

FONDAZIONE IRCCS CA' GRANDA Ospedale Maggiore Policlinico



Fondazione Istituto Nazionale Genetica Molecolare

Ca' Granda Lectures and Seminars in Molecular Medicine Biobanche: questioni giuridiche, casi pratici, opportunità

- Esperienze Italiane ed estere nelle Biobanche
- Pasquale De Blasio
 ESBB Founding President
 CEO of Integrating Systems Engineering srl Milano IT





The importance of Biobanking



The "Quality of the biological materials" used in a research is fundamental for the "results that are published" and for its "confirmation in different labs".





Different types of Biobanks



Disease development



Collect/Process/Inventory/Store





Search/Request



Biorepository Collection



Evaluate

Use

Develop New research protocols

New Clinical Application (diagnostic, prognostic, therapeutic)



Publish/ Submit to Regulatory body

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Current and Emerging Infectious Risks of Blood Transfusions

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Analyze / Verify / Validate





Distribute



Key Components of a Biobank

BBMRI-ERIC Biobanking and BioMolecular resources Research Infrastructure



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Biopreservation 8

Blood

Society for

Biobanking



- Lifestyle Information
 - Basic Researchers
 - Epidemiologists
 - Lab technicians
 - Biobanking Experts

- Physician
- Nurse
- Administrative assistants
- Ethical oversight



Courtesy from Jim Vaugt - OBBR - NIH Office of Biorepositories and Biospecimens Research





The Importance of Biobanking Biopreservation.

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Society for

Biobanking







Cell, Vol. 100, 57-70, January 7, 2000,

NEW Disease Classifications (The most quoted paper in the forthcoming 10 yrs.....)



Hallmarks of Cancer: The Next Generation

Douglas Hanahan^{1,2,*} and Robert A. Weinberg^{3,*}



NEW Disease Classifications (Standard Classification of Cancers)























Genome Journey













Different people respond differently to the same therapy: while one treatment brings about the desired success in one group of patients with e.g. colon cancer, it does not change the condition of other groups at all, or even leads to adverse effects (left). The reason: the genetic makeup and metabolic profile of each individual patient influences the effect of a drug. Personalized medicine takes these individual patterns of cellular and metabolic products into account in the diagnostic phase: biomarker diagnostics separates patients into groups with similar characteristics, and provides information on the best individual treatment. This should enable all patients to benefit from their own, "personal" therapy.

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Dovepress open a corest to scientific and medical research

REVIEW

Biobanking shifts to "precision medicine"

This article was published in the following Dove Press journal: Journal of Biorepository Science for Applied Medicine 24 July 2014 Number of times this article has been viewed

Aikaterini Ntai¹ Simona Baronchelli² Tatiana Pellegrino¹ Pasquale De Blasio¹ Ida Biunno^{2,3}

¹Integrated Systems Engineering, Milan, Italy; ²Institute for Genetic and Biomedical Research, National Research Council, Milan, Italy; ³IRCCS Multimedica, Milan, Italy Abstract: The shape of the global health care system is changing rapidly to an approach that is much more patient-centered and focused on "precision medicine." This is especially due to the development of large-scale "omics" biology results that rely on using and sharing sample collections and databases contained within bioresource facilities. "Personalized medicine" or "precision medicine" is the premise to help individuals to get the "right medicine for the right problem at the right time." For several decades, tissues, body fluids, and cells obtained from patients with selected diseases have been cryopreserved in hospital-based biobanks, but samples were not accessible worldwide. Instead, the value of biobanks relies on the availability, at a necessary scale, of high-quality biospecimens and related data in order to respond to specific biological questions. However, the next generation of biobanks needs to face a major challenge – the costs related to the collection and processing of a large number of samples. Here, we describe the shift of biobanks from conventional repositories to functional infrastructures able to respond to specific medical demands.

Keywords: next-generation biobanking, personalized medicine, tumor biotypes



Need to make better use of Clinical Records







Biospecimen Science



What is biospecimen science?

Biospecimen Science is the multidisciplinary field of study responsible for establishing tested and proven biospecimen resource-related procedures based on experimentation in the areas of specimen collection, processing, shipping, and storage

Why is it needed?

Biospecimens are composed of active and reactive living cells or cell products, making them highly complex.

The collection, handling, and storage process can profoundly alter the molecular profile and quality of biospecimens.

Such alterations, though artificial, can be misinterpreted as disease related or disease specific.

High degrees of sensitivity and specificity in new molecular techniques raise the bar for analyte (specimen) data and quality.











Biobanking experiences

| Public Biobanks | Private Biobanks | | | |
|-----------------------------------|------------------------------|--|--|--|
| Population Based | Population Based | | | |
| Hospital/Disease based | Service Providers | | | |
| Cord Blood Banks | Cord Blood Banks | | | |
| • Stem Cell (MSC, ESC, iPS, etc.) | • Stem Cell (MCS, ESC, etc.) | | | |
| | • iPSC | | | |
| Animal Biobanks | | | | |
| Enviro Bio Biobanks | | | | |
| Agriculture/seeds Biobanks | | | | |
| Museum Biobanks | | | | |

| ABOUT | NODES | MEETINGS | NEWS | BBBMRI Biobanking and BioMolecular resou Research Infrastruct | -ERIC Irrces ture | |
|---------|---------------------------|------------|--------------------------|--|-------------------------|---|
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WELCOME TO BBMRI-ERIC

Essential for the understanding of the diversity of human diseases, biological samples and corresponding data are required for the development of any new drug or diagnostic assay and are therefore critical for the advancement in health research, ultimately leading to personalised medicine. Biobanks also will provide key information on the influence of environment and lifestyle on health, constituting a basis for disease prevention programmes and the improvement of public health.

Hence, a close collaboration between researchers, biobankers, patient advocacy groups, and the biotech and pharma industry is essential in addressing both common and rare diseases. Keeping in mind the need for better prevention, diagnostics, and therapy for all, we are aware that every single sample impacts our ability to comprehend disease and, thus, achieve our goal for a healthier life. Sixteen Member States and one International Organisation have thus joined forces in establishing BBMRI-ERIC, which is one of the largest health Research Infrastructure in Europe today. BBMRI-ERIC primarily aims at establishing, operating, and developing a pan-European distributed research infrastructure of *biobanks* and *biomolecular resources*. This will facilitate the access to biological resources as well as biomedical facilities and support high-quality biomolecular and medical research.

Imagine the countless possible applications for the billions of biological samples that are available from biobanks across Europe.

Welcome to BBMRI-ERIC - Welcome to the Gateway for Health!

Prof. Jan-Eric Litton BBMRI-ERIC Director General

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The BiobankCloud project develops a software stack for the secure storage and analysis of...

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BBMRI-ERIC to host HandsOn: Biobanks at EXPO Milan 2015

Following the "HandsOn: Biobanks 2014: From Biobanks to Medical Innovations" last month in...

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WE KNOW GENETICS

deCODE genetics is a global leader in analyzing and understanding the human genome. Using its unique expertise and population resources, deCODE has discovered genetic risk factors for dozens of common diseases. The purpose of understanding the genetics of disease is to use that information to create new means of diagnosing, treating and preventing disease.

UNIQUE EXPERTISE



Using its unique expertise and population resources, deCODE has discovered key genetic risk factors for dozens of common diseases ranging from cardiovascular disease to cancer.

UNIQUE CAPABILITIES



We operate the most productive human gene discovery engine in the world, employing our discoveries to identify genetic variations associated with human disease.

OUR PUBLICATIONS



We regularly publish our discoveries in major, peer-reviewed journals, enabling others to further validate and expand upon our findings

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Resources Scientists

Data Showcase

Register & apply

Approved research

Publications



Participants

| ~ | Update your contact details |
|---|---|
| E | Genetic studies underway |
| 2 | Find out how the resource is being used |
| | Access Procedures |

Activity monitor ->

Imaging study -+

Look at the Data Showcase →

Scientists



Web questionnaires: submit a proposal

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Work for us: new vacancies - apply today

UK Biobank Axiom Array

UK Blobank Eye & Vision Consortium



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A healthier future starts with you



Welcome to Qatar Biobank

Qatar Biobank is a platform that will make vital health research possible through its collection of samples and information on health and lifestyle from large numbers of members of the Qatari population, Qatar Biobank, Qatar's long-term medical health initiative, was created to give Qatar's people better chances of avoiding serious illnesses, and to promote better health for our future generations.

Participating



You are being invited to take part in Qatar Biobank, Qatar's long-term medical health initiative for Qatar's population. To help you decide whether to contribute, here is some information on Qatar Biobank and what taking part involves.

Latest News



15/07/13 8:00 AM Deading Geneticist Takes The Helm At Qatar Biobanking its 300th participant

Read More

Video



Qatar Biobank Educational Video

Email: takepart@qatarbiobank.org.qa Tel: +974 4439 8899



Ricerca e Salute incontrano la Gente

Un'intera regione diventa laboratorio per la ricerca contro le malattie cardiovascolari ed i tumori

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- Stati Uniti

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- Dopo un infarto o un ictus il comportamento di ciascuno farà la differenza
- Cancro al seno, la dieta mediterranea protegge dopo la menopausa

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anche come si dorme.

Leggi tutto...

essere pigri



risultato di una ricerca americana da dove emerge che l'aumento di peso dovuto a una dieta costituita da cibo spazzatura è causa di pigrizia, stancherra e cedentarieti

La dieta mediterranea riduce l'infiammazione cronica silente: risultati dello studio Moli-sani



L'inflammazione cronica silente, alla base malattie cronico di numerose



Attività

| ** | Novembre 2014 | | | | | | | |
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| 17 | 18 | 19 | 20 | 21 | 22 | 23 | | |
| 24 | 25 | 26 | 27 | 28 | 29 | 30 | | |



Destina il tuo 5 per mille dell'IRPEF all'Associazione Cuore Sano ONLUS

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convegno

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Registries and Biobanks for Human Stem Cell Lines

Glyn Stacey, UK Stem Cell Bank, NIBSC ESHRE Course, Valencia, 8th November 2010







Health Protection Agency



National Institute for Biological Standards and Control Assuring the quality of biological medicines

List of partners

The EBISC Consortium represents all relevant stakeholders from donors to clinical and academic iPSC researchers and industrial us thus provides the scientific expertise, facilities, networks and expe achieve the project goals and respond appropriately to advances in and society.

Led by Pfizer Ltd and managed by Roslin Cells, the Consortium 8 active participant IPSC Centres with clinical and patient network leader in industrial iPSC supply, international experts in iPSC scient biobanking, bioengineering, regenerative medicine and data man and scholars in law and ethics.

EFPIA companies

Pfizer Ltd, United Kingdom

Novo Nordisk A/S, Denmark

AstraZeneca AB, Sweden

H. Lundbeck A/S, Denmark

Janssen Pharmaceutica NV a pharmaceutical company of Johnson & Johnson, Belgium

UCB Biopharma SPRL, Belgium

SME's

Roslin Cells Ltd, Unite Kingdom

ARTTIC, France

DefiniGEN Ltd, United

Douglas Connect Gmb (working communitie Germany

Bioneer A/S, Denmark

Stem Cell Banking for Personalized and Regenerative Medicine

Alkaterini Ntai¹⁸, Tatiana Pellegrino¹, Simona Baronchelli², Davide Giuseppe D'Urso², Alberto La Spada², Alessandra Storaci², Monica Cattaneo², Andrea De Blasio¹, Ida Biunno^{2,3}, Pasquale De Blasio¹



Figure 1: STR postiling analysis performers in the second state of the second state of

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Integrated Systems Engineering Sci, Via Fantoli, 16/15, 20138 Milan, Italy; Institute for Genetic and Biomedical Research, Via Fantoli 16/15, 20138 Milan, Italy; IRCCS Multimedica, Via Fantoli 16/15, 20138 Milan, Italy

Reproventive medicine, tissue engineering and gene therapy offer the opportunity to treat and cure many of today's intractable afflictions. In recent years, knowledge gained from the study of homan embryonic stem cells and mammalian sumatic cell reprogramming has led to the routine production of hiPSCs in inhoratories worldwide, giving promise for use in transplantation, high throughput drug screening, "disease-in-a-dish" modeling and gene discovery. The ability to cryogenically preserve pluripotent stem cells at their most potent state for later use, provides a potentially andimited source for basic research and clinical applications. However, several factors need to be considered when banking stem edb, including the methodology required to bank each stem cell source. One of the biggest challenges in harnessing the potential of hiPSCs is the variability in the cell production process, regarding the quality of the starting cell source, differences in the raw materials used for reprogramming and protocols employed for growth and differentiation. Identifying and controlling these variables by establishing standardized methods for growing and differentiating cells and performing quality control testing, minimizes the possibility of introducing anacceptable risk. ISE, is a research-grade Stem Cell Biobank that provides, in a timely manner, a unique ressource for human and animal pluripotent stem cells including IPSCs. Qualification services and QC assays, adapted to each stem cell source, ensure process reproducibility and the ability to consistently produce "high-quality biospecimens" that meet key specifications (viability, purity, sterility, function and efficacy) and assure long-term storage and procervation of the ull original features.

*aikaterini.ntai@gmail.com

ISE: Your Partner in Stem Cell Research and Quality Assurance Stem Cell Biobank Sample Traceability tegrity of the stored samples is one of th securing the integrity ISU, ID & RESEARCH-grade entry most important goals of effective storage. Till use Pressment ell biobank, represents a to capture scientific and other relevant data that are denote limited to the familamental enurge of highlyingland states impolled hosmaterial that Distribution 9 ifills the most stringers. minifieds. Taking part in a comber of European and National Basearch Projects and by collaborating with sundemis sless anti Acquisitio aboratorian. ISE angaint ryopreserves, characterize Sample Workflow within ... and distributes well white. destamented biospeciaters. INCOME. many Neural Clear, Programs 2 wile-The shaft represents the Addate into Street Section, allow ercourage of the different col affit home interest formant have igin oper stored in 15E biobert MINO Journ Obern Store On All call stocks, feaving a unique and univocal sample ID that its including human and improve service out Darlie Neutral Expansion Cryspresswati Bu their hannels Type, are lisked to all assuranted data and information state arfis. Our self like Mile form Discoverification establight is available at Bile provided barry Column regarding that origin, phenotype, donne, STR diversity, generate ignal lower armon, epigeorite signature, gree expression profiler CHOIC LABRAT.L contact water en **Quality Assurance** Stem Cell Services Cell Line Authentication **Microbiological** Testing Genetic/omic analysis eactic analysis is a fundamental process of cell monitoring as genetic Cross cell commitation and pathogen presence in the cell cultures may STR Profiling rangement on the exp changes can occur by entoneive in view extering. It is then recommended that cell cultures should be tested periodically to check working is recommended to be assayed on the cell lines befor hether they cotain their diploid karyonype with the use of more th sity is the first thing that should be and after property after. d when a cell line enters the bird delity of mix-Mycoplasma detection OFO - banding karvotyping rant in long term or We perform standard kery SE performs surfily tests project flavoing to assess the prostors of contaminants in the cultures. These include repeoplasma (PCR analysis, 11 11 11 11 (000) ading) is order to central growth in matthew mucha for 3 works and indirect DNA mai alte ien repest antiyals on DNA on such cell line al and is more





Global Biobanking Market:



• Biospecimen banking is a growing enterprises crucial to health science research and other biological sciences.



- worldwide medical biobanking industry forecast is:
 - \$14.4 billion in 2014
 - \$22.7 billion in 2018.

Ref: Biobanking for Medicine: Technology, Industry and Market 2014-2024 Visiogain: Publication date: 25/03/2014



Global Private Cord Blood Industry



Most industries worldwide are dominated by a few large industry players, this is also true than for the "global private cord blood industry".

Key market leaders within this space include:

- Cord Blood Registry (USA): 500,000+ cord blood and tissue units
- ViaCord (USA): 350,000 cord blood and tissue units
- China Cord Blood Corporation (China): 312,000 cord blood and tissue units
- Cryo-Save (Europe): 268,000 cord blood and tissue units
- Cryo-Cell (USA): 240,000 cord blood and tissue units

Even More Evidence That Growth Rates are Lower Than 33.5% CAGR



STAMINA

ONLUS

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Pay attention not to give false hope



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🕜 Area Utenti

Registrandoti hai accesso all'area riservata. Per effettuare Il login è sufficiente compilare i campi sottostanti.

Username

STAMINA FOUNDATION

ATTENZIONE: per gualsiasi informazione sulla fondazione, si prega di contattare dalle 10:00 alle 12:00 - il dott. Marino Andolina, al numero:



Se vuoi sostenere la ricerca della Stamina Foundation sulle teraple con le cellule staminali adulte, è possibile effettuare una donazione.

Come sostenere la ricerca sulle staminali adulte



Pay attention not to give false hope

Human cryopreservation???:

Cryonics is the practice of freezing patients doomed to death down to ultralow (cryogenic) temperatures and their further preservation in liquid nitrogen. By means of cryonics patients can be preserved till some time in future when advanced technologies, in particular, nanotechnologies can repair cells, tissues and all functions of the human organism in the whole body



-FRIC

In the US cryonics services have been offered since the 1960

In Russia, since 2005





Acknowledgments:

Thanks for your attention!



BBMRI-ERIC Biobanking and BioMolecular resources Research Infrastructure