

Trial Update – November 2017

Dear friends and colleagues

Since the family conference, we have been working hard to get the European clinical trial up and running. Our medicine supplier, Guy's and Thomas's pharmacy manufacturing unit, London, has been working with an outside contractor to develop a reliable method of testing stability of our medicine when outside its manufacturer's packaging; they are refining this method, and will then share with Guy's and Thomas's to complete the testing.

In the meantime, our Rebecca Storey and Shazia Ahmed, in our Clinical Trials Unit, have been assembling the documents to go in the regulatory application to the Health Research Authority. Rebecca has updated the clinical trial protocol, created the patient consent forms, and Shazia has prepared all the data forms needed when we enrol people to the trial.

All being well, we will submit the regulatory application to University of Birmingham's legal team for checking by 1st December; with the intention of submitting to the Health Regulatory Authority (HRA) by 15th December.

If we get approval first time, then we are still hoping to start the clinical trial at the end of February 2018.

Meanwhile we have appointed Dr Heather Rose as our trial imaging scientist. Her job will be to make sure that brain imaging scans can be compared between patients recruited from any of the international centres. If she's lucky, she may get to visit each centre and be scanned on their local machine, to align each scanner against her own brain image.

Thank you for your patience, there is a lot of work to do in setting up an international clinical trial, but we are finally making progress, and all this work increases the likelihood that the trial will achieve a conclusive result

Sincerely

Tim Barrett