وزارة الصحة
Ministry of Health

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مركز سلامة الدواء
Drug Safety Center

Guideline on Acronyms & Definitions used by the Drug Safety Center

Drug Safety Center

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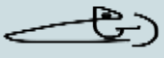
Signature		**Signature**	
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- Ph. Safiya Al Aghbari
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Adapted from global standards, including WHO-UMC and CIOMS terminologies and style manuals for acronym usage.

Table of Contents

Acronyms:

(Alphabetical table of all approved acronyms used across DSC documents)

CIOMS	Council for International Organizations of Medical Sciences
DSC	Drug Safety Center
QASM	Quality Assurance and Safety Management
SOP	Standard Operating Procedure
UMC	Uppsala Monitoring Centre
WHO	World Health Organization

Definitions

Acronym	A term formed from the initial letters of a series of words, typically pronounced as a single word, such as DSC or WHO—in line with ISO's principles for term formation in terminology work
Definition	A statement that conveys the essential characteristics of a concept by stating its class and defining characteristics, distinguishing it from other members of that class.

CHAPTER ONE

Introduction

Establishing clear, standardized terminology is essential for ensuring consistent and effective communication throughout all departments and sections of the Drug Safety Center (DSC), as well as with external stakeholders.

Purpose

To define and regulate the use of acronyms and definitions within DSC's documentations (e.g. guidelines, SOPs, polices, reports, and communication).

Scope

This guideline is applicable across all DSC departments and sections and pertains to all types of documentation.

Structure

This is the first version of this guideline and is organized into four chapters. CHAPTER ONE covers the Introduction, Purpose, Scope, and Structure. CHAPTER TWO outlines the detailed procedures and methods. CHAPTER THREE defines responsibilities in relation to this guideline. CHAPTER FOUR includes the document history and version control table, references, and the Annex.

CHAPTER TWO

2.1 Use of Acronyms

2.1.1 On first use in any document (including each chapter or separate section), spell out the term fully with the acronym in brackets.

2.1.2 Thereafter, use the acronym consistently.

2.1.3 Do not introduce acronyms for terms used fewer than two times.

2.2 Presentation & Formatting

2.2.1 Acronyms should appear in uppercase without periods (for example, “PSUR” rather than “P.S.U.R.”), except in cases where lowercase forms are internationally recognized (such as “eudravigilance”).

2.2.2 Maintain the Acronyms and Definitions list as two separate sections for clarity and streamlined referencing.

2.3 Updated Definitions

2.3.1 Definitions should be precise and aligned with international standards (e.g. WHO-UMC, CIOMS).

2.3.2 To propose new Acronyms or Definitions, submit your request to the Quality Assurance and Safety Management (QASM) Section. Upon review and approval, it will be included in the next version update.

CHAPTER THREE

Responsibilities:

- **Quality Assurance and Safety Management Section**: Oversees the implementation of this guideline.
- **DSC Departments and Sections**: Ensure use of approved terminology and update requests.

CHAPTER FOUR

Document History and Version Control

Version	Description	Review Date
1	Initial Release	October 2025
2		
3		

References:

CIOMS cumulative glossary with a focus on pharmacovigilance. Version 2.3. Geneva, Switzerland: Council for International Organizations of Medical Sciences (CIOMS), 2025.

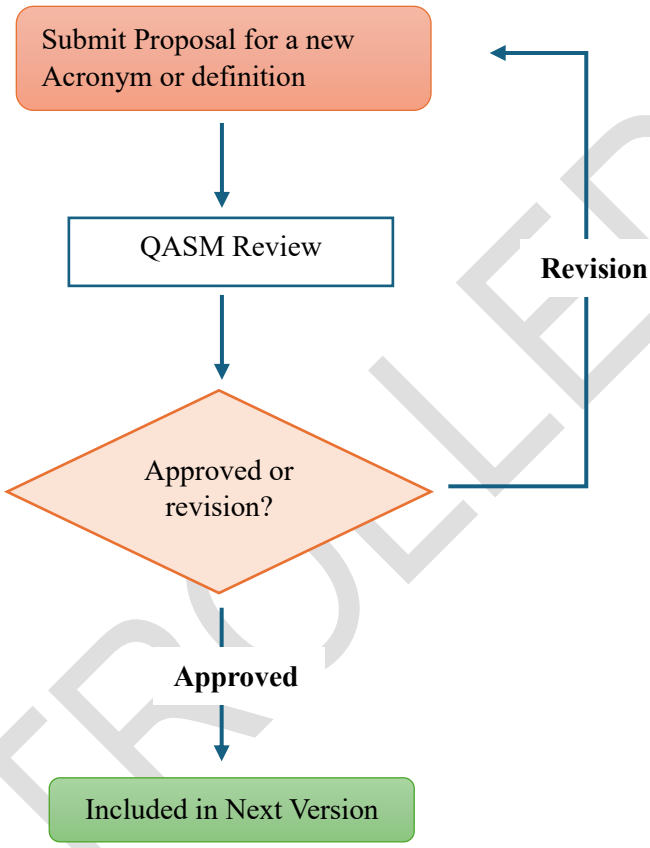
CIOMS. *Glossary of ICH Terms and Definitions*. Compiled by CIOMS from ICH guidelines. Version 8, 5 June 2025. CIOMS

International Organization for Standardization (ISO). *ISO 704:2022 – Terminology Work: Principles and Methods*. Geneva: ISO; 2022.

WHO Uppsala Monitoring Centre (UMC) (n.d.) *WHO-UMC Pharmacovigilance Glossary*. Available at: https://who-umc.org/pharmacovigilance-communications/glossary/ (Accessed: 1 October 2025).

Annexes

Appendix 1: Process Flow Chart



Appendix 2: Glossary Request Form – Proposal for New or revision of Acronym or Definition

1. Date of Submission	[DD/MM/YYYY]
2. Requester Name	
3. Department/Section	
4. Request Type	☐ New Acronym ☐ New Definition ☐ Revision of Existing ☐ Addition/Revision to Source List
5. Proposed Acronym	(If applicable)
6. Full Term/Definition	(Write full term the acronym stands for or provide the full definition text)
7. Justification	(Explain why this term or acronym should be added or updated. Include reference to relevant SOPs, policies, or regulatory needs)
8. Suggested Source/Reference	(For definitions: list at least one source from source list. For source additions: include full reference.)
9. Document(s) Where This Term Will Be Used	(e.g., SOP title, report type)
10. Priority Level	☐ High ☐ Medium ☐ Low
11. Reviewed by Department/ Section Head	Name: Signature: Date:
12. QASM	☐ Approved ☐ Not Approved ☐ More Information Required
13. Decision Comments	(To be filled by QASM)
14. Final Action Date	[DD/MM/YYYY]
15. Glossary Version for Inclusion	[e.g., Version 1.2]

Instructions for Use:

- Any new acronym or term proposed for inclusion in the DSC glossary must be cross-verified against at least one source from this list.
- If a term is not found in these sources, provide a justification and proposed source in the Glossary Request Form.

Appendix 3: Source List for Glossary Verification

(*Used to verify and validate all acronyms and definitions adopted by the Drug Safety Center)*

#	Source Title	Publishing Body	Scope & Description
1	*Pharmacovigilance Glossary*	WHO– (UMC)	Standard definitions for pharmacovigilance terms
2	*CIOMS Cumulative Pharmacovigilance Glossary*	CIOMS	Definitions of drug safety and pharmacovigilance terminology
3	*Good Pharmacovigilance Practices (GVP) Module VI*	European Medicines Agency (EMA)	Terms related to reporting and ICSR definitions in EU PV
4	*MedDRA*	ICH	Standard terminology for regulatory reporting and post-marketing surveillance
5	*Glossary – WHO Medicines Regulatory Package*	WHO	Definitions for clinical trials, regulatory inspection, etc.
6	*WHO GBT – Global Benchmarking Tool*	WHO	Terms across NRA regulatory functions—marketing authorization, licensing, inspection, lab testing, clinical trials, lot release
7	*FDA – Drugs@FDA Glossary* & *FDA Regulatory Procedures Manual Glossary*	US FDA	Marketing authorization terms (NDA, ANDA, BLA), inspection classifications (OAI, VAI, NAI)
8	*FDA Bioresearch Monitoring Definitions*	US FDA	Definitions for clinical trials sponsors, investigators
9	*TOPRA Regulatory Healthcare Abbreviations Glossary*	TOPRA	Abbreviations across clinical trials, licensing, vigilance (e.g., EV, OCABR, EudraCT)
10	*Canada – Clinical Trials Inspection Strategy*	Health Canada	Definitions related to clinical trials inspection
11	*WHOCC Glossary of Pharmaceutical Terms*	WHO Collaborating Centre PPRI	Terms for clinical trials, licensing, pricing, reimbursement
12	*ICH – About ICH*	ICH	Clarifies terminology around marketing authorization and clinical trial oversight
13	*Trial Master File*	ICH/GCP	Terms related to clinical trials documentation
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Guidance for Use

- All DSC departments/sections may request additions or revisions to this Source List using the Glossary Request Form.