Council for International Organizations of Medical Sciences

7ᵗʰ meeting of the CIOMS Working Group WG XIV on
Artificial Intelligence in Pharmacovigilance

11 January 2024, virtual meeting

Minutes

Summary

The CIOMS Working Group XIV on Artificial Intelligence in Pharmacovigilance held its 7ᵗʰ meeting virtually on 11 January 2024. The Chapter Teams gave progress updates and discussed future plans. A combined chapters draft will be prepared and distributed on a shared platform. Next in-person meeting will be held on 7-8 March in Geneva.

Minutes of discussion

1. Opening and welcome

Lembit Rägo, CIOMS Secretary General, welcomed the members to the 7ᵗʰ meeting of the CIOMS Working Group XIV on Artificial Intelligence (AI) in Pharmacovigilance (PV) and opened the meeting as Chairman (for a list of participants see **Annex 1**).

Lembit made the following announcements:

- CIOMS report International guidelines on good governance practice for research institutions was published in December, 2023 and is freely available at CIOMS website: https://doi.org/10.56759/hslk3269

- WG XII Benefit-risk balance for medicinal products and WG XIII Real-world data and real-world evidence in regulatory decision making are expected to be published in 2024.

- There are several CIOMS WGs continuing their work with information available at the CIOMS website.

The meeting agenda was adopted.
All materials presented are available in the WG private member area.

2. Progress updates on chapter drafts

Chapter 1-4 Introduction, landscape and scope, guiding principles
- Walter updated the WG on Chapters 1-4 progress and the following only represents the discussion points.

- The text still requires further work, which is expected to be completed in the coming weeks. A joint review of the entire document is suggested before detailed fine-tuning to prevent redundant effort and ensure consistency across chapters.

- Andrew highlighted the importance of distinguishing between established and novel AI issues, suggesting the need for diagrams to clarify the challenges posed by generative AI's openness and lack of transparency.

- Satoko highlighted the impact of introducing large language models (LLMs) early in the document, which necessitates corresponding content in Chapter 5 related to quality assurance and implications for regulatory considerations later in the document. Andrew raised questions about the application and validity of traditional validation methods to newer, more open-ended AI and ML techniques. A balanced presentation of pros and cons is considered necessary.

- Lembit suggested the need for good practices in using AI in PV, noting that the rapid pace of change and potential undisclosed use of AI pose significant challenges.

- The following discussion further stressed transparency, with Satoko mentioning the importance of disclosure in the use of AI to ensure quality and regulatory compliance.

- Concerns about potential misuse of AI tools and the necessity of training PV professionals on compliance and ethical considerations, especially in the context of LLMs being developed by companies and CROs were voiced.

Chapters 5-7 Validation and qualification considerations, Implementation and maintenance lifecycle aspects

- Taxiarchis updated the WG on Chapters 5-7, emphasizing the integration of a quality management system framework into the structure.

- A coherent writing style is needed, as noted by Satoko, and the group will aim to harmonise the text.

- Suggestions for the next steps include refining the structure and approach to the document, deciding whether to center around a specific framework, or considering a different organising principle.

- The WG emphasised the importance of ensuring the document's consistency and cohesion. It was proposed that a small editorial team be formed after the in-person meeting to refine and streamline the text.

- It was agreed that a consolidated draft will be created and distributed. This will be reviewed before in-person meeting in Geneva.

Chapter 8 Future vision

- Denny presented Chapter 8's progress. The main themes proposed were: achieving operational excellence with AI in pharmacovigilance; advanced risk management strategies enabled by this technology; and envisioning future regulatory guidance frameworks for its application. The validity of full automation in pharmacovigilance was questioned due to concerns over maintaining human oversight throughout processes.

- The chapter will aim to present a future perspective on regulatory guidance and AI in PV, while ensuring it does not propose a fully autonomous system without human oversight.

- The need for clear and concrete current practices and future-proofing the document against methodological developments was highlighted.

- Transparency was reiterated as a key principle, with suggestions to mandate disclosure of AI use by companies and regulators.
- We should decide on a reference management system, e.g. EndNote or Zotero.
- Satoko has drafted a section on regulatory expectations and is open to feedback. She intends to request permission to distribute a subset of her training slides for inspectors, which outline six general principles of safe AI use.

3. Next steps / next meeting

- The next full WG meeting will be held in 7-8 March 2024, in Geneva, Switzerland. Chapter teams will report on progress and discuss any questions on draft chapters. CIOMS Secretariat will assist with organising the meeting.
- The WG will aim to consolidate the chapters and prepare for a combined draft to be reviewed in the next in-person meeting. The draft will be uploaded on a shared platform for easier collaboration and editing. Members unable to access the Google Docs are invited to inform the CIOMS Secretariat for assistance.
- The WG will discuss forming an editorial group once the draft is mature enough.
- The CIOMS Secretariat will circulate the combined chapters draft and editorial guidelines prior the in-person meeting.

4. Closing remarks

Lembit thanked the WG members for joining and for their work in progressing the draft.

5. Annex 1: List of participants

Participants

Justyna Amelio (AbbVie), Robert Ball (US FDA), Luisa Barrios (MSD), Andrew Bate (GlaxoSmithKline), Arvind Bellur (CSL Behring), Adrian Berridge (Takeda), Taxiarchis Botsis (Johns Hopkins University School of Medicine, US), Brian Burch (MHRA), Hua Carroll (Biogen), Julie Durand (European Medicines Agency), Piero Francesco Franco (Pfizer), Neal Grabowski (Sanofi), Thomas Henn* (Unither), Satoko Hirokawa (Health and Youth Care Inspectorate, Netherlands), Kirsten Egebjerg Juul (Danish Medicines Agency), Vijay Kara* (GlaxoSmithKline), Dieter Kempf (Genentech, Roche), Kostadinos Kidos (Takeda), Benny Ling (Health Canada), Denny Lorenz (Bayer), Beth MacEntee Pileggi (Johnson & Johnson), Yusuke Matsunuga (Pharmaceuticals and Medical Devices Agency, Japan), Eva-Lisa Meldau* (World Health Organization /Uppsala Monitoring Centre), Manuela Messelhaeusser* (PEI), Niklas Norén (World Health Organization / Uppsala Monitoring Centre), Ravi Patel (Unither), Kateriina Rannula (CIOMS), Lembit Rägo (CIOMS), Hans-Jörg Römming (Merck Group), Irene Scholz (Swissmedic), Monica da Luz Carvalho Soares* (ANVISA, Brazil), Thomas Stammschulte* (Swissmedic), Walter Straus (Moderna), Phil Tregunno (The Medicines and Healthcare Products Regulatory Agency, UK), Panos Tsintis (CIOMS Senior Adviser), and Brian Yau (WHO).

Apologies

Russ Altman (Stanford University, US), Yauheniya Cherkas (Johnson & Johnson), Shaun Comfort* (Genentech), Selin Cooper* (Abbvie), Flávia Moreira Cruz (ANVISA, Brazil), Jean-Michel Dogné (University of Namur), Julie Girod* (Sanofi), Kendal Harrison* (The Medicines and Healthcare Products Regulatory Agency, UK), Stephen Heaton* (CIOMS), Kostadinos Kidos* (Takeda), Yuki Kikuchi* (Pharmaceuticals and Medical Devices Agency, Japan), Roli Mathur (India Council Medical Research), Dirk Mentzer (Paul-Ehrlich Institute), Richard McAteer* (Health Canada), Nicolas Perez* (Swissmedic), John Reinhard Pietzsch* (Bayer), Stephen Rosenfeld (North Star Review Board).

*Alternate