

Independent Scientific Advisory Committee for MHRA database research (ISAC)

Summary Minutes of the meeting held on Thursday 30 October 2008

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)
Prof Jacqueline Cassell²
Prof Richard Donnelly
Prof Corinne de Vries
Dr Martin Gulliford
Dr Umesh Kadam
Prof Paul Little
Ms Barbara Meredith
Dr Simon Mitchell
Dr Ruben Thanacoody
Dr Sarah Meredith

MHRA¹:

Dr John Parkinson
Mr Mick Foy
Dr Tim Williams (Secretariat)
Mr Philip Tregunno
Mr Stephen Fawbert (Secretariat)
Ms Shahin Kauser
Ms Sharon Suri

Apologies:

Prof Pali Hungin
Dr David Lovell
Prof Richard Martin
Ms Marcia Saunders

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 Left after item 11

1.2. Apologies had been received from Prof Pali Hungin, Dr David Lovell, Prof Richard Martin and Ms Marcia Saunders.

2. Minutes of the ISAC meeting held on Friday 27 June 2008 and summary minutes for publication on the MHRA website

2.1. Clarification was sought on section 11.1 of the minutes circulated in Paper 1. Revised minutes would be circulated by email for agreement after the meeting.

3. Matters arising from the minutes

3.1. MHRA Finance Department should again be asked to raise the issue of tax liability for member expenses with HM Revenue and Customs.

GENERAL ITEMS

4. ISAC Annual Report 1 April 2007-31 March 2008

4.1. The second ISAC annual report had been published on the MHRA website that day and a copy sent to stakeholders in Tabled Paper 1. A hard copy of the report was tabled for members and would be sent to those not present.

5. ISAC Reappointment of Members and appraisals Nov 2007-Dec 2008

5.1. The terms of office of four members expired in February 2009. Those members concerned had been informed of the reappointment process and would complete their appraisal for Nov 2007-Dec 2008 early as the Appointments Commission required this in early November if they were to be reappointed.

5.2. Other members should make an appointment to see the Chairman after the ISAC meetings in January or March 2009 for their appraisal.

5.3. The next reporting period would be January 2009-December 2009 and would run based on calendar years in future years.

6. NHS Connecting for Health Consultation on Public, Patients, and other interested parties views on Additional Uses of Patient Data

6.1. MHRA had been made aware that NHS Connecting for Health, an agency of the Department of Health, had commissioned Tribal Consulting to independently collect and analyse the views of interested parties about how patient information held by the NHS should be used for additional purposes.

6.2. The consultation ran until December and the Secretariat would circulate the draft MHRA response to ISAC members by email when available.

GPRD DATA

7. Protocols reviewed electronically since the last meeting

7.1. The Committee noted tabled paper 2.

7.2. The Chair advised committee members to exercise caution when reviewing new protocols that were submitted following a decision of 'Reject'. This was because some researchers had the tendency to simply reword the document instead of making substantive changes as suggested in the feedback document.

8. Hypothesis testing in descriptive studies

8.1. It had been noted recently that a number of protocols submitted for review were branded as 'descriptive studies' although hypothesis testing was implied or explicitly stated. The Committee discussed whether there might be a need to conduct an audit of such studies to quantify the magnitude of the problem.

The Committee would decide at the next meeting on the best solution or combination of solutions to address this issue.

9. Patient involvement document prepared by lay members.

9.1. Committee members endorsed the document and this would be posted on the ISAC webpage following final edits based on earlier feedback.

10. Other GPRD matters:

10.1. Protocol Deviations

The Committee discussed the need to exercise some judgement about when analysis undertaken by researchers was regarded as protocol deviation. It was vital that researchers did not engage in major and substantial deviations from the protocol. The Committee would formally consider at the next meeting what factors would constitute major deviations from the protocol so that these could be communicated to applicants via the GPRD website.

10.2. Fast tracking of GPRD ISAC Approval

Some members were unaware of the process for fast-tracking of GPRD ISAC applications and were concerned about how they would distinguish normal applications from fast-tracked requests. There was some concern that the timeline of 2 days may be unrealistic. The Committee felt that this was an area that could be covered by the SOP the Secretariat was developing on committee working practices.

YELLOW CARD DATA

11. The Committee advised that one application be rejected.

12. The Committee advised that one application be resubmitted.

13. The Committee noted that an application put to them for information was an appropriate use of Yellow Card data.

14. Any other business

14.1. None

15. Date of next meeting

15.1. The next meeting would be on Friday 23 January 2009 at 10:30am. (post meeting note – January meeting cancelled)

Close