



Ninth meeting of the CIOMS Working Group XII:
Benefit-Risk Balance for Medicinal Products – Update of CIOMS IV
26 January 2023, virtual meeting

Meeting Minutes

Participants

Guacira Corrêa de Matos (Anvisa), Scott Evans (GWSPH), Stephen Evans (LSHTM), Richard Forshee (FDA), Stewart Geary (Eisai), Sanna Hill (CIOMS), Vicky Hogan (Health Canada), Claudia Ianos (Pfizer), Mari Kihara (PMDA), Shahrul Mt-Isa (MSD), Leo Plouffe (Bayer), Lembit Rägo (CIOMS), Tomas Salmonson (former Chair CHMP), Barbara da Silva (AbbVie), Carmit Strauss (Amgen), Stéphanie Tcherny-Lessenot (Sanofi), Graham Thompson (FDA), Panos Tsintis (CIOMS Senior Adviser), Hong Yang (FDA), Qun-Ying Yue (UMC) and Xi Sherry Zhang (Gilead).

Apologies: Patrick Caubel (Pfizer), Sergei Glagolev (Ministry of Health of Russia), Luther Gwaza (WHO), Shuichi Kawarasaki (PMDA), Wataru Kuga (PMDA), Shanthi Pal (WHO), George Quartey (Roche), Sabine Straus (MEB, Chair of PRAC), Steffen Thirstrup (CORS), Sebastian Vulcu (BI), and Julie Williams (MHRA).

Alternates who did not attend: Karen Kaplan (MSD), Eun Mi Kim (WHO), Sara Khosrovani (MEB), Hussein Laljee (Gilead), Fumihito Takanashi (WHO), and Maria Verdugo (AbbVie).

Welcome and opening of the meeting

- Lembit welcomed the participants.
- Claudia has secured a session to speak about the WG XII report at the [DIA 2023 Global Annual Meeting](#) taking place 25-29 June 2023 at the Boston Convention and Exhibition Center (Title: Benefit-Risk Balance for Medicinal Products: CIOMS Working Group XII Report; Track: 01 Clinical Safety and Pharmacovigilance; Date and Time: Tuesday, 27.6.2023 at 10:30 am - 11:30 am). The 1-hour session will be introduced by Claudia, Scott will represent academia and Subgroup 3, Richard will represent regulators and Subgroup 1, Carmit will represent industry and Subgroup 2, the Q&A will be facilitated by Claudia. The slide set will be shared. DIA recommends using its own template and can include the CIOMS logo; the FDA must use its own template. We will share the generic CIOMS template for content.

Outstanding items

Preface

- To be drafted by Vicky.

Executive summary

- This has been drafted by Stéphanie.
- Once it has been reviewed by Vicky, the Executive Summary will be circulated among the full WG.

Acknowledgements

- To be drafted by the CIOMS Secretariat.

Tables and Figures

- To be generated once the draft has been completed.

Glossary

- We will not have a glossary in the report and new terms, such as “Medicinal product”, are to be added as footnotes.
- Subgroup Co-Leads are requested to place into footnotes the terms, definitions and sources when they are not using definitions provided in [the CIOMS Cumulative Glossary, with a focus on Pharmacovigilance \(Version 2.0\)](#), e.g. when they feel a different definition is required.
- Please note that only terms that have been put into footnotes will be picked up into the CIOMS Cumulative Glossary, with a focus on Pharmacovigilance (Version 2.0), or a subsequent edition, going forward.
- [Post-meeting note: terms in the footnotes will be added to the CIOMS Cumulative Glossary only once the CIOMS WG XII report has been published.]
- Authors are welcome to include definitions, whether in the CIOMS Cumulative Glossary or not, within their body text or in the footnotes, if they feel they improve the text. Please always provide sources.
- In the electronic version of the report, we can include hyperlinks to references of added value where it improves the readability. The DOI number links will typically have a longer shelf life and we will favour their usage where possible.

Public Consultation

- The Public Consultation will last approximately four to six weeks.
- Having a Public Consultation will add validity to our work and make sure we have not overlooked anything important.
- It would be especially good to allow some of the key groups we have worked with to have an opportunity to comment e.g. ASA BRAP and ISPE BRACE.
- The disadvantage is that it will slow us down as handling the comments can take months.
- The Public Consultation will involve posting the draft report on the CIOMS website and all parties promoting the opportunity to those who are likely to comment and add value with their comments.
- The full WG XII needs to agree when we are ready to begin the Public Consultation. Once the current review period is concluded at the 17th of Feb., the subgroups may require three to four weeks to implement changes, the CIOMS Secretariat will then require two weeks at least to conform all the references to the same style throughout the document, and a further three weeks at least to finalise the editorial finalising of the document, which will bring us to May.
- There is strong interest outside the WG to review the draft report. E.g. the ASA PRAP (American Statistical Association, Benefit-Risk Assessment Planning working group) is working on a BR planning template and some of our report content is very relevant. The ASA WG wishes to align across plans, and although the CIOMS WG XII is in agreement in principle, it was felt we do not wish to share any visuals before the Public Consultation. Hong will work on sharing written content.

Progress updates on chapter drafts

- Subgroups 1, 2, and 3 have not received any comments to date.
- Deadline for sending in comments is the 17th of February. This is the final opportunity to share comment formally WG-internally.
- Hong offered to help generate the Timeline of Global Benefit-Risk Initiatives figure that is now located in Chapter 1 – the current figure is simply an example taken from the internet – but she did not yet receive a reply from Subgroup 3.

Cell / gene therapy case study

- The cell / gene therapy case study has been removed and Panos and Leo have been looking into possibilities for an alternative in the public domain.

CIOMS Working Group XII structure

Chairwoman: Vicky

Co-Chair: Patrick (currently less active in this capacity) supported by Claudia

Co-Chair: Scott

Subgroups and Co-Leads (Co-Leads' names are underlined)

Subgroup 1

Methods

Including integrated B-R methodologies / patient level

Leo

Richard

Claudia

Patrick

Scott

Stephen

Shahrul/Karen

Stéphanie

Luther

Ying

Panos

Subgroup 2

SDA

Structured descriptive assessment

Hong

Sherry/Hussein

Stewart

Barbara/Maria

Stéphanie

Carmit

Sebastian

Julie

Mari/Shuichi

Wataru

Subgroup 3

Benefit-risk landscape

Steffen

Tomas

Graham

Sabine/Sara

Guacira

George

Shanthi

Glossary team: Vicky, Hong, Leo, Steffen, Panos, Stephen, and Lembit