Case Study

Global Consolidation of Medical/Regulatory Documentation

Center of Excellence Model for Top 3 Global Pharma

Global consolidation of Medical/Regulatory Documentation

Top 3 Global Pharma

Business Need

- The company had outsourced its clinical research and CDM activities. As part of its global productivity and consolidation activities, the company was looking for a functional service provider to handle advanced regulatory documentation.

Our Solution

- Indegene was selected as the partner to establish an offshore Center of Excellence to write:
  - CSRs
  - Ibs
  - ICDs
  - Sections of CTDs.
- This is a multi-year, multi-FTE engagement for medical documentation across therapeutic areas and regulatory jurisdictions.

Outcome

The team developed high-quality regulatory submission documents on time; engagement was expanded in terms of document types and scope of activity to include planning and designing study protocol, narrative writing, and other safety documents.

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

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