What's on @ CIOMS

COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES

70 YEARS 1949 - 2019

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In 2019 CIOMS celebrates its 70th Anniversary. The event will be marked at the Open Meeting of the CIOMS Working Group on Patient Involvement in the Development and Safe Use of Medicines (see page 7). Throughout the year, we will be looking back in our Newsletters on some of the events that have made CIOMS what it is today.

HIGHLIGHTS

International events and visits 1
Looking back: Interview with Sev S. Fluss 4
Looking to the future: CIOMS-supported internships at WHO 5
News from CIOMS partners 6
News from the CIOMS Working Groups 7
News from the CIOMS Secretariat 8

International events and visits

Building stronger food and drug regulatory systems

In 2012 the U.S. Institute of Medicines (IOM – now called the National Academy of Medicine, NAM) had issued a report on Ensuring Safe Food and Medical Products through Stronger Regulatory Systems Abroad. The report called for capacity-building in developing countries to make food and medicines safer globally.

While progress has been made on these goals, the global regulatory landscape has changed since 2012. It was therefore considered timely to reassess the situation. An ad hoc committee has been convened by the National Academies of Sciences, Engineering and Medicine to recommend ways in which low- and middle-income countries can make their food and drug regulatory authorities more scientifically robust and increase the political will to build stronger national and regional regulatory systems.

Because of international trade, product safety failures in any one country can have ramifications around the world. The 2012 IOM report called for stronger regulatory systems in developing countries to improve the safety of food and medical products globally. (Image by hectorgalarza on Pixabay)

The Keck Center of the National Academies in Washington, D.C.

The ad hoc Committee on Stronger Food and Drug Regulatory Systems Abroad held its first meeting on 8-9 January 2019 at the Keck Center in Washington D.C. Dr Lembit Rägo, Secretary-General of CIOMS, was invited as a resource person to contribute his substantive background in regulatory affairs. He was a member of the discussion panel on the topic of *Management of the Regulatory Agency,* together with Mikel Arriola, (Committee Member), Kenneth Hartigan-Go (Asian Institute of Management), and Dali Yang (William C. Reavis Professor of Political Science and Senior Advisor to the President and the Provost on Global Initiatives, University of Chicago).

More information about this project is found here.

Mutual Recognition Agreements in Medicines Regulation

The ad hoc Committee on Mutual Recognition Agreements in the Regulation of Medicines was first convened on 4 and 5 February 2019 in the beautiful building of the National Academies in the centre of Washington DC.

Mutual recognition agreements allow regulators to rely on information from their counterparts at foreign medicines regulatory authorities. But how are these agreements used, for example in inspection, enforcement actions and product registration? How is sensitive information protected? Do the agreements help to save or redirect resources, and does this increase essential regulatory competencies in the long term, enabling the authorities to do a better job to protect public health?

Recently an *ad hoc* committee was set up under the auspices of the U.S. National Academies of Sciences, Engineering and Medicine to answer these questions. The Committee consisting of 12 members will undertake a study that is sponsored by the U.S. FDA. Due to his substantive background in regulatory affairs Dr Lembit Rägo, Secretary-General of CIOMS, was nominated as one of only two foreign Committee members.

More information about this project is found on the National Academies website.

The Albert Einstein Memorial in front of the National Academies building. One of the three quotations engraved in the bench is about the obligations that come with academic freedom: "The right to search for truth implies also a duty; one must not conceal any part of what one has recognized to be true."

User-adapted knowledge bases and real world data in health care

New therapies are opening up new avenues in clinical care, but are also adding complexity. Recently, medical errors[1] have been claimed to be the third leading cause of death in the U.S. Can user-adapted knowledge bases, linked with real world data and artificial intelligence, support decision-making on medical treatments?

The International Research Workshop on User Adapted Knowledge Bases and Real World Data in Medicine and Pharmacology: data acquisition, design, implementation and effects, organized on 24-25 January 2019 by the Karolinska Institute and the Swedish Institute for Drug Informatics (SIDI), brought together database and software providers, users and providers of clinical decision support systems (CDSS), clinicians and regulators.

CDSS are computer-based applications that analyse health information, for example to check for drug interactions, flag certain abnormal findings or remind doctors to check for certain risk factors. Interestingly, CDSS are classified as medical devices from a regulatory point of view. They must therefore be tested and approved by a regulator.

CDSS are often developed in isolation and their data kept in regulatory files where they are not readily searchable for third parties. As a result they do not always interact well with other components, and they may be difficult to integrate into the clinical information system, in particular electronic health records. In principle, marketing authorization holders could make information available in open, user-friendly databases. However, questions of bias and interest may likely arise when dealing with CDSSs.

The workshop participants agreed that in building CDSS there is a need for common principles and standards. There may be a role for CIOMS to offer a platform to build consensus around some of the issues discussed at the workshop.

CIOMS President Hervé Le Louët and Secretary-General Lembit Rägo at the Karolinska Institute, one of the founding centres of clinical pharmacology.

[1] Corrected from the initially published wording "prescribing and dosing errors". Medical errors also include other categories of errors. See Makary M, Daniel M. Medical error—the third leading cause of death in the US. BMJ 2016; 353:i2139.

New Working Group topic explored

Visit to the National Taiwan University Hospital in Taipei.

In February 2019, Professor Hervé Le Louët, President of CIOMS, visited the National Taiwan University Hospital (NTUH) to explore the possibility to create a CIOMS working group on **Severe Cutaneous Adverse Reactions (SCARs)**. Taiwanese colleagues have long-standing, recognized expertise in this area and are part of international scientific networks such as i-SCARs and RegiSCAR.

Guidance on SCARs is important for clinicians, regulators and the pharmaceutical industry: Clinicians need to know how to diagnose a SCARs identify the medicine that caused the reaction and initiate the best possible treatment. Regulators need solid evidence with well-defined cases and a causality assessment, so that they can make decisions on how to manage the risks of products marketed in their countries. And the pharmaceutical industry must ensure that the information supplied with their products is clear and helpful for healthcare professionals and patients.

There is therefore a strong need for a clear and flexible guideline on how to diagnose, assess and address SCARs. A concept paper with an action plan for establishing a new CIOMS Working Group is in preparation.

Monitoring vaccines in Europe (VAC4EU)

Confidence in vaccination continues to be at stake in Europe, with a large impact on the return of potentially serious vaccine-preventable diseases such as measles or whooping cough. In 2013 the Innovative Medicines Initiative (IMI) launched the ADVANCE public-private consortium, which has demonstrated that real-world health care data in the European Union can be used to generate evidence on vaccine coverage, benefits and risks.

On 6 March 2019, Professor Hervé Le Louët, CIOMS President, attended a conference on the *EU ecosystem for monitoring of post-licensure vaccine benefit and risk: from ADVANCE to VAC4EU,* held at the Royal Academy of Science in Brussels. It is envisaged that the new VAccine monitoring Collaboration for Europe (VAC4EU) will implement the ADVANCE Blueprint to support a sustainable environment for monitoring of post-licensure vaccine coverage, benefits and risk. VAC4EU will be a non-profit international association open to both institutional and personal members.

Contacts have been established to discuss the possible participation of CIOMS in this promising collaboration, making use of the Council's wide experience in this field.

To maintain confidence in vaccines, doctors and citizens need reliable evidence. VAC4EU will provide a public study network with access to data on vaccines. (Picture from: https://twitter.com/VAC4EU)

Assessing drug-induced liver injury

Drug-induced liver injury (DILI) is a major challenge for clinicians, the pharmaceutical industry and regulatory agencies worldwide. There is a clear need for a deeper understanding of this complex disorder.

In March, Professor Hervé Le Louët participated in a course on DILI assessment that combined conceptual discussions with problem-solving exercises illustrating some key rules and common pitfalls in a real world setting. The training was funded by the European Cooperation in Science and Technology (COST) as part of the Prospective European Drug-Induced Liver Injury Network (Pro-Euro-DILI-Net), which aims to coordinate efforts, facilitate a multi-disciplinary knowledge exchange, and promote the translation of this knowledge into clinical practice.

Several leading members of Pro-Euro-DILI-Net are part of the CIOMS DILI Working Group, which is developing a consensus document on DILI. The collaboration with Pro-Euro-DILI-Net will support the implementation of the CIOMS guidance in Europe.

More than 60 participants attended the 1st Training Course on Assessment of Drug-Induced Liver Injury held on 14-15 March 2019 at the University of Málaga, Spain.

Looking back: Interview with Sev S. Fluss

Sev S. Fluss, a British citizen born in Poland, studied in Edinburgh, Cambridge and Wisconsin. He was appointed to a post in the Health Legislation Unit of WHO in 1965. In 1988 he was appointed as speechwriter to the Director-General of WHO, the late Dr Hiroshi Nakajima. After retiring in 1997 he joined CIOMS as a Special Adviser. He has published numerous papers on diverse aspects of health law and bioethics. He was a member of the Board of Governors of the World Association for Medical Law for many years and also served on the International Council of Environmental Law.

When was your first contact with CIOMS?

At a regulatory meeting in 1976. I had joined WHO in 1965 as an editor. My first direct boss was an Englishman. But his wife hated it here in Geneva, to the point that she would only listen to the British weather forecast! After his departure and the retirement of the Belgian Chief, I became Responsible Officer and later Chief of Health Legislation.

In the 1970s Dr Mahler was WHO Director-General…

Yes, he was a truly inspiring man. Everyone had good things to say about him. In 1979 Dr Mahler called me to his office and offered me three months' study leave at any place of my choice. I discussed with my wife and we chose Washington. My task was to identify how health legislation is generated at the Federal level in the United States. I had an introduction letter from Jack Bryant…

Jack Bryant, who became CIOMS President in 1993…

That's right. He was Deputy Assistant Secretary for International Health in the U.S., and he knew a lot of people. That letter opened every door for me, except that of Senator Edward Kennedy. I spoke to some of his staff though. Jack Bryant was close friends with Zbigniew Bankowski *[CIOMS Secretary General from 1975 to 1999]*. They were a good tandem, with a wide network that was very useful for CIOMS. Stuart Nightingale from the U.S. FDA was in that same group.

You then became the next WHO Director-General's speechwriter…

Yes, the years with Dr Nakajima were interesting. He was asked to speak in French at the first meeting of the International Ethical Committee on AIDS, in Paris. I wrote this in bad French, and my elder daughter improved it. President Mitterrand smiled at one of the funny stories, and that was said to be a rare thing to happen! That was the year after the AIDS conference where Judge Michael Kirby gave his speech about the discovery of three new viruses: HIL 1, 2 and 3. So people asked, what is HIL? And he said, it stands for "Highly Inefficient Laws".

You did a lot of work on AIDS…

Yes. I also had close relations with Jonathan Mann, Chief of the WHO AIDS programme. A great man. He arranged for me to attend the first five International AIDS Conferences, and two superb meetings at the Mérieux estate near Annecy.

You worked for WHO for a long time …

Oh yes, for 32 years. When I reached the official retirement age, Nakajima said he had a gift for me. I thought it was a box of chocolates, but it turned out to be a one-year extension of my contract. And that happened in two successive years. I enjoyed writing his speeches and preparing "briefing documents" for his official visits.

And then in 1997 you became an adviser to CIOMS …

That's right. It was a smooth transition. At the time CIOMS was still housed at WHO, and I knew Bankowski well. I had met Juhana *[Juhana Idänpään-Heikkilä, CIOMS Secretary-General from 1999 to 2006]* two years before at a reception in Finland. He introduced himself by his full name, and I said: "Sir, we will be happy to have you in Geneva … but first you must simplify your name!"

What do you think makes CIOMS special?

It's all about personalities and dynamics. The CIOMS Round Table Conferences were memorable. The WHO Boardroom was full—around the table were the speakers, and the CIOMS members were at the back. CIOMS was quite bold in taking up some topics. For example there was a meeting in Berne on battered children and child abuse. Now that's a unique subject for a conference! No one in WHO would have touched that.

CIOMS, like WHO, does not have any regulatory authority. And yet it has been making an impact …

It's all about giving good advice about the right topic at the right time. And you never know in advance about the impact something will have. Soon after I started at WHO I was asked to write a comparative study of global abortion laws. So I got to work and wrote a nice little paper. One day a woman came in to see my boss. She asked for something about abortion law, so I gave her this paper. She then wrote a publication for the American Journal of Public Health, giving credit to me, and this eventually led to a relatively liberal abortion law being enacted in California in 1967.

What do you think could be next for CIOMS?

I recently saw a documentary about the CRISP-R technology and I thought, that would be a perfect topic for CIOMS.

Looking to the future:
CIOMS-supported internships at WHO

The IFMSA-CIOMS World Health Organization Internship Programme 2018 has been a great success. In the words of the first two interns in this programme:

"I was amazed at how much I felt like a full member of the team from my very first day at WHO. And, being a member of the Intern Board, I got to know so many interesting potential future health leaders from around the world! … I organized sport sessions for my fellow interns and the weekly «Unnamed» social meeting, where all of us got together, sharing food and drinks and discussing the fun facts of the week.

I am profoundly changed and motivated to further my studies and career, to help building stronger pharmacovigilance systems across the world. At this point I would like to express my deepest gratitude for the generous scholarship that was given to me by CIOMS."

Christos Samaras

Chris is from Greece, and is in his 6th year of medical studies at Sofia University, Bulgaria. A self-declared global health enthusiast and advocate, he has participated in many international events and programmes as a delegate, trainee and ambassador.

"As someone who interacted with other interns daily, I can boldly say that this IFMSA opportunity put me in a much better position to gain the experience I needed without a financial burden on my head. The highlight of the internship for me was when I gave the keynote address at the 41st Annual Meeting of Representatives of National Pharmacovigilance Centres participating in the WHO Programme for International Drug Monitoring (PIDM). I never imagined that one day I'd be on a panel inside the Executive Boardroom of the WHO, sharing my perspectives as a young «pharmacovigilante» and presenting my vision to hundreds of global Pharmacovigilance experts."

Rose Adjei-Bempah

Rose is a medical student at the University of Ghana Medical School. Before medical school she obtained her Bachelor's degree in medical physics in Ghana, after which she was motivated to pursue a Master's degree in Public Health from the Ecole des Hautes Etudes en Santé Publique in Paris, France.

From: Report from IFMSA-CIOMS World Health Organization Internship Program 2018

CIOMS offers students from IFMSA Member Organizations financial support to pursue an internship in WHO units in Geneva dealing with medical research ethics, with medicines and vaccines safety, or with vigilance for medical devices including in-vitro diagnostics. This helps medical students – tomorrow's medical doctors – to participate in WHO's technical work. See more at: https://cioms.ch/cioms-support-internships-geneva/.

News from CIOMS partners

New FDA guidance on biomarkers

The U.S. Food and Drug Administration (FDA) has released its draft guidance on Biomarker Qualification: Evidentiary Framework for public comment. A biomarker is a measurable indicator of biological processes or responses to an exposure or intervention. For example, serum ALT, AST, ALP and total bilirubin levels can be used as biomarkers to detect liver injury and grade its severity.

Biomarkers must be qualified by regulatory authorities. Once a biomarker has been shown to have a specific interpretation and application within its stated context of use (COU) it can be used across multiple drug development programmes under that COU.

Both the EMA and the FDA have programmes for the qualification of biomarkers, but only the FDA has guidance documents that define the terminology to a sufficiently detailed extent. The new FDA guidance is relevant to the work of the CIOMS Working Group on Drug-Induced Liver Injury (DILI).

Conference on Person-Centered Medicine

The International College of Person-Centered Medicine (ICPCM) organized its 12th Geneva Conference on 25-27 March 2019 at the World Council of Churches Main Conference Hall, in the same building as the CIOMS offices. The conference was co-organized by ICPCM and the World Medical Association (a CIOMS member). Dr Lembit Rägo, Secretary-General of CIOMS, was among the presenters.

The Conference's main theme, *Promoting well-being and overcoming burn-out of health professionals,* is topical and relevant to many CIOMS constituencies and working groups. The declarations from the ICPCM annual conferences are available on the ICPCM website.

Meds We Can Trust to fight tuberculosis

On 24 March—World Tuberculosis Day—the Medicines We Can Trust campaign has called for action against substandard medicines to prevent drug resistance in tuberculosis (TB) patients. A recent study has now shown that rifampicin containing a specific degradation product fuelled the development of resistance to medicines of the rifamycin class.

Multidrug-resistant TB has been deemed a "global public health crisis" by WHO, making quality assurance of TB medicines more critical than ever.

WHO Executive Board meets

The WHO Executive Board held its 144th session in Geneva on 24 January-1 February 2019. Decisions were taken on supporting the prevention and control of non-communicable diseases, on increasing access to influenza vaccine and sharing pandemic influenza viruses, and on accelerating the elimination of cervical cancer. Furthermore a number of resolutions were proposed for adoption by the World Health Assembly, including a resolution on water, sanitation and hygiene in health care facilities.

Secretary-General Dr Lembit Rägo attended the Executive Board meeting on behalf of CIOMS.

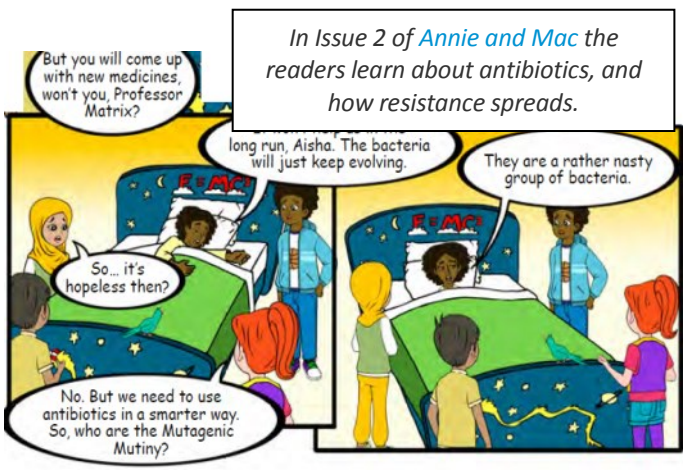
Teaching children about medicines

Teaching children about the benefits and dangers of medicines can have a positive impact on their communities, and can thus make a change in how future generations think about medicines safety.

During his recent visit to the Uppsala Monitoring Centre (UMC), Dr Lembit Rägo came across the UMC's new children's book on Drugs and Bugs that sets out to answer questions about medicine, diseases and the human body in a fun way. The book is available in Arabic, English, French, Mandarin, Russian, Spanish and Swedish.

The UMC has also brought out two comics for children aged 9 to 13 that tell the story of some important issues with medicines. In the first issue Annie and her side-kick Mac, an eagle in the body of a hummingbird, set out to stop the evil Lord Fake from producing and selling fake medicines. In the second issue Annie and her friends shrink to the size of bacteria and confront mean-spirited microbes.

In Issue 2 of Annie and Mac the readers learn about antibiotics, and how resistance spreads.



News from the CIOMS Working Groups

Clinical Research in Resource-Limited Settings

4th Working Group Meeting
Geneva, Switzerland, 27-28 February 2019

Finding patients for a DNDi-supported study on a new treatment for sleeping sickness. Watch the video on YouTube.

Clinical research is not easy to conduct, much less so in resource-limited settings where finance and staff are lacking, bureaucracy can be overwhelming and sanitary conditions are often poor. And yet, clinical research is needed in these settings as it contributes directly to improving health and health services. Also, certain diseases are concentrated in populations living in resource-limited settings, which means that the studies cannot be conducted anywhere else.

The CIOMS Working Group on Clinical Research in Resource-Limited Settings is making good progress with drafting pragmatic guidance on how to conduct ethical and scientifically sound clinical research in these difficult environments. To start its meeting the group members—prominent researchers, regulators and product developers—took turns to speak about their own experiences, from testing of vaccines or treatments for Ebola to genome sequencing in India and Latin America. More about this Working Group, including its past meeting minutes, is found here.

New topics

The following new topics are envisaged for CIOMS Working Groups:

- Using MedDRA Labelling Groupings for clearer information on adverse events in product information: A new expert group has been established and will meet on 2-3 April 2019 in Geneva.
- Severe cutaneous adverse reactions (SCARs): See page **3.**
- Risk-benefit assessment of medicines: A new group may be established to update and expand on the CIOMS Working Group IV report.

Patient involvement in the development and safe use of medicines

3rd Working Group Meeting
Geneva, Switzerland, 30 April-2 May 2019

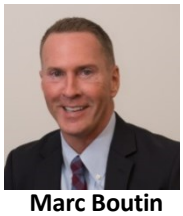
This CIOMS Working Group is preparing for a one-day **Open Meeting** on 30 April 2019. The main aim of the meeting is to open up the Group's work for questions, comments and suggestions from patient groups not represented in WGXI. The event will also mark the 70th Anniversary of CIOMS. All interested persons are welcome to attend. Click here for the Open Meeting programme and online registration.

More information about this Working Group, including the minutes of its past two meetings, is found here.

The Working Group values your input. Contact us at info@cioms.ch to send us your thoughts.

Speakers:

Kaisa Immonen
European Patient Forum



Marc Boutin
U.S. National Health Council

Kerry Leeson-Beevers
Alström Syndrome UK

Theresa Mullin
U.S. Food and Drug Administration

Corinna Schaefer
German Agency for Quality in Medicine (AEZQ) / World Medical Association

Isabelle Moulon
European Medicines Agency

…and many more.

News from the CIOMS Secretariat

New CIOMS member organisation

IFAPP Pharmaceutical Medicine

International Federation of Associations of Pharmaceutical Physicians & Pharmaceutical Medicine

In December 2018 the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP) became an international member of CIOMS.

Pharmaceutical medicine is concerned with the discovery, development, evaluation, registration, monitoring and medical aspects of marketing of medicines for the benefit of patients and public health. IFAPP aims to bring together institutions and professionals from industry, academia, regulatory bodies, authorities and policy makers working in this field worldwide, and to enhance their competencies through specifically designed certification programmes Currently IFAPP's 30 National Member Associations represent the interests and goals of over 7 000 professionals.

Current CIOMS membership

13
International members

10
National members

18
Associate members

See more at: https://cioms.ch/cioms-members/

Official relations with WHO reconfirmed

The official relations of CIOMS with WHO have been reconfirmed by decision EB144(5) of the WHO's Executive Board, which met in January 2019.

WHO reviews its official relations with non-State actors every three years in line with its Framework of Engagement with Non-State Actors (FENSA). This framework was adopted by the Health Assembly in resolution WHA69.10 in 2016.

We take this occasion to thank **Dr Shanthi Pal**, the Designated Technical Officer (DTO) for the WHO–CIOMS relations, for her guidance and support during this triennial review process.

Submission for best student paper

CIOMS is pleased to have received a review by Connie Rees and co-authors as submission for the best scientific article published in the areas of pharmacovigilance and research ethics by a student from a member organization of the International Federation of Medical Students' Associations (IMFSA).

Connie's paper reviews the reasons why people participate in research in low- and middle-income countries (LMICs). Overall, altruism, personal health benefits and access to health care were the most frequent motivations. The most common reasons for not participating were safety concerns, inconvenience and stigmatisation.

A decision by the award committee is pending.

Browne JL, Rees CO, van Delden JJM et al. The willingness to participate in biomedical research involving human beings in low- and middle-income countries: a systematic review. Trop Med Int Health. 2018 Dec 18.

New translations available

*Practical Aspects of Signal Detection in Pharmacovigilance (2010) in **Chinese***

*International Ethical Guidelines for Health-related Research Involving Humans (2016) in **Russian***

CIOMS IN THE MEDIA

Where available, articles about CIOMS can be accessed through our website at: http://www.cioms.ch/cioms-in-the-media/

Aarons D. **Addressing the challenge for expedient ethical review of research in disasters and disease outbreaks**. Bioethics. 2018;00:1–4. https://doi.org/10.1111/bioe.12543.

Abtroun SN. **Vulnérabilité des femmes enceintes en éthique de la recherche : un problème sémantique.** Canadian Journal of Bioethics 2019; 2(2):11-14. https://cjb-rcb.ca/index.php/cjb-rcb/article/view/53.

Bahri P, Rägo L, on behalf of the CIOMS Working Group on Vaccine Safety. **CIOMS Guide To Vaccine Safety Communication – Executive summary**. [Conference report]. Vaccine. 2019; 37(3): 401-408. https://doi.org/10.1016/j.vaccine.2018.11.082.

Ballantyne A. **Adjusting the focus: a public health ethics approach to data research.** Bioethics. 22 January 2019. https://doi.org/10.1111/bioe.12551.

Browne JL, Rees CO, van Delden JJM *et al*. **The willingness to participate in biomedical research involving human beings in low- and middle-income countries: a systematic review**. Trop Med Int Health. 2018 Dec 18. https://onlinelibrary.wiley.com/doi/full/10.1111/tmi.13195. *Submitted for the CIOMS Award of the best student article published in the fields of bioethics or pharmacovigilance.*

Chiauzzi E, Wicks P. **Digital Trespass: Ethical and Terms-of-Use Violations by Researchers Accessing Data From an Online Patient Community**. J Med Internet Res 2019;21(2):e11985. https://doi.org/10.2196/11985.

Ekmekci PE, Guner MD. **Inconsistencies in institutional review board decisions: A proposal to regulate the decision-making process**. Bratislava Medical Journal. 2019; 120 (2): 95-101. https://doi.org/10.4149/BLL_2019_015

Kurosawa T.M. **Alternative Research (3Rs) in the World, Asia and Japan.** In: Kojima H., Seidle T., Spielmann H. (eds). Alternatives to Animal Testing. Springer, Singapore; 2019. https://link.springer.com/chapter/10.1007/978-981-13-2447-5_4

Nijsingh N, Joakim Larsson DG, Persson de Fine Licht K, Munthe C. **Justifying Antibiotic Resistance Interventions: Uncertainty, Precaution and Ethics**. In: Jamrozik E., Selgelid M.J. (eds). Ethics and Drug-Resistant Infections: Collective Responsibility for Global Public Health. Cham, Switzerland: Springer; 2019. Available at: https://www.gu.se/english/research/publication/?publicationId=261616.

Sanchez MC, Sarria-Santamera A. **Unlocking data: Where is the key?** Bioethics. 25 January 2019. https://doi.org/10.1111/bioe.12565.

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UPCOMING MEETINGS

15th Meeting of the Implementation Working Group on Standardized MedDRA Queries (SMQs)
2 April 2019, Geneva, Switzerland

1st Meeting of the MedDRA Labelling Groupings (MLG) Expert Working Group
3-4 April 2019, Geneva, Switzerland

3rd Meeting of the CIOMS Working Group on Patient Involvement in the Development and Safe Use of Medicines
▶ Open meeting: 30 April 2019, Geneva, Switzerland
Working Group meeting: 1-2 May 2019, Geneva, Switzerland

5th Meeting of the CIOMS Working Group on Drug-Induced Liver Injury (DILI)
15-16 June 2019, Tallinn, Estonia