

## Cardiomyopathy and Myocarditis Registry

### Newsletter N°16 – October 2016

**Page 1**  
Some words from  
the Chairman

**Page 2 to 4.**  
- Study plan  
- Registry status  
- Some key variables

**Page 4 to 6**  
- Data management  
- Ancillary analyses

Dear Investigators,

It was a great pleasure to meet some of you at the investigator meeting held during the ESC congress 2016 in Rome.

The enrolment period is nearly ending but I am still encouraging centres to continue the recruitment until December 2016 to reach the goal of enrolling a total number of 3 000 Adults Cardiomyopathy, 300 Myocarditis and 300 Paediatrics Cardiomyopathy in this registry.

The registry is progressing well and I would like to thank you all for your efforts to contribute to its success.

The global results will be produced from the merged Pilot and long-term registries and will be presented at the next ESC congress 2017 in Barcelona.

At this stage, it is important that you submit all your patient data, including the data from the 1 year follow-up.

Also, I would like to inform you that the genetics section of the eCRF can be filled in independently from the baseline in order to facilitate the data lock and that a new class of medication has been implemented (Sacubitril/Valsartan) in the eCRF to comply with the ESC guidelines.

Again, thank you for your collaboration

Yours sincerely,

Philippe Charron  
Chair of the Registry

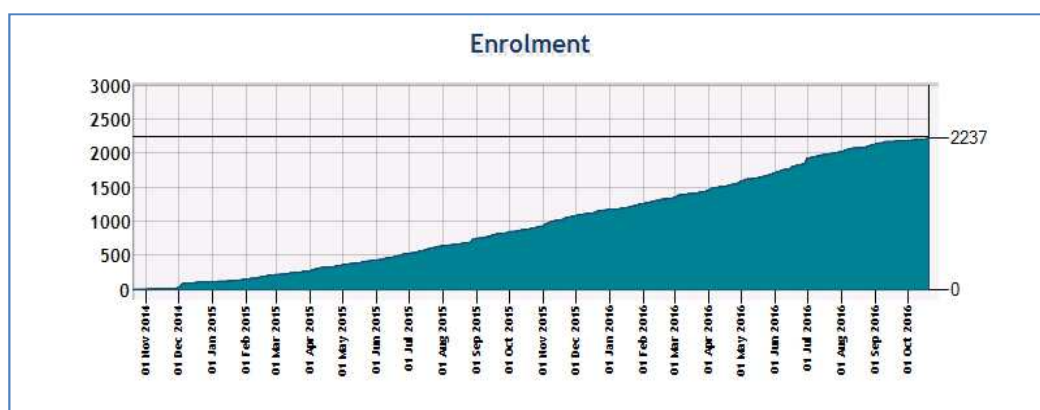


## STUDY PLAN

End of enrolment (main part)	December 2016
Presentation of main part results (on merged pilot & long-term registries)	ESC congress 2017 Barcelona
End of 1 year Follow-Up	December 2017
Presentation of 1 year Follow-Up results	ESC Congress 2018

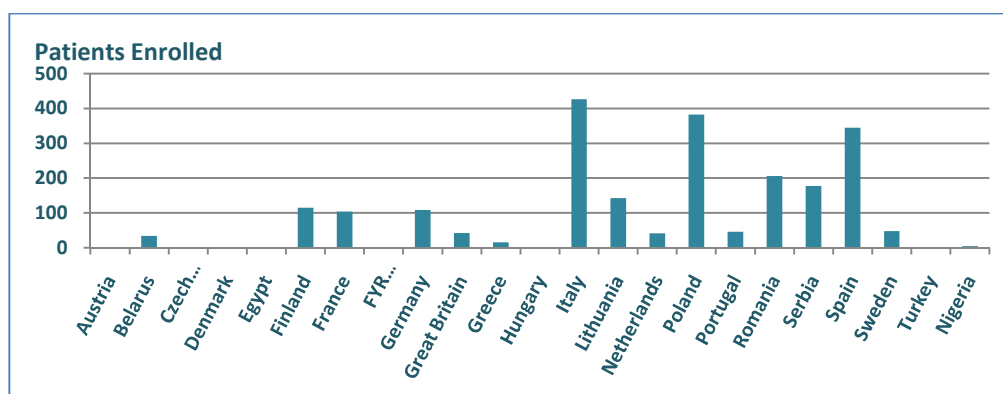
## REGISTRY STATUS – October 21<sup>st</sup>, 2016

### Overall patient enrolment



To reach our recruitment goal of 3,000 Adult Cardiomyopathy, 300 Myocarditis, 300 Paediatrics by December 2016, we encourage all centres to continue the patient recruitment.

### Enrolment per country



## Centres activity

Country	Participating Centres	Active Centres	Patients Enrolled	CRF Signed off	CRF Locked
Austria	1	0	0	0	0
Belarus	1	1	34	19	9
Czech Republic	1	0	0	0	0
Denmark	1	0	0	0	0
Egypt	3	0	0	0	0
Finland	2	2	115	59	56
France	7	2	104	4	0
FYR Macedonia	1	0	0	0	0
Germany	14	3	108	53	52
Great Britain	7	1	42	42	41
Greece	2	2	15	8	6
Hungary	1	0	0	0	0
Italy	17	9	427	398	320
Lithuania	2	2	142	123	112
Netherlands	1	1	41	41	25
Poland	6	6	383	369	222
Portugal	5	2	46	0	0
Romania	2	2	206	205	190
Serbia	2	2	177	150	121
Spain	18	12	345	275	262
Sweden	1	1	48	0	0
Turkey	1	0	0	0	0
Nigeria	1	1	4	2	0
<b>Total</b>	<b>97</b>	<b>49</b>	<b>2237</b>	<b>1748</b>	<b>1416</b>

## Congratulations to

the following centres who have the highest number of enrolled patients:

1. John Paul II Hospital - Krakow (Poland)
2. Emergency Institute of Cardiovascular Diseases – Bucharest (Romania)
3. Policlinico Casilino – Roma (Italy)
4. Helsinki University Central Hospital Meilahti – Helsinki (Finland)
5. Azienda Ospedaliero-Universitaria Ospedali Riuniti – Trieste (Italy)

## SOME REGISTRY KEY VARIABLES

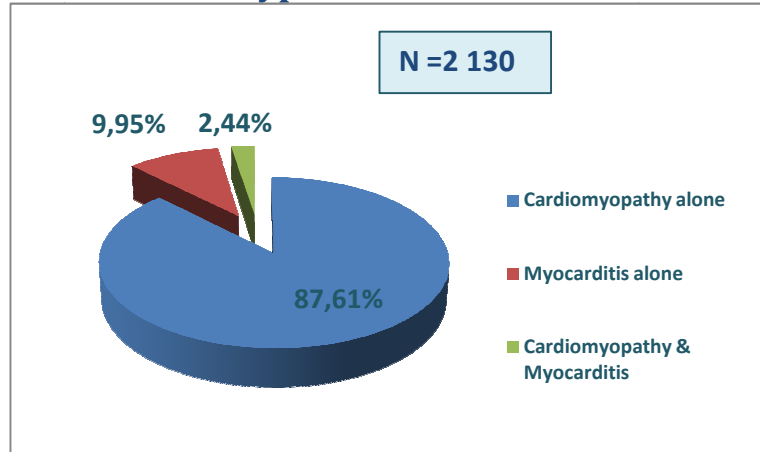
### Types of active centres

**20 Adult centres, 3 Paediatric centres and  
17 both Adult & Paediatric centres**

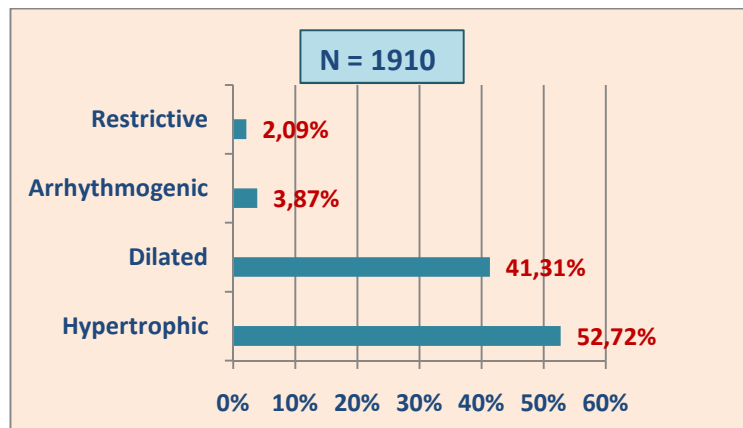
## Type of patients

1906 Adults patients vs 99 Paediatrics patients

## Type of inclusions



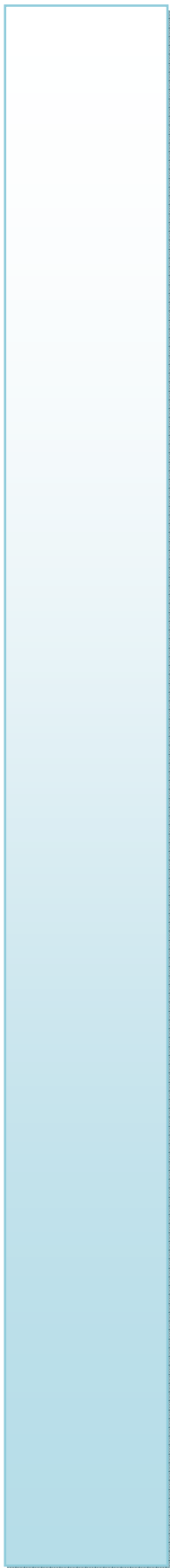
## Type of Cardiomyopathies



## DATAMANAGEMENT

### IMPORTANT

It is important at this stage of the registry that centres from Belarus, Finland, France, Germany and Portugal enter and submit their patient data ASAP.



Once you have entered your data in the eCRF, make sure to tick YES and NEXT to sign off



CRF Completed

Answer YES to the question below to confirm that you have completed the main section.

CRF Completed:  No  Yes ✓

Next

## Two minor changes in the eCRF

### 1- Genetic section



The genetics section in the eCRF can be filled in and signed off independently from the baseline. So the baseline can be submitted without the genetic data which will be entered when available later (since results may require several months after enrollment).

Independent section from Baseline: can be completed and signed off at any

### 2 – New class of medication

A new class of medication Sacubitril/Valsartan (*recommended as a replacement for an ACE-I to further reduce the risk of HF hospitalization and death in ambulatory patients with HFrEF who remain symptomatic despite optimal treatment with an ACE-I, a beta-blocker and an MRA*) has been implemented in the medication section of the eCRF to comply with the ESC guidelines.

## Ancillary analyses

### **A big thanks to**

the lead authors for the presentation of their proposals of ancillary analyses at the investigator meeting in Rome.

### **THANK YOU ALL**

Should you have any suggestions, questions or requests, please do not hesitate to contact us at [eorp@escardio.org](mailto:eorp@escardio.org)