

Wen Jin Wu, MD, PhD

Senior Investigator, Laboratory of Molecular Oncology

Research program focused on HER/ErbB receptor tyrosine kinases and downstream pathways in breast cancer progression and HER2-targeted therapies:

- Investigating the roles of HER2/ErbB2, Rho GTPases and VPS34 (class III PI3K) in cancer progression
- Optimizing therapeutic strategies for trastuzumab and ado-trastuzumab emtansine (licensed anti-HER2 antibody-based therapies)-resistant breast cancers
- Elucidating mechanisms of toxicities induced by trastuzumab and ado-trastuzumab emtansine, and enhancing safety profiles for HER2-targeted antibody therapeutics

Research critically relevant to safety and efficacy of oncology targeted therapies

Wen Jin Wu, MD, PhD

- Member, Biological Research Coordination Council, OBP&CBER, FDA
- Vice-Chair: CDER Committee for Advanced Scientific Education (CASE), 2010-11
- Mentor: NCI/FDA Interagency Oncology Task Force
- Internal funding awards (7 competitive grants): CDER Critical Path; FDA Office of Women's Health
- Published 34 research/review articles and 4 book chapters
- CDER nominee: FDA Scientific Achievement Award, Excellence in Laboratory Science (pending)
- Invited/keynote speaker, national and international meetings
 - Session chair/moderator
- Editorial board member (3 journals)
- Ad hoc peer reviewer:
 - Scientific Journals (including Cancer Research, Oncogene, JBC, mAb, Cancer letter, European Journal of Cancer)
 - Intramural NIH tenure track scientific program review
 - Scotland Government Chief Scientist Grant
- President: Society of Chinese Bioscientists in America: DC and Baltimore Chapter (2016-17)
- AACR Selection Committee, WICR Charlotte Friend Memorial Lectureship

Dr. Wu: Laboratory progress since Site Visit, January 2016

- Three peer reviewed primary research publications:
 - Mohan N, et al. *Oncotarget*, July 2016, DOI: 10.18632/oncotarget.10469.
 - Mohan N, et al. *Mol Cancer Ther* 2016;15:1321-1331.
 - Yan H*, Endo Y*, et al. *Mol Cancer Ther* 2016;15:480-490. (*equal contribution)
- Grant funding: FDA Office of Women's Health (FY2016 and FY2017) - \$280,000 (competitive)
 - Established collaboration with clinical investigators at MGH, Harvard Medical School to investigate potential biomarker (cMLC1) for trastuzumab-induced cardiotoxicity
- Invited speaker: 12th Annual PEGS Boston (May, 2016)
- Book chapter manuscript: "Trastuzumab-induced cardiotoxicity and its impact on the development of ErbB family receptor-targeted agents"
- Established technology in lab for generation of bispecific antibodies
- Established T-DM1-resistant breast cancer cell lines

Dr Wu: Regulatory responsibilities and accomplishments since Site Visit, January 2016

- Invited speaker at International meeting: 6th World ADC Berlin 2016: Regulatory perspective on the requirements for successful ADC drug development. Feb. 8-10, 2016, Berlin, Germany
- Leader of team that drafted internal regulatory policy document: Recommended practice for antibody-drug conjugates
- Primary product reviewer for multiple new molecular entities (preIND, IND, IND amendments, and biosimilar, EOP2 and preBLA meeting packages)
- Continued mentorship and oversight of regulatory review performed by laboratory members (2 current staff fellows)