Allucent®
Helping bring new therapies to light

SHIFTING FRONTIERS:
Navigating the Evolution of Cell & Gene Therapies from Oncology to Autoimmune Studies

Why Autoimmune CGT Matters

Traditional Treatments	Cell & Gene Therapies
Symptom management only	Potentially curative
Chronic use = long-term risk	Immune system reprogramming
Broad immunosuppression	Single or short-course treatments
	Less systemic side effects

GOAL: Break the cycle of relapse, flare and irreversible damage

Industry Growth & Market Evolution

- 43 FDA-approved CGT products by end of 2024, up from 3 in 2015
- Global CGT market growth: $25.03B (2025) → $117.46B (2034) ➤ CAGR: 18.7%
- Seed + Series A funding in the CGT sector totalled $609.2M in Q4 2024 ➤ this is +26% vs. Q3 2024
- 7 CGT FDA approvals in 2024, including non-oncology indications
- First 2 adoptive cell therapies approved for solid tumors in 2024

Autoimmune CGT Trial Expansion

Cell Therapy Trials in Autoimmune Diseases

~50 (2018) → 8x increase → ~400 (2024)

Gene Therapy Trials in Autoimmune Diseases

~30 (2018) → 6x increase → ~180 (2024)

Reference: ASGCT Citeline 2024-25

CGT in Oncology vs. Autoimmune Diseases: What's Changing?

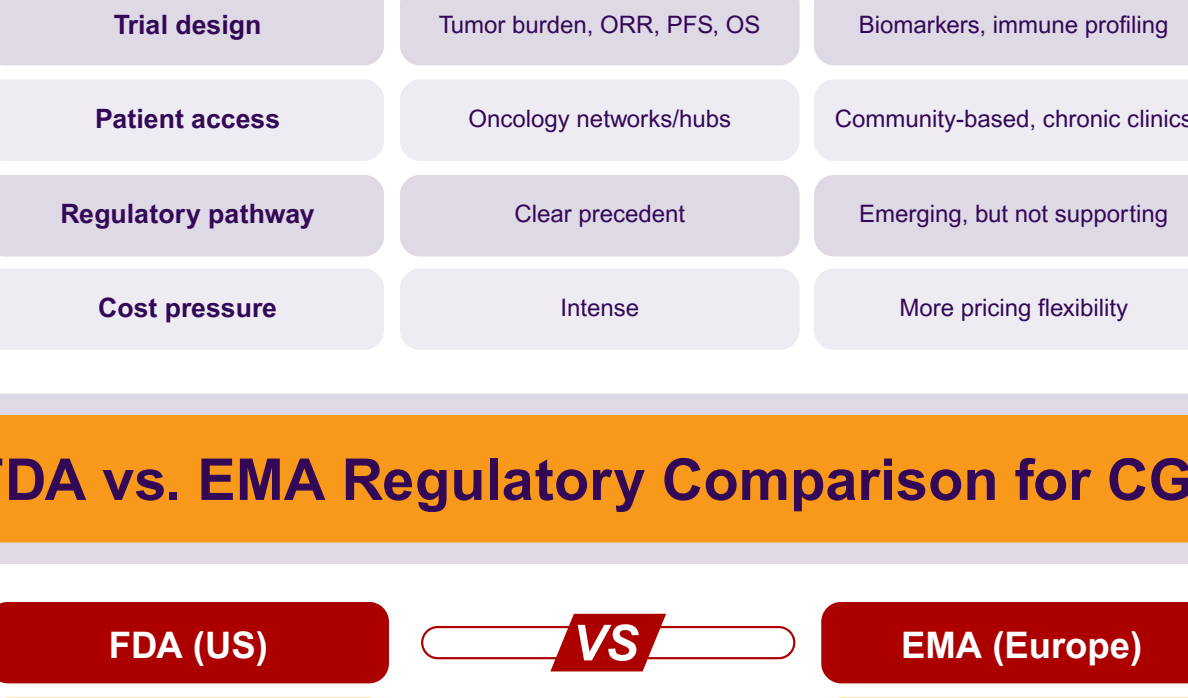
Category	Oncology	Autoimmune
Trial phase	Commercial & late phase	Early-phase, proof of concept
Unmet need	High in solid tumors	High across 80+ chronic diseases
Trial design	Tumor burden, ORR, PFS, OS	Biomarkers, immune profiling
Patient access	Oncology networks/hubs	Community-based, chronic clinics
Regulatory pathway	Clear precedent	Emerging, but not supporting
Cost pressure	Intense	More pricing flexibility

FDA vs. EMA Regulatory Comparison for CGT

FDA (US)	VS	EMA (Europe)
Strong in oncology; growing in autoimmune	CGT track record	Cautious; emphasis on orphan/pediatric
Open via INTERACT[1], RMAT[2], Fast Track	Autoimmune readiness	Interest via PRIME[4]/Orphan Designation
Biomarker focused	Trial design	Longitudinal safety data emphasis
Advanced for autologous CARs	CMC guidance	Longer feedback timelines
Faster path for rare diseases	Pediatric CGT	PIPs[5] support pediatric strategies
15-year LTFU[3], registries common	Post-market obligations	Varies by country; may need multiple site frameworks

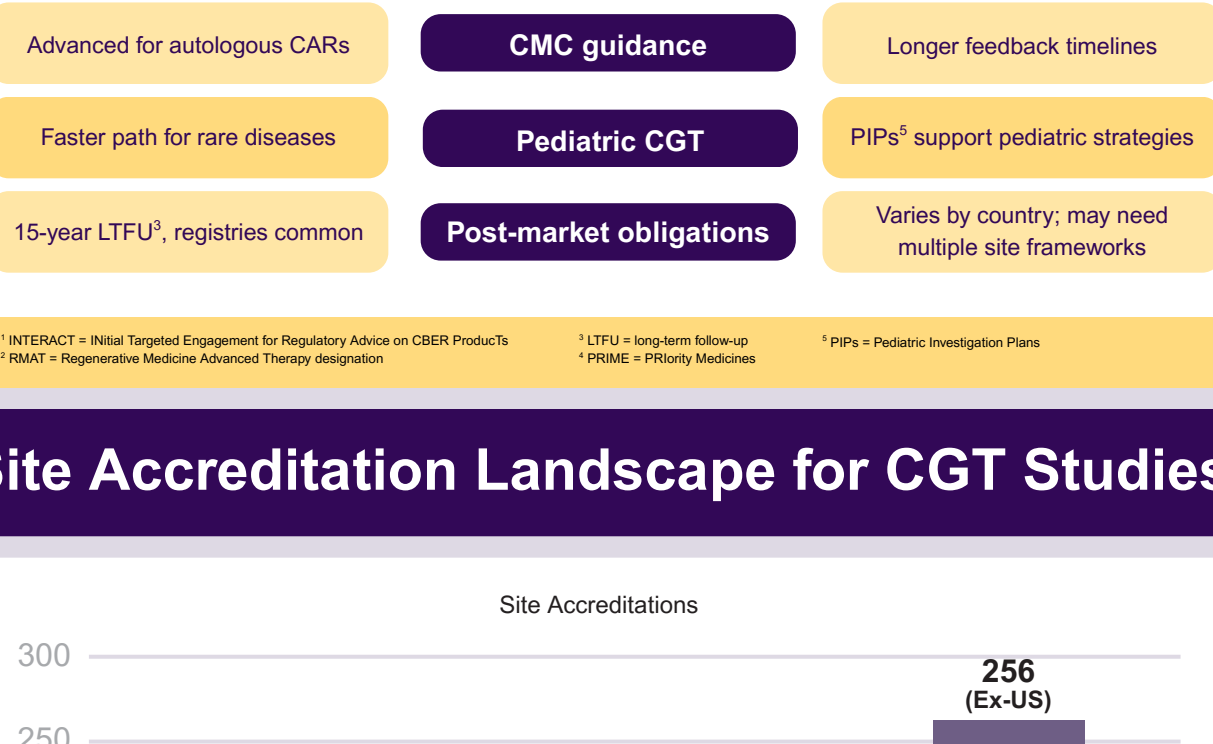
[1] INTERACT = INitial Targeted Engagement for Regulatory Advice on CBER ProducTs
[2] RMAT = Regenerative Medicine Advanced Therapy designation
[3] LTFU = long-term follow-up
[4] PRIME = PRIority Medicines
[5] PIPs = Pediatric Investigation Plans

Site Accreditation Landscape for CGT Studies



* ISCT-Europe: International Society for Cell & Gene Therapy – Europe
**EBMT: European Society for Blood and Marrow Transplantation

Future Outlook for CGT in Autoimmune Diseases



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