CIOMS Research Guidelines: Considering the Needs of Developing Countries

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Webinar

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CIOMS – Introduction ([https://cioms.ch/](https://cioms.ch/))

Council for International Organizations of Medical Sciences

Founded in 1949 by WHO and UNESCO

In official relations with WHO

UNESCO associated partner

ICH Observer since 2016

Mission Statement

CIOMS mission is to advance public health through guidance on health research including ethics, medical product development and safety
CIOMS membership

2023 - European Network of Research Ethics Committees (EUREC) joined CIOMS
• In the mid-1960s, the world went through some huge political and technological developments. At the same time, biomedical scientific and technological advances were transforming the practice and potential of medicine, with unprecedented social, cultural and ethical implications.

• In 1977 the World Health Assembly adopted the goal of *health for all*. This asserted the need for health policy to be informed by ethics and human values, indicating the field in which CIOMS could best complement the work of WHO.

• A particular aspect of biomedical technology—*the development and safe use of medicines*—became another dominant theme of CIOMS. Since the 1990s most of CIOMS working groups have focused on various aspects of pharmacovigilance without abandoning research ethics and other topics of product development.
**Main areas of work**

**Bioethics**

- Since 1967; 1st CIOMS Round Table Conference 'Biomedical Science and the dilemma of Human Experimentation'
- Issued significant guidelines
  - Latest revision 2016
- Focus on ‘low-and middle-income countries’
- Available in 10 languages, e.g. Chinese, Spanish, Japanese, Russian

**Pharmacovigilance**

- 1986: first PV Working Group
- 13 more working group reports to date
- Several ICH Guidelines are based on results of CIOMS Working Groups
- Cumulative Glossary 2021

**Product development**

- Since 1977 CIOMS Round Table Conference, ‘Trends and Prospects in Drug Research and Development’ ....
- 2021: Clinical Research in Resource-Limited Settings, CIOMS Working Group report
- 2022: Patient Involvement … WG XI
- 2022: Glossary of ICH terms and definitions
CIOMS Recent Pharmacovigilance-related Publications

https://cioms.ch/publications/

Chinese translation was made available in 2018
CHAPTER 8. LIVER INJURY ATTRIBUTED TO HERBAL AND DIETARY SUPPLEMENTS

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SUPPLEMENTAL APPENDICES

Online only – freely available on the CIOMS website at:

APPENDIX 5 Data analysis for DILI assessment: Supplemental figures

APPENDIX 6 Genetic susceptibility loci for DILI identified in GWAS and candidate gene studies

APPENDIX 7 DILI registries and epidemiological studies

APPENDIX 8 Information on DILI risks shown in product information of selected drug classes
Anti-cancer drugs
Tuberculosis chemotherapies
Antiretrovirals

APPENDIX 9 Differences in label safety information on hepatotoxicity: Two examples

APPENDIX 10 Example of a causality assessment process for HDS-induced liver injury: the algorithm used in China

APPENDIX 11 Post-publication updates

https://doi.org/10.56759/ojsg8296
New training online courses

• Joint CIOMS/Uppsala Monitoring Centre (UMC) training modules based on CIOMS DILI WG report (started 2021, finalized April 2022)

May 2022
Enrolled learners: 270
Completed the course and received a certificate: 130

In 2023
Average per month enrolled learners 130, and 65 certificate
CIOMS latest, 2016 Ethical Guidelines - In all 6 UN languages + Japanese, Korean, Polish, Portuguese, Ukrainian ...
<table>
<thead>
<tr>
<th>1 – Scientific and social value and respect for rights</th>
<th>10 – Modifications and waivers of informed consent</th>
<th>18 – Women as research participants</th>
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<td>2 – Research conducted in low-resource settings</td>
<td>11 – Collection, storage and use of biological materials and related data</td>
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<td>3 – Equitable distribution of benefits and burdens in the selection of groups of participants</td>
<td>12 – Collection, storage and use of data in health-related research</td>
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<td>4 – Potential benefits and risks of research</td>
<td>13 – Reimbursement and compensation for research participants</td>
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<td>6 – Caring for participants’ health needs</td>
<td>15 – Research involving vulnerable persons</td>
<td>23 – Research ethics committees and review</td>
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<td>7 – Community engagement</td>
<td>16 – Research involving individuals who are incapable of giving informed consent</td>
<td>24 – Public accountability</td>
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<td>8 – Collaborative partnership and capacity building</td>
<td>17 – Research involving children and adolescents</td>
<td>25 – Conflicts of interest</td>
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E-training course

https://cioms.blendleren.nl/Navigating-the-2016-CIOMS-International-Ethical-Guidelines

Introducing the course

Learning objectives

This course will help you to grasp and to navigate the 2016 CIOMS International Ethical Guidelines for Health-related research.

At the end of the course you will ...

- be able to navigate the Guidelines in order to find the Guidelines applicable to your case,
- have a comprehensive idea of the topics described in the Guidelines,
- understand the position of CIOMS on specific issues, such as the use of placebo or the level of acceptable risks.
Clinical research in resource-limited settings

A consensus by a CIOMS Working Group
Council for International Organizations of Medical Sciences (CIOMS)

CIOMS 2021

https://doi.org/10.56759/cyqe7288
## Report Content

**Clinical research in resource-limited settings**

A consensus by a CIOMS Working Group

Council for International Organizations of Medical Sciences (CIOMS)

- **Foreword**
- **Executive summary**
- **Recommendations**
- **Chapter 1: Background and problem statement**
- **Chapter 2: The Research environment: obstacles and enablers**
- **Chapter 3: Guiding principles for clinical research**
- **Chapter 4: Ethical considerations**
- **Chapter 5: Scientific considerations**
- **Conclusion**
- **References**

**Appendices:**
1. Special populations
2. Digital technology and electronic health records
3. Outbreaks
4. Cervical cancer screening in India
5. Pharmacogenetics and personalized medicines
6. CIOMS WG membership and meetings
7. List of commentators
CIOMS WG XI: Patient Involvement in the Development, Regulation and Safe Use of Medicines 2022

Report Content

- Ethical considerations for patient involvement
  - Executive summary
  - Chapter 1: Introduction
  - Chapter 2: Landscape
  - Chapter 3: Guiding principles
  - Chapter 4: Advancing treatments
  - Chapter 5: Use of real-world data and evidence
  - Chapter 6: Product labeling
  - Chapter 7: Rapid safety communication
  - Chapter 8: Additional risk minimization
  - Chapter 9: Clinical practice guideline
  - Chapter 10: Low- and middle-income countries
  - Chapter 11: Pandemic considerations

Appendices:
1. Glossary
2. Case studies
3. CIOMS WG XI statement
4. CIOMS WG membership and meetings
5. List of commentators

https://doi.org/10.56759/iiew8982
Some snapshots

Figure 1a: Patient involvement during a medicine life-cycle

Pre-authorization period
Some snapshots (ct’d)

Figure 1b: Patient involvement during a medicine life-cycle

Post-authorization period
### Appendices

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<th>Glossary</th>
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<td><strong>Case studies</strong></td>
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<tr>
<td>A</td>
<td>Medication formulation created to meet patients’ and doctors’ needs (AdrenalNET)</td>
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<tr>
<td>B</td>
<td>A regulatory agency involving patients; public hearing on valproate (EMA)</td>
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<td>C</td>
<td>Pilot collaboration between Lareb and a patient organisation in communicating a signal (Lareb)</td>
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<td>D</td>
<td>Creating partnerships between industry and patient groups for therapy development (Roche)</td>
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<td>E</td>
<td>Example of a pharmaceutical company working with patients to develop an additional risk minimisation measure</td>
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<td>F</td>
<td>Engaging patients in early development plans for a novel treatment (Takeda)</td>
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<td>G</td>
<td>Patient activism to counter AIDS denialism and improve access to HIV medicines in South Africa</td>
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### Each case study describes:

- Purpose and objective of the case study
- Pharmacology
- Indication/disease treated
- Stage of the drug development lifecycle
- Why were patients involved?
- How was contact established with the patients?
- What did the patients do?
- Was the process adjusted to the patients’ needs?
- If patients were asked to help disseminate information, how was it done?
- Did the patients receive payment or compensation?
- Were any patient requests or recommendations discarded and why?
- Conclusion
- Contact details

(...
CIOMS Ongoing Working Groups in 2023

► MedDRA Labelling Groupings. Started April 2019 *

► Benefit-Risk Balance for Medicinal Products. CIOMS WG XII. Started: September 2019 *

► Real-World Data and Real-World Evidence in Regulatory Decision-Making. CIOMS WG XIII. Started: March 2020 *

► Severe Cutaneous Adverse Reactions (SCARs). Started: February 2021 *

► Recommended Standards of Education and Training for Health Professionals Participating in Medicines Development. Started: April 2021


► Artificial Intelligence in Pharmacovigilance. CIOMS WG XIV. Started: May 2022

► Harnessing the potential of pharmacoepidemiology for public health. CIOMS WG XV. Started: November 2023

* Finalization in 2023
* Finalization in 1Q/2Q 2024
CIOMS Glossaries – 2 complementary successful projects

* First version in 2021.

https://doi.org/10.56759/ocef1297

* First Version in 2022

https://doi.org/10.56759/eftb6868
Instead of conclusion

Working for public health and patients has a little difficulty

No matter how good we are we can and should always do better!
Thank you for your attention