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Integrado en

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BIOBANCO SSPA
PROYECTOS EUROPEOS
Y PRB2

Biobanco del Sistema Sanitario Público de Andalucía
CONSEJERÍA DE IGUALDAD, SALUD Y POLÍTICAS SOCIALES

Málaga Noviembre 2016

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STEM CELL LINES NATIONAL BANK

PRB²

Biobanco del Sistema Sanitario Público de Andalucía
CONSEJERÍA DE IGUALDAD, SALUD Y POLÍTICAS SOCIALES

REPORT OF ACTIVITIES

1. Background
2. Available sample collections
3. Quality control measures
4. Additional services
5. Training courses
6. Dissemination activities and publications
7. International projects

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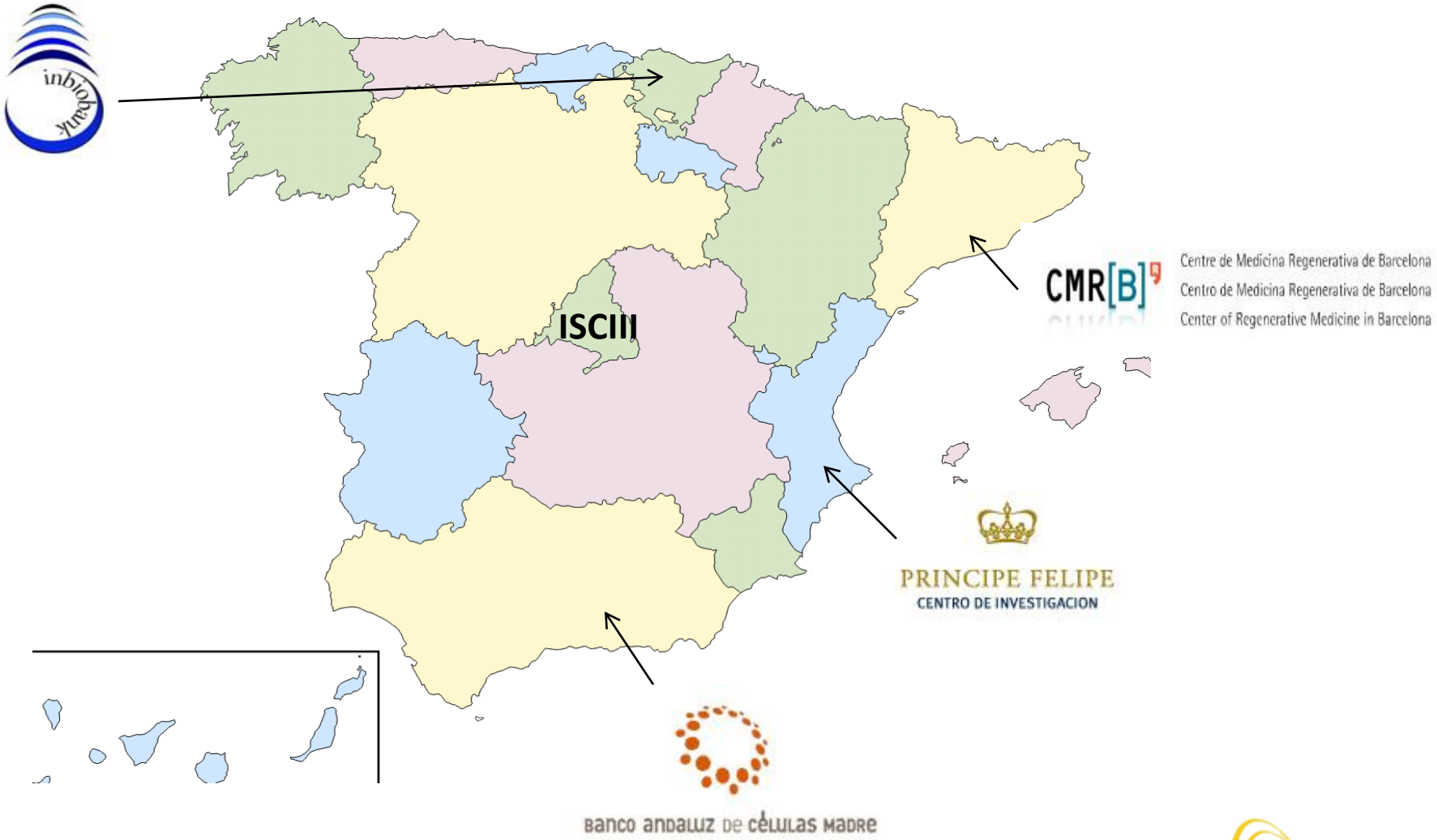
BACKGROUND



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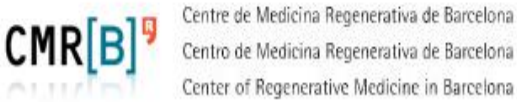
Banco Nacional de Líneas Celulares: BNLC

PRINCIPE FELIPE
CENTRO DE INVESTIGACION



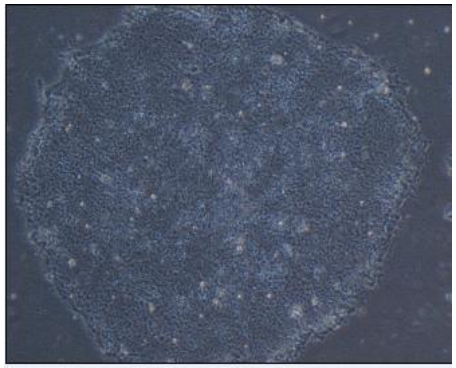
- Cuatro nodos: Catalunya, Euskadi, C Valenciana y Andalucía (Nodo Coordinador)
- Dirección: ISCIII
- Actividades (mandato legal): Preservación, expansión y cesión de líneas celulares troncales
- Actividad dependiente de la revisión de solicitudes y autorización previa de la Comisión de Garantías y la Comisión Técnica del Banco

Banco Nacional de Líneas Celulares. BNLC. Depósito y Acceso a las Líneas

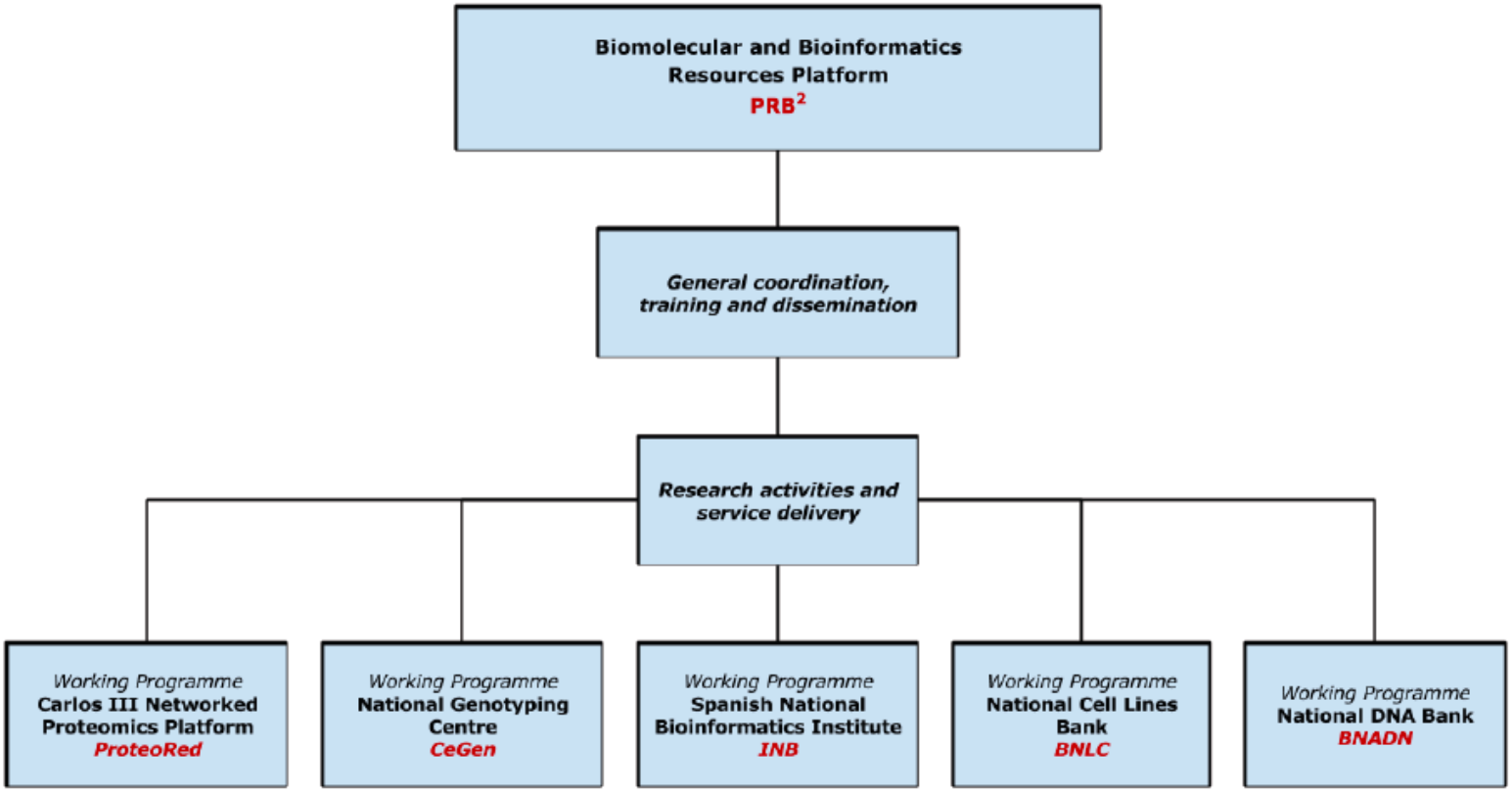
- Proyectos que pueden llegar a desarrollar lineas celulares pluripotentes**: Comisión de Garantías**

- Proyectos que necesitan usar líneas del BNLC: **Comisión de Garantías y Comisión Técnica del BNLC**

- **En Andalucía: Comisión Homóloga**



Welcome to the
Plataforma en Red de Recursos Biomoleculares y Bioinformáticos, PRB^2
(Biomolecular and Bioinformatics Resources Platform).



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Oportunidades de Progresión dentro de la plataforma PRB2

- Interconexión y cooperación
- Protocolización y sistemática común de trabajo
- Ampliación de la cartera de servicios. Apoyo a la Investigación biomédica
- Contactos con otras plataformas/unidades/consorcios
- Participación conjunta en proyectos (nacionales/Internacionales)

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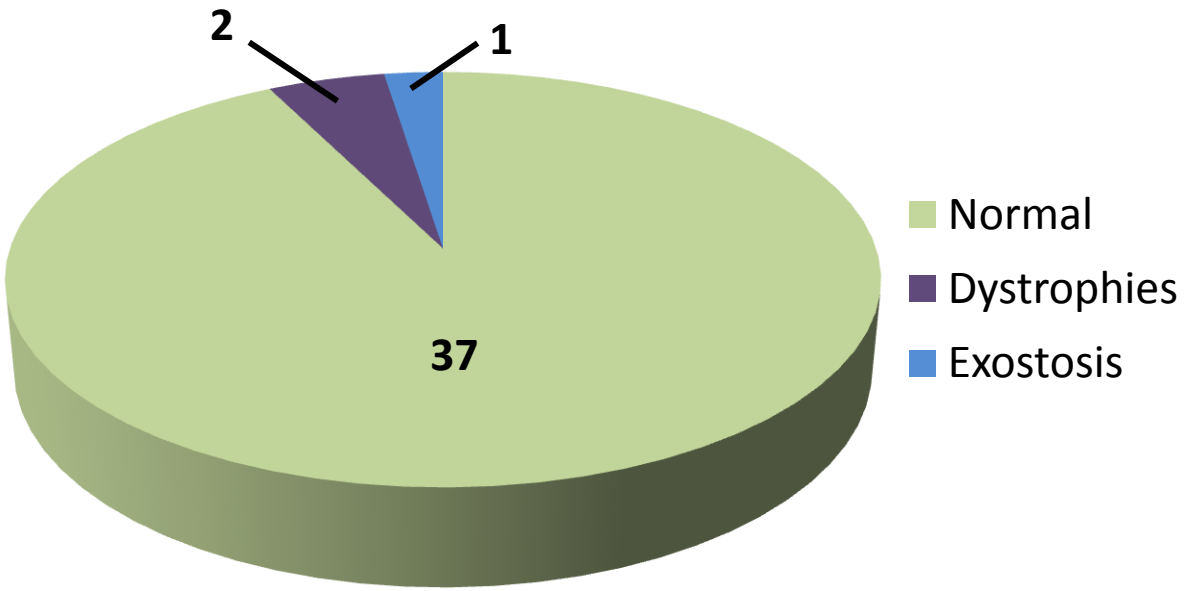
AVAILABLE SAMPLE COLLECTIONS

hESCs (n = 39)



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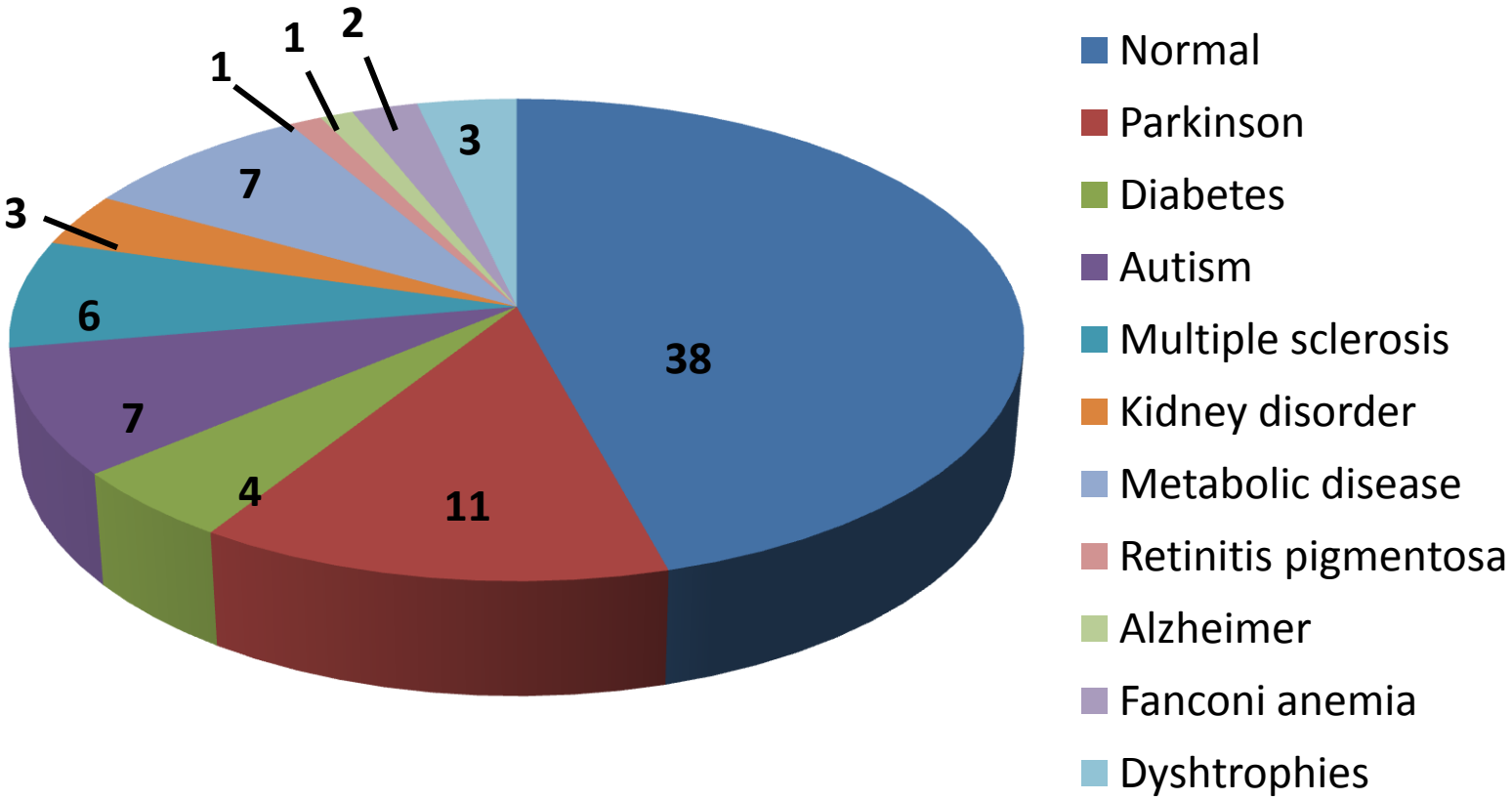
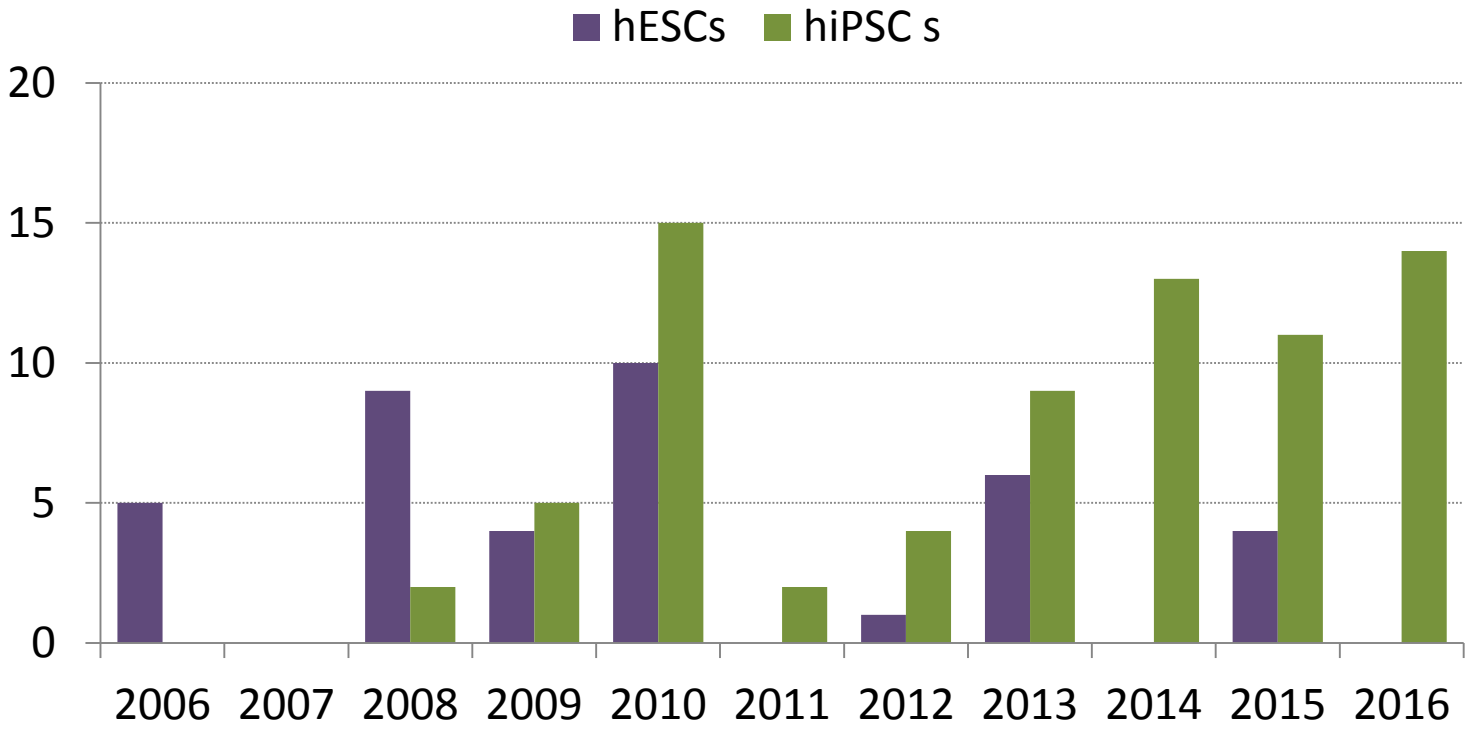
AVAILABLE SAMPLE COLLECTIONS

hiPSCs (n = 83)



AVAILABLE SAMPLE COLLECTIONS

DEPOSITED CELL LINES



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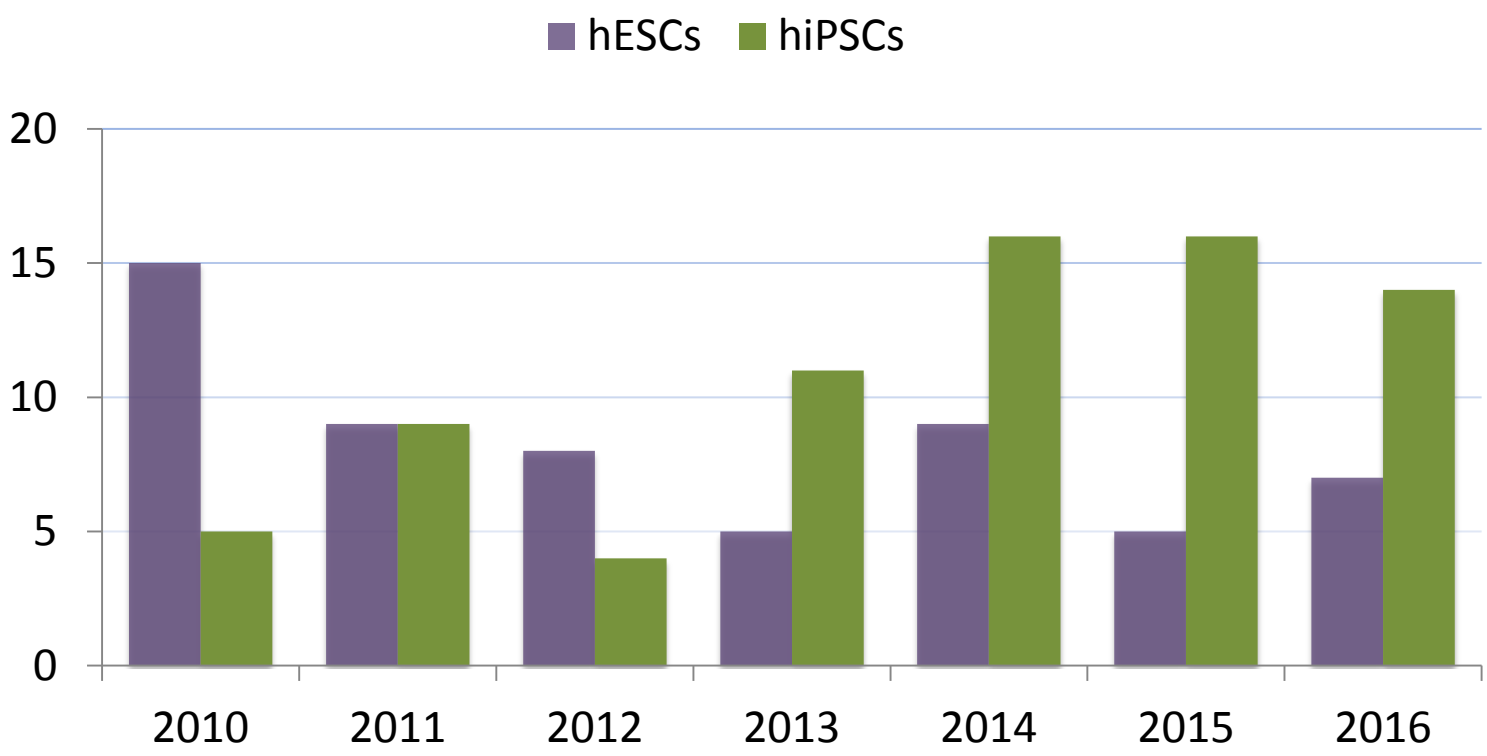
AVAILABLE SAMPLE COLLECTIONS

REQUESTED CELL LINES



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QUALITY CONTROL MEASURES

1. QUALITY CONTROL FOR CELL LINES

- Mycoplasma detection

- Cell li

CONVENTIONAL PCR LookOut

	5 STRs detection method	10 STRs detection method (Geneprint 10 System, Promega)
Discrimination between individual samples	Yes	Yes
STRs analyzed	5	10
Metodology	PCR + Agarose electrophoresis	PCR + Capilar electrophoresis
Tecnich complexity	Medium	High
Interpretation	Sometimes a bit subjective, depending user expertise	Objetive (High sensitivity and resolution)
Cost/assay	7.90 €	33.40 €

sma
1)

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QUALITY CONTROL MEASURES

2. QUALITY CONTROL FOR STORED SAMPLES

- Local and remote alarms for Tº, humidity, O_2 and CO_2.
- Back-up systems:
  - CO_2 bottles
  - Empty freezers
- Continuous temperature controls (24-7)

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QUALITY CONTROL MEASURES

3. QUALITY MANAGEMENT SYSTEM CERTIFICATION

Certificado del
Sistema de Gestión de la Calidad

AENOR
Empresa Registrada
UNE-EN ISO 9001

ER-0074/2014

AENOR, Asociación Española de Normalización y Certificación, certifica que la organización

BIOBANCO DEL SISTEMA SANITARIO PÚBLICO DE ANDALUCÍA - NODO SECTORIAL GRANADA

dispone de un sistema de gestión de la calidad conforme con la Norma UNE-EN ISO 9001:2008

para las actividades: La prestación de servicios de provisión, custodia y procesado de productos sanguíneos o derivados, tejidos, sustancias o muestras biológicas de origen humano, para el uso de investigación.
Asesoramiento técnico en gestión de muestras humanas para investigación. Diseño e impartición de formación en el área de investigación biomédica.

que se realizan en: AV DEL CONOCIMIENTO, S/N, EDIF. CENTRO DE INVESTIGACIONES BIOMÉDICAS, PARQUE TECNOLÓGICO DE CIENCIAS DE LA SALUD. 18100 - ARMILLA (GRANADA)
HOSPITAL UNIVERSITARIO SAN CECILIO. AVDA. DR. OLÓRIZ, 16. EDIFICIO DE DIRECCIÓN Y CONSULTAS. 18012 - GRANADA

Fecha de primera emisión: 2014-02-11
Fecha de expiración: 2017-02-11

AENOR Asociación Española de Normalización y Certificación

Avelino BRITO MARQUINA
Director General de AENOR

AENOR Asociación Española de Normalización y Certificación | Génova, 6. 28004 Madrid, España Tel. 902 102 201 – www.aenor.es

IAF ENAC IQNet

PROTOCOL

Characterization of pluripotent stem cells

Mercè Martí[1], Lola Mulero[1], Cristina Pardo[1], Cristina Morera[1], Meritxell Carrió[1], Leopoldo Laricchia-Robbio[1], Concepcion Rodriguez Esteban[1,2] & Juan Carlos Izpisua Belmonte[1,2]

[1]Center of Regenerative Medicine in Barcelona, Barcelona, Spain. [2]Gene Expression Laboratory, Salk Institute for Biological Studies, La Jolla, California, USA. Correspondence should be addressed to J.C.I.B. (belmonte@salk.edu or izpisua@cmrb.eu).

Published online 10 January 2013; doi:10.1038/nprot.2012.154

Characterization of pluripotent stem cells is required for the registration of stem cell lines and allows for an impartial and objective comparison of the results obtained when generating multiple lines. It is therefore crucial to establish specific, fast and reliable protocols to detect the hallmarks of pluripotency. Such protocols should include immunocytochemistry (takes 2 d), identification of the three germ layers in *in vitro*–derived embryoid bodies by immunocytochemistry (immunodetection takes 3 d) and detection of differentiation markers in *in vivo*–generated teratomas by immunohistochemistry (differentiation marker detection takes 4 d). Standardization of the immunodetection protocols used ensures minimum variations owing to the source, the animal species, the endogenous fluorescence or the inability to collect large amounts of cells, thereby yielding results as fast as possible without loss of quality. This protocol provides a description of all the immunodetection procedures necessary to characterize mouse and human stem cell lines in different circumstances.

Supplement

Regenerative Medicine

Points to consider in the development of seed stocks of pluripotent stem cells for clinical applications: International Stem Cell Banking Initiative (ISCBI)

1. Background and utility of this document

In 2009 the International Stem Cell Banking Initiative (ISCBI) contributors and the Ethics Working Party of the International Stem Cell Forum published a consensus on principles of best practice for the procurement, cell banking, testing and distribution of human embryonic stem cell (hESC) lines for research purposes [1], which was broadly also applicable to human

Second, it has been assumed that undifferentiated pluripotent stem cells would not be inoculated into patients. Third, where feeder cells are used to culture hPSC lines, their cellular nature and intimate contact with the therapeutic cells means that they should be subject to similar risk assessment and banking procedures as applied to the hPSC cells.

It is important to note that responsibility for establishing and updating national regula-

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Division of Cell Biology & Imaging, National Institute for Biological Standards and Control, Blanche Lane, South Mimms, Potters Bar, Hertfordshire, EN6 3QG, UK
glyn.stacey@nibsc.hpa.org.uk

Complete list of contributers can be found at the end of this article.

iPSC Nomenclature:

The name should include the following:

1. Pathology or specificity of the cell line (abbreviation) followed by the sample number
2. Cell type of origin (abbreviation)
3. iPS
4. Number of factors used for the cell line reprogramming
5. Clon number

It is recommended to register just one clone of each line, unless to register more than one is justified.

Examples:

cFA404-FiPS4F1
cFA404-KiPS4F1
CBiPS-3F1

The name of the cell line should be the same that appears in the publication (if there is one), and if the names are different, it should be noted in the registry.

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Cartera de Servicios

- Depósito de líneas
- Identificación y codificación
- Preservación
- Expansión y cesión de líneas
- Trazabilidad
- Seguimiento de la producción científica

Banco Nacional de Líneas Celulares

Cartera de Servicios (II)

	Banco Nacional Líneas Celulares	Investigadores
Asesoramiento y/o Gestión de un proyecto		
Generación de líneas pluripotentes		
Caracterización de las líneas		

Banco Nacional de Líneas Celulares

Cartera de Servicios (II)

	Banco Nacional Líneas Celulares	Investigadores
Asesoramiento y/o Gestión de un proyecto	X	
Generación de líneas pluripotentes	X	
Caracterización de las líneas	X	

Banco Nacional de Líneas Celulares

Cartera de Servicios (II)

	Banco Nacional Líneas Celulares	Investigadores
Asesoramiento y/o Gestión de un proyecto		X
Generación de líneas pluripotentes		X
Caracterización de las líneas		X

Banco Nacional de Líneas Celulares

Cartera de Servicios (II)

	Banco Nacional Líneas Celulares	Investigadores
Asesoramiento y/o Gestión de un proyecto	X	
Generación de líneas pluripotentes		X
Caracterización de las líneas	X	

ADDITIONAL SERVICES

1. MANAGEMENT OF PLURIPOTENT STEM CELLS PROJECTS

2. PLURIPOTENT STEM CELL LINE GENERATION

- 34 total requests from 2014

	Integrative systems	**Non integrative systems**		
	Retrovirus	mRNA	Episomal vectors	Sendai virus
Fibroblasts	20	2	2	4
Adipose mesenquimal stem cells			3	
CD133+ (SCU)	3			

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ADDITIONAL SERVICES

3. PLURIPOTENT STEM CELL LINE CHARACTERIZATION

	2015	2016
Karyotyping	34	21
Microsatellite genotyping	28	127
In vivo differentiation	10	4
Immunohistochemistry	7	1
TOTAL	**79**	**152**

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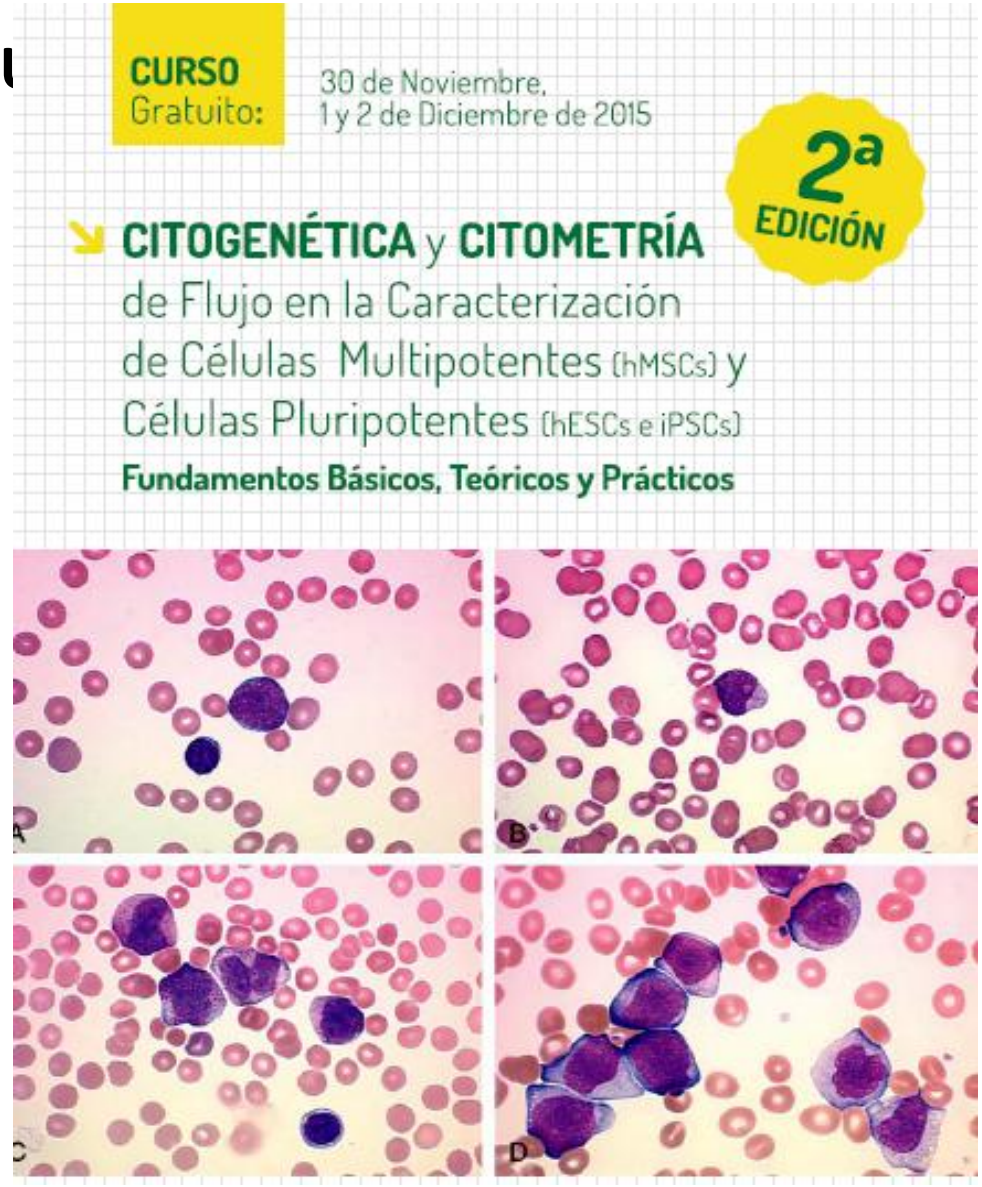
TRAINING COURSES

1. POSTGRADU



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TRAINING COURSES

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TRAINING COURSES

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TRAINING COURSES

2. PRACTICAL COURSES FOR UNDERGRADUATED AND GRADUATED STUDENTS

3. MASTER'S DEGREE

- Biobanks and human sample management in biomedical research (UCV)
- Transfusion medicine and advanced cell therapies (UAB)
- Regenerative biomedicine (UGR)
- Biotechnology (UCV)

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DISSEMINATION ACTIVITIES AND PUBLICATIONS

1. DISSEMINATION ACTIVITIES

- European Researchers night
- Science's week
- Dissemination seminars
- Patients associations meetings
- Interviews in media

DISSEMINATION ACTIVITIES AND PUBLICATIONS

2. PARTICIPATION IN CONFERENCES

- European Society for Biopreservation and Biobanking (ESBB)
- Internatinoal Society for Biological and Environmental Repositories (ISBER)
- National Biobanks Platform (PNB)
- European Society of gene and cell therapy
- International Society for Stem Cell Research (ISSCR)
- Spanish Society for Gene and Cell Therapy (SETGyC)
- International Congress on Neuropathic Pain
- Mediterranean Society for Reproductive Medicine (MSRM)

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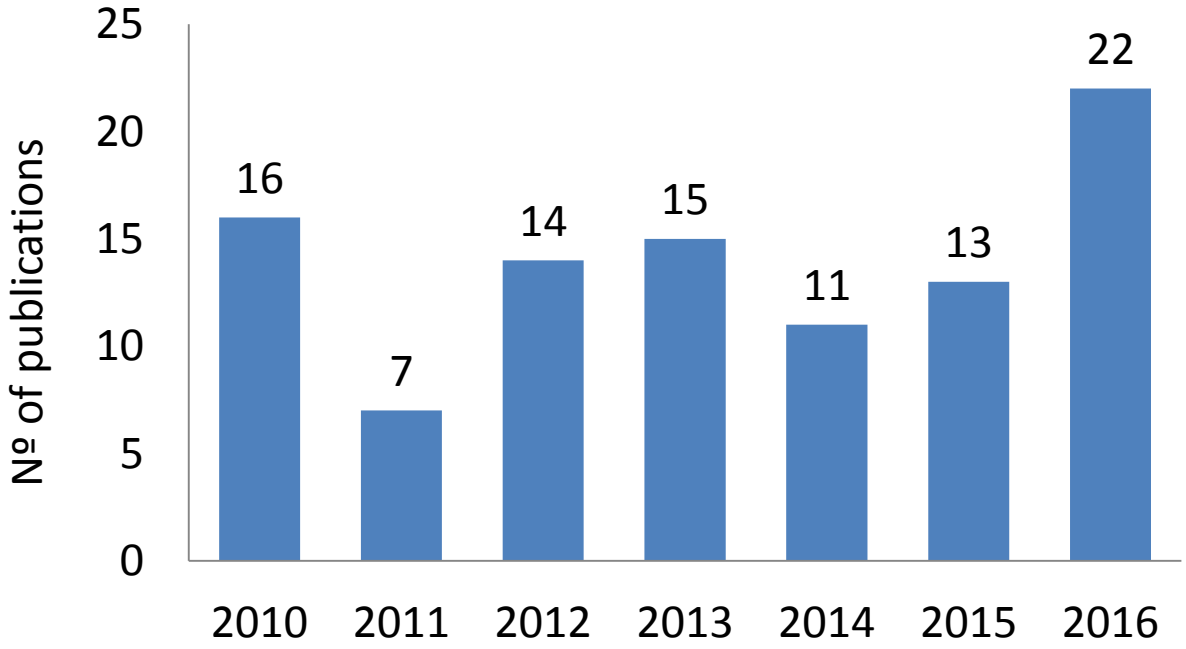
DISSEMINATION ACTIVITIES AND PUBLICATIONS

3. PUBLICATIONS

YEAR	2010	2011	2012	2013	2014	2015	2016
Nº of publications per year	16	7	14	15	11	13	22



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efpia

imi
Innovative Medicines Initiative

EBiSC
European Bank for induced pluripotent Stem Cells

IMI 8th Call (IMI-JU-8-2012)

INTERNATIONAL PROJECTS

EBiSC joint forces

EFPIA companies
- Pfizer Ltd, United Kingdom
- Novo Nordisk, Denmark
- AstraZeneca AB, Sweden
- H. Lundbeck A/S, Denmark
- Janssen Pharmaceutica NV, Belgium
- UCB Biopharma SPRL, Belgium

SME's
- Roslin Cells Ltd, United Kingdom
- ARTTIC, France
- DefiniGEN, United Kingdom
- Douglas Connect GmbH, Switzerland
- Bioneer A/S, Denmark

Universities, research organisations, public bodies, non-profit groups
- University of Edinburgh, United Kingdom
- Fraunhofer-Gesellschaft, Germany
- Fraunhofer Institute for Biomedical Engineering (IBMT)
- Fraunhofer Institute for Molecular Biology and Applied Ecology ScreeningPort (IME SP)
- Genome Research Limited (Wellcome Trust Sanger Institute), United Kingdom
- European Molecular Biology Laboratory (European Bioinformatics Institute), Germany
- Charité University Medicine Berlin, Germany
- University of Newcastle upon Tyne, United Kingdom
- University Hospital Cologne, Germany
- Leibniz University Hannover, Germany
- Royal Netherlands Academy of Arts and Sciences (Hubrecht Institute), The Netherlands
- University College London, United Kingdom
- Culture Collections of Public Health England, United Kingdom
- National Institute for Biological Standards and Control, United Kingdom
- University Hospital Bonn, Germany
- Institute of Health Carlos III., Spain
- Progress and Health Foundation, Spain
- Center for Regenerative Medicine in Barcelona, Spain
- Inbiomed, Spain

EBiSC
European Bank for induced pluripotent Stem Cells

Contact us

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Cambridge / United Kingdom

Managing Entity
University of Edinburgh
Edinburgh / United Kingdom

Manager of the Public Partners
Mr. Aidan Courtney
Chief Executive Officer
Roslin Cells Ltd.
Edinburgh / United Kingdom

EBiSC Project Administration Office
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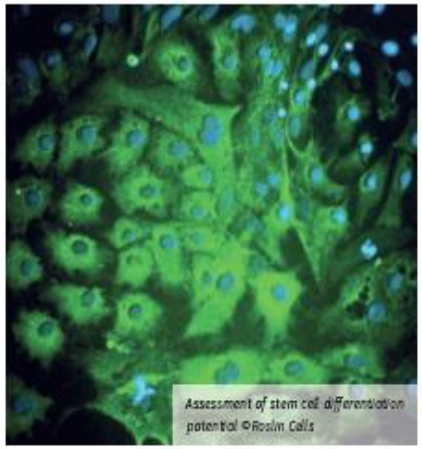
www.ebisc.eu

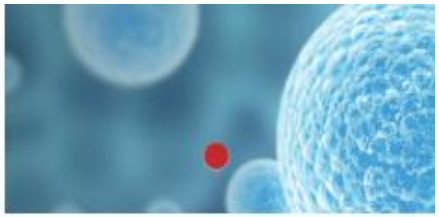
EBiSC
European Bank for induced pluripotent Stem Cells

European Bank for induced pluripotent Stem Cells



Assessment of stem cell differentiation potential ©Roslin Cells

The EBiSC – European Bank for Induced pluripotent Stem Cells project has received support from the Innovative Medicines Initiative Joint Undertaking under grant agreement n° 115542, resources of which are composed of financial contribution from the European Union's Seventh Framework Programme (FP7/2007-2013) and EFPIA companies' in kind contribution. www.imi.europa.eu



EBiSC at a glance

EBiSC enables researchers to access quality-controlled, disease relevant, research-grade iPSC lines, data and cell services. Its goal is to demonstrate an operational banking and distribution service of iPSC lines after 3 years and to establish for Europe a centralised, not-for-profit, self-sustaining bank providing all categories of international stakeholders with access to high-quality, scalable, cost-efficient and customised products.

The **EBiSC project consortium** represents all relevant stakeholders from tissue donors to clinical and academic iPSC researchers, banking, distribution and ethics experts, and industrial users. Under the leadership of Pfizer Ltd and Roslin Cells, it provides the scientific expertise, facilities and network to build a robust, reliable supply chain from the generation of cell lines, their characterisation to internationally accepted quality criteria and world-wide distribution to any qualified user. The EBiSC consortium has the ability to respond appropriately to advances in science and society.

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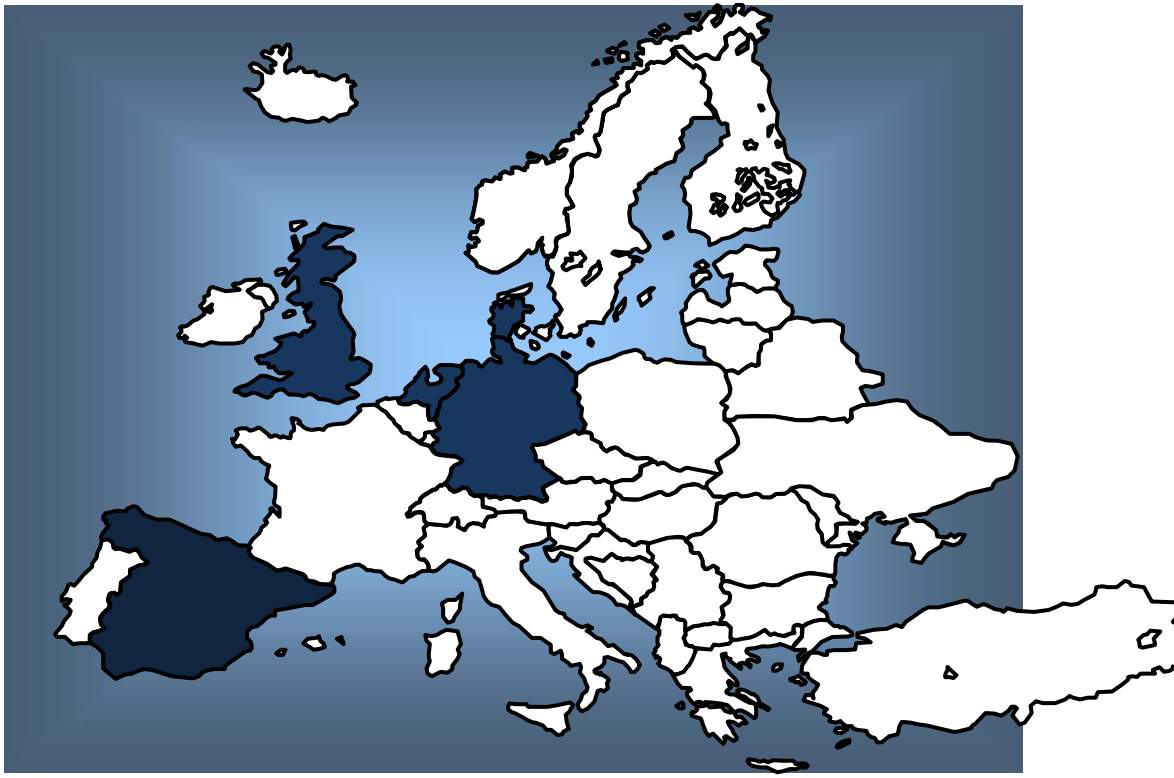
Compañías FPA

Pfizer (UK)
Astra Zeneca (Sw)
H Lundbeck (Dk)
Janssen P (be)
Novo Nordisk (Dk)
UCB Ph. (Be)

Academias y Non for Profit
(14 grupos)

UK: 5
DK:1
Ge:6
Sp:1
Ned:1



Coord. Adm.

Fr


Roslin Cells


Delivering Cell Therapy

Banco Europeo de lineas celulares iPS

Ejecución **36 m**

Dos sedes (UK y Ge)

1000 líneas celulares

Colección basal a partir de las existentes en los centros participantes

Aportación de **50-100 líneas anuales de cada laboratorio** participante

Armonización de prácticas y tecnología de derivación, conservación y expansión

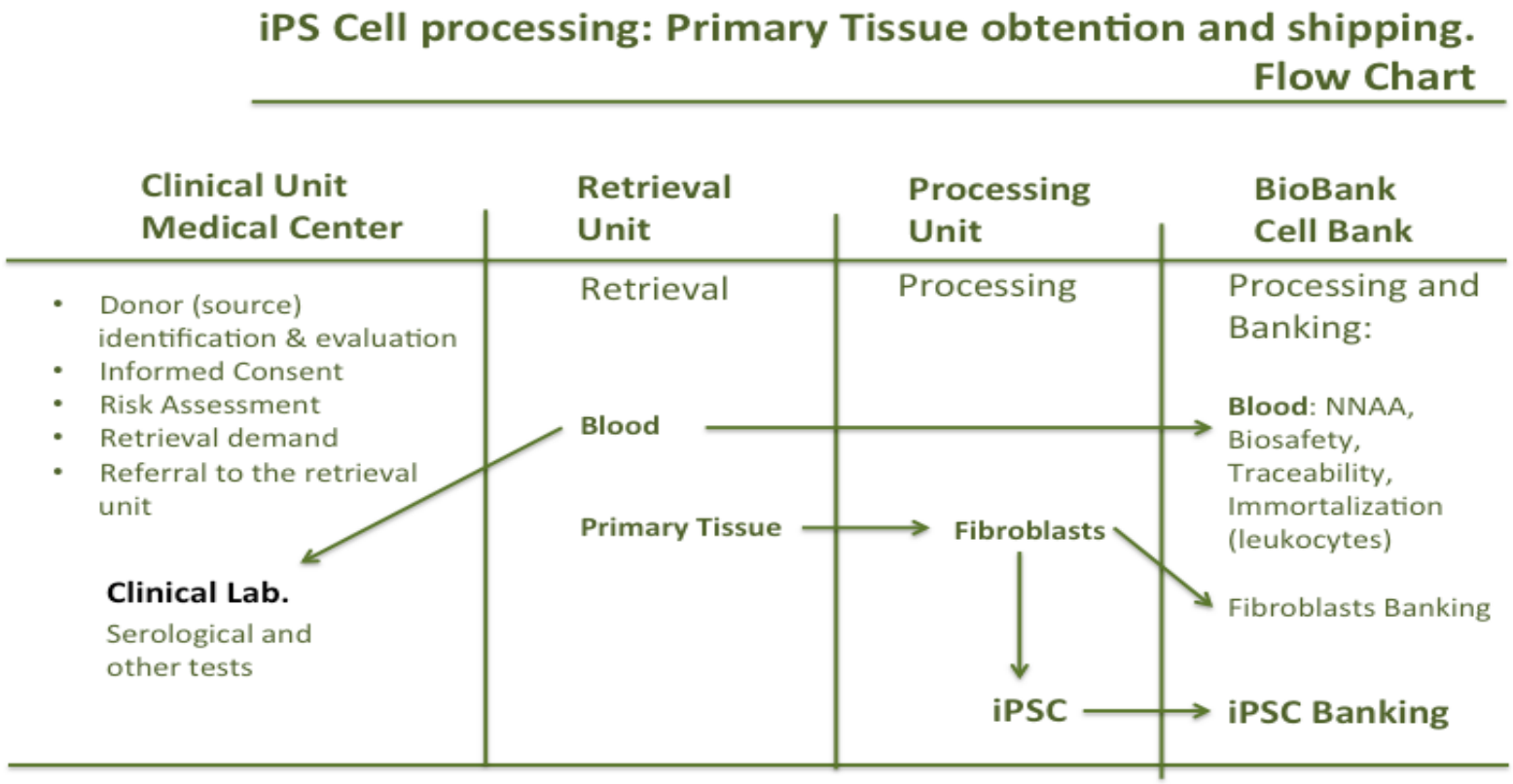
Milestones

No	When	What	Why
1	M6	Strategic Plan and Vision in White Paper & Business Plan	Demonstrates alignment between EBiSC and users
2	M12	SOPs for banking and distribution leading to 1st distribution of cell lines	Demonstrates end-to-end capacity of EBiSC operation
3	M24	Over 200 cell line samples supplied to users	Demonstrates capacity to distribute samples to customers
4	M36	Gap analysis of available iPSC lines leading to commissioning of new lines with standard SOPs	EBiSC actively developing its iPSC line catalogue
5	M36	Integration of all development activities into mainstream operations	Shows impact of the development activities of the EBiSC project
6	M36	Babraham facility fully operational	Shows EBiSC is operating in mature operation mode
7	M36	1,000 iPS cell lines available	Shows EBiSC is in operating at scale

IMI 8th Call (IMI-JU-8-2012)

Milestone M2.1.3:
Harmonised standard for donor information and tissue procurement

Description



The document compiles standardized instructions for all the process, from the identification and evaluation of the donor (source of the primary tissue) to the shipment of this material to the processing laboratory facilities.

OBTENTION OF SAMPLES (SKIN AND BLOOD) as primary tissue for iPSC derivation

☐ **REQUEST SAMPLES FOR OBTAINING iPSC (send to the laboratory for processing or "local" biobank)**

- ☐ **Tissue**
  - ☐ Skin biopsy (total: 2 cylinders, if possible)
  - ☐ Others (indicate) .....
- ☐ **Others** sample (type, origin organ, ...) .....

☐ **REQUEST SAMPLES FOR TRACEABILITY AND BIOSECURITY PURPOSES (send to the laboratory for processing or "local" biobank)**

- ☐ **Blood**
  - ☐ **1** drop of blood in FTA card*
  - ☐ **2** tubes with anticoagulant: EDTA (total: 10 ml of blood) (* 5 ml)
  - ☐ **1** tubes without anticoagulant, with separating gel (total: 8-10 ml of blood) (* 5 ml)
  - ☐ **2** tubes with anticoagulant: ACD (total: 8-10 ml of blood)
  - ☐ **1** tube PAXGENE® (total: 8 ml of blood)

Note: If blood collection is difficult and not is possible to obtain all types of samples, the priority should be the samples marked with an asterisk.

- ☐ ***Others** sample type, origin organ,....)* .....

☐ **REQUEST SAMPLES FOR COMPLETE EVALUATION OF THE DONOR (send to laboratory for diagnosis**

- ☐ **Blood**
  - ☐ **2** tubes with anticoagulant: EDTA (total: 10 ml of blood)
  - ☐ **2** tubes without anticoagulant, with separating gel (total: 10 ml of blood)
- ☐ **Others** (indicate sample type, origin organ,....)

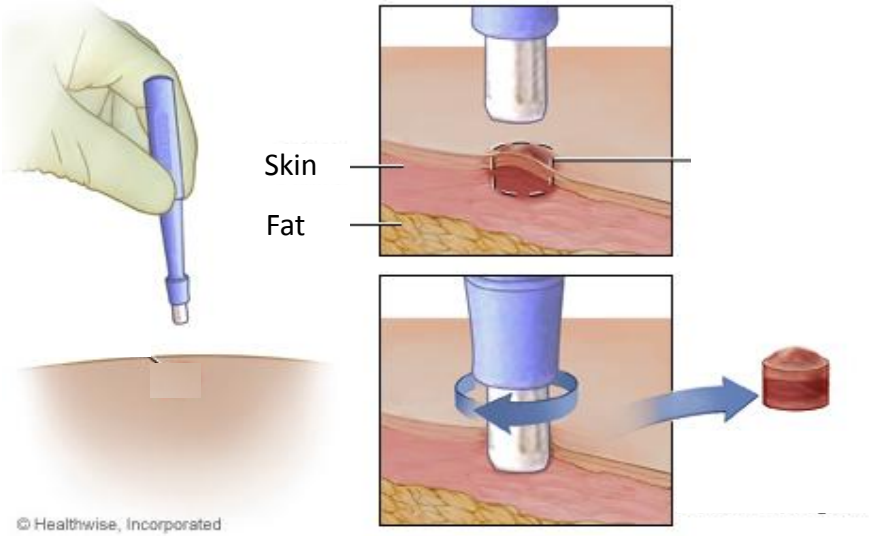
DESTINY LABORATORY ☐ Serology ☐ Others (indicate) .....)

☐ **REQUEST SAMPLES FOR COMPLETE EVALUATION OF THE DONOR (send to laboratory for diagnosis**

- ☐ **Tissue**
  - ☐ Skin biopsy (total:.(nº) .....cylinders,
- ☐ **Others** (indicate sample type, origin organ,....) .....

DESTINY LABORATORY ☐ Pathology ☐ Microbiology ☐ Others (indicate) .....

PROTOCOL FOR EXTRACTION OF SKIN BIOPSIES & VENIPUNCTION



This Standard Operating Procedure (SOP) can be adapted for any other alternative primary source of cells for iPSC generation (. Ie. Peripheral or cord blood, urine, bone marrow by amendment of section 3.2.4.1 Protocol for retrieval/biopsy.

OBTENTION OF SAMPLES (SKIN AND BLOOD)
as primary tissue for iPSC derivation

☒ **EXTRACTED SPECIMENS (send to the laboratory for processing or "local" biobank)**

- ☐ **Tissue**
  - ☐ Skin biopsy (total: 1-2 cylinders (6 mm), if possible)
  - ☐ Others (indicate) .....

☐ **Others (** sample type, origin organ,....**)**.....

Identification of the samples (code number, ...)

Amount of extracted sample;

Number of samples;

Description of the sample

Operating procedure used;

REPORT OF THE EXTRACTION

LABELED AND SHIPPING TO EACH DESTINATION

Accompanying documentation

- Copy of Informed Consent (1)
- Copy of Report of donor identification and evaluation (1)
- F_Clinical and social information
- F_Check list form the evaluation of donors
- F_Physical exam
- Copy of report extraction (1)
- Copy Request form of serological determinations (if applicable) (2)
- Copy Request form of pathological studies (if applicable) (2)
- Copy of the form for microbiological studies (if applicable) (2)

Transport of Samples

REQUIREMENTS PACKAGING, LABELLING AND DOCUMENTATION

- **Comply with current regulations** and do not present any risk to humans during handling.
- The packaging must be **secure** and **robust enough,** depending on the size and weight of the package
- **Proper labelling** to identify potentially infectious samples and to alert that those samples require special precautions in case of accidental leakage.

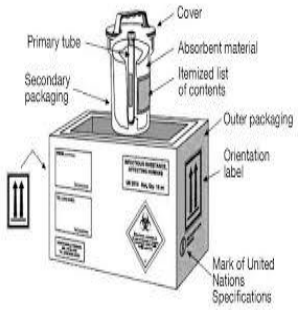
Type of sample	Format of shipping
Fresh tissue for culture	4 ºC
DNA -80ºC	Dry Ice * 
RNA -80ºC	
Medium culture -80ºC	
Plasma -80ºC	
Serum -80ºC	
Frozen tissue -80ºC	
Frozen cells -196ºC	Nitrogen tank transport **
Cells in culture 37ºC	Room temperature

Figure 6 Table 1: Terms of sending samples

Transport of Samples

LOGISTIC / TRANSPORT COMPANY	
Identification: Address: Contact in case of any contingency (Name, phone, ...): Shipment identification number (Locator):	
Professional responsible for transport (storage)	Responsible Sign Date/ time of storage in centre of collection:
Professional responsible for the transport (delivery)	Responsible Sign Date/ time of delivery in recipient centre:

RECIPIENT CENTRE	
Identification and address**:** Contact in case of any contingency (Name, phone, ...):	
Professional responsible for the reception of the package in the recipient centre	Responsible Sign Date/ time of reception in recipient centre:

Reception of Samples

F_ CHECKING TO ENTRY REGISTRY

Page 1: Reception packages

TARGET CENTRE (ID)	
Professional responsible for validating receipt	Responsible Date/ time

RECEPTION PACKAGES

IDENTIFICATION AND LABELLING OF THE OUTER CONTAINER (RIGID OUTER PACKAGING) ORIGIN

IDENTIFICATION AND ADDRESS

- Identification and address of the centre of origin ☐ Yes ☐ No // Observation: ……..
- Staff and number phone or other form to contact for any contingency ☐ Yes ☐ No
- Date and time of the departure. ☐ Yes ☐ No // Observation: ……..
- Labels or specific precautions during transport ☐ Yes ☐ No // Observation: ……..

PACKAGE INTEGRITY

- Check if the centre of origin is identified ☐ Yes ☐ No // Observation: ……..
- Check if the centre of origin is correct ☐ Yes ☐ No // Observation: ……..
- Check if the target centre is identified ☐ Yes ☐ No // Observation: ……..
- Check if the destination centre address is correct ☐ Yes ☐ No // Observation: ……..
- Indicate whether any observed damaged packaging ☐ Yes ☐ No // Observation: ……..

CHECKING THE CONDITION OF TRANSPORT

- Indicate if there is a temperature record ☐ Yes ☐ No // Observation: ……..
- Check if the temperature of transport has been adequate (within the defined range for each type of sample)

  ☐ Yes ☐ No // Observation: ……..
- Check if there is a shipping date ☐ Yes ☐ No // Observation: ……..
- Indicate whether the time of transit has been adequate (within the defined range for each type of sample)

  ☐ Yes ☐ No // Observation: ……..

RESULT : ☐ **According** ☐ **Not According**

OBSERVATION

F_ CHECKING TO ENTRY REGISTRY

Page 2: Checking documents

CHECKING DOCUMENTS

INFORMED CONSENT

- Check if a copy of the informed consent form is attached ☐ Yes ☐ No // Observation: ……..
- Check if it is properly identified and signed ☐ Yes ☐ No // Observation: ……..

IDENTIFICATION AND EVALUATION OF DONOR

- Check if a copy of the form of identification and evaluation of the donor is attached
- Identification of donor/donation (Identification number, ….) ☐ Yes ☐ No // Observation: ……..
- Identification and signature of the person responsible for evaluation ☐ Yes ☐ No // Observation: ……..
- Centre of origin ☐ Yes ☐ No // Observation: ……..
- Date ☐ Yes ☐ No // Observation: ……..
- Clinical and social information sheet ☐ Yes ☐ No // Observation: ……..
- Checklist for evaluation of donors sheet ☐ Yes ☐ No // Observation: ……..
- Physical exam sheet ☐ Yes ☐ No // Observation: ……..

REPORT SAMPLES

- Verify if a copy of the sample retrieval report is attached ☐ Yes ☐ No // Observation: ……..
- Verify if it is adequately filled ☐ Yes ☐ No // Observation: ……..
- Centre of retrieval ☐ Yes ☐ No // Observation: ……..
- Date and time of retrieval ☐ Yes ☐ No // Observation: ……..
- Identification and number of samples ☐ Yes ☐ No // Observation: ……..
- Type and description of the samples ☐ Yes ☐ No // Observation: ……..

RESULT : ☐ **According** ☐ **Not According**

OBSERVATION

Banco Nacional de Líneas Celulares: BNLC

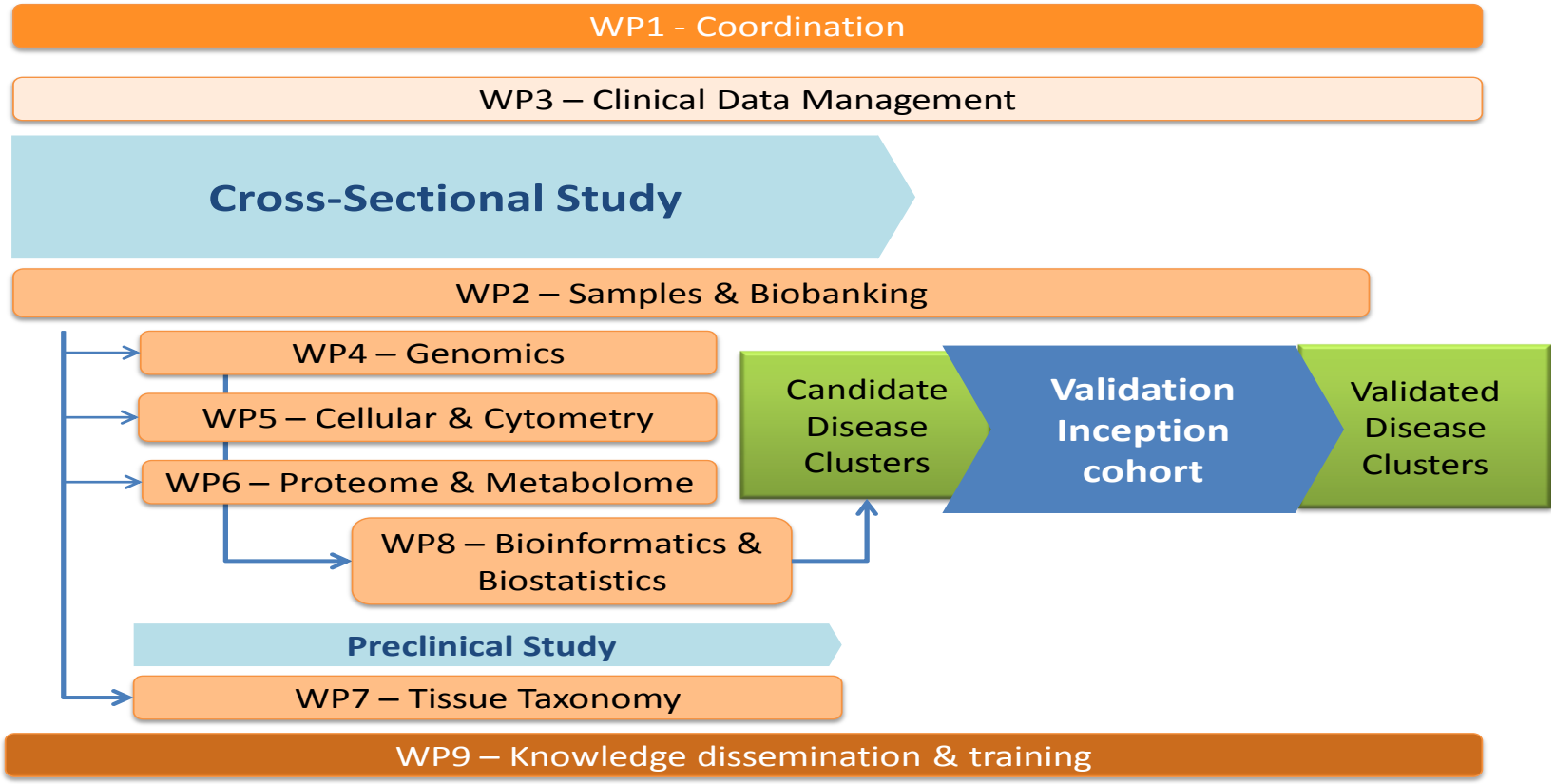
- **Proceso de autorización de derivación y uso muy complicado. / No se realiza seguimiento**
- **Asimilación de células embrionarias e iPS como iguales: Obligatoriedad de depósito. Participación en proyectos Internacionales. Desobediencia/Rebeldía**
- **Proliferación de nodos. Financiación / Supervivencia**
- **Otros usos de las líneas: Docencia. Puesta a punto de técnicas. Validación**
- **Pre-embriones donados a la ciencia**

WP2
Samples & Biobanking

PRECISESADS

Molecular Reclassification to Find Clinically Useful Biomarkers for Systemic Autoimmune Diseases

WP Structure of PRECISESADS



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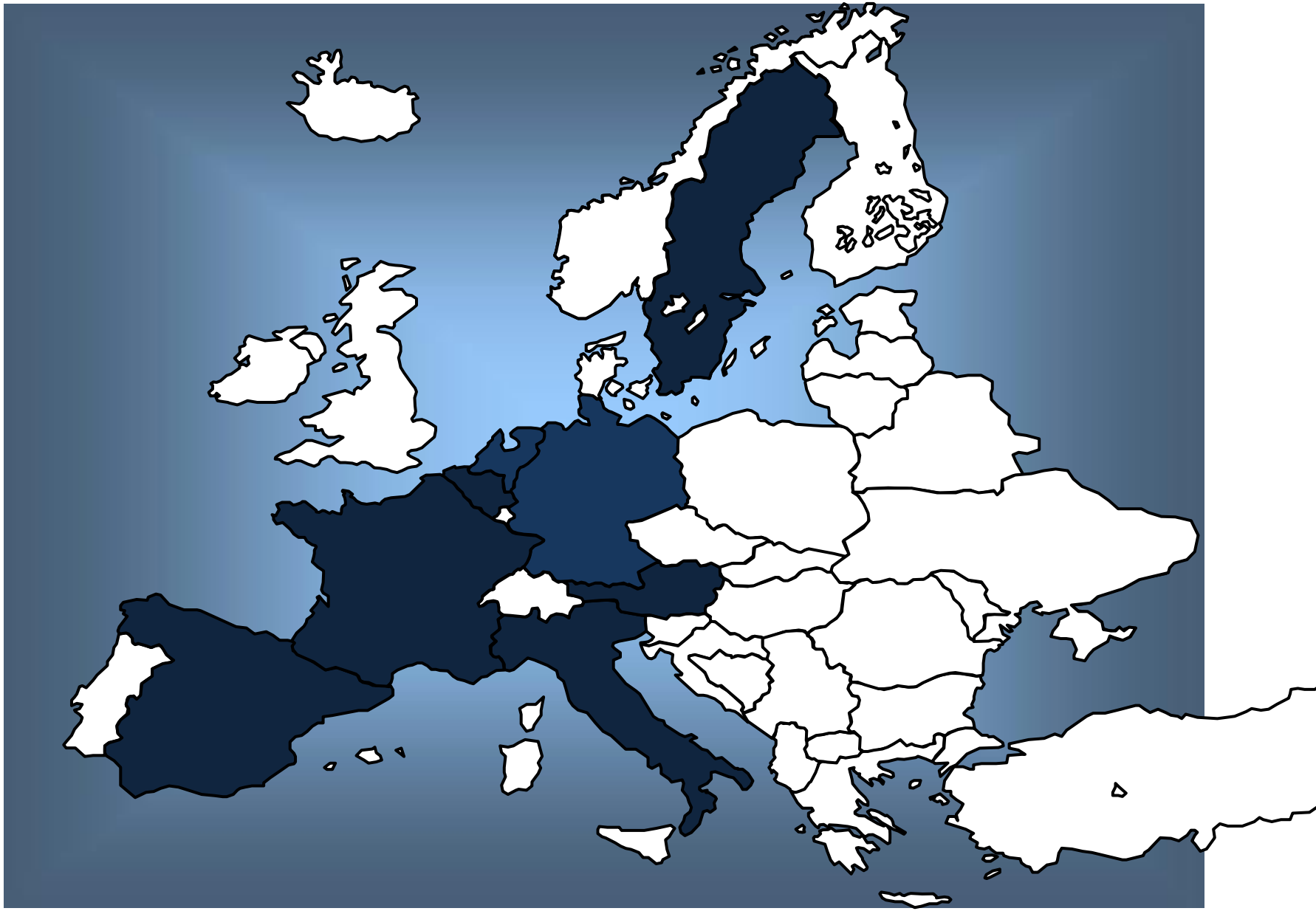
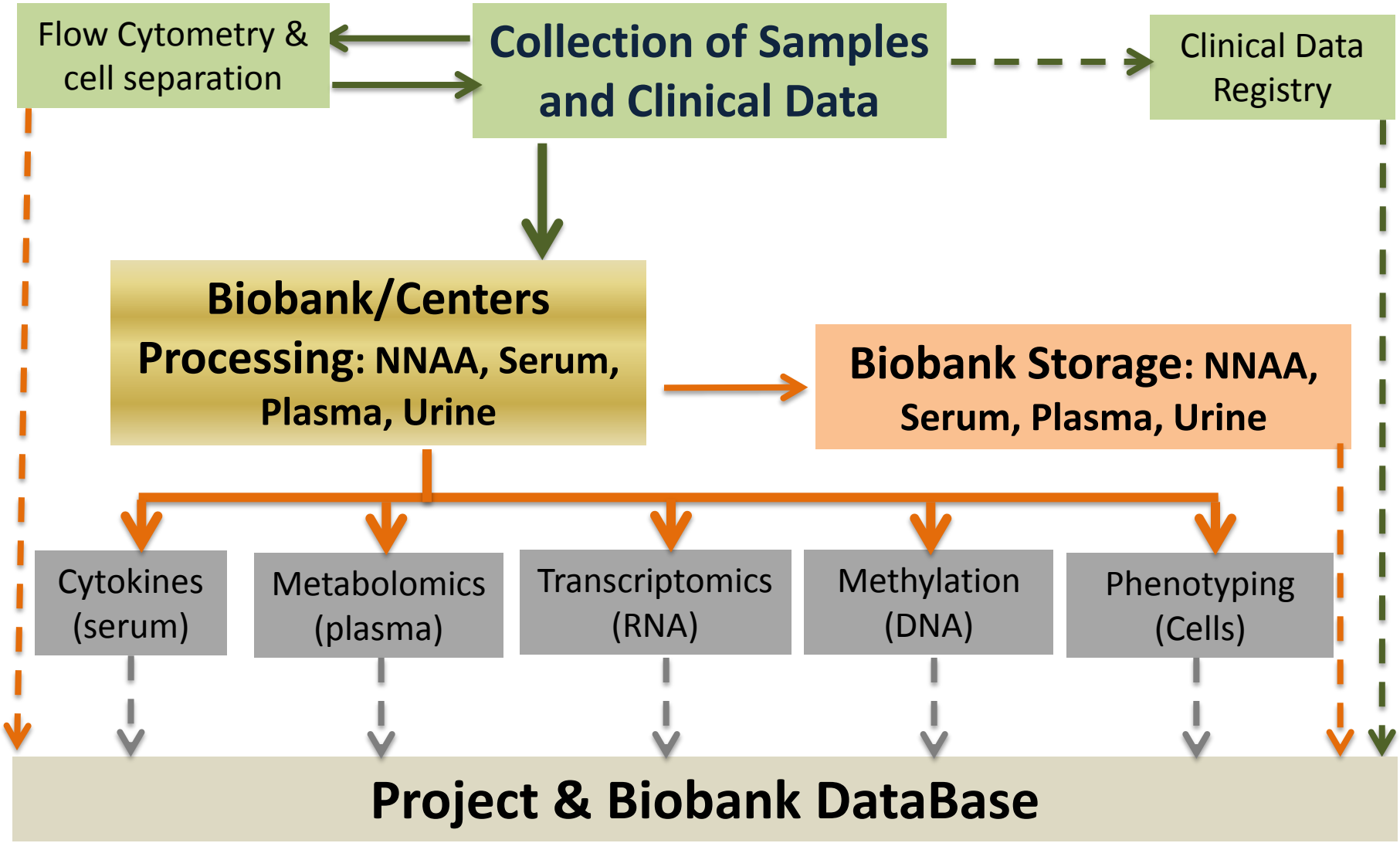
PRECISESADS
Molecular Reclassification to Find Clinically Useful Biomarkers for Systemic Autoimmune Diseases



Flow of Biological Samples.



Flow of Biological Samples.

Collection Centre / Local Lab

Tasks done in the collection centers or local laboratories

Biobank / Collection Centre

Tasks done in the collection centers and in Biobank

Biobank

Tasks done in Biobank

Reference Lab.

Tasks done in Reference's Laboratory

Project & Biobank DataBase

Data Transfer

Local Sample's shipment

External Sample's shipment

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PRECISESADS

Molecular Reclassification to Find Clinically Useful Biomarkers for Systemic Autoimmune Diseases

N	WP and Tasks	Time-lines	S1	S2	S3	S4	S5	S6	S7	S8	S9	S10
2	**Sample Collection and Biobanking**	**1-60**										
2.1	Establishment of a protocol for the enrollment of patients and their samples (cross-sectional cohort)	1-6										
2.2	Full recruitment of the first288 SADs patients and healthy controls + collection of biological samples	3-12										
2.3	Establishment for a protocol for the recruitment of the inception cohort, and recruitment.	1-52										
2.4	Procurement of ethical approval (ETHICS TASK)	1-52										
2.5	Full recruitment of the complete set of 2000 SAD patients and 666 controls + biological samples	8-24										
2.6	Protocols for sample's package preparation, labelling and shipment	1-6										
2.7	Organize the centralized preservation and banking management of biological samples.	1-60										
2.8	Maintenance and sampling of the pre-clinical models	6-60										

General steps on WP2: Biobanking and samples

		PHASE 1ª CROSS-SECTIONAL COHORT	PHASE 2 CROSS-SECTIONAL COHORT	INCEPTION COHORT
DONATIONS		302	2921	626
PROCESSING	SAMPLE EXTRACTION	**X**	**X**	**X**
	CYTOMETRY / CELL SEPARAT.	**X**	**X**	**X**
	CITRATE PLASMA	**X**	**X**	**X**
	SERUM	**X**	**X**	**X**
	PLASMA/DNA	**X**	**X**	**X**
	URINE	**X**	**X**	**X**
	RNA	**X**	**X**	**X**
	TEMPORAL STORE	**X**	**X**	**X**
SENDING TO BIOBANCK		DOCUMENTS AND SAMPLES	DOCUMENTS AND SAMPLES	DOCUMENTS AND SAMPLES

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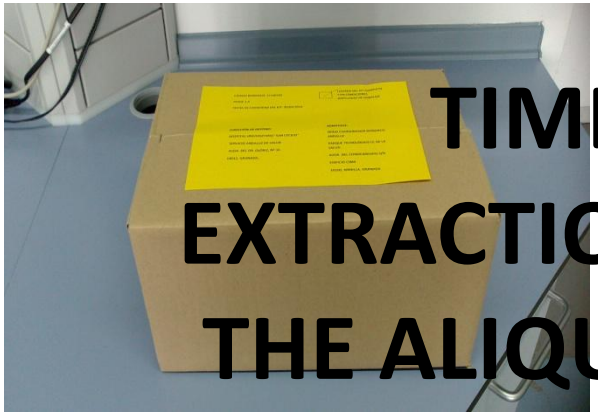
Molecular Reclassification to Find Clinically Useful Biomarkers for Systemic Autoimmune Diseases

PHASE 1 A CROSS SECTIONAL COHORT

PHASE 2 CROSS SECTIONAL COHORT

INCEPTION COHORT



TIME ELAPSED FROM EXTRACTION TO THE STORAGE OF THE ALIQUOTS CAN NOT EXCEED 2 HOURS.

- ***DO NOT USE THE KITS AFTER THE EXPIRATION DATE PRINTED ON THE LABEL ON TOP.***
- ***STORE THE KITS AT (18-25)ºC.***

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PRECISESADS
Molecular Reclassification to Find Clinically Useful Biomarkers for Systemic Autoimmune Diseases

The kit contains

- **Necessary tubes in two bags for samples collection and processing with their labels (OMIC code).**

DO NOT USE OTHER CODES - DO NOT USE OTHER LABELS

- **Documentation**

ONE KIT, ONE DONATION!!! WE WILL SEND KITS WITH TUBES AND LABELS JUST IN CASE OF REPLACEMENT.

IF ANY INCIDENT IS DETECTED TO ONE KIT

DO NOT USE IT AND OPEN A NEW KIT (THIS POINT WILL BE NOTICED TO BIOBANK).

COMPLETE THE KIT CHECKLIST

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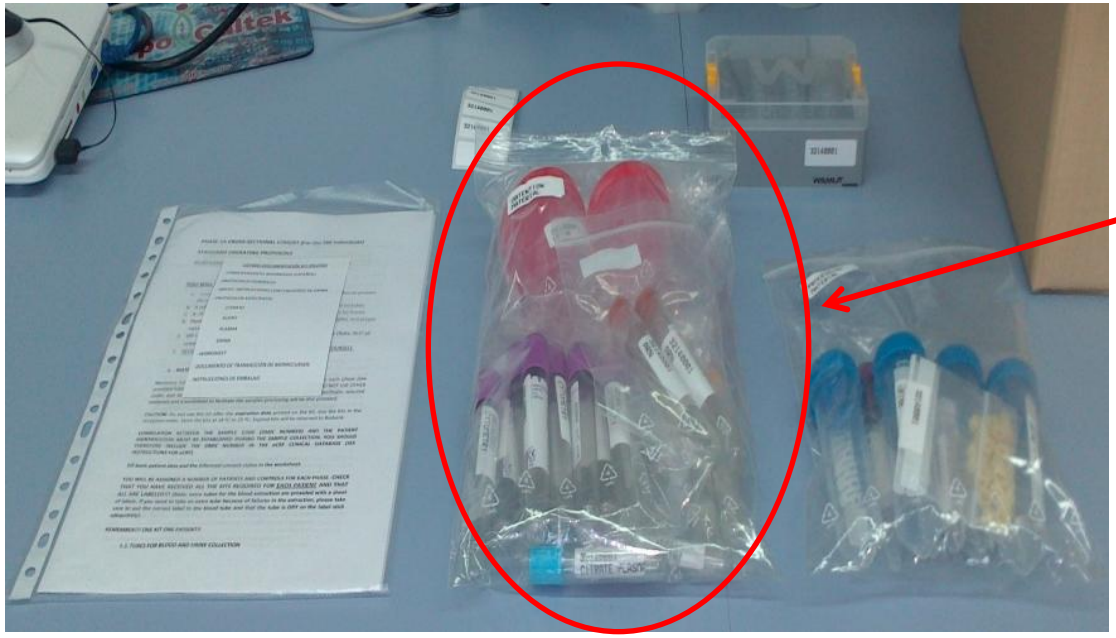
Collecting the samples



YOU NEED THIS BAG

BAG CONTAINING OBTENTION MATERIAL.

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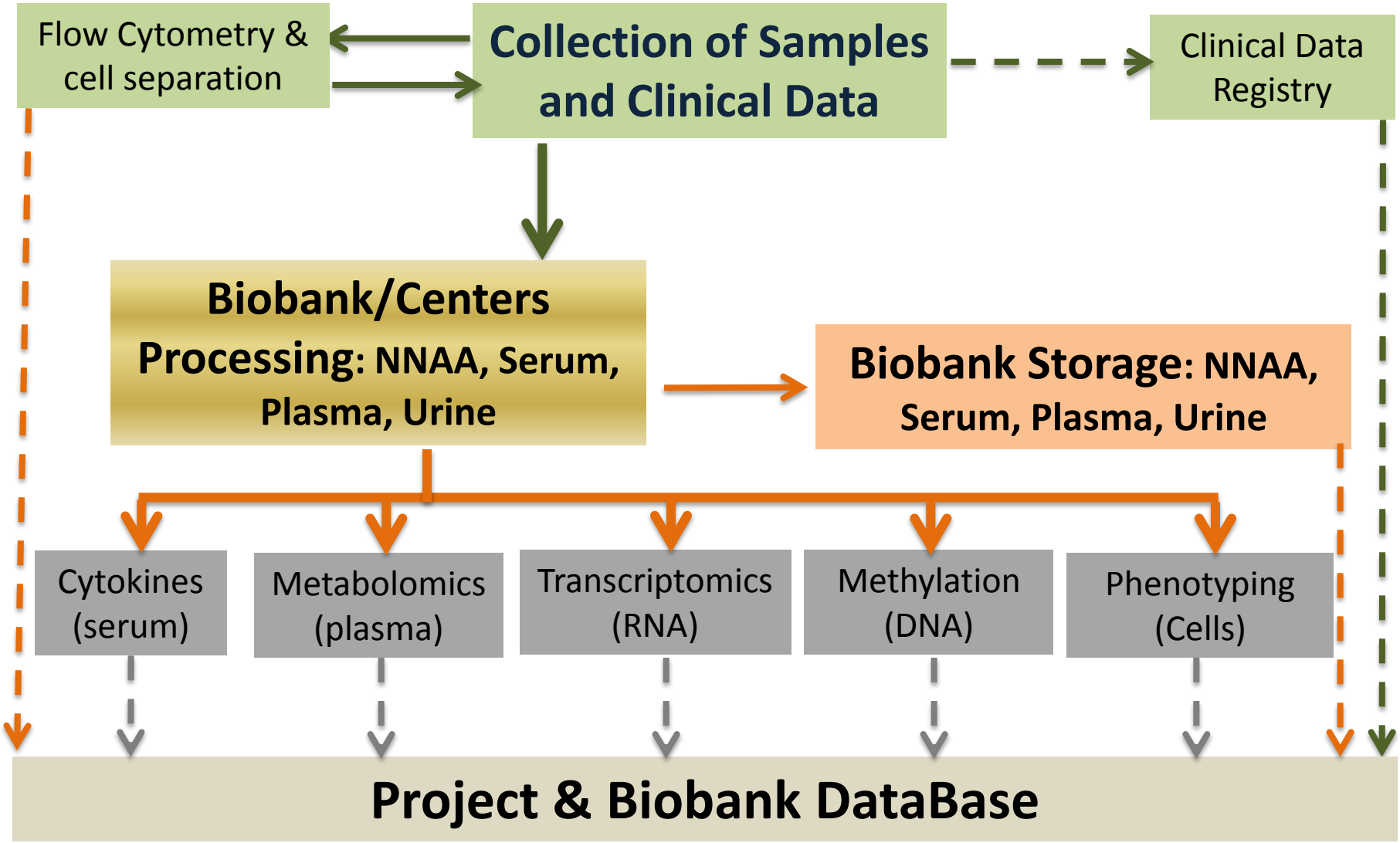
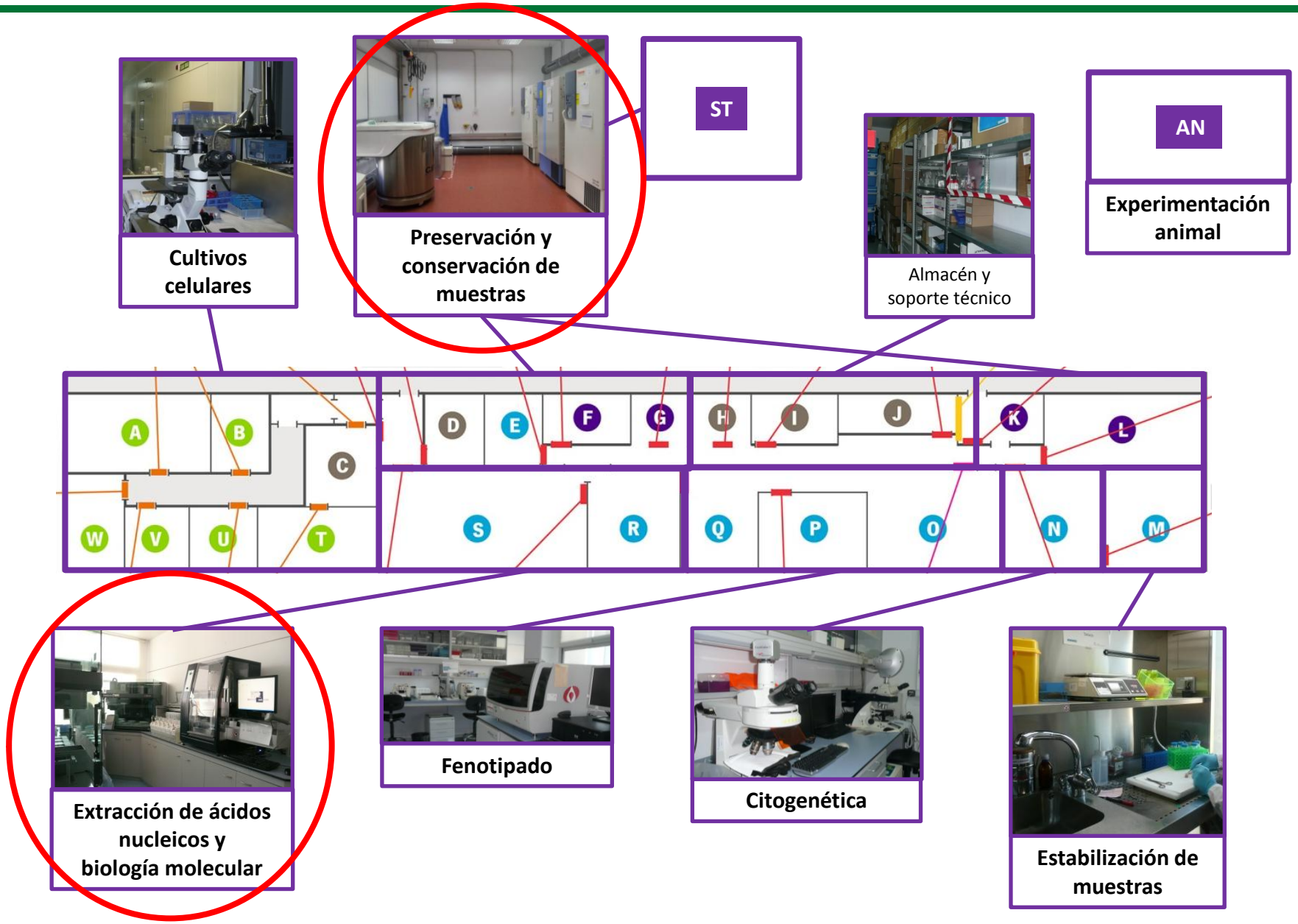
Flow of Biological Samples.



Biobanco del Sistema Sanitario Público de Andalucía

Procesamiento y preservación centralizada de muestras



CURRENT STATE: Biobanking and samples

		PHASE 1ª CROSS-SECTIONAL COHORT	PHASE 2 CROSS-SECTIONAL COHORT	INCEPTION COHORT
DONATIONS		302	2921	626
PROCESSING	SENT KITS	**302**	**2112**	**469**
	EDTA PLASMA	**302**	**206**	**0**
	CITRATE PLASMA	**302**	**18**	**0**
	SERUM	**302**	**228**	**19**
	DNA	**302**	**278**	**47**
	URINE	**302**	**232**	**2**
	RNA	**302**	**491**	**0**
		DOCUMENTS AND SAMPLES	**1497 DOCUMENTS AND SAMPLES RECEIVED IN BIOBANK**	**253 DOCUMENTS AND SAMPLES RECEIVED IN BIOBANK**

COMPLETED

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PRECISESADS
Molecular Reclassification to Find Clinically Useful Biomarkers for Systemic Autoimmune Diseases

Biobanco del Sistema Sanitario Público de Andalucía
CONSEJERÍA DE IGUALDAD, SALUD Y POLÍTICAS SOCIALES

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THANKS

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