



# Are you looking for a niche CRO?

## Why clients choose AKOS

Since 1986, Akos has been a leading provider of Pharmacovigilance, QPPV and Regulatory Services to Pharmaceutical, Biotech, Generic, and Medical Device companies. Akos provides a global or Regional service offering with offices located in Harpenden, UK and Research Triangle Park, NC, USA.

### AKOS offers you:

#### Pharmacovigilance Services:

- Remote entry into sponsor's global safety database
- Customized Client-specific global safety Database
- Comprehensive SAE & AE Management
- MedWatch & CIOMS reporting
- Services for both Clinical Trials and Post Marketed Products
- ICSR case processing
- EudraVigilance Reporting
- PSURs/PADERS
- Pharmacovigilance SOPs
- Weekly Literature Searches/reviews
- Signal Detection
- Project Management
- Quality
- Ad-hoc Consultancy

#### QPPV Services:

- European Union Resident
- 24 hours/day, 7 days a week support
- Support for MAA submission
- Audit of trading partners/distributors
- Oversee the structure and performance of the PV System
- Address all requests from the Competent Authorities
- Overview of all Safety profiles
- MAH's contact point for PV Inspections
- In-House training
- Cover absence of the EU QPPV

#### Regulatory Services:

- Advice, Strategy and Support for Product Development
- Attendance at Agency Meetings
- CMC Strategy – Development to Market
- Orphan Drug Designation Applications
- CTA Application – FIM to Phase IV
- PIPS and Waivers
- RMPs and REMs
- MAA Preparation and Submission
- Life Cycle Management Services
- Ad-hoc Consultancy

## CALL US NOW TO FIND OUT MORE...

#### AKOS US

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## Top level metrics on a selection of AKOS Pharmacovigilance, QPPV and Regulatory experience:

Client	Description/Scope of RA services
US based, small Biotech	Maintain global safety database, managed all PV aspects of >15 Phase I/II FIM & Phase I/II Oncology clinical studies
Global Blue Chip Pharma	Comprehensive case management via remote entry of SAEs into client global database
EU based speciality Pharma company	Maintain global safety database, managed all PV aspects of the Phase III Gene Therapy clinical study
EU based Pharma company	Maintain global safety database, managed all PV aspects of surgical device clinical studies
UK based, top 10 Biotechnology company	Maintain global safety database, managed all PV aspects of 2 Phase III UK & US based Oncology clinical studies
Global Generics company	Maintain global safety database, full service Post Marketing PV services supporting their Dermatology product portfolio in EU/US market
Trans European based Speciality Pharma	Maintain global safety database, full service Post Marketing PV & QPPV services supporting their Oncology products in EU
US based Pharma	Preparation and submission of CTA applications to 6 EU Member States for a novel biological product
UK based Pharma	National MAA submission for an Oncology product
US based Pharma	Wrote an RMP for an Anthrax Vaccine for use in the prevention of Anthrax Infection following bioterrorist attack

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