CURRICULUM VITAE

Name: Udayan Guha, M.D., Ph.D.
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Citizenship: United States

Education:

2003	Ph.D., (Neuroscience), Albert Einstein College of Medicine, Bronx, NY
1995	M.B.B.S., All India Institute of Medical Sciences, New Delhi, India
1990	B.S., R.K.M.Residential College, Narendrapur, India

Brief Chronology of Employment:

2023-current	Senior Vice President, Clinical and Translational Development, NextCure Inc., Beltsville, MD
2022-2023	Vice President, Head of Clinical Development, TCR^2 Therapeutics, Cambridge, MA
2021-2022	Senior Director, Early Clinical Development, Bristol-Myers Squibb, Princeton Pike, Lawrenceville, NJ
2020-2021	Director, Early Clinical Development, Bristol-Myers Squibb, Princeton Pike, Lawrenceville, NJ
2020-present	Senior Clinical Advisory Staff, National Cancer Institute (NCI), NIH Clinical Center and Special Volunteer, Thoracic and GI Malignancies Branch, Center for Cancer Research, National Cancer Institute, Bethesda, MD
2011-2020	Investigator, Thoracic and GI Malignancies Branch, Center for Cancer Research, National Cancer Institute, Bethesda, MD
2008-2011	Clinical Fellow, Hematology and Oncology, Memorial Sloan-Kettering Cancer Center, NY, NY
2005-2008	Research Fellow, Cancer Biology and Genetics, Memorial Sloan-Kettering Cancer Center, NY, NY (Mentor: Dr. Harold Varmus)
2003-2008	Residency in Internal Medicine, Department of Medicine, Jacobi Medical Center, Albert Einstein College of Medicine, Bronx, NY
1996-1998	Research Fellow, Department of Radiation Oncology, Montefiore Medical Center, Albert Einstein College of Medicine. (Mentor: Dr. Bhadrasain Vikram, MD)

Certification:

Cornell University Biotech and Pharmaceutical Management Foundations, 2023
e-Cornell Biotech and Pharmaceutical Management Program, 2023
Ph.D, 2003
ECFMG, 1998
M.B.B.S (MD equivalent), 1995.

Medical Licensure:

New York State Licensure, 2008 #247993-1 (active)
California State Licensure, 2009 (inactive)

Board Certification:

Diplomat, American Board of Internal Medicine, 2008
Diplomat, Subspecialty of Medical Oncology, 2009 (active)

Professional Memberships:

American Association of Cancer Research (AACR)

American Society of Clinical Oncology (ASCO)

Society for Immunotherapy of Cancer (SITC)

International Association for the Study of Lung Cancer (IASLC)

American Society for Mass Spectrometry (ASMS)

Human Proteome Organization (HUPO)

Honors and Other Special Scientific Recognition:

2015-2018	Major Opportunity Award: Metabolic Basis of Cancer
2012-2013	Lung Cancer Research Foundation Award
2013	NCI Director's Postdoctoral Innovation Award
2012	NCI Director's PI innovation Award
2009-2012	NIH K99/R00 (Howard Temin Pathway to Independence Award; relinquished 2/12/2011 after joining NCI intramural program)
2006-2009	American Cancer Society Postdoctoral Fellowship.
2006-2008	Lung Cancer Research Initiative Award- Labrecque Foundation

Professional Activities:

Scientific Advisory Board Member- Keystone Symposia- 2022-2023

Journal Ad hoc Reviewer:

Nature Biotechnology, Nature Communication, Science Signaling, Cancer Discovery, Cancer Research, Clinical Cancer Research, Oncogene, Journal of Immunotherapy of Cancer, Molecular and Cellular Proteomics, Journal of Clinical Investigation, Proteomics, CSHL Molecular Case Studies, Cancer Prevention Research, Cell Death and Differentiation, Cancers, Scientific Reports, PLOS One, Theronostics

Guest Editor:

Cancers, Special Issue: Proteomics in Cancer, 2021

Ad hoc Grant Reviewer for:

AACR Fellowships in Lung Cancer Research 2016-2018

Medical Research Council Grant- review of grant application under the Developmental Pathway Funding Scheme (DPFS) Devolved Portfolios Pilot to The Severnside Alliance for Translational Research (SARTRE)

Belgian Foundation Against Cancer Grants 2018

External reviewer for the FDA:

2011: external reviewer/consultant for the accelerated approval of Crizotinib for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) that is ALK positive.

2013: external reviewer/consultant for the full approval of Crizotinib for the treatment of locally advanced or metastatic NSCLC that is ALK positive.

Invited Talks (since 2011):

2020: FASEB Meeting, Protein Phosphorylation Networks in Health and Disease. Snowmass, CO.

2019: IASLC 20th World Conference on Lung Cancer, Barcelona, Spain.

2019: Cancer R&D 2019, Baltimore, MD.

2019: Department of Hematology/Oncology Grand Rounds, Montefiore Medical Center/Albert Einstein College of Medicine, Bronx, NY

2018: IASLC 19th World Conference on Lung Cancer, Toronto, Canada.

2018: FASEB meeting, Cell Signaling in Cancer: from Mechanisms to Therapy, Steamboat Springs, Colorado.

2018: HPLC 2018 - 47th International Symposium on High Performance Liquid Phase Separations and Related Techniques.

2018: NCI-University of Maryland Partnership for Integrative Cancer Research, Bethesda, MD.

2018: Georgetown University, Biochemistry and Molecular and Cellular Biology Department, Research Seminar Series.

2017: Precision Medicine World Conference, Silicon Valley, San Diego, California.

2017: Jonsson Comprehensive Cancer Center, UCLA, "Leaders in the Field" Research seminar series, Los Angeles, CA.

2017: MedImmune/AstraZeneca, Rockville, MD

2017: FDA/CDER Genetics and Genomics seminar series, Silver Spring, MD.

2017: Oncology Grand Rounds Lecture Series, Georgetown-Lombardi Comprehensive Cancer Center.

2017: US HUPO (Human Proteome Organization) 13th Annual Conference, San Diego, CA, USA

2017: FDA/OCE Research Projects Presentation, Silver Spring, MD.

2016: US HUPO (Human Proteome Organization) 12th Annual Conference, Boston, USA.

2016: 12th International Conference of Asian Clinical Oncology Society (ACOS), N. Delhi, India

2016: 9th Annual World Protein and Peptide Conference, Dalian, China

2016: Center for Advanced Preclinical Research (CAPR), Center for Cancer Research, NCI

2015: Lung Cancer Oncogenome Group, Memorial Sloan-Kettering Cancer Center, NY, NY.

2015: Omics meeting, NIH, Bethesda, MD.

2014: Advanced Oncology Education series: Clinical Research Protocols in Oncology- A Systems Approach, NIH, Bethesda, MD.

2013: Department of Biochemistry and Molecular and Cellular Biology, Georgetown University, Washington, D.C.

2011: Laboratory of Cancer Biology and Genetics, Center for Cancer Research, NCI, Bethesda, MD.

Clinical Development / Clinical Trial Experience

NextCure Inc: 2023-current

SVP, Clinical and Translational Development

NextCure Inc. has developed novel first-in-class immunomedicines targeting the LAIR-1 immunecheckpoint expressed on T cells and myeloid cells. NC410 is a LAIR-2 IgG1 fusion protein that is designed to block immunosuppression mediated by LAIR-1. NC525 is an agonistic monoclonal antibody that binds to LAIR-1 to functionally kill AML blast cells and leukemic stem cells. Three Phase ½ first-in-human studies are underway to study the safety, tolerability and preliminary efficacy of immunotherapies targeting the LAIR-1 and B7-H4 pathways.

Study Physician for the following studies:

- A safety, tolerability and efficacy study of NC410 plus pembrolizumab in participants with advanced unresectable or metastatic solid tumors.
- A safety, tolerability and efficacy study of NC525 in subjects with advanced myeloid neoplasms (AML, MDS, CMML)
- A safety and tolerability study of NC762 in subjects with advanced or metastatic solid tumors

Guide the translational and biomarker teams to develop biomarker assays and analyze biomarker data from all clinical studies.

Participate in all Board meetings, executive meetings, and advice on business development for NextCure Inc.

TCR^2 Therapeutics: 2022-2023

VP, Head of Clinical Development

TCR^2 Therapeutics has developed a novel autologous T cell therapy platform. This involves T cell receptor fusion construct (TRuC) that consists of a tumor antigen binding domain tethered to CD3ε receptor subunit that when expressed in autologous T cells incorporates into endogenous eight subunits-containing T cell receptor (TCR), thus engaging the complete TCR signaling for HLA class non-restricted autologous T cell therapy.

Study Physician for the following studies:

- A Phase ½ single arm open-label clinical trial of TC-510 in patients with advanced mesothelin-expressing cancer
- A Phase ½ single arm open-label clinical trial of gavocabtagene autoleucel (Gavo-cel) in patients with advanced mesothelin-expressing cancer

Provide guidance and collaborate with the Translational Medicine team for translational studies and Discovery for IND-enabling studies at TCR^2 Therapeutics

Develop clinical developmental strategies for additional tumor antigen-directed TRuC T cell therapies that are in pre-clinical development

Bristol Myers Squibb: 2020-2022

Senior Early Clinical Lead and Director, Bristol Myers Squibb: Jan 2020-2021

Senior Director, Bristol Myers Squibb 2021- 2022

Clinical Lead and Study Director/Medical Monitor for the following studies:

- A Phase I study of BMS-986299 as monotherapy and in combination with nivolumab and ipilimumab in participants with advanced solid cancers (NLRP3 innate agonist)

- A Phase ½ study of BMS-986340 as monotherapy and in combination with nivolumab in participants with advanced solid tumors (anti-CCR8 monoclonal antibody)- IND submission and approval of this first-in-class first-in-human study. Currently enrolling.

Leading clinical protocol development for first-in-human, first-in-class studies for the following assets:

- Oral PD-L1 inhibitor
- Anti-TIGIT bispecific

Clinical Development/protocol strategy for few other early development assets and presentation in Governance meetings

Clinical Development representative in the Diligence team that evaluated the anti-TIGIT bispecific mAb from Agenus that resulted in the licensing of the Agenus bispecific antibody by BMS.

National Cancer Institute (NCI)/ National Institutes of Health (NIH): 2011-2020

Principal Investigator (Investigator-initiated clinical studies) of the following clinical studies:

- A pilot study of local ablative therapy for treatment of oligoprogressive, EGFR-mutated, non-small cell lung cancer (NSCLC) after treatment with Osimertinib (Phase 2 study; Clinical Trial Agreement with AstraZeneca)

- A pilot study of inpatient hospice with procurement of tissue on expiration in thoracic malignancies. (Rapid autopsy study, established first time at the NCI)

- Tissue procurement and natural history study of patients with non-small cell lung cancer, small cell lung cancer, extrapulmonary small cell cancer, pulmonary neuroendocrine tumors, and thymic epithelial tumors. (First Natural History study for Thoracic Malignancies at the NCI)

- Pilot trial of molecular profiling and targeted therapy for advanced Non-Small Cell Lung Cancer, Small Cell Lung Cancer, and Thymic malignancies (Phase 2 study)

Associate Investigator of multiple clinical studies in Thoracic and GI Malignancies Branch at the NCI- 2011-2020. – most Immunotherapy studies

BIBLIOGRAPHY

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2. Caswell DR et. al. The role of APOBEC3B in lung tumor evolution and targeted cancer therapy resistance. **Nature Genetics.** 56(1):60-73, 2024

3. Ade CM, Sporn MJ, Das S, Yu Z, Hanada K, Qi YA, Maity T, Zhang X, **Guha U**, Andresson T, Yang JC. Identification of neoepitope reactive T-cell receptors guided by HLA A*03:01 and HLA A*11:01 immunopeptidomics. **J Immunother Cancer**. 11(9):e007097.doi:10.1136/jitc-2023-007097, 2023

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