, contributing just over 30% of all participants recruited to date, and just over 20% of the overall recruitment target.
- BHSCT is lead site (Professor Lorcan McGarvey, CI) for major multi-centre (Europe-wide) study **NEUROCOUGH** - New understanding of the treatment of cough; European Chronic Cough Registry and Bio-Resource Protocol.
- BHSCT is the top recruiting site for the **NEUROCOUGH** study, contributing almost 40% of all participants recruited to date; and just over 15% of the overall recruitment target so far.
- Successful recruitment of Band 5 Senior Administrator for Cluster 3.
- Successful recruitment of Band 4 Research Administrator for BHSCT Respiratory Research.

Relevant Publications. Airway clearance treatments in bronchiectasis: Feasibility of linking survey results to Registry data and a survey of patients' and

physiotherapists' practices. (McLeese, R. H ... **Bradley, J.M** et al), 01 Mar 2023, In: ERJ Open Research. 9, 2, 12 p., 00540-2022. (BRONCH-UK/EMBARC)

Safety and efficacy of the NVX-CoV2373 COVID-19 vaccine at completion of the placebo-controlled phase of a randomized controlled trial. Heath, P. T,....., **Bradley, J. M.**, et al) , 01 Feb 2023, In: Clinical Infectious Diseases. 76, 3, p. 398–407. (NOVAVAX)

Prevalence of physical frailty, including risk factors, up to 1 year after hospitalisation for COVID-19 in the UK: a multicentre, longitudinal cohort study. (McAuley, H. J,...., **McGarvey, L.P.**, et al), 11 Mar 2023, In: eClinicalMedicine. 57, 101896. (P-HOSP)

SARS-CoV-2-specific nasal IgA wanes 9 months after hospitalisation with COVID-19 and is not induced by subsequent vaccination. (Liew, F,....., **McGarvey, L.P.**, et al), 16 Jan 2023, In: EBioMedicine. 87, 104402. (P-HOSP)

Clinical characteristics with inflammation profiling of long COVID and association with 1-year recovery following hospitalisation in the UK: a prospective observational study. The PHOSP-COVID Collaborative Group,(Evans, R. A., ..., **Heaney, L. G.**, et al) 01 Aug 2022, In: The Lancet Respiratory Medicine. 10, 8, p. 761-775 15 p. (P-HOSP)

Early-phase clinical trials in a pandemic: learning from the response to COVID-19. NIHR Respiratory Translational Research Collaboration network,(**McGarvey, L.P.**, **Heaney, L.G.**, et al), Jul 2022, In: The Lancet. Respiratory medicine. 10, 7, p. 625-627. (RECOVERY)

Future therapies for cystic fibrosis. (Allen, L., ...**Downey, D.** et al)., 08 Feb 2023, In: Nature Communications. 14, 693. (ECFS Studies)

Characteristics and risk factors for post-COVID-19 breathlessness after hospitalisation for COVID-19. (Daines, L., ...,**Heaney, L. G.**, et al), 20 Feb 2023, In: ERJ Open Research. 9, 1, 15 p., 00274-2022. (P-HOSP)

Determinants of recovery from post-COVID-19 dyspnoea: analysis of UK prospective cohorts of hospitalised COVID-19 patients and community-based controls. (Zheng, B., ..., **Heaney, L. G.**, et al), 28 Apr 2023, (Early online date) In: The Lancet regional health. Europe. 100635. (P-HOSP)

SARS-CoV-2-specific nasal IgA wanes 9 months after hospitalisation with COVID-19 and is not induced by subsequent vaccination. (Liew, F.,, **Heaney, L. G.**, et al) 16 Jan 2023, In: EBioMedicine. 87, 104402. (P-HOSP)

Corticosteroid responsiveness following mepolizumab in severe eosinophilic asthma - a randomised, placebo-controlled crossover trial (MAPLE). (Yang, F,...., **Heaney, L. G, et al**)., 18 Jul 2022, (Early online date) In: The Journal of Allergy and Clinical Immunology: In Practice. (MAPLE)

Prevalence, risk factors and treatments for post-COVID-19 breathlessness: a systematic review and meta-analysis. (Zheng, B., ...**Heaney, L. G, et al).**., 31 Dec 2022, In: European Respiratory Review. 31, 166, 220071. (COVID Studies – analysis of 102 eligible papers)

Awards/Good News Stories

BHSCT Recognition Award for our Clinical Research Network Senior Administrator Chris Wright.

BHSCT Recognition Award for Bernadette King for her outstanding work on the **PHosp** trial, making BHSCT one of the top 5 recruiting sites in the UK. (See Figure 10)

BHSCT Respiratory Coordinator Roisin Stone has presented to a group of Specialist Nurse Students at a seminar held in QUB on Clinical Trials. Covering subjects such as Feasibility, Research Capacity & Capability (C&C), contributing to the future of Clinical Trials and the various phases of Clinical Trial emphasising the role that the NICRN performs in the delivery of all clinical trials.

BHSCT Respiratory Research has been working with VERTEX Pharmaceutical Cystic Fibrosis Transmembrane Regulator Modulator Programme, which is now the approved treatment in normal clinical practice for Cystic Fibrosis. This triple-therapy drug known as Kaftrio has massively improved the quality and longevity of the lives of those patients living with Cystic Fibrosis.

Craigavon Area Hospital in top 10 recruiters UK wide for the **HEAL-COVID** trial. NI contributed 4.4% of total recruitment, despite making up only 2.8% of the total patient population.



Figure 11 NI Clinical Research Network Director with BHSCT Respiratory Research Team, Mrs Bernie king, Ms Esther Ramsey and Dr Nick Magee

Stroke (STR)

Clinical Leads, Active PIs and CMG Members

Stroke Group Clinical Leads Patricia Fearon - BHSCT Carolee McLaughlin - BHSCT Principal Investigators Patricia Fearon - 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	CMG Members: BHSCT – Patricia Fearon, Carolee McLaughlin NHSCT – Djamil Vahidassr, Murudappa Bhattad SEHSCT – Mark Bowman SHSCT – Michael McCormick WHSCT - Roisin Healy, Breffni Keegan Northern Ireland Stroke Improvement Network - Fiona Quigg PPI Representatives Position Vacant (PPI engagement is currently under review)
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Group Background/Summary

As we emerged from the pandemic the Stroke CMG and research nursing staff returned from roles in COVID trials the Stroke CMG began to expand the portfolio and increase recruitment to stroke clinical trials. Our group held 4 CMG meetings, with excellent attendance and engagement by representatives across the five trusts. There are 12 open studies on the portfolio, 10 randomised and 2 non-randomised. The majority of studies focus on interventions for acute stroke with a smaller number of studies focussed on stroke rehabilitation. All studies are non-commercial in keeping with the vast majority of current stroke studies on the NIHR portfolio.

Given the hyperacute focus of the current portfolio, the majority of patients have been recruited at the regional thrombectomy centre in the Royal Victoria Hospital (RVH), Belfast. However, patients have also been recruited in the Southern, Northern and Western Health and Social Care Trust (WHSCT). The SEHSCT has recently welcomed a new PI and hopes to open recruitment to stroke trials again soon.

Two new studies were adopted to the NICRN stroke portfolio during the 2022/23 academic year. The **MAPS-2** Trial, an RCT to compare regular metoclopramide versus placebo for patients with significant stroke and dysphagia, was successfully opened in Belfast. In addition the **TICH-3** trial, an RCT to compare immediate administration of tranexamic acid versus

placebo for patients with acute intracerebral haemorrhage, opened across four trusts (Belfast, Northern, Southern and Western).

Key Achievements

- Belfast continues to be one of very few sites within the UK capable of delivering endovascular stroke research. We were delighted to open the **ESCAPE-MeVO** trial in 2022. This important trial will expand the existing evidence base for large vessel occlusion ischaemic stroke by comparing thrombectomy for patients with medium vessel occlusion ischaemic stroke to current standard care. As with all thrombectomy studies to date, **ESCAPE-MeVO** has both an interventional neuroradiologist (Dr P Burns) and Stroke Physician (Dr E Kerr) as co-PIs. This is the fourth thrombectomy RCT to open in Belfast.
- We are very proud of our 4 junior colleagues, and stroke PIs of the future, who have taken the first step in their research career by joining the NIHR Associate PI Scheme. In particular, Dr Mark Hawthorne, supervised by Dr Michael McCormick in the Southern Health and Social Care Trust (SHSCT), was the first Associate PI appointed in the UK for the **TICH-3** study.
- The WHSCT were successful in being chosen as a site for the **ENRICH-AF** trial, based on their previous performance in recruiting to the **SoSTART** trial. This is a great achievement and testament to the hard work and dedication of our stroke colleagues in the WHSCT. Both trials examine the safety and efficacy of anticoagulant therapies for patients with prior intracranial haemorrhage.
- Both the **MAPS-2** and **TICH 3** trials are co-ordinated via Nottingham Stroke Trials Unit (NSTU) and in March 2023 the Acute Stroke Unit in Belfast was congratulated as the highest recruiting site for the NSTU nationally.

Relevant Publications

Xanthine oxidase inhibition and white matter hyperintensity progression following ischaemic stroke and transient ischaemic attack (XILO-FIST): a multicentre, double-blinded, randomised, placebo-controlled trial. (Dawson J,... [Keegan, B](#), et al). *EClinicalMedicine*. 2023 Feb 16;57:101863. doi: 10.1016/j.eclinm.2023.101863. PMID: 36864979; PMCID: PMC9972492.

SWIFT DIRECT: Solitaire™ With the Intention For Thrombectomy Plus Intravenous t-PA Versus DIRECT Solitaire™ Stent-retriever Thrombectomy in Acute Anterior Circulation Stroke: Methodology of a randomized, controlled, multicentre study. (Fischer U, ... [Dr P Fearon. et al](#)); *Int J Stroke*. 2022 Jul;17(6):698-705. doi: 10.1177/17474930211048768. Epub 2021 Oct 14. PMID: 34569878.

Awards/Good New Stories

We would like to pay tribute to Dr Djamil Vahidassr, a PI for stroke trials within the NHSCT for many years and an active member of our CMG. Djamil is stepping back from his role in research and we would like to thank him for his dedication to, and support for, the delivery of stroke research in Northern Ireland and wish him well in all his future endeavours! We would also like to formally welcome Dr Murudappa Bhattad to our CMG.



Figure 12 SHSCT Stroke Research Team, Ms Denise McFarland, Dr Michael McCormick, Ms Fiona Thompson and Ms Denise Cosgrove celebrating Red for Research Day.

Vision (VIS)

Clinical Leads, Active PIs and CMG Members

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

COVID-19 has had a very significant impact on the time available to coordinate NICRN activity with the result that CMG meetings have been reduced over the last 2 years. The last formal CMG meeting was in December 2022 (8/13 CI/PI's were in attendance). The next CMG is scheduled for the summer of 2023. The Vision CIs/PIs have however continued to meet regularly with the Vision clinical research team and when necessary CI's and PI's meet informally to discuss ongoing trials, challenges and direction.

Prior to the onset of COVID-19 the Vision Team had 2 full time clinical research nurses who were responsible for co-ordinating studies and activities. Since then, and due to a combination of factors, nursing research support had dropped, at its lowest point, to with less than 1 session of research nurse support per week. Clinical leads have come to rely heavily on

our existing team members who have adapted their core roles, taking on a range of responsibilities that would not normally have fallen within their job plans. PIs and CIs have been very appreciative of this and the opportunities that this has created for personal development has enabled the Clinical Leads to reformat the team creating a more flexible workforce for the future with added resilience.

During the course of 2022-23 we are delighted to report the expansion of our PI group. One of our heavily active research investigators has now indicated a desire to assume a principal investigator role, and we are actively supporting her in finding studies with expressions of interest.

Of the 20 studies on the Vision portfolio during 2022-23, the group actively worked on 15 studies and closed out the year with 1 study still in setup and 4 studies abandoned due to COVID-19. The group adopted 4 new Vision studies (**ACE**, **CHIP**, **REVAMP** and **GALTOS**) and agreed to support a new cancer trial (**Determine**). In this reporting period, recruitment closed for 2 studies: **CANBERRA**, (recruiting 60% to target it proved difficult to recruit and required large numbers of pre-screenings 779). **MDY** (Methodology) Dry Eye Study recruited 100% of target and will remain in follow up for 5 years.

It would be remiss not to note the group's endeavour to work collaboratively with colleagues in University Ulster(UU, Coleraine) to expand the coverage of Vision research across NI. Prior to the COVID-19 outbreak, we had agreed to provide assistance with adoptable UU trials, with the caveat that capacity was available. Unfortunately, we were unable to assist in this endeavour through out COVID-19. However, this year we are delighted to report that through the established links we currently have 2 UU trials (**CHIP** and **REVAMP**) recruiting steadily in our portfolio with our support.

Key Achievements

TIGER STUDY: The BHSCT site has been the top recruiter for several months and has featured on the TIGER STUDY newsletters.

On the 17 August 2022 Mr Ian Nickson advised that the NIHR Impact team is producing a Case Study Infographic for the NIHR website on Diabetic retinopathy in the following areas:

- a) Improving treatments
- b) Diagnostic and screening.

We were able to contribute from investigator-led studies by CI Professor Noemi Lois (**DIAMONDS** and **EMERALD** supported by NICRN) that the results from **EMERALD** will produce cost saving for the NHS (a new pathway involving graders, rather than ophthalmologists to review people with treated and stable diabetic macular oedema and proliferative diabetic retinopathy). In addition, **DIAMONDS** reports on a new treatment: subthreshold micropulse laser (SML) for DMO with < 400 microns in central retinal thickness. The recommendations may also result in savings if SML is used instead of anti-VEGFs to treat people with DMO with < 400 microns in central retinal thickness.

In 2022 the All Ireland Retinal Degenerations Partnership (**AIRD**) study closed to recruitment. The study was investigator led by Professor Julie Silvestri and funded by the MRCG-HRB. The aim of the study was to work across the Island of Ireland in collaboration

with Co-investigators in the Dublin Mater and Eye & Ear Hospitals and with Trinity College Dublin to identify and genotype individuals with Inherited retinal degenerations which a view to providing patients with the information to allow inclusion into future gene-therapy trials. The Trial recruitment was 200.5%

Relevant Publications

Standard threshold laser versus subthreshold micro pulse laser for adults with diabetic macular oedema: the DIAMONDS non-inferiority RCT. (Lois N, ... , Azuara-Blanco A, et al). Health Technol Assess. 2022 Dec; 26(50):1-86. doi: 10.3310/SZKI2484. PMID: 36541393

Diabetic Macular Edema and Diode Subthreshold Micropulse Laser: A Randomized Double-Masked No inferiority Clinical Trial. (Lois N, ... Azuara-Blanco A, et al). Ophthalmology. 2023 Jan; 130(1):14-27. doi: 10.1016/j.ophtha.2022.08.012. Epub 2022 Aug 13. PMID: 35973593

Patient's views on a new surveillance pathway involving allied non-medical staff for people with treated diabetic macular oedema and proliferative diabetic retinopathy. (Prior L, Lois N, et al). Eye (Lond). 2023 Apr; 37(6):1155-1159. doi: 10.1038/s41433-022-02050-1. Epub 2022 May 6. PMID: 35523861

Clinical and Genetic Re-Evaluation of Inherited Retinal Degeneration Pedigrees following Initial Negative Findings on Panel-Based Next Generation Sequencing. Stephenson KAJ, Silvestri J, et al Int J Mol Sci. 2022 Jan 17; 23(2):995. doi: 10.3390/ijms23020995. PMID: 35055178

Worthy of note is the fact that in the period 2019-2021, 4 key publications reporting results from the EMERALD & DIAMOND studies, and listing CSG PI/CIs, have been published in key clinical journals.

Awards/Good New Stories

The T5000 pathway paper published in 2021 was awarded 1st place at for the 2022 RAMI (Royal Academy of Medicine in Ireland) awards in the category of the best scientific paper in Ophthalmology for 2021. This was a great accolade for our All-Ireland Translational Research for patients with Inherited Retinal Degenerations

Optometrists Dr Emma McConnell and Dr Lesley Doyle created content, and Dr Emma McConnell presented an overview on Myopia Management in the 21st Century, to the Departmental Clinical Audit Meeting in February 2022.

Optometrist Dr Shelley Black presented NICRN at the Macular Society at their Macular region training day on the November 2022.

All three Optometrists have also featured in Acuity Magazine.

As part of SAS week in December 2022, the RCO interviewed Dr Karen Gillvray about SAS doctors in Research. Click here for the vlog: <https://www.rcophth.ac.uk/our-work/ophthalmology-careers/resources-for-sas-doctors/>. Dr Gillvray has also had an article

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



Figure 13 BHSCT Vision Research Team Optometrists Dr Lesley Doyle and Dr Emma McConnell presenting on Vision Research at the NI Clinical Research network Staff Conference

COVID Delivery Team (CDT)

Clinical Leads, Active PIs and CMG Members

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

Since the beginning of the pandemic, all Northern Ireland HSC Trusts were engaged in the delivery of nationally prioritised UPH COVID-19 studies. More than a dozen UPH COVID-19 studies supported by the Northern Ireland Clinical Research Network (NICRN) had opened, recruiting more than 3500 participants.

The great majority of the UPH COVID-19 study burden fell on respiratory and critical care specialty groups in Cluster 3 of the NICRN, but support has also been provided from clinical research nurse teams in other NICRN CSGs. In particular, the Novavax COVID-19 vaccine study delivered in the Northern Ireland Clinical Research Facility (NICRF) in Belfast was very resource intensive and required support from the Northern Ireland Clinical Trials Unit, NICRN staff from across CSGs (including cancer) and from HSC Trusts outside Belfast who travelled to the NICRF.

As the COVID-19 pandemic receded and routine clinical services resumed, NICRN wanted to restart its non-COVID-19 clinical research. This included not only studies that were on the portfolio in 2020 but also new studies as there were pressures nationally to return to business as normal. However, we recognise that there will be an ongoing need for support for many COVID-19 studies going forward and this needed balanced against our need to resume our other high-quality studies

As a first step in clinical research recovery, resilience and regrowth in Northern Ireland, we needed to try to ensure that the infrastructure resources for non-COVID research were available for those specialities. In keeping with the emerging recommendations and actions for the implementation plan for Northern Ireland clinical research recovery, resilience and growth (NICRRRG), and as agreed by the associated Taskforce, the NICRN suggested the appointment of additional NICRN staff that would allow the restart of non-COVID-19 clinical research portfolio by providing dedicated support for COVID-19 studies.

It was therefore proposed (in May 2021) to establish a separate COVID-19 study delivery team (CDT) which would sit within and be coordinated by the wider umbrella of NICRN to ensure equitable distribution of staffing resources throughout all specialty interest.

We recognised the need for the CDT to be agile and flexible in the face of fluctuations in the demand for work on COVID-19 clinical research studies. During periods of reduced activity, the team would act in a peripatetic manner to support the delivery of non-UPH studies under pressure, cover staff absences and undertake specialist training to bolster their skill set. If there was a substantial reduction in COVID-19 clinical research and this new team becomes no longer needed, a reconfiguration of their roles will be agreed between the NICRN and the Management Board for the NICRRRG fund in order to maximise the contribution to recovery, resilience and growth.

Our experience

In November 2021 the management board for the NICRRRG fund approved the proposal for the CDT and agreed, to provide the funding for 9.5 Band 6 posts and a 0.5 Band 4 admin support post to support the following: five Band 6 CRN posts, 0.5 WTE Band 6 Clinical trials pharmacist post and 0.5 WTE Band 4 admin support post in BHSCT and one Band 6 CRN posts in each of the other four HSC Trusts.

However, the time taken to agree funding and the even lengthier delay in recruitment and selection meant that the posts were not all filled until May 2023 by which point the immediate urgency in maintaining the COVID-19 portfolio was waning with falling COVID-19 cases nationally. The CDT were redirected to support the remaining COVID-19 studies and to support the specialities where indicated. This meant the CDT essentially were absorbed into the respiratory and critical care teams which were the most impacted.

Figure 14: Recruitment in each reporting year broken down by CSG and compared over the past five years.

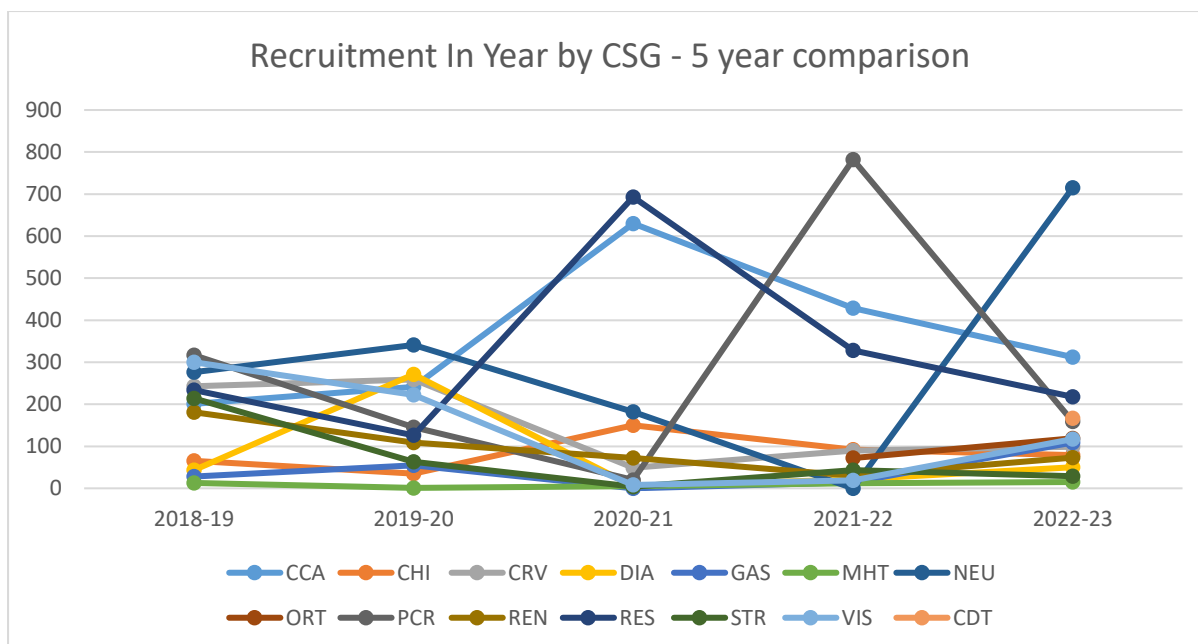


Figure 14 highlights recruitment over the last five years by specialty. Comparison of the 2018-19 data with that for 2019-20 (Pre COVID-19 Pandemic) suggests stability across almost all specialities. However, from the first quarter 2020 there was heightened activity, specifically in our respiratory and critical care groups due to UPH COVID-19 studies. In relation to the annual figures, that activity clearly peaked in 2020-21. With the adoption and support of the community based PANORAMIC platform and its initial Molnipavir arm, our primary care group showed a peak in activity in 2021/22. General activity in the other specialities was much reduced through the years of the pandemic. The peak in recruitment for our Neurodegenerative group in 2022/23 is due to a single high performing study using existing data sets of participants from other large studies such as NICOLA.

Figure 15: Total Number of Active Studies in each reporting year broken down by CSG and compared over the past five years.

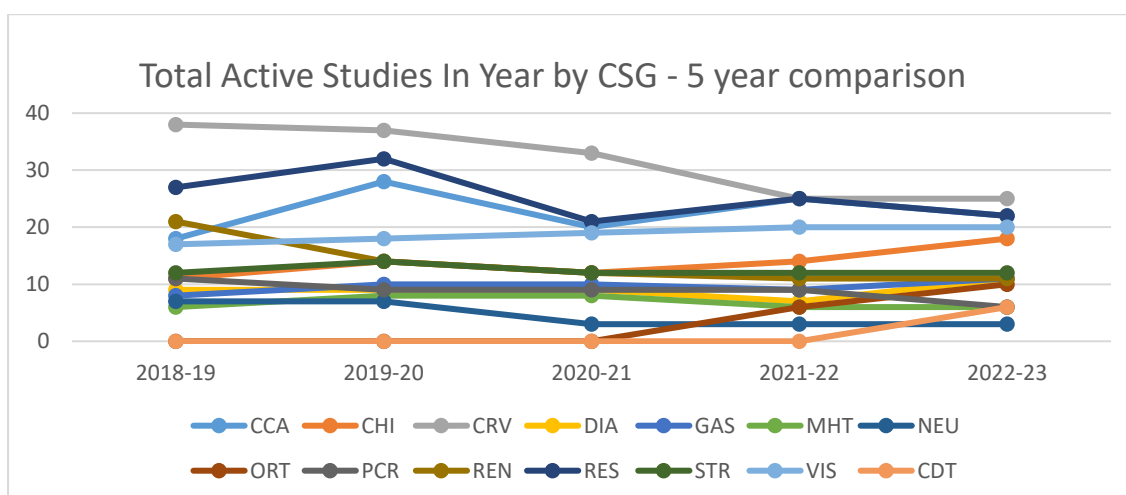
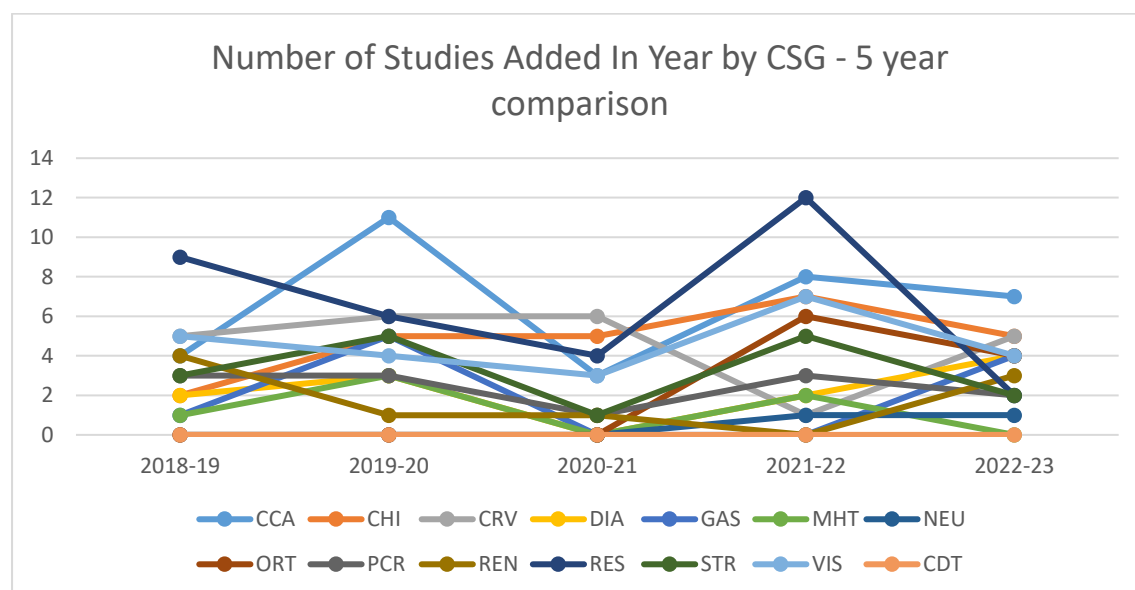


Figure 15 illustrates the impact COVID-19 has had on the number of active studies that NICRN was able to support during the first phase of service downturn in 2019-20. As services commenced recovery the numbers of supported studies increased slightly in 2021-22 and most recent data highlights the fact that this trend continues.

Figure 16 : Number of Studies Added in each reporting year broken down by CSG and compared over the past five years.



As can be seen in Figure 16, the CDT portfolio has not increased because the incidence of COVID-19 was much reduced, and we didn't bring on any new COVID-19 studies. However, the CDT played an important role in maintaining this section of the portfolio because they picked up the follow-up activity related to existing COVID-19 studies on the portfolio.

Figures 14-16 highlights the reactivity and agility of the NICRN team in service delivery despite the challenges imposed on the health care system within which we operate.

NICTN: CANCER

Clinical Leads, Active PIs and CMG Members

Leads & Active PIs

NICTN Clinical Director: Stuart McIntosh

NICTN Operational Director: Melanie Morris

NICTN Executive Committee:

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

BELFAST EXPERIMENTAL CANCER CENTER STEERING GROUP

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

NI Cancer Research Consumer Forum supports NICTN and Belfast ECMC and provides PPI input at numerous levels, including review of all new studies being considered for adoption. There are currently 34 Northern Ireland Cancer Research Consumer Forum (NICRCF) members.

Active PIs in 2022-23 (PIs with studies actively recruiting or in follow up in year). Due to the high number of oncology PIs they can be accessed in the embedded pdf below.



Group Background/Summary

During the past year, 32 new cancer trials were considered for adoption following review by the multi-professional NI Cancer Clinical Trials Coordinating Committee. Twenty nine studies subsequently commenced set-up. The adopted trials spanned a number of different disease sites, with a quarter of new studies (n: 8) being brought forward by our Breast Cancer Clinical Study Group. Other areas, such as Early Phase, Lung, Urology and Skin were also well represented, with each group proposing between 3-5 new clinical trials. Twenty-four of the trials adopted were interventional in nature, with fourteen being commercially sponsored.

In 2022-23, the NICTN offered a portfolio of 88 cancer clinical trials and research studies to both adult and paediatric cancer patients. 302 participants were recruited to the regional trials portfolio. 69% of trials (n: 61) were interventional in design and accounted for 44% of overall recruitment (133 participants). Although the overall NICTN portfolio continues to be predominated by non-commercial studies, this year saw an encouraging increase in regional commercial trial activity with 19% of trials (n: 17) being sponsored by industry partners.

Key Achievements

Related to NICTN adopted studies

- The **SPORT** High-Risk Trial (A Randomised Feasibility Study Evaluating Stereotactic Prostate RadioTherapy in High-Risk Localised Prostate Cancer with or without Elective Nodal Irradiation) completed recruitment on target in December 2022. This Belfast Trust sponsored, single centre study informed the design of the UK multi-centre **PACE-NODES** study (A phase III randomised trial of 5 fraction prostate SBRT versus 5 fraction prostate and pelvic nodal SBRT), sponsored by the Institute of Cancer Research. Professor Suneil Jain (QUB), CI for the **SPORT** study, is co-clinical Lead for **PACE-NODES**, Conor McGarry (BHSCT) is Study Medical Physicist and NI Cancer Research Consumer Forum member, Ken McBride, is PPI Rep for the trial Steering Group.
- First patient in Northern Ireland was treated with Lu-177-PSMA in NI on 21 March 2023. This treatment was only made available through the **PSMAddition** study being conducted in the NICC (PI: Prof O'Sullivan).
- The UK **CONCORDE** trial, a platform study of DNA damage response inhibitors in combination with conventional radiotherapy in non-small cell lung cancer, opened in Belfast in November 2022
 - UK study leadership includes Belfast's Prof Gerry Hanna and Dr Gerard Walls.

Funding successes:

- Belfast Experimental Cancer Medicine Centre (ECMC) quinquennial review/application was successful, securing ~£1.7 million over 5 years commencing April 2023. This award was announced in January 2023 across media, including BBC NI Radio and TV news. Our Belfast ECMC PPI representative Tim Kerr played a role in both the bid and interview process and subsequent media.
- Trials Acceleration Programme (TAP) Centre status was retained after NICTN successfully secured continued funding from CureLeukaemia for a further 3 years for a Band 6 Clinical Research commencing Apr 2023.
- BHSCT Charitable Funding was secured to support two Band 6 Clinical Research Nurses and two Band 4 Data Managers for 3 years.
- Funding for a Prostate Cancer Centre of Excellence, announced in October 2022, is enabling funding for an additional Clinical Research Nurse in prostate cancer research.

Raising the profile of cancer research:

- An NICTN/Belfast ECMC/NI Cancer Research Consumer Forum Twitter account @nicancertrials was launched in September 2022, supporting objectives to expand awareness of cancer trials in NI.
- Dr Melanie Morris presented at the CRUK Round Table Event in the Long Gallery, Stormont, involving MLAs, researchers, clinicians, industry, charities, Public Health Agency (PHA) and DOH and patient representatives in a consultation about cancer research, 07 February 2023.
- Prof Mary Frances McMullin and Laura Croan spoke at the LLNI Patient Forum, 18th February 22 to raise awareness of how LLNI funding is used to support haematology research
- UK Oncology Nursing Society Annual Conference – Belfast 11/12 Nov
- Internal team and clinician consultation, alongside liaison with senior research nurses at CRFs in England and Scotland, helped to inform NICTN's on-going engagement in the development of iREACH Health, including PPI and public engagement.
- Activities to increase clinical trials awareness continued throughout the year e.g. to the regional group of Teenage and Youth Adults Clinical Nurse Specialists January 2023.
- Ruth Boyd linking with working groups as part of NI Practice and Education Council for Nursing and Midwifery cancer nursing careers project - to represent cancer research nursing
- CRUK Senior Research Nurse Ruth Boyd co-facilitated a parallel session at the CRUK UK meeting for Cancer Research Nurses 07 February 2023

PPI Activity

- CRUK Senior Research Nurse Ruth Boyd and NICTN collaborated on the Health and Social Care Research and Development (HSC R&D) PPI Training course Building Research Partnership – video recorded material were developed this year as an adjunct to TEAMS facilitated sessions held October 2022 and February 2023.
- NICTN re-started face-to-face engagement with the public at the Open Day event for the Patrick G Johnston Centre for Cancer Research Feb 18, 2023, which is part of the NI Science Festival.
- Forum Members and Ruth Boyd facilitated a PPI Workshop with EU students as part of the Targeted Anti-cancer Therapies (TACT) Consortium, during their training visit to PGJCCR, QUB in March 2023. After an interval of 2 years of TEAMS meetings, the NICRCF met face-to-face in the Cancer Centre 30 March 2023
- Speaking role and information stand for NICRCF Chair and Forum member at Irish Association of Cancer Research (IACR) conference in Athlone February 2023. These PPI representatives made a significant impression at the Junior Council (early career researchers) and the main conference. New enduring links made with researchers in UU re PPI.
- NICRCF Chair, Aidan McCormick, spoke at the Joint Committee on Good Friday Agreement Implementation meeting in Leinster House, Dublin

Relevant Publications

Due to the large, diverse nature of this specialty and that they are publishing widely throughout the year, we have included their submitted publications as a hyperlink. Please follow for the complete listing as submitted.

A randomized, Phase 3, Trial of Interferon- γ versus hydroxyurea in polycythemia vera and essential thrombocythaemia. (Mascarenhas J, Kosiorek HE, Prchal JT, Rambaldi A, Berenzon D, Yacoub A, Harrison CN, **McMullin MF**, Vannucchi AM, Ewing J, O'Connell CL, Kiladjian JJ, Mead AJ, Winton EF, Leibowitz DS, De Stefano V, Arcasoy MD, Kessler CM, Catchatourian R, Rondelli D, Silver RT, Bacigalupo A, Nagler A, Kremyanskaya M, Levine MF, Arango Ossa JE, McGovern EM, Sandy L, Salama ME, Najfeld V, Tripodi J, Farnoud N, Penson AV, Weinberg RS, Price L, Goldberg JD, Marchioli R, Tognoni G, Rampal RK, Mesa RA, Dueck AC, Hoffman R, Barbui T.) Blood (2022) 139 (19):2931-2941. PMID: 35007321

Addition of four doses of rituximab to standard induction chemotherapy in adult patients with precursor B-cell acute lymphoblastic leukaemia (UKALL 14): a phase 3, RCT. (Marks DI, Kirkwood AA, Rowntree CJ, Agular M, Bailey KE, Beaton B, Cahalin P, Castleton AZ, Clifton-Hadley L, Copland M, Goldstone AH, Kelly R, Lawrie E, Lee S, McMillan AK, **McMullin MF**,

Menne TF, Mitchell RJ, Moorman AV, Patel B, Patrick P, Taussig D, Yallop D, Alapi KZ, Fielding AK.) Lancet Haematology (2022) Apr 9 e262-e275. PMID: 35358441.

Imaging Modality and Frequency in Surveillance of Stage I Seminoma Testicular Cancer: Results From a Randomized, Phase III, Noninferiority Trial (TRISST) .Mussai F, De Santo C, Cheng P, Thomas IF, Ariti C, Upton L, Stavrou V, Sydenham M, Burnett AK, Knapper SK, Metha P, **McMullin MF**, Copland M, Russell NH, Dennis M.

A randomised evaluation of low dose Ara-C plus pegylated recombinant BCT-100 versus low dose Ara-C in older unfit patients with acute myeloid leukaemia: Results for the LI-1 trial.(Francis Mussai¹, Carmela De Santo¹, Paul Cheng², Ian F Thomas³, Cono Ariti³, Laura Upton³, Ugo Scarpa¹, Victoria Stavrou¹, Mia Sydenham³, Alan K Burnett⁴, Steven K Knapper³, Priyanka Mehta⁵, Mary F McMullin⁶, Mhairi Copland³, Nigel H Russell⁷, Mike Dennis⁸) British Journal for Haematology (2023) 200(5)573-578 PMID: 36413792

Risk-adjusted safety analysis of the oral JAK2/IRAK1 inhibitor pacritinib in patients with myelofibrosis. Pemmaraju N, Harrison C, Gupta V, Verstovsek S, Scott B, Oh ST, Palandri F, Al-Ali HK, Sobas M, **McMullin MF**, Mesa R, Buckley S, Roman-Torres K, Vannucchi A, Yacoub A. EJHaem (2022)3(4)1346-1351. PMID:36467816.

A phase IV study evaluating QT interval, pharmacokinetics and safety following fractionated dosing of gemtuzumab ozogamicin in patients with relapsed/refractory CD33-positive acute myeloid leukemia.(Montesinos P, Kota V, Brandwein, J, Bousset P, Benner RJ, Vandendries E, Chen Y, **McMullin MF**). Cancer Chemotherapy Pharmacology (2023) 1-6 PMID: 36892676

Symptomatic benefit of momelotinib in patients with myelofibrosis: Results for the SIMPLIFY phase III studies. (Mesa RA, Hudgens S, Floden L, Harrison CN, Palmer J, Gupta V, McLornan DP, **McMullin MF**, Kiladjian JJ, Foltz L, Platzbecker U, Fox ML, Mead AJ, Ross DM, Oh ST, Perkins A, Leahy MF, Deheshi S, Donahue R, Klencke BJ, Verstovsek S). Cancer Medicine (2023) online ahead PMID: 37021939

Ruxolitinib versus best available therapy for Polycythemia vera intolerant of or resistant to hydroxycarbamide in a randomised trial. (Harrison, CN, Nangalia J, Boucher R, Jackson A, Yap C, O'Sullivan J, Fox S, Ailts I, Dueck AC, Geyer HL, Mesa RA, Dunn WG, Nadezhdin E, Curto-Garcia N, Green A, Wilkins B, Coppell J, Laurie J, Garg M, Ewing J, Knapper S, Crowe J, Chen F, Koutsavlis I, Godfrey A, Arami S, Drummond M, Byrne J, Clark F, Mead-Harvey C, Baxter EJ, **McMullin MF**, Mead AJ.) Journal of Clinical Oncology (2023) PMID37126762

A first-in-human Phase I dose-escalation trial of the novel therapeutic peptide, ALM201, demonstrates a favourable safety profile in unselected patients with ovarian cancer and other advanced solid tumours (El Helali A, Plummer R, Jayson GC, **Coyle VM**, Drew Y, Mescallado N, Harris N, Clamp AR, McCann J, Swaisland H, **Kennedy RD**, Cranston AN, **Wilson RH**). Br J

Cancer. 2022 Jul;127(1):92-101. doi: 10.1038/s41416-022-01780-z. Epub 2022 May 14. PMID: 35568736; PMCID: PMC9276671.

Imaging Modality and Frequency in Surveillance of Stage I Seminoma Testicular Cancer: Results From a Randomized, Phase III, Noninferiority Trial (TRISST)

(Joffe JK, Cafferty FH, Murphy L, Rustin GJS, Sohaib SA, Gabe R, Stenning SP, James E, Noor D, Wade S, Schiavone F, Swift S, Dunwoodie E, Hall M, Sharma A, Braybrooke J, Shamash J, Logue J, Taylor HH, Hennig I, White J, Rudman S, Worlding J, Bloomfield D, Faust G, Glen H, Jones R, Seckl M, MacDonald G, Sreenivasan T, Kumar S, Protheroe A, Venkitaraman R, Mazhar D, **Coyle V**, Highley M, Geldart T, Laing R, Kaplan RS, Huddart RA; TRISST Trial Management Group and Investigators.) J Clin Oncol. 2022 Aug 1;40(22):2468-2478. doi: 10.1200/JCO.21.01199. Epub 2022 Mar 17. PMID: 35298280; PMCID: PMC7614664.

A randomised feasibility trial of stereotactic prostate radiotherapy with or without elective nodal irradiation in high-risk localised prostate cancer (SPORT Trial) Houlihan, O. A., Redmond, K., **Fairmichael, C.**, Lyons, C. A., McGarry, C. K., Mitchell, D., Cole, A., O'Connor, J., McMahon, S., Irvine, D., Hyland, W., Hanna, M., Prise, K. M., **Hounsell, A. R., O'Sullivan, J. M. & Jain, S.**, 08 Mar 2023, (Early online date) In: International Journal of Radiation Oncology Biology Physics.

Delphi study to identify consensus on patient selection for hydrogel rectal spacer use during radiation therapy for prostate cancer in the UK Payne, H. A., **Jain, S.**, Peedell, C., Edwards, A., Thomas, J. A., Das, P., Hansson Hedblom, A., Woodward, E., Saunders, R. & Bahl, A., 20 Jul 2022, In: BMJ Open. 12, 7, e060506.

Exercise for metastatic castrate-resistant prostate cancer: A feasibility trial in progress during the COVID-19 pandemic (EXACT). Brown, M., **O'Sullivan, J., Jain, S.**, Murphy, M., McAneney, H. & Prue, G., 01 Jun 2022, In: Supportive Care in Cancer. 30, supplement issue 1, p. S41 1 p., EXERC-02

10-Year efficacy and co-morbidity outcomes of a phase III randomised trial of conventional vs. hypofractionated high dose intensity modulated radiotherapy for prostate cancer (CHHiP; CRUK/06/016) Syndikus, I., Griffin, C., Philipps, L., Tree, A., Khoo, V., Birtle, A. J., Choudhury, A., Ferguson, C., **O'Sullivan, J. M.**, Panades, M., Rimmer, Y. L., Scrase, C. D., Staffurth, J., Cruickshank, C., Hassan, S., Pugh, J., Dearnaley, D. P. & Hall, E., 20 Feb 2023, In: Journal of Clinical Oncology. 41, 6_suppl, p. 304-304 1 p

Combined Perioperative Lapatinib and Trastuzumab in Early HER2-Positive Breast Cancer Identifies Early Responders: Randomized UK EPHOS-B Trial Long-Term Results

Bundred, N., Porta, N., Brunt, A. M., Cramer, A., Hanby, A., Shaaban, A. M., Rakha, E. A., Armstrong, A., Cutress, R. I., Dodwell, D., Emson, M. A., Evans, A., Hartup, S. M., Horgan, K., Miller, S. E., **McIntosh, S. A.**, Morden, J. P., Naik, J., Narayanan, S., Ooi, J., & 3 others, 14 Feb 2022, (Early online date) In: Clinical Cancer Research

Simultaneous integrated boost (SIB) to dominant intra-prostatic lesions during extreme hypofractionation for prostate cancer: the impact of rectal spacers. Osman SOS, Fairmichael C, Whitten G, Lundy GS, Wesselman R, Wilson ML, Hounsell AR, Prise KM, Irvine D, McGarry CK, **Jain S**. *Radiat Oncol*. 2022 Feb 22;17(1):38. doi: 10.1186/s13014-022-02003-8. PMID: 35193630; PMCID: PMC8862253.

Intensity-modulated radiotherapy versus stereotactic body radiotherapy for prostate cancer (PACE-B): 2-year toxicity results from an open-label, randomised, phase 3, non-inferiority trial. Tree AC, Ostler P, van der Voet H, Chu W, Loblaw A, Ford D, Tolan S, **Jain S**, Martin A, Staffurth J, Armstrong J, Camilleri P, Kancharla K, Frew J, Chan A, Dayes IS, Duffton A, Brand DH, Henderson D, Morrison K, Brown S, Pugh J, Burnett S, Mahmud M, Hinder V, Naismith O, Hall E, van As N; PACE Trial Investigators. *Lancet Oncol*. 2022 Oct;23(10):1308-1320. doi: 10.1016/S1470-2045(22)00517-4. Epub 2022 Sep 13.

Other key publications

High impact trial that NICTN recruited to:

Geyer CE Jr, Garber JE, Gelber RD, Yothers G, Taboada M, Ross L, Rastogi P, Cui K, Arahmani A, Aktan G, Armstrong AC, Arnedos M, Balmaña J, Bergh J, Bliss J, Delaloge S, Domchek SM, Eisen A, Elsayf F, Fein LE, Fielding A, Ford JM, Friedman S, Gelmon KA, Gianni L, Gnant M, Hollingsworth SJ, Im SA, Jager A, Jóhannsson ÓP, Lakhani SR, Janni W, Linderholm B, Liu TW, Loman N, Korde L, Loibl S, Lucas PC, Marmé F, Martinez de Dueñas E, McConnell R, Phillips KA, Piccart M, Rossi G, Schmutzler R, Senkus E, Shao Z, Sharma P, Singer CF, Španić T, Stickeler E, Toi M, Traina TA, Viale G, Zoppoli G, Park YH, Yerushalmi R, Yang H, Pang D, Jung KH, Mailliez A, Fan Z, Tennevet I, Zhang J, Nagy T, Sonke GS, Sun Q, Parton M, Colleoni MA, Schmidt M, Brufsky AM, Razaq W, Kaufman B, Cameron D, Campbell C, Tutt ANJ; OlympiA Clinical Trial Steering Committee and **Investigators. Overall survival in the OlympiA phase III trial of adjuvant olaparib in patients with germline pathogenic variants in BRCA1/2 and high-risk, early breast cancer.** *Ann Oncol*. 2022 Dec;33(12):1250-1268. doi: 10.1016/j.annonc.2022.09.159. Epub 2022 Oct 10. PMID: 36228963; PMCID: PMC10207856.

Abiraterone acetate and prednisolone with or without enzalutamide for high-risk non-metastatic prostate cancer: a meta-analysis of primary results from two randomised controlled phase 3 trials of the STAMPEDE platform protocol

Systemic Therapy in Advancing or Metastatic Prostate cancer: Evaluation of Drug Efficacy (STAMPEDE) investigators, 28 Jan 2022, In: Lancet (London, England). 399, 10323, p. 447-460

Abiraterone acetate plus prednisolone for metastatic patients starting hormone therapy: 5-year follow-up results from the STAMPEDE randomised trial (NCT00268476)

James, N. D., Clarke, N. W., Cook, A., Ali, A., Hoyle, A. P., Attard, G., Brawley, C. D., Chowdhury, S., Cross, W. R., Dearnaley, D. P., Bono, J. S., Montana, C. D., Gilbert, D., Gillessen, S., Gilson, C., Jones, R. J., Langley, R. E., Malik, Z. I., Matheson, D. J., Millman, R., **& 36 others**, 12 Apr 2022, (Early online date) In: International Journal of Cancer.

Docetaxel for Nonmetastatic Prostate Cancer: Long-Term Survival Outcomes in the STAMPEDE Randomized Controlled Trial

James, N. D., Ingleby, F. C., Clarke, N. W., Amos, C. L., Attard, G., Brawley, C. D., Chowdhury, S., Cross, W., Dearnaley, D. P., Gilbert, D. C., Gillessen, S., Jones, R. J., Langley, R. E., Macnair, A., Malik, Z. I., Mason, M. D., Matheson, D. J., Millman, R., Parker, C. C., Rush, H. L., **& 27 others**, 01 Aug 2022, In: JNCI Cancer Spectrum. 6, 4, pkac043

Radiotherapy to the prostate for men with metastatic prostate cancer in the UK and Switzerland: Long-term results from the STAMPEDE RCT

STAMPEDE Trial Collaborative Group, Parker, C. C., James, N. D., Brawley, C. D., Clarke, N. W., Ali, A., Amos, C. L., Attard, G., Chowdhury, S., Cook, A., Cross, W., Dearnaley, D. P., Douis, H., Gilbert, D. C., Gilson, C., Gillessen, S., Hoyle, A., Jones, R. J., Langley, R. E., Malik, Z. I., **& 27 others**, 07 Jun 2022, (Early online date) In: PLoS Medicine. 19, 6, e1003998.

Other publication relating to Clinical research nursing:

Hood B, **Boyd R**, Crowe T et al (2022) Effect of COVID-19 on cancer research nursing services. Cancer Nursing Practice. doi: 10.7748/cnp.2022.e1821

Blog: 20 years of Cancer Research UK: Celebrating our research nurses

[Celebrating our research nurses - Cancer Research UK](#)

Published 07 December 2022 Cancer Research UK website:

Several NICTN research nurses attended the UK Oncology Nursing Society annual conference, held in November 2022 in Belfast. Posters were:

- Soraya Manoucheri (NHSCT) 'Developing virtual resources to increase cancer research engagement: a service improvement approach'
- Ruth Boyd et al (BHSCT) 'Clinical Trials are shaping the future of cancer treatment – how is patient experience shaping up?'

Awards/Good New Stories

- Friends of the Cancer Centre 'Celebrate Great Awards' recognise those who go above and beyond for their patients. NICTN Staff Margot Creighton (CRN), Michael Hanna (Data Manager) and Dr Sarah Lawless (PI) were just some of the recipients from across the NI Cancer Centre who received this award in 2022/23.
- BHSCT Certificates of recognition were awarded across all sections of the NICTN team through the year
- Margot Creighton, Clinical Research Nurse for the **DIAdIC** Study (Protocol for an International Randomized Controlled Trial to evaluate the effectiveness of a nurse-

delivered (FOCUS+) and a web-based (iFOCUS) psychoeducational intervention for people with Advanced cancer and their family caregivers), was a finalist in the RCNi Nursing Awards, Excellence in Research Nursing category. She attended the awards ceremony in London, 06 October 2022. Margot had maintained UK recruitment to this EU study during the COVID-19 pandemic.

Staffing Update

During the course of 2022-23 we employed 92 clinical staff in HSC NI. 2022-23 was a much more pleasant year for our clinical teams across NI. The senior management team would firstly wish to open this section, by conveying our thanks to the dedicated NICRN team past and present for their commitment to their roles. Secondly to welcome all new staff, especially our 10 new NIRRRG staff helping to assist research and recovery from the pandemic throughout 2022-23.

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

HSC Trust	2018/2019 WTE Deployed	2019/2020 WTE Deployed	2020/2021 WTE Deployed	2021/2022 WTE Deployed	2022/2023 WTE Deployed
BHSCT	29.43	29.83	27.08	28.63	32.60
NHSCT	4.85	4.00	4.50	4.50	5.50
SEHSCT	5.30	3.80	4.80	3.30	4.30
SHSCT	4.80	4.00	5.35	4.80	5.80
WHSCT	5.00	4.50	3.85	5.35	5.65
TOTAL	49.38	46.13	45.58	46.58	53.85*

*Note: includes 9 x NIRRRG funded Band 6 staff across NI

A huge excitement for the clinical team was the relocation to Dunluce 4th floor, to join our PC colleagues. Everyone has settled in and it provides office space and meeting rooms for all NICRN clinical staff. On the 20th March 2022, Northern Ireland's Minister of Health came for a visit on International Clinical Trials Day to congratulate the Primary Care team on their excellent recruitment to the **PANORMIC** Study. (See Figure 14)

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

CSG	2022/2023 WTE funded		2022/2023 WTE Staff in Post		No. Staff in Post (01/04/22 - 31/03/2023)
	PHA funded	Non-PHA funded	PHA funded	Non-PHA funded	
Cardiovascular	5.30		4.05		12
Child Health	3.50		3.30		7
Critical Care	6.30		5.90		11
Diabetes	3.50		2.50		7
Gastroenterology	1.50	0.50	1.50	0.50	4
Mental Health	2.00		1.00		1
Neurodegenerative	2.00	2.00	1.50	2.00	5
Orthopaedics	1.00		0.50		1
Primary Care	2.50		2.50		3
Renal	3.80		3.30		6
Respiratory Health	6.00	2.50	2.80	2.00	11
Stroke	3.85		2.85		7
Vision	3.60		2.10		5
COVID	9		8.50		12
Total	53.85	5.00	42.30	4.50	92*

*Note: includes Band 6 and Band 7 staff



Figure 14 NI Health Minister Robin Swann visits the NICRN Panoramic Research team at Dunluce Health Centre.
Pictured: (L-R) Professor Stuart Elborn, Professor Jonathan Jackson, Mr Robin Swann, Professor Nigel Hart, Mrs Claire Leatham and Dr Daniel Butler

This relocation has been a fruitful collaboration and is continuing to develop collaborative opportunities. This will give a great deal of flexibility in staff development and team building and will path find some shared challenges for future collaborative working practices across academia and clinical infrastructure.



Figure 15 Clinical Research Panel at Queens University Belfast, School of Nursing and Midwifery. Pictured: (L-R) Ms Angela Abbate, Ms Sonia McKenna, Ms Julie Brown QUB, Ms Roisin Stone, Ms Laura Creighton QUB and Ms Sharon Carr (NICRF)

One of the main challenges over the reporting period was managing staff under unpredictable and ever-changing conditions within the HSC environment. Following a busy 2021-2022 many staff were emotionally and physically exhausted, clinical staffing levels depleted and recruitment presented challenges. This was especially noticeable in areas such as critical care where clinical teams were under sizable clinical pressures.

As social distancing measures were eventually beginning to lift, NICRN staff were delighted to attend our first face-to-face conference in May 2022. Here NICRN met the new NICRN Director Prof Jonathan Jackson and bid farewell to Dr O'Kane. The event was a great success and feedback has been very positive.



Figure 16 Dr Paul Biagioni, Dr Aaron Peace, Dr Clive Wolsey, Professor Judy Bradley, Dr Janice Baillie, Dr Maurice O’Kane and Professor Jonathan Jackson at the NI Clinical Research Network Staff Conference

Recruitment in studies from our dedicated hardworking clinical CRN’s has been showcased on our new website throughout 22 /23. Staff have had major achievements with awards as top recruiting sites across the UK.

Staff training events

Ongoing training of staff is essential in developing staff skillsets appropriate to the rapidly changing clinical research environment. Locally delivered staff training events in 2022-23 included:

- Celebration to mark International Nurses Day 12th May 2022.
- International Clinical Trials Day 17th May 2022.
- “Learning bursts with Clinical Scenarios” facilitated by Karl Ward 22nd Dec 2022
- Edge & IT training (Ongoing)
- Introduction of R&D Workshops commenced 2022.

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

- RCN International Nursing Research Conference 7th - 9th Sept 2022.
- RCN Clinical Research Nursing Conference 24th April 2022

- NICRN Clinical Research Information Session Programme at Queen's University Belfast, School of Nursing and Midwifery
- ICU staff X4 from across the 5 trusts attended CC Reviews
- ICU CRN BHDCT CC attended UK CC Research group conference.
- SHSCT Stroke CRN attended BACCN Conference 17th & 18th Oct Belfast
- BHSCT CRN attended Alzheimer's Society Annual Conference
- BHSCT CRN attended CC Conference Sweden
- BHSCT Ortho CRN attended TORC Conference
- SHSCT CRN Stroke attended UK 3 day Stroke Conference 29th Nov – 1st Dec
- BHSCT Stroke CRN attended UK 3 day Stroke Conference 29th Nov – 1st Dec

Staff continuously update and maintain their statutory and mandatory training through e-learning and NICRN staff have also been supported throughout 2022-23, to attend investigators meetings across UK & Europe.

CRNM Census:

The landmark 2021 Clinical Research Nurse and Midwife (CRNM) census³ was the first project to formally seek to identify the number of CRNMs across the UK and Republic of Ireland.

7,469 CRNMs responded to the survey, providing baseline information on geographical location, sector, grade / Agenda for Change banding, and specialty areas of practice. The census identified CRNMs from Band 5 -9 in the UK. In the Republic of Ireland roles ranged from Staff Nurse to Director of Nursing. The data indicates the existence of opportunities to practice as a CRNM at every level, with continued potential for career progression into senior leadership and specialist roles. CRNMs are a specialist workforce, with knowledge, skills and expertise in both clinical practice and research delivery.

Dr Janice Bailie, Assistant Director, Health and Social Care Research and Development (HSC R&D) Division, Public Health Agency, Northern Ireland said, "Research nurses and midwives are at the heart of high-quality clinical research and trials which help to improve outcomes for patients. I welcome this report which for the first time, provides the baseline data needed to inform the development of a proper career pathway for this important group of professionals."

³ [The United Kingdom and Republic of Ireland Clinical Research Nurse and Midwife Census 2021 | NIHR](#)

Challenges

One challenge which is occupying a significant proportion of the senior staff management teams time is the continued turnover of staff. This is obvious from Table 3 (staff in post column), where we can see that within several specialities and posts the number of staff in post over the reporting year is significantly greater than the core funded posts number. For example, within our CDT we have 9 clinical research nurse posts over the 5 HSC Trusts. However, these posts have had 12 different occupancies, and this is observed across all specialities and sites but is most notable across cardiovascular, critical care and respiratory health. This turnover results in the management team being burdened with continual recruitment and selection exercises with their incumbent administrative burden of use of HSC HR systems, securing potentially additional financial agreements, recruitment days, induction, mentoring/supervision etc. The team have moved to a rolling programme of recruitment 3 times per year generating waiting lists to help fast track backfill. However, the reality is that many applicants have little research experience and more notably now many are not long qualified and so their general clinical experience is often minimal. This means as a service we need to maintain stringent induction, supervision processes and monthly 1-2-1 meetings to ensure the safety of our participants. This reduces the time available to dedicate to other staff management responsibilities. All of which detracts from other core duties.

Portfolio metrics

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

Data quality and confidence checking are key elements in underpinning the integrity of our portfolio. We manage our portfolio using the EDGE local portfolio management system. We operate a year round process of regularly emailing all staff to update the status of their studies, and also provide timely recording of their research activity. In general terms the headline figures from this year's portfolio report would suggest sustained modest growth in most key metrics. The total number of active studies this year (183) is almost on a par with 2018-19 figures (185) [Table 4]. This sense of resilience after suffering the impact of the COVID-19 pandemic is further underpinned by examining the recruitment figures for this year (2261) which represents the highest recruitment numbers in year, achieved in the last 5 years [Table 9]. New this year is the inclusion of the activity data relating to the NIRRRG – COVID Delivery Team (CDT). The CDT became operational from mid-April 2022 onwards and so we have included the CDT as an additional CSG throughout this report and also in the tables and appendices below.

(Please note - Data relating to NICTN(Cancer) activity will appear in a separate report and is not included in the following tables).

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

A.R. Year	In Year TOTALS		
	New Studies (n)	Studies Closed (n)	Total Active Studies (n)
2018-19	39	63	185
2019-20	52	65	200
2020-21	24	59	168
2021-22	54	30	172
2022-23	43	29	183

Note: New Studies are eligible studies which have been supported by NICRN and therefore added to the portfolio during the reporting period. Studies Closed are studies which have ended activity and have closed during the reporting period. These two data points are new for 2022-23 and have been reported retrospectively for the previous 5 years. 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.

CRV				CHI			CCA			DIA			GAS			A.R. Year
A.R. Year	New Studies INY (n)	Studies Closed INY (n)	Total Active Studies INY (n)	New Studies INY (n)	Studies Closed INY (n)	Total Active Studies INY (n)	New Studies INY (n)	Studies Closed INY (n)	Total Active Studies INY (n)	New Studies INY (n)	Studies Closed INY (n)	Total Active Studies INY (n)	New Studies INY (n)	Studies Closed INY (n)	Total Active Studies INY (n)	
2018-19	5	12	38	2	3	11	4	7	18	2	4	9	1	3	8	2018-19
2019-20	6	11	37	5	3	14	11	5	28	3	1	9	5	3	10	2019-20
2020-21	6	11	33	5	5	12	3	4	20	0	3	9	0	4	10	2020-21
2021-22	1	5	25	7	2	14	8	6	25	2	0	7			9	2021-22
2022-23	5	4	25	5	0	18	7	2	22	4	1	11	4	3	11	2022-23

MHT				NEU			ORT			PCR			REN			A.R. Year
A.R. Year	New Studies INY (n)	Studies Closed INY (n)	Total Active Studies INY (n)	New Studies INY (n)	Studies Closed INY (n)	Total Active Studies INY (n)	New Studies INY (n)	Studies Closed INY (n)	Total Active Studies INY (n)	New Studies INY (n)	Studies Closed INY (n)	Total Active Studies INY (n)	New Studies INY (n)	Studies Closed INY (n)	Total Active Studies INY (n)	
2018-19	1	1	6	0	3	7				3	0	11	4	9	21	2018-19
2019-20	3	2	8	0	5	7				3	5	9	1	5	14	2019-20
2020-21	0	5	8	0	1	3				1	1	9	1	6	12	2020-21
2021-22	2	0	6	1	2	3	6	0	6	3	5	9			11	2021-22
2022-23	0	3	6	1	1	3	4	1	10	2	1	6	3	0	11	2022-23

RES				STR			VIS			CDT			A.R. Year
A.R. Year	New Studies INY (n)	Studies Closed INY (n)	Total Active Studies INY (n)	New Studies INY (n)	Studies Closed INY (n)	Total Active Studies INY (n)	New Studies INY (n)	Studies Closed INY (n)	Total Active Studies INY (n)	New Studies INY (n)	Studies Closed INY (n)	Total Active Studies INY (n)	
2018-19	9	11	27	3	3	12	5	7	17				2018-19
2019-20	6	15	32	5	3	14	4	7	18				2019-20
2020-21	4	9	21	1	4	12	3	6	19				2020-21
2021-22	12	4	25	5	2	12	7	4	20				2021-22
2022-23	2	7	22	2	2	12	4	4	20	0	0	6	2022-23

Note: Table 5 has been similarly expanded to include New Studies and Studies Closed broken down here by CSG and reported retrospectively over the last 5 years. The CDT Total Active Studies (6) were previously delivered by, and therefore associated with, the CCA and RES CSGs. This explains why their Total Active Studies values each appear to drop by 3 studies.

Table 6: The total number of NICRN supported studies active in each HSC (Health and Social Care) Trust.

A.R. Year	Total Active Studies - in Year TOTALS					
	BHSCT	NHSCT	SEHSCT	SHSCT	WHSCT	Study / Sites
2018-19	125	40	32	44	37	278
2019-20	138	37	28	44	36	283
2020-21	120	41	36	39	36	272
2021-22	130	41	37	43	35	286
2022-23	140	57	35	40	34	306

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[^]) of Active commercial/non-commercial studies in NICRN portfolio.

A.R. Year	in Year Totals				Total No of Studies
	Comm		Non-Comm		
	No of Studies	P^(%)	No of Studies	P^(%)	
2018-19	67	36.22%	118	63.78%	185
2019-20	69	34.50%	131	65.50%	200
2020-21	58	34.52%	110	65.48%	168
2021-22	49	28.49%	123	71.51%	172
2022-23	47	25.68%	136	74.32%	183

Note: Within NICRN we have taken the approach of balancing the commercial vs non-commercial elements of our portfolio to maintain an approximate split of 40:60%. 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 Network recognises the central role our commercial partners have in allowing the generation of income for further reinvestment augmenting our capacity.

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

A.R. Year	In Year Totals (Study Design)					
	Int		Obs		Not Spec	
	No of Studies	P^(%)	No of Studies	P^(%)	No of Studies	P^(%)
2018-19	121	65.41%	60	32.43%	4	2.16%
2019-20	143	71.50%	56	28.00%	1	0.50%
2020-21	120	72.73%	45	27.27%	0	0.00%
2021-22	115	71.43%	46	28.57%	0	0.00%
2022-23	126	68.85%	57	31.15%	0	0.00%

Note: This breakdown has remained relatively stable over the last 5 years. Specialities are asked to balance their portfolio across observational and interventional to maximise the participant recruitment and engagement to maximise participant engagement with research teams.

Portfolio activity: Recruitment (Patients screened and accrued)

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

A.R. Year	in Year Totals	
	Screened	Recruited
2018-19	8931	2115
2019-20	4437	1868
2020-21	3463	1818
2021-22	3991	1932
2022-23	8133	2261

Note: This table demonstrates that to achieve good recruitment numbers we don't want to burden the process by having a large screen to recruitment ratio. This was originally the case within several specialities and by collecting data previously it has allowed for a more focussed and targeted approach to what type of study we can and should support which will provide the best return on staffing allocation provided. Although the screening to recruitment ratio varies significantly depending of the nature of the study being adopted, our strategy is always to maximise the best return on staffing allocation by encouraging targeted screening.

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

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

in Year Totals (recruitment)				
A.R. Year	Interventional	Observational	Not Specified	A.R. Year
2018-19	1022	1067	26	2018-19
2019-20	747	1121	0	2019-20
2020-21	1346	472	0	2020-21
2021-22	1302	630	0	2021-22
2022-23	1002	1259	0	2022-23

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

in Year Totals (recruitment)			
A.R. Year	Commercial	Non-Commercial	Total Recruitment
2018-19	113	2002	2115
2019-20	86	1782	1868
2020-21	23	1801	1824
2021-22	103	1829	1932
2022-23	80	2181	2261

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

Achieving high levels of recruitment to target (RtT) is one of the main objectives of the network. As a service, we are fully appreciative of this metric's importance and its role in supporting commercial investment and assurance of our capabilities to our partners. To this end, we embed the aim of reaching a 90% RtT when assessing our capacity to deliver on target. Following a significant reduction in our median RtT in 2019/20 we have seen a steady state increase in the median % RtT metric over the last 3 years back to a regional level of 87% (Table 12). As can be seen in Table 14 the network has maintained a median % RtT of approximately 66% for our commercial portfolio but have increased our median % RtT for our non-commercial portfolio to a very respectable 98%. Likewise, we observed continued stability in our median % RtT for our observational portfolio from 96% to 100% as seen in Table 13 (range 71%-220% appendix 8).

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

A.R. Year	in Year Total Median (% RtT)
2018-19	91.95%
2019-20	75.16%
2020-21	80.03%
2021-22	86.34%
2022-23	87.00%

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

Median across CSGs(% RtT)			
A.R. Year	Int	Obs	Not Spec
2018-19	84.27%	94.74%	145.83%
2019-20	73.40%	89.48%	11.11%
2020-21	73.36%	100.00%	
2021-22	74.61%	96.28%	
2022-23	85.00%	100.00%	

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

Median across CSGs (% RtT)		
A.R. Year	Comm	Non-Comm
2018-19	85.00%	84.07%
2019-20	78.89%	94.90%
2020-21	62.61%	80.74%
2021-22	67.72%	80.74%
2022-23	65.72%	98.33%

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

HSC Trust	Totals 2018-19		Totals 2019-20		Totals 2020-21		Totals 2021-22		Totals 2022-23		HSC Trust
	No. Active Studies	Median % RtT	No. Active Studies	Median % RtT	No. Active Studies	Median % RtT	No. Active Studies	Median % RtT	No. Active Studies	Median % RtT	
BHSCT	125	82.02%	138	78.71%	120	65.37%	130	81.35%	140	80.00%	BHSCT
NHSCT	40	80.40%	37	49.78%	41	89.32%	41	80.75%	57	48.33%	NHSCT
SEHSCT	32	107.22%	28	100.00%	36	75.00%	37	75.00%	35	74.61%	SEHSCT
SHSCT	44	71.84%	44	96.91%	39	80.91%	43	62.63%	40	78.13%	SHSCT
WHSCT	37	78.91%	36	85.42%	36	84.33%	35	68.13%	34	63.67%	WHSCT

The BHSCT site has continued a steady state return to pre-COVID levels of recruitment to Target and due to the excellent work within SHSCT we can see an increase in their median % recruitment to target back to pre-COVID levels too. The SEHSCT is relatively stable however both NHSCT and WHSCT have reduced median % RtT and this could be attributable to the significant impact the clinical teams went through in relation to COVID recovery.

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

The First Patient First Visit (FPFV) window (number of days from site opening to recruitment and first participant recruited) is a key metric for the NICRN. We aim to meet an FPFV window of less than 30 days across our new studies as this metric is often cited and used by stakeholders in determining a sites ability to set up quickly and reflects on delivery teams systems and capabilities. Across tables 16-18 we show the FPFV windows over the last 5 years

for our commercial and non-commercial portfolios across all CSG's. Table 18 also shows what P^ of these studies achieved the <30-day window.

Only NHSCT achieved the <30-day window in 2022-23 for commercial study set up times (n=5), (Table 16). The sites ranged from medians of 28.5 days in NHSCT up to 146.5 days in SHSCT for commercially sponsored studies. The non-commercial portfolio was much improved, and the NI sites ranged from a median of 21.5 days for SEHSCT up to 39.3 days for the SHSCT (Table 17). The combined median FPFV (days) interval for the NI non-commercial portfolio came out at 29.9 days. Whilst the figures for the non-commercial portfolio are much better than the commercial portfolio, the results are still well out with national expectations. The NICRN team are currently addressing this as a matter of urgency as it carries a significant risk of impacting on potential future collaborations.

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

Commercial						
HSC Trust	All CSGs 2018-19 FPFV (days)	All CSGs 2019-20 FPFV (days)	All CSGs 2020-21 FPFV (days)	All CSGs 2021-22 FPFV (days)	All CSGs 2022-23 FPFV (days)	HSC Trust
BHSCT	63.9	68.7	29.0	75.3	85.0	BHSCT
NHSCT	176.8	115.8	217.0	220.5	28.5	NHSCT
SEHSCT	47.0	36.7	40.0	39.8	40.5	SEHSCT
SHSCT	95.3	87.3	130.8	146.5	146.5	SHSCT
WHsCT	22.0	36.3	257.0	235.5	59.0	WHsCT
All trusts	81.0	68.9	134.8	143.5	71.9	All trusts

Note: whilst the return, over all trusts has significantly improved to a median FPFV number of 71.9 days, this may in part be due to the small number of commercial studies adopted and live during the reporting period. Whilst this may be seen as an improvement it is still significantly longer than the team would wish for and will be a focus that we plan to address over 23/24, especially in relation to how the Northern Ireland HSC environment reacts to the O'Shaughnessy report.

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

Non-Commercial						
HSC Trust	All CSGs 2018-19 FPFV (days)	All CSGs 2019-20 FPFV (days)	All CSGs 2020-21 FPFV (days)	All CSGs 2021-22 FPFV (days)	All CSGs 2022-23 FPFV (days)	HSC Trust
BHSCT	42.5	37.3	34.8	39.7	33.5	BHSCT
NHSCT	90.4	57.3	26.3	73.2	24.0	NHSCT
SEHSCT	172.3	105.5	27.0	28.8	21.5	SEHSCT
SHSCT	56.5	64.1	42.5	91.0	39.3	SHSCT
WHSCT	131.4	74.4	21.0	86.0	31.0	WHSCT
All Trusts	98.6	67.7	30.3	63.7	29.9	All Trusts

Note: The FPFV data for the non-commercial section is the best we have ever achieved across NI over the last five years. This even includes 2020-21 when every effort was being made to open COVID related studies up to participants as quickly as possible.

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[^]) of those studies achieving FPFV < 30days.

A.R. Year	in Year Totals					
	Comm		Non-Comm		Combined (All Studies)	
	Avg Median FPFV (days)	Avg P [^] Studies < 30 days	Avg Median FPFV (days)	Avg P [^] Studies < 30 days	Avg Median FPFV (days)	Avg P [^] Studies < 30 days
2018-19	60.6	38.51%	46.7	47.00%	53.5	42.81%
2019-20	51.1	44.52%	46.7	50.49%	49.0	47.67%
2020-21	58.3	38.94%	50.7	48.15%	54.6	43.91%
2021-22	77.6	21.09%	60.7	48.11%	68.9	36.44%
2022-23	88.5	31.55%	55.2	52.02%	70.0	43.93%

Table 18 shows the P[^] of the commercial and non-commercial studies that are achieving the <30-day metric. The table shows that for the commercial portfolio, across all sites and CSGs less than a third of our studies achieve the 30-day target and just over half achieved the target for the non-commercial portfolio.

Patient and Public Involvement (PPI)

Engagement

Our engagement with the public sector bodies and patient representatives had sadly been very much reduced in line with the social distancing regulations within HSC. We were not holding our CMGs as regularly as we would have wanted and as such our PPI role dropped off as can be seen from most of the disease speciality groups own sections in this report. As we have transitioned out of the pandemic our CMGs have been reintroduced and we are trying to establish more resilient platforms for our PPI engagement. Within our plans to establish working clusters we are aiming to set up a much higher-level PPI platform which will have more impact and leverage as compared to a PPI role at adoption within the CSG structure as this often minimises the PPI ability to influence change in a proposal. Whilst we will maintain the PPI role on our CMGs we will augment this with a lead PPI role on our Steering group and potentially within our most senior executive platform. Development of these plans will be a priority for 2023-24.

Appendices

Appendix 1 - Additional data for Staffing Levels for previous reporting periods.

	2019/2020 WTE		2019/2020 Staff in Post		2020/2021 WTE		2020/2021 Staff in Post		2021/2022 Staff in Post		Staff in Post
	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	
Cardiovascular	5.50	0.00	6	3	5.50		4.30		5.50		6
Child Health	2.50	0.80	5	0	3.50		3.00		3.50		5
Critical Care	7.80	0.50	7.5	2.5	6.80		6.80		7.30		9
Diabetes	3.53	0.00	4	0	3.53				3.53		5
Gastroenterology	2.50	1.00	4.5	1.5	2.50	1.00	2.50	1.00	2.00	0.50	5
Mental Health	1.50	0.00	2	0	1.50		1.00		1.50		1
Neurodegenerative	2.50	2.00	3	2	2.00	2.00	1.50	2.00	2.00	2.00	4
Orthopaedics									1.00		1
Primary Care	2.50	0.00	3	0	2.50		2.50		2.50		3
Renal	3.30	0.00	6	0	3.80		3.80		3.80		7
Respiratory Health	6.00	2.00	8	1	6.00	1.00	6.00	1.00	6.00	1.00	8
Stroke	3.50	0.00	7	0	3.85		2.00		3.85		5
Vision	5.00	0.00	7	0	4.10		4.10		4.10		6
COVID											
Total	46.13	6.30	63	10	45.58	4.00	37.50	4.00	46.58	3.50	65

Appendix 2 – Additional data for Portfolio breakdown: Study numbers and Proportion (P[^]) by funding type (commercial, non-commercial sponsorship)

	CRV				CHI				CCA				DIA				GAS				MHT				NEU			
	Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm	
	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)
2018-19	19	50.00%	19	50.00%	1	9.09%	10	90.91%	1	5.56%	17	94.44%	6	66.67%	3	33.33%	4	50.00%	4	50.00%	2	33.33%	4	66.67%	3	42.86%	4	57.14%
2019-20	17	45.95%	20	54.05%	2	14.29%	12	85.71%	1	3.57%	27	96.43%	5	55.56%	4	44.44%	6	60.00%	4	40.00%	2	25.00%	6	75.00%	1	14.29%	6	85.71%
2020-21	15	45.45%	18	54.55%	2	16.67%	10	83.33%	0	0.00%	20	100.00%	5	55.56%	4	44.44%	7	70.00%	3	30.00%	3	37.50%	5	62.50%	0	0.00%	3	100.00%
2021-22	11	44.00%	14	56.00%	2	14.29%	12	85.71%	1	40.00%	24	96.00%	5	71.43%	2	28.57%	5	55.56%	4	44.44%	2	33.33%	4	66.67%	0	0.00%	3	100.00%
2022-23	9	36.00%	16	64.00%	3	16.67%	15	83.33%	1	4.55%	21	95.45%	7	63.64%	4	36.36%	6	54.55%	5	45.45%	2	33.33%	4	66.67%	0	0.00%	3	100.00%

	ORT				PCR				REN				RES				STR				VIS				CDT			
	Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm	
	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)
2018-19					4	36.36%	7	63.64%	4	19.05%	17	80.95%	14	51.85%	13	48.15%	4	33.33%	8	66.67%	5	29.41%	12	70.59%				
2019-20					2	22.22%	7	77.78%	4	28.57%	10	71.43%	17	53.13%	15	46.88%	3	21.43%	11	78.57%	9	50.00%	9	50.00%				
2020-21					1	11.11%	8	88.89%	4	33.33%	8	66.67%	11	52.38%	10	47.62%	2	16.67%	10	83.33%	8	42.11%	11	57.89%				
2021-22	0	0.00%	6	100.00%	1	11.11%	8	88.89%	2	18.18%	9	81.82%	7	28.00%	18	72.00%	2	16.67%	10	83.33%	11	55.00%	9	45.00%				
2022-23	0	0.00%	10	100.00%	1	16.67%	5	83.33%	2	18.18%	9	81.82%	6	27.27%	16	72.73%	1	8.33%	11	91.67%	9	45.00%	11	55.00%	0	0.00%	6	100.00%

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

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

	MHT (Study Design)						NEU (Study Design)						ORT (Study Design)						PCR (Study Design)						REN (Study Design)					
	Int		Obs		Not Spec		Int		Obs		Not Spec		Int		Obs		Not Spec		Int		Obs		Not Spec		Int		Obs		Not Spec	
	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)	No of Studies	P [^] (%)
2018-19	3	50.00%	3	50.00%	0	0.00%	4	57.14%	3	42.86%	0	0.00%							6	54.55%	2	18.18%	3	27.27%	8	38.10%	13	61.90%	0	0.00%
2019-20	6	66.67%	3	33.33%	0	0.00%	4	57.14%	3	42.86%	0	0.00%							7	77.78%	1	11.11%	1	11.11%	6	42.86%	8	57.14%	0	0.00%
2020-21	5	62.50%	3	37.50%	0	0.00%	1	33.33%	2	66.67%	0	0.00%							6	75.00%	2	25.00%	0	0.00%	6	50.00%	6	50.00%	0	0.00%
2021-22	3	50.00%	3	50.00%	0	n/a	1	33.33%	2	66.67%	0	0.00%	5	83.33%	1	16.67%	0	0.00%	7	75.51%	2	50.00%	0	0.00%	6	70.21%	5	45.45%	0	0.00%
2022-23	4	66.67%	2	33.33%	0	0.00%	2	66.67%	1	33.33%	0	0.00%	8	80.00%	2	20.00%	0	0.00%	3	50.00%	3	50.00%	0	0.00%	5	45.45%	6	54.55%	0	0.00%

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

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

	CRV		CHI		CCA		DIA		GAS		MHT		NEU	
	Scr	Rec	Scr	Rec	Scr	Rec	Scr	Rec	Scr	Rec	Scr	Rec	Scr	Rec
2018-19	521	243	133	65	2057	201	341	43	45	28	15	13	551	276
2019-20	361	259	74	35	327	241	279	271	57	55	3	1	344	341
2020-21	57	49	153	150	2633	630	6	5	1	0	6	5	182	182
2021-22	100	90	330	92	1567	429	35	21	24	14	19	12	0	0
2022-23	221	99	138	79	1652	312	119	50	123	109	20	15	715	715

	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
2018-19			459	317	456	181	1322	234	411	214	2620	300			8931	2115
2019-20			2242	145	184	109	176	126	77	63	313	222			4437	1868
2020-21			20	20	100	72	287	693	10	4	8	8			3463	1818
2021-22	152	72	782	782	46	30	709	328	193	43	34	19			3991	1932
2022-23	248	119	159	159	387	73	942	218	71	29	298	117	3040	167	8133	2261

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

	CRV (recruitment)			CHI (recruitment)			CCA (recruitment)			DIA (recruitment)			GAS (recruitment)			MHT (recruitment)			NEU (recruitment)			ORT (recruitment)		
	Int	Obs	Not Spec	Int	Obs	Not Spec	Int	Obs	Not Spec	Int	Obs	Not Spec	Int	Obs	Not Spec	Int	Obs	Not Spec	Int	Obs	Not Spec	Int	Obs	Not Spec
2018-19	157	86	0	13	52	0	93	85	23	21	22	0	4	24	0	11	2	0	5	271	0			
2019-20	35	224	0	12	23	0	126	115	0	43	228	0	2	53	0	1	0	0	0	341	0			
2020-21	14	35	0	26	124	0	487	143	0	5	0	0	0	0	0	5	0	0	168	14	0			
2021-22	78	12	0	31	61	0	218	211	0	0	21	0	2	12	0	10	2	0	0	0	0	39	33	0
2022-23	94	5	0	28	51	0	249	63	0	0	50	0	109	0	0	15	0	0	2	713	0	59	60	0

	PCR (recruitment)			REN (recruitment)			RES (recruitment)			STR (recruitment)			VIS (recruitment)			CDT (recruitment)			in Year Totals (recruitment)		
	Int	Obs	Not Spec	Int	Obs	Not Spec	Int	Obs	Not Spec	Int	Obs	Not Spec	Int	Obs	Not Spec	Int	Obs	Not Spec	Interventional	Observational	Not Specified
2018-19	314	0	3	17	164	0	104	130	0	12	202	0	271	29	0				1022	1067	26
2019-20	145	0	0	66	43	0	54	72	0	63	0	0	200	22	0				747	1121	0
2020-21	20	0	0	45	27	0	564	129	0	4	0	0	8	0	0				1346	472	0
2021-22	732	50	0	1	29	0	136	192	0	36	7	0	19	0	0				1302	630	0
2022-23	102	57	0	60	13	0	50	168	0	26	3	0	59	58	0	149	18	0	1002	1259	0

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

	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
2018-19	53	190	0	65	0	201	8	35	4	24	0	13	2	274
2019-20	7	252	7	28	0	241	25	246	1	54	0	1	0	341
2020-21	12	37	0	150	0	630	6	5	0	0	0	5	0	182
2021-22	54	36	3	89	0	429	21	0	1	13	0	12	0	0
2022-23	8	91	3	76	12	300	47	3	0	109	0	15	0	715

	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
2018-19			0	317	8	173	26	208	4	210	8	292			113	2002
2019-20			0	145	5	104	16	110	6	57	19	203			86	1782
2020-21			0	20	0	72	4	689	0	4	1	7			23	1801
2021-22	0	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

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

	CRV	CHI	CCA	DIA	GAS	MHT	NEU	ORT	PCR	REN	RES	STR	VIS	CDT	in Year Total Median (% RtT)
2018-19	100.00%	94.74%	81.46%	89.17%	100.00%	12.70%	60.00%		103.00%	75.00%	100.00%	45.00%	102.50%		91.95%
2019-20	80.00%	78.89%	70.00%	58.33%	100.00%	29.79%	60.00%		108.00%	65.40%	100.00%	71.43%	102.50%		75.16%
2020-21	80.00%	65.33%	100.00%	86.67%	75.00%		100.72%			80.06%	65.33%	71.43%	162.50%		80.03%
2021-22	75.00%	5.90%	87.78%	97.33%	100.00%	n/a	85.62%	122.00%	63.33%	78.13%	87.06%	75.00%	100.00%		86.34%
2022-23	93.50%	80.00%	76.00%	97.33%	75.00%	85.00%	95.14%	122.00%	100.00%	73.21%	65.33%	87.00%	100.00%		87.00%

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

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

	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	Not Spec	Int	Obs	Not Spec	Int	Obs	Not Spec	Int	Obs	Not Spec	Int	Obs	Not Spec	Int	Obs	Not Spec	Int	Obs	Not Spec	Int	Obs	Not Spec
2018-19				103.00%	211.00%	100.00%	60.92%	76.94%		88.72%	87.03%		51.02%	74.91%		96.13%	151.50%					84.27%	94.74%	145.83%
2019-20				77.78%	11.11%	11.11%	88.23%	102.82%		89.40%	80.51%		48.57%	74.91%		100.32%	153.20%					73.40%	89.48%	11.11%
2020-21				81.26%	40.00%		66.84%	107.06%		56.87%	107.06%		74.11%			143.30%	107.06%					73.36%	100.00%	
2021-22	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%	

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

	CRV (Median % RtT)		CHI (Median % RtT)		CCA (Median % RtT)		DIA (Median % RtT)		GAS (Median % RtT)		MHT (Median % RtT)		NEU (Median % RtT)	
	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm	Comm	Non-Comm
2018-19	100.77%	89.10%		88.17%		81.46%	85.00%	86.67%	103.33%	75.00%		18.70%	80.00%	60.42%
2019-20	80.80%	97.44%	77.78%	75.37%		82.87%	58.33%		33.33%	125.00%		24.62%	80.00%	51.67%
2020-21	138.46%	95.76%	77.78%	54.13%		89.95%	62.11%	90.55%	50.00%	100.00%		11.91%		80.74%
2021-22	79.24%	108.62%		46.67%		80.74%	64.00%	80.74%	83.33%	100.00%	n/a	n/a		92.08%
2022-23	85.00%	100.00%	60.00%	150.00%		76.00%	94.00%	98.33%	50.00%	100.00%		92.50%	0.00%	95.14%

	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
2018-19			101.00%	119.00%	83.33%	71.21%	76.28%	101.23%	29.56%	70.46%	85.33%	124.34%			85.00%	84.07%
2019-20			62.50%	100.10%	133.33%	94.90%	81.56%	102.45%	28.86%	91.39%	84.08%	166.03%			78.89%	94.90%
2020-21			50.00%	79.60%	50.00%	80.74%	62.61%	73.69%	75.00%	55.36%	88.89%	80.74%			62.61%	80.74%
2021-22		80.74%	50.00%	75.51%	71.43%	75.69%	56.89%	80.74%	47.50%	100.00%	103.33%	192.50%			67.72%	80.74%
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%

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

	CRV				CHI				CCA				DIA				GAS				MHT				NEU			
	Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm	
	Median FPFV (days)	P* Studies < 30 days	Median FPFV (days)	P* Studies < 30 days	Median FPFV (days)	P* Studies < 30 days	Median FPFV (days)	P* Studies < 30 days	Median FPFV (days)	P* Studies < 30 days	Median FPFV (days)	P* Studies < 30 days	Median FPFV (days)	P* Studies < 30 days	Median FPFV (days)	P* Studies < 30 days	Median FPFV (days)	P* Studies < 30 days	Median FPFV (days)	P* Studies < 30 days	Median FPFV (days)	P* Studies < 30 days	Median FPFV (days)	P* Studies < 30 days	Median FPFV (days)	P* Studies < 30 days	Median FPFV (days)	P* Studies < 30 days
BHSCT	16.0	50.00%	25.0	50.00%	42.0	0.00%	55.5	20.00%	85.0	0.00%	16.0	66.67%	45.0	50.00%	62.0	0.00%	196.0	0.00%	21.5	100.00%			285.0	100.00%			6.0	100.00%
NHSCT			11.0	100.00%									49.5	0.00%	28.5	100.00%	48.0	0.00%					24.0	0.00%				
SEHSCT	37.0	0.00%	56.0	50.00%									71.0	33.33%					17.0	100.00%								
SHSCT	69.0	33.33%	38.0	33.33%			70.0	0.00%					23.0	75.00%														
WHSCT	59.0	0.00%									70.5	50.00%			21.0	100.00%												

	ORT				PCR				REN				RES				STR				VIS				CDT				In Year Totals (2022-23)							
	Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm		Comm		Non-Comm	
	Median FPFV (days)	P* Studies < 30 days	Median FPFV (days)	P* Studies < 30 days	Median FPFV (days)	P* Studies < 30 days	Median FPFV (days)	P* Studies < 30 days	Median FPFV (days)	P* Studies < 30 days	Median FPFV (days)	P* Studies < 30 days	Median FPFV (days)	P* Studies < 30 days	Median FPFV (days)	P* Studies < 30 days	Median FPFV (days)	P* Studies < 30 days	Median FPFV (days)	P* Studies < 30 days	Median FPFV (days)	P* Studies < 30 days	Median FPFV (days)	P* Studies < 30 days	Median FPFV (days)	P* Studies < 30 days	Median FPFV (days)	P* Studies < 30 days	Median FPFV (days)	P* Studies < 30 days	Median FPFV (days)	P* Studies < 30 days	Median FPFV (days)	P* Studies < 30 days	Median FPFV (days)	P* Studies < 30 days
BHSCT			41.5	50.00%			7.0	60.00%	93.0	0.00%	103.0	0.00%	194.5	50.00%	25.5	50.00%	126.0	0.00%	58.5	25.00%	13.0	57.14%	71.5	25.00%			4.0	100.00%	85.0	0.00%	33.5	50.00%				
NHSCT					0.0	100.00%	0.0	70.00%	406.0	0.00%	15.0	66.67%			94.0	0.00%			56.5	50.00%							7.0	66.67%	28.5	100.00%	24.0	50.00%				
SEHSCT							0.0	77.78%	44.0	0.00%	26.0	60.00%															13.0	66.67%	40.5	0.00%	21.5	63.33%				
SHSCT							0.0	71.43%	224.0	0.00%	247.0	28.57%			40.5	50.00%			121.0	20.00%							1.0	100.00%	166.5	16.67%	39.3	41.67%				
WHSCT							30.0	50.00%			166.5	50.00%			31.0	50.00%			338.5	0.00%							8.5	100.00%	59.0	0.00%	31.0	50.00%				