

# 4<sup>th</sup> US – Japan Clinical Trials in Oncology Workshop

Thursday June 9<sup>th</sup>, 2016

This workshop is intended to assist young investigators in all aspects of designing a scientifically compelling, hypothesis driven clinical trial research study for novel drug development. The workshop is follow-on to the previous three workshops, Japan-US Clinical Trial Workshop in DC in June 2010, Sep 2013, and April 2015. Attendees will review key concepts underlying cancer therapeutic clinical trials and facilitate networking among U.S. academia investigators, NCI, MHLW, Pharmaceutical industry, Japanese academia and cancer center investigators, and Japanese physician researchers visiting the US. The organizers also hope to foster future information exchange and closer collaboration in the following areas:

- Promotion of participation in global clinical studies and leading investigator-initiated oncology clinical trials in Japan
- Introduction to the NCI clinical trials network and NCI Center of Global Health's role in promoting clinical trials methodology for Japanese medical staff, scientists, pharmacists, and statisticians to further clinical development of anti-cancer drugs and to understand the importance of establishing proof of concept clinical trials to facilitate the novel therapeutic product or findings from bench to bedside which will be ultimately developed into randomized efficacy endpoint clinical trials.
- To understand NCI Precision Medicine Initiative driven precision medicine clinical trials which are currently conducted under the NCI leadership throughout the NCI Clinical Trials Network.
- To understand the ongoing research in translational science at the National Center for Advancing Translational Sciences.
- Increase scientific enthusiasm towards clinical trials among medical staff, and provide instruction in the design of meaningful and successful clinical trials in oncology
- Introduce translational research and clinical trials as a career development issue in oncology in Japan and the US.
- To build a network for discussing and promoting oncology clinical trials in Japan. This network will include Japanese physician scientists, workshop faculty members from various institutions, and other officials interested in promoting cancer clinical trials in Japan.

Sponsor:

- Embassy of Japan in the United States of America

Schedule:

Workshop	Date: June 9, 2016 Time: 9:30 am - 17:00 pm (Reception following, 17:15 pm - 19:00 pm) Place: Japan Information and Culture Center, Embassy of Japan, Washington DC. 1150 18 <sup>th</sup> St NW Washington DC 20036 <b>(202)238-6900</b> <a href="http://www.us.emb-japan.go.jp/jicc/">http://www.us.emb-japan.go.jp/jicc/</a>
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14:40- 15:05 pm	2-3) How does MHLW support Japanese investigator initiated clinical trials, which are conducted in multi-institutions? Does Japanese government continue to support non IND investigator initiated clinical trials? (tentative title)	Dr. Tatsuya Suzuki (MHLW)
15:05- 15:30 pm	2-4) AMED future plan in supporting Japanese investigator initiated clinical trials in oncology: bridging Pharma and Academia investigators (tentative title)	AMED
15:30- 15:55 pm	2-5) Precision Medicine Initiative in Japan (tentative title)	Dr. Masayuki Nagahashi (Niigata University)
15:55- 16:10 pm	Coffee Break	
16:10- 17:10 pm	2-6) Q &A: Speakers on the stage with 2 moderators	Dr. Takabe and Dr. Takebe
17:10- 17:20 pm	Wrap up and Closing Statement	Dr. Takabe Mr. Harada (Embassy of Japan)

#### Connecting Reception: JICC Hall Way

17:30 pm- 19:00 pm	Opening Remarks	Mr. Kanji Yamanouchi (Minister for Economic Affairs, Embassy of Japan)
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#### Points of discussion at the last session:

- Oncology clinical trials and career development in Japan
- Case studies only provide anecdotal reports, need prospective studies to test the hypothesis
- Conducting the clinical trial will provide the best opportunity to translate the laboratory findings into clinical phase
- Lack of training opportunities or lack of environment for the investigators to design and conduct an investigator initiated clinical trials (IIT) which are to be proof of principle (POC) clinical trial with incorporation of correlative studies (exploratory, integrated, and integral biomarkers) in collaboration with basic scientist, translational scientist, and clinical scientist. It is crucial to collaborate and work as a team to design and conduct state of the art biomarker driven trials.
- Competitive government funding to conduct IIT.
- Lack of translational scientist with expertise in assay development which can be used as validated and fit for purpose assay.
- Awareness of the importance of pre-analytical assay development in clinical trials
- Need sufficient number of oncologist or investigators with expertise in clinical trials and translational research to design the trials that can answer the scientific question
- Lack of enthusiasm for clinical trials due to basic science focus of medical research in Japan
- Lack of infrastructure support by the government grant and contract support for clinical trials

- Lack of manpower (logistic staffs such as coordinators) to conduct clinical studies
- Regulations and restrictions on advertisement of clinical trials to the public
- The clinical trial groups supported by the government funding are not able to use novel agents or unable to receive any additional funding from industry- mainly phase 3 studies cannot include new agents to be tested – need for central government organization to provide novel agents? – need for regulation to be changed?

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