

# Project of Translational and Clinical Research Core Centers

- Department of Clinical Research and Trials
- Division of Clinical Research and Trials
- Office of Regulatory Science and Clinical Research Support

# Grant Programs

Based on the Plan for Promotion of Medical Research and Development prescribed by the government of Japan, AMED promotes integrated R&D in the field of medicine, from basic research to clinical trials, focusing on nine interrelated areas including regenerative medicine and oncology. In addition to ensuring that outcomes are linked through to practical application, it undertakes projects with the aim of comprehensively and effectively establishing and maintaining an environment for this R&D. These projects are conducted on the basis of wide-ranging invitations for proposals from researchers at universities, research institutes, and corporations, as well as from institutions. Proposals received are evaluated appropriately, selecting projects and the researchers to implement them. In order to maximize research outcomes, AMED provides a variety of support, including initiatives for the prevention of research misconduct in order to ensure proper research, support for research institutes working to secure intellectual property, support for corporate alliances targeting practical application, and support for international joint research.

## Current Projects with Corresponding Divisions at AMED

### Nine interrelated Projects supported by Three Ministries

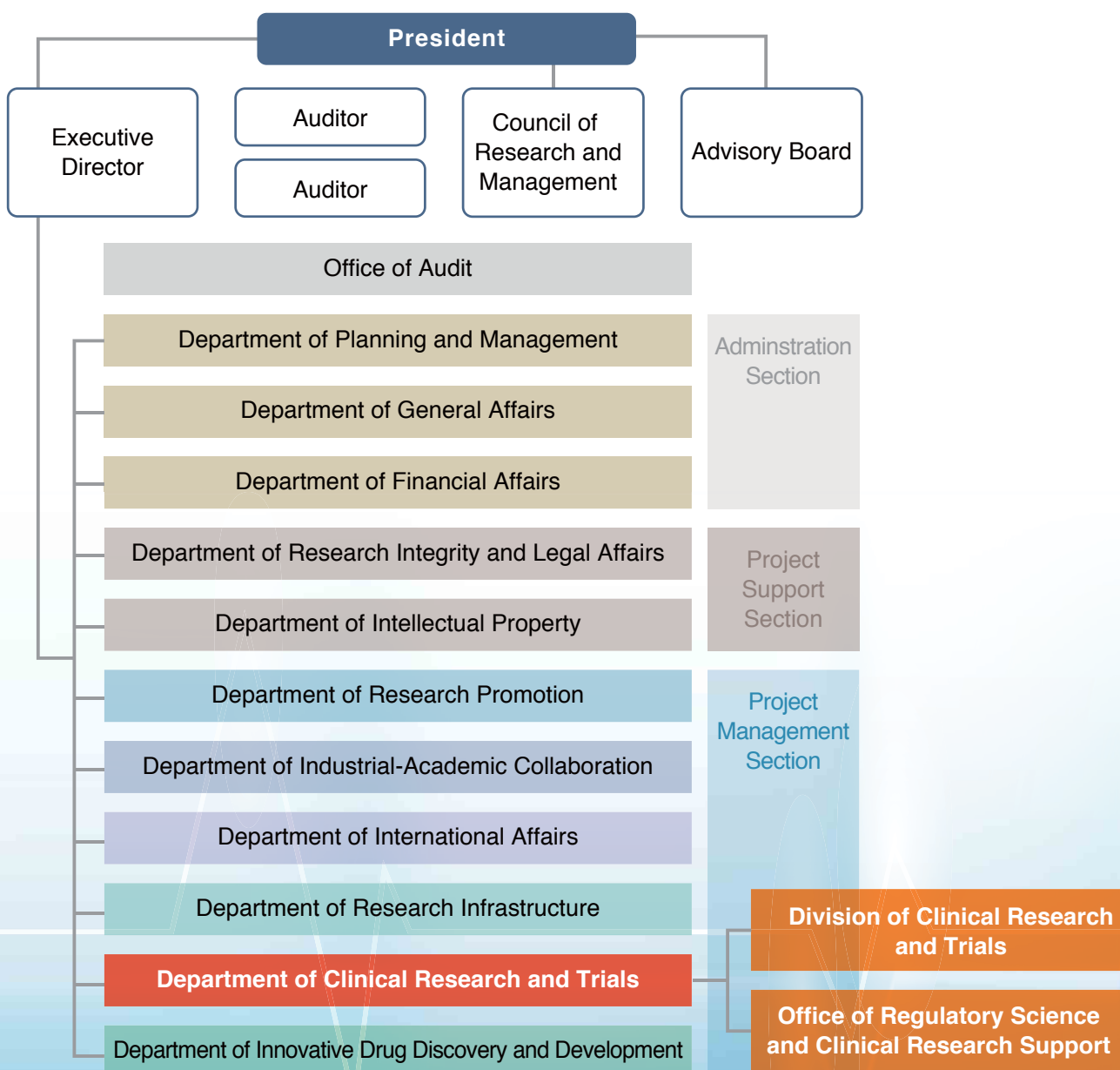
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|---|--|
| 1. Project for Drug Discovery and Development                         | Promotes development of innovative drugs, and strengthens support functions aimed at new drug discovery.   |
| 2. Project for Medical Device Development                             | Develops medical devices that meet medical needs, and establishes / maintains support system therefor.   |
| 3. Project for Japan Translational and Clinical Research Core Centers | Works to strengthen / enhance centers that can achieve seamless implementation, from basic research to practical application, in line with the establishment of the Medical Care Act, and promotes practical application of innovative medical technology.     |
| 4. Japan Regenerative Medicine Project                                | Aims to move new research topics to clinical research stage by the end of FY 2015, and promotes development of regenerative medicine products.   |
| 5. Japan Genomic Medicine Project                                     | Promotes joint research between the national centers for advanced and specialized medicine and BioBank Japan aimed at clinical application.  |
| 6. Japan Cancer Research Project                                      | Stringently selects promising outcomes from basic research and promotes further research aimed at practical application. Feeds data obtained from clinical research and trials back to basic research, accelerating practical application to cancer treatment. |
| 7. Project for Psychiatric and Neurological Disorders                 | Accelerates endeavors aimed at overcoming dementia and other psychiatric disorders.  |
| 8. Emerging /Re-emerging Infectious Disease Project of Japan          | Provides greater promotion of the accumulation and analysis of whole-genome information of pathogens, and links this to identification of drug target sites.   |
| 9. Rare/Intractable Disease Project of Japan                          | Promotes development of innovative drugs, and strengthens support functions aimed at new drug discovery.   |
| 10. Other Projects  | Supports research and development essential to promote health and medical strategies beyond the projects mentioned above.  |

Programs related to the Project for Japan Translational and Clinical Research Core Centers are managed by the Division of Clinical Research and Trials and the Office of Regulatory Science and Clinical Research Support that are positioned under the Department of Clinical Research and Trials.

To construct an integrated medical research and development system that facilitates translation of innovative basic research performed at universities into practical applications, the Division of Clinical Research and Trials does the following: supports research projects for medical devices and drugs in various ways; strengthens core center functions; intermediates between core centers to facilitate these measures; and develops the functions of an academic research organization (ARO) and a system for conducting highly qualified clinical trials compliant with ICH-GCP.

The Office of Regulatory Science and Clinical Research Support focuses on not only training and securing clinical research personnel but also promoting regulatory science research to realize the clinical use of innovative pharmaceuticals, medical devices and regenerative medical products rapidly and safely. Regulatory science is a field of study related to the prediction, assessment and judgement of the quality, efficacy and safety of these products based on scientific knowledge. These researches will provide new tools, standards and approaches to assess the quality, efficacy and safety, and clarify the criteria and scientific standards required for regulatory approval.

## Organization Chart



# Project of Translational and Clinical Research Core Centers

AMED has built an integrated project that unifies and implements projects by the Ministry of Education, Culture, Sports, Science and Technology and the Ministry of Health, Labor and Welfare.

The aim of this project is to construct a system which puts the achievements of innovative basic research at universities into practice seamlessly. It consists of two themes: (1) infrastructure development to fulfill the functions of core centers, such as developing human resources and networking; and (2) promotion of translational research and investigator-led clinical trials aiming for practical application of the basic research conducted at universities.

## Japan Translational Research and Clinical Trials Core Centers



# Japan Translational Research and Clinical Trials Core Centers

Japan Translational Research and Clinical Trials Core Centers promote applied science directed toward the development of drugs and medical devices. This applied science is founded upon basic research seeds developed both in and outside of the core centers. Among others, the core centers develop biomarker assessment facilities, cell processing centers and secure data management centers for clinical trials, thereby supporting the work of pharmaceutical affairs specialists in the areas of biostatistics, project management and intellectual property. Please contact each center directly for detailed information about support services.

	Core Centers	TEL/FAX/E-mail	HP	QR
1	Hokkaido Organization for Translational Research (HTR)	TEL: 81-11-706-6899 FAX: 81-11-706-5025	<a href="http://htr.ctr.hokudai.ac.jp/en/">http://htr.ctr.hokudai.ac.jp/en/</a>	
2	Hokkaido University Hospital, Clinical Research and Medical Innovation Center	TEL: 81-11-706-7429 FAX: 81-11-706-5025	<a href="http://www.huhp.hokudai.ac.jp/english/med01.html">http://www.huhp.hokudai.ac.jp/english/med01.html</a>	
3	Tohoku University Hospital, Clinical Research, Innovation and Education Center (CRIETO)	TEL: 81-22-717-7122 FAX: 81-22-717-7104	<a href="http://www.crieto.hosp.tohoku.ac.jp/">http://www.crieto.hosp.tohoku.ac.jp/</a>	
4	National Cancer Center Hospital East, Clinical Research Support Office	TEL: 81-4-7134-6956 E-mail: EPOC_office@east.ncc.go.jp	<a href="http://www.ncc.go.jp/en/ncce/">http://www.ncc.go.jp/en/ncce/</a>	
5	Chiba University Clinical Research Center (CCRC)	TEL: 81-43-226-2737 FAX: 81-43-226-2629	<a href="http://www.chiba-crc.jp/english/">http://www.chiba-crc.jp/english/</a>	
6	The University of Tokyo Hospital, Translational Research Center	TEL: 81-35-800-9070 FAX: 81-35-800-9071	<a href="http://www.h.u-tokyo.ac.jp/english/">http://www.h.u-tokyo.ac.jp/english/</a>	
7	Keio University Hospital Clinical and Translational Research Center	TEL: 81-3-5363-3961 FAX: 81-3-5363-3293 E-mail: ctr@info.keio.ac.jp		
8	National Cancer Center Hospital, Clinical Research Support Office	TEL: 81-3-3542-2511 ext 5663 E-mail: NCCH_CTM@ml.res.ncc.go.jp	<a href="http://www.ncc.go.jp/en/ncch/">http://www.ncc.go.jp/en/ncch/</a>	
9	National Center for Child Health and Development	TEL: 81-33-416-0181 FAX: 81-33-416-2222	<a href="https://www.ncchd.go.jp/en/">https://www.ncchd.go.jp/en/</a>	
10	National Hospital Organization Nagoya Medical Center, Clinical Research Center (CRC)	TEL: 81-52-951-1111 FAX: 81-52-212-7360 E-mail: aro.office@nnh.go.jp	<a href="http://www.nnh.go.jp/en/aro/">http://www.nnh.go.jp/en/aro/</a>	
11	Nagoya University Hospital, Center for Advanced Medicine and Clinical Research	TEL: 81-52-744-2942 FAX: 81-52-744-1303	<a href="http://www.nu-camcr.org/cms/en/">http://www.nu-camcr.org/cms/en/</a>	
12	Kyoto University Hospital, Institute for Advancement of Clinical and Translational Science (IACT)	TEL: 81-75-751-4899 FAX: 81-75-751-4905		
13	Osaka University Hospital, Department of Medical Innovation, Medical Center for Translational and Clinical Research	TEL: 81-66-210-8289 FAX: 81-66-210-8301	<a href="http://www.hp-mctr.med.osaka-u.ac.jp/english/">http://www.hp-mctr.med.osaka-u.ac.jp/english/</a>	
14	Okayama University Hospital, Center for Innovative Clinical Medicine	TEL: 81-86-235-6504 FAX: 81-86-235-6505		
15	Kyushu University, Center for Clinical and Translational Research (CCTR)	TEL: 81-92-642-4787 FAX: 81-92-642-4528	<a href="http://www.med.kyushu-u.ac.jp/crc/english/">http://www.med.kyushu-u.ac.jp/crc/english/</a>	
16	Kitasato University, Global Clinical Trials Coordinating Center	TEL: 81-35-791-6398 E-mail: global@insti.kitasato-u.ac.jp	<a href="http://www.kitasato-u.ac.jp/global-ctcc/en/">http://www.kitasato-u.ac.jp/global-ctcc/en/</a>	
17	Foundation for Biomedical Research and Innovation, Translational Research Informatics Center (TRI)	TEL: 81-78-303-9108 FAX: 81-78-303-9094	<a href="https://www.tri-kobe.org/koho/documents/TRI_brochure_En_v4.pdf">https://www.tri-kobe.org/koho/documents/TRI_brochure_En_v4.pdf</a>	



# Feature of Japan Translational Research and Clinical Trials Core Centers

## **1 Hokkaido Organization for Translational Research (HTR) /**

### **2 Hokkaido University Hospital, Clinical Research and Medical Innovation Center**

At Hokkaido Organization for Translational Research (HTR), based on project management supported with enriched experiences, we proceed with research development of medicine, medical device, regenerative medicine and in vitro diagnostic medical device. We have achieved productization of several innovative medical devices. Moreover, we actively support development of medicine and clinical studies using bio-bank.

### **3 Tohoku University Hospital, Clinical Research, Innovation and Education Center (CRIETO)**

The aim of CRIETO is to promote practical application of the results in life science R&D through seamless support for basic, translational, and clinical studies and clinical trials. In particular, we are making every effort to develop innovative medical devices. This has, as of now, lead us to support more than 200 research seeds.

### **4 National Cancer Center Hospital East**

National Cancer Center Hospital East focuses on early clinical development of novel anti-cancer drug and devices, and also conducts a nation-wide genome screening network and immune TR consortium in Japan.

### **5 Chiba University Clinical Research Center (CCRC)**

Chiba University Hospital Clinical Research Center strongly believes in its mission, "To improve patient care with scientific leadership and high ethical standards through innovative and collaborative clinical research"

### **6 The University of Tokyo Hospital, Translational Research Center**

The University of Tokyo Hospital is able to offer TR support to researchers in various way, such as arranging every clinical trial at Phase 1 unit which is in-house, manufacturing investigational product at the Cell Processing Center, assistance in pharmaceutical affairs consultation on R&D strategy, intellectual property strategy, planning of clinical trial protocol, etc.

### **7 Keio University Hospital Clinical and Translational Research Center**

Keio University Hospital, located in the middle of Tokyo, is easily accessible from anywhere in Japan and abroad, and makes a research consortium with neighboring metropolitan academic organizations to push translational and clinical researches forward in an efficient way. In addition to the top level of basic researches, especially in regenerative medicine, immunology and oncology fields, our university is consolidating the supporting system of development of scientific outcomes for clinical applications, which allows the ideas ready for proof-of-concept testing in humans to move promptly to early phase clinical trials in well-established high-spec phase I unit in our hospital.

### **8 National Cancer Center Hospital**

National Cancer Center Hospital has most profound expertise in cancer research (drug, devices, cell therapy) including first in human and global Phase 3 trials, supported by world-class diagnosis capabilities (IVR, PET imaging and Microsatellite Instability (MSI)) together with Full-spec ICU, CLIA-compatible NGS and ISO15189 Certified Laboratory.

### **9 National Center for Child Health and Development**

Development of clinical evidence on the treatment and prevention of diseases in children and pregnant women has been behind in Japan. The National Center for Child Health and Development addresses this gap by facilitating collaboration between clinical and research departments, and promotes high-quality medical care through planning, performing and supporting clinical research.

### **10 National Hospital Organization Nagoya Medical Center, Clinical Research Center (CRC)**

The National Hospital Organization (NHO) is an independent administrative institution that administers 143 former national hospitals across Japan. The NHO, which is actively involved in clinical research, and educational activities, has established the largest hospital networks in Japan, consisting of more than 50,000 beds and 60,000 staff members including over 7,700 medical doctors. In addition to our ISO9001/27001-certified data center that has been supporting more than 1,000 medical institutions and 100 prospective clinical trials, we provide comprehensive support for large scale multicenter trials.

### **11 Nagoya University Hospital, Center for Advanced Medicine and Clinical Research**

Under the mission that we develop new medical service for the next generation, Nagoya University Hospital, Center for Advanced Medicine and Clinical Research (CAMCR) provides researchers with the one-stop service to incubate various seeds, to build a sustainable R & D pipeline.

CAMCR is expanding its activity from the Nagoya University to the collaborating academic organizations in Chubu (central-Japan) region to establish the Chubu Regional Consortium for Advanced Medicine (CCAM), ten university hospitals and two national clinical centers clustered in network to deliver the clinical research findings from Chubu to the world.

### **12 Kyoto University Hospital, Institute for Advancement of Clinical and Translational Science (iACT)**

Leading experts and specialists, from a variety of areas of clinical research, work at the Institute for Advancement of Clinical and Translational Science(iACT). The institute provides strong support to highly motivated researchers in their projects, from design to implementation. We have built a network among university hospitals throughout Japan and are actively seeking research proposals and helping drug discovery efforts, placing special emphasis on treatment research in both areas.

The institute is committed to furthering clinical research in Japan by steadily implementing safe, effective and innovative treatment of intractable diseases.

### **13 Osaka University Hospital, Department of Medical Innovation, Medical Center for Translational and Clinical Research**

Osaka University promotes seamless medical innovation by continuous support from Bench to Bedside through various programs such as Translational Research promotion, Cell Processing Facility (CPF) Operation, GCTP Quality Cellbank and more.

#### **14 Okayama University Hospital, Center for Innovative Clinical Medicine**

Okayama University has established the clinical trial contract system, as a base in Mid-west Japan (Chugoku and Shikoku regions) in order to provide continuous support covering from basic research to practical application for innovative drugs and medical devices. The characteristic development fields and advantages of Okayama University are cancer chemotherapy, less-invasive surgery, regenerative medicine, gene therapy, organ transplantation, dental treatment and medical device development.

#### **15 Kyushu University, Center for Clinical and Translational Research (CCTR)**

The Center for Clinical and Translational research in Kyushu University supports and promotes medical innovation. One of its division, Clinical Research Promoting Division, has a role to promote the conduction of high-quality clinical trials inside and outside of Kyushu University Hospital, one of the Clinical Research Core Hospital. The strong points of the center are well organized networks such as the West Japan Academia TR Network (WAT-NeW) consist of 20 universities in West Japan and the Asia Pacific Research and Development Network (ARDENT) consist of more than 140 organization including pharmaceutical companies, as well as outstanding achievements in research fields of cardiovascular diseases, malignant diseases, eye disorders and medical devices.

#### **16 Kitasato University, Global for Clinical Trials Coordinating Center**

Global Clinical Trials Coordinating Center, Kitasato Academic Research Organization, Kitasato University (Kitasato-ARO) has supported more than 50 multi-center clinical trials of variable diseases (especially gynecologic cancer, rare and incurable diseases) in the past decade. Kitasato-ARO functions as a high-quality clinical trial center in compliance with ICH-GCP including study planning, data management, monitoring, auditing, medical writing, and strategic & regulatory consultations.

#### **17 Foundation for Biomedical Research and Innovation, Translational Research Informatics Center (TRI)**

Foundation for Biomedical Research and Innovation (FBRI) has been successfully supporting Japanese academic research organizations (AROs) to promote global clinical trials and global registries for cancers and rare intractable diseases. To establish the global ARO network, FBRI has been also closely communicating with clinical trial supporting organizations and AROs in the United States, Europe and Asian countries.

## Promotion of Global Clinical Trial Implementation

AMED proceeds the Japan-Initiated Global Clinical Trials Development Project to promote Japan's efforts to take initiatives for global clinical trials, mainly focusing on Asia. AMED has selected and supported the core facilities to organize a system to implement plans, act as a liaison between participating institutions and serve as a central IRB, as well as to perform monitoring, data management and inspection for global clinical trials.

As of October 2016, AMED runs a program called the Global Clinical Trial Development Project, in which it selects core centers from among the Core Clinical Research Hospitals to take part in global clinical trials under the legislation. This enables Japan to initiate ICH-GCP-compliant qualified-investigator-led and industry-initiated global clinical trials to be implemented globally in conjunction with the Japan-Initiated Global Clinical Trials Core Centers and Core Clinical Research Hospitals.

## Central IRB

In Japan, Institutional and Ethical Review Boards (IRBs) are based at and serve each organization on an individual basis, a practice that has resulted in causing quality difference among reviews. Also, the use of a single, central IRB is uncommon.

In light of this, in "The Plan for Promotion of Medical Research and Development" (approved by Headquarters for Healthcare Policy, July 22, 2014) it is stipulated to utilize the ARO functions of Innovative Medical Technology Creation Centers, which will serve as bases for various networks, as well as the functions of central ethical review boards and institutional review boards. The stipulation aims to improve the quality of clinical research, including case collection, speed of conduction and cost optimization, and to promote ICH-GCP standards. However, the relevant laws and regulations have not yet been formulated and thus this is an issue that needs to be addressed immediately.

For this reason, AMED aims to equalize review quality for research conducted at multiple sites as well as to encourage the use of central IRBs and improve speed and efficiency by promoting the project to establish a central IRB standard model and developing guidelines.

In FY 2014, for the purpose of guaranteeing and further encouraging high-quality reviews, Japanese government started to certify IRBs that meet certain criteria. Fifteen IRBs were certified in FY 2014-2015.



Japan Agency for Medical Research and Development

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