Medicines & Healthcare products Regulatory Agency

Independent Scientific Advisory Committee

Summary Minutes of the meeting held on Wednesday 13th July 2016 at **11:00am** in **R-T-503**, **5th Floor**, **151 Buckingham Palace Road, Victoria, SW1W 9SZ**.

Members attending

Member	Role
Prof Deborah Saltman AM	Chair
Dr Krishnan Bhaskaran	Scientific member
Prof Sinead Brophy	Scientific member
Dr Benjamin Cairns	Scientific member
Dr Christopher Edwards	Scientific member
Dr Duncan Edwards	Scientific member
Prof Peter Helms	Scientific member
Dr Caroline Jackson	Scientific member
Dr Wendy Knibb	Scientific member
Prof Benjamin Lipsky	Scientific member
Ms Sally Malin	Lay member
Prof Keith Neal	Scientific member
Ms Marcia Saunders	Lay member
Dr Sara Thomas	Scientific member
Dr Hester Ward (arrived at 12:45)	Scientific member

Apologies

Member	Role
Dr Angelyn Bethel	Scientific member
Prof Umesh Kadam	Scientific member
Dr Emily McFadden	Scientific member
Dr Simon Mitchell	Scientific member
Dr Jenny Quint	Scientific member
Dr Richard Stevens	Scientific member
Prof Ian Wong	Scientific member

In attendance

Attendee	Role/Post
Miss Sophia Amjad (minutes)	CPRD Research Applications Officer
Mr Steven Blackburn	CPRD Operations Manager
Mr Tony Haworth	CPRD Head of Information Governance & Assurance
Dr Stephen Mak	CPRD Information Governance Manager
Ms Tarita Murray-Thomas	CPRD Senior Researcher

1. **Introductions, apologies and announcements**

   1.1.   The Chair welcomed members to the meeting, with seven of the members providing apologies.

   1.2.   No conflicts of interest regarding business on the agenda were raised by members.

   1.3.   The Chair also welcomed several new CPRD staff members who were in attendance: the CPRD Head of Information, Governance and Assurance; the CPRD Operations Manager and the CPRD Information Governance Manager.

2. **Minutes of the ISAC meeting held on Wednesday 13th April 2016 and summary minutes for publication on the MHRA website**

   2.1.   Full and summary minutes were approved with minor corrections:

      i)   that the attendee list be updated to reflect all members who were present;
      ii)   item 9 be clarified that discussions were regarding audit in general and not the ISAC audit project. **Action: ISAC Secretariat.**

   2.2.   Summary minutes would be published on the MHRA and CPRD website. **Action: ISAC Secretariat.**

3. **Chair's Report**

   3.1.   The Chair introduced the agenda for the meeting which included a new section on protocols of interest for discussion, and indicated that these would be a standing agenda item for future meetings. The Chair requested feedback be provided by members either at the end of the meeting or subsequently.

   3.2.   The Chair thanked members for their commitment to the committee and their efforts to provide expedient advice in response to the increased numbers of protocols that required review.

   3.3.   An overview of the current protocol review process, and the Chair's involvement, was provided. The Chair was responsible for approving each step of the ISAC protocol assessment process, which included: review of protocols; assignment of external reviewers; review of reviewer feedback; feedback to applicants; assessment of Confidentiality Advisory Group (CAG) status, and final approval.

   3.4.   The Chair reaffirmed that when two reviewers have conflicting outcomes (e.g. approval *vs.* resubmission) the Chair would take the most stringent approach to ensure maximum integrity and safety where a protocol was being assessed.

4. **Secretariat's Report**

3.5. Tarita Murray-Thomas reported that there had been an increase in the number of protocols sent to ISAC members. It was reported that 43% of all protocols submitted between April 13th 2016 and 10th July 2016 were classified as requiring external review, a 63% increase for ISAC member reviewers when compared to numbers reviewed during the last quarter. The Chair advised that this was largely due to application of an approach to ensure maximum integrity and safety, which resulted in a more conservative approach in allocating protocols for external review.

4.1. Tarita Murray-Thomas updated the committee on the new CPRD structure and how this affected the ISAC Secretariat function. Members were informed that the Secretariat function had been divided into a scientific role, managed by the Observational Research Team, and an administration role, managed by the Information Governance and Assurance (IG&A) team. The CPRD Information Governance Manager would now be overseeing the administrative running of ISAC. The Research Applications Officer post, which reported to the IG Manager, would undertake day to day processing of protocols and provide committee support.

4.2. The committee discussed the importance of providing feedback to applicants to avoid a culture of rejection and to ensure the science proposed was correct, to protect public health/public interest and to facilitate use of the CPRD database. It was noted that clinical issues were also important; confounding by indication was an issue which regularly was picked up by reviewers.

5. **CPRD Director Brief**

5.1. The Director's Brief was provided by Tony Haworth, CRPD's new Head of Information Governance & Assurance.

5.2. **CPRD Staff recruitment update**

A staff recruitment update was provided including positions relating to ISAC.

5.3. **Update on CPRD access to GP Software systems**
An update on CPRD access to GP software systems was provided.

5.4. **The National Data Guardian Review**
The Department of Health had published The National Data Guardian for Health and Care's "Review of Data Security, Consent and Opt-Outs". It was agreed that further discussion on the National Data Guardian review would be arranged for the next meeting.

6. **Draft Terms of Reference**

    6.1.   Members were asked to comment on and approve the draft Terms of Reference (ToR). Members approved these, subject to revisions.

    6.2.   The final version of the ToR would be approved on behalf of the committee by the Chair. **Action: Chair**

7. **Protocol Reviewing Process**

    7.1.   The protocol reviewing process was discussed by the committee.

    7.2.   The Chair discussed the pilot of hybrid reviews and explained that these provided a more comprehensive review compared to a wholly external/ internal review. Members agreed that this process would replace the current protocol review process. **Action: ISAC Secretariat**

    7.3.   Members also agreed that where lay review was required, this might replace the external scientific reviewer.

    7.4.   7.3 above was retracted at 19 October 2016 ISAC meeting to state that it should also be possible to assign an external scientific reviewer to a protocol when a lay review is required.

    7.5.   The CPRD Head of Information Governance & Assurance informed the committee that CPRD would be reviewing the process over the coming months and would feedback at the next meeting. **Action: ISAC Secretariat**

8. **Protocols for Discussion**

    8.1.   The committee discussed three protocols which were highlighted as of interest from over the last few months.

9. **A.O.B., ISAC audit processes and future meeting dates**

    9.1   An overview of the aims and objectives of audits of ISAC-related activities and a summary of the outcomes of the discussions of the subcommittee were provided. A recommendation was that particular attention be applied to consideration of ISAC's duty to stakeholders. The committee discussed what method of monitoring was suitable and appropriate for ISAC to conduct.

10. **Review of outcomes for protocols received since the last meeting (Paper 1)**

    10.1   The relevant paper was noted.

Date and time of next meeting: Wednesday 19 October 2016