

CURRICULUM VITAE

Jane Doe, MD, MS

Personal E-mail: janedoe@gmail.com

POSITIONS & HIGHLIGHTS

9/2024 – Present

Consultant for Clinical Development Strategy (Independent), Oncology

- Working directly with biotech CEO/CSO/CMO on data interpretation, clinical development strategy, and regulatory strategy in oncology drug development

11/2017 – Present

Clinical Assistant Professor of Medicine (Courtesy), Medical Oncology, New York-Presbyterian Weill Cornell Medical College, New York, NY

- Voluntary attending physician supervising medical oncology fellows

10/2023 – 7/2024

Senior Vice President, Global Clinical Development, Oncology

Puma Biotechnology, Los Angeles, CA

- Lead of clinical development for the pipeline of the company, focusing on breast cancer and lung cancer indications of alisertib, working directly with its CEO and Board of Directors

3/2022 – 10/2023

Executive Medical Director, Global Clinical Development, Oncology

Eli Lilly and Company, New York, NY

- Medical lead representing Lilly leadership, in collaboration with SWOG leadership, Merck leadership, and the FDA leadership, for Pragmatica-Lung (phase 3 study of ramucirumab + pembrolizumab in previously treated NSCLC)
- Medical lead for developing lung cancer indications of selpercatinib and ramucirumab

10/2017 – 2/2022

Senior Medical Director, Global Clinical Development, Oncology

Eli Lilly and Company, New York, NY

- Medical lead representing Lilly leadership in collaboration with SWOG/Lung-MAP for various collaborative studies involving ramucirumab
- Medical lead obtaining IND approval by the FDA for selpercatinib
- Medical lead for BLA submission and ODAC preparation of sintilimab
- Medical lead for developing lung cancer indications of selpercatinib, ramucirumab, sintilimab, and pegilodecakin
- Q4 2020 Lilly Innovator Award

2/2015 – 9/2017

Medical Director, Global Clinical Development, Oncology

Eli Lilly and Company, Bridgewater, NJ

- Medical lead obtaining MAA approval by the EMA for ramucirumab
- Medical lead for developing lung cancer indications of ramucirumab

8/2012 – 1/2015

Assistant Professor, Department of Medicine, Division of Medical Oncology

The Ohio State University, Columbus, OH

- Institutional Principal Investigator for 20 clinical studies focused on lung cancer, including phase 1, 2, and 3

7/2011 – 6/2012

Clinical Instructor, Department of Medicine, Division of Hematology and Oncology

University of Wisconsin, Madison, WI

- NIH NRSA T32 physician scientist trainee

EXTERNAL ADVISORY BOARD

US NCI Cooperative Group

2020–2023 Southwest Oncology Group (SWOG) Lung-MAP Company Advisory Board Member

Development strategy of novel regimens in stage IV NSCLC; representing Eli Lilly

SELECTED REGULATORY SUBMISSIONS

Medical Lead

Investigational New Drug Application	Selpercatinib (2021)
Biologics License Application	Alisertib plus endocrine therapy of choice (2024)
Marketing Authorization Application	Sintilimab (2021)
	Ramucirumab (2015)

UNITED STATES PATENT APPROVAL

Inventor

US-11471457-B2 (2022)

Method of treating epithelial growth factor receptor (EGFR) T790M-positive non-small cell lung cancer by administering a combination of a VEGFR-2 antibody and osimertinib

SELECTED CLINICAL STUDIES & HIGHLIGHTS

Phase 1 Studies

- Where I led concept, design, implementation, and publication of primary outcome: I4T-MC-JVDF (NCT02443324), I4T-MC-JVDL (NCT02789345)
- Where I was a Principal Investigator: NP28761 (NCT01871805), AP26113-11-101 (NCT01449461), 200858 (NCT02034123), CO-1686-008 (NCT01526928)

Phase 2 Studies

- Where I led concept, design, and implementation including IND approval: J2G-OX-JZJA (NCT03157128), PUMA-ALI-1201 (NCT06369285)
- Where I led design, implementation, and publication of primary outcome: J1L-AM-JZGC (NCT03382899), J1L-AM-JZGD (NCT03382912)
- Where I led design and implementation: PUMA-ALI-4201 (NCT06095505)
- Where I led concept and design: Lung-MAP S1800A (NCT03971474)

Phase 3 Studies

- Where I led concept, design, and implementation including IND approval: LIBRETTO-432 (NCT04819100; selpercatinib)

- Where I led concept and design: Pragmatica-Lung (NCT05633602; ramucirumab and pembrolizumab), LIBRETTO-431 (NCT04194944; selpercatinib)
- Where I led regulatory submissions after primary readout: REVEL (NCT01168973; ramucirumab; MAA/EMA), ORIENT-11 (NCT03607539; sintilimab; BLA/FDA)

EDUCATION

Undergraduate:

6/1995 – 8/1996	Chemical Engineering Auburn University, Auburn, AL
9/1996 – 6/1999	Bachelor of Chemical Engineering, <i>Magna Cum Laude</i> Minors in Chemistry and Biology University of Minnesota, Twin Cities, MN

Graduate:

6/2001 – 6/2003	Master of Science in Biomedical Engineering Minor in Mechanical Engineering University of Minnesota, Twin Cities, MN
7/1999 – 5/2005	Doctor of Medicine University of Minnesota Medical School, Minneapolis, MN

Post Graduate Training:

7/2005 – 6/2006	Internship, Internal Medicine Virginia Commonwealth University Health System, Richmond, VA
7/2006 – 6/2008	Residency, Internal Medicine Virginia Commonwealth University Health System, Richmond, VA
7/2009 – 6/2011	Clinical Fellowship, Medical Oncology University of Wisconsin Hospital and Clinics, Madison, WI
7/2010 – 6/2012	NIH NRSA T32 Postdoctoral Trainee, Biomedical Engineering/Oncology University of Wisconsin Carbone Cancer Center, Madison, WI

CERTIFICATIONS

ABIM Board Certified in Internal Medicine, 2008 – 2022
ABIM Board Certified in Medical Oncology, 2011 – Present

LICENSURE

Commonwealth of Virginia Medical License, 2008 – 2010 (Expired)
State of Wisconsin Medical License, 2009 – 2013 (Expired)
State of Ohio Medical License, 2012 – 2019 (Expired)
State of New York Medical License, 2017 – 2026 (Active)

SOCIETY MEMBERSHIPS

2009 – Present	American Society of Clinical Oncology
2009 – Present	American Association for Cancer Research
2013 – Present	International Association for the Study of Lung Cancer
2014 – 2015	Southwest Oncology Group

PUBLICATIONS

1. Pre-treatment inflammation induced by TNF-alpha augments cryosurgical injury on human prostate cancer.
2. Fatal Loeffler's endocarditis due to hypereosinophilic syndrome.
3. Intrathoracic malignant peripheral nerve sheath tumor in neurofibromatosis 1.
4. Methicillin-resistant *Staphylococcus aureus* bacteremia due to prostatic abscess.
5. Alterations in the Noxa/Mcl-1 axis determine sensitivity of small cell lung cancer to the BH3 mimetic ABT-737.
6. Clinical use of the low-molecular-weight heparins in cancer patients: Focus on the improved patient outcomes.
7. Pharmacodynamic study using FLT PET/CT in patients with renal cell cancer and other solid malignancies treated with sunitinib malate.
8. RET fusion genes in non-small-cell lung cancer.
9. Alectinib in ALK-positive, crizotinib-resistant, non-small-cell lung cancer: a single-group, multicentre, phase 2 trial.
10. Oncolytic reovirus in combination with chemotherapy in metastatic or recurrent non-small cell lung cancer patients with KRAS-activated tumors.
11. Epidermal growth factor receptor (EGFR) mutations in small cell lung cancers: Two cases and a review of the literature.
12. FIR: Efficacy, Safety, and Biomarker Analysis of a Phase II Open-Label Study of Atezolizumab in PD-L1-Selected Patients with Non-Small-Cell Lung Cancer.
13. Phase 1 Study of the Efficacy and Safety of Ramucirumab in Combination with Osimertinib in Advanced T790M-Positive EGFR-Mutant Non-Small Cell Lung Cancer.
14. Phase 1 Expansion Cohort of Ramucirumab Plus Pembrolizumab in Advanced Treatment-Naive NSCLC.
15. Randomized Phase 2 Studies of Checkpoint Inhibitors Alone or in Combination with Pegilodecakin in Patients with Metastatic NSCLC (CYPRESS-1 and CYPRESS-2).

16. LIBRETTO-432, a phase III study of adjuvant selpercatinib or placebo in stage IB-IIIA RET fusion-positive non-small-cell lung cancer.
17. Case Report: Complete Pathological Response to Neoadjuvant Selpercatinib in a Patient with Resectable Early-Stage RET Fusion-Positive Non-Small Cell Lung Cancer.

CLINICAL STUDIES

Industry-Sponsored Clinical Studies

- 2013–2014 NP28761 (NCT01871805)
 Title: A Phase I/II Study of the ALK Inhibitor CH5424802 in Patients with ALK-Rearranged Non-Small Cell Lung Cancer
- 2013–2014 PUMA-NER-4201 (NCT01827267)
 Title: A Phase 2 Study of Neratinib and Neratinib Plus Temsirolimus in Patients with Non-Small Cell Lung Cancer Carrying Known HER2 Activating Mutations
- 2013–2014 GO28625 (NCT01846416)
 Title: A Phase II, Multicenter, Single-Arm Study of MPDL3280A in Patients with PD-L1-Positive Locally Advanced or Metastatic Non-Small Cell Lung Cancer (FIR)
- 2014 CLDK378A2303 (NCT01828112)
 Title: A Phase III, Multicenter, Randomized, Open-Label Study of Oral LDK378 versus Standard Chemotherapy in Adult Patients with ALK-Rearranged (ALK-Positive) Advanced Non-Small Cell Lung Cancer Who Have Been Treated Previously with Chemotherapy (Platinum Doublet) and Crizotinib
- 2014 1199.93 (NCT01907100)
 Title: Double Blind, Randomised, Multicentre, Phase II Study of Nintedanib in Combination with Pemetrexed / Cisplatin Followed by Continuing Nintedanib Monotherapy versus Placebo in Combination with Pemetrexed / Cisplatin Followed by Continuing Placebo Monotherapy for the Treatment of Patients with Unresectable Malignant Pleural Mesothelioma
- 2014 AP26113-11-101 (NCT01449461)
 Title: A Phase 1/2 Study of the Safety, Tolerability, Pharmacokinetics and Preliminary Anti-Tumor Activity of the Oral ALK/EGFR Inhibitor AP26113
- 2014–2015 200858 (NCT02034123)
 Title: A Phase I Open-Label, Dose Escalation Study to Investigate the Safety, Pharmacokinetics, Pharmacodynamics and Clinical Activity of GSK2879552 Given Orally in Subjects with Relapsed/Refractory Small Cell Lung Carcinoma

2014–2015	CO-1686-008 (NCT01526928) Title: A Phase 1/2, Open-Label, Safety, Pharmacokinetic and Preliminary Efficacy Study of Oral CO-1686 in Patients with Previously Treated Mutant EGFR Non-Small Cell Lung Cancer (NSCLC)
2014–2015	CA209-026 (NCT02041533) Title: An Open-Label, Randomized, Phase 3 Trial of Nivolumab versus Investigator's Choice Chemotherapy as First-Line Therapy for Stage IV or Recurrent PD-L1+ Non-Small Cell Lung Cancer (CheckMate 026)
2016–2021	I4T-MC-JVDL (NCT02789345) Title: An Open-Label, Multicenter, Phase 1 Study with Expansion Cohorts of Ramucirumab or Necitumumab in Combination with Osimertinib in Patients with Advanced T790M-Positive EGFR-Mutant Non-Small Cell Lung Cancer after Progression on First-Line EGFR TKI Therapy
2019–2023	I4T-MC-JVCY (NCT02411448) Title: A Multicenter, Randomized, Double-Blind Study of Erlotinib in Combination With Ramucirumab or Placebo in Previously Untreated Patients With EGFR Mutation-Positive Metastatic Non-Small Cell Lung Cancer
2019–2020	J1L-AM-JZGD (NCT03382912) Title: A Randomized Phase 2 Trial of AM0010 in Combination With Nivolumab vs. Nivolumab Alone as Second-Line Therapy in Subjects With Stage IV / Metastatic Wild Type Non-Small Cell Lung Cancer and Low Tumor Expression of PD-L1
2019–2020	J1L-AM-JZGC (NCT03382899) Title: A Randomized Phase 2 Trial of AM0010 in Combination With Pembrolizumab vs. Pembrolizumab Alone as First-Line (1L) Therapy in Patients With Stage IV / Metastatic Wild Type (WT) Non-Small Cell Lung Cancer and Tumors With High Expression of PD-L1 (> 50%)
2021–2022	J2G-OX-JZJA (NCT03157128) Title: A Study of Oral LOXO-292 in Patients With Advanced Solid Tumors, Including RET Fusion-Positive Solid Tumors, Medullary Thyroid Cancer, and Other Tumors With RET Activation (LIBRETTO-001); Cohort 7
2021–2023	J2G-MC-JZJX (NCT04819100)

Title: LIBRETTO-432: A Placebo-controlled Double-Blinded Randomized Phase 3 Study of Adjuvant Selpercatinib Following Definitive Locoregional Treatment in Participants With Stage IB-IIIA RET Fusion-Positive NSCLC

- 2023–2024 PUMA-ALI-4201 (NCT06095505)
Title: A Study of Alisertib in Patients With Extensive Stage Small Cell Lung Cancer (ALISCA-Lung1)
- 2024–2024 PUMA-ALI-1201 (NCT06369285)
Title: A Study of Alisertib in Combination With Endocrine Therapy in Patients With HR-positive, HER2-negative Recurrent or Metastatic Breast Cancer (ALISCA-Breast1)

Investigator-Initiated Clinical Studies

- 2012–2013 REO 016 (NCT00861627)
Title: Phase 2 Study of REOLYSIN® in Combination With Paclitaxel and Carboplatin for Non-Small Cell Lung Cancer With KRAS or EGFR Activation
- 2012–2013 NCI-2011-03631 (NCT01468896)
Title: Cetuximab and Interleukin-12 in Treating Patients With Head and Neck Cancer That is Recurrent, Metastatic, or Cannot Be Removed By Surgery
- 2012–2013 NCI-2009-01606 (NCT01064921)
Title: Phase I Vorinostat in the Treatment of Advanced Staged Oropharyngeal Squamous Cell Carcinoma
- 2014 13-103 (NCT01813734)
Title: A Phase II, Open-Label Study of Ponatinib, A Multi-targeted Oral Tyrosine Kinase Inhibitor, in Advanced Non-Small Cell Lung Cancer Harboring RET Translocations

NCI-Sponsored Cooperative Group Studies

- 2012–2013 E 1505
Title: Chemotherapy With or Without Bevacizumab in Treating Patients With Stage IB, Stage II, or Stage IIIA Non-Small Lung Cancer That Was Removed By Surgery
- 2012–2013 CALGB 30801

Title: Gemcitabine Hydrochloride or Pemetrexed Disodium and Carboplatin With or Without Celecoxib in Treating Patients With Advanced Non-Small Cell Lung Cancer

- 2012–2013 RTOG 1016
Title: Radiation Therapy With Cisplatin or Cetuximab in Treating Patients With Oropharyngeal Cancer
- 2012–2015 E 5508
Title: Randomized Phase III Study of Maintenance Therapy with Bevacizumab, Pemetrexed, or a Combination of Bevacizumab and Pemetrexed Following Carboplatin, Paclitaxel and Bevacizumab for Advanced Non-Squamous NSCLC
- 2018–2023 Lung-MAP S1800A
Title: Phase II Randomized Study of Ramucirumab and Pembrolizumab Versus Standard of Care in Advanced Non-Small-Cell Lung Cancer Previously Treated With Immunotherapy
- 2022–2023 SWOG S2302
Title: Pragmatica-Lung: A Prospective Randomized Study of Ramucirumab (LY3009806; NSC 749128) Plus Pembrolizumab (MK-3475; NSC 776864) Versus Standard of Care for Participants Previously Treated With Immunotherapy for Stage IV or Recurrent Non-Small Cell Lung Cancer