Thirteenth virtual meeting of the CIOMS Working Group XIII Defining Intent, and Guiding Harmonization and Ethics Standards for Real-World Data and Real-World Evidence in Regulatory Decision-Making

5 April 2022, Virtual Meeting

Meeting Minutes

Participants

Yoshiko Atsuta (Japan Data Center for Hematopetic Cell Transplantation), Elodie Aubrun (Novartis), Laurent Azoulay (McGill University), Mariette Boerstoel (AstraZeneca), John Concato (US FDA), Gracy Crane (Roche), Wim Goettsch (Utrecht Centre for Pharmaceutical Policy), Sean Hennessy (University of Pennsylvania), Sanna Hill (CIOMS), Alar Irs (State Agency of Medicines, Estonia), Juhaeri Juhaeri (Sanofi), Laurie Lambert (CADTH), Jie Li (US FDA), Monica da Luz Carvalho Soares (Agência Nacional de Vigilância Sanitária, Brazil), Andrea Machlitt (Bayer), Manami Nomura (Pharmaceuticals and Medical Devices Agency, Japan)*, Takahiro Nonaka (Osaka Metropolitan University), Kateriina Rannula (CIOMS), Heather Rubino (Pfizer), Lembit Rägo (CIOMS), David Shaw (University of Bern), David Townend (Maastricht University), Rika Wakao (Pharmaceuticals and Medical Devices Agency, Japan)*, Julia Wicherski (Bundesinstitut für Arzneimittel und Medizinprodukte), David Wormser (Novartis) and Kristina Zint (Boehringer Ingelheim).

Regrets

Enrica Alteri (former EMA), Elodie Baumfeld Andre (Roche), Stella Blackburn (IQVIA), Thomas Brookland (Roche), Britta Haenisch (Bundesinstitut für Arzneimittel und Medizinprodukte), Steffen Heß (Bundesinstitut für Arzneimittel und Medizinprodukte), Lu Hong (National Medical Products Administration, China), Solomon Iyasu (Merck, Merck Sharp & Dohme Corp), Michele Jonsson Funk (University of North Carolina), Cynthia de Luise (Pfizer), Miguel-Angel Mayer (Universitat Pompeu Fabra Barcelona), Mareike Millner (Maastricht University), Monika Nothacker (Association of the Scientific Medical Societies), Daniela Rojas (Maastricht University), Andreas Rudkjoebing (World Medical Association), Anja Schiel (Norwegian Medicines Agency), and Julia Stingl (University of Aachen, Germany).

*New members since previous meeting.

Introduction

- Lembit welcomed the WG members and chaired the meeting.
- The CIOMS Working Group XI: Patient Involvement in the development, regulation and safe use of medicines draft report is available for public consultation until 11 April 2022.
- A new CIOMS WG will be launched at the end of May on artificial intelligence in pharmacovigilance.

- We are pleased to welcome Rika Wakao and her alternate member, Manami Nomura, from the Pharmaceuticals and Medical Devices Agency in Japan. Akihiro Ishiguro has left the WG, and Takahiro Nonaka has started work at Osaka Metropolitan University and will continue as a member of the WG.
- The meeting agenda was adopted.
- Kateriina was rapporteur.

Progress updates and discussions on chapters

Chapter 1. Introduction.

- The content of the chapter 1 draft is being fine-tuned and will be finalised as soon as the other chapters are ready.
- Chapter leads are invited to review the last paragraph of the introduction presenting the framework of the report, and if needed, suggest changes.
- The WG agreed that patient groups should be included as a target audience of the report and mentioned in the introduction.

Chapter 2. Uses of RWE in the regulatory process during the product lifecycle

- The Chapter 2 team is finalising the sections needing additional input. Contributions and feedback from WG members are welcome.
- There are sections of the chapter 2 draft that may be better placed in other parts of the report, e.g. it was suggested that the section on the external control arm be moved to chapter 4 and the section on the STROBE checklist and GRADE framework be moved to chapter 3. Respective chapter leads have been contacted and are invited to comment.
- The WG members are invited to contribute their expertise and make suggestions and edits as appropriate.

Chapter 3: Real-world data and data sources

- Revisions discussed at the last meeting, e.g. issues on data linkage, data fusion, tokenisation and inclusion of FDA guidelines on RWD / RWE, will be added to the chapter draft.
- John will review the section on FDA guidelines.
- Laurie is welcome to add a brief section on quality of data.
- Juhaeri will send the updated version to Sanna for uploading to Google Docs. Feedback from WG is welcome.

Chapter 4: Key scientific considerations in regulatory RWE generation

- The Chapter 4 team will continue addressing the potential sections that need additional input.
- The team welcomes the WG members' comments regarding the chapter draft.

Chapter 5. Ethics, governance, and related issues

- The chapter team is currently working to incorporate the perspectives of different jurisdictions, e.g. the US, Canada, Japan, etc., to create a more global approach on legislation regarding data protection.

- We have received information on Canadian and Brazilian jurisdictions, and Gracy has reached out to her colleagues in China and other parts of Asia for information on their jurisdictions.
- David S. will send Lembit the questions so that he can forward them to his contacts in African organisations.
- The African Medicines Agency will be approached to contribute to the general discussion on data protection legislation.
- COVID -19 examples will be added to the draft chapter where necessary, along with a paragraph discussing the impact of the pandemic on ethical / legal issues.
- Wim informed the Chapter 5 team that he is unable to continue participating in the chapter's work, but will continue to be available as a member of the Chapter 4 team and of the WG in general.
- The Chapter 5 team is planning to meet to finalise the draft. The WG members are welcome to comment on the general flow and content of the chapter.
- Sanna will send out a Doodle poll to help schedule the next meeting in April.

Executive summary

- The WG agreed to include a brief and informative executive summary in the report.
- The chapter leads will summarise the key messages from the chapters and decide on future recommendations to be included in the conclusion of the summary.

Editorial committee and publishing an article

- All interested WG members are invited to inform Sanna of their availability to join the Editorial committee. [Post-meeting note: Juhaeri and Jenni have volunteered to join.]
- The WG is invited to consider publishing a scientific article in a peer-reviewed journal, preferably open access, to inform the public of the availability of the WG XIII report. Volunteers are welcome. [Post-meeting note: Juhaeri has expressed an interest to draft an article, time permitting, and requested to receive a sample CIOMS article.]
- In case the report is made available for public consultation, the Editorial committee will be responsible for integrating the received comments into the report, as far as possible. Public consultation is recommended as it adds to the transparency of creating a report and contributes to its improvement.

Glossary

- Following the discussion, the WG decided not to include a glossary in the report. However, the key terms and definitions will be used consistently throughout the chapters, while considering the target audience of the report.
- Should the need to create a glossary arise as a result of comments received during the public consultation of the draft report, the WG may reconvene and discuss the format and volume of the possible glossary.
- Wim shared a GetReal glossary as an example to be considered when discussing a possible future glossary.
- The terms and definitions of any third party glossary would need to be included in the WG's report to maintain the original intended meaning, as the original glossary may to some extent develop in directions other than stated in the WG report.

Future meetings and closing remarks

- We will schedule the next WG meeting for late May or early June by which time the chapter teams will aim to finalise their drafts.
- Once the chapter teams agree that their drafts are ready, the chapters will be merged into one draft and prepared for editing by the Editorial committee to prepare the draft report for public consultation.
- The possibility of organising a face-to-face meeting in Geneva will be researched. Sanna will send a Doodle poll to decide on the meeting and include a question to find out if WG members are able to attend in person.
- Due to the different time zones of WG members, a hybrid meeting is not preferred.
- Lembit concluded the meeting by thanking all WG members for their time and work.