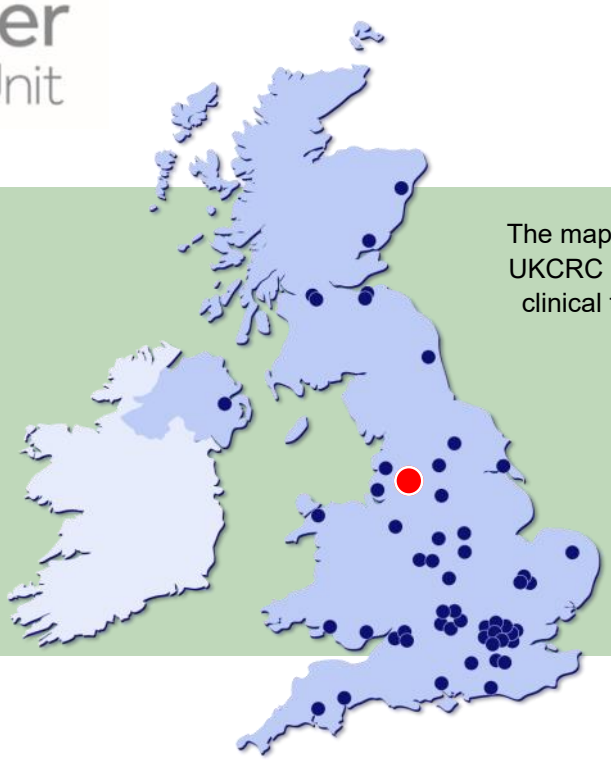
UKCRC Registered Clinical Trials Units

MANCHESTER 1824 The University of Manchester

Manchester Clinical Trials Unit

MCTU opens Intensive Care COVID-19 trial in just 5 weeks whilst fully remotely based



The map shows all UKCRC registered clinical trials units

Serious COVID-19 infections leading to acute respiratory distress syndrome (ARDS) has created an unprecedented pressure on critical care units. There was an obvious need to target the cause of ARDS to reduce the need for, or duration of, mechanical ventilation, thereby improving morbidity and reducing the current strain on critical care resources.

MCTU is a UKCRC-registered academic clinical trials unit that has been located within University of Manchester since August 2018, and is an integral part of the UoM's COVID-19 research strategy, being involved in the design, quality assessment and set-up of multiple COVID trials and observational studies.

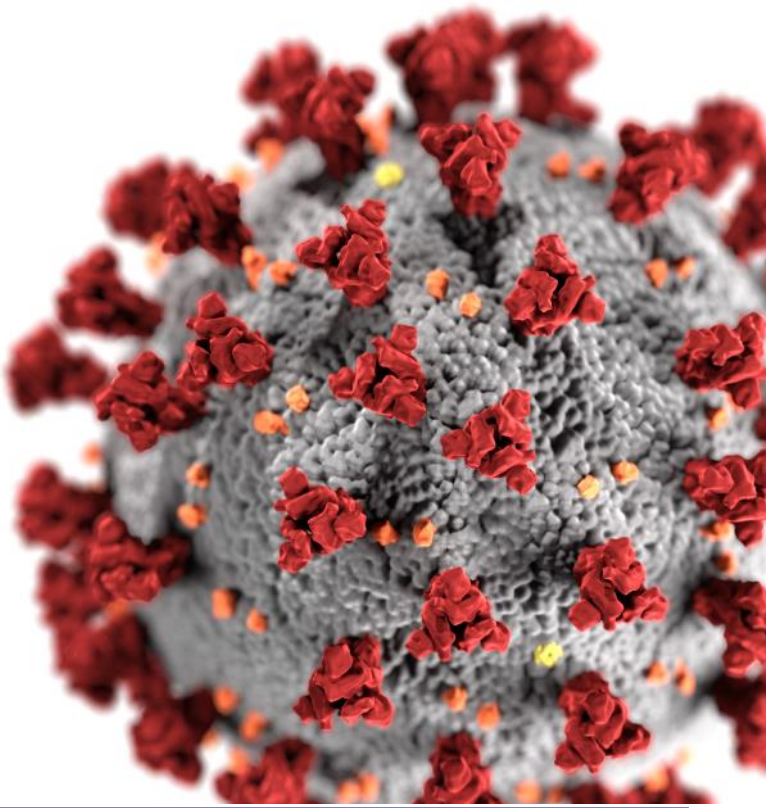
MCTU's agile response to this crisis has been clearly demonstrated by the set-up in an incredibly short time of a COVID-19 research trial focused on adults on intensive care with COVID-related acute respiratory distress syndrome ('Subcutaneous & Intravenous anakinra in COVID-19 Infection: Feasibility & Pharmacokinetics/Pharmacodynamics (SCIL COV Trial)', chief investigator: Tim Felton).

Observational data suggest that there is a subgroup of patients that demonstrate a hyper inflammatory response (excessive inflammation)

in response to COVID-19 and have a higher requirement for Critical Care and higher mortality. There is a strong case for the use of the naturally occurring anti-inflammatory cytokine interleukin-1 receptor antagonist (IL-1Ra) to 'turn down' the inflammation in these patients. Anakinra is a recombinant form of IL-1Ra that is licensed for clinical use. Success of use of anakinra in COVID-19 trials will be greatly enhanced by robust scientific evidence and established pharmacokinetics which inform the most effective dosing regimens. The latter is especially important when, as in the case of

anakinra, drug supplies are limited, the drug has short half-life and clinical ease of application is critical.

MCTU collaborated with the CI to design and set up this randomised, open-label, parallel group feasibility and pharmacokinetic/pharmacodynamics (assessing the effects of the drug on the body, and assessing how it works) Clinical Trial of Investigational Medicinal Products study, having moved to an entirely remote working model only weeks before. We were able to re-purpose capacity in the MCTU to ensure rapid development of the study, protocol peer review, sponsorship review and funding approval by the NIHR BRC.



Virus image: CDC / Alissa Eckert & Dan Higgins