NI CRN
CLINICAL RESEARCH NETWORK

NORTHERN IRELAND CLINICAL RESEARCH NETWORK ANNUAL REPORT

2018/19

CONTENTS

1.0 EXECUTIVE SUMMARY

Clinical research is essential for better understanding of disease processes and for the development of new tests, treatments and interventions. The purpose of NICRN is to provide and manage the infrastructure necessary to support high quality clinical research in the Health and Social Care (HSC) Trusts and in primary care across N. Ireland. NICRN currently supports research (deploying 49.38 Whole Time Equivalent research staff) across twelve Clinical Specialty Groups : Cardiovascular, Child Health, Critical Care, Dementia, Diabetes, Gastroenterology, Mental Health, Renal medicine, Respiratory Health, Stroke, Primary Care and Vision. NICRN remains committed to ensuring that patient and public involvement (PPI) is integrated into its research activities through representation on the NICRN Steering Committee and in individual Clinical Specialty Groups.

In 2018/19 all five HSC Trusts and 65 out of 330 (20%) general practices were actively involved in recruiting to NICRN adopted studies. Over this period there were 185 active research studies and a total of 2116 participants were recruited. NICRN aims to support a broad spectrum of high quality clinical research studies of both observational and interventional design, including national publically funded studies and commercially sponsored studies. In 2018/19 65% of the studies were interventional and one third were commercially sponsored.

Recruitment of participants to research studies to time and target is an important quality measure and NICRN performance continues to improve with a median recruitment to target of 92% and with 35% of commercial contract studies recruiting the first patient within 30 days of set up.

A major challenge facing NICRN has been the need to support research in disease areas not covered by the existing Clinical Specialty Groups. A review of NICRN structures was undertaken, informed by a consultative workshop with key stakeholders including public and patient representatives. The outcome has been a decision to move to a model in which research support will be delivered through four separate 'Clusters' rather than through the Clinical Specialty Groups as is the case at present. Each Cluster will incorporate a range of related disease areas; the existing N. Ireland Cancer Network will form one of the four Clusters. It is hoped that the new structures will allow support for research in a broader range of disease areas, enhance collaboration between clinical research teams and will maximise efficiency of working. Migration towards the new structures will be the major task of the next 12 – 18 months.

2018/19 has been a busy and productive year for NICRN and I commend all NICRN staff, investigators and the Clinical Specialty Groups for their commitment and dedication to clinical research. A number of leads of the NICRN Clinical Specialty Groups have stood down in 2018/19 (Dr Peter Watson, Dr Stephen Todd, Prof Vivien Coates, Dr Hamish Courtney, Dr Michael Power) and I wish to thank them for their hard work and leadership in developing research within their clinical specialties.

I particularly wish to thank all those patients and members of the public who have contributed to NICRN either in an advisory capacity or as research participants who have given so generously of their time and energy.

Dr Maurice O'Kane

NICRN Director

Northern Ireland Clinical Research Network

2 BACKGROUND

The Northern Ireland Clinical Research Network (NICRN) was established in 2008 to support the staff and service users of the five Health and Social Care (HSC) Trusts and the primary care sector to participate in high quality clinical research studies. Clinical research is essential to improve understanding of disease processes and the development of new tests and treatments. From a patient perspective, involvement in clinical research offers the opportunity of prioritising research questions of most relevance to patients or carers and the possibility of contributing to and participating in high quality research studies. Patient needs are placed at the centre of NICRN activities and this is informed by Patient and Public Involvement (PPI) through representation on the Steering Committee and at Clinical Specialty Group management committee level. For health care organisations active participation in clinical research helps foster an organisational ethos of intellectual rigour and enquiry all of which go and in hand with excellence in the delivery of care.

NICRN currently comprises 12 Clinical Speciality Groups (CSGs) which are focussed on areas of existing excellence in clinical research: Cardiovascular, Child Health, Critical Care, Dementia, Diabetes, Gastroenterology, Mental Health, Primary Care, Renal, Respiratory Health, Stroke and Vision.

The NICRN provides the staffing infrastructure (including clinical research nurses, Allied Health Professionals [AHPs] along with and managerial and administrative staff) to support studies within each of the five Health and Social Care Trusts in N. Ireland.

Figure 1: Operational structure of NICRN

NICRN is organised on a hub and spoke design (**Figure 1**), with the NICRN Co-ordinating Centre providing management and administrative support to ensure effective management and co-ordination of regional activity with good communication and connectivity between the stakeholders throughout N. Ireland. The NICRN Co-ordinating Centre is hosted by the Belfast Trust and comprises the NICRN Director, Senior Manager, Senior Nurse and administrative staff.

Each CSG is directed by a Lead, or more commonly two Co-leads, who chair a clinical management group comprising research active clinical staff from across N. Ireland, including HSC Trusts, Queens University and Ulster University. There may also be patient and public representation. The responsibility of the clinical management group is to direct and oversee the activity of the CMG by prioritising and adopting new studies onto the CSG portfolio taking into account study quality, local capacity and capability. The CSG Leads are listed in **Appendix 1**.

There has been an increasing number of requests for NICRN support for clinical research in specialties outside the current twelve Clinical Specialty Groups and for the establishment of additional Clinical Specialty Groups. In consequence of this and informed by a consultative workshop of key stakeholders including PPI representatives, a restructuring of NICRN has been proposed. The outcome has been a decision to move to a model in which research support will be delivered through four separate 'Clusters' rather than through the Clinical Specialty Groups as is the case at present. Each Cluster will incorporate a range of related disease areas; the existing N. Ireland Cancer Network will form one of the four Clusters. It is hoped that the new structures will allow support for research in a broader range of disease areas, enhance collaboration between clinical research teams and will maximise efficiency of working.

3 MAJOR DEVELOPMENTS IN REPORTING YEAR

3.1 STAFFING

NICRN currently deploys 80 staff members (49.38 Whole Time Equivalents [WTE]) distributed across the five Health and Social Care (HSC) Trusts and primary care. The primary care research nurses who support studies throughout N. Ireland, are employed by the Belfast HSC Trust. Staffing levels have increased slightly from 2017/18 (Table 1).

In addition to the above, the NICRN Co-ordinating Centre staff comprise a 1.0 WTE senior manager, 1.0 WTE regional staff manager, 1.0 WTE regional portfolio manager, 0.6 WTE adoption/co-ordinator and 1.0 WTE administrator.

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	2017 - 2018		2018-2019	
Clinical Specialty Group	**WTE[1]**	**POSTS**	**WTE[1]**	**Posts**
Cardiovascular	6	10	6.2	12
Child Health	3.5	5	3.5	6
Critical Care	6.8	9	7.8	10
Dementia	2.00	3	2	2
Diabetes	3.53	6	3.53	6
Gastroenterology	1.50	3	2.5	4
Mental Health	1.00	1	1.5	2
Primary Care	2.50	3	2.5	3
Renal	3.03	6	3.1	7
Respiratory Health	7.10	11	7.4	12
Stroke	3.85	7	4.35	8
Vision	5.00	8	5	8
Total	**45.81**	**72**	**49.38**	**80**

Table 1. Staff resource supporting each of the Clinical Specialty Groups [CSG]. [1]Whole time equivalent

Of the NICRN total staff complement, 59.6% are based in Belfast HSC Trust and 40.4% % in the other four HSC Trusts (**Table 2**). The NICRN Co-ordinating Centre staff and the Primary Care team staff are employed by the Belfast HSC Trust but provide support to NICRN adopted studies across N. Ireland.

HSC Trust	2017 – 2018 [1]WTE Deployed	2018-2019 [1]WTE Deployed
BHSCT	28.63	29.43
WHSCT	5	5
NHSCT	3.85	4.85
SEHSCT	4.8	5.3
SHSCT	3.53	4.8
	45.81	49.38

Table 2. Staff resource allocation across the five HSC Trusts. [1]Whole time equivalent

3.2 STAFF TRAINING AND EDUCATION

NICRN supports continuing professional development and training of network staff. In addition to mandatory training (both HSC Trust and professional body requirements), NICRN hosts a series of half or whole day training sessions for network staff. In 2018-19 the NICRN training was delivered on the following topics:

1. Procedures for NICRN engagement with industry
2. Effective and efficient working with Clinical Research Organisationss
3. The NI Research environment
4. Optimizing clinical trials placement – the Scottish experience
5. Inspection readiness for a MHRA inspection
6. Good clinical practice
7. Time management
8. Bespoke Archive Training "Getting it right for the future"

NICRN supported a Vision Conference organised by the Vision co-leads (Prof Julie Silvestri and Prof Jonathan Jackson) on 15th March 2019, Riddle Hall, Belfast with an array of national and local speakers. The meeting was very successful, attracted over 80 attendees including clinicians and academic staff from both local universities. The conference was later praised by the UK Ophthalmology Speciality Chair Professor Rupert Bourne during a national meeting. In a separate email to the co-leads after the conference Professor Bourne described NICRN Vision as a "jewel in the CRN crown" and "really cohesive unit you have in NI and the clinical translation successes are really evident".

3.3 PORTFOLIO ACTIVITY: ADOPTED STUDIES

The number of active studies across the network varies year on year , with a small reduction in 2018/19 compared to previous years. This may reflect in part the more complex nature of active studies in the reporting period (Table 3).

Year	Total active studies across NICRN Portfolio
2015/16	198
2016/17	204
2017/18	203
2018/19	185

Table 3. Active studies across the NICRN portfolio from 2015 to 2019

The number of active studies varies between Clinical Specialty Groups and over time within individual Clinical Specialty Groups (**Tables 4a and 4b**).

Year	Cardiovascular	Child Health	Critical care	Diabetes	Dementia	Gastroenterology
2015/16	35	18	13	16	5	-
2016/17	39	16	17	17	7	1
2017/18	35	19	24	10	8	6
2018/19	38	11	18	9	7	8

Table 4a. Number of active studies by Clinical Specialty Group

Year	Mental Health	Primary Care	Renal	Respiratory Health	Stroke	Vision
2015/16	-	13	23	33	15	27
2016/17	-	13	22	31	14	28
2017/18	6	11	21	27	12	17

Table 4b. Number of active studies by Clinical Specialty Group

There is NICRN supported research activity all five N. Ireland HSC Trusts. As in previous years the Belfast HSC Trust accounts for just under half (46%) of the total active study sites delivering the NICRN portfolio (**Table 5**). The greater activity at Belfast HSC Trust reflects a number of factors which include the size of the Trust, the co-location of the Queen's University Medical School with research active academic staff and the range of specialist regional clinical services not delivered at the other Trust sites. Patients from throughout N. Ireland receiving care from a regional clinical specialty service in the Belfast HSC Trust will therefore have an opportunity to participate in clinical trials.

Of the 330 general medical practices in N. Ireland, 65 (19.7%) hosted NICRN adopted clinical studies in 2018/19. Research was also supported in 19 general dental practices.

HSC Trust	2015/16	2016/17	2017/18	2018/19
Belfast	138	133	135	125
Northern	28	35	41	40
South Eastern	27	32	37	32
Southern	41	40	39	44
Western	43	41	45	37

Table 5. The number of NICRN adopted studies active in each HSC Trust

3.4 PORTFOLIO ACTIVITY: PARTICIPANTS SCREENED AND ACCRUED

Recruitment into a clinical research study requires initial screening to ensure that the potential participant fulfils the required study inclusion and exclusion criteria. Screening may be a time consuming process for both participants and staff. NICRN has been supporting the direct clinical care teams in ensuring that screening procedures are as efficient as possible. Accrual rates will be affected by the complexity of an individual study and the stringency of the particular inclusion and exclusion criteria. As an example recruitment to observational studies may be less challenging than recruitment to more complex and onerous interventional studies. In 2018/19 there was an increase in participant recruitment compared to the previous year and accrual of approximately 1 : 4 of participants screened for eligibility (**Table 6**).

	2015/16	2016/17	2017/18	2018/19
Screened	**14276**	**9149**	**5570**	**8931**
Recruited	**4384**	**2814**	**1532**	**2115**
% Accrual	**30.7%**	**30.8%**	**27.5%**	**23.7%**

Table 6. Number of participants screened and recruited across the NICRN Study portfolio.

Recruitment within individual Clinical Specialty Groups varied from 276 participants (Dementia) to 13 (Mental Health), (**Supplementary Table 1**). These differences relate to NICRN staffing levels within individual Clinical Specialty Groups and both the number and complexity of studies coming forward for adoption.

3.5 PORTFOLIO ACTIVITY: RECRUITMENT TO TARGET

It is essential for study sponsors that research sites can accurately estimate potential participant recruitment numbers and deliver on agreed recruitment targets. Target recruitment figures will be estimated taking into account a range of factors including the study design, the target patient population and local capacity to deliver the studies. For some studies requiring stringent inclusion and exclusion criteria or which are seeking to access difficult to reach patient groups or where the study protocol is complex and labour intensive for the research team, recruitment may be challenging. For the overall success of a study it is important that recruitment targets at individual sites are realistic and feasible so that the study sponsor can ensure that a sufficient number of study sites have been enrolled. The ability to estimate and attain realistic treatment targets is an import skillset of the site research team which is based on research experience, efficient participant screening and recruitment.

Across the NICRN portfolio the median percentage recruitment to target for studies closed to recruitment has been broadly stable over the last 3 years in the range 90% to 92% **(Tables 7)**. Between individual Clinical Specialty Groups , this varied from 12.7% to 103% to 155% (**Supplementary Table 2**).

	Median % Target Recruitment
2015/16	80.8%
2016/17	90.5%
2017/18	91.7%
2018/19	92%

Table 7. Median % target recruitment attained across the NICRN portfolio for studies that have closed to recruitment.

For individual HSC Trusts the median percentage target recruitment varied from 51.4% to 104.2% **(Table 8)**. The variation between HSC Trusts reflects in major part the different portfolio of studies active at each HSC Trust site.

	2015/16		**2016/17**		**2017/18**		**2018/19**	
HSC Trust	No of active studies	Median % [1]TR	No of active studies	Median % [1]TR	No of active studies	Median % [1]TR	No of active studies	Median % [1]TR
Belfast	138	69%	133	90%	135	90%	125	82%
Northern	28	73%	35	78.3%	41	78.3%	40	80.4%
South Eastern	27	93%	32	86.4%	37	104.2%	32	107.2%
Southern	41	100%	40	57%	39	51.4%	44	71.8%
Western	43	78%	41	98.5%	45	85.4%	37	78.9%

Table 8. The median % target recruitment attained at each HSC Trust.

[1]Target Recruitment

3.6 PORTFOLIO BREAKDOWN: COMMERCIAL V. NON–COMMERCIAL SPONSORSHIP

NICRN recognises the essential role the commercial sector plays in developing new therapies and interventions. While NICRN prioritises high quality, national publicly funded studies (e.g. NIHR, MRC etc.) it does seek to strike a balance between commercial and non-commercial sector studies. Over the past four years the proportion of commercial sponsored studies has been broadly static between 35% and 41% (**Table 9**). The great majority of the commercial sector studies have been pharmaceutical industry sponsored studies of Investigational Medicinal Products (IMPs). Between Clinical Specialty Groups the proportion of commercial sponsored studies varied markedly from 5.6% (Critical Care) to 67% % (Diabetes), (**Supplementary Table 3**); this wide variation reflects the pipeline of new IMP development in different disease areas.

Year	Commercial	Non-commercial	% commercial
2015/16	78	120	39%
2016/17	82	123	40%
2017/18	72	131	35.5%
2018/19	67	118	36.2%

Table 9. Breakdown between commercial and non-commercial sponsor studies across the entire NICRN portfolio

3.7 PORTFOLIO BREAKDOWN BY STUDY TYPE

Different types of clinical study design may be deployed to answer clinical research questions and which fall into two broad categories: Interventional studies (most commonly involving using an investigational medicinal product or medical device) and Observational studies. NICRN seeks to maintain a balanced portfolio of study types that can address problems relevant to patients; in the reporting year some two thirds of studies were interventional (**Table 10**). The proportion of interventional studies varies between specialty groups, from 38% in renal medicine to 76% in Vision **(Supplementary Table 4).**

	Interventional	**Observational**	[1]**Not specified**
2018/19	121 [65.4%]	60 [32.4%]	4 [2.2%]

Table 10. Study breakdown by type [interventional, Observational, [1]Not specified]

[1]**Not specified** indicates that the study type was not recorded in the portfolio database as being either Interventional or Observational

3.8 PORTFOLIO ACTIVITY: TIME FROM STUDY SET UP TO FIRST PATIENT RECRUITED

The time interval from study set up to first patient recruited is an important measure of performance as it indicates the speed with which research teams can recruit participants to the study. The time measurement commences when a study has received all relevant approvals to proceed (research ethics and local Trust research governance approval) and when the study sponsor has put in place all other arrangements necessary for the study to commence (e.g. the provision of study investigational medicinal product, study specific training etc).

Across the NICRN portfolio the median time to first patient recruited was 41 days for commercial contract studies (range 0 to 164 days) between Clinical Specialty Groups) and 44 days for non-commercial contract studies (range 27 to 85 days between Clinical Specialty Groups), (**Table 11 and Supplementary Table 5).**

Across the NICRN portfolio the proportion of studies recording first patient recruited < 30 days was 35.1 % for commercial contract studies (range 0 to 100% between Clinical Specialty Groups) and 47% for non-commercial contract studies (range 14.3 to 75%), (**Table 11 and Supplementary Table 5).**

	Commercial contract studies	**Non - commercial contract studies**
2017/18 % of studies meeting 30 day target	33.1%	46.7%
2017/18 Median time (days) to first patient recruited	51 days	34 days
2018/19 % of studies meeting 30 day target	35.1%	47%
2018/19 Median time (days) to first patient recruited	41 days	44 days

Table 11. Time to first patient recruited for commercial contract and non-commercial contract studies across the NICRN portfolio.

There was significant variation between Trusts in both the median time to first patient recruited and in the proportion of studies with first patient recruited < 30 days (**Table 12**); this variation relates in major part to differences the study portfolios between Trusts.

2018/19	Commercial Contract		Non-Commercial contract	
	Median time (days)	% < 30 days	Median time (days)	% < 30 days
BHSCT	64	35.8%	43	41.2%
NHSCT	177	44.4%	90	41.4%
SEHSCT	47	5.0 %	172	52.8%
SHSCT	95	16.7%	57	46.7%
WHSCT	22	77.8%	131	57.7%

Table 12. Median time to first patient recruited (days) and percentage of NICRN studies recruiting first patient < 30 days in HSC Trusts for commercial and non-commercial contract studies

3.9 COMPARISON WITH NIHR HIGH LEVEL OBJECTIVES

NIHR reports annually on performance against NIHR CRN High Level Objectives (HLO) with the most recent report available for 2018/19 (National Institute for Health Research, NIHR CRN High Level Objectives Year End Performance report-2018/19). Direct comparison of NICRN performance with NIHR HLOs is hampered by the use of differing definitions for the various items measured. The recent development of an agreed set of consistent UK-wide metrics is therefore welcome and should allow more meaningful comparison.

HLO 1 ***Participant recruitment target.***

No recruitment target is set for N. Ireland.

HLO2 A and B ***Proportion of commercial contract studies and non-commercial contract studies achieving recruitment to time and target. The NIHR HLO is 80% of studies recruiting to time and target. (The NIHR attainment was 67% for commercial and 82% for non-commercial contract studies in 2018/19).***

The prospective recruitment period end date is not yet consistently recorded in N. Ireland; a direct comparison is not therefore possible. Across the NICRN portfolio the median recruitment to target was 92% in 2018/19.

HLO3A ***Number of commercial contract studies undertaken (Target 700 new studies, attained 740).***

NICRN added 67 commercial contract studies in 2018/19. No NICRN target is set for this.

HLO3B ***The percentage of commercial contract studies supported by NIHR CRN when compared to the total number of commercial MHRA Clinical Trial Authorisation approvals for Phase II-IV studies (Target 75%, attained 75%).***

No NICRN target is set for this and it is difficult to compute for N. Ireland.

HLO4 ***The percentage of studies which achieved NHS set up at all sites within 40 calender days (from 'Date Site Selected to Date Site Confirmed).***

Data are not currently collected in this format.

HLO5A ***The percentage of commercial contract studies which achieved first participant recruited within 30 calender days (Target 80%, attained 36%).***

For NICRN the proportion of commercial contract studies recruiting the first participant within 30 days was 35.1% in 2018/19.

HLO5B ***The percentage of non-commercial contract studies which achieved first participant recruited within 30 calender days (Target 80%, attained 46%)***

For NICRN the proportion of non-commercial contract studies recruiting the first participant within 30 days was 47% in 2018/19.

HLO6A. ***The proportion of Trusts recruiting into portfolio studies (Target 99%, attained 99%).***

All N. Ireland Trusts i.e. 100% recruit into NICRN portfolio studies.

HLO6b. ***The proportion of Trusts recruiting to commercial contract studies. (Target 70%, attained 79%).***

All N. Ireland Trusts i.e. 100% recruited to commercial contract studies.

HLO6C ***The proportion of General Medical Practices recruiting to portfolio studies. (Target 45%, attained 38%)***

In N. Ireland 19.7% of General Medical Practices recruited to portfolio studies in 2018/19.

HLO7 ***The number of patients recruited into Dementias and Neurodegeneration Specialty Studies.***

No recruitment target is set for N. Ireland.

4. NICRN STEERING COMMITTEE

The NICRN Steering committee met on one occasion over the reporting period (11 December 2018).

Membership of the NICRN Steering Committee

Maurice O'Kane	NICRN Director (Chair)
Paul Biagioni	NICRN senior manager
Margaret McFarland	BSHCT pharmact
Judy Bradley	Clinical Specialty Group lead
Sonia McKenna	NICRN senior staff manager
Trevor Lyttle	PPI
Sonia Patton	PPI
Frances Johnston	Research Manager NHSCT
Melanie Morris	NICTN senior manager
Janice Bailie	PHA R&D Division
Clive Wolsley	PHA R&D Division
Colette Donaghy	Venn Life Sciences
Dermot Hughes	Medical Director WHSCT
James McElnay,	QUB
Cherie Armour,	Ulster University
Danny McAuley,	Clinical Specialty Group lead
Collette Goldrick	APBI
Shane Jackson	NICRN Co-ordinating Centre
Roisin Kerr	NICRN Co-ordinating Centre
Ciara McKenna	NICRN Co-ordinating Centre

5 PATIENT &PUBLIC ENGAGEMENT

In line with HSC Research and Development Division policy, NICRN wishes to ensure that Patient and Public Involvement (PPI) is integrated into the research cycle so that researchers prioritise topics that are important to service users and carers and formulate questions, processes and outcomes that are meaningful to people other than just the researcher.

The NICRN Steering Committee includes two PPI representatives. For each of the Clinical Specialty Groups, the management committee must be able to demonstrate appropriate Personal and Public Involvement (PPI) in the decision making process but there is no mandated approach to PPI and committees are free to choose the most appropriate way to involve patients, carers and the public. Five of the 12 clinical management groups currently have PPI members and have full voting rights as regards study adoption.

On International Clinical Trials Day teams of NICRN staff based in each of the HSC Trusts participated in public engagement events to raise the profile of clinical research and to encourage patients, carers and the public to ask their health professional about research opportunities that might be available to them and remind health and social care professionals to be research aware.

The NICRN team at SHSCT publicising International Clinical Trials Day on 21 May 2018.

6. PUBLICATIONS ARISING FROM NICRN ADOPTED STUDIES

The NICRN Co-ordinating Centre has been informed of the following publications arising from NICRN supported studies. There may be additional publications of which the Co-ordinating Centre is unaware.

Child Health

1. Griffiths J et al. Enteral lactoferrin to prevent infection for very preterm infants: the ELFIN RCT. Health Technol Assess. 2018 Dec;22(74):1-60.
2. Griffiths J et al. ELFIN trial investigators group. Lancet. 2019 Feb 2;393(10170):423-433. (

Critical Care

1. Development and validation of parsimonious algorithms to classify ARDS phenotypes. Sinha P Delucchi KL McAuley DF O'Kane CM Matthay MA Calfee CS. Lancet Respiratory Medicine (in press).

2. Randomised controlled trial of biomarker-guided antibiotic stewardship in suspected ventilator-associated pneumonia. Hellyer TP McAuley DF Walsh TS Anderson NH Conway Morris A Singh S Dark P Roy AI Perkins GD McMullan R Emerson LM Blackwood B Wright SE Kefala K O'Kane CM Baudouin SV Paterson AL Rostron AJ Agus AM Bannard-Smith J Robin NM Welters ID Bassford C Yates B Spencer C Laha SK Hulme J Bonner S Linnett V Sonksen J Van Den Broeck T Boschman G Keenan J Scott J Allen AJ Phair G Parker J Bowett S Simpson AJ. Lancet Respiratory Medicine (in press).

3. Statistical Analysis Plan for the Standard versus Accelerated Initiation of Renal Replacement Therapy in Acute Kidney Injury (STARRT-AKI) trial. The STARRT-AKI Investigators. Critical Care and Resuscitation (in press).

4. Heterogeneity of treatment effect by baseline risk of mortality in critically ill patients: Re-analysis of three recent sepsis and ARDS randomised controlled trials (2019). Santhakumaran S Gordon A Prevost AT O'Kane C McAuley DF Shankar-Hari M. Critical Care (in press).

5. Prevention of post-operative complications by using a HMG-CoA reductase inhibitor in patients undergoing one-lung ventilation for non-cardiac surgery: study protocol for a randomised controlled trial (2018). Shyamsundar M O'Kane C. Perkins GD Kennedy G Campbell C Agus A Phair G McAuley DF. Trials 19:690

6. Role of Active Deresuscitation After Resuscitation-2 (RADAR-2) - a pilot randomised controlled trial of conservative fluid administration and deresuscitation in critical illness: study protocol (2018). Silversides JA Marshall JC Ferguson AJ Blackwood B McAuley DF Critical Care Horizons 2018:9-15

7. ASpirin as a Treatment for Acute Respiratory Distress Syndrome – a multi-centre, randomised, double-blind, placebo-controlled trial (STAR): study protocol (2018). Toner P O'Kane C McNamee JJ Verghis R McAuley DF Critical Care Horizons 2018:1-7

8. Identifying associations between diabetes and acute respiratory distress syndrome in patients with acute hypoxemic respiratory failure: an analysis of the LUNG SAFE database (2018). Boyle AJ Madotto F Laffey JG Bellani G Pham T Pesenti A Thompson BT O'Kane CM Deane AM McAuley DF on behalf of the LUNG SAFE Investigators and the ESICM Trials Group. Critical Care 22:268

9. Deresuscitation of patients with iatrogenic fluid overload is associated with reduced mortality (2018). Silversides JA Fitzgerald E Manickavasagam U Lapinsky SE Nisenbaum R Hemmings N Nutt C Trinder TJ Pogson D Fan E Ferguson AJ McAuley DF Marshall JC for the Role of Active Deresuscitation After Resuscitation (RADAR) investigators. Critical Care Medicine 46:1600-1607.

10. Extracorporeal carbon dioxide removal for lowering the risk of mechanical ventilation: Research questions and clinical potential for the future (2018). Boyle AJ Sklar MC McNamee JJ Brodie D Slutsky AS Brochard L McAuley DF on behalf of the International ECMO Network (ECMONet). Lancet Respiratory Medicine 6:874–84.

Diabetes Publications

1. Coates VE, Slevin M, Carey M, Slater P, Davies M. (2018) Declining structured diabetes education in those with type 2 diabetes: A plethora of individual and organisational reasons. Patient Education and Counseling. 101(4):696-702. doi: 10.1016/j.pec.2017.10.013.

2. Carey ME; Horne R, Davies M; Slevin M, Coates VE. Exploring organisational support for the provision of structured self-management education for people with Type 2 diabetes: findings from a qualitative study. Diabetic Medicine. 36 (6); 761-770. DOI: 10.1111/dme.13946

3. A Randomized Controlled Trial Comparing Efficacy and Safety of Insulin Glargine 300 Units/mL Versus 100 Units/mL in Older People With Type 2 Diabetes: Results From the SENIOR Study Ritzel R et al. Diabetes Care 2018;41:1672-80

4. A multicentre, UK, retrospective, observational study to assess the effectiveness of insulin glargine 300 units/ml in treating people with Type 1 diabetes mellitus in routine clinical practice (SPARTA). Pang T, Bain SC, Black RNA, Boyle JG, Elliott J, Holcombe A, Lee KCS, Mulligan C, Saunders L, Yousseif A, Baxter M. Diabet Med. 2019 Jan;36(1):110-119. Epub 2018 Nov 16.

5. Coates VE Co-Chair, Session at YDEF SESSION OUTLINE "Supporting the next generation of researchers to deliver high quality diabetes research in the UK" Date: Tuesday 5th March 2019 13:00-14:45. Location: ACC Liverpool

6. Dulaglutide and cardiovascular outcomes in type 2 diabetes (REWIND): a double-blind, randomised placebo-controlled trial. Gerstein HC et al; REWIND Investigators. Lancet. 2019 Jul 13;394(10193):121-130. Epub 2019 Jun 9.

7. Dulaglutide and renal outcomes in type 2 diabetes: an exploratory analysis of the REWIND randomised, placebo-controlled trial. Gerstein HC et al. ; REWIND Investigators. Lancet. 2019 Jul 13;394(10193):131-138. Epub 2019 Jun 9.

8. Canagliflozin and Renal Outcomes in Type 2 Diabetes and Nephropathy. N Engl J Med. 2019 Jun 13;380(24):2295-2306. doi: 10.1056/NEJMoa1811744. Epub 2019 Apr 14. Perkovic V et al. ; CREDENCE Trial Investigators. Epub 2019 Apr 14

Primary Care

The ASCEND STUDY

1. ASCEND Study Collaborative Group, 2018. Effects of aspirin for primary prevention in persons with diabetes mellitus. *New England Journal of Medicine*, *379*(16), pp.1529-1539.Published: 18 October 2018.

The GARFIELD INTERNATION REGISTRY

1. Alberts, M., Lin, J.H., Chen, Y.W., Ding, Z., Bisht, D., Kogan, E., Twyman, K. and Milentijevic, D., 2018. P3847 Risk of stroke overall and by stroke severity among newly diagnosed non-valvular atrial fibrillation patients initiating treatment with rivaroxaban versus warfarin. European Heart Journal, 39(suppl_1), pp.ehy563-P3847. Published: August 2018.

2. Camm, A.J., Cools, F., Virdone, S., Bassand, J.P., Fitzmaurice, D.A., Fox, K.A.A., Goldhaber, S.Z., Goto, S., Haas, S., Mantovani, L.G. and Pieper, K., 2018. 1354 The effect of non-recommended dosing of non-vitamin K antagonist oral anticoagulants (NOACs) on 1-year mortality in patients with newly diagnosed AF, Results from the GARFIELD-AF registry. European Heart Journal, 39(suppl_1), pp.ehy565-1354. Published: August 2018.

3. Proietti, M., Rivera-Caravaca, J.M., Esteve-Pastor, M.A., Romiti, G.F., Marin, F. and Lip, G.Y.H., 2018. 219 Predicting bleeding events in anticoagulated patients with atrial fibrillation: a comparison between HAS-BLED and GARFIELD-AF bleeding score. European Heart Journal, 39(suppl_1), pp.ehy564-219. Published: 13 September 2018.

4. Siegal, D.M., Verbrugge, F., Martin, A.C., Fiarresga, A., Camm, J., Pieper, K., Fox, K.A.A., Bassand, J.P., Haas, S., Goldhaber, S.Z. and Kakkar, A.K., 2018. P3848 Why do clinicians withhold anticoagulation in patients with atrial fibrillation and CHA2DS2VASc score of 2 or higher? European Heart Journal, 39(suppl_1), pp.ehy563-P3848. Published: August 2018.

5. Cozzolino, P., Ambrosio, G., Bassand, J.P., Cate, H.T., Cools, F., Darius, H., Fitzmaurice, D.A., Haas, S., Leheuzey, J.Y., Agnelli, G. and Rosenkvist, M., 2018. P2889 The economic burden attributable to atrial fibrillation in nine European countries: perspectives from the GARFIELD-AF registry. European Heart Journal, 39(suppl_1), pp.ehy565-P2889. Published: August 2018.

6. Bassand, J.P., Virdone, S., Goldhaber, S.Z., Camm, A.J., Fitzmaurice, D.A., Fox, K.A., Goto, S., Haas, S., Hacke, W., Kayani, G. and Mantovani, L.G., 2018. Early Risks of Death, Stroke/Systemic Embolism, and Major Bleeding in Patients with Newly Diagnosed Atrial Fibrillation: Results from the GARFIELD-AF Registry. Circulation, 139(6), pp.787-798. Published: 28 November 2018.

7. Libby P, Glynn R, Thuren T, Hilkert R, Ridker P.,2018. 358 Understanding and mitigating the risk of infection with canakinumab. European Heart Journal. 2018 Aug 1; 39(suppl_1):ehy564-358.

8. Fox, K.A.A., Berchuck, S., Camm, A.J., Bassand, J.P., Fitzmaurice, D.A., Gersh, B.J., Goldhaber, S.Z., Goto, S., Haas, S., Misselwitz, F. and Pieper, K., 2018. P2895 Evaluation of the effect of oral anticoagulants on all-cause mortality within 3 months of the diagnosis of atrial fibrillation: results from the GARFIELD-AF prospective registry. European Heart Journal, 39(suppl_1), pp.ehy565-P2895. Published: 28 August 2018.

9. Schirripa, V., Radic, P., Pieper, K., Illingworth, L., Le Heuzey, J.Y., Jansky, P., Fitzmaurice, D.A., Connolly, S., Cappato, R., Camm, J. and Atar, D., 2018. 360 Role of cardioversion in the management of non-valvular atrial fibrillation: insights from the GARFIELD-AF registry. European Heart Journal, 39(suppl_1), pp.ehy564-360. Published: August 2018.

10. Zwart, L.A.R., Geermans, T., Simsek, S., De Ruiter, J.H. and Jansen, R.W.M.M., 2018. P2893 Cognitive decline is more common in persistent atrial fibrillation than in paroxysmal atrial fibrillation in geriatric patients. European Heart Journal, 39(suppl_1), pp.ehy565-P2893. Published: August 2018.

11. Rivera Caravaca, J.M., Esteve-Pastor, M.A., Vilchez, J.A., Galvez, J., Vicente, V., Marin, F., Roldan, V. and Lip, G.Y.H., 2018. P3850 Refining stroke and bleeding risk prediction by adding consecutive biomarkers to CHA2DS2-VASc and HAS-BLED scores. European Heart Journal, 39(suppl_1), pp.ehy563-P3850. Published: August 2018.

12. Wazni, O., Hutt, E., Saliba, W., Saqi, B., Barakat, A., Tarakji, K., Kanj, M., Lindsay, B. and Hussein, A., 2018. P3849 Watchman implantation in patients with very high stroke risk. European Heart Journal, 39(suppl_1), pp.ehy563-P3849. Published: August 2018.

13. Himmelreich, J.C.L., Lucassen, W.A.M., Heugen, M., Bossuyt, P.M.M., Tan, H.L., Harskamp, R.E., Van Etten-Jamaludin, F.S. and Van Weert, H.C.P.M., 2018. 1353 Premature atrial contractions are associated with atrial fibrillation, brain ischemia, and mortality: a systematic review and meta-analysis. European Heart Journal, 39(suppl_1), pp.ehy565-1353. Published: August 2018.

14. Balci, K.G., Balcı, M.M., Çetin, E.H., Çelebi, Ö.Ö. and Maden, O., 2019. Lower rates of vitamin-K-antagonists usage are also related to physicians' and patients' comfort with novel oral anticoagulants. Acta cardiologica, pp.1-1. Published online: 16 Jan 2019.

The INTERVAL STUDY

15. Clarkson, J.E., Pitts, N.B., Bonetti, D., Boyers, D., Braid, H., Elford, R., Fee, P.A., Floate, R., Goulão, B., Humphris, G. and Needleman, I., 2018. INTERVAL (investigation of NICE technologies for enabling risk-variable-adjusted-length) dental recalls trial: a multicentre randomised controlled trial investigating the best dental recall interval for optimum, cost-effective maintenance of oral health in dentate adults attending dental primary care. BMC oral health, 18(1), p.135. Published: August 2018.

The Prefer in VTE Study

16. Kroep, S., Chuang, L.H., Cohen, A., Gumbs, P., van Hout, B., Monreal, M., Willich, S.N., Gitt, A., Bauersachs, R. and Agnelli, G., 2018. The impact of co-morbidity on the disease burden of VTE. Journal of thrombosis and thrombolysis, 46(4), pp.507-515. Published: November 2018.

Medicines Management in People with Dementia in Primary Care

17. McGrattan, M., Barry, H.E., Ryan, C., Cooper, J.A., Passmore, A.P., Robinson, A.L., Molloy, G.J., Darcy, C.M., Buchanan, H. and Hughes, C.M., 2018. The development of a Core Outcome Set for medicines management interventions for people with dementia in primary care. Age and ageing, 48(2), pp.260-266. Published: March 2018.

The Polypharmacy Study

18. Rankin, A., Cadogan, C.A., Patterson, S.M., Kerse, N., Cardwell, C.R., Bradley, M.C., Ryan, C. and Hughes, C., 2018. Interventions to improve the appropriate use of polypharmacy for older people. Cochrane Database of Systematic Reviews, (9). Published: September 2018.

19. Cadogan, C., Rankin, A., Lewin, S. and Hughes, C., 2018. 33 Assessing Complexity in Interventions to Improve Appropriate Polypharmacy in Older People using the Intervention Complexity Assessment Tool for Systematic Reviews. Age and Ageing, 47(suppl_5). Published: September 2018.

The Med-Diet Study

20. Moore, S.E., McEvoy, C.T., Prior, L., Lawton, J., Patterson, C.C., Kee, F., Cupples, M., Young, I.S., Appleton, K., McKinley, M.C. and Woodside, J.V., 2018. Barriers to adopting a Mediterranean diet in Northern European adults at high risk of developing cardiovascular disease. Journal of human nutrition and dietetics, 2018 Aug; 31(4):451-462. doi: 10.1111/jhn.12523. Published: August 2018.

21. Erwin CM, McEvoy CT, Moore SE, Prior L, Lawton J, Kee F, Cupples ME, Young IS, Appleton K, McKinley MC, Woodside JV.,2018 A qualitative analysis exploring preferred methods of peer support to encourage adherence to a Mediterranean diet in a Northern European population at high risk of cardiovascular disease. BMC public health. Dec; 18(1):213. Published: 18 Dec 2018.

The TEAM-MED Study

22. McEvoy, C., Moore, S., Appleton, K., Cupples, M., Erwin, C., Hunter, S., Kee, F., McCance, D., Patterson, C., Young, I. and McKinley, M., 2018. Trial to Encourage Adoption and Maintenance of a Mediterranean Diet (TEAM-MED): Protocol for a Randomised Feasibility Trial of a Peer Support Intervention for Dietary Behaviour Change in Adults at High Cardiovascular Disease Risk. International journal of environmental research and public health. Int J Environ Res Public Health. 15(6), p.1130, 2018 Jun. Published: June 2018.

The SHARE- D Study

23. Cupples, M.E., Cole, J.A., Hart, N.D., Heron, N., McKinley, M.C. and Tully, M.A., 2018. Shared decision-making (SHARE-D) for healthy behaviour change: a feasibility study in general practice. BJGP open, 2(2), p.bjgpopen, Vol 2 (2) 18X101517. Published: April 2018.

The Walk with Me Study

24. Tully, M.A., Cunningham, C., Cupples, M.E., Farrell, D., Hardeman, W., Hunter, R.F., Laventure, B., McDonough, S.M., Morgan, J., Murphy, M.H. and Simpson, E.E., 2018. Walk with Me: a protocol for a pilot RCT of a peer-led walking programme to increase physical activity in inactive older adults. Pilot and feasibility studies, 4(1), p.117. Published: 21 June 2018.

The Northern Ireland Baby Hearts Study

25. McCullough, N., Dolk, H., Loane, M., Lagan, B.M., Casey, F. and Craig, B., 2018. The Northern Ireland Baby Hearts Study: A Case-Control study using a hybrid data linkage method. International Journal of Population Data Science, 3(2). Published online: 14 June 2018.

The SNAC TRIAL (NN9924-3790)

26. Bækdal, T.A., Breitschaft, A., Navarria, A. and Hansen, C.W., 2018. A randomized study investigating the effect of omeprazole on the pharmacokinetics of oral semaglutide. Expert opinion on drug metabolism & toxicology, 14(8), pp.869-877. Published online: 30 June 2018

International Cancer Benchmarking Partnership –ICPB Study

27. Weller, D., Menon, U., Falborg, A.Z., Jensen, H., Barisic, A., Knudsen, A.K., Bergin, R.J., Brewster, D.H., Cairnduff, V., Gavin, A.T. and Grunfeld, E., 2018. Diagnostic routes and time intervals for patients with colorectal cancer in 10 international jurisdictions; findings from a cross-sectional study from the International Cancer Benchmarking Partnership (ICBP). BMJ open, 8(11), p.e023870.Published: 28 Sept 2018.

28. Eden, M., Harrison, S., Griffin, M., Lambe, M., Pettersson, D., Gavin, A., Brewster, D.H., Lin, Y., Johannesen, T.B., Milne, R.L. and Farrugia, H., 2019. Impact of variation in cancer registration practice on observed international cancer survival differences between International Cancer Benchmarking Partnership (ICBP) jurisdictions. Cancer epidemiology, 58, pp.184-192. Published: Feb 2019

The Vitamin –D Study

29. Wallace, H.J., Holmes, L., Ennis, C.N., Cardwell, C., Woodside, J.V., Young, I.S., Bell, P.M., Hunter, S.J. and McKinley, M.C., 2019. Effect of Vitamin D3 Supplementation on Insulin Resistance and β-Cell Function in Prediabetes: A Double-Blind Randomised Placebo Controlled Trial. Available at SSRN 3323114. Published: 28 Jan 2019.

Dose-Finding of Semaglutide Administered Subcutaneously Once Daily Versus Placebo and Liraglutide in Subjects with Type 2 Diabetes (NN9535-4191)

30. Christou, G.A., Katsiki, N., Blundell, J., Fruhbeck, G. and Kiortsis, D.N., 2019. Semaglutide as a promising antiobesity drug. Obesity Reviews, 20(6), pp.805-815. Published: 12 February 2019

Renal medicine

1. Quality of life with conservative care compared with assisted peritoneal dialysis and haemodialysis.

   Iyasere O, Brown EA, Johansson L, Davenport A, Farrington K, Maxwell AP, Collinson H, Fan S, Habib AM, Stoves J, Woodrow G.

   Clin Kidney J. 2018 Jul 20;12(2):262-268. doi: 10.1093/ckj/sfy059. eCollection 2019 Apr.

   PMID: 30976407 Free PMC Article

2. Longitudinal Trends in Quality of Life and Physical Function in Frail Older Dialysis Patients: A Comparison of Assisted Peritoneal Dialysis and In-Center Hemodialysis.

   Iyasere O, Brown E, Gordon F, Collinson H, Fielding R, Fluck R, Johansson L, Morgan N, Stoves J, Vardhan A, Woodrow G, Davenport A.

   Perit Dial Int. 2019 Mar-Apr;39(2):112-118. doi: 10.3747/pdi.2018.00086. Epub 2019 Jan 18.

   PMID: 30661007

3. Healthcare use, costs and quality of life in patients with end-stage kidney disease receiving conservative management: results from a multi-centre observational study (PACKS).

   Phair G, Agus A, Normand C, Brazil K, Burns A, Roderick P, Maxwell AP, Thompson C, Yaqoob M, Noble H.

   Palliat Med. 2018 Sep;32(8):1401-1409. doi: 10.1177/0269216318775247. Epub 2018 May 16.

   PMID:29767579

4. Establishing a clinical phenotype for cachexia in end stage kidney disease - study protocol.

   Reid J, Noble HR, Adamson G, Davenport A, Farrington K, Fouque D, Kalantar-Zadeh K, Mallett J, McKeaveney C, Porter S, Seres DS, Shields J, Slee A, Witham MD, Maxwell AP.

   BMC Nephrol. 2018 Feb 13;19(1):38. doi: 10.1186/s12882-018-0819-3.

   PMID:29439674 Free PMC Article

5. Atrasentan and renal events in patients with type 2 diabetes and chronic kidney disease (SONAR): a double-blind, randomised, placebo-controlled trial.

   Heerspink HJL, Parving HH, Andress DL, Bakris G, Correa-Rotter R, Hou FF, Kitzman DW, Kohan D, Makino H, McMurray JJV, Melnick JZ, Miller MG, Pergola PE, Perkovic V, Tobe S, Yi T, Wigderson M, de Zeeuw D; SONAR Committees and Investigators.

   Lancet. 2019 May 11;393(10184):1937-1947. doi: 10.1016/S0140-6736(19)30772-X. Epub 2019 Apr 14 Erratum in: Lancet. 2019 May 11;393(10184):1936. PMID: 30995972

6. Intravenous Iron in Patients Undergoing Maintenance Hemodialysis.

   Macdougall IC, White C, Anker SD, Bhandari S, Farrington K, Kalra PA, McMurray JJV, Murray H, Tomson CRV, Wheeler DC, Winearls CG, Ford I; PIVOTAL Investigators and Committees.

   N Engl J Med. 2019 Jan 31;380(5):447-458. doi: 10.1056/NEJMoa1810742. Epub 2018 Oct 26. Erratum in: N Engl J Med. 2019 Jan 14;:.

7. P**Risk prediction** for **acute kidney injury** in **acute** medical admissions in the UK.

Risk Investigators .

QJM. 2019 Mar 1;112(3):197-205. doi: 10.1093/qjmed/hcy277. PMID: 30496574 MID: 30365356

Vision

The Glaucoma studies TAGS and LIGHT, supported by NICRN have completed.

- 15-minute laser is best treatment for glaucoma patients, says study; https://www.theguardian.com/society/2019/mar/09/15-minute-laser-treatment-best-for-glaucoma-patients
- Laser trabeculoplasty as first-line glaucoma treatment; https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)32553-4/fulltext
- Gazzard G, et al, Selective laser trabeculoplasty versus eye drops for first-line treatment of ocular hypertension and glaucoma (LiGHT): a multicentre randomised controlled. March 09, 2019; https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)32213-X/fulltext ial

The Safari study supported by NICRN article, which has been accepted into the British journal of Ophthalmology:

- Gale R; Anatomical and Functional Outcomes Following Switching from Aflibercept to Ranibizumab in Neovascular Age-Related Macular Degeneration in Europe. In process of being published.

- Or C, et al, (Das R, Chakravarthy U); Combined Multimodal Analysis of Peripheral Retinal and Macular Circulation in Diabetic Retinopathy (COPRA Study). Ophthalmol Retina. 2019 Jul;3(7):580-588. doi: 10.1016/j.oret.2019.03.001. Epub 2019 Mar 20.
- Das R, et al, (Hogg RE, Chakravarthy U); Disorganization of Inner Retina and Outer Retinal Morphology in Diabetic Macular Edema. JAMA Ophthalmol. 2018 Feb 1;136(2):202-208. doi: 10.1001/jamaophthalmol.2017.6256.

The LEAD study supported by NICRN:

- Guymer RH, et al, (Chakravarthy U); Laser Intervention in Early Stages of Age-Related Macular Degeneration Study Group. Subthreshold Nanosecond Laser Intervention in Age-Related Macular Degeneration: The LEAD Randomized Controlled Clinical Trial.Ophthalmology. 2019 Jun;126(6):829-838. doi: 10.1016/j.ophtha.2018.09.015. Epub 2018 Sep 20. Update in: Ophthalmology. 2019 Jun;126(6):839-840.

The INTREPID study supported by NICRN:

- Freiberg FJ, et al, (Chakravarthy U); Microvascular abnormalities secondary to radiation therapy in neovascular age-related macular degeneration: findings from the INTREPID clinical trial. Br J Ophthalmol. 2019 Apr;103(4):469-474. doi: 10.1136/bjophthalmol-2018-311865. Epub 2018 Jun 21.

The LOBS study supported by NICRN:

- Nittala MG, et al, (Hogg RE, Chakravarthy U); Changes in Retinal Layer Thickness in the Contralateral Eye of Patients with Unilateral Neovascular Age-Related Macular Degeneration. Ophthalmol Retina. 2019 Feb;3(2):112-121. doi: 10.1016/j.oret.2018.09.017. Epub 2018 Sep 27.

The IVAN study supported by NICRN:

- Bailey C, et al, (Peto T, Chakravarthy U); writing committee for the IVAN Study Group. Intralesional Macular Atrophy in Anti-Vascular Endothelial Growth Factor Therapy for Age-Related Macular Degeneration in the IVAN Trial. Ophthalmology. 2019 Jan;126(1):75-86. doi: 10.1016/j.ophtha.2018.07.013. Epub 2018 Oct 6.
- Rogers CA, et al, (Chakravarthy U); Serum Vascular Endothelial Growth Factor Levels in the IVAN Trial; Relationships with Drug, Dosing, and Systemic Serious Adverse Events. Ophthalmol Retina. 2018 Feb;2(2):118-127. doi: 10.1016/j.oret.2017.05.015.
- IVAN enrolled in Belfast supported by NICRN

The IRIS study supported by NICRN:

- Chakravarthy U, et al; Changes in intraocular pressure after intravitreal fluocinolone acetonide (ILUVIEN): real-world experience in three European countries. Br J Ophthalmol. 2018 Sep 21. pii: bjophthalmol-2018-312284. doi: 10.1136/bjophthalmol-2018-312284.

The EMERALD study supported by NICRN:

- Lois N, et al, (Azuara-Blanco A); EMERALD Study Group. Effectiveness of Multimodal imaging for the Evaluation of Retinal oedema And new vesseLs in Diabetic retinopathy (EMERALD). BMJ Open. 2019 Jun 28;9(6):e027795. doi: 10.1136/bmjopen-2018-027795. PubMed PMID: 31256030; PubMed Central PMCID: PMC6609061.

The DIAMOND study supported by NICRN:

- Lois N, et al, (Azuara-Blanco A); DIAMONDS Study Group. Diabetic macular oedema and diode subthreshold micropulse laser (DIAMONDS): study protocol for a randomised controlled trial. Trials. 2019 Feb 12;20(1):122. doi: 10.1186/s13063-019-3199-5. PubMed PMID: 30755274; PubMed Central PMCID: PMC6373040.

An overview paper outlining the activity of NIHR. NICRN Vision Co-Leads and Professor U Chakravarthy are contributing authors

- Dawson S, et al, (Chakravarthy U) , NIHR Ophthalmology Specialty Group (including ***Jackson J & Silvestri G***) (2018).“Ophthalmology research in the UK’s National Health Service: the structure and performance of the NIHR’s Ophthalmology research portfolio”
  EYE 33(4) 610-618

The NUN study supported by NICRN:

- Dietary patterns were not associated with age-related macular degeneration: a cross-sectional analysis in the Irish Nun **Eye** Study. McCarter RV, Neville CE, **Silvestri G**, Montgomery S, Moore E, Silvestri V, Cardwell CR, Hogg RE, Woodside JV, McKay GJ. Ir J Med Sci. 2019 Aug;188(3):1005-1012. doi: 10.1007/s11845-018-1932-9. Epub 2018 Nov 22.
- Dietary Patterns and Retinal Vessel Caliber in the Irish Nun Eye Study. Neville CE, Montgomery S, **Silvestri G**, McGowan A, Moore E, Silvestri V, Cardwell C, McEvoy CT, Maxwell AP, Woodside JV, McKay GJ. J Nutr Health Aging. 2018;22(7):751-758. doi: 10.1007/s12603-017-0992-2.
- Dietary patterns and chronic kidney disease: a cross-sectional association in the Irish Nun Eye Study.

  Paterson EN, Neville CE, **Silvestri G**, Montgomery S, Moore E, Silvestri V, Cardwell CR, MacGillivray TJ, Maxwell AP, Woodside JV, McKay GJ.

  Sci Rep. 2018 Apr 27;8(1):6654. doi: 10.1038/s41598-018-25067-7.

The ROSA study supported by NICRN**:**

- Sophie D. West, et al, Continuous positive airway pressure effect on visual acuity in patients with type 2 diabetes and obstructive sleep apnoea: a multicentre randomised controlled trial

  European Respiratory Journal 2018 52: 1801177; **DOI:** 10.1183/13993003.01177-2018.

  http://erj.ersjournals.com/content/52/4/1801177

The IRISS study supported by NICRN:

- Chakravarthy U, Et al, Changes in intraocular pressure after intravitreal fluocinolone acetonide (ILUVIEN): real-world experience in three European countries

https://bjo.bmj.com/content/early/2018/09/21/bjophthalmol-2018-312284

This open access article is cited on PubMed

https://www.ncbi.nlm.nih.gov/pubmed/30242062

APPENDICES

APPENDIX 1: CLINICAL SPECIALTY GROUP LEADS

Clinical Specialty Group	Lead(s)
Cardiovascular	Professor Donna Fitzsimons (QUB) / Dr Patrick Donnelly (SEHSCT)
Child Health	Dr David Sweet (BHSCT) / Dr Anthony McCarthy (BHSCT)
Critical Care	Professor Danny McAuley (QUB)
Dementia	Professor Peter Passmore (QUB) / Dr Bernadette McGuinness (QUB)[1]
Diabetes	Dr Alyson Hill (UU)[2] / Dr John Lindsay (BHSCT)[3]
Gastroenterology	Dr Seamus Murphy (SHSCT)[4] / Dr Patrick Allen (SEHSCT)
Mental Health	Professor Gerry Leavey (UU) / Dr Ciaran Mulholland (NHSCT)
Primary Care	Mrs Claire Leathem (BHSCT) / Dr Nigel Hart (QUB)
Renal	Professor Peter Maxwell (BHSCT) / Dr Neal Morgan (SHSCT)
Respiratory Health	Professor Judy Bradley (QUB) / Professor Lorcan McGarvey (QUB)
Stroke	Dr Patricia Fearon (BHSCT)[5] / Mrs Carolee McLaughlin (BHSCT)
Vision	Professor Julie Silvestri (BHSCT) / Professor Jonathan Jackson (BHSCT)

[1]Replacing Dr Stephen Todd (WHSCT)

[2]Replacing Prof Vivien Coates (UU)

[3]Replacing Dr Hamish Courtney (BHSCT)

[4]Replacing Dr Peter Watson (BHSCT)

[5]Replacing Dr Stephen Todd (WHSCT)

Supplementary Table 1

Number of patients screened and recruited by Clinical Specialty Group

	Cardiovascular		Child Health		Critical Care		Diabetes		Dementia		Gastro – enterology	
Year	**S**	**R**	**S**	**R**	**S**	**R**	**S**	**R**	**S**	**R**	**S**	**R**
2015/16	856	404	190	138	2365	220	2148	382	255	2	-	-
2016/17	825	553	196	75	1723	479	1136	287	689	412	6	0
2017/18	785	283	261	73	1262	427	371	96	137	93	33	8
2018/19	521	243	133	65	2057	201	341	43	551	276	45	28

	Mental Health		Primary Care		Renal		Respiratory Health		Stroke		Vision	
Year	**S**	**R**	**S**	**R**	**S**	**R**	**S**	**R**	**S**	**R**	**S**	**R**
2015/16			4049	2587	696	337	2145	101	1389	94	183	119
2016/17			1175	111	247	213	1439	154	1320	205	393	325
2017/18	16	7	358	48	331	177	1489	195	366	61	161	64
2018/19	15	13	459	317	456	181	1322	234	411	214	2620	300

Supplementary Table 2

Median % attainment of recruitment target by Clinical Specialty Group

Year	Cardiovascular	Child Health	Critical Care	Dementia	Diabetes	Gastro - enterology	Mental health
2015/16	90%	50%	80%	2%	110%	-	-
2016/17	97%	40%	77%	100%	100%	-	-
2017/18	88%	76%	155%	102%	91.7%	60%	-
2018/19	100%	94.8%	81.5%	89.1%	60%	100%	12.7%

Year	Primary care	Renal	Respiratory Health	Stroke	Vision
2015/16	105%	67%	82%	71%	88%
2016/17	106%	84%	100%	77%	80%
2017/18	100	75%	100%	68%	105%
2018/19	103%	75%	100%	45%	102.5%

Supplementary Table 3

Proportion of commercial sponsored studies by Clinical Specialty Group

Year	Cardiovas-cular	Child Health	Critical Care	Dementia	Diabetes	Gastro-enterology
2015/16	54.3%	16.7%	7.7%	20%	62.5%	-
2016/17	56.4%	18.8%	5.9%	14.3%%	82.4%	-
2017/18	54.3%	15.8%	8.3%	25%	70%	66.7%
2018/19	50%	9.1%	5.6%	43%	66.7%	50%

Year	Mental Health	Primary Care	Renal	Respiratory Health	Stroke	Vision
2015/16	-	30.8%	21.7%	57.6%	13.3%	51.9%
2016/17	-	38.5%	13.6%	58%	21.4%	42.9%
2017/18	20%	42.9%	23.8%	51.9%	17.7%	37.5%
2018/19	33.3%	42.9%	19.1%	51.9%	33.3%	29.4%

Supplementary Table 4

Study type (i.e. interventional or observational) breakdown by Clinical Specialty Group

Clinical Specialty Group	Interventional N [% of total]	Observational N [% of total]	Not stated N [% of total]
Cardiovascular	29 [76.3%]	9 [23.7%]	0 [0%]
Child Health	7 [63.6%]	4 [36.4%]	0 [0%]
Critical Care	13 [72.2%]	4 [22.2%]	1 [5.6%]
Diabetes	7 [77.8%]	2 [22.2%]	0 [0%]
Dementia	4 [57.4%]	3 [42.9%]	0 [0%]
Gastroenterology	4 [50%]	4 [50%]	0 [0%}
Mental Health	3 [50%]	3 [50%]	0 [0%]
Primary Care	6 [54.6%]	2 [18.2%]	3 [27.3%]
Renal	8 [38.1%]	13 [61.9%]	0 [0%]
Respiratory health	18 [66.7%]	9 [33.3%]	0 [0%]
Stroke	9 [75%]	3 [25%]	0 [0%]
Vision	13 [76.5%]	4 [23.5%]	0 [0%]

Supplementary Table 5

Time to first patient recruited by Clinical Specialty Group

	Commercial		Non-commercial	
	Median	% < 30 days	Median	% <30 days
Cardiovascular				
2017/18	19	50%	34	37.5%
2018/19	40	44%	32	50%
Child Health				
2017/18	65	33.3%	15	36.1%
2018/19	0	100%	58	37.5%
Critical Care				
2017/18	42	0%	8	36.2%
2018/19	-	-%	55.5	37.5%
Diabetes				
2017/18	65	30%	11	100%
2018/19	52	25%	41,5	50%
Dementia				
2017/18	164	0%	52	50%
2018/19	164	0%	78	14.3%
Gastroenterology				
2017/18	85	0%		
2018/19	85	0%	27	66.7%
Mental Health	-	-		
2017/18			45	0%
2018/19			68	40%
Primary Care				
2017/18	21	66.7%	30	75%
2018/19	30	75%	22	75%
Renal				
2017/18	31	50%	49	44.7%
2018/19	114	16.7%	46	42.5%
Respiratory health				
2017/18	51	40%	20	71.7%
2018/19	38.5	50%	27	58.8%
Stroke				
2017/18	19	50%	83	22.5%
2018/19	42.5	25%	85	33.3%
Vision				
2017/18	58	44.4%	35	40%
2018/19	39.5	50%	20.5	58.3%