What's on @ CIOMS
COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES
70 YEARS 1949 - 2019

WWW.CIOMS.CH | June 2019 | **Newsletter** | **# 26**

HIGHLIGHTS

International events and visits

Launch of the CIOMS/WHO Ethical Guidelines in Chinese

Shanghai, China, 27 April 2019

The Chinese translation of the 2016 CIOMS/WHO *International Ethical Guidelines for Health-related Research Involving Humans (1)* was officially launched during an event held at the Shanghai Clinical Research Center (SCRC). Invited guests from research institutions, ethics committees and health authorities attended the launch.

The translation was prepared by a group affiliated with the Independent Ethics Committee for clinical research at the SCRC, and reviewed by Professor Ching-Li Hu, Dr Wei Zhu and Dr Naiqing Zhao.

The CIOMS guidelines are fully in line with the World Medical Association's Declaration of Helsinki and address a wide range of activities that fall under health-related research involving humans, such as observational research, clinical trials, biobanking, epidemiological studies and research with health-related data.

China is making rapid progress in medical research, as shown in a BMJ special collection that analyzes the new challenges and opportunities arising in China in the areas of evidence-informed policy, guidelines development, real world evidence, and big data.*(2)* On this backdrop the Chinese translation of the CIOMS ethical guidelines, with their detailed commentaries supporting practical implementation, has the potential to be useful to a vast number of researchers.

(1) CIOMS/WHO. International Ethical Guidelines for Health-related Research Involving Humans [in Chinese]. Translation supported by Shanghai Clinical Research Center.

(2) Wu Y, Yin D, Abbasi K. China's medical research revolution [Editorial]. BMJ 2018;360:k547.

***Left**: Professor Ching-Li **Hu**, Honorary Chairperson of the SCRC's Independent Ethics Committee, during his address at the launch of the guideline.*

***Right**: Dr Lembit **Rägo**, CIOMS Secretary-General, participated in the event by teleconference.*

(Photographs: SCRC)

Linking up with →

→ The IFPMA Regulatory Science Committee

Campus Biotech, Geneva, 20 March 2019

The Regulatory Science Committee of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) invited the CIOMS Secretary-General to give an overview of CIOMS activities. In his presentation Dr Rägo introduced current and planned future activities of CIOMS in the year of the Council's 70th Anniversary, which was marked at the Open Meeting of the CIOMS Working Group XI: Patient Involvement in Drug Development and Safe Use (see page 3). The CIOMS Working Group XI is developing guidance on patient involvement during the entire life-cycle of medicines, from the early phases of development until their retirement from the market.

→ The Swiss Malaria Group

Maison de la Paix, Geneva, 24 April 2019

On World Malaria Day 2019 the Swiss Malaria Group invited the CIOMS Secretary-General to a reception held to look back on 20 years of Swiss collaborations for new malaria medicines and discuss the way forward for malaria elimination. Speakers included representatives from the Swiss Agency for Development and Cooperation, the Swiss Tropical and Public Health Institute, the Swiss Academy of Sciences, Novartis, the Permanent Mission of Zambia to the United Nations Office in Geneva, and the Medicines for Malaria Venture. The event was an opportunity for networking and exchange.

→ Legal experts on pharmacovigilance

Chilly-Mazarin (Paris), France, 27 May 2019

At the biannual pvlegal network meeting, which was hosted by Sanofi-Aventis at its Research Development campus near Paris, the CIOMS Secretary-General was invited to give a presentation about CIOMS and its activities. The presentation focused on the Working Group on Patient Involvement in the Development and Safe Use of Medicines (CIOMS Working Group XI). It was followed by questions and discussion.

pvlegal ("pharmacovigilance legal") is a group of in-house lawyers of more than 20 pharmaceutical companies who advise their drug safety departments on legal aspects of pharmacovigilance, often globally. The group was created more than ten years ago and meets twice a year: once in Europe, and once in the United States. It is one of five membership-based legal networks that conduct benchmarking to determine best practices and follow the adoption and implementation of new rules around the world, in particular in the EU, the U.S. and China. Contacts will be maintained between some of these legal networks and CIOMS. In September Dr Rägo will give a presentation about CIOMS to ctlegal, the group focusing on legal aspects of clinical trials.

→ ICH

Amsterdam, the Netherlands, 1-6 June 2019

Twice a year the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) holds a set of meetings at which observers such as CIOMS can give their input. CIOMS Secretary General Lembit Rägo attended this year's first meetings. Details are found in the ICH Press release.

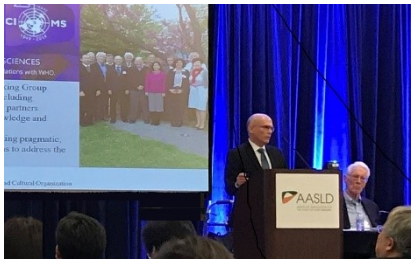
AASLD/FDA DILI conference

Hyattsville (near Washington DC), U.S., 7-8 May 2019

CIOMS President Hervé Le Louët attended the international conference sponsored by the U.S. Food and Drug Authority (FDA) and the American Association for the Study of Liver Diseases (AASLD). This academic-industry-government meeting took place one week before the 5th meeting of the CIOMS Working Group on Drug-Induced Liver Injury (DILI) (see also page 5). It focused on new treatments with a hepatotoxic potential and discussed study populations of growing concern, as well as state-of-the-art scientific tools and methods that are now becoming available for the assessment of DILI risk.

There are growing challenges to accurately predict DILI risk linked to evolving immunotherapies and in patients with underlying chronic liver disease. There was a robust exchange of ideas and debate towards establishing consensus among participants on DILI risk assessment.

*Dr Arie **Regev**, Vice-Chair of the CIOMS DILI WG and co-organizer of the AASLD/FDA conference, highlighted the complementarity between ongoing DILI initiatives and the fantastic opportunity of dissemination offered by the CIOMS DILI Working Group. (Photograph by Hervé Le Louët)*



CIOMS Anniversary:
Open Meeting on Patient Involvement

On 30 April 2019, CIOMS held an Open Meeting in Geneva, Switzerland, to gather wide input to the international guidance document that is being developed by its Working Group XI on Patient Involvement in the Development and Safe Use of Medicines. Find the meeting report here.

The event also marked the 70th Anniversary of CIOMS.
Read the CIOMS Anniversary Newsletter here.

Above: Almost 100 participants met in Geneva to provide input to the proposed CIOMS guidance on patient involvement.

Below: The meeting brought together delegates from patient organizations, regulatory authorities, industry, academia, and from professional and international organizations. The main objective was to listen to representatives from patient organizations and geographical regions not represented in the CIOMS Working Group XI.

Looking back: Three decades of work with CIOMS – Ruth Macklin

*Ruth **Macklin** has worked with CIOMS since 1988 in several different capacities. Between 1999 and 2007 she served as Vice President and member of the CIOMS Executive Committee. During that period she was also President of the International Association of Bioethics (IAB) and a member of its Board of Directors. She retired from her position as professor of bioethics at Albert Einstein College of Medicine in 2016, but remains active in the field of global health, in particular, research with human beings.*

In my most recent work with CIOMS, I served on the working group that produced the 2016 revised CIOMS International Ethical Guidelines for Health-related Research Involving Humans. Starting in 2012, our group met three times each year under the excellent leadership of Hans van Delden. This activity was of special interest to me, as I had also been a member of the steering committee that revised the 1993 CIOMS guidelines. That revision was issued in 2002. Each revision added new material and revised both the guidelines themselves and the explanatory commentaries that follow each guideline.

A major addition in the 2016 version were two new guidelines: one that addresses research involving the use of data in health-related research, and another on the collection, storage, and use of biological materials and related data. The addition of these and other new guidelines reflects scientific and social developments in health-related research.

The discussion of vulnerable research subjects is an important innovation in the CIOMS guidelines. The past versions, along with virtually all other guidelines for ethics in research, contained lengthy lists of research participants considered to be vulnerable—making it appear that the only people who are not vulnerable are economically well-off white men between the ages of 25 and 50 living in upper income countries! The new CIOMS guideline 15 on *Research Involving Vulnerable Persons and Groups* focuses on the characteristics that render individuals or groups vulnerable, and recommends specific protections to safeguard their rights and welfare in the conduct of research.

The CIOMS guidelines are available on line, and I was eager to incorporate them in my teaching and writing in bioethics. I am affiliated with a U.S. government-sponsored educational and training program in research ethics that takes place in different developing countries. Two of the programs are in Argentina and Mexico. My presentations at conferences and classroom teaching in those countries are in Spanish, and it was a great help when the guidelines were translated into Spanish. In 2017, I was the speaker in a webinar organized by the Pan American Health Organization (PAHO) to introduce the new CIOMS guidelines in Latin America. I have also used the guidelines in an educational and training program in India. I usually have to explain what CIOMS is, and I mention the long-standing collaboration with WHO in the process of revising the guidelines.

My first experience with CIOMS goes back to a 1988 conference on "Ethics and Human Values in Family Planning", which was jointly organized in Bangkok by WHO and CIOMS. A colleague and personal friend was a member of the small group at CIOMS that planned the agenda for the conference. Since the topic was ethics and human reproduction, my friend suggested that it would be good to have a woman deliver the keynote address. The other members of the group (all men) agreed, and my participation marked the beginning of the next 30 years of my work in global health.

In 1999 I convinced my fellow IAB Board members that it would be a good idea for the IAB to become a member of CIOMS. Since that was also the period when the 1993 CIOMS guidelines were undergoing revision, and I was a member of that working group, the IAB Board readily agreed. Unfortunately, however, after my tenure on the IAB Board ended, the new Board declined to renew its membership in CIOMS. In one respect, that was understandable since the Association has very little money and it was a bit of a hardship to pay membership dues to another organization. Still, I maintain that membership of an ethics organization in CIOMS is mutually beneficial and I regret the IAB Board's decision.

The CIOMS guidelines will continue to be a centerpiece of my teaching and conference presentations as I pursue my work in ethics in international research. I take pride in having worked with international colleagues on a document that is especially useful to researchers and scholars in developing countries.

News from the CIOMS Working Groups

Drug-induced Liver Injury (DILI)

5th Working Group meeting
Tallinn, Estonia, 15-16 May 2019

The CIOMS group brings together some of the world experts in DILI. *From left to right: Guruprasad **Aithal**, Arie **Regev**, Hervé **Le Louët**, Lembit **Rägo**, Einar **Björnsson**, Stewart **Geary**, Hajime **Takikawa** and Michael **Merz**.*
*Some group members gave updates on other DILI-related initiatives in which they participate: the AASLD/FDA DILI Conference (Mark **Avigan**, see also page **2**); the Prospective European Drug-Induced Liver Injury Network Pro-Euro DILI Net (Raul J **Andrade**) the IQ-DILI Initiative (Arie Regev); the HBV Forum, (Robert **Fontana**) and the Translational Safety Biomarker Pipeline (TransBioLine) project (Gerd **Kullak-Ublick**). (Photograph: Jia-bo **Wang**).*

The Working Group made good progress at its 5th face-to-face meeting. Drafting of the content for its consensus guidance on DILI detection, causality assessment, monitoring and management is largely completed. An important part of the guidance will be a model Case Report Form, for investigators and clinicians to report data on suspected DILI cases in a standardized way. This would help specialists to build valuable evidence in this complex and rapidly growing field. Severe DILI is rare but can be fatal, is often unpredictable, and can mimic almost every known type of liver disease.

The remaining tasks are now to fine-tune some parts of the draft report and to bring it together into a single, user-friendly document. An editorial team will work together over the coming months to finalize the guidance for publication.

☞ Meeting minutes are found on the CIOMS DILI Working Group's webpage.

The CIOMS DILI meeting attracted considerable local media interest. *A live interview with Dr **Rägo** was broadcast on 15 May in a popular morning TV show, and on the same day Professor Raul J **Andrade** from Malaga University, Dr Mark **Avigan** from US FDA, CIOMS President Professor Hervé **Le Louët** and Dr Arie **Regev** from Eli Lilly were interviewed for the Lege Artis medical journal.*

***Above**: The CIOMS DILI group visited the old town of Tallinn.*
***Right**: The Town Hall pharmacy is one of the oldest continuously running pharmacies in Europe, with records dating back to 1422. (Photographs: Jia-bo Wang)*

Visit to medicines regulatory authority of Estonia

Following the DILI Working Group meeting the President and the Secretary-General of CIOMS visited the Estonian State Agency of Medicines (SAM) in Tartu, Estonia's second largest town. They met with the Director-General of SAM, Dr Kristin Raudsepp, and the Head of the Bureau of Pharmacovigilance, Dr Maia Uusküla, to discuss several topics of mutual interest. The CIOMS officials thanked SAM for their help in organizing and contributing to the 3rd Meeting of the CIOMS WG on Clinical Research in Resource-Limited Settings held in Tallinn in October 2018. The CIOMS officials took the opportunity to visit some historical sites at Tartu University, which was founded in 1632 by Swedish King Gustavus Adolphus II under the name of Academia Dorpatensis (Tartu was called Dorpat at an earlier time in its history).

*The Old Anatomical Theatre (Vana Anatoomikum) in Tartu, constructed in 1805. (Photograph by Bernt Rostad - Flickr: Vana Anatonoomikum, CC BY 2.0, https://commons.wikimedia.org). Tartu University was home to several famous medical scientists during the 19th Century: In 1886 Professor August **Rauber** (1) authored an internationally acclaimed anatomy textbook republished 20 times, with the last updated edition published in Germany in 1987. Karl **Kupffer** is regarded as the founder of comparative embryology.*

(1) Aunapuu M, Puusepp M, Toomsalu M, Arend A. Tartu Old Anatomical Theatre 200 – Contribution of German Anatomists. Ann Anat. 2005 Sep; 187(4): 415-20.

Visit to medicines regulatory authority in Tartu
(continued)

The former Institute of Pharmacology at the Old Anatomical Theatre in Tartu carries a memorial plate dedicated to Professor Rudolph ***Buchheim,*** *who worked at Dorpat University from 1847 until 1867. He then he accepted the chair of pharmacology at Giessen, in the Grand Duchy of Hesse (Germany). Buchheim's name is associated with starting the systematic exploration of experimental pharmacological methods, and he is considered as one of the founders of experimental pharmacology.(2)*
(Photograph by Jaanus Harro)

(2) Sheindlin S. Our Man in Dorpat: Rudolf Buchheim and the Birth of Pharmacology. Molecular Interventions. December 2010;10(6): 331-335.

Patient Involvement in the Development and Safe Use of Medicines

3rd Meeting of Working Group XI
Geneva, Switzerland, 1-2 May 2019

At its 3rd Meeting the CIOMS Working Group XI (WG XI) continued developing its guidance and discussed the learnings from the Open Meeting held on 30 April. Some of the main points that resonated with group members included: The need for a truly global perspective (*"It's a whole world out there not operating to the same understanding"*), issues of representativeness (who is "the patient"? For example, who speaks for people with depression?), and the value of the CIOMS as an internationally respected platform that can make practical, yet ambitious recommendations to be taken up by policy-makers all over the world.

The 4th Meeting of this Working Group will be held in Basel on 16–17 October.

☞ See more about this group on the WGXI webpage.

☞ **CIOMS WG XI at the DIA 2019 Annual Meeting:**
The work of the CIOMS WGXI was presented at the DIA 2019 Annual Meeting in San Diego on 24 and 25 June. A forum and a round table discussion on Current initiatives on Patient Involvement in the Medicinal Product Lifecycle provided opportunities to gather additional input to the draft CIOMS guidance on patient involvement.

Standardized MedDRA Queries (SMQs)

15th Meeting of the Implementation Working Group
Geneva, Switzerland, 2 April 2019

This group discussed: (1) the status of SMQs and terms that are in production in version 22.0 of the ICH's Medical Dictionary for Drug Regulatory Activities (MedDRA); (2) the final documentation status of two SMQs in development; and (3) a report on testing results of a candidate SMQ.

This longest-running CIOMS group, which originated in 2002, will end formally on 31 December 2019. After that, the management of SMQs will be the responsibility of the MedDRA Maintenance and Support Services Organization (MSSO) under the oversight of the ICH MedDRA Management Committee.

MedDRA Labelling Groupings (MLGs)

1st Expert Working Group Meeting
Geneva, Switzerland, 3-4 April 2019

This new group has emerged from the CIOMS Implementation Working Group on SMQs. It will explore harmonized principles for grouping MedDRA terms when communicating potential adverse reactions and their expected frequency in approved product information. This work is timely as several organizations have already independently created their own groupings. Harmonized MLGs would be clearer for health professionals and would make it easier to calculate frequencies of suspected adverse reactions from clinical trial data and compare these between products.

☞ Read more about the two MedDRA-related CIOMS Working Groups on the CIOMS website.

☞ **CIOMS Expert Working Group on MLGs at the DIA 2019 Annual Meeting:**
Experts from the CIOMS Group explained the concept of MedDRA Labelling Groupings at a forum and a round table discussion both titled The Elephant in the Room: Meaningful Communication on Near Synonyms as Suspected Adverse Reactions.

News from CIOMS members

World Medical Association (WMA)

H20 meeting on Universal health coverage
Tokyo, Japan, 13-14 June 2019

The Health Professional Meeting (H20) 2019, a pre-conference to the G20 Summit 2019 in Osaka, was co-hosted by the WMA and the Japanese Medical Association. CIOMS President, Professor Hervé Le Louët, attended the H20 meeting on behalf of CIOMS.

The event was themed *The Road to Universal Health Coverage.* Access to high quality health care services and medical products for everyone when needed is one of the targets within the Sustainable Development Goals (SDG) set by the UN General Assembly in 2014. Speakers and commentators representing patients, UN organizations, governments, NGOs and donors discussed open questions in achieving universal health coverage, especially in countries with limited resources. A Memorandum was adopted and transmitted to the G20 decision-makers.

At the H20 meeting the CIOMS President met with representatives of the national medical associations of the U.S, Kenya, Japan, Bangladesh, Israel and other countries, and with the WMA President-Elect, Professor Miguel Jorge from Brazil, who expressed a keen interest in strengthening the relations between CIOMS and WMA. It was agreed to organize a meeting in Geneva to explore new ways of collaboration.

The WMA, a CIOMS member, is the global federation of National Medical Associations representing the millions of physicians worldwide. Acting on behalf of patients and physicians, the WMA endeavours to achieve the highest possible standards of medical care, ethics, education and health-related human rights for all people.

☞ https://www.wma.net/

Meeting announcement

World Association for Medical Law (WAML)

25th World Medical Law Congress
Tokyo, Japan, 5-8 August 2019

The 25th World Medical Law Congress will be held at one of the largest universities of Japan, Waseda University, at which seven prime ministers of Japan have graduated. The main themes of the congress will be *The role of medical law in the 21st Century*, and *Collaboration between medical law, bioethics and legal medicine*.

☞ http://wafml.memberlodge.org/

Delegates at the WMA Health Professional Meeting (H20) 2019 on The road to Universal Health Coverage. *Professor Hervé* ***Le Louët*** *attended on behalf of CIOMS. Universal health coverage was his previous area of expertise when he was an advisor to the president of France.*

News from WHO

Seventy-Second World Health Assembly

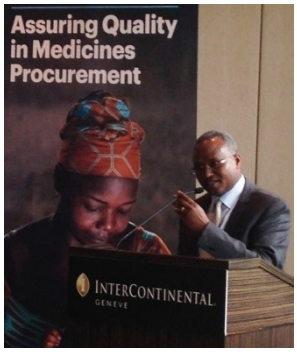
Geneva, Switzerland, 20-28 May 2019

The World Health Assembly (WHA) is the most important global annual event in public health. During WHA, which is the decision-making body of the World Health Organization (WHO), Ministers of Health and other high-ranking health officials from WHO's 193 Member States come together in Geneva to discuss current topics of health care and give direction to WHO's work. The agenda of the Seventy-Second WHA with links to background documents, and the address by WHO Director-General Dr Tedros Adhanom Ghebreyesus, are available on the WHO website.

WHA side events

In addition to the official WHA programme, an impressive number of events are organized by various non-State actors and non-governmental organizations (a list is found on the website of the Geneva Global Health Hub, G2H2). CIOMS President Hervé Le Louët and Secretary-General Lembit Rägo attended the following side events:

- *Assuring Quality in Medicines Procurement* (Bill & Melinda Gates Foundation, Department of Health of South Africa, Government of Belgium, Swedish International Development Cooperation Agency and U.S. Pharmacopoeia);
- *Universal Health Coverage: Moving Together, Stronger Together* (IFPMA); and
- *Vaccination in an ageing world: Listening to older people* (International Longevity Centre UK, supported by Sanofi).



*Dr Hiiti **Sillo** (WHO), at the WHA side event on* Assuring Quality in Medicines Procurement*. A discussion paper proposing calls to action by different stakeholders is in preparation. (Photograph: Lembit Rägo)*

Briefing for non-State actors

CIOMS is in official relations with WHO as a "non-State actor". On 28 June 2019 Dr Lembit Rägo attended a briefing about the current status of the Organization's ongoing transformation. This is driven by WHO's 13th General Programme of Work approved by the WHA in 2018. It aims to re-design WHO's core processes along four pillars: external relations and governance, business operations, programmes and emergencies.

WHO Advisory Committee on Safety of Medicinal Products (ACSoMP)

16th Meeting, Geneva, Switzerland, 7-8 May 2019

*Participants at the 16th meeting of the WHO ACSoMP. Sitting, first, second and third from right: Dr Shanthi **Pal** (WHO Medicines Safety group lead and liaison officer for CIOMS), and ACSoMP Chairs Dr June **Raine** (MHRA) and Dr Gerald **Dal Pan** (U.S. FDA).*

Pharmacovigilance is one of the major areas where CIOMS works closely with WHO. A WHO representative is routinely invited to participate in all CIOMS Working Groups, and although the Organization is facing its own resource constraints it has actively participated in most CIOMS Working Groups. Conversely, CIOMS Secretary-General Lembit Rägo has attended the annual meetings of the ACSoMP, which was established in 2003 and advises WHO on safety issues relating to medicinal products.

An example of the CIOMS/WHO cooperation in pharmacovigilance is related to a specific antimalarial combination drug that was to be introduced in new geographical locations. During the 16th ACSoMP meeting a report about the safety review of this antimalarial combination drug was presented. As there was some information about the potential hepatotoxicity of this medicine, a sub-committee of the ACSoMP carried out an additional safety review. CIOMS has an active Working Group on Drug-Induced Liver Injury (DILI), which includes a number of the world's foremost hepatologists from academia, industry and regulatory authorities. Some CIOMS DILI Working Group members provided their expertise to the WHO sub-committee dealing with this particular medicine.

☞ Click here to find out more about WHO's work on pharmacovigilance.

☞ www.who.int

News from the CIOMS Secretariat

CIOMS registered as a Swiss association

We are very pleased to announce that CIOMS has been registered as an association under Swiss law with registration number CHE-270.896.260. The registration was approved by the Swiss Federal Commercial Register on 26 April 2019.

CIOMS was constituted in 1949 at a conference in Brussels, where its Secretariat was initially located. In 1970 it was transferred to the headquarters of the World Health Organization (WHO) in Geneva, and since 2012 CIOMS has its premises down the road from WHO at the Ecumenical Centre. Formal registration as a Swiss association became necessary for CIOMS to continue its international activities in the era of digital globalization.

New translation

CIOMS/WHO International Ethical Guidelines for Health-related Research Involving Humans (2016) in **Chinese**.
ISBN: 978-92903609-64.

Launched on 27 April 2019 in Shanghai, China **(see page 1)**

The CIOMS/WHO ethical guidelines are now available in English, French, Spanish, Portuguese, Ukrainian, Russian and Chinese. Possibilities for an Arabic translation are being explored.

CIOMS IN THE MEDIA

https://cioms.ch/cioms-in-the-media/

Dal Ré R, Avendaño Solà C, de Boer A *et al.* A limited number of medicines pragmatic trials had potential for waived informed consent following the 2016 CIOMS ethical guidelines. J Clin Epidemiol. 2019 Jun 15. pii: S0895-4356(19)30344-0. doi: 10.1016/j.jclinepi.2019.06.007. [Epub ahead of print]

Pitts PJ. Towards Meaningful Engagement for the Patient Voice. Patient. 2019. DOI:10.1007/s40271-019-00366-x. Published online 5 June 2019.

Pirard V et al. AFREENET (AFRica ethics excellence NETwork): a network of national research ethics committees engaged in the reinforcement of their capacities. [Presentation abstract]. BMJ Global Health 2019;4:A4.

Munthe C, Nijsingh N, de Fine Licht K, Joakim Larsson DG. Health-related Research Ethics and Social Value: Antibiotic Resistance Intervention Research and Pragmatic Risks. Bioethics. 2019 Mar;33(3):335-342. doi: 10.1111/bioe.12580.

Ballantyne A, Eriksson S. Special issue: Research ethics revised. The new CIOMS guidelines and the World Medical Association Declaration of Helsinki in context. [Editorial]. Bioethics 33 (3), 309-405.

Xing M, Zhai L, Li J *et al*. Assessment of cholestasis in drug-induced liver injury by different methods. Medicine (Baltimore). 2019 Feb;98(6):e14399. doi: 10.1097/MD.0000000000014399.

Machlab S, Miquel M, Vergara M *et al*. Apixaban-induced liver injury. Rev Esp Enferm Dig. 2019 Feb;111(2):161-163. doi: 10.17235/reed.2018.5877/2018 (in Spanish).

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UPCOMING MEETINGS

Risk-Benefit Balance for Medicinal Products
1st Working Group meeting, 17-18 September 2019, Geneva, Switzerland

MedDRA Labelling Groupings
2nd Working Group meeting, 25-26 September 2019, Geneva, Switzerland

Clinical Research in Resource-Limited Settings
5th Working Group meeting , 8-9 October 2019, Extremadura, Spain

Patient Involvement in the Development and Safe Use of Medicines
4th Working Group meeting, 16-17 October 2019, Basel, Switzerland

CIOMS 86th Executive Committee Meeting and XXIIIrd General Assembly
18 December 2019, Geneva, Switzerland