
ADVANCED PRACTICE PROVIDER
The Expanding World of Cellular Therapy
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Beginning in 2025

Advanced Practice Provider series is moving to:

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Thank you for spreading the word!

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Our Presenter

Brianne Buchanan, PA-C

Brianne Buchanan is a Physician Assistant working for the Bone Marrow Transplant and Cellular therapy Program at theUniversity of North Carolina Chapel Hill since 2013.

Her clinical focus is working with patients receiving both commercial andresearch CAR-T therapies and on CAR-T program development, which she has been extensively involved with since 2016.

Prior toworking at UNC, she worked in both Bone Marrow transplant and outreach oncology at Duke University, and received her PAdegree from George Washington University in 2005.

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Our Presenter

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Our Presenter

5. Brianne Buchanan, PA-C, started her career in outreach oncology where she often flew in a small plane or drove three hours to clinic each day.

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4. She spent most of her career in Bone Marrow Transplantation departments, where she tended feel like most of her patients were nearly family.

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3. She bikes or walks to work, so she is a great go-to for patient care when it snows.

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2. Brianne developed her love of bone marrow transplant after being a BMT elective in PA at the NIH with many of the leaders in the field.

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2. Brianne developed her love of bone marrow transplant after being a BMT elective in PA at the NIH with many of the leaders in the field.
1. She provides CAR-T customer service and is motivated to increase access to CAR-T treatment in NC.

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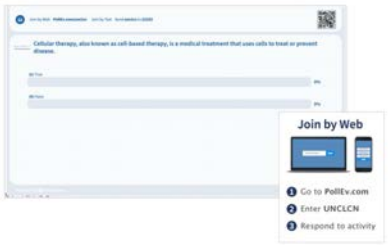
Sample Poll Everywhere Question



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ACCME Disclosure

This activity has been planned and implemented under the sole supervision of the Course Director, Stephanie Wheeler, PhD, MPH, in association with the UNC Office of Continuing Professional Development (CPD). The course director received research support from AstraZeneca (ended June 2023) and Pfizer Medical Foundation (ended December 2023). These financial relationships have been mitigated. CPD staff have no relevant financial relationships with ineligible companies as defined by the ACCME.

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The Expanding World of Cellular Therapy

Faith Brianne Buchanan, PA-C
UNC Bone Marrow Transplant and Cellular Therapy
faith.buchanan@unchealth.unc.edu

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Learning Objectives

- Recall the mechanism and use of CAR-T Immunotherapy
- Describe current CAR-T therapies available in clinical trials
- Recognize patients that may be appropriate for the option of a cellular therapy clinical trial

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"Cell therapy is **the transfer of a specific cell type into a person to treat or prevent a disease**."

- Stem cell transplant (The OG)
- **Chimeric Antigen Receptor T-Cell (CAR-T)**
- Tumor infiltrating lymphocytes
- Gene therapy
- Mesenchymal stem cells

American Society of Gene and Cell Therapy. "Cell Therapy Basics." Last Updated: 12/18/2023. https://patientadvocates.asgct.org/gene-therapy-101/cell-therapy-basics

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What is CAR-T Cell Therapy?

- Cellular therapy that utilizes the body's immune system to treat cancers
- Attaches an antigen receptor to a patient's own T-cells to identify cancer cells and kill them
- Common antigens: CD19+ (leukemia/lymphoma), BCMA+ (multiple myeloma)
- Primarily used as treatment for relapsed/refractory hematologic malignancies currently
- Commercially available products to treat Leukemia, Lymphoma, and Multiple Myeloma
- Requires a specialized center to administer the CAR-T cells and manage side effects
- Side effects: Cytokine Release syndrome (CRS), Immune-effector cell associated neurotoxicity syndrome (ICANS), Cytopenias, Hypogammaglobulinemia, Hemophagocytic lymphohistiocytosis (HLH)

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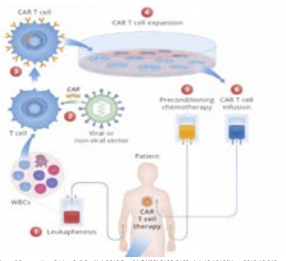
CAR-T Cell Therapy Process

- T-cells are collected from the patient and re-engineered with a CAR
- Takes ~4 weeks
- Give lymphodepleting chemotherapy
- Cells are given through an IV
- Monitored intensively for a minimum of 4 weeks



Ganatra, Sanja, et al. "Chimeric Antigen Receptor T-Cell Therapy for Cancer and Heart: JACC Council Perspectives." J Am Coll Cardiol. 2019 Dec 24;74(25):3153-3163. doi: 10.1016/j.jacc.2019.10.049.

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Commercially Approved CAR-T

Brand	Generic	Indication	Target
Yescarta	Axicabtagene ciloleucel	Lymphoma	CD19+
Tecartus	Brexucabtagene autoleucel	Lymphoma/ALL	CD19+
Breyanzi	Lisocabtagene maraleucel	Lymphoma/ALL	CD19+
Kymriah	Tisagenlecleucel	Lymphoma/ALL	CD19+
Abecma	Idecabtagene vicleucel	Multiple Myeloma	BCMA+
Carvykti	Ciltacabtagene autoleucel	Multiple Myeloma	BCMA+

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Current Clinical Trials

New CARs for Hematologic Malignancies

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Goals for Innovation

- Options for patients that progress following commercial CAR-T and other immune therapy such as Bispecific antibodies
- New effective targets
- Expanding targets for greater efficacy
- Faster manufacturing
- Reduction in Cost

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CD30+ for Hodgkin's Lymphoma

- The majority of Hodgkins pts are cured with first-line chemotherapy
- About 15% will be refractory or progress
- Second line is high-dose chemotherapy followed by Autologous stem cell transplant
- Half of those patients will progress, and treatment options at that point are dismal
- CD30+ is universally expressed on Reed-Sternberg cells
- Trial: 32pts, ORR 72%, CR 59%
- Toxicities were minimal with only Grade 1 CRS seen and no neurotoxicity
- Follow-up trial evaluating a CD30+/CCR4+ CAR-T for HD

Ramos, Carlos A., et al. "Anti-CD30 CAR-T Cell Therapy in Relapsed and Refractory Hodgkin Lymphoma." J Clin Oncol. 2020 Nov 10;38(32):3794-3804. doi: 10.1200/JCO.20.01342. Epub 2020 Jul 23.

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Kappa+ for B-Cell Malignancies

- Targeting Kappa+ light chains can be as effective as targeting CD19+ on some B-Cell malignancies such as DLBCL
- Similar toxicities to CD19+ CAR-Ts, however milder side effect profile
- A nice option for patients that have progressed following CD19+ CAR-T
- Following one CAR-T with another on a clinical trial often requires a washout period.
- Washouts based on trial, anywhere from 6mon to 1yr since last CAR-T treatment

Ruppaner R, et al. "CAR T cells Targeting Human Immunoglobulin Light Chains Eradicate Mature B-cell Malignancies While Sparing a Subset of Normal B Cells." Clin Cancer Res. 2021 Nov 1;27(21):5951-5960. doi: 10.1158/1078-0432.CCR-20-2754. Epub 2021 Apr 15.

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GPRC5D for Multiple Myeloma

- Currently FDA approved bispecific antibody targeting GPRC5D (G protein-coupled receptor, Class C, group 5, Member D)
- Expressed on Multiple Myeloma cells
- Patients have been demonstrated to respond, even when previously treated with BCMA+ CAR-T
- Also expressed on skin, nail, and hair follicles

Mailankody, Sham, et al. "GPRC5D-Targeted CAR T Cells for Myeloma." N Engl J Med. 2022 Sep 29;387(13):1196-1206. doi: 10.1056/NEJMoa2209900. https://pubmed.ncbi.nlm.nih.gov/36170501/

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Dual Targeting CARs

- Two Targets – One CAR-T
- Primarily used in Lymphomas and Leukemias
- Pros: Increased binding: May help avoid antigen escape
- Cons: Possibly increased toxicity due to increased target binding
- Examples:
  - CD19+/CD20+ for Lymphomas
  - CD19+/CD22+ for Leukemias
  - CD19+/BCMA+ for Multiple Myeloma

Xie Baiju, et al. "Current Status and Perspectives of Dual-Targeting Chimeric Antigen Receptor T-Cell Therapy for the Treatment of Hematological Malignancies." Cancers (Basel). 2022 Jun 30;14(13):3230. doi: 10.3390/cancers14133230. https://pubmed.ncbi.nlm.nih.gov/35804994/

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Allogeneic CARs

- "Off the Shelf" CAR-Ts from volunteer donors
- Pros:
  - Faster availabilty
  - Healthy T-cells used to make the CAR
  - Potentially lower cost: Can mass manufacture vs individual manufacture for autologous CARs
- Cons:
  - Risk of immune reactions: Graft vs Host Disease
  - Shorter lifespan compared to autologous CAR-T cells
  - Possible need to HLA match donor CAR-T to patient to prevent rejection

Caldwell KJ, Gottschalk S, Talleur AC. "Allogeneic CAR Cell Therapy-More Than a Pipe Dream." Front Immunol. 2021 Jan 8;11:618427. doi: 10.3389/fimmu.2020.618427. eCollection 2020. https://pubmed.ncbi.nlm.nih.gov/33488621/

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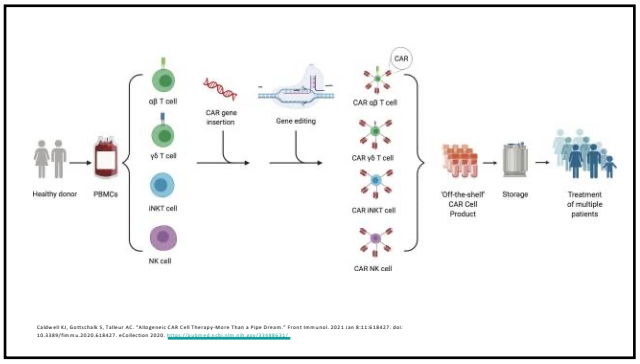

Caldwell KJ, Gottschalk S, Talleur AC. "Allogeneic CAR Cell Therapy-More Than a Pipe Dream." Front Immunol. 2021 Jan 8;11:618427. doi: 10.3389/fimmu.2020.618427. eCollection 2020.

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Current Clinical Trials

Solid Tumors

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Goals for Innovation

- Finding effective Targets!
- Increasing penetrance of toxic tumor microenvironments
- Seeking response in cancers with limited treatment modalities

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HER-2 CAR-M for HER-2+ Solid Tumors

- Utilizing a CAR-M (Macrophage)
- T-cells struggle to penetrate the tumor microenvironment
- Macrophages are actively recruited into and more abundantly present in the tumor microenvironment
- Preclinical studies have shown CAR-M cells have shown the ability to recognize and ingest targeted cancer cells, modulate the microenvironment and present neoantigens to T-cells bringing them in to help
- HER-2 is commonly overexpressed on breast and gastric cancers
- For patients who have progressed on current FDA approved anti-HER-2 therapy

Doherty, Kyle. "CAR-M Therapy CT-0508 Shows Promise in HER2-Overexpressing Recurrent/Metastatic Solid Tumors." OncLive. November 19, 2023. https://www.onclive.com/view/car-m-therapy-ct-0508-shows-promise-in-her2-overexpressing-recurrent-metastatic-solid-tumors

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B7-H3 for Metastatic Ovarian Cancer

- B7-H3 is expressed in tumor tissues, malignant ascites, and blood. It is highly expressed in many cancer, including ovarian cancer.
- Ovarian cancers can be treated with hyperthermic chemotherapy directly to the intraperitoneal space to increase sensitivity and penetration
- Current Phase 1 trial: Pt completes lymphodepletion, then cells are infused directly into the abdomen through an intraperitoneal catheter
- Also trials available for Metastatic Pancreatic and Triple Negative Breast cancers utilizing B7-H3

Cai, D., et al. "Tumor-expressed B7-H3 mediates the inhibition of antitumor T-cell functions in ovarian cancer insensitive to PD-1 blockade therapy." Cell Mol Immunol. 2020 Mar;17(3):227-236. doi: 10.1038/s41423-019-0305-2. Epub 2019 Oct 14. https://pubmed.ncbi.nlm.nih.gov/31611651/

Willemien, J van Driel, et al. "Hyperthermic Intraperitoneal Chemotherapy in Ovarian Cancer." N Engl J Med. 2018 Jan 18;378(3):230-240. doi: 10.1056/NEJMoa1708618. https://pubmed.ncbi.nlm.nih.gov/29342393/

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Glioblastoma Brain Tumors- a special population

- Most common and aggressive brain tumor
- Standard of care has remained unchanged since 2005: Surgical resection in conjunction with radiation and temozolomide
- Glioblastoma remains and incuragle disease with a median survival of only 15 months
- Current five-year survival is about 5 percent
- All Glioblastomas eventually progress and there is no standard of care at recurrence
- Clinical Trials in this population are critical and needed!

National Comprehensive Cancer Network: https://www.nccn.org

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Regression of Glioblastoma after Chimeric Antigen Receptor T-Cell Therapy

Transient complete response lasting 7.5 months

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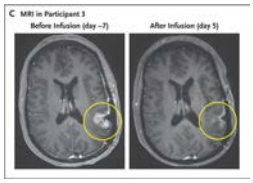
CAR-TEAM cells for Glioblastoma

- Massachusetts General combined a CAR-T Targeting EGFR receptor, a common cancer mutation, with a TEAM (T-cell engaging activating molecules)
- All patients had recurrence following standard of care Temozolimide and radiation therapy
- Cells were infused directly into the brain
- Patients had dramatic reductions in tumor size, with one achieving near resolution
- All eventually progressed, but responses were very encouraging
- Team will be investigating multiple infusions or adding lymphodepleting chemotherapy



Choi, Bryan, et al. "Intraventricular CARv3-TEAM-E T Cells in Recurrent Glioblastoma." N Engl J Med. 2024 Apr 11;390(14):1290-1298. doi: 10.1056/NEJMoa2314390. Epub 2024 Mar 13.

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B7-H3 CAR-T for Glioblastoma multiforme

- B7- Homolog 3 (B7- H3) is highly expressed in most solid tumors.
- Expression of B7- H3 in GBM
  - Assessed by evaluating the B7 H3 mRNA expression in the Cancer Genome Atlas (TCGA) dataset.
  - 77% of GBM samples showed high expression of B7- H3.
  - B7- H3 expressed at similar levels in primary and recurrent GBM.
- B7 H3 specific monoclonal antibody showed anti tumor activity against B7 H3 tumor cells in preclinical xenograft models and phase I clinical trials are currently ongoing.

Choi, Bryan, et al. "Intraventricular CARv3-TEAM-E T Cells in Recurrent Glioblastoma." N Engl J Med. 2024 Apr 11;390(14):1290-1298. doi: 10.1056/NEJMoa2314390. Epub 2024 Mar 13. https://pubmed.ncbi.nlm.nih.gov/38477966/

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UNC Glioblastoma Trial

- B7-H3 CAR-T cells given in increasing dose cohorts
- Ommaya resevoir is placed and cells are infused through this directly to the tumor bed
- Patients receive three weekly doses
- Currently on Dose level 3/6, one partial response at 3 months was seen on Dose level 2

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Current Clinical Trials- Outside the Cancer World

Autoimmune Diseases

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Goals for Innovation

- Chronic Diseases require low risk of toxicity with CAR-T treatments
- Reduce need for lifelong immune suppression
- Improve Quality of Life
- Need for long duration of response

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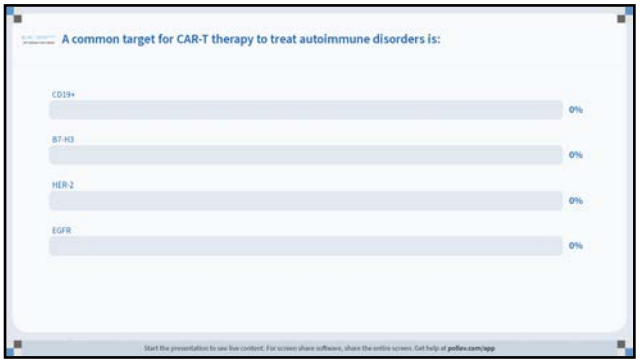

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CD19+ for Systemic Lupus Erythematous

- Lupus can have a variety of manifestations in most major organ systems and be debiliating
- Treatments involve long-term steroid and immunsuppression
- Early trial published in Nature Medicine showed complete remission of Lupus symptoms in 5 pts after receiving lymphodepletion and CD19+ CAR-T
- The remission lasted >8mon off previous immunsuppression
- B-Cells recovered post CAR-T, however these were normal niave B-cells
- Only mild, Grade 1 Cytokine release syndrome was seen

Mackensen, A., et al. "Anti-CD19 CAR T cell therapy for refractory systemic lupus erythematosus." Nat Med. 2022 Oct;28(10):2124-2132. doi: 10.1038/s41591-022-02017-5. Epub 2022 Sep 15.

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BCMA+ RNA CAR-T for Myasthenia Gravis

- Chronic Autoimmune disorder resulting in weakness of skeletal muscles due to a breakdown in communication between nerve and muscle fibers
- BCMA+ is located on plasma cells
- Does not require lymphodepleting chemotherapy because can be overly toxic for some autoimmune patients
- Given as 6 weekly doses
- Initial Phase 2 data saw meaningful decreases in MG severity scores up to 9 months following treatment

Granit, Volkan, et al. "Safety and clinical activity of autologous RNA chimeric antigen receptor T-cell therapy in myasthenia gravis (MG-001): a prospective, multicentre, open-label, non-randomised phase 1b/2a study." Lancet Neurol. 2023 Jul;22(7):578-590. doi: 10.1016/S1474-4422(23)00194-1.

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Identifying patients for CAR-T Clinical Trials

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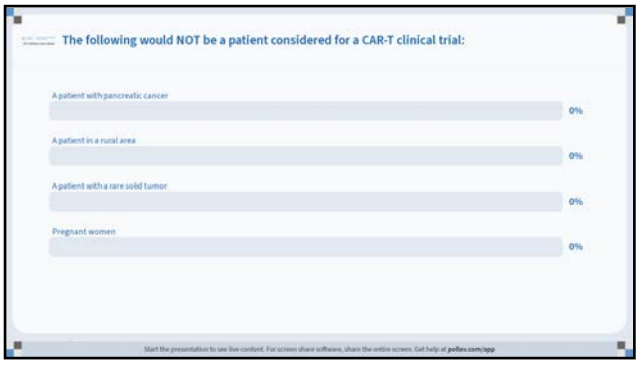

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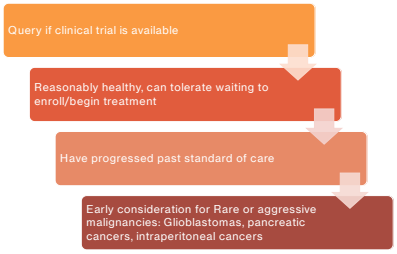
ClinicalTrials.gov



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Barriers to Clinical Trial Participation

- Patients:
  - Beliefs/Attitude and mistrust; Distance to trial site; Insurance coverage; Language, Immigration status
- Healthcare Providers:
  - Limited awareness/knowledge of ongoing trials; Time constraints; Non-cooperation of teammates
- Clinical:
  - Strict eligibility criteria and complex clinical design
- Institutional/Structural:
  - Policy; Limited logistic support (staff, financial, and IRB)

Kumar G, Chaudhary P, Quinn A, Su D. "Barriers for cancer clinical trial enrollment: A qualitative study of the perspectives of healthcare providers." Contemp Clin Trials Commun. 2022 May 28;28:100939. doi: 10.1016/j.conctc.2022.100939. eCollection 2022 Aug. PMID: [illegible]

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Common Clinical Trial exclusion criteria

- Pregnant women
- Previous CAR-T therapy (This varies and is not always an exclusion)
- Previous severe CAR-T toxicity

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Currently Open CAR-T Clinical Trials at UNC

Lymphomas:

- **CD19+/CD20+ Dual Allogeneic CAR for B-cell lymphomas**: P-CD19CD20-ALLO1-001: Open-Label, Multicenter, Phase 1 Study to Assess the Safety of P-CD19CD20-ALLO1 in Subjects with Selected Relapsed/Refractory B Cell Malignancies
- **CD30+/CCR4+ for Hodgkins:** LCCC 1606-ATL: Phase I Study of the Administration of T Lymphocytes CoExpressing the CD30 Chimeric Antigen Receptor (CAR) and CCR4 for Relapsed/Refractory CD30+ Hodgkin Lymphoma and Cutaneous T-Cell Lymphoma
- **Kappa+ CAR for DLBCL and CLL/SLL:** LCCC1811-ATL: Phase 1 Study of the Administration of T lymphocytes Expressing the Kappa Chimeric Antigen Receptor (CAR) and CD28 Endodomain for Relapsed/Refractory Kappa+ Non-Hodgkin Lymphoma and Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma.
- **CD30+ CAR-T for Peripheral T-cell Lymphoma:** LCCC 1904-ATL Phase II Study of the Administration of T Lymphocytes Expressing the CD30 Chimeric Antigen Receptor (CAR) for Relapsed/Refractory CD30+ peripheral T Cell Lymphoma

Multiple Myeloma:

- **GPRC5D CAR for MM**: A phase 2 open label multicenter study of BMS-986393, a GPRC5D-directed CAR T cell therapy in adult participants with relapsed or refractory multiple myeloma
- **CD138 CAR-T for MM:** LCCC 1603-ATL: A Phase I Study of Autologous CAR T-Cells Targeting the CD138 Antigen for Relapsed or Refractory Multiple Myeloma

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Currently Open CAR-T Clinical Trials at UNC

Solid Tumors:

- **B7-H3 for Ovarian Cancer**: Phase I Study of Administration of T Cells Expressing B7-H3 Specific Chimeric Antigen Receptors (CAR) and Containing the Inducible Caspase 9 Safety Switch in Subjects with Recurrent Platinum Resistant Epithelial Ovarian Cancer
- **B7-H3 for Pancreatic Cancer**: LCCC2223-ATL Phase I Study of Administration of T Cells Expressing B7-H3 Specific Chimeric Antigen Receptors (CAR) and Containing the Inducible Caspase 9 Safety Switch in Subjects with Refractory Pancreatic Ductal Adenocarcinoma (PDAC) having failed 2 or more standard treatments
- **B7-H3 for Triple Negative Breast Cancer**: LCCC2158-ATL Phase I Study of Administration of T Cells Expressing B7-H3 Specific Chimeric Antigen Receptors (CAR) and Containing the Inducible Caspase 9 Safety Switch in Subjects with Triple Negative Breast Cancer (TNBC)
- **Anti-HER-2 CAR-M for Breast and GI:** CT-0525-102: An Open-Label, Single-Arm Study of Autologous Anti-HER2 Chimeric Antigen Receptor Monocytes (CT- 0525), in Participants With HER2 Over Expressing Solid Tumors
- **B7-H3 for Glioblastoma:** LCCC2059-ATL (NCT05366179) is a phase 1 clinical trial that studies the use of autologous CAR-T cells to treat recurrent or refractory glioblastoma (GBM)
- **CSPG4 for Head and Neck Squamous Cell Cancer:** LCCC2060-ATL Phase I Study of Administration of T Cells Expressing Chondroitin-Sulfate-Proteoglycan-4 Specific Chimeric Antigen Receptors (CAR) in Subjects with Head and Neck Squamous Cell Carcinoma (HNSCC)
- **HLA Matched CAR-T for locally advanced or metastatic solid tumors**: A Phase 1 Basket Study Evaluating the Safety and Feasibility of T-Plex, Autologous Customized T Cell Receptor-Engineered T Cells Targeting Multiple Peptide/HLA Antigens in Participants with Antigen-positive Locally Advanced (Unresectable) or Metastatic Solid Tumors
- **GD2 for ES-SCLC or Metastatic Lung Cancer**: LCCC 2115-ATL: Phase I Study of Administration of T Cells Expressing a 2nd Generation GD2 Chimeric Antigen Receptor, IL-15, and iCaspase9 Safety Switch in Subjects with Lung Cancer
- **GD2 for Osteosarcoma**: LCCC 1743-ATL: A Phase I Study of Autologous Activated T-Cells Expressing a 2nd Generation GD2 Chimeric Antigen Receptor, IL-15, and iCaspase9 Safety Switch Administered To Patients with Relapsed/Refractory Neuroblastoma or Relapsed/Refractory Osteosarcoma

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Currently Open Clinical Trials at UNC

Autoimmune Diseases:

CD19+ CAR-T for Lupus: A Phase 1/2, Open-Label Study to Evaluate the Safety and Efficacy of Autologous CD19-specific Chimeric Antigen Receptor T cells (CABA-201) in Subjects with Active Systemic Lupus Erythematosus

CD19+ CAR-T for Lupus: A Study of CC-97540, CD-19-Targeted Nex-T CAR T Cells, in Participants With Severe, Refractory Autoimmune Diseases

BCMA+ CAR-T for Myasthenia Gravis: Autologous T-Cells Expressing A Chimeric Antigen Receptor Directed To B-Cell Maturation Antigen (BCMA) In Patients With Generalized Myasthenia Gravis (MG)

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Contacting UNC Cellular Therapy Clinical Trial Program

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Fax: (984) 974-8788

Initial Intake Form: https://unclineberger.org/cellular-immunotherapy/contact-us

Lineberger Clinical Trials website: https://unclineberger.org/cellular-immunotherapy

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References

American Society of Gene and Cell Therapy. "Cell Therapy Basics." Last Updated: 12/18/2023. https://patienteducation.asgct.org/gene-therapy-101/cell-therapy-basics

Brown, Christine, et al. "Regression of Glioblastoma after Chimeric Antigen Receptor T-Cell Therapy." N Engl J Med. 2016 Dec 29;375(26):2561-9. doi: 10.1056/NEJMoa1610497. https://pubmed.ncbi.nlm.nih.gov/28029927/ **Landmark Study.**

Cai, D., Li, J., Liu, D. et al. "Tumor-expressed B7-H3 mediates the inhibition of antitumor T-cell functions in ovarian cancer insensitive to PD-1 blockade therapy." Cell Mol Immunol. 2020 Mar;17(3):227-236. doi: 10.1038/s41423-019-0305-2. Epub 2019 Oct 14. https://pubmed.ncbi.nlm.nih.gov/31611650/

Choi, Bryan, et al. "Intraventricular CARv3-TEAM-E T Cells in Recurrent Glioblastoma." N Engl J Med. 2024 Apr 11;390(14):1290-1298. doi: 10.1056/NEJMoa2314390. Epub 2024 Mar 13. https://pubmed.ncbi.nlm.nih.gov/38477966/

Caldwell KJ, Gottschalk S, Talleur AC. "Allogeneic CAR Cell Therapy-More Than a Pipe Dream." Front Immunol. 2021 Jan 8:11:618427. doi: 10.3389/fimmu.2020.618427. eCollection 2020. https://pubmed.ncbi.nlm.nih.gov/33488631/

Doherty, Kyle. "CAR-M Therapy CT-0508 Shows Promise in HER2-Overexpressing Recurrent/Metastatic Solid Tumors." OncLive. November 19, 2023. https://www.onclive.com/view/car-m-therapy-ct-0508-shows-promise-in-her2-overexpressing-recurrent-metastatic-solid-tumors

Ganatra, Sarju, et al. "Chimeric Antigen Receptor T-Cell Therapy for Cancer and Heart: JACC Council Perspectives." J Am Coll Cardiol. 2019 Dec 24;74(25):3153-3163. doi: 10.1016/j.jacc.2019.10.049. https://pubmed.ncbi.nlm.nih.gov/31856973/

Granit, Volkan, et al. "Safety and clinical activity of autologous RNA chimeric antigen receptor T-cell therapy in myasthenia gravis (MG-001): a prospective, multicentre, open-label, non-randomised phase 1b/2a study." Lancet Neurol. 2023 Jul;22(7):578-590. doi: 10.1016/S1474-4422(23)00194-1. https://pubmed.ncbi.nlm.nih.gov/37353278/

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References

Kumar G, Chaudhary P, Quinn A, Su D. "Barriers for cancer clinical trial enrollment: A qualitative study of the perspectives of healthcare providers." Contemp Clin Trials Commun. 2022 May 28:28:100939. doi: 10.1016/j.conctc.2022.100939. eCollection 2022 Aug. https://pubmed.ncbi.nlm.nih.gov/35707483/

Lineberger Comprehensive Cancer Center. "Clinical Immunotherapy Program." Last Updated: October 8, 2024. https://unclineberger.org/cellular-immunotherapy

Mackensen, A., et al. "Anti-CD19 CAR T cell therapy for refractory systemic lupus erythematosus." Nat Med. 2022 Oct;28(10):2124-2132. doi: 10.1038/s41591-022-02017-5. Epub 2022 Sep 15. https://pubmed.ncbi.nlm.nih.gov/36109639/

Mailankody, Sham, et al. "GPRC5D-Targeted CAR T Cells for Myeloma." N Engl J Med. 2022 Sep 29;387(13):1196-1206. doi: 10.1056/NEJMoa2209900. https://pubmed.ncbi.nlm.nih.gov/36170501/

National Comprehensive Cancer Network. https://www.nccn.org

Ramos, Carlos A., et al. "Anti-CD30 CAR-T Cell Therapy in Relapsed and Refractory Hodgkin Lymphoma." J Clin Oncol. 2020 Nov 10;38(32):3794-3804. doi: 10.1200/JCO.20.01342. Epub 2020 Jul 23. https://pubmed.ncbi.nlm.nih.gov/32701411/

Ranganathan R, et al. "CAR T cells Targeting Human Immunoglobulin Light Chains Eradicate Mature B-cell Malignancies While Sparing a Subset of Normal B Cells." Clin Cancer Res. 2021 Nov 1;27(21):5951-5960. doi: 10.1158/1078-0432.CCR-20-2754. Epub 2021 Apr 15. https://pubmed.ncbi.nlm.nih.gov/33858958/

Xie Bailu, et al. "Current Status and Perspectives of Dual-Targeting Chimeric Antigen Receptor T-Cell Therapy for the Treatment of Hematological Malignancies." Cancers (Basel). 2022 Jun 30;14(13):3230. doi: 10.3390/cancers14133230. https://pubmed.ncbi.nlm.nih.gov/35805001/

Willemien, J van Driel, et al. "Hyperthermic Intraperitoneal Chemotherapy in Ovarian Cancer." N Engl J Med. 2018 Jan 18;378(3):230-240. doi: 10.1056/NEJMoa1708618. https://pubmed.ncbi.nlm.nih.gov/29342393/

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