



**5th meeting of the CIOMS Working Group WG XIV on
Artificial Intelligence in Pharmacovigilance**

6-7 June 2023, Zurich, Switzerland

Minutes

Overview:

Summary	2
Minutes of discussion	1
Day 1	1
1. Opening and welcome	1
2. Progress updates on chapter drafts	3
Chapter 1-3 Introduction, landscape and scope	3
Chapter 2 Landscape	5
Chapter 4 Guiding principles	5
Chapter 5 Validation and qualification considerations	6
Chapter 6 and 7 Consideration of AI; Implementation and maintenance lifecycle aspects	8
Chapter 8 Future vision	9
Glossary.....	10
3. Forming teams and timelines	12
4. Way of working.....	13
5. Next meeting	13
6. Closing remarks.....	13
7. Annex 1: List of participants	17

Summary

The CIOMS Working Group XIV on Artificial Intelligence in Pharmacovigilance held its 5th meeting in Zurich, Switzerland on 6-7 June 2023. The meeting was kindly hosted by Takeda. During the meeting, the Chapter teams provided progress updates and made further developments to chapter drafts.

Minutes of discussion

Day 1

1. Opening and welcome

Hervé le Louët, CIOMS President, welcomed the members to the 5th meeting of the CIOMS Working Group XIV on Artificial Intelligence (AI) in Pharmacovigilance (PV) hosted by Takeda, and wished all a fruitful meeting.

Lembit Rägo, CIOMS Secretary General, added his words of welcome and opened the meeting as Chairman for the two days (for a list of participants see [Annex 1](#))

Lembit made the following announcements:

5th Meeting, 6-7 June 2023, minutes

- The CIOMS Working Groups (WGs) [WG XII Benefit-risk balance for medicinal products](#) and [WG XIII Real-world data and real-world evidence in regulatory decision making](#) have published their draft reports for public comments.
- [CIOMS Glossary of ICH terms and definitions: Version 3](#) and [CIOMS Cumulative Glossary with a focus on Pharmacovigilance \(Version 2.1\)](#) are available on the CIOMS website.
- There are several CIOMS WGs continuing their work with information available at the [CIOMS website](#).

Tour de Table: all participants introduced themselves.

The meeting agenda was adopted.

Introductory discussion on recent developments in the AI space

- Lembit opened the discussions by highlighting the existence of controversial opinions in society regarding the use of AI. Recent public news has featured calls for a more cautious approach in the utilisation of AI.
- Robert briefly introduced some of the recent activities by the United States Food and Drug Administration (FDA) regarding AI regulation. The Center for Devices and Radiological Health (CDRH) at the FDA has published a white paper outlining general principles and considerations for AI regulation. The document focuses on how device manufacturers incorporating AI should prepare for changes to the AI algorithm over time. The Center for Drugs and Biologics (CDB) at the FDA has issued a white paper and on the application of AI to drug development and PV.
- the European Medicines Agency (EMA) is planning to publish a white paper on AI and has expressed their interest in potentially participating in CIOMS WG XIV.
- The WG decided to establish a constant liaison with Pharmaceutical Inspection Co-operation Scheme (PIC /S) working group and invite their representative to join the WG. An official invitation will be sent to PIC/S after the meeting to encourage their active involvement.
- Recent developments in the AI space, particularly with large language models (LLMs) and application programming interfaces (APIs), have significant implications for the PV industry.
- Key areas of focus include stringent testing and validation of systems using appropriate data, governance approaches, change management, and evaluating the suitability of APIs for PV purposes.
- LLMs such as ChatGPT, are currently the most powerful and widely used AI tools, but their impact is dynamic and subject to future developments.
- While the core models are mature and available for various tasks, there may be fine-tuning and specialization in the future, moving away from a one-size-fits-all approach.
- It is crucial to consider the functioning and limitations of AI models and avoid overfitting to the current state, as the AI landscape is likely to change in the future.
- Will vendors continue investing in their own AI models or adopt existing models and overlay them within their systems? This shift in approach leads to a fundamentally different situation compared to expectations from a year ago, where vendors were expected to develop their own models for validation.
- Reframing certain elements of the guidelines may be necessary, as some aspects may be less important now than they were previously.

- There is a risk associated with the motivation behind the existing AI models, which are primarily generated for a public audience and driven by factors that prioritise precision over recall.
- In the field of PV, the focus should be on recall, as it is important to identify unexpected events and capture as much relevant information as possible.
- The perspective on AI in PV should consider the specific tasks that AI can help with.
- There is uncertainty regarding the marketing and distribution of LLMs and how companies will be able to access and use them.
- The size and infrastructure requirements of LLMs pose challenges for widespread adoption, leading to the possibility of smaller versions being developed.
- The rapid advancement of technology allows for the development of smaller LLMs by various organizations, resulting in the challenge of dealing with multiple models.
- Ensuring consistency, integrity, accuracy, and predictability becomes crucial when dealing with decentralised models.
- The implementation of LLMs raises concerns about where the tool resides and who has control over the data.
- Pharmaceutical companies prefer to have full control over the tool and access their own data, rather than relying on external models.
- The reliance on a single model can lead to concerns and potential limitations in various use cases. Having only one model hinders the ability to perform central capture-recapture analysis, which requires multiple independent sources of data, while having multiple models can provide more diverse perspectives and enhance the accuracy and reliability of the results.

Advisory group of vendors and consultants

- Several companies offering consultancy have approached CIOMS with a request to participate in the discussions of the WG XIV. Lembit suggested considering the inclusion of interested parties, particularly consultants and companies, in the Advisory Group.
- The Advisory Group will not participate fully in the WG meetings but will attend the WG meetings for an agreed time. All communication with the WG will be fully transparent and documented.
- Understanding how vendors and consultants plan to integrate AI into their systems is more valuable than focusing solely on the models themselves.
- Exploring their commercialization strategies and different approaches can provide insights into the direction of AI implementation. Incentivising vendors to build reliable and trustworthy AI models is important.
- We should consider a separate supplement to the report to address the role of vendors and consultants in the overall context of the working group.

2. Progress updates on chapter drafts

All materials presented are available in the [WG private member area](#).

Chapter 1-3 Introduction, landscape and scope

- Walter gave the Chapters 1-3 team's presentation. The following represents the discussion points raised after the presentation.

- We should include use cases to illustrate the application of automation and success rates in specific scenarios.
- There are potential risks of categorizing processes as unsuitable for automation and then later realizing their feasibility.
- The focus could be on highlighting what can currently be accomplished through automation, considering the evolving nature of AI technologies.
- Certain tasks may require a higher level of human intervention despite the potential for automation to be applied to some extent. It does not mean ruling out the possibility of automation but acknowledging the need for human involvement in the process.
- We will include considerations for evaluating the suitability of applying AI and ML to different areas of PV while considering factors such as impact, ease, and risk when determining whether to pursue AI and ML solutions in specific areas.
- A document that is more focused on underlying principles will likely have a longer period of relevance compared to one that is more prescriptive in nature.
- We should recognize that certain tasks or processes may not be suitable for full automation at present but could benefit from augmentation with AI technologies. Is automation the best term to use?
- There is potential for AI to enhance human capabilities and decision-making rather than replacing them entirely.
- We should recognize the continued relevance and importance of the Individual Case Safety Report (ICSR) system in the foreseeable future.
- Avoiding overly broad statements or speculation about future developments, while ensuring the completeness and accuracy of the information provided will aid in creating a comprehensive document that can remain relevant and useful for at least a decade.
- We should consider a perspective shift, where the established data source becomes the starting point for analysis and signal detection. It is important to consider data sources from various channels and integrating them for comprehensive analysis and decision-making. Recognize the evolving nature of these concepts and the ongoing learning process within the working group.
- A significant portion of ML work in PV has focused on the analysis side rather than case processing. We need to consider developments and advancements in ML for case processing tasks and addressing the current state of ML applications in PV.
- We should address the readership's interest in understanding how AI will contribute to advancing the field of PV and improving safety and focus on providing insights and guidance to individuals and entities involved in PV, including vendors, academics, researchers, pharmaceutical companies, legal professionals, and those interested in ethical principles.
- AI in PV interests a wider readership, including patients who seek information from sources like ChatGPT. We should consider the potential risks associated with patients relying solely on AI-generated information and the importance of guiding patients to seek professional medical advice. It is important to address the interests and concerns of various stakeholders, including patients, in order to foster responsible and effective use of AI in PV.
- There may be over-expectation of what is currently possible with language models and an under-expectation of their future potential. The future vision involves language models being able to uncover risks and insights that may be challenging for humans to understand.

- It may be valuable to compare AI performance to human performance and potentially collect data for benchmarking purposes in the chapter.
- Highlighting the importance of addressing considerations related to decision-making, implementation, maintenance, and review of AI systems in PV and providing practical and enduring guidance for stakeholders on effectively utilising and evaluating AI outputs in the field of PV will add value to the report.
- We should address the differentiation and provide guidance in using an internal in-house LLM versus an external one.
- It was decided to focus on the PV aspect and separate it from benefit-risk assessment and population-based data sources.

Chapter 2 Landscape

Niklas presented the Chapter 2 outline. The following represents the viewpoints shared after the presentation.

- The qualitative difference brought by AI is crucial and serves as the foundation for future developments.
- Changes in training LLMs to accommodate smaller datasets in specialised fields should be mentioned.
- The current literature on AI in PV is often task-focused, with limited discussion on the holistic implications. There is a lack of literature addressing the broader picture and the impact of ML on labor activity in PV.
- Categorising different approaches and methodologies, such as supervised and unsupervised learning, can provide a framework for understanding the current landscape.
- The inclusion of secondary data and data enrichment techniques should be considered, including the exploration of ICSR enriched with additional data sources. The document should acknowledge that these categories and approaches may evolve and change over time as new developments and advancements occur.
- It is important to consider the actual capacity of AI models, as they may have limitations in terms of data ingestion and output capabilities. The document should address the need to handle large volumes of data and potential challenges related to stitching together information from multiple sources.
- It may be beneficial to include guiding principles or considerations related to data quality and completeness to ensure accurate and reliable outcomes from AI models, while highlighting the importance of evaluating and validating input data can help mitigate potential biases or inaccuracies in the results generated by AI models.

Chapter 4 Guiding principles

- Beth updated the WG on the Chapter 4 progress.
- The framework presented in Chapter 4 considers the willingness to accept or tolerate risk in AI and ML in PV, determining if AI is the appropriate solution for a given problem, and assessing the benefits and acceptance of AI.
- The framework may be influenced by chapters 2 and 3, and modifications may be made accordingly.

- Team members are currently signing up to draft specific principles, and the group will review and provide feedback.
- The principles are being evaluated to incorporate considerations for the dynamic nature of models. The shift from static models to dynamic models that can be continuously trained and updated is being considered in the development of principles.
- The implications of the models presenting data in different ways within the sample need further exploration. The principles should consider the potential variations and ensure appropriate handling of the dynamic nature of the models. Stability is the key metric.
- The chapter on validation or verification may not be the most suitable section to address the issue of multiple responses that may not be identical but can still be considered acceptable.
- Testing the interaction between humans and computers is an important principle. It is important to acknowledge the potential challenges that may arise as reliance on AI systems increases, potentially leading to a reduction in critical thinking and a diminished understanding of the underlying reasons. We should include quality system principles throughout the chapters and provide technical examples to support the implementation of a quality system approach.
- It is important to capture provenance information in the context of LLMs. We need to understand the source and origin of information, including whether it was provided by humans, humans with AI support, or solely generated by AI.

Chapter 5 Validation and qualification considerations

- Hans-Jörg gave the Chapter 5 team presentation and the following only represents the discussion points made after the presentation.
- We should discuss the importance of defining clear guidelines or principles for effective human involvement in AI processes. What is the current state of human involvement and what are the areas for improvement or enhancement?
- There are potential differences in validation requirements based on the source and ownership of the language model.
- The general principles of quality management could be included at the beginning of the document. We should explore the relationship between quality management and validation, identifying areas where they intersect and complement each other and provide specific solutions and recommendations related to quality management.
- We should address the concept of error tolerance and quality standards.
- It was suggested to conduct an experiment to compare human and AI performance for specific tasks, such as MedDRA coding and seriousness assessment, to measure the overlap and identify areas of agreement and ambiguity. There is a need for balancing human and AI performance and understanding the common mistakes or variations in human performance while highlighting the potential advantages of AI, such as consistency and the ability to handle large volumes of data effectively.
- It is important to provide a plan for validation and have it reviewed by regulatory agencies, considering factors such as device benefit, risk, and adequacy of the plan.
- Concepts such as sampling and other validation approaches in the technical quality management section should be included to provide a more comprehensive understanding of validation methodologies.

- The transition from human review to automated processes raises concerns about data governance and the need for proper oversight.
- Ensuring the accuracy and reliability of automated systems without compromising patient safety is a critical challenge.
- Defining new roles and responsibilities for human oversight and quality assurance in AI-driven processes may be required.
- The chapter should address the challenges and considerations related to validation and sampling in the context of AI systems in PV. Examples and case studies illustrating validation and sampling approaches can provide practical insights for implementation.
- The chapter should address the perception that AI in PV carries a higher risk compared to other applications of AI. The concept of human errors and their impact in PV should be discussed.
- The concept of non-human review and its potential benefits in enabling more focused analysis should be explored.
- The chapter should provide insights on how AI can complement human efforts in reviewing data, mitigating risks, and enhancing PV processes.
- Consideration should be given to the impact of AI tools in improving the quality and specificity of causality assessments compared to human reviewers.
- The chapter should provide insights on how to address the challenge of meeting regulatory expectations while leveraging the benefits of AI in causality assessment.
- One of the chapters' objectives is to provide education to the readers regarding the transition from a conventional perspective of validation, which emphasizes reproducibility, to a more quality-oriented approach. Examples are beneficial in illustrating the concepts and principles discussed in the chapter, as examples tend to resonate well with readers and facilitate their understanding.
- Encouraging readers to consider individual AI systems' capabilities and limitations and how they can be leveraged to accomplish specific goals is crucial.
- One possibility that could be emphasised in the chapter is the importance of moving away from reproducibility as the sole measure of validation and focus on the concept of explainability. Explainability should be understood as not only providing the algorithm's prediction but also offering insights into the underlying reasons and uncertainties associated with the prediction. Examples and case studies illustrating explainability in AI systems can effectively demonstrate its value and help readers grasp the concept.
- It is important to highlight that decisions in signal evaluation are not always clear-cut and can be influenced by factors that may not be transparent or easily quantifiable. Discussing the challenges and limitations of automated decision-making models in the context of signal evaluation will provide readers with a realistic understanding of the capabilities and constraints of AI in this domain.
- AI offers the advantage of processing information consistently over time and considering multiple variables, thereby reducing subjectivity.
- The chapter should convey to the reader that the choice of AI is not a simple yes or no decision, but rather a consideration of which AI is most suitable for their specific context. selecting the appropriate AI involves considering factors such as existing processes, available resources, and organizational requirements.

- Overall, the focus should be on promoting a thoughtful and context-aware approach to AI implementation and evaluation within the field of PV.
- Unlike the other chapters that are specific to AI in PV, Chapter 5 has a broader perspective and presents an opportunity to examine how other domains outside of PV validate their AI methodologies and algorithms.
- Reproducibility should be considered as a fundamental principle in the validation of AI algorithms. Exploring how traditional validation principles translate into the world of AI can provide insights into ensuring the reliability and robustness of AI algorithms.
- Regular evaluation and review of reproducibility requirements can help organizations strike the right balance between reproducibility and the flexibility needed for evolving AI algorithms and data sources.
- Understanding all the rules in AI may not always be necessary, but it is important to have reassurance that there are established rules in place.

Chapter 6 and 7 Consideration of AI; Implementation and maintenance lifecycle aspects

- Taxiarchis gave the Chapters 6 and 7 presentation and the following only represents the discussion points made after the presentation.
- How much of the regulatory considerations related to AI in PV should be included in this document? What is the balance between including general scientific principles and leaving interpretation to be implemented by different regulators?
- It should be noted that the future report is not a regulatory document and does not provide specific regulatory guidelines.
- There are no limits to exploring topics that regulators may consider, but it is up to them to decide how to incorporate the recommendations. The principles provided can facilitate subsequent discussions and collaborations among all stakeholders.
- The document aims to address the industry's uncertainty regarding how regulators will respond to AI in PV. We should strike a balance between providing a framework and avoiding becoming overly prescriptive.
- We should signpost good practices for internal auditing in the context of AI implementation in PV but also address poor practices of using AI in PV. Also, address common themes related to appropriate use and trust in AI, considering the perspectives of both regulators and vendors. It is beneficial to discuss and present different perspectives on challenging subjects when harmonised agreement is not possible, allowing readers to understand varying viewpoints.
- There is a need for collaboration between industry, regulators, and other stakeholders to navigate the evolving landscape of AI in PV, and to address potential gaps or areas of concern.
- We should provide a comprehensive list of relevant websites and resources where readers can access specific guidance documents from different regulatory authorities and encourage readers to explore and familiarise themselves with the guidance materials applicable to their jurisdiction or specific context.
- We should position CIOMS as a platform that facilitates open discussion and exploration of AI's direction in PV, allowing for a more flexible and nuanced approach compared to strict regulatory frameworks. The report could serve as a reference that stakeholders can use to demonstrate consensus among experts regarding sensible AI use, while acknowledging that individual implementation may vary based on specific contexts and regulatory requirements.

- The inclusion of specific advice (documents, websites, etc.) may be added as and annex to the report.
- Defining concise one-sentence objectives for each chapter would enhance clarity and assist in determining the proper placement of sections.
- The changes made by the AI model and the proposed changes should be clearly identified and explained to maintain transparency and facilitate decision-making. Transparency in the AI's decision-making process can be achieved by providing information on how the model operates and the logic behind its suggestions.
- Reviewers should have the opportunity to understand and review the changes made to the text by AI model. High-risk changes may require direct human review and oversight, while lower-risk changes may provide the option to explore the modifications if desired.
- Transparency should be ensured regarding the use and extent of AI in decision-making processes. Describing design principles for the system, both in the back end and the front end, is crucial for ensuring transparency and usability.
- The document should include high-level considerations regarding data copywriting, ensuring compliance with legislative, ethical, and privacy requirements.
- Consideration should be given to the potential variations in AI regulation across jurisdictions, especially when implementing AI in PV processes that span multiple countries.
- The concerns about job displacement by AI systems should be addressed - AI should be seen as a supportive tool rather than a replacement for human expertise.
- A section on the business case for implementing AI in PV would be beneficial, providing guidance on how to quantify and articulate the value proposition and provide practical examples and case studies.
- We should also discuss the role of trust in the context of AI implementation in PV, focusing on trust among PV professionals and trust in compliance with data privacy regulations.
- Discuss strategies to ensure the continuous professional development of PV personnel, even as AI takes over certain tasks, to foster their growth into senior assessors and domain experts.
- Highlight the importance of providing opportunities for skill development, critical thinking, and decision-making in areas where human expertise is still essential, ensuring a sustainable workforce in PV.

Chapter 8 Future vision

- Ravi and Denny introduced the Chapter 8 work in progress.
- The development efforts may be divided into two phases:
 - Automation of processes to drive efficiency and cost-effectiveness, leveraging technology to support and enhance outcomes.
 - Utilisation of large data to generate new information, incorporating inputs from various sources such as literature, spontaneous reports, and patient feedback, to drive novel insights and patient-centric outcomes.
- It is important to recognise the self-learning capabilities in AI models, allowing them to continuously improve and adapt based on feedback and data connections.
- Consider the balance between utilizing AI models trained on proprietary data for greater precision within the organization and leveraging universal data, including clinical trials and similar studies, to gain broader insights and analysis.

- The shift in signal detection focus from product-event combinations to indication-therapy/event combinations are to be addressed, highlighting the need for updated statistical models and quantitative signal detection approaches to accommodate this change.
- It was suggested to discuss the ethical and regulatory considerations surrounding the sharing of AI-generated insights, including the rules and responsibilities related to sharing insights with patients and ensuring transparency in the communication of findings derived from AI systems.
- The challenges related to data collection for improved signal detection should be addressed, considering factors such as patient follow-up duration, frequency of data collection, comprehensiveness of data, and the potential role of automation and AI in streamlining case review processes and reducing inefficiencies.
- Chapter 8 team would appreciate being invited to other Chapter team meetings, as it would be an occasion to contribute to discussions and further progress Chapter 8.
- Chapter teams are invited to share notes on potential topics to be added to Chapter 8.

Niklas presented slides “Critical Appraisal of AI Solution for PV”. The slides are available on the members’ area.

Glossary

- The glossary aims to establish common definitions that can be used by all stakeholders in the field of PV, promoting consistency and clarity.
- Chapter teams are invited to identify and collect relevant terms during the development of their respective chapters.
- It is encouraged to use existing definitions, but new definitions may be created, or existing definitions modified as needed.
- In the glossary, terms with multiple definitions depending on context are addressed by providing specific definitions tailored to the context of the document or objective at hand. We should ensure clarity and consistency in the understanding of terms to mitigate the risks of misunderstanding.
- [CIOMS Glossary of ICH terms and definitions: Version 3](#) and [CIOMS Cumulative Glossary with a focus on Pharmacovigilance \(Version 2.1\)](#) are available on the CIOMS website. CIOMS Cumulative Glossary is a living document and terms from the CIOMS WG XIV report glossary will be added in time.

Hervé and Lembit concluded the meeting and thanked all for their participation and discussions.

DAY 2

Hervé welcomed the WG and thanked all for the fruitful discussion the previous day. The aim for the second day is to focus the discussions towards developing chapter drafts further.

Lembit summarised the Day 1 discussions and opened the Day 2 discussions.

- The WG was divided into three subgroups: Chapters 1-4, Chapters 5-7, and Chapter 8 to facilitate focused discussions and decision-making regarding the proposed content of the future report.

- The WG continued working in two breakout sessions where Chapter 8 team divided themselves between the two teams. The teams aimed to address any hesitancy or uncertainties regarding the division of topics among the different chapters and encourage focused writing and development of each chapter.
- Following the breakout sessions, the two groups provided updates on their discussions, and the following points summarise the discussions that took place.

Chapters 1-4 team

- Walter updated the WG on their discussions. He presented the proposed objective of the working group, which is to provide a framework for the critical appraisal, implementation, and maintenance of AI solutions for PV.
- He emphasised the inclusion of issues related to compliance, governance with the specific focus on medicines and vaccines in the PV context. The objective is not to address the safety of AI itself, but rather to focus on PV-related aspects.
- The document aims to be inclusive of various stakeholders within the biomedical research spectrum, including professionals, specialists, investors, regulatory authorities, industry, academia, students, international organizations, contract research organizations, vendors, and consultants.
- We should emphasize the importance of compliance with existing regulations and guidelines in all activities related to AI in PV, while acknowledging the absence of specific regulations for AI at present.
- Focus the scope of the document on medicines and biologics, excluding wearables and other non-pharmaceutical devices, as the considerations for PV may differ in those areas. Combination product will be in scope.
- Clarify in the document that the scope includes the use of AI in PV activities across all types of products.
- Include a glossary entry for "device" that provides a specific definition within the context of the document, excluding AI within the device.
- Finding a balance between addressing the current state and exploring future possibilities was recognized as important.
- Further dialogue and consensus-building are necessary to determine the future reports' focus.

Chapters 5-7 team

- Phil summarised the Chapters 5-7 team discussions.
- The aim is to start with a chapter on the quality management system that applies to all implementation and maintenance steps.
- A chapter on the flow of implementation, covering different aspects such as validation, use case validation, and performance assessment will follow. The chapters' structure will be aligned with the purpose and audience of the document.
- The team will favour a cyclical writing process rather than a linear one, acknowledging that different stages may require different approach.

- Using the term ‘validation’ may not be the best option and needs further discussion.
- The report would include a section on the importance of efficiency and improvement in the context of a business case.
- The influence of efficiency and improvement metrics are discussed at each stage of development.
- Consider including a description of the principles of performance evaluation in the chapter on principles which will provide a foundation for understanding the evaluation process.
- The principles of performance evaluation in the specific sections that discuss metrics, methods, and criteria for system performance evaluation should be included.

3. Forming teams and timelines

- The WG divided itself into three new teams based on their related content: Chapters 1-4, Chapter 5-7, and Chapter 8 to explore the opportunity for more consolidation among the chapters.
- An email will be sent to the members not being able to attend to inform them about the division into two major groups and request them to indicate their preferred group, taking into account the need for balance and diversity in group composition.
- The decision to split into two major groups and one smaller group was made to address commonalities and improve consistency between the chapters. This division allows each group to focus on their specific areas of expertise and develop their chapters accordingly.
- The objective is to merge the existing text from chapters and determine what additional content needs to be written. Once the necessary assignments are made, individuals will have time to write their respective sections.
- The next step will be to assemble the sections and conduct a review. Editing of the document will be left for the next full meeting. The goal is to have this process completed by the end of September.
- Lembit urged the WG to aim to draft a preliminary draft of the entire combined document before the next in-person meeting. This is to ensure that the meeting can be more productive with a comprehensive understanding of the overall content, even if the draft is still rough. Having a preliminary draft allows us to see the entirety of the document and facilitates more focused discussions during the meeting.
- The process that is being proposed is to complete the document and send it out for review. After receiving comments and feedback, the in-person meeting will serve as a review of the overall concept and focus on editing the document. The goal is to incorporate the necessary revisions and improvements based on the feedback received during the review process.
- By combining virtual meetings for initial review (in September) and refinement and in-person meetings for deeper discussions, the process can be optimized to ensure a comprehensive document.
- The focus should be more on high-level principles rather than getting overly granular in certain areas.
- Chapter 8 team will join different groups at different times to get a bit more for the future vision and listening some of the discussions.

Way of working

- CIOMS reports are usually finalised by an editorial team consisting of five to six members from the WG. A near-final draft is presented to the whole WG during the final meeting.
- CIOMS Secretariat will provide editing to refine the draft report.
- CIOMS Secretariat will aim to find a collaborative editing environment that is accessible to all WG members, considering their different IT systems and limitations. If all members are not able to access the selected environment, all efforts must be made to ensure equal opportunities for all members to contribute. [Post meeting comment: Microsoft Teams was chosen as the most suitable environment]
- The working mode and communication approach for each group should be determined by the group leads of the respective chapters. They have the responsibility to establish clear guidelines and expectations for collaboration, communication, and progress within their groups. CIOMS Secretariat will assist if needed.
- Clear instructions and guidelines from the chapter leads regarding the timing and process of providing comments and making edits are crucial. Setting specific timelines and emphasising the use of track changes in the document will help streamline the collaboration process and minimise back-and-forth discussions.

Public consultation

- A public consultation will be held upon the decision of WG in the final stage of finalising the report. The consultation period will be approximately six weeks and will provide an opportunity to gather additional feedback. The WG editorial committee will decide on the inclusion of comments received.

Publishing a research letter

- Andrew proposed drafting a preliminary communication to announce the upcoming publication and highlight key points or considerations of the document.
- Volunteers are welcome to form a small group, and with the consensus and approval of the larger group, to refine and finalise the proposed document.

4. Next meeting

- The next full WG meeting will be held virtually on 27 September 2023. Chapter teams will report on progress and discuss any questions on draft chapters. CIOMS Secretariat will schedule the meeting.
- It was agreed to identify three available dates for an in-person meeting in the end of November or beginning of December and send out calendar holds for those dates.¹
- WG will remain flexible in deciding whether to convert the in-person meeting to a virtual meeting if needed.

5. Closing remarks

Hervé and Lembit thanked the WG members for joining and for the progress made.

¹ [Post-meeting comment: the proposed dates for the next in-person meeting are **7-8 or 9-10 November**, and the current location is Geneva, but please note that the dates and location may be subject to change]

Annex 1: List of participants

Participants

Justyna Amelio (AbbVie), Robert Ball (US FDA), Luisa Barrios (Merck Sharp & Dohme), Andrew Bate (GlaxoSmithKline), Taxiarchis Botsis (Johns Hopkins University School of Medicine, US), Hua Carroll (Biogen), Piero Francesco Franco (Pfizer), Kirsten Egebjerg Juul* (Danish Medicines Agency), Dieter Kempf (Genentech, Roche), Kostadin Kidos (Takeda), Benny Ling (Health Canada), Denny Lorenz (Bayer), Hervé Le Louët (CIOMS), Yusuke Matsunaga (Pharmaceuticals and Medical Devices Agency, Japan), Manuela Messelhaeuser* (PEI), Beth MacEntee Pileggi (Johnson & Johnson), Monica da Luz Carvalho Soares (ANVISA, Brazil), Niklas Norén (World Health Organization / Uppsala Monitoring Centre), Ravi Patel (Unither), Kateriina Rannula (CIOMS), Lembit Rägo (CIOMS), Hans-Jörg Römmling (Merck Group), Walter Straus (Moderna), Irene Scholz (Swissmedic), Thomas Stammschulte (Swissmedic) **, Phil Tregunno (The Medicines and Healthcare Products Regulatory Agency, UK), Brian Yau (WHO).

Apologies

Arvind Bellur (Sanofi), Russ Altman (Stanford University, US), Adrian Berridge (Takeda), Kendal Harrison* (The Medicines and Healthcare Products Regulatory Agency, UK), Stephen Heaton* (CIOMS), Thomas Henn * (Unither), Vijay Kara* (GlaxoSmithKline Jesper Kjær (Danish Medicines Agency), Roli Mathur (India Council Medical Research), Dirk Mentzer (Paul-Ehrlich Institute), Flávia Moreira Cruz (ANVISA, Brazil), Richard McAteer* (Health Canada), Yuki Kikuchi* (Pharmaceuticals and Medical Devices Agency, Japan), Nicolas Perez * (Swissmedic), John Reinhard Pietzsch* (Bayer), Stephen Rosenfeld (North Star Review Board), Panos Tsintis (CIOMS Senior Adviser).

*Alternate

** Attended Day 1