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Sharing pharmacovigilance data in the WHO Programme for International Drug Monitoring

Reporting fact sheet

The appointed National Centre (NC) for Pharmacovigilance (PV) in each member country is responsible for sharing their Individual Case Safety Reports (ICSRs) with other members of the WHO Programme for International Drug Monitoring by sending the ICSRs to Uppsala Monitoring Centre (UMC) for inclusion in VigiBase, the WHO global ICSRs database.

Transmission options

NCs can send ICSRs to UMC either as e-mail attachments (preferably as encrypted files), via Eudralink from where UMC can then download them¹ (for countries in EEA), or on a CD by regular mail. UMC also provides an API (Application Programming Interface) for countries that wish to fully automate the transmission process using server-to-server communication.

Frequency of transmissions

Member countries are expected to share their PV data on a regular basis; preferably more often than once a month, and at the very least every quarter, to keep VigiBase as up-to-date as possible.

Aiming for the shortest possible lag-time from the event to availability of the ICSR in VigiBase is important in order to facilitate early discovery of new potential safety signals in the data – the core mission of the WHO Programme.

Case report exchange standards

Only ICSRs sent electronically are accepted. Case reports should be submitted according to the international standard for PV information exchange, ICH² E2B. This standard xml format is used both by NCs and companies, and allows for exchange of detailed information on each case.

Confirmation of received cases

UMC sends a confirmation e-mail within three days for cases received via e-mail/Eudralink/regular mail. Please contact UMC at vigibase@who-umc.org if no feedback on submitted cases has been received.

VigiFlow

For member countries lacking an E2B compatible database for ICSR management, UMC has developed VigiFlow, a web-based ICSR management system. Copies of the domestic data can easily be shared with the WHO Programme by an automated service to VigiBase.

What information to share

All adverse events occurring in a post-marketing situation and qualifying for your national ICSR database should be shared with the other members of the WHO Programme, both serious and non-serious cases. VigiBase is mainly a database for spontaneous ICSRs on registered medicinal products. However, UMC also accepts cases from clinical trials and literature; the type of report should be specified in the ICSR.

ICSRs on medication errors, counterfeit/substandard medicines and therapeutic failure should also be submitted.

ICSRs on ordinary allopathic medicines, traditional medicines (herbals), as well as biological medicines, including vaccines, should be shared. Medicines in combination with medical devices (for example coated stents) should also be sent.

ICSRs on veterinary medicines, cosmetic/hygiene products or medical devices (not containing any active substance) are not within the scope of the WHO Programme and should **not** be shared in VigiBase.

Case report content – quality versus quantity

The minimum information required for an ICSR to be valid is a case identifier, reporter and patient information, and information on suspect medicine and reaction/event. All national case reports fulfilling the minimum requirements should be shared with the WHO Programme.

However, quality of data and completeness of case reports are always important and reports should include as much information as possible to facilitate assessment. Free text/additional information can be provided in the original language. All information available on the original case report should be included when sending an ICSR to VigiBase, with the exception of confidential patient and reporter details that could potentially be used to identify individuals. More on the

¹ UMC has no gateway and cannot receive ICSRs automatically via Eudravigilance

² International Council for Harmonisation

importance of quality of ICSRs can be found on our website.

Reporter qualification

Case reports originating from physicians, pharmacists, other health care professionals, lawyers, other non-health care professionals and consumers (patients) are all accepted in VigiBase. The qualification of the reporter should be specified in the ICSR.

Follow-up case reports

A follow-up ICSR should be sent to VigiBase if a case report is updated with new information. Follow-up reports should have the same case identifiers as the original to enable automatic replacement in VigiBase.

Foreign cases

Foreign cases, i.e. case reports originating from other countries are also accepted. However, while their potential additional value versus the risk for duplication is being evaluated, the foreign cases are not available for search or used in statistics in VigiBase.

Duplicate case reports

If an NC receives the same ICSR from different sources, for example from a physician and from a pharmaceutical company, ideally the information from these cases should be merged prior to submitting a single report.

If duplicate ICSRs have already been sent to VigiBase, UMC should be notified which ICSR to keep in VigiBase and which to remove. With the ICH E2B standard there is an electronic process to follow to nullify such cases.

VigiBase duplicate detection – vigiMatch

UMC can identify suspected duplicates in VigiBase by a probabilistic method for duplicate detection. The results may be communicated to originating countries for verification or dismissal. Duplicates verified after such communication should be handled according to the principles previously described.

Terminologies

The Medical Dictionary for Drug Regulatory Activities (MedDRA) is recommended for coding reactions/events as well as indications and medical history. WHO Adverse Reaction Terminology (WHO-ART) can also still be used for coding of reaction terms, but it is no longer actively maintained or updated. If WHO-ART is used for coding of reactions, the International Classifications of Diseases (ICD) should be used for coding indications and medical history.

When case reports are entered into VigiBase, reactions and event terms are automatically coded to both MedDRA and WHO-ART. Drug information is automatically coded to WHODrug, a medicinal dictionary specifically designed for meaningful analysis of drugs on ICSRs and in clinical trials. It is developed and maintained by Uppsala Monitoring Centre and is the drug dictionary used within all UMC ICSR tools for NCs, available free of charge in these tools.

If adverse reactions or suspected drug names cannot be automatically coded to any of these terminologies, UMC's coding specialists undertake manual coding to ensure the usefulness of the information in statistical analysis. If issues cannot be resolved manually, UMC staff may contact national centres for more information.

VigiLyze – access to VigiBase data

Structured information from the ICSRs shared within the WHO Programme is available to all NCs through VigiLyze, a web-based search and analysis tool. A quick general search function allows easy filtering of all ICSRs in VigiBase. Graphical results give a quick and accessible overview of the data, and drilling down using filters lets the user see and export individual ICSRs. Information on disproportionality can be useful to NCs in their assessment of potential safety issues.

More on the obligations and benefits of WHO Programme members can be found on our website.

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