

Integrated PV Tech and Services Solution

Situation

Client needed to **review legacy records maintained by a third-party vendor**, who previously supported their REMS program for 2 products. The source data included interactions between the vendor's agents and **~2,500 patients** captured in **different formats**.

Due to a recent update in documentation, the client wanted to **ensure that there were no missed safety events** related to their products and reconcile what had already been booked into their safety database.

With an upcoming periodic report due, the client was **eager to complete this review as soon as possible**.

Solution

IQVIA's Lifecycle Safety Services (LCS) team partnered with **IQVIA's Vigilance Detect** (safety risk identification tech) team to optimize a compliance-centric solution **combining technology and services**.

An instance of Vigilance Detect was deployed to **automatically identify potential adverse events** from source data and provide a **GxP compliant workflow** to accommodate a centralized PV review.

LCS were able to **leverage an internal talent pool** and **quickly onboard a global team of PV Specialists** to support the manual reviews required to validate the technology outputs and remediate findings within the client's safety database.

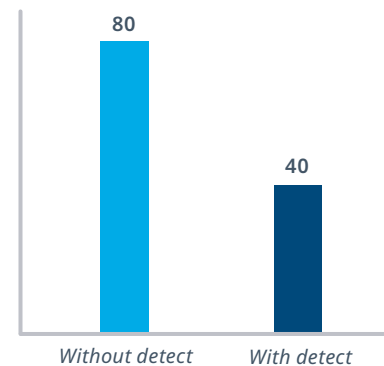
Results

277K records reviewed in <2 months

54% records automatically filtered out of workflow

15K safety events confirmed by PV analysts

FTE REQUIRED



- **Combined technology and services solution** was in production in <4 weeks and the project was delivered **<2 months from go-live**.
- **OCR was implemented and rolled out 2-weeks after go-live** to enable the machine to review >15K PDF documents which were the most laboursome source type to manually review.
- LCS successfully **onboarded 40 PV specialists** from multiple locations to **critically assess data for safety significance**.

CONTACT US
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