



Research Annual Report 2018/19

Abbreviations

CCF	Central Commissioning Facility
CRN	Clinical Research Network
ETC	Excess Treatment Cost
HLO	High Level Objective
HRA	Health Research Authority
NHS	National Health Service
NIHR	National Institute of Health Research
ODP	Open Data Platform
PI	Principal Investigator
RTT	Recruitment to Time and Target

Purpose

To provide Clinical Governance Committee and the Board with assurance regarding Trust compliance with the Trust Key Performance Indicators for research for 2018/19.

Executive Summary

Table 1: Targets 2018/19 – Overview of progress

	Objective	Target	Target met by Trust ¹ ?	National performance
1	Increase the number of participants recruited into NIHR portfolio studies	Set by CRN – 1582 participants	1581 99.9%	
		8877 weighted points	7518.5 85%	
2	Increase the proportion of studies in the NIHR portfolio delivering to recruitment target and time – commercial contract studies	80%	88%	71%
3	Increase the proportion of studies in the NIHR portfolio delivering to recruitment target and time – non-commercial studies	80%	81%	81%
4	Reduce the time taken for eligible studies to achieve set up in the NHS: confirmation of capacity	80% within 40 days	77%	72%
5	Reduce the time taken to recruit the first participant into NIHR portfolio studies – confirmation of capacity to date first patient recruited	80% within 30 days	100% commercial 37% non-commercial Adjusted non-commercial 93%	37% commercial 48% non-commercial

¹ Green = over 80% achieving target; amber= between 60-80%; red = less than 60% achieving target

The NIHR Clinical Research Network (CRN) enables NHS Trusts to participate in high quality research that benefits the NHS and the public. This sheet shows the Trust's activity in numbers for 2018-19.



Record numbers take part

1581 participants took part in clinical research in the Trust; equivalent to 30 people a week. The top recruiting study, NICEFIT, recruited 316 participants. The Trust has now recruited over 10,000 people since national records began in 2008.



Year on year growth

The number of participants recruited into studies when adjusted for complexity hit record levels, exceeding all previous years. 2018/19 also saw an increase in the number of members of staff leading studies, and an increase in the number of specialties involved.



Record numbers compared to similar sized Trusts

The Trust is the top Small Acute Trust in the country for recruitment in the following specialties; *Ageing; Cancer; Children; ENT; Haematology*. The Trust is ranked 2 or 3 for a further 9 specialties

TOP

Record number of recruiting studies

The Trust recruited participants into 91 studies. The Trust offered people the opportunity to take part in more research studies than any other small acute Trust in the country, and was in the top 13% of Trusts nationally.



Life sciences industry research thriving

The Trust recruited 55 patients into 3 commercial contract research studies during 2018/19. 88% of the commercial studies that ended recruited the target number of participants before the end of the study.



Dementia and Neurodegeneration

Dementia and Neurodegeneration is a NIHR high priority area. The Trust recruited 132 people into studies that were adopted or co-adopted by the Dementia and Neurodegeneration specialty.



Set up and delivery

Ensuring studies are set up on time, recruited to target and delivered more efficiently is a key objective of the NIHR CRN. The Trust set up 77% of new studies within 40 days, which is just under the national target of 80%, but exceeds national performance (72%). The Trust delivered 81% of non-commercial studies to time and target.



Recognition of excellence

Dr Chris Anderson was awarded the CRN:Wessex award for 'excellence in the delivery of commercial research studies'

Sarah Diment was shortlisted for the Nursing Times Research Nurse award.

Professor Nick Cross was awarded the Rowley Prize by the International Chronic Myeloid Leukemia Foundation for his scientific achievements.

Introduction

Professor Dame Sally Davies believes that “*every patient should have the opportunity to participate in appropriate research which is relevant to her or him.... if we all work together to ensure that the NHS plays its full part in promoting and supporting research, every patient can be offered this opportunity, ...so that we can truly state: Every patient a research patient!*”².

NHS England has a statutory responsibility to promote research^{3,4}. The NHS Constitution for England (2015) has a commitment to “*promotion, conduct and use of research to improve the current and future health and care of the population’ and to ensure that patients are made aware of research that is of relevance to them*”.

The National Institute for Health Research (NIHR)⁵ is funded by the Department of Health to “*deliver research to make patients, and the NHS, better*”. There are 15 NIHR CRNs across England, each delivering research across 30 clinical specialties⁶. The NIHR only supports research that is demonstrably of the highest quality and is eligible for the NIHR Portfolio (‘the Portfolio’)⁷. The Trust is part of the CRN:Wessex, and receives infrastructure funding from CRN:Wessex to support the governance and conduct of portfolio studies.

Information included in this report

This report describes the progress made with the NIHR High Level Objectives (HLO) which covers the following:

- Objective 1: Increase the number of participants recruited into NIHR portfolio studies
- Objective 2: Increase the proportion of studies in the NIHR portfolio delivering to recruitment target and time – commercial contract studies
- Objective 3: Increase the proportion of studies in the NIHR portfolio delivering to recruitment target and time – non-commercial studies
- Objective 4: Reduce the time taken for eligible studies to achieve set up in the NHS: confirmation of capacity
- Objective 5: Reduce the time taken to recruit the first participant into NIHR portfolio studies – confirmation of capacity to date first patient recruited

Targets are also set for 2019/20.

Period covered by this report

This report covers the Trust’s research activities in the period 01 April 2018 – 31 March 2019. The information contained in the report represents the most complete information available at the time of writing. It is important to note that data on studies and patient recruitment are uploaded to the NIHR CRN Open Data Platform (ODP) by the Chief Investigator (or their delegate) on an ongoing basis. The year end cut off for submission was on 27 April 2019. Investigators are encouraged to upload data promptly, so that data reporting is accurate. However, to ensure maximum data capture, this data upload can occur months after the end of a financial year. For this reason, data reports for the same financial year may change over the course of the reporting year. The data reported in this report were downloaded from the ODP on 27 April 2019.

Summary details for individual studies (searching for ID number or short title) may be found at:

http://public-odp.nihr.ac.uk/QvAJAXZfc/opendoc.htm?document=CRNCC_Users%2FFind%20A%20Clinical%20Research%20Study.qvw&host=QVS%40win-qs1ilmcfh2h&anonymous=true&sheet=SH75&bookmark=Document\BM02&select=LB572,=StudyID=9615

² Excerpt for NIHRtv youtube video ‘enhancing patient care through research’ 2010

³ NHS Constitution (2015)

⁴ Health and Social Care Act (2012).

⁵ NIHR website (www.nihr.ac.uk).

⁶ CRN website (<https://www.nihr.ac.uk/about-us/how-we-are-managed/managing-centres/crn/>)

⁷ <http://www.nihr.ac.uk/research>

Objective 1: Increase the number of participants recruited into NIHR portfolio studies

The NHS Operating Framework states that NHS Trusts are expected to “work with the NIHR CRN locally” to contribute to “the national ambition is to double the number of patients taking part in clinical trials and other well designed research studies within five years”. The Trust research strategy endorses this ambition.

The Trust is set a recruitment target each year by CRN:Wessex. The target at the beginning of 2018/19 was 1582 participants, with a weighted recruitment of 8877. This represents an increase of 23% and 26% on our 2017/18 recruitment respectively. The trust received an increase in funding of 6%.

Annual performance commentary

- Figure 1 shows 1581 study participants were recruited into 91 NIHR CRN Portfolio studies during 2018/19 (full breakdown of the NIHR snapshot of Trust recruitment on 27 April 2019 is shown at Appendix A), and the recruitment target was missed by a single recruit. . The complexity weighting in 2018/19 was 7518.5 (Figure 2). We recruited 23% more participants in 2018/19 than in 2017/18, and increased the complexity weighting by 7%.
- The top recruiting study was a cancer study, NICEFIT. NICE FIT was investigating whether a new test could be used to diagnose bowel cancer. The Trust recruited 316 patients during 2018/19. The national complexity weighting for this study was downgraded from 11 points to 1 point per patient towards the end of the study. This change lost the Trust 3160 complexity weighted points.
- The complexity weighting informed the core funding allocation from CRN:Wessex. The Trust received the maximum uplift for 2018/19;
- A breakdown of recruitment/ specialty is shown at Figure 3. Cancer was the highest recruiting specialty in 2018/19, followed by reproductive health and cardiology. The Trust recruited into 23 of the 30 national specialties. When adjusted for complexity, reproductive health had the highest weighted recruitment (Figure 4). This reflects to differing complexities of the studies across specialties.
- The Trust recruiting studies to 91 (Figure 5). The Trust offers more studies than any other small acute Trust in the country, and is in the top 14% of Trusts nationally. These studies were led locally by 45 Principal Investigators;
- The Trust is the top Small Acute Trust in the country for recruitment in the following specialties:
 - Ageing
 - Cancer
 - Children
 - ENT
 - HaematologyThe Trust is ranked 2 or 3 for a further 9 specialties.
- The Trust maintained ranking as the top small acute Trust (out of 22) for the number of recruiting studies (Figure 6), and increased the ranking from 5th to 4th for the number of study participants recruited (Figure 7); The top 2 recruiting small acute trusts (Harrogate; Milton Keynes) both have some extremely high recruiting studies which recruit only to their local area (Yorkshire Health Study - 1352 recruits for Harrogate; Newborn Cross Sectional Study – 1744 for Milton Keynes);
- The Trust secured £20,000 funding to support 2 new ‘Hub and spoke’ Research Fellows during 2018/19. The fellows were based in Ophthalmology and Urology in the Trust and in Southampton. Funding was renewed for both posts during 2019/20. The Ophthalmology post continues as a Hub and Spoke with Southampton, and the Urology fellow is Trust based;
- Professor Nick Cross was awarded the Rowley Prize by the International Chronic Myeloid Leukemia Foundation for scientific achievements to better understand the molecular pathogenesis of CML and the development, validation and standardisation of genetic tests.
- The Trust also provided anonymised data and/or tissue for studies; acted as a Participant Identification Centre & continued care site as needed; followed up patients who have completed their treatment phase; and made clinical referrals to other Trusts so patients could take part in trials not hosted in the Trust.

Target(s) for next year

- CRN recruitment target: 1507 study participants: 7755 weighted points.

Figure 1: Trust recruitment per year

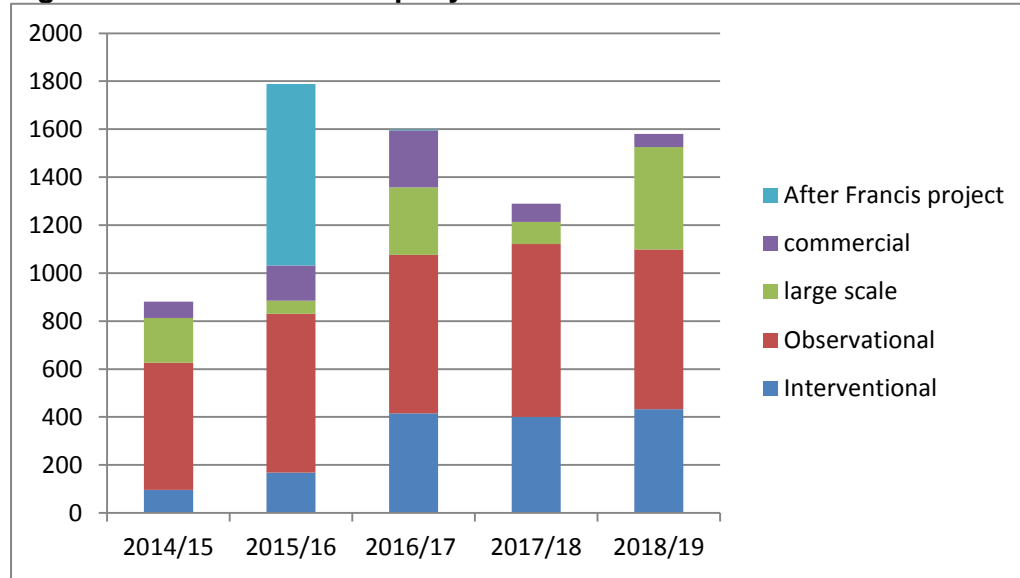


Figure 2: Trust weighted recruitment per year

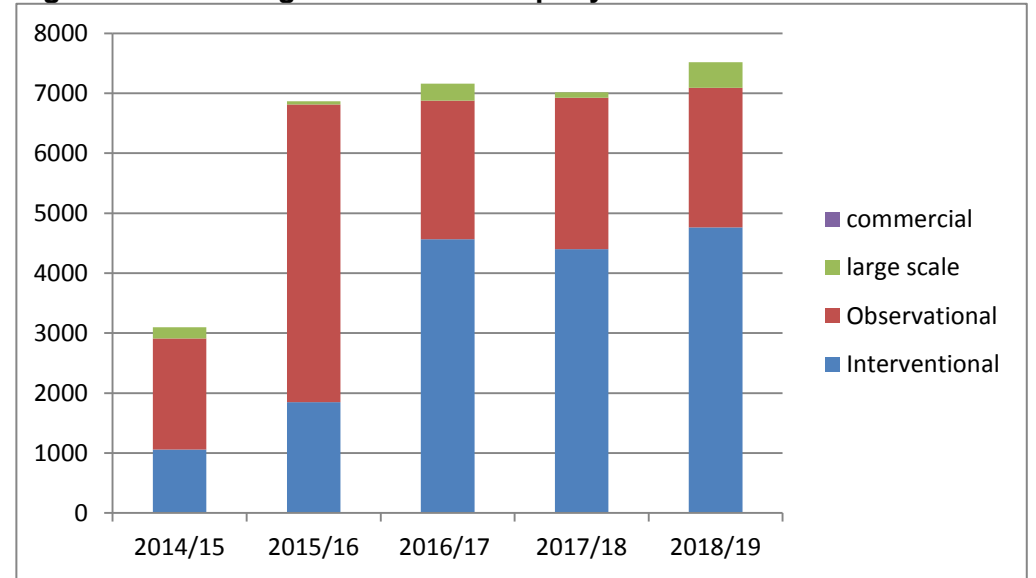


Figure 3: Breakdown of recruitment by lead specialty 2018/19

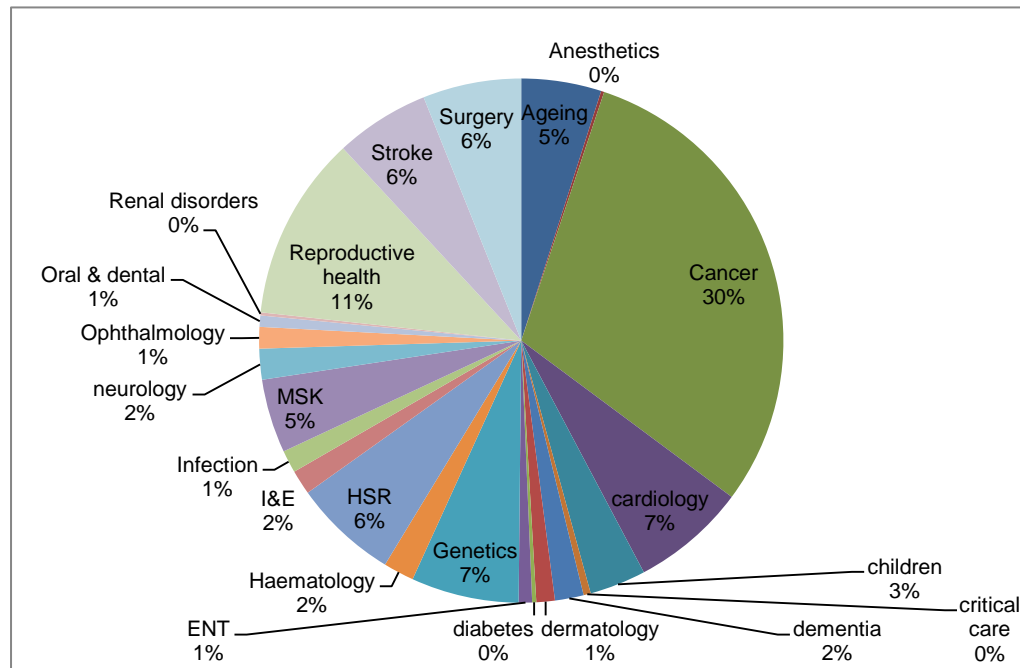


Figure 4: Breakdown of weighted recruitment by lead specialty 2018/19

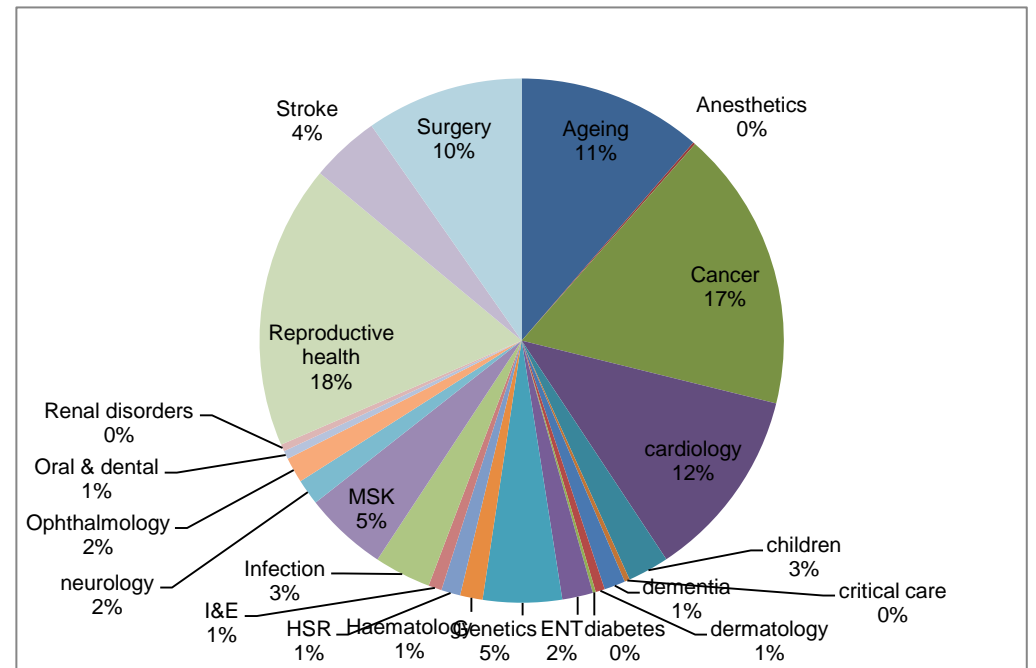


Figure 5: Number of recruiting studies per year

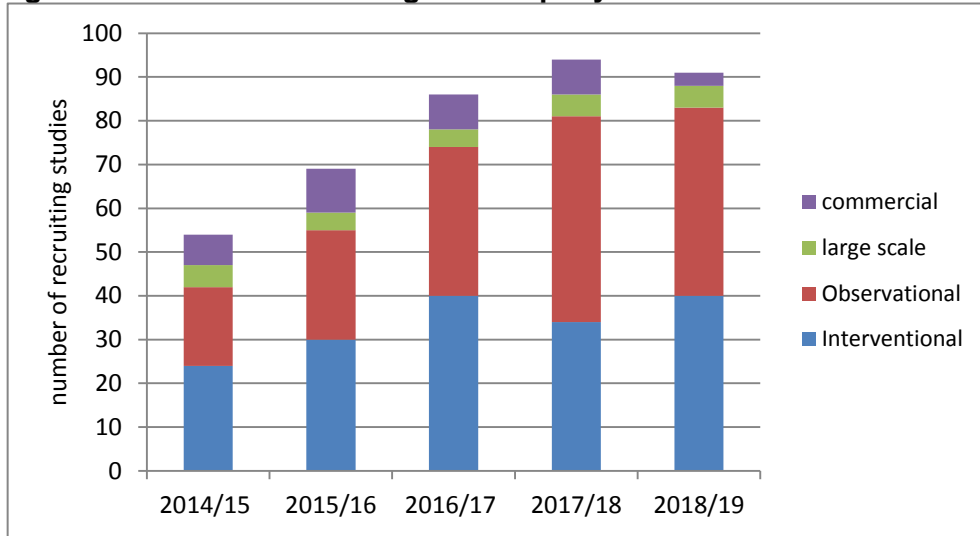


Figure 6: Ranking of small acute Trusts number of studies 2018/19

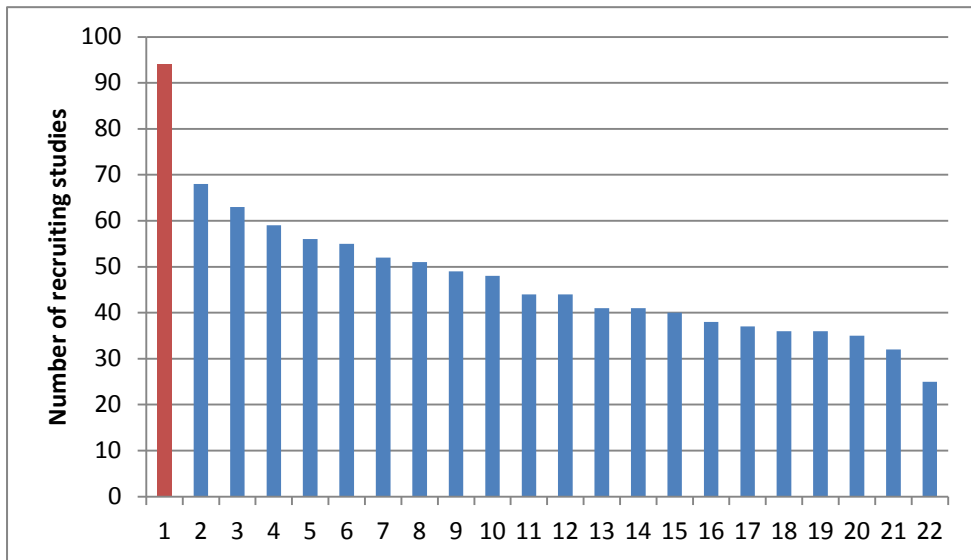
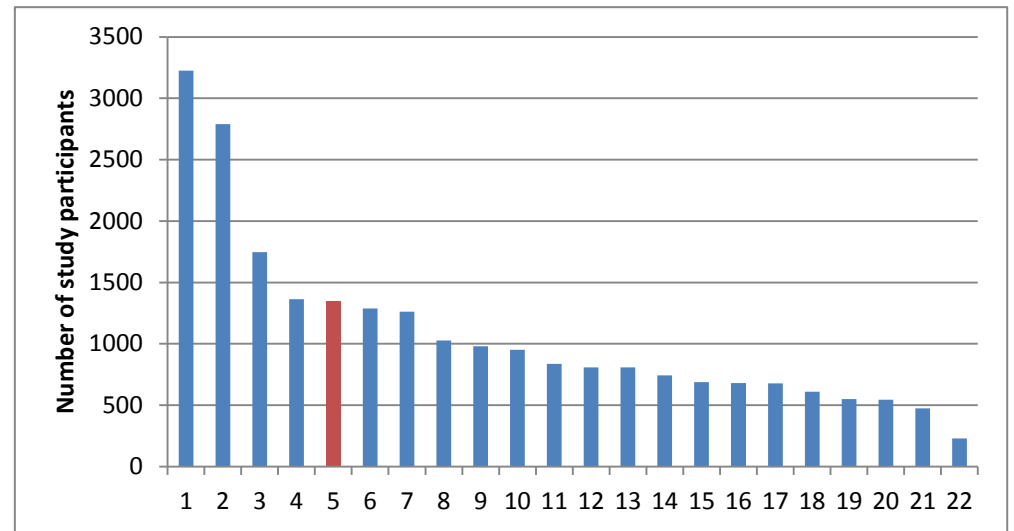


Figure 7: Ranking of small acute Trust recruitment 2018/19



Priority 2: Increase the proportion of studies in the NIHR CRN Portfolio delivering to recruitment time and target: Commercial studies

Description of issue and rationale for prioritising

NIHR funding to providers of NHS services is now conditional on meeting a series of benchmarks, including the ability of Trusts to recruit the number of Trust study participants declared on the research application for NHS 'permission to proceed' in the agreed timescale (recruitment to time and target [RTT]). The Trust is performance managed by both the NIHR Central Commissioning Facility (NIHR CCF) and CRN:Wessex for commercial RTT.

Annual performance commentary

- Priority applied to 8 NIHR CRN commercial contract Portfolio studies that closed to recruitment during 2018/19 (see Table 2).
- 8 of the 9 studies that closed during 2018/19 recruited to time and target, giving us an overall percentage of 88%. This exceeded both the NIHR target of 80%, and the national performance of 71%. This data is included in a mandatory returns to the NIHR CCF, and is published on the Trust website;
- 2 Consultants from the Trust acted as Chief Investigator for 2 studies. The CI is responsible for the conduct of the research at a site, and for the design, management and reporting of the study nationally, co-ordinating the investigators who take the lead at each site;
- 10 commercial studies (i.e. those that closed 1 Oct 17 – 31 Sept 18) attracted a CRN:Wessex Performance Premium of £3000 each. The Trust also received the 'global first patient' payment of £10,000 for the PUGS project. These payments form part of the 2019/20 Trust infrastructure funding for research;
- Dr Chris Anderson was awarded the CRN:Wessex award for 'excellence in the delivery of commercial research studies'
- All the Trust's commercial studies are currently in set up, and will open to recruitment in 2019/20. ;

Target(s) for next year

- Identify and open suitable commercial research studies;
- % RTT commercial & non-commercial studies $\geq 80\%$.

Priority 3: Increase the proportion of studies in the NIHR CRN Portfolio delivering to recruitment time and target: Non- Commercial studies

Description of issue and rationale for prioritising

See previous section on commercial RTT.

Annual performance commentary

- Priority applied to 33 NIHR CRN non-commercial Portfolio studies that closed to recruitment during 2018/19 (see Table 3). 26 of the 32 studies (81%) that closed during 2018/19 recruited to time and target, exceeds the NIHR target of 80%, and matches both the Trust performance for 2017/18 and the performance nationally for 2018/19 (also 81%). The majority of studies that failed to recruit to time and target missed the recruitment target because of overly optimistic target setting at the outset.
- A performance premium for non-commercial RTT was also included in the infrastructure funding for 2018/19. The payment was calculated using a retrospective model informed by both the number of studies recruiting to time and target, and the overall % for 01 Oct 2017 – 31 Sept 2018. The Trust secured a performance premium of £21,855.

Target(s) for next year

- Improved target setting and review
- % RTT commercial & non-commercial studies $\geq 80\%$.

Table 2: RTT for NIHR CRN commercial contract Portfolio studies during 2018/19.

Patient Directorate	Managing Specialty	Study Name	Closed to recruitment date	PI	Target	Recruitment	Target on track
CS&FS	Children	PUGS	31/05/2018	Anderson, Dr Chris	6	8	Met
Medicine	Haematology	ETNA DUS	31/05/2018	Everington, Dr Tamara	5	30	Met
Medicine	Haematology	HAEM 4528 – ETNA	31/08/2018	Everington, Dr Tamara	4	6	Met
Medicine	Haematology	RE-COVERY DVT/PE	28/02/2018	Everington, Dr Tamara (CI)	4	246	Met
Medicine	Cardiovascular	EMIT-AF/VTE	01/06/2018	Everington, Dr Tamara	2	11	Met
Medicine	Cardiovascular	3708 CARD e-ULTIMASTER Registry	03/09/2018	Wells, Dr Tim	100	115	Met
Surgery	Ophthalmology	OPHT 4824	30/06/2018	Arora, Dr Rashi	5	7	Met
Surgery	Ophthalmology	AZURE	30/10/2018	Arora, Dr Rashi	5	0	
MSK	Musculoskeletal	RA unmet	31/03/2019	Cole, Dr Zoe (CI)	25	32	Met

Table 3: RTT for NIHR CRN non-commercial Portfolio studies during 2018/19.

Patient Directorate	Managing Specialty	Study Name	Closed to recruitment date	PI	Target	Recruitment	Target on track
CS&FS	HSR	UK BIO-TRAC study	31/08/2018	No Local investigator	1	2	Met
CS & FS	Children	Opti-prem	18/08/2018	Baird, Dr Jim	1	5	Met
CS&FS	Diabetes	DRN 552 (ADDRESS-2)	31/12/2018	Anderson, Dr Chris	5	11	Met
CS&FS	Diabetes	ADDRESS C-Peptide	31/12/2018	Anderson, Dr Chris	1	2	Met
CS & FS	Reproductive health & childbirth	iPLAN	28/08/2018	Diment, Sarah	36	132	Met
CS&FS	Reproductive health & childbirth	STOPPIT-2	14/02/2019	Verdin, Mr Stuart	5	7	Met
Medicine	Ageing	CLECC	15/10/2018	Wilkinson, Lorna	64	96	Met
Medicine	Cancer	UKALL60+	21/12/2018	Cullis, Dr Jonathan	1	1	Met
Medicine	Cancer	ESPAC4	05/12/2018	Shablak, Dr Alaaeldin	9	11	Met
Medicine	Cardiovascular	AFGEN UK	30/06/2018	Sinha, Dr Manas	5	5	Met
Medicine	Cardiovascular	ROSE ACS	20/09/2018	Wells, Dr Tim	10	61	Met
Medicine	Genetics	Consent and Confidentiality in Genetic Medicine	01/01/2018	Salisbury, Mrs Sarah	1	0	
Medicine	Gastroenterology	IBD Bioresource	30/06/2020	Loehry, Dr Juliette	25	16	
Medicine	HSR	DemCARE	29/03/2019	Stobie, Emma	1	2	Met
Medicine	Stroke	PLORAS	02/05/2018	Black, Dr Toby	12	12	Met
Medicine	Stroke	RESTART study	31/05/2018	Black, Dr Toby	5	3	
Medicine	HSR	HISLAC project	31/01/2019	Henderson, Dr Stuart	7	194	Met
Medicine	Haematology	Cares	17/07/2018	Everington, Dr Tamara	1	7	Met
Medicine	Haematology	ITP Registry	27/09/2018	Everington, Dr Tamara	20	16	
Medicine	Haematology	The PEP-WARF Study	27/09/2018	Everington, Dr Tamara	10	6	
Medicine	Haematology	First	31/10/2018	Cullis, Dr Jonathan	50	90	Met
Medicine	Hepatology	The UK-AIH Cohort	09/01/2019	Jamil, Dr Aqeel	10	15	Met
Medicine	Cancer	Flight	08/02/2019	Cullis, Dr Jonathan	4	1	
Medicine	Cancer	RIALTO	31/04/2018	Cullis, Dr Jonathan	6	8	Met
Surgery	Cancer	DETECT II	31/08/2018	Borwell, Jonathan	8	26	Met
Surgery	Cancer	MAMMO-50	30/09/2018	Brown, Ms Victoria	57	64	Met
Surgery	Cancer	SAILOR	31/03/2019	Branagan, Mr Graham	6	0	
Surgery	Anaesthesia,	DREAMY	31/08/2018	Onslow, Julie	10	11	Met
Surgery	Surgery	GAPS	30/01/2019	Everington, Dr Tamara	320	324	Met
MSK	Injuries&Emergencies	UK Star	01/05/2018	Sampalli, Mr Sridhar Rao	12	15	Met
MSK	Musculoskeletal	ART V1.0	31/08/2018	Jacobs, Mr Neal	20	22	Met
MSK	Children	CLEFT-Q Fieldtest	02/05/2018	Phippen, Ginette	30	42	Met
MSK/WHC	Musculoskeletal	BOOST	16/08/2018	Wright, Alison	1	20	Met

*Closed at this site only, continues to recruit nationally

Priority 4:

Reduce the time taken to achieve NHS confirmation of capacity for NIHR studies

Description of issue and rationale for prioritising

The Health Research Agency (HRA) conducts the research governance checks for all research projects on behalf of all host organisations. The Trust 'assesses, arranges and confirms' capacity to support the research project. The NIHR target for confirmation of capacity is 80%.

Annual performance commentary

- The Trust confirmed capacity for 31 projects, with a median time of 39 days. 24 were confirmed capacity within the target of 40 day, i.e. 77% (Table 4). The NIHR target of 80% was not achieved, but our performance exceeds national performance (72%). 77% is an improvement on performance during 2017/18 (58%);
- The reasons for not confirming capacity within the target of 40 days are varied. In some cases, the reasons are outside of the Trust's control (e.g. waiting for equipment to be delivered, national approval of an amendment); others are within the Trust's control (e.g. staffing issues). The Trust is reviewing (and revising, where appropriate) out internal processes to try and identify these issues at the feasibility stage (i.e. before formal submission);
- Quarterly reports were uploaded to the NIHR and published on the Trust website in accordance with our contractual requirements. Please note the national PID reports for 2018/19 exclude observational studies. The data published on the Trust website therefore differs from the data included in this report (which includes all studies).

Target(s) for next year

- 80% within 40 days.

Table 4: The time (calendar days) taken to issue confirmation of capacity

Patient Directorate	Managing Specialty	Study Name	Date site selected	Date site approval	Approval days	PI	Comments
CS&FS	Children	Petechiae in children	23/05/2018	28/06/2018	36	Gray, Dr Sebastian	
CS&FS	Children	Pre-appointment written materials in children's therapy services	18/11/2018	19/11/2018	1	Diment, Sarah	
CS&FS	Children	CF Start	09/07/2018	17/08/2018	39	Gray, Dr Sebastian	
CS&FS	Children	DRN100 (TrialNet)	08/11/2018	18/12/2018	40	Anderson, Dr Chris	
CS&FS	Neurological Disorders	REGAIN	16/07/2018	24/08/2018	39	Baird, Dr Jim	
CS&FS	HSR	UK BIO-TRAC study	11/04/2018	11/04/2018	1	No local investigator	
CS&FS	Injuries& Emergencies	NINJA	30/07/2018	07/09/2018	39	Nicolaou, Mr Marios	
CS&FS	Reproductive health & childbirth	CPIT III	19/09/2018	29/10/2018	40	Rand, Mrs Abby	
CS&FS	Reproductive health & childbirth	The Big Baby Trial	21/09/2018	31/10/2018	40	Baden-Fuller. Dr Jo	
Medicine	Cardiology	Af-gen UK	08/12/2017	04/04/2018	156	Sinha, Dr Manas	Local staffing issues
Medicine	Cardiology	Atrial Fibrillation III (AF III) Registry	14/02/2019	22/03/2019	36	Sinha, Dr Manas	
Medicine	Cardiology	ORION-4	24/01/2019	01/03/2019	36	Wells, Dr Tim	
Medicine	Cardiology	IRONMAN	25/01/2019	15/03/2019	49	Wells, Dr Tim	PI Changeover amendment
Medicine	Stroke	Prediction of stroke outcome using brain imaging machine-learning	13/11/2017	18/04/2018	56	Black, Dr Toby	Delay in confirming targets (Sponsor and local)
Medicine	Neurological Disorders	Neuro LTC Study Version 1.0	08/10/2018	07/11/2018	30	Anthony, Mrs Alpha	
Medicine	Cancer	ROSCO	19/11/2018	10/01/2019	52	Bradbury, Dr Jenny	Ionising radiation medical exposure regulations review (IRMER) and Christmas holidays
Medicine	Cancer	Flight	22/03/2018	02/05/2018	41	Cullis, Dr Jonathan	Postal delays getting signed agreement
Medicine	Cancer	Developing new tests for ovarian cancer	18/06/2018	27/07/2018	39	Dimopoulos, Dr Prokopios	
Surgery	Ophthalmology	AZURE	20/02/2018	18/06/2018	143	Arora, Dr Rashi	Delivery of equipment delay
Surgery	Ophthalmology	Epiretinal membrane and cystoid macular oedema post-cataract surgery	06/09/2018	11/10/2018	35	Arora, Dr Rashi	
Surgery	Critical Care	POETICS 2	16/11/2018	04/12/2018	18	Donnison, Dr Phil	
Surgery	Anaesthetics	Chemical analysis of organophosphate exposed patients	12/06/2018	18/06/2018	6	Haslam, Dr James	
Surgery	Anaesthesia	FROGs	15/08/2018	30/08/2018	14	Bond, Miss Amanda	
Surgery	Reproductive health & childbirth	The Future Study	09/05/2018	04/07/2018	56	Davies, Miss Melissa	Ethics query – schedule of events not complete
Surgery	Renal Disorders	PURE	31/10/2018	10/12/2018	40	Brewin, Mr James	
Surgery	Oral and Dental	Determining adolescent/parent priorities in hypodontia	24/05/2018	25/05/2018	1	No local investigator	PIC

MSK	Injuries and Emergencies	Proffer 2	18/06/2018	27/07/2018	39	Sampalli, Mr Sridhar Rao	
MSK	Musculoskeletal	ACL SNAPP	31/07/2018	29/08/2018	29	Vachtsevanos, Mr Leonidas	
MSK	Musculoskeletal	RA unmet	29/03/2018	18/06/2018	25	Cole, Dr Zoe	
MSK	Neurological	Upper-body interval training in persons with chronic paraplegia	21/02/2019	05/03/2019	12	Coy, Dr Aisling	
MSK	Neurological	Pressure ulcer prevention after spinal cord injury	05/07/2018	08/08/2018	34	Fryer, Sarah	

Priority 5:

Reduce the time taken to recruit first participant into NIHR CRN Portfolio studies

Description of issue and rationale for prioritising

NIHR funding to providers of NHS services is conditional on meeting a series of benchmarks, including the ability of Trusts to recruit the first study participant within 30 calendar days of confirmation of capacity for the project. NHS Trusts are performance managed (by the NIHR CCF) for NIHR Portfolio clinical trials, and are required to submit data on a quarterly basis. Trusts failing to submit or comply with the required standard may be financially penalised.

Annual performance commentary

- The 30 day target applied to 31 studies, shown in Table 5. 12 projects (39%) recruited the first study participant within 30 days. In many cases, the reason for not consenting the first study participant within 30 days was beyond our control. For example, the majority of Trust studies have a low recruitment target (e.g. an annual target of less than 12) and would not reasonably expect to recruit the first study participant within 30 days. For these studies, it is important that we are actively screening patients within 30 days, so that we can approach and recruit study participants as appropriate. In other cases, the sponsor wants us to delay the start of recruitment (e.g. the first stage of the study is an anonymised retrospective data collection). These studies are classed as 'neither' in the table. Only 2 studies failed to recruit the first study participant due to reasons within the trust's control. This gives an overall adjusted compliance with the target of 94%. The national compliance measures commercial and non-commercial studies separately. Commercial compliance is 100% (1 study) and non-commercial 37% (11 out of 30 studies) with an adjusted compliance of 93%.

- *Target(s) for next year*
- 80% within 30 days

Table 5: 30 day target for recruitment of the first study participant

Patient Directorate	Managing Speciality	Study title	Confirmation of capacity (cc)	First patient recruited	Duration between CC to first patient recruited	Comments	Reason for delay
CS&FS	Children	Petechiae in children	28/06/2018	16/07/2018	18		
CS&FS	Children	CF Start	17/08/2018	n/a		Screening no patients seen	Neither
CS&FS	Children	DRN100 (TrialNet)	18/12/2018	14/02/2019	58	Administration delays by Sponsor	Sponsor
CS&FS	Children	Pre-appointment written materials in children's therapy services	19/11/2018	22/11/2018	3		
CS&FS	Neurological Disorders	REGAIN	24/08/2018	25/09/2018	32	Screening no patients seen	Neither
CS&FS	Health Services Research	UK BIO-TRAC study	11/04/2018	06/07/2018	57	Delayed response from participant	Neither
CS&FS	Reproductive health & childbirth	CPIT III	29/10/2018	28/12/2018	60	Main study site databases not ready	Sponsor
CS&FS	Reproductive health & childbirth	The Big Baby Trial	31/10/2018	29/11/2018	29		
CS&FS	Injuries and Emergencies	NINJA	30/07/2018	27/09/2018	20		
Medicine	Cancer	ROSCO	10/01/2019	05/03/2019	46	Screening – no eligible patients	Neither
Medicine	Cardiology	AFGEN UK	04/04/2018	11/05/2018	37	screening- no patients agreed to take part	Neither
Medicine	Cardiology	ORION-4	01/03/2019	n/a	32	Sponsor dispensation	Sponsor
Medicine	Cardiology	Atrial Fibrillation III (AF III) Registry	22/03/2019	11/04/2019	20		
Medicine	Cardiology	IRONMAN	15/03/2019	n/a		Still within 30 day target	
Medicine	Dementias and neurodegeneration	Vision in Parkinson's Disease	29/03/2018	06/09/2018	161	Screening- no eligible patients	Neither
Medicine	Stroke	Prediction of stroke outcome using brain imaging machine-learning	18/04/2018	02/05/2018	14		
Medicine	Neurological disorders	Neuro LTC Study Version 1.0	07/11/2018	09/11/2018	2		
Medicine	Cancer	Developing new tests for ovarian cancer	27/07/2018	18/02/2019	206	Delayed SIV	Sponsor
Medicine	Cancer	Flight	02/05/2018	07/09/2018	128	Screening- no eligible patients	Neither
Surgery	Cancer	NICEFIT	20/02/2018	06/04/2018	45	Delay SIV (sponsor), screening and	Sponsor

						approach started prior to 30 days but recruitment took place later due to nature of protocol	
Surgery	Critical Care	POETICS 2	04/12/2018	18/01/2019	45	Screened patients – patients unable to participate	Neither
Surgery	Reproductive health and childbirth	The Future Study	04/07/2018	22/07/2018	18		
Surgery	Renal Disorders	PUrE	10/12/2018	08/01/2019	29		
Surgery	ENT	NAIROS	22/03/2018	1/05/2018	40	IT issues	Trust
Surgery	Ophthalmology	AZURE	18/06/2018	n/a	n/a	Delay opening site –sending equipment and access to database	Sponsor
Surgery	Ophthalmology	Epiretinal membrane and cystoid macular oedema post-cataract surgery	06/10/2018	07/11/2018	27		
Surgery	Anaesthesia	FROGS	30/08/2018	n/a	n/a	Retrospective data collection first	Sponsor
Surgery	Anaesthesia	Chemical analysis of organophosphate exposed patients	18/06/2018	n/a	n/a	Not applicable – does not contribute to our targets	
MSK	Musculoskeletal	RA unmet	18/06/2018	11/07/2018	23		
MSK	Musculoskeletal	ACL SNAPP	29/08/2018	26/09/2018	28		
MSK	Injuries and Emergencies	Prother 2	27/07/2018	14/09/2018	49	Local staff training issue	Trust
MSK	Neurological Disorders	Upper-body interval training in persons with chronic paraplegia	05/03/2019	n/a		Participant Identification Centre. Not taking consent	
MSK	Neurological Disorders	Pressure ulcer prevention after spinal cord injury	08/08/2018	07/12/2018	121		

- Studies coded red in n/a = have gone past both their 30 day and 70 day targets and are yet to recruit a patient.
- Studies coded white in n/a = are still within the timescale of meeting both 30 and 70 day target and will turn either red or green next month.

Targets for 2019/20

This report covers the Trust's research activities during 2018/19, and describes the contribution that the Trust has made towards the NIHR HLOs. The Targets set for 2019/20 are shown in Table 7.

Table 7: Targets for 2018/19

	Objective	Target
HLO 1	Increase the number of participants recruited into NIHR portfolio studies - recruits	1507
HLO 1	Increase the number of participants recruited into NIHR portfolio studies – complexity weighting	7755
HLO 2a	Increase the proportion of studies in the NIHR portfolio delivering to recruitment target and time – commercial contract studies	80%
HLO 2b	Increase the proportion of studies in the NIHR portfolio delivering to recruitment target and time – non-commercial studies	80%
HLO 4	Reduce the time taken for eligible studies to achieve set-up in the NHS	80% within 40 days
HLO 5a	Reduce the time taken to recruit the first participant into NIHR portfolio studies - commercial contract studies	80% within 30 days
HLO 5b	Reduce the time taken to recruit the first participant into NIHR portfolio studies - non-commercial contract studies	80% within 30 days

Appendices

Appendix A:

Recruitment figures for Salisbury NHS Foundation Trust 2018/19

Directorate	Managing Specialty	Short Name	Participants	Study type	Complexity weighted points	Principal Investigator
CS&FS	Anaesthesia, Perioperative Medicine and Pain Management	DREAMY	3	Observational	10.5	Onslow, Julie
CS&FS	Children	DRN100 (TrialNet)	4	Observational	14	Anderson, Dr Chris
CS&FS	Children	OPTI-PREM	5	Observational	17.5	Baird, Dr Jim
CS&FS	Children	Pre-appointment written materials in children's therapy services	2	Observational	7	Diment, Sarah
CS&FS	Children	Petechiae In Children (PIC) Study	25	Observational	87.5	Gray, Sebastian
CS&FS	Children	Identification of factors associated with speech disorder-cleft palate	12	Observational	42	Phippen, Ginette
CS&FS	Children	Speech processing in children born with cleft palate	4	Observational	14	Phippen, Ginette
CS&FS	Diabetes	DRN 552 – ADDRESS-2	4	Observational	14	Anderson, Dr Chris
CS&FS	Genetics	Molecular pathogenesis of chronic myeloproliferative neoplasms	92	Observational	322	cross, Nick
CS&FS	Haematology	UK Childhood ITP Registry	3	Observational	10.5	Diment, Sarah
CS&FS	Infection	PrEP Impact Trial	18	large scale	18	Morris, Dr Georgina
CS&FS	Injuries and Emergencies	NINJA	8	Large Scale	88	Nicolaou, Marios
CS&FS	Neurological Disorders	REGAIN	4	Observational	14	Baird, Dr Jim
CS&FS	Reproductive Health & childbirth	The 'Big Baby Trial'	8	Interventional	88	Baden-Fuller, Jo
CS&FS	Reproductive Health & childbirth	iPLAN	64	Interventional	704	Diment, Sarah
CS&FS	Reproductive Health & childbirth	CPIT III	8	Interventional	88	Rand, Mrs Abby
CS&FS	Reproductive Health & childbirth	STOPPIT-2	2	Interventional	22	Verdin, Mr Stuart
Medicine	Ageing	CLECC	78	Interventional	858	Wilkinson, Lorna
medicine	Cardiovascular Disease	AF-GEN-UK	14	Observational	49	Sinha, Dr Manas
Medicine	Cardiovascular Disease	ARTESiA	7	Interventional	77	Wells, Dr Tim
Medicine	Cardiovascular Disease	UKGRIS	58	Interventional	638	Wells, Dr Tim
Medicine	Cardiovascular Disease	MPP VARR	2	Interventional	22	Wells, Dr Tim
Medicine	Cardiovascular Disease	ROSE ACS	31	Observational	108.5	Wells, Dr Tim
medicine	Dementias & Neurodegeneration	The Parkinson's Pain Study	8	Observational	28	Padiachy, Dr Diran
medicine	Dementias & Neurodegeneration	Parkinson's Families Project (PFP)	5	Observational	17.5	Padiachy, Dr Diran
medicine	Dementias & Neurodegeneration	Vision in Parkinson's Disease	15	Observational	52.5	Padiachy, Dr Diran
medicine	Dermatology	BADBIR	8	large scale	8	Mellor, Dr Serap
medicine	Dermatology	Bio-markers of systemic treatment outcomes in Psoriasis	10	Observational	35	Mellor, Dr Serap
medicine	Genetics	NIHR BioResource - Rare Diseases	13	Observational	45.5	Everington, Dr Tamara
medicine	Haematology	FLIGHT Study	1	interventional	11	Cullis, Dr Jonathan
Medicine	Haematology	Improving diagnosis in idiopathic cytopenia using gene sequencing	4	Observational	14	Cullis, Dr Jonathan
medicine	Haematology	HAEM 4528	2	commercial	0	Everington, Dr Tamara
medicine	Haematology	UKAITPR	5	Observational	17.5	Everington, Dr Tamara
medicine	Haematology	Follow-up in Rivaroxaban patients in setting of thromboembolism	15	Observational	52.5	Everington, Dr Tamara
medicine	Health Services Research	ETNA-DUS	23	commercial	0	Everington, Dr Tamara
Medicine	Health Services Research	HiSLAC	75	large scale	75	Henderson, Dr Stuart
medicine	Health Services Research	Optimising acute care for people with dementia	2	observational	7	Stobie, Emma
medicine	Infection	EASI-SWITCH v1.0	4	Interventional	44	Grand, Dr Effie
medicine	Musculoskeletal Disorders	ACL SNNAP	13	Interventional	143	Vachtsevanos, Leonidas
Medicine	Neurological Disorders	Neuro LTC	24	observational	84	Anthony, Alpha
medicine	Stroke	Determinants of prognosis in stroke	80	Observational	280	Black, Dr Toby
medicine	Stroke	Prediction of stroke outcome using brain imaging machine-learning	12	Observational	42	Black, Dr Toby
Medicine	Cancer	ROSCO	1	Interventional	11	Bradbury, Dr Jenny
medicine	Cancer	LI-1	1	interventional	11	Cullis, Dr Jonathan
medicine	Cancer	AML18	3	Interventional	33	Cullis, Dr Jonathan
medicine	Cancer	FLAIR	1	interventional	11	Cullis, Dr Jonathan

medicine	Cancer	AML19	1	Interventional	11	Cullis, Dr Jonathan
Medicine	Cancer	ENRICH	1	Interventional	11	Cullis, Dr Jonathan
medicine	Cancer	Myeloma XII (ACCoRd trial) Version 1.0	2	Interventional	22	Cullis, Dr Jonathan
medicine	Cancer	UKALL60+	1	observational	3.5	Cullis, Dr Jonathan
medicine	Cancer	MEASURES	9	Observational	31.5	Cullis, Dr Jonathan
medicine	Cancer	MaPLe: Molecular profiling for lymphoma	9	Observational	31.5	Cullis, Dr Jonathan
medicine	Cancer	MCL Biobank Observational Study	1	Observational	3.5	Cullis, Dr Jonathan
medicine	Cancer	Mature Lymphoid Malignancies Observational Study	6	Observational	21	Cullis, Dr Jonathan
Medicine	Cancer	TREATT	1	Interventional	11	Grand, Dr Effie
medicine	Cancer	HORIZONS	30	Observational	105	Reed, Mrs Catherine
medicine	Cancer	ESPAC-4	1	interventional	11	Shablack, Dr Alaadelin
Medicine	Cancer	PLATFORM	2	Interventional	22	Shablak, Dr Alaeldin
Medicine	Cancer	BALLAD	1	Interventional	11	Shablak, Dr Alaeldin
medicine	Cancer	CR UK Stratified Medicine Pilot study	11	large scale	11	Thompson, Dr Catherine
surgery	Cancer	DETECT II	10	Observational	35	Borwell, Jonathan
surgery	Cancer	IMPRESS Trial	7	Interventional	77	Branagan, Mr Graham
surgery	Cancer	SERENADE	15	Interventional	165	Branagan, Mr Graham
surgery	Cancer	Add-Aspirin	15	Interventional	165	Branagan, Mr Graham
surgery	Cancer	TRIGGER	1	interventional	11	Branagan, Mr Graham
surgery	Cancer	NICE FIT	316	Interventional	316	Branagan, Mr Graham
surgery	Cancer	TRACC	20	observational	70	Branagan, Mr Graham
surgery	Cancer	OPTIMA	8	Interventional	88	Brown, Ms Victoria
surgery	Cancer	MAMMO-50	1	Interventional	11	Brown, Ms Victoria
Surgery	Critical Care	POETICS 2	7	Observational	24.5	Donnison, Phil
surgery	Ear, Nose and Throat	NAIROS	13	Interventional	143	Dennis, Mr Simon
Surgery	Ophthalmology	STAR	4	Interventional	44	Arora, Dr Rashi
Surgery	Ophthalmology	EPIC	13	Observational	45.5	Arora, Dr Rashi
surgery	Ophthalmology	Nationwide survey of prosthetic eye users	2	Observational	7	Arora, Rashi
surgery	Ophthalmology	EuPatch	2	Interventional	22	Elliot, Sue
Surgery	Renal Disorders	PURÉ	3	Interventional	33	Brewin, James
surgery	Reproductive Health & childbirth	FUTURE	6	Interventional	66	Davies, Miss Melissa
Surgery	Surgery	FROGS	26	Observational	91	Bond, Amanda
surgery	Surgery	The CIPHER study	17	Observational	59.5	Branagan, Mr Graham
surgery	Surgery	GAPS	53	Interventional	583	Everington, Dr Tamara
MSK	Children	FACE-Q KIDS PROM	3	Observational	10.5	Khan, Mansoor
MSK	Injuries and Emergencies	DRAFFT 2	13	Interventional	143	Sampalli, Mr Sridhar Rao
MSK	Injuries and Emergencies	PROFHER2	3	Interventional	33	Sampalli, Mr Sridhar Rao
MSK	Musculoskeletal Disorders	RA UNMET	30	commercial	0	Cole, Zoe
MSK	Musculoskeletal Disorders	ART	2	Interventional	22	Jacobs, Mr Neal
MSK	Musculoskeletal Disorders	PREVeNT RA	10	Observational	35	Smith, Dr Richard
MSK	Neurological Disorders	Pressure ulcer prevention after spinal cord injury	2	Interventional	22	Fryer, sarah
MSK	Oral and Dental Health	Determining adolescent/parent priorities in hypodontia	11	Observational	38.5	INVESTIGATOR, NO LOCAL
MSK	Reproductive Health & childbirth	The Cleft Collective Cohort Studies	92	Observational	322	Phippen, Ginette
other	Health Services Research	UK BIO-TRAC	2	Observational	7	INVESTIGATOR, NO LOCAL
other	Musculoskeletal Disorders	BOOST	17	Interventional	187	Wright, Alison
TOTALS					1581	7518.5