

EHRA Summit 2010

E-health and personalized health care in arrhythmias

22-23 March 2010 – European Heart House Sophia Antipolis

Telemonitoring in arrhythmias and CRM devices

National experiences: Italy

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System availability in Italy

✓ Home Monitoring™, Biotronik



✓ CareLink™, Medtronic



✓ Merlin.net System™, St. Jude Medical

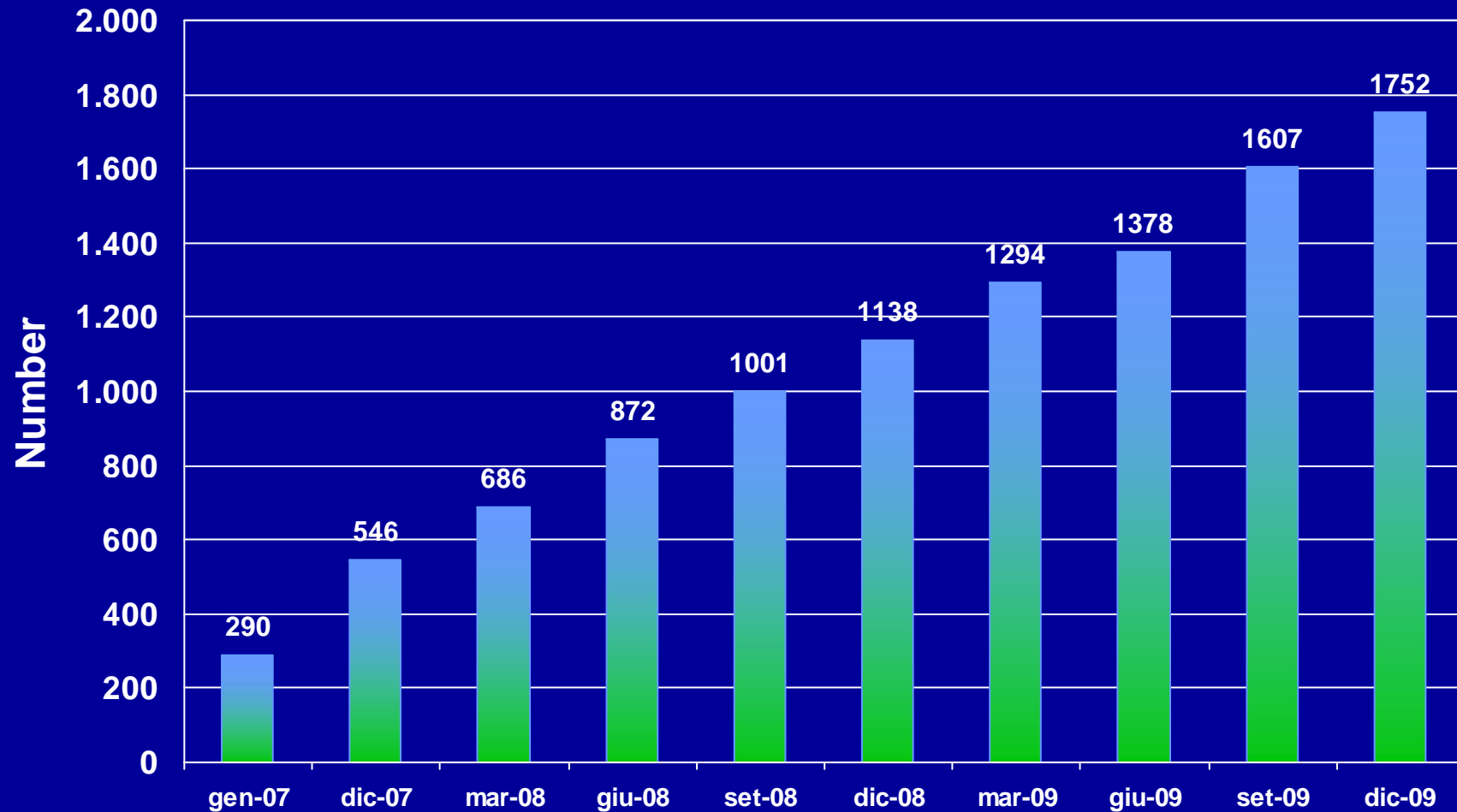


✓ Latitude™, Boston Scientific



Biotronik Home Monitoring in Italy

(introduced in 2000; about 2800 patients enrolled)

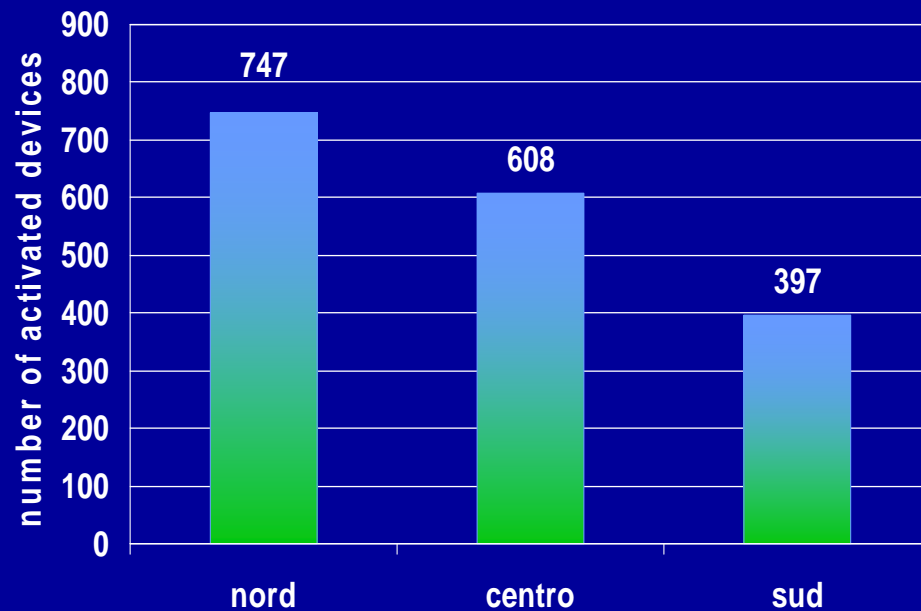


Actively followed patients in the web site

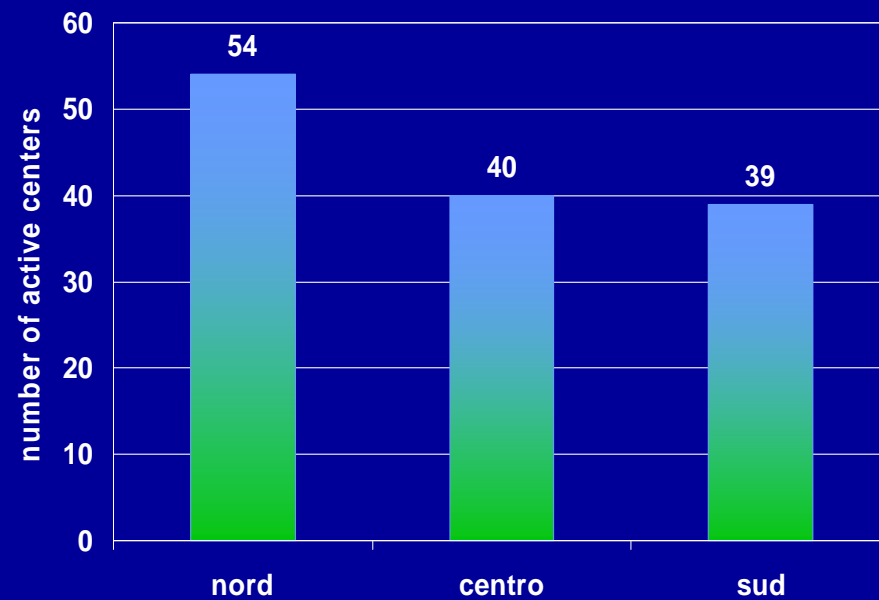
Biotronik Home Monitoring in Italy

Regional distribution of patients and centres

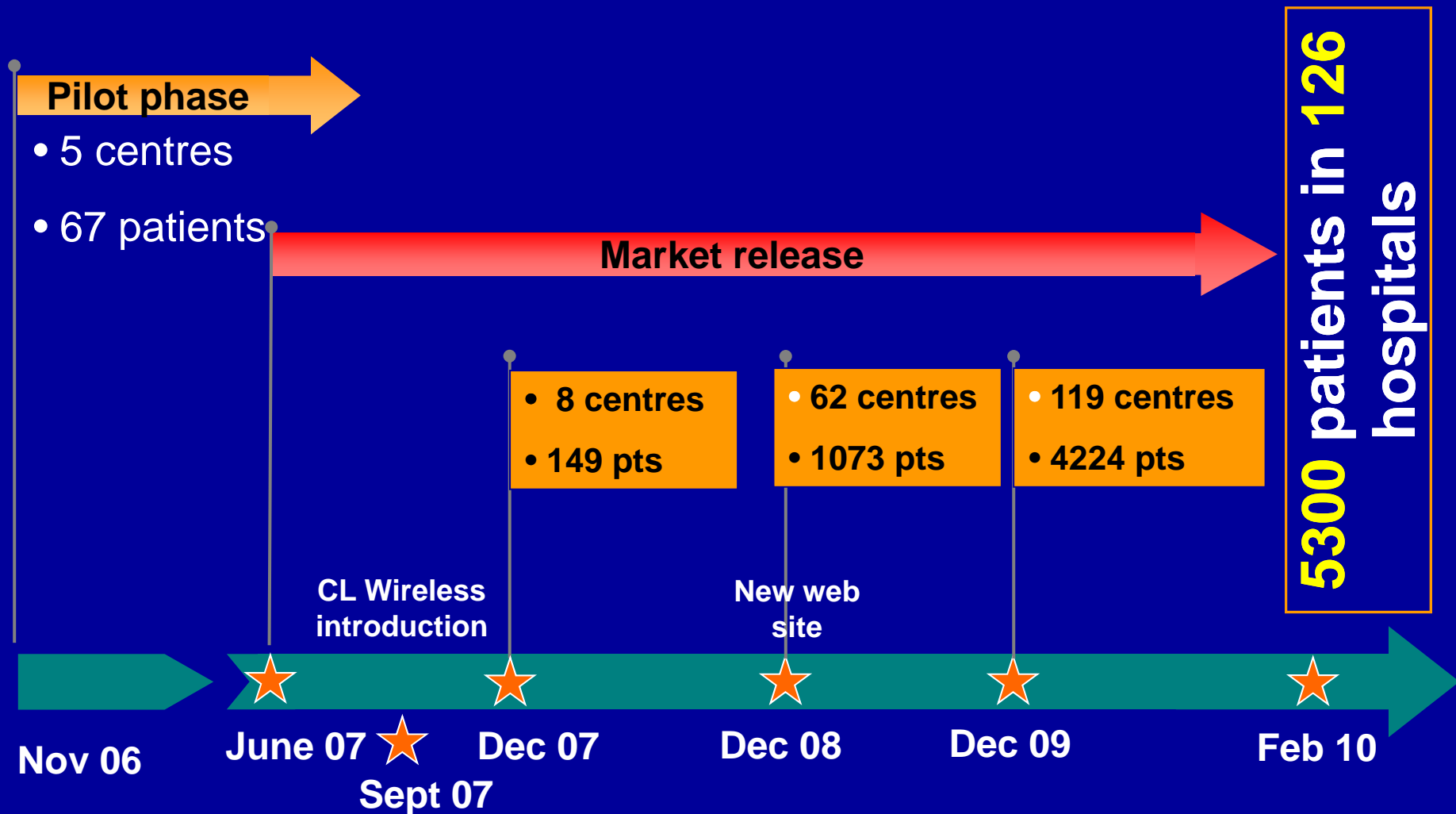
PATIENTS



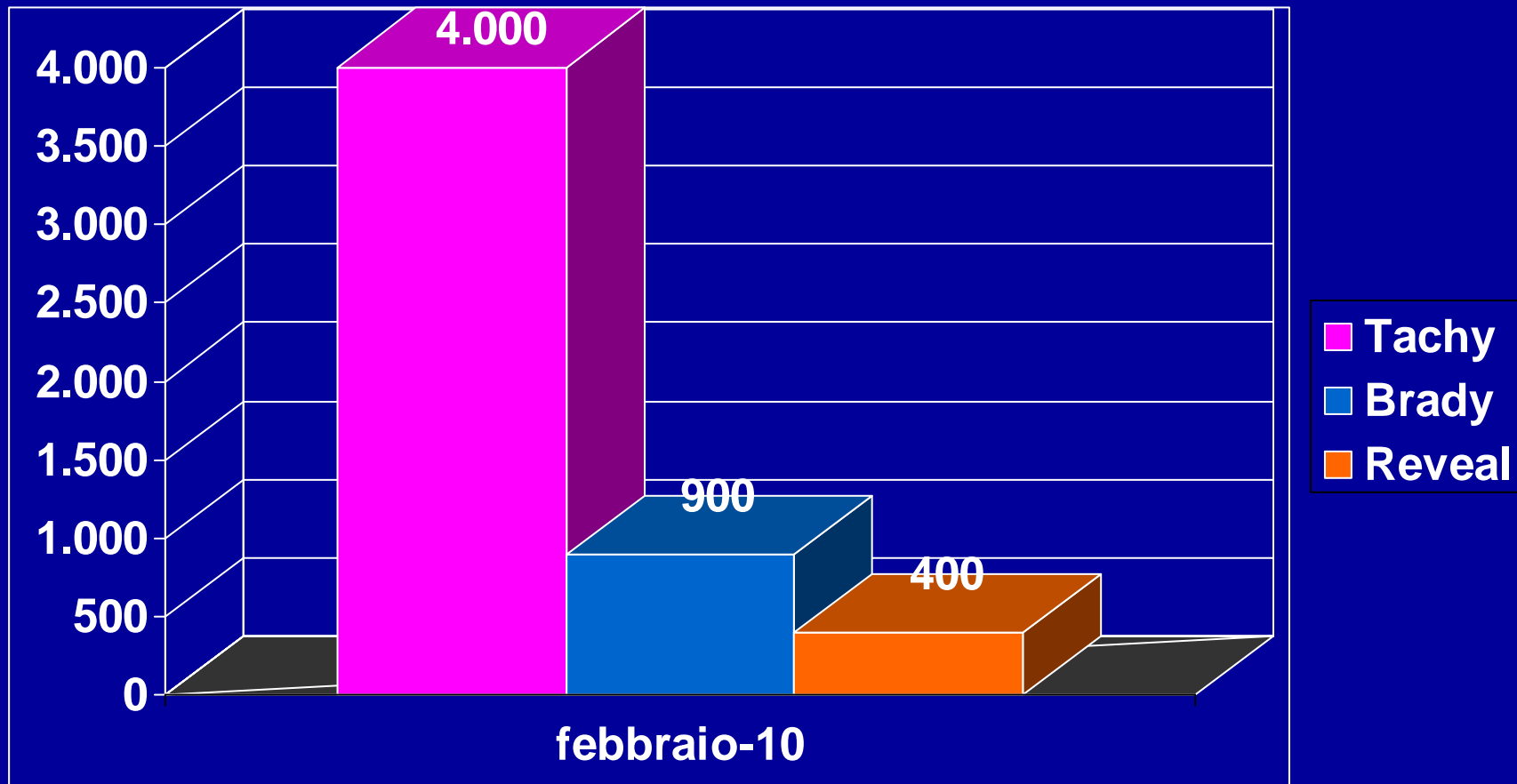
CENTRES



Medtronic CareLink in Italy



Medtronic CareLink in Italy Devices



St Jude Merlin.net System in Italy

Introduction	July 6, 2009
Active Centres in Italy	21
North	12
Middle	5
South	4
Patients enrolled	167
of whom with GSM/UMTS	40

Boston Latitude System in Italy

Introduction	July 7, 2009
Active Centres in Italy	33
North	13
Middle	4
South	16
Patients enrolled	135
of whom with HF sensors	38



Telecardiology working group

Consensus Document

Il monitoraggio remoto dei dispositivi impiantabili:
tecnologie disponibili, indicazioni, modelli organizzativi,
accettabilità, responsabilità ed aspetti economici.

R. Ricci, G. Calcagnini, A. Castro, F. Giada, D. Igidbashan, M.
Landolina, D. Melissano, G.B. Perego, T. Toselli

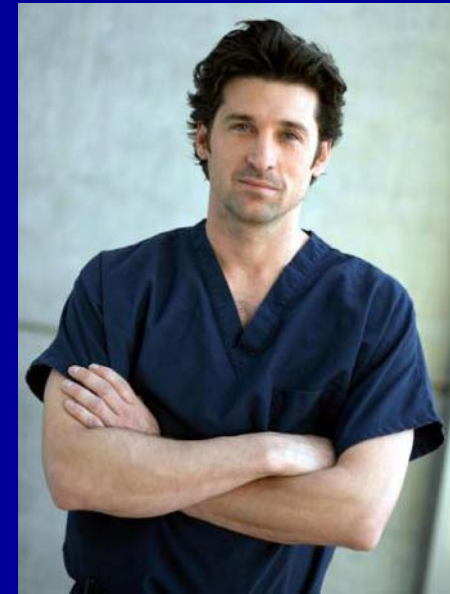
AIAC web site: www.aiac.it 14 giugno 2009

Giornale Italiano di Aritmologia e Cardiolazione 2009,12:92-119.

Organizational aspects: Human Sources



Nurse



Physician

- ✓ Patient training and education
- ✓ Web site data entering
- ✓ HM data and alert reviewing
- ✓ Data screening
- ✓ Submitting critical cases to the physician
- ✓ Contact with the patients
- ✓ Monitoring of patient compliance and therapy benefits

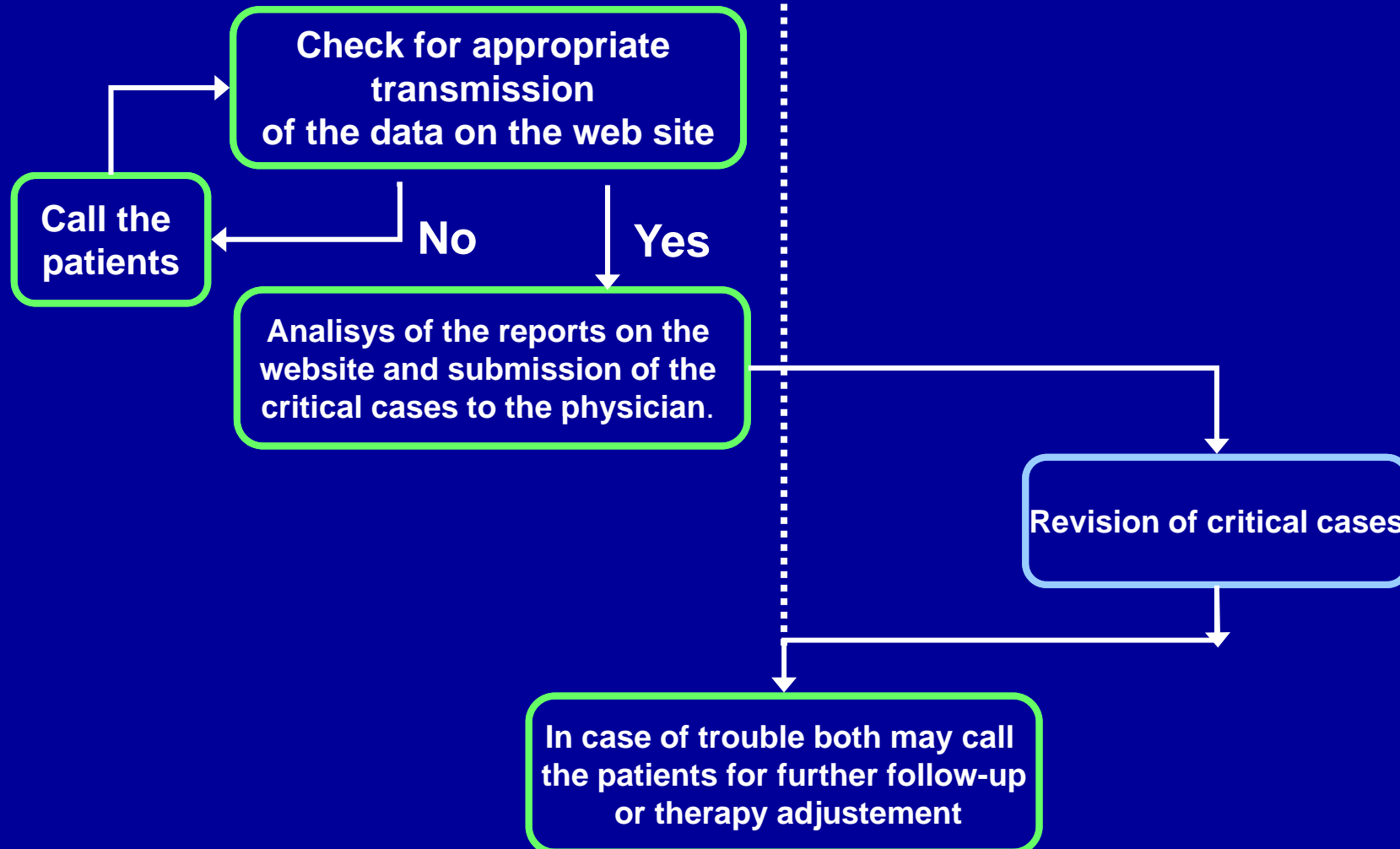
- ✓ Informed consent submission
- ✓ Overview and check
- ✓ Clinical judgement in critical cases

Organizational Model

(based on Primary Nursing Model)

NURSE or TECHNICIAN

PHYSICIAN



Home Monitoring in clinical practice

Web data analysis (April 2006 – June 2007)

- Analysis number: **2512** (nurse 2249 – physician 263)
- Mean number of analysis per patient: **22 ± 19 (1-100)**

web data analysis by the nurse

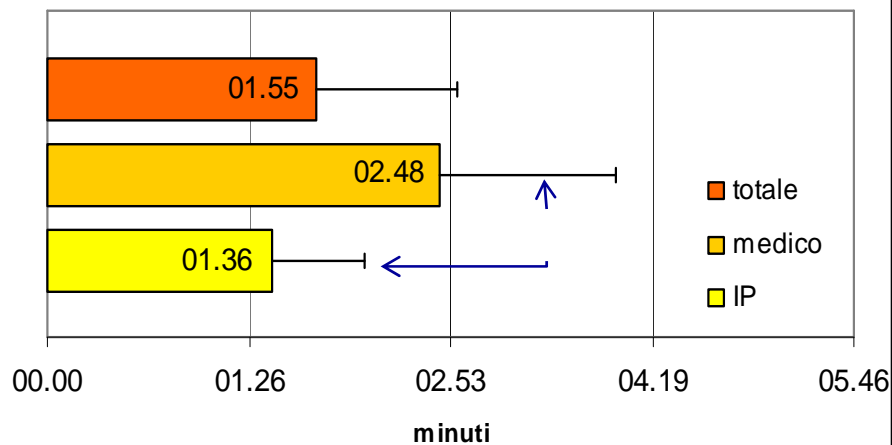
Classification of events	Number	Percentage
Everything fine	2061	92%
Ask the physician	133	6%
Call the patient for follow-up	5	0.2%
Contact the patient by phone	50	2.2%

transmission
interruption

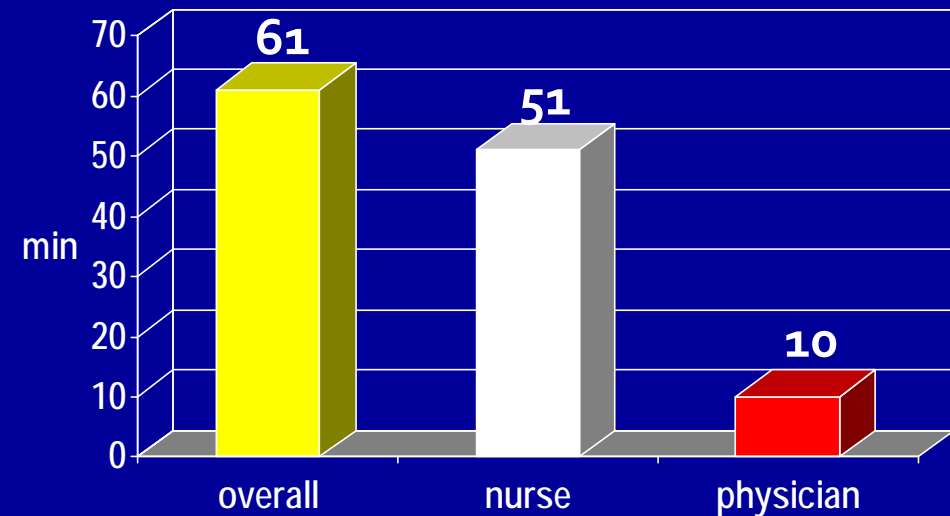
Home Monitoring™ in clinical practice

Web site sessions – health care source consumption

tempo medio connessione per paziente



Time consumption per 100 patients/week



AIAC to certify nurses / technicians



COMPETENCE IN ARITMOLOGIA E CARDIOSTIMOLAZIONE

BANDO PER LA PARTECIPAZIONE AL

1° CORSO DI ACCREDITAMENTO PROFESSIONALE PER
INFERMIERI E TECNICI DI CARDIOLOGIA PER LA
CERTIFICAZIONE DELLA COMPETENZA
IN ARITMOLOGIA E CARDIOSTIMOLAZIONE

1° course 2008 – 2009 with final exam on September 24, 2009
in Bellaria: **70 nurses / technicians certified**

2° course 2009 – 2010 with final exam on April, 17, 2010 in
Catania, in progress
















Telecardiology working group

National Model

Information to the patient regarding the use of remote monitoring system of implanted electronic devices (pacemaker, loop recorder, ICD): purposes, technical aspects, privacy, organizational aspects, patient and clinical staff duties, emergency management.

Patient **informed consent** to the use of remote monitoring system of implanted electronic devices

Reimbursement issues

COUNTRY	<u>In-clinic</u> device check	<u>Remote</u> device check	<u>Remote</u> disease management
Germany 	✓	✓	✓ X
Portugal 	✓	✓	X
Spain 	n/a	n/a	n/a
UK 	✓	✓	X
Netherlands 	✓	✓∞	X
Nordics    	✓	✓∞	X
France 	✓	X	X
Italy 	✓	X	X
Switzerland 	✓	X	X
Belgium 	✓	X	X

Remote Monitoring of implanted devices

Reaction time to the first AF alert

	Median (days)	Interquartile interval (days)	
Median time from the last in-hospital follow-up visit to the detection and the first intervention for AF	50	10	244
Median value of reaction time to AF in advance to the scheduled follow-up	148	75	170

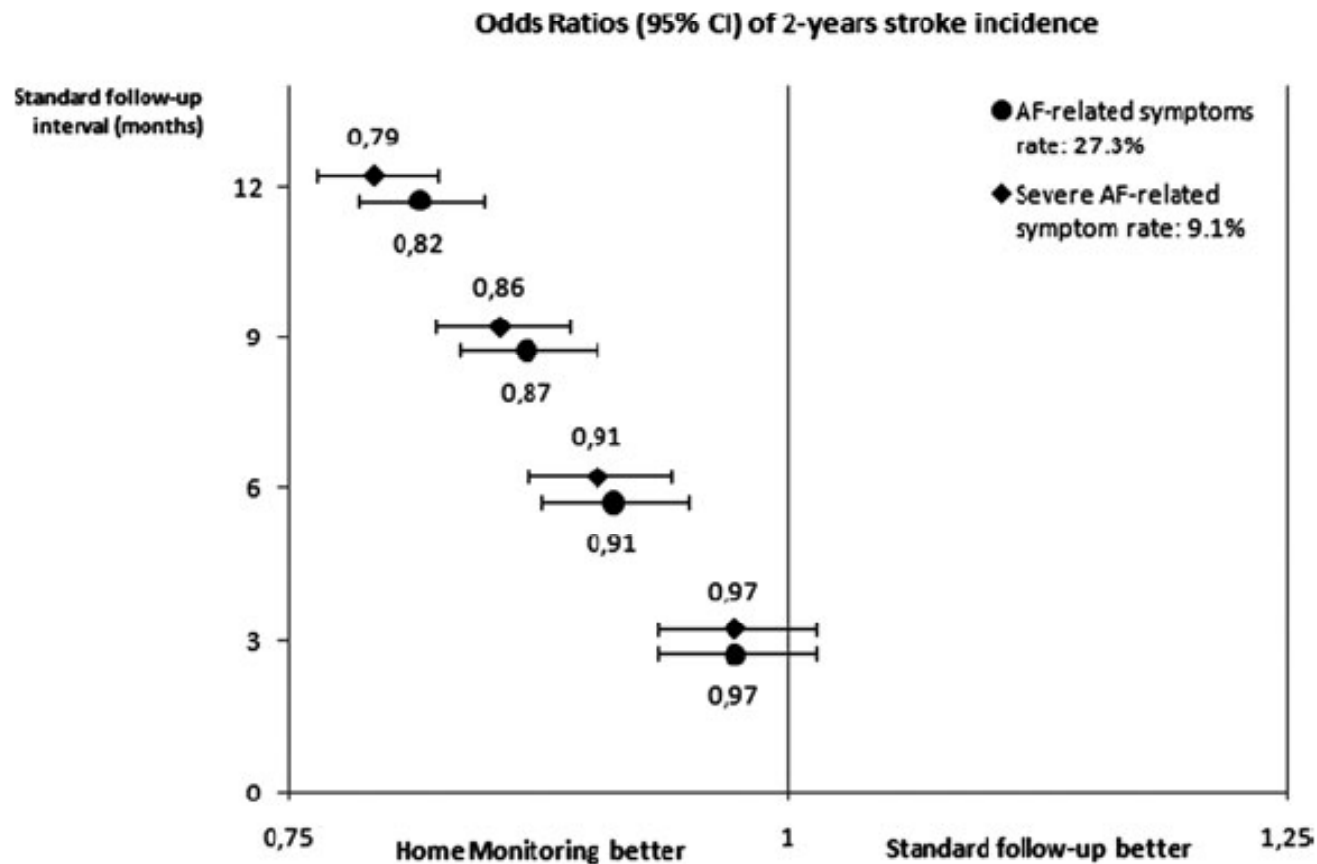
166 pts, follow-up 488 ± 203 days

33 pts (20%) alerts for AF (52% no prior history of AF)

73% asymptomatic, 18% mildly symptomatic 9% severely symptomatic

Home Monitoring in Patients with Implantable Cardiac Devices: Is There a Potential Reduction of Stroke Risk? Results from a Computer Model Tested Through Monte Carlo Simulations

RENATO P. RICCI, M.D.,* LOREDANA MORICHELLI, M.S.N.,* ALESSIO GARGARO, Ph.D.†
MARIA T. LAUDADIO, Ph.D.,† and MASSIMO SANTINI, M.D., F.A.C.C., F.E.S.C.*



(J Cardiovasc Electrophysiol, Vol. 20, pp. 1244-1251, November 2009)

Home Guide Registry

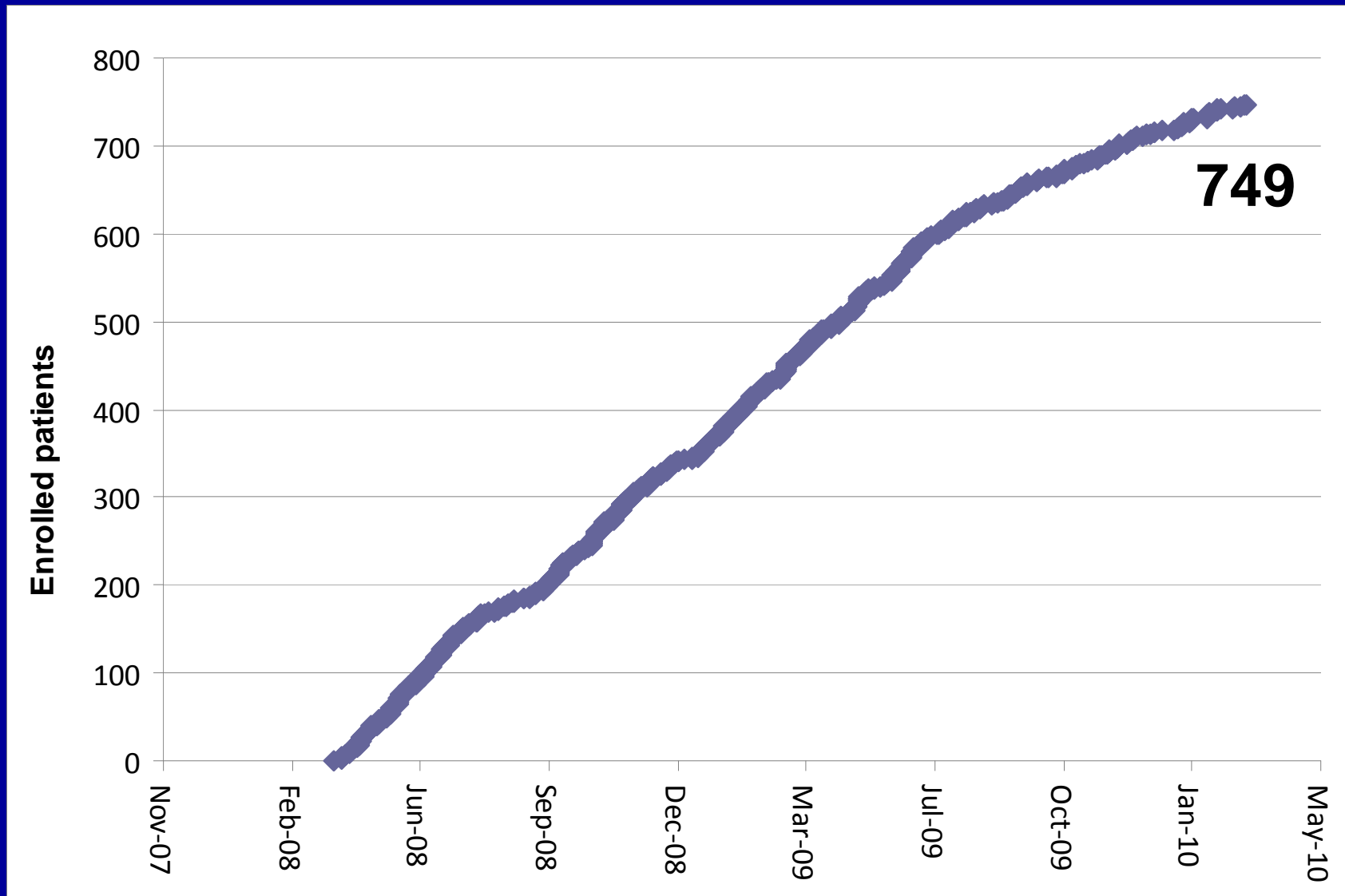
(Biotronik Home Monitoring System)

Objectives of the Registry

To evaluate:

- clinical application of a **New Organizational Model** in standard practice;
- **clinical benefits** obtained through remote control of patients with implanted devices;
- **Health care resource** consumption.

Home Guide Registry enrollment curve



MORE – CARE study

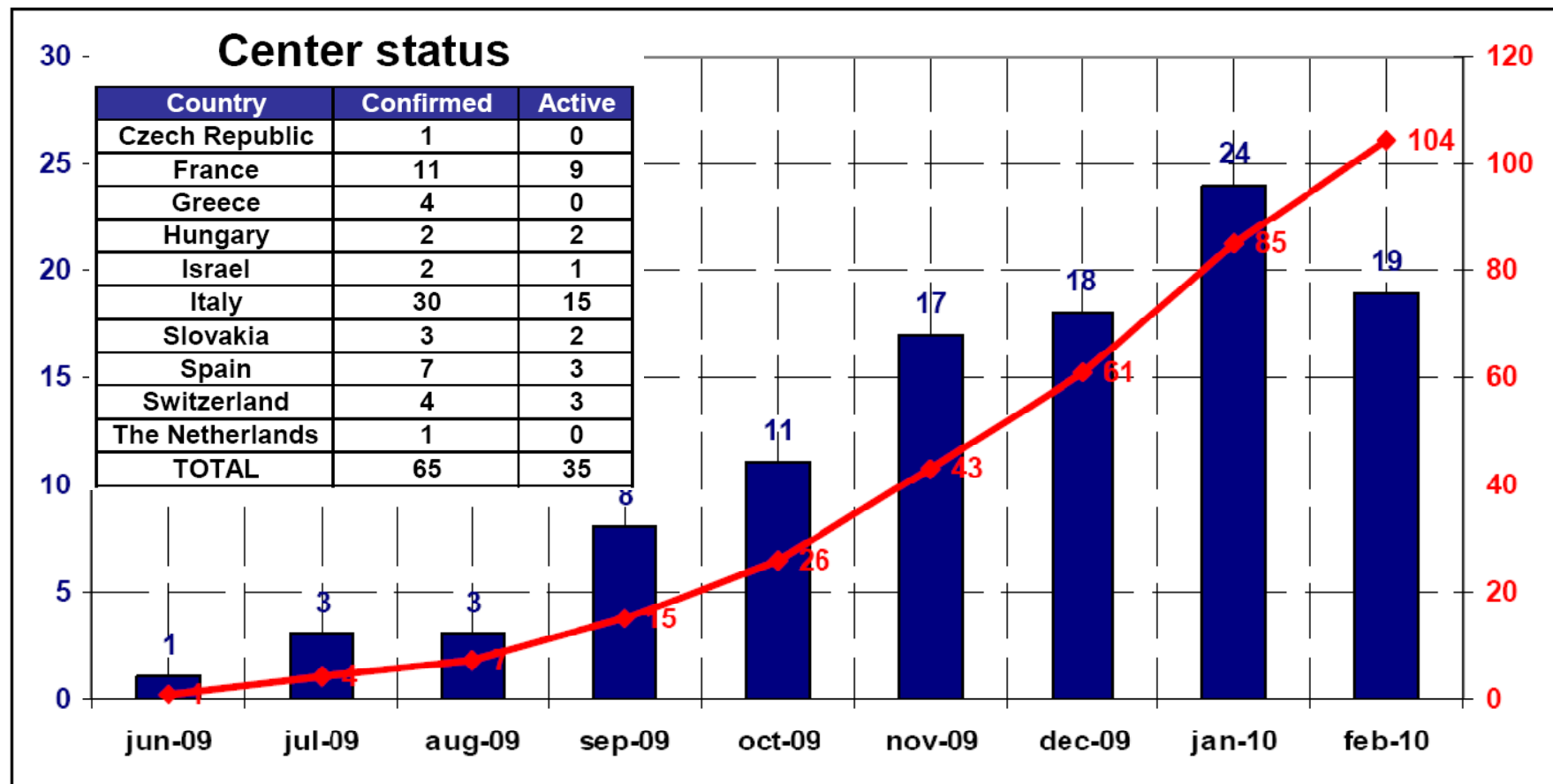
Medtronic Care Link system

The MORE-CARE study is aimed at demonstrating the **superiority of a management strategy of CRT-D patients based on continuous remote monitoring**, with respect to the standard management strategy based only on scheduled in-office visits.

Study Steering Committee: G. Boriani, Bologna, Italy, H. Burri, Genève, Switzerland, A. Da Costa, Saint-Etienne, France, S. Favale, Bari, Italy, J. Kautzner, Prague, Czech Republic, X. Navarro Medtronic Iberica, Spain, A. Quesada, Valencia, Spain, R.P. Ricci, Rome, Italy

MORE – CARE study

Enrollment curve



TARIFF study

Health Economics Evaluation Registry For Remote Followup

Study Purposes

1. To evaluate costs and effects of remote monitoring of ICD by the Merlin@home system when compared with standard in-hospital follow up.
2. To identify through the actually measured overall costs and benefits the appropriate amount of reimbursement for remote monitoring of implanted devices

TARIFF study

Endpoints

- To evaluate the actual costs related to remote monitoring and to standard follow-up during 1-year follow-up from the point of view of:
 - the patient
 - the hospital
 - the National Health Care System.
- To evaluated patient quality of life.

Sample size: 200 patients (100 remote follow-up and 100 standard follow-up. As of March 17, 2010, 21 patients enrolled.