

THE ASTRIX DIGITAL TRANSFORMATION PODCAST SERIES

Top 6 Considerations When Selecting a Safety System



Program #7: June 2022



Top 6 Considerations When Selecting a Safety System

A conversation with Alan Summer, Vice President, Astrix and

Heather Adinolfi, Senior Consultant, ResultWorks

Program #7 - June 2022



[Play the Podcast](#)



Alan Summer
Vice President of
Pharmacovigilance Delivery
Services at Astrix



Heather Adinolfi
Senior Consultant at
ResultWorks, an Astrix Business



Astrix Digital Transformation Podcast Productions tackles today's most compelling issues shaping digital transformation in scientific businesses. In this series, interviews with thought leaders from across the industry deliver expert insights for accelerating your digital transformation strategy.

About this Program

Pharmacovigilance is an extremely important component to success for organizations in the Pharma and Biotech industries. We are at an interesting time in today's PV landscape as there are several new systems coming to market as well as significant upgrades to systems already in the market. Choosing the proper system to support an organization's safety efforts requires considering many factors. It involves managing the critical decisions that are involved to come to the optimal solution and a digital transformation of the way things are done. In this Episode, in our service focused on digital transformation, we focus on 6 key considerations when selecting a safety system for your organization. We look at the critical factors contributing to selecting the right system to manage the pharmacovigilance process by speaking with experts on the topic.



Below is a transcript of this informative session:

Kevin: Welcome to Astrix's Digital Transformation Podcast Series – This series presents interviews with thought leaders and experts focusing on helping you to develop successful strategies that transform your business.

I'm Kevin Miller, your host for today's podcast, and I want to welcome you to another insightful conversation which I'm confident you'll find both interesting and instructive.

In this podcast we're sharing "6 important considerations when selecting a safety system". I'll be speaking today with two experts on this important topic,



and I'd like to begin by introducing them to you.

Heather Adinolfi, is a Senior Consultant at ResultWorks, which is now an Astrix business. Ms. Adinolfi assists clients with Pharmacovigilance program development and optimization. She brings to today's conversation over 10 years of experience in the pharmaceutical and informatics industries. As a Senior Consultant, Heather works closely with client and software vendor teams to drive regulatory and safety management solutions. Heather pays particular attention to streamlining workflows and ensuring effective cross-functional communication.

In addition to Regulatory and Safety, Heather has extensive experience in molecular biology techniques, cell culture, and drug discovery pipelines through her prior roles in which she managed biopharma laboratory informatics applications portfolio at Thermo Fisher Scientific and led cell line generation projects at Bristol-Myers Squibb.

Heather, welcome to our podcast and thanks for joining us today to share your insights with pharmacovigilance. To start things off, maybe you could provide some additional context with respect to ResultWorks and the focus of the organization relative to assisting organizations around the safety area?

Heather: Sure Kevin. Thanks. So, ResultWorks was founded over 18 years ago as a professional services organization with a mission to assist Life Sciences organizations to improve their operations through helping them with their strategy development, business process optimization, technical assessments, requirements definition, and data management and data governance. Our mission has expanded to help organizations achieve a digital transformation of their business in various areas and that includes pharmacovigilance. We help organizations, from a strategic consulting perspective, in the area of pharmacovigilance. This is a critical component for our pharma or biotech client's business since ensuring patient safety is their number one priority. Any digital transformation requires a solid strategy and plan to guarantee that client's operations continue to run efficiently and effectively. This is an imperative given the nature of this area.

Kevin: Heather, thanks for adding that additional context. It was very helpful. I'm very pleased to also welcome to our conversation Alan Summer. Alan is Vice President of Pharmacovigilance Delivery Services at Astrix. He brings to his leadership of the Pharmacovigilance practice over 20 years of experience throughout all phases of the product development cycle. His Pharmaceutical industry



development cycle. His Pharmaceutical industry experience began as a lead architect and project manager for developing J&J's E2B solution. Prior to joining Astrix, Mr. Summer helped to lead Oracle's Pharmaceutical consulting team focusing on AERS implementations. More recently, Alan co-founded LSWorks, which assisted companies with Pharmacovigilance needs and, when LSWorks merged with November Research Group, Allan oversaw their consulting services and pharmacovigilance projects.

Alan, Thanks for joining the podcast and bringing your fresh insights to today's conversation on safety. Based on your own experience in prior roles, and what you see happening in the industry today, what are you planning for Astrix' new Pharmacovigilance practice? How do see your practice enabling that transformative advancement in safety to which Heather just referred?

Alan: Hi Kevin. Thanks for the introduction, this is an exciting time in the PV space because not only are there some new vendors that are developing systems but also there are new technologies such as AI/ML and automation that can really improve a company's business response. Because of these, I am seeing many companies evaluating their current system and vendor to ensure that they are best positioned for the future. So, I am excited for our conversation today

discussing several considerations that a company should think through as part of this evaluation as it is a big decision for any company.

Regarding, our new Pharmacovigilance practice, we aim to provide premier level service to our clients that will help them successfully implement, upgrade and maintain their system. We will be able to accomplish this with a team a very experienced PV consultants that will not only know the individual PV system but are also very knowledgeable in the PV space. We will be able to provide a team that can ensure all workstreams including Project Management, Requirement Definition, Configuration, Data Migration, System testing and Go-Live including system support. We can also augment a client's existing team by providing individual contributors that have experience with these complex projects. I consistently see how 1 or 2 key people can really make a difference.

Astrix has been offering similar services in the Lab Informatics space for over 25 years. So, not only will we leverage all of those years of experience, templates and processes but also building upon them based my teams and my PV experience.

Kevin: Thanks, Alan. No doubt there will be people listening to your description who will want to follow up with you on those points, alone, but for now let's turn to

some specific questions which we believe will help our listeners in the very near term on our topic for today.

Q&A Session:



Unique System Requirements

Kevin: Ok, so let's get into this topic. Given the industrywide interest in digital transformation, what would you say are the best ways for an organization to approach the planning of the future state of their Pharmacovigilance system? Specifically, if an organization is in the pursuit of a new system to handle their unique set of organizational needs in this area, what are the best ways for them to leverage their current requirements when planning that future system? Alan, what are your thoughts on this?

Alan: Yes Kevin. The key phrase in your question is unique organizational needs. To ensure that a company get what they need for their unique situation, the PV leaders need to take the time to clearly define the functionality they are looking for in a system. They can't just use their existing set of requirements but rather leverage them to develop what their future requirements need to be. They should assess them to see if their required functionality is current as well as identify new functionality due to regulatory requirements, such as, IDMP or E2B R3, as well as take into consideration any new technology. Keep in mind that these are the organizational requirements that will be used to assess vendor capabilities in an RFP and later as the basis for the requirements of your system or user testing. So, the time and effort spent on this activity now will not only have immediate benefits but also will have benefits during the implementation.

Kevin: Great insight. I really appreciate it. Obviously very critical. Heather, what's your take on this?

Heather: Yes. To emphasis what Alan was saying, 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 in that respect is emerging technologies – technologies like



AI/ML, Natural Language Generation, Predictive Analytics, automations. Things that can make your life simpler as you move towards that future state vision. You may not have these implemented today or you may have some of it but you need to be looking at what you can do in this space in the near future to ensure an optimized digital transformation that most organizations are looking for.

Kevin: Yes, that's a great point. Going through a technology implementation you need to have one eye on what you're trying to accomplish today and at the same time putting a foundation in place that's going to leverage that technology especially in the analytics side like predictive analytics or AI technology that is coming down the pike.

"The time and effort spent on this activity now will not only have immediate benefits but also will have benefits during the implementation."



System Cost

Kevin: Another important area to discuss relative to a system evaluation is the cost. You both have experience advising PV leaders when they are comparing multiple vendor's proposed systems. What do you recommend when one or more of the solutions is a much higher cost than the others?

Alan: Kevin, when vendors do respond to an RFP, it is not uncommon for license and implementation costs to have significant differences between vendors. I always stress to companies, that they shouldn't discard a system just because of its cost. You need to keep in mind that when vendors submit their RFP, the cost they provide is only a starting point and has many assumptions built into it. As part of the selection process, vendors will be able to confirm or modify their



assumptions and adjust the cost accordingly. In addition, another factor in the cost difference is that it is common that one vendor will include an item in the cost, for example integrations or report development, and another vendor views this as add-on work. In general, I would recommend that if a vendor satisfies most of your requirements, you should still consider including them in your demonstrations and work out the cost after you have had discussions and seen demos. Also, keep in mind that when approached, vendors are typically open to negotiating to be competitive.

Kevin: I've had that experience myself in a few situations. Heather, what's your perspective on this.

Heather: Sure. My thoughts are right in line with Alan's. I think there a couple of things to consider. First, price can always be negotiated, and the solution may fulfill the requirements in a more elegant way or add additional functions that were not considered originally as important. Second, the vendor may have made some assumptions in their pricing that might not be accurate, so it is worth a discussion. Vendors are usually open to that discussion.

"In addition, another factor in the cost difference is that it is common that one vendor will include an item in the cost, for example integrations or report development, and another vendor views this as add-on work."



Use Cases

Kevin: Question 3: You've both assisted many organizations with their vendor selection process. In those situations, how important is it for the client to have clear use case scenarios that the vendor can demonstrate? Moreover, what are some ways that PV executives can improve these scenarios to enhance the clarity of their definition to ensure the vendors meet their needs? What's the best way for our audience to address this situation? Heather, what do you think of this?



Heather: Sure, Kevin. That's a great question. So, defining use cases for vendors to follow will ensure that vendors are evaluated on the same capabilities (apples-to-apples). Also, that the organization is getting what they are looking for 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, so they need to make sure they are focusing on the "make-or-break" items for the organization. You really want to be looking at those capabilities that you feel are the "must haves" in order for the organization to reach that future state vision.

Kevin: Excellent. Great perspective on that. Alan, I'm sure you have thoughts this.

Alan: Yes. Heather covered some great points here. As she mentioned, the use cases for vendors ensures a standard evaluation and that your make-or-break items are covered. Another key point is to draft a clear Demo agenda with the use cases. You don't want to let the vendor to pick and choose what they would like to show in the order they want to show it. Because they will focus on the items they think will wow or impress you the most. So, taking the time to develop those Use Cases/Scenarios that clearly define what is imperative for the vendor to demonstrate is critical. By having the use cases, it will also make it easier for your team to

compare systems and fairly score each vendor. 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.

"So, defining use cases for vendors to follow will ensure that vendors are evaluated on the same capabilities (apples-to-apples)."





Allocating Appropriate Demonstration Time

Kevin: I'd like to turn now to the topic of allocating appropriate amount of time for demonstrations. You both have experience in this area. What advice do you have to Pharmacovigilance executives who are under tight deadlines and need to document a fit for a safety system?

Alan: Kevin, my advice on this key point is: Don't shortchange the Vendor on the time for their 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. This could take anywhere from a day to two days to get really get a full-fledged

understanding of the system. What you don't want to do is make a decision when you haven't fully covered your requirements and possibly those other vendor unique capabilities that will build the best solution for your PV department because you're going to be with this system for many years to come. While it may not be planned, you can always setup additional sessions with the vendors to complete the demonstration of the requirements, if you do need additional time.

Kevin: How about you Heather?

Heather: Yes, I agree with Alan, the leaders definitely need to ensure that there's enough time allocated for the demonstration process as well as planning time in for Q&A with the vendor. A lot of questions come up during the demonstration and you want to ensure you cover them. If you're doing a day or two-day long demonstration, there's a lot of information coming in, so you want to ensure you do a debrief to understand all the questions from all participants. It is extremely important to the evaluation process and selection.

"There's a lot of information coming in, so you want to ensure you do a debrief to understand all the questions from all participants."





Eliminating Bias During Selecting process

Kevin: Anyone who has been involved with a software evaluation knows that biases happen during the selection process. You have a team looking at a lot of technology and chiming in on what they want or what they think is the best solution. How do you manage that. Bias aren't necessarily a bad thing in this case. It's just the people on the selection team coming in to the process with what they think is most important and which vendor they like the most along with which feature and functions they think they need the most.

What are some tips you have for PV executives to reduce or eliminate bias during the vendor selection process? How do you manage that, so you ensure you

stay on track with the bigger picture goal? Heather, how would you manage that?

Heather: Yes. That comes up all the time. So, I would recommend the team involves develops a scorecard. Just like we are giving the vendors a set of use cases to follow, we want to give the participants a scorecard against those use cases. This again allows a apples-to-apples comparison. You want to also ensure all participants understand the scoring system and what is expected of them. In that way you can standardize the information you are getting back and ensure a level playing field throughout the process.

Kevin: Yes. I think that's an area where outside help is super important because there's no way in the world. I would know how to develop a scorecard. Alan what you think about that?

Alan: Yes, Kevin. As Heather said, creating a score card is definitely important to ensure you have an evaluation of the vendors at the end of the demos and you're not simply going by memory. Moreover, you shouldn't let evaluators share feedback or scores with each other. This could lead to people being influenced and changing their score to be more in line with their peers. You want to get everyone's non-biased opinion that is not influenced by others around them. And always keep



in mind you want to keep the vendors separated from participants. As we know, the vendor will always be attempting to influence the participants or get additional information so they can have a leg up on the competition.

"I would recommend the team involves develops a scorecard. Just like we are giving the vendors a set of use cases to follow, we want to give the participates a scorecard against those use cases."



Staying on Track

Kevin: So, let's go to our last question. What advice you would provide Pharmacovigilance executives who want to ensure that their vendor selection process stays on track, especially when it comes to their leadership/steering committee? Alan, I let you give us your thoughts on this.

Alan: Yes. Thanks Kevin. Great question. As you can imagine, it is critical to include the leadership or steering committee members throughout the process. Keeping them informed of your progress and any challenges you may have. You also want to keep them aware of decisions the team is making and most importantly, 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.



Kevin: Great. And Heather, your thoughts on that?

Heather: I agree with Alan. You don't want to get their thoughts or advice after the fact. You want to keep them as part of your feedback loop and get some advice and direction from your executives. They are helping to lead this project as well.

Kevin: That's great insight and thoughts on that. I'd like to thank both of you first and foremost for an excellent session with a lot of detail. We touched on only a few of the key topics associated with PV system selection as well as the digital transformation side, but I'm confident that the folks that listed in on this today are going to walk away with some additional advice that they can use to help them make a better evaluation. So again thank you Heather and Alan for joining us on the podcast today. What final comments would you like to share? Alan, maybe you can go first.

Alan: Thanks Kevin. Selecting a new system is a big decision that companies have to live with for many years. There are several factors and considerations that can impact the success of the selection process. At Astrix and throughout my career, we have advised companies and led the selection processes leveraging the topics we discussed today as well as others that we have accrued through our years of experience.

truly hope that people find this discussion helpful especially in today's market. And please feel free to reach out to me for further discussion or any questions about this topic or anything PV related. Thanks, Kevin, for moderating this session and Heather it was great to participate alongside you.

Heather: Thanks Alan. It was great to participate alongside you as well. I agree, this was a great session. I think we covered the key areas that the organization needs to consider with their system selections. Thanks to you again Kevin for bringing us along on this ride.

Kevin: 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 a digital transformation. Today's topic is obviously one that companies are wrestling with, so I know it will provide some value and listeners will walk away from this session with a few "aha moments" and if they do they can reach out to the Astrix and ResultWorks organizations to get some help. Again, stay tuned for our next podcast coming in the series as well as a wealth of other great resources on our website. Again, thank you for listening.



THE ASTRIX DIGITAL TRANSFORMATION PODCAST SERIES

Astrix enables leading laboratories to realize their visions for LIMS implementation, providing comprehensive services that encompass:

- Business requirement analysis
- Cloud Migration
- Computer systems validation
- Configuration
- Data migration
- Design and implementation
- Computer systems validation
- Configuration
- Performance management
- Project management
- Software development
- Solution architecting
- System integration/consolidation
- Testing and transition
- User training

To learn more about why Astrix people and processes are the preferred partner for a growing number of digital transformation projects, visit www.astrixinc.com or connect with Michael Zachowski, VP of Professional Services, at mzachowski@astrixinc.com

