What is BBJ?

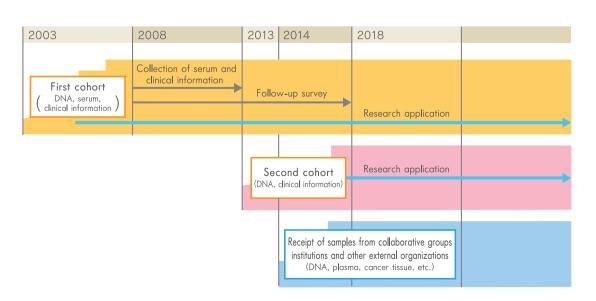
BioBank Japan (BBJ) is one of the largest disease biobanks* in the world. BBJ collects and stores biological samples and information from patients throughout Japan. BBJ also provides the samples and information to various research projects in compliance with relevant regulations in Japan. As basic infrastructure of research, BBJ contributes to the success of many medical research projects.

In fiscal 2003, the Tailor-made Medical Treatment Program funded by the Ministry of Education, Culture, Sports, Science and Technology (MEXT) was started. In this program, BBJ collected DNA, serum and clinical information from more than 200,000 patients nationwide suffering from at least one of the 47 common diseases as the first cohort**.

From fiscal 2013 to 2017, under a new phase of the Tailor-made Medical Treatment Program, BBJ collected DNA and clinical information from around 60,000 newly registered patients with 38 diseases as the second cohort. In fiscal 2014, the serum and plasma storage facility was expanded and a new tissue bank was established. In fiscal 2015, BBJ started storing biological samples provided by clinical cooperative research groups on cancer or common diseases in Japan (National Hospital Organization, Japan Clinical Oncology Group and Japan Children's Cancer Group).

BBJ's research findings based on its samples and information, including the association between genetic differences of individuals and common diseases in the Japanese population, have regularly been published in international scientific journals. In fiscal 2018, BBJ was succeeded by the Biobank Program for Genomic and Clinical Research. By promoting the effective utilization of the samples, clinical information and genome data acquired over the years by BBJ, the new Program is managing them with the aim of offering a useful biobank. The Program also collaborates with other biobanks with the aim of contributing to the achievement of genomic medicine.

^{**} A cohort means a group of individuals followed up over a certain period of time. A cohort study constitutes conducting a follow-up survey on a certain group of individuals over time to elucidate the association between the group's characteristics and, for example, the onset of diseases and their clinical courses.



Affiliated medical institutions (from 2003 to March 2018)

- Osaka International Cancer Institute
- Cancer Institute Hospital of Japanese Foundation for Cancer Research (JFCR)
- Juntendo University
- Tokyo Metropolitan Geriatric Hospital and Institute of Gerontology
- Nippon Medical School
- Nihon University

- Iwate Medical University
- Tokushukai Group
- Shiga University of Medical Science
- Fukujuji Hospital
- National Hospital Organization Osaka National Hospital
- Aso lizuka Hospital



* Affiliated medical institutions are located in the prefectures with .

Target diseases

First cohort (47 diseases)

Gastric cancer Colorectal cancer Lung cancer Esophageal cancer Gallbladder/Cholangiocarcinoma Liver cancer Pancreas cancer Prostate cancer Breast cancer Cervical cancer Uterine cancer Ovarian cancer Hematopoietic tumor Cerebral infarction Cerebral aneurysm Epilepsy Bronchial asthma Pulmonary tuberculosis Chronic obstructive pulmonary disease Interstitial lung disease/Pulmonary fibrosis Myocardial infarction Unstable angina Stable angina Arrhythmia Heart failure Peripheral arterial diseases Chronic hepatitis B Chronic hepatitis C Liver cirrhosis Nephrotic syndrome Urolithiasis Osteoporosis Diabetes mellitus Dyslipidemia Graves'disease Rheumatoid arthritis Hay fever Drug eruption Atopic dermatitis Keloid Uterine fibroid Endometriosis Periodontitis Febrile seizure Glaucoma Cataract Amyotrophic lateral sclerosis

Second cohort (38 diseases)

Lung cancer	Esophageal cancer	Gastric cancer	Colorectal cancer
Liver cancer	Pancreas cancer	Gallbladder/Cholangiocarcinoma	
Prostate cancer	Renal cancer	Breast cancer	Cervical cancer
Uterine cancer	Ovarian cancer	Hematopoietic tumor	Cerebral infarction
Cerebral aneurysm	Cerebral hemorrhage	Epilepsy	Dementia
Depression	Bronchial asthma	Chronic obstructive pulmonary disease	е
Interstitial lung disease/Pulmonary fibrosis		Myocardial infarction	Unstable angina
Stable angina	Arrhythmia	Heart failure	Peripheral arterial disease
Chronic hepatitis B	Chronic hepatitis C	Liver cirrhosis	Osteoporosis
Diabetes mellitus	Dyslipidemia	Rheumatoid arthritis	Drug eruption
Atopic dermatitis			

Collaborative groups (since 2014)

National Hospital Organization (NHO)

Japan Clinical Oncology Group (JCOG)







Japan Children's Cancer Group (JCCG)

Office of BioBank Japan

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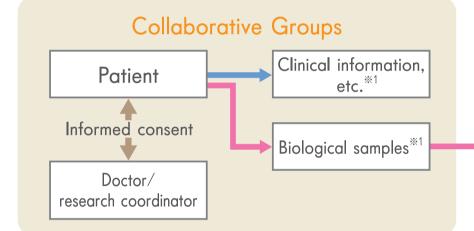




^{*} A biobank is a repository for storing DNA, serum and other biological samples provided by healthy individuals and patients, and the database derived from them.

The flow of biological samples and information

Affiliated medical institutions (The collection of biological samples and clinical information ended in March 2018.) Clinical information. **Patient** etc.^{*1} Informed consent Biological samples* Research coordinator



Strict security management

In our research, biological samples and clinical information of patients are managed by assigning an ID number to each patient after removing all information that can be used to identify individual patients, such as name, address and date of birth. When we provide these samples and

information to external parties, these assigned ID numbers alone are used. Each storage room for samples and information is equipped with a security device that permits only specific persons to enter. Computers that control receipt and removal from the storage can only be accessed by specific persons whose information is registered in the finger vein authentication device. We thus constantly ensure the security of information.

BioBank Japan (BBJ), which was established within the Institute of Medical Science, the University of Tokyo, is a repository where human biological samples and their relevant information are systematically managed. In the robust building, DNA^{*2}, serum/plasma, tissues^{*3} and other samples provided by patients are managed under strict security. These samples are provided to research projects that have been reviewed by the BBJ review board.

Integrated Clinical Database

Clinical information and information on the volume of sample solution, among other information, are carefully stored, managed and operated in such a way as to quickly respond to requests for samples and information from researchers. In carefully stores their samples as well.



DNA Storage

storage is maintained at 4°C ubes can be stored. The storage is equipped with an automatic conveying system







Data

Control

Bank

he IDs of shipped amples are linke

he ID information

vithin the BBJ

s collectively

Serum and Plasma Storage

serum and plasma can be stored in tanks, the inside of

Tissue Storage

hich is maintained at -150°C.

The storage is equipped with an







Users



Commercial organizations



E.g., NBDC Human Database

Public databases*5

Examined Data Access

Provision of clinical information.

institutions

Provision of biological samples, etc.

Provision of genome data

Registration of genome data

BioBank Virtual Tour

Biological samples —— Clinical information, etc —— Genome^{*2} data

BBJ's Online Biological Sample Search System

https://searchweb.svc.biobankjp.org/



https://biobankjp.org/public/tour.html



The BioBank Virtual Tour is a video about the DNA storage, serum and olasma storage and ssue storage.

See website for more information.





*1 Biological samples and clinical information, etc.

In the first cohort study, a total of 14 mL of blood for DNA and serum samples was collected from each patient. In the second cohort study, 7 mL of blood for DNA samples was collected. Information collected includes medical information provided by hospitals, information on lifestyle, and information described on resident certificates. From collaborative groups institutions, we only receive samples (DNA, blood, tissue) provided by patients and information related to the samples. Clinical information is retained by each institution.

*2 DNA/genome

The cells in our body contain a substance called DNA (deoxyribonucleic acid). DNA is made up of four constituents: adenine (A), guanine (G), cytosine (C) and thymine (T). The sequence of these four bases encodes genetic information. The whole genetic information encoded in DNA in a cell is called the genome. Equating one DNA base to one English letter, the human genome sequence contains about three billion letters. We inherit a set of genomes from each parent, which is stored in 23 pairs of chromosomes. The genome contains information about the genes that make up our body and information on how these genes are controlled.

*3 Serum/plasma/tissue

Plasma is the part of blood that remains after the cellular components (red blood cells, white blood cells, platelets) are removed, and serum is that which remains after components involved in blood coagulation are removed. They are separated by affiliated medical institutions and contract testing companies. Of cancer tissues collected for testing or during surgery, those that are not used for testing are partially collected according to the predetermined protocol.

****4 BBJ Sample and Data Access Committee**

BBJ examines how biological samples and clinical information are utilized to ensure their effective use. Before providing them to researchers, the committee examines the research plans after their validity has been affirmed by the Ethical Review Committee.

*5 Public databases

Databases are a collection of information that has been systematically organized. Public databases established for sharing research data are created by efficiently integrating and organizing data to promote their increased sharing and utilization, thereby advancing research as a society-wide engagement. The NBDC Human Database managed by the National Bioscience Database Center (NBDC) of the Japan Science and Technology Agency is an example of a public database.