

From: Ian Ford Ian.Ford@glasgow.ac.uk

Subject: RE: TARDIS idmc

Date: 2 December 2013 at 19:21

To: Philip Bath philip.bath@nottingham.ac.uk

Cc: Cathie.sudlow@ed.ac.uk, Didier.LEYS@CHRU-LILLE.FR, gcl203@clinmed.gla.ac.uk



Dear Philip

The TARDIS IDMC met again this morning. There are still some problems with the report. This is being looked into and we will meet again, probably in around 2 weeks time.

For the moment, we would like to provide the following feedback:

The TARDIS IDMC was concerned to hear that some participants in the trial might be being maintained on triple anti-platelet therapy beyond the initial 30 day period. We believe that the Steering Committee should take action to educate investigators and should make every attempt possible to prevent this from happening in the future.

We also believe that it is important for us to be able to understand the extent of the problem. This would require collecting information on anti-platelet therapy after 30 days. In particular, the IDMC would like to receive data describing the antiplatelet treatments and periods of treatment (until the bleeding event) for all patients who had a bleeding event after 30 days. We suggest that you prioritise the collection of data for major and fatal bleeds and provide us with this information as soon as it is available.

Ian

