GlaxoSmithKline Research
& Development Limited
980 Great West Road
Brentford
Middlesex
TW8 9GS

Tel. +44 (0)20 8047 5000
www.gsk.com

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

20 January 2014

Dear Professor Jureidini

Thank you for your letter of 6 January 2014 and for confirming separately that you will sign the proposed data sharing agreement. I remain committed to granting your team access to the data required for your analysis and I am pleased that we have reached an agreement.

Please be reassured that the wording you have questioned in the agreement does not impact your responsible use of the data for your analyses. It is standard wording used in data sharing agreements in order for us to protect confidential information and patient privacy. We always ask that such information remains the property of GSK and where necessary is returned to us or destroyed following the completion of a piece of work. This applies only to the GSK Confidential Information and not to your analysis of that data. Recognising the particular focus of your work, the agreement also explicitly states that if you believe there are inaccuracies or omissions in our dataset that you identify, you are free to document these and deposit a spread sheet of the corrected data with a journal as part of publishing your research in the peer-reviewed literature.

I understand your perspective on conducting your analyses independently. Nonetheless if you think there would be value in your team talking to the statistician for the study to ensure your team understands and is able to effectively navigate the datasets, please let me know. We offer this type of support to other researchers who access datasets we provide. I do not believe that this type of support compromises the independence of the research and it can help reduce potential misunderstandings of the datasets.

In my previous letter to you I provided information related to two re-analyses of suicidality in paediatrics given serotonin re-uptake inhibitors. With respect, I do not agree with your comments and the interpretation you have made in your letter. GSK carried out multiple paroxetine paediatric trials that showed an inconsistent and variable pattern of efficacy and safety results. A statistically significant difference in suicide-related adverse events and a signal emerged only when adverse event data was interrogated further and data from individual trials were pooled together.

With regard to the points you raise about the follow-up of patients in clinical trials, as is standard in clinical trials carried out according to good clinical practice guidelines,

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investigators and treating physicians involved in GSK-sponsored clinical trials have responsibility for ensuring participating patients receive the appropriate medical care both during and after the trial[1]. They are the physicians who will be most familiar with patients' medical histories and best placed to help patients in the medical management of any condition. All sponsors and investigators must conduct clinical trials to the same scientific and ethical standards, following international regulations and guidelines which protect the safety and well-being of participants. The follow-up of patients in clinical trials is an important topic within these guidelines and if you would be interested in discussing this further, perhaps with other relevant parties, please let me know.

I would like to reiterate that I am more than happy to talk through any of these aspects with you in more detail over the phone, or face to face.

Yours sincerely

James Shannon
Chief Medical Officer

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[1] ICH Harmonised Tripartite Guideline for Good Clinical Practice
http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1__Guideline.pdf