Council for International Organizations of Medical Sciences

First meeting of the CIOMS Working Group (WG) XVI on the Development Safety Update Report (DSUR)

25-26 February 2025, Geneva, Switzerland, hybrid meeting

Minutes

Overview:

Summary

The CIOMS Working Group (WG) XVI on the Development Safety Update Report (DSUR) held its first meeting in Geneva, Switzerland, on 25-26 February 2025, with participants attending both in-person and virtually. The WG discussed the improvements to the Development Safety Update Report (DSUR), aiming to enhance its structure, relevance, and efficiency. The next meeting (virtual) will be held on 3 June 2025, while a subgroup formed from the WG members will continue its work with an aim of distributing a revised DSUR draft to the full WG before the next meeting.

Minutes of discussion

Day 1

1. Opening and welcome

- Hervé le Louët, CIOMS President, opened the session and welcomed the members to the 1st meeting of the CIOMS WG XVI on DSUR. He emphasised the significance of open discussions within the WG and urged all participants to actively engage and contribute their ideas.
- Lembit Rägo, CIOMS Secretary General, added his words of welcome and thanks. He opened the meeting as chairman for the two days (for a list of participants see Annex 1).
- Lembit made the following announcements:
    - The WG XII report on Benefit-Risk Balance for Medicinal Products is expected to be published in April 2025.
    - The WG report on Severe Cutaneous Adverse Reactions – SCAR is also expected to be published in early April.
    - The WG XIV Artificial Intelligence in Pharmacovigilance is nearing the public consultation stage.
- There are several ongoing CIOMS WGs, among which WG XV Pharmacoepidemiology for Public Health addresses challenges in epidemiology and regulatory science and WG on Recommended Standards of Education and Training for Health Professionals Participating in Medicines Development addresses gaps in education and training. Several potential new topics for working groups (WGs) are currently being considered.
- Agenda was adopted.
- Kateriina was rapporteur.

2. Background, Scope, Outline and Target audience of CIOMS WG XVI: *Development Safety Update Report (DSUR)*

Tour de table

- Lembit opens the discussions and notes that the final CIOMS report will serve as a recommendation document but may inform future ICH or regional regulatory updates.
- Emphasis should be placed on practical usability, ensuring that recommendations are adoptable by regulators and industry.

Interventions from participants: Regulatory perspectives

- Lembit acknowledges that a significant amount of time has passed since the original CIOMS WG VII (2006) and the ICH E2F (2010) guidance was established, and the regulatory environment has evolved.
- The objective of this discussion is to understand how DSURs can be more effective in ensuring clinical trial safety oversight.

- DSURs have a monitoring function by providing an insight into the use of an active substance in the studies of different sponsors and by documenting new findings and measures to improve safety of study participants during the reporting period.
- Regulators are responsible for ensuring that safety issues identified in one study do not pose risks in other studies within their jurisdiction.
- Differences in DSUR approach were mentioned: pharmaceutical companies' DSURs are often broad, covering their active substance across multiple trials while academic sponsors' DSURs are often study-specific, making comparisons across different DSURs challenging.
- Assessing whether safety signals vary based on patient demographics is crucial, but DSURs currently make this difficult to extract.

- **Format and usability issues**
- DSURs can be difficult to interpret.
- The variation in detail and scope between DSURs in the early development phase and those for authorised products mean that different approaches are required when interpreting the data.
- The format does not always facilitate direct comparisons across studies.

- **Balancing safety and benefit considerations**
- Current DSURs focus predominantly on risks, but do not provide insights into the benefits of the investigational product.
- A stronger focus on benefit-risk balance is necessary, rather than looking at risks in isolation.
- There is a lack of follow-up information on risk mitigation measures:
    - If a mitigation measure is implemented, regulators need to know if it was effective.
    - Current DSURs do not track the reduction in severity, seriousness, or frequency of adverse reactions after mitigation strategies are applied.

- **Duplication and redundancy in reporting**
- Often, the same investigational product is used in commercial and non-commercial trials.
- If the originator (innovator company) of the investigational product is involved in an academic or non-commercial trial (e.g., providing the drug or financial support), regulators prefer that the originator include those data in their global DSUR rather than having multiple separate DSURs. This would reduce redundant submissions and ensure comprehensive safety monitoring.
- Challenges of early-phase DSURs were highlighted:
    - Early-stage trials have limited data, making causality assessments difficult.
    - Later-phase DSURs for already marketed drugs can rely on existing pharmacovigilance tools (e.g., Periodic Safety Update Reports), creating overlap.

Interventions from participants: Industry perspectives

- There is a significant difference in DSUR utility across phases: Phase 1 & 2: Limited data, making a full benefit-risk analysis impractical. Phase 3 & 4: More comprehensive safety and efficacy data allow for more structured assessments. There should be different approaches for early vs late-stage clinical trials, with Phase 3 & 4 reports aligning more closely with Periodic Benefit-Risk Evaluation Reports (PBRERs), while Phases 1 & 2 may need a simplified approach.

- **Regulatory expectations vs industry reality**
- Industry needs regulators to define clearly what they expect in DSURs, particularly how they should differ from Investigator's Brochures (IBs), Periodic Safety Update Reports (PSURs), and protocol documents.

- There is uncertainty about what new insights DSURs should provide beyond existing safety monitoring measures.
- The compilation of DSURs, especially for large-scale programmes, is complex, involving multiple contributors, data sources, and regulatory requirements.
- Variability in global regulatory expectations makes creating a single, universally useful DSUR format difficult.
- ICH guidelines enforce rigid reporting structures that sometimes limit the ability to present data in the most meaningful way. Companies have attempted more user-friendly tables but were instructed to revert to ICH-mandated formats.

- **The evolving role of DSURs**
- We should move towards a more modular approach, integrating DSURs with other safety reporting documents to avoid redundancy.
- The evolution of clinical trials, particularly platform studies, challenges the current DSUR model, requiring a more adaptable reporting system.
- Companies often treat DSURs as a "box-checking" exercise, reusing previous versions with minor updates.
- Some regulators have only recently begun providing DSUR feedback, with requests sometimes focusing on administrative details rather than substantive safety concerns.
- Do DSURs serve a meaningful function or merely fulfil a regulatory requirement? The regulators answered this question with an unequivocal ´yes´.

- **Benefit-Risk assessment in DSURs**
- DSURs currently focus heavily on safety, with minimal discussion of emerging efficacy data.
- Some regulators advocate for a structured benefit-risk assessment within DSURs, but industry raises concerns:
    - In early-phase trials, efficacy data are often insufficient to make meaningful benefit-risk conclusions.
    - Companies will always frame benefit-risk as positive unless a programme is being discontinued.
    - Full benefit-risk assessments are more appropriate in PBRERs or marketing applications rather than development-stage DSURs.
- Industry suggests that DSURs should provide a narrative explaining how safety data are analysed and why decisions are made, rather than simply presenting data tables.
- The goal should be a document that is useful to both regulators and physicians rather than a compliance-driven report.

- **Future Directions for DSURs**
- Global inconsistencies in DSUR expectations create inefficiencies, with companies often preparing different versions for different agencies. A unified approach would enhance the value of DSURs while reducing unnecessary regulatory burdens.
- Both industry and regulators recognise the need for improvement in DSURs, focusing on clarity, utility, and efficiency.
- Industry emphasises reducing redundant efforts, improving global alignment, and ensuring clinical relevance in reporting.
- DSURs should be more than a regulatory obligation—they should serve as a valuable tool in ensuring patient safety and supporting informed decision-making.

- **Initiatives relevant to the WG**
- By mapping ongoing initiatives related to DSUR improvements we aim to avoid duplication of effort and to identify opportunities for collaboration with other WGs.
- A request will be made to share the draft of the Benefit-Risk WG's report with the DSUR working group for reference, even before formal publication.
- Several initiatives were mentioned:
    - The European COMBINE project, which focuses on integrating data from studies involving investigational medicinal products (IMPs), medical devices, and in vitro diagnostics (IVDs). It was suggested that members of the project could be invited to present their findings at a future DSUR WG meeting. If their work aligns with DSUR objectives, there may be an opportunity for direct collaboration or knowledge-sharing. Corina, a member of the COMBINE project's working group 2, will reach out and investigate the possibility of arranging such a presentation.
    - Tessy is a member of a subgroup within European Federation of Pharmaceutical Industries and Associations) (EFPIA) working on the implementation of the EU Clinical Trials Regulation (CTR) and its impact on DSURs. Future collaboration is welcome.
    - Antonella is a member of the Clinical Trials Coordination Group (CTCG) safety subgroup involved in the drafting of regulatory documents on safety in clinical trials. As a CTCG safety subgroup member, she is currently part of a subgroup working on the revision/simplification of the Clinical Trials Regulation (EU) NO 536/2014 Questions & Answers (last version n° 7 dated JAN-2025), for the safety part.
    - TransCelerate BioPharma Inc. may also be working on DSUR-related topics. There was a suggestion to reach out to Transcelerate representatives to determine if there is potential overlap or opportunities for collaboration.
    - Project on Artificial Intelligence from various initiatives, including CIOMS WG XIV on Artificial Intelligence in Pharmacovigilance are to be monitored.
- WG members are welcome to share relevant publications via the CIOMS Secretariat, which will then be posted to the WG's password-protected area of CIOMS´ website.

- **Involving stakeholders**
- CIOMS working groups traditionally involve three primary stakeholder groups: regulators, industry Experts and academia. However, in this case, academia's involvement has been minimal, as academic institutions typically do not engage deeply in DSUR-related activities. Participants were encouraged to propose additional stakeholders who could provide value to the WG.
- Input from ethics committees could add value by applying their risk-benefit expertise to DSUR assessments**.** Access to DSURs varies across different countries and regulatory frameworks.
- Ethics committees lack resources and specialised expertise in certain areas, which may limit their ability to assess complex clinical trials adequately.
- CIOMS Secretariat will explore engaging with the European Network of Ethics Committees to identify a relevant representative for future discussions.
- The WG raised the importance of engaging with the US FDA**,** given its influence in global regulatory frameworks. The group will continue to monitor opportunities to reconnect.
- The MHRA has expressed support for the WG but was unable to join this meeting. They have indicated their intention to nominate a representative for future discussions
- The group will maintain close collaboration with EMA and ensure alignment with ongoing European initiatives.

- **Access to DSURs in low-resource countries and use in pandemic situations**
- In many low- and middle-income countries (LMICs), DSUR submission is not mandated, leading to limited regulatory oversight of clinical trials. The absence of clear regulatory requirements results in fragmented access to safety data, making it difficult to monitor clinical trial safety in real time.
- Even when DSURs are available, some LMIC regulators lack the expertise to analyse them effectively. Instead of customizing DSURs for different countries, training programs and reliance mechanisms could be strengthened.
- Instead of customizing DSURs per country, focus on enhancing local expertise through training and regulatory reliance and work-sharing.
- Future training sessions or webinars could help regulators better interpret DSURs.
- DSURs were not the primary safety reporting tool during COVID-19 due to delayed periodicity**.** Alternative reporting mechanisms (e.g., monthly safety updates) played a greater role in pandemic pharmacovigilance.
- The application of Development Safety Update Reports (DSURs) in pharmacovigilance for pandemic response could be further investigated, particularly during the accelerated development of new vaccines and medicinal products. A modified DSUR format for emergency situations could be explored.

- **Enhancing DSUR format & clarity**
- We should consider adding guidance on long-term follow-up requirements for gene therapy and tissue-engineered products and clarify investigational product reporting requirements in complex trials.
- Industry should better explain safety decision-making processes in the DSUR.
- A dedicated section on safety signal management could reduce repetitive regulatory queries.
- Consider simplifying and structuring DSUR summaries to be more accessible.
- Scientific-style formatting would improve narrative clarity and logical flow.
- We should define minimum content requirements to ensure consistent reporting across companies.

- **Artificial Intelligence & Non-Commercial DSURs**
- AI was raised by multiple stakeholders as a potential tool to improve DSUR quality and risk assessment.
- The CIOMS Working Group on AI in Pharmacovigilance is currently developing a guidance document. This will soon be open for public consultation. While the current guidance does not focus solely on DSURs, some higher-level AI principles may be applicable to the DSUR process.
- The WG were encouraged to review the draft guidance once available and provide input from a DSUR-specific perspective.
- AI could enhance data validation and consistency, ensuring that submitted DSURs contain high-quality information.
- AI can support risk assessment by analysing large datasets from clinical trials.
- There is a need for AI-driven models to help determine ongoing trial risks and benefit-risk balance.
- When AI is utilized to support risk assessment by analysing safety data from clinical trials, it is necessary to ensure the protection of confidential information and prevent breaches of sensitive patient data.
- Further discussions are needed to explore how AI could be integrated into DSUR risk assessment frameworks.
- Industry and regulators must work together to ensure AI transparency and reliability.
- Non-commercial sponsors (e.g., academic institutions) often lack resources to prepare full DSURs.

- Many submit DSURs per individual clinical trial, which is not aligned with standard regulatory expectations.
- Regulators acknowledged the difficulty of assessing DSURs from non-commercial sponsors, as they often lack sufficient detail or do not follow standard formats.
- Some European regulators have introduced a reduced DSUR template for non-commercial sponsors running a single clinical trial with an authorized investigational medicinal product (IMP). This template allows sponsors to omit non-applicable sections and focus only on relevant safety data. It has been endorsed by the Clinical Trials Coordination Group (CTCG) and is now available on the HMA (Heads of Medicines Agencies) website.
- Limited awareness among non-commercial sponsors about the availability of the simplified DSUR format.
- Variable compliance levels – some sponsors either fail to meet guidance expectations or submit incomplete safety data
- There is a need for further regulatory support – ensuring non-commercial sponsors understand their DSUR obligations and can access appropriate resources.

3. Rethinking the DSUR: Format, Purpose, and Future Directions

- Should we modify the current DSUR format or create a new version (DSUR 2.0)?
- What should be the key objectives and structure of an improved DSUR?
- Rather than completely overhauling DSUR into a "DSUR 2.0," the WG agreed to revise and optimise the current format.
- The focus will be on removing redundancies, improving clarity, and making the report more useful for regulators and industry.
- A flexible, modular structure was proposed, where sections can be adapted based on product risk profile and stage of development.
- Companies would justify which sections are included/excluded based on scientific reasoning.
- A cumulative benefit-risk evaluation should be included, explaining decisions, signal detection, and risk minimization measures more clearly.
- The process for Reference Safety Information (RSI) updates and signal detection should be more transparent.
- Some data-heavy sections (e.g., cumulative Serious Adverse Event (SAE) listings) may be revised or moved to appendices.
- The most important sections (e.g., actions taken for safety reasons, benefit-risk assessment) will be prioritized.
- The use of clinical trial exposure-adjusted data instead of absolute numbers was emphasized to avoid misleading conclusions.
- The differences in regional DSUR requirements (e.g., China, EU, US) will be mapped to identify commonalities and avoid unnecessary duplication.
- Future changes may align with potential ICH E2F updates.

DAY 2

4. Working in subgroups

The WG split into two subgroups to discuss improvements to the DSUR process and format in a more in-depth way. Both groups were tasked with identifying improvements to the DSUR process and format to make it more meaningful and fit for the future, ensuring alignment with evolving regulatory needs and industry practices. The WG would then compare and consolidate insights from both groups.

- **Pete presented the first subgroup's work (group members: Pete, Tessy, Anita, Antonella, Eun Mi, Carmen, and Indra)**

1. Introduction

- The group proposed a modified DSUR template, improving focus while maintaining essential components.
- The revised format aims to be more structured, meaningful, and aligned with evolving regulatory and industry needs.
- The introduction should be an integral part of the document, setting the scene by summarizing current indications, formulations, and benefit-risk considerations.
- The status of ongoing clinical trials will be included here, with a reference to the IB effective at the beginning of the reporting period.

2. Clinical Trial Exposure Data

- This section will focus only on new indications, formulations, and populations rather than historical data.
- Demographic tables (age, race, sex, etc.) should be included here instead of in an appendix.
- Exposure data will be aligned with a modified SAE cumulative table to improve interpretability.

3. Line Listings and Summary Tabulations

- Line listings will focus on serious adverse reactions (SARs) occurring in the reporting period.
- The cumulative SAR tabulation will be reviewed, with an emphasis on making data more interpretable and relevant.
- SUSARs should be indicated clearly in the tables.
- Data should focus only on the drug under investigation, rather than all products used in a study.
- Cumulative SAE tabulations should be structured by indication, study, formulation, and population for better clarity.

4. Clinical Trial Safety Review Process

- This section will provide an overview of the company's safety review process, which is meant to assure reviewers that a robust process is in place for safety evaluations without unnecessary data dumps.
- Routine assessments and the corresponding actions taken in response to findings will also be emphasised.

5. Actions Taken for Safety Reasons

- This section will summarise regulatory actions taken during the reporting period.
- Instead of a cumulative list, only ongoing or newly implemented actions will be included.
- If a study hold or restriction was placed previously, the DSUR should state whether it remains in place or has been lifted.

6. Overview of Safety Signals

- A concise summary of new safety signals, including rationale and discussion, should be provided.
- A table of safety signals (aligned with PSUR requirements) will be included as an appendix.
- The focus should be on new or ongoing signals, with a clear rationale for any conclusions.

7. Summary of Identified Risks

- Important risks should be categorized into:
    - New important risks identified during the reporting period.
    - Cumulative important risks (summarised, with reference to a separate table).
    - New risks considered non-important during the period (if applicable).
- Discussions on risk minimization effectiveness assessment were inconclusive and will require further deliberation.

8. Summary of Benefits

- For marketed products, a summary of the existing benefit profile should be included.
- For investigational products, the summary should be based on mode of action, related compounds, non-clinical data, and early-phase clinical trials.
- Emerging efficacy data from completed trials should be discussed, particularly for new indications.

9. Benefit-Risk Considerations

- This section should integrate the findings from risk and benefit sections, evaluating their impact on ongoing trials.
- It should conclude whether the benefit-risk profile remains favourable, unknown, or unfavourable.

10. Late-Breaking Information

- This section should focus only on key developments occurring between the data lock point and finalisation of the DSUR. This could include:
    - Urgent safety measures.
    - Important regulatory actions.
    - Emerging safety findings requiring immediate attention.

11. Conclusion

- A final summary reinforcing the safety status of the product and any pending safety issues.

12. Appendices

- The following were identified as critical appendices:
  - Table of Safety Signals.
  - Line listing of serious adverse reactions - SARs (highlighting suspected unexpected serious adverse reactions - SUSARs).
  - Investigator's Brochure (if required by regulators, though rarely requested).

- The proposed modifications aim to streamline the DSUR process by making the document more focused and eliminating redundant information.
- The new structure will prioritise meaningful safety data rather than exhaustive but unhelpful content.

Discussion points following the subgroup presentation

- Clearer alignment between clinical trial exposure data and SAE tables will improve data interpretation.
- Further discussions are required on risk minimization effectiveness and whether additional cumulative summaries are needed.
- The revised DSUR should be a better tool for both regulators and industry, improving efficiency and decision-making.
- Focus on new indications, formulations, and populations rather than including closed-out programs or historical data.
- Tables on demographics (age, race, etc.) will be included directly in the main document instead of appendices.
- Serious Adverse Reactions (SARs) will be reported only for the drug under investigation, rather than all products in the study.
- The cumulative Serious Adverse Event (SAE) table will be restructured to separate data by indication, formulation, and population to improve readability.

- Emphasis on line listings of SUSARs, with specific differentiation from cumulative SAR listings.
- Inclusion of deaths and their contextual analysis was strongly recommended.
- The classification of "signals" in early-phase trials was debated. It was suggested that a different term may be needed to reflect the evolving nature of safety data in development vs. post-marketing.

- The listing of regulatory actions will be limited to those impacting safety and trial continuity, excluding irrelevant administrative actions.
- Cumulative tables of past regulatory restrictions will be replaced with a summary of ongoing or newly imposed restrictions.
- The summary of safety profile section will integrate signals, emerging risks, and observed trends, rather than presenting them in isolation.

- The benefit-risk assessment will be refined to:
  - Focus on new and emerging efficacy data rather than revisiting historical studies.
  - Summarise anticipated benefits based on mode of action, non-clinical data, and comparator studies.
  - Provide a clear narrative linking risks and benefits.

- The late-breaking section will only include urgent safety updates (e.g., regulatory actions, major risk changes).
- Appendices will include key tables such as signals, line listings, and RSI-related updates, but will be streamlined to avoid unnecessary duplication.

- Further clarity is needed on RSI definitions and how it relates to safety reporting.
- The working group will review regulatory expectations for cumulative vs. interval safety data.
- A harmonized approach to signal evaluation in early-phase trials will be explored.

- **Peter presented subgroup 2 work (group members: Peter, Donald, Andrzej, Mamiko, Juliana, Corina)**

  - The second group had a similar overall structure but with key differences in approach.
  - Emphasis was placed on telling a structured safety story, ensuring the document provides regulators with a clear and concise overview of safety operations.
  - The introduction should provide a high-level overview of the investigational medicinal product (IMP), its indications, regulatory status, and historical development to give a comprehensive understanding of the programme.

  1. Programme Status & Safety Actions

  - A detailed programme status section was proposed, covering:
    - Historical and ongoing clinical trials
    - New trials initiated and those completed during the reporting period
    - Cumulative exposure data
    - Special cases (e.g., investigator-initiated studies, long-term follow-ups, DSMBs)
  - Actions taken for safety reasons should be placed upfront, including:
    - Urgent safety measures
    - Significant late-breaking information (post-data lock point)
    - Regulatory holds or major amendments

  2. RSI & Safety Profile Evolution

  - Proposed a clear distinction between RSI (expectedness assessment) and the core safety profile of the drug.
  - The development safety profile should track evolving risks, ensuring clarity on how risks are being identified, assessed, and managed over time.

  3. Preclinical & Clinical Safety Data

  - Preclinical data should be summarised only when relevant to clinical safety.
  - The clinical safety section should integrate:
    - Investigational use signals (distinct from post-marketing signals)
    - Newly identified risks and their mitigations
    - Effectiveness of risk minimization measures (e.g., did safety interventions reduce adverse events?)
  - The aggregate safety review should provide:
    - Interval-based safety data (by trial)
    - Cumulative safety trends and emerging issues including impact of postmarketing signals
    - A structured overview of serious adverse reactions (SARS) per study rather than an undifferentiated dataset

  4. Benefit-Risk Discussion

  - Major debate on whether benefit-risk should be included:

- Some advocated for avoiding efficacy discussions due to commercial sensitivity and the evolving nature of data in development.
- Others argued that some level of expected benefit is necessary for contextualizing risk.
- A possible compromise: including preclinical and mechanistic expectations rather than emerging efficacy data.

5. Reporting Format & Frequency

- Discussion on whether the annual DSUR timeline is still appropriate.
- Some questioned if a more flexible approach based on risk assessment could be feasible.
- Consensus remained that the DSUR is still needed, as it provides a structured snapshot of safety in trials, distinct from IBs, urgent safety measures, or regulatory reports.

6. Aggregate Safety Review & Future Considerations

- Debate on how to incorporate aggregate safety analysis in clinical development:
  - The US FDA has raised expectations for cumulative safety reviews, but clear global guidance is lacking.
  - A structured guidance on how to conduct aggregate safety assessments during development could be helpful, especially for smaller sponsors.
  - Further brainstorming is needed on when and how aggregate safety reviews should be performed.

Key Takeaways from the subgroups' presentations:

- Both groups share a common vision:
  - Reducing unnecessary data, increasing clarity, and focusing on meaningful safety insights.
- Agreement on avoiding excessive "checkbox reporting" and instead focusing on scientific judgment and interpretability.
- The next steps involve:
  - Aligning on how flexible the structure should be
  - Further defining investigational safety signals vs. post-marketing signals
  - Determining the role of benefit-risk discussion
  - Exploring aggregate safety review frameworks

5. Way of working

Lembit explained a few practical matters about the CIOMS WGs in general:

- Each CIOMS group finalises a guideline, usually in 2-4 years, which will be both in electronic and print formats. All CIOMS reports are free to be downloaded from the CIOMS website.
- The draft minutes from meetings will always be provided to the members to review and approve before being uploaded to the public WG page on the CIOMS website.
- Where WG members consent to meetings being recorded for the purposes for taking minutes, the recordings will not be used for any other purpose and will be deleted as soon as possible.

- The CIOMS Secretariat will help with setting up Zoom meetings, writing minutes, and will assist with general communications.
- Each WG has its own section on the CIOMS website where the WG documents are available. Some content is open to the public e.g. the Concept Note and full WG meeting minutes, and other content is available only to the WG members behind password-protection e.g. working documents and publications of outstanding importance shared among the WG members.
- SharePoint will be explored as a platform for document collaboration. If SharePoint is not effective, an alternative password-protected section on the CIOMS website will be used for document access.
- If the WG agrees on it, the final document will go through a public consultation phase before official publication.
- The consultation process may include patient groups, academia, and regulators to gather diverse perspectives.

6. Next steps / next meeting

- The dates will be researched, and a Doodle poll will be circulated asap.
- Post-meeting comment: the next, virtual WG meeting will take place on 3 June 2025.
- A dedicated subgroup including regulators and industry members: Tessy, Indra, Antonella, Donald, Peter, Corina, and Pete, will consolidate the two proposals into a single revised DSUR draft. The subgroup will meet separately in the interim to finalise content. Once the merged draft is ready, it will be sent to the full group at least a week before the 3 June meeting for review.

7. Closing remarks

Hervé and Lembit thanked the WG members for joining in-person and virtually, and for the productive discussions.

8. Actions

Who?	What?
All members	• Inform CIOMS Secretariat on additional initiatives relevant to the CIOOMS WG that the members are aware of or participate in. • Reach out to TransCelerate BioPharma Inc. and investigate the possibility of knowledge-sharing related to DSURs • Propose additional stakeholders who could provide value to the WG.
Lembit	• Explore engaging with the European Network of Ethics Committees to identify a relevant representative for future discussions. • Continue discussions with MHRA to agree on a representative for future discussions. [done]
Corina	• Corina will reach out to the COMBINE project's WG and investigate the possibility of arranging a presentation for the next full WG meeting.

Tessy, Indra, Corina, Antonella, Peter, Pete, and Donald	• Consolidate the two proposals into a single revised DSUR draft • Distribute the draft a week before the next full WG meeting.
Kateriina	• Share the Benefit-Risk WG's draft report with the DSUR WG for reference. [done] • Research potential dates and circulate a Doodle poll to schedule the next virtual meeting for late May-June 2025. [done] • Research dates and circulate a Doodle poll for the subgroup meeting. [done] • Circulate the draft meeting minutes. [done]

9. Annex 1: List of participants

Attending in person

Antonella Caselli (Italian Medicines Agency), Carmen Campanile (Swissmedic), Andrzej Czarnecki (Eli Lilly), Peter De Veene (MSD), Juliana Dornelles (ANVISA), Mamiko Konishi (Eisai), Hervé Le Louët (CIOMS), Eun Mi Kim (WHO), Pete Nash (Gilead), Donald Puccio (Pfizer), Kateriina Rannula (CIOMS), Lembit Rägo (CIOMS), Tessy Ruijgrok (Biogen), Anita Shenoy (AbbVie), Corina Spreitzer (Austrian Medicines Agency), and Indra Purevjal (Bayer).

Attending virtually

Mutsuhiro Ikuma (PMDA), Elena Prokofyeva (FAMHP), Wang Xiangyu (NMPA), Wang Haixue (NMPA), Maria Grazia Malpezzi * (Italian Medicines Agency), and Panos Tsintis (CIOMS Senior Adviser).

*Alternate

Apologies
Beatrice Panico (Individual expert) and Richard Pendlebury (Novartis).