

April 23rd 2008, Seoul

AMC TRIAS Pilot Study

RCT Genous vs TAXUS

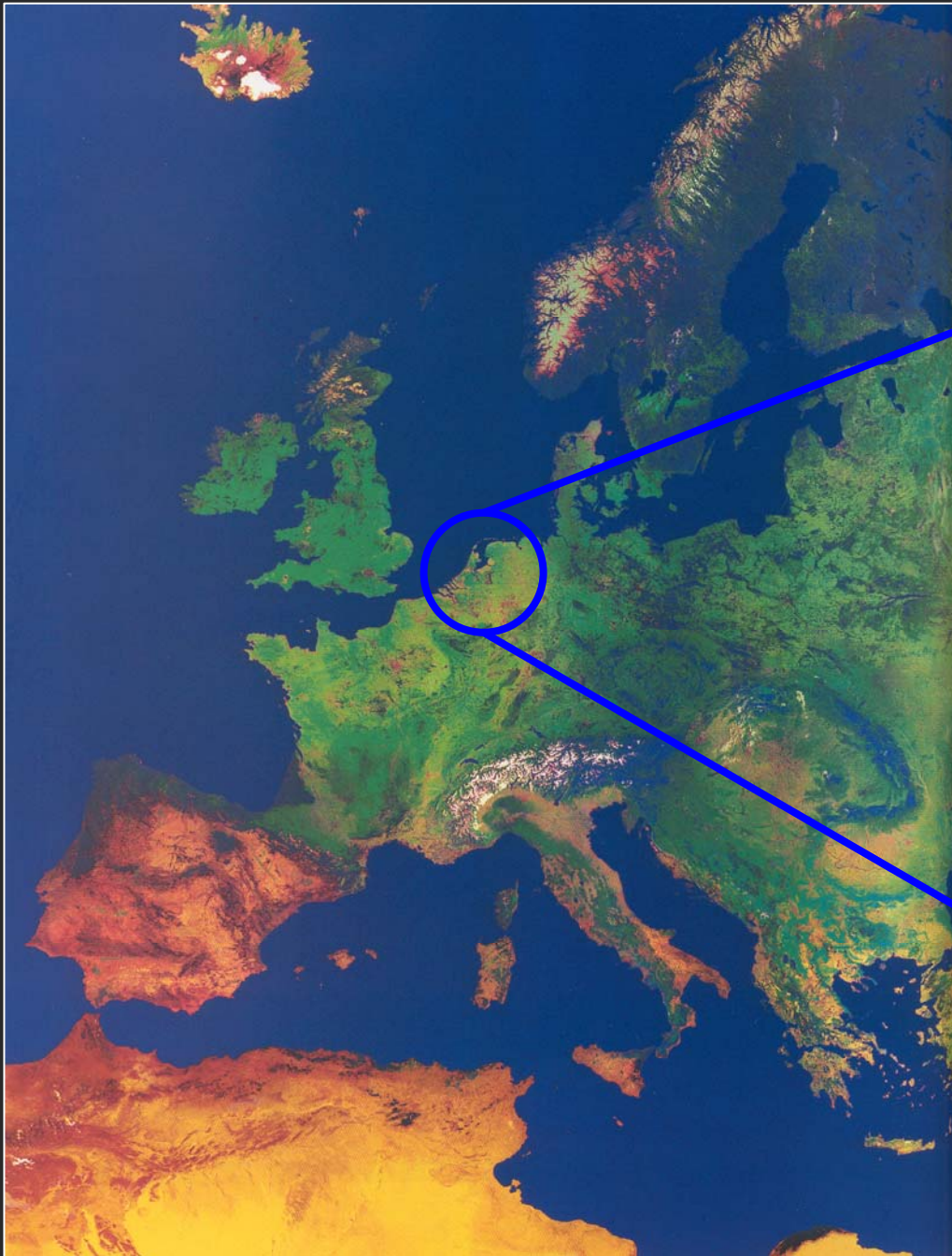
Long-term Clinical Results

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The Netherlands***

Disclosures Dr. R.J. de Winter

Grant and / or Research Support
OrbusNeich



Europe
The Netherlands
Amsterdam



Academic Medical Center, Amsterdam



DES vs BMS

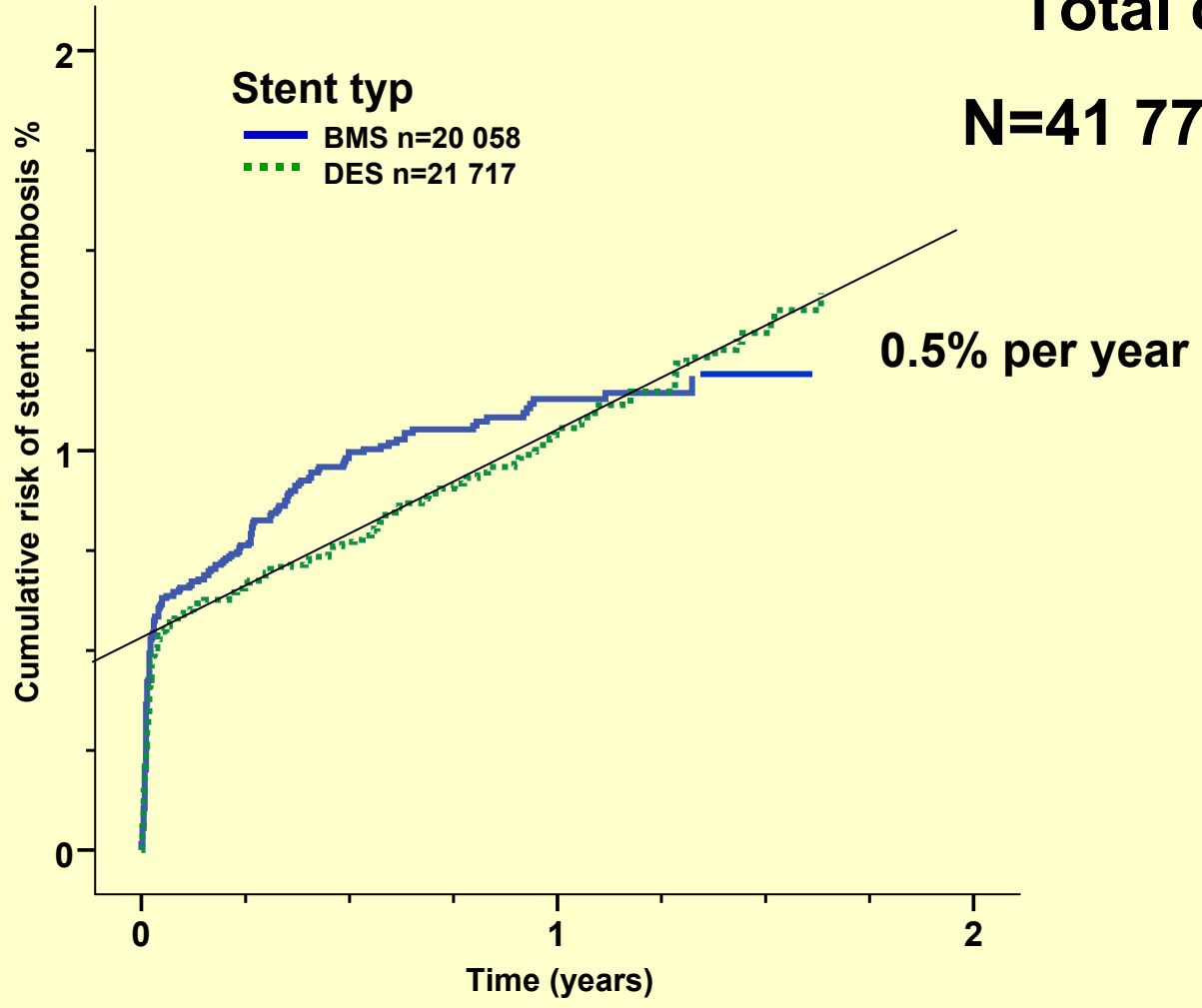
- ♥ **Long term safety concerns have diminished**
- ♥ **No clear increase in mortality with DES in RCT's, meta-analyses and large registries**
- ♥ **Late stent thrombosis is a small but real signal, no solution for dual anti-platelet**
- ♥ **We need better technologies**

Stent thrombosis

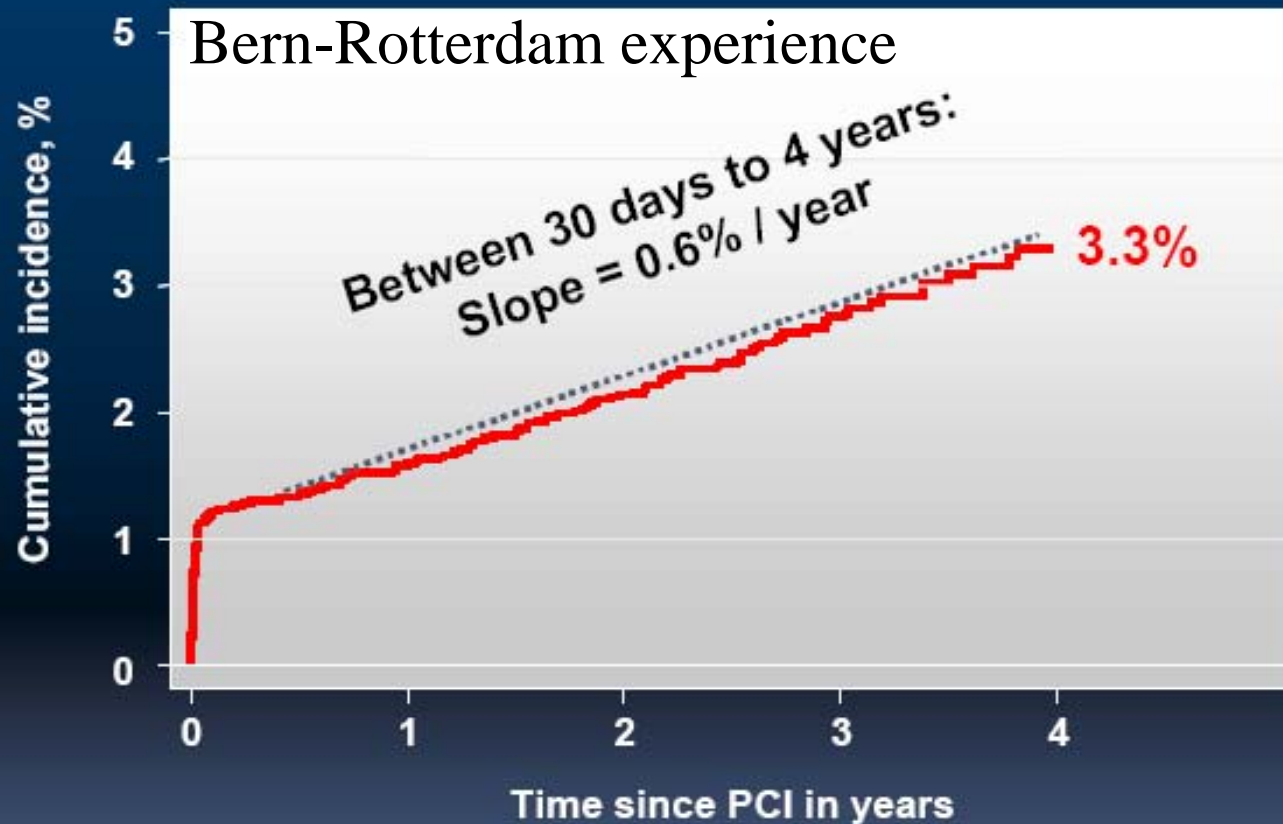
Unadjusted

Total cohort

N=41 775 stents

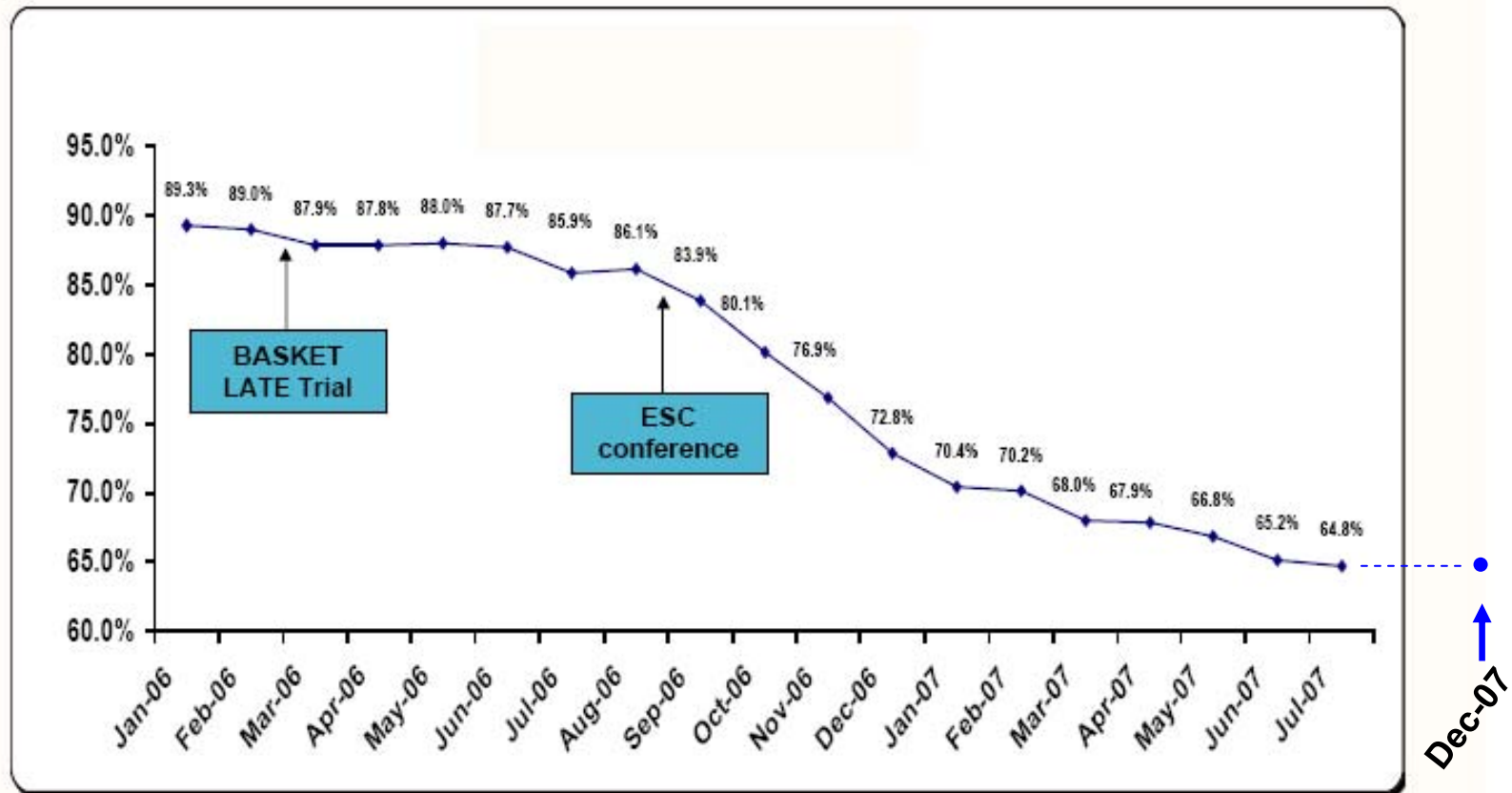


Cumulative Incidence of Stent Thrombosis



Days	30	365	730	1095	1460
Cumulative incidence, %	1.2	1.6	2.1	2.7	3.3
Patients at risk	7538	7210	5163	2789	1051

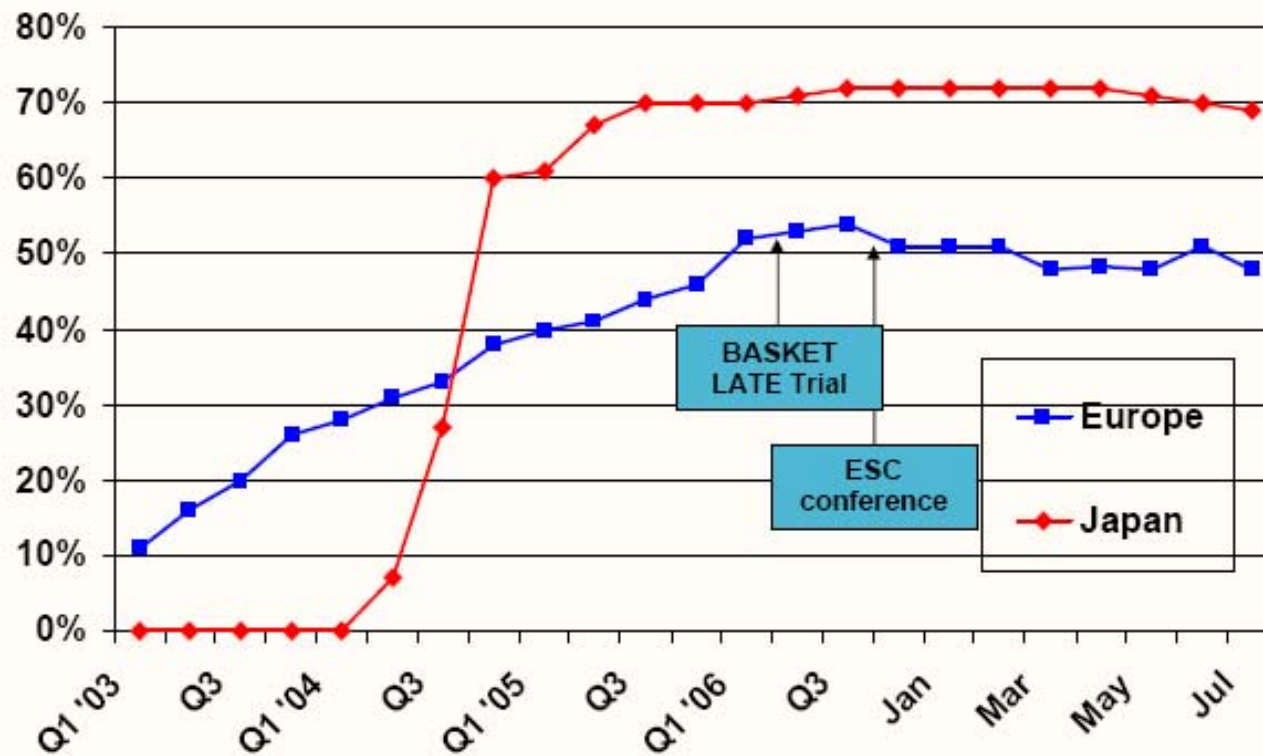
US DES Penetration



Source: MRG



Europe and Japan DES Penetration



**AMC
DES 30%**

Source: MRG

TRIAS HR Pilot study

***Academic Medical Center
Amsterdam
The Netherlands***



To compare the feasibility and efficacy of the Genous EPC-attracting stent with the Taxus paclitaxel-eluting stent in the treatment of coronary artery stenosis in patients / lesions with high risk of restenosis.

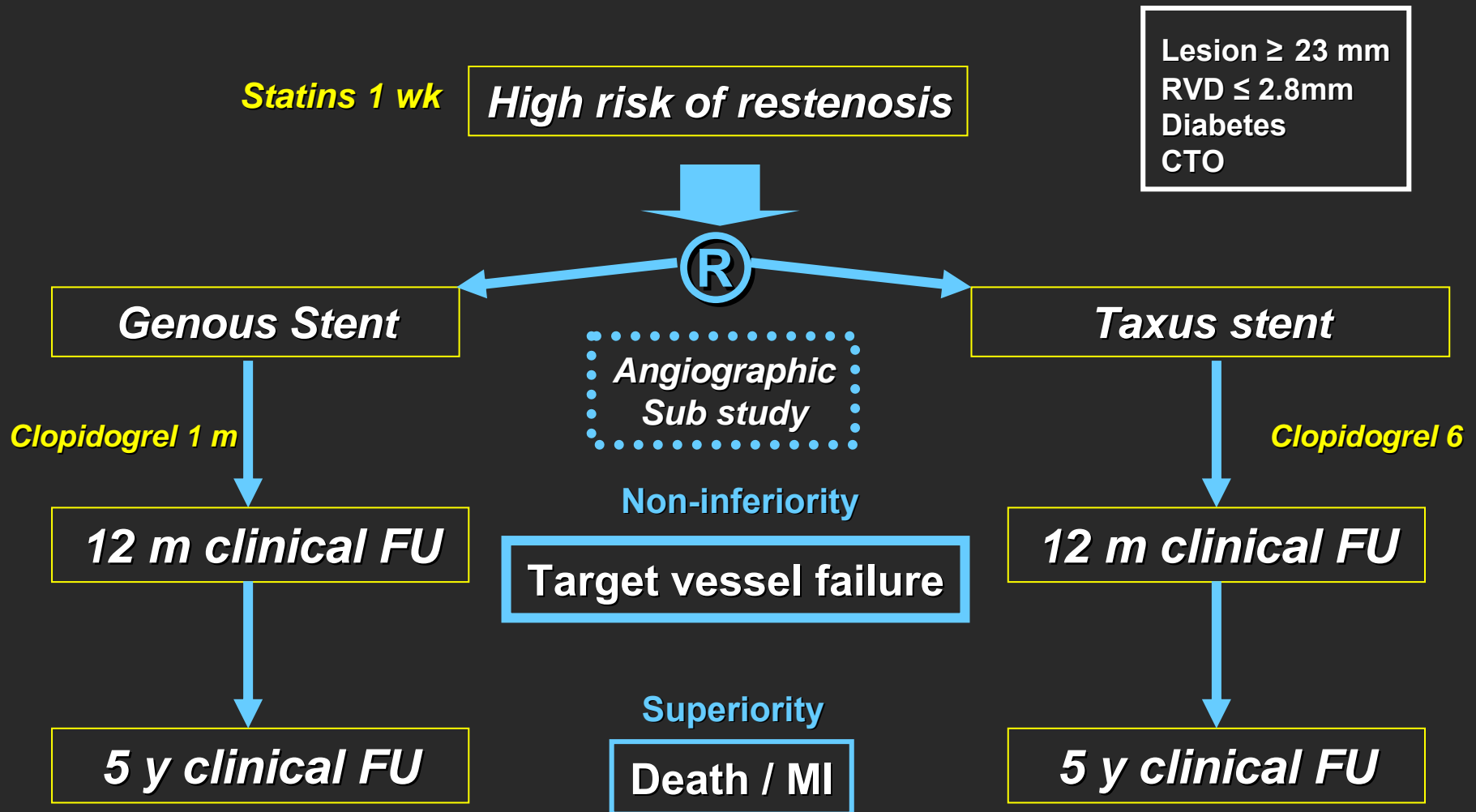
Restricted DES use in selected patients with high risk of restenosis, BMS in patients with low risk of restenosis

High risk of restenosis is defined as:

- ♥ **Lesion \geq 23 mm in length**
- ♥ **Lesions in vessels \leq 2.8 mm in diameter**
- ♥ **Any lesion in diabetic patients**
- ♥ **Chronic total occlusion**

TRIAS HR Pilot study

Design



TRIAS HR Pilot study

Results

Baseline characteristics

	Genous N = 98		Taxus N = 95		P-value
Age	62	± 10 y	63	± 10 y	Ns
Male	72	(73%)	70	(74%)	Ns
Risk factors					
Diabetes	14	(14%)	26	(27%)	0.025
Hypertension	45	(46%)	53	(56%)	Ns
Hypercholesterolemia	62	(63%)	50	(53%)	Ns
Family history of CAD	52	(53%)	61	(64%)	Ns
Current smoking	32	(33)%	30	(32%)	Ns
Stable angina	80	(82%)	81	(85%)	Ns
Unstable angina	18	(18%)	14	(15%)	Ns
Previous MI	37	(38%)	39	(41%)	Ns
Previous PCI	25	(26%)	25	(26%)	Ns
Previous CABG	3	(3%)	3	(3%)	Ns
Aspirin	93	(95%)	91	(96%)	Ns
Statins	98	(100%)	93	(98%)	Ns

Lesion characteristics

	Genous N = 121	Taxus N = 125	P-value
Type of lesion			Ns
A	0 (0%)	2 (2%)	
B1	10 (8%)	15 (12%)	
B2	54 (45%)	52 (42%)	
C	57 (47%)	52 (42%)	
Total chronic occlusion	39 (32%)	30 (24%)	Ns
Lesions \geq 23 mm	101 (83%)	100 (80%)	Ns
Vessels \leq 2.8 mm	9 (7%)	25 (20%)	0.004
Treated vessel			Ns
RCA	41 (34%)	49 (39%)	
LM	1 (1%)	1 (1%)	
LAD	48 (40%)	46 (37%)	
CX	31 (26%)	29 (23%)	

TRIAS HR Pilot study

Procedural characteristics

Results

	Genous N = 121		Taxus N = 125		P-value
Pre-procedure TIMI 3 flow	74	(61%)	83	(66%)	Ns
Pre-dilatation	108	(89%)	111	(89%)	Ns
Stents per lesion	1.2	± 0.54	1.2	± 0.48	Ns
Lesion length, mm	26.8	± 12	25.4	± 10	Ns
Ref vessel diameter, mm	3.2	± 0.3	3.2	± 0.5	Ns
Total stent length, mm	31.7	± 14.3	30.7	± 12	Ns
Max Atm stent placement	13	± 2.6	14	± 2.5	Ns
Post dilatation	88	(73%)	88	(70%)	Ns
Max Atm post dilatation	18.6	± 3.6	18	± 3.5	Ns
Procedural success	119	(98%)	124	(99%)	Ns

TRIAS HR Pilot study

6-month clinical outcome

Results

Stent thrombosis:

Genous

@ 6 hours

TLR, no MI

Taxus

@ 24 hours

MI, TLR

@ 10 days

MI, TLR

@ 155 days

MI, TLR

- ♥ All angiographically documented stent thrombosis**
- ♥ All on dual antiplatelet therapy at time of ST**

TRIAS HR Pilot study

6-month clinical outcome

Results

	Genous N=95	Taxus N=92	P-value
Death	0	0	
MI	1 (1.1%)	3 (3.2%)	Ns
Repeat PCI			
TLR	5 (5.3%)	4 (4.3%)	Ns
TVR remote	0	0	
Non TVR	3 (3.2%)	13 (14%)	0.007
CABG	2 (2.1%)	1 (1.1%)	Ns

TRIAS HR Pilot study

6-month clinical outcome

Results

	Genous N=95	Taxus N=92	P-value
Death	0	0	
MI	1 (1.1%)	3 (3.2%)	Ns
Repeat PCI			
TLR	5 (5.3%)	4 (4.3%)	Ns
TVR remote	0	0	
CABG	2 (2.1%)	1 (1.1%)	Ns
Target vessel failure	8 (8.4%)	5 (5.4%)	Ns

TRIAS HR Pilot study

12-month clinical outcome

Results

Stent thrombosis:

Genous

@ 6 hours

TLR, no MI

Taxus

@ 24 hours

MI, TLR

@ 10 days

MI, TLR

@ 155 days

MI, TLR

@ 200 days

MI, TLR

- ♥ All angiographically documented stent thrombosis**
- ♥ All on dual antiplatelet therapy at time of ST**

TRIAS HR Pilot study

Results

12-month clinical outcome

	Genous N=95	Taxus N=92	P-value
Cardiac death	0	0	
Non cardiac death	0	2 (2.2%)	Ns
MI	1 (1.1%)	5 (5.4%)	0.09
Repeat PCI			
TLR	11 (11.6%)	8 (8.7%)	Ns
TVR remote	1 (1.1%)	0	Ns
Non TVR	8 (8.4%)	13 (14.1%)	0.15
CABG	3 (3.2%)	1 (1.1%)	Ns

TRIAS HR Pilot study

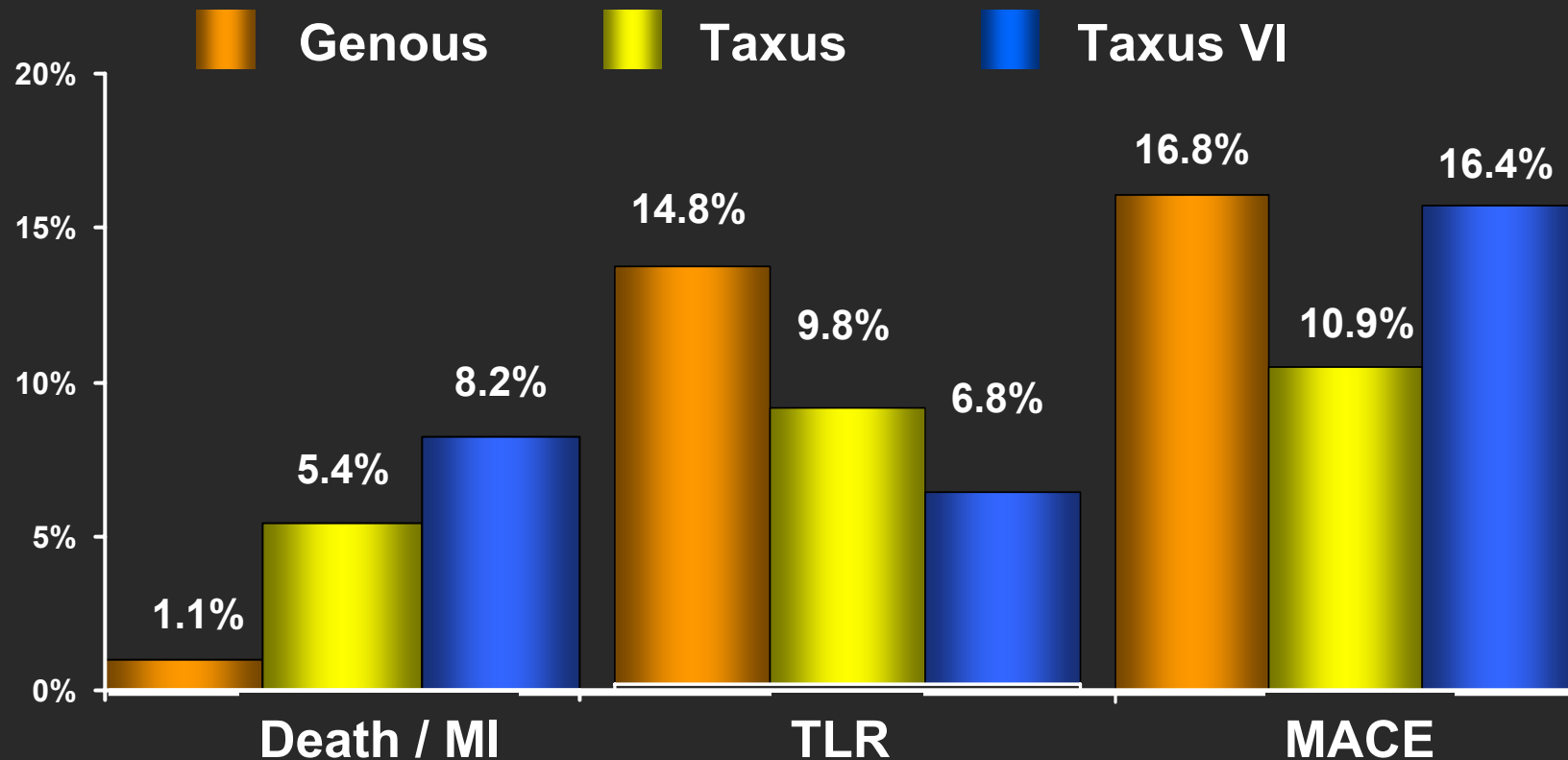
Results

12-month clinical outcome

	Genous N=95	Taxus N=92	P-value
Cardiac death	0	0	
Non cardiac death	0	2	Ns
MI	1 (1.1%)	5 (5.4%)	0.09
Repeat PCI			
TLR	11 (11.6%)	8 (8.7%)	Ns
TVR remote	1 (1.1%)	0	Ns
CABG	3 (3.2%)	1 (1.1%)	Ns
Target vessel failure	16 (16.8%)	10 (10.9%)	Ns

**Clinical Efficacy of Polymer-Based Paclitaxel-Eluting Stents
in the Treatment of Complex, Long Coronary Artery
Lesions From a Multicenter, Randomized Trial**
Support for the Use of Drug-Eluting Stents in Contemporary Clinical Practice

Comparing TRIAS HR Pilot study with Taxus VI



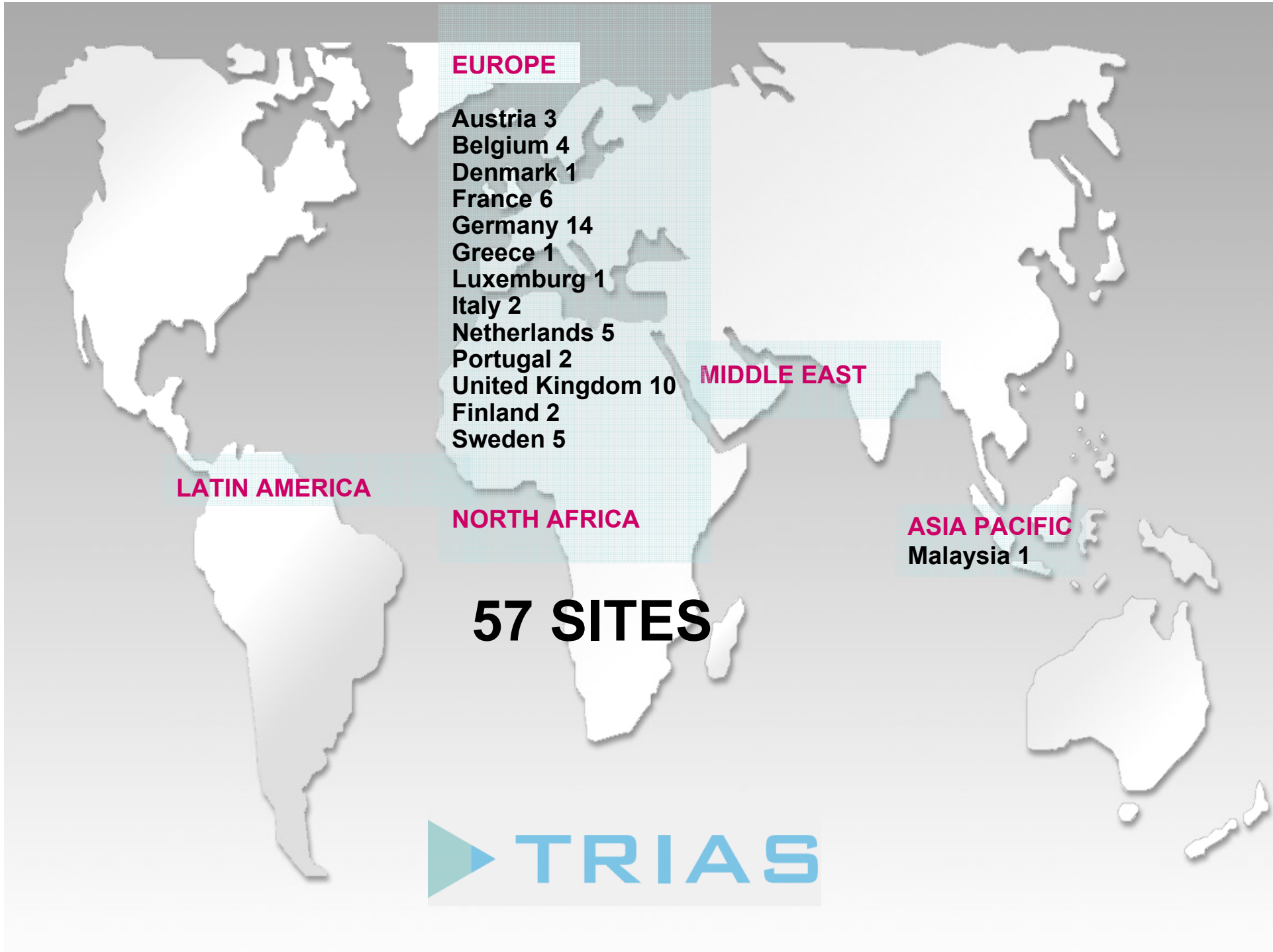
Randomized study comparing the Genous stent and first generation DES is feasible in patients treated with PCI for high risk restenosis lesions

Similar clinical outcomes at 6-months and 12-months between the Genous EPC-capturing stent and the Taxus paclitaxel eluting stent

MACE at 12 month in Genous similar to Taxus VI at 9 months

Slight increase in TLR in Genous compared to Taxus, but this is offset by higher stent thrombosis in Taxus group

The pilot study is followed by a large multi-center study



EUROPE

- Austria 3
- Belgium 4
- Denmark 1
- France 6
- Germany 14
- Greece 1
- Luxemburg 1
- Italy 2
- Netherlands 5
- Portugal 2
- United Kingdom 10
- Finland 2
- Sweden 5

MIDDLE EAST

LATIN AMERICA

NORTH AFRICA

ASIA PACIFIC

- Malaysia 1

57 SITES



TRIAS study design

Study questions:

♥ **Genous better than BMS ?**

♥ **Genous safer than DES ?**

TRIAS study design

High risk of restenosis

TRIAS HR

RCT

Genous versus DES

Low risk of restenosis

TRIAS LR

RCT

Genous versus BMS



TRIAS Program

Patient enrollment-cumulative

