

4th Annual Brain Metastases Research and Emerging Therapy Conference

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Public-Private Relationships in Biobanking: Bottlenecks and Roadblocks and Potential Tools for Improvement



Paul Hofman
hofman@unice.fr

PACA Biobank & Nice Hospital-Related Biobank
University of Nice Sophia Antipolis, France





Agenda

- Biobanking: Current context in oncology
- Main bottlenecks during the public-private relationships in biobanking
- Possible explanations for existing bottlenecks
- Solutions to breaking the roadblocks
- Main criteria of an attractive biobank for public-private partnerships
- End-points



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MARCH 23, 2009

Annual Special Issue

TIME

10 IDEAS CHANGING THE WORLD RIGHT NOW

The global economy is being remade before our eyes. Here's what's on the horizon

- WHY **YOUR JOB** IS YOUR MOST VALUABLE ASSET
- REPURPOSING THE **SUBURBS**
- **SURVIVAL-STORE** SHOPPING
- **BIOBANKS**: SAVING YOUR PARTS
- NEED LAND? **RENT A COUNTRY**
- THE NEW **CALVINISM**
- **ECOLOGICAL** INTELLIGENCE
- AMORTALITY: **FOREVER YOUNG**
- **AFRICA**: OPEN FOR BUSINESS
- REINVENTING THE **HIGHWAY**

Biobanking Field:

A Major Issue of Today and Tomorrow

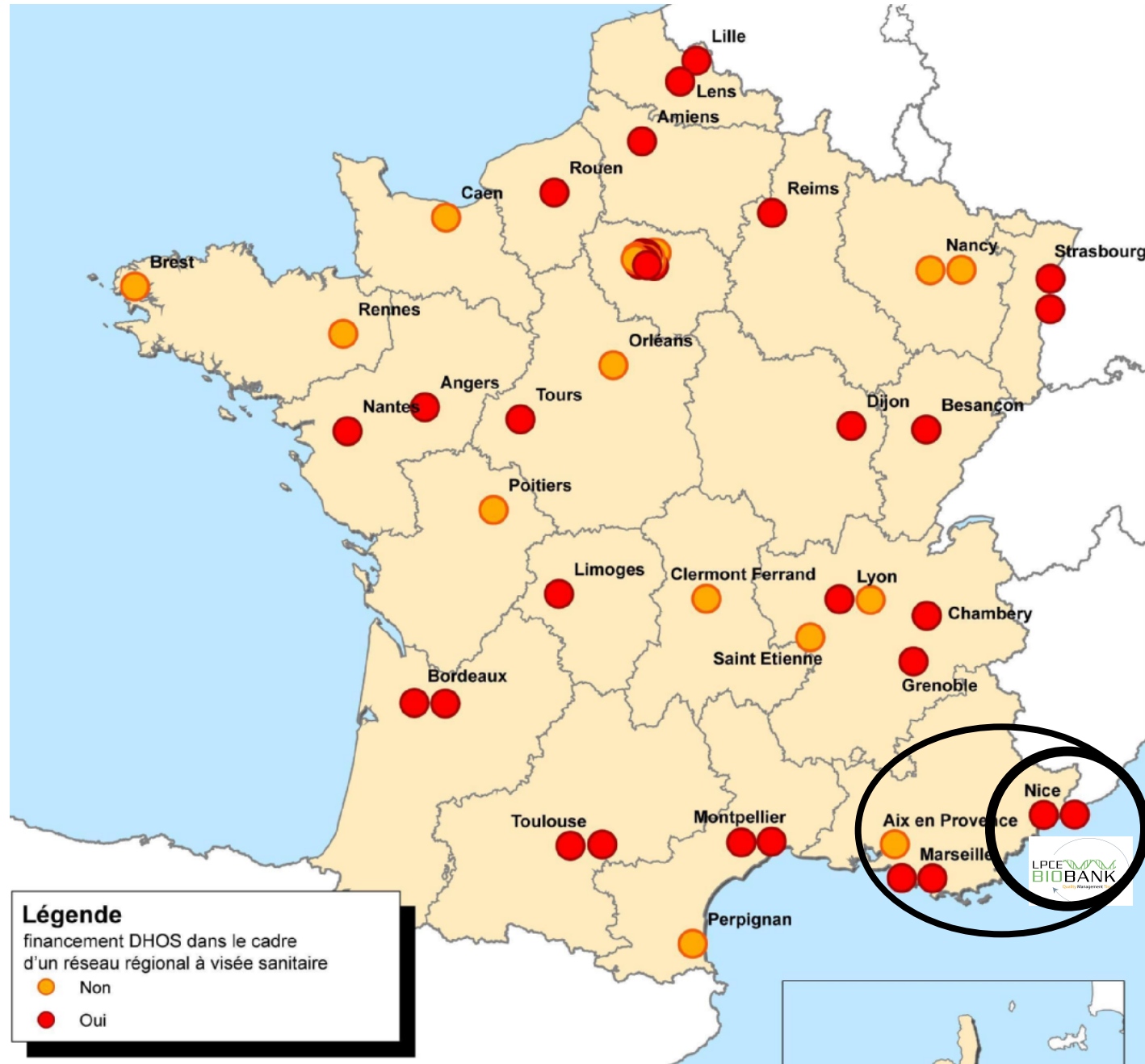
www.time.com

Current Context



The impact of using bioresources
in translational research projects

Tumour Biobanks in France



Légende

financement DHOS dans le cadre
d'un réseau régional à visée sanitaire

● Non

● Oui



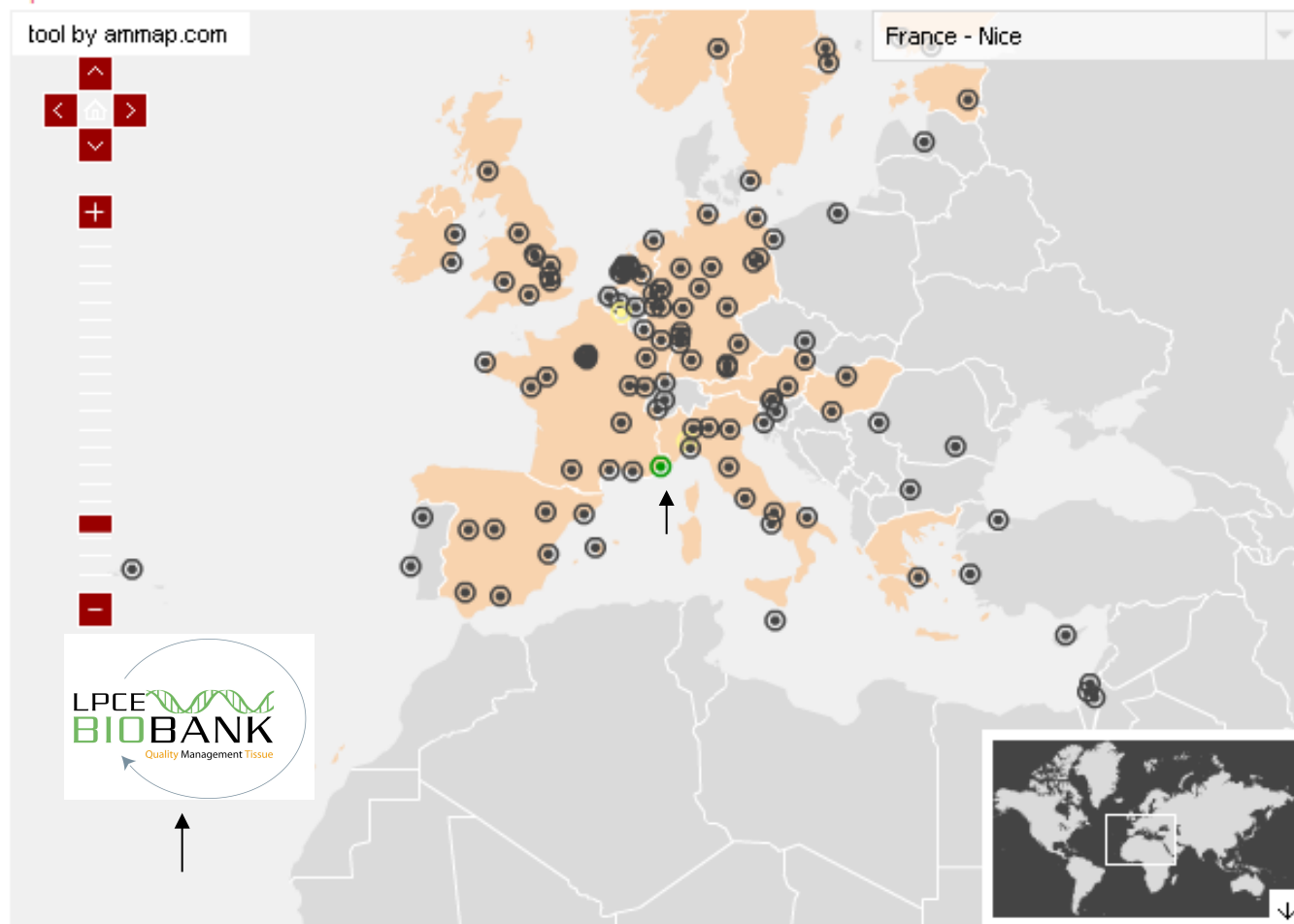
BBMRI
Biobanking and
Biomolecular
Resources Research
Infrastructure

Managing resources for the
future of biomedical research

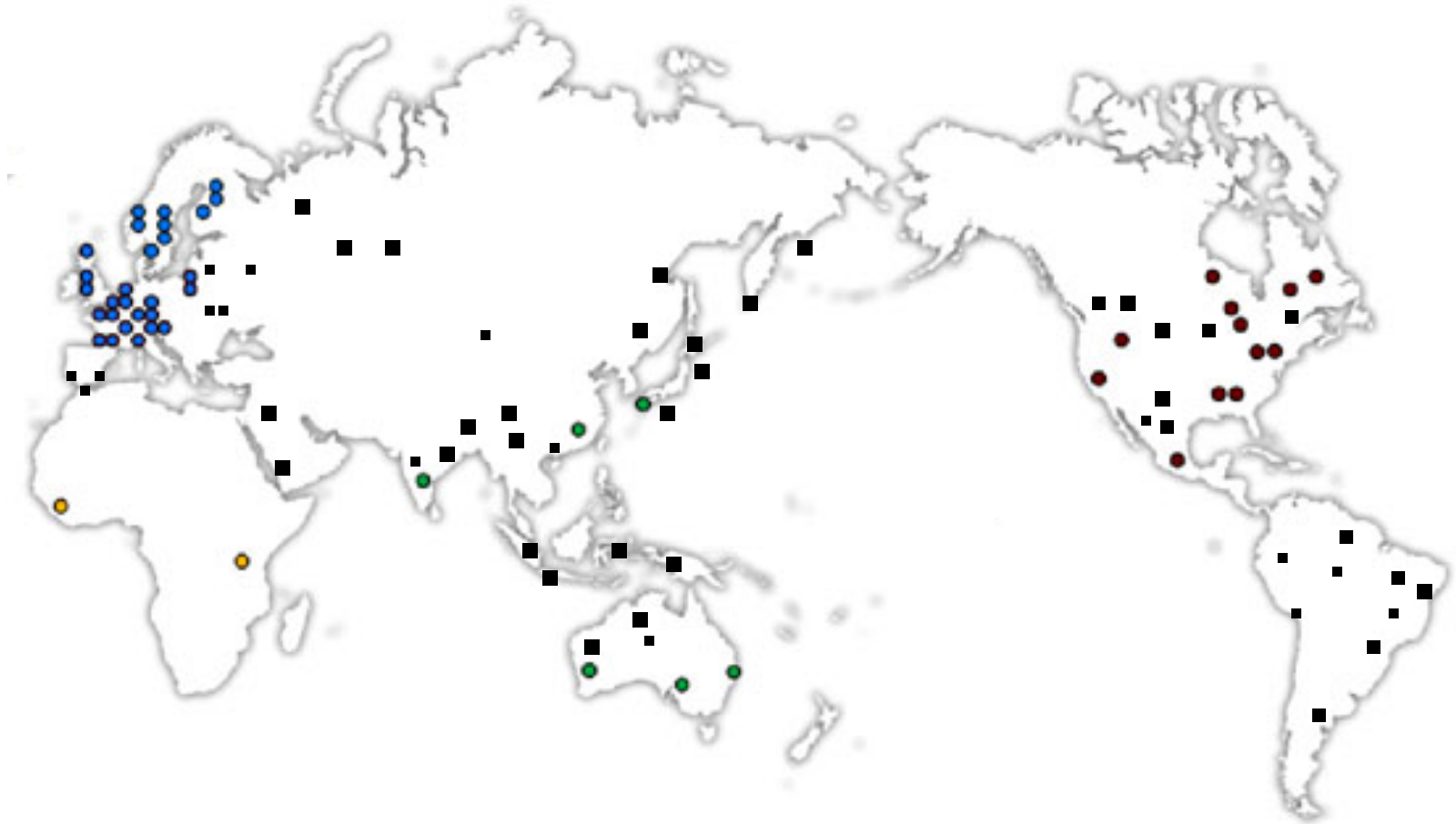
Partners & Membership

More than 380 Biobanks !

Open full Screen



More than 1800 Biobanks all Around the World !



International Societies of Biobanking



Biobanking in Oncology

Ex: The lung cancer field

Lung cancer is the most prevalent neoplasm in the World

Lung cancer is the major cause of tumor-related mortality

The cure rate of patients with lung cancer remains low (15% at 5 years)



Rapid emergence of potential targeted therapies

Onset of primary and secondary drug resistances



CLINICAL TRIALS

Experimental Treatment
May Be Right For You

*Contribution to the development of personalized medicine
by using human bioresources
(Biomarker validation, PDX development, etc.)*

What should we expect from preclinical research to help clinical drug development

Preclinical Research

Clinical Research

Functional tests

In vitro tests

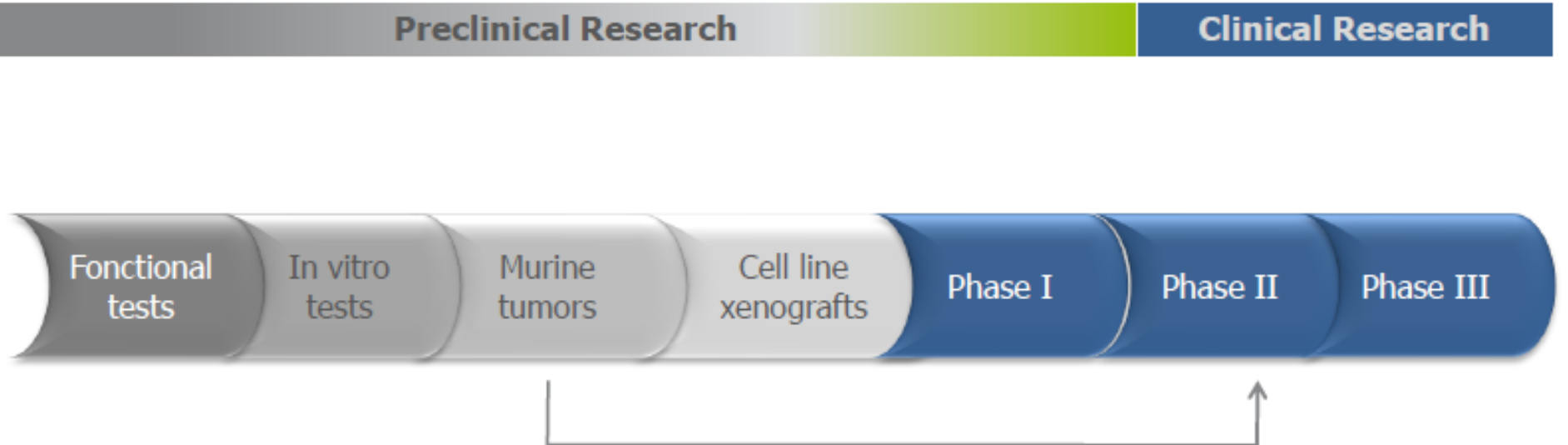
Murine tumors

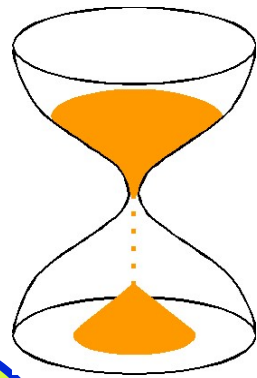
Cell line xenografts

Phase I

Phase II

Phase III

- 
- Predict safety
 - Predict clinical efficacy
 - Orient drugs to specific tumor indications
 - Guide drug-to-patient targeting



The right drug

The right patient

The right time

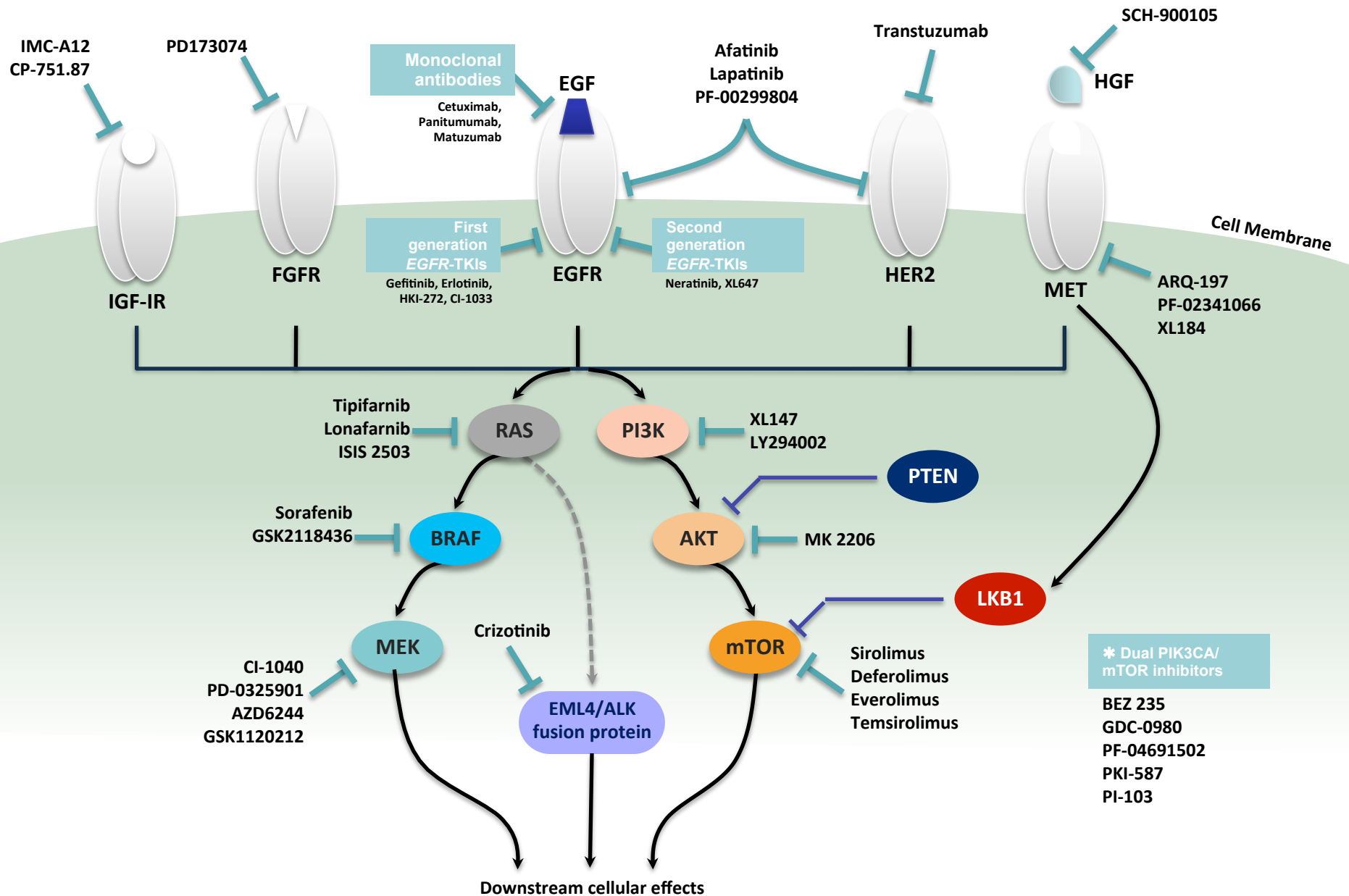
**Stratified Medicine
in Cancer Patients**

The right approach

The right cost

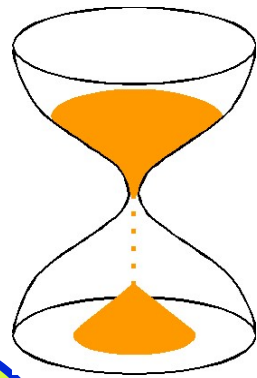


Target therapies in lung carcinoma



Nucleus

Ilie and Hofman, CMC 2012



The right drug

The right patient

The right time

**Stratified Medicine
in Cancer Patients**

The right sample

The right approach

The right cost

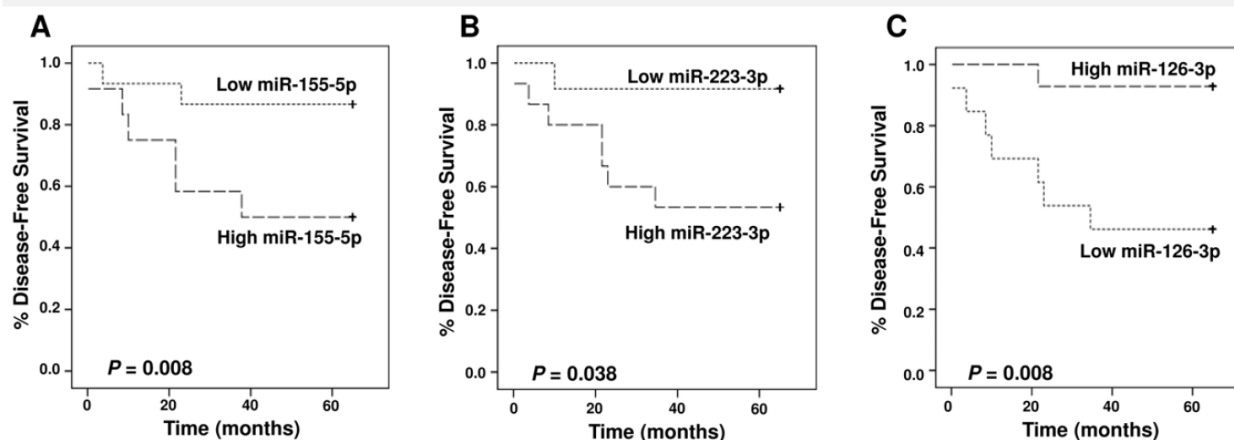


Two Panels of Plasma MicroRNAs as Non-Invasive Biomarkers for Prediction of Recurrence in Resectable NSCLC

Céline Sanfiorenzo^{1,2,3,9}, Marius I. Ilie^{1,3,4,5,9}, Amine Belaid¹, Fabrice Barlési⁶, Jérôme Mouroux^{1,3,7}, Charles-Hugo Marquette^{1,2,3}, Patrick Brest^{1,3,¶}, Paul Hofman^{1,3,4,5,*¶}

1 Institute for Research on Cancer and Ageing in Nice IRCAN, INSERM U1081 – CNRS UMR 7284, Team 3, Nice, France, **2** University Hospital Center of Nice, Pasteur Hospital, Department of Pneumology, Nice, France, **3** University of Nice Sophia Antipolis, Faculty of Medicine, Team 3, Nice, France, **4** University Hospital Center of Nice, Pasteur Hospital, Laboratory of Clinical and Experimental Pathology, Nice, France, **5** University Hospital Center of Nice, Pasteur Hospital, Human Biobank, Nice, France, **6** Aix Marseille Université – Assistance Publique Hôpitaux de Marseille, Multidisciplinary Oncology and Therapeutic Innovations Department, Marseille, France, **7** University Hospital Center of Nice, Pasteur Hospital, Department of Thoracic Surgery, Nice, France

LUNG ADENOCARCINOMA

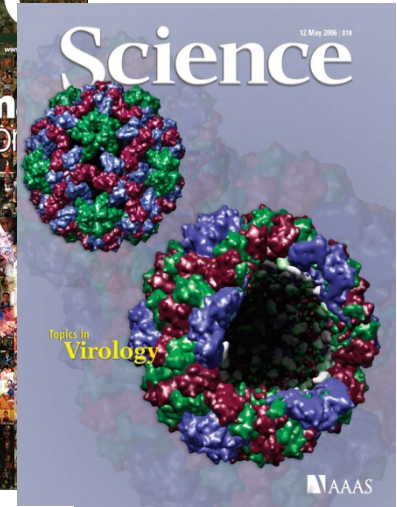


Why to set up a Biobank ?

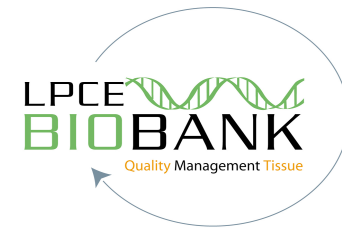
- To get public-public partnerships
- To get public-private partnerships
- To get good visibility for the University
- To get open option for financial support project
- To integrate « big » consortia and networks



High Number of Biobanks & Strong Competition



The Key for a Biobank Success Story



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- Heterogeneity of the contract forms, ethics and regulations according to the different partners
- Difficulties in the intellectual property perimeter assessment
- Cost evaluation of biological samples and associated data
- Long turnaround time for release of samples to the private partner



- Associated clinical data
- Knowledge of the hazard status (HIV, HpB, HpC)
- Availability to get a catalogue of samples
- Availability to different types and origins of specimen from the same cohort of patients

Legal & Ethical issues

Workflow from the partner request to the delivery of the bioresources



currently in:



WHO ?

Partners (public or private)

Head of the Biobank

Head of the Biobank,
Manager
Clients

Data Manager
Pathologist

Head of the Biobank
Physicians
Scientific committee
Bioethic committee

Clients,
Head of the Biobank,
Manager,
Legal institution
representative

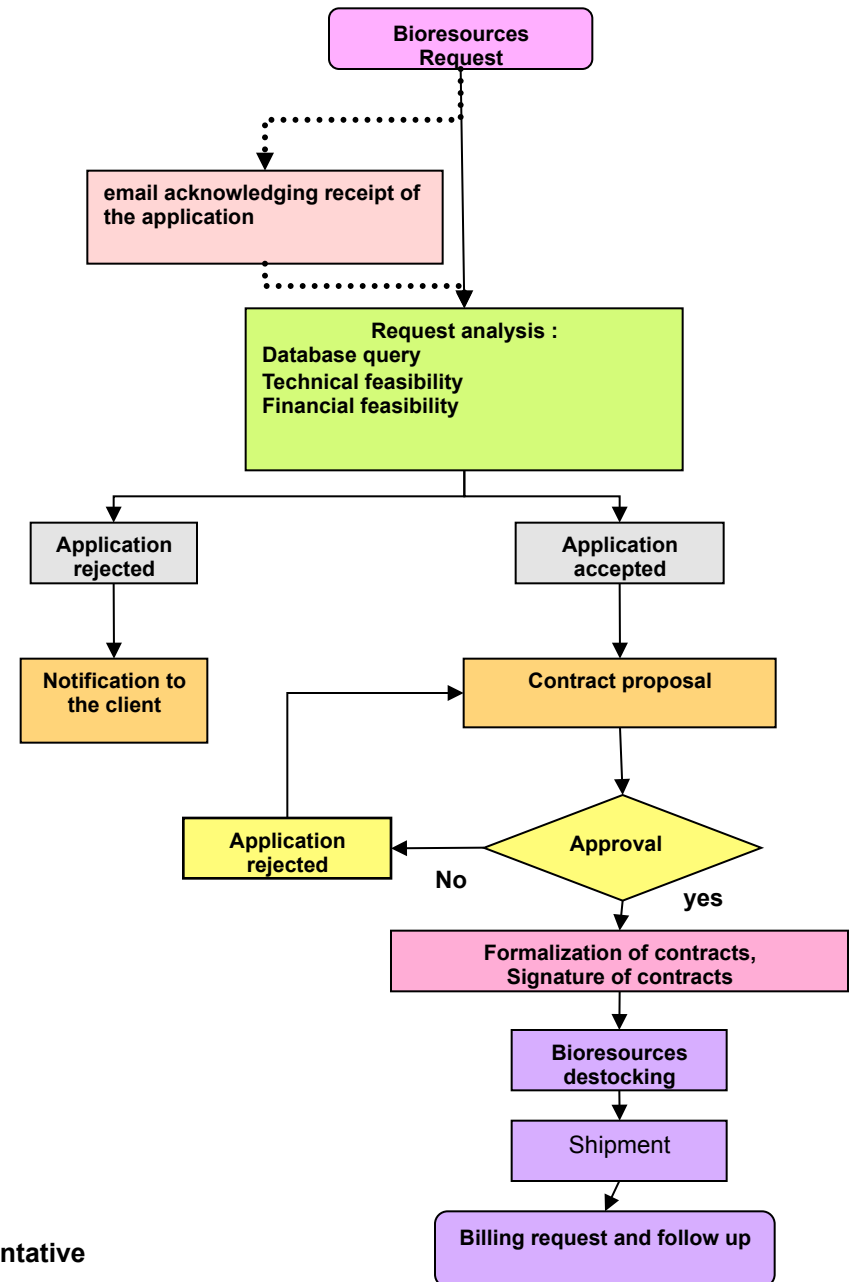
Clients,
Head of the Biobank
Pathologist

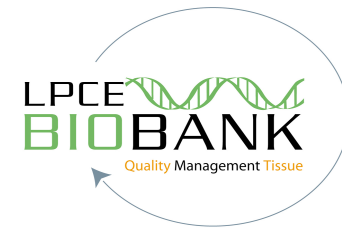
Head of the Biobank
Legal institution
representative

Biobank
technicians
and engineers

Head of the Biobank
Legal institution representative
Manager

WHAT ?



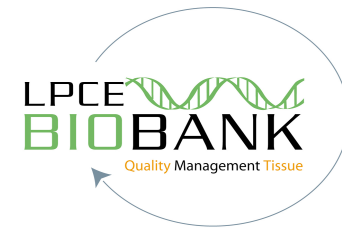


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Public World and Private World

- Differences in vision and policy
- Differences in business models
- Limited number of expertt biobank centers in a specific pathological field
- Heterogeneity in the professional practices of the different biobanks



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- *On the academic side*

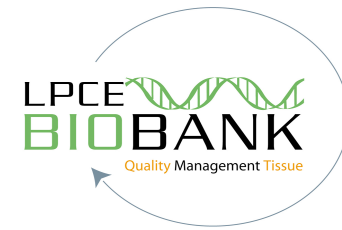
- Provide assurance/quality procedures according to international guidelines and recommendations (OECD, WHO)
- Offer a strong medico-scientific expertise in a specific pathological field (s)
- Establish strict governance for the project's management

- *On the private side*

- Involve the biobanker as an « active partner » instead of a « supplier-only »
- Define intellectual property rights related to the project

- *On both sides...*

- Design the objectives and outlines of the project
- Establish a contract according to international recommendations
- Define the real cost and contributions on both side



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- Indicators demonstrating the « good value » of biological samples and clinical associated data
- Certification and/or accreditation of the biobank, according to OECD recommendations
- Strict and transparent governance of the biobank
- In-house expertises and R&D capacity
- Willingness, tools and capacity to collaborate

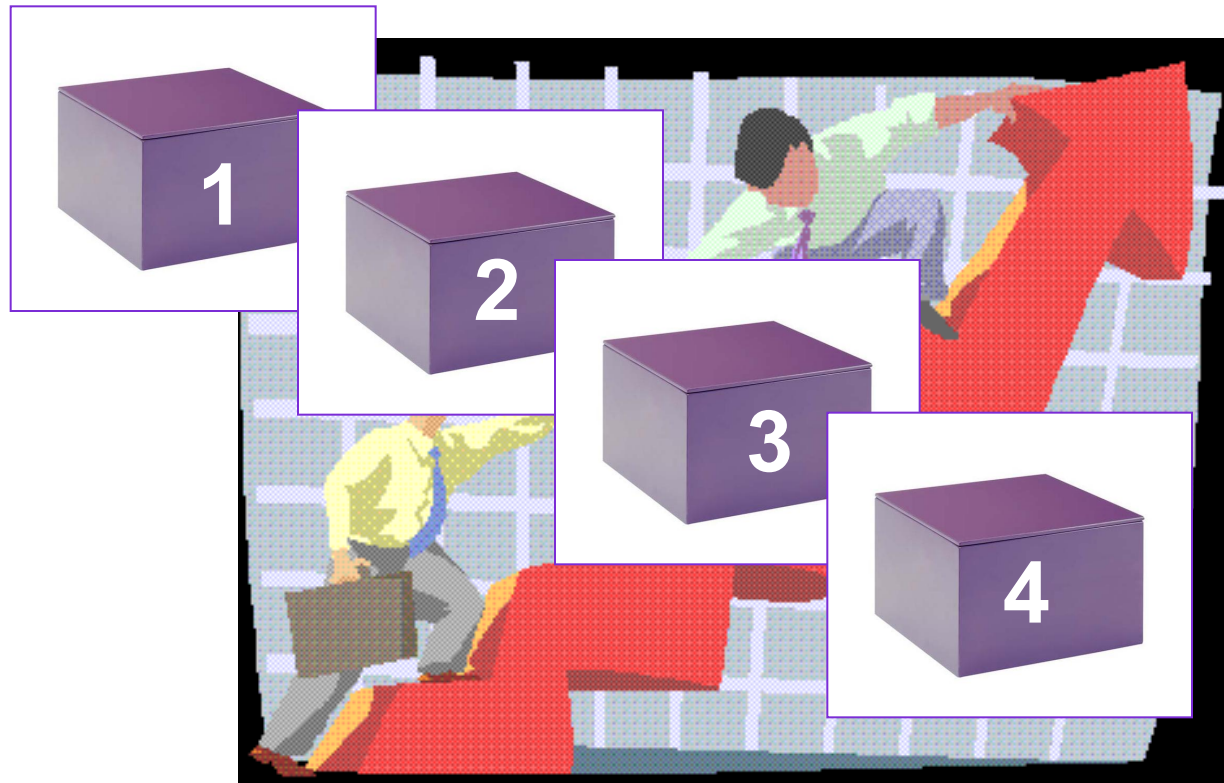


Establishment of pivotal indicators





Establishment of pivotal indicators

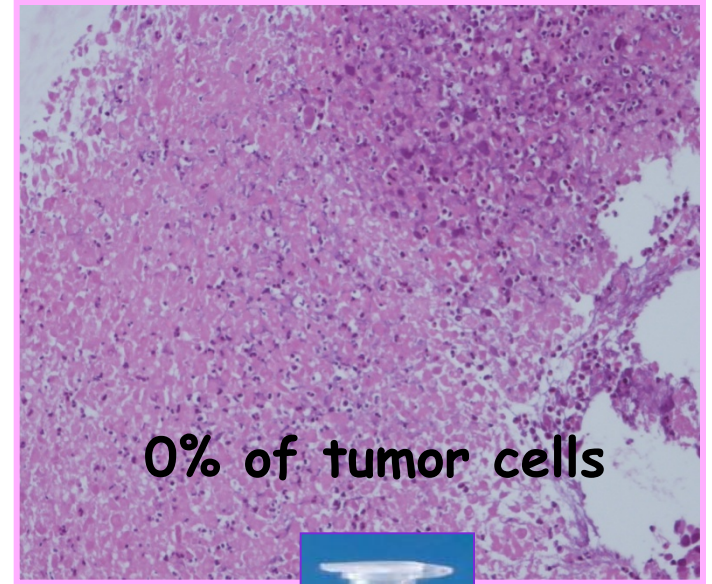
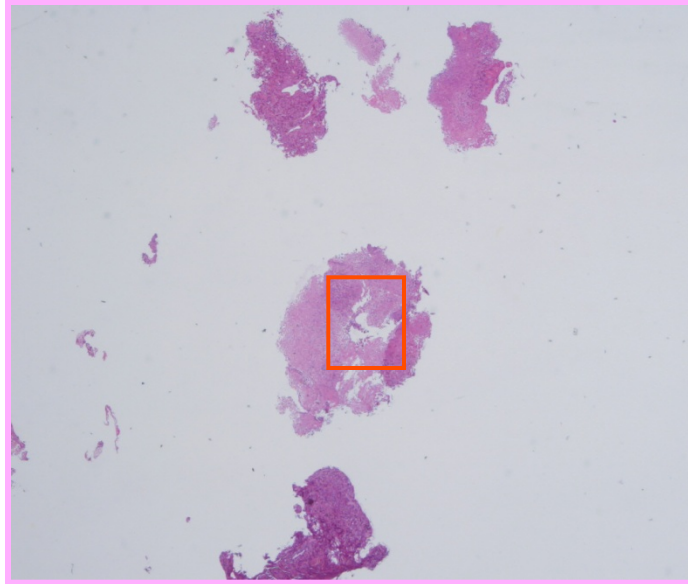
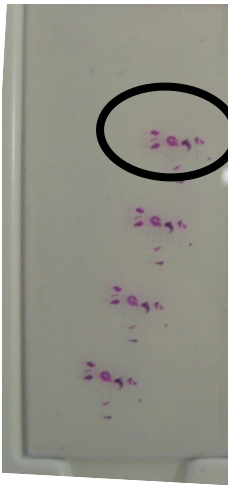


Box 1. Biobank Performance Indicators Related to Quality

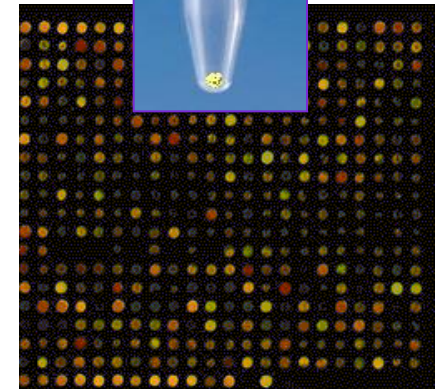


Indicator Category	Indicator Criteria
SAMPLE QUALITY (COEFFICIENT: 20)	DNA quality and control mode
	RNA quality and control mode
	Sample quantity and/or available nucleic acids (DNA & RNA)
	Control of morphology (cutting the mirror block, imprint cytology, frozen slides)
	Availability of biological fluids and tissue (from the same patient)
	Other collections (primary cell culture, paraffin blocks, TMAs)
	Availability of both control non-tumor tissue and tumor tissue
QUALITY OF ASSOCIATED CLINICAL DATA (COEFFICIENT: 20)	Epidemiological data (e.g., age, sex, place of birth)
	Specific data related to pathology <ul style="list-style-type: none"> Pathological data Genomic alteration data Clinical data Codification system
	Data on patient follow-up and collection of dynamic annotations
ETHICS (COEFFICIENT: 20)	Procedure for collecting informed consent from patients and security
	Ratio of consent/registered files
OTHER PARAMETERS IMPACTING ON QUALITY (COEFFICIENT: 5)	Serological status (HIV, HBV, HCV)
	Computer system and ability to request data
	Duplication of the collection

Large area of necrosis

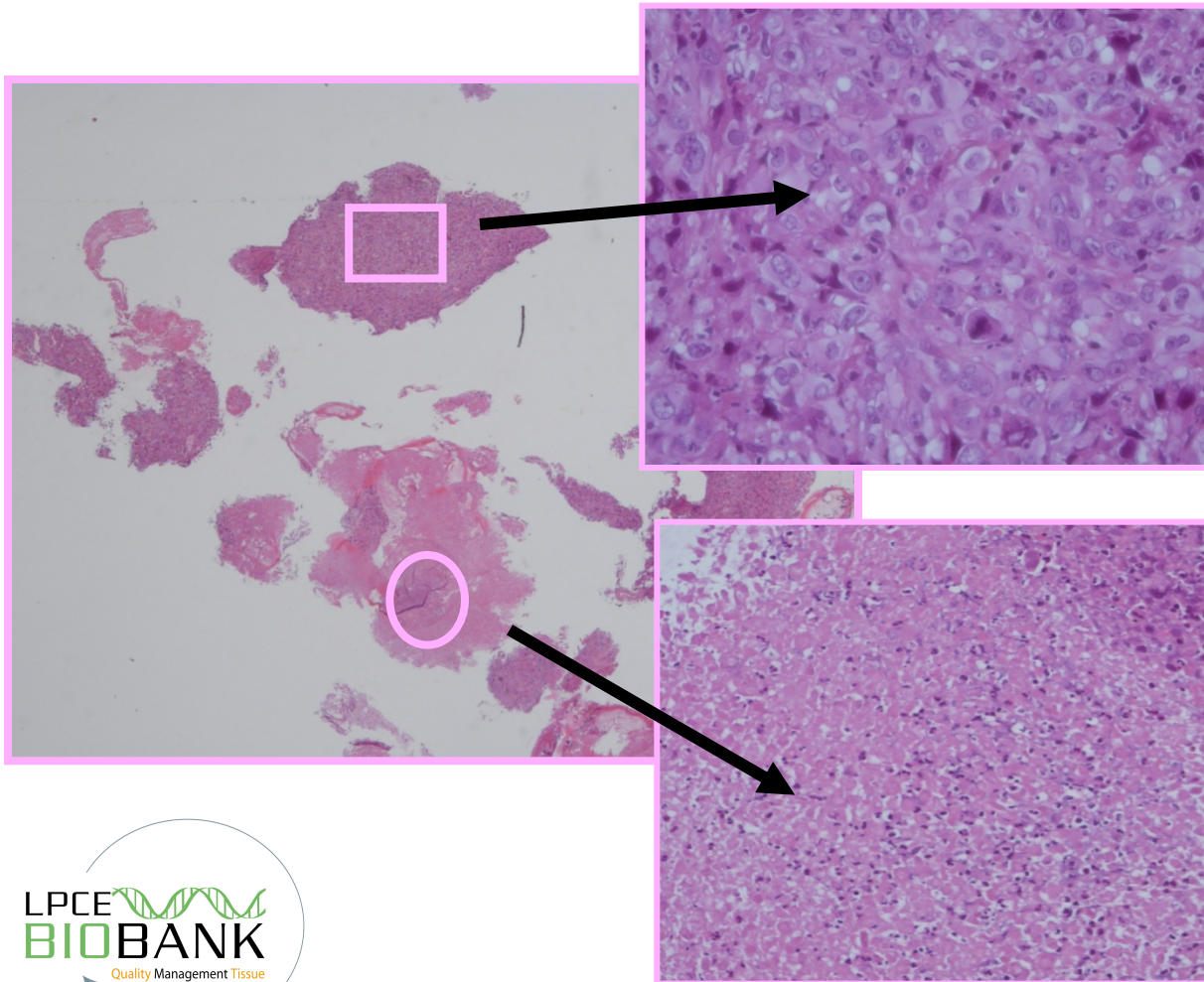


Lung specimen



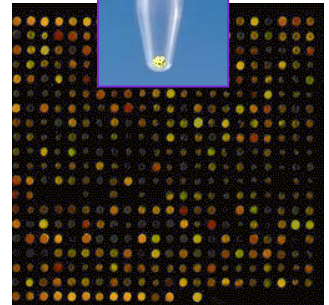
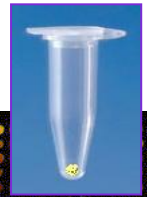
Variability of the percentage of tumor cells

According to the tumor
According to the tumor area



100%
of tumor cells

5 %
of tumor cells



Diversity of Bioresource Available

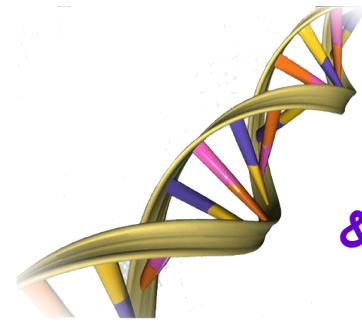
Frozen tissues



FFPE tissues & Tissue Micro Arrays



Plasma & Sera & CTCs



DNA & RNA & Primary Cultures

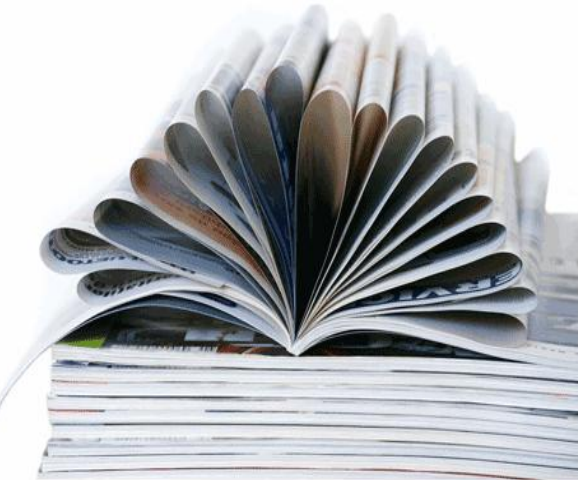


Box 2. Biobank Performance Indicators Related to Activity

Indicator Category	Indicator Criteria
STORAGE, SUPPLY (COEFFICIENT: 10)	For each collection For each biological product
DESTOCKING ACTIVITY (COEFFICIENT: 15)	For each collection For each biological product
EXISTENCE OF A DYNAMIC STRATEGY (COEFFICIENT: 5)	Based on the ratio «storage/destocking» Based on the submitted projects
HUMAN RESOURCE MANAGEMENT (COEFFICIENT: 5)	Adaptation to the work load
TIME RELATED TO THE PROVISION OF SAMPLES (COEFFICIENT: 5)	Based on the requested sample quantity Based on the nature of the requested biological resource
BIOLOGICAL RESOURCE COST RECOVERY AND BUSINESS PLAN (COEFFICIENT: 10)	Pricing policies
DYNAMIC MONITORING (COEFFICIENT: 10)	Monitoring procedures (non-compliances and effectiveness of the corrective actions) Material transfer agreement and contracts Consistency of statistical tests of data in data base

Box 3. Indicators Related to Scientific Productivity

Indicator Category	Indicator Criteria
SCIENTIFIC PUBLICATIONS (COEFFICIENT: 10)	Biobank member as co-author
	Biobank member cited in the Acknowledgements section
	Biobank cited in Materials and Methods section
	Biobank cited in Acknowledgements section
IMPACT FACTORS (COEFFICIENT: 25)	Cumulative impact factors per year and per collection
	Cumulative impact factors per year for the biobank
	SIGAPS points per year and per collection
FINALIZED RESEARCH (COEFFICIENT: 10)	Patents Achieved through collaboration with the biobank Achieved through biobank research work
	Organization of national or international conferences or symposia
	Books and other activities in the field of biobanking
COMMUNICATIONS (COEFFICIENT: 5)	Targeting the «Biobanking» thematic area (national or international)
	Associating the biobank (national or international)
GRANTS (COEFFICIENT: 10)	Budget obtained by the biobank (direct financing)
	Budget obtained for the biobank (partnership)

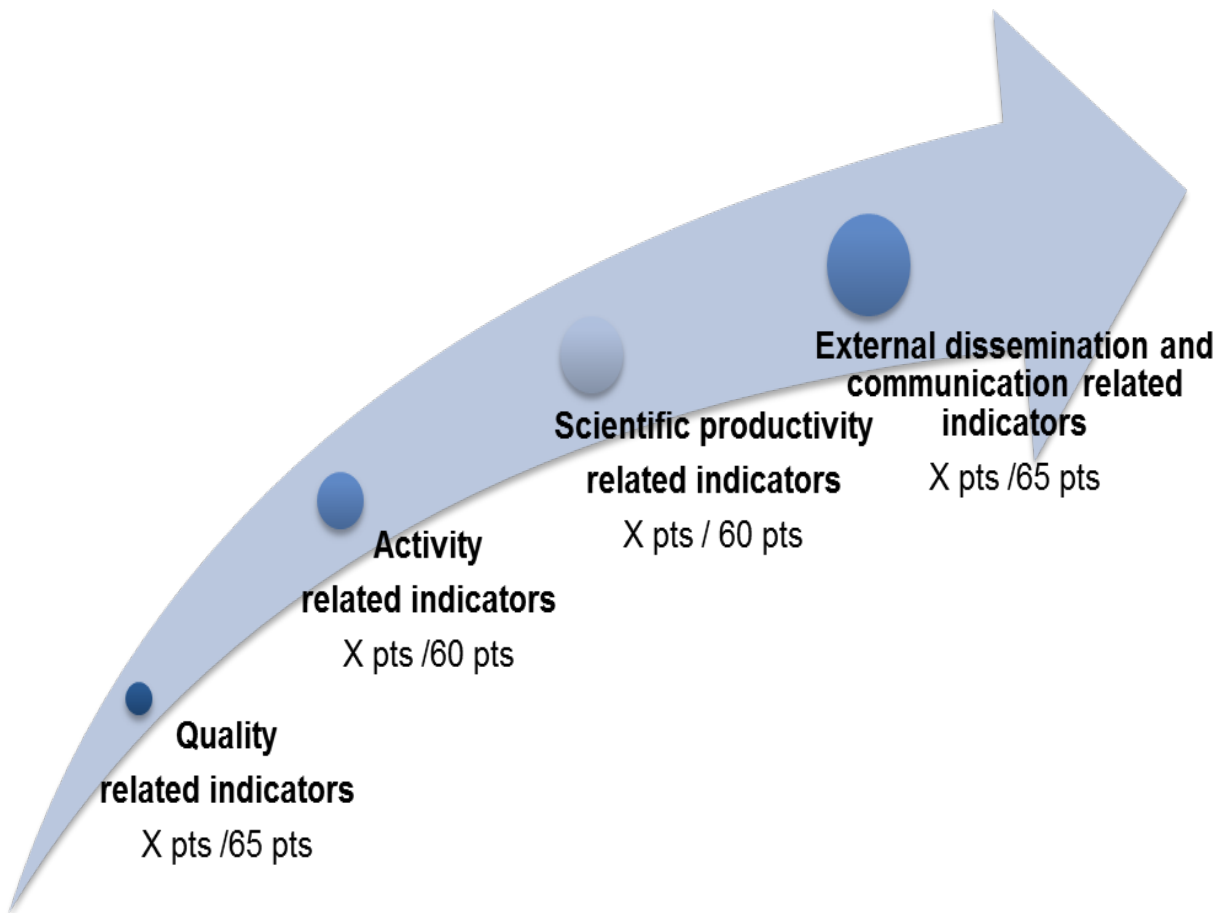


Box 4. Indicators of External Dissemination and Communication



Indicator Category	Options
CERTIFICATION, ACCREDITATION AND LABELS (COEFFICIENT: 20)	ISO 9001/2000
	NF S96-900
	ISO 15189
	ISO 17025
	IBiSA label
NETWORKING AND COLLABORATION (COEFFICIENT: 10)	National
	International
MEMBERSHIP IN BIOBANKING SOCIETIES (COEFFICIENT: 5)	National
	International
EDUCATIONAL PROGRAMS AND DISSEMINATION OF INFORMATION (COEFFICIENT: 5)	
COMPETENCE OF THE HITB TEAM (COEFFICIENT: 5)	
INTEGRATED OR ASSOCIATED TECHNOLOGY PLATFORMS (COEFFICIENT: 5)	
MARKETING ACTIVITY AND PATIENT INVOLVEMENT (COEFFICIENT: 5)	
PARTNERSHIPS WITH INDUSTRY (COEFFICIENT:10)	In the framework of a collaborative research project





TOTAL= X PTS /250 PTS

➤ **200-250= Excellent (A+)**

➤ **150-200= Very good (A)**

➤ **120-150= Good (B)**

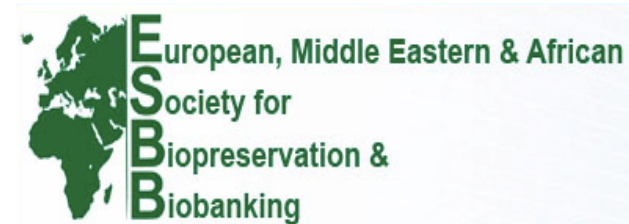
➤ **100-120= Moderate (C)**

➤ **<100= Weak (D)**

Major contributors and collaborators for establishment of indicators



CHU de Nice



Nice University Biobank

Véronique Hofman
Elodie Long
Marius Ilie
Kevin Washetine

BRIF members

Laurence Mabille
Anne Cambon
Barbara Parodi

Infrastructure Biobank

Georges Dagher
Bruno Clément
Pascal Bouchet

ESBB

Robert Hewitt
Christian Chabannon

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DOI: 10.1089/bio.2013.0015

Measuring the Contribution of Tumor Biobanks to Research in Oncology: Surrogate Indicators and Bibliographic Output

Véronique Hofman,^{1,2} Marius Ilie,^{1,2} Elodie Long,^{1,2} Kevin Washetine,^{1,2} Christian Chabannon,^{3,4}
Dominique Figarella-Branger,^{4,5} Bruno Clément,^{6,7} Laurence Mabille,^{8,#} Anne Cambon-Thomsen,^{8,#}
Pascal Boucher,^{9,#} Georges Dagher,^{6,#} Robert Hewitt,^{10,#} Barbara Parodi,^{11,#} and Paul Hofman,^{1,2,4,6,#}

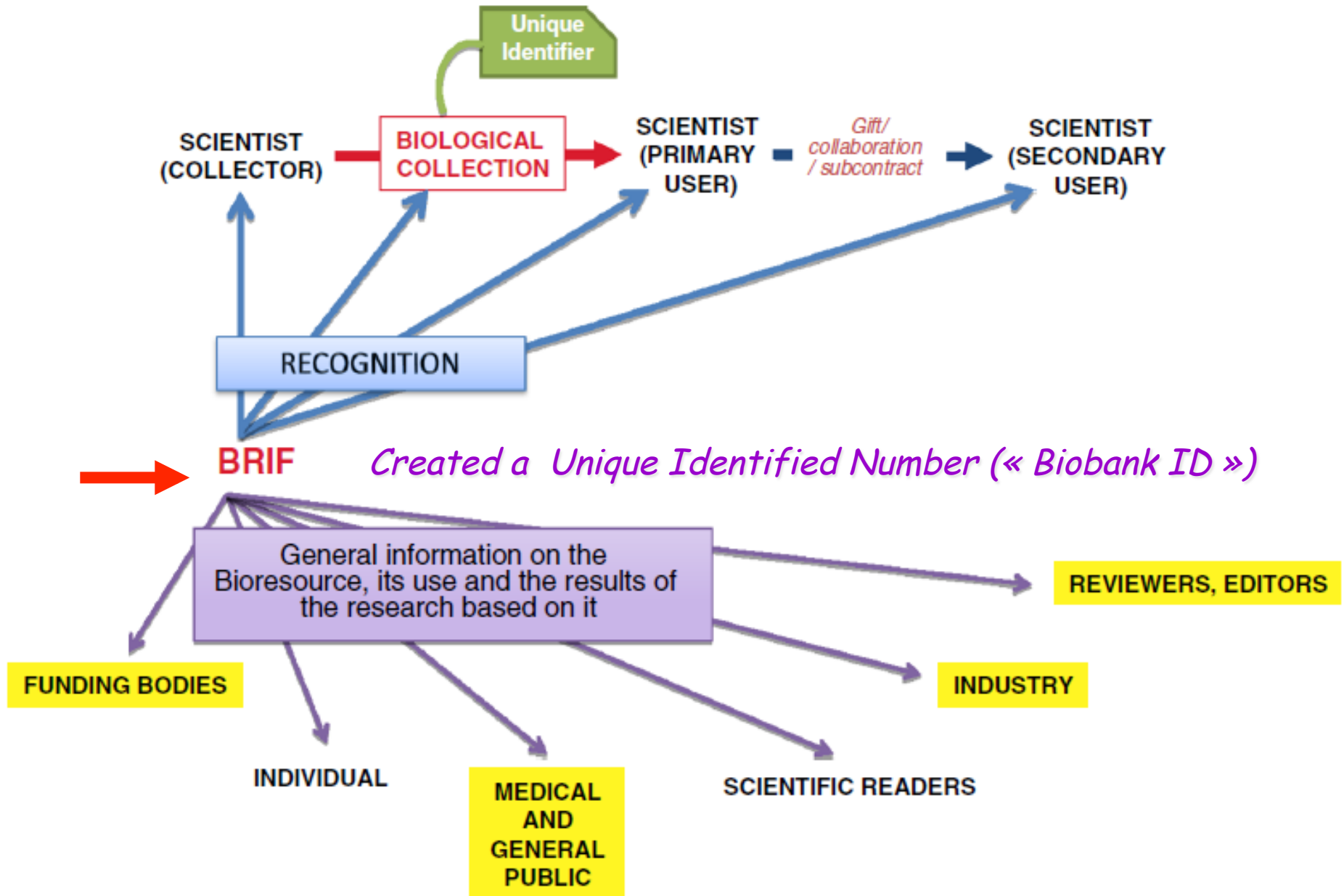
The role of a bioresource research impact factor as an incentive to share human bioresources

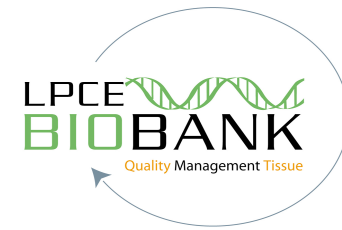
Cambon-Thomsen A, Thorisson GA,, Andrieu S, Bertier G, Hofman P
Boeckhout M, Hewitt R, Kauffmann F, Mabile L



« *Increasing the Quality of Bioresource for Research Activity* »

Actors involved in the « Complex World » of Bioresources





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End-Points →



- The public sector should support biobanking infrastructures by sharing with industry, the costs, risks and knowledge
- Better dissemination of information to the general public should promote the benefit of collaborating with private partners on a fair and transparent basis



Biobank working as a Biorepository
(accommodation/simple provider)



and/or

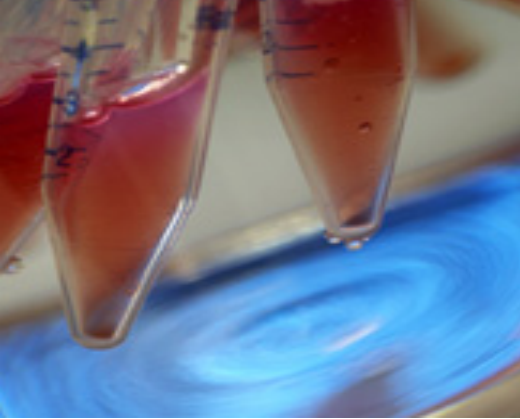
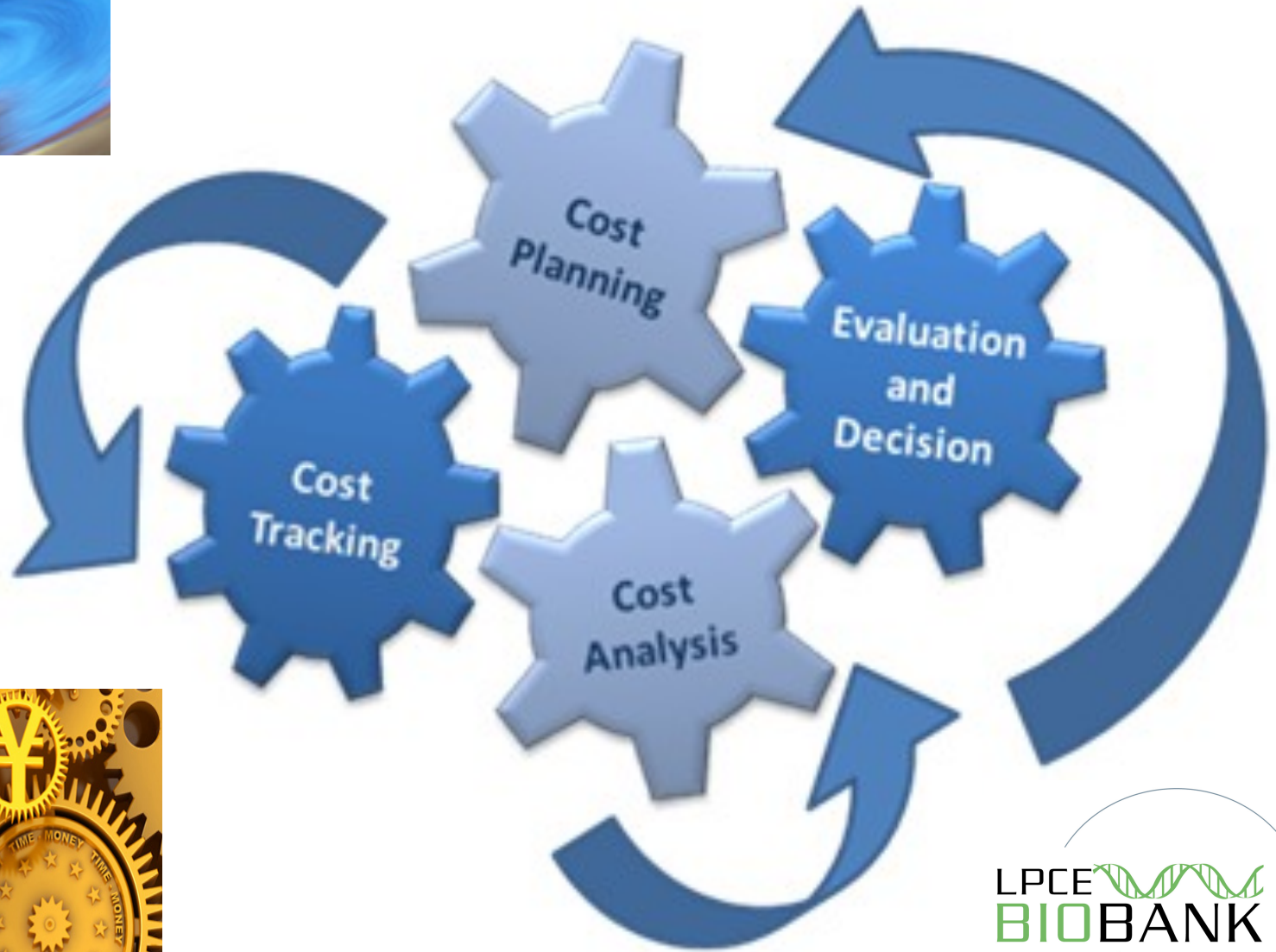
Biobank working as an Expert Center
(scientific collaborations/research)

Optimizing the functioning between biobanks and diagnostic companies and big pharma

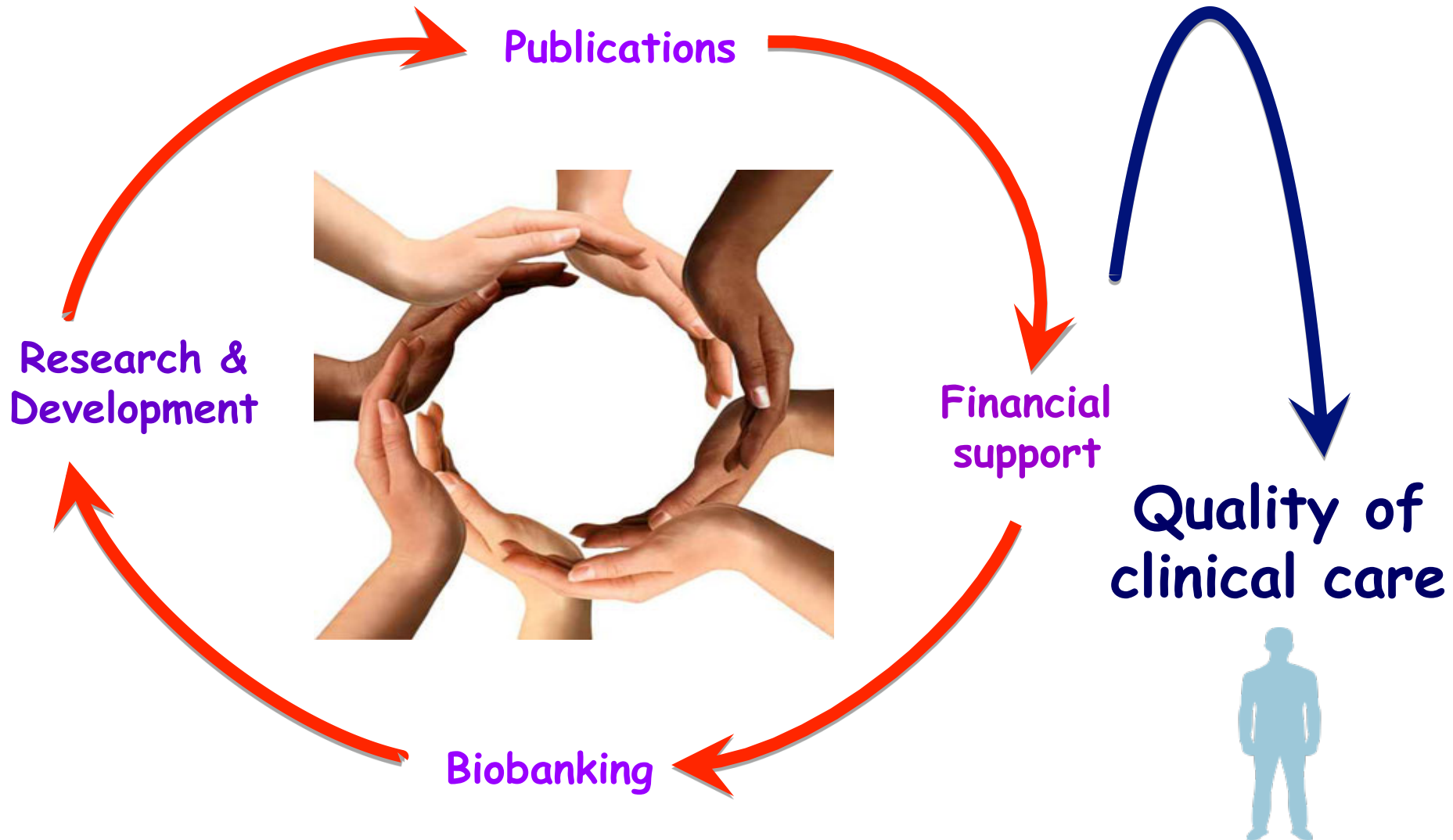
A close-up photograph of four hands, two from the left and two from the right, shaking in a circular gesture. The hands are of different skin tones, suggesting a diverse group of people. The background is a soft, out-of-focus mix of purple and blue light. The overall image conveys a sense of collaboration and partnership.

For a better collaboration with researchers,
oncologists & biopathologists

Setting up a business plan is
a key issue for an academic biobank



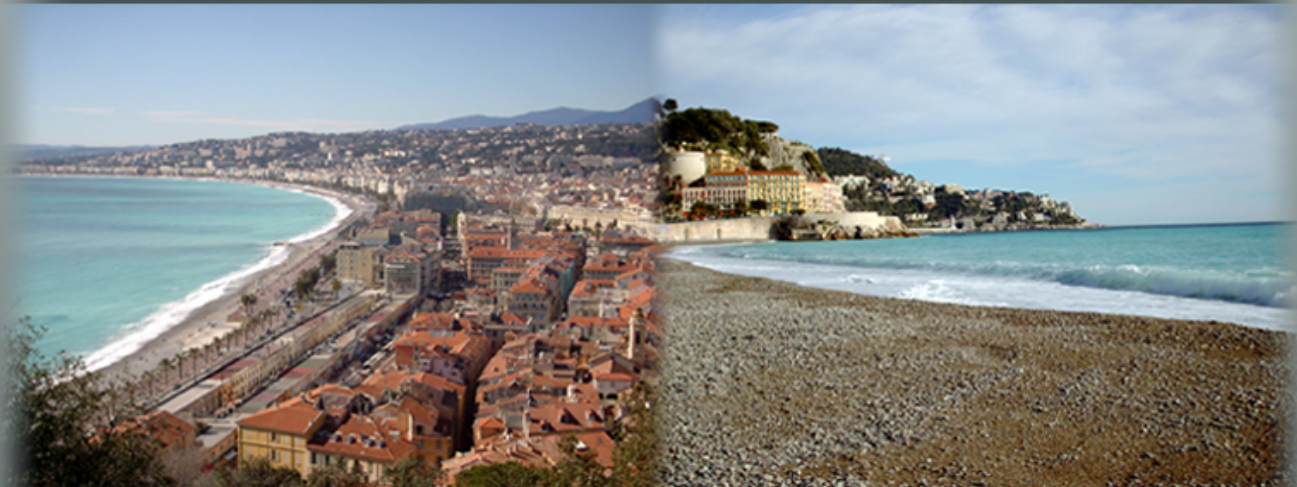
Creating a virtuous circle







BIOBANK | LPCE
Quality Management Tissue



► **Selectionnez la langue - Select your country**



Réalisé par le CHU de Nice

<https://www.biobank06.com>



LPCE
BIOBANK
Quality Management Tissue



CHU de Nice



hofman.p@chu-nice.fr
www.biobank06.com

Inserm

Institut national
de la santé et de la recherche médicale