

Medicine and Device Development in the COVID-19 pandemic and keeping the FPM membership enthused

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Abstract

The two companies I work for are Akari Therapeutics plc and Camcon Medical Ltd, a pharmaceutical company and medical device company. In addition I am the current president of the Faculty of Pharmaceutical Medicine (Royal Colleges of the UK). Firstly with the Faculty we took advantage of the investments into technology made during 2019, a new website, a number of video platforms and on-line examinations. Sadly we closed our office on 6th of April 2020 and like many others in London not to open again until August 2021. We transitioned quickly into Zoom and Teams meetings along with GoToMeetings. We held a planning meeting to build a programme of communications with our members to keep them up to date on COVID-19 and them to join us in a number of activities including meeting and blogs. Within a month the FPM had set up the basis for on-line examinations and cleared this with the GMC. Our CEO Marcia Philbin organised FPM training for the DPM exam and enlisted Alan Boyd to assist using his team of lecturers. Our first Blog went out – leading author Penny Ward got 36,000 reads- got started!

Akari Tx has a biologic – small recombinant dual inhibitor of Complement C5 and LTB4 discovered in the saliva of a tick *Ornithodoros moubata*. As an obligatory blood feeder it development inhibitors of the mammalian innate immune system to stay alive – hence the C5 and LTB4 inhibition. This treatment is in phase III studies for two rare but catastrophic illnesses, Bullous Pemphigoid and Thrombotic microangiopathy (TMA). As severe COVID-19 seems to be an illness driven by dysregulation of the terminal pathway of Complement we became keen to enter it into the efforts to treat the hyper-inflammatory state, the main cause of death. We undertook an observational study in Portsmouth University Hospital led by Anoop Chauhan comparing hospitalised patients with and without COVID-19. We also undertook a compassionate use study in Ohio USA and investigator led study in Brazil. In brief we found that circulating C5b-9 levels (formed from C5 and is a component of the Membrane Attack Protein) predicted those who went on to need invasive mechanical ventilation or sadly died. Also LTB4 we elevated in many of the patients. Our hypothesis is that viral infections, often in the winter, can in at risk patients trigger life threatening illness. This is not confined to SARS-CoV-2 but all the respiratory viruses especially Influenza. Interestingly the treatment of 7 USA patients was successful in 6 who recovered quickly and only one died (through delayed start of therapy) and in Brazil 10 out of 15 recover in the usual dose and 5 needed an increase daily dose to control their illness.

With Camcon Medical we adapted a pulsed oxygen delivery device to deliver short burst of gas 10 to 150mL, at flow rates between 10 and 75 L/min to nasal cannulae. We were trying to avoid the enormous wastage of oxygen with NHFO (nasal high flow oxygen) which appears to get oxygen to the remaining normal lung in those patients in severe respiratory failure. Our work continues to develop the device to enable the patients high level of inspiratory flow, that results for the severe respiratory failure, to be matched by the flow of the pulse gas from the device. Our expectation is that this will be demonstrated over the next three months to enable a clinical device to be produced for clinical trials. We are indebted to Dr Ian Smith, Dr Michael Davies and Dr Alain Vuylsteke at the Royal Papworth Hospital. A reflection – clinical development of medicines and devices takes time and needs help and support from many colleagues.

Biography

Tim Higenbottam is experienced director with a record of discovery of new therapeutics for rare diseases and gaining market authorisation in Europe and USA for medicinal products in neonates, asthma and COPD. Strong professional skills in

Pharmaceutics, Biomarkers, Translational Medicine, Medical Devices, and Vaccines. Led multinational collaborative programmes in the European Framework V and Innovative Medicines Initiatives.