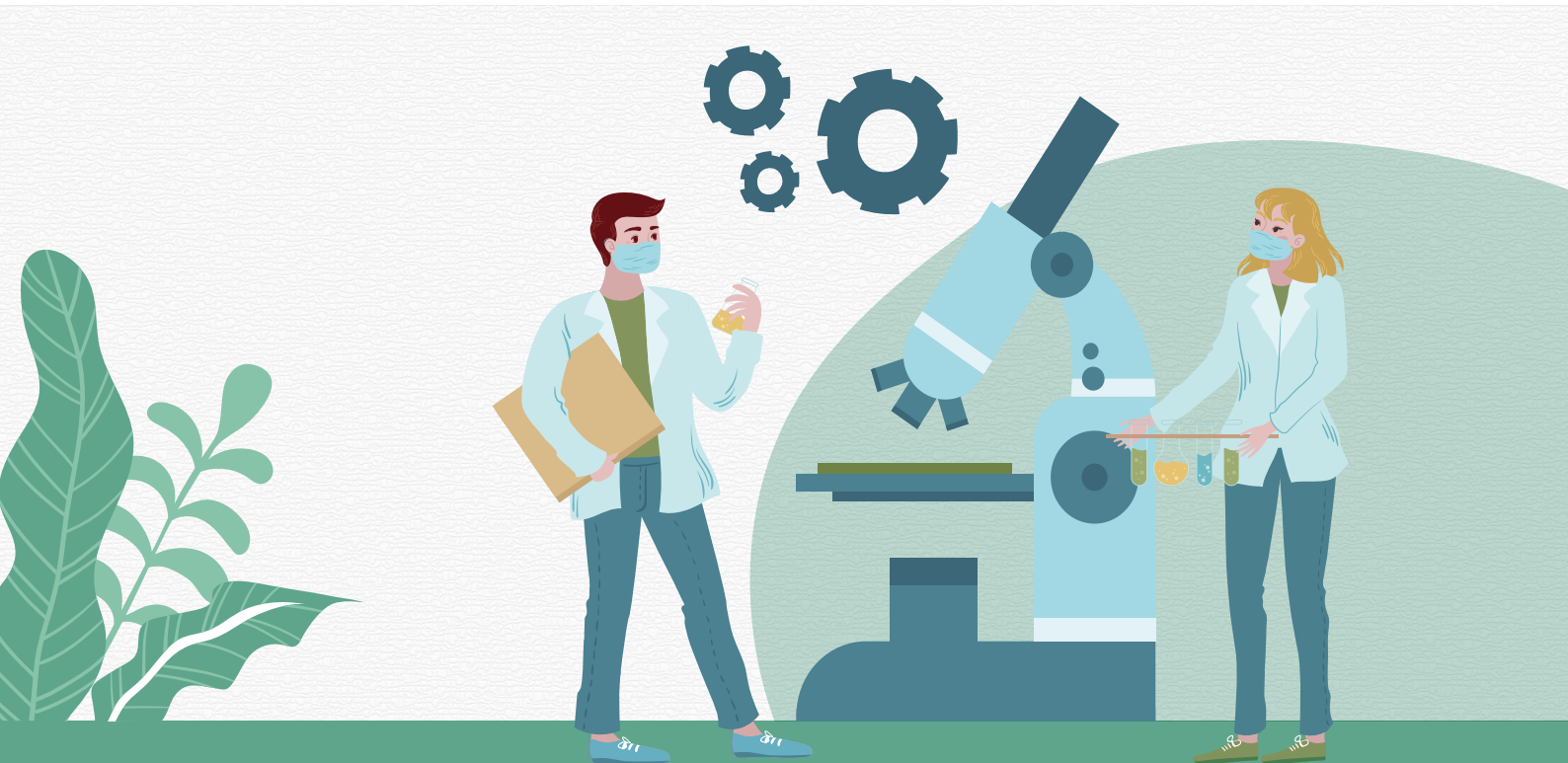


# Development of Advanced Medicine Portfolio

# 2022



Department of  
**Advanced Medicine**  
Nagoya University Hospital

CAMCR & DCC



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# 1 List of supported seeds







# C [Definition] Clinical POC

Control Number	Project Title	Organization	Principal Investigator
<b>C02</b>	Development of Virus Specific Cytotoxic T cells Therapy for Refractory Viral Infection after Allogeneic Hematopoietic Stem Cell Transplantation	Nagoya University	Yoshiyuki Takahashi
<b>C14</b>	Multicenter clinical trial of the Patient-Specific Cardiac Support Device (CSD) with less constraint on Right Ventricle (RV) for Dilated Cardiomyopathy	Nagoya University	Toshiaki Akita
<b>C16</b>	Alternative treatment of combined physical therapy for postoperative lymphedema	Nagoya University	Hitoshi Hirata • Katsuyuki Iwatsuki
<b>C22</b>	Research and development for the medical treatment of achondroplasia by attenuating FGFR3 signaling	Nagoya University	Masaki Matsushita
<b>C25</b>	Multicenter Clinical Trial of Hyper Dry Human amnion membrane (HD amnion) as Medical Device for Therapeutic Use	University of Toyama	Toshiko Yoshida
<b>C26</b>	Research aimed at creating the development of devices for hyperthermia therapy for superficial lesions	Nagoya University	Nobuhisa Yoshikawa
<b>C27</b>	Phase I study of piggyBac transposon mediated chimeric antigen receptor gene modified T cells for CD19 positive acute lymphoblastic leukemia	Nagoya University	Yoshiyuki Takahashi
<b>C29</b>	Clinical study to evaluate the safety of co-injection of adipose-derived MSC and cord blood hematopoietic stem cells into the bone marrow cavity	Aichi Medical University	Takayuki Nakayama
<b>C30</b>	A multi-center, single-arm clinical study of the efficacy and safety of rituximab in CIDP patients with IgG4 autoantibodies	Nagoya University	Masahiro Iijima
<b>C31</b>	Development a novel regenerative treatment for perinatal brain injury with Muse cells - Exploratory investigator-initiated clinical trial -	Nagoya University	Yoshiaki Sato
<b>C33</b>	Development of allogeneic adipose derived stem cells therapy for the treatment of IgA nephropathy	Nagoya University	Syouichi Maruyama
<b>C34</b>	Physician-initiated clinical trial on the efficacy and safety of auranofin for aggressive fibromatosis	Nagoya University	Yoshihiro Nishida
<b>C37</b>	Open-label phase I/II investigator-initiated clinical trial based on a drug repositioning approach that reprograms the stroma of pancreatic cancer	University of Tokyo	Mitsuhiro Fujishiro
<b>C39</b>	Multicenter clinical trial of the Patient-Specific Cardiac Support Device (CSD) with less constraint on RV for Dilated Cardiomyopathy	Nagoya University	Toshiaki Akita
<b>C40</b>	Protocol preparation of investigator-initiated clinical trial to assess efficacy and safety of mexiletine hydrochloride for the patients with spinal and bulbar muscular atrophy	Nagoya University	Shinichiro Yamada
<b>C41</b>	Preparation of an Investigator-Initiated Clinical Trial Protocol for Idiopathic Membranous Nephropathy with Nephrotic Syndrome Using Rituximab	Nagoya University	Akihito Tanaka
<b>C42</b>	Development of novel therapies targeting pulmonary microthrombosis of coronavirus disease 2019	Nagoya University	Yukari Goto
<b>C43</b>	Basket study of afatinib maleate (BIBW2992) in patients with solid tumors harboring NRG1 fusion for evaluating efficacy and safety	Nagoya University	Masahiro Morise
<b>C44</b>	A placebo-controlled, double-blind crossover study investigating the ameliorative effect of shakuyakukanzoto on paclitaxel (Tri-weekly)-induced muscle pain and arthralgia	University of Toyama	Akitoshi Nakashima





## List of supported seeds

Psychiatry	Neurology	Ophthalmology	Otorhinolaryngology	Oral Surgery	Respiratory	Cardiology	Gastroenterology	Nephrology	Urology	Gynecology	Hematology	Musculoskeletal System	Dermatology	Immunology	Endocrinology	Oncology	Infectious Diseases	Pain	Child Health	Pediatrics	Senile Dementia	Lifestyle Disease	Other	Modality	Page Number
																								Regenerative Medicines	8
																								Devices	9
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## 2 Details of supported seeds







## Disease Classification

Psychiatry

Neurology

Ophthalmology

Otorhinolaryngology

Oral Surgery

Respiratory

Cardiology

Gastroenterology

Nephrology

Urology

Gynecology

Hematology

Musculoskeletal System

Dermatology

Immunology

Endocrinology

Oncology

Infectious Diseases

Pain

Child Health

Pediatrics

Senile Dementia

Lifestyle Disease

Other



## Project Title

Development of Virus Specific Cytotoxic T cells Therapy for Refractory Viral Infection after Allogeneic Hematopoietic Stem Cell Transplantation

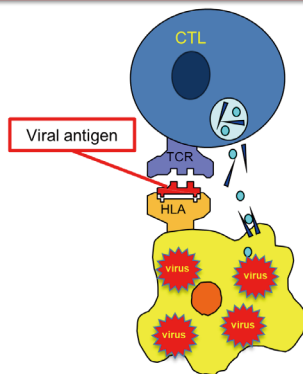
## Organization

Nagoya University

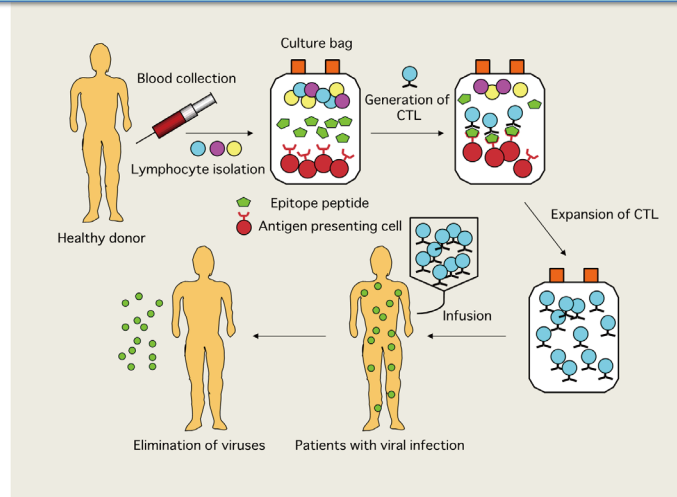
## Principal Investigator

Yoshiyuki Takahashi

**Virus-specific cytotoxic T cells (CTL) recognize viral antigens expressed with HLA on infected cells and kill them.**



## Generation of virus specific CTL and infusion to the patient



## Clinical Study

**Phase I study of Third party derived Epstein-Barr virus (EBV) Specific CTL for Refractory Infection after Allogeneic Hematopoietic Stem Cell Transplantation**  
(jRCTa040190110)

Target Disease (Applications)	Refractory EBV associated Post-transplant Lymphoproliferative Disease (PTLD) after allogeneic hematopoietic stem cell transplantation
Abstract	Production of 3rd party derived virus specific cytotoxic T cells and infusion to the patient
Advantages	eligible to rituximab resistant PTLD "off the shelf" product eligible for unrelated stem cell transplantation
Patent Information	Process patent
Market Overview	30 patients/year in Japan
Stage of Development	Clinical trial





## Project Title

Multicenter clinical trial of the Patient-Specific Cardiac Support Device (CSD) with less constraint on Right Ventricle (RV) for Dilated Cardiomyopathy

## Organization

Nagoya University

## Principal Investigator

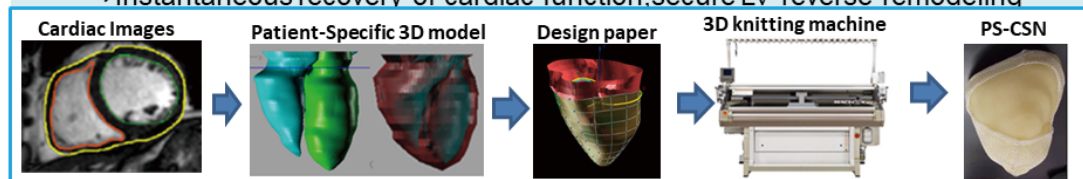
Toshiaki Akita

New Innovative Treatment for advanced Heart Failure :

**Patient-Specific Cardiac Support Net (PS-CSN):**

- ✓ Personalized design from CT or MRI images (Patented in US, EU, CN, JP)
- ✓ Less constraint on RV side (Patented in US, CN, JP)

⇒ Instantaneous recovery of cardiac function, secure LV reverse remodeling

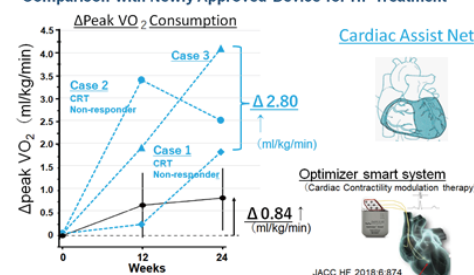


**Sakigake First tract Approval System (2020.Jun)**

Benefits: Improvement in Exercise Capacity by Cardiac Assist Net - Comparison with Newly Approved Device for HF Treatment

**Multi-institutional Clinical trial underway (JRCT s042180025)**

PS-CSN		術前	術後 12週	術後 24週
Case 1	Peak VO <sub>2</sub> (ml/kg/min)	12.5	12.7	14.3
	6MWT(m)	576	630	611
Case 2	Peak VO <sub>2</sub> (ml/kg/min)	11.9	15.3	14.4
	6MWT(m)	411	522	555



Target Disease (Applications)	Idiopathic dilated cardiomyopathy (DCM) Secondary cardiomyopathy
Abstract	Multicenter clinical trial is running to evaluate the safety and the usefulness of the Patient-Specific Cardiac Support Device (CSD) with less constraint on RV for Dilated Cardiomyopathy.
Advantages	Patient-specific design→Less invasive and more effective Less constraint on RV→Preserve RV diastolic function and cardiac output Multi-scale & multi-physics cardiac simulation by UT-Heart Inc. → Select the suitable candidate and predict the postoperative cardiac function
Patent Information	Basic patent : registered Method of creating design paper for patient-specific heart correction net: US, EP, CN, JP registered Heart correction net : JP,US, EP, CN registered Registered design : JP(2), CN(1), US(2), EP(1)
Market Overview	Huge market for heart failure (Japan; 1000 cases/year, ¥3.5 billion/year, worldwide >20,000/year \$350 million/year) Superior technology to competitor (Mardil: Acorn CorCap successor)
Stage of Development	To establish the safety of this device through small feasibility clinical trial (First in Human study:2019-2021) To establish the efficacy for improvement in cardiac function, cardiac remodeling indices, and QOL through investigator-initiated feasibility clinical trials in 2022, pivotal study in 2023.

## Disease Classification

- Psychiatry
- Neurology
- Ophthalmology
- Otorhinolaryngology
- Oral Surgery
- Respiratory
- Cardiology
- Gastroenterology
- Nephrology
- Urology
- Gynecology
- Hematology
- Musculoskeletal System
- Dermatology
- Immunology
- Endocrinology
- Oncology
- Infectious Diseases
- Pain
- Child Health
- Pediatrics
- Senile Dementia
- Lifestyle Disease
- Other







## Project Title

## Alternative treatment of combined physical therapy for postoperative lymphedema

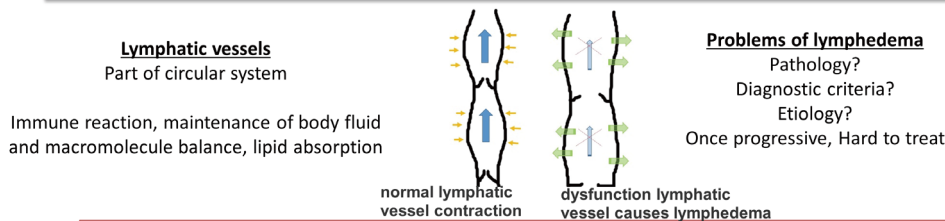
## Organization

Nagoya University

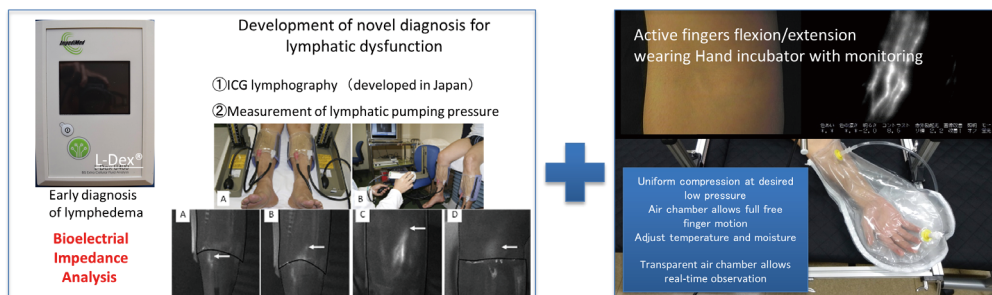
## Principal Investigator

Hitoshi Hirata · Katsuyuki Iwatsuki

### Early diagnosis and novel treatment for lymphedema



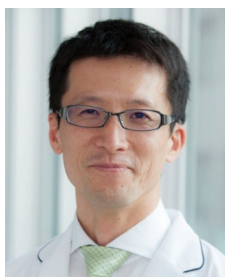
Recent reports: Lymphatic dysfunction → lymphedema  
Treatment of lymphedema ✕ proper evaluation & intervention



With monitoring of lymphatic function, active motion exercise under low pressure can promote lymphatic flow safely. We will establish a novel treatment algorithm for the subclinical lymphedema.

Target Disease (Applications)	Lymphedema
Abstract	Lymphedema is a potential side effect of cancer surgery, especially in breast cancer and uterine cancer. Once lymphedema is developed, it can be difficult to treat. Based on the evaluation of the lymphatic system in early stage of each patient, we will establish a novel treatment algorithm for the lymphedema.
Advantages	The standard therapy for postoperative lymphedema is complex physical therapy, which is covered by health insurance in Japan. However, the patients should be continued for the rest of their life and should be performed at a medical institution. The advantage of the medical equipment we are developing is that it can be used at home and can be used easily by themselves.
Patent Information	PCT/JP2007/067078, WO2008/044400
Market Overview	Breast cancer (about 80 thousands/year) patients are increased recently in Japan. There are about 100-150 thousands patients with lymphedema in Japan, and about 6000 new lymphedema patients are increased annually. Worldwide, about 1.38 million women are diagnosed with breast cancer per year.
Stage of Development	Now recruiting clinical study for expand indication.





### Project Title

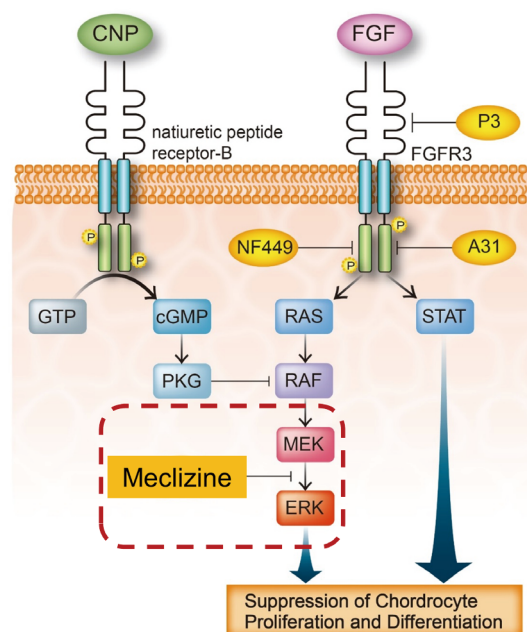
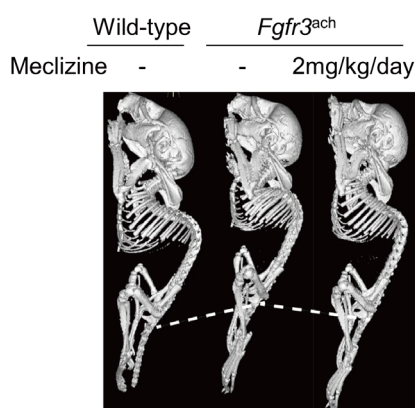
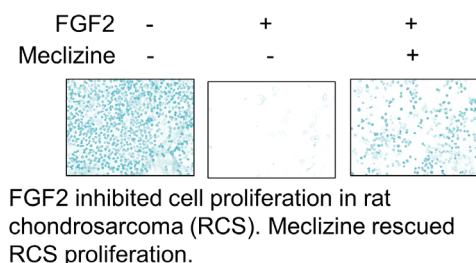
Research and development for the medical treatment of achondroplasia by attenuating FGFR3 signaling

### Organization

Nagoya University

### Principal Investigator

Masaki Matsushita



Meclizine attenuated ERK phosphorylation in FGFR3 signaling.

Completion of physician-initiated phase 1 clinical trial (12 child patients with achondroplasia).

Target Disease (Applications)	FGFR3-related skeletal dysplasias (achondroplasia, hypochondroplasia, thanatophoric dysplasia)
Abstract	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 a mouse model of achondroplasia. 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.
Advantages	Meclizine inhibited FGFR3 signaling. Compliance is expected for children due to the oral administration. Economic benefit for developing the treatment of intractable disease by using cheap drug.
Patent Information	Utility patent
Market Overview	1,000 in Japan, 60,000 in worldwide
Stage of Development	Single dose Phase1a clinical trial was completed. Repeated dose Phase 1b clinical trial was completed. Repeated dose Phase 2 clinical trial is in preparation. Juvenile animals test was completed. Long-term toxicity test using animals are ongoing. We are analyzing detail mechanism of meclizine.







## Disease Classification

Psychiatry

Neurology

Ophthalmology

Otorhinolaryngology

Oral Surgery

Respiratory

Cardiology

Gastroenterology

Nephrology

Urology

Gynecology

Hematology

Musculoskeletal System

Dermatology

Immunology

Endocrinology

Oncology

Infectious Diseases

Pain

Child Health

Pediatrics

Senile Dementia

Lifestyle Disease

Other



## Project Title

Phase I study of piggyBac transposon mediated chimeric antigen receptor gene modified T cells for CD19 positive acute lymphoblastic leukemia

## Organization

Nagoya University

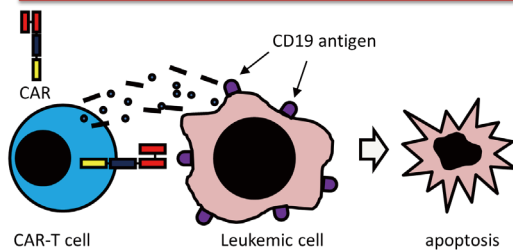
## Principal Investigator

Yoshiyuki Takahashi

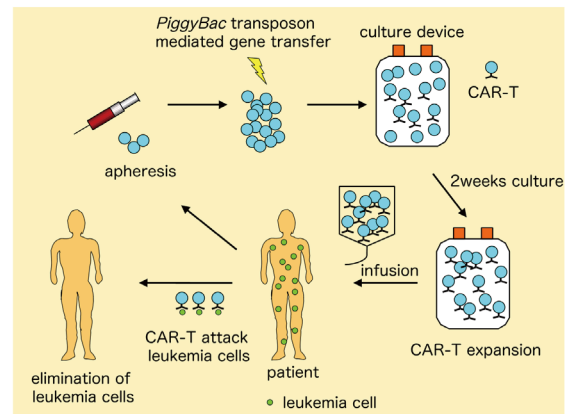
## CAR-T Therapy\*

\* CAR(chimeric antigen receptor)-T cell therapy

CAR-T cells recognize CD19 antigens on leukemic cells and kill them.



## Production of CAR-T and infusion to the patient



## Clinical Trial (autologous CAR-T therapy)

Phase I study of *piggyBac* transposon mediated chimeric antigen receptor gene modified T cells for CD19 positive acute lymphoblastic leukemia (jRCTa040190099)

Phase I/II study of *piggyBac* transposon mediated chimeric antigen receptor gene modified T cells for CD19 positive malignant lymphoma

Target Disease (Applications)	CD19 positive acute lymphoblastic leukemia, CD19 positive malignant lymphoma, chronic lymphocytic leukemia
Abstract	Production of autologous CD19 CAR-T cells and infusion back to the patient
Advantages	PiggyBac transposon mediated gene transfer (non-viral gene transfer) Reduced cost
Patent Information	Process patent
Market Overview	Acute lymphoblastic leukemia: 1,000 patients/year in Japan Malignant lymphoma: 10,000 patients/year in Japan Chronic lymphocytic leukemia: 2,000 patients/year in Japan
Stage of Development	Acute lymphoblastic leukemia: Clinical trial, sponsor initiated clinical trial Malignant lymphoma: investigator initiated clinical trial





### Project Title

Clinical study to evaluate the safety of co-injection of adipose-derived MSC and cord blood hematopoietic stem cells into the bone marrow cavity

### Organization

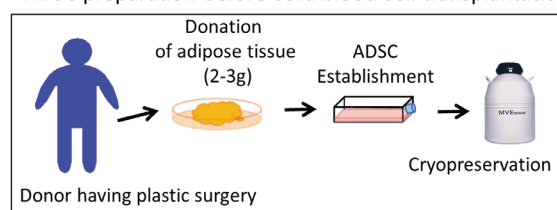
Aichi Medical University

### Principal Investigator

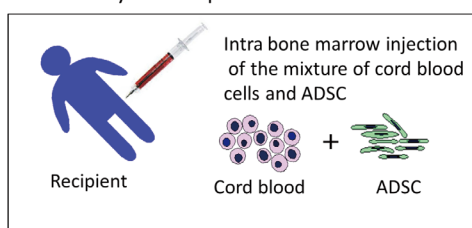
Takayuki Nakayama

Schematic presentation of phase I clinical study to support hematopoiesis with adipose-derived mesenchymal stromal cells (ADSC) in the setting of cord blood transplantation

#### ADSC preparation before cord blood cell transplantation



#### On the day of transplantation



Adipose-derived mesenchymal stromal cells possess higher hematopoietic-supportive abilities compared to conventional bone marrow derived stromal cells which establish the hematopoietic microenvironment in the bone marrow.

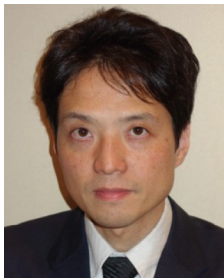
Target Disease (Applications)	Patients who will have cord blood transplantation to treat hematological disorders such as leukemia
Abstract	Engraftment failure will be prevented by intra-bone marrow injection of adipose-derived mesenchymal stromal cells with higher hematopoietic supportive abilities in the setting of cord blood cell transplantation.
Advantages	No other treatment to promote the engraftment of cord blood cells has not been invented yet.
Patent Information	Adipose-derived mesenchymal stromal cells as support medium for cord blood cells Patent Number : Tokugan 2017-162233
Market Overview	Over 1000 patients per a year have cord blood transplantation in Japan.
Stage of Development	Phase I clinical trial is ongoing.

#### Disease Classification

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- Gynecology
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- Dermatology
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- Infectious Diseases
- Pain
- Child Health
- Pediatrics
- Senile Dementia
- Lifestyle Disease
- Other







## Project Title

A multi-center, single-arm clinical study of the efficacy and safety of rituximab in CIPD patients with IgG4 autoantibodies

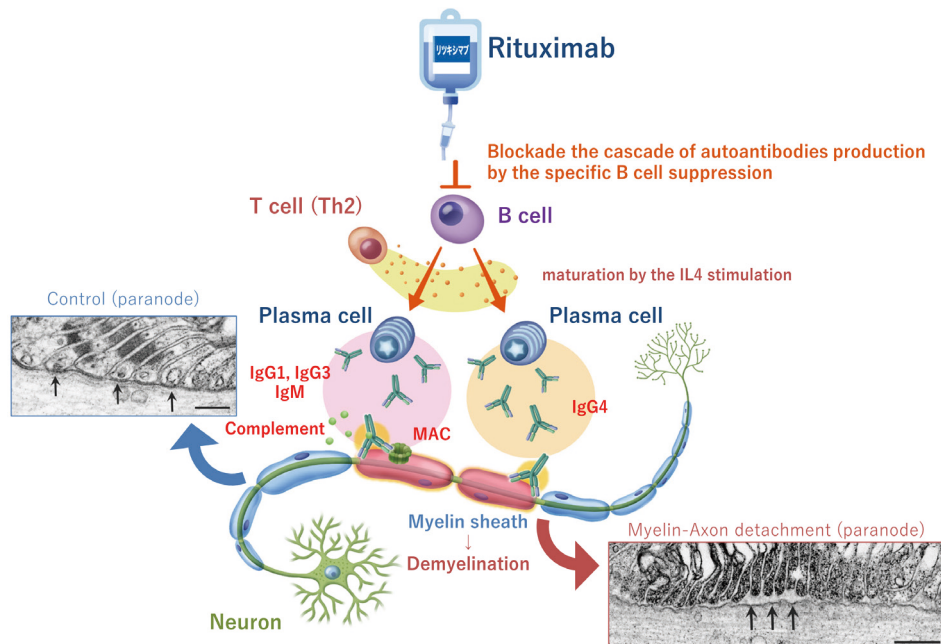
## Organization

Nagoya University

## Principal Investigator

Masahiro Iijima

**Rituximab can exert its therapeutic effect by selective intervention to the B cell-derived pathogenesis of refractory CIPD including IgG4 autoantibodies**



2

Target Disease (Applications)	CIPD (chronic inflammatory demyelinating polyneuropathy) (The expected efficacy is an improvement of motor dysfunction in refractory CIPD, especially with IgG4 subclass autoantibodies.)
Abstract	A certain percentage of patients with CIPD are positive for autoantibodies belonging to the IgG4 subclass and show resistance to conventional therapies. On the other hand, rituximab strongly suppresses antibody production through B cell inhibition. It is a fundamental strategy for refractory CIPD with known or unknown autoantibodies. Therefore, we plan the investigator-initiated clinical trial (the RECIPE trial).
Advantages	Among conventional therapies (steroid, intravenous immunoglobulins (IVIg), plasmapheresis), IVIg is used as the first-line. On the other hand, IVIg is ineffective for patients with IgG4 autoantibodies, and the others are less effective. Rituximab is a molecular targeting therapy and selectively inhibits antibodies. This is the first trial to verify the efficacy of rituximab for refractory CIPD. Note that IgG4 is a specific subclass lacking complement binding ability, and rituximab is an ideal drug to eliminate the etiology of refractory CIPD involved in autoantibodies.
Patent Information	None
Market Overview	CIPD is one of the designated intractable diseases in Japan, and the number of people with a specified medical expense (specified refractory disease) beneficiary certificate is 4,315 (as of 2008). Of these, IgG4 autoantibody positive cases account for around 10%. Other unknown autoantibodies are also assumed to be involved, but the specific number of patients is unknown. CIPD is mainly treated with IVIg, and refractory cases are treated with progression control therapy that requires intermittent administration for at least one year. Rituximab is expected to be a promising treatment for refractory CIPD since it can be completed in four weekly doses and is expected to be effective over a long period. In contrast, conservative therapeutics such as continuous IVIg maintenance therapy are costly.
Stage of Development	As an exploratory clinical trial, the inclusion of clinical trial participants started in the first quarter of 2019 and was closed in June 2020. We completed the evaluation of all patients in June 2021. During the evaluation period, we had never experienced severe safety episodes. After completing the exploratory clinical trial with a summary report, we will progress early approval or transition to further confirmatory clinical trial.





## Project Title

Development a novel regenerative treatment for perinatal brain injury with Muse cells - Exploratory investigator-initiated clinical trial -

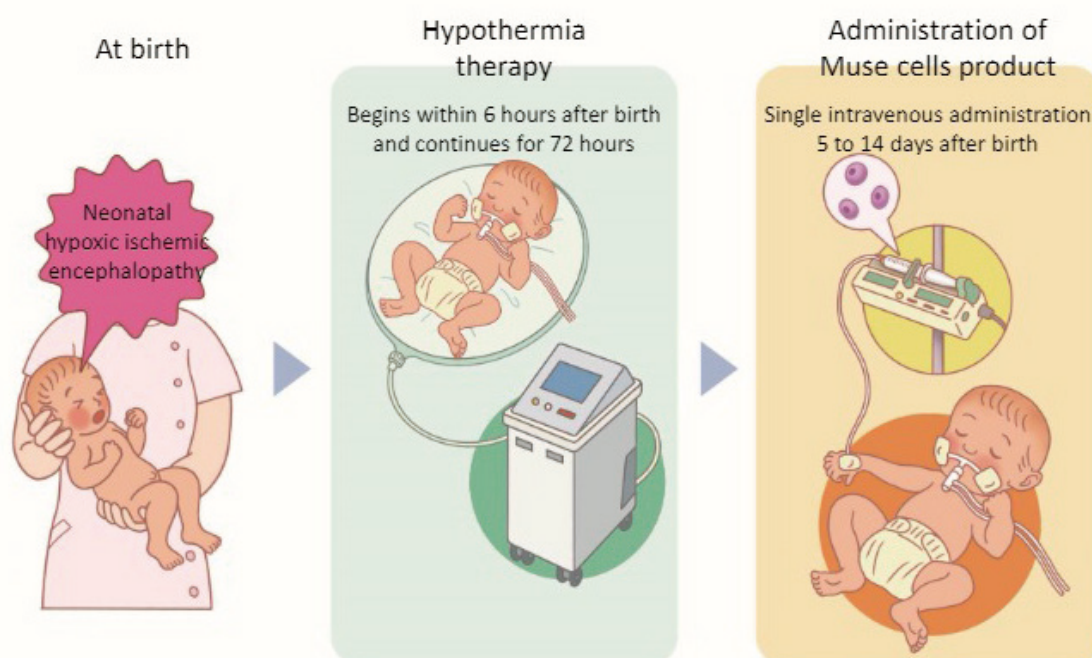
## Organization

Nagoya University

## Principal Investigator

Yoshiaki Sato

## A novel treatment for Neonatal Hypoxic Ischemic Encephalopathy



Target Disease (Applications)	Perinatal brain damage (Hypoxic Ischemic Encephalopathy: HIE)
Abstract	Multilineage-differentiating Stress Enduring (Muse) cells exist in bone marrow, skin, adipose, and other mesenchymal tissues, as well as in the connective tissues of many organs. So far, our non-clinical study with HIE model rats showed that Muse cells administered intravenously were detected in the injured brain, and ameliorated behavioral and learning impairments and movement abnormalities. The administration of Muse cells should be a promising therapy for HIE.
Advantages	Muse cells have the potential to self-renew and can differentiate into various types of somatic cells. Moreover, Muse cells readily integrate into injured sites and mediate tissue repair via tissue-specific differentiation.
Patent Information	Filed patent application
Market Overview	As the frequency of occurrence of HIE is 2 to 4 people per 1,000 live births, but the social impact is considered to be great.
Stage of Development	We evaluated the treatment effect and safety with clinical grade Muse cells-based product, CL2020 in non-clinical studies and performed several experiments to reveal the underlying mechanism of the treatment effect of the Muse cells on HIE. We have just proceeded to an investigator-initiated clinical trial.







## Project Title

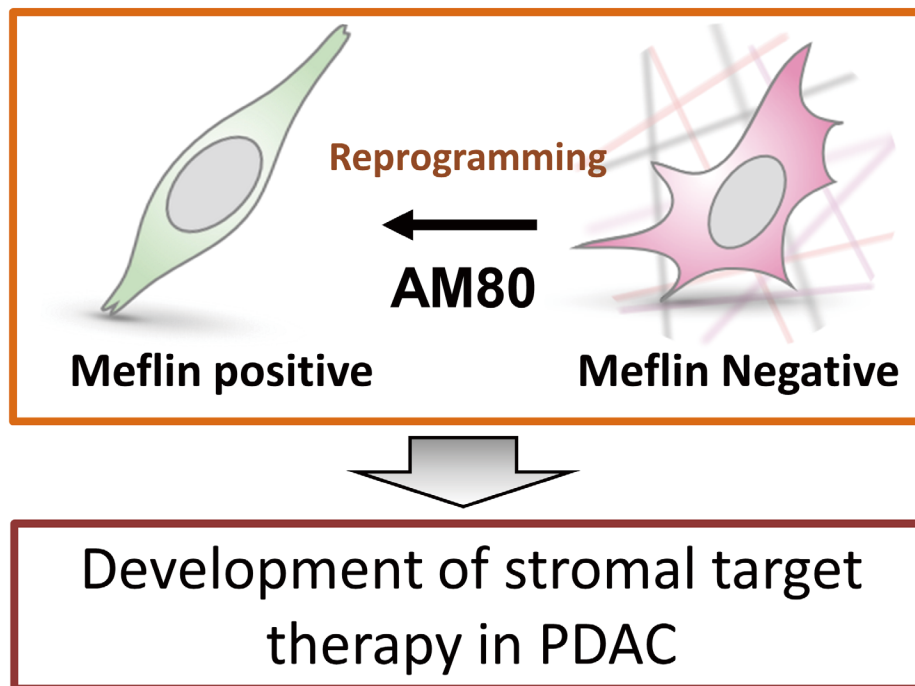
Open-label phase I/II investigator-initiated clinical trial based on a drug repositioning approach that reprograms the stroma of pancreatic cancer

## Organization

University of Tokyo

## Principal Investigator

Mitsuhiro Fujishiro



Target Disease (Applications)	Unresectable pancreatic cancer Combination therapy with standard therapy
Abstract	The object of this study is to perform an investigator-initiated clinical study to investigate the effect of AM80 on pancreatic cancer with a combination of conventional tumoricidal agents including gemcitabine and nab-paclitaxel.
Advantages	MIKE-1 is a drug that can be an enhancer of a new concept that greatly improves the drug distribution of anticancer drugs in the cancer stroma, and there is no similar drug approved by the regulatory affairs for this purpose at this time.
Patent Information	Patent Application 2020-110560
Market Overview	Untreated, unresectable pancreatic cancer patients(Stage III or IV)(Japan 14,000,US 29,000, Rationale: Pancreatic cancer clinical practice guidelines 2019,Cancer.Net <a href="https://www.cancer.net/">https://www.cancer.net/</a> )
Stage of Development	Phase I / II investigator-initiated clinical trial





## Project Title

Multicenter clinical trial of the Patient-Specific Cardiac Support Device (CSD) with less constraint on RV for Dilated Cardiomyopathy

## Organization

Nagoya University

## Principal Investigator

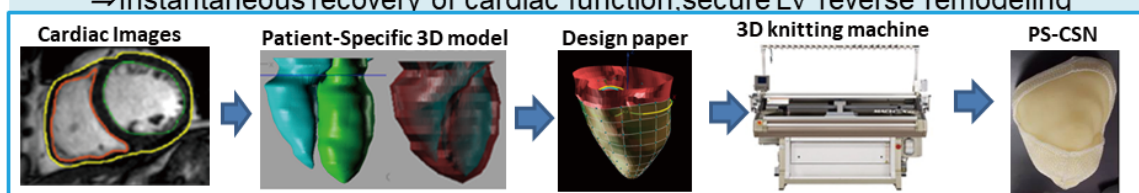
Toshiaki Akita

New Innovative Treatment for advanced Heart Failure:

**Patient-Specific Cardiac Support Net (PS-CSN):**

- ✓ Personalized design from CT or MRI images (Patented in US, EU, CN, JP)
- ✓ Less constraint on RV side (Patented in US, CN, JP)


⇒ Instantaneous recovery of cardiac function, secure LV reverse remodeling

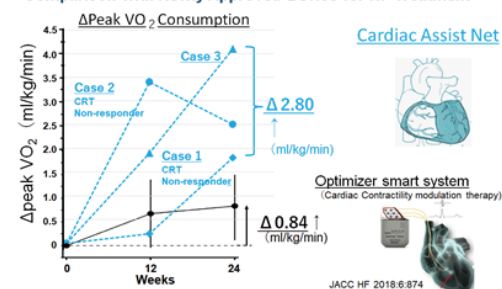


**Sakigake First tract Approval System (2020.Jun)**

Benefits: Improvement in Exercise Capacity by Cardiac Assist Net - Comparison with Newly Approved Device for HF Treatment

Multi-institutional Clinical trial underway (jRCT s042180025)

PS-CSN		術前	術後 12週	術後 24週
	Case 1 Peak VO <sub>2</sub> (ml/kg/min)	12.5	12.7	14.3
	6MWT(m)	576	630	611
Case 2	Peak VO <sub>2</sub> (ml/kg/min)	11.9	15.3	14.4
	6MWT(m)	411	522	555



Target Disease (Applications)	Idiopathic dilated cardiomyopathy (DCM) Secondary cardiomyopathy Ischemic cardiomyopathy
Abstract	Multicenter clinical trial will be conducted to evaluate the safety and the usefulness of the Patient-Specific Cardiac Support Device (PS-CSD) with less constraint on RV for Dilated Cardiomyopathy.
Advantages	Patient-specific design → Less invasive and more effective Less constraint on RV → Preserve RV diastolic function and cardiac output Multi-scale & multi-physics cardiac simulation by UT-Heart Inc. → Select the suitable candidate and predict the postoperative cardiac function
Patent Information	Basic patent : registered, Method of creating design paper for patient-specific heart correction net: PCT→US, EP, CN, JP registered, Heart correction net : JP,US, EP, CN registered Registered design : JP(2), CN(1), US(2), EP(1)
Market Overview	Huge market for heart failure treatment (620 millions people in US) (Japan; 2,000 cases/year, 7 billion yen/year) Superior technology to competitor (Mardil: Acorn CorCap successor)
Stage of Development	To establish the safety of this device through small feasibility (First in Human study) in 2019 To establish the efficacy for improvement in cardiac function, cardiac remodeling indices, and QOL through investigator-initiated feasibility clinical trials in 2022, and pivotal study in 2023.







## Project Title

Development of novel therapies targeting pulmonary microthrombosis of coronavirus disease 2019

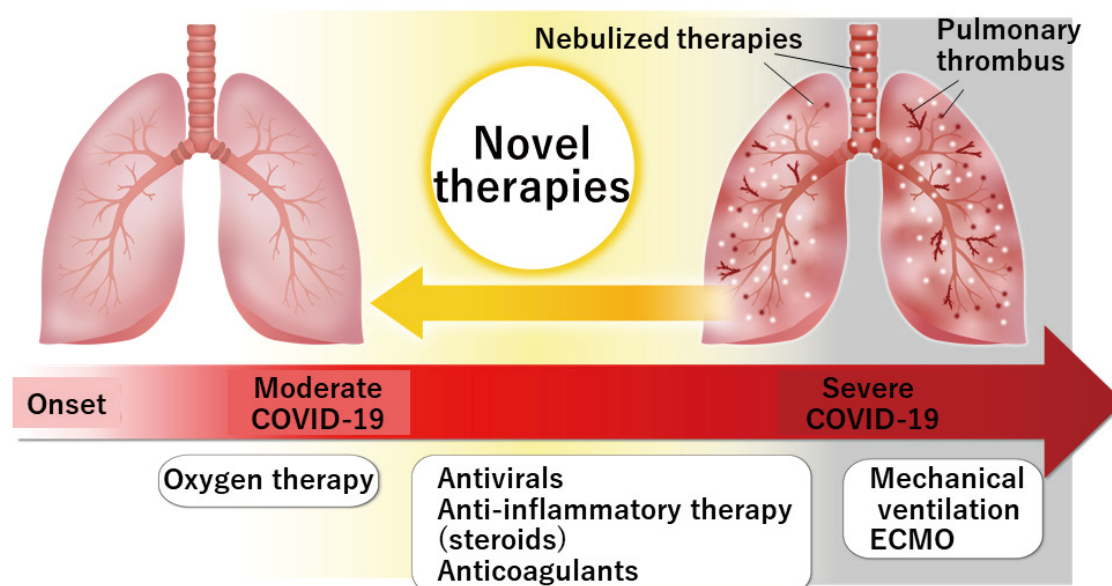
## Organization

Nagoya University

## Principal Investigator

Yukari Goto

## Development of novel therapies targeting pulmonary microthrombosis of COVID-2019



Target Disease (Applications)	Severe coronavirus disease 2019 (COVID-19)
Abstract	<p>A feature of SARS-CoV-2 pathogenesis is COVID-19-associated coagulopathy, characterized by multiple pulmonary microthrombosis. Nebulized pharmacotherapies targeting multiple thrombosis are expected as novel therapies for severe COVID-19.</p> <p>We have established a research platform such as selection criteria for patients and an evaluation system for confirming safety. We are preparing for investigator-initiated clinical trial.</p>
Advantages	Conventional therapies (antivirals, steroids, and anticoagulants) have not improved the prognosis of severe cases of COVID-19. Novel therapies (nebulized therapies) targeting multiple pulmonary microthrombosis are suitable for the pathology of severe cases and can be expected to improve the prognosis.
Patent Information	None
Market Overview	Cumulative number of patients with COVID-19: About 1.7 million. The market will be large when a new epidemic occurs in the future.
Stage of Development	We are preparing for investigator-initiated clinical trial.



# 3 Services & Facility







# Clinical Trials



## Center for Advanced Medicine and Clinical Research

- **Project Management**
- **Creating Documents**
  - Protocol
  - Investigator's Brochure
  - Informed Consent Form
  - Manufacturing Related Documents of GMP for Investigational Drugs
- **Creating Standard Operating Procedures**
  - Operating Procedure for Outsourcing to Study Coordinating Committee
  - Operating Procedure for Clinical Study Coordinating Committee
  - Operating Procedure for Issuing Protocol and a Sample of Case Report Forms
  - Operating Procedure for Investigator's brochure
  - Operating Procedure for Creating an Informed Consent Form
  - Operating Procedure for Handling Safety Information
  - Operating Procedure for Keeping Records
  - Operating Procedure for Efficacy and Safety Evaluating Committee
  - Operating Procedure for Auditing
  - Operating Procedure for Issuing the Clinical Study Report
  - Operating Procedure for Sample Storage/Management/Transport
  - Operating Procedure for Study Drug Management

### ● Preparation phase



## Data Coordinating Center

- **Statistical Analysis**
  - Plan for Statistical Matters of Clinical Study (Trial Design, Sample Size, Proposal and Description of Statistical Analysis Part)
  - Creating the Statistical Analysis Plan (SAP)
- **Data Management**
- **Creating Standard Operating Procedures**
  - Operating Procedure for Monitoring
  - Operating Procedure for Data Management
  - Operating Procedure for Case Registration and Assignment
  - Operating Procedure about Biostatistics

# Patent

- **Support for Patent Application**
- **Support for Patent Investigation**





## Services

### • Support for Clinical Research

- Support for Minister in Verifying Conformance to Guidelines(Regenerative Medicine, Gene Treatment, Advanced Therapy)
- Consultation with PMDA
- Clinical Research Coordination
- Monitoring(Investigator Initiated Study)
- Study Drug Management at Study Coordinating Office
- Study Drug Management
- Support for Administration Office
- Auditing

### • Issuing the Report

- Clinical Study Report
- Statistical Analysis Report

## ● Implementation phase

### • Support for Clinical Research

- Support for Data Monitoring Committee

### • Statistic Analysis

- Programming and Data Analysis in accordance with SAP, Mock
- Gene Expression / DNA methylation Data
- SNP/CNV Data

### • Data Management

- Maintenance of Case Registration and Assignment System
- Enrollment and Assignment
- Maintenance of Data Management System
- Data Management

## ● Reporting phase

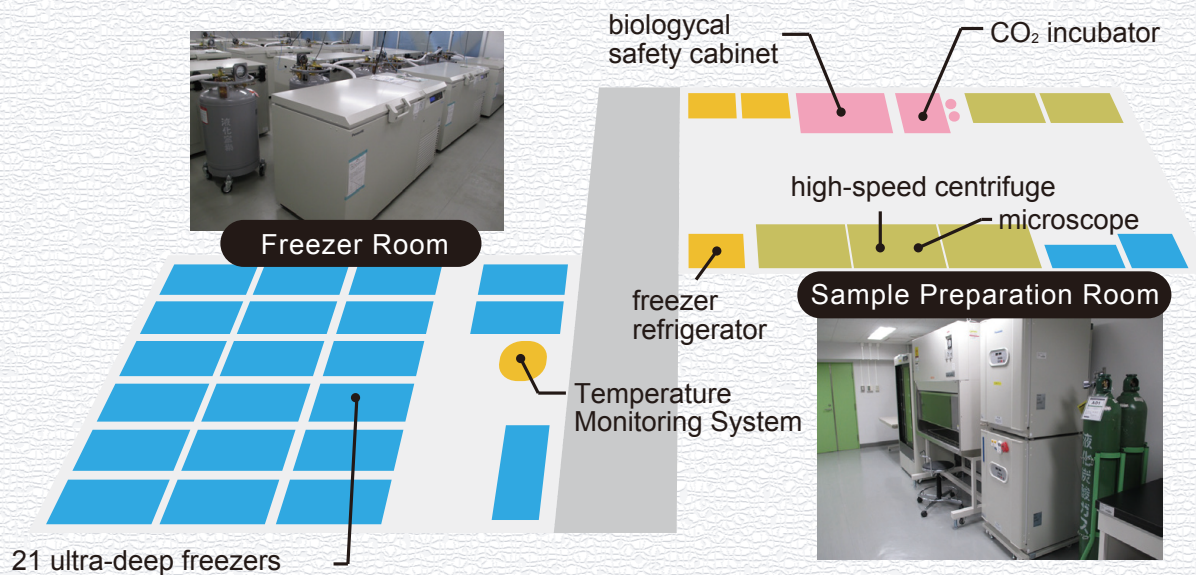
## Regulatory Affairs

### • Communication with Regulatory Agencies





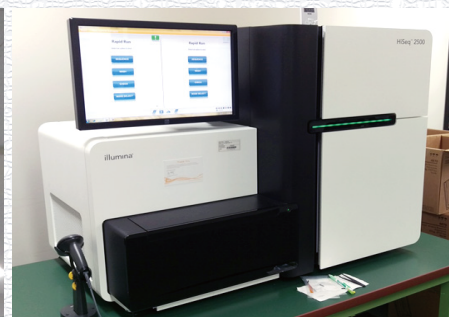
## Bio-bank Sample Storage Room



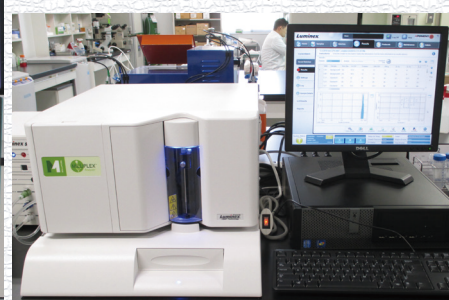
## Major Equipment



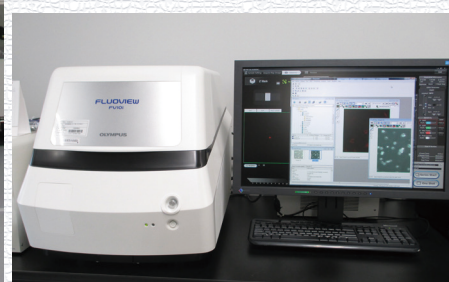
FACS Aria™ Fusion (BD)



HiSeq 2500 (Illumina)



Luminex 200 (MERCK MILLIPORE)



FLUOVIEW FV10i (OLYMPUS)

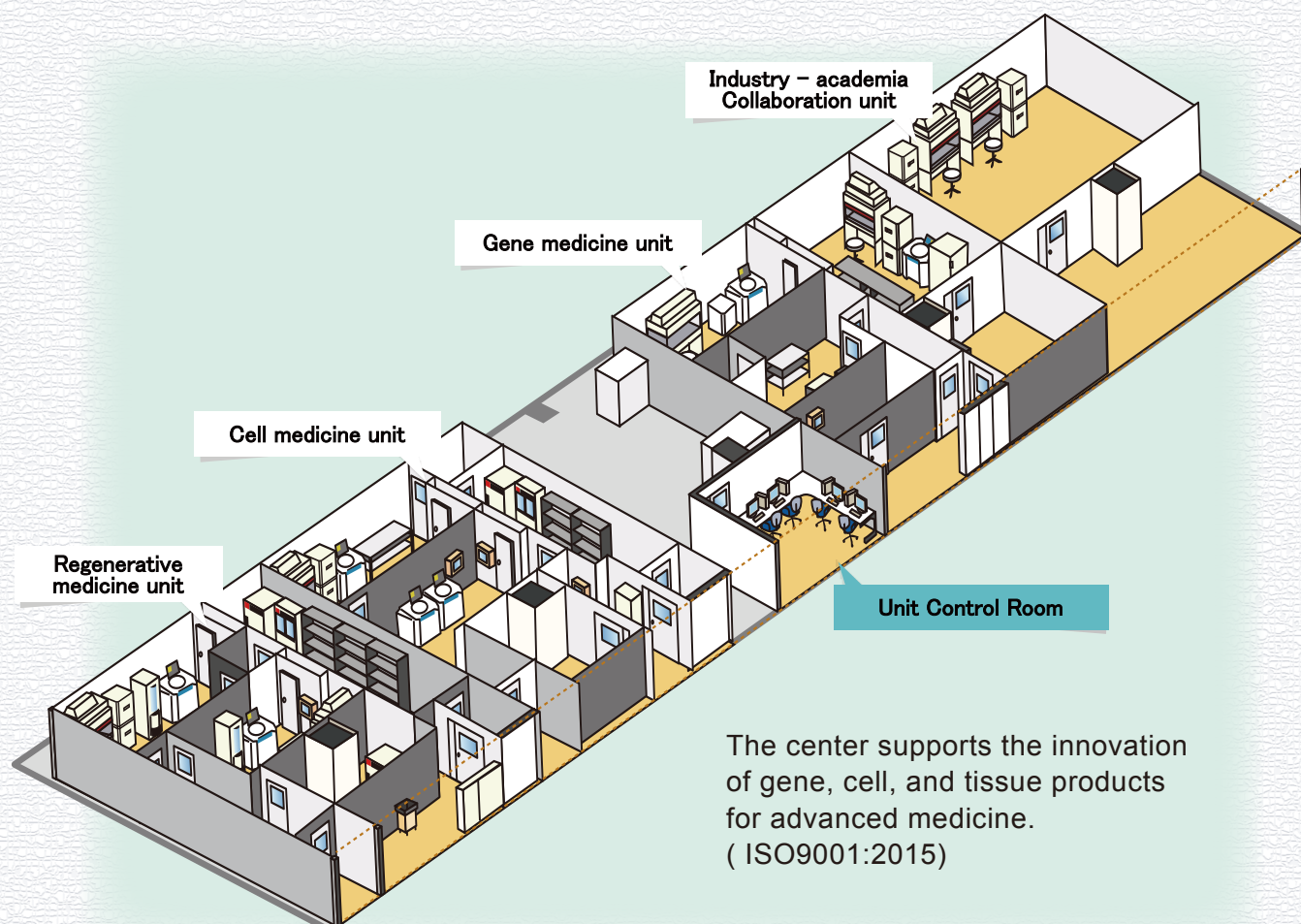




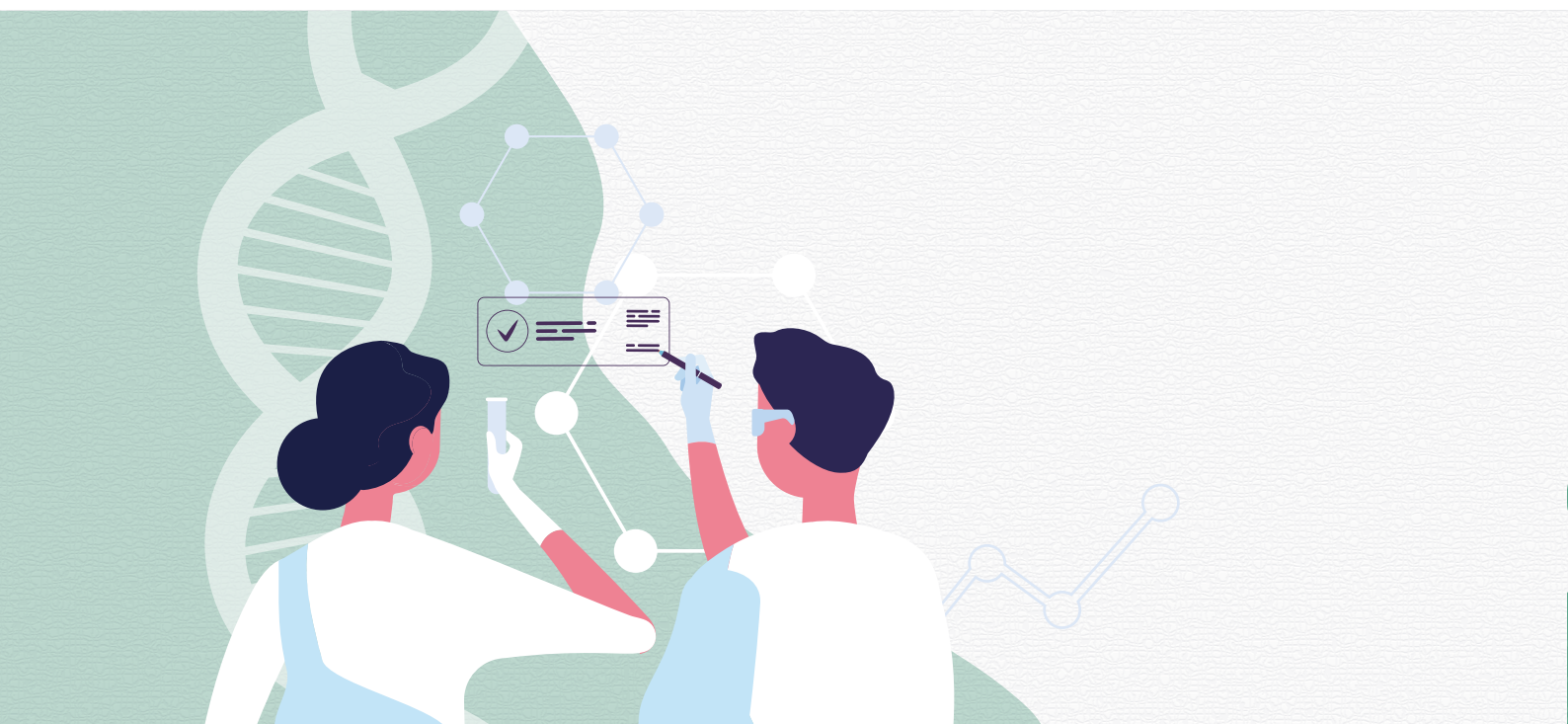
## Facility

Center for Advanced Medicine and Clinical Research

# Bio-material Preparation Unit







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