Dear Dr Shannon

Thank you for your preparedness to help our team gain access to CRFs from study 329, and your offer to discuss by telephone and agree a way forward.

On reflection, I do not think that a telephone conversation is the best way to proceed. Can we instead interact by email?

So to begin, I would be grateful if you could indicate what in your opinion is the safest way of getting all CRFs from study to me, suitably de-identified, but otherwise complete with narrative elements intact.

Our purpose is to ensure the fidelity of transfer of information from CRFs to the study 329 CSR, especially adverse events.

If you could begin by answering this question, and posing any questions you have for us, I hope that we will be able to rapidly make progress towards a greater understanding of the outcomes of study 329.

Sincerely

Jon Jureidini