Welcome

Regulatory systems and regulations to support clinical trial conduct in Africa

19 JANUARY 2023 | 13:30-15:00 CET

IFPMA

CIOMS

Event in English, with interpretation in

THANK YOU FOR JOINING

Guide for participants

- The webinar is held in English, with interpretation in French and Portuguese. You can switch between languages using the “globe” icon.
- All participants are muted.
- Please use the Q&A box to raise questions to the speakers. If a question you would like to ask has already been raised, you can also “like” that question.
- The webinar is recorded. Presentations and the video will be made available on the ifpma.org website after the event.

AUDIENCE POLL

- We would like to collect feedback from the audience, through a poll. To take part, a QR code will be displayed on screen and a link will be shared. You can take part in English, French, or Portuguese.

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Regulatory systems and regulations to support clinical trial conduct in Africa

How can collaboration between stakeholders in the clinical research community build on each other's expertise, capabilities and capacities? How can strengthening clinical research infrastructure lead to a sustainable ecosystem?

19 JANUARY 2023 | 13:30-15:00 CET

Webinar in English, with interpretation in

Agenda

Welcome and opening remarks	Zainab Aziz (IFPMA)
High-level presentations	• Samvel Azatyan (WHO) • Lembit Rägo (CIOMS)
Poll: gathering input from audience (Zainab Aziz)	
Panel discussion Facilitated by Lembit Rägo (CIOMS)	• Dr Walter Jaoko, Director, KAVI-Institute of Clinical Research, University of Nairobi • Ms Imene Ben Abdallah, IFPMA • Dr Fabienne Benoist, Head of Regulatory Affairs, DNDi • Dr Beno Nyam Yakubu, Deputy Director, Head Clinical Trial Division, NAFDAC, Nigeria. Chair of AVAREF Technical Committee • Dr Boitumelo Semete Makokotlela, CEO, South African Health Products Regulatory Authority Dr Diadié Maiga, Regional Vaccine Regulation Officer, WHO Regional Office for Africa
Q&A from the audience (moderated by Zainab Aziz, IFPMA)	
Key takeaways and recommendations	• Lembit Rägo (CIOMS)

World Health Organization

IFPMA/CIOMS Webinar: Regulatory Systems and regulations to support clinical trial conduct in Africa

19 January 2023

Dr Samvel Azatyan
Team Lead, Regulatory Convergence and Networks
Team Lead a.i., Facilitated Product Introduction
Regulation and Safety Unit, Regulation and
Prequalification Department
World Health Organization

Regulatory Considerations for Clinical Trials: towards implementation of WHA Resolution WHA 75.8 of 2022

Medical products – instrument for public heath

SDG 3 – Target 3.8

Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and **access to safe, effective, quality and affordable essential medicines and vaccines for all**

World Health Organization

Access to medical products – global challenge

- Good health is impossible without access to medical products;
- An estimated **two billion people have no access to essential medicines**, effectively shutting them off from the benefits of advances in modern science and medicine;
- Reasons for limited/insufficient access are numerous – including insufficient/inadequate regulatory capacity and lack of collaboration and work sharing between countries in regulation of medical products.
- Public Health Emergencies and military conflicts not only cause direct losses of lives but also have severe consequences – from breakdown of health services to decrease of access to medical products.

World Health Organization

https://www.sciencephoto.com

Advancements in biomedical science and technology

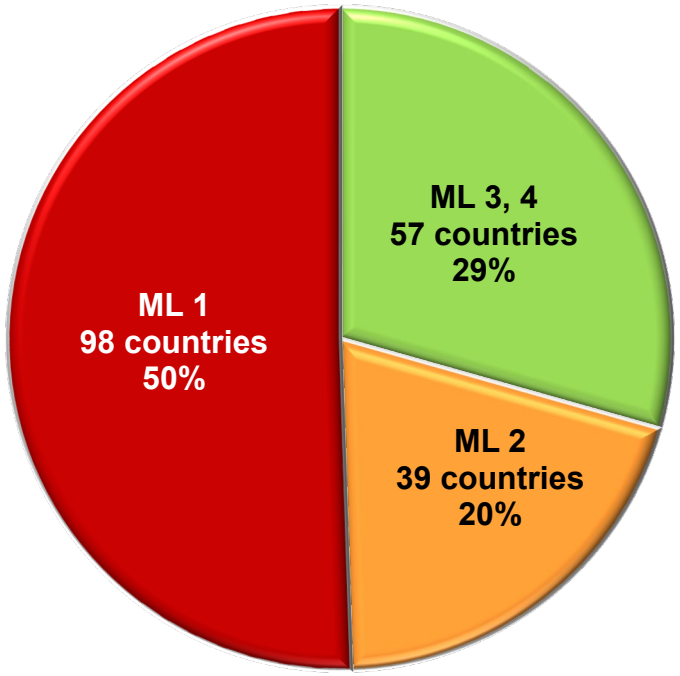
- **Science** - from innovative chemistry, to molecular drug design, and genetics;
- **Medicine**- from art, to experience, to evidence;
- **Technology** – from manual to automation and computer-controlled operations;

Complexity of regulatory processes and requirements has dramatically increased over the years

Capacity to regulate medical products globally

Strong regulatory capacity is an essential component of a well-functioning healthcare system (Resolution WHA 67.20, 2014)

- Globally, >70% of countries have weak national regulatory systems:
  - Only 57 countries (29%) have regulatory systems at GBT **maturity level 3 or 4** (https://www.who.int/initiatives/who-listed-authority-reg-authorities):
    - Lack of skilled personnel;
    - Lack of appropriate technology;
    - Lack of regulatory tools and guidelines;
    - Lack of requirements that are publicly available.



World Health Organization

WHO efforts to facilitate good quality decisions – based on reliance

- Promoting good governance and transparency in medical products sector – **Good Regulatory Practices** process;
- Promoting and facilitating the processes to build strong national regulatory systems as:
  - part of overall health systems strengthening – Global Benchmarking process;
  - as important contributor to achieving universal health coverage and able to address public health priorities;
- Supporting regulatory workforce development – Global Competency Framework and Regulatory Curriculum;
- Promoting **reliance** through regulatory cooperation, convergence and harmonization;
- Promoting work sharing – based on **reliance** on the work of trusted regulatory authorities to inform national regulatory decision-making – including in the **area of regulation of clinical trials**.

World Health Organization

Analysis of some of the Clinical Trial indicators for the 34 countries benchmarked by WHO between 2016 to December 2022

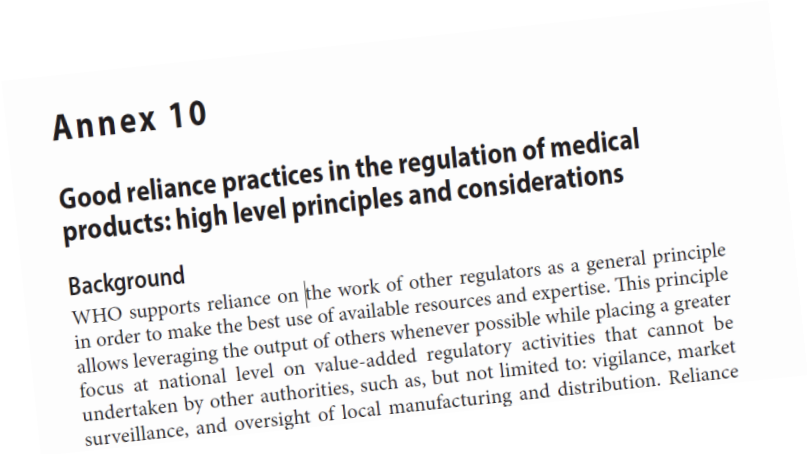
- CT01.01: Legal provisions and regulations for clinical trials (CTs) oversight exist.
- CT01.05: There are legal provisions or regulations covering circumstances in which the routine CT evaluation procedures may not be followed (e.g. for public-health interests)
- CT01.07: There are legal provisions or regulations that require the establishment of an IEC
- CT01.11: Legal provisions or regulations allow the NRA to recognize and use relevant CT decisions, reports or information from other NRAs or from regional and international bodies
- CT02.01: There is a defined structure with clear responsibilities to conduct CT oversight activities
- CT04.02: The existence of the ECs with clearly defined composition
- CT04.04: There are defined roles for ECs at all levels (e.g., national, sub-national, or institutional)
- CT05.01: There is clarity about the funding of the EC and its members

Analysis publicly available https://cdn.who.int/media/docs/default-source/research-for-health/ct_sub-ind-v4-final.pdf?sfvrsn=fde671a7_3&download=true

Please visit the WHA75.8 Webpage https://www.who.int/our-work/science-division/research-for-health/implementation-of-the-resolution-on-clinical-trials

World Health Organization

WHO Good Reliance Practices



Annex 10

Good reliance practices in the regulation of medical products: high level principles and considerations

Background

WHO supports reliance on the work of other regulators as a general principle in order to make the best use of available resources and expertise. This principle allows leveraging the output of others whenever possible while placing a greater focus at national level on value-added regulatory activities that cannot be undertaken by other authorities, such as, but not limited to: vigilance, market surveillance, and oversight of local manufacturing and distribution. Reliance

The act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information in reaching its own decision.

Adopted by WHO Expert Committee on Specification for Pharmaceutical Products in October 2020, published in March 2021
https://www.who.int/publications/i/item/55th-report-of-the-who-expert-committee-on-specifications-for-pharmaceutical-preparations

- Importance of **international cooperation** to ensure the safety, quality and efficacy/performance of locally used medical products;
- **Make best use of available resources and expertise**, avoid duplication and concentrate regulatory efforts and resources where most needed;
- The concept of reliance for regulation of medical products is applicable throughout the life cycle of medical products and to all regulatory functions – including regulation of Clinical Trials.

World Health Organization

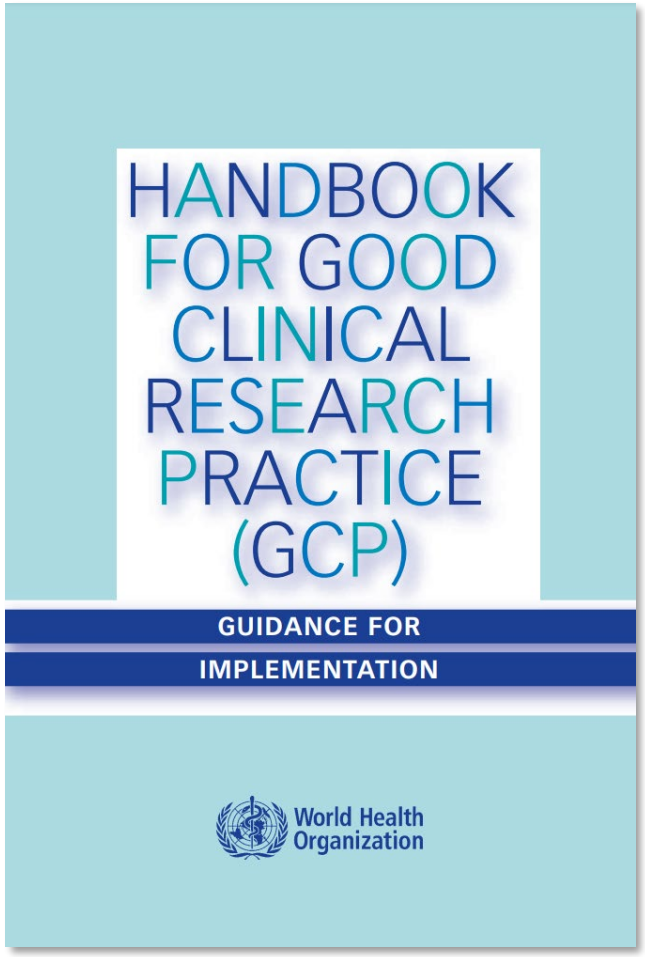
Reliance in regulation of clinical trials

- Work-sharing in the assessment of clinical trials is being effectively used in some regions:
  - Coordinated assessment in the European Union;
  - African Vaccine Regulatory Forum (AVAREF).
- By assessing clinical trial applications together, NRAs (and ethics committees) in different countries can benefit from the assessments performed by different participating countries with a view to facilitating and ensuring the robustness of the clinical trials application assessment process across countries;
- Reliance is key to effective access and oversight of medical products in case of public health emergencies, including in the area of regulation of Clinical Trials.

Optimizing research and development processes for accelerated access to health products – WHO strategy

- Access to appropriate health products is essential to achieve WHO's mission to ensure universal health coverage, respond to global health threats and promote a healthier population;
- Promoting research and development of innovative products and facilitating their introduction are vital activities to ensure the global community can address unmet health needs;
- WHO optimized process allows our activities in following areas to become linked, efficient, and coherent, with consequent increased impact on health outcomes:
  - research prioritization,
  - health product development advice,
  - WHO policy guidance production,
  - product assessment through prequalification,
  - support to implementation in countries;
- The ultimate goal of the process is to ensure the development of health products that address global health needs and to accelerate implementation and uptake in countries.

WHO handbook for Good Clinical Research Practice (GCP) - Guidance for implementation



For the purposes of this handbook, a general definition of human research is:

Any proposal relating to human subjects including healthy volunteers that cannot be considered as an element of accepted clinical management or public health practice and that involves either (i) physical or psychological intervention or observation, or (ii) collection, storage and dissemination of information relating to individuals.

This definition relates not only to planned trials involving human subjects but to research in which environmental factors are manipulated in a way that could incidentally expose individuals to undue risks.

World Health Organization,
Governance, rules and procedures,
WHO Manual XVII.

Principles of GCP

World Health Organization

- Principle 1: Ethical Conduct
- Principle 2: Research described in a protocol
- Principle 3: **Risk Identification**
- Principle 4: **Benefit-Risk Assessment**
- Principle 5: Review by Independent Ethics Committee/Independent Review Board
- Principle 6: Protocol Compliance
- Principle 7: **Informed Consent**
- Principle 8: Continuing Review/Ongoing Benefit-Risk Assessment
- Principle 9: Investigator Qualifications
- Principle 10: Staff Qualifications
- Principle 11: Records
- Principle 12: **Confidentiality/Privacy**
- Principle 13: Good Manufacturing Practice
- Principle 14: Quality Systems

Regulation of clinical trials: focus on patient safety

Recommendations to WHO:

- Facilitate exchange of safety information from clinical trials and other related activities at local, regional, and global level.

Recommendations to Member States:

- Implement any existing WHO guidance for inclusion of vulnerable populations, children, pregnant women and women of child bearing age in clinical trials to gain knowledge of safety in these populations in a controlled setting. This will facilitate access, if benefit/risk is favourable, in these populations to important medical products.

- Utilize opportunities for collaboration through networks such as AVAREF to assess clinical trial applications and develop process for monitoring and follow up on safety data.

World Health Organization

SEVENTY-FIFTH WORLD HEALTH ASSEMBLY
Agenda item 16.2

WHA75.8
27 May 2022

Strengthening clinical trials[1] to provide high-quality evidence on health interventions and to improve research quality and coordination

The Seventy-fifth World Health Assembly,

Recalling resolutions WHA58.34 (2005) acknowledging that high-quality, ethical research and the generation and application of knowledge are critical in achieving internationally agreed health-related development goals, WHA63.21 (2010) outlining WHO's role and responsibilities in health research, WHA66.22 (2013) and WHA69.23 (2016) on the follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination, WHA67.20 (2014) on regulatory system strengthening for medical products, WHA67.23 (2014) on health intervention and technology assessment in support of universal health coverage, WHA74.6 (2021) on strengthening local production of medicines and other health technologies to improve access, and WHA74.7 (2021) on strengthening WHO preparedness for and response to health emergencies, which notes the importance of basic and clinical research and recognizes the critical role of international collaboration in research and development, including in multicountry clinical and vaccine trials, as well as rapid diagnostics test and assay development, while acknowledging the need for further rigorous scientific evidence;

Noting the recommendations made by the Independent Panel for Pandemic Preparedness and Response in their review "COVID-19: make it the last pandemic"[2] relating to health research and development, including clinical trials;

[1] "A clinical trial is defined by WHO as any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials may also be referred to as interventional trials. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc. This definition includes Phase I to Phase IV trials." Joint statement on public disclosure of results from clinical trials, 2017 (https://www.who.int/news/item/18-05-2017-joint-statement-on-registration, accessed 25 May 2022).

[2] Independent Panel for Pandemic Preparedness and Response. COVID-19: make it the last pandemic, 2021 (https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf, accessed 25 May 2022).

Instead of conclusion:

- "CT Storm" : COVID-19 pandemic has triggered the initiation of more than **17,000 Randomized Clinical Trials** all over the world;
- **Less than 10%*** of these trials led to the useful evidence generated – enormous resources were spent on trials that contributed nothing to global health, while challenging other non-COVID areas of work..
- **WHA Resolution 75.8** recognized that well-designed and well-implemented clinical trials are indispensable for assessing the safety and efficacy of health interventions;
- WHA Resolution 75.8 called :
  - to better coordinate clinical trials research priorities based on public health needs of Member States including collaborative and, as appropriate, multicountry and multiregional clinical trials.. while avoiding unnecessary duplication of work;
  - to review existing guidance and develop, following the standard WHO processes, new guidance as needed on best practices for clinical trials, including on strengthening the infrastructure needed for clinical trials, taking into account relevant initiatives and guidelines such as those led by ICH;
  - to identify and propose best practices and other measures to strengthen the global clinical trial ecosystem, taking into account relevant initiatives where appropriate.

*Trends in COVID-19 therapeutic clinical trials. Bugin K, Woodstock J. Nature Reviews Drug Discovery. 25 Feb 2021.

www.who.int/medicines

- **Thank you for your attention!**

World Health Organization

Regulatory systems and regulations to support clinical trial conduct in Africa: CIOMS perspective

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Council for International Organizations of Medical Sciences (CIOMS)
Geneva, Switzerland
ragol@cioms.ch

CIOMS/IFPMA Webinar
19 January 2023

Presentation outline

Council for International Organizations of Medical Sciences

Introduction

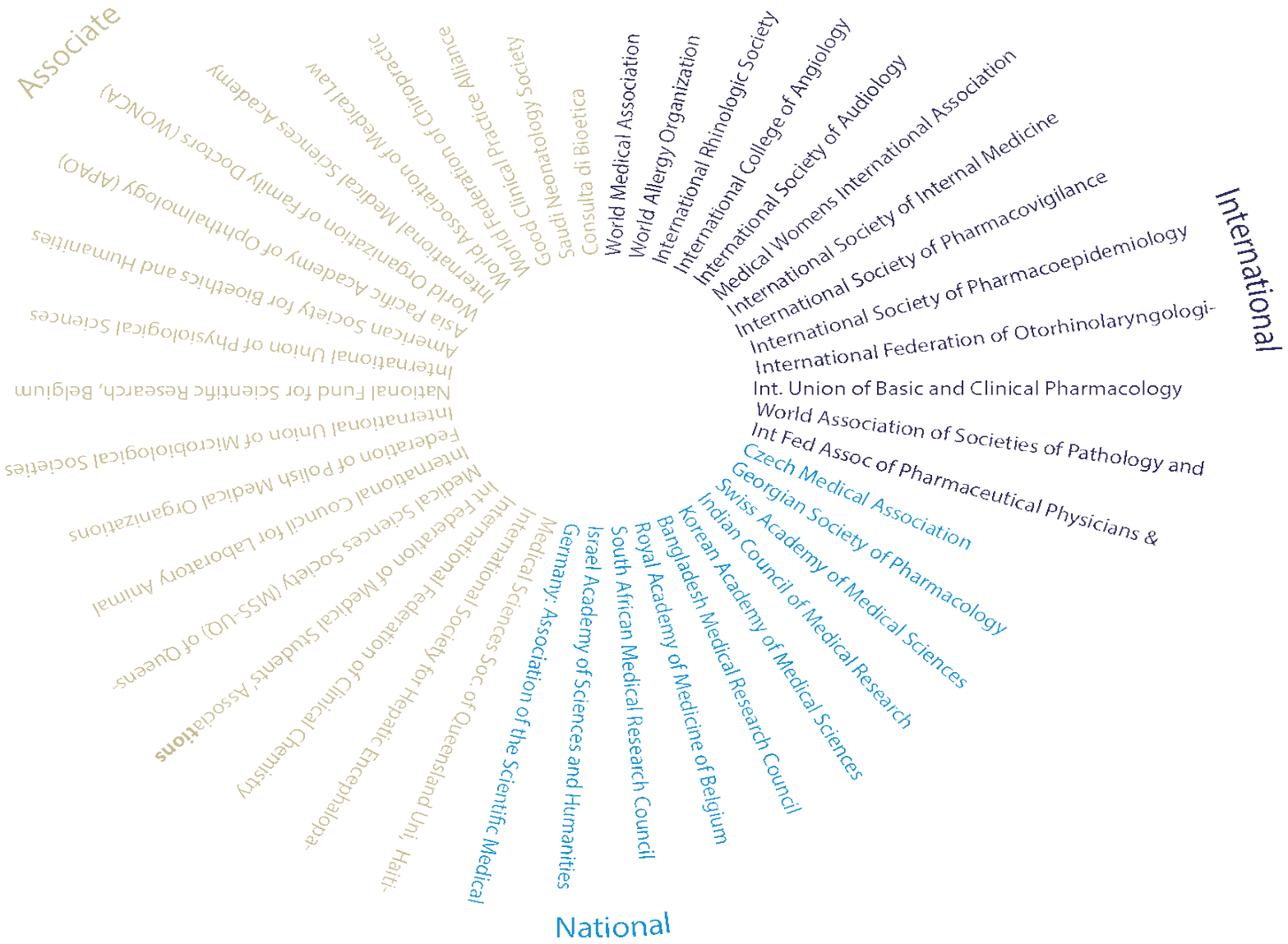
Founded in 1949 by WHO and UNESCO

- **In official relations with WHO**
- **UNESCO associated partner**
- **ICH Observer since 2016**

Mission Statement

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

CIOMS membership

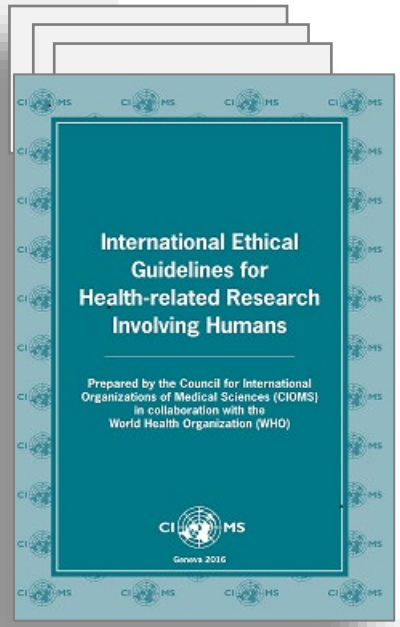


CIOMS areas of work

https://cioms.ch/publications

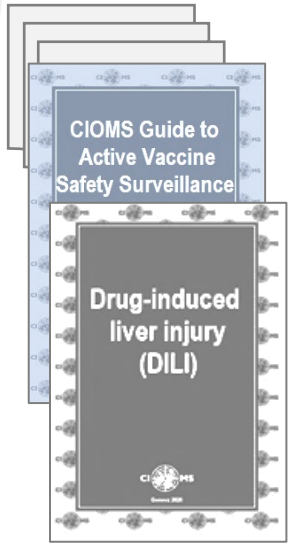
Bioethics (since 1967)

- Significant ethics guidelines
- Focus on low-resource settings



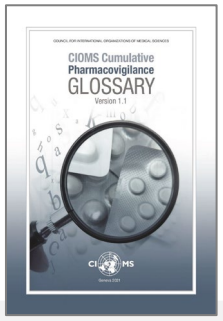
CIOMS International ethical guide-lines for health-related research involving humans (2016)

Pharmacovigilance (since 1986)



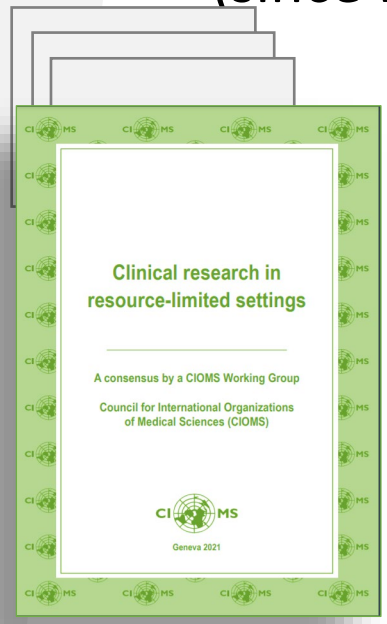
Twenty Working Group reports to date

Taken up in several ICH Guidelines

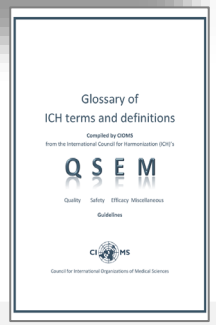


Cumulative Glossary (2021)

Product development (since 1977)



Clinical Research in Resource-Limited Settings (2021)

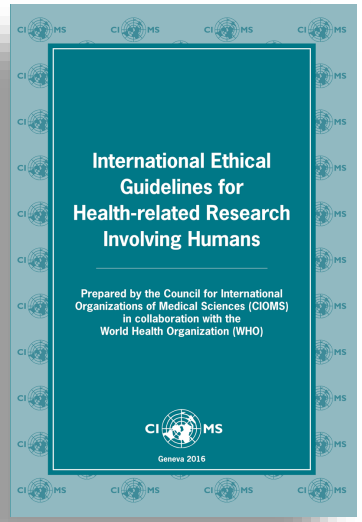


Glossary of ICH terms and definitions (2022)

Two complementary CIOMS guidance documents

International ethical guidelines for health-related research involving humans (2016)

Objective: To facilitate the implementation of the WMA Declaration of Helsinki

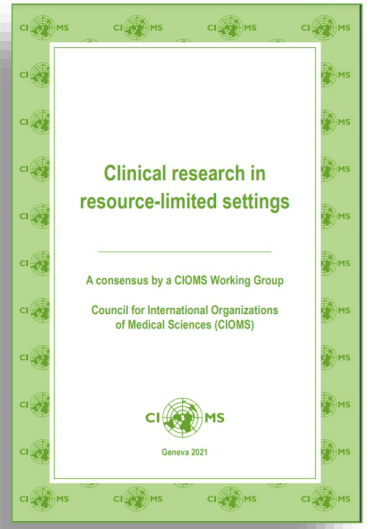


- Available in all six UN languages, and in Japanese, Korean, Portuguese, Ukrainian
- Online training module on how to navigate the guidelines freely available at: https://cioms.ch/online-training/

https://doi.org/10.56759/rgxl7405

Clinical research in resource-limited settings (2021)

Objective: To promote ethical, good quality clinical research in resource-limited settings (RLS)

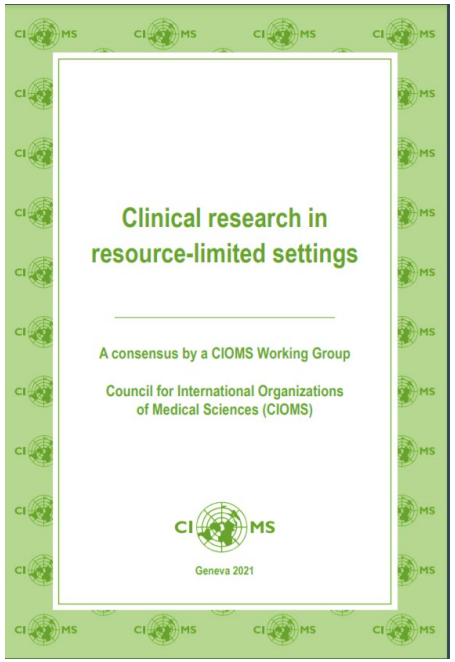


- Synopsis in: S Afr J Bioethics Law 2022; 15(3) (in press)
- 2021 webinar held by the Center for Informed Consent Integrity (GE2P2 Foundation, U.S.)
  Link to recording posted at: https://cioms.ch/webinars

https://doi.org/10.56759/cyqe7288

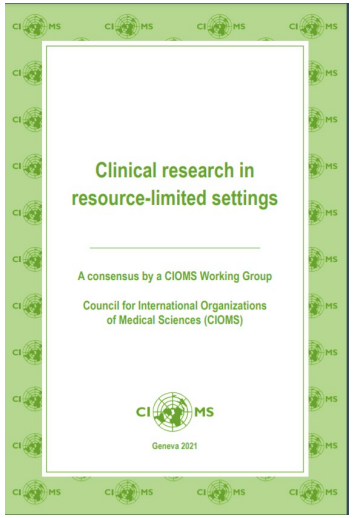
Clinical research in resource-limited settings

Report development



Nov 2017	**CIOMS convened a Working Group** of senior scientists from regulatory authorities, the pharmaceutical industry, public-private partnerships for product development, and academia **Working Group meetings** (6 in-person, 3 virtual) + remote work
Aug 2020	**Editorial subgroup** formed Monthly teleconferences + remote work (Dec 2020) Input sought informally from peer reviewers
Mar 2021	**Draft report published for comment** (6 weeks) Comments actively invited from RLS-based scientists >130 comments received and addressed
June 2021	**Report published**

Content



Recommendations: Target groups

➢ To governments and regulatory authorities

This would include relevant ministries e.g. of health or science; authorities in charge of regulating health products, and bodies in charge of scientific and ethical review of research protocols.

Governments and regulatory authorities of countries that host clinical research should take measures to create a conducive research environment.

(Recommendations 1-8)

➢ To researchers

This would include researchers from academic institutions, the health care industry, contract research organizations, and non-commercial entities conducting research in low-resource settings.

(… Recommendations 9-15)

➢ To international organizations and funders

Examples include organizations such as the Bill & Melinda Gates Foundation or the Wellcome Trust; public-private partnerships such as the Drugs for Neglected Diseases initiative (DNDi), Medicines for Malaria Venture (MMV) and other new actors mentioned in section 1.4 of this report.

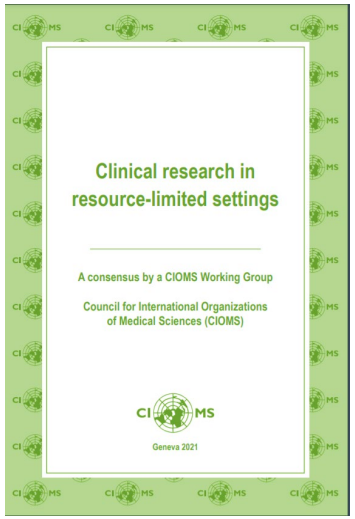
(… Recommendations 16-20)

Recommendations: Some examples

To governments and regulatory authorities

Chapter 2 Environment	1) (…) **2)** When planning to introduce **electronic health records, consider lessons learned in other countries** and aspire to bring clinical research and information technology experts together to build efficient and transparent systems that can be used for high quality clinical research (see Appendix 2). **3)** **Combat inefficiency and corruption** in governmental institutions and ethics committees as a priority. 4) (…)
Chapter 3 Guiding principles	**5)** **Clarify regulatory requirements** and harmonize them with those of other countries; identify unnecessary obstacles and reduce bureaucracy; shorten ethics and regulatory review timelines and rely on the decisions of other authorities wherever possible.
Chapter 4 Ethical considerations	**6)** Establish and enforce **effective regulations for ethical review**; ensure appropriate **protection—which does not mean exclusion—of vulnerable** persons and groups in research. **7)** Support the establishment of **platforms for researchers** to engage with patient representatives and communities, e.g. community advisory boards; request and consider formal communication plans as part of applications for clinical studies.
Chapter 5	8) (…)

In-chapter recommendations



2. **Environment**	2.2 Creating a research-friendly environment 2.3 Building research infrastructure and capacity
3. **Guiding principles** 3.1 Origins 3.2 GCP	3.3 Benefit-risk assessment in emergencies 3.4 Regulatory capacity, cooperation and reliance 3.5 Implementing Good Clinical Practice (GCP)
4. **Ethical considerations** 4.1 Vulnerability in the context of RLS	4.2 Protecting research participants 4.3 Avoiding exploitative research 4.4 Ethical review and capacity-building 4.5 Participant and community engagement
5. **Scientific considerations**	5.1 Conceptualizing and designing research 5.2 Responsible information-sharing
APPENDIX 1. **Special populations**	A. Children B. Women of childbearing age
APPENDIX 2.	B. Electronic health records

←Regulatory aspects

In-chapter recommendations (example)

Section 3.3

Benefit-risk assessment in emergencies — Recommendations

▶ For governments and regulatory authorities*
▶ For researchers*
▶ For funders*

*Find examples of these categories on pages 4-6.

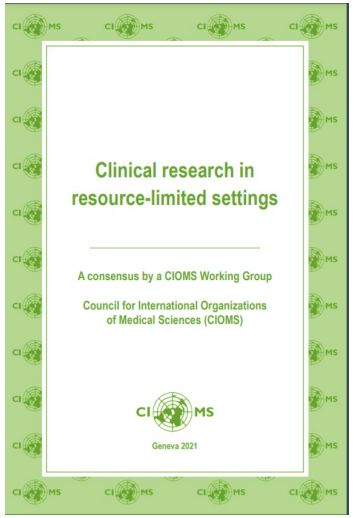
▶ Regulatory authorities should maintain solid, scientific and evidence-based principles and best practices to ensure that a proper review of research applications and benefit/risk assessment of potential new health interventions is conducted in emergencies.

▶ Wherever possible, regulatory processes should be accelerated to enable a timely response in an emergency situation. Regulators should cooperate effectively, and should rely on each other's decisions as much as possible.

▶ ▶ Sponsors and regulatory authorities should monitor the safety and effectiveness of new therapies e.g. through phase 4 clinical trials, observational studies, manufacturer-run patient registries and/or patient support programmes, patient focus groups and by implementing proactive adverse reaction monitoring strategies. (See also 2.3.2).

▶ ▶ ▶ All stakeholders should follow best practices for communication and provide information that is timely, accurate, credible, understandable, actionable, consistent, and empathetic.

Conclusions



- More clinical research is needed to fight the diseases affecting people in resource-limited settings.
- Ethical review systems and regulatory oversight in LMICs remain fragile.
- Current GCP guidelines originated in industrialised countries and are challenging to implement meaningfully in RLS.
- Each study is different. Researchers and sponsors have a responsibility to reflect on ethical and scientific aspects in context before submitting any new clinical research proposal for approval.
- The report is a call to action for funders, scientists, the pharmaceutical industry, community representatives, regulators and governments, to collaborate in addressing the proposed recommendations.

Next steps?

> “Taken together, the 2016 CIOMS ethics guidance—which is very robust— and this report are **a powerful complement** to other core guidance and norms on clinical research, and **should govern most research**, including social science research and other research that might not be formally termed clinical research.”
>
> David Curry, President & CEO, GE2P2 Global Foundation, at the webinar held on 21 July 2021 by the Center for Informed Consent Integrity. https://ge2p2global-centerforinformedconsentintegrity.org/webinar-series/

- Panellists at the above webinar and some commentators have stressed the need for implementing the guidance in LMICs
- CIOMS has been increasing its outreach activities in 2022
- Resolution WHA75.8 on *Strengthening clinical trials* requests WHO to develop guidance on Best Practices for Clinical Trials. The CIOMS report has been identified as a resource to take into account

Thank you

Questions: ragol@cioms.ch

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PANEL DISCUSSION

Dr Boitumelo Semete Makokotlela
CEO, South African Health Products Regulatory Authority

Dr Walter Jaoko
Director, KAVI-Institute of Clinical Research, University of Nairobi

Dr Beno Nyam Yakubu
Deputy Director, Head of Clinical Trial Division, NAFDAC, Nigeria. Chair of AVAREF Technical Committee

Ms Imene Ben Abdallah
IFPMA

Dr Diadié Maiga
Regional Vaccine Regulation Officer, WHO Regional Office for Africa

Dr Fabienne Benoist
Head of Regulatory Affairs, DNDi

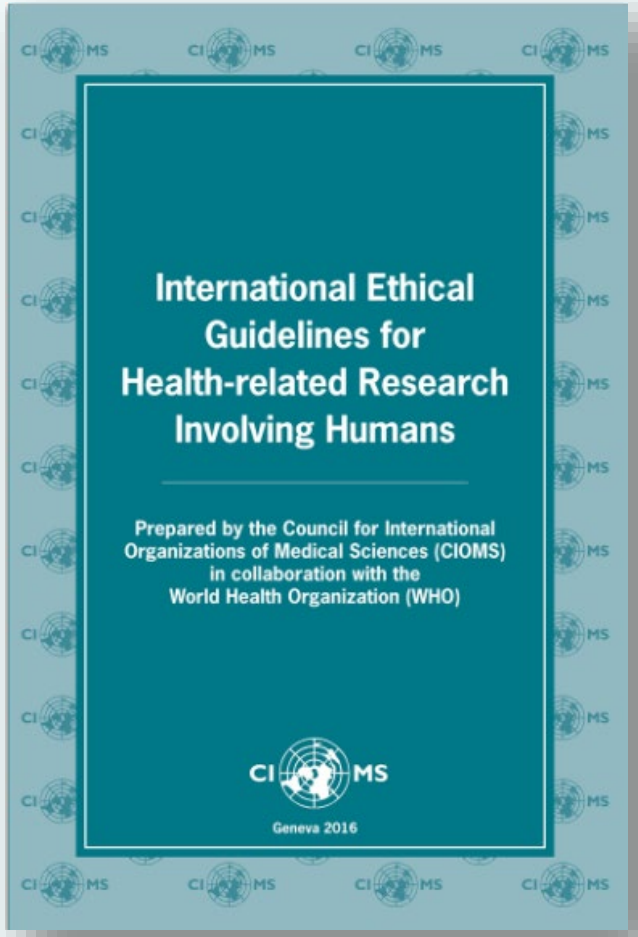
Please submit your questions in the Q&A box. If possible, include your name and organization.
Veuillez soumettre vos questions dans l'espace Q&A. Si possible, veuillez inclure votre nom et organisation.
Por favor, envie suas perguntas na caixa de perguntas e respostas. Se possível, inclua seu nome e organização.
All presentations will be circulated to registered participants after the webinar

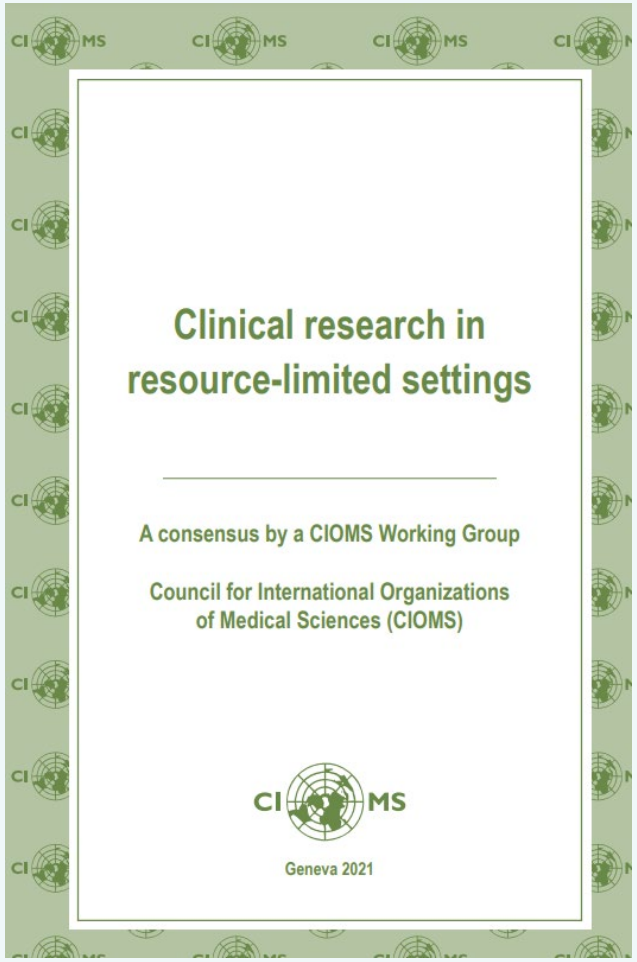
KEY TAKEAWAYS & RECOMMENDATIONS

Conclusion

Conclusão

RESOURCES


International Ethical Guidelines for Health-related Research Involving Humans
Prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO)
CIOMS
Geneva 2016


Clinical research in resource-limited settings
A consensus by a CIOMS Working Group
Council for International Organizations of Medical Sciences (CIOMS)
CIOMS
Geneva 2021


IFPMA
IFPMA Perspective on:
CLINICAL RESEARCH IN RESOURCE-LIMITED SETTINGS
The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) congratulates the Council for International Organizations of Medical Sciences (CIOMS) and the work of its technical working group for the very comprehensive report on clinical research in resource-limited settings[1]. The biopharmaceutical industry is already actively engaged and contributes to the evolving clinical research ecosystem.
IFPMA members conduct high quality, science-driven studies to develop innovative medicines and vaccines for unmet patient needs. These studies are conducted consistently according to international ethical and regulatory standards, such as the Declaration of Helsinki and ICH standards to ensure patient safety and data integrity. We also conduct our research in compliance with local regulations and ethical requirements. In addition, we are committed to support local policy makers to align on global and local standards as part of capacity building and a sustainable ecosystem.
The private sector is a crucial contributor to this ecosystem due to its vast experience in designing, initiating, and running global clinical trials according to the highest regulatory and ethical standards to deliver robust data for the development of innovative medicines and vaccines for patients worldwide.
The speed and mutual success of our development efforts depends on close collaboration with other partners. The availability of an ethical and scientific clinical research ecosystem ensures participant safety and can deliver high quality results that meet regulators' expectations. The creation of such a sustainable ecosystem requires open and transparent collaboration between all stakeholders to build trust, long term investment to develop sufficient capacity of trained clinical trial researchers, adequate healthcare infrastructure, quality assurance mechanisms and data collection tools.

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Thank you!