



## CASE STUDY

# Response to Regulatory Request with Subsequent Full Signal Assessment

## Introduction

A life sciences client received a regulatory authority request to update product labeling following concerns regarding a potential neurotoxicity signal.

The product was licensed across multiple territories and belonged to a broader drug class, requiring the client to assess whether similar risks could affect other related products.



The client engaged ProPharma to provide pharmacovigilance expertise and develop a comprehensive response within a compressed regulatory timeline.

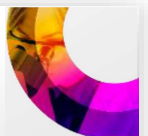
## Challenge

The client faced several operational and regulatory challenges:

- A regulatory authority requested an update to product labeling related to potential neurotoxicity risk.
- The product was licensed in multiple territories, requiring evaluation of global labeling implications.
- The product belonged to a broader drug class, raising the possibility of a class-wide safety signal.
- A full signal evaluation needed to be conducted quickly to support a timely regulatory response.

Contact us to learn how our experienced team can help ensure successful outcomes throughout the product lifecycle.

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## Solution



ProPharma implemented a structured pharmacovigilance strategy to address the regulatory request and assess the broader safety implications.

Key actions included:

- Coordinating collaboration between the client and key stakeholders to determine strategy and next steps.
- Developing a regulatory response aligned with pharmacovigilance and safety reporting best practices.
- Conducting a comprehensive signal assessment to evaluate potential impacts on other licensed products.
- Collecting and analyzing safety data from multiple sources, including:
  - Cases from the client's safety database
  - More than 200 published scientific articles
  - Over 100 Individual Case Safety Reports (ICSRs) from regulatory and public databases
- Assessing whether the findings represented a potential class effect.
- Providing recommendations for updates to product labeling where appropriate.

## Result



Working closely with the client, ProPharma successfully:

- Submitted a complete regulatory response within the required timelines.
- Delivered a full signal assessment evaluating the neurotoxicity risk.
- Identified sufficient evidence to support labeling updates for the product and two additional products within the same drug class across multiple territories.
- Provided high-quality medical writing and analysis recognized by the client.

When a regulatory authority requested urgent updates to product labeling related to potential neurotoxicity risk, ProPharma rapidly coordinated a cross-functional pharmacovigilance response. By conducting a comprehensive signal assessment and evaluating the broader drug class, the team delivered a timely regulatory response and supported labeling updates across multiple territories.

By combining pharmacovigilance expertise, comprehensive data analysis, and coordinated stakeholder collaboration, ProPharma enabled the client to respond confidently to regulatory scrutiny.

The engagement not only addressed the immediate regulatory request but also strengthened the client's global labeling strategy and safety evaluation processes for related products.

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