Total IN.PACT All-Subjects Pooled 1-Year Analysis

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Disclosure

Speaker name: Marianne Brodmann, MD

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I have the following potential conflicts of interest to report:

- ☒ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

☐ I do not have any potential conflict of interest

Total IN.PACT Pooled Analysis Initiative

- 1,980 pooled subjects from a diverse population across 147 sites, 28 countries, and 6 continents
- Gain insights into outcomes across a broad spectrum of patient and lesion types
- Offer an independent data analysis (Baim Institute for Clinical Research formerly known as HCRI)

Primary Endpoints

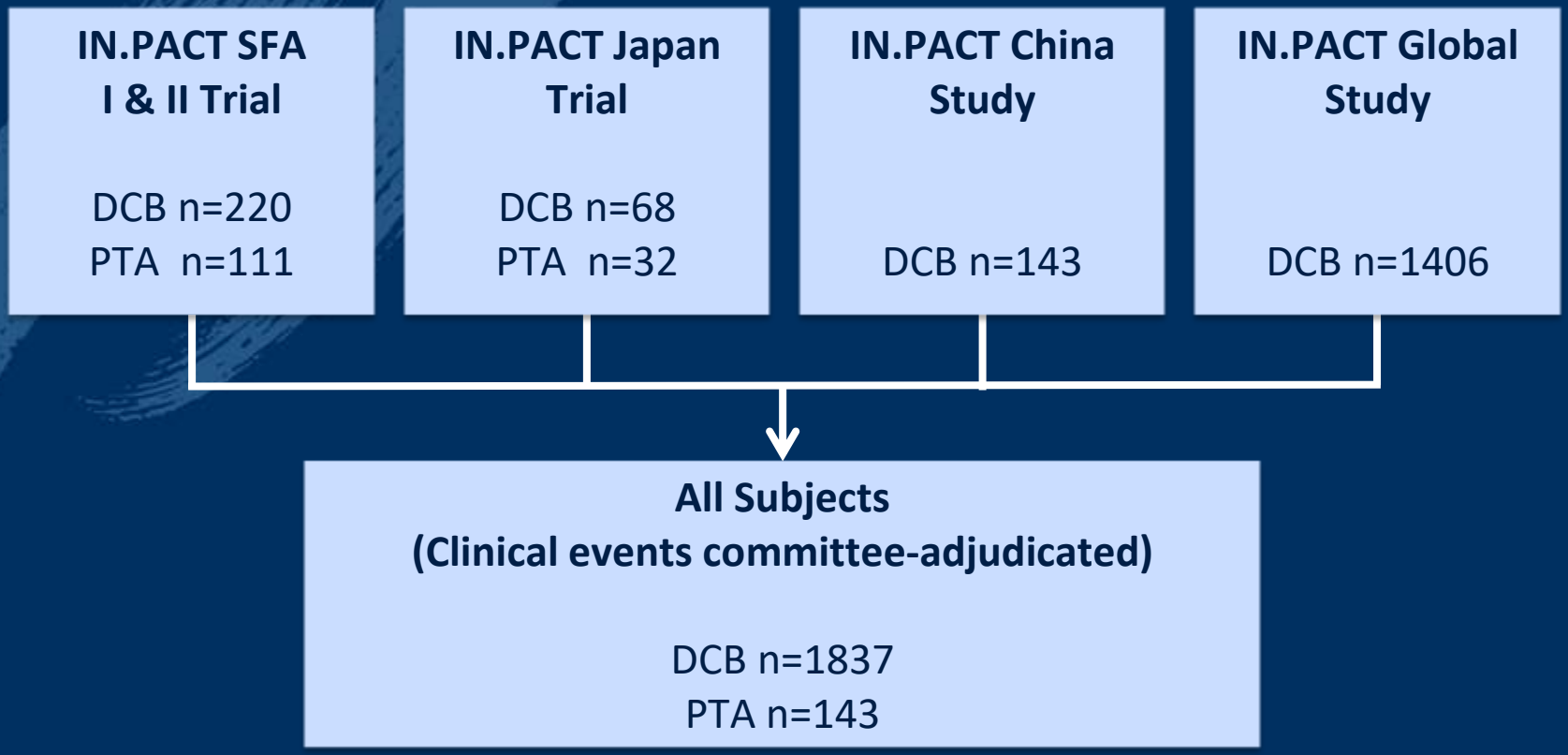
Primary Efficacy Endpoint	•Freedom from clinically-driven target lesion revascularization[1] within 12 months
Primary Safety Endpoint	•Freedom from device- and procedure-related death through 30 days, and freedom from target limb major amputation and clinically-driven target lesion revascularization within 12 months

These endpoints were prospectively defined in all individual studies pooled within the Total IN.PACT analyses

All revascularization and safety events were adjudicated by a Clinical Events Committee

1. Any re-intervention within the target lesion(s) due to symptoms or drop of ABI of ≥ 20% or > 0.15 when compared to post-index procedure baseline ABI.

Total IN.PACT Pooled Analysis Initiative



Baseline Clinical Characteristics

	Total IN.PACT All-Subjects Analysis		
Baseline Characteristics	**DCB (N= 1837 Subjects)**	**PTA (N= 143 Subjects)**	**P-value**
Age	68.5±9.8	69.4±9.0	0.279
Male	68.2%	70.6%	0.577
Hypertension	83.6%	88.1%	0.193
Hyperlipidemia	69.6%	81.1%	0.003
Diabetes	41.2%	50.3%	0.035
Active Smoker	32.8%	35.0%	0.581
Previous Peripheral Revascularization	48.8%	52.4%	0.435
Below-the-knee Disease of Target Leg	46.4%	49.0%	0.601
Rutherford Category			0.016
2	34.1%	42.7%	-
3	55.6%	51.7%	-
4	8.3%	4.9%	-
5	2.0%	0.7%	-
ABI/TBI*(mmHg)	0.69±0.22 (1699)	0.74±0.18 (138)	0.001

*TBI allowed / used in case of incompressible vessels in IN.PACT SFA II phase

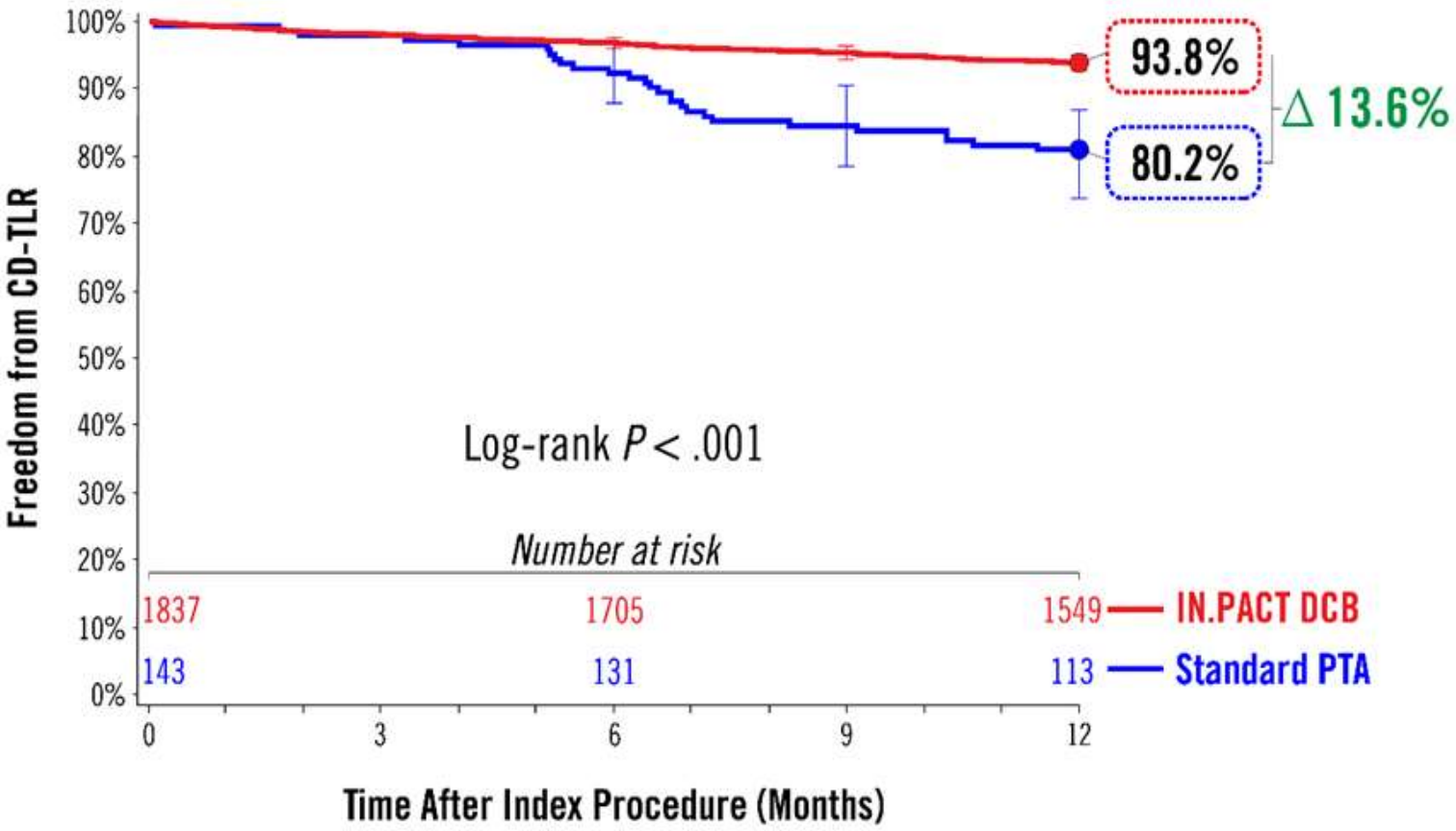
Baseline Lesion/Procedural Characteristics

	Total IN.PACT All-Subjects Analysis		
Lesion/Procedural Characteristics*	**DCB (N=1837 Subjects) (N=2204 Lesions)**	**PTA (N=143 Subjects) (N=143 Lesions)**	**P-value**
Lesion Characteristics			
Lesion Type			
De Novo	**78.5%**	**95.8%**	**<.001**
Restenotic (non-stented)	**7.0%**	**4.2%**	**0.233**
In-stent restenosis	**18.0%**	**0%**	
Lesion Length (cm)	**11.53±8.91**	**9.55±4.86**	**<.001**
Calcification	**67.4%**	**56.6%**	**0.011**
Occluded Lesion (100% stenosis)	**35.3%**	**16.1%**	**<.001**
Procedural Characteristics			
Provisional Stent	**20.7%**	**10.5%**	**0.002**

* Site reported

Primary Efficacy Outcome

Total IN.PACT All-Subjects Freedom From CD-TLR through 12



Primary Safety Outcomes

12-month Outcomes	Total IN.PACT All-Subjects Analysis		
Safety	DCB (N=1837 Subjects)	PTA (N=143 Subjects)	P-value
Clinically-driven TLR[1]	6.2%	19.9%	<.001
Any TLR	6.5%	19.9%	<.001
Primary Safety Endpoint[2]	93.4%	78.0%	<.001
Device- or procedure- related death (30 days)	0.2%	0.0%	1.000
Major Adverse Events[3]	10.2%	22.7%	<.001
All-cause death	3.1%	0.0%	0.030
Major Target Limb Amputation	0.2%	0.0%	1.000
Clinically-driven TVR[4]	7.0%	22.0%	<.001
Thrombosis	2.5%	2.8%	0.777

1. Clinically-driven TLR defined as any re-intervention within the target lesion(s) due to symptoms or drop of ABI ≥ 20% or > 0.15 when compared to post-index procedure baseline ABI.
2. Primary Safety Endpoint is a composite of freedom from device- and procedure-related mortality through 30 days, freedom from major target limb amputation and TLR within 12 months post-index procedure
3. Major adverse events is defined as all-cause mortality, clinically-driven TVR, major target limb amputation, thrombosis at the target lesion site
4. Clinically-driven TVR is defined as any re-intervention within the target vessel due to symptoms or drop of ABI of ≥ 20% or > 0.15 when compared to post-index procedure baseline ABI

Total IN.PACT All Subjects
Standard vs Broader Subgroup Analysis

Standard Use

Defined as IDE-like patients and lesions typical of pivotal trials, including:

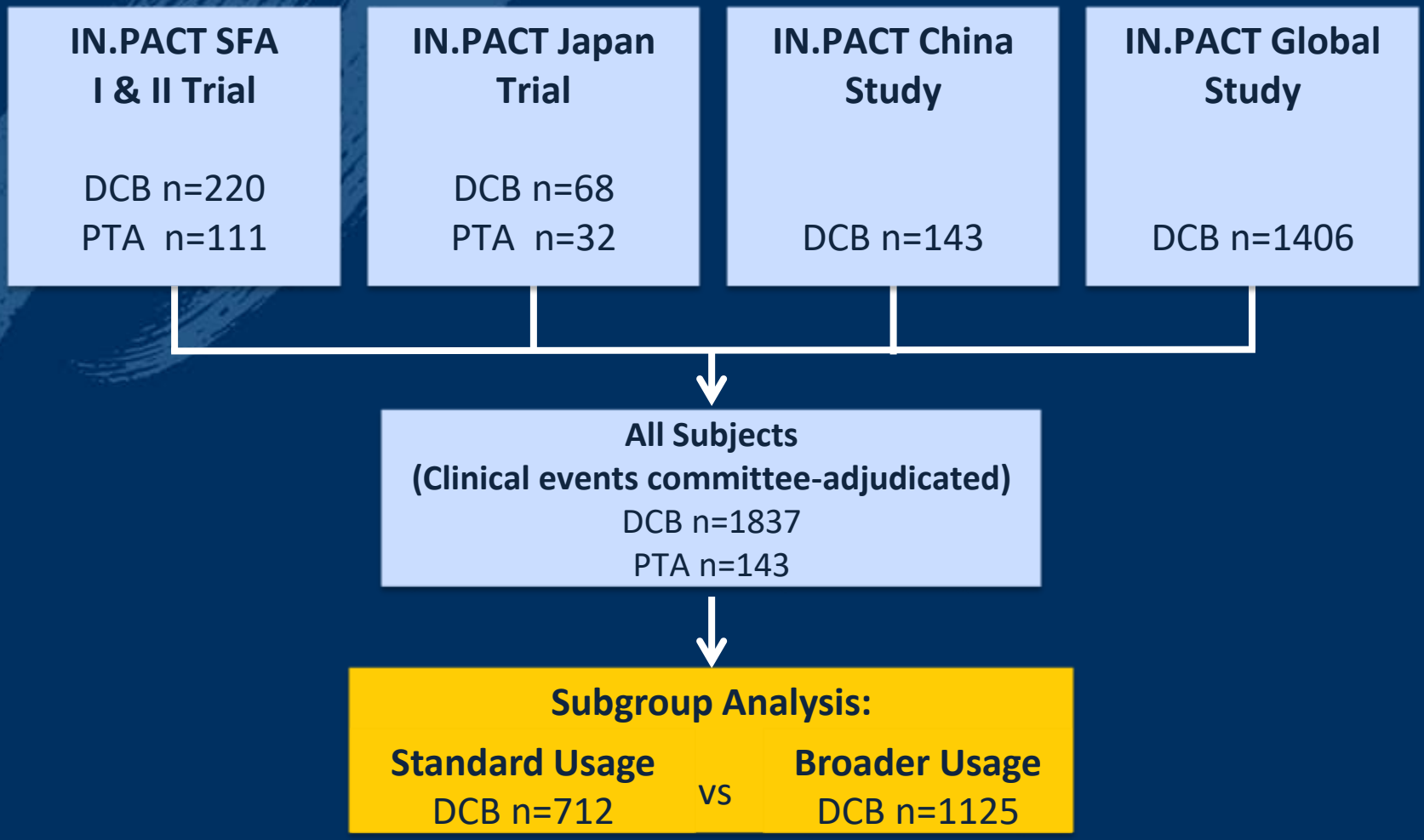
- Simple *de novo* lesions, lesion length ≤ 20 cm
- Single lesion
- Total occlusions ≤ 10 cm
- Calcium (none to mild)
- Excludes In-stent restenosis

Broader Use

Defined as complex patients and lesions, typically excluded from pivotal trials, including:

- Bilateral, multiple lesions
- Calcium (moderate to severe)
- All subjects that do not meet the “Standard Use” criteria

Total IN.PACT Subgroup Analysis



Baseline Characteristics

	Total IN.PACT All-Subjects: Standard vs Broader Usage Analysis		
Baseline Characteristics	**Standard (N= 712 Subjects)**	**Broader (N= 1125 Subjects)**	**P-value**
Age	67.8±9.5	68.9±10.0	0.018
Male	67.1%	68.9%	0.441
Hypertension	81.3%	85.1%	0.032
Hyperlipidemia	67.5%	70.9%	0.140
Diabetes	41.8%	40.8%	0.661
Active Smoker	36.8%	30.2%	0.004
Previous Peripheral Revascularization	37.2%	56.1%	<.001
Below-the-knee Disease of Target Leg	46.9%	46.1%	0.731
Rutherford Category			<.001
2	41.6%	29.3%	-
3	50.7%	58.6%	-
4	7.7%	8.7%	-
5	0%	3.2%	-
ABI/TBI*(mmHg)	0.71±0.23 (670)	0.67±0.22 (1029)	0.001

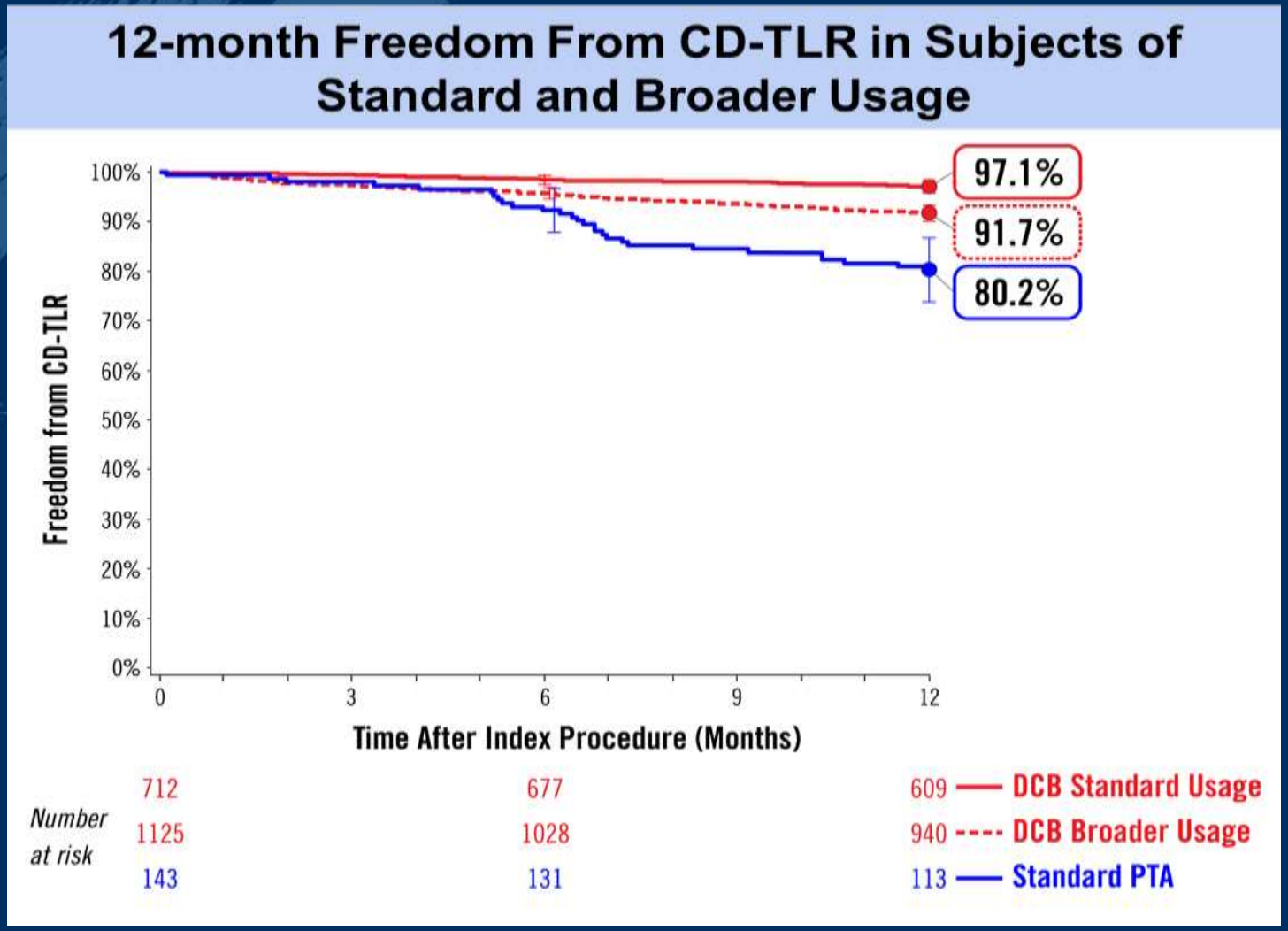
*TBI allowed / used in case of incompressible vessels in IN.PACT SFA II phase

Lesion/Procedural Characteristics

	Total IN.PACT All-Subjects: Standard vs Broader Usage Analysis		
Lesion/Procedural Characteristics*	**Standard (N= 712 Subjects) (N= 712 Lesions)**	**Broader (N= 1125 Subjects) (N= 1492 Lesions)**	**P-value**
Lesion Characteristics			
Lesion Type			
De Novo	**94.5%**	**70.8%**	**<.001**
Restenotic (non-stented)	**5.5%**	**7.7%**	**0.060**
In-stent restenosis	**0%**	**21.5%**	**<.001**
Lesion Length (cm)	**8.68±4.89**	**12.88±10.01**	**<.001**
Calcification	**55.3%**	**73.3%**	**<.001**
Occluded Lesion (100% stenosis)	**34.4%**	**35.7%**	**0.568**
Procedural Characteristics			
Provisional Stent	**9.8%**	**27.6%**	**<.001**

* Site reported

Total IN.PACT
Standard vs Broader Subgroup Analysis



Summary

- The Total IN.PACT All-Subjects Analysis is the largest, multi-ethnic, pooled, independently-adjudicated drug-coated balloon (DCB) series to date
- The IN.PACT™ Admiral™ DCB continues to demonstrate superior safety and freedom from revascularization rates compared to PTA
- Total IN.PACT Imaging and Propensity-matched analyses have previously shown that clinical efficacy of DCB is independent of lesion length
- In the Total IN.PACT All-Subjects subgroup analysis, both the standard and broader application of the IN.PACT™ Admiral™ DCB demonstrated superior outcomes to PTA

THANK YOU

Total IN.PACT All-Subjects Pooled 1-Year Analysis

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