## COVID-19 response from the UKCRC network: Case studies



BIRMINGHAM CANCER RESEARCH UK CLINICAL TRIALS UNIT







Patients with AML and COVID-19 Epidemiology

The impact of COVID-19 on patients with Acute Myeloid Leukaemia (AML) undergoing chemotherapy: an epidemiological study The map shows all UKCRC registered clinical trials units

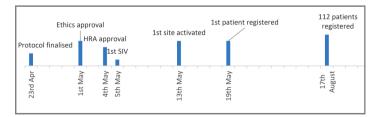
The Trials Acceleration Programme (TAP) hub at the Cancer Research UK Clinical Trials Unit (CRCTU) was already in discussions with the Chief investigator, Prof Simon Stanworth (Oxford University Hospitals), at the start of this year around an observational study in AML patients to investigate infection during chemotherapy.

As the standard chemotherapy options make these patients more likely to pick up infections, and treatment cannot be delayed, the emergence of the COVID-19 pandemic was of significant concern. Therefore, the Trial Management Group decided to move the main focus of this study to understanding the impact of COVID-19 on patients with AML.

This observational study will recruit 200 patients with AML who are receiving, or due to receive, treatment with chemotherapy. The main aims of this study are to record how many of these patients have had COVID-19 previously, have an active infection or go on to develop COVID-19 whilst receiving treatment for their AML.

Data is collected for 6 months on COVID-19 testing and any other infections patients' experience. The study will look at symptoms and severity, treatments received and outcome, for both infections and the patients underlying AML. An additional grant has recently been secured to enable sample collection from these patients to further understand the immune response and changes in the gastrointestinal microbiome (normal gut bacteria) in association with infection.

The CRCTU was well placed to deliver this study with extensive experience in clinical research in haemato-oncology (cancers of the blood system), and expertise in trial and quality management and statistics. The comprehensive CRCTU Quality Management System has guidance and templates available which could very quickly be adapted for the PACE study allowing rapid development. The time between the protocol being finalised to the first patient recruited was 26 days.



The study is funded by Cure Leukaemia as part of the Trial Acceleration Programme grant.

