

Graduate School of Medicine, Nagoya University

Clinical Research Education : CRE

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Providing companion support to researchers in order to disseminate research achievement as well as educating clinical researchers

Within the medical field, clinical research is one of the most important academic regions and plays an important role in the search for the causes of diseases, the development of new medical technologies, the formation of evidence necessary for the provision of optimal medical care, etc. In the late 19th century, a cholera outbreak occurred around Broad Street in London, England. John Snow identified the vector pathway, and resolved the situation by closing the well pump. At approximately the same time, beriberi was widespread among the Japanese Navy. TAKAKI, Kanehiro discovered the cause was due to a difference in their diet, and could control its spread by changing meal contents. These events opened the way to modern clinical research, which has become increasingly more important especially in today's world as translational research, which applies basic research in life science to the clinical world, has gained momentum. However, according to the data compiled by the Office of Pharmaceutical Industry Research, Japan ranks in 6th place in the number of papers published in major basic research journals (Nat Med, Cell, J Exp Med) by country during the two-year period of 2013-2014. However, regarding the number of original papers published in major clinical research journals (New Engl J Med, Lancet, JAMA) by country, it ranks 19th. In order for clinical research in Japan to be steadily and appropriately promoted, it is essential, not only for each clinical

researcher to conscientiously engage in clinical research, but also creating and maintaining a supportive environment for such researchers. Under such conditions, Nagoya University Graduate School of Medicine has established the Department of Clinical Research Education: CRE. This department has been launched with the aim of improving research literacy and enhancing the quality and quantity of research capabilities at Nagoya University.

To enhance literacy in medical clinical research at Nagoya University, the department performs two important missions, clinical research education and support for clinical research (Fig.1). Regarding clinical

research education, activities began last year for medical school students in the first year (Medical Science Cafe), fourth year (special lecture "Clinical Trial"), fifth year (Clinical Training I), and sixth year (Clinical Training II). In addition, for graduate students and other clinical researchers with some degree of clinical experience and who are affiliated with the University, "Introduction to the preparation of protocol for clinical trials" and "Clinical Research Seminar" have been prepared as a place for practical education. In "Introduction to the preparation of protocol for clinical trials" participants read a hypothetical clinical research plan and explanatory document in advance, and then discuss points of improvement in a workshop style environment. Although held online due to COVID-19, enthusiastic discussions were held each time and the event has been well received by participants. The "Clinical Research Seminar" is held in cooperation with the Department of Clinical Research Education, Department of Advanced Medicine, Tokai National Higher Education and Research System/Center for Healthcare Information Technology(C-Hit), and the Convolution of Informatics and Biomedical Sciences on Global Alliances (CIBoG). From "Clinical Research A to Z: From Planning to Publication" given in a lecture style, to "Planning Research Using Electronic Medical Chart Information in Hospitals," a participatory style where each participant personally designs and prepares a research plan outline and after which all participants seek to brush up the contents of the plan. The seminar was a complete success, with more than 30 people consistently attending each time. This event will continue to be held in the future, in recognition of the needs of the participants.

Core activities regarding "clinical research support" in clinical research education include reviewing clinical research outlines for all new clinical research subjects, and providing companion support for researchers. As of October 2021, all research plan outlines for new clinical research subjects must be reviewed by the Department of Clinical Research Education prior to submission to the Ethics Review Committee. For researchers, it means there is one more step before actual research begins. However, this advance confirmation is expected to improve the review process by the Bioethics Review Committee and enhance the overall quality of clinical research conducted at Nagoya University.

The current, overall support system for clinical research at Nagoya University is shown in Figure 2. Specifically, the Department of

(Fig.1) Trans-departmental missions of Clinical Research Education

Main Missions

1. Goal-oriented clinical research education and human resource development and their implementation
2. Support for clinical research other than clinical trials and specified clinical studies
(In coordination with Department of Advanced Medicine)
3. Clinical trial design according to the significance and purpose of the research, data quality control and guarantee
4. Establishment of places for co-creation in clinical research which transcend specialization, departments and positions
(In cooperation with MIU and C-Hit)

Other Missions

5. Establishment and maintenance of a registry /cohort and research activation (In cooperation with C-Hit)
6. Implementation of clinical research as needed by society (including PPI)
7. Degree acquisition by research support personnel
8. Acquisition of leadership in domestic and international collaborations
9. Response for diversification and digitalization of clinical research
10. Ensuring the sustainability of a fundamental system of research

MIU : Medical and Healthcare Innovation Unit
C-Hit : Tokai National Higher Education and Research System / Center for Healthcare Information Technology
PPI : Patients and Public Involvement in Clinical Research

Advanced Medicine provides research support for clinical trials and specified clinical studies, while the Department of Clinical Research Education provides research support for other clinical research. The Department of Clinical Research Education has organized an arrangement to support the needs of researchers from research planning and design to quality control and publication after research. This is referred to as "companion support." In fact, many researchers need support at various stages of clinical research, and meetings are held as needed to assist such researchers in their steady advance in their research.

Over time, the direction required for clinical research has rapidly changed. Just looking ahead to the next 5 to 10 years, the list is endless, including strengthening cooperation between industry, government, and academia, promoting preventive medicine and personalized medicine, responding to the diversification of drug and medical device modalities, and digitalization of clinical research, etc. In addition to basic clinical research education for students and graduate students, the Department of Clinical Research Education will continue to take the lead in addressing issues related to clinical research by responding to the changes in times, and striving to enhance the medical clinical research capability at Nagoya University.

(Fig.2) Clinical research support system

