



BRS & DES: Current Status, Future Perspectives, Data, Practical Tips and Tricks

# Updated BRS Data Trials and Registries

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# Disclosure Statement of Financial Interest

Within the past 12 months, I, **Davide Capodanno**, have had a financial interest/arrangement or affiliation with the organization(s) listed below.

## Affiliation/Financial relationship

## Company

- **Speakers' honoraria**

None

- **Consulting**

Abbott Vascular (VHD branch)

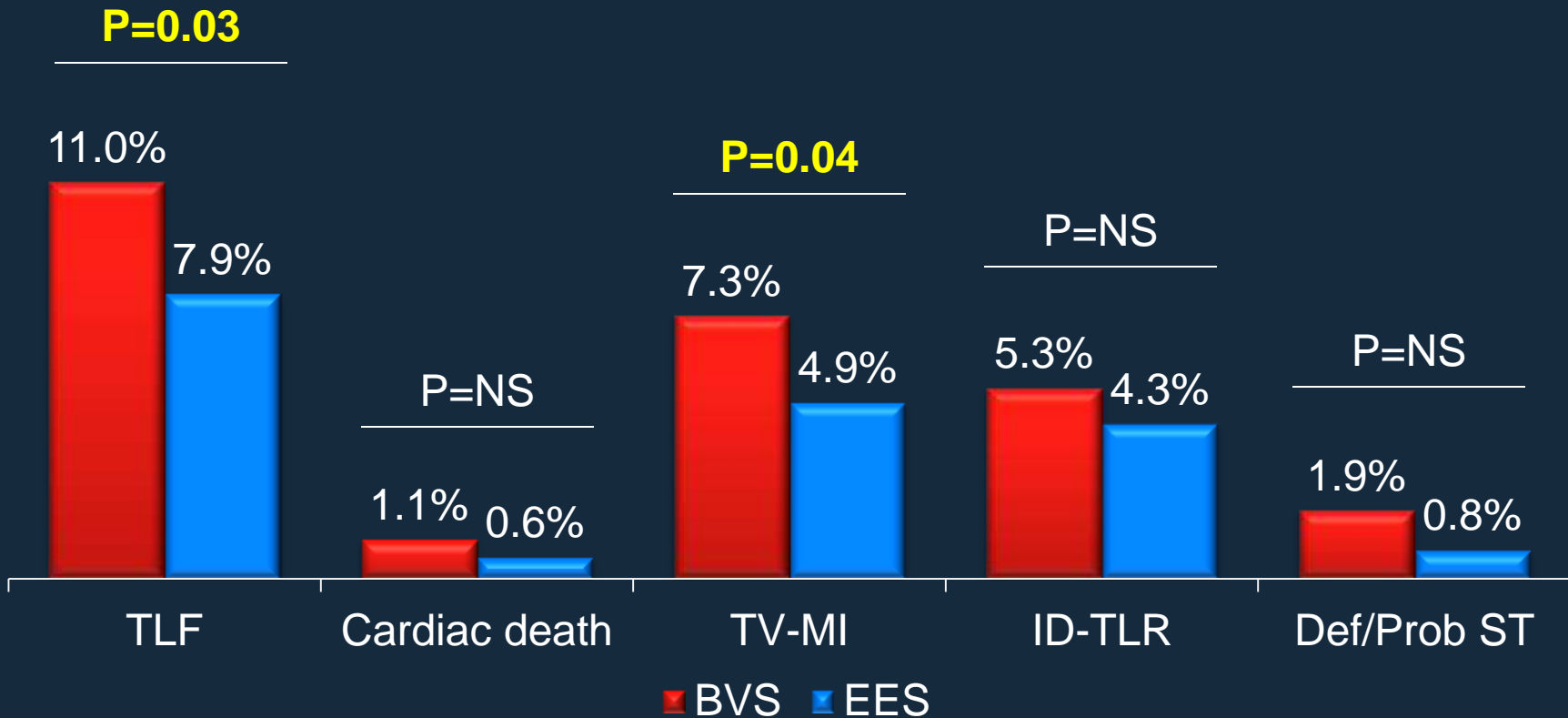
- **Advisory Board**

None

# ABSORB III - 2-Year Outcomes

2,008 patients with CAD undergoing PCI randomized 2:1 to BVS or EES

ACC 2017



# Dear Cardiovascular Specialists and Interventional Cardiologists...

## FDA letter to health care providers (March 18, 2017)

### The FDA recommends that health care providers:

- Follow the instructions for target heart vessel selection (e.g., avoiding BVS use in small heart vessels) and optimal device implantation that are included in the BVS physician labeling.
- Advise patients experiencing any new cardiac symptoms such as irregular heartbeats, chest pain, or shortness of breath to seek clinical care. For more information about risks associated with the BVS, refer to the BVS physician labeling.
- Advise BVS patients to follow the recommendations for DAPT prescribed by their health care providers.
- Report any adverse events related to the BVS that come to your attention. If you suspect a problem with the BVS, we encourage you to file a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting Program. Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.

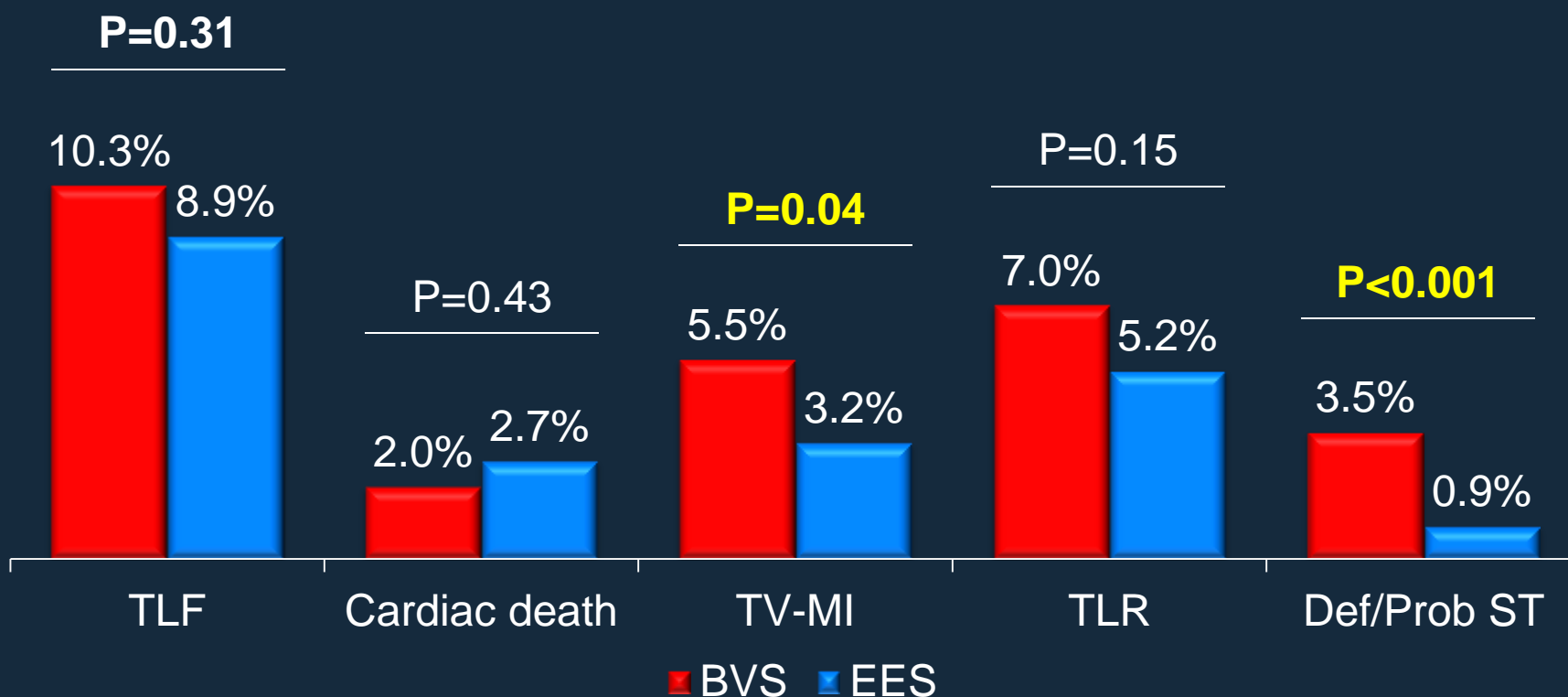
# Dear Cardiovascular Specialists and Interventional Cardiologists... / 2

## Manufacturer Remarks on ABSORB III

- ① No statistically significant difference in TLF at 2 years in vessels  $\geq 2.25$  mm by QCA, consistent with IFUs
- ② No PSP in the 4 new scaffold thrombosis cases reported between 1 and 2 years
- ③ Only 8% of patients received full PSP, but they had event rates comparable to patients who received Xience EES
- ④ Blinded, pooled, interim results from ABSORB IV (4% of patients with vessels  $< 2.25$  mm by QCA, 84% of post-dilation in the BVS arm) suggest 0.4% ST at 30 days and 0.5% at 1 year

# AIDA – Interim 2-Year Outcomes

1,845 patients with CAD undergoing PCI randomized 1:1 to BVS or EES



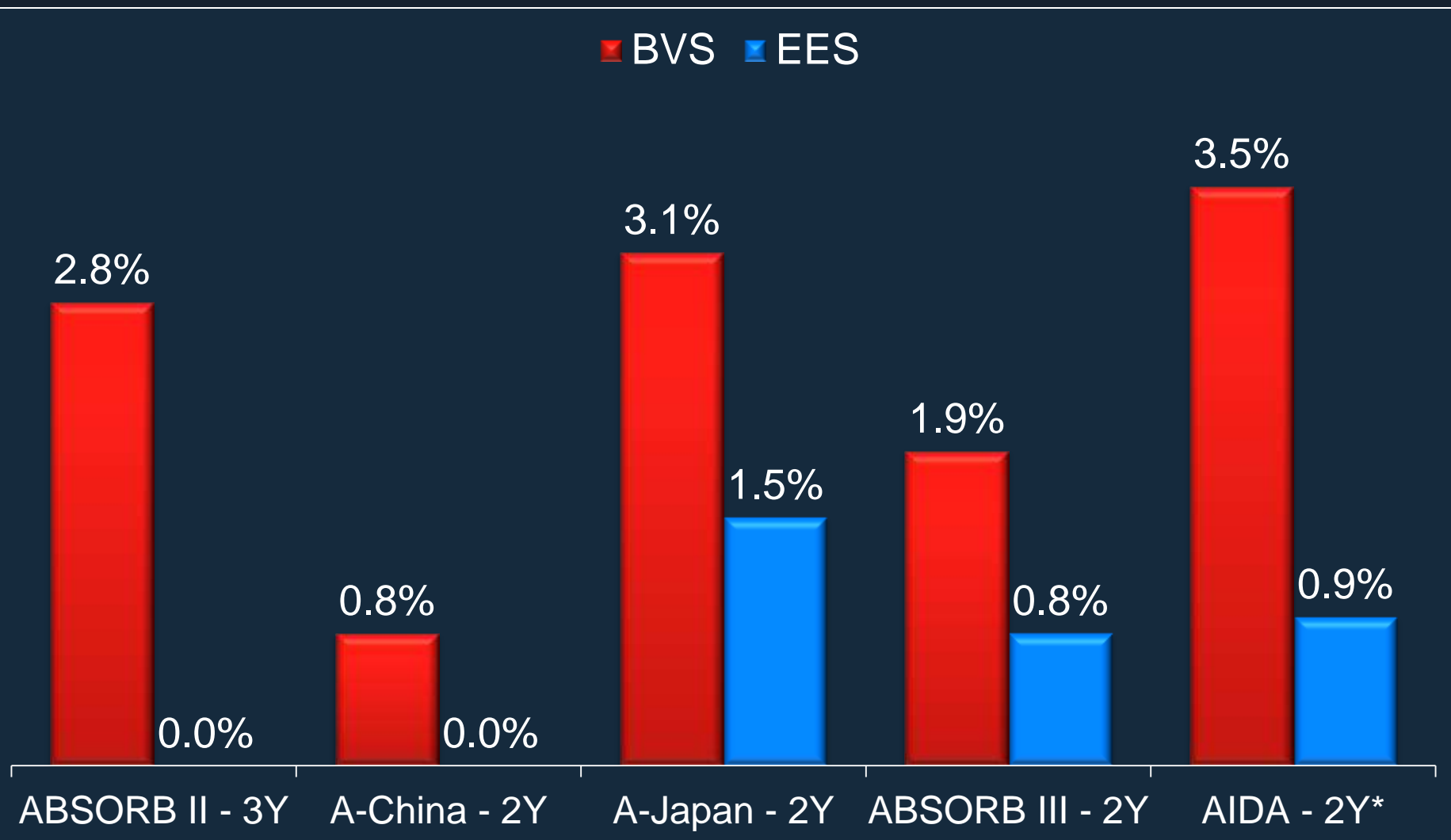
# Dear Cardiovascular Specialists and Interventional Cardiologists... / 3

## Manufacturer Urgent Physician Advisory

- ★ “Effective May 31, 2017, the device will only be available for use in clinical registry setting until summer 2018 at which time the situation will be reassessed with the authorities. Note that sites not enrolling patients in a study will not receive shipments as of March 31<sup>st</sup>, 2017.”

# BVS vs. EES Thrombosis (Absolute Risks)

Definite or probable thrombosis from 0 to 2-3 yrs in ABSORB RCTs

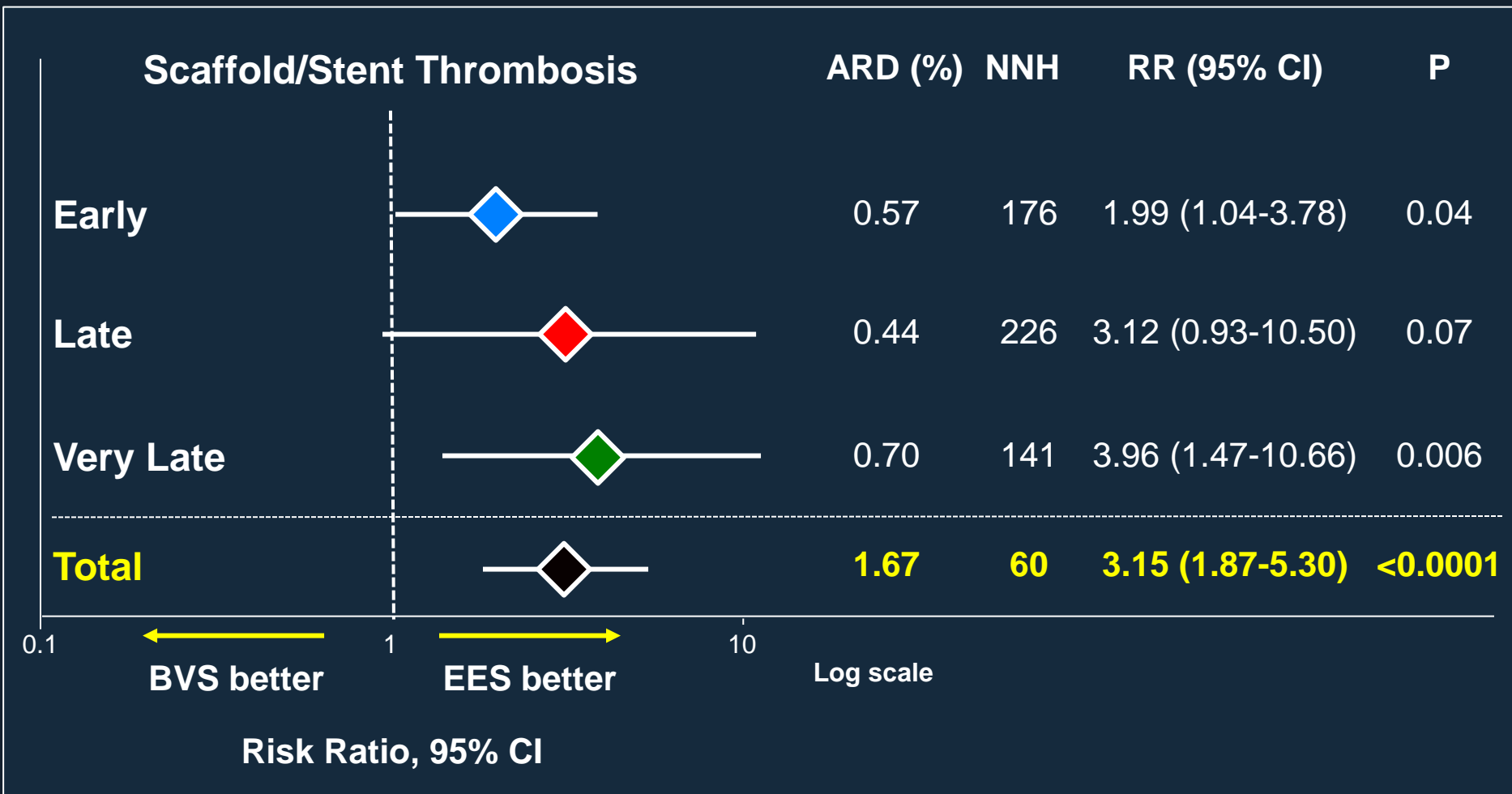


\*Follow up of AIDA is incomplete (median 707 days)



# BVS vs. EES Thrombosis (Relative Risk)

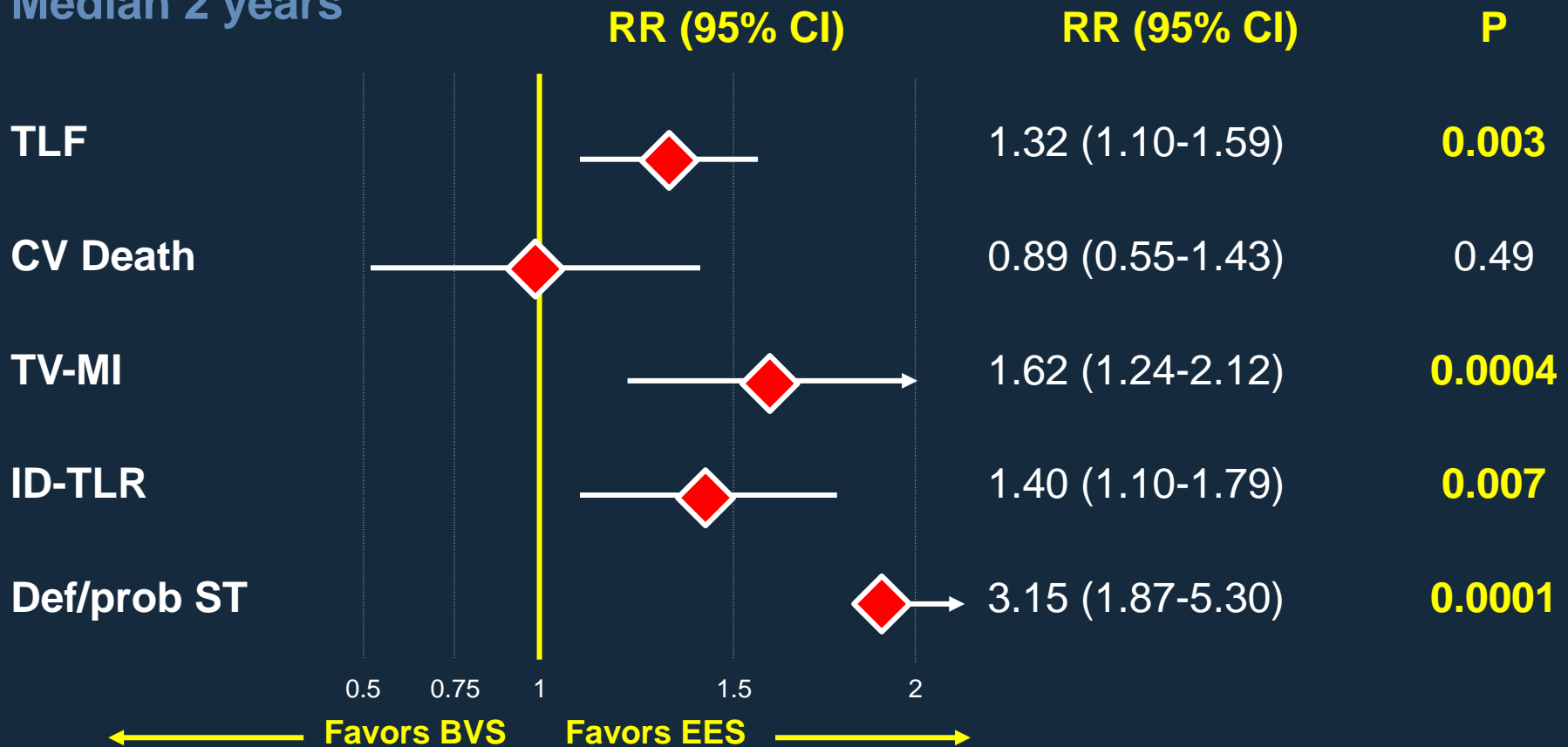
Meta-analysis of 5,584 patients from 7 RCTs (ABSORB II, ABSORB China, ABSORB Japan, ABSORB III, EVERBIO II, TROFI II, AIDA)



# Outcomes of BVS vs. EES (Relative Risks)

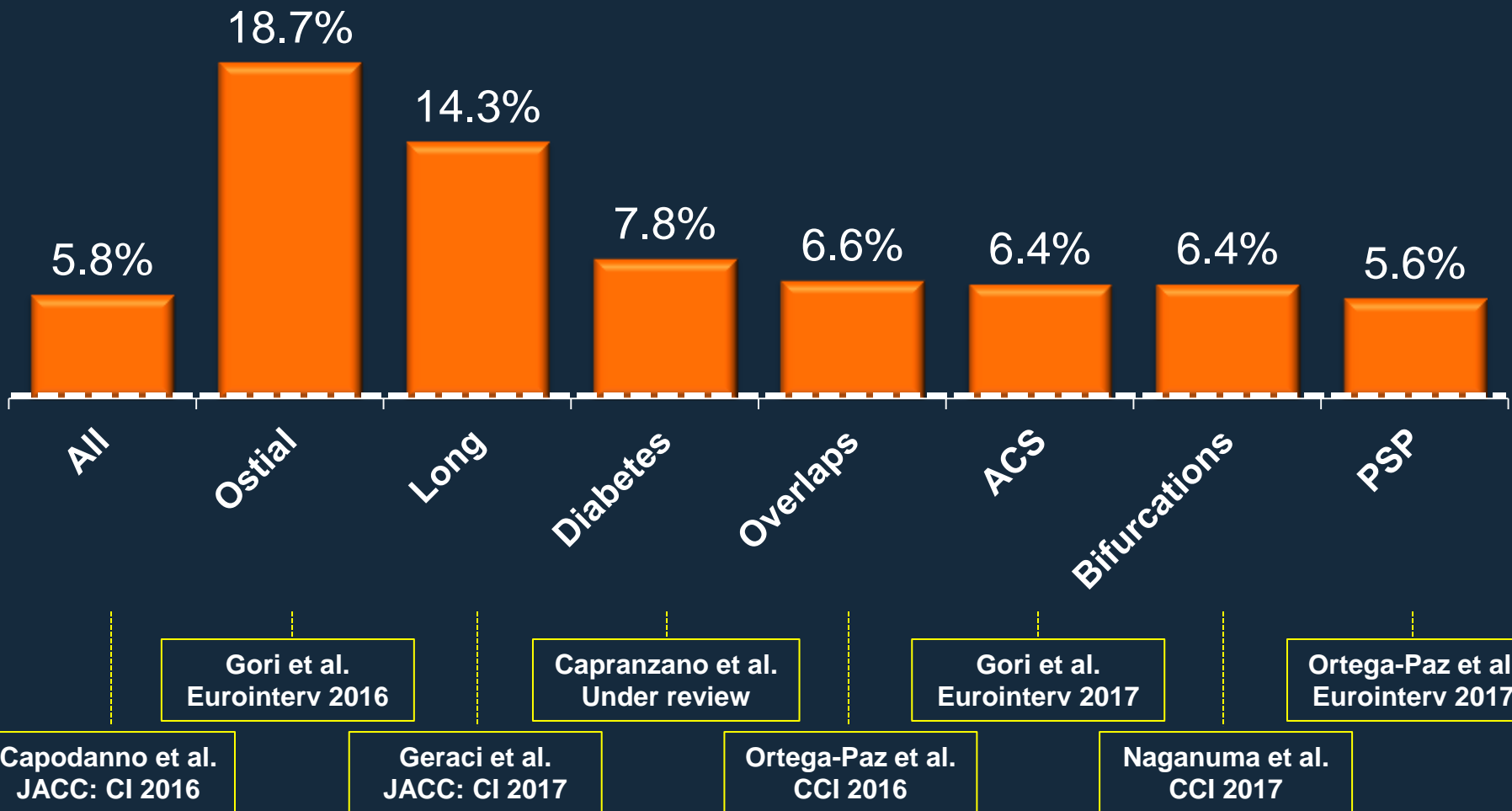
Meta-analysis of 5,584 patients from 7 RCTs (ABSORB II, ABSORB China, ABSORB Japan, ABSORB III, EVERBIO II, TROFI II, AIDA)

Median 2 years



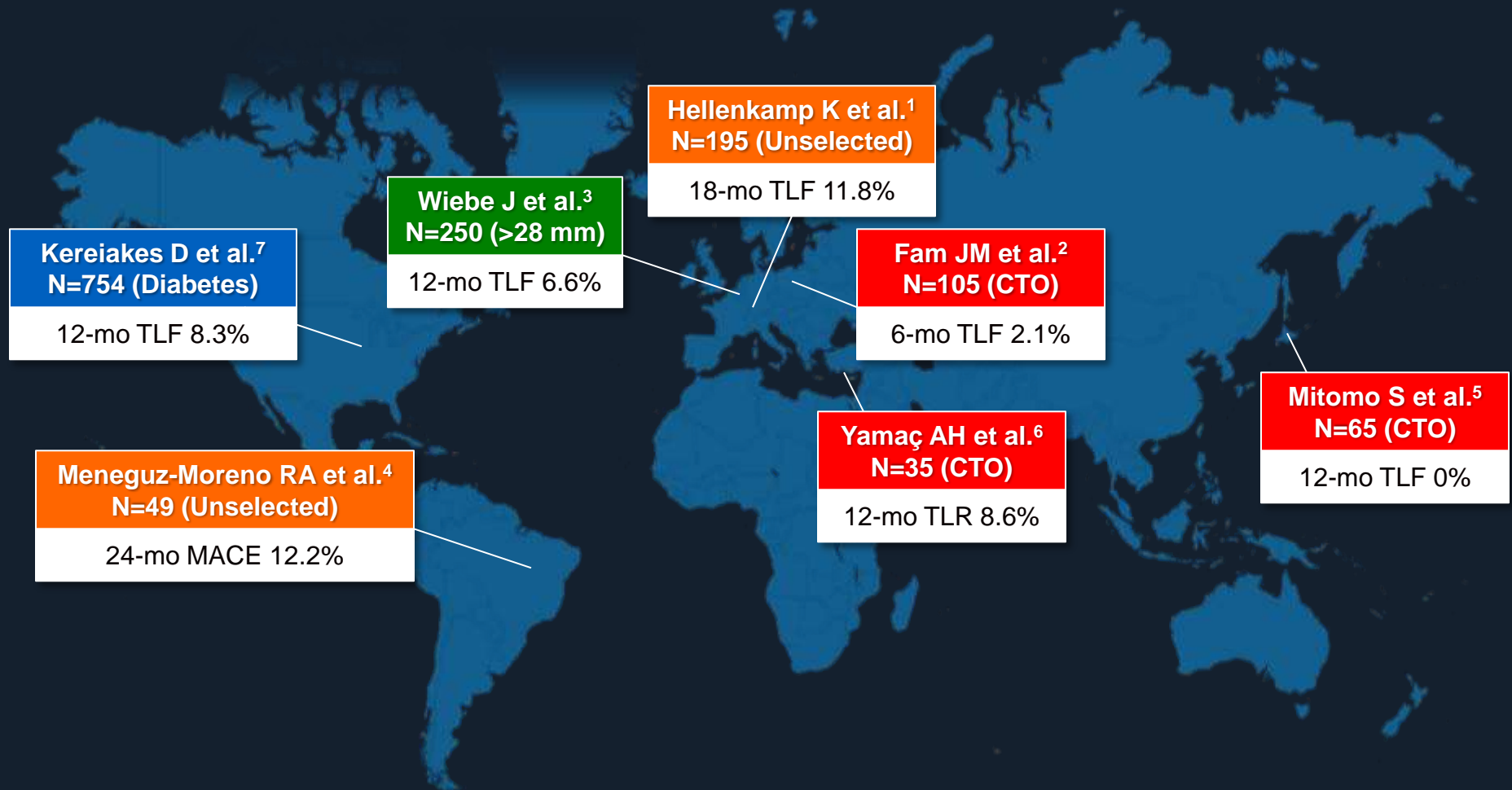
# GHOST-EU and Substudies

## Target lesion failure at 12 months



# Other Registry Data of BVS in 2017

■ Diabetes   
 ■ Long lesions   
 ■ CTOs   
 ■ Unselected



<sup>1</sup>Int J Cardiol. 2017 May 1;234:58-63; <sup>2</sup>EuroIntervention. 2017 [ePub ahead of print]; <sup>3</sup>Rev Esp Cardiol.2016;69:1144-1151; <sup>4</sup>Arq Bras Cardiol. 2017 [ePub ahead of print]; <sup>5</sup>Circ Cardiovasc Interv. 2017 [ePub ahead of print]; <sup>6</sup>Turk Kardiyol Dern Ars. 2016;44:647-655; <sup>7</sup>JACC Cardiovasc Interv. 2017;10:42-49

# Current Landscape of CE-Marked BRS

## ABSORB GT1

Bioresorbable  
vascular scaffold  
(BVS)



PLLA, everolimus-eluting  
Strut thickness 150  $\mu\text{m}$ ,  
coat thickness 3  $\mu\text{m}/\text{side}$

Full mass loss at  
approximately 3 years

CE mark in October 2011

## DESsolve

Bioresorbable  
coronary scaffold  
(BCS)



PLLA, novolimus-eluting  
Strut thickness 150  $\mu\text{m}$ ,  
coat thickness <3  $\mu\text{m}/\text{side}$

Full mass loss at  
approximately 1 year

CE mark in May 2014

## ART

Pure bioresorbable  
scaffold  
(PBS)



PDLLA, drug-free  
Strut thickness 170  $\mu\text{m}$ ,  
uncoated

Full mass loss at  
approximately 1 year

CE mark in May 2015

## Magmaris

Resorbable  
magnesium scaffold  
(BCS)



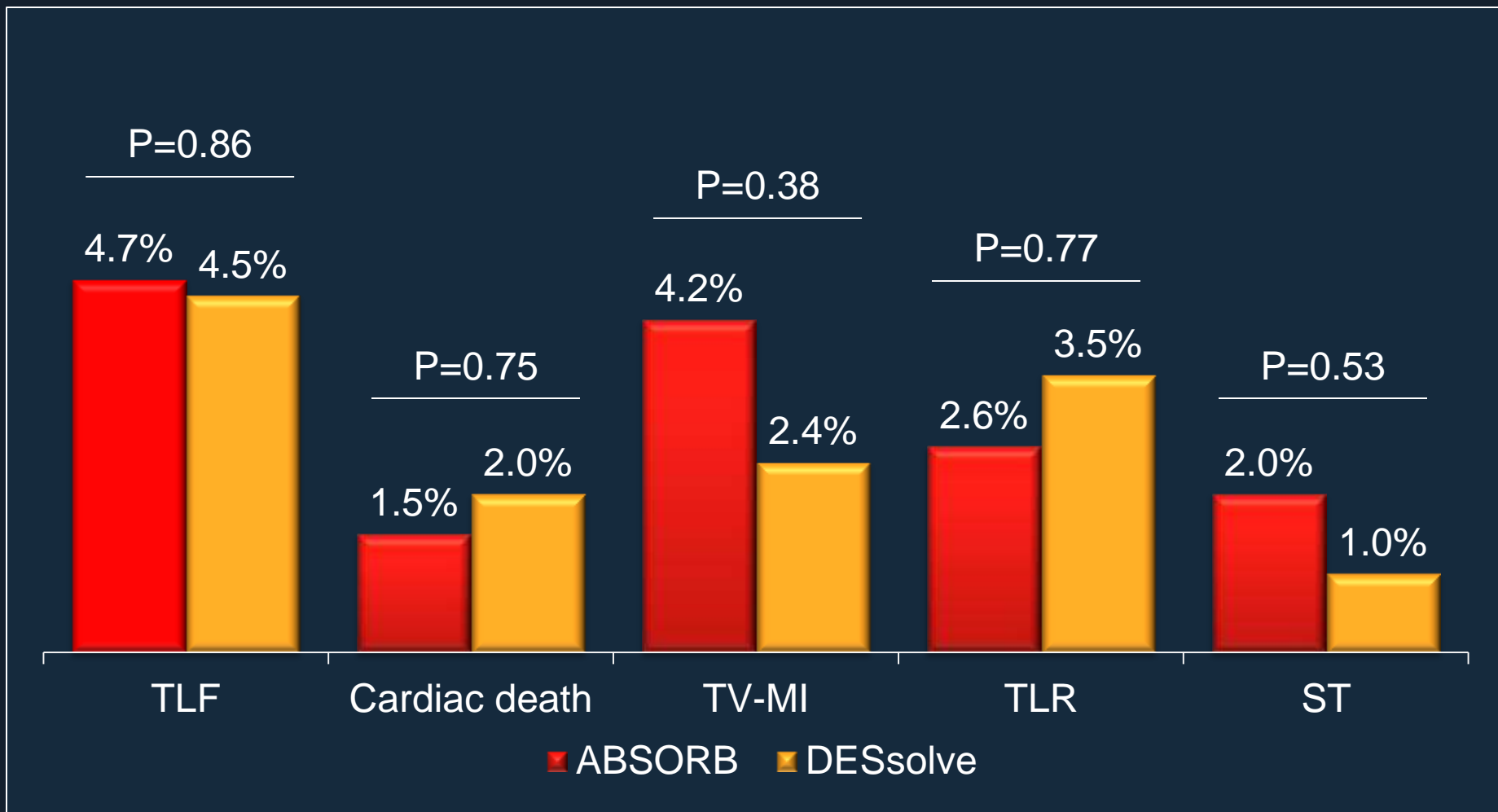
Mg, sirolimus-eluting  
Strut thickness 150  $\mu\text{m}$ ,  
coat thickness 8  $\mu\text{m}/\text{side}$

Full mass loss at  
approximately 1 year

CE mark in June 2016

# BVS vs BCS - 1-Year Outcomes

212 Absorb patients matched 2:1 with 106 DESsolve patients



# What's Next? Eyes on EuroPCR 2017



- ★ **Magmaris BRS**: Combined data of the BIOSOLVE-II and BIOSOLVE-III trials
- ★ **Aptitude BRS**: The RENASCENT II study
- ★ **DESsolve 120 $\mu$ m BRS**: 6-month clinical and imaging outcomes
- ★ **DESsolve BRS**: 4-year imaging and clinical outcomes
- ★ **Fantom BRS**: 1-year outcomes of the FANTOM II study
- ★ **MeRes 100**: 1-year clinical and multi-slice CT outcomes of the MERES-1 study
- ★ **Absorb BRS**: 3-year clinical outcomes of ABSORB China
- ★ **Absorb BRS**: 3-year clinical and angiographic outcomes of ABSORB Japan
- ★ **Absorb BRS**: Clinical outcomes from the SCAAR registry
- ★ **And more...** GABI-R, RAI, Absorb UK, IT-DISAPPEARS, France Absorb