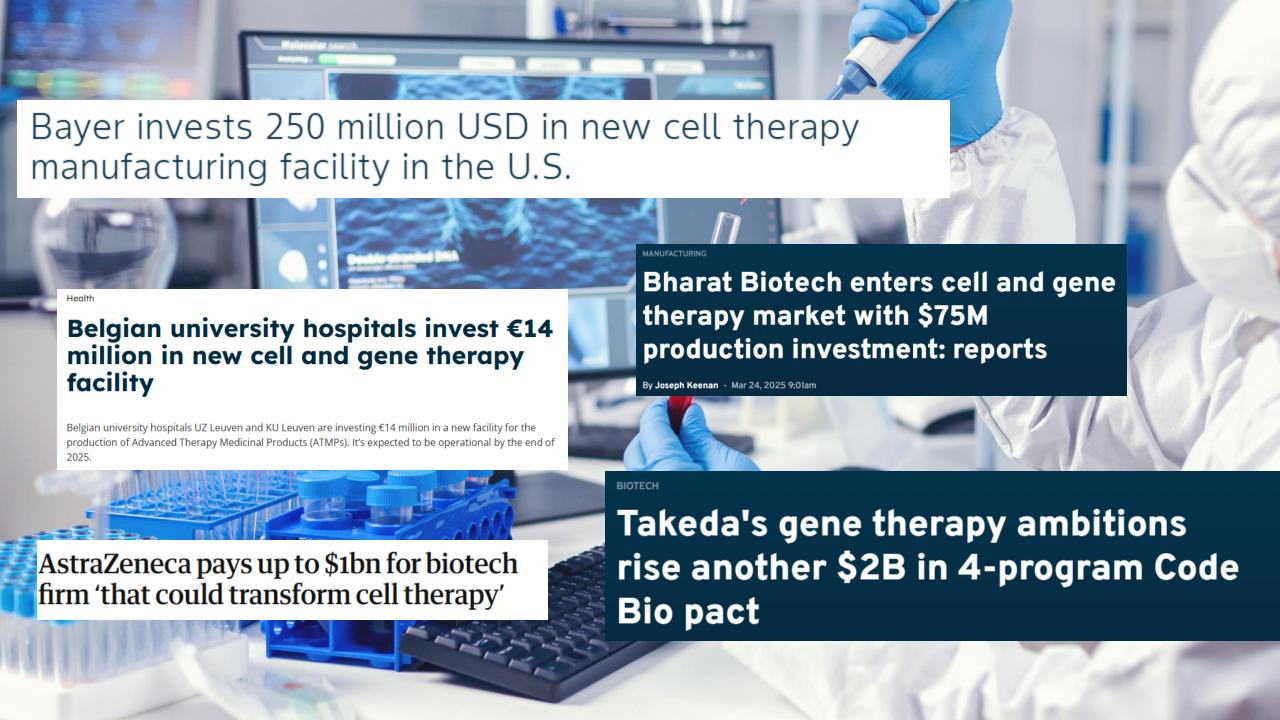


Precision Therapies

"Precision therapies are medical treatments tailored to the specific characteristics of individual patients, such as their genetic profile"







Eisa Hussain received the treatment for leukocyte adhesion deficiency 1, a disease that means children cannot fight off infections

Scientists give pioneering gene therapy to infant patient

Child suffering from rare liver disease shows improved health after treatment

Thursday, May 15, 2025

Infant with rare, incurable disease is first to successfully receive personalized gene therapy treatment

NIH-supported gene-editing platform lays groundwork to rapidly develop treatments for other rare genetic diseases.

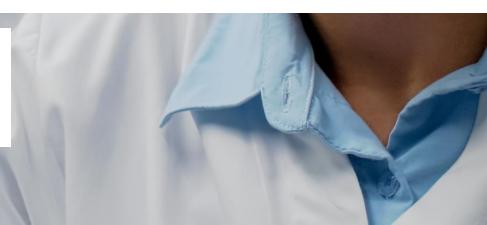
Breakthrough Gene Therapy Saves Infant With Rare Metabolic Disease

May 19, 2025 By Ryan Flinn

6-Year-Old Boy Who Was Born Blind Gets Vision Partially Restored After 'Life-Changing' Gene Therapy

Jace, now 6, was born with a rare genetic condition that causes blindness

By Vanessa Etienne | Published on February 21, 2025 02:59PM EST



Logistical Challenges

Supply Chain	Manufacturer	Freight Forwarder	Customs	Ground Handler	Airline	Ground Handler	Customs	Freight Forwarder	44
Challen ges		Arrival delaysTruck priorization	- Custom delays	 Loading/off-loading issues Temperature issues Compliance & screening 	 Temperature issues on tarmac Safety and security Fleet utilization 	 Loading/off-loading issues Temperature issues Compliance & screening 	- Custom delays	Arrival delaysTruck priorization	

Logistical Challenges





Source: Pharma. Aero (december 2024), Precision Therapy Logistics - White Paper

Logistical Challenges



No possible (f.e autologous therapies

INVENTORY

Strict temperature control required

PRODUCT STABILITY Very short shelf life and lead times.

SHELF LIFE



PROCESS

Limited standardization and harmonization

STANDARDIZATION

Complex processes and quality management

QUALITY

Transparency and real-time visibility often lacking

TRACKING



Lack of knowledge among customs and logistics personnel

KNOWLEDGE

Training needed in cold chain management

TRAINING

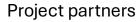
24/7 availability is required

RESPONSIVENESS



Precision Therapy Logistics Gateway

"The **Precision Therapy Logistics Gateway (PTLG)** project aims to develop a **secure**, **reliable**, **and standardized logistics chain** for innovative precision therapies, such as cell and gene therapies. By designing and validating specific standards, the initiative seeks to establish an **international benchmark** for the transport of patient-critical, fragile, and high-value medical shipments."











Funding partners





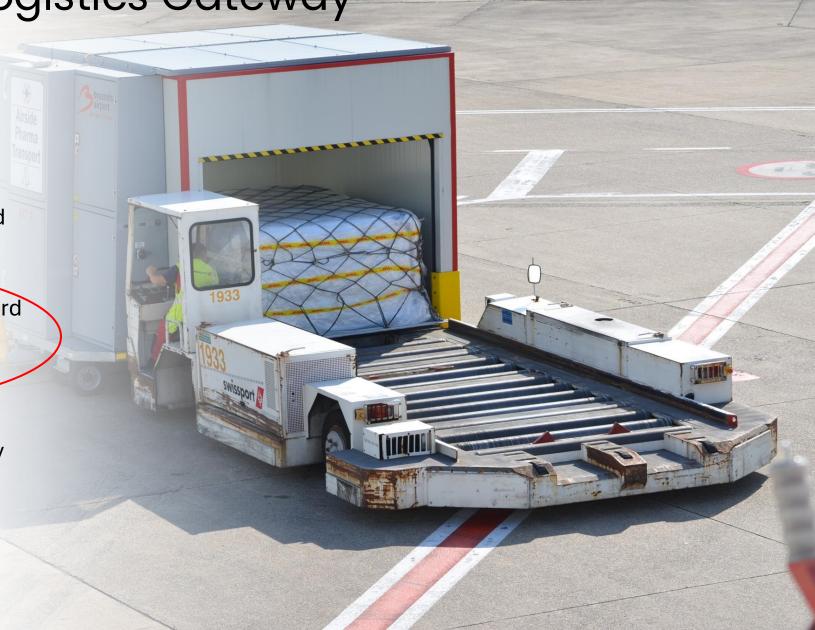




Precision Therapy Logistics Gateway

3 Phases

- Phase 1: Exploratory analysis of the current situation and risks (COMPLETED)
- Phase 2a: In-depth, evidence-based analysis of the current situation and risks
- Phase 2b: Development of a Standard Operating Procedure (SOP) and an internationally recognized transport label
- Phase 3: Development of a physical Precision Therapy Logistics Gateway



Ecosystems

Hospitals

Hospitals are key partners,

enabling patient cell collection,

treatment administration, and

clinical follow-up.

Manufacturers

Production and quality control to ensure safe and effective cell therapies, aligning with regulatory standards and patient demand, while coordinating with suppliers and healthcare providers



Technology Providers

Real-time control tower capabilities including Chain of Identity, Chain of Custody and close communication with partners and treatment centers are crucial for CGT

ECOSYSTEM

Logistics

Governmental **Bodies**

Packaging

Packaging companies ensure safe, sterile, and traceable handling of cell and gene therapies, often under ultra-cold conditions. They are essential for maintaining product integrity across the ecosystem.

Providers

Key capabilities include the management of storage and shipping for CGT products from



SOP Groups

SOP Consortium

Expert Group:

Neutral or non-commercial actors











PHARMA

WE CONNECT AER

Deloitte.

SOP Advisory board:

Experts from governmental and regulatory agencies, leading international airports, legal and ethical professionals, international networks, patient organizations, and customs.











SOP User Group (to be confirmed):

Representatives from the operational side of the supply chain, including logistics providers, transportation companies, handling agents, air carriers, ATMP manufacturers,...















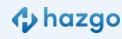


































Galápagos









Logistical Sector Needs

Takeways SOP groups and pharmae.aero PTLG workshop



A standardized process

While the industry acknowledges the need for a new logistics plan to manage ATMPs, a harmonised framework is still lacking



Clear shipment requirements

Misalignments occur when shippers provide an incomplete or inaccurate view of the logistics needs of their products



Stakeholder training

Thorough operator training helps avoid potential downstream delays (such as at customs) and ensures swift response to any deviations.



Overcoming customs challenges

Efficient customs clearance continues to be a common challenge, partly because there are no product codes specifically designated for ATMPs



An international ATMP shipping label

To enhance the speed and safety of ATMP shipments, a standardized label will highlight their critical nature throughout the logistics process

Key Takeways

- Precision therapies are the future of pharmaceutical healthcare
- High demanding logistics requirements are in place for these products
- A broad and collaborative ecosystem is vital
- Logistical excellence is hindered by insufficient standardization and lack of knowledge

