

# The CHIRON Objectives

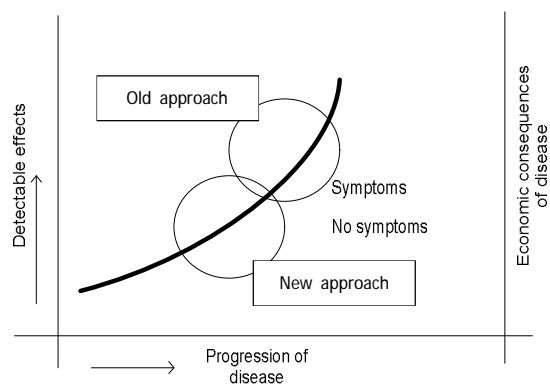
## A. CHIRON Scientific and technological (S&T) objectives

Objective	Description
<p><b>Create an open system architecture capable of seamlessly connecting heterogeneous devices and systems in widely dispersed domains</b></p>	<p>Heterogeneous subsystems – built with their own local data analysis and long or short-term repositories – will be able to be integrated, collaborate and at the same time to operate autonomously and give partial input to the person centric health information system.</p> <p>Design and realization of a <b>body area sensor network</b> in the home environment, a <b>person-centric health information system</b> and an <b>imaging system platform</b> integrated all together and demonstrating functionality and effectiveness of the common system architecture.</p>
<p><b>Design an architecture with high level of adaptability, efficiency and reliability</b></p>	<p>The developed CHIRON architecture will have the capability to be easily adapted to different specified environments. The focus will be on:</p> <ul style="list-style-type: none"> <li>• Adaptability of data structures,</li> <li>• Adaptability to hardware devices and network facilities,</li> <li>• Organizational environment adaptability, i.e. adaptability to infrastructure of organization,</li> <li>• System software environmental adaptability (adaptability to operating system, network software and cooperative application software)</li> </ul> <p>Other key design goals will be efficiency (resource utilization) and reliability attributes (such as integrity, ease of recover, last saved status)</p>
<p><b>Design a Virtual Patient Repository (VPR) with patient information and demonstrate its possible impact on the complete care cycle through providing new and detailed support to practitioners and doctors in the hospital.</b></p>	<p>The VPR will contain the following main patient information such as:</p> <ul style="list-style-type: none"> <li>- Data from sensor networks, which will provide real-time inputs concerning vital parameters of the (healthy) patient;</li> <li>- Data derived from the connected Hospital Information System;</li> <li>- Data from improved imaging systems which will give better diagnosis in very early stages of a developing disease.</li> <li>- Other data such as genetic information, laboratory values, epidemiologic data, possibly also lifestyle information, family history as well as administrative information.</li> </ul> <p>All these data will be interpreted through algorithms devoted to specific diseases.</p> <p>The model will be flexible enough to allow removal or adding of new info categories and adaptation to other diseases.</p>
<p><b>Design and develop new sensor nodes with enhanced features and proved networking capabilities</b></p>	<p>Energy harvesting, power management, local processing and local storage capabilities, privacy/security provisions realized at BAN level will be among the features of the sensor nodes. They will be part of an integrated network architecture supporting reliability, security, scalability.</p>
<p><b>Develop high-speed electronics and embedded software for medical images processing and visualization for a fast and more accurate diagnosis</b></p>	<p>The solution will realize computer aided analysis of medical images for a first, automated detection of suspicious regions and new, advanced visualization solutions (dual layer LCD display with high dynamic range).</p> <p>Integration of the imaging system into the overall CHIRON architecture will be realized too.</p>

## B. Medical objectives

CHIRON aims at contributing in promoting a paradigm shift from diagnosis and treatment of patients based on symptoms to diagnosis of patients based on risk assessment of healthy persons.

In currently applied healthcare practice, a disease is commonly discovered after symptoms have emerged. Only then, people become patients and apply for medical care; a diagnosis is made and a treatment is proposed and initiated. As shown in the graph below, diagnostic equipment (e.g. X-ray imaging) are employed at a certain state of progression of a given disease.



A shift from diagnosis and treatment based on symptoms to diagnosis based on risk assessment of healthy persons

On the contrary diseases need to be detected earlier and subsequent diagnosis and treatment need to be carried out earlier. Obviously, the benefit will be better quality of life and, on a global scale, a more healthy and cost-effective economy

Monitoring programs, screening plans or regular check-ups help to detect diseases in an early stage, before symptoms have occurred.

To be effective these approaches need to provide accurate information i.e. to provide early detection and – at the same time – to avoid an excessive percentage of “false negative” causing useless further studies and to avoid additional costs.

CHIRON aims at contributing to this new approach in healthcare.

The achievement of the medical objectives will be assessed through a clinical trial. It consists in a randomized study whereby Congestive Heart Failure (CHF) class III<sup>1</sup> patients are either provided or not with the home system using embedded technology to monitor them continuously. The trial will have a length of 12 months and will involve approx. 400 patients split into two groups. (one using the CHIRON approach and the other one treated with a conventional approach); the two groups will be equivalent as much as possible in terms of age distribution, gender and overall health status of the participants.

It is important to notice how the limited scale of the trial planned in CHIRON (both in terms of number of involved persons and length of the trial) does not allow to derive statistically relevant conclusions. Nevertheless the trial will provide a proof of concept and give useful information on the potential benefits of the CHIRON solution.

<sup>1</sup> See the New York Heart Association Classification (<http://www.hcoa.org/hcoacme/chf-cme/chf00070.htm>) which consider four classes.

The CHIRON Partners believe that in some way – even outside the Project – it will be important to continue the follow-up of enrolled patients to see if in the longer term there might be an evidence of the survival advantage in being equipped with the patient-centric monitoring.

Objective	Description
<b>Reduction in hospitalization</b>	<p>CHIRON aims at preventing the occurrence of degenerative episodes and in such way to reduce the frequency of hospitalization in patients suffering from chronic diseases and in any case to reduce the days of hospitalization.</p> <p>One of the main advantages of Remote Monitoring is represented by the availability of continuous rather than sporadic data to enhance understanding of the dynamic disease state. As an example, daily measurements of IPI (Intrathoracic Pulmonary Impedance) have been predictive of heart failure decompensation and atrial and ventricular arrhythmogenesis, but with variable relationships between daily changes and other measures of heart failure.</p>
<b>Reduction of the mortality in CHF class III patients</b>	<p>Mortality in CHF is related to the severity of the disease, in turn related to the severity of left ventricular dysfunction (which might be assessed by left ventricular ejection fraction by imaging techniques, also relatively non-invasively). If one concentrates on class III a high proportion of death (&gt;40%) might be anticipated in 12 months, particularly in the elderly.</p> <p>The goal of CHIRON is to contribute to reduce this percentage.</p>
<b>Effect of availability of a larger quantity and variety of data for a better accuracy of the diagnosis and for the effectiveness of the therapy</b>	<p>A key contribution of CHIRON will be to verify how the availability of more data (multi-parametric monitoring) has impact on the accuracy of the diagnosis. A possible outcome is that even simple (and likely cost effective) measurements are sufficient instead of building complex platforms. However, we need the complex CHIRON architecture to prove or dismiss the above interesting conjecture.</p> <p>CHIRON will develop an architecture able to collect and manage a large quantity of data from the entire community of patients that – analyzed case-by-case by a powerful expert system – will support the physicians in their decision process and will foster the development of new diagnostic and treatment methodologies.</p> <p>The architecture will be flexible enough to add or to remove sensors / parameters in the monitoring section of the system.</p>
<b>Enhanced accuracy of the diagnosis through medical images</b>	<p>CHIRON will propose novel solutions for automation in the detection of suspicious regions of interest (ROIs) in the image and advanced visualization solutions supporting the doctor in his diagnostic task. The integration of medical image analysis (e.g., tissue analysis in the case of CHF) with multi-parametric monitoring data will contribute to a better accuracy and an improved productivity.</p>
<b>Introduction of innovative solutions in health monitoring at home</b>	<p>Development of innovative solutions such as:</p> <ul style="list-style-type: none"> <li>- Blood pressure measurement,</li> <li>- Measurement of liquid retention using the ECG, and</li> <li>- Measurement of blood serum potassium using the ECG.</li> <li>- Measurement of geriatric relevant trends of activities of daily living to measure a functional overall health status.</li> </ul>

### C. Socio-economic objectives

Objective	Description	Measures and Indicators
<b>Enhancement of the quality of life of the patients</b>	<p>The patient is at the centre of the health system; he will be the master of his/her health status, rehabilitation, and care plan and can rely on a continuous medical and psychological support from physicians, caregivers and the overall community. He/she will get reassurance by knowing that his/her health is under continuous monitoring.</p>	<p>Surveys before, during and after the execution of the clinical trials; success criterion: min. 70% of the involved persons declaring an enhancement of their quality of life.</p>
<b>Acceptance of the solution by the patients and by the main stakeholders</b>	<p>The acceptance of new technological solutions mainly by elderly persons is not so obvious. It is often linked to the perception of the benefits they bring and to their unobtrusiveness. Moreover concerns about privacy and personal data security could be a serious obstacle. Additionally the unobtrusiveness of continuous home monitoring solutions has a high impact on the overall acceptance by elderly persons.</p> <p>In the CHIRON project we will pay a lot of attention to these issues; the requirements of the users (the patients, their family members, the medical professionals) will be constantly at the center of the development activity to be sure that the proposed solutions will be accepted and that the patients will ensure adherence to the new approach.</p>	<p>Field tests with representatives of relevant user groups will be organized. Workshops and User Forums will be planned – during and at the end of the design phase – to have feedbacks on the usability, accessibility and acceptance of the developed solutions.</p> <p>The success criterion will be represented by a percentage in excess of 75% of end-users accepting the CHIRON approach (with specific reference to the monitoring solutions and the overall service and its personalization). Same usability and acceptance tests will be planned with the group of patients selected for the clinical trials in UK and in Italy.</p>
<b>Reduction in the overall healthcare costs</b>	<p>CHIRON will contribute to an <b>effective move of healthcare from hospital to home</b> and to a reduction of the socio-economical burden of the National Health and social Systems by fostering prevention rather than expensive in-hospital treatments and improving productivity.</p> <p>We will assess the economic benefits that the solution proposed by CHIRON will foster through:</p> <ol style="list-style-type: none"> <li>Reduced frequency of hospitalization,</li> <li>Reduced number of hospitalization days,</li> <li>Reduced time spent by doctors for each patient for consultation and minor interventions,</li> <li>Reduced need of additional hospital examinations and lab analysis as effect of a better diagnosis</li> </ol>	<p>Analysis based on first outcomes of the trials and on available statistical data. Success criterion: overall cost saving per patient per annum in excess of 25%</p>