Future Goals of the CCRC

The CCRC strongly believes in its mission, "**To improve patient care with scientific leadership and high ethical standards through innovative and collaborative clinical research**" .

Based on this mission, the CCRC aims to obtain approval for drugs and medical equipment through personnel education, organizational structuring, and advanced technology. Although it has only been 10 years since our establishment, we hope to grow further through continued cooperation with universities, regulatory agencies, and pharmaceutical companies.

Development of advanced medicine
Stem cell transplant, regenerative medicine, gene transfer

Clinical trials for drug indication expansion

Global clinical trials

Seed development with venture companies

Post-marketing clinical trials

CCRC

Personnel education

ARO

Advanced technology

Organizational structuring

Principal investigators across 29 departments

Acceleration of clinical trials

Approval of medical drugs, equipment, and technology

Establishment of evidence

Journal publication

Activation of participation in global clinical trials

Reflection on treatment guidelines

Cochrane Review

Medical Departments

- Gastroenterology
- Nephrology
- Diabetes Metabolism and Endocrinology
- Respiratory Medicine
- Hematology
- Allergy and Clinical Immunology
- Cardiovascular Medicine
- Japanese Kampo Medicine

Surgical Departments

- Cardiovascular Surgery
- Urology
- General Thoracic Surgery
- Anesthesiology, Pain and Palliative Care Medicine
- General Surgery, Division of Hepato-Biliary -Pancreatic Unit
- Esophago-Gastro-Intestinal Surgery
- Breast and Thyroid Surgery

Sensory/Motor Function Departments

- Orthopedic Surgery
- Otorhinolaryngology, Head and Neck Surgery
- Dentistry and Oral-Maxillofacial Surgery
- Plastic, Reconstructive, and Anesthetic Surgery
- Dermatology
- Ophthalmology

Neurological and Psychiatric Departments

- Psychiatry
- Neurology
- Neurological Surgery

Pediatric and Maternal/Women's Health Departments

- Gynecology
- Pediatrics
- Maternal-Fetal Medicine
- Pediatric Surgery

Radiological Departments

- Radiology

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CCRC

CHIBA UNIVERSITY HOSPITAL CLINICAL RESEARCH CENTER

GUIDE

Chiba University Hospital Clinical Research Center

Our Mission:

To improve patient care with scientific leadership and high ethical standards through innovative and collaborative clinical research

About CCRC

Chiba University Hospital, founded in 1874, has a long tradition of excellence in healthcare services with over 500,000 outpatient visits per year, and is recognized as one of Japan's leading clinical research institutions contributing to the development of medicine.

The **Chiba Clinical Research Center (CCRC)** was established at Chiba University Hospital in the year 2000 for the advancement of clinical research. The CCRC has conducted extensive clinical trials with its professional expertise, and just in the year 2012 alone, over 100 clinical trials were executed by the CCRC.

The CCRC is governed by the **CCRC Steering Committee** which provides strategic guidance and direction for the CCRC's activities and academic priorities. The committee is composed of the president of Chiba University, the directors at Chiba University Hospital, and professionals in pharmacy and nursing.

The **External Advisory Board** is responsible for supervising the activities of the CCRC to evaluate and improve its performance on a biannual basis, and advises us specifically on how we can further develop our function as an **Academic Research Organization (ARO)**. The Board is composed of staff from external institutions including the National Cancer Center, universities, and pharmaceutical companies.

In 2012, the **Ministry of Health, Labor, and Welfare (MHLW)** launched the 5 Year Clinical Trial Activation Plan and designated the top 5 hospitals taking initiative in developing clinical research in Japan as **core research centers.** The CCRC is one of them, and we place high priority on creating a productive and unique clinical trial environment as an ARO, strengthening collaboration with regulatory agencies and university hospitals in Japan, Asia, the United States, and Europe.

Our Clinical Trial Environment

We believe that **the partnership between our faculty leaders and the project leaders** is crucial for the development and innovation of clinical research. The faculty leaders provide their scientific and ethical perspectives as principal investigators to make the clinical trials scientifically accurate and successful. Project leaders are assigned to each clinical trial which is conducted at the CCRC, and organize a project team of professionals with expertise. With the partnership between faculty leaders and project leaders, we are able to increase our capacity to tackle any issues which may arise in the process of drug development. The CCRC is also devoted to education and translational research to enrich the clinical trial environment.

Faculty Leadership and Project Leadership

Principal Investigators (Faculty leaders)

Our principal investigators are responsible for providing their medical expertise in designing protocols which accurately meet the aims of the trials. With their abundant experience in the treatment of various diseases including cancer, neurology, hyperlipidemia, and rare diseases, we have conducted clinical trials with doctors across 29 treatment departments.

Project Leaders

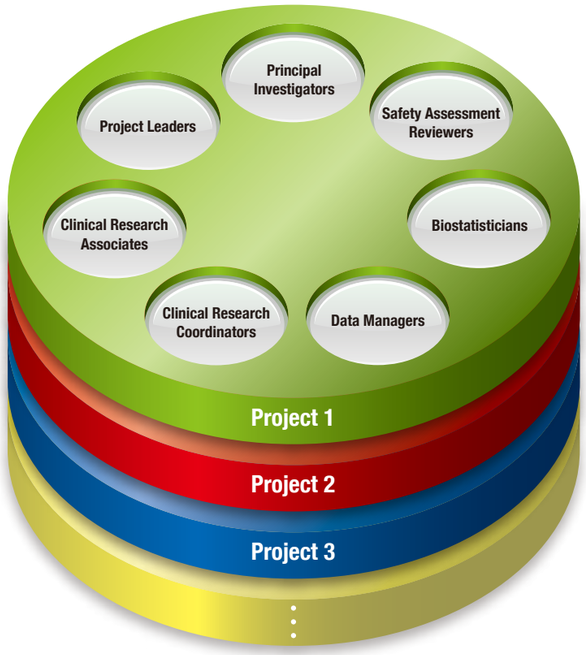
Our project leaders have distinguished expertise in pharmacology and pharmaceutical affairs. When executing a clinical trial, they gather experts from each department to develop a project team. The project leaders cooperate with the principal investigators and lead the trials by making decisions on the plans and principles so trials are conducted smoothly.

Clinical Research Associates

Our clinical research associates (CRAs) play a significant role in assuring the quality and speed of the process of clinical trials by building the trust between the CCRC and the trial sites. The CRAs undergo training to strengthen their knowledge on SOPs, GCP, quality control, quality assurance, and SDVs.

Clinical Research Coordinators

Our clinical research coordinators (CRCs) are crucial in conducting reliable trials and supporting the principal investigators and subjects. The nurses, pharmacists, and medical laboratory specialists work as CRCs to ensure that patients are informed with the appropriate medical information when enrolling in a trial.



Data Managers

Our data managers are indispensable for the quality assurance of the trials. We have introduced the EDC systems HITCANDIS, Medidata Rave, and DATATRAK ONE to conduct our clinical trials smoothly and efficiently. The latest methods of data management are used to secure the authenticity of the data.

Biostatisticians

Our biostatisticians provide statistical leadership in the design, execution, and analysis of clinical studies and epidemiologic investigations. They ensure that our study results achieve the highest scientific integrity and meet rigorous biostatistical standards.

Safety Assessment Reviewers

At the CCRC, our medical doctors review any suspected and unexpected serious adverse reactions (SUSARs). The CCRC plays an important role in enhancing the use of the electronic data sharing system which reports and shares the SUSARs among the University Hospital Clinical Trial (UHCT) Alliance〔p.6〕members in Japan.

Education and Training

Staff and Medical Professionals

The CCRC offers classes on clinical research, drug development, and regulatory affairs to doctors, pharmacists, nurses, and all staff involved in research at Chiba University Hospital and neighboring clinical institutions. In addition, training programs required for job qualification on topics such as ICH-GCP, SOPs, ethics, and safety information, are offered to all staff members of the CCRC.


Seminar for IRB members

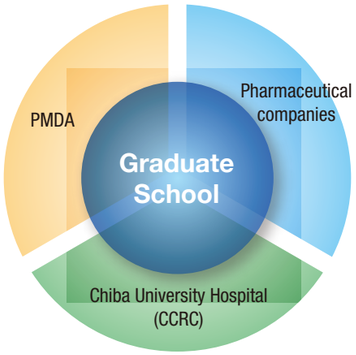

IRB and CRC text books


Training for nurses


CCRC seminar

Chiba University Graduate School of Medical and Pharmaceutical Sciences

The CCRC offers a course on medical regulatory affairs in collaboration with the MHLW and the PMDA (Pharmaceuticals and Medical Devices Agency) at the Graduate School of Medical and Pharmaceutical Sciences. This course aims to educate students and staff who can play a central role in the areas of regulatory science and drug development in order to accelerate the clinical trial processes in Japan. After students complete this course, they receive a PhD degree in medical regulatory affairs.



The Younger Generation

We believe that it is necessary to educate the younger generation to develop the future clinical trial environment in Japan. Through simple experiments in the classrooms, we teach the students in junior high schools on the importance and necessity of clinical trials.


Classes for students

Translational Research

The Center for Advanced Medicine (CAM) was established at Chiba University in 2008 as a hub facility to develop and bridge treatment methods for untreatable, intractable diseases, especially in the fields of immunological cell therapy, neovascularization therapy and gene therapy. At our **Cell Processing Center (CPC)**, operations are performed in accordance with the Good Manufacturing Practice to offer the safest aseptic cellular products to our patients for their treatment. The CCRC has established a system to create opportunities for seed discoveries via regular **seeds evaluation meeting**s between pharmaceutical researchers, professors, intellectual property right specialists, and doctors, and to provide comprehensive advice on protocol design and application preparation.

Discovery of opportunity ▶ Establishment of protocol design/Regulatory filing ▶ Approval by the board ▶ Cell production at Cell Processing Center (CPC) ▶ Clinical trials Phase Ⅰ or PoC

Partnerships and Networks

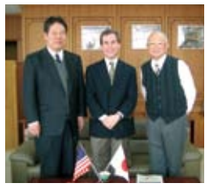
To accelerate the process of clinical trials, the CCRC is engaged in strengthening a clinical research network with domestic and global partners such as regulatory agencies, academic research organizations, local clinics and hospitals, pharmaceutical companies, and venture companies.

Regulatory Agencies

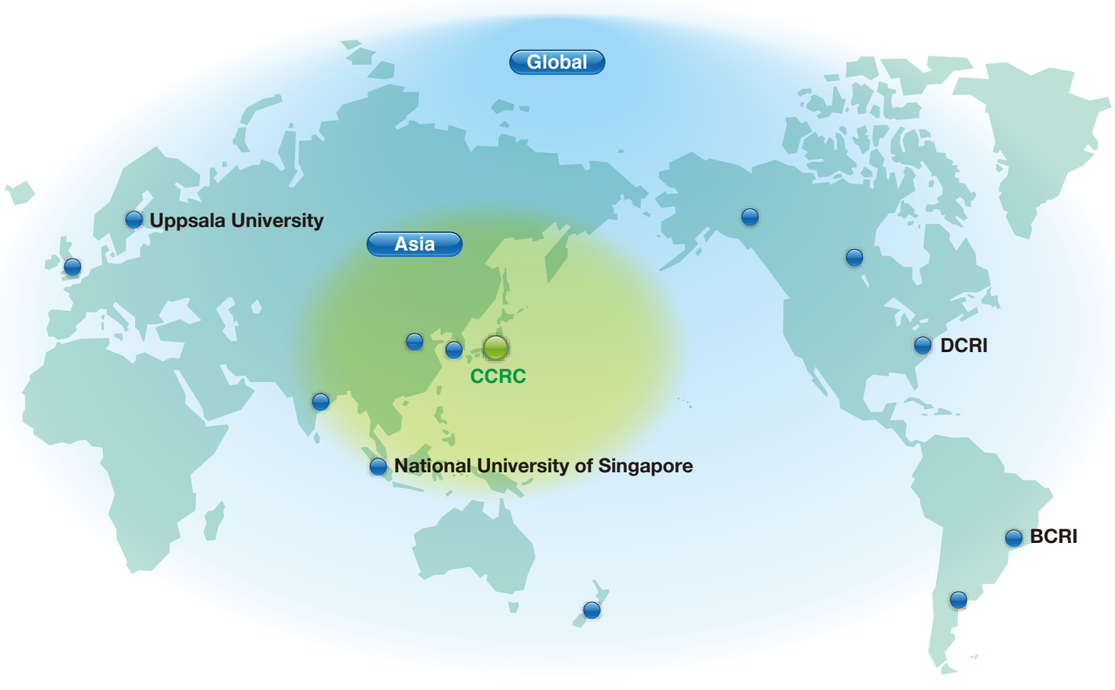
At the PMDA

The CCRC collaborates with **the PMDA** in the exchange of personnel to develop professional expertise in areas such as pharmaceutical affairs law, regulatory science, and new drug development. Our staff includes doctors with past careers at the PMDA, and qualified experts with experience in project management of drug research in pharmaceutical companies.

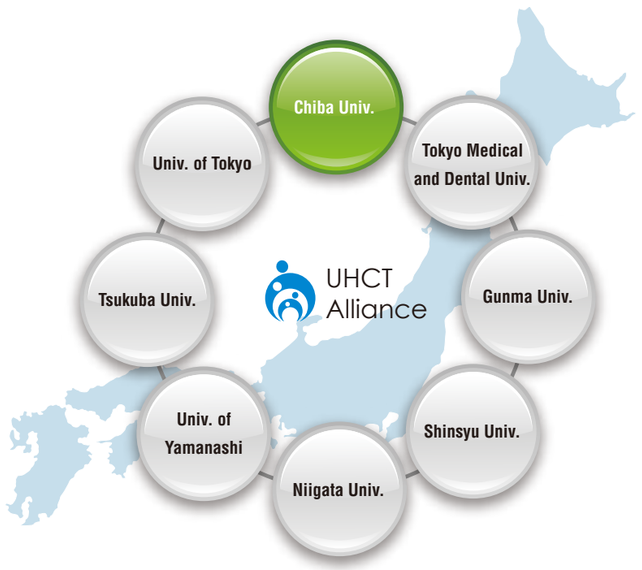
International AROs


Meeting with the DCRI

The globalization of clinical research is an urgent goal which needs to be achieved for the simultaneous, global approval of new drugs. The CCRC aims to collaborate with **AROs** around the world to establish a global partnership. Since 2003, the CCRC has a partnership with **the Duke Clinical Research Institute (DCRI)** and our doctors are sent as research fellows. Informational exchange between Asian and European university hospitals such as **the Brazilian Clinical Research Institute (BCRI), Uppsala University, and the National University of Singapore** are also actively conducted.

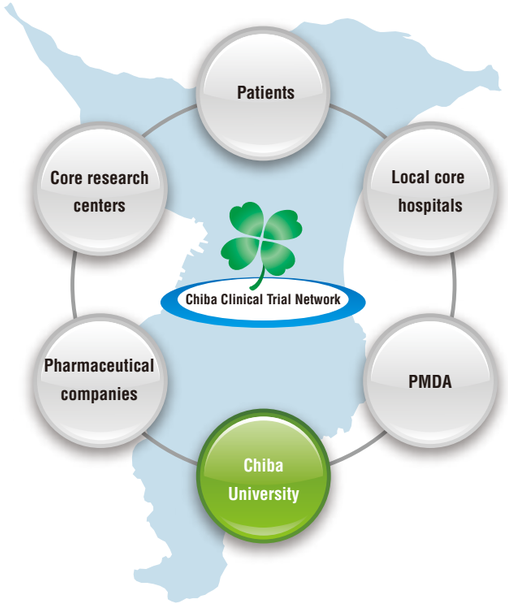


UHCT Alliance



In order for Japan to enhance active participation in global clinical trials, **the UHCT Alliance** was set up in 2006 between Chiba University and seven other Japanese university hospitals with outstanding achievements in clinical trials.

CCTN(Chiba Clinical Trial Network)



The Chiba Clinical Trial Network (CCTN) was established in 2004 under the subsidy of the PMDA. This network consists of local core hospitals, Chiba University Hospital, pharmaceutical companies, the PMDA, and core research centers. The partnership integrates community practitioners into our research which allows us to enroll enough eligible subjects in a timely manner and to collect sufficient data for the contribution to regionally based science.