Twelfth meeting of the CIOMS Working Group XII:
Benefit-Risk Balance for Medicinal Products – Update of CIOMS IV
20 November 2023, virtual meeting

Meeting Minutes

Participants

Stephen Evans (LSHTM), Richard Forshee (FDA), Stewart Geary (Eisai), Wataru Kuga (PMDA), Sanna Hill (CIOMS), Mutsuhiro Ikuma (PMDA), Leo Plouffe (Gilead), George Quartey (Roche), Lembit Rägo (CIOMS), Barbara da Silva (AbbVie), Carmit Strauss (Amgen), Stéphanie Tcherny-Lessenot (Sanofi), Graham Thompson (FDA), Hong Yang (FDA), and Qun-Ying Yue (UMC).

Apologies: Patrick Caubel (Pfizer), Guacira Corrêa de Matos (Anvisa), Scott Evans (GWSPH), Sergei Glagolev (Ministry of Health of Russia), Luther Gwaza (WHO), Vicky Hogan (Health Canada), Claudia Ianos (Pfizer), Shuichi Kawarasaki (PMDA), Shahrul Mt-Isa (MSD), Shanthi Pal (WHO), Tomas Salmonson (former Chair CHMP), Sabine Straus (MEB, Chair of PRAC), Steffen Thirstrup (EMA), Panos Tsintis (CIOMS Senior Adviser), Maria Verdugo (AbbVie), Sebastian Vulcu (BI), Julie Williams (MHRA), and Xi Sherry Zhang (Gilead).

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

Welcome and opening remarks

- Lembit welcomed the Working Group (WG) members.
- On the 6th of December, CIOMS will launch the report of the WG on *Good Governance Practice for Research Institutions*.
- The CIOMS WG XIII on Real-World Data and Real-World Evidence in Regulatory Decision Making is finalising working through the 900+ Public Consultation comments received.
- The CIOMS WG on Severe Cutaneous Adverse Reactions to Drugs – SCAR will begin its Public Consultation in early 2024.
- A new WG was lanched on 2-3 November: CIOMS WG XV on Pharmacoepidemiology for Public Health. Stephen made the point that pharmacoepidemiology must be at the forefront of ensuring that data are handled scientifically properly but also that privacy is ensured. A trusted research environment has been set up – he recommended the Goldacre Review in the UK.
- The agenda was adopted.

Foreword

The Foreword will be finalised once the chapters are close to being finished as there are e.g. some outstanding issues around consistent nomenclature. In addition, it will be necessary to remove mention of certain concepts/sections (eg. Risk Management), which were formerly discussed in some detail in the report but have been either greatly reduced or removed entirely in response to comments received

in the Public Consultation.

Executive summary

Stéphanie is waiting for other elements to be updated before revising the Executive Summary.

Chapter 1

Most comments have been addressed. The chapter team is going through a final confirmation round.

Chapter 2

- The team has finished revisions for the most part based on the comments with only a few comments left to confirm.
- There remains some redundancy between Chapters 2 and 3. Some repetition is welcome but not too much. Once both chapters have been completed the teams will reconvene to review again.
- Work continues on the case study.

Chapter 3

- Claudia addressed most of the editorial comments.
- Two sections in Chapter 3 required more attention. Scott went through his section and addressed the comments there, and Leo simplified the other section.
- The chapter is in need of one final review by the chapter team.

Chapter 4

- Definitions have been added for "Legacy product" and "Advanced therapies".
- Two new sections have been added on non-prescription drugs and combination products (e.g. drug-drug and drug-device).
- Cross-references have been added to other chapters, e.g. on methods and patients, as well as a reference to the CIOMS WG XIII report on Real-World Data and Real-World Evidence in Regulatory Decision Making.

Overarching notes

- In some cases, comments that apply across several chapters have been left for the Editorial Team to address.
- Where decisions have been provided in the the comments in the report (Word document), Sanna can update the Excel spreadsheet at a later date.
- In some cases, references have been provided within the comments to be implemented by Sanna.
- The chapter teams should continue using their own versions of their chapters, not the "snapshot" version that was circulated recently.

Next steps

- We will aim to combine the chapters in time for a meeting before mid-December, e.g around Friday 8th of December, and have an Editorial Team meeting, e.g. around w/c 11th of December.
- Time permitting, when the chapters are combined next time, more time can be invested into working on fixing the references, cross-references, acronyms, etc.

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	**Subgroup 2** **SDA** Structured descriptive assessment	**Subgroup 3** **Benefit-risk landscape**
Leo	Hong	Steffen
Richard	Sherry/Hussein	Tomas
Claudia	Stewart	Graham
Patrick	Barbara/Maria	Sabine/Sara
Scott	Stéphanie	Guacira
Stephen	Carmit	George
Shahrul/Karen	Sebastian	Shanthi
Stéphanie	Julie	
Luther	Mutsuhiro/Shuichi	
Ying	Wataru	
Panos		