

## **Independent Scientific Advisory Committee for MHRA database research (ISAC) - Summary Minutes**

The third meeting of the Independent Scientific Advisory Committee for MHRA database research of 2015 was held on **Wednesday the 8th of July 2015** at **11:00am** in **[R-T-410], 4th Floor, 151 Buckingham Palace Road, Victoria, SW1W 9SZ.**

### **Present**

#### **MHRA:**

Miss Sophia Amjad (CPRD)  
Miss Heather Dorricott (CPRD)  
Dr James Ellis (CPRD)  
Dr Mira Harrison-Woolrych (VRMM)  
Ms Tarita Murray-Thomas (CPRD)  
Miss Jessie Oyinlola (CPRD)  
Miss Rebecca Owen (MHRA)  
Dr Janet Valentine (CPRD)  
Dr Mark Wright (CPRD)  
Mr Simon Halpin (CPRD)

#### **ISAC Members:**

Prof Patrick Waller (Chair)  
Dr Krishnan Bhaskaran  
Dr Benjamin Cairns  
Prof Jacqueline Cassell  
Dr Christopher Edwards  
Prof Peter Helms  
Dr Iskander Idris  
Prof Benjamin Lipsky  
Prof Umesh Kadam  
Ms Sally Malin  
Prof Keith Neal  
Ms Marcia Saunders  
Dr Emily McFadden  
Dr Richard Martin  
Dr Richard Stevens  
Dr Ruben Thanacoody

### **Apologies**

#### **ISAC Members:**

Dr Wendy Knibb  
Professor Martin Gulliford  
Prof Simon Mitchell

## **AGENDA**

### **1. Introductions, apologies and announcements**

1.1. Apologies were received from Professor Martin Gulliford, Dr Wendy Knibb and Professor Simon Mitchell. Written comments were received from Wendy Knibb and tabled.

1.2. Rebecca Owen (acting Yellow Card Secretary) was welcomed to the meeting, along with Dr Mira Harrison-Woolrych (Senior Medical Assessor in VRMM) who attended as an observer.

1.3. The Committee acknowledged that this was Richard Martin's last meeting, and thanked Professor Martin for his longstanding and valuable contribution.

### **2. Minutes of the ISAC meeting held on Tuesday 14<sup>th</sup> April 2015 and summary minutes for publication on the MHRA website**

2.1. Full and summary minutes were approved with minor changes to be made before publishing. **Action CPRD.**

2.2. Summary minutes will be published on the MHRA website. **Action MHRA.**

### **3. Matters arising from the minutes**

3.1. Members confirmed that the quorum for an ISAC meeting was "more than a third of the membership". The quorum currently stands at 7 members.

3.2. The ISAC open meeting is now tentatively planned to be part of the January 2016 meeting. Detailed plans are to be brought to the next ISAC meeting. **Action CPRD.**

## **General Items**

### **4. Verbal Update from CPRD and VRMM on Transparency (CPRD Transparency)**

4.1. Rebecca Owen informed the Committee that VRMM are planning to increase transparency in a similar manner to CPRD and will be discussed at the next meeting. **Action VRMM.**

4.2. Rebecca Owen informed the committee that an optional Yellow Card training session will take place before the next meeting. **Action VRMM.**

4.3. It was agreed that when a dataset is requested, CPRD will publish the information for transparency three months after the dataset has been received. **Action CPRD.**

### **5. Verbal update from Janet Valentine**

5.1. Janet Valentine informed the Committee that the proposed review of the ISAC was on hold pending wider developments.

5.2. The Committee was informed that The Agency (MHRA) has taken over the recruitment of ISAC members from the Department of Health.

5.3. The Committee were informed that the member performance review system will no longer be used; however, the currently agreed objectives will be used as a basis for considering reappointments.

5.4. The whole Committee will be asked to agree annual objectives.

#### **6. Update from James Ellis on the new ISAC protocol review system**

6.1. Members were updated on the implementation of the new review process and reminded of the new review form and internal guidance documents. Members were informed that the new process came into place from the 1<sup>st</sup> of July 2015, and very few protocols had been reviewed by the time of the meeting. A further update will be presented at the October meeting. **Action CPRD.**

#### **7. Verbal Update from Mark Wright about Clinical Trials**

7.1. The committee requested that this be discussed at the next meeting regarding the ISAC application and review process for clinical trials; this was requested such that the committee would be ready to deal with clinical trial applications. It was noted that the new assessment form might need to be adapted. **Action CPRD.**

#### **8. Demonstration from Simon Halpin (Business Development) of the E-learning software**

8.1. Members will be sent information so that they (and their colleagues) can access all the CPRD modules of the E-learning. The module regarding ISAC needs to be reviewed in light of the recent changes to the processes and guidance of the ISAC. **Action CPRD.**

#### **CPRD Items**

#### **9 ISAC Audit project - self audits of the major deviations identified in the third round and a final round of potential major deviations (Paper 4)**

9.1. The three self-audits (**09\_117R**, **11\_140** and **11\_054**) which all came from the same applicant and had similar issues, were reviewed by the ISAC and still considered to be major deviations. Rather than three separate standard letters being sent to the applicant, only one letter would be sent out, adapted as appropriate by the chair to detail the major deviations.

9.2. Six papers were considered to be major deviations from the following related protocols:

**07\_036R, 06\_027, 09\_002R, 10\_037, 10\_093R and 09\_110A/09\_111**

9.3. Protocols **10\_165A, 11\_067, 10\_074R and 12\_048** were considered the subject of minor or no deviations.

#### **10. Review of outcomes for protocols received since the last meeting**

**10.1** This was noted.

#### **11. AOB**

None

**Date and time of next meeting: Wednesday the 21<sup>th</sup> of October at 11.00 a.m.**