

Independent Scientific Advisory Committee for MHRA database research (ISAC)

Minutes of the meeting held on **Wednesday July 9, 2014** at **11:00am** in [R-T-503], 5th 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 Martin Gulliford
Prof Benjamin Lipsky
Ms Sally Malin
Ms Marcia Saunders
Dr Richard Stevens

MHRA¹:

Dr Belinda Quinn (CPRD) Items 1-13
Mr Jon Ford (CPRD) Items 1-7 and 10
Ms Anna Higgins (CPRD) Item 12
Ms Kendal Chidwick (CPRD Secretary) All items

Apologies**ISAC Members:**

Prof Peter Helms
Dr Iskandar Idris
Dr Umesh Kadam
Dr Richard Martin
Dr Simon Mitchell
Dr Ruben Thanacoody

MHRA:

Dr Tim Williams (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 Prof Peter Helms, Dr Iskandar Idris, Dr Umesh Kadam, Dr Richard Martin, Dr Simon Mitchell, Dr Ruben Thanacoody, and Dr Tim Williams.
- 1.3. The committee were introduced to interim director of CPRD Dr Belinda Quinn.

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.
- 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

None

General Items

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 April 2014 meeting:

- 4.1.1. As the CPRD Director (Dr John Parkinson) retired, an interim director is now in place (Dr Belinda Quinn). The recruitment process for a new Director is ongoing with involvement from the CPRD senior management team (SMT). A permanent appointment is anticipated in October 2014 until then Belinda will be helping CPRD maintain the business direction and manage ongoing work.

5. The workload and future operation of ISAC; CPRD's response to the Chair's letters (Paper 2)

5.1. Noted

6. Update on the ISAC Strategy meeting (tabled paper)

6.1. The following outcomes of the ISAC strategy meeting held on 2nd of July were discussed:

- Refinements to the risk review system
 - CV system
 - Researcher accreditation system (exempting descriptive studies from ISAC review)
 - Ways to reduce the number of resubmissions
- Transparency of ISAC protocols
- Self-auditing of protocols
- Open ISAC meeting in 2015

6.2. On balance, the members agreed not to pursue an accreditation scheme at present. Accreditation isn't expected to greatly reduce the ISAC workload; whilst there would be less descriptive studies to review, accredited groups would still have to submit hypothesis testing studies (the majority of their work), however, establishing and maintaining an accreditation scheme would be a considerable piece of work.

6.3. The CV system and COI declaration should be taken forward – **ACTION CPRD**

6.4. Members support a 2015 ISAC open satellite meeting for CPRD users to be discussed at the next meeting and suggested:

- it be a satellite meeting to coincide with a European conference.
- the content include an update for users on the work of ISAC (eg. the audit), a consultation on plans (eg. transparency/ self-audit), and giving users an opportunity to provide feedback
- Could approach the organising committee of the conference to suggest an overarching topic around the broad issues of data oversight.

7. Update on the vice chair and member recruitment campaign

7.1. There were three applications for the vice/deputy chair role and five for the professional member roles; interviews to be held on 29th July

CPRD Items**8. Protocol 14_036R5 - The use of incretin agents and pancreatic outcomes: a population-based cohort study – summary of the outcome (Paper 3)**

8.1. Statistical members of the Committee to proposed changes to guidance regarding multiple testing, to be incorporated into the main guidance document.

9. Update on the eLearning modules on role of ISAC and successful applications

9.1. Materials will be reviewed at the next meeting.

10. ISAC audit project - first round results (Paper 4)

10.1. The tabled draft letter to applicants in cases of major deviations requires revision to soften the tone and will be recirculated for comment by members present before use.

10.2. It was agreed that if the protocol and paper have been matched correctly the applicants would be asked to self-audit, if not the correct protocol and paper will be put back in to the system and audited in the next round.

10.3. The Committee agreed that the following five protocols appeared to be major deviations and would receive the letter once finalised: 11_031, 09_064, 12_063RA, 06_069R and 09_130.

10.4. The other two potential major deviations considered were reclassified as minor.

10.5. Krishnan Bhaskaran declared a conflict of interest which precluded his involvement in decision making in relation to protocol 12_063RA

10.6. Ben Cairns declared a conflict of interest in relation to 09_064R; members agreed this did not preclude his involvement in the discussion

11. Amendment guidance when part of a study isn't going to be done (Paper 5)

11.1. Proposed text to be simplified; "what to do if you're not going to do the whole of your study"

12. Clinical trials facilitated by CPRD and ISAC approval (Paper 6)

12.1. Discussion with Anna Higgins (CPRD Head of Clinical Trials) regarding trials not covered under Protocol 13_170

12.2. Bespoke procedure agreed with early lay member input (pre-ethics approval) and then overall ISAC review after ethics approval.

12.3. Normal risk review procedure to be used but a specific application form would be developed and the ISAC protocol would cover only CPRD aspects of the trial with a summary of the full protocol appended.

13. ISAC exemption for aggregated data reports requested of the regulator (Paper 7)

13.1. The proposal was agreed by members, and once finalised should appear on the website – **Action CPRD**

Information Items**14. Annual CAG Renewal – implications for ISAC (Paper 8)**

14.1. Noted

15. Update to 2015 meeting dates (Paper 9)

15.1. The first two meeting of 2015 have been moved from Wednesday to Tuesday, the revised dates are as follows:

- Tuesday 20th January
- Tuesday 14th April
- Wednesday 8th July
- Wednesday 21st October

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

16.1. Noted

17. AOB

17.1. None

Date and time of next meeting: Tuesday the 21st of October at 11.00 a.m.