Cooperation

CIOMS - A nongovernmental organization in official relations with WHO

The Council for International Organizations of Medical Sciences (CIOMS) aims to facilitate and promote international activities in the field of biomedical sciences, in collaboration with the United Nations (UN) and WHO. CIOMS has initiated and coordinated major long-term programmes around the topics of *Health Policy, Ethics and Human Values - An International Dialogue* and *International Nomenclature of Diseases*. Currently the main activities are within the areas of bioethics and drug development and use.

Background

The Council for International Organizations of Medical Sciences (CIOMS)[1] was established by the World Health Organization (WHO) and the United Nations Educational, Scientific and Cultural Organization (UNESCO) in 1949. Its offices are located in Geneva, close to WHO and the UN Palais des Nations. CIOMS has enjoyed excellent relations with both its "parents" since its creation and is in official relations with WHO and an associate partner of UNESCO.

Through its membership, CIOMS is representative of the biomedical scientific community. The members of CIOMS include international and national professional associations, representing many of the biomedical disciplines, national academies of sciences and medical research councils *(Annex 1)*. WHO is represented by at least one senior staff member in all CIOMS working groups. CIOMS also cooperates with the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA).

Activities

In its more than six decades of existence, CIOMS has fostered a unique cooperation between specialized international medical associations and societies and other relevant stakeholders, and has promoted global activities in certain areas of the medical sciences whenever international cooperation is called for. CIOMS seeks to take into account the priorities, needs and resources of both industrialized and low-and-middle income countries (LMICs). As a nongovernmental organization, it is also able to draw on the considerable expertise existing in the research-based pharmaceutical industry where appropriate.

Bioethics

In the field of biomedical research involving human subjects, the World Medical Association (WMA) and CIOMS have been among the key international actors. In addition, the WHO input to

[1] www.cioms.ch

CIOMS activities in the field of research ethics is significant. A major output of this work have been the successive versions of the CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects *(1)*. First issued in 1982 and revised in 1993 and 2002, these guidelines have been conceived to facilitate the practical implementation of the WMA's Declaration of Helsinki *(2)* in WHO Member States, including low and middle income countries.

A public consultation is ongoing for an update of these guidelines in line with recent developments, including the revision of the Declaration of Helsinki in 2013. The proposed revised text integrates the previous guidelines for biomedical research and those for epidemiological research *(3)* in one document. The draft text covers 25 distinct areas *(Box 1)*, and is available for comments until 1st March 2016. This is a valuable opportunity for non-commercial research groups to provide their input.

Box 1. **Proposed updated CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects**

► Available for public comment until 1st March 2016*

Guideline 1	Social value
Guideline 2	Research conducted in low-resource settings
Guideline 3	Equitable distribution of benefits and burdens in the selection of groups of participants in research
Guideline 4	Potential benefits and risks of research
Guideline 5	Choice of control in clinical trials
Guideline 6	Caring for participants' health needs
Guideline 7	Community engagement
Guideline 8	Collaborative partnership and capacity building for research and review
Guideline 9	Individual informed consent
Guideline 10	Modifications and waivers of informed consent
Guideline 11	Use of stored biological materials and related data
Guideline 12	Use of health-related data in research
Guideline 13	Reimbursement and compensation for research participants
Guideline 14	Treatment and compensation for research-related harms
Guideline 15	Research involving vulnerable persons
Guideline 16	Research involving individuals who are not capable of giving informed consent
Guideline 17	Research involving children and adolescents
Guideline 18	Women as research participants
Guideline 19	Pregnant women and lactating women as research participants
Guideline 20	Research in disaster situations
Guideline 21	Implementation research
Guideline 22	Use of online information
Guideline 23	Research ethics committees and review
Guideline 24	Public accountability
Guideline 25	Conflicts of interest

* http://www.cioms.ch/index.php/guidelines-test

Box 2. **Drug development and use: examples of CIOMS documents***

- Management of drug safety data in the pre-and post-approval phases *(4, 5)*
- Adverse drug reaction terminology and reporting *(6)*
- International reporting of adverse drug reactions (CIOMS I reporting form**)
- Pharmacogenetics *(7)*
- Clinical pharmacology *(8)*
- Pharmacovigilance in resource-limited countries *(9)*
- Vaccine pharmacovigilance *(10)*
- Practical aspects of signal detection in pharmacovigilance *(11)*
- Practical approaches to risk minimization for medicinal products *(12)*

* The CIOMS publications are available through the web sites of CIOMS and WHO (see footnotes on the next page)

** www.cioms.ch/index.php/cioms-form-i

Drug development and use

CIOMS contributes significantly to the field of drug development and use. Its programme on drug development includes a series of working groups and other projects, which have addressed some fundamental topics and a wide range of issues centered around harmonizing the views of international systems and terminologies used for the safety surveillance of medicinal products and vaccines between stakeholders *(Box 2)*. Some of the documents emanating from this work have served as a basis for ICH development and have led to the adoption of regulatory documents in WHO Member States.

Given the aim of harmonization, it has been crucial to collaborate with all stakeholders. The independent status of CIOMS has permitted it to coordinate the contributions and expertise of senior scientists from research-based biopharmaceutical companies, national drug regulatory authorities, academia, and representative bodies of medical specialties to this harmonizing and strengthening of drug-safety surveillance measures. Scientists are invited to contribute based on their recognized specific expertise and, if required, in consultation with their background institution. Members and consulted experts and their affiliations are listed in the publications.

CIOMS publications

The consensus reports and documents discuss and recommend general principles and do not focus on individual medicinal products. As the CIOMS working groups have no legal jurisdiction or mandate to make binding decisions, reliance is placed on other bodies to incorporate the CIOMS recommendations, guidelines or good practices into a regulatory or legislative framework.

Two publications created by CIOMS working groups are expected to be finalized in 2015: a publication by the CIOMS Working Group X on meta-analysis practices for clinical safety data, and an update of the report on *Development and Rational Use of Standardised MedDRA® Queries (SMQs): Retrieving Adverse Drug Reactions with MedDRA (6)*. For 2016, a series of publications around vaccine safety and

communication is expected from a CIOMS Working Group on Vaccine Safety which was established in 2013 and is linked to WHO's Global Vaccine Safety Initiative (GVSI).

The findings and recommendations of groups convened under the auspices of CIOMS are widely disseminated. Many are available for ordering in printed form[2], while others can be consulted online and in several cases downloaded without charge[3]. CIOMS publications can also be purchased directly from the CIOMS Secretariat, from WHO[4], or from specialized bookshops. It should be emphasized that while the sole official versions of all CIOMS reports and guidelines are in English, several publications have been translated into other languages, generally at no cost to CIOMS.

References

1 International Ethical Guidelines for Biomedical Research Involving Human Subjects. Geneva: Council for International Organizations of Medical Sciences (CIOMS), 2002.

2 World Medical Association Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects. JAMA. 2013;310(20):2191-2194. doi:10.1001/jama.2013.281053.

3 International Ethical Guidelines on Epidemiological Studies. Geneva: Council for International Organizations of Medical Sciences (CIOMS), 2009.

4 Development Safety Update Report (DSUR) Harmonizing the Format and Content for Periodic Safety Report during Clinical Trials: Report of CIOMS Working Group VII. Geneva: Council for International Organizations ofCIOMS, 2006.

5 Management of Safety Information from Clinical Trials: Report of CIOMS Working Group VI. Geneva: CIOMS, 2005.

6 Development and Rational Use of Standardised MedDRA Queries (SMQs): Retrieving Adverse Drug Reactions with MedDRA. Geneva: CIOMS, 2004.

7 Pharmacogenetics : Towards improving treatment with medicines (Report of the CIOMS Working Group). Geneva: CIOMS, 2005.

8 WHO, IUPHAR, CIOMS. Clinical Pharmacology in Health Care, Teaching and Research. Geneva: CIOMS, 2012.

9 Current Challenges in Pharmacovigilance: Pragmatic Approaches. Report of CIOMS Working Group V. Geneva: CIOMS, 2013.

10 Definitions and Applications of Terms for Vaccine Pharmacovigilance. Geneva: CIOMS, 2012.

11 Practical Aspects of Signal Detection in Pharmacovigilance: Report of CIOMS Working Group VIII. Geneva: CIOMS, 2010.

12 Practical approaches to risk minimisation for medicinal products: Report of CIOMS Working Group IX. Geneva, Switzerland: Council for International Organizations of Medical Sciences (CIOMS), 2014.

[2] CIOMS Available Publications: http://www.cioms.ch/index.php/publications/available-publications/540/showCategory

[3] CIOMS Printable Publications: http://www.cioms.ch/index.php/publications/printablev3/541/showCategory

[4] WHO Bookshop. www.who.int/bookorders

Annex 1: CIOMS membership

International members

- World Allergy Organization
- International College of Angiology
- International Society of Audiology
- International Union of Basic and Clinical Pharmacology (IUPHAR)
- International Association of Bioethics
- International Society of Internal Medicine
- International Federation of Otorhinolaryngological Societies
- World Association of Societies of Pathology and Laboratory Medicine (WASPaLM)
- International Society for Pharmacoepidemiology (ISPE)
- International Society of Pharmacovigilance (ISOP)
- World Psychiatric Association
- International Rhinologic Society
- Medical Women's International Association
- World Medical Association

National members

- Comité des Académies Royales de Médecine, Belgium
- Union of the Scientific Medical Societies of Bulgaria
- Czech Medical Association, Czech Republic
- Association of the Scientific Medical Societies in Germany
- The Israel Academy of Sciences and Humanities, Israel
- Korean Academy of Medical Sciences, Republic of Korea
- Islamic Organization for Medical Sciences (IOMS), Kuwait
- Royal Netherlands Academy of Arts and Sciences, Netherlands
- The Research Council for Norway/ The National Committee for Medical Research Ethics, Norway
- South African Medical Research Council, South Africa
- Swiss Academy of Medical Sciences, Switzerland

Associate members

- Medical Sciences Society (MSS-UQ) of Queensland University, Haiti
- American Society for Bioethics and Humanities
- Consulta di Bioetica
- World Federation of Chiropractic
- International Federation of Clinical Chemistry and Laboratory Medicine
- World Organization of Family Doctors (WONCA)
- Good Clinical Practice - Alliance
- International Council for Laboratory Animal Science (ICLAS)
- International Society of Hepatic Encephalopathies & Nitrogen Metabolism (ISHEN)
- Academy of Medical, Dental and Pharmaceutical Sciences of Japan
- The World Association for Medical Law
- International Union of Microbiological Societies
- Asia Pacific Academy of Ophthalmology
- International Union of Physiological Sciences
- Federation of Polish Medical Organizations Abroad
- Federation of Polish Medical Societies
- International Medical Sciences Academy
- National Fund for Scientific Research (NSFR)
- International Federation of Medical Student Associations

▶ Source: http://www.cioms.ch/index.php/2012-06-07-19-16-08/membership ⬢