



Medicines & Healthcare products
Regulatory Agency

Independent Scientific Advisory Committee

Summary minutes of the meeting held on Wednesday 19th October 2016 at 11:00am in R-M-410, 5th Floor, 151 Buckingham Palace Road, Victoria, SW1W 9SZ.

Members attending

Member	Role
Prof Deborah Saltman AM	Chair
Prof Sinead Brophy	Scientific member
Dr Krishnan Bhaskaran	Scientific member
Dr Benjamin Cairns	Scientific member
Dr Christopher Edwards	Scientific member
Prof Peter Helms	Scientific member
Dr Caroline Jackson	Scientific member
Prof Umesh Kadam	Scientific member
Prof Wendy Knibb	Scientific member
Prof Keith Neal	Scientific member
Dr Hester Ward	Scientific member
Ms Marcia Saunders	Lay member
Dr Richard Stevens	Deputy Chair and Scientific member
Dr Sara Thomas	Scientific member
Prof Ian Wong	Scientific member

Apologies & on leave

Member	Role
Dr Angelyn Bethel	Scientific member
Dr Duncan Edwards	Scientific member
Prof Benjamin Lipsky	Scientific member
Dr Simon Mitchell	Scientific member
Ms Sally Malin	Lay member
Dr Jenny Quint	Scientific member
On leave from ISAC duties: Dr Emily McFadden	Scientific member

In attendance

Attendee	Role/Post
Mr Tony Haworth	CPRD Head of Information Governance & Assurance
Mr Chris Jaggs (minutes)	CPRD Information Governance & Assurance Co-ordinator
Dr Stephen Mak (ISAC Secretary)	CPRD Information Governance Manager
Mrs Tarita Murray-Thomas	CPRD Senior Researcher
Mr Steven Blackburn	CPRD Operations Manager

1. Welcome and apologies

The Chair opened the meeting and welcomed those attending. Apologies were received from Dr Angelyn Bethel, Dr Duncan Edwards, Prof Benjamin Lipsky, Ms Sally Malin, Dr Simon Mitchell and Dr Jennifer Quint. Dr Emily McFadden was on leave from ISAC duties. Mr Tony Haworth (CPRD Head of Information Governance and Assurance) attended on behalf of Dr Janet Valentine (CPRD Director) on this occasion.

The Secretariat confirmed that according to the current Terms of Reference of the ISAC, quorum at formal meetings must consist of more than one third of the whole membership, including the Chair (or nominated deputy). The Secretariat confirmed that according to the current Terms of Reference that there was no requirement for at least one lay member to be present for a meeting to be considered quorate.

Action: The Secretariat to add the requirement for at least one lay member to be present at formal meetings for the meeting to be considered quorate.

2. Minutes of the previous meeting

2.1 Hybrid review process of ISAC protocols

The minutes from the previous meeting held on 13 July 2016 were considered. The Chair confirmed that following a pilot, the decision to implement a new research protocol review process of 'hybrid' reviews, where one internal reviewer (a CPRD Researcher) assessed low-risk protocols, and one internal reviewer and one external reviewer (an ISAC member) assessed high-risk ones, had been taken by the Chair in conjunction with the ISAC Secretariat. Members indicated their support for the new review process.

It was agreed that the ISAC Secretariat would clarify for members' information, the role of the ISAC as part of CPRD's Research Ethics Committee (REC) approval and to clarify that the new review process did not compromise the CPRD REC approval.

The Secretariat confirmed that the potential need still existed for two or more external reviewers to assess a protocol, for example where significant clinical, ethical or public interest test issues were apparent. This would require a lay as well as scientific member to evaluate.

The minutes of the meeting from 13th July 2016 were approved subject to the above amendments being made. Summary minutes of previous meetings would also be published on the CPRD and MHRA websites.

Actions: Secretariat to share with the Committee an extract from CPRD REC approval that related to the role of the ISAC.

Secretariat to amend the review process flowchart to reflect the agreed changes.

Secretariat to publish summary minutes of 13th July 2016 meeting on CPRD and MHRA websites.

3. Matters arising

The actions list from the previous meeting was discussed. The Chair noted that several actions would be considered under agenda items for the meeting.

4. Chair's Report

The Chair updated the Committee on changes to membership, noting that Profs Umesh Kadam, Benjamin Lipsky and Dr Simon Mitchell's membership of the Committee was being extended until 31 March 2017.

Two recommendations for appointment of new members had been made by MHRA. These new members will be formally offered the membership positions, once approved by the CPRD Director.

5. Secretariat's Report

The ISAC Secretariat presented a progress report on protocol processing for the year to date, and on the Secretariat resourcing since the meeting in July 2016. A new visual 'dashboard' of metrics relating to processing protocols was provided to Members.

The ISAC Secretariat noted that there had been significant staff turnover in the Secretariat over the summer.

6. CPRD Director's Report

Mr Tony Haworth presented a report from the CPRD Director in her absence. In September 2016, CPRD co-ordinated the MHRA's response to the public consultation on the National Data Guardian Review on Data Security, Consent and Opt-Outs. CPRD was meeting with colleagues in the Department of Health to discuss the potential implementation of the policy following the consultation.

The International Conference on Pharmacoepidemiology (ICPE) had taken place in August 2016. CPRD hosted an annual User Group meeting to coincide with the conference. The meeting was over-subscribed with representatives from over 20 different CPRD user organisations attending. Presentation from CPRD staff including characterisation of EMIS data, new linkages and an update on new value adding services. Positive feedback was received from those attending.

A brief update on staff changes in CPRD was provided. New Heads of Observational Research (OR) and Business Development (BD) had been appointed. Jessie Oyinlola, who had previously supported the ISAC Secretariat, had been promoted to Research Assistant and a new Researcher had also started. In BD, new staff had started in the roles of Head of Clinical Communications, Science Writer and Business Development Manager.

7. ISAC Annual Report

The ISAC Secretariat informed members as to the status of the 2015/16 Annual Report. Members agreed to formally delegate approval for the Report to the Chair.

8. Protocols for discussion

The Committee discussed five protocols that had been highlighted as of interest over the last few months.

9. Committee members update

Members present updated on their activities since the last meeting.

10. Evaluation of the meeting

It was noted that the discussion of contexts and specific criteria for decision-making on protocols had been extremely helpful.

The Committee noted that clinical practice was constantly changing, making clinical expertise within the ISAC membership very important. Lay and clinical expertise should complement effectively the scientific expertise held across the Committee.

The Committee also stressed the importance of applicants understanding the context in which health/patient data had been collected when submitting protocols for review.

11. A.O.B.

The next meeting would be held at 151 Buckingham Palace Road, London at 11am to 3pm on Tuesday 17th January 2017.