



Draft Agenda

Fourteenth meeting of the CIOMS Implementation Working Group on Standardised MedDRA Queries (SMQs)

11-12 September 2018

CIOMS offices, Ecumenical Centre, 150 Route de Ferney, 1218 Geneva, Switzerland

Tuesday 11 September: Opening and CIOMS report **09:30-10:15**
 MedDRA Labelling Groupings **10:15-12:30**
 SMQs **13:30-17:30**

Wednesday 12 September: MLGs optional session: input for ISOP presentation **10:00–11:00**
 MLGs plenary session: ISOP presentation **11:15-12:15**
 FDA Presentation SMQ Analysis **14:00-15:00**

DAY ONE: Tuesday 11 September

1. **Opening and Tour de Table (CIOMS)**
2. **Election of Chairpersons and Rapporteurs (CIOMS)**
3. **Approval of the Agenda and previous meeting minutes (CIOMS)**
4. **Report from the CIOMS Secretariat (CIOMS)**
5. **MedDRA Labelling Groupings (Grosse-Michaelis, Brajovic, Gregory, Jones, MacDonald, Santoro)**

12:30 – 13:30 Lunch

6. **Logistics and date for next meeting**
7. **Status of SMQs in production in v21.1 (Moraleda)**
 - 7.1. **New SMQs in production**

No new SMQs went into production in v21.1



7.2. Status of change requests resulting from IWG activity

SMQ *Acute renal failure*. PT *Hyponatriuria* was moved from narrow scope to broad scope.

7.3. Status of 18–24 month production review

8. Discuss **Review of SMQ Medication errors**, which came into production 2 years ago, in v19.0 as part of SMQ batch #29 (**Brajovic**) **Status of SMQs in Development/Evaluation**

8.1. Hypokalaemia (Michel, Grosse-Michaelis, Jones.)

Discuss final documentation status.

8.2. Opportunistic infections (Mirea, Bader-Weder, Jones, Ohta, Paeschke, Moraleda).

Discuss final documentation status.

8.3. Progressive multifocal leukoencephalopathy (Jones, Bader-Weder, Michel).

Discuss final documentation status.

7.4 Hallucinations (Michel, MacDonald, Jones)

Discuss final documentation status.

7.5 Autoimmune diseases/Immune mediated medical conditions (Bader-Weder, Brajovic).

Report on testing results.

9. Hepatic disorders (Paeschke, Bader-Weder, Jones, Brajovic, Michel)

Discuss modification of SMQ to better address DILI.
Review minutes from CIOMS DILI group.

DAY TWO: Wednesday 12 September

10. MedDRA Labelling Groupings 10:00-11:00 – optional session: preparing the ISOP presentation

11:00-11:15 Coffee

11. MedDRA Labelling Groupings 11:15-12:15 – plenary session: ISOP presentation

12:15 – 14:00 Lunch

12. Presentation from FDA on SMQ Analysis (followed by discussion) 14:00-15:00
(Chris Breder - remote)

Close of meeting 3pm

*The traditional WG dinner will be hosted by CIOMS on Tuesday 11 September
7pm at Relais de Chambésy, Place de Chambésy 8, 1292 Pregny-Chambésy*