



Minutes of the meeting held on Thursday 02 May 2019 from 11:00am at the MHRA office, 10 South Colonnade, Canary Wharf, London, E14 4PU.

Members attending	
Member	Role
Prof Deborah Saltman AM	Chair
Prof Sinead Brophy	Scientific member
Dr Iain Carey	Scientific member
Ms Rosie Cornish	Scientific member
Dr Kate Fleming	Scientific member
Ms Sally Malin	Lay person (co-opted for this meeting)
Dr Emily McFadden	Scientific member
Prof Andrew Morris	Scientific member
Prof Keith Neal	Scientific member
Dr Grace Okoli	Scientific member
Dr Jennifer Quint	Scientific member
Ms Marcia Saunders	Lay person (co-opted for this meeting)
Dr Paul Welsh	Scientific member
Dr Stephen Weng	Scientific member
Prof Ian Wong	Scientific member

Apologies	
Member	Role
Prof Richard Stevens	Deputy Chair and Scientific member
Dr Duncan Edwards	Scientific member
Prof David Fishwick	Scientific member
Prof Evangelos Kontopantelis	Scientific member
Prof Martin Tobin	Scientific member
Dr Hester Ward	Scientific member

In attendance	
Attendee	Role/Post
Dr Janet Valentine	CPRD Director
Dr Puja Myles	CPRD Head of Observational Research
Ms Tarita Murray-Thomas	CPRD Senior Researcher
Mr Jonathan Lind	CPRD Research Applications Manager
Ms Elizabeth Crellin	CPRD Researcher
Mr Sam Speer	CPRD Research Applications Coordinator

1. Welcome and apologies

The Chair opened the meeting and welcomed those members in attendance.

Dr Emily McFadden was welcomed back to the Committee as a standing member, having been an observer at the previous meeting.

Profs Richard Stevens, David Fishwick, Evangelos Kontopantelis, and Martin Tobin, and Drs Duncan Edwards and Hester Ward had sent their apologies for the meeting.

The Chair acknowledged that Professor Sara Thomas had resigned from the Committee and thanked her for her service in absentia.

The Chair noted that retired members Sally Malin and Marcia Saunders had been co-opted for this meeting and thanked them for their service.

2. Minutes of the last meeting

The full and summary versions of the minutes from the October 2018 meeting were approved remotely by the Committee and had been published on the CPRD and MHRA websites.

A correction to the minutes of the October 2018 meeting was agreed by the Committee.

In Section 1 para.6, where the minutes state “Sally Malin and Marcia Saunders would be tendering their resignations from the Committee following the meeting, and the Chair thanked them for their longstanding work on the Committee” read “Members Sally Malin and Marcia Saunders had reached the end of their terms of appointment and would be stepping down from the Committee following the meeting. The Chair thanked them for their longstanding work on the Committee.”

3. Matters Arising

The Committee were informed that the lay members had been co-opted in order to achieve quorum for this meeting as new members could not be recruited till the external review of CPRD data access governance was completed.

The next meeting to be held in October 2019 would be an extraordinary meeting on the external review recommendations which would not be subject to quorum requirements.

4. ISAC Secretariat Report

Jonathan Lind provided an update to the Committee on the reporting metrics for the previous financial year. The Committee were thanked for their considerable efforts during the reporting period. The figures would be presented in the upcoming 2018/19 ISAC Annual Report.

The Committee approved the revised internal review document, which incorporated recommendations from the meeting in October 2018.

The Committee approved the 2017/18 ISAC Annual Report with no amendments.

The Committee were asked to approve updates to the ISAC Protocol Application Form and accompanying guidance. Members approved the documents with minor changes. The Committee discussed section R in the Protocol Application Form, on patient or user group involvement. While it was acknowledged that on occasions patient and user involvement may not be appropriate, the applicants would still need to explain why this was the case.

Applications which simply state “not applicable” in response to this section on the protocol form should be returned as invalid.

Action: The Secretariat to amend Section R of the Protocol form to remove ‘(if applicable)’

5. Head of Observational Research Report

Dr Puja Myles updated the Committee on the progress of the pilot process for feasibility studies. The Committee were reminded that the Health Research Authority (HRA) had confirmed that feasibility studies to inform research were outside the remit of CPRD’s Research Ethics Committee (REC) approvals, and therefore did not require ISAC approval.

Members were told that the application form and guidance for submitting a feasibility study to CPRD were available on the CPRD website (<https://cprd.com/research-applications>).

To date, there had been 7 feasibility study applications, of which 4 had been approved.

CPRD would continue the pilot and would provide a further update to the Committee later in the year.

6. CPRD Director’s Report

The CPRD Director updated the ISAC on the expansion of the CPRD primary care database to include data contributions from 1 in 7 GP practices in the UK, providing coverage of over 15% of the UK population. With the onboarding of EMIS GP practice data into the new CPRD Aurum database, the total number of patients available had increased to over 35 million. The number of patients available for data linkage had also doubled as a result of CPRD Aurum.

Data volumes were set to grow significantly in the future with the recent public commitment from TPP to flow data from TPP/SystemOne GP practices to CPRD. At the time of the meeting, CPRD had received pilot data from TPP and discussions were ongoing regarding full provision.

Dr Valentine noted the significant number of publications resulting from studies using CPRD data, including 6 recent studies authored by CPRD.

Action: The Secretariat to provide Committee members with links to CPRD authored publications.

The Committee was updated on the new pricing structure, which had been developed in response to customer feedback and the need for a scalable data access model in line with the increasing volumes of data available. The Committee thanked CPRD for the publication of clear pricing information on the CPRD website.

The CPRD Director reminded the Committee of the external review, which had been commissioned by the MHRA Chief Executive, and acknowledged that some ISAC members had been interviewed as part of the independent review of CPRD data access governance. Once completed, the recommendations of the review would be considered by the MHRA Executive. The Committee were reminded that there would be no recruitment to the ISAC until the conclusion of the external review.

7. eRAP Project Update

Steve Blackburn provided an update to the Committee on progress with the electronic research applications portal (eRAP) project.

Following a tendering exercise in February, a supplier had been chosen and the project was due to commence in June.

The Committee was thanked for their contributions during the discovery phase of the project, and members would be consulted again at a later stage in the development lifecycle.

8. Absent Prescriptions in Primary Care Databases

Grace Okoli presented an updated paper looking at prescriptions that are absent in CPRD primary care databases.

The Committee agreed that applicants would benefit from considering the potential impact of absent prescriptions when applying to use CPRD data for certain studies.

Action: The Secretariat to update the guidance on completing the protocol application form with wording on absent prescriptions.

9. Protocols discussed

Ian Wong, Kate Fleming, Iain Carey, and Elizabeth Crellin led discussions on issues raised during the reviews of various ISAC protocols.

10. AOB

The Committee were reminded that the July Committee meeting had been cancelled, and that an extraordinary meeting would be held on Monday 28 October 2019 at the MHRA Office, 10 South Colonnade, Canary Wharf, E14 4PU.

Members were asked to provide outstanding biographies and signed conflict of interest statements by 08 May.

Action: Committee members were asked to confirm availability for the October 2019 meeting as soon as possible, and to return biographies and signed conflict of interest statements by 08 May.

Actions

Agenda item	Action	Date to be completed
4.	The Secretariat to amend Section R of the Protocol form to remove '(if applicable)'	May 2019
6.	The Secretariat to provide Committee members with links to CPRD authored publications.	May 2019
8.	The Secretariat to update the guidance on completing the protocol application form with wording on absent prescriptions.	May 2019
11.	Committee members were asked to confirm availability for the October 2019 meeting as soon as possible, and to return biographies and signed conflict of interest statements by 08 May.	May 2019