CIOMS Research Guidelines: Considering the Needs of Developing Countries

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Webinar
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CIOMS – Introduction (https://cioms.ch/)

Council for

International

Organizations of

Medical

Sciences

Founded in 1949 by WHO and UNESCO

In official relations with WHO

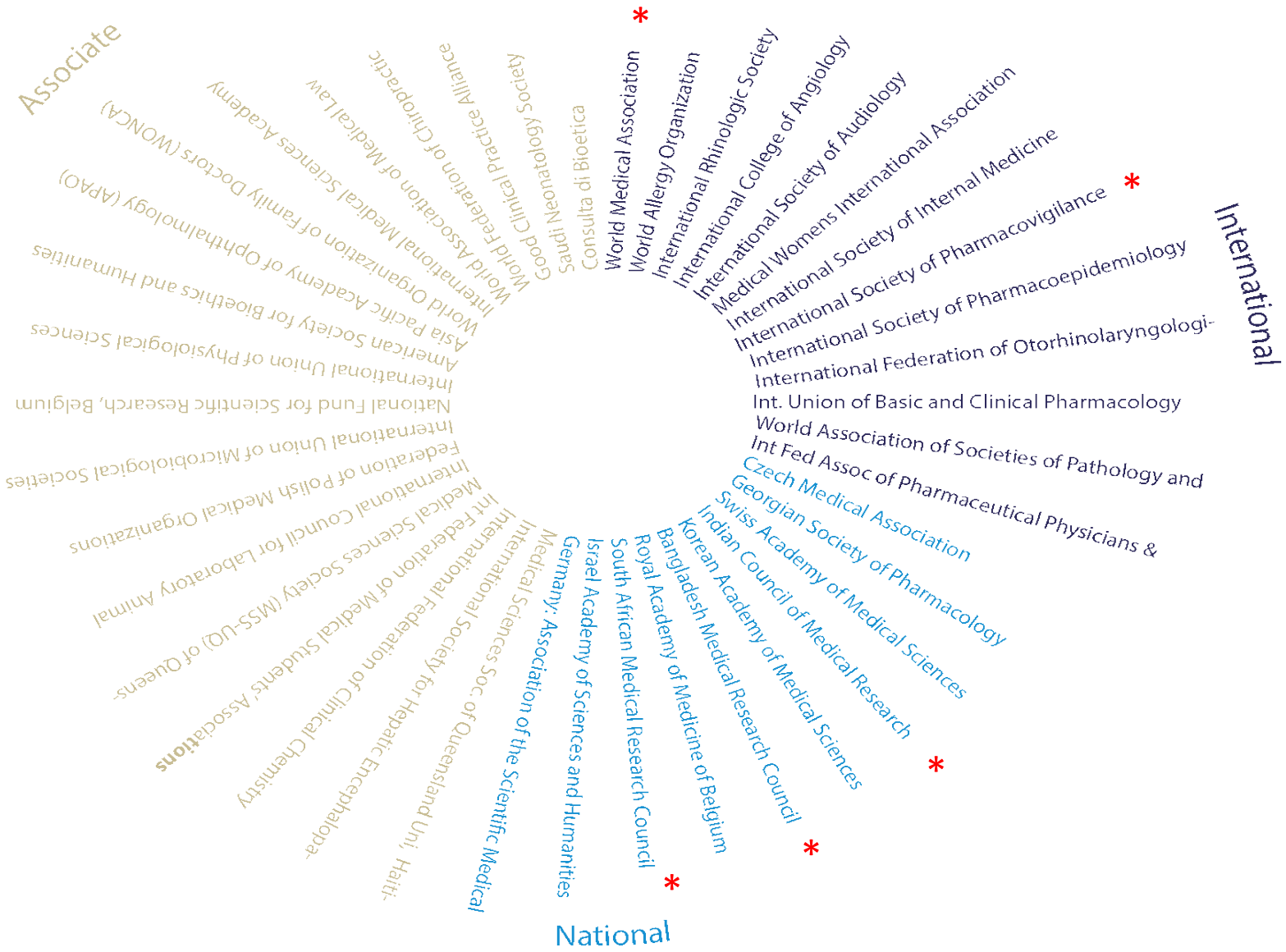
UNESCO associated partner

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

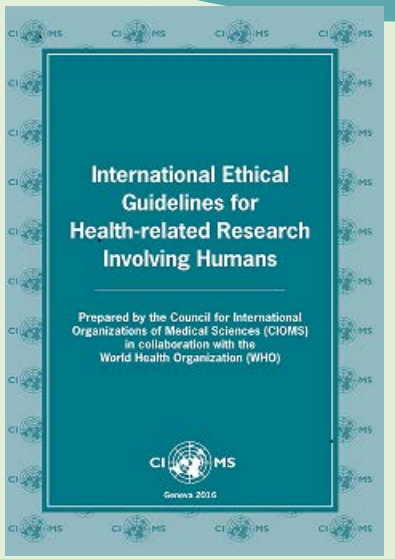


2023 - European Network of Research Ethics Committees (EUREC) joined CIOMS

- 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

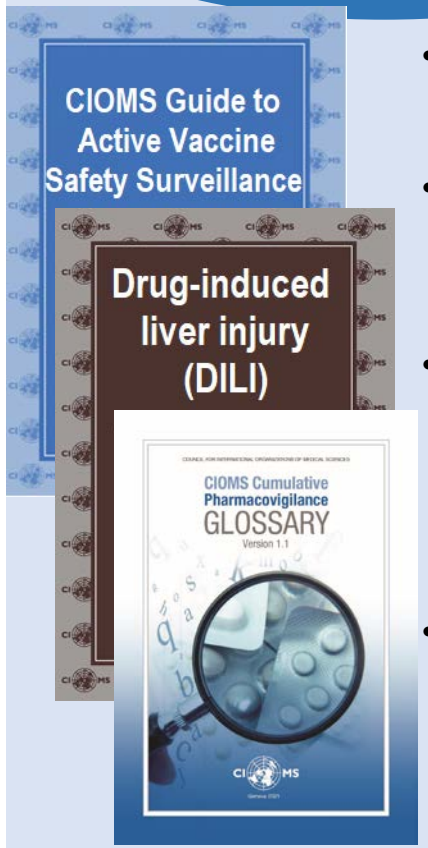
Main areas of work

Bioethics



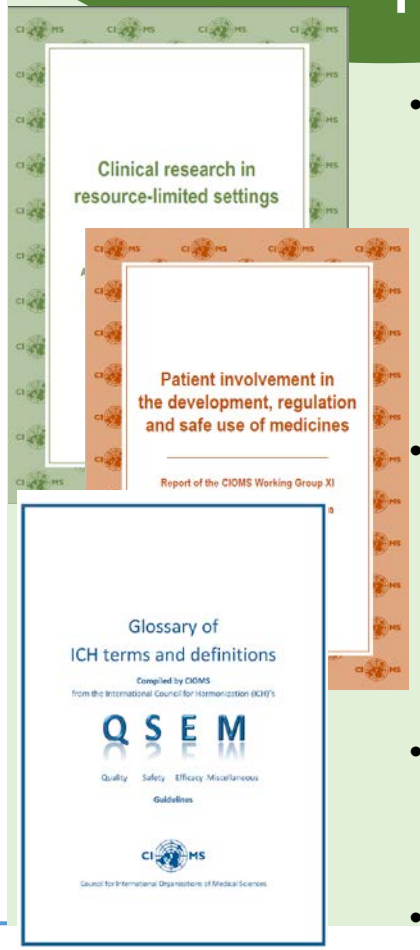
- Since 1967; 1st CIOMS Round Table Conference 'Biomedical Science and the dilemma of Human Experimentation'
- Issued significant guidelines
  - Latest revision 2016
  - Focus on 'low -and middle- income countries'
  - Available in 10 languages, e.g. Chinese, Spanish, Japanese, Russian

Pharmaco-vigilance



- 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

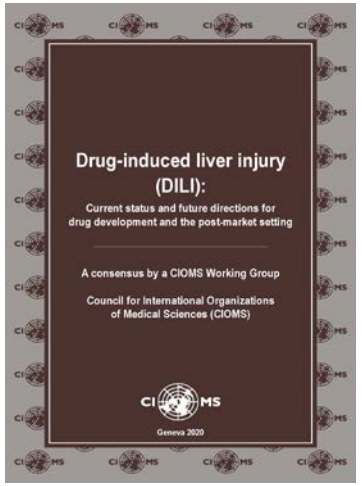
Product development

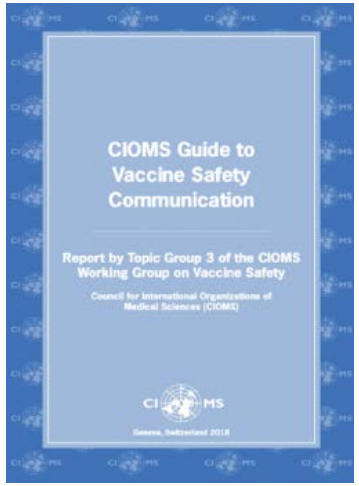


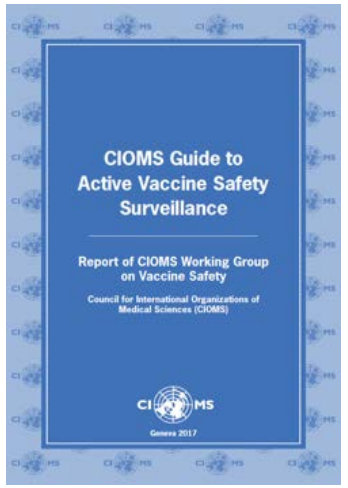
- Since 1977 CIOMS Round Table Conference, 'Trends and Prospects in Drug Research and Development' ….
- 2021: Clinical Research in Resource-Limited Settings, CIOMS Working Group report
- 2022: Patient Involvement ... WG XI
- 2022: Glossary of ICH terms and definitions

CIOMS Recent Pharmacovigilance related Publications

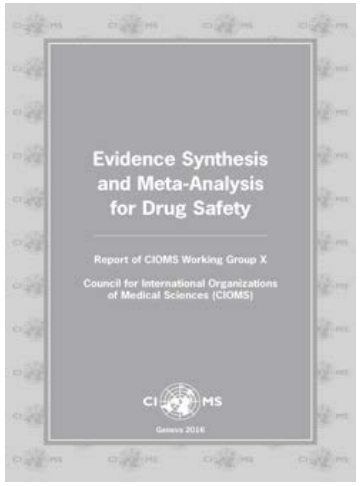
https://cioms.ch/publications/

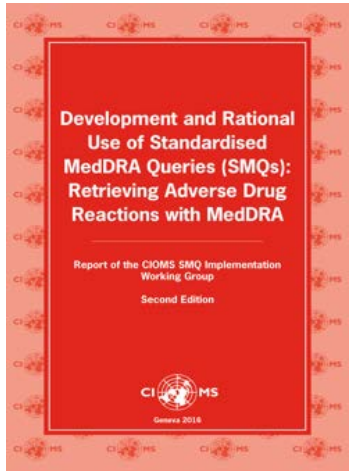


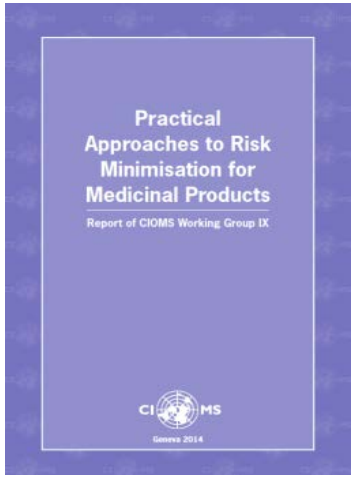


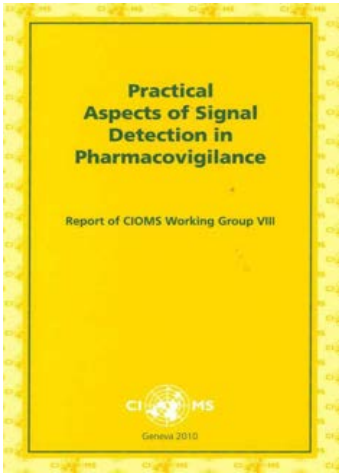


Chinese translation was made available in 2018









CIOMS WG on DILI – report 2020

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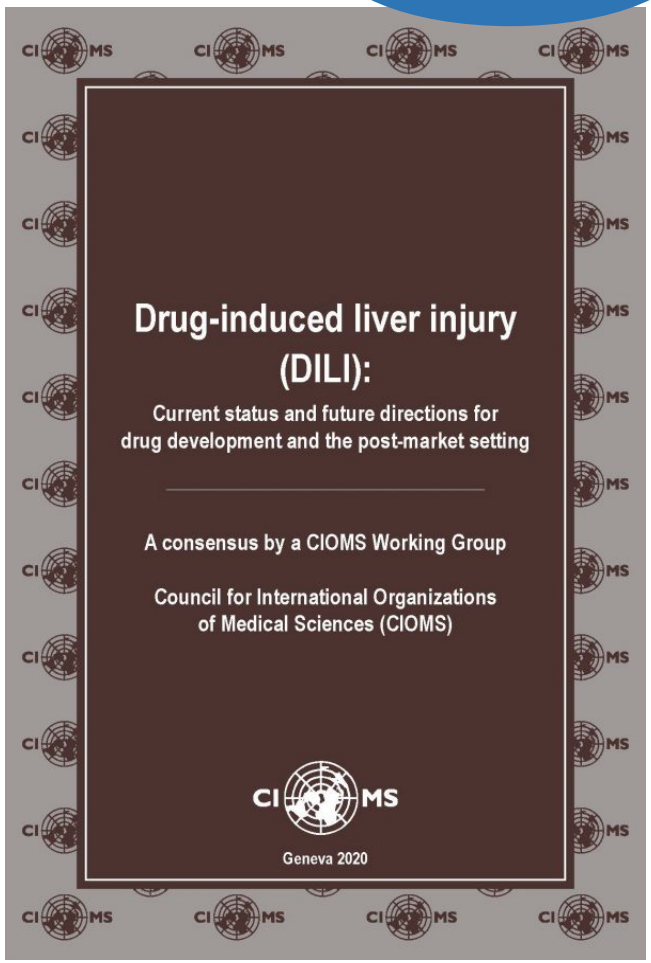
SUPPLEMENTAL APPENDICES

Online only – freely available on the CIOMS website at:
https://cioms.ch/publications/product/drug-induced-liver-injury/

Pharmaco-vigilance

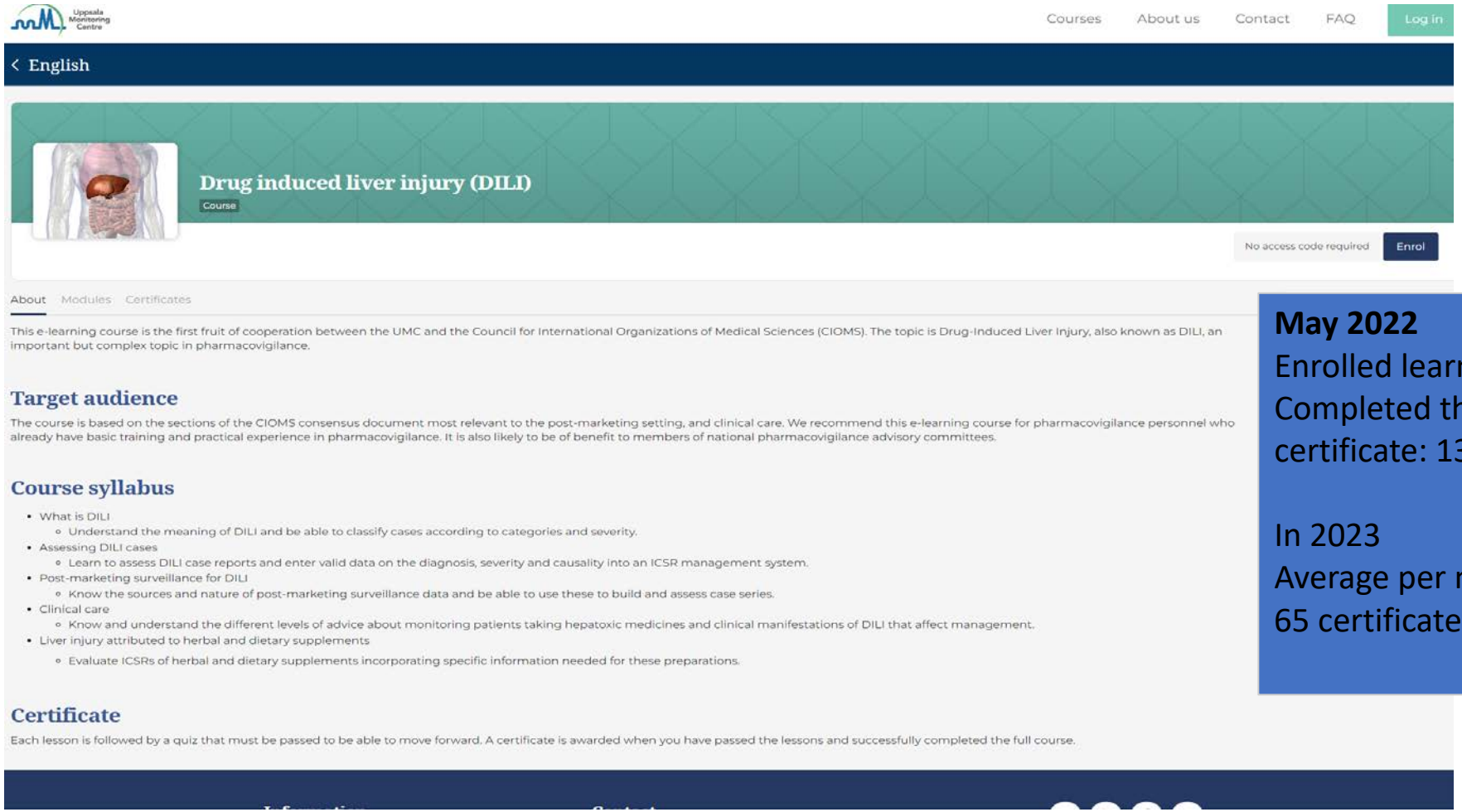


https://doi.org/10.56759/ojsg8296

New training online courses

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

Pharmaco-vigilance

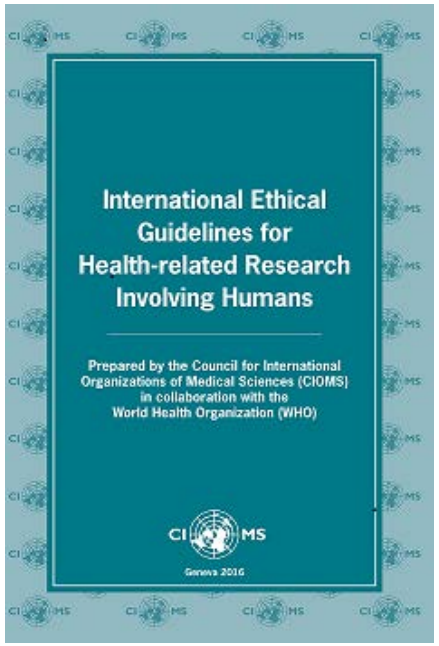


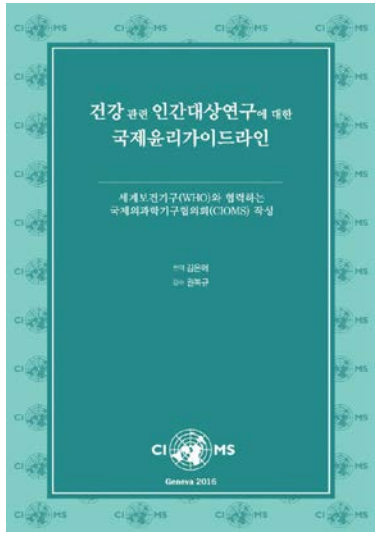
May 2022
Enrolled learners: 270
Completed the course and received a certificate: 130

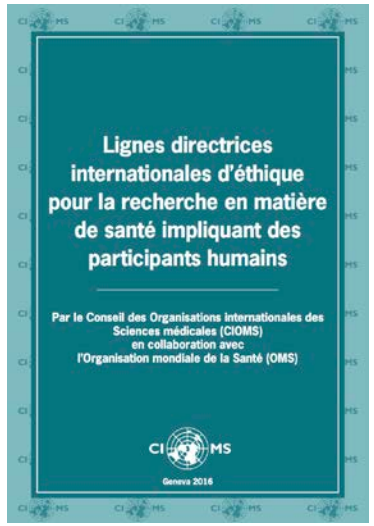
In 2023
Average per month enrolled learners 130, and 65 certificate

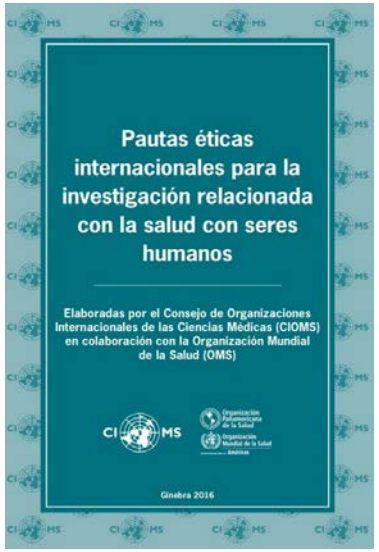
CIOMS latest, 2016 Ethical Guidelines - In all 6 UN languages +

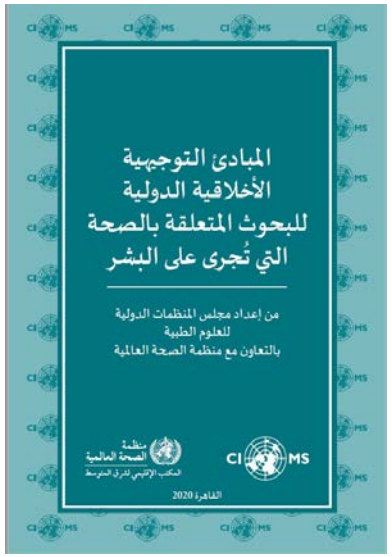
Japanese, Korean, Polish, Portuguese, Ukrainian …











CIOMS 2016 Ethical Guidelines: 25 guidelines on hot topics

1 – Scientific and social value and respect for rights

2 – Research conducted in low-resource settings

3 – Equitable distribution of benefits and burdens in the selection of groups of participants

4 – Potential benefits and risks of research

5 – Choice of control in clinical trials

6 – Caring for participants' health needs

7 – Community engagement

8 – Collaborative partnership and capacity building

9 – Individual informed consent

10 – Modifications and waivers of informed consent

11 – Collection, storage and use of biological materials and related data

12 – Collection, storage and use of data in health-related research

13 – Reimbursement and compensation for research participants

14 – Treatment and compensation for research-related harms

15 – Research involving vulnerable persons

16 – Research involving individuals who are incapable of giving informed consent

17 – Research involving children and adolescents

18 – Women as research participants

19 – Pregnant women and lactating women as research participants

20 – Research in disasters and disease outbreaks

21 – Cluster randomized trials

22 – Use of online environment and digital tools

23 – Research ethics committees and review

24 – Public accountability

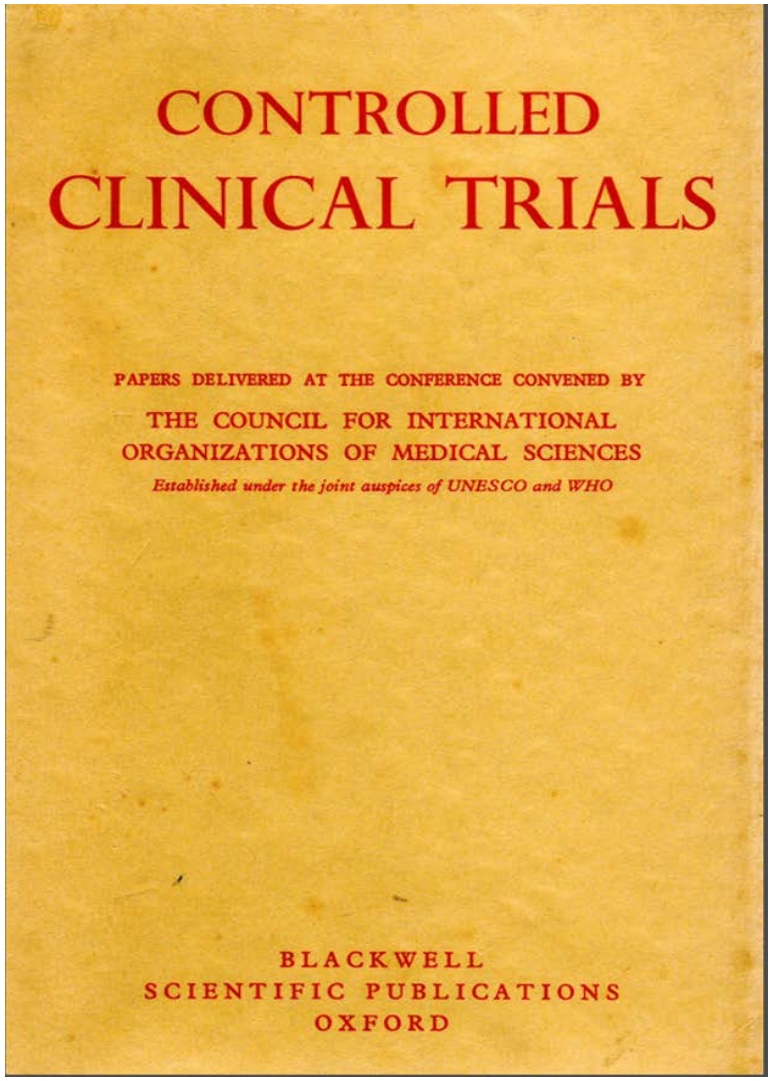
25 – Conflicts of interest

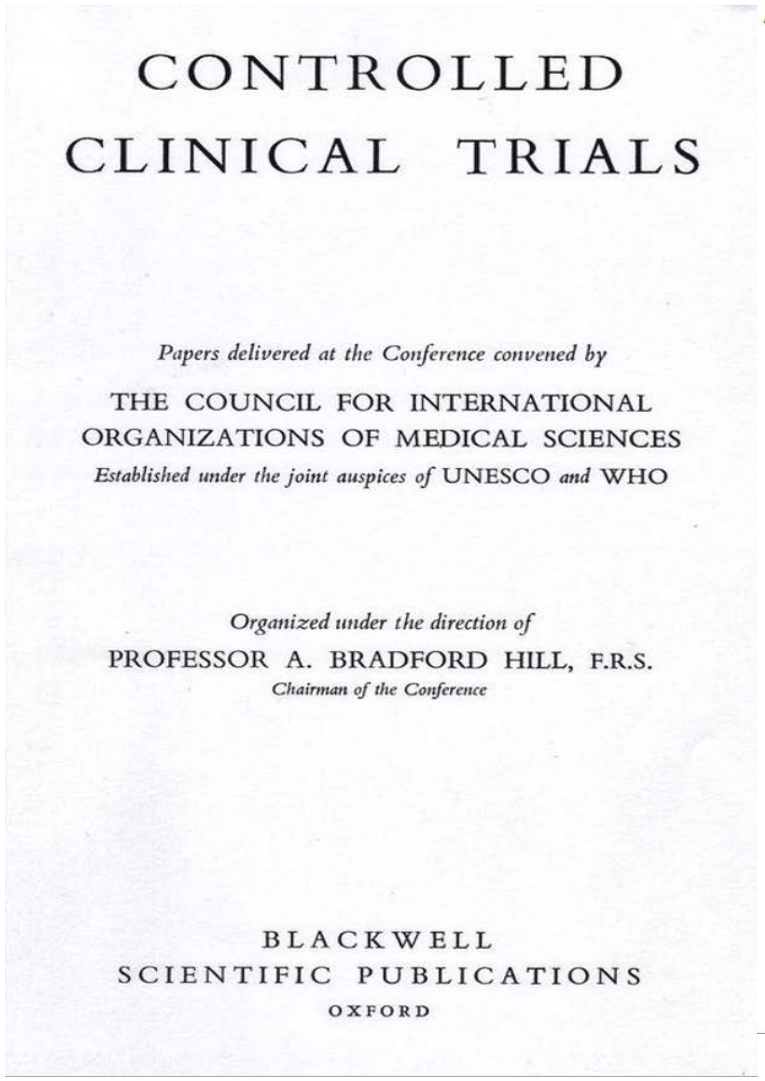
E-training course

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

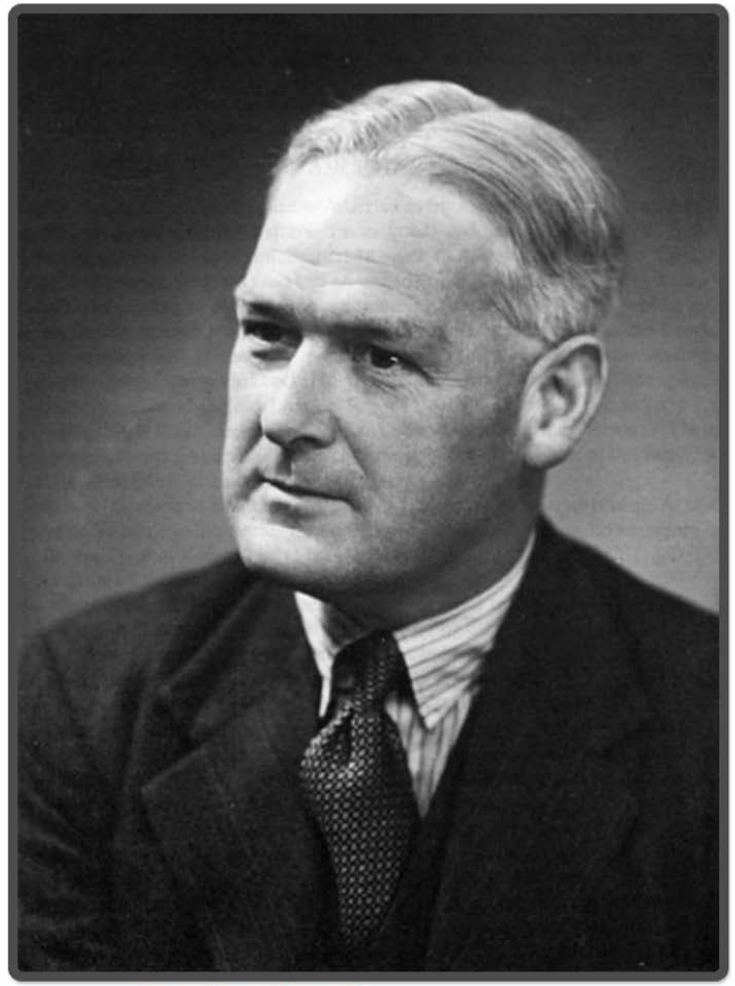
Controlled Clinical Trials, Sir Austin Bradford Hill and CIOMS (I)

Year 1960

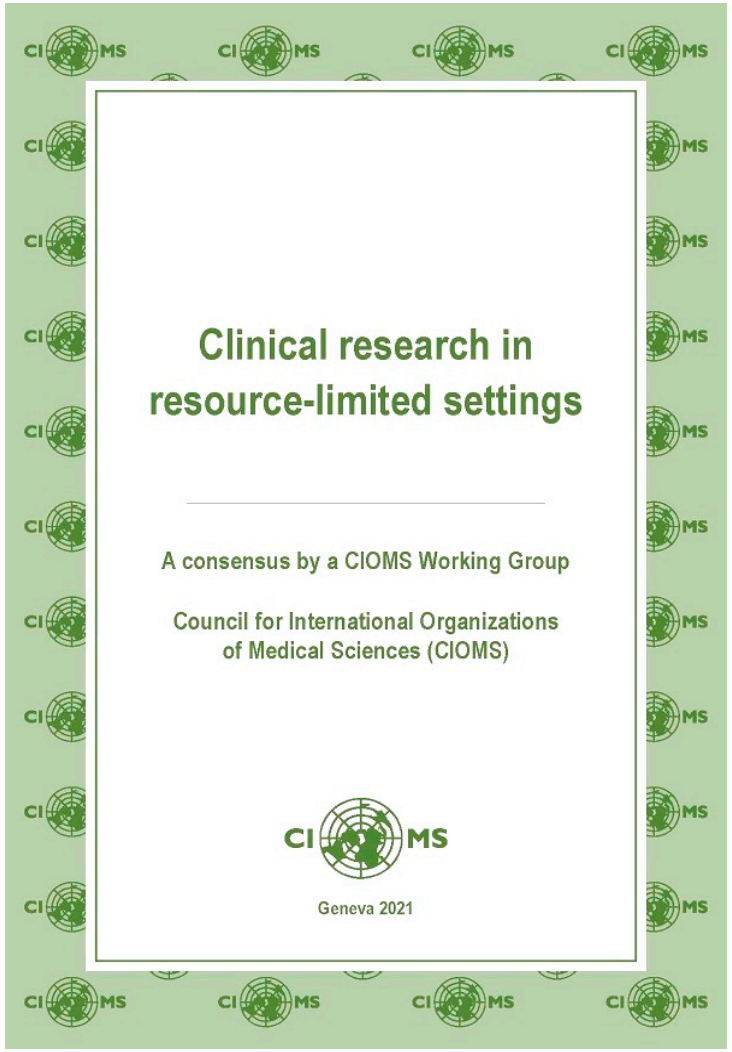




Austin Bradford Hill (1897-1991)



CIOMS WG on Clinical research in resource-limited settings – report 2021



https://doi.org/10.56759/cyqe7288

Bioethics

Product development

World Health Organization

SEVENTY-FIFTH WORLD HEALTH ASSEMBLY
Agenda item 16.2

WHA75.8
27 May 2022

Strengthening clinical trials[1] to provide high-quality evidence on health interventions and to improve research quality and coordination

The Seventy-fifth World Health Assembly,

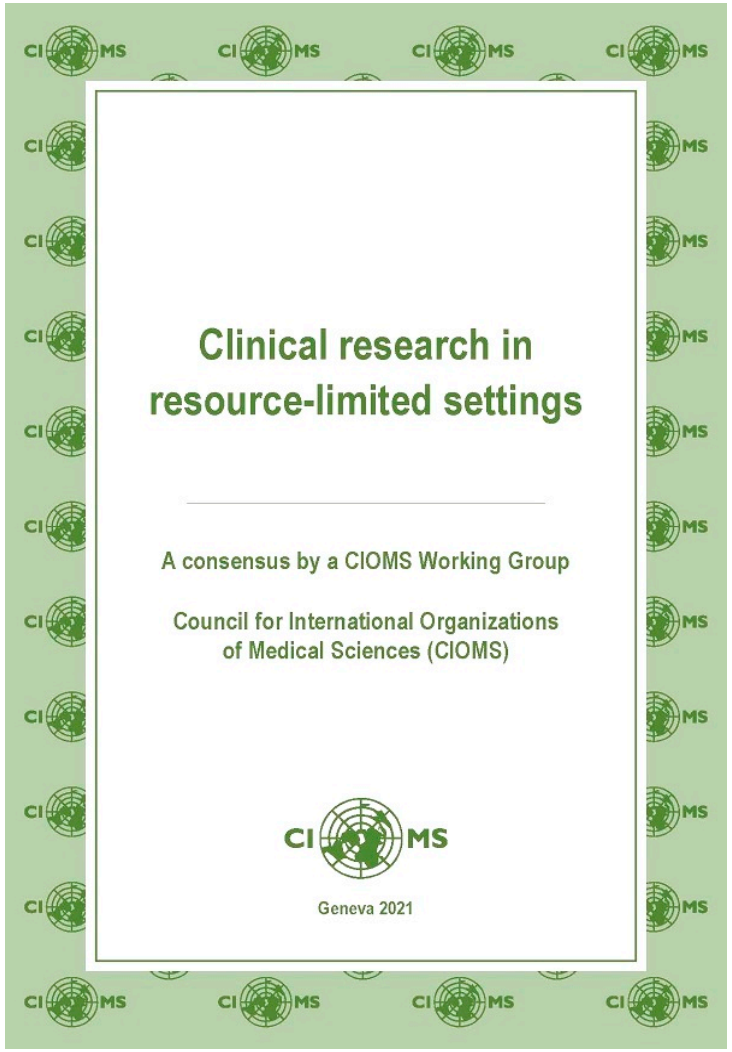
Recalling resolutions WHA58.34 (2005) acknowledging that high-quality, ethical research and the generation and application of knowledge are critical in achieving internationally agreed health-related development goals, WHA63.21 (2010) outlining WHO's role and responsibilities in health research, WHA66.22 (2013) and WHA69.23 (2016) on the follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination, WHA67.20 (2014) on regulatory system strengthening for medical products, WHA67.23 (2014) on health intervention and technology assessment in support of universal health coverage, WHA74.6 (2021) on strengthening local production of medicines and other health technologies to improve access, and WHA74.7 (2021) on strengthening WHO preparedness for and response to health emergencies, which notes the importance of basic and clinical research and recognizes the critical role of international collaboration in research and development, including in multicountry clinical and vaccine trials, as well as rapid diagnostics test and assay development, while acknowledging the need for further rigorous scientific evidence;

Noting the recommendations made by the Independent Panel for Pandemic Preparedness and Response in their review "COVID-19: make it the last pandemic"[2] relating to health research and development, including clinical trials;

[1] "A clinical trial is defined by WHO as any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials may also be referred to as interventional trials. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc. This definition includes Phase I to Phase IV trials." Joint statement on public disclosure of results from clinical trials, 2017 (https://www.who.int/news/item/18-05-2017-joint-statement-on-registration, accessed 25 May 2022).

[2] Independent Panel for Pandemic Preparedness and Response. COVID-19: make it the last pandemic, 2021 (https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf, accessed 25 May 2022).

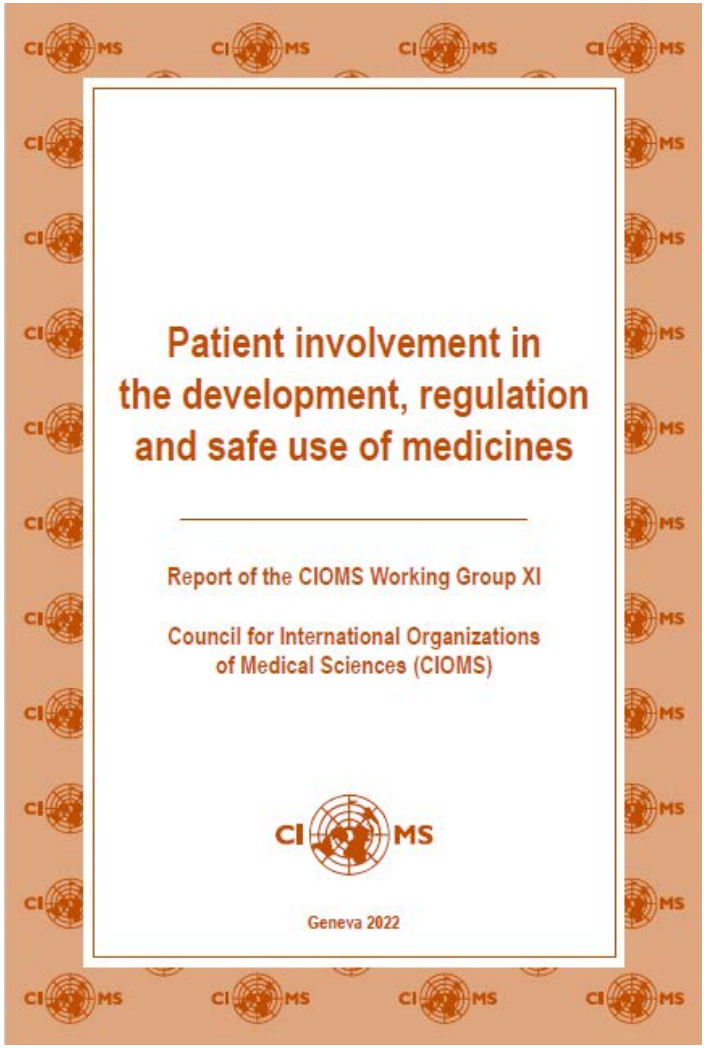
Report Content



Bioethics

Product development

Report Content



https://doi.org/10.56759/iiew8982

Bioethics

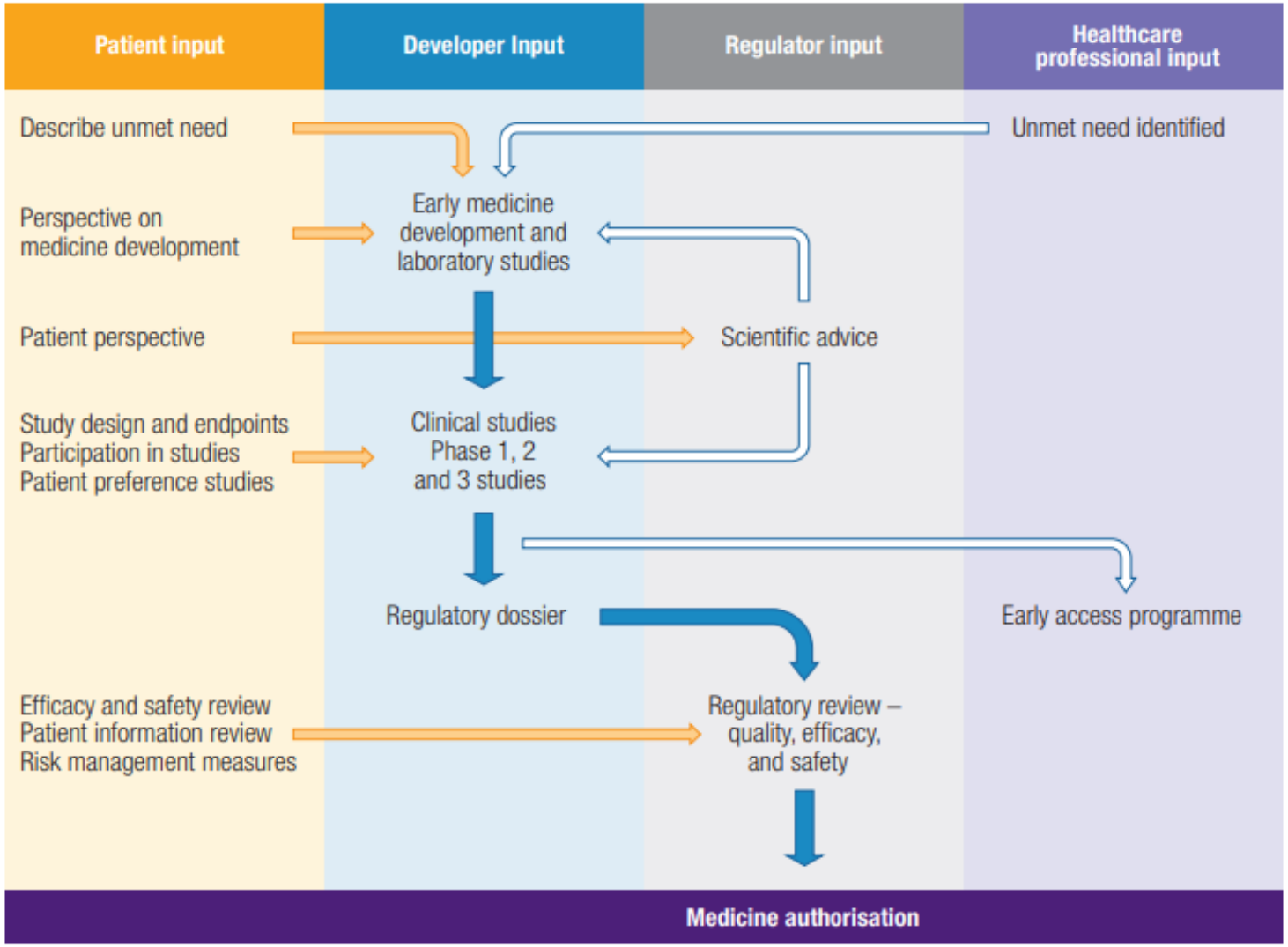
Pharmaco-

Product development

Some snapshots

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

Pre-authorization period

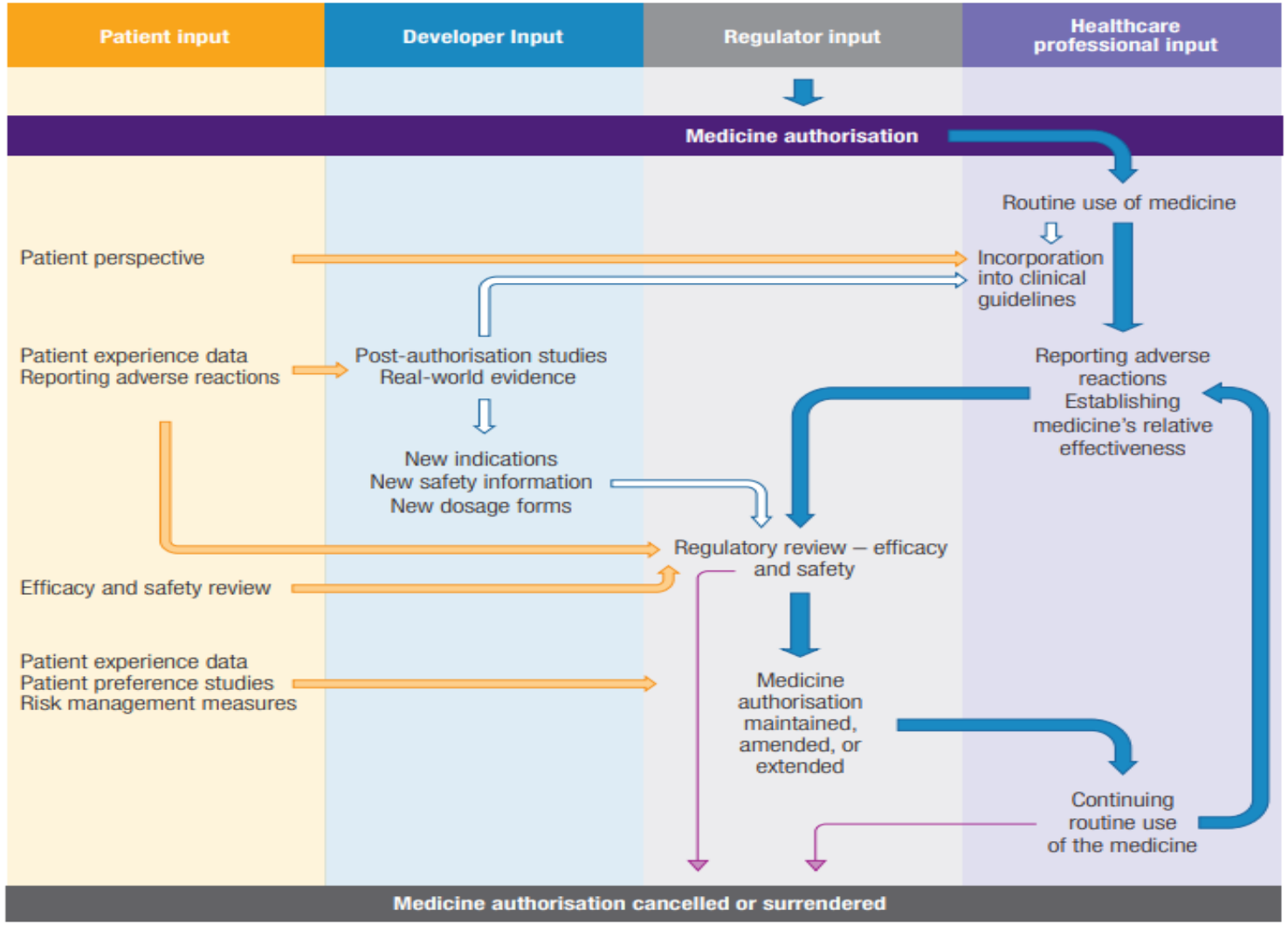


Source: CIOMS Working Group XI

Some snapshots (ct'd)

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

Post-authorization period



Source: CIOMS Working Group XI

Appendices

1		Glossary
2		**Case studies**
	A	Medication formulation created to meet patients' and doctors' needs (AdrenalNET)
	B	A regulatory agency involving patients; public hearing on valproate (EMA)
	C	Pilot collaboration between Lareb and a patient organisation in communicating a signal (Lareb)
	D	Creating partnerships between industry and patient groups for therapy development (Roche)
	E	Example of a pharmaceutical company working with patients to develop an additional risk minimisation measure
	F	Engaging patients in early development plans for a novel treatment (Takeda)
	G	Patient activism to counter AIDS denialism and improve access to HIV medicines in South Africa
3		(…)

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

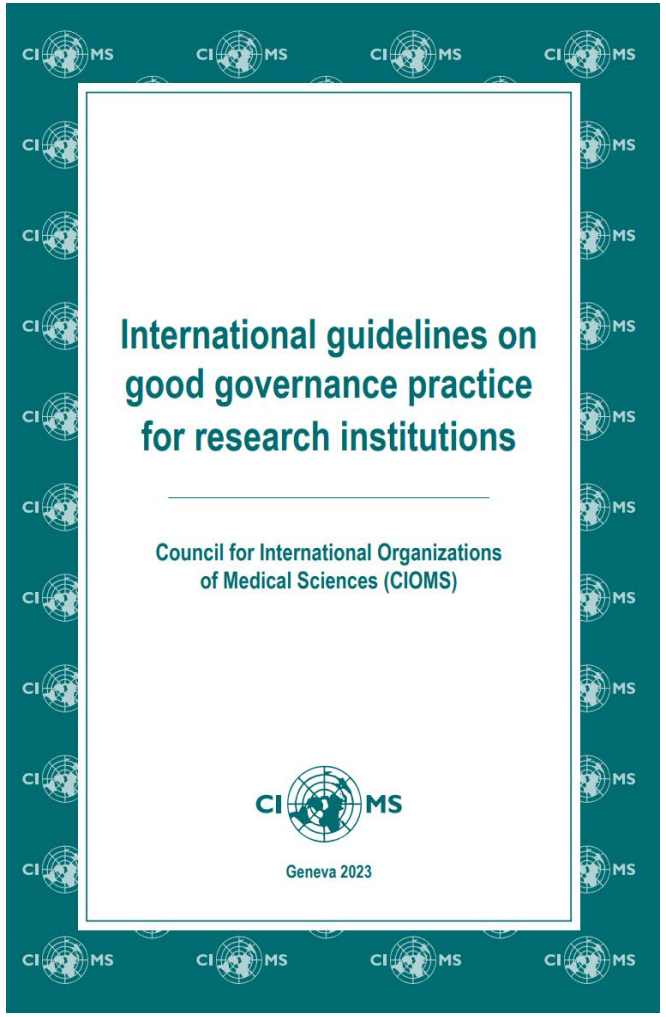
CIOMS Ongoing Working Groups in 2023

- **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
- **International Guidelines on Good Governance Practices for Research Institutions**. Started: July 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

In-person participants at the 1st Meeting of CIOMS WG XIV

* Finalization in 2023
* Finalization in 1Q/2Q 2024

New CIOMS WG report – launched 28/11/2023



This publication is freely available on the CIOMS website at: https://doi.org/10.56759/hslk3269

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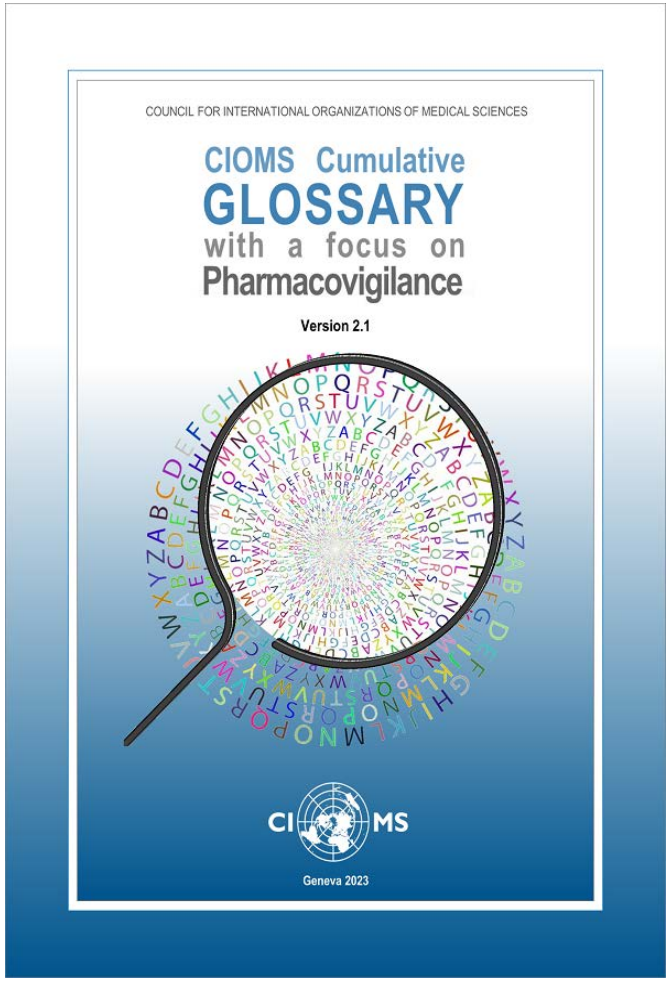
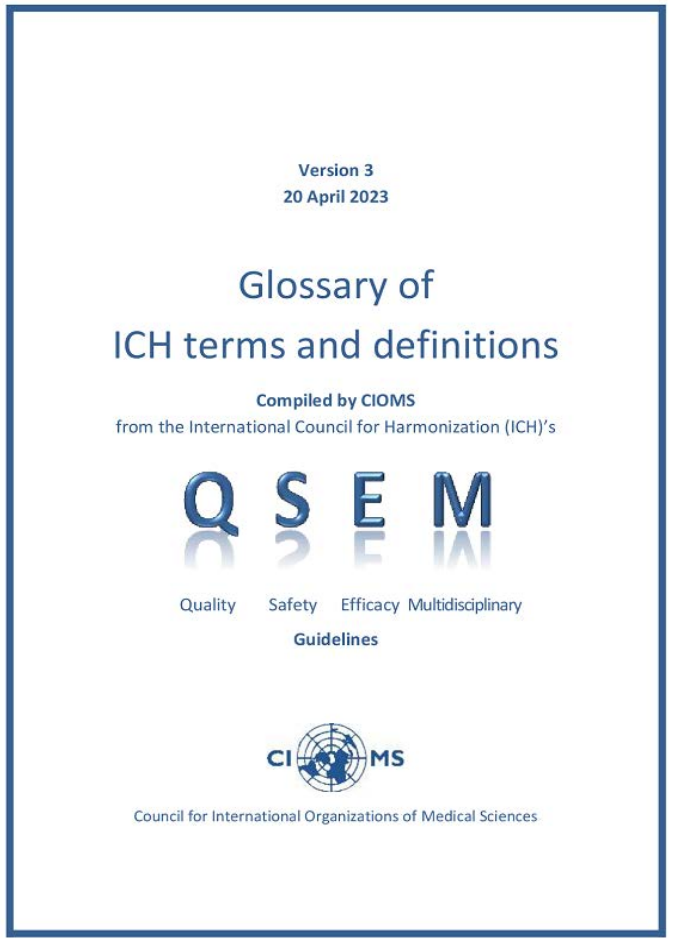
CIOMS Glossaries – 2 complimentarty successful projects

https://doi.org/10.56759/ocef1297



* First version in 2021.

https://doi.org/10.56759/eftb6868



* First Version in 2022

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!

How can we do better for public health?

Image by Gordon Johnson from Pixabay

Thank you for your attention