HEARTFAID

D2 – Project Handbook

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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)

D2 Project Handbook

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Short description
This document contains the description of the overall structure of HEARTFAID project, detailing the management organization, the scientific and technical activities, and the administrative and financial issues.

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Executive Summary

This document details the general structure of the HEARTFAID project, describes the project management structure, by showing the relevant decision making organization, and synthetically gives evidence of the project workplan.
Particular attention is devoted to the quality issues of the project, with specific reference to the technical risk analysis and contingency planning and conflict resolution.
Very useful for the entire consortium is the definition of the reporting structure and procedures, as well as the presentation of the functionalities of the project web site and the organization of the internal communication among the partners.
Since dissemination is one of the key activities of the project, the relevant aspects and procedures are extensively reported; moreover, the publication and press release policies are delineated.
Finally, some important issues relate to the financial aspects of the project, namely costs and payment and cost statement forms are presented.

1 Project Management Structure

1.1 Introduction

As far as the project management is concerned, the interaction and collaboration among the partners of this project is organised as a network. In this way, neither duplication of efforts nor excess of resources required by a single group will occur. Conformingly with the latest ISO 9001 advices in matter of development organisation, highly effective communication channels between all partners are established (circular links in the Fig.1), while the coordination core will supervise the activities by means of very frequent conference calls (one a month), frequent meetings and a well efficient reporting system and check points (radial links in Fig.1).

In particular the establishment of dedicated web pages (accessible from each partner) ensures an on-line up date of the working progress by each group. In addition, plenary meetings of partners and WP leaders are planned every 4 months in average. Each meeting will produce minutes that will be published on the web site, therefore accessible by all members of the project. In the frame of the same meetings discussion of result, publication and protection of intellectual properties will also be deliberated. Other specific meetings will be arranged inside each WP, according to specific needs. Special meeting will be called for urgent problem solving. The co-ordinator will promote panel debates and workshops at the end of each milestone to spread results and stimulate discussions within the community close to the topic.

In synthesis, the parties actively participate to this project as suggested from the following figure.

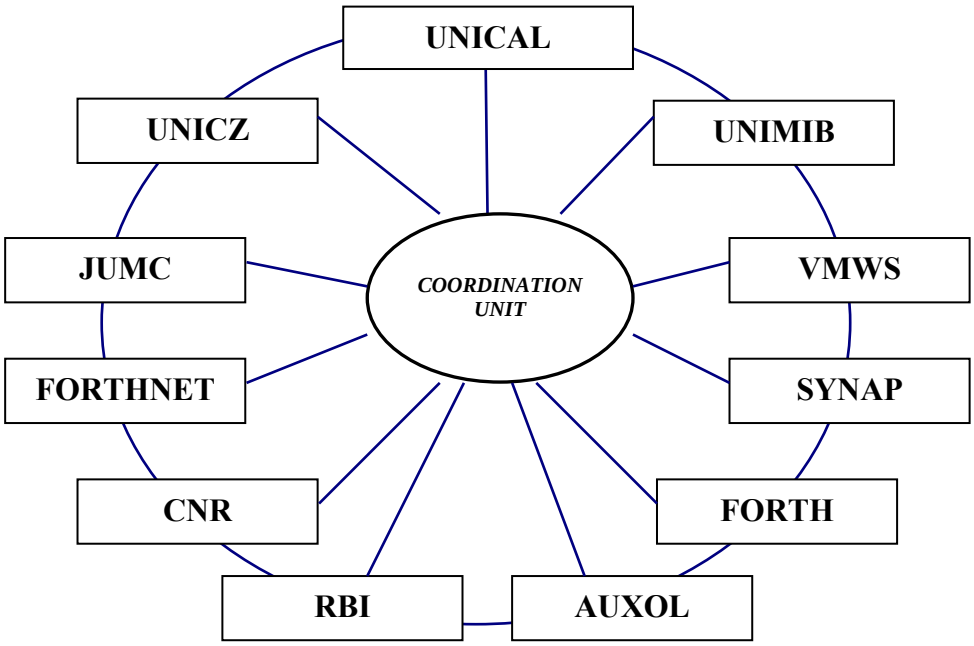

Figure 1 – The management organisation scheme

1.2 Management Structure

The HEARTFAID Project organisation shall comprise the following:

a. *Co-ordinator* is the intermediary to the *European Commission* and is authorised to execute the project management.

b. *Management Board (MB)* is the principal decision-making body of HEARTFAID Project and shall comprise all *Contractors.*

c. *Scientific and Technical Advisory Board (STAB)* is the scientific and technical coordination body of HEARTFAID Project, with the specific aim to give scientific and technical advisory support.

d. *Work Package Leaders Group (WPLG)* is the technical and operative coordination body responsible of the technical and operational management of the Work packages

1.2.1 Co-ordinator

The *Co-ordinator* shall be the intermediary between the *Contractors* and the *Commission* and shall perform all tasks assigned to it as described in the *Contract* and hereunder. The *Co-ordinator* is responsible for the overall management of the *Project.*
In particular, the *Co-ordinator* shall be responsible for:

Vis-à-vis the *Commission*:

i. signing the *Contract* with the *Commission* after authorisation by all the *Contractors* representing at least eighty percent (80%) of the *Project Shares*;
ii. receiving the entire financial contribution from the *Commission*. The *Co-ordinator* will manage this contribution by promptly allocating it to the *Contractors* pursuant to the *Programme of Activities* and the decisions taken by the appropriate bodies and no later than fifteen (15) days from receipt of such contribution from the *Commission*;
iii. supervising the scientific, technical, financial and administrative progress of the *Project*, and keep informed the *Commission* of all the relevant information as specified in the *Contract*;
iv. co-ordinating the reporting to the *Commission* on the basis of the information gathered from the *Contractors*;
v. submitting documentation to the *Commission*, including all reports, *Project Deliverables* and any other necessary information required. If one or more *Contractors* are late in submission of deliverables under the *Contract*, the *Co-ordinator* may submit the other *Contractors*' deliverables to the *Commission*.

vi. presenting amendments to the *Contract* approved by the *Management Board* to the *Commission*.

Vis-à-vis the other *Contractors*:

i. organising the activities and chairing the meetings of the *Management Board* and *Scientific and Technological Advisory Board*;
ii. forwarding any documents and information connected with the *Contract* performance to the *Management Board* and *Scientific and Technological Advisory Board* and the *Contractors* concerned;
iii. setting up an Handbook for the *Project's* management to be approved by the *Management Board*;
iv. acting as an intermediate between the *Contractors*;
v. following up the *Project* expenses and monitoring the cost statements prepared and certified by the *Contractors*;
vi. transferring sums allocated among the *Contractors* as per their *Project Shares* according to the decisions of the *Management Board* and keeping related records identifying what portion of the payments made by the *Commission* has been allocated and/or paid to each *Contractor*.

Except in its capacity as the representative of the *Contractors* described in the *Contract*, the *Co-ordinator* shall not be entitled to act or to make legally binding declarations on behalf of any other *Contractor* nor to enlarge its role beyond the one described herein and in the *Contract*.
The position of *Co-ordinator* is entrusted to *Contractor* UNICAL.

1.2.2 Management Board (MB)

The *Management Board* shall consist of one representative of each *Contractor*. The *Co-ordinator* shall chair all meetings of the *Management Board*. All decisions will be taken by consensus. If it will not be met, decision will be taken by majority voting. Each representative shall have one vote and may appoint a substitute to attend and vote at any meeting of the *Management Board*. The *Management Board* is in charge of all decisions regarding the management of the Consortium as to budget, project planning, contingency plan and risk management, IPR and relationships with other projects and external organisations.

The *Management Board* shall in particular be entitled for:

i. deciding political and strategic orientation of the *Project*; its *Programme of Activities* and *Budget*;
ii. deciding upon the *Programme of Activities* and its major changes;
iii. deciding upon the allocation of the *Budget* to the *Programme of Activities* and approving the changes of the *Project Shares,* if exceeding 20% of the *EC contribution*;
iv. deciding upon the Handbook for the *Project's* management prepared by the *Coordinator*;
v. deciding upon the rules for the management of the funds received from the

Commission, including the transfer of the payment from the *Co-ordinator* to the *Contractors;*

vi. supporting the *Co-ordinator* in fulfilling obligations towards the *Commission,*

vii. if necessary, may decide on staggered payments of the contribution to a *Contractor* for justified reasons;

viii. deciding upon the review and/or amendment of terms of the *Contract* and this *Consortium Agreement*;

ix. deciding on the further commitments proposed by the *Scientific and Technological Advisory Board*;

x. deciding to suspend all or part of the *Project* or to terminate all or part of the *Contract*, or to request the *Commission* to terminate the participation of one or more *Contractors*;

xi. in case of default of a *Contractor*, agreeing on actions to be taken against the *Defaulting Contractor;*

xii. agreeing procedures and policies in accordance with the *Commission* contractual rules, Annex II General Conditions - Part B for the management of the *Knowledge*, IPR and Publications matters;

xiii. settling any dispute arising from the *Project* implementation;

xiv. deciding upon the enlargement of the *Consortium* and the access of new *Contractors* to the *Contract* and the *Consortium Agreement*, including related Competitive Calls and their procedures;

xv. supporting the *Co-ordinator* in preparing meetings with the *Commission* and related data;

xvi. agreeing on press releases of the *Contractors* with regard to the *Projec*t.

All Contractors shall implement the decisions taken by the Management Board. Refusal by a Contractor to implement a decision of the Management Board shall be dealt with as per the provisions on Dispute Settlement.

1.2.3 Scientific and Technological Advisory Board (STAB)

The *Scientific and Technological Advisory Board* shall consist of one representative of each *Contractor* plus four outstanding external scientific advisors. The *Co-ordinator* shall chair all meetings of the *Scientific and Technological Advisory Board*. Each *Contractor*'s representative shall have one vote and may appoint a substitute to attend and vote at any meeting of the *Scientific and Technological Advisory Board*. Each external scientific advisor shall have one vote at any meeting of the *Scientific and Technological Advisory Board*.

The STAB shall be entitled for:

i. identify a common methodological approach for all partners involved in a given WP;

ii. ensure uniformity of results (as to execution, presentation, etc.);

iii. prevent specific technical problems that would affect the project schedule;
iv. explore alternative technical solutions in order to overcome specific hindrances met by the project;
v. monitor the overall progression of the project;
vi. discuss and present to the MB a range of choices about technical issues affecting the organization and/or schedule of the project.

Moreover, with the end to guarantee a fair and reliable monitoring and an overall evaluation of the scientific and technical development and results of the whole project, the STAB will be completed by the presence of outstanding external scientific advisors, both from the technological domain and the medical-clinical domain, namely:

- Prof. Nada LAVRAC from Jozef Stefan Institute, Department of Knowledge Technologies, Ljubljana, Slovenia;
- M.D. Ph.D. Goran KRSTAČIĆ from Institute for Cardiovascular Diseases and Rehabilitation, Zagreb, Croatia;
- MD Mihai GHEORGHIADE from Northwestern University Medical School, Chicago, USA;
- Prof. Daniele CUSI, MD PhD, Full Professor of Nephrology, Faculty of Medicine, University of Milan.

1.2.4 Work Package Leaders Group (WPLG)

The technical coordination activities will be further carried out and complete by the WP Leaders Group (WPLG), that will have technical responsibility for the WPs and for the adequate progress towards functional and quality goals.
Each WP leader will be nominated by the corresponding partner leader of the given WP, as indicated in the Programme of Activities.
Under the control of and in compliance with the decisions of the *Management Board*, the *WPLG* shall be in charge of the operational management of the *Project.*

The *WPLG* shall in particular be responsible for:

i. implementing the political and strategic orientation decided by the *Management Board*;
ii. implementing and updating the *Programme of activity*;
iii. monitoring the *Project Deliverables*;
iv. deciding upon measures to ensure effective day-to-day *Project* co-ordination in the framework of controls and audit procedures;

The specific tasks of the WP leaders group will be:

i. distribute the responsibilities required to adequately accomplish the tasks in each WP between the participant partners considering their assigned manpower;
ii. coordinate the WP level meetings;
iii. define the structure and overall index of the WP deliverables, complying

with the management directives;

iv. production of the final WP deliverables;

v. produce, review and approve WP contributions to periodic reports to the MB and STAB.

1.2.5 Common rules for the bodies

The Procedure Common Rules applicable to the bodies are as follows:

a. **Meetings**
The chairman of the body shall convene meetings typically every three (3) months and shall also convene meetings at any time upon written request of any *Contractor* in the case of an emergency situation.

b. **Preparation and Organisation of the Meetings**
The Chairman shall provide an agenda to the members of the body (and also a copy to the all *Contractors*, even if not members) not later than ten (10) calendar days in advance of the relevant *Board* meeting. The agenda must give full details and background to any proposed decision.
Should a *Contractor* suggest adding a discussion/decision to the proposed agenda, it shall do so in writing to all other members at least seven (7) calendar days prior to the meeting date.
The Chairman may decide, notifying it with the agenda, that the meeting shall be held by means of electronic mail, video conference, telephone conference or similar communication systems.

c. **Rules of voting**
Each *Contractor*'s representative shall have one vote and may appoint a substitute to attend and vote at any meeting.
Meetings of the bodies shall constitute a quorum if more than fifty (50) percent of the members are present or duly represented by proxy.
Decision shall not be taken validly unless a majority of two-thirds (2/3) of its members are present or represented.
In any case, decisions shall be taken by a majority of 75% of the votes of members present or represented, provided always that a *Contractor* may issue its veto only in the case of a decision to accept a new *Contractor* in the *Consortium* if a substantial threat to its commercial or strategic interests is likely to exist which cannot be resolved by any other measure.

d. **Minutes**
The Chairman shall draft the minutes of each meeting to formalise in writing all decisions taken and shall dispatch them to the members (and also a copy to the all *Contractors*, even if not members) within fifteen (15) calendar days of the concerned meeting.
The minutes shall be considered as accepted by the members if, within fifteen (15) calendar days from receipt thereof, nobody has objected in writing to the

Chairman, provided that objection shall be either on such formalisation or on a decision that was not part of the agenda and which was not accepted by all members.

2 Workplan

2.1 Introduction

The overall work plan of the project is structured into five main phases that, in their turn, are made of one or more workpackages dedicated to the different components of the Heartfaid platform.

- Phase 1, "Medical Domain Analysis", is devoted to the study of HF medical domain in order to clearly state the relevant processes and requirements and formulate the medical decision making problems. Moreover, issues related to the organization and management of the relevant health care delivery will be addressed.
- Phase 2, "Biomedical Data Identification, Collection and Integration", includes the identification of all the relevant biomedical data, and their appropriate measurement, acquisition, coding, integration and organization.
- Phase 3, "Methodologies Analysis and Design", is devoted to devise, design and develop the most promising models and algorithms for effectively and efficiently solving the relevant medical decision making problems identified in Phase 1.
- Phase 4, "System Architecture Definition, Designing and Prototyping", is devoted to select and develop the most advanced and innovative technologies in order to define and design the overall system architecture and realise a prototype that satisfies the requirements identified in Phase 1.
- Phase 5 "Testing, Clinical Validation, Dissemination and Exploitation", is devoted to the installation and validation of the final system prototype in a real medical-clinical environment. Moreover, a dissemination and exploitation activities will be carried out.

The activities of the first phase are carried out in WP1 - Heart Failure Domain Analysis, which is responsible of investigating the state of the art of the medical and clinical processes in the specific domain of the project.
The identification and the collection of the biomedical data are performed in WP2 - Biomedical Data Identification and Collection. In this workpackage the design and the development of the data acquisition and transmission infrastructure will be carried out, and both homecare and healthcare figures will be involved in the acquisition process.
Phase 3 is spitted into two workpackages: WP4 - Knowledge Representation, Discovery and Management, and WP5 - Data processing and Decision Support Services. In particular, WP4 will implement Knowledge Discovery in Databases

processes and will provide a formal representation of the pre-existing and new elicited medical/clinical knowledge. WP5 will design and develop an inference engine and explanation system for medical decision support.
The activities of Phase 4 are carried out in WP3 - Middleware, Interoperability and Integration, and WP6 - End-Users Applications and Services. In particular, WP3 will face interoperability and integration issues, by designing and developing a two layers middleware. The design and the integration issues related to the End-User Services and Interaction functionalities, as well as the implementation of prototypes, will be carried out in WP6.
Finally, WP7 - Testing and Validation, and WP8 - Dissemination and Exploitation, will carry out the activities of Phase 5.

2.2 Planning and Timetable

As it is clearly apparent, the project follows a rather "standard" life-cycle for the development and application of innovative software system prototypes. From the analysis of the medical domain, with its requirements and specification, in Phase 1, the project moves contextually both on the definition of the relevant biomedical data (Phase 2) and on the analysis of the methodologies (Phase 3). Then, Phase 4 defines the overall system architecture and realizes the components development and integration into a system prototype. All test and validation activities are carried out in Phase 5. Many critical research and development activities are carried out within all the tasks. Integration, usability and tuning problems typically arise in Phases 2, 4 and 5. Obviously, the real development cycle cannot avoid, for the nature of the project, feedback from one Phase to the previous ones and interaction among the Phase.
As a matter of fact, a typical risk in this kind of projects is that some preliminary choices could be more easily reverted / biased by subsequent results in order to avoid unexpected limitations, improve efficiencies, etc. To this aim, in order to cope with such modifications, the workplan includes a structural control and recovery mechanism to take into account "feed-back" to previous tasks and interaction among the tasks. Times and resources are correspondingly assigned to such revisions and related work.
In addition, the project relies on the control mechanism based on well established communication channels, frequent meetings and efficient check points in order to minimise problems.
In the following table is reported the estimated elapsed time related to the project activities.

Estimated Elapsed Time of the Project Activities (duration in days)

Project Activity	Duration
WP0:Management	787
WP1: HEART FAILURE DOMAIN ANALYSIS	175

T1.1 - SoA analysis of the medical and clinical processes in the domain	65
T1.2 - Problem statement and formulation of the relevant Decision Making problems	86
T1.3 - Organization and management models for the Healthcare delivery	132
WP2: BIOMEDICAL DATA IDENTIFICATION AND COLLECTION	654
T2.1 - Identification of all BM, signs and symptoms relevant to the hearth failure pathology	87
T2.2 - Design and development of the data Acquisition and Transmission infrastructure	327
T2.3 - Data Collection	327
WP3: MIDDLEWARE, INTEROPERABILITY AND INTEGRATION	481
T3.1 - Middleware requirements and functional specifications	176
T3.2 - Identification of the clinical standards for representation and communication of data	109
T3.3 - Integration Middleware	372
T3.3.1 - Early mock-up prototype implementation of the Data Management and Exchange System	283
T3.3.2 - Prototype refinement	89
T3.4 - Interoperability Middleware	370
WP4: KNOWLEDGE REPRESENTATION, DISCOVERY AND MANAGEMENT	569
T4.1 - Implementation of a suitable data warehouse for knowledge discovery	176
T4.2 - Data understanding and preparation	196
T4.3 - Implementation of Knowledge Discovery in Databases processes	436
T4.4 - Ontologies and medical knowledge representation in the domain	241
WP5: DATA PROCESSING AND DECISION SUPPORT SERVICES	568
T5.1 - Identification of representation features for signals and images processing	176
T5.2 - Design and development of models and methods for signals and images processing	282
T5.3 - Requirements and functional specification of the Decision Support System	174
T5.4 - Implementation of the Decision Support System	413

WP6: END-USERS APPLICATIONS AND SERVICES	458
T6.1 - Design of the End-User Services Interaction functionalities	175
T6.2 - Development of End-User applications and services	220
T6.3 - Knowledge discovery system for web-based data extraction and analysis	327
T6.4 - Integration of Services	262
WP7: TESTING AND VALIDATION	263
T7.1 - Deployment of the prototypes in suitable clinical settings	175
T7.2 - Clinical validation	197
WP8: DISSEMINATION AND EXPLOITATION	788
T8.1 - Dissemination activities	788
T8.2 - Exploitation activities	395
T8.2.1 - Investigation of new models for Healthcare Processes	262
T8.2.2 - Cost/Benefits analysis	220
T8.2.3 - Exploitation plan	133

2.3 Milestones and Expected Results

In terms of milestones and expected results, the overall activities carried out during the project lifetime will be organised in the following 6 macro-step:

1. State of the art and user's needs and system requirements
2. Functional Specifications
3. Early mock-up of the main components of the HEARTFAID platform
4. Early mock-up of the HEARTFAID web-based platform of services
5. HEARTFAID platform prototype
6. Validation and Exploitation

These macro steps will be marked by the following main deadlines:

1. Within month six (M06) the State of the Art analysis and the problem statement, as well as the user requirements, should be completed. This includes an official milestone "MS1.1: Identification of medical clinical requirements and relevant decision making problems" at M05.
2. Within M12 a preliminary design of both the general architecture of the system and the single components, should have been outlines. This includes three official milestones: "MS1.2: Definition of new models for health care delivery processes" to be delivered at M08, "MS2.1: Functional specifications of the data Acquisition and Transmission infrastructure" and "MS3.1: Functional specifications of Middleware and Identification of the clinical standards" to be delivered at M12. Moreover, within M12 three important Deliverables concerning the functional specifications of the Heartfaid system components will be released: D2.1

"Specifications of all biomedical data, signs and symptoms relevant to the HF", in the framework of the WP2, D3.1 "Functional specifications of the Middleware", in the framework of the WP3 and D5.1 "Functional specifications of Data Processing and Decision Support Services" in the WP5.

3. Within M18 we will have an early mock-up of the data acquisition platform, the Integration Middleware and the Decision Support System. During this period, three different technological milestones will be delivered, all at M18: "MS2.2: Technological infrastructure for the acquisition and transmission of the relevant BM data", "MS3.2: Early mock-up prototype implementation of the Data Management and Exchange System" and "MS5.1: Early mock-up prototype of data processing and decision support services". An additional milestone "MS4.1: Ontology and knowledge representation" will be released at M18.
4. Within M24 we will have an early mock-up of the HEARTFAID web-based platform of services with a first prototype of all the components of the HEARTFAID system. During this period three official milestones will be released, all at M24: "MS3.3: HEARTFAID middleware prototype", "MS4.2: Knowledge Discovery in Databases tuning" and "MS6.1: Early mock-up prototype of the HEARTFAID web-based platform of services".
5. Within M30 we will release the final integrated prototype of the HEARTFAID platform, ready for the validation phase. The main milestone that will be delivered during this phase is "MS6.2: HEARTFAID End-User services and application prototype". Within the M30 the "Data processing and decision support system prototype" will be also released according to the milestone MS5.2.
6. Within M36, the end of the project, a validation of the HEARTFAID platform with the dissemination and the exploitation of the results will be performed. These activities will be marked by the milestone "MS7.1: Validated final prototype" and "MS8.2: Exploitation plan".

Concerning the management roadmap, the milestones related to the management will coincide with the "1st Periodic Report" at M12 (MS0.1), the "2nd Periodic Report" at M24 (MS0.2) and the "Final Report" at M36 (MS0.3).

A graphic representation of the macro-steps of the project is shown in the following table.

	M06 SoA, user's needs and System requirements	**M12** Functional specifications	**M18** Early mock-up of main components	**M24** Early mock-up of web-based platform	**M30** Prototype of the platform	**M36** Validation and Exploitation
WP1	♦ **MS1.1:** Identification of medical clinical requirements …	♦ **MS1.2:** Definition of new models for health care delivery processes				
WP2		♦ **MS2.1:** Functional specifications of the data Acquits. and Transmission infrastructure	♦ **MS2.2:** Technological infrastructure for the acquisition and transmission of the relevant BM data			
WP3		♦ **MS3.1:** Functional specifications of Middleware …	♦ **MS3.2:** Early mock-up prototype implementation of the Data Management and Exchange System	♦ **MS3.3:** HEARTFAID middleware prototype		
WP4			♦ **MS4.1:** Ontology and knowledge representation	♦ **MS4.2:** KDD tuning		
WP5			♦ **MS5.1:** Early mock-up of data processing and decision support services		♦ **MS5.2:** Data processing and decision support system prototype	
WP6				♦ **MS6.1:** Early mock-up of the HEARTFAID web-based platform of services	♦ **MS6.2:** HEARTFAID End-User services and application prototype	
WP7						♦ **MS7.1:** Validated final prototype
WP8	♦ **MS8.1:** Dissemination plan					♦ **MS8.2:** Exploitation plan

The following table shows the list of prototypes that will be released during the project lifetime, in order of delivery, while Fig. 2 shows a graphical representation of the prototypes related to the components of the platform:

Name of Prototype	Month of delivery
♦ **MS2.2:** Technological infrastructure for the acquisition and transmission of the relevant BM data	M18
♦ **MS3.2:** Early mock-up prototype implementation of the Data Management and Exchange System	M18
♦ **MS5.1:** Early mock-up of data processing and decision support services	M18
♦ **MS3.3:** HEARTFAID middleware prototype	M24
♦ **MS6.1:** Early mock-up of the HEARTFAID web-based platform of services	M24
♦ **MS5.2:** Data processing and decision support system prototype	M30
♦ **MS6.2:** HEARTFAID End-User services and application prototype	M30
♦ **MS7.1:** Validated final prototype	M36

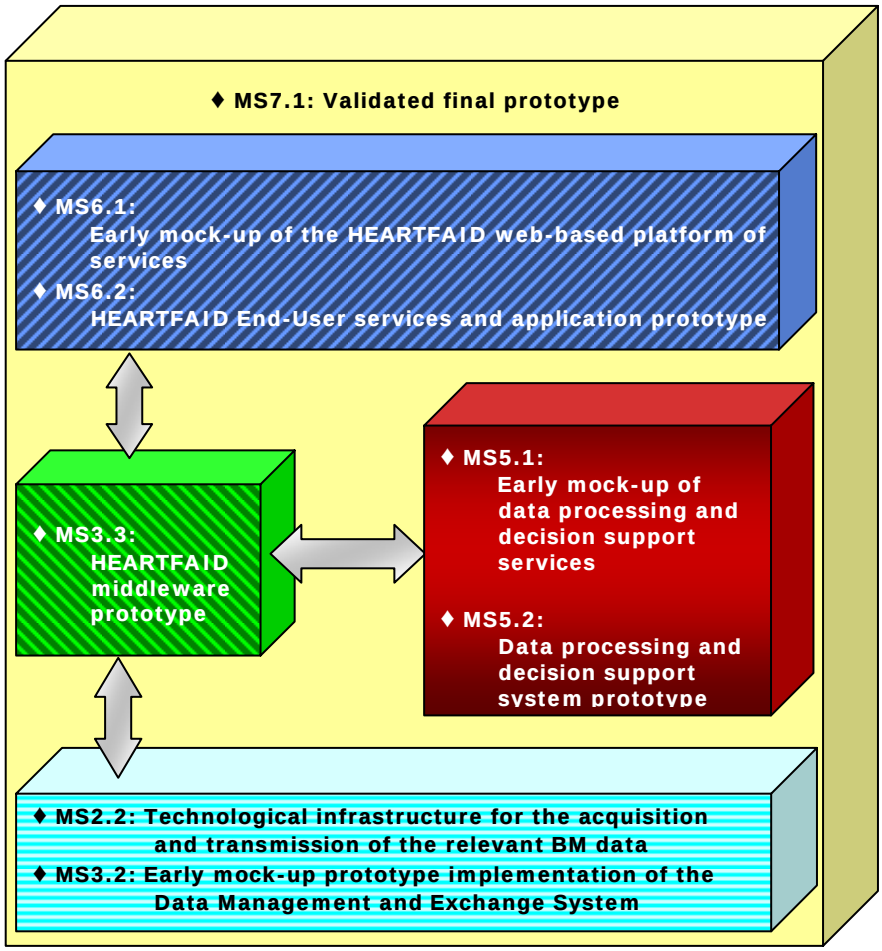

Figure 2 – Graphical representation of the HEARTFAID prototypes

3 Quality Management

3.1 Quality Assurance Plan

In order to ensure the quality of all technical, development and management activities, processes and procedures, the quality of deliverables and the smooth running of the HEARTFAID project, there will be issued a detailed report on Quality Assurance processes. The performing of Quality Assurance processes will involves a set of specific activities that will examine the processes, procedures and policies used during the development of the project and will ensure that they will contribute to the desired outcomes and expected results. This plan will contain (among the others) all the procedures with regard to the communication between the partners, the documentation standard of all the deliverables, the full detailed workplan, and any other relevant standards to conform to.

Quality assurance will be stressed during all the software development activities. In particular during the HEARTFAID project it will be adopted the Unified Software Development Process (USDP). As suggested by the best practices in software development, real distinguishing aspects of the USDP are captured in three keywords: Use-Case driven, Architecture-Centric, Iterative and Incremental. Moreover the USDP may be approached by two different but integrated perspectives: the management perspective, dealing with financial, strategic, commercial, project and human management aspects; the technical perspective, dealing with quality, engineering and design method aspects. In particular from a technical perspective the development process is seen as a succession of iterations, through which the product under development evolves incrementally. Each iteration is concluded by the release of an executable product/service or a supporting artefact: development plans, release description, user's documentation, dissemination plans, marketing plans, etc. Iteration consists of the activities of planning, analysis, design, implementation, and testing in various proportions depending on where the iteration is located in the development cycle. Of course this kind of work organization allows developers to perform an optimal quality assurance process.
Moreover the management perspective and the technical perspective are led simultaneously; in other words, each management phase is broken down into one or more technical iterations. However the two perspectives, management and technical, do more than just synchronize on a few well identified milestones: they both contribute to a common set of products/services and artefacts that evolve over time. Some artefacts are more under the control of the technical side, some more under control of the management side.

3.2 Quality Control Procedures and Checking

Quality control procedures and checking are detailed in the deliverable D3 – Report on Quality Assurance Process.

3.3 Technical Risk Analysis and Contingency Planning

As far as the Technical Risk Analysis and Contingency Planning are concerned, these aspects regard, in general, all the activities of the project, i.e. management activities, research and development activities and demonstration activities.
In terms of management activities, the main reasons for critical situations and failures are largely due to one of the following causes:

- complexity of the project;
- non-compliance of a partner;
- non-compliance with the time schedule;
- disputes among partners.

In all cases, contingency plans have been set up in order to ensure continuation of the project despite any delays and problems. The STAB is in charge of proposing (a set of) suitable technical solutions while the MB will adopt the final decision (as to budget and commitment).

Complexity of the project
The wide articulation of HEARTFAID could represent a factor of risk regarding the achievement of the project goals. In fact, delays and inefficiencies could be taken place due to the existing interdependences between the several parts of the plan. The wide employment of resources for the activities of management and the organizational procedures, indicated in section 6.1, have just the aim to manage and to diminish these types of risks.
Moreover the organizational procedures and the qualitative standards of the deliverables will be detailed ulterior in the "Quality Assurance Processes Report".

Non-compliance of a partner
To avoid the cutting of project objectives the failed partner will be replaced by the Consortium. The replacement could be achieved by using internal resources of the Consortium or by selecting a new partner.

Non-compliance with the time schedule
Continuous reporting and check for milestones will reduce the situation of non-compliance with the time schedule to a minimum. In case that, despite all efforts, serious excess or non-compliance of the time schedule will be observed, a specific contingency plan will be taken in order to solve the advance or the delay. In particular, a re-modulation of the personnel effort (by appropriately increasing the resources), or the involvement of other partners, or the involvement of external advanced competence will be performed.

Disputes among partners
Disputes among partners could arise for two reasons:

1 - Discord on the obtained quality of the deliverables in the various workpackage.
This kind of disputes can be born in case a partner must use some results developed by a second partner and it is not satisfied of the qualitative level of the product. In this case the dispute will be resolved by the MB and the STAB through the quality criteria collected in the Quality Assurance Processes Report.

2 - Disputes on the economic terms of the contract.
In order to avoid that this kind of disputes among partners could cause a delay in the fulfilment of the project or the failure of the project, specific articles will be inserted in the Consortium Agreement. In particular, the articles inserted in the Consortium Agreement will stretch to assure the ideal conditions for the maximum transparency in the relationships between the partners. In any case, the solution of the dispute will be pursued within the MB and within the STAB.

In terms of research and development activities, some critical aspects can be pointed out within most of the WPs of the project.

In **WP1 - HEART FAILURE DOMAIN ANALYSIS** the main factors of risk are concerned with the strategic importance that the deliverables of this work package have for the entire plan: in fact the validity of the platform of services developed within HEARTFAID will depend on the thoroughness and correctness of the analysis of the medical domain carried out in WP1. The presence of four clinical partners assures, with a good safety margin that the analysis of the domain will be carried out in such way to avoid eventual omissions or inaccuracies in the final reports. In particular the deliverables of WP1 will have to be judges corrected by all the clinical partners.
Moreover the following risk factors can be indicated:

1 - Representation models used in the analysis of the medical domain.
The analysis of the domain will have to be usable directly for the definition and the implementation of the prototypes of HEARTFAID platform. Therefore the participation of UNICAL to WP1 will assure that the produced reports will follow some standards (e.g. UML) easy interpretable also from the other partners.

2 - Development of some not – implementable new management models.
The introduction of new organizational models frequently engenders phenomena of resistance to the change. In order to avoid the risk connected to the cultural variables it will be necessary to take account of this kind of variables during the planning of the new managerial models.

In **WP2 – BIOMEDICAL DATA IDENTIFICATION AND COLLECTION** and **WP3 – MIDDLEWARE, INTEROPERABILITY AND INTEGRATION**, many aspects arise related to integration, usability and tuning of methodologies, technologies and tools. In these cases, the more critical risks are related to possible difficulties in effectively collecting reliable biomedical data and integrating and storing the same data into efficient repository.
Moreover the following risk factors can be indicated:

1. In Task 2.1 the correct identification of the biomedical data is a critical activity for the validity of HEARTFAID prototypes. As already marked for WP1, the presence of four clinical partners should assure the correct execution of the activity.
2. Task 2.2 (design and development of the data acquisition and transmission infrastructure) have the following critical points:
   - Security in data transmission. To avoid the risks connected with the involuntary spread or with the theft of the data they will be implemented several countermeasures at management level (e.g. identification of security responsible) and at software level (e.g. adoption of HTTPS, etc.). More about these issues are indicated in the section 7.6, “Work Package descriptions”.

- Reliability of the data. The use of new dispositives for the collection of the biomedical data places the problems of the reliability in the transmission and of the quality of the collected data.

3. Task 3.2 (identification of the clinical standards for representation and communication of data) introduces some critical points. In fact globally accepted standards do not exist for the transmission of medical data. Therefore this situation could the risk to adopt some standards that will become obsolete within few years.

To prevent eventual damages caused by the critical points of Tasks 2.2 and 3.2 it will be adopted the strategy of experiencing and tuning various methodologies and technologies in parallel, with the aim of identifying the best one.

In **WP4 – KNOWLEDGE REPRESENTATION, DISCOVERY AND MANAGEMENT** and **WP5 – DATA PROCESSING AND DECISION SUPPORT SERVICES**, critical aspects are related to the devising and development of new models, methods and algorithms, whereas the effective tuning of well founded methodologies could arise some risk. Specially the development of some new approaches for knowledge discovery (for instances the development of new Kernel functions) and signals and image processing (in particular the task related to the 3D image reconstruction) could bring some risk in terms of expected performance, efficient embedding into the technological platform and suitable applicability.

WP6 – END-USER APPLICATIONS AND SERVICES is characterized by development activities and use and tuning of advanced and well establishes technologies. Also in this case, aspect related to integration, usability and tuning could arise. Under this respect, risk issues are mostly related to the properly definition of end-user requirements and development of effective and quite friendly end user functionalities. In particular the definition of the logical measures for the security (e.g. the identifications of the access rights for the end users) is a critical task.

By looking the single tasks of the Work Packages, the following classification can be performed:

1 - Tasks concerning to the design of the platform and its components.
They are Tasks T2.1, T2.2, T3.1, T3.2, T4.1, T4.4, T5.1, T5.2, T5.3, T6.1, and all the Tasks of WP1. Possible errors or omissions carried out during these Tasks would bring direct and indirect damages. As an example the survey of an error of design during the exploitation phase would involve damages for the image of the whole project. Moreover the activities of identification of requirements demand the presence of ICT experts and medical staff, and that creates another factor of risk due to the necessity to create and to manage specific teams for every Task.

2 - Tasks concerning the implementation of the platform and its components.
These tasks are not as critical as the previous ones. In fact in this case the risk factors are related to the innovative nature of the technical solutions searched.

In order to effectively face all the above mentioned critical aspects, some specific actions will be performed:

1. In order to cope with some modifications in the activities of the work packages, the work plan includes a control and recovery mechanism, by feed-back to previous tasks and interaction among the tasks.
2. In the definition of the expected elapsed time of each project task, sufficient time has been assigned to revision activities.
3. For all the scientific and technical activities related to integration, usability and tuning of existing methodologies, technologies and tools, and for the design and development of new methodologies and technologies, several alternatives, according the characteristics of the specific WP, will be assessed and tuned in parallel, with the end to detect the best one. Under this respect, relevant decisions will be assumed within the partners involved in the WP, with the coordination of the WP Leader. In case of failure or difficulties, decisions from higher level will be requested, by involving the WP Leaders Group, with the possible supporting of the STAB.
4. As showed in the subsequent subsection 7.2, the structure and timing of the Milestones of the whole project, have been organized with the end to efficiently tackle any hindrance that could happen:
   - within month 12, a preliminary design of both the general architecture of the system and the single components, will be outlined;
   - within month 18, early mock-up prototypes (data acquisition platform, integration middleware and DSS) and functional specifications of knowledge discovery and data processing;
   - within month 24, early mock-up of web-based platform of services, with a first prototype of all the components of HEARTFAID;
   - within month 30, final integrated prototype of the HEARTFAID platform, ready for the validation phase;
   - within month 36 final validated HEARTFAID prototype.

The demonstration activities (WP7) are related to the clinical testing and validation of the HEARTFAID prototype. In this case critical aspects could arise in the effective deployment of the prototype within clinical settings, in the definition of the sample of patients, in the suitable interaction with the medical and clinical end-users. Also in these cases, sufficient time has been foreseen for effectively cope with these aspects. More specifically, particular attention will be devoted to adequately prepare the clinical context, by a suitable training of the involved health care operators.

Moreover the phase of clinical validation of the prototypes is particularly critical. In fact the involvement of the patients in the experimentations engenders risk factors connected with the probability of malfunctioning of the prototypes. In such scene there would be direct damages for the patient, and some consequences for the outcome of the project. The adoptable strategies to diminish this kind of risk have been described in section 5.3, Risk assessment and communication strategy, and they will be ulterior detailed in the course of the HEARTFAID development.

Finally in the WP8 - Dissemination and Exploitation, the major critical points are related with the activities of exploitation. The main factor of risk for these activities is the uncertainty of the market. However this risk will be managed through specific market analysis, carried out with the aim of finding the most effective marketing plans. The Exploitation Plan will be prepared to manage such factors of risk. Secondarily, also the Task T8.2.1 (Investigation of new models for Healthcare processes) introduces some factors of risk connected with the resistance to the organizational change that could be found in some medical contexts. This type of risk factor can be faced (like already indicated for the WP7) through appropriate activities of training of the medical staff.

3.4 Conflict Resolution

It is the goal of the project to ensure a smooth, productive and harmonious project. However, it is recognised that there are occasionally situations that may arise during a project that can lead to conflict. By experience, we see the following classes of potential problem:

1. Non-performance of a partner
2. Redistribution of project funding between partners
3. Strategic direction of the project
4. Distribution of roles
5. Differing priorities of partners
6. Conflict in commercial interests of partners

Potential conflicts must be identified early and escalated to the Project Coordinator. If such conflicts cannot be amicably settled at the appropriate level they should be ultimately escalated to the Management Board for resolution.
Wherever possible conflicts should be settled by consensus agreement of the parties involved, each recognising the others basic interests. Situations where this is not possible should be brought to the vote for ultimate resolution.
Of the six types of potential conflict identified above, the first two are the most difficult to deal with, especially if a partner has “gone silent” in support activities but still claims against budget.

4 Reporting Procedures and Document Standards

Reporting can be seen as being carried out within the project in two parallel tracks. The Operational Track and the Organisational and Management Track. The former is related to specific activities carried out within tasks of Workpackages and is reported up the operational chain. The latter is an overall participant view and summarises all the work carried out by each participating organisation and is used to justify the expected plan of resources requested as well as addressing participant level items. Of course there must be a strict correlation between the activities reported under both tracks.

4.1 Project level

The Project Coordinator will issue a report (Quarterly Managerial Report) to the Commission every three months, based on the following reports he shall receive.

4.2 Operational level

These are reports of the Workpackage leaders to the Project Coordinator. They must be made every three months and are a summarization and consolidation of the individual task activity for that Workpackage. The key content must be progress against plan, problems and actions. They must be lodged within ten days of the end of the period.

4.3 Workpackage level

This is technical reporting to the WP leader and should be as required by the WP leader from each partner involved in the specific task activity to the WP leader. The report should be by the Reporting and File Sharing server available on the Project Web Site.

4.4 Organisation and Management level

These reports should be filed by each organisation for the Project Coordinator every three months via the on line Project Diary as below.
Once a year each partner must submit information required by the Project Manager for the Project Periodic Report which is a formal deliverable.
Audited and Signed Financial Statements must be submitted annually by each partner in a timely fashion. If a partner is two weeks late in this activity, the Project Coordinator at his discretion can submit the received Financial Statements without the late partner report. He will only do this in exceptional circumstances as it will result in a partner's payment being delayed until the next cost period. In particular, this will not be applied to final report.

4.5 On-line Project Partner Diary

All project partners will give short feedback every one month. This will consist of:

1. Progress in last period against plan
2. Any problems encountered
3. Plans for next period
4. Manpower and expenditures of the period

It will be the responsibility of the project management to ensure correct implementation of this reporting by all partners in a timely fashion.
The preferred method for submittal of regular reports will be via a suitable form available on the Project Web Site under the Internal Site, File Sharing and Reporting server. However it is essential that all such reports will be time and date stamped by the system to ensure an audit trail.

4.6 Document Standards

Generally, all official project deliverables will be issued to the Commission in PDF format to minimize incompatibilities and chances of spreading viruses.
Internally, document will be produced, edited and stored in Word formats.
All details concerning various formats and templates are reported in the deliverable D3 – Report on Quality Assurance Process.

5 Project Web Site and Internal Communication

5.1 Introduction

A specific project web site will be set up to:

- facilitate the communication among the partners. To this aim, services and documentation will be available to partners in a restricted access area;
- present up-to-date and differentiated information on the overall issues tackled by the project as well as on the project achievements. Information will be made available to the public, in several formats: scientific reports, press releases, animations and simulations, etc;
- provide a set of applications and functionalities for supporting the development and coordination among the partners of all the scientific and technical activities of the whole project.

For the sake of a transparent and effective communication among the partners, a multiple communication channel is established. It is based on:

- a “reserved” part of the project web site equipped with an on-line archive, offering to authorized users: upload/download functions, commenting capabilities and versioning for all project documents, software modules and financial statements;
- a minimal on-line support for planning project meetings, conference calls, etc. and for recording meeting results (minutes, participants, etc.);
- support to audio/video conference meetings. Partners are equipped for audio/video conference meetings, taking place at close intervals (monthly).

Support for the internal communication infrastructure is provided by the Co-ordinator.

5.2 Web Standards

In general, the project will move towards compliance with W3C web standards for the Project Web Site. The goal is to be compatible with HTML 4.01 transitional standard and subsequent updates to it.
See http://www.w3.org and the validator http://validator.w3.org

6 Dissemination

6.1 Introduction

Raising public participation and awareness is a strategic activity of the whole project, which will involve all the partners.
In order to create a wider project awareness impact, the main objectives of raising public participation and awareness are the effective involvement of all relevant intermediaries, actors and stakeholders, with particular attention to European regional governmental bodies, health care professional associations, patient associations and Higher Education institutions.
With the contribution of all the partners, an inner circle of User Interest Groups made of healthcare organizations and institutions from the 5 countries of the consortium will be established. In the different countries, a larger circle of a User Interest Group will also be established, to publicise by seminars in each country the project to a wider audience of healthcare institutions. The involvement and interaction with end-users health care organizations will encourage further experimentation and clinical validation of the developed systems, services and tools
Also with the interested intermediary organisations (European regional governmental bodies, healthcare professional associations and patient associations) strong interactions will be established, by holding, in cooperation, seminars, workshops and press conferences. This will further support the dissemination and will create wide publicity of the project and its results.
Particular attention will be addressed to the interaction with European higher education institutions (i.e. Universities and Colleges), with the end to disseminate the innovative results of HEARTFAID to young student at several grade levels (bachelor, master and PhD). By suitable connections and agreements with Schools of Medicine, Faculties of Biology and Faculties of Engineering, this will be done by organizing specific initiatives, based, for instances, on e-learning and face-to-face short courses. This will be done also by involving secondary education institutions, at European level, by disclosing events which could improve the awareness of young people on the broad matter of information technologies in medicine and health care delivery.
Especially at the launch of the project, but also during its run, particular attention will be paid to the issue of press releases, in order to give wide public resonance to the overall project's activities.

The resources made available by the Commission for media and information activities will be closely monitored and put to use to increase the impact the HEARTFAID results and publications on the general public.
Finally, all publication material developed during the project's lifetime (fact sheets, leaflets, press releases, web links and articles, etc.) will be provide to the Commission.
A dissemination plan will be developed at the beginning of the project setting out an agreed approach to dissemination throughout the project. Appropriate marketing material will be designed and produced in several languages. A project website will be set up by the coordinating partner, providing up-to-date information about the project and its results to the public. The project will be presented at conferences across Europe on Cardiology, Cardiology Imaging, Knowledge Management and similar topics.
The results of the scientific research work conducted in the development workpackages of the project will be submitted for publication to international, peer-reviewed journals. These results combined with outcomes from the implementation and evaluation workpackages will also be submitted for publication in journals.
The HEARTFAID consortium will carry on dissemination activities along the entire duration of the project. These activities will be related to the diffusion and distribution of information related to this project and to the establishment of a close cooperation with potential end-users, the scientific community and professional organizations. The consortium will always try to balance the need of a capillary diffusion of the information that can better be done using individual efforts by all the partners with the provision of a uniform image of the consortium itself.
Each partner will undertake dissemination according to the agreed dissemination plan. The dissemination activities will be mainly organized as follow:

- The members of the HEARTFAID consortium will raise awareness of their own project but will also actively participate in activities that will raise the profile of the HEARTFAID initiative in general. The contractors will seek to collaborate and cooperate amongst each other, and participating in any "clustering" activity which may be organized in the future, e.g. workshops or joint review meetings. In addition to the planned activities at project level, the partners will contribute to common dissemination activities of the project (as e.g. organising press conferences, inviting press to major project events, spreading articles to specialised and non-specialised press, and organising events with different stakeholders' participation as part of conferences or seminars).
- A common website will be created and maintained during the project period and beyond it in order to inform the public worldwide about the aims and the main results of the HEARTFAID project. Public deliverables will be made available on this common web site.
- Each partner will operate its own dissemination activity as well using its web site and its dissemination channels mainly on a geographical base. Thus the

English partner will take care of the UK, Iceland, Ireland, Benelux and France. The Italian partners will take care of Italy, Malta, Spain, Portugal, Switzerland, Austria and Germany. The Croatian partner will take care of Croatia, Slovenia, Serbia & Montenegro, Bosnia, FYROM, Hungary, Romania and Albania. The Polish partner will take care of Poland, Denmark, Scandinavian countries, Czech Republic, Slovakia, Russia and the other ex URSS countries. The Greek partners will take care of Greece, Bulgaria, Turkey, Cyprus and the Middle East.

- Dissemination activities beyond the consortium: publications, conferences, workshops and Web-based activities aiming at disseminating the knowledge and technology produced. As far as the participation to relevant conferences and workshop, the following will be a fairly probable event list:
    - Computers in Cardiology 2006 (Valencia, Spain)
    - Computers in Cardiology 2007 (Duke University, North Carolina, USA)
    - Computers in Cardiology 2008 (Bologna, Italy)
    - World Congress of Cardiology 2006 (Joint Congress of the European Society and the World Heart Federation, Barcelona, Spain)
    - EUGMS – European Union Geriatric Medicine Society 2006 Congress (Geneva, Switzerland)
    - VI European Congress on Gerontology (Saint Petersburg, Russia, 2007)
    - European Society of Cardiology Annual Congress 2007 (Vienna, Austria)
    - European Society of Cardiology Annual Congress 2008 (Munich, Germany)
    - International Society of Electrocardiology Meeting 2006 (Koln, Germany)
    - International Society of Electrocardiology Meeting 2007 (Istanbul, Turkey)
    - International Society of Electrocardiology Meeting 2008
    - Euroecho Annual Meeting 2006 (Florence, Italy)
    - Euroecho Annual Meeting 2007
    - Euroecho Annual Meeting 2008
    - Heart Failure 2006 (Helsinki, Finland)
    - Heart Failure 2007
    - Heart Failure 2008
- Studies on socio-economic aspects: assessment of the expected socio-economic impact of the knowledge and technology generated, as well as analysis of the factors that would influence their exploitation (e.g. standardisation, ethical and regulatory aspects, etc.).
- Activities promoting the exploitation of the results: development of the plan for the use and dissemination of the knowledge produced.
- Finally, the project will promote both the coordinated publication in research journals as well as in sector oriented magazines. Under this respect, a plausible list could be the following:

- Annals of Non-invasive Electrocardiology
- Circulation
- IEEE Transactions on Biomedical Engineering
- International Journal of Cardiology
- Journal of Applied Physiology
- IEEE Transactions on Information Technology in Biomedicine
- Technology and Health Care
- Journal of Medical Systems
- European Journal of Operational Research
- Computers and Operations Research
- Operations Research
- Journal of Operational Research Society
- Health Care Management Science
- INFORMS Journal of Computing
- Journal of Machine Learning Research
- Bioinformatics
- Artificial Intelligence in Medicine
- Machine Learning
- Journal of Biomedical Informatics.

6.2 Publications and Press Releases

If the Work Package Leaders Group has agreed a Project Deliverable to be available to the public, any Contractor may publish information included in such Project Deliverable without any notifications to the other Contractors and without any other Contractors' consent.

For the avoidance of doubt, it is stated that no Contractor shall have the right to publish or allow the publishing of data which constitutes another Contractor's Knowledge, Pre-Existing Know-How or confidential information, even where such data are amalgamated with such first Contractor's Knowledge, Pre-Existing Know-How or other information, document or material. Any use of such other Contractor's data justifies, save for further remedies, objection to the publication by the Contractor concerned in accordance with the Contract.

All the publications shall make reference to the Project title, the Contractor and to the funding institutions (wording to be defined at the first project team meeting).

This obligation shall remain applicable three (3) years after the end of the Consortium Agreement and of the Contract.

The publishing Contractors must supply their planned publication to the other Contractors. Any opposition to the planned publication shall be made on justified grounds in accordance with the Consortium Agreement and the Contract.

When there is an opposition, the involved Contractors shall discuss how to overcome the justified grounds of the opposition by removal of any disclosure of copyright (for example software) owned by a non publishing Contractor and the opposing Contractor shall not unreasonably continue the opposition if actions are performed following the discussion.

The justified grounds of opposition are:

- for business or other legitimate (oriented to research, public bodies, and not necessarily to private commercial enterprises, bodies) reasons concerning the inclusion of the opposing Contractor's Knowledge or Pre-Existing Know-How.
- for protection reasons concerning Knowledge or Pre-Existing Know-How and if the publication of the material identified in opposition would adversely affect such protection.

However a delay to publication, for any reason, must be no longer than two (2) months.
The Management Board shall try a prior settlement of the disputes on the matters provided by this article.

7 Financial Statements

7.1 Costs and Payment

7.1.1 General principle

The Budget comprises the total costs agreed for each Contractor and allocated to each Project's activity as defined in the Description of Work.
The Budget includes only eligible costs according to the art. II.19 (General Conditions) of the Contract.

7.1.2 Transfer of payments

The Co-ordinator shall receive all payments made by the Commission. The Co-ordinator undertakes to transfer the appropriate sums to the respective Contractors with minimum delay no more than fifteen (15) days from receipt, in accordance with the Contract and the modalities agreed by the Management Board.
The Co-ordinator will notify each other Contractor promptly of the date and amount transferred to its respective bank account and shall give the relevant references.

7.1.3 Management of EC contribution

The Co-ordinator shall manage EC contribution, respecting the rules approved by the Management Board and shall provide periodically the Management Board a report on its management.

7.1.4 Management costs

Each Contractor undertakes reasonable endeavours not exceed the ceiling of its management costs, according to the Project Share. Duly justified exemptions concerning audit costs should be agreed by the Management Board.
Banking and transaction costs related to the payments made by the Commission shall be borne by the while banking and transaction costs related to the handling of any financial resources shall be born by each Contractor.

7.2 Cost Statements

Six-month internal cost statements will be performed and annual cost statements will be released to the European Commission.
Specific tailored cost statement forms for internal use of the Consortium will be available on the Project Web Site, wile the Electronic Form C will be used for submitting cost statement to the Commission.