IQVIA Vigilance Signal

Multi source signal detection and management

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Situation

Regulators continue to sharpen their focus on robust data analysis and risk management, while data volumes and sources increase in size and complexity.

Existing data mining technologies partially alleviate the burden of manual signal identification, but do not provide a holistic solution to support safety professionals with proactive signal detection and end-to-end management.

- Signals hidden in exhaustive cumulative data exports
- Medical expertise burdened with administrative tasks
- Paper-based assessment driven by analysis of multiple exports and documents
- Additional structured and unstructured sources requiring analysis
- Disparate processes and tracking mechanisms across product areas

60% of critical audit findings are related to safety evaluation and risk management.[1]
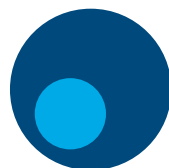
50% of resource in signal management is used for administrative tasks, such as manual data tracking and spreadsheet-driven analysis.[2]

Solution

Vigilance Signal performs automated real-time analysis on multiple diverse data sets to proactively detect, compare and evaluate potential signals. Intelligent management of the signal allows subject matter experts to quickly identify and evaluate signals in a user-friendly and visual format. Vigilance Signal seamlessly enables the identification, prioritization, analysis, documentation and tracking of all signal management activities.
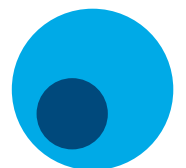
TRADITIONAL SIGNAL: SLOW, INEFFICIENT AND REACTIVE

- Manual data cleaning
- Manual identification
- Manual evaluation
- Manual workflow management
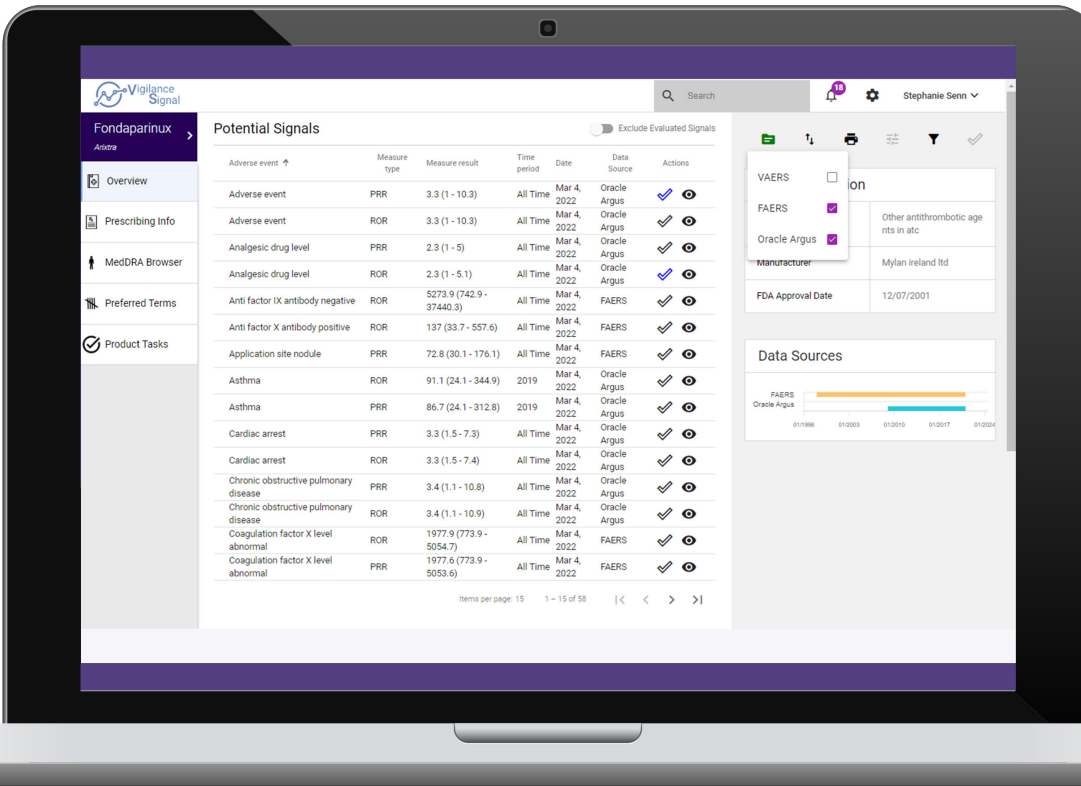- Reactive studies requiring months and years

VIGILANCE SIGNAL – AI/ML-SUPPORTED SIGNAL: FAST, AUTOMATED AND FLEXIBLE

- Automated data cleaning of multiple sources
- Automated identification of potential signals
- Regulatory compliant workflow and tracking
- Proactive analysis of adverse event data
- Supports creation of signal documentation
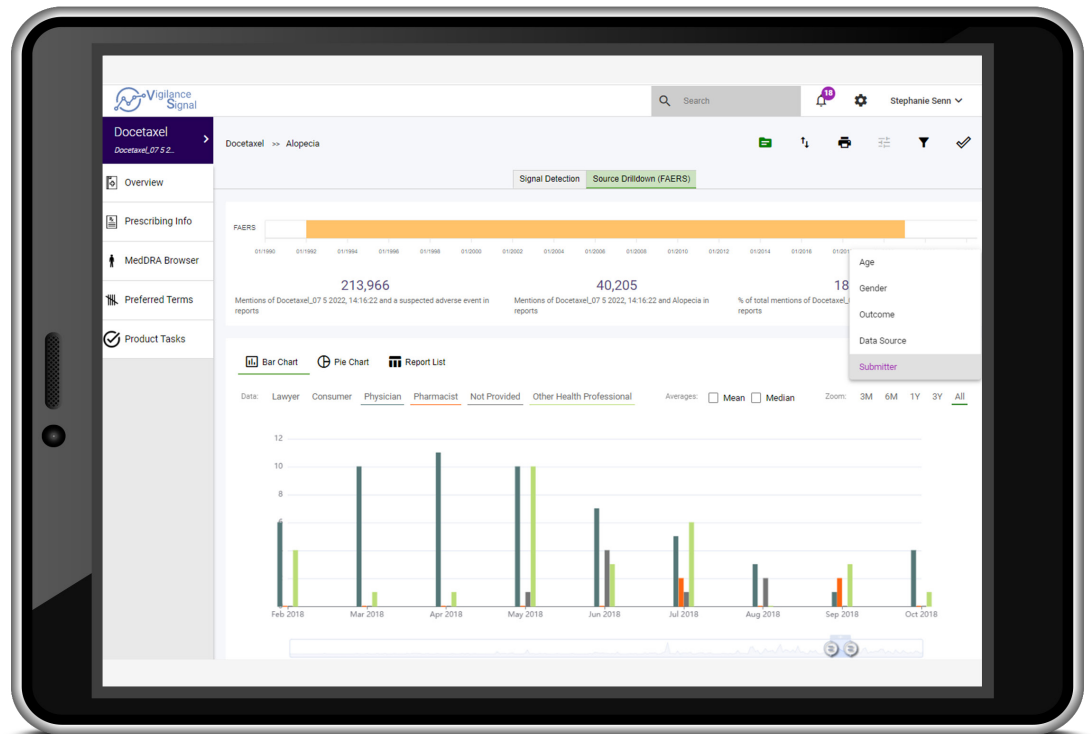
■ **EFFORT**
■ **VALUE**

Multi source signal detection and management

- Potential signals automatically calculated for the selected drug
- View 'Notifications' for new updates since previous log-in
- Structured, prioritized list immediately available for review
- Multiple sources presented in one singular view
- Create signal records and documentation to track actions and capture assessment

- Select a source to drill-down and assess in-line
- Use filters to define case series
- Easily select and deselect elements to refine parameters

Visual data representations significantly reduce assessment time by highlighting trends

References:
1. MHRA inspection statistics 2012 to 2021
2. Internal client research/project data

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