Innovation in Breast Cancer
LISBON EDITION
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VIRTUAL FORMAT

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(WEST) Western European Summer Time

Edith A. Perez

Mayo Clinic, Florida, USA

Edith A. Perez, MD is an internationally recognized translational researcher and cancer specialist, Chief Medical Officer of Bolt Therapeutics, Inc., Professor of Medicine at Mayo Clinic, and Director of the Mayo Clinic Breast Cancer Translational Genomics Program. Dr. Perez is known for her strategic vision in designing innovative clinical trials, her passion for patient care, and her strong team leadership. Her experience includes leadership in academic and biopharmaceutical environments, as well as focused philanthropic endeavors.

Skills & Abilities:

- Medical leadership for oncology drug development, translational clinical trials, biomarkers, and precision medicine
- Development and leadership of translational trials with global & U.S. regulatory intent
- Product/trial late and early-stage (first-in human) drug development (Genentech/Roche & Mayo Clinic and Bolt Biotherapeutics)
- Leadership in multiple NCI (National Cancer Institute) projects and committees
- Excellent Communicator: Influential interactions with academic thought leaders, investigators, cooperative groups, and other clinical stakeholders
- Media trained to represent the Institution/Company and its programs to external audiences, including the investment, medical and regulatory communities, as well as pharmaceutical or biotechnology industry collaborators/partners
- Fostering a corporate culture for ethical & scientific rigor for decision-making
- Creation of innovative and collaborative partnerships (ie, Stand Up to Cancer, MD Anderson Cancer Center, American Association for Cancer Research (AACR), imCORE (Immunotherapy Centers of Research Excellence)
- Open and transparent leadership, goal and people-oriented, innovative, collaborative, visionary, inspirational, accountability

Bolt Biotherapeutics, Inc., Chief Medical Officer April 2020 – present

- Responsible for overall leadership, oversight, and management of clinical, regulatory, pharmacovigilance, biostatistics, and medical affairs activities
- Responsible for the strategy, direction, fiscal planning, and execution of clinical development plans
- Directs the development of clinical/translational strategies and plans to integrate Bolt's clinical candidate therapeutics into the standard practice of oncology/hematology malignancies
- Provides oversight for clinical aspects of regulatory strategies and interactions with Health Authorities
- Leads interactions with academic thought leaders, investigators, cooperative groups, and other clinical stakeholders
- Oversees the analysis and interpretation of clinical trial data and the reporting of clinical trial results
- Leads the evolution of the clinical organization in terms of vision, culture, and succession, as well as broad effectiveness and reach that is consistent with the Company's mission

Genentech/Roche, Head US BioOncology /Vice President US Medical Affairs 2015 – 2018
Co-leadership Global Cancer Immunotherapy Group
Member, Joint Oncology Leadership Team
Member, Medical Leadership Team

- Led a diverse medical portfolio of hematologic & solid tumor malignancies including strategic and budgetary responsibilities ($200M pre and post commercial trials)
- Comprehensive clinical and translational portfolio spanning investigational & marketed products, integration of biomarkers, scientific collaborations with academic institutions and foundations
- Member of Cancer Immunotherapy Governance Committee, co-leadership for the development of a global cancer immunotherapy group (imCORE) -- a collaborative effort between early drug development, medical affairs, product development, and academic institutions in multiple countries
- Led, mentored & managed a complex organizational team of 150
- Executive member of the Foundation of NIH PACT (Program for Accelerating Cancer Therapies) Immune Biomarker project, representing Genentech
- Assessment and funding of >300 translational trials with multiple investigators in the U.S. and globally
- Leadership for development of 9 phase III registrational with regulatory intent in the U.S.
- Oversight for U.S. BioOncology Advisory Boards (hematologic and solid tumors)
- Led preparation and successful medical launches in the U.S. oncology market including
- Alecensa as second-line and also first-line therapy for patients with ALK+ non-small cell lung cancer
- Perjeta as adjuvant and neoadjuvant therapy for patients with early-stage HER2+ breast cancer
- Tecentriq as second-line and then first-line bladder cancer
- Tecentriq as second-line for refractory non-small cell lung cancer
- Gazyva as first-line therapy for patients with follicular lymphoma
- Venetoclax as second-line therapy for patients with 17p- chronic lymphocytic leukemia
- Rituxan Hycela for the management of multiple hematologic malignancies
- Comprehensive clinical and translational portfolio spanning investigational & marketed products, integration of biomarkers, scientific collaborations with academic institutions and foundations

Mayo Clinic Cancer Center Mayo Clinic 1995 – present

- Assistant Professor, with progression to Professor of Medicine as of 2001; Department of Cancer Biology; Department of Hematology/Oncology
- Authored more than 400 peer-reviewed articles
- Multiple NCI and NIH extramurally funded grants, including R01 grants, until 2015
- Active grant (2015-2020) as Co-Principal Investigator: Department of Defense grant (basic research, development & conducting randomized phase II trial for a newly developed vaccine for patients with triple-negative breast cancer)
- Multiple committee memberships and leadership positions with ASCO, AACR
- Leadership in IDMC (Independent Monitoring Boards) with various pharmaceutical companies addressing targeted and immune therapies, biomarkers, and precision medicine. A select list of them includes Merck, BMS, Amgen, Novartis
- Institute of Medicine (IOM) Committees with goals to offer national recommendations to reorganize the NCI-sponsored Cooperative Groups System, and the use of biomarkers for use of molecularly targeted therapies
- Member in multiple NCI committees, including Board of Scientific Advisors (BSA) and Clinical Trials and Translational Committee (CTAC)
- Group Vice-Chair, Alliance of Clinical Trials in Oncology (NCI-sponsored cancer cooperative group until 2015)
- Deputy Director at Large, Mayo Clinic Cancer Center (2010-2015)

Short Biography

Dr. Perez's career has spanned from her medical school in Puerto Rico, electives while a student at Mt. Sinai Hospital in NY, residency and fellowship training in California, an academic career at Mayo Clinic, and 3 year-period of experience in the biopharmaceutical industry. Moreover, she has been involved in NCI, NIH, IOM, ASCO, AACR committees, added to volunteering in philanthropic and advocacy groups. She is frequently invited to lecture at national and international meetings across the globe. Known for her integration of basic science, trial work, and patient management, Dr. Perez is often a keynote speaker who inspires the health care professional audiences and patients. She has been honored by receiving many scientific and humanitarian awards over the years.

Throughout her career, Dr. Perez developed a wide range of translational clinical trials exploring the use of new therapeutic agents for the treatment and prevention of breast and other cancers. These translational studies started in lung cancer, then breast cancer, biomarker discovery, and applicability to better understand their prognostic and predictive applicability. A salient example of her experience developing and leading practice-changing studies, Dr. Perez was the principal investigator of the NCI-funded N9831 trial, which was one of the pivotal studies that demonstrated the impactful data of adding trastuzumab (Herceptin®) to improve disease-free and overall survival for patients with early-stage HER2-positive breast cancer. This work set a new standard of care for women globally, including leadership in standards for molecular tissue testing. The data from this study were used for regulatory agency approvals globally and provided a platform for educational activities and discussions with a wide range of health care professionals throughout the world.

Her academic work has been extensive, including chairing the NCCTG Breast Committee, serving in multiple committees with the NCI (such as the Board of Scientific Advisors, Clinical Trials and Translational Advisory Committee, amongst others), grant reviewer for the NIH, extensive editorial board and reviewer for multiple journals, participation, and leadership in Independent Data Monitoring Committees, leading the Publication Committee for the Alliance for Clinical Trials in Oncology, membership in Institute of Medicine Committees including the most recent one Use of Biomarkers for Selection of Molecularly Targeted Therapies.

Added to academic and biomedical industry pursuits, Dr. Perez is the co-developer of the 26.2 National Marathon to Finish Breast Cancer (breastcancermarathon.com), with goals to raise funds for underserved women and genomics/immunologic translational cancer research. More than 10,000 families have received assistance from the proceeds and more than $ 4M raised for cancer research.

She has also been involved in multiple diversity leadership initiatives with ASCO and AACR, and currently serves as the Chair of the Health Equity Committee for Stand Up to Cancer. Her passion for advancing science, research, prevention, education, and access to medicines are drivers of her career. With respect for all aspects of the health care system, integrity, and compliance have been pivotal in her path.

Dr. Perez earned her medical degree from the University of Puerto Rico School of Medicine in San Juan and completed her residency in internal medicine at the Loma Linda University Medical Center in California. She served as a general internist in the Division of National Health Services Corps, Los Angeles, and completed her Hematology/Oncology fellowship at the University of California, Davis School of Medicine. Dr. Perez also pursued additional leadership, management, and executive development at The Wharton School of the University of Pennsylvania and Harvard Kennedy School in Boston. Dr. Perez is board certified in internal medicine, medical oncology, and hematology.