



2019 Towards the Development of the Life Sciences Industry

Osaka Bio Headquarters

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Gathering of Osaka's life science related universities and research facilities, etc.

Osaka has been known as "a town of pharmaceuticals" since about 400 years ago.

With many excellent life science related universities and research facilities, etc., in northern Osaka,

Pharmaceutical companies, etc. are also gathering in places like

Saito (International Culture Park) and Doshomachi in Osaka City.

In Osaka, industry, academia and government are working toward

further development such as gathering

drug discovery support agencies in Ume-Kita in central Osaka,

regarding life science field as one of our strengths.

Osaka has a good business environment so that you can

develop life science related business easily here.

①Osaka University

- •Research Institute for Microbial Diseases, Osaka University (RIMD)
- •Osaka University Immunology Frontier Research Center (IFReC)
- Osaka University Hospital
- •Institute for Protein Reseach, Osaka University (IPR)
- 2 Osaka City University
- 3 Osaka Prefecture University
- 4 National Institutes of Biomedical Innovation, Health and Nutrition (NIBIOHN)
- 5 National Cerebral and Cardiovascular Center (NCVC)
- **6** RIKEN Center for Biosystems Dynamics Research (BDR)
- 7 AIST Kansai, National Institute of Advanced Industrial Science and Technology (AIST)
- 8 Japan Agency for Medical Research and Development (AMED)
- Department of Innovative Drug Discovery and Development
- (INPIT) Mansai Office
- (1)Osaka University of Pharmaceutical Science
- ¹²Osaka Medical Collage
- ⁽¹⁾Kansai Medical University
- ¹⁴Center for Information and Neural Networks (CiNet)
- 15 Kindai University
- (6) Osaka Research Institute of Industrial Science and Technology (ORIST)
- ①Center for iPS Cell Research and Application, Kyoto University (CiRA)
- ®Advanced Telecommunications Research Institute International (ATR)
- ②RIKEN Center for Computational Science (R-CCS)

K computer



We are working on creating an international hub in Nakanoshima, Osaka to promote the commercialization and industrialization of the Innovative Medicine based on regenerative medicine.

International Hub for Innovative Medicine

(provisional name)

Osaka Prefecture is working to create the International Hub for Innovative Medicine, with the aim of promoting the industrialization of the latest regenerative medicine-based Innovative Medicine in response to progress in medical technologies in the future—including the use of genomic medicine, artificial intelligence (AI), and Internet of Things (IoT)—and enhancing global contributions by providing such future medical technologies to patients in Japan and abroad.



Under the framework of "All-Japan", we seek to promote our global contributions by industrializing the Innovative Medicine and providing them to patients in Japan and abroad.

- < Concept of the International Hub for Innovative Medicine >
- Promote industrialization of latest regenerative medicine-based <u>Innovative Medicine</u> in response to progress in medical technologies in the future, including the use of genomic medicine, artificial intelligence (AI), and Internet of Things (IoT).
- Enhance international contributions by providing Innovative Medicine to patients in Japan and abroad.

*The term "the Innovative Medicine" used for this hub refers to:

New medical technologies that should be made available in the next era while responding in a timely manner to ever-changing circumstances related to the medical industry, such as changing needs for medical care and innovations in scientific technologies

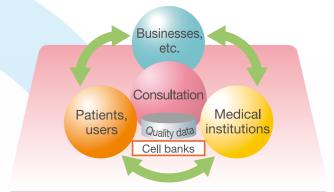


We seek to establish a co-creation platform for the Innovative Medicine, aiming toward co-creation of the Innovative Medicine.

Organization for Innovative Medicine

< Mission >

To promote commercialization and industrialization of the Innovative Medicine, the Organization for Innovative Medicine plays a role as an organizer of the International Hub for Innovative Medicine to enable medical institutions, universities, research institutes, businesses (including venture companies), and support organizations to organically collaborate with each other in research support, support for entrepreneurs, and medical practice mainly through opportunities for open innovation.



Platform for Co-creation of Innovative Medicine organized by the Organization for Innovative Medicine (provisional name)

The Nakanoshima area has become increasingly convenient.

Nakanoshima is a major business district in Osaka and a hub for dissemination of culture and information, featuring international conference halls and art museums. The planned construction there of a station on the new Naniwasuji Line (scheduled start of operation in 2031) that will connect directly to Kansai International Airport, the main gateway to Osaka/Kansai, will make this area more accessible for both domestic and international visitors.

Planned site for the International Hub for Innovative Medicine (approx. 8,600 m²)



< Location and Access >



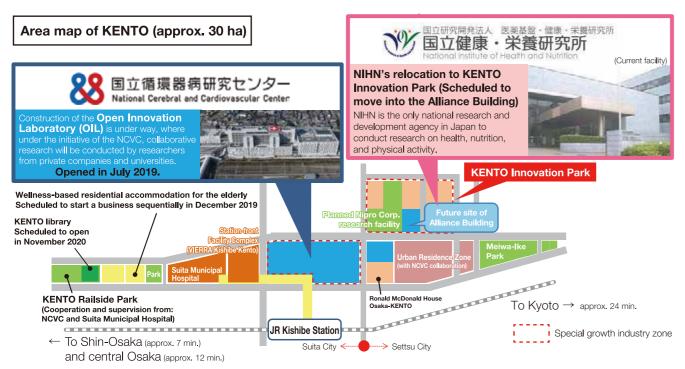
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Northern Osaka Health and Biomedical Innovation Town (a.k.a. "KENTO")





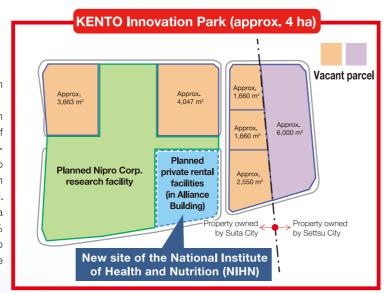
In KENTO (approx. 30 ha), a hub for health and medical innovation is being formed, embracing the National Cerebral and Cardiovascular Center (NCVC) and the National Institute of Health and Nutrition (NIHN) to be relocated from Tokyo as its core. KENTO, which is located in close proximity to city center of Osaka and Shin-Osaka, Shinkansen (bullet train) station, offers excellent transportation access.



Cluster of health and medical companies **KENTO Innovation Park**

KENTO Innovation Park is designed to be a cluster of research and development facilities of businesses and related entities.

Nipro Corp. has already decided to construct a research facility in the Park. The Alliance Building, in which the National Institute of Health and Nutrition (NIHN) will relocate, is planning to accommodate laboratories and offices for rent as well as other functions to promote collaboration between companies and research institutes, through which innovations are expected to be created. In addition, KENTO Innovation Park has been designated as a special zone for growth industries. Tax incentives (up to 100% exemption from the local Osaka Prefectural tax) will be given to businesses that decide to move into the Park and meet the necessary requirements.



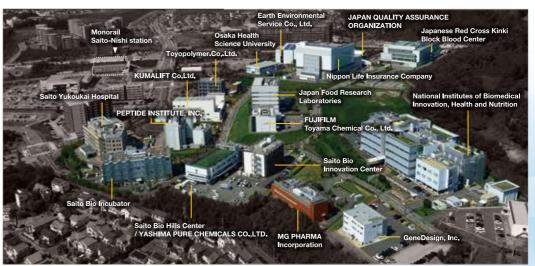
Symbol zone of Saito spreading in the hills of Ibaraki City, Minoo City, Osaka Prefecture



Saito Life Science Park

SAITO

Saito Life Science Park that came up in 2004 is a major base of facilities having research and technology development functions in various life science fields such as biotechnology-based pharmaceuticals, food items, cosmetics, and healthcare related facilities association with the same.



Incubation facilities		
Saito Bio Incubator	Saito Bio Hills Center	Saito Bio Innovation Center
Structure: Steel beam, 4-story Total floor: approx 4,900 m² Lab: 32rooms + 1 floor There are Animal experimentation facility	Structur: steel beam, partially reiuforced concrete, 3-story and one basement floor 3rd floor: approx. 800 m ² Lab: 10rooms	Structure: Steel beam, 4-story Total floor: approx 2,500 m ² Lab: 18 rooms + 1 floor There are investigational drug manufacturing facility
Maintenance: Organization for Small & Medium Enterprises and Regional Innovation Public-private rental lab Established: 2004 July	Maintenance: YASHIMA PURE CHEMICALS CO.,LTD. Public-private rental lab Established: 2006 April	Maintenance: Organization for Small & Medium Enterprises and Regional Innovation Public-private rental lab Established: 2008 October
Rental grants: facilities grant system.		

Voice of a company located in Saito



Recognizing the importance of developing nucleic acid medicines, recently gaining attention as medicines for the next generation, in 2010 GeneDesign quickly constructed one of the nation's largest nucleic acid investigational new drug manufacturing facility in the Saito Bio-Innovation Center and became the nation's first company to obtain a license for production of nucleic acid medicines. In 2013, they established the Oligonucleotide CMC earch Center, the first nucleic acid medicine-related research center in Japan, within the Saito Life Science Park.

In 2016, GeneDesign merged with the Ajinomoto Group, a joint research partner for many years. In April 2019, they set up the Oligonucleotide API nucleic acid pharmaceutical ingredients, where technology development is promoted to enable high-volume production of nucleic acid pharmaceutical both solid-phase and liquid-phase methods.

research institutes from around the country have gathered in and around collaborative industry-academia-government projects. We have been certified as a special zone business and allowed to receive funding support With the new base completed, we hope to meet market demands for

- ●"Saito Hills Club" is also available as a place for information exchange, research exchange, human exchange, etc. of companies and research institutes around Saito
- For inquiries regarding incubation facilities, please contact Bio Site Capital Co., Ltd./TEL.+81-72-640-1060/URL http://www.bs-capital.co.jp/



High-performance, easy-to-use video conferencing system enables users to communicate smoothly.

PMDA Kansai Branch video conferencing system

The PMDA Kansai Branch provides consultation services on regulatory science (RS) strategies and clinical trials, using a video conferencing system.

This video conferencing system offers users various benefits:

- Reduced travel expenses and travel times
- Easier adjustment of meeting schedules, such as when connecting users in Tokyo and Osaka

We have exemption and reduction system (full exemption / reduced by half) in the fee for using the video conferencing system.

PMDA Kansai Branch Grand Front Osaka, Tower B 12F (3-1 Ofuka-cho, Kita-ku, Osaka) Fundamental Advanced / Technica General consultation consultation ull exemption Consultation available in Kansai Branch through video conferencing The usage fee for the video conferencing system are required. Clinical trial Full-scale consultation, etc. Consultations on drugs in the post-marketing stage * Full-scale consultation, etc: guidance and advice on clinical trials and Half] other tests, etc. as well as on data for regulatory submission to gain pharmaceutical approval.

Useful (easy-to-use) video conferencing system of the PMDA Kansai Branch

This video conferencing system, which uses a dedicated circuit, ensures confidentiality of information and offers smooth, stress-free communication. (The system provides high-definition images and clear sounds, so that users can clearly see the facial expressions of the remote participants.) A firsthand experience can be offered for a seminar with a certain number of persons. Feel free to contact us.





< A video conference room of the Tokyo headquarters >

The monitors show live images of the room of the Tokyo headquarters.



< A video conference room of the Kansai Branch office >

User feedback

- It's as if we were meeting and talking in person.
- We were able to save the time and expense required to travel to Tokyo.
- We want to use the video conferencing system again.

Collaboration launched with the U.S.

ALLIANCI

In FY 2019, we have initiated collaboration with BIOCOM, a non-profit life science organization based in California, in the U.S.

We will further promote business matching between

Osaka/Kansai-based life sciences companies and American companies.

European Biotech & Pharma Partnering Conference 2019 to be held in Osaka,

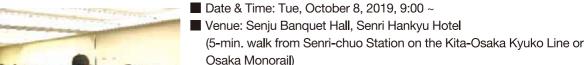
with about 50 European life sciences companies participating

To support companies in Osaka/Kansai expand their business abroad, we hold an annual one-on-one matching event with the participation of many Europe-based life sciences companies.

This fourth event to promote business matching, whose scope (target fields) of collaboration has been expanded to include Al and IoT technologies,* will provide participants with a great opportunity to make inroads into the European market. Please join us on this occasion.

 * Al and IoT technologies: Limited to that which pertains to drug discovery, drug discovery support, regenerative medicine, therapeutic agents, diagnostic agents, etc.





- Target fields: drug discovery, drug discovery support, regenerative medicine, therapeutic agents, diagnostic agents, Al and IoT technologies*
- Application Deadline: Fri, September 20, 2019, 17:00

< Last year's data >

Participants: 118 companies (from Japan and Europe)

One-on-one meetings: 278

Participating countries: Germany, France, Belgium, and others

MOUs exchanged with counterparts in foreign countries

As part of efforts to enhance our global competitiveness, we signed memorandums of understanding (MOUs) for partnership engagement with bioclusters abroad.

We are working on efforts to raise global awareness of Osaka's strengths in the life sciences field, including building a platform from which to promote international exchange programs.





Consolidated presence of major universities and research institutuions.

Osaka Bio Headquarters is striving to form a world-class life sciences cluster in Osaka, taking full advantage of the fact that Osaka Prefecture boasts many world-leading universities and research institutes.





1 Research Institute for Microbial Diseases (RIMD)

Research Institute for Microbial Diseases (RIMD), Osaka University is a world's foremost institute for basic biological researches including microbiology, immunology and oncology.

RIMD has specialized facilities to study microbiology, immunology and oncology equipped with BSL2 and 3 laboratories. RIMD conducts world-class researches and foster the talented human resources in





Office for Research Promotion 1-1 Yamada-oka, Suita City, Osaka Tel: +81-6-6877-5111



1 Osaka University Hospital

Osaka University Hospital is one of the leading hospitals for advanced medical development in Japan, and its philosophy is to provide high-quality medical care services and contribute to fostering medical professionals and medical

Osaka University Hospital, as a clinical research, core hospital, aims to contribute to the further development of the medical and pharmaceuticall industry in Japan by taking advantage of various measures designed for national strategic special zones, including those for "pharmaceutical affairs strategic consultation" and "accelerated development of innovative pharmaceuticals."



2-15 Yamada-oka, Suita City, Osaka Tel: +81-6-6879-5111





Osaka University

Osaka University is one of Japan's leading universities, comprisin 11 undergraduate schools and 16 graduate schools, six affiliated research institutes, and two affiliated hospitals. Renowned as an academic institution strong in biomedical sciences, especially immunological research, Osaka University has produced many researchers. In addition, the university actively undertakes initiati for commercializing research outcomes.



- Alliance Laboratories, and concluding comprehensive partnership agreements

 Promoting technology transfer of intellectual properties
- · Providing support to university-originated venture businesse



1-1 Yamada-oka, Suita City, Osaka Tel: +81-6-6877-5111



大阪大学

Osaka University Immunology Frontier Research Center (IFReC)

The Osaka University Immunology Frontier Research Center (IFReC) is an international hub for immunology research launched as a part of Japan's World Premier International Research Center Initiative (WPI). Now that over ten years have passed since its founding in 2007, IFReC is accelerating its expansion into innovative basic research and medical science.

IFReC provides researchers with a research environment up to international standards and support system. It is currently working on creating an open innovation laboratory for joint research, while pursuing cutting-edge immune system research using bioimaging and bioinformatics



Research Planning and Management Office 3-1 Yamada-oka, Suita City, Osaka Tel: +81-6-6879-4273



1) Institute for Protein Research, Osaka University (IPR)

With the aim of shedding light on the principles of life activities through fundamental research on proteins, IPR has been working on the promotion of joint research through shared use of facilities and equipment with researchers in Japan and abroad (including those from industry), as well as the development of human resources.

- (SR-Beamline, NMR, cryoEM)
- Developing the Protein Data Bank (PDB) and disclosing data OSAKA UNIVERSITY
- Holding protein research seminars
- · Promoting multi-scale structural life sciences As a hub for shared use of facilities and collaborative research, IPR is equipped with the operating system required for advanced research



3-2 Yamada-oka, Suita City, Osaka Tel: +81-6-6877-5111



2 University Public Corporation Osaka, Osaka City University

Osaka City University (OCU) serves as a think tank for urban Osaka and intends to promote education, research activities and contribute to the community. OCU seeks to promote the creation of new industries with developing new research, business and health areas.

- · Developing new health areas
- · Developing next-generation energy sources
- ·Serving as an urban disaster preparedness base The Center for Health Science Innovation has established a system to create new products and services through industry-university collaboration centering on the medicine and science of fatigue/anti-fatigue.



3-3-138 Sugimoto, Sumiyoshi-ku, Osaka

Tel: +81-6-6605-3550





4 National Institutes of Biomedical Innovation, Health, and Nutrition (NIBIOHN

The objective of NIBIOHN is to contribute to improving the health of Japanese people, by preparing a foundation for enhancing technologies related to drugs, medical devices and other products, and by conducting surveys and studies pertaining to the maintenance and promotion of the health, nutrition, and diet of Japanese people. To this end, NIBIOHN is engaged in the six projects below and services under the Health Promotion Act.

- 1) Research and support of drug discovery related to fundamental technologies NIBIOHN 2) Research and support of drug discovery related to biological resources
- 3) Promotion of development of drugs and other products 4) Surveys and studies pertaining to the maintenance and promotion of Japanese
- 5) Surveys and studies regarding the nutrition and diet of Japanese people 6) Nutrition physiology tests of food



7-6-8 Saito-Asagi, Ibaraki City, Osaka Tel: +81-72-641-9811 (Main)



6 RIKEN Center for Biosystems Dynamics Research (BDR)

BDR Osaka strives to develop the underlying technologies for analysis and simulation of molecular dynamics inside living cells in order to comprehensively understand the systemic properties essential for living things, such as resilience and robust homeostasis, and then integrate such understanding into better treatments and medicines.



- fluorescent probes, body tissue transparency technologies. microfabrication devices, etc.) Highly efficient genetic engineering of mice (Triple-CRISPR)
- espiration-based sleep analysis technique for mice
- Drug-discovery simulations



Section responsible for business partnerships 6-2-3 Furuedai, Suita City, Osaka partner@ml.riken.ip



3 BioMedical Forum, Osaka Prefecture University

Osaka Prefecture University has established the BioMedical Forum as a bioscience research center to provide professional advice concerning research strategies, including initiatives in the bio industry.

The BioMedical Forum, comprising two research laboratories and three centers, which are all deeply involved in key R&D processes up to the preclinical stage of drug development, plans and proposes biomedical strategies and promotes mutual collaboration between





1-1 Gakuen-cho, Naka-ku, Sakai City, Osaka Tel: +81-72-254-9128



Solution (Note: Note: 10 National Cerebral and Cardiovascular Center (NCVC)

The National Cerebral and Cardiovascular Center (NCVC) was established as a national center for advanced and specialized medical care and research, with the mission to understand and control cerebral and cardiovascular diseases. Specialists - both medical practitioners and researchers - in the fields of heart disease and cerebrovascular disease and businesses work together to improve treatment outcomes and develop new technologies

- Implementation of the largest number of heart transplants in Japan
- Establishment of a mobile telemedicine system
- Establishment of a mobile telemedicine system
 A core facility for acute-phase treatment of cerebral infarction

 A core facility for acute-phase treatment of cerebral infarction Basic research to elucidate the pathogenesis of
- cardiovascular diseases
- . Development of new therapeutic devices Minimally invasive cardiovascular surgery
- Advanced check-ups to prevent cardiovascular disease



6-1 Kishibe-shinmachi, Suita City, Osaka Tel: +81-6-6170-1070 (Main)



AIST Kansai, the National Institute of Advanced Industrial

AIST Kansai is working on the development of diagnostic devices, drug discovery infrastructure technologies, and health and welfare equipment in the biomedical research field, with an eye toward realizing a healthy society.

- Developing diagnostic and testing devices such as the Ultra-Fast
- Biological production using genome editing and other techniques Analysis of brain diseases, etc. and search for biomarkers
- · Strengthening industry-academia collaboration through AIST Kansa
- Promoting collaboration of research institutes, government agencies, and companies both in Japan and abroad



Industry-academia-government Collaboration Prom 1-8-31 Midorigaoka, Ikeda City, Osaka Tel: +81-72-751-9681



Support Organizations (Drug discovery, etc.)

The Department of Innovative Drug Discovery and Development (iD3) is currently missioned to improve the pharmaceutical R&D environment in Japan, operating multiple national projects, including public-private partnership, to support and accelerate innovative drug discovery and development programs at universities, public research organizations, bio-venture companies and pharmaceutical companies. The iD3 is distinctive in its core constituents, i.e., more than 20 Science Coordinators who are drug discovery experts with rich industry experience, spanning a wide range of expertise and disciplines enabling efficient drug discovery, such as pharmacology, chemistry, drug safety, pharmacokinetics/pharmacodynamics, intel lectual property management, and industry-university collaboration.

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Pharmaceuticals and Medical Devices Agency (PMDA), Kansai Branch

To help academia and venture companies create innovative drugs, etc. in Japan, the PMDA Kansai Branch conducts Regulatory Science (RS) General Consultations and RS Strategic Consultations for designing both non-clinical trial plans and clinical trial plans required in the early phase of

PMDA also provides face-to-face consultation regarding clinical trials and application materials, using a high-performance video conference ing system that connects the Tokyo HQ and Kansai Branch, PMDA undertakes inspections whether facilities and control procedures for manufacturing medicinal chemicals comply with GMP, etc.





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