

Independent Scientific Advisory Committee for MHRA database research (ISAC)

Summary minutes of the meeting held on Thursday 31 January 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)
Dr Jacqueline Cassell²
Dr Corinne de Vries²
Dr Martin Gulliford²
Prof Amrit Hungin²
Dr Umesh T Kadam
Dr David Lovell²
Ms Barbara Meredith²
Dr Sarah Meredith²
Dr Simon Mitchell
Ms Marcia Saunders²
Dr Ruben Thanacoody

MHRA¹:

Dr Sarah Davis
Mr Mick Foy
Dr John Parkinson
Mr Stephen Fawbert (Secretariat)
Ms Shahin Kauser
Ms Arlene Gallagher (Secretariat)

Apologies:

Prof Richard Donnelly
Prof Paul Little
Dr Richard Martin

Part One – New members only

1. Introductions, apologies and announcements

1.1. New members were welcomed to the Committee by the Chairman. The morning meeting was an induction for new members only and existing members would join after lunch.

1.2. The Chairman reminded members that the papers and proceedings were confidential and should not be disclosed. Members were also

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 Present for Part 2 only

reminded to declare their personal specific, personal non-specific, non-personal specific and non-personal non-specific interests in the agenda items.

INTRODUCTION TO ISAC

2. Terms of reference

2.1. The Committee discussed the terms of reference of the Committee that had been agreed in February 2006, to which no amendments were proposed (Tabled Paper 1).

3. Committee administration and ways of working

3.1. MHRA explained that there were separate secretariats for GPRD and Yellow Card sections of meetings where applications were discussed. General papers would be covered at the start of meetings, with the Yellow Card Secretary taking the lead on these.

3.2. The Committee were reminded that in addition to the annual declaration of interests, they would need to consider any potential conflicts of interest when reviewing individual protocols. There was a Deputy Chair (Sarah Meredith) where a conflict of interest (e.g. a protocol from her organisation) did not permit the Chairman to participate in the review of a specific protocol.

3.3. Members were informed which team they would be in for review of GPRD protocols. This would be updated on the MHRA website.

4. YELLOW CARD DATA

4.1. Introduction to the Yellow Card Scheme

The MHRA gave a presentation on the history of the Yellow Card Scheme, reporting rates and reporting methods.

4.2. The Yellow Card ISAC application process and requests received to date

The MHRA gave a presentation on the 2004 Independent Review chaired by Dr Jeremy Metters. The presentation also included information on the data categories the Interim Committee on Yellow Card data had devised in line with Data Protection and Freedom of Information requirements and the application form and guidance notes. Information was provided on applications received to date.

4.3. Tour of Pharmacovigilance Departments

Members were given a tour of the Pharmacovigilance Group of the MHRA to see how the Yellow Card process operates and how Signal Detection is carried out. The Sentinel and Lincoln IT systems were demonstrated, as was the signal case folder.

5. GPRD DATA

5.1. The GPRD Group presented an overview of the GPRD, describing the data held within the database and the principles under which it is

operated by the GPRD Group within the MHRA. The arrangements in place to control access to and use of the data were described, including Section 60 and ethical approval.

- 5.2. The GPRD Group outlined the procedures for the review of GPRD protocols by ISAC; based on those used previously by SEAG (including the fast track review process which could be requested for studies relating to serious public health issues).
- 5.3. The GPRD Group explained the agreement between the MRC and the GPRD Group which facilitates access to GPRD data for 50 protocols per year by UK academics. The Committee was informed that review of protocols seeking access to GPRD data under the MRC licence would involve the same procedure as used for other protocols, but that they would be required to comment on the suitability of the protocol for funding by the MRC. A modified reviewers' comment form had been prepared for this purpose; this form included the issues members would need to consider when assessing suitability of a protocol for MRC funding.

Part 2 – All members

6. Introductions, apologies and announcements

- 6.1. Existing ISAC members joined the second part of the meeting, to discuss routine ISAC business. Apologies had been received from Paul Little, Richard Donnelly and Richard Martin.
- 6.2. 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.

7. Minutes of the ISAC meeting held on Friday 26 October 2007 and summary minutes for publication on the MHRA website

- 7.1. The minutes of the meeting held on Friday 26 October 2007 were agreed as a true record

8. Matters arising from the minutes

- 8.1. All matters arising had been actioned or included on the agenda, with the exception that the MHRA was still awaiting all appraisal forms back from Dr Gennery. Dr Gennery had only met with 3 members and would like members who had not already contacted him should do so.

YELLOW CARD DATA

9. Yellow Card application

- 9.1. The Committee was informed of a study MHRA had received to investigate potential adverse drug reactions. The data fields requested did not require ISAC approval.

10. Ministry of Justice Data Sharing review

10.1. On 25 October the Prime Minister had asked Richard Thomas, the Information Commissioner, and Dr Mark Walport, Director of the Wellcome Trust, to carry out an independent review of the use and sharing of personal information in the public and private sectors. This review would consider whether there should be any changes to the Data Protection Act 1998 and the options for implementing any such changes.

10.2. The MHRA would be submitting a response to the consultation which would close in February. Committee members were asked to send any written comments on the draft consultation response to the secretariat by Thursday 7 February.

GPRD DATA

11. GPRD protocol

11.1. The GPRD had received a resubmission of a protocol. This protocol had had substantial revisions and the title had been changed. The researchers would be informed that this protocol was rejected. This resubmission should therefore be treated as a new submission, given a new protocol number, and should receive a full review by the Committee.

12. Lay summaries on GPRD application form

12.1. There had been at least one protocol submitted where the protocol was very complex. Members of the Committee had problems understanding the rationale. It was therefore suggested that a 200 word lay summary be submitted with every protocol from now on. The application form would be amended to include a box in which to enter a 200 word lay summary. If possible, this box would be fixed to a maximum size limit. The application form would also have a version number so that it could be quickly and easily identified when a researcher had not used the most up-to-date version. The website would be updated to include a request for this lay summary in protocol submissions.

13. SEAG v ISAC approval

13.1. In the past, SEAG had given 'blanket' approval to researchers who wished to undertake multiple studies using the GPRD and the historical extract (EPIC). The Committee had previously decided that any researcher wishing to conduct future studies on the basis of this approval should resubmit to ISAC (since 01 January 2008). The Committee discussed the issue of protocols that had been approved by SEAG and outlined an approach for handling future requests for amendments or to conduct a validation study requiring GP input. It was agreed that:

- Requests for a validation study, where this was not originally mentioned in the protocol, should be treated as new submissions and therefore subject to full review.

- Requests for amendments on all protocols approved prior to 15/03/2006 (SEAG to ISAC handover) should be treated as new submissions and therefore subject to full review
- Requests for amendments or validation studies for protocols approved since 15/03/2006 (i.e. by ISAC) would continue to be reviewed only by the chair.
- For future submissions, there would be a two year window from approval date, after which all amendments or new validations would be treated as new submissions and therefore subject to full review.

13.2. All researchers would be informed of the changes with immediate effect, by updating the ISAC information on the GPRD website and individual email where possible.

14. Guidance documents in relation to age discrimination

14.1. In response to an issue raised about age discrimination at the last meeting, the Committee advised that guidance documents from the NHS be placed on the website to inform users of the framework within which the Committee operates. The reasoning behind this was discussed again. The area for discussion was wider than age discrimination alone. It included gender discrimination or any restriction of a cohort. The Committee requested that researchers give a justification for their restrictions. This could be added to the application form, or researchers should explicitly explain this in the appropriate section of the protocol.

15. Use of GPRD for training purposes outside the GPRD group

15.1. An academic institution was considering running a training course targeting academic users of GPRD data obtained under the MRC scheme. As the terms and conditions of the MRC agreement have stipulated that data provided for a study should not be used for teaching purposes, the Committee felt that this was a topic the institution needed to raise with the MRC if the use of such data was being sought. However, the Committee did not see any issues with the use of GPRD data for this purpose and agreed they would have no issues with the institution using a sample of GPRD data as an alternative.

16. Linkage in GPRD

16.1. The upcoming linkage to other databases was a “hot topic” in GPRD. GPRD gave a presentation on how this works and what the output would be.

Any other business

17. MHRA Drug Safety Update Vol 1/Issue 6 - January 2008

17.1. A copy was provided for members’ information as there was an ISAC article on page 8.

Date of next meeting – Wednesday 30 April 2008 at 10:30am