

**Heart Failure Long-Term
Registry
Executive Committee
Steering Committee
Investigators
meetings**

September 1, 2013



**EUROPEAN
SOCIETY OF
CARDIOLOGY®**

Agenda

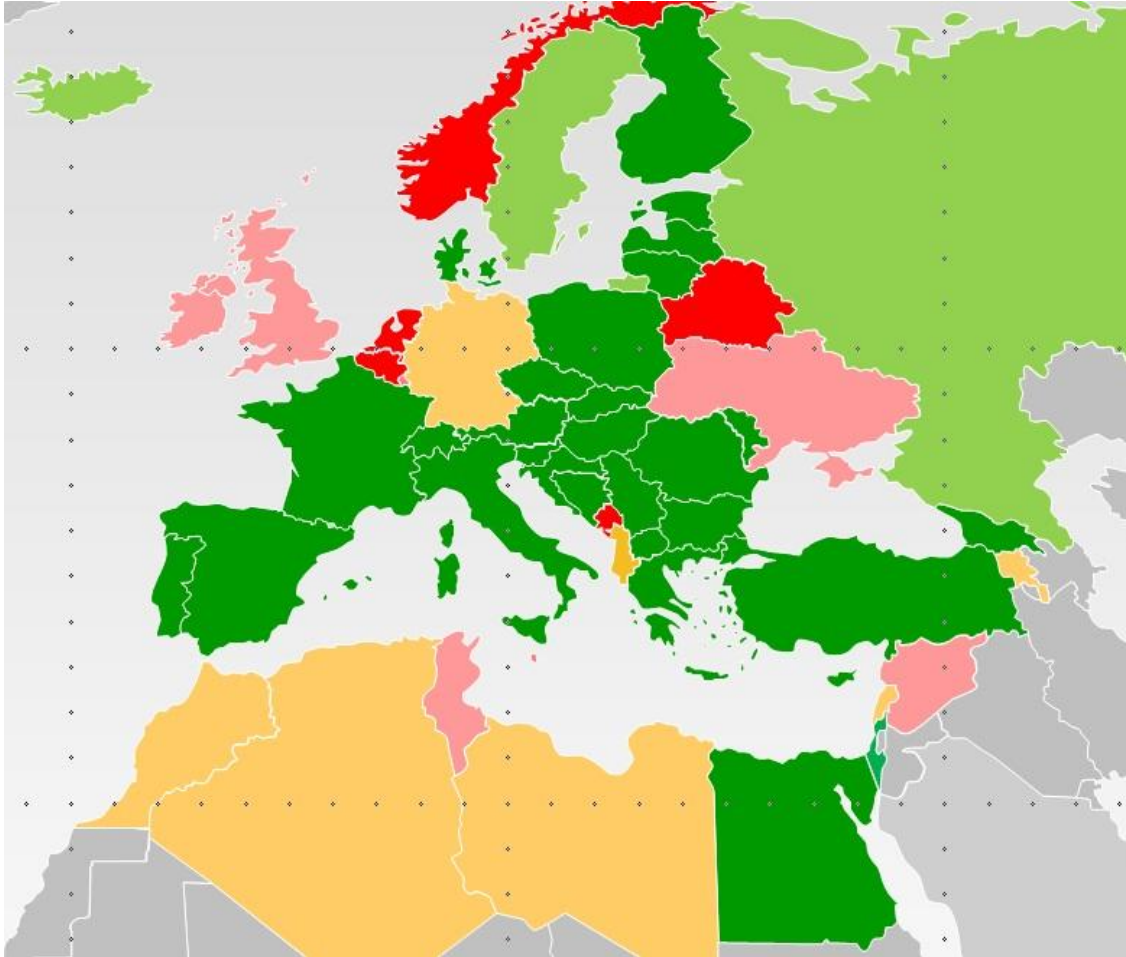
- **Update of recruitment**
- **Presentation/Publication at the ESC Congress**
 - Population
 - Main topic
 - Further analyses
- **New Executive Committee**
- **Update of protocol and CRF**

Agenda

- **Update of recruitment**

Heart Failure Long-Term Registry

Participating countries as of August 19th, 2013



32 Potential participants (ESC):

- 29 started enrolment
- 3 accepted to merge National database (Sweden, Iceland, Russia)

8 Expressed interested
but did not confirm or start

8 Did not answer (Ireland, Luxembourg, Malta, San Marino, Syria, Tunisia, Ukraine, UK)

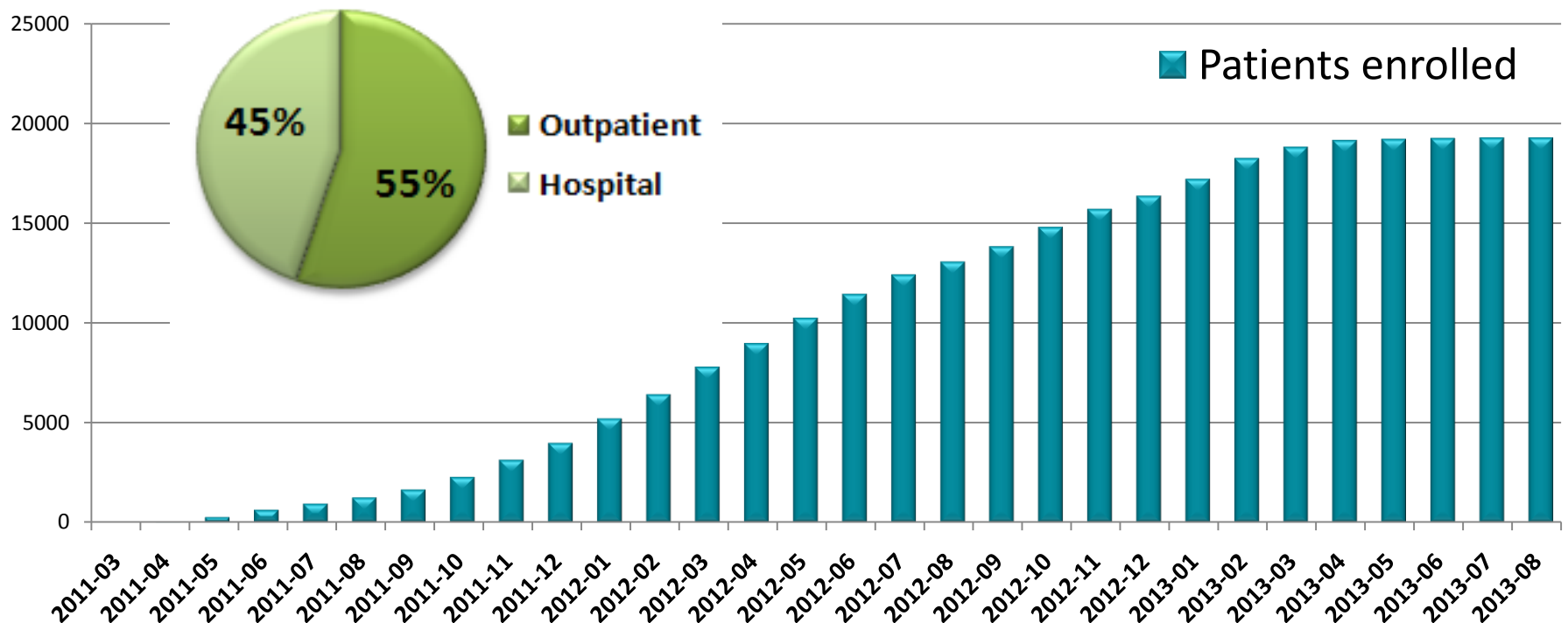
5 Did not accept (Belarus, Belgium, Montenegro, Netherlands, Norway)

+ Participation of:
Affiliated Countries: Argentina, Uruguay
Asian Pacific Society of Cardiology

Heart Failure Long-Term Registry

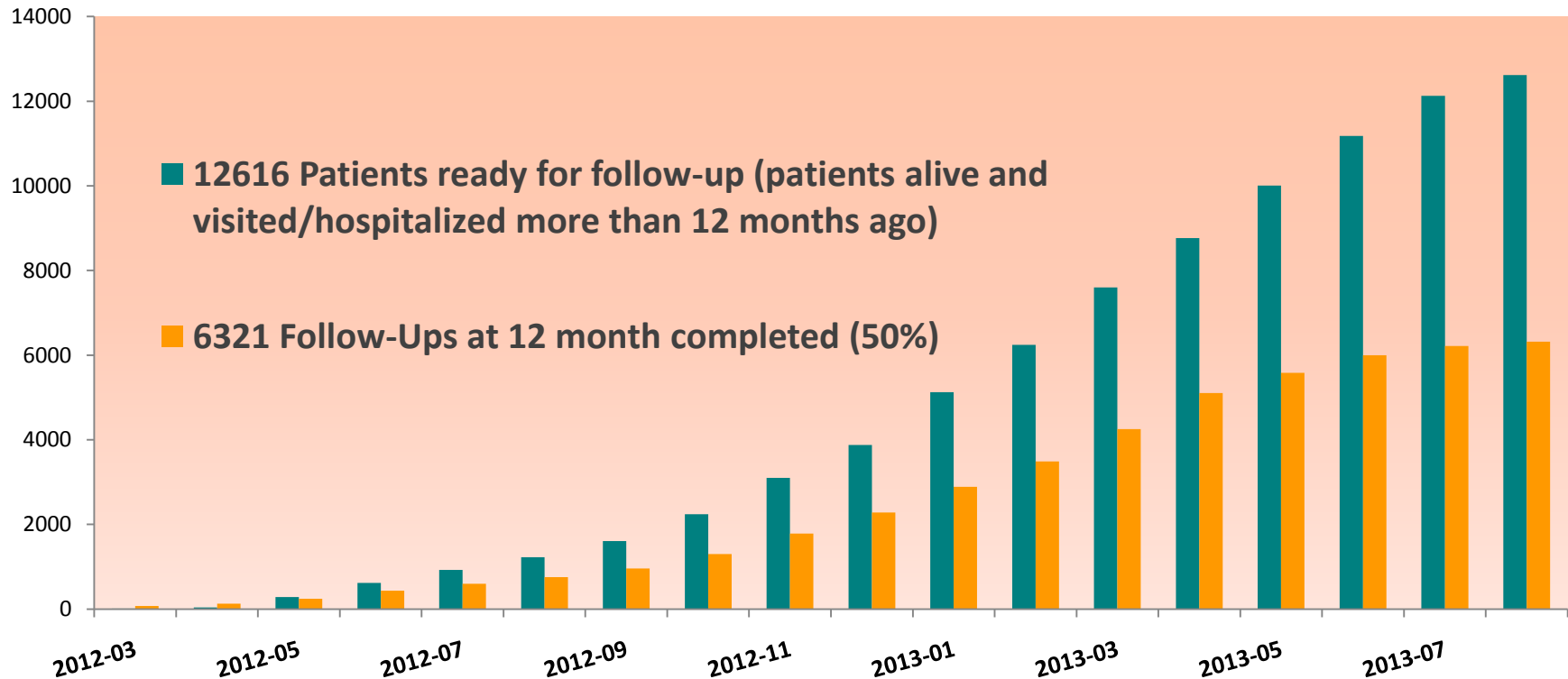
Recruitment by month as of August 19th, 2013

19,241 patients enrolled



Heart Failure Long-Term Registry

Follow Up at 12 months as of August 19th, 2013

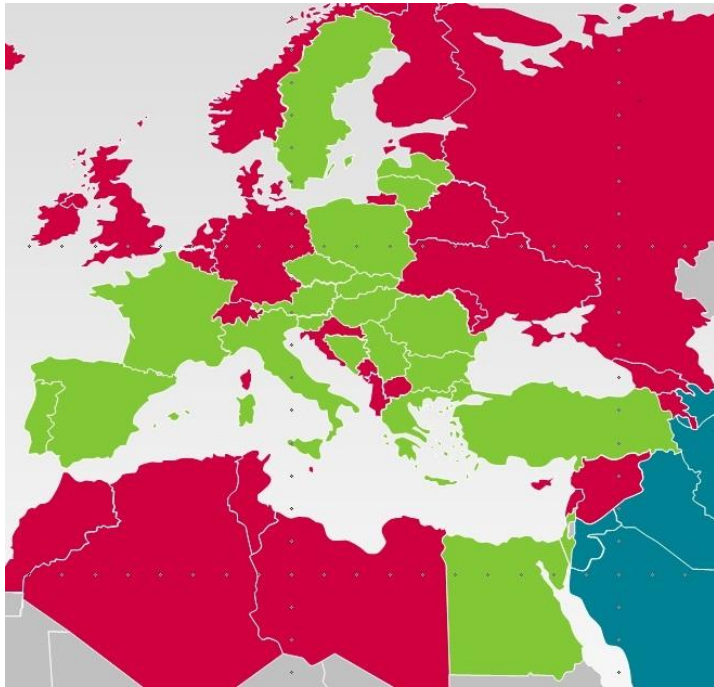


- High rate of Follow Up data (at least 95%) is crucial for meaningful statistical analysis
- Follow-Up is easy and fast to populate (only 1 page, less than 5 minutes per patient)
- We are counting on your collaboration for this important aspect of the registry

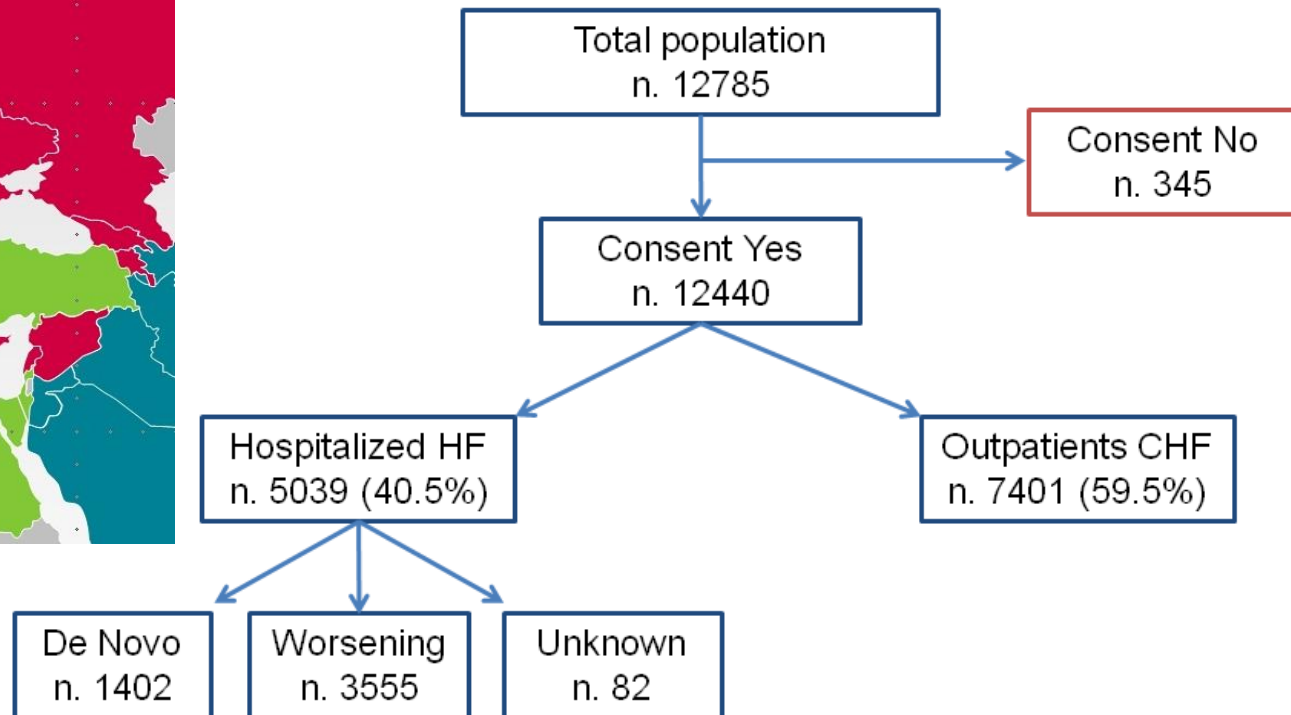
Agenda

- Update of recruitment
- **Presentation/Publication at the ESC Congress**
 - Population

12,440 patients from 211 centres of 21 ESC Countries



Patient disposition



Geographic areas and patients

Areas	Total (n. 12440)	HHF (n. 5039)	CHF (n. 7401)
Eastern, n. (%)	2922 (23.5)	1587 (31.5)	1335 (18.0)
Northern, n. (%)	821 (6.6)	386 (7.7)	435 (5.9)
Southern, n. (%)	5807 (46.7)	1486 (29.5)	4321 (58.4)
Western, n. (%)	810 (6.5)	257 (5.1)	553 (7.5)
North Africa, n. (%)	1613 (13.0)	1145 (22.7)	468 (6.3)
Middle East, n. (%)	467 (3.7)	178 (3.5)	289 (3.9)

Eastern: Bulgaria, Czech Republic, Hungary, Poland, Romania, Slovakia

Northern: Latvia, Lithuania, Sweden

Southern: Bosnia Erzegovina, Greece, Italy, Portugal, Serbia, Slovenia, Spain, Turkey

Western: Austria, France

North Africa: Egypt

Middle East: Israel

HF LT Registry: Baseline characteristics

	HHF (n. 5039)	CHF (n. 7401)	p
Age (years), median [IQR]	71 [61-79]	66 [57-75]	<0.0001
≥75 years, %	39.5	26.0	<0.0001
Females, %	37.3	28.8	<0.0001
SBP (mmHg), median [IQR]	130 [110-150]	120 [110-136]	<0.0001
HR ≥70 bpm, %	83.0	55.6	<0.0001
EF >45%, %	32.8	23.1	<0.0001
Mitral regurgitation, %	44.4	26.2	<0.0001
Ischaemic aetiology, %	54.0	43.0	<0.0001

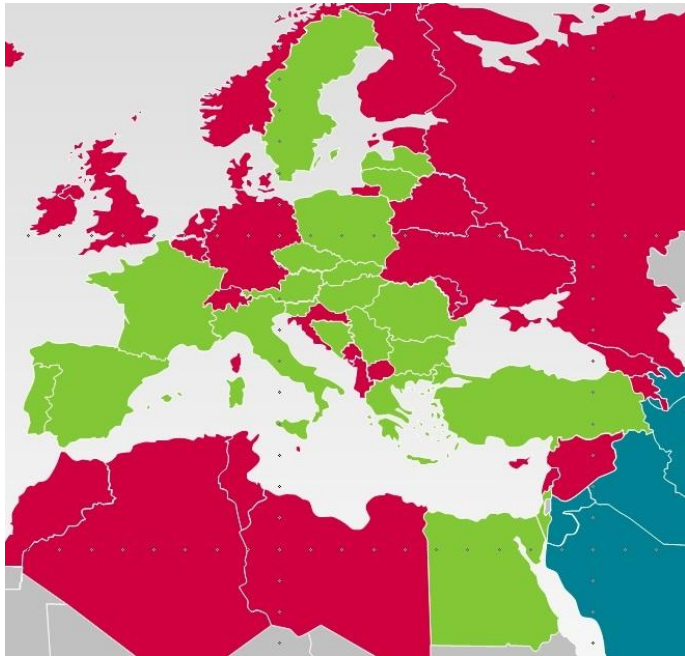
HF LT Registry: Comorbidities

	HHF (n. 5039)	CHF (n. 7401)	p
Atrial fibrillation, %	44.0	37.6	<0.0001
Diabetes mellitus, %	38.9	31.8	<0.0001
PAD, %	14.2	12.3	0.0021
Hypertension, %	64.5	58.2	<0.0001
COPD, %	20.2	13.8	<0.0001
Prior stroke/TIA, %	13.0	9.4	<0.0001
Renal dysfunction, %	26.4	18.2	<0.0001
Hepatic dysfunction, %	8.4	3.4	<0.0001
Depression, %	7.9	7.6	0.553

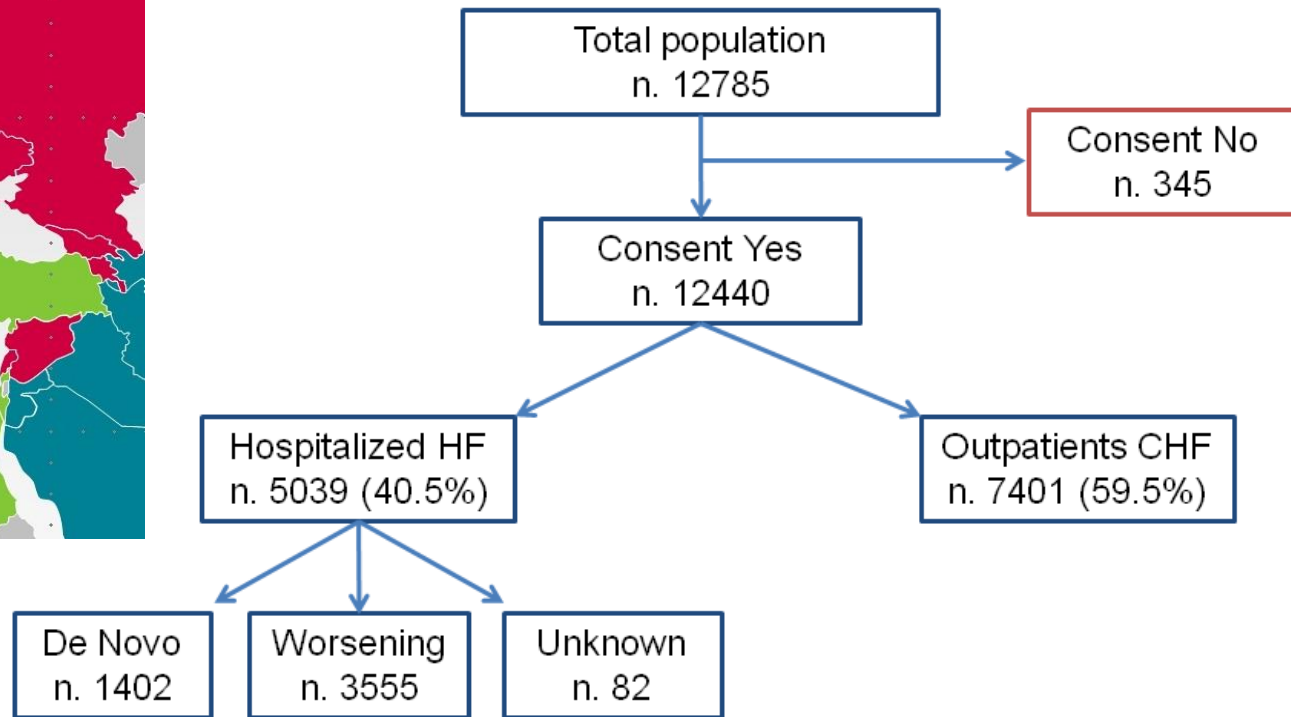
Agenda

- Update of recruitment
- **Presentation/Publication at the ESC Congress**
 - Population
 - Main topics

12,440 pts from 211 centres of 21 ESC Countries



Patient disposition



Aim: To evaluate how recommendations of European guidelines regarding pharmacological and non-pharmacological treatments for HF are adopted in clinical practice



Are hospitalized or ambulatory patients with heart failure treated in accordance with European Society of Cardiology guidelines? Evidence from 12 440 patients of the ESC Heart Failure Long-Term Registry

Aldo P. Maggioni^{1*}, Stefan D. Anker², Ulf Dahlström³, Gerasimos Filippatos⁴, Piotr Ponikowski⁵, Faiez Zannad⁶, Offer Amir⁷, Ovidiu Chioncel⁸, Marisa Crespo Leiro⁹, Jaroslaw Drozd¹⁰, Andrejs Erglis¹¹, Emir Fazlibegovic¹², Candida Fonseca¹³, Friedrich Fruhwald¹⁴, Plamen Gatzov¹⁵, Eva Goncalvesova¹⁶, Mahmoud Hassanein¹⁷, Jaromir Hradec¹⁸, Ausra Kavoliuniene¹⁹, Mitja Lainscak²⁰, Damien Logeart²¹, Bela Merkely²², Marco Metra²³, Hans Persson²⁴, Petar Seferovic²⁵, Ahmet Temizhan²⁶, Dimitris Tousoulis²⁷, and Luigi Tavazzi²⁸ on behalf of the Heart Failure Association of the ESC (HFA)[†]

Intravenous and oral treatments of hospitalized HF patients (n. 5039)

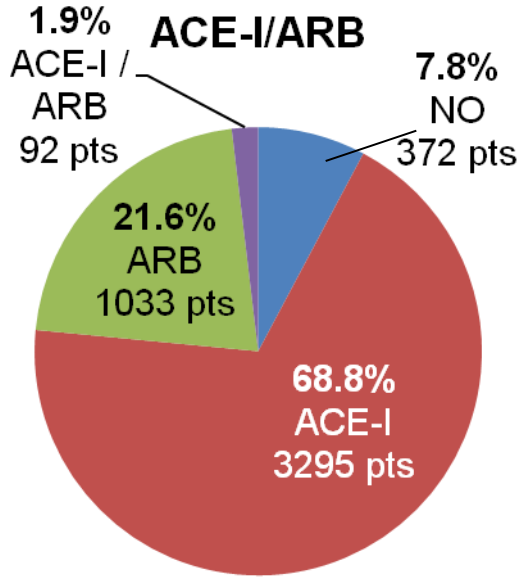
IV treatments at hospital entry (for 296 patients SBP at entry was not reported)

According to 2012 ESC guidelines (<i>Eur J Heart Fail 2012; 14:803-869</i>)				
	Total (n. 5039)	<85 mmHg (n. 90)	85-110 mmHg (n. 1169)	>110 mmHg (n. 3484)
IV inotropes, %	11.9	73.3	22.3	6.8
IV nitrates, %	20.4	10.0	13.3	23.0
IV diuretics, %	81.5	77.8	82.9	81.1
According to 2008 ESC guidelines (<i>Eur J Heart Fail 2008; 10:933-989</i>)				
	Total (n. 5039)	<90 mmHg (n. 117)	90-100 mmHg (n. 539)	>100 mmHg (n. 4087)
IV inotropes, %	11.9	70.1	29.9	7.8
IV nitrates, %	20.4	12.0	11.2	21.9
IV diuretics, %	81.5	78.6	83.1	81.4

Drug treatments in outpatients with HF

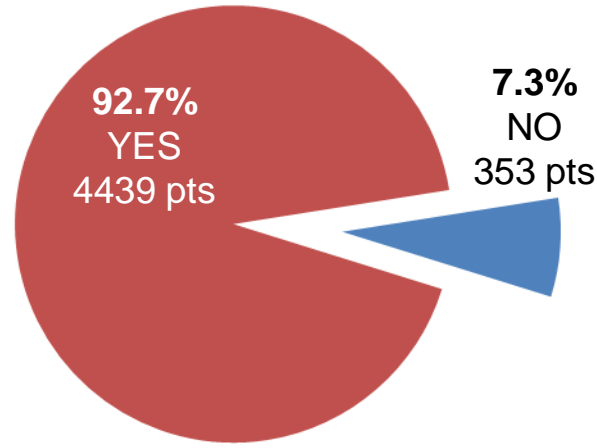
Treatments	Total population (n. 7041) %	Reduced EF ($\leq 45\%$) (n. 4792) %	Preserved EF ($>45\%$) (n. 1499) %
ACE-I/ARBs	89.2	92.2	79.7
Betablockers	88.9	92.7	78.8
MRAs	59.3	67.0	40.8
Diuretics	83.1	84.3	78.5
Digitalis	23.0	23.9	19.0
Ivabradine	8.5	10.5	4.9
Antiplatelets	48.7	51.5	40.4
Oral anticoagulant	42.4	41.9	45.6
Statins	60.9	61.8	55.6

Reason for non use of recommended treatments in outpatients with reduced EF



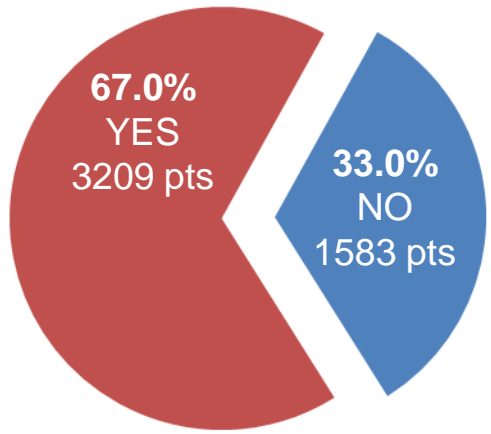
Contraindicated	n. 94 (2.0%)
Severe renal dysfunction	n. 61 (64.9%)
Symptomatic hypotension	n. 13 (13.8%)
Hyperkalemia	n. 8 (8.5%)
Other	n. 12 (12.8%)
Not tolerated	n. 123 (2.6%)
Worsening renal function	n. 22 (17.9%)
Symptomatic hypotension	n. 83 (67.5%)
Hyperkalemia	n. 6 (4.9%)
Angioedema	n. 2 (1.6%)
Other	n. 10 (8.1%)
Real undertreatment	n. 155 (3.2%)

Betablockers



Contraindicated	n. 78 (1.6%)
Asthma/COPD	n. 28 (35.9%)
Bradyarrhythmia	n. 11 (14.1%)
Symptomatic hypotension	n. 11 (14.1%)
PAD	n. 3 (3.8%)
Other	n. 25 (32.1%)
Not tolerated	n. 165 (3.4%)
Bronchospasm	n. 39 (23.6%)
Symptomatic hypotension	n. 46 (27.9%)
Bradyarrhythmia	n. 22 (13.3%)
Worsening HF	n. 36 (21.8%)
Other	n. 22 (13.3%)
Real undertreatment	n. 110 (2.3%)

MRAs



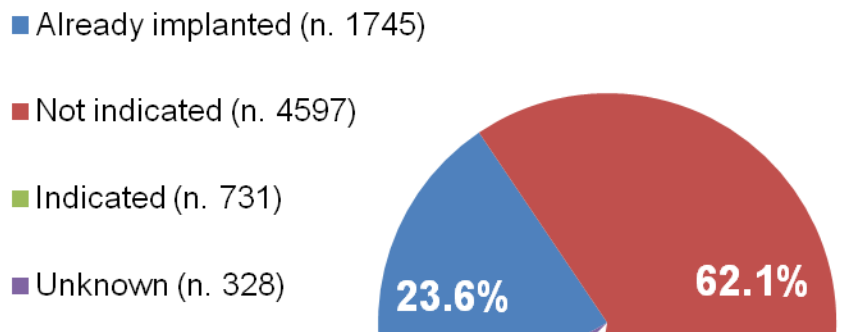
Contraindicated	n. 268 (5.6%)
Hyperkalemia	n. 94 (35.1%)
Renal dysfunction	n. 153 (57.1%)
Other	n. 21 (7.8%)
Not tolerated	n. 147 (3.1%)
Hyperkalemia	n. 53 (36.1%)
Worsening renal function	n. 34 (23.1%)
Gynecomastia	n. 34 (23.1%)
Other	n. 26 (17.7%)
Not indicated	n. 908 (18.9%)
Real undertreatment	n. 260 (5.4%)

Rate of outpatients at target dosages of recommended pharmacological treatments

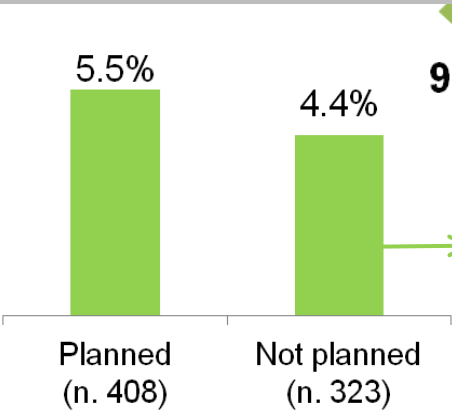
	At target n. (%)	Not at target <u>and</u> Reason for not at target, n. (%)
ACE-I (4710 pts)	1380 (29.3)	3330 (70.7) 1123 (33.7) Still in uptitration 866 (26.0) Symptomatic hypotension 264 (7.9) Worsening renal function 958 (28.8) Other/Unknown 85 (2.6) Hyperkalemia 29 (0.9) Cough 5 (0.2) Angioedema
ARBs (1500 pts)	362 (24.1)	1138 (75.9) 369 (32.4) Still in uptitration 295 (25.9) Symptomatic hypotension 115 (10.1) Worsening renal function 333 (29.3) Other/Unknown 25 (2.2) Hyperkalemia 1 (0.1) Angioedema
Betablockers (6468 pts)	1130 (17.5)	5338 (82.5) 1871 (35.1) Still in uptitration 904 (16.9) Symptomatic hypotension 586 (11.0) Bradyarrhythmia 1557 (29.2) Other/Unknown 185 (3.5) Worsening HF 146 (2.7) Bronchospasm 56 (1.1) Worsening PAD 33 (0.6) Sexual dysfunction
MRAs (4226 pts)	1290 (30.5)	2936 (69.5) 864 (29.4) Still in uptitration 350 (11.9) Hyperkalemia 1378 (46.9) Other/Unknown 284 (9.7) Worsening renal function 60 (2.0) Gynecomastia

Rate of implantation of devices and reasons for non implantation in outpatients with HF

ICD – Total population (7401 pts)

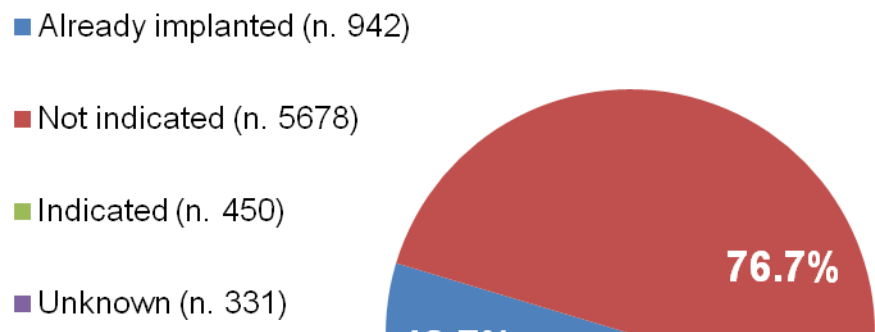


323/731=44%
Indicated but not planned

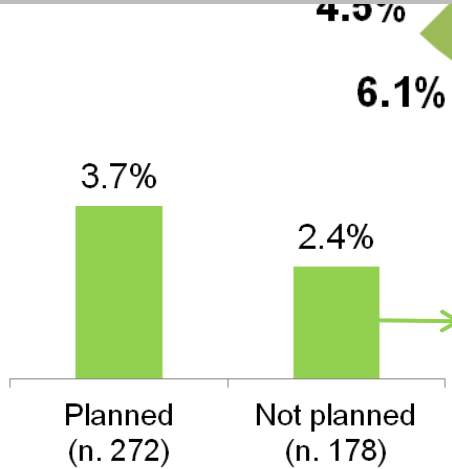


Reasons
161 pts Uncertainty in the indication
81 pts Patient refusal
51 pts Logistic/cost issue
30 pts Unknown

CRT – Total population (7401 pts)



178/450=40%
Indicated but not planned



Reasons
85 pts Uncertainty in the indication
36 pts Patient refusal
34 pts Logistic/cost issue
23 pts Unknown

EORP Heart Failure Long Term Registry: Summary slide

- ✓ The pharmacological treatment of patients with chronic HF can be considered acceptably adherent to the recommendations of current ESC guidelines
- ✓ However, less than a third of patients is receiving the target dosage of recommended drugs
- ✓ But when the reasons for non-adherence are appropriately taken into account the real rate of under-treatment or under-dosage is shown to be limited
- ✓ With respect to device implantation, the gap between guidelines and practice seems to be greater, probably due to different local medical practice but also to differences in healthcare systems

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Primary analyses of the HF LT Registry: current status

	Primary analyses	Proposer	Reference persons	Comments
1	Differences in HF management across the different regions	Protocol, A Kavoliuniene	A Maggioni	Follow-up needed
2	Preserved EF	Protocol	G Filippatos, M Lainscak, O Chioncel	Follow-up needed
3	COPD (<i>asthma</i>), Diabetes	Protocol	M Lainscak, L Tavazzi	Follow-up needed
4	Clinical presentation of AHF plus proposal 2 and 7 of the ancillary	Protocol	O Chioncel, A Mebazaa	Follow-up needed
5	Long-term outcomes and predictors	Protocol	L Tavazzi, C Fonseca	Follow-up needed
6	Adherence to recommended treatments	Protocol	A Maggioni	Published

Ancillary analyses of the HF LT Registry: current status

	Ancillary analyses	Proposer(s)	
1	Further detailed analyses on adherence to treatments and drug dosages: by age, with different target (i.e. 50% of the maximal target dose)	U Dahlström, M Lainscak, C Fonseca	
2	Prescription of inotropes, iv-nitrates and iv-diuretics in AHF-patients	F Fruhwald, G Sinagra, C Fonseca	Follow-up needed
3	Body Surface Area as a Prognostic Marker in Heart Failure Patients	O Amir	Follow-up needed
4	HR in HFpEF	C Fonseca	Follow-up needed
5	Role of anemia	C Fonseca	Follow-up needed
6	Renal function and prognosis	C Fonseca	Follow-up needed
7	Diagnostic and therapeutic tools used in AHF patients in European countries	L Tavazzi	
8	Further detailed analyses on adherence to guidelines with regard to device implantation	L Tavazzi	
9	Thromboembolic and bleeding risk in HF	L Tavazzi	Follow-up needed
10	CRT: change in clinical conditions and medical treatments (further stratification for the presence of Afib)	B Merkely	Follow-up needed

Agenda

- **Update of recruitment**
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 - Further analyses
- **New Executive Committee**

HFA HF LT Registry: New Executive Committee

- *Marisa Crespo Leiro (chairperson)*
- *Alexandre Mebazaa*
- *Massimo Piepoli*
- *Andrew Coats*

- *Stefan Anker*
- *Gerasimos Filippatos*
- *Luigi Tavazzi* to be replaced by the incoming chairman of the EORP OC
- *Aldo Maggioni* (ex officio as EORP)

- **Conclusion of the activities of the current committee with the presentation/publication of the first phase of the HF LT**

- **New committee will start activities in September 2013 (ESC Congress)**

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- **Update of recruitment**
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- **New Executive Committee**
- **Update of protocol and CRF**
 - New specific questions and variables October 2013
 - Ivabradine use
 - Use of prognostic scores in practice
 - Data collection: One week (5 days) every 3 months
 - Second week of October 2013
 - Third week of January 2014
 - Last week of April 2014
 - Second week of June 2014

POST-MEETING DECISION:

The Executive Committee has decided to allow **more flexibility** for the enrolment days:

Each country or centre can choose **5 consecutive working days** in four weeks. e.g. for Autumn: 5 days between 13 October and 8 November.

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- **New Executive Committee**
- **Update of protocol and CRF**
- **AOB**