ISAC/13/2nd MEETING

Independent Scientific Advisory Committee for MHRA database research (ISAC)

Summary minutes of the meeting held on Wednesday April 17, 2013 at 13:00am in [R-T-310], 3rd Floor, 151 Buckingham Palace Road, Victoria, SW1W 9SZ.

Present:

ISAC Members:  

MHRA:\n
Prof Patrick Waller (Chair)  
Dr John Parkinson (CPRD)  
Dr Richard Stevens  
Ms Kendal Chidwick (CPRD Secretary)  
Ms Marcia Saunders  
Ms Sharon Suri (Yellow Card Secretary)  
Prof Peter Helms  
Prof Benjamin Lipsky  
Dr Umesh Kadam  
Ms Sharon Suri (Yellow Card Secretary)  
Dr Benjamin Cairns  
Dr Krishnan Bhaskaran  
Dr Christopher Edwards  
Dr Iskandar Idris  
Ms Sally Malin  
Dr Richard Martin  
Dr Simon Mitchell  
Dr Ruben Thanacoody  
Ms Kavita Chadda (VRMM)

1. Introductions, apologies and announcements
   1.1. The Chair reminded members that the papers and proceedings were confidential and should not be disclosed. Members were also reminded to declare their personal specific, personal non-specific, non-personal specific and non-personal non-specific interests in the agenda items.
   1.2. Apologies were received from Prof Jackie Cassell and Prof Martin Gulliford.

2. Minutes of the ISAC meeting held on 23rd January 2013 and summary minutes for publication on the MHRA website
   2.1. Full and summary minutes were reviewed and approved without comment.
   2.2. A copy of the minutes was endorsed by the Chair.
   2.3. Summary minutes will be published on the MHRA website. Action MHRA.

3. Matters arising from the minutes
   3.1. ISAC Secretary informed the committee on the transparency stakeholder consultation; recommendation from members to consult NICE.

   General items

4. Annual Report
   4.1. The Annual Report was reviewed and approved with minor amendments.

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1 MHRA staff may be present for all or part of the meeting, or for specific items. CPRD staff are not present when Yellow Card applications are discussed and VRMM staff are not present for CPRD applications.
5. Objectives and Performance Review of ISAC Members
5.1. Tabled Paper 1 (the response from the DH) was noted by members and
Tabled Paper 2 (proposed ISAC procedure) was agreed by members and
supported by MHRA.

Yellow Card data

6. Updating the Yellow Card data application form guidance notes
6.1. The guidance notes were discussed and agreed with minor amendments.
6.2. The issue of declaration of COI on the application forms (VRMM & CPRD) to
be considered further.

CPRD Data

7. Verbal Update from Dr. Parkinson on CPRD matters
7.1. John Parkinson provided an overview on the CPRD since the January 2013
meeting:

8. Protocol 12_149R
8.1. Committee members discussed the application and approved it with
comments.

9. Protocol 13_007R2
9.1. Committee members discussed the application and ISAC decision; no further
feedback to applicant needed.

10. Protocol 13_057
10.1. The CPRD Secretary provided members with a presentation on the HTI
database linked with CPRD GOLD.
10.2. Members approved the protocol with one amendment.

11. Approach to auditing published papers vs approved protocols: an example
11.1. Members agreed on the general approach for making comparisons.
11.2. Professional members each to review one protocol against a resultant
publication for discussion at the next meeting (optional for lay members).

12. Update to the ISAC Application form and Risk Review Form resulting from
the new CPRD/ECC approval
12.1. Members agreed to the proposed changes made to the application form.

13. Review of outcomes for protocols received to date during 2012
13.1. Noted

Information Items

14. AOB
14.1. The Chair informed the committee of a recently submitted application which
may require discussion at the next meeting.
Date and time of next meeting: Wednesday 10\textsuperscript{th} July at 11.00 a.m.