Title	Observational Cohort Trial -T-cells Antibodies and Vaccine Efficacy in SARS-CoV-2
Trial Design	Multi-centre, multi-disease, prospective observational cohort trial of the immune response to SARS-CoV-2 vaccination.
Background	The rapid development and subsequent authorisation of vaccines against coronavirus (formal name SARS-CoV-2) has been a major step forward for medical science. In the UK, three vaccines have been approved by the regulatory agency so far. It is likely that further vaccines will become available in the coming months. The participants of the vaccine trials were generally healthy volunteers and questions remain as to the level of protection these vaccines will afford patients with chronic illnesses who may have deficiencies in their immune system and may not generate the same protective responses observed in healthy volunteers.
Aim	To evaluate the way the body defends itself against coronavirus (the immune response) following vaccination in clinically vulnerable groups.
Objective	The main objective of the trial is to determine: • the magnitude of the antibody response (referred to as humeral immunity); and • to measure the response of immune cells called T cells (referred to as cellular immunity) in participants with chronic diseases, and/or who have immune deficiency as a result of the treatment they are receiving for their disease, after they receive the vaccine.
Patient Population	Vaccine naive participants with end stage kidney disease, liver disease or gastrointestinal disease on immune suppressive therapy, cancer, immune-mediated rheumatic diseases (e.g. rheumatoid arthritis) and stem cell transplant recipients.
Sample Size	Deep Immunophenotyping Group (Group 1): 150 patients per disease type Serology Group (Group 2): up to 850 per disease type

Inclusion Criteria	• Are eligible for coronavirus vaccination and:
	  ▪ For the Deep Immunophenotyping Group, have not received the second dose of vaccine (booster)
	  ▪ For the Serology Group, have not passed 28 days after the second dose of vaccine (booster)
	• Have an anticipated life expectancy of more than 6 months
	• Fall into one (or more) of the disease groups being studied

Sample and Data Collection	Blood samples and saliva samples(only Group 1) will be collected at the following time points: • Before the first injection of vaccine (optional) - Group 1 and 2 • 1 day after first injection (optional) - Group 1 • Before the boost injection - Group 1, optional for Group 2 • 28 days after the boost injection (+/- 3 days) - Group 1 • 28 days after the boost injection (-7/+14 days) – Group 2 • 6 months after the first injection- Group 1 Clinical data will be collected including: type of disease, treatments received, whether the participant goes onto catch coronavirus.

Trial Duration	Patients will be recruited over a 6 month period and followed up for 6 months in accordance with standard clinical practice for the relevant disease cohort.
Analysis and Results	Samples will be analysed in laboratories around the UK. The results of these laboratory tests and the clinical data will then be analysed and the results published. A lay summary of the results will be posted on the trials website: https://www.birmingham.ac.uk/research/crctu/trials/index.aspx (currently under construction).