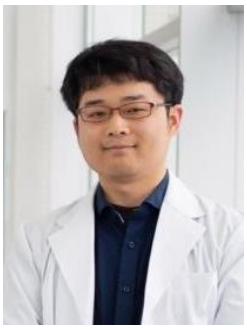
THE MAUREEN AND MIKE MANSFIELD FOUNDATION

Mansfield-PhRMA Research Scholars Program 2022
Participant Biographies

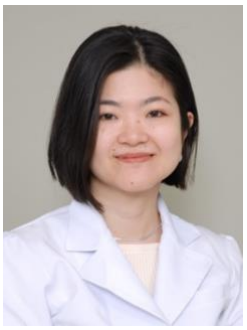
Naohiko Aketa is currently working at the Clinical and Translational Research Center at Keio University Hospital, mainly supporting clinical research on regenerative medicine. From 2014 to 2019, he worked as an ophthalmologist at Keio University and its affiliated hospitals, eventually becoming a cornea fellow and engaged in clinical research on ocular surface diseases, performing numerous cataract surgeries and corneal transplants. Aiming to reduce blindness, he and his colleagues invented a smartphone-attachable slit lamp that can easily diagnose eye diseases and won the top prize at the KEIO Healthcare Venture Contest 2018. Making the most of his experience as a physician and an entrepreneur, he spent three years at the Pharmaceuticals and Medical Devices Agency (PMDA) from 2019 to 2022 reviewing more than fifteen drugs, medical devices, and regenerative medical products before taking his current position.



Kazuki Heishima is a G-YLC (the Young Leaders Cultivating program)-designated Assistant Professor at the Gifu University Institute for Advanced Study (GUiAS). His area of expertise includes experimental pathology and mitochondrial molecular biology. His research focuses on developing novel anti-cancer strategies targeting mitochondrial metabolism. He joins the MMMF-PhRMA program with a strong desire and ambition to develop more efficient and safer anti-cancer agents targeting mitochondria-associated cancer metabolism. Dr. Heishima received a PhD in cancer biology from Gifu University United Graduate School of Veterinary Medicine and attended Yale Cancer Center, Yale University as a postdoctoral associate. He also received a DVM degree from Iwate University and is certified as a Diplomate JCVP (Japanese College of Veterinary Pathologists).

Emi Inagaki is a project lecturer at the Department of Ophthalmology, Keio University School of Medicine. She is a board-certified ophthalmologist and a regenerative medicine physician. Inagaki is currently serving as a principal investigator for clinical trials using stem cells for ocular surface intractable diseases. In addition, she is also a research fellow of the Japan Society for the Promotion of Science (JSPS) at the Department of Physiology, Keio University School of Medicine. Her research areas include disease modelling in cell culture

dishes using stem cells and attempts at age-modifying factor interventions, targeting senescence. Inagaki has published extensively in her field, with her most recent research on in vivo tumorigenicity tests accepted by *Stem Cell Translational Medicine* this year. Dr. Inagaki holds an MD from Hamamatsu University School of Medicine and a PhD in Ophthalmology from Keio University School of Medicine.

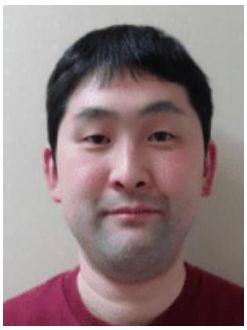


Asuka Kawai-Kawachi is a clinical scientist at the National Cancer Center Tokyo Hospital since March 2022. She works in three departments, the Cancer RNA Research Unit, the Department of Medical Oncology, and the International Translational Research Section. She is primarily responsible for leading basic research projects, as well as implementing and supporting translational research. Kawai-Kawachi completed her training as an oncologist at the National Cancer Center Hospital Tokyo in 2017. During her training, she supported two investigator-initiated clinical trials for uterine sarcoma and clear cell sarcoma. Coming to the conclusion that a solid biological hypothesis was necessary for successful clinical trials, she then began training as a scientist. After one year in the division of Epigenomics at NCCH at 2018, Kawai-Kawachi moved to Gustave Roussy as an ESMO translational research fellow, where she is now leading a project investigating new treatment strategies for desmoplastic small round cell tumors under the supervision of Dr. Postel-Vinay.

Anna Kiyomi is a researcher focusing on clinical pharmacology, drug safety, pharmacoepidemiology, and economic evaluation of health care and medication outcomes. She received a bachelor's degree and PhD in Clinical Pharmacology from the Tokyo University of Pharmacy and Life Sciences. Kiyomi's current project aims to identify the incidence rate and risk factors of the side effect of anticancer drugs using a Japanese nationwide administrative database. She was a visiting scholar at the University of California, San Francisco (UCSF) from 2021-2022 and is affiliated with the Medication Outcomes Center at UCSF. As a joint researcher with UCSF, she conducts pharmacoepidemiologic research regarding COVID-19 treatment outcomes, health disparities, and health policy. Kiyomi also has experience as a community pharmacist, as post-marketing surveillance staff for the Department of Hematology in Tokyo Medical University, and as a clinical trials pharmacist. Now, she is concurrently a visiting researcher at the Institute of Medical Science Hospital at the University of Tokyo and the National Hospital Organization.

Miho Nakajima is a pediatric oncologist at the Department of Pediatric Oncology, National Cancer Center Hospital. She graduated from Miyazaki University in 2002 and received training in general pediatrics and pediatric oncology in Japan and the United States. After returning to Japan, she realized that standard treatments for pediatric cancer, such as anti-GD2 antibody for neuroblastoma, have not yet been established in Japan and that Japan is clearly behind Europe and the United States in the development of new molecular-targeted drugs and other drugs that are known to be effective in the treatment of childhood cancer. The problem of 'drug lag' in rare cancer treatments, including pediatric cancer, is very serious, and Nakajima seeks to help solve this problem by utilizing her experience and the knowledge of physicians in Japan and the United States. Nakajima's long-term goals are to establish translational research and drug development programs to avoid drug lag, provide better treatment for cancer patients, and establish and improve educational curriculums for future researchers in this field.

Yoko Takahashi is a breast surgeon working in collaboration with basic researchers as a member of the NEXT-Ganken program at the Cancer Institute Hospital for the Japanese Foundation for Cancer Research. As a clinician, she performs patient treatments at inpatient and outpatient clinics, while also teaching. Previously, she worked at a Keio University Hospital and focused on drug delivery systems via nanoparticles. She is interested in translational research. Currently, her research focuses on ctDNA and epigenomics to formulate novel strategies for breast cancer treatment. She is a member of the Inflammatory Breast Cancer (IBC) Connect Team with MD Anderson Cancer Center. Takahashi's research for IBC with MDA researchers is ongoing, and she is currently scheduling the implementation of clinical trials. She received her MD from Yamagata University in 2000.



Yuma Yokoi is the section chief of clinical research and educational promotion at the National Center of Neurology and Psychiatry (NCNP). He graduated from Tokyo Medical and Dental University in 2004, with a Bachelor of Medicine and also gained clinical experience in psychiatry. He then conducted clinical research, specifically for Alzheimer's disease patients, at Johns Hopkins University from 2011 to 2013. After returning to Japan, he obtained board certification in psychiatry and geriatric psychiatry. While involved in clinical studies, he became increasingly interested in clinical trials and began a career as a medical reviewer at

PMDA in 2018. Since spring 2022, he has been working at NCNP to support clinical research on treatments and tests that benefit psychiatric and dementia patients, along with educating clinical researchers.

Observers from AMED and PMDA

Mayu Fujita is a reviewer for Pharmaceuticals and Medical Devices Agency (PMDA). She graduated from the Nagoya City University Graduate School of Pharmaceutical Sciences with a master's degree in Pharmacy in March of 2010. After graduation, she joined PMDA where she worked on post-marketing safety measures for six and a half years, with a specific expertise in digestive drugs, and then for 3 years in the regulatory review of anti-infective drugs. Since January 2020, Fujita is doing her second stint in the post-marketing safety measures department, in charge of oncology drugs. Her work involves analyzing adverse drug reports and reviewing medical literature from pharmaceutical companies and healthcare professionals to determine if any further safety information is needed on drug packaging.

Naoko Kojima is Deputy Manager of the Office of International Collaboration in the Department of International Strategy at AMED. Since she joined AMED in 2017, she has been responsible for funding programs in Asia and the Pacific region, such as the e-ASIA Joint Research Program and the Strategic International Collaborative Research Program (SICORP) with Singapore, Australia, and other countries. Before joining AMED, she worked as an Assistant Professor at the Department of Research and Development of Next Generation Medicine at Kyushu University and later engaged in nine years of data management and statistical analysis in the clinical developmental phase in the pharmaceutical and medical device industry, including at CRO and Johnson & Johnson K.K. Kojima holds a Master of Professional Studies in Bioenvironmental Engineering from Cornell University (USA) and a PhD in Medicine from Fukuoka University in Japan.