Déjeuner/Repas Débat ABBOTT

« Docteur, je veux un stent qui se dissout »
ABSORB,la révolution oui, mais chez quel patient ?

Les dernières données ABSORB

Didier Carrié
CHU Toulouse

APPAC 4 Juin 2014

Aucun conflit d’intérêt

Let's make a dream:

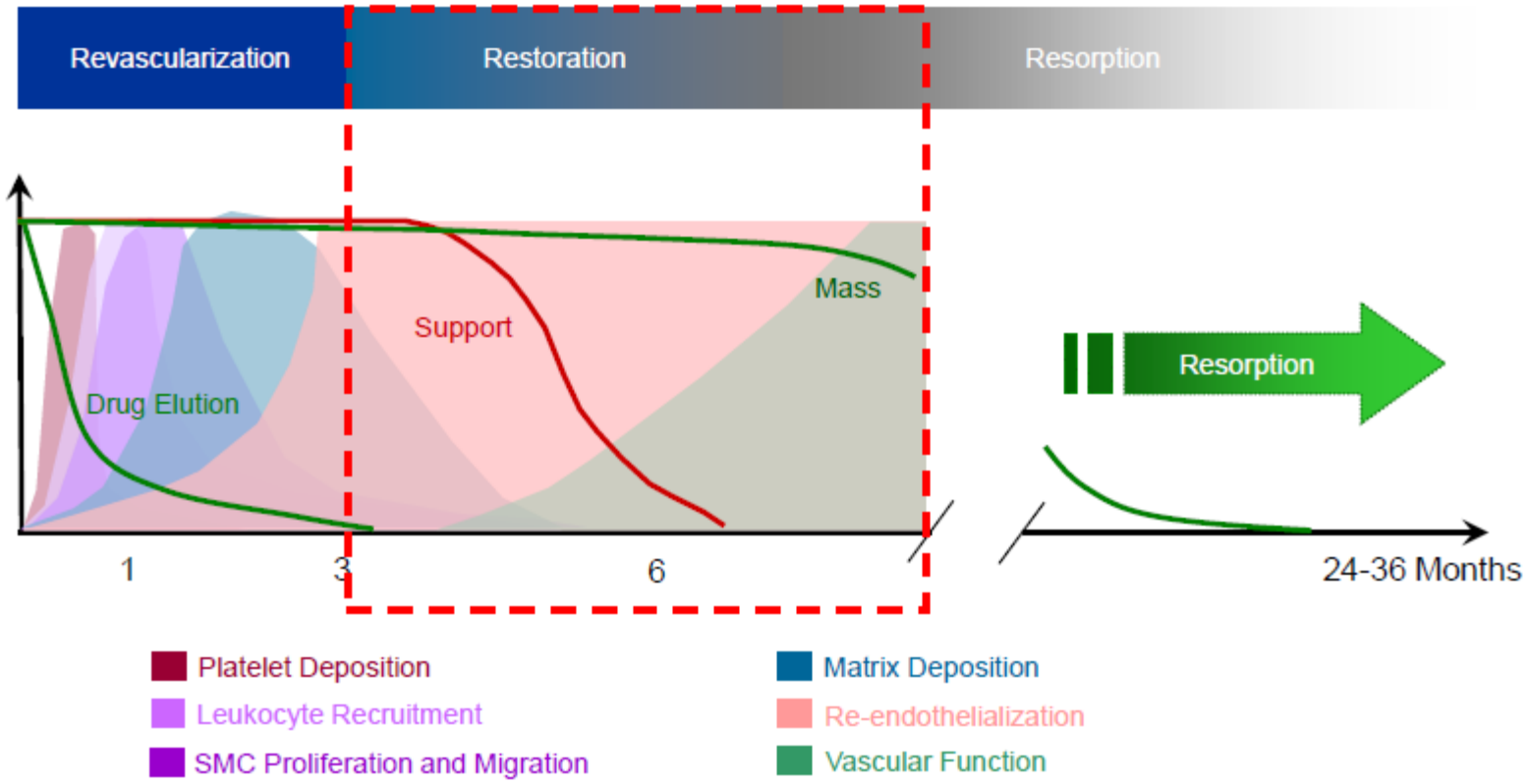
imagine a stent that offers:

- ✓ Transient instead of permanent; no foreign body left behind
- ✓ Reduction late stent thrombosis risk: no foreign body left behind
- ✓ Reduction expensive, inconvenient dual anti-platelet therapy
- ✓ Sustain natural remodeling, restore vasomotion
- ✓ Preserve future: no interference at re-intervention
- ✓ Allow non-invasive follow-up with MRI and multislice CT

In order for BVS to become a disruptive technology vs. DES it has to….

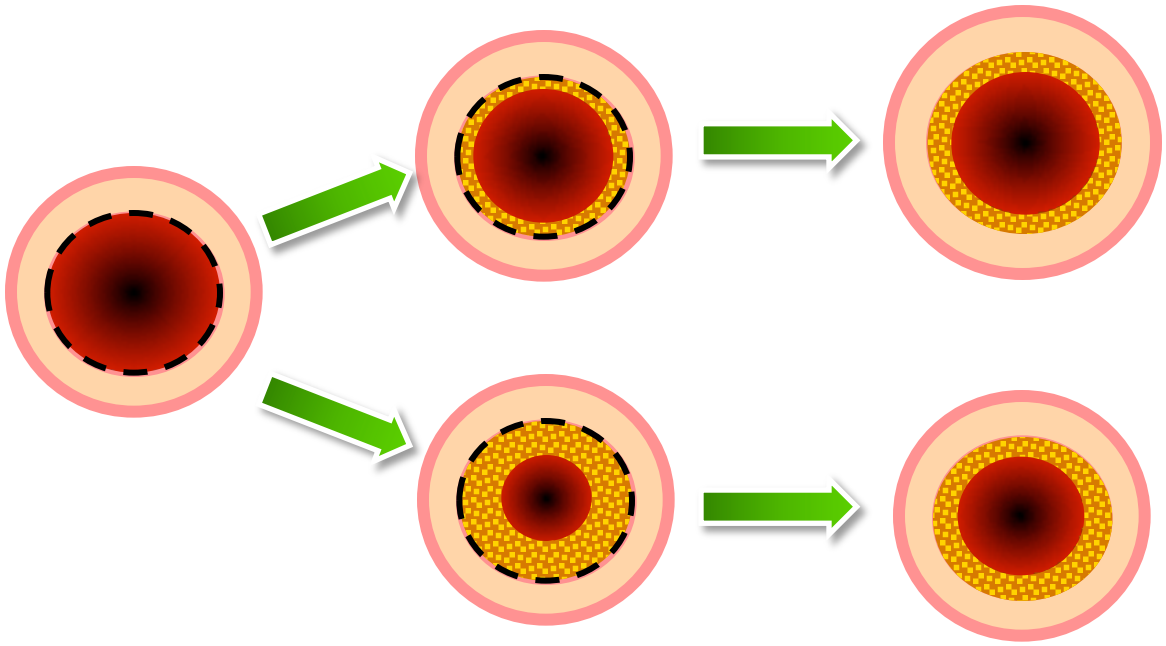
- Improve clinical outcomes vs. OMT
- Improve clinical outcomes vs. DES
- Provide equivalent outcomes vs. CABG
- Restore the coronary physiology
- Define the target population and lesions
- Become an affordable technology

Performance Criteria for a Fully Bioresorbable Device



Forrester JS, *et al*., *J. Am. Coll. Cardiol*. **17**, 758 (1991)
Oberhauser JP, *et al*., *EuroInterv*. **5**, F15 (2009)

Potential of a Fully* Bioresorbable Vascular Scaffold

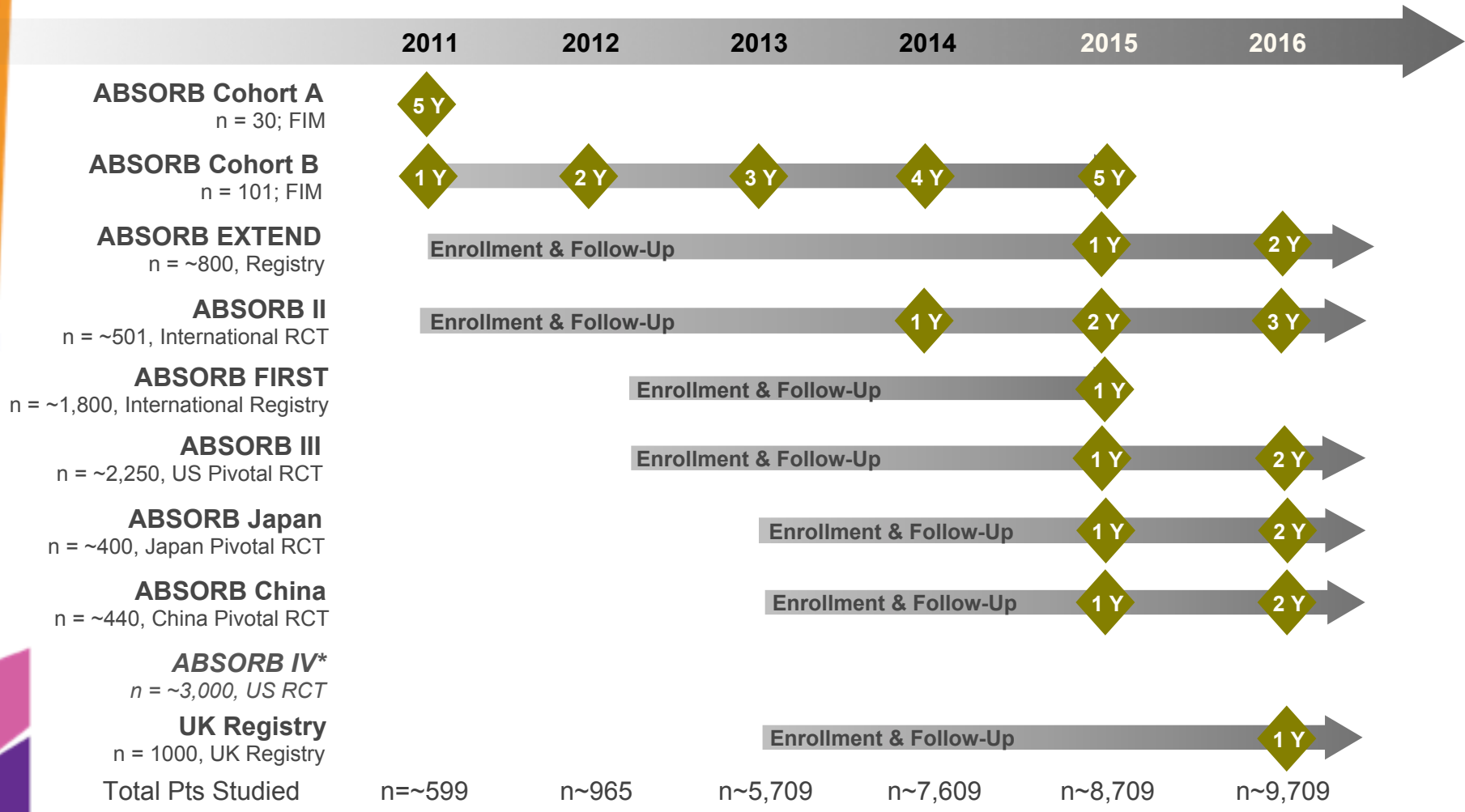


Since struts disappear, issues related to very late persistent strut malapposition and chronically uncovered struts become irrelevant

[1]Serruys, PW, ACC 2011 / [2]Serruys, PW, et al. *Lancet*. 2009; 373: 897-910.
*Small platinum markers at scaffold edges remain for fluoroscopic landmarking.
NIH: NeoIntimal Hyperplasia

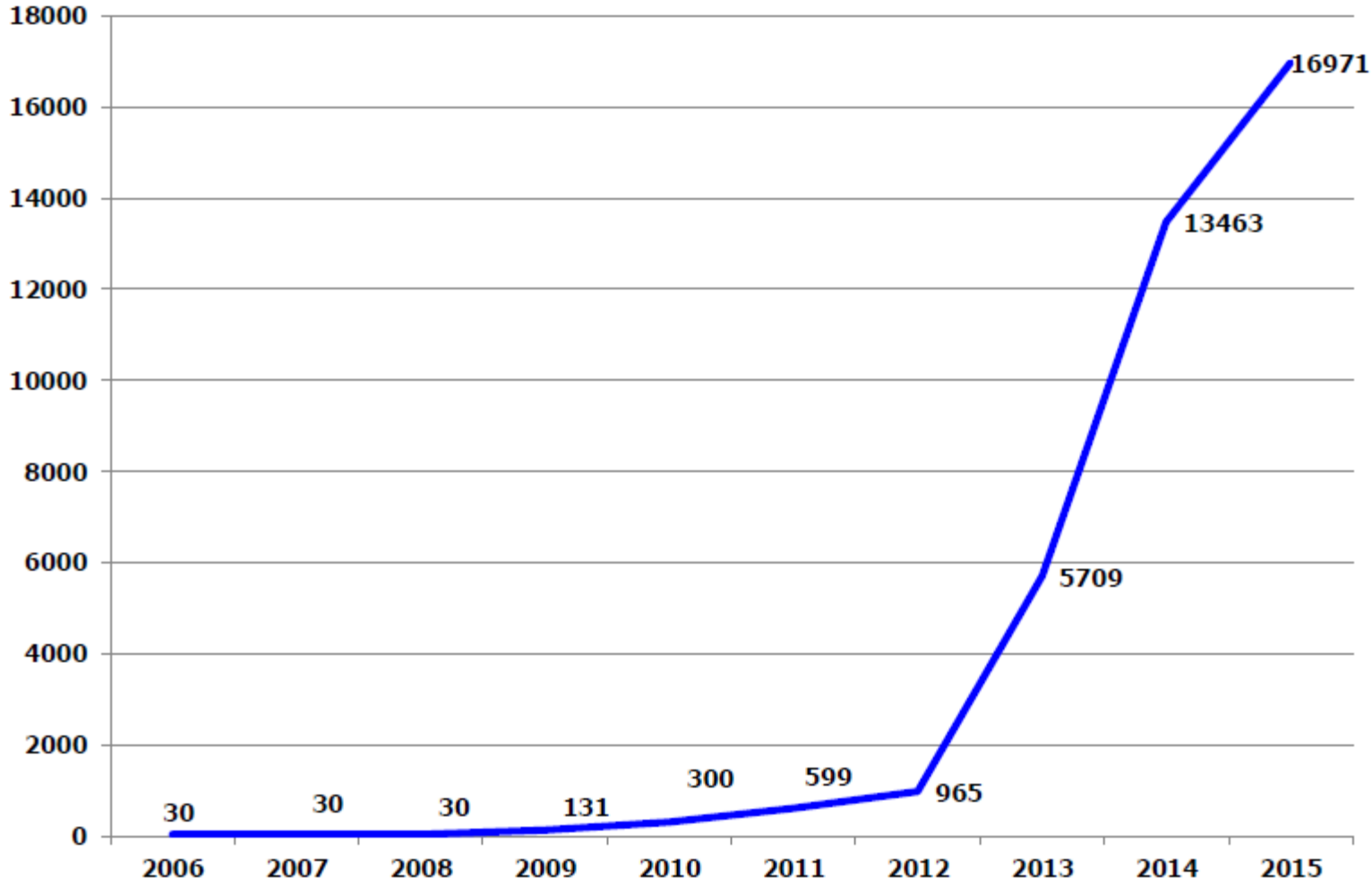
Absorb

Comprehensive AV-Sponsored Clinical Program: >9000pts



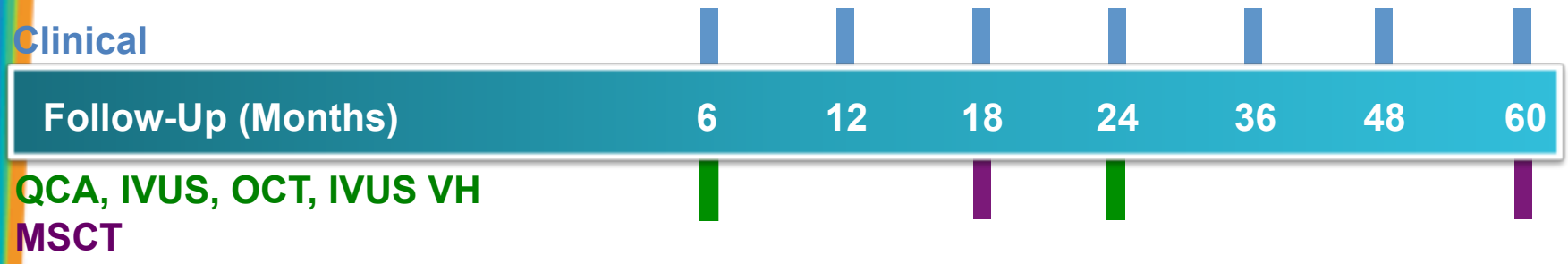
Each trial n reflects total patients. Data effective 9/2013.
*ABSORB IV trial is in the planning stage and subject to change.

No. of patients included in the ABSORB trials



ABSORB Cohort A

30 subjects
(Non-randomized) 4 sites in Europe & New Zealand



Study Objective	First In Man, Single Arm – safety/performance
Endpoints	Typical PCI clinical and imaging endpoints
Treatment	Single, *de novo* native coronary lesion in a vessel with a reference vessel diameter of 3.0 mm
Device Sizes	3.0 x 12 mm scaffolds (3.0 x 18 mm scaffolds available after enrollment start and used in 2 pts)

ABSORB Cohort A Clinical Long-term Results

Intention-to-Treat

	RESTORATION		RESORPTION	
Hierarchical	**6 Months 30 Patients**	**1 year 29 Patients****	**2 Year 29 Patients****	**5 Year 29 Patients****
Ischemia Driven MACE***	1 (3.3%)*	1 (3.4%)*	1 (3.4%)*	1 (3.4%)*
Cardiac Death	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
MI	1 (3.3%)*	1 (3.4%)*	1 (3.4%)*	1 (3.4%)*
Q-Wave MI	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Non Q-Wave MI	1 (3.3%)*	1 (3.4%)*	1 (3.4%)*	1 (3.4%)*
Ischemia Driven TLR	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
by PCI	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.%)
by CABG	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.%)

No scaffold thrombosis by ARC or Protocol

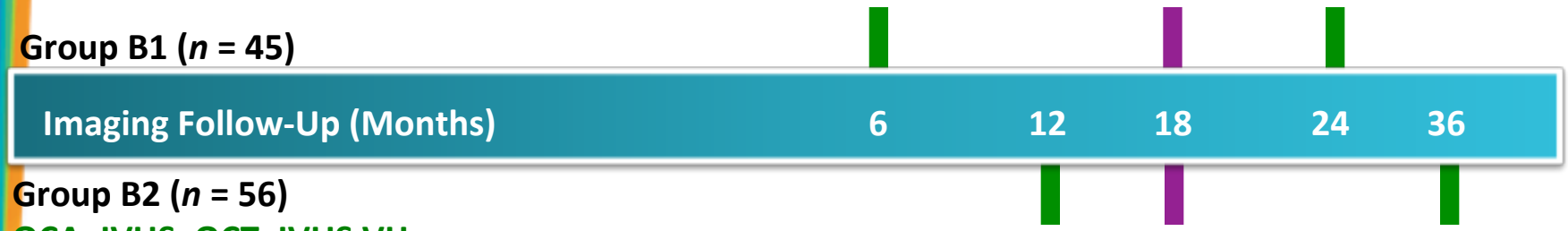
*Same patient – this patient also underwent a TLR, not qualified as ID-TLR (DS = 42%). **One patient withdrew consent and missed the 9, 12, 18 month and 2, 3, and 4 year visits; two patients died from a non-cardiac causes, one at 706 days and one at 888 days post procedure. ***MACE – Composite endpoint comprised of cardiac death, myocardial infarction (MI) and ischemia-driven target lesion revascularization (TLR) by PCI or CABG.

Serruys, ABSORB Cohort A 5-year results; TCT, 2011

ABSORB Cohort B

4 Yr ACC14

101 subjects
(Non-randomized) 12 sites in Europe, Australia, New Zealand



Study Objective	First In Man, Single Arm – safety/performance
Endpoints	Typical PCI clinical and imaging endpoints
Treatment	Up to 2 *de novo* lesions in different epicardial vessels Reference vessel diameter of 3.0 mm, lesions ≤ 14 mm in length
Device Sizes	3.0 x 18 mm devices

ABSORB Cohort B1 Clinical Long-term Results

Intention-to-Treat

Non-Hierarchical	30 Days	6 Months	12 Months	2 Years	3 Years	4 Years
	N = 45	N = 45	N = 45	N = 44*	N = 44*	N = 44*
Cardiac Death %	0	0	0	0	0	0
Myocardial Infarction % (n)	2.2 (1)	2.2 (1)	2.2 (1)	2.3 (1)	2.3 (1)	2.3 (1)
Q-wave MI	0	0	0	0	0	0
Non Q-wave MI	2.2 (1)	2.2 (1)	2.2 (1)	2.3 (1)	2.3 (1)	2.3 (1)
Ischemia driven TLR % (n)	0	2.2 (1)	4.4 (2)	4.5 (2)	4.5 (2)	4.5 (2)
CABG	0	0	0	0	0	0
PCI	0	2.2 (1)	4.4 (2)	4.5 (2)	4.5 (2)	4.5 (2)
Hierarchical MACE % (n)	2.2 (1)	4.4 (2)	6.7 (3)	6.8 (3)	6.8 (3)	6.8 (3)
Hierarchical TVF % (n)	2.2 (1)	4.4 (2)	6.7 (3)	6.8 (3)	9.1 (4)**	9.1 (4)**

ABSORB Cohort B1 – 4 Yr Clinical Results, B. Chevalier, TCT2013

*One patient lost to FUP

**Non-TLR TVR at 957 days

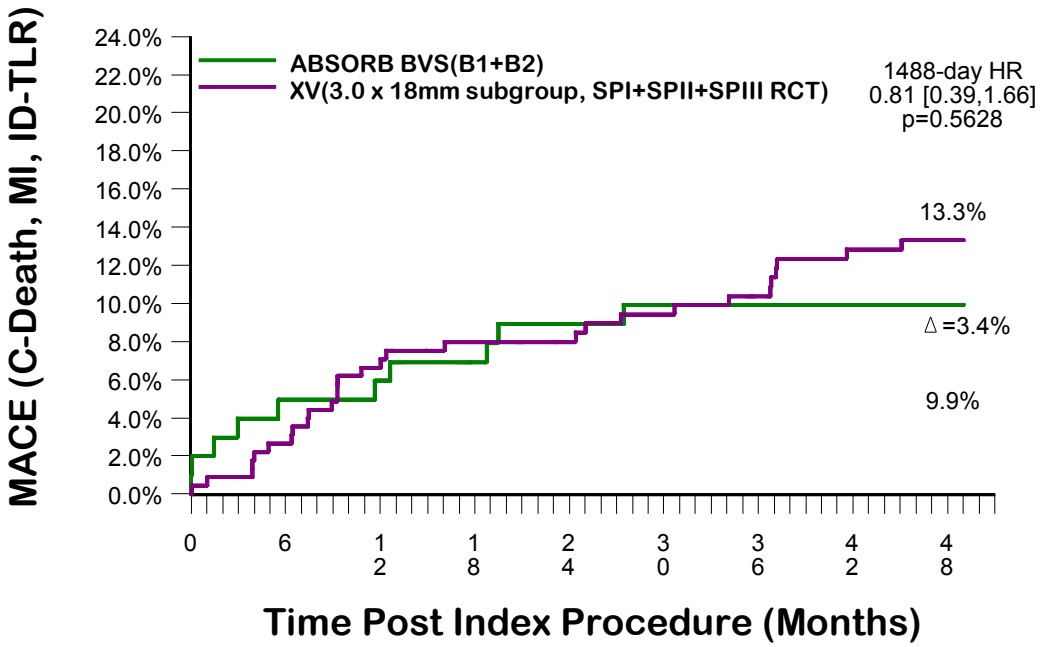
No new MACE between 1-year and 4-years

No scaffold thrombosis by ARC or Protocol

MACE: Cardiac death, MI, ischemia-driven TLR, TVF: Cardiac death, MI, ischemia-driven TLR, ischemia-driven TVR

ABSORB Cohort B

KM Estimate of MACE Rate in Patients Treated with Absorb vs. Patients Treated with a Single 3.0x 18 mm Metallic XIENCE V



Time After Index Procedure (days)								
	0	**37**	**194**	**284**	**393**	**758**	**1123**	**1488**
ABSORB BVS(B1+B2) At Risk	101	99	96	96	94	91	89	39
XV(3.0 x 18mm subgroup, SPI+SPII +SPIII RCT) At Risk	227	224	219	211	204	191	182	178

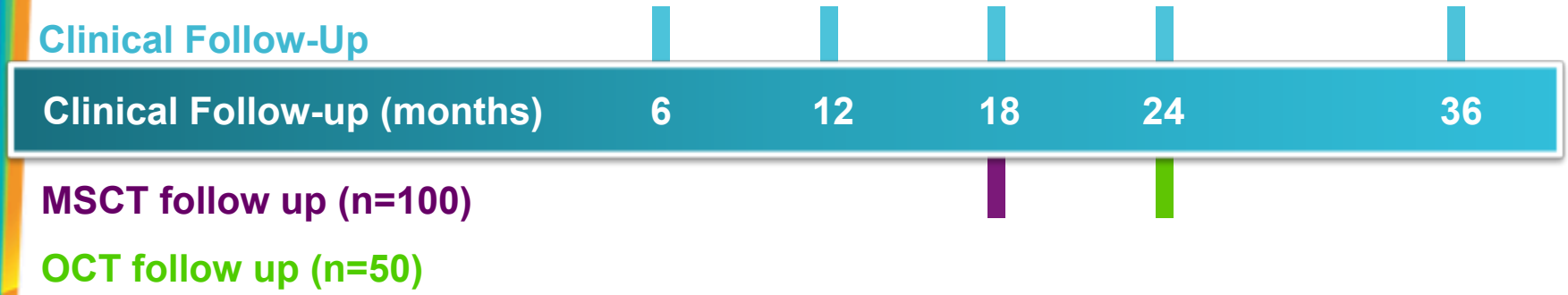
P-values are not from formal hypotheses testing and are displayed for exploratory purpose only.

ABSORB Cohort B1 – 4 Yr Clinical Results, B. Chevalier, TCT2013

ABSORB Extend

2 Yr 450pts ACC14

814 subjects enrolled
Up to 100 global (non US) sites



Study Objective	**Continued Access trial. FPI: Jan 11, 2011**
Endpoints	**Typical PCI clinical endpoints**
Treatment	**Up to 2 *de novo* lesions in different epicardial vessels** **Planned overlapping allowed in lesions >22 and ≤ 28 mm**
Device Sizes	**Scaffold diameters: 2.5, 3.0, 3.5 mm** **Scaffold lengths: 12*, 18, 28 mm**

* Available in EU only

An Interim 24-month Propensity Score Analysis Comparison of Clinical Outcomes of ABSORB EXTEND & ABSORB Cohort B Patients to XIENCE V Patients

Baseline Clinical Characteristics	Cohort B / EXTEND (N = 501)	SPIRIT FIRST, II & III (N = 628)	p value
Male (%)	72	71	0.88
Mean age (years)	61	62	0.25
Prior Cardiac Intervention on Target Vessel (%)	7	7	0.97
Previous MI (%)	26	26	1.00
Unstable Angina (%)	24	23	0.60
Diabetes mellitus (%)	24	26	0.59
Dyslipidemia req. med. (%)	71	69	0.71
Hypertension req. med. (%)	69	69	0.91
Current smoker (%)	22	24	0.49

An Interim 24-month Propensity Score Analysis Comparison of Clinical Outcomes of ABSORB EXTEND & ABSORB Cohort B Patients to XIENCE V Patients (2)

Baseline Lesion Characteristics	Cohort B / EXTEND (N = 501)	SPIRIT FIRST, II & III (N = 628)	p value
Lesion Location LCX (%)	27	29	0.52
At least one B2/C Lesion (%)	53	53	0.97
Single Lesion Treated (%)	87	88	0.34
QCA pre-procedure			
Mean RVD (mm)	2.63± 0.36	2.67 ± 0.46	0.07
Mean % DS (%)	63±11	63 ±13	0.62
Mean Lesion Length (mm)	12.97±5.27	13.01±5.21	0.91
Range (min, max)	(3.13,33.78)	(3.80, 31.10)	n/a

An Interim 24-month Propensity Score Analysis Comparison of Clinical Outcomes of ABSORB EXTEND & ABSORB Cohort B Patients to XIENCE V Patients (3)

2-Year Clinical Results: Non-Hierarchical %	Cohort B / EXTEND (N = 501)	SPIRIT FIRST, II & III (N = 628)	p value
Cardiac Death	0.53	1.11	0.30
Myocardial Infarction*	4.50	3.06	0.20
Q-wave MI	0.66	0.38	0.50
Non Q-wave MI	3.83	2.68	0.28
Ischemia driven TLR	4.28	3.98	0.80
CABG	1.07	0.11	0.03
PCI	4.17	3.88	0.80
Hierarchical MACE	7.57	7.32	0.87
Hierarchical TLF	7.28	6.85	0.78
Hierarchical TVF	8.43	11.34	0.11

* Per Protocol Definition
MACE: Cardiac Death, Protocol-defined MI, Ischemia Driven-TLR
TLF: Cardiac Death, Protocol-defined Target Vessel-MI, Ischemia Driven-TLR
TVF: Cardiac Death, Protocol-defined MI, Ischemia Driven-TLR, Ischemia Driven-Non-TLR TVR

An Interim 24-month Propensity Score Analysis Comparison of Clinical Outcomes of ABSORB EXTEND & ABSORB Cohort B Patients to XIENCE V Patients (4)

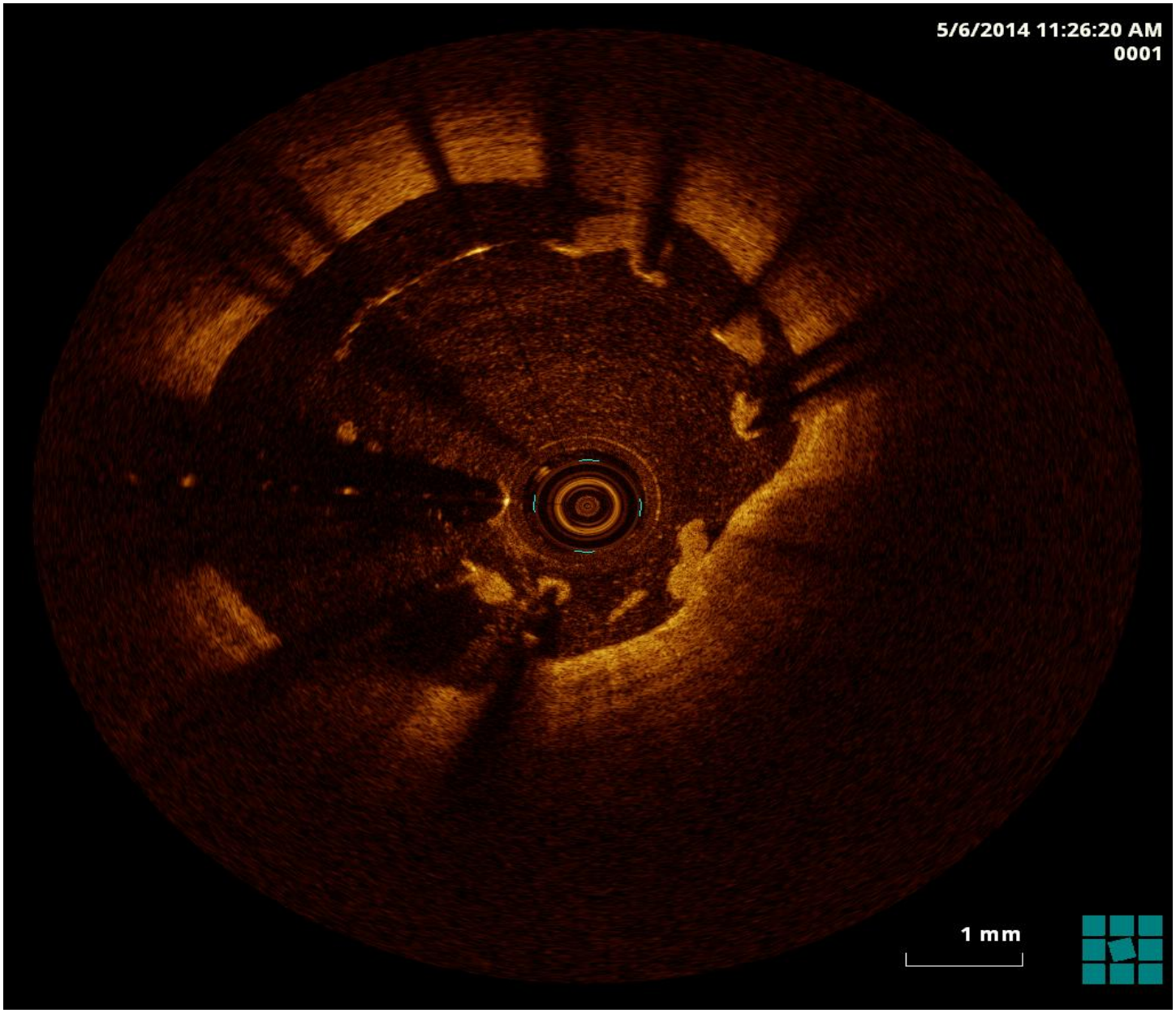
2-Year Thrombosis (ARC Def/Prob) %	Cohort B / EXTEND (N = 501)	SPIRIT FIRST, II & III (N = 628)	p value
0 - 758 Days Total	**0.76**	**1.21**	**0.45**

CONCLUSION

At 2 years, in this population, the clinical safety and effectiveness of ABSORB remained similar to XIENCE:

- No statistical significant difference in Cardiac Death, MI, ID-TLR, MACE, TLF and TVF
- Low rates of thrombosis at 2 years; 0.76% for ABSORB vs 1.21% for XIENCE, (NS)

These data will be confirmed in several ongoing randomized trials across different geographies, namely ABSORB II, ABSORB III, ABSORB Japan and ABSORB China


5/6/2014 11:26:20 AM
0001
1 mm

Règle des 5P…

pour une mise en place optimale d'Absorb

- **P**réparer la lésion
- **P**rendre des mesures précises de la taille du vaisseau
- **P**rendre en compte les limites d'expansion
- **P**ost-dilater avec un ballon non-compliant
- **P**réconiser un traitement DAPT

En synthèse …

- ABSORB est sûr et efficace dans les indications actuelles issues des premières études
- Le respect d'une bonne préparation avec la règle des 4P est obligatoire
- La post dilatation est recommandée pour assurer une parfaite apposition
- Les thromboses seront évitées si on respecte bien les règles d'implantation

Quelle est l'expérience des centres Francais aujourd'hui ?

Quels sont les patients Absorb aujourd'hui en France ?

=> Expérience Sud

=> Expérience Nord

=> Absorb en Image