

BIORESOURCE PAPER

SDN Biobank: Bioresource of Human Samples Associated with Functional and/or Morphological Bioimaging Results for the Study of Oncological, Cardiological, Neurological, and Metabolic Diseases

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SDN Biobank is a not-for-profit service unit. Initially, it was established by the IRCCS SDN in 2012 as a collection of serum and plasma samples from patients who underwent advanced bioimaging exams, such as those performed with Positron Emission Tomography with integrated Magnetic Resonance Imaging (PET/MRI). In July 2015, SDN Biobank was approved by the local ethics committee to collect human samples from patients affected by oncological, cardiological, neurological, and metabolic diseases when performing diagnostic exams at the IRCCS SDN. All samples are coded and associated with clinical and iconographic documentation related to the performed functional or morphological bioimaging exams. SDN Biobank procedures are carried out according to the ISO 9001 Quality Management System with internal and external audits.

Keywords: Biobanking; human samples; radiology; imaging

Funding statement: The SDN Biobank was established and continues through institutional funding from the IRCCS SDN.

(1) Bioresource Overview

Project description

SDN Biobank was started as a resource center in 2015 with dedicated space and infrastructure at the IRCCS SDN in Naples, Italy. The mission coincides with the institutional role (recognized by the Italian Ministry of Health) of the IRCCS SDN, which is to optimize and improve scientific knowledge in the field of in vivo and in vitro diagnostic integration [1, 2]. The IRCCS SDN is equipped with cutting-edge technologies that include positron emission tomography with integrated computed tomography (PET/CT) and PET with integrated magnetic resonance imaging (PET/MRI). Additionally, the institute has a proper radiopharmacy for the production and employment of specific radiopharmaceuticals, such as 18 fluorodeoxyglucose (18-FDG), 18-fluorocholine, 18F-di-idrossi-fenilalanina (18F-DOPA), and 18F Florbetapir (Amyvid®).

The SDN Biobank was designed to provide a collection of human biological samples derived from patients affected by oncological, cardiological, neurological, and metabolic diseases, that come to IRCCS SDN for functional and

morphological bioimaging exams where the radiotracers reported above are frequently used [3].

The development of the SDN Biobank has been possible thanks to strong collaborations between skilled clinicians, radiologists, pathologists, biochemists, and molecular biologists working at the IRCCS SDN. Actually, the SDN Biobank has recruited approximately 1000 subjects. The majority of these subjects (80%) are patients with oncological diseases, with breast, lung, colon-rectum, and prostate cancer as the most prevalent cases. The remaining portion of the cohort is composed of cardiological (15%) and neurological (5%) patients. For each of the enrolled patients, the clinical-iconographic information is linked to the biological samples collected in the SDN Biobank. Furthermore, the SDN Biobank is a member of the Biobanking and Biomolecular Resources Research Infrastructure (BBMRI) with the aim of offering their biological samples to the national and international research community.

Classification (1)

Human

Species

Human samples

Classification (2)

Biological samples and associated data, including imaging results.

Context**Spatial coverage**

Spatial coverage: The SDN Biobank is located inside the IRCCS SDN S.p.A. in Via Emanuele Gianturco 113, Naples, Italy.

Latitude (North): 40 degrees, 51 minutes, 19.757 seconds.

Longitude (Est): 14 degrees, 17 minutes, 16.726 seconds.

Temporal coverage

Start date: July 2015. End date: ongoing.

Temporal coverage for accessibility

N/A.

(2) Methods**Steps**

To collect biological samples, patients undergoing diagnostic imaging exams are interviewed and recruited before the execution of diagnostic procedure. During the interviews, patients who agree to participate sign a specific written informed consent. Clinical and epidemiological data from the patients are collected by specific medical history forms at the same time. All data are saved and coded to protect patient privacy and confidentiality [4].

Stabilization/preservation

Venous blood samples (15–20 mL) are collected by venipuncture from recruited patients using BD Serum (ref. 367953) and BD K3EDTA (ref. 367953) vacutainer tubes.

All samples are transported to the SDN Biobank laboratory and processed within 1 h of collection as follows:

- Serum and plasma separation is performed by refrigerated (+4°C) centrifugation at 1900 × g for 10 minutes. Aliquots are obtained under sterile conditions and then stored in –80°C freezers (Angelantoni, Massa Martana, PG, Italy) until use.
- Mononuclear cells (MNCs) are purified by Pancoll® (density 1,077 g/L, PanBiotech, Aidenbach, Germany) gradient centrifugation at 400 × g for 30 min. After collection, MNCs are resuspended in a 10% dimethyl sulfoxide (DMSO)-based cryopreservation solution, and aliquoted into 1-mL vials at 2–3 × 10⁶ cells/mL.

All instruments used in the SDN Biobank are routinely checked for function and maintenance is performed periodically.

Type of long-term preservation

Vertical ultra-cold temperature freezers and liquid nitrogen dewar.

Storage temperature

Serum and plasma samples are stored in dedicated vertical, ultra-cold freezers (–80°C).

Mononuclear cells are stored in vapor-phase liquid nitrogen (–120°C to –150°C) dewars.

Shipping temperature from patient/source to preservation or research use

Transportation from collection sites to the SDN Biobank laboratory occurs at room temperature within 15–20 min of collection.

Shipping temperature from storage to research use

Samples are transported from the SDN Biobank laboratory to research sites on dry-ice in less than 24 hours.

Quality assurance measures

The IRCCS SDN, as well as the SDN Biobank, operates in compliance with the ISO 9001 International Standard for Quality Management System. A quality manual has been prepared that, following a hierarchical structure, includes process maps, process flowcharts, standard operating procedures, records, and forms. Furthermore, the SDN Biobank is subjected to internal and external audits to verify compliance, conformance, and performance with respect to its policy and mission. The staff of the SDN Biobank has been individually trained and each year the staff is updated by participating in annual meetings planned by scientific organizations operating within the field of biobanking, such as the European and Italian node of BBMRI [5].

Source of associated data

Associated data are derived from questionnaires and medical records where co-morbid conditions, such as diabetes, hypertension, tobacco, and alcohol consumption, are reported. Information about patient cancer history and previous bioimaging exams is also registered.

Ethics Statement

Informed consent is obtained using a form approved by the local ethics committee (Comitato Etico IRCCS Pascale – Napoli). In addition, the SDN Biobank operates in compliance with:

- Recommendations issued by the Oviedo Agreement, 1997 (Oviedo – Convention on Human Rights and Biomedicine, 04 April 1997) and the Additional Protocol Concerning Genetic Testing for Health Purposes (CETS n. 203), 2008 (Strasbourg, 27 November 2008).
- Italian Data Protection Authority (Garante Privacy), Personal Data Protection Code, Legislative Decree No. 196, 30 June 2003, published in the Official Gazette No. 174 of the Italian Republic, 29 July 2003.
- Italian Data Protection Authority (Garante Privacy), General Authorization to process personal data for scientific research purposes, 01 March 2012, published in the Official Gazette No. 72 of the Italian Republic, 26 March 2012.

Constraints

None, except national regulations on personal data and biological materials.

(3) Bioresource description**Object name**

Disease-oriented Biobank.

Bioresource name

- SDN Biobank
- Acronym: BB-SDN

Bioresource location

IRCCS SDN-S.p.A., Via Emanuele Gianturco n°113, 80143 – Napoli, Italia.

Bioresource contact

biobanca@sdn-napoli.it

Bioresource URL

<http://www.sdn-napoli.it/irccs-sdn/biobanca-sdn/>

Identifier used

N/A.

Bioresource type

Biological materials (serum, plasma, and mononuclear cells) from patients with oncological, cardiological, neurological, and metabolic diseases.

Type of sampling

Disease-based, sampled during clinical care.

Anatomical site

N/A.

Disease status of patients/source

Patients affected by oncological, cardiological, neurological, and metabolic diseases with associated bioimaging data.

Clinical characteristics of patients/source

Patient anamnesis with clinical, epidemiological, and bioimaging data.

Size of the bioresource

- To date: approximately 1.000 individuals and 10.000 samples
- Average number of incoming samples per year: approximately 350 samples
- Average number of outgoing samples per year: not available due to the early period of the biobank.

Vital state of patients/source

Alive at time of sampling.

Clinical diagnosis of patients/source

- Oncological patients: This is the primary cohort of patients enrolled in the SDN Biobank. This cohort is composed of patients affected by solid cancers, the most representative are breast, lung, colon, prostate

cancer, and Hodgkin and non-Hodgkin lymphoma. These patients are generally examined using functional and morphological bioimaging, such as PET/CT and/or PET/MRI.

- Cardiological patients: This cohort is composed of patients affected by ischemic cardiomyopathy, idiopathic cardiomyopathy, and Fabry disease. These patients underwent myocardial single photon emission computed tomography (SPECT), computed tomography coronary-angiography (CTCA), or cardiac PET/MRI.
- Neurological patients: This cohort of patients is composed of patients affected by neurological disease such as Parkinson's disease, mild cognitive impairment, dementia, Alzheimer's disease, and multiple sclerosis. In some cases, selected neurological patients are recruited from those doing PET exams where specific radio tracers are used, such as PET with Fluoro-DOPA for Parkinson's disease and PET with Amyvid for Alzheimer's disease.

The biological samples are linked to the bioimaging exams performed at the SDN.

Pathology diagnosis

Available through medical records.

Control samples

Most of the control cohort volunteers are healthy women and men recruited at the SDN laboratory of clinical biochemistry. The volunteers are selected on the basis of age, clinical history, and absence of familiar history for oncological, cardiological, or neurological disease. An ad hoc anamnestic form has been created for recruiting control subjects. The biospecimens from this cohort include serum, plasma, and mononuclear cells.

Biospecimen type

Serum, Plasma, and mononuclear cells.

Size of the bioresource

Approximately 1000 individuals.

Release date

July 2015.

Access criteria

The following basic rules are applied to all researchers, including the Biobank staff, for accessing the sample collection:

- Requests from researchers should be sent to the e-mail address of the SDN Biobank (biobanca@sdn-napoli.it). The interested scientist must provide an authorized research project with all legal and ethical permissions. Biological samples will be sent to the researcher only after the receipt of the Material Transfer Agreement form signed by the principle investigator.
- Only scientists at research or medical institutions are authorized to present their requests.

- The provided samples will be used only for not-for-profit research protocols and will be not sold to third parties.
- Research projects in agreement with the SDN Biobank mission will be eligible for sample transfer.
- The principal investigator must guarantee proper acknowledgement of the SDN Biobank in any resulting scientific publications.
- Payment will be asked for to cover costs of shipping and basic procedures related to the distribution service.
- Emanuele Nicolai – Director of nuclear medicine unit of IRCCS SDN.
- Andrea Soricelli – Vice Scientific Director of IRCCS SDN, coordinates the research activities of the institute and the working activities of the SDN Biobank.
- Salvatore Marco – Scientific Director of IRCCS SDN, coordinates the research activities of the institute and the working activities of the SDN Biobank.

(4) Reuse potential

Because the SDN biobank generates multiple aliquots from the same sample, our policy is to not reuse aliquots already sent to research partners, to avoid providing a deteriorated sample due to the freeze-thawing cycles. To allow the research data to be reused for further data analyses, replication of previous findings, or meta-analyses, the SDN biobank requires the results produced by the investigators to be recorded in the electronic database. The reuse of sample-associated data will be possible on a collaborative basis with the permission of the respective principle investigators and the SDN Biobank manager.

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Competing Interests

The authors have no competing interests to declare.

Author Roles

- Peppino Mirabelli – Biobank curator, collector of samples, and annotation of data.
- Mariarosaria Incoronato – Biobank co-curator, collector of samples, and annotation of data.
- Luigi Coppola – Collector of samples and annotation of data.
- Teresa Infante – Collector of samples and annotation of data.
- Chiara Parente – Statistical data analysis and software development.

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