BIOGRAPHICAL SKETCH

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NAME: GOEL, SANJAY

eRA COMMONS USER NAME (credential, e.g., agency login): sanjaygoel

POSITION TITLE: Professor of Medicine

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE (if applicable)	END DATE MM/YYYY	FIELD OF STUDY
Christian Medical College, Vellore, Tamil Nadu	MBBS	01/1995	Medical School
State University of New York, Brooklyn, NY	MD	06/1999	Residency in Internal Medicine
University of Colorado, Denver, CO		06/2000	Fellowship in Hematology and Medical Oncology
Albert Einstein College of Medicine, Bronx, NY		06/2002	Fellowship in Hematology and Medical Oncology
Albert Einstein College of Medicine, Bronx, NY	MS	06/2003	Clinical Research

A. Personal Statement

My interest lies in the scientific field of drug and biomarker development for colorectal cancer. I have a special interest in identifying differences in outcome based on race and access to care and in comparative effectiveness research. I lead the phase I program in my current position and have an interest in phase one/developmental therapeutics program and gastrointestinal cancer. I have over 20 years of experience in developmental therapeutics, with a focus on early drug trials and clinical trials for colorectal cancer.

My research experience began as a first-year medical student in the human physiology lab wherein I used a simple “Harvard Step Up” test to assess exercise tolerance among 4 groups of medical students, namely, normal controls; asthmatics; those with atopia/allergies; and the last group included those with asthma and h/o of atopia/allergies. This experience gave me invaluable experience in clinical research, an introduction to biostatistics, and the need for rigor in research. My next project was to assess cerebrospinal fluid samples for myelin basic protein in patients with multiple sclerosis. This exposed me to the nature of translational research, collection of patient samples, laboratory techniques, and working in a collaborative environment, including working at odd hours. While unable to peer review publish this research, it earned me an “Undergraduate Research Award” and invaluable skills.

Cancer-focused research began during my fellowship and has continued. I have 20 years of clinical trial experience, ranging from investigator-initiated, industry-sponsored, and cooperative and NCI-sponsored trials. My strong background in biostatistics and ability to handle large data and my clinical experience in providing firsthand care to racial and ethnic minority patients led to my interest in understanding and resolving the observed disparities in cancer. I have leadership experience and have been the PI on over 100 clinical trials, spanning the entire spectrum from phase I through phase IV and also the invaluable experience of setting up an independent wet lab. These experiences have given me extensive experience in being a team leader, managing and guiding personnel, resolving conflicts, understanding human nature, making and following budgets, handling financial appropriations, and conceiving ideas and projects and bringing them to fruition. I also directed the Protocol Review and Monitoring System (PRMS) of the Albert Einstein Cancer Center, which has been of tremendous help in understanding the regulatory aspects of research.

I have over 125 peer-reviewed publications in international journals. Of these 77 are either as first or last/senior/corresponding authors, and 19 are as second (or second last) authors. I have been recognized throughout my oncology career with multiple awards. As a senior fellow, I was awarded the “Best Podium Presentation” in a nationwide competition of oncology fellows. As a junior faculty, I won the ECOG “Young

Investigator Award" at their annual meeting in 2007. In 2010, I was awarded the "Advanced Clinical Research Award (ACRA)" by the Conquer Cancer Foundation (CCF, an independent part of ASCO) for my research project in colorectal cancer. Incidentally, this was the only ACRA ever awarded in CRC by the CCF, in its three-decade history. I also had a NIH R21 award in minority research.

I have been funded by the NIH in the field of "Disparity Research" as detailed below
1R21AG058027-01, NIA, GOEL, SANJAY (PI), 06/01/18-05/31/21
COMPARATIVE EFFECTIVENESS OF BIOLOGIC AGENTS IN ETHNIC MINORITIES WITH COLORECTAL CANCER
To identify and describe the real-world impact of the use of biologic agents when added to cytotoxic chemotherapy for patients with metastatic colorectal cancer (mCRC).

My role in the current project will be to serve as the PI of the translational research grant, which focuses on the continued development of reovirus for patients with KRAS-mutated colorectal cancer, which is borne out of very compelling prior data. My prior research and clinical experience make me **uniquely qualified** to lead the current grant and project aims. I have committed lab space of 600 square feet on the third floor of the main campus of Rutgers Cancer Institute of New Jersey in New Brunswick. My overarching role will be to supervise the project in its entirety. Specifically, I will focus on the transcriptome analysis and the conduct and interpretation of the results of the analysis of the human plasma samples. I will also supervise the studies that will utilize the human specimens that have been collected as part of a completed clinical research project. I will also be responsible for maintaining IACUC approval for the vertebrate studies. I will work directly with Dr. Maitra (MPI) through weekly meetings (in person or zoom/remote) and with the entire research staff. My role as the PRMS Director has trained me to lead a team based in multiple geographical locations.

List of publications that captures my expertise

1. Augustine T, John P, Friedman T, Jiffry J, Guzik H, Mannan R, Gupta R, Delano C, Mariadason JM, Zang X, Maitra R, **Goel S**. Potentiating effect of reovirus on immune checkpoint inhibition in microsatellite stable colorectal cancer. Front Oncol. 2022 Oct 25;12:1018767. doi: 10.3389/fonc.2022.1018767. PMID: 36387154; PMCID: PMC9642964.
2. Myer PA, Lee JK, Madison RW, Pradhan K, Newberg JY, Isasi CR, Klempner SJ, Frampton GM, Ross JS, Venstrom JM, Schrock AB, Das S, Augenlicht L, Verma A, Greally JM, Raj SM, **Goel S**, Ali SM. The Genomics of Colorectal Cancer in Populations with African and European Ancestry. Cancer Discov. 2022 Feb 17:candisc.0813.2021. doi: 10.1158/2159-8290.CD-21-0813. Epub ahead of print. PMID: 35176763. PMCID: PMC9169495
3. **Goel S**, Ocean AJ, Parakrama RY, Ghalib MH, Chaudhary I, Shah U, Viswanathan S, Kharkwal H, Coffey M, Maitra R. Elucidation of Pelareorep Pharmacodynamics in A Phase I Trial in Patients with *KRAS*-Mutated Colorectal Cancer. Mol Cancer Ther. 2020 May;19(5):1148-1156. PubMed PMID: 32156785; PubMed Central PMCID: PMC7207225.
4. Jiffry J, Thavornwatanayong T, Rao D, Fogel EJ, Saytoo D, Nahata R, Guzik H, Chaudhary I, Augustine T, **Goel S**, Maitra R. Oncolytic Reovirus (pelareorep) Induces Autophagy in KRAS-mutated Colorectal Cancer. Clin Cancer Res. 2020 Nov 9; PubMed PMID: 33168658.

B. Positions, Scientific Appointments, and Honors

Positions and Employment

2022 -	Attending, Department of Medical Oncology, RWJ Barnabas Rutgers CINJ, NJ
2022 -	Professor of Medicine, RWJ Medical School
2021 - 2022	Vice Chairman for Clinical Research, Department of Oncology, Montefiore Medical Center
2016 - 2022	Professor of Medicine, Albert Einstein College of Medicine, Bronx, NY
2010 – 2016	Associate Professor of Medicine, Albert Einstein College of Medicine, Bronx, NY
2003 - 2010	Assistant Professor of Medicine, Albert Einstein College of Medicine, Bronx, NY
2002 - 2003	Instructor of Medicine, Albert Einstein College of Medicine, Bronx, NY
2002 - 2022	Attending, Department of Medical Oncology, Montefiore Medical Center, Bronx, NY

Other Experience and Professional Memberships

2020 -	Member, Grant Selection Committee, Conquer Cancer Foundation, American Society of Clinical Oncology

2017 - 2018	Track Leader, Scientific Program Committee, Developmental Therapeutics - Immunotherapy, American Society of Clinical Oncology
2016 - 2019	Member, Scientific Program Committee, Developmental Therapeutics - Immunotherapy, American Society of Clinical Oncology
2013 - 2018	Grant Selection Committee, Conquer Cancer Foundation, American Society of Clinical Oncology

Honors

2016	Best Faculty Teaching Award, Montefiore/Albert Einstein College of Medicine, New York, USA
2013	ASCO Leadership Development Program, American Society of Clinical Oncology
2013	Maintenance of Certification - Medical Oncology, American Board of Internal Medicine
2010 - 2013	Advanced Clinical Research Award (ACRA), American Society of Clinical Oncology
2007	ECOG Young Investigator Translational Research Award, Eastern Cooperative Oncology Group
2005	Best Junior Faculty Teaching Award, Montefiore/Albert Einstein College of Medicine, New York, USA
2002	Board Certified in Hematology, American Board of Internal Medicine
2002	Board Certified in Medical Oncology, American Board of Internal Medicine

C. Contributions to Science

1. **Developed reovirus as an immune-oncolytic biological agent for the treatment of cancer.**

   My professional contributions to science are exemplified by my primary interest in drug development. A major contribution has been in the development of reovirus (Respiratory Enteric Orphan virus) as an immune-oncolytic biological agent for the treatment of cancer. This focus highlights my expertise in "bedside to bench to bedside" transition of drug development and science. I was the PI and carried out the first United States phase I intravenous study and identified the safe dose of the virus. Subsequently, we transitioned to the laboratory, and conducted pre-clinical modeling and demonstrated synergy with irinotecan, in vitro and in vivo xenograft models. Taking it back to the bedside/patient, we established efficacy and identified a unique immune phenomenon from patient samples using FACS. We next demonstrated that reovirus induces autophagy, particularly under KRAS mutant conditions. Finally, we have established pre-clinical models of synergy of reovirus with immune therapy in CRC.

   a. Augustine T, John P, Friedman T, Jiffry J, Guzik H, Mannan R, Gupta R, Delano C, Mariadason JM, Zang X, Maitra R, **Goel S**. Potentiating effect of reovirus on immune checkpoint inhibition in microsatellite stable colorectal cancer. Front Oncol. 2022 Oct 25;12:1018767. doi: 10.3389/fonc.2022.1018767. PMID: 36387154; PMCID: PMC9642964.
   b. **Goel S**, Ocean AJ, Parakrama RY, Ghalib MH, Chaudhary I, Shah U, Viswanathan S, Kharkwal H, Coffey M, Maitra R. Elucidation of Pelareorep Pharmacodynamics in A Phase I Trial in Patients with *KRAS*-Mutated Colorectal Cancer. Mol Cancer Ther. 2020 May;19(5):1148-1156. PubMed PMID: 32156785; PubMed Central PMCID: PMC7207225.
   c. Jiffry J, Thavornwatanayong T, Rao D, Fogel EJ, Saytoo D, Nahata R, Guzik H, Chaudhary I, Augustine T, **Goel S**, Maitra R. Oncolytic Reovirus (pelareorep) Induces Autophagy in KRAS-mutated Colorectal Cancer. Clin Cancer Res. 2020 Nov 9;PubMed PMID: 33168658. PMCID: PMC8130598
   d. Maitra R, Seetharam R, Tesfa L, Augustine TA, Klampfer L, Coffey MC, Mariadason JM, **Goel S**. Oncolytic reovirus preferentially induces apoptosis in KRAS mutant colorectal cancer cells and synergizes with irinotecan. Oncotarget. 2014 May 15;5(9):2807-19. PubMed PMID: 24798549; PMCID: PMC4058046.

2. **Disparities and outcome research among racial and ethnic minorities.**

   My interest lies in the area of outcomes research among racial and ethnic minorities. I believe that most clinical trials enroll a predominantly Caucasian dominated population, and the real-world outcome is bound to be different. I seek to scientifically study the disparate outcomes and find solutions that are practical, and implementable. I have constantly cared for minority patients, been a champion of their enrollment into prospective clinical trials and been funded in this area of research.

a. Myer PA, Lee JK, Madison RW, Pradhan K, Newberg JY, Isasi CR, Klempner SJ, Frampton GM, Ross JS, Venstrom JM, Schrock AB, Das S, Augenlicht L, Verma A, Greally JM, Raj SM, **Goel S**, Ali SM. The Genomics of Colorectal Cancer in Populations with African and European Ancestry. Cancer Discov. 2022 Feb 17:candisc.0813.2021. doi: 10.1158/2159-8290.CD-21-0813. Epub ahead of print. PMID: 35176763. PMCID: PMC9169495
b. **Goel S**, Negassa A, Acuna-Villaorduna A. Comparative Effectiveness of Biologic Agents Among Black and White Medicare Patients in the US with Metastatic Colorectal Cancer. JAMA Netw Open. 2021 Dec 1;4(12):e2136378. doi: 10.1001/jamanetworkopen.2021.36378. PMID: 34910154. PMCID: PMC8674750
c. Acuna-Villaorduna AR, Lin J, Kim M, **Goel S** (corresponding author). Racial/ethnic disparities in early-onset colorectal cancer: implications for a racial/ethnic-specific screening strategy. Cancer Med. 2021 Mar;10(6):2080-2087. doi: 10.1002/cam4.3811. Epub 2021 Feb 28. PMID: 33641251; PMCID: PMC7957207.
d. Osarogiagbon RU, Sineshaw HM, Unger JM, Acuña-Villaorduña A, **Goel S**. Immune-Based Cancer Treatment: Addressing Disparities in Access and Outcomes. Am Soc Clin Oncol Educ Book. 2021 Mar;41:1-13. doi: 10.1200/EDBK_323523. PMID: 33830825.

3. **Contributed to better delineation of patients with metastatic colorectal cancer and completed multiple studies on KRAS mutant CRC.**

There are over 15 drugs currently available for use for these patients. The use of anti-EGFR agents has led to incremental gains in the treatment and outcome of patients; however, only a fraction of patients derives real clinical benefit. It is widely recognized that KRAS mutations are negative biomarkers of lack of benefit. Working with my collaborators, I initially showed strong in vitro and in vivo data that the presence of mutations in the PI3K pathway and loss of PTEN expression were markers of resistance to these drugs. We then went on to validate our findings in human samples, adding to the knowledge being generated from other centers. This work was recognized for its novelty by the granting of a patent by the USPTO (Method of Determining The Sensitivity Of Cancer Cells To EGFR Inhibitors Including Cetuximab, Panitumumab And Erlotinib. Patent No. 20090258364). We finally looked at a very novel marker, namely the telomere length (TL) and showed that longer TL predicts better outcome with these agents. Currently, the effort is focused on characterization of KRAS mutant tumors, and targeted drug development.

a. Maitra R, Augustine T, Dayan Y, Chandy C, Coffey M, **Goel S**. Toll like receptor 3 as an immunotherapeutic target for KRAS mutated colorectal cancer. Oncotarget. 2017 May 23;8(21):35138-35153. PubMed PMID: 28422714; PubMed Central PMCID: PMC5471041.
b. Augustine TA, Baig M, Sood A, Budagov T, Atzmon G, Mariadason JM, Aparo S, Maitra R, **Goel S**. Telomere length is a novel predictive biomarker of sensitivity to anti-EGFR therapy in metastatic colorectal cancer. Br J Cancer. 2015 Jan 20;112(2):313-8. PubMed PMID: 25412235; PubMed Central PMCID: PMC4453445.
c. Sood A, McClain D, Maitra R, Basu-Mallick A, Seetharam R, Kaubisch A, Rajdev L, Mariadason JM, Tanaka K, **Goel S**. PTEN gene expression and mutations in the PIK3CA gene as predictors of clinical benefit to anti-epidermal growth factor receptor antibody therapy in patients with KRAS wild-type metastatic colorectal cancer. Clin Colorectal Cancer. 2012 Jun;11(2):143-50. PubMed PMID: 22285706; PubMed Central PMCID: PMC3350566.
d. Jhawer M, **Goel S**, Wilson AJ, Montagna C, Ling YH, Byun DS, Nasser S, Arango D, Shin J, Klampfer L, Augenlicht LH, Perez-Soler R, Mariadason JM. PIK3CA mutation/PTEN expression status predicts response of colon cancer cells to the epidermal growth factor receptor inhibitor cetuximab. Cancer Res. 2008 Mar 15;68(6):1953-61. PubMed PMID: 18339877; PubMed Central PMCID: PMC3972216.

4. **Leader in the development of novel immunotherapeutics.**

As a demonstrated leader in drug development, I have played a major role in the development of drugs that target the immune system, within the field of developmental therapeutics/immunotherapy. Selective bibliography is detailed below. Further, I have served on the scientific program committee (SPC) of the American Society of Clinical Oncology (ASCO) within the developmental therapeutics/immunotherapy track (2016-19). As recognition of my expertise, I served as the track leader for the 2017-18 year. In addition to the peer reviewed publications, I have been an invited speaker at that Annual Meeting of ASCO, as a discussant for the oral abstract session for immunotherapy trials and have been an invited speaker at multiple international meetings in defining radiographic criteria for determining response to immunotherapy.

a. **Goel S**. “Expanding the Horizon of Rational Immunotherapy Combinations”. Discussant, Oral Abstract Session, Developmental Therapeutics – Immunotherapy, 55th Annual Meeting of the American Society of Clinical Oncology, Jun 2019
b. Borcoman E, Nandikolla A, Long G, **Goel S**, Le Tourneau C. Patterns of Response and Progression to Immunotherapy. Am Soc Clin Oncol Educ Book. 2018 May 23;38:169-178. PubMed PMID: 30231380.
c. Glisson BS, Leidner RS, Ferris RL, Powderly J, Rizvi NA, Keam B, Schneider R, **Goel S**, Ohr JP, Burton J, Zheng Y, Eck S, Gribbin M, Streicher K, Townsley DM, Patel SP. Safety and Clinical Activity of MEDI0562, a Humanized OX40 Agonist Monoclonal Antibody, in Adult Patients with Advanced Solid Tumors. Clin Cancer Res. 2020 Oct 15;26(20):5358-5367. PubMed PMID: 32816951.
d. Naing A, Infante J, **Goel S**, Burris H, Black C, Marshall S, Achour I, Barbee S, May R, Morehouse C, Pollizzi K, Song X, Steele K, Elgeioushi N, Walcott F, Karakunnel J, LoRusso P, Weise A, Eder J, Curti B, Oberst M. Anti-PD-1 monoclonal antibody MEDI0680 in a phase I study of patients with advanced solid malignancies. J Immunother Cancer. 2019 Aug 22;7(1):225. PubMed PMID: 31439037; PubMed Central PMCID: PMC6704567.

5. **Described susceptibility of patients with cancer and complications they suffered during the unprecedented COVID 19 pandemic.**

COVID 19 presented itself with all its might and struck New York City in early 2020. Montefiore Medical Center was particularly hard hit and taking care of these patients who were afflicted with cancer and COVID created a particular challenge. We observed high morbidity and mortality among our patients. With time we also observed uncommon complications. This led to cohort studies, including the one published in “Cancer Discovery” which was the most cited article for that journal in 2020. We then moved to intervention studies with vaccine hesitancy and testing antibody titers post vaccination and post COVID.

a. Mehta V, **Goel S**, Kabarriti R, Cole D, Goldfinger M, Acuna-Villaorduna A, Pradhan K, Thota R, Reissman S, Sparano JA, Gartrell BA, Smith RV, Ohri N, Garg M, Racine AD, Kalnicki S, Perez-Soler R, Halmos B, Verma A. Case Fatality Rate of Cancer Patients with COVID-19 in a New York Hospital System. Cancer Discov. 2020 Jul;10(7):935-941. doi: 10.1158/2159-8290.CD-20-0516. Epub 2020 May 1. PMID: 32357994; PMCID: PMC7334098.
b. Thakkar A, Pradhan K, Jindal S, Cui Z, Rockwell B, Shah AP, Packer S, Sica RA, Sparano J, Goldstein DY, Verma A, **Goel S**, Halmos B. Patterns of seroconversion for SARS-CoV2-IgG in patients with malignant disease and association with anticancer therapy. Nat Cancer. 2021 Apr;2(4):392-399. doi: 10.1038/s43018-021-00191-y. Epub 2021 Mar 22. PMID: 34661163; PMCID: PMC8519533.
c. Thakkar A, Gonzalez-Lugo JD, Goradia N, Gali R, Shapiro LC, Pradhan K, Rahman S, Kim SY, Ko B, Sica RA, Kornblum N, Bachier-Rodriguez L, McCort M, **Goel S**, Perez-Soler R, Packer S, Sparano J, Gartrell B, Makower D, Goldstein YD, Wolgast L, Verma A, Halmos B. Seroconversion rates following COVID-19 vaccination among patients with cancer. Cancer Cell. 2021 Aug 9;39(8):1081-1090.e2. doi: 10.1016/j.ccell.2021.06.002. Epub 2021 Jun 5. PMID: 34133951; PMCID: PMC8179248.
d. Lee M, Miao E, Rapkin B, Halmos B, Shankar V, **Goel S**. Prevalence and Assessment of Factors Associated with COVID-19 Vaccine Hesitancy in an Ethnic Minority Oncology Patient Population. Vaccines (Basel). 2022 Oct 14;10(10):1711. doi: 10.3390/vaccines10101711. PMID: 36298576; PMCID: PMC9611923.

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