

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

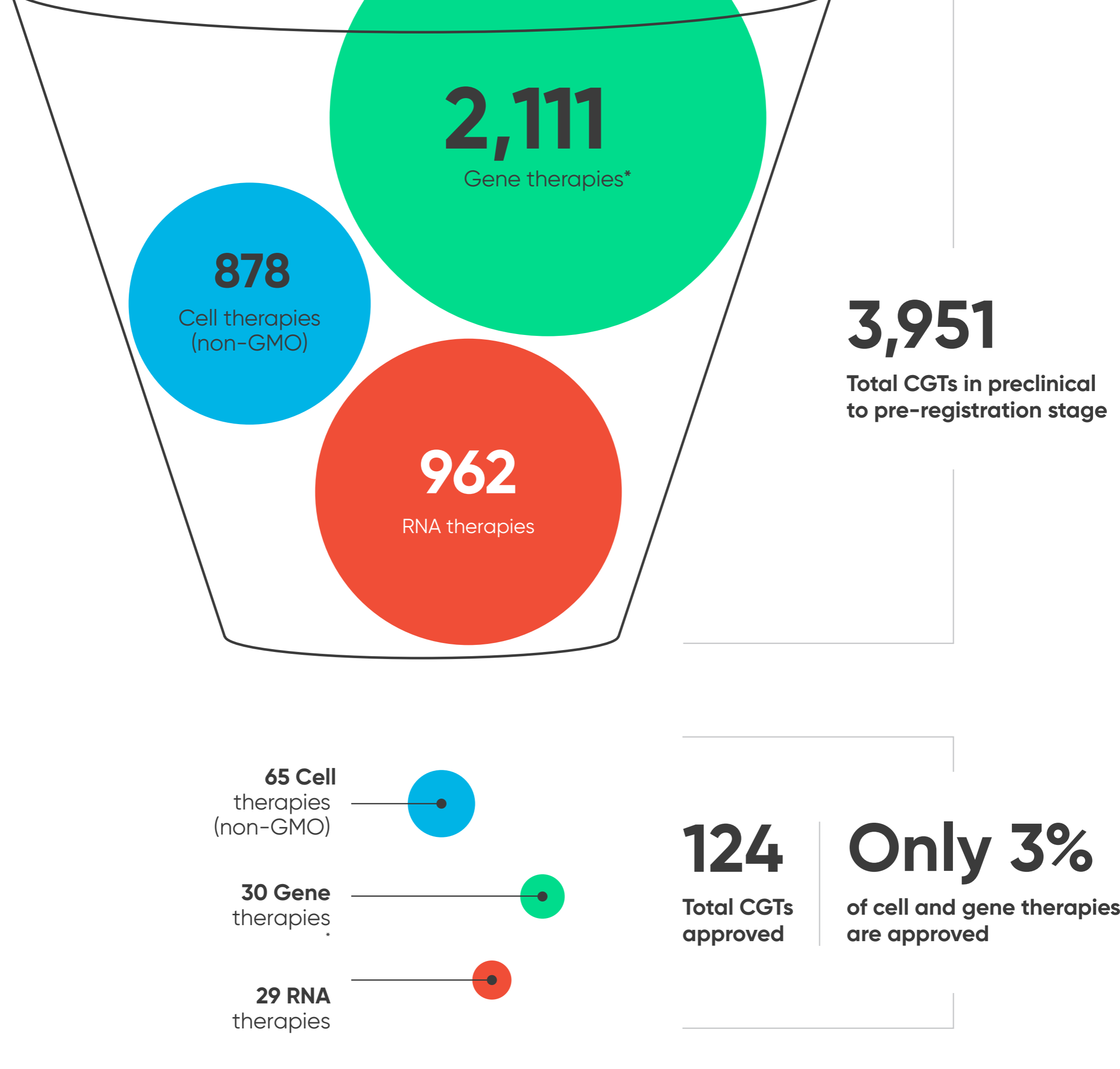
Cell and gene therapies (CGTs) are shaping the future of medicine and offering new hope to patients worldwide. These advanced therapies possess the power to target a wide range of conditions. However, it is crucial to recognize that the CGT landscape is dynamic and therapeutic success requires careful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

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From concept to cure:

Healthy CGT pipeline reveals potential with steady drip of approvals



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 2023 report

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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

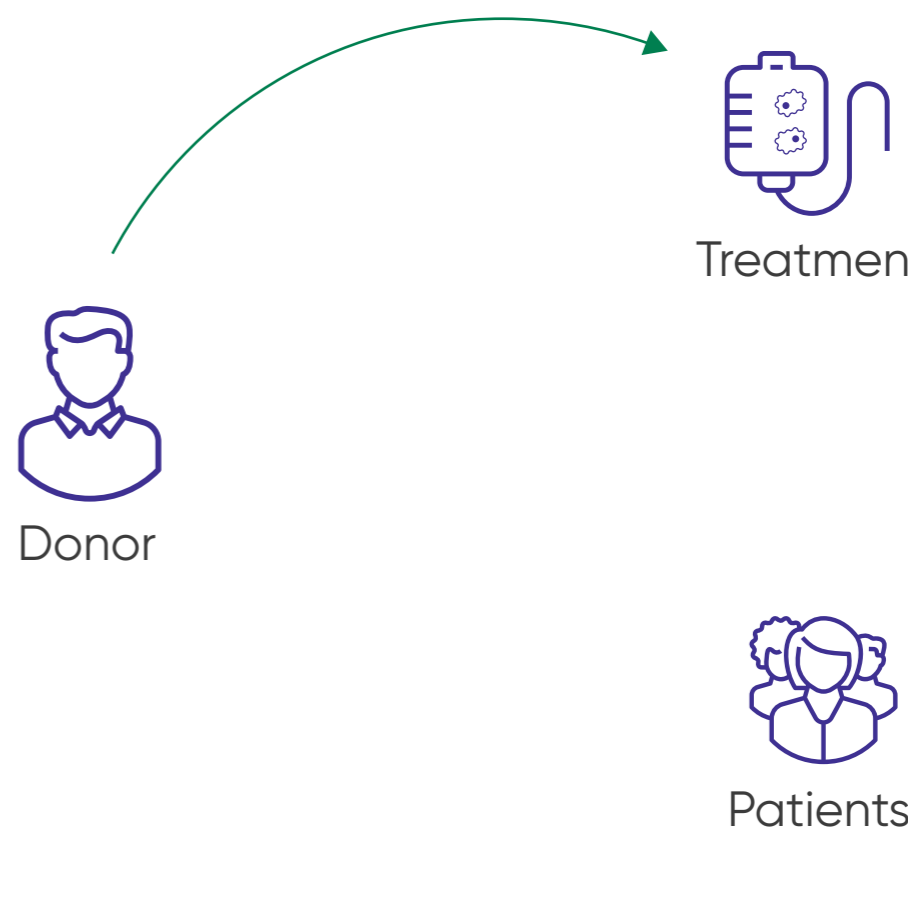
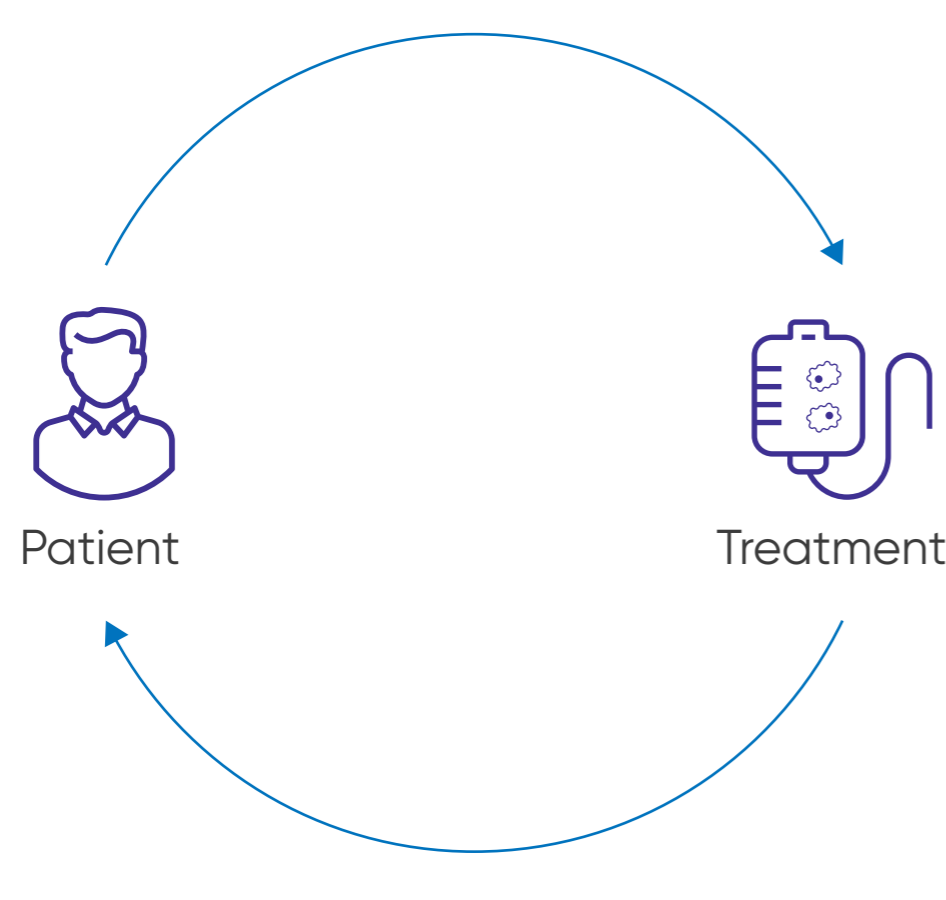
Simplified design with a standardized product

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

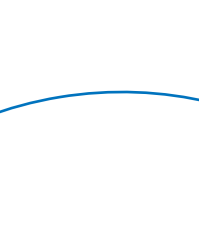


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The journey and nuanced diversity of CGT modalities

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