

# Gene Therapy Clinical Trials Training Course

~ Ongoing Clinical Trials in Japan~



Date: July 20, 2019 (13:00 -17:00)

Venue: The University of Tokyo Hongo Campus  
Sanjo Kaikan

Sponsor: Japan Society of Gene & Cell Therapy

The fifth training course for gene therapy clinical trials in Japan!

## Program (Sessions are given in Japanese)

### Session I. Regulatory Issues (13:00 -15:00)

1. Ethical guidelines being revised for medical and health researches  
M. Taira (MHLW)
2. Points to consider for quality control of oncolytic virus products  
A. Okamoto (PMDA)
3. Points to consider for quality control of *ex vivo* gene therapy products  
Y. Horiike (PMDA)
4. Points to consider for non-clinical assessment of gene therapy products  
K. Maki (PMDA)

### Coffee Break (15:00 -15:15)

### Session II. Clinical Development (15:15 – 17:00)

5. Fundamentals of clinical trial design  
Y. Fujiwara (PMDA)
6. Implementation system of oncolytic virus therapy.  
T. Kojima (NCI East Hospital)
7. Building a clinical CAR-T program – Jichi Medical University Experience  
K. Ohmine (Jichi Med Univ)
8. General discussion  
A. Kume (Jichi Med Univ)