

# BCU Imaging Biobank, an Innovative Digital Resource for Biomedical Research Collecting Imaging and Clinical Data From Human Healthy and Pathological Subjects



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## ABSTRACT

BCU Imaging Biobank (BCU-IB) is a non-profit biorepository aimed at the collection, storage and retrieval of diagnostic images, derived descriptors and clinical data. The main scope of BCU-IB is to foster scientific advances in imaging and analysis, opening up new ways for biomedical research to diagnose, treat and potentially prevent diseases.

BCU-IB collects a vast amount of images of the human body, including healthy and pathological subjects. Diagnostic images, clinical, anamnestic and demographic data are made available to study the associations between imaging phenotypes, diagnostic and prognostic factors. Curated datasets are stored and organized in a secure and reliable dedicated information systems based on the Extensible Neuroimaging Archive Toolkit (XNAT), hosted by Bio Check Up Srl.

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## KEYWORDS:

Biobanking; imaging; data;  
biomarker; radiomics

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### PROJECT DESCRIPTION

A general and shared definition of biobank is still debated by scientific organizations and guidelines at national and international level [1]. A recent advancement of biobanking is the development of imaging biobanks, defined by the European Society of Radiology as “organized databases of medical images, and associated imaging biomarkers, shared among multiple researchers, and linked to other bio-repositories” [2]. Imaging biobanks collect high quality digital images, such as magnetic resonance imaging (MRI), computed tomography (CT), and positron emission tomography (PET), together with raw data, associated metadata and measurements to allow the extraction of quantitative radiomic features from images, which might evolve into so-called “imaging biomarker” [3, 4, 5]. These new biobanks can contribute to developing innovative research fields such as radiomics and radiogenomics [6, 7, 8].

In this paper, we propose an innovative digital resource represented by the Bio Check Up Imaging Biobank (BCU-IB). BCU Imaging Biobank is a non-profit biorepository aimed at the collection and storage of human diagnostic images and related clinical, anamnestic and demographic data, whose main purpose is supporting biomedical research and innovation. As a collection-based repository, BCU-IB stores retrospective and prospective cohorts and is open to a variety of pathologies, anatomical regions, and imaging modalities.

BCU Imaging Biobank has been created in the frame of “Molim Onco Brain Lab” project. Subsequently, the biobank received ethical approval on 15 December 2020. Since March 2021, BCU-IB is part of Biobanking and Biomolecular Resources Research Infrastructure (BBMRI-ERIC) and its national node BBMRI.it. Image collections have been included in the BBMRI-ERIC directory, including the recently established cohorts of COVID-19 patients.

The biobank is hosted on a state-of-the-art IT platform based on XNAT that facilitates imaging data management and allows the application of high-performance calculation algorithms [9]. BCU-IB has been tested before its release in order to check its performance [10].

BCU Imaging Biobank guarantees the application of high technological and security standards, and the respect of ethical principles and legal requirements by using de-identification algorithms and perimeter security based i.e. on access control and firewalls. Materials are made available to researchers exclusively for selected research projects according to the informed consent given by the patient/citizen.

### CLASSIFICATION (1)

Human medical diagnostic images and data.

### SPECIES

Human

### CLASSIFICATION (2)

Multidisciplinary human medical diagnostic images and data, including oncological, cardiological and neurological diseases.

### KEYWORDS

Imaging biobank, clinical data, imaging biomarker, radiomics, data curation.

### CONTEXT

#### Spatial coverage

BCU Imaging Biobank is located in the operational headquarters of Bio Check Up S.r.l., via Riviera di Chiaia n°9, Naples, Italy.

Latitude (North): 40.833611°

Longitude (East): 14.233611°

## Temporal coverage

Start date: 2014 (collection of images and data), 2018 (establishment of the imaging biobank)

End date: to be defined (TBD)

## Temporal coverage for accessibility

N/A

## (2) METHODS

### STEPS

- Only images and data from patients and citizens who agree with and voluntarily sign the “Privacy protection form” and the “Informed consent” are included.
- Preliminary de-identification (pseudonymization), using BCU-IB protocols based on Digital Imaging and COmmunications in Medicine (DICOM), are executed on data.
- De-identified data and images are sent to BCU-IB, picture archiving and communication system (PACS) with secure sockets layer/transport layer security (SSL/TLS) end-to-end encryption or a secure virtual private network (VPN) connection.
- Data are stored and then assigned to a cohort, depending on the pathology and anatomic region.
- Access to images/data collections is granted on the basis of the submission of a research project and pre-approved by the researchers’ home institutions and the validation from the Scientific and Ethic Committee and Advisory Board of BCU-IB.

### STABILIZATION/PRESERVATION

Data and images are collected and safely stored in a repository located in the server room, protected through a firewall. Only authorized personnel can access the area and periodic controls are scheduled for the correct preservation of data. In order to avoid loss of data, BCU-IB data center uses redundant array of independent disks (RAID) data storage virtualization technology for data redundancy and redundant power line and power supply units. Building of a second site to guarantee disaster recovery is in progress. Additionally, the internal policy for data breach is constantly upgraded. Images and data are pseudonymised and handled by authorized personnel only.

### TYPE OF LONG-TERM PRESERVATION

N/A (as BCU-IB does not collect biological samples).

### STORAGE TEMPERATURE

N/A (as BCU-IB does not collect biological samples).

### SHIPPING TEMPERATURE FROM PATIENT/SOURCE TO PRESERVATION OR RESEARCH USE

N/A

### SHIPPING TEMPERATURE FROM STORAGE TO RESEARCH USE

N/A

### QUALITY ASSURANCE MEASURES

BCU-IB implements quality assurance measures and internal checks, consisting of a continuous test of the platform, periodic audit procedures, surveys and feedback from users. Additionally, data and images are safely stored in BCU-IB servers, which include a redundancy system for data (RAID).

Bio Check Up Srl is part of the BBMRI-ERIC Expert Centres and has also obtained the following certifications:

- ISO 9001:2015;
- Diamond level certification of the Virtual Medicine module of Accreditation Canada.

## SOURCE OF ASSOCIATED DATA

Associated data derived from health records, questionnaires, DICOM metadata and imaging analysis (segmentations, regions of interest (ROI), radiomic features, annotations).

## ETHICS STATEMENT

Informed consent and privacy protection forms were developed and approved by the local ethics committee (Comitato Etico A.S.L. Napoli 1 – Centro, Italy), BBMRI.it and BBMRI-ERIC. Access to images and data is granted following approval by the scientific and ethic committee. Internal code of conduct and ethics code are made available to employees and researchers.

Ethics committee approved the following observational studies:

- Molim Onco Brain Lab;
- Covid-19;
- Big Data.

## CONSTRAINTS

BCU-IB operates in compliance with National and European recommendations on biobanking and regulations on personal and health data:

- 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.
- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).
- World Medical Association – Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects. 64th WMA General Assembly, Fortaleza, Brazil, October 2013.

## (3) BIORESOURCE DESCRIPTION

### OBJECT NAME

Organ-based collections of human diagnostic images and related data.

### BIORESOURCE NAME

- BCU Imaging Biobank
- Acronym: BCU-IB

### BIORESOURCE LOCATION

Bio Check Up Srl., via Riviera di Chiaia n°9, 80122 – Naples, Italy

## BIORESOURCE CONTACT

[biobanca@biocheckup.net](mailto:biobanca@biocheckup.net)

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## BIORESOURCE URL

<https://bcuib.biocheckup.net/en/>

## IDENTIFIER USED

N/A

## BIORESOURCE TYPE

Images and clinical data from healthy subjects or patients with oncological, cardiological, neurological and metabolic diseases.

## TYPE OF SAMPLING

Disease based, sampled in research protocols and in clinical care.

## ANATOMICAL SITE

Abdomen, Breast (bilateral), Brain, Chest, Colon, Lung, Prostate, Spine, Total Body.

## DISEASE STATUS OF PATIENTS/SOURCE

Healthy subjects and patients with oncological, cardiological, neurological and metabolic diseases.

## CLINICAL CHARACTERISTICS OF PATIENTS/SOURCE:

Patients and subjects with clinical, anamnestic, demographic and medical imaging data that have signed the informed consent and the privacy protection form. Inclusion criteria depend on the single project or collection. At this time, no specific constraints are applied for citizens or patients who wish to participate in BCU-IB.

## SIZE OF THE BIORESOURCE

Approximately 12,000 individuals and 14,000 imaging studies (up to 20/06/2021).

Average number of incoming cases per year: 2,000 since 2014.

Average number of outgoing cases per year: not available due to the early period of the biobank (since 2018).

## VITAL STATE OF PATIENTS/SOURCE

Alive at time of sampling.

## CLINICAL DIAGNOSIS OF PATIENTS/SOURCE

- Oncological patients: This cohort includes patients affected by solid cancers. Patients are examined using functional and morphological imaging PET/MR and PET/CT.
- Cardiovascular diseases: This cohort includes patients affected by cardiovascular diseases and examined using MR functional imaging.
- Neurological diseases patients: This cohort includes patients affected by neurological diseases such as Parkinson and Alzheimer. Patients are examined using PET/MR and PET/CT functional imaging.
- Covid patients: this cohort has been collected during the coronavirus SARS-CoV-2 pandemic. Patients are examined using morphological imaging (thorax CT).

## **PATHOLOGY DIAGNOSIS**

Available through medical records. Among these, there are Covid patients with pathological diagnosis: U07.1 (COVID19, virus identified) and U07.2 (COVID19, virus not identified).

## **CONTROL SAMPLES**

Healthy subjects: this cohort includes images, clinical records and data from healthy subjects (females and males) and it will be used as comparisons for anatomical regions, pathological states or quality control checks.

## **BIOSPECIMEN TYPE**

N/A

## **SIZE OF THE BIORESOURCE**

BCU Imaging Biobank has collected imaging exams from approximately 12.000 subjects (up to 20/06/2021). The majority of these images are grouped in organ-based collections (55%). Another part includes patients suspected or diagnosed with COVID19 (25%). The remaining cohorts are composed of patients with oncological (10%) and neurological diseases (10%).

## **RELEASE DATE**

The BCU-IB biobank is accessible since January 16, 2020 following the approval of the Ethics Committee of the “Molim Onco Brain Lab” project.

## **ACCESS CRITERIA**

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

- Requests should be sent by e-mail to BCU Imaging Biobank ([biobanca@biocheckup.net](mailto:biobanca@biocheckup.net)). Researchers must provide the scientific and ethical committee approval of their research project. Diagnostic images and data will be made accessible to the researcher only after the signature of the Material and Data Transfer Agreement (MDTA) form by the Principal Investigator.
- Access to BCU-IB is restricted to scientists from research and academic medical institutions.
- The provided material should be used only for not-for-profit research projects and should not be transferred to third parties.
- Research projects in line with the BCU-IB mission will be eligible for data and image access.
- The Principal Investigator must guarantee proper acknowledgement of BCU-IB in any resulting scientific publications.
- Since BCU-IB is a digital biobank, cost recovery will be asked on a case-by-case basis in order to face the costs for the maintenance of the platform and according to specific needs of the research project.

## **(4) REUSE POTENTIAL**

Images and data are collected according to the FAIR principles (Findable, Accessible, Interoperable, Reusable). Through the submission of a project, the pre-approval of the researchers' home institution and the final validation from the Scientific and Ethics Committee and Advisory Board of BCU-IB, researchers can use the collections of BCU-IB in research including, and not limited to, radiomics, big data, pathology, diagnostics, precision medicine, predictive medicine.

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- “C.I.R.O. – Campania Imaging Infrastructure for Research in Oncology” (CUP B61G17000190007);
- “Protocolli TC del torace a bassissima dose e tecniche di intelligenza artificiale per la diagnosi precoce e quantificazione della malattia da covid-19” (CUP D54I20001410002).

## COMPETING INTERESTS

The authors have no competing interests to declare.

## AUTHOR ROLES

1. Executive Responsible
2. Executive Responsible
3. Data Management Responsible
4. Quality and Management Responsible
5. Member of Scientific Committee
6. Member of Scientific Committee
7. Scientific Director

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