Medicines & Healthcare products Regulatory Agency

Central Advisory Committee (CAC)

Minutes of the meeting held on 26 July 2021 at 3:00pm via Microsoft Teams

Members attending	
Member	**Role**
Dr Benjamin Cairns	Chair
Edward Chapman	Lay member
Prof Deborah Saltman AM *(attended first item only)*	Scientific member
Richard Stevens	Scientific member
Dr Kate Fleming	Scientific member
Dr Susan Jick	Scientific member
Dr Jennifer Quint	Scientific member
Sonia Patton	Lay member
Prof Li Wei	Scientific member

Apologies	
Member	**Role**
Prof David Fishwick	Scientific member
Martin Gulliford	Scientific member
Umesh Kadam	Scientific member

In attendance	
Attendee	**Role/Post**
Dr Janet Valentine	CPRD Director
Dr Puja Myles	Head of Observational Research
Tarita Murray-Thomas	Senior Researcher
Preveina Mahadevan	Researcher
Zara Cuccu	Researcher

1. Welcome and apologies

The Chair welcomed attendees to the first ever meeting of the newly formed Central Advisory Committee (CAC) and noted apologies. Members were reminded of the Terms of Reference of the Committee. The Chair then invited all attendees to introduce themselves.

2. Director's Update (Janet Valentine)

JV provided an update to the CAC. Members were thanked for attending the first meeting since the launch of the new Research Data Governance (RDG) process on 01 June 2021, marking a departure from the previous ISAC process.

Members were informed that the rollout of the new RDG process would be iterative, and there would be learning and opportunities for feedback at each stage, which would be critical to the development and success of the process.

JV reiterated the key responsibilities of the CAC, including ensuring the consistency of moderation, providing oversight of the standard/non-standard triage process, and maintaining public trust.

JV highlighted the changing environment, with an increased public awareness of how data is used in the research community, greater familiarity with epidemiology, data sharing and opt-outs, and the importance of trusted research environments. It is therefore of utmost importance that the CAC operates with transparency in order to earn trust.

3. Secretariat Update (Tarita Murray-Thomas)

TMT provided an update to the CAC on metrics relating to applications received since 01 June 2021. Since 01 June 21, 23 new applications were received, 10 of these were triaged as routine for internal review and 13 triaged as non-routine for ERC review.

The Chair asked if the number of applications received in this period was typical. TMT responded that, based on previous years, we would expect to receive about 90 applications over a three-month period, averaging 30 applications a month. There tend to be fewer applications over the summer with spikes in submissions in September and over the Christmas period

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

TMT provided a presentation to Members on the protocol triage process in order to facilitate discussion. Members were then asked what information the CAC would like to receive in future when providing oversight of the triage process.

Members felt that they would like to trial various options before deciding on a definitive approach for assurance of the triage process. Some members felt a hybrid approach of reviewing some summaries and some full protocols would be helpful especially as in some cases the summaries may not reflect the detail in the protocol. For the next CAC meeting it was agreed that CAC members would be provided with summaries of all protocols for a defined period (for e.g. a month or a quarter) along with the triage decision and reason.

5. Approaches to ERC Moderation (Chair / Tarita Murray-Thomas)

TMT delivered a presentation on protocol moderation as part of Expert Review Committee (ERC) review. Members were then asked individually to discuss moderating protocols for their ERC, noting particularly any difficulty in interpretation or application of the reviewer guidance.

Overall, ERC Chairs felt the submitted protocols were well-written. The following key points for clarification and consistency were noted:
* the level of detail on code lists required from applicants
* technical issues that were discretionary versus those that needed to be addressed and required protocol resubmission
* what was expected in the sample size and feasibility count sections

It was agreed that where there was a serious flaw in the study design or technical approach that would impact on study findings, it was appropriate to require a resubmission on grounds of public health risk.

Members were asked what support they would like to facilitate consistency of moderation based on the three criteria (feasibility, public health benefits/ risk, information governance/ risk). Some ERC Chairs reported that they had already conducted, or had planned, feedback meetings with their ERC members for calibration. Members supported the proposal for a peer review and sharing mechanism outside of the CAC meetings to facilitate learning and calibration across ERCs.

It was noted that more guidance on how to provide discretionary feedback on the electronic Research Application Portal (eRAP) would be helpful. The CAC Chair summarised the discussion and requested CPRD to provide practical guidance for reviewers and moderators on how to use the eRAP system, especially in relation to discretionary comments, to facilitate consistency.

6. 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 triage
- Further discussion of ERC moderation

7. AOB (Chair)

The Chair clarified that the 50% requirement for being quorate could be fulfilled by either scientific or lay members for any decision-making purposes, though the preference would be to have at least one lay member representative at all meetings

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

Agenda item	Action	Date to be completed by
6	CPRD to canvass and book the next CAC meeting	04/10/2021
4	CPRD to provide further information on triage decisions for the next meeting	04/10/2021