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# Exploring the landscape, modalities, and logistics of cell and gene therapies

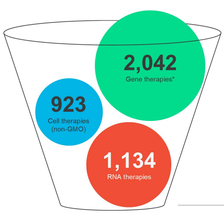
Cell and gene therapies (CGTs) are shaping the future of medicine and offering new hope to patients worldwide. These advanced therapies possess the power to target a wide range of conditions. However, it is crucial to recognize that the CGT landscape is dynamic and therapeutic success requires careful consideration of multiple factors throughout the entire drug development and distribution process.

**In this infographic, we explore the latest market trends and the nuances of various CGT modalities, along with autologous and allogeneic therapies.**

## 1

**From concept to cure:**

## Healthy CGT pipeline reveals potential with steady drip of approvals




**4,099**
Total therapies in preclinical to pre-registration stage

**68 Cell** therapies (non-GMO)
**32 Gene** therapies*
**34 RNA** therapies

**134**
Total CGTs approved

**Only 3%**
of cell and gene therapies are approved

### Therapeutic areas with the largest number of CGTs in development:

**Anticancer and oncology:**
CAR-T dominates gene and gene-altered cell therapies

**Rare diseases:**
- Acute respiratory distress syndrome
- COVID-19 complications
- Osteoarthritis

*Including RNA and vector-based therapies | Source: ASCGT Q4 2022 report

## 2

## Requirements for autologous and allogeneic CGT approaches

**Autologous approach**
Uses **patient's own cells**, tailored to specific treatment needs

**Availability**
Restricted due to patient specificity

**Immune response**
Low rejection risk

**Clinical trials**
Complex design due to patient variability

**Approval process**
Patient-specific product manufacturing considerations

**Logistical implications**
- Patient-specific batches manufactured in small production units
- Time critical
- Chain of custody and chain of identity are crucial
- Cryogenic and temperature-controlled shippers with GPS loggers needed
- Complex coordination with patient specific logistics and processing required


**vs**

**Allogeneic approach**
Uses **donor cells** tailored to specific treatment needs

**Availability**
Broad standardized or off-the-shelf

**Immune response**
Potential for rejection

**Clinical trials**
Simplified design with a standardized product

**Approval process**
Considerations for donor screening and safety

**Logistical implications**
- Large central manufacturing sites
- Batch production with many doses in vials or bags
- Central and regional cryo-storage hubs needed for distribution – for both fresh or frozen shipment to patients
- Cryogenic and temperature-controlled shippers with GPS loggers needed
- Logistics challenges in donor selection and management


## 3

## The journey and nuanced diversity of CGT modalities

### Cell therapies (non-genetically modified)
Using implanted cells to treat diseases

**Approach**
Autologous or allogeneic

**Regulatory pathway**
Varied, based on jurisdiction and product complexity

**Clinical trials**
Complex trial design

#### Logistical implications

**Long-term stability**
below -150°C

**Stable for months**
at deep-frozen temperatures (-70 to -80°C)

**Cryogenic/ temperature-controlled**
transport crucial

**24–96 hr shelf-life**
at refrigerated temperatures (2–8°C)

### Gene therapies*
Modification of genes for therapeutic purposes

**Approach**
Autologous or allogeneic

**Clinical trials**
Rigorous trial design based on specific gene modification

**Regulatory pathway**
Evolving to accelerate development and enhance safety

#### Logistical implications

**Vectors /plasmids (naked DNA/RNA):**
Long-term stability between -15 to -25°C

**Viruses:**
Long-term stability -70°C to -80°C temperature control and delivery challenges

**Genetically modified cells:**
Logistical considerations listed in cell therapy section

## Navigating the challenges of cell and gene therapy logistics

World Courier has the full-service logistics and cryogenic solutions you need to seamlessly deliver CGT innovation.

Start a conversation