

Research Performance Report 2020/21

Contents

Summary

Trust recruitment into COVID-19 & non-COVID-19 trials

Benchmarking – Small Acute Trusts

Global impact of local involvement in COVID-19 trials

Non COVID-19 research results

CRN:Wessex Research Awards

NIHR Portfolio Restart (non COVID-19 studies)

Research Grants Secured

Strategic plan for 2021/22

Appendix A: Trust recruitment per trial

Appendix B: Publications from Trust trials

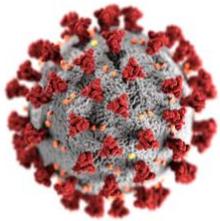
Summary



More people than ever before took part in Trust research



The Trust performed well compared to other Trusts of a similar size



Local involvement in 9 COVID-19 studies



Local COVID-19 research:
Local Involvement
↓
global impact



12% of patients with COVID-19 were recruited into interventional trials



£705,32 research funding secured for 3 new research grants

Staff helped develop 2 COVID-19 vaccines

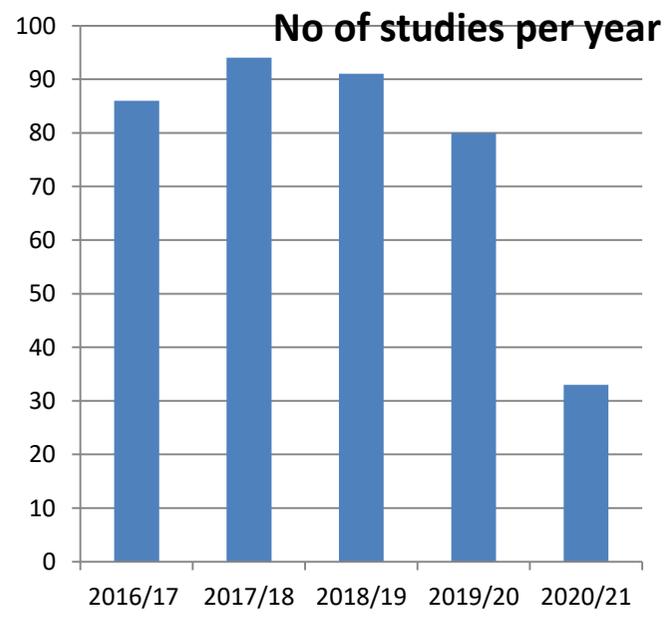
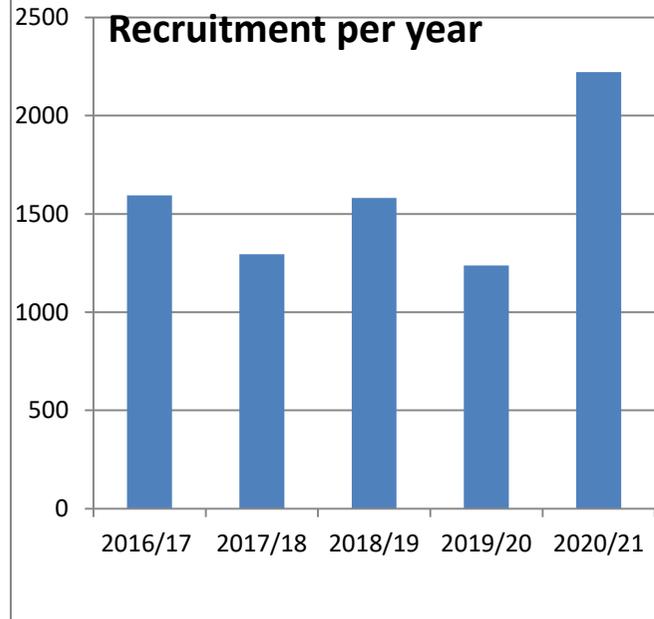


% of the pre-COVID-19 research portfolio restarted



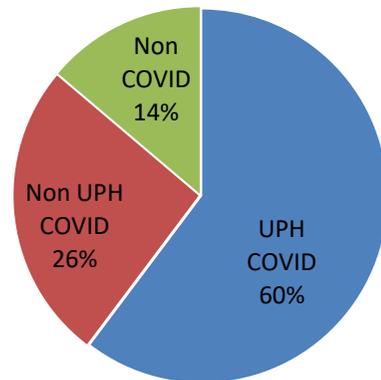
2 CRN:Wessex Research Awards for outstanding individual and team contribution to COVID-19 research awarded

Trust recruitment into COVID-19 & non-COVID-19 trials



The Trust recruited 2222 study participants into NIHR portfolio research projects which more than any other year previously. 33 studies recruited study participants, which is considerably lower than previous years, and demonstrates what may be achieved when the research effort is focused on a small number of high recruiting studies. Unsurprisingly, the majority (86%) of participants took part in Urgent Public health (UPH) COVID-19 studies. At the beginning of the pandemic, the research dept was quickly re-organised to deliver 8 national UPH studies locally. This included 2 platform treatment trials (RECOVERY & REMAP-CAP), diagnostic studies (SIREN & FALCON), national data collection studies (ISARIC, PAN COVID, CLARITY) and the genetics study GENOMICC. Overall, 12% of the COVID-19 admissions into the Trust were recruited into an interventional trial. Our local involvement in these studies has helped save lives locally, and has had global impact (as described later in this report).

Breakdown of recruitment 2020/21



Wessex Vaccine Hub

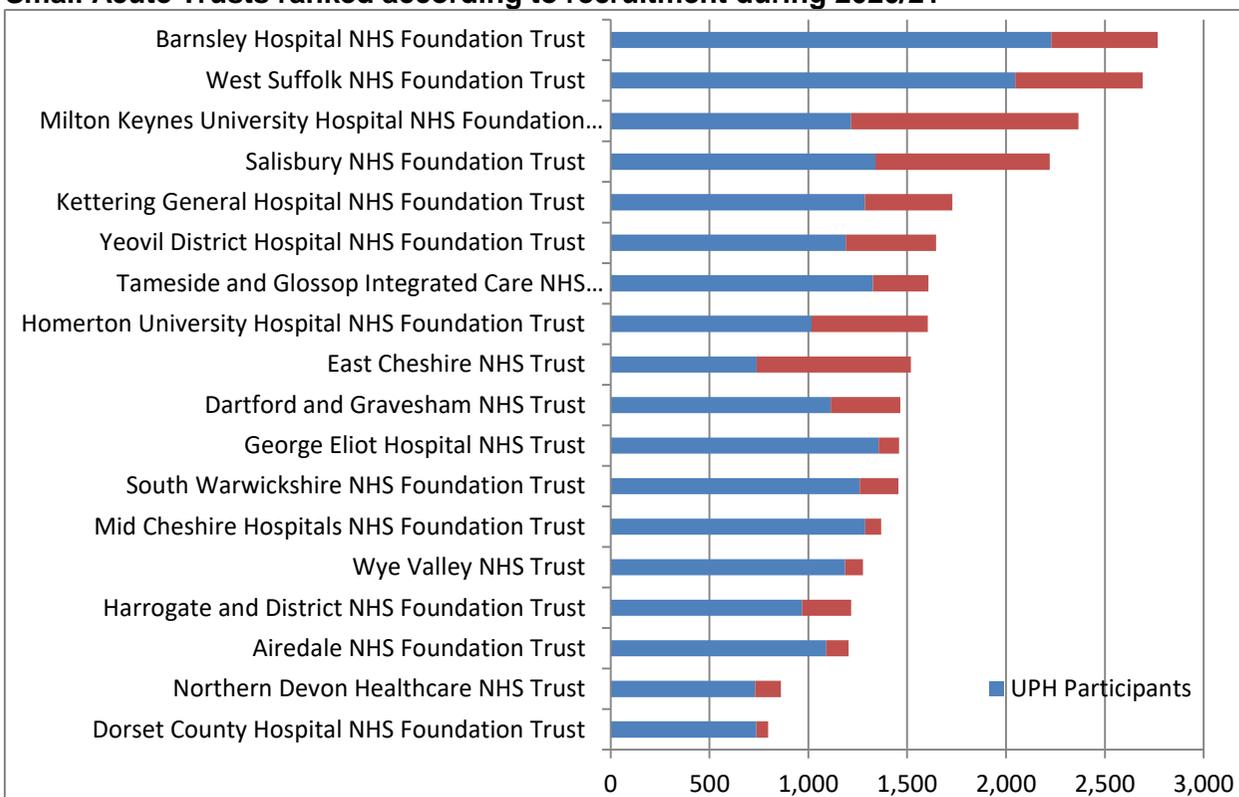
- Workforce from across Wessex NHS, including SFT
- Novavax
- Janssen

CRN:Wessex mobilised the existing CRN funded NHS workforce to support vaccine trials in 2 Hubs. Trust staff worked both at the Hub and remotely to support the development of the Novavax and Janssen (J&J) vaccines. The Novavax vaccine will be submitted for UK regulatory approval later in the year. The Janssen vaccine is approved for use in the UK.

Ordinarily CRN:Wessex use a funding formulae and performance against targets to allocate funds to NHS Organisations. In the absence of targets for 2020/21, the Trust will receive flat funding from the network of £643,101.

Benchmarking – Small Acute Trusts

Small Acute Trusts ranked according to recruitment during 2020/21



High recruiting studies in SAT with greater recruitment than the Trust:
 Barnsley – recruited 1635 into ISARIC
 West Suffolk – recruited 600 into SIREN
 Milton Keynes – recruited 452 into the Newborn cross-sectional study (NCSS)

The Trust performed well during 2020/21 when compared to other SATs, ranking 4th overall.

The Trust could have recruited more patients with COVID-19 during the second wave if the research dept had been fully staffed. Redeployment, staff sickness and staff shielding meant that the Trust lacked the capacity to be able to approach every patient with COVID-19.

Furthermore, the SATs that recruited more participants in 2020/21 that the Trust each has a unique situation with a study:

- Barnsley Hospital NHS FT recruited the highest number of participants, particularly into UPH studies. Barnsley had a much higher incidence of COVID-19 admissions than the Trust, recruiting 1635 into the ISARIC COVID-19 data collection study alone.
- West Suffolk chose to recruit 600 staff members into the SIREN study, compared to 128 in the Trust. The Trust stopped recruitment at 128 because we do not have the capacity or the room space to run daily follow up SIREN clinics for a year.
- Milton Keynes continues to recruit well into the NCSS study, which only recruits in the MK area.

The Trust was the second highest recruiting SAT into non-UPH studies, thanks to high recruitment into a Psychological impact of COVID-19 survey, and the 'molecular pathogenesis of atypical chronic myeloproliferative neoplasms and related diseases' study. Milton Keynes were the top non-UPH recruiter, thanks to the NCSS study.

Global Impact of local involvement in COVID-19 Research

<p>How are we doing? More than 100 participants took part in 9 C19 research studies in the Trust in 2020/21. Results from this research are saving lives globally.</p>	<p>Vaccine development Novavax & Janessen vaccines developed in collaboration with the Wessex Vaccine Hub and are undergoing UK regulatory approval. Janessen vaccine used in the USA.</p>
<p>UK Public Health response to C19 The results from C19 research provided critical data to inform the UK's public health response to COVID-19, and is used for early indications of trends, featuring regularly in Downing Street briefings</p>	<p>Pfizer vaccine is effective The vaccine provides high levels of protection against infection and symptomatic disease from the first dose</p>
<p>Dexamethasone Helps save lives of C19 patients with severe respiratory complications. Now part of NHS standard care for patients hospitalized with C19. Estimated to have saved over a million lives globally.</p>	<p>Genetic link identified 5 genes identified that make some people more susceptible to severe C19 symptoms. Drugs that targets these genes are to be included in C19 treatment trials</p>
<p>Tocilizumab & Sarilumab Reduces deaths of C19 patients receiving organ support. Now part of NHS standard care for our sickest patients with C19.</p>	<p>C19 resistance Most people who have had C19 are protected from catching it again for at least 5 months.</p>
<p>Treatments that do not work Hydroxychloroquine, Lopinavir-Ritonavir, Azithromycin, convalescent plasma do not benefit hospitalised C19 patients and are not recommended for use in the NHS</p>	<p>C19 & pregnancy There is an increased risk of preterm delivery & maternal mortality if C19 is contracted during pregnancy. Enhanced precautions are now being taken.</p>
<p>Clinical tools developed To help work out which adults with C19 are likely to deteriorate and who has a high risk of dying</p>	<p>C19 & inflammatory bowel disease Delayed second dose of the SARS-CoV-2 vaccine should be avoided in IBD patients treated with infliximab</p>

A full list of publications may be found at Appendix B

Non-COVID-19 Research Results

<p>Antibiotics and cystic fibrosis Intravenous antibiotics should not be used to treat P aeruginosa in patients with cystic fibrosis</p>	<p>Treatment for psoriasis Secukinumab is more effective than Ustekinumab when treating psoriasis</p>
<p>Treatment for GI Bleed Tranexamic acid should not be used in GI bleeding patients.</p>	<p>Genome sequencing for rare diseases Shown to improve diagnosis and treatment for patients with rare diseases.</p>
<p>Wellbeing & emergency physicians Evidence-based strategies to improve well-being such as proportional out-of-hours working and improved access to annual and study leave should be carefully considered and implemented where feasible to improve Need For Recovery.</p>	<p>Genetic link identified 4 genes identified that are linked to immunodeficiency.</p>
<p>Configuration of Early Pregnancy Assessment Units Early Pregnancy Assessment Units run by senior or specialist nurses and supported by sonographers and consultants may represent the optimal early pregnancy assessment unit configuration.</p>	<p>Compression stockings not needed after surgery Patients taking heparin after surgery have similar rates of blood clots to patients just taking heparin.</p>

A full list of publications may be found at Appendix B

CRN:Wessex Research Awards



CRN:Wessex have a regular awards ceremony to celebrate outstanding research in the region. This year's CRN Wessex awards ceremony was a virtual event, via Zoom. Due to the pandemic, awards were presented to individuals and teams who had made an outstanding contribution to COVID-19 research throughout the year. Each NHS organisation was asked for nominations, and was also asked to decide who deserved to win within your organisation. The nominees from the Trust were as follows:

Outstanding individual:

- Manas Sinha
- Phil Donnison

Outstanding team:

- Radnor (ITU) team
- RCU
- RemapCAP and Recovery study research teams.

The winners were Dr Manas Sinha (individual award) and Radnor (team award). The winners were presented with their awards by Stacey Hunter. This was captured on video, and forms part of the CRN:Wessex awards ceremony, which may be viewed here:

[CRN Wessex Awards 2021 - Zoom](#)



NIHR Portfolio Restart (non COVID-19 studies).

NIHR Priorities for restart:

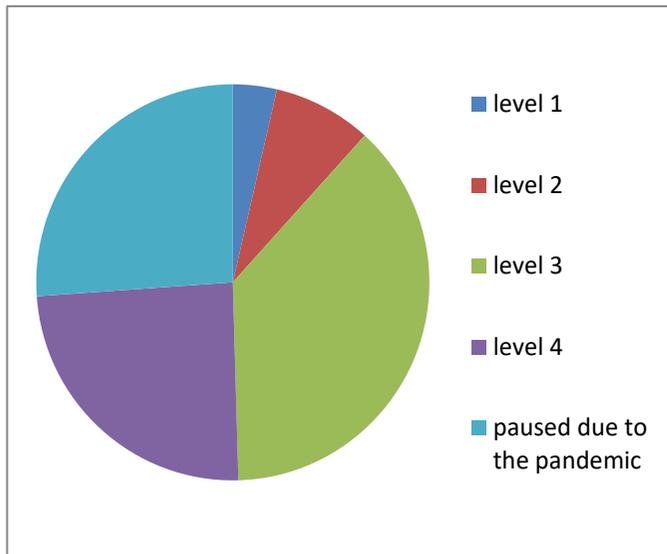
- Level 1: COVID-19 Urgent Public Health vaccine, prophylactic studies and platform therapeutics trials
- Level 2: Other COVID-19 Urgent Public Health studies
- Level 3: Studies where the research protocol includes an urgent treatment or intervention without which patients could come to harm
- Level 4: All other studies

NIHR High level objectives for 2021/22

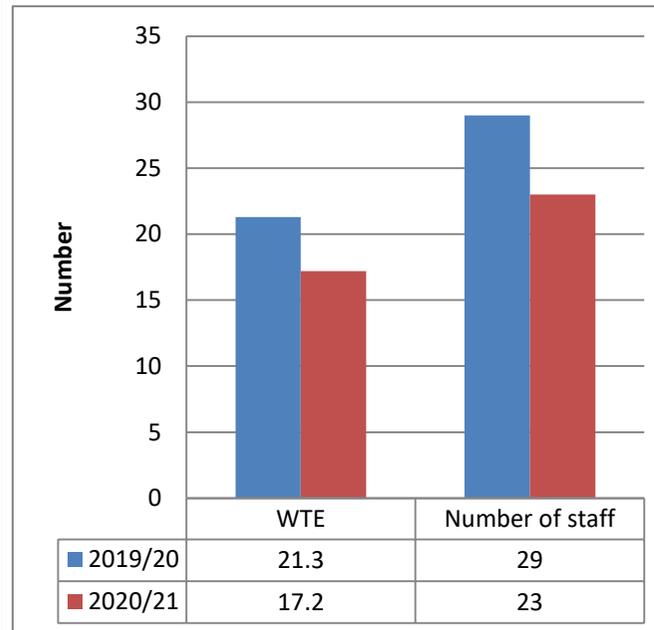
- 80% of new commercial studies recruiting to time and target (RTT)
- 80% of new commercial studies in the managed recovery process RTT
- 99% of NHS Trusts recruiting into NIHR portfolio studies
- 70% of NHS Trusts recruiting into NIHR portfolio commercial studies
- 12,000 study participants responding to the Participant Experience Survey (PES)

The majority of the Trust research portfolio was suspended during the pandemic, alongside suspension of the clinical services and the national focus on running COVID-19 UPH therapeutic trials. Suspension of these studies meant that there was little/no income from these funding sources – a loss of approx.. £100 -150k income for 2020/21. When research staff came to the end of contracts, or left, funding was not available to replace them. The staffing levels in the research dept at the end of March 2021 was therefore 20% lower than March 2020. This has an impact on the ability to restart.

Trust restart as of 31 March



Research Dept Staffing levels



The NIHR priorities for restart and NIHR high level objectives are shown on the left. The portfolio was re-opened in accordance with the NIHR priorities, whilst also maximising Trust recruitment and performance against the other NIHR objectives (which influences future funding from CRN:Wessex). The Trust has restarted 75% of the portfolio, including the majority of the level 3 interventional studies, some of which are game changers for the patients. Most of the level 4 studies that are open are easy, high recruiting studies, or require very little/no input from the research dept. Interventional studies that are currently paused will be re-opened during 2021/22 if and when capacity becomes available.

The Trust hosts both commercial and non-commercial NIHR portfolio studies, and actively monitors and manages RTT. The Trust will offer participants the opportunity to complete a PES when available.

Research Grants Secured

Grants secured & recruitment starting in 2021/22:

<p>ELABS Early Laser for Burn Scars - A prospective randomised, controlled trial to study the effectiveness of the treatment of hypertrophic burn scars with Pulsed Dye Laser and standard care compared to standard care alone</p> <p>PI: Dr Mark Brewin Funding: NIHR RfPB £348,209 over 36 months Design: interventional</p>	<p>HIIT A Feasibility Study of High Intensity Interval Training to Reduce Cardio-metabolic Disease Risks in Individuals with Acute Spinal Cord Injury</p> <p>PI: Prof James Bilzon- Uni Bath Funding: NIHR RfPB £250,000 over 27 months Design: interventional</p>	<p>BOWMAN A Randomised, Sham-Controlled, Proof of Principle Study of Abdominal Functional Electrical Stimulation for Bowel Management in Spinal Cord Injury</p> <p>PI: Dr Tamsyn Street Funding: Inspire Foundation £107,111 over 36 months Design: interventional</p>	<p>3 research projects secured £705,320 external grant funding and are in the process of being set up. The 3 grants are predicted to recruit 60 participants between them in 2021/22. A fourth grant is currently under consideration by the NIHR EME funding scheme.</p> <p>Research Capacity Funding (RCF) is awarded to research active NHS Organisations that recruit >500 participants (£20k) OR received NIHR income in the previous calendar year (0.28 of income), whichever is greater. The Trust received £20k RCF funding for both 2020/21 and 2021/22. The grant income secured should provide a RCF income of £50k for 2022/23 and £64k for 2023/24. This is estimated to rise to £117k in 2024/25 if STEPS II grant application is successful. This funding will be used to increase the research capacity in the Trust.</p>
--	---	---	---

Grants applications submitted:

<p>STEPS II The Efficacy of Peroneal Nerve Functional Electrical Stimulation for the Reduction of Bradykinesia in Parkinson's Disease: An Assessor Blinded Randomised Controlled Trial</p> <p>PI: Prof Paul Taylor Funding: NIHR EME £1,188,545 over 44 months Design: interventional</p>
--





No going back

This year has delivered unprecedented challenges for us all. The NHS has led the world in COVID-19 research, with all NHS organisations contributing to the global effort. This has completely changed the way the research dept. works. Small teams supporting specific clinical teams has been replaced by the whole dept. working as 1 large team to support, at the peak of the pandemic, just 2 innovative platform trials that provided our sickest patients with the latest C19 treatments. Such an approach strengthened team working, communication, handovers, and demonstrated that it is possible to recruit 100 patients into a complex interventional study in a month with a reduced funding and workforce. We will work hard, as a team, to continue with what has worked well during the pandemic, and to build and strengthen these new ways of working.

We will also work to incorporate the NHS Health Research Authority Research Strategy 'the Future of UK Clinical Research Delivery' into the Trust wide and research specific strategies. *'The public and staff have never been so aware of clinical research, and now is the time to embed the idea that research.....is an essential and rewarding part of effective patient care'*. Research in the Trust can be seen as an optional extra, reserved predominantly for staff in the research dept. The research dept has grown the Trust research portfolio considerably over the last few years, but is now at capacity. If the Trust research portfolio is to grow further, then clinical teams need to engage with research differently. Some clinical teams already embed research into routine day to day clinical practice, working in partnership with the research team, and this is a model that we will work to roll out across the research active clinical depts. in the Trust. Such an approach will be supported by the national plans to properly embed research into CQC inspections and revalidation.

We will continue to develop our non-clinical research delivery roles, and support healthcare professionals to develop research skills relevant to their clinical roles (e.g. associate PI scheme).

Dedicated space for research clinics is also a priority.

A Trust wide strategy will be developed to expand on these ideas further.

Appendix A - Research recruitment 2020/21

Urgent Public Health (COVID-19) studies

Short Name	Managing Specialty	Design Type	Recruitment	Public Link
REMAP-CAP	Critical Care	Interventional	32	38197
GenOMICC	Critical Care	Observational	11	30540
CLARITY	Gastroenterology	Observational	51	46188
FALCON C-19	Infection	Observational	65	45932
ISARIC	Infection	Observational	899	14152
SIREN	Infection	Observational	128	45906
PAN-COVID	Reproductive Health and Childbirth	Observational	44	45571
RECOVERY	Infection	Interventional	110	45388
TOTAL			1340	

COVID-19 studies not UPH

Short Name	Managing Specialty	Design Type	Recruitment	Public Link
Psychological Impact of COVID-19	Mental Health	Observational	574	45621

Non COVID-19 studies

Short Name	Managing Specialty	Design Type	Recruitment	Public Link
CASAP	Anaesthesia, Perioperative Medicine and Pain Management	Observational	7	41168
Add-Aspirin	Cancer	Interventional	1	18067
FLAIR	Cancer	Interventional	1	16675
IMPRESS	Cancer	Interventional	2	17006
LCH-IV	Cancer	Both	1	19926
OPTIMA	Cancer	Interventional	6	12255
SERENADE	Cancer	Both	3	17059
TRIGGER	Cancer	Interventional	1	20576
CLEAR SYNERGY	Cardiovascular Disease	Both	2	37105
BADBIR	Dermatology	Observational	7	8090
CLEARA	Ear, Nose and Throat	Commercial, Observational	14	-
Molecular pathogenesis of chronic myeloproliferative neoplasms	Genetics	Observational	201	9615
UK Childhood ITP Registry	Haematology	Observational	3	14145
PrEP Impact	Infection	Observational	5	35405
CLIMB survey	Mental Health	Observational	28	44205
UNITS	Mental Health	Observational	1	42099
Neuro LTC	Neurological Disorders	Observational	1	35622
PINNACLE	Ophthalmology	Observational	1	41819
FUTURE	Reproductive Health and Childbirth	Both	1	36043
Big Baby	Reproductive Health and Childbirth	Both	3	36723
The Cleft Collective Cohort Studies	Reproductive Health and Childbirth	Observational	2	14362
OPTIMAS	Stroke	Interventional	2	40836
CIPHER	Surgery	Observational	12	35821
SOLARIO	Surgery	Interventional	3	40430
TOTAL			308	

Appendix B – Research publications

COVID-19 trial publications:

study	summary	link
Clarity IBD	patients with inflammatory bowel disease treated with infliximab have attenuated serological responses to a single dose of a SARS-CoV-2 vaccine. Delayed second dosing should be avoided in patients treated with infliximab	https://gut.bmj.com/content/early/2021/04/25/gutjnl-2021-324789
ISARIC	Our 4C Deterioration model thus demonstrates unprecedented clinical utility and generalisability to predict clinical deterioration among adults hospitalised with COVID-19.	https://www.medrxiv.org/content/10.1101/2020.10.09.20209957v1
PAN COVID	Pregnancy and neonatal outcomes of COVID-19 – co-reporting of common outcomes from the PAN-COVID and AAP SONPM registry	https://www.medrxiv.org/content/10.1101/2021.01.06.21249325v1
Psychological Impact of COVID-19 survey	An evaluation of the mental health impact of SARS-CoV-2 on patients, general public and healthcare professionals: A systematic review and meta-analysis	https://www.sciencedirect.com/science/article/pii/S2589537021000869
RECOVERY	Dexamethasone improves survival rate in hospitalised COVID-19 patients with severe respiratory complications.	https://bit.ly/COVID-dexamethasone
RECOVERY	COVID-19 clinical trials: learning from exceptions in the research chaos	https://www.nature.com/articles/s41591-020-1077-z
RECOVERY	In patients admitted to hospital with COVID-19, lopinavir–ritonavir did not reduce 28-day mortality, duration of hospital stay, or risk of progressing to invasive mechanical ventilation or death	https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32013-4/fulltext
RECOVERY	Completion of clinical trials in light of COVID-19	https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(20)30460-4/fulltext
RECOVERY	The trial has found no clinical benefit from the antibiotic azithromycin for hospitalised patients with severe COVID-19.	https://www.nihr.ac.uk/news/recovery-trial-shows-no-clinical-benefit-from-azithromycin-for-hospitalised-patients/26401
RECOVERY	Between July & Dec 20, dexamethasone is estimated to have saved 12,000 lives in the UK and 650,000 globally	https://www.nature.com/articles/s41467-021-21134-2#disqus_thread
RECOVERY	tocilizumab reduces the risk of death for hospitalised patients with severe COVID-19. the drug reduces the length of hospital admission, and the risk of patients requiring mechanical ventilation.	https://www.nihr.ac.uk/news/recovery-trial-shows-tocilizumab-reduces-deaths-in-patients-hospitalised-with-covid-19/26844
REMAP-CAP	In critically ill patients with COVID-19 receiving organ support in intensive care, treatment with the IL-6 receptor antagonists, tocilizumab and sarilumab, improved outcome, including survival.	https://www.medrxiv.org/content/10.1101/2021.01.07.21249390v1
SIREN	Pfizer-BioNTech vaccine provides high levels of protection against infection and symptomatic disease from the first dose. Data shows one dose reduces the risk of catching infection by more than 70%, rising to 85% after the second dose. This suggests the vaccine may also help to interrupt virus transmission, as you cannot spread the virus if you do not have infection.	https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3790399

Non- COVID-19 trial publications

study	specialty	summary	link
TORPEDO	children	Compared with oral therapy, intravenous antibiotics did not achieve sustained eradication of P aeruginosa in a greater proportion of patients with cystic fibrosis and was more expensive. These results do not support the use of intravenous antibiotics to eradicate P aeruginosa in cystic fibrosis.	Lancet Respir Med 2020; 8: 975–86
BADBIR	Dermatology	Randomized Trial Replication Using Observational Data for Comparative Effectiveness of Secukinumab and Ustekinumab in Psoriasis. secukinumab resulted in more patients achieving a PASI of 2 or lower after 12 months of therapy compared with ustekinumab in patients with psoriasis	https://jamanetwork.com/journals/jamadermatology/fullarticle/10.1001/jamadermatol.2020.4202?guestAccessKey=d3e5aa1d-3a73-4ae4-9c6d-1cc56753ab79&utm_source=twitter&utm_medium=social_jamaderm&utm_term=4270895183&utm_campaign=article_alert&linkId=106090065
Halt-it	ED	Tranexamic acid does not improve outcomes in GI bleeding patients but instead may increase side effects	https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)30848-5/fulltext
TIRED	ED	Higher NFR scores were observed among emergency physicians than reported in any other profession or population to date. While out-of-hours working is unavoidable, the linear relationship observed suggests that any reduction may result in NFR improvement.	https://bmjopen.bmj.com/content/10/11/e041485
NIHR Bioresource	Genetics	The researchers looked at 886 patients with primary immunodeficiency, which affects the ability to fight infections caused by microbes. The analysis identified four new genetic associations linked with this condition	https://www.nature.com/articles/s41586-020-2265-1
NIHR Bioresource	Genetics	The study looked at the genetics of rare diseases. The research team found that 'sequencing whole genomes for patients with rare diseases can improve their diagnosis and care'. The researchers 'identified 95 genes associated with rare diseases in these tissues. For at least 79 of these diseases, variants in the genes were shown to definitively cause the disease.	https://www.nature.com/articles/s41586-020-2434-2
VESPA	Reproductive Health	There was no evidence of an association between consultant presence in Early Pregnancy Assessment Units and clinical outcomes measured as the proportion of women who were admitted as emergencies.	https://www.journalslibrary.nihr.ac.uk/hsdr/hsdr08460/#/abstract
GAPS	Surgery	Low-dose low-molecular-weight heparin was non-inferior in reducing venous thromboembolism events in surgical patients at medium or high risk compared with use of graduated compression stockings in addition to heparin.	https://www.journalslibrary.nihr.ac.uk/hta/hta24690/#/abstract