Deloitte.

Signal Detection, Evaluation, and Management

ConvergeHEALTH Safety platform can improve efficiency and accuracy leading to a complete end-to-end view of your signal lifecycle and enhanced compliance.

Regulations require that Pharmacovigilance (PV) organizations continually detect, evaluate, and manage safety signals. However, multiple data sources and approaches, combined with disconnected workflows, make fulfilling these requirements easier said than done. Now there's a better way.

Today, few organizations can have complete confidence that their signal detection, evaluation, and management processes deliver a complete end-to-end view of potential signals from identification through final disposition. That's understandable; signals are identified through multiple approaches across disparate data sets, potential signal creation is a manual process, and validation workflows are disconnected from analytics and evidence used for assessment. This makes maintaining an accurate evidence-based history of the signal difficult and inefficient.

Deloitte's Signal Detection, Evaluation, and Management module of the ConvergeHEALTH Safety platform can improve efficiency and accuracy leading to a complete end-to-end view of your signal lifecycle and enhanced compliance.

All together now
Deloitte's integrated module consolidates and streamlines detection, evaluation, and management processes and systems. Signal detection can become easier and more thorough when statistical and non-statistical methods are automated, located in one place, and executed on a common foundation of your internal safety data combined with additional spontaneous data sets.

Safety analysts can perform validation and assessment activities and capture results and annotations without leaving the system, leading to more efficient, accurate signal management. We embed analytics and integrate it into each step of the workflow, with evidence automatically captured for regulatory submission and future analysis. The module also enables the creation and maintenance of the full analysis chain, providing a complete history of the signal within the context of the workflow.

ConvergeHEALTH Safety™

Key features

- **Signal detection.** Brings statistical and non-statistical methods together in a single location and makes available standard public data sets, in addition to company data.

- **Signal management.** Manually and automatically creates potential signals from rule-based, predictive, and manual analysis of company data and data from external and public sources.

- **Signal evaluation.** Validates signal through multiple analysis models on safety data and spontaneous and real-world evidence (RWE) data sources.

- **Workflow.** Provides a flexible workflow from creation through validation and disposition.

- **Evidence capture and lineage.** Enables users to capture all required evidence from internal analyses and external documents with full lineage and history.

- **Collaboration and annotation.** Enables sharing and collaborating on analyses and signals including tagging and annotating signals, analyses, case series, and cases.

Potential benefits

- **Simplifies compliance.** Creates, manages, and evaluates signals through the full lifecycle—from topic of interest through confirmed signal and risk—according to Module IX procedures.

- **Enhances accuracy.** Analyses are performed and entered in the system automatically, decreasing chance of oversight or error.

- **Integrates data in one location.** Consolidates safety detection data across internal safety, external spontaneous, and real-world evidence data sets in one platform.

- **Streamlines analysis.** Integrates analysis into the context of the validation workflow with pre-defined views auto-generated at key steps in the process.

- **Enables new statistical methods.** Uses existing accepted statistical methods developed on an open platform so that enhanced methods can be developed from internal innovation or collaboration with partners or academia.

Should we talk?

Deloitte's leading life sciences practice can deliver the experience, knowledge, and technologies needed to help you effectively navigate the rapidly evolving world of drug safety. If you're looking for professionals who understand today's PV issues and deliver innovative solutions, let's talk.

Glenn Carroll
Principal
Deloitte Consulting LLP
gcarroll@deloitte.com

John Whitebrook
Managing Director
Deloitte Consulting LLP
jowhitebrook@deloitte.com

Aditya Kudumala
Principal
Deloitte Consulting LLP
akudumala@deloitte.com

There's more to ConvergeHEALTH Safety

The ConvergeHEALTH Safety platform enables an end-to-end, integrated, and evidence-based model for safety intelligence to help mitigate risk, reduce cost, and improve patient outcomes. The platform architecture supports four modular applications, which can be deployed separately or in combination.

- Cognitive AE Intake and Processing

- Aggregate Reporting and Safety Analysis

- Safety Operations and Compliance

- Signal Detection, Evaluation, and Management

ⓘ **For more information visit www.deloitte.com/us/ convergehealth.html**