

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

The second meeting of the Independent Scientific Advisory Committee for MHRA database research of 2016 was held on **Wednesday 13th April 2016** at **11:00am** in **[R-T-410], 4th Floor, 151 Buckingham Palace Road, Victoria, SW1W 9SZ.**

Present

ISAC Members:

Prof Deborah Saltman AM
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 Jenny Quint
Dr Krishnan Bhaskaran
Dr Richard Stevens
Dr Sara Thomas
Dr Wendy Knibb
Ms Marcia Saunders
Ms Sally Malin
Dr Caroline Jackson

MHRA:

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

Apologies

ISAC Members:

Dr Simon Mitchell

AGENDA

1. Introductions, apologies and announcements

- 1.1. Apologies were received from Simon Mitchel.
- 1.2. The Committee were reminded of the need to declare conflicts of interest, to which none were noted.
- 1.3. The committee welcomed the announcement that Professor Richard Stevens has been appointed as the deputy chair of the ISAC.

2. Minutes of the ISAC meeting held on Wednesday 19th January 2016 and summary minutes for publication on the MHRA website (Paper 1)

- 2.1. Full and summary minutes were approved with the need only for minor corrections. Namely that Tuesday be changed to Wednesday in the minutes where it mentions the next meeting and that the wording of **item 4.6** be changed from “a few members” to “members”. **Action CPRD.**
- 2.2. Summary minutes will be published on the MHRA and CPRD website. **Action CPRD.**
- 2.3. No matters arising (that weren't already covered in the meeting agenda) were raised during the meeting.

3. Chair's Report

- 3.1. The chair introduced the new format of the ISAC meeting and asked for feedback on the changes to be provided at the end of the meeting or in subsequent correspondence.
- 3.2. Members were informed that there has been an increase in the number of high-risk protocols and as such, more had been sent to members. Members were thanked for their commitment to the ISAC and their efforts to provide expedient advice.
- 3.3. Members were informed of the new processes for review of protocols. The Chair is responsible for approving each step of the ISAC protocol assessment process: review of protocols and assignment of risk status; assignment of external reviewers; review of reviewer feedback; feedback to applicants; assessment of CAG status and final approval.
- 3.4. Members were informed that when two reviewers have conflicting outcomes (e.g. approval vs. resubmission) the Chair will take the most stringent approach.
- 3.5. The Chair informed the committee that from January each protocol for wider review was sent to three members to help train the new members in addition to the training programmes available to ISAC members and access to relevant reviews through the portal. After each new member has reviewed at least one protocol, their initial training is considered to be complete. Subsequently any protocol sent for wider review will now be sent to two ISAC members.

- 3.6. To help members with their training and ongoing quality assurance, the Secretariat agreed to upload the feedback from applicants to the portal to enable ISAC members to see the comments that come back from applicants.
Action CPRD.

4. **Secretariats Report (paper 16_06)**

- 4.1. The ISAC secretary reported that there had been an increase in the high-risk protocols sent to the ISAC. It was reported that 38% of all protocols submitted between January 19th and 4th April were classified as high-risk, this was in comparison to the 21% categorised as such for the same period in 2015.
- 4.2. Members were informed that there had been a **2.69** % increase in the number of approved protocols since last financial year. For the financial year April 2014 – March 2015 **223** protocols were approved, compared to **229** for the financial year of April 2015-March 2016.
- 4.3. Members were informed that the total number of protocols submitted in 2016 was broadly similar to that submitted in the same period for 2015. As an additional 84 protocols were returned to applicants requiring corrections before being submitted to the ISAC

5. **Head of CPRD report**

- 5.1 The report was noted.

6. **Draft Terms of Reference**

- 6.1. Members were asked to read and comment on the draft Terms of Reference (ToR) and check that it was commensurate with the committee's objectives. A summary of the ToR were provided. Further details will be provided at a later date. **Action CPRD.**

7. **The New ISAC forms**

- 7.1. The new ISAC forms and guidance were discussed with the committee. The committee were impressed with the high profile transparency of the proposed forms.

8. **Low/High Risk Protocols and Risk Variables**

- 8.1. The committee discussed the nomenclature for protocols, and it was agreed that the terms "low" and "high risk" to describe protocols were misnomers and should be reworded. A consensus agreement was reached for the adoption of the terms "Internal" and "External" Review for "Low" and "High" risk respectively.

9. **The ISAC Audit**

- 9.1. Further work on the implications of the audit will be presented to the next meeting.

10. **ISAC publication strategy**

- 10.1. The committee considered that there was no need for a publication/communication strategy at present.

11. **Committee members update**

- 11.1. Each member of the committee discussed their career experiences, what they are working on and their experience with the review system. In general there was agreement that the processes were operating smoothly.
- 11.2. Newer ISAC members expressed the wish to gain more feedback on their reviews, and were informed that the feedback to applicants is uploaded to the portal, so they can see the feedback that comes out.

12. **AOB- including future meetings.**

- 12.1. This information was noted.

13. **Review of outcomes for protocols received since the last meeting (Paper tabled)**

- 13.1 This was noted.

Date and time of next meeting: Wednesday 13th July 2016