



## **Third Meeting of the CIOMS Working Group on MedDRA Labeling Groupings (MLG)-Virtual Meeting**

25–26 August 2020

By video conference

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### **Report from the MedDRA Labeling Groupings (MLGs) Expert Working Group (EWG)**

The CIOMS MLG EWG 3rd meeting was conducted virtually on Zoom. A short Zoom introduction and Zoom housekeeping rules were described by Susanne Le Roux. Ilona Große-Michaelis welcomed the participants of CIOMS 3rd Virtual meeting of MedDRA Labeling Groupings (MLG) Expert Working Group (EWG). Lembit Rägo shared with the EWG briefly that all working groups are well adjusted to the new normal in the pandemic and are continuing their work. Lembit shared his vision for this MLG EWG and offered support and encouragement.

The group reviewed minutes from the MLG EWG second meeting and the virtual DIA 2020 presentation.

### **Minute of Silence for Dr. Judith Jones**

One Minute silence was observed to pay respects to Dr. Judith Jones as a colleague and to her contributions to CIOMS Working Groups.

### **Review of ICH MedDRA Management Committee Response, MLG Principles, and General Discussion**

The MLG EWG reviewed the document response for “questions and points for clarification” from ICH. Following this review, a detailed discussion ensued on aligning the principles referred to in this response to the MLG principles created by the EWG.

The EWG discussed in detail the scope of MLGs in terms of transparency of the Preferred Terms used in the MLG.



The team further considered the use of MLGs for Adverse Drug Reaction (ADR) representation in product label for communicating safety information to healthcare providers and MLG use for signal detection using examples of MLGs.

The EWG also reviewed topics such as long-term support for maintenance of MLGs.

The team reviewed at length the proposed MLG principles and achieved consensus on a group of MLG principles.

The EWG finalized the ICH Response document and MLG principles document and is anticipating feedback from the ICH.

The EWG also discussed next steps for a potential manuscript (report), delineating these MLG principles and the concepts captured by the EWG.

## **General Discussion and Next Steps**

Participants agreed on the following next steps:

1. EWG continue their work on creating examples of MLGs to gain practical experience with potential international consensus
2. EWG work towards writing a manuscript for publication
3. Propose the MLG Principles and response document to ICH MedDRA Management Committee

## **Date of next meeting**

The date of the next meeting is currently pending.



## Participants

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### CIOMS

Lembit Rägo	Secretary-General
Susanne Le Roux	Administrative Officer

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### Regulators

Scott Proestel	FDA, U.S.
Sonja Brajovic	FDA, U.S.
Kanae Kobayashi	PMDA, Japan
Tomohiko Hara	PMDA, Japan
Yutaka Nagao	MedDRA, Japan
Tomoko Narita	MedDRA, Japan
Alima Tapsoba	Health Canada
Lynn Macdonald	Health Canada
Aniello Santoro	European Medicines Agency (EMA)

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### Product R&D

Brian S Dillman	Eli Lilly
Ilona Große-Michaelis	Bayer
Diane Farkas	Sanofi Aventis (Day one)
Radhika Rao	AbbVie
Andrea Brown	Gilead
Silvia Bader-Weder	Roche
Christiane Michel	Novartis

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