6 Key Considerations When Selecting a Safety System

astrix

Introduction

We are at an interesting time in today's Pharmacovigilance (PV) landscape as there are several new systems coming to market as well as significant upgrades to systems already in the market. These PV systems are not only meeting the changing regulatory landscape (e.g. IDMP, drug/device combo) but also incorporating modern technologies like AI/ML NLG, Predictive Analytics, automations to streamline case processing making it more efficient. A strong Pharmacovigilance (PV) selection process will set you up for not only a system that meets your requirements but also a successful implementation. Included in this paper are 6 Do's and Don'ts to consider when going through this process. Additionally, we discuss the organizational change management aspect of the selection process since that plays an important role in the ultimate success of the project.

1   Do start with a strong set of user/system requirements.

To ensure that an organization receives the right solution for its unique situation, the PV leaders need to take the time to clearly define the requirement/functionality they are looking for in a system. The organization should not simply use their existing set of system requirements but rather leverage them to develop what their future system requirements need to be. There needs to be a thorough assessment to determine the current functionality that is still required as well as a determination of new functionality that should be included due to new technologies available as well as new regulatory requirements.

These organizational requirements will be used to assess vendor capabilities in an RFP and later as the basis for the requirements for system design as well as your system/user testing. So, the time and effort spent on these activities now will not only have immediate benefits but also will provide significant value throughout the implementation.

Within the PV area of the organization, leaders typically have a good handle on their current requirements, however they need to go further and look into the future. One extremely important area to consider is emerging technologies. Technologies like AI/ML, NLG, Predictive Analytics, automations. You may not have these available today, however, they may be implemented soon to ensure an optimized digital transformation. Lastly, also consider the integrations that you will require to other systems such as your Signaling and Risk Management and Literature search tools.

2 Don't discard a system just because of cost.

When vendors respond to RFPs, it is not uncommon for license and implementation costs to have significant differences between vendors. Your organization shouldn't discard a system just because of its license and implementation cost. It is important to note, that when vendors submit their RFP, the cost they provide is only a starting point and has many assumptions built in. As part of the selection process, vendors will be able to confirm or modify their assumptions and adjust the cost accordingly. Moreover, another factor in the cost difference that it is common is that one vendor will include an item in the cost (e.g. integrations, custom report development) and another vendor views this as add-on work, which will account for a cost difference. Also, one solution may fulfill the requirements in a more elegant way or add additional functions that were not considered originally as important

Because of these factors, the recommendation is to include all vendors who satisfy most of your requirements in your demonstrations and work out the cost after you have had discussions and seen demos.

It is important to note that when approached, vendors are typically open to negotiating to be competitive.

3 Do draft a clear demo agenda with use cases.

Drafting a clear Demo agenda with well-defined use cases/scenarios is imperative. The organization cannot rely on the vendor to pick and choose what they would like to show. Taking the time to develop Use cases/scenarios that clearly define what is imperative for the vendor to demonstrate is critical to ensure that you are seeing your important features as well as to evaluate the vendors on the same capabilities (i.e., apples-to-apples). By having the use cases, it will also make it easier for your team to compare systems and fairly score each vendor.

The organization needs to ensure they are getting what they require from the system and that the vendor sticks to the schedule. At this stage of the process, the organization may not be able to see all the bells and whistles of the solution, so they need to make sure they are focusing on the "make-or-break" items for the organization – those capabilities that you feel are the "must haves" in order for the organization to reach that future vision.

Of course, if after seeing the defined requirements there is time to see the additional unique capabilities of the vendor's solution and these capabilities would provide additional value, then they should be shown. New approaches or technologies that are presented can then be added to the requirements if they would make a major impact to the organization.

4   Don't shortchange the amount of time allotted for the vendor demo.

Too often, not enough time is provided to the vendor to demonstrate how the system meets the organization's requirements as well as review their implementation strategy and timeline. What you don't want to do is decide on a solution before you have fully covered your requirements and possibly those other vendor unique capabilities that will build the best solution for your PV department. While it may not be planned, you can setup additional sessions with the vendors to complete demonstrating the requirements if you do need additional time.

As a part of the process there should be planned time for Q&A with the vendor and debriefing with colleagues. These questions and feedback, from all the participants, is extremely important to the evaluation process and selection.

5   Do avoid vendor bias.

The team involved should develop a scorecard and ensure all participants understand the scoring system. This really assists the team in ensuring a level playing field throughout the process.

Moreover, you shouldn't let evaluators share feedback or scores with each other as this could lead to people being influenced. You want to get everyone's non-biased opinion that is not influenced by others around them. As we know, the vendor will always be attempting to influence the participants or to get additional information so they can get a leg up on the competition.

6   Do include your leadership/steering committee throughout the process.

It is critical to include the leadership/steering committee throughout the process. Keep them aware of the progress and decisions that the team is making. Don't hesitate to bring them into key meetings requiring their input or decisions.

Too often, 10 minutes of their time can save the team hours of discussions. You don't want to get their thoughts or advice after the fact. They should be part of the feedback loop and key decision making process.

The Organization Change Aspect of a System Selection

Selecting a new system is a big decision that companies will have to live with for many years into the future. The 6 considerations that we have discussed impact the success of the selection process. At Astrix, we advise our clients and assist in leading the selection process leveraging the areas we discussed in this paper.

The process of selecting a new system involves organizational change management. A critical aspect to any change like this is to ensure that there is a strong alignment with the leadership team, and everyone involved in the selection process. That cohesion is imperative. Leadership needs to follow these best practices

- Develop clearly defined objectives for the system selection.
- Understand the key stakeholders and be visible from the beginning, conveying a sense of urgency along with the business rationale for why this new system change is needed.
- Develop consistent messaging that is tailored to specific stakeholders (or stakeholder groups) so they understand why this change is not only important to the business but also important to them.
- Provide regular reinforcement around the tenets and reasons for change throughout its implementation

There also needs to be an alignment on measurable goals related to the objective of the selection and implementation of this new system.

Moreover, having the right people involved in the selection process is also critical. Typically, you should look for change agents, early adopters and organizational influencers to actively participate in the project. This is particularly important during the Definition & Engagement phase of the project as this team will set the direction and lay the foundation for the overall project.

Identify the right team for the project, who have:

- Authority to make decisions around the planned selection process.
- Insight into the overall workflow that will be affected as well as the larger impacts organizationally.
- Credibility and respect of the organization, from the bench to the leadership team.

astrix

Additionally, Key stakeholders, both internal and external to the organization, must be identified early in the program. To ensure success in the system selection process these best practices should be utilized:

- Clearly defining roles and responsibilities related to the system selection.
- Ensure organization-wide understanding which will be supported by the alignment and metrics.
- Ensure everyone understands their accountability for their new responsibilities within the system selection process.

Finally, it is important to ensure excellent communications across the team involved in this project. Regular meetings leveraging the best channel is necessary whether that is a phone meeting or a video conference. This will ensure everyone is on the same page.

Conclusion

The system selection process is not easy. There are many considerations beyond the six we have outlined in this paper. The key to success is to ensure you leverage both your internal and external resources to facilitate an effective and efficient process to evaluate and select the optimal solution for your business.

Each organization is different, and the people involved in the project are critical. Everyone involved needs to understand the objectives and their role and responsibilities. Effective communication and alignment of the organization on a common objective is imperative. Utilizing the right people both internally and from a consulting perspective will help to ensure success.

About Astrix

For over 25 years, Astrix has been a market-leader in delivering innovative solutions through world class people, process, and technology that fundamentally improves scientific outcomes and quality of life everywhere. Founded by scientists to solve the unique challenges life sciences and other science-based business face. Astrix offers a growing array of strategic, technical, and staffing services designed to deliver value to clients across their organizations.

For more information, visit our website www.astrixinc.com or contact us at: Astrix Technology, LLC, CORPORATE HEADQUARTERS, 125 Half Mile Rd, Suite 200, Red Bank, NJ 07701, 732-661-0400