An intelligent network of Volatile Organic Compounds (VOC) sensors for Surveillance & Infection Control in healthcare facilities

D1.5 Summary of the Main Results Achieved by Sens4Care Consortium and Conclusions from Phase 1

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Introduction 3
The Innovative Solution 4
Sens4Care Solution Design (Phase 1) 4
Innovative Aspects of the Solution 5
Outputs Achieved in Phase 1 5
Forecast for Phases 2 and 3 6
Maturity and Commercialisation 6
Technology Readiness Level (TRL) Achieved 6
Intellectual Property Rights (IPRs) 6
Regulatory Compliance 6
Potential for Commercialisation 7
Conclusions from Phase 1 7

INTRODUCTION

This deliverable aims to summarise the main results and lessons learnt by the SENS4CARE consortium – Tech4Care (www.tech4care.it) and Sens.Solutions (www.sens.solutions) – during the Anti-Superbugs PCP Phase 1 (March-May 2020).
The deliverable is structured as follows. First, it provides a brief description of the Sens4Care solution as conceived and designed. Second, it offers a short analysis of technological value and business potential of the solution. Finally, conclusions are drawn from the R&D work concluded in Phase 1.

THE INNOVATIVE SOLUTION

SENS4CARE SOLUTION DESIGN (PHASE 1)

The Sense4Care (S4C) consortium aims to develop a new ground-breaking "Surveillance & Infection Control Systems" targeting Multi-Drug Resistant Organisms (MRDOs). S4C will be a solution able to:

- detect most common MDROs in critical hospital settings;
- support health care professionals and managers to improve hygiene and better control environment;
- train staff, patients and visitors on appropriate behaviours for primary, secondary and tertiary prevention.

The ultimate goals of the S4C solution are to:

- improve the quality of care processes in hospitals;
- reduce costs and operational impact of infections caused by MDROs;
- improve appropriateness of antimicrobial medicine usage;
- reduce community and social care impact of MDROs acquired in hospitals.

S4C will be an active medical device, designed as a modular solution including:

1. a novel sensors network able to detect Volatile Organic Compounds (VOC) of the target microorganisms without the use of any intrusive or invasive sampling;
2. a modular ICT (client and server) platform for managing the related alerts system (allowing the geo-localization, the time-stamping, and the characterisation of each alert) and supporting the health practitioners in the management of the sensors-enhanced screening protocols. The ICT platform will include several features to allow health care professionals to manage patients, rooms, active (clinician-led) and passive surveillance (either sensors based or exploiting the available Lab data), manage infective agents report, Create and execute protocols, manage the antibiotic Therapy (prescription, administration and monitoring adherence). A profile for hospital managers and citizens will also be created including the access to education centre and summary dashboards,
3. a (local) server-based interoperability module allowing S4C to store data in an easy-to-use format and integrate with the patient Electronic Health Record (EHR) including the patient history (previous infections, hospitalizations, etc.); the Laboratory Information System; existing electronic hygiene control systems and other indication-relation control systems sending the screening outcomes and alerts on detections.

During Phase 1 of the Anti-SuperBugs PCP, the S4C consortium achieved to:

a) design the solution and determine the technological approach to be taken;
b) create the technical and commercial plans which confirm the technical and financial feasibility of the proposed approach;
c) outline potential ethical considerations and explain how these would be addressed in Phases 2-3;

d) deliver the lab prototype validation protocol to be followed in Phase 2.

INNOVATIVE ASPECTS OF THE SOLUTION

The S4C solution brings two key innovative aspects to the Anti-Superbugs PCP challenge:

1) Technological approach to MDRO detection: at the end of the benchmarking analysis in Phase 1, we concluded that, despite current technical limitations, Raman spectroscopy combined with Artificial Intelligence (AI) approaches have a real potential to provide label-free bacterial detection, identification, and antibiotic susceptibility testing in a single step. Preliminary scientific results showed that this approach has potential for culture-free pathogen identification and antibiotic susceptibility testing, which constitutes a real big step forward in the field, not yet used or available in the market. The S4C VOC detector will have a low rate of false positive/negative and high percentage (>98%) of true positive/negative and sensitivity and specificity will be higher (>98%) for all the pathogens detected;
2) Scalable and portable solution: S4C will be portable, easy to install and deployable, ready to be used into existing healthcare environments, facilities and architecture since it can be anchored to the walls or placed where is needed. The user interface will be easy, and users will have access to the relevant data, warnings and they can add additional comments into the reports. The datasets generated and/or analysed during the screenings with the S4C VOC detector will be stored and available for healthcare personnel at any times (24/7), thanks to a tailored IoT platform;
3) Transferability: the technological approach adopted by the S4C solution is flexible and can be easily adapted also to the detection of further MDROs or viral organisms (after due detection validation in both lab and real environment conditions). This will be extremely useful for enlarging the spectrum of threats detected and offer a wider preventive service to hospitals and healthcare providers;
4) Clinical workflow: S4C will definitely impact and improve the clinical workflow by overcoming current well-known limitations, like:
    a. the delay in detection of MDROs and production of reports: S4C offers a real time, 24/7 automatic air detection;
    b. low compliance to infection control practices (ICP): S4C provides alerts on specific areas infected and to clean;
    c. inefficient cleaning in hospital and surgical rooms: S4C detects MDROs with high precision, with recommended actions;
    d. spread of superbugs from regional hospitals to long-term care facilities: S4C includes an information system enabling high-level analysis across multiple healthcare organisations of the presence of same MDROs;
    e. dependency on operators for laboratory detection protocols: S4C VOC detection procedure is independent from operators;
    f. intermittent outbreaks of different MDROs during specific time periods: S4C allows to study eventual competition between these MDROs, detecting their changing different presence in VOC.

OUTPUTS ACHIEVED IN PHASE 1

During Phase 1 (17 March-22 May 2020), S4C partners have performed R&D activity to design our solution, conduct a technical and financial feasibility analysis, and develop a validation

protocol in lab condition for Phase 2. The project has been executed in line with the original work plan and no changes or deviations occurred. All due deliverables (D1.1, D1.2, D1.3, D1.4, D1.5) and milestones (M1.1, M1.2) were submitted/achieved in time so far, whereas remaining ones (D1.6, M1.3) will be submitted/achieved as due by 28 May 2020.

FORECAST FOR PHASES 2 AND 3

The positive results of the feasibility study in Phase 1 give a boost to S4C partners to seek further advancement in the R&D work for designing, developing and testing the solution. In the next possible Phases, the development of S4C will produce a working prototype during Phase 2, to be validated in lab conditions and presented to Buyers Group (TRL 4). Finally, in case of Sens4Care selection for Phase 3, we will test it in real environments (i.e. procurers' designated hospital sites) the prototype for validation and demonstration (TRL 7).
More in general, partners are enthusiastic and fully engaged to continue the work with S4C solution also after and beyond Anti-Superbugs PCP. The clear business opportunity and market readiness for such a solution will be addressed in order to advance exploitation and reach commercialisation in a reasonable timeframe (by 2022).

MATURITY AND COMMERCIALISATION

TECHNOLOGY READINESS LEVEL (TRL) ACHIEVED

At the end of Phase 1, we developed a solution design, which includes a complete technology concept (TRL 2). The full solution design, business plan, data protection and risk management plans are all detailed in D1.4. S4C partners are engaged to move fast along the TRL ladder, in order to reach an experimental proof-of-concept (TRL 3) and lab validation of the S4C working prototype (TRL 4) in Phase 2. This will constitute a strong basis enabling us to demonstrate it in a relevant environment (procurers' hospitals) in Phase 3 (up to TRL 7).

INTELLECTUAL PROPERTY RIGHTS (IPRS)

During Phase 1, the consortium took first measures to protect IPRs by means of a consortium agreement (based on the Horizon 2020 DESCA framework model) which clearly describes use and protection of background and foreground IPRs. Further IPR protection measures for foreground results have been explored and will lead by 2020 to file a patent application of system and method employed in S4C.

REGULATORY COMPLIANCE

The prototype of S4C can guarantee CE marking, thanks to exploitation of hardware devices already in the market. A preliminary analysis was conducted in order to check whether S4C shall be considered as a medical device under Medical Device Regulation (MDR) (EU) 2017/745, In-Vitro Diagnostic Device Regulation (IVDR) (EU) 2017/746 and Directive 2007/47/EC. At this stage, S4C can be classified as a non-invasive, active Class I medical device.

POTENTIAL FOR COMMERCIALISATION

The potential of S4C constitutes a clear business opportunity for Tech4Care and Sensing Solutions, which will be absolutely engaged in the exploitation of the business idea and R&D work. We expect to launch S4C commercialization in the second half of 2022, covering Germany, Italy, Spain and United Kingdom (first targeted countries) as initial target for the first year. The market strategy will be refined in due project course according to the evidence which the user-centred design will generate. The S4C team has articulated a preliminary roadmap, business plan and financial forecast, according to which the S4C solution will be developed and brought to the market.

The consortium has been exploiting continuously its networks and partnerships for establishing wider collaborations with clinicians, engineers, hardware manufacturers (a large HW-producer has formally endorsed the initiative), consultants, big pharma companies and healthcare organisations to enhance the project idea, verify the technological approach, advance the R&D work and find new business opportunities and models.

CONCLUSIONS FROM PHASE 1

The Anti-Superbugs PCP Phase 1 lasted 3 months and it contributed to increase partners' knowledge in the fields of MDROs, VOC detectors and available technologies and solutions. The preliminary results from Phase 1 are very positive and encourage further efforts for development, testing and exploitation of our S4C solution design. Results clearly indicate the technical and financial feasibility of the S4C solution, which has indeed a potential for revolutionise the fight of MDROs in hospital settings and deserves further R&D work for validation and demonstration.

After Phase 1 (beyond and eventually in parallel to Phases 2-3), the consortium will continue exploring other opportunities for attracting external investors and funds for exploiting the solution concept and business idea. We will search for further business opportunities, emerging from ongoing contacts and interactions with the consortium ecosystem.

Furthermore, the Anti-Superbugs PCP project contributed to stimulate further Tech4Care and Sensing Solutions concerning the extension of our concept for detecting a wider range of bacteria and possibly viruses. In this respect, we are exploring a challenging but interesting possibility to integrate the S4C solution with a VOC detector able to identify SARS-CoV-2 and other coronaviruses. Such innovation would add even more value to the S4C solution concept.

Finally, a freedom-to-operate analysis and IPR protection measures shall be kept in mind by S4C partners during next months. The VOC detection market is growing and many possible competitors might start investing new ideas and technologies for addressing related challenges. S4C competitive advantage should be preserved by carrying out different activities in parallel: technical development, lab test and field test; continuous consultation with healthcare professionals for co-design and feedback on the solution; IPR identification and protection; freedom-to-operate analysis and compliance with applicable law/regulations; market analysis and business model development.