# What's on @ CIOMS

COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES

WWW.CIOMS.CH | June 2021 | **Newsletter** | **# 34**


## Quick links



# Just published

## Clinical research in resource-limited settings

**CIOMS Working Group report**

*Great strides have been made in past decades to address the health needs of people living in low-resource settings. But the global health landscape is evolving, and many populations are still missing out on vaccines, diagnostics and treatments that are needed as part of sustainable development. More good quality clinical research is needed in resource-limited settings, where most of the preventable morbidity and mortality occurs.*

*Image by eveliendm from Pixabay*

**The CIOMS Working Group on Clinical Research in Resource-Limited Settings has published its consensus report, providing balanced arguments and targeted recommendations to promote good quality clinical research in low-resource settings.**

Clinical research— *i.e.* studies involving human participants—are needed to generate the evidence that is required to advance health care. However, interventions studied in one population are not necessarily useful, safe and effective in another. Research in low- and middle-income countries (LMICs) is challenging to do, and most clinical studies today are still being conducted in and for high-income countries (HICs).

The CIOMS Working Group was composed of experts in drug development, ethics and medicines regulation from across economic settings. Before publication the draft report was posted on the CIOMS website for a five-week public consultation. We thank all reviewers for their input, which has been extremely valuable for the Working Group to finalize its guidance.

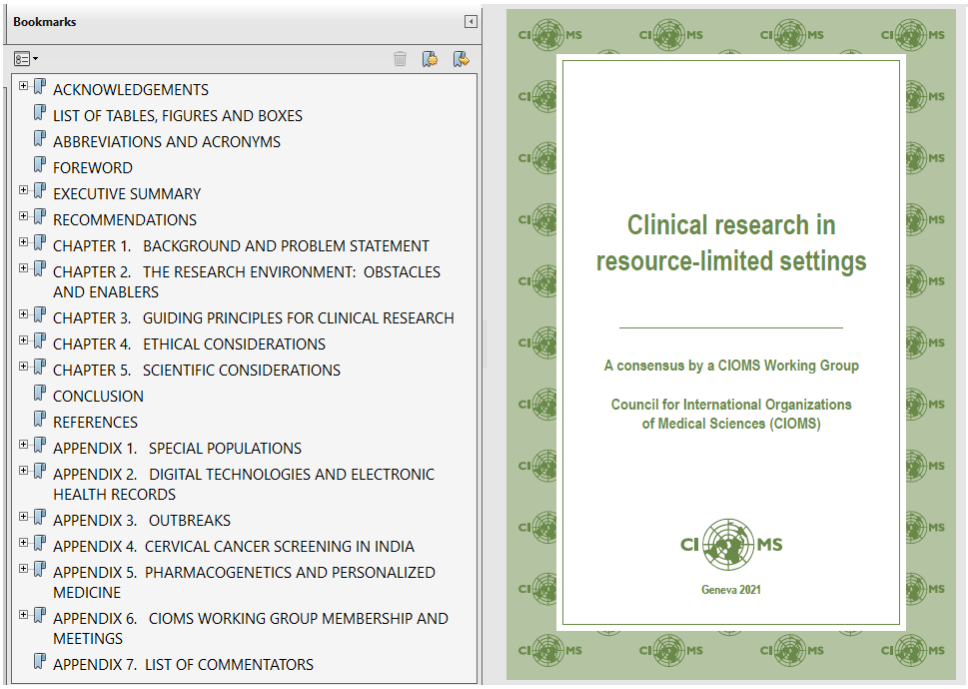
*(continued)*

# **Just published** (continued)

## Clinical research in resource-limited settings *(continued)*

As has been noted in recently published guidelines for good epidemiological practice, research integrity can be difficult to balance with the realities of conducting fair global health research; yet these values are essential for high-quality, impactful research.[1] It is hoped that the CIOMS guidelines and recommendations will help to advance scientifically sound, good quality clinical research in low-resource settings.

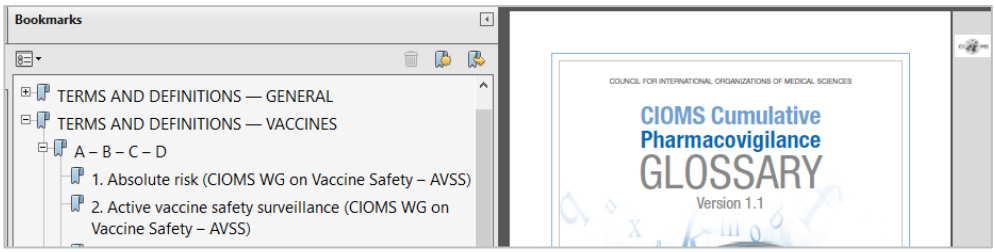
1 Alba S, *et al*. BMJ Glob Health. 2020. (Full reference on page 7)




*The CIOMS Working Group report on Clinical research in resource-limited settings is freely available on the CIOMS website; printed copies can be ordered online. Since its publication on 16 June the PDF has been downloaded over 330 times by visitors from almost 60 countries.*

## CIOMS Cumulative pharmacovigilance glossary Version 1.1

**Living document**




*Version 1.1 of the CIOMS cumulative glossary was published on 10 June 2021 and is freely available on the CIOMS website. This version newly includes terms and definitions for vaccines as shown in the reports of the CIOMS/WHO Working Group on Vaccine Pharmacovigilance (2012) and the CIOMS Working Group on Vaccine Safety (2017, 2018).*

# Events and publications

Information from CIOMS partners in the areas of research ethics, medical product development and safety.

## WHO World Health Organization

### Technical guidance for pharmaceuticals


The WHO Expert Committee on Specifications for Pharmaceutical Preparations has adopted two new guidelines to promote regulatory cooperation (Annexes 10 and 11 to its 55th report). The Committee works towards clear, practical standards and guidelines for quality assurance and regulation of medicines. Its guidelines and working documents under public consultation are available on the WHO website.

☞ **WHO norms and standards for pharmaceuticals**

### Seventy-fourth World Health Assembly

**24 May – 1 June 2021 (virtual meeting)**

The theme of this year's World Health Assembly (WHA) was "Ending this pandemic, preventing the next one." More than 30 resolutions and decisions were adopted in different areas of public health. In his closing remarks, the WHO Secretary-General reminded delegates that a strong WHO needs to be properly financed and urged Member States to chart a course towards a sustainable financial model.

☞ **WHA74 documents**

The WHA was followed by the 149th meeting of the WHO Executive Board, held on 2 June 2021.

☞ **EB149 documents**

## ICH International Council for Harmonisation

### ICH Assembly

**2–3 June 2021 (virtual meeting)**

ICH is expanding and now has 18 members and 33 observers. Good progress is being made by regulatory authorities in implementing ICH guidelines. In discussing new areas of harmonization the Assembly supported a revised ICH Reflection Paper on patient-focused drug development in line with comments received during a public consultation.

☞ **ICH Press release, 10 June 2021**

### International Nonproprietary Names (INN): When a name is not enough

The World Health Organization assigns International Nonproprietary Names (INN) to pharmaceutical substances to ensure that each substance is globally recognized by a unique name. More and more applications are being received for INN for advanced therapy medicinal products (ATMP). These cannot be named using the same nomenclature rules as for chemical substances.

To avoid overly long and complicated names, WHO publishes INN of new ATMP, and in particular cell therapy and cell-based gene therapy substances, together with textual definition paragraphs that unambiguously describe their characteristics of each substance. This definition is an integral part of the INN.

**nivadstrocelum**

| | |
|---|---|
| nivadstrocel | Allogeneic mesenchymal stromal cells derived from subcutaneous adipose tissue collected by liposuction. The cells are isolated from the adipose tissue by enzymatic digestion and are expanded in a three-dimensional hydrogel matrix with scaffold structure. The cells express cell surface markers CD105 and CD90 (≥95%), lack cell surface expression (<2% positive) of CD45, CD34, and do not express T cell co-stimulatory molecules CD40, CD80 or CD86 and major histo-compatibility complex (MHC) class II (HLA-DR). The cells also secrete various growth factors (e.g. insulin-like growth factor (IGF), hepatocyte growth factor (HGF) and vascular endothelial growth factor (VEGF)) and express extracellular matrix proteins, in particular collagen type VII. *cell therapy* |
| nivadstrocel | Cellules stromales mésenchymateuses allogéniques dérivées du tissu adipeux sous-cutané recueillies par liposuccion. Les • • • |
| nivadstrocel | Células estromales mesenquimales alogénicas derivadas de tejido adiposo subcutáneo obtenido por liposucción. Las células • • • |

(Source: Proposed INN: List 124, 2020)

*Example: The INN of nivadstrocel. INN contribute to patient safety, as they help to distinguish regulated substances from cell-based interventions that have no INN and are marketed without regulatory oversight.*

☞ **More about INN for cell-based substances:**
Loizides U, Dominici M, Manderson T, Rizzi M, Robertson JS, de Sousa Guimarães Koch S, Timón M, Balocco R. **The harmonization of WHO INN definitions for cell and cell-based gene therapy substances: when a name is not enough.** Cytotherapy 2021 May 01.

☞ **What information should companies provide when applying for an INN for a cell-based substance?**
**Cell-based therapies - Mandatory information for INN selection and publication.**

# What's new with COVID-19?

## Research and development

- The International Coalition of Medicines Regulatory Authorities (ICMRA) and WHO have issued a **joint statement on transparency and data integrity.** Data are crucial to support research and development, regulatory and treatment decisions, and public confidence in vaccines and therapeutics. And yet more than half of all clinical trials go unreported.

- A new WHO report provides a summary of global **research initiatives and achievements**. The impact of regulatory science is acknowledged, and priority areas for future regulatory science are highlighted.
  - ☞ **WHO. COVID-19 research and innovation achievements. April 2021.**

## Vaccines

- A WHO policy brief on COVID-19 and mandatory vaccination identifies **ethical considerations** and caveats to be considered by governments and institutional policy-makers.

- WHO has published the report of an ad hoc consultation on **research needs** for COVID vaccines.
  - ☞ **WHO R&D Blueprint. COVID-19 vaccines: Knowledge gaps and research priorities. 23 April 2021.**

- The WHO International Nonproprietary Name (INN) Expert Group has adopted a **nomenclature** for COVID-19 vaccine substances dedicated to SARS-CoV-2 variants of concern (VOCs). The INN Programme encourages vaccine developers to submit INN requests for COVID-19 vaccine substances and urges regulatory authorities to facilitate their implementation.
  - ☞ **International Nonproprietary Names for Variant COVID-19 Vaccine Active Substances. INN Working Document 21.520, April 2021**
  - ☞ See also the lists of proposed INN for COVID-19:
    List No. 125–special edition, 8 June 2021.
    List No. 124–special edition. 9 October 2020.

## Vaccine safety

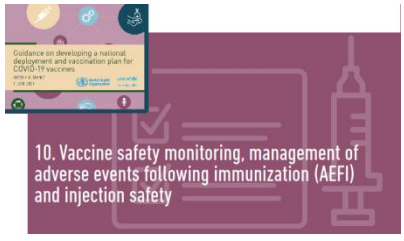
The WHO COVID-19 vaccines safety surveillance manual—developed, among others, on the principles described in the CIOMS Guide to active vaccine safety surveillance— encourages developers to adopt existing formats of **risk management strategies**, such as the EU risk management plan (RMP). A COVAX webinar workshop on COVID-19 risk management planning was held in April 2021 for pharmacovigilance specialists from industry and regulatory authorities.

- ☞ **EMA. Consideration on core requirements for RMPs of COVID-19 vaccines. coreRMP19 guidance v2.0. 10 June 2021.**
- ☞ **COVAX Workshop: Covid-19 Vaccines Risk Management Planning: Stakeholders' Experiences and Perspectives. 28 April 2021.**


*Moderator: Lembit Rägo, CIOMS Secretary-General*

This webinar, held on 9 June, described the UMC's VigiBase— the WHO global database of individual case safety reports (ICSR)—with a focus on COVID-19 vaccines, and presented three ongoing related activities at the UMC Research department.

*CIOMS definitions are being used in WHO guidance on COVID-19 vaccines. The CIOMS vaccine-related terms and definitions are included in the CIOMS cumulative pharmacovigilance glossary Version 1.1 (see page 2).*




*Main source of information on this page: 34th WHO Regulatory Update on COVID-19. 14 May 2021*

# Update on CIOMS Working Groups

Meeting minutes are published on the Working Groups' webpages. All meetings were held in virtual format.

## Started | Working Group (oldest to newest)

*Nov 2017*

### Clinical research in resource-limited settings

**Work completed ▶**

**Working Group report published** (see page 1)


*Apr 2018*

### Patient involvement in the development and safe use of medicines (Working Group XI)

Draft report being prepared for public consultation

**Updates presented at DIA 2021 ▶**

DIA 2021 Global Annual Meeting: Session held 30 June 2021

Patient-Focused Benefit-Risk Assessment and Risk Management: Methodology for Engaging with Patients – What has been Learned?

**Updates from the organizations of CIOMS Working Group members:**

**Juan Garcia Burgos**
EMA (Chair)

**Lembit Rägo**
CIOMS

**Theresa Mullin**
FDA

**Talia Lacroix**
Health Canada

**François Houÿez**
Eurordis

*Apr 2019*

### MedDRA labelling groupings

4th Meeting held 4 March 2021
Editorial subgroup formed

*Sep 2019*

### Benefit-risk balance for medicinal products (Working Group XII)

**5th Meeting held 18 June 2021 ▶**

The CIOMS Working Group XII at its 5th meeting


*Mar 2020*

### Real-world data and real-world evidence in regulatory decision-making (Working Group XIII)

7th Meeting held 1 April 2021
8th Meeting held 6 May 2021
9th Meeting held 22 June 2021

*Feb 2021*

### Severe cutaneous adverse reactions (SCARs)

2nd Meeting held 13 April 2021
3rd Meeting held 29 June 2021

*Apr 2021*

### Educational standards

1st Meeting held 26-27 April 2021

**CIOMS concept paper ▶**


## Starting soon

*July 2021*

### Good governance for research institutions

1st Meeting to be held in July 2021

# News from the CIOMS Secretariat

## XXIV CIOMS General Assembly and 88th session of the CIOMS Executive Committee

**28 June 2021 (virtual meeting)**

CIOMS President Hervé Le Louët welcomed the CIOMS member representatives and Executive Committee members. Secretary-General Lembit Rägo presented the CIOMS activities since the XXIII General Assembly held in December 2019. Despite the ongoing pandemic, CIOMS activities have progressed well in several areas. Highlights included the publication of two new Working Group reports, the posting of the CIOMS cumulative pharmacovigilance glossary as a living document on the web, two CIOMS Working Group statements relating to COVID-19, several conference presentations and webinars, and the 2020 CIOMS award for the best scientific paper by a medical student, which went to Ronald Olum from Uganda. The CIOMS activities are documented in the quarterly CIOMS newsletters.

The delegates then heard updates on financial and asset management and discussed and approved related proposals, including two proposed changes to the CIOMS statutes required for its tax exoneration status in Switzerland.


*Some of the CIOMS achievements in 2020*

## 2021 student award

**Submission deadline: 31 October 2021**

Submissions are being accepted for the **CIOMS award of US $1500** for the best scientific article published by a medical student. The article must be in the areas of pharmacovigilance or research ethics and must have been published in a peer-reviewed scientific journal in English.

☞ **Find details here.**

**Conference announcement**

## Rudolf Buchheim 200 Conference "New Essays on the Doctrine of Drugs"

**Tartu, Estonia, 9–11 September 2021**

Registration is now open for the Rudolf Buchheim 200 conference, which was originally planned to take place in May 2020. The event will celebrate the 200th Anniversary of Rudolf Buchheim, the "Grandfather of Pharmacology". Tartu became the cradle of pharmacology with Rudolf Buchheim, Oswald Schmiedeberg, Hans Horst Meyer and Rudolf Boehm as successive holders of the chair.

The conference will look back at the history of pharmacology and review the state of the art of clinical practice and modern technologies to develop better medicines.

*Above: The premises at the University of Tartu—then called Dorpat— where Rudolf Buchheim created the first academic institute for the study of the action of drugs in 1847.(Photograph from the conference website: https://buchheim200.eu/)*

Dr Lembit Rägo, CIOMS Secretary General, is a member of International Advisory Board for the conference and will speak on the topic "Pharmacovigilance: from reactive to proactive and predictive".

# News from the CIOMS Secretariat (continued)

## CIOMS cited


Alba S, Verdonck K, Lenglet A, *et al*. **Bridging research integrity and global health epidemiology (BRIDGE) statement: guidelines for good epidemiological practice**. BMJ Glob Health. 2020 Oct;5(10):e003236. doi: 10.1136/bmjgh-2020-003236

*Companion article:* Alba S, Lenglet A, Verdonck K, *et al*. **Bridging research integrity and global health epidemiology (BRIDGE) guidelines: explanation and elaboration**. BMJ Glob Health. 2020 Oct;5(10):e003237. doi: 10.1136/bmjgh-2020-003237

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Raciti CG, Enane LA, MacDonald KR, *et al*. **Ethical considerations for research involving pregnant women living with HIV and their young children: a systematic review of the empiric literature and discussion.** BMC Med Ethics. 2021 Apr 1;22(1):38. doi: 10.1186/s12910-021-00601-x

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Silva H, Stonier P, Kerpel-Fronius S, Dubois D. **Editorial: Grand Challenges in Pharmaceutical Medicine: Competencies and Ethics in Medicines Development.** Front Pharmacol. 2021 May 13;12:666406. doi: 10.3389/fphar.2021.666406

Wilkinson A, Slack C, Crews C, Singh N, Salzwedel J, Wassenaar D. How **can research ethics committees help to strengthen stakeholder engagement in health research in South Africa? An evaluation of REC documents.** S Afr J Bioethics Law 2021;14(1):6-10. (Journal free access)

**THEME ISSUE — DOUBLE STANDARDS REDUX: THE ETHICS OF FUTURE COVID-19 VACCINE RESEARCH:**

Greco DB. **Ethical limits to placebo use and access to Covid-19 vaccines as a human right**. Indian J Med Ethics. 2021 Apr-Jun;VI(2):1-14. doi: 10.20529/IJME.2021.027

Haire B. **The continued use of placebo arms in COVID-19 vaccine trials does not adequately protect the well-being of participants**. Indian J Med Ethics. 2021 Apr-Jun;VI(2):1-10. doi: 10.20529/IJME.2021.020.

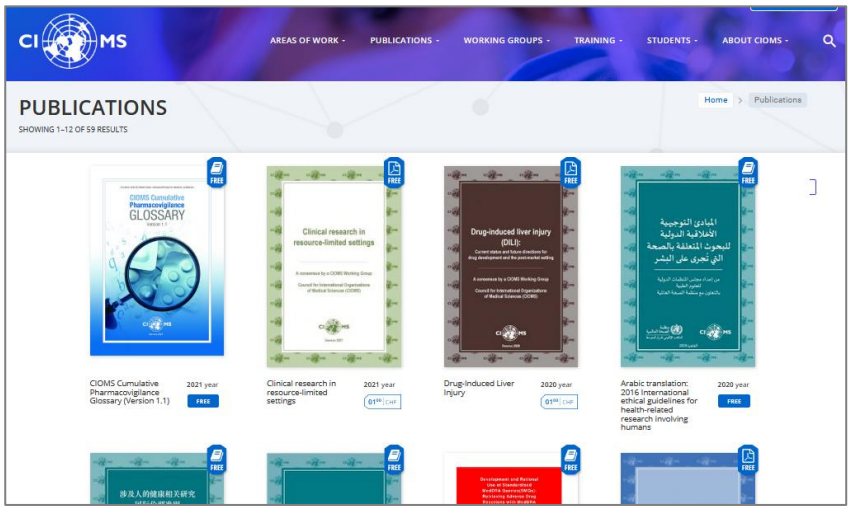
Wiesing U, Ehni HJ. **Placebo control in Covid-19 trials: A missed opportunity for international guidance**. Indian J Med Ethics. 2021 Apr-Jun;VI(2):1-7. doi: 10.20529/IJME.2021.022

**Apropos CIOMS**:

ten Have H, Patrão Neves M. **CIOMS**. In: Dictionary of Global Bioethics.2021; Springer, Cham. doi: 10.1007/978-3-030-54161-3_2

# News from the CIOMS Secretariat (continued)

## Access to CIOMS publications




As from 1 June, hardcopies are priced at a symbolic CHF 1 (one Swiss Franc), and older publication hardcopies are free. Postage charges apply.

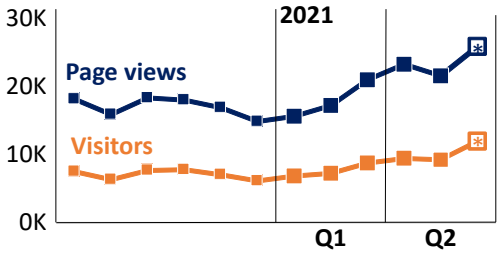
All PDFs are free to download. Hardcopies can be ordered online at https://cioms.ch/publications

## Find us on the web

https://cioms.ch

January–June 2021 (as at 23 June)

| Top 3 countries | | | Top 3 downloads | | |
|---|---|---|---|---|---|
| 1 | U.S. | 11953 | 1 | CIOMS I Form for reporting adverse events | 4881 |
| 2 | India | 6174 | 2 | CIOMS cumulative pharmaco-vigilance glossary Version 1.0* | 1757 |
| 3 | China | 4009 | 3 | International ethical guidelines (2016) | 1251 |
| **Total visitors** | | **82048** | **Total downloads** | | 18404 |




* Extrapolated to end of June

* Version 1.1 was published 10 June 2021 and has since been downloaded over 340 times.

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Ms Catherine Bates – Welcome to the CIOMS team
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▶ At the end of June 2021, Monika is retiring from CIOMS. Her excellent skills will be missed, however she will continue to edit this Newsletter.* Happy retirement Monika!

**Note from Monika: It will be an honour and a pleasure: CIOMS is dynamic! So, watch this space.*

*CIOMS Newsletters*