The Galliera Genetic Bank is part of the Laboratory of Human Genetics of Galliera Hospital in Genoa and has collected samples from patients affected by genetic diseases since 1983. Presently, it stores 10,259 biospecimens and associated data from about 200 genetic disorders. The most representative disorders are chromosome disorders (Down s., Ring chromosome 14 s., Cri du chat s. and Isodicentric 15 chromosome), neurological diseases (Fragile X s., Mowat Wilson s. and Dravet s.), rare bone diseases (Crouzon s., Achondroplasia, Grieg s. and Thanatophoric dwarfism), overgrowth syndromes (Sotos s.), familial hypertrophic cardiomyopathy and other rare disease such as IPEX and Aarskog s. The biobank has been supported by Italian Telethon grants since 1993 and since 2008 is partner of the Telethon Network of Genetic Biobanks. It operates according to Italian and international regulations. Since 2008 the biobank is certified ISO 9001, and in 2010 it was officially authorized by the Liguria Region to operate as a facility in support of diagnosis and research on genetic diseases. Since its inception, the biobank has offered the following services to the biomedical community: (i) access to sample and data collection; (ii) sample processing (e.g., cell lines establishment, DNA/RNA extraction, etc); (iii) preservation of biological specimens and related data (repository service), garnering more than 110 acknowledgements in scientific articles.

Keywords: Biological Resource Center; genetic diseases; biobanking; biospecimen; cryopreservation

Funding statement: This work was supported by Telethon Foundation (grant GTB12001).
Species

Classification (2)
Biological samples and associated data

Context
Spatial coverage
Latitude: 44.401097
Longitude: 8.94137
Latitude: 44 degrees, 24 minutes, 3.949 seconds
Longitude: 8 degrees, 56 minutes, 28.9638 seconds

Description: Via Alessandro Volta 6, 16128 Genova, Italy
Northern boundary: +/- x.x
Southern boundary: +/- x.x
Eastern boundary: +/- x.x
Western boundary: +/- x.x

Temporal coverage
The Galliera Genetic Bank has been active since 1983, at the time of writing the biobank is operating.
Dates: from 1983 to present.

Temporal coverage for accessibility
Not applicable

(2) Methods
Steps
To deposit biological samples users are requested to fill in a submission form detailing: subject/patient’s personal details (name, date of birth, address, ethnic origin, gender), essential anamnestic data (presence of consanguinity and/or familiarity, tissues and/or organs anomalies, laboratory test anomalies, etc.), data about diagnosis or suspected diagnosis (centre performing diagnosis and methodology used), phenotype (affected/not affected) and sample information (type, date of sampling, etc.). According to Italian laws, GGB only accepts samples accompanied by an informed consent signed by the donor or his/her legal representative. Once a sample arrives at the biobank, the staff check its quality, the accuracy of labeling and make sure it is accompanied by the signed informed consent and the submission form. To protect donor’s identity, each new sample arriving at GGB immediately receives an alphanumeric code. The Biobank Curator and authorised staff members are the only ones entitled to decode the donor’s identity and to track back the linked data (clinical, genetic, genealogical, etc.). The access to the database is controlled by double personalised passwords and it is restricted to the GGB staff only to prevent the risk of illegal or non authorised accesses. The service guidelines, biobank contacts and forms are available on the biobank web-site: ggb.galliera.it. Contact the biobank staff before sending biological samples is recommended to avoid shipping problems.

Stabilization/preservation
- cell lines cryopreservation: cryovial, DMSO or glycerol solution
- tissues cryopreservation: cryovial
- DNA preservation: vial, TE1X and other buffers
- RNA preservation: vial, H₂O

Type of long-term preservation
- cell lines cryopreservation: frozen, DMSO or glycerol solution, stored in liquid nitrogen
- tissues cryopreservation: frozen, cryovial, stored in liquid nitrogen
- DNA preservation: vial, TE1X and other buffers, stored at +4°C/-20°C
- RNA’s vial: H₂O, stored at −80°C

Storage temperature
Cell lines and tissues: liquid nitrogen (~196°C)
DNA samples: 4°C/-20°C
RNA samples: −80°C

Shipping temperature from patient/source to preservation or research use
Room temperature and/or dry ice depending on bi-specimen type

Shipping temperature from storage to research use
Room temperature (cultured cell lines and DNA samples) and/or dry ice (frozen cells, tissues and RNA samples)

Quality assurance measures
The entirety of biobank activities (e.g., sample collection, processing, storage and distribution) complies with Italian regulations and its operational quality system is certified ISO 9001 in order to guarantee high quality standards in terms of procedures, sample preservation, security and respect of privacy. The biobank has also obtained the SIGUCERT© Certification, a Quality Assurance Standards for genetic biobanks developed by Italian Society of Human Genetics (http://www.sigu.net/show/documenti/5/1/linee%20guida).

The Biobank quality system lays down the following procedures:
- Check for cell lines vitality and exclusion of contamination by bacteria, fungi and mycoplasma
- Routine mycoplasma contamination assessment in cell cultures before shipping
- Check for nucleic acids integrity by Nanodrop and agarose gel electrophoresis
- STR analysis for samples authentication
- Cryo room/Cold room equipped with n°7 liquid nitrogen refrigerators with restricted access to biobank staff only
- Freezers and CO₂ incubators equipped with alarm systems to check temperature and CO₂ variations.

Source of associated data
Clinicians and researchers who deposit samples to the GGB are responsible for associated data. The sources of associated data are laboratory and clinical reports.

Ethics Statement
The most recent version of the GGB informed consent form has been approved by the Ethics Committee of Liguria region (15th September 2015). For all the ethical,
legal and societal issues, the Biobank adopts the principles stated in the TNGB Charter. Reference documents are:

- Recommendations issued by the Oviedo Agreement, 1997 (Convention on Human Rights and Biomedicine, Oviedo, 4th April 1997) and the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes (CETS n. 203), 2008 (Strasbourg, 27th November 2008)
- Telethon – SIGU Guidelines for Genetic Biobanks, 2003
- International Declaration on Human Genetic Data, 2003 (16th October 2003, 32nd session, the General Conference of UNESCO – The International Declaration on Human Genetic Data)
- Italian Data Protection Authority (Garante Privacy), Personal Data Protection Code, Legislative Decree no. 196, 30th June 2003, published in Official Gazette No. 174 of the Italian Republic, 29th July 2003
- Italian Data Protection Authority (Garante Privacy), General Authorisation no. 8/2014 for the Processing of Genetic Data. Published in Italy’s Official Journal No. 301 of 30th December 2014
- Italian Data Protection Authority (Garante Privacy), Authorisation no. 9/2014 – General Authorisation to Process Personal Data for Scientific Research Purposes. Published in Italy’s Official Journal No. 301 of 30th December 2014.

**Constraints**
No constrains

**(3) Bioresource description**

**Object name**
Genetic diseases biobank

**Bioresource name**
Galliera Genetic Bank
Acronym: GGB

**Bioresource location**
Galliera Genetic Bank
c/o Laboratory of Human Genetics – Galliera Hospital
Via A. Volta 6, 16128 Genoa
Italy

**Bioresource contact**
ggb@galliera.it
chiara.baldo@galliera.it (biobank curator)
Phone +39 010 5634386 (83)

**Bioresource URL**
http://ggb.galliera.it

**Identifier used**
Not available

**Bioresource type**
Genetic Biobank

**Type of sampling**
Genetic disease based, family, sampled in research protocol

**Anatomical site**
Not applicable

**Disease status of patients/source**
Subjects and their relatives (healthy carriers, normal controls) affected by several different genetic diseases

**Clinical characteristics of patients/source**
Subjects and their relatives (healthy carriers, normal controls) affected by several different genetic diseases.

**Size of the bioresource**
Total number of biospecimens: 10,259.
Estimated number at the end of the project: not applicable.

**Vital state of patients/source**
Alive donors at the time of sampling and prenatal samples

**Clinical diagnosis of patients/source**
Various genetic diseases (diagnosed and still undiagnosed) and normal controls

**Pathology diagnosis**
Chromosomal disorders, genetic diseases, rare diseases

**Control samples**
Healthy relatives of affected patients and healthy subjects with normal anamnesis data and genetic testing with respect to the pathology of interest (e.g. intellectual disabilities associated with chromosomal disorders, hypertrophic cardiomyopathy, mild cognitive impairment, etc).

**Biospecimen type**
Cell lines (EBV-lymphoblasts, T-lymphocytes activated with IL-2, fibroblasts, amniocytes, trophoblast cells), peripheral blood mononuclear cells (PBMCs), foetal tissues, DNAs, RNAs, blood, sera, plasma, other.

**Size of the bioresource**
Total number of biospecimens: 10,259.
Estimated number at the end of the project: not applicable.
The biobank operates as a facility of the hosting institution that has ensured its sustainability over the years. Telethon grants have enabled the biobank to improve its procedures and policies in order to provide researchers with high quality services.

**Release date**
Not applicable

**Access criteria**
Samples are made available to users for research purposes according to the following access rules:
– an adequate portion of the sample is safeguarded to the patient's advantage to allow retrospective analyses
– samples are made available only to qualified professionals working at research or medical institutions engaged in scientific projects on genetic diseases
– appropriate justification for use (description of the research project, grant sponsor, expected results)
– samples provided must be used only for the research project stated on a relevant form by the Principal Investigator
– biobank must be properly acknowledged in scientific publications for having provided the biospecimens and/or related services
– users are requested to pay for shipping and distribution costs. The biobank distribution service is subject to cost recovery.

(4) Reuse potential
Sample request management is fully handled through the IT infrastructure shared by all the TNGB partners.

Users can select the samples of interest by browsing the TNGB catalogue available at http://biobanknetwork.telethon.it/. Users online registration is mandatory to submit requests of samples. All requests are collected in a Request Control Panel where all biobank directors (i.e., Network Board) can review the requests on the basis of the access rules and priority criteria stated in the TNGB Charter. Once the request has been approved by the Network Board, the TNGB coordination office assigns it to the sample-holding biobank's staff, who will send a “Material Transfer Agreement” form for acceptance of the TNGB policy.

Users are requested to inform biobank(s) of any published scientific paper resulting from the supplied by filling the “Confirmation of sample use” form.

Up to now the Galliera Genetic Bank has been acknowledged in 112 scientific papers.

Competing Interests
The authors declare that they have no competing interests.

Author Roles
Baldo Chiara – Curator.
Mogni Massimo – Bioresource Manager.
Viotti Valeria – Cell lines procedures.
Maio1 Elizabetta – DNA RNA extraction.
Castagnetta Mauro – Management of database.
Cavani Simona – Cytogenetic diagnosis.
Piombo Giuseppe – Cytogenetic diagnosis.

Coviello Domenico – Director of the Laboratory hosting the Bioresource.

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