

Independent Scientific Advisory Committee for MHRA database research (ISAC)

The fourth meeting of the Independent Scientific Advisory Committee for MHRA database research of 2014 was held on **Tuesday 21st October, 2014 at 11:00am** in **[R-T-501], 4th Floor, 151 Buckingham Palace Road, Victoria, SW1W 9SZ.**

Present

ISAC Members:

Prof Patrick Waller (Chair)
Mr David Irvine (Deputy Chair)
Dr Krishnan Bhaskaran
Dr Benjamin Cairns
Prof Jacqueline Cassell
Dr Christopher Edwards
Prof Martin Gulliford
Prof Peter Helms
Prof Benjamin Lipsky
Dr Wendy Knibb
Ms Sally Malin
Dr Richard Martin
Dr Emily McFadden
Dr Simon Mitchell
Prof Keith Neal
Ms Marcia Saunders
Dr Richard Stevens
Dr Ruben Thanacoody

MHRA¹:

Mr Jon Ford (CPRD) Items 1-5
Ms Anna Higgins (CPRD) Item 1-11
Ms Kendal Chidwick (CPRD Secretary) All items

Apologies

ISAC Members:

Dr Iskandar Idris
Dr Umesh Kadam

MHRA:

Dr Belinda Quinn (CPRD)
Dr Tim Williams (CPRD)

AGENDA

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 Dr Iskandar Idris and Dr Umesh Kadam, Dr Tim Williams and Dr Belinda Quinn.
- 1.3. The committee welcomed the new Deputy Chair, David Irvine, and new members Wendy Knibb, Emily McFadden and Keith Neal
- 1.4. The Chair, Benjamin Lipsky and Marcia Saunders have been reappointed for further two year terms and Peter Helms for a further three year term.
- 1.5. The new Director of CPRD will be Janet Valentine starting in January 2015
- 1.6. CPRD Secretary Kendal Chidwick is leaving soon and this was her last meeting; she was thanked by the Committee for her excellent work and a presentation made.

2. **Minutes of the ISAC meeting held on Wednesday 9th July, 2014 and summary minutes for publication on the MHRA website**
 - 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 July 2014 meeting:
 - 4.1.1. Belinda Quinn remains as the interim Director of CPRD until Dr Janet Valentine is in place as Director.

CPRD Items

5. **Retrospective approvals**
 - 5.1. The proposed procedure was agreed in principle with comments.
 - 5.2. A joint policy should be brought to the next meeting and included in the protocol guidance – **Action CPRD**
6. **Requesting an explicit statement on the ISAC application form regarding the public health benefit / impact of research using CPRD data**
 - 6.1. The proposal was supported by the Committee with a change of emphasis towards public interest rather than public health.
 - 6.2. Policy with guidance to be brought to the next meeting – **Action CPRD**
7. **Draft process for ISAC notification or approval of research using CPRD clinical trial services**
 - 7.1. The proposed procedure and form were agreed with amendments.
 - 7.2. Guidance documentation should now be developed and a discussed at the next meeting – **Action CPRD**
8. **Update on proposed Clinical Trial)**
 - 8.1. Members provided comments on the “information for patients” and the patient consent form.
 - 8.2. Patient consent to be reviewed by lay members pre-ethics.
 - 8.3. Trial will be reviewed using new procedure when submitted.
9. **Revision of amendment guidance in relation to when part of a study is not going to be done**
 - 9.1. Members agreed the revised guidance on amendments.
10. **Guidance on multiple testing**
 - 10.1. Members agreed the guidance on multiple testing.
 - 10.2. Further thought should be given to additional wording about the issue multiple testing biasing the results
11. **Proposed changes to the ISAC application form and guidance**
 - 11.1. Members agreed the changes with one addition; to add the reference to the ICJME guidance on what constitutes a conflict of interest.
 - 11.2. New application form and guidance to be added to the website – **Action CPRD**

12. Verbal update on the eLearning modules on role of ISAC and successful applications

12.1. Noted and Krishnan Bhaskaran thanked for his contribution

13. ISAC audit project – Update

13.1. The committee discussed the self-audits that had been returned by the applicants.

14. ISAC audit project – preliminary findings

14.1. The committee discussed the audit project and discussed six publications of interest.

15. ISAC open workshop

15.1. The Committee was not in favour of the proposal to link this to the ISPE meeting in Bordeaux in April and proposed that it should become part of the routine ISAC meeting planned for July 2015

Information Items

16. CPRD implementation of the CV system

16.1. This was noted

16.2. The CV of non-principal investigators added after approval should be notified to the Secretariat

16.3. Principal investigators should be senior researchers who would act as guarantors for the research (precise wording to be developed so it can be added to the guidance) – **Action ISAC**

17. COPE guidance

17.1. Noted

18. EnCEPP guidance

18.1. Noted

19. Review of outcomes for protocols received since the last meeting

20. AOB

20.1. None

Date and time of next meeting: Tuesday 20th January, 2015 at 11.00 a.m.