TIMBRE DEL ESTADO
0,03 EUROS
TRES CÉNTIMOS DE EURO
ON4665704
CLASE 8.ª
FEDER
Fondo Europeo de Desarrollo Regional
Una manera de hacer Europa
UNIÓN EUROPEA
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ANNEX I. ASURANT

The following specifications of a non-covered need are approximate and are formed during signature of the agreement with information and knowledge that SAS (Andalusian Health System) had at that time. Therefore, these specifications may evolve in step with updating of the state of the art in each one of the fields.

1. Precision medicine in infectious diseases

One of the greatest medical steps forward in the past century was the discovery and development of antimicrobials, initially with sulphamides and penicillin. Antimicrobials have saved millions of human lives and permitted great progress in modern medicine such as transplants, complex surgery and cancer chemotherapy. Fleming himself warned about development of resistance by bacteria against antimicrobials, benefits for individual patients were considered to be more important than "potential" problems with resistance in the future. In fact, as time went on and new antimicrobials were developed, there was a belief that even if they developed resistance, there would always be new antimicrobials that would be able to deal with the problem. Unfortunately, this has not been so, and in 2014 the Director of the WHO defined bacterial resistance as one of the greatest threats for world public health. This year, the Spanish Society of Infectious Diseases and Clinical Microbiology (SSIDCM), has carried out a study in 82 hospitals in the country to know the real impact of infections caused by multi-resistant bacteria (MRB) during one week, finding 903 patients with these infections of which 177 (19.6%) died. With these results, the SSIDCM carried out an estimate for 2018, assuming that the incidence and mortality of these infections would remain stable throughout the year, and in the rest of the hospitals of the country. If so during 2018 in Spain, 180.600 people will suffer a MRB infection and of these 35.400 will die. A recent report estimates that if the trend continues in 2050 a million Europeans will die each year from MRB infections, surpassing cancer as first cause of death[2].

In this worrying global setting, Spain is the leading world consumer of antibiotics without any epidemiological reason to justify this[3], and one of the leading countries in Europe with MRB[4] infections.

The battle against bacterial resistance is a world priority. Research is one of the chief measures to invent new antimicrobials that are active against these bacteria and to accelerate microbiological diagnosis of them, including the determination of sensitivity of the bacteria causing infection to antimicrobials. Because in patients with serious infections, effective early antibiotic treatment is key to reduce mortality, and this is difficult to establish in an empiric way in MRB infections.

Because of this application of the PM, will enable early diagnosis of the etiology and sensitivity of the bacteria cause of the infection, to indicate in an immediate way, most effective antibiotic

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treatment and reduce the mortality of these patients and at the same time contribute to reduce bacterial resistance with optimization use of antibiotics.

2. State of the art in Diagnosis Susceptibility Devices and Resistance to Antimicrobials

A key concept in the field of infectious diseases is identification of the causal organism with later proof of antimicrobial sensitivity of it. This information is crucial for selecting the most suitable antimicrobial and indicate its administration within the first hours after diagnosis of the infection. Kumar and colleagues proved that in patients with septic shock, every hour of delay (during the first 6 hours) in administration of the most suitable antimicrobial, reduces the chances of survival of the patient by 7.6%. Standard microbiological techniques for identification of microorganisms is based on phenotype methods, and require at least 24-72 hours from the moment of obtaining the clinical simple to produce final results, in comparison to fast diagnosis tests, that provide final results in minutes or few hours. Studies have shown that fast microbiology tests benefit individual patients by allowing best optimization of antimicrobials, which in turn can cause a reduction of mortality,

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shorter hospital stays and lower hospitalization costs. Microbiological tests are considered "game changers" and represent an important step forward in treatment of infectious diseases.

3. Not covered need

Immediate microbiological diagnosis in patients with serious infections is essential for choosing the most effective and safest antimicrobial for that patient for the following reasons:

- Serious infections by MRB have a worst prognosis.
- Standard microbiological diagnosis achieves results that enable the safest choice of the most effective and safe antibiotic in 24-72 hours, too late in serious infections.
- Because early appropriate antibiotic treatment is a protective factor against death in these infections.
- Therefore, new methods are needed to carry out fast diagnosis of the sensitivity of the bacteria to antimicrobials.

4. General Goals

Development and manufacture of a fast method for diagnosis of sensitivity of bacteria to antibiotics, to improve prognosis of patients with serious infections, reducing their mortality and morbidity.

5. Specific goals

The solution aimed should:

i. Be based on one or several existing advanced techniques or in development using human clinical samples.

ii. Achieve determination of the population patterns of bacterial response to antimicrobials in a time span of under TWO HOURS from the time of taking the clinical simple, without the need to isolate strains by cultivation.

iii. Easy application and use.

6. Expected results

i. Improve prognosis of patients with serious infections.

ii. Improve efficiency and safety in antimicrobial treatment.

iii. Reduce bacterial resistances.

7. Impact indicators to be considered

i. Time until obtention of bacterial sensitivity to antimicrobials (hours).

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ii. Mortality (percentage).

iii. Total hospital stay and ICU stay (days).

iv. Average cost of hospital stay and in ICU (euros).

v. Improved use of antibiotics by patient (percentage).

vi. Cost of antibiotic treatment (euros).

Mrs. María de la Presentación Aguilera Crespillo, Official Sworn Translator-Interpreter appointed by the Spanish Ministry of Foreign Affairs and Cooperation, does hereby certify that the prior translation is a faithful and complete translation from Spanish into English of the original document.

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