TECH-DRIVEN OPERATIONS: PATIENTS, ANTIBODIES & DAISY THE AI TOOL LABS FOR THE FUTURE

AUDIO TRANSCRIPT

Tom Lehmann 00:00
Welcome to Driving Digital in Biopharma.

Áine Hanley 00:04
Thank you, Tom for this opportunity, I'm really excited to share my insights and experiences and looking forward to the conversation.

Tom Lehmann 00:11
Fantastic. So why don't we start with an introduction for our listeners with a little bit of your background and your current role?

Áine Hanley 00:20
Well, I've been in the industry about 25 plus years (I hate to say that), but throughout my career, I've been involved in all aspects of bringing medicines to patients under the umbrella of CMC functions, chemistry, manufacturing and controls. So really taking molecules from that research interface, and working across the lifecycle of process and product development and commercialization, to ultimately bring medicines through to patients.

Tom Lehmann 00:54
And where are you today? What's your current role?

Áine Hanley 00:56
So today, I'm at Vir Biotechnology here in San Francisco. My role is Chief Technology Officer, which is another name for Head of Technical Operations. And so I cover the functions, process development, manufacturing, supply chain, quality, safety. All the operational functions that come together with technology in order to bring these medicines to patients.

Tom Lehmann 01:24
All right, so maybe let's sort of big picture. So as you look at where your time in the industry, as you mentioned, you started out and worked across research and process development into the commercialization and manufacturing of products, give me a sense of where you've seen the role of technology across that lifecycle. Some of those notable points across the lifecycle where it's made an impact.

Áine Hanley 01:49
So certainly, Tom, I think the biggest advancement over the years has truly been in the data space. And you know, from those years ago, where there were volumes and volumes of data that we had to weave through, to today, where literally on the click of a button, we can access data that was historically archived in a server at a manufacturing site. Today, we can actually see that data in real time, and use that data to gain insights on, performance opportunities, improvement opportunities, but also how we can use that data to ultimately help us make our medicines more efficiently as we go forward. So it's data and also automation are the kind of two big areas that have really propelled in the last number of years in our industry. And that's not, we're not unique, and it's across the, across the board, we're seeing these improvements.

Tom Lehmann 02:51
So maybe we start with the data side of this. Given the, as you said, the volume of data that's generated, how it's used, and the insights that are derived from it, I would presume that in order to do that properly, there needs to be a thoughtful data strategy in place. How have you approached thinking about the data strategy side of it?

Áine Hanley 03:12
Certainly, Tom. And I didn't mention at the beginning, but my role here at Vir is to lead data strategy for the company. And, that's an end to end responsibility, right from the very beginning of discovery all the way through to how we deliver our medicines to patients. And so really, the key to a data strategy is understanding all the elements of data insights that are needed in order to bring all the functions and the program strategies together in order to drive innovation**.**

Áine Hanley 03:45
And so when we have all the relevant teams and functions coming together, partnering with data science, and partnering with IT, we really have a much more effective way of moving the products forward in a very efficient manner. And so that data strategy and getting alignment on the data strategy is one of the most important things in order to realize the vision, which is often, driving innovation, ensuring efficiency, and ultimately, getting to a place where we can get to our marketing authorization in a very timely manner.

Tom Lehmann 04:27
So we see sometimes people, allow me the expression, not being able to see the forest for the trees, when looking at data; that their so in the details of something so far removed from why it was generated, how it's used... How do you balance the need to understand the detail with the fact... I think you started to say... what's the business purpose? What are we trying to accomplish with this? Because I imagine there's a balancing act there.

Áine Hanley 04:51
Yeah, certainly. I think the thing that that we've done here at Vir, which has proven very effective, is understanding our corporate strategy as a whole company and understanding where we're going with that broad lens, and then ensuring that we're using data in each area in order to deliver the outcomes that we need for that year.

Áine Hanley 05:14
So it truly is, you know, starting at the widest part of the funnel, and then narrowing down. And then the participants on our teams, you have somebody who's, you know, really capable of writing an algorithm for a particular data review area, and you've got somebody who's in thinking about a regulatory filing. And when you bring these functions together, these cross functional groups together with a clear strategy, it becomes much easier to prioritize, what we need to go after first, and ultimately, you know, have alignment on our ultimate vision.

Áine Hanley 05:57
But the wood from the trees comment is very relevant, because data is nothing without the architecture, and without the transformations that are needed in order to understand data. So I always say, our data engineers are our most valuable assets with this strategy, because they're the ones that can pull this data and ensure that we're looking at it in a way that is relevant, but also insightful for the business needs that we're addressing.

Tom Lehmann 06:32
And when you go put it in practice, so as you go from just a strategy into action, you just mentioned as data engineers—and this is a critical talent component—what are some of the other challenges that you have seen as you go from strategy to action?

Áine Hanley 06:46
Well, I think I mentioned the alignment of the prioritization, talent, and the capabilities that you have is obviously very critical. And so I mentioned that our strategy goes right from the early stages of discovery and research. And so our research team are the team that actually, for many years, have used data in the bioinformatics space, in order to be able to have better understanding on our targets in discovery. And so the talent that we built in this research area has been applied then to the more operational functions. So getting the right people, getting them excited with the early discovery, early research, and then applying those skills, to the operational functions, becomes much more straightforward and seamless when you have an integrated strategy.

Áine Hanley 07:35
And so the key for us at Vir, we hired a core group, and we continue to build on that team. But we also have very strong partnerships externally, with which we can supplement the building blocks that we have, but also ensure that we're competitive, we're continuing to stay ahead in the areas that were that were focused in. So talent is really key, and retaining that talent, of course, but also developing that talent beyond their core area, into functions where they might not naturally have resided.

Tom Lehmann 08:20
So you mentioned in there external partnerships being a critical component. Maybe we'll just stay with that for a moment. Is that more on data type of partnerships? Are these development partnerships or outsourced operations? All of the above?

Áine Hanley 08:35
Well at Vir, we rely on external partners for manufacturing, for example. And on the other hand, we're sitting here in Silicon Valley, we have academic partners, or even advisors at Stanford University, at UCSF, and so it's on both ends of the spectrum, Tom. So on the one hand, we're leveraging external CMOs for manufacturing, and ensuring that we have alignment with those external partners, on what data we need and how we need to receive data is critically important. And then from an insights perspective, using the latest, you know, progress from the academic world to ensure that we're staying ahead. We recently had a KoL meeting (a key opinion leader) meeting here where we brought some key experts in from outside from different academic institutions to make sure that we're really challenging ourselves internally to be applying the most sophisticated of tools and models to the various projects that we have.

Tom Lehmann 09:47
So maybe with that in mind, could we maybe walk the R&D to manufacturing value chain, if you will, to say again, in your experience—and sounds like also in an aspect of your current role—there are a host of opportunities here, from early research all the way through medicine manufacturing. Where have you seen some of those opportunities? Whether it's things that you've seen the industry take great steps for or where you see the potential... maybe starting in your space with the design of antibodies, which is obviously core and central to your products, and then work your way forward, if you will?

Áine Hanley 10:30
Absolutely, Tom. So at Vir, we really have a fantastic team of antibody researchers, scientists, engineers. We have a team in Bellinzona, Switzerland, formerly, they were Humabs and became part of Vir at the very beginning of Vir's journey, actually. And so from an antibody perspective, we use data to help us after we have isolated key antibodies that we want to work on. Our early research was in the area of infectious disease, we're broadening that aperture right now to beyond just infectious disease and into areas including oncology. But designing those antibodies with the best characteristics for potency, for stability, for PK, is a really important aspect of the research strategy.

Áine Hanley 11:32
And antibody design allows us to ultimately understand what the patient needs, and so really align with the target product profile. At Vir, we have a tool, an AI tool called Daisy "D A I S Y" and this tool is a combination of in house models, as well as some other proprietary tools that allow us to ultimately design and fine tune the desirable MAB characteristics to get us to an antibody that has the highest potential, and allows us ultimately to accelerate the process of antibody optimization over a number of months.

Áine Hanley 12:18
So antibody optimization is maybe I will say step number one, and aligning that antibody with what's needed from a patient perspective, is a key priority. But we can do that now, at a much more accelerated pace than what we might have done, you know, two to three years ago. So literally that acceleration happens in weeks instead of within months or years.

Áine Hanley 12:46
And once we have an antibody in research, and we've identified that it's a candidate for progression, then the technical operations team, the CMC team, get involved, and then ultimately, select that antibody, do cell line development, and then early process development, scale up and ultimately manufacturing. And in that process, we're generating data that will support the control of that process in manufacturing, and allow us, with the various regulatory responsibilities that we have, gain approval to use that material in the clinic. And so it's an ongoing process of iteration to optimize manufacturing.

Áine Hanley 13:33
And then once we're in scale up, and we're progressing towards full scale manufacturing, we've locked the process. And that's the point where the millions of data points that we're generating, can be used to assess and determine the opportunities that exist to optimize that process. And so we've used principal component analysis, for example, to help us understand, what are the key parameters of our manufacturing process that allow us improve the output and improving our yield, ensuring consistency, and ensuring control of our processes is a really important responsibility at that late stage of manufacturing.

Áine Hanley 14:17
So hopefully, I've showed, you know from end to end, you've got antibody design, antibody optimization, all the way through to small scale, process development scale up. And then at manufacturing, data generation is key along the way, and then leveraging these more sophisticated tools to help us optimize, accelerate and ultimately be assured all along the way that we have control over our manufacturing.

Tom Lehmann 14:47
Those are great example and certainly a good testament to not only just what's being done, but the progress that's being made. You said a couple things in there that I found interesting. And maybe there's a broad question here... maybe if I look at the early stage, if you're looking at the balance of a traditional, call it wet science versus computational science You talked about that the cycles are reducing from a timing standpoint. But are you also just seeing the amount of traditional science also reducing because you can do that much more in a computational method?

Áine Hanley 15:19
I think that's a tricky question, Tom. It is true that if you are working in a lab today, there are many opportunities for us to get knee deep in data and manipulating data outside the lab at our computers, I can't say that we're moving away from traditional science, because that's the fundamental element to all of this. And you still need to do the wet lab experiments to verify the antibody that we've designed, and test that it is, you know, the same molecule every time if you're, if you're in the technical operations, CMC world; and then, you know, continue to iterate to generate data for scale up requires wet lab, maybe it's moved to, you know, 50/50, 50% wet lab and 50% dry lab. That's, just an estimate, if you look at everything holistically, but definitely not where it used to be, 20 years ago, for sure.

Áine Hanley 16:34
And maybe if I can just make one other comment, Tom, it's not just data and data access, data insights, it's also automation. So along the way, we've also taken advantage of this knowledge, this data to allow us to look for opportunities to automate various steps along the way.

Tom Lehmann 16:58
Are there some examples that are that come to mind as far as what you've been able to automate?

Áine Hanley 17:03
Sure. Traditional cell line development took many, many weeks or months and you know, all those amazing biologists and molecular biologists that we work with, remember the approaches towards limiting dilution for cloning methods. Today, we have really fantastic single cell manipulation technology using Berkeley Lights equipment, for automated cell line development, that's really reduced that particular cycle time by about two months. We also have other technologies to do high throughput, early process development. Here at Vir, we're using Amber technology, and it's much smaller scale, we can run 12, small scale bioreactors at a time and reduce the numbers... the volumes of raw materials, and access data from that number of little small bioreactors. And you can correlate that small scale data with what was traditionally a five liter bioreactor, so 250 ml to five liters. That's another example. In fact, we have some cool technologies that allows us to manipulate that equipment remotely, which was very, very helpful during COVID, as well. They're just a couple of examples come to mind.

Tom Lehmann 18:38
From what you've seen across the industry, are you on the leading edge of some of these? Are you seeing the rest of the industry moving at pace to make the types of changes in advance that you've just been talking about?

Áine Hanley 18:49
I think everyone is taking advantage of the data advancements. And I have to say, being at a small company, allows us to move very efficiently., and I don't have direct insights to larger organizations. There's pros and cons, you know, there might be more financial investment made in a larger company for obvious reasons, than what is possible in a small company, but I have to say the flexibility and the agility of a small company is really powerful. And our ability to be able to touch end to end, right from even target identification, all the way through to delivering a medicine to patient is really powerful.

Áine Hanley 19:38
And, Vir had the really fortunate opportunity to have developed a COVID antibody COVID therapy, and we delivered sotrovimab to over 2 million patients. And that's, certainly for a company that was only in existence for six years was a was a phenomenal achievement. And so the speed at which we were able to move as a small company during that COVID time allowed us to test and road test our commercialization workflows and partnerships as well. GSK was a key partner for us. As we advanced sotrovimab and it allowed us to really take advantage of the capabilities of a large company but still have the agility of a small company, as we were progressing through those late stages.

Tom Lehmann 20:34
And are you finding post COVID, because this is a conversation I think across the industry, to say we achieved things and certain timeframes that we never thought possible... part of it was all the stars were aligned, of course, at that moment, because we needed to for humanity's sake... are there key lessons around how do you continue to operate at that pace, breaking down some of those silos, working with that end to end mindset. Is that sort of just native to the organization? Or have you found that there are certain things that they perhaps you weren't doing pre COVID, but you're doing now, which was one of those key positive outcomes from COVID?

Áine Hanley 21:47
So pre COVID, I don't think anyone would have imagined the speed at which we would have been able to progress or advance our medicines, our vaccines to patients. At Vir, we were able to get to FIH, first in human, in four and a half months. And I think traditionally, two years was probably not an unreasonable timeframe to achieve that milestone. Today, I'm seeing a significant improvement on the two years. But we're probably not quite at the four and a half months stage, because the regulatory pathways that enabled some of those accelerations, are not in existence for traditional molecules, traditional medicines. But there are other ways of working, that absolutely have contributed to continued accelerations.
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Áine Hanley 22:42
And some of these I've mentioned, you know, some of the automation technologies, and some of the partnerships that we've established, some of the collaborations, but also just understanding risk-based approaches of what is absolutely needed at various stages of development. There's much more, you know, in depth conversations about what's needed now versus what's needed later. And, and partnering with the regulators to ensure that we're fit for purpose, but at the same time considering everything that's needed for the various different regulatory milestones

Tom Lehmann 23:23
It does make sense, the conditions were right for things to just be different. But it does feel, as you said, there's a different conversation that has happened since then. And does it come back to where we were while everybody was focused on that one outcome? Probably not. But does it actually allow us to learn from that to move some things along? Certainly some of this end to end mindset and actually breaking down some of the silos does seem to be a pretty common dialogue here across the industry at this point.

Áine Hanley 23:49
Absolutely.

Tom Lehmann 23:52
So sticking with just that point, you talk about, which may be a little bit unique to your organization, around the ability to look end to end... one of the places and certainly in your space that we continue to see from an industry challenge of that interface between R&D and manufacturing—particularly as you move from process development in a clinical scale, if you will, into the scale that you need for commercial manufacturing—and it seems at times, there's almost two worlds that exist. How have you navigated through that? Because that, again, continues... feels like is an industry challenge.

Áine Hanley 24:24
So Tom, are you asking the question about the handover from research into process development and manufacturing?

Tom Lehmann 24:32
Yes.

Áine Hanley 24:34
So I would say, and you rightly pointed out, the smaller organizations, you know, have the ability to have stronger partnerships and have greater insights to each other's business. I think, whether it's a small company or a large company, you know, the cross functional teams, and the effectiveness of cross functional teams is really powerful, particularly in that stage of handover between research and process development. And one of the key attributes of drug development at that stage is understanding manufacturability. What are the characteristics of these molecules? What has been designed in research? And what are the liabilities that need to be considered if we're thinking about scale up?

Áine Hanley 25:26
And so having a really strong technical and scientific partnership between process development and research is extremely important to mitigate against stability risks, to mitigate against any other liabilities associated with a molecule, as it goes through those early stages of process development. And so it really is cross functional partnership, deeply understanding the molecules, understanding the characteristics, and bringing the learnings and the real time data that we generate, to demonstrate how these molecules need to be designed in order to be effective for scale up. And of course, here is where we're taking advantage of our AI tools to help improve some of those manufacturability challenges. And the speed at which we can, replace an amino acid based on the information that we're gaining through the joint conversations is really powerful. And we've many examples, whether it's stability improvement, or affinity maturation, to improve potency. And, these joint discussions are what make the difference.

Tom Lehmann 29:04
So you mentioned AI, and let me broaden that a little bit to say we're seeing a lot of interest right now, just generally, what is the potential for AI, but also a lot of focus around generative AI or Gen AI as people refer to it as... Where do you see opportunities in your space for particularly Gen AI?

Áine Hanley 29:22
Thanks, Tom. That's a really hot topic, everyday for us, actually and internally we have our own Vir chat tools and our own search tools that allow us to, you know, extract information, summarize reports. I think one of the areas that I'm most excited about, particularly in my area, is how we can use generative AI to help us streamline reports and ultimately simplify our regulatory filing process. So the volume of documents that we need to generate to support advancement of a molecule, and throughout the lifecycle is really phenomenal. And, those reports end up getting summarized and populated into the various sections of the regulatory documentation.

Áine Hanley 30:13
And if we can automate that, and ultimately simplify that using generative AI tools, it will not only make that whole process more efficient, I think it will ensure that we're, using our scientists and engineers, time in the in the best ways possible to bring even more medicines through the process. But really automation of regulatory documentation, automation of reports, using AI to simplify, summarize, and ultimately compile in a way that meets global regulatory requirements is a big opportunity that we've made some progress on already.

Tom Lehmann 30:56
Well and it sounds like that will build nicely on the automation journey that you've already been on, as you mentioned before.

Áine Hanley 31:02
Yeah, I mean, I think it's really trying to see how we can get people out of the reams of data. And, ultimately, having access to the tools to allow us to be more efficient in what we're doing.

Tom Lehmann 31:23
How much of that journey do you think is then going to be perhaps constrained by just the talent side of things? So if the underlying technology moves along, is your organization—or maybe if you look at maybe if you were to sort of speculate for the industry—does this become a talent challenge for us, because while we've advanced the technology, our talent is not moving as fast as perhaps needs to, to be able to leverage those technologies.

Áine Hanley 31:48
I think it depends on what area we're talking. You know in technical operations, our engineers have always been very data savvy. And I think are applying these new tools and coming up with new interfaces, that allow us to have these insights, much more broadly, and in a shorter period of time. There may be other areas across the business, where there is a need for some upskilling.

Áine Hanley 32:23
But I have to say, our data science team have been really fabulous in rolling out training programs, and giving us demos, so they've been leading the way and allowing us to upskill, each and every one of us, to ensure that we're taking on the latest and greatest technology opportunities. But from an outside in perspective, you know, hiring, we've not seen any significant issues. Maybe it's our location here in San Francisco, but I can imagine that as the demand gets higher for more sophisticated tools we may encounter a challenge. But right now, we're not we're not seeing any issue in this area.

Tom Lehmann 33:18
Okay. All right. Thank you.

Tom Lehmann 33:21
So let me switch gears. We touched a little bit on this before, but I want to come back to a topic just around some of the tools that you're using, particularly around just supply chain forecasting, supply chain planning, just given the areas that you're in... have you found that—again, back to data and analytics, and in the investments that you've made—that you're really starting to move up that curve, as far as the ability to predict demand, and then to be able to then match supply with demand through some of these tools?

Áine Hanley 33:51
I think the industry in general is getting much more sophisticated with respect to supply, demand, forecasting, leveraging tools to predict where and how our drug has been utilized across the supply chain. As a small company, we're still in this nimble space where we're probably not using the most sophisticated ERP systems that maybe a much larger pharma company is using. But nonetheless, I think, in general, right through plan, source, make and deliver. All of these core capabilities are taking advantage of the latest technologies. It's the obvious place where I think you can make the greatest impact and reducing inventory would be a key objective in order to ultimately ensure that we're being efficient about our resources.

Tom Lehmann 34:58
Alright, so close with a question here, we have spent some time where you've been, a little bit of what you're focusing on now. Look in the future for me, and just a little bit of future gazing. What's on the horizon? When you think about this, broadly speaking, we'll call it a digital journey. What do you think the next couple of years includes for you?

Áine Hanley 35:21
I think it's a continuation of our strategy, Tom. I described in the beginning that we have, here at Vir, a strong foundation in data science. And we use that strong foundation to drive innovation right across the end to end lifecycle. We're very excited about our hepatitis program here at Vir. And, you know, we have phase two trials ongoing for hepatitis D and hepatitis B and we have a research strategy that's really exciting. We've definitely ensured that right across the lifecycle, that the data is an important component, to allowing us to deliver these differentiated medicines to patients and in the next two years, maturing our data architecture, ensuring that we're capturing the data; working with our partners... I mentioned at an earlier segment, that our external partners are a really important priority for us, as we think about how to bring data in house and having seamless transfer of data and transfer of information to allow us to gain those insights and ultimately get to a place where we're submitting our filings in the most efficient way is really a key priority. So, you know, continuing to advance, look for opportunities to accelerate, ensure we're aligned with our corporate strategy. And in the end of the day, our patients are waiting, we're ready to deliver.

Tom Lehmann 37:02
Sounds great, and it sounds like both pipeline as well as the data side, as you said, are moving along with some serious pace here, which is which is great. And I look forward to hearing about the success over the next couple of years.

Áine Hanley 37:14
Thank you, Tom. It was a pleasure to catch up.

Tom Lehmann 37:25
Thank you for joining. I appreciate the insights today.

Áine Hanley 37:28
Cheers. Bye bye.