THE ASTRIX DIGITAL TRANSFORMATION PODCAST SERIES

7 Techniques to Ensure Your PV Implementation Succeeds

Program #10: September 2022

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7 Techniques to Ensure Your PV Implementation Succeeds

A conversation with Alan Summer, Vice President, Astrix

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This episode features industry best practices for implementing, and updating, pharmacovigilance systems from an expert who'll share both industry best practices and his own insights from two decades of successful PV program management. This conversation is nothing short of a Master Class in working with pharmacovigilance systems.

About this Program

Implementing a new PV system can be overwhelming but knowing how experienced pros prepare for a project can give you—and your team—the confidence you need to succeed.

And, since success in this critical function is imperative, our expert is going to share some very specific insights that he's developed from years of his own direct experience in developing inclusive strategies and comprehensive plans.

Alan Summer
Vice President of
Pharmacovigilance Delivery
Services at Astrix

Kevin: I'm pleased to welcome back Alan Summer, Vice President of Pharmacovigilance Delivery Services at Astrix. For those of you who have yet to hear our other conversations with him (which I recommend), Alan brings over 20 years of experience throughout all phases of the product development cycle to his leadership of the Pharmacovigilance practice at Astrix.

Alan Summer started his PV career as a lead architect and project manager, developing the E2B solution for Johnson & Johnson.

Later, Alan was a Partner at November Research Group leading their PV service division, which implemented and supported over 100 client systems. Prior to joining Astrix, Alan also helped to lead Oracle's Pharmaceutical consulting team focusing on AERS implementations. Most recently, Mr. Summer led the Global Service Organization for Genpact and the US service organization for ArisGlobal.
Alan, welcome back to this series, and thanks for bringing even more of your insights on PV system implementation.

Let's get to the topic at hand. How do see your practice assisting organizations' implementation of their PV systems in what feels like a dynamic environment? Also, I have been hearing a lot about AI/ML in the industry.Can you share a little about your thoughts on this.

Alan: Implementing or upgrading a new PV system for any company is a huge undertaking—irrespective of federal regulations and standards. It's something that can have a very positive—rather than disruptive—impact on a company. The key is for it to occur smoothly.

There are two keys to making the transition to a new system as smooth as possible and give the business community confidence in the new system: The first is to have a comprehensive plan as early as possible. The second is to organize it with maximal efficiency—which will ensure the effort will be effective—irrespective of the regulatory changes.

It's that comprehensive plan and a laser focus on efficiency that my team uses to help ensure that our clients' PV systems are implemented to harmonize both their business and regulatory requirements.
It is an exciting time in our industry with many commercial systems incorporating AI/ML techniques in their system and companies developing business processes to take advantage of the functionality. While AI/ML has been out there for a while, it is relatively new in the PV systems and industry. If a company is moving forward with an AI/ML system and business process, I would really urge companies to utilize a vendor like Astrix to ensure that they are maximizing the benefits.

"In making the transition to a new system, it is critical to have a comprehensive plan as early as possible and to organize with maximal efficiency. This will ensure the effort will be effective."

Q&A Session:

1 Complete System Requirements

Kevin: Well, let's dig into your first point, about having a comprehensive plan, since it seems to be the foundation of success. I'm sure that anyone facing the planning for a change, or upgrade, to their PV program thinks that they need to address comprehensiveness. So, what would be your first insight to ensure an implementation plan succeeds?

Alan: Thanks Kevin, I think the number one key factor to success has to do with compiling accurate and complete system requirements. Having the organization take the time to define the system requirements before the

project starts is one of the first keys to success in implementing a PV system. Once this is done, the essential work of prioritizing them can proceed.

When requirements aren't defined properly upfront, this will cause more effort, time, and cost than originally budgeted. If requirements are missing or not well defined, then they will need to be identified during the project. This will cause scope creep and have an impact on the timeline and cost of the system. Moreover, if the requirements are not caught during the project, the system will fall short of meeting the business and regulatory requirements causing key functionality gaps when the system is live and the need for additional releases.

By sticking to the requirements and the implementation plan, you can stay on track and put the essential components of your new system in place and to their intended use.

"When requirements aren't defined properly upfront, this will cause more effort, time, and cost than originally budgeted."

2 Properly Chosen Team

Kevin: In a whitepaper on PV Implementations your team recently published on the Astrix website, there's a point about the necessity of having "the right people" on the implementation team. This seems like a rather obvious concept, so what have you learned that provides specific advice to someone listening who's been tasked with leading a PV project—which presumably entails assembling their team?

Alan: Sure, Kevin. A company is going to need to provide several people to work on the project on all workstreams to make decisions as well as confirm that the functionality is working as expected. For a PV implementation to succeed the project team members need to be properly chosen, and their responsibilities

clearly delineated and documented. You need to make sure it is clear who are the decision makers and decision influencers for each workstream or key activity of the project. This includes but is not limited to Project Management, Periodic and Ad-hoc Reporting, Validation, Training, and Various business workstream like Intake, Medical Review, Expedited Reporting.

But, it is not only about choosing the right people but also appreciating the work effort and time that these individuals will need to commit to the project. Too often, I hear from team members that they feel over worked or falling behind some of their other job responsibilities. Staff assigned to the implementation team need to be provided with the time required to work on the project. So, it's important to ensure some of their previous responsibilities are being properly managed or assigned to other non-team members. You need to keep in mind that the vendor resources are full-time on this project and your implementation is their only responsibility. You don't want your team to be the bottleneck or cause for the project to be delayed. So, it is critical to make sure that you have assigned the appropriate resources and as a PV organization ensure that their other responsibilities are being managed.

"...project team members need to be properly chosen, and their responsibilities clearly delineated and documented."

3 Integration Points

Kevin: In that same whitepaper you assert that proper integration of the various systems is extremely important to the success of the PV implementation. Can you provide insight into some of the key elements of success for this area?

Alan: Every PV system will have several upstream and downstream points of integration that need to be considered when implementing a PV system. Frequently, these systems that need to be integrated are not part of or controlled by the PV organization such as the Clinical system in the Clinical Reconciliation integration. Effective system integration requires a thorough audit of all the parts that need to

be joined in one interconnected infrastructure. Since this aspect of the process is can be fraught with oversights, neglect, and forgotten elements, it is essential that the team members conducting this phase of the project possess firsthand experience with the various touchpoints, data streams and applications being considered for integration. You want to make sure that what was working is as effective and efficient if not more.

Documenting the organization's physical connections and data flow also provides a valuable opportunity to review and analyze the logic of each connection. Whenever you must connect three or more systems and your project involves multiple use cases with interdependencies, it is best practice to create an integration map.

Once all software and hardware components are integrated and working as a whole you want to make sure that they are tested with migrated data and produce the expected results from both a data and timing perspective.

"Effective system integration requires a thorough audit of all the parts that need to be joined in one interconnected infrastructure."

4 Data Migration

Kevin: Since data is the lifeblood of a life science operation—and especially a pharmaceutical company, what are the key points to keep in mind when migrating to a new system?

Alan: First, you need to make sure that you have a thorough Data Migration Plan that details your strategy including what data you will be migrating, how you will be migrating that data, and your strategy to test the completeness of the data migration.

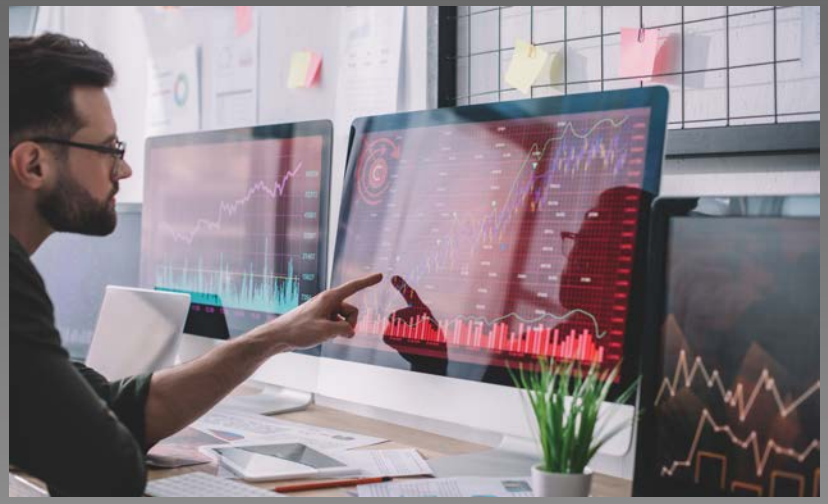
Then, the business and vendor need to work together to develop a migration mapping document.This document will identify all the fields that are getting migrated and their appropriate location in the destination database. The mapping document should detail all the

transformation and logic for both the visible and non-visible fields. While it is possible that the data will not appear exactly the same in your new system it should have the same medical interpretation.

The vendor will then be able to prepare and transfer the data to the new system as per the mapping document. Before handing it over to your team, the vendor should perform through testing to ensure that you are reviewing quality data that functions in the system.

Eventually, you will have to perform your formal testing as per the Data Migration Plan and corresponding test scripts. All results should be captured in a Data Migration or Validation Summary report.

"While it is possible that the data will not appear exactly the same in your new system it should have the same medical interpretation."



5 Testing

Kevin: Let's turn our attention to the issue of testing your system before it goes live. What specific suggestions do you have for ensuring the system will function properly for the organization's specific requirements?

Alan: We could probably talk for hours on validation as this is a critical step in the implementation and of course every company wants to ensure that when they Go-Live the system is working as well as would pass an audit. The key is that it starts with a strong Validation plan that at least includes what you are going to test, how you will test it, the documentation that you will produce to show it has been tested. While we are probably familiar with testing a system's functionality, it is important to test

the non-functional requirements of a system as well. Non-functional tests include usability tests such as performance, load or stress tests as well as recovery tests in the situation of an outage or disaster. Also consider doing some negative testing for key features to ensure that they system performs as expected with invalid data.

Also, it is critical to test all aspects of your system with real world data including your data migration, integration, and reporting data.

"The key is that it starts with a strong validation plan that at least includes what you are going to test, how you will test it, the documentation that you will produce to show it has been tested."

6 Training

Kevin: Ok, now I'd like to focus on what can be done to ensure success in the post-implementation phase. What advice do you have for our listeners relative to ensuring proper training of their users?

Alan: You can have the best system in the world but if the team doesn't feel comfortable using it or understanding the functionality, then the system will not be used properly. It is important that early on you engage a training specialist to develop an effective training program.

Software training is most effective when it is focused on the end-user point of view. Training will succeed when personnel are made aware of the procedures specific to their position within the PV system. There

will be several different roles within the system, so it is important to have specific training that focuses on each unique role.

We have seen, in multiple instances, that training is not considered early enough in the project and lacks the planning that could have prevented widespread disruptions and frustrations with newly installed systems. It is one of the most prevalent culprits in troubled system implementations.

There are several different strategies that companies can take for their training. A "train-the-trainer" strategy can be an excellent strategy for rapidly accomplishing the adoption of new processes. By leveraging your project team and "super users" to instruct the other users, people familiar with the organizational culture are enabled to lead change. In addition, once you are live, the rest of the team can rely on them to answer many questions.

Where this approach is not preferred or manageable due to the size or availability of your team, there are several other approaches you can take. Another similar approach is to have a 3rd party trainer that is not part of your PV department conduct the training to everyone in your PV organization. Another option is to leverage the documentation and/or videos offered by the software publisher or if you have the budget develop your own videos. Regardless of the approach your organization chooses, the scheduling of the training, the subject matter, the duration, and the audience are all essential elements that must be considered in planning for a successful training program.

"Training will succeed when personnel are made aware of the procedures specific to their position within the PV system."

7 Launch Meeting

Kevin: Alan, although our time for this podcast is close to an end, what one tip do you have that can prevent an essential ingredient for success in a PV implementation from being overlooked or done improperly?

Alan: Keep the team that is not involved with project informed of the progress from the beginning to the end. It's important to have a “kick-off” or “launch” meeting before the project begins. At this meeting, it is important to inform the team the benefits the changes will bring and the benefits to the organization, the anticipated timeframe, and communication plan going forward.

It is not unusual for teams to become overwhelmed by all the new information a new PV system provides. It’s good to phase in the details of the system over a defined interval, rather than suddenly and all at once. The onboarding process should be planned for introduction across multiple stages that divide the information into easily understandable emails, guides, and meetings.

Bringing in an outside expert with specific experience in PV system implementation can be a cost-effective approach to training that saves time and facilitates uptake of information across the organization.
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"It's important to have a “kick-off” or “launch” meeting before the project begins."

Closing Remarks

Kevin: Alan, thank you for these seven important insights. We’re just about out of time so what are your final thoughts on this critical topic?

Alan: I’d like to end by reminding our listener where we began in this conversation: There are really two keys to making the transition to a new system as smooth as

possible and giving the organization confidence in the new system: The first is to have a comprehensive plan as early as possible. The second is to organize it with maximal efficiency—which will ensure the effort will be effective.

So, here's the takeaway: Unlike our clients' teams, who are tasked with managing the selection and implementation of new PV systems in addition to their day jobs, the Astrix PV team provides these services as our singular focus. We bring dedicated experience in areas that, frankly, many companies find overwhelming to do really well while they're focusing on maintaining their core operational excellence.

What distinguishes Astrix is our quarter-century of assisting life science companies with projects of enterprise-wide scope and complexity. And, rather than having a business model founded on charging clients for software, our service-based mandate is to ensure that third-party software works the way our clients' need it to —specific to their unique organization, timeframe, and culture.

Unlike PV System vendors, who look to get the project done as quickly as possible as a key to make their margins, recognize license revenue, and move on to the next project, Astrix is different because we focus on ensuring each software implementation is customized to succeed.

Astrix's Pharmacovigilance staff has many years of experience assisting organizations in managing their implementations. We can provide experienced project leaders to assist in ensuring your project remains on schedule and meets the organization's requirements. Moreover, we can support your business in developing the proper test data and scenarios to ensure the system will operate as required when you go live, along with ensuring the data migration and integration is completed according to the demands of the business.

Kevin: Thank you again Alan for joining us today and providing some very insightful informative relative to this topic of ensuring PV implementation success. It was my pleasure, and again for everyone who's listening to today's podcast thank you for your time. Our podcast series on digital transformation is certainly growing in both popularity and the number of downloads each month as we cover many different and important topics related to digital transformation. Stay tuned for our next podcast coming in the series as well as a wealth of other great resources on our website. Thank you for listening.

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