STUDY TITLE	**FIM-LIMUS-DCB TRIAL : Treatment of Coronary In-Stent Restenosis by a Sirolimus (Rapamycin) Coated Balloon or a Paclitaxel Coated Balloon**
STUDY POPULATION	**Patient with 2 or less primary drug eluting stent in-stent restenosis lesion**
PRINCIPAL INVESTIGATOR	Datuk Dr. Rosli Mohd Ali
STUDY COORDINATOR	Salizah Selamat Contact number : 03 – 2617 8200 ext 3132
START DATE	26 Jan 2016
END DATE	30 Jun 2016
INCLUSION	• At least 18 years of age and able to give informed consent • Clinical evidence of stable or unstable angina (acute coronary syndrome) or an abnormal functional study demonstrating myocardial ischemia due to the target lesion(s) • Patients with primary 2 or less primary drug-eluting stent in-stent restenosis (DES-ISR) lesions (70% diameter stenosis or more or 50% or more and positive functional study) including margin-stenosis with max 5 mm distance to the stent in the native coronary arteries* • Lesion length 25 mm or less • Patients with lesions suitable for percutaneous coronary intervention (PCI) • Patients who are mentally and linguistically able to understand the aim of the study and to show sufficient compliance in following the study protocol • Patients must agree to undergo the 6-month angiographic and clinical follow-up • Patients must agree to undergo the 1 year clinical follow-up • The patients, by providing their informed consent, agree to these risks and benefits as stated in the patient informed consent document *Treatment of an additional lesion in the non-target vessel, including non-ISR lesions, is permissible if the lesion is treated prior to the target lesion (ideally 24hrs or more) without any evidence of post-procedural MACE.

EXCLUSION	• Reference vessel diameter (RVD) less than 2.5 mm • Lesion length more than 25 mm • Intended treatment of more than 2 DES-ISR lesions or a total of more than 3 lesions (including native vessel disease) per patient • ST-elevation myocardial infarction (MI) within the past 72 hours • Severe renal failure with creatinine more than 2.0 mg/dL (177 µmol/L) • Known hypersensitivity or contraindication to aspirin, heparin, clopidogrel or ticlopidine, or sirolimus • Sensitivity to contrast media not amenable to premedication • Left ventricular ejection fraction less than 35% known prior to the intervention • Untreated pre-procedural hemoglobin less than 10 g/dL • Coagulopathy manifested by platelet count less than 100,000 • Women who are known or suspected to be pregnant; women who are breast-feeding • Patients in cardiogenic shock • Patients with concomitant medical illnesses that require cytostatic or radiation therapy • Patients with a life expectancy of less than 2 years • Unprotected Left Main diameter stenosis 50% or more • Visible thrombus (by angiography) at target lesion site • Patients who are concurrently participating in an investigational study when such participation could confound the treatment or outcomes of this study • Patients under administrative or judicial custody