

## 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) Alisertib plus endocrine therapy of choice (2024)
Biologics License Application	Sintilimab (2021)
Marketing Authorization Application	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; selipercatinib)
- 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, *Magna Cum Laude*  
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 Pegilodexakin 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)<br>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)<br>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)<br>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)<br>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)<br>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)<br>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)<br>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-III A 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 III A 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