Junta de Andalucía
Consejería de Salud y Consumo
Escuela Andaluza de Salud Pública

LOS BIOBANCOS: PILARES BÁSICOS EN LA MEDICINA TRASLACIONAL

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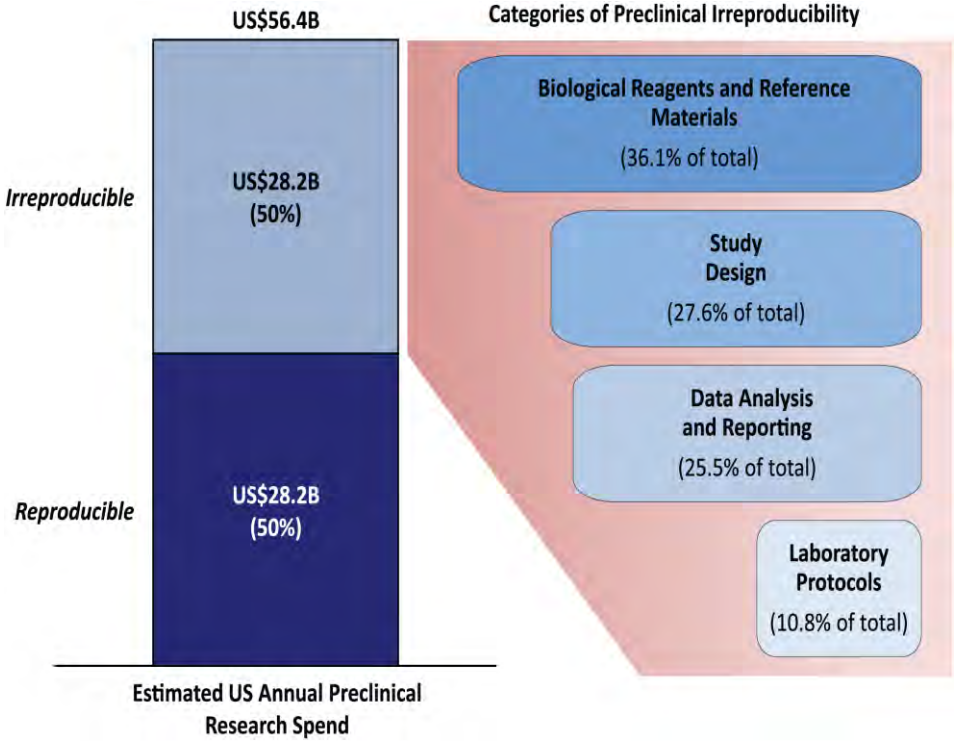
DIRECTORA CIENTÍFICA DEL BIOBANCO
CNIO

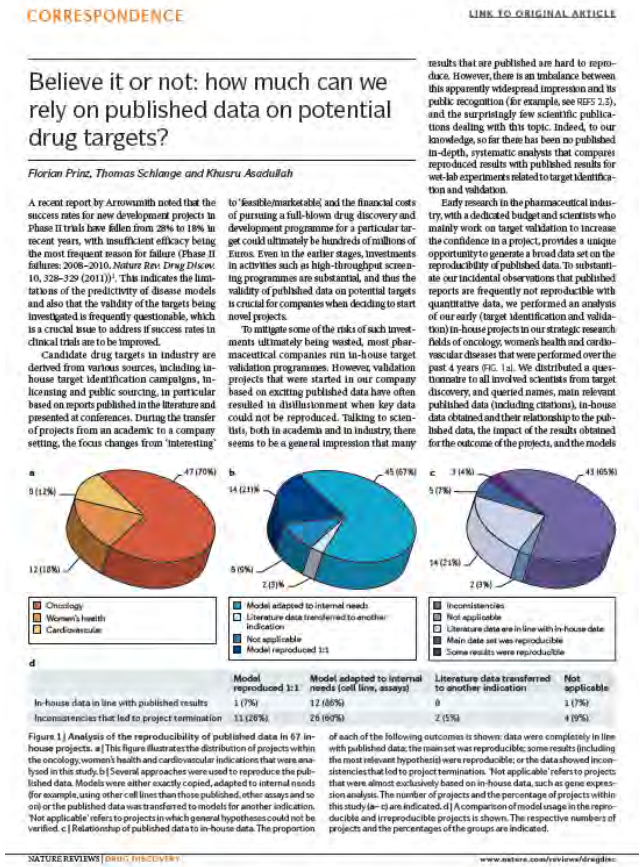
Estrategia de Bioética del Sistema Sanitario Público de Andalucía

En la búsqueda de biomarcadores....

The Economics of Reproducibility in Preclinical Research



Leonard P. Freedman et al.
PLOS Biology | DOI:10.1371/journal.pbio.1002165 June 9, 2015



CORRESPONDENCE LINK TO ORIGINAL ARTICLE

Believe it or not: how much can we rely on published data on potential drug targets?

Florian Prinz, Thomas Schlange and Khusru Asadullah

A recent report by Arrowsmith noted that the success rates for new development projects in Phase II trials have fallen from 28% to 18% in recent years, with insufficient efficacy being the most frequent reason for failure (Phase II failures: 2008–2010. *Nature Rev. Drug Discov.* 10, 328–329 (2011))[1]. This indicates the limitations of the predictivity of disease models and also that the validity of the targets being investigated is frequently questionable, which is a crucial issue to address if success rates in clinical trials are to be improved.

Candidate drug targets in industry are derived from various sources, including in-house target identification campaigns, in-licensing and public sourcing, in particular based on reports published in the literature and presented at conferences. During the transfer of projects from an academic to a company setting, the focus changes from 'interesting' to 'feasible/marketable' and the financial costs of pursuing a full-blown drug discovery and development programme for a particular target could ultimately be hundreds of millions of Euros. Even in the earlier stages, investments in activities such as high-throughput screening programmes are substantial, and thus the validity of published data on potential targets is crucial for companies when deciding to start novel projects.

To mitigate some of the risks of such investments ultimately being wasted, most pharmaceutical companies run in-house target validation programmes. However, validation projects that were started in our company based on exciting published data have often resulted in disillusionment when key data could not be reproduced. Talking to scientists, both in academia and in industry, there seems to be a general impression that many results that are published are hard to reproduce. However, there is an imbalance between this apparently widespread impression and its public recognition (for example, see REFS 2,3), and the surprisingly few scientific publications dealing with this topic. Indeed, to our knowledge, so far there has been no published in-depth, systematic analysis that compares reproduced results with published results for wet-lab experiments related to target identification and validation.

Early research in the pharmaceutical industry, with a dedicated budget and scientists who mainly work on target validation to increase the confidence in a project, provides a unique opportunity to generate a broad data set on the reproducibility of published data. To substantiate our incidental observations that published reports are frequently not reproducible with quantitative data, we performed an analysis of our early (target identification and validation) in-house projects in our strategic research fields of oncology, women's health and cardiovascular diseases that were performed over the past 4 years (FIG. 1a). We distributed a questionnaire to all involved scientists from target discovery, and queried names, main relevant published data (including citations), in-house data obtained and their relationship to the published data, the impact of the results obtained for the outcome of the projects, and the models

d

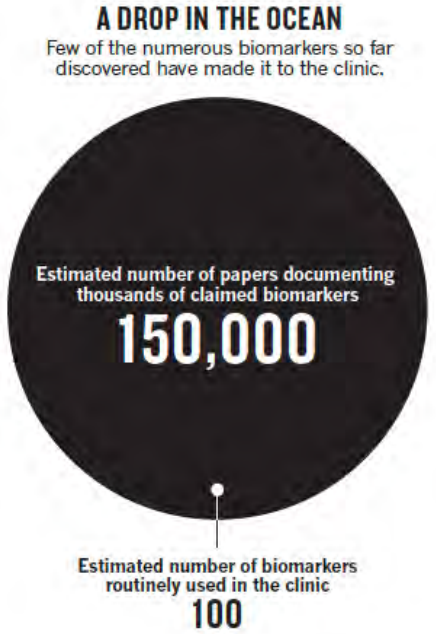
	Model reproduced 1:1	Model adapted to internal needs (cell line, assays)	Literature data transferred to another indication	Not applicable
In-house data in line with published results	1 (7%)	12 (86%)	0	1 (7%)
Inconsistencies that led to project termination	11 (26%)	26 (60%)	2 (5%)	4 (9%)

Figure 1 | Analysis of the reproducibility of published data in 67 in-house projects. a | This figure illustrates the distribution of projects within the oncology, women's health and cardiovascular indications that were analysed in this study. b | Several approaches were used to reproduce the published data. Models were either exactly copied, adapted to internal needs (for example, using other cell lines than those published, other assays and so on) or the published data was transferred to models for another indication. 'Not applicable' refers to projects in which general hypotheses could not be verified. c | Relationship of published data to in-house data. The proportion of each of the following outcomes is shown: data were completely in line with published data; the main set was reproducible; some results (including the most relevant hypothesis) were reproducible; or the data showed inconsistencies that led to project termination. 'Not applicable' refers to projects that were almost exclusively based on in-house data, such as gene expression analysis. The number of projects and the percentage of projects within this study (a–c) are indicated. d | A comparison of model usage in the reproducible and irreproducible projects is shown. The respective numbers of projects and the percentages of the groups are indicated.

13 JANUARY 2011 | VOL 469 | NATURE | 157

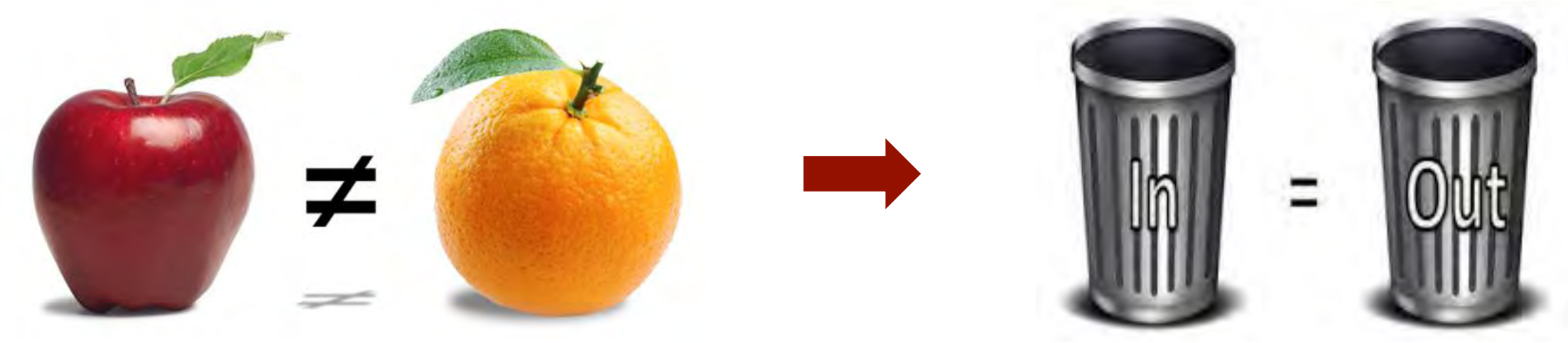
Bring on the biomarkers

George Poste



Bring on the Biomarkers. George *Poste*. Nature. 2011

*"**La** falta de normalización en la recogida y almacenamiento de muestras puede afectar la investigación **ulterior**"*



TIME 2009

10 Ideas Changing the World Right Now

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

Like 198 Tweet Share

Full List

What's Next 2009

- Jobs Are The New Assets
- Recycling the Suburbs
- The New Calvinism
- Reinstating the Interstate
- Amortality
- Africa, Business Destination
- The Rent-A-Country
- ~~Biobanks~~
- Survival Stores
- Ecological Intelligence

Los pilares de un biobanco

Calidad de muestras

Fuente de errores (≈75%) en pruebas de laboratorio

Analíticas

- Metodología
- Calibración
- Precisión
- Manipulación de la muestra
- Monitorización de equipamiento y reactivos
- Substancias interferentes

Preanalíticas

Postanalíticas

- Recogida de datos y cálculos
- Validación de resultados
- Interpretación de resultados
- Transferencia de datos
- Informe

VARIABLES

Temas Éticos, Legales y Sociales

- Section 44.2 de la Constitución (promueve la ciencia como un bien social)

- Ley de Investigación Biomédica 14/2007, of Julio 3,

- Real Decreto de Biobancos 1716/2011, del 18 de noviembre.

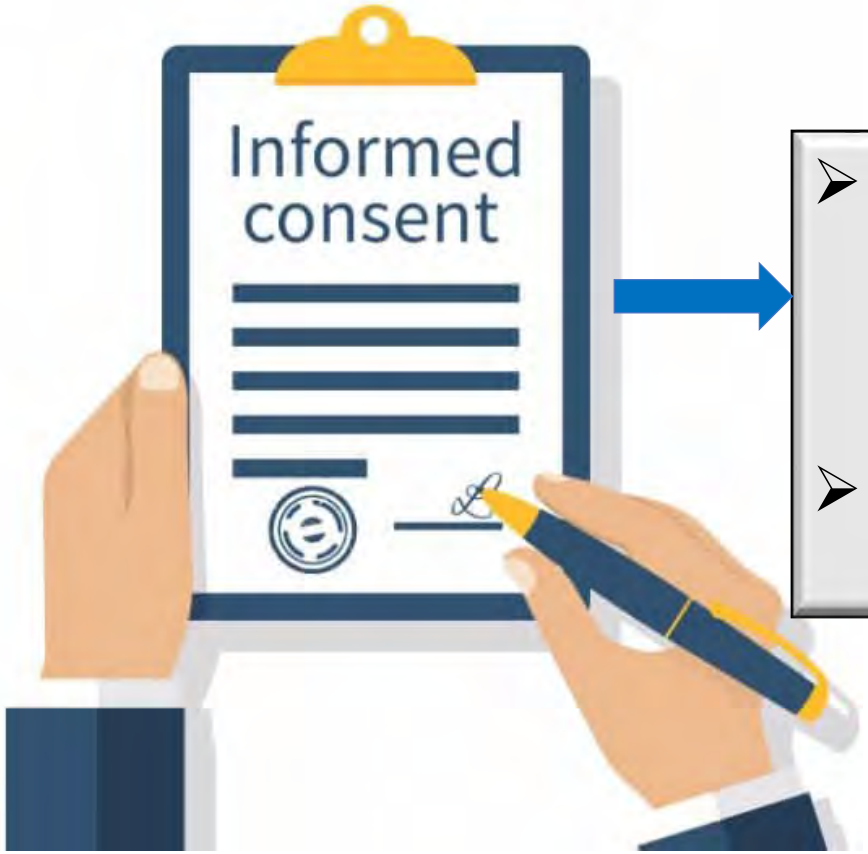
- Regulación (EU) 2016/679 – Ley Orgánica 3/2018, 5 Diciembre, procesamiento de información personal…..

Philippe de Champaigne - Moses with the Ten Commandments

Casuísta de uso de material humano

	Proyecto	Colección	Biobanco
RNB	✗	✓	✓
Evaluación Ética	CEI	CEI	CEI y comités de biobanco
Autorización Administrativa	✗	✗	✓
Alcance del CI	Solo proyecto	Línea de investigación	Cualquier investigación con posibles restricciones
Restricción en el tiempo	Sí	No	No
Uso por terceras partes	No	No	Sí

Consentimiento Informado- Clave de la donación



- Hoja de información al paciente
- Consentimiento /Acuerdo

Sistemas de Gestión de Información (LIMS)

Gestión- IT

Estrategias

Reto: sistematizar y normalizar la incorporación de la información clínica y del seguimiento de los donatnes.

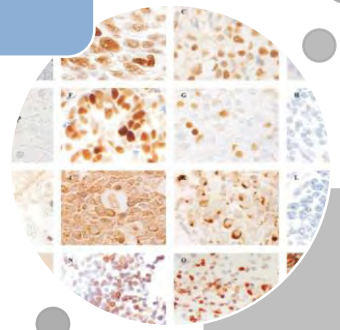
Un poco de historia...

PLATAFORMA ISCIII
BIOBANCOS Y BIOMODELOS

2021-2023

2010-2020

Red Nacional de Biobancos



2000-2010

Red de Banco de Tumores

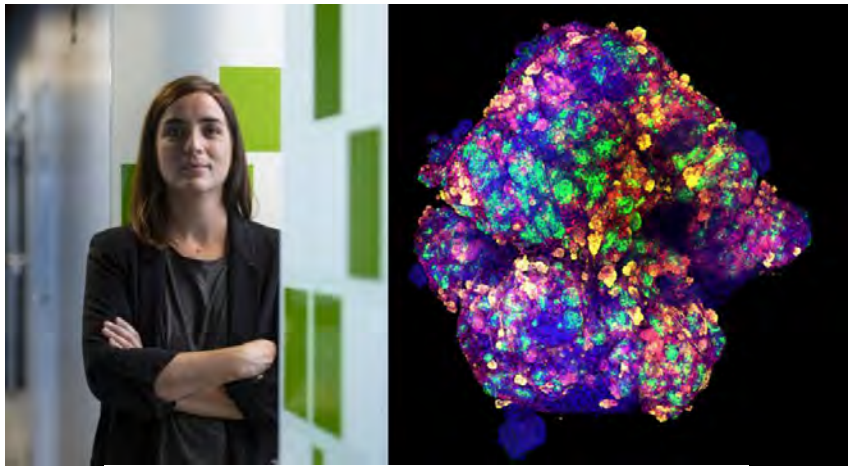
2000

Departamento Patología

Banco de Tumores

cnio
Centro Nacional de Investigaciones Oncológicas

Plataforma ISCIII de Biobancos y Biomodelos



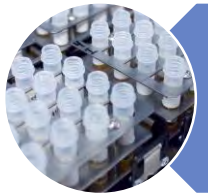
PLATAFORMA ISCIII
BIOBANCOS Y
BIOMODELOS

Visión de la PNBB-ISCIII

Image source: https://www.bordis.org

Datos actuales

57 biobancos



3459 colecciones

1.069.872 muestras

109000 donantes

JORNADA DE LOS COMITÉS DE ÉTICA DE LA INVESTIGACIÓN DEL SSPA - 2022

Junta de Andalucía
Consejería de Salud y Consumo
Escuela Andaluza de Salud Pública

Bancos de Tejidos Neurológicos

- Informe ONT
- Euro- HD

ELSI

- Consultorio ELSI
- Difusión y Divulgación
  - Días mundiales/ nacionales
  - Actividad biobancos

Calidad/Gestión/Acreditación

- Calidad de muestras
- Calidad de datos y codificación
- Acreditación, Certificación y Gestión
- Consultorio Calidad

Catálogo/Tarifas/Ventanilla única

- Catálogo Virtual- Back-office
- Tarifas- Análisis comparativo de costes
- Ventanilla única

Trabajo transversal con objetivos comunes

BOLETÍN OFICIAL DEL ESTADO

Núm. 135 Lunes 7 de junio de 2021 Sec. III. Pág. 69448

III. OTRAS DISPOSICIONES

MINISTERIO DE CIENCIA E INNOVACIÓN

9488 *Resolución de 31 de mayo de 2021, del Instituto de Salud Carlos III, O.A., M.P., por la que se publica el Convenio con el Ministerio de Ciencia e Innovación, para la participación de España en el Consorcio de Infraestructuras de Investigación Europeas, dedicado a la investigación en biobancos y recursos biomoleculares.*

18 miembros de pleno derecho
5 observadores
1 Organización- IARC

- ✓ ~ 700 biobancos
- ✓ + colaboradores afiliados
- ✓ 3 centros expertos
- ✓ 1 sede central

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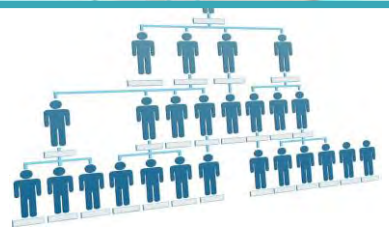
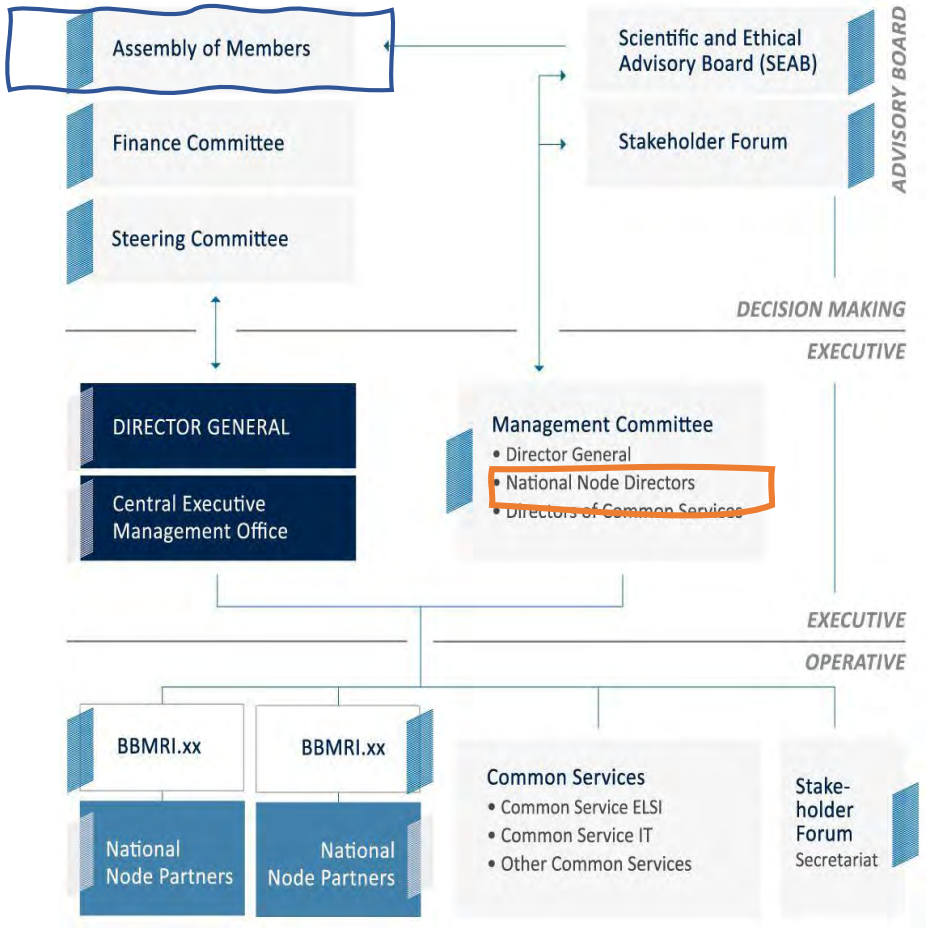
Objetivos

https://www.kpiestudios.com/objetivos-evaluacion-de-desempeno
https://www.bbmri-eric.eu/



Marina López
Elena María Domenech: Departamento de Internacionales del ISCIII

Node Scientific Coordination



Organización/ Gobernanza

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BBMRI-ERIC®

BBMRI enabling precision medicine through:

Biobanking Development
- Biobanks & Cohorts
- Biomolecular Resources
- BBMRI Expert Centres
- Universities & Clinics

Natalia Cal
IdISNA

ELSI Services & Research
- Knowledge Base
- Helpdesk Network
- Ethics Check
- Training
- Code of Conduct for Health Research

Pilar Nicolás
Universidad del País Vasco

Roberto Bilbao
Biobanco del País Vasco

IT Services & Research
- Discovery of biobanking resources
- Access to samples and data
- Data deposition, pooling, analyses
- Interoperability
- Data protection and access control
- Quality controlling & reusability
- Training & Support

Public Affairs & Stakeholder Engagement
- Member States & Strategic Partners
- EU & Global Affairs
- Patients & Public
- Scientific Societies
- Industry Collaborations

Teresa Escámez
IMIB

Quality Management Services & Research
- Knowledge Hub
- Training & Support
- Auditing
- Quality Assurance

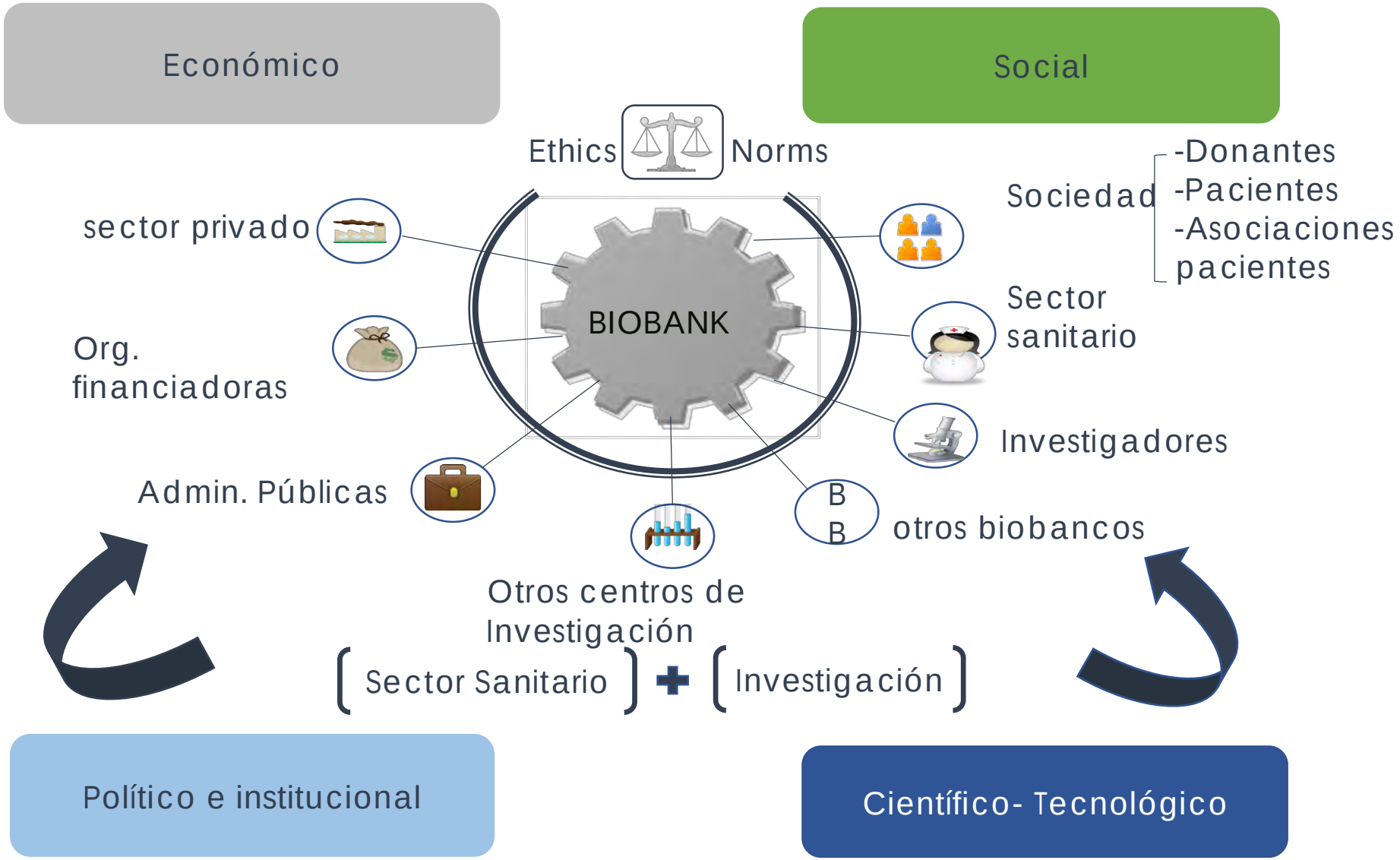
bbmri-eric.eu

Proxy: Enrique de Álava (Hosp. Virgen del Rocío/IBiS)

Administration Point: PNBB-Oficina de Coordinación—Aurora García

Nodo Nacional BBMRI.es

Ecosistema de los biobancos




TOGETHER WE CAN
MAKE A DIFFERENCE