

Independent Scientific Advisory Committee for MHRA database research (ISAC)**Minutes of the meeting held on Wednesday April 16, 2014 at 11:00am in [R-T-310], 3rd 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 Umesh Kadam
Ms Sally Malin
Dr Richard Martin
Ms Marcia Saunders
Dr Richard Stevens

MHRA¹:

Dr Tim Williams (CPRD) Items 1-6
Mr Jon Ford (CPRD) Items 1-6
Mrs Kendal Chidwick (CPRD Secretary) All items
Mrs Sharon Jethwa (Yellow Card Secretary) Items 1-7
Ms Kavita Chadda (VRMM) Items 1-7

Apologies**ISAC Members:**

Prof Martin Gulliford
Dr Iskandar Idris
Prof Benjamin Lipsky
Dr Simon Mitchel
Ruben Thanacoody

MHRA:

Dr John Parkinson (CPRD)

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 Dr John Parkinson, Prof Martin Gulliford, Prof Benjamin Lipsky, Dr Iskandar Idris, Ruben Thanacoody and Dr Simon Mitchell.

2. Minutes of the ISAC meeting held on Wednesday 20th January, 2014 and summary minutes for publication on the MHRA website (Paper 1)

- 2.1. Full and summary minutes were approved with a minor comment; point 5.3 should be amended to "Brighton and Sussex Medical School".
- 2.2. A copy of the minutes was endorsed by the Chair.
- 2.3. Summary minutes would be published on the MHRA website. **Action MHRA**

3. Matters arising from the minutes

- 3.1. None

CPRD Data

4. Verbal Update from Jon Ford (CPRD Head of Operations) on CPRD matters

- 4.1. Jon Ford provided an overview on the CPRD since the October 2013 meeting:
- 4.1.1. The CPRD Director (Dr John Parkinson) is retiring. There will be an interim director in place in June.

5. Update from Tim Williams (CPRD Head of Research) on care.data

- 5.1. Care.data will be re-launched in October.
- 5.2. If care.data becomes a potential source of data to feed in to CPRD for research purposes this would be well received.

6. The workload and future operation of ISAC (Paper 2)

- 6.1. In response to the concerns raised by the Chair and members, CPRD tabled an outline plan to manage the increasing workload, including the following elements.
- 6.1.1. Recruit a co- or deputy chair
- 6.1.2. Chair to be invited to seek reappointment with amended contract
- 6.1.3. Recruit 3 new professional members to the Committee
- 6.1.4. Assign additional secretariat resource
- 6.1.5. Reassess the current risk review system to see if it could be made more efficient
- 6.2. The Committee agreed with this plan in principle
- 6.3. In due course CPRD will respond in writing to Chair's letter of 19 March and the response will be circulated at the next meeting. **Action CPRD**

7. Draft ISAC Annual Report 2013 (Paper 3)

- 7.1. The Annual Report was agreed with minor changes

CPRD Items**8. Protocol 14_036R4 (Paper 4)**

- 8.1. Jackie Cassell declared a conflict of interest as she is planning a piece of work with the PI. JC heard the discussion but was barred from participating in the decision making.
- 8.2. Members decided the protocol should be resubmitted to address the one outstanding issue regarding multiple testing.

9. ISAC's draft response to BCDSP letter for agreement (Paper 5)

- 9.1. The draft response was agreed with some additional comments and text to be provided by statistical members regarding the missing data issue

10. Guidance on non-trivial changes to the analysis strategy when defining major versus minor amendments for agreement (Paper 6)

- 10.1. A list of examples will be provided by statistical members.

11. Proposed changes to the ISAC Application form (Paper 7)

- 11.1. The proposed changes were agreed with minor additions.

12. Draft script for eLearning modules on role of ISAC and successful applications (Paper 8)

- 12.1. The Committee agreed that this proposal would be useful and will review the material produced at the next meeting.

13. Protocol 14_076 (Paper 9)

- 13.1. Members agreed that a protocol was still required
- 13.2. The applicant will be reminded of their responsibilities and of the guidance available

Information Items

14. ISAC Audit Project Commencing – Comparing publications with protocols to identify deviations (Paper 10)

- 14.1. Members will also be asked to identify studies likely to be the subject of multiple publications.
- 14.2. The first batch of papers and protocols will be circulated by 25 April and should be returned by 24 June

15. Review of outcomes for protocols received since the last meeting (Paper to be tabled)

- 15.1. Noted

16. AOB

- 16.1. It was agreed that guidance should be developed for discussion at the next meeting regarding the need for submission of a protocol amendment when something specified in a protocol is not to be done.

Date and time of next meeting: Wednesday the 9th of July at 11.00 a.m.