Council for International Organizations of Medical Sciences

7th meeting of the CIOMS Working Group on Patient Involvement

11 September 2020, virtual meeting

Minutes

Participants

Patrick Beeler (Swissmedic), Fatima Bhayat (Takeda), Stella Blackburn (IQVIA), Matthias Boedding (Merck), Juan Garcia (EMA), Charles Garrigan (Janssen), Sanna Hill (CIOMS), Shinji Hirasawa (PMDA), François Houÿez (EURORDIS), Stefan Kaehler (Celgene), Kerry Leeson-Beevers (Alström Syndrome), Dinesh Mehta (EMA)*, Marilyn Metcalf (GSK), Theresa Mullin (US FDA), Rebecca Noel (Eli Lilly), Elisabeth Oehrlein (US NHC), Sten Olsson (ISOP), Ravi Patel (United Therapeutics Industry), Peter Pitts (CMPI), Lembit Rägo (CIOMS), Theo Raynor (former Leeds University), Cheryl Renz (AbbVie), Ken Sakushima (PMDA), Meredith Smith (Alexion), Sabine Straus (MEB), Panos Tsintis (CIOMS), Jun Urushidani (PMDA)*, Pujita Vaidya (Amgen), Jamie Wilkins (Pfizer)*, and Judy Zander (US FDA).

Absent members (including Alternates)

Leanne Angst-Wu (Roche), Nathalie Bere (EMA), Marc Boutin (NHC), Wang Dan (CFDA), Ton de Boer (MEB), Nikos Dedes (EATG), Ratna Devi (IAPG/IAPO), Mick Foy (MHRA), Yan Gao (NMPA), Linda Härmark (Lareb), Beverly Harrison (Janssen), Stephen Heaton (former Bayer), Javier Hourcade Bellocq (Civil Society Sustainability Network/International Civil Society Support/Independent Consultant, Argentina), Kaisa Immonen (EPF), Regina Kamoga (CHAIN), Veronique Kugener (Takeda), Talia Lacroix (Health Canada), Hervé le Louët (CIOMS), Marie Lindquist (UMC), Shanthi Pal (WHO), Leo Russo (Pfizer), Daisaku Sato (PMDA), Corinna Schaefer (WMA), Kawaldip Sehmi (IAPO), Christine Stürchler (Novartis), Oi Tsunehiro (MHLW), Annemiek van Rensen (MEB), Peggy Webster (Takeda), and Manal Younus (ISOP).

* New member since 6th meeting on 26 June 2020

Prior to the meeting

- The minutes of the 6th WG meeting held virtually on 26 June 2020 were approved by absence of comments.

Welcome and opening remarks

- Lembit welcomed everyone and thanked them for their time.
- The agenda was adopted.

Issues that touch on all aspects of the working group

Covid-19 Statement

- *The New England Journal of Medicine* and *Health Affairs* have declined to publish the Statement.
- *Therapeutic Innovation & Regulatory Science*, the official scientific journal of DIA (https://www.springer.com/journal/43441), is expected to provide its feedback around the 16th of September 2020.
- CIOMS would accept paying for open access publication.

- Once the decision from the *Therapeutic Innovation & Regulatory Science* has been received, we will plan when to publish the Statement on the CIOMS website and in the CIOMS Newsletter (next issue end of September), and will distribute to all our collective contacts.

Editorial team

- Dinesh Mehta, EMA, has joined the editorial team, of which the existing members are: Annemiek, Cheryl, Elisabeth, François, Meredith, Panos, Stella, Stephen, and Theo.
- Isabelle had been invited to join the editorial team too but, unfortunately, she has had to leave the working group for personal reasons.
- We hope all chapters reach an advanced draft stage by the next virtual working group meeting scheduled for 20-21 October 2020.
- After the October meeting, the editorial team will take over with the mature chapters and we will provide more proactive assistance to the chapter teams with less mature drafts.
- All working group members are encouraged to read the combined chapters to ensure all chapters receive helpful feedback.
- Theresa requested more time spent on Chapter 7 to enable her to complete Chapter 1.
- There was support for having box-outs of key take-aways at the start of each chapter and recommendations at the end of each one.

Implementation strategy team

- The implementation strategy team includes: Christine, Elisabeth, Meredith, Peter and Talia.
- In Talia's absence, this team did not provide a progress update.

Chapters overview

Chapter 1: Introduction, presented by Theresa

- Theresa plans to edit the chapter and integrate suggestions from Panos once the other chapters have matured.

Chapter 2: The landscape of patient engagement in the development and safe use of medicines, presented by Elisabeth

- Elisabeth requested feedback on the second half of the chapter and additional case examples, vignettes and/or references, especially concerning safety aspects.
- She thanked Theo for providing vignettes and references.
- Elisabeth plans to edit the chapter to enhance the flow.

Chapter 3. Guiding principles for patient engagement, presented by Charles

- The chapter team integrated the last set of feedback from June and the draft is nearly ready for handing over to the editorial team.
- The team has incorporated key words representing the principles and shortened higher-level principles and headers.
- Annemiek and Charles recommend incorporating the key words into the margins throughout the book for impact. At the moment, the key words are in a table which will be moved into an appendix.
- The editorial team may need to edit the title and subtitle formats in line with the final report.

Chapter 4. Patient involvement in advancing treatments for their disease, presented by Marilyn

- Marilyn has continued to update the cyclical diagram in line with feedback received.
- Some of the material, particularly the regulatory material, and examples were moved into an appendix.
- Marilyn thanked for the contributions from PMDA, which have been included alongside content from FDA and EMA.

- Chapter 4 includes key take-aways at the front of the chapter and recommendations at the end.
- Other WG members are invited to provide feedback on the format.
- Marilyn added an appendix for phases of drug development for all the chapters to share, where she envisages adding a text from a patient group already in existence.
- She removed some content to avoid overlaps with other chapters.

Chapter 5. Guiding principles for patient involvement in patient product labelling, presented by Meredith

- Comments from PMDA will be integrated within the next week.
- Meredith thanked Theo for his comments.
- Chapter 5 is close to a final draft.

Chapter 6. Opportunities for patient involvement in additional risk minimisation, presented by Cheryl

- The chapter has progressed since June.
- The figure entitled "CIOMS Framework for Patient Involvement in Additional Risk Minimisation" was framed as a centrepiece for the chapter, and the chapter content has been re-ordered accordingly.
- Some of the background information was moved into an appendix.
- Cheryl highlighted the link with the CIOMS WG IX report.
- The section on FMEA (Failure Mode and Effects Analysis) was condensed.
- All comments received since the last meeting in June have been addressed.

Chapter 7. Guiding principles for patient engagement in the development and use of safety and effectiveness data, presented by Peter

- The most recent group meeting was cancelled.
- Peter offered to edit the chapter into a more logical sequence.
- Theresa questioned whether some of the content is covered in earlier chapters. Some aspects, e.g. real-world evidence, are touched on only in this chapter but others are covered elsewhere too e.g. preference studies and patient-generated information.

Chapter 8. Patient involvement in developing time-bound safety communications regarding medicinal products, presented by Stefan

- The most recent comments have been incorporated.
- The chapter is nearly final and ready for the editorial team.

Chapter 9. Challenges and opportunities for patient involvement in resource-limited settings (RLS) by Lembit

- Javier Hourcade Bellocq, who had provided a first draft of the RLS chapter, has had to handover his work back to Regina due to health reasons.
- Regina has accepted to re-start work on the RLS chapter from mid-October.

Chapter 10. Guiding principles for patient participation in therapeutic decision-making: patient and public involvement in clinical practice guidelines by Lembit

- Lembit confirmed there have been no updates on this chapter.

Glossary by Sanna, Stella and Panos

- The Chapter Leads are requested to send the terms and definitions used in their chapters to the Glossary team, if they have not already done so.
- The glossary team includes: Elisabeth, Panos, Pujita, Sanna, Stella, and Stephen.
- The Glossary team is working on
    a) The CIOMS WG XI report glossary – this will be public-friendly language.
    b) The CIOMS Cumulative Pharmacovigilance Glossary – this compiles terms and definitions from the CIOMS pharmacovigilance WG reports. It will cover some clinical elements, but

not straightforward medical diagnosis, as alternative sources exist. Usually the most recent definition is prioritised.

Comments from the discussion

- Juan mentioned the EMA glossary, which covers more than regulatory terms, and that he is willing to contribute this towards the CIOMS WG XI glossary work.
- Theresa requested to receive a definition for patient engagement for use in the introduction.
- Public-friendly language tends to use the active voice and we should favour this in our writing. The active voice also makes text shorter and is easier to understand.

General discussion

- Regarding new vignettes, reference sources other than peer-review journals will be considered on a case-by-case basis, such as those published in patient community press, e.g. the *Health Democracy Journal*.
- Where possible, all feedback should be provided to the Chapter Leads as soon as possible rather than at the editorial stage.
- Stella questioned the wording in a passage in Chapter 4 that focuses on the injustice of excluding vulnerable groups from research in the name of equitability. A supporting reference is given to the CIOMS report on *International ethical guidelines for health-related research involving humans* published in 2016. The wording in question seems to misrepresent research because it does not provide the historical context whereby the exclusion was done for good reasons i.e. to protect vulnerable people. There are also good scientific reasons, e.g. we do not carry out a first-in-man study in pregnant women unless the drug is solely to treat a pregnancy-related condition. This passage seems to require more contextualisation.
- Peter agreed that as much as the primary use of the CIOMS WG XI report is partly to help patients understand how to better use the system, it is still important to let science drive it.
- Marilyn will remove the quote and re-phrase the contributor text. She believes the point was to explain how in the past some vulnerable populations have been excluded from clinical trials, even with the best of intentions, and how healthcare providers have had to adjust doses without the guidance of research.

Next meeting

- The next virtual meeting is scheduled for 20-21 October 2020.

Working group structure

In the table below, the Chapter Leads are in bold.

Group 1 **Chair: Juan, co-chair: Kerry**				**Group 2** **Chair: Meredith, co-chair Stefan**						
Ch. 1	**Ch. 2**	**Ch. 3**	**Ch. 4**	**Ch. 5**	**Ch. 6**	**Ch. 7**	**Ch. 8**	**RLS**	**HCP**	**Covid-19**
Theresa	**Elizabeth**	**Beverly**	**Marilyn**	**Meredith**	**Cheryl**	**Leo**	**Stefan**	**Regina**	**Corinna**	**Stephen**
	Talia	Charles	Becky	Ton	Stephen	Linda	Linda	**Shanthi**		**François**
	Theresa	Matthias	Christine	Panos	Leanne	Kaisa	Marie	Lembit		Fatima
	Shanthi	Annemiek	Theresa	Patient rep. to review	Peter	Peter	Sabine	Ratna		Lembit
	Kerry	Regina	Kerry		Judy	Elizabeth	Ravi	Manal		Meredith
	Ken		François		Stella	Ravi	Elizabeth			Nathalie

			Pujita		Nikos	Manal	Fatima?			Panos
			Kaisa to review		Jun	Patrick?	Kerry to review			Peter
					Shinji					Ton
					Jamie					
Glossary team **Stephen** Elisabeth, Panos, Sanna, Stella, and Pujita										
Implementation strategy team Christine, Elisabeth, Meredith, Peter and Talia										
Editorial team Annemiek, Cheryl, Dinesh, Elisabeth, François, Meredith, Panos, Stella, Stephen, and Theo.										