



*University of Tsukuba*

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# Tsukuba Clinical Research & Development Organization (T-CReDO)



## T-CReDO

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## Message from the Director

Tsukuba Clinical Research and Development Organization (T-CReDO) was established on June 1, 2015 as a result of the collaboration between Faculty of Medicine and University of Tsukuba Hospital.

This organization was a result of positive consolidation and reorganization. It originates from the Clinical Trial and Research Center, Center for Innovative Medicine and Engineering in University Hospital, and Critical Path Research Education Integrated Leading Center in Faculty of Medicine. The Department of Research and Development Management and Quality Assurance Office were newly organized for efficient management, and a Council with external and internal members was introduced for governance.

With experience and function gained from the former organization, we have made progress in clinical development at the University of Tsukuba as well as at the industry-government-university research institutes around Tsukuba Science City. We aim to develop medical seeds and foster researchers and professionals. Without an exit strategy, medical research results cannot make an effective translation into practical use. T-CReDO provides seamless support for practical application of medical seeds and tremendous support in areas concerning intellectual property rights, fund raising, and education for entrepreneurs and professional staff in research field.

The University of Tsukuba was selected as one of the Translational and Clinical Research Core Centers by Japan Agency for Medical Research and Development (AMED) in March, 2017. T-CReDO promotes medical development to constantly generate innovative medicines and medical devices, to contribute to public health, to develop the medical industry, and to serve as an international core center for medical research and development. Your support in achieving the abovementioned aims and objects will be highly appreciated.



**Yoshihiro Arakawa, PhD;**

Director;  
Tsukuba Clinical Research and  
Development Organization (T-CReDO)

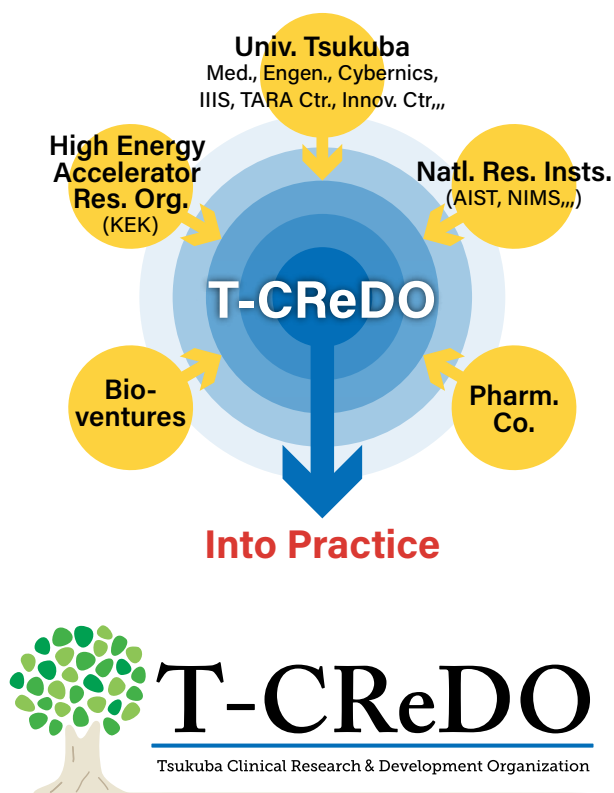


## Aiming for the practical application of medical technology by collecting wisdom we will foster medical seeds, support clinical development, and foster researchers

T-CReDO is centered on the University of Tsukuba and Tsukuba Science City. We collect wisdom from research institutes and develop research results (seeds) on medical technology and ultimately practically apply the results in fields such as clinical development. We support the implementation of clinical trials to obtain clinically useful findings. We also encourage young researchers who aim at the development of medical technology and promote lifelong education and training of researchers involved in clinical research. Through these measures, we aim to accelerate the development of innovative pharmaceuticals, medical devices, regenerative medicine, etc. In addition to contributing to the health and welfare of the people, we aim for sustainable growth and strive to develop international clinical development bases.

T-CReDO will perform the following tasks to achieve the above mentioned objectives:

- (1) Clinical development window and consultation (intellectual property, development strategy, etc.)
- (2) R & D management (pipeline management, planning promotion, finance, etc.)
- (3) Training medical seeds and promoting open innovation
- (4) Supporting empirical research aiming for clinical introduction
- (5) Supporting company-led and doctor-led clinical trials and clinical research
- (6) Promotion of clinical trial and clinical research network
- (7) Entrepreneur education
- (8) Provision of a lifelong education program for clinical researchers and professionals
- (9) Audit of T-CReDO and individual clinical research
- (10) Clinical Research Ethics Review Committee, Secretariat Operations of Institutional Review Board, etc.



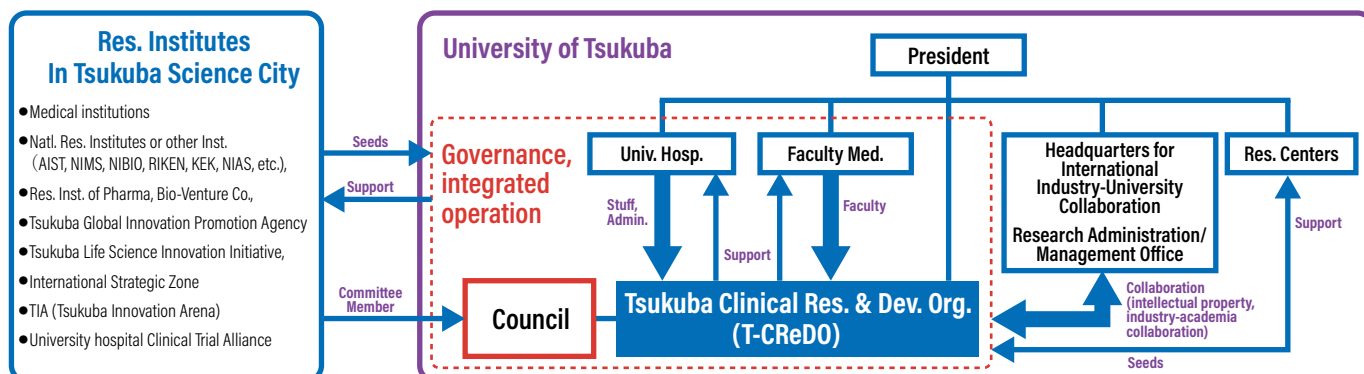
"Credo" is derived from the Latin word *crēdō*, which means to believe and signifies promise, creed, etc. The logo is firm on the ground similar to the Tulip trees along the campus, signifying the wish to grow richly.



# Internal and External Collaborations

## 1) Fostering medical seeds and supporting clinical development

T-CReDO supports medical seeds and clinical development by collaborating with the University Hospital, Faculty of Medicine, and organizations inside and outside the university.



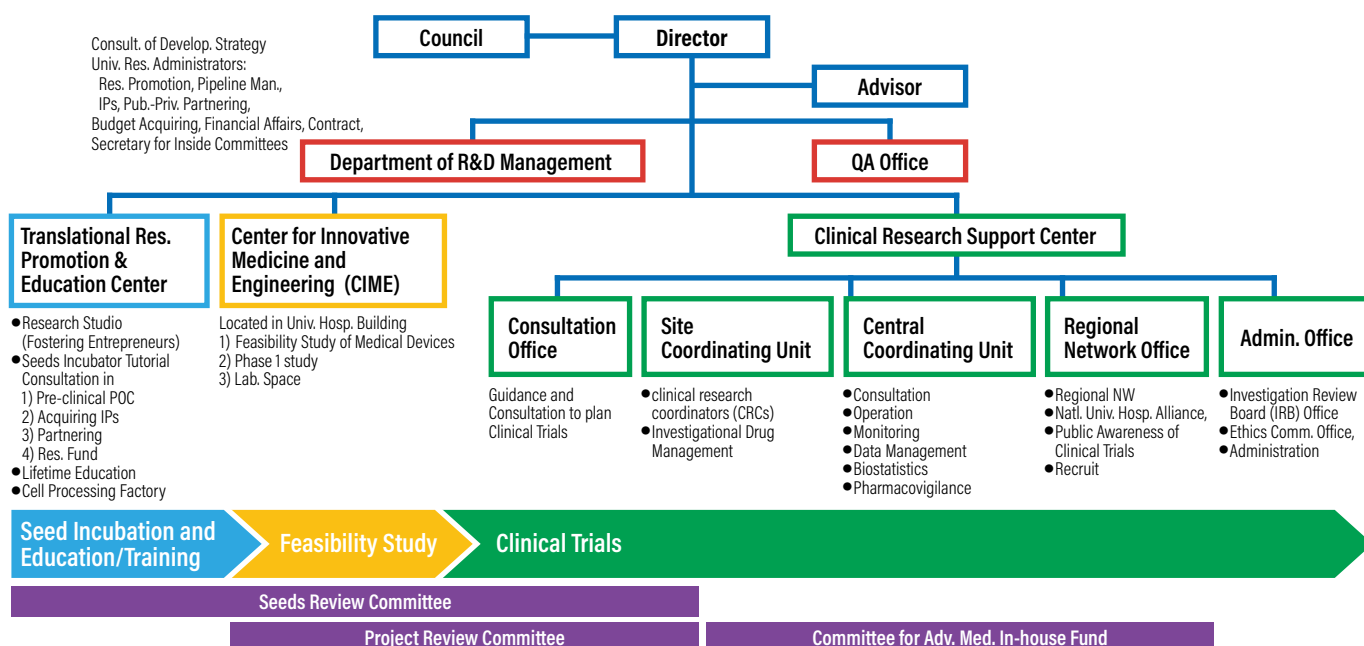
University of Tsukuba has signed a comprehensive and collaborative postgraduate agreement with the Pharmaceuticals Medical Devices Agency (PMDA), which make personal exchanges active.

## 2) Training researchers and entrepreneurs interested in R & D

We initiated a program, known as Research Studio, for medical entrepreneurs to provide support based on real industry experience. The program involves the collaboration of experienced researchers and entrepreneurs from Tsukuba and other areas around Tsukuba. In addition, we have established the lifelong education program for researchers and specialized staff.

# Organization

Organizations are classified based on functions and occupations and matrix project management is conducted to enable smooth support. TR Promotion and Education Center is responsible for pre-clinical seed development, entrepreneur cultivation, and for conducting lifelong education programs for researchers. Empirical research and feasibility studies for clinical trials are performed by the Center for Innovative Medicine and Engineering, and clinical trials are supported by the Clinical Research Service Center.



**Seeds Review Committee** comprises members with expertise in relevant fields and provides advice, reviews priority of support, and manages projects that involve specific milestones.

**Project Review Committee** reviews the validity of the use of the space in CIME by the project, in addition to reviewing the validity of support by the Central Coordinating Unit.

**Committee for Advanced Medicine In-house fund** reviews projects that are part of investigator-initiated clinical trials or advanced medicine to evaluate the utilization of funding.

Provides “one-stop service” for medical seed development support

## Department of Research and Development Management

Responsibilities:

- ✓Contact point for support provided by T-CReDO for R & D of medical seeds (Collaboration with each department of T-CReDO and the research promotion and industry-academia collaboration department of the university)
- ✓Progress management at all stages of medical R & D (Pipeline management)
- ✓Consultation service for commercialization of medical seeds (Support for acquiring intellectual property rights and regarding development strategy and regulatory compliance)
- ✓Support for company partnering, obtaining public research funding, etc.

For reliable clinical research and development

## Quality Assurance Office

Our goal is to protect the human rights of study subjects and to increase the reliability of clinical trials by verifying compliance with protocols, SOPs, and regulations, such as the GCP, Clinical Trials ACT, Ethical Guidelines for Medical and Health Research Involving Human Subjects, and the Declaration of Helsinki from an objective standpoint. We also support medical institutions and trial sites in system audits by evaluating design and performance of the computer system.

These activities support to increase the reliability of clinical trials.

Educational platform for taking scientific achievements to the bedside

## Translational Research Promotion and Education Center

- 1) **Research Studio** (Entrepreneurship course) is an acceleration program for clinical scientists, basic scientists, and young entrepreneurs who are willing to launch or join startup companies in the healthcare field based on their academic research achievements. The course provides basic knowledge regarding the preparation of a target product profile (TPP), sharing the image of the final product with internal and external stakeholders, and generation of a road map of product development with a proper fund-raising plan under the supervision of professional mentors from local institutes, venture capitalists, senior entrepreneurs, and other international partners.
- 2) **Seeds Incubator** is a system that provides advice regarding non-clinical testing, intellectual properties, collaboration, fundraising, etc., to scientists who perform research and aim to conduct clinical trials.
- 3) **Lifetime Education for Scientists and Professionals**, provided by the center, is based on their occupations and positions. We provide Clinical Research courses for Principal Investigators, Data Managers, Monitors, and CRCs, as well as Business Strategy and Regulatory Science courses for professionals in the drug and medical device development field. We supervise the translational research thesis work of graduate students in the Master's Program in Medical Sciences and provide on-the-job training regarding clinical research support, clinical data management, and CRC. The comprehensive alliance between the University of Tsukuba and PMDA, including the HR exchange or the linked graduate school system, provide exposure to graduate students with respect to real regulatory affairs work.
- 4) **Cell Processing Factory (CPF)** manages the operation of the cell processing facility and supports researches in the field of tissue and cell therapy.



Seamless support for clinical development and clinical trial

## Clinical Research Support Center

The Clinical Research Support Center is responsible for supporting clinical trials and clinical studies. It comprises several units and offices with the following diverse functions:

**Central Coordinating Unit** co-ordinates clinical trials and acts as a data center.

**Site Management Unit** provides on-site support for clinical trials and clinical studies conducted in the University Hospital.

**Regional Network Office** maintains a network of regional medical institutions for better case accumulation.

**Consultation Office** provides support for the planning of clinical studies.

**Administration Office** manages the IRB and the Ethics Committee

The center has a matrix management scheme based on both functions and projects to provide seamless help.

Reliable project management and high-quality data collection and analysis.

## Central Coordinating Unit

The Central Coordinating Unit, in association with other departments, conducts various clinical trials, including nationwide multicenter, single-facility, or investigator-initiated clinical trials. Our services are diverse, for example, we provide advice regarding development strategy and protocol writing by experienced staff with R & D expertise in pharmaceuticals, data management using the electronic data capture (EDC) system, central and on-site monitoring, and statistical analysis by biostatisticians. We enhance the credibility of high-quality clinical data and data analysis based on our experience of managing more than 70 projects.



We support researchers in the planning of their clinical trials.

## Consultation Office

We support researchers in the planning of their clinical research under the Clinical Trials Act or Ethical Guidelines for Medical and Health Research Involving Human Subjects. We aim to clarify their clinical questions, hypotheses, and PICO questions. We advise researchers regarding a variety of subjects, including research design, end-point, optimal sample size, etc. We also collaborate with other units of T-CReDO considering exit strategies with respect to the quality of research and the applicable regulatory requirements.

Individual-oriented on-site coordination for trial

## Site Coordinating Unit

To cope with the diversification of clinical trials and clinical studies, experienced CRCs prepare to present the trial before the IRB and communicate closely with clients, support subjects, and investigators to ensure smooth implementation of the trial. Our management of test drugs or information is strict enough for global trials or complicated protocols. We also handle serious adverse event (SAE) reports. Collaboration and information sharing with the Central Coordinating Unit and other departments of T-CReDO makes our support more practical.



It is based on reliability, speed, and efficiency

## Administration Office

As the Secretariat of the Institutional Review Board and the Clinical Research Ethics Review Committee, the Administration Office is responsible for organizing work and research ethics workshops, in addition to managing the general affairs of other departments. We perform collective duties and work hard to manage the organization. During clinical trials, we consistently perform administrative procedures including feasibility studies and contract.

With respect to clinical research, we conduct ethical review procedures and store management of reports. We respond flexibly to requests on the trial from the sponsor and researchers, coordinate with each department efficiently, and support the operation of clinical trial.



High-quality clinical research with efficiency and information sharing

## Regional Network Office

Networking among medical institutes is essential for development of pharmaceuticals and medical devices. Regional networks, such as the Clinical Trial & Research Network IBARAKI, which has core hospitals in the area, and the University Hospitals Alliance, make trials effective and enhance the quality of clinical research by information sharing. We handle feasibility studies, central IRB operations, and progress management *as a whole*. We also reach out to citizens to encourage them to participate in the clinical trials and research.



Realization of innovative medicine through collaboration of state-of-the-art science

## Center for Innovative Medicine and Engineering

We promote clinical development of medicine and medical devices through interdisciplinary research such as medicine and engineering collaboration. Located in the University Hospital building, our center gives researchers from outside an easy access to the study site and helps them to contact on-site researchers and medical staff who can take care of patients easily. To meet the wide range of study requirements, we have studios and rooms on rent, which can be used to reproduce the patients' room environments. In addition, we also have various instruments, such as those for image analysis including devices for motion-capture.

We have supported several collaborative researches by the university, industry, and research institutes. We also help researchers contact relevant departments in the university and university hospital.



**CIME**  
Center for Innovative  
Medicine and Engineering



Researches we promote

## Endowed Courses: Clinical Research and Regional Innovation, University of Tsukuba, Faculty of medicine, etc.

We have our own clinical researches in practice. Collaborating with researchers inside and outside the university and industry, we promote research conducted for searching seeds, clinical research for prevention of life-style related diseases, and practical studies on effective clinical development and medical treatment. One such fields is the JA IBARAKI supported Regional Clinical Research Innovation.



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