PHARMALEX

SMARTVIGISCREEN - AUTOMATED AND INTELLIGENT PROCESSING TECHNOLOGY FOR SCREENING EUDRAVIGILANCE CASES

BACKGROUND

In 2017 the EMA updated the EudraVigilance system providing MAHs with wider access to relevant ICSRs accompanied by an obligation to monitor these cases with a frequency proportionate to the identified risk. Companies were challenged with the following pain points: higher volume of downloaded cases, segregation of company vs. non-company cases, added effort in triaging the downloaded cases, duplication of cases and difficult to understand E2B(R3) format.

WHAT IS SMARTVIGISCREEN?

SMARTVIGISCREEN is a cloud-based software solution that processes incoming ICSRs automating the analysis of company vs non-company cases and reducing screening workload by upto 70-80%.

Incoming batches of E2B(R3) format ICSRs from **EudraVigilance database (for both L2A and MLM)** are processed to extract all the data within and make this available in a variety of formats e.g. E2B(R3), E2B(R2) & readable HTML (all formats are available).

FEATURES OF SMARTVIGISCREEN

- Intelligent text processing technology ensures quality by identifying potential cases with partial matches whilst safely excluding those which are not relevant for screening.
- GxP validated system according to GAMP 5 guidelines and CFR Title 21 Part 11 compliant.
- Audit trail with an audited screening process capturing all decisions made, the related exclusion criteria and company products
- Product configuration of **SMARTVIGISCREEN** is mirroring XEVMPD, hence XEVMPD needs to be up to date

BENEFITS OF SMARTVIGISCREEN

- Drastically reduces effort required in screening cases as well as load on the company's PV safety database.
- Intuitive, accessible, filtered and sorted display of all case data for efficient screening.
- Automated triage of company cases with an intelligent text processing technology to exclude those not relevant to the MAH
- Export of full case processing reports and confirmed cases in readable format in XML

SMARTVIGISCREEN Application for screening individual case safety reports of adverse reactions to medicinal products.

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