



Fourth meeting of the CIOMS Working Group on Severe Cutaneous Adverse Reactions of Drugs (SCARs)

7 October 2021

Meeting Minutes

Members

Priya Bahri (EMA), David Brott (Takeda), Siew Eng Choon (Monash University), Chia-Yu Chu (National Taiwan University Hospital), Roni P. Dodiuk-Gad (Emek Medical Center), Leslie Dondey-Nouvel (Sanofi), Koji Hashimoto (Ehime Prefectural University of Health Science), Alexandre Kiazand (AstraZeneca), Gerd Kullak-Ublick (Novartis), Haur Yueh Lee (Singapore General Hospital), Sylvia Lesperance (Novartis), Hervé le Louët (UMC/WHO), Filippa Nyberg (Karolinska University Hospital), Ariel Porcalla (AbbVie), Violeta Regnier Galvao (Eli Lilly), Melissa Reyes (FDA), Sarah Schlieff (Bayer), Neil Shear (University of Toronto), Takahiro Ueda (Office of Pharmaceutical Safety I, PMDA)

Guests: Natalia Kuzmina*, Niki Radros (Karolinska Institute)

* N. Kuzmina will be F. Nyberg's alternate.

CIOMS : Catherine Bates, Lembit Rägo

Regrets: Matt Doogue (IUPHAR/University of Otago/Christchurch), Sabine Straus (MEB)

Key action or decision items

- The group agreed that the lack of academic representation in Chapter four (Post-marketing surveillance) was not a problem as all chapters will be reread by members at a later stage.
- The lack of geographical representation in some chapters will also be addressed in this way.
- Alex will join the Conclusions chapter
- The Intro and Conclusions chapters will merge into one group
- Filippa's colleagues will let the group know which chapters they would like to join
- Members agreed with the new order of the chapters.
- Chapter outlines should be developed and presented/discussed at the 5th WG before year-end.
- 6th WG to be scheduled end Q1 or beginning Q2
- Members can share the working materials with colleagues internally for further expert input
- The group will get back to CIOMS to confirm that MS Teams can be used as a collaborative work tool.

Introduction

Lembit welcomed the group and then asked Hervé to say a few words. He informed the group that the pandemic is not sufficiently under control yet to allow for in-person meetings. So, the group needs to wait a little longer. He thanked the members for their commitment, in particular, Melissa and Chia-Yu. Because Hervé could not stay for the whole duration of the meeting, he asked Lembit to appoint one of the co-chairs to act as chair. Lembit reminded the group that two CIOMS publications were issued before the summer break, namely [Clinical Research in Low Resource Settings](#) and the [CIOMS Cumulative Pharmacovigilance Glossary \(Version 1.1\)](#) which is very popular and enjoying an enormous number of downloads. It is an informative document with definitions and



references to original sources. The Secretariat is monitoring other organizations' travel policies and will lift restrictions as soon as it is safe to hold in-person meetings again. Most likely, this will not happen before 2022.

The agenda was shared with the group and Lembit asked if anybody had any comments. To which the group said no. Then, Catherine provided a recap of WG progress since the last meeting, announcing the total number of members for each chapter:

- Largest group: Chap 4 «Pharmacovigilance» = eight writers
- Smallest groups: Intro, Chap 6 «Risk management/Comms», Conclusion = three-four writers each

Then the group posed for a photo which will be used for the next CIOMS newsletter.

Melissa, then introduced the next agenda item and began by saying that she and Chia-Yu took everyone's rankings and kept their top three choices. She asked the group for their feedback on the rankings and also raised the point about geographical representation and representation across the three stakeholder groups. Melissa pointed out that, the mix reflected that there were more clinicians on the clinical chapters, and more regulatory and industry, on the surveillance chapters. She asked Lembit for suggestions as how to use members' strengths and interests in an optimal way. Also, for her as a regulator, she appreciates academia's input particularly in post-marketing where clinicians submit spontaneous reports. Currently, in Chapter four, she remarked that there were no members from academia. She asked the group to look at this chapter and provide any comments to Chia-Yu and herself.

Lembit asked if there were any volunteers from academia to join Chapter four. He followed up by saying that it was difficult to always have the perfect mix of stakeholders, but that members would be able to read all the chapters and so, could provide their input at a later stage.

Hervé stated that in this chapter, in particular, on post-marketing surveillance, the academic view is well-known as compared to other side effects. There is nothing specific to say about skin reactions except that they are more visible than others. He concurred with Lembit that members will have the opportunity to read all the chapters and thus, to him, the fact that there were no academics was not an issue.

Melissa thanked Hervé for this and asked the group if they thought the writers' mix was evenly spread across geographical locations, e.g. Asia, Americas, Europe. It is slightly skewed, but this is in part because the group does not have as many participants from Asia. Melissa acknowledged that taking on more than three chapters would be challenging, but that as above, the chapters will all go through review later on and so, it does not necessarily need geographical representation now.

Hervé asked about the chapter order. Melissa and Chia-Yu stated that this would be discussed in the next agenda item. However, given Hervé's time constraint, Melissa suggested addressing this point at this time and shared the revised table on the screen for the group to comment.



Group Agreement on Revised Chapter Order

Chia-Yu explained which chapters had been moved, saying that he believed the concern would be about Chapters two, three, four, five and six. He asked Hervé for his thoughts on the new order. Hervé said he agreed with it. Hervé asked if other members of the group had any comments. Leslie said it seemed logical. The end was “easy” i.e. pre-marketing, post-marketing and risk management, did not pose any particular problems. It looks good. Ariel agreed, saying it makes sense to start with the theoretical and clinical issues. These would be a platform to discuss pre and post-marketing and risk management. He thanked the chairs for this new order. He is comfortable with the new version. Neil concurred, saying that he liked to flow as well. Chia-Yu asked if there were other comments. Siew Eng liked the new arrangement too and thanked the vice-chairs. David shared this view and said chapters five and six could be arranged either way, but was fine with this order. Chia-Yu said if there were no other comments, he could close the discussion on this item as the group had come to an agreement. He thanks everyone for their input.

Next Steps: Chapter Outlines

Regarding timelines and next steps, Melissa proposed that each chapter group develop its own outline and that the whole WG would meet to share their outlines with each other, preferably before year_end. The next WG would be held after a longer interval e.g. end Q1 or beginning Q2 to allow enough time for producing content.

Alex asked Melissa if some of the chapters were undersubscribed, to which she replied that if members were able to take more than three chapters on, that would be extremely helpful. Alex volunteered to add his name to the Conclusions.

Filippa introduced her colleagues and said they could help with e.g. chapter five. Lembit asked Melissa to remind the group which chapter needed greater academic representation, six? Melissa replied that chapter four had many writers, but no academic contributors. Filippa said her colleagues and she would discuss after the meeting and come back to the group. Lembit stated that if any of the groups needed help from the Secretariat, they could ask Catherine to organize meetings in person, that could be an option.

Priya asked if she could involve colleagues with clinical expertise from EMA, in a confidential way? Lembit said this was fine.

Which Collaborative Platform to Use?

Lembit moved onto the last agenda item about collaborative platforms and which one the group should use as they are not all equally accessible by all members. Catherine asked Melissa if the groups would be working via email, would they need an IT tool at this stage? Melissa responded that it would help with version control if it wasn't too difficult to set up. Catherine asked Priya and Melissa if MS Teams was an option for them as regulatory bodies often had the more restrictive IT policies.

Priya remarked that at EMA, one cannot access Dropbox or Google Docs and working on a private computer wouldn't be possible either as she cannot be online on both computers. However, their IT manager suggested MS Teams/Sharepoint could work. If this is suitable for CIOMS. These programs are more reliable and more secure than Dropbox because they require double identification.



Similar to Priya, FDA has very strict requirements and forbids access to Dropbox, Google Drive, and tools with external document storage capability. She could, however, access them via her private email, if needed. She would need to check if she can use MS Teams for non-FDA documents.

WG to check if they can work on MS Teams/Sharepoint

Lembit invited members to check if MS Teams is an acceptable platform and to let CIOMS know before moving forward. He asked if there were any other points to discuss on today's call.

Regarding the next meeting, Ariel asked Melissa and Chia-Yu to let the group know what expectations are so the different chapter groups know what they need to present. Melissa confirmed she and Chia-Yu would do so, but in general, the idea for the next meeting, was for each chapter group to present their outline to the larger group. Ariel followed up by asking if, in preparation for the next WG, the chapter groups would meet in sub-groups. Melissa said that they could, if needed. Most of the work could be done by email, but if zoom calls were required, Catherine could be asked to help.

Priya asked for clarification on what was meant by "outline". Is it the scope? Which points the group intends to cover without any text? But rather, bullet points? Melissa agreed, that an outline is expressed as bullet points, but the ideas are not yet fleshed out. Some groups might have more detailed outlines than others, but as long as main points are conveyed to the larger group to ensure there is no overlap, that would be fine.

Catherine asked if the conclusion group would have to wait for the content from the other groups. Melissa agreed as it still early days. However, Chia-Yu, said Neil would probably be able to write the outlines for the conclusion. Neil stated it was already written, but that it was important to synthesize it in a rational way. Alex followed up to say that the introduction would comprise the points to be addressed and the conclusion would address all those issues as well. Maybe the two chapters could be written simultaneously, the group could already begin writing the conclusion. Chia-Yu agreed and added that if there is an issue that arose in the conclusion, but was not addressed in one of the chapters, it should be added to one of the chapters as appropriate.

Catherine asked if it would make sense to merge the intro and conclusion groups. Melissa said she was thinking the same thing. Chia-Yu said this is fine. Catherine then said she would reorganize the table as discussed and share with the group. She asked if there were any other changes. Neil said that would be fine, e.g., the old chapter five would now be chapter three. Filippa asked if the group would be receiving a summary of the meeting as she arrived a little late. Catherine said, yes. The group would get the minutes. She will send the revised table around first, then do the minutes.

Include an Executive Summary at Beginning of Minutes

Regarding the minutes, Priya asked if an executive summary or a few bullets could be provided at the beginning with key points so members who attended the meeting do not need to read through the whole document. Catherine said this was fine.

Lembit thanked everyone and ended the meeting.