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Welcome

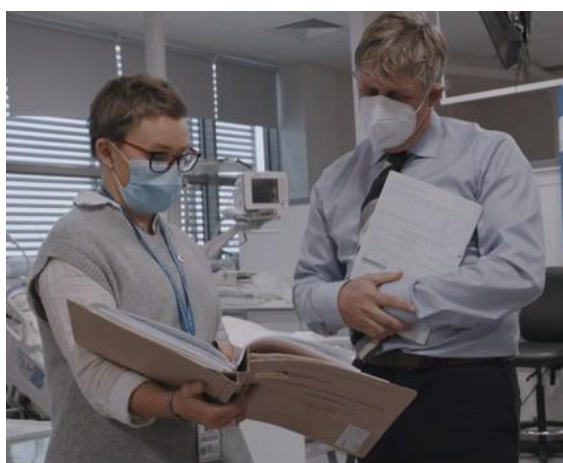
Welcome to the first issue of the Irish Critical Care - Clinical Trials Network (ICC - CTN) newsletter. Through these bi-annual newsletters, we aim to provide updates on our latest research activities including current, upcoming and closed trials, training and education opportunities, upcoming events, publications and more.

We have chosen to mark International Clinical Trials Day (ICTD) 2022 by distributing our first issue and to kick off, we want to highlight the **significant collaborative effort we have all made in response to the COVID-19 pandemic**. This observational, interventional, laboratory and patient-perspectives research program has significantly impacted patients and families, practice guidelines, bedside care and beyond by saving lives and ICU bed days. Well done to all of the ICC-CTN team throughout Ireland on these achievements. We have dedicated a spotlight section to this work below.

Inside this Issue

- Recent news and activities
- Upcoming events
- Spotlight on - pandemic resilience
- Current and upcoming studies
- Closed and completed studies

Additionally, to **highlight some recent news & activities, hot off the Press** - REMAP-CAP has been awarded the Australian Clinical Trials Alliance (ACTA) Trial of the Year Award 2022! We are celebrating ICTD by sharing the good news on our [Twitter page](#) along with some other exciting posts.



The ICC-CTN was also one of six Clinical Trials Networks awarded funding under the HRB CTN-2021 award scheme. We are delighted to start this new chapter and preparations for the implementation of new projects and activities under the award are underway. We look forward to informing you about these exciting initiatives (**PPI, Training, Education & more!**) and on getting your feedback on them as they develop.

Take care
Alistair, On behalf of the ICC-CTN Executive

Upcoming Events

You are invited to the ICC-CTN Summer Meeting 2022. We hope to see you in the Titanic Belfast on June 14th for an exciting meeting programme soon to be announced! We look forward to welcoming you next month!

Spotlight on – Pandemic Resilience

Our clinical research portfolio to prepare for, and respond to pandemics began over 10 years ago with work characterising the 2009 H1N1 Influenza pandemic. This led to the establishment of several initiatives laying the infrastructure for the projects we have all been a key part of within the ICC-CTN COVID-19 pandemic response. These projects have improved knowledge of COVID-19 disease, pandemic-research methodology, public and clinician perceptions of pandemic research, education and support of clinicians/ researchers, clinical practice and guidelines, and, fundamentally – survival and recovery of our patients.

Collectively, to date, these projects have included more than **1,500 Irish patients across 18 ICUs** as part of a larger global collaboration that includes >530,000 COVID-19 patients, 1,651 centres and 63 countries. Ireland has punched well above its weight (per capita) in these studies. It is a testament to all the hard work done by our clinicians and researchers, but also the understanding of our patients and their families during the COVID-19 pandemic.



PREPARE – the Platform for European Preparedness Against (Re-) emerging Epidemics

PREPARE (EU FP-7 program – 2014 – 2020) included several projects investigating aspects of pandemic research: a clinical trial to test treatments, determining ethical and regulatory barriers to conducting clinical trials during a pandemic, and obtaining public and clinical perceptions of pandemic research. This work has laid foundations for a rapid adaptive response to the COVID-19 pandemic as the following studies show



GenOMICC – Genetics of Mortality in Critical Care

Led by Edinburgh University, GenOMICC aims to determine genetic factors that influence outcomes in critically ill patients. In the last two years GenOMICC has focused on identifying several genetic factors for susceptibility to critical illness with COVID-19. Two publications in Nature in **2021** and **2022** revealed the GenOMICC study identified new therapeutic targets (with more than 14,000 genetic samples taken so far) which are now helping to inform the design of new clinical trials. GenOMICC also looks at genetic markers in other disease areas and we are busy getting approvals ready to investigate those areas in Ireland – we are actively recruiting additional sites.

Irish National Pandemic Biological Sampling in COVID-19

SVUH UCD-CRC has initiated this study for the rapid, coordinated clinical investigation of COVID-19. This protocol has been designed to enable data and biological samples to be collected and shared rapidly through a globally harmonised sampling schedule. The ICU Research team in SVUH are actively taking part in this study and we are recruiting additional sites.

REMAP-CAP - RANDOMISED, EMBEDDED, MULTIFACTORIAL ADAPTIVE PLATFORM TRIAL FOR COMMUNITY-ACQUIRED PNEUMONIA



In March 2020, a previously sleeping stratum within this adaptive trial was activated allowing patients with suspected/proven COVID-19 access to potential life-saving treatment options within the safety of a clinical trial.

Since then, 11 COVID-19 treatments have been fully tested in REMAP-CAP. We have demonstrated that [corticosteroids](#) and [IL-6 receptor antagonists](#) improve ICU patient survival and reduce organ failure, [kaletra and hydroxychloroquine](#) are ineffective, and may actually harm patients, while [therapeutic anticoagulation](#) might be beneficial to COVID-19 patients who are not critically ill, [but may be harmful in critically ill patients](#) but may be harmful in critically ill patients. Additionally, [convalescent plasma](#) and [antiplatelet therapies](#) were not likely to lead to an improvement in the number of organ support-free days among critically ill patients. These conclusions and publications have influenced WHO and HSE interim guidelines for COVID-19.

REMAP-CAP is a global collaborative trial. The ICC-CTN has been delegated to assist the coordination of REMAP-CAP in Ireland in coordination with the European Sponsor UMC Utrecht and international collaborators. There has been significant Irish leadership of the whole trial but also of individual domains. The participation of the 6 (4 more in various stages of set up) Irish hospitals has guaranteed that the REMAP-CAP results have been generalizable to Irish patients. As many as 11 treatments are currently being tested in REMAP-CAP with ICC-CTN investigators leading and co-leading five of these domains.

SPRINT SARI - SHORT PERIOD INCIDENCE STUDY OF SEVERE ACUTE RESPIRATORY INFECTION

Established pre-COVID to prepare the research environment for tackling a pandemic, SPRINT SARI ensures data are collected in a harmonised way across different countries and settings. Because of this, in response to COVID-19, 1,651 hospitals across 63 countries have collected common data on patients with severe acute respiratory infection. This work has been fundamental to understanding the disease as the pandemic raged on. ICC-CTN Investigators helped establish this project nationally. We continue to produce regular reports of the Irish data and more recently the first [global SPRINT-SARI findings](#) regarding the clinical characteristics, risk factors and patient outcomes in those with severe COVID-19 was published including a total of 40,440 patients from six continents in this analysis.

We thank the HRB for their support in delivering the ICC-CTN pandemic research response programme.



Current and Upcoming Studies



EPO-Trauma – ERYTHROPOIETIN ALFA IN CRITICALLY ILL TRAUMA PATIENTS

This is a prospective, multicentre, randomised, double-blind placebo-controlled, stratified phase III trial of epoetin alfa vs. placebo in critically ill trauma patients. This is a collaboration between European, Australian, and New Zealand colleagues. This ICC-CTN will manage all European sites across 7 countries in conjunction with co-sponsor UCD and support from the HRB. Start up for participating sites in Ireland, Finland and Switzerland is underway in Spring-Summer 2022. This study will finally address the question raised by our EPO-TBI study published in the Lancet in 2015, does EPO improve outcomes in critically ill trauma patients?

MegaROX

The MegaROX randomised trial comparing conservative v. liberal oxygenation targets is a series of multicentre, multinational, randomised, parallel-group, registry-embedded clinical trials nested within an overall 40,000-patients trial sample. The study is globally coordinated by the Medical Research Institute New Zealand with support and funding from the ICC-CTN in Ireland. SVUH is the first ICU in Ireland to start MEGAROX and has enrolled 15 patients to date. This study is actively recruiting for additional sites.



To enquire about or get involved in our active studies please email [Kate](mailto:kate@svuh.ie)



Closed and Completed Studies

TAME – TARGETTED THERAPEUTIC MILD HYPERCAPNIA AFTER RESUSCITATED CARDIAC ARREST

In collaboration with the ANZIC-RC, the ICC-CTN coordinates TAME, and manages the trial in 20 ICUs across 5 European countries. These sites have collectively recruited over 500 patients out of 1700 patient sample size that successfully completed recruitment in August 2021. Data analysis is imminent with publication expected later this year alongside biomarker analysis of the biological samples sub-study. **We'd like to extend a huge thank you and well done to participating centres for their efforts.**



REST – PROTECTIVE VENTILATION WITH VENOVENOUS LUNG ASSIST IN RESPIRATORY FAILURE

REST demonstrated that the use of extracorporeal carbon dioxide removal to facilitate lower tidal volume ventilation did not significantly reduce 90-day mortality in ARDS patients. **Well done to Professor Danny McAuley, Dr James McNamee and the whole team at the Northern Ireland Clinical Trials Unit** on the successful completion, and dissemination of REST ([JAMA, 2021](https://doi.org/10.1093/ajph/2021.11.1911))!

