



## **CIED 2: Current Status of Korean Multicenter CIED Studies** **BENEFIT-RM Study** **: CIEDs with Remote Monitoring**



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# Disclosure

Relationships with commercial interests  
: Nothing to disclose



# Agenda

- 1. Evidence about remote monitoring**
- 2. Recommendations from current guidelines**
- 3. Current status of remote monitoring use**
- 4. BENEFIT-RM Trial**



# Evidence about Remote monitoring

1. **Survival benefit ?**
2. **Reduction of frequency of in-office visit**
3. **Reduction of inappropriate shocks**
4. **Economic effect**
5. **Arrhythmia detection**
6. **Prediction of the risk for HF hospitalization**



# Evidence about Remote monitoring

## 1. Survival benefit ??

**IN-TIME trial** : a RCT enrolling 664 primary prevention ICD/CRT-D (58.7%) patients

**Telemonitoring (every day + tachy detection)** + standard care vs. Standard care only

→ Reduced **death and CV hospitalizations** in telemonitoring arm

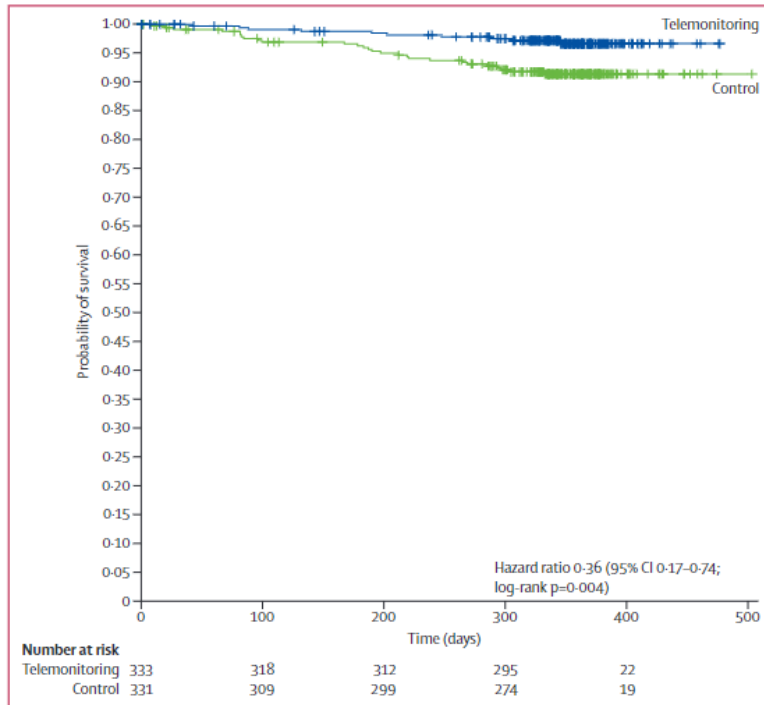


Figure 2: Kaplan-Meier curves of patient survival

	Telemonitoring group (n=333)	Control group (n=331)	p value
Worsened	63 (18.9%)	90 (27.2%)	0.013*
Death	10 (3.0%)	27 (8.2%)	0.004*
Overnight admission to hospital for worsening heart failure†	23 (6.9%)	27 (8.2%)	..
Worsened NYHA functional class and global self-assessment	0 (0.0%)	1 (0.3%)	..
Worsened NYHA functional class only	23 (6.9%)	31 (9.4%)	..
Worsened global self-assessment only	7 (2.1%)	4 (1.2%)	..
Improved‡	111 (33.3%)	105 (31.7%)	..
Unchanged	159 (47.8%)	136 (41.1%)	..

Hindricks, et al. *Lancet* (2014) 384, 583-590



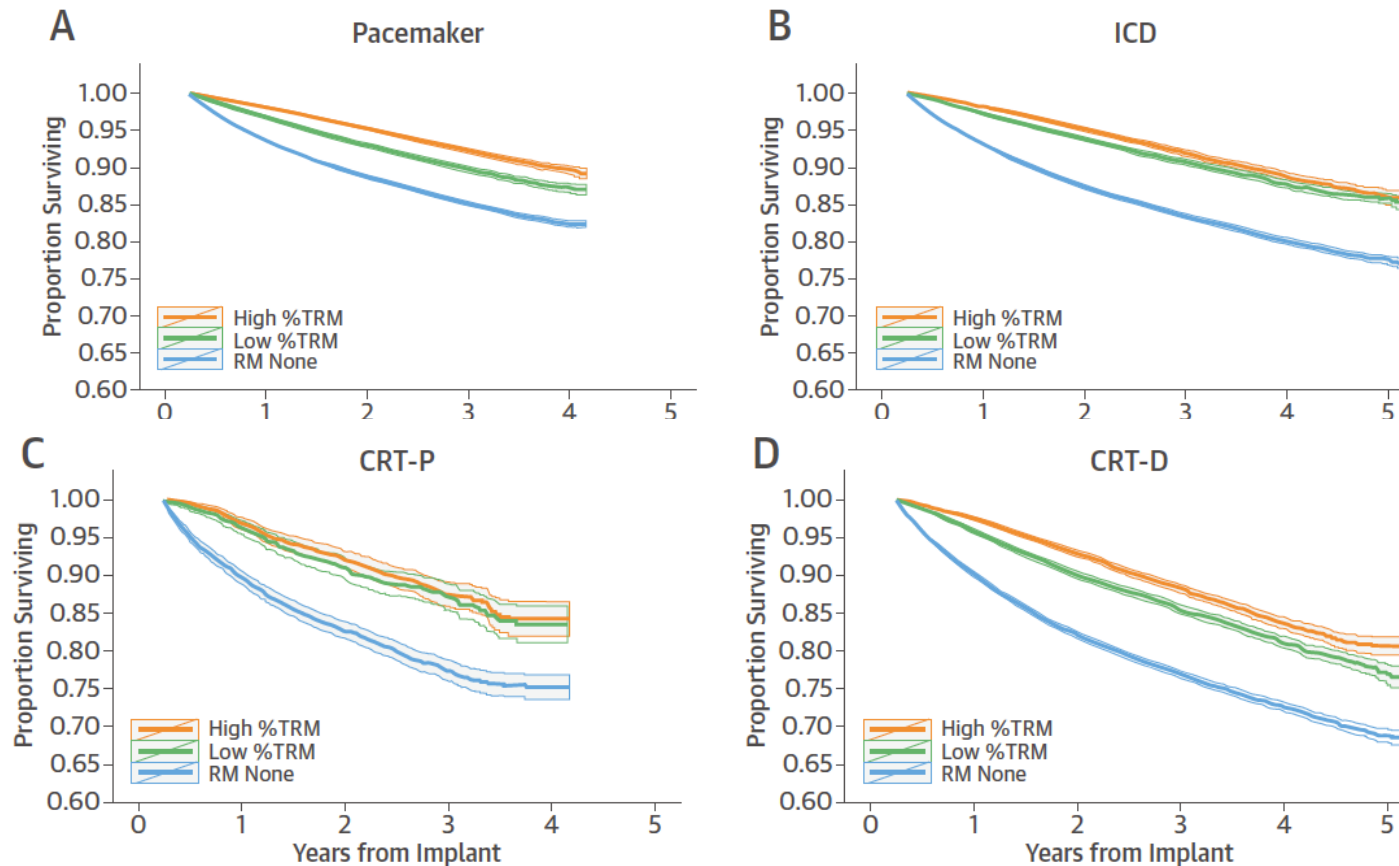
# Evidence about Remote monitoring

## 1. Survival benefit ??

A retrospective data using the U.S. St. Jude market registry

enrolling 269,471 PM/ICD/CRT patients

Adherence to RM → Improved survival irrespectively of CIED type



# Evidence about Remote monitoring

## 2. Reduction of frequency of in-office visit

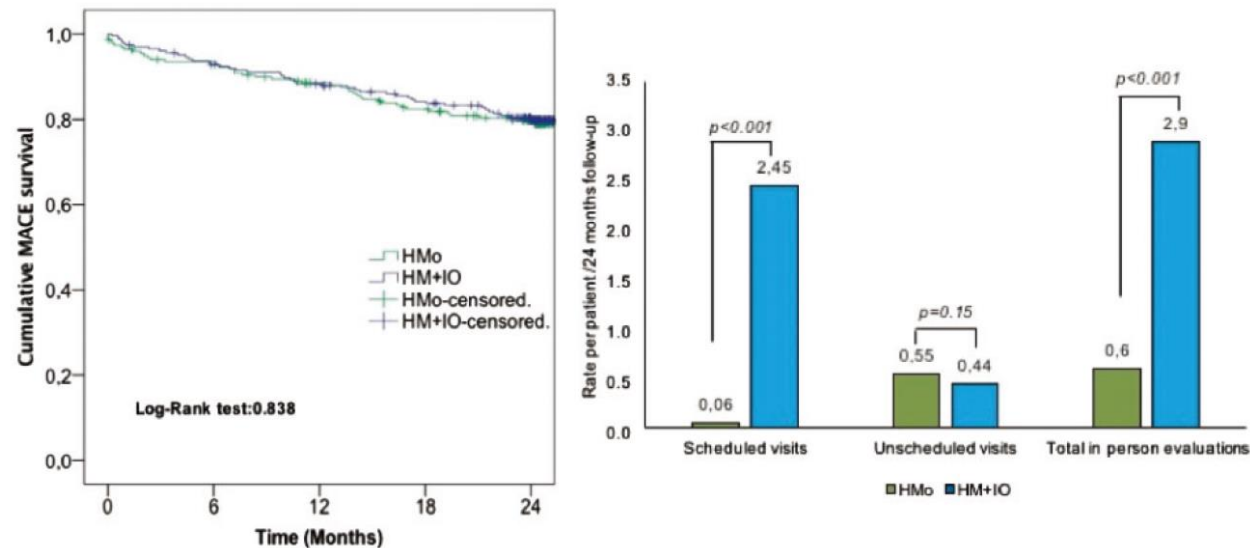
RM-ALONE trial enrolling 294 PMs and 151 ICDs

including patients PM-dependent and 2ndary prevention

Remote interrogation vs. In-office interrogation (every 6 months)

: non-inferior in MACE risk and reduced hospital visits and staff workload.

(Death + Stroke + Hospitalization due to cardiac cause or device + Device-related surgical intervention)



Garcia-Fernandez et al. *European Heart Journal* (2019) 40, 1837–1846

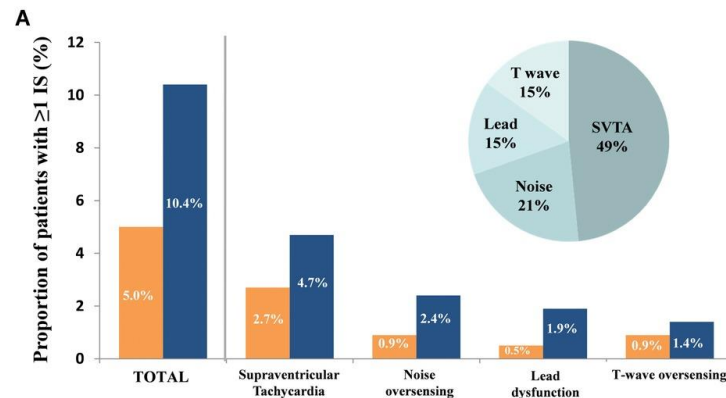


# Evidence about Remote monitoring

## 3. Reduction of inappropriate shock

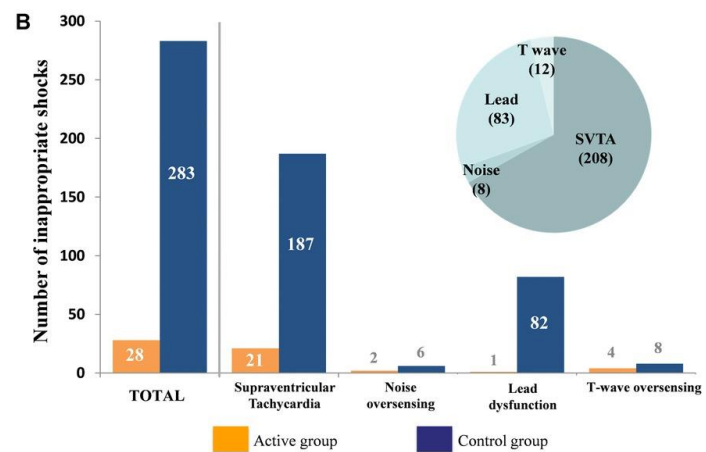
ECOST trial enrolling 433 ICDs

RM (once a year visit) vs. ambulatory (every 6 months visit)



- Over a follow-up of 27 months,  $\geq 1$  inappropriate shock happened in **5.0%** of patients in the **RM** group vs. **10.4%** in the **ambulatory** group ( $P = 0.03$ )

- In particular, the vigorous treatment of SVT and meticulous programming of the devices



Gu'edon-Moreau et al. JCE 2014;25:763-770



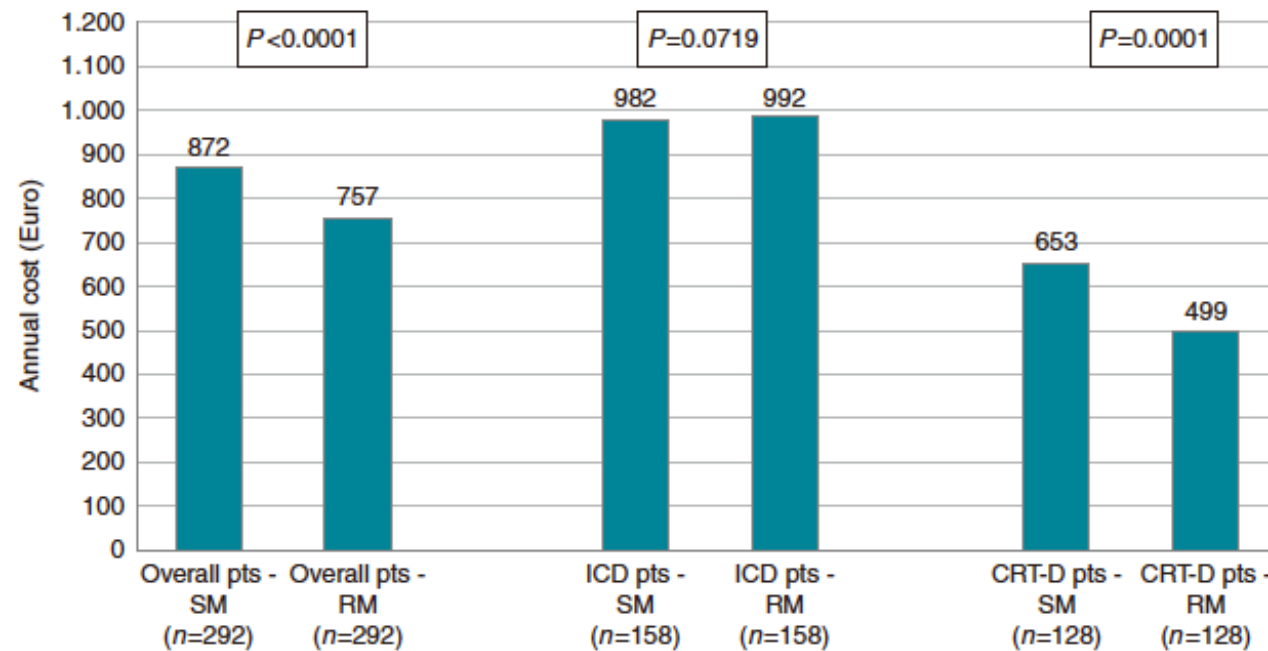


# Evidence about Remote monitoring

## 4. Economic effect

Economic evaluation of the results of EFFECT : a multi-centre trial from Europe

→ RM produces **lower costs for the healthcare service** in a real-world cohort of HF, especially with CRT-D



Capucci, et al. *Europace* (2017) 19, 1493–1499



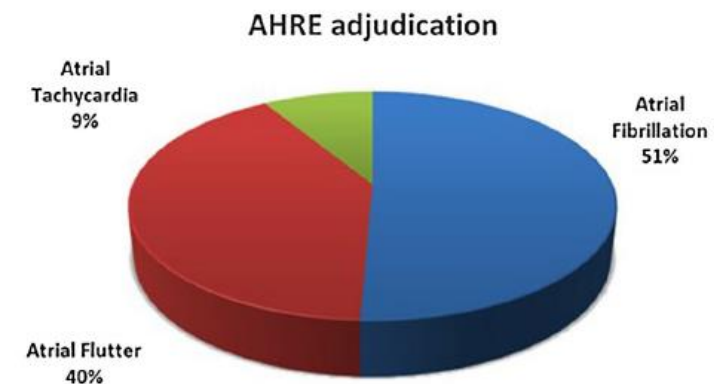
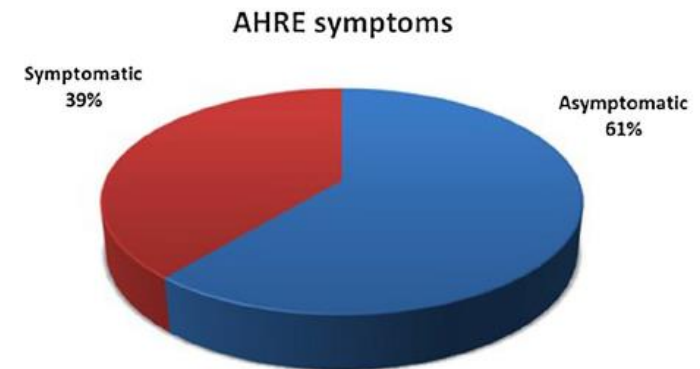
# Evidence about Remote monitoring

## 5. Arrhythmia detection

**RM (RM-ON group; N = 64) : 1 and 18 months in-office visits**

**vs. Conventional in-office visits (RM-OFF group; N = 33) : 1, 6, 12, and 18 months in-office visits**

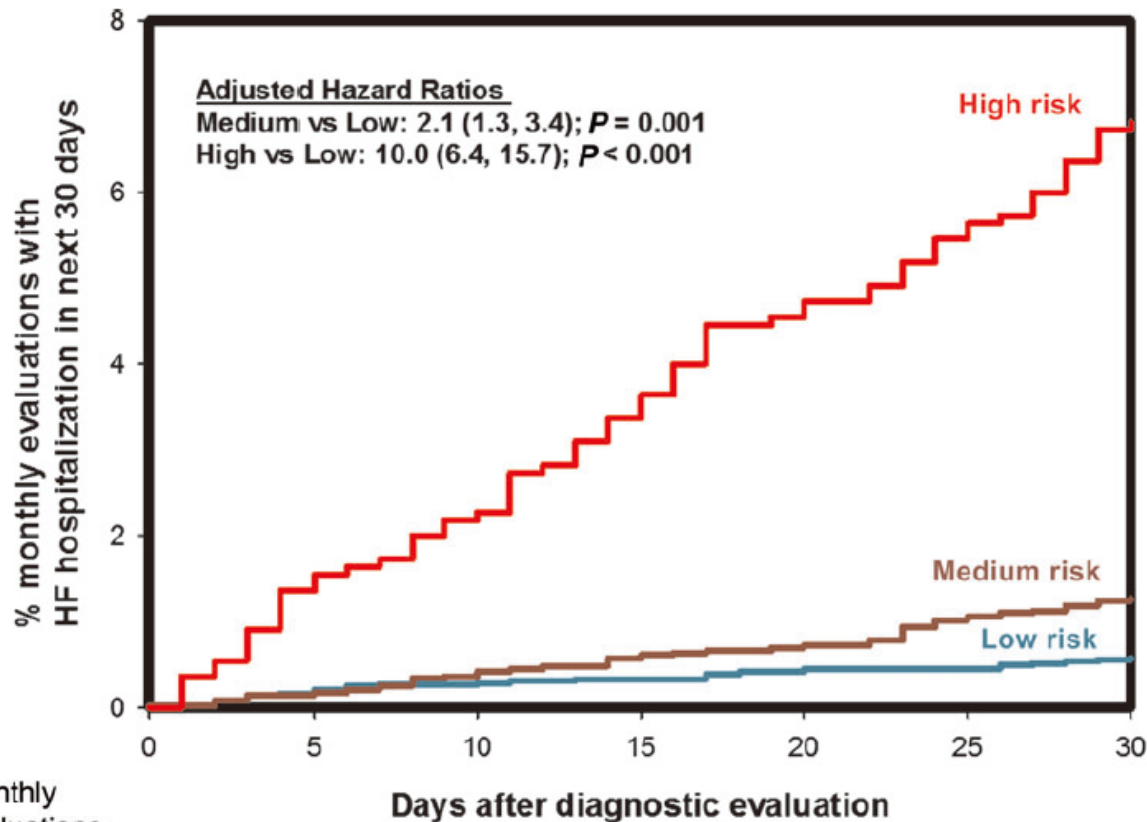
	RM-ON	RM-OFF	<i>p</i> <sup>a</sup>
<b>AHRE evaluation delay (days)</b>			
All episodes			
No. of episodes	155	84	
Evaluation delay (days)	2 (2-4)	81 (23-103)	<.0001
		<b>79 days of delay</b>	
<b>Actionable episodes</b>			
No. of episodes (%)	23 (15%)	10 (12%)	
Evaluation delay (days)	3 (2-4)	80 (53-150)	<.0001
<b>AHRE &gt;1 h</b>			
No. of episodes (%)	54 (35%)	12 (14%)	
Evaluation delay (days)	2 (2-3)	103 (38-156)	<.0001
<b>AHRE &gt;6 h</b>			
No. of episodes (%)	25 (16%)	1 (1%)	
Evaluation delay (days)	2 (2-3)	121 (121-121)	.04 <sup>b</sup>



# Evidence about Remote monitoring

## 6. Prediction of the risk for HF hospitalization

### TRIAGEHF from Medtronic ICDs



The risk status reported for the patient for the **next 30 days** is based on the maximum daily risk status for the **previous 30 days**.

Monthly evaluations at risk

High risk	1100	1085	1076	1063	1050	1040	1026
Medium risk	4717	4710	4700	4690	4684	4669	4658
Low risk	4838	4830	4825	4822	4818	4816	4811

Cowie, et al. *European Heart Journal* (2013) 34, 2472–248



# Evidence about Remote monitoring: Summary

## 1. Survival benefit ?

Addition of RM → Survival benefit in ICD patients (IN-TIME trial)

## 2. Reduction of frequency of in-office visit

Up to 24 months of interval for PM is safe

## 3. Reduction of inappropriate shocks

53% reduction in inappropriate shocks (ECOST trial)

## 4. Economic effect

Reduction in health-care costs

## 5. Arrhythmia detection

79 days of earlier detection

## 6. Prediction of the risk for HF hospitalization

High risk group : x10 HFH risk

Low risk group : 94% of NPV



# Recommendations from current guidelines

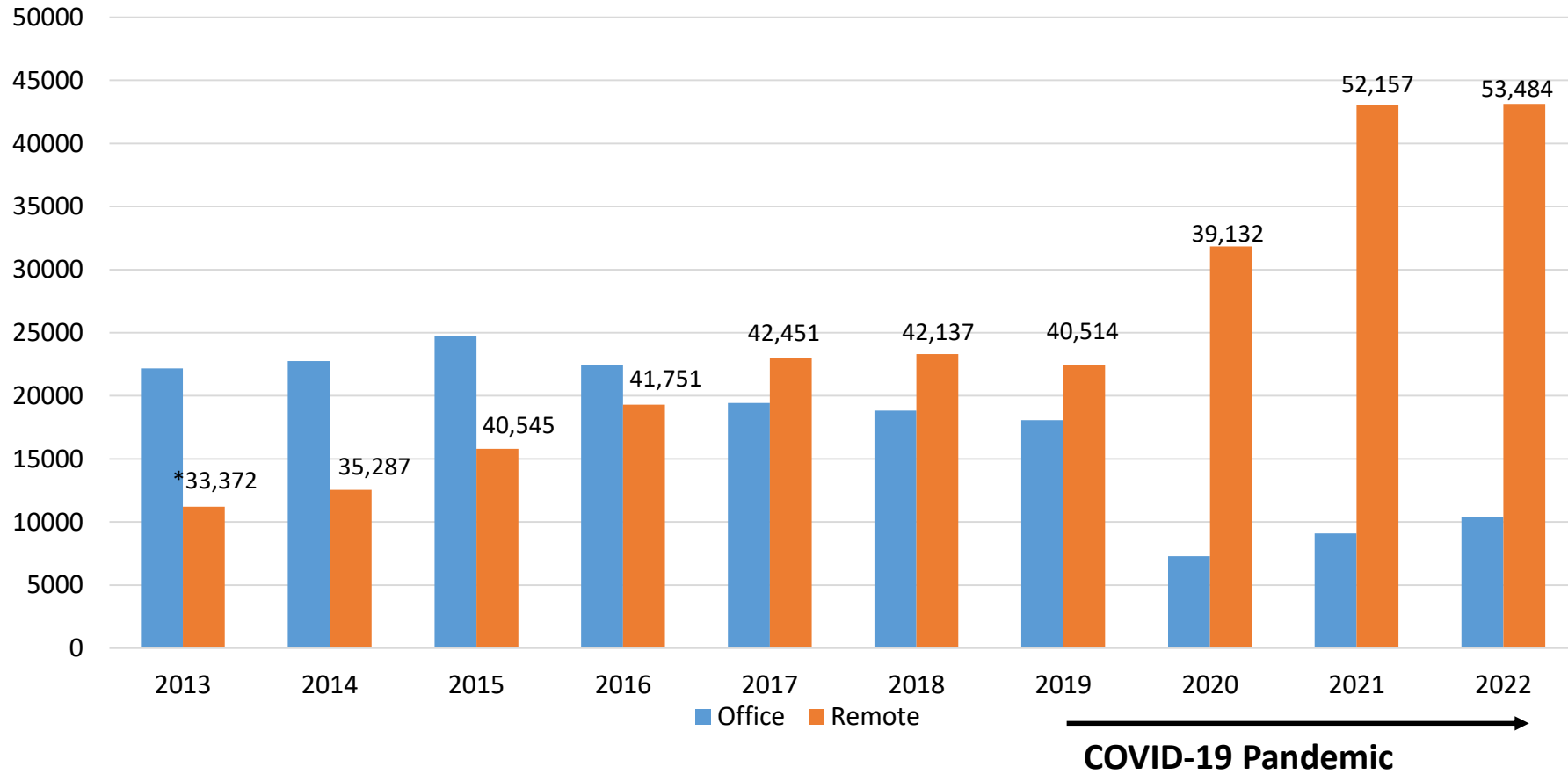
Recommendations	PM	Class <sup>a</sup>	Level <sup>b</sup>
Remote device management is recommended to <u>reduce the number of in-office follow-ups</u> in patients with pacemakers who have difficulties to attend in-office visits (e.g. due to reduced mobility or other commitments, or according to patient preference). <sup>805,806,809</sup>		I	A
Remote monitoring is recommended in the case of a device component that <u>has been recalled or is on advisory, to enable early detection of actionable events</u> in patients, particularly those who are at increased risk (e.g. in the case of pacemaker dependency).		I	C
In-office routine follow-up of single- and dual-chamber pacemakers may be spaced by up to <u>24 months</u> in patients on remote device management. <sup>805,806</sup>		IIa	A
Remote device management of pacemakers should be considered in order to provide <u>earlier detection of clinical problems (e.g. arrhythmias) or technical issues (e.g. lead failure or battery depletion)</u> . <sup>806,810</sup>		IIa	B

Recommendations	ICD	Class <sup>a</sup>	Level <sup>b</sup>
Remote monitoring is recommended to <u>reduce the incidence of inappropriate shocks</u> . <sup>395</sup>		I	B

	In-office only	In-office + remote
All devices	Within 72 h and 2–12 weeks after implantation	In-office within 72 h and 2–12 weeks after implantation
CRT-P or HBP	Every 6 months	Remote every 6 months and in-office every 12 months <sup>a</sup>
Single/dual-chamber	Every 12 months then every 3-6 months at signs of battery depletion	Remote every 6 months and in-office every 18-24 months <sup>a</sup>



# Current status of remote monitoring in U.S



Figures in courtesy of Rohit Mehta



# BENEFIT-RM Trial : Overview

## Economic and Clinical Benefit of Remote Monitoring among Defibrillator Patients by Indication Subgroups (BENEFIT-RM) trial

- **Multicenter (10 sites), prospective randomized controlled trial in South Korea**

- **Study perspectives**

To compare **economic** and **clinical benefits of remote monitoring** in overall and by different subgroups.

- **Eligibility criteria**

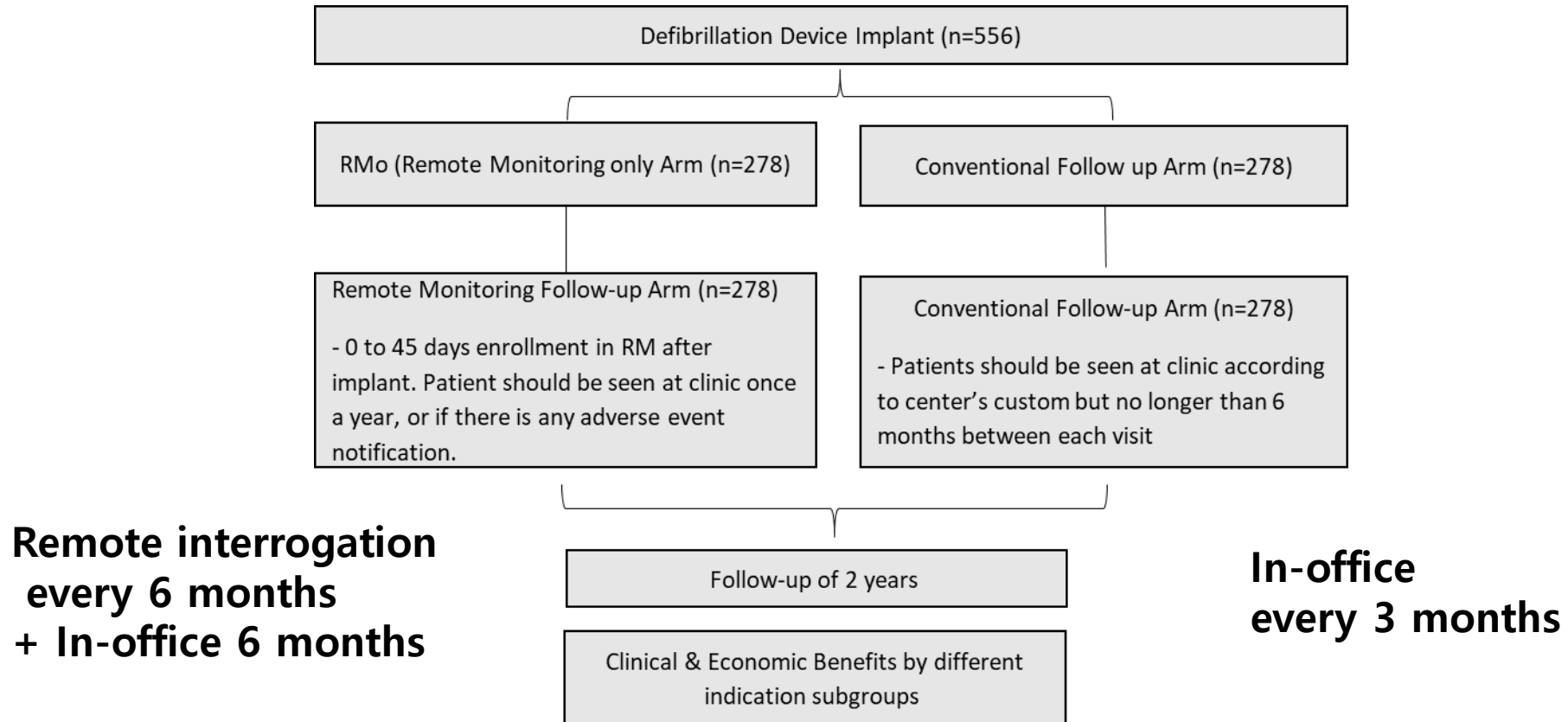
**All ICD and CRT-D** patients who are over the age of 18

- **Randomization**

0 to 45 days after successful device implantation



# BENEFIT-RM Trial : Study Flow





# Remote Monitoring System

## Merlin.net

- Gallant ICD & CRTD
- Confirm Rx ILR
- Daily Alert and Patient Initiated Alert are automatically transmitted to the **Merlin.net Remote Monitoring System**

Clinic Patients ▾ All ▾  Archive Print More Actions ▾

Patient	Transmission	Schedule	Device	DirectAlerts™	Alerts List	Latest Comments	
	2022-11-03,09:56 AM Patient initiated	2022-11-21 18 days	Confirm Rx™ ICM, DM3500 : 6483125			2022.10.25/임지은/ 이상무	<input type="checkbox"/>
	2022-11-03,07:41 AM Patient initiated	None	Confirm Rx™ ICM, DM3500 : 6438372		Continuous AF; Tachy Episode; High V.Rate during AF; AF Burden; AF Episode;	2022.11.3/김선운/ 이상무	<input type="checkbox"/>
	2022-11-03,06:38 AM Patient initiated	None	Gallant™ HF, CDHFA500Q : 111003974			2022.11.3/김선운/ 이상무	<input type="checkbox"/>
	2022-11-03,03:17 AM Alert initiated	None	Gallant™ DR, CDDRA500Q : 810012071		Non-sustained VT/VF; Tachy Episodes:41	2022.11.3/김선운/ 이상무	<input type="checkbox"/>
	2022-11-03,02:02 AM Alert initiated	None	Gallant™ DR, CDDRA500Q : 810022232		AT/AF burden; ATP successful; Tachy Episodes:1	2022.11.3/김선운/ 이상무	<input type="checkbox"/>
	2022-11-03,02:01 AM Alert initiated	None	Gallant™ HF, CDHFA500Q : 810012843		AT/AF burden; AT/AF duration;	2022.11.3/김선운/ 이상무	<input type="checkbox"/>
	2022-11-03,02:00 AM Alert initiated	None	Gallant™ DR, CDDRA500Q : 111022317		AT/AF burden; AT/AF duration; A sense threshold;	2022.11.3/김선운/ 이상무	<input type="checkbox"/>
	2022-11-03,02:00 AM Alert initiated	None	Gallant™ DR, CDDRA500Q : 810007689		AT/AF burden; AT/AF duration;	2022.11.3/김선운/ 이상무	<input type="checkbox"/>
	2022-11-02,11:29 AM Patient initiated	None	Gallant™ HF, CDHFA500Q : 111003974			2022.11.3/김선운/ 이상무	<input type="checkbox"/>
	2022-11-02,02:09 AM Alert initiated	None	Gallant™ DR, CDDRA500Q : 810022232		AT/AF burden; ATP successful; Tachy Episodes:1	2022.11.3/김선운/ 이상무	<input type="checkbox"/>
	2022-11-02,02:05 AM Scheduled	2022-11-02 ---	Confirm Rx™ ICM, DM3500 : 6312907		Continuous AF; AF Episode;	2022.11.2/김선운/ 이전양상과유사	<input type="checkbox"/>
	2022-11-02,02:02 AM Alert initiated	None	Gallant™ DR, CDDRA500Q : 810007689		AT/AF burden; AT/AF duration;	2022.11.3/김선운/ 이상무	<input type="checkbox"/>



# BENEFIT-RM Trial : Outcomes

- **Primary outcome : Major adverse events**
  1. fatal or life-threatening
  2. prompted or prolonged a hospitalization
  3. caused major or permanent disability or injury
  4. required an intervention to prevent permanent disability or injury
- **Secondary outcomes**
  - Device-related adverse events
  - Economic Benefits : Hospitalization Cost per year / Length of stay (days) per year
  - Clinical Benefits
    1. Number of days of earlier intervention including reprogramming of device, medication change, lead/generator changes
    2. Number of **adverse events detected earlier** than regular follow-up date
    3. Mortality rate after 2 years follow-up



# BENEFIT-RM Trial : When to complete?

- 476 of 566 (planned) (82.6%) have been enrolled.
- Expected to complete the enrollment at the second half of 2023 and to be completed finally at the end of 2025.



# Summary

- **Remote device monitoring is recommended (Class I for PM and ICD)**  
to **reduce the number of in-office follow-ups for PM (Class I)**  
In-office visits may be spaced **24 months (PM) / 12 months (CRT-P) (Class IIa)**  
  
to enable **early detection of actionable events** in patients with **recalled devices (Class I)**  
to provide earlier detection of clinical problems (**e.g. arrhythmias**)  
or **technical issues** (e.g. lead failure or battery depletion) (Class IIa)  
  
to reduce **the incidence of inappropriate shocks for ICD (Class I)**
- Due to the problem of approval and reimbursement, **remote monitoring has been underused in Korea.**
- As the **first RCT** regarding clinical and economic outcomes of remote monitoring,  
the **REMOTE-RM Trial** is nearing completion of enrollment.



**Thank you for your attention!**

