

BUSINESS CASE

Case Study: EU Pharmacovigilance local contact services

Bringing safety everywhere

CHALLENGE

Small biopharmaceutical company with one pharmaceutical product authorized through a Decentralized Procedure in 10 European countries.

The Client has all **PV local activities outsourced to different vendors** in each country, which poses the following challenges:

- **Complex coordination** and communication of all local vendors
- Lack of **homogeneous quality standards** and working procedures
- **Management of local PV activities** according to the specific PV **requirements in each country**
- **Inconsistent deliverables** from each local vendor

SOLUTION

Asphalion provides a tailored assessment to the Marketing Authorisation Holder according to the product status, local requirements and country legislation.

Asphalion acts as liaison point by **coordinating all local pharmacovigilance activities in each country.**

Furthermore, Asphalion makes sure that all partners are following a common **Standard Operational Procedure** when performing PV activities, such as local literature searches, ICSR intake and management, regulatory, intelligence, etc.

OUTCOME



TIME-SAVING

Easier communication and coordination. As complexity decreases, time and **costs efficiency increases.**



SIMPLICITY

Single contact point and unique source of information. Reporting **improvement by homogenization of deliverables.**



HIGH QUALITY STANDARDS

Quality control of deliverables ensured by Asphalion. Tailored services in accordance with client requirements and local legislations



COMPLIANCE:

Up to date with local legislation to anticipate any change or demands. Being able to take early strategic decisions.