

Independent Scientific Advisory Committee for MHRA database research (ISAC)

Summary minutes of the meeting held on Thursday 2 July 2009 at 10:30am in room CR2, 19th floor Market Towers SW8 5NQ

Information regarding ongoing deliberations, or that could identify applicants and names of products is withheld under sections 35 (Formulation of policy), 40 (Personal Information), 41 (Information Provided In Confidence) and 43 (Commercial Interests) of the Freedom of Information Act 2000 (FOIA). Further details on successful applications will be published in ISAC annual reports once research using ISAC-approved data has been published - this will also be subject to any relevant exemptions under the FOIA

Present:**ISAC Members:**

Prof Jennifer Adgey (Chair)
Dr Martin Gulliford
Prof Pali Hungin
Dr Umesh Kadam
Prof Paul Little
Dr David Lovell
Dr Sarah Meredith
Prof Simon Mitchell²
Prof Barbara Pierscionek
Ms Marcia Saunders

MHRA¹:

Dr John Parkinson
Mrs Tarita Murray Thomas (Secretariat)
Mr Stephen Fawbert (Secretariat)
Mr Philip Tregunno
Mr Rauf Pathan
Mr Rowan Snell

Apologies:

Prof Jacqueline Cassell
Prof Corinne de Vries
Prof Richard Donnelly
Prof Richard Martin
Dr Richard Stevens
Dr Ruben Thanacoody

1. Introductions, apologies and announcements

1.1. The Chairman reminded members that the papers and proceedings were confidential and should not be disclosed. Members were also reminded to declare their personal specific, personal non-specific, non-personal specific and non-personal non-specific interests in the agenda items.

¹ MHRA staff may be present for all or part of the meeting, or for specific items. GPRD staff are not present when Yellow Card applications are discussed and VRMM staff are not present for GPRD applications

² Arrived during item 4

- 1.2. Apologies had been received from Prof Jacqueline Cassell, Prof Corinne de Vries, Prof Richard Donnelly, Prof Richard Martin, Dr Richard Stevens and Dr Ruben Thanacoody.
2. **Minutes of the ISAC meeting held on Tuesday 24 March 2009 and summary minutes for publication on the MHRA website**
 - 2.1. The minutes were agreed without amendment. Summary minutes would be published on the MHRA website.
3. **Matters arising from the minutes**
 - 3.1. All actions had been completed or included on the agenda.
4. **Remit**
 - 4.1. The Committee discussed its remit as some recent applications had raised issues that could be considered of an ethical nature. ISAC's predecessor the Scientific and Ethical Advisory Group had considered ethics but this was not in ISAC's remit.

GPRD DATA

5. **Novel Approaches using the GPRD**
 - 5.1. Prior to the meeting, two studies were circulated to the full Committee for electronic review as novel uses of the GPRD were being proposed. Although approval had already been granted to undertake both studies, it was felt that a round table discussion would help to highlight some of the difficulties that members encountered in reviewing the respective protocols and how these were resolved.
6. **Governance procedures for review of studies seeking access under the GPRD- MRC scheme**
 - 6.1. The Committee discussed the decision making process for granting access to funding under the GPRD-MRC Scheme. The Committee maintained that access to funding under the scheme should be mainly for those studies of sufficiently high quality, originality and for exploratory work. The Committee considered whether it should adopt a formal framework to assess access to funding but agreed that this may be unnecessarily rigid. It was therefore decided that access to funding would be decided on a case-by-case basis along the lines agreed between the MRC and the GPRD and once studies met the quality criteria.
 - 6.2. The Committee was keen to know whether the GPRD-MRC Scheme would be continued by the MRC at the end of the five year period in November 2010. A member of the GPRD Team would be invited to attend the next ISAC meeting to provide an update on the scheme.
7. **Update of the ISAC Application Form**
 - 7.1. The Committee approved the updates to version v1.0 of the ISAC Application form with minor edits put before them in tabled paper 4. As

outlined in para 4.3 above, extra fields will be added to the form (version 2.0) to capture information on prior peer review.

8. Protocols reviewed electronically since the last meeting

8.1. The Committee noted tabled paper 1 (Annex A).

YELLOW CARD DATA**9. Review of Yellow Card applications**

9.1. The Committee noted Paper 2 and endorsed the proposal for electronic review of Yellow Card data and for there to be three ISAC meetings per year.

10. Consideration of Yellow Card applications

10.1. The Committee considered one application. The Secretariat should circulate the application electronically after further discussion with the applicant and the Committee would give a final view.

GENERAL ITEMS**11. Third annual report**

11.1. Members' comments were invited on the draft of the third annual report. This was tabled paper 2 and a hard copy of the draft would be sent to members not present.

11.2. A copy of the previous annual reports was sent to the head of key organisations with an interest in the work of the ISAC. This list was attached at Annex 1 to Paper 4 and any amendments were invited from members, as these organisations would also receive a copy of the third annual report.

12. Date of next meeting

12.1. The next meeting would be on Tuesday 29 September 2009 at 10:30am.

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