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Dear Professor Jureidini

Many thanks for your response to my letter of 5 November.

With regard to exploring how we might provide your team with access to the CRFs you have requested, I propose that we provide you with the CRFs through the same web-based system we have established to provide researchers with access to anonymised patient level data. To protect patient privacy, the CRFs will have direct identifiers such as names, initials and dates of birth removed. Patient codes will be left intact enabling you to link the CRFs to the Clinical Study Report (CSR) and electronic datasets of anonymised patient level data. The CRFs would be provided under the data sharing agreement required for access to the anonymised datasets to protect patient privacy. If you are happy with this approach, I will work with colleagues on preparing the necessary agreement.

In your letter of 29 October you referred to discrepancies in the adverse event tables for Study 329. This is obviously of concern to me and was something I would have liked to talk to you about. I would be grateful for any further details you are able to provide on this so I can investigate further.

Again, I'd be more than happy to talk this through on the phone. I look forward to hearing from you.

Yours sincerely



James Shannon
Chief Medical Officer