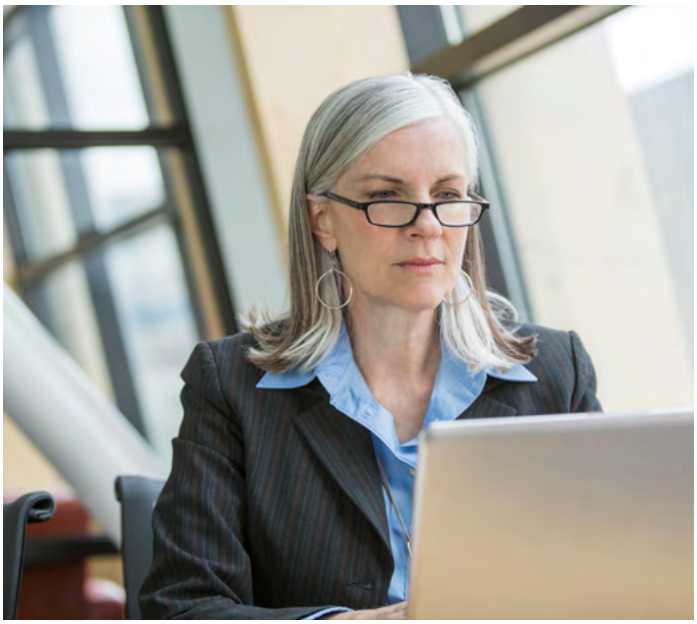
Fact Sheet

IQVIA Vigilance Case

Situation

Pharmacovigilance organizations are tasked with managing increasing adverse event volumes while facing mounting expectations for compliance from local and global and regulatory agencies.



Lack of human and financial resources, coupled with outdated technologies, are insufficient to meet the demands faced by PV organizations within life sciences companies today, necessitating new ways of managing data receipt, storage and analysis.

More products, market expansion and new data sources

Siloed information

Lack of real-time oversight impacts decision making

Strict data privacy requirements that requires removal of PII at the local level

Translation for processing by global teams

Decentralized teams

Solution

Vigilance Case provides real-time management, oversight and reporting of Safety cases, streamlining operations such as medical review and regulatory reporting across global and local teams.

Built by experienced hands-on Safety professionals to efficiently meet the latest compliance obligations, powered by automation and best practice.

Applying AI, ML and NLP, Vigilance Intake automates the receipt and management of adverse events and transforms how key activities such as case validation, duplicate check and redaction are performed. Additionally, intake streamlines the receipt of safety information while allowing organizations to perform upfront case processing activities, including full data entry and dictionary coding to improve efficiency, quality and decision-making.

Operational Costs

- ✓ Accelerate and streamline the intake process
- ✓ Ensure data consistency and quality e.g., early identification of follow ups
- ✓ Determine that the data is complete and reportable prior to entry in the safety system

Efficiency & Productivity

AUTOMATION, CODING AND CASE ANALYSIS SUPPORTS AND ENABLES INTAKE

- **Comprehensive data entry powered by automation**
- **MedDRA, WHODrug and Company Dictionary coding**
- **Algorithmic identification of follow-up and duplicate cases**

Moving core tasks to intake

INTAKE

Sources

Information is received in multiple ways...

Spontaneous
Clinical trial
Literature
License partner

Channels

...and in multiple formats....

Email
Fax
Web
Call center
EDI gateway
Agency

Structured / Unstructured

Intake

Intake performs a variety of activities

Data acquisition
Validate
Check for duplicates
Prioritize / Triage
Translate
Alert cases of interest
Redact
Track local cases
Submit local cases
Prepare and send to global

Case Processing

Case processing activities can begin during intake

Follow-up merge
Coding
Full data entry
Workflow management

Overview of Vigilance Case

KEY FUNCTIONALITY

Worklists and Dashboards

Powerful worklists and dashboards that allow you to see and manage all your activities

Worklist functionality:

- Sort, filter, search, export, print capabilities
- Bulk and individual case functionality for print, changing case owner, search

Dashboard functionality:

- Real-time dashboards monitoring the entire process
- Workflow reports can be sent automatically to users

Data Entry

AI, NLP, and Automated Translation from Case Intake integrated into Case Processing

Access-based case unblinding functionality

Access-based case archive/ unarchive capabilities

Product Event Assessment interface based on client configuration

Allows incorporation of multiple follow-ups into a single case version (dependent on workflow status)

Vigilance case form designed with central, local, and both fields

Report scheduling

Draft Report Generation

Automated Workflow

System-created milestones automatically route case through workflow stages and automatically assigns to appropriate user group.

Allows Central and Local case processing in a single system.

Fixed workflow stages (Data Entry, Review, Finalization, Submission, Closed) but sub-workflows configurable.

Final verification of case data. Helps ensure no backwards routing (which aligns with industry best practice for maximum efficiency in case processing.

Submission

Designed to manage distribution of case data to configured reporting destinations

Schedule/generate draft/final reports

in MedWatch 3500A, CIOMS I, E2B R2 and R3 formats

Download final submission-ready reports for offline submission to desired recipients

Attach documentation to reports including acknowledgements of receipt

Mark reports as submitted and enter submission date

Track status of reports

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