



Fourth Meeting of the CIOMS Working Group on MedDRA Labeling Groupings (MLG)-Virtual Meeting 04 March 2021

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Report from the CIOMS Secretariat

Dr Lembit Rägo welcomed participants of the MedDRA Labeling Groupings (MLG), Expert Working Group (EWG) fourth meeting. Short zoom Introduction was completed.

The group reviewed minutes from the MLG EWG third meeting. Dr Lembit Rägo updated the group on CIOMS activities with all the current CIOMS working groups.

Review of the EWG work for MLG Examples, Manuscript and General discussion

The MLG EWG proposed draft manuscript capturing the work of MLG EWG thus far. A detailed discussion ensued encompassing all the sections of the draft manuscript including the MLG principles.

The EWG came to a consensus for the next steps for the draft manuscript publication.

The EWG discussed their experience and methodology of creating the MLG examples. The EWG reviewed the MLG Examples and discussed the pros and cons of methodology of the creating MLG examples.

The EWG also discussed next steps to continue developing MLG examples and creation of a potential CIOMS working group report, envisioned as a more comprehensive report for key stakeholder review.

Next Steps

Participants agreed on the following next steps:

1. EWG continue their efforts on publication of the manuscript.
2. The EWG plan to work towards a CIOMS working group report.

Date of next meeting

To be determined.

Participants

CIOMS	Lembit Rägo Susanne Le Roux	Secretary-General Administrative Officer
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Regulators	Scott Proestel Kanae Kobayashi Tomohiko Hara Yutaka Nagao Alima Tapsoba Lynn Macdonald Norbert Paeschke Aniello Santoro	FDA, U.S. PMDA, Japan PMDA , Japan MedDRA, Japan Health Canada Independent BfArM, Germany European Medicines Agency (EMA)
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