TABLE 1. Key points to bear in mind when choosing a non-inferiority margin

Considerations when choosing the non-inferiority margin
1. Accurately estimate the efficacy of the active control (over placebo or previous controls)
2. Nature and clinical relevance of events (misleading composite outcomes)
3. Implications of choosing an absolute or relative difference
4. Weight of the new treatment´s ancillary benefit
5. Achievable sample size

TABLE 2. Summary of key findings from 9 non-inferiority trials of new stent vs. 2nd generation stent comparator. Relative risk margins (RR) have been calculated. Asterisk: reference provided for value. A: Absorb; B: Biomatrix; N: Nobori; O: Orsiro; P: Promus; PE: Promus Element; R: Resolute; U: Ultimaster; X: Xience

					Control arm			Experimental arm		
Study name	% Expected event rate	% MNI (RR)	Beta	Alpha (one-sided)	stent	n	% Observed event rate	stent	n	% Observed event rate
RESOLUTE AC	8	3.5 (1.44)*	0.1	0.05	X	1126	8.3	RE	1119	8.2
PLATINUM	5.5	3.5 (1.64)*	0.11	0.05	X/P	737	3.1	P	742	3.5
COMPARE II	9.5	4 (1.42)	0.1	0.05	X/P	912	4.8	N	1795	5.2
CENTURY II	10	5.5 (1.55)*	0.1	0.05	X	557	5	U	562	4.6
BIOSCIENCE	8	3.5 (1.44)*	0.2	0.05	X	1056	6.6	O	1063	6.5
DUTCH PEERS	10	3.6 (1.36)*	0.2	0.05	P	905	5.2	RI	905	6.1
SORT OUT VI	6.5	2.5 (1.38)*	0.2	0.05	RI	1497	5	B	1502	5.3
ABSORB III	7*	4.5 (1.64)	0.04	0.025	X	677	6.1	A	1313	7.8
ABSORB Japan	9*	8.6 (1.96)*	0.1	0.05	X	133	3.8	A	265	4.2

TABLE 3. Intention-to-treat and per-protocol or as-treated analyses from the stent trials. The pre-defined absolute NI margin used in the designs and their relative proportion to the expected event rate. 95% and 97.5% upper CI limit for the difference and for the RR in brackets, derived from ITT or PP/AT analyses. Asterisks indicate the values used for testing non-inferiority by each study.

		One-sided CI for ITT analysis %(RR)		One-sided CI for PP/AT analysis %(RR)	
Study name	% NI margin (RR)	95% CI	97.5% CI	95% CI	97.5% CI
RESOLUTE AC	3.5 (1.44)	1.8 (1.24) *	2.2 (1.30)	2.0 (1.29)	2.3 (1.35)
PLATINUM	3.5 (1.64)	1.9 (1.78) *	2.2 (1.95)	2.0 (1.88)	2.3 (2.06)
COMPARE II	4.0 (1.42)	1.8 (1.44) *	2.1 (1.52)	1.9 (1.52)	2.2 (1.62)
CENTURY II	5.5 (1.55)	1.7 (1.42) *	2.1 (1.55)	1.5 (1.39)	1.9 (1.52)
BIOSCIENCE	3.5 (1.44)	1.6 (1.28) *	2.0 (1.35)	1.2 (1.21)	1.6 (1.27)
DUTCH PEERS	3.6 (1.36)	2.7 (1.61) *	3.0 (1.71)	2.7 (1.63)	3.0 (1.74)
SORT OUT VI	2.5 (1.38)	1.6 (1.36) *	1.8 (1.43)	not presented	not presented
ABSORB III	4.5 (1.64)	3.6 (1.72)	4.0 (1.82) *	3.8 (1.75)	4.2 (1.85)
ABSORB Japan	8.6 (1.96)	3.8 (2.63) *	4.4 (3.11)	not presented	not presented