

Best Practice Fact Sheet

Ensuring Successful Pharmacovigilance Program Selection

OVERVIEW:

Selecting a new system is a big decision that companies will live with for years into the future. Astrix advises our clients and assists in leading the selection process by leveraging direct experience. In this fact sheet, we offer insights that help throughout the process of selecting a new system to support your PV programs.



Gartner Recommendations

Gartner recommends the following three practices for selecting the most appropriate technology solution, and vendor, to ensure a successful safety program:

- Collaborate with the business to prioritize investments and future-proof product safety strategy by reviewing technology trends, market forces, and regulatory direction and requirements.
- Advance AI and analytics in safety vigilance by understanding areas of impact and vendor solution development. Assess the fit of these technologies to your existing architecture and allow the judicious application of AI in high-compliance areas.
- Review vendor offerings and applicable use cases to determine whether they are developing, maturing, or actively delivering value with their solutions. Do this by collaborating with business teams to capture the business value of new solutions.

Astrix Recommendations

Astrix's direct experience in assisting clients with the selection process enables us to recommend the following additional practices that we have found to enhance success during vendor selection:

- **Start with a strong set of User/System Requirements.** Take the time to clearly define the requirement/functionality. Invest up-front, time to thoroughly assess current functionality against current and anticipated regulatory requirements.
 - Review functionalities offered by new technologies to determine fit and value against the current as well as anticipated System Requirements.
 - Consider the integrations with other systems such as Signaling and Risk Management and Literature search tools.

- **Ensure any third party being considered to advise your team on evaluation and selection is fully independent and, so, financially agnostic.** It can be difficult to know when, and where, third-party bias will impact assessments and recommendations. If you feel that your team would benefit from an expert opinion on which system makes the most sense for your specific operation and unique needs, the best way to ensure an unbiased—entirely client-centric evaluation—is to work with an expert who won't receive any financial benefit from a specific selection system. You should ask if the advice you're buying is biased by any commercial relationship with one or more system vendors.
- **Include all vendors who satisfy most of your requirements.** Costs for license, implementation, integrations, and custom report development vary and can represent significant differences between vendors and their original price quotes.
- **Draft a clear Demo agenda with Use cases.** Drafting a clear Demo agenda with well-defined use cases/scenarios is imperative to enabling candidate vendors to demonstrate their ability to meet expectations via product features and capabilities. This will also aid your team in comparing vendors, products, capabilities, and pricing.
- **Create a scorecard and ensure all participants understand the scoring system.** To ensure that vendor bias is avoided, a scoring system assists the team to ensure the playing field remains level throughout the evaluation process. To ensure evaluators' personal biases won't have undue influence, take steps to:
 - prevent evaluators from sharing their scores among the team.
 - prevent evaluators from voicing their opinions before the conclusion of the process.
 - prevent vendors from attempting to influence evaluations through direct contact with evaluators—including the provision of additional information or requests for feedback.
- **Include your leadership/steering committee throughout the process to keep them aware of the progress and decisions that the team is making.** Ten minutes of their time can save the team hours of discussions and ensure their input can be factored into the team's discussions within planned timeframes. After vendors' presentations, their presence will save critical time during the evaluation process.
- **Allocate plenty of time for vendor demos.** Bear in mind, when scheduling demos, that time allotments should enable each vendor to both:
 - demonstrate how the system meets the organization's requirements
 - describe their implementation strategy.

Anticipate, assess, and prepare for organizational change. The process of selecting a new system involves organizational change management. The impact of a new system on current, and future staff, is a consideration best approached during the evaluation phase of the selection process. A critical aspect of any change in systems is ensuring that there is a strong alignment with the leadership team and everyone involved in the selection process. That cohesion is imperative. A key reason for involving members of your leadership/steering committee in the evaluation and selection process is to ensure their understanding of a selection's impact on the people who will be tasked to use it—and how the organization may be changed by new patterns and activities. [For specific insights and case studies on successful preparation for organizational change visit <https://astrixinc.com/astrix-resouce-center-white-papers/>.]

About Astrix

Astrix is the unrivaled market-leader in creating & delivering innovative strategies, solutions, and people to the life science community. Through world class people, process, and technology, Astrix works with clients to fundamentally improve business & scientific outcomes and the quality of life everywhere. Founded by scientists to solve the unique challenges of the life science community, Astrix offers a growing array of strategic, technical, and staffing services designed to deliver value to clients across their organizations.