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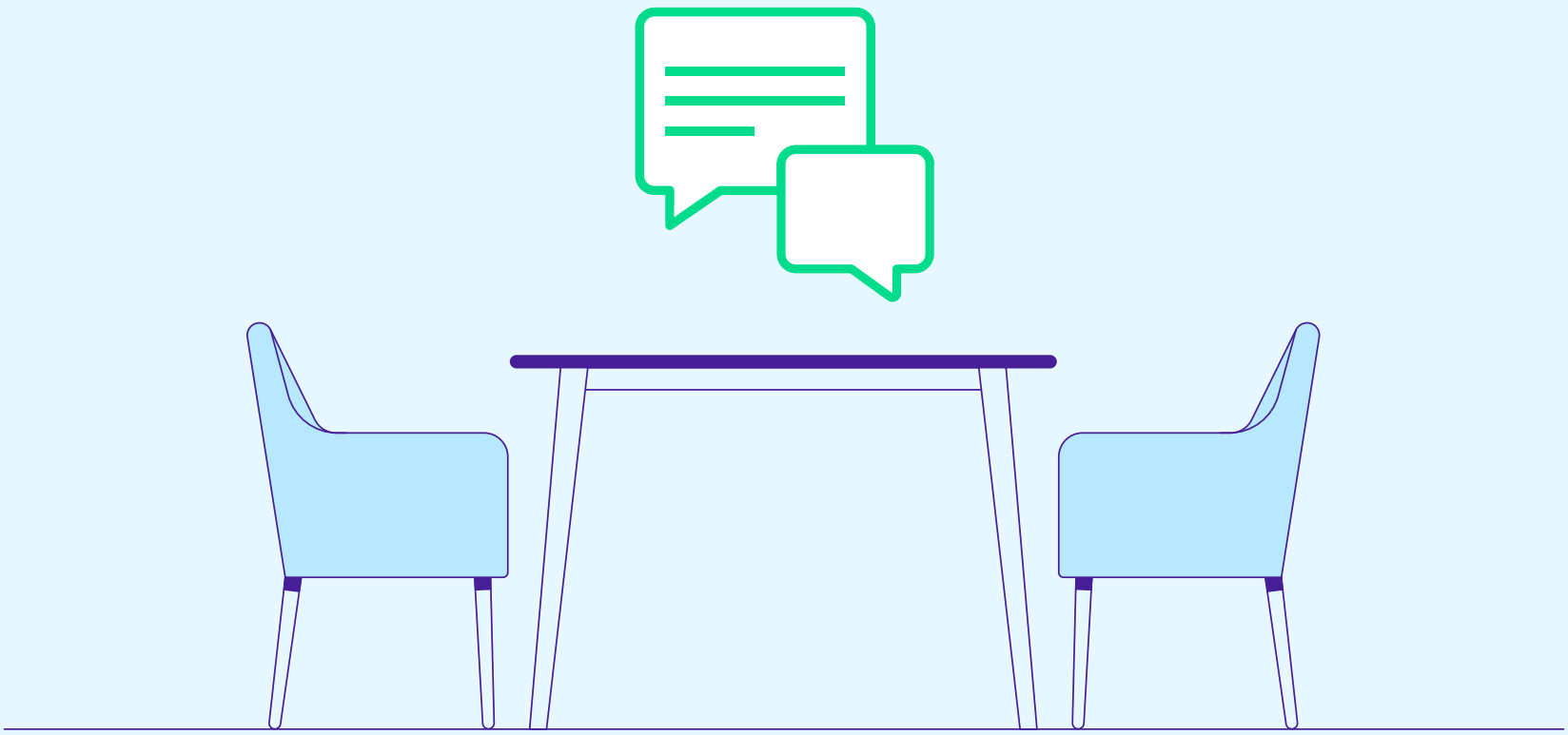
Table Talk



Beyond the breakthrough

Helping CGT developers get the jump on commercialization, distribution, and more

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In the world of personalized medicine, cell and gene therapy (CGT) developers understandably focus on the science. With their targeted use of living cells or genetic material to fight disease at the root cause, these treatments offer hope to patients with few, if any, other options. But a breakthrough is only the beginning. I recently sat down with two Cencora CGT experts to discuss how developers can better navigate challenges ranging from commercialization to sites of care. Because a cure isn't valuable if it doesn't reach the people who need it most.

Commercialization

Commercialization can be daunting, especially for a specialty drug. Orchestrating a successful CGT launch requires coordinated logistics and distribution networks, regulatory expertise, market access strategy, and much more. And it all needs to be timed right. What's your advice to CGT developers about when to bring in a commercialization partner?

The textbook answer is that you want to establish a partnership before the end of phase II so that as you move into phase III, you've got your commercialization partner in place. But you should be thinking about having a viable commercial program from day one, which is why I like to start collaborating with CGT developers as early as possible.

As a scientist myself, I know there's a tendency to compartmentalize the science from the commercial strategy. But thinking about commercialization early is critical. It can inform your clinical study design, how you're going to formulate your Biologics License Application (BLA), and so on.

Eventually you'll have to layer in your regulatory strategy, your market access strategy, your site of care selection, and patient access strategy. You might as well start early.

Also, with the FDA's new, more flexible approach to chemistry, manufacturing, and control (CMC), you may be able to accelerate phase II. You want to be ready for the opportunity.

And if you're not ready, that's okay. We have tools to help you catch up.

Value narrative

Every exciting new treatment also demands a compelling story about how its benefits address an unmet need. Getting this value narrative right is crucial to success. Do you have the same "start early" message for CGT developers? I can imagine them saying that early on there are too many unknowns.

The unknowns are exactly why it's smart to start early. The value narrative is the connective tissue between the science and the market and, eventually, the patient. I don't think it's ever too soon to develop and stress-test the story of why your new therapy is viable.

We've seen promising treatments fail at later stages because the argument for that treatment fell apart. No one wants that. Instead, you want your value narrative to hold up every step of the way — through regulatory scrutiny, payer assessments, site-of-care considerations, and patient adoption.

I like to think of it as an opportunity. Having time to explore different versions of your value narrative is a practical way to develop the strongest language possible, which will ultimately help derisk your portfolio, depending on the indication or the technology you're working on.

Storage and distribution

The variables and dependencies of CGTs can get very overwhelming, very fast. What's an easy win for therapy developers?

I recommend visiting a 3PL facility. It's inspiring to see a vial lifted out of liquid nitrogen, put into specialized packaging built to maintain ideal temperature throughout the journey, and taken away by a specialty logistics provider who will eventually walk that package into a hospital where a patient is waiting. The complexity and care that goes into getting that therapy to the patient puts into perspective how much attention to detail is needed from the earliest planning stages.

There's also a strategic advantage. The storage and handling decisions you make during development can have far-reaching implications on everything from your regulatory submission to provider uptake. A visit to one of our 3PL facilities will kickstart your thinking. You'll see how we can partner with you on operational infrastructure, chain of custody, visibility of product, and other important factors to successful commercialization.

Sites of care

Let's look into the future. Congratulations, your cell or gene therapy is approved. The product is commercially launched. Now sites of care are facing the reality of administering. This is a stage of the process manufacturers may not focus on until later in the development process. But the right approach has an impact on the success of their treatment. What is your perspective?

These programs are complex and require different handling, different preparation, different laboratory environments, different expertise or qualifications, and even different accreditations to be able to administer these drugs.

Even something that seems routine, like your standard operating procedure (SOP), can make a difference. When you're designing your study or designing your protocol, is the SOP going to be 150 or 15 pages? I promise the site of care will appreciate the latter.

You also want an operations team that understands that every health system, community practice, and clinic is different. Would they benefit from a pre-commercial site visit? A mock shipment test? Field team support? How will this work from a financial perspective? And how do you make sure the patients have the absolute best experience possible?

The future is personal

Finally, I want to talk about the human side of personalized medicine. What does it feel like to be in this field right now?

When you talk to researchers and developers, it's often very personal. A son or daughter has a condition that compels a researcher to find a cure. Or a parent died from a disease that somehow felt preventable. This makes every challenge deeply emotional. We try to honor that with the work we do every day.

My day-to-day is on the business side, but the human side is what motivates me. What's exciting is that we're about to see a lot more patient access. Stakeholders across the board are working to alleviate barriers, which means more and more people are going to be able to benefit from these innovative treatments.

These are durable therapies aimed at treating the underlying cause of disease. For folks who didn't have hope before, now they do, and their hope fuels my optimism for the future. We're in a transformational moment. What comes next is going to change a lot of lives for the better.

This edition of Table Talk has been brought to you by Cencora. We've partnered with more than **200 manufacturers** and supported over **30 FDA- and EMA-approved CGT/ATMP products**.

Our integrated suite of commercialization solutions is designed to help CGT developers move from strategy to execution with fewer handoffs and greater continuity. We offer market access strategy, operational infrastructure, specialty logistics, distribution, and services across global markets.

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