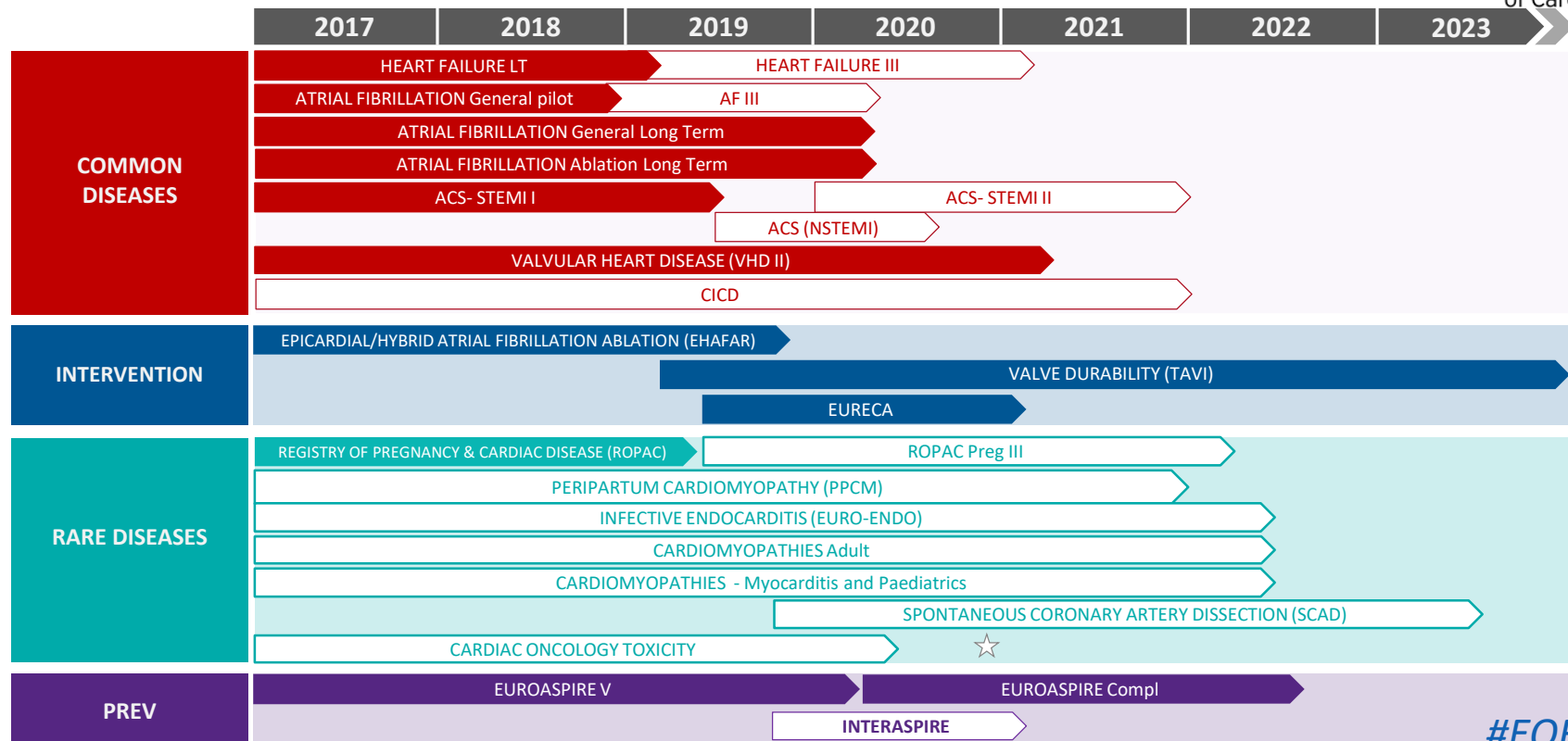


EORP: EurObservational Research Programme



REGISTRY Snapshot (enrolment: ≤ 6 months)

☆ Release of the corresponding Guidelines

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ESC

EORP Symposium 2020

Quality is Key

EORP Symposium 2020 - Quality is Key

Monday January 27th, 2020

1. **Welcome**
2. **EORP Key achievements**
3. **Methods - CRF designs, stats plan designs, experience of center/snapshot approach**
 - **Experience and design**
 - **Methods re observational studies design/ bias/analyses**
4. **Quality indicators**

C. Gale

C. Gale

A. Maggioni

J. Emberson

S. Aktaa

Tuesday January 28th, 2020

5. **Authorship and Publication Policy (& cohort profile papers for all EORP registries)**
6. **Education: Good Registry Practices**
7. **How to improve the participation of countries/centres?**

V. Tursini

M. Kayikçioğlu

K. Nagy

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EORP Key Achievements 2019

Pr. Chris Gale

Chairman of EORP

27th January 2020



EORP Key achievements 2019

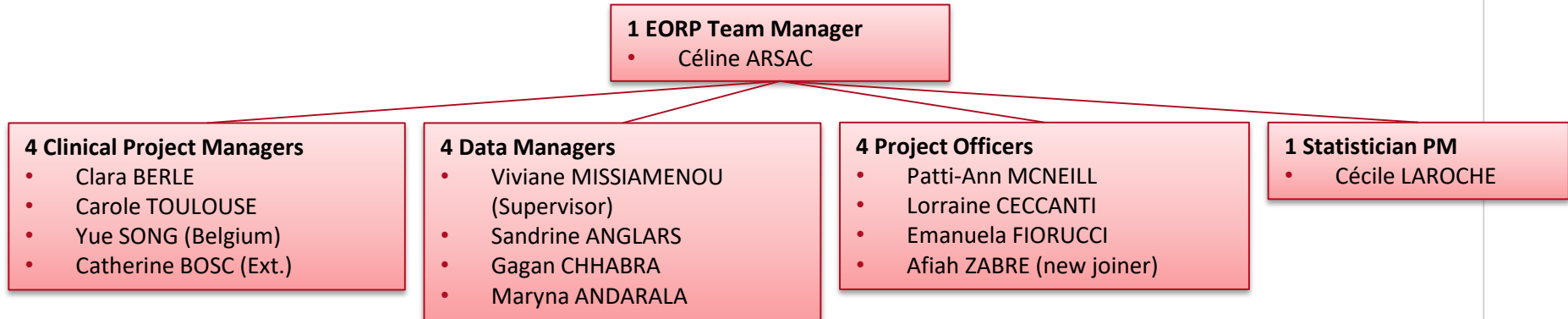
- 1. HR – Organisation in Project Management Mode**
- 2. Tooling to become more and more professional**
- 3. Studies key deliveries**
- 4. ESC Congress Paris 2019**
- 5. Working groups**

1. HR – Organisation in Project Management Mode ESC

European Society
of Cardiology

EORP staff : a professional and expert team organised in PM mode:

- **1 Study Core team** per registry: 1 CPM + 1 PO + 1DM + 1Stat dealing with:
- **1 Executive Committee + 1 Steering Committee** per study



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2. Tooling – to increase QUALITY

EORP departement signed contracts with 2 eCRF providers

CLINFILE & ENNOV



The objective is to **improve the level of data quality** by :

- collaborating with professional tools in data collection and data management
- implement and anticipate a maximum data accuracy & consistency
- work during start-up phase on Data Validation Plan
- decrease the number of queries
- decrease the time spent on eCRF pages by investigators

➔ **To use these tools, protocols and paper CRF must be final and validated by chairs before programming the eCRF.**

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2. Tooling – to increase QUALITY

EORP launch a collaboration with ESC IT department to develop a **CTMS (Clinical Trial Management System)**

The objective is to **improve the level of data quality** by :

- Decreasing the manual tasks performed by the staff
- Avoid mistakes because of manual tasks or not updated data used (ie: emails, names)
- Provide automatic reports and status to relevant stakeholder (NCS, Sponsors)

➔ **To use these tool, processes and RACI matrix (Roles & Resp) to be implemented in the department.**

3. Studies key deliveries

8 Studies start-up:

Study Name	Country based/ Center based	Category	FPI	Enrollment duration	# patients
ROPAC Preg III	Center based	Rare disease	5-Mar-19	24 months	900
Heart Failure III_HFA	Country based	Common disease	29-Apr-19	12 months	10 000
TAVI Valve Durability	Center based	Intervention	15-May-19	19.5 months	2 000
N-STEMI	Country based	Common disease	1-Jul-19	6 months	10 000
EURECA	Center based	Intervention	1-Sep-19	6 months	3 000
SCAD _ Spontaneous Coronary Arterious Dissection	Center based	Rare disease	1-Feb-20	24 months	1 000
InterAspire Pilot	Country based	Prevention	1-Mar-20	7 months	800
ACS STEMI II	Country based	Common disease	1-Jul-20	12 months	10 000

3. Studies key deliveries

3 Studies DBL for Main part and 3 Follow-up Part

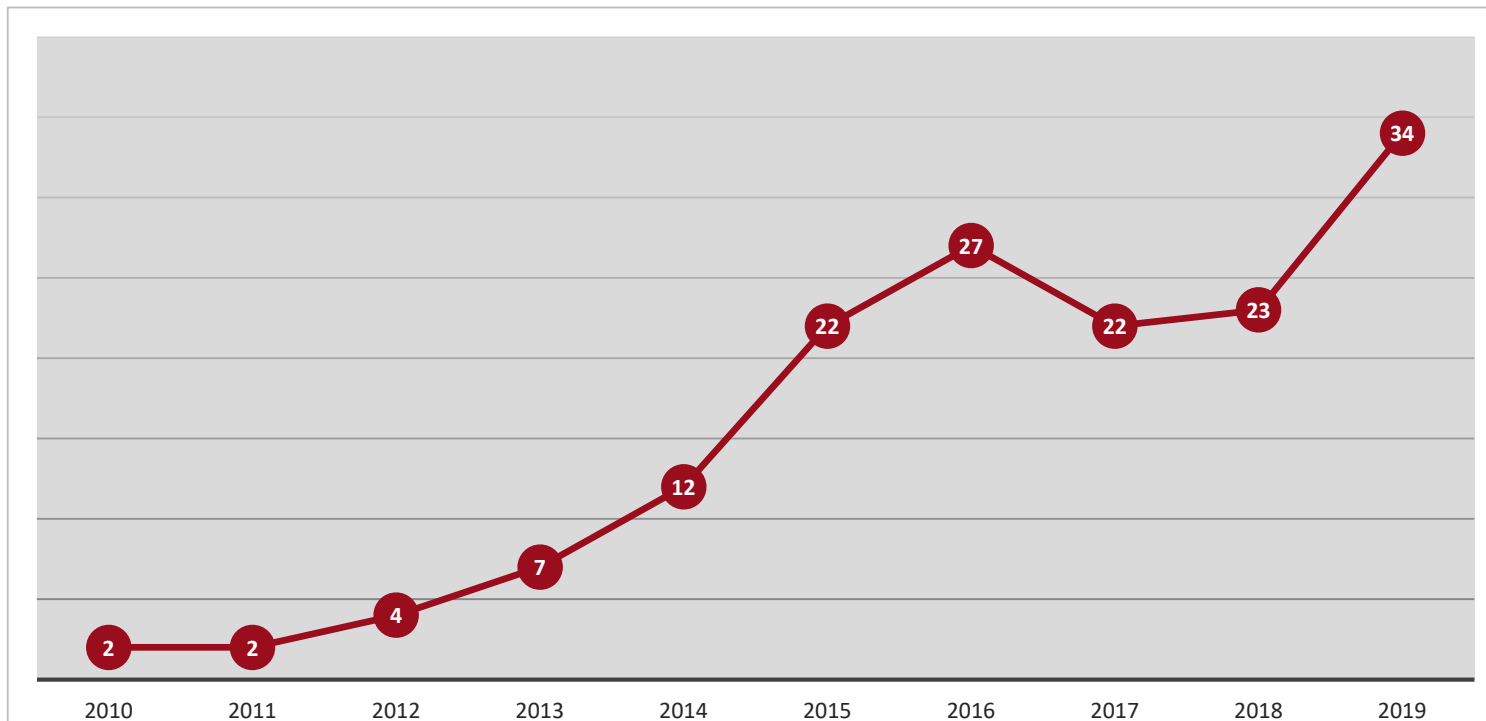
Study Name	Country based/ Center based	Category	FPI	Date DBL	# patients	Recruit target
AF III	Country based	Common disease	1-Jul-18	2-Dec-19	8300	10 000
CMY _ Cardiomyopathy Long Term - Adults + Paediatrics and Myocarditis	Center based	Rare disease	10-Jun-14	29-May-19	1246	1 200
EHRA _ EHAFAR	EHRA registry	Intervention	5-Jan-16	15-Mar-19	469	750

3 Studies DBL for Follow-up Part

Study Name	Country based/ Center based	Category	FPI	Date DBL	# patients	Recruit target
VHD II	Country based	Common disease	16-Jan-17	11-Feb-19		5 000
ACS STEMI I	Country based	Common disease	1-Jan-15	30-Sep-19		10 000
EURO-ENDO_ Infective Endocarditis	Center based	Rare disease	22-Jan-16	3-Oct-19		2 000

3. Studies key deliveries

2010 – 2019 EORP PUBLICATIONS EVOLUTION*



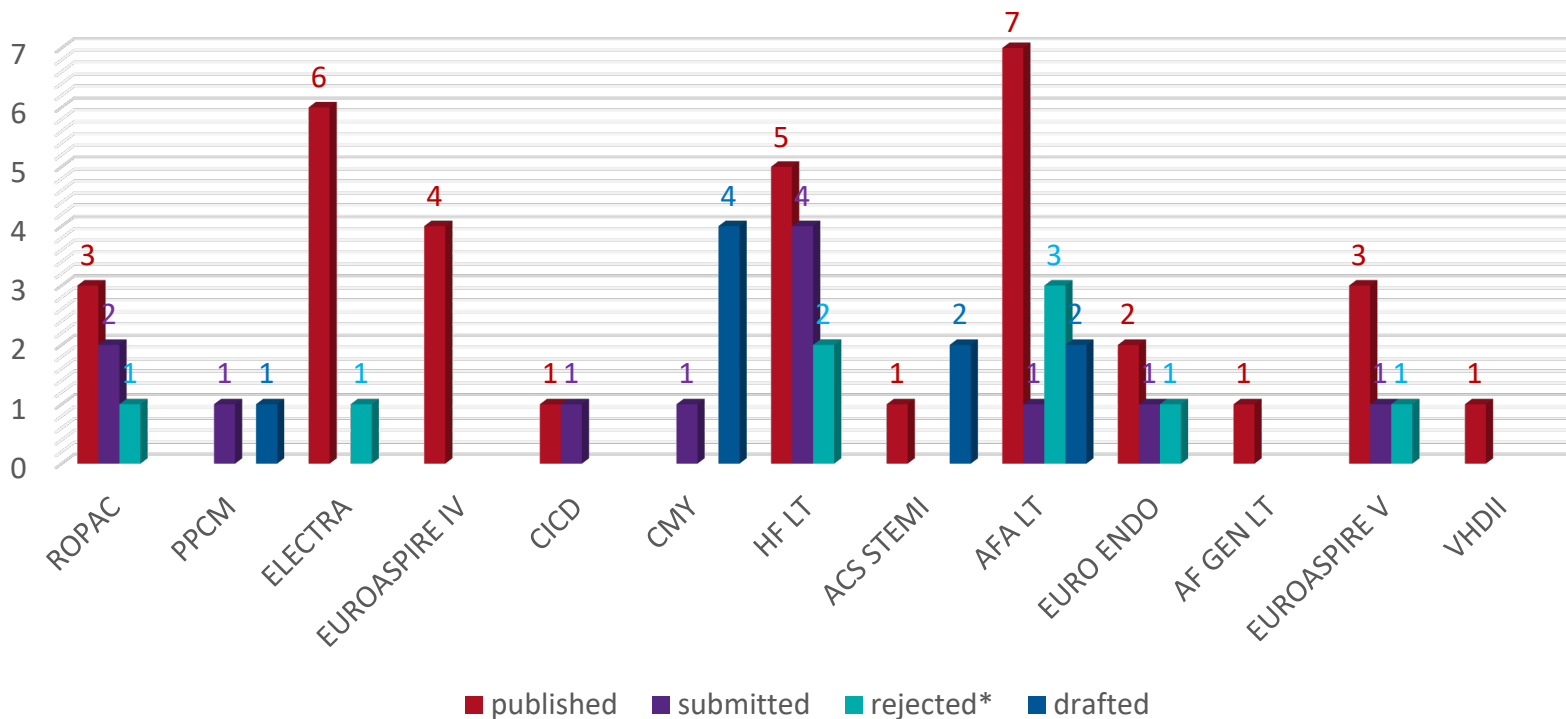
* If you would like to receive the detail of all EORP publications from 2010 to 2019, please let us know

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34 Published Manuscripts in 2019

Registry	Type	Journals
Atrial Fibrillation Ablation Long-Term AFA LT	6 Ancillaries, 1 Research Letter	PACE, EUROPACE, EJHF Research Letter
European Lead Extraction ConTRolled ELECTRa	6 Ancillaries	EUROPACE, JCE
Heart Failure Long-Term HF LT	4 Ancillaries + 1 country paper	EJHF, HF, Revista Española de Cardiología
European Survey of Cardiovascular Disease Prevention and Diabetes EUROASPIRE IV	4 Ancillaries	Journal of Hypertension, IJC, Quality of Life Research
Pregnancy And Cardiac disease ROPAC	1 Baseline, 1 ancillary, 1 Abstract	EHJ, JACC Heart Failure
European Survey of Cardiovascular Disease Prevention and Diabetes EUROASPIRE V	1 Baseline, 2 ancillaries	EJPC, Atherosclerosis, IJC
European Infective Endocarditis EURO ENDO	1 Cohort, 1 Baseline	QCCO, EHJ
Valvular Heart Disease VHD2	1 Baseline	Circulation
Chronic Ischemic Cardiovascular Disease CICD	1 Cohort paper	QCCO
Acute Coronary Syndromes ACS STEMI	1 Cohort paper	QCCO
Atrial Fibrillation General Long Term AFGen LT	1 Ancillary	EUROPACE

All manuscripts status in 2019

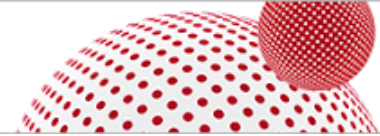


* To resubmit elsewhere

4. ESC Congress in Paris

ESC Congress
Paris 2019

Together with
World Congress
of Cardiology



31 August
- 4 September

➤ 1 OverSight Committee Meeting

➤ > 15 Study specific meetings: Executive Committees & Investigators Meetings

- Cardiomyopathies: A. Caforio
- PPCM: K. Sliwa-Hahnle
- VHD II: B. Lung
- InterAspire Pilot: D. Wood
- HFIII: L. Lund
- Euro-Endo: G. Habib + P. Lancellotti
- NSTEMI: C. Gale
- Eureka: D. Neglia + V. Delgado
- ROPAC: J.W. Roos - Hesselink
- SCAD: D. Adlam
- AF Gen: G. Boriani+ G. Lip
- TAVI: S. Petronio
- AF III: T. Potpara
- ACS STEMI II: U. Zeimer

➤ 1 EORP Symposium with 5 presentations

- **PPCM:** K. Sliwa-Hahnle - Peripartum cardiomyopathy - A global disease: update from the PPCM EORP Registry.
- **Euro-Endo:** G. Habib - Results of the EURO-ENDO (European Infective Endocarditis) registry
- **CICD:** The Chronic ischemic cardio vascular disease registry(CICD) baseline characteristics– M. Komajda
- **ROPAC:** J.W. Roos - Hesselink - ROPAC Preg II - Cardiac disease and pregnancy
- **Cardiomyopathy:** A. Caforio - Clinically suspected and biopsy-proven myocarditis: insights from the Cardiomyopathy Myocarditis ESC Registry
- **Cardiomyopathy:** J.P. Kaski - The EORP Cardiomyopathy and Myocarditis Registry: early insights into paediatric cardi



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5. Three working groups initiated

- **Quality Indicators – Suleman AKTAA**
- **Good Registries Practices – Meral KAYIKÇIOĞLU**
- **Publication Policy – Chris GALE**