



Medicines & Healthcare products
Regulatory Agency

Independent Scientific Advisory Committee

Summary Minutes of the meeting held on Tuesday 11 July 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 Christopher Edwards	Scientific member
Dr Duncan Edwards	Scientific member
Prof Peter Helms	Scientific member
Dr Evangelos Kontopantelis	Scientific member
Dr Wendy Knibb	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	Scientific member

Apologies	
Member	Role
Prof Ian Wong	Scientific member
Dr Jennifer Quint	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 (for item 9)	CPRD Director

1. Welcome and apologies

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

2. Minutes of the last meeting

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

3. Matters Arising

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

3.4 ISAC Quality Assurance

Dr Richard Stevens presented a paper (Paper 2A) on quality assurance of ISAC reviews and how to promote consistency across reviews. It was noted that if the applicant was in touch with CPRD, advice could be provided by the CPRD Observational Research team before an ISAC application was made. It was also noted that ISAC members could access all reviewer feedback and the final decision on each protocol, via the portal.

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 – 30 June 2017. There had been 83 protocols submitted for review and 74 protocols approved by ISAC during the period.

Since the last meeting, the Secretariat had initiated a recruitment round for scientific members of the Committee, that had run from 10 May until 18 June 2017. The next recruitment round was expected to begin in August 2017 to coincide with the International Conference on Pharmacoepidemiology.

The following new routine data linkages were now available and had been added to the ISAC application form:

- NCRAS (National Cancer Registration and Analysis Service) Cancer Registration Data
- NCRAS Cancer Patient Experience Survey (CPES) data
- NCRAS Systemic Anti-Cancer Treatment (SACT) data
- Mental Health Services Data Set (MHDS)

Paper 7 had been provided for information on these new data linkages.

Mr Jonathan Lind had joined CPRD as Research Applications Manager. He would be responsible for overseeing the day-to-day management of the ISAC Secretariat and co-ordination of data release processes.

Ms Aleksandra Korzeniowska had joined CPRD as Information Governance & Assurance (IG&A) Co-ordinator. She will support the provision of CPRD IG&A services and the management of ISAC protocols.

6 Head of Observational Research Report

Dr Puja Myles (Head of Observational Research) reported on the review of ISAC related processes and procedures, ranging from initial client contact with CPRD, the ISAC research protocol review process, to post-ISAC approval and provision of data.

7 An overview of MHRA pharmacovigilance methods and the use of CPRD

Dr Katherine Donegan, Pharmacoepidemiology Unit Manager, Vigilance and Risk Management of Medicines (VRMM), MHRA, presented an overview of VRMM's approach to pharmacovigilance and the benefits of the MHRA regulator having access to CPRD data. The Committee noted the importance of VRMM's surveillance work on UK public health.

8 Machine Learning and Data Mining

Dr Ben Cairns presented an update to the Machine Learning and Data Mining paper, examining some key issues arising from applications proposing use of machine learning techniques.

9 CPRD Director's Report

Dr Janet Valentine presented the CPRD Director's Report. It was reported that work was underway that would soon support EMIS data linkage and other CPRD services. The new format of EMIS data was expected to be released to researchers in Autumn 2017, with data linkage available in early 2018.

The CPRD Director noted that the new dataset linkages available were important additions to the suite of quarterly routine data linkage. It was noted that one-third of enquiries to CPRD since April 2017 had related to cancer datasets.

The Committee members were invited to contribute to the CPRD User Group meeting to be held in London next year, with a date to be confirmed.

10 Protocols for Discussion

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

11 Next meeting

The next meeting will be held at 11am on 3 October 2017 at 151 Buckingham Palace Road, Victoria, SW1W 9SZ.