

## **Important Update – 30<sup>th</sup> April 2018**

I wanted to update you about the TREATWOLFRAM clinical trial. Rebecca Storey, our clinical trials coordinator, has done a fantastic job in writing all the regulatory documents. These include things like patient information sheets, consent forms, ethics submission, clinical trial reporting documents, insurance and adverse event notification. She submitted the whole package in January. We had the ethics committee interview in February, the ethics approval in March, and last week we finally received the UK Health Research Authority approval letter. This means all the approval documents are in place! This has been a fantastic amount of work, and I am really grateful to Rebecca and the clinical trials team in Birmingham for pulling these all together. I am now sending the whole package to our partners in Spain, France, and Poland, so that they can get their own country regulatory approvals in place to start the trial.

The next rate limiting step is production of the medicine. As you know, we have had great difficulty in proving the medicine remains stable when outside its manufacturers' packaging. Our pharmacy production unit at Guy's and Thomas's hospital in London have been working hard to find a method to prove stability; they have made some progress over the last 2 weeks. At the same time, I have been in touch with bulk medicines suppliers, who have found a couple of alternative sources of the medicine that come in old fashioned glass bottles. This could be interesting as the medicine could stay in its original container.

We have a telephone conference about this next week and I remain hopeful that we can solve this problem in the near future. I will keep you all updated through Tracy as soon as I have more information

In the meantime, I am spending the next 2 days with Susan Gleeson meeting some wonderful families at our children's Wolfram clinic here in Birmingham. I hope you all have a relaxing (and sunny) May bank holiday

With best wishes

Tim