

UNIT-V

CIOMS



CENTURION
UNIVERSITY
*Shaping Lives...
Empowering Communities!*

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- **CIOMS Working Groups**
 - **CIOMS Form**

MISSION

- ▶ The Council for International Organizations of Medical Sciences (CIOMS) is an international, non-governmental, non-profit organization established jointly by WHO and UNESCO in 1949. CIOMS represents a substantial proportion of the biomedical scientific community through its member organizations, which include many of the biomedical disciplines, national academies of sciences and medical research councils. CIOMS mission is to advance public health through guidance on health research including ethics, medical product development and safety.

History

Year	Event
2016	New CIOMS Ethical Guidelines for Health-related research involving humans
1993	Start of CIOMS focus on pharmacovigilance and reporting adverse drug reactions
1982	Adoption by UN of CIOMS Medical Ethics for prisoners
1977	Launch of Ethics of Research involving humans.
1959	Vienna meeting on controlled clinical trials
1952	Present name CIOMS adopted
1949	Council formally constituted in Brussels by WHO and UNESCO

Working Group XII – Benefit-Risk Balance for Medicinal Products

- ▶ The CIOMS Working Group (WG) XII on ***Benefit-Risk Balance for Medicinal Products*** was launched in September 2019 and includes participants from industry, regulators, academia and the World Health Organization. The group is working together to update CIOMS IV on *Benefit-Risk Balance for Marketed Drugs: Evaluation of Safety Signals*, originally published in 1998, and potentially but not necessarily, to extend the scope to include pre-approval as well as post-marketing considerations for medicinal products.

Working Group XII Objectives

- ▶ WG will build on previous considerations established by CIOMS WG IV, incorporating the latest thinking in quantitative and qualitative approaches to the evaluation of benefit-risk (B-R), as well as assimilating visual presentations of benefits and risks to improve transparency and understanding amongst key stakeholders, including patients.
- ▶ The perspective of healthcare professionals and patients will be considered based on other ongoing initiatives as well as new guidelines from regulatory authorities and public-private partnerships. Specific aspects of the (B-R) evaluation may include considerations during drug development, approval for marketing, post-marketing pharmacovigilance and risk management.

Working Group XI – Patient Involvement

- ▶ The importance of patient involvement throughout the life cycle of pharmaceutical products, from their development to their use on the market has increasingly been recognized.
- ▶ Patients are now invited to state their perspectives and preferences on new needed medicines, to provide input to regulatory benefit-risk assessments through public hearings and consultations, and to submit adverse reaction reports to pharmacovigilance systems using new technologies such as mobile apps or social media.
- ▶ Previous CIOMS guidelines have recognized the role of patients as key stakeholders in the safe and effective use of medicines

Working Group XI Objectives

- ▶ The CIOMS Working Group XI on patient involvement in the development and safe use of medicines was launched in April 2018.
- ▶ It includes participants from patient organizations, industry, regulators, academia and the World Medical Association
- ▶ These experts are working together to formulate pragmatic *Points to Consider* in patient involvement.
- ▶ The guidance will provide a comprehensive overview of present knowledge and existing initiatives, and will address a wide range of the remaining challenges and practice gaps. The optimal consideration of patient perspectives will support the safe and effective use of medicines

FORMER WORKING GROUPS

- ▶ Vaccine safety
- ▶ Bioethics
- ▶ Working group X Meta analysis
- ▶ Working group IX Risk minimization
- ▶ Working group VIII Signal detection
- ▶ Vaccine pharmacovigilance

SUSPECT ADVERSE REACTION REPORT																				
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I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION <input type="checkbox"/> PATIENT DIED <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING
		Day	Month	Year	Years		Day	Month	Year	
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)										

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)		20 DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION	21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
17. INDICATION(S) FOR USE		
18. THERAPY DATES (from/to)	19. THERAPY DURATION	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergics, pregnancy with last month of period, etc.)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER

24b. MFR CONTROL NO.

24c. DATE RECEIVED
BY MANUFACTURER

24d. REPORT SOURCE
 STUDY LITERATURE
 HEALTH PROFESSIONAL

DATE OF THIS REPORT

25a. REPORT TYPE
 INITIAL FOLLOWUP