



This is PV Solved

Astrix is distinguished by our client-centric and product-agnostic approach to ensure the success of each Pharmacovigilance program.

- ✓ **Optimizing** critical functions
- ✓ **Enabling** continuous operation
- ✓ **Minimizing** staff disruption
- ✓ **Ensuring** timeline achievement



Our deep experience with PV and Safety processes enables Astrix to provide premier assistance that’s tailored to each client’s unique environment. Astrix can ensure success at critical phases in the **Selection, Implementation, Data Migration, Optimization, and Validation** of third-party software programs.

Astrix’s dedicated team of Pharmacovigilance (“PV”) experts ensures that your program is tailored to succeed at achieving the goals and objectives unique to your organization, your process, and your culture.

EXPERT GUIDANCE

PROVEN
METHODOLOGIES

EXCEPTIONALLY
CLIENT-CENTRIC

SUCCESS DEFINED BY
YOUR SATISFACTION

Uniquely Collaborative Approach & Guidance

Astrix achieves results using proven methodologies during guided and collaborative sessions led by highly experienced PV pros who keep our client’s needs at the forefront of every decision.

Together we determine the optimal implementation strategy and business roadmap, as well as third-party software and hosting choices that represent the best fit for our clients.

Our comprehensive suite of PV services helps guide clients through the evolving challenges impacting pharmacovigilance and safety. As a strategic and management partner (rather than an IT vendor), we understand and collaborate in solving challenges through the **Requirement, Design, Implementation, Testing, and Go-live** phases of SDLC.

Exceptionally Client-Centric

Since Astrix does not offer proprietary products or receive any compensation from software vendors, you can be assured that every recommendation we offer is based on your criteria.

Success is defined by your satisfaction with the outcomes of our PV planning, design, and implementation. We can start by assisting with strategic planning, RFP management, and vendor selection to ensure the right fit from the earliest stages of your initiative—which makes a substantial difference in preventing costly challenges during late stages of implementation, validation, and staffing.

For over a quarter century, Astrix has specialized in assisting scientific and pharmaceutical sector-leading clients by providing close support for informatics services. We focus on enabling companies to optimize information management infrastructure essential to drug R&D, safety, and regulatory compliance today and well into the future.

Throughout our 25+ years serving Life Science and Pharmaceutical clients, we continue to be driven to ensure your goals are achieved

Astrix helps solve PV challenges with:

STRATEGIC SERVICES

Astrix's comprehensive plans solve complex Pharmacovigilance challenges by:

- Transforming end-to-end workflows.
- Optimizing data-centricity and data flows.
- Identifying opportunities for leveraging current and emerging technologies.

ENTERPRISE ARCHITECTURE

Our team collaborates with you to design an enhanced data ecosystem based on your unique Pharmacovigilance technical environment, its challenges, gaps, barriers, and opportunities.

DATA MANAGEMENT & GOVERNANCE

We construct pragmatic strategies and frameworks for data governance, data quality assessments, and planning for optimized management of enterprise-wide digital PV assets.

SYSTEM SELECTION CONSULTATION

Vendor Evaluation and Selection services begin with a System and Technology Assessment utilizing a thorough, best-practice method to:

- Assess your current environment.
- Determine and validate your requirements.
- Develop a future state.
- Evaluate the market.
- Present a list of vetted commercial solutions meeting your requirements.

Astrix is current on all relevant trends and products in the Pharmacovigilance and Safety areas and specializes in managing system evaluations, selections, and implementations of third-party software, and integration of optimized systems into clients' infrastructures.

PROGRAM LEAD, PROJECT MANAGEMENT

Our team will provide industry-leading services to manage your project including documents such as Project Plans, Project Charters, and issue and Risk Registries, and employ our methodologies for Project Governance, Escalation Model, and Communication Strategy. Astrix assigns seasoned professionals to oversee, lead, or manage each project or workstream.

PROCESS DESIGN & OPTIMIZATION

We optimize your business process, leveraging the system's unique capabilities while considering your safety system capabilities. Astrix team members have worked with safety organizations to evaluate their current business processes, assess gaps and future needs, and develop a future state process.

DATA MIGRATION, MAPPING, AND IMPLEMENTATION

Our experts determine the best way to map current source data to future systems through collaborative mapping sessions to ensure client data is migrated cleanly and efficiently, whether moving to a new system, acquiring a new product, or receiving data from a partner or other company. Once the mapping document and requirements are completed, our technical team develops a series of migration scripts to migrate data efficiently and effectively.

SYSTEM IMPLEMENTATION AND UPGRADE

We guide project teams throughout implementations, to maximize system capabilities, combining our expert knowledge of PV systems. Our PV team brings to each engagement deep experience in some of the largest and most complex system implementations.

SYSTEM INTEGRATION

During our workshop sessions, we define the business and technical requirements for each integration since many of our clients require integrations with third-party or custom software. We develop and test the required integrations in collaboration with designated team members.

SYSTEM VALIDATION

We develop well-defined Validation Strategy documents, User Requirements, Traceability Matrices, Validation Test scripts, and Summary reports for both corporate governance and regulatory compliance in collaboration with client team leaders.



Corporate Headquarters
125 Half Mile Rd Suite 200
Red Bank, NJ 07701 USA

☎ 732-661-0400
✉ info@astrixinc.com

For more information, visit:
www.astrixinc.com/pharmacovigilance-services