SOLUTION FOR CLINICAL EVALUATION REPORT SUBMISSION IN TWO DIFFERENT GEOGRAPHIES

ABOUT THE CLIENT

A leading US-based medical device company was looking for support to develop Clinical Evaluation Report (CER) and consecutive regulatory submissions for 2 geographies.

BUSINESS NEEDS

- Support required for the development of CER for a device which recently received a 510(k) clearance in the US market and was being submitted for regulatory approval in Europe and China.
- The client had limited internal bandwidth for CER development, requiring back-to-back submissions within a short time frame.
- The scope involved time-bound submission, expertise in clinical evaluation landscape, and knowledge on the regulatory requirements in each geography.

OUR SOLUTION

- A dedicated multi-shore team comprising 1 medical reviewer, 2 senior medical writers, 1 medical editor, 1 statistician, and 1 program manager was deployed to handle this dual geography requirement.
- The authors and medical reviewer involved in the development of CERs were MDTI certified with relevant higher educational qualification and related professional expertise across diverse therapy areas.
- For submission of CER to the EU Notified Body, Indegene team coordinated and worked along with the reviewers from the design, quality, regulatory, and clinical departments to obtain their inputs throughout the development of the report.

- For China Food and Drug Administration (CFDA) submission, Indegene cross-functional team with a scientific writer, proficient in Mandarin, was additionally involved in literature appraisal and analysis of clinical evidence from China Academic Journals Full-text Database and Chinese Clinical Trial Registry.
- Evidence from clinical literature was analyzed in depth using appropriate statistical tools.
- CERs were developed in accordance with the respective regulatory guidelines of each geography.

OUTCOMES DELIVERED

Witnessed an overall 30% reduction in the time taken for clinical literature evaluation because of the deployment of experienced team and overlap of time frame in literature search

Demonstrated efficiency in developing consecutive CERs, meeting the EU and China Food and Drug Administration CFDA regulatory requirements within critical timeline

Gained expertise in adapting to dynamic changes in the regulatory landscape for both the geographies

Provided inputs for revamping existing client SOPs and templates

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