IMSUT Hospital

Center for Translational Research
トランスレーショナルリサーチ・治験センター

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Our primary mission is to support the conduct of clinical trials, particularly sponsor-investigator clinical trials based on Translational Research (TR). Our roles on TR range from providing advice on intellectual property acquisition to preparing for and supporting the conduct of clinical trials. Our center comprises a coordinator section, an administrative section, a data management/biostatistics section, and a project management section.

1. Promotion of Translational Research at IMSUT Hospital

All members of staff.

We have an unwavering commitment to delivering novel therapies through translational research. To advance basic research findings into clinical applications, we offer investigators the following services:

1. Planning research and development (R&D) strategies, including the selection of target diseases, product design planning, and clarification of development pathways;
2. Providing opportunities to consult with appointed patent attorneys regarding the acquisition and maintenance of intellectual property rights, as well as patent strategies;
3. Providing information necessary for the preclinical phase of R&D, including regulatory affairs and preclinical study requirements;
4. Encouraging investigators to consult with regulatory advisors at the Pharmaceuticals and Medical Devices Agency (PMDA) in a timely manner;
5. Participating in meetings between investigators and regulators to support investigators in addressing issues raised during these meetings;
6. Advising on clinical trial design to ensure that feasible and scientifically sound trials are conducted;
7. Reviewing clinical study protocols, informed consent forms, and related documents prior to Institutional Review Board (IRB) review to ensure the quality of clinical trials conducted at the IMSUT Research Hospital;
8. Assigning Translational Research Coordinators (TRCs) to each translational research project during the clinical trial phase. TRCs help patients participating in clinical trials understand study protocols and cope with negative emotions, including fear, confusion, and depression, and also provide support to investigators.

2. Statistics and Quality control in Clinical Trials

Masanori Nojima, Koshi Kataoka, Shiori Sato, Fumitaka Nagamura

We have planned and performed data management, monitoring, and statistical works in clinical trials.

[Data management]: Planning, EDC and CRF preparation, registration, allocation, database management, data cleaning, coding

[Monitoring]: Monitoring for drug management.

[Statistics]: Planning and perform for statistical analyses, Sample size calculation.

3. Support for the investigator-initiated clinical trials under an Investigational New Drug Application

All members of staff

Our mission is to develop efficient approaches for conducting investigator-initiated clinical trials under Investigational New Drug (IND) applications in order to promote translational research. In 2025, we supported five sponsor-investigator–initiated clinical trials through site management and project management, including trial preparation. These clinical trials included: an oncolytic virus therapy for malignant melanoma; an oncolytic virus encoding the bevacizumab gene for glioma; an adjuvant vector vaccine against SARS-CoV-2 for heavily treated patients with B-cell malignancies (conducted at another institution); a gene-modified measles virus vaccine for nectin-4–positive tumors; and dendritic cell therapy for adult T-cell leukemia/lymphoma (ATLL).

4. Management of "Translational Research Program" of Japan Agency for Medical Research and Development.

Miwako Okada, Fumitaka Nagamura

The Ministry of Education, Culture, Sports, Science and Technology launched the "Translational Research Network Program" to promote translational research based on findings from basic science in academia. In 2015, this program was transferred to the Japan Agency for Medical Research and Development (AMED) and has since been expected to support translational research projects, from basic science through the acquisition of intellectual property to the early stages of clinical trials.

In 2025, under this program, we supported 26 basic research projects (20 from institutions other than IMSUT), 8 preclinical studies (2 from institutions other than IMSUT), and 12 clinical studies (5 from institutions other than IMSUT). The number of studies we support has been increasing year by year, necessitating more efficient organizational operations.

5. Statistical consulting for basic research

Masanori Nojima

We provide consulting services for study design and statistical analysis across a wide range of research fields, including clinical research as well as basic medical and biological research. Through these consulting activities, we have collaborated with other members of IMSUT and with researchers at external institutions.

Publications

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6. Fujimori M, Toriyabe Y, Sakakibara N, Nojima M, Makino S; Hokkaido Association of Hospital Dentistry Medication-Related Osteonecrosis of the

Jaw Research Group. Do Healing Rates Differ Between Medication-Related and Medication-Unrelated Osteonecrosis of the Jaw? J Oral Maxillofac Surg. 2025 Sep; 83(9):1143-1156. doi: 10.1016/j.joms. 2025. 05. 023. Epub 2025 Jun 6. PMID: 40550482.

7. Amano K, Fujii T, Sawada A, Nagao A, Nagae C, Nojima M, Suzuki N, Kawano M, Shimura T, Sugao Y, Hattori N, Nogami K. TSUBASA Study: Evaluating Association of Physical Activity and Bleeding Events in People With Haemophilia A Without Factor VIII Inhibitors Receiving Emicizumab. Haemophilia. 2025 Jul;31(4):703-712. doi: 10. 1111/hae. 70070. Epub 2025 Jun 18. PMID: 40534253; PMCID: PMC12311898.
8. Iimura Y, Ishiguro H, Hashimoto H, Nojima M, Oyamada S, Mori K, Ariyoshi K, Kuroda S, Hirakawa S, Fujiwara N, Yokota T, Zenda S, Matsuoka H, Boku N. A randomized, double-blind, placebo-controlled phase III study evaluating the preventive effect of diclofenac cream on capecitabine-related hand-foot syndrome: study protocol of J-SUPPORT2401/JORTC-SUP06 (J-DIRECT). Int J Clin Oncol. 2025 Aug;30(8):1553-1561. doi: 10.1007/s10147-025-02789-z. Epub 2025 May 14. PMID: 40369354; PMCID: PMC12296980.
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