



Dr Lembit Rägo  
Secretary-General  
of CIOMS

# CIOMS activities during 2022

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- Introduction
- Main activities in 2022
- CIOMS Working Groups in 2022 and 2023
- Future visions
- Discussion and conclusions



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# Introduction

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Council for  
International  
Organizations of  
Medical  
Sciences

CIOMS will be 75 in  
2024



Founded in 1949 by WHO and UNESCO

In official relations with WHO and  
UNESCO associated partner

ICH Observer since 2016

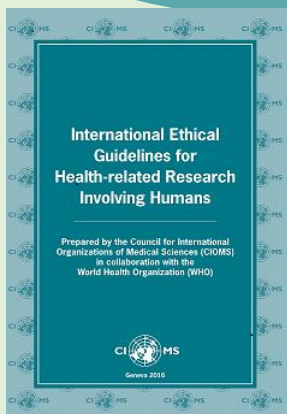
President - Professor Hervé Le Louet (since 2016)

Secretary-General – Dr Lembit Rägo (since 2016)

## Mission Statement

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

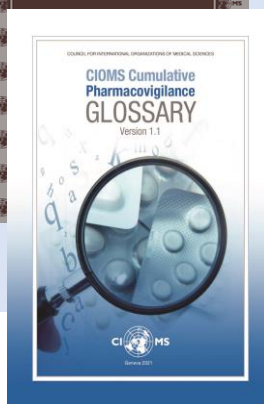
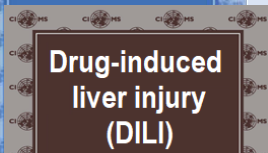
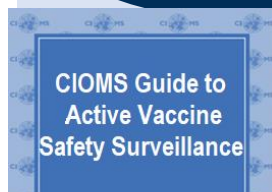
## Bioethics



- Since 1967; 1st CIOMS Round Table Conference 'Biomedical Science and the dilemma of Human Experimentation'
- Issued significant guidelines
- Latest revision 2016

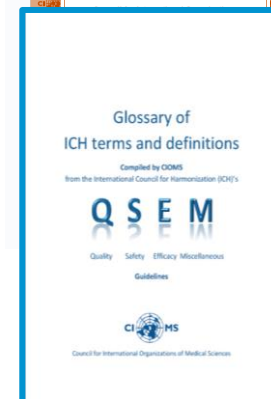
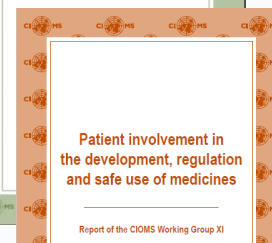
- Focus on 'low -and middle- income countries'
- Available in 10 languages, e.g. Chinese, Spanish, Japanese, Russian

## 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



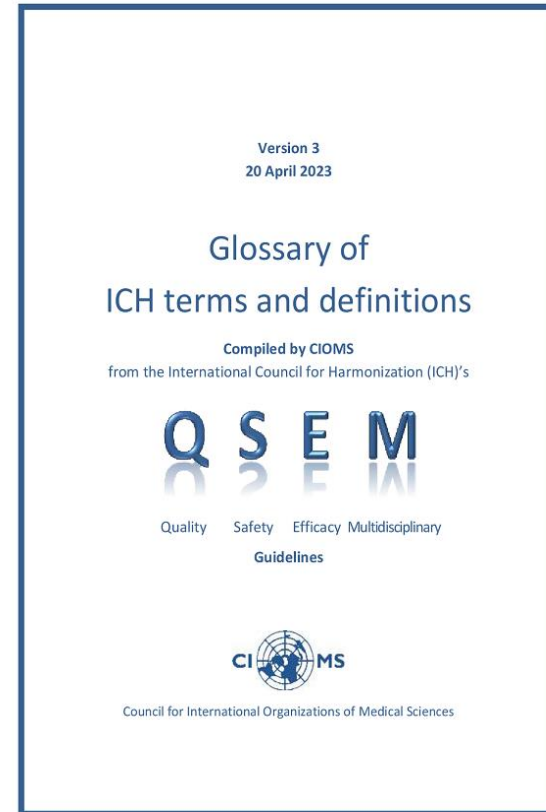
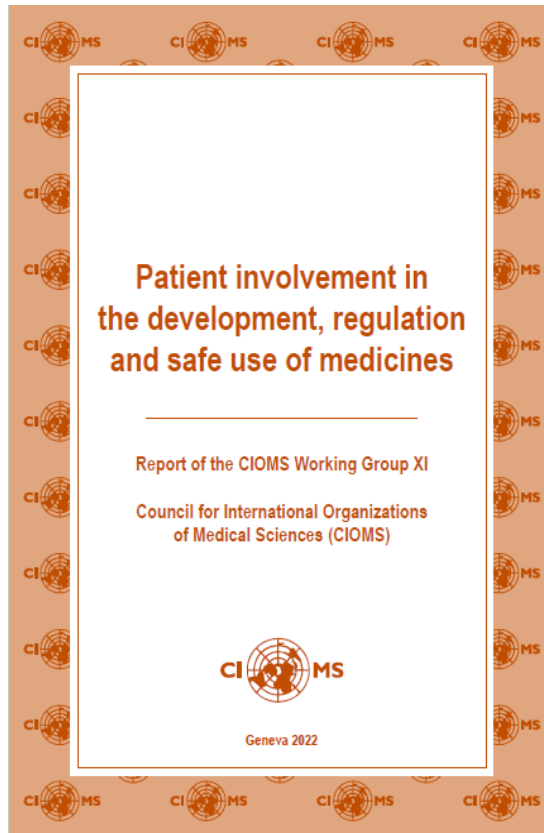
- Since 1977 CIOMS Round Table Conference, 'Trends and Prospects in Drug Research and Development' ....
- 2021: Clinical Research in Resource-Limited Settings, CIOMS Working Group report
- 2022: Glossary of ICH terms and definitions



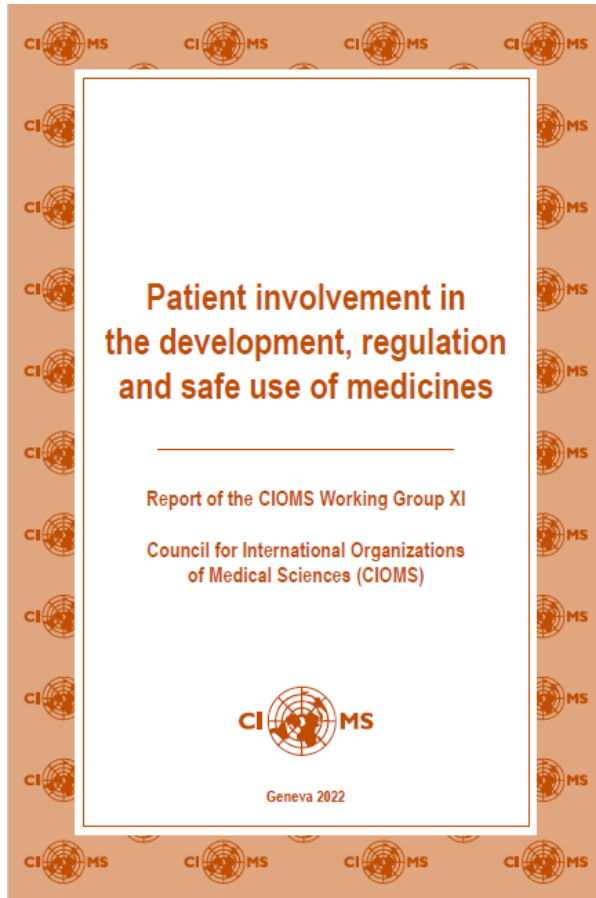
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Some highlights from  
2022

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## Report Content



<https://doi.org/10.56759/iiew8982>

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**Ethical considerations for patient involvement**

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**Executive summary**

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**Chapter 1: Introduction**

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**Chapter 2: Landscape**

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**Chapter 3: Guiding principles**

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**Chapter 4: Advancing treatments**

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**Chapter 5: Use of real-world data and evidence**

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**Chapter 6: Product labeling**

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**Chapter 7: Rapid safety communication**

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**Chapter 8: Additional risk minimization**

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**Chapter 9: Clinical practice guideline**

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**Chapter 10: Low- and middle-income countries**

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**Chapter 11: Pandemic considerations**

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**Appendices:**

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

Pharmaco-  
vigilance

Product  
development



- 1.1 **Terminology**  
Opportunities to incorporate the patient's perspective
- 1.2 **Increasing engagement and incorporating the patient's perspective**

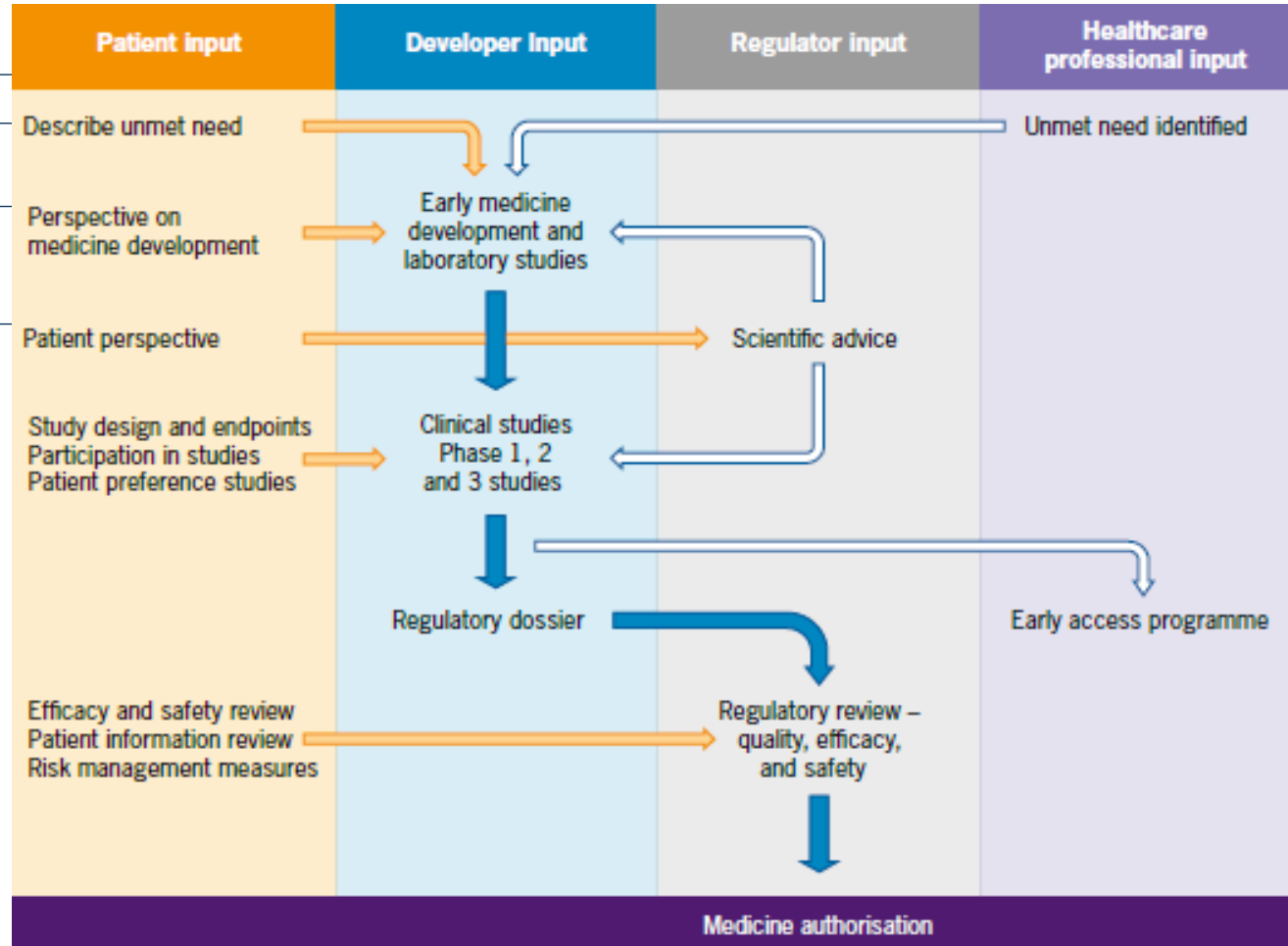


Figure 1a: Patient involvement during a medicine lifecycle: **pre-authorisation**

Source: CIOMS Working Group WG XI

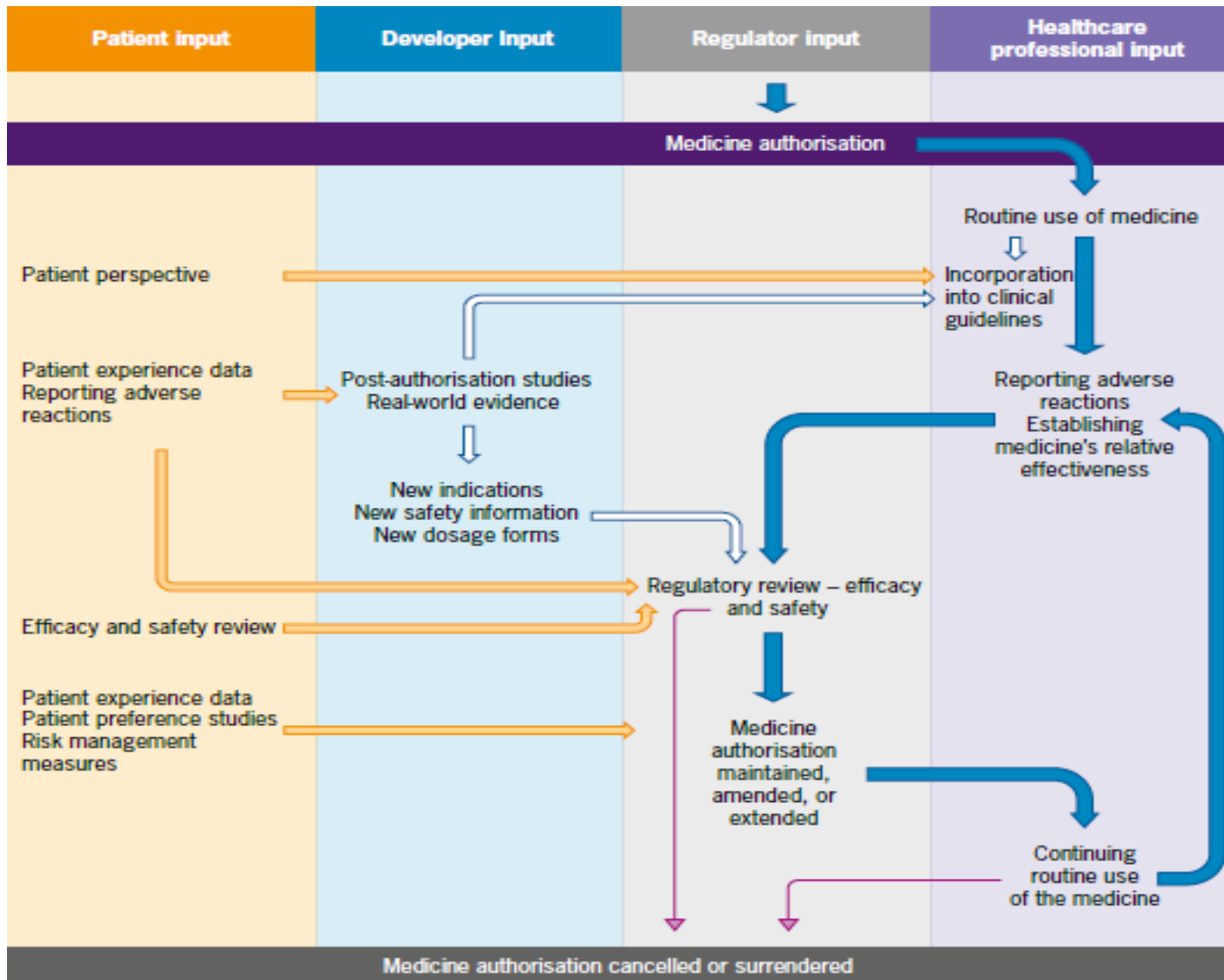


Figure 1b:  
Patient involvement during a  
medicine lifecycle:  
**post authorisation**

Source: CIOMS Working Group WG XI

## CHAPTER 4. ADVANCING TREATMENTS

In this chapter we talk about the important roles patients and patient communities can play in developing treatments when working with other stakeholders.

### Key points

1. Many stakeholders are involved in discovering treatments, developing them through the product lifecycle, and promoting their safe use.
2. Stakeholders include patients themselves, along with healthcare professionals, sponsors (academics, funders, and biotechnology developers), regulators, and payers.
3. Patient participation is needed in planning, testing, reviewing, approving, and monitoring treatments throughout the lifecycle of medicines.
4. Improving treatment development and delivery depends on transparent and evidence-based communications among all stakeholders.

**3. Patient participation is needed in planning, testing, reviewing, approving, and monitoring treatments throughout the lifecycle of medicines.**

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

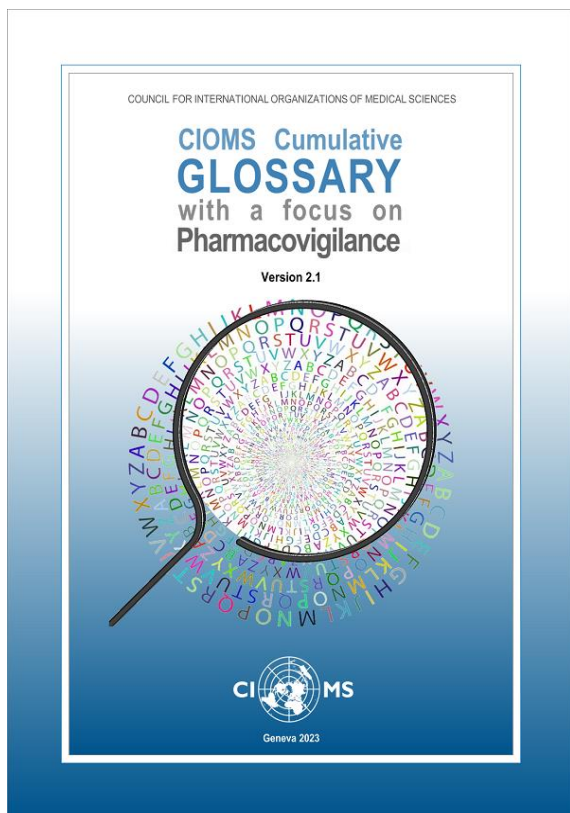
## Each case study describes:

- 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 Glossaries – 2 complementary successful projects

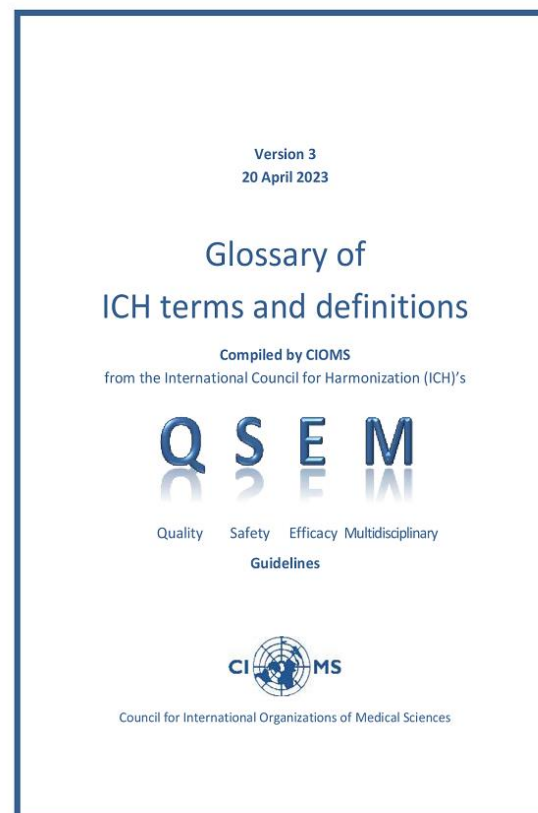


<https://doi.org/10.56759/ocef1297>



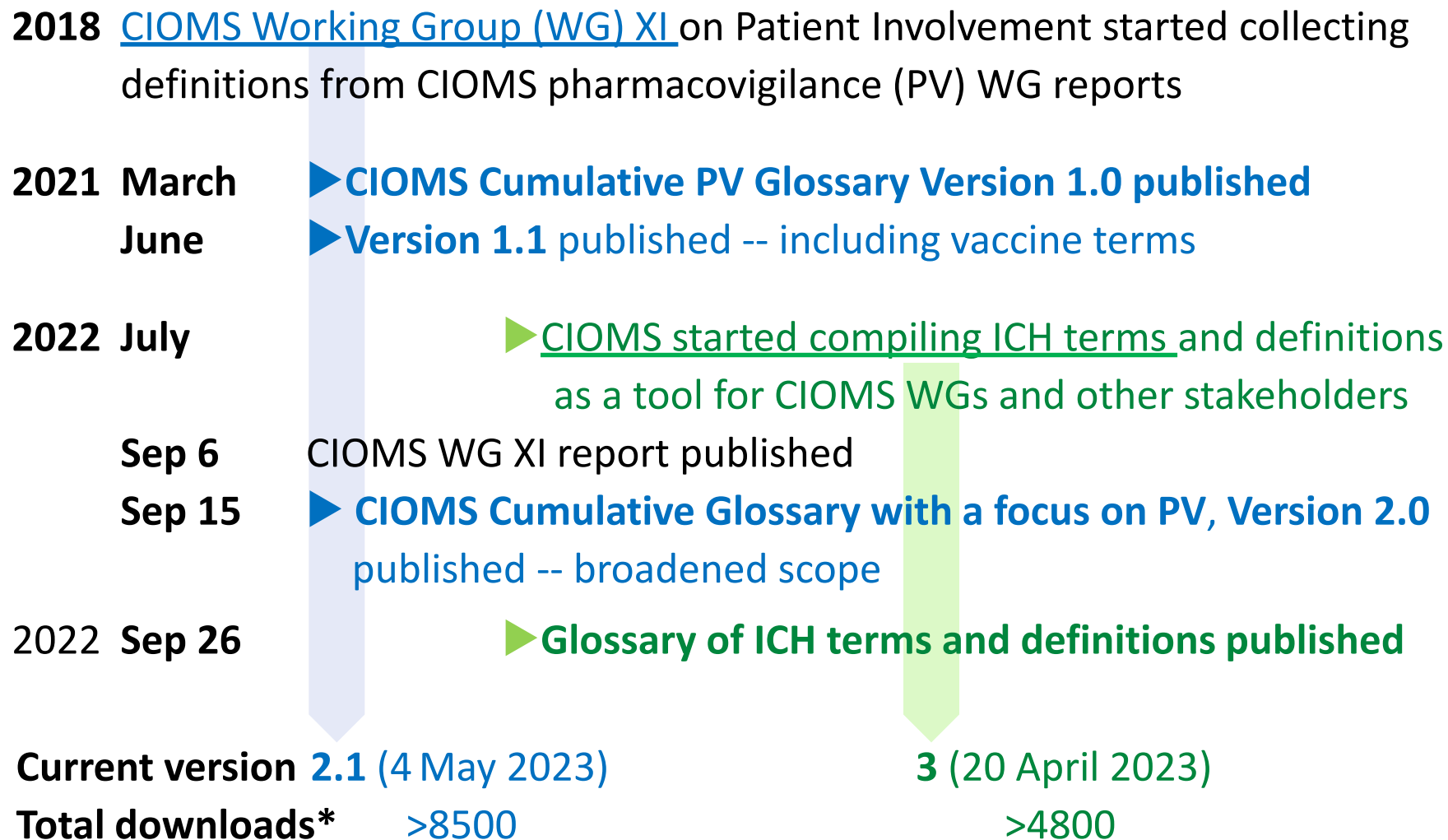
\* First version in 2021.

<https://doi.org/10.56759/efb6868>



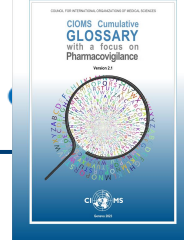
\* First Version in 2022

# How the glossaries came about?



\* As of 19 June 2023

# CIOMS Cumulative Glossary



RY SECTION

TERMS AND DEFINITIONS: GENERAL

## 17. **Benefit** (CIOMS IX: Risk minimisation 2014 | Japanese)

Definition from the most recent report

An estimated gain for an individual or a population.

Source: WHO 2002: The Importance of Pharmacovigilance. (Safety monitoring of medicinal products).

“Historical” definition(s) from earlier reports

### **Benefit** (CIOMS IV: Benefit-risk 1998)

Benefit usually refers to a gain (positive result) for an individual or a population. “Expected” benefit can be expressed quantitatively, and this would ordinarily incorporate an estimate of the probability of achieving the gain. These uses of the term benefit are those employed in this report. Some current definitions of benefit include reference not only to clinical improvement but also to quality of life and economic consequences, as in the following example [Footnote 1]:

“The improvement attributable to the drug, in terms of human health, health-related quality of life, and/or economic benefit to the individual or group.”

[Footnote 1 in the CIOMS IV report:] Benefit, Risk and Cost Management of Drugs. Report of the CPHA National Advisory Panel on Risk/Benefit Management of Drugs. Canadian Public Health Association, January 1993.

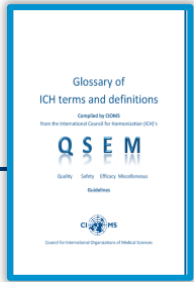
Proposed by CIOMS Working Group IV.

## 18. **Bias** (CIOMS X: Meta-analysis 2016 | Japanese)

A systematic deviation in results from the truth.

→ Separate section” Terms and def’s: VACCINES

# CIOMS – Glossary of ICH terms and definitions



## Three sections:

### 1. About this glossary/disclaimer (not shown here)

### 2. Definitions

Example:  
“Risk”.  
Occurs in  
several ICH  
guidelines/  
sections  
thereof

**Risk**

**\*Q9(R1) EWG Quality Risk Management -- Step 4 (final); 18 January 2023 -- Definitions**

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

**E8(R1) General Considerations for Clinical Studies -- Step 4 (final); 6 October 2021 -- 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 -- Step 4 (final); 26 April 2022 -- Glossary**

### 3. List of ICH guidelines referenced

<b>E10</b> Choice of Control Group and Related Issues in Clinical Trials <a href="https://database.ich.org/sites/default/files/E10_Guideline.pdf">https://database.ich.org/sites/default/files/E10_Guideline.pdf</a>	0
<b>E11(R1)</b> Addendum: Clinical Investigation of Medicinal Products in the Pediatric Population <a href="https://database.ich.org/sites/default/files/E11_R1_Addendum.pdf">https://database.ich.org/sites/default/files/E11_R1_Addendum.pdf</a>	6

Includes links to guidelines and counts of definitions found



- Both glossaries are freely available on the CIOMS website
- Periodically updated as new guidelines are published
- Can be useful inside CIOMS, e.g. members of CIOMS Working Groups
- Can be useful outside CIOMS, e.g. ICH new Working Groups, for various other purposes in industry, academia and regulatory settings
- Can support training in various settings, e.g. pharmaceutical physicians, patient experts
- ...

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# II. Newsletters in 2022



➤ In 2022 four quarterly regular NL editions were produced + one specialized issue dedicated to AMR



WWW.CIOMS.CH March 2022 | Newsletter # 37

### Quick links

Page	Content
2	<b>Published</b> For comment: CIOMS Working Group XI report on Patient Involvement New Translation: CIOMS Ethical Guidelines in Korean   Announcing: 2022 student award
3	<b>International events</b> Insem ethics workshop and other meeting news
4	<b>What's new with COVID-19?</b>
5	<b>News roundup</b> WHO news   U.S. FDA: Guidance on patient-focused drug development EMA: Draft EU GVP addendum for comment
6	<b>CIOMS cited</b>
7	<b>News from the CIOMS Secretariat</b> Official relations with WHO   New Executive Committee member

## Published for comment

Draft report of CIOMS Working Group XI on Patient Involvement



WWW.CIOMS.CH September 2022 | Newsletter # 39

### Quick links

<b>Just published</b>	CIOMS Working Group report on Patient Involvement CIOMS Cumulative Glossary 2.0   ICH Glossary   Article on MedDRA labeling groupings
<b>International events</b>	Eleventh WPRA Meeting   BioST 2022   ISO-P Annual Meeting
<b>Announcements</b>	CoRE conference on patient involvement   IFAPP: 20th ICPM   6th European PV congress CIOMS/IFPMA webinar: clinical trials in Africa
<b>Health emergency news</b>	Access to Genomics   Unproven clinical interventions: ethical considerations
<b>Publications</b>	Code of digital ethics   CIRS R&D briefing   IFPMA policy briefings CIOMS cited   @ Medical students: Submit your article for the CIOMS award
<b>News from the CIOMS Secretariat</b>	



WWW.CIOMS.CH June 2022 | Newsletter # 38

### Quick links

Page	Content
1	<b>New CIOMS Working Group: WG XI on Artificial Intelligence in Pharmacovigilance</b>
2	<b>Health emergency news</b>
3	<b>International events</b> WHA75   ICH Assembly   10 <sup>th</sup> Youth PreWHA   CoRE Conference announcement
4	<b>Focus on Drug-induced liver injury:</b> IQ DILI   New CIOMS/UMC e-learning course
5	<b>Publications:</b> Draft FDA guidance on gene therapy   CIOMS cited
6	<b>In memoriam:</b> Sten Olsson   Brian S. Dillman
7	<b>News from the CIOMS Secretariat:</b> XXV General Assembly   Online training   CIOMS Working Groups

## New CIOMS Working Group



WWW.CIOMS.CH December 2022 | Newsletter # 40

### Quick links

<b>CIOMS @ Conferences</b>	CoRE Scientific Conference   20 <sup>th</sup> ICPM   6 <sup>th</sup> EUPV   .. and more
<b>CIOMS @ International meetings</b>	EMA Working Parties' meeting   ICH Assembly   Webinars: <b>Save the dates</b>
<b>CIOMS Working Groups</b>	In-person meetings   Ongoing Working Groups
<b>Global health issues</b>	Health emergencies   Priority pathogens   ICMRA framework
<b>News roundup</b>	WHA Resolution on clinical trials and WHO Call for Experts   Other news
<b>CIOMS Secretariat news</b>	CIOMS VI report in Chinese   CIOMS cited   Student award   Top 10 downloads

## Conferences

2022 CoRE Scientific Conference  
**Patients as Partners for Health:  
 Co-creating Equitable Access to Health Products and Services**

CIOMS General Assembly, 22 June 2023 | 18

## What's on @ CIOMS

COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES



WWW.CIOMS.CH

Special Newsletter | November 2022

### Fighting antimicrobial resistance

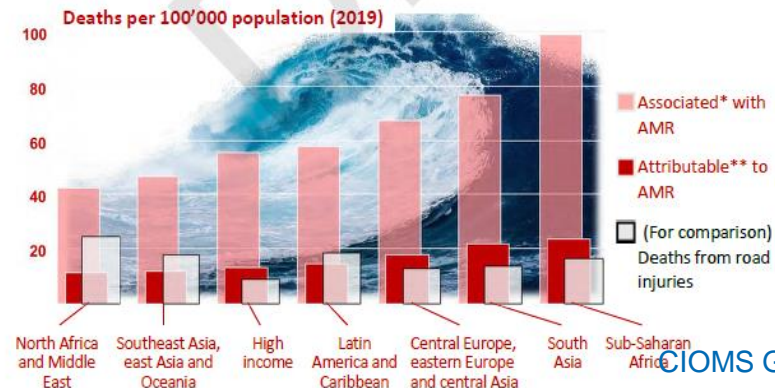
Antimicrobials – including antibiotics, antivirals, antifungals and antiparasitics – are medicines used to prevent and treat infections in humans, animals and plants. Antimicrobial resistance (AMR)—including bacterial resistance to antibiotics—poses a profound threat to human health. This newsletter provides an overview of the situation and references for further reading. We thank Valeria Gigante (WHO) and Peter Beyer (GARDP) for their review and comments.

#### Quick links

- [A silent pandemic](#)
- [Drivers of AMR](#) | [Resistance levels](#) | [Impact](#)
- [One Health response](#)
- [Innovation](#) | [New actors](#)
- [Making it happen](#)
- [References](#)

#### ▶ A silent pandemic

The world's first comprehensive assessment of available global data [1] has confirmed that bacterial antimicrobial resistance (AMR) is a leading cause of death around the world. The highest burden, and the largest data gaps, are in low-resource settings.



### III. Other activities in 2022

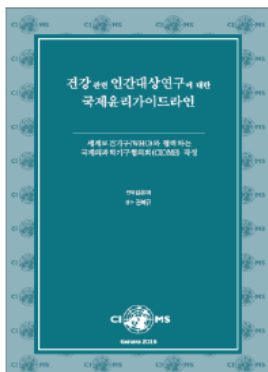
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- Translations
- Introducing CIOMS work at international conferences
- Webinars on CIOMS WG reports
- Online training modules created based on CIOMS reports
- Working with students
- Monitoring website

## New translation

### Korean translation of CIOMS Ethical Guidelines



The Korean translation of the 2016 CIOMS/WHO *International ethical guidelines for health-related research involving humans* is now freely available on the CIOMS website [here](#). We thank the Korean Association of Institutional Review Boards for preparing this translation.

The CIOMS/WHO ethical guidelines are universally acknowledged as a standard in health research. They provide internationally vetted ethical principles and detailed commentary on how these principles should be applied, with particular attention to conducting research in low- and middle-income countries. With this latest translation, the guidelines are now available in ten languages (click to access):

[English](#), [French](#), [Spanish](#), [Russian](#), [Arabic](#), [Chinese](#), [Portuguese](#), [Ukrainian](#), [Japanese](#) and [Korean](#).

### Now available: Chinese translation

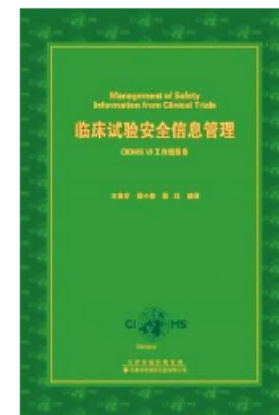
#### Management of Safety Information from Clinical Trials Report of CIOMS Working Group VI

The Chinese translation of the CIOMS Working Group VI report is now available [here](#). This translation will be instrumental in further promoting pharmacovigilance during clinical trials in China in line with international standards.

The translation was produced by the Pharmacovigilance Professional Committee of the Zhejiang Pharmaceutical Association, with extensive input from regulatory and scientific experts. CIOMS thanks the translation and review team for their outstanding collaborative work.

*Publishers: Tianjin Science and Technology Translation & Publishing Co Ltd, [www.tsttpc.com](http://www.tsttpc.com)*

*To obtain this publication in hard copy, please contact [pvinchina@126.com](mailto:pvinchina@126.com)*



2022 CoRE Scientific Conference  
**Patients as Partners for Health:  
Co-creating Equitable Access to Health Products and Services**

5–6 October 2022, Singapore / hybrid event

Hosted by the Centre of Regulatory Excellence (CoRE) at Duke-NUS Medical School in Singapore, this two-day event focused on areas of patient engagement for health products access equity and sustainable health systems. Adjunct Professor John Skerritt, Deputy Secretary for Health Products Regulation within the Australian Government Department of Health and Aged Care, and CIOMS Secretary-General

Lembit Rägo served as Scientific Chair and Vice Chair of the conference respectively, and five CIOMS Working Group members were among the speakers.

In conjunction with the conference, CoRE and CIOMS signed a Memorandum of Understanding (MoU) to explore opportunities for information exchange and cooperation.

[Conference website](#)

*(Below, first row from left) The CIOMS report on Patient Involvement. — Four Working Group members (▶) were part of the conference’s scientific committee. — At the MoU signing ceremony. (Second row) Impressions from the conference.*



## 20<sup>th</sup> International Conference on Pharmaceutical Medicine (ICPM)

19–21 October 2022, Athens, Greece / hybrid event

CIOMS Secretary-General Lembit Rägo delivered the welcome address from CIOMS, and Executive Committee member Dominique Sprumont spoke about the Principles for [good research governance](#), which are being developed in an ongoing CIOMS Working Group.

[Conference website](#)



(Above) At the official opening of the 20<sup>th</sup> ICPM

IFAPP is a CIOMS member organization. Two recent CIOMS publications featured in the [October issue](#) of [IFAPP TODAY](#).

## 6<sup>th</sup> European Pharmacovigilance Congress (EUPV)

7–8 November 2022 (virtual); 10 November 2022, Milan, Italy



(Above) Among the speakers at the 6<sup>th</sup> EUPV, from left: Lembit Rägo, Hervé Le Louët, Chia-Yu Qu, Panos Tsintis and Andrew Bates.

CIOMS was again well represented at the European Pharmacovigilance Congress, with presentations by Working Group members on the following topics:

- Patient involvement in the development, regulation and safe use of medicines;
- Serious cutaneous adverse reactions (SCARs);
- Benefit/risk of medicines; and
- Artificial intelligence in pharmacovigilance.

[Conference website](#) | [Agenda and speakers](#)

## CIOMS/IFPMA webinar Regulatory Systems and regulations to support clinical trial conduct in Africa

5 December 2022, virtual event


CIOMS and the International Federation of Pharmaceutical Manufacturers & Association (IFPMA) are joining efforts to create a platform for dialogue on clinical research in low- and middle-income countries. This first webinar will focus on Africa. It will address how collaboration within the clinical research community can strengthen clinical research infrastructure and lead to a sustainable ecosystem.

👉 Follow updates for the event [here](#).





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



[Courses](#)
[About us](#)
[Contact](#)
[FAQ](#)
[Log in](#)

< English



### Drug induced liver injury (DILI)

Course

[About](#) [Modules](#) [Certificates](#)

This e-learning course is the first fruit of cooperation between the UMC and the Council for International Organizations for Drug Regulation and Research in Pharmacovigilance (CIOMS) on an important but complex topic in pharmacovigilance.

#### Target audience

The course is based on the sections of the CIOMS consensus document most relevant to the post-marketing surveillance of DILI. Learners should already have basic training and practical experience in pharmacovigilance. It is also likely to be of benefit to those who are involved in the management of patients with DILI.

#### Course syllabus

- What is DILI
  - Understand the meaning of DILI and be able to classify cases according to categories and severity.
- Assessing DILI cases
  - Learn to assess DILI case reports and enter valid data on the diagnosis, severity and causality into an ICSR management system.
- Post-marketing surveillance for DILI
  - Know the sources and nature of post-marketing surveillance data and be able to use these to build and assess case series.
- Clinical care
  - Know and understand the different levels of advice about monitoring patients taking hepatotoxic medicines and clinical manifestations of DILI that affect management.
- Liver injury attributed to herbal and dietary supplements
  - Evaluate ICSRs of herbal and dietary supplements incorporating specific information needed for these preparations.

#### Certificate

Each lesson is followed by a quiz that must be passed to be able to move forward. A certificate is awarded when you have passed the lessons and successfully completed the full course.

**April 2022:** Enrolled learners: 11  
Completed the course and received a certificate: 10

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

**Cumulative, to date (31 May 2023)** Enrolled: 2565  
Completed: **1200**

<https://cioms.ch/online-training/>



CIOMS is a proud supporter of the Youth Pre World Health Assembly (Youth PreWHA), organized by the International Federation of Medical Students' Associations (IFMSA).

CIOMS was represented by speakers at two events during 2022 Youth PreWHA:

- CIOMS EC member Otmar Kloiber co-hosted a panel discussion on “Universal health coverage as a multisectoral concept” on 18 May (photo), and
- CIOMS Secretary-General Lembit Rägo delivered the keynote speech at the reflection session held on 4 June.



*Participants at the panel discussion held on 18 May 2022*

## 2022 CIOMS student award

The CIOMS annual award of US\$ 1500 for the best scientific article in the areas of pharmacovigilance and research ethics is available to medical students. The article must have been published in a scientific peer-reviewed journal in English. The deadline for submissions is **31 October 2022**.



2018



2019



2020



2021



You?

2022

Past winners:

[Read more](#)

- For best student authored paper published in peer-reviewed journals
- in the area of clinical research ethics, clinical product development and pharmacovigilance
- The winners will be made public in CIOMS Newsletter (quarterly)
- Hopefully in 2023 we will get more mature applications

<https://cioms.ch/cioms-establishes-annual-award-medical-students/>

No student award  
given in 2022 !

*\* Lack of quality applications*

## Find us on the web

### ----- Year 2022 -----

 **103 102**  
visitors from

 **205**  
countries/  
territories

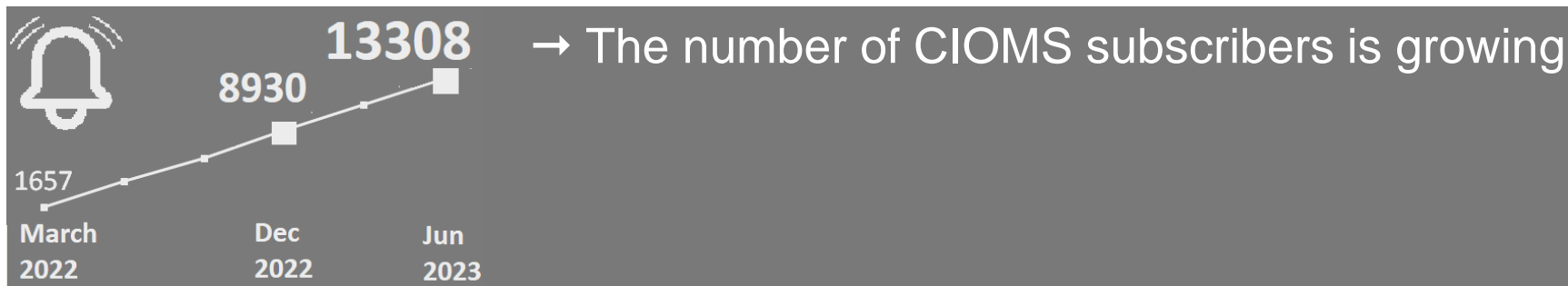
 **8 930**  
subscribers

#### Top CIOMS publications\*

	Released	Downloads
1 CIOMS Cumulative glossary (all versions)	2021	3063
2 Patient involvement (report of Working Group XI)	15 Sep 2022	1628
3 Glossary of ICH terms and definitions	26 Sep 2022	1287
4 International ethical guidelines	2016	814
5 Drug-induced liver injury	2020	690
6 Practical aspects of signal detection in pharmacovigilance	2010	688
7 Management of Safety Information from Clinical Trials	2005	663
8 Clinical research in resource-limited settings	2021	556

 Discover all CIOMS publications at: <https://cioms.ch/publications>

\*Period: 11 February 2022 (launch of new download module) to 31 December 2022





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# CIOMS Working Groups

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# 2022 – In-person meetings are back

In-person Working Group meetings are back! After two years of travel restrictions, CIOMS Working Group members are getting together again to develop their reports and recommendations.

## In-person meetings

3<sup>rd</sup> Meeting of the CIOMS Working Group on  
**Education and Training for Health Professionals  
Participating in Medicines Development**  
6–7 September 2022, Geneva



2<sup>nd</sup> Meeting of the CIOMS Working Group on  
**Artificial Intelligence in Pharmacovigilance**  
10–11 October 2022, Geneva (hybrid event)



5<sup>th</sup> Meeting of the CIOMS WG on  
**Good Governance Practice for Research Institutions**  
10–12 November 2022, Geneva (hybrid event)



**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

**Good Governance for Research Institutions.** Started July  
2021 \*

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



In-person  
participants at  
the 1<sup>st</sup>  
Meeting of  
CIOMS WG  
XIV

\* *Draft out for public comments, \* Public consultation finished*



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# Discussion and Conclusions

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- *The Working Groups continue to be core of CIOMS activities*
- *Webinars and e-learning opportunities are on increase*
- *CIOMS has gradually increased its outreach – very soon we will reach out to 15 000 + individuals in our data base*
- *The year 2022 was a successful year*
- *The year 2023 will likely be at least as successful as 2022 in terms of publications*

## Questions?



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