

Case Study

European Case Intake

Managing pharmacovigilance case intake across multiple sources and countries requires seamless processes, strong oversight, and full regulatory compliance.

Project Overview | 27 countries



Case intake (incl. triage), follow-up, LCPPV&LLS



Client with sources provided from:

- +30 partners that provide solicited reports (like registries, support programmes, market research,...)
- LCPPVs
- Medical info services
- Licensing partners
- Distributors
- Global safety database holder (fup requests)

Challenge

- Lack of oversight over sources management – data received & assessed in an unharmonized manner
- Vendor quality & responsiveness unsatisfactory
- Mailbox management difficult
- Reconciliation process poorly managed
- Concerns with GDPR compliance
- Intake taking too long

Approach

- Detailed transition/set-up plan
- Customised case intake & redaction tool (semi-automated)
- Tool replaced mailbox
- Centralised team managing full case intake/translations
- Taken ownership over reconciliation process (establishing frequent check of all parties & contacts)
- Detailed operational guideline, R&Rs & training matrix put in place

Result

- Better control over sources receipt per sender – enabled set of activities that improved quality of data provided especially from solicited sources
- Great oversight of translation process
- Significantly improved reconciliation & mailbox management process
- All KPIs met since project start
- Additional PV work awarded