

Independent Scientific Advisory Committee for MHRA database research (ISAC)

The second meeting of the Independent Scientific Advisory Committee for MHRA database research of 2015 was held on **Tuesday 14th April 2015** at **11:00am** in **[R-T-410]**, 4th Floor, **151 Buckingham Palace Road, Victoria, SW1W 9SZ**.

Present**ISAC Members:**

Prof Patrick Waller (Chair)
Prof Jacqueline Cassell
Dr Christopher Edwards
Prof Peter Helms
Prof Benjamin Lipsky
Prof Umesh Kadam
Dr Wendy Knibb
Ms Sally Malin
Dr Emily McFadden
Prof Keith Neal
Dr Ruben Thanacoody

MHRA:

Ms Heather Dorricott (CPRD) Item 8
Dr James Ellis (CPRD) All Items
Ms Jessie Oyinlola (CPRD) All Items
Dr Janet Valentine (CPRD) All Items
Miss Sophia Amjad
Tarita
Dr Mark Wright

Apologies**ISAC Members:**

David Irvine
Dr Krishnan Bhaskaran
Dr Benjamin Cairns
Dr Iskandar Idris
Prof Umesh Kadam
Ms Sally Malin
Professor Keith Neal
Prof Richard Stevens
Prof Richard Martin
Dr Ruben Thanacoody

MHRA:

Dr Tim Williams

AGENDA

1. Introductions, apologies and announcements

- 1.1. Apologies were received from David Irvine, Dr Krishnan Bhaskaran, Dr Benjamin Cairns, Dr Iskandar Idris, Prof. Umesh Kadam, Ms. Sally Malin, Prof. Keith Neal, Prof. Richard Stevens, Prof. Richard Martin and Dr. Ruben Thanacoody.
- 1.2. Prof Stevens and martin joined the meeting by telephone. Written comments from all absent members were contributed as tabled papers
- 1.3. The committee acknowledged that David Irvine will be leaving his post as deputy chair on the 30th of June 2015. The committee thanked David for his considerable efforts and wished him well.
- 1.4. The committee welcomed Ms Sophia Amjad, who is the Customer Scientific Support Officer, supporting Dr James Ellis in his role of Scientific Secretary.
- 1.5. Members provisionally agreed the suggestion by the Chair that the quorum for ISAC meetings should be set at **more than a third** of the membership (**i.e. seven at present**), it was provisionally agreed that telephone attendance did not count. Members will be asked to ratify this decision at the next meeting.
- 1.6. Correspondence between Marcia Saunders and the Agency in relation to both the Chair and the role of the committee were circulated for information.

2. Minutes of the ISAC meeting held on Tuesday 21st October 2014 and summary minutes for publication on the MHRA website (Paper 1)

- 2.1. Full and summary minutes were approved and agreed to be published. **Action CPRD**
- 2.2. Summary minutes will be published on the MHRA website. **Action MHRA**

3. Matters arising from the minutes

- 3.1. The e-learning module is undergoing further testing and the Committee will be updated at the next meeting. **Action CPRD.**
- 3.2. The ISAC open meeting will be delayed beyond October and considered further at a future meeting. **Action CPRD**
- 3.3.
- 3.4. The Committee agreed that completion of the ISAC e-learning module (or other relevant CPRD GOLD training) should be taken into account and that ISAC will normally expect at least one member of the applicant's research team to have undertaken such training. This will be further discussed at the next ISAC meeting

General Items

4. **Verbal Update from Janet Valentine (CPRD Director)**
 - 4.1. Dr Valentine updated members on the strategic development of CPRD.
 - 4.2. Dr Valentine discussed a review that the Agency will be carrying out in the near future, with the aim of understanding how to manage applications to use CPRD data. Dr Valentine informed members that further information will be provided in due course. **Action CPRD.**
 - 4.3. Dr Valentine discussed a manuscript that has been accepted that summarised the current status of CPRD. This is to be circulated to members once it becomes available. **Action CPRD (JE)**

5. **Verbal Update from Heather Dorricott (Quality Governance Manager)**
 - 5.1. No incidences were reported to members
 - 5.2. CAG no longer wish to see redacted disclosures on the website

CPRD Items

6. **Draft ISAC Annual report (Paper 2)**
 - 6.1. The draft report for 2014 was agreed, with minor changes to be made. **Action CPRD**
 - 6.2. Members were asked to check their biographies and conflicts of interest, and to notify the secretary by the 30th of April. **Action ISAC and CPRD.**

7. **Proposed new process for review of ISAC protocol applications and associated form (**
 - 7.1. CPRD presented a proposed change to the way that ISAC protocol applications were processed by CPRD to lighten the burden on the Chair.
 - 7.2. Members agreed in principle that the proposed new process was acceptable for low risk protocols that would be handled with ISAC oversight.
 - 7.3. Members did not agree that the current process for high-risk protocols (i.e the member review system) should be changed or that the criteria for determining low and high risk should be different from that proposed in **paper 4a.**
 - 7.4. Members advised that the chair should maintain the final decision on the risk rating
 - 7.5. A summary of the new process is to be circulated to members along with draft of supporting forms for comment. **Action CPRD**
 - 7.6. Members agreed that one structured scientific assessment form should be used for all applications (i.e. both high and low risk) in the new system.
 - 7.7. Members agreed that the medium risk category for the scientific assessment should be abolished. Low, Medium and High risk categories are still required for the CAG risk rating.
 - 7.8. Members were asked to review the draft guidance documents relating to the assessment of ISAC protocols, and provide those to the chair **within one month** of this meeting. **Action ISAC.**

8. Updated ISAC application form and Protocol Guidance (Paper 5)

- 8.1. Members agreed that a technical/scientific summary should be mandatory as part of the protocol. This should be included in the new ISAC application and corresponding guidance. **Action CPRD**
- 8.2. The maximum length of the protocol text was set to 12 pages in a 12 point fixed font. Application forms and Guidance document to be updated. **Action CPRD.**
- 8.3. The new form and guidance document were approved with minor changes.
- 8.4. A paragraph is to be written in the guidance explaining the difference between Vision and Emis. **Action CPRD**
- 8.5. The new forms are to be circulated to members. **Action CPRD.**
- 8.6. The new ISAC form and Guidance will become mandatory on the 1st of July. The website is to be updated to reflect the changes to the protocols. **Action CPRD.**

9. Plans for the implementation of the ISAC CV System (Paper 6)

- 9.1. The committee discussed the requirements for studies to have primary care support and decided that at least one applicant should have either primary care experience or be an experienced CPRD user.
- 9.2. Members agreed that a user may be classified as experienced if they have published 3 papers using CPRD data.

10. Proposed new CPRD policy on transparency in relation to ISAC protocols

10.1. The Committee agreed the policy in relation to increased transparency, and that the proposals will be implemented prospectively from the 1st of July 2015. **Action CPRD.**

10.2. The Committee agreed that both lay and scientific summaries would be made available, and that a check would be made to ensure that the lay summary was in plain English during the validation.

10.3 The committee suggested that a communication strategy should be developed to inform potential applicants of the changes. **Action CPRD.**

11. CPRD update on the ISAC audit project- discussion of the potential major deviations

- 11.1. Responses from applicants was considered and the members upheld the classification of **11_100** as a **major deviation**, however members agreed that in light of comments from the applicant, **09_094** should be considered a minor deviation.
- 11.2. ISAC considered **11_152A** to be a **major deviation**, however members concluded that the protocol may not be a match.
- 11.3. **09_117R, 11_140** and **11_054** were considered to be **major deviations**.
- 11.4. **12_014R** and **10_045** were considered to be minor deviations, despite the deviations not being mentioned in the paper.
- 11.5. Other protocols had been audited by members not present and will be discussed at the next meeting.

- 11.6. Members were asked to complete any outstanding audits within **one month**. Any protocols not completed by then will be reallocated so that a final round can be considered in July.

12. Update on clinical trials from Mark Wright (Acting Head of Interventional Research)

12.1. Dr. Wright was welcomed by the committee. The role that ISAC plays in clinical trials was discussed, along with the requirements of interventional studies to obtain ISAC approval. Mark Wright and the lay members will have a discussion over the exact requirements and report back to the July meeting. **Action ISAC and CPRD.**

12.2. ISAC indicated that ISAC approval should be generally obtained before the involvement of ethics committees.

Information Items

13. Review of protocols received since the last meeting

Members reviewed protocols that were received since the last meeting

14. AOB

None

Date and time of next meeting: Wednesday the 8th July 2015 at 11.00 a.m.