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Dear Howard

Re: CVLPRIT Trial

Further to our recent exchange of emails and letters I am pleased to say that the DMC met on 22/10/12. We reviewed the general statistics of the trial as well as the results to date. The latter review was carried out in camera by medical members of the DMC and statisticians without any members of the trial organisation present.

Review of the information to date led to the conclusion that there are no problems apparent that would prejudice the trial continuing. Under these circumstances our view is that the trial can continue safely.

The only concern of the DMC, which is not a matter that would lead to stopping the trial, is that there seems to be a significant disparity between the centres in terms of the numbers of patients entered into the registry and into the trial. The DMC is somewhat concerned that the data in the end may be biased by the fact that there seems to be a large degree of choice among operators as to which cases they should do. Clearly this is not something that can be changed at this stage and it is simply an observation.

With best wishes
Yours sincerely

