



Astrix puts your Requirements at the Heart of Optimizing Pharmacovigilance

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, process, and culture. From vendor and program selection through implementation, optimization, and staffing, our deep experience in each of these key phases enables Astrix to provide premier assistance that's tailored to each client's unique environment so that we can ensure success at critical phases in selecting, implementing, data migrating, optimizing, and validating third-party software programs.

Astrix is distinguished in the market by our client-centric and product-agnostic approach to ensuring the success of each implementation. Throughout our 25+ years in service to life science and pharmaceutical clients, we continue to be driven to ensure your goals are achieved through:

- Optimizing operations
- Enabling continuous operations
- Minimizing impact of implementations on staff's focus on core organizational responsibilities



Since Astrix does not offer proprietary products or receive any compensation from software vendors, you can be assured that all recommendations are based on client-centric criteria. Moreover, since our success is defined by your satisfaction with the outcomes of our PV planning, design, and implementation, we can start by assisting with RFP management and vendor selection to actually ensure the right fit from the earliest stages—which makes a substantial difference in preventing costly challenges during late stages of implementation, validation, and staffing.

Our comprehensive PVSolved® suite of 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 throughout the Requirement, Design, Implementation, Testing, and Go-live phases of SDLC.

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.

For over a quarter century, Astrix has specialized in the scientific and pharmaceutical market providing close support for informatics services to sector-leading companies. Our focus in assisting pharmaceutical and biotech companies is to enable the information management infrastructure essential to drug R&D, safety, and regulatory compliance today and well into the future.

Astrix's Services Include:

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| <p>Strategic Services</p> | <p>We bring new approaches to solving complex Pharmacovigilance business problems that propel forward movement via innovative thinking, collaboration, process optimization, data-centricity, and consideration of emerging technologies. A comprehensive plan is specifically designed to transform end-to-end workflows, data flows, and identify technology opportunities. Once completed, we can lead or assist in follow-on activities to achieve the envisioned future PV business capabilities.</p> |
| <p>Enterprise Architecture</p> | <p>Our team identifies challenges, gaps, barriers, and opportunities within your current Pharmacovigilance technical environment and collaborates with you to co-create the desired future technical and data ecosystem.</p> |
| <p>Data Management and Governance</p> | <p>We construct pragmatic strategies and frameworks for data governance, assessments of data quality, and planning for optimized management of digital assets across the PV organization.</p> |
| <p>System Selection Consultation</p> | <p>Astrix specializes in managing system evaluations, selections, and implementations of third-party software, as well as providing services that integrate optimized systems into organization infrastructures. Our vendor Evaluation and Selection Service begins with a System and Technology Assessment. In this assessment, we utilize a thorough, best-practice method to assess your current (As-Is) environment, determine and validate your requirements, develop a future (To-Be) state, evaluate the market, and present you with a list of vetted commercial solutions that meet your requirements.</p> <p>Given the number of different solutions on the market for Pharmacovigilance and Safety, it can be challenging to maintain a current understanding of the different options to the degree that enables an effective decision in a timely manner. At Astrix, we make it our business to stay current on all relevant trends and products in the Pharmacovigilance and Safety areas.</p> |

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| <p>Program Lead, Project Management</p> | <p>Having the right individual with both industry and implementation experience can make the difference to any project or workstream. Astrix provides seasoned professionals to oversee or lead your project or an experienced PM to manage your project or workstream. Our team will provide industry best services to manage your project including documents such as project plans, project charters, and issue and risk registries as well as applying our methodology including project governance, escalation model and communication strategy.</p> |
| <p>Process Design and Optimization</p> | <p>Astrix team members have worked with safety organizations evaluating their current business process, assessing gaps and future needs, and developing a future state process. We will take into consideration your safety system capabilities and optimize your business process to take advantage of the system's unique capabilities.</p> |
| <p>Data Migration Mapping and Execution</p> | <p>Whether you are moving to a new system, acquiring a new product, or receiving data from a partner or other company, Astrix experienced migration experts can ensure that your data is migrated cleanly and efficiently. Our detailed mapping sessions will analyze your current source data and work with you to determine the best way to map it to your future system. Once the mapping document and requirements are completed, our technical team will develop a series of migration scripts to efficiently and effectively migrate your data.</p> |
| <p>System Implementation and Upgrade</p> | <p>Our team of experts have been involved in some of the largest and most complex system implementations. Using our industry and system knowledge, we will guide the team through the implementation process leveraging our experience and maximizing the system capabilities.</p> |
| <p>System Integration</p> | <p>Many of our clients require integrations with third party or custom software. Both technical and industry knowledge is required for success. During our workshop sessions, we will define the business and technical requirements for each integration. Then working with appropriate internal and external members, develop and test the required integrations.</p> |
| <p>System Validation</p> | <p>In order to ensure compliance and that the system meets your requirements, detailed testing documentation is required. We will work with you to develop well defined validation strategy document, user requirements, traceability matrix, validation test scripts and summary report.</p> |

Contact us:

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