

VIGISCREEN - AUTOMATED AND INTELLIGENT PROCESSING TECHNOLOGY FOR SCREENING EUDRAVIGILANCE CASES

BACKGROUND

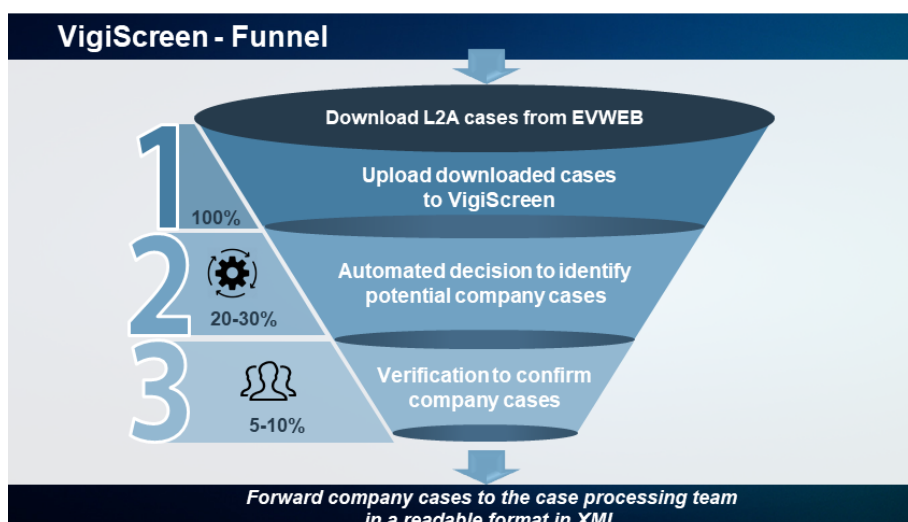
In 2017 the EMA updated the EudraVigilance system providing MAHs with wider access to relevant ICSRs accompanied by an obligation to monitor these cases with a frequency proportionate to the identified risk. Companies were challenged with the following pain points: higher volume of downloaded cases, 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?

VigiScreen is a cloud-based software solution that processes incoming ICSRs, automating the analysis of company vs non-company cases, reducing screening workload by up to 80%. A GxP validated system according to GAMP 5 guidelines, CFR Title 21 Part 11 compliant.

WHY USE VIGISCREEN?

- ▶ Automated triage of company cases with an intelligent text processing technology to exclude those not relevant to the MAH
- ▶ Audit trail with an audited screening process capturing all decisions made, the related exclusion criteria and company products
- ▶ Drastically reduces effort required in screening cases as well as load on the company's PV safety database
- ▶ Backwards-Forwards conversion between E2B(R3) & E2B(R2) formats
- ▶ Export of full case processing reports and confirmed cases in readable format in XML
- ▶ Intuitive, accessible, filtered and sorted display of all case data for efficient screening



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