# ≣IQVIA

# **IQVIA Vigilance Collect**

# Situation

It is complex and time consuming to gather adverse events from your Medical Representative Team.

Many organizations face the challenge of having to use different processes across the regions and a need for continuous training, leading to varying degrees of accuracy, requiring extensive follow up.

# Solution

Vigilance Collect is a web and mobile application that allows your Medical Representative Team to report adverse events in a simple, user friendly and structured way with minimal training. It also removes the need for additional training when new products are added to the portfolio.

Collect uses an interactive interface that adapts to the users input. For example, it asks tailored questions based on the event being reported and provides dropdown menus for company products. This ensures high quality data that is correct the first time, reducing workloads for the Safety team by eliminating data processing and reducing follow up, while at the same time improving efficiency and enhancing quality.

# Methodology

## HOW COLLECT WORKS

Vigilance Collect captures Adverse Events via a simple, structured UI and transfers them seamlessly to the Safety team.

The system:

- Stores the submitted information in an E2B+ format
- Validates each submission automatically
- Informs submitters immediately about potential issues
- Creates the case automatically in the safety database via the standard E2B+ feature found in many commercial safety systems
- Performs reconciliation automatically with Safety; status/reports can be exported from Collect
- Routes reports to different systems based on business rules e.g.; Global, Japan and Affiliates



# **Key Benefits**





### PLATFORM

Simplified way to collect Adverse Events through one platform

#### REPORTING

Easily locate all supporting documents associated with the case

### INTEGRATION

Quick and straightforward deployment into your website, call center or Medical Representatives

#### FEATURES

- Supports multiple languages
- Supports attachment of source documents
- Immediate feedback for users if issues occur for submitted items
- Integrates with both commercial and bespoke safety systems
- 24/7 availability through the secure and scalable IQVIA Cloud
- Conduct searches and run reports to view status and content of submitted items;
   Compliant with 21 CFR Part 11, an electronic signature is required on all user actions
   (e.g., user ID and password) with an audit trail to ensure all events, data, users, and reasons are tracked

1	2
Product	Side Effect
Side effect information:	
Feves	
Side effect information:	
What was the outcome of the side effect? * Required	
Please select	
Preset month	
Additional information	
What was the duration for which adverse event was experienced?	
Start Date Day V Month V Year V	
End Date Day V Month V Year V	
Describe the side effect in more detail and if any treatment was needed	
Seriousness	
Was the side effect serious?	
O Unknown O Nio, it was not services O Yes, it was services	
How serious was the side effect?	
Resulted in death	
Was He threatening	
Resulted in or prolonged hospitalization	
Resulted in a disability or was incapacitating 1	
<ul> <li>Resulted in a congenital anomaly or birth defect</li> </ul>	
Medically significant I	
Save and Add another	
	-



4820 Emperor Boulevard | Durham | NC 27703 | United States iqvia.com