DGPharMed
Deutsche Gesellschaft für Pharmazeutische Medizin e.V.

DGPharMed White Paper

Pharmacovigilance Database

Version A: No E2B compliant database; ICSR submission via EVWeb tool

Processes: If the decision is made *not to implement a PV database* for ICSR collection and expedited submission, all valid and not-valid ICSRs should be documented in a *password protected Excel-spreadsheet*. The Excel-spreadsheet should be converted to a PDF-file every month or after each update and saved with the respective date integrated in the file name on the company's server. In that case, a *limit for the volume of cases* should be set for this approach, e.g. up until the receipt of 30 ICSRs. From the 31st ICSR on, a safety database would then be implemented and all ICSRs that have been received by this date, would be entered into the database at that time.

Expedited submission to EudraVigilance and other CAs will be done *via EVWeb*. This web interface is specifically designed for Small and Medium Size Enterprises (SMEs) and non-commercial sponsors, which do not have a fully ICH E2B compliant PV system and/or ESTRI gateway in place. As such it provides the necessary tool to allow SMEs secure electronic submission to the EMA and all CAs in the European Economic Area (EEA).

Quality aspects: ICSR processing with all "mechanisms used to assure the integrity and accessibility of the safety data, and in particular the collation of information about adverse drug reactions" (GVP II.B.4.4) as well as data storage and business continuity that includes the IT systems and hardware, back up strategies and recovery options must be ensured and described in SOPs, and a summary included in the PSMF.

Version B: E2B compliant database; ICSR submission via EVWeb tool or gateway

Processes: If an *E2B compliant PV database* is in place, all incoming valid and non-valid ICSRs will be entered, processed, stored and maintained there. Daily backups of these data should be performed and stored by the database provider in a location different from the server location.

Expedited submission to EudraVigilance can be done either *via EVWeb* (see above), by downloading the respective ICSR as xml and then uploading it into the webtool, *or via the gateway function* if that is implemented in the PV database.

Quality aspects: For a PV database, the validation status of its functionality should be described in the PSMF; also "the change control, nature of testing, back-up procedures and electronic data repositories vital to pharmacovigilance compliance should be included in summary, and the nature of the documentation available described" (GVP II.B.4.4).
In addition, ICSR processing, PV database management, as well as data storage and business continuity that includes the IT systems and hardware must be described in SOPs and summarized in the PSMF.

Ein White Paper der Deutschen Gesellschaft für Pharmazeutische Medizin e.V.
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