

Element Clinical Program

Perseus Late Breaking News and the Platinum Study Design

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Element™ Stent Platform

Clinical Program

Paclitaxel

TAXUS™ Element™
Stent System

Element Stent



1-Year Data
@ ACC 2010
N=1,486

TAXUS
PERSEUS

Everolimus

Promus™ Element™
Stent System

Element Stent

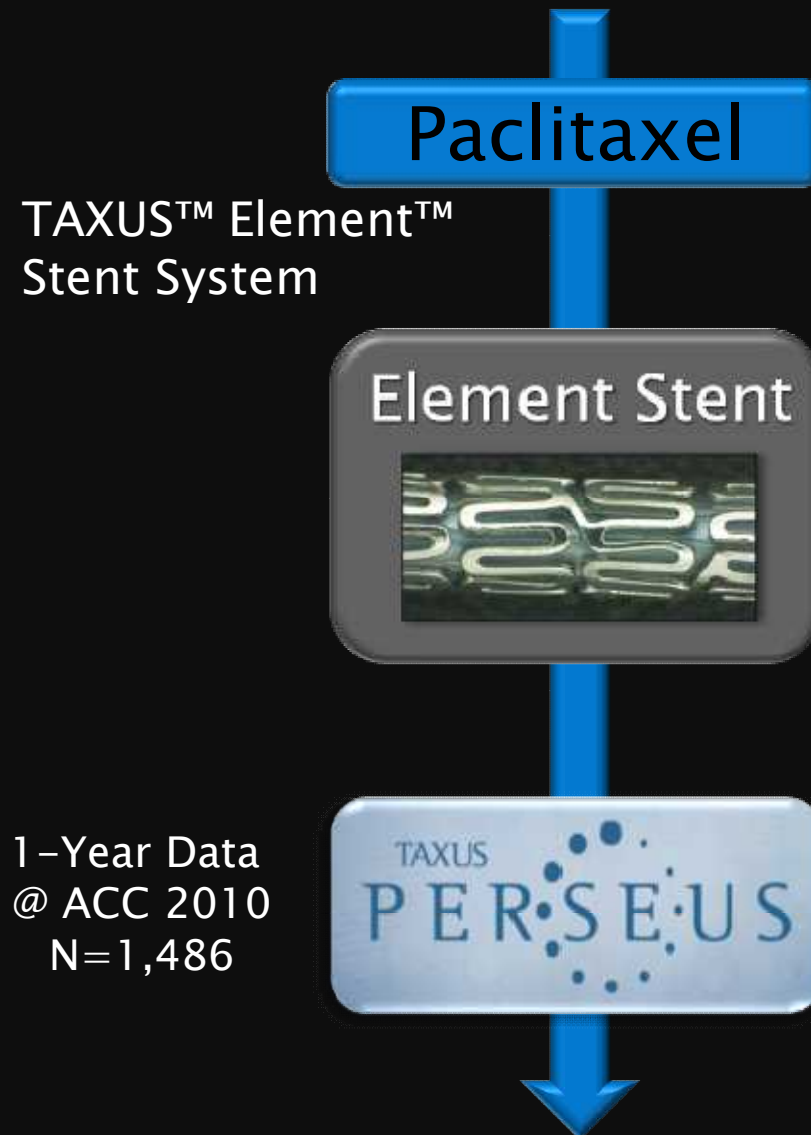


Enrollment
Complete
N=1,727

PROMUS
PLATINUM

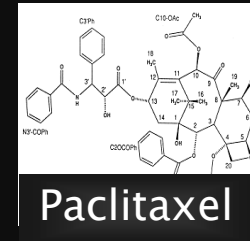
Element™ Stent Platform

Clinical Program



TAXUS™ Element™ Stent

TAXUS™ Stent Drug And Polymer



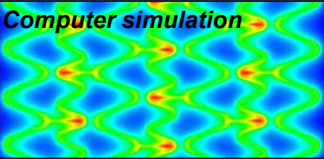
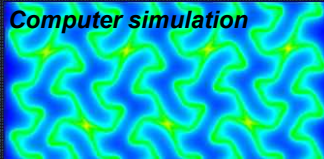
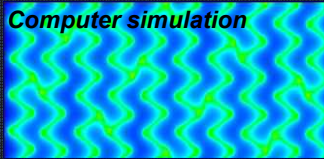
New Element™ Stent Platform

<u>Alloy</u> Platinum Chromium	<u>Stent Design</u> Element™ Stent	<u>Delivery System</u> Element™ Catheter
<ul style="list-style-type: none">•Designed for coronary stenting•Proprietary BSC alloy 	<ul style="list-style-type: none">•Thin struts - 0.0032” (0.081mm)*•New geometry 	<ul style="list-style-type: none">•New Bi-Segment Inner Lumen•Low profile 

*Strut thickness for 2.25 mm - 3.5 mm models; 0.086mm for 4.0 mm models. Data on file. Bench test results may not necessarily be indicative of clinical performance. All images courtesy of BSC.

Stent Technology Evolution:

3 Generations of TAXUS Stent

		TAXUS™ Express™ Stent	TAXUS™ Liberté™ Stent	TAXUS™ Element™ Stent	Impact of Change
Design & Delivery	Metal	Stainless Steel	Stainless Steel	Pt Cr	↑ <i>Strength</i> ↓ <i>Recoil</i>
	Radial Strength	0.23N/mm	0.24N/mm	0.26N/mm	
	Density	8.0g/cc	8.0g/cc	9.9g/cc	↑ <i>Radiopacity</i>
	Strut Thickness	132µm	97µm	81µm	↑ <i>Flexibility</i>
	Nickel Content	14%	14%	9%	
Function	Stent Models	2	3	4	<i>Enhanced/ more uniform drug distribution</i>
	Surface-to-Artery Ratio (across diameters)	11.1–16.7%	11.8–15.8%	12.4–15.1%	
	<i>Computer simulation</i>				

PERSEUS Clinical Program

2 parallel Trials in single, de novo lesions

PERSEUS Workhorse (WH)

NON-INFERIORITY

of

TAXUS™ Element™
Paclitaxel-Eluting Stent

compared to

TAXUS™ Express™
Paclitaxel-Eluting Stent

in vessels

$\geq 2.75\text{mm}$ and $\leq 4.0\text{ mm}$

PERSEUS Small Vessel (SV)

SUPERIORITY

of

TAXUS™ Element™
Paclitaxel-Eluting Stent

compared to

Bare Metal Express™
Stent from TAXUS V
(historical control)

in vessels

$\geq 2.25\text{mm}$ and $< 2.75\text{ mm}$

Trial Design

PERSEUS WH

PERSEUS Workhorse (WH), $\geq 2.75\text{mm}$ – $\leq 4.0\text{mm}$, $\leq 28\text{mm}$

NON-INFERIORITY Design, Randomized 3:1

**TAXUS™ Element™
Paclitaxel-Eluting Stent
(N=942)**

**TAXUS™ Express™
Paclitaxel-Eluting Stent
(N=320)**

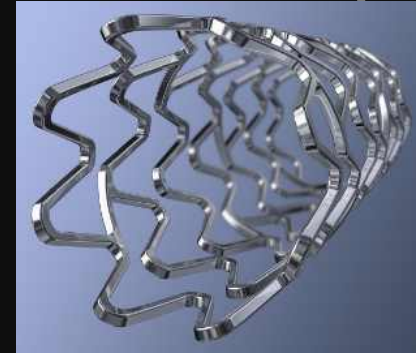
Primary Endpoint: TLF* (12 mos)

Secondary Endpoint: in-segment %DS (9 mos)**

*TLF=ischemia-driven TLR or MI/cardiac death related to target vessel **QCA cohort randomly assigned

Statistical Methods

- Bayesian analysis used to power the 1° and 2° endpoints
- Success criteria: $\geq 95\%$ Bayesian probability that TAXUS Element Stent is non-inferior to TAXUS Express Stent
- Predefined delta: 4.1% (TLF); 0.20 ln (%DS)*
- Standard (frequentist) method used for all other endpoints



Perseus Trial Results

Results Presented by Dean J. Kereiakes, MD at ACC 2010
on behalf of

Dean J. Kereiakes, MD; Louis A. Cannon, MD;

Robert L. Feldman, MD; Gregory J. Mishkel, MD; Abram C. Rabinowitz, MD; Robert Whitbourn, MBBS; Raymond Magorien, MD; Paul Underwood, MD; Keith D. Dawkins, MD

Clinical & Angiographic Characteristics

PERSEUS WH RCT

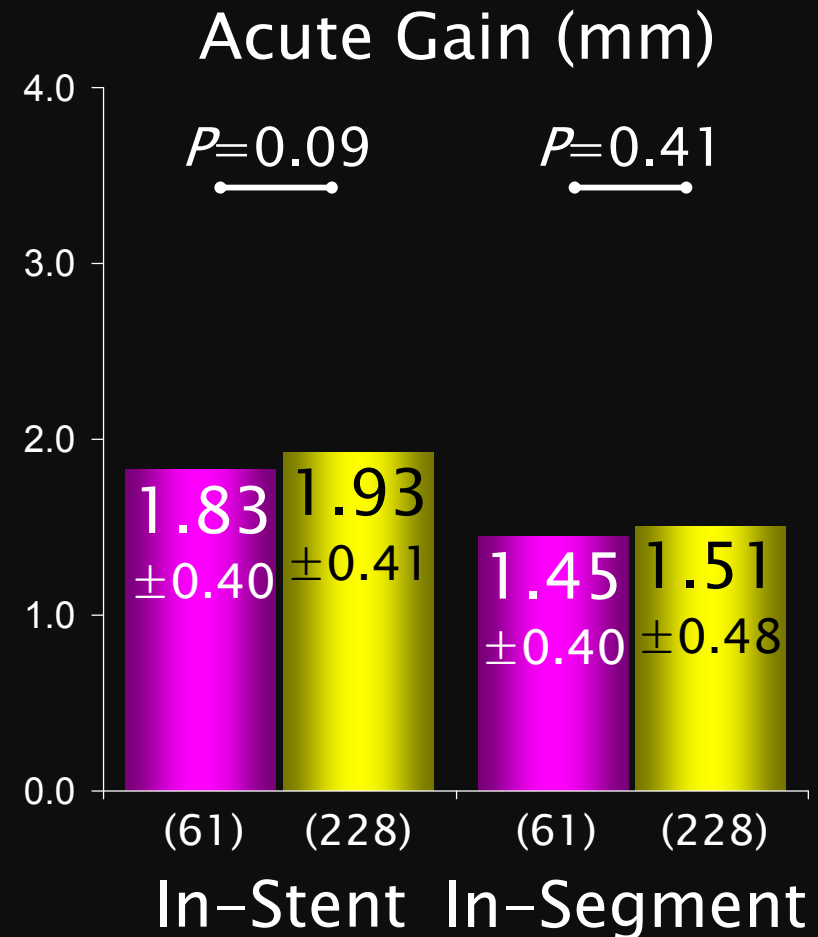
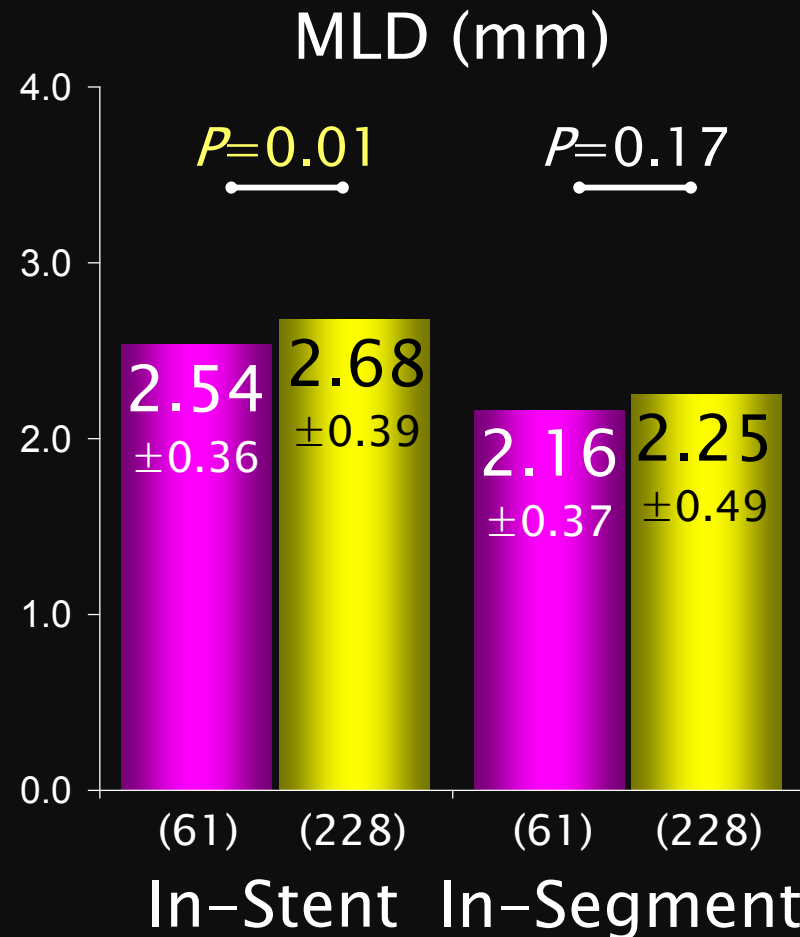
Values are % (n/N) or mean±SD (N)	TAXUS™ Express™ Stent (N=320)	TAXUS™ Element™ Stent (N=942)	P Value
Age, years	63.5±9.5 (320)	62.2±9.6 (942)	0.03
Male	68.8 (220/320)	70.8 (667/942)	0.49
Diabetes	25.0 (80/320)	24.6 (232/942)	0.89
Insulin	7.5 (24/320)	7.3 (69/942)	0.92
Current Smoker	23.5 (73/311)	24.3 (223/916)	0.76
Unstable Angina	21.3 (68/320)	20.7 (195/942)	0.84
Prior CHF	7.5 (24/318)	6.0 (56/937)	0.32
Ejection Fraction	57.8±9.8 (317)	58.0±9.3 (939)	0.73
RVD, mm	2.8±0.5 (320)	2.8±0.5 (942)	0.37
Lesion Length, mm	14.1±5.8 (320)	14.2±6.1 (942)	0.68
Diameter Stenosis	71.7±10.9 (320)	72.1±10.9 (942)	0.58
B2/C Lesions	64.7 (207/320)	66.9 (630/942)	0.47

Post-Procedure QCA

PERSEUS WH

TAXUS™ Express™ Stent

TAXUS™ Element™ Stent



QCA Subset, Paired Lesion Analysis

Presented by Dean J. Kereiakes, MD at ACC 2010

Procedural Outcomes

PERSEUS WH

	TAXUS™ Express™ Stent (N=320)	TAXUS™ Element™ Stent (N=942)	<i>P</i> Value
Technical Success*	98.8 (338/342 stents)	99.2 (1005/1013 stents)	0.51
Stent Length:Lesion Length	1.60±0.73 (319)	1.55±0.64 (940)	0.25
Multiple Stents†	8.4 (27/320)	7.6 (72/942)	0.65
Max Stent Deploy Pressure	14.0±2.8 (316)	13.7±2.4 (932)	0.15
Post-Dilation Used	53.8 (172/320)	53.6 (505/942)	0.97
Max Post-Dilation Pressure	16.6±3.3 (172)	16.6±3.6 (506)	0.95

*Successful stent delivery and deployment to target vessel, without balloon rupture or stent embolization; per stent.

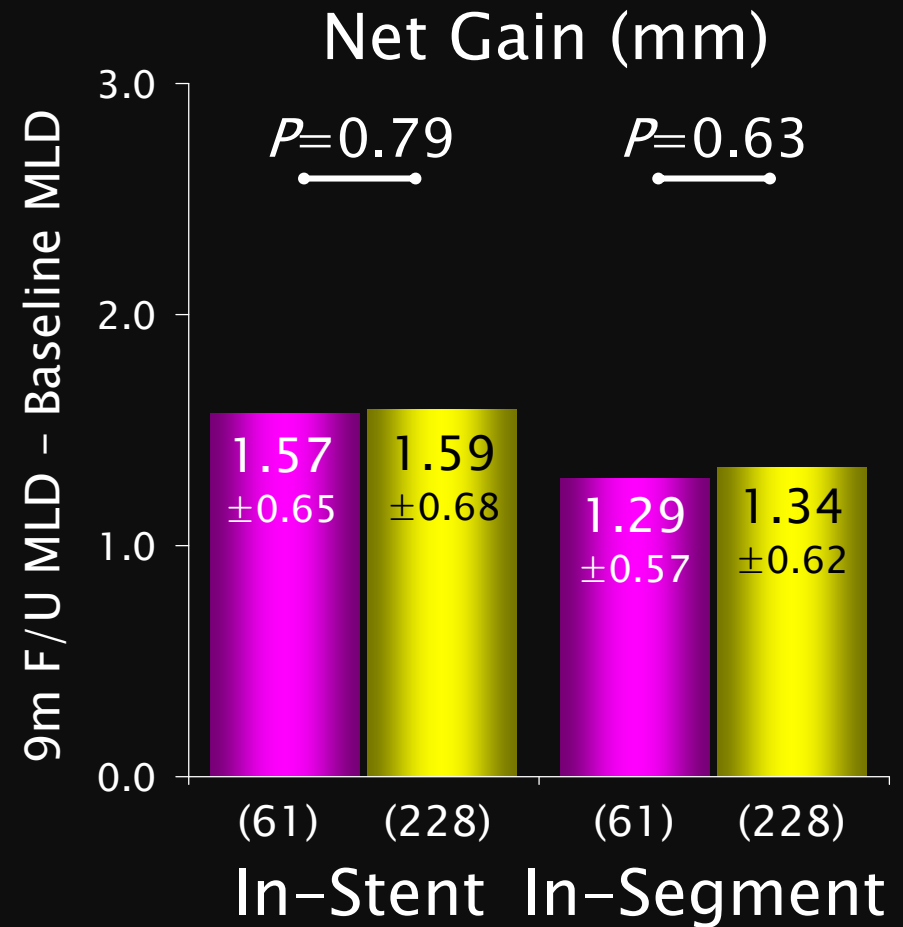
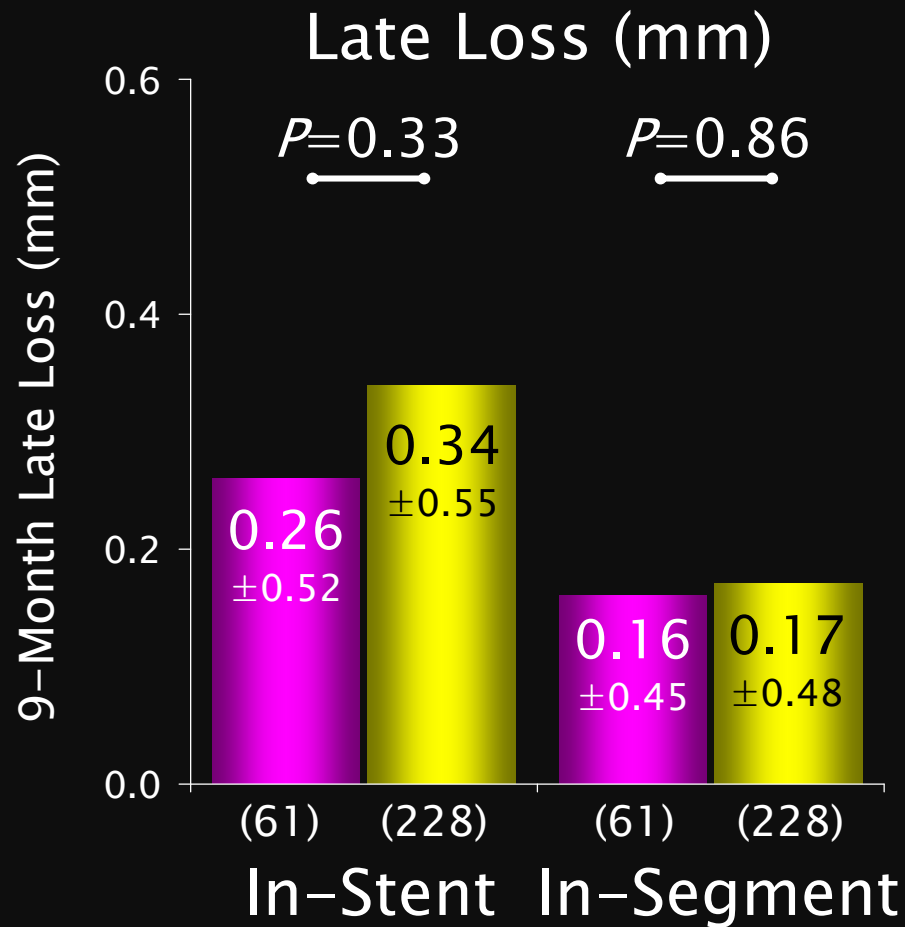
†Use of multiple stents for bailout indication only

9-Month QCA Outcomes

PERSEUS WH

TAXUS™ Express™ Stent

TAXUS™ Element™ Stent



QCA Subset, Paired Lesion Analysis

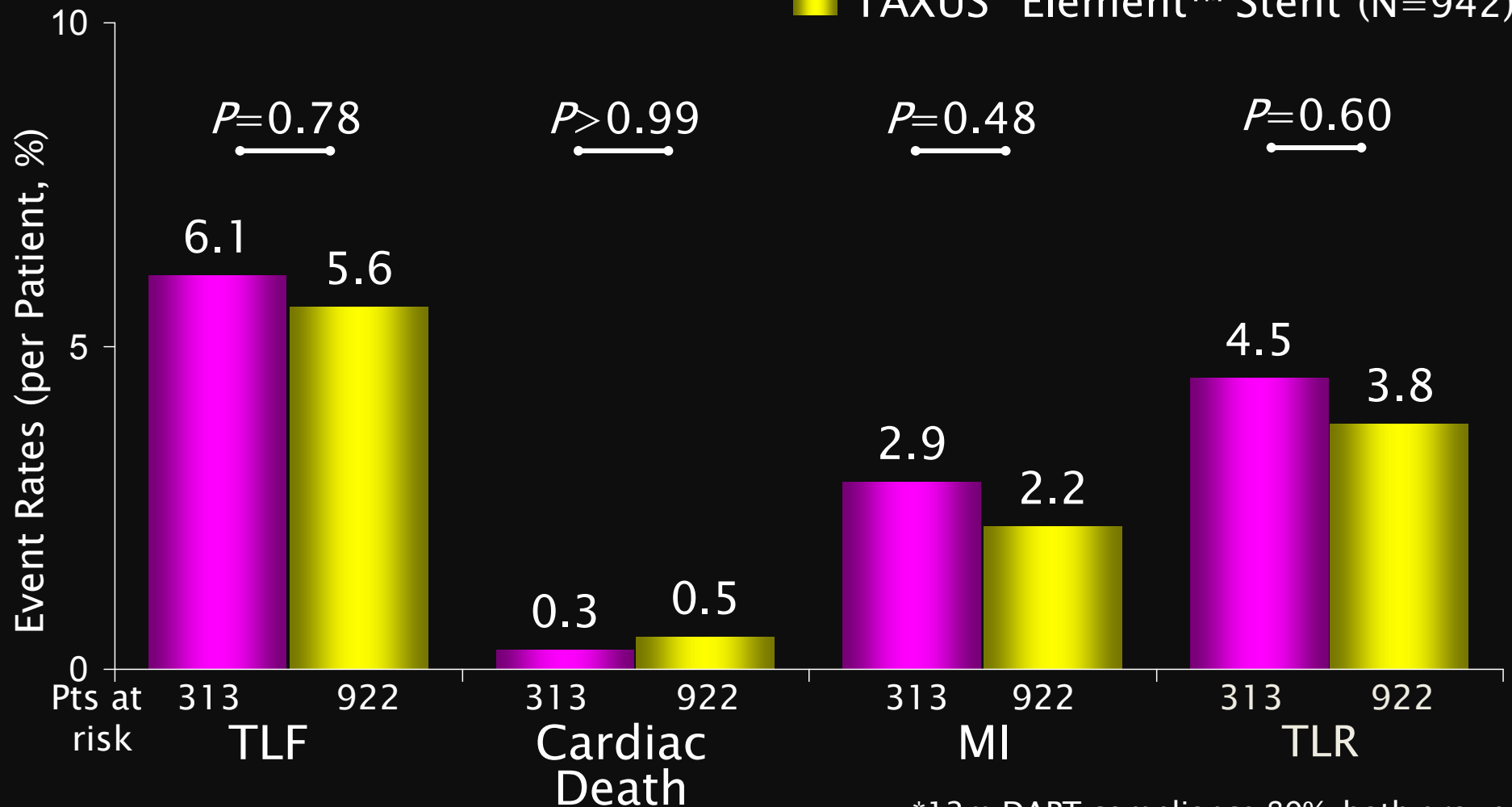
Late loss presented by Dean J. Kereiakes, MD at ACC 2010.

Net gain data on file at BSC.

12-Month Clinical Outcomes

PERSEUS WH

TAXUS™ Express™ Stent (N=320)
TAXUS™ Element™ Stent (N=942)



*TLF: ischemia-driven TLR, or MI/cardiac death related to the target vessel.

Primary/Secondary Endpoints

PERSEUS WH (Bayesian Analysis)

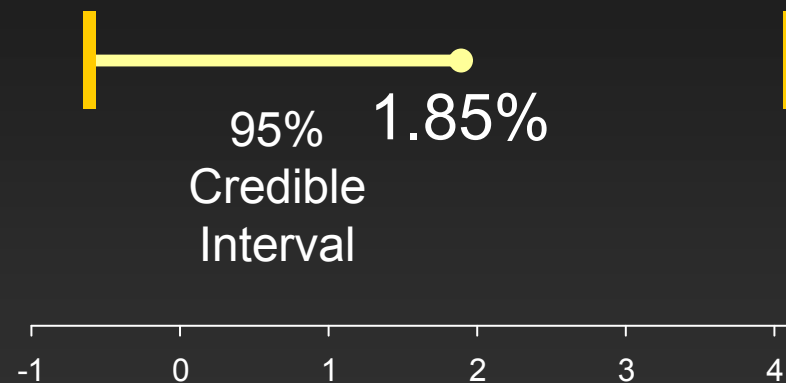
1° Clinical Endpoint: TLF

(97.7% complete F/U 12 mos)

2° QCA Endpoint: In(%DS)

(87.6% complete F/U 9 mos)

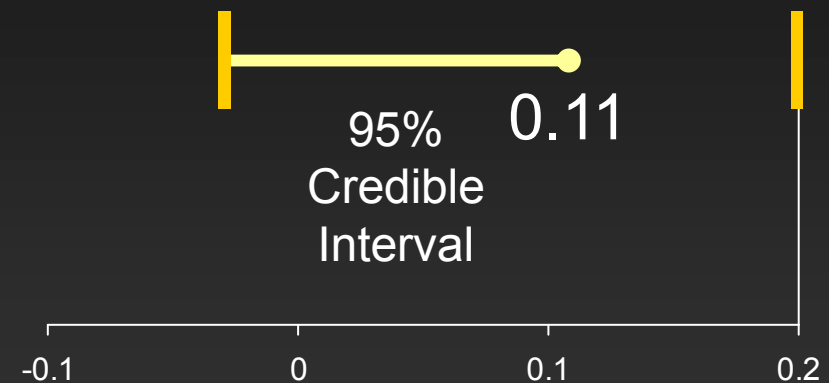
Difference: Δ
-0.57% 4.1%



Posterior Probability of Non-Inferiority = 0.9996

$P(\theta_1 - \theta_2 < 4.1\% \mid \text{data}) \geq 0.95$

Difference: Δ
-0.03 0.20



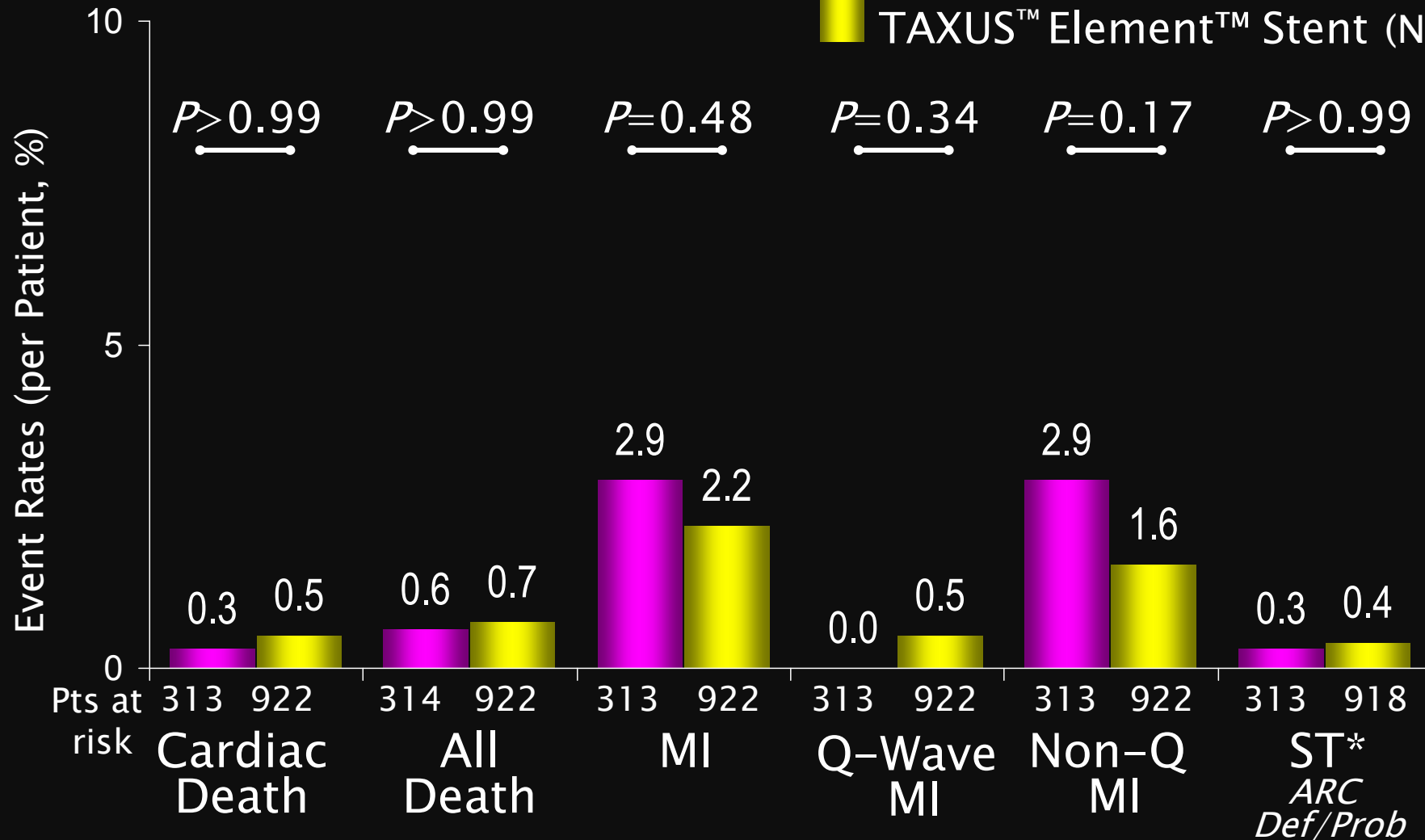
Posterior Probability of Non-Inferiority = 0.9970

$(\mu_1 - \mu_2 < 0.20 \mid \text{data}) \geq 0.95$

12-Month Clinical Outcomes – Safety

PERSEUS WH

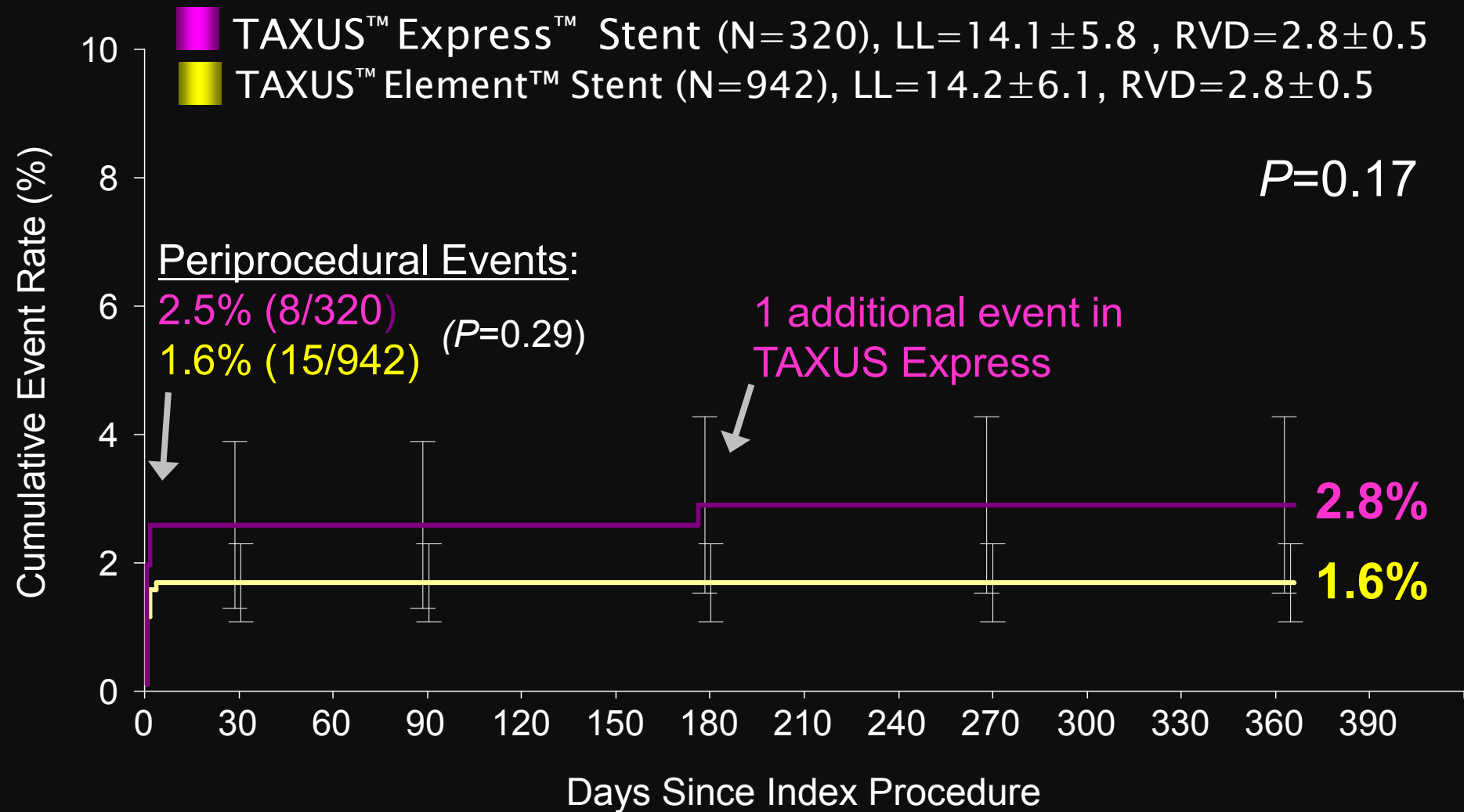
■ TAXUS™ Express™ Stent (N=320)
■ TAXUS™ Element™ Stent (N=942)



*12m DAPT compliance 89%, both groups

Non-Q-Wave MI to 12 Months

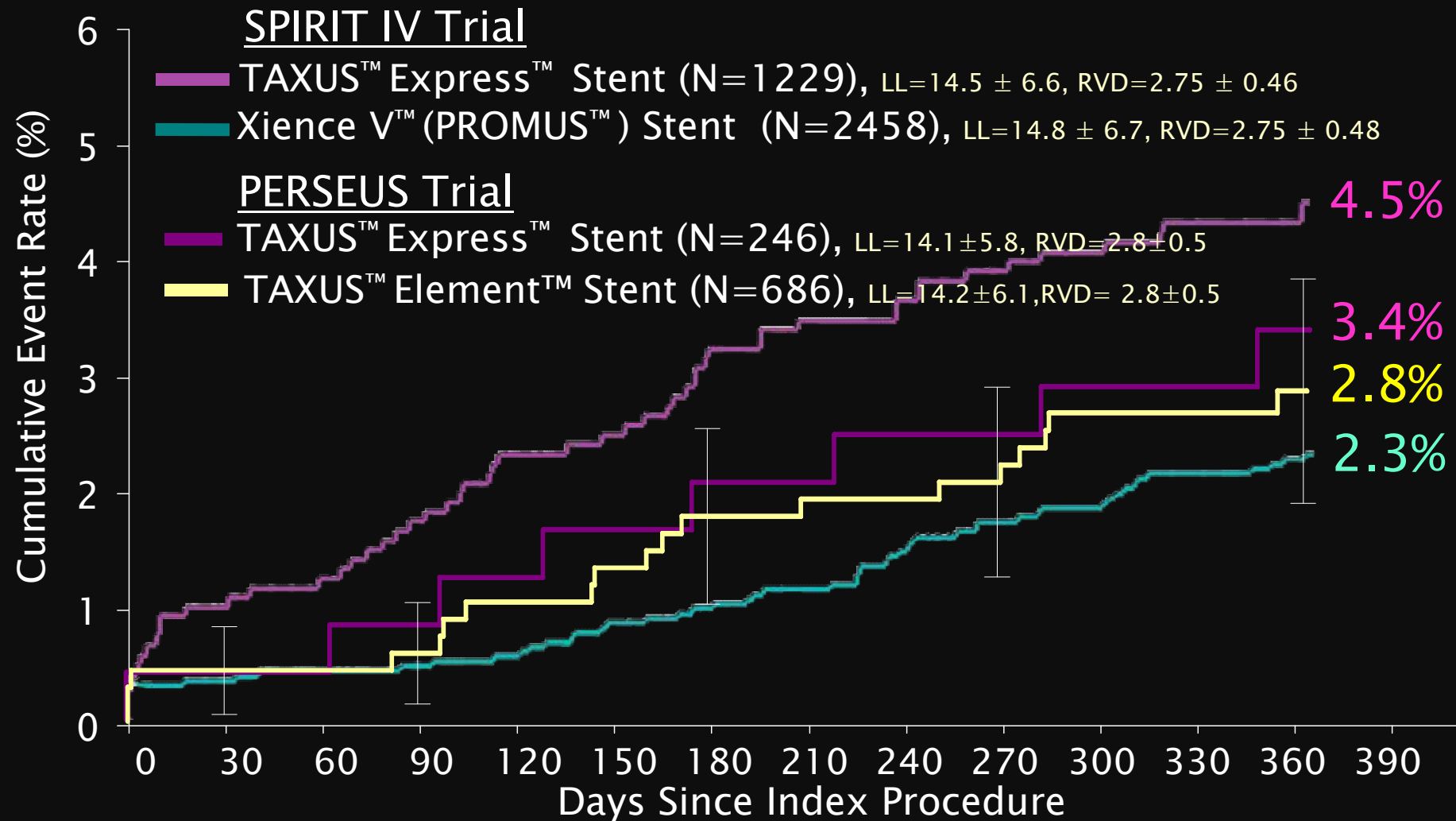
PERSEUS WH



Event Rate±SE; Log-Rank P Value

Ischemia-Driven TLR

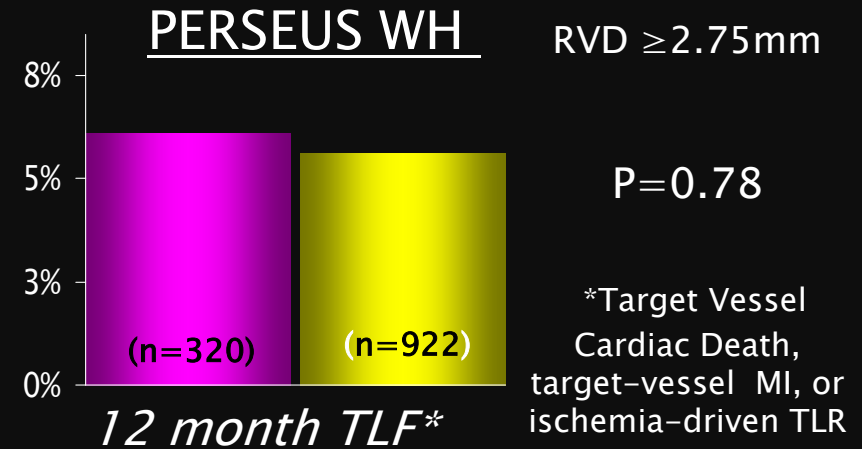
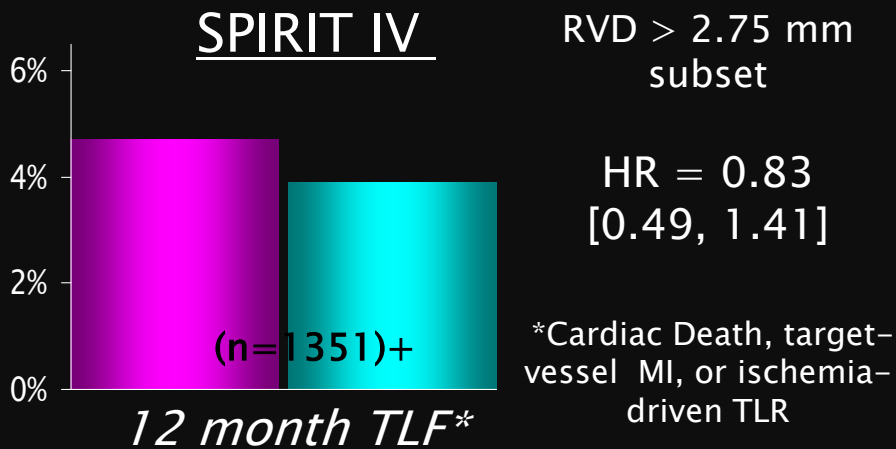
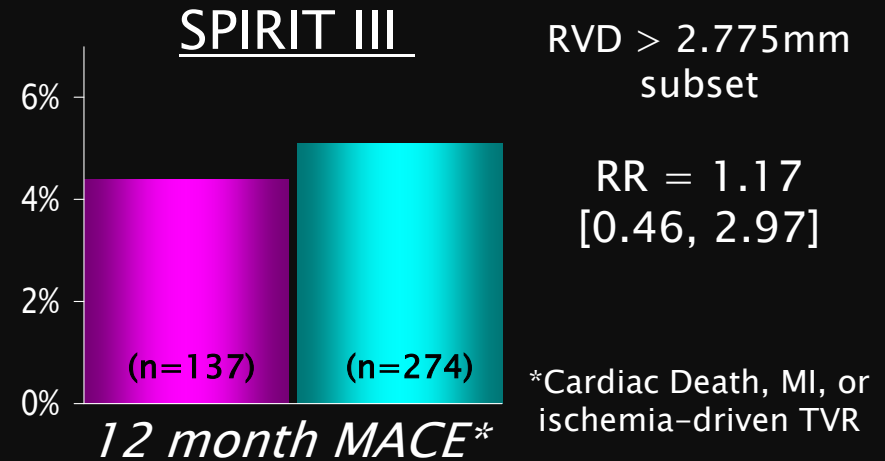
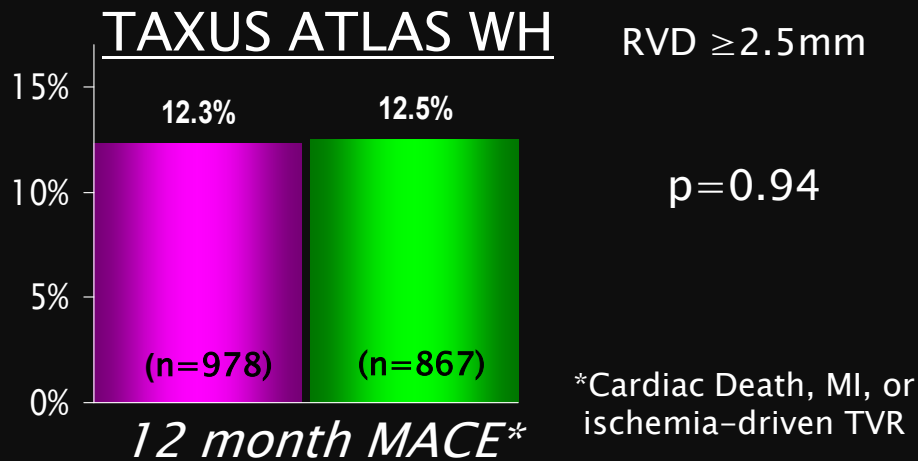
Non-QCA Stent Cohorts



Presented by Dean J. Kereiakes, MD at ACC 2010 *SPIRIT IV* presented by G. Stone, TCT 2009. Data points represent similar lesion types from the two trials but are not head-to-head trials. The PROMUS™ Stent is a private-labeled XIENCE V™ Everolimus Eluting Coronary Stent System manufactured by Abbott and distributed by Boston Scientific Corporation. XIENCE V is a trademark of Abbott Laboratories group of companies. SPIRIT is sponsored by Abbott.

PERSEUS, TAXUS ATLAS, SPIRIT Trials

Data Sets in Absence of Small Vessels



TAXUSTM ExpressTM Stent

TAXUSTM LibertéTM Stent

Xience VTM (PROMUSTM) Stent

TAXUSTM ElementTM Stent

Trial Design

PERSEUS SV

PERSEUS Small Vessel (SV), $\geq 2.25\text{mm}$ – $< 2.75\text{mm}$, $\leq 20\text{mm}$

SUPERIORITY Design, Single Arm, Open Label

**TAXUS Element
Paclitaxel-Eluting Stent
(N=224)**

**Historical Control BMS
Express™ Stent (TAXUS V)
(N=125)**

Primary Endpoint: in-stent late loss (9 mos)

Secondary Endpoint: TLF (12 mos) vs. Prespecified Performance Goal (PG)

*TLF=ischemia-driven TLR or MI/cardiac death related to target vessel **QCA cohort randomly assigned

Statistical Methods

- Frequentist approach used for all endpoints
- 1° Endpoint: 2-sided *t*-test vs. historical BMS control
- 2° Endpoint: 1-sided binomial test vs. a prespecified performance goal*

*Based on TAXUS IV/V results

Allocco et al. Trials 2010;11:1.

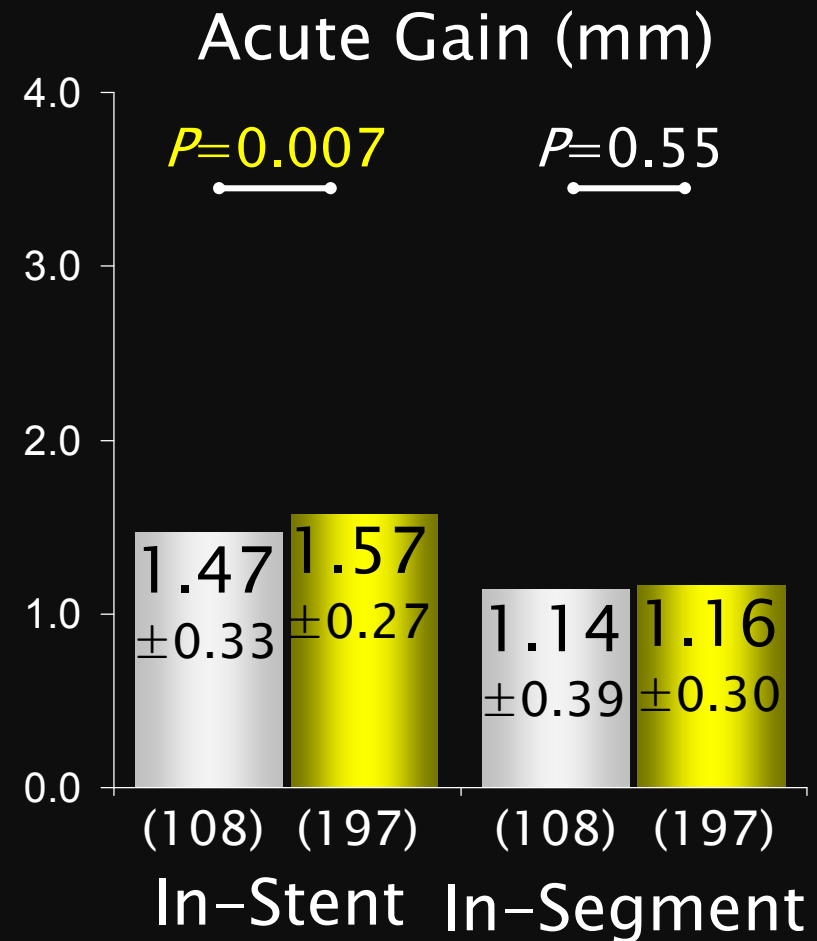
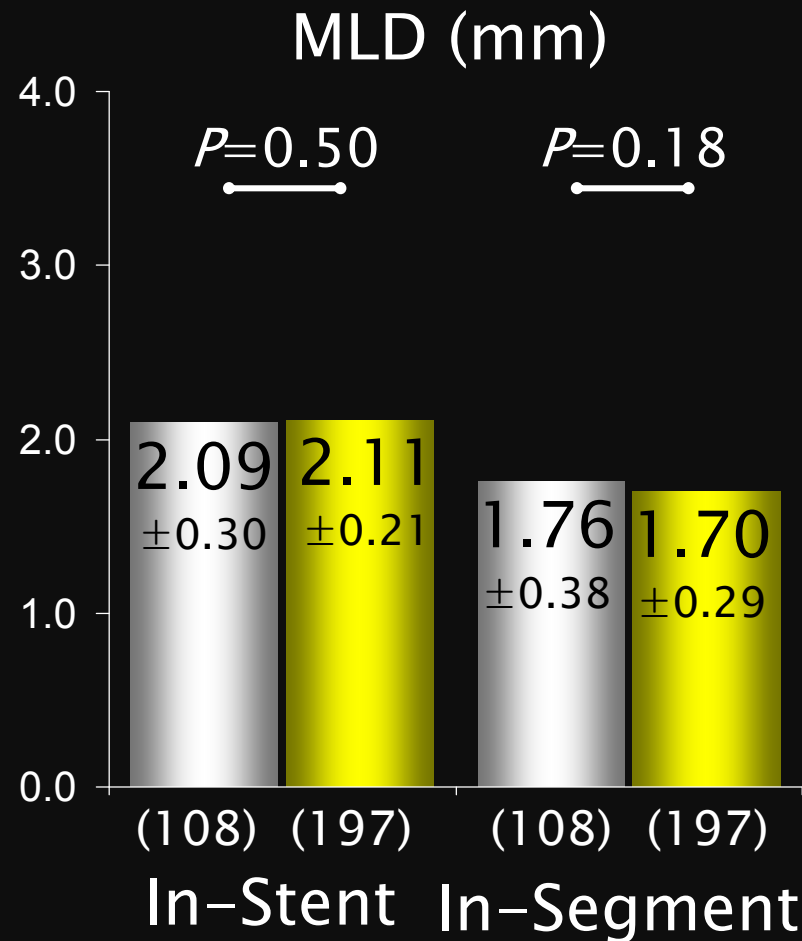
Post-Procedure QCA

PERSEUS SV

Express™ Stent

TAXUS™ Element™ Stent

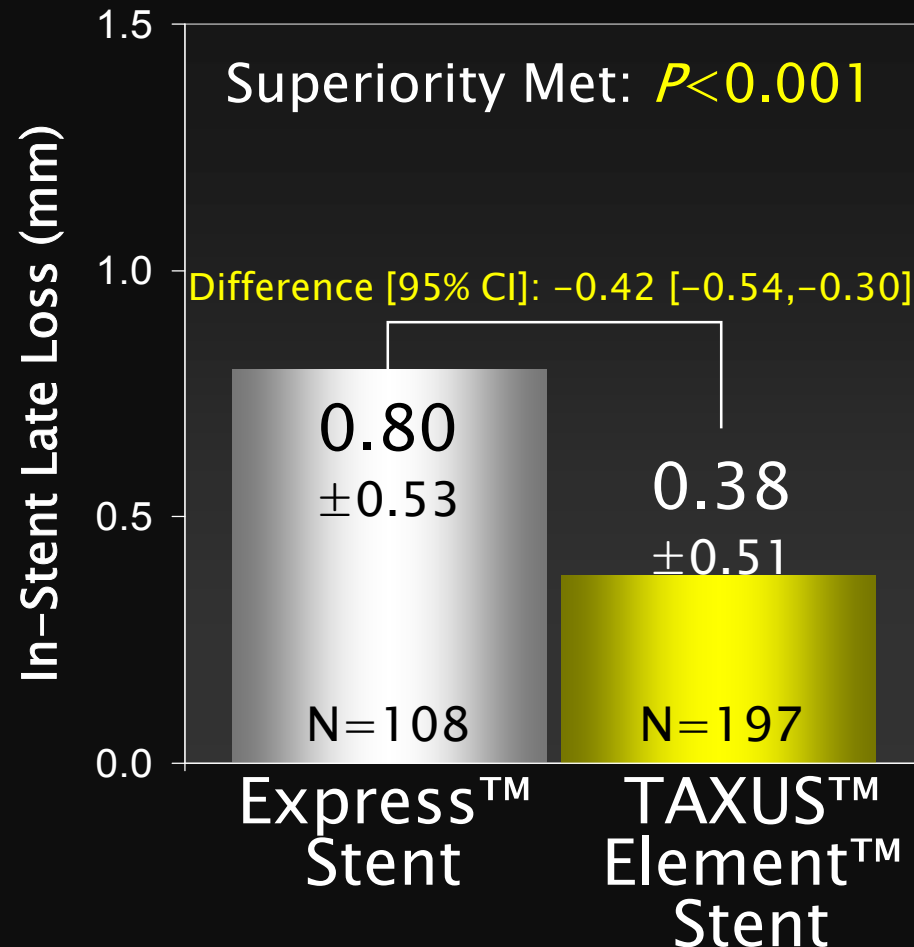
Paired Lesion Analysis



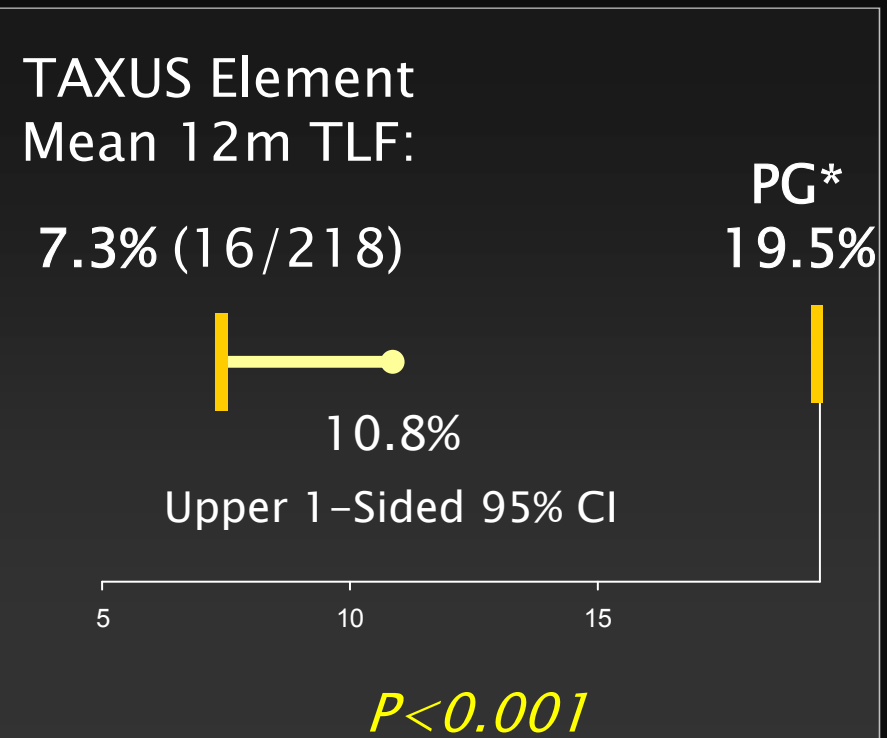
Primary & Secondary Endpoints

PERSEUS SV

1° Endpoint: Late Loss
(87.4% complete F/U 9 mos)



2° Endpoint: TLF
(97.4% complete F/U 12 mos)



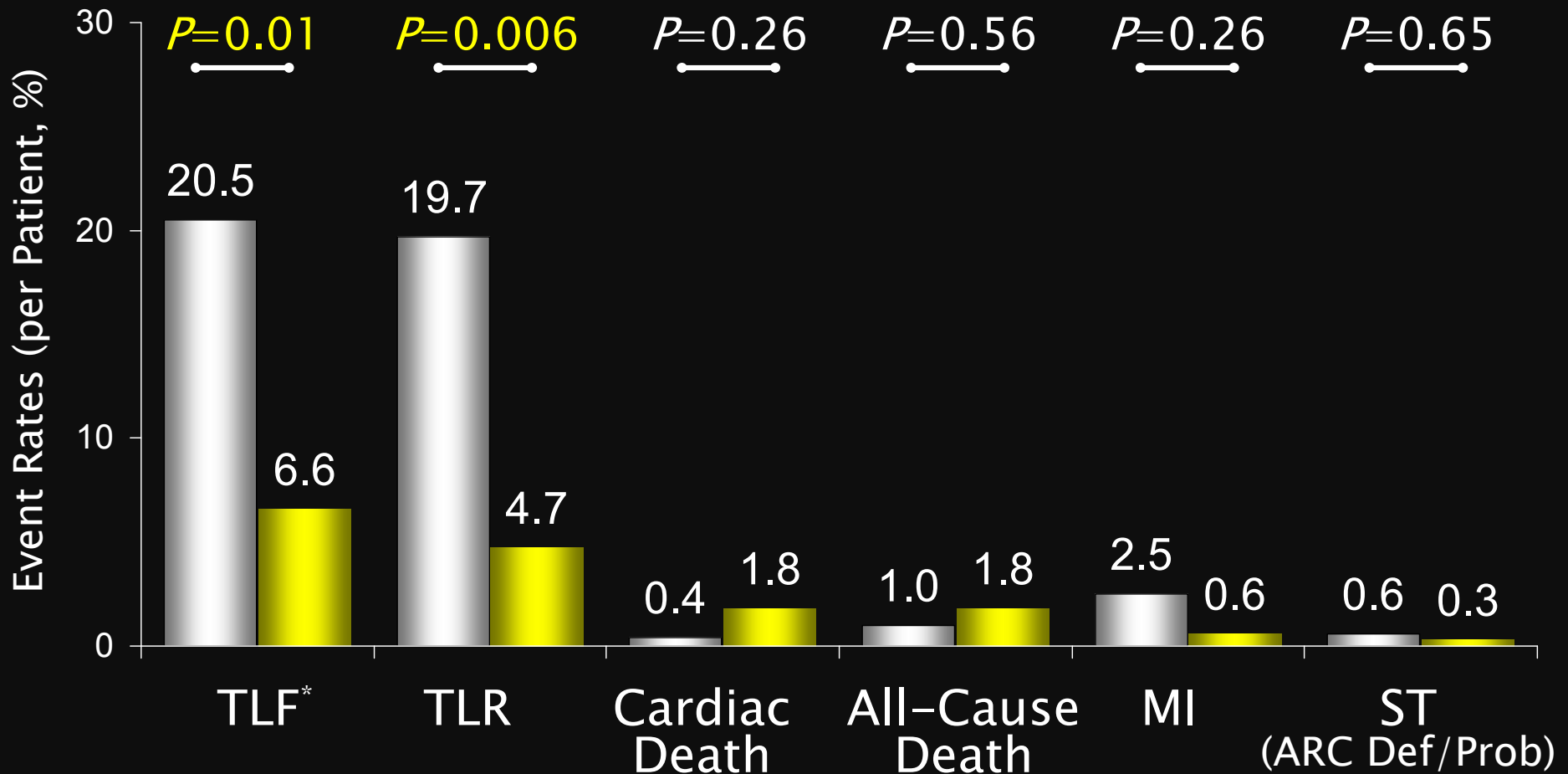
*Prespecified Performance Goal
(lesion-matched TAXUS IV/V PES cohort)

Clinical Outcomes (12 Month)

PERSEUS SV, Propensity Score Adjusted

Express™ Stent (N=125)

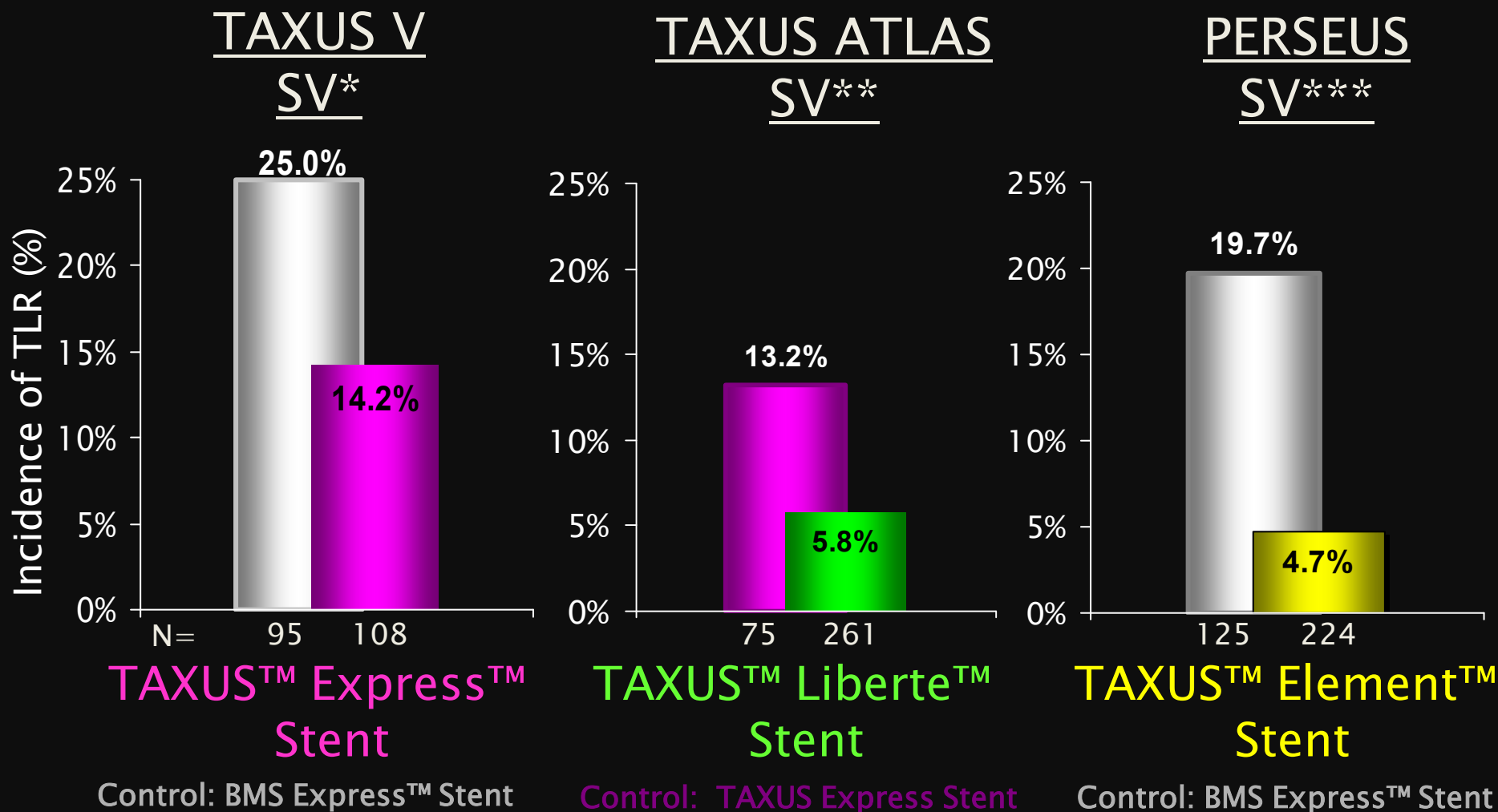
TAXUS™ Element™ Stent (N=224)



*TLF: ischemia-driven TLR, or MI/cardiac death related to the target vessel.

PERSEUS Clinical Program

12-month TLR Rates in SV Pivotal Approval Trials



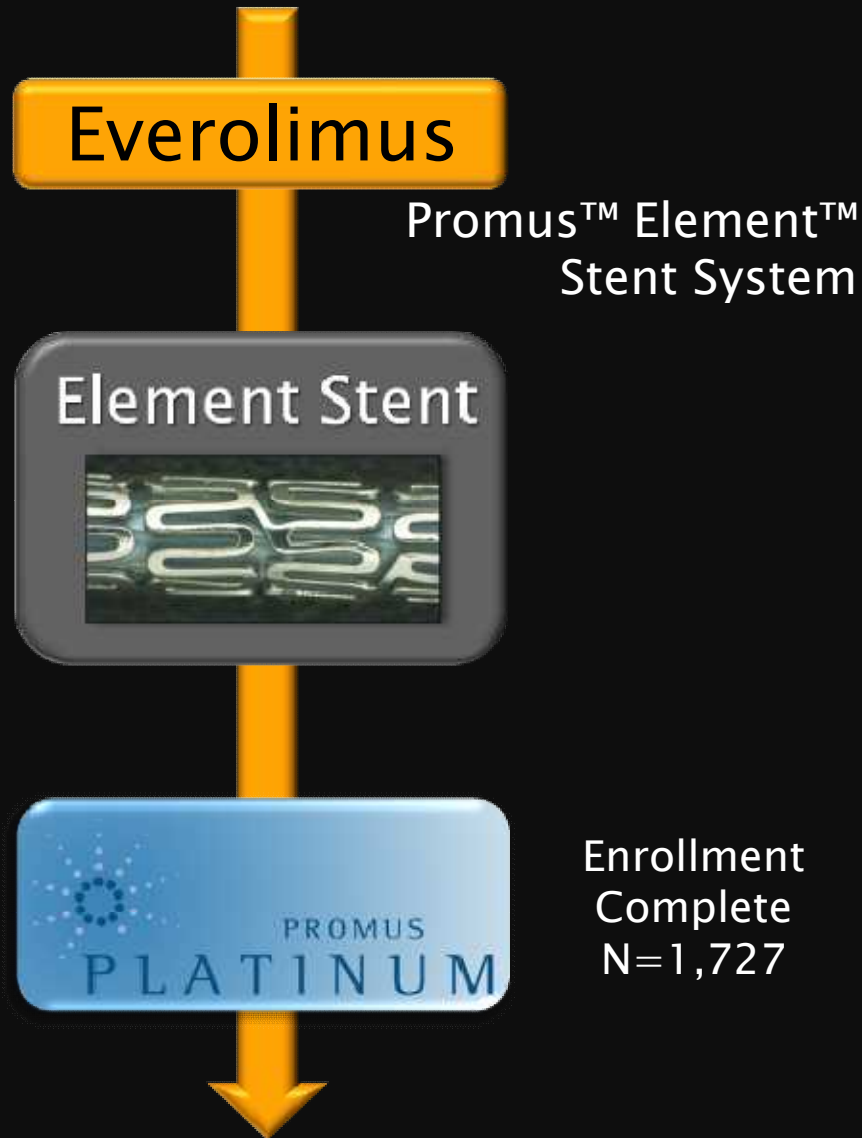
* 2.25 mm subgroup of the randomized TAXUS V Trial. Data presented by Ellis, TCT 2005. Mean RVD for TAXUS Express Stent arm = 2.07 mm

**Propensity adjusted data. JACC Vol. 1 No. 8, 2008. Mean RVD for TAXUS Liberté stent arm = 2.02 mm.

***Propensity Adjusted values. Data on file at BSC. PERSEUS SV arm. Mean RVD for TAXUS Element stent arm = 2.08 mm

Element™ Stent Platform

Platinum Clinical Program

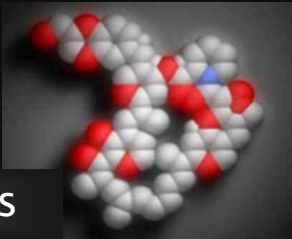


PLATINUM Clinical Program

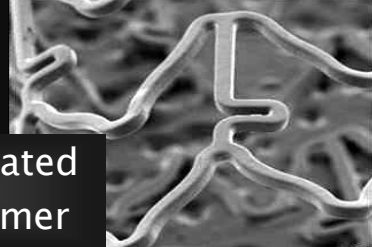
Enrollment complete

PROMUS™ Element™ Stent

Drug And Polymer
 PROMUS™ (Xience V™)
 Stent



Everolimus



Fluorinated Copolymer

Stent Platform
 New Element™ Stent



PtCr



Flex Push

Clinical Program Overview

Trial/Subtrial	Workhorse RCT	Small Vessel	Long Lesion	PLATINUM QCA
# of Patients	1,531	94	102	100
Comparator	PROMUS™ (Xience V) Stent Control Group	Performance Goal Based on Historical TAXUS Express Results		N/A

PLATINUM Clinical Program (I)

PROMUS® ELEMENT™ Stent in *de novo* lesions



	PLATINUM WH, SV, LL			PLATINUM
Trial/Subtrial	Workhorse	Small Vessel	Long Lesion	QCA
# of Patients	1,531	94	102	100
# of Sites	160 (Worldwide)	20 (US & Japan)	20 (US & Japan)	10 (IC)
Trial Design	1:1 Randomized, Single Blind	Single Arm	Single Arm	Single Arm
Success Criteria	Non-inferiority	Non-inferiority	Non-inferiority	N/A
Test Stent	PROMUS Element Stent			PROMUS Element Stent
Control Stent	PROMUS Stent	Historical PROMUS Stent Data from SPIRIT Trials		N/A
Primary Endpoint	12M TLF	12M TLF	12M TLF	30 day cardiac events

PLATINUM Clinical Program (II)

PROMUS® ELEMENT™ Stent in *de novo* lesions



	PLATINUM WH, SV, LL			PLATINUM QCA
Trial/Subtrial	Workhorse	Small Vessel	Long Lesion	QCA
Total Lesions	Up to 2	Up to 2	Up to 2	One
Target Lesions	Up to 2 <i>de novo</i>	Single <i>de novo</i>	Single <i>de novo</i>	Single <i>de novo</i>
Stent Size (mm)	2.5, 3.0, 3.5, 4.0 × 12, 20, 28	2.25 × 12, 20, 28, 32	2.5, 3.0, 3.5, 4.0 × 32, 38	2.5, 3.0, 3.5, 4.0 12, 20, 28
Target Lesion Diameter (mm)	≥2.50 to ≤4.25	≥2.25 to <2.5	≥2.5 to ≤4.25	>2.5 <4.25
Target Lesion Length (mm)	≤24	≤28	>24 to ≤34	≤24
Clinical Follow-up	1M, 6M, 12M, 18M, 2Y, 3Y, 4Y, 5Y	1M, 6M, 12M, 18M, 2Y, 3Y, 4Y, 5Y	1M, 6M, 12M, 18M, 2Y, 3Y, 4Y, 5Y	1M, 9M, 12M
QCA/IVUS Follow-up	None	None	None	9M/9M

PLATINUM Clinical Program

PROMUS® ELEMENT™ Stent in WH, SV, LL lesions

160 clinical sites

- Asia Pacific
- Europe
- Japan
- South America
- United States

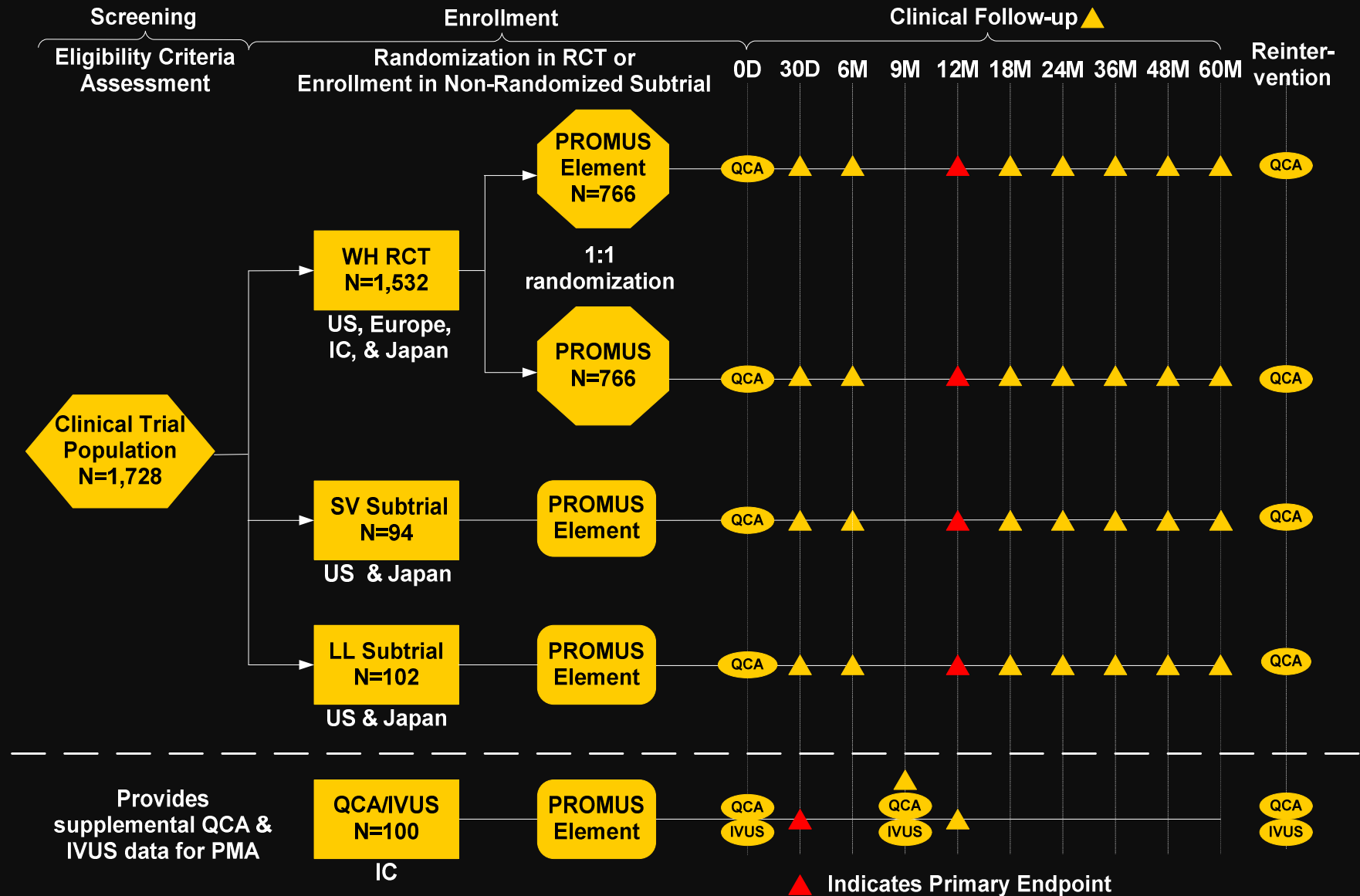
PLATINUM Clinical Program

PROMUS® ELEMENT™ Stent in QCA Study

18 clinical sites

- Australia
- Malaysia
- New Zealand
- Singapore

Platinum Trial Designs



Element Clinical Program

Perseus Results & Platinum Study Design

- PtCr “Element” Stent design provides thinner stent struts with improved radial strength and flexibility without trading off visibility and radiopacity
- PERSEUS Trial indicates that TAXUS Element stent has:
 - comparable efficacy to the TAXUS Express stent in workhorse lesions
 - superior in efficacy to the bare metal Express stent in small caliber vessels
 - no safety concerns
- Platinum suite of trials including the large RCT comparing Promus Element to Promus have recently been completed