

# Cell & Gene Therapy - Orchestrating Products and Processes from Vein to Vein



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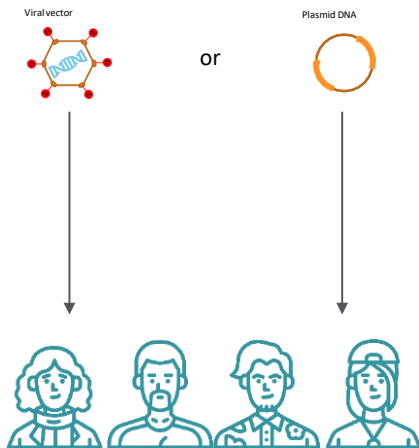
# Session Backdrop

- The **topography of the cell and gene therapy network**, how it works, and the digitalization challenges inherent
- The **systems, transactions, and information flows involved**, and how digital supply chain orchestration capabilities can be applied to **increase visibility, eliminate delays, and reduce risk**.
- Insights on how life sciences companies, logistics service providers, and other network members can get started **in building the critical digitalised visibility and collaboration networks** for these emerging therapies.

# Cell & Gene Therapy Taxonomy

## In Vivo (Gene Therapy)

The viral vector / plasmid is directly introduced in the body to remove or change in the content of a person's genetic code with the goal of treating or curing a disease



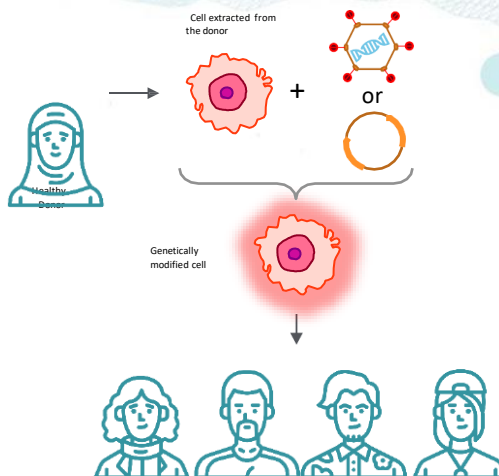
zolgensma®

onpattro®  
(patisirán)  
lipid complex injection  
ViroGen, Inc.

## Ex Vivo (Cell and Gene Therapy)

### Allogenic

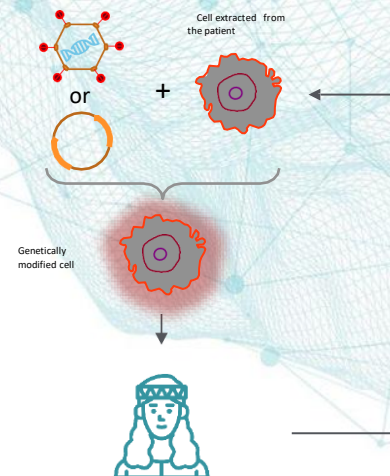
The cells belong to a healthy donor



Allogene  
BIOPHARMACEUTICALS

### Autologous

The cells are extracted from a patient



YESCARTA®  
(axicabtagene ciloleucel)  
Genentech  
Astellera

# Q2 2024 Cell & Gene Therapy Sector Data

	Developers	Clinical Trials	Investment
North America	1,234	974	\$3.8B
Asia Pacific	1,000	784	\$0.1B
Europe	579	341	\$0.3B
Total	2,919*	1,851*	\$4.2B*

# Need to increase patient access is shifting the market to a decentralized manufacturing and operating model, increasing nodes for cell logistics



## TREATMENT CENTER

Out-patient care at municipal hospitals & certified treatment centers that will provide care, conduct apheresis and cryo preserve cells, and transplant cells. Select centers will also be capable of local CGT manufacturing.



## CELL/TISSUE COLLECTION

Apheresis and/or blood collection centers will extend the network. These need not be associated with a treatment center, but will be located close to the patient, and have cryogenic cell lab capabilities, and could act as a central cryo facility too.



## CELL PROCESSING

Serve as a spoke to the network. They might be close to the patients. The center receives the extracted cells/tissue and conducts initial processing and cryo preservation or completes the final drug formulation.

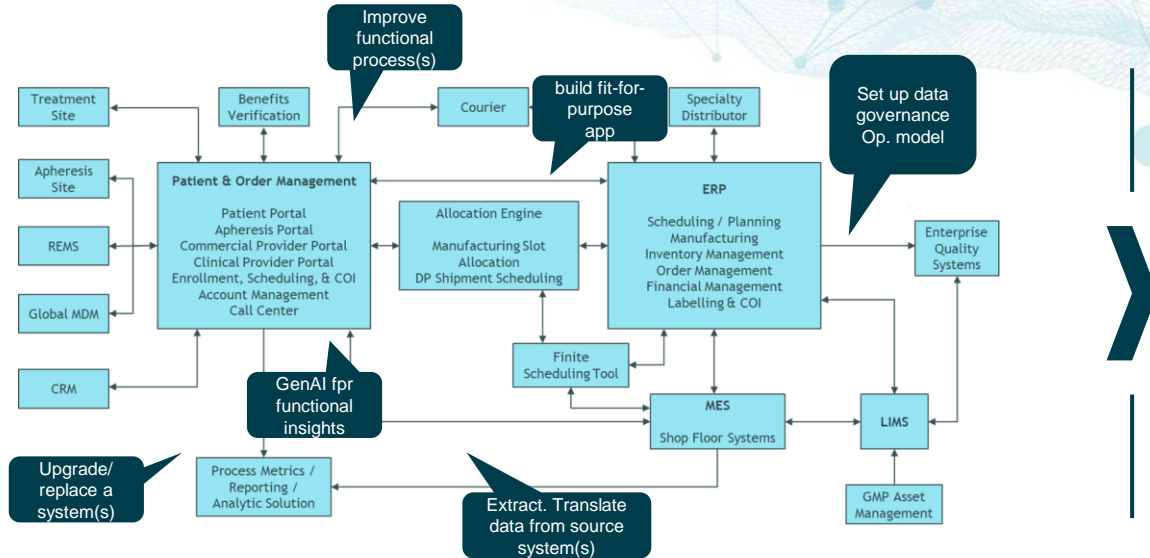


## CELL/TISSUE MANUFACTURING

Act as a Hub for the manufacturing network. The hub is capable of performing Day 0 processing as well as E2E CGT manufacturing and product preservation.

Decentralized model is creating additional nodes where the assets need to be stored, transported and managed

# Industry isn't approaching its programs holistically; it continues to deliver CGT capabilities as a series of discrete IT projects










- Redundant Systems
- Legacy Technology
- High Cost to Maintain
- No E2E integrated Data & Process
- Limited Knowledge-Sharing
- No E2E Visibility
- Rearview of contextualized data

A need for a common process orchestration and integration approach that is anchored on common data model, code, and tooling

# Advanced Therapy Orchestration Design for Personalized Therapy Value Chains Requires 2 Distinct Platforms Working in Tandem

## Treatment Center Platform (TCP)

*Facing HCPs & treatment centers*








-  **Interface to HCPs**, therapy specific treatment ordering forms, therapy specific process overview and key milestones
-  Capabilities to support the **Patient Operations** teams, therapy certificate management and therapy access control
-  Central entry point for all patient personal and **protected health data**
-  Registration and submission of **patient blood and tissue samples** in case of individualized therapies
-  **Patient outcome documentation** and **outcome based pricing** milestone reporting
-  System internal **Chain of Custody (CoC)** and **Chain of identity (Col)**, CoC/Col event report to TMP
-  **Training and support material**, document management integration, **support interface** for HCPs

The objective of the TCP is to simplify the engagement with and relationship between Pharma / Biotech companies and treatment centers and patients.



## Value Chain Mgmt. Platform (VCMP)

*Internal facing to manage & facilitate the VC*

-  **Process facilitation** of TCP, TMP and core ERP transactions to enable rapid execution of the flow of goods, flow of funds, flow of documents.
-  Enablement of **kit personalization and label printing** with patient data for single identified patient delivery
-  Support new pricing and **risk sharing models for market access** by capturing the **outcomes based reimbursement** plan to trigger ERP transactions
-  Realization of a **Chain of Custody (CoC)** and **Chain of identity (Col)** consolidating TCP, ERP, logger data to create **end-to-end** audit report that is required from regulatory perspective
-  **Slot scheduling** for individualized therapies, **capacity / stock confirmation** and reservation for GTs
-  **Manufacturing integration** in case of in-house production (i.e. ERP integration)
-  Courier, Lab and CMO **collaboration** and organization

The objective of the TMP is to facilitate, manage, and drive the value chain to ensure that patient orders are fulfilled effectively. The TMP is the conduit between all the functions, ensuring the flow of information between the TCP and the VC service providers responsible for delivering the order on time with zero defects or errors.

# Accenture's Industry Solution for Standardized, Interactions Between HCPs & CGT Manufacturers

**A common industry solution, built for the community, informed by the community** to reduce administrative burden on HCPs and their interactions with CGT developers and manufacturers

## **Insights, Intelligent**

Dashboards and reporting supporting improved visibility, coordination between stakeholders

## **Configurable, Modular, Interoperable**

Tailored patient / therapy onboarding workflow and data capture, API-First Architecture, and modular to meet customers where they are in lifecycle

**Unify  
for Cell & Gene**

## **Single Front Door**

Single portal for treatment center to onboard and coordinate patients for therapies from multiple manufacturers; Streamlined and standardized for clinician efficiency, optimized for stakeholder interactions

## **Flexible Workflows, Multi-Modal**

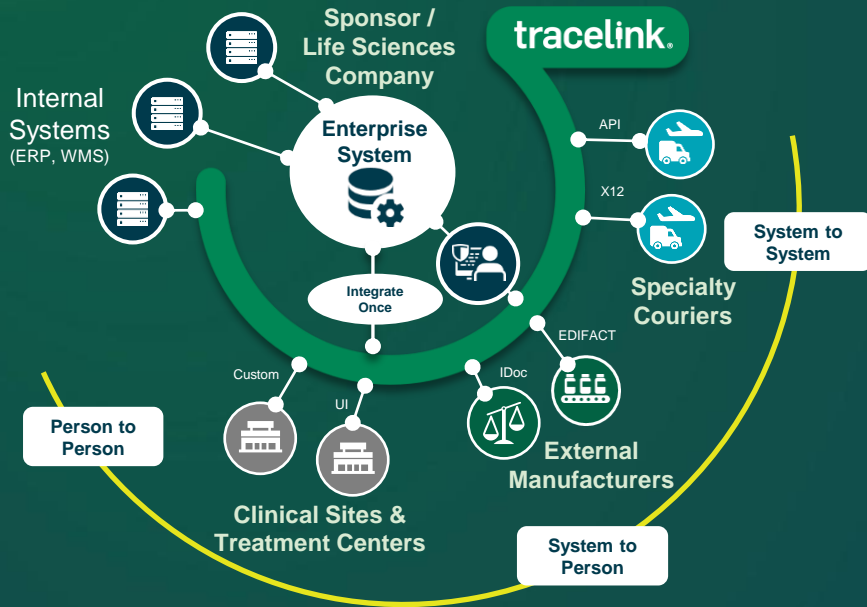
Designed with flexible, configurable workflows supporting multimodal sponsor portfolios

## **Compliant and Secure**

GxP and HIPAA compliant, safeguarding the privacy of patient data and manufacturer intellectual property, with country-specific flexibility for changing regulations



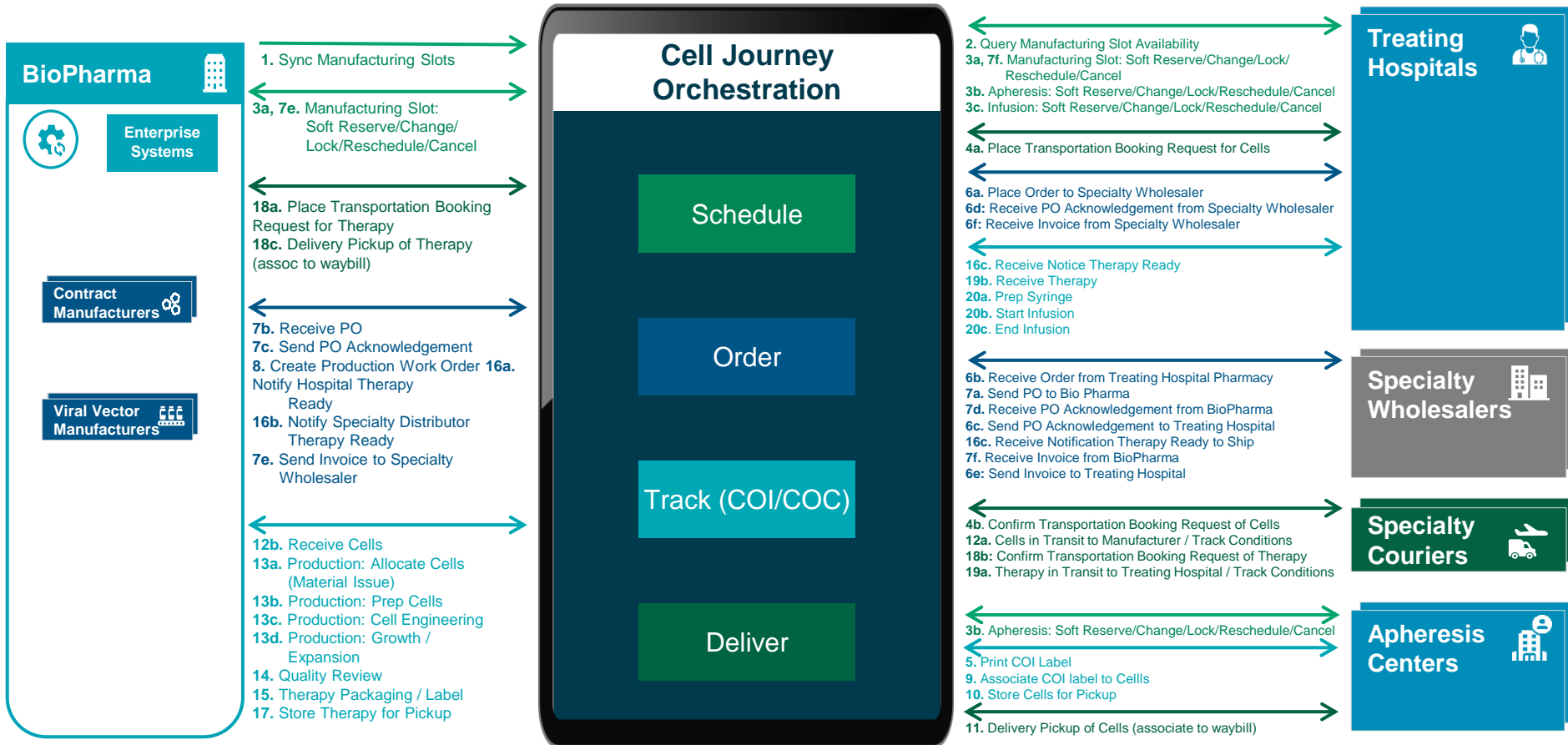
# TraceLink MINT for Cell & Gene Therapy



## Integrate-Once™ for the Cell Journey across Order Management, Production, Shipment and Status with full COI/COC:

- Purchase Order
- PO Acknowledgement
- Transportation Booking Request & Response
- Transportation Carrier Shipment Status
- Production Status
- Order Status
- Inventory Balance
- Warehouse Ship Order & Shipping Advice
- Advance Ship Notice
- Receiving Advice/Acceptance
- Invoice
- Remittance Advice
- Dispensing Advice
- Drug Return Order
- Destruction Confirmation


# End-to-End Cell Journey Orchestration




# Lessons Learned from Prior Personalized Therapy Launches

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 **Start by designing the E2E business process first**, the appropriate data flows and system architecture can then be derived

 **Plan for exception scenarios up-front**, most will occur infrequently and can be managed manually – automate only the most common exceptions

 **Build 3<sup>rd</sup> party data exchange requirements into the contracts**, including frequency and format

 **A differentiated treatment center portal is NOT a critical capability**, try to avoid introducing another login and workflow for HCPs and nurses to learn