HEARTFAID

D35 – Summary on data collection activities

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HEARTFAID

A KNOWLEDGE BASED PLATFORM OF SERVICES FOR SUPPORTING MEDICAL-CLINICAL MANAGEMENT OF THE HEART FAILURE WITHIN THE ELDERLY POPULATION

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Consortium

- UNICAL- Università della Calabria (Italy)
- UNICZ- Università degli studi Magna Graecia di Catanzaro (Italy)
- UNIMIB- Università degli studi di Milano Bicocca (Italy)
- JUMC- Jagiellonian University Medical College (Poland)
- VMWS- Virtual Medical World Solutions Ltd (United Kingdom)
- FORTHNET S. A.- Hellenic Telecommunications and Telematic Applications Company S. A. (Greece)
- SYNAP- Synapsis s.r.l. (Italy)
- CNR- Consiglio Nazionale delle Ricerche (Italy)
- FORTH-Foundation for Research and Technology Hellas (Greece)
- RBI- Rudjer Boskovic Institute (Croatia)
- AUXOL- Istituto Auxologico Italiano (Italy)

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This document describes the activities on data collection carried on in the scope of T2.3

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1. Executive Summary

The deliverable D35, "Summary on data collection activities" describes the activities pertaining tasks T2.3 of the Work Package 2. The partners involved in preparing the document have been UNICZ, JUMC, UNIMIB, AUXOL, CNR, and VMWS

This document describes the activities carried on by both the clinical partners and some of the technical partners of the consortium. Such activities pertain the clinical data collection in both the home and hospital scenarios in view of the upcoming platform testing and validation in such sites.

Data collected on the clinical features of patients with congestive heart failure, on diagnostic test results and on dedicated questionnaires are generally described by collection site. The list, meaning, and features of such data have been previously described in detail.

2. Data collection activities: AUXOL/UNIMIB

Both UNIMIB and AUXOL have performed data collection from patients with chronic heart failure, by considering both patients referred to their CHF clinic in the hospital setting and patients included in a remote monitoring program through telemedicine facilities. This was done aimed at increasing the information necessary for building a platform able to assist in the diagnosis of CHF and at identifying early decompensation symptoms. UNIMIB and AUXOL have also performed research activities aimed at improving a system of wearable sensors (MagIc vest) aimed at collecting data on ECG (and thus heart rate), physical activity and respiratory frequency in subjects monitored on the move. Such a system will represent an innovative solution for remote patients' monitoring. Solutions for wireless communication between such a homecare device (for example Bluetooth technology) and tools capable of remote data transmission (such as a PDA or smartphone) have also been sought.

MagIC is composed of a sensorized vest and a portable electronic module. The vest is mainly made of cotton and lycra and is fully washable. At the thorax level the vest includes two woven electrodes made by conductive fibers for the assessment of the electrocardiogram. The contact between textile electrodes and the thorax is guaranteed by the elastic properties of the garment. The vest also includes a textile-based transducer for the measurement of respiratory frequency. Signals originating from these sensors reach the electronic board via embedded conductive paths still made of conductive fibers. The electronic module has size and weight of a small cell phone and is linked to the vest by a standard connector. The electronics also includes a 3-axis accelerometer that detects the subject's posture and movement. All data originating from the sensors are locally stored on a memory card and can be transmitted via a Bluetooth connection to an external computer (within a range of about 30-50 m) for visualization, on-line analyses and, possibly, relay transmission to a remote monitoring center. The results of studies testing the device so far indicate that MagIC has a capability to detect cardiac rhythm features and arrhythmic events which is practically superimposable to what obtainable by a traditional one-lead ECG recording. With the advantage that MagIC may provide a signal of better quality during movements than the traditional recorders. These characteristics, coupled with the easiness of use, comfort and possibility to either locally store or transmit data to a proximal or remote monitoring station, make the system suitable for clinical field use whenever the focus is on the detection of arrhythmic events.

The system has been used also for recording data in healthy subjects during daily life activities, at work, sport activities and under gravitational stress

In the Hospital setting, the data from CHF patients have been introduced in a database of the CHF clinic containing the biomedical signs and symptoms, and parameters of selected tests such as Electrocardiogram, Holter electrocardiography, Chest X-ray, Echocardiography, Clinical chemistry, Thoracic Impedance. Data have been obtained both from basal assessments (initial visits) and additional clinical visits. Moreover, data obtained from additional patients followed up at home through telemonitoring technologies over

12 months have also been collected using telemonitoring facilities. Data collected in the Home environment include systolic blood pressure, heart rate, respiratory rate, body weight, urine output and specific symptoms, all parameters known to be useful to achieve an early diagnosis of heart failure decompensation, as indicated in deliverable D5. The MagIC vest has also been used to collect additional data on the move also during physical exercise on a cycloergometer.

UNIMIB and AUXOL have also prepared a proposal for WP7 activities, focusing on testing and validation of the platform. The proposed protocol focuses on the collection of the set of parameters defined in our previous deliverables, both in the hospital setting and at home and on the move.

The same patients will be evaluated in the Hospital environment and will also be assessed in the HOME/on-the-move setting. The proposed recruitment will include at least 7 patients in each center (total number: at least 21 patients from the 3 centers UNICZ, UNIMIB/AUXOL, JUMC). These 21 patients will be selected with a CHF severity ranging from NYHA class II and NYHA class III. In the platform validation phase, data collection in the Home setting will be done either by using "Manual" acquisition procedures, or "Automatic" acquisition devices (using suitable tools and devices described in D19 – "Prototype of Data Acquisition and Transmission Infrastructure"). These parameters should be collected from patients' home making use of methods available at the various clinical centers, enhanced by the data acquisition and transmission mechanisms developed in the scope of WP2. These patients should be followed-up for at least 3 months, with the aim of comparing the indications on management provided by the platform with the decision spontaneously taken by the physicians in charge.

3. Data collection activities: CNR

3.1. Proposed Acquisition Protocol

A protocol, first proposed by JUMC, has been discussed and adopted for the acquisition of transthoracic echocardiographic (TTE) data. The protocol is rich enough to allow for the application, testing and validation of the developed

methods for image processing. The protocol includes also Doppler images that may be useful in the future and that have already been considered by the HEARTFAID Image Archive (see Deliverable D30). This document describes the protocol for the image acquisition and for the image sequences' acquisition:

- Parasternal long-axis:
  - 2 D of LV
  - M-mode cursor perpendicular through left ventricle just below the level of the mitral leaflet tips
  - M-mode cursor perpendicular through aorta and left atrium : record M-mode 5 beats
  - Colour flow Doppler recordings for mitral and aortic regurgitation
- Parasternal short-axis:
  - 2D of LV at level of mitral valve (basal)
  - 2D of LV at level of papillary muscles (middle)
- Apical four-chamber view :
  - 2D of LV
  - Colour flow Doppler recordings of mitral valve
  - Colour flow Doppler recordings of aortic valve
  - Colour flow Doppler recordings in tricuspidal valve and CW Doppler recordings for detection of tricuspidal regurgitation
  - PW Doppler transmitral flow recordings during diastole
  - CW Doppler aortic valve recordings
- Apical two-chamber view
  - 2D of LV
  - Apical three-chamber view
  - 2D of LV during quiet respiration
- Subcostal view
  - 2D of inferior vena cava
  - 2D of inferior vena cava during inspiration

Notice that all 2D acquisitions are image sequences during at least 3 heart beats to be stored in DICOM format.

3.2. Data Transmission and Storing

Clinical partners should be able to upload image to the HEARTFAID Image Archive. If the echocardiographic lab is equipped with a PACS connected to the network, connection may be directly established with HEARTFAID Image Archive. However, since this is not currently feasible in the validation sites, an interface dedicated to image upload has been provided.

The current implementation of the Image Archive has been tested with 1) K-Pacs and 2) Conquest DICOM servers, 3) DCM4CHE DICOM-send utility, 4) ClearCanvas Workstation and 5) TUDOR DICOM Viewer to upload images to the image archive within DICOM standard. The results were always satisfactory as much as the feedback received by the clinical site. In particular, K-Pacs and a customized version of the open source TUDOR DICOM Viewer made the internal management of images inside two of the validation sites (where no image archive is used for echocardiography but the echocardiography device workstation itself) easier.

3.3. Anonymization for clinical trials

It is clear that the information contained within DICOM objects may be considered as protected healthcare information (PHI). So, attention must be paid in keeping such data anonymous for clinical trial purposes.

To this purpose, methods for removing all protected information have been provided by the technical partners and communicated to the clinical ones. In particular, using these methods, the same conventions used for the collection of the other non-imaging data (for example the ones stored in the eCRF) may be used.

More in detail, two ways for editing or anonymizing PHI have been described.

The first method is based on data anonymization before the actual storing to the Image Archive. Thus, anonymization is performed directly on the DICOM client running on the physician's workstation. A guide has been provided to perform this procedure using the aforementioned DICOM clients. On the other hand, the second method is accomplished via the native web-interface of the Image Archive and takes places after the data have been stored. Such method is easy and fast; furthermore, it allows also patient reconciliation procedures (merging/splitting of patient's identities and studies).

Notice, however, that at the current stage the first method should be preferred for privacy reasons. Actually, in the current prototypal installation, the Image Archive is shared by different clinical partners and by the archive

administrators (belonging to the ISTI-CNR staff). This means that the data stored are visible to all of such users that will be able to access them before the actual anonymization in the web-interface takes place.

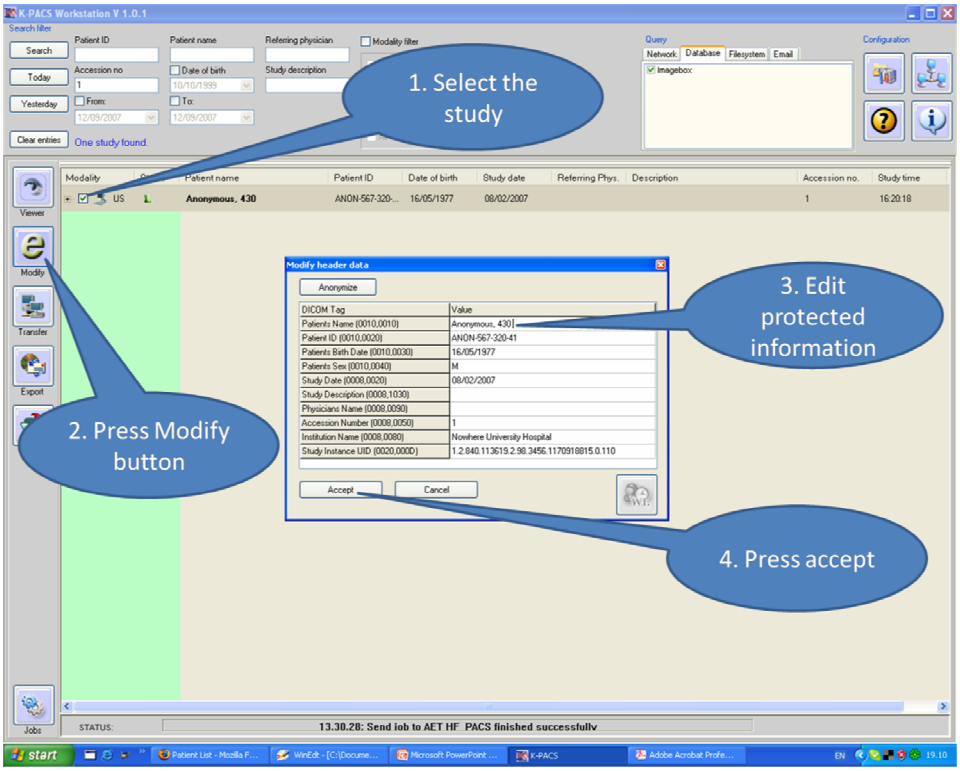

Figure 1. Graphical instructions for anonymizing a study before transferring it to HF Image Archive

4. Data collection activities: JUMC

JUMC according to the project schedule officially was not participating in task T2.3 of WP 2 concerning data collection. All activity was performed as JUMC's internal contribution.

In collaboration with other clinical and technical partners JUMC have worked collecting the biomedical data from patients with congestive heart failure (CHF) according to the electronic Case Report Form (eCRF). eCRF was developed involving an internal cooperation with JUMC Department of Bioinformatics and Telemedicine. It is serving as a tool for structured biomedical data collection from CHF patients being useful both for clinical partners (data collection, HF platform testing and validation, research activities) and for

technological partners (HFP data mining-related work and further HF platform development).

The prototype of eCRF application has been deployed at a JUMC's server and is accessible for registered clinical and technical partners on the Internet. JUMC participated also in the work on eCRF integration with other software modules from the prototype of HF platform. The graphical design of the eCRF has been adjusted to the needs of the Heartfaid Portal. An automated eCRF login from the Heartfaid Portal has been enabled and an interface to medical data, collected by eCRF, has been made available for the KDD system

The eCRF contains the patients' data being crucial for HF diagnosis, management, treatment and assessing the prognosis. These include CHF patients' medical history and physical examination; additionally it includes the results of additional tests mostly generated from devices, which cannot be automatically integrated with the platform in the actual hospital premises. The results of the following tests were collected: cardiopulmonary exercise test, echocardiography (stored also in the DICOM format), chest X-Ray, laboratory tests, 24 h ECG monitoring, quality of life questionnaire and continuous noninvasive blood-pressure monitoring for future research development. Up until now about 50 subjects have been enrolled at the JUMC site and the appropriate forms for baseline and follow-up visits have been fulfilled.

Moreover, as it was agreed between clinical partners during the HEARTFAID MB & STAB Meeting in Krakow on November 8-9th 2007, JUMC have performed a daily remote collection of clinical parameters in another subset of patients which might be of particular importance for CHF decompensation prediction in home setting. In detail, patients have been daily collecting, in a standardized manner, values of blood pressure, heart rate, body weight, respiratory frequency. Patients have also recorded any changes in CHF symptoms and treatment.

The biomedical data collection will provide the necessary bases for the upcoming project phases, especially HF platform testing and validation.

5. Data collection activities: UNICZ

At UNICZ clinical site, data collection from patients with Chronic Heart Failure (CHF) has started since the beginning of the project and a remarkable amount of clinical data have been collected. A large group of patients was already followed in UNICZ CHF unit, whereas other patients have a recent and confirmed diagnosis of heart failure. In this case, new patients have been enrolled in Heartfaid project. The data of this population have been introduced in a specific database of CHF unit, that contains all available list of biomedical signs and symptoms, and the list of parameters extracted from selected tests: Electrocardiogram, Holter electrocardiography, Chest X-ray, Echocardiography, Clinical chemistry. All these data have been filled also in the e-CRF developed by JUMC, both basal assessments and additional clinical visits, for making available data to the whole consortium. At the date of May 31st the mentioned data bases have been filled with the data from 103 patients with heart failure diagnosis.

The clinical assessment in these patients is scheduled every one-two months, and also earlier if clinical conditions are worsening and every new change in clinical condition is reported in database/e-CRF.

In addition, the storage of digital ECG files in SCP format (44 ECGs stored) and the possibility to visualize and to store the echocardiographic images in DICOM format (32 echocardiograms stored) have been provided.

Moreover, within Home Care environment, the following data have been collected, in a standardized manner, from a group of 49 patients: systolic blood pressure, heart rate, respiratory rate, % of body water, weight, body temperature, in order to achieve an early diagnosis of heart failure decompensation, so as indicated in deliverable D5. These data have been utilized within the knowledge discovery approaches in WP4.

6. Conclusions

This document summarizes the data collection activities performed by several partners of the Consortium until May 2008. Such activities, overall, have taken place both in the clinical and in the home scenarios, and include procedures for acquisition of cardiac images and their digitalization and processing. All of the clinical data collected so far represent the core information necessary to complete the development of the working platform

The contributions by the different partners are summarized in the following table.

Partner name	Healthcare Data Collection	Homecare Data Collection
UNIMIB/ AUXOL	• Data collection from patients in the clinical settings • Initial visits and additional visits • Electrocardiogram, Holter electrocardiography, Chest X-ray, Echocardiography, Clinical chemistry, Thoracic Impedance • Data storage in local database	• In home and on-the move remote patient monitoring utilising the MagIC vest and telemonitoring technologies • Follow-up period of patients at home: 12 months • Systolic blood pressure, heart rate, respiratory rate, body weight, urine output
CNR	• acquisition of images (transthoracic echocardiographic data)	
UNICZ	• Data collection from patients in the clinical settings • Initial visits and follow-up • Storage of data in local database • Electrocardiogram, Holter electrocardiography, Chest X-ray, Echocardiography, Clinical chemistry • Stored information was filled in the Electronic Case Report Form (eCRF) • Collection of data from 103 patients • Storage of ECG files in SCP format (44 stored ECGs) • Storage of echocardiographic images in DICOM format (32 echocardiograms)	• Collection of data from 49 patients in home settings • systolic blood pressure, heart rate, respiratory rate, % of body water and weight, body temperature
JUMC	• Data collection from patients in the clinical settings • Storage of data using the Electronic Case Report Form (eCRF) • medical history and physical examination • cardiopulmonary exercise test, echocardiography (stored also in the DICOM format), chest X-Ray, laboratory tests, 24 h ECG monitoring, quality of life questionnaire and continuous noninvasive blood-pressure monitoring • Collection of data from 50 patients	• Data collection from patients in the home settings • blood pressure, heart rate, body weight, respiratory frequency • changes in CHF symptoms and treatment.