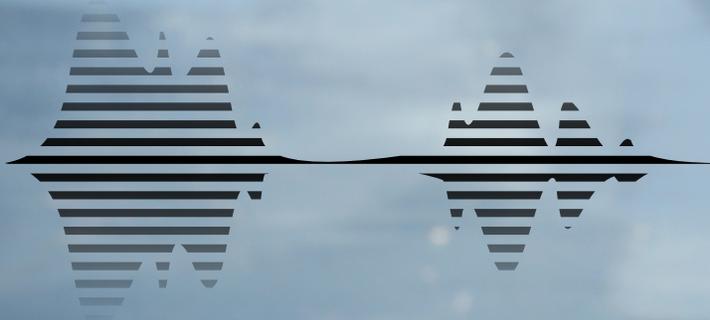


# THE ASTRIX DIGITAL TRANSFORMATION PODCAST SERIES

## Blueprint for Building a Better Data Governance Framework

Program #5: April 2022



**RESULTWORKS**

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# Blueprint for Building a Better Data Governance Framework

A conversation with Bob O'Hara, Vice President and co-founder, ResultWorks and  
Susan Butler, Vice President Strategic Consulting Services, ResultWorks

Program #5 - April 2022



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Bob O'Hara, Vice President of Business Development at ResultWorks, which is now an Astrix Business. Bob is one of the two co-founders of ResultWorks.



Susan Butler, Vice President Strategic Consulting Services, ResultWorks



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:

Data Governance is an extremely important component of a digital transformation and being able to manage the critical implementation of strategies, methods, and frameworks for data governance is an imperative to ensure success overall in the transformation.

In this episode, we focus on the importance of Data Governance in the biopharma industry. We look at some key factors contributing to developing a successful Data Governance program speaking with our experts on the topic.

Here is a transcript of this informative session!



Kevin: Welcome everyone to the Astrix Digital Transformation Podcast Series which include interviews with thought leaders and experts on developing a successful digital first strategy for transforming your business. My name is Kevin Miller and I'm your host for today's podcast and I want to thank everyone for listening and downloading. Before we get into the introductions I want to set the stage for what we're going to be discussing today. If you haven't participated in an Astrix podcast, we tend to focus on digital transformation. On today's session we will be focusing on a "Blueprint for Building a Better Data Governance Framework".



So to get us started on this very important subject, I'd like to introduce you to our first speaker. We have with us Bob O'Hara who's the Vice President of Business Development at ResultWorks. He's one of the co-founders of ResultWorks, which is now an Astrix business. We're thrilled and excited about having ResultWorks as a part of the Astrix family. Bob is an accomplished senior executive with more than 35 years of experience in building and leading organizations including professional services product management software development. He's managed organizations and projects which have provided information technology solutions including, R&D informatics, laboratory systems, clinical information management, supply chain management, process, and manufacturing management. Bob, first of all, thanks for joining us today on our podcast we're glad you're here to discuss this area of data governance. To start things off, could you give some additional context with respect to ResultWorks and the focus of the organization?

**Bob:** Sure Kevin. So we founded ResultWorks over 18 years ago as a professional services organization. Our mission has been to assist life sciences organizations to improve their operations by helping them with their strategy development, business process optimization, technical assessments requirements definitions, and

data management and data governance. Our mission has expanded to help organizations achieve digital transformation of their business in various areas as you mentioned previously. We believe that data governance is an extremely important element of a digital transformation and being able to manage the critical implementation of strategies methods and frameworks for data governance is really imperative to ensure success overall in the transformation.

**Kevin:** Great. I appreciate the background, Bob. We also have with us today Susan Butler from ResultWorks. Susan is the other Co-Founder and now Vice President of Strategic Consulting Services which includes the Data Management and Governance Practice. She has more than 35 years of successful business process optimization, project management and consulting expertise in Life Sciences and Technology Services. She specializes in leading organizations to transform how they work and in developing actionable plans to operationalize business strategies and deliver successful technology and process initiatives across research, nonclinical and clinical development, regulatory, safety and manufacturing. Susan, Thanks for being part of today's podcast on Data Governance. Could you also provide some additional information regarding your background with respect to this topic?



Susan: Thank you, Kevin. I'd be happy to. Here at ResultWorks we work with clients at all levels on data management and governance. That spans all of R&D from the enterprise level down to each of the functional areas. At every level, organizations are focused on their data and really treating data as an asset of the company. Strong data management and governance is a critical foundation to digital transformation. We've been developing data management and governance strategies for clients for years. Driving for FAIR data practices. FAIR stands for, Findable, Accessible, and Interoperable, and Reusable data practices; and we've done this long before the term FAIR was coined. As both Bob and you mentioned, data governance is really an essential component to ensuring data is FAIR and provides a foundation for everything that we're doing in Life Sciences R&D.

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### Common Understanding Amongst Cross-Functional Stakeholders



Kevin: Excellent. I appreciate the introduction from both of you. So let's dig into this topic. I know one question we want to tackle first. Based on what you said, you know data governance is obviously a key element in a digital transformation and ensuring its success in the life science industry. Of course we know many life science organizations are currently going through some kind of a digital transformation initiative or an effort to modernize their operations across various areas of business. In a recent data governance white paper, Data Governance Myths and a Foundation for Success, that I read by ResultWorks, it states that it's essential to solidify a common understanding amongst cross-functional stakeholders. Regarding the current state of an organization's data governance landscape. Bob, could you expand on this?

Bob: Sure Kevin. I think the keyword there is cross functional. Most organizations that we've worked with have a reasonable handle on their own data within their function. Not always, but they usually do. Where things really start to breakdown in terms of data quality is when you start to move across functions, and then across systems those functions use. Over the last five years or so organizations have been much more focused on leveraging data across the organization, but without the proper attention, that is data governance, things can fall apart pretty quickly.



Kevin: How does the international aspect play into this? When you talk about data governance across multiple areas are we also talking about data governance across multiple countries? I'm sure that complicates things.

Bob: It sure does and especially as you get down into the clinical and regulatory areas. It's an absolutely critical facet of data governance. So yes, cross "everything" really applies here, cross-functional, cross-country, that all applies and adds up pretty quickly.

Kevin: Great. I appreciate that awesome perspective. Susan, what are your thoughts on this?

Susan: So, I agree with Bob on this. Most functions within an organization pretty much have a handle on their own data and many are working to optimize their processes for generating that data. In fact pending on the size of the organization, they can be spending millions of dollars annually acquiring and generating data, but here's the thing, more often than not the valuable data is often locked in departmental silos and is not easily leveraged across the rest of the organization. This challenge coupled with industry drivers such as designing and implementing more efficient, patient centric clinical trials, leveraging real-

world evidence and real-world data to support evidence generation for regulatory decision making, and the ever pressing drive to develop more innovative therapeutics faster, are all sounding a call to action to make better, data driven decisions. To make better, data driven decisions and to be able to leverage the data that an organization has spent untold amount of time and energy creating, you really need reliable data – and effective data governance is absolutely critical to achieving this.

*"To make better, data driven decisions and to be able to leverage the data that an organization has spent untold amount of time and energy creating, you really need reliable data"*



## The Elephant in the Room – Poor Data Quality



**Kevin:** Thanks Susan. Excellent perspective. Let me go back to the data governance white paper because there is a lot of information in that paper relative to what we're talking about today. The white paper has an interesting way of characterizing what will say is the underlining challenges that are going to be faced by teams working to create effective frameworks for data governance. From your perspective what's the difference between what we call the elephant in the room, or "poor data quality" and the red herrings which are the misconceptions. Bob your thoughts on that.

**Bob:** Yes. I think most organizations don't want to admit that they have a data quality issue, and it's not always obvious whether there is or is not an issue.

Everyone thinks they're doing a pretty good job" of it. It's not until you really start to take data seriously, measure data quality and start to apply some ongoing metrics, that you can get a handle on it and do something about it. Until such a time, the perception of data quality can largely be anecdotal which really can be dangerous to be driving your organization around.

**Kevin:** I can imagine. Susan that in your travels you've probably run into this quite a bit. What are your thoughts on the "data quality elephant in the room".

**Susan:** I think there's a couple of things going on here. One, many organizations know they have real challenges in leveraging their data, but oftentimes they don't have a handle on what the root causes are. Two, and this is in the category I would say of red herrings, they may think that a data governance program is going to get in the way of innovation or may lead to a large bureaucratic governance structure that's just going to slow everything down, or oftentimes they think this is something that the IT department should be able to deal with on their own; and so it's this combination of the elephant in the room, that is not really having a handle on their quality issue, and the red herrings that can unfortunately paralyze and organizations digital transformation efforts.



*"It's not until you really start to take data seriously, measure data quality and start to apply some ongoing metrics, that you can get a handle on it and do something about it"*

Kevin: That one part you mentioned was definitely telling in terms of people just assume that you know IT will take this on and manage this by themselves. How prevalent do you see that when you walk into an organization?

Susan: It's pretty common and it's something that the organizations have been struggling with for years. Data governance is not just an IT function it's an organizational capability. Everybody has to participate to be successful.

Kevin: Yes, I couldn't agree more. Definitely one of the myths. What would you say are some other myths that are actually hindering organizations ability to achieve success with data governance. Could you provide the top two or three in your experience and what would be the best way for our audience to address them.

Susan: Well, as I mentioned before there's a fear that data governance will interject bureaucracy and slow things down and inhibit an organization's ability to innovate, or you know they'll say something like we've tried these remediation efforts before and they don't work long term. I think it's extremely important to recognize that there's not a one size fits all data governance framework. We've got to right size it. We always conduct a current state data governance assessment so that a shared understanding of the real issues and themes are understood and importantly agreed. These can then be used to form the basis of approaches and solutions to resolve them; once again getting at the real issues and rightsizing it. I also think it's important to recognize that data governance is not a one and done initiative. It's more of a journey than a Sprint. That's why it's so important to develop a road map that effectively balances shorter term tactical or low hanging fruit initiatives along with the work toward more longer term strategic goals. The ultimate aspiration is to have a sustainable organizational capability that ensures data driven decisions can be made swiftly and importantly with high degree of confidence. You've got to take those steps.

Kevin: Great. A wonderful perspective there. Bob I'd love to get your thoughts on that as well.



Bob: Sure Kevin. I think it is a myth that data governance means time-consuming large scale remediation efforts. I've seen major turnarounds just by providing some common sense timely feedback, preferably automated feedback to people or groups on data quality. People don't want to supply bad data. More often they're providing data in a way that they think meets the needs of the receiving function. I've also seen major breakthroughs just by regular consistent diligence in terms of planning the data they need, agreeing on everything about the data, standards, timing, format, vehicle for transfer, error checking. These things can go a long way to improving data quality in the organization.

Kevin: No doubt. Makes perfect sense. Let's circle back to the white paper again since we're focusing on that quite a bit here. In it, it states that, gathering a clear understanding of the underlying root causes is crucial and that you need to distinguish between issues that are systemic versus those that are what we call an isolated incidents. What should our listeners use to distinguish between the two and are you seeing teams mistake one for the other? Bob what are your thoughts on this?

Bob: Again, I'd argue that by and large people want to do a good job. They want to generate and supply high quality data. However, if the culture of an organization doesn't value high quality data, no one is going to worry too much about following the rules around data. That's where governance can be effective. It's essentially establishing a position that the leadership is taking to address data quality on a consistent basis and then the organization will start to follow suit.

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### The Root Cause



*"If the culture of an organization doesn't value high quality data, no one is going to worry too much about following the rules around data"*



Kevin: That top down approach obviously is crucial.  
Susan what do you feel about that?

Susan: So I would say that most organizations probably do value high quality data. They just don't always understand why they don't have it. This is why starting any data governance program really should include doing a cross functional root cause analysis by identifying those issues which are systemic versus those that are isolated, you can reduce the noise which a lot of data governance efforts get caught up in. I'm going to say that a root cause analysis is a fundamental first step so that you can determine which issues are systemic and which are isolated, and then reduce the noise and focus on the signal. Teams that have this information at hand are much better equipped to focus on and prioritize their most pressing needs and establishing what I would say is a pragmatic data governance program.

Kevin: And then hopefully that gets them away from one of the earlier problems you mentioned, which is that IT has this covered and assuming they don't really have to think about it.

Susan: That's exactly right.

## Mindset Shift and Culture Shift



Kevin: Great. Well, let's talk about one of the areas you advise clients on in the white paper, and that is the need to build a "shift mindset" to achieve a "shift in culture". Susan what does this look like in practice? Do you find it's easy to accomplish when you're coming from the outside versus if someone were to try to do this internally?

Susan: So I think there's a great opportunity coming from the outside, but I would say that in our consulting practice the role that we find most beneficial to our clients is when we help to catalyze that shift in mindset because ultimately that's got to come from within. We do this by partnering with our clients to develop



programs that mobilize what I would call the Holy Grail of organizational enablers that really need to be in place and aligned in order to have to achieve a shift in the culture. One, and we have talked about this, senior leaders must actively champion the need for and the value of data governance. I'm going to emphasize the word actively because it can't be happening that you say it once in a town hall or once in an organizational memo. It's has to happen regularly. There should also be a clear and above all a consistent message regarding the value that effective data governance brings to the organization. That message needs to be delivered in such a way that regardless of where you sit in the organization you understand your role in achieving this goal and the benefits it will bring. This is best achieved by engaging departmental leaders and managers since they're in the best position to catalyze change in a way that is aligned yet specific to their area of responsibility. So the top down goes so far but the middle management and leaders are really extremely important in this effort. Lastly, and I would say this is where we've had a lot of success, identifying and recruiting what we call change agents within the organization. These change agents don't have to be the most senior people in the organization, but they should be really influential. They need to be identified. They can serve this invaluable role of translating these high

level objectives into the day-to-day operations of a given area of the business as well as providing insight back to the team that's working on this program. They can provide insight into the challenges and the roadblocks that may exist in a real way. So those are the big things that we think are important to help an organization catalyze that cultural shift.

*For Data Governance to work, senior leaders must actively champion the need for and the value of data governance. I'm going to emphasize the word actively because it can't be happening that you say it once in a town hall or once in an organizational memo. It's has to happen regularly.*

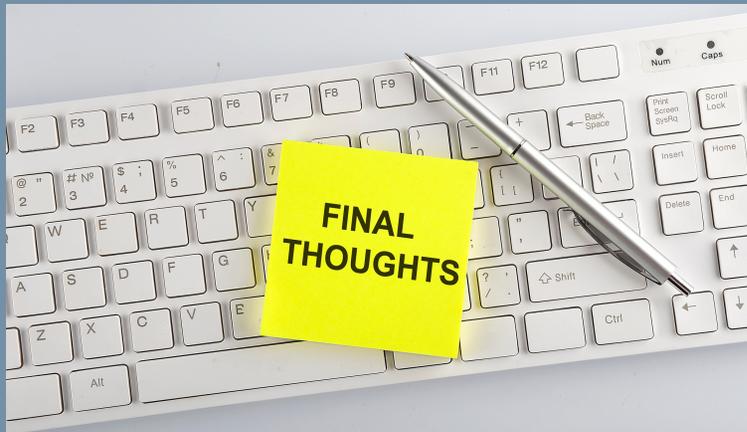
Kevin: That's great and makes perfect sense. Bob I'm sure you've got some thoughts on this? If you want to chime in you're welcome to.

Bob: Sure. Susan covered a lot of ground and all the right topics. I think the culture around data quality is really a critical thing. If you don't have that, the mindset really needs to change and where does it change, it changes at the top. At the same time it never hurts to



have an objective forcing function that is a consulting organization coming in from the outside to change the focus on the problem. Outsiders bring perspectives as to what other organizations are doing to improve their data quality, the speed with which the organizations can move, and so on, as a result of having a higher quality of data available to them.

## Closing Remarks



**Kevin:** Yes. That's great and I know from my perspective, seeing the work that Astrix and ResultWorks do with many companies across a very broad spectrum, people need to remember when you're working with an organization like this you're working with the collection of knowledge acquired from working with many large

and small national and international organizations, so they're seeing more scenarios than they see internally. We all live in our own little myopic universe, so to speak, so we oftentimes won't see outside of our own little world. It's just human nature, whereas you know bringing someone from the outside in who's dealt with these problems consistently across multiple organizations is a great way to make progress. I think the big items that I heard from your dissemination of some great information in the white paper, is that there has to be kind of a top down approach. The organization has to look at data governance as a mission critical element to driving the business forward. This is not something that can be relegated to IT simply because it has the word data in it. There are many stakeholders involved. Also there has to be a mindset around data quality where it's a business driver. It's not just an annoying little thing that we have to do to keep ourselves from getting in trouble. So those are some of my key takeaways. I certainly learned from today's talk which was a great conversation. Bob if you want to say a few closing remarks before we wrap up the session. I'd love to hear them.

**Bob:** Thanks Kevin, and thanks for an excellent session today. We touched on a number of topics that are



always relevant in digital transformations. I'll share one closing story of a client who based on our data governance project with them instituted some pretty straightforward practices in terms of planning and managing data. This happened to be in a clinical environment. They were essentially managing clinical data standards in a spreadsheet, but they were very inclusive in terms of representation across the development organization, meeting regularly communicating the standards regularly, utilizing the standards at the start of every new clinical trial, and all of this with management support. In the course of our ongoing data governance work with them, the team itself identified this as one of the most significant points of evidence of management commitment to high quality data. So this seems like a no brainer for others to emulate. Pretty straightforward, simple, but big payback. So thanks again for the time today. I appreciated talking on this topic.

**Kevin:** I enjoyed it as well and it certainly won't be the last time we talk about it. Susan, would love to have some of your insights to wrap us up as well.

**Susan:** I would just say it's really important to keep in mind that data governance is not the end game, but it's a means to get to a data driven business.

Well managed and governed data, allows for the application of all sorts of emerging technologies which we didn't mention before. Things like data analytic, data sciences, adaptive artificial intelligence systems, and application of machine learning. It's easier to do that with consistent data where you can apply training datasets, and so on and so on. Our data is being leveraged in so many more ways these days, more than ever before, to offer secondary and tertiary insights into drug development, disease models, patient insights etc., etc. But none of it happens as effectively unless we manage and govern our data responsibly and work to drive towards FAIR data practices; and I'll echo Bob in thanking you Kevin for allowing us to talk about this today.

**Kevin:** It's been a pleasure and again today's session was Episode 5, April 2022, Blueprint for Building a Better Data Governance Framework. Our discussion was largely based on a data governance white paper, Data Governance Myths and a Foundation for Success, that was recently distributed by ResultWorks and Astrix. I want to thank you for joining us for this episode on Astrix Podcast Productions Digital Transformation Series. Again, my name is Kevin Miller and we wish you a great day.



## Additional Details

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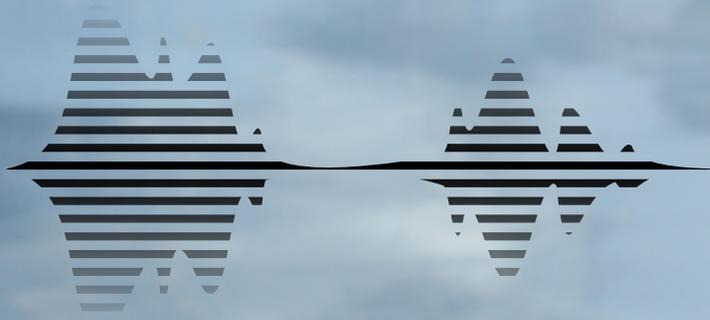
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For over 25 years, Astrix has been a market-leader in delivering innovative solutions through world class people, process, and technology that fundamentally improves scientific outcomes and quality of life everywhere. Founded by scientists to solve 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. ResultWorks, an Astrix business, achieves success for our clients through skilled facilitation and exceptional management leadership across Life Science domains from Research, Non-Clinical & Clinical Development, Regulatory Affairs, to Safety, Manufacturing, and Pharmacovigilance. To learn more about how ResultWorks enables biopharmaceutical leaders' success, visit [www.resultworkslc.com](http://www.resultworkslc.com).

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