



# Telecardiology 1999-2009

**CHARITÉ**  
UNIVERSITÄTSMEDIZIN BERLIN

# Charité-Universitätsmedizin Berlin

## Facts



- founded in 1710
- 11 Nobel prize winner
- 15.000 employees
- 9.600 students
- 110 departments
- turn over 2008:  
1.1 billion €
- scientific budget 2008:  
112 million €



## Connectivity over Long Distance for Cardiological Content

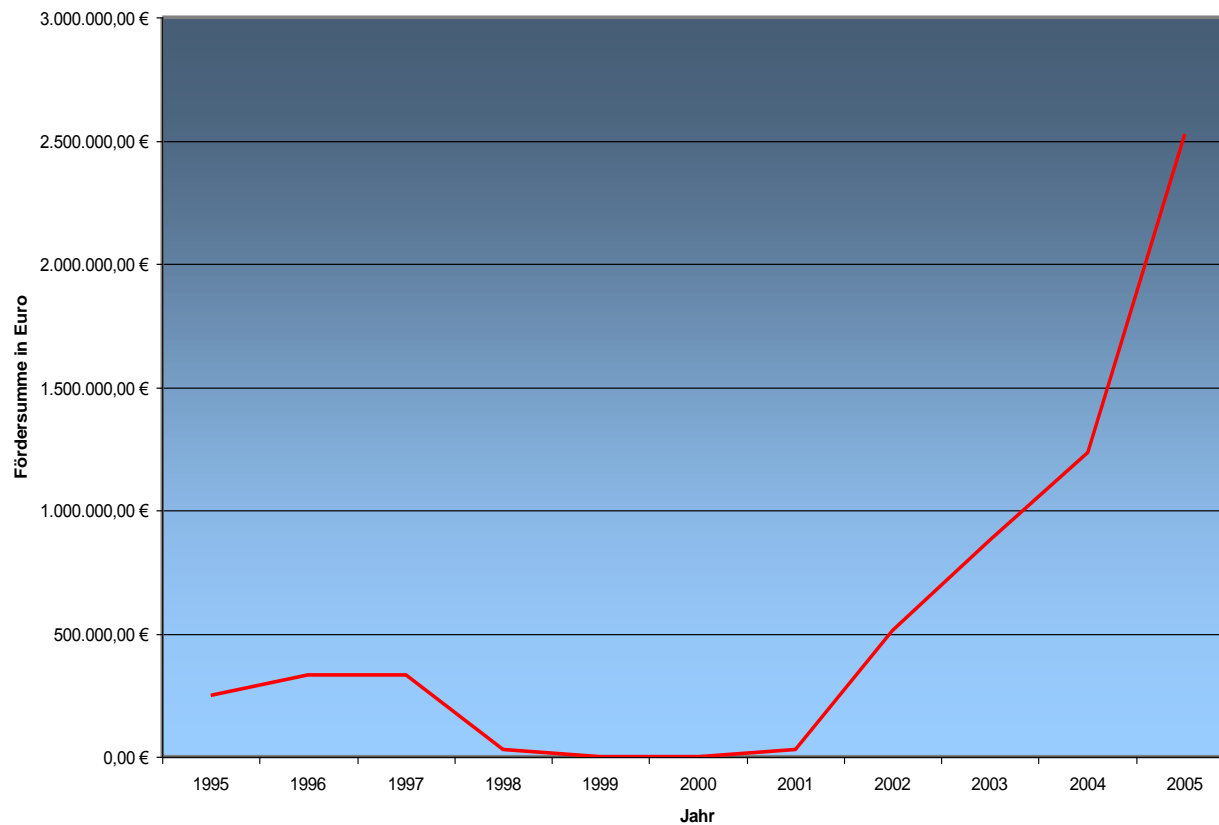
- 1) „doc2doc“ Systems – Connectivity between Health Care Providers
- 2) „doc2patient“ Systems – Remote Patient Monitoring

**Know-how Transfer Programme between  
Germany and the Baltic States (Estonia, Latvia and Lithuania)  
in the Treatment of Patients with Congenital Heart Defects (CHD  
using modern information technologies**

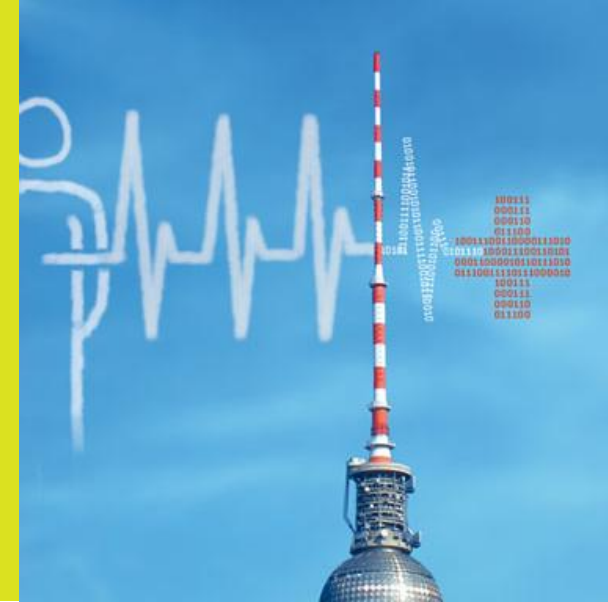
# Telemedicine Funding by federal grants



Förderung Telemedizin



# Congenital Heart Defects (CHD) – epidemiological Background



- CHD are the most frequent malformations
- 1 Per cent of all newborns suffer from CHD
- CHD influences the infant mortality
- Natural Course of Disease (80 Per cent mortality)
- „Gold Standard“ is the Cardiac Surgery during infancy ( 85 Per cent Survival)



# „Telemedicine-Bridge“ (Charité-Tartu) 7.11.2000



# Educational-Programme



17 Visits of Estonian Experts in Germany  
32 Operations in Estonia, 5 Operations in Germany





# Results Estonia

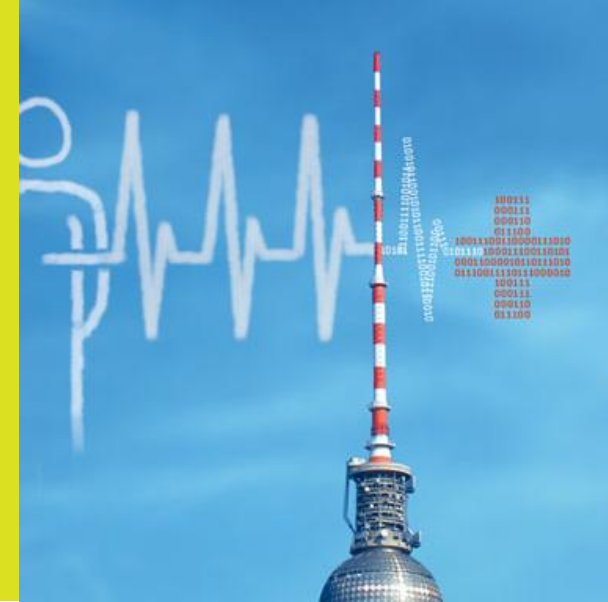


	2000	2005
Population	1.4 Mio.	1.33 Mio.
Life-Births	13.067	12.218
CHD-Patients/a	99	95
Surgery for CHD (Uni Tartu)	56	61
Infant-Mortality	<b>8,42 ‰</b>	<b>6,11 ‰</b>

# „Partnership for the Heart“

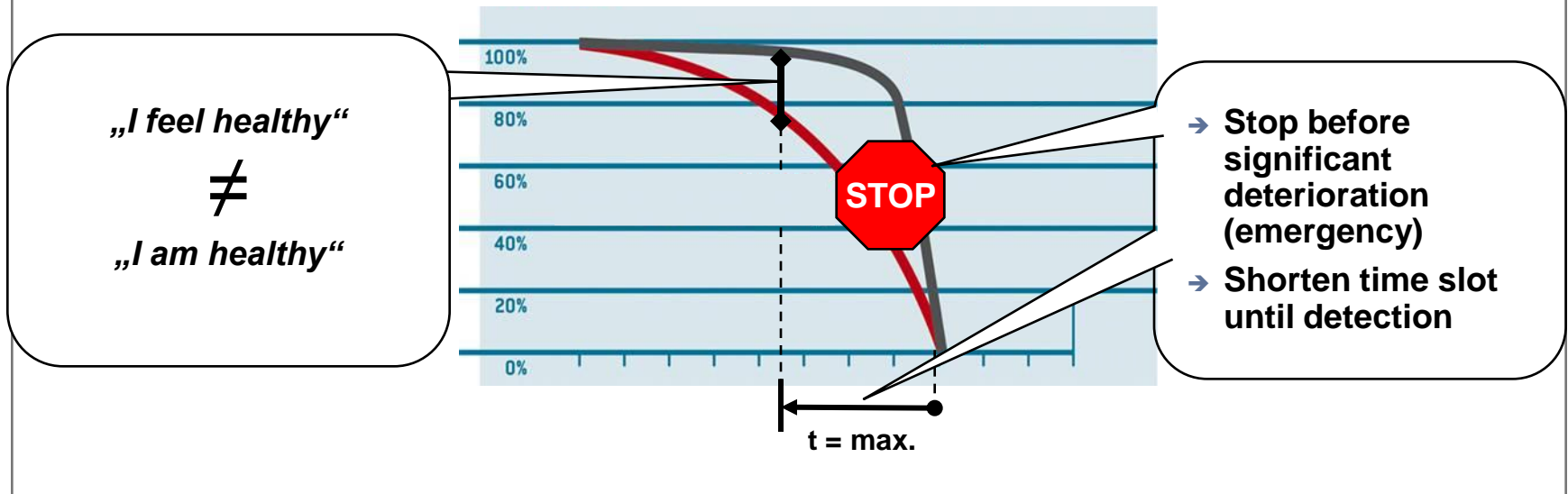
## Remote Patient Monitoring in Heart Failure:

Research and Development Project of the  
German Federal Ministry of Economics and Technology (BMWi)



# Why remote patient monitoring in CHF?

Gap between objective deterioration and subjective perception of cardiac function



# Trends in remote patient monitoring systems since 2000



## - Evidence of Effectiveness

Journal of the American College of Cardiology  
© 2005 by the American College of Cardiology Foundation  
Published by Elsevier Inc.

Vol. 45, No. 10, 2005  
ISSN 0735-1097/05/\$30.00  
doi:10.1016/j.jacc.2005.01.050

### Heart Failure

## Noninvasive Home Telemonitoring for Patients With Heart Failure at High Risk of Recurrent Admission and Death

The Trans-European Network–Home-Care  
Management System (TEN-HMS) Study

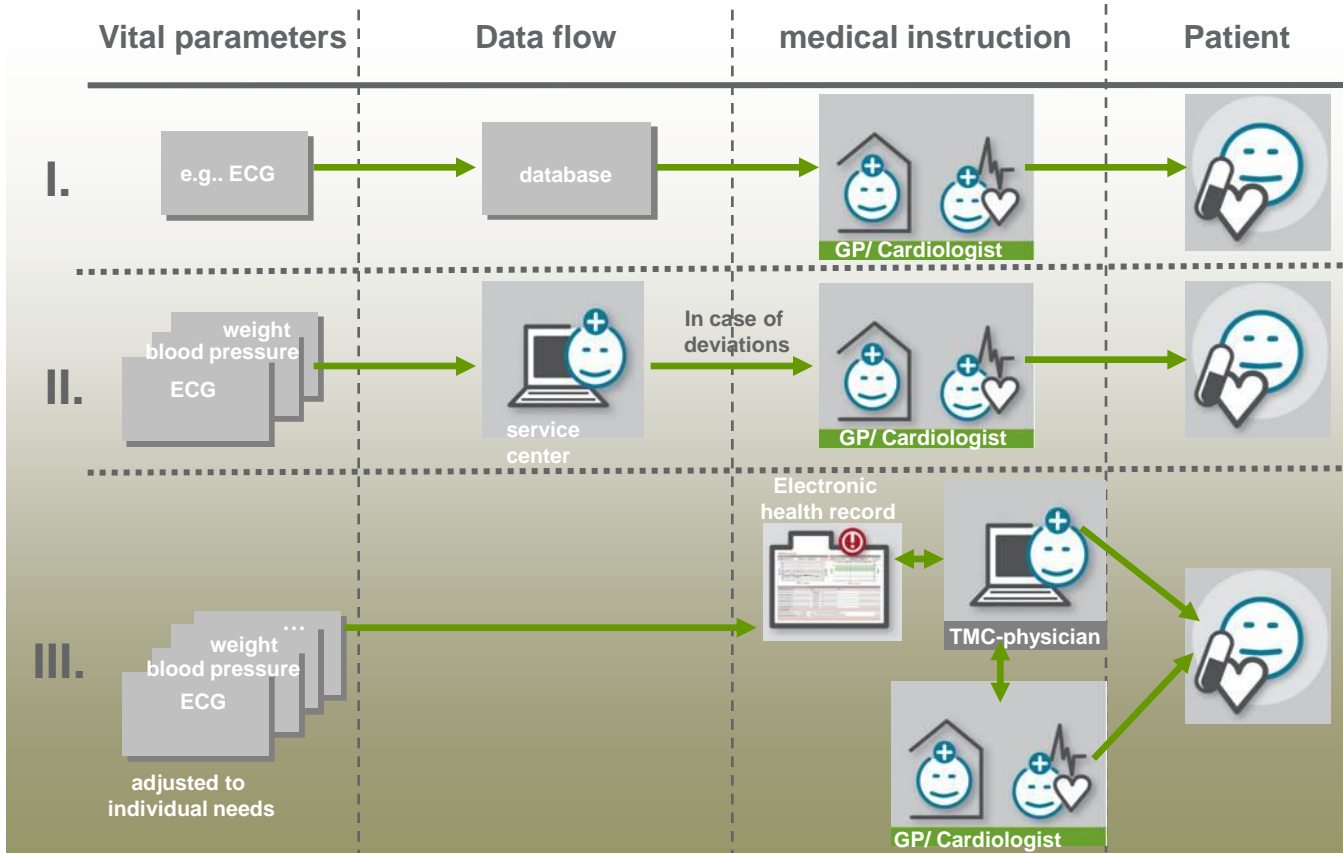
John G. F. Cleland, MD,\* Amala A. Louis, MD,\* Alan S. Rigby, PhD,\* Uwe Janssens, MD,†  
Aggie H. M. M. Balk, MD,‡ on behalf of the TEN-HMS Investigators

*Kingston Upon Hull, United Kingdom; Aachen, Germany; and Rotterdam, the Netherlands*

## - Rapid Development in IT

## - Decrease in Costs for Mobile Communication

# 3 „generations“ in the development of remote patient monitoring systems



Koehler F., Anker SD.  
J Am Coll Cardiol 2006;48:850-851

# BMWi-Competition: „Nextgenerationmedia 2005-2008“



## Federal Ministry of Economics and Technology (BMWi)



- Innovation program „next generation media“
- 11 projects in total, 2 health care projects
- [www.nextgenerationmedia.de](http://www.nextgenerationmedia.de)

## BMWi- Requirements


- ▶ **Platform-concept** : sensor devices produced by a wide range of different manufacturers must be integratable
- ▶ **Compatibility to the German e-Health Infrastructure**
- ▶ **Usability** for middle aged patients without an previous knowledge of IT
- ▶ **Expandable** to cover other cardiological and non-cardiological Indication

# Project partners and responsibilities






Development

  
**Project leadership**

Clinical trial

 **BOSCH**  
**Technical management**

  
**Clinical trial management**

				
<ul style="list-style-type: none"> <li>→ Sensor platform for data transfer</li> </ul>	<ul style="list-style-type: none"> <li>→ Platform for exchange of medical data (electronic patient record)</li> </ul>	<ul style="list-style-type: none"> <li>→ System integration</li> <li>→ hardware, operation</li> <li>→ Quality man.</li> </ul>	<ul style="list-style-type: none"> <li>→ Study center 1 (Open 24/ 7)</li> <li>→ clinical trial management</li> </ul>	<ul style="list-style-type: none"> <li>→ Study center 2 (Open 7-21/7)</li> </ul>

# Associated partners & grant

## Associated partners



→ Support in patient recruitment



→ Cross-sectional contracts between patients, medical partners, health care providers, TMC

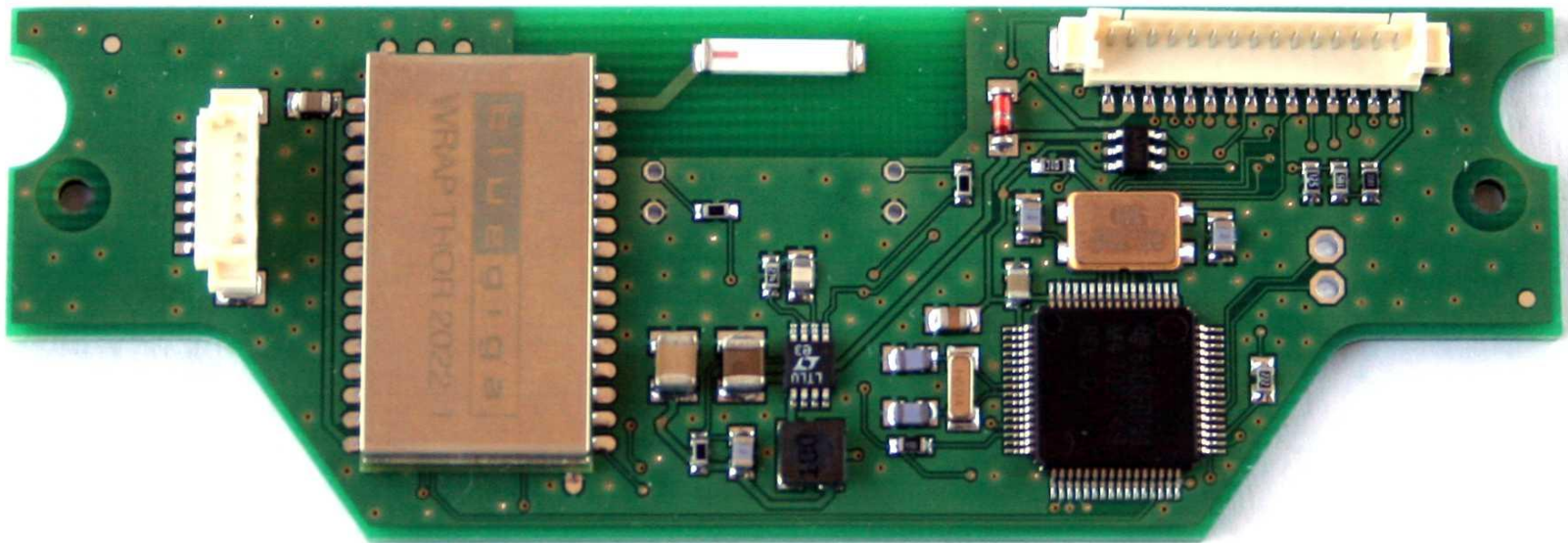
## PfH – facts and figures



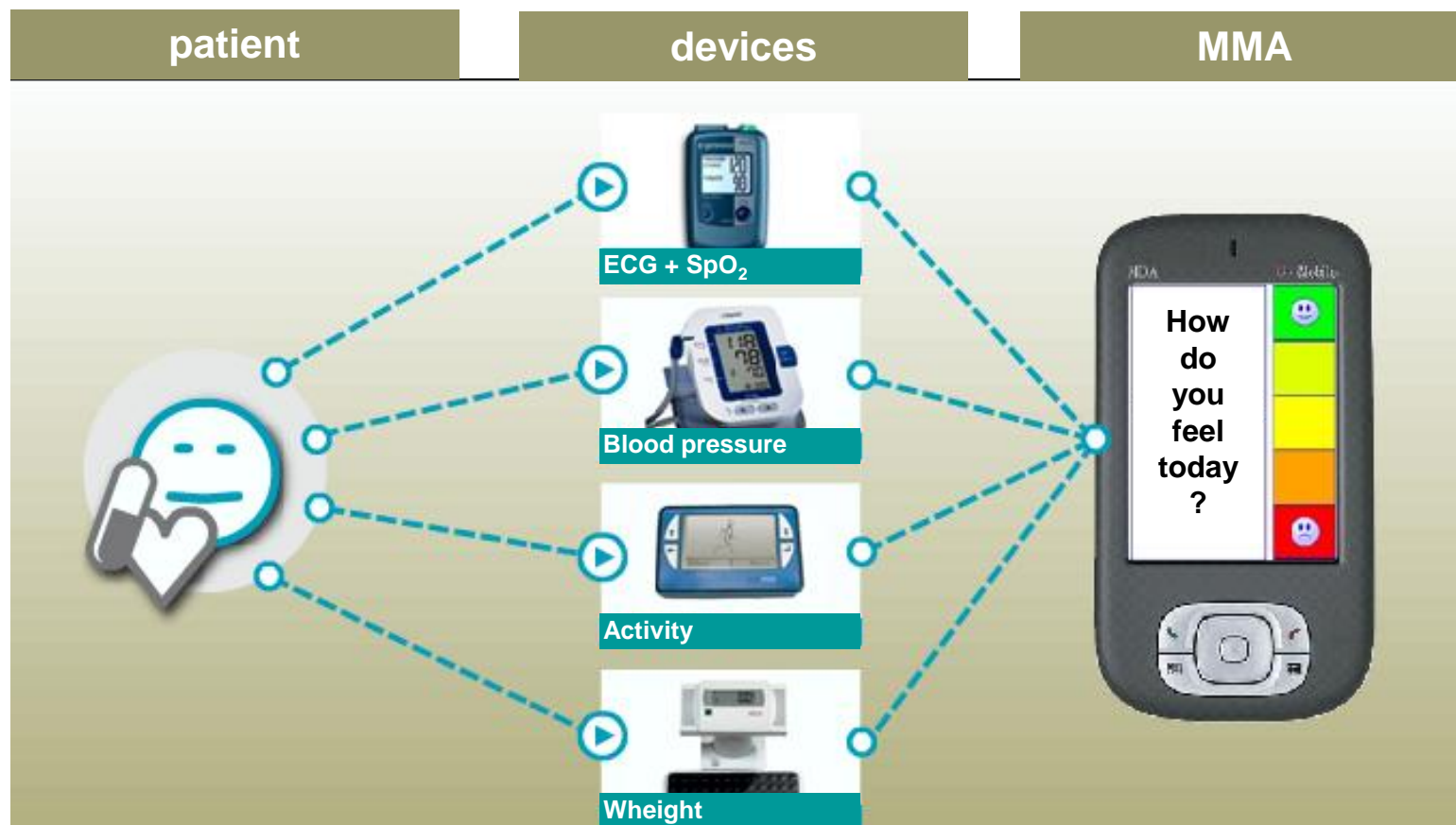
- Project: 01 MG532
- Federal Grant: 5 Mio €
- Total Volume: 12.2 Mio €
- Project Duration: 2005-2008,
- Clinical Trial: 1'08 - 12'08
- [www.partnership-for-the-heart.de](http://www.partnership-for-the-heart.de)



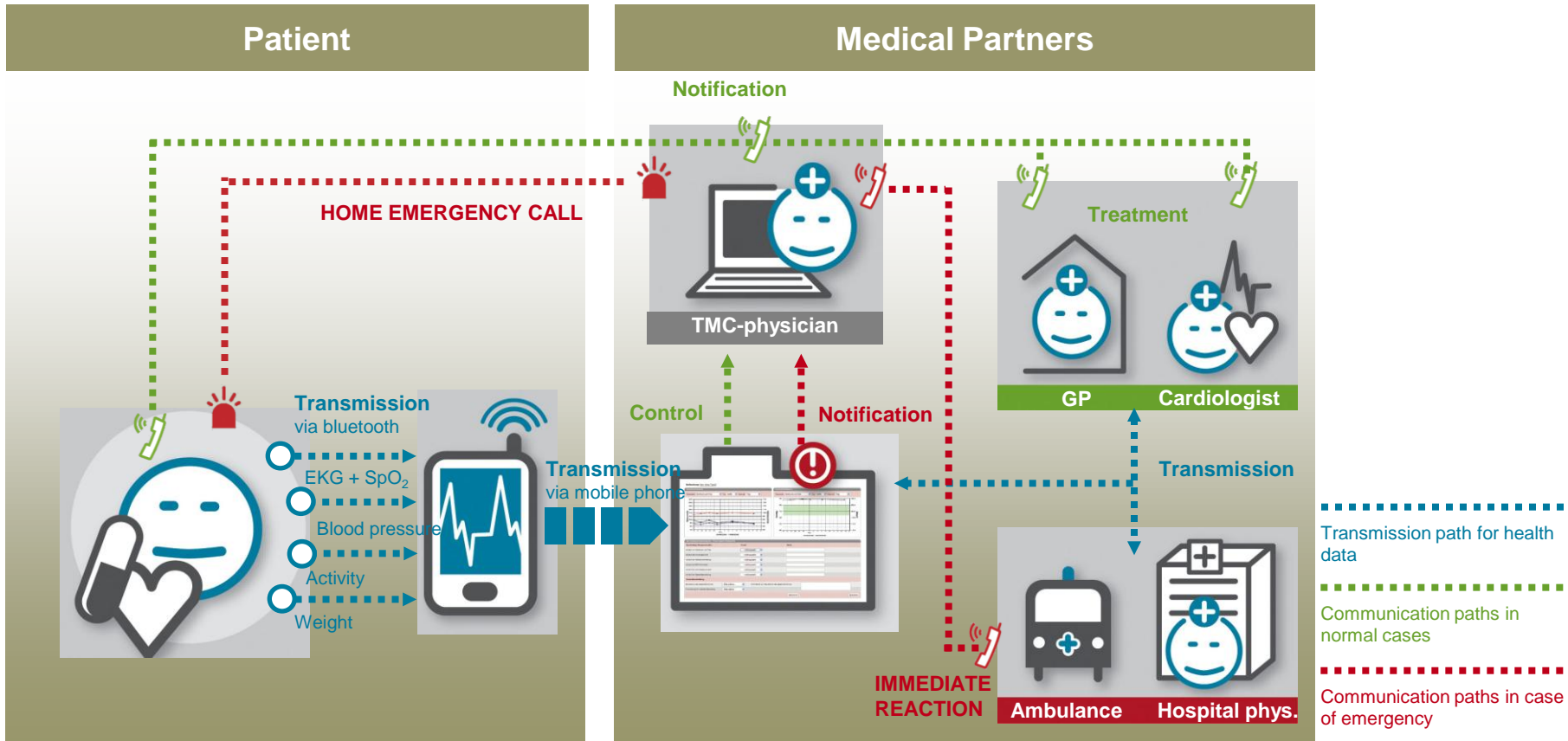
# Secure sensor module



# Patients' measuring devices



# PfH patient monitoring system



# TIM-Study - Studydesign

Objectives	Trial design	Endpoints
<ol style="list-style-type: none"> <li>1. superiority of remote patient monitoring compared with “usual care” in terms of               <ul style="list-style-type: none"> <li>▶ <b>mortality rate</b></li> <li>▶ <b>hospitalization</b></li> <li>▶ <b>cost effectiveness</b></li> </ul> </li> <li>2. superiority in terms of               <ul style="list-style-type: none"> <li>▶ <b>Life quality</b></li> <li>▶ <b>neurohumoral status</b></li> </ul> </li> <li>3. Relative meaning of variables in terms of trial aim 1</li> </ol>	<ul style="list-style-type: none"> <li>▶ randomised, prospective, controlled open, parallel, multicenter</li> <li>▶ 600 patients (1:1)</li> <li>▶ remote patient monitoring for at least 12 months</li> <li>▶ therapy based on guidelines</li> </ul> <div style="background-color: #cccccc; padding: 5px; text-align: center; margin: 5px 0;"><b>Inclusion criteria</b></div> <ul style="list-style-type: none"> <li>▶ ejection fraction below 35%</li> <li>▶ advanced CHF (NYHA II-III)</li> <li>▶ hospitalization (cardiac decompensation) within 18 months prior to the study</li> </ul>	<p><b>Primary endpoint</b></p> <ul style="list-style-type: none"> <li>▶ overall mortality</li> </ul> <p><b>Secondary endpoints</b></p> <ul style="list-style-type: none"> <li>▶ days alive and out of hospital due to heart failure</li> <li>▶ cardiovascular mortality rate</li> <li>▶ overall non-elective hospitalization</li> <li>▶ cardiovascular hospitalization</li> <li>▶ plasma level of NT-proBNP</li> <li>▶ patients' quality of life</li> <li>▶ cost effectiveness</li> </ul>

# Recruitment (region north-east)

## Berlin/Brandenburg (6 million Inhabitants)

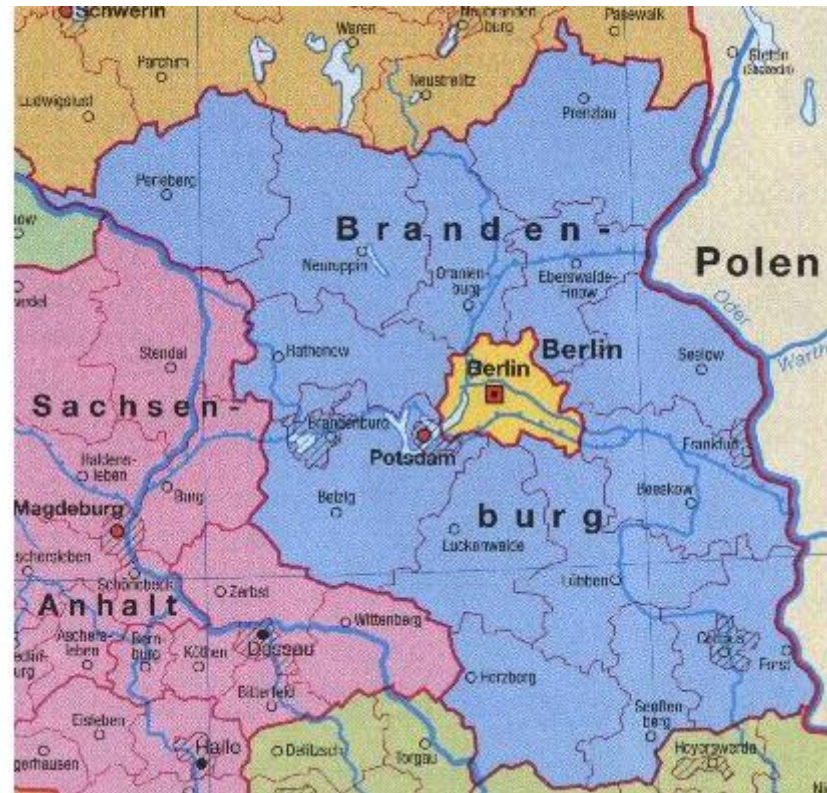
61 Study-Centres

(82 % GPs )

6 „Back up“ Cardiologists

1-3 suitable Patients per  
Center

133 Patients screened



# Recruitment (region south-west)

**Baden-Wuerttemberg**  
10.7 million Inhabitants

81 Study-Centres

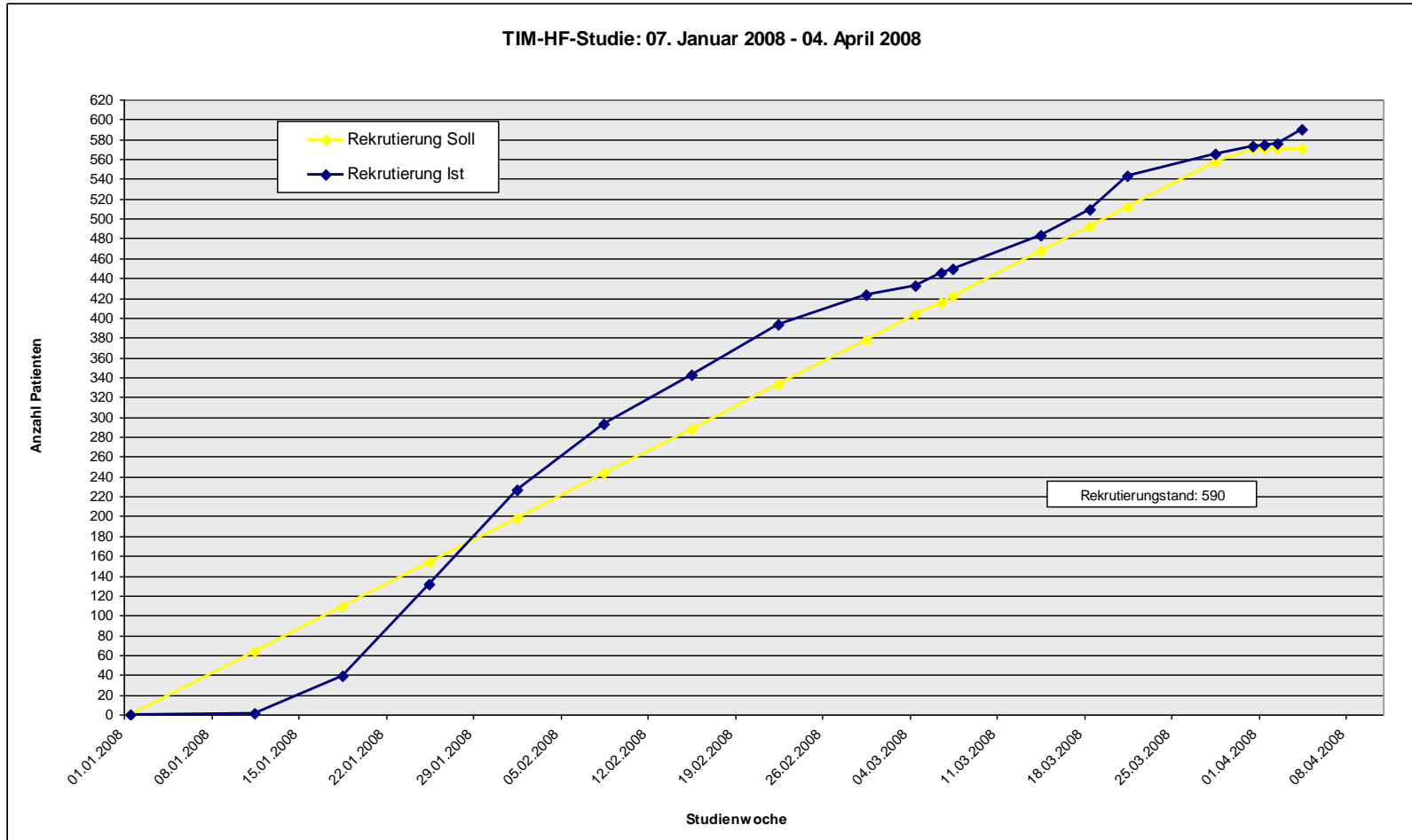
(96 % Cardiologists)

1-10 suitable Patients per  
Center

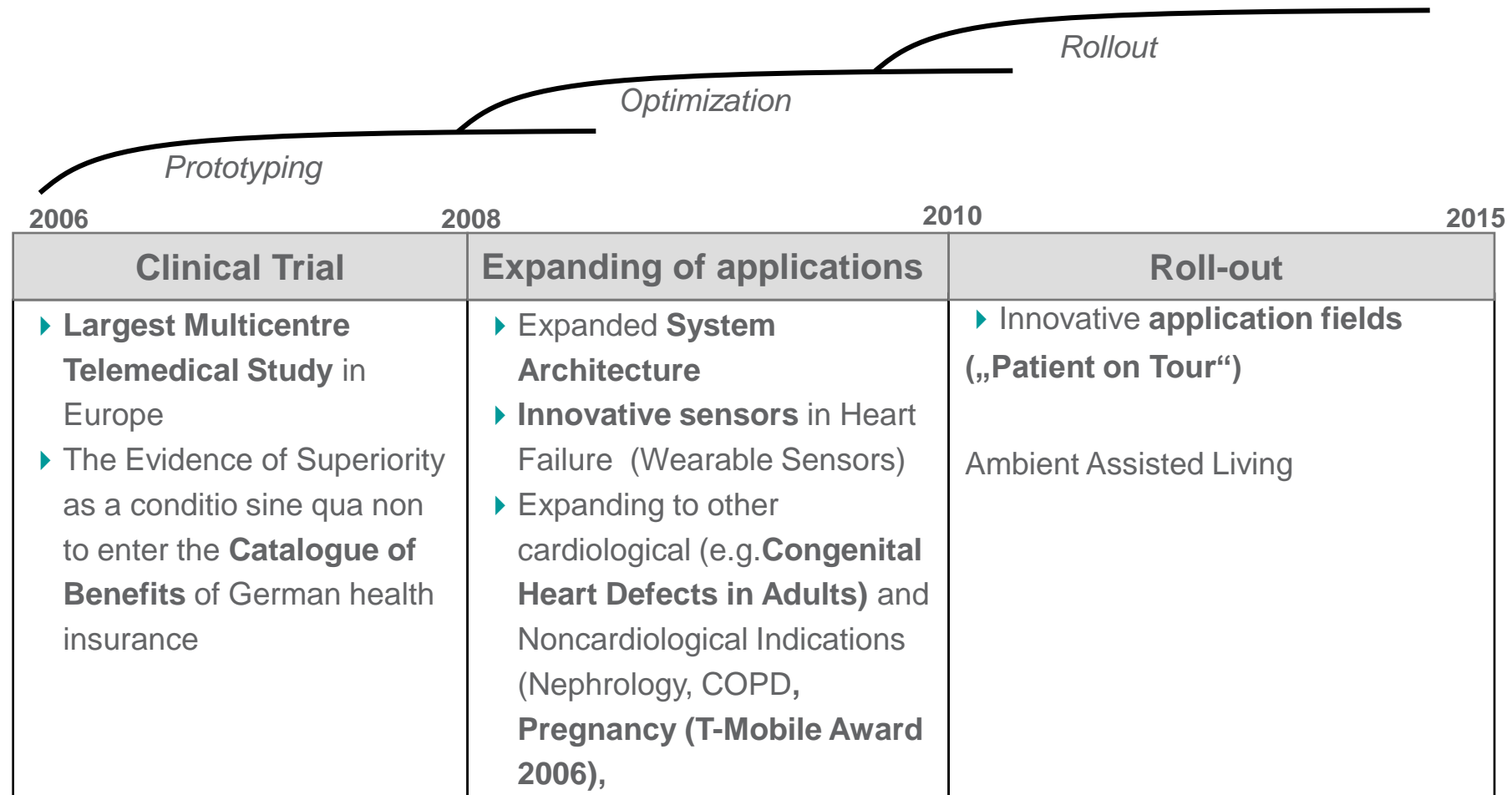
258 Patients screened



# Recrutiment of the Patients


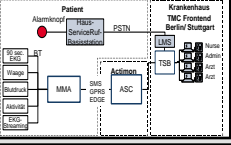
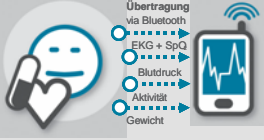



# Outlook – remote patient monitoring and PfH





# Features of the PfH-system

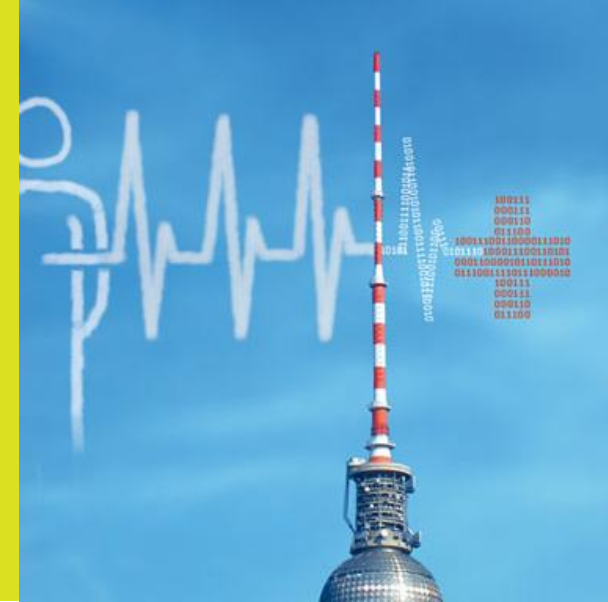
	Criteria	PfH
<b>Aim</b> 	<ul style="list-style-type: none"> <li>▶ Controlled Randomized Trial</li> <li>▶ Health economics</li> </ul>	<p>✓</p> <p>✓</p>
<b>System architecture</b> 	<ul style="list-style-type: none"> <li>▶ Open platform concept</li> <li>▶ Compatibility on national level (telematics infrastructure)</li> <li>▶ Communication (Incl.Education) to the Patients</li> <li>▶ Expandable to other indications</li> </ul>	<p>✓</p> <p>✓</p> <p>✓</p> <p>✓</p>
<b>Patient</b> 	<ul style="list-style-type: none"> <li>▶ Usability and acceptance by the target group (60 years +)</li> <li>▶ Assessment around the clock</li> </ul>	<p>✓</p> <p>✓</p>
<b>Players in the health care system</b> 	<p>Cross-sector integration:</p> <ul style="list-style-type: none"> <li>▶ GPs / Cardiologists / hospitals</li> <li>▶ health insurance funds</li> </ul>	<p>✓</p> <p>✓</p>

# Remote patient monitoring in heart failure for high risk patients

- ▶ should be a part of an integrated, cross-sectional care programme
- ▶ should be organized in the regions (1 TMC per 4 Mio Inhabitants)
- ▶ should a new task for a cardiological department
- ▶ could be profitable

# „Partnership for the Heart“

## Thanks to the project group



Head of the Telemedical Centre Stuttgart: **Dr. Michael Schieber** (Robert-Bosch-Krankenhaus Stuttgart)

Technical management: **Dr. Sascha Henke / Martin Bräcklein** (Robert-Bosch GmbH)

Electronic patient record: **Dr. Peter Heinze** (InterComponentWare AG)

Sensor platform: **Dr. Dominik Wegertseder** (Aipermon GmbH)

Project management and communication. **Dr. Stephanie Lücke** (Charité Berlin)

Further information: [www.partnership-for-the-heart.de](http://www.partnership-for-the-heart.de)

