

Independent Scientific Advisory Committee for MHRA database research (ISAC)

The first meeting of the Independent Scientific Advisory Committee for MHRA database research of 2015 was held on **Tuesday 20th January 2015 at 11:00am in [R-T-410], 4th Floor, 151 Buckingham Palace Road, Victoria, SW1W 9SZ.**

Present**ISAC Members:**

Prof Patrick Waller (Chair)
Mr David Irvine (Deputy Chair)
Dr Benjamin Cairns
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
Mr Simon Halpin (CPRD) Item 13
Ms Anna Higgins (CPRD) Item 11
Dr Dervla Mahoney (CPRD) All Items
Ms Wilhelmine Meeraus (CPRD) All Items
Ms Jessie Oyinlola (CPRD) All Items
Dr Janet Valentine (CPRD) All Items
Dr Tim Williams (CPRD) All Items

Apologies**ISAC Members:**

Dr Krishnan Bhaskaran
Prof Martin Gulliford
Dr Iskandar Idris
Dr Richard Martin
Ms Marcia Saunders
Prof Richard Stevens

MHRA:**AGENDA****1. Introductions, apologies and announcements**

- 1.1. Apologies were received from Prof Richard Martin, Dr Krishnan Bhaskaran, Ms Marcia Saunders, Prof Martin Gulliford, Dr Iskander Idris and Prof Richard Stevens
- 1.2. Prof Stevens joined the meeting by telephone until 12:00. Written comments from Prof Stevens, Ms Malin and Ms Saunders were contributed as tabled papers
- 1.3. The committee welcomed the new CPRD Director Dr Janet Valentine, the next ISAC CPRD Secretary Dr James Ellis (who starts on 26 January) and Ms Wilhelmine Meeraus and Dr Dervla Mahoney who have been covering the ISAC Secretariat since Ms Kendal Chidwick's departure

- 1.4. The Committee congratulated Umesh Kadam and Richard Stevens on their appointments as Professor and Associate Professor respectively.
 - 1.5. Ms Meeraus and Dr Mahoney were thanked for their support of the ISAC Secretariat
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 subject to two amendments.
Action CPRD
 - 2.2. A copy of the amended minutes will be endorsed by the Chair. **Action Chair**
 - 2.3. Summary minutes will be published on the MHRA website. **Action MHRA**
3. **Matters arising from the minutes**
- 3.1. A new ISAC CV system will be implemented in 2015
 - 3.2. 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. **Introduction from Janet Valentine (New CPRD Director)**
- 4.1. The Committee warmly welcomed Dr Janet Valentine, new director for CPRD. Dr Valentine expressed her support for the important work that ISAC does
 - 4.2. The Committee is in favour of Dr Valentine's suggestion that, for data governance reasons increased transparency of ISAC applications should be pursued. A paper will be brought to discuss this further at the next ISAC meeting in April. **Action CPRD**
5. **Verbal Update from Tim Williams (CPRD Head of Research) on CPRD matters**
- 5.1. Noted

CPRD Items

6. **ISAC Audit project - self audits of the major deviations identified in the second round (Paper 4)**
- 6.1. Members considered the applicants' responses for protocols 07_094, 10_064, 10_034 and 11_050. All were upheld as major deviations and standard feedback letters will be sent to these applicants. **Action CPRD**
 - 6.2. The applicants' for protocols 09_094 and 11_100 have not responded to email contact from the ISAC Secretariat. All agreed that the applicants should receive another reminder, and if they do not respond before the next meeting, the categorisation of major deviation will become final automatically. **Action CPRD**

7. **ISAC Audit project - interim report (Paper 5)**
 - 7.1. The Committee agreed that the audit project should be completed, particularly as the more difficult papers, including those without protocols, had been left until last. A final round of the audit involving all members will soon be sent out for review. This final round will include 48 papers which have been matched with protocols and a further 25 which have yet to be matched. **Action ISAC**
 - 7.2. All publications and protocols which have not been matched will be audited by the Chair, the Deputy Chair and the new secretary. **Action ISAC**
 - 7.3. Regarding publication, it was agreed that all members (including Kendal Chidwick as first or second author) should be co-authors.
 - 7.4. A suggestion was raised to prepare an additional paper for publication that would focus on the work of ISAC and the current status of CPRD.
 - 7.5. General medical journals (e.g. BMJ, Lancet) will be targeted for the paper(s). In the spirit of openness and transparency, the results of the audit could be published on the CPRD website and that the target journal should be a high impact journal.

8. **Consented studies and linkage (Paper 6)**
 - 8.1. The proposed policy was endorsed by the Committee, and the Committee agreed that specific consent should be sought

9. **Studies undertaken without ISAC approval (Paper 2)**
 - 9.1. The proposed policy was noted and endorsed by the Committee with the recommendation that the policy be made publically available. **Action CPRD**

10. **CPRD policy and guidance on the requirement to describe how the study fulfils the criteria "health related research of public benefit" in <100 words plain English (Paper 3)**
 - 10.1. Paper and tabled paper (which included part of the new application form) were noted, and the proposed statement for the CPRD website was endorsed
 - 10.2. Members agreed that in cases where the applicant ticked a specific box (e.g. disease epidemiology) it would not be necessary for the applicant to provide a statement explaining "health related research of public benefit". Alternatively, if the "other box" is ticked then an indication of the nature of the study should be provided and that a statement explaining the benefit should be required as part of the lay summary
 - 10.3. An addition to ISAC guidance will be prepared. **Action CPRD**

11. **Verbal update from Anna Higgins (CPRD Head of Clinical Trials) on ISAC notification or approval of research using CPRD clinical trial services**
 - 11.1. Noted
 - 11.2. Anna Higgins (or deputy) to provide further updates on Clinical Trial activities at the next ISAC meeting

12. **Role of principal investigator (Paper 7)**
 - 12.1. Members supported the principles of the paper and agreed that the ISAC application form should be amended to distinguish between the corresponding applicant and the chief investigator

- 12.2. Members noted that the corresponding applicant and chief investigator could be the same person and agreed that all initial applications must be signed by the chief investigator
- 12.3. ISAC guidance will be prepared. **Action ISAC**

- 13. **ISAC open workshop (Paper 8)**
 - 13.1. All members were in support of postponing the ISAC Open Working until the October meeting
 - 13.2. CPRD will consult users of the database in time for a draft plan for the workshop to be considered at the next meeting. **Action CPRD/ISAC**

Information Items

- 14. **Chair and Deputy Chair Work sharing agreement (Paper 9)**
 - 14.1. Noted

- 15. **Date of future ISAC meetings: 2015 / 2016 (Paper 10)**
 - 15.1. Members were reminded of the dates of future meetings

- 16. **Review of outcomes for protocols received since the last meeting (Paper to be tabled)**
 - 16.1. Tabled paper noted

- 17. **AOB**
 - 17.1. None

Date and time of next meeting: Tuesday 14th April, 2015 at 11.00 a.m.