

Roger Kirby, President Elect of the Royal Society of Medicine talked to Divya Chadha Manek, Head of Business Development, National Institute of Health Research (NIHR) and Professor Graham Cooke, Professor of Infectious Diseases, Imperial College, London.

Founded in 2006, the NIHR is substantially funded by Government - receiving one billion pounds annually from the Department of Health and Social Care - and is the research arm of the NHS.

NIHR is unique in the world in being an integrated delivery system within a National Health Service.

It's Medical Director is Professor Chris Whitty, Chief Medical Officer for England.

Divya Chada Manek was appointed in 2012/13 to attract more commercial research within this NHS related structure. Under her direction the numbers - researchers 20,000, commercial trials 300 - have both more than doubled.

Why should Drug companies and Governments approach NIHR? It is valued because of the quality and independence of its work, and for the speed and efficiency with which trials are started and completed. Work done by NIHR is very likely to carry through to FDA (US Food and Drug Administration) approval. The phenomenon of "British Exceptionalism" is celebrated!

As COVID 19 approached, Prof. Whitty ordered an immediate pause on all research activity and asked that 100% of NIHR resources be devoted to COVID 19 Research. He called together an Urgent Public Health Group (UPHG) to answer key questions on the pandemic.

Professor Cooke was asked to report on trials, progress and outcomes.

The most significant trial coming out of the COVID19 initiative is **the "Recovery" Trial** which was planned on 20th February and was underway by March 2020 across 176 sites in the UK.

In the 'Virus Targeting Group' of drugs considered for repurposing – he reported, Calibri (an anti HIV drug) does not work. Hydroxychloroquine also does not work - although there is a little more *late* data yet to be released. **In the**

"Host Targeting Group", Dexamethazone seemed to reduce mortality at 28 days, mostly in the oxygen dependant patient group. *Many clinicians were reluctant to enrol their patients* because traditional teaching emphasises that steroids suppress the natural inflammatory response. These results have brought welcome clarification.

In the Remdesivir (anti HIV drug) trial, the UK was the top global recruiter. This was partly because NIHR was asked to over recruit to make up for the short fall in numbers from other countries. **An intravenous preparation of Remdesivir** is still under patent and Gilead Pharmaceutical is reluctant to enter it into the Recovery trial. **Tocilizumab**

(Roche, Atlizumab) is a 'Humanised monoclonal antibody' against the Interleukin 6 receptor (IL6).

It is an immuno suppressive drug currently given for certain auto immune diseases such as Rheumatoid and juvenile Arthritis. Early results on IL6 use in COVID19 are expected soon. **He spoke of a large post mortem study**, just concluded, which has shown wide spread clotting in blood vessels, confirming the multi system consequences of Covid 19 infection seen in life. He **doubted that anti thrombosis trial would be viable** because there would be considerable physician reluctance to enrol their patients knowing the **control group would not receive anti coagulation.**

The **Southampton Company, Synairgen**, is conducting a trial of SNG001, an inhaled drug, (**interferon beta**), currently used for patients with chronic lung disease (COPD) who get colds or flu

Gilead, assisted by NIHR, is looking to start trials for treatment against COVID 19 in the first 72 hours of symptoms i.e. a primary care prescription.

In the UK more than 30,000 subjects have been recruited into COVID 19 treatment trials so far. **Professor Cooke remarked** that one of the challenges “Recovery” faces is **when to share data**. The **Oxford trials** (final stage Phase 3) hope to receive early feedback from UK, USA and Brazil. The **Imperial** trials are in Phase 2.

The emerging expectation is that Vaccination will need one or more booster doses.

David R Hughes

President

21th July 2020

Stop Press. Newspapers are carrying news of the Synairgen trial. Inhalation of Interferon beta is reported to reduce the risk of patients needing Intensive Care.