NEXT Study

11 European Sites: 323 enrolled patients, randomised 1:1

Single de novo lesions (max 2 in 2 different vessels) in native coronary arteries

Cre8 (n=162 pts)	**TAXUS™ Liberté® (n=161 pts)**

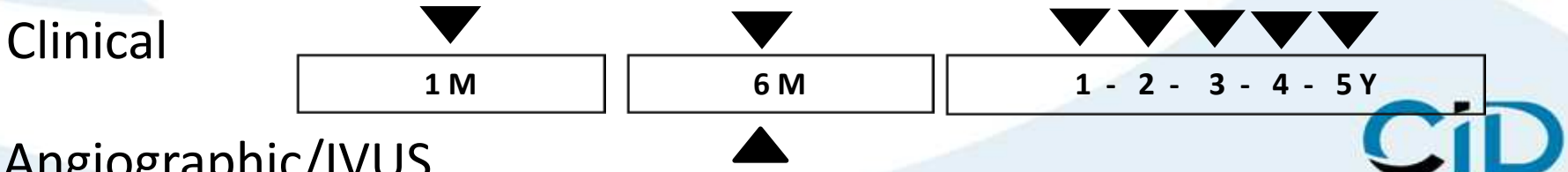
ENROLMENT PHASE COMPLETE: 13/09/2010

Primary Endpoint:

- **LLL in-stent at 6 months post-procedure (non inferiority margin= 0.16 mm)**

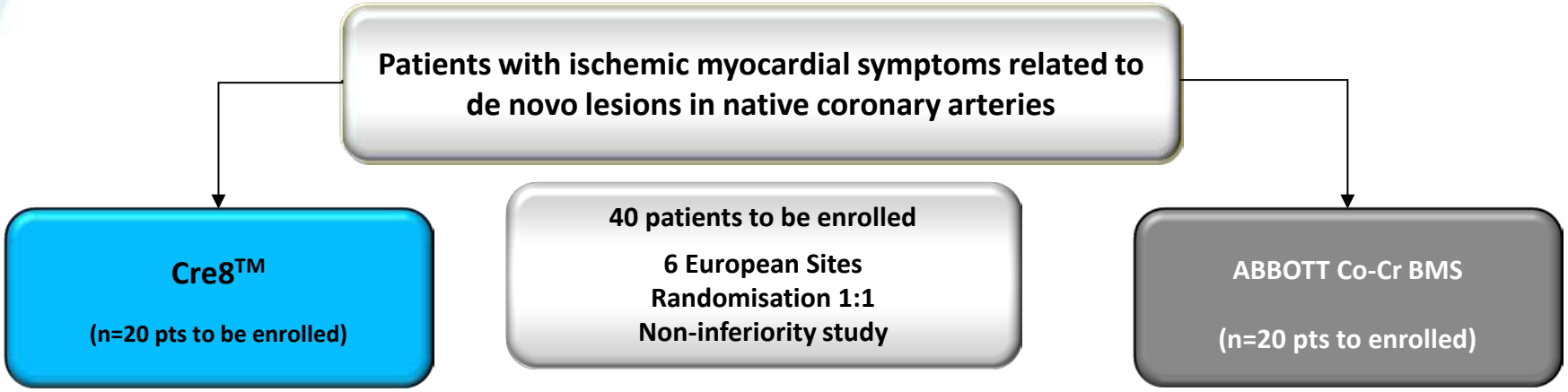
Secondary Endpoints:

- QCA measurements in-stent and in-segment at 6 months
- IVUS measurements at 6 months (20% of the enrolled patients)
- Clinical composite occurrence of death, MI, any revascularization at 1 and 6 months, and yearly up to 5 years
- Thrombosis throughout the study duration, according to ARC definition



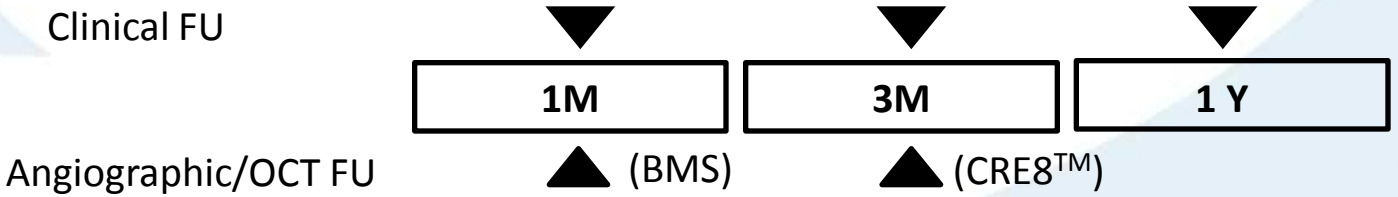
DEMONSTR8 Study

Randomized comparison between a DES and a BMS to assess neointimal coverage by OCT evaluation



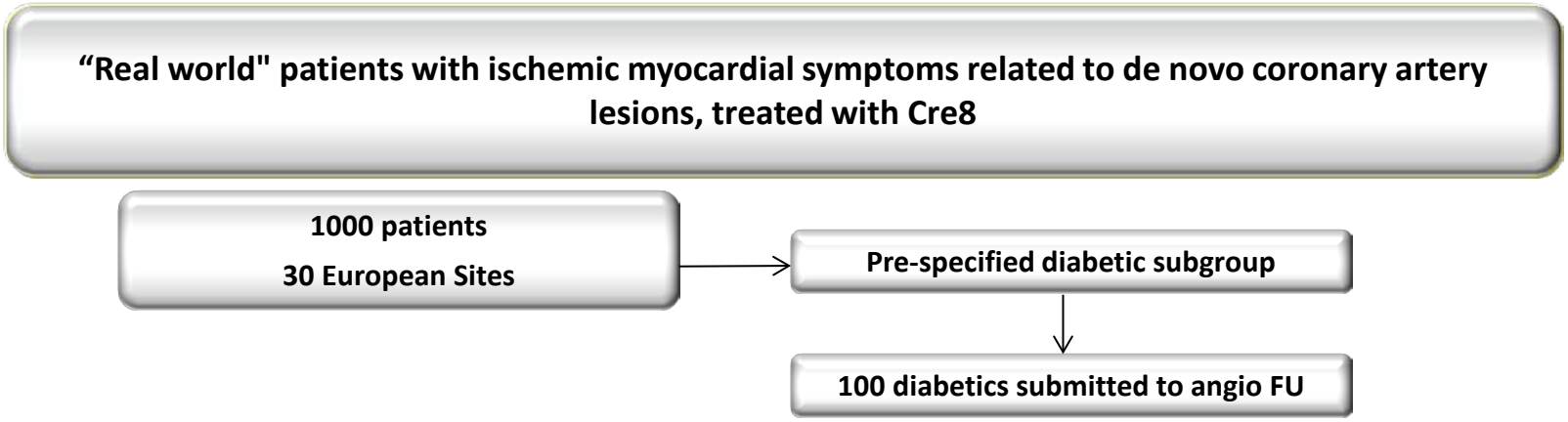
Primary Endpoint:

Cre8™ percentage of sections with RUTTS* score < 30% @ 3-month non inferior to Vision Multilink percentage of sections with RUTTS score < 30% @ 1-month

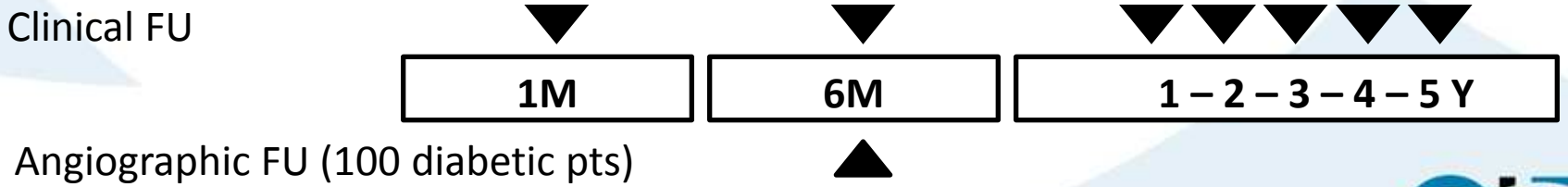


PARTICIP8 Study

Prove ART (Abluminal Reservoir Technology) clinICal benefIt in “all comers” PATiEnts



- **COORDINATING CLINICAL INVESTIGATOR:** Dr. A. Colombo, San Raffaele H., Milan (Italy)
- **ANGIOGRAPHIC&OCT CORE LAB**: Mediolanum Cardio Research (Italy)
- **TRIAL COMMITTEE:** Clinical Events Committee (CEC)



CID
Carbostent & Implantable Devices

eCRE8 Clinical Registry

Consecutive subjects with evidence of myocardial ischemia requiring a revascularization procedure with a CRE8 stent.

Prospective, Non randomised,
4 centers in Italy)
n= 500 pts
Dr. Colombo (Coordinating Clinical Investigator, OSR-Milan)
eCRFs on USB key

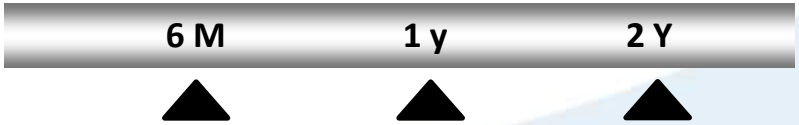
Primary Endpoint:

Incidence of composite rate of cardiac death, all MI, clinically driven TLR at 1 year

Secondary Endpoints:

- Incidence of composite rate of all death, all MI, TVR at 6 months, 1 and 2 years;
- Thrombosis rate according to ARC definition for each follow-up period.

Phone call



CID
Carbostent & Implantable Devices

DIAB8 Study

Clinical benefit in “all comers” patients with **DIAB**etes to prove Cre**8** ART (Abluminal Reservoir Technology)

Subjects over 18 years who are undergoing a clinically indicated coronary angiogram and angioplasty on de-novo lesion located in native coronary arteries. At least 20% of the patients enrolled in this study will be patients with Diabetes Mellitus requiring insulin.

Prospective, Multicenter (20 centers in Europe, Latin America and Asia)
n= 600 pts
Dr. A. Colombo (Coordinating Clinical Investigator)
eCRFs; CEC

Primary Endpoint:

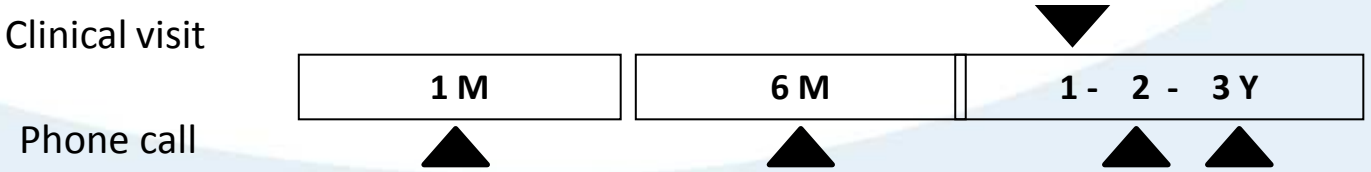
Incidence of 12 month device-oriented clinical composite endpoint, defined as:

Cardiac death / Target vessel MI / Clinically indicated TLR*

Secondary Endpoints:

- Incidence of clinical composite endpoint at 1, 6 , 12 months and yearly up to 3 years:
  - Cardiac death/Target vessel MI/Clinically indicated TLR*
  - All death/All MI/All Repeat Revascularization**

  **Device oriented composite endpoint **Patients oriented composite endpoint*
- Incidence of stent thrombosis throughout the study duration, classified according to ARC definition
- Procedural success



CID
Carbostent & Implantable Devices

ACCUR8 Clinical Study Design

A prospe**C**tive randomised **C**omparison in patients undergoing PCI who are perceived to be good BMS candidates and s**U**itable for 1 month DAPT of C**Re8** DES vs BMS

1:1 randomization

BMS | **Cre8**

779 pts per group (N=1,558) to have 85% power to detect a 4.5% absolute difference corresponding to a 37.5% relative risk reduction. Sample size will ben increased to 1,600 to account for lost to follow-up

1 Month DAPT duration

Antiplatelet monotherapy for 11 months in both arms

30-35 EU Centres involved

Primary combined Safety and Efficacy Endpoint for Stent comparison (superiority EP)

Cardiovascular death, non-fatal MI, Definite or probable ST, or any clinically driven TVR at 12 months