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DRIVING DIGITAL IN BIOPHARMA EDDIE REILLY OF SANOFI

AUDIO TRANSCRIPT

Stinger: "You're listening to Driving Digital in Biopharma. Your host is Tom Lehmann."

Pull Quote: One of the main benefits of digital is actually using the power of digital to mine information, that you may not have been able to mine in a manual manner. So using some artificial intelligence, using different algorithms to get different parts of information that are there, but are just it's too complicated for the human brain to manually pick this up.

So using and overlaying some algorithms on this is absolutely key. In order to do that, we need to make sure that we have our data standards correct, and for that to work at a global level, that needs to be standardized across the industry and with the regulators as well. And that's where things like IDMP, but not only really play a very important role.

Introduction: Hello and welcome to this episode of Driving Digital in BioPharma. I'm your host, Tom Lehmann. In this episode, we continue our podcast series by exploring the role that data is playing in the transformation of regulatory affairs within the biopharma industry.

Joining me for this conversation is Sanofi's Chief Regulatory Officer Eddie Reilley. Eddie, welcome to Driving Digital in Bio Pharma.

Eddie Reilly: I'm glad to be here, Tom.

Tom Lehmann: Would you mind introducing yourself and sharing your background with our listeners?

Eddie Reilly: Yes, sure, Tom. So as you said, my name is Eddie Reilly. I'm the chief regulatory officer and head of global regulatory affairs at Sanofi, which is one of the leading biopharmaceutical companies.

Tom Lehmann: Excellent. And tell me a little bit about your journey to get to the current role that you're in.

Eddie Reilly: So I am coming to you from France, coming to you from Paris, but as you can gather from my accent and indeed my name, I'm not a native French person. So I'm Irish by nationality, I'm a pharmacist by training. I've worked in the pharmaceutical industry for maybe a little bit longer than I'd like to mention. Working in many different areas, including with the health authority.

So I worked as a regulatory assessor with, what was then known as the Irish Medicines Board in Ireland or the HPRA as it's now known. And I've been with Sanofi for the last seven years, and heading up the global regulatory affairs organization for the past two years.

Tom Lehmann: And I'd imagine in your time in the industry, you've seen digital as a concept and an area focus evolve, certainly to the point we're at today. So why don't we maybe just start with your perspective on a few things.

So the concept of digital or that area of focus is pretty broad. Maybe start about how you think about digital and its application to regulatory, since you spent your career in the regulatory space.

Eddie Reilly: Yes Tom, and indeed, digital is a very broad term as well. And it means different things to different people. Usually, when I think of digital, I also think of data—and in fact data being the most powerful part. Digital, whether it's using artificial intelligence or using digital to present your structuring data, really allows us to use data in a better way and data is incredibly important for making decisions.

Digital can also mean streamlining processes. So whether that's robotic process automation, or indeed, using natural language processing for automated reports, and R&D translations, it can really also simplify our life. But digital also can be used in how we share information. So the interoperability of data, and whether that's sharing the data internally or an information internally or externally.

I really see this as being really the art of the possible, because the applications of digital can go from something very basic, to automate something, through to really unleashing the power of data, and really also finding that data and data-mining as well.

Tom Lehmann: And so if you look at your journey at Sanofi, where are you on that journey?

Eddie Reilly: Well, I suppose it's like all journeys. It's also a little bit about getting prepared and being set up for success. So within Sanofi, we have spent a lot of time in equipping ourselves with tools systems and processes, and really taking the approach of simplifying our end-to-end processes, standardizing those processes so that we can then digitalize them.

Sanofi like a lot of companies is a very large broad global company with many different processes behind it, and has grown up through also an amalgamation of different acquisitions etc. So one of the real drives forward is simplification and standardization, and therefore, then overlaying digital on top of that.

So we've invested a lot in getting our digital platforms correct. So moving a lot of our data and documentation into the cloud, simplifying also some of our end-to-end processes and standardizing them at a global level, and then seeing where we can apply some digital solutions, to really reduce a lot of the workload, a lot of the manual manipulation of what we do. Streamlining that so that we can spend more time on more of the strategic elements of global regulatory affairs.

As you'd highlighted, I spent a lot of my career in regulatory affairs, and regulatory is such a key role in the company that interface with the health authorities, that partnership with the health authorities as well, and creating that conduit between the company and the authorities. So I really see digital as an enabler to allow regulatory professionals operate at the highest possible level.

Tom Lehmann: And have you found that the regulatory function is on the leading edge, a fast follower, well behind some of the other functions? What's your experience been as you look not only just within your organization, but even across the industry and in the application of the potential of digital?

Eddie Reilly: I think in a regulated industry like the pharmaceutical industry, perhaps digital has not been embraced as much as in some other industries like the banking industry comes to mind. So if we all think of how we manage our personal finances, that has changed dramatically over the years, everyone is now doing online banking on their phones.

The pharmaceutical industry is moving towards really taking the full advantage of digital, but is a little bit more cautious, I would say, than maybe some of the other industries. Regulatory affairs

itself, I think has a very important role to play within a company in showing the way, showing what is the art of the possible, what can be done there, and also liaising and partnering with the health authorities and finding that common path forward.

Again, when you look at the pharmaceutical industry, one of the most important stakeholders is indeed the regulators. So looking at how we can have those global standards, and what different bodies the role, they would play in creating those global standards for the broader pharmaceutical industry is key. And regulatory being at that interface is a very key enabler for companies, and for the pharmaceutical industry as a whole.

Tom Lehmann: And are you now seeing the health authorities move along at a similar pace to what Biopharma organizations are doing?

Eddie Reilly: I think yes, I see that there is an appetite for that. It's a little bit like building a plane and flying it at the same time, because obviously, the rhythm of work, the amount of information, the amount of data that needs to be analyzed, shared, is continuously increasing. So it's really like building the plane as you're flying it. But there is an appetite across, with the health authorities as well, in creating that future state.

Acumulus Synergy, and I don't know Tom, if you're familiar, the listeners are familiar with Acumulus Synergy. But Acumulus Synergy is a very good example of that. Acumulus Synergy is a company that has been set up perhaps two years ago now, and is sponsored by 11 of the large pharmaceutical companies to create that future paradigm with the health authorities. So partnering with the health authorities in really looking at data exchange, looking at how we can really change the paradigm of submissions with health authorities, data exchange with health authorities, to speed up that review process with the ultimate goal of providing medicines, life-changing medicines to patients faster and more efficiently.

Tom Lehmann: What's your sense of what the industry needs to really embrace that type of a collaboration, and really come together to push that forward? Because those seem like really good positive potential outcomes. But what does the industry need to do to really come together around that?

Eddie Reilly: I think the industry is already doing a lot in it. I mentioned standards at the start, and I think it all starts with standards as well. So as we're developing new standards across the industry, so that we're calling everything by the same name, so that we can then use that interoperability and make those connections across those large data sets is absolutely key.

IDMP is a very good example of that. So for your listeners and for those who don't know what IDMP is, IDMP is the identification of medicinal products. And it's a suite or a series of five standards developed within the international organization of standardization, so the ISO standards and I think most people are familiar with ISO standards. And that's really to facilitate the unique identification of medicinal products, so of medicines. Mainly in the context of pharmacovigilance and the safety of medications throughout the world.

These standards that have been set up provide an international framework to uniquely identify and describe the products with consistent documentation and terminologies, as well as to ensure the exchange of product information between global regulators, manufacturers, suppliers and distributors. So getting those standards, getting that common language set up is a key enabler for really unleashing the power that there is between digital and data utilization and maximization.

Tom Lehmann: So let's just stay on IDMP for a moment. It's been pursued in various forms over the last several years. What's different this time or at this point in time, to really drive that forward?

Eddie Reilly: I think there's a realization happening of the real value behind this. So as you say, it's been pursued in different forms over many years. But really, now as it's come together with design the suite of ISO standards, and its adoption by the different global regulators as well, perhaps European Medicines Agency leading the way on this. There is a realization that really to maximize the benefit of digital and data, that there is a need for this standardization.

So it is a lot of work, it will be a huge amount of investment, because maybe we need to restructure how we talk about our products, how we categorize things, how we describe things. But getting those standards right, getting the foundations right, is absolutely key.

We've seen some of the implementation dates of this slip with the regulators as well, because obviously, the regulators need to be set up for this as well, it's not only the industry. But there is a realization across all the different stakeholders that this is something that really needs to happen.

Tom Lehmann: And I'm curious, if you look at IDMP within the context of Biopharma organizations—let's assume it will move forward as you just described—this isn't just about the regulatory function, there's other areas that will benefit from this as well. How do you see that playing out?

Eddie Reilly: Yes, absolutely. I think it comes to, first of all, acknowledgement within companies of the need for very clear master data management. So again, within a company or within the industry, being very deliberate and standard as to what where we call different elements, so that we have the same building blocks across companies.

I think that in the end will allow us to really maximize the value of all the data that exists out there. We mentioned at the very start about you know the term digital and what does it mean. One of the main benefits of digital is actually using the power of digital to mine information, that you may not have been able to mine in a manual manner. So using some artificial intelligence, using different algorithms to get different parts of information that are there, but are just it's too complicated for the human brain to manually pick this up. So using and overlaying some algorithms on this is absolutely key.

In order to do that, we need to make sure that we have our data standards correct, and for that to work at a global level, that needs to be standardized across the industry and with the regulators as well. And that's where things like IDMP, but not only really play a very important role.

Tom Lehmann: And do you also see other parts of the, of just say of your organization benefiting from that as well? Whether that's within the supply chain and manufacturing, or broader with the CMC space. What's your sense on the other parts within the organization that would also benefit from this?

Eddie Reilly: Yes, absolutely. You bring up supply chain as an example, and I think supply chain is absolutely critical for things like this. We all know that the paradigm of supply chain is evolving, it has been globalized over the past several years, and in the current geopolitical circumstances, supply chains are under a lot of strain as well. So anything that helps us stabilize and standardize our supply chain, how we look at materials, how we can strengthen that whole end-to-end process is absolutely key. And this would be a factor in strengthening, not the only factor, obviously, but a key factor of also in strengthening that.

Tom Lehmann: Okay. Let me come back to maybe a different topic here around just you mentioned data mining, and you've mentioned now just data being the most powerful part here. And if I connect the parts of the conversation, standards being an absolute critical part of master data management as you just mentioned. Let's talk a little bit about just the power of data within regulatory.

So, can you give me some examples of just mentioned data mining. How would you use data within regulatory to again answer questions that you can't answer today easily or just business problems you're trying to solve? Maybe a couple of examples would be helpful.

Eddie Reilly: So as you said, Tom, absolutely, there's huge value in data and the use of artificial intelligence to mine data is absolutely key moving forward. For large pharmaceutical companies, that may deal with over a different hundred regulators across the world, and on its portfolio, it's very important and it's of a huge benefit to be able to join the dots and for different parts of information that are being requested by different regulators. So that we can build that proactively into our dossiers, and strengthen the information behind the products.

Obviously, also, if you look at trending and signal detection in pharmacovigilance, that also becomes incredibly important as well, and it really strengthens our understanding of real use of data as well. And you know that real world data, and real-world evidence is very much an evolving area as well. And the more that we can use data for that indeed, the general use of drugs, the more we understand behind our drugs as well. And that is the benefit for patients in the long run.

And looking at how we can also generate data. So if I think of wearables, I think a lot of your listeners might be wearing smart watches etc. which are collecting a lot of data, telling you how many steps you're moving, or telling you how fit you are, or how fit you're not, or how fit you should be. How we collect all of that data as well, and use that to augment our understanding is critically important.

And that in the regulatory affairs world becomes really important, because we need to ensure that data is of use, that it doesn't have biases, etc. And if we use that for any regulatory purposes, we need to ensure that data is very strong and very robust and without biases as well.

And that whole area of connected health becomes incredibly important I think as we move forward. It's really information beyond the pill, so information beyond the drug itself, but really its use in real world, and how we can use that to augment our understanding as well.

Tom Lehmann: And how are those areas changing the day-to-day for regulatory professionals? You've mentioned real world data and connected devices and digital health. Certainly, this is creating change in the clinical function within a bio-pharma organization. What's the impact for a regulatory function?

Eddie Reilly: Yes. I think the impact for a regulatory function is really that the regulatory function needs to really think about what's the future of the regulatory paradigm moving forward. We speak a lot about different processes, different requirements, looking at regulatory intelligence, looking at the rules in different countries etc.

I see that as obviously being incredibly important moving forward, but not that it really needs to be on the top of everyone's mind. Because if you think of Amazon's Alexa or something, you know you'll be able to ask and get information very quickly. We're all able to get information very quickly about what are the rules and regulations.

But really looking at the regulatory professional, it's really about the implementation and interpretation of those rules, that partnership with the health authority moving forward, so that we can take this changing, evolving environment and build something that is of benefit for patients moving forward. And what I had mentioned with respect to connected health, wearables etc. is very much an evolving area for the regulators as well. There are different rules in place for example, software as a medical device, but perhaps, that needs to continuously evolve as well. And we've seen the FDA recently launched a new center for virtual health as well.

So we need to continue to partner, and that's the role of the regulatory professional, to partner with the health authorities in creating the framework that's fit for purpose.

Tom Lehmann: And I'd suspect you're seeing a very different level of evolution depending on where you are around the globe? So you mentioned working with over 100 health authorities—that process, that evolution needs to be kept track of depending on where you are across the globe.

Eddie Reilly: Yes, absolutely. And bodies like ICH etc. are very important in kind of creating those standards, and bringing the different health authorities and bringing that alignment. I think one of the challenges that there are at the moment is to have a fit for purpose frameworks that evolve fast enough to match the fast-evolving technology evolution that there is.

There's still some work to happen there. But I've seen, and I continually see that there is an appetite with the regulators, to understand what's happening at a global level, to collaborate with one another as well. I think there's a lot of forums and collaboration across the global regulators network.

I think that's a very important evolution, because we really do need in this globalized world, in this global village, we need to ensure that the regulators are speaking to one another, and also learning from one another as well.

And then also, that important partnership that I mentioned at the start between the industry and the regulators as well is key, so that there's this common understanding, and that we create this framework that is that is fit for future.

Tom Lehmann: Connect for me then if you will, where does digital, perhaps as an augmentation to regulatory intelligence fit alongside all of these things, right? So you have sort of evolving demands placed on a regulatory function with some of the things we've just talked about. You have more collaboration with the industry and health authorities. You have health authorities perhaps getting more aligned in the way that they connect with each other. Regulatory intelligence I would imagine then connects the dots across all of these.

But what role does digital play in that space? Historically, obviously it's been very much about the depth of knowledge of an individual, versus having technology to help augment that. What are you seeing as the opportunity there?

Eddie Reilly: Yes, I think it's a used term opportunity, I really do see it as an opportunity. Digital, I see is an instrument or an enabler to really go to the next level. So as you said in the previous paradigm, or the previous world, it was around the depth of someone's knowledge, both on the technical side, but then very much on how you interpret that data and your experience there.

That interpretation application experience is still incredibly important or it is incredibly important. But one of the advantages of using those augmented solutions for providing the rules, the regulations, etc. are key. And I really encourage any regulatory professionals out there to be curious about the power of data or of digital as well, and how digital can serve you.

One of the misconceptionsand that's also due to how some of these solutions have been put into placeis that sometimes it can feel as if we're a slave to digital, rather than digital serving us. So for those of us who are a little bit older, sometimes digital can feel like a great unknown, and okay, we're not as digitally savvy perhaps as the younger generation, but I would ask people to be curious and really to understand how we can use digital to help us and then overlay that regulatory acumen over that. Both for interpreting what we need for today, but very importantly, for building what is needed for tomorrow.

Tom Lehmann: What's your sense on the talent side are digital natives existing within regulatory

organizations, or are you creating that digital talent for the future?

Eddie Reilly: It's a great question. I always look at this as being a little bit bilingual. So you have your people who are very fluent on the digital side, and then you have people who are very fluent on the regulatory side, the regulatory sciences. As we move forward, it's really important that we have bilingual people, so people who really understand what is needed from a regulatory side. Understand the importance of creating frameworks that really deliver safe and effective medicines to people. But then, how really to use digital in order to strengthen that.

So you need to have that curiosity, you need to create a little bit of that bilingualism. I see it as a journey. Tom, a little while ago, you use the term journey, I do see that as a journey. I think that as we look at the next generation of regulatory professionals, it's really important that we spend time.

We, as in the older regulatory generation, spend time with the younger generation coming through in regulatory, and focus on the regulatory acumen that has been built up more from an application point of view, an interpretation point of view, that partnership with the regulators, looking at that ultimate goal of having more efficient system for managing medicinal products, whether that be in development or very importantly also on the market as well. How to get products to the market in the most efficient manner. How that fits in with access as well, and what are the data sources that allow you create that value for patients.

I think that is absolutely key, but I think that people who are more savvy on the digital side is really looking at the art of the possible, and understanding how you can use tools in order to reinforce that. And that combination I really see as being the future of the regulatory professional.

And I see that culminating in a very strong partnership with the regulators and indeed, other stakeholders as well. Because regulatory really fits at that interface between the regulators and the company. We're in a very unique position in any pharmaceutical company to connect with all parts of the company, be that interface with the regulators and indeed other stakeholders as well.

And therefore, it is on us to also ensure that we use all of the tools that are there, that we help develop that new framework, and that will be so important for the future to maximize and to harness the value that data and digital will bring—that data and digital are already bringing, but will bring even more in the future.

I use the term data and digital on purpose, because as I mentioned at the start, and I usually speak about data or think of digital, data always comes to my mind first, because that is really where the power is.

Tom Lehmann: So if you think a little bit about the value, you mentioned a couple times, and there's different ways to assess that, and obviously you've been on a journey as we've talked about here with both data and digital. How do you assess the impact of the investments that you're making, or the time you're putting into any of these initiatives?

Eddie Reilly: Yes, it's a great question, Tom. And it is really an investment. I think that one of the important elements is really to also demonstrate early on where the value is on this. Because if you're investing a lot of effort in inputting different data points into different systems, different databases, etc. If people don't see the value of that very early on, then it becomes a bit of a chore.

And one of the critical success factors is that data needs to be accurate, complete and inputted in a timely manner. And if you don't create some very quick wins, where you demonstrate to the organization the value of this,

then you start losing some momentum.

So one of the critical success factors that I see is really about understanding and demonstrating the value of this. Whether it is, you had mentioned supply chain earlier on, whether it's linked to supply chain and streamlining change control processes, or processes that control variations or changes to manufacturing processes, and then are linked to release processes in different countries due to the approval of different variations or changes... If you can demonstrate that to an organization, how some effort and investment up front can really reap the benefits later on, and build that quality up in front, rather than trying to manage everything at the tail end. I think that's a critical success factor.

And then you continue and you build off that momentum as well. But it is an investment. Not only from a solution point of view and under dollars or Euros associated with that, but also from a time point of view as well. Because in order to maximize the power and really unleash the power of data, there is an investment, and sometimes, it's also manual investment in inputting data etc. Because it's not just all automatically done, at least not yet, until you get everything joined up together. So there is an investment up front.

We spoke earlier about standardization as well, that's another critical investment as well, because if you don't get the building blocks correct, then you will be missing some connections that there is in the data, and therefore, you will not capture the real power behind the data as well. But making some of that very visible within an organization, and demonstrating the impact of data and digital is really important.

So as we said at the start about digital, some of it is easy to explain: natural language processing, automated reports, or looking at automated translations as well. It's very easy for people to see where the value is there, that's clear. So you simplify, you standardize and you digitalize processes, I think that's clear for everyone.

Where the additional value, and I would argue probably the biggest value is on the data side. So how do we use digital to unleash the power of that data? And that's the key element. So that standardization is very important across the industry, but also with the regulators.

Using the digital and digital solutions to either mine that data or structure that data, or use algorithms or artificial intelligence in order to create some additional insights that you may not have had before, that then really increases the value of your portfolio, of your understanding of your portfolio and ways of doing things differently perhaps as well, with the end goal of getting medicines to patients quicker.

Tom Lehmann: What's your sense as you look at the future here, then? So you've made a good amount of progress today putting in that technology foundation, moving towards standards, really starting to articulate the value of data. We're seeing some changes in the industry as far as level of collaboration and coordination. What's on the horizon then for the future?

Eddie Reilly: Yes. If I look at my crystal ball, which is maybe not a very digital way of looking at things.

Tom Lehmann: It's a digital crystal ball.

Eddie Reilly: It's a digital crystal ball, exactly. But if I look at my crystal ball, I think a lot of—and use the term investment area—I think a lot of investment has already happened. We look at this in a way of okay, we will increase our understanding. We spoke a little bit earlier about some automation, we looked at the value of data, we looked at connected health and wearables as well.

So generating more data also in real life

settings, so like real-world data/real-world evidence. How we're bringing the regulators and that collaboration between industry and the regulators forward, both in the use of real-world data, real-world evidence, but also data sharing. So we spoke a little bit earlier about Acumulus Synergy.

I also think that there's probably areas that we're not really aware of yet, where there's even more value as well. Because they're just the pieces that we really see at the moment. But the more that we use data, and the more that data gives us different insights, and allows us to take better decisions as well, I think that we will continue to build off that.

And that's what I'm really looking forward to for the future. It's really unleashing that power of data and digital. Again, as I said, I think that if we look to the future, a lot of manual steps that we do currently in across all departments, but I'll speak to regulatory, will be automated. Looking at natural language processing, and archiving cover letters or generating cover letters, archiving responses from health authorities. Automatically generating some responses, draft responses, then that are reviewed by subject matter experts, automating a lot of those end-to-end processes.

Looking at labeling as an example, so if you look at labeling at the moment, so you get your box, your patient information leaflet, how you can digitalize all of that. Looking at 2D barcodes or whatever the future will be on that as well. So that people have rather than a lag time of getting information into the medicines packaging, you have that information immediate.

So there's all of these possibilities, and the art of the possible really built off foundations of digital, and there built-off foundations of standardization. I think that as we move forward as an industry, we will learn more and more about what the art of the possible really is.

So if you'll have me back, I'm really looking forward to coming back in a couple of years, and maybe not even in a couple of years, in a very short time frame, to actually build off this conversation. Because I think we will see many more areas, and many more uses that will be game changing.

Tom Lehmann: We will of course have you back, Eddie. And it does feel like, it's interesting because as much progress has been made, and as we've talked about today, it does almost feel like we're just getting started. Like maybe it's that, again, this next horizon, or this next generation of what will happen. But it does feel like we said we're just getting started, there's so much still ahead of us, even though we've made great progress.

Eddie Reilly: Yes, absolutely. And that's what it is, it's a journey. We don't know really where the end is of the journey, because our understanding will continue to evolve. So yes, it's great. I've seen huge progress, huge progress, in one the acknowledgement of the value that goes well beyond efficiencies, etc. And there's all of that. But it's really around the power behind what we can learn, the power of how we can really improve our understanding and increase also our power of communicating with the regulators and providing information to end users, to patients and end users as quickly as possible. And as we move forward, I think this will only go from strength to strength.

Tom Lehmann: Yes. I think it's well said. And I think a great way for us to bring this to a close. Again, I think you're right, we're going to move from strength to strength, that you've talked a couple times around just the art of the possible. And it does feel like it's an exciting time here, not only just generally within the industry, but particularly within the function that you represent. And it's exciting to see the industry coming together, seeing the health authorities collaborating.

Again, there's quite exciting few years ahead of us, and we will absolutely have you back. So I do appreciate you joining today and really enjoyed the discussion.

Eddie Reilly: Thanks, Tom.

Tom Lehmann: A big thank you to Eddie for joining me today.

As I reflect on today's discussion, the goal of delivering new products and therapies to patients more efficiently is certainly being enabled on multiple levels by regulatory affairs organizations, from standardizing data to more efficiently exchanging data with health authorities. And now we're seeing the early stages of data mining and artificial intelligence applied to regulatory.

As momentum builds around how data is evolving today's work, Eddie did remind us that demonstrating value and quick wins to teams is important, so new data related processes aren't seen as burdensome and are more likely to become a standard way of operating.

Before I close, I'd like to leave you with three questions to consider: First, how do you and your organization determine the value of your data? Second, how can data standardization be improved within your team, your organization, and for the industry as a whole? And finally, in a data driven business, how are you ensuring that no team members are left behind?

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