Form 3-3

Japan-U.S. Brain Research Cooperation Program
Information Exchange Seminar Program FY2024: Report

Research Field: _____4_____

1. Seminar title:

Making Acute Stroke Trials Succeed: Challenges and Potential Solutions

2. Dates, from/to (mm/dd/yyyy)

09/12/2024 – 09/13/2024

3. Location:

Senri Hankyu Hotel Osaka, 2-1 Shinsenri-Higashimachi, Toyonaka City, Osaka, 560-0082, Japan

4. Coordinators

Japanese Coordinator
Name: Haruko Yamamoto
Title: Executive Director
Affiliation: National Cerebral and Cardiovascular Center

U.S. Coordinator
Name: Joseph P. Broderick
Title: Professor of Neurology and Rehabilitation Medicine and Director of Neuroscience Institute
Affiliation: University of Cincinnati College of Medicine

5. Participants:

Japan: Invited participants _11_ people Others _10_ people

(Please give names, titles and affiliations of invited participants)

Name	Title	Affiliation
Koko Asakura	Division Chief	National Cerebral and Cardiovascular Center, Department of Data Science
Etsuko Arita	Professor	Kitasato University Graduate School of Pharmaceutical Science, Division of Medical Psychology
Akiko Ishigami	Division Chief	National Cerebral and Cardiovascular Center, Department of Cerebrovascular Medicine
Hiroyuki Kawakatsu	Executive Director	The Japan Stroke Association
Hiroyuki Kawano	Associate Professor	Kyorin University Hospital, Stroke Center
Masatoshi Koga	Director	National Cerebral and Cardiovascular Center
Kazunori Toyoda	Deputy Director General	National Cerebral and Cardiovascular Center Hospital
Yutaka Hishiyama	Program Supervisor	Japan Agency for Medical Research and Development
Teruyuki Hirano	Deputy Director General	Kyorin University Hospital
Mayumi Fukuda-Doi	Division Chief	National Cerebral and Cardiovascular Center, Department of Data Science
Manabu Minami	Chief Medical Officer	Pharmaceuticals and Medical Devices Agency

U.S.: Invited participants _10_ people Others __1_ people

(Please give names, titles and affiliations of invited participants)

Name	Title	Affiliation
Adeoye, Opeolu	Professor and Chair	Washington University, Department of Emergency Medicine
Afzal, Mariam	StrokeNet Program Officer	NIH/NINDS
Elm, Jordan	Professor	Medical University of South Carolina, Public Health Sciences
Hamasaki, Toshi	Professor	The George Washington University, Biostatistics Center
Janis, Scott	StrokeNet Program Director	NIH/NINDS
Khatri, Pooja	Professor, Vice Chair and Division Director	University of Cincinnati, Department of Neurology and Rehabilitation Medicine
Mistry, Eva	Associate Professor	University of Cincinnati, Department of Neurology and Rehabilitation Medicine
Mocco, J	Professor and Chair	Mt. Sinai Health System, Department of Neurosurgery
Srinivasan, Sudha	Program Director	NIH/NINDS
Wright, Clinton	Associate Director	NIH/NINDS

6. Seminar Outline and Significance:

In this seminar, two main topics were discussed. One was innovative clinical trial methodology, the other was about exception from informed content or emergency consenting procedures.

The first day was dedicated to discussions on the topic of clinical trial methodology. Several biostatisticians and trialists from the US and Japan discussed innovative clinical trial methodology including pragmatic trial designs, platform trials, adaptive designs, and patient-centered outcomes. These presentations were followed by in-depth discussion by all participants regarding feasibility and the obstacles in applying trial innovations to the clinical settings by clinical trial research teams. The participants identified ongoing or proposed trials that have potential for collaboration.

The second day was dedicated to discussions on the topic of exception of informed content or emergency consenting procedures. The US Researchers presented the EFIC (Exception from informed consent) approach and its advantages and weaknesses as well as current state of emergency consent in other countries. Following the discussion regarding risks and benefits of exception from informed consent, Japanese researchers discussed informed consent in the clinical settings of acute stroke trials and the results of an international survey on the regulatory status of informed consent exemption and their plans going forward.

7. Seminar Results and Future Implications:

The meeting was very productive. The first day focused on innovations in trial design and patient-centered and innovative stroke outcomes. Next, novel approaches in trial design and trial outcomes were presented by US and Japanese investigators. Participants recommended a paper summarizing new outcomes approaches such as DOOR, Win-Ratio and utility-rated approaches. Next, a host of various ongoing and recently completed trials were presented. Several proposed trials were identified where collaboration may be possible as these trials are funded in the U.S.

The second day focused on emergency consent. Japanese investigators reported their survey work in Japan regarding patient and investigator attitudes toward consent in emergency settings. They also summarized the history of work underlying Japan’s efforts. A Japanese stroke survivor also participated,

commenting on the clinical trials from the patients' perspective. US investigators presented the history of emergency consent from the 1990s forward and how this differs in various countries. The subsequent discussion was productive with planned ongoing collaborations between US StrokeNet investigators and Japanese investigators as they pursue establishment of emergency consent in Japan for ongoing and future stroke trials.
In summary, this highly productive meeting continued the ongoing collaboration between US an d Japanese stroke investigators first begun in 2010 and which has resulted in multiple acute str oke trials with enrollment in both countries. We expect future collaborations in planned stroke t rials moving forward.

8. Other (implementation issues, feedback, etc.)

A stroke survivor attended the seminar for the first time and joined the discussion. Interpreters had to be arranged for him, and we are grateful that we were allowed to pay for this. Although Patient-Public Involvement (PPI) is encouraged in the clinical research, the language hurdle is high for patients to attend international meetings. We believe that having the cost of interpreters recognized by such research funds will further promote PPI.