

AmerisourceBergen & TrakCel Q&A: Future Challenges and Predictions for CGT Patient Focussed Solutions

Exclusive interview with Dale Hanna & Dr Matthew Lakelin.



Dr Matthew Lakelin

VP Scientific Affairs & Product Development TrakCel
Co-Founder

TrakCel design, deploy and support digital cellular orchestration solutions to manage CGT value chains from clinical trial to commercialization, ensuring therapies reach patients quickly and safely and in line with quality and regulatory requirements. The OCELLOS cell orchestration platform can be configured to match specific CGT supply chains, tracking Chain of Identity, Chain of Custody and automating processes.

Dr Lakelin is a co-founder of TrakCel. Using his knowledge in handling and distribution of CGTs he has assisted with the development of the technology platform, he is passionate about democratising advanced therapies.



Dale Hanna

Director, Cell and Gene Therapy Solutions
BioPharma Services, AmerisourceBergen

Dale Hanna is the Director, Cell and Gene Therapy Solutions, at AmerisourceBergen, supporting the development of innovative solutions to support biopharma manufacturers, providers, and patients. He is responsible for supporting the development and continued innovation needed for a unified AmerisourceBergen strategy that addresses cell and gene customer needs across the global enterprise.

Dale has been with AmerisourceBergen for 8 years, most recently leading the Clinical & Adherence services product strategy team within the patient services organization, Lash Group.



Can you give us an overview of how AmerisourceBergen helps CGT clients and your role within the team?



Lash Group, our patient services experts within AmerisourceBergen, supports our clients with coordinated case management solutions, ensuring patients receive top-notch support throughout their treatment journey. We undertake a diverse range of tasks, from preparing prior authorizations for submission, to helping patients overcome financial barriers, or providing clinical education and support. All intended to simplify the complex cell and gene therapy journey.

My role is to support the continued evolution of services offered by AmerisourceBergen to meet the needs that stakeholders like providers, payers, patients, and biopharma manufacturers have with challenges around logistics, patient access, data and evidence collection, clinical trials, and more.

The CGT sector is rapidly evolving, how are you positioned to meet future needs?



Put simply, Fusion, Lash Group's patient services CRM, triggers necessary services for the patient and provider at the right time in the treatment journey. From the point of prescription and enrolment, the patient services team receive data electronically, in real-time and utilize predictive analytics to determine things like benefit eligibility or patient outreach where additional support may be needed. Fusion continues to learn over time, so the support model adjusts as needed.

As more CGTs come to market, we are committed to continuously advance support for all stakeholders. For instance, if there is a need for a heavier focus on patient engagement solutions as treatments move to an out-patient setting, we will aim to provide solutions to meet both biopharma manufacturers' and patients' needs.



I think one of the key aspects for us is collaboration and integration. As the numbers and types of therapies approaching commercialization increase and diversify, more supporting partners and more steps are needed to deliver these therapies safely to patients. As a result, collaboration between partners in the sector is proving critical. These are complex therapy journeys, and they can't be delivered and scaled up appropriately if suppliers work in silos. The information transfer around partners

needs to be seamless, accurate and secure, and what is more it needs to be fast. Speed to treatment is critical for the patients as these therapies may be their final treatment option, and this is where digital technologies really come into their own.

As Dale has mentioned, there is a lot of exciting technology out there that can help to predict, model and analyse data and scenarios, and this in turn can be used to improve resource allocation, patient experience, reduce time to treatment and drive cost and safety efficiencies. As a result, partner integrations are, and will continue to be core to TrakCel's product offering as we strive to offer the most complete orchestration landscape possible.

Have you encountered any challenges that are specific to the CGT sector?



There are bound to be challenges in a complex area like CGTs. Patients often need to travel to qualified treatment centers away from their homes. To that end, our patient services team is proactive in removing transportation barriers for patients and caregivers with minimal out-of-pocket expenses. This means patients get to the facility as quickly as possible,

while adhering to the regulatory and compliance frameworks, which is an essential requirement for CGT.





TrakCel was formed specifically because the challenges within the CGT sector were unique. Personalized medicines demand a robust Chain of Identity and just this lone factor brings complexity into the process. You are dealing with batches of one, and each therapy needs to be tracked through each step of the supply chain. The patient and the patient data are an integral part of this, so now you have a data protection element to add to your extensive tracking challenge! Add to this that this is a new field and the regulations and best practice are still being developed, tested and implemented as the sector evolves. It really has been a privilege to have been so closely involved in this evolution over the last decade, and to work in an industry where the nuances and challenges continue to evolve. It is exceptionally rewarding to have had insight into so many different therapy processes and to be able to use the lessons from these to help other developers bring new therapies to patients.

What are the key industry challenges you anticipate in the near future?



We anticipate that advancements in autologous cell therapies will continue alongside new allogeneic cell therapies and gene therapies that are considered off-the-shelf and indicated for larger patient populations. A key challenge will be developing new models that deliver high-touch services on a large scale. Because biopharma companies currently use siloed vendor solutions for cell and gene commercialization, new challenges will arise. Being able to select and carry out effective development and commercial strategies with limited financial resources and few therapeutic-specific models or precedents, and to determine the product-appropriate approach for differing provider channels and support patients as an integral part of the supply chain, will be part of those challenges.



This very much an area of focus that we are seeing become more prevalent. Therapy developers are frequently asking us for connected and integrated solutions that make managing the differing supply chain processes for their various protocols possible. As therapies progress, inevitably supply chains become more complex but remain time critical. The range of integration types and providers that are needed to support this will only continue to grow.

Collaboration and communication are going to be more critical than ever when it comes to offering a high level of patient support. TrakCel have been patient focussed since we were formed so it is really exciting that both the industry and our own platform have reached the stage when scale-up is such a prominent topic and patient support as more therapies commercialize is now in the forefront of so many minds.



Finally, biopharma companies will need to ensure robust tracking and control to meet regulatory requirements as well as evidence generation that supports new reimbursement solutions when traditional models don't apply. Whilst these therapies are curative, the cost per dose can be extremely high and that in itself makes special consideration of the chain of custody and title transfer within a commercial model key.

What is the key benefit to the industry of integrating patient hub services with cell orchestration?



Orchestration integration serves a very important role in AmerisourceBergen's ability to service our manufacturer clients, treating facilities and physicians, and most importantly, our patients. With visibility to the ordering and prescribing process, our patient and physician-facing support teams can proactively resolve issues that arise while ensuring that the treatment process is uninterrupted.

Our integration with TrakCel's OCELLOS is one example of how we can provide bi-directional data for near real-time stakeholder collaboration along with targeted capabilities like chain of custody and chain of identity. An integrated solution can provide timely information about key patient and product milestones, outcomes reporting, patient expense reporting, and other program-specific data elements.





As I mentioned earlier, TrakCel's key focus has always been on getting these therapies to more patients successfully, and as the industry grows, the complex nature of the supply chain makes this near impossible without robust support of the supply chain. Ultimately, the goal for all of these therapies is to progress successfully through clinical trials and reach as many patients as possible, so this makes it necessary to reach into the commercial modelling as well as providing the information to support the best possible patient experience. The orchestration platform has all the information to keep case managers, commercial stakeholders, caregivers etc. informed in near real time, allowing them to actively manage the processes and information to make the therapy journey as safe, fast and stress-free as possible and this is where the integration with systems like Fusion is invaluable.



In my perspective, there is a lack of adequate emphasis placed on patient experiences and on alleviating the discomfort or anxiety they may experience. Nevertheless, a significant opportunity exists to address this issue effectively. With so much complexity to manage in the CGT manufacturing and overall access process, it could seem that patient experience is left behind. Limited treatment networks create transportation barriers and lack of visibility into the manufacturing. But these are just a few areas where angst and discomfort can arise. Our goal in providing an integrated experience for physicians' workflow is that it makes the experience across multiple treatments more consistent – maintaining a single platform process. The other goal as a by-product is that the data captured and processes associated can become actionable for patients to consume. We see a great opportunity to provide solutions that keep patients and caregivers updated in real-time, just as the physicians are. This allows patients to be part of the process, further driving their interest in going forward with treatment and remaining hopeful for the desired positive outcome.

In addition, cell and gene developers gain value through our integrated model of support with an orchestration solution provider, TrakCel. The integrated solution set allows providers access within a single workflow to patient support services and other AmerisourceBergen solutions, such as logistics and courier ordering, so that a seamless experience, full visibility, and traceability can be achieved. This is a critical need as physicians have shared the desire for a singular platform experience to minimize variability across treatments.

What are the most compelling reasons developers should integrate Patient Hub Services into their digital supply chain?



Integrating patient hub services into the supply chain provides value in a variety of ways. First, physicians' most common complaint is that they lose the ability to follow the patient journey and as a result, physician adoption of biopharma brands is slower. By providing them and their care teams with full end-to-end service details and statuses within the supply chain, greater utilization and comfort for prescribing can be achieved. Secondly, physicians need clear insight into the manufacturing availability and near real-time delivery

updates. Without this integration and proactive capability for communicating status, patients and physicians will likely experience more frustration and stress throughout the treatment experience. Lastly, time is of the essence to get patients prepared and scheduled for treatment. Treatment sites often face capacity constraints and need support to manage patient benefits, prior authorization, travel, and overall coordination. By integrating patient services into this process, care teams can shift their focus to managing patients receiving or recovering treatment, knowing that valuable and trustworthy support is completing the necessary work to get the next patient ready for their treatment.

About the OCELLOS Platform | www.trakcel.com

The OCELLOS platform powers both OCELLOS and OCELLOS Lite, cellular orchestration solutions for both clinical and commercial therapies. The system modules are connected with leading third-party software and service providers (couriers, manufacturing systems, etc.) through our industry-leading "Integration Hub" built on the leading middleware solution from MuleSoft. From patient enrollment, scheduling, manufacture, right through to final product delivery and administration, OCELLOS gives complete visibility of the patient's journey. Implementing a cellular orchestration platform for your advanced therapy has never been easier.

About AmerisourceBergen | amerisourcebergen.com

AmerisourceBergen is a leading global pharmaceutical solutions organization centered on improving the lives of people and animals around the world. We partner with pharmaceutical innovators across the value chain to facilitate and optimize market access to therapies. Care providers depend on us for the secure, reliable delivery of pharmaceuticals, healthcare products, and solutions. Our 46,000+ worldwide team members contribute to positive health outcomes through the power of our purpose: We are united in our responsibility to create healthier futures. AmerisourceBergen is ranked #11 on the Fortune 500 and #24 on the Global Fortune 500 with more than \$200 billion in annual revenue.