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CIOMS Glossaries

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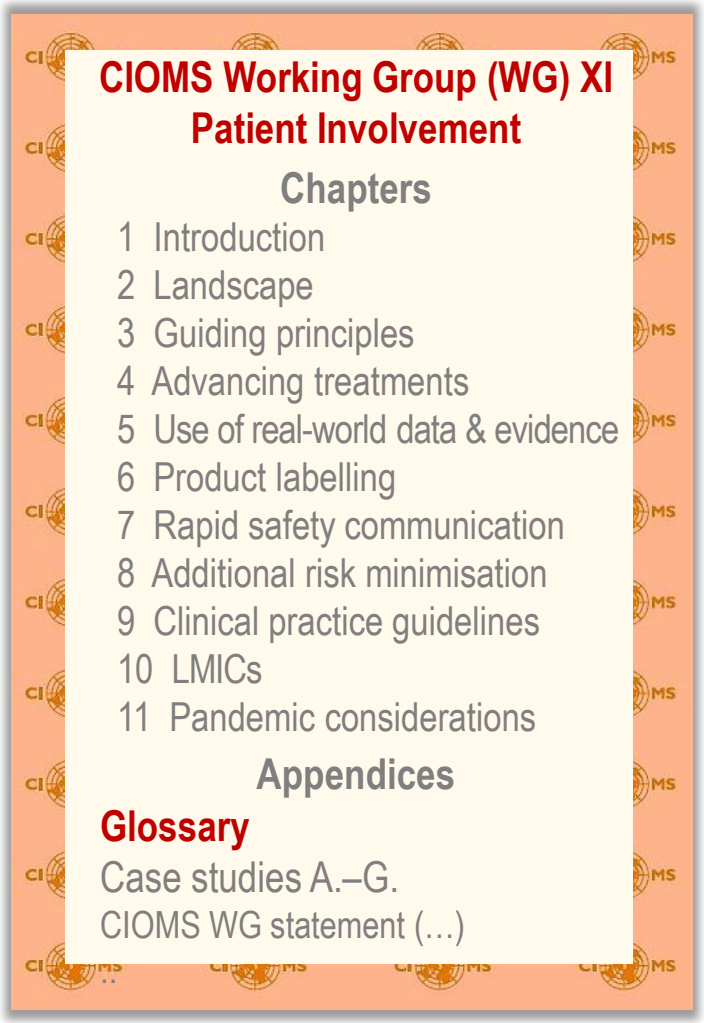
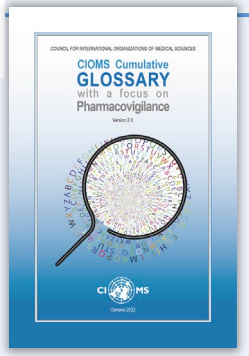
How the glossaries came about



1. WG XI had a dedicated "Glossary" subgroup
   Collected definitions from past CIOMS pharmacovigilance (PV) Working Group reports
   - →03/2021 CIOMS Cumulative PV glossary 1.0
   - →06/2021 CIOMS Cumulative PV glossary 1.1 (+ vaccine terms)
   - →**09/2022 CIOMS Working Group (WG) XI report published**
   - →**09/2022 CIOMS Cumulative Glossary with a focus on PV, Version 2.0 (broadened scope)**

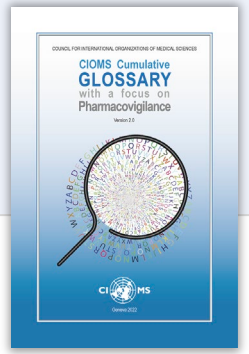
2. CIOMS reports include some ICH definitions, and vice-versa.
   In 2022 CIOMS started compiling ICH definitions as a tool for CIOMS and other stakeholders
   - →**09/2022 Glossary of ICH terms and definitions**

1. CIOMS Cumulative Glossary (1/2)



- Shows CIOMS recommended definitions of terms used in pharmacovigilance and related fields, for informational and educational purposes
- Published at a time of increased global interest in the safety and effectiveness of medicinal products (COVID-19)
- Current version (2.0) combines the terms and definitions of twelve published CIOMS Working Group reports
- Shows evolving definitions over time – see example on next slide ▶
- **Freely available at:**
  https //doi.org/10.56759/ocef1297

Evolving definitions – example: "Risk"



Most recent definition is emphasized

247. **Risk** (CIOMS XI: Patient involvement 2022)

The probability of an adverse event, or an outcome, in a defined population over a specified time interval.

Modified from: A dictionary of Epidemiology. 6th edition. Miquel Porta (editor). Oxford University Press; 2014. (Online dictionary accessed 8 February 2022)

Risk (CIOMS IX: Risk minimisation 2014 | Japanese)

The probability of developing undesirable outcomes relating to the quality, safety or efficacy of the medici… patients' health or public health or any… regard to the environment.

Combined from:
Lindquist, M. The need for definitions in pharmacov… 830.
EU Guideline on good pharmacovigilance practices (GVP) – Annex I - Definitions (28 April 2014).

Risk (CIOMS VIII: Signal detection 2010 | Chinese)

The probability of developing an outcome.

Note: The term risk normally, but not always, refers to a negative outcome. When used for medicinal products, the concept of risk concerns adverse drug reactions. Contrary to harm, the concept of risk does not involve severity of an outcome. The time interval at risk should be specified.

Modified from: Lindquist, M. The need for definitions in pharmacovigilance. Drug Safety, 2007, 30:825-830.

=Hyperlinks to CIOMS guidelines
=Hyperlinks to translations

Risk (CIOMS VI: Clinical trial safety information 2005) New: Chinese

{Synonym in CIOMS VI: Absolute risk}

…f adverse experiences, it is the proportion of … event out of all those who could possibly …oups can be compared either by taking their … subtracting the two risks. The latter is called an absolute risk difference.

Proposed by CIOMS Working Group VI.

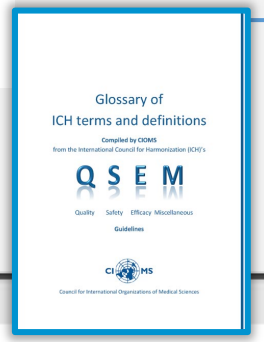
Risk (CIOMS IV: Benefit-risk 1998)

The simple, standard, epidemiological definition of risk is the probability that something will happen.

Note: In the context of medical interventions (drugs, *e.g.*), the "something" is almost always associated with a negative event. In defining or describing a specific risk, it is always important to include information on intensity (severity, *e.g.*), time of the event (onset or duration), and time period over which the probability applies. Some definitions attempt to include concepts of rate, intensity and time: The probability of the occurrence of an adverse or untoward outcome and the severity of the resultant harm to the health of individuals in a defined population, associated with the use of a medical technology for a specified medical problem under specified conditions of use.

Proposed by CIOMS Working Group IV.

2. Glossary of ICH terms and definitions



- Includes >1000 definitions from the current, publicly available ICH guidelines and Q&A documents
- Has a list of guidelines referenced, with links to PDFs on the ICH website
- **Freely available at:** https://doi.org/10.56759/eftb6868

Example: "Risk"

Risk

E8(R1) General Considerations for Clinical Studies, 3.2

The term risk is used here in the context of general risk management methodology applicable to all factors of a study.

Q3D(R2) Guideline for Elemental Impurities, Glossary

The combination of the probability of occurrence of harm
Guide51, ICH Q9)

Guideline subheading, with section where the definition is found

Q9 Quality Risk Management, Definitions

The combination of the probability of occurrence of harm and the severity of that harm (ISO/IEC Guide 51).
{Reference: ISO/IEC Guide 51:1999 - Safety Aspects - Guideline for their inclusion in standards.}

Q9(R1) EWG Quality Risk Management, Definitions

The combination of the probability of occurrence of harm and the severity of that harm (ISO/IEC Guide 51).
{Reference: ISO/IEC Guide 51:2014 - Safety Aspects - Guideline for their inclusion in standards.}

Conclusions

- Both glossaries are freely available on the CIOMS website
- Periodically updated as new guidelines are published
- Can be useful to support training, e.g. of patient experts

▶ CIOMS welcomes your feedback

- Suggestions for improvement?
- Feedback from use in patient engagement initiatives?

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Thank you

Questions?