

# SCAAR

Long term outcome after treatment of de novo coronary artery lesions using three different drug-coated balloons

## Conclusions

- In this large real-world retrospective analysis, Pantera® Lux® exhibits similar efficacy and safety outcomes with two contemporary Drug-Coated Balloons (DCB) during long-term follow-up.
- Pantera Lux numerically shows lowest cumulative rate of clinically driven restenosis\* (4.4%) compared to SeQuent Please (5.9%) and IN.PACT Falcon (5.0%).
- DCB angioplasty in de novo lesions was feasible for all three DCBs, with high success rate<sup>††</sup> (98.5%), low use of bailout stenting (6.7%) and low risk for clinically driven restenosis\* and Target Lesion Thrombosis (TLT) during long-term follow-up over four years. These results emphasize the potential use case of Pantera Lux in de novo lesions.

## Study design

Retrospective analysis of SCAAR data collected between 2009 and 2017, comparing three contemporary DCBs for the treatment of coronary de novo lesions.

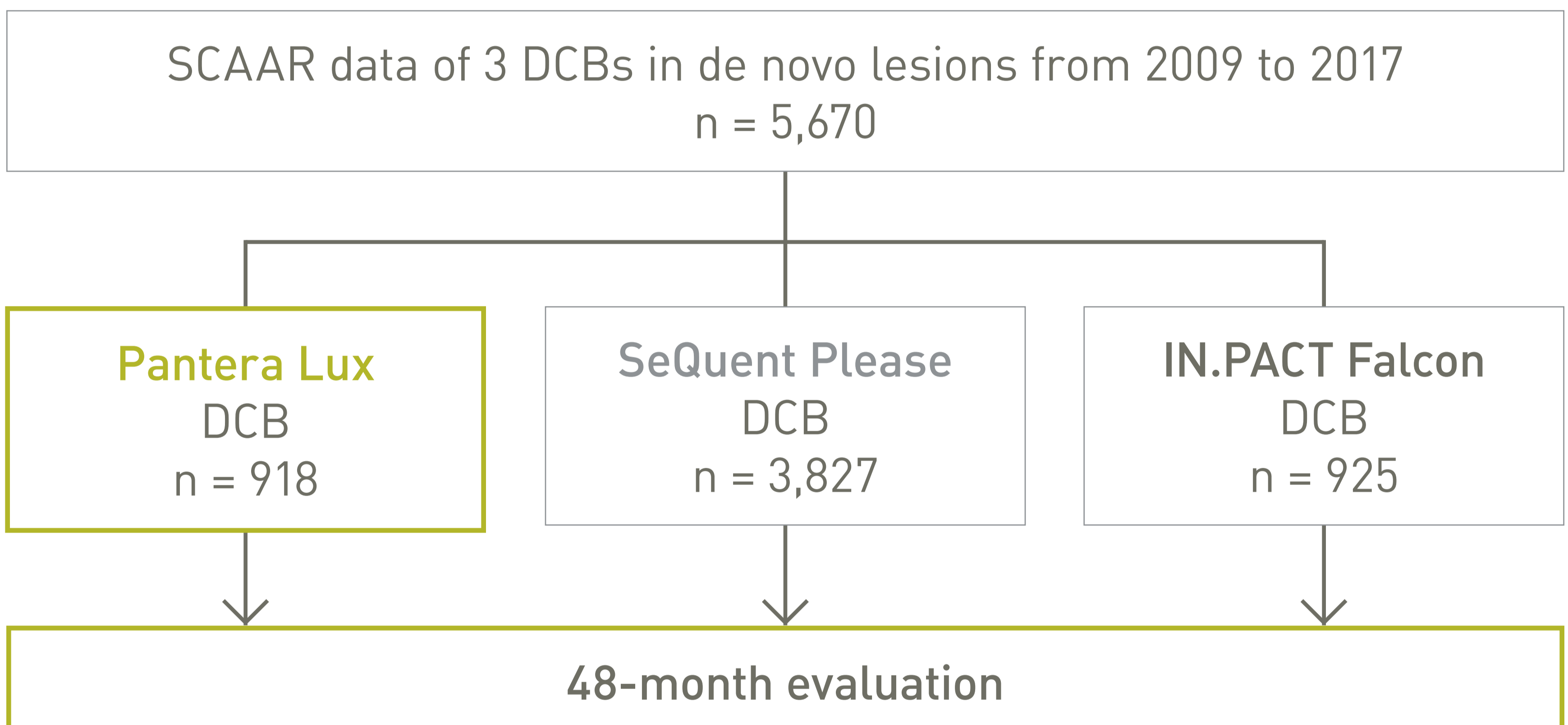
## Endpoints

### Primary Endpoint

- Cumulative 4-year rate of reported clinically driven restenosis\* and definite Target Lesion Thrombosis (TLT) (per DCB).

### Secondary Endpoint (selected)

- Cumulative 4-year rate of Major Adverse Cardiac Events (MACE)\*\*



Patient characteristics	All DECB n = 5,670	Pantera Lux n = 918	SeQuent Please n = 3,827	IN.PACT Falcon n = 925	p-value
Age, yrs <sup>†</sup>	67.9 ± 10.7	68.0 ± 10.9	67.8 ± 10.6	67.7 ± 10.6	0.76
Female	24.4%	23.4%	24.6%	24.1%	0.73
Hypertension	72.6%	73.7%	72.9%	70.0%	0.14
Diabetes	27.6%	29.9%	27.1%	27.5%	0.87
Previous MI	36.6%	40.0%	35.8%	36.6%	0.06

Lesion and procedural characteristics	All DECB n = 5,670	Pantera Lux n = 918	SeQuent Please n = 3,827	IN.PACT Falcon n = 925	p-value
Number of lesions	6,715	1,161	4,483	1,071	-
Stenosis class B2/C	52.7%	55.9%	52.0%	52.2%	0.06
Bifurcation	25.9%	28.4%	26.3%	21.8%	<0.01
Chronic total occlusion	3.4%	4.2%	3.1%	4.0%	0.08
DCB diameter (mm) <sup>†</sup>	2.43 ± 0.44	2.36 ± 0.41	2.47 ± 0.45	2.34 ± 0.40	<0.01
Diameter ≤2.75 mm	82.3%	85.4%	79.8%	89.3%	<0.01
Diameter <2.25 mm	37.2%	45.7%	33.9%	41.6%	<0.01
Bailout stent	6.7%	5.9%	7.2%	5.6%	0.09
Local success <sup>††</sup>	98.5%	98.6%	98.4%	98.8%	0.67

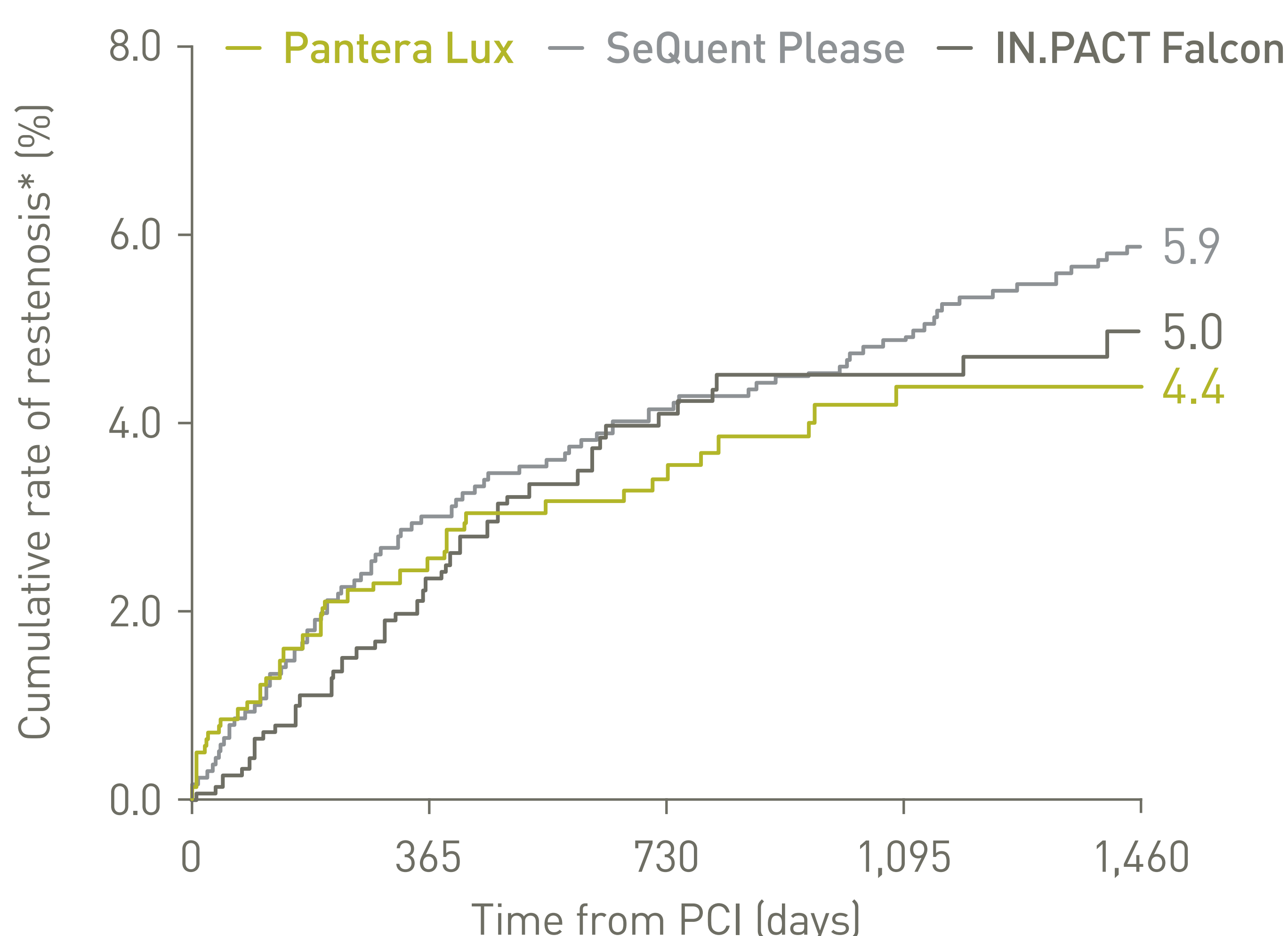
\* Restenosis was defined as clinically relevant >50% stenosis in a previously treated segment, by visual assessment, or by a significant fractional flow reserve or instantaneous wave-free ratio in a subsequent and clinically driven coronary angiography.

\*\* Defined as the composite of death, myocardial infarction (MI) and target vessel revascularization with PCI (TVR) and the individual components of MACE (per patient).

† Data shown as mean ± SD

†† Defined in SCAAR as residual stenosis less than 50%, with normal flow, without any serious complication.

## Primary Endpoints up to 4 years (1,460 days)



**25%**  
lower restenosis rate\* vs. SeQuent Please

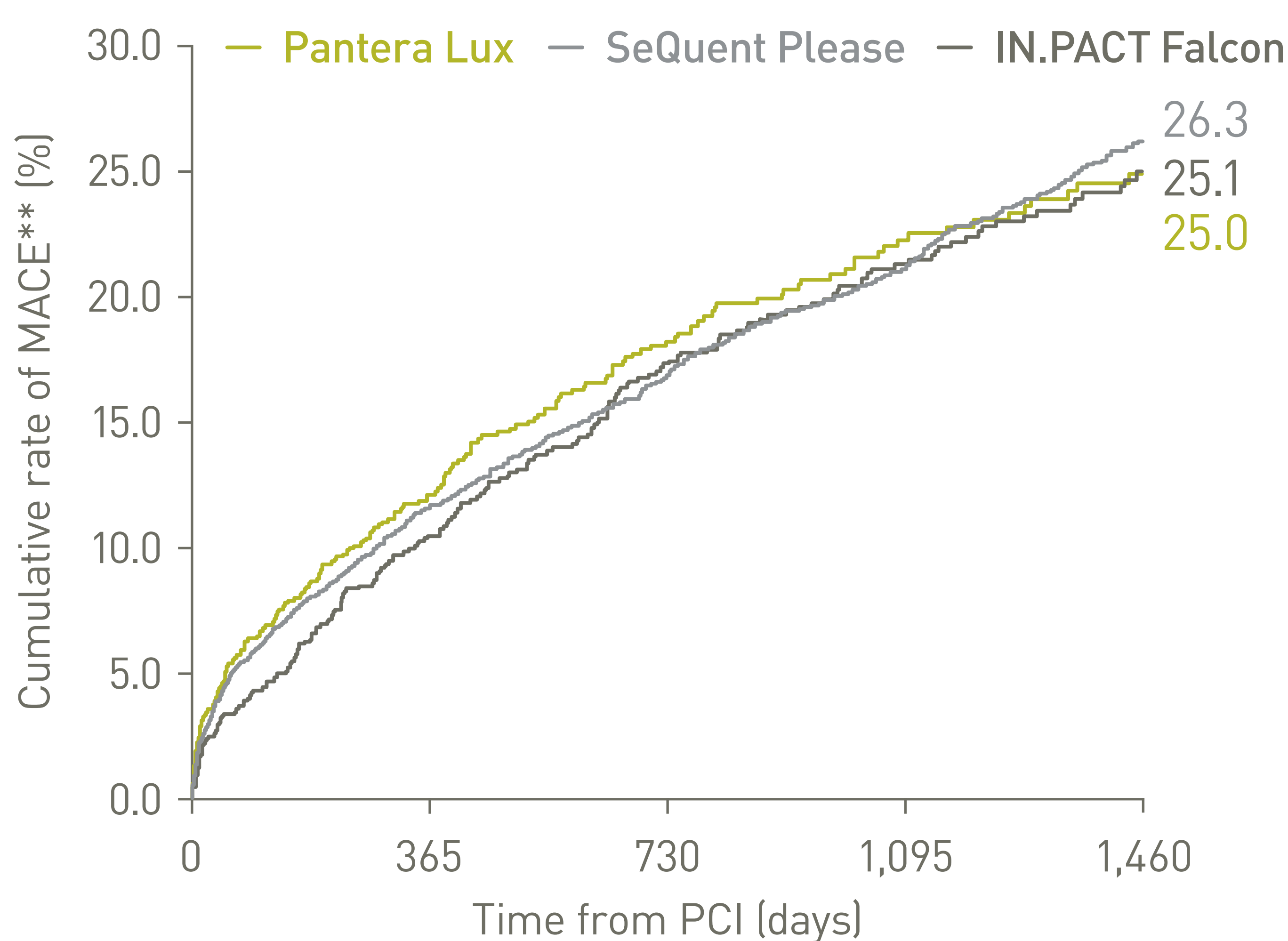
### Cumulative rate of clinically-driven restenosis\*

	<b>Pantera Lux</b> n (DCBs) = 1,161	SeQuent Please n (DCBs) = 4,483	IN.PACT Falcon n (DCBs) = 1,071	HR (95% CI) <sub>adjusted</sub>
IN.PACT Falcon vs. SeQuent Please	-	5.9%	5.0%	0.96 (0.69–1.34)
Pantera Lux vs. SeQuent Please	4.4%	5.9%	-	0.88 (0.63–1.23)
IN.PACT Falcon vs. Pantera Lux	4.4%	-	5.0%	1.10 (0.72–1.68)

### Cumulative rate of definite TLT

	<b>Pantera Lux</b> n (DCBs) = 1,161	SeQuent Please n (DCBs) = 4,483	IN.PACT Falcon n (DCBs) = 1,071	HR (95% CI) <sub>adjusted</sub>
IN.PACT Falcon vs. SeQuent Please	-	0.8%	0.8%	1.01 (0.44–2.31)
Pantera Lux vs. SeQuent Please	0.8%	0.8%	-	1.32 (0.62–2.80)
IN.PACT Falcon vs. Pantera Lux	0.8%	-	0.8%	0.75 (0.28–2.02)

## Selected secondary endpoint up to 4 years (1,460 days)



Numerically lowest MACE\*\* rate up to 4 years.

### Cumulative rate of MACE\*\*

	<b>Pantera Lux</b> n (DCBs) = 918	SeQuent Please n (DCBs) = 3,827	IN.PACT Falcon n (DCBs) = 925	HR (95% CI) <sub>adjusted</sub>
IN.PACT Falcon vs. SeQuent Please	-	26.3%	25.1%	1.04 (0.89–1.23)
Pantera Lux vs. SeQuent Please	25.0%	26.3%	-	1.07 (0.90–1.25)
IN.PACT Falcon vs. Pantera Lux	25.0%	-	25.1%	0.98 (0.80–1.21)

1. Reference: Venetsanos D, Omerovic E, Sarno G et al. Long term outcome after treatment of de novo coronary artery lesions using three different drug coated balloons. International Journal of Cardiology. 2020; 1-7. doi: 10.1016/j.ijcard.2020.09.054.

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