

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

The fourth meeting of the Independent Scientific Advisory Committee for MHRA database research of 2015 was held on **Wednesday 21st October 2015 at 11:00am** in **[R-T-410], 4th Floor, 151 Buckingham Palace Road, Victoria, SW1W 9SZ.**

Present

ISAC Members:

Prof Patrick Waller (Chair)
Dr Krishnan Bhaskaran
Dr Benjamin Cairns
Dr Christopher Edwards
Prof Peter Helms
Dr Iskander Idris
Prof Benjamin Lipsky
Prof Umesh Kadam
Prof Keith Neal
Dr Emily McFadden
Dr Richard Stevens

MHRA:

Miss Sophia Amjad (CPRD)
Dr James Ellis (CPRD)
Ms Tarita Murray-Thomas (CPRD)
Miss Jessie Oyinlola (CPRD)
Miss Rebecca Owen (MHRA)
Dr Tim Williams

Apologies

ISAC Members:

Prof Jackie Cassell
Ms Sally Malin
Dr Richard Martin
Dr Simon Mitchell
Ms Marcia Saunders
Dr Ruben Thanacoody

AGENDA

1. **Introductions, apologies and announcements**

- 1.1. Apologies were received from Jackie Cassell, Sally Malin, Richard Martin, Simon Mitchell, Marcia Saunders and Ruben Thanacoody; written comments from Ruben Thanacoody on various items were tabled and taken into account.
- 1.2. Martin Gulliford, Iskander Idris, Richard Martin and Ruben Thanacoody are retiring from the Committee before the next meeting and were thanked for their service.
- 1.3. The terms of Krishnan Bhaskaran, Benjamin Cairns, Christopher Edwards, Sally Malin and Richard Stevens will be ending soon and they will be offered reappointment.

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

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

3. **Matters arising from the minutes**

- 3.1. Regarding the e-learning facility, members have recently been sent information regarding registration and can also request that colleagues/students gain access; Krishnan Bhaskaran and the chair will propose an update to reflect recent changes in the review system and guidance. **Action KB.**
- 3.2. The ISAC meeting will be planned for later in the year, and will be added to the agenda of the next meetings to remind members. **Action CPRD.**

General Items

4. **Update from CPRD on ISAC membership and verbal update on the arrangements following the departure of the chair**

- 4.1. The ISAC advised the Agency on issues relating to length of contract for New ISAC members.
- 4.2. The committee was advised that the agency is currently recruiting for a new ISAC chair to replace Patrick Waller who is retiring at the end of January.

VRMM items

5. **Transparency of Yellow Card data researcher and research protocols**

- 5.1. The Committee saw the new transparency proposals for Yellow card applications as broadly in line with those in place for CPRD applications and

supported their introduction; it did not feel that there was a significant risk of them inducing scares or discouraging researchers.

6. **New Yellow Card Application**

6.1. The Committee identified several areas in which the application was deficient and recommended that these be rectified before it was reviewed further.

7. **Update from Mick Foy (VRMM) on changes to Yellow Cards**

7.1. The update from Mick Foy on the changes to Yellow Cards was noted.

CPRD Items

8. **Verbal Update From Tim Williams on CPRD Matters**

8.1. The update from Tim Williams on CPRD matters was noted.

9. **Update from James Ellis on the new ISAC protocol review system**

9.1. The committee noted the update on the new ISAC protocol system, and were pleased to hear that the system was working efficiently.

10. **Advice to be sought in relation to issues around lay summaries in ISAC protocols**

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. **Action CPRD.**

11. **Update from CPRD on interventional research**

11.1. The committee agreed to draft advice to the Chief Executive of the agency in relation to changes to the role of the ISAC in interventional research. This advice and the ultimate response from the agency is to be circulated to ISAC members. **Action CPRD.**

12. **ISAC Audit -update**

12.1. The committee discussed the Audit and concluded that the audit had been successfully completed. **Action CPRD.**

13. **Review of outcomes for protocols received since the last meeting**

13.1 This was noted.

14. **AOB**

None

Date and time of next meeting: Tuesday 19th January 2016