CIOMS working group XI

On patient involvement in clinical development and safe use of medicines

Progress report

Council for International Organizations of Medical Sciences

Founded in 1949 by WHO and UNESCO

Mission

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

President Prof Hervé Le Louet

SCOPE Joint Action

Former PRAC member

Former advisor to French MofH

Past President of the International Society of Pharmacovigilance (ISoP)

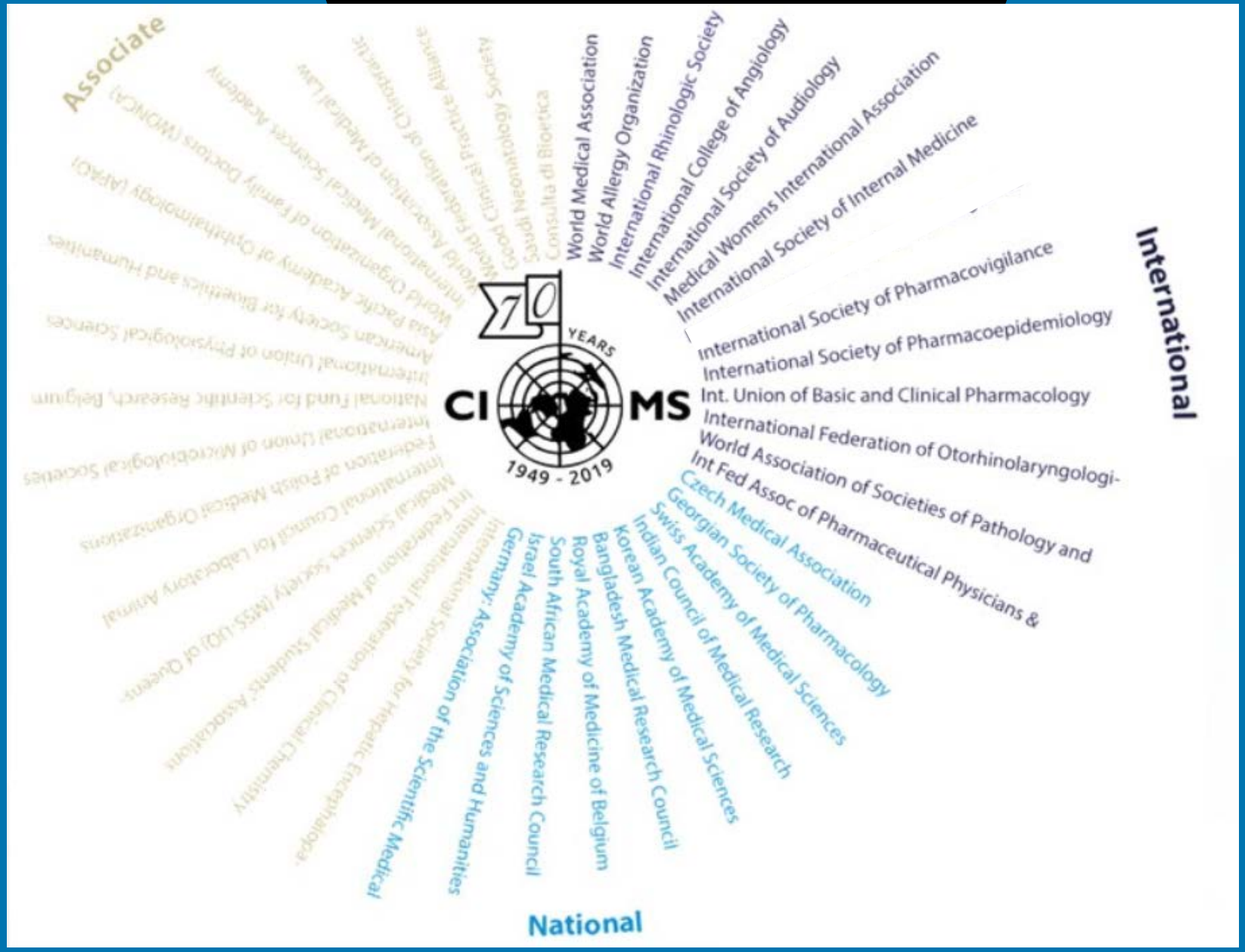
Secretary General Dr Lembit Rägo

Prof Clinical Pharmacology (Tartu University) and founder and first Director General of the Estonian Drug Regulatory Authority.

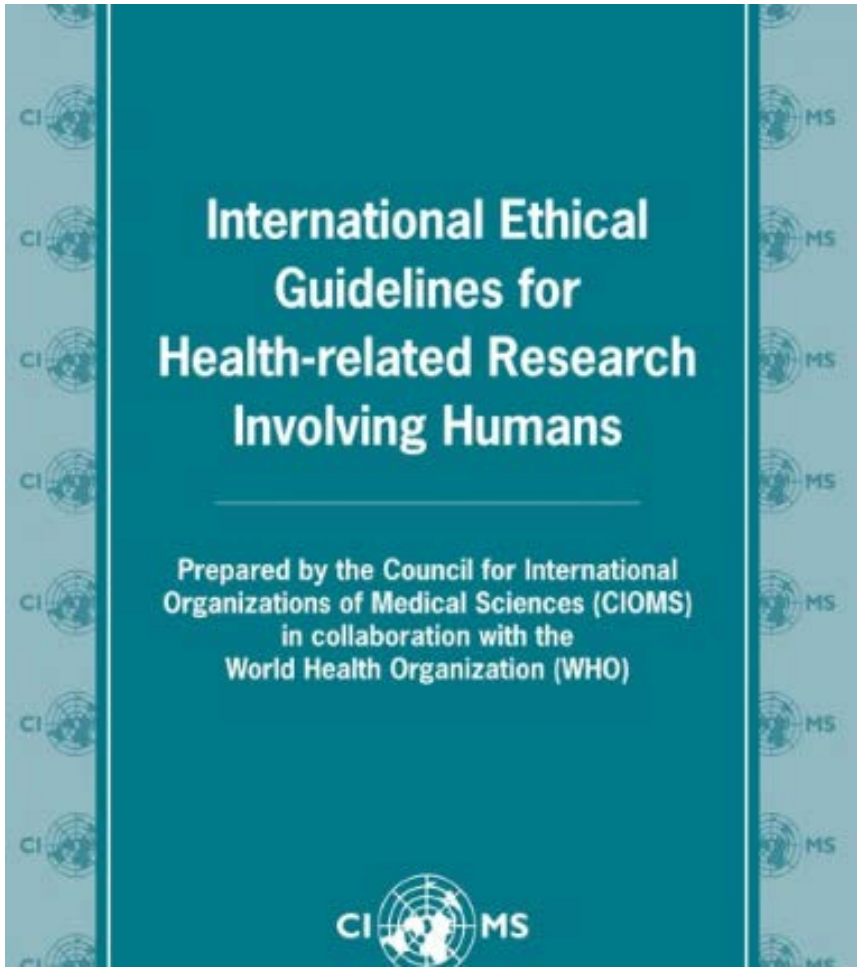
From September 2013, served as the Head of WHO's Regulation of Medicines and Other Health Technologies unit

CIOMS members

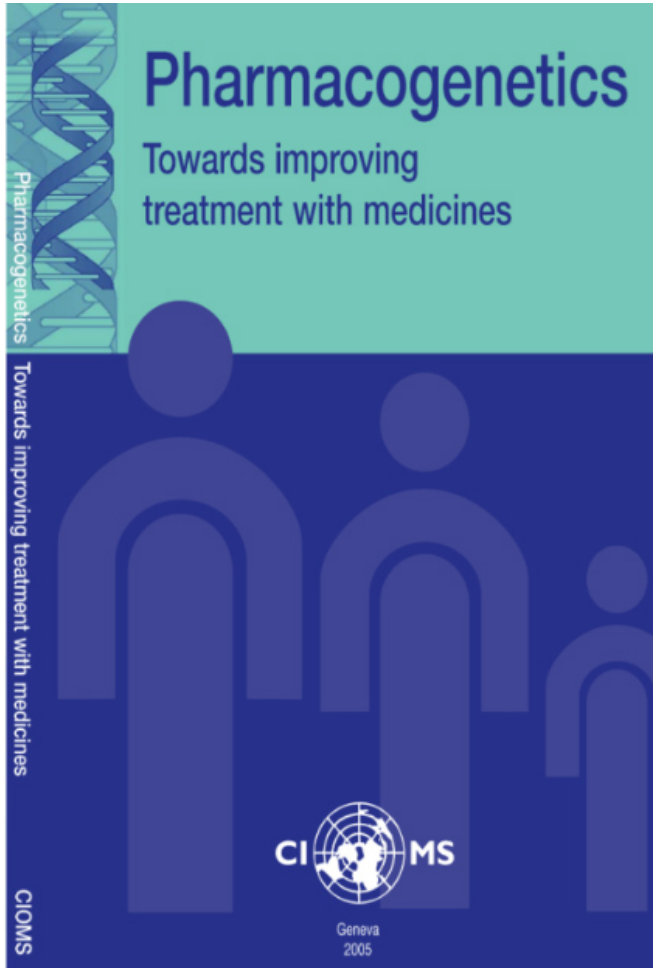
https://cioms.ch/cioms-members



Bioethics



Drug development



Pharmacovigilance

CIOMS
Current work

Working Groups – core of CIOMS

Ongoing Working Groups

- Implementation of Standardised MedDRA Queries (started 2004)
- Drug Induced Liver Injury (started 2017)
- Clinical Research in Resource Limited Settings (started 2017)
- Patient Involvement in Development and Safe Use of Medicines (04/2018)
- MedDRA Labelling Groupings (04/2019)

New WG starting

Revision of CIOMS IV: Benefit-Risk Balance for Marketed Drugs - Evaluating Safety Signals (09/2019)

Working group XI (+ Nikos, Kaisa, Kerry) total 49 members

Scope

International recommendations on Patient Involvement in Development and Safe Use of Medicines

Patient organisations

1. European AIDS Treatment Group (EATG)
2. European Organisation for Rare Diseases (EURORDIS)
3. European Patients' Forum (EPF)
4. International Alliance of Patients' Organizations (IAPO)
5. Alström Syndrome UK
6. National Health Council, U.S.

Regulators

1. Medicines Evaluation Board (MEB)
2. Health Canada
3. Pharmaceuticals and Medical Devices Agency (PMDA)
4. European Medicines Agency (EMA)
5. U.S. FDA
6. MHRA
7. Health Products Regulatory Authority (HPRA)
8. Swissmedic
9. (CFDA China)

Pharmacovigilance stakeholders

1. International Society of Pharmacovigilance (ISOP)
2. Netherlands Pharmacovigilance Centre Lareb
3. Uppsala Monitoring Centre (UMC)
4. Center for Medicine in the Public Interest (CMPI)
5. Leeds University, U.K.
6. World Medical Association

Scope

International recommendations on Patient Involvement in Development and Safe Use of Medicines

Industry

1. Roche
2. Takeda
3. IQVIA
4. Merck
5. Janssen
6. GSK
7. Eli Lilly
8. AbbVie

Industry

9. Bristol-Myers Squibb
10. Pfizer
11. Amgen Inc.
12. Novartis
13. Bayer AG
14. United Therapeutics

CIOMS and WHO

1. Secretary-General
2. Senior Advisor
3. Technical writer
4. WHO: Safety and Vigilance Team (SAV)

Objectives and timelines

1

To formulate pragmatic Points to Consider in patient involvement

2

The guidance will provide a comprehensive overview of present knowledge and existing initiatives

3

Will address a wide range of the remaining challenges and practice gaps

4

CIOMS WGs take ≅ 2-4 years to finalise their guidance and recommendations

18 months to go

More than 80 pages already

5

- 1st meeting held on 19-20 April 2018, Geneva, Switzerland
- 2nd meeting held on 23–24 October 2018, Berlin, Germany
- Open meeting on patient involvement in development and safe use of medicines, 30 April 2019
- 3rd meeting held on 1-2 May 2019 in Geneva, Switzerland

Guidance Document

Overview of the proposedCIOMS guidance
Kerry Leeson-Beevers
National Development Manager
Alström Syndrome UK

- First global guidance document on this topic
- Patient involvement in the life cycle of medicines

- Recognition of the importance of patient involvement
- 'Meaningful Engagement'
- Recognising the benefit of working together for the benefit of patients and their carers

Table of content - Principles of patient involvement (group 1) chapters

1

Introduction

Historical context, what is meant by engagement, whom to engage, when

2

Landscape of patient involvement in the development and safe use

Vignettes on key milestones organised by stakeholder group

3

Patient involvement in advancing treatments for their disease

Collaboration across the lifecycle of treatment dev. and safe use: contributions from stakeholders

4

Guiding principles for engagement

Transparency Communication, Supporting frameworks, selection of patients, training, legal/ regulatory, privacy considerations…

5

Measures for Success

Definition of success based on multi-stakeholder discussion

Table of content - Patient involvement in pharmacovigilance and risk management, guiding principles for (group 2)

chapters

6

Patient involvement in patient product labelling

- *Info on benefit/risk*
- *What is high quality labelling*
- *Involving patients?*
- *Evaluation of effectiveness of patient labelling*

7

Patient participation in design, implementation and evaluation of additional risk minimization measures

8

Patient participation in the generation and utilisation of safety and effectiveness data

9

Patient input in developing safety issue communications regarding medicinal products

10

Patient participation in therapeutic decision-making

Some issues

International recommendations on Patient Involvement in Development and Safe Use of Medicines

Addressing all regions of the world

1. Need for a global guidance
   - Recognise diversity, and free of cultural bias
2. Challenges in low-and middle income countries (LMIC)
3. Who is "the patient", and how can fair representation be achieved?
   - Patients with diseases of poverty, depression or chronic conditions of old age are not well represented.
   - The stigma of some diseases may also prevent patient involvement

Policies and practical aspects

1. Transparency and conflicts of Interests
2. Using patient data to evaluate the benefits and risks of medicines
   - Different methods
   - Data dividend / monetary value of patient data
   - Re-identification issues

Other points

1. Are there examples where patient involvement has led to better products?
2. Buy-in from stakeholder groups
   - Will help in disseminating / implementing the guidance

Future work

International recommendations on Patient Involvement in Development and Safe Use of Medicines

Ethics

Specific areas of ethical principles to be further explored and possibly documented in guidelines or other resource documents

Barriers

Change management approaches specific to overcoming barriers/resistance to patient involvement in drug development organisations

And also

1. Considerations for companies of different sizes and available resources
2. Further work into translating measures of success for patient involvement into monetary value / return

How could PCWP share their opinion?

Is there a need for a larger patient survey to explore some hypothesis? Or another method?

Other experiences of patient advocacy in other regions than US and EU, or publications not in English: do you have references?

CIOMS, ICH, and EMA own guidelines and their revisions, IMI PARADIGM: how to streamline?

Questions?

THANK YOU