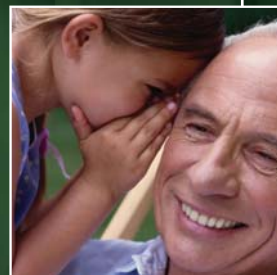


PHARMACOVIGILANCE AT ACCOVION:

Strategic Safety Services



ACCOVION

ACCOVION offers you full-service pharmacovigilance solutions, including support for the regulatory transition of your product from submission to registration. Just as important: We ensure that you are well prepared for the first two years on the market, the most critical years from both a patient safety and a product market perspective.



Let ACCOVION by your strategic pharmacovigilance partner:

- ✓ **Acting as your drug safety department**
- ✓ **Augmenting your safety resources**
- ✓ **Supporting your clinical trials and submissions**

✓ Processes: Compliance, Reliability and Quality

Our processes are the result of many years of experience in pharmacovigilance standards and training. We follow good pharmacovigilance practices, giving expert attention to risk detection and medical assessment of safety signals. Compliance with regulatory requirements – such as expedited reporting to EMEA, national agencies, concerned ethics committees, and investigators in a timely manner – is the natural result.

Full pharmacovigilance system audits and project-specific pharmacovigilance audits were successfully passed. Processes and systems used in the pharmacovigilance department were subject of these reviews including our comprehensive state-of-the-art set of pharmacovigilance SOPs and Working Procedures. Affirmative feedback by our clients and the auditors was also received on qualification, extensive experience and regulatory knowledge of our pharmacovigilance staff, our ability to transfer applicable requirements into project-specific processes and on ACCOVION's pharmacovigilance database.

ACCOVION's client-specific processes ensure high quality, regulatory compliance, reliability, and cost-effectiveness.

✓ Expertise and Experience

You can benefit from our many years of experience, knowledge and cross-functional work in over 20 successful submissions to the FDA and EU authorities in key therapeutic areas.

- ✓ Highly skilled pharmacovigilance specialists ensure continuous SAE processing, MedDRA coding and timely distribution of regulatory reports.
- ✓ Board-certified physicians with special knowledge in key therapeutic areas ensure ongoing data analysis and safety evaluation throughout your studies and your product life cycle.
- ✓ Profit by our industry-wide safety experience with investigational new drugs in numerous studies ranging from first-in-man studies and phase III megatrials to phase IV studies in clinical development, including the pharmacovigilance of marketed products.
- ✓ Our clients rank among the "Top 20" pharmaceutical companies as well as mid-size and small companies.
- ✓ ACCOVION, especially the pharmacovigilance department, underwent numerous audits by clients and other organizations and has successfully passed regulatory inspections without any findings.

Over 20 successful submissions to the FDA and EU authorities in key therapeutic areas

Therapeutic area expertise:

- Allergology
- Anti-Infectives
- Cardiology
- Dermatology
- Hematology
- Immunology
- Inflammation and Rheumatology
- Metabolism and Diabetes
- Neurology and Psychiatry
- Oncology
- Pain
- Pediatric Medicine
- Plasma Proteins
- Vaccines

ACCOVION offers you full service pharmacovigilance solutions that smoothly integrate with your teams, and expert consultancy you can count on:

- ✓ Serious adverse event (SAE) management:
 - Collection and documentation
 - MedDRA Coding
 - Qualified medical evaluation and regulatory assessment
 - Active query and follow-up process
- ✓ Processing of SAEs, spontaneous and other types of reports in different pharmacovigilance databases (e.g. Argus Safety™, ARISg™, ClinTrace™ or non-commercial systems)
- ✓ Regulatory reporting to authorities, investigators, and ethics committees
- ✓ Electronic Safety Reporting according to ICH E2B
- ✓ Ongoing safety monitoring
- ✓ Writing of safety narratives for study reports
- ✓ Data reconciliation between pharmacovigilance and clinical trials databases
- ✓ Preparation and submission of Annual Safety Reports (ASRs) and Periodic Safety Update Reports (PSURs)
- ✓ Regulatory safety support including ad hoc responses to regulatory authorities
- ✓ Project-specific standard operation procedures
- ✓ Risk assessment and risk management

✓ Electronic Safety Reporting (ICH E2B) and Electronic Submissions

Be assured that you have competent and expert support for any GCP and pharmacovigilance audits and inspections.

Increasingly, regulators and licensing partners require electronic reporting of individual case safety reports. Our **Argus Safety™ database** complies fully with the validation, MedDRA coding and security standards defined by ICH E2B and the FDA's 21 CFR Part 11. Additionally, our electronic reporting services allow expedited reporting to authorities as well as transmission of additional data. At ACCOVION, your safety data are hosted in a protected IT environment.



✓ A track record in the USA and Europe

Over 20 successful regulatory submission dossiers for the USA and Europe including:

- Altace® /Delix® (heart failure)
- Altace® /Delix® (hypertension with high cardiovascular risk)
- Altace® /Delix® (renoprotection in hypertension)
- Amaryl® (diabetes)
- Apidra® (diabetes type I / II)
- Arava® (rheumatoid arthritis)
- Beriglobin® (primary immunodeficiency)
- Delmuno® (hypertension)
- Dynepo® (anemia in chronic renal failure)
- Erbitux® (metastatic colorectal cancer)
- Insuman® (diabetes)
- Ketek® (bacterial infections)
- Lantus® (diabetes)
- Loprox® /Batrafen® shampoo (seborrhoeic dermatitis)
- Mononine® P (hemophilia B)
- Penlac® nail lacquer (onychomycosis)
- Profact® (endometriosis)
- Profact® (leiomyoma)
- Profact® (prostate cancer)
- Tavanic® (bacterial infections)
- Tavanic® (severe bacterial infections)
- Venimmun® N (idiopathic thrombocytopenic purpura)
- Zemaira® (alpha-1-proteinase inhibitor deficiency)

[Contact us and find out how we can support you with clinical safety and pharmacovigilance services.](#)



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