Deloitte.

Aggregate & Operational Reporting

Regulatory bodies require Pharmacovigilance (PV) organizations to produce complex, laborious reports. Disparate systems and data sources, combined with a lack of visibility into responsibilities, make this difficult to accomplish. Now there's a better way.

ConvergeHEALTH Safety™ platform facilitates the lifecycle of regulatory reporting—supplying a seamless workflow for all PV reporting and analytics needs.

Aggregate and regulatory reporting is complex—it is time-consuming, requires multiple systems, and can set the team behind on other important tasks.

Operational metrics are imperative to monitoring quality and compliance. Although most Safety systems have reports to monitor some of these metrics, they are not available out-of-the-box, so enterprises must spend time and money to create and maintain custom reports that often aren't real time.

PV reporting is a source of contention for a lot of organizations. Companies need a bird's eye view into operations and control over compliance—Deloitte has created a solution to help.

All together now
Deloitte's integrated module provides a single solution for all reporting needs, including aggregate and self-serve, ad-hoc reporting. The module is scalable and is designed for high case volumes and large data sets.

The module has been designed with the end user in mind—report packages are pre-programmed, a workflow guides the user through the process, and milestones can be scheduled and calendared. Additionally, best-in-breed analytics allow the user to easily parse data and build advanced visualizations.

The end result is that your team's efficiency, quality and compliance goes up.

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ConvergeHEALTH Safety™

Key features

· **Calendaring.** Robust calendaring and assignment of reports including tools to visually graph and modify schedules.

· **Templates.** Report-specific templates and prompts for seamless report creation.

· **Case Lists.** Standard case list creation with integrated functionality for data visualization, analysis and advanced querying.

· **Generation.** Flexible report generation to include ancillary reports and/or graphical or tabular visualizations.

· **Workflow.** Assignment and status tracking at the overall report and milestone levels, with notification center for users assigned to the report.

· **Aggregate Reporting Narrative.** Auto-generation of narrative based on case data from the reporting period

· **Edit Controls.** Functionality to manage contributions, compilation, and editing of draft versions, and to maintain a locked final version with up-version capability; includes tracking and notification alerts

Potential benefits

· **Single Reporting & Analytics.** One system for all reporting and analytics needs for Global and Japanese aggregates, operational reports, and management dashboards.

· **User First.** Designed for users by users—based on the way that safety teams prefer to do their work

· **Information Fast.** Robust query library with user-focused design, collaboration, and security features.

· **Insight into the Management of Safety Reporting.** Integrated workflow with calendaring, scheduling, and automation capabilities.

· **Content Creation.** Generate report packages with analytics and content sections leveraging traditional and automated natural language generation capabilities.

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.

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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 Case Processing

· Aggregate and Operational Reporting

· Safety Metrics

· Signal Detection, Evaluation, and management

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