Department of

Advanced Medicine

Nagoya University Hospital

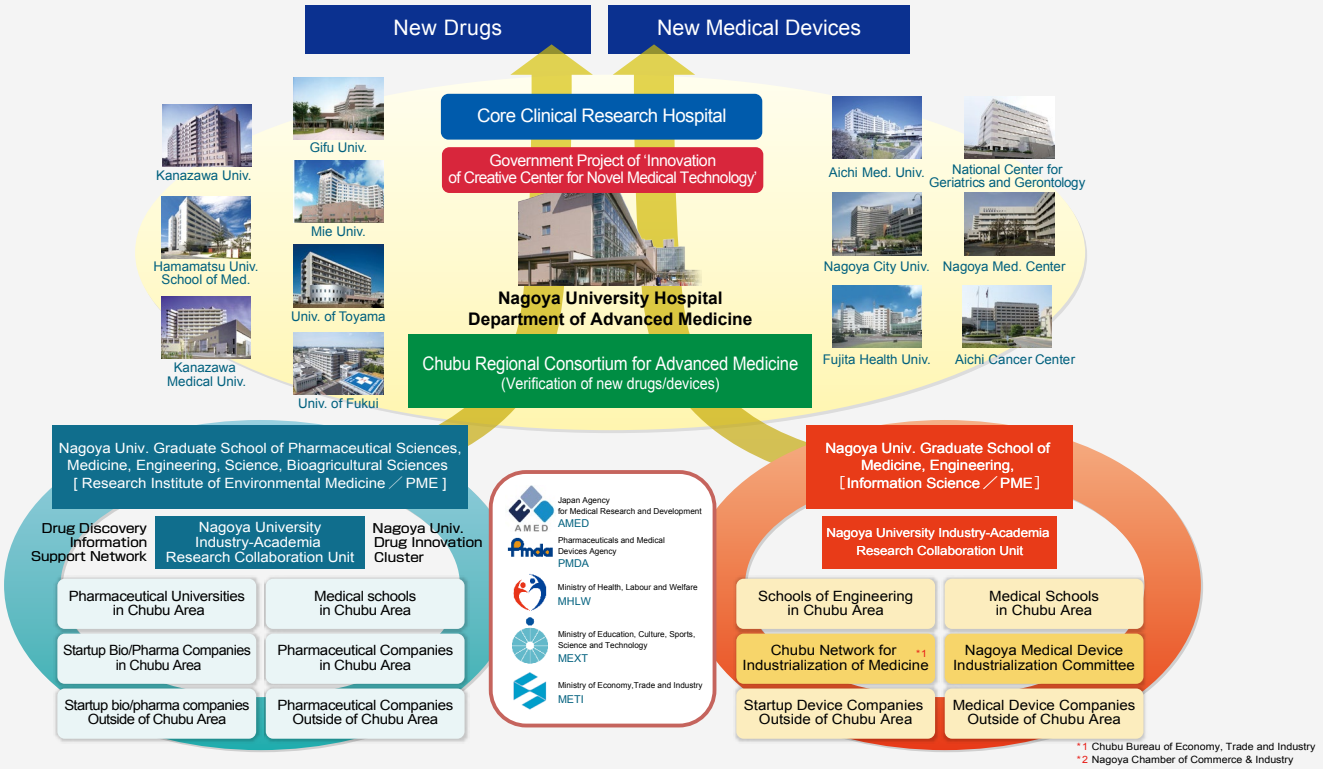
Center for Advanced Medicine and Clinical Research

Data Coordinating Center

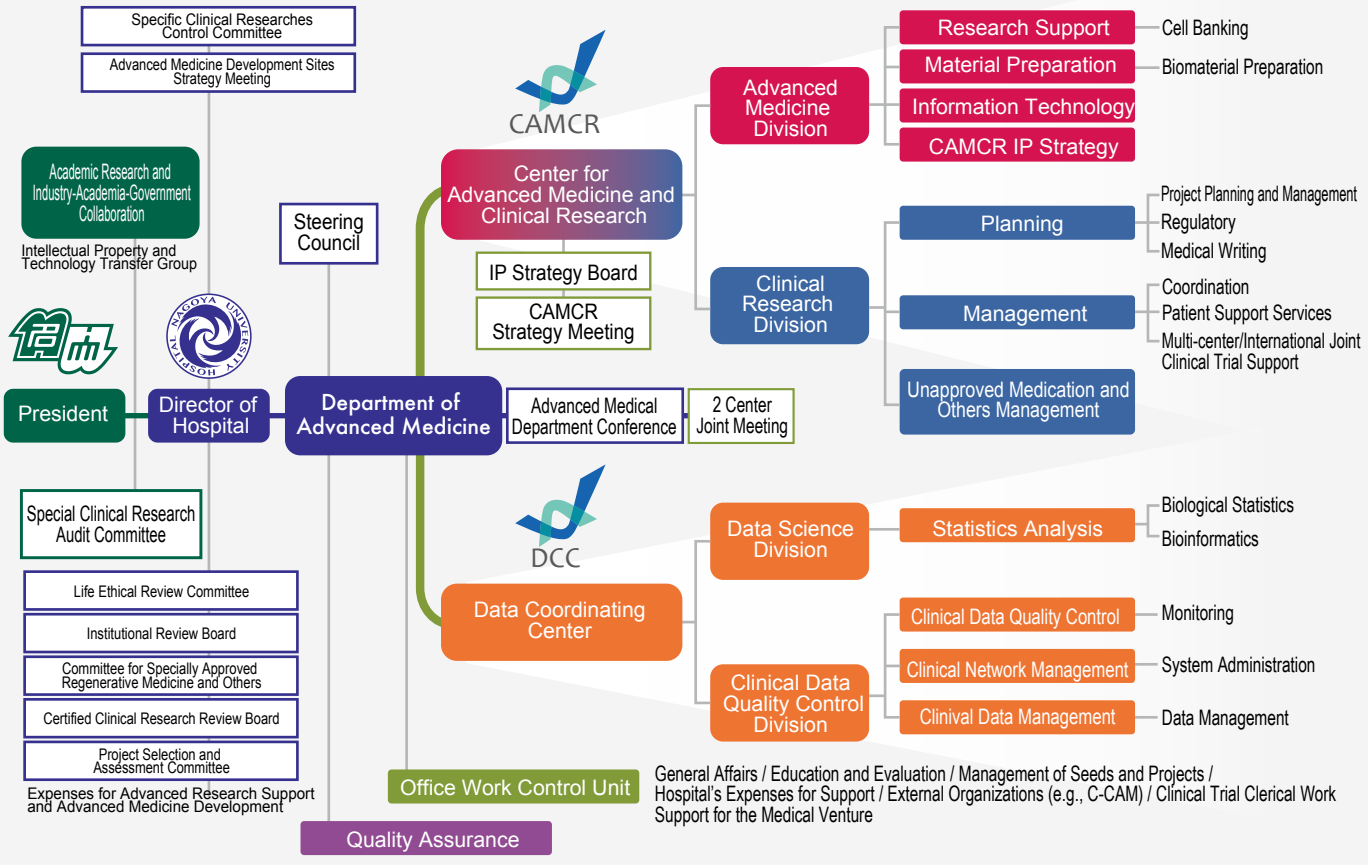
NAGOYA UNIVERSITY

Advanced Medicine Development System Established at Nagoya University

In 2012, Nagoya University was selected for “Translational Research Network Program” of the Ministry of Education, Culture, Sports, Science and Technology and for “Clinical Trials Core Hospital Program” of the Ministry of Health, Labour and Welfare. Thereafter, Nagoya University Hospital has intended to establish the network system to develop advanced medicine and to enhance Industry-Academia-Government collaboration, and its core organization is Department of Advanced Medicine, Nagoya University Hospital.



Organization of Department of Advanced Medicine



Department of Advanced Medicine

Greeting

Director
Professor
Yuichi ANDO

Nagoya University School of Medicine Hospital (Nagoya University Hospital), reorganized the “Department of Advanced Medicine and Clinical Research” in August 2018, by separating the Data Quality Control Division from the Advanced Medicine Division of the formerly the Center for Advanced Medicine and Clinical Research and integrating these two centers. Nagoya University Hospital is a university hospital, and has been designated as a Translational Research Network Program Bridging Research Support Base since 2012, a Clinical Research Core Hospital since 2016, and a Cancer Genome Core Hospital since 2018. Nagoya University Hospital is also at the heart of the 14 Chūbu-area facilities, 11 university hospitals and 3 centers, which consist of the Chūbu Regional Consortium for Advanced Medicine aiming to dispatch novel medical treatment to the world. Nagoya University Hospital and the Graduate School of Medicine have more than 100 research seeds related to the advanced medicine. Each of them either has applied for or obtained a patent. Indeed, the Department of Advanced Medicine and Clinical Research brings together the wisdom of Nagoya University to facilitate an advanced medical development system that entirely covers basic research, seed development to insurance medical examination, as well as human resource development and education for next generation.

Mission Statement

To complete our mission as a designated clinical research core hospital through the development of next-generation medical care

Department of Advanced Medicine
Center for Advanced Medicine and Clinical Research

Greeting

Director
Clinical Professor
Masaaki MIZUNO

The Center for Advanced Medicine and Clinical Research (CAMCR) adheres to the basic principle of Nagoya University Hospital "We will contribute to society through medical care, education, and research", and pioneers next-generation medical technologies and care through harmonization of translational science and regulatory science. The Department of Advanced Medicine was newly established in 2018, and a new start was made with the Data Coordinating Center under that. The CAMCR aims to achieve self-sustainable advanced medical development through virtuous circles of (1) development process, (2) human exchange, (3) funds, (4) intelligence, (5) network, and (6) clinical data.

Mission Statement

To develop new medical service for the next generation through harmonization of translational science and gulatory science

Department of Advanced Medicine
Data Coordinating Center

Greeting

Director
Clinical Professor
Masahiko ANDO

Data Coordinating Center, established in August 2018, take responsibility for the integrity of research data from clinical trials conducted at Nagoya University Hospital through the quality control process. As a member of Academic Research Organizations founded at Translational and Clinical Research Core Centers and/or Clinical Research Core Hospital, we also support external clinical researchers to conduct high-quality clinical trials. We will continuously assist clinical researchers to provide clinically meaningful outcomes as far as possible by efficient allocation of limited resources.

Mission Statement

To secure scientific validity and reliability of clinical trials through the quality control process of clinical data

Center for Advanced Medicine and Clinical Research

Under the strong leadership of the president, director of hospital, director of department, and director of center, CAMCR has 2 major divisions: Advanced Medicine Division and Clinical Research Division. Advanced Medicine Division is primarily in charge of the processes ranging from basic research to first-in-human clinical trials. On the other hand, Clinical Research Division is primarily responsible for the processes subsequent to the initiation of clinical studies and endeavors to manage the processes under ICH-GCP wherever possible in an attempt to ensure the reliability of advanced medicine and investigator-initiated clinical trials.

Advanced Medicine Division

Mission Statement

To explore and advance potential new treatments from laboratory discoveries.

1 Research Support

Manager

Yuka OKABE
Designated Assistant Professor

Cell Banking

Mission

To construct bioresource banks capable of providing high-quality clinical specimens for use in omics-based research and others.

Staff

Yuko ARIOKA
Designated Assistant Professor

2 Material Preparation

Mission

To prepare material for gene medicine, material for cell medicine, and material for regenerative medicine by utilizing biomaterial preparation equipment.

3 Information Technology

Manager

Akitaka SUGISHITA
Clinical Assistant Professor

Mission

To comprehensively operate the CAMCR-related systems.

4 CAMCR IP Strategy

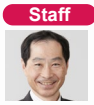
Manager

Yutaka ISOBE
Designated Professor

Mission

To efficaciously manage and operate intellectual properties.

Staff



Hitoshi FUJITA
Designated Professor

Centralization of Processes Ranging from Seeds Discovery to Medical Services Stabilization

Clinical Research Division

Manager, Clinical Research Division

Shinobu SHIMIZU
Associate Professor

Mission Statement

To deliver the findings in high-standard clinical research from Nagoya and Chubu to the world.

5 Planning

Project Planning and Management / Medical Writing

Mission To accelerate and streamline clinical studies.

Regulatory

Mission

To forward in academia the rapid development of more efficacious, safer, and innovative medical technologies (e.g., drugs, medical devices, and regenerative medicine products) based on regulations, notifications, evidence, and others.

Staff

Manabu AMANO
Designated Professor
Project Manager

Toshihisa TSURUTA
Designated Professor
Project Manager

Yasuhiro NAKAI
Designated Professor
Project Manager

Nobuhiro NISHIO
Designated Lecturer
Project Manager

6 Management

Coordination

Mission

To provide and conduct CRC services for allowing the smooth conduct of clinical studies and clinical trials.

Patient Support Services

Mission

To afford patient services for allowing the smooth conduct of clinical studies and clinical trials in an attempt to improve patient satisfaction.

Multi-center/International Joint Clinical Trial Support

Mission

We will promote multicenter and international clinical trials.

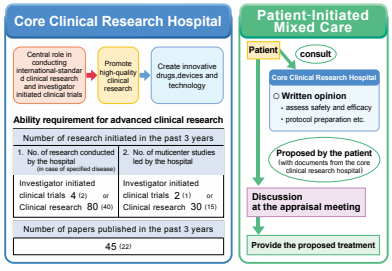
7 Unapproved Medication and Others Management

Manager

Satoshi NISHIWAKI
Clinical Lecturer

Mission

To support advanced medical care by accelerating high-quality clinical research.



Data Coordinating Center

Data Coordinating Center is charged to secure scientific validity and reliability of clinical trials by performing quality control of clinical data. From an objective standpoint, specialists in the area of clinical data monitoring, clinical data management, and biostatistics support clinical researchers in building and managing EDC-based data collection systems, monitoring clinical data including instructions to researchers, planning and conducting data analysis,and creating reports.

Clinical Data Quality Control Division

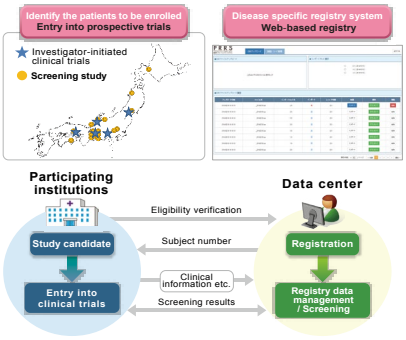
Mission Statement

To control the quality and integrity of clinical trial data by clinical monitoring and data management

Clinical Network Management

Mission

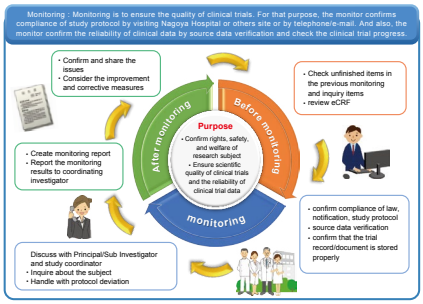
To forward patient enrollment in investigator-initiated clinical trials and clinical studies through subject recruiting using the patient accumulation registry and to support the clinical network collaboration inside and outside the Chubu region.



Clinical Data Quality Control

Mission

To forward in academia the conduct of highly confident clinical studies based on regulations, notifications, protocols, and others, to protect the human rights, maintain the safety, and improve the welfare of subjects, as well as to contribute to the reliability of clinical study results.



Clinival Data Management

Manager

Yachiyo KUWATSUKA

Clinical Assistant Professor

Mission

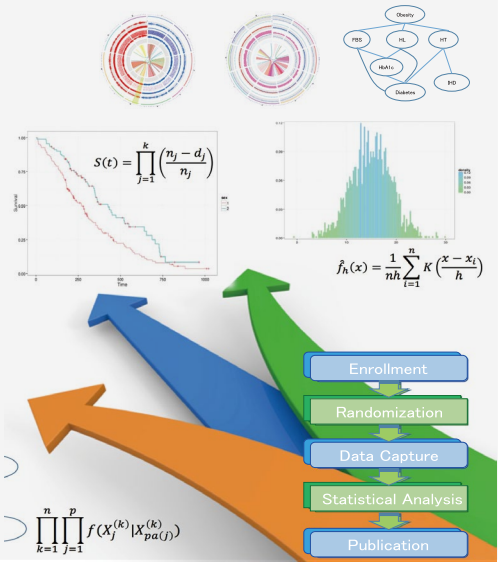
To appropriately design scientific, rational, and ethical clinical research. To support investigators in an attempt to guarantee the reliability thereof and from objective and professional standpoints.

Data Science Division

Mission Statement

Implementing data science solutions for supporting medical research, and accelerating advances in public health and medicine

In the Data Science Division, specialists of biostatistics and bioinformatics support medical research. We support wide range of researches as small clinical trial to analysis of medical big data. Statistics is essential to high quality results. Our professional staff in data science can deal various medical research.



Statistics Analysis

Manager

Fumie KINOSHITA

Clinical Assistant Professor

Mission

To enhance quality of medical research conducted in central Japan through excellent use of methods in biostatistics and bioinformatics.

Quality Assurance

Manager

Kohei UEDA

Designated Professor

Mission

To assure that the clinical study was conducted and its data were prepared, recorded, and reported in compliance with regulations, guidelines, and others and in accordance with the approved protocol.

Office Work Control Unit

- General Affairs
- Education and Evaluation
- Management of Seeds and Projects
- Hospital's Expenses for Support
- External Organizations (e.g., C-CAM)
- Clinical Trial Clerical Work
- Support for the Medical Venture

Non-Profit Organization

Chubu Regional Consortium for Advanced Medicine

C-CAM

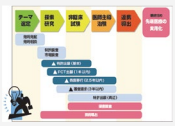
Chubu Regional Consortium for Advanced Medicine

Board of Directors

Operation Committee

- WG for ELSI
- WG for Multicenter Study Management
- WG for Education and Training
- WG for Industry, Academia Collaboration
- WG for Information Sharing
- WG for IP
- WG for Clinical Data Science

Each WG has established its missions and annual goals and intends to achieve them.

WG for ELSI	WG for Multicenter Study Management	WG for Education and Training	WG for Industry, Academia Collaboration	WG for Information Sharing	WG for IP	WG for Clinical Data Science
Mission Holding of the meetings of collaborative ethical comittee and others	**Mission** Planning, arrangement, conduct, and evaluation of respective multicenter collaborative clinical studies	**Mission** Cultivation of human resources through personnel exchanges	**Mission** Matching with companies through Industry-Academia collaboration and support of the control of intellectual properties	**Mission** Establishment of the information sharing system	**Mission** Arrangement, management, and strategy of the intellectual properties of collaborated projects	**Mission** Development of the system to conduct clinical studies in compliance with ICH-GCP at each university, as well as the sharing of information thereof
 Placement of and deliberation by collaborative Ethical Review Board	 Establishment of the interinstitutional monitoring system (interinstitutional SOP)	 Delivery of live videos (> once per month) to the participating institutions of clinical research seminars -> clinical researcher certification system and monitor certification system	 Operation of the seeds-needs matching system and business negotiation with Medical Devices Industry Promotion Council, the Nagoya Chamber of Commerce and Industry	 Seeds information collection and control system -> Initiation of the disease registry	 Opening of Interinstitutional Intellectual Property and Resources Collaboration Council -> Sharing of intellectual property information and leveling of evaluations (professional judgment)	 Clinical study expert WG mainly comprising biostatisticians -> Enrollment, assignment, EDC, SOP/ manuals, seminars/OJT

Achievements

Overview

Chubu Regional Consortium for Advanced Medicine (C-CAM) was established to achieve rapid delivery of new medical technology and devices that fulfil societal needs through mutual participation among Chubu-area universities and other institutions. The consortium comprises 14 members: Aichi Medical University, Kanazawa Medical University, Kanazawa University, Gifu University, University of Toyama, Nagoya City University, Nagoya University, Hamamatsu University School of Medicine, University of Fukui, Fujita Health University, Mie University, Aichi Cancer Center, National Hospital Organization Nagoya Medical Center and the National Center for Geriatrics and Gerontology.

愛知医科大学 Aichi Medical University
金沢大学 KANAZAWA UNIVERSITY
金沢医科大学 Kanazawa Medical University
国立大学法人 岐阜大学 GIFU UNIVERSITY
富山大学
名古屋大学 NAGOYA UNIVERSITY
公立大学法人 名古屋市立大学 Nagoya City University
国立大学法人 浜松医科大学 Hamamatsu University School of Medicine
藤田医科大学 FUJITA HEALTH UNIVERSITY
国立大学法人 福井大学 UNIVERSITY OF FUKUI
三重大学 Mie University
愛知県がんセンター Aichi Cancer Center
独立行政法人 国立長寿医療研究センター National Center for Geriatrics and Gerontology
独立行政法人 国立病院機構 名古屋医療センター National Hospital Organization Nagoya Medical Center

Incorporation

The consortium was incorporated as non-profit organization, Chubu Regional Consortium for Advanced Medicine (C-CAM) in April, 2017.

Mission

1.Our Goals

To achieve rapid delivery of new medical technology and devices that fulfill societal needs through mutual participation among Chubu-area universities and other institutions.

To improve human health and peace worldwide through our service.

2.Responsibilities

We strive to:

plan, organize, conduct and evaluate multi-institutional clinical research

- convene Joint Ethics Committee
- educate and train staff engaged in the development of advanced medicine
- foster cooperative agreements with private companies and appropriately manage resulting intellectual property

3.Administrative Office

Center for Advanced Medicine and Clinical Research, Nagoya University Hospital

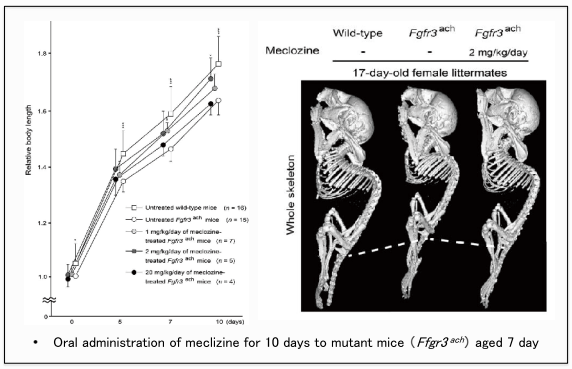
Structure

Under the Board of Directors and Operation Committee, C-CAM comprises seven Working Groups (WG); WG for ELSI, WG for Multicenter Study Management, WG for Education and Training, WG for Industry-Academia Collaboration, WG for Information Sharing, WG for IP and WG for Clinical Data Science.

Investigator-initiated clinical trials about which the clinical trial notification was accepted or submitted

[Target Diseases] Achondroplasia
[Product Name] Meclizine hydrochloride
[Development phase] Phase I

Treatment for short stature by the FGFR3 inhibitory drug, meclizine

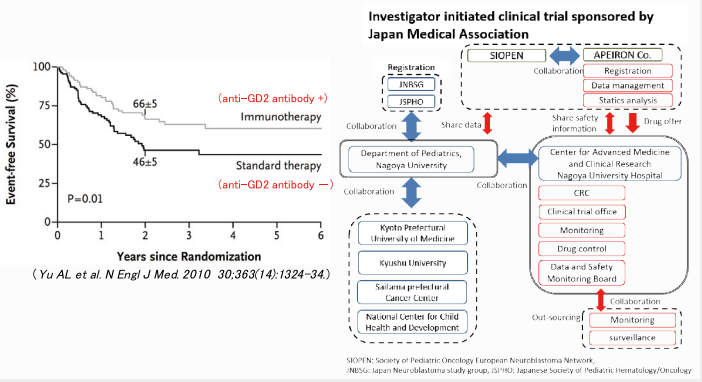


- Oral administration of meclizine for 10 days to mutant mice (*Ffgr3 ach*) aged 7 day

◆ Completion of physician-initiated phase 1 clinical trial (December 2018)

FGFR3 is a negative regulator of longitudinal bone growth and over-activation of FGFR3 causes several short-limbed skeletal dysplasias. By FDA-approved drug screening, we identified that meclizine, an anti-histamine OTC drug, ameliorated abnormally activated FGFR3 signaling in vitro. Meclizine significantly increased the body length in mutant mice as well as in the wild type mice in vivo. The plasma concentration of meclizine during treatment was within the range that has been used in clinical settings. We examine potential clinical feasibility of meclizine for the improvement of short stature in FGFR3-related disorders.

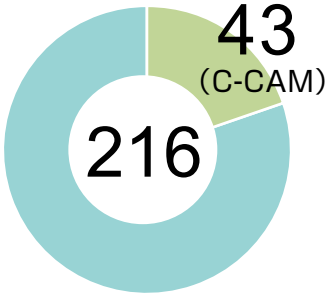
[Target Diseases] Neuroblastoma
[Product Name] ch14.18/CHO
[Development phase] Phase I



Children with relapsed/refractory high-risk neuroblastoma (NB) have a poor prognosis. Clinical trials provide strong evidence that anti-GD2 antibody are useful in patients with high-risk NB. However, no clinical trials with anti-GD2 antibody have been conducted in Japan. This clinical trial is to assess safety and efficacy of single-agent monoclonal anti-GD2 antibody in Japanese NB patients. These results bridge data of ch14.18/CHO between Asian and Caucasian patients.

[Target Diseases]	[Product Name]	[Development phase]
non-small cell lung cancer	Vorinostat	Phase I
Stress urinary incontinence	Centrifuge for cells	Phase III
Synovial cell carcinoma	NY-ESO-1 specific T cells	Phase I

Supported Projects



FY2017

Achievements

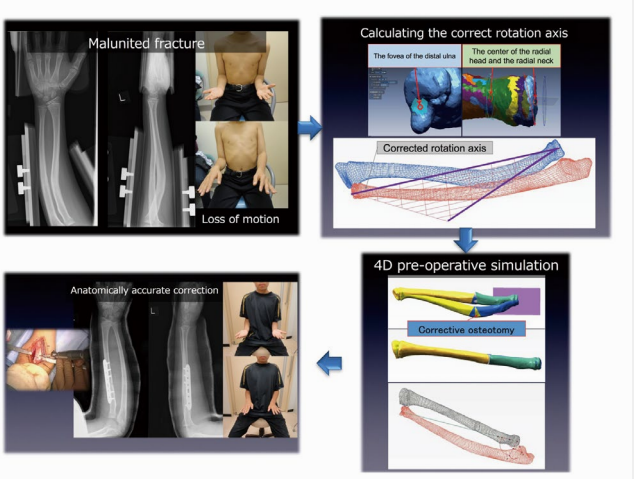
until FY2017

- Number of investigator-initiated clinical trials about which the clinical trial notification was accepted or submitted
- Number of investigational drugs/devices that were licensed out to companies
- Number of investigational drugs/devices that were approved as advanced medicine
- Number of investigational drugs/devices that were applied for the approval (authentication) of manufacture or distribution
- Number of investigational drugs that were approved (authenticated) for manufacture or distribution
- Number of investigational drugs/devices that were commercialized other than those described above

Number of investigational drugs/devices that were licensed out to companies

[Target Diseases] Malunited fractures
[Product Name] Skeletal correction surgery simulator

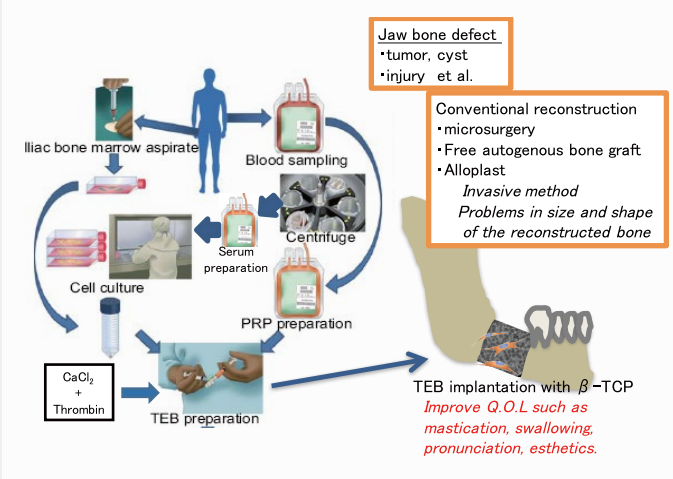
Malunited fractures cause severe disabilities, such as pain, loss of motion, and instability. A 4D pre-operative simulation system is made by adding the anatomical axis to three-dimensional CT data obtained with the affected arm in one position. The use of computer simulation for corrective osteotomy of a malunited fracture enable accurate correction of the deformity and improves the clinical outcome.



Number of investigational drugs/devices that were approved as advanced medicine

[Target Diseases] Jaw bone defect (due to injury, tumor, cyst of jaw bone)
[Product Name] Bone marrow-derived mesenchymal cells
[Development phase] Phase II

This technic will improve the patients' Q.O.L. through the reconstruction of the oral function such as the mastication, swallowing, pronunciation using the autogenous cells and/or dental implants or prosthesis.



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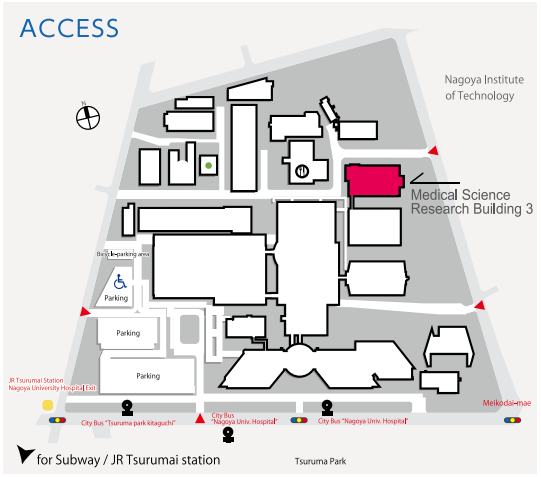

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