IN-HF Outcome
Italian Network on Heart Failure Outcome

Prospective, non-interventional, multicentric observational study

Study Sponsor and Coordinator:
Heart Care Foundation-Onlus

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Signature page for Study Chairman

Protocol IN-HF Outcome

Approved by:

Luigi Tavazzi, M.D.       Signature
(Chairman)               date

July 17, 2007
Signature page for Principal Investigator

Protocol IN-IHF Outcome

I have read this protocol and agree to conduct this trial in accordance with all stipulations of the protocol and in accordance with the Declaration of Helsinki.

(Principal Investigator) ___________________________  Signature ___________________________  Date ___________________________
# STUDY SYNOPSIS

**Italian Network on Heart Failure (IN-HF) Outcome**

<table>
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<th>Population</th>
<th>Patients with chronic (CHF) and acute heart failure (AHF)</th>
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<tr>
<td>Study design</td>
<td>Prospective, non-interventional, multicentric observational study</td>
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<tr>
<td>Main study objectives</td>
<td>To describe the demographic, clinical, and biological characteristics of patients with CHF and AHF followed by a setting of Italian cardiology centers. To describe the diagnostic and pharmacological/non-pharmacological therapeutic approaches undertaken in the routine practice of cardiologists in following out-patients with CHF and during the hospital phase for AHF. To assess the in-hospital and out-of-hospital outcome of patients with CHF and the prognostic predictors of this outcome.</td>
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<tr>
<td>Study population</td>
<td>Out-patients with CHF diagnosed according to the ESC guidelines and followed-up by the participating cardiology centers. Patients with HF in whom ICD, CRT or both are implanted during the course of the study. Patients admitted for AHF with a history of hypertension and a SBP &gt;160 mmHg and patients admitted for AHF receiving IV inotropes or vasodilators. In all patients admitted for AHF in the participating centers during the 12 month period of study enrollment a simplified form describing the most relevant variables will be collected.</td>
</tr>
<tr>
<td>Enrollment Period</td>
<td>Twelve months for each centre</td>
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<td>Follow-up Period</td>
<td>Twelve months for each patients</td>
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<tr>
<td>Number of sites and location</td>
<td>Approximately 70 Italian Cardiology Centers</td>
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<td>Sample size</td>
<td>Being the study observational, a formal sample size was not calculated. With respect to the different categories of patients the expectations in terms of numerosity are reported below: CHF: approximately 2500-3500 patients AHF: approximately 2500-3000 patients Subgroup of patients with hypertension: approximately 1300-1800 patients Subgroup of patients with implanted devices: approximately 325-550 patients Subgroup of patients admitted for AHF treated with IV inotropes or vasodilators: approximately 1500 patients.</td>
</tr>
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</table>
**Background and rationale**

Chronic Heart Failure (CHF) is associated with a high burden of mortality and morbidity, reduced quality of life and increasing healthcare costs in both US and Europe (1-4). Evidence-based medicine represents the most effective mean of ensuring that patients receive high-quality care and appropriate pharmacological/non-pharmacological management (5, 6).

With the increased prevalence of CHF there is a concomitant increase in the number of related hospitalizations and, as CHF progresses, the risk of acute exacerbation increases. Acute Heart Failure (AHF) is a complex, heterogenous, clinical syndrome characterized by a rapid onset of signs and symptoms secondary to abnormal cardiac function, and it is often life threatening, requiring urgent therapy (7-9). In the United States, a primary diagnosis of AHF accounts for more than one million hospitalizations each year, with similar numbers suggested for Europe (2, 7, 8). Despite significant advances in diagnosis and therapy, patients with AHF continue to have a poor long-term prognosis (9-12). Clinical destabilizations leading to hospitalization are associated with haemodynamic and neuro-hormonal alterations which can contribute to progressive ventricular dysfunction and dilation, mitral regurgitation, increased wall stress, and progressive myocyte loss as a result of apoptosis and necrosis (7).

Registries and surveys have been conducted in patients with either CHF or AHF but a description of the whole clinical story of patients with HF including the acute episodes and the consequent changes in clinical conditions and in the management strategies are not available. A survey able to capture all the relevant clinical information of patients with CHF including their acute episodes of decompensation could allow the improve our knowledge on epidemiology and outcomes of real world patients with this clinical condition.

**Study Design and Methods**

The IN-HF Outcome is a prospective, multicentric, observational study of patients presenting to about 70 Cardiology Centers in Italy. Site selection will target a mix of academic and community hospitals from which patients will be recruited, with a focus of capturing a broad spectrum of cardiology and HF specialty clinics regularly following patients with CHF and admitting them in case of AHF.

For this specific Survey of the IN-HF Registry, patients will be enrolled for 12 months and followed up for 1 year. Outpatients visit will be performed at 3, 6 and 12 months after the entry visit.

The primary objective of the IN-HF Outcome is to describe the clinical epidemiology of patients with CHF and/or AHF. For patients already enrolled in the IN-HF Registry, time zero for the Survey is the date at the visit/hospital admission occurring for the first time during the enrollment period. For patients never enrolled in the registry time zero is the date of the first visit/hospital admission.

Standard management of patients will be the diagnostic and therapeutic interventions currently performed at each center for patients presenting with signs and symptoms of CHF/AHF. Drug prescriptions and the indications to perform diagnostic/therapeutic procedures will be completely
left to the decisions of the participating cardiologists. No specific protocols, or recommendations for evaluation, management, and/or treatment will be put forth during this observational study. Current guidelines for the management of CHF/AHF will be discussed during the Investigator meeting and doctors, participating in the Survey, will be strongly invited to be adherent to them. In this context, the following topics have been considered as particularly relevant for assuring an adequate care of the patients:
- completeness of neuro-hormonal therapy;
- timing and doses of i.v. drug treatments during the acute HF phases
- appropriate indication for device implantation;
- a documented etiologic definition.

Specific aims of the study
- To describe the demographic, clinical, and biological characteristics of patients with CHF and AHF followed by a setting of Italian cardiology centers;
- to investigate the factors precipitating acute clinical destabilization in a known profile of CHF (already included as such in the data-base);
- to describe the diagnostic and therapeutic approaches undertaken in the routine practice of cardiologists in following out-patients with CHF and during the hospital phase for AHF;
- to assess the in-hospital and out-of-hospital outcome of patients with CHF and the prognostic predictors of this outcome;
- to evaluate how the recommendations of the most recent international guidelines regarding new pharmacological (ARBs) and non-pharmacological (ICD, CRT, or both) treatments are adopted in clinical practice and how their application can impact on patient outcomes (mainly hospitalization for AHF);
- to evaluate the prevalence of specific clinical profiles according to the definitions proposed by the major international cardiac Societies, in particular the European Society of Cardiology (8, 13);
- to encourage the continuity of care of patients with CHF/AHF;
- to evaluate the clinical epidemiology and the outcomes of specific cohorts of patients:
  • patients with HF implanted with devices (ICD, CRT, or both);
  • patients with CHF and a history of hypertension and those acutely admitted to hospital with a story of hypertension and a SBP at entry >160 mmHg;
  • patients admitted for AHF receiving IV inotropes or vasodilators.

Selection of study population
All patients with CHF and those admitted for AHF to participating centers during the enrollment period.

Chronic Heart Failure
All out-patients with CHF diagnosed according to the ESC guidelines and followed-up by the participating cardiology centers will be entered in the Survey.
There are no specific exclusion criteria, with the exception of age that should be higher than 18 years.

**Acute Heart Failure**

Patients admitted to hospital for AHF in NYHA class III or IV, or with pulmonary edema or cardiogenic shock, for whom an IV therapy (inotropes, vasodilators or diuretics) is needed.

**Specific subpopulations of the study**

Subpopulations of HF patients will be specifically focused with larger and more detailed data collection:

- patients with chronic HF in whom an ICD, a CRT or both are implanted during the course of the study in the participating centers will enter in the IN-HF Outcome;
- patients with acute HF and history of hypertension and SBP at entry >160 mmHg follow-up visits will be required;
- patients with acute HF receiving IV inotropic agents or vasodilators.

No data will be collected before detailed information is given to the patient and a signed informed consent is obtained.

**Follow-up visits**

The patients with AHF treated with IV inotropes and those admitted for hypertensive HF will followed-up at 3, 6 and 12 months. After discharge, all the other patients admitted for AHF will be visited once after 12 months from study inclusion. All patients with CHF (including those with implanted device) will be followed-up for 1 year with clinical visits at 3, 6 and 12 months (see Appendix A).

**Data collection**

Data will be collected using a web based system (HCF-SCOL).

**Enrollment data:**

- In all patients admitted for AHF in the participating cardiology centers during the 12 month period of study enrollment a simplified form describing the most relevant variables will be collected. A more extensive form will be filled only in the cases of admission for AHF in patients with a story of hypertension and SBP at entry >160 mmHg and in those who needed a treatment with IV inotropes or vasodilators.
- In all patients with CHF enrolled as out-patients (including those with an ICD or a CRT or both implanted) the out-patient form will be filled.

The following information will be captured for each enrolled patient:

- demographic characteristics
- risk factors for cardiovascular diseases
- comorbidities
- precipitating factors of acute HF
- clinical signs and symptoms
- biohumoral profiles
- use of pharmacological treatments
- use of non pharmacological treatments

use of invasive/non invasive diagnostic procedures

Follow-up data:
Out-patient visits at 3, 6 and 12 months will be scheduled for all out-patients (including those with ICD/CRT or both implanted) and for patients admitted for AHF with a history of hypertension and SBP >160 mmHg and in those admitted for AHF treated with IV inotropes or vasodilators. For all the other patients admitted for AHF, just one visit at 12 months will be scheduled.
For enrolled patients admitted in a different hospital during follow up, a simplified form will be filled.

Specific warnings will be implemented in the software in order to recall the recommendations of recent guidelines regarding:
- the triple neuro-hormonal therapy (ACE-inhibitors, beta-blockers in association with ARBs or aldosterone blockers);
- ICD, CRT, or both;
- evaluation of the status of the coronary arteries (through coronary angiography or CT scan) in patients with HF in whom primary dilated cardiomyopathy is considered the main etiology but only on clinical ground.

Statistical considerations and sample size
All patients enrolled will be included in the analysis. Since this is an observational study, descriptive summaries will be presented for all the patients, and for subgroups of patients. Statistical tests may be carried out for exploratory purposes, as appropriate. Multivariable analysis may be used to explore relationship between baseline covariates and post-baseline endpoints, as appropriate.

Being the study fully observational, a formal sample size was not calculated.
With respect to the different categories of patients the expectations in terms of numerosity are reported below.

**CHF**: each participating center is expected to admit a minimum of 50 consecutive and unselected patients. The study population will be composed by 2500-3500 patients, in whom nearly 500-700 hospital admission for AHF will occur during the year of follow-up.

**AHF**: over the same study period (1 year), it is estimated that nearly 2500-3000 hospital admissions for AHF will occur in the same 50-70 participating centers.

**Subgroup of patients with hypertension**: by the analyses of the data of Italian available registries, we assume that nearly 1/3 of the patients with CHF has a story of hypertension and 20% of those with AHF has both a story of hypertension and a SBP >160 mmHg at hospital entry. Therefore, this subgroup of patients should be composed by an approximate number of 1300-1800 patients.

**Subgroup of patients with implanted devices**: among enrolled patients with CHF, from 125 to 250 patients should have already an implanted device. In a real world setting, other 200-300 patients
should be newly implanted with a device over a period of 1 year. Overall, the numerosity of this subgroup should be around 325-550 patients.

Subgroup of patients admitted for AHF treated with IV inotropes or vasodilators: according to the estimates performed on available Italian registries, we assume that approximately 1500 with these characteristics will be enrolled.

The sample of the whole population of out-patients with CHF, that of the specific cohorts of patients (those with a story of hypertension, those with AHF receiving IV inotropes or vasodilators and those with newly implanted devices) should allow a reliable evaluation of the clinical epidemiology, use of resources and outcomes of real world patients with HF.

**Logistics, property of the database, publication policy**

The study promoter is Heart Care Foundation (HCF), that will be in charge of study management from the procedure regarding local IRB authorization to data collection analysis and publication. The coordination of the study, the collection of data and their analysis will be performed by the ANMCO Research Center under the responsibility of the Steering Committee of the study.

The coordination of the study, the collection of data and their analysis will be under the complete responsibility of the Steering Committee of the study.

Young doctors (1 for 5-7 participating centers) will help the participating cardiologists in filling the web-based forms, scheduling the follow-up visits, managing potential queries and logistic problems occurring during the study.

Data will be published under the responsibility of the Steering Committee of the study. Requests for further analyses to support ancillary publications must be submitted to the IN-HF Outcome Steering Committee for review and approval. Any publication of data collected as a result of this study will be considered a joint publication by the investigator, Steering Committee members and personnel of the Coordinating Center. Authorship will be determined by mutual agreement. Contribution of the author to the study design, enrollment, data review, and manuscript preparation and review will be considered when determining the order of authorship. The ANMCO Coordinating Center must receive a copy of any presentation, manuscript, or abstract prior to dissemination according to the terms outlined in the IN-HF Outcome protocol.

**Participating centers and ethical issues**

Data will be collected by nearly 70 Italian Cardiology centers.

The protocol will be submitted to the local Italian IRBs for specific approval. Patients to be entered in the Survey must sign an informed consent for data collection and centralization and availability to be periodically visited during the follow-up period.

Each site is required to obtain the necessary regulatory, safety, and ethical approvals prior to enrolling patients. A copy of these approvals must be forwarded to the Coordinating Center for regulatory purposes.

**Informed consent:**
In accordance with individual local and national subject privacy regulations, the investigator or designee must explain to each subject prior to enrollment that the subject’s private health information, in an anonymous form, obtained during the study may be shared with the Coordinating Center and its designees and regulatory agencies.

As the study sponsor, Heart Care Foundation will not use the subject’s private health information or disclose it to a third party without applicable subject authorization. It is the investigator’s or designee’s responsibility to obtain written permission to use private health information from each subject. If a subject withdraws from the study, it is the investigator’s responsibility to obtain a written request from the subject and to ensure that no further data will be collected from the subject. Any data collected on the subject prior to withdrawal will be used in the analysis of study results.

Protection of Human Subjects:
IN-HF Outcome is an observational study that does not dictate the manner in which patients are evaluated or treated for AHF/CHF. Physicians may choose to evaluate and manage AHF/CHF in any way they choose according to the local standard of care. Patients are not randomized in any way and the principal risk to patients is that of confidentiality. Patient data collected will be strictly anonymous. Only a code, gender, date of birth will identify patients. No other patient identifiers will be collected. In order to maintain strict security, each investigator/study personnel will have a unique login and password to enter patient’s information. There will be no storage of clinical data outside of the data collection instrument, which will be a secure, web-based form. The main database will be secured according to current standards to ensure both ethical and integrity requirements of the data.

Expected results of the study
The adoption in the real world of care of the recommendations of current guidelines will be monitored together with the evaluation of its impact on the need for hospitalization for AHF.
A whole comprehensive description of the clinical epidemiology of patients with CHF or AHF or both will be available in a representative setting of clinical centers dealing with this clinical condition in routine clinical practice.
The description of the epidemiology of the avoidable causes of hospital admissions for AHF can provide useful information for the implementation of specific programs aimed to reduce hospitalizations and the related costs and to improve patient outcomes.
A detailed analysis of the clinical characteristics, evolution and outcome of a specific cohort of hypertensive patients (with and without a recent acute decompensation) may allow to gain insights into the still debated issue of the transition towards HF of the hypertensive cardiac disease.
The clinical epidemiology of patients admitted for severe AHF (defined as those who need an IV treatment with vasodilators or inotropes) will be available. A detailed description of the use of resources in these patients, for whom the management strategies are still under discussion, will be provided.
The still huge gap between the guidelines recommendations on the use of cardiac devices and the clinical practice will be interpreted (on the base of reasons reported for not meeting the warnings) and the process of guidelines incorporation will be monitored.

**Steering Committee**
A Steering Committee chaired by Professor Luigi Tavazzi and composed by designed members of the ANMCO Working Group on HF will be appointed to help with the development of the study documents, assist in the implementation and the conduct of the Survey, as well as the analysis/interpretation of the data and the main publication of the results.

**Timelines**
Study set-up activities: January 2007-July 2007
Enrollment of patients: September 2007 - September 2008
End of follow-up: September 2009
Analysis of data: January-June 2010
References

1. Académie Nationale de Médecine, January 2002
4. German Association for Cardiology and Cardiovascular Research, 2004
Appendix A. Study flow-chart

Enrolled patients

- All CHF patients
- All AHF patients
  - With Hypertension* or Treated with IV inotropes or vasodilators
  - Other AHF patients

Follow-up

Clinic visit at 3, 6, 12 months

Follow-up

Clinic visit at 12 months

* History of hypertension and SBP > 160 mmHg
Titolo dello studio: **IN-HF on line e IN-HF Outcome**

Centro N°: ………………………………  Paz. N° …………………

Lo scompenso cardiaco costituisce una delle cause principali di mortalità e di ricovero ospedaliero nei paesi occidentali. Lo scompenso è una condizione clinica dovuta a malattie cardiovascolari diverse ed è caratterizzato dalle frequenti instabilizzazioni con peggioramento dei sintomi e necessità di aggiustamenti terapeutici.

Allo scopo di migliorare le conoscenze sulle modalità di diagnosi e di trattamento dei pazienti che, come Lei, sono affetti da scompenso cardiaco, la Fondazione Italiana per la lotta alle Malattie Cardiovascolari ha deciso di costituire un registro permanente (denominato IN-HF on line) che descriva le caratteristiche cliniche, le procedure diagnostiche, i trattamenti ed il decorso clinico dei pazienti con questa patologia. Nell’ambito di questo registro è stato poi pianificato uno studio denominato IN-HF Outcome che prevede delle visite periodiche di controllo che possono essere una (12 mesi) o tre (3, 6, 12 mesi) a seconda della sua patologia. Questo progetto ci consentirà di valutare l’incidenza degli eventi cardiovascolari nei pazienti con scompenso cardiaco.

In questo contesto le chiediamo unicamente il suo consenso al trattamento dei dati personali, in quanto la partecipazione a questo progetto non prevede nessuna particolare procedura diagnostica e terapeutica che non sia quella decisa dal suo cardiologo curante.

Io sottoscritto/a (nome e cognome in stampatello )……………………………………
……………………………………………………………………………………………
ai sensi del D.Lgs. n. 196/2003, autorizzo la Fondazione Italiana per la lotta alle Malattie Cardiovascolari, sponsor di questo studio, a sottoporre a trattamento (nel senso specificato dalla legge) i dati personali che mi riguardano, raccolti, per incarico dello sponsor, dallo sperimentatore, in quanto necessari alla mia partecipazione al registro in oggetto.

In particolare autorizzo lo sponsor a:

- Trattare, oltre ai dati comuni, anche i miei dati personali così detti sensibili (cioè idonei a rilevare il mio stato di salute);
- A diffondere i miei dati personali, anche sensibili, resi anonimi, nei limiti indicati nella nota informativa al punto c).

Dichiaro che mi sono state preventivamente fornite, al momento iniziale della raccolta dati, le prescritte informazioni circa le caratteristiche, le finalità e le modalità del trattamento dei dati personali, esplicate per iscritto nel documento allegato (nota informativa al paziente in tutela della riservatezza dei propri dati personali).

Firma ___________________________________ Data ____________________
Nota informativa al paziente in tutela della riservatezza
dei propri dati personali

Protezione dei dati personali

Ogni informazione, dato personale che La riguardi ed il cui trattamento risulti connesso e indispensabile alla Sua partecipazione al presente studio clinico, sarà trattato dallo sponsor con modalità idonee a garantire l’assoluta riservatezza, confidenzialità e sicurezza degli stessi, in conformità alle norme di buona pratica clinica (decreto Ministero della Sanità 15 luglio 1997) nonché a quelle per la tutela delle persone e di altri soggetti rispetto al trattamento di dati personali (D.Lgs. 30 giugno 2003, n. 196 e successive modifiche e integrazioni).

In particolare, ai sensi e per gli effetti dell’art. 23, comma 1, del D.Lgs. n. 196/2003, Le chiediamo di tener conto di quanto nel seguito esplicitato.

a) Finalità e modalità dei trattamenti

I Suoi dati personali, oggetto di trattamento da parte dello sponsor di questo studio saranno costituiti dai dati comuni, le generalità (cognome e nome) e le informazioni anagrafiche (indirizzo e telefono) che proprio in connessione alle esigenze di assoluta riservatezza, confidenzialità e sicurezza sopra menzionate saranno criptate nel database dello studio, oltre ai dati sensibili, vale a dire i dati clinici e comunque idonei a rivelare il suo stato di salute. Detti dati raccolti presso di Lei o per Suo tramite dallo sperimentatore, su incarico dello sponsor, saranno da quest’ultimo registrati, elaborati, gestiti e archiviati – in forma cartacea, automatizzata e/o informatizzata – per le esclusive finalità connesse all’espletamento delle varie vasi del presente studio clinico e, in particolare, al fine di verificare lo stato di avanzamento dello stesso. I dati personali saranno successivamente soggetti ad elaborazione statistica, e quindi, trasformati in forma totalmente anonima e, in questa forma, eventualmente inseriti in pubblicazioni e/o presentati in congressi, convegni e seminarini a carattere scientifico.

b) Natura obbligatoria o facoltativa dei dati e conseguenze di un eventuale rifiuto di fornire i dati

Il consenso al trattamento dei suoi dati personali come sopra descritti, pur avendo natura facoltativa, risulta indispensabile ai fini dell’espletamento del presente studio clinico nonché per l’adempimento dei connessi obblighi di legge. In assenza di detto conferimento, lo sponsor non potrà effettuare lo studio con la Sua partecipazione.

c) Ambito di comunicazione e di diffusione

I dati personali non saranno resi accessibili e disponibili a terzi, fatta eccezione della comunicazione alle Autorità sanitarie, richiesta ai sensi di legge; dette Autorità potranno, altresì, richiedere di verificare la Sua cartella clinica, con lo scopo di valutare la correttezza dei dati raccolti e con modalità tali da garantire la riservatezza e la confidenzialità dei dati.

L’eventuale diffusione dei dati, per il tramite di pubblicazioni scientifiche e/o di presentazione in congressi, convegni e seminarini, avverrà esclusivamente a seguito di un’elaborazione meramente statistica degli stessi e, quindi, in forma assolutamente anonima.

d) Diritti dell’interessato ai sensi dell’art. 7, D.Lgs. n. 196/2003

In qualità di interessato al trattamento dei dati personali (come definito dall’art. 4, comma 1, lettera i), Lei potrà in qualunque momento avvalersi della facoltà e dei diritti a Lei attribuiti ai sensi dell’art. 7, D.Lgs. n. 196/2003 e più precisamente:

- potrà accedere al Registro generale dei trattamenti gestito dal Garante per la protezione dei dati personali;
- potrà essere informato in merito a quanto concerne:
  1. l’origine dei dati personali;
  2. le finalità e le modalità del trattamento;
  3. la logica applicata in caso di trattamento effettuato con l’ausilio di strumenti elettronici;
  4. gli estremi identificativi del titolare, dei responsabili e del rappresentante designato ai sensi dell’articolo 5, comma 2 del D.Lgs. n. 196/2003;
  5. i soggetti o le categorie di soggetti ai quali i dati personali possono essere comunicati o che possono venire a conoscenza in qualità di rappresentante designato nel territorio dello Stato, di responsabili o incaricati.
- potrà ottenere, a cura del Titolare o del Responsabile del trattamento, senza ritardo:
  1. la conferma dell’esistenza e la comunicazione in forma comprensibile di dati personali che La riguardano, anche se non ancora registrati, e la loro comunicazione in forma intelligibile;
  2. la cancellazione, la trasformazione in forma anonima o il blocco dei dati trattati in violazione della legge, compresi quelli di cui non è necessaria la conservazione in relazione agli scopi per i quali i dati sono stati raccolti o successivamente trattati;
  3. l’aggiornamento, la rettifica e, quando vi ha interesse, l’integrazione dei dati;
  4. l’attestazione che le operazioni di cui numeri 2 e 3 sono state portate a conoscenza anche per quanto riguarda il loro contenuto, di coloro ai quali i dati sono stati comunicati o diffusi, eccettuato il caso in cui tale
adempimento si rivela impossibile o comporta un impiego di mezzi manifestamente sproporzionato rispetto al diritto tutelato;

- potrà opporsi, in tutto o in parte:
  5. per motivi legittimi al trattamento dei dati personali che lo riguardano, ancorché pertinenti allo scopo della raccolta;
  6. al trattamento di dati personali che lo riguardano a fini di invio di materiale pubblicitario o di vendita diretta o per il compimento di ricerche di mercato o di comunicazione commerciale.

e) Titolare e Responsabile
Il Titolare del trattamento dei Suoi dati personali è la Fondazione Italiana per la lotta alle Malattie Cardiovascolari, sponsor di questo studio, con sede in via La Marmora, 36 a Firenze, legalmente rappresentata dal suo rappresentante legale. I Responsabili del trattamento sono:
per IN-HF on line il Direttore del Centro Studi ANMCO della Fondazione Italiana per la lotta alle Malattie Cardiovascolari domiciliato per la funzione presso lo sponsor nonché lo sperimentatore presso l’ospedale;
per IN-HF Outcome il Prof. Luigi Tavazzi, Chairman dello studio, domiciliato per la funzione presso lo sponsor, nonché lo sperimentatore presso l’ospedale.