

Independent Scientific Advisory Committee for MHRA database research (ISAC)

Summary minutes of the meeting held on Friday 6th July, 2007

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:

Dr Brian Gennery (Chair)
Dr Jacqueline Cassell
Dr Martin Gulliford
Prof Richard Donnelly
Dr Sarah Meredith
Dr Corinne de Vries
Ms Barbara Meredith

MHRA¹:

Dr Tim Williams
Mr Mick Foy
Dr John Parkinson
Mr Stephen Fawbert (Secretariat)
Mrs Tarita Murray-Thomas (Secretariat)
Ms Shahin Kauser

Apologies:

Prof Paul Little
Dr David Lovell
Prof Amrit Hungin
Ms Marcia Saunders
Dr Richard Martin

Others:

Prof Phil Routledge

1. Welcome and apologies

- 1.1. The Chairman welcomed Professor Phil Routledge, Head of Yellow Card Centre Wales, who was attending as guest member for the day with expertise in the Yellow Card Scheme.
- 1.2. Apologies had been received from Paul Little, Richard Martin, David Lovell, Marcia Saunders and Amrit Hungin for the day.
- 1.3. 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. **Minutes of the ISAC meeting held on 10 May 2007**

The minutes (Paper 1) were agreed without amendment.

3. **Matters arising**

All items had been included on the agenda for the meeting, with the exception of changes to the GPRD application form. Further changes to the ISAC application form were discussed. These focused on future access to anonymised patient data via the GPRD data linkage initiative. Selected questions on the GPRD ISAC application form would be re-drafted to accommodate the extended access.

GENERAL ITEMS

4. **First Annual report**

Members were provided with Tabled Paper 3, the draft annual report, and asked to send comments to Secretariat by 13 July. The MHRA would also reconsider what information should be published on successful protocols, given sensitivities around release of information.

GPRD DATA

5. **Information paper on GPRD applications reviewed electronically since last meeting**

The Committee noted Tabled Paper 1, the list of applications reviewed since the previous meeting. It was noted that several protocols seeking access to GPRD data under the MRC licence were unsuitable for funding. The committee suggested that there might be a greater need for academic applicants to utilise the resources of GPRD to undertake preliminary protocol review / study feasibility. Reference to this point should be highlighted in the annual report.

6. **Protocol 07- 049:**

The Committee recommended that this protocol be revised and resubmitted for further consideration.

7. **A publication incorporating aggregated data from a 'conditional probability tool' based upon the GPRD**

Tabled Paper 2 proposed various mathematical models for projecting all-cause and cause-specific mortality in the general population. The Committee was interested to know how well these models compared with findings based on individual level data.

YELLOW CARD DATA

8. **Application 13 - Active surveillance of adverse drug reactions in Scottish children: a proof of concept study**

The application was approved

9. **Application 15 - Formal Patient Reporting Evaluation**

The application was approved

Any other business

10. Dates paper for 2008

Members were asked to note the provisional dates for 2008 in Paper 4. These would be published on the MHRA website.

Date of next meeting Wednesday 24 October 2007

Post meeting note – amended to Friday 26 October 2007