Six Cell and Gene Therapy Commercialization Trends

What to Watch in the Next 12 Months and Beyond

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2020 was a noteworthy year for cell and gene therapies (CGT), which conservatively account for 12% of the pharma industry's clinical pipeline and 16% of its preclinical pipeline. Despite unprecedented global challenges caused by COVID-19, the CGT market attracted a record-breaking $19.9 billion in capital in 2020, according to the Alliance for Regenerative Medicine.

For those developing CGTs and planning commercial launches, the next few years promise to be an exciting time. Based on our experience supporting these novel therapies from clinical development through commercialization, we see six key commercialization trends that are likely to shape the CGT market over this year and beyond.

Trend No. 1: COVID-19 Ripple Effects Will Continue to Have an Impact

The speed with which CGT developers are able to reach development milestones will continue to be affected by COVID-19. FDA officials have expressed concern about the impact COVID-19 may have in the near term on clinical trials, global harmonization efforts, its own shifting priorities, and in-person inspections. However, over the long term, the accelerated processes adopted for COVID vaccine approvals may translate into a faster review process for CGTs.

Trend No. 2: CGT CMC Guidance Will Be Applied With Even Broader Rigor

Given the patient-specific nature of many CGT products, chemistry, manufacturing and controls (CMC) processes carry increased importance during regulatory reviews, compared with traditional drugs. With 1,220-plus CGT developers currently pursuing trials and a new FDA guidance issued early this year, we can expect FDA and other regulatory bodies to apply extended rigor on CMC processes that have a significant impact on production and safety.

Trend No. 3: Standards Development Will Continue to Grow in Importance

Due to the nascent nature of the advanced therapy sector and hybrid of academic and private settings that gives rise to many of these therapeutics, the sector doesn't yet operate from a harmonized foundation. However, there is growing recognition that developing industry standards for CGT management will help to streamline and expedite care – and ultimately enable novel therapies to reach more patients. Leadership from the Standards Coordinating Body for Regenerative Medicine will play an increasingly critical role in accelerating the development and use of standards that improve the safety and quality of regenerative medicines, while reducing healthcare costs.

> While the individual steps in the CGT development and commercialization process are each important, it's even more critical that the various components work in coordination.

Trend No. 4: Providers Will Demand Standardized Digital Capabilities That Simplify Product Ordering and Tracking

Healthcare providers (HCPs) are allocating far too much valuable staff time to using multiple CGT product ordering and tracking portals and processes, which means less time for patients. This won't be practical as dozens of new CGTs become commercialized over the next five years. HCPs will increasingly demand ordering and product tracking processes for these products that are standardized and intuitive, like the processes they follow for ordering other specialty pharmaceuticals.

Trend No. 5: Mitigating Financial Risk and Reducing Cash Flow Burdens Will Be Essential

The providers who administer CGTs often must take on significant financial risk due to the high value of the therapies. Pharma companies that provide a high level of coordination with sites of care and financial processes that ease cash flow burdens, including order-to-cash management solutions to streamline reimbursement, will distinguish their CGTs in an increasingly competitive environment.

Trend No. 6: Patient Hub Services Will Drive Differentiation

As more CGTs come to market, pharma companies will increasingly differentiate their therapies by offering wrap-around patient hub services. Some administration sites have patient navigators who serve as a single point of contact for coordinating the care of CGT patients. In cases where these roles don't exist, pharma companies will step in with their patient hubs to deliver high-touch support for these often-fragile patients and caregivers.

Pharma companies and investors have collectively directed billions of dollars toward the development and commercialization of CGTs — and an increasing number of transformative therapies are now offering new hope to patients. While the individual steps in the CGT development and commercialization process are each important, it's even more critical that the various components work in coordination. Creating harmonization across the value chain is essential to meeting the needs of patients today and in the future. PV

Cell and gene therapies present enormous new challenges, but that doesn't have to stop your success.

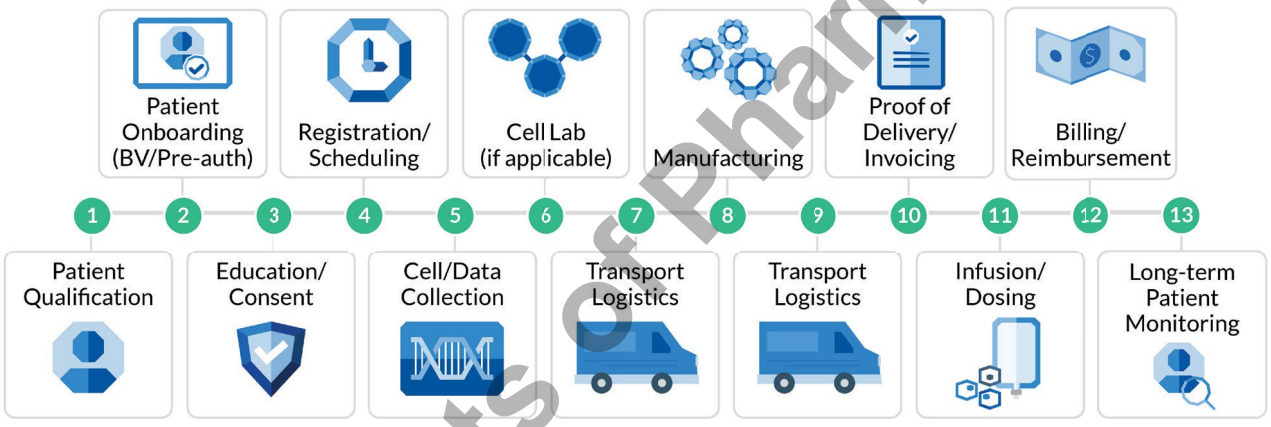
Vineti

In collaboration with

CardinalHealth™

CGT Commercial Value Chain

The patient is the process is the product. Vineti and Cardinal Health know how it's done.



Together, Cardinal Health and Vineti offer a collaborative solution to help you realize faster speed to market, reduce risk, and deliver a consistent customer experience.

Your value chain represents the full range of activities that make a product valuable. It includes the supply chain but it's much more - from product development through patient identification, production, treatment, and more.

Get in touch to learn more

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