



Research bulletin, October 2020

First patient in UK and Europe enters ONE RCC, cohort 2 at ELHT

The first patient in the UK and Europe has been entered into cohort 2 of the ONE RCC study at ELHT by Consultant Clinical Oncologist, Dr Omi Parikh and Research Nurse Sarah Keith. The research, which opened at ELHT just days earlier, is looking at patient reported outcomes and treatment experiences in patients diagnosed with advanced renal cell carcinoma (aRCC). So far 3 East Lancashire patients have been entered into the research.

The study was an opportunity for the ELHT Cancer Research Team to open new research, despite the challenges of COVID-19. The set-up of the study proved a learning experience for the team, utilising the latest NIHR interactive costing template and, in light of COVID-19 restrictions, a virtual site initiation visit.

This international study will involve 4000 adult patients and is sponsored by Bristol-Myers Squibb. Dr Parikh is Chief Investigator the study in the UK. Cohort 2 of the study involves 3 years of data collection and will look at response to treatment in a real-world setting for patients about to initiate first and subsequent treatments for aRCC.

Senior Research Nurse/Team Lead, Rachel Bolton said: "East Lancashire has strong track record in supporting urology cancer studies and we are committed to continuing to provide access to quality research during these challenging times."

ELHT top recruiting site for ACE prostate cancer study

The ELHT remains the highest recruiting site for the ACE prostate cancer study. The research is supported at ELHT by Consultant Clinical Oncologist Dr Omi Parikh and the Cancer Research Team. The research is looking at whether there is a difference in cognitive abilities, mood and fatigue in patients with metastatic castrate resistant prostate cancer who are receiving hormonal treatment (Abiraterone Acetate in combination with either Prednisolone or Enzalutamide).

After opening at ELHT in November 2018, the entry of patients was temporarily paused for COVID-19. The research restarted in August and 38 East Lancashire patients have now joined the study. ACE is led by Chief Investigator, Professor Amit Bahl, Consultant Clinical Oncologist at University Hospitals Bristol NHS Foundation Trust.

ELHT Senior Research Nurse/Team Lead, Rachel Bolton said: "We take a team approach to supporting the ACE study and do everything we can to provide access to quality research during our patients' cancer journeys. We continue to support patients and collect data during follow-up. We would like to thank all the patients that contribute their time in helping us learn more about their experience."

Research

Contact us

Research, Development and Innovation, Level 3, Royal Blackburn Hospital, Blackburn, BB2 3HH.
Tel: 01254 733008; Email: research@elht.nhs.uk; www.elht.nhs.uk/research; @ELHTresearch

COVID-19 research

Over 1000 East Lancashire patients support ISARIC COVID-19 research study

The ISARIC Clinical Characterisation Protocol UK (CCP-UK) is an observational cohort study which employs rapid data gathering and near real-time analysis, using a pre-approved questionnaire adopted by the World Health Organisation. Since opening at ELHT in March, under the leadership of Principal Investigator Dr Srikanth Chukkambotla, 1083 East Lancashire patients have entered the study.

Wendy Goddard, Senior Research Nurse/Team Lead said: "I'd like to thank the COVID-19 Research Team for their hard work and dedication." Nationally, over **200,000 people have taken part in COVID-19 research** studies with 10,400 of those coming from the Greater Manchester Research Network footprint.

Convalescent plasma arm of the RECOVERY trial now open at ELHT

The RECOVERY trial is a randomised trial investigating a series of treatments among patients hospitalised with a confirmed diagnosis of COVID-19. Eligible patients taking part in the trial are randomly allocated between treatment arms, each given in addition to the usual standard of care. The research which is sponsored by the University of Oxford, has already demonstrated benefit for ventilated patients with COVID 19 who receive the steroid dexamethasone.

ELHT is now able to enter patients into the convalescent plasma arm of the trial. Convalescent plasma is the antibody rich plasma of people who have recovered from COVID-19, which can be transfused into people who are struggling to develop their own immune response. Although there is some promising evidence of patient benefit, its effectiveness needs to be tested through robust clinical trials before it can be provided for general use. The ELHT COVID-19 research team has enrolled three patients so far to this arm, two of which have been randomised to receive the convalescent plasma.

BRIDGeS group

The **Blackburn Research Innovation Development Group in General Surgery (BRIDGeS) Group** has launched a **new website**.

The group aims to provide a platform for all research activity including regional and international collaborative work.

Members of the group have collaborated on research on patient outcomes in hepatobiliary, colorectal and upper gastrointestinal surgery and the paper, "The impact of prehabilitation on patient outcomes in hepatobiliary, colorectal, and upper gastrointestinal cancer surgery: a PRISMA-accordant meta-analysis", authored by Dr Joel Lambert, has been accepted for publication in the *Annals of Surgery*.

Children's ward staff thanked for supporting the CASAP study



The CASAP study, which looks at perioperative outcomes for children undergoing emergency abdominal surgery, reopened in August after pausing recruitment due to COVID-19. The study is led locally by Consultant Anaesthetist and Principal Investigator, Dr Ian Clegg.

Dr Clegg thanked staff for their dedication and support after the recruitment of 17 patients: "Recruitment of patients for non COVID-19 studies is a challenge at present. Nursing staff on the paediatric ward have been a pleasure to work with and their engagement in the study is a key to its success. The research team have been brilliant and have worked incredibly hard to capture as many patients as possible including facilitating the consent for patients in the evening and at weekends, alongside clinical staff".

Team Leader for the Women and Children' Health Research Team, Bev Hammond re-iterated Dr Clegg's praise of ward staff and highlighted that the success in recruitment was a fantastic collaboration. The research is sponsored by University College London.

Chloe Davison awarded RaCES Internship



Chloe Davison, Research Support Officer at ELHT, has been awarded an Applied Research Collaboration North West Coast (ARC NWC) Rapid Conversion Evidence Summary (RaCES) internship.

Rapid Conversion Evidence Summaries (RaCES) are supported by the University of Central Lancashire (UCLan). They aim to develop the intern's academic writing skills and understanding of systematic reviews.

Chloe described the work she is planning to do during the internship: "My project is looking at the health inequalities of children with Autism Spectrum Disorder (ASD), and bridging the gap between health professionals and patients. I will be using current research which outlines what the current issues are and what has been suggested to fix this, along with input from health care professionals and children (via their advocates) to get the most accurate and robust outcome. I have the support of the ELCAS team, especially Dr Timothy Morris who heads up the new ASD team there. I will be working along a team from UCLan to assist me with all of this, and will be taking part in a few MSc level modules over the course of the next year, including an implementation science module."

East Lancashire trial activity

East Lancashire Hospitals NHS Trust Recruitment by Specialty FY2021



Publications

Mifemiso study

Results of the Mifemiso study have been **published in the Lancet**. The study, which was led by Professor Arri Coomarasamy at the University of Birmingham and conducted by the Birmingham Clinical Trials Unit, took place at 28 UK hospitals. The research investigated whether a combination of mifepristone (an anti-progesterone drug) and misoprostol (a prostaglandin) was more effective than administering misoprostol alone for the treatment of missed miscarriage. The results showed that pre-treatment with mifepristone followed by misoprostol resolved miscarriage in more women than treatment with misoprostol alone and reduced the need for follow-up surgery. The study was led at ELHT by Dr Kalsang Bhatia and supported by the Women and Children's Health Research Team.

Network news

NIHR Participant in Research Experience Survey 2020

This year's NIHR Participant in Research Experience Survey (PRES) has been launched. The survey is open to participants who have previously or are currently taking part in research supported by the National Institute for Health Research (NIHR). The PRES can be completed by participants using the online [google form](#). The survey is conducted each year, across all regions in England, to understand more about the experiences of clinical research participants.

Last year's survey showed that 90 per cent participants involved in research within the NIHR CRN Greater Manchester had a good or excellent experience while 83.1 per cent said they would be happy to take part in another research study. A recurring theme in participant comments was that they are proud to be contributing to research which could improve outcomes for future patients.

Vaccine research registry



NHS Digital and the National Institute for Health Research (NIHR) developed a **volunteer sign-up service for coronavirus vaccine studies**. The registry is providing a pool of volunteers who consent to be contacted about vaccine research across the United Kingdom.

Currently over 287,560 people have signed up across the UK with almost 11% of those coming from the Greater Manchester region.

However, people from ethnic minority backgrounds are currently under-represented in vaccine clinical trials in the UK, with only 11,000 volunteers from Asian and British Asian backgrounds and 1,200 Black, African, Caribbean or Black British volunteers. Black, Asian and Minority Ethnic communities are disproportionately affected by Covid-19. Researchers have called on more people from Black, Asian and Minority Ethnic backgrounds to participate in COVID-19 vaccine studies to ensure that any vaccines developed will work effectively for the whole population. **UK researchers are also encouraging additional volunteers** from people with underlying health conditions such as chronic diseases and the over 65s, to be part of clinical trials so that any vaccines developed will work for as many people as possible.

NIHR guidance for a second-wave of COVID-19 activity

The NIHR has issued **guidance** for the prioritisation of infrastructure resources (including NIHR Clinical Research Network resources) during a 'second wave' of high COVID-19 activity. The guidance applies to England, but has been developed in consultation with representatives of the devolved administrations.

The guidance highlights that the deployment of staff funded through an NIHR Infrastructure award or funded by the NIHR Clinical Research Network (CRN) to front-line duties should only occur in exceptional circumstances and that NIHR research activities and restart decisions should continue to be locally led. The prioritisation levels in the **Restart Framework** remain unchanged and, wherever possible, the restart of non-COVID-19 research studies within the NIHR CRN Portfolio, which were paused by sponsors and sites due to the pandemic, is encouraged. This includes opening new commercial and non-commercial studies.

Public perceptions towards vaccine trial research



The NIHR Clinical Research Network has established a COVID-19 Vaccine Research Delivery Group. The role of the group is to coordinate resources and intelligence to deliver new COVID-19 vaccine studies across the UK and to establish regional facilities which will recruit participants at scale and pace.

In support of this work, the Clinical Research Network East Midlands (CRN EM) Vaccine Research Delivery Group commissioned a community consultation to support the understanding and delivery of the COVID-19 vaccine studies. The consultation was undertaken by the University of Leicester, Centre for BME Health. Topics covered in the discussions included contributor's feelings towards attending hospital for research, towards COVID-19 vaccine research and the role of patient and public involvement and community involvement. To **view the full report**, visit the NIHR Applied Research Collaboration East Midlands website.

The Directorate of Education, Research and Innovation issued the following statement to investigators:

"Along with the rest of the Trust, we in DERI are following the current guidance to maintain business as usual, whilst monitoring the effects of the rising numbers of Covid-19 cases on the Trust resources and acting accordingly.

In the Research & Development team, we have restarted 52% of studies which were paused at the beginning of the first wave in March. However, given the increase in Covid-19 incidence and current Trust pressures, including the impact on staffing, we have decided to follow the NIHR guidance and make a local decision to take a temporary halt on restarting any more paused studies or to open any new ones, with the exception of those in relation to Covid-19.

We will continue to carry out background work, preparing for studies that are in the pipeline and completing feasibility for studies already in consideration, but we will not be submitting any newly received Expressions of Interest at this time.

We apologise for any inconvenience or disappointment that this may cause, but the safety of our staff and patients remain our top priority and we do not wish to take on any commitments that we cannot fulfil. This situation will be reviewed by the DERI Research and Development Senior Management Team on a weekly basis and we will ensure the Team Leaders keep you updated regarding your studies."

Regulatory news

Good Clinical Practice Guideline (ICH E6), revision 3

An expert working group has convened to revise the ICH Good Clinical Practice Guideline (E6 revision 2). The review will address the application of GCP principles to the increasingly diverse trial types and data sources being employed to support regulatory and healthcare related decision-making on drugs. The UK medicines regulator, the MHRA is contributing to the review. The revised guideline will aim to provide flexibility when appropriate to facilitate the use of technological innovations in clinical trials. [Further information](#) can be viewed on the ICH website.

MHRA guidelines for clinical trials

From 1st January 2021, the Medicines and Healthcare products Regulatory Agency (MHRA) will be the UK's standalone medicines and medical devices regulator. [Guidance for industry and organisations to follow](#) can be accessed via the MHRA website.

UK medicines regulator joins the Access Consortium

The Medicines and Healthcare products Regulatory Agency (MHRA) is the latest regulator to join the Australia-Canada-Singapore-Switzerland (ACSS) Consortium. The MHRA will officially commence working with Consortium partners as a full member from 1st January 2021 and the group will now be known as the Access Consortium.

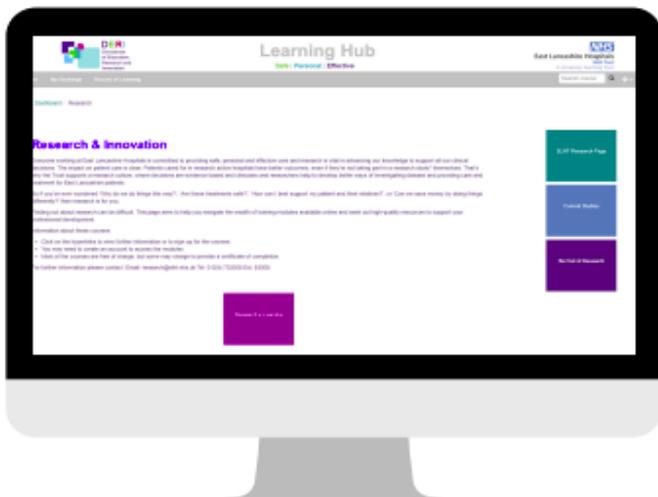
The aim of the group is to provide patients with timely access to high quality, safe and effective therapeutic products across the five countries. This is accomplished by Access partners working together with reduced regulatory duplication.

The addition of the UK brings the combined population of countries participating in the Consortium to approximately 145 million. Pharmaceutical companies that submit applications to some or all of the five Access countries will benefit from having their products evaluated for marketing in those countries simultaneously with reduced evaluation times.

Guidance for industry on how to apply to have products considered for a marketing authorisation across the five member countries, including the UK will be available on 1st January 2021.

Professional development

Research e-Learning page updated



The research e-learning page has been revised and updated. The page is available through the ELHT learning hub and provides a single point of information to a wide variety of on-line learning modules in research. Details of learning provided by the Medical Research Council, Health Research Authority and the National Institute for Health Research can be explored, together with information about how to access the online modules.

Hazel Aston, Research Quality Manager commented: "We're really grateful to the DERI team for supporting this work and in particular to Rio Agnello who's worked so hard to develop the resource."

The research e-learning page can be accessed through the [Learning and Development Journey](#) tab on the ELHT Learning Hub.

Creative communications - the poster presentation

Date: 12th November 2020, 1-2pm

Venue: Via MS Teams

To register interest: Please contact Cathie Melvin, Clinical Research Development Lead on 07977503545

Your poster presentation advertises your research. It should combine text and graphics to present in a way that is visually interesting and accessible, and allows you to display your work to a large group of people, and to talk to and receive feedback from interested viewers. This workshop is aimed at anyone who wants to be a bit more imaginative with their poster. Come and spend your lunch hour exploring and creating the poster of your dreams, with Gillian Southgate, Director of Collaboration & Communication, NHS Research & Development North West.

ELHT Foundation Conference: Virtual event

Date: 21st January 2021

Facebook <https://fb.me/e/aCliWRRdy>; Twitter @elhtposterevent

This year's ELHT Foundation Conference, aimed at Foundation Doctors and Junior Clinical Fellows around the UK, will include poster and oral presentations on the theme of Quality Improvement. Submissions to the conference will be assessed by a panel of ELHT Medical and Surgical Consultants and members of the QI team. A selection of high quality workshops will be available throughout the day, educating trainee doctors about Quality Improvement.

HEE/NIHR bridging scheme deadline extended

Application deadline extended to 30th November 2020

Further information:

The Health Education England (HEE)/National Institute for Health Research (NIHR) bridging scheme is designed to help nurses, midwives, allied health professionals, pharmacists and healthcare scientists to build the strongest possible applications for a PhD or a post-doctoral level fellowship. To be eligible, applicants must be about to complete a master's degree or PhD, hold a professional registration and have begun to develop a research profile within an NHS organisation.

NIHR Fellowship

The National Institute for Health Research (NIHR) Academy provides training and career development awards in order to build a leading health and social care research faculty and to develop research careers, research leaders and collaborators. A range of awards are available at different levels and to suit different work arrangements, types of professional backgrounds and career paths.

A masterclass, on how to improve the chances of success when applying for an NIHR Fellowship was held by the Research Design Service South East. The event took place on-line and the **slides** and a series of supporting **video resources**, are now available on the Research Design Service website.

Nursing research careers

The Royal College of Nursing **online professional development resources** support registered nurses to use knowledge and innovation to transform patient care. The resources guide those looking to use or develop research to enhance their practice. There's also a section dedicated to the **role of the clinical research nurse** and a series of case studies to inform and support nurses to move into the field of research.

Genomics in healthcare on-line training

The Health Education England 'Genomics 101' course is now available online via the Genomics Education Programme website. This on-line course explains the fundamental principles of genomics and the applications in healthcare. It has been developed for healthcare professionals with little or no previous genomics knowledge. The course is part of a series and at the end of each course, there is an opportunity for learners to demonstrate what they have learnt and download a certificate of participation. The e-learning module is free to all NHS staff and UK Universities and can be accessed via the **Genomics Education Programme website**.

Save the date

Annual non-commercial sponsors symposium: 9th December 2020



The event includes keynote and parallel presentations from regulators, policy makers and academic leaders in research quality and management, and non-commercial sponsors of research.

Reflect and Connect: 25-29th January 2021



The NHS Research and Development Forum in partnership with the Research Quality Association (RQA) will hold a series of online sessions to reflect on the future of research. Speakers will include national leaders from key government departments, research regulators, members of the R&D community, as well as the research leads of high-profile studies.

CRN GM Clinical Research Nursing Resources

The CRN Greater Manchester Workforce Learning and Development Team have collated a set of resources to support their attendance at Higher Education Institution (HEI) employability events. The resources are aimed primarily at undergraduate nurses but will also support experienced nurses wishing to explore information about the field of Clinical Research Nursing. The **resources are now available** to view on the CRN GM Workforce, Learning and Development webpage. For further information, please contact the **CRN Greater Manchester Workforce Learning and Development Team**.

