

Independent Scientific Advisory Committee for MHRA database research (ISAC) – Summary Minutes

The first meeting of the Independent Scientific Advisory Committee for MHRA database research of 2016 was held on **Tuesday 19th January 2016 at 11:00am** in **[R-502], 5th Floor, 151 Buckingham Palace Road, Victoria, SW1W 9SZ.**

Present

ISAC Members:

Prof Patrick Waller (outgoing Chair)
Prof Deborah Saltman AM (incoming Chair)
Prof Ian Wong
Prof Keith Neal
Prof Benjamin Lipsky
Prof Peter Helms
Prof Sinead Brophy
Prof Umesh Kadam
Dr Angelyn Bethel
Dr Emily McFadden
Dr Benjamin Cairns
Dr Christopher Edwards
Dr Duncan Edwards
Dr Hester Ward
Dr Iskander Idris
Dr Jenny Quint
Dr Krishnan Bhaskaran
Dr Richard Stevens
Dr Ruben Thanacoody
Dr Sara Thomas
Dr Simon Mitchell
Dr Wendy Knibb
Ms Marcia Saunders
Ms Sally Malin

Apologies

ISAC Members:

Dr Caroline Jackson

MHRA:

Dr James Ellis (CPRD)
Ms Tarita Murray-Thomas (CPRD)
Miss Jessie Oyinlola (CPRD)
Dr Janet Valentine (CPRD)

AGENDA

1. Introductions, apologies and announcements

- 1.1. Apologies were received from Caroline Jackson who had submitted written comments, which were tabled and taken into account.
- 1.2. The Chair introduced Deborah Saltman AM, the incoming Chair to the committee. Professor Saltman's term began on the day of the meeting and she will work closely with Patrick Waller until he finishes his term on the 28th of January.
- 1.3. The Committee welcomed 8 new professional members: Angelyn Bethel, Sinead Brophy, Duncan Edwards, Caroline Jackson (absent), Jenny Quint, Sara Thomas, Hester Ward and Ian Wong. All members briefly introduced themselves.
- 1.4. Ben Lipksy expressed the appreciation of Committee members to Patrick Waller for his commitment and service to the Committee and wished him well in his retirement. The Chair of the MHRA, Michael Rawlins, also thanked Patrick Waller for his service, and presented him with a gift on behalf of the agency.

2. Minutes of the ISAC meeting held on Tuesday 14th April 2015 and summary minutes for publication on the MHRA website (Paper 1)

- 2.1. Full and summary minutes were approved. It was requested that future minutes have the "Sensitive Commercial" comment removed from the header. **Action CPRD.**
- 2.2. Summary minutes will be published on the MHRA and CPRD website. **Action CPRD.**

3. Matters arising from the minutes

- 3.1. No comments were raised.

CPRD Items

4. CPRD update

- 4.1. Dr Valentine welcomed new members and updated the committee on the major staff restructure that CPRD is undertaking. The committee were informed that CPRD was almost doubling in size with an additional 35 new vacancies.
- 4.2. Dr Valentine announced that the position of Head of Observational Research will be advertised.
- 4.3. The Third Caldicott review will be published at the end of January 2016.
- 4.4. Members were informed that due to increased governance requirements by the information commissioner's office the Free Text service previously offered by CPRD will end in March 2016. Protocols requesting free text need to be approved, and the data requested before the end of March to use this service.

- 4.5. The Terms of Reference (TOR) of the ISAC will be finalised once the Yellow Card element has been transferred.
5. **ISAC Audit project – final outcome of audits held in the fourth round (Paper 2)**
 - 5.1. A conflict of interest from a member was declared but this did not disbar the member from the item since there was no decision to be made.
 - 5.2. New members were given a brief introduction to the audit project.
 - 5.3. In view of the lack of self-audits from the applicants, Protocols 11_047, 09_002R and 09_110A/09_111 (Paper 143) and Protocol 10_042 were upheld as major deviations. The Committee noted that the self-audit for 10_042 acknowledged that a major deviation had occurred. Paper 10 from the April 2014 meeting has been appended to the minutes as an appendix to remind members of the definition of major and minor deviation. Given the number of major deviations, the committee discussed the learning points for the committee. Future discussions are planned around these learning points and the implications for the committee. It is anticipated that this original audit will be used to inform future activities of the committee.
 - 5.4. A tabled paper from Ben Cairns was considered by the Committee. Members agreed that it would not be advantageous to do a second audit of the data. In terms of publications, it was suggested that the results be published in an open access journal. The BMJ was suggested as a target for publication. The committee discussed the need to formalise arrangement for the approval of papers emanating from the committee, this will be discussed in a future meeting.
6. **Proposal to introduce guidance on timescales for the resubmission of protocols (Paper 3)**
 - 6.1. Members accepted that applicants should be advised to submit resubmissions in a timely manner, and that the secretariat be advised if there is a delay of greater than 6 months. The Committee suggested that maternity leave be changed to parental leave.
7. **Proposed review on the guidance to applicants for Amendments (Paper 4)**
 - 7.1. The proposed review of the guidance to applicants was noted by the committee. In Annex 2 under "Minor amendments" it was suggested that the bullet point starting "Not using linked data which are part of the approved protocol" should be changed, removing "(in which case this would be a major amendment)" and replacing it with "(See Major Amendments)".
8. **ISAC open meeting**
 - 8.1. The ISAC open meeting will be further discussed at a future meeting of the committee.

9. Proposed publication in the scientific literature (Paper 5)

9.1 The Committee welcomed the suggested publication, although it advised reconsideration of the title as the Committee does not decide how data are to be used. It was recognised that the draft would need further revision, including a need to describe the role that the devolved governments have in relation to primary care data. The Committee was happy for the proposed publication to be progressed.

10. Advice to be sought in relation to issues around lay summaries in ISAC protocols (Paper 6)

10.1. The committee supported the introduction of the new guidance including the example summaries with minor changes; they also supported changing the title to "Summary in Plain English" when the application form was next being amended; they did not support inclusion of a public health benefit statement for all protocols at the present time, and suggested this be revisited at a later time.

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

11.1. Noted.

12. AOB

12.1. Patrick Waller thanked the Committee for their generosity and kind words. He said that it had been a privilege to chair the Committee, and thanked the members, and James Ellis, Sophia Amjad and Tarita Murray-Thomas for their support.

12.2. Deborah Saltman thanked Patrick and the ISAC secretariat for the effective handover and welcomed thoughts from the committee on new initiatives the committee might like to see implemented.

Date and time of next meeting: Tuesday 13th April 2016 at 11 am.