

HORIZON
2020

Launching the Breakthrough in Lupus Diagnostics

Informe

Información del proyecto

ClarifyLupus

Identificador del acuerdo de subvención:
854501

[Sitio web del proyecto](#)

DOI

[10.3030/854501](https://doi.org/10.3030/854501)

Proyecto cerrado

Fecha de la firma de la CE

26 Febrero 2019

Fecha de inicio

1 Marzo 2019

Fecha de finalización

31 Agosto 2019

Financiado con arreglo a

INDUSTRIAL LEADERSHIP - Innovation In SMEs

Coste total

€ 71 429,00

Aportación de la UE

€ 50 000,00

Coordinado por

CLARIFY ANALYTICAL LDA



Portugal

Periodic Reporting for period 1 - ClarifyLupus (Launching the Breakthrough in Lupus Diagnostics)

Período documentado: 2019-03-01 hasta 2019-08-31

Resumen del contexto y de los objetivos generales del proyecto

Lupus is a devastating chronic autoimmune disease that, if not properly controlled with efficient therapies, can lead to organ failure and death. However, currently, the diagnosis of lupus can take up

to 6 years and during this period the disease not only progresses but also becomes more severe which results in less therapeutic efficiency.

Our solution, ClarifyLupus, is a test for Lupus diagnosis that consists of the detection and quantification of the Lupus-specific biomarker by mass spectrometry. Whilst the state-of-the-art existing solutions focus on the detection of antibodies and have been associated with low specificity, ClarifyLupus relies on monitoring a lupus-specific event, thereby offering less false positives/negatives.

Trabajo realizado desde el comienzo del proyecto hasta el final del período abarcado por el informe y los principales resultados hasta la fecha



During this 6 month project our main objective was to evaluate some important aspects for the technological feasibility of our biomarker and requirements for production scale-up, certification and go-to market. We first focused on the identification of alternative consumables providers and mass spectrometer vendor partners prior to the clinical trials. Moreover, we conducted a thorough IP research with a specialised legal team to define an IP strategy that will create competitive barriers and thereby prevent our competitors from capturing our market share. We also worked towards identifying partners for clinical study and certifications needed to operate in EU and USA. Finally, we created a comprehensive Work Plan for the Phase 2 project, clearly defining tasks, and resource and timing for assignments. We conducted a risk assessment, including likelihood, impact and contingency plans. Analyse the implemented status-quo as one of the major obstacles to growth and critical mass adoption.

Avances que van más allá del estado de la técnica e impacto potencial esperado (incluida la repercusión socioeconómica y las implicaciones sociales más amplias del proyecto hasta la fecha)



With the current state-of-the-art solutions, Lupus patients deal with misdiagnosis and with the inability to prevent/predict flares. At ClarifyAnalytical our mission is to translate our knowledge in toxicology and analytical technologies into useful clinical tools to diagnose Lupus earlier and more accurately than is currently possible.

Our research and tests have proven the Lupus-specificity of our biomarker by analysing blood samples from Lupus patients and other confounding diseases, and healthy groups. In fact, our biomarker was absent from blood samples of healthy volunteers and rheumatoid arthritis patients analysed and were identified in 90% of lupus patients analysed enabling early lupus diagnosis, with less false positives and negatives, improving performance over currently available tests. Although our competitors are conducting research on Lupus biomarker discovery, they are all focused on autoantibodies and immune response biomarkers identification that are highly unspecific.

ClarifyLupus allows Lupus patients to ensure on-time and easy diagnosis. A proof-of-concept is at its early stage where a large cohort of lupus patients, confounding diseases cohorts and healthy groups are currently being recruited, for determining accurately the specificity of our biomarker.

The logo for CLARIFY ANALYTICAL is a dark purple square. Inside the square, the word "CLARIFY" is written in a large, bold, white sans-serif font. Below it, the word "ANALYTICAL" is written in a smaller, white sans-serif font.

CLARIFY
ANALYTICAL

clarify.png

Última actualización: 11 Noviembre 2019

Permalink: <https://cordis.europa.eu/project/id/854501/reporting/es>

European Union, 2025