



Independent Scientific Advisory Committee

Minutes of the meeting held on Monday 28 October 2019 from 12 noon at the MHRA office, 10 South Colonnade, Canary Wharf, London, E14 4PU.

Members attending	
Member	Role
Prof Deborah Saltman AM	Chair
Prof Richard Stevens	Deputy Chair and Scientific member
Prof Sinead Brophy	Scientific member
Dr Iain Carey	Scientific member
Ms Rosie Cornish	Scientific member
Dr Duncan Edwards	Scientific member
Dr Kate Fleming	Scientific member
Prof Evangelos Kontopantelis	Scientific member
Prof Keith Neal	Scientific member
Dr Grace Okoli	Scientific member
Dr Jennifer Quint	Scientific member
Dr Paul Welsh	Scientific member
Dr Stephen Weng	Scientific member

Apologies	
Member	Role
Prof David Fishwick	Scientific member
Prof Andrew Morris	Scientific member
Prof Martin Tobin	Scientific member
Dr Hester Ward	Scientific member
Prof Ian Wong	Scientific member

On leave	
Member	Role
Dr Emily McFadden	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 Jessica Haddrell	CPRD Research Applications Officer
Mr Sam Speer	CPRD Research Applications Coordinator

1. Welcome and apologies

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

The Committee were reminded that this was an extraordinary meeting, called in order to share the report of the Independent Review of CPRD Internal Governance Framework.

Profs David Fishwick, Andrew Morris, Martin Tobin and Ian Wong, and Dr Hester Ward had sent their apologies for the meeting.

Dr Janet Valentine read a message from MHRA's Interim Chief Executive, Dr June Raine. Dr Raine stated that she had wanted to be present but had to send her apologies as she was attending a meeting out of the country. She thanked members for their ongoing work and acknowledged the important items being discussed at the meeting. She stated that she had spoken to all relevant parties and believed that a sensible direction of travel was being adopted, and she looked forward to hearing the outcomes of the discussions.

2. Minutes of the last meeting

The full and summary versions of the minutes from the May 2019 meeting had been approved remotely by the Committee and were published on the CPRD and MHRA websites.

3. ISAC Annual Report

Jonathan Lind presented the 2018/19 ISAC Annual Report to the Committee. The report was approved with no amendments.

4. Report on the Independent Review of CPRD Internal Governance Framework

Dr Janet Valentine gave the Committee an overview of Prof Mike Kelly's report, highlighting the reason and purpose for its undertaking, the key recommendations and next steps going forward.

The Chair reminded members that the recommendations in the report had been approved in full by MHRA Corporate Executive and MHRA Board, and that members were being consulted on the implementation of the report's recommendations.

The Committee had received the report in advance of the meeting. In discussions, members endorsed the importance of ensuring consistency across reviewers in a future model and agreed it would be helpful for reviewers to have an opportunity to discuss challenging proposals together. Members also reinforced the need to maintain a wide range of disciplinary and topic expertise amongst reviewers.

It was reported that the review will be published alongside the implementation plan, following approval of the plan by the MHRA Corporate Executive, MHRA Board and the National Institute of Health Research (NIHR).

5. Audit Closure Report

Dr Puja Myles and Professor Richard Stevens informed ISAC members of errors in the audit closure report they co-authored and presented to ISAC at the October 2018 meeting. Errors in the report had come to light when the MHRA was alerted to these by the former ISAC Chair, Professor Patrick Waller, after reading the public minutes of the October 2018 meeting. Once alerted, Dr Myles and Professor Stevens reviewed ISAC minutes and papers dating back to 2012 and confirmed that there were errors in the closure report. It was

explained that these mistakes had arisen from misreading past Committee minutes and the co-authors apologised to the Committee for these errors.

The Committee decided that the closure report presented at the October 2018 meeting should be retracted. This retraction would be noted in an addendum to the existing text relating to the closure report in the public minutes of the October 2018 meeting. In addition, the slides presented by Professor Stevens at the CPRD Mid-year User Group in May 2018 providing an overview of the audit project, would be published in the 2018-2019 ISAC Annual Report.

The ISAC Chair reminded the Committee that because of the methodological limitations of the audit project, the Committee had decided not to publish the audit findings in an academic journal. It was noted nevertheless that the audit was a valuable exercise for ISAC that led to a number of positive outcomes. The Committee noted that the positive outcomes from this exercise included:

- ISAC guidance on major and minor amendments has been clarified;
- CPRD data licence terms now placed an obligation on researchers to specify the approved ISAC protocol number in the resulting publication to enable cross-referencing for future audits;
- CPRD has published summaries of all approved ISAC protocols submitted to CPRD since 1st July 2015 (<https://www.cprd.com/protocol-list>);
- CPRD conducts a monthly online search of publications using CPRD data and maintains a bibliography of such publications on the website (<https://www.cprd.com/bibliography>);
- The CPRD Research team monitors publications based on CPRD data on a quarterly basis to ensure that any work conducted is within the scope of the data access terms and conditions.

6. eRAP Update

Jonathan Lind provided an update to the Committee on progress of development of the electronic research applications portal (eRAP) project, which would replace the current paper-based ISAC application process.

The eRAP system would enable applications to access CPRD to be submitted online, including CV Template Forms replacing individual user logins. eRAP would use intelligent forms with inbuilt validation to ensure that applications were completed correctly. It is anticipated that these changes should greatly increase the efficiency of the application process.

The discovery phase for the project began in 2017, with a competitive tendering process for developing and delivering the electronic application system taking place in April 2019. Following a period of internal testing, the alpha phase had been completed. The Beta phase would likely continue until February 2020, with an aimed eRAP 'go live' date of early 2020.

The Committee had previously provided feedback on the early design of eRAP. Members welcomed the progress made to date and the potential efficiency gains compared to the current application process.

7. Next steps

It was noted that the implementation of the recommendations of the Independent Review would take time, and the Committee agreed that it would be helpful to meet again during the implementation period. The Secretariat would canvass members for a suitable date in 2020.

8. Recap and Close

The Committee were informed that minutes of the meeting were to be approved remotely.