Independent Scientific Advisory Committee for MHRA database research (ISAC)

Minutes of the meeting held on Tuesday October 22, 2013 at 11:00am in [R-T-410], 4th Floor, 151 Buckingham Palace Road, Victoria, SW1W 9SZ.

Present

ISAC Members:

Prof Patrick Waller (Chair)
Dr Krishnan Bhaskaran
Dr Benjamin Cairns
Prof Jacqueline Cassell
Dr Christopher Edwards
Prof Peter Helms
Dr Iskandar Idris
Dr Umesh Kadam
Prof Benjamin Lipsky
Prof Simon Mitchell
Ms Marcia Saunders
Dr Richard Stevens
Dr Ruben Thanacoody

MHRA:

Dr John Parkinson (CPRD) Items 4-5
Ms Kendal Chidwick (CPRD Secretary) All items
Ms Helen Strongman (CPRD) Item 6
Ms Jessie Oyinlola (CPRD Secretariat) Items 1-6
Mr Tim Williams (CPRD) Items 9-10
Ms Tarita Murray-Thomas (CPRD) Item 11

1. **Introductions, apologies and announcements**
   1.1. The Chair reminded members that the meeting materials are 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 Richard Martin, Ms Sally Malin and Prof Martin Gulliford.

2. **Minutes of the ISAC meeting held on Wednesday 10th July, 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. The DH has accepted the ISAC member appraisal process and it has since been used to during the reappointment process of three members (see agenda item 15)

CPRD Data

4. **Verbal Update from Dr. Parkinson on CPRD matters**
   4.1. John Parkinson provided an overview on the CPRD since the July 2013 meeting

5. **Future arrangements for the Chairmanship of ISAC**

5.1. The Chair and the Director of CPRD presented this item.
5.2. Members agreed with the proposal to recruit a Deputy Chair 0.5FTE to support the Chair with the increased workload next year.
5.3. Once CPRD has formalised the position recruitment will begin and suggestions for suitable candidates are welcomed **– ACTION CPRD**

6. CPRD Audit -
6.1. The CPRD Audit was agreed with minor changes.

7. ISAC Audit
7.1.

8. Potential protocol discussion 09_025R
8.1. Members discussed the protocol and agreed by consensus that no further discussion was required.

9. Proposed CPRD policy on studies from the insurance/actuarial sector (CPRD Response to ISAC feedback on Protocol 13_102)
9.1. The members agreed that advice be communicated to CPRD regarding the unresolved issues; including the transparency issue around health research

10. Generic Protocol on CPRD and Clinical Trial Services
10.1. Members approved the protocol with a recommendation to audit in future

11. Proposed revision to the ISAC Guidance on the Content of Protocols for research using CPRD data
11.1. The members discussed the guidance and made various suggestions.
11.2. A revised version is to be circulated for further comment in the near future – **ACTION CPRD**

12. Proposal to change the 'ISAC exemptions' to include estimates of disease incidence and/or prevalence for regulatory requests
12.1. The committee agreed this would be approvable provided researchers followed a Standard Operating Procedure or CPRD protocol for calculating incidence and prevalence counts.

13. The need to upload protocols under member review on the portal
13.1. Members agreed this is no longer required

Information Items

13.2. **Review of outcomes for protocols received since the last meeting**
Noted.

14. Reappointment of three ISAC members
14.1. The Chair was pleased to announce that Umesh Kadam, Simon Mitchell and Ruben Thanacoody have all been reappointed for a second term.

15. CAG risk rating process
15.1. Noted.

16. Feedback from applicant on protocol 11_061R
16.1. Noted.

17. MHRA Data mining workshop

17.1. Noted.

18. AOB

18.1. None.

Date and time of next meeting: <u>Wednesday the 22nd of January at 11.00 a.m.</u>