excelya

Case Study

Type:	Geography:	Service Type:	Client:
Pharmaco-vigilance	EU/US	FS	Biotech

PROJECT TITLE:

"Clinical Safety Activities for First in Human Study (Phase I)"

Project Challenges:

- Lack of experience by the Client (first study conducted)
- Several CROs involved
- Unknown product safety profile
- Management of DSMB Committee
- US reporting responsibilities under new/amended FDA legislation
- Excelya project management

Excelya Solutions:

- Project manager and deputy as single contact points for oversight and communication
- Flexible team (5 experts) to adapt to workload, 24/7 monitoring
- MultiVigilance fully validated, E2B(R3) compliant Global Safety Database solution, compliant with EU and US requirements
- Implementation of Excelya PV QMS
- KPIs monitoring

Key metrics

Assignement of 2nd Study to Excelya PV

No PV findings during study audits

Excellent communicati on

Benefits for the Client

- Successful conduction of FIH study with no safety related issues
- On-budget

Feedback from Client

- Investigating to centralize clinical safety activities for all future studies to Excelya