



ANTISUPERBUGS

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PROVINCIA AUTONOMA DI TRENTO



D1.5 ANTISUPERBUGS Phase 1

Summary of main results achieved

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This report intends to describe the work undertaken during the contract and to inform about the projected budget and its execution. Hence, contractors shall describe what work was completed during the relevant phase project and why this was important, how funds were spent with reference to the plan and the next steps to be taken within the ANTISUPERBUGS project.

The main evidence to be provided are about:

- a) the work undertaken, its success in meeting the project's agreed objectives and provide information on the work so that this can be used in the assessment of further applications (if required and appropriate);*
- b) the use of resources and expenditure and,*
- c) the comprehensive project description to be shared with stakeholders and those that may help further commercialization.*





Deliverable D1.5: End of Phase 1

Results & conclusions

Report main results and lessons learned for publication.

Contactors

1. Main Results: The innovative solution *(mark parts that are not suitable for publication purposes)*.

The innovative solution (in its current form):

The CULTURE project involves the development of a comprehensive platform to support healthcare professionals in their efforts to minimize the pace of resistance. This will be done not only by studying emergent microorganisms and resistance mechanisms, but also through diagnostic technologies like advanced sensing devices and information systems with capacities to gather information from different clinical datasets and to monitor and prevent infectious episodes in a connected and interoperable way. The solution is the result of a combination of different technologies

- 1) A real time detection system for the top priority pathogens identified in the ANTISUPERBUGS health challenge based on Photoionization detection, a technology with high sensitivity and that allows miniaturization, low energy consumption and that it has all attributes to become a real-time and portable technology.
- 2) A digital solution that will integrate, in a single point and with high interoperability, the data obtained from the CULTURE sensing device as well as other relevant datasets.
- 3) A smart and efficient surveillance system, able to exploit the combined data gathered from the different sources and to support healthcare professionals on their daily decisions regarding how to manage patients, infectious episodes, and Antimicrobial Stewardship programs.

Where exactly lies the innovativeness in the solution: In which ways and to which extent does the solution go beyond what existing solutions can achieve

The project involves very disruptive technologies. Main R&D activities are concentrated on the development of the sensing device. CULTURE will explore new energy sources or the combination of different sources that have not been explored before. These R&D activities involve the study of a combination of PID lamps for the ionization and detection of the complex mixture of VOCs that are released by bacteria in real hospital environments.

The project will also explore the application of the latest computational methods and algorithms to improve the selectivity performance indicators of the sensing device. R&D on Artificial intelligence will be extended to the development of smart Local control and Surveillance systems.

The level of innovativeness of the CULTURE solution is increased through a brand-new ICT solution that will integrate all information related to Hospital infectious episodes. This information not only includes hospital datasets but also the new data that will be obtained by the CULTURE sensing device. As far as we know nobody has developed a similar technology so far.

The degree of innovation: indicate if your innovative solution is (a) a totally new product / service / process / method; (b) an improvement to an existing product / service / process / method; (c) a new combination of existing products / services / processes / methods (d) a new use for existing products / services / processes / methods), (e) otherwise

The CULTURE project intends the development of a comprehensive solution to offer a unique value proposition to HCWs. The comprehensive solution is a totally new product that is the result of a combination of existing technologies (mostly open source technologies integrated in the ICT solution) and radical new technologies (mostly integrated in the sensing device). Therefore, we are working on a totally new product. This new product will also open new services. For instance, the combination of the PID sensing technologies and the computational models developed under the ANTISUPERBUGS project could also be commercialised through new surveillance services for the anticipation of infectious episodes in hospitals.

2. Main Results: Benefits obtained

Provide a short description (mark parts that are not suitable for publication purposes) of any benefits that you obtained from participating in the procurement.

The ANTISUPERBUGS Phase 1 gave us several benefits

- i) Explore with higher level of detail all implications related to the sensing device. We have worked on the development of this technology considering not only classical R&D procedures but also paying special attention to the specific requirements that are demanded by the ANTISUPERBUGS RfT. We have therefore designed a technology that is more oriented to the uncovered clinical need and the already identified user preferences
- ii) Phase 1 also gave us the possibility to advance with the main detection technology that will be incorporated to the sensing device. We have investigated about the current limitations of the available commercial products that are also based on PID detection, developing a new R&D line to attain higher sensitivity and selectivity limits.
- iii) Phase 1 also gives us the opportunity to implement more R&D collaborations among the teams of the three members of the CULTURE partners. We have found especially synergies to apply the research on Artificial Intelligence to the sensing device as well as to the ICT solution.
- iv) Phase 1 gave us also the opportunity to establish new collaborations through subcontracting activities for phase 2 and phase 3: We have taken this decision to cover part of the gaps identified during phase 1. It is better to take decisions about subcontractors during phase 1, because you have a clearer idea about your technology.
- v) We have gained a better knowledge about the health challenge identified by the ANS team. During Phase 1 we have been in contact with several experts, getting a better understanding not only about infectious disease but also about the market, potential competitors, hospital protocols, etc.
- vi) We have also gained knowledge about the CRO market. CROs will play an important role during phase 3. The deliverable about how to select CRO in phase 3 was highly useful to understand the value of these companies during the product development of a medical device.
- vii) Phase 1 also served to create new teams within our consortium that were not initially considered in phase 0. Particularly we created a Quality and Ethics team to address some of the challenges raised by ASB in these fields.
- viii) Finally, the Phase 1 also served to have constructive discussions about the implementation of an IPR strategy. The legal and technology transfer teams of the three organizations involved in CULTURE discussed from the very beginning about the background and foreground knowledge related to our project, helping us to define a clear IPR strategy for the future exploitation of the potential results .

Getting easier access to (a new segment of) the public procurement market *(did the procurement enable you to work with procurers/end-users that you were not working with beforehand)*

We are at a very preliminary stage, so we have just had a reduced number of contacts with other procurers. These contacts started with organizations and key people that have worked with us in the past because the challenge raised by the ASB is of higher interest. In other words, infectious disease and antimicrobial resistance is a major problem and there are many hospitals demanding new solutions and investigating about new technologies and protocols. For that reason, we contacted the people who already know because it was not necessary to contact a specific expert from a very distant location working on a specific technology.

Other benefits: complete if applicable

Finally, the ANTISUPERBUGS Phase 1 helped us to better design a technology with a great potential thanks to the unique combination of modular components and services. The design considered not only technical aspects but also the requirements defined by the ASB team as well as an analysis of its market potential. We have also realized other funding opportunities to continue with our R&D strategy in case of ASB Phase 2 withdrawal.

3. Lessons learned

Provide a short description (mark parts that are not suitable for publication purposes) of any lessons learned from participating in the procurement.

PCP is an outstanding tool to promote innovation in SMEs. The methodology in three phases reduces development risks and increases the feeling of competition. In our case, the feeling of competition increased

the commitment level of our team (three very different organizations), so we expect to attain better results in the development of the CULTURE technology.

PCP also helps companies to get a good understanding of public and private market. On the one hand, public procurers identified a health challenge not well covered with the existing technologies and this challenge represents an inspiration to develop new risky ideas. On the second hand, participants enter in contact with other organizations with experience in the health challenge. Consequently, the PCP the contractors and the procurers get highly valuable knowledge through this interaction.

PCP demands real R&D and disruptive technologies. Companies should interact with top researchers and carry out an extensive literature review, get a deep knowledge of the latest scientific discoveries in the field and enter in contact with R&D groups or specialized startups. These fruitful collaborations can be extended to other innovation projects and challenges.

PCP also serves to rethink how R&D and product development is done in a particular company. Some companies initiate R&D activities with internal resources or through a R&D national or European grant, but PCP requires a different approach. From the very beginning, PCP projects force the parties involved in the project to discuss about the commercialisation strategy, the IPR management and to reach agreements among the project partners on future exploitation strategies, even before the collaboration starts. Besides companies must think in important aspects like ethics, data management, data security, etc. In our view and comparing PCP calls with national or European grants, the level of exigency is higher in PCP calls, but the rewards can be also higher.

4. Final remarks *(not for publication purposes, to assess how further EU support could best help you)*

What are remaining bottlenecks to commercialise your solution (e.g. certification, legislation etc.)

The development of health technologies is very complex, takes too much time and it is very expensive. Part of these complex and expensive process is due to the tedious and costly certification of health technologies. In our opinion, we are experiencing an explosion of ehealth technologies, and the regulatory bodies have not enough time and knowledgeable resources to speed up this process.

The acquisition of enough scientific evidence is also a significant bottleneck for companies of our size. The ANTISUPERBUGS PCP project will give us access to patients and hospital environments but this number and the time to validate the CULTURE technology will be clearly not enough. We need longer projects and more ambitious clinical studies.

Public Procurement of Innovation (PPI) calls can cover partially this bottleneck, but we believe that we need other innovation mechanisms and calls to promote clinical validations of health technologies across Europe through public Private Partnerships between hospitals and SMEs working in the health sector.

Another important bottleneck is related with the introduction of innovative digital solutions in public health systems. The number of public health systems that launch PCP and PPI tenders in Europe is extremely low. The commercialisation of innovative technologies is therefore very difficult because we will compete with other providers with less efficient technologies and they will probably win because they will offer a lower tender prices (not a better solution, neither a cheaper solution during the full technology lifecycle). We therefore need to incentivize PPI calls related to the PCP projects (with very similar health challenges).

What type(s) of assistance do you need to address those bottlenecks and grow your business / commercialise your solution more widely (e.g. EU regulation on x, finding investors, IPR help etc.)

The first and more important need is related with the political commitment to implement technologies that really provide benefits to patients and health professionals. Health systems across Europe are clearly unsustainable but the governments across EU are not really adopting ehealth strategies as it is required. The recent COVID-19 crisis has demonstrated that we need more technology and organizational models to provide better services at lower cost.

The political commitment needs to be backed by sustainable funding and new procurement practices for the implementation of eHealth solutions that compete in value and not in price.

As an ehealth company specialized in ehealth interoperability, we believe that there is still plenty of room for improvement in relation with the adoption of ehealth standards across Europe. The lack of interoperable datasets at scale reduces considerably the innovation capacity of European organizations to develop technologies that support patients, clinicians, payers, regulators, governments, and the society in general.

Other aspects like access to finance and IPR issues are also important, but the companies and entrepreneurs usually find mechanisms to overcome them.

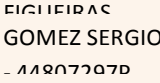
How important was the procurement for your business (could you have done it on your own?)

The ANTISUPERBUGS project represents an outstanding opportunity for the three organizations involved in the CULTURE consortium and particularly to BAHIA SOFTWARE, a company highly oriented to the health sector. The two R&D centres that are part of CULTURE are also discovering new R&D lines with enough potential to apply for additional funding: This is very important because the ASB challenge is inspiring in some way new research activities and new collaborations for these technological centres.

From a more business-oriented perspective, the ASB has also helped to identified and attractive niche market. Besides ASB is a European project and from the very beginning we have been working with and European (even global) ambition. We designed a technology to compete in the European market with the giants. During phase 0 and phase 1, we have analysed IPR factors, regulatory issues, standards and other important aspects like future scalability and relevant partnerships to deploy the technology across Europe and beyond.

Last but not the least, the ANTISUPERBUGS is also giving us knowledge about the different ehealth systems across Europe, how are they organized, what are the pros and cons of the Beveridge and Bismarck models and how these systems impact on budgets, purchasing powers and procurement practices.

The organizations that participate in the CULTURE consortium would never have initiated or developed a such ambitious project like CULTURE without ANTISUPERBUGS.

Compiled by:	Position	Date of signature	Signature
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