



Medicines & Healthcare products  
Regulatory Agency

## Independent Scientific Advisory Committee

**Minutes of the meeting held on Tuesday 3 October 2017 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
Dr Angelyn Bethel	Scientific member
Dr Krishnan Bhaskaran	Scientific member
Prof Sinead Brophy	Scientific member
Dr Benjamin Cairns	Scientific member
Ms Rosie Cornish	Scientific member
Dr Duncan Edwards	Scientific member
Dr Evangelos Kontopantelis	Scientific member
Ms Sally Malin	Lay member
Prof Keith Neal	Scientific member
Dr Jennifer Quint	Scientific member
Dr Sara Thomas	Scientific member
Prof Ian Wong	Scientific member

### Apologies

Member	Role
Dr Christopher Edwards	Scientific member
Prof Peter Helms	Scientific member
Dr Wendy Knibb	Scientific member
Ms Marcia Saunders	Lay member
Dr Hester Ward	Scientific member

### On leave

Member	Role
Dr Emily McFadden	Scientific member

### In attendance

Attendee	Role/Post
Dr Puja Myles	CPRD Head of Observational Research
Mrs Tarita Murray-Thomas	CPRD Senior Researcher
Mr Antony Haworth	CPRD Head of Information Governance & Assurance
Mr Daniel Brett	ISAC Secretariat
Ms Sonia Coton	CPRD Researcher
Mr Jonathan Lind	CPRD Research Applications Manager
Dr Janet Valentine	CPRD Director

## **1. Welcome and apologies**

The Chair opened the meeting and welcomed those members in attendance. Prof Peter Helms, Drs Hester Ward, Wendy Knibb, Chris Edwards and Marcia Saunders had sent their apologies for the meeting.

The Chair acknowledged that Drs Ben Cairns, Chris Edwards, and Krishnan Bhaskaran were attending the final Committee meeting before the end of their terms of appointment, and these members were thanked for their valuable contributions to the Committee throughout their tenure. Professor Peter Helms' term on ISAC was also coming to an end, and he was thanked in his absence.

## **2. Minutes of the last meeting**

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

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

## **3. Matters Arising**

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

**3.1 Action from July 2017: The draft Annual Report for 2016/17 is to be shared with Committee members for comments before final approval.**

## **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**

Mr Daniel Brett presented a report (Paper 3) on ISAC protocols received from 1 April – 25 September 2017.

Since the last meeting, the Secretariat had initiated a recruitment round for scientific members of the Committee, between 25 August and 17 September 2017.

The ISAC application form had been updated in order to comply with the new requirements of the data sharing agreement with NHS Digital.

## **6. Machine Learning and Data Mining**

Dr Puja Myles reported on the two stakeholder consultation workshops on machine learning (ML) that were hosted by CPRD on 2 July 2017 and 22 September 2017. The workshops had included representatives from CPRD, ISAC, academia, ethics committees and medicines regulation. Recommendations arising from the workshops would inform the CPRD machine learning policy.

## **7. CPRD Director's Report**

Dr Janet Valentine presented the CPRD Director's Report. The Data Protection Act would be replaced by the General Data Protection Regulation (GDPR) in May 2018, and that the new legislation was not expected to have a detrimental effect on services provided by CPRD. A group led by the Health Research Authority was developing research-specific guidance and CPRD was a member of this group. The Committee would be kept informed of any changes to the ISAC process arising from the GDPR.

The Government's response to the Data Guardian Review had been published, with the Government intending to take forward the recommendations of the Review. The Committee would be informed when further information was available on implementation.

An update was provided on progress with the ISAC electronic application form, (eISAC), which had been delayed due to ongoing work redeveloping the CPRD website. The structure and content of eISAC would be influenced by work underway in a parallel project, involving CPRD collaborating with the Medical Research Council, NHS Digital, Public Health England and the Health Research Authority on harmonising language across health data research application forms.

CPRD staff had attended the International Conference for Pharmacoepidemiology, where it was noted that there were 70 study abstracts from 8 different countries presented, which cited research using CPRD data.

Although CPRD had been able to receive EMIS data for some time, it was not in a format that supported data linkage. EMIS and CPRD had been working in partnership over the past 12 months to develop bespoke software and systems that enable CPRD to extract near real time EMIS data. The uploading of the full historic data collection from over 600 EMIS practices into the CPRD database had begun, amounting to more than 10 terabytes of data.

Finally, the Director noted that the CPRD had reached a milestone of 870 GP practices signed-up to contributing data to CPRD.

## **8. Reviewer comments weighting in resubmissions and approvals with comments**

Drs Jennifer Quint and Sara Thomas presented a paper on the weighting of reviewer comments. The Committee noted the importance of ensuring consistency across reviewers, particularly in classification of comments as 'high priority', which would necessitate resubmission of a protocol.

**Action: Drs Jennifer Quint, Sara Thomas and Evangelos Kontopantelis to update the ISAC weighting of comments paper for discussion at the next ISAC meeting.**

## **9. Protocols for discussion**

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