



1st NCCH Workshop on Methods in Oncology Phase I trials and Translational Research

October 15, 2016

National Interchange Conference Building, National Cancer Center Hospital, Tokyo, Japan

NCCH have designed this intensive workshop to increase the reliability and effectiveness of clinical trials by introducing the principles of early clinical trial design. This Workshop is designed for young scientists, medical doctors and pharmaceuticals who are actively involved in basic/clinical cancer research especially in new drug development as well as having an interest in developing a protocol of investigator-initiated registration-directed trials (IIRDTs) in view of new approaches to developing or enhancing agents or combinations of agents against advanced cancers. Both overseas and Japanese experts on each field of cancer research will give intensive lectures regarding the basic elements of “How to write a protocol of IIRDTs” including both the essentials of effective clinical trial designs of therapeutic interventions and regulatory issues in the treatment of cancer for clinical fellow and junior faculty clinical researchers.

Toshio Shimizu, M.D., Ph.D.

Secretariat-General, the 1st NCCH Workshop on
Methods in Oncology Phase 1 trials and Translational Research
Head of Medical Staff, Department of Experimental Therapeutics
National Cancer Center Hospital

Program

- **9:00 - 10:00 Registration**

- **10:00 Opening Remarks**

| **Hitoshi Nakagama, M.D.** (President, National Cancer Center)

- **10:05 Introduction/Overviews**

| **Yasuhiro Fujiwara, M.D.** (Director-General, Strategic Planning Bureau National Cancer Center,
Deputy Director of the Hospital (Research), National Cancer Center Hospital)

- **10:15 - 10:35 Introduction of New NCCH Excellency for New Drug
Development “Towards Best in Asia Phase 1 Center”**

| **Noboru Yamamoto, M.D., Ph.D.** (Director of Experimental Therapeutics, National Cancer Center Hospital)

● **10:35 - 11:15 Session-I**

Yoshihiro Emura, MSc, RPh. (New Drug Regulatory Affairs Department, Daiichi-Sankyo Co., Ltd)

Required knowledges of Pre-IND process for conducting investigator-initiated registration-directed phase I clinical trials

- *The design of nonclinical pharmacology, toxicology, and drug activity studies, including design and potential uses of any proposed treatment studies in animal models; data requirements for IND application; initial drug development plans, and regulatory requirements for demonstrating safety and efficacy.*

● **11:15 - 12:05 Session-II**

Naoko Takebe, M.D., Ph.D. (Investigational Drug Branch, CTEP DCTD, NCI, NIH, USA)

Protocol Design Consideration for Phase 1 Trials

- *Basic concept of protocol design consideration for oncology phase 1 trials*
- *Biomarker-based early phase trials*
- *Special considerations in the design of immunotherapy studies*

● **12:05 - 12:20 Comments from an alumnus of CTEP/NCI/NIH Fellowship Program**

Kan Yonemori, M.D. (National Cancer Center Hospital)

The experience of NCI-CTEP Fellowship Program

● **12:20 - 13:20 Lunch Break**

● **13:20 - 14:10 Session-III**

Daniel SW Tan, M.D. (National Cancer Centre of Singapore, Singapore)

Translational Research - Pragmatic Biomarker Development in Phase 1 Studies

- *Incorporation of biological correlative studies into early clinical trials*
- *Feasibility and reproducibility in biomarker Studies*

● **14:10 - 15:00 Session-IV**

Dejan Juric, M.D. (Termeer Center for Targeted Therapies, Massachusetts General Hospital, USA)

Next-Generation Sequencing (NGS) for Cancer Precision Medicine: a Practical Perspective

- *Introduction and Principles of NGS*
- *Clinical application of NGS – Towards gene-directed drug development and patients selection*

● **15:00 - 15:15 Coffee Break**

● **15:15 - 15:55 Session-V**

Aya Kuchiba, Ph.D. (National Cancer Center Research Institute)

Statistical Consideration for Oncology Phase 1 Trials

Statistical considerations in protocol development: From hypothesis to analysis

Choosing appropriate dose escalation design

- *Design and analysis of phase I clinical trials in cancer therapy*
- *Novel statistical designs in phase I studies*

● **15:55 - 16:35 Session-VI**

Akinobu Hamada, Ph.D. (National Cancer Center Research Institute)

Pharmacokinetic/Pharmacodynamic Analysis in Oncology Phase 1 Studies

• *Principles of clinical pharmacology*

• *PK/PD study design in phase I studies*

● **16:35 - 16:50 Break**

● **16:50 - 17:30 Session-VII**

Teruyo Arato, Ph.D. (Professor, Department of Regulatory Science, Research Center for Cooperative Projects,
Hokkaido University Graduate School of Medicine)

Cancer Immunotherapy- Regulatory Implications and Perspectives of Phase 1 Trials

• *Overviews - Cancer Immunotherapy- Regulatory Implications and Perspectives*

• *CAR-T Cell Therapy*

• *Cartagena Protocol on Biosafety*

● **17:30 - 18:10 Session-VIII**

Hironobu Saito, Ph.D. (New Drug Development Division, Daiichi-Sankyo Co., Ltd.)

Regulatory Issues to Conduct Oncology Phase 1 Trials

• *Understanding the regulatory process*

• *ICH Topics & Guidelines "Q-E-S-M"*

● **18:10 Closing Remarks**

| **Toshirou Nishida, M.D., Ph.D., FACS** (Director, National Cancer Center Hospital)