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PHASE

T4.1.1 - Validation of Pilot 3 - Output

Version n. 1 - 12/2023

PROJECT NAME: "Promoting eHealth in cb Area by Stimulating local Economies" - **ACRONYM:** PHASE - **PROJECT NUMBER:** 365

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PROJECT: "Promoting eHealth in cb Area by Stimulating local Economies"

ACRONYM: **PHASE**

Output

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1. Executive Summary

The document is structured primarily in an introduction to the PHASE project, detailing its main objectives. Subsequently, it outlines the background of the Pilot action n. 3, highlighting the key challenges the Pilot aims to address.
Then the Pilot action is described focusing on the technical functioning of the platform. The fourth paragraph provides a more concise description, while the fifth also includes the description of the externalized services.
The involved stakeholders and the strategies used to engage them in the Pilot implementation are then identified. Additionally, a section is dedicated to the lessons learned from the Pilot implementation, including the impact observed on the patient's quality of life. Furthermore, the main challenges encountered during the Pilot's execution are outlined, as well as the adopted solutions to tackle them.
Finally, the main expressions of the cross-border added value of the Pilot action are identified.
It should be specified that although the description of the Pilot in this report is presented in the past tense, the system created through its implementation is still fully operational.
For the same latter reason, descriptions of the software and platform are articulated in the present tense, considering the continued functionality of these tools.

2. Introduction

E-Health is a strategic business sector for European economic development, as mainly reported in EC strategy regarding the "Digital Transformation of Health and Care in the Digital Single Market". Significant efforts and investments are demanded to National and local governments in order to align with EU standards, in terms of innovative services organization, digital platforms and sharing services among citizens.

The development of eHealth sector boosts European territories, not only for the improvement of public and private healthcare services, but also by stimulating competitiveness and innovation of MSMEs in ICT and digital technologies sector. However, the digital transformation of healthcare sector involves also traditional companies providing social and healthcare services to patients such as nurses, physicians, private clinics and ambulatories, pharmacies and drug stores, gyms and rehabilitation centers, etc. The latter have to improve and innovate the way they provide their services through the use of mobile apps, digital platforms, wearable sensors, personalized data, etc.

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Digital technologies such as 4G/5G mobile communication, artificial intelligence or supercomputing offer new opportunities to transform the way we receive and provide health and care services, enabling innovative approaches to independent living or integrated health and social care. Furthermore health data and advanced data analytics can help accelerate scientific research, personalized medicine, early diagnosis of diseases and more effective treatments.

Finally, the recent COVID-19 pandemic has furtherly increased the general public sensitiveness on eHealth, stimulating debates and propositions, while policy makers boosted up the efforts and investments (at national and regional scale) to regulate and define standards in the e-health sector.

Starting from these considerations, **the PHASE project aimed at**:

- creating an ecosystem of policies, practices and tools acting as facilitator of competitiveness of MSMEs in healthcare sector and e-health;
- boosting the creation and the development of eHealth digital MSMEs by providing non-financial services
- increasing competences in MSMEs, awareness in public authorities and empowerment in common citizens in CB area about eHealth;
- promoting the CB cooperation among private and public stakeholders through the creation of a transnational network
- improving the overall health and the quality of life of citizens in the CB area by using information and communication technologies (ICT) to increase self-management of healthcare and diseases

The PHASE project developed ICT platforms and procedures to address territorial needs (i.e. patient's needs). The approach has been tested and validate in n.3 different Pilot actions, addressing 3 different types of clinical needs from patients:

1. **Infarct Network**, a territorial network of ICT nodes and equipped ambulances aiming at a prompt and appropriate clinical intervention in early phases of heart-attack (emergency/urgency)
2. **Management of Integrated Care Pathways** with specific reference to Neurodegenerative diseases. It is the case for patients requiring multi-specialistic support for their complex disease.
3. **Remote monitoring of chronic patients**, for those who requires continuous but low intensity care on the territory, without the need to go to hospitals. It basically extends the healthcare services even to patients' house.

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The PHASE project aimed at creating the right conditions for the boost of eHealth sector in CB area, by providing services and supporting local MSMEs as well as increasing competence and awareness in public authorities and empower patients and caregivers. The project posed the base for the development of common shared open protocols and digital tools, a crucial aspect to guarantee interoperability among different platforms and increase the efficiency of the processes. The digital eHealth ecosystem of services promoted by PHASE project has the potential to contribute to the implementation of the most advanced models of eHealth in the world such as the territorial Virtual Hospital.

3. Output T4.1.1: Objectives

The purpose of this report, which represents one of the PHASE Project main output, is **providing evidence of the validation of the Pilot action n. 3** related to the remote monitoring of chronic patients, especially affected by chronic cardiovascular diseases, needing frequent reassessments for the prevention of complication or the treatment of exacerbations.

In particular, in line with the Application Form, the report provides the Number of business and research institutions involved/offering non-financial support, according to the Programme output indicators (at least 3).

For this purpose, the key involved stakeholders are mentioned and briefly described also in terms of role played within the Pilot implementation; in particular, after describing the challenges that the Pilot aimed at addressing and its main characteristics, in addition to the identification of the "lessons learned", the major problems encountered and the cross-border added value of the Pilot, the main occasions and project events in which different stakeholders played an effective role are specified.

4. Background, scope and description of the Pilot action

The Pilot n. 3, foreseen within WPT4 of PHASE Project, has been represented by the **Remote monitoring of chronic patients,** especially affected by chronic cardiovascular diseases, needing frequent reassessments for the prevention of complication or the treatment of exacerbations.

The Pilot action was designed and implemented in order to face several key challenges, common the project area. Every year, Cardio Vascular Diseases (CVD) cause over 1.8 million deaths in the European Union (EU), which is equivalent to 37.1 % of all deaths. Overall CVD is estimated to cost the EU economy

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€210 billion a year, whose 53% (€111 billion) is due to health care costs, 26% (€54 billion) to productivity losses and 21% (€45 billion) to the informal care. Cardiovascular Diseases include patients in acute phase (heart attack) and in chronic conditions (heart failure). Despite the improvement of treatments, heart failure represents a pathology burdened by a negative prognosis and a re-hospitalization rate at 12 months that in European cases reaches 44% leads to focus on this population the attention to intervention methods that can improve the risk profile.
Numerous experiences show that a remote control of certain parameters can detect early signs of deterioration of the clinical condition of a patient with heart failure, preventing further deterioration and therefore death or re-hospitalization.
Many patients suffering from chronic heart failure are already equipped with implantable cardiac devices (CIED), such as defibrillators (ICD), resynchronizers (CRT-D or CRT-P), loop recorders, or wearable defibrillation and monitoring systems (life vest). All the mentioned devices are equipped with the possibility of transmitting data collected from the patients at homes to the monitoring centers; many of the data collected by the devices give information not only on the electrical status of the system but also on the clinical conditions of the patients. In some cases, the same telemonitoring systems can be coupled with external instruments, such as automatic sphygmomanometers, bathroom scales, saturation meters.
In this framework, the ageing of population and the request for a high quality of life (ageing well) represent further challenging issues, in addition to the disruptive advancements in ICT and digital technologies applied to healthcare, increasing efficiency and quality of services.
Considering that revenues in the "eHealth" market amounts to more than € 3 billion in 2018 and they are expected to show an annual growth rate (CAGR 2018-2020) of 14.3% resulting in a market volume of €4,048m in 2020, other challenges to face are linked to the role played by the eHealth business sector and local MSMEs in the development, the adoption and the diffusion of such systems.
Therefore, a challenge the territories involved in the project needed to face was represented by filling the gap with the EU average in terms of **quality and availability of care**, life expectancy and efficiency of the healthcare system, and the Pilot action n. 3, as well as the first and the second one, really aimed at contributing to bridge this gap. Particularly, the Pilot n. 3 involved patients with CIED or life vest having the possibility of remote data transmission.

Within this field, it has been noted that data are collected by individual dedicated platforms that refer to the various manufacturers of devices and transmitted, in a disaggregated manner to clinical centers of reference for the management of patients.

In view of this scenario, the Pilot n.3 involved the creation of a **single platform allowing the management of all devices referring to individual patients**, rather than to implanted equipment; the platform,

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implemented in the telemonitoring system and connected to the clinical databases of patients, allows to acquire information useful for remote teleconsultation.

The **architecture of the service** included the presence of **n.3 Control Rooms** one for each country, interconnected with each other, with the possibility to acquire data from the technological platforms of the devices and, where necessary, provide teleconsultation services.
The service included the remote control of the devices, the acquisition of relevant data according to the schedule that each center provides based on clinical decisions, and also enabled to connect remotely with other clinical centers, with treating physicians and with the patients themselves or with care givers.
Furthermore, the service consisted of several activities performed remotely at the Polyclinic of Bari: adaptation and profiling of the HELIS EMS application in its hospital version currently in use in the wards of the Polyclinic of Bari, in the "Management of chronic patients with CIED/Life Vest" platform; connection of the platform through protocols shared with implantable cardiac device manufacturers; installation and configuration of the platform "Management of chronic patients" at the workstations of the 3 Control Rooms and the 3 territorial nodes in Italy, Albania and Montenegro, training operators (doctors, health workers, caregivers); assistance and application management; evolutionary maintenance following explicit requests during the management phase.
For these purposes, the Polyclinic also provided connections at the sites of the Control Rooms and territorial nodes in Albania and Montenegro.

Therefore, the Pilot action has been represented by the creation of a **digital platform for remote monitoring**, which included connected medical devices to measure vital parameters (standing as a key output of the project). The main objective was improving the quality of life for chronic patients, particularly those dealing with chronic cardiovascular diseases, who often require frequent reassessments to prevent complications or manage exacerbations, yet medical services are costly, and accessibility is limited due to resource scarcity.
As scientific studies and literature also demonstrate, empowering patients to self-manage their care enables more efficient use of healthcare services, lessening the strain on available resources.
For instance, as it will be outlined in the following paragraphs, it can reduce visits to primary health centers, emergency units, or hospital admissions prompted by disease exacerbation.

In view of all these considerations, the Pilot tested a technological platform that directly provides patients with various services, including **bi-directional communication with physicians/nurses, educational materials, informational resources, and monitoring of biological parameters**.

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This platform adheres to "open" standards and can integrate existing ICT services like electronic clinical records. It's customizable, allowing for the addition of new functionalities ("applications") based on individual user needs.
The three participating countries tailored different settings according to their specific requirements. The platform's openness and versatility allow for easy integration of third-party applications, and even traditional companies offering social and healthcare services can access the system to enhance their service quality, thus serving as a facilitator for competitiveness.

5. Implementation of the Pilot action

Considering the current epidemiology in the involved countries, the intervention has been directed towards cardiovascular pathologies, particularly heart failure, which has a high incidence of adverse events and significant social costs. Remote monitoring of patients with heart failure has demonstrated an improvement in both the quality and quantity of life for these individuals, and telemedicine tools have proven instrumental in delivering this mode of care, allowing for the collection of clinical data directly from the patient's home. This data is transmitted to a central facility staffed by specialists who can promptly detect any alterations in clinical conditions and intervene as quickly as possible to prevent clinical deterioration.
In order to meet the previously proposed clinical objectives aimed at demonstrating the ability to develop a telematic platform capable of channeling clinical data to one or more operational centers for reception and processing, it was decided to utilize transmissions from the current Cardiac Implantable Electronic Devices (CIEDs): Pacemakers, defibrillators, loop recorders.
CIEDs, apart from providing data related to the functioning of the electronic system (such as battery status and electrode integrity), offer a **range of clinically valuable information**. This includes the presence of arrhythmias, circadian variations in heart rhythm, pulmonary congestion status, the patient's activity levels, time spent in a supine position, and sleep hours. Extensive documentation supports the use of this information for early identification of worsening heart failure.
Therefore, the decision was made **to develop the IT platform capable of receiving data from implanted devices**, enabling transmission from the patient's home or connected cardiology clinics. These data converged into a unified system where the cardiologist at the operational center could evaluate transmission data and provide the most appropriate clinical advice for individual patients.

Under a technical perspective, the implementation of the Pilot action n. 3 envisaged the **Helis Chronical software**, for the remote monitoring of chronic patients, through the implanted devices which gave (and

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currently gives) the doctors information both on how the devices works and on patients' cardiovascular disease. This information, acquired remotely through the devices implanted at patient's location, has been collected in a single operations center, communicating with the patients or with doctors, caregivers and specialists.

As outlined in the User Manuals, the platform allows the use to create new clinical events within which it is possible to make one or more requests for examinations and consultations, with the aid of diagnostic devices.
The user in charge of the request can create events and request exams and consultations for the same patient within them, by entering the credentials, and then indicating the environment code, which identifies the requesting operating unit, to be used.

Once entered the room code, the Operator can select the operation to be carried out. The states of the events can be:

- Cancel: for an open event for which no examination or visit request has been made;
- Pending reporting: it is an event for which at least one exam was requested between ECG, ECO, SECOND OPINION and TELECONSULTO;
- Report Available: which indicates the presence of at least one exam in the reported status;
- Concluded or closed: it is a finished event.

The Operator can also search for a Concluded event thought he Event List section.

For the execution of a new event which consists in the request for one or more exams and/or teleconsultation, Operator clicks the Start button and enters the identification code of the event to be carried out in the Event Code field.

Helis Chronicle assigns a unique progressive number to the event in progress.

In the form for selecting the examination method to be performed the Operator can assign a priority level to the reporting request he is about to perform (not-urgent, minor urgency, urgency, deferrable emergency, emergency). Then the execution of the exam can begin. It is possible to request several ECG, ECHO CARDIO type exams at the same time, while requests for SECOND OPINION or TELECONSULTO inhibit other types of requests. The choice "End of Intervention" puts an end to the event and allows the

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system to produce the final report of the entire clinical event. From that moment on, the event is available in the Events List section, by selecting the "Closed" event history".

As regards to the types of exams, the Operator can schedule the booking of a consultation in Second Opinion or a Teleconsultation for further diagnostic investigations or as a first clinical choice.

In the first instance, the Operator selects whether to perform a consultation in Second Opinion or schedule a consultation via video conference by selecting one of the two options in the list of exams available on the platform.

In case of Second Opinion, the operator indicates the date and time for the doctor's request for a report; via "acquisition of other exam", he selects the attachment item in the menu and uploads the pdf extract of the implantable application to be sent.

Once the exam has been sent to the referring doctor, the latter logs into the Helis Chronical application and displays the Second Opinion tests to be reported on the main screen, can view the patients' episodes in the tracking log and proceeds with the reporting of the second opinion after checking all the information sent by the operator.

Once the report has been completed the doctor is directed to the confirmation page and can see the report pdf format; he enters his password to confirm the report as final. From the side of the caregiver, in the event list, he can see that the report for which he has requested the second opinion is available and can view the pdf of the report. In this way the remote monitoring of chronic patients is ensured.

By selecting the teleconsultation, the operator must select the facility and the doctor associated with the facility with whom the video conference visit is performed.
Once the facility has been selected from the list, it immediately appears under the list of doctors belonging to that facility. Once both have been selected by pressing the "Next" button, the operator goes to the following screen. For both the Second Opinion and the Teleconsultation, the operator must select the date and time from the calendar.
Once a second opinion or teleconsultation has been started, after accessing the section by clicking on "Pending SECOND OPINION or TELECONSULTATION Report", the system opens a new section in which it is possible to carry out various operations.
The exams which the platform allows to perform are: ECG, Echo Cardio, Cardiac Auscultation, new measurements of the Vital Parameters, New Exams (upload external reports), Tele Video Consultation (TVC).

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For the teleconsultation, data collection can be carried out both before and during the video call with the consulting specialist.
When the indication corresponding to the exam is GREEN TELE CONSULTO Report Available or SECOND OPINION Report Available, it means that the doctor in the control room has forwarded the report. Automatically, upon confirmation of download of the report, the patient report is notified on the medical report screen. After viewing the PDF Report, the operator, returning to Helis Chronical, can decide, depending on the indications provided by the referring physician who prepared the Report, whether to schedule a further examination or proceed with closing the event on Helis Chronical.
If the method chosen is teletext consultation, the Operator can carry out a Tele Video Consultation (TVC), in Video Conference, with the Doctor/Specialist booked and enabled for the service, who knows that everything written in the video conferencing system chat is recorded, reported in the event tracking log and also in the final report.

By selecting Proceed with ECG examination, the operator starts with the execution of the 12-lead electrocardiogram.

When the report is available, corresponding to the event, the message "Waiting for Report" changes to "Report available" colored GREEN and the operator can access the part that allows viewing by clicking on the line containing the Patient's name. By clicking on "Clinical Health Data", the operator sees the list of exams screen. After clicking on "ECG Report Available", colored GREEN, it is possible to download the pdf file of the report. This function allows to download a PDF file on the Operator PC containing the electrocardiographic trace and the Report drawn up by the referring physician. Upon confirmation of download of the report, the patient report is notified on the medical report screen.
After viewing the PDF Report, the operator, returning to Helis Chronical, can decide, depending on the indications provided by the referring physician who prepared the Report, whether to schedule a further examination or proceed with closing the event on Helis Chronical.
In the Control Room part, the Doctor/Specialist/Technical Operator/Monitoring Operator can also notice, at the upper left, immediately before the Events List, a Legend indicating the Priority levels and the relative assigned colors.
By selecting HEADPHONES, the user can use simple headphones connected to the PC. It is advisable that the headphones connected are equipped with a microphone, in The Priority Level Assigned to the single event by the POC/POCT Operator, for convenience and easy consultation, is displayed in the PRI (Priority) column as a colored square.
From the settings menu, the doctor can select the device from which he can listen to any audio samples for Phonendoscopy present, and can communicate during a teleconsultation. Otherwise, he can only

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listen. By selecting LITTMAN STETHOSCOPE, the doctor can use a stethoscope configured and connected via Bluetooth to the PC.
Through the use of this tool, the doctor is able to listen to any audio samples present during the reporting or can use the same tool to produce the same samples that will be loaded within the event. The receipt of an event is notified by **an acoustic signal** that alerts the referring physician of the arrival of an ECG. From here the user has a first summary of the main information regarding the patient.
The ECG Reporting Tool allows the doctor to view two-dimensional traces in DICOM format, helping the doctor in an easier and faster interpretation of the trace.
Once the POC has read the report and has concluded the event, the final event report is available for both the POC and the doctor. This report provides all the electrocardiographic reports performed on the patient including the complete tracking log.
To view the final report, the doctor has to simply access an event in the list and select the last item present from the tracking log, or INTERVENTION CLOSURE. Through the tracking log, the doctor as well as viewing the final report can access all the exams uploaded and the reports previously submitted.

In case of Second Opinion and Teleconsulting Consultancy, the receipt of an event is notified by an acoustic signal that alerts the referring physician of the arrival of a SECOND OPINION or TELE CONSULTO event. The doctor uses the tools of the reporting tool for a correct analysis of the reports in image format, and also for a correct analysis of the audio samples for Phonendoscopy, scrolling to CARDIAC AUSCULTATION.

Regardless of whether the method selected for the event is Second opinion or Tele Consultation, the doctor can carry out a Tele Video Consultation, in Video Conference, with the POC who booked it on the predetermined date and time.
During the tele-conference it is possible for the POC (if it had not done so previously) to upload any tests that the doctor can view on the Helis Chronical page as described in the chapter on reporting the event in second opinion.
In addition, the doctor can help the POC operator in the detection of any vital parameters or in the positioning of the stethoscope for correct detection of the audio samples that has been loaded into the Helis event and that the doctor can analyze during the video conference.
Once the video conference has been completed or the analysis of the exams present in the Second Opinion or Tele Consultation event has been completed, the doctor draws up the report in the appropriate text box at the bottom of the reporting tool. Once the report has been filled in, the doctor, after clicking on CONFIRM REPORT, is directed to the summary page where there is a preview of the report that the POC station will receive. To definitively confirm the report, the doctor must enter the

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password he used to log in to the Helis Chronical system in the field immediately below the preview of the report and press CONFIRM REPORT again.

Once the POC has read the report and has concluded the event, the final event report is available for both the POC and the doctor. This report contains all the reports of all the types of event requested, the exams uploaded, the complete tracking log and the history of the chat used during the remote consultation.

Through the tracking log, the doctor, as well as viewing the final report, can access all the exams uploaded and the reports previously submitted.

Under an operative point of view, for the installation of **Helis Chronical** it is possible to request only and exclusively the following exams:

1. TWELVE LEADS ELECTROCARDIOGRAM
2. ECHO CARDIO
3. ELECTROPHYSIOLOGY DATA

In case of an ECG acquisition, to register the electrocardiographic trace, the Operator uses the Cardioline TouchECG software.

The software opening is managed directly by Helis Chronical.

When the Operator displays the reception waiting screen, Helis Chronical starts the software automatically by filling in the necessary patient data.

After selected "Proceed with Echo Cardio exam" and Clicked "Next" to start with the acquisition of the Echo Cardio by the Helis Chronical software, it is necessary to connect the GE-VScan Extend device to the PC using the appropriate USB cable an to click on "allow". After about 5/30 seconds the device will be recognized by the PC.

After confirmation, the exam is sent to the Helis Chronical subsystem Server for subsequent reporting. The operator can click on "Next" to conclude the sending phase of the exam.

Concerning the **acquisition of the Electrophysiology data**, by selecting "Proceed with Electrophysiology Examination", the POC/POCT Operator asks, for the current Patient, the recent acquired Electrophysiology data got from its implanted device. The operator gets the list of configured platforms

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used for acquiring Electrophysiology data, select the available, then press on button Next, thus Helis sends a request for Electrophysiology data toward the selected platform.

From the side of the doctor reporting electrophysiology examination, on **Ebit SuitEstensa**, the doctor reports the service requested by the Montenegrin, Albanian or Italian caregiver; he displays the request and associates it with the patient and then checks all the events sent the programmer including serial numbers and parameters and processes with the reporting. He enters his password to confirm and makes the report final.
From the PC/POCT side, when the external platform sends the Electrophysiology Report data, the request changes its status in: Report Electrophysiology available, which means it is ready to be downloaded.
From the Control Room side, at the same time the report is sent by the external Electrophysiology Platform, this results available on the Control Room side of Helis Platform, in the worklist of the enabled Doctor/Specialist. Opening the event, the Doctor/Specialist can evaluate this exam and take a look to the other ones executed in the same Event Request.

The described platform has been developed by the company **CONSIS**, which is responsible in case of malfunctions detected by users, or errors received during the execution of the program; in fact, users are requested to notify the CONSIS Helpdesk of any malfunction and / or defect, and CONSIS undertakes to resolve any problems not arising from misuse by the user as quickly as possible from receipt of the report. Moreover, it should be emphasized that the **application interface between individual implantable device platforms and the Helis Chronical platform**, allowing access to all data gathered from devices implanted in patients affected by chronic cardiovascular diseases, from a **single access point**, is called **FYSICON**.

This application interface - developed by Fysicon, (part of Canon Medical Systems since 2018), Dutch developer and producer of innovative medical technologies in the field of structural heart defects and medical imaging for hospitals, research institutes and industry – was provided by **EBIT Ltd.**

6. Information about stakeholders' role/involvement

The stakeholders involved in the implementation and validation of the Pilot n. 3 encompassed both the physicians and patients directly engaged in using the eHealth service, as well as business and research institutions offering non-financial support that have played various roles.

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Physicians predominantly included **general doctors**, practicing **primary care medicine** on the territories involved, in addition to **specialized technical cardiologists**.
Within the Pilot n. 3 implementation, the milestone of n**. 600 transmissions** from implanted devices of **patients** affected by cardiovascular diseases, has been achieved at a cross-border level.
Patients who benefited from remote monitoring are those defined at high risk of events for worsening heart failure or CV hospitalisations (risk-driven management, NYHA class III e IV), those in the vulnerable phase after hospital discharge (30 days – 3 months), and those with objective limitation due to functional, geographic, socioeconomical barriers.

Regarding other involved entities, they played an essential role in training, informing, and raising awareness on the project's focal themes, notably during the accredited events by the Ministry of Health for specialized physicians on November 18, 20220. The topics were "Telemedicine for dehospitalization and support of territorial continuity" and "Digital ecosystems for support in care continuity: Taking charge of the territory".

The entities involved in this framework comprised:

- **ARESS Puglia**, the Regional Agency for Health and Social Affairs of Puglia, involved in discussions related to Core eHealth project governance and information interoperability.
- **ASL Foggia,** presenting on cardiovascular monitoring during the same event.
- **Uniba**, presenting on telemedicine models in cardiology, digital transition in healthcare, and diabetic patient monitoring.
- **University of Foggia**, presenting on cardiac telerehabilitation.

Further significant contributions came from:

- **ASL Brindisi**, informing participants about the Telehome Care project.
- **Giovanni Paolo II Cancer Institute Bari**, presenting on digital distributed hospitals.
- **ASL Bari**, regarding patient monitoring with neurological pathologies.
- **IRCCS Casa Sollievo della Sofferenza-San Giovanni Rotondo**, presenting on oncological patient telemonitoring.

During the roundtable discussion on November 29, 2022, titled 'Data Science for eHealth and Business Opportunities,' **ARTI Puglia** (Regional Agency for Technology and Innovation), **Tecnopolis PST (Technological Scientific Park)**, **Confindustria**, and **Unioncamere Puglia** significantly contributed to raising awareness and providing information.

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In the workshop dedicated to public administration on December 1, 2022, titled 'Digital Transition,' the involvement extended to the Regional Department of Health on data protection and privacy, and **Polytechnic of Bari** on intelligent diagnostic systems.

For the afternoon session on "eHealth for Emergency Urgency" both the **Department of Health of Puglia Region** and ARESS played important roles.

Regarding the workshop on December 2, 2022, centered on "eHealth Applications for Chronicity", apart from previously mentioned stakeholders, the **Maugeri Bari Scientific Institute** contributed with insights into the digital ecosystem, sustainability, and the management of chronic COPD patients.

To further amplify the project's activities and ensure broader dissemination, **AiSDeT (Italian Association of Digital Health and Telemedicine)** was also involved, considering that it gathers an extensive national network of professionals and enthusiasts in digital innovation within the healthcare sector, and aims at enhancing healthcare governance, clinical efficiency, and effectiveness of care.

Another entity that played a role in raising awareness on the Pilot action is the **Italian Society of Cardiology (SIC),** specifically the Working Group on Telecardiology and AI, and SIC Puglia Basilicata.

SIC organized an educational event aimed at Specialized Cardiologists, Emergency and Acceptance Surgeons, Sports Medicine Practitioners, General Practitioners, Internal Medicine Specialists, and nurses.

This event took place on October 24, 2023, at the Chamber of Commerce in Bari.

Moreover, within the PHASE project Final Conference, the **Polytechnic of Torino**, specifically one of the teachers of this University, Prof. Eros Pasero, was also involved delivering a keynote lecture on the topic "eHealth and Artificial Intelligence: The New Paradigm of Medicine 4.0".

In addition, all the PHASE Project Partners have played a role in the Pilot n. 3 validation, namely University Hospital Consortium Corporation Polyclinic of Bari; University Hospital Ospedali Riuniti di Foggia; Molise Region; Ministry of Health and Social Protection of Albania, National Center of Medical Emergencies of Albania, Union of Chambers of Commerce and Industry of Albania, Clinical Center of Montenegro, Ministry of health of Montenegro, Chamber of Economy of Montenegro.

Lastly, it should be mentioned that the companies **CONSIS** and **EBIT Ltd.**, already mentioned in the previous paragraph, have been at the heart of the development of softwares, platforms and interface application on which the Pilot n. 3 is focused.

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7. Lessons learned by implementing the Pilot action

Within the Pilot n. 3 validation, it should be firstly considered that, as mentioned also in relation to the Pilot n. 1, a model and a method have been developed whose results and impacts will be better appreciated in the long term yet have already allowed for the identification of positive data within the 6-month pilot testing period.
These positive effects, translatable into lessons learned, are also based on scientific literature as well as insights gained from discussions within and among the team of specialist doctors involved in the Pilot's development, thus stemming from their direct experience.
Among the lessons learned by implementing the Pilot it should be mentioned that it primarily enables **predictive health information** about the patient with the implanted device, which can prevent the possibility of deterioration in their health status. This aspect significantly enhanced the **quality of life** for patients dealing with chronic illnesses, particularly cardiovascular conditions, in various ways. In fact, remote monitoring of implanted devices spared patients the need for physical travel, eliminating routine visits to medical facilities and reducing the stress associated with travel. This not only positively impacted their mental well-being but also had economic benefits, especially for individuals residing in remote areas far from hospitals, where connectivity is limited.
Decreasing the frequency of medical appointments had a favorable effect on the overall lifestyle of chronic patients, allowing them to focus on their daily activities without feeling restricted by their health concerns. Under this point of view, the PHASE consortium expectations were realistic.

Moreover, as mentioned before, remote monitoring facilitated the **early detection of health imbalances**, such as anomalies or changes in cardiac parameters, potentially foreseeing future critical issues. Immediate local examinations to investigate detected imbalances allowed for swift identification and intervention, possibly saving lives. This not only optimized resources but also ensured personalized and prompt consultations for the patients.

The Pilot action showed the importance of the role played by both patients and caregivers, stressing the relevance of **empowering** them. Empowering patients to self-monitor and manage their chronic conditions independently, fostering a sense of accountability and autonomy, also contributed to an improved adherence to prescribed treatments. This increased empowerment instilled in patients a feeling of capability in managing their condition, equipped with the necessary tools and assured of specialized medical support at the first sign of concern, such as suspected cardiac decompensation.

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An additional result was a higher engagement of the chronic patients in their health management, a deeper understanding of the factors affecting their chronic conditions, and enhanced satisfaction due to reduced dependence on continuous medical check-ups for leading a more normal life.

Another lesson learned in implementing the Pilot n. 3 is represented by the fact that patients' empowerment for self-management of care allows a better and **more efficient use of healthcare services**, reducing the burden on the available resources, by lowering, for instance, the number of visits to primary health centers, emergency units or hospital admissions due to worsening or exacerbation of the disease. This aspect also resulted in an optimization of hospital staff resources.

Under another point of view, timely identification of potential issues thanks to the remote management of chronic patients, reduces the likelihood of medical emergencies, thereby decreasing the need for sudden hospitalization which represent a significant part of healthcare expenses.

In **quantitative** terms, remote monitoring is estimated to have **reduced hospitalizations** for heart failure-related conditions by 30%. It's important to note that in the case of hospitalization for these conditions, the average duration ranges from 12 to 14 days, each costing up to 2,500 euros per day.

Furthermore, the system has resulted in savings in terms of working hours: an in-person checkup typically takes at least 30 minutes per patient, whereas a remote checkup lasts only 10 minutes. Considering these figures, it's evident that the benefits stemming from the implementation of the Pilot should be regarded not only in social terms but also economically.

Implementing the Pilot 3 showed the importance of ensuring the optimal functioning of the service by a **reliable and secure technological platform** for transmitting medical data; also the personnel/staff training, carried out in parallel with the Pilot implemental, played a fundamental role. In particular, we ensured that the medical staff was adequately **trained** in both the use of the technology involved in the Pilot service and in the management of the pathology remotely.

Moreover, it was fundamental to establish **efficient communication channels** (such as through secure messaging, video calls, etc.) both between healthcare providers/medical staff and patients, ensuring a flow of information that was clear, continuous, compliant with privacy regulatory framework, but also aimed at maximizing the effectiveness of the eHealth intervention performed.

Furthermore, it was needed to provide a **continuous support system** envisaging assistance to the eHealth application users, offering support in the eventuality of issues detected and reported in using the service (see "Safety" domain).

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Last lesson learned is referred to the importance of integrating the service on which the Pilot is focused with the existing healthcare system (under a technological, organizational, and regulatory perspective) and of enhancing the interoperability of all data, also continuously improving the service through ongoing monitoring.

However, considering the valuable insights gained through the Pilot implementation and the social benefits to the population, as well as the economic advantages in terms of cost reduction, there is a clear opportunity to **further enhance** the remote monitoring system at cross-border level, especially considering that there are numerically fewer implanted devices equipped with remote monitoring in Albania and Montenegro.

With reference to the main problems PHASE consortium had to face within the Pilot action n. 3 implementation, the major issue was related to the **accessibility** on the FYSICON interface application where all data from different implantable devices is collected. Therefore, the critical matter was to retrieve data from different devices into a single platform.

Moreover, from an organizational point of view, some critical aspects emerged, common to the implementation of all three Pilot actions, related to the opportunity to identify better, more efficient, and uniform **organizational models for medical and technical staff** across the involved countries.

Other problems found are the specific focus of the following paragraph.

8. Problems found and adopted solutions

Main problems PHASE Consortium had to face within the Pilot action implementation were linked to **administrative-legal aspects**, specifically concerning the management of extensive healthcare data categorized as sensitive.

Ensuring informed consent for remote monitoring and diagnosis, as well as maintaining the accuracy and confidentiality of transmitted medical data, posed critical issues. The objective was to align the primary use of this data with the existing and evolving regulatory framework at the European Union level, particularly in reference to GDPR (General Data Protection Regulation) and the proposed European Health Data Space, with an emphasis on interoperability. A specific issue was related to patient data privacy, considering the limited applicability of GDPR in Albania and Montenegro.

Therefore, a fundamental step in the PHASE project involved the analysis of the regulatory framework to fully comprehend it and verify the complete compliance of the three Pilots' implementation with existing regulations. This process, in addition to the organization of round tables with key stakeholders to discuss

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on this challenging topic, was fundamental to ensure the proper management and protection of patients' sensitive data and to guarantee the project's alignment with evolving regulatory demands.

In particular, a multidisciplinary approach involving legal professionals, regulatory compliance experts, healthcare technologists, and providers was essential. This approach aimed to ensure data security, regulatory adherence, and effective adoption of new technologies in the healthcare sector.

Moreover, another significant challenge arose from the **perspectives of certain healthcare professionals** and **patients.** In fact, in should be considered that many elderly patients are accustomed to being visited in person by doctors, and they undergo regular in-person visits for check-ups and monitoring their parameters. One crucial aspect of the Pilot n. 3, therefore, is represented by the empowerment of the patients, and caregivers as well.

On the other hand, doctors had to adapt their knowledge and practices. Some of them are not convinced about the opportunity to give up the direct doctor-patient relationship, which within the Pilot n. 3 is required only in case of effective need.

The integration of technological tools in the healthcare sector needs a learning curve and skill adjustment, representing a critical aspect in transitioning to remote and digital monitoring solutions.

Overcoming this challenge required the implementation of specific training activities tailored to healthcare personnel and to public as well, aiming at enhancing technical skills and raising overall awareness regarding the utilization of these new diagnostic and treatment tools, even from a cross-border perspective.

Lastly, it was noted that there aren't many devices implanted in Albania and Montenegro from a quantitative perspective, but it can be observed as a growing trend, nonetheless.

9. Cross-Border added value of the Pilot action

Firstly, the cross-border added value of the Pilot action n. 3 has been represented by fostering collaboration among physicians from different countries. This collaboration facilitated the exchange of knowledge and resources, enabling medical professionals to collaborate in managing chronic conditions, including remote diagnosis and continuous monitoring.

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The monitoring application, available in all program languages alongside English, facilitated the provision of a second medical opinion, which can contribute to create an integrated healthcare transnational space.

The cross-border added value has been also evident by encouraging the exchange of clinical experiences, best practices, and treatments among professionals, benefiting the care and treatment perspectives of all patients within the program area. Establishing an integrated diagnostic and monitoring space within the cross-border area allowed for a multidimensional approach to specific cases, even those involving patients in remote areas.

Moreover, as evidenced by the Pilot n. 3, its implementation fostered innovation in diagnosing and monitoring chronic conditions while standardizing monitoring and intervention processes across borders, which also represented a clear expression of the cross-border added value of the Pilot action.

As further aspect of the transnational dimension of the Pilot action n. 3, is should also be mentioned that it led to broadening access to healthcare by offering constant specialized monitoring of chronic conditions to individuals in distant or isolated areas.

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