



# Safety and Effectiveness of ICD Follow-up using Remote Monitoring

## **ECOST Study**

Salem Kacet , Laurence Guédon-Moreau  
On behalf of the ECOST Study Investigators



# Disclosure

---

- Research grants, Advisory board, conferences fees from:
  - Biotronik, Boston Scientific, Medtronic, Saint Jude Medical, Sorin Group
  - Bayer, Boehringer-Ingelheim  
Meda, Sanofi-Aventis
- ECOST Study is supported by grants from Biotronik SE & Co KG



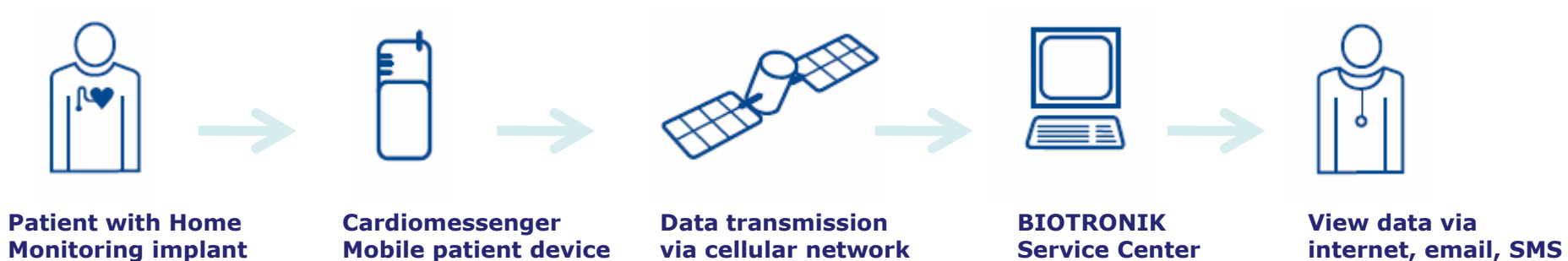
# Background

---

- The implant rate for ICD in the prevention of Sudden Cardiac Death has reached in 2010 an average of
  - ~250 per million population in Europe
  - ~675 per million population in USA
- HRS/EHRA 2008 expert consensus on the monitoring of CIEDs points out
  - The potential of remote ICD follow-up to increase patient safety and convenience
  - The need of proofs with clinical studies
- Remote follow-up of ICDs (TRUST) has been demonstrated to reduce the number of in person device F.U. without increasing death, strokes and ICD related AE requiring surgical interventions
- Global cardiovascular safety of Remote follow-up remains uncertain

# Home Monitoring system

- HM allows the **transmission of diagnostic data** from the ICD to the physician by:
  - Communication by a radiofrequency transmitter circuitry integrated in the ICD
  - Acceptance and transfert data from the ICD to a service center using a telephone landline via the Cardiomessenger®
  - Data reception by the service center and generation of a cardiologic report accessible online by the physician via a secure Internet access
  - Potential alerts to the physician of clinical or technical events





# Primary Hypothesis

- We hypothesized that ICD follow-up with Home Monitoring would be **safe** and **cost-effective** when compared with standard ambulatory follow-up
- Safety was defined as **Major Adverse Events (MAE)** including
  - Death from any cause
  - Major cardiovascular adverse event
  - Major device-related adverse event
- **Adverse Event(AE)** was defined as major if:
  - Fatal or life-threatening
  - Prompts or prolongs a hospitalization
  - Causes major or permanent disability or injury
  - Requires an intervention to prevent permanent impairment or damage



# Secondary Hypothesis

---

- Objective: **Evaluation of the effectiveness** of Home Monitoring on:
  - Inappropriate therapies
  - Number of ICD charges
- Objective: **Cost of Care** in ICD recipients  
(not available)



# Study Design

- Designed to detect the **non-inferiority** in the primary end point:
  - 80% power
  - 5% significance level
  - Sample size requirement of 400 patients

- **Randomized controlled trial**

Randomization on a 1:1 basis to:

Remote Monitoring Follow-up

Vs.

In-Person Follow-up



# Inclusion / Exclusion Criteria

---

## **Key Inclusion criterias:**

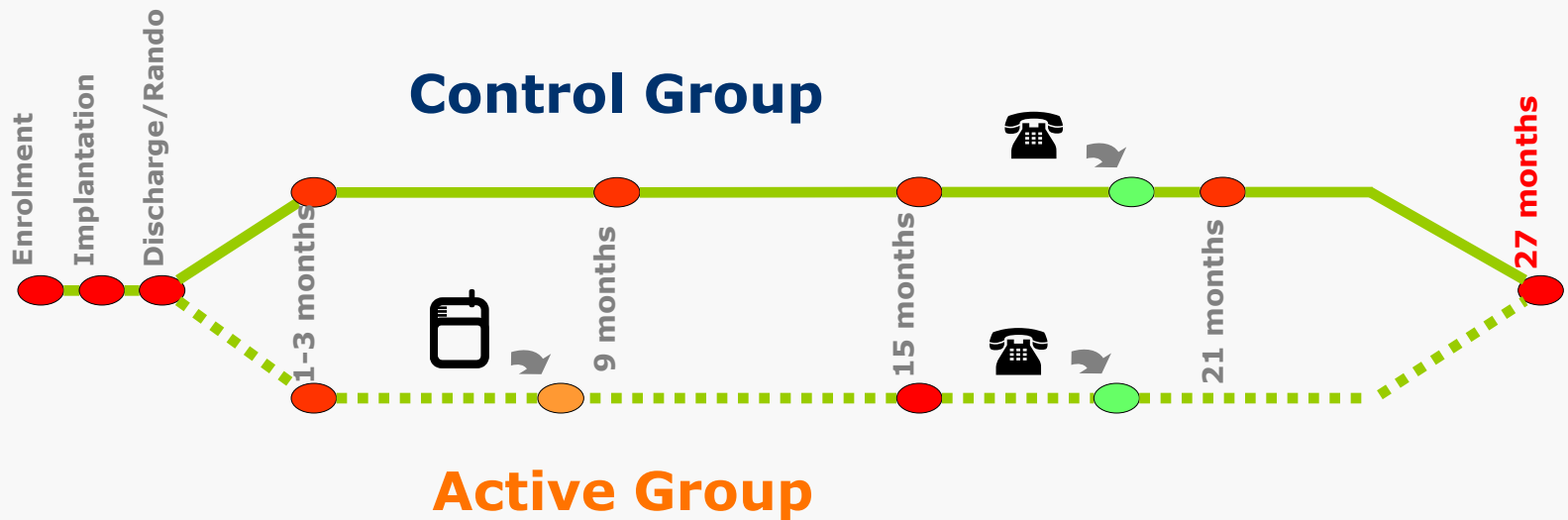
- **Indication or single or dual chamber ICD (without CRT)**




## **Key Exclusion criterias:**

- **NYHA class IV**
- Pregnant woman or woman who plan to become pregnant during the trial
- Patient whose medical situation is not stable
- Presence of any disease, other than patient's cardiac disease, associated with reduced likelihood of survival for the duration of the trial, e.g. cancer, uraemia (urea > 70mg/dl or creatinine >3mg/dl), liver failure, etc.
- Age < 18 years
- Patient unable to handle Home Monitoring system correctly
- The patient is not willing and able to comply with the protocol
- Change of residence expected during study
- Participation in another clinical study
- Patient unwilling to sign the consent for participation.

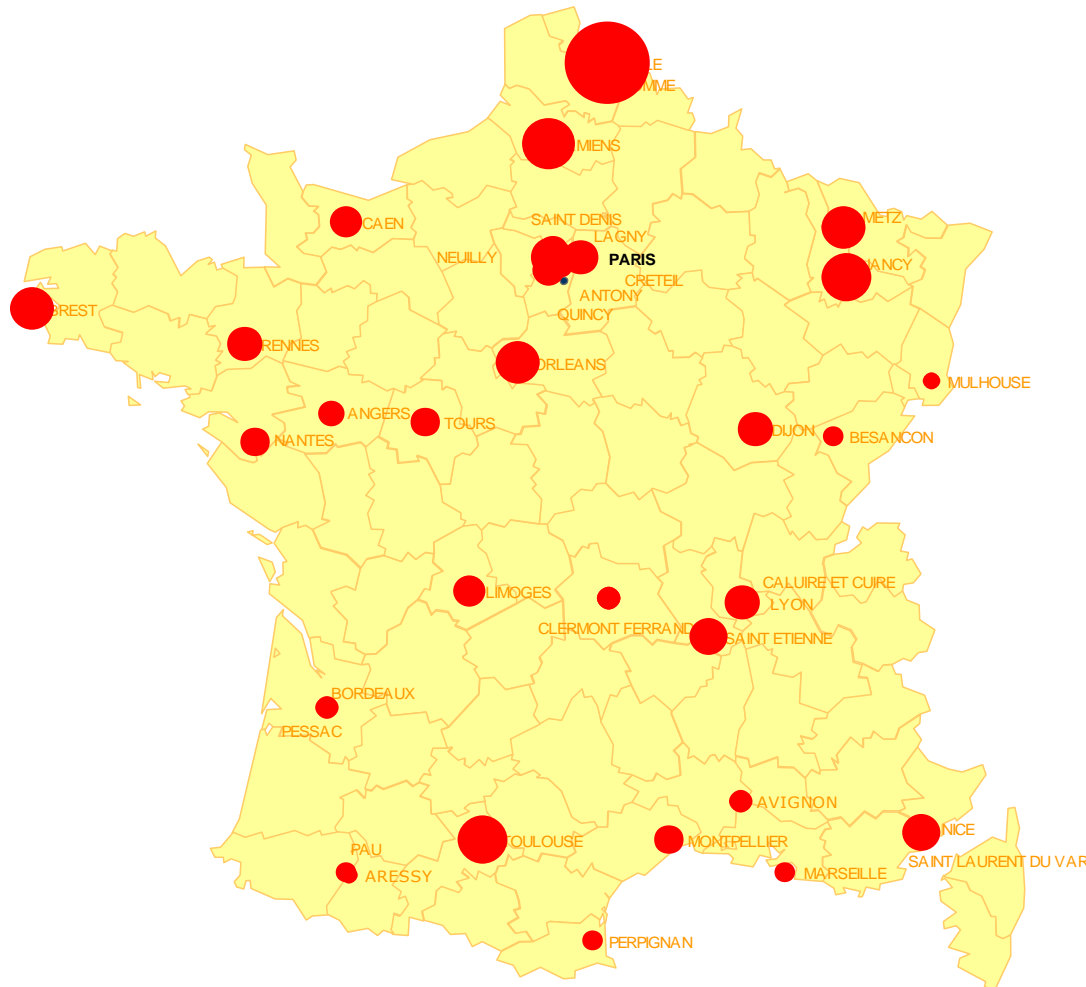


# Study Flow



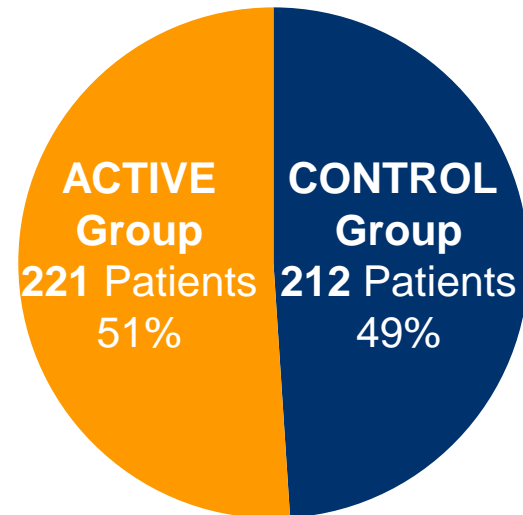
-  Mandatory follow-up (in-office visit)
-  Additional follow-up triggered by Home-Monitoring
-  Additional follow-up triggered by Patient and/or Physician

# ECOST Study Sites



433 patients were enrolled, randomised and followed for a mean of  $24 \pm 7$  months

43 investigational centers in France



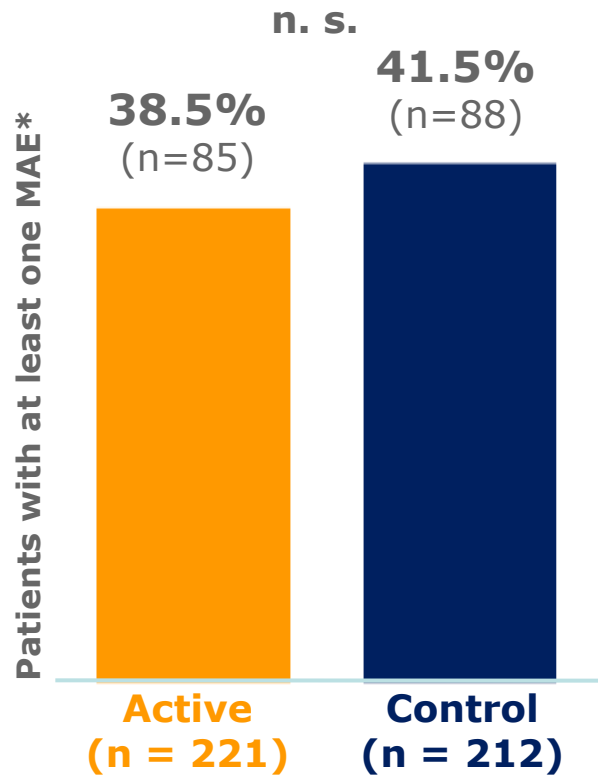


# Population: Baseline Characteristics

Non significant difference	ACTIVE	CONTROL
Number of patients	221	212
Age	62.0±13.0	61.2 ±12.0
Gender (male) (%)	87.3	89.2
LVEF (%)	34.7±13.0	35.1±13.6
NYHA (%) I / II / III	27 / 63 / 6	25 / 61 / 12
History of SVT (%)	17	14
Ischemic cardiop. /Non Ischemic cardiop. (%)	65 / 35	67 / 33
Primary prevention (%)	53.8	53.3
Dual chamber implants (%)	27.1	33.5
First implantation (%)	84.2	86.3



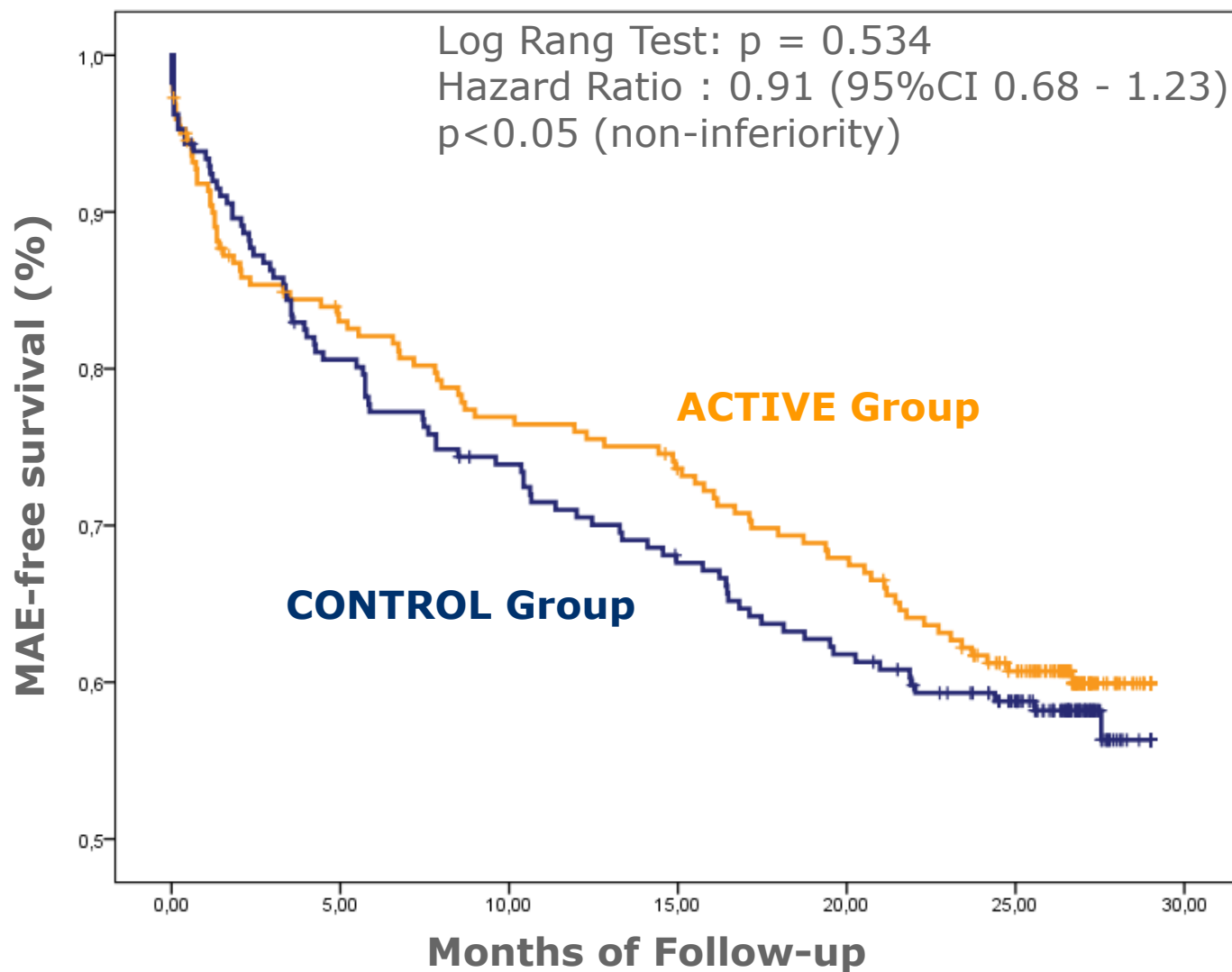
# Primary End Point: Safety



- Home Monitoring follow-up associated with a non inferior safety

\* MAE = Major Adverse Event

# Cumulative Survival free of MAE





# Primary End Point by Component

## Procedure implant related MAE

Non significant difference

	<b>ACTIVE</b> (n=221)	<b>CONTROL</b> (n=212)
<b>Hematoma</b>	2	1
<b>Infection</b>	4	2
<b>Venous thrombosis</b>	0	2
<b>Pneumothorax</b>	3	0
<b>Lead dislodgment (&lt; 1 month)</b>	5	1
<b>VF Induction: test failure</b>	1	3
<b>Other</b>	0	2
<b>TOTAL</b>	<b>15 MAE</b> (14 pt: 6.3%)	<b>11 MAE</b> (11 pts: 5.2%)



# Primary End Point by Component

## Cardiovascular MAE

Non significant difference

	ACTIVE (n=221)		CONTROL (n=212)	
	Events	Patients	Events	Patients
Ventricular arrhythmia without shock	10	8	4	4
Ventricular arrhythmia with shock	10	9	5	5
Electrical storm	15	11	17	12
Myocardial infarction	0	0	1	1
Supra ventricular arrhythmia	6	5	1	1
Stroke	7	4	0	0
Heart failure	40	25	61	32
Acute coronary syndrom	6	6	12	10
Other	1	1	6	6
<b>TOTAL</b>	<b>95 MAE</b> (59 pts: 26.7%)		<b>107 MAE</b> (63 pts: 29.7%)	



# Primary End Point by Component

## Device related MAE

Non significant difference

	ACTIVE (n=221)		CONTROL (n=212)	
	Events	Patients	Events	Patients
<b>Inappropriate shock</b>				
- related to SVT	3	2	6	6
- related to T-wave oversensing	1	1	1	1
- related to lead dysfunction	1	1	5	4
<b>Lead dysfunction without shock</b>	<b>5</b>	<b>5</b>	<b>1</b>	<b>1</b>
<b>Other</b>	<b>3</b>	<b>3</b>	<b>4</b>	<b>4</b>
<b>TOTAL</b>	<b>13 MAE</b> (12 pt: 5.4%)		<b>17 MAE</b> (14 pts: 6.6%)	





# Primary End Point by Component

- Death occurred in 20 (9.0%) patients in the active group and 20 (9.4%) patients in the control group.
- No significant difference between groups

<b>Deaths</b>	<b>ACTIVE</b> (n=221)	<b>CONTROL</b> (n=212)
Stroke	1	0
Heart failure	7	8
Infarction	0	1
Arrhythmia	3	1
Non cardiac	7	8
Unknown	2	2
<b>TOTAL</b>	<b>20 (9.0%)</b>	<b>20 (9.4%)</b>



# Secondary End Point: Effectiveness

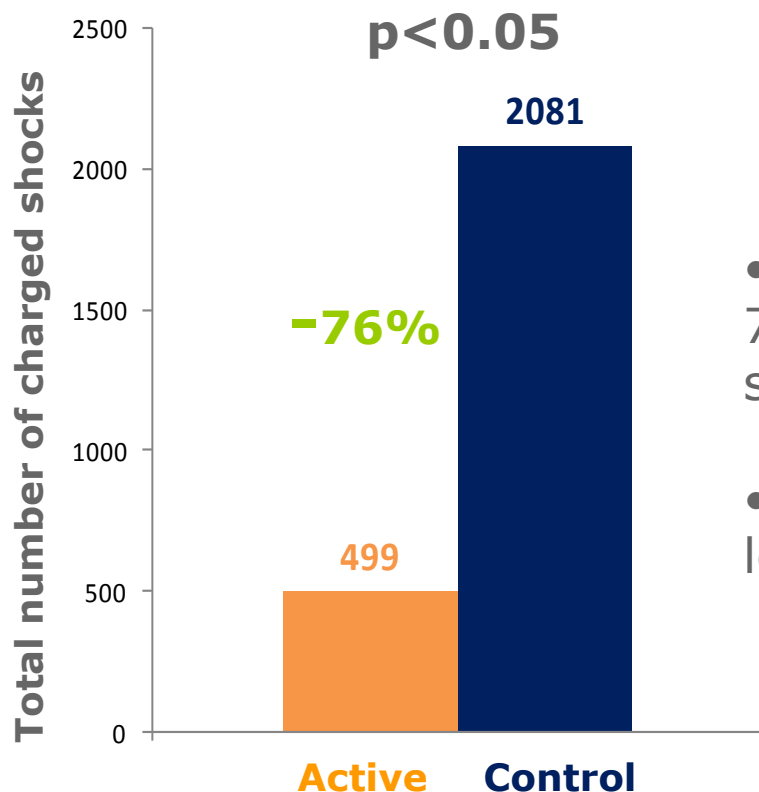
## Inappropriate Shocks (IS)

- Remote Monitoring associated with a 52% reduction in the number of patients with inappropriate shocks and with a 72% reduction in the risk of IS related hospitalizations

	<b>ACTIVE</b> (n=221)	<b>CONTROL</b> (n=212)	<b>P</b> <b>value</b>
<b>Number of patients with <math>\geq 1</math> IS</b>	<b>11 (5.0%)</b>	<b>22 (10.4%)</b>	0.03
<b>Number of IS delivered</b>	<b>28</b>	<b>283</b>	0.05
Mean per patient	2.5 $\pm$ 2.2	12.9 $\pm$ 25.2	
Range	[1-8]	[1-87]	
<b>Number of patients hospitalized</b>	<b>3</b>	<b>11</b>	0.02

# Secondary End Point: Effectiveness

## Charged shocks



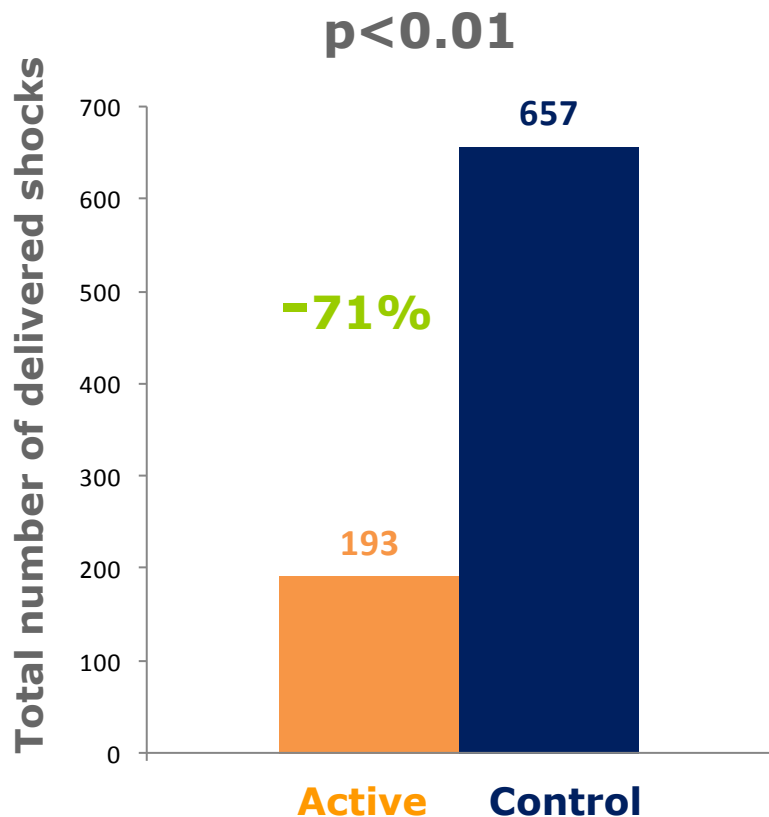
- Remote Monitoring associated with a 76% reduction in the risk of charged shocks
- With a significant impact on battery longevity (60% gain  $p = 0.02$ )

Mean per patient:	2.3±6.3	9.8±61.5
Number of patients:	69	72
Range [Nb shocks]:	[0-58]	[0-760]

# Secondary End Point: Effectiveness

## Delivered shocks

(appropriate and inappropriate)



- Remote Monitoring associated with a 71% reduction in the risk of delivered shocks

	Active	Control
Mean per patient:	0.9±3.3	3.1±12.9
Number of patients:	47	56
Range [Nb shocks]:	[0-33]	[0-116]



# Conclusions

---

- Device management of patients with ICD using Home Monitoring<sup>®</sup> system with daily telemetry is safe
- It is not inferior to conventional In-person follow-up
- Remote follow-up is significantly associated with:
  - Reduction of 52% in the number of patients with inappropriate shocks
- Remote Monitoring might soon set a new gold standard of care for the FU of ICD recipients

**Steering Committee** – S. Kacet (Chairman), L. Guédon-Moreau, N. Canot

**Endpoint Adjudication Committee** – J. Clémenty, D. Lacroix, N. Sadoul

**Electrogram Analysis Core Laboratory** – L. Guédon-Moreau, X. Laroche

**Study Coordinator** – S. Fauquembergue

**Funding Source** – Biotronik SE & Co. KG

**Statistical Analysis Group** – X. Bry, A. Gannoun

**ECOST investigators** – S. Abbey, E. Aliot, W. Amara, D. Babuty, H. Bader, M. Belhameche, H. Benkemoun, J.P. Bernis, G. Bertaux, O. Bizeau, J.J. Blanc, P. Blanc, D. Bleinc, P. Bordachar, M. Boursier, S. Boveda, F. Briand, F. Brigadeau, J.P. Camous, A. Chapelet, S. Cheggour, P. Chenevez, P. Chevalier, X. Copie, P. Couderc, A. Da Costa, J.M. Davy, J.C. Deharo, N. Delarche, M. Delay, A. Duparc, J.M. Dupuis, P. Durand, N. Elbaz, D. Flammang, R. Frank, J. Graux, A. Gressard, L. Guédon-Moreau, J.S. Hermida, D. Klug, C. Kouakam, A. Kowsar, D. Lamaison, L. Larouchi, G. Lascault, A. Leenhardt, J. Levy, P. Mabo, H. Mansour, J. Mansourati, C. Marquié, C.J. Mariottini, C. Moini, J.L. Pasquie, O. Paziaud, O. Piot, H. Poty, M. Salvador, P. Sbragia, P. Scanu, O. Thomas