Retrospective safety database audits

IQVIA
TECHNOLOGIES

Situation

PRAC-EMA discovered that a client had overlooked pregnancy cases in their safety database. A 30-day deadline was given to the client to **audit their safety database and identify any missed pregnancy exposure events** and report them to PRAC.

Client approached IQVIA to use Vigilance Detect to support their retrospective review across 91 products.

Solution

Vigilance Detect was rapidly configured to enable the automated identification of potential pregnancy and exposure cases.

Pharmacovigilance specialists were deployed to validate the technology outputs.

Results

855K+
CASES REVIEWED
in 30 days

91
PRODUCTS

100%
ACCURACY
using IQVIA technology

96%
REDUCTION
in manual effort

- **Vigilance Detect rapidly reviewed 855,121 cases for 91 products**, identifying pregnancy and exposure cases with **100% accuracy** *(no false negatives, no new terms detected during the audit)*.

- Significantly cut down the **manual review by 96%.**

- **9% of total records** were identified as true pregnancy-exposed cases.

- Client met PRAC-EMA audit deadlines with **zero missed pregnancy cases.**

Source: Anonymized client_Statistics

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