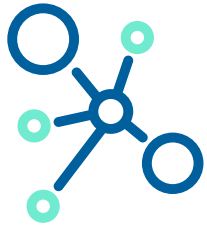


# ASPHANET

**Pharmacovigilance & Regulatory Affairs**  
European Local Contact Network

**A network of partners that allows Asphalion to provide local regulatory services throughout Europe**



# ASPHEANET

**Regulatory Affairs**  
European Local Contact Network

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Single point of RA management throughout Europe



Reliable RA partners



Sound knowledge of local regulation



Native speakers for labelling and artworks management



Local contact with access to national Health Authorities

## Local RA Services

- **National phases of DCPs and MRPs for initial MAA** and variations (product information translations, mock-ups review, follow up with authorities until approval)
- **Management of national authorities'** portals and databases
- **Mandatory activities before launch**
- Annual mandatory activities for **maintenance of MA**
- **Local variations** and MA transfers
- **Renewal** of National MA
- Update and request of **price and reimbursement** for new and generic products
- **Promotional materials** (submission to national competent authority, support in material preparation according to national requirements, proof-reading, regulatory and medical validation)
- **Continuous update on changes of local requirements** (Regulatory Intelligence)
- **CTIS Local Support**

## Advantages of having a solid network

**Trust:** Reliable regulatory affairs experts in all EU markets

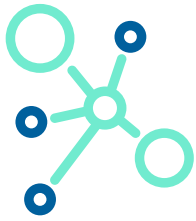
**Local presence throughout Europe:** knowledge of local regulation

**Knowledge of all EU languages**

**Close relationship with health authorities**

**Time optimization and simplicity:** Single point management of all your European registrations

**General oversight** improves the final outcome



# ASPHEANET

**Pharmacovigilance**  
European Local Contact Network

**A network of partners that allows Asphalion to provide local Pharmacovigilance services throughout Europe**



Qualified and validated pharmacovigilance partners



Single point of PV management throughout Europe



Standardised procedure for PV activities, including: local literature searches and ICSR management



Strong knowledge of local PV legislation and local requirements and know-how

## Local PV Services

- **Cell phone availability** for Local Authorities
- **Direct interaction with local competent authorities** in pharmacovigilance and regulatory matters
- **Set up of local pharmacovigilance requirements**
- Local **literature searches**
- Periodic Agency Website screening to maintain updated **client knowledge of PV local requirements**
- Collaboration with client on **audits and inspections**
- **Contact person in case of urgent safety issues** from Local Authorities
- **Local medical information**

## Advantages of having a solid network

**Tailored Service:** Assessment according to marketing authorisation status in each country and applicable requirements

**Simplicity:** Single management point of PV activities across Europe

**High Quality Standards:** Qualified Partners through audits, validation questionnaires, training and testing

**Compliance:** Strong knowledge and know-how of local pharmacovigilance activities and Competent Authorities preferences