Council for International Organizations of Medical Sciences

Fifth meeting of the CIOMS Working Group (WG) XVI on the Development Safety Update Report (DSUR)

23 April 2026, virtual meeting

Draft Minutes

Overview:

Summary

The CIOMS Working Group XVI convened its fifth meeting virtually on 23 April 2026. The WG reviewed updates relevant to ongoing report development and subgroup activities, with discussion focusing particularly on emerging European developments related to safety reporting in combined studies involving medicinal products and medical devices. The group reviewed progress on report drafting, discussed the proposed report structure and subgroup organization and agreed on several coordination activities to support ongoing subgroup work and facilitate progress ahead of the September meeting in Tallinn.

Minutes of discussion

1. Opening and welcome

- Lembit Rägo, CIOMS Secretary-General, opened the meeting and welcomed all participants. For a list of participants see Annex 1.
- Lembit informed the group of a forthcoming change in PMDA representation within the WG and welcomed the new PMDA member, Miki Nakamura.
- He continued to provide an overview of CIOMS activities:
    - CIOMS had published the CIOMS Working Group XIV – Artificial Intelligence in Pharmacovigilance during the previous year. A series of three webinars introducing the report had recently been completed. The webinars had attracted substantial interest and participation, and feedback from attendees had been very positive.
    - Similar introductory webinars could be organised for future CIOMS Working Group reports once finalised.
    - CIOMS WG XV – Pharmacoepidemiology for Public Health report is expected to be finalised later in the year. The WG Is currently incorporating comments received during public consultation.

- Agenda was adopted.
- Kateriina was rapporteur.

2. Updates relevant to the WG

- Tessy shared information on updated guidance from the Medicines and Healthcare products Regulatory Agency (MHRA) on the collection, verification and reporting of safety events in clinical trials (effective 28 April 2026), as well as MHRA guidance on medical devices (Post-market Surveillance Requirements). Tessy will circulate these guidance documents to the WG.

3. Subgroup updates

Subgroup 4 – Medical devices

- Corina gave a presentation on an ongoing European development related to safety reporting in combined studies involving medicinal products and medical devices.

Discussion and Reflections

The following represents the discussion points only. Corina will share the presentation with the WG.

- The presentation was considered highly relevant and informative, particularly regarding ongoing European developments in combined studies and safety reporting requirements.
- Support was expressed for facilitating combined studies in Europe, however, concerns were raised regarding potential additional administrative burden if device-related reporting requirements were added to DSURs.
- It was noted that sponsors already comply with separate medicinal product and medical device requirements, and duplication of reporting should be avoided.

- Discussion also touched on the challenge of determining who would review additional device-related information, considering varying levels of regulatory expertise.
- It was clarified that the intention of integrating device-related safety information into DSURs was to facilitate reporting and provide a consolidated view of safety in combined studies, rather than create additional burden.
  - It was noted that in the SwissMedic context, medicinal product and medical device aspects are reviewed by separate teams, with joint discussions where needed.
  - It was further clarified that this approach would not replace existing legal reporting obligations.
- Support was expressed for maintaining an integrated and holistic overview of safety across medicinal products and devices within combined studies.
- Discussion continued with concerns being raised regarding extensive line listings and inclusion of large volumes of unrelated serious adverse event data.
  - DSURs should remain focused on information relevant to benefit–risk assessment and important risks.
  - Excessive listings were considered likely to obscure signals and reduce the usefulness of safety assessments, particularly in large development programmes.
- Participants noted that significant device-related issues affecting study conduct or safety would already be captured within existing DSUR sections, particularly safety actions and benefit–risk assessment sections.
- A possible approach was proposed whereby important device- or procedure-related risks would continue to be addressed within existing DSUR sections without requiring extensive additional listings.
- It was agreed that further discussion and refinement would be needed to focus on essential safety information for combined studies.
  - Key priorities identified included clear reporting of important safety actions, significant safety-related modifications, and assessment of the relevance and patient safety impact of serious adverse events.
  - The role and format of potential line listings remained an open topic for future discussion.
- Practical and logistical challenges were highlighted. Device-related data may originate from different systems and be managed by different functions within organizations.
- It was suggested that more detailed information could be useful during early development stages to better understand safety aspects of combined products, while some participants preferred fewer but more focused adverse event summaries.
- It was emphasized that increasing complexity and workload associated with additional safety reporting requirements could have implications for smaller organizations and companies and implementation challenges may differ substantially between large pharmaceutical companies and smaller organizations.
- Working group members enquired about the expected timeline for finalisation of the proposed guidance and related discussions.
  - Corina noted that next steps would include review of sponsor perspectives, European working group comments, and medical device input.
  - Stakeholders would subsequently have approximately 28 days to review the proposal and provide comments.
  - It was confirmed that stakeholder participation would be included in future discussions and review activities.
- Questions were raised regarding practical implementation, including alignment with previous international guidance and approaches developed by GlobalS and CIOMS.

- It was acknowledged that development in Europe may need to combine existing guidance while remaining sufficiently flexible for global application. Participants noted that the proposed guidance was intended to provide practical recommendations rather than establish legislation.
- Corina acknowledged the comments and concerns raised and confirmed that they would be brought forward into ongoing discussions within the relevant working groups and stakeholder processes.

Other subgroup updates

- An update was provided from the Reference Safety Information (RSI) subgroup.
  - The subgroup had intentionally remained at a high-level stage pending developments within ongoing external discussions and proposals related to the Investigator's Brochure (IB) and RSI.
  - It was noted that proposed changes under discussion appeared broadly aligned with the subgroup's own views and proposals.
- It was reported that comments from commercial and non-commercial sponsors, as well as industry representatives, had been incorporated into updates of the relevant European Union Clinical Trials Regulation (EU CTR) Questions and Answers (Q&A) documents.
  - The revised Q&A document was reported to be approaching finalization.
  - Changes included more flexible wording and removal of diagrams previously considered confusing.
- It was noted that one important proposed clarification would allow sponsors to either maintain the RSI version applicable at the beginning of the reporting period or adopt an updated RSI during the reporting period, without requiring retrospective reassessment.
- Discussion took place regarding subgroup organization and coordination.
  - Clarification of subgroup responsibilities and coordination processes may be helpful to support subgroup activities and meeting organization.
  - It was suggested that each subgroup could have a designated coordinator responsible for organizing meetings and facilitating subgroup progress. (Please see the subgroups and members below).
- For artificial intelligence, it was agreed that the section should remain concise and specific to DSURs, with reference made to the recent CIOMS report on Artificial Intelligence in Pharmacovigilance rather than developing new general AI guidance.
- For emergency trials, it was agreed that only a short statement would likely be needed, noting that the DSUR may not be fully fit for purpose in this context.
- It was agreed to combine the combination products and complex studies topics, given overlap in membership and content.
- Kateriina would support subgroup coordination, including circulating drafts where needed and arranging Doodle polls, as requested by subgroup leads.

Report drafting, subgroup coordination

- An update was provided on drafting of the opening section of the report.
  - The draft had already been shared with the WG for comments and feedback. Members were encouraged to review the draft and provide comments.
- Discussion took place regarding document-sharing platforms and collection of feedback.
  - It was acknowledged that no single platform currently works smoothly for all participants due to institutional access limitations.
  - Lembit suggested that the latest versions of draft documents could be distributed by email to those unable to access collaborative platforms.
  - It was agreed to explore use of Google Docs as a central repository for draft sections and

comments.
  - Participants unable to access Google Docs would provide comments separately by email.
- The Signal subgroup agreed to meet before the September meeting.
  - Kateriina will assist with organizing a two-hour subgroup meeting during May or June.
  - The subgroup would also verify and identify the latest draft version before the meeting.
- Lembit emphasized that maintaining a central collection point for draft documents would be important for coordination and version management.
  - Draft sections could also be circulated more broadly to the full WG where appropriate.
- Discussion took place regarding interpretation of the MHRA expectations.
  - It was noted that the wording appeared open to interpretation, particularly regarding whether narrative evaluations should be provided for all deaths or only for significant new safety information.
  - It was emphasized that significant safety findings would already be discussed in the main body of the DSUR under relevant sections.
- Concerns were raised regarding the potential additional workload associated with preparation of interval listings and narrative analyses, particularly where many unrelated deaths are included. It was suggested that clearer cross-referencing within the DSUR and more focused presentation of relevant information may help address regulatory expectations while avoiding unnecessary duplication.

Report structure, drafting status and next steps

- The proposed outline of the report was reviewed:

  o Introduction;
  o General principles, including future directions;
  o Guidance on content;
  o Appendices;
  o Template;
  o Glossary.

- It was discussed that the structure could remain flexible, depending on how best to present the material and integrate the different draft sections.
- The general principles section was considered likely to be one of the later sections to finalize, once the substantive sections are further developed.
  - It was noted that the introduction already addresses several general principles.
  - The group agreed that existing principles from the previous CIOMS DSUR report should be reviewed and reused or updated where appropriate.
- The guidance on content and template sections was discussed. The current draft template was considered to provide a useful blueprint. Additional guidance text would need to be inserted around the relevant template sections. It was suggested that the template should also be cleaned up and included as a stand-alone template in an appendix once the headings and structure are agreed.
- It was agreed that a concise glossary would be useful for specific terms used in the report.
  - The CIOMS Cumulative Glossary and Glossary of ICH terms and definitions compiled by CIOMS should be used as reference sources.
  - Existing definitions may be reused where appropriate but could be fine-tuned if needed for the purpose of the report.

- The WG agreed that all available draft sections should be matured as much as possible before the September meeting. The aim is to bring together the different sections into a near-final draft, if possible.
- It was agreed that stronger project management support would help move the work forward. Post-meeting comment: subgroup leads will meet to discuss the preferred shared online editing environment, define timelines and clarify responsibilities for ongoing work.
- Beatrice asked whether the signal subgroup had a draft available for review, to support alignment with the benefit–risk section. A draft will be resent to the WG for review. The signal subgroup would then incorporate comments and suggestions.

4. Next steps / Next meeting

- The subgroups will continue working on their respective topics before the 28-29 September 2026 meeting in Tallinn.

5. Closing remarks

- Lembit closed the meeting by thanking participants and noting that the group had made further progress towards bringing together the report.

Subgroups and topics

The participants are listed in no particular order.

1. Combination products (FDC, NFDC, AUX) / Complex studies – Tessy, Beatrice, Elena, **Pete** (lead)
2. Simplified DSUR – Hiro, Miki, **Tessy** (lead), Donald, Juliana
3. Devices – **Corina** (lead), Mamiko, Carmen
4. Emergency trials – **Donald** (lead), Andrzej
5. Artificial Intelligence – Eun Mi Kim, Pete, **Elena** (lead)

Annex 1: List of participants

Participants

Samvel Azatyan (CIOMS), Carmen Campanile (Swissmedic), Huanhuan Cui (NMPA), Andrzej Czarnecki (Eli Lilly), Juliana Dornelles (ANVISA), Mutsuhiro Ikuma (PMDA), Eun Mi Kim (WHO), Mamiko Konishi (Eisai), Miki Nakamura (PMDA), Pete Nash (Gilead), Beatrice Panico (Individual expert), Donald Puccio (Pfizer), Indra Purevjal (Bayer), Elena Prokofyeva (FAMHP), Lembit Rägo (CIOMS), Kateriina Rannula (CIOMS), Tessy Ruijgrok (Biogen), Anita Shenoy (AbbVie), Corina Spreitzer (Austrian Medicines Agency), and Wang Haixue (NMPA).

Apologies

Antonella Caselli (Italian Medicines Agency), Peter De Veene (MSD), Maria Grazia Malpezzi* (Italian Medicines Agency), Richard Pendlebury (Novartis), and Wang Xiangyu (NMPA).

*Alternate