



# Benefit-Risk Evaluation Reports

Dedicated Center of Excellence for  
Authoring Benefit-Risk Evaluation Reports for  
EU-based Biopharmaceutical Company

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## EU-based Biopharmaceutical Company

### *Business Need*

- The company needed support in authoring the Benefit-Risk Evaluation Reports for regulatory submission in Europe for 20 established products.

### *Our Solution*

- Indegene dedicated a team of medical writers with relevant therapy area expertise to research the literature, analyze the company's internal safety and efficacy data, and author the BRE reports for submission.

### *Outcome*

The benefit-risk documents for all the 20 products were submitted on time to the regulatory body for product renewal.

Discussions are ongoing for periodic updates for other established products.



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



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