COVID-19 Research Activities in NHS GG&C

1. NHS GG&C R&D have established a COVID-19 Task force and Clinical Research Team to support recruitment and delivery of COVID-19 trials across NHS GG&C.

The aim is to ensure that NHS GG&C patients and clinicians have

1) access to the best possible experimental treatments and that this will lead to improved knowledge and availability of drugs that are proven to work to the wider population
2) increase our understanding of COVID-19 to help improve patient care and public health policy
3) increase are knowledge of the genetic “make up” of the virus, so we can get better ways to detect, prevent and treat COVID-19

NHS GG&C (patients, clinicians, research nurses, pharmacy teams, and wider research team) are participating not only in in drug trials but projects which collect data and samples.

All of these studies which are currently active have been approved as priority by the NIHR Urgent Public Health Group, and by the CMOs. [https://www.nihr.ac.uk/covid-19/urgent-public-health-studies-covid-19.htm](https://www.nihr.ac.uk/covid-19/urgent-public-health-studies-covid-19.htm)

Please see NHS GGC R&D website for further details [https://www.nhsggc.org.uk/about-us/professional-support-sites/research-development/#](https://www.nhsggc.org.uk/about-us/professional-support-sites/research-development/#)

1.2 How to contact us
All communications from clinical staff and clinical academic staff with respect to new requests for COVID-19 trial(s) and/or research data should be sent to: RandDRecruitment@ggc.scot.nhs.uk. This is a monitored in-box.

For active studies if you have queries please contact the team via the Clinical Research Facilities: QEUH & RAH on: 0141 2327600 and GRI 0141 2116800. For studies involving IMP, Clinical Trials Pharmacy can be contacted at QEUH CRF 0141 232 4066, QEUH Main Pharmacy 0141 452 2974, GRI 0141 211 1188, OR R&D Pharmacy at 0141 314 4018.

NHS GG&C current COVID19 research activity is summarized below

2. Non-Drug studies (adults and paediatrics)

The follow trials/projects are active in NHS GG&C

2.1 ISARIC Clinical Characterisation Protocol (CCP) Tier 0 (CO-CIN) Data collection, no consent COVID19 Clinical Information Network (DHSC-funded, CI Calum Semple, Liverpool). Near real-time analysis and reporting of the clinical characteristics of patients admitted to hospital with SARS-CoV-2 infection, to inform the research and public health responses.

Clinical research nurses and administrators are gathering data from clinical notes and entering it into an online database. (Info at [https://www.recoverytrial.net/](https://www.recoverytrial.net/) Set up by contacting ncov@isaric.org.)

2.2 ISARIC CCP Tiers 1/2 (4C) Sample collection, consent needed
COVID19 Clinical Characterisation Consortium (MRC-funded, CI: Kenneth Baillie, Edinburgh).
Research samples: either one sample set at recruitment, or 4 sample sets on Day 1, 3, and 9 and (if possible) another set 28 days after discharge.

Aims to understand transmission, pathogenesis, and prognosis.

Covid 19 Clinical research team: PPE-trained research nurses obtain consent, and samples of pathogen shedding sites and blood.

(Info at https://isaric.net/4c/virtual_site_visit/ Set up by contacting ccp@liv.ac.uk.)

2.3 GenOMICC Genetic study, consent needed

Genetics Of Mortality In Critical Care (Wellcome-funded, CI Kenneth Baillie, Edinburgh).

Case-control study to identify variants underlying genetic susceptibility to critical illness with coronavirus, which may help identify new targets for treatment and mechanisms of disease.

(Info at: http://genomicc.org/virtual_site_visit_uk)

Covid 19 Clinical research team : principal investigators at GRI, QEUH and PAH are supported by GCP-trained research nurses from the clinical research facility.

Data projects supported, where and when able by local clinical teams

UKOSS: pandemic influenza in pregnancy

National NIHR supported study of women hospitalised with confirmed COVID-19 in pregnancy. Uses the UK Obstetric Surveillance System (UKOSS) to collect anonymized information about all pregnant women admitted to hospital who are confirmed to have the virus infection. The information will be analysed on a continuous basis to inform ongoing guidance for women and maternity staff as we respond to the pandemic. Specifically, the study will describe incidence, management and outcomes of COVID-19 in pregnancy and identify factors associated with better outcomes for women and their babies.

Others: include audit projects such as Covid Surg

3. Drug studies (adults only at present)

The follow trials/projects involving drug therapy are active in NHS GG&C. Please note that no drugs are currently licensed for the treatment of COVID-19

3.1 RECOVERY TRIAL

Randomised Evaluation of COVID-19 Therapy (MRC/DHSC-funded, CI Peter Horby, Oxford).

The RECOVERY trial: This is supported and funded by UK government, and is being rapidly set-up across UK hospitals. This is an open label, randomised controlled trial. The trial is a platform design and will begin by testing some of these suggested treatments in patients who are COVID-19 positive:

- Lopinavir-Ritonavir (commonly used to treat HIV)
- Low-dose Dexamethasone (a type of steroid, which is used in a range of conditions typically to reduce inflammation).
• Hydroxychloroquine (related to an anti-malarial drug)
• Inhaled interferon-beta1a (an antiviral drug; this arm is not currently approved for use in this trial)

The trial will add new potential treatments as they become available, and drop ones that are not working or harmful. The trial is currently the best chance of providing these treatments (free of charge) as supplies are limited and will be targeted to trial participants.

Local NHS GG&C Investigators: our Principal Investigators for RECOVERY are anaesthetists, respiratory physicians, ED consultants etc. supported by a team of GCP trained CRF nurses and pharmacy teams. The CRF nurses will review patients daily, do all data collection (essential it is provided contemporaneously) and be rostered to provide a 7 day week service at GRI, QEUH & RAH. Pharmacy teams have offered similar 7 day support.

3.2 REMAP CAP
This is a Global study, which is supported by the UK Government. This is non-competitive to RECOVERY, involves patients with community acquired pneumonia who have suspected COVID-19 and is set within ITU. Again this is a platform design. Further information will be provided once regulatory approvals are in place to allow this study to start in Scotland. As with above this will be supported by team of GCP trained CRF nurses and pharmacy teams from across NHS GGC and will be active in QEUH and GRI.

3.3 Commercially Sponsored trials
The following studies are being fast-tracked through contractual approvals:
**Remdesivir, Gilead:** we plan to start this trial early next week (at QEUH only as the company have limited us to one site) which will allow us to access to Remdesivir for COVID19 patients with either severe or moderate disease, which appears promising: the ID clinicians have been very keen to progress this. Our lead Principal Investigator is Dr Ray Fox, supported by clinicians in ED, respiratory and ICU and a team of GCP trained CRF nurses and pharmacy teams from across GRI, QEUH and RAH.

**Tocilizumab-Roche:** in set up phase, we are currently the only site selected in Scotland, with Lothian due to come on board in the near future. As with above this will be supported by team of GCP trained CRF nurses and pharmacy teams from across NHS GGC.

**Future studies:** these will be updated on the website as they become active
It is anticipate that there will be a number of local studies funded through the CSO funding call (deadline 8/4/20)