I congratulate CIOMS on the occasion of its 70th Anniversary. CIOMS is a very important and unique international organization that has provided, and continues to provide, unbiased information and guidelines in research ethics and on a variety of pharmaceutical-related safety concerns.

My first introduction to CIOMS goes back to my early work at FDA in the early 1980s, where I was exposed to CIOMS pharmacovigilance activities. Subsequently, most of my interactions with CIOMS have centered on its essential contributions to international guidelines for the protection of human research subjects, especially in the provision of comments during their revision process.

In my work, the CIOMS ethical guidelines have been important resources in developing presentations, curricula for educational workshops, and informational materials for institutional review boards and clinical investigators. The guidelines have been especially important internationally in facilitating the practical implementation of the Declaration of Helsinki.

CIOMS leadership and staff have been, and are, outstanding. The Secretaries-General with whom I have worked most closely, Drs Idänpää-Heikkilä and Lembit Rägo, have brought a wealth of experience from their extensive work in pharmaceuticals at WHO. This has helped in many ways, for example, in selecting impressive expert consultants to serve on working groups. In addition, Mr Sev Fluss has brought his experience at WHO and his expertise as one of the world’s experts on bioethics guidelines to his role as a staff member and advisor. I recall his excellent presentation at the U.S. Holocaust Museum symposium on the anniversary of the Nuremberg Code. I have had occasion to call upon all three of them for advice on ethical issues over the years. They have been friends as well as professional colleagues.

Today, CIOMS is leading the way in transparency through its regular newsletters and public working group minutes. Transparency will become increasingly important in all facets of guideline development, and other organizations will need to emulate CIOMS.

In the future, CIOMS should continue developing guidelines targeted to the special needs of LMICs for example in emerging bioethical issues, broad consent, international data sharing, and many other areas. It is essential for CIOMS to stay closely involved with the work of ICH, WMA, and WHO. In fact, it is a testimonial to the small but excellent staff of its Secretariat that CIOMS is able to support so many well-run and productive working groups.
CIOMS membership

CIOMS was founded in 1949 as an organization to form a link between specialized international medical associations with research interests. Initially its activities were focused on the coordination of international medical congresses globally, and assistance to member organizations for the standardization of nomenclature in various medical disciplines.

In the 1960s, when fundamental changes were transforming the practice and potential of medicine, CIOMS as a non-governmental organization, with a mandate to collaborate with the United Nations and its specialized agencies, was in a position to provide a forum for representatives of different fields to make explicit the ethical and other non-technical considerations to be taken into account along with the technical ones in determining and implementing health policy.

CIOMS is an associate partner of UNESCO, in official relations with the World Health Organization (WHO). Through its members CIOMS reaches out to a large part of the global health community. For example:

- **IFMSA**
  - International Federation of Medical Students’ Associations
  - is one of the world’s oldest and largest student-run organizations. It unites 1.3 million medical students through its network of member organizations in 127 countries. By working with IFMSA CIOMS reaches out to the health professionals of tomorrow.
  - CIOMS has an agreement with IFMSA to support medical student internships at WHO every year.

- **IUPHAR**
  - International Union of Basic and Clinical Pharmacology
  - aims to improve health through pharmacology education and research. IUPHAR has 63 member societies all over the world.

- **Room Association**
  - World Medical Association
  - brings together physicians from over 100 countries through their national associations.

- **International Society of Pharmacology**
  - ISoP
  - fosters science and learning to support the safe use of medicines. ISoP has 61 member countries in all five continents.
Message from CIOMS

We are happy to celebrate the 70th Anniversary of CIOMS with all of our stakeholders. We are proud to lead this small but recognized influential and creative organization. On behalf of the Executive Committee and the Secretariat we would like to pay tribute to all the past Presidents, Secretaries-General, staff members, and members of the Executive Committee. It is their vision, their dedication to improving public health and their success in handling complex problems that we are celebrating. We will do our best to continue in their footsteps.

It is with tremendous gratitude that we would also like to acknowledge the contribution of all past and present members of numerous CIOMS international Working Groups. The Working Groups are the core of CIOMS!

Professor Hervé Le Louët
President

Dr Lembit Rägo
Secretary-General

How CIOMS is governed

General Assembly
Consists of representatives from all international and national members

elects

Executive Committee
Consists of up to 12 representatives of member organizations, and has full powers to act on behalf of CIOMS

President
Since 2016 Hervé Le Louët

Secretariat
Carries out the day-to-day management of CIOMS in line with the directions of the Executive Committee

Secretary-General
Since 2016 Lembit Rägo

Past Presidents
2010 Johannes JM van Delden
2003 Michel Vallotton
1993 John H (Jack) Bryant
1987 Francisco Vilardell
1980 Murillo Belchior
1970 Alfred Gellhorn
1964 Marcel Florkin
1961 Robert Cruickshank
1955 Ronald Ernest Tunbridge
1949 Joseph Maisin (Chairman of the Executive Committee)

Past Secretaries-General
2010 Gunilla Sjölin-Forsberg
2006 Gottfried Kreutz
1999 Juhana Idänpään-Heikkilä
1975 Zbigniew Bankowski
1974 Louis Verhoestraete
1971 Simon Btesh
1966 Vittorio Fattorusso
1961 Paul Albert Messerli
1950 Jean Delafresnaye
Unique topics: the Round Table conferences

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.

These developments are reflected in the 30-year history of Round Table Conferences organized by CIOMS. The Council has not hesitated to take up some bold topics.

I. Biomedical Science and the Dilemma of Human Experimentation
   Paris, France
   1967

II. Heart Transplantation
    Geneva, Switzerland
    1968

III. Evaluation of Drugs: WHOse Responsibility?
     Liège, Belgium
     1968

IV. Medical Research: Priorities and Responsibilities
    Geneva
    1969

V. Training of Research Workers in Medical Sciences
    Geneva
    1970

VI. Drug Abuse: Non-Medical Use of Dependence-Producing Drugs
    Geneva
    1971

VII. Recent Progress in Biology and Medicine: Its Social and Ethical Implications
     Paris
     1972

VIII. Protection of Human Rights in the Light of Scientific and Technological Progress in Biology and Medicine
      Geneva
      1973

IX. Medical Care and Society
    Rio de Janeiro, Brazil
    1974

X. Health Needs of Society: A Challenge for Medical Education
   Ulm, Germany
   1976

XI. Trends and Prospects in Drug Research and Development
    Geneva
    1977

XII. Medical Ethics and the Protection of Human Rights
     Cascais, Portugal
     1978

XIII. Economics and Health Policy
      Geneva
      1979

XIV. Medical Ethics and Medical Education
      Mexico
      1980

XV. Human Experimentation and Medical Ethics
    Manila, Philippines
    1981

XVI. Health for All – a Challenge to Research in Health Manpower Development
     Ibadan, Nigeria
     1982

XVII. Biomedical Research Involving Animals – Proposed International Guiding Principles
      Geneva
      1983

XVIII. Health Policy Ethics and Human Values: An International Dialogue
       Athens, Greece
       1984

XIV. Battered Children and Child Abuse
     Berne, Switzerland
     1985

XX. Health Manpower out of Balance. Conflicts and Prospects
    Acapulco, Mexico
    1986

XXI. Health Policy, Ethics and Human Values: European and North American Perspectives
     Noordwijk, the Netherlands
     1987

XXII. Ethics and Human Values in Family Planning
      Bangkok, Thailand
      1988

XXIII. Health Technology Transfer: Whose Responsibility?
      Geneva
      1989

XXIV. Genetics, Ethics and Human Values: Human Genome Mapping, Genetic Screening and Gene Therapy
      Tokyo and Inuyama City, Japan
      1990

XXV. Ethics and Epidemiology: International Guidelines
     Geneva
     1990

XXVI. Ethics and Research on Human Subjects. International Guidelines
       Geneva
       1992

XXVII. Drug Surveillance: International Cooperation – Past, Present and Future
       Geneva
       1993

XXVIII. Poverty, Vulnerability, the Value of Human Life and the Emergence of Bioethics
        Ixtapa, Mexico
        1994

The Declaration of Inuyama, a follow-up to the 1990 Conference
      Inuyama and Nagayo
      1995

XXIX. Ethics, Equity and Health for All
      Geneva
      1997
Did you know?

Over the decades, the work of CIOMS has had a lasting impact on many areas of medical sciences.

A landmark CIOMS meeting put controlled clinical trials on the map

The meeting took place in Vienna on 23–27 March 1959 and was chaired by Austin Bradford Hill, director of the British Medical Research Council’s Statistical Research Unit. The proceedings described the British concept of the controlled clinical trial and the place that it held in medicine.

See also: Bird SM. The 1959 meeting in Vienna on controlled clinical trials – a methodological landmark. JLL Bulletin: Commentaries on the history of treatment evaluation.

As I sat on the dais in Room X of UNESCO House in Paris, about to deliver one of two introductory presentations to the “round table” of assembled experts, I felt anxious. The hall was gigantic. In addition to the front rows, occupied by scientists from near and far, there were rows upon rows of seats, each with a desk and microphone, reserved for ambassadors of the UNESCO countries, other rows for representatives of international scientific associations, and still others for the press. Booths for simultaneous translation overlooked the hall.

Amitai Etzioni

The longest-serving CIOMS Secretary-General was in office for 25 years

Zbigniew Bankowski was Secretary-General of CIOMS from 1975 to 1999. He passed away in 2010.

This was the first time that, as a result of several years of laborious and extensive international consultations, the supreme body of the United Nations – the nearest we have to a World parliament – had taken action on a matter specifically affecting the medical and allied professions.

Zbigniew Bankowski, in his Background Note to the 1983 CIOMS publication

There is much I could say about my esteemed friend. Suffice it to say that, by his personal commitment and his seemingly inexhaustible energy, he has succeeded in bringing CIOMS to the forefront of the global dialogue on ethics in health policy.

Hiroshi Nakajima, then WHO Director-General, at the Opening of the XXVth CIOMS Round Table Conference

CIOMS guidelines have been adopted as a UN resolution

The CIOMS Principles of Medical Ethics relevant to the role of health personnel, particularly physicians, in the protection of prisoners against torture and other cruel, inhuman or degrading treatment or punishment were adopted by the General Assembly as an annex to UN Resolution 37/194 of 9 March 1983.

In the leaflet supplied with your medicine, the frequency of side effects is presented according to CIOMS guidance

The frequency categories are stated as recommended in the 1990s by the CIOMS III Working Group.

CIOMS reports formed the basis of several ICH guidelines (ICH E2A, E2C, E2D and E2F), laying the foundations for modern pharmacovigilance.

The 25-year experience of RUCAM use confirmed that the success was due to its objective, standardized, and liver-injury-specific approach structured with defined key elements derived from a series of DILI cases with positive rechallenge.

Danan G, Teschke R.
Drug Safety. 2018;41 (8), 735–743.

A CIOMS scale for liver injury has been used for 25 years

Launched in 1993 and partially based on the results of an international consensus meeting organized under the auspices of CIOMS, the Roussel Uclaf Causality Assessment Method (RUCAM) is the most used causality assessment tool worldwide for the diagnosis of drug-induced liver injury (DILI) and herb-induced liver injury (HILI).

In 2017 CIOMS started a new Working Group on DILI. The proceedings from this Working Group are expected to replace RUCAM.
CIOMS publications

**Ethical guidelines**

“CIOMS is a small organization but represents a big name in research ethics. The guidelines for the ethical evaluation of health related research guidelines are up to date, comprehensive, coherent and widely used. By providing extensive commentaries, they have proved to be a valuable tool for research ethics committees worldwide.”

*Johannes JM van Delden, Past President of CIOMS*

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### Guidelines on ethics and product development

<table>
<thead>
<tr>
<th>Title</th>
<th>Year</th>
<th>Languages</th>
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<tbody>
<tr>
<td>International ethical guidelines for health-related research involving humans</td>
<td>2016</td>
<td>En, Fr, Es, Pt, Uk, Ru, Ch*</td>
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<tr>
<td>International Ethical Guidelines for Epidemiological Studies</td>
<td>2009</td>
<td>En</td>
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<td>Pharmacogenetics: Towards improving treatment with medicines</td>
<td>2005</td>
<td>En</td>
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<td>International Ethical Guidelines for Biomedical Research Involving Human Subjects</td>
<td>2002</td>
<td>En, Fr, Cz, Pt, Cz*, Ch*, Jp*</td>
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<td>Biomedical Research Ethics: Updating International Guidelines: A Consultation</td>
<td>2000</td>
<td>En</td>
</tr>
<tr>
<td>Ethics, Equity and Health for All</td>
<td>1997</td>
<td>En</td>
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<td>Biomedical Research Involving Animals: Proposed International Guiding Principles</td>
<td>1984</td>
<td>En</td>
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<tr>
<td>Principles of Medical Ethics Relevant to the Protection of Prisoners Against Torture</td>
<td>1983</td>
<td>En, Fr, Es, Ar, Ch, Ru</td>
</tr>
<tr>
<td>Human Experimentation and Medical Ethics</td>
<td>1982</td>
<td>En</td>
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### Clinical pharmacology

**WHO / IUPHAR / CIOMS**

Clinical Pharmacology in Health Care, Teaching and Research | 2012 | En, Jp |

Clinical pharmacology is one of the core disciplines for medicines development and safe use. This position paper was composed and edited by representatives of the International Union of Basic and Clinical Pharmacology (IUPHAR), WHO and CIOMS. It is an updated and edited version of a 2010 publication and contains new chapters of special relevance to global health.

En=English; Fr=French; Es=Spanish; Pt=Portuguese; Uk=Ukrainian; Ru=Russian; Cz=Chinese; Ar=Arabic; Cz=Czech; Jp=Japanese

*=Not (yet) available through the online ordering system. Please contact info@cioms.ch
Pharmacovigilance

Click on the coloured blocks in the online version of this Newsletter, or visit us at: https://cioms.ch/shop/

CIOMS Guide to Vaccine Safety Communication 2018
CIOMS Guide to Active Vaccine Safety Surveillance 2017
Development and Rational Use of Standardised MedDRA Queries (SMQs): Retrieving Adverse Drug Reactions with MedDRA 2016
Evidence Synthesis and Meta-Analysis for Drug Safety (CIOMS X) 2016
Practical Approaches to Risk Minimisation for Medicinal Products (CIOMS IX) 2014
Definition and Application of Terms for Vaccine Pharmacovigilance 2012
Practical Aspects of Signal Detection in Pharmacovigilance (CIOMS VIII) 2010
Development Safety Update Reports (DSUR): Harmonizing the Format and Content for Periodic Safety Report during Clinical Trials (CIOMS VII) 2006
Management of Safety Information from Clinical Trials (CIOMS VI) 2005
Development and Rational Use of Standardized MedDRA Queries (SMQs): Retrieving Adverse Drug Reactions with MedDRA 2004
Current Challenges in Pharmacovigilance: Pragmatic Approaches (CIOMS V) 1999
Guidelines for Preparing Core Clinical Safety Information on Drugs (second edition) (CIOMS III and V) 1999
Reporting Adverse Drug Reactions: Definitions of Terms and Criteria for Their Use 1999
Benefit-risk balance for marketed drugs: Evaluating safety signals (CIOMS IV) 1998
Guidelines for Preparing Core Clinical Safety Information on Drugs (CIOMS III and V) 1995
Drug Surveillance: International Cooperation Past, Present and Future (XXVIIth Round Table Conference) 1994
International Reporting of Periodic Drug Safety Update Summaries (CIOMS II) 1992
International Reporting of Adverse Drug Reactions (CIOMS I) 1987
Monitoring and Assessment of Adverse Drug Effects (CIOMS I) 1985
Safety Requirements for the First Use of New Drugs and Diagnostic Agents in Man 1983

For more than 20 years I have been involved in adverse drug reaction detection, analysis and reporting. The CIOMS criteria have been the most valuable resource for causality assessment and standards for pharmacovigilance.

Petra Thürmann (IUPHAR, and CIOMS Executive Committee member

CIOMS has a rich history of bringing together a fair balance of industry and government stakeholders and other relevant parties to develop consensus approaches to gnarly pharmacovigilance and ethics issues. Many of the CIOMS consensus recommendations and principles have been adopted by regulators for protection of study subjects and patients around the globe. I am proud to have been an active contributor to several Work Groups.

Bill Gregory, Pfizer

International nomenclature of diseases

In 1975 CIOMS and WHO jointly undertook the International Nomenclature of Diseases project. More than 20,000 synonymous terms were listed in a total of 11 published volumes, 7 of which can still be ordered through the CIOMS website.

I was part of five of the early CIOMS safety working groups. The reports of these working groups formed the direct basis for several of the ICH guidances on product safety surveillance and ongoing assessment. The benefit of the CIOMS forum was as a neutral, comprehensive “think tank” in which stakeholders could develop trust in each other and discover their common ground. With that trust and common ground recognition, we were able to develop documents that expressed strategic goals, specific process ideas and consensus aspirations. ICH, given its regulatory imprimatur, was then able to take these ideas and change them from aspirations into the actual way that these issues are addressed globally.

Murray (“Mac”) Lumpkin, Bill & Melinda Gates Foundation, Senior U.S. FDA official at the time of his involvement in the CIOMS Working Group
Where to from here?

I took a fond farewell of CIOMS in Geneva at the end of 2015. I am grateful to have seen, during my time in office, three WG reports being published and four initiated. The main pillar of these publications was the excellent contribution of involved experts. The very friendly working climate at CIOMS encouraged new initiatives, and it is with great satisfaction and happiness that I have seen the recent commencement of the new CIOMS WG on patient involvement at all steps during the life-cycle of a medicine. The three other new CIOMS WGs initiated since my departure – Drug Induced Liver Injury, Clinical Research in Resource-Limited Settings and MedDRA Labeling Groupings – are also covering highly relevant and very important topics.

There are a lot of motivating topics in need of global harmonization but also an increased number of interested actors willing to take a lead. The strengths of CIOMS is the platform itself, involving all stakeholders, the global perspective involving all regions of the world, and the close collaboration with UNESCO and WHO. Over the years there has also been a fruitful collaboration with the International Conference on Harmonization (ICH), and since 2016 CIOMS is an ICH observer.

The future of CIOMS looks promising although it includes challenges. I am convinced that CIOMS will seize its opportunities. I wish all experts involved in CIOMS activities and the dedicated staff at the CIOMS Secretariat a successful future!

Gunilla Sjölin-Forsberg, Immediate Past Secretary-General

It was an honour for me to work with industry and regulatory colleagues who were willing to set aside personal and institutional beliefs in order to agree on the best standards for managing and reporting drug safety information. The working groups under CIOMS perform an invaluable service by providing unbiased, scientifically- and ethically-based advice.

In that spirit, for purposes of making presentations over the years on the work of CIOMS, I created a disclaimer which for me summarizes what CIOMS is all about: “CIOMS Does Not Have any Official Regulatory or Other Authority. It Influences and Persuades by the Strength of its Ideas and its Credibility.”

May it continue to serve!

Arnold J Gordon, Pharmaceutical Consultant

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