



Minutes of the meeting held on 28 January 2022 at 3:00pm via Microsoft Teams

Members attending	
Member	Role
Prof Martin Gulliford	Chair
Edward Chapman	Lay member
Prof David Fishwick	Scientific member
Prof Susan Jick	Scientific member
Prof Jennifer Quint	Scientific member
Prof Richard Stevens	Scientific member
Dr Benjamin Cairns	Scientific member
Prof Li Wei	Scientific member
Sonia Patton	Lay member
Prof Deborah Saltman AM	Scientific member
Dr Kate Fleming	Scientific member

Apologies	
Member	Role
Prof Umesh Kadam	Scientific member

In attendance	
Attendee	Role/Post
Dr Puja Myles	Joint Interim Director of CPRD / Head of Observational Research
Tarita Murray-Thomas	Senior Researcher
Zara Cuccu	CPRD Researcher
Jonathan Lind	Research Applications Manager
Tarryn Gourley	Research Applications Coordinator
Guest Attendees	Role/Post
Yemi Macaulay	RDG Officer
Dr Susan Hodgson	CPRD Senior Researcher

1. Welcome and apologies

The Chair welcomed attendees to the third meeting of the Central Advisory Committee (CAC) and noted apologies. Members were reminded of the Terms of Reference of the Committee.

The Chair explained that the meeting continues the triage and calibration exercises discussed and developed in previous meetings.

2. Minutes

The minutes of the CAC meeting held on 4 October 2021 were reviewed and confirmed as an accurate record. There were no outstanding actions.

3. Director's Update (Puja Myles)

PM provided an update to the CAC on recent developments in (CPRD).

PM informed the CAC that Janet Valentine had left CPRD. PM is now joint Interim Director of CPRD with Head of Interventional Research, Tim Williams.

Members were informed that the MHRA is undergoing an organisational transformation to a more integrated One Agency model of working. CPRD will be part of the 'Safety and Surveillance' group. The CPRD remit remains the same but there will be some changes to its branding. CPRD's relationship with the National Institute for Health Research (NIHR) will continue. There are no planned changes to RDG.

In alignment with the national direction of travel, CPRD will be moving towards a trusted research environment (TRE) model of data access. CPRD has planned major technology infrastructure developments to enable onboarding of new types of data and support CPRD's vision to position itself as a leader in real-world data services including data-enabled patient recruitment to clinical trials.

There has been a major refresh of CPRD's ethics approval from the Health Research Authority (HRA), which provides generic approval to CPRD to supply data to external researchers.

In February 2022, the latest update of priority linked data to support COVID-19 research will be made available and will include Intensive Care National Audit and Research Centre (ICNARC) data on COVID-19 intensive care admissions up to 17/03/2021.

The Chair thanked PM for the update and conveyed the committee's thanks and best wishes to the previous CPRD Director, Dr Janet Valentine.

4. Secretariat Update (Jonathan Lind)

JL provided an update to the CAC on metrics relating to applications received between 1 October 2021 - 10 Jan 2022. 86 new applications were received of which 28 (33%) were triaged as routine for internal review and 58 (67%) were triaged as non-routine for ERC review. For studies triaged as routine 10 (45%) were approved on first submission and 12 (55%) required resubmission. For studies triaged as non-routine 4 (10%) were approved on first submission and 35 (90%). CPRD will monitor the difference in required resubmissions between applications triaged as routine and non-routine. Overall review times are just under 9 working days for routinely triaged studies, whilst external reviews average just under 11 working days. This is in keeping with timeframe commitments for protocol reviews. The move to the online eRAP system has not had any notable impact on review times.

JL also notified the CAC that the eRAP amendment function went live in October 2021. All studies approved within the 4-year time limit can now be amended via eRAP. Additional admin tools also allow the RDG Secretariat to resolve issues more quickly. Automated email notifications for all reviewers and several updates for CPRD and applicants are planned in the coming months.

JL welcomed suggestions and feedback from reviewers using eRAP. CAC members agreed that moving to an online system has brought significant benefits.

5. Oversight of Routine/Non-Routine Protocol Triage (Chair / Tarita Murray-Thomas)

CAC members were asked to provide feedback on the triage proforma exercise circulated prior to the meeting. Group Chairs provided summaries on whether their group agreed or disagreed with CPRD's triage rating for a selection of protocols, which were reviewed between 18 October 2021 - 15 November 2021.

TMT reported broad agreement with CPRD's triage decisions, while noting that the reasons for the same rating could be different. While some variation is to be expected, there may be areas where guidance for reviewers can be improved. CPRD is currently reviewing all guidance, including the triage criteria guidance related to drug/treatment effectiveness studies, and TMT welcomed suggestions from CAC members in this area. There would be further discussion of the triage criteria at the next CAC meeting.

6. When to request an IG review (Yemi Macaulay)

Two protocols were presented that were referred to IG for review. The presentation covered questions to consider when submitting an IG review. CAC members were reminded that information governance risks can be identified at any stage in the application process - application validation, protocol triage, or during the protocol review process.

Members thanked YM for the presentation and examples. Further IG training is to be provided in March 2022 as part of the RDG Reviewer Training Session.

7. Approaches to ERC Moderation (Chair / Susan Jick / Tarita Murray-Thomas)

CAC members were reminded that one of the Committee's responsibilities is to facilitate calibration of reviews across the ERCs for consistency. This is important to ensure that there is consistent application of the reviewer guidelines and issuing of feedback to applicants. At the last meeting, members agreed to discuss one protocol nominated by a CAC member and one protocol nominated by CPRD.

SJ presented a protocol, and members discussed issues relating to the review of studies with large scope. Members agreed that reviewers would benefit from clearer guidance and standard lines to assist in addressing issues of broad scope.

TMT presented a protocol which was triaged for review internally. Members discussed the importance of providing robust, actionable comments for applicants, and the role of moderators in ensuring this. The Committee was reminded that applicants are only able to see the moderator comments in the final feedback, not individual reviewer comments. The use of discretionary comments was reflected on by attendees, and the Committee felt these were useful for providing valuable feedback to applicants for sections which were otherwise satisfactory.

The Committee agreed that this exercise was helpful and should be repeated for the next meeting.

8. Agenda for Next Meeting (Chair)

The Chair noted that the following items were on the agenda for the next CAC meeting:

- Minutes of the previous meeting
- Secretariat update
- Oversight of protocol triage
- Oversight of ERC moderation

9. AOB (Chair)

BC raised the possibility of cross-ERC group meetings, which would provide the opportunity for reviewers to discuss their experiences with people in different ERC Groups. Members broadly agreed that this would be useful. CPRD agreed to explore this idea further and update at the next meeting.

10. Summary and Close (Chair / Tarita Murray-Thomas)

Agenda item	Action	Date to be completed by
N/A	CPRD to canvass CAC members for dates and book the next CAC meeting in April-May 2022	Feb 2022
6	RDG Reviewer Training Session (for all internal and external CPRD/RDG reviewers)	14 March 2022, 15:00-17:00
9	Feedback on any pilot meetings between ERC groups	Next CAC meeting