John Doe

MD, MPH & TM, MS TR & CI

PERSONAL PROFILE

Motivated, scientifically driven, and result oriented physician-scientist with innovative clinical development and global strategic medical management skills. Trained as a medical oncologist with over 15 years of international drug development experience. Expertise in global drug development, from IND to Phase IV design and execution, approval, medical and regulatory affairs strategic planning in Oncology, Non-Oncology, Infectious Diseases, and Diagnostics.

EXPERTISE

Pharmaceutical Physician: IND, Phase I-IV clinical development, med-affairs, lifecycle management.

Strategic Development: Globalization of development plans, KOL relationship building.

Clinical Team Lead: Global pivotal studies, marketing authorization applications and launch preparation.

Medical: Study design, IB, CSR, Common Technical Document, SUSAR.

Therapeutic Areas: Bio-oncology, Infectious Disease, Diagnostic Development.

WORK EXPERIENCE /POSITIONS HELD

Genentech, South San Francisco, CA **December 2007 - November 2010**
Senior Medical Director

Medical Director at Genentech on KADCYLA, an antibody-drug-conjugate designed for HER2 over expressing cancers. Included phase I through phase III international trial development. Expertise in the globalization of oncology development plans and global KOL relation building. Designed phase I - III studies. Proficiency in study design, IB, CSR, Common Technical Document, and SUSAR.

Merrimack, Cambridge, MA **November 2010 - December 2011**
Senior Medical Director

Clinical Lead for oncology therapeutic agents: MM-302 (IND/Phase I), MM-111 (Phase I/Phase II), and MM-141 (IND). Clinical Lead for an imaging diagnostics agent MM-DX-929 (IND). Global strategic clinical development, regulatory/medical affairs, and risk management responsibilities.

Agios, Cambridge, MA **December 2011 - July 2018**
VP, Head of Clinical Development *(February 2013 - July 2018)*

Therapeutic areas include cancer metabolism and inborn errors of metabolism/rare genetic diseases in multiple large and ultra-rare cancer and non-cancer indications. Clinical programs included TIBSOVO, IDHIFA, PYRUKYND, and Vorasidenib. Accountable for Clinical Oncology Development, Clinical Operations, Regulatory, and Clinical Medical Writing. Led the FDA submissions for both TIBSOVO and IDHIFA in AML and MDS.

Infinity Pharmaceuticals, Cambridge, MA **July 2018 - August 2019**
CMO

Responsible for the Phase 1 and 2 developments of IPI-549 in solid tumors.

Infinity, Cambridge, MA **August 2019 - June 2023**
Board of Directors

Served on the Research and Development Subcommittee.

Foghorn, Cambridge, MA **August 2019 - September 2023**
CMO

Built the clinical development team. Therapeutic areas include solid and liquid tumors. Therapeutic modalities include small molecules and degraders. Responsible for 3 INDs thru Phase 1 development in AML and MDS, uveal melanoma, and synovial cell sarcoma.

Foghorn, Cambridge, MA **September 2023 to Present**
Clinical Advisor

Clinical advisor for Foghorn's clinical development strategy.

ACADEMIC APPOINTMENTS

Clinical Instructor, **Tulane University Health Science Center** 2002 - 2003

Assistant Professor, **USF/Moffitt Cancer Center** 2005 - 2007

EDUCATION/TRAINING

Education:

- The Haverford School, Haverford, PA 1986 - 1990
- B.S., Georgetown University, Washington, D.C. 1990 - 1994
- M.P.H. & T.M, Tulane School of Public Health & Tropical Medicine, New Orleans, LA 1994 - 1999
- M.D., Tulane University Medical School, New Orleans, LA 1995 - 1999
- M.S., Clinical Investigation, University of South Florida, FL 2006 - 2009

Post Graduate Training:

- Resident, Internal Medicine. Tulane University Health Science Center 1999 - 2002
- Chief, Internal Medicine. Tulane University Health Science Center 2002 - 2003
- Fellow, Hematology and Oncology. Moffitt Cancer Center 2003 – 2006

AWARDS, HONORS, MEMBERSHIPS IN HONOR SOCIETIES

- Medical Center of Louisiana, Intern of the Year Nominee, 1999
- John Her Musser Prize for Scholarship in Medicine, 2000
- Owl Club Award, Internal Medicine Intern, 2000
- Arnold P. Gold Foundation Humanism & Excellence in Teaching Award Owl Club Award, Honorable Mention, Internal Medicine Resident, 2001
- LMS Direct Research Foundation, Excellence in Care Nominee, 2007
- Present member of the American Society of Hematology
- Present member of the American Society of Oncology

PUBLICATIONS

1. Clinical pharmacokinetics and pharmacodynamics of ivosidenib in patients with advanced hematologic malignancies with an IDH1 mutation.

2. Phase I Study of the Mutant IDH1 Inhibitor Ivosidenib: Safety and Clinical Activity in Patients With Advanced Chondrosarcoma.

3. Ivosidenib induces deep durable remissions in patients with newly diagnosed IDH1-mutant acute myeloid leukemia.

4. Safety and activity of ivosidenib in patients with IDH1-mutant advanced cholangiocarcinoma: a phase 1 study.

5. Clinical pharmacokinetics and pharmacodynamics of ivosidenib, an oral, targeted inhibitor of mutant IDH1, in patients with advanced solid tumors.

6. Effect of itraconazole, food, and ethnic origin on the pharmacokinetics of ivosidenib in healthy subjects.

7. Enasidenib, an inhibitor of mutant IDH2 proteins, induces durable remissions in older patients with newly diagnosed acute myeloid leukemia.

8. Pharmacokinetics, absorption, metabolism, and excretion of [^{14}C]ivosidenib (AG-120) in healthy male subjects.

9. Isocitrate dehydrogenase 1 and 2 mutations, 2-hydroxyglutarate levels, and response to standard chemotherapy for patients with newly diagnosed acute myeloid leukemia.

10. Phase 1 Single- and Multiple-Ascending-Dose Randomized Studies of the Safety, Pharmacokinetics, and Pharmacodynamics of AG-348, a First-in-Class Allosteric Activator of Pyruvate Kinase R, in Healthy Volunteers.

11. Clonal heterogeneity of acute myeloid leukemia treated with the IDH2 inhibitor enasidenib.

12. Durable Remissions with Ivosidenib in IDH1-Mutated Relapsed or Refractory AML.

13. Enasidenib in mutant *IDH2* relapsed or refractory acute myeloid leukemia.

14. A small molecule inhibitor of mutant IDH2 rescues cardiomyopathy in a D-2-hydroxyglutaric aciduria type II mouse model.

15. Characteristics, clinical outcome, and prognostic significance of IDH mutations in AML.

16. IDH2 mutation-induced histone and DNA hypermethylation is progressively reversed by small-molecule inhibition.

17. Isocitrate dehydrogenase 1 (IDH1) mutation in breast adenocarcinoma is associated with elevated levels of serum and urine 2-hydroxyglutarate.

18. Circulating oncometabolite 2-hydroxyglutarate is a potential surrogate biomarker in patients with isocitrate dehydrogenase-mutant intrahepatic cholangiocarcinoma.

19. Serum 2-hydroxyglutarate levels predict isocitrate dehydrogenase mutations and clinical outcome in acute myeloid leukemia.

20. Targeted inhibition of mutant IDH2 in leukemia cells induces cellular differentiation.

21. Prospective serial evaluation of 2-hydroxyglutarate, during treatment of newly diagnosed acute myeloid leukemia, to assess disease activity and therapeutic response.

22. HER2-targeted liposomal doxorubicin displays enhanced anti-tumorigenic effects without associated cardiotoxicity.

23. Clinical implications of pathophysiological and demographic covariates on the population pharmacokinetics of trastuzumab emtansine, a HER2-targeted antibody-drug conjugate, in patients with HER2-positive metastatic breast cancer..

24. Phase II study of sunitinib malate, a multitargeted tyrosine kinase inhibitor in patients with relapsed or refractory soft tissue sarcomas. Focus on three prevalent histologies: leiomyosarcoma, liposarcoma and malignant fibrous histiocytoma.

25. Current issues in adolescent and young adult cancer survivorship.

26. Therapeutic potential of directed tyrosine kinase inhibitor therapy in sarcomas.

27. Practical issues of intraoperative frozen section diagnosis of bone and soft tissue lesions.

28. Rhabdomyosarcoma of the maxillary gingiva.