Eduard Hergenreider

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Thierry Harlingue

Cell & Gene Therapy E2E Value Chain Product Manager, Roche

Cell & Gene Therapy Orchestration Use Case

October 31th, 2025

Eduard Hergenreider, SAP Product Manager for CGTO
Thierry Harlingue, Cell & Individual Therapy End to End Value Chain IT Product Manager, Roche

Roche at a Glance

Maintaining a long-term orientation

1896
Founded in Basel
Family still holds
majority stake

Reliable partner during
COVID-19 pandemic

Leader in Diagnostics
and Pharma

#1
R&D investor in
healthcare

100,920
Employees worldwide

16.4 million
People treated with our
medicines in 2021

32 medicines
on the WHO List of
Essential Medicines

Sustainable
one of the most sustainable healthcare company in
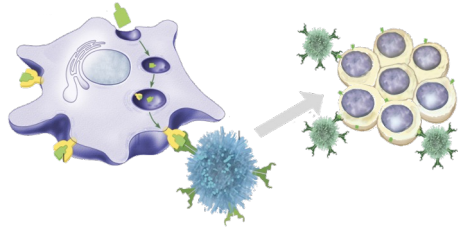the Dow Jones Sustainability Indices

27 billion
tests conducted with
our Diagnostics products
in 2021

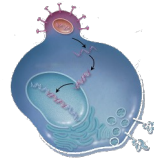# A Complex Cell & Gene Therapy (CGT) Portfolio

Roche/Genentech has a diverse multi-modality cell & gene therapy portfolio spanning clinical and commercial globally
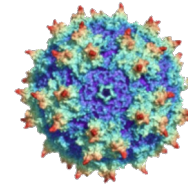
A Diverse & Growing CGT Portfolio

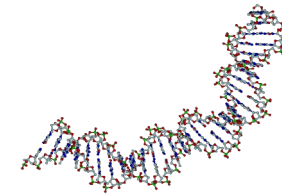**Individualized Neoantigen-Specific Therapies (iNeST)**

Autologous & Allogeneic Cell Therapies

Gene Therapies

Gene Editing

CGT supply chain logistics are complex and heterogeneous
Different modalities require different value chains

Modality							
In vivo gene therapy		Cell line/gene transfer		Made-to-stock vectors		Many patients	Linear
Somatic stem cell therapy		Pluripotent stem cells		Off-the-shelf doses		Many patients	Linear
Ex vivo allogeneic cell therapy		Donor cells		Off-the-shelf doses		Many patients	Linear
Ex vivo autologous cell therapy		Cells from one patient		Personalized batch		Same patient	Circular
In vivo personalized cancer vaccine		Tissue from one patient		Personalized batch		Same patient	Circular

CGT Supply Chains are Highly Individualized

We must ensure the right patient is treated with the right product at the right time with zero failure

Raw Material Supplier → Drug Substance/Product Site → Packaging Site → Regional Warehouse → Local Warehouse → Distributor
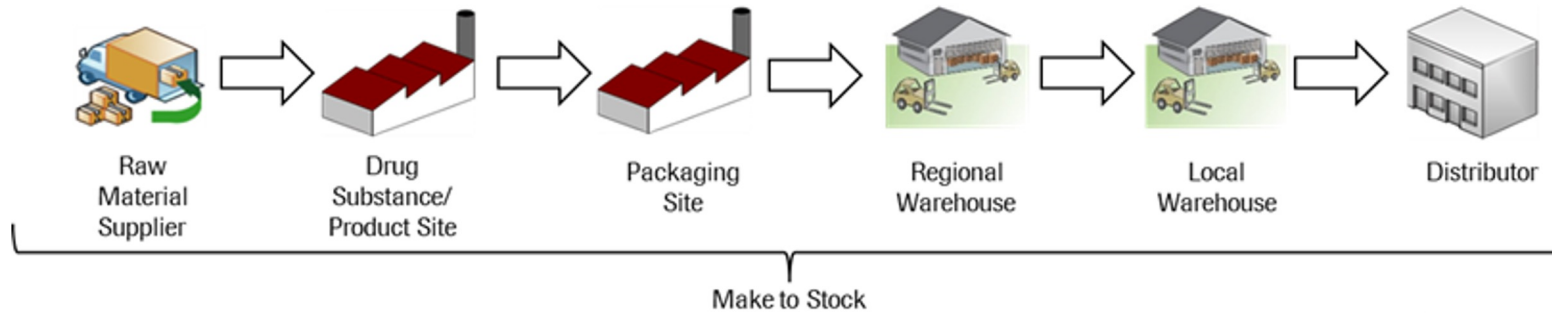
Make to Stock

Existing Modalities

One Batch – Several Patients
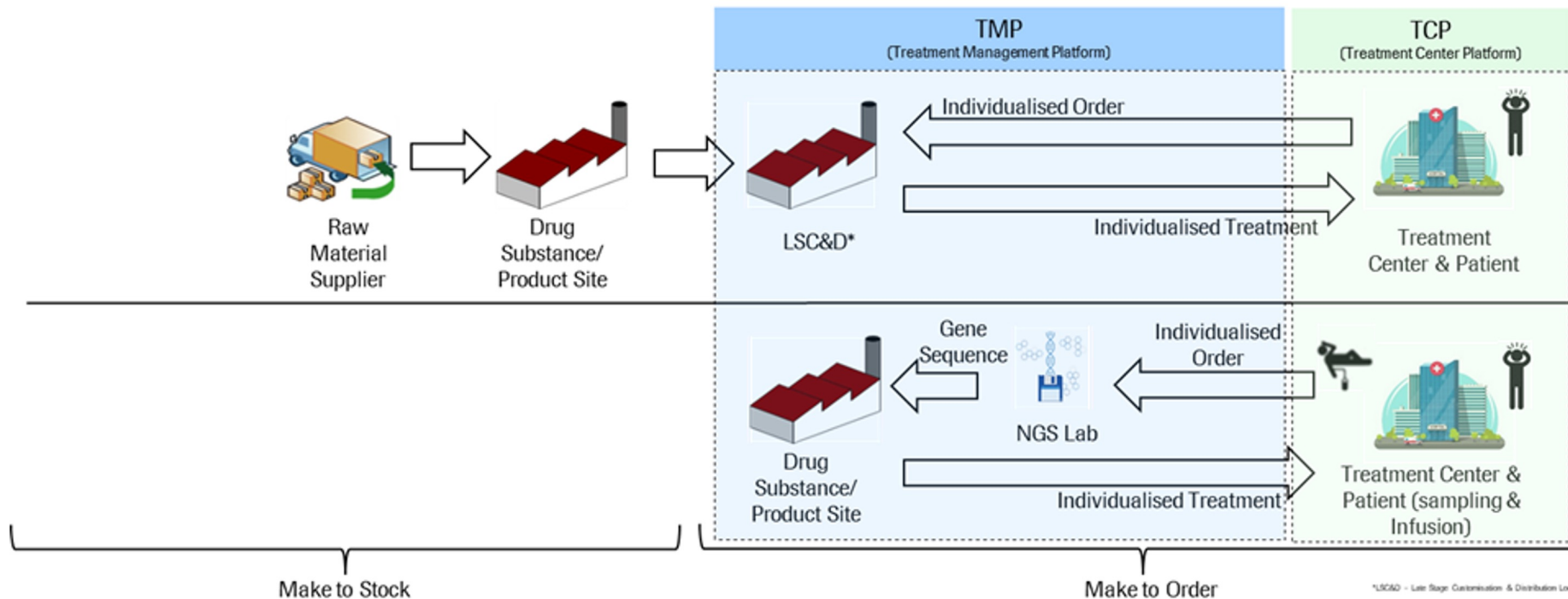*Pure "Make to Stock"*

TMP (Treatment Management Platform)

TCP (Treatment Center Platform)

Raw Material Supplier → Drug Substance/Product Site → LSC&D*

Individualised Order

Individualised Treatment

Treatment Center & Patient

Gene Therapy

One Batch – Several Patients
"Make to Stock" with make to order kit (elevidys)

Drug Substance/Product Site — Gene Sequence — NGS Lab

Individualised Order

Individualised Treatment

Treatment Center & Patient (sampling & Infusion)

Indiv. Therapies

One Batch – One Patient
"Make to Order" (iNeST)

Make to Stock

Make to Order

*LSC&D - Late Stage Customisation & Distribution Location

6

Key Challenges with Cell and Gene Therapies

CGTs bring unique challenges requiring innovative digital solutions

Diversity & Scale

New therapies across modalities need to be brought to patients quickly. New technologies provide an opportunity to move faster and scale made-to-order treatments to large patient volumes.

Regulatory & Compliance

Patient safety depends on zero failure chain of custody & chain of identity. Compliant capture & processing of patient identifying & health information is a required capability.

Visibility & Simplicity

We need a single streamlined portal to engage Healthcare Professionals and Customers. Real time visibility across the value chain is key for delivering treatments to patients rapidly.

Patient Operations, Supply Chain, and O&EM

Jointly realizing the end-to-end value chain for cell & gene therapies

Patient Operations	Supply Chain	Orchestration & Exceptions Management
• Interface to the treatment sites • Coordinates site onboarding, patient onboarding, biospecimen collection • Provides patient & HCP services before, during, and after treatment	• Defines the overall supply chain configuration • Plans demand and supply • Collaborates with CDMOs • Manages the logistics of the value chain	• End-to-end operations and facilitation of transactions across parties, "Control Tower" • Perform speed-critical transactions that can't be automated (ERP transactions) • Data management and support

SAP CGTO delivers a **trusted, compliant, and scalable platform** — at significantly lower effort and risk than building it yourself.

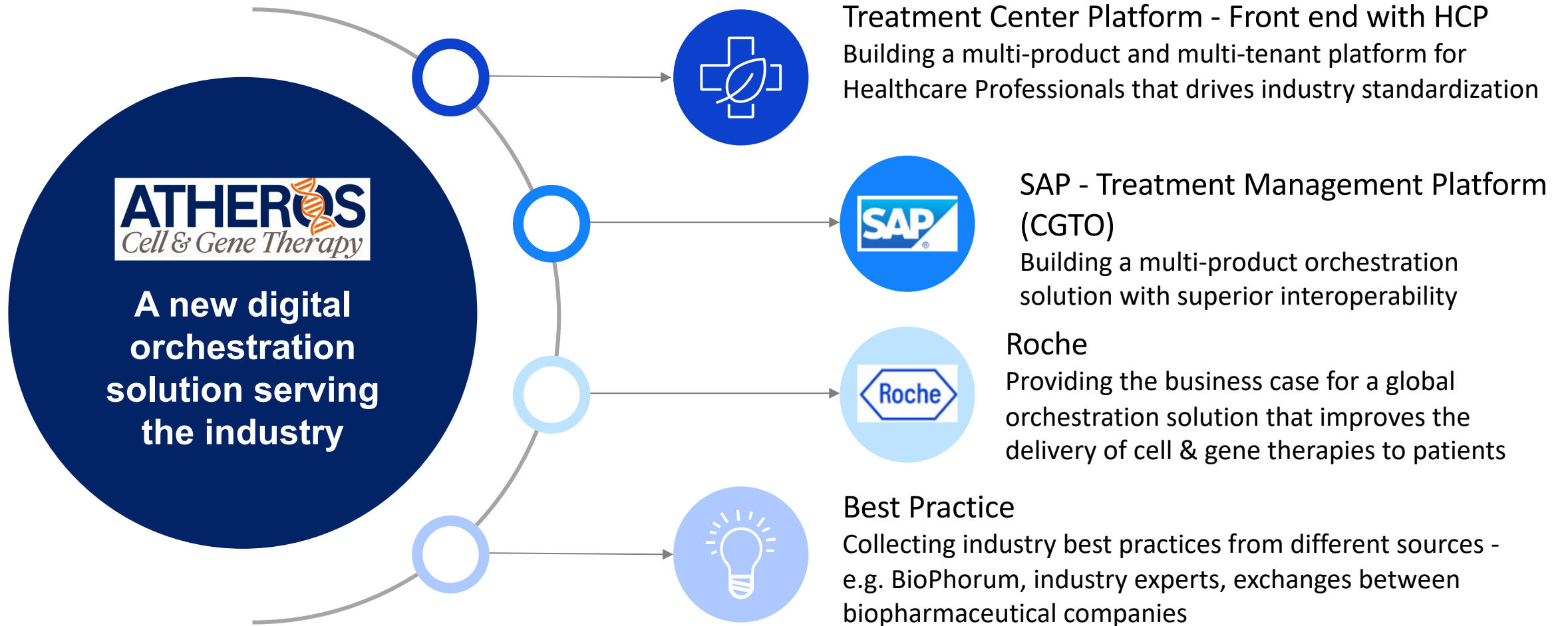## Business Value and Strategic Benefits

- **Faster time-to-value:** Proven, industry-standard solution accelerates deployment and adoption.
- **Reduced risk:** Built-in compliance (GxP, PHI, audit trails, e-signatures) lowers regulatory and operational risks.
- **End-to-end orchestration:** Out-of-the-box treatment order, COI/COC tracking, and business partner collaboration with configurability to support different modalities.
- **Future-proof:** Continuous enhancements aligned within a consortium and SAP's Life Sciences roadmap.

IT Value & Technical Benefits

- **Clean core:** Keeps S/4HANA standard, avoiding non-compliant customizations.
- **Lower TCO:** No need to invest thousands of person-days in custom development and ongoing maintenance.
- **Integration by design:** Standard APIs, events, and S/4HANA add-on simplify integration to internal and external systems and business partners.
- **Cloud-native:** Leverages SAP BTP for scalability, automation, and innovation.

Investing in an Innovative Orchestration Solution for the Industry

Strategic partnerships established to build an orchestration solution for the industry that enables the safe treatment of patients with the right product at the right time

Treatment Center Platform - Front end with HCP

Building a multi-product and multi-tenant platform for Healthcare Professionals that drives industry standardization

SAP - Treatment Management Platform (CGTO)

Building a multi-product orchestration solution with superior interoperability

Roche

Providing the business case for a global orchestration solution that improves the delivery of cell & gene therapies to patients

Best Practice

Collecting industry best practices from different sources - e.g. BioPhorum, industry experts, exchanges between biopharmaceutical companies

ATHEROS *Cell & Gene Therapy*

A new digital orchestration solution serving the industry

Additional Information

1. Patient Onboarding & Screening (Treatment Site)

- Patient Enrollment
- Eligibility Screening

1 COI/COC generation

2. Patient Order

- Product Order Placement

3. Schedule Confirmation & Shipment Booking

- Therapy Order Confirmation
- Detailed Scheduling
- Courier Booking

3
- Therapy Order creation / update (in),
- Therapy notification (in/out),
- Courrier booking (out)

5. Final Product Shipment & Receipt

- Product Acceptance
- Receive & Verify FP
- FP Provided to Courier

5
- Courier tracking (in/out)
- FP disposition (in)

4. Patient Kit Packaging & Disposition (Mannheim)

- FP Disposition
- Personalized-Kit Assembly

4
- Label printing (in/out)
- Process Milestone (in/out)
- Finished Product (FP) delivery (in/out),
- Event Integration (in/out)

6. Preparation and Infusion

- Patient Prepped for Infusion
- Patient Infused

7. Patient Care

- Patient Monitored
- Rehab & In-Home Care
- Outpatient Follow Ups

KEY

- TCP Action
- TCP + CGTO Action
- Offline Actions

SAP CGTO Mission and Strategy : 2025 - 2027

Provide a cloud-based SaaS solution that streamlines advanced therapy supply chains, reducing costs, optimizing capacity, and managing risks to ensure timely delivery of effective treatments. Our goal is to lead the industry by developing intelligent software that drives innovation, improves patient care, and expands access to affordable therapies.

Mission

Regulatory Compliance

Real-time Collaboration

End-to-End Visibility

Solve Supply Chain Challenges

Access to affordable Therapy

Strategy

Integrations

2027

2026

2025

Continuous Improvements

AI Infusion

Plug and Play

SAP Business Data Cloud

Progressive SAP S/4HANA Integration

CMO Collaboration

Direct SAP MES

Product Adoption & Maturity
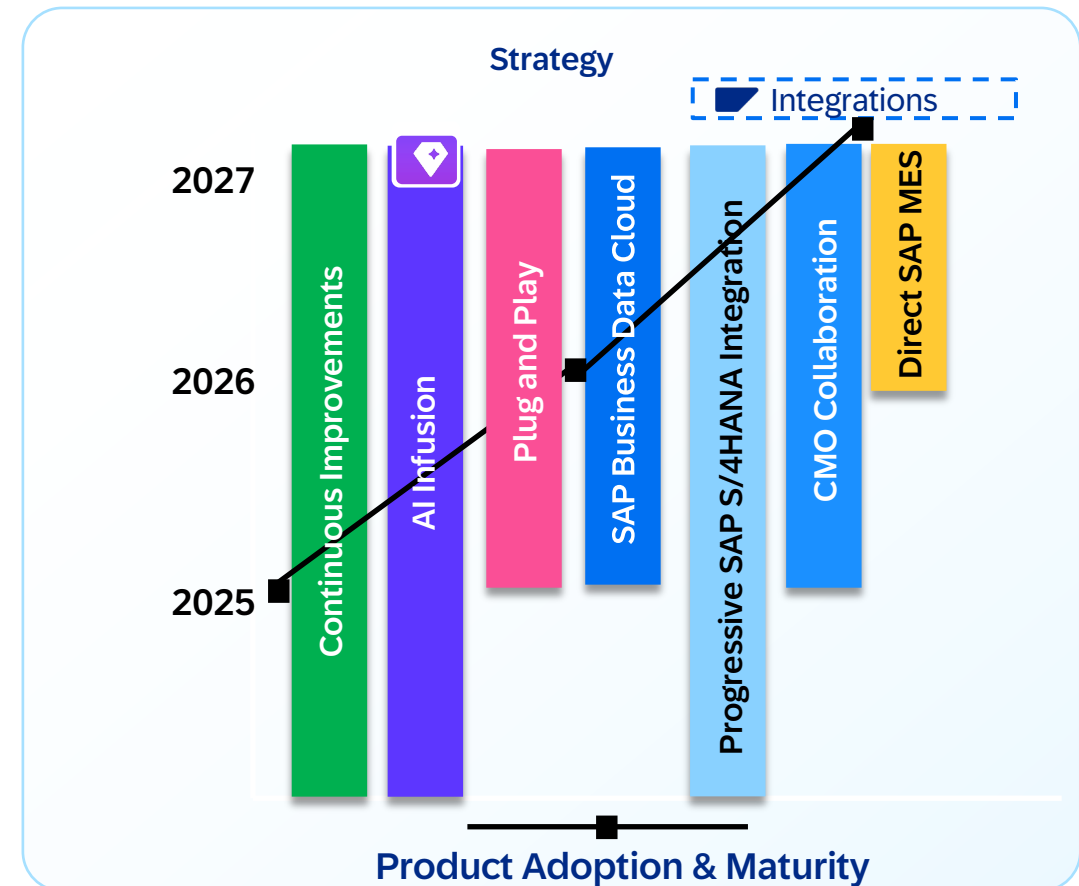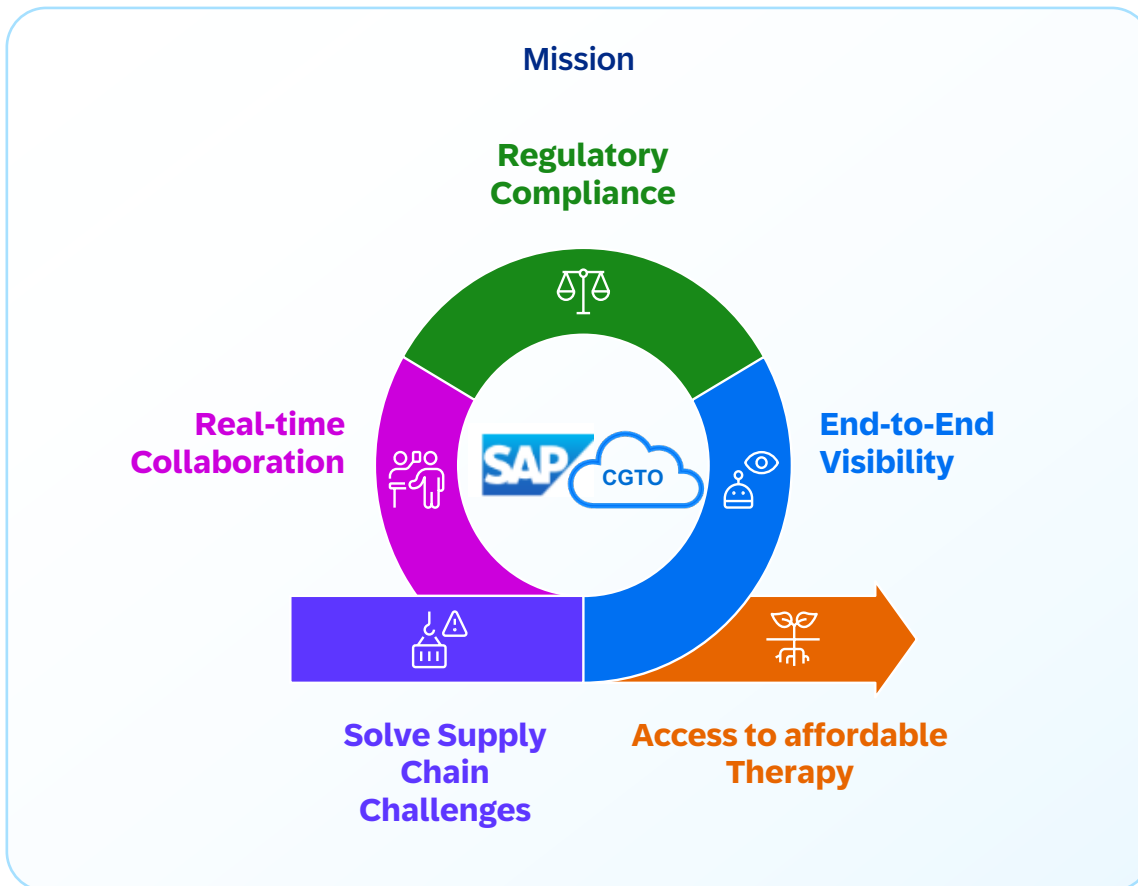
SAP Cell and Gene Therapy Orchestration Consortium participants

We need your help
to create the future
standards of the industry!

Doing now what patients need next