

Safety/Patient Narratives

Patient Narratives—Authoring and QC Review
for Top10 Global Biopharmaceutical Company

Patient Narratives—Authoring and QC Review

Global Biopharmaceutical Company

Business Need

- A multinational biopharmaceutical had a requirement to draft patient narratives to be part of the clinical study report for oncology products. There was also requirement for QC support in reviewing the drafted narratives

Our Solution

- Deployed a team of medical writers, QC reviewers, and medical reviewers to complete authoring of 100 narratives and QC review of approximately 2000 narratives within the stipulated timelines (90 days

Outcome

Narratives were submitted within the stipulated timelines, which enabled on-time submission to the Regulatory Authority.

The client returned with a request for to QC review ISS, ISEs, and CSRs.



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



Marketing.global@indegene.com



www.indegene.com/lifesciences



www.indegene.com/lifesciences