The role of biobanking in Italian Neutropenia Registry

F Fioredda
Unit of Hematology
IRCCS –GasliniHospital

INNOCHRON
Training School in Biobanking
April 6-8- Thessaloniki- Greece

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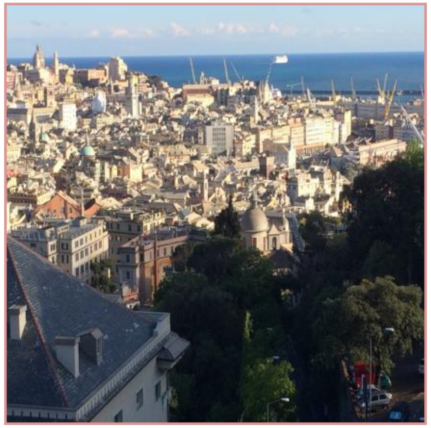
ITALIAN NEUTROPENIA REGISTRY

AIMS

- Data collection/analysis to increase knowledge in the field
- Common approach and the management of neutropenia
- Development of clinical and biological research by promoting collaboration inside and outside the country

60 millions inhabitants

301.338 km²



DATA COLLECTION

AIEOP (Associazione Italiana Onco-Ematologia Pediatrica)

~30 centers

-Informed consent/local
ethic commitee

Anagraphic data

-History of disease

-Biological data

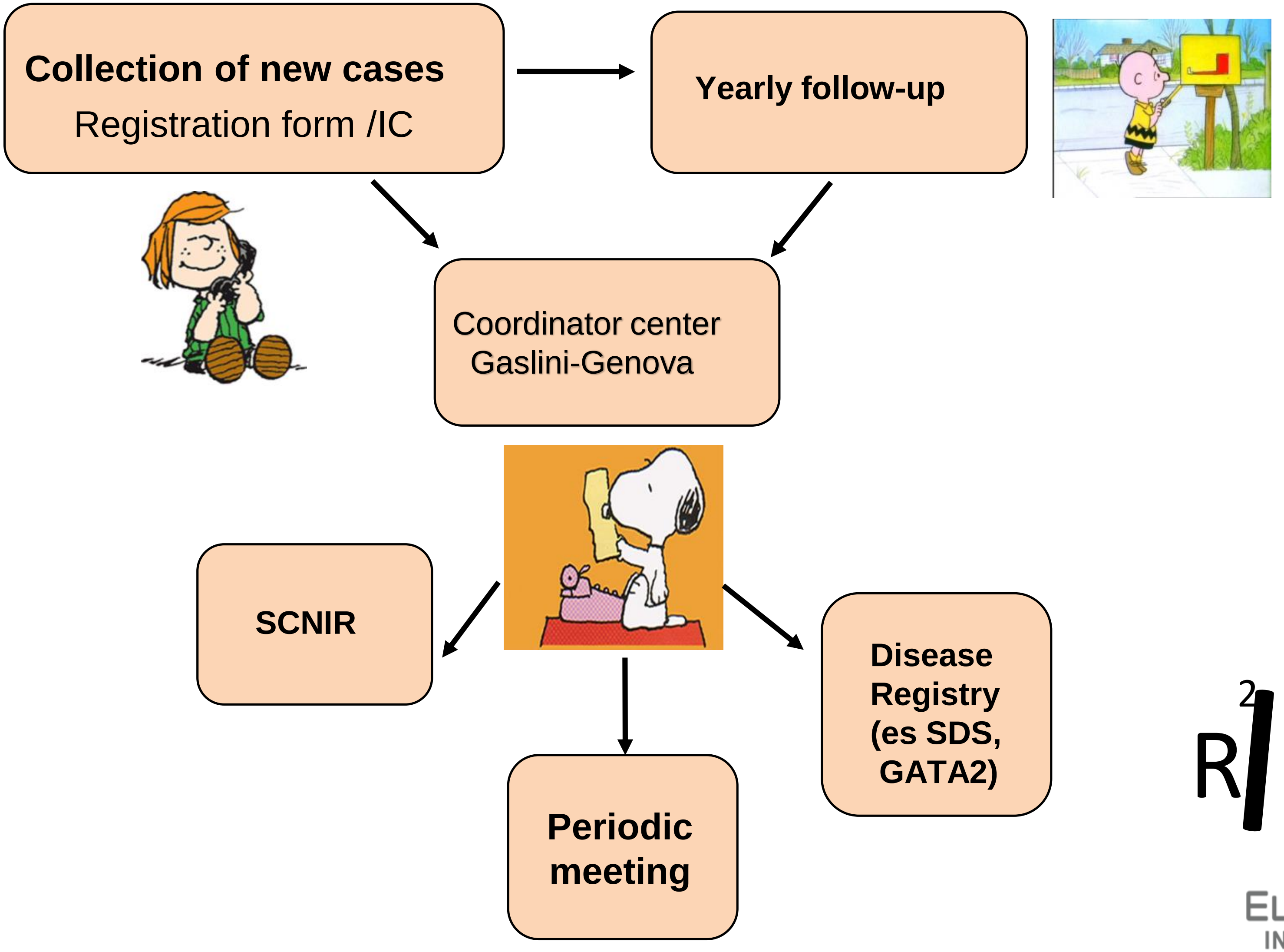
(immunological and genetic)

-Data on therapy

Registration and yearly follow up data

ITALIAN NEUTROPENIA REGISTRY

DATA FLUX



Collection of new cases

Registration form /IC

Yearly follow-up

Coordinator center
Gaslini-Genova

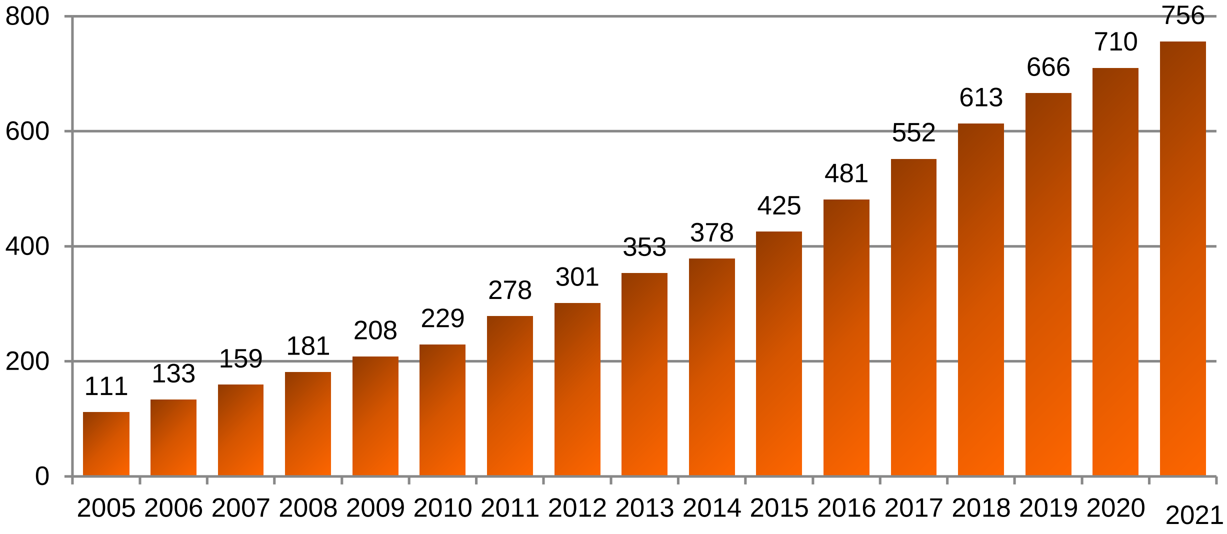
SCNIR

Periodic meeting

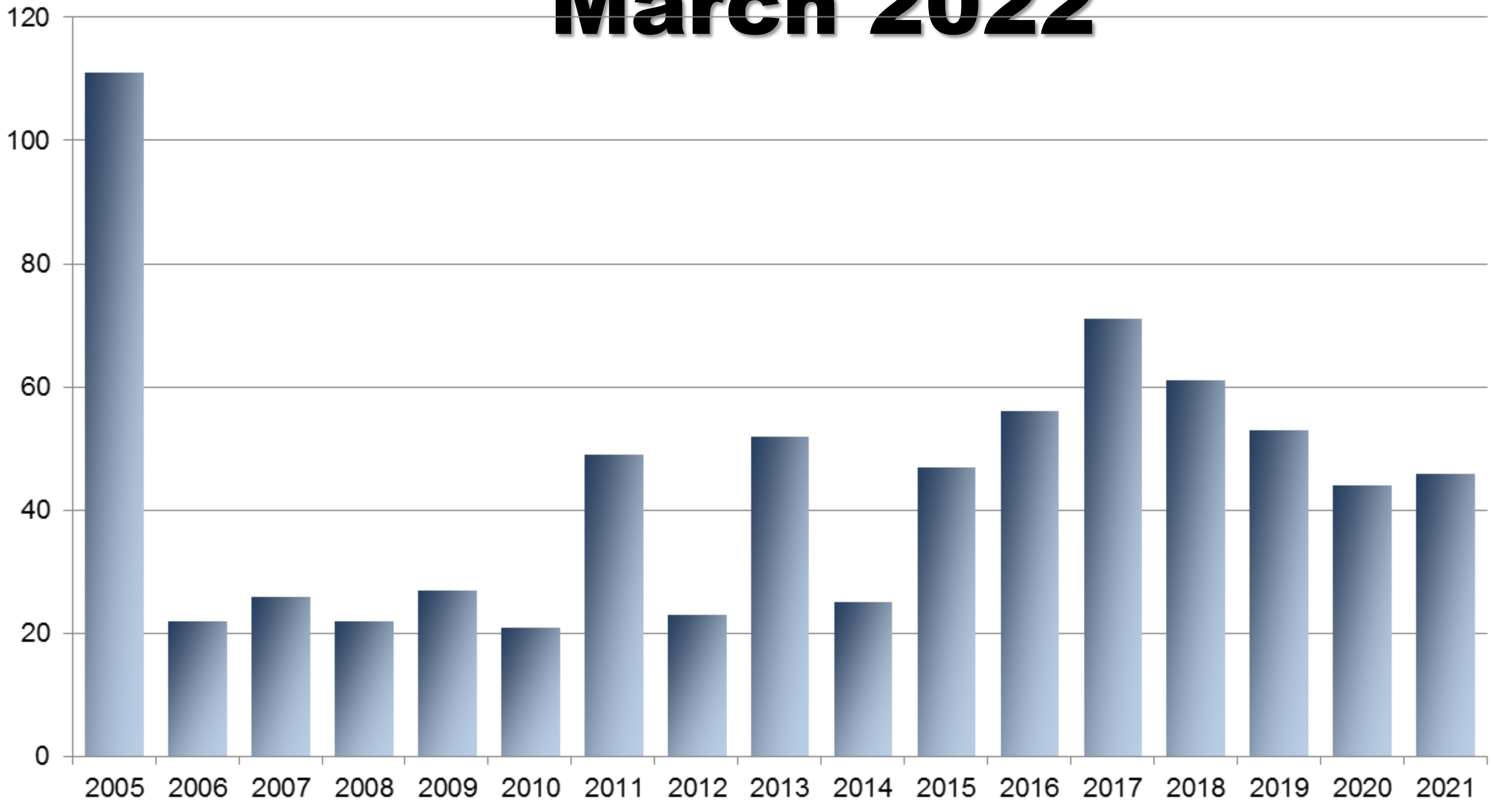
Disease Registry (es SDS, GATA2)

REGISTRATION

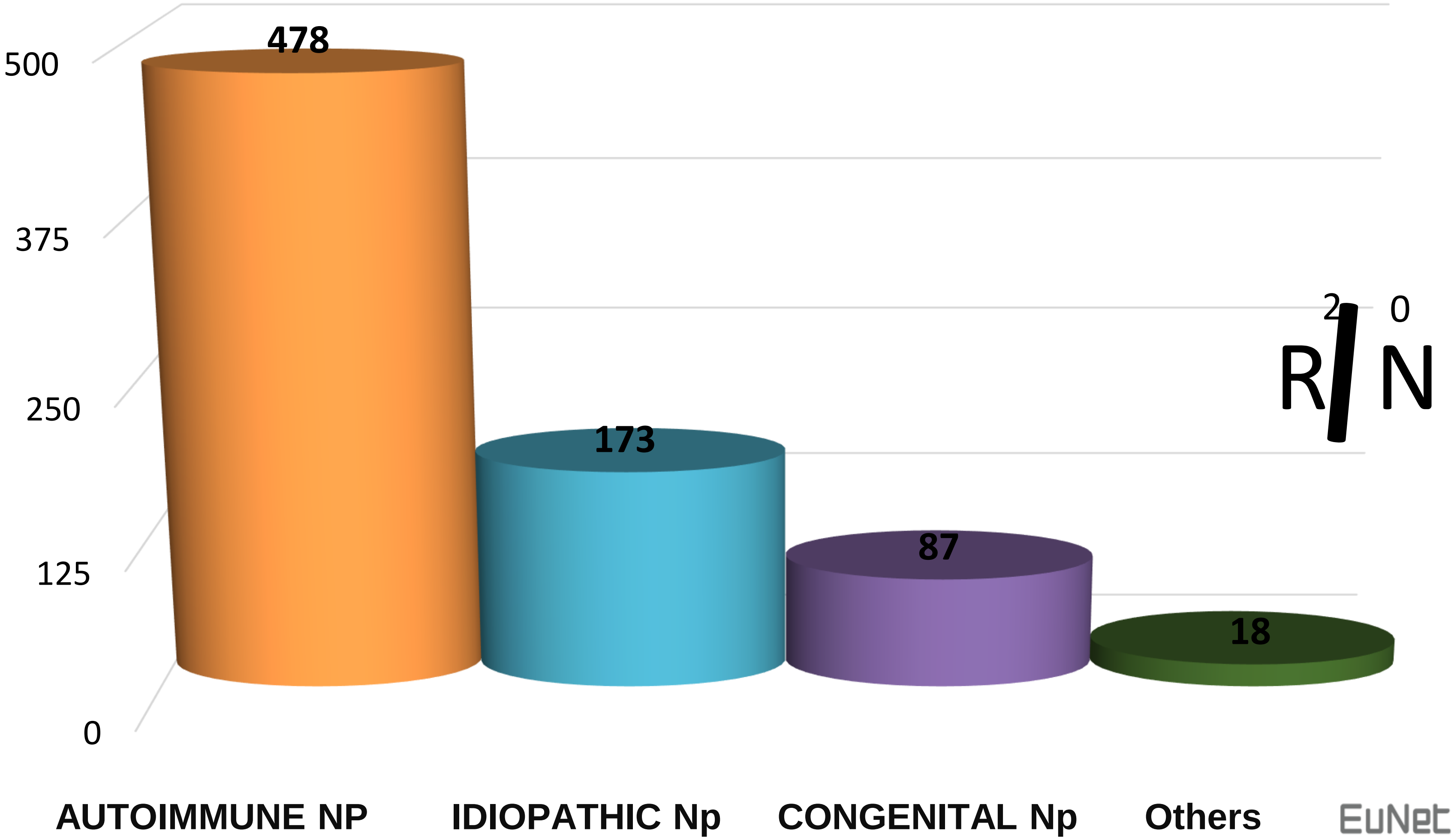
March 2022 update



REGISTRATION
yearly increase
March 2022



REGISTRATION
by diagnosis
March 2022



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BIOLOGICAL SAMPLES COLLECTIONS/ Rules

Informed consent - Ethic Committee

Informed consent

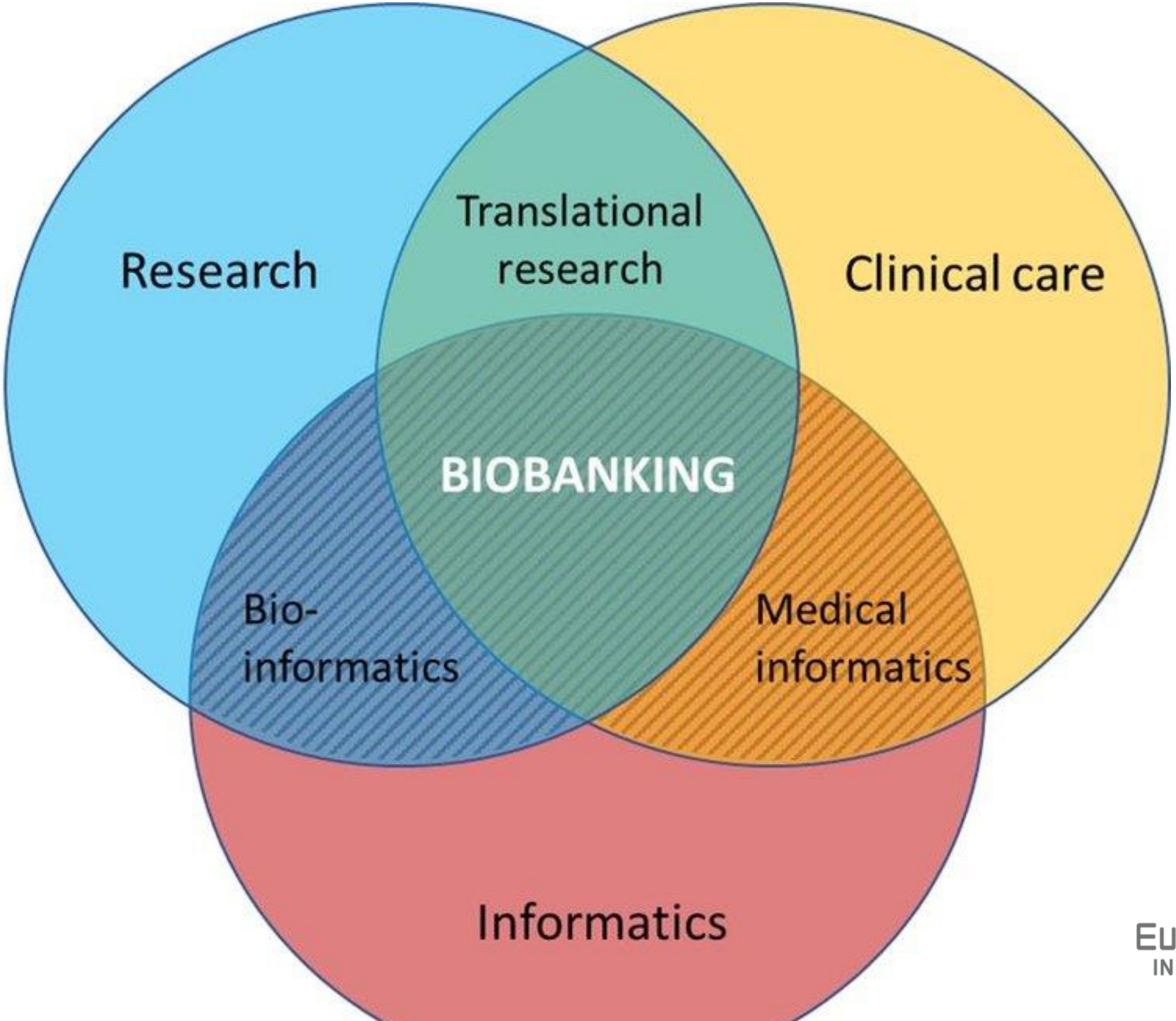
Collection of ***Peripheral Blood/Bone Marrow Serum/Plasma***

Storage at -20°C o -80°C at least 10 years c/o Centralized Biobanking (Network Telethon Affiliation, Genetic Lab)

Use of samples : research goals and diagnostic tests
(methods: sanger PCR,NGS, WES, phenotype, Flow fish, Cytokines…)

Sampling: collection in routine controls

Role of biobanking



Research

Translational research

Clinical care

BIOBANKING

Bio-informatics

Medical informatics

Informatics

GASLINI BIOBANK

Certified ISO 9001-2015

Certified SIGUCERT (genetic standard compliant to ISO 15189-2012

In preparation:

ISO 20387-2018 ACCREDITATION

Developing standard procedures and common quality assurance policy

BUREAU VERITAS
Certification

Certificato di Conformità
Rilasciato a

E.O. OSPEDALI GALLIERA DI GENOVA
STRUTTURA COMPLESSA DI LABORATORIO
DI GENETICA UMANA

SEDE LEGALE:
Mura delle Cappuccine, 14 - 16128 GENOVA (GE)

SEDE OPERATIVA:
Via Alessandro Volta, 6 - 16128 GENOVA (GE)

Bureau Veritas Italia S.p.A. certifica che il Sistema di Gestione di questa organizzazione è stato valutato e giudicato conforme ai requisiti della norma

ISO 9001:2008
in relazione al seguente scopo

Sviluppo ed erogazione di:
- test genetici e consulenza correlata;
- servizi di biobanca genetica "Galliera Genetic Bank".
Sviluppo della ricerca scientifica nell'ambito
della genetica finalizzata alla salute dell'uomo.

Settore/i EA di attività 38C

Data inizio validità 17/07/2008
Revisione del 17/07/2011
Scadenza 16/07/2014

Certificato N° 229871

BUREAU VERITAS
Certification

Bureau Veritas
Certificato di

E.O. OSPEDALI GAL
Struttura Complessa di LABORA

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Mura delle Ca
16128 GEN

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Via Alessand
16128 GEN

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stato valutato e giudicato conforme ai

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*Lo standard comprende
ISO 15189:2007,

in relazione al se

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Scadenza 16/07/2014

Certificato N° 229873

CERTIFICATO DI
ACCREDITAMENTO
n. 011

Società Italiana di Genetica Umana

SIGUCERT®

Rilasciato a

E.O. OSPEDALI GALLIERA DI GENOVA
Struttura Complessa di LABORATORIO DI GENETICA UMANA
SEDE LEGALE: Mura delle Cappuccine, 14 - 16128 GENOVA (GE)
SEDE OPERATIVA: Via Alessandro Volta, 6 16128 GENOVA (GE)

Società Italiana di Genetica Umana (SIGU - www.sigu.net)
accredita questa Organizzazione con

LABORATORIO D
ED

Data inizio validità 27/04/2011
Scadenza 26/04/2014

Data: 27/04/2011
Certificato di accreditamento N° 011
BUREAU VERITAS ITALIA SpA - v.le Monza 261 - 20126 Milano

BUREAU
VERITAS
Move Forward with Confidence

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MAIN SERVICES

- **Acquisition of biological samples**
- **Sample processing:** cell lines preparation (lymphoblastoid lines, primary lines from skin biopsies, from amniotic fluid, ...), separated lymphocytes, plasma / serum, DNA / RNA extraction from blood and tissues
- **Samples diagnostic** Indirect GIFT Antibodies against neutrophils
- Cytokine dosage (IL 10 , IL18), Sanger PCR , WES , NGS, Immunophenotype, Bone Marrow Cultures
- PK PEGfilgrastim Biological/ biochemical validation on cell lines
- **Storage of biological material** in the fridge (+ 4 ° C), freezer (-20 °C), freezer (-80 ° C) and liquid nitrogen (-196 °C)
- **Distribution of samples to researchers**, according to specific/regulated projects

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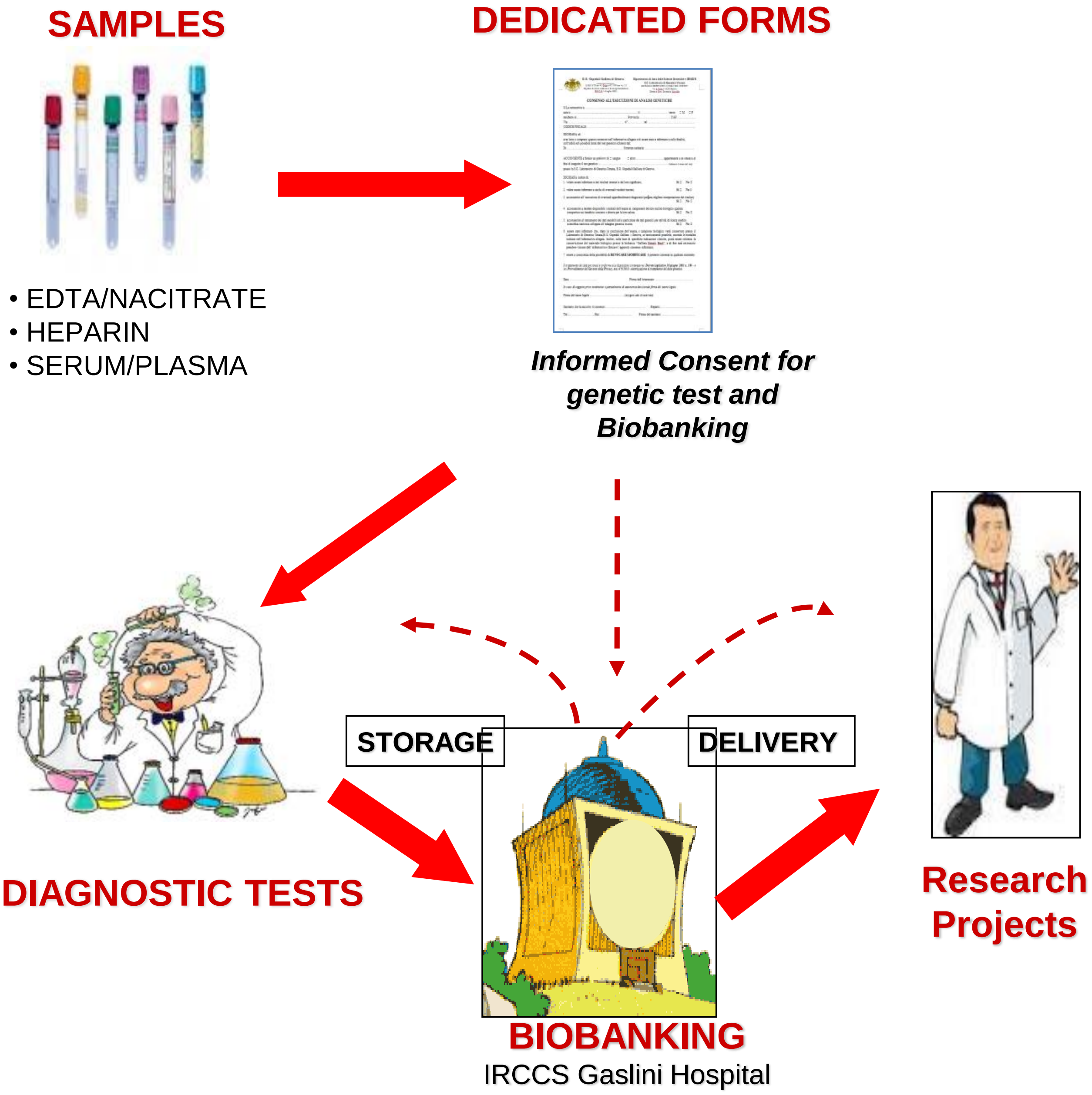
SAMPLES AND DATA COLLECTION



SAMPLES

- EDTA/NACITRATE
- HEPARIN
- SERUM/PLASMA

DEDICATED FORMS

Informed Consent for genetic test and Biobanking

DIAGNOSTIC TESTS

STORAGE

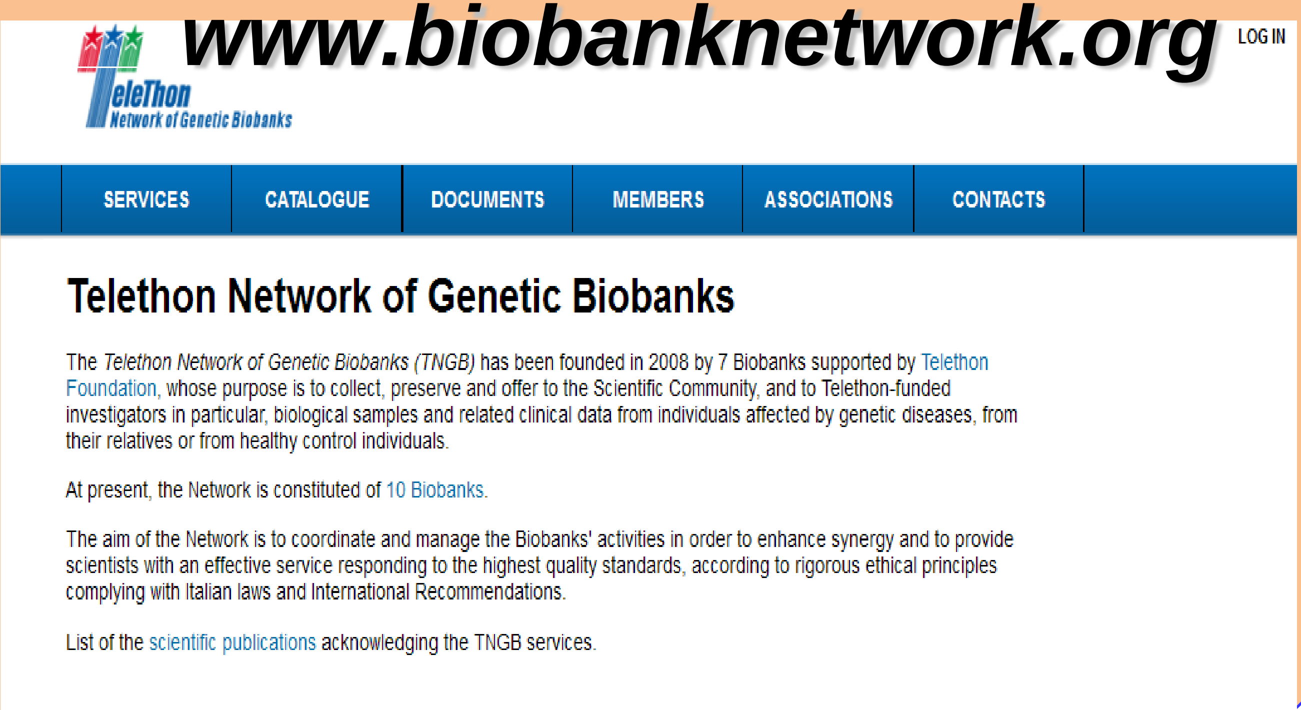
DELIVERY

BIOBANKING

IRCCS Gaslini Hospital

Research Projects

www.biobanknetwork.org



Telethon Network of Genetic Biobanks

The *Telethon Network of Genetic Biobanks (TNGB)* has been founded in 2008 by 7 Biobanks supported by Telethon Foundation, whose purpose is to collect, preserve and offer to the Scientific Community, and to Telethon-funded investigators in particular, biological samples and related clinical data from individuals affected by genetic diseases, from their relatives or from healthy control individuals.

At present, the Network is constituted of 10 Biobanks.

The aim of the Network is to coordinate and manage the Biobanks' activities in order to enhance synergy and to provide scientists with an effective service responding to the highest quality standards, according to rigorous ethical principles complying with Italian laws and International Recommendations.

List of the scientific publications acknowledging the TNGB services.

Research

Telethon Network of Genetic Biobanks: a key service for diagnosis and research on rare diseases

Mirella Filocamo, Chiara Baldo, Stefano Goldwurm, Alessandra Renieri, Corrado Angelini, Maurizio Moggio, Marina Mora, Giuseppe Merla, Luisa Politano, Barbara Garavaglia, Lorena Casareto, Francesca Bricarelli, for Telethon Network of Genetic Biobanks Staff

Orphanet Journal of Rare Diseases 2013, **8**:129 (30 August 2013)

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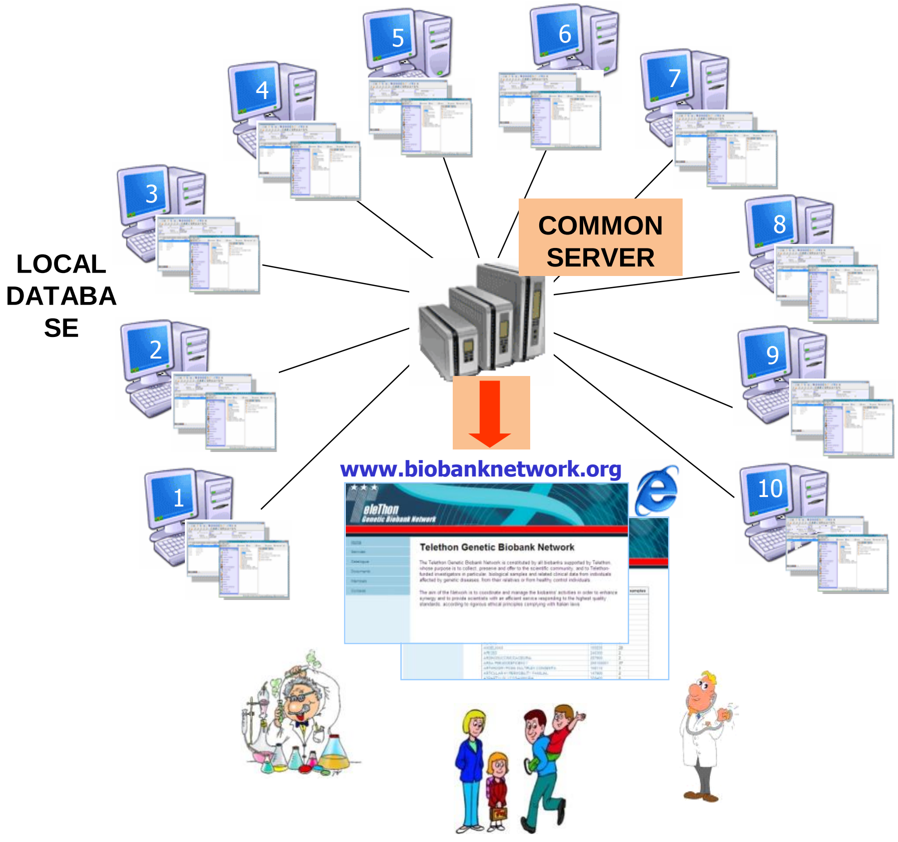
TNGB: IT STRUCTURE

Each Biobank manages the data using a local database equipped with specific modules designed on the basis of the type of samples and pathologies of competence.
The anonymized data is automatically aggregated and published in the Network's online catalog, accessible from the website: www.biobanknetwork.org



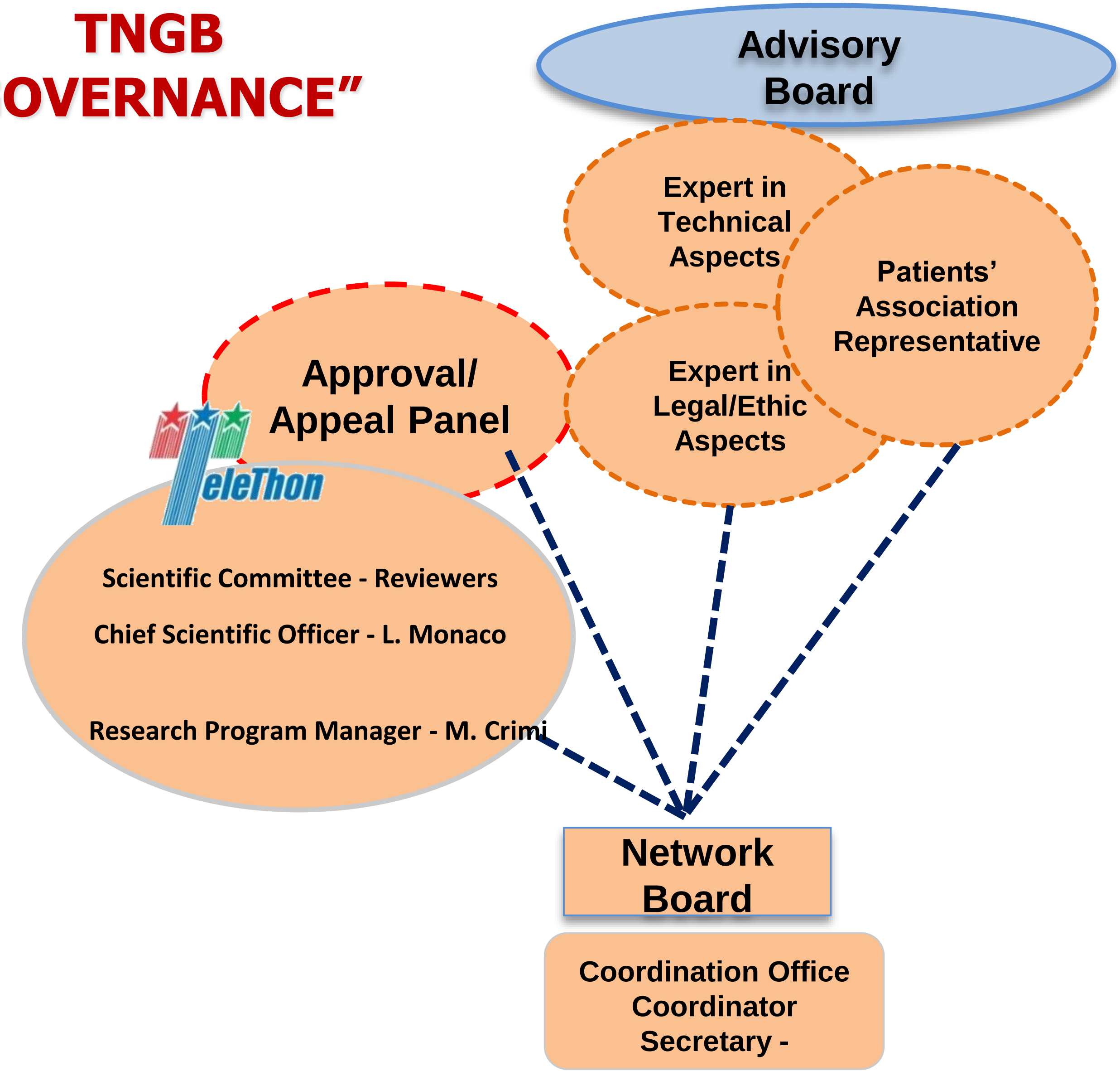
LOCAL DATABA SE

COMMON SERVER

www.biobanknetwork.org

Telethon Genetic Biobank Network

TNGB
“GOVERNANCE”



Advisory Board

Expert in Technical Aspects

Patients’ Association Representative

Approval/ Appeal Panel

Expert in Legal/Ethic Aspects

Scientific Committee - Reviewers

Chief Scientific Officer - L. Monaco

Research Program Manager - M. Crimi

Network Board

Coordination Office
Coordinator
Secretary -

EuNet
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ANY JOIN VENTURE VERY WELCOME!!

Aknowledgements

AIEOP CENTERS

Pisa
Bologna
Modena
Roma OBG
Roma Sapienza
Bari Policlinico
Bari Giovanni XXIII
San Giovanni Rotondo
Lecce
Monza
Torino
Pescara
Perugia
Cagliari
Milano
Milano HSR
Monza
Napoli Pausillipon
Napoli Federico II
Catanzaro
Catania
Palermo
Brescia
Firenze
Padova
Trieste
Udine
Bolzano

Hematology Lab

M. Lanciotti
M. Lupia
P. Terranova
C. Schiazza

Genetic Lab

D. Coviello
C. Baldo
A. Grossi
I. Ceccherini

Data managers

Sabrina Zanardi

Secretary

Elena Ricolfi

C Dufour
A Beccaria
P Casartelli

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