QuickSTAT

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Webinar: Commercialization Strategies for Cell & Gene Therapies

Speaker 1 (00:00:03):
Hello everyone. Thank you for attending today's webinar, commercialization Strategies for Cell and Gene Therapies presented by Kan Nagel International Ag. My name is Jenna DeAngelo and I'll be hosting today's webinar. I'd like to start by introducing our speakers today. We have Mike Sweeney, global head of Strategy, CGT and DTP from Quickstep we have Joel Wayman, vice President, three PL services from Cardinal Health, Fran Gregory PharmD, MBA Vice President, emerging Therapies also from Cardinal Health and Akha P PhD, senior VP of Product at traxell. You can read their full bios on the left side of your window by selecting the speakers tab. Just a few notes before we begin. You can access closed captions from the bottom right corner of the video player. This webinar is being recorded and will be available to watch on demand within 24 hours. We'd love to hear from you during the presentation. Please submit any questions you have using the q and a tab on the left side of your screen. For today's agenda, we will be going over process standardization network channel strategy design, looking at scaling logistics supply chains, and then we will have a q and a session at the end. Okay, let's begin. Joel, please go ahead.

Speaker 2 (00:01:21):
Thanks Jenna and good morning and good afternoon everybody. Thanks for joining us today to discuss this important topic regarding cell and gene therapies and how we can help continue to improve the processes to supporting these innovative products that are coming to market. And so as Jenna talked about, talk about the various topics related to these cell and gene therapies and how we're working together as an organization across multiple entities to simplify and standardize these processes. So on this first slide, what I want to just talk about is at a high level, a three PL organization provides various services to manufacture partners to help in supporting these products that are coming to market through the supply chain. And so each of these services play a critical role in supporting these types of products coming to market. Now, when we look at and talk about the processes that are there today and the need to standardize this next slide really shows kind of a model that was put into place back in 2017 when we were privileged to support the first CAR T therapies that came to market.

(00:02:22):
But as you can see on this slide, there's a lot of complexity that still exists in these processes today. And so we've been spending a lot of time as an organization here at Cardinal Health in working with the different stakeholders across the supply chain and looking at ways we can work to simplify and standardize these processes so we can make it easier for sites of care to focus on the things that they want to focus on most, which is taking care of the patient and minimize the challenges that these sites experience and trying to get these products for these patients that need these therapies. And so with this program we here on this slide, this is our flash title model program that we implemented back in 2017, but I do want to emphasize the opportunities to simplify this process. As we've talked to a lot of the sites of care, one of the things that we hear loud and clear from our partners in the supply chain is there needs to be a better way. There needs to be a way to standardize and simplify what we're doing today. And so I'm thrilled to be working with the various organizations that are on this call today, such as track sale, as well as quick stat at Kon Nale to really look at ways and how we can partner better to simplify these processes and make it easier for these sites of care to get the product that they need. Actually, with that, I'll turn it to you.

Speaker 3 (00:03:43):
Thank you, Joe. Thank you very much. Oops, sorry I jumped to slide. So hi everyone. My name's actually I'm from Drexel. It's, I was introduced, if you see on the top of the screen, we basically have great, out of some of the stages that you have to make sure are built into any sort of process that you are supporting as a part of an autologous therapy, allogeneic therapy. So essentially there needs to be a process where you are managing some of the stuff that Joel was mentioning about standardization. So how do I place an order? What kind of information do I need to record when I'm placing an order? So I'm talking about a healthcare provider. Who does that information need to go to what kind of format that information needs to come in? So all of that needs to be defined on every single, every product level.

(00:04:34):
So at trel we essentially provide a technology platform that orchestrates and manages these different requirements from different clients. So we've worked with clients that develop a autologous therapies, allogeneic therapies, CRISPR cas nine based therapies, personalized cancer vaccines. So essentially I wanted to sort of bring some of that experience that we've gained over the last 12 years in our presentation today. So when there isn't really a sort of animation here, I had a little bit of animation involved here, but essentially if you look at the insight of this slide deck, so the first red bit, which is the autologous cell therapy journey, you kind of really start from the patient on the top where you are identifying a patient when you are essentially enrolling them into a clinical trial or you are placing an order, then you are scheduling when the apheresis can be collected following by actually doing the collection of the apheresis.

(00:05:40):
After that, it sort of gets transported. The starting period gets transported to a manufacturing facility for further work followed by product release, and then in certain cases it's supplied fresh. In most cases it's stored in liquid nitrogen before it's supplied back to the treatment site for infusion. So that's a very sort of well-known, I guess autologous CAR T sort of model. Then I basically wanted to add some vene on, there are allogeneic journeys where the patient and donor a difference. So that takes a slightly different journey type in itself of the product and the patient and also the data that needs to be shared among various organizations. Then if you look at personalized cancer vaccines where you're collecting the patient's tumor type or tumor tissue, which goes to a sequencing lab where you sequence the tumor tissue, identify the antigens, and then based on that make plasmid or a similar kind of vaccine.

(00:06:44):
And also we've seen the four type where it's kind of a cross between the CAR T process and the personalized cancer vaccine, which is the immunotherapy where you are collecting patient's tumor samples, but also collecting a patient apheresis for creating the final drug product. So essentially, depending on the type of therapy, depending on the type of product, it takes a lot of different organizations to come together. As Joel mentioned, working together with the likes of Quickstar and Cardinal. What we are trying to do is standardize this process so as new and exciting new therapies come to market, we can support them out of the box without making it too onerous for the healthcare providers and other parties involved. The next slide I basically just I'm talking about is patient journey. So essentially you've got, as a company that's commercializing a product, one of the things that you need to look at is what is the patient journey?

(00:07:44):
What does the experience of the patient from the time they are enrolled or they are registered into utilizing this product or the product is being ordered with therapy, and then till the time of discharge, what is their experience? What kind of information and what kind of experience do they go through? You have the drug product journey, which is what I just described in my previous slides, is essentially depending on the type of the product and the amount of work that needs to be done on the product, you need to map out and identify your constraints and your bottlenecks. So as you scale up, you can try and address them as much as possible. Then finally there is the data journey itself. What kind of data needs to be recorded by whom at what point of time and who does it need to go to is something that you need to do as early as possible because as you sort of go from clinical trials to commercial, what we've learned is understanding and having good view of all these three journeys makes it easier to move into commercialization and generally expanding into other territories beyond the first sort of approval.

(00:08:51):
So from a standardization perspective, as Joel mentioned, what we are doing is trying to standardize as much as possible from the trasa perspective. So we are currently active at about a hundred sixty one seventy clinical centers across the globe. So what that means is we are learning a lot from the healthcare providers themselves about these journeys, about the data journey, the patient journey, the drug product journey, and how the healthcare providers in different jurisdictions, different territories are interacting with different portals. So every commercial company out there right now has their own portal. So what we are trying to do right now at Track is trying to harmonize this across the industry, working very closely with LI likes of Joel and Mike and others to make sure we can provide a standard approach on ordering collections, logistics, benefits, verification, any of the steps that are needed to be handled by the industry, which right now are very heavy on the healthcare providers is being managed as a part of that process. So I can talk a lot more about it later, but I just wanted to give you a quick view of some of the work that we are doing around that standardization piece as well. With that, I'll hand over to Mike.

Speaker 4 (00:10:09):
Thank you and thanks everybody for attending today. This is an exciting opportunity for us all to talk about the things that we collaborate on a day-to-day basis and our swim lane within cell and gene therapy. Quick stats, overall company vision is dedicated to the healthcare industry, but even with that being said, we really found out that within cell and gene therapy, it requires dedicated focus. So we really do spend time developing that talent, bringing talent in to help us with customers that have various projects that range from small domestic to large multinational and from clinical through commercial commercialization. So I think as both Joel and actually I already mentioned one of the keys is trying to standardize and align these processes and it's definitely easier said than done. There's a lot of work going on to make things more streamlined, more effective, more efficient, but we're always striving to kind of work together and listen to our customers and our other collaborators within the supply chain to continuously improve.

(00:11:19):
And I think from a lessons learned perspective, really what we take away from where we are today is without planning, in advance planning and working with our customers and deeply understanding what they need and trying to collaborate and that collaboration is usually not standalone within our organization and with our customer. There are several other entities that are involved typically in the supply chain. So making sure we identify those stakeholders work well with them, look at all of the high risk in our world, that's lanes that could be problematic. So we're always looking to assess and mitigate any risks that could arise given the timeframes and the temperature requirements that we have. And I think one of the biggest keys that we can impart is making sure that there's a plan to communicate and have escalation and contingency activities in place. And that's simply because there's no margin for error. And as part of that process, we really look to everybody that's involved working on the same goals to build that collaborative trust to lean on one another as we're working through really honestly very high intensity situations and projects overall.

(00:12:42):
So some of the challenges from our standpoint and we try to make sure that our company culture is always looking and thinking about the patient and the patient impact and with what we're doing within the supply chain, each shipment can have an impact on the patient that fundamentally is where our DNA begins and it's very important for us to continue to keep that in mind. Every shipment we handle is extremely important. There are very tight temperature and timeline requirements that need to be adhered to any deviations along the way. Again, we have to have a means to communicate supply chains, let's be honest or fractured. I don't think anybody is surprised to hear that, but we need to be honest about it. But we also have to embrace the new technologies like GPS that help us close some of those gaps that are there and really look for the future.

(00:13:39):
How are we going to scale? We're always thinking about how can we take what we're doing today? And as much as we're growing and cell and gene therapy is growing as a whole, we really need to continuously look at how we're doing what we do, what innovations can we leverage, what's coming down the pike and what do we need to be aware of in terms of new ways to do things and the resourcing problem that we see as something that's very real, and this is across the sites of care, it's across our entire industry and the supply chain, again, we need to be honest about that and work in ways together to build expertise together to share knowledge like we're trying to do today and making sure that really at the end of the day, like I said, the risk for error or the tolerance for error is very low.

(00:14:30):
Failure is not an option and we try to take that as a positive, much more than a negative in the way that we do things. So our solutions and what we need to do again, really heavily relies on that collaboration and that consultative approach, making sure that we fully understand what's being asked of us, but also those within the supply chain. Where are the responsibilities starting and finishing within each of our organizations? We need to assess the priorities, feasibility and certainly the risks. We also like to share our experiences. Sometimes our customers or others in the supply chain may have very defined ways they like to do things. Sometimes we have to be a little bit disruptive in making sure that everybody understands, Hey, we've seen it work really well this way, maybe not so well another way. So I think just being honest about our experience and why things succeed and why things may be challenging and look to avoid those collectively.

(00:15:35):
And we're always looking to be innovative and creative. We have to be be agile, we have to be flexible, but then again, we have to kind of balance that flexibility with always looking to standardize as much as we can within our processes and with the supply chain as a whole. And the biggest key I will say definitely for me is always to have a backup plan. We can't just assume that our ideal situation based on a certain pickup time and delivery time and temperature is going to go exactly as we anticipate. So if anything changes, a delay in pickup, a flight delay, any issues with temperature, we have to have a plan to enact and enact immediately. A couple quick things about the specifics of what we do within the logistics piece of this chain of identity is something that I think we can do a much better job overall with the technology, but there's various ways to make sure that the right products are produced for the right patient and the right products get back to that patient.

(00:16:42):
And I think the key is really looking at a variety of physical things like security seals, labels, and also using technology more and more such as QR codes and other systems like actually within cell system. There are great capabilities to kind of make sure that we're all aligned on what is the chain of identity, what are the different references we need to manage and really tie together. And the integration with these orchestration platforms is really challenging. It's something that I think the track cell team is working very hard and others are working to solve, but for the sites of care, it's really problematic when you think about the challenges they have and all the different systems that they may need to use and the different processes, various customers of theirs may need them to use. So I think it's something that we can improve on.

(00:17:36):
And again, the key for this moving forward as much as practical is standardization. And I've talked about the risks and I'll just mention the key two issues in our world are definitely delays in temperature excursion, and this is really different from a lot of the other business we do even as a specialty courier, even handling temperature and time sensitive pharmaceuticals and biologicals around the world cell and gene therapy, it's kind of the next level. You need to make sure that your collection and delivery requirements are very clear that there are strict time windows, whether it's 30 minutes or less in some cases. We need to make sure that we're not arriving too early, especially at a treatment location where there are patients that are coming in for various procedures and a lot of times the folks that we're working with are also working directly with the patient.

(00:18:36):
So showing up too early when we're supposed to be somewhere at noon say, and we show up at 11 or 1130 can be very disruptive because it's very likely that that individual we're looking to find is not going to be available until the time we're supposed to be there or closer to it. So again, that's something that's a little bit in many other situations, being early is a good thing and this situation it might be disruptive and communication, again, I can't stress, I think communication and standardization are keys, but making sure that we have a documented process. If we need to change that, that's fine along the way, we just need to make sure that everybody is in the loop on any changes and make sure that we have contacts that are always updated and reachable should there need to be any type of situation that comes up that needs some escalation.

(00:19:31):
So we always have to be thinking about contingencies. It's sort of if it's a bad weather day, we know we could have issues with flight delays, so what do we need to do? Do we need to drive something several hundred miles perhaps, or do we need to look at chartering a flight or doing something different? It's always thinking outside of the box thinking of what is possible, what can we do that would be effective to help this patient and our customer manage the challenges that we face that are very real. And another final point is just on temperature deviation. This can be very critical to make sure that it's being communicated back to our customers in a very efficient manner. So this is something that is a key priority along with any delays. So making sure that we're and deviations frankly in our world are rare. They don't happen that often, but we have to be prepared for them when they do. And I will stop here and pause and pass it on to Fran.

Speaker 5 (00:20:40):
Thanks, Mike. Let's see here. Let's get to my slides. So I kind of wanted to, as the last presenter here today, kind of just take a big picture, look at the cell and gene therapy industry that we're talking about and kind of put some of these things in perspective for the listeners here today and give you a few additional nuggets to think about. So what Joel Han and Mike have been talking about is really putting processes together and working cross-functionally and really cross industry to solve some of these huge challenges that we're faced with in this unique and innovative category of treatments. And today we really focus on working proactively and preparing for launches almost kind of one by one. There are a few products on the market. I think there are 21, 22 cell and gene therapy products on the market depending on how you define those.

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So we kind of have had time to figure out what we need to do to work together, how we work with providers, how we work with the logistics and supply chain, how we work with the manufacturers and even the payers to really get these products to market and make sure that the patients have access to them and they're at the right place at the right time. And all of this is much easier said than done. I think what you've heard from the previous presenters have made that pretty clear. But as we're looking at these launches and we're really paying very specific attention to each one as they become commercialized, we're also looking at standardization opportunities as we do that because today what we're learning and what we're doing is working fine, but if you look at this pipeline, it is extremely exciting, but it's also a little daunting if we think about the vast number of products coming to the market in the extreme complexity that these products bring with them.

(00:22:42):
So we're all across the industry and you can see it here with quick stat Traxell and Cardinal Health, just a few of the organizations who are looking for standardization opportunities so that when we see more of these products coming to market, we're finding new solutions, we're inventing things as we go here that will make processes so much easier for providers, for patients and manufacturers to ensure that not only we're creating standardization, so these launches are easier, but there are also requirements that each product has that are very specific and individual to that product, but how do we build those specifications and requirements for each product into a broader, more standardized solution? So that's really where we're all focused across the organizations that you see here today and really across the industry and anyone that's involved in cell and gene therapy products knows that it's up to us to make sure that we figure this out so that these patients can get these therapies today and into the future.

(00:23:42):
So we're all very passionate about this and it's obviously really exciting area. Again, focusing your attention back onto your screen there. We have a hugely bright future in the cell and gene therapy space. If you just look at the year 2030, we expect to have almost 140 products commercialized on the market available to patients by the year 2030. So our estimate based on a number of data sources is that equates to about a hundred thousand patients that can be treated by 2030 with a cell and gene therapy product. So when we talk about standardization and simplification hopefully is very apparent as to why we need to create these easier processes. It's because we have to, what I'm showing here is a very simplified version of what's coming in cell and gene therapy, but the complexity does not stop. So if you look at the right hand side of this chart here, you can see the therapeutic categories that cell and gene therapies will be focused on in the future.

(00:24:49):
So this is a 2030 snapshot, and of course all of this is subject to change based on FDA approvals and changes in pipeline development, et cetera. But you can see here that a lot of times we think synonymously that oncology and cell and gene therapies kind of go hand in hand. Oncology providers are amazing. They're fabulous at figuring out reimbursement challenges. They're used to dealing with high cost drugs. They know how to do buy and bill, they know how to do white bagging, they know all the tricks of reimbursement and they know how to get patients their drugs. They've been doing this for years and it's extremely complex, but that market is only 32% of the future of cell and gene therapy. So if you think about some of these 28% under the other category on the pie chart, these may be providers who have never had to deal with a high cost complex drug.

(00:25:44):
We're talking about ophthalmologists, we're talking about endocrinologists, immunologists who might have some exposure to some of these extremely high cost ultra specialty drugs but may have no exposure at all. So it's really, really critical for us to make the processes as easy as possible from start to finish so that a provider who has absolutely no experience in helping a patient get access to an ultra high cost ultra complex drug can actually do that successfully. So again, it's really up to us to find solutions to make sure that the entire healthcare stakeholder picture understands how to get these products to patients effectively. So I don't know if anyone mentioned this either, apologies if one of you guys did, but the prices that we're looking at for these products right now range from around $400,000 up to the most recent product that was approved is $4.25 million. And again, this is for a one-time dose, but these products are life-changing and lifesaving for these patients.

(00:27:05):
Many of these patients have absolutely no other treatment options available. They would absolutely perish if these products were not coming to market and becoming available to 'em. So again, I just can't reiterate enough how important they are. And although these price tags are high, the long-term outcomes and the long-term cost offsets that we see with many of these products shows that there's a huge, huge, significant financial and clinical value long-term for these products in these patients. So just one more thing to highlight here, many of the manufacturers that we work with are smaller manufacturers who might only have one product that they're bringing to market for commercialization. So while we talked about providers who might have less experience in extremely complex treatment situations, we're also working with some manufacturers who might not have as many broad resources and deep bench strength as far as ability to commercialize a product very efficiently.

(00:28:11):
And that's not to say anything negative about these small manufacturers at all. They're extremely innovative. I absolutely love their passion for their products and we love working with them, but it makes it that much more important that we are strong and trusted partners that can help them bring these products effectively and safely to patients. So there are a number of areas that we could dig into further where it just becomes so important that we are not competing with each other in this market. We all want to work together to get these products to patients and that's why we feel it's so important to share not only Cardinal Health's involvement in this area, and like Joel said, we've been involved in this cell and gene therapy space since 2017, but we rely on partners like Quick Stat and Traxell to bring the whole picture together to really create that ease of use and facilitate the process for the providers and the patients and all of the other healthcare stakeholders.

(00:29:13):
So on the next slide, I'm just going to talk through a few of those key areas where we do engage with stakeholders that are again critical to bringing these products to patients efficiently. So the first one here, I mentioned the cost of these treatments. It's so important to be thinking when you're a biotech manufacturer working on developing a cell or gene therapy product to think about patient access early in that development journey. And really that involves creating a value story in the form of health economics analysis and working really closely very early with that ultimate prescriber and payer. So we know patients need these medications and they need these treatments, but sometimes it's a little bit of a slower process than what we might like to see to get prescribers, physicians as well as payers on board to feel that same sense of urgency that we do in our seat.

(00:30:20):
Secondly, the logistics. We already talk about the importance of the logistics and making the process as easy as possible for those stakeholders, the healthcare providers who are out there trying to get these treatments to patients. So one of the things that we are hyper-focused on at Cardinal Health is creating technology solutions to ensure that providers have tools and resources to help them order cell and gene therapy products much more easily and with less manual work, which will result in a higher level of accuracy because like Mike said, there is zero room for error when we're talking about a multimillion dollar treatment that includes patient materials as a key ingredient. So we can't mess this up and we're going to make sure that we don't by creating efficient tools, resources, technology solutions that will really elevate that provider's experience with cell and gene therapies and enable them to order more of these in the future when patients need 'em.

(00:31:26):
Third point here that I want to talk about is we're talking a lot about standardization and creating more efficient processes during this call, but we still want to make sure that we have that white glove, high acuity care that is needed for each one of these treatments. So you can hear all of those solutions that we're talking about. We're committed to finding solutions that work for all of the stakeholders involved in this process that really lead to improved patient access without losing the need for that white glove treatment and that customization for each product. And finally, being a pharmacist myself, I am absolutely excited about these products. I think they're amazing for patients. I love seeing outcomes that the patients are getting from these treatments. We've never seen anything like this before in healthcare, but we've got to track those outcomes better. We treat these patients with a multimillion dollar drug, we need to know if that patient has a long-term response.

(00:32:31):
We need better mechanisms to track patients short-term and long-term to identify adverse events that they might experience as well as to identify responses or lack of responses to these treatments. These mechanisms are also things that we're working on putting into place at Cardinal Health through a number of our partner business units within Cardinal Health to track patient outcomes and better identify value-based agreements that will help facilitate the financial support that these products need longterm. So really with all of these key things that Cardinal's doing, that quick stat is doing track sell. We are all working hand in hand to ensure that these products are able to come to market effectively, efficiently, safely, and we really want to support these products not only today but far into the future. And I think that's clear with our message today. So with that, I am going to hand it back to Jenna and we will be glad to take your questions.

Speaker 1 (00:33:35):
Yes, great. It's time for q and a reminder to submit your questions using the q and a tab to the left of your screen. We have lots of great questions already, so we're going to try to get to as many as possible. First question here asks, what are some of the challenges and solutions for applying standard practices within cell and gene therapy programs?

Speaker 5 (00:33:59):
I'll take that one first and then I think because I just talked about it a little bit, I think one of the key things that we're seeing, we work with 450 provider sites, certified provider sites throughout the US and Joel's team works very closely with them day-to-day and placing orders and seeing those orders through and the manual processes are something that we see a huge opportunity to eliminate. So that's one of the things that we are really focused on at Cardinal Health is working to ease the ordering process by creating those more automated and more sophisticated technology solutions, but also working to integrate our technology solutions with the other organizations that are needed to get these products to patients. So really integrating what we do electronically and in a more automated way with quick stat, with traxell, with other vendors that we work with to make sure that that process as easy as can be for the provider. We don't need them trying to figure out all these various components of getting that product to the patient. So that's one thing that I would just highlight.

Speaker 2 (00:35:10):
Yeah, the other thing I'll just quickly piggyback off of Fran therefore is that it sounds simple to say let's just standardize the process, but as you work with these sites of care, these centers of excellence, they want standardization, but they want their standardization. Everyone has a different interpretation or thought about what standardization is, and so trying to really get the industry to come together as a whole to agree on what is standard and what's the best standard approach can be challenging. But I think as we work with the different sites and make sure they're involved in the process and are sharing feedback and helping to create that standard, that'll help mitigate some of the challenges and getting adoption on the standard processes. But that can be a challenge that's out there today as well.

Speaker 1 (00:35:57):
Great, thank you both. Speaking of standardization, if you had one standardization wish, what would it be?

Speaker 2 (00:36:09):
Well, I'll jump on that one. I'll tell you the first one that I would have as a wish is just the ordering process, the onboarding of a site of care. If that was all standardized, I think that would simplify a lot of challenges that manufacturer partners, the different providers out there experiences is just working through those different difficulties and challenges.

Speaker 3 (00:36:34):
I think I agree with Joel completely on this one, the ordering process and some of the registration processes, which is in my opinion kind of go hand in hand as a part of I guess the overall ordering process of a patient needs to be standardized. We ran a workshop with six or seven sites just about a month ago, and what we realized is that there was a lot of variation between what was required from every single therapy company out there as a part of the overall ordering and patient registration process and having a level of standardization just makes the healthcare provider's lives easier so they know exactly what they need from therapy to therapy between BMS and JJ. I'm not saying exactly that they have these intricacies, but let's say there were some variations. You have to remember essentially what every single manufacturer needs. And that challenge gets exasperated as we use sort of scale up and add more and more therapies into the market. So having, as Joe mentioned, having that level of standardization just is going to make lives easier for the healthcare provider so they can really focus on caring for the patient and not worrying too much about what's the difference between patient therapy and therapy B,

Speaker 4 (00:37:52):
I'm going to just add real quickly to this because I completely agree that the sites are a focal point in this, and one of the things that I think sometimes is easy to forget is they are overwhelmed already and there's more coming and they know it. So I'm seeing already there are more restraints that are put in terms of timelines, in terms of certain activities that are going to happen at certain times of day. So I think that that is tricky to manage in terms of when you think about the various, and I think Joel alluded to it, everybody kind of has their own way of doing things and what we need to do is find a way to support them as much as possible because the reality is right now we all have to extend more of a hand probably than we should in an ideal world, but we're far from an ideal world from resourcing and expertise in that space. So I think we just have to be patient, we have to do everything we can to assist, but driving to that standardization is key, and I think a lot of it does start with the technology,

Speaker 3 (00:38:57):
And I think for those who don't know, the A-S-G-C-T is running an 80 20 initiative as we speak. So the whole idea of that initiative is that they try and standardize the 80% of the processes and with 20% variation. So the hope is because it's coming from A-S-G-C-T and not from a company like traxell or others, the sites are willing to change as well, because as Joel rightly mentioned, right, if sites are thinking about standardization, they're thinking standardization based on their processes, we need an industrywide change both from the healthcare providers and from the manufacturers for this to work.

Speaker 1 (00:39:39):
Excellent feedback. Thank you all. Our next question asks what differences in approach do you see in Europe versus the us?

Speaker 3 (00:39:50):
I can start here and others can add. So I think the biggest change we see is just some of the processes and the process owners that are undertaking some of the responsibilities within Europe compared to the us. In the US the transplant coordinators are more active. They're sort of generally the single source of information and they coordinate the patient care, but also the ordering procedures. While in Europe, it's generally the pharmacies that take more of a leading position on these, so you have a physician or prescriber, but the main point of contact generally becomes the pharmacy and the products are provided by pharmacy. But also I think we know there is a QP release required in Europe, so you cannot administer a product if there is a QP release done or qualified person release done in Europe. So even if the product is manufactured in US and you ship it across to Europe for infusion, you do need to do a QP release. So when you are designing your clinical or commercial supply chains, you have to incorporate these variations. So from our perspective, when we design solutions for our clients, we have to design for variations between different territories so that when your end users interact with these solutions, those constraints, those processes are already built in.

Speaker 4 (00:41:23):
I think one of the big things that I would say is a difference is Europe, obviously they have country by country regulations that need to be adhered to. So when you're talking about import export, there are definitely unique challenges that can occur. I would say on a positive side that a lot of what I see process wise is similar between the EU and us. There is a very nice amount of maturity. There's been more products approved in the US to date, but Europe is not far behind. I think we are seeing kind of a good situation as Fran really well laid out in all of the different products and the trajectory going forward for approvals, but there's a lot of work that's going on and a lot of collaboration. I think part of that that from our perspective we see is where's the manufacturing going to be done? That's always a key question. And for patients that are being treated in Europe, is there a way to do the manufacturing, perform the manufacturing there? So the QP process is not necessarily required versus other places where it needs to be shipped in. There's a lot of different strategies being analyzed and looked at, and at the end of the day there's always analysis on how can we best serve the patient and how can we be most effective and efficient in doing so.

Speaker 2 (00:42:44):
Yeah, Mike, one thing I want to just comment on, and I think you probably experienced this more than most of us on this call, but in the us even in Europe, we spend so much time on how do we align the patient and the product to arrive at the same time, right? Given the fact that these products have very unique and specific temperature handling requirements, a lot of these sites aren't necessarily prepared to store abundance of these products at their sites because you're talking cryo, you're talking minus a D, C and other things, and so you're trying to align patient and product at the same time. That's challenging the us I think that's even more challenging in Europe because of what you said with the regulations of from country to country. So trying to make that work from where it's going manufacturing site to the site of care that maybe is another country and a patient that maybe is another country, there's a lot of logistics to sort through.

Speaker 1 (00:43:40):
Thank you all for your comments. Our next question says, understanding the involvement early in commercial access planning, curious to understand the panelist's opinions on input into the clinical program, choosing endpoints and study design that resonate best with payers.

Speaker 5 (00:43:58):
I'll jump in on this one. So I think this is a huge area of opportunity for manufacturers. When you think about a payer's view on treatment options for their members or beneficiaries, they're really thinking about all treatment options. When you're talking about an oncology indication, we're talking about the NCCN guidelines and making sure that it's a step-by-step approach and putting pathway protocols into place that they're very stepwise, which could mean that a patient might not be able to access one of these medications and rightfully so based on the clinical trials until fifth line or later. So by that time, is the patient really an appropriate candidate to go through some of the pre-treatment requirements that a cell therapy or gene therapy might require? Maybe not. Maybe that's a difficult patient to treat at that point. So really thinking proactively about how to position the product in the treatment paradigm is something that needs to be done much, much earlier rather than later.

(00:45:04):
We're also seeing some treatment options that have absolutely no treatment available. So complete clinical unmet need, you would think these products would be supported and paid for relatively easily by most payers. And again, I'm speaking mainly in the us, XUS is a little different, but if you think about that, we should see uptake of these products pretty quickly and there are a lot of challenges between prescribing patterns with physicians and the way the economics are set up for physicians that treat some of these patients with these chronic diseases. And then secondarily, the one-time payment that the payers are often facing with these very high cost therapies. So that combination of things creates complexity that needs to be solved for much, much sooner than the time of commercialization. So those payer strategies and provider strategies should really be in play at least a year before the product comes to market because you want your product to be positioned favorably at launch, not a year or two post-launch. So these are extremely critical clinical decisions to be making much, much earlier and very strategic relationship building and health, economic value, story creation, sharing, and many, many activities that should happen much earlier I think, than they are currently.

Speaker 1 (00:46:35):
Thank you, Fran. Our next question asks, is there a real-time tracking service for drug products from manufacturing site to shipper to clinical site? Is there GPS location available online with temperatures

Speaker 4 (00:46:50):
I can start? Yes, there's multiple GPS options available that will do both location, temperature and a variety of other measurements. And I think that it is one of the things that's saved us in a lot of ways with the instability with the airline industry, which is definitely doing the best it can. I'm working more with the airline industry than I have at any point in the last 20 years, and they want to be partners, they want to do the best they can, but there are occasional breakdowns and GPS, there's no better true up. There are a lot of different manufacturers and a lot of different products and more coming. So I think it's been a great innovation that's really helped this space a tremendous amount.

Speaker 2 (00:47:40):
I think one of the things Mike, you guys quick start, have done that's really incredible is just creating transparency and visibility throughout the journey of the product, right? The ability to know where it's at in the process and understanding, okay, how much time has elapsed since the product was packed out to its delivery point and the ability to intervene if you need to when there is something that goes awry in the process.

Speaker 4 (00:48:06):
Appreciate that, Joel. I think it's something that we really all have to aspire to work to, and I think we've all touched on technology and the key aspects. The more we can be transparent and share that information in real time, the better off we're all going to be. There's been a lot of debates over the last few years prior to covid even about how much information should be shared with a customer before we review it. At this point, the gloves are off, everybody should have that information immediately. We all need to be challenged with the ability to take that technology and really improve the transparency. And again, I think it, it's truly the best way we can measure the reality of what's going on. Should there be any flight delays? For example, if a shipment we know is at the airport in Atlanta and the airline says, no, it's not here, we can say, yes it is. That's huge. And in years past, that would be a challenge that could go back and forth for hours if not days. So we've eliminated a lot of those challenges and we have the technology to be thankful for and everybody on this call working together to help support that is really been proven in the success.

Speaker 2 (00:49:24):
One thing I would just challenge the audience today on this call as well is beyond thinking about the tracking and the visibility, which is there and it's important, but it's what you do with that information. If you see something is hung up or delayed, what's the path forward? And that's why I think, again, working with the folks with Mike and ask Kate, because again, you got to think about how does this impact the patient arriving for the treatment, but is there an option where you need to go to a depot and have the do or recharged or something else to protect the product? So think beyond just the tracking visibility is great, you need it, but what do you do with that information? How do you use the information that you're getting?

Speaker 3 (00:50:12):
Yeah, I was just going to add Thanks Joel for that. I totally agree. So I think with platform like ours and others, you can integrate that information and actually have some actionable outputs that you can do or contact someone or they could have notifications go out. But I think most importantly, as Mike already suggested, you have the GPS for the shippers themselves, but there is also temperature tracking, pressure tracking, light sensitivity. So depending on the kind of material that is being transported, you can also monitor the condition of the material that is being transported. I think that's quite important, especially within this industry. And I know with Quickstart, they sort of track those variables as well because the ship is provided by different manufacturers can record that information that goes across and within the quick stack portal. I think the question mentioned about the temp tail, so I'm just making sure we cover that part of the question as well.

Speaker 1 (00:51:17):
Thank you all. Our next question here asks, can you share your most valuable lessons learned or tips on how to mitigate risks?

Speaker 4 (00:51:29):
I'll jump in real quick. For me, it's planning early and I didn't understand why in some cases customers were sending us 200, 300 lanes to assess until I realized that a lot of them are actually choosing countries and sites of care specifically to enable them to enroll patients. So if we find these exercises challenging, which we do, we go through the process and really look at this and make sure if it's 48 hours that we need to be delivering by, how close are we to that deadline in the best case scenario? And then we need to have a backup and then potentially a contingency beyond those backups. So I think the key for us is really understanding what are the goals and really what's it worth If we need to pivot and make a change, what is the mechanism we need to do to communicate that as well as in some cases it's going to be a higher cost.

(00:52:35):
If you need to charter a plane, do we have the approval to do that? Is it to X number of dollars? And that's not every day, but that does happen. So I think we just need to have a plan as much as practical, so we're not always alerting somebody to have to make that decision in addition to alerting them that this is happening. So I think that it really is key in our world to look at the plan in advance, collaborate, understand what the challenging countries and lanes may be, and then assess those in a deeper level to really say can this is about expanding access to patients. We want to be able to serve them, but we also don't want to risk the treatment and the process.

Speaker 2 (00:53:20):
The other thing I think that we learned early on in the launch of some of these cell and gene therapies is that to Mike's point, regarding the collaboration, making sure that all the stakeholders have a seat at the table and they're part of the discussion rather than assuming that everybody knows what they're going to do and how it's going to work. Because there is this lack of standardization that's out there and all these processes can be different. Even though a site of care might have experience with a cell therapy or a gene therapy doesn't mean they understand the process for your specific one. So making sure that there's engagement and discussion and clarity around the roles and responsibilities of all the parties, how the processes are going to work is an important aspect. And so there are plenty of times, I know that in a recent launch that we worked on with quick stat and team on really preparing, we had a lot of meetings and discussions, we had a lot of whiteboard sessions to map out and say, how's this going to work? How are the handoffs going to work? How are we making sure that nothing's going to go in the wrong direction? And if you don't have all the stakeholders there, that's going to surprises pop up, that's when you run into issues.

Speaker 1 (00:54:33):
Great, thank you. Our next question asks, how can therapy developers be best prepared for the operational aspects of a commercial launch?

Speaker 2 (00:54:47):
I'll start to reiterate some of the things we've talked about. Planning, making sure you're giving yourself enough time to plan for what's going to happen and making sure that, again, you're talking to all the right stakeholders from how are you're going to onboard the sites of care all the way down to what's the credit process look like. We see that in some cases there are things that are coming up regarding what's the financial viability of a particular location? Are they prepared for these products that are priced at 3 million, $4 million per dose? So making sure that you're planning all those different aspects. And for me, it's making sure that you don't look at these things in silos. You shouldn't just focus on transportation as one bucket and sites of care now the bucket, those buckets got to come together and they need to be engaged together.

Speaker 4 (00:55:36):
I really agree with what Joel just said, and I think there's been a lot of news coverage on issues with paying for some of these therapies already. We're going to see more of that, and I don't think that it's going to be an easy solution. I think we all know that this is expensive, it's very disruptive to healthcare systems around the world. We need to be honest about that, but we also need to be practical about what we can do to help support the access. And I think that this is something that we all take very seriously and we're doing the best we can to support, but there's, in some cases, there are definitely going to be challenges along the way and we need to continue to work with everybody in the supply chain, all the stakeholders involved from manufacturer to patient, and really look for ways to keep this access as practical as possible.

(00:56:28):
And the regulators have done a pretty good job as well. In some cases, these treatments that are coming onto the market are only going to be available to patients that have already been treated with drugs previously that are no longer effective or have not been effective, which if you think about it ethically, it makes a lot of sense. You're trying to give that person hope, you're trying to give them perhaps their last chance at a cure at something that's going to be a measurable impact on their life. And so I think these are all very high stakes questions, but to me, we can't ignore the fact that paying for it all at the end of the day remains a continued focus and challenge.

Speaker 3 (00:57:10):
I think I'd also like to add from a purely reoperation perspective, just trying to understand what I would call the failure mode analysis of your intern supply chain. So within one territory, and expanding that globally kind of relates to what we were talking about before on the risks, identifying the risks early and trying to put some mitigation strategies together. I think that makes a lot of sense to me as you sort of scale up from territory to territory. What are my risks as I expand my supply chain? What are I call failure mode and how do I mitigate against this? I think that's one aspect of it that cannot be stressed enough. So going from a clinical trial where you treated 20, 30, 40 patients, now all of a sudden you are managing a global footprint where you have sites of care, your customer experience working with different sites, you have multiple manufacturing facilities, maybe multiple couriers, maybe multiple three pls that you are working with. How do I manage my relationships with my vendors? How do I manage my relationships with the therapy providers and how do I essentially map the end-to-end data flow becomes extremely important I think as you sort of operationalize your commercial launch.

Speaker 6 (00:58:30):
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Speaker 5 (00:58:33):
Think I'll just add one more comment. I know we're almost out of time, but one of the things that Mike said resonated, and this could be the patient's last chance at surviving. So I mentioned before, their cells are part of the, they're the main ingredient of these treatments, so they might not have another opportunity to donate more cells. They might not have an additional batch of viable cells. So we have one chance and I think it's so critical, there are so many different complexities throughout this process, but when you think about it, this could be their one chance that we're responsible for delivering on. And I think you can hear it through all of us today. We are very committed to making sure that we get that product to that patient because they deserve it. As a healthcare industry and healthcare providers, the commitment to making sure this works is not only something that we need to deliver today, but it really will set up the future for these products to be successful long-term.

Speaker 1 (00:59:42):
Great. Thank you all and unfortunately, that was our last question. We had a lot of great questions today. Couldn't get to them all, but we will try our best to get back to everyone who submitted personally after this webinar. As a reminder, this webinar has been recorded. You can access the recording within 24 hours by using the same link sent to you earlier. Thank you for joining today's webinar and we look forward to seeing you next time.