

Mansfield-PhRMA Research Program 2024 Participant Biographies

Dr. KIDA Kumiko

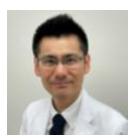


Dr. Kumiko Kida is an Associate Medical Director of the Department of Breast Surgical Oncology at St. Luke's International Hospital, Tokyo. She is an attending breast surgeon and a board-certified clinical geneticist. She is one of the leaders of the Hereditary Breast Cancer Guideline Committee and a member of the Risk Prediction Working Group in the Japanese Breast Cancer Society. On the research front, she is involved in the planning and execution of clinical studies on breast cancer, collaborative translational research projects, and serves

as the institutional principal investigator for clinical trials as well as the facility representative for clinical trial groups. She is currently engaged in ongoing translational research projects with teams from MD Anderson Cancer Center and the University of Hawaii.

Dr. Kida holds an MD and PhD from Yokohama City University and completed her surgical training and fellowship at St. Luke's International Hospital. She completed her postdoctoral research fellowship in the Department of Breast Medical Oncology at the University of Texas MD Anderson Cancer Center.

Dr. MINAMISAWA Masatoshi



Dr. Masatoshi Minamisawa is an Assistant Professor of Cardiovascular Medicine at Shinshu University School of Medicine and a Research Collaborator at Brigham and Women's Hospital and Harvard Medical School. He graduated from Shinshu University in 2007 and worked at Shinshu University Hospital and Shinshu Ueda Medical Center, completing an internal medicine residency and a general cardiology fellowship. He obtained his Doctor of Medicine degree, specializing in clinical research on ischemic heart disease, heart failure, and

echocardiography, in 2016. He then worked as a postdoctoral fellow in the Cardiovascular Division (Professor Scott D. Solomon's lab) at Brigham and Women's Hospital and Harvard Medical School from 2017 to 2021. He returned to Shinshu University and joined the faculty in 2022. He collaborates with both domestic and international clinical trial groups to conduct research aimed at advancing heart failure care, serving as a site investigator or sub-investigator.

Dr. NAKAYAMA Tojo



Dr. Tojo Nakayama is a Project Associate Professor of Neurology and Neurological Science at the Tokyo Medical and Dental School. He is a physicianscientist with expertise in pediatric neurology and genetics. He completed pediatric neurology training at the National Center for Neurology & Psychiatry (NCNP). After earning his PhD in molecular genetics research on intractable epilepsy at RIKEN, he spent eight years at Boston Children's Hospital as a postdoc, working on drug discovery programs for pediatric epilepsy disorders.

Since relocating to Tokyo Medical and Dental University in 2022, Tojo Nakayama has been engaged in setting up the N-of-1 drug discovery research program in Japan.

Dr. OGURA Koichi



Dr. Koichi Ogura is Head of the Department of Musculoskeletal Oncology and International Clinical Development at the National Cancer Center Hospital. He has trained in the fields of musculoskeletal oncology as an orthopaedic surgeon, and completed his graduate PhD work at The University of Tokyo and National Cancer Center (Tokyo, Japan) by focusing on comprehensive characterization of the sarcoma genome using the NGS-based approach. This experience as well as extensive clinical experience as an orthopaedic oncologist has provided him

with a deep understanding of sarcoma biology and urged him to choose a postdoctoral career as a research fellow in the Department of Molecular Pathology, Memorial Sloan Kettering Cancer Center. He has developed an innovative approach to apply CRISPR-Cas9 genomic editing to generate model systems to study functional significance and therapeutic implication of clinically relevant molecules which was identified in MSK-IMPACT in Ewing sarcoma.

He is currently appointed as a head surgeon in the Department of Musculoskeletal Oncology and his duties include clinic, operating room, and several basic and translational research projects on sarcoma in collaboration with laboratories at the National Cancer Center Research Institute and some pharmaceutical companies.

Dr. OKAZAKI Atsuko



Dr. Atsuko Imai-Okazaki, M.D., Ph.D., M.P.H., an Associate Professor of Diagnostics and Therapeutics of Intractable Diseases, Juntendo University, obtained her M.D. degree from Kobe University in 2005 and subsequently received a Ph.D. degree in medicine from Osaka University and M.P.H. degree from University of Manchester in the UK. She is a cardiologist and a specialist in clinical genetics. Dr. Okazaki obtained the skills of bioinformatics, biostatistics, and statistical genetics at McGill University, Baylor College of

Medicine, Harvard Medical School and Rockefeller University.

By combining statistical genetics, clinical genetics and computer science, Dr. Okazaki developed a novel statistical method to prioritize sequence variants using Hamming distance. One of the clinical applications of her method is a mitochondrial disease cohort in Japan. She has assessed the relationship between long-term prognosis and genetic background of mitochondrial diseases. Her group also discovered a novel therapeutic agent that improved heart function by increasing mitochondrial energy production.

Dr. OKITA Yasutaka



Dr. Okita, Assistant Professor of the Department of Medical Center for Translational Research, Osaka University, is deeply passionate about medical innovation. To that end, he plays three roles at Osaka University. First, as a project manager of R&D section, he supports the practical application of basic research discoveries. To date, he has assisted about 20 seeds to develop in vitro diagnostics, small molecule drugs, gene therapies and cell therapies, and he has a particular interest in supporting start-up companies. Second, as a

rheumatologist, he examines approximately 70 patients every week and serves as the principal or coinvestigator for several clinical studies and trials. Last, as a researcher, he carries out projects such as artificial intelligence development, basic research unraveling the mysteries of autoimmune diseases, and cohort studies as clinical research.

His goal is the improvement of medical care and the development of a curative treatment for autoimmune diseases. His vision drives his commitment to these diverse roles, ensuring that breakthroughs in research translate into real-world medical solutions.

Dr. SUDO Kazuki



Dr. Sudo graduated from Niigata University School of Medicine in 2006 and joined St. Luke's International Hospital in 2006, where he received initial and specialized surgical training. In 2012, he obtained a Board Certification in Surgery. The same year, he began studying at MD Anderson Cancer Center as a postdoctoral fellow in GI Medical Oncology for research on gastrointestinal cancers.

When he returned to Japan in 2014, he moved to the National Cancer Center Hospital to continue his clinical and research work in medical oncology. In 2017, he obtained a board of medical oncology. In the same year, he became a staff member in the Department of Breast and Oncology at the same hospital. At the same time, he concurrently assumed a position at the Rare Cancer Center. In 2020, he was promoted to head of physicians at the Department of Breast and Oncology (now the Department of Medical Oncology), with the concurrent appointment of Director of the Translational Research Promotion Office, International Development Division. In 2021, he was appointed the Director of the Office of Advanced Medical Care and Cost-Effectiveness Evaluation.

TERADA Mitsumi



Dr. Terada graduated with his MD from the Jikei University in 2009 and obtained a PhD in 2019. From 2011 to 2016, he worked as a surgeon for gastrointestinal cancer, especially for gastric cancer from 2014. He joined the EORTC in 2017 as a medical research fellow and learned methodology of international clinical trials on European basis. At the EORTC, he proposed and organized some collaborative projects and events between JCOG (Japan Clinical Oncology Group) and EORTC, which let him realize the importance and

significance of international collaboration. He is also interested in PRO/QOL research for cancer patients and a chief investigator of an international collaborative study to update the EORTC QLQ STO22, which is a QOL questionnaire for gastric cancer.

In 2019, he was mainly involved in the establishment of Asian Partnerships Office (APO) in Bangkok, Thailand under the ATLAS project and appointed General Manager of APO in September 2021. Since December 2021, he has resided in Bangkok, where has has contributed to the development of partnerships with multiple stakeholders including academic institutions, regulatory agencies and pharmaceutical industries, and the establishment of a governance structure for the ATLAS network.

Observers from AMED, PMDA, and METI

Ms. YOSHIDA Ai

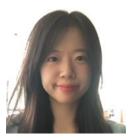


Joining the Japan Agency for Medical Research and Development (AMED) in August, 2017, Ms. Yoshida is currently serving as a manager in the Division of Data Utilization at the Department of Health and Clinical Data since April 2022. Her work focuses on establishing frameworks and platforms to facilitate the secondary use of data generated from publicly funded research. AMED platforms aim for not only utilizing data but also nexus of interdisciplinary research. Prior to this, from August 2015 to July 2017, on secondment from

University of Occupational and Environmental Health, she worked as a section chief in the Division of Health for the Elderly within the Health and Welfare Bureau for the Elderly. She managed the Long-Term Care Insurance Comprehensive Database, which has the anonymized data from long-term care facilities to insurers. Her role involved preparation of connecting this database with another one. She also worked as an assistant professor in the Department of Preventive Medicine and Community Health from July 2015 to July 2017. She used big data to analyze the clinical conditions of sub-acute inpatients.

She is currently a Visiting Researcher at the Department of Preventive Medicine and Community Health at the University of Occupational and Environmental Health. Previously, She completed coursework in the Department of Social Medicine at Toho University School of Medicine without obtaining a degree in March 2015. She holds a Master of Science in Health Care Management from Keio University, earned in March 2008, and a Bachelor of Economy, also from Keio University, obtained in March 2006.

Ms. KUBO Akiho



Ms. Akiko Kubo has been a reviewer of the Office of Pharmacovigilance II in the Pharmaceutical and Medical Devices Agency (PMDA) since 2019. She is involved in post-marketing safety monitoring of vaccine products and blood products. Additionally, she has served as a program coordinator at the Asia Training Center for PMDA and been responsible for providing training courses on pharmacovigilance to foreign regulatory authorities. Through the training courses, she contributes to enhancing mutual understanding of regulations, and

strengthening the collaboration with Asia and other parts of the world. Recently, her role is expanded as a reviewer of drug applications, including vaccine products and blood products from 2024.

She has a Master's degree of Pharmacy from Keio University. Prior to her current position, she completed a pharmacy residency at Juntendo hospital, receiving a comprehensive training experience in pediatric pharmacotherapy.

Ms. KODERA Reina



Ms. Reina Kodera joined the Ministry of Economy, Trade and Industry (METI) in 2020 and currently serves as a Deputy Director in the Bio-industry Division, with a focus on the Commerce and Service Industry Policy group. Initially, Ms. Reina worked in the Policy Division of the Energy Conservation and New Energy Department, where she was involved in the overall management of renewable energy-related policies and energy conservation policies. She then spent her second and third years in the Wind Energy Policy Office, New Energy

Division, where she worked on human resource development policies, international negotiations (with the EU and embassies of various countries), and the establishment of domestic supply chains. From her fourth year to the present, she has been working as a regenerative medicine, cell and gene therapy manager in the bio-technology division, supporting various related R&D and drug discovery ventures. In particular, she has been working on the development and planning of policies to support the development of automated equipment and manufacturing infrastructure in the manufacturing sector, such as CDMOs.