



Jon Jureidini
Clinical Professor
Discipline of Psychiatry
The University of Adelaide
Department of Psychological Medicine
Women's and Children's Hospital
North Adelaide
5006
Australia

**GlaxoSmithKline Research
& Development Limited**
980 Great West Road
Brentford
Middlesex
TW8 9GS
Tel. +44 (0)20 8047 5000
www.gsk.com

11 October 2013

Dear Professor Jureidini

Thank you for your follow-up letter to Sir Andrew dated September 30th 2013.

I wanted to follow up to my last letter to you of September 6th to clarify the information available for this study and our approach to providing electronic anonymised patient level data for further research in a SAS environment.

As you document, Dr. Nisen expressed GSK's support for the RIAT process and we will, as he noted, make Clinical Study Reports (CSRs) available for our studies. Normally, Case Report Forms (CRFs) are not included in a CSR. For study 329, some CRFs are included in Appendix H, namely CRFs for patients having Adverse Experiences leading to withdrawal, serious adverse experiences or death. The narratives for these events are included in the CSRs. The content of Appendix H is not posted on our website because it contains information (such as names) that can be used to readily identify the patients concerned.

All of the data that study 329 was set up to obtain, including that from the CRFs in Appendix H, is contained in the CSRs and the associated appendices which are posted on our website.

We do not publicly disclose Case Report Forms (CRFs) and we do not provide them to other researchers. Complete CRFs are available to regulatory authorities for audit and for them to assure the integrity of the data sets and CSRs. This use of patients' information for these audit purposes is part of the informed consent process for clinical trials and patients' confidentiality is protected.

With regard to the electronic database, we have established a process to provide researchers with access to the electronic anonymised patient level data from our studies; following this process will enable you to request access to these data so that you can conduct your analysis of both the acute and maintenance (continuation) phases of study 329. As with every other investigator requesting access to such data, I would ask that you do indeed submit an analysis plan via the website and sign a data sharing agreement. I have an obligation to protect patient confidentiality and appropriate use of patients' data and so I must insist on these steps.

In conclusion, I believe that you have the complete study data from the CRFs available to you in the listings of the CSR, we have offered (under the conditions noted above) to make the patient level data available to you in an electronic searchable format in a SAS environment and I therefore believe that you have the ability to access the data from study 329 to complete your analysis.

Please let me know if you need any additional assistance.

Yours sincerely

A handwritten signature in black ink, appearing to read "James Shannon". The signature is written in a cursive, flowing style with a large initial "J" and "S".

James Shannon
Chief Medical Officer