

## Independent Scientific Advisory Committee for MHRA database research (ISAC)

Summary Minutes of the meeting held on Friday 27 June 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 Cassell<sup>2</sup>  
Prof Richard Donnelly  
Dr Martin Gulliford  
Prof Paul Little  
Dr Simon Mitchell  
Dr Ruben Thanacoody<sup>3</sup>  
Dr Sarah Meredith<sup>4</sup>

#### MHRA<sup>1</sup>:

Dr June Raine  
Dr John Parkinson  
Ms Tarita Murray Thomas (Secretariat)  
Mr Stephen Fawbert (Secretariat)  
Dr Jacqueline O'Shea  
Mr Jeremy Mean  
Mrs Shelley Gandhi

#### Apologies:

Prof Pali Hungin  
Dr Umesh Kadam  
Prof Corinne de Vries  
Dr David Lovell  
Dr Richard Martin  
Ms Barbara Meredith  
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.

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<sup>1</sup> 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

<sup>2</sup> Left after item 5

<sup>3</sup> Arrived during item 9

<sup>4</sup> Arrived during item 5

- 1.2. Apologies had been received from Prof Pali Hungin, Dr Umesh Kadam, Prof Corinne de Vries, Dr David Lovell, Dr Richard Martin, Ms Barbara Meredith and Ms Marcia Saunders.
2. **Minutes of the ISAC meeting held on Wednesday 30 April 2008 and summary minutes for publication on the MHRA website**
  - 2.1. The minutes of the meeting held on Wednesday 30 April 2008 (Paper 1) were agreed as a true record.
3. **Matters arising from the minutes**
  - 3.1. MHRA Finance Department had raised the issue of tax liability for member expenses with HM Revenue and Customs and would report back in due course.

## **GENERAL ITEMS**

4. **ISAC Annual Report 1 April 2007-31 March 2008**
  - 4.1. Members had been sent a copy of the draft annual report and MHRA should find an opportunity to launch it that would attract interest from the research community. An amendment should be made to section 2.2.3 around research governance. Applicants should not be allowed to change the question they were answering once data had been provided, although changes to methodology to answer the same hypothesis should be permitted. A final draft of the report would be re-circulated to members.

## **YELLOW CARD DATA**

5. ***Application***
  - 5.1. The application was discussed and should be brought back to the Committee once a more detailed application had been prepared.
6. ***Application***
  - 6.1. A more detailed application would be brought to a future meeting.
7. ***Application***
  - 7.1. This item would be discussed at a future meeting.

## **GPRD DATA**

8. **Protocols reviewed electronically since the last meeting**
  - 8.1. The Committee noted tabled paper 1.
9. **Standard operating procedure for review of GPRD protocols**
  - 9.1. There was currently a SOP in existence to guide the administrative functions of the Secretariat but there were no formal written procedures available to guide and manage the GPRD protocol reviewing process. To ensure uniformity and continuity of operations over time, a SOP relating to the scope and functions of the Committee in this respect was recommended.

9.2. Aspects of the SOP would be made available to users as a 'policy document'. This would be placed on the GPRD website and communicated to current users.

9.3. The secretariat would provide a draft document for review by the Committee before the next meeting.

## **10. Patient Involvement**

10.1. A guidance document had been produced by the lay members of the Committee to assist users with the completion of the section on 'Patient/User Group Involvement' as per the requirements of the ISAC application form. To assess the utility of this document to users, permission was sought to circulate the statement to a sample of users to ascertain the extent to which this document was able to guide users. Committee members agreed to review the document and to provide feedback to MHRA.

## **11. Further update of ISAC GPRD application**

11.1. To satisfy ONS requirements relating to the linkage and incorporation of death data in GPRD, the ISAC application form may need to be updated to capture the researcher's willingness to comply with the terms and conditions for the use of such data (as specified by the ONS). Once ongoing arrangements with the ONS had been finalised, the GPRD ISAC application form would be updated and circulated to Committee members for feedback and approval.

## **12. Research Governance**

12.1. Committee members were concerned about the growing *misuse* of GPRD data by some users. This was clearly reflected in some protocols in which users appeared to have sufficiently explored or potentially answered their study questions before protocol submission to ISAC. Although retrospective requests for protocol approval were not supported by the ISAC, in instances where this had been granted because of exceptional circumstances, researchers would be required to declare this fact during the publication process.

## **13. Any other business**

13.1. Members who had not already had their appraisal for last year could meet Dr Brian Gennery after lunch to complete this process.

13.2. The date of the first meeting in 2009 would move from Friday 30 January 2009 to Friday 23 January 2009.

## **14. Date of next meeting**

14.1. The next meeting would be on Thursday 30 October 2008 at 10:30am.

**Close**

*After the formal business of the meeting had finished, Dr Brian Gennery was invited to join the meeting. Dr Gennery had been awarded the MBE in the Queen's Birthday Honours for his service to MHRA committees and a reception was held in his honour.*