

# Safety Assessment Reports

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Global Consolidation of Aggregated  
Safety Reporting for Top 3 Pharma

# Global Consolidation of Aggregated Safety Reporting

## Top 3 Global Pharma

### *Business Need*

- The company wanted to expand its pharmacovigilance outsourcing initiative beyond case processing to include authoring of aggregated reports.
- However, its regular case-processing vendor was unable to meet the quality requirements of advanced safety reporting.

### *Our Solution*

- Indegene was selected as the company's strategic partner for safety reporting after a structured 6-month pilot period, to assess quality and scalability.
- Indegene continues to be the main strategic partner for authoring PSURs, PBRERs, etc.

### *Outcome*

Initial scope of work was to author non-safety sections of PSURs/PBRERs/PADERS and coordinate call for contributions. The scope was expanded within 6 months of engagement to include authoring of all sections of PSURs/PBRERs/PADERS, with increase in volumes. We continue to be the strategic partner for authoring aggregate reports.



To learn more about how we can help your organization, please contact:



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