

## CURRICULUM VITAE

Name: Nirali N. Shah, MD, MHSc

Citizenship: United States

Education:

2012 MHS, (Clinical Research) Duke University-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 Lasker Clinical Research Scholar, National Cancer Institute, Bethesda, MD  
2019-Present NIH Distinguished Scholar, National Institutes of Health, Bethesda, MD  
2017-2019 Associate Research Physician, Pediatric Oncology Branch, National Cancer Institute, Bethesda, MD  
2015-2017 Staff Clinician, 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  
2008-2009 Associate Physician, Emergency Department, Children's National Medical Center, Washington DC (Assistant Clinical Professor of Pediatrics, George Washington University School of Medicine)  
2009-2013 Fellow, Pediatric Hematology/Oncology Fellowship Program, Johns Hopkins Hospital, National Cancer Institute, Bethesda, MD 2004-2008 Resident, Harvard Combined Internal Medicine-Pediatrics Residency Program, Boston, MA

Military Service: None

Medical License and Board Certification:

Medical License

2013-Present American Board of Pediatrics, Hematology/Oncology  
2008-Present American Board of Pediatrics  
2008-Present American Board of Internal Medicine

Board Certification

2013-Present Maryland Medical License  
2008-2018 District of Columbia Medical License

Societies:

2018-Present Society of Immunotherapy of Cancer (SITC)  
2013-Present Children's Oncology Group (COG)  
Pediatric Blood and Marrow Transplant Consortium (PBMTTC)  
Therapeutic Advances in Childhood Leukemia & Lymphoma (TACL)  
2012-Present The American Society of Hematology  
2011-Present The American Society for Blood and Marrow Transplantation

Editorial Responsibilities:

Editorial Board

- 2020-Present Journal for ImmunoTherapy of Cancer, Associate Editor, Immune Cell Therapies and Immune Cell Engineering Section  
2018-Present Advances in Cell and Gene Therapy

Ad Hoc Reviewer

American Journal of Hematology  
Biology of Blood and Marrow Transplantation/Transplantation Cellular Therapy  
Blood  
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 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 Other Specific Scientific Recognition:

- 2021 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 Selection  
2019 Children's Cancer Foundation/Grant Recipient  
NIH Distinguished Scholar  
SITC Women's Immunotherapy Network Leadership Institute  
2018 Clinical Research Forum, Top 10 Clinical Research Achievement Award: "New CAR 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 PBMT/ASPHO

- 2012 Conference “New Frontiers in Allogeneic Stem Cell Transplant”  
2012 American Society for Blood and Marrow Transplantation Clinical Research Training Course  
2012 Young Investigator Award, National Cancer Institute 2<sup>nd</sup> International Workshop on the Biology, Prevention and Treatment of Relapse after Allogeneic Hematopoietic Stem Cell Transplantation  
2011 The American Society of Hematology Achievement Award for Trainee Abstract  
2008 Chief Resident, Harvard Combined Internal Medicine/Pediatrics Residency Program  
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:

- 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 Hopkins Joint Fellowship Program in Pediatric Hematology/Oncology  
2016-2019 National Cancer Institute (NCI), Institutional Review Board, Scientific Member, 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; Scientific Member  
2013-Present NIH BMT Consortium Member  
2013-Present Pediatric Oncology Branch Scientific Protocol Review Committee

Extramural Committees/Boards/Leadership Positions:

- 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  
American Society of Transplantation and Cellular Therapy Committee on Cellular Therapy  
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, In press*)
- 2019-Present Steering Prioritization Committee, Therapeutic Advances in Childhood 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 or Refractory CD22+ B-Acute Lymphoblastic Leukemia (B-ALL)
- 2015-Present Center for International Blood and Marrow Transplant Research (CIBMTR) 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 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
  - 20-C-0028, Phase I Dose-Escalation Study of anti-CD33 CAR in Children and Young Adults with Relapsed/Refractory AML.
  - 18-C-0059 Phase I Dose-Escalation Study of anti-CD19/CD22 Bispecific CAR in Children and Young Adults with Relapsed/Refractory Leukemia.
  - 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.
  - 17-C-0137: Leukapheresis for CAR-Therapy Manufacturing
  - 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
  - 10-C-0174: Related and Unrelated Donor Hematopoietic Stem Cell Transplantation for DOCK8 Deficiency
  
- 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. (Shalabi-PI)
- Phase I Dose-Escalation Study of Bryostatin1 in Children and Young Adults with CD22+ Hematologic Malignancies.
- Treatment/Intervention Trials: Data Analysis Only
  - 12-C-0112: Phase I Dose-Escalation Study of anti-CD19 CAR
- Retrospective Studies:
  - 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

Medical Advisory Investigator:

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

Patents Issued/Pending: None

Grants:

- 2019 Children's Cancer Foundation/Grant Recipient
- 2014 Children's Cancer Foundation/Giant Food Next Gen Award for Children's Cancer Research

Meeting Organizer or Chair:

- CAR T-cell Therapy: Beyond the Storm, Thursday, May 14, 2020. Conference Chair and Organizer. Bethesda, MD
- 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)
- 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.
- 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
- 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

Invited Talks/Meetings (Intramural):

- Several yearly educational conferences to NCI/NHLBI/DTM and POB. Bethesda, MD (NIH Clinical Center)
- NIH Clinical Center Grand Rounds. "CAR T-cell Therapy in Pediatric Leukemia: Current Status and Future Directions." Wednesday, January 6, 2021

- FDA/NCI/CTEP Meeting. NIH COVID-19 Platform Trials. “*Compassionate Use Study of Tocilizumab in Cancer Patient with COVID-19*” June 5, 2020
- AACR SU2C Monthly Meeting NCI Presentation. “HLH-like Manifestations of CD22 CAR T-cells: More than Just Severe CRS?” Monday, March 9, 2020
- NIH Myelodysplastic Syndromes Symposium. “*CAR T-Cell Therapy in Pediatric Leukemia.*” Friday, July 12, 2019.
- Advanced Oncology Education Series for Nurses, “*Adoptive Cell Therapy: CAR T-Cells.*” Tuesday, April 30, 2019.
- Demystifying Medicine Talk, “*CAR T-Cell Therapy in Pediatric Leukemia.*” Tuesday, February 26, 2019
- NCI Workshop on Cell-Based Immunotherapy for Solid Tumors, “*CAR T-Cell Therapy: Going Beyond the Test Drive.*” Tuesday, December 11, 2018
- Advanced Oncology Education Series for Nurses, “*Adoptive Cell Therapy: CAR T-Cells.*” November 27, 2018
- POB Research Seminar: “*CAR-T Cell Therapy in Pediatric Leukemias: Bench to Bedside and Back Again.*” Thursday, October 11, 2018.
- NIH Research Festival. Talk, “*CAR-T Cell Therapy for AML.*” Wednesday, September 12, 2018.
- Advanced Oncology Education Series for Nurses: Cancer Immunotherapy Course. Talk, “*Adoptive Cell Therapy: CAR T-Cells.*” April 23, 2018.
- Cancer Autoimmunity and Immunology Meeting. Talk: “*Toxicities Associated with Adoptive Cell Transfer.*” March 23, 2018
- Chronic GVHD Intramural Retreat. Talk: “*GVHD in the Era of Cell and Immunotherapy.*” February 6, 2018. Bethesda, MD (NIH)
- 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>
- 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.
- POB Research Seminar. “*The Race Against ALL, One CAR at a Time.*” Thursday, February 9, 2017. Bethesda, MD (NIH Clinical Center)
- 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)
- 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
- Laboratory of Molecular Biology, NIH Seminar. “*Moxetumomab pasudotox in Pediatric ALL.*” Monday, October 27, 2014.
- 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)
- POB Research Seminar: “*Pediatric Allogeneic Hematopoietic Cell Donors on Clinical Research Protocols.*” January 17, 2013. Bethesda, MD (NIH Clinical Center)
- 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):

1. Mayo Clinic Updates in CAR T-cell Therapy 2021. “*CAR T-cell therapy: Beyond CD19.*” Thursday, August 26, 2021

2. 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
3. TATA Memorial Hospital “*CAR T-cell Therapy in Pediatric Leukemia: Current Status and Future Directions.*” Saturday, July 17, 2021
4. 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
5. Children’s Wisconsin, Northwest Mutual Foundation, Pediatric Cancer Symposium: Exploring Immunotherapy in Pediatric Cancers. “*CAR T-cell therapy: Beyond CD19.*” Wednesday, May 12, 2021
6. 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
7. Baylor College of Medicine, Texas Children’s Hospital. Pediatric Hematology/Oncology Research Seminar Series. “*CAR T-cell therapy: Beyond CD19.*” Thursday, May 6, 2021
8. Cellicon Valley ’21: Future of cell and gene therapies. “*Long-term toxicities, hypogammaglobulinemia, cytopenias and infection risks.*” Thursday, May 6, 2021
9. 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
10. 3<sup>rd</sup> International Workshop on CAR-T. “*Approaches to Dual Targeting with CARTs.*” Wednesday, April 21, 2021.
11. 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
12. 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
13. 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
14. 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, 2021
15. American Society of Hematology (ASH) Workshop on Developing Biomarkers for CAR T-cells and BiTES Toxicity and Efficacy. October 7, 2020
16. 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)
17. Children’s National Medical Center, Pediatric Hematology/Oncology Grand Rounds. “*CAR T-cell Associated HLH.*” October 1, 2020.
18. 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)
19. Walter Reed Systems Pediatric Hematology/Oncology Speaker. “*CAR T-cell trials in the Pediatric Oncology Branch.*” (Virtual) Friday, July 24, 2020
20. Seventh Annual Pediatric Cancer Symposium: Exploring Immunotherapy 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)
21. 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

22. 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)
23. 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
24. 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
25. First International Workshop on CAR-T (iWCAR), “Mechanisms of Resistance to CAR T-cells.” Session Chair. Sunday, October 13, 2019. Miami, FL
26. Society of Hematology Oncology, (SOHO), “*CAR-T Therapy for ALL: Moving Beyond Single Agent Targeting.*” Thursday, September 12, 2019. Houston, TX
27. 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.
28. 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.
29. American Society for Transplantation and Cellular Therapy. Consensus Conference on Management of T-cell Therapy Toxicities. Tuesday, July 30, 2019. Silver Spring, MD
30. 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
31. 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
32. 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
33. 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
34. 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.
35. 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
36. 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.
37. 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
  1. *Novel Therapies as a Bridge to HSCT and Maintenance Therapy post-HSCT in ALL*
  2. *Relapse post CAR-T Cell Therapy*
38. Translational Science 2018 Conference, “Top 10 Clinical Achievement Award,” Talk, “New CAR Therapy for Relapsed Leukemia Patients.” April 20, 2018.
39. FAES-CAR Technology Course. Talk, “Current Clinical Applications and Considerations of CAR-T Cell Therapy.” March 16, 2018.
40. American Society of Clinical Oncology, Abstract Discussant. “*Expanding CAR-T Cells for Extramedullary Disease.*” Saturday, June 3, 2017. Chicago, IL



41. Children's Oncology Group, Spring Meeting. "Targeting CD33 and CD123 for AML CAR." March 29, 2017.
42. ISBioTech 7<sup>th</sup> Spring Meeting. "Lessons Learned with CAR T-Cell Therapies for Acute Lymphoblastic Leukemia." March 6, 2017. Washington DC.
43. 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.
44. Children's Oncology Group: Novel Therapies for Relapsed ALL. "CD22 Antigen Expression." Wednesday, September 14, 2016. Atlanta, GA.
45. Children's Cancer Foundation Research Symposia. "Immunotherapy for Childhood Leukemia." June 1, 2016. Landover, MD.
46. 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.
47. 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
48. 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.
49. 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.
50. Pediatric Grand Rounds, University of Virginia, Department of Pediatrics. "Tackling Post-Transplant Relapse, One Trial at a Time" September 26, 2014. Charlottesville, VA
51. HSCT Transplantation: Antibody and other Immunotherapeutic Approaches to Treat Post-HSCT Relapse." Friday, November 7, 2014. Minneapolis, MN.
52. National Marrow Donor Program Council Meeting. "Treating Disease Relapse after Allogeneic
53. Life with Cancer Organization, Family Center. Pediatric Oncology Parent Night. "Childhood Leukemia: Past, Present and Future." September 24, 2013. Fairfax, VA.

#### Mentorship:

Dr. Shah is involved with the direct mentorship of students and trainees and previously served as the Associate program director for the JHH-NCI combined pediatric hematology/oncology fellowship.

#### **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)

1. 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. Transplantation and Cellular Therapy 2021 (In Press)
2. 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 (In Press)
3. Myers RM, Taraseviciute A, Steinberg SM, Lambie 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. J Clin Oncol. 2021 (In Press)
  4. 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. British Journal of Hematology. 2021 (In Press)
  5. 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 (In Press)
  6. 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, Ruppel E, Stroncek DF, **Shah NN**. Characterization of HLH-Like Manifestations as a CRS Variant in Patients Receiving CD22 CAR T-cells. Blood 2021 (In Press)
  7. 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. J Immunother Cancer. 2021 (In Press)
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