### **CURRICULUM VITAE**

Name: Nirali N. Shah, MD, MHSc

**Citizenship**: United States

# **Education**:

| 2012 | MHSc, ( | (Clinical Research) | ) Duke University | y-National Institutes | of Health. | Bethesda, MD |
|------|---------|---------------------|-------------------|-----------------------|------------|--------------|
|------|---------|---------------------|-------------------|-----------------------|------------|--------------|

2004 M.D., University of Illinois, College of Medicine, Chicago, IL

2000 B.S. (Secondary Education in Chemistry), University of Illinois, Chicago, IL

# **Brief Chronology of Employment:**

| 2019-Present | <ul> <li>Lasker Clinical Research Scholar, National Cancer Institute, Bethesda, MD</li> <li>NIH Distinguished Scholar, National Institutes of Health, Bethesda, MD</li> <li>Head, Hematologic Malignancies Section, Pediatric Oncology Branch</li> <li>Adjunct Investigator, Immune Deficiency Cellular Therapy Program (2023-present)</li> </ul> |
|--------------|---|
| 2017-2019    | Associate Research Physician, Pediatric Oncology Branch, National Cancer  |
|              | Institute, Bethesda, MD   |
| 2015-2017    | Assistant Research Physician, Pediatric Oncology Branch, National Cancer  |
|              | Institute, Bethesda, MD   |
| 2018-Present | Assistant Professor in Pediatric Oncology, Part-Time, Johns Hopkins University  |
| 2013-2019    | Instructor in Pediatric Oncology, Part-Time, Johns Hopkins University   |
| 2013-2015    | Clinical Fellow, Advanced Studies Program in Pediatric Oncology, Pediatric  |
|              | Oncology Branch, National Cancer Institute, Bethesda, MD  |
| 2009-2013    | Fellow, Pediatric Hematology/Oncology Fellowship Program, Johns Hopkins   |
|              | Hospital, National Cancer Institute, Bethesda, MD   |
| 2008-2009    | Associate Physician, Emergency Department, Children's National Medical  |
|              | Center, Washington DC (Assistant Clinical Professor of Pediatrics, George   |
|              | Washington University   |
| 2004-2008    | Resident, Harvard Combined Internal Medicine-Pediatrics Residency Program,  |
| 200.2000     | Boston, MA School of Medicine)  |
|              | Doston, this believe of integrating   |

# Medical Licenses and Board Certifications:

| Land  | L'artitiontione |
|-------|-----------------|
| DOALG | Certifications  |
|       |                 |

| 2013-Present  | American Board      | l of Pediatrics. | Hematology/Oncology     |
|---------------|---------------------|------------------|-------------------------|
| 2013 11030110 | I Illicitedii Douit | t of i caladios. | , ilematology, oneology |

2008-Present American Board of Pediatrics

2008-Present American Board of Internal Medicine

### **Medical Licenses**

| 2013-Present | Maryland Medical License |
|--------------|--------------------------|
|--------------|--------------------------|

2008-2018 District of Columbia Medical License

# Societies:

| 2022-Present | American Society of Gene + Cell Therapy (ASGCT)           |
|--------------|---|
| 2021-Present | American Society of Pediatric Hematology/Oncology (ASPHO) |
|              | American Association for Cancer Research (AACR)           |
| 2018-Present | Society of Immunotherapy of Cancer (SITC)                 |
| 2013-Present | Children's Oncology Group (COG)                           |

Pediatric Blood and Marrow Transplant Consortium (now officially, Pediatric

Transplantation and Cell Therapy Consortium, PTCTC)

Therapeutic Advances in Childhood Leukemia & Lymphoma (TACL)

2012-Present American Society of Hematology (ASH)

2011-Present American Society for Blood and Marrow Transplantation (now officially

American Society of Transplantation and Cell Therapy, ASTCT)

# **Editorial Responsibilities:**

**Editorial Board** 

2022-Present Blood Cancer Discovery, Associate Editor

2020-Present Journal for Immuno Therapy of Cancer, Associate Editor, Immune Cell Therapies

and Immune Cell Engineering Section

2020-Present Frontiers in Immunology, Associate Editor, Cancer Immunity and

Immunotherapy

2018-2019 Advances in Cell and Gene Therapy

### Ad Hoc Reviewer

American Journal of Hematology

Biology of Blood and Marrow Transplantation/Transplantation Cellular Therapy

Blood

Blood Cancer Discovery

**Blood Advances** 

Bone Marrow Transplantation

British Journal of Haematology

Cancer Cell

Cancer Discovery

Cytotherapy

European Journal of Haematology

*Immunotherapy* 

Journal of Clinical Oncology

Journal of Immunotherapy of Cancer

Lancet Haematology

Lancet Oncology

Lancet Respiratory

Leukemia

Molecular Cancer Research

Molecular Therapy

Nature Communications

Nature Medicine

New England Journal of Medicine

**Pediatrics** 

Pediatric Blood and Cancer

Pediatric Transplantation

#### Honors and Specific Scientific Recognition:

American Society of Pediatric Hematology/Oncology Frank A. Oski Memorial Lectureship (to be awarded in April 2024)

CCR Special Act Award: Leukemia, Lymphoma, Transplantation and Cellular Therapy Team

CCR Special Act Award: Office of the Clinical Director, Advisory Committee Chair

2022 CCR Group Special Act Award: Myeloid Malignancies Program Steering Committee CCR Special Act Award: CD22 CAR Project 2021 NIH Directors Award: CCR Woman Scientific Advisory Board AACR Team Science Award (For Stand Up 2 Cancer Dream Team) 2020 Federal Tech Transfer Award NCI Director's Award: Team Science-Clinical: "Development of CD22 CAR T-cell Therapy for Pediatric ALL" Length of Service Award: 10 years **ASTCT Leadership Course** NCI Senior Executive Enrichment and Development (SEED) Training 2019 Children's Cancer Foundation/Grant Recipient NIH Distinguished Scholar SITC Women's Immunotherapy Network Leadership Institute Clinical Research Forum, Top 10 Clinical Research Achievement Award: "New CAR 2018 Therapy for Relapsed Leukemia." NCI Woman's Scientific Advisory Board, Staff Clinician Representative 2017 JHH-NCI Pediatric Hematology Oncology Fellowship Faculty Teaching Award NIH Director's Award: Pediatric Hematologic Malignancies Translational Team 2014 Children's Cancer Foundation/Giant Food Next Gen Award for Children's Cancer Research 2013 Young Investigator Travel Award, First Annual Tandem PBMTC/ASPHO Conference "New Frontiers in Allogeneic Stem Cell Transplant" 2012 American Society for Blood and Marrow Transplantation Clinical Research Training Young Investigator Award, National Cancer Institute 2<sup>nd</sup> International Workshop on the 2012 Biology, Prevention and Treatment of Relapse after Allogeneic Hematopoietic Stem Cell Transplantation The American Society of Hematology Achievement Award for Trainee Abstract 2011 Chief Resident, Harvard Combined Internal Medicine/Pediatrics Residency Program 2008 2007 Yale/Johnson & Johnson Physician Scholars International Health 2000-2004 University of Illinois, College of Medicine **AOA Honor Society** Graduation with Honors Rute Medenis Prize in Pediatrics Gold Humanism Society Grove Outstanding Student Award Sustained Service Award Student Leadership Award Pathology Honor Society (top pathology student) 1997-2000 University of Illinois at Chicago **University Honors** Rietz Award (top chemistry student) University Scholar Guaranteed Professional Program Admissions (GPPA)

#### Intramural Committees/Boards/Leadership Positions:

| 2022-Present | Chair, Office of the Clinical Director Advisory Committee           |
|--------------|---|
| 2021-Present | NIH Medical Research Scholars Program Board of Advisors             |
| 2019-Present | NCI, Center for Cellular Engineering, Advisory Committee            |
| 2019-Present | NCI, Office of Sponsor and Regulatory Oversight, Advisory Committee |

| 2017-Present         | National Cancer Institute (NCI), Scientific Review Committee, Scientific Member  |
|----------------------|--|
| 2016-2021            | Associate Fellowship Program Director, Pediatric Oncology Branch, NCI/Johns  |
| 2016-2019            | Hopkins Joint Fellowship Program in Pediatric Hematology/Oncology<br>National Cancer Institute (NCI), Institutional Review Board, Scientific Member, |
| 2016 Day             | Alternate Member   |
| 2016-Present         | National Heart, Lung and Blood Institute (NHLBI), Scientific Review Committee  |
| 2015-2017            | CCR Protocol Scientific Reviewer   |
| 2015-2018            | Pediatric Oncology Branch QA Committee Head  |
| 2013-2016            | National Heart, Lung and Blood Institute (NHLBI), Institutional Review Board;<br>Scientific Member   |
| 2013-Present         | NIH BMT Consortium Member  |
| 2013-Present         | Pediatric Oncology Branch Scientific Protocol Review Committee   |
| Extramural Committee | s/Boards/Leadership Positions:   |
| 2023-Present         | ISCT Immuno-Gene Therapy Scientific Committee (Effective, August 2023)   |
|                      | PTCTC Executive Committee, Member at Large Federal Liaison (Effective, July 2023)  |
|                      | ASTCT Board of Directors, Director at Large (Effective, February 2023)   |
| 2022-Present         | Pediatric Transplantation and Cellular Therapy Consortium (PTCTC), Cellular  |
|                      | Therapeutics Strategy Group, Chair (Effective, August 31, 2022)  |
|                      | American Society of Transplantation and Cellular Therapy Committee on  |
|                      | Cellular Therapy, Chair: CAR T-cells and HLH-like toxicities working group   |
| 2021-Present         | Pediatric Transplantation and Cellular Therapy Consortium (PTCTC) Scientific   |
|                      | Review Committee   |
|                      | Center for International Blood and Marrow Transplant Research (CIBMTR)   |
|                      | Cellular Immunotherapy Data Resource (CIDR) Executive Committee Member   |
| 2020-Present         | American Society of Hematology Subcommittee on Emerging Gene and Cell Therapies, Committee Member  |
|                      | American Society of Transplantation and Cellular Therapy Committee on  |
|                      | Cellular Therapy, Committee Member   |
|                      | Blood and Marrow Transplant Clinical Trials Network (BMT-CTN) State of the   |
|                      | Science Symposium Pediatric Malignant Diseases Committee. (See reference:  |
|                      | Heslop HE et al. Blood and Marrow Transplant Clinical Trials Network State of  |
|                      | the Science Symposium 2021: Looking Forward as the Network Celebrates its  |
|                      | 20 <sup>th</sup> year. Transplant Cell Ther. 2021)   |
| 2019-Present         | Steering Prioritization Committee, Therapeutic Advances in Childhood   |
| 2016 B               | Leukemia & Lymphoma (TACL)   |
| 2016-Present         | Children's Oncology Group Study Committee member, AALL1621 A Phase 2   |
|                      | Study of Inotuzumab Ozogamicin in Children and Young Adults with Relapsed  |
| 2015 D               | or Refractory CD22+ B-Acute Lymphoblastic Leukemia (B-ALL)   |
| 2015-Present         | Center for International Blood and Marrow Transplant Research (CIBMTR)   |
| 2015 2016            | Donor Health and Safety Working Committee Chair  |
| 2015-2016            | American Society for Blood and Marrow Transplantation (ASBMT); Committee on Practice Guidelines  |
| 2014-Present         | Pediatric Blood and Marrow Transplant Consortium (PBMTC), Oncology   |
| 2012 B               | Strategy Committee (2018-Protocol Chair)   |
| 2012-Present         | Therapeutic Advances in Childhood Leukemia & Lymphoma (TACL) Protocol Chair, T2012-002 Protocol, A Pilot Study of Vincristine Sulfate Liposome       |

Injection (Marqibo®) in Combination with UK ALL R3 Induction Chemotherapy for Children, Adolescents and Young Adults with Relapse of Acute Lymphoblastic Leukemia.

## Active Clinical Trials:

# Principal Investigator

- Treatment/Intervention Trials: Actively Accruing
  - o 00731, A First-in-Human, Open-Label, Multicenter Study of VOR33 in Patients with Acute Myeloid Leukemia who are at High-Risk for Leukemia Relapse following Hematopoietic Cell Transplantation.
  - o 00732, A Long-Term Follow-Up Study of Patients who Received VOR33.
  - 00792, A Pilot Trial to Evaluate Next-Generation Sequencing (NGS) Testing and Monitoring of B-Cell Recovery to Guide Management Following CAR T-cell Induced Remission in Pediatric Patients with B Lineage Acute Lymphoblastic Leukemia
  - 000324, Phase 1/2 Dose Escalation Study of CD19/CD22 Bicistronic Chimeric Antigen Receptor CAR T-cells in Children and Young Adults with Recurrent or Refractory C19/CD22 expressing B-cell Malignancies
  - o 20-C-0028, Phase I Dose-Escalation Study of anti-CD33 CAR in Children and Young Adults with Relapsed/Refractory AML.
  - o 18-C-0059 Phase I Dose-Escalation Study of anti-CD19/CD22 Bispecific CAR in Children and Young Adults with Relapsed/Refractory Leukemia.
  - o 18-C-0026: Children's Oncology Group, Phase II Study of Inotuzumab Ozogamicin in Children and Young Adults with Relapsed or Refractory CD22+ B-ALL. (Providing leadership and oversight for biology studies that are being performed at the NIH)
  - 15-C-0029: Phase I Dose Escalation Study of Anti-CD22 Chimeric Receptor T Cells in Pediatric and Young Adults with Recurrent or Refractory CD22-expressing B Cell Malignancies.
  - o 17-C-0137: Leukapheresis for CAR-Therapy Manufacturing
- Treatment/Intervention Trials: Future/In Development
  - Phase I Dose-Escalation Study of anti-TSLPR CAR in Children and Young Adults with Relapsed/Refractory TSLPR+ Hematologic Malignancies.
- Treatment/Intervention Trials: Data Analysis Only
  - o 12-C-0112: Phase I Dose-Escalation Study of anti-CD19 CAR
  - o 17-C-0028: A Pilot Study of Vincristine Sulfate Liposome Injection (Marqibo®) in Combination with UK ALL R2 Induction Chemotherapy for Children, Adolescents, and Young Adults with Relapse of Acute Lymphoblastic Leukemia
- Retrospective Studies:
  - o 19-CN-044: Retrospective Study of Immunotherapy Related Toxicities in Children and Adults with Cancer
  - 18-CN-131: Retrospective Study of Optimal Methods of Disease Detection in Children and Young Adults with Acute Lymphoblastic Leukemia in the Pediatric Oncology Branch
  - o 000651-C: CAR-Multicenter Analysis (CAR-MA): Retrospective Study to Characterize CAR T-cell outcomes and Related Toxicities in Children and Young Adults with B-ALL

### Medical Advisory Investigator:

• 13-C-0132: Allogeneic Hematopoietic Stem Cell Transplant for Patients with Mutations in GATA2 or the MonoMAC Syndrome (PI: Hickstein)

# Associate Investigator

### Treatment/Intervention:

- 21-C-0019: Phase I Study of Anti-CD22 CAR T-cells in Patients with Relapsed/Refractory Hairy Cell Leukemia and Variant.
- 21-C-0032: GD2-CAR Persist: Production and Engineering of GD2-Targeted, Receptor Modified CAR T-cells (GD2CART) for Osteosarcoma or Neuroblastoma to Increase Systemic Tumor Exposure
- 20-C-0042: A Phase II Pilot Trial to Estimate Survival after a Non-TBI Based Conditioning Regimen in Patients Diagnosed with B-ALL who are Pre-Allogeneic Hematopoietic Cell Transplantation Next-Generation Sequence Minimal Residual Disease Negative
- 000631-C: Investigation of the Cognitive Aftereffects of Neurotoxicity in Children and Young Adults with Relapsed/Refractory Hematologic Malignancies who Received CAR T-cell therapy
- 000067-C: Understanding the Patient Experience: Symptom Burden in Pediatric Patients Receiving CAR T-cell Therapy
- 13-C-0132: Allogeneic Hematopoietic Stem Cell Transplant for Patients with Mutations in GATA2 or the MonoMAC Syndrome (PI: Hickstein)
- 10-C-0174: Related and Unrelated Donor Hematopoietic Stem Cell Transplantation for DOCK8 Deficiency

### Retrospective Studies:

- 000362-C: CAR Neuro-Image Virtual Archive and Lesion Identification
- 000124-C: A Phase 2 Study of the MEK inhibitor Trametinib in Children with Relapsed or Refractory JMML

Patents Issued: None

Inventor: CD22 CAR T-cells, materials and scope of use

#### Grants:

#### Intramural:

2022 FLEX: CCR Basic-Translational-Clinical Axis (Co-PIs: Nirali N. Shah, Jack Shern, Naomi Taylor), "Identification of mechanisms resulting in CD22 modulation following CD22-CART therapy"

NIH Bench to Bedside and Back/Cancer Moonshot Supplemental (PIs: Nirali N. Shah, Andrei Thomas-Tikhonenko), "Alternative splicing of CD22 following Inotuzumab"

NIH Bench to Bedside and Back/Cancer Moonshot (PIs: Naomi Taylor, Crystal Mackall; AIs: Nirali N. Shah, Gregoire Altan-Bonnet, Sneha Ramakrishna), "CAR design and manufacturing for childhood ALL"

2020 FLEX: CCR Synergy Award (Co-PIs: Grégoire Altan-Bonnet, Naomi Taylor, Nirali N. Shah), "High-dimensional dynamic profiling of CAR T-cells to optimizing immunotherapies for B-cell leukemia/lymphoma."

#### Extramural

- 2023 Rally Foundation Grant Recipient: Prospective evaluation of delayed effects of pediatric CAR T-cell therapy (PROSPECT) Trial. \$50,000 (Will go to extramural sites for study start up costs at St. Jude Children's Hospital)
- 2022 Children's Cancer Foundation/Grant Recipient: A Pilot Study Incorporating Prospective PET-CT Imaging with Peripheral Blood Next-Generation Sequencing and Cell-Free DNA to Identify and Optimize Outcomes of CAR T-cell Therapy in Extramedullary B-Cell Acute Lymphoblastic Leukemia (B-ALL); \$75,000
  - Peach Bowl/Grant Co-PI: CAR-CURE Study: \$750,000 (Will go to Extramural sites and towards data management, clinical trial conduct and per patient reimbursement)
- 2019 Children's Cancer Foundation/Grant Recipient: A Phase I/II Clinical Trial Testing a Novel Combinatorial CD19/CD22 CART + Checkpoint Inhibitor to Prevent Antigen Loss and Improve Durable Responses in Acute Lymphoblastic Leukemia, \$75,000
- 2014 Children's Cancer Foundation/Giant Food Next Gen Award for Children's Cancer Research, \$100,000

# Meeting Organizer or Chair:

- 1. ASTCT and CIBMTR Tandem Meetings,
  - Pediatric Track Chair, Late effects after CAR T-cell therapy: A new paradigm. February 21, 2024
  - Scientific Concurrent Session Chair: Evolving landscape for treatment of B-ALL
- 2. Relapse after HSCT Workshop, Steering Committee Member and Session Chair, November 10-11 2023
- 3. DMV Cell and Gene Therapy Forum, Planning Committee, November 2, 2023
- 4. International Society for Cell & Gene Therapy and the American Society for Transplantation and Cellular Therapy, Cellular Therapy Training Course. Invited faculty and planning committee member. October 23-27, 2023
- 5. 2023 AcCELLerate Forum: Creating a sustainable ecosystem of cell and gene therapy. Co-Chair, Emergent toxicities and management thereof. October 2-3, 2023.
- 6. Accelerate innovation for children and adolescents with cancer. Hybrid models for development of CAR T-cells in children and adolescents with malignancy: Relative roles of academia and industry, Co-Chair. September 22, 2023.
- 7. SITC Advances in Cancer Immunotherapy Workshop: Co-Chair, Cell therapies and T-cell engagers workshop. August 17, 2023
- 8. ASGCT CAR T-cell and Immune Effectors Workshop, Chair. Tuesday, May 16, 2023
- 9. Insights in Pediatric CAR T-cell Immunotherapy: Recent Advances and Future Directions (INSPIRED) Symposium, Meeting organized and Chair. Wednesday, March 1, 2023. <a href="https://ncifrederick.cancer.gov/events/conferences/INSPIRED2023">https://ncifrederick.cancer.gov/events/conferences/INSPIRED2023</a>
- 10. ASTCT-CIBMTR Annual Meetings, Oral Abstract Session Chair. Wednesday, February 15, 2023
- 11. American Society of Hematology, Annual Meetings, Scientific Workshop Chair. "Bedside to Bench: Dissecting Emergent CAR T-cell Toxicities Beyond CRS and ICANS." Friday, December 9, 2022
- 12. ASTCT AcCELLerate Forum, Chair for "Toxicities" Thursday, November 17-Friday, November 18, 2022.
- 13. Investigations in Myeloid neoPlasms and Acute lymphoblastic leukemia in Children with Trisomy 21. (IMPACT21) Conference Chair and Organizer. Tuesday, May 10, 2022. https://ncifrederick.cancer.gov/events/conferences/impact21

- 14. American Society of Pediatric Hematology Oncology, Workshop Chair. "Challenges of AML CAR T-cell Therapy in Children and Young Adults." May 5, 2022
- 15. American Society of Transplantation and Cellular Therapy/CIBMTR, Pediatrics Day. Session Chair: "CAR T-cell therapy: Real World Topics" April 25, 2022.
- 16. CAR T-cell Therapy: Beyond the Storm, Thursday, May 14, 2020. Conference Chair and Organizer. Bethesda, MD. <a href="https://ncifrederick.cancer.gov/events/conferences/car-t-cell-therapy-beyond-storm">https://ncifrederick.cancer.gov/events/conferences/car-t-cell-therapy-beyond-storm</a>
- 17. 5<sup>th</sup> International Workshop on the Biology, Prevent, and Treatment of Relapsed After Allogeneic Hematopoietic Stem Cell Transplantation. Session Chair. October 2020, New York, New York (Rescheduled to October 2021 due to COVID19)
- 18. American Course on Drug Development and Regulatory Sciences-NIH Workshop: Cell-Based Immunotherapy: From Bench to Bedside and Beyond. Chair, Session 4: Challenges and Opportunities in Clinical Studies.
- 19. 4<sup>th</sup> International Workshop, Biology, Prevention, Treatment of Relapse After Allogeneic Hematopoietic Stem Cell Transplantation. Steering Committee, Session Head, Invited Speaker. September 21-22, 2018. Chicago, IL
- 20. Minor Donor Ethics Conference, Co-Sponsored by CCR-Pediatric Oncology Branch and the Pediatric Blood and Marrow Transplant Consortium. "Children as Stem Cell Donors in Research: When is it Ethical? When is it approvable?" Program Chair. March 13, 2015

#### <u>Invited Talks/Meetings (Intramural)</u>:

#### Future:

- 1. Thoracic and GI Malignancies Branch Seminar, February 2024
- 2. Translational Research in Clinical Oncology (TRACO), "CAR T-cell Therapy in Pediatric Leukemia: Current Status and Future Directions." 2023 TBD

## Completed:

- 1. Translational Research in Clinical Oncology (TRACO), "CAR T-cell Therapy in Pediatric Leukemia: Current Status and Future Directions." October 3, 2022
- 2022 NCI Cancer Immunology and Immunotherapy Conferencee, CCR Center of Excellence in Immunology. "CAR T-cell Therapy in Pediatric Leukemia. Current Status and Future Directions." September 15, 2022
- 3. NIH Clinical Center, Pediatric Remembrance Day, Keynote speaker. March 3, 2022.
- 4. MDS Symposium, "CD33 CAR T-cells" February 25, 2022.
- 5. Several yearly educational conferences to NCI/NHLBI/DTM and POB. Bethesda, MD (NIH Clinical Center)
- 6. NIH Clinical Center Grand Rounds. "CAR T-cell Therapy in Pediatric Leukemia: Current Status and Future Directions." Wednesday, January 6, 2021
- 7. FDA/NCI/CTEP Meeting. NIH COVID-19 Platform Trials. "Compassionate Use Study of Tocilizumab in Cancer Patient with COVID-19" June 5, 2020
- 8. AACR SU2C Monthly Meeting NCI Presentation. "HLH-like Manifestations of CD22 CAR T-cells: More than Just Severe CRS?" Monday, March 9, 2020
- 9. NIH Myelodysplastic Syndromes Symposium. "CAR T-Cell Therapy in Pediatric Leukemia." Friday, July 12, 2019.
- 10. Advanced Oncology Education Series for Nurses, "Adoptive Cell Therapy: CAR T-Cells." Tuesday, April 30, 2019.
- 11. Demystifying Medicine Talk, "CAR T-Cell Therapy in Pediatric Leukemia." Tuesday, February 26, 2019
- 12. NCI Workshop on Cell-Based Immunotherapy for Solid Tumors, "CAR T-Cell Therapy: Going Beyond the Test Drive." Tuesday, December 11, 2018

- 13. Advanced Oncology Education Series for Nurses, "Adoptive Cell Therapy: CAR T-Cells." November 27, 2018
- 14. POB Research Seminar: "CAR-T Cell Therapy in Pediatric Leukemias: Bench to Bedside and Back Again." Thursday, October 11, 2018.
- 15. NIH Research Festival. Talk, "CAR-T Cell Therapy for AML." Wednesday, September 12, 2018.
- 16. Advanced Oncology Education Series for Nurses: Cancer Immunotherapy Course. Talk, "Adoptive Cell Therapy: CAR T-Cells." April 23, 2018.
- 17. Cancer Autoimmunity and Immunology Meeting. Talk: "Toxicities Associated with Adoptive Cell Transfer." March 23, 2018
- 18. Chronic GVHD Intramural Retreat. Talk: "GVHD in the Era of Cell and Immunotherapy." February 6, 2018. Bethesda, MD (NIH)
- 19. Demystifying Medicine Talk: "Is Leukemia Curable? Challenges and Milestones in Current Approaches." January 16, 2018. Bethesda, MD (NIH). https://videocast.nih.gov/summary.asp?Live=26659&bhcp=1
- 20. Office of AIDS Research. Conference Speaker, Beyond HIV: The Benefits of HIV Research/World AIDS Day, "HIV- Inspires Effective Anti-Leukemia Therapy." December 1, 2017. NIH: National Institute of Allergy and Infectious Disease, Fishers Lane, Rockville, MD.
- 21. POB Research Seminar. "The Race Against ALL, One CAR at a Time." Thursday, February 9, 2017. Bethesda, MD (NIH Clinical Center)
- 22. National Institute of Allergy and Infectious Diseases, Grand Rounds. "A Patient with DOCK8 Deficiency and Two Transplants." Friday, September 30 2016. Bethesda, MD (NIH Clinical Center)
- 23. Minor Donor Ethics Conference, Co-Sponsored by CCR-Pediatric Oncology Branch and the Pediatric Blood and Marrow Transplant Consortium. "Children as Stem Cell Donors in Research: When is it Ethical? When is it approvable?" March 13, 2015
- 24. Laboratory of Molecular Biology, NIH Seminar. "Moxetumomab pasudotox in Pediatric ALL." Monday, October 27, 2014.
- 25. Ethics Grand Rounds, National Institutes of Health. "Children as Stem Cell Donors in Research: When is it ethical? When is it approvable?" Wednesday, February 6, 2013. Bethesda, MD (NIH Clinical Center)
- 26. POB Research Seminar: "Pediatric Allogeneic Hematopoietic Cell Donors on Clinical Research Protocols." January 17, 2013. Bethesda, MD (NIH Clinical Center)
- 27. 2<sup>nd</sup> International Workshop, Biology, Prevention, Treatment of Relapse After Allogeneic Hematopoietic Stem Cell Transplantation. Abstract Discussant. November 2012. Bethesda, MD (NIH)

#### Invited Talks/Meetings (Extramural):

### 2024:

Future/scheduled.

- 1. Cellular Immunotherapy in Pediatric Oncology, St. Jude Children's Research Hospital, Memphis, TN. June 2023
- 2. 6<sup>th</sup> International workshop on CAR-T and Immunotherapies (iwCAR-T),
  - a. CAR T-cells and Pediatric Access, April 20, 2024
  - b. CAR T-cells and pediatric AML, April 21, 2024
- 3. ASPHO American Society of Pediatric Hematology/Oncology Frank A. Oski Memorial Lectureship, Seattle, WA. April 5, 2024
- 4. ASTCT & CIBMTR Tandem Meetings February 2024
  - a. APP Track: How I treat refractory cytokine release syndrome and ICANS
  - b. Scientific Concurrent Sessions: Implications of sequential targeting and biomarker informed risk stratification

# Completed.

- 1. Columbia University, Department of Hematology/Oncology Grand Rounds, "CAR T-cells for long-term cure in B-ALL" (Virtual) February 14, 2024
- 2. Series on Advancements in Cell Therapy "CAR T-cells for Myeloid Malignancies: So near and yet so far." Mumbai, India. February 3, 2024.
- 3. Pediatric Immunotherapy-Discovery and Development Network Presentation, "Immune effector cell associated HLH-like syndrome." (Virtual) January 12, 2024

# <u>2023</u>

- 1. American Society of Hematology Annual Meeting. Education Program Speaker. "Long term follow up of CD19-CAR T-cell Therapy in Children and Young Adults with B-ALL." San Diego, CA
- 2. SITC 38<sup>th</sup> Annual Meeting. Immune therapy toxicities, evolving frontiers. "*Immune effector cell associated HLH-like syndrome*." November 4, 2023. San Diego, CA.
- 3. Updates in Cancer Novel Immunotherapies 2023. Mayo Clinic. "Post CAR T-cell Transplant in B-ALL" October 6, 2023. Rochester, MN
- 4. AML CAR T-cell workshop. "CD33 CAR T-cells in children and young adults with relapsed/refractory AML" St. Jude Children's Hospital. September 25, 2023. Memphis, TN
- 5. LUPUS2023. Keynote speaker. "CD19 CAR T-cells: Current status and future directions." September 30, 2023. Naples, FL
- 6. Lymphoma Research Foundation. "Minimal residual disease in pediatric B-ALL" September 20, 2023. Arlington, VA
- 7. International Society Cell & Gene Therapy North American Regional Meeting. Plenary Speaker. "Peri-CAR T-cell risk factors: Optimizing durable remissions in B-ALL." September 9, 2023. Houston, TX
- 8. Children's Oncology Group Annual Meeting. "CAR T-cell related multicenter collaborations." September 6, 2023. Atlanta, GA
- 9. SITC Advances in Clinical Immunotherapy. "CD19 CAR T-cells in children and young adults with B-ALL." August 17, 2023, Washington DC
- 10. American Society of Clinical Oncology. "CAR T-Related Toxicities: Everything Clinicians Need to know. "Perspective on cytopenias and HLH: Management in Patents with Hematologic Malignancies." June 5, 2023. Chicago, IL
- 11. Children's Hospital Los Angeles, Hematology Grand Rounds. "CAR T-cells: a Decade in Review." Wednesday, May 17, 2023. Los Angeles, CA
- 12. 3<sup>rd</sup> International Symposium on Biology, Prevention and Treatment of Toxicities After Transplantation and Cellular Therapy. Friday, April 28, 2023. "*Immune effector cell associated HLH-like syndrome*." Memorial Sloan Kettering Cancer Center, New York
- 13. Westhafen Intercontinental Group, April 22-23, 2023. "Evaluation of Lineage Switch" Paris, France.
- 14. Pediatric Onco-Critical Care Conference, April 19-20, 2023. "*HLH-like Cytokine Release Syndrome*." St. Jude Children's Research Hospital, Memphis, TN.
- 15. ASH Summit on Immunotherapies for Hematologic Diseases, March 2-3, 2023. "Mechanism of Resistance to CAR T-cell Immunotherapy: Relapse Associated with Late Immunotherapy Failure." Washington DC.
- 16. 2023 Tandem Meetings: Transplantation and Cellular Meetings of ASTCT and CIBMTR. February 15-19, 2023, Orlando FL
  - a. "HLH-like Toxicities and CAR T-cells, Nursing Track, Friday, February 17, 2023
  - b. "Delayed Hematopoietic recovery in a Pediatric Patient Undergoing CAR T-cell Therapy". Saturday, February 18, 2023
- 17. Keystone Symposia, Emerging Cellular Therapies at the Forefront of Cancer Immunotherapy. "*CAR T-cells in pediatric B-cell ALL: Reflections on the past decade.*" January 30, 2023
- 18. Memorial Sloan Kettering Pediatric Grand Rounds, "CAR T-cells: Prevention and Treatment of Relapse." January 26, 2023

- 19. Society for Immunotherapy in Cancer, Winter School. Faculty Speaker. "Immunotherapeutic Strategy: Adoptive Cell Therapy." January 17, 2023
- 20. Series on Advancements in Cell Therapy, CAR T & Cell Therapy Centre (CTCTC), Tata Memorial Hospital. "CAR T-cell Therapy: Factors Affecting Clinical Outcomes in B-Cell Malignancies." January 6, 2023, Mumbai, India (Virtual)

# 2022

- 21. TATA Memorial Hospital. "CAR T-cell Trials for Hematologic Malignancies in Children and the AYA Population" November 25, 2022
- 22. National Marrow Donor Program, the ONE Forum. "The Role of CAR T-cell Therapy in Pediatric Patients." November 5, 2022
- 23. FDA Speaker Series-American Society of Hematology. "CAR T-cell Trials for Hematologic Malignancies in Children and the AYA Population" November 1, 2022
- 24. PI-DDN, "HLH-like complications of CAR T-cell Therapy." October 26, 2022
- 25. 10<sup>th</sup> Annual Translational Workshop on Hematologic Malignancies. "Extramedullary Disease and Response to CAR T-cells." September 22, 2022
- 26. PALISI (Pediatric Acute Lung Injury and Sepsis) HCT-CI Subgroup. "CAR T-cells and HLH" September 19, 2022
- 27. 38<sup>th</sup> Annual Meeting, Histiocyte Society. "CAR T-cells and HLH" September 18, 2022.
- 28. 8<sup>th</sup> Conference on Cell Therapy and Regenerative Medicine, Midwest Stem Cell Therapy Center. "CD19 CAR T-cells and Pediatric ALL: Current Status and Future Directions." September 16, 2022.
- 29. Terapias Avancadas Celulas e Gene (TACG). "Relapse after CAR T-cell failure: Mechanisms and Management." August 6, 2022
- 30. Saudi Arabian Pediatric Hematology Oncology Society, Annual Symposium. "Treatment of Post CAR T-cell Relapse." May 20, 2022.
- 31. American Society of Gene and Cell Therapy, Pre-Meeting: Immune Effectors Cell Therapies Workshop. "CarHLH—An Initially Overlooked Complication of CAR T-cell Therapy." May 15, 2022
- 32. Women in Lymphoma, WiLing Wednesdays. "Mechanism of Resistance to CAR T-cells." May 11, 2022.
- 33. American Society of Pediatric Hematology Oncology, Workshop. "AML Directed CAR T-cells: The Next Frontier." May 5, 2022
- 34. International Workshop on CAR-T and Immunotherapies (iwCAR), 4<sup>th</sup> International Workshop on CAR-T, "CD22 CAR T-cells: Current Status and Future Directions." Saturday, April 20, 2022
- 35. American Society of Transplantation and Cellular Therapy/CIBMTR Tandem Annual Meeting, Pediatrics Day. "Meet-the-Professor" April 25, 2022.
- 36. American Society of Transplantation and Cellular Therapy/CIBMTR Tandem Annual Meeting, Pediatrics Day. "Treatment of Post CAR T-cell Relapse." April 25, 2022.
- 37. American Society of Transplantation and Cellular Therapy/CIBMTR Tandem Annual Meeting, Advanced Practice Provider. "CAR T-cells and Pediatric ALL: Updates and Future Directions." April 23, 2022.
- 38. Children's Oncology Group, HSCT and Cell Therapy Committee, Spring Meeting. "CAR T-cells and Pediatric ALL: Next0Gen Approaches." April 5, 2022.
- 39. UCSF Pediatric Malignancies Meeting, Advances in Immunotherapy and CAR-T cell therapy. "CAR T-cells and Pediatric Leukemia: Where do we go from here?" March 23, 2022.
- 40. Pediatric Acute Lung Injury & Sepsis Investigators Network (PALISI), Hematopoietic Cell Transplant-Comorbidities Subgroup Meeting. "*CAR-HLH*" March 28, 2022.
- 41. Memorial Sloan Kettering Cancer Center, Grand Rounds. "CAR T-cell associated HLH (CarHLH)" March 8, 2022.

- 42. Histiocyte Society Invited Talk. "The Yin and Yang of HLH and T-cell engaging Therapies: CAR T-cell associated HLH." February 10, 2022
- 43. Medical College of Wisconsin, Hematology & Oncology Grand Rounds. "CAR T-cells and Pediatric ALL: Where do we go from here?" January 13, 2022.
- 44. Caring Cross, Monthly Seminar. "Current Challenges in CD19 CAR T-cells for Pediatric ALL: Implications for the Global Community." January 21, 2022.

## 2021

- 45. Johns Hopkins Hospital/Sidney Kimmel Comprehensive Cancer Center Oncology Grand Rounds. "CAR T-cells in Hematologic Malignancies: Beyond CD19." December 10, 2021
- 46. AcCELLerate Forum Virtual Workshop. "CAR T-cells and HLH." November 19, 2021
- 47. National Marrow Donor Program: Mid-Atlantic Virtual Roundtable. "CAR-T for pediatric patients with B-ALL: Complement or cure?" November 3, 2021.
- 48. Society of ImmunoTherapy of Cancer: Bispecific T cell engagers virtual workshop. "CRS and neurotoxicity: Lessons learned from CAR T-cells." October 1, 2021
- 49. 6<sup>th</sup> Annual Congress on Controversies in Stem Cell Transplantation and Cellular Therapies (COSTEM). "Controversy: Are dual CAR T-cells more effective?" October 24, 2021
- 50. Infectious Disease (ID) Week. "Novel cell and immunotherapies: how do they work and effect on immunotherapy." Saturday, October 2, 2021
- 51. St. Jude Children's Research Hospital, Research Seminar. "CAR T-cells: Beyond CD19." September 29, 2021
- 52. Pediatric Transplantation and Cell Therapy Fall Meeting: CAR T-cell Late effects and CD33 CAR T-cell updates. September 27, 2021
- 53. Blood Cancer Discovery, Webinar, CAR T-cell manufacturing. September 27, 2021
- 54. Mayo Clinic Updates in CAR T-cell Therapy 2021. "CAR T-cell therapy: Beyond CD19." Thursday, August 26, 2021
- 55. International Congress of BMT 2021, 26<sup>th</sup> Annual Congress of Korean Society of Blood and Marrow Transplantation Meeting. "*CAR T-cell therapy: Beyond CD19*." Thursday, August 26, 2021
- 56. TATA Memorial Hospital "CAR T-cell Therapy in Pediatric Leukemia: Current Status and Future Directions." Saturday, July 17, 2021
- 57. A.C. Camargo Cancer Center's 5<sup>th</sup> Next Frontiers to Cure Cancer 2021. "CAR T-cell therapy: Beyond CD19." Saturday, June 26, 2021
- 58. Children's Wisconsin, Northwest Mutual Foundation, Pediatric Cancer Symposium: Exploring Immunotherapy in Pediatric Cancers. "CAR T-cell therapy: Beyond CD19." Wednesday, May 12, 2021
- 59. ACCELERATE: Innovation for Children and Adolescents with Cancer, in collaboration with the European Medicines Agency with participation of the US Food and Drug Administration. Paediatric Strategy Forum for Medicinal Product Development of CAR T-cells in children. "Alternate Targets for B-Cell ALL." May 25, 2021
- 60. Baylor College of Medicine, Texas Children's Hospital. Pediatric Hematology/Oncology Research Seminar Series. "*CAR T-cell therapy: Beyond CD19*." Thursday, May 6, 2021
- 61. Cellicon Valley '21: Future of cell and gene therapies. "Long-term toxicities, hypogammaglobulinemia, cytopenias and infection risks." Thursday, May 6, 2021
- 62. Massachusetts General Hospital, Internal Medicine and Pediatrics Grand Rounds. "CAR T-cell Therapy in Pediatric Leukemia: Current Status and Future Directions." Thursday, April 29, 2021
- 63. 3<sup>rd</sup> International Workshop on CAR-T. "Approaches to Dual Targeting with CARTs." Wednesday, April 21, 2021.
- 64. Societe Internationale D'oncologie Pediatrique (SIOP)-ASIA 2021. Mumbai, India. "The Emerging Role and Future Direction of CAR T-cell Therapies." Friday, March 19, 2021

65. Pediatric Specialists of Virginia at INOVA Schar Cancer Institute Journal Club. "CAR T-cell Therapy in Pediatric Leukemia: Current Status and Future Directions." Tuesday, January 19, 2021

#### 2020

- 66. Programme Preparatory Call: Paediatric Strategy Forum on Medicinal Product Development of CAR T-cells children. "CAR T-cell Therapy in Pediatric ALL: Considerations and Future Directions." Friday, December 18, 2020
- 67. Immuno-Oncology Society of India, 2<sup>nd</sup> Annual Congress 2020, "Immuno-Oncology towards 2021: Reboot, Resolve and Evolve." Invited as a Keynote Speaker, "*CAR T-cells: Beyond CD19*." October 31, 2020
- 68. American Society of Hematology (ASH) Workshop on Developing Biomarkers for CAR T-cells and BiTES Toxicity and Efficacy. October 7, 2020
- 69. 8<sup>th</sup> Annual Translational Workshop on Hematologic Malignancies: Transforming Therapy in Blood Cancers. "CAR T-cells in Pediatric ALL: Current Status and Future Directions." Friday, October 16, 2020 (Virtual)
- 70. Children's National Medical Center, Pediatric Hematology/Oncology Grand Rounds. "CAR T-cell Associated HLH." October 1, 2020.
- 71. 5<sup>th</sup> International Conference on Immunotherapy in Pediatric Oncology (CIPO2020): Expanding the Therapeutic Potential of Immunotherapy in Pediatric Oncology. "CD22 CAR T-cells in the Clinic" Friday, September 25, 2020 (Rescheduled due to COVID19)
- 72. Walter Reed Systems Pediatric Hematology/Oncology Speaker. "CAR T-cell trials in the Pediatric Oncology Branch." (Virtual) Friday, July 24, 2020
- 73. Seventh Annual Pediatric Cancer Symposium: Exploring Imunotherapy in Pediatric Cancers. Children's Hospital of Wisconsin MACC Fun Center for Cancer and Blood Disorders. "CAR T-cell therapy: Going beyond CD19." (Rescheduled due to COVID)
- 74. European Society for Blood and Marrow Transplantation (EBMT)/American Society for Transplantation and Cellular Therapy (ASTCT) Joint Webinar: Treatment Options of COVID19 Patients with a Focus on Stem Cell Transplant. "CAR T-Cells and COVID-19" Tuesday, May 26, 2020
- 75. CARTOX Program Seminar Speaker. MD Anderson. "HLH-like Manifestations of CD22 CAR T-cells: More than just Severe CRS?" Friday, May 1, 2020. Houston, TX (Virtual)
- 76. Stanford Cancer Cell Therapy and Blood and Marrow Transplant Symposium: Update on Current Advances in BMT and Cancer Cell Therapy. *Update on CD22 CAR T-cells for B-ALL*. April 2, 2020 (Rescheduled due to COVID19). Stanford, CA
- 77. XIII International Society of Paediatric Oncology ASIA Conference 2020. "The Emerging Role and Future Directions of CAR T-cell Therapies." Friday, March 27, 2020 (Cancelled-COVID19). Mumbai, India

#### 2019

- 78. First International Workshop on CAR-T (iWCAR), "Mechanisms of Resistance to CAR T-cells." Session Chair. Sunday, October 13, 2019. Miami, FL
- 79. Society of Hematology Oncology, (SOHO), "CAR-T Therapy for ALL: Moving Beyond Single Agent Targeting." Thursday, September 12, 2019. Houston, TX
- 80. Children's Mercy Hospital, Visiting Professor, Division of Pediatric Hematology/Oncology. "CAR T-Cell Therapy: Beyond CD19 Targeting." Tuesday, July 23, 2019. Kansas City, MO.
- 81. University Hospitals: Cleveland Medical Center, Division of Pediatric Hematology/Oncology. Invited Speaker. "*CAR T-Cell Therapy: Beyond CD19 Targeting*." Friday, July 19, 2019. Cleveland, OH.
- 82. American Society for Transplantation and Cellular Therapy. Consensus Conference on Management of T-cell Therapy Toxicities. Tuesday, July 30, 2019. Silver Spring, MD
- 83. Food and Drug Administration (FDA); Center for Drug Evaluation and Research (CDER); Pediatric Subcommittee of the Oncologic Drugs Advisory Committee (pedsODAC) Meeting. June 20, 2019

- 84. The Children's Cancer Foundation, Inc. 4<sup>th</sup> Annual Research Symposium: Solving Childhood Cancer through Collaboration. "*Phase I CD22 CAR T-Cell Trial Updates*." June 5, 2019. Landover, MD
- 85. Therapeutic Advances in Childhood Leukemia and Lymphoma: Investigators Conference. BC Children's Hospital and Research Institute. "Updates on Protocol T2012-002, A Pilot Study of Vincristine Sulfate Liposome Injection (Marqibo®) in Combination with UK ALL R3 Induction Chemotherapy for Children, Adolescents and Young Adults with Relapse of Acute Lymphoblastic Leukemia." April 7-9, 2019. Vancouver, BC
- 86. American Association of Cancer Research: Advances in Organ Site Research, Emerging Immunotherapies for Childhood Cancer. "The Evolving Landscape of CAR T-Cell Based Immunotherapy in Hematologic Malignancies." Monday, April 1, 2019. Atlanta, GA
- 87. 1<sup>st</sup> Immuno-Oncology Society of India Congress, 2019. Immunotherapies in Cancer: Challenge in translating from bench to bedside. Tata Memorial Centre (TMC) Mumbai. "*CAR T-Cell Therapy in ALL: Challenges and Future Directions.*" March 15-17, 2019. Mumbai, India.
- 88. Memorial Sloan Kettering Cancer Center: Clinical Application of CAR T-Cells. "CAR T-cell Therapy: Workflow Challenges and Optimal Timing for Delivery" March 14-15, 2019. New York, New York

## 2018 and prior

- 89. Society for Adolescent and Young Adult Oncology Conference, From Pediatric to Adult Acute Lymphoblastic Leukemia: The Age of Cellular Therapy. "Multispecific CAR-T Cell Targeting in ALL: What Does the Future Hold?," November 5, 2018. Newport Beach, California.
- 90. 4<sup>th</sup> International Workshop, Biology, Prevention, Treatment of Relapse After Allogeneic Hematopoietic Stem Cell Transplantation. Steering Committee, Session Head, Invited Speaker. September 21-22, 2018. Chicago, IL
  - a. Novel Therapies as a Bridge to HSCT and Maintenance Therapy post-HSCT in ALL
  - b. Relapse post CAR-T Cell Therapy
- 91. Translational Science 2018 Conference, "Top 10 Clinical Achievement Award," Talk, "New CAR Therapy for Relapsed Leukemia Patients." April 20, 2018.
- 92. FAES-CAR Technology Course. Talk, "Current Clinical Applications and Considerations of CAR-T Cell Therapy." March 16, 2018.
- 93. American Society of Clinical Oncology, Abstract Discussant. "Expanding CAR-T Cells for Extramedullary Disease." Saturday, June 3, 2017. Chicago, IL
- 94. Children's Oncology Group, Spring Meeting. "*Targeting CD33 and CD123 for AML CAR*." March 29, 2017.
- 95. ISBioTech 7<sup>th</sup> Spring Meeting. "Lessons Learned with CAR T-Cell Therapies for Acute Lymphoblastic Leukemia." March 6, 2017. Washington DC.
- 96. Children's National Medical Center, Pediatric BMT Departmental Meeting. "My Love Hate Relationship with CD22: The blood, sweat and tears of clinical research." January 12, 2017. Washington DC.
- 97. Children's Oncology Group: Novel Therapies for Relapsed ALL. "CD22 Antigen Expression." Wednesday, September 14, 2016. Atlanta, GA.
- 98. Children's Cancer Foundation Research Symposia. "Immunotherapy for Childhood Leukemia." June 1, 2016. Landover, MD.
- 99. Pediatric Blood and Marrow Transplant Consortium/American Society of Pediatric Hematology Oncology—Plenary Session: Advances in Stem Cell Therapy for Pediatric ALL. "Bridging Therapy Prior to BMT for ALL." May 11, 2016. Minneapolis, MN.
- 100. Society of Adolescent and Young Adult Oncology: From Pediatric to Adult Acute Lymphoblastic Leukemia: A Common Strategy for Cure. "Marqibo® in Acute Lymphoblastic Leukemia." Monday, October 26, 2015. Los Angeles, CA

- 101.2015-Innovative Therapies for Children with Cancer (ITCC)/International BFM/Therapeutic Advances in Childhood Leukemia & Lymphoma (TACL) International Meeting. "Marqibo® in Acute Lymphoblastic Leukemia." Monday, October 19, 2015. Toronto, Canada.
- 102. Children's Hospital of Philadelphia, Division of Pediatric Hematology/Oncology and Transplantation. Departmental Meeting. "Vasculopathy, Infection and Cancer: A Role for Transplantation." May 13, 2015. Philadelphia, PA.
- 103. Pediatric Grand Rounds, University of Virginia, Department of Pediatrics. "*Tackling Post-Transplant Relapse, One Trial at a Time*" September 26, 2014. Charlottesville, VA
- 104. HSCT Transplantation: Antibody and other Immunotherapeutic Approaches to Treat Post-HSCT Relapse." Friday, November 7, 2014. Minneapolis, MN.
- 105. National Marrow Donor Program Council Meeting. "Treating Disease Relapse after Allogeneic
- 106.Life with Cancer Organization, Family Center. Pediatric Oncology Parent Night. "Childhood Leukemia: Past, Present and Future." September 24, 2013. Fairfax, VA.

### Mentorship:

|                   | Position During Years of Training  | Year of direct mentorship | Current Position (as of August 1, 2023)  |
|-------------------|--|---------------------------|--|
| D. Nate Biery     | 1 <sup>st</sup> year medical student, George<br>Washington School of Medicine  | June 2023-<br>August 2023 | 1 <sup>st</sup> year medical student, George<br>Washington School of Medicine  |
| Paul Borgman      | 1 <sup>st</sup> year medical student, Florida<br>State University, College of<br>Medicine                            | June 2021-<br>August 2021 | 3rd year medical student, Florida<br>State University, College of<br>Medicine. Doing a research year at<br>NIH 2023-2024 |
| Julia Cohen, M.D. | Pediatric Hematology/Oncology<br>Fellow, National Cancer<br>Institute; Johns Hopkins<br>Hospital                     | July 2017-<br>June 2019   | Clinical Director, Early oncology<br>development. Merck Research Labs  |
| Alexandra Dreyzin | Pediatric Hematology/Oncology<br>Fellow, Children's National<br>Medical Center                                       | June 2021-<br>present     | Instructor, Children's National<br>Medical Center  |
| Aiman Faruqi      | Medical Research Scholars Program, 3 <sup>rd</sup> year Medical student, Cleveland Clinic Lerner College of Medicine | July 2021-<br>June 2022   | Internal Medicine Resident, Mayo<br>Clinic, Rochester, MN  |
| Cynthia Harrison  | Postbaccalaureate cancer research training award (CRTA)  | July 2022-<br>July 2023   | First year medical student, NYU  |
| Elizabeth Holland | Postbaccalaureate cancer research training award (CRTA)  | August 2020-<br>July 2023 | First year medical student,<br>University of Maryland  |
| Jennifer Jess     | Medical Research Scholars<br>Program, 3 <sup>rd</sup> year Medical<br>student, Michigan State<br>University          | July 2020-<br>June 2021   | Pediatric Resident, Cleveland Clinic   |
| Eli Kane          | Undergraduate student,<br>University of Maryland   | June 2017-<br>August 2017 | Digital Learning Associate, Society for Neuroscience   |

| Amita Kulshreshtha       | 2 <sup>nd</sup> year medical student, UT<br>Southwestern School of<br>Medicine   | April 2018-<br>June 2018         | Ob/Gyn Resident  |
|--------------------------|--|----------------------------------|--|
| Michael LaLoggia         | 1 <sup>st</sup> year medical student, Lake<br>Erie College of Osteopathic  | June 2020-<br>July 2020          | Internal Medicine, Cooper<br>University Hospital   |
| Diane Libert             | Medical Research Scholars Program, 3 <sup>rd</sup> year Medical Student, Cleveland Clinic Lerner College of Medicine                                     | 2018-2019                        | Pathology Resident, Stanford<br>University   |
| Dan Lichtenstein         | Medical Research Scholars Program, 3 <sup>rd</sup> year Medical Student, State University of New York, Upstate Medical University                        | 2019-2020                        | Internal Medicine/Pediatrics<br>Resident, Cincinnati Children's<br>Hospital and University of<br>Cincinnati Medical Center |
| John Ligon, MD*          | Immunotherapy Fellow, POB, NCI   | August 2020-<br>December<br>2021 | Assistant Professor, Department of<br>Pediatrics, Pediatric Oncology,<br>University of Florida                             |
| Keagan Lipak             | Medical Research Scholars Program, 2nd year Medical Student, Ohio University Heritage College of Osteopathic Medicine                                    | August 2022-<br>July 2023        | 3rd year Medical Student, Ohio<br>University Heritage College of<br>Osteopathic Medicine                                   |
| Lekha Mikkilineni, M.D.  | Staff Clinician, Surgery Branch, NCI   | 2019-2021                        | Assistant Professor, Stanford University   |
| John Molina, MD*         | Pediatric Hematology/Oncology<br>Fellow, National Cancer<br>Institute; Johns Hopkins<br>Hospital   | 2019-July<br>2022                | Instructor, Cleveland Clinic   |
| Alexa Morales<br>Arana*  | 1 <sup>st</sup> year medical student, UC<br>Davis School of Medicine,<br>Medical student summer<br>opportunities to advance<br>research program (M-SOAR) | June 2023-<br>July 2023          | 2 <sup>nd</sup> year medical student, UC Davis<br>School of Medicine   |
| Anusha Ponduri           | Postbaccalaureate cancer research training award (CRTA)  | June 2017-<br>June 2018          | 2 <sup>nd</sup> year Medical Student, Albert<br>Einstein College of Medicine, NY   |
| Haris Qureshi            | Postbaccalaureate cancer research training award (CRTA)  | September 2018-July 2019         | Internal Medicine resident, Yale<br>University   |
| Sneha<br>Ramakrishna, MD | Pediatric Hematology/Oncology<br>Fellow, National Cancer<br>Institute; Johns Hopkins<br>Hospital   | 2017-ongoing                     | Assistant Professor, Department of<br>Pediatrics, Stanford Hospital  |
| Angela Sarkisian         | 1 <sup>st</sup> year medical student, George<br>Washington School of Medicine  |                                  | 3 <sup>rd</sup> year Medical Student, George<br>Washington University  |
| Christopher Sesi         | 1 <sup>st</sup> year medical student,<br>Midwestern University   | June 2019-<br>August 2019        | Internal Medicine, Detroit Medical<br>Center   |

| Shilpa Shahani, MD               | Immunotherapy Fellow, POB, NCI   | 2019-2020                 | Pediatric Oncology, City of Hope,<br>CA   |  |
|----------------------------------|--|---------------------------|---|--|
| Haneen Shalabi,<br>DO            | Immunotherapy Fellow, POB, NCI   | 2016-ongoing              | Staff Clinician, POB, NCI   |  |
| Sara Silbert, MD                 | Pediatric Hematology/Oncology<br>Fellow, Children's National<br>Medical Center                                   | July 2020-<br>ongoing     | Staff Clinician, POB, NCI   |  |
| Hannah Smith                     | Undergraduate student, St.<br>Mary's College   | June 2018-<br>August 2018 | NOVA Southeastern University<br>College of Osteopathic Medicine                         |  |
| David Turicek*                   | Undergraduate student,<br>University of Wisconsin,<br>Madison  | June 2022-<br>August 2022 | PhD student, Washington<br>University, St. Louis  |  |
| Priya Vadlamudi                  | 1 <sup>st</sup> year medical student,<br>University of North Carolina  | June 2023-<br>August 2024 | 2 <sup>nd</sup> year medical student, University of North Carolina                      |  |
| Lila Yang                        | 1 <sup>st</sup> year medical student, New<br>York Institute of Technology—<br>College of Osteopathic<br>Medicine | June 2019-<br>August 2019 | Medical student, New York Institute<br>of Technology—College of<br>Osteopathic Medicine |  |
| *Underrepresented minority (URM) |  |                           |   |  |

### **BIBLIOGRAPHY**

Complete list of published work in MyBibliography:

https://www.ncbi.nlm.nih.gov/myncbi/nirali.shah.1/bibliography/public/

#### Peer Reviewed Primary Research Manuscripts (Published/In Press)

- Aminov S, Giricz O, Melnekoff D, Sica A, Polischuk V, Papazoglu C, Yates B, Wang H-W, Sahu S, Wang Y, Gordon-Mitchell S, Leschenko V, Schinke C, Pradhan K, Aluri S, Sohn M, Barta SK, Agarwal B, Goldfinger M, Mantzaris I, Shastri A, Matsui W, Steidl U, Brody J, Shah NN, Parekh S, Verma A. Immunotherapy-resistant acute lymphoblastic leukemia cells exhibit reduced CD19 and CD22 expression and BTK pathway dependency. <u>Journal of Clinical Investigation</u>. 2024. In Press (Cocorresponding)
- Song, HW, Benzaoui M, Underwood S, Dwivedi A, Shao L, Achar S, Posarac V, Remley VA, Prochazkova M, Cai Y, Jin, P, Somerville RP, Stroncek DF, Altan-Bonnet G, Shah NN, Chien CD, Taylor N, Highfill SL. Manufacture of CD22 chimeric antigen receptor T cells following positive versus negative selection results in distinct cytokine secretion profiles and γδ T cell output. Molecular Therapy -Methods and Clinical Development. 2023. In Press
  - a. Commentary by: Orentas RJ. A positive take on negative selection for CAR-T manufacturing. Molecular Therapy-Methods & Clinical Development. 2024. In Press
- 3. Shalabi H, Harrison, C, Yates B, Calvo KR, Lee DW, **Shah NN**. Intrathecal hydrocortisone for treatment of children and young adults with CAR T-cell immune-effector cell-associated neurotoxicty syndrome. Pediatr Blood Cancer. 2024; 71 (1) e30741
- 4. Holland EM, Yates B, Steinberg SM, Yuan CM, Wang H-W, Annesley C, Shalabi H, Stroncek D, Fry TJ, Kreuger J, Jacoby E, Hsieh E, Bhojwani D, Gardner RA, Maude SL, **Shah NN**. CAR T-cells as Salvaget Therapy for post CAR T-cell Failure. <u>Transplantation and Cellular Therapy</u>. 2023 (Online ahead of print)
- 5. Hassan R, Butler M, O'Cearbbhaill RE, Oh DY, Johnson M, Zikaras K, Smalley M, Ross M, Tanyi JL, Ghafoor A, **Shah NN**, Saboury B, Cao L, Quintas-Cardama A, Hong D. Mesothelin-targeting T cell

- receptor fusion construct cell therapy in refractory solid tumors: phsae 1/2 trial interim results. <u>Nature Medicine</u>. 2023 (Online ahead of print)
- 6. Silbert SK, Madan S, Holland EM, Steinberg SM, Little L, Foley T, Epstein M, Sarkisian A, Lee DW, Nikitina E, Kakumanu S, Ruppin E, Shalabi H, Yates B, **Shah NN**. A comprehensive analysis of adverse events in the first 30 days of phase 1 pediatric CAR T-cell trials. <u>Blood Adv.</u> 2023 (Online ahead of print)
- 7. Rocco JM, Inglefield J, Yates B, Lichtenstein DA, Wang Y, Goffin L, Filipovic D, Schiffrin EJ, **Shah** NN. Free interleukin-18 is elevated in CD22 CAR T-cell associated hemophagocytic lymphohistiocytosis-like toxicities. <u>Blood Advances</u>. 2023 (Online ahead of print)
- 8. Turicek DP, Giordani VM, Moraly J, Taylor N, **Shah NN**. CAR T-cell Detection Scoping Review: An Essential Biomarker in Critical Need of Standardization. <u>Journal of ImmunoTherapy of Cancer</u>. 2023. 11(5):e006596
- Jess J, Yates B, Dulau-Florea A, Parker KR, Inglefield J, Lichtenstein DA, Schischlik F, Ongkeko M, Wang Y, Shahani SA, Cullinane A, Smith H, Kane E, Little L, Chen D, Fry TJ, Shalabi H, Wang H-W, Satpathy AT, Lozier JN, Shah NN. CD22 CAR T-cell Associated Hematologic Toxicities, Endothelial Activation and Relationship to Neurotoxicity. <u>Journal of ImmunoTherapy of Cancer</u>. 2023. 11(6):e005898
- 10. Hines MR, Knight TE, McNerney KO, Leick MB, Jain T, Ahmed S, Frigault MJ, Hill JA, Jain MD, Johnson WT, Lin Y, Mahadeo KM, Maron GM, Marsh RA, Neelapu SS, Nikiforow S, Ombrellow AK, Shah NN, Talleur AC, Turicek D, Vatsayan A, Wong SW, Maus MV, Komanduri KV, Berliner N, Henter J-I, Perales M-A, Frey NV, Teachey DT, Frank MJ, Shah NN. Immune Effector Cell associated Hemophagocytic Lymphohistiocytosis-like Syndrome. <u>Transplantation and Cellular Therapy</u>. 2023. 29(7): 438e1-438e16.
- 11. de Jesus A, Chen G, Yang D, Brdika T, Ruth N, Bennin D, Cebecauerova D, Malcova H, Freeman H, Martin N, Svojgr K, Passo M, Bhuyan F, Alehashemi S, Rastegar A, Uss K, Kardava L, Marrero B, Duric I, Omoyinmi E, Peldova P, Lee C-C, Kleiner D, Hadigan C, Hewitt S, Pittaluga S, Carmona-Rivera C, Calvo K, **Shah N**, Balascakova M, Rink D, Kotalova R, Parackova Z, Peterkova L, Kuzikova D, Campr V, Sramkova L, Biancotto A, Brooks S, Manes C, Meffre E, Harper R, Kuehn H, Kaplan M, Brogan P, Rosenzweig S, Merchant M, Deng Z, Huttenlocher A, Moir S, Kuhns D, Boehm M, Kramarzova K, Goldbach-Mansky R. Constitutively active Lyn kinase causes a cutaneous small vessel vasculitis and liver fibrosis syndrome. Nature Communications. 2023. 14(1): 1502.
- 12. Cornetta K, Yao J, House K, Duffy L, Adusumilli PS, Beyer R, Booth C, Brenner M, Curran K, Grilley B, Heslop H, Hinrichs CS, Kaplan RN, Kiem H-P, Kochenderfer J, Kohn DB, Mailankody S, Norberg SM, O'Cearbhaill RE, Pappas J, Park J, Ramos C, Ribas A, Riviera I, Rosenberg SA, Sauter C, **Shah NN**, Slovin SF, Thrasher, Williams DA. Replication Competent Retrovirus Testing (RCR) in the National Gene Vector Biorepository: No Evidence of RCR in 1595 Post-Treatment Peripheral Blood Samples Obtained from 60 Clinical Trials. Molecular Therapy. 2023. 31 (3): 801-809.
- 13. Dreyzin A, Panch SR, Shalabi H, Yates H, Highfill SL, Jin P, Stroncek D, **Shah NN**. Cryopreserved anti-CD22 and bispecific anti-CD19/22 CAR T-cells are as effective as freshly infused cells. <u>Molecular Therapy—Methods & Clinical Development</u>. 2022. (28): 51-61.
- 14. Zhou T, Karrs J, Ho T, Kochenderfer J, Shah NN, Yuan C, Wang H-W. Circulating CD22+/CD19-/CD24- Progenitors and CD22+/CD19+/CD24- Mature B cells: Diagnostic Pitfalls for Minimal Residual Disease Detection in B-Lymphoblastic Leukemia. <a href="Cytometry: Part B Clinical Cytometry">Cytometry: Part B Clinical Cytometry</a>. (Online ahead of print)
- 15. Shao L, Shi R, Zhao Y, Liu H, Lu A, Ma J, Cai Y, Fuksenko T, Peleyo A, **Shah NN**, Kochenderfer JN, Norberg SM, Hinrichs C, Highfill SL, Somerville RP, Panch SR, Jin P, Stroncek DF. Genome-wide profiling of retroviral DNA integration and its effect on clinical pre-infusion CAR T-cell products. <u>J</u> Transl Med. 2022; 20 (1): 514.
- 16. Molina JC, Li Y, Otto WR, Miller TP, Getz KD, Mccoubrey C, Ramos M, Krause E, Cao L, Gramatges MM, Rabing K, Scheurer M, Elgarten CW, Myers RM, Seif AE, Fisher BT, **Shah NN**,\* Aplenc R\*

- Absolute Lymphocyte Count Recovery Following Initial Acute Myelogenous Leukemia Therapy: Implications for Adoptive Cell Therapy. <u>Pediatric Blood Cancer</u>. 2023. (70) 1: e30062. (\*=co-contributing)
- 17. Sharma A, Farnia S, Otegbeye F, Rinkle A, Shah J, **Shah NN**, Gill S, Maus MV. Nomenclature for Cellular and Genetic therapies: A Need for Standardization. <u>Transplantation and Cellular Therapy</u>. 2022.
- Silbert S, Cole K, Bedoya S, Freeman AF, Whangbo JS, Avila D, Su HC, Yates B, Epstein M, Wendler DS, Pai S-Y, Hickstein DD, Wiener L, Shah NN. Tandem Hematopoietic Stem Cell Transplant Considerations in Families with Multiple Siblings Affected by DOCK8 Deficiency. <u>Bone Marrow Transplantation</u>. 2022. 57 (11): 1721-1723
- 19. Shao L, Pelayo A, Shi R, Ma J, Liu H, Cai Y, Prochazkova M, Somerville R, Panch SR, **Shah NN**, Stroncek DF, Jin P. Identification of Genomic Determinants Contributing to Cytokine Release in Immunotherapies and Human Diseases. <u>Journal of Translational Medicine</u>. 2022. 20 (1): 338
- 20. Faruqi AJ, Ligon AJ, Borgman P, Steinberg SM, Foley T, Little L, Mackall CL, Lee DW, Fry TJ, Shalabi H, Brudno J, Yates B, Mikkilineni L, Kochenderfer J, **Shah NN**. The Impact of Race, Ethnicity and Obesity on CAR T-cell Therapy Outcomes. <u>Blood Adv.</u> 2022. 6 (23): 6040-6050.
- 21. Hsieh EM, Myers RM, Yates B, Annesley C, Taraseviciute A, Steinberg SM, Sheppard JD, Chung P, Chen L, Lee DW, Dinofia A, Grupp SA, Verneris MR, Laetsch TW, Bhojwani D, Brown PA, Pulsipher MA, Rheingold SR, Gardner RA, Gore L, **Shah NN**, Lamble A. Low Rate of Subsequent Neoplasms Following CAR T-cell Therapy. <u>Blood Adv</u>. 2022. 6 (17): 5222-5226.
- 22. Ligon JA, Fry A, Maher JY, Foley T, Silbert S, Yates B, Gomez-Lobo V, Wiener L, **Shah NN**. Fertility and CAR T-cells: Current Practice and Future Directions. <u>Transplantation and Cell Therapy</u>. 2022. 28 (9): 605.e1-605.e8.
- 23. Faruqi AJ, Ligon JA, Cohen JW, Akshintala S, Widemann BC, **Shah NN**. Letter to the Editor: Reporting of Racial and Ethnic Minority Representation in Early Phase Pediatric Oncology Clinical Trials. The Oncologist. 2022. 27 (8): e681-682
- 24. Shalabi H, Qin H, Su A, Yates B, Wolters PL, Steinberg SM, Ligon JA, Silbert S, Dede K, Benzaoui M, Goldberg SY, Achar S, Schneider D, Shahani SA, Little L, Foley T, Molina JC, Panch S, Mackall CL, Lee DW, Chien CD, Pouzolles M, Ahlman MA, Yuan CM, Wang H-w, Wang Y, Inglefield J, Tamla MA, Martin S, Highfill SL, Altan-Bonnet G, Stroncek DE, Fry TJ, Taylor N, Shah NN. CD19/22 CAR T-cells in Children and Young Adults with B-ALL: Phase I Results and Development of a Novel Bicistronic CAR. Blood. 2022. 140 (5): 451-463.
  - a. Commentary by: Rouce RH and Scherer L. Reverse translational studies informa dual-targeted CAR T-cell design. Blood 2022.
- 25. Holland EM, Molina JC, Dede K, Moyer D, Zhour T, Yuan CM, Wang HW, Stetler-Stevenson M, Mackall CL, Fry TJ, Panch S, Highfill S, Stroncek D, Little L, Lee DW, Shalabi H, Yates B, Shah NN. Efficacy of Second CAR-T (CART2) Infusion Limited by Poor CART Expansion and Antigen Modulation. <u>Journal of Immunotherapy of Cancer</u>. 2022. 10 (5):e004483
- 26. Wintering A, Ishiyama K, Tamaki S, Tamaki C, Fandel J, Ji L, Wood BL, **Shah NN**, Yuan CM, O'Brien MM, Loh ML, Diaz-Flores E. CD22<sup>low</sup>/Bcl-2<sup>high</sup> expression identified poor response to Inotuzumab in relapsed/refractory acute lymphoblastic leukemia. <u>Blood Advances</u>. 2022. 7 (2): 251-255
- 27. Lamble A, Myers RM, Taraseviciute A, John S, Yate B, Steinberg SM, Sheppard J, Kovach AE, Wood B, Borowitz MJ, Stetler-Stevenson M, Yuan CM, Pillai V, Foley T, Chung P, Chen L, Lee DW, Annesley C, Dinofia A, Grupp SA, Verneris MR, Gore L, Laetsch TW, Bhojwani D, Brown PA, Pulsipher MA, Rheingold SR, Gardner RA, Shah NN. Pre-infusion risk factors impacting relapse immunophenotype following CD19 CAR T-cells. <u>Blood Adv.</u> 2023. 7 (4) 575-585.
- 28. Diorio C, Vatsayan A, Talleur AC, Annesley C, Jaroscak J, Shalabi H, Ombrello AK, Hudspeth M, Maude SL, Gardner RA, **Shah NN**. Letter to the Editor: Anakinra utilization in refractory pediatric CAR T-cell associated toxicities. Blood Advances. 2022. 6 (11): 3398-3403.

- 29. Shalabi H, Martin S, Yates B, Wolters PL, Kaplan C, Smith H, Sesi CR, Jess J, Toledo-Tamula MA Struemph K, Delbrook CP, Mackall CL, Lee DW, **Shah NN**. Comprehensive Analysis of Neurotoxicity Following CD19/28z CAR T-cells in Chidlren and Young Adults with B-cell Malignancies. <u>Neuro Oncology</u>. 2022. 24 (9): 1584-1597.
- 30. O'Brien M, Ji L, **Shah NN**, Rheingold SR, Bhojwani D, Yuan CM, Xu X, Yi J, Harris AC, Brown PA, Borowitz MJ, Militano O, Kairalla J, Devidas M, Raetz EA, Gore L, Loh ML. Phase II Trial of Inotuzumab Ozogamicin in Children and Adolescents with Relapsed or Refractory B-Cell Acute Lymphoblastic Leukemia: Children's Oncology Group Protocol AALL1621. <u>Journal of Clinical Oncology</u>. 2022. 40 (9): 956-967.
- 31. Pennarola BW, Fry A, Prichett L, Beri AE, **Shah NN**, Wiener L. Mapping the Landscape of Advance Care Planning in Adolescents and Young Adults Receiving Allogeneic Hematopoietic Stem Cell Transplantation: a 5-year retrospective review. <u>Transplantation and Cellular Therapy</u>. 2022. 28 (3): 164.e1-164.e8.
- 32. Holland EM, Yates B, Ling A, Yuan CM, Wang H-W, Stetler-Stevenson M, LaLoggia M, Molina JC, Lichtenstein DA, Lee DW, Ligon JA, Shalabi H, Ahlman MA, **Shah NN**. Characterization of Extramedullary Disease in B-ALL and Response to CAR T-cell Therapy. <u>Blood Advances</u>. 2022. 6 (7): 2167-2182
- 33. Molina JC, Steinberg SM, Yates B, Lee DW, Little L, Mackall CL, Shalabi H, **Shah NN**. Factors Impacting Overall and Event Free Survival Following Post-CAR T-cell Consolidative Hematopoietic Stem Cell Transplant. <u>Transplantation and Cellular Therapy</u> 2022. 28 (1): 31.e1-31..e9
- 34. Pearson A, Rossig C, Mackall C, **Shah NN**, Baruchel A, Reaman G, Ricafort R, Heenen D, Bassan A, Berntgen M, Bird N, Bleickardt E, Bouchkouj N, Bross P, Brownstein C, Cohen S, de Rojas T, Ehrlich L, Fox E, Gottschalk S, Hanssens L, Hawkins DS, Horak ID, Horton-Taylor D, Johnson C, Karres D, Ligas F, Ludwinski D, Mamonk M, Marshall L, Kharabi-Masouleh B, Matloub Y, Maude S, McDonough J, Minard-Colin V, Norga K, Nysom K, Pappo A, Pearce L, Pieters R, Pule M, Quintas-Cardama A, Richardson N, SchuBler-Lenz M, Scobie N, Sersch MA, Smith MA, Sterba J, Tasian SK, Weigel B, Weiner SL, Zwann CM, Lesa G, Vassal G. Paediatric Strategy Forum for Medicinal Product Development of CAR T-cells in children and adolescents with cancer. ACCELERATE in collaboration with the European Medicines Agency with participation of the Food and Drug Administration. European Journal of Cancer. 2021. 160: 112-133.
- 35. Myers RM, Taraseviciute A, Steinberg SM, Lamble AJ, Sheppard J, Yates B, Kovach AE, Wood B, Borowitz MJ, Stetler-Stevenson M, Yuan CM, Pillai V, Foley T, Chung P, Chen L, Lee DW, Annesley C, DiNofia A, Grupp SA, John S, Bhojwani D, Brown PA, Laetsch TW, Gore L, Gardner RA, Rheingold SR, Pulsipher MA, **Shah NN**. Blinatumomab non-response and high disease burden are associated with inferior outcomes after CD19-CAR for B-ALL. <u>J Clin Oncol</u>. 2022. 40 (9): 932-944.
  - a. Commentary by: Newman HM and Teachey DT. Taking a BiTE out of CAR T-cell efficacy. J Clin Oncol. 2022. 40 (9): 921-923.
  - b. Commentary in Cancer Discovery "Research Watch" doi: 10.1158/2159-8290.CD-RW2021-172
- 36. Nichols-Vinueza DX, Parta M, **Shah NN**, Cuellar-Rodriguez MJ, Bauer TR, West RR, Hsu AP, Calvo KR, Notarangelo LD, Holland SM, Hickstein DD. Donor Source and Post-Transplantation Cyclophosphamide Influence Outcome in Allogeneic Stem Cell Transplantation for GATA2 Deficiency. <u>British Journal of Hematology</u>. 2022. 196 (1): 169-178.
- 37. Mikkilineni L, Yates B, Steinberg SM, Shahani SA, Molina J, Palmore T, Lee DW, Kaplan RN, Mackall CL, Fry TJ, Gea-Banacloche J, Jerussi T, Nussenblatt V, Kochenderfer JN, **Shah NN**. Infectious Complications of CAR T-cell Therapy Across Novel Antigen Targets in the First 30 days. Blood Advances. 2021. 5 (23): 5312-5322
- 38. Lichtenstein D, Schischlik F, Shao L, Steinberg SM, Yates B, Wang H-W, Wang Y, Inglefield J, Dulau-Flores A, Ceppi F, Hermida LC, Stringaris K, Dunham K, Homan P, Jailwala P, Mirazee J, Robinson W, Chisholm KM, Yuan CM, Stetler-Stevenson M, Ombrello AK, Jin J, Fry TJ, Taylor N, Highfill SL,

- Jin P, Gardner RA, Shalabi H, Ruppid E, Stroncek DF, **Shah NN**. Characterization of HLH-Like Manifestations as a CRS Variant in Patients Receiving CD22 CAR T-cells. <u>Blood</u> 2021. 138 (24): 2469-2484
- 39. Qin H, Yang L, Chukinas JA, **Shah NN**, Tarun S, Pouzolles M, Chien CD, Niswander LM, Welch AR, Taylor NA, Tasian SK, Fry TJ. Systematic Preclinical Evaluation of CD33-directed Chimeric Antigen Receptor T-cell Immunotherapy for Acute Myeloid Leukemia Defines Optimized Construct Design. <u>J Immunother Cancer</u>. 2021. 9 (9): e003149
- 40. Spiegel JY, Patel S, Muffly L, Hossain NM, Oak J, Baird JH, Frank MJ, Shiraz P, Sahaf B, Craig J, Iglesias M, Younes S, Natkunam Y, Ozawa MG, Yang E, Tamaresis J, Chinnasamy H, Ehlinger Z, Reynolds W, Lynn R, Rotiroti MC, Gkitsas N, Arai S, Johnston L, Lowsky R, Majzner RG, Meyer E, Negrin RS, Rezvani AR, Sidana S, Shizuru J, Weng WK, Mullins C, Jacob A, Kirsch I, Bazzano M, Zhou J, Mackay S, Bornheimer SJ, Schultz L, Ramakrishna S, Davis KL, Kong KA, Shah NN, Qin H, Fry T, Feldman S, Mackall CL, Miklos DB. CAR T cells with dual targeting of CD19 and CD22 in adult patients with recurrent or refractory B cell malignancies: a phase 1 trial. Nat Med 2021. 27 (8): 1419-1431.
- 41. Fogli LK, Aurigemma R, Sommer CL, Singh A, Bourcier K, Ernstoff MS, NCI Cell Therapy Workshop Committee (\*On committee). Challenges and Challenges and next steps in the advancement of immunotherapy: summary of the 2018 and 2020 National Cancer Institute workshops on cell-based immunotherapy for solid tumors. J Immunother Cancer. 2021. 9(7): e003048
- 42. Panch SR, Logan B, Sees JA, Bo-Subait S, Savani B, **Shah NN**, Hsu JW, Switzer G, Lazarus HM, Anderlini P, Hematti P, Confer D, Pulsipher MA, Shaw BE, Stroncek DF. Shorter interdonation interval contributes to lower cell counts in subsequent stem cell donations. <u>Transplant Cell Thera</u>. 2021. 27 (6): 503.e1-503.e8.
- 43. Hsu JW, Farhadfar N, Murthy H, Logan BR, Bo-Subait S, Frey N, Goldstein SC, Horowitz MM, Lazarus H, Schwanke JD, **Shah NN**, Spellman SR, Switzer GE, Devine SM, Shawa BE, Wingarad JF. The effect of donor graft cryopreservation on allogeneic hemaopoietic cell transplantation outcomes: A center for international blood and marrow transplant research analysis. Implications during the COVID-19 pandemic. Transplant Cell Ther. 2021. 27 (6): 507-516
- 44. Dwivedi A, Karulkar A, Ghosh S, Srinivasan S, Vasant Kumbhar B, Jaiswal AK, Kizhakeyil A, Asija S, Asija S, Rafiq A, Kumar S, Nisar A, Pandit D, Poojary M, Jain H, Banavali SD, Highfill SL, Stroncek DF, **Shah NN**, Fry TJ, Narula G, Purwar R. Robust Antitumo Activity and Low Cytokine Productino by Novel Humanized Anti-CD19 CAR T Cells.. <u>Molecular Cancer Therapeutics</u>. 2021. 20 (5): 846-858.
- 45. **Shah NN**,\* Lee DW,\* Yates B, Yuan CM, Shalabi H, Martin S, Wolters PL, Steinberg SM, Baker EH, Delbrook C, Stetler-Stevenson M, Fry TJ, Stroncek DF, Mackall CL. Long-term follow-up of CD19 CAR T-cell therapy in children and young adults with B-ALL. <u>J Clin Oncol</u>. 2021. (39 (15): 1650-1659, \*co-first author)
- 46. Mo G, Wang HW, Talleur AC, Shahani SA, Yates B, Shalabi H, Douvas MG, Calvo KR, Shern JF, Chaganti S, Patrick K, Song Y, Fry TJ, Wu X, Triplett BM, Khan J, Gardner RA, **Shah NN**. Diagnostic approach to the evaluation of myeloid malignancies following CAR T-cell therapy in B-cell acute lymphoblastic leukemia. <u>J Immunother Cancer</u>. 2020. 8(2):e001563.
- 47. Parta M, Cole K, Avila D, Duncan L, Baird K, Blacklock Schuver B, Wilder J, Palmer C, Daub J, Hsu AP, Zerbe CS, Marciano BE, Cuellar-Rodriguez JM, Bauer TR, Nason M, Calvo K, Merideth M, Stratton P, DeCherney A, **Shah NN**, Holland SM, Hickstein DD. Hematopoietic Cell Transplantation and Outcomes Related to Human Papillomavirus Disease in GATA2 Deficiency. <u>Transplantation and Cellular Therapy</u>. 2021; 27(5): 435.e1-435.e11.
- 48. Gutierrez C, Brown ART, Herr MM, Kadri SS, Hill B, Rajendram P, Duggal A, Turtle CH, Patel K, Lin Y, May HP, Gallo de Moraes A, Maus MV, Frigault MJ, Brudno JN, Athale J, Shah NN, Kochenderfer JN, Dharshan A, Beitinjaneh A, Arias AS, McEvory C, Mead E, Stephans RS, Nates JL, Neelapu SS, Pastores SM. The chimeric antigen receptor-intensive care unit (CAR-ICU) initiative:

- Sureying intensive care unit practices in the management of CAR T-cell associated toxicities. <u>J Crit Care</u>. 2020; 58 (58-64).
- 49. Qayed M, Ahn, K.W., Kitko CL, Johnson MH, **Shah NN**, Dvorak CC, Mellgren KM, Friend BD, Verneris MR, Leung WH, Toporski J, Levine JE, Chewning J, Wayne AS, Kapoor U, Triplett BM, Schultz KR, Yanik GA, Eapen M. A Validated Pediatric Disease Risk Index for Allogeneic Hematopoietic Cell Transplantation. <u>Blood</u>. 2021. 137 (7): 983-993.
- 50. Shalabi H., Sachdev V, Kulshreshtha A, Cohen JW, Yates B, Rosing DR, Sidenko S, Delbrook C, Mackall C, Wiley B, Lee DW, **Shah NN**. Impact of Cytokine Release Syndrome on Cardiac Function Following CD19 CAR T-cell Therapy in Children and Young Adults with Hematologic Malignancies. J Immunother Cancer. 2020. 8 (2): e001159.
- 51. Ishii K, Pouzolles M, Chien CD, Erwin-Cohen RA, Kohler ME, Qin H, Lei H, Kihn S, Ombrellow AK, Dulau-Florea A, Eckhaus MA, Shalabi H, Yates B, Lichtenstein DA, Zimmermann VS, Kondo T, Shern JF, Young HA, Taylor N, **Shah NN**,\* Fry TJ.\* Perforin-deficient CAR T-Cells Recapitulate Hemophagocytic Lymphohistiocytosis-like Toxicities Occurring in Humans. <u>J Clin Invest</u>. 2020. 130 (10): 5425-5443. (\*Co-senior author)
- 52. Hsu JW, Shaw BE, Kim S, Logan BR, Sees JA, Confer DL, Pulsipher MA, **Shah NN**, Switzer GE, Abidi MH, Ahmed IA, Anderlini PN, Bredeson C, Chhabra S, Dandoy CE, Diaz MA, Farhadfar N, Ganguly S, Gergis U, Hale GA, Hematti P, Kamble RT, Kasow KA, Lazarus HM, Liesveld JL, Murthy HS, Olsson RF, Savani BN, Schears R, Seo S, Solh M, Spitzer T, Steinberg A, Sugrue M, Warkentin P, Wingard JR. Collection of Peripheral Blood progenitor Cells in 1 Day is Associated with Decreased Donor Toxicity Compared to 2 Days in Unrelated Donors. <u>Biol Blood Marrow Transplant</u>. 2020. Jun;26(6): 1210-1217.
- 53. Farhadfar N, Murthy HS, Logan BR, Sees JA, Ayas M, Battiwalla M, Beitinjaneh AM, Chhabra S, Diaz MA, Engles K, Frangoul H, Ganguly S, Gergis U, Kamani NR, Kamble RT, Kasow KA, Lazarus HM, Liesveld JL, Norkin M, O' Donnell PV, Olsson RF, Rossmann S, Savani BN, Schears R, Seo S, Solh MM, Spitzer T, Sugrue M, Yared JA, Linenberger M, Schwartz J, Pulsipher MA, Shah NN, Switzer GE, Confer DL, Shaw BE, Wingard JR. Impact of autologous blood transfusion after bone marrow harvest on unrelated donor's health and outcome: a CIBMTR analysis. Bone Marrow Transplant. 2020 [Epub ahead of print]
- 54. Ben Yakov G, Sharma D, Cho MH, **Shah NN**, Hickstein D, Urban A, Darnell D, Kapuria D, Marko J, Kleiner DE, Hadigan CM, Danielson J, Ham H, Vittal A, Su HC, Freeman AF, Heller T. Cryptosporidum infection in Dedicator of Cytokinesis 8 (DOCK8) Deficiency. <u>J Allergy Clin Immunol Pract</u>. 2020. [Epub ahead of print]
- 55. Seftel Kuxhausen M, Burns L, Chitphakdithai P, Confer D, Kiefer D, Lee S, Logan B, O'Donnell P, Pulsipher M, **Shah NN**, Switzer G, Shaw BE. Clonal Hematopoiesis in Related Allogeneic Transplant Donors: Implications for Screening and Management. <u>Biol Blood Marrow Transplant</u>. 2020 Jun;26(6):e142-e144
- 56. Steineck A, Wiener L, Mack JW, **Shah NN**, Summers C, Rosenberg AR. Psychosocial Care for Children Receiving Chimeric Antigen Receptor (CAR) T-cell Therapy. <u>Pediatric Blood and Cancer</u>. 2020. 67 (5): e28249
- 57. Shah NN, Highfill SL, Shalabi H, Yates B, Jin J, Wolters PL, Ombrello A, Steinberg SM, Martin S, Delbrook C, Hoffman L, Little L, Ponduri A, Qin H, Qureshi H, Dulau-Florea A, Salem D, Wang HW, Yuan C, Stetler-Stevenson M, Panch S, Tran M, Mackall CL, Stroncek DF, Fry TJ. CD4/CD8 T-Cell Selection Impacts CAR T-Cell Potency and Toxicity: Updated Results from a Phase I Anti-CD22 CAR T-Cell Trial. <u>Journal of Clinical Oncology</u>. 2020, Epub 2020 Apr 14.
- 58. Farhadfar N, Hsu JW, Logan BR, Sees JA, Chitphakdithai P, Sugrue MW, Abdel-Azim H, Anderlini PN, Bredeson C, Chhabra S, Diaz MA, Ganguly S, Hematti P, Kamble RT, Kasow KA, Lazarus HM, Lynch DK, Murthy HS, Olsson RF, Papari M, Przepiorka D, Savani BN, Schears R, Seo S, Solh MM, Spitzer T, Yared JA, Pulsipher MA, **Shah NN**, Switzer GE, Confer DL, Shaw BE, Wingard JR.

- Weighty choices: Selecting optimal G-CSF doses for stem cell mobilization to optimize yield. <u>Blood Adv.</u> 2020. 4(4): 706-716.
- 59. Shalabi H., Yuan CM, Kulshreshtha A, Dulau-Florea A, Salem D, Gupta GK, Roth M, Filie AC, Yates B, Delbrook C, Derdak J, Mackall CL, Lee DW, Fry TJ, Wayne AS, Stetler-Stevenson M, **Shah NN**. Disease Detection Methodologies in Relapsed B-Cell Acute Lymphoblastic Leukemia: Opportunities for Improvement. <u>Pediatric Blood and Cancer</u>. 2020. 67 (4): e28149.
- 60. Libert D, Yuan CM, Masih KE, Galera P, Salem D, Shalabi H, Yates B, Delbrook C, Shern JF, Fry TJ, Khan J, Stetler-Stevenson M, **Shah NN**. Serial Evaluation of CD19 Surface Expression in Pediatric B-Cell Malignancies Following CD19 Targeted Therapy. <u>Leukemia</u>. 2020. 34 (11): 3064-3069.
- 61. Cohen JW, Akshintala S, Kane E, Gnanapragasam H, Widemann BC, Steinberg SM, **Shah NN**. A Systematic Review of Pediatric Phase I Trials in Oncology: Toxicity and Outcomes in the Era of Targeted Therapies. The Oncologist. 2020. (25 (6): 532-540.
- 62. **Shah NN**, Bhojwani D, August K, Baruchel A, Bertrand Y, Boklan J, Dalla-Pozza L, Dennis R, Hijiya N, Locatelli F, Martin PL, Mechinaud F, Moppett J, Rheingold SR, Schmitt C, Trippett TM, Liang M, Balic K, Li X, Vainshtein I, Yao NS, Pastan I, Wayne AS. Results from an International Phase 2 Study of the Anti-CD22 Immunotoxin Moxetumomab Pasudotox in Relapsed or Refractory Childhood B-Lineage Acute Lymphoblastic Leukemia. Pediatr Blood Cancer. 2020. 67(5):e28112.
- 63. Wong WH, Bhatt S, Trinkaus K, Pusic I, Elliott K, Mahajan N, Wan F, Switzer GE, Confer DL, DiPersio JF, Pulsipher MA, **Shah NN**, Sees J, Bystry A, Blundell J, Shaw BE, Druley TE: Engraftment of rare, pathogenic donor hematopoietic clones with mutations in unrelated hematopoietic stem cell transplantation. <u>Sci Transl Med</u>. 2020. 12 (256): eaax6249.
- 64. Wiener L, Hoag JA, Pelletier W, **Shah NN**, Shaw BE, Pulsipher MA, Bruce J, Bader P, Willasch AM, Dalissier A, Guilcher G, Anthias C, Confer DL, Sees JA, Logan B, Switzer GE: Transplant center practices for psychosocial assessment and management of pediatric hematopoietic stem cell donors. <u>Bone Marrow Transplant</u>, 2019. 54(11): 1780-1788.
- 65. Ramakrishna S, Highfill SL, Walsh Z, Nguyen SM, Lei H, Shern JF, Qin H, Kraft IL, Stetler-Stevenson M, Yuan CM, Hwang JD, Feng Y, Zhu Z, Dimitrov D, Shah NN, Fry TJ: Modulation of Target Antigen Density Improves CAR T-cell Functionality and Persistence. <u>Clin Cancer Res</u>, 2019. 25(17): 5329-5341
- 66. Prokopishyn NL, Logan BR, Kiefer DM, Sees JA, Chitphakdithai P, Ahmed IA, Anderlini PN, Beitinjaneh AM, Bredeson C, Cerny J, Chhabra S, Daly A, Diaz MA, Farhadfar N, Frangoul HA, Ganguly S, Gastineau DA, Gergis U, Hale GA, Hematti P, Kamble RT, Kasow KA, Lazarus HM, Liesveld JL, Murthy HS, Norkin M, Olsson RF, Papari M, Savani BN, Szer J, Waller EK, Wirk B, Yared JA, Pulsipher MA, Shah NN, Switzer GE, O'Donnell PV, Confer DL, Shaw BE: The Concentration of Total Nucleated Cells in Harvested Bone Marrow for Transplantation Has Decreased over Time. Biol Blood Marrow Transplant 25:1325-1330, 2019
- 67. Pillay BA, Avery DT, Smart JM, Cole T, Choo S, Chan D, Gray PE, Frith K, Mitchell R, Phan TG, Wong M, Campbell DE, Hsu P, Ziegler JB, Peake J, Alvaro F, Picard C, Bustamante J, Neven B, Cant AJ, Uzel G, Arkwright PD, Casanova JL, Su HC, Freeman AF, **Shah N**, Hickstein DD, Tangye SG, Ma CS: Hematopoietic stem cell transplant effectively rescues lymphocyte differentiation and function in DOCK8-deficient patients. <u>JCI Insight</u> 5, 2019
- 68. Panch SR, Srivastava SK, Elavia N, McManus A, Liu S, Jin P, Highfill SL, Li X, Dagur P, Kochenderfer JN, Fry TJ, Mackall CL, Lee D, **Shah NN**, Stroncek DF: Effect of Cryopreservation on Autologous Chimeric Antigen Receptor T Cell Characteristics. <u>Mol Ther</u> 27:1275-1285, 2019
- 69. Panch SR, Reddy OL, Li K, Bikkani T, Rao A, Yarlagadda S, Highfill S, Fowler D, Childs RW, Battiwalla M, Barrett J, Larochelle A, Mackall C, **Shah N**, Stroncek DF. Robust Selections of Various Hematopoieitc Cell Franctions on the CliniMACS Plus Instrument. <u>Clin Hematol Int</u>. 1 (3): 161-167, 2019.
- 70. Melendez-Munoz R, Marchalik R, Jerussi T, Dimitrova D, Nussenblatt V, Beri A, Rai K, Wilder JS, Barrett AJ, Battiwalla M, Childs RW, Fitzhugh CD, Fowler DH, Fry TJ, Gress RE, Hsieh MM, Ito S,

- Kang EM, Pavletic SZ, **Shah NN**, Tisdale JF, Gea-Banacloche J, Kanakry CG, Kanakry JA: Cytomegalovirus Infection Incidence and Risk Factors Across Diverse Hematopoietic Cell Transplantation Platforms Using a Standardized Monitoring and Treatment Approach: A Comprehensive Evaluation from a Single Institution. <u>Biol Blood Marrow Transplant</u> 25:577-586, 2019
- 71. Kansagra AJ, Frey NV, Bar M, Laetsch TW, Carpenter PA, Savani BN, Heslop HE, Bollard CM, Komanduri KV, Gastineau DA, Chabannon C, Perales MA, Hudecek M, Aljurf M, Andritsos L, Barrett JA, Bachanova V, Bonini C, Ghobadi A, Gill SI, Hill JA, Kenderian S, Kebriaei P, Nagler A, Maloney D, Liu HD, Shah NN, Kharfan-Dabaja MA, Shpall EJ, Mufti GJ, Johnston L, Jacoby E, Bazarbachi A, DiPersio JF, Pavletic SZ, Porter DL, Grupp SA, Sadelain M, Litzow MR, Mohty M, Hashmi SK: Clinical utilization of Chimeric Antigen Receptor T-cells (CAR-T) in B-cell acute lymphoblastic leukemia (ALL)-an expert opinion from the European Society for Blood and Marrow Transplantation (EBMT) and the American Society for Blood and Marrow Transplantation (ASBMT). Bone Marrow Transplant, 2019
- 72. Kansagra AJ, Frey NV, Bar M, Laetsch TW, Carpenter PA, Savani BN, Heslop HE, Bollard CM, Komanduri KV, Gastineau DA, Chabannon C, Perales MA, Hudecek M, Aljurf M, Andritsos L, Barrett JA, Bachanova V, Bonini C, Ghobadi A, Gill SI, Hill J, Kenderian S, Kebriaei P, Nagler A, Maloney D, Liu HD, Shah NN, Kharfan-Dabaja MA, Shpall EJ, Mufti GJ, Johnston L, Jacoby E, Bazarbachi A, DiPersio JF, Pavletic SZ, Porter DL, Grupp SA, Sadelain M, Litzow MR, Mohty M, Hashmi SK: Clinical Utilization of Chimeric Antigen Receptor T Cells in B Cell Acute Lymphoblastic Leukemia: An Expert Opinion from the European Society for Blood and Marrow Transplantation and the American Society for Blood and Marrow Transplant 25:e76-e85, 2019
- 73. Dimitrova D, Gea-Banacloche J, Steinberg SM, Sadler JL, Hicks SN, Carroll E, Wilder JS, Parta M, Skeffington L, Hughes TE, Blau JE, Broadney MM, Rose JJ, Hsu AP, Fletcher R, Nunes NS, Yan XY, Telford WG, Kapoor V, Cohen JI, Freeman AF, Garabedian E, Holland SM, Lisco A, Malech HL, Notarangelo LD, Sereti I, **Shah NN**, Uzel G, Zerbe CS, Fowler DH, Gress RE, Kanakry CG, Kanakry JA: Prospective Study of a Novel, Radiation-Free, Reduced-Intensity Bone Marrow Transplantation Platform for Primary Immunodeficiency Diseases. Biol Blood Marrow Transplant, 2019
- 74. Wiener L, Childs RW, **Shah NN**. Pilot Study of Educational Interventions for Pediatric Hematopoietic Stem Cell Sibling Donors to Increase Knowledge of Donation and Transplantation Procedures. J Psychosoc Oncol Res Pract. 2019; 1(1): 1-5.
- 75. Cuviello A, Boss R, **Shah N**, Battles H, Beri A, Wiener L: Utilization of palliative care consultations in pediatric oncology phase I clinical trials. <u>Pediatr Blood Cancer</u> 66:e27771, 2019
- 76. Cole K, Avila D, Parta M, Schuver B, Holland S, **Shah N**, Hickstein D: GATA2 Deficiency: Early Identification for Improved Clinical Outcomes. Clin J Oncol Nurs 23:417-422, 2019
- 77. Buchbinder D, Kirov I, Danielson J, **Shah NN**, Freeman AF, Chavan RS, Su HC: Compound Heterozygous DOCK8 Mutations in a Patient with B Lymphoblastic Leukemia and EBV-Associated Diffuse Large B Cell Lymphoma. J Clin Immunol 39:592-595, 2019
- 78. Bhojwani D, Sposto R, **Shah NN**, Rodriguez V, Yuan C, Stetler-Stevenson M, O'Brien MM, McNeer JL, Quereshi A, Cabannes A, Schlegel P, Rossig C, Dalla-Pozza L, August K, Alexander S, Bourquin JP, Zwaan M, Raetz EA, Loh ML, Rheingold SR: Inotuzumab ozogamicin in pediatric patients with relapsed/refractory acute lymphoblastic leukemia. <u>Leukemia</u> 33:884-892, 2019
- 79. Bader P, Salzmann-Manrique E, Balduzzi A, Dalle J, Woolfrey AE, Bar M, Verneris MR, Borowitz MJ, **Shah NN**, Gossai N, Shaw PJ, Chen AR, Schultz KR, Kreyenberg H, Di Maio L, Cazzaniga G, Eckert C, van der Velden V, Sutton R, Lankester A, Peters C, Klingebiel T, Willasch AM, Grupp SA, Pulsipher MA: More Precisely Defining Risk Peri-HCT in Pediatric ALL: Pre- vs Post MRD measures, Serial Positivity, and Risk Modeling. <u>Blood Advances</u> 2019. 3 (21): 3393-3405
- 80. Aydin SE, Freeman AF, Al-Herz W, Al-Mousa HA, Arnaout RK, Aydin RC, Barlogis V, Belohradsky BH, Bonfim C, Bredius RG, Chu JI, Ciocarlie OC, Dogu F, Gaspar HB, Geha RS, Gennery AR, Hauck F, Hawwari A, Hickstein DD, Hoenig M, Ikinciogullari A, Klein C, Kumar A, Ifversen MRS, Matthes

- S, Metin A, Neven B, Pai SY, Parikh SH, Picard C, Renner ED, Sanal O, Schulz AS, Schuster F, **Shah NN**, Shereck EB, Slatter MA, Su HC, van Montfrans J, Woessmann W, Ziegler JB, Albert MH, Inborn Errors Working Party of the European Group for B, Marrow T, the European Society for Primary I: Hematopoietic Stem Cell Transplantation as Treatment for Patients with DOCK8 Deficiency. <u>J Allergy Clin Immunol Pract</u> 7:848-855, 2019
- 81. Xiao W, Salem D, McCoy CS, Lee D, **Shah NN**, Stetler-Stevenson M, Yuan CM: Early recovery of circulating immature B cells in B-lymphoblastic leukemia patients after CD19 targeted CAR T cell therapy: A pitfall for minimal residual disease detection. Cytometry B Clin Cytom 94:434-443, 2018
- 82. Stroncek DF, Logan BR, Kiefer DM, Savani BN, Anderlini P, Bredeson CN, Hematti P, Ganguly S, Diaz MA, Abdel-Azim H, Ahmed I, Maharaj D, Seftel M, Beitinjaneh A, Seo S, Yared JA, Halter J, O'Donnell PV, Hale GA, DeFilipp Z, Lazarus H, Liesveld JL, Zhou Z, Munshi P, Olsson RF, Kasow KA, Szer J, Switzer GE, Chitphakdithai P, **Shah N**, Confer DL, Pulsipher MA: Donor Experiences of Second Marrow or Peripheral Blood Stem Cell Collection Mirror the First, but CD34(+) Yields Are Less. Biol Blood Marrow Transplant 24:175-184, 2018
- 83. Shalabi H, Wolters PL, Martin S, Toledo-Tamula MA, Roderick MC, Struemph K, Kane E, Yates B, Delbrook C, Mackall CL, Lee DW, Fry TJ, **Shah NN**: Systematic Evaluation of Neurotoxicity in Children and Young Adults Undergoing CD22 Chimeric Antigen Receptor T-Cell Therapy. <u>J</u> Immunother 41:350-358, 2018
- 84. Shalabi H, Kraft IL, Wang HW, Yuan CM, Yates B, Delbrook C, Zimbelman JD, Giller R, Stetler-Stevenson M, Jaffe ES, Lee DW, Shern JF, Fry TJ, **Shah NN**: Sequential loss of tumor surface antigens following chimeric antigen receptor T-cell therapies in diffuse large B-cell lymphoma. <u>Haematologica</u> 103:e215-e218, 2018
- 85. Qin H, Ramakrishna S, Nguyen S, Fountaine TJ, Ponduri A, Stetler-Stevenson M, Yuan CM, Haso W, Shern JF, **Shah NN**, Fry TJ: Preclinical Development of Bivalent Chimeric Antigen Receptors Targeting Both CD19 and CD22. Mol Ther Oncolytics 11:127-137, 2018
- 86. Qin H, Ishii K, Nguyen S, Su PP, Burk CR, Kim BH, Duncan BB, Tarun S, **Shah NN**, Kohler ME, Fry TJ: Murine pre-B-cell ALL induces T-cell dysfunction not fully reversed by introduction of a chimeric antigen receptor. <u>Blood</u> 132:1899-1910, 2018
- 87. Parta M, Shah NN, Baird K, Rafei H, Calvo KR, Hughes T, Cole K, Kenyon M, Schuver BB, Cuellar-Rodriguez J, Zerbe CS, Holland SM, Hickstein DD: Allogeneic Hematopoietic Stem Cell Transplantation for GATA2 Deficiency Using a Busulfan-Based Regimen. <u>Biol Blood Marrow Transplant</u> 24:1250-1259, 2018
- 88. Fry TJ, **Shah NN**, Orentas RJ, Stetler-Stevenson M, Yuan CM, Ramakrishna S, Wolters P, Martin S, Delbrook C, Yates B, Shalabi H, Fountaine TJ, Shern JF, Majzner RG, Stroncek DF, Sabatino M, Feng Y, Dimitrov DS, Zhang L, Nguyen S, Qin H, Dropulic B, Lee DW, Mackall CL: CD22-targeted CAR T cells induce remission in B-ALL that is naive or resistant to CD19-targeted CAR immunotherapy. Nat Med 24:20-28, 2018
- 89. Cornetta K, Duffy L, Feldman SA, Mackall CL, Davila ML, Curran KJ, Junghans RP, Tang JY, Kochenderfer JN, O'Cearbhaill R, Archer G, Kiem HP, **Shah NN**, Delbrook C, Kaplan R, Brentjens RJ, Riviere I, Sadelain M, Rosenberg SA: Screening Clinical Cell Products for Replication Competent Retrovirus: The National Gene Vector Biorepository Experience. Mol Ther Methods Clin Dev 10:371-378, 2018
- Brooks KM, Jarosinski P, Hughes T, Kang E, Shah NN, Gall JBL, Hickstein DD, De Ravin SS, George JM, Kumar P: Test Dose Pharmacokinetics in Pediatric Patients Receiving Once-Daily IV Busulfan Conditioning for Hematopoietic Stem Cell Transplant: A Reliable Approach? <u>J Clin Pharmacol</u> 58:332-339, 2018
- 91. Wayne AS, **Shah NN**, Bhojwani D, Silverman LB, Whitlock JA, Stetler-Stevenson M, Sun W, Liang M, Yang J, Kreitman RJ, Lanasa MC, Pastan I: Phase 1 study of the anti-CD22 immunotoxin moxetumomab pasudotox for childhood acute lymphoblastic leukemia. <u>Blood</u> 130:1620-1627, 2017

- 92. Stroncek DF, Lee DW, Ren J, Sabatino M, Highfill S, Khuu H, **Shah NN**, Kaplan RN, Fry TJ, Mackall CL: Elutriated lymphocytes for manufacturing chimeric antigen receptor T cells. <u>J Transl Med</u> 15:59, 2017
- 93. **Shah NN**, Watson TM, Yates B, Liewehr DJ, Steinberg SM, Jacobsohn D, Fry TJ: Procalcitonin and cytokine profiles in engraftment syndrome in pediatric stem cell transplantation. <u>Pediatr Blood Cancer</u> 64, 2017
- 94. **Shah NN**, Parta M, Baird K, Rafei H, Cole K, Holland SM, Hickstein DD: Monozygotic twins with GATA2 deficiency: same haploidentical-related donor, different severity of GvHD. <u>Bone Marrow Transplant</u> 52:1580-1582, 2017
- 95. **Shah NN**, Freeman AF, Su H, Cole K, Parta M, Moutsopoulos NM, Baris S, Karakoc-Aydiner E, Hughes TE, Kong HH, Holland SM, Hickstein DD: Haploidentical Related Donor Hematopoietic Stem Cell Transplantation for Dedicator-of-Cytokinesis 8 Deficiency Using Post-Transplantation Cyclophosphamide. Biol Blood Marrow Transplant 23:980-990, 2017;
  - a. Addendum: Shah NN, Freeman AF, Hickstein DD; Haploidentical Related Donor Hematopoietic Stem Cell Transplantation for DOCK8 Deficiency Using Post-Transplantation Cyclophosphamide. <u>Biol Blood Marrow Transplant</u> 25:e65-e67, 2019
- 96. Nunes AT, Jain P, Kleiner DE, **Shah NN**, Anandi P, Chinian F, Muranski P, Battiwalla M, Barrett AJ, Ito S: High angiopoietin-2 and suppression of tumorigenicity-2 levels correlate with onset of sinusoidal obstructive syndrome-implication for the utility of serial biomarker monitoring. <u>Bone Marrow</u> Transplant 52:926-928, 2017
- 97. Bitan M, Ahn KW, Millard HR, Pulsipher MA, Abdel-Azim H, Auletta JJ, Brown V, Chan KW, Diaz MA, Dietz A, Vincent MG, Guilcher G, Hale GA, Hayashi RJ, Keating A, Mehta P, Myers K, Page K, Prestidge T, **Shah NN**, Smith AR, Woolfrey A, Thiel E, Davies SM, Eapen M: Personalized Prognostic Risk Score for Long-Term Survival for Children with Acute Leukemia after Allogeneic Transplantation. Biol Blood Marrow Transplant 23:1523-1530, 2017
- 98. Wendler D, **Shah NN**, Pulsipher MA, Fry T, Grady C: Research involving pediatric stem cell donors: A way forward. Clin Trials 13:304-10, 2016
- 99. **Shah NN**, Merchant MS, Cole DE, Jayaprakash N, Bernstein D, Delbrook C, Richards K, Widemann BC, Wayne AS: Vincristine Sulfate Liposomes Injection (VSLI, Marqibo(R)): Results From a Phase I Study in Children, Adolescents, and Young Adults With Refractory Solid Tumors or Leukemias. Pediatr Blood Cancer 63:997-1005, 2016
- 100. **Shah NN**, Loeb DM, Khuu H, Stroncek D, Ariyo T, Raffeld M, Delbrook C, Mackall CL, Wayne AS, Fry TJ: Induction of Immune Response after Allogeneic Wilms' Tumor 1 Dendritic Cell Vaccination and Donor Lymphocyte Infusion in Patients with Hematologic Malignancies and Post-Transplantation Relapse. <u>Biol Blood Marrow Transplant</u> 22:2149-2154, 2016
- 101. **Shah NN**, Cole DE, Lester-McCully CM, Wayne AS, Warren KE, Widemann BC: Plasma and cerebrospinal fluid pharmacokinetics of vincristine and vincristine sulfate liposomes injection (VSLI, margibo(R)) after intravenous administration in Non-human primates. Invest New Drugs 34:61-5, 2016
- 102. Happel CS, Stone KD, Freeman AF, **Shah NN**, Wang A, Lyons JJ, Guerrerio PA, Hickstein DD, Su HC: Food allergies can persist after myeloablative hematopoietic stem cell transplantation in dedicator of cytokinesis 8-deficient patients. <u>J Allergy Clin Immunol</u> 137:1895-1898 e5, 2016
- 103. Freeman AF, Shah NN, Parta M, Su HC, Brofferio A, Gradus-Pizlo I, Butty S, Hughes TE, Kleiner DE, Avila D, Heller T, Kong HH, Holland SM, Hickstein DD: Haploidentical related donor hematopoietic stem cell transplantation with post-transplantation cyclophosphamide for DOCK8 deficiency. J Allergy Clin Immunol Pract 4:1239-1242 e1, 2016
- 104. Anthias C, Shaw BE, Kiefer DM, Liesveld JL, Yared J, Kamble RT, D'Souza A, Hematti P, Seftel MD, Norkin M, DeFilipp Z, Kasow KA, Abidi MH, Savani BN, Shah NN, Anderlini P, Diaz MA, Malone AK, Halter JP, Lazarus HM, Logan BR, Switzer GE, Pulsipher MA, Confer DL, O'Donnell PV: Significant Improvements in the Practice Patterns of Adult Related Donor Care in US Transplantation Centers. <u>Biol Blood Marrow Transplant</u> 22:520-7, 2016

- 105. **Shah N**N, Wayne AS, Grady C, Fry T, Wendler D: Children as hematopoietic cell donors in research: when is it approvable? <u>Bone Marrow Transplant</u> 50:15-9, 2015
- 106. Shah NN, Stevenson MS, Yuan CM, Richards K, Delbrook C, Kreitman RJ, Pastan I, Wayne AS: Characterization of CD22 expression in acute lymphoblastic leukemia. <u>Pediatr Blood Cancer</u> 62:964-9, 2015
- 107. Shah NN, Baird K, Delbrook CP, Fleisher TA, Kohler ME, Rampertaap S, Lemberg K, Hurley CK, Kleiner DE, Merchant MS, Pittaluga S, Sabatino M, Stroncek DF, Wayne AS, Zhang H, Fry TJ, Mackall CL: Acute GVHD in patients receiving IL-15/4-1BBL activated NK cells following T-cell-depleted stem cell transplantation. Blood 125:784-92, 2015
- 108. Lee DW, Kochenderfer JN, Stetler-Stevenson M, Cui YK, Delbrook C, Feldman SA, Fry TJ, Orentas R, Sabatino M, Shah NN, Steinberg SM, Stroncek D, Tschernia N, Yuan C, Zhang H, Zhang L, Rosenberg SA, Wayne AS, Mackall CL: T cells expressing CD19 chimeric antigen receptors for acute lymphoblastic leukaemia in children and young adults: a phase 1 dose-escalation trial. <u>Lancet</u> 385:517-528, 2015
- 109. Inamoto Y, Shah NN, Savani BN, Shaw BE, Abraham AA, Ahmed IA, Akpek G, Atsuta Y, Baker KS, Basak GW, Bitan M, DeFilipp Z, Gregory TK, Greinix HT, Hamadani M, Hamilton BK, Hayashi RJ, Jacobsohn DA, Kamble RT, Kasow KA, Khera N, Lazarus HM, Malone AK, Lupo-Stanghellini MT, Margossian SP, Muffly LS, Norkin M, Ramanathan M, Salooja N, Schoemans H, Wingard JR, Wirk B, Wood WA, Yong A, Duncan CN, Flowers ME, Majhail NS: Secondary solid cancer screening following hematopoietic cell transplantation. Bone Marrow Transplant 50:1013-23, 2015
- 110. Cuellar-Rodriguez J, Freeman AF, Grossman J, Su H, Parta M, Murdock H, Shah N, Bollard C, Kong HH, Moutsopoulos N, Stone K, Gea-Banacloche J, Holland SM, Hickstein DD: Matched related and unrelated donor hematopoietic stem cell transplantation for DOCK8 deficiency. <u>Biol Blood</u> Marrow Transplant 21:1037-45, 2015
- 111. Burke MJ, Verneris MR, Le Rademacher J, He W, Abdel-Azim H, Abraham AA, Auletta JJ, Ayas M, Brown VI, Cairo MS, Chan KW, Diaz Perez MA, Dvorak CC, Egeler RM, Eldjerou L, Frangoul H, Guilcher GMT, Hayashi RJ, Ibrahim A, Kasow KA, Leung WH, Olsson RF, Pulsipher MA, Shah N, Shah NN, Thiel E, Talano JA, Kitko CL: Transplant Outcomes for Children with T Cell Acute Lymphoblastic Leukemia in Second Remission: A Report from the Center for International Blood and Marrow Transplant Research. Biol Blood Marrow Transplant 21:2154-2159, 2015
- 112. **Shah NN**, Borowitz MJ, Steinberg SM, Robey NC, Gamper CJ, Symons HJ, Loeb DM, Wayne AS, Chen AR: Factors predictive of relapse of acute leukemia in children after allogeneic hematopoietic cell transplantation. Biol Blood Marrow Transplant 20:1033-9, 2014
- 113. **Shah NN**, Borowitz MJ, Robey NC, Gamper CJ, Symons HJ, Loeb DM, Wayne AS, Chen AR: Feasibility of treating post-transplantation minimal residual disease in children with acute leukemia. Biol Blood Marrow Transplant 20:1000-7, 2014
- 114. Li X, Brazauskas R, Wang Z, Al-Seraihy A, Baker KS, Cahn JY, Frangoul HA, Gajewski JL, Hale GA, Hsu JW, Kamble RT, Lazarus HM, Marks DI, Maziarz RT, Savani BN, Shah AJ, Shah N, Sorror ML, Wood WA, Majhail NS: Avascular necrosis of bone after allogeneic hematopoietic cell transplantation in children and adolescents. Biol Blood Marrow Transplant 20:587-92, 2014
- 115. Bitan M, He W, Zhang MJ, Abdel-Azim H, Ayas MF, Bielorai B, Carpenter PA, Cairo MS, Diaz MA, Horan JT, Jodele S, Kitko CL, Schultz KR, Kletzel M, Kasow KA, Lehmann LE, Mehta PA, Shah N, Pulsipher MA, Prestidge T, Seber A, Shenoy S, Woolfrey AE, Yu LC, Davies SM: Transplantation for children with acute myeloid leukemia: a comparison of outcomes with reduced intensity and myeloablative regimens. <u>Blood</u> 123:1615-20, 2014
- 116. Haso W, Lee DW, **Shah NN**, Stetler-Stevenson M, Yuan CM, Pastan IH, Dimitrov DS, Morgan RA, FitzGerald DJ, Barrett DM, Wayne AS, Mackall CL, Orentas RJ: Anti-CD22-chimeric antigen receptors targeting B-cell precursor acute lymphoblastic leukemia. <u>Blood</u> 121:1165-74, 2013
- 117. **Shah NN**, Bacher U, Fry T, Calvo KR, Stetler-Stevenson M, Arthur DC, Kurlander R, Baird K, Wise B, Giralt S, Bishop M, Hardy NM, Wayne AS: Myelodysplastic syndrome after allogeneic

- hematopoietic stem cell transplantation: diagnostic and therapeutic challenges. <u>Am J Hematol</u> 87:916-22, 2012
- 118. Corey KE, **Shah N**, Misdraji J, Abu Dayyeh BK, Zheng H, Bhan AK, Chung RT: The effect of angiotensin-blocking agents on liver fibrosis in patients with hepatitis C. <u>Liver Int</u> 29:748-53, 2009
- 119. Rodriguez-Galindo C, **Shah N**, McCarville MB, Billups CA, Neel MN, Rao BN, Daw NC: Outcome after local recurrence of osteosarcoma: the St. Jude Children's Research Hospital experience (1970-2000). Cancer 100:1928-35, 2004
- 120. Rodriguez-Galindo C, Wilson MW, Haik BG, Merchant TE, Billups CA, **Shah N**, Cain A, Langston J, Lipson M, Kun LE, Pratt CB: Treatment of intraocular retinoblastoma with vincristine and carboplatin. <u>J Clin Oncol</u> 21:2019-25, 2003

### Peer Reviewed Case Reports/Series:

- 121. Porter TJ, Lazarevic A, Ziggas JE, Fuchs E, Kim K, Byrnes H, Luznik L, Bolanos-Meade J, Ali SA **Shah NN**, Wagner-Johnston N, Jain T. Delayed Hyperinflammatory Syndrome Resembling Hemophagocytic Lymphohistiocytosis Following Axicabtagene ciloleucel and Brexucabtagene autoleucel. British Journal of Haematology. 2022. 199 (5): 720-727
- 122. Holland EM, Gonzalez C, Levy E, Valera VA, Chalfin H, Klick-Skeels J, Yates B, Kleiner DE, Hadigan C, Dave H, Shalabi H, Hickstein DD, Su HC, Grimley M, Freeman AF, Shah NN. Fatal complications of BK virus-hemorrhagic cystits and severe cytokine release syndrome following BK virus-specific T-cells. Frontiers in Immunology. 2021. 12:801281
- 123. Masih KE, Ligon JA, Yates B, Shalabi H, Little L, Islam Z, Ombrello AK, Inglefield J, Nussenblatt V, Manion M, Khan J, **Shah NN**. Consequences of hemophagocytic lympohistiocytosis-like cytokine release syndrome toxicities and concurrent bactermia. <u>Pediatric Blood and Cancer</u>. 2021 ePub ahead of print.
- 124. Yates B, Molloy E, Dulau-Florea A, Braylan R, Hogan L, Hickstein DD, Freeman AF, Kalsi SS, **Shah NN**. Daratumumab for delayed RBC engraftment following major ABO mismatched haploidentical bone marrow transplantation. Transfusion. 2021. Epub ahead of print.
- 125. Molina J, Asare JM, Tuschong L, West RR, Calvo KR, Persky R, Boyce AM, Hammoud DA, Holland SM, Hickstein D, **Shah NN**. Venetoclax/decitabine for a pediatric patient with chronic myelomonocytic leukemia. <u>Pediatr Blood Cancer</u>. 2021. 68 (3): e28865
- 126. **Shah NN**., Schneiderman J, Kuruvilla D, Bhojwani D, Fry TJ, Martin PL, Schultz KR, Silverman LB, Whitlock JA, Wood B, Vainshtein I, Adams A, Confer D, Pulsipher MA, Chaudhury S, Wayne AS. Fatal capillary leak syndrome in a child with acute lymphoblastic leukemia treated with moxetumomab pasudotox for pre-transplant minimal residual disease reduction. <a href="Pediatric Blood and Cancer">Pediatric Blood and Cancer</a>. 2021. 68(1):e28574.
- 127. Good M., Malekzadeh P, Kriley IR, **Shah NN**, Kleiner DE, Calvo K, Hernandez JM, Davis JL. Intrahepatic cholangiocarcinoma as a rare secondary malignancy after allogeneic hematopoietic stem cell transplantation for childhood acute lymphoblastic leukemia: a case report. Pediatr Transplant. 2020, 24(2):e13653
- 128. Shalabi H, Koegel A, Ponduri A, Qin H, Salem D, Stetler-Stevenson M, Yuan C, Yates B, Delbrook C, Loh ML, Fry TJ, **Shah NN**: Case Report: Impact of BITE on CAR T-Cell Expansion. <u>Advances in Cell and Gene Therapy</u>, 2019
- 129. **Shah NN**, Qin H, Yates B, Su L, Shalabi H, Raffeld M, Ahlman MA, Stetler-Stevenson M, Yuan C, Guo S, Liu S, Hughes SH, Fry TJ, Wu X: Clonal expansion of CAR T cells harboring lentivector integration in the CBL gene following anti-CD22 CAR T-cell therapy. <u>Blood Adv</u> 3:2317-2322, 2019
- 130. Freeman AF, Yazigi N, Shah NN, Kleiner DE, Parta M, Atkinson P, Heller T, Holland SM, Kaufman SS, Khan KM, Hickstein DD: Tandem Orthotopic Living Donor Liver Transplantation Followed by Same Donor Haploidentical Hematopoietic Stem Cell Transplantation for DOCK8 Deficiency: Tandem Liver and Bone Marrow Transplant in DOCK8 Deficiency. <u>Transplantation</u>, 2019

- 131. Ligon JA, Natarajan M, Shalabi H, Yates B, Bishop R, Bianchi D, Alencar A, Lionakis MS, **Shah NN**: Invasive fusariosis masquerading as extramedullary disease in rapidly progressive acute lymphoblastic leukemia. Pediatr Blood Cancer 66:e27732, 2019
- 132. Dimitriades VR, Devlin V, Pittaluga S, Su HC, Holland SM, Wilson W, Dunleavy K, **Shah NN**, Freeman AF: DOCK 8 Deficiency, EBV+ Lymphomatoid Granulomatosis, and Intrafamilial Variation in Presentation. Front Pediatr 5:38, 2017
- 133. **Shah NN**, Price MR, Loeb DM: Cardiac metastasis and hypertrophic osteoarthropathy in recurrent infantile fibrosarcoma. Pediatr Blood Cancer 59:179-81, 2012
- 134. Yachimski P, Shah N, Chung RT: Porphyria cutanea tarda. Clin Gastroenterol Hepatol 5:e6, 2007

### Peer-Reviewed Review Manuscripts:

- 135. Rejeski K, Jain MD, **Shah NN**, Perales MA, Subklewe M. Immune effector cell-associated hematotoxicity after CAR T-cell therapy: from mechanism to management. Lancet Haematology. 2024 (In press)
- 136. Epperly R, **Shah NN**. Long-term follow-up of CD19 CAR T-cell therapy in children and young adults with B-ALL. <u>The Hematologist</u>. 2023 (In press)
- 137. Sureda A, Luugtenburg PJ, Kersten MJ, Subklewe M, Spanjaart A, **Shah NN**, Kerbauy LN, Roddie C, Pennings ERA, Mahuad C, Poon M, Hendricks CL, Kamdar M, Jacobson CA. Cellular Therapy in Lymphoma. <u>Hematological Oncology</u>. 2023 (Online ahead of print)
- 138. Epperly R, Giordani VM, Mikkilineni L, Shah NN. Early and Late Toxicities of Chimeric Antigen Receptor T-cells. Hematol Oncol Clin North Am. 2023. S0889-8588 (23). Online ahead of print.
- 139. Jain M, Smith M, **Shah NN**. How I Treat Refractory CRS and ICANS following CAR T-cell therapy. Blood. 2023. 141(20): 2430-2442.
- 140. Verma A, Lupo PJ, **Shah NN**, Hitzler J, Rabin KR. Management of Down syndrome associated leukemia--a review. <u>JAMA Oncology</u>. (Online ahead of print)
- 141. Myers RM, **Shah NN**,\* Pulsipher MA. How I Use Risk Factors for Success or Failure of CD19 CAR T-ells to Guide Management of Children, Adolescents and Young Adults with B-cell ALL. <u>Blood</u> 2023. 141 (11): 1251-1264. (\*co-first author)
- 142. Gustafson M, Ligon L, Bersenev A, McCann CD, **Shah NN**, Hanley PJ. Emerging Frontiers in Immuno and Gene Therapy for Cancer. Cytotherapy. 2023. 25 (1): 20-32.
- 143. Schroeder BA, Jess J, Sankaran H, **Shah NN**. Clinical Trials for Chimeric Antigen Receptor T-cell Therapy: Lessons Learned and Future Directions. <u>Current Opinion in Hematology</u>. 2022. 29 (4): 225-232.
- 144. Amini L, Silbert SK, Maude SL, Nastoupil LJ, Ramos CR, Brentjens RJ, Sauter CS, **Shah NN**, Abou-el-Enein. Preparing for CAR T-cells: patient selection, bridging therapies and lymphodepletion. Nature Reviews Clinical Oncology. 2022. 19 (5): 342-355.
- 145. Ligon J, Wessel KM, Shah NN, Glod J. Adoptive Cell Therapy in Pediatric and Young Adult Solid Tumors: Current Status and Future Directions. Frontiers in Immunology. 2022. 13:846346
- 146. Shalabi H, Nellan A, Shah NN, Gust J. Immunotherapy associated Neurotoxciity in Pediatric Oncology. <u>Frontiers in Oncology</u>. 2022. 12:836452
- 147. Qayed M, Bleakley M, **Shah NN**. Role of Chimeric Antigen Receptor T-Cell Therapy: Bridge to Transplantation or Stand-Alone Therapy in Pediatric Acute Lymphoblastic Leukemia. <u>Current Opinion in Hematology</u>. 2021. 137 (7): 983-993.
- 148. Wagner DL, Fritsche E, Pulsipher MA, Ahmed N, Hamieh M, Hegde M, Ruella M, Savoldo B, **Shah NN**, Turtle CJ, Wayne AS, Abou-el-Enein M. Immunogenicity of CAR T cells in cancer therapy. Nat Rev Clin Oncol. 2021. 18 (6): 379-393.
- 149. Shalabi H, Gust J, Taraseviciute A, Wolters PL, Leahy AB, Sandi C, Laetsch TW, Wiener L, Gardner RA, Nussenblatt V, Hill JA, Curran KJ, Olson TS, Annesley C, Wang HW, Khan J, Pasquini

- MC, Duncan CN, Grupp SA, Pulsipher MA, **Shah NN**. Beyond the storm- subacute toxicities and late effects in children receiving CAR T cells. <u>Nat Rev Clin Oncol</u>. 2021. 18 (6): 363-378.
- 150. Marple AH, Bonifant CL, **Shah NN**. Improving CAR T-cells: The next generation. Semin Hematol. 2020. 57 (3): 115-121.
- 151. Pierce SK, Schwartzberg PL, **Shah NN**, Taylor N. Woman in Immunology: 2020 and beyond. <u>Nat</u> Immunol. 2020 Mar;21(3):254-258.
- 152. **Shah NN**, Fry TJ: Mechanisms of resistance to CAR T cell therapy. Nat Rev Clin Oncol 16:372-385, 2019.
- 153. Jacoby E, Shahani SA, **Shah NN**. Updates on CAR T-cell therapy in B-cell malignancies. <u>Immunol Rev</u>. 2019;290(1):39-59.
- 154. Shah NN: Antibody Based Therapies in Acute Leukemia. Curr Drug Targets 18:257-270, 2017
- 155. Shah NN, Dave H, Wayne AS: Immunotherapy for pediatric leukemia. Front Oncol 3:166, 2013

#### **Invited Commentaries:**

- 156. Gardner RA, **Shah NN**. CAR T-cells for Cure in Pediatric B-ALL. Journal of Clinical Oncology, 2023. 41 (9): 1646-1648.
- 157. Shalabi H, **Shah NN**. CD19 CAR T-cells for Infants and Young Children. Lancet Haematology. 2022. 9 (10): e712-e714.
- 158. **Shah NN**, Pai SY. Current Status and Future Directions of Gene-Based Therapy for Pediatric Diseases. <u>Hematol Oncol Clin North Am</u>. 2022. 36 (4).
- 159. Benzaoui M, Taylor N, **Shah NN**. A SNIPpet of Safety: A Goldilocks approach to modulating CAR T-cell efficacy and toxicity. <u>Cell Research</u>. 2022. 32 (7): 603-604.
- 160. Mirazee J, **Shah NN**. CD70 CAR T-cells in AML—Form follows Function. <u>Cell Reports Medicine</u>. 2022. 3 (5): 100639
- 161. Shah NN, Fry TJ. The CD19<sup>neg</sup> Needle in the Haystack. Blood. 2022. 140 (1): 4-6
- 162. Holtzman NG, **Shah NN**. CAR T-cell therapy for indolent lymphoma: a new treatment paradigm? Lancent Oncology. 2021. 23 (1): 6-8.
- 163. Athale J, **Shah NN.** Surviving the Storm: Critical Care Outcomes of CAR T-cell Therapy. Lancet Hameatology. 2021. 8 (5): e311-e312.
- 164. Molina JC, Shah NN. CAR T cells better than BiTEs. Blood Adv. 2021. 5(2): 602-606.
- 165. Ramakrishna S, **Shah NN**. Using single-cell analysis to predict CAR T cell outcomes. Nat Med. 2020. 26 (12): 1813-1814.
- 166. Hawkins C, Pfister SM, Jones DT, Shah NN, Gilbertson RJ, Sweet-Cordero EA, Dyer MA, Mosse YP, Haber M, DuBois SG. Advances and Challenges in Pediatric and Childhood Cancers. <u>Cancer Cell</u>. 2020. 38 (4): 429-432.
- 167. **Shah NN**. The One-Two Punch (of CAR T-Cells). <u>Blood</u> 2020. 135(5): 303-304.
- 168. **Shah NN**, Fry TJ. *CD19 Negativity "Stems" From Hematopoietic Progenitors*. <u>Blood</u> 2017 Nov 2;130(18):1961-1963.
- 169. Shah NN, Waldmann T. Inside Blood: GVL for ATL? Invited commentary. Blood 2013;121(1):6-

#### Journal Series Editor

1. Pai S-YP and Shah NN. Hematology/Oncology Clinics of North America. Special series editor, section, "Gene-Based therapies for Pediatric Blood Diseases."

#### Book Editor:

1. Lee DW and **Shah NN**. Chimeric Antigen Receptor T-Cell Therapies for Cancer: A Practical Guide. First Edition, Elsevier, 2020

# **Book Chapter Contributions:**

1. Shah NN, Goff S. Cancer: Principles & Practice of Oncology, 12<sup>th</sup> edition. "Immunotherapy Agents: Cellular Therapies." Lippincott Williams & Wilkins/Wolters Kluwer Health. 2022.

- 2. Shalabi H, **Shah NN**. "Relapse Management and Role for Consolidative Hematopoietic Stem Cell Transplantation Following CAR T-Cell Therapy." Chimeric Antigen Receptor T-Cell Therapies for Cancer: A Practical Guide. First Edition. Lee DW and Shah NN (eds), Elsevier, 2020.
- 3. Molina JC, **Shah NN**. Monoclonal antibody-based treatment and other new agents for B-lineage ALL. Acute lymphoblastic leukemia: Translational science and clinical management for children and adults from the bench to the bedside. Springer. 2020. In Press.
- 4. Shalabi H, Khuu H, Fry TJ, **Shah NN**. "Cell-Based Therapies: A New Frontier of Personalized Medicine." Early Phase Trial Designs for Targeted Cancer Therapeutics. Academic Press. 2018
- 5. **Shah NN**, Wayne AS, Wilson WH: Burkitt's and Lymphoblastic Lymphomas; in <u>Lymphomas</u>: Pathology, Diagnosis, and Treatment, 2<sup>nd</sup> Edition, Marcus R, Sweetenham JW, Williams ME (eds), Cambridge University Press, Cambridge, UK, 2013
- 6. **Shah NN**, Wayne AS. Acute Lymphoblastic Leukemia; in Bethesda Handbook of Clinical Hematology, Third Edition. Rodgers GP and Young NS (eds), Philadelphia: Lippincott, Williams & Wilkins 2012
- 7. **Shah, N**. Hematology. Prasad, P. <u>Pocket Pediatrics</u>. Philadelphia: Lippincott, Williams & Wilkins 2010.
- 8. **Shah NN**, Wayne AS. Leukemias and Lymphomas; in Quick Reference for Pediatric Oncology Clinicians: The Psychiatric and Psychological Dimensions of Pediatric Cancer Symptom Management, American Psychosocial Oncology Society. Second Edition. Wiener LS and Pao M (eds). Charlottesville, VA: IPOS Press; 2009

# Conference Proceedings Articles (Chair or served on committee):

- 1. INSPIRED Meeting Series:
  - Schultz L, Jacoby E, Lamble AJ, Maude SL, McNerney KO, Moskop A, Myers RM, Pulsipher MA, Shah NN. Intorduction to the Reports from the Insights in Pediatric CAR T-cell Immunotherapy: Recent Advances and future directions (INSPIRED) symposium. <u>Transplant Cell Ther</u>. 2023 (Online ahead of print)
  - 2. Myers RM, Jacoby E, Pulsipher MA, Pasquini MC, Grupp SA, **Shah NN**, Laetsch TW, Curran KJ, Schultz LM. INSPIRED Sympoisium Part 1: Clinical variables associated with improved outcomes for children and young adults treated with chimeric antigen receptor T cells for B cell acute lymphoblastic leukmeia. <u>Transplant Cell Ther.</u> 2023 (Online ahead of print)
  - 3. Lamble A, Moskop A, Maude SL, Summers C, Annesley C, Baruchel A, Gore L, Amrolia P, **Shah NN**. INPSIRED Symposium Part 2: Prevention and Management of Relapse Following CAR T-cell therapy for B-ALL. Transplant Cell Ther. 2023 (Online ahead of print)
- 2. Fogli LK, Aurigemma R, Sommer CL, Singh A, Bourcier K, Ernstoff MS, NCI Cell Therapy Workshop Committee (\*On committee). Challenges and Challenges and next steps in the advancement of immunotherapy: summary of the 2018 and 2020 National Cancer Institute workshops on cell-based immunotherapy for solid tumors. <u>J Immunother Cancer</u>. 2021. 9(7): e003048
- 3. Heslop HE, Stadtmauer EA, Levine JE, Ballen KK, Chen Y, DeZern AE, Eapen M, Hamadani M, Hamilton BK, Hari P, Jones RJ, Logan BR, Kean LS, Leifer ES, Locke FL, Maziarz RT, Nemecek ER, Pasquini M, Phelan R, Riches ML, Shaw BE, Walters MC, Foley A, Devine SM, Horowitz MM. Blood and Marrow Transplant Clinical Trials Network State of the Scient Symposium 2021: Looking Forwaerd as the Network Celebrates its 20<sup>th</sup> Year. <u>Transplant Cell Ther</u>. 2021 (11): 885-907

### Submitted (In Review/revisions)

#### Non-Academic Publications/Interviews:

• American Society of Hematology Blood Podcast: How I treat series: Emergent CAR T-cell Toxicities: <a href="https://ashpublications.org/blood/pages/b

- CAR T-cell Therapy in Pediatric Leukemia: Past, Present and Future: <a href="https://www.hematologyadvisor.com/home/topics/leukemia/cart-therapy-pediatric-leukemia-past-present-future-treatment-risk/">https://www.hematologyadvisor.com/home/topics/leukemia/cart-therapy-pediatric-leukemia-past-present-future-treatment-risk/</a> (December 9, 2022)
- In remission for 10 years: Long-term toxicity data on CAR T-cells. https://www.medscape.com/viewarticle/934286 (July 21, 2020)
- 'Very much a calling': one clinician's journey from solving word problems to curing cancer.

  <a href="https://www.healio.com/news/hematology-oncology/20230817/very-much-a-calling-one-clinicians-journey-from-solving-word-problems-to-curing-cancer">https://www.healio.com/news/hematology-oncology/20230817/very-much-a-calling-one-clinicians-journey-from-solving-word-problems-to-curing-cancer</a>