Presentation ISCIII

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PRECISESADS

Molecular Reclassification to Find Clinically Useful Biomarkers for Systemic Autoimmune Diseases

What is **PRECISESADS**?





PRECISESADS

Coordinator: Chris Chamberlain (UCB) Management Entity Head: Marta Alarcón (FPS)



F2F GA Meeting in Berlin, February 2015

Time: Start February 1st, 2014 (5 years)

Budget: 22.3 M€ (Equal EFPIA in-kind and IMI contributions)





The PRECISESADS Vision

 The Reclassification of the systemic autoimmune diseases (SADs) using OMICS approaches to find molecular diagnostic tools





The Problem: Systemic Autoimmune Diseases have partly shared genetics, shared biomarkers and signatures, delayed diagnosis and bad treatment responses with present day clinical criteria



Mix them together.....





Identify Differentiated Clusters of Individuals that will contain various proportions of patients with the diseases but with similar mechanisms



Project structure – Patients' cohorts





Molecular Reclassification to Find Clinically Useful Biomarkers for Systemic Autoimmune Diseases



The PRECISESADS objectives

- Unique set of data will be prepared from new samples
 - Challenge: organize the recruitment and clinical data of patients throughout 18 clinical centers in Europe; samples with various requirements (serum, plasma, urine, EDTA blood) including ethical, clinical and laboratory protocols
 - Challenge: flow cytometry needs to be done on fresh cells
- Full genomic data integration: transcript data (microarrays and RNASeq), genetic data, epigenetic data (methylation, ChIPSeq), flow cytometry data, metabolomic data (MS/LC and NMR), serology (antibodies, autoantibodies and cytokines)
 - Challenge: integrate different sources of data
- Preclinical models will be studied in a similar fashion posing similar challenges





WP2: C: Processing of PLASMA aliquots and freezing of total blood for



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Molecular Reclassification to Find Clinically Useful Riomarkers for Systemic Automitiume Diseases

RECRUITMENT NEWSLETTER

16th of June 2015



302 patients recruited



WP5: Fluorescence compatibility between cytometers

Use of 8-color cytometers with compatible optical benches:

-Beckman-Coulter: Navios, Gallios

-Becton-Dickinson: FACSCanto II, FACSVerse, LSR2, Aria



LASER	FILTRO	FLUOROCROMO				
405 nm	448/45	V450, Pacific Blue ^{1M}				
	528/45	V500, AmCyan, Pacific Orange ^{2M}				
488 nm	527/32	FITC, GFP, Alexa Fluor 488				
	586/42	PE/PI				
	700/54	PerCp-Cy 5.5/PerCp/7-AAD				
	783/56	PE-Cy7				
640 nm	40 nm 660/10 APC/AlexaFluor 647					
	783/56	APC-CY7/APC-H7				

FLUOROCHROMES USED IN THE STUDY

FITC	PE	PC5.5	PC7	APC	APC AF750	Pacific Blue	Krome Orange
525nm	575nm	700nm	770nm	660nm	780nm	450nm	550nm
Excitation 488nm				Excitation 638nm		Excitation 405nm	

Where we are today



Scientific level

- Established protocols for the recruitment of patients and their samples, for cross-sectional & Inception cohorts
- Obtained ethical approvals for all recruitment
- Carried out a pilot study for sample collection
- ✓ Carried out the Biobank and eCRF training on September 26th, 2014
- Established the web-based eCRF for the CS & IC cohorts
- Established the Data Governance Plan



Where we are today



Scientific level

- Flow Cytometric Analysis panels validation and optimization of flow cytometers - SOPs established
- Validation of Cellular Separation methods and SOP ready
- Definition of arrays for genotyping and gene expression including protocols for ChIP-SEQ and RNA-SEQ ready
- First results on control kidney biopsies
 - Extraction of RNA and proteins from all samples accomplished by end 2014
- Integration Programs installed on the PRECISESADS OMIC server.



We have Accomplished an Organized Structure and Follow-Up



PRECISESADS Work Packages

Strong co-operation between Public and EFPIA members

WP1_Management and coordination

- WP Leader: UCB (Chris Chamberlain)
- WP co-L: Prof. Alarcón-Riquelme: Management entity, FPS
- WP2: Biobanking and sample collection
- WP leader: FPS (Alarcón-Riquelme)- Andalusian Biobanking system (Blanca Miranda)
- WP co-L: Eli-Lily (Dr Ernst Dow)
- WP3: Clinical Data Management
- WP Leader: IRCCS (Dr Lorenzo Beretta)
- WP Co-L: SERVIER (Dr Laurence Laigle)
- WP4: Genomics, epigenomics and trascriptomics
- WP Leader: CSIC (Dr Javier Martin)
- WP Co-Leader: SARD (Dr Jozsef Karman (Sanofi/Genzyme)

- WP5: Flow cytometryc analysis
- WP Leader: UBO (Dr Jacques-Olivier Pers- Brest)
- WP Co-leader: Sanofi/Genzyme (Jozsef Karman)
- WP6: Proteomics, metabolomics & serology
- WP Leader: KI (Dr Johan Frostegård)
- WP co-leader: UCB (lan White)
- WP7: Tissue taxonomy and imaging analysis
- WP Leader: UCL (Dr. Bernard LAUWERYS)
- WP co-leader: BAYER Pharma (Fiona McDonald)
- WP8: Bioinformatics and biostatistics
- WP Leader: QuartzBIO (Dr Jerome Wojcik)
- WP Co-leader: BAYER (Jörg Muller)
- WP9: Knowledge dissemination & training
- WP Leader: FPS (Prof. Alarcón-Riquelme/Lazslo Kovacs)
- WP co-leader: UCB (lan White)





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USEFUL LINKS

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ABOUT PRECISESADS PARTNERS NEWS & MEDIA EVENTS

Collaboration between the public academy and pharmaceuticals

Supported by the Innovative Medicines Initiative (IMI)

Welcome to PRECISESADS

PRECISESADS is an EU project formed by 21 academic, 2 SMEs and 5 industrial

UPDATE! News & Events

PATIENT RECRUITMENT HAS SARTED!

PRECISESADS Partner profile

CHP

Thank You



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