

Electronic Supplementary Material 1 (ESM 1) Information	
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Electronic Supplementary Material 1: Glossary

CIOMS	The Council for International Organisations of Medical Sciences (CIOMS) is an international, non-governmental, non-profit organisation 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. Source: https://cioms.ch/
ESI	Emerging Safety Issue: A safety issue considered by a marketing authorisation holder to require urgent attention by the competent authority because of the potential major impact on the risk-benefit balance of the medicinal product and/or on patients' or public health and the potential need for prompt regulatory action and communication to patients and healthcare professionals Source: https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-gvp-module-ix-signal-management-rev-1_en.pdf
EURD list	List of EU Reference Dates (EURD) and frequency of submission of periodic safety update reports: is a comprehensive list of active substances and combinations of active substances contained in medicinal products subject to different marketing authorisations in the EU, together with the corresponding EU reference dates, frequencies for submission of PSURs and related data lock points. The EU reference date corresponds to the date of the first marketing authorisation of a medicine containing that active substance or that combination of active substances in the EU, or alternatively the earliest of the known dates of the marketing authorisations for a medicine containing that active substance or that combination of active substances. Source: https://www.ema.europa.eu/en/news/european-medicines-agency-publishes-list-eu-reference-dates-frequency-psur-submission
ICH	The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) brings together regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration. ICH's mission is to achieve greater harmonisation worldwide to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner. Prominent work products include the ICH guidelines, the Common Technical Document (CTD) for the registration of pharmaceuticals for human use, the Medical Dictionary for Regulatory Activities (MedDRA), and Electronic Standards for the Transfer of Regulatory Information. Source: https://www.ich.org/home.html
ICSR	This refers to the format and content for the submission of an individual report of suspected adverse reactions in relation to a medicinal product that occur in a single patient at a specific point of time. An ICSR valid for expedited reporting should include at least one identifiable reporter, one single identifiable patient, at least one suspect adverse reaction, and at least one suspect medicinal product Source: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-good-pharmacovigilance-practices-gvp-module-vi-collection-management-submission-reports_en.pdf

Effective Pharmacovigilance System Development

PSUSA	Periodic Safety Update Report Single Assessment is a single assessment of related PSURs is carried out for medicines authorized in the EU that contain the same active substance or combination of active substances, as included in the list of EU reference dates (EURD list). Source: https://www.ema.europa.eu/en/medicines/download-medicine-data#periodic-safety-update-report-single-assessments-section
SCOPE	The Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) Joint Action, funding by the Consumers, Health and Food Executive Agency (CHAFEA), ran from 2013 to 2017. SCOPE was created to support pharmacovigilance operations in Europe following new requirements introduced by the European pharmacovigilance legislation of June 2012. SCOPE gathered information and expertise on how regulators in Member States run their national pharmacovigilance systems. Using this information, a variety of tools were developed including guidance documents, pharmacovigilance training materials and other tools to support best practice. Source: https://www.ema.europa.eu/en/learning-module/signal-management/story_html5.html and https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6223699/ Drug Saf. 2018; 41(12): 1285–1302. Published online 2018 Aug 21. doi: 10.1007/s40264-018-0708-5 PMID: 30128638
VigiFlow	VigiFlow is a web-based Individual Case Safety Report (ICSR) management system that is available for use by national pharmacovigilance centers of the WHO Program for International Drug Monitoring. VigiFlow supports the collection, processing and sharing of data of ICSRs to facilitate effective data analysis. Source: https://www.who-umc.org/global-pharmacovigilance/vigiflow/about-vigiflow/
VigiLyze	VigiLyze is an online resource that delivers useful search and analysis functions and provides a quick and clear overview of VigiBase. The WHO safety database. VigiLyze is available to PV national centers in all member countries of the WHO Program for International Drug Monitoring. VigiLyze is used to provide a global, regional or national view of the suspected adverse effects of a medicine. It may also be used to find supporting evidence when, for example, assessing one country's case reports. Access to safety information on drugs that are marketed elsewhere but are not yet on the national market is another benefit. Source: https://www.who-umc.org/vigibase/vigilyze/
UMC	Uppsala Monitoring Center in Uppsala, Sweden is the World Health Organization (WHO) Collaborating Centre for International Drug Monitoring. UMC operates the technical and scientific aspects of the WHO's worldwide pharmacovigilance network. Source: https://www.who-umc.org/about-us/who-we-are/
WEB-RADR	WEB-RADR is a mobile application, which allows patients to directly report potential medicine side effects and receive reliable information on their drugs. The application was developed under the Web-RADR project of Innovative Medicines Initiative (IMI), a public-private partnership between the European Community and the European Federation of Pharmaceutical Industries and Associations, EFPIA. Source: https://www.imi.europa.eu/projects-results/project-factsheets/web-radr

