Best Practices for Evaluating Pharmacovigilance System Providers

BEST PRACTICE FACT SHEET

Your choice of system provider will impact your safety program for years into the future. In the near term, however, a system chosen without the appropriate awareness of installation requirements - and limitations - could bust your budget and disrupt your timetable. Although system functionality typically dominates the selection criteria, each candidate system vendor has certain characteristics that we have learned to factor into the selection process as early as possible before determining the optimal fit. Astrix's direct experience with assisting clients to select their system providers, combined with our policies of vendor neutrality and absence of financial interest, enables us to offer insights to assist you throughout the entire process of selecting the company that's best suited to serve your organization's unique needs and preferences:

1 Global Compliance

While all systems must meet the same Global Regulatory requirements, it is important to know each company's timeliness for, and focus on, maintaining global regulatory compliance. For example, some companies may be more focused on a geographical area due to client needs. Make sure that the regulatory focus of each vendor whose system you choose to evaluate is closely aligned with your near-term and potential long-term needs.

2 Experience

Some key aspects of client service are enabled—by a vendor's direct experience as evidenced by their longevity in business. While the length of time in this space doesn't necessarily mean they are the better vendor, it is an objectively reliable indicator of their ability to make good on their commitment to clients' satisfaction. Some newer vendor systems might incorporate the latest technology better than some of the long-standing existing systems but will their client bases—and commitment to this space—still be here in the next five or ten years? Each vendor's history and apparent sustainability should be examined.

3 Company Culture

Consistency within the client service account team enables a level of comfort and confidence that is quite valuable. A vendor that keeps its employees happy and excited to be part of the company will have longer retention which, in turn, means a more knowledgeable team that brings deeper experiences to understanding their clients' needs. One characteristic of a strong supplier partner is the respect and professionalism they've demonstrated for their employees over time.

4 System Compatibility

Prior to a system demonstration, it is important to know whether the prospective supplier partner has clients with products, processes, and requirements consistent with yours. If, for example, you are the first (or only) vaccine company in their client portfolio, can you be assured that their expertise will adequately and rapidly incorporate new requirements and resolve defects impacting your operation—and be prioritized to meet your unique needs?

5 System Maintenance

Although it may be considered an issue for the end of a presentation, it is a high priority to know - up front - a potential supplier's plan to support their product. It is wisest to know if they:

- Provide a schedule for regular releases for upgrades and/or maintenance patches, or
- Plan to maintain their system primarily via emergency fixes.

If a system provider doesn't automatically, or cannot promptly, provide their schedule for anticipated upgrades and patches, it is crucial to obtain their documented process for identifying, capturing, and resolving operating defects you report to them.

6 Help Desk or Onsite Support

Does the vendor have a Help Desk that matches your operating hours when support is likeliest to be needed? What is the level of their Help Desk staff's experience? Vendors sometimes view Help Desk duty as a training ground for new employees. If this is the case, you need to ascertain that policy—upfront—so that you are comfortable with the level of training that will be standing by to remedy a problem—or stop a crisis in your operation. Lastly, on this critical aspect of support, it's essential to know the expected turnaround times for help desk requests so that you can assess their acceptability for your operational requirements.

7   System Administration

Since system maintenance is critical to maximizing uptime and minimizing interruptions to normal operations, it is important to know how candidate systems should be maintained. Based on your staffing and capabilities, only you will be able to assess the acceptability of having to do this internally, or by relying on the vendor to do this at a mutually convenient time. Some examples of administration include:

- Adding a new lot to a product,
- Obtaining, or resetting, a user password, or
- Setting up a new agency for reporting.

The following questions are best posed before a system is demonstrated:

- Who will perform critical system maintenance activities?
- How are these critical system maintenance activities done?
- How easily are critical system maintenance activities performed?

8   Technical Architecture

Although it is not uncommon for system vendors to promise seamless compliance with organizational preferences, it will save a lot of time, cost, and anxiety, to know their preferred environment for optimal installation and smooth operation. As part of the initial information gathering on compatibility, it is important to know:

- Does the vendor's technical architecture allow customization with your corporate IT management's direction?
- If your organization's preference is to have systems in the cloud, you will want to ensure the candidate vendor provides robust support for the cloud-based operation.
- Does the vendor support your SSO and other integrations?
- How easily can vendors' systems integrate with other systems (e.g., Signal Detection software)?

Selecting a new system is a big decision and project for any company so it is important that you not only evaluate the system's functionality as well as the vendor that will be providing and supporting the software. It is important to have confidence in a strong partnership with the selected vendor which includes their ability to support your company and its regulatory requirements. Astrix's unique system agnostic position allows us to help you determine the best vendor and system for your needs and preferences.