Interreg - IPA CBC
Greece - Republic of North Macedonia
COMETECH

User Requirements of

Software Functionalities

WP3 / D3.3

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1. INTRODUCTION

1.0 Background

This document is the deliverable D3.1.3 of the WP3 of the project titled "Continuity of care in metabolic diseases through modern technology", with an acronym "COMETECH", implemented under the Subsidy Contract No.SC027, COMETECH–CN1–SO1.2–SC027 upon the 1st Call for proposals within the INTERREG IPA Cross-border Cooperation Programme Greece – the North Macedonia 2014-2020.

This report refers to the identification of the functional and non-functional technical and medical specifications of the proposed software application. The software application is one of the key deliverables of the COMETECH project. It supports the clinical care of the patients and maintain clinical information for monitoring, evaluation and administration purposes.

1.1 Purpose of the document

This report has two (2) main objectives:

- To present and analyze the general and specific (functional and non-functional) requirements of the proposed software application, which will manage the clinical data of the pilot project.
- To become the basis for the WP4/D4.1.3 WP4: "Development and installation of software application" deliverable of the WP4.

1.2 Document control

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2. GENERAL DESCRIPTION

2.0 Project scope

The Interreg IPA CBC Programme "Greece – Republic of North Macedonia 2014-2020" is a cross-border cooperation Programme co-financed by the European Union under the Instrument for Pre-Accession Assistance (IPA II). The strategy statement of the Programme is "to enhance territorial cohesion by improving living standards and employment opportunities holding respect to the environment and by using the natural resources for upgrading of the tourism product". The total budget of the Programme for the period 2014-2020 is 45,470,066.00 €.

COMETECH is implemented by a partnership consisted of five partners from both participating countries:

Table 1. COMETECH Partners

Pr. Nr.	Partner title	Country
LB (PP1)	International Hellenic University (former Alexander Technological Educational Institute of Thessaloniki)	Greece
PP2	Florina Prefectural General Hospital	Greece
PP3	Medical Association of Thessaloniki	Greece
PP4	Clinical Hospital Bitola	Republic of North Macedonia
PP5	General Hospital Veles	Republic of North Macedonia

COMETECH project aims to address the problem of inadequate access to the health system services to people who live in isolated communities at Greece- Republic of North Macedonia cross-border areas. The project will establish 4 e-health units -2 in each country- at isolated and deprived communities collaborated each other, aiming at introducing "Continuity of Care" in the border region between Republic of North Macedonia and Greece. In order to accomplish the above, the provision of medical devices capable of telemedicine is essential.

The establishment of the e-health units will allow affordable access to medical services within Greece- Republic of North Macedonia cross-border area. These units (equipped by state-of-the-art medical devices, supported by an advanced software application and medical staff) will record data of local people, inform them about environmental and other risk factors, and offer valuable and high quality medical care services. The records of the citizens using the COMETECH services will be safely and easily accessible by their physicians. The involved public bodies will be encouraged to use COMETECH services as a tool for introducing high quality continuity of health care in their respective regions.

2.1 COMETECH objectives

COMETECH specific objectives are the following:

- To support a collaboration between research teams from Republic of North Macedonia and Greece of scientists from different scientific fields (such as doctors, biologists, etc.) and closer cooperation among the two national health care systems so as to develop a common strategy for prevention, early diagnosis and treatment of Obesity, DM and CardioVascular Disease (CVD).
- To raise awareness of the local and national authorities regarding the above health issues.
- To inform the regional population on the prevention, diagnosis, and treatment of DM, Obesity and CVD.
- To identify the environmental and other risk factors that are involved in the development of DM, Obesity and CVD in the population that will participate in the project.
- To facilitate access for doctors on both sides of the border to their patients' data through telehealth.
- To develop four e-health units equipped by hi-technology medical devices and supported by an advanced software application for ensuring "Continuity

of Care" through telehealth.

- To support the life-long education of the COMETECH involved population and medical practitioners by utilizing their telehealth interaction with experts as the means for training.

2.2 COMETECH expected results

Patients with type 2 DM are usually asymptomatic and the diagnosis of diabetes delays until serious complications develop. Therefore, the assessment of DM, Obesity and Cardiovascular risk factors and the providing of up to date information on these diseases will increase the awareness of the population. This will reduce the occurrence of above diseases in the targeted isolated areas.

On the other hand, the cost of DM, Obesity and CVD is tremendous. Over the lifetime, DM imposes a substantial economic burden on healthcare systems. It has been calculated that the medical per person costs of treating DM and its complications, during a lifetime, is in average 85,200 Euros. The total annual cost of DM, Obesity and CVD in EU is about 550 billion Euros. Considering this, the current research project is of great value not just in terms of medical but also in terms of the high economic benefit for every citizen separately and for the national health system, as a whole. COMETECH project will also promote the cooperation between healthcare authorities.

Total Project budget amounts 1.018.189 EUR, i.e. 321.486, 00 EUR for project activities that are to be implemented in the former Yugoslav Republic of Macedonia, while the remaining amount of 696.703 EUR is allocated for the implementation of activities in Greece. The project duration is 24 months.

2.3 COMETECH e-health units architecture

COMETECH will establish four (4) e-health units collaborated each other, aiming at introducing "Continuity of Care" in the border regions. These units (equipped by state-of-the-art medical devices, supported by an advanced software application and medical staff) will record data of local people, inform them about

environmental and other risk factors, and offer valuable and high quality medical care services.

The architecture of the e-health units is illustrated below:

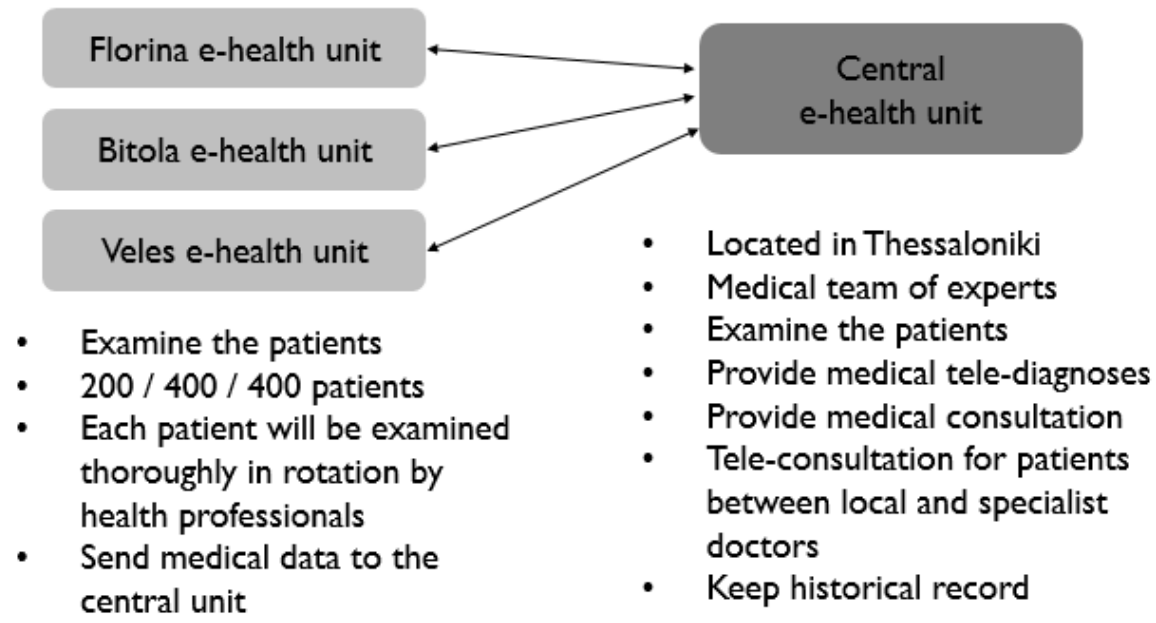

Figure 1. COMETECH architecture

In overall, the proposed application belongs to the Electronic Health Management Information Systems (eHMIS) category. We can define the EHMIS as the facility based data aggregation system that is used for public health-related decision-making. Its main users are public policy makers, health officers, researchers, planning departments of health offices, HMIS focal persons, data entry clerks and many others ranging from health facility to federal management levels.

Furthermore, eHMIS is best referred as a system that is designed to fulfill the need of automated national health information management system. It helps to accurately and timely collect, aggregate, store, analyze and evaluate health related data from health facility to federal level.

The following prerequisite services can be supported through the above infrastructure:

- Tele-consulting, and
- Remote medical data management.

3. FUNCTIONAL REQUIREMENTS

3.0 Introduction

For success of any e-health system/project, the following key factors need to be in place (Figure 2):

Type of criteria	Examples
Functional	• Functionality: Comprehensive functionality, Supports various ways of system use, Balance between new functionality and stability*, User-tailored ICT • Usability: High usability*, Good fit between user and system, Intuitive user interface, Not too many different screens*
Organizational	• Historical Context: Earlier positive experience with new way of working, Previous experiences of users with ICT • Fit of perceived cost and benefit: ICT answers perceived, continuous need*, Positive cost-benefit perceptions of users*, Positive influence on patient care, Patients feels benefit, too*, Balance between expectations and ICT outcome • Support of workflow: ICT supports core process of patient care , ICT embedded in clinical workflow, ICT supports concrete clinical tasks, Activities made easier through ICT*, Reduction of routine documentation activities, Not too many changes on work organization and workload*
Technical	• Development process: Development in small teams, Continuous user involvement and user participation*, Sufficiently modeling health care processes, Use of open standards • System Architecture: Flexible system concept*, Modular and scalable system concept*, Good interoperability and integration with other ICT systems*, Low complexity of the overall system* • Technology: Stable, not too innovative technologies*, Affordable technologies, Easy-to-use devices
Managerial	• Sufficient funding available • Good and flexible project management: Strong motivation of project team, Good public relation of project team, No interpersonal tensions in project team, Use of tools for project management • ICT Introduction: Availability of skilled IT staff, Sufficient user training and user education*, Extensive user support*
Cultural	• Availability of promoters with a vision: Active marketing of new system, Forming a support based for change, Support through various user groups, Conviction of project idea* • Openness to change and innovation: Acceptance of new way of care delivery, Acceptance of standardized way of care delivery, Not too independent professional status of users, Alignment of individual goals with institutional goals
Legal	• Appropriate legislation, Willingness for health care reforms, Willingness to change legislation, Involvement of ICT expert in legislation committees, Health authorities promote innovation

Figure 2. e-health key functionality factors

Both functional and non-functional requirements (also called quality attributes) should be considered when developing software applications in general. In the following sections these types of functionalities of the COMETECH Project are examined.

3.1 General functional requirements

Functional requirements are statements of services the system should provide, how the system should react to particular inputs, and how the system should behave in particular situations (Sommerville, 2010).

Specifically, functional requirements are those processes that a user wants a system to perform. Functional requirements for any given organization can be described at a high level, in five or 10 functions, or at a very detailed level, potentially numbering in the hundreds. At the end of 2003, the Institute of Medicine (IOM) Committee on Data Standards for Patient Safety developed recommendations on core medical functionalities for four (4) types of care settings: hospitals, ambulatory care, nursing homes, and care in the community - now referred to as the personal health record. There are eight (8) core functions identified by the IOM are probably the closest to what may be considered a standard set of functionality for an e-health unit:

1) Health information and data.
2) Results management.
3) Order entry/management.
4) Decision support.
5) Electronic communication and connectivity.
6) Patient support.
7) Administrative processes.
8) Reporting and population health management.

An important resource for greater specificity in functionality is the Health Level Seven (HL7) EHR-System Functional Model and Standard List of Functional Statements (www.HL7.org/ehr). This set of functional statements is described as a set of functional descriptors applicable in an ideal EHR for all types of providers. It describes functions applicable both to clinics and hospitals, but not all functions needed by a hospital would be needed by a clinic. The Certification Commission for Healthcare Information Technology (CCHIT) has compiled criteria for functionality, interoperability, and security for ambulatory EHR products and for the foundation of inpatient EHRs. These criteria draw from the IOM and HL7 as well as other standards. Products that are certified according to these criteria must demonstrate that they meet the requirements. Review these criteria to ensure that any vendor from whom

you acquire HIT is certified. See www.cchit.org for a list of certified vendors as well as the criteria.

3.2 System architecture

The proposed software application is a complete telemetry / telehealth system, recording and monitoring of biological signals and health parameters, which supports the management of the targeted diseases, but also prevention through the improvement of health indicators that can contribute to the manifestation of these diseases.

The provided services can be accessed through the healthcare professional or the general practitioner, who records in the application via laptop / mobile phone / tablet data concerning the patient's health (history, medical history, biochemical indicators, medication, etc.), as well as, biological signals either manually (or automatically) from specialized and easy-to-use Bluetooth medical devices.

To provide telemetry, a laptop or tablet is used, with the specialized application and connected to special portable vital signal measuring devices. The telemetry will be done by trained specialized health professionals who will organize special mobile scales. The mobile scales will consist of nursing / medical staff and will record patient measurements (e.g. glucose, abduction cardiograms, blood pressure, oximetry, spirometry, etc.), which are then automatically transferred to the laptop via Bluetooth.

The measurements are then sent via the Internet from the internet access device such as a tablet to the e-health unit server and then via the Virtual Private Network (VPN) to the server of the central e-health unit in Thessaloniki, where the specialized doctors have direct access and studies the recordings, evaluates them, sends his advice or records a comment or prints the examinations or contacts immediately with the patient or nurse if necessary.

All the above are illustrated in the Figure 3.

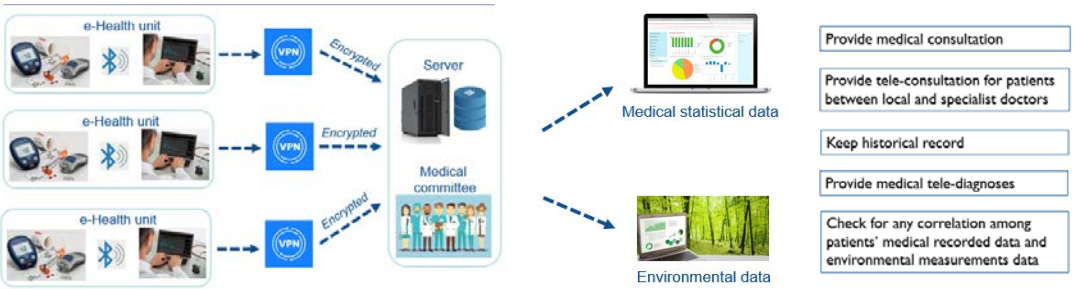

Figure 3. Systems architecture

3.3 System requirements

In a web health application, some basic modules which common e-health field needed will be designed and implemented. The most important point and initial idea of the whole application aims to offer a platform where the user can realize self-care management and health self-education.

For different roles, the system developers set corresponding authorities according the reality requirement. Then some basic function modules will be developed, such as the Home page Introduction, Forum page offering a platform to communicating and getting the admin's global notifications and different roles' function modules, etc. The next step is to apply the responsive web design technique to realize the proper view and layout transferring from the PC or tablet to handheld devices automatically. Then another important part about the diabetes patients' data collecting and presentation will be involved in this system to offer a longtime recording and checking for specific properties such as glucoses, weight, exercises and diets, etc. Once referencing to the data storage, the database selection and designing will be considered. Moreover, the personal privacy and data security will be solved in the system. Lastly, the whole will be deployed on the MWA web server to serve for the user and make its sense. The system function and modules designing will be introduced in detail as the following:

1. Self-care education: The application should offer an education tour platform where the user can obtain some basic information what they want for the diabetes such as the diabetes influence factors, diabetes treatment, diabetes types and nursing method, etc.
2. Communication platform: The application should offer a communication platform where different roles can share the resources what you have and

get the information what they want. In this part, the user can create a subject and read the existed content and the admin can publish the global notification to all the users.

3. Authorities assigning: The application should offer different roles management, which are the user, doctor and admin. For different roles, they will have corresponding authorities.
    - The user can login in its specific page to record and present its own data. Moreover, the user can assign some specific permission to the other users or doctors who they want to share the personal information with.
    - The doctor also has its authorities that they can access the specific user's information according to the awarded authorities.
    - The admin has the authority to view all the user and doctor's information such as the username, e-mail except login password.
4. Data collecting and presentation: Aiming at the user's personal data, the application should offer an easier method to record their personal data and offer a concise presentation. The presentation should include the query to different data according to the record date time with different presentation format such as, histogram, line chart and pie chart, etc.
5. Concise view: Due to this application, mainly serve for the diabetes, and the major crowds of the diabetes patients are the older people. So the application should has a concise view both on the PC and handheld by responsive web design method. Bigger text and more figure presentation will be preferred by
6. Security: It is a quite important point for any user due to the privacy data existing.
7. Nobody want its personal information exposed to the public. Therefore, it requires the protection measures such as access control and database selection and management.
8. Reliability: The application will offer a longtime service for self-care,

education and personal diabetes data storage and checking. So the system should has a relative reliable performance. So it references to the database and cloud platform selection, etc.

Based on the above, the required functionalities of an e-health information system are presented below:

- Ability to create a user-patient tab.
- Possibility of nutritional evaluation of a diabetic patient based on scientifically substantiated nutritional instructions.
- Interconnection with the medical devices of the telemedicine units.
- Possibility of off-line local storage of basic data of the medical file and the latest measurements.
- Registration of structured information concerning the patient's health, eg medical memory, biochemical tests, laboratory tests, Family History, Hereditary, diseases, surgeries, history and history of the immune system, Physical condition, Diseases.
- Risk indicator based on indicators, e.g. 10-year cardiovascular risk by Framigam and ESC.
- Image measurements from medical telemetry devices.
- View diagrams.
- Data synchronization with the telemetry application.
- Possibility of remote connection with a specialized doctor for teleconferencing.
- To offer the necessary licenses based on the needs of the project.
- Support for SQL international standards (ISO, ANSI 92 standard SQL).
- Show exams waiting to be answered.
- View exam time.

- Analysis of results based on special algorithms.
- Ability to enter doctor's comments.
- Ability to create reports.
- Data encryption when storing in the Medical Electronic Comprehensive Diabetes Care File.
- View statistics in the form of graphs.
- Send warning emails / sms for a new examination to the doctor.
- View pressure measurements, glucose, ECG, oximetry, spirometry, thermometer, stethoscopy, otorhinolaryngology, plantar fasciitis, measurement by age reader and from a bottom camera.
- Sending comments and notification messages to the software for receiving / sending and managing medical parameters.
- Management of notifications to the software for receiving / sending and managing medical parameters.
- Ability to enter standard counseling messages about the goals from various professionals (nutritionist, psychologist, diabetologist, etc.)
- All patients, symptoms, etc. will be coded based on ICD-10, 10th WHO Review.
- Possibility of validation of the existence of the application for the participation of the participants.
- General Pharmaceutical Education.
- Antidiabetic Pharmaceutical Education.
- Medical Individual Memorial based on ICD 10, 10th Review of WHO1.
- Clinical examination.
- Assessment of Diabetic Complications.
- Nutrition card.

- Show / manage questionnaires.
- Nutritional knowledge questionnaire.
- Quality of life questionnaire.
- Self-efficacy questionnaire for self-management of diabetes.
- Questionnaire on eating habits.
- Questionnaire on patients' health status and score calculation automatically.

Based on the above, the following list presents the required functionalities for the COMETECH project:

- Creation of registration with the personal data of the medical and nursing staff that will be involved in the pilot implementation of the project in the four health units.
- Management of medical staff users.
- Recording by the doctors of the patients, they are attending as well as registration of the respective examinations that they will perform.
- Management of medical records of patients.
- Receiving Medical Data from Recording Devices (Glucose, Arterial Pressure, Cardiogram, Oximetry, Spirometry, Thermometry, Stethoscopy, Otolaryngology, Pelvic Painting, Electrolyte Dilochronate Measurement, from Camera Camera, etc.
- Supported Database: MySQL.
- Easy to use Graphic Environment in Greek and English.
- Ability to store data locally and send it to another time it is within network coverage.
- Ability to view locally stored exams in the form of a history.
- Get answers from health professionals and view locally.

- Possibility of synchronization with the Medical Electronic Integrated Diabetes Folder.
- Connect the software with the recording devices of at least Glucose, Arterial Pressure, ECG, Oximeter, Spirometer, Thermometer, Stethoscope, Pediatrician, age reader and by bottom camera for receiving wireless medical signals.
- Ability to complete algorithmic questionnaires and synchronize with the Medical Electronic Integrated Diabetes Folder.
- Introduction of personalized limits and selection of notifications per patient.
- Possibility of receiving notifications / reinforcing messages from the Medical Electronic Comprehensive Diabetes File.
- Possibility to select goals from a nutritionist, immediate information through the Medical Electronic Integrated Care Diabetic File.
- Nutritional knowledge questionnaire based on scientific methodology.
- Ability to assess the current situation using a scaled barrier incentive scale.
- Produce automatic messages according to the options in the questionnaire.
- Ability to track targets set by nutritionists and diabetologists through the Integrated Diabetic E-Medical Medical File.
- Integration of the following algorithmic questionnaires:
    - Quality of life questionnaire.
    - Self-efficacy questionnaire for self-management of diabetes.
    - Questionnaire on eating habits.
    - Questionnaire on patients' health status.
- User access control to certify and identify the user's rights when accessing the application at system level and application of telemedicine.
- Authorization to access information different by user and by type of information.

- Observance of the provisions of Law 2472/1997, EU 2016/679 (GDPR) regarding the Protection of Personal Data.
- Preservation of medical data in encrypted form.
- User interface friendliness.
- All subsystems provide immediate support and help to users per process and screen.
- The error messages that the applications present to the end users, should be in Greek and English and the users should be notified in terms familiar to them.
- The technologies that will be used for the development of the application to ensure its easy maintenance and allow the expansion of its functionality by adding additional subsystems that will cover possible future needs.
- Open standard support: ensuring the viability and future expansion of the system, all offered development tools, server software as well as the application are based on open templates and are available under the terms of the GNU / GPL license.
- Systemic article architecture to allow future extensions and replacements, integrations, upgrades or changes to separate software or hardware components.
- Open architecture where the proposed / offered software services, security and the database management system and application are based on proven mature and tested systems platforms in the open to facilitate its support and maintenance.
- Access to system functions should also be possible via BlueTooth portable devices at least for ECG, spirometry, oximetry, glucose, blood pressure, weighing and BMI tests.
- Find the files of the examinees / patients in a fast and easy way (eg use of demographics, etc.).

3.4 Roles' requirements

The software application should meet different roles' requirement and access authority management, which will be used as a basic model in some specific application in the future. For example, different roles such as diabetes patients, doctors and administrator can be created, and the discussion between patients and doctors should be available. Moreover, the authenticated doctor can access the specified items of the patients, which will solve the problem of security.

1. *Patient's requirements*. The patients need an e-health unit model, which they can view their electric record and get self-care education, moreover, the patients need advice from specify doctors, so they hope that they can manage the access authority. The patient need to have the right to assign some specific authorities for the doctors, for example when a diabetes patient want to share their medical record like glucose, exercise, weight vary and daily diet during some periods, sometimes, they just want to share part of their information like glucose, and they don't want the doctor to see the others' privacy data. When the patients do not want the doctor to access their medical record, they can cancel the doctors' authorities. An authority's record history is needed to remind the patients whom they has given the authorities to. Search function is also needed in this system; the patients can find the registered doctor, as they want to give access control. In our E-health model, the patient can view the record whenever they want and share their own thought with other patients in the communication platform.

2. *Doctor's requirements*. To the doctor, they would like the system to be flexible that they can also access the website at anywhere and get the information from the patients who they give the authority, they also don't want to view a handwritten record because of it will always led some mistakes and wastes time, which can reduce the medical accident caused by misunderstanding, the doctors hope that they can share their experience and view the patients record clearly.

3. *Administrator's requirements*. The e-health model need an administrator, who can manage and monitor the software application. The administrator would like to monitor the application in case of change the patient information for illegal purpose and has the power to manage the register users. In COMETECH project, the administrator can manage roles and users (e.g. delete some illegal users) and can publish a global notification to all the users to remind some important things. The administrator also can view all the information of the registered users except password.
4. *Security requirements*. To avoid abusive registration, all the users in the proposed system can register only one account for each person. In addition, a security mechanism for the users can be offered when they want to change the password or forget their password. In COMETECH project, users need to answer the security questions and give the email so that when users want to change their password. Moreover, it is general idea that only the person who knows the password can login the account. The password is encrypted during the transmission. In the transmission of medical records and personal information, those information are encrypted.

3.5 Data and database requirements

Aiming to the specific field, the following parts need to take into account regarding the designing, computing and data format.

- Data Format: The data in the system should follow the medical standard format and rules, such as the unit of glucose, it is mmol/L. The medical words should be used seriously.
- Data Storage: Considering the security issue of the data storage, such as the storage format and privacy information data protection. A proper database with higher security level.
- Data Presentation: In order to provide a concise and beautiful view of the data. The data presentation can combine with different presentation formats such as histogram and table, etc. according the medical data

requirement.

Regarding the health record, the following data must be recorded:

- Visit details.
- Social - demographic data.
- Anthropomorphic data.
- Hematological Examinations.
- Biochemical tests.
- General urine test.
- Glycosylated Hemoglobin.
- Display a total number of active participants.
- Monitoring goals for all participants during the project and its completion.
- Objectives to be followed:
    - Glycosylated Hemoglobin ≤ 7%.
    - Decrease in the number of hypoglycemia per month.
    - Compliance with the proposed number of telemedicine measurements (AP, Blood Glucose, Oximetry, Spirometry, etc.).
    - Score of dietary questionnaires.
    - Take glucose tapes per month.
    - Evaluation of physical activity.
- Display automatic notification on receiving / sending and managing medical parameters software whenever a goal is not achieved.
- Visit and appointment management.
- Monitoring the patient's progress on the workflow engine, at the following points:
    - When the consent form is signed.
    - When laboratory and other tests are completed.
    - Participants - patients admitted to the system for follow-up.
    - Participants - patients who are no longer monitored.
    - Observance of the provisions of Law 2472/1997, EU 2016/679 (GDPR) regarding the Protection of Personal Data.

The following functionalities can be considered as critical regarding the information/data of the COMETECH project:

- General characteristics.
- Automated recording and monitoring of biological signals and health parameters for complete preventive control.
- Personalized algorithms for early prevention.
- Classic health file in the form of a history for better organization of personal health data per patient - individual, hereditary, medication, chronic diseases, allergies, etc.
- Introduction of limits and selection of notifications per patient.
- Facilitate / automate the entry of information (ICD-10 for recording diagnoses, etc.)
- Functionality with third party systems.
- Direct access from any browser and portable device (responsive design).

In addition, it provides the ability to register / maintain the following:

- Diagnosis.
- History of Examinations, Diagnosis, Demographics.
- Family history.
- Individual history (which includes Social, Immunization, Interventions, Chronic Diseases and Chronic Medication).
- Hereditary, diseases, interventions, history and history of the immune system.
- Physical condition (e.g. weight, height).
- Habits that affect physical condition (eg smoking, exercise, etc.).
- Illnesses.
- Current treatment.
- Education.
- Ability to enter doctor's comments.

3.5 Privacy requirements

Patients' personal data needs too be stored in the encrypted database based on a common standard. One reliable solution is the AES256 standard, which describes a symmetric secret key encryption block process. The encryption process is repetitive. This means that in each data block a processing is performed which is repeated a number of times depending on the key length.

Specifically, the Rijndael 256 is the encryption algorithm used for AES encryption. In addition, the code uses block segregation through the "Electronic Code Book" and encrypts them separately, which increases security. The communication with the servers is done through https security protocols and the start SSL PKI (128bit). Both User-Id and user passwords are stored in encrypted form in the database. To increase security, an active connection test will be used, so that after the connection to the application a certain idle time has elapsed without any execution.

More the proposed system must provide the ability to determine the access of a user of the system or not to an application-subsystem. Therefore, users of the app, in fact, define a subset of system users. Applications-subsystems then determine the roles and rights of their users.

The selective access process depending on the authorization requires the identification of the user by providing a password and password. More specifically, for each user of the system, the following information is entered, which is unique to each user and inaccessible to any unauthorized person:

- User name (unique for each user)
- User data, which are formatted according to the login account
- User group
- Password for authentication and authentication of user rights when accessing the application
- Access privileges different from per user and per type of information.

Selective authorization prevents both unauthorized additions, deletions or modifications to the data contained in patients' files, and unauthorized transfer of information. In addition, there is no unauthorized disclosure of information and access to the system through the operating system and through passwords per user (username and password) allows access only to data that have the right to access. This means that each user or group of users has access only to the screens and the data concerning him / her. In cases where there is special authorization, the user may have access to data other than his own. In this way, medical and personal confidentiality is ensured, as well as the security of the system's data.

3.6 System and data security requirements

The following security measures must be taken are as follows:

- A system and user access control is supported.
- Safe management, registration and encryption of passwords (SHA - 256, Secure Hash Algorithm).
- Process of identification and authentication of users.
- Central user management and rights determination system.
- Firewall mode, IDS.
- Check out the latest versions of software, malicious code.
- Unauthorized access and software detection functions.
- Software operation.
- Absence of Single Points of failure in infrastructure
- Backups are performed on a daily basis throughout the system
- At regular intervals, risk management work / risk assessment is performed
- All connections to the system are encrypted and are made through https and SSL (Secure Sockets Layer) protocols with a 256bit certificate.

4. NON-FUNCTIONAL REQUIREMENTS

Non-functional requirements are attributes that either the system or the environment must have (Garmus and Herron, 2000). IEEE (1993) defines non-functional requirements in software system engineering, "*a software requirement that describes not what the software will do, but how the software will do it, for example, software performance requirements, software external interface requirements, design constraints, and software quality attributes*".

Some of these are requirements that many stakeholders gravitate to, and some are requirements few if any end users recognize are needed. Non-functional requirements and their descriptions for the COMETECH Project (adapted from (McEwen, 2004) are presented in the following table:

Table 2. Non-Functional Requirements

Non-Functional Requirement	Description
Usability	Describes the ease with which the system can be learned, managed or used. Usability gives the measure of how much user friendly the system is. This also includes the Internationalization/localization requirements such as, languages, spellings, etc. This is critical for the COMETECH project because doctors and nurses are not experienced software application users and they are working based on a rotation-based schedule. Therefore, the system should be sufficiently intuitive to allow new users to learn basic operations within one day of use; users must need no more than two screens to complete a task and/or one measurement. Moreover, the application should support the monitoring of the procedures for ensuring quality service, through the database management tool and the administrators can have access directly to the application.
Reliability	Describes the degree to which the system must work for users. It also refers to the mean time between failures, means what can be the maximum down time. For example, two hours in six months etc. It also deals with the time taken by the system to recover if failure occurs; this is also termed as mean time to recovery.

	Therefore, specifications for reliability typically refer to availability, downtime, time to repair, accuracy, etc. For the COMETECH project for example, in case of a power outage e-health units and software application will have sufficient local and remote redundancy to power down all none critical systems. All critical systems will run on a backup generator or local battery power (UPS) for at least 12 hours.
Performance	Performance specifications typically refer to response time, transaction throughput, and capacity. They deal with response time, which means the time taken by the system to load, reload, screen open and refresh times etc. The processing time, which is due to functions, calculations, imports, exports. Query and reporting time is also accountable for system's performance. For example in the COMETECH and during the pilot project, while executing a search for a medication, the system must be able to display all the main results of a patient examination.
Supportability	It refers to the application's ability to be easily modified or maintained to accommodate typical usage or change scenarios. For example, the software application will allow users to create new workflows without the need for additional programming. In addition, the system will allow the medical staff to modify a clinical decision support rule after obtaining applicable approval.
Compatibility	Compatibility of a system deals with what ease the system is able to operate with shared applications. These shared applications can be the 3rd part applications as well. This also covers the system's compatibility on different-different platforms. The platforms can be either hardware, software or both. In the COMETECH project, compatibility mainly refers to the connection with the medical devices.
Interoperability	It refers to the ability of one application to exchange data with another. Interoperability requires the adoption of standards that enable interfaces to be written. Interoperability may also incorporate concepts of connectivity, messaging, and interactive

	portals. For example, in the COMETECH project a medical examination in one e-health unit must provide oversight of services between the other two e-health units and the central e-health unit.
Scalability	It refers to the ability of the proposed software application to increase the number of users or applications associated with the product. For the COMETECH project, the software can provide more functionalities to the users in the future and can support more medical devices.
System	These requirements generally include required operating systems, commercial-grade software development tools (e.g., reusable components), specific hardware or platform requirements, and any environmental requirements. Some would include reliability and performance requirements in system requirements, but these may be issues that end users are particularly concerned about and may best be separated. In the COMETECH project one non-functional requirement can be the ad-hoc printing options, as well as, dashboard capabilities.
Modularity	Modular architecture of the system, allows future extensions and replacements, integrations, upgrades or changes of distinct software or equipment. One good approach is the adaptation of the modular architecture of MVC Model, the use of which in combination with Database Abstraction Layer is possible to fully separate the structural elements of the portal and user interface with the business logic of the system and mechanism processing, analysis and completion of procedures. Database Abstraction Layer is essential for uninterrupted reading from different sources and recording them. The adoption of the model by the offered software of the system as well as by the framework that will be used for the development of code igniter but also the general construction of the architecture in multiple subsystems show the modular character of the proposed architecture.
Open standards	It ensures the viability and future expansion of the system, all

	offered development tools, server software, as well as, the application are based on open templates and are available under the terms of the General Public License.
Open architecture	Open architecture, the proposed / offered software services, security and DBMS and the application are based on proven mature and tested systems platforms in the open to facilitate its support and maintenance, such as: • Third-party interoperability through support for SOAP protocols, and RESTful web services, CGI, FastCGI, Perl, PHP, etc.). • Utilization of international standards of interoperability in health. • Ability to share the structural components of the application to multiple servers to distribute the workload to multiple processors (scalability). • Use open source Apache tomcat, MySQL, Linux software tools.
Availability	Availability tells the operating hours of the system and when it is available. High availability, in terms of ensuring the high availability of the services of the system, the proposed architecture combines applications that can work perfectly in Network Load Balancing layout. High security, integrity, this must be achieved at the data level by the efficient use of integrity and graded access rules in the database, at the business logic level by enforcing graded access rules and controlling and certifying users and at the level of graphical interface data by imposing rules in their system entry forms.
Legal/Regulatory	Requirements include the capability to generate an acceptable representation of a legal health record, intellectual property rights, adherence to telecommunication requirements, and other features. This is a requirement of critical interest to the COMETECH project. The system must be able to support upgrades

	to any required data collection process, rules for regulatory review, and new code sets as they may become mandated (such as ICD-10-CM).
Security	It refers to the ability to provide confidentiality, data integrity, and data availability. Reference is often made to the national and European Union (EU) policies and law. Clinicians who do not have a treatment relationship with a client will be permitted to access the client's protected health information through a break-the-glass function only in a documented emergency and only with a separate audit log being generated. For the COMETECH Project the software application must follow the CE 0653 Class IIa, according to EU law of MDR 2017/745. Also, of the N.2472/1997, EU 2016/679 of the General Data Protection Regulation (GDPR).
Maintainability	Maintainability of a system is the level of ease with which a system can be modified or some changes may be brought into. This change or modification can be due to the addition of some new functionality to the system or for the sake of bug fixing.
Recovery	Recovery is the ability of the software system to recover after some damage. The time taken by the system to recover back to its original shape is the recovery time.
Robustness	Robustness is the ability of a computer system to cope with errors during execution or the ability of an algorithm to continue to operate despite abnormalities in input, calculations, etc.
Resilience	Resilience is the ability to provide and maintain an acceptable level of service when some faults occurs and performs normally.

5. CONCLUSIONS

This report presents the functional and non-functional user requirements of the application software system for the COMETECH Project.

The examined software application is a telemetry system that uses the latest wireless communication technologies (Mobile Phone Network), a Tablet PC or a Smartphone device and medical monitoring devices. Specially designed to allow patient and physician to monitor the patient's health anywhere and anytime. It is an Internet-based application (web), through which you can easily access data, thanks to the user-friendly environment, through a browser.

Authorized users of the Hospitals of the program (Bitola, Florina, Veles) will be able to access the web application in order to evaluate the medical data and patient measurements in order to provide medical advice to the physician of the telemedicine units where required.

The system, will be installed on a central server of the International Hellenic University in Thessaloniki, Greece where they will be collected, tested for quality and stored measurements of biological parameters of patients, which will be sent wirelessly from remote locations, i.e. health units and the Hospitals (Bitola, Florina, Veles), as well as, the Central Coordination Center in Thessaloniki will have authorized access.

In remote locations, trained nurses / medical staff will record data on the patient's health (history, personal memory, etc.) via a laptop or tablet, as well as the results of measurements of medical devices installed at remote telemedicine points and will sync them to the central server (web application). In the web application, specialized doctors of the aforementioned health units will have access, in order to evaluate the medical data and the measurements of the patients in order to provide where necessary medical advice to the doctor of the telemedicine units.

6. REFERENCES

AHIC's 14 use cases are in the public domain. Use them as a starter set of use cases from which you can further refine or develop your own (http://healthit.hhs.gov/portal/server.pt?open=512&objID=1255&parentname=CommunityPage&parentid=6&mode=2&in_hi_userid=10741&cached=true).

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