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T2.1.1 - Validation of the Infarct.NET Pilot - 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

Table of Contents

Table of Contents 3

1. Executive Summary 4
2. Introduction 4
3. Output T2.1.1: Objectives 6
4. Background, scope and description of the Pilot action 6
5. Implementation of the Pilot action 8
6. Information about stakeholders' role/involvement 16
7. Lessons learned by implementing the Pilot action.... 17
8. Problems found and adopted solutions 19
9. Cross-Border added value of the Pilot action 20

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 Infarct.NET, highlighting the key challenges this Pilot action aims to address.
Then the Pilot action implementation 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, needed to effectively develop the platform.
The involved stakeholders within 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 Infarct.NET are identified. It should be specified that although the description of the Pilot implementation 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

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

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.

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.

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

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.

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 T2.1.1: Objectives

The aim of this report, which represents one of the PHASE Project main outputs, is **providing evidence of the validation of the Pilot action n. 1**, related to the digital platform for Infarct.NET, including control rooms in Albania and Montenegro.
According to the Application Form, the report provides the number of business and research institutions involved/offering non-financial support, in line with the Program output indicators (at least 5).
For this purpose, 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 key stakeholders involved in the Pilot implementation are listed, and the involvement strategies adopted, in terms of occasions within which they have been engaged, are briefly outlined too.

4. Background, scope and description of the Pilot action

The Pilot n. 1, foreseen within WPT2 of PHASE Project, was represented by the implementation of the Hearth attack network in the cross-border territories, Infarct.NET, addressed to patients who experienced heart attacks, whether they had cardiovascular diseases (CVD) or not or were suspected to be having a heart attack. It was conceived to face several key challenges, common the project area.
Every year, Cardiovascular 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 €210 billion a year, whose 53% (€111 billion) is due to health care costs, 26% (€54 billion) to productivity losses and 21% (€45

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

billion) to the informal care. Cardiovascular Diseases include patients in acute phase (heart attack) and in chronic conditions (heart failure).

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 have been linked to the role played by the eHealth business sector and local MSMEs in the development, the adoption and the diffusion of such systems.

In view of all this complex scenario, the territories involved in the project needed to fill 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. 1 really aimed at contributing to bridge this gap.

The Infarct. NET Pilot was represented by a territorial network of structural nodes (control rooms) and equipped ambulances aimed at timely and appropriate clinical interventions in the early stages of heart attacks.

In particular, it aimed at optimizing the time of intervention in case of a heart attack, reducing complications and improving outcomes, anticipating the first cares even in the ambulance or at patient's house with the available healthcare operator. Therefore, this model supervised and optimized the preliminary emergency process by coordinating the arrival of the closest ambulance or first aid proximity center, allowing the transmission in real time of ECG signals and other biometric data to control room with cardiologists (interconnected in the three involved countries), remotely supporting the decisions of local nurse or operator.

Once the diagnosis has been defined, thanks to this service the closest hospital or clinical centers with the available treatment unit for the specific case was identified.

The interconnection between the control rooms in the three countries enabled (and actually does) real time second opinion among doctors and favored the transfer of knowledge from expert physicians to new private stakeholders (nurses, doctors, cooperatives). The system has been also equipped with a clinical Decision Support System allowing automatically an initial report, afterwards validated by the cardiologist, thus making a first diagnosis of the electrocardiogram. It defined the priorities among the ECG arriving in the control room, processing patients' data anonymously and providing a base of clinical information to MSMEs (pharmacies, social cooperatives, private hospitals, etc.) who could discover a new set of patients, previously unknown, which are in need for care and assistance services because of their current clinical conditions. In this way private sector has been enabled to provide them clinical and non-clinical services in the sub-acute and follow-up phase, even at home.

In other words, the Infarct.NET platform consisted in implementing, adapting and validating the Regional Telecardiology platform, in use at the Control Room of the Polyclinic of Bari, and at the n.2 cardiology Control Rooms, one for each country, respectively located in Albania and Montenegro.
The platform allowed each Control Room to connect a potentially unlimited number of territorial nodes located within ambulances and first aid proximity centers.
Each territorial node was governed by a health operator, not necessarily a doctor, who collected an ECG trace from a patient and transmitted it to the Control Room for a real-time cardiology report.
Each node was equipped with a kit of communication and electro-medical devices.
It had a multilanguage interface including English, Italian, Albanian and Montenegrin.
The activities in which the service has been structured are: adaptation and profiling of the HELIS EMS application, in use at the Polyclinic of Bari, in the Infarct.NET platform; installation and configuration of the Infarct.NET platform at the workstations of the n.2 Control Rooms and n.2 territorial nodes in Albania and Montenegro, training of operators (doctors, health workers); assistance and application management to support users in the realization of electrocardiographic reports.
All the above activities have been performed remotely at the Polyclinic and/or provider premises, and it ensured the connections at the Control Room sites and at the territorial nodes of Albania and Montenegro.

5. Implementation of the Pilot action

In view of what clarified in the previous paragraph, the purpose of the Pilot n. 1 was using a telematic platform to initiate the correct pathway for patients with acute cardiac conditions.
The focal point, in this patient setting arose from specialists acquiring and interpreting an electrocardiogram (ECG) in the shortest possible time. To achieve this goal, it was essential to have an extensive network of locations where patients can undergo an ECG 24/7 (emergency departments, outpatient clinics, ambulances, hospitals). Furthermore, the ability to transmit the ECG tracing to an operational center staffed by cardiology personnel 24/7 was crucial. This center had to be capable of interpreting the ECG tracing and directing the patient toward the most appropriate clinical pathway, also providing telecardiology consultations if necessary.
The planned pathway to implement the Pilot 1 has been confirmed. Necessary initiatives have been planned to expedite the clinical verification process, including expanding the network points designated for data transmission to the three operational centers located in Italy, Montenegro, and Albania.
Additionally, data convergence occurred at the Italian operational center, which is manned 24/7, in case of need. Together with partners, the possibility to intervene in any operational center if required, to

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

reinforce the network's working capacity, in compliance with the regulatory frameworks in each country, has been defined.

Training interventions have been scheduled to make the platform dedicated to cardiac emergencies/urgencies accessible. Start and end times for recruitment have been established, with the goal of achieving 1.800 ECG tracing transmissions and analyses by the project's end date.

At the heart of the implemented Pilot n. 1 stands the platform **Helis Infarct.net**, intended for the diagnosis of the patient's state of health in various areas.
From the operator perspective, the platform allows the user 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. The operator enters the credentials to access the platform, and afterwards indicates the environment code to be used, which identifies the requesting operating unit. Once entering the room code, the operator can select the operation to be carried out, including the request for one or more exams and/or teleconsultation. The operator enters the identification code of the event to be carried out in the "Event Code" field.
Helis Infarct.net assigns a unique progressive number to the event in progress which is the Helis Code (which cannot be changed by the operator). By clicking on "Personal Data", the operator enters the patient's personal data, if not automatically populated following additions made in the installation domain, plus additional notes about the patient. Completed the patient census, the operator can select the operation to be performed; he can also assign a priority to the reporting request he is about to perform.
At this point, it is possible for the operator to proceed with the **ECG examination**, starting with the execution of the 12-lead ECG (for installation of Helis Infarct.net it is possible to request 12-lead ECG and Echo cardio exams).
In particular, registered the electrocardiographic trace, the operator can use the Cardioline TouchECG software. The software opening is managed directly by Helis Infarct.net.
When the operator displays the reception waiting screen, Helis Infarct.net starts the software automatically by automatically filling in the necessary patient data.
Once ECG acquisition is complete, the Operator must click on the button to return to Helis Infarct.net.
When the report is available, corresponding to the event, the message “Report available” shows that the operator can access the part allowing 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

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

Available", colored GREEN, a Pop-up window appears to download the report. Automatically, upon confirmation of download of the report performed by the requesting operator, the report sent is notified on the **referring doctor's screen**. After viewing the report in PDF, the operator, returning to Helis Infarct.net, can decide, according to 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 Infarct.net.
From the perspective of the doctor, he can manage the list of events in the system by clicking on the menu item "Events menu", and see the interventions differentiated from each other based on their status (to be reported, to be reported in charge to others, reported). In the **Control Room** part, the Doctor/Specialist/Technical Operator/Monitoring Operator can see a Legend indicating the Priority levels and the relative assigned colors.
From the section "Event search" the doctor can carry out research on specific tracks., including the Helis Code (unique code of the event created by the mobile station) and the Event Code.
The list contains both interventions already notified and interventions that have yet to be reported. Once the search has been carried out, it is possible to manage the interventions from the list. If already notified, it is possible to access the event to view the reports already submitted previously; if the interventions are to be reported, it is possible to access the reporting phase.
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 and the event such as priority, surname and name of the patient, date of birth, helis code, description - an automated report performed by the Software using the Glasgow algorithm which gives the doctor an initial (approximate) evaluation of the ECG. In case of multiple ECGs, this self-report gives the doctor the opportunity to evaluate the severity of the ECG er to give precedence to any emergencies that require an immediate event-status of the event, history of all the tests performed for the same patient.
Once the ECG has been taken over, the ECG Reporting Tool allows the doctor to view two-dimensional traces in DICOM format and help the doctor in an easier and faster interpretation of the trace.
Once the report has been completed, the user is directed to the confirmation page where he has to manually re-enter his password (password corresponding to the one with which he logs in on the Helis Infarct.net portal) and click on confirm report.
The password request upon confirmation of the report is made as an additional security measure: if the doctor were to leave the workstation, entering the password would prevent someone else from sending incorrect reports that could compromise the event in progress. In the lower part of the screen, in the box the doctor writes the report and immediately above a set of temporal measurements.
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 includes all the electrocardiographic reports performed on the patient including the complete tracking log.

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

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To view the final report, the doctor can 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, is able to access all the exams uploaded and the reports previously submitted.
The **company CONSIS**, which offers products and services in the field of ICT, information systems, consultancy, and training, developed this platform and is responsible in case of malfunctions detected or errors received during the execution of the program; in fact, as the User Manual clarifies, the users are requested to notify the CONSIS Helpdesk of any malfunction and / or defect, and the company undertakes to resolve any problems not arising from misuse by the user as quickly as possible from receipt of the report.

In order to connect to the system the hospitals in Montenegro and Albania, a crucial part of the implementation of the Pilot action has been represented by the **necessary hardware infrastructure** to set up the **Control Room** and any **Peripheral Locations and/ or Mobile workstations** in Albania and in Montenegro, in the same way as the set-up carried out at the Control Room of the Policlinico di Bari and the Peripheral Locations (PPI) and Mobile Workstations of the Puglia Region.
To this regard, LP listed the minimum requirements needed.
In particular, the details of the computer equipment provided in the Control Rooms were the following:

- Number of Referring Physician stations (Cardiologist)2;
- Workstation number possible Support operator: 1;
- Network Printer Number: 1

Each workstation consisted of a workstation and 2 monitors.

The minimum required hardware features of the WORKSTATION Control Room were as follows:

- Quad core processor 1.6 GHz or higher;
- RAM: no less than 16 GB;
- Internal drive: SSD 256 GB;
- Operating System: Windows 10 or 10 Pro or 11 Pro;
- Video Sockets: 4 Video Ports (HDMI and/or Display Port v. 1.2) with UHD/4K monitor support;
- Ethernet interface 1Gbps RJ45;
- USB ports: 4 USB 3.0 ports;
- Integrated audio and microphone with jacks or 1 video connection cable with a minimum length of 150cm DisplayPort/DisplayPort type (Male/Male UHD/4K);
- Webcam;
- Bluetooth® 2.1 + EDR;
- Mouse and keyboard.

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

The minimum required hardware features of the Monitor Control Room were as follows:
- Monitor diagonal between 21" and 24";
- Integrated monitor power supply;
- Built-in speakers;
- Adjustable base and bracket mounting attachments;
- video cable, necessary for its correct attachment to the workstation, with a length of no less than 1.5 metres.

The details of the computer equipment provided in the **peripheral Area for electrocardiographic examination** requests were the following:

- Number of Applicant Operator Stations (Caregiver): 1;
- Network Printer Number: 1.

Each workstation consisted of a **workstation and a monitor** or **notebook and a wheeled or portable electrocardiograph**.

Regarding the **OPTION 1** outlined by LP, the minimum required hardware features for the Workstation, Monitor and Electrocardiograph were as follows:
WORKSTATION:
- Quad core processor 1.6 GHz or higher;
- RAM: not less than 16 GB;
- Internal drive: SSD 256 GB;
- Operating System: Windows 10 or 10 Pro or 11 Pro;
- Video Sockets: 4 Video Ports (HDMI and/or Display Port v. 1.2) with UHD/4K monitor support;
- Ethernet interface 1Gbps RJ45;
- USB ports: 4 USB 3.0 ports;
- Integrated audio and microphone with jacks or 1 video connection cable with a minimum length of 150cm DisplayPort/DisplayPort type (Male/Male UHD/4K);
- Webcam;
- Bluetooth® 2.1 + EDR;
- Mouse and keyboard.

MONITOR:
- Monitor diagonal between 16" and 24";
- Integrated monitor power supply;

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

- Built-in speakers;
- Adjustable base and bracket mounting attachments;
- video cable, necessary for its correct attachment to the workstation, with a length of no less than 1.5 metres.

ELECTROCARDIOGRAPH - The required technical characteristics were the follow:

- 12-lead electrocardiograph (I, II, III, aVR, aVL, aVF, V1-V6);
- AAMI, ANSI, AHA, ACC certifications;
- A/D conversion: 24 bit;
- Minimum sampling frequency: 500Hz/channel;
- Standard acquisition mode: 10secs sample;
- Storage of ECG traces: in Local;
- ECG trace export formats: SCP and/or DICOM;

It was necessary that any ''proprietary software'' for using the electrocardiograph could be integrated with third-party applications and was compatible with the Windows environment.

The models of electrocardiographs in use at the Bari General Hospital were the following:

- Cardioline HD Plus v.3 with TouchECG software (Portable Electrocardiograph);
- Cardioline ECG 100+/200+ with Cardioline Connectivity Tools software (Wheeled Electrocardiograph).

Regarding the **OPTION 2,** the minimum required hardware features of the NOTEBOOK were as follows:

- Quad core processor 1.6 GHz or higher;
- RAM: not less than 8 GB;
- Internal drive: SSD 256 GB;
- Operating System: Windows 10 or 10 Pro or 11 Pro;
- Video Sockets: 2 Video Ports (HDMI and/or Display Port v. 1.2);
- Ethernet 1Gbps RJ45 interface;
- USB ports: 2 USB 3.0 ports;
- Integrated audio and microphone with jacks;
- Built-in webcam;
- Bluetooth® 2.1 + EDR;
- WiFi 802.11 AC.

ELECTROCARDIOGRAPH - The required technical characteristics were:

- 12-lead electrocardiograph (I, II, III, aVR, aVL, aVF, V1-V6);
- AAMI, ANSI, AHA, ACC certifications;
- A/D conversion: 24 bits;
- Minimum sampling frequency: 500Hz/channel;
- Standard acquisition mode: 10sec sample;
- Storage of ECG traces: in Local;
- ECG trace export formats: SCP and/or DICOM.

Regarding the detail of the **IT equipment** provided for the **Mobile Workstation for requesting electrocardiographic examination:**

- Number of Applicant Operator Stations (Caregiver): 1;

Each mobile workstation consisted of a **Notebook** or **Tablet** and **a portable electrocardiograph**.

OPTION 1

NOTEBOOK Mobile Workstation - The minimum required hardware features were as follows:

- Quad core processor 1.6 GHz or higher;
- RAM: not less than 8 GB;
- Internal drive: SSD 256 GB;
- Operating System: Windows 10 or 10 Pro or 11 Pro;
- Screen between 14" and 16"
- Video Sockets: 2 Video Ports (HDMI and/or Display Port v. 1.2);
- Ethernet interface 1Gbps RJ45;
- USB ports: 2 USB 3.0 ports;
- Integrated audio and microphone with jacks;
- Built-in Webcam;
- Bluetooth® 2.1 + EDR;
- WiFi 802.11 AC;
- Data SIM slot.

ELECTROCARDIOGRAPH - The required technical characteristics were:

- 12-lead electrocardiograph (I, II, III, aVR, aVL, aVF, V1-V6);
- AAMI, ANSI, AHA, ACC certifications;
- A/D conversion: 24 bits;
- Minimum sampling frequency: 500Hz/channel;

- Standard acquisition mode: 10sec sample;
- Storage of ECG traces: in Local;
- ECG trace export formats: SCP and/or DICOM.

Also in this case, it was necessary that any 'proprietary software' for using the electrocardiograph could be integrated with third-party applications and was compatible with the Windows environment.
The model of the portable electrocardiograph in use at the Mobile Workstation is Cardioline HD Plus v.3 with TouchECG software.

OPTION 2
TABLET Mobile Workstation - The minimum required hardware features were as follows:

- Quad core processor 1.6 GHz or higher;
- RAM: no less than 8 GB;
- Internal drive: SSD 256 GB;
- Operating System: Windows 10 or 10 Pro or 11 Pro;
- Touch-screen between 14" and 16";
- USB ports: 2 USB 3.0 ports;
- Integrated audio and microphone with jacks;
- Built-in Webcam;
- Bluetooth® 2.1 + EDR;
- WiFi 802.11 AC;
- Data SIM slot.

ELETTROCARDIOGRAPH - The required technical characteristics were:

- 12-lead electrocardiograph (I, II, III, aVR, aVL, aVF, V1-V6);
- AAMI, ANSI, AHA, ACC certifications;
- A/D conversion: 24 bits;
- Minimum sampling frequency: 500Hz/channel
- Standard acquisition mode: 10sec sample;
- Storage of ECG traces: in Local;
- ECG trace export formats: SCP and/or DICOM.

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

6. Information about stakeholders' role/involvement

The stakeholders involved in the implementation of the Infarct.NET Pilot 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 in the Pilot's development and validation.

In the foreseeable future, **pharmacies** might also have a significant role in the Pilot's evolution.

Physicians predominantly included **remote diagnosticians**, alongside caregivers providing emergency ECG. In particular, the specialists involved in the pilot implementation were **referring cardiologists.**

The **treated patients** amounted to **2,364** on a cross-border level.

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 across disciplines 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 involved entities 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.

Furthermore, 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), **Tecnolopolis PST (Technological Scientific Park)**, **Confindustria**, and **Unioncamere Puglia** significantly contributed to raising awareness and providing information.

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

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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 Regional Department of Health of Puglia 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 the Pilot's implementation 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 project Final Conference, the **Polytechnic of Torino**, specifically Prof. Eros Pasero was also involved. He delivered 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. 1 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.

7. Lessons learned by implementing the Pilot action

For the Infarct.NET Pilot validation, it should be firstly considered that 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.

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

Among the lessons learned by implementing the Pilot it should be mentioned that it primarily allowed for obtaining **crucial managerial information** in advance, enabling the optimization of hospital admissions and stays. Moreover, **optimal treatment opportunities** for patients affected by heart attacks, heart failure, or suspected heart-related illness episodes, thereby indirectly enhancing their quality of life, has been ensured by implementing the Pilot. This improvement stemmed from **reduced intervention times.** In fact, conducting an ECG directly in the ambulance/ first aid proximity center, coupled with remote review by specialized physicians, enabled immediate assessment, decreasing the time between detecting a heart attack and commencing treatment. This significantly increased the chances of preventing severe cardiac damage, positively impacting patients' overall recovery. Under this perspective, PHASE project consortium expectations can be considered realistic.
In quantitative terms, given that the permissible time intervention for heart attacks is a maximum of 90 minutes, a **time saving of approximately 60 minutes** has been quantified, encompassing saved time in transportation and triage in the emergency department.

Furthermore, remote evaluation by specialized physicians led to faster and more precise heart attack diagnoses, facilitating expedited and targeted treatment, also reducing the risks associated with long-term complications and hospitalization.
It should also be emphasized that the average hospital stay for cardiac conditions typically ranges between 12 to 15 days. Early diagnosis allows for **more targeted and shorter hospitalizations**, which have indeed reduced by an average of **20%.**

We had the opportunity to verify that all the reactions showed by the patients who benefited from Pilot service n. 1 were positive, and they were generally satisfied by the promptness of the intervention and the possibility of performing an ECG directly at primary emergency point.
In terms of useful advice for the replicability of this Pilot action, it should be emphasized that the implementation of the Infarct.NET Pilot has demonstrated the crucial importance to ensure the optimal functioning of the service through a **reliable and secure technological platform** for transmitting medical data. Concurrently, the training of personnel/staff, conducted alongside the Pilot's implementation, played a pivotal role.
Organizational measures to recommend also involve the definition of clear and standardized protocols for patient treatment, including data collection, and the setting of efficient communication channels, compliant with privacy regulations while maximizing the effectiveness of the eHealth intervention.
Additionally, providing continuous support to eHealth application users, offering assistance in resolving any reported issues with using the service was of fundamental importance, as well as integrating the

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

service focused on by the Pilot with the existing healthcare system from technological, organizational, and regulatory standpoints.
Overall, the lesson learned is that the **system implemented through the Pilot n.1 is entirely feasible** and **appreciated** by all parties involved, even on a cross-border level.

With reference to the main problems PHASE consortium had to face within this Pilot action implementation, they are related to technical aspects, referred to the **interoperability** of the devices.
To overcome this challenge and ensure platform functionality from the beginning, the Project Lead Partner provided precise guidance to all project partners regarding the technical specifications of the devices to be purchased.
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.
To further investigate the encountered problems, please refer to the following paragraph.

8. Problems found and adopted solutions

In addition to the mentioned issue related to the interoperability of information systems and databases, major problems found in implementing the Pilot n. 1 were linked to **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.
Therefore, a pivotal 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 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. Moreover, targeted training **courses on data protection, privacy, and security** have been conducted for this purpose. This approach aimed to ensure data security, regulatory adherence, and effective adoption of new technologies in the healthcare sector.

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

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. On the other hand, doctors had to adapt their knowledge and practices to incorporate technological devices. The integration of technological tools in the healthcare sector necessitates a learning curve and skill adjustment, representing a critical aspect in transitioning to remote and digital monitoring solutions. Furthermore, there's hesitation among some doctors to let go of direct patient engagement. In fact, within the Pilot action n. 1, such interaction was contingent upon a genuine need for an in-person visit or hospitalization. However, routine procedures, like ECG examinations, could typically be conducted remotely with results assessed at a distance.

Overcoming this challenge required the implementation of specific training activities tailored to healthcare personnel and to general 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.

9. Cross-Border added value of the Pilot action

The Cross-Border Added Value of the Pilot Action was represented by the creation of an integrated space for diagnosis, reporting, and medical consultations across the involved territories. This was crucial due to the potential for remote second medical opinions offered by the application.

Specifically, specialized doctors in Italy had the opportunity to assist and train those in Montenegro and Albania, and vice versa. Looking ahead, this could facilitate cross-border assessments of particular clinical cases where there might be a lack of diagnostic consensus. It would promote multidimensional diagnoses involving physicians from the involved regions, aiming to provide comprehensive health evaluations for patients and, consequently, enhance treatment possibilities.

Moreover, the Pilot experience embodied the principle of equitable healthcare access on a transnational level. It achieved this by enabling patients in remote areas to access clinical consultations from specialists. Beyond the promotion of innovation in cross-border telemedicine to improve healthcare service effectiveness, the cross-border value lied in promoting fairness and equality as foundational principles of healthcare systems.

Lastly, it should be stressed that the cross-border value in the Pilot implementation was also expressed by the effective integration of the applications between Italy, Albania and Montenegro, with the concrete implementation of the control rooms in all the involved territories. In fact, when the doctor accesses the

Helis Infarct.net application using his own credentials to manage the events listed in the Control Room section, he can select the Italian, English, Albanian and Montenegrin languages, proving that the platform can be used by all the countries involved. The same thing applied in the phase of carrying out the electrocardiographic examination: the caregiver starts the Helis Infarct.NET application and, from the login, selects the language among those mentioned, because it works from all the territories involved in the project.

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