



THE ASTRIX DIGITAL TRANSFORMATION PODCAST SERIES

# Next-Level Digital Transformation: Reimagining What's Possible

Program #3: February 2022



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A conversation with Dave Dorsett, Principal Software Architect, Astrix

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The Astrix Digital Transformation Podcast Series presents thought leaders and their unique insights into enabling success in your scientific operations. Here's the transcript of this week's program.



## About this Program:

Everyone pursues digital transformation but many fail to fully realize its potential. Why is this? More urgently, though, what can you do to avoid both the buyer's remorse and frustration that follows so many efforts at modernization via automation? Dave Dorset, Astrix Principal Software Architect, has some valuable insights from his time on both sides of the client-consultant table. You're going to want to hear his insights on ways to ensure your digital transformation initiative delivers the changes you envision in your organization.

**Kevin:** I want to welcome everybody to the Astrix digital transformation podcast series. These are interviews with thought leaders and experts on developing a successful digital first strategy for transforming life science R&D.

My name is Kevin Miller. I'm going to be your host for today's podcast and thank you very much for listening in. Before we get into the topic of course I want to introduce our speaker for today. Our topic is going to be next level digital transformation, which is reimagining what is possible. To get us started on a very timely topic, I'd like to introduce our speaker Dave Dorsett, who's a principal software architect with Astrix.

I've done a lot of programs and webinars with Dave, so we're thrilled to have him today. He is a very experienced leader in the R&D field, especially R&D informatics, he's led global digital transformation initiatives that drive critical data science strategies to improve overall life science R&D from early research through product development, scale up, and manufacturing. Dave, thanks so much for joining us today. If you want to, take a few moments and tell us a little bit more about yourself and what you're going to do today.



**Dave:** Sure, well thank you very much for having me. I appreciate the opportunity to speak with you today. So, as you mentioned before, I've been around this industry—life sciences, chemical manufacturing, consumer products, for quite a while. I've been on the vendor side of things producing software commercial software for R&D laboratories. I've been on the customer side as well. I worked at a large pharmaceutical company for about 10 years, and last 5 years or so, I've been doing consulting work. So, helping small companies and large companies with various strategic problems like how best to spend your money from an informatics perspective based upon where you sort of are as a company and your R&D strategy up through large digital transformation efforts as well. So, I'm very pleased to be here today and thank you very much for the invitation.

**Kevin:** Great, and like I said I've had an opportunity to speak with you on webinars—those tend to be a little bit more passive. Now we get a chance to kind of chat back and forth, which I'm excited about and thank you for making the trek down from beautiful Vermont. We're glad you get a little bit of warmer weather, which is Philadelphia in January.

So, obviously we're excited to hear more about how to

bring digital transformation to the next level. Many companies are obviously thinking about this right now or are involved in one level or another with digital transformation. It's a big term. It encompasses a lot of stuff, and you know for science-based businesses, regardless of whatever their vision is of the future, or what products they're trying to bring to market, digital transformation is going to be a part of it one way or the other. With digital transformation and putting data in the cloud or what have you, data integrity obviously is going to come into play, right? So, let's kick it off with this question. How can organizations ensure data integrity and compliance is preserved during what is a highly disruptive process of digital transformation?

**Dave:** I think from my perspective at least in the digital transformation realm, as you say, it's a very popular topic of today and the last five years or so. With these programs, I look at the aspects of data integrity with it—not as an opportunity to preserve data integrity, but actually improve data integrity as part of as part of these efforts.

Digital transformation in its purest sense of the word is transformative—if you believe the words. And in that sense, it's going to be disruptive!



There's pretty much no way around that. It is generally disruptive more in a cultural sense from an R&D organization perspective than it is in any technical sense, and in fact, the biggest challenges of digital transformation programs are cultural in nature. It's changing the way that people think and work together as groups, units, departments and teams, etc. Really, the aspects of data integrity is applied to it. They're the core fundamentals of what we consider data integrity. ALCOA or FAIR types of acronyms aren't in conflict with digital transformation, in fact at all. They're necessary but not sufficient in some ways.

Part of the effort is really understanding that as you go through this journey of digital transformation, maintaining and enhancing your data integrity along the way is important, not just from a regulatory perspective or all the reasons that we're used to talking about data integrity, but in fact from a scientific perspective.

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Guarding the provenance of your data, guarding the completeness and accuracy of your data, and moving forward is actually a critical part of a successful digital transformation exercise. So, to me, it's not about just preserving data integrity, it's actually an opportunity to improve your data integrity in scientifically meaningful ways along with of course maintaining the regulatory aspects of it as well.

Kevin: So, that's an interesting thing you said—a couple of points that maybe I wanted to drill down on. Inter departments, you might have departments that historically don't talk to each other much, but once they start to go through the transformation process, do they have to start kind of bumping up against each other and then they have to figure out how one person's data interacts with another person? Maybe they didn't have to think about that before?

Dave: That's very much the most fundamental part of digital transformation. Guiding the principles of a digital transformation is really looking at how is the data actually being used. We're used to building our systems and we're used to approaching R&D informatics from the perspective of how we create data, and building our systems around capturing that data, which again is a very important part of things. Certainly, to data integrity



aspects, but it's not sufficient from a transformative point of view. To truly transform, you actually have to look at who's using your data. It's not about you, the creator of the data, the designer of the experiment, the guy at the bench executing, capturing the results, doing all that, which is the classic way we look at informatics in an R&D setting.

It's really getting out of your shoes, getting out of your box, and going down the hall, finding out who's actually looking at your experiments and what are they looking at and what are they actually using. That's part of the cultural aspect of these transformations, really coming out of the mindset of capturing all of the data, you know, that you produce day in and day out and really starting to focus on who's using it for what purpose and how can we make that consumption of the data actually better and improve the integrity from the point of view of the person consuming the data. What aspects of the data might they need or want, to better understand it, to better believe that it's complete and accurate and relevant to the problem set that they're actually looking at.

Kevin: Great, and those are awesome insights. Taking that a step further, you kind of start to think about what does this 'lab of the future' look like? Obviously, people

are trying to get to that. It's a popular buzzword, 'digitally connected lab'—you know, all these terms associated with digital transformation. When you delve a little bit further, it generally means that the lab will be off-paper. Laboratory systems will no longer be siloed. Departments will be digitally connected to each other and the tasks that will be considered manual have the potential to be automated. That's the common perception of what the end result of digital transformation is.

Would you agree, however, that throughout the course of planning and digital transformation, that the opportunity to wipe the slate clean, so to speak, and completely reinvent the way your lab operates. I mean, is that is that a fair assessment?

*"It is definitely an opportunity to sort of put aside some of the assumptions that have existed in the way that your environments are created, how you're managing and communicating your data, and the way your teams are working together across functions and disciplines. Look at it basically with a clean slate."*



**Dave:** Absolutely! It's certainly an opportunity if you truly, again, buy into the transformation part of digital transformation, right? It is definitely an opportunity to sort of put aside some of the assumptions that have existed in the way that your environments are created, how you're managing and communicating your data, and the way your teams are working together across functions and disciplines. Look at it basically with a clean slate. In that sense, that's the type of thing that is really driving people's interest in a transformation.

The way we've been doing things, it's not that it hasn't been successful of course, as an industry. But the general thought is that it could clearly be better. So, let's rethink exactly how we manage the process from discovery to product. How we manage that process of taking something that is a new idea, a new compound or a new therapeutic of some form in the pharmaceutical industry and actually making it all the way out to the patient itself. How do we re-look at that process in way while still maintaining the critical regulatory compliance aspects of course in all that. But how do we as scientists rethink how we work with each other—that's the critical part of the digital transformation.

**Kevin:** That's a great point, very topical. Are there any

particularly effective ways that people could reimagine workflows? So, an example might be to integrate compliance with the overall R&D data flow during a digital transformation program, right?

**Dave:** So, again, looking holistically at things is part of the key. One thing that's challenging in speaking about this is every company is a little different. I mentioned before the importance of culture and the impact of culture in the overall digital transformation programs. Because of the importance of culture, there's not like a handbook. You can't go buy a handbook and say follow the checklist and you will be digitally transformed. There's a lot of cultural aspects to it that you really have to pay attention to.

**Kevin:** You can't just do a YouTube video on it and figure that out?

**Dave:** Right, or can't Google it and be happy with what you're going to find out. Find meaningful, practical things, certainly. I guess that's one of the things that's really key to me in what I do—the practical things. I want to actually see things change as a result of this. Not transformation in name, but transformation in terms of what happens in the actual process itself. So, it is that opportunity to look holistically, you



know, step out of the position of just improving what you're doing that moment in that lab, right? Not just focusing on bringing in a system to automate a specific set of experiments or do better data capture on that specific set of experiments but really look at it in the bigger picture point of view. And from a transformation point of view, that holistic viewpoint is really the best place to be.

That means, again, back to culture—that doing this requires high level support. You're going to fundamentally be looking at the relationships between organizations and teams in an R&D setting, and you can't do that entirely sort of bottoms up from the point of view of the individual scientists. You really also need to have strong management support to look at these questions, because they it does raise tough questions about how companies are actually performing the work.

Kevin: Definitely, and of course, you know when you get into these discussions about large-scale transformation of how companies operate, on one side of the fence you've got culture and processes. And then on the other side of the fence you've got technology, which can oftentimes be one of the drivers, and there's no discussion of digital transformation in life sciences

without the discussion of data science, artificial intelligence, machine learning, where do these pieces fit in? Are people just chasing the next buzzword of tech or are they appropriately incorporating these new technologies into their workflows? Do they not fully understand them yet? You know, what are some ways that they can incorporate these in intelligent ways they can actually use them without just going out and buying technology that might sit on the shelf?

Dave: That's a very fair question. There certainly is an amount of buzzword happiness in this. The phrase digital transformation itself is in fact a buzzword—AI, ML, unsupervised learning and all these things. The industry has been through this many times. I've been through this many times over the decades. I've been working in this industry and you know the latest set of buzzwords, right, and how that's going to radically change things. So, there is an element of that, but I think the other thing that's different right now, and every time frame, every change essentially that we've gone through in the environment in the R&D world has taken advantage of certain aspects of technology that have clearly evolved over time.

From a technical point of view, the current technologies around data capture, data storage and use of data,





whether that be from a direct point of view, tools like visualization and all that, or from the machine point of view of using it for AI and ML and doing unsupervised learning and that, technology has advanced remarkably. Every day we're now our phones, we're faced with image recognition that's far beyond what we would have expected even years ago. Walk into a store holding your phone up to something and you can get immediate feedback about where you can buy that item cheaper within your locality or order it online, etc., so there is a practical aspect of being able to use those technologies in an R&D environment, absolutely. And that's a reasonable goal for digital transformation programs.

But to use those technologies effectively, there's a number of steps that you actually have to go through in order to be able to get to that point. My concern is sometimes we overlook the prerequisites to getting to that point to being able to use unsupervised learning, for example, and those types of things on our data. The data itself has to be ready to be used in that particular way. And the big part of digital transformation is all the homework that's actually required to get data into a format, into a structure, not so much a technical format, but actually a structure and contextualized in

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the right kind of way that people can use it beyond the person who created the data.

That's one of the bigger challenges as a scientist working in a laboratory designing an experiment, executing an experiment. You're holding in your head a tremendous amount of context for why you did the experiment and how to interpret the results that have actually come out of that, and we are still working through the process of how to actually capture that kind of context and communicate that to other people that can then use our data. That's a critical part of the cultural aspect that I was talking about before.



When I talked about the idea of going to find people who are trying to use your data and ask them what they're trying to do with it, and what's their frustration points with it, and were they able to use it successfully? That's the kind of feedback loop that can help you understand the missing pieces of context that needs to be augmented and captured for that data to be useful. Reviewing that person-to-person is as effective as a tool as being able to treat that data with machine technologies. The same kinds of gaps that a machine is going to find in being able to properly interpret the data to use it in an AI/ML kind of sense, people are going to find those same gaps for you. So, this whole process of digital transformation can be viewed people to people, but clearly can also be viewed as making data more useful for machines as well. I think the two are inherently linked to each other that way.

**Kevin:** I guess like the age-old thing like you can have a conversation with someone and understand the context but if they send you a text and you don't have context behind the little sentence of that, you can misconstrue it. You don't know what it means or you can take things out of context, so context is certainly important and that cultural aspect it plays a big role.

So, tech, all the data, all the new methods for

processing data, all the new advanced learning technologies, etc., how do these practically play a role in data integrity, you know as we kind of get to the end of this digital transformation? Of course, you've got the cultural aspect of it, the executive sponsorship has to say "okay, we're going to do this," the interdepartmental connections that have to be made that maybe didn't exist before. All these different pieces leading up to the capture of good data so that you can feed these systems. Once these systems are doing their thing, do you have some experience or some thoughts on how that helps with the compliance and the data integrity piece?

**Dave:** I think what's important here is that there are two different ways to look at data integrity—at least two different ways to look at data integrity, but two main ways I try to think about it. So, one is from the compliance point of view. So, what you need from a regulator's point of view to ensure the integrity of your data—the meaningfulness of it, there's a number of technical aspects, if you will, that need to be incorporated into your thinking and into your programs, basically. So, you need to make sure that you're appropriately tracking the provenance of your data and that you have made appropriate allocations in your system sense for where did this data come from, where



did it go, how do we know it is the same that it was when it was actually created and came off the original instrument, etc.

So, there's a number of very technical things that become requirements, effectively, in the program itself as you decide what data flows you're actually going to use. So that's one important aspect of data integrity and that's more formulaic in some ways, right? You should be able at the end of that to assert that type of data integrity. Prove that type of data integrity by the way that you've constructed your systems, and the relationships between the systems.

The other type of data integrity is from a scientific point of view. As a scientist, and that's another layer right on top of this, I want to know that the data hasn't been changed, that the data is complete, that it's accurate. All the things that we would normally sort of check off against ALCOA+, or other sorts of notions of data integrity. In addition to that, I need those other pieces of context as a scientist for that type of definition of data integrity.

I truly think that these programs that were that we're embarking on now, this decade if you will, of improvement on laboratory data management and the

use of digital transformation, is not just an opportunity to improve the regulatory type of data integrity, but also the scientific type of data integrity and make our data more useful to other scientists. That's always been a critical struggle in science. You know scientists never like to throw away data, right? We keep everything—the ultimate pack rats from a data perspective. But you know, to people other than the person who's created it, that data has always struggled to have usefulness. I think that approaching data integrity from that point of view, layering on top of the compliance and the regulatory definition of data integrity, to reach for those types of goals is really the opportunity with these kinds of programs.

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**Kevin:** It's great to hear a scientist talk about these types of projects because that's one of the things that has been a hallmark of Astrix. We hire scientists, and our scientists are the people who go in and work with customers to drive these projects forward. So, people who've been on the bench, and people who've done this—it's a unique thing with how Astrix deploys folks to help with these digital transformations.

It's an exciting time I think for life science. There's a flurry of new technologies and there's a realization that you have to come off paper, and we've got to really use this data to drive forth these products into the market and make people you know feel better, hopefully. So, leave us off with a couple of thoughts—round us out and then we'll wrap up.

**Dave:** Sure, so just building on something there in your response, I think all too often we view digital transformation programs as technology projects and that's not the true nature of this right? I practice science vicariously, right, to be clear. I mean I don't do science anymore. I was trained as a scientist, but now I get to, basically, apply the technology of IT to science, and be around the science essentially in that sort of sense, which is where I get a lot of my motivation and energy from. But the technology aspect of things is

really at most secondary, maybe even tertiary in these types of transformative programs.

All too often, one of the traps I see people falling into around these programs is really viewing it as an opportunity to do very specific system-oriented kinds of things and being too fixated on the “I've got this cool technology let me go find a problem that I can apply it to” mindset. What I advocate in terms of the digital transformation side of things is really to look at it from the scientist point of view, from the people point of view.

So, it's not that systems and technology aren't important and clearly at the end of the day you're going to want to implement things, right? At the end of the day, it has to be realizable. There is a very important technology and you know aspects of choosing the right technology, making sure it's scalable and all those all those kinds of things, performance, etc. But, really, the start and the driving forces in a digital transformation exercise are about the scientists—the scientist level of things. So, I guess one word of encouragement I would have for people is don't just think of it as another system implementation, pick your three-letter acronym—ELN, LIMS, whatever. It's not another implementation of another system like that. It's not an upgrade of those



systems. It's really got to be a whole way of thinking about things that's different from the way we've been doing things traditionally.

*"What I advocate in terms of the digital transformation side of things is really to look at it from the scientist point of view, from the people point of view."*

Kevin: It's always a great time to listen to you talk, Dave, and hear your thoughts on these things. As I said, it's an interesting and compelling time in life science with such a wave of technological innovation and pushing forward off of paper onto digital. So, thank you for making a trip down. It's always great to work with you. Thank you all for listening and downloading the podcast today. Stay tuned as there are plenty more podcasts coming as part of the series in the future.

Again, my name is Kevin Miller, we're with Astrix and this was our digital transformation podcast. Dave, thank you very much.

Dave: Thank you very much and thanks everybody for listening. Hopefully you've got a few things to take away for thought material. That would be my goal.

Kevin: Thanks everybody, appreciate it!

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### About Astrix

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