Yakuzenkai Medical Corporation

Tsukuba International Clinical Pharmacology Clinic

Our Vision

Hideo Miyahara, M.D.
Chief Director , Medical Corporation Yakuzenkai

Naoyuki Kamatani, M.D.
Director, Tsukuba International Clinical Pharmacology Clinic

Tsukuba International Clinical Pharmacology Clinic, an affiliated clinic of Medical Corporation Yakuzenkai is a medical facility specialized in clinical trials. The clinic added new advanced technologies after succeeding the tradition of Kan-nondai Clinic with a 20-year history. We have experienced repeated inspections of the management system by PMDA of Japan as to whether it accords with GCP. Based on such an experience, we perform high-grade phase I and biological equivalence trials that are completely in accord with new GCP.

In addition, we accept the requests of clinical trials requiring the knowledge of genome-based drug development, statistical genetics, pharmacogenomics, clinical epidemiology and medical statistics that are essential in the modern drug development.

Our clinical trials have been trusted by both clients and regulatory offices since we respect the rights of examinees, keep the quality of clinical trials, maximize the reliability of the data and confirm the complete preservation of the records.

In phase I trials, we perform studies to obtain data that are as faithful and useful as possible so that they can be effectively used to design the subsequent phase II and phase III trials. In bioequivalence studies, we perform not only reliable but also efficient studies so that the drugs are approved by the regulatory office without delay. We respond to the requests of making protocols for clinical trials, designing of the studies, statistical analyses of the data and making manuscripts to be submitted to journals.

Our staff are the leaders in Japan in the field of clinical trials to which genome-based new drug development, pharmacogenomics, medical statistics and clinical epidemiology are applied. We provide sufficient information and consultation to maximize the success rate in the early phase of clinical trials. We respond to the requests of obtaining the data that are useful to make phase II and phase III trials more efficient, and solve problems that may occur in post-marketing surveillance or sales. We follow laws, ministerial ordinance, notification from the government and guidelines, and perform steady operations and answer to the detailed and diversified requests of the clients.

Hideo Miyahara, M.D., Chief Director, Medical Corporation Yakuzenkai
Naoyuki Kamatani, M.D., Director, Tsukuba International Clinical Pharmacology Clinic

Facility

Tsukuba International Clinical Pharmacology Clinic

(Member of JACICP: Japan Association of Contract Institutes for Clinical Pharmacology)

History

Medical corporation was established in May, 2010
Opening of clinic was approved in July, 2010
Use of the facility was approved in Sep, 2010
（Succeeding the tradition of Kan-nondai Clinic）
Chief Director of the Corporation Hideo Miyahara, M.D.
Director of the Clinic Naoyuki Kamatani, M.D.
Location Kan-nondai 1-21-16, Tsukuba-shi, Ibaraki, Japan 305-0856
Total area 991.95 m^2（3 floors）

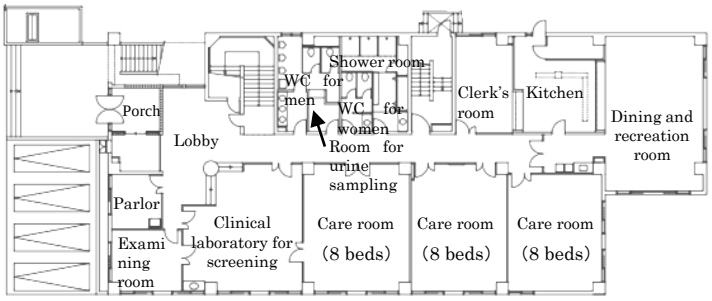
Features of Clinic

① Clinic can perform varieties of clinical trials including phase I, bioequivalence, bioavailability, drug-interaction, micro-dosing, and QT/QTc prolongation studies.
② Clinic has experiences of trials of medicine for external use, those on post-menopausal , and those on patients with mild diseases such as hyperuricemia.
③ Clinic can perform studies based on pharmacogenomics – selection of subjects with specific genotypes, PK study based on genomic data, GWAS (genome-wide association study), study using NGS (next-generation sequencers), DNA banking, etc.
④ Hideo Miyahara is an expert of ECG, and participated in the first trial of QT/QTc prolongation study in Japan.
⑤ Naoyuki Kamatani served as the Director of Institute of Rheumatology, Tokyo Women's Medical University and Director of Center for Genomic Medicine, RIKEN. He is the national leader in medical genetics, statistical genetics, pharmacogenomics, clinical epidemiology and medical statistics, and has a sufficient experience of new drug development in the world.
⑥ Comfortable facility - First and second floors are completely independent/Privacy can be protected when private rooms are used. Clinic has own kitchen and cook within the clinic.
⑦ Clinic has an own panel of volunteers with high quality – the panel has various kinds of volunteers

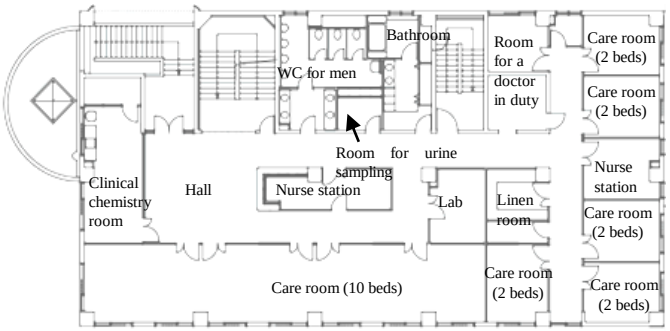
Sketch of the floors

Dining and Recreation room

Sketch of the 1st floor



Sketch of the 2nd floor

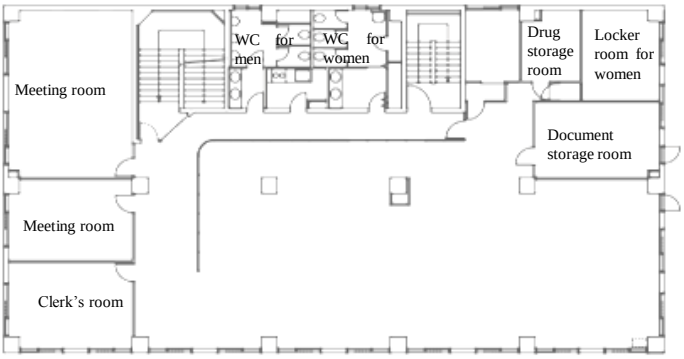


Care room

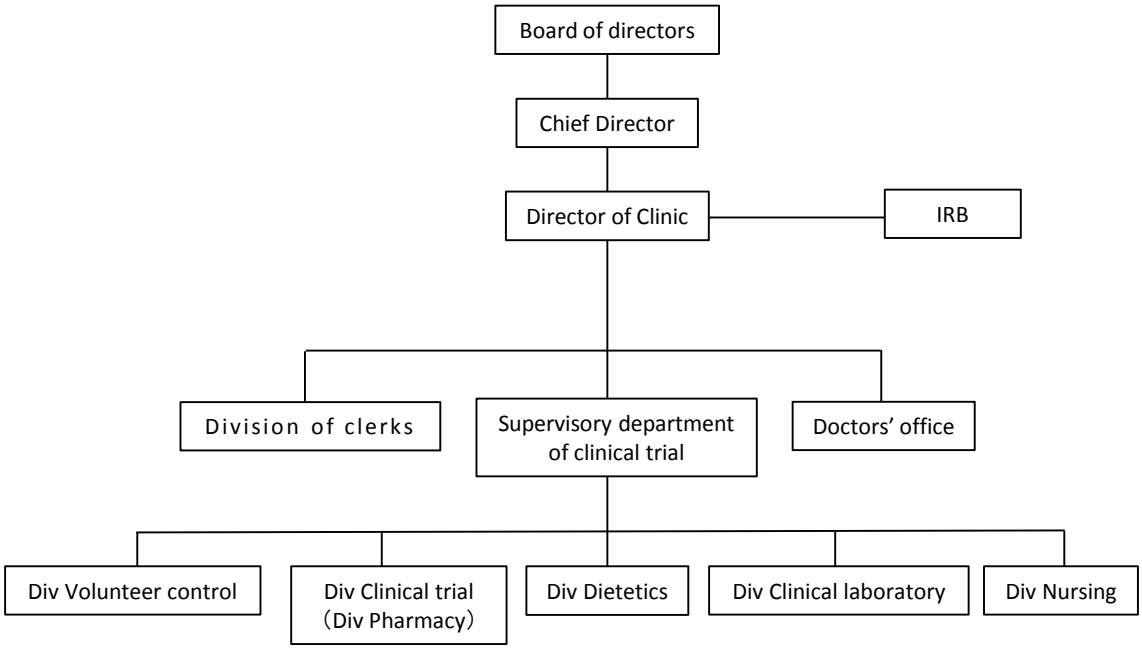
Meeting room

Two- bed room

Sketch of the 3rd floor



Management of Our Clinic



Ambulance system

Neighboring Hospitals	Distance	Time to Clinic
Tsukuba Gakuen Hospital	2 km	5 min
Tsukuba Medical Center Hospital	7 km	15 min

(Transfer method is by either ambulance car or car of our clinic)

Achievements

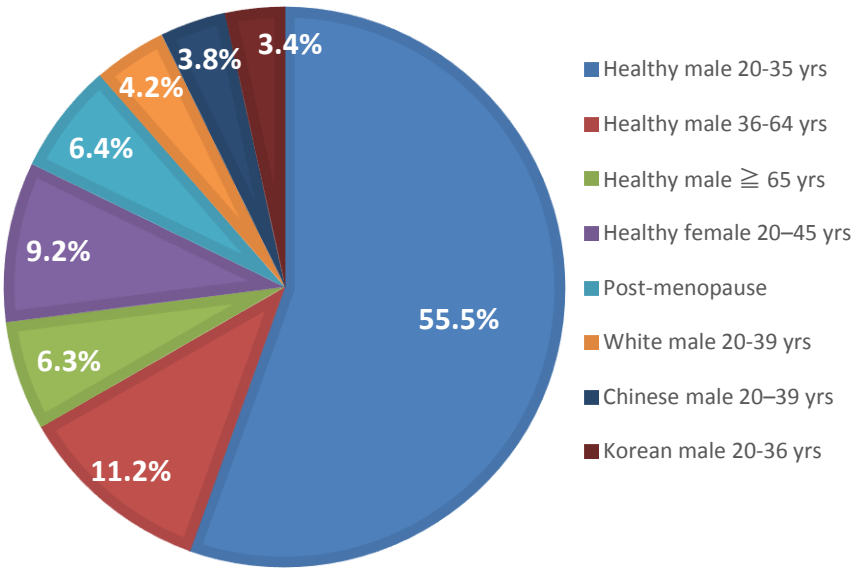
	Year						
	2011	2012	2013	2014	2015	2016	2017
Phase I / Phase II				1			
Bioequivalence study	12	15	12	8	11	8	7
Oral	8	14	11	7	8	6	6
External medication	4	1	1	1	3	2	
Injection							1
Pharmacodynamic study					1	1	1
DPK study	3	1	1	1	2	2	
Residual drug study	1						
Pharmacokinetic study						2	2
Patch / Photo-patch test		1					
Medical research	2	2	2	2	3	9	1
Total number of protocols	14	18	14	11	14	19	10

Staff

Medical Doctor	7
Nurse	13
Pharmacist	5
Clinical technologist	1
Volunteer manager	2
Dietician, Cook	2

(Jan, 2017)

Panel of volunteers (Number of registries:7170)



GCP On-site Inspection

Clinic has experienced inspections by the regulatory office to assure the accordance with GCP

The date of change: Aug 7, 2012 （Generic Medicine）

Feb 16, 2015 （Generic Medicine）

Institutional Review Board (IRB)

	Name	Affiliation
Chairman	Kyoichi Totsuka	Professor, Department of Infectious Diseases, Tokyo Women's Medical University
Chairman	Yukinao Kohda	Professor, Department of Medical Health, Tsukuba International Univerisity
Member	Eriko Kawata	REDAS Corporation
Member	Eishi katoh	Secretary General,Frendship Society of Gouty Patient
Member	Chieko Kurihara	Editorial Staff, Publication Society of "Clinical Evaluation"
Member	Hironori Shiozaki	Corporation More-Selections
Member	Atsuo taniguchi	Professor, Department of Institute of Rheumatology Tokyo Women's Medical University

IRB meeting is held on the 1st Wednesday, every month （Jan,2018）
(Provisional meeting may be held on request)

Phase I and Bioequivalence trials

The principal aim of our clinic is to perform reliable phase I and bioequivalence studies based on our sufficient experience and tradition.

Our clinic has a high quality panel of registered volunteers. The panel consists of 7,170 volunteers, and we can cope with varieties of requests from clients. Our panel includes females as well as non-Japanese subjects. The frequencies of initial drop-out and withdrawal during a study by volunteers are extremely low, due to our warm hospitality to the volunteers, comfortable atmosphere in the clinic, wide rooms, protection of the privacy and good foods provided from our own kitchen within the clinic.

Our facility consists of two separate units one on the first floor and the other on the second floor, and we can run two protocols with complete independence. Contaminations of tools, samples or data of two independent studies can never happen. Since we have two-bed rooms on the second floor, trials using female and foreigner volunteers can be performed without problems using those rooms. Using our own kitchen within the clinic, diet and calories can be controlled very accurately. Since our clinic is located far from cities, we can control precisely the diet and daily activities of the volunteers. Administration of drugs to the volunteers can be as accurate as it can be.

Our clinic is equipped with a complete set of SOPs (standard operating procedures), and can respond to varieties of searches and inspections including data monitoring, SDV and GCP inspection within the clinic. We can provide a broad and comfortable meeting room for the persons who may visit our clinic for the searches and inspections.

We have a plenty of experiences in phase I and bioequivalence studies of various kinds. We have skills in studies on medicine applied to skins. We also have experiences of studies of continuous infusion using transfusion pumps, trials on post-menopause women with ages over 64 years, trials on young women and trials using patients with mild diseases such as hyperlipidemia.

In case something serious happens, although we have no such experience, the director of the clinic has sufficient experience in the practice of medicine and cope with any events using various methods including the ambulance system as described in a separate sheet.

Phase I Study Using Advanced Technologies

Recently, a low success rate in the development of new drugs is a big problem. More and more drugs that had been considered to be effective and safe in the pre-clinical stage failed to be approved and sold in the market. Even after the marketing, some drugs have been withdrawn because of problems in safety or efficacy. The technologies to maximize the success rate of the development of a new drug are serioulsy needed even if the success rate from the discovery to the marketing can never be 100%. Naoyuki Kamatani, M.D., Ph.D., the director of our clinic has tackled with this problem for a long time, and has succeeded to increase the success rate of new drug development by applying individual human genomic data, a blue print of humans, based on statistics. The power of the data from experimental animals to predict the efficacy and safety of a drug in humans is known to be very weak. Drugs that had been safe in animal experiments often turned out to be unsafe, and, conversely, some drugs that had been unsafe in animal experiments turned out to be safe in humans. We propose a method to predict the safety and efficacy of a drug before the administration to humans by the data from researches on genomes of diseases. This method will predict both acute and long-term outcomes of the perturbation of a molecule in humans.

Naoyuki Kamatani has been involved in the study on genetic diseases (PNAS 79, 3848, 1982) that lead to the development of cladribine, a drug for malignancies. Recently, he served as the principal clinical investigator and was involved in the development of a new anti-gout drug, febuxostat from the very early stage (Monograph “Japanese researchers who challenged to develop new drugs” by Asako Tsukazaki, Kodansha, Japan). In addition, he has been involved in pharmacogenomic studies on drugs for gout, rheumatoid arthritis, hepatitis and neurological diseases, and thereby contributed to safer and more effective treatments.

To increase the success rate of new drug development, broad knowledge on genomes associated with diseases and drug reactions covering wide medical fields and statistical analyses based on such data are necessary. This is an international trend, and genomics, genetics and statistics are used as essential technologies to develop new drugs used for rheumatoid arthritis, malignancies, gout, chronic hepatitis, diabetes, and hematological diseases.

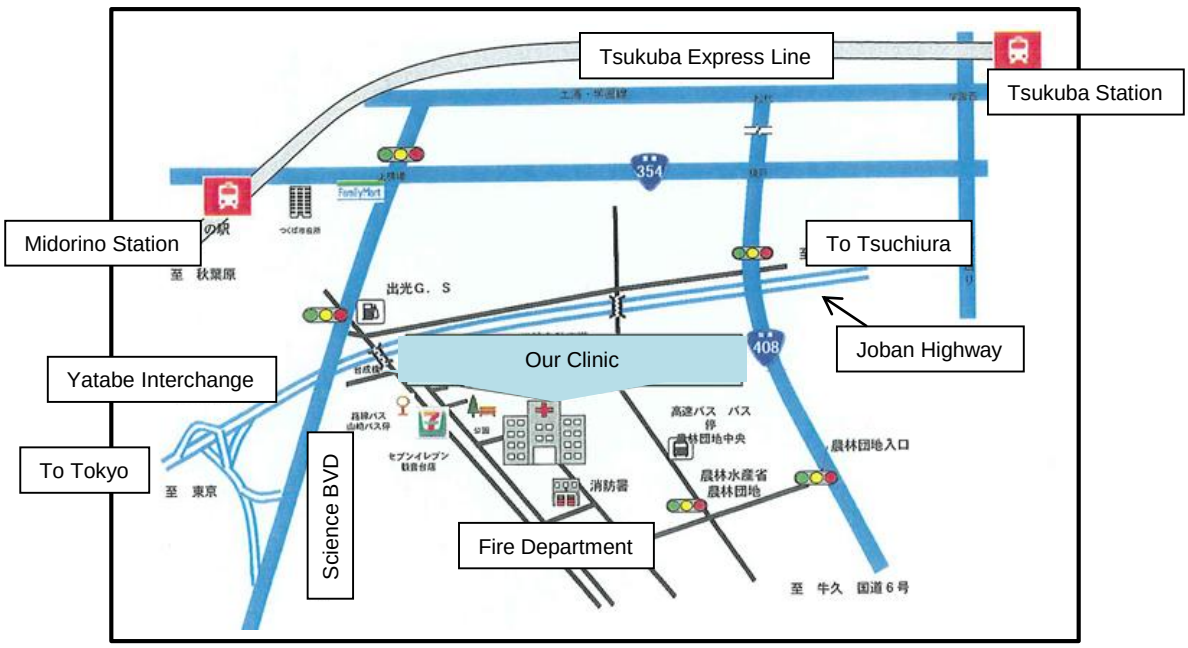
Tsukuba International Clinical Pharmacology Clinic plays an important role as the most reliable facility in this field not only by performing reliable phase I and bioequivalence studies but also by providing the consultation concerning the feasibility of phase I studies planned, designing of phase I studies, and consultations and necessary information for phase II and III studies.

Access

Name Tsukuba International Clinical Pharmacology Clinic
Location 〒305-0856 Kan-nondai 1-21-16, Tsukuba-shi, Ibaraki-ken, Japan
TEL 029-839-1150 FAX 029-839-1151 (From outside Japan, dial 81-29-839-1150)
E-Mail info@tsukuba-icp.jp URL: http://tsukuba-icp.jp/

Access

1. To Midorino Station, use Tsukuba Express Line (Regular or Semi-Rapid)
   From Midorino Station, use either taxi (10 min), or bus (Take a bus to Ushiku Station and get off at Yamazaki Busstop. Our clinic is 5 min walk)
2. To Ushiku Station, use Joban Line of JR. From Ushiku Station, use either txi (20 min) or bus (Take a bus to Midorino Station and get off at Yamazaki Busstop. Our clinic is 5 min walk)
3. By car, use Joban Highway and leave it at Yatabe Interchange. Our clinic is 5 min drive from Yatabe Interchange.



Made on Jan 15, 2018