Medicines & Healthcare products Regulatory Agency

Independent Scientific Advisory Committee

Minutes of the meeting held on Monday 29 January 2018 at **11:00am** in **R-T-410 4th Floor**, **151 Buckingham Palace Road, Victoria, SW1W 9SZ**

Members attending	
Member	**Role**
Prof Deborah Saltman AM	Chair
Dr Richard Stevens	Deputy Chair and Scientific member
Prof Sinead Brophy	Scientific member
Dr Iain Carey	Scientific member
Prof David Fishwick	Scientific member
Dr Kate Fleming	Scientific member
Dr Evangelos Kontopantelis	Scientific member
Dr Wendy Knibb	Scientific member
Ms Sally Malin	Lay member
Prof Keith Neal	Scientific member
Dr Grace Okoli	Scientific member
Dr Jennifer Quint	Scientific member
Ms Marcia Saunders	Lay member
Dr Sara Thomas	Scientific member
Prof Martin Tobin	Scientific member
Dr Hester Ward	Scientific member
Dr Paul Welsh	Scientific member
Dr Stephen Weng	Scientific member
Prof Ian Wong	Scientific member

Apologies	
Member	**Role**
Dr Angelyn Bethel	Scientific member
Ms Rosie Cornish	Scientific member
Dr Duncan Edwards	Scientific member
Prof Ann John	Scientific member
Prof Andrew Morris	Scientific member
Prof Sonia Saxena	Scientific member

On leave	
Member	**Role**
Dr Emily McFadden	Scientific member

In attendance	
Attendee	**Role/Post**
Dr Puja Myles	CPRD Head of Observational Research
Ms Tarita Murray-Thomas	CPRD Senior Researcher
Mr Daniel Brett	ISAC Secretariat
Dr Eleanor Yelland	CPRD Researcher
Mr Jonathan Lind	CPRD Research Applications Manager

V1.00

1. Welcome and apologies

The Chair opened the meeting and welcomed those members in attendance. Ms Rosie Cornish, Dr Duncan Edwards, and Professors Ann John, Andrew Morris and Sonia Saxena had sent their apologies for the meeting.

The Chair acknowledged that Drs Iain Carey, Kate Fleming, Grace Okoli, Paul Welsh, Stephen Weng, and Professors David Fishwick and Martin Tobin were attending their first ISAC meeting.

2. Minutes of the last meeting

The full and summary versions of the minutes from the October 2017 meeting were approved by the Committee as circulated in the meeting papers.

Action: Secretariat to upload approved summary minutes for October 2017 meeting to CPRD and MHRA websites.

3. Matters Arising

The actions list from the previous meeting (Paper 2) was presented by the Chair.

The draft 2016/17 Annual Report had been shared with the Committee for comment and the finalised Report would be published in the near future.

4. Chair's Report

There had been a large number of protocols submitted to the Committee since the last meeting and the Chair thanked Committee members for their work in reviewing these protocols.

5. ISAC Secretariat Report

Daniel Brett presented a report (Paper 3) on ISAC protocols received from 1 April 2017 – 22 January 2018. There had been 227 protocols submitted for review and 221 protocols approved by ISAC during the period.

Since the last meeting, ten new members of the Committee had completed their induction sessions and were continuing their training period as new members.

Sam Speer had joined CPRD as Information Governance and Assurance Coordinator in January 2018. In this role Sam would support ISAC protocol processing and meeting management.

6. ISAC Lay Member Reviews

Sally Malin presented a paper (Paper 4) on the approach taken by lay reviewers of ISAC protocols. The Committee agreed that the purpose of reviewing protocols was not to re-write the application, but to assess whether the right questions are being asked for the data being requested. Committee member feedback should aid applicants in asking the right questions. The Committee also discussed patient group involvement and the dissemination of research.

7. eISAC

Steve Blackburn (CPRD Business Operations Manager) and Kareen Taiwo-Odukoya (CPRD Programme Manager) presented an update on the eISAC electronic research application platform project.

8. ISAC Quality Assurance

Richard Stevens presented the findings of the ISAC quality assurance exercise. Comments were invited from the Committee. An updated presentation would be given to the Committee at the next ISAC meeting prior to be presented to a CPRD User Group meeting at a future date.

9. Reviewer comments weighting in resubmissions and approvals with comments

Dr Jennifer Quint led a discussion on the importance of consistency across ISAC reviewers in what is considered a 'high priority' comment which would warrant resubmission of the protocol.

The Committee agreed that research proposing direct contact with patients should include a clear statement of public involvement in the research. It was agreed that the subcommittee would revisit the topic of advisory comments, in addition to low or high priority comments. Advisory comments would allow the Committee to make suggestions to the applicants that were for the benefit of the research, but would not necessitate a resubmission.

10. Protocols for discussion

Dr Evangelos Kontopantelis led a discussion on the issues raised in the review of an ISAC Protocol

11. Director's Report

Dr Puja Myles presented the report on behalf of the CPRD Director. The Committee was informed of the launch of a new database CPRD Aurum in December 2017. More information including a data specification was available on the CPRD website (https://www.cprd.com/cprdaurum/). A meeting based on CPRD Aurum data would be held in spring/summer 2018, and members would be invited to attend.

There had been a significant increase in the number of GP practices signed up to CPRD in recent months.

Plans to implement the patient opt-out model recommended by the National Data Guardian in the 2016 review were being finalised by the Department of Health (DH). DH had been in consultation with stakeholders, including CPRD, on the potential impacts of the national opt-out. The model would be implemented in May 2018 and accompanied by a publicity campaign on the use of patient data. CPRD had contributed case studies for use in these patient-facing communications.

CPRD had launched a twitter account with the handle @CPRD.

12. Machine Learning

Dr Puja Myles briefed the Committee on findings from the recent CPRD stakeholder consultation workshops on machine learning. The workshop report outlined broad principles underpinning appropriate use and governance of machine learning techniques, but further guidance would be needed for ISAC applicants and reviewers on this topic.