Research Areas

- Biomarker Research
  - Diagnostic
- Basic Research

At a Glance

- Status: Active Consortium
- Year Launched: 2014
- Initiating Organization: Innovative Medicines Initiative
- Initiator Type: Government
- Location: Europe

Abstract

Inflammatory autoimmune diseases such as rheumatoid arthritis and lupus affect 1-3 percent of the population, and although treatments exist, they are costly and have a number of serious side effects. There is growing evidence that many of these conditions may be incorrectly classified. The PRECISESADS project will study 2,500 people with various autoimmune diseases, gathering data on the molecular causes of their disease as well as their clinical symptoms. Using this information, the project will pave the way for a new classification of these diseases, something that will allow doctors to offer patients more personalized treatments at an earlier stage of their disease. The project duration is 60 months.

Mission

The goal of this project is to use the power of “-omics” and bioinformatics to identify new classifications for diseases known to share common pathophysiological mechanisms. Such knowledge has not been applied to individual patients, depriving them of potential benefits in terms of the use of new therapeutic agents that are being developed for one disease but cannot be applied to another because of current clinical classifications.
PRECISESADS is investigating individuals with systemic lupus erythematosus (SLE), systemic sclerosis (SSc), Sjögren’s syndrome (Sjs), rheumatoid arthritis (RA), primary antiphospholipid syndrome (PAPS), and mixed connective tissue disease (MCTD), jointly known as systemic autoimmune diseases (SADs).

**Consortium History**

January 2014: Project start date  
February 2014: Kickoff meeting in Brussels

**Structure & Governance**

This project is divided into nine Work Packages (WPs), with the ninth being the project output:

WP1: Coordination (Project Management and Governance)  
WP2: Sample Collection and Biobanking  
WP3: Clinical Data Management  
WP4: Genomics, Transcriptomics, Epigenomics  
WP5: Flow Citometry and Cellular Separations from Blood of Patients with SADS and Preclinical Models  
WP6: Proteomics, Metabolomics, and Serology of SADS  
WP7: Tissue Taxonomy and Imaging Analysis  
WP8: Data Analysis, Bioinformatics, and Biostatistics

Work on preclinical models done in parallel runs through WPs 4 to 8 transversally.

With the aim to molecularly reclassify SADs, PRECISESADS has designed a structure that has, at its base, two patient cohorts, one for discovery (cross-sectional) and one for validation (inception) and a pre-clinical set. To do this, the overall project follows a structure with WPs 2-7 representing activity cores that are fed by the cohorts and converge onto WP8 on bioinformatics and biostatistics. WP8 integrates the data from the cores and ends up in the validated, systemic, and tissue-based taxonomies, and therefore constitutes the central axis of the project. WP1 and WP9 are transversal
throughout the whole project and oversee through management structures the correct function of the parts, including monitoring of ethical and regulatory approvals. WP9 is the output WP with dissemination of results and evaluation/incidence reports to the advisory boards, scientific community, and stakeholders with adequate training on all aspects.

PRECISESADS gathers a well-balanced partnership and focuses on diseases that have been little studied but that share pathogenic mechanisms. While SLE is a prototype systemic autoimmune disease, its clinical relationship with scleroderma, SjS, RA, PAPS, and MCTD is well documented. The pharmaceutical members are completely integrated in the activities, and two small to medium-sized enterprises (SMEs) take care of important aspects of the project. The research complementarities are ensured with “-omics” cores, clinical teams, and a biostatistics team:

Financing

This project is funded by the Innovative Medicines Initiative (IMI), a public-private partnership between the European Union (EU) and the European Federation of Pharmaceutical Industries and Associations (EFPIA), resources of which are composed of financial contribution from the EU Seventh Framework Programme and EFPIA companies’ in kind contribution. Large pharmaceutical companies participating in IMI projects do not receive IMI funding. IMI contributed €10.0 million, EFPIA contributed €9.9 million in kind, and other sources contributed €2.8 million, for a total cost of €22.7 million.

Intellectual Property

The IMI intellectual property (IP) policy governs the IP regime of all projects funded by the IMI Joint Undertaking. To assist with specific IP queries, IMI has set up a dedicated IP Helpdesk, which can be contacted by emailing IMI-IP-Helpdesk@imi.europa.eu. The IMI IP policy can be accessed at http://www.imi.europa.eu/sites/default/files/uploads/documents/imi-ipr-policy01august2007_en.pdf

Data Sharing

According to IMI’s IP policy, the participants undertake to disseminate the data as soon as reasonably practicable but not later than one year after the termination or expiry of the project. The project
agreement shall include a description of the material, which must be disseminated in accordance with the IP policy and referenced in the grant agreement. If the participants do not disseminate within such time periods without good reason, then the Executive Office has the right to disseminate such results in a manner consistent with the grant agreement.

Results will be widely shared to deliver a new molecular taxonomy of SADs that can be directly accessed by physicians, patients, regulators, and drug developers to help define, refine, and discover better treatments for SADs. In order to achieve this, PRECISEADS is will inform punctually and regularly on the project implementation and results and will involve stakeholders from Europe in its activities in order to broaden the projects’ impact and increase opportunities for cooperation.

Impact/Accomplishment

By means of state-of-the-art, high-throughput technologies and the application of integrative bioinformatics strategies PRECISESADS expects to yield major impacts at multiple levels. The following outcomes will directly result from the activities of the PRECISESADS consortium:

Links/Social Media Feed

- Homepage: http://www.precisesads.eu/
- Other website: http://www.imi.europa.eu/content/precisesads
- Facebook: https://www.facebook.com/profile.php?id=100008204445009
- Twitter: https://twitter.com/PRECISESADS

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