

Setting up a Global PV System



Challenge

Situation

- The company, founded in April 2015, needed to establish UK/EU QPPV coverage by January 1, 2021, to meet regulatory requirements.
- Safety data and product license responsibilities were held by an existing licensing partner, necessitating a structured, compliant transition of PV activities.

Task

- Mitigate risks associated with transitioning pharmacovigilance activities from the licensing partner.
- Establish a new, compliant partnership framework to support ongoing UK/EU QPPV and global PV operations.

Solution


Action

- Developed a comprehensive transition and implementation plan with the new partner.
- Rapidly mobilized full-scope PV services: including UK/EU QPPV support, global safety database setup, aggregate reporting, signal detection, and literature surveillance –within four weeks.
- Negotiated a Safety Data Exchange Agreement (SDEA) to support the transition of license responsibilities back to the originator company.
- Facilitated an efficient and coordinated transfer of safety data and database migration, despite complex stakeholder dynamics.

Result

- Achieved a fully operational PV system within the required timeframe.
- Successfully completed a client audit with no critical findings.
- Expanded PV support over the following two years to 12 launch countries and more than 40 countries receiving unlicensed product supply across the EU, Americas, and APAC regions.

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

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