

治験推進のためのインフラストラクチャー整備

—国立がんセンター中央病院の取り組みについて—*

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**Infrastructure Development and Human Resources Training
for Clinical Trials**

—The National Cancer Center Hospital as an Example—

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Summary

“Research That Serves as a Bridge Between Clinical Research and Clinical Practice” was selected as a strategic science and technology priority in the life sciences field, for the Third Science and Technology Basic Plan that was initiated in 2006 against a background of demands 1) to develop and strengthen the support system, etc., and 2) to prepare a suitable environment to secure and train clinical investigators and clinical research support personnel. With voices warning of the risk of reducing Japan’s international competitiveness in regard to clinical research growing louder, in 2006 the Health and Labour Sciences Research Grants, Research on Clinical Trials’ Infrastructure Development were inaugurated to support “framework development to promote clinical trials”. A study on the “Development of individual health care institution infrastructure models aimed at equally sharing cancer research infrastructure development” (principal investigator: the speaker) at our center was selected in the first year of the project, and as a result it became possible to institute infrastructure development and human resources training for clinical research in our hospital.

Thinking that the training and adequate deployment of co-medical personnel who were clinical trial specialists was essential to the promotion of clinical research, we first attempted to fully implement the operations of a Clinical Trial Coordinating Office (CTCO) that had started out as a virtual in-hospital organization in the fall of 2004. The CTCO is composed of 4 parts: 1) the Data Center Division, 2) various committees, namely, i) the Protocol Review Committee, ii) the Auditing Division, iii) Safety Information Gathering Division, iv) Education Division, and v) Ethics Review Committee Office, 3) the Group Coordinating Division, and 4) the Administrative Division.

Based on this project, we hope to complete the development of a system that enables smooth and rapid implementation of clinical trials of an advanced and challenging nature by the time the Center becomes an independent administrative institute (“Dokuritsu-gyousei-hojin”) in 2010.

Key words

Third Science and Technology Basic Plan, Health and Labour Sciences Research Grants, Clinical Trial, Clinical Trial Coordinating Office