How Challenges Are Shaping ALLOGENEIC Cell Therapy Drug Product Manufacturing and CMC Strategies

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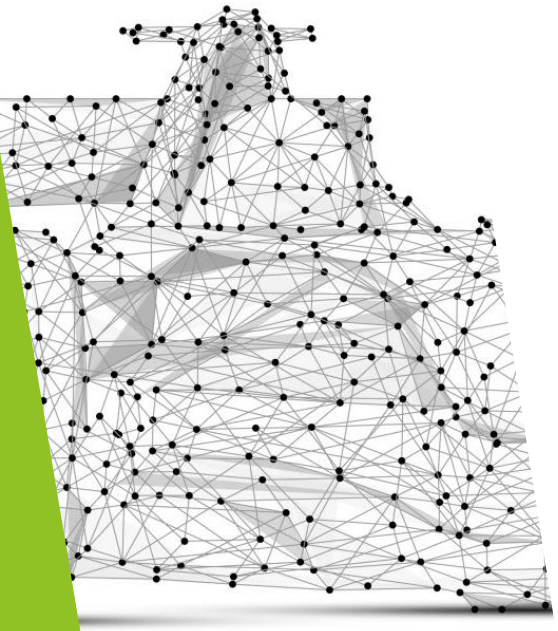
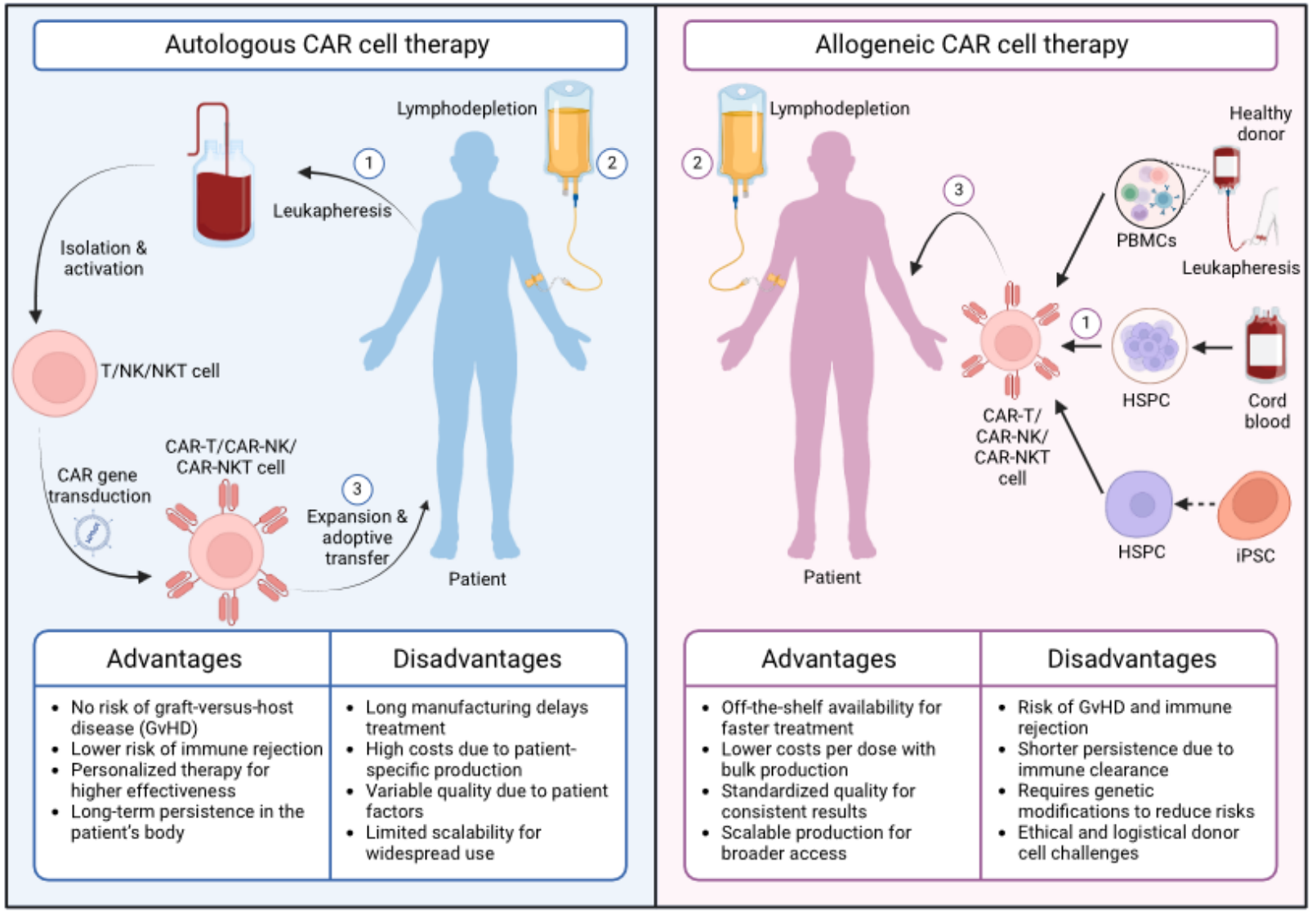
6/22/2026

Presentation Outline

- Current State of Allogeneic CAR-T Products
  - Potential advantages of Allogeneic CAR T Products
  - Review of Allogeneic off-the-shelf CAR-T Products
    - Cell Source and Cell Types
    - Manufacturing Process
- Major Challenges with Allogeneic CAR-T products manufacturing
- Future Direction
  - From Ex Vivo to in Vivo CAR-T Cell Engineering



Potential Advantages and Disadvantages



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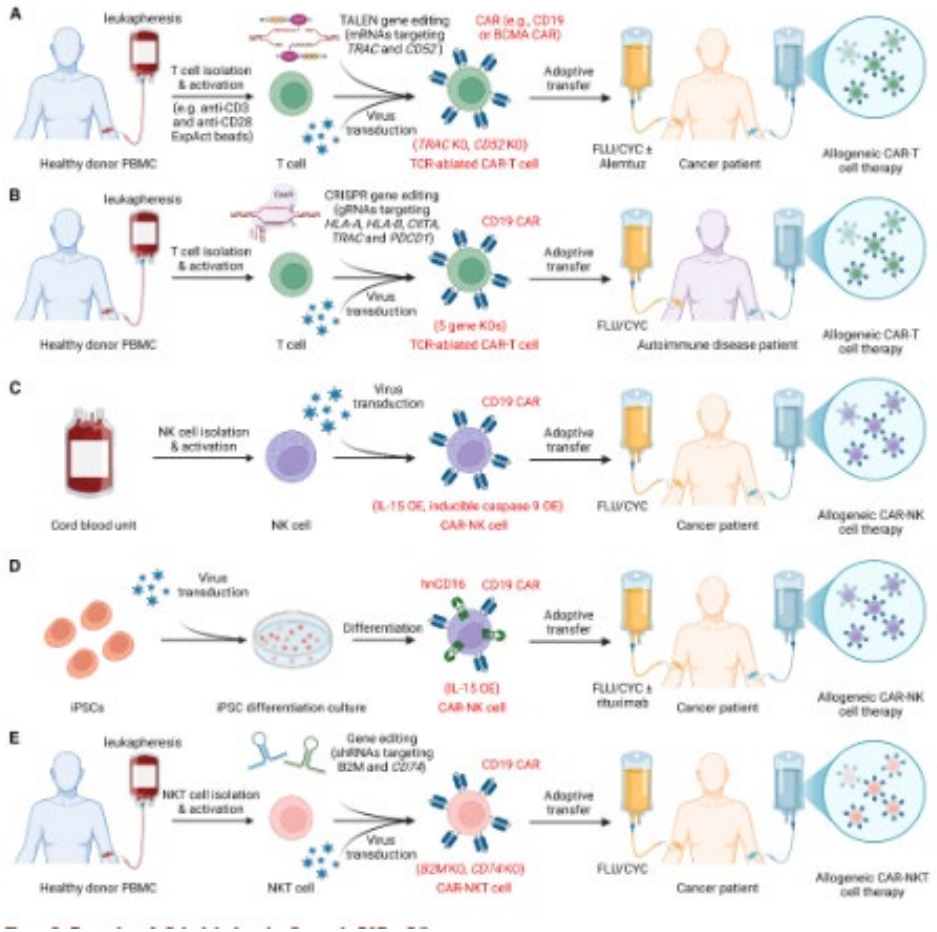
https://doi.org/10.1016/j.medj.2025.100677

Overview of the Manufacturing Process



- Manufacturing Process:
  - Sequential edit and modification
  - Simultaneous multi editing
- Complexity of multi step enrichment and depletion
  - Example KI CAR into TRAC locus
- Impact on Product Purity, Potency and Yield*
- *iPSC derived allo CAR-T could potentially allow for clonal selection of highly potent products

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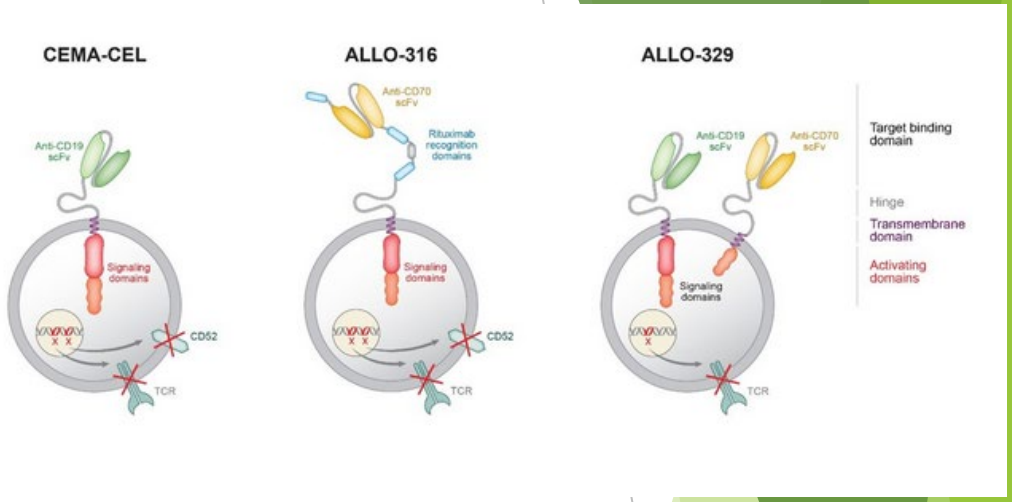
Allogeneic Product versus Autologous

- Autologous
- Time of manufacturing (12 days but reducing)
- Batch to batch consistency (not so good)
- Cost of Manufacturing (high but reducing)
- Immunogenicity (very low)
- Time to access (currently about 2 weeks)
- Repeated administration is very difficult
- Safety (ICANS,CRS)
- Persistence (good)
- Logistics are very complex
- Manufacturing complexity is low for approved products

- Allogeneic
- Upfront time of manufacturing is longer than autologous products but one batch can treat many patients on demand
- Manufacturing capacity is limited to the "batch" size (for iPSC derived CAR-T manufacturing capacity theoretically less limited)
  - Batch Size is theoretically large but is actually around 100 doses per batch
- Batch to Batch consistency is better than autologous. Theoretically for iPSC derived consistency should be best!
- Cost of manufacturing is potentially lower than autologous
- Immunogenicity (Host versus graft or allo rejection is a major issue but being addressed partially)
- Functional Exhaustion?
- Persistence (theoretically possible with HLA KO)
- Time to access is immediate after manufacturing is completed (off-the-shelf)
- Repeated administration is possible
- Safety (ICANS, CRS, GvHD and tumor formation for iPSC derived only)
  - GVHD is fully addressed by TCR KO
- Manufacturing complexity (very high due to multiple genetic changes)
  - Impact on safety, expandability and function

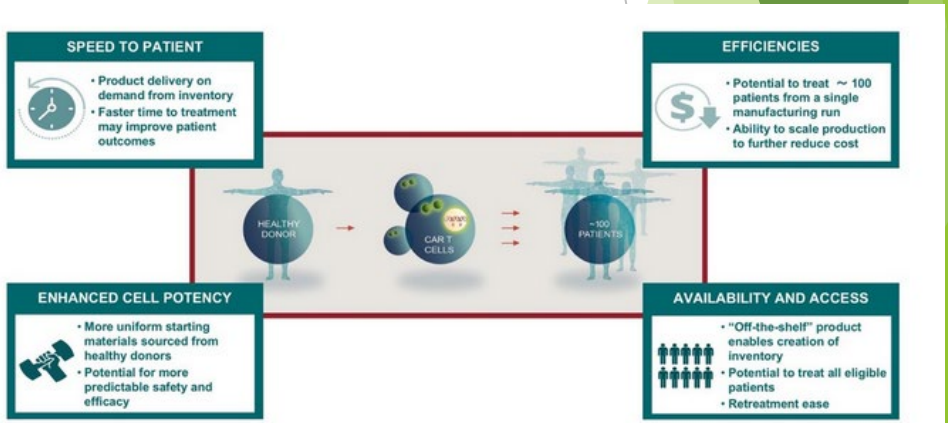
Allogene Results (Case Study)

Target	Program	Trial	Study Population	Discovery	IND-enabling	Phase 1	Phase 2[1]	Approved	Designation	Status
HEMATOLOGIC MALIGNANCIES										
CD19 (Key Program)	Cemacabtagene ansegedleucel (cema-cel)	ALPHA3	LBCL							Enrolling; Mid-2025: Lymphodepletion selection
CD70	ALLO-316		CD70+ Heme Malignancies							
SOLID TUMORS										
CD70 (Key Program)	ALLO-316	TRAVERSE	ccRCC						FTD RMAT	Mid-2025: Ph1b Data Update
CD70	ALLO-316		Other Solid Tumors							
DLL3	ALLO-213		SCLC & Neuroendocrine tumors							
Claudin 18.2	ALLO-182		Gastric & Pancreatic							
AUTOIMMUNE DISEASE										
CD19/ CD70 (Key Program)	ALLO-329	RESOLUTION	Rheumatology Disorders							Mid-2025: Phase 1 Basket Trial Initiation



Results from the Phase 1 ALLO-501 ALPHA Trial and the Phase 1 cema-cel ALPHA2 Trial

	Patients Treated with Phase 2 Regimen (n=12)
Overall Response Rate (ORR), n (%)	8 (67)
Complete Response (CR), n (%)	7 (58)
6 Month CR Rate, n (%)	5 (42)



https://www.sec.gov/Archives/edgar/data/1737287/000173728725000036/allo-20241231.htm

Allogeneic Chimeric Antigen Receptor T-Cell Products Cemacabtagene Ansegedleucel/ALLO-501 in Relapsed/Refractory Large B-Cell Lymphoma: Phase I Experience From the ALPHA2/ALPHA Clinical Studies

- **Methods**
- In the ALPHA2/ALPHA studies, the safety and efficacy of allogeneic CD19 CAR T cells were evaluated in CD19 CAR T treatment-naïve patients with R/R LBCL. Patients received healthy donor-derived, human leukocyte antigen–unmatched cema-cel/ALLO-501 following a 3-day lymphodepletion regimen of fludarabine (30 mg/m^2 once daily), cyclophosphamide (300 or 500 mg/m^2 once daily), ***and escalating doses of the anti-CD52 monoclonal antibody, ALLO-647***.
- **Results**
- As of September 26, 2024, 33 CD19 CAR T-naïve patients with LBCL (median age, 66 years; median number of previous therapies, 3) received allogeneic CAR T cells. **CAR T-cell expansion was observed following infusion, with persistence observed up to 4 months. The overall and complete response (CR) rates were 58% and 42%, respectively**; the median duration of response in patients with a CR was 23.1 months. The most common treatment-emergent adverse events were hematologic toxicities. No cases of graft-versus-host disease, immune effector cell–associated neurotoxicity syndrome, or grade ≥3 cytokine release syndrome were reported.

https://ascopubs.org/doi/10.1200/JCO-24-01933

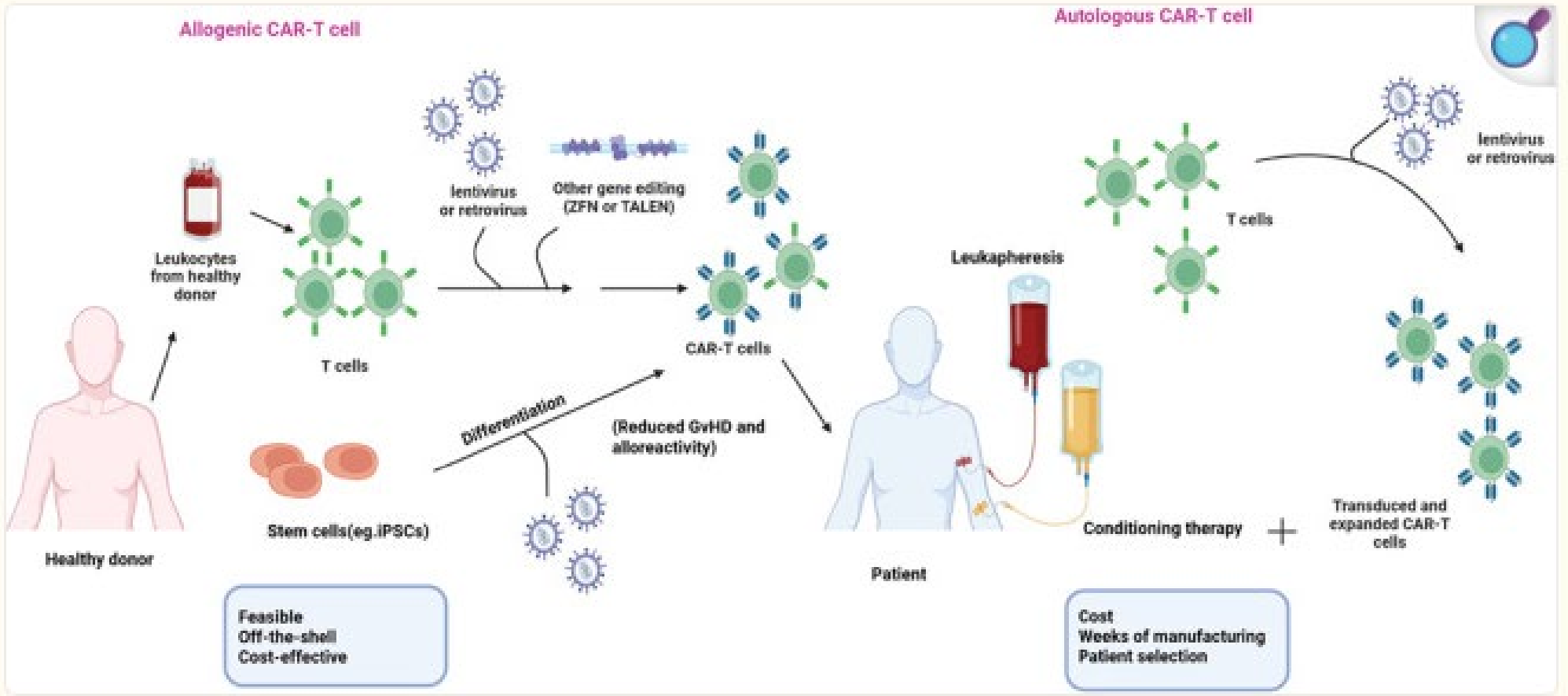
Allogeneic Chimeric Antigen Receptor T-Cell Products Cemacabtagene Ansegedleucel/ALLO-501 in Relapsed/Refractory Large B-Cell Lymphoma: Phase I Experience From the ALPHA2/ALPHA Clinical Studies

Outcome	CAR T-Naïve R/R LBCL	
	All Patients (N = 33)	Patients Who Received Selected Phase II Dose[a] (n = 12)
Best overall response, No. (%)		
CR	14 (42)	7 (58)
CR at 6 months	10 (30)	5 (42)
CR at 12 months	8 (24)	4 (33)
PR	5 (15)	1 (8)
SD	4 (12)	1 (8)
PD/death	10 (30)	3 (25)

General challenges in Manufacturing of Off The Shelf Products

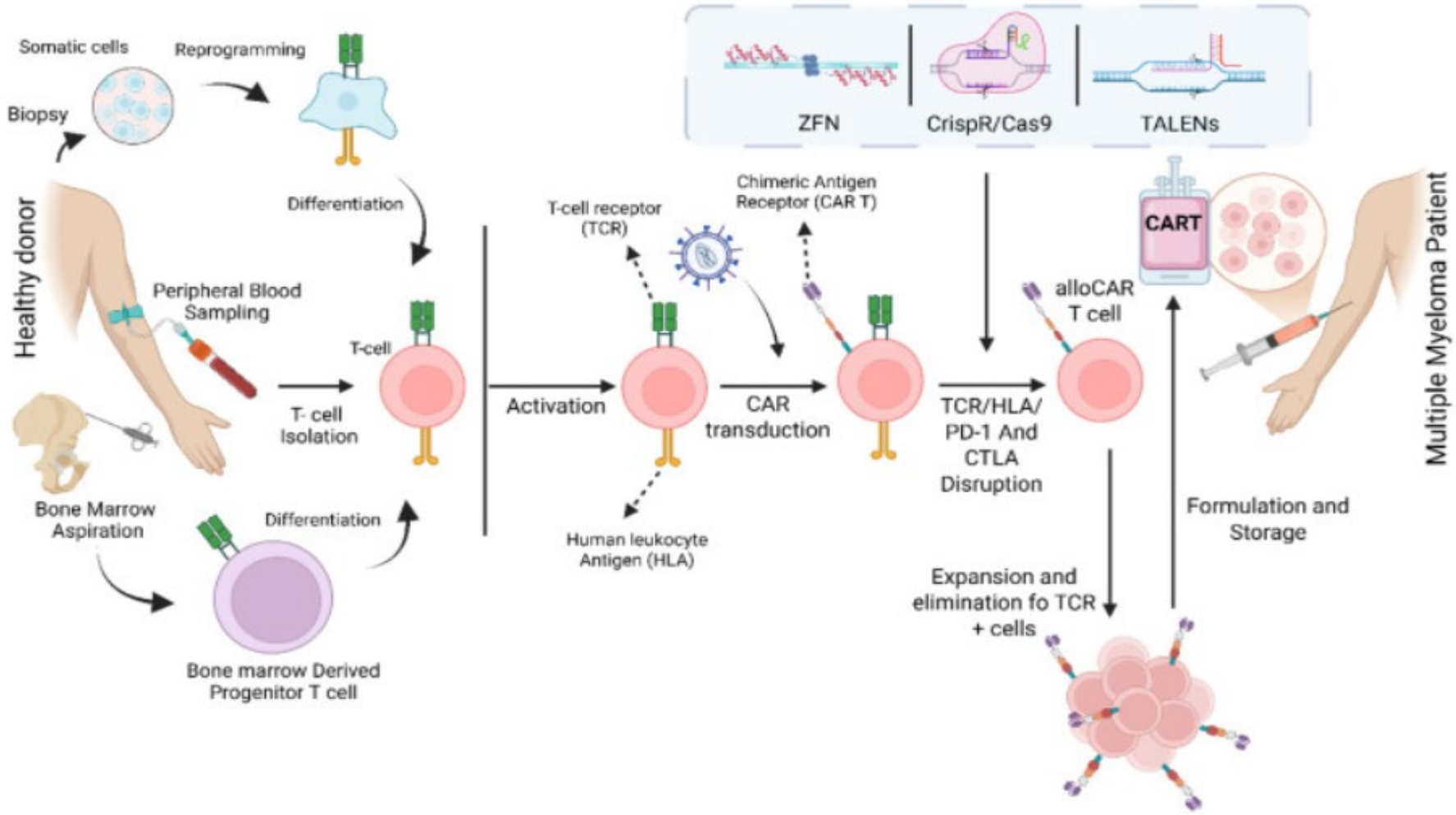
- Starting material
  - Donor to donor variability
  - Donor Material Quality
  - Donor Material Selection
- **Product is defined by a process**
  - Product is often very complex (Multi edited)
    - **CAR-T, HLA KO, TCR KO**
- Product quality assessment
  - Critical quality attributes and critical process parameters are challenging to establish
- Commercial scale manufacturing is still challenging
  - Batch to Batch comparability

Overview of manufacturing of Allogeneic CAR-T Products from healthy donor materials



Front. Immunol., 11 June 2025 Sec. Cancer Immunity and Immunotherapy
2025 Jun 12;16:1557157. doi: 10.3389/fimmu.2025.1557157

Overview of manufacturing of Allogeneic CAR-T Products from healthy donor materials



Transplantation and cellular Therapy Review Volume 32, Issue 2, February 2026, p125-140

Cell Source and Cell Types

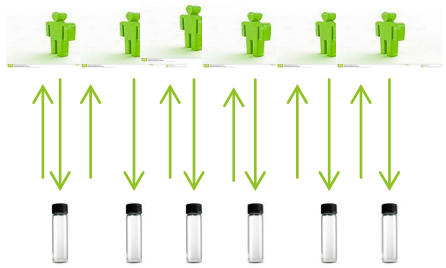
- Source:
  - Healthy adult donor tissue, not matched (Bone Marrow, Peripheral Blood)
  - Healthy cord blood donors
- Cell Types
  - Isolated T cells
    - Alpha beta, gamma delta (naïve memory T cells?)
  - Other immune cells (NK, Macrophage)
  - iPSC derived T cells
    - iPSC cell source (skin fibroblast, **CD34+** from PBMC/bone marrow or cord blood)

Background: Product Types , Autologous, Off-the-shelf and in Between. Regulatory Considerations

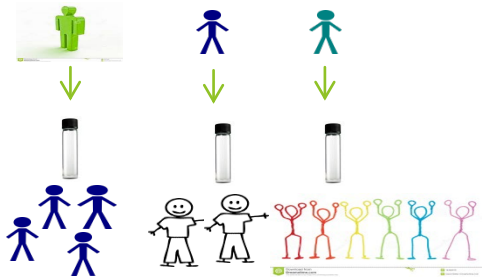
Common Considerations
Mechanism of Action, material qualification, challenges with establishing specifications, manufacturing facility, product shipping/handling, major manufacturing changes

Product tracking and segregation, high product variability, short half life, manufacturing logistics, scale out

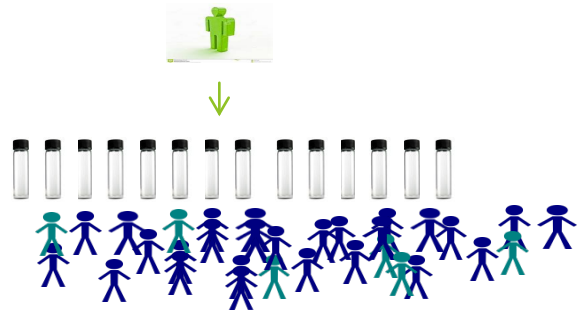
Donor Eligibility, qualification of cell bank, reproducibility of replacement MCB, stability of cell banks and intermediate and scale up



Autologous



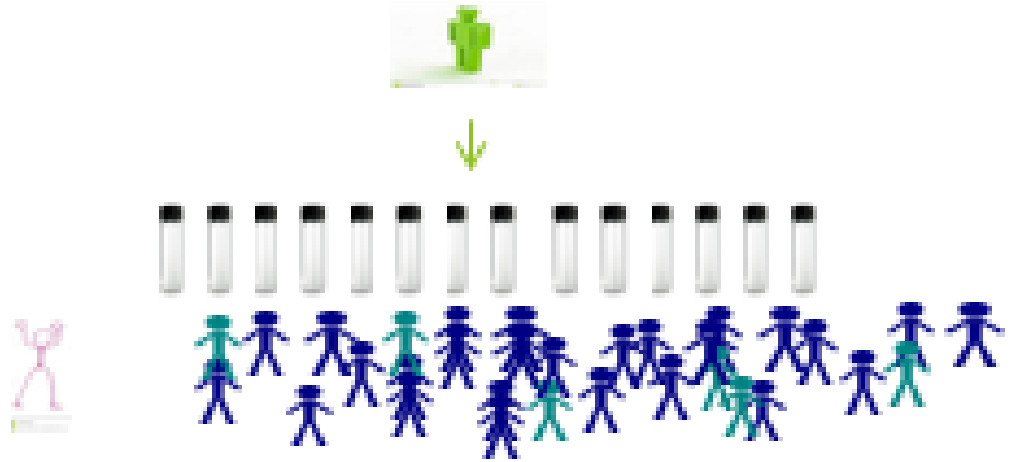
Semi-Allogeneic
Limited HLA
Matching



Allogeneic
Off-the Shelf
No HLA matching
Cryopreserved

Qualification of starting biological materials

- Starting Biological Materials
  - Donor Eligibility 21 CFR 1271 subpart C
    - Donor screening and testing
    - Test kits are FDA cleared
    - Test labs are CLIA certified
    - Donor screening involves extensive review of donor medical record, travel history, medical questionnaire and exam
  - Donor Consent
  - Donor Qualification, extended characterization
  - **Products manufactured from ineligible donors can not be licensed but may be used under exemption during IND**



Donor Qualification and Extended Characterization

- Donor materials should be extensively characterized from several healthy donors
  - *I do recommend companies to establish well defined acceptance criteria for donor materials beyond donor screening and testing*
  - Acceptance criteria should be determined based on attributes that could impact product quality (risk assessment)
    - For example genetic susceptibility to the relevant diseases should be evaluated

High Incidence of Secondary Malignancy after Allogeneic Hematopoietic Stem Cell Transplant in Adults: A Call for Surveillance

Ms. Alia Cibich, BHSc(Hons)[1] · Naranie Shanmuganathan, MBBS, FRACP, FRCPA[2] · Gauri Wechalekar[3] · … · David T Yeung, BSc(Med), MBBS(Hons), PhD, FRACP, FRCPA[6] · Devendra Hiwase, MBBS, MD, FRACP, FRCPA, PhD[7] · Peter Bardy, MBBS, FRACP, FRCPA, FRCPath[8]

CAR+ T-Cell Lymphoma after Cilta-cel Therapy for Relapsed or Refractory Myeloma

Authors: Simon J. Harrison, M.B., B.S., Ph.D. https://orcid.org/0000-0003-4555-6582, Cyrille Touzeau, M.D., Ph.D., Nicolas Kint, M.D., Ph.D., Katherine Li, M.S., Tamia Nguyen, B.Sc., M.Lab.Med., Caroline Mayeur-Rousse, M.D., Marzia Rahman, B.Med.Sci., M.B., B.S., +37 , and Piers Blombery, M.B., B.S., Ph.D.Author Info & Affiliations

N Engl J Med 2025;392:677-685, DOI: 10.1056/NEJMoa2309728

Rare Secondary Malignancy (Manufacturing Process or Rare Genetic Risk!

- ***The Cause:*** *Genomic sequencing revealed the secondary T-cell cancers were "CAR-positive" (contain the CAR transgene) but did* ***not*** *result from random viral vector integration.*

Instead, the original therapeutic T-cell product contained trace amounts of pre-existing, dormant ***aberrant T-cells***

that were unwittingly collected, engineered with the CAR, and subsequently multiplied.

- **Pre-existing Genetic Risk:** Researchers identified that these patients possessed pre-existing clonal abnormalities and inherited genetic variants (such as *JAK3* variants) that predisposed them to T-cell malignancies.

. 2026 Feb 19;18(4):678. doi: 10.3390/cancers18040678

At the Crossroads of Lineage: Secondary Malignancies After CAR-Based Immunotherapy

Logan Lorentzen [1,*], Mazie Tsang [2], Talal Hilal [2], Allison Rosenthal [2], Javier Munoz [2]
Editor: Sonia Vallet

•PMCID: PMC12939506 PMID: 41749931

https://www.petermac.org/about-us/news-and-events/news/details/call-to-watch-for-rare-secondary-blood-cancer-after-car-t-cell-therapy

Current Ongoing Clinical Trials

Current Ongoing Clinical Trials Contributing to "off-the-shelf" Allogeneic CAR-T Cell Therapy

Clinical Trial Name	Phase	CAR-T Cell Agent	CAR Construct Details	Target Antigen	Clinical Application	Sponsor	Trial Identifier (NTC)
P-BCMA-ALLO1	I	P-BCMA-ALLO1	piggyBac transposon-based system with anti-BCMA scFv linked to 4-1BB costimulatory domain and CD3ζ signaling domain; includes Cas-CLOVER-mediated knockout of β2M, TCR-β and safety switch	BCMA	Relapsed or refractory multiple myeloma	Poseida Therapeutics	NCT04960579
UNIVERSAL	I	ALLO-715*	Anti-BCMA scFv with FMC63-derived binding domain, CD28 hinge/transmembrane domain, 4-1BB costimulatory domain and CD3ζ signaling domain; TALEN-mediated disruption of TRAC and CD52 genes	BCMA	Relapsed or refractory multiple myeloma	Allogene Therapeutics	NCT04093596
ALPHA3	I/II	ALLO-501A†	FMC63-derived anti-CD19 scFv, CD28 hinge/transmembrane domain, 4-1BB costimulatory domain and CD3ζ signaling domain; TALEN-mediated knockout of TRAC and CD52 genes; rituximab-binding domain removed from ALLO-501	CD19	Relapsed or refractory large B-cell lymphoma	Allogene Therapeutics	NCT06500273
BALLI-01	I/II	UCART22	Anti-CD22 scFv, CD28 costimulatory domain, CD3ζ signaling domain; TALEN-mediated disruption of TRAC and CD52 loci	CD22	Relapsed or refractory B-cell acute lymphoblastic leukemia	Cellectis S.A.	NCT04150497
CALM	I	UCART19	FMC63-derived anti-CD19 scFv, 4-1BB costimulatory domain, CD3ζ signaling domain; TALEN-mediated knockout of TRAC and CD52 genes	CD19	Relapsed or refractory B-cell acute lymphoblastic leukemia	Institut de Recherches Internationales Servier	NCT02746952
AMELI-01	I	UCART123	Anti-CD123 scFv, CD28 costimulatory domain, CD3ζ signaling domain; TALEN-engineered with TRAC and CD52 disruption	CD123	Relapsed or refractory acute myeloid leukemia	Cellectis S.A.	NCT03190278
CD30.CAR-EBVSTs	I	CD30.CAR-EBVSTs	Anti-CD30 scFv linked to CD28 costimulatory domain and CD3ζ signaling domain; uses EBV-specific T cells as a cell source without gene editing	CD30	Relapsed or refractory lymphomas	Baylor College of Medicine	NCT04288726
FT819	I	FT819	Anti-CD19 CAR inserted into TRAC locus via CRISPR/Cas9, with 4-1BB costimulatory domain and CD3ζ signaling domain; derived from engineered iPSC master cell line	CD19	B-cell malignancies	Fate Therapeutics	NCT04629729
TRAVERSE	I	ALLO-316	Anti-CD70 scFv, 4-1BB costimulatory domain, CD3ζ signaling domain; TALEN-edited with TRAC and CD52 disruption	CD70	Advanced or metastatic renal cell carcinoma	Allogene Therapeutics	NCT04696731
BEAM-201	I	BEAM-201	Multiplex base-edited allo-CAR-T with edits in TRAC, CD7, CD52, PDCD1; anti-CD7 CAR	CD7	Relapsed/refractory T-cell acute lymphoblastic leukemia and other T-cell malignancies	Beam Therapeutics	NCT06934382
WU-CART-007	I/II	WU-CART-007	Allogeneic CAR-T with CD7 disruption and TRAC knockout to prevent fratricide and reduce GvHD	CD7	Relapsed or refractory T-cell acute lymphoblastic leukemia or lymphoblastic lymphoma	Wugen	NCT04984356

Current Ongoing Clinical Trials Comparison of CAR-T from Different Sources

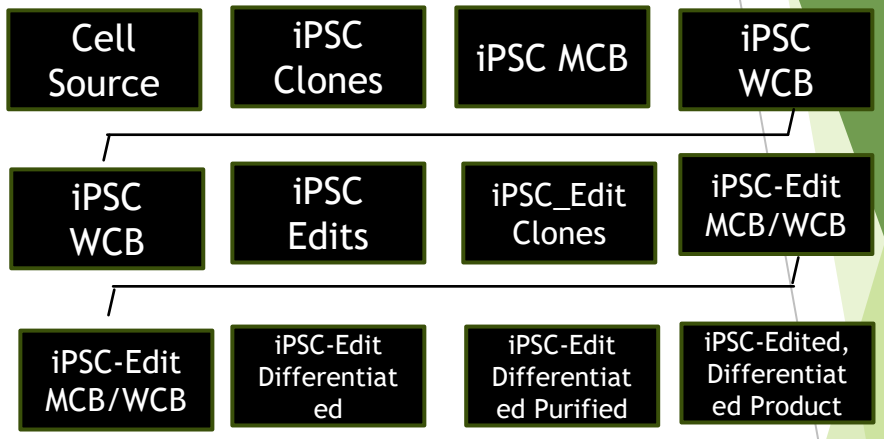
TABLE 1 Comparison of CAR-T cells derived from different sources.

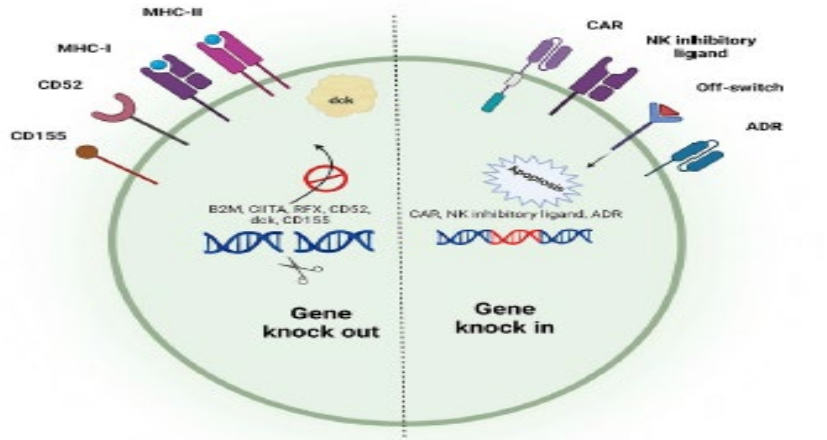
	Autologous CAR-T	Third-party donor-derived CAR-T	Cord blood-derived CAR-T	HSC-derived CAR-T	IPSC-derived CAR-T
Cellular fitness of the final product	Unfavorable	Favorable	Favorable	Favorable	favorable
Batch-to-batch consistency	Inconsistent	Inconsistent	Inconsistent	Inconsistent	Consistent
Manufacturing capacity	Limited	Limited (from a single donor)	Limited (from one unit)	Limited (from a single donor)	Potentially unlimited
Immunogenicity	Low	High	Relatively Low	High	High
Multiplexed gene editing	Possible but challenging	Possible but challenging	Possible but challenging	Possible but challenging	More straight forward
Safety concerns	CRS, ICANS	GvHD, CRS, ICANS	GvHD, CRS, ICANS	GvHD, CRS, ICANS	GvHD, CRS, ICANS, Teratoma
Accessing time	2–4 weeks	Readily available	Readily available	Readily available	Readily available
Re-administration	Difficult	Possible	Possible	Possible	Possible

Combining the induced pluripotent stem cell (iPSC) technology with chimeric antigen receptor (CAR)-based immunotherapy: recent advances, challenges, and future prospects Front. Cell Dev. Biol., 17 November 2024
Sec. Stem Cell Research
Volume 12 - 2024 | https://doi.org/10.3389/fcell.2024.1491282

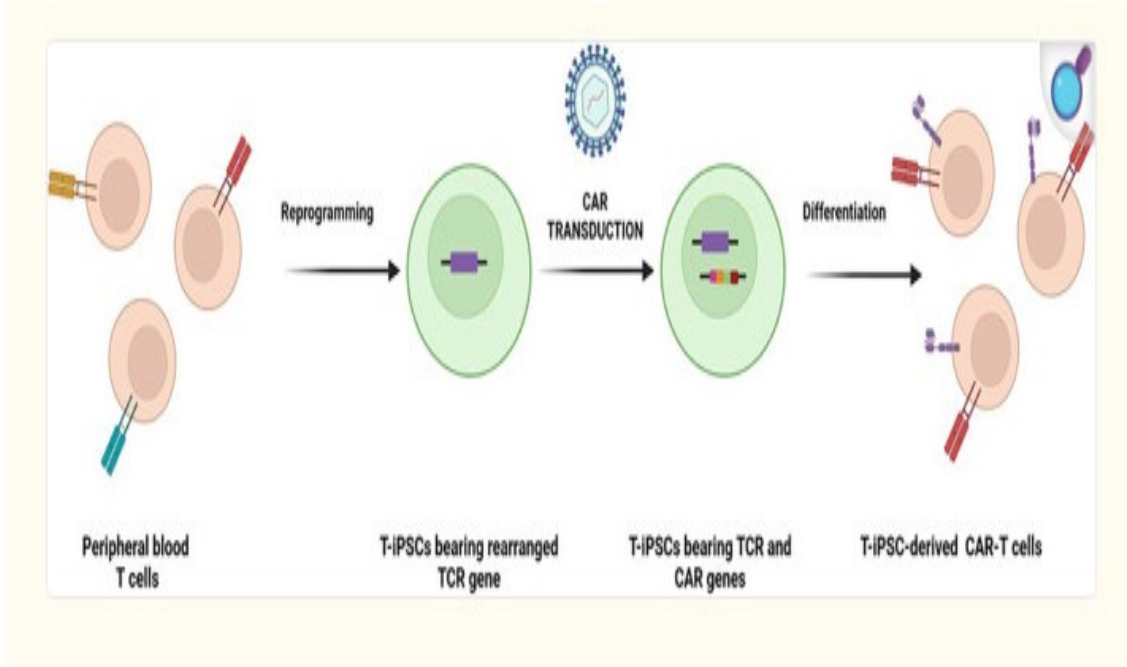
Alternative to Healthy Donor Materials; iPSC Derived Allogeneic CAR-T Products

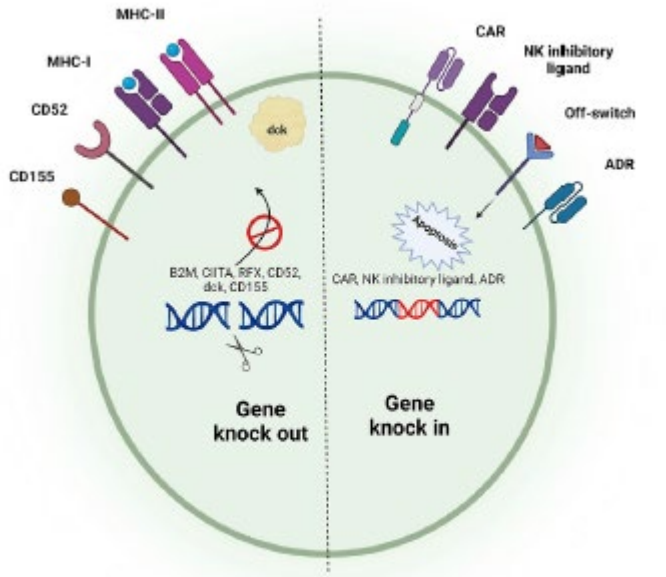
- Cell Source
- IPSC manufacturing and selection of clones based on pluripotency and stability (seed bank, MCB)
- IPSC genome engineering
- Engineered iPSC clone selections based on extensive characterization of putative genetic changes and genome stability.
- Differentiation and selection of iCAR-T cells
  - Identity (Cell surface marker expression or lack of thereof)
  - Purity (quantitation of residual undifferentiated iPSC)
  - Potency (target tumor killing)

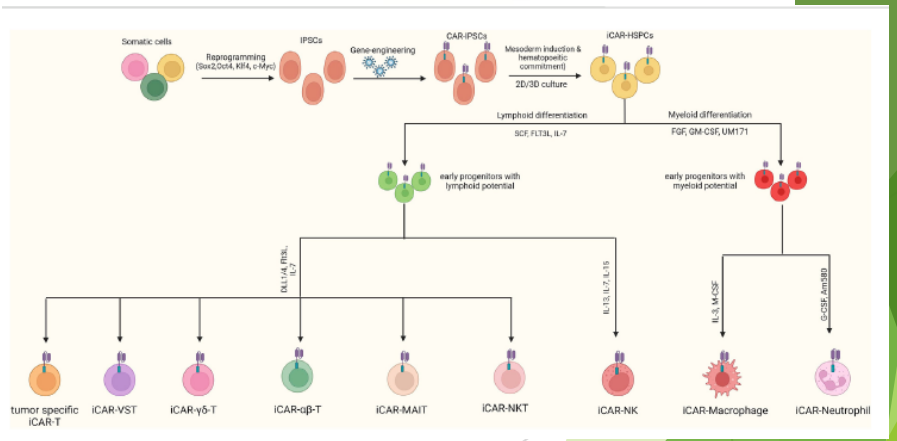




iPSC Derived Allogeneic CAR-T







Frontiers in Cell and Developmental Biology PUBLISHED 18 November 2024
DOI 10.3389/fcell.2024.1491282
Mehdi Alidadiet al.

iPSC derived CAR-T Programs

TABLE 2 Clinical trials of iPSC-derived CAR-modified cells.

Cell type	Product name	NCT number	Developer	CAR target Ag	Genome modifications		Disease	Study phase
					Inserted genes	Disrupted genes		
iCAR-T	FT819	NCT04629729	Fate Therapeutics	CD19	CD19	TRAC	CD19$^+$ B-cell malignancies	I
	FT825	NCT06241456	Fate Therapeutics	HER2	HER2 CAR, IL7RF, hnCD16a, CXCR2, TGFβ-signal redirection receptor	TRAC, CD38	Advanced solid tumors	I
iCAR-NK	FT522	NCT05950334	Fate Therapeutics	CD19	CD19 CAR, hnCD16, IL-15/IL-15Rα, anti-4-1BB ADR	CD38	CD19$^+$ B-cell malignancies	I
	FT576	NCT05182073	Fate Therapeutics	BCMA	BCMA CAR, hnCD16, IL-15/IL-15Rα	CD38	Multiple myeloma	I
	FT596	NCT04555811	Fate Therapeutics	CD19	CD19 CAR, hnCD16, IL-15/IL-15Rα	none	CD19$^+$ B-cell malignancies	I
	CNTY-101	NCT05336409/ NCT06255028	Century Therapeutics	CD19	CD19 CAR, IL-15, Safety switch, HLA-E	β2M and CIITA	CD19$^+$ B-cell malignancies/lupus Erythematosus	I
	Anti-CD19 iCAR NK Cells	NCT03824951	Allife Medical Science and Technology Co., Ltd	CD19	Undisclosed	Undisclosed	CD19$^+$ B Cell Lymphoma	I
	CLL1 CAR-NK cell	NCT06027853	Zhejiang University	CLL1	Undisclosed	Undisclosed	AML	I
	iPSC-NK cells	NCT06367673	Zhejiang University	CLL1 or CD33	Undisclosed	Undisclosed	AML	I

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Clinical Outcomes Allogeneic CAR-T Products from all Allogeneic Sources

- Dose ranging from 1e8-1e10
- Clinical outcome complete response (ORR) of 40-80% but it does not appear to be durable
- Safety Considerations:
  - Low GVHD
  - Lack of Persistence
  - Infection concern is high
    - Cytopenia very high
    - Neutropenia
  - Low to moderate CRS (faster onset but lower grade)
  - Low to moderate ICANS

Outstanding Challenges of Allogeneic CAR-T Products

- Donor material selection and qualification
- Time of manufacturing is longer upfront more than autologous products but one batch can treat many patients on demand
- Manufacturing capacity is limited to the batch size (for iPSC derived CAR-T theoretically less limited)
- Batch to Batch consistency is better than autologous. Theoretically for iPSC derived consistency should be most optimal!
- Cost of manufacturing is potentially lower than autologous per dose theoretically.
  - Cost of manufacturing depends on the batch size and the process
  - For iPSC derived CAR-T the overall cost is affected by reagent cost needed for differentiation process
- Repeated administration may be required for establishing a durable response
- Safety (ICANS, CRS, GvHD and tumor formation for iPSC derived only)
- Persistence (theoretically possible with HLA KO) but data is not conclusive as to the durability of response
  - Immunogenicity (allo-rejection is a major issue)
  - HLA KO make product more susceptible to clearance by NK cells
- GvHD appears to be fully addressed TRAC gene knockout
- Manufacturing complexity (very high due to multiple genetic changes)
  - Multi editing could potentially impact safety, expandability and function

Next Steps

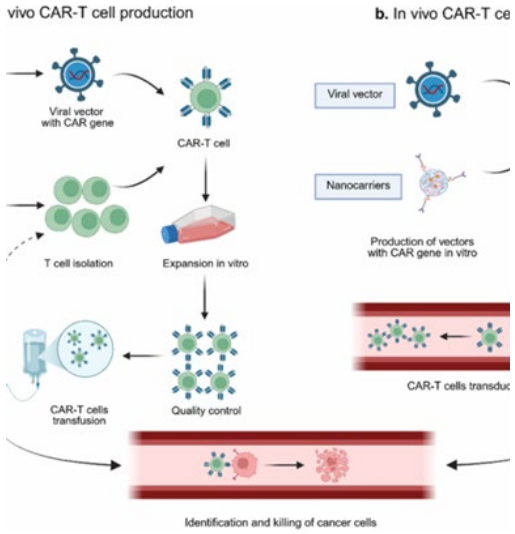
- Improvement in the process, consider minimizing genetic changes to the product while improving potency
  - Evaluate alternative methods for multiple editing, reduce complexity of manufacturing if feasible
- Enhance long term durability of allogeneic products (KO of additional HLA Class I and II, beta 2 microglobulin or other HLA molecules)
- Increase batch size per one manufacturing run (increase yield)
- Reduce batch to batch variability by establishing process optimization and QbD approach
- Establish accelerated comparability studies when new batches are manufactured.
- Improve safety profile of allogeneic CAR-T products
  - Incorporate into design of allogeneic CAR-T our expanding knowledge of suitable target(s) under evaluation for autologous CAR-T along with other interventions to enhance durability of CAR-T cells in a suppressive microenvironments (improved CAR design)
- For iPSC derived allogeneic CAR-T improve safety, genetic and functional stability of the final product
- Consider further evaluation of allogeneic CAR-T products for other conditions such as autoimmune diseases
- Consider further development of CAR using other starting cell types and explore in vivo CAR-T strategies

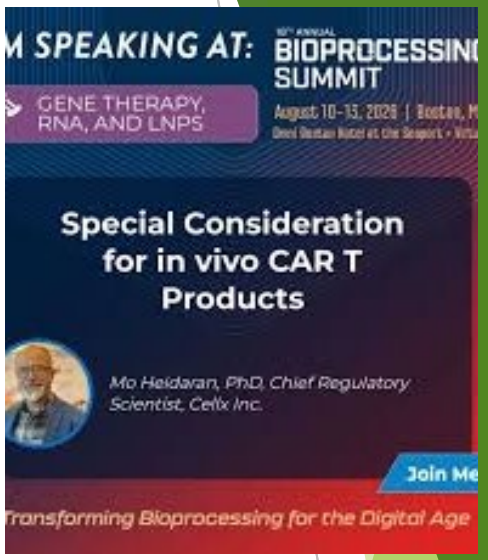
Conclusions

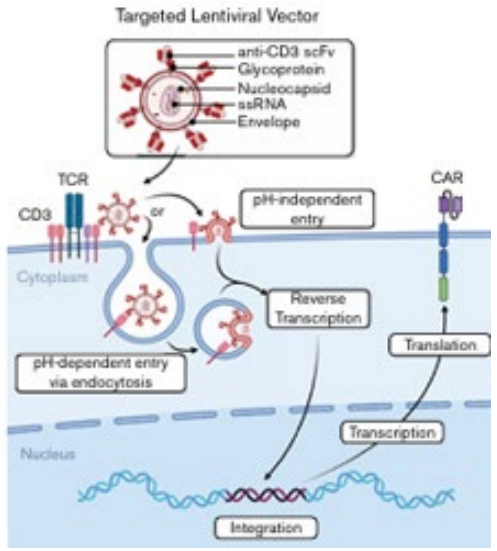
- Starting with healthy donor and T cell may provide advantage over autologous CAR-T products and cost of manufacturing could potentially come down due to the scale of manufacturing
- Off-the-shelf product provides many advantages logistically
- Upfront process of manufacturing is currently very complex requiring maximal manipulations, batch size remains a factor
- Long term persistence and durability of responses have not been established
- It is not clear how allogeneic CAR-T products (targeting same antigen in same disease) can replace existing approved autologous CAR-T products
- Allogeneic CAR-T products showing some initial promising results in clinic- however,
  - While initial overall response rate is good these products don't appear to be persistent and response is not durable
  - Improvement is potentially needed in the design of CAR, multi editing strategy, and the choice of starting cell type(s)

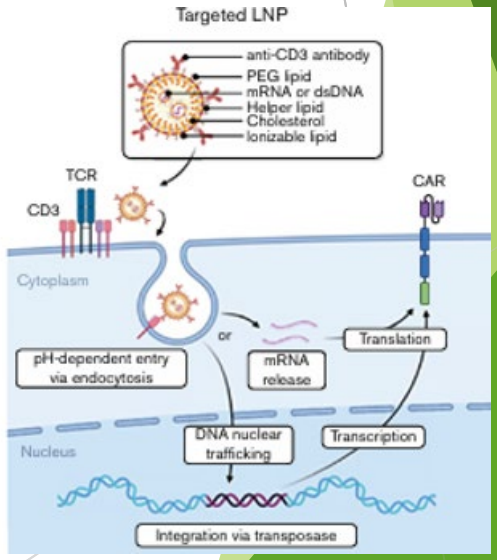
Toward Application of In Vivo CAR-T?

- In vivo
  - Product is modified LVV or LNP (Gene Therapy)
  - LVV modification involves changes in targeting envelop (VSV-G, antibody) plus CAR
  - LNP modification involves conjugation of targeting to lipid moiety, plus CAR









Company	Gene Edit	Target	Cell Source	Indication
Cellectis Allogene	Talen	CD19, BCMA, CD70	Healthy donor T cells	BCMA (relapse or refractory MM CD19 (Relapse or refractory large B lymphoma
Cellectis	Talen	CD123, CD22, SLAMF7	Healthy donor T cells	CD22 (Relapse or refractory B cell lymphoblastic leukemia
City of Hope	ZFN	IL13-zetakine	Healthy donor T cells	
Precision Biosciences	ARCUS	CD19, BCMA, CD20	Healthy donor T cells	
Crispr therapeutics	CRSPR/Cas9	CD19 CD70	Healthy donor T cells	
Caribou Biosciences	CRSPR/Cas9	BCMA CD19	Healthy donor T cells	MM (rB cell NHL PD-1 KO for Tcell exhaustion
Gracell Biotechnologies		CD17/CD7	Healthy donor T cells	R/R B Cell Malignancy
Beam Therapeutics	Base Edit	CD7 (CD7 KO, prevent fratricide	Healthy donor T cells	Relapse or refractory acute lymphoblastic leukemia or lymphoblastic lymphoma
Wugen		CD7	Healthy Donor T cells	Relapse or refractory acute lymphoblastic leukemia or lymphoblastic lymphoma
Poseida Therapeutics	Cas-Clover, Transposon piggyBac	BCMA, FKBP12, MUC1-C		Relapse or refractory multiple myeloma
Fate therapeutics	CRSPR/Cas9	CD19/CD38	iPSC from healthy donors	
Nkarta		CD19, IL-15 (CAR-NK)	Healthy Donor NK cells	Autoimmune
Century Therapeutics		CD19 (CAR-NK)	iPSC from healthy donors	B-NHL and basket trial autoimmune

Questions

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SCAN ME

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