

Japan-U.S. Brain Research Cooperation Program  
Information Exchange Seminar FY2010: Report

Field: (4) others

## 1. Seminar title:

**Workshop on Clinical Trial**

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

06/28/2010 – 06/30/2010

## 3. Location:

Hotel Kabuki, San Francisco, California, USA

## 4. Coordinators

Japanese Coordinator

Name: Kazuo Minematsu

Title: Deputy Director General

Affiliation: National Cerebral and Cardiovascular Center Hospital

U.S. Coordinator

Name: Yuko Y. Palesch

Title: Professor

Affiliation: Department of Biostatistics, Bioinformatics and Epidemiology,  
Medical University of South Carolina

## 5. Participants:

Japan: Invited participants 5 people Others 7 people

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

Kazuo Minematsu	Deputy Director General	National Cerebral and Cardiovascular Center
Haruko Yamamoto	Director	National Cerebral and Cardiovascular Center
Etsuro Mori	Professor	Tohoku University Graduate School of Medicine
Nobuyuki Sakai	Director	Kobe City Medical Center General Hospital
Toshio Miyata	Medical Officer	Ministry of Health, Labor and Welfare

U.S.: Invited participants 9 people Others 12 people

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

Joseph Broderick	Research Director	University of Cincinnati
Raul Noguiera	MD	Massachusetts General Hospital
Pooja Khatri	Asst. Prof.	University of Cincinnati
Thomas Tomsick	Professor	University of Cincinnati
Michael Hill	Associate Prof.	University of Calgary
Yuko Palesch	Professor	Medical University of South Carolina
Walter Koroshetz	Director	NINDS, NIH
Natalie Getzoff	Medical Officer	CDRH, FDA
Billy Dunn	MD	CDER, FDA

## 6. Seminar Outline and Significance:

Purpose of the workshop was to (a) exchange information about the opportunities and barriers to conducting collaborative acute stroke clinical trials, including differences in the culture, the health care and regulatory systems, and financial resources; (b) explore the feasibility of collaboration on a currently ongoing acute stroke therapy clinical trials, Interventional Management of Stroke III (IMS III) Trial directed by Drs. Joseph Broderick and Thomas Tomsick at the University of Cincinnati, and Antihypertensive Treatment of Cerebral Hemorrhage (ATACH II) trial directed by Dr. Adnan Qureshi at the University of Minnesota. From US side, the investigators and other staffs who work with these two trials, the medical officers of FDA and the director of NINDS attended. Participants from Japan side were the stroke specialists in the potential participating institutes to the trials and medical officers of Ministry of Health, Labor and Welfare and Pharmaceutical and Medical Device Agency.

## 7. Seminar Results and Future Implications:

In the workshop, the feasibility of collaboration on IMS III was discussed in the first 2 days, and trial protocol details of ATACH II were discussed in the last day.

### A) Discussion results on IMS III

The participants from the both sides confirmed that the difference of the quality of medical care for acute stroke between in US and in Japan was subtle except officially approved dose of alteplase. To enable the participation of Japanese institutes to IMS III, trial protocol amendment was proposed and most of the participants thought that the proposal deserved deeper examination. Trial biostatisticians will examine further consideration to the protocol amendment. Once the protocol amendment will be realized, US and Japanese sides will reopen the discussion about the participation of Japanese institutes.

### B) Discussion results on ATACH II

The US and Japanese investigators had already started the discussion about the trial protocol. They had confirmed that the difficulties to conduct the trial in Japanese institutes would be only administrative and financial problems, because medical care for acute cerebral hemorrhage was almost the same in the both countries. They agreed to maintain close contact to get the solution for the administrative issues, financial matters, and insurance matters.

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

The both US and Japanese participants revealed the high degree of interest to US-Japan collaboration for executing clinical trials in the field of acute stroke care. The Japanese investigators also found the difficulty to complete these two trials only in US, because in these trials the patients should be registered just a few hours after stroke onset. All the seminar members confirmed that the two countries collaboration could drive the trials success.