

Focusing on Quality in Global Pharmacovigilance Services



With patient safety as the critical component in product development, our quality focus aligns us to partner with our customers to provide both standalone and integrated services throughout the life cycle of a product.

Functional Service or Full-Service Model

At Syneos Health™, our customized services meet your needs and have the flexibility to work in any region across the globe based on customer specifications.

- Dedicated or flexible teams, including safety project management
- Streamlined operations with maintenance of premium quality and efficiency
- Dedicated strategic resourcing group for staffing solutions
- Experience in customer safety systems and processes

Global Safety Reporting

In recent years, pharmacovigilance legislation has become more stringent than ever, dramatically changing the game for compliance. Syneos Health provides:

- Centralized submissions team
- Multi-tenant, fully validated, 21-CFR part 11 and E2B compliant safety database
- Dedicated regulatory safety intelligence team for monitoring global regulatory requirements
- Automated safety report distribution system

Safety Surveillance Across the Globe

What sets us apart is our people: highly qualified safety scientists and skilled healthcare professionals, including physicians, nurses and pharmacists with experience in direct patient care, industry-specific pharmacovigilance services and a deep knowledge of regulatory legislation and dedication to providing quality safety services.

Clinical Trial and Post-Marketing Services

Syneos Health™ manages safety and pharmacovigilance needs at any stage of product (drug/device) development to ensure quality and compliance.

Clinical Trial Safety

Phase I-IV, from data entry to case closure, full processing, including expedited/periodic reporting

Post-Marketing Safety

AE case processing, reporting, signal detection, U.S.-based call center, literature search and review, product complaints, litigation case processing, EU QPPV, PSMF creation and maintenance, local safety officers (LSO)

Safety Regulatory Submissions

Dedicated subject matter experts in safety regulatory

legislation and submissions with access to a regulatory intelligence database

Safety Physicians

Dedicated/trained physicians in all aspects of the life cycle of safety and pharmacovigilance, including risk-management expertise

Safety Database

Dedicated support team with in-house Oracle Argus expertise and experience with client safety systems including Oracle Argus and ARISg

Lab to Life Global Pharmacovigilance

Phase I	Phase II	Phase III	Marketed / Phase IV	
Targeted Safety Evaluations	Establish Product Safety and Efficacy		Regulatory Filing Strategy and Submissions/Late Stage Studies	Risk Management and Long-Term Safety/Registries
Case Processing with Medical Review				
Regulatory Safety Report Production and Submissions Expedited Safety Reports				
DSUR			PADER/PSUR/PBRER	
Signal Detection				
			PSMF Creation/Maintenance	
			QPPV	
Global literature search/review				
		Risk Management Plans/REMS		

About Syneos Health

Syneos Health™ (Nasdaq:SYNH) is the only fully integrated biopharmaceutical solutions organization. The Company, including a Contract Research Organization (CRO) and Contract Commercial Organization (CCO), is purpose-built to accelerate customer performance to address modern market realities. Learn more about how we are **shortening the distance from lab to life®** at syneoshealth.com.

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