

Una manera de hacer Europa



BUENAS PRÁCTICAS

Actuaciones Cofinanciadas

Precision diagnosis and treatment in infectious diseases and cáncer

Andalusian Health Service

**Programa Operativo
Plurirregional de España**

Año 2022

Fondo Europeo de Desarrollo Regional

BEST PRACTICE. PRECISION DIAGNOSIS AND TREATMENT IN INFECTIOUS DISEASES AND CANCER

The initiative "**Precision diagnosis and treatment in infectious diseases and cancer**" (DyTPrecision) is divided into several projects aimed at solving relevant public health problems in the fields of infectious and oncological diseases, therefore it is composed of two associated lines of action, which are closely related to each other, but with independent implementation processes.

The first line is ANALYSIS OF SUSCEPTIBILITY AND ANTIMICROBIAL RESISTANCE (ASURANT).

The general objective of this line is the development and manufacture of a rapid diagnostic method, which can establish the sensitivity of bacteria to antibiotics, in order to improve the prediction of patients with severe infections, thereby reducing their mortality and morbidity.

The second line consists of a NEW DIAGNOSTIC SYSTEM FOR LIQUID BIOPSY (LIQUID BIOPSY).

The main objectives of this line are to obtain innovative platforms that allow the identification and characterization of biomarkers in blood (CTCs and ctDNA), for the personalisation and monitoring of patient treatment; and the development and implementation of a comprehensive clinical protocol for the determination of blood biomarkers (CTCs, exosomes, miRNA and free DNA), which will go from sample collection to clinical decision.

These are two lines of action that raise innovative and high added value solutions in the field of precision medicine, in order to address unmet challenges in the approach of these diseases.

DyTPrecision falls within the scope of an agreement signed on the 4th of December, 2017 between the Andalusian Health Service (hereinafter SAS) and the Economy, Industry and Competitiveness Ministry, now Science and Innovation Ministry (hereinafter MCIN). It has a total budget of 6,040,784.00€. This project is part of the Demand-Side Innovation Promotion Program (FID SALUD) of the MCIN, co-financed by the European Union with 80% through the European Regional Development Fund (ERDF), Multiregional Operational Programme of Spain (POPE) 2014-2020, for an amount of 4,832,627.20€, as well as with SAS funds.

This project with two lines of work is presented as a Best Practice because it meets the following criteria:

1. THE ACTION HAS BEEN PROPERLY DISSEMINATED AMONG BENEFICIARIES, POTENTIAL BENEFICIARIES AND THE GENERAL PUBLIC.

The DyTPrecision project has a Communication and Dissemination Plan that covers from its initial phases to the end of its implementation, including the further analysis of the final results. The information of the funds received from Europe has been disseminate through: the beneficiary's website; the two specific websites (one for each line of work); on an information plaque, which also shows the ERDF co-financing; in public events dedicated to the projects presentation; in social networks and in the media.

Thus, the SAS web portal includes, on its homepage, an image with the logo of the European Union, which is visible as soon as it is opened. It leads to a page dedicated to all the projects funded with European funds, which includes links to the different programmes, as well as to regulations and other sections of interest, such as Anti-fraud Measures.

Links:

SAS website homepage: <https://www.sspa.juntadeandalucia.es/servicioandaluzdesalud/>

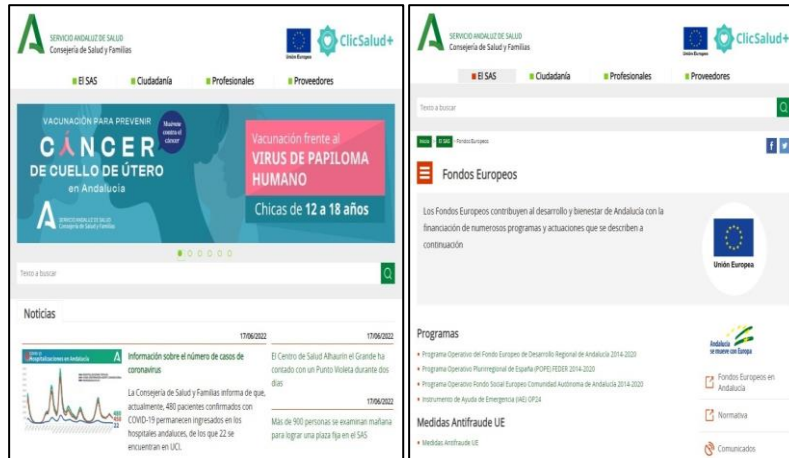
European Funds page on SAS website: https://bit.ly/SAS_Fondos_Europeos

POPE page on SAS website: https://bit.ly/SAS_POPE

ASURANT and Liquid Biopsy page on SAS website: https://bit.ly/SAS_DyTP

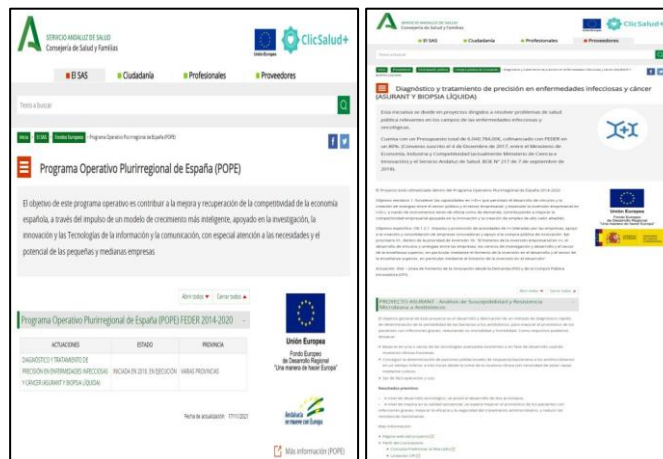
ASURANT website: <http://www.asurantproject.com/>

LIQUID BIOPSY website: <http://www.liquidbiopsyproject.com/>



SAS website homepage European Funds page on SAS website

On the section dedicated to the Spanish Multi-regional Operational Programme (POPE) on the SAS website, by clicking on the DyTPrecision project's link it is possible to access to the section which describes the two lines of work that comprise this project. It explains the objectives and expected results of both projects, and provides regulatory and funding information in accordance with legal obligations and best practices in terms of dissemination and transparency: regulatory agreement, budget, ERDF funding (programme, objectives, co-funding rate), anti-fraud measures, etc. In addition, a link to each project's own website is included.



POPE section on SAS website DyTPrecision section on SAS website

In addition to the development of the sections described above (on the beneficiary's website), two specific websites have been created:



ASURANT website Liquid Biopsy website

The projects co-funding with ERDF funds is described on the home page of each of them.

In order to enhance the promotion and dissemination of the projects, and to know the web impact of both portals as well as of the project's specific sections available on SAS website, the Google Analytics tool has been configured to collect statistical data on website's access. These data act as impact indicators when launching different messages and events. And they help to define improvements in the communication strategies of both project lines.

An information plaque about both projects (A3 format) has been installed in the main building of SAS (18 Constitution Avenue, Seville).



The project information has been disseminated on several websites related to the field of health, innovation and medical outreach. For example, in *Agenda de la empresa*, *Redacción Médica*, *Con Salud*, *Planta Doce* and *El Global*.



Digital newspaper



Youtube video



Website of the selected company

Social networks as Twitter, YouTube and LinkedIn, have disseminated the advances made in both lines, ASURANT and LIQUID BIOPSY.

Both project lines have been presented publicly on several occasions so far, in different forums, congresses or conferences, such as: BioSpain 2018, Transfiere Forum 2019, XXVI National Conference on Innovation and Health in Andalusia (SEIS), Transfiere Forum 2020, etc. They have also been presented at specific project's reporting events, about different stages reached in the projects, such as: Preliminary Market Consultation Information Workshops, Preliminary Market Consultation Conclusions Presentation Event, etc.

In all of these acts, the two sub-projects have been explained with presentations which included the logos of the EU and the Ministry of Science and Innovation, as well as information on their ERDF funding rate.

A schedule of communication actions to be carried out throughout the life of both sub-projects has been established, including promotional actions such as informative videos, use of promotional material, as well as the organisation of an event to present the results at the end of the project. These actions intend

to promote the projects and their ERDF funding through different channels, including social networks.

In addition, the selected companies also communicate and disseminate the projects' information through their corporate websites and social media, referring to their ERDF funding.

2.- THE ACTION INCORPORATES INNOVATIVE ELEMENTS.

The two lines of action provide highly relevant innovative aspects in their development and in the results achieved for the precision diagnosis and treatment in infectious diseases and cancer.

In the case of ASURANT, current rapid diagnostic methods to determinate the sensitivity of bacteria to existing antibiotics are slow, resulting in a diagnosis and treatment that sometimes arrives to the patients too late, and can even lead to their death. The aim of this project is to find much faster diagnostic methods (less than 3 hours), in order to offer the patient a tailored treatment, much sooner and, therefore, with a higher rate of recovery and survival. Besides, the controlled and optimised use of medicines will reduce the rate of acquisition of resistance to them.

In the case of LIQUID BIOPSY, the innovation challenge consists of the development and incorporation of new methodologies that overcome the limitations of current biopsies through a new approach aimed, not at obtaining a biopsy of tumour tissue, but at identifying biochemical signals from the tumour in the patient's body fluids, which has been called "liquid biopsies". This technology, which is less invasive for the patient, must be implemented in a simple way and at a cost that guarantees its sustainability and accessibility within the Andalusian Public Health System (APHS). The development of this technology would allow to establish personalised treatments for patients with the types of cancer addressed, thus improving results; as well as to extend and improve diagnosis (e.g. new screening policies), treatment response monitoring and relapse prognosis.

3.- ADEQUACY OF THE RESULTS OBTAINED TO THE ESTABLISHED OBJECTIVES.

ASURANT

The proposals awarded by SAS, as contracting body in the tender, reflect a high degree of similarity to the objectives initially set out in the project. Therefore, the successful tenderers have completed the development of devices (currently in the validation phase) that will allow, quickly and easily, whether a sample is positive or negative for the study targets to be determined. The proposed panels will show if a sample has one or more of certain pathogens, together with the main resistance coding genes to different groups of antibiotics, including third and fourth generation antibiotics.

The analysis and interpretation of the results will be carried out automatically, using the equipment's software, in accordance with the manufacturer's operating instructions.

LIQUID BIOPSY

This line proposes the development of innovative solutions based on two different technologies, in order to encourage different solutions and increase the chances of success.

As in the Asurant line, the Research and Development (R&D) services proposed by the successful tenderer of Liquid Biopsy are aligned with the objectives established in the project. Therefore, the chosen companies propose the development and validation of new diagnostic kits, which allow the establishment of appropriate clinical guidelines on liquid biopsy analysis, based on the detection and characterisation of circulating tumour DNA (ctDNA) and circulating tumour cells (CTC).

The methodological proposals will allow the identification of the main genetic alterations of proven clinical evidence in therapy, prognosis or diagnosis in patients affected by lung, colon and breast cancer.

4.- CONTRIBUTION TO THE RESOLUTION OF A PROBLEM OR WEAKNESS IDENTIFIED IN THE TERRITORIAL AREA OF IMPLEMENTATION.

ASURANT

At the healthcare level, the proposed solutions considerably reduce determination times, therefore

speeding up the diagnosis by the hospital's microbiology service. At the same time, the characterisation of the samples and the precision of the technique will allow clinicians to make better decisions on the antibiotic therapy to be administered to the patient, thus favouring their recovery and, at the same time, reducing all the problems associated with antimicrobial resistance due to the wrong use of antibiotic-based treatments.

Overall, a reduction in morbidity, mortality and healthcare costs is expected. In addition, a considerable reduction in nosocomial outbreaks caused by antibiotic resistant micro-organisms is expected as well.

LIQUID BIOPSY

The strategy of approaching circulating tumour DNA (ctDNA) and circulating tumour cells (CTC) described will allow the generation of an innovative platform that facilitates the real execution of liquid biopsy in oncology clinical practice. The deployment of this technology in APHS centres will improve patient survival rates, by choosing the most appropriate therapy at the right time and by the real-time monitoring of the emergence of resistance mutations.

In addition, this technology will enable efficient spending on target medicines, as it will allow a routine efficacy monitoring, something that cannot be done with solid biopsies.

5.- HIGH RATE OF TARGET POPULATION COVERAGE.

ASURANT

Due to an excessive use of antimicrobials, microorganisms eventually lose their natural sensitivity to these agents, through the selection and transmission of various resistance mechanisms. If no action is taken and projects such as this one are not developed, according to estimates, 10 million people will die every year, by 2050, from antibiotic resistance.

The technology developed is expected to improve the diagnosis and treatment of hospitalised patients (especially in ICUs). It will be validated in the Virgen del Rocío (Seville) and Reina Sofía (Cordova) Hospitals and could be transferred to the rest of the health centres which are part of the APHS.

LIQUID BIOPSY

Cancer covers a range of diseases that have a major impact on our society, one out of two men and one out of three women will be diagnosed with cancer before the age of 75. WHO forecasts a 70% increase in incidence over the next 20 years.

In the case of Spain, with 247,771 cases in 2015, the estimated incidence for 2020 has been exceeded, being responsible for 27% of deaths in our country.

As mentioned above, current techniques for monitoring tumour disease and determining treatment response have many obvious limitations to assess the evolutionary process of cancer and metastasis in an agile, non-invasive and economically affordable way. Thus, liquid biopsy appears as a complementary tool and as an alternative when tumour biopsy is not possible.

The LIQUID BIOPSY project will provide the possibility of offering cancer patients a better, individualised and personalised treatment, extending and improving diagnosis, monitoring and prognosis, with a lower cost of the process and in a much more sustainable way for the APHS.

6.- CONSIDERATION OF THE HORIZONTAL CRITERIA OF EQUAL OPPORTUNITIES AND NON-DISCRIMINATION, AS WELL AS SOCIAL RESPONSIBILITY AND ENVIRONMENTAL SUSTAINABILITY.

The orientation and objectives of the two lines of action of DyTPrecision aim to develop technologies and infrastructures that enhance the sustainability of health systems and the improvement of the service offered to citizens. The action has sought innovative solutions that improve the current state of the art of the available on the market. It also has required that the technologies to be developed are affordable technologies and assumable by public health care systems.

Among its values and commitments, SAS contracting body assumes that the care provided to citizens must contribute to the achievement of equal opportunities between women and men, and it try to accomplish the same goal for its professionals. If it achieves the expected results, SAS would be the first public health system in offering the public precision medicine methodologies in oncological and infectious diseases.

Furthermore, in accordance with the criteria of equal opportunities and non-discrimination, the implementation of these two projects will be carried out in the same way in both male and female patients, and the benefits of their application will be obtained without any distinction as to the sex of the patient to whom they are applied. These principles are also taken into account throughout the implementation of both projects in the language used to communicate, inform and publicise the actions of SAS.

The successful tenderers hold ISO 9001:2008 and ISO 13485:2003 certifications for the manufacture of IVD products (in vitro diagnostics) under European standards. Therefore, the products derived from the developments carried out in this project, both reagents, packaging and machinery, will be environmentally friendly, unlike other similar diagnostic kits, which contain harmful components (solvents, intercalating agents, etc.) that must be treated appropriately for their elimination.

Finally, it is estimated that both project lines will reduce the environmental impact of current methods, on the one hand by allowing the optimised use of medicines and on the other by reducing the use of consumables: in LIQUID BIOPSY by reducing surgical interventions that are associated with sterility conditions and the use of single-use material; and in ASURANT by reducing the preparation of bacterial cultures and blood cultures that use high impact contaminated disposable materials.

7.- SYNERGIES WITH OTHER POLICIES OR INSTRUMENTS OF PUBLIC INTERVENTION.

The solutions proposed are also very much in line with strategies and policies to encourage innovation and the development of innovative solutions proposed by the Regional Ministry of Health and Consumer Affairs of the Andalusian Regional Government and therefore by the contracting body.

As an example, we could mention:

The ASURANT project is directly related to the strategy of the Integrated Programme for the prevention and control of healthcare-associated infections and appropriate use of antimicrobials: PIRASOA Programme. It is a healthcare quality programme, approved in Andalusia by the health authorities at the beginning of 2013 and during that year the design, implementation and dissemination throughout the healthcare system, including primary care and hospitals, was developed and became operational on the 1st of January, 2014. This programme has two objectives: on the one hand, to improve our use of antibiotics, which is an objective that the World Health Organisation has been warning about; on the other hand, to reduce hospital-acquired and healthcare-associated infections and, usually, infections caused by antibiotic-resistant bacteria. It was a pioneer in our country, has shown excellent acceptance by healthcare professionals and has partially achieved its objectives with very positive results. A progressive reduction in antibiotic consumption has been achieved. Moreover, it is known that the more antibiotic treatments are carried out, the more bacteria defend themselves and increase their resistance to antibiotics, but the programme has shown that this is reversible and this is great news.

According to data published by Regional Ministry of Health and Consumer Affairs of Andalusia in November 2019, the autonomous community has **reduced antibiotic consumption by 34% in primary care and by 4.6% in hospitals**; while the consumption of amoxicillin-clavulanic acid has been decreased by 34% in primary care and the use of carbapenems has been decreased by 11.6% in hospitals. The solutions generated by the ASURANT project are expected to further improve these results.

The LIQUID BIOPSY project is directly linked with the **Personalised Medicine Programme**. This programme, promoted by the Regional Ministry of Health and Consumer Affairs, has as its main mission the continuous improvement of diagnosis, prognosis and the optimisation of individualised patient treatment, enabling the development of new knowledge in the form of biomarkers, algorithms and software for the application of genomic medicine in the health system, which allows to address new challenges as they arise.

Precision medicine is a strategic line at national and European level, and its application in the fields of infectious diseases and cancer is among those with the greatest application and impact. Some of these strategies and policies are the Recovery, Transformation and Resilience Plan (PERTE) for cutting-edge health, the Spanish Strategy for Science, Technology and Innovation (EECTI) 2021-2027, the Andalusian Health Research and Innovation Strategy 2020-2023 and the Smart Specialisation Strategy for the Sustainability of Andalusia for the period 2021-2027 (S4 Andalusia).

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