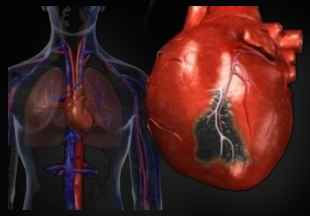
MEDIGENIUM

INNOVATION THAT REALLY MATTERS

Cardioshield



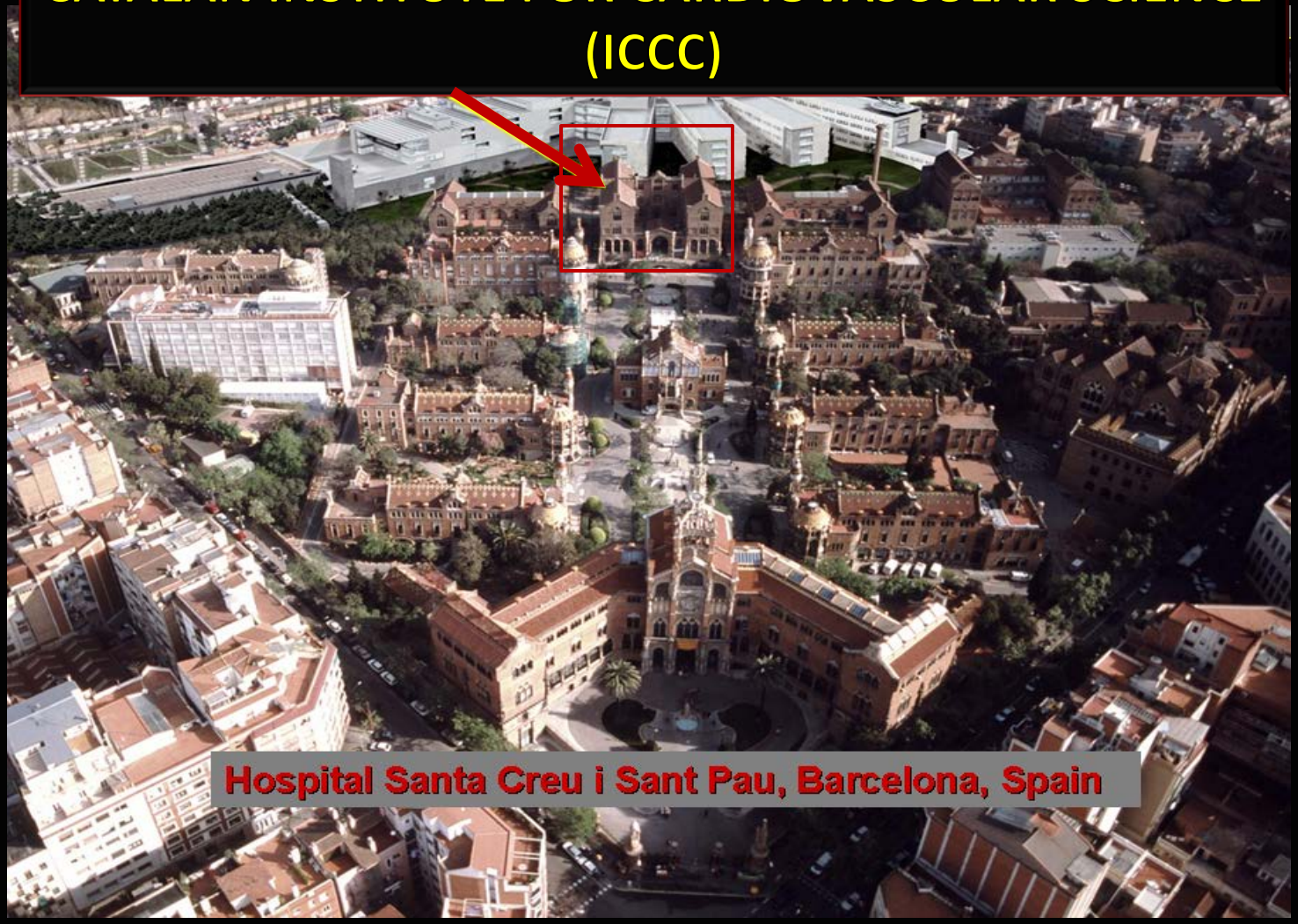
Prof. Lina Badimon

Institut Català de Ciències Cardiovasculars (ICCC), Barcelona

THE INSTITUTION

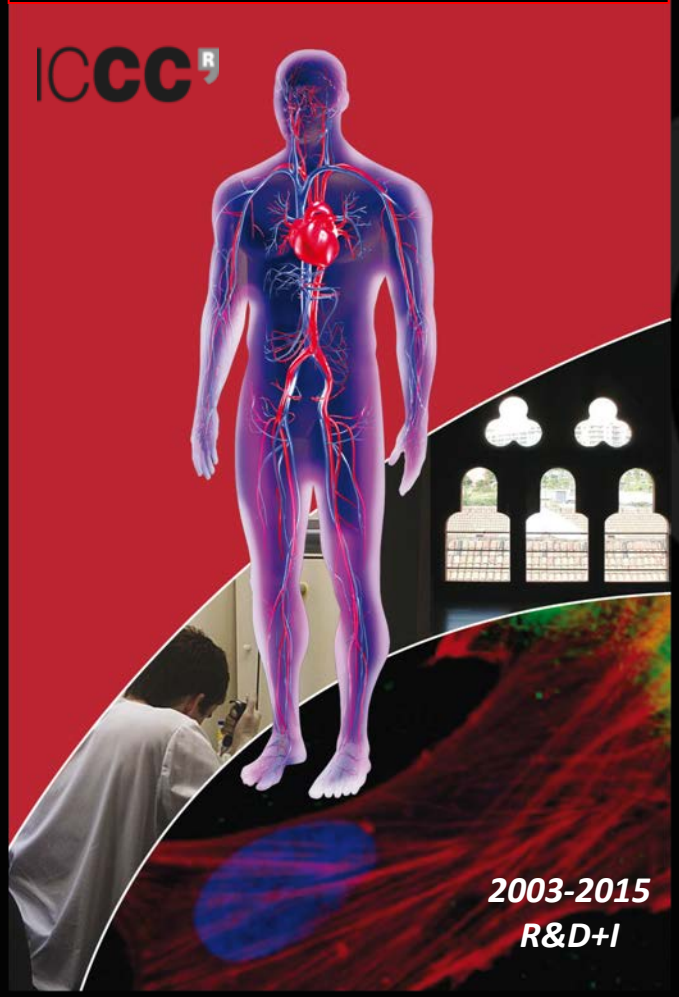
THE INSTITUTION

CATALAN INSTITUTE FOR CARDIOVASCULAR SCIENCE (ICCC)



THE ICCC

CATALAN INSTITUTE FOR CARDIOVASCULAR SCIENCE (ICCC)



Objectives

- LEADING AN STRATEGIC PLANNING IN CVR
- SCIENTIFIC EXCELLENCE
- INTERNATIONAL PRESENCE
- AVAILABILITY OF NEEDED INFRASTRUCTURE
- NETWORKING AND COLLABORATIONS
- FUNDAMENTAL RESEARCH
- TRANSLATIONAL RESEARCH

TRANSFERERENCE of INNOVATION

THERAPEUTICS **DIAGNOSTICS**

CLINICAL PRACTICE

FUNCTIONAL ORGANIZATION

European Projects
Spanish Governmental Projects (PN. FIS)
Pharmaceutical Companies
Private Foundations

FUND RAISING

INTERNATIONAL VISIBILITY

EXTERNAL RELATIONS

DIRECTOR

ADMINISTRATIVE OFFICERS

SCIENTISTS

TEACHING EDUCATION FOR FELLOWS AND TECHNICAL PERSONNEL

TECHNICAL PLATFORMS

HISTOPATHOLY UNIT
INTRAVITAL CONFOCAL MICROSCOPY
MICRODISSECTION UNIT(LCM)
CONFOCAL MICROSCOPY
FLOW CYTOMETRY UNIT
ANIMAL RESEARCH UNIT (UEA)
FOTONIC IMAGES TECHNIQUES
GENOMIC UNIT
PROTEOMICS
CELL CULTURE
NMR NON-INVASIVE IMAGING
BIO-BANKING

STRATEGICAL RESEARCH LINES (2003-2015)

1. MOLECULAR PATHOLOGY OF ATHEROSCLEROSIS
2. MOLECULAR PATHOLOGY OF ARTERIAL THROMBOSIS
3. PATHOPHYSIOLOGY OF ISCHEMIC HEART DISEASE
4. CARIOPROTECTION AND CARDIAC REMODELING
5. CELL THERAPY & ANGIOGENESIS
6. SYSTEMS BIOLOGY – GENOMICS AND PROTEOMICS
7. BIOMARKERS

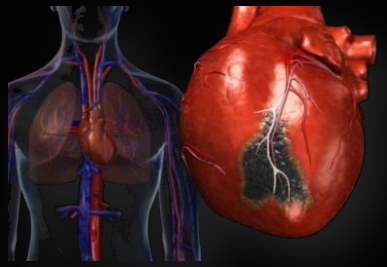
Molecular Pathology and Therapeutic of Ischaemic and Atherothrombotic Diseases.

IP: L. Badimon

Institut Català de Ciències Cardiovasculars (ICCC)

THE PRODUCT

TARGET INDICATION: ISCHEMIC HEART DISEASE



WORLD

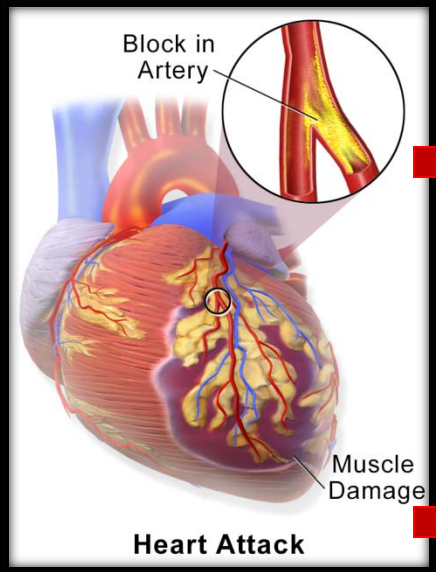
WHO 2012: 17,5 million people died from CVD

LEADING CAUSE OF DEATH GLOBALLY: **31% total deaths**

Ischemic heart disease is the leading cause of death from CVS

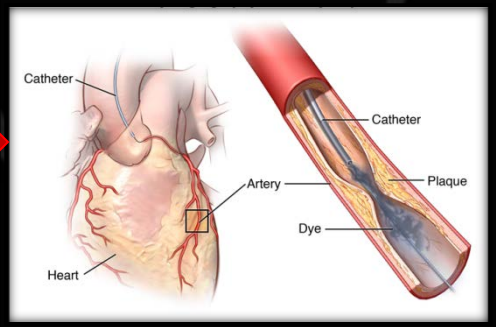
ISCHEMIA

Myocardial infarction



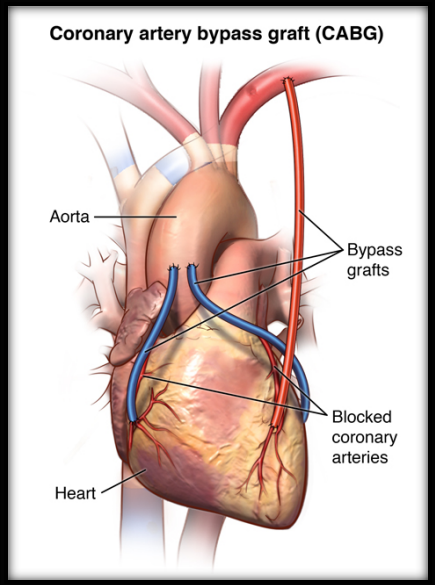
REPERFUSION

Percutaneous coronary intervention



REPERFUSION

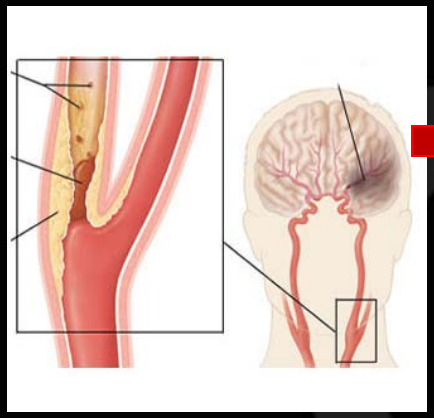
Coronary artery bypass graft (CABG)



TARGET INDICATION: STROKE & ORGAN TRANSPLANT

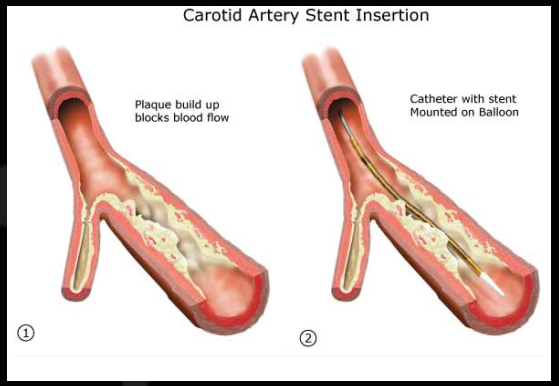
ISCHEMIA

Stroke



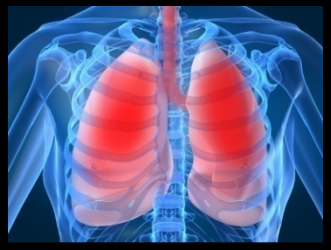
REPERFUSION

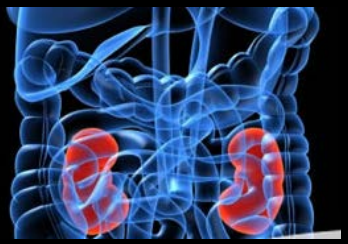
Carotid artery intervention



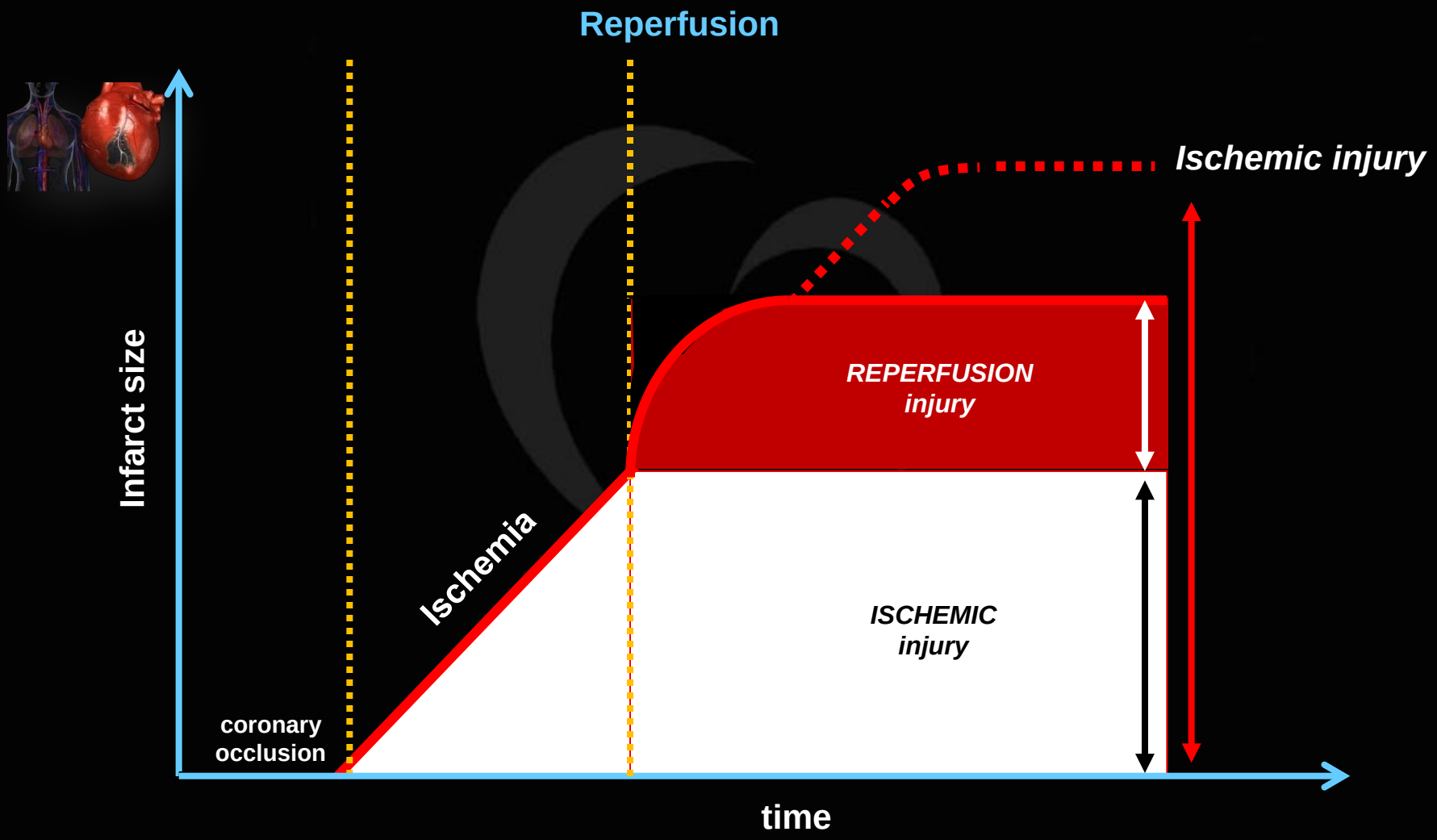
ISCHEMIA/REPERFUSION

Organ transplant





ISCHEMIA / REPERFUSION : a two-component damage



Piper, García-Dorado & Ovize Cardiovasc Res 1998 *Ovize et al Cardiovasc Res 2010* *Terkelsen et al. JAMA. 2010;304(7):763-771*

HOW BIG IS THE PROBLEM WE ARE FACING?

CORONARY INTERVENTIONS (myocardial infarction) - EUROPE

	2012	PCI	1.132.014
		CABG	45,256
		TOTAL	1.177.270

CORONARY INTERVENTIONS (myocardial infarction) - NORTH AMERICA

		Intervention	Number interventions/year
USA	*2011*	PCI	954,000
		CABG	300.000
		TOTAL	1.254.000
CANADA	*2004*	PCI	33.408
		CABG	16.07
		TOTAL	49.478

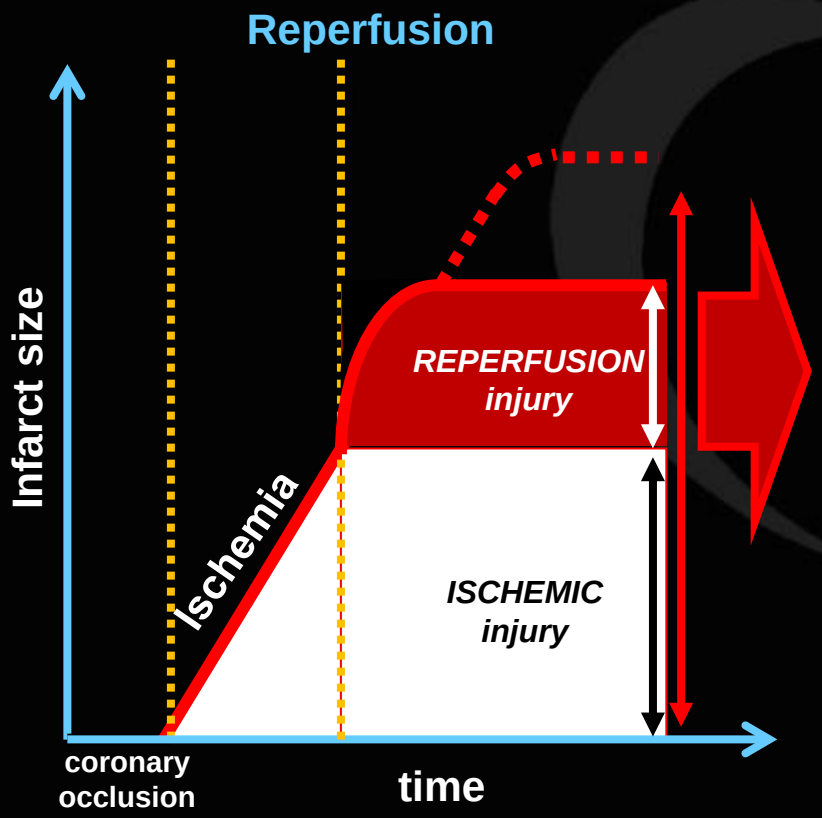
CAROTID INTERVENTIONS (stroke) - EUROPE

	Intervention	Number interventions/year
2011	THROMBOTIC STROKE	40.325
	TOTAL	40.325

ORGAN TRANSPLANT (liver, kidney, lung) - EUROPE

	Intervention	Number interventions/year
2013	LIVER/KIDNEY/LUNG	30.721
	TOTAL	30.721

EUROPE	**1.248.316**
EUROPE + NORTH AMERICA	**2.551.794**



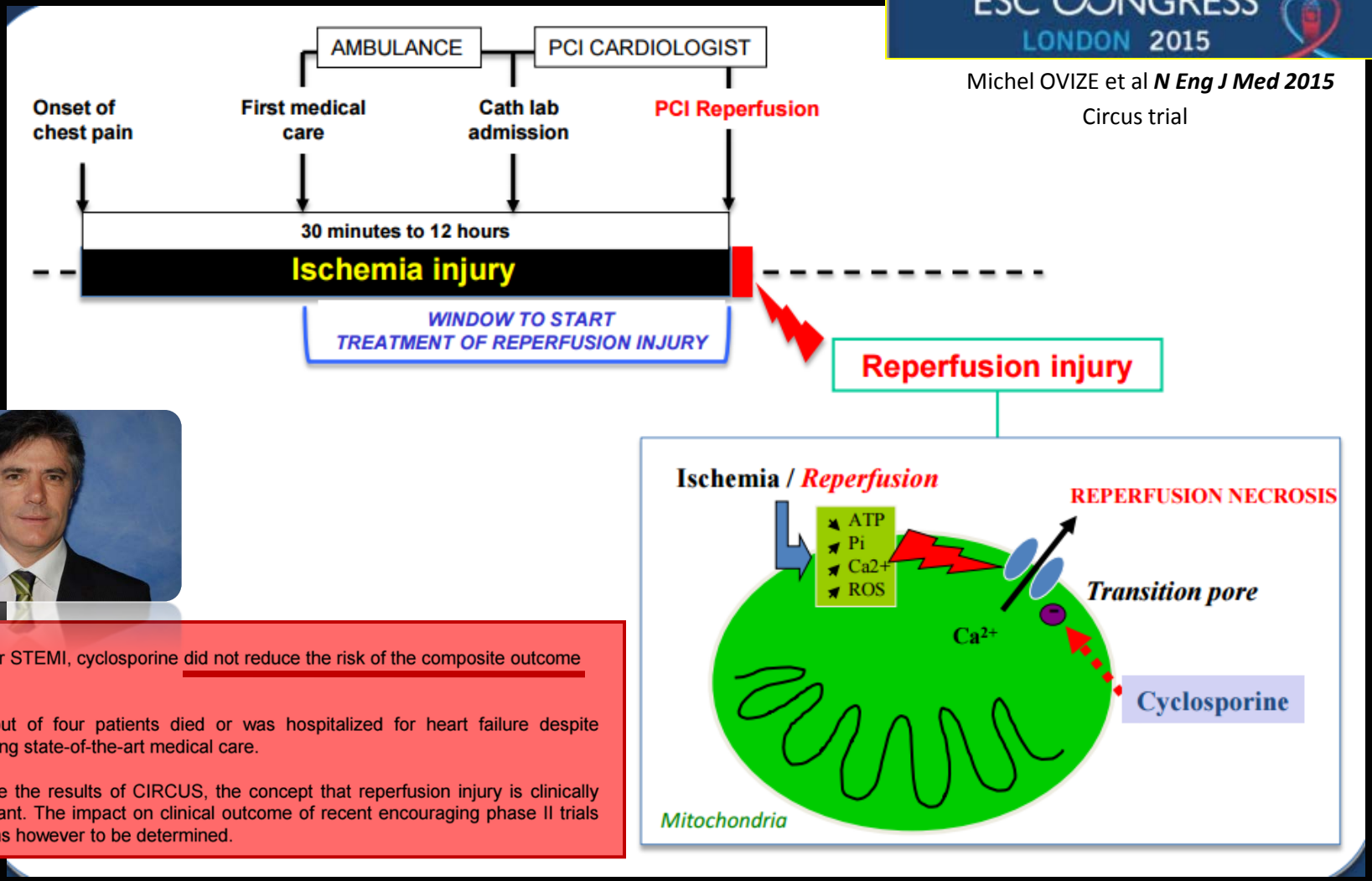
EFFORTS ARE CURRENTLY FOCUSED IN THE SEARCH OF NEW CARDIOPROTECTIVE STRATEGIES SINCE THERE IS NO DRUG AVAILABLE TO LIMIT CARDIAC DAMAGE IN THE SETTING OF ACUTE MYOCARDIAL INFARCTION

The only PHASE III clinial trial so far in cardioprotection…

ESC CONGRESS LONDON 2015

Michel OVIZE et al ***N Eng J Med 2015***

Circus trial



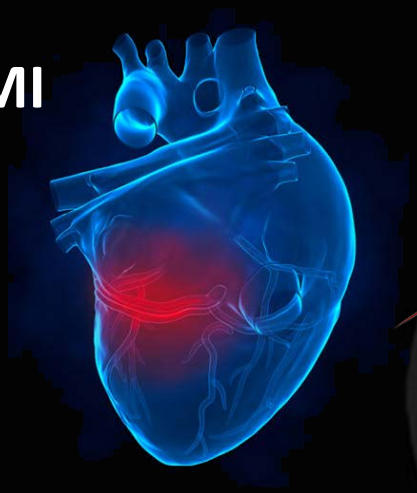
In anterior STEMI, cyclosporine did not reduce the risk of the composite outcome

- One out of four patients died or was hospitalized for heart failure despite receiving state-of-the-art medical care.
- Despite the results of CIRCUS, the concept that reperfusion injury is clinically important. The impact on clinical outcome of recent encouraging phase II trials remains however to be determined.

OUR CARDIOPROTECTIVE APPROACH

REDUCE INFARCT SIZE AND IMPROVE CARDIAC PERFORMANCE LOWERING THE BURDEN OF HEART FAILURE

AMI



TRANSFER 2h

Cath lab for PCI

CARDIOSHIELD (intravenous)

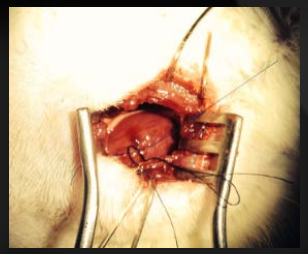
CARDIOSHIELD PROTECTS AGAINST ISCHEMIC DAMAGE

G.Mendieta, L.Badimon. G. Vilahur, *SEC Bilbao 2015*

MI-induction
45 min ischemia

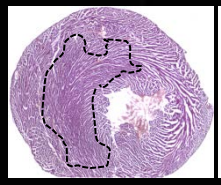
1- CARDIOSHIELD
2- RhoA inhibitor

30 min | 15min

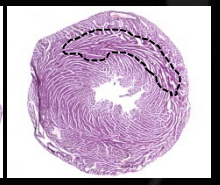


Infarct size

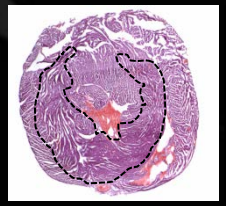
Vehicle



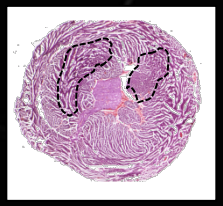
I-HMGCoAR-like

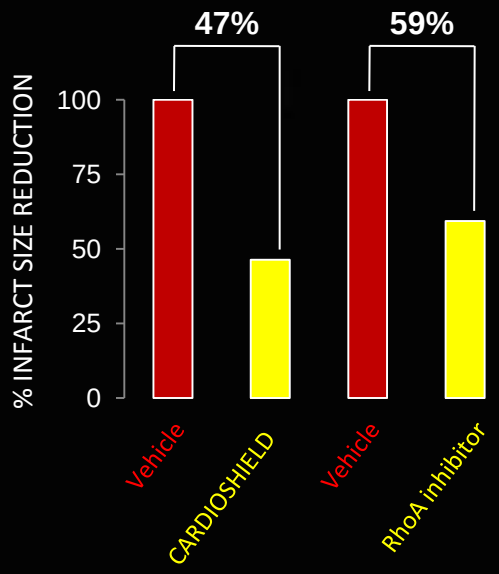


Vehicle



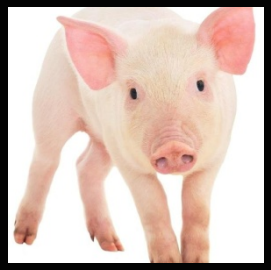
RhoA inhibitor

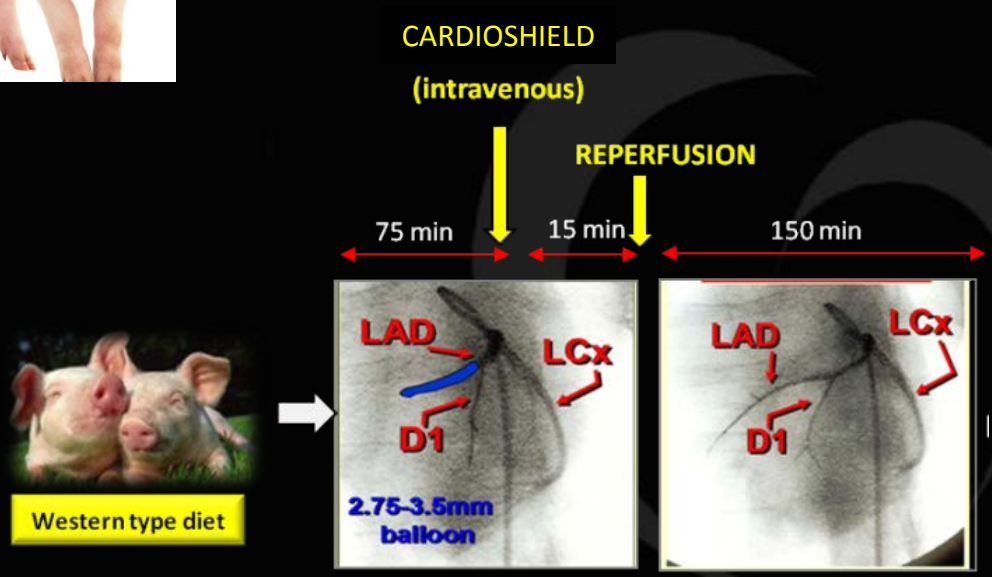


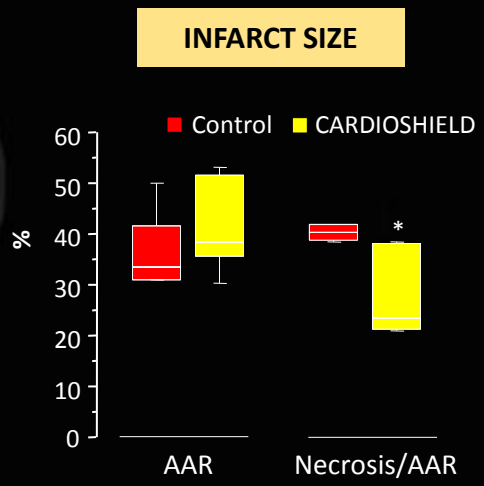


CARDIOSHIELD PROTECTS AGAINST REPERFUSION INJURY

G. Vilahur, L. Casaní, E. Peña, G.Mendieta, L.Badimon. *Int J Cardiol 2014*





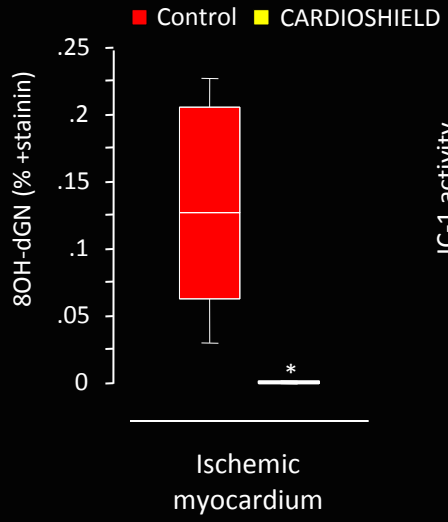


CARDIOSHIELD PROTECTS AGAINST REPERFUSION INJURY: MECHANISMS INVOLVED

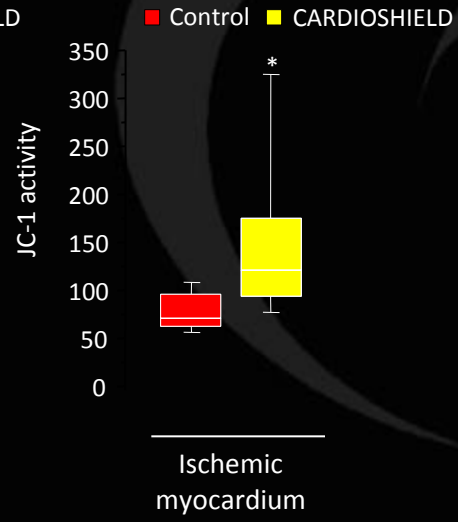
G. Vilahur, L. Casaní, E. Peña, G.Mendieta, L.Badimon. *Int J Cardiol 2014*

I/R injury features

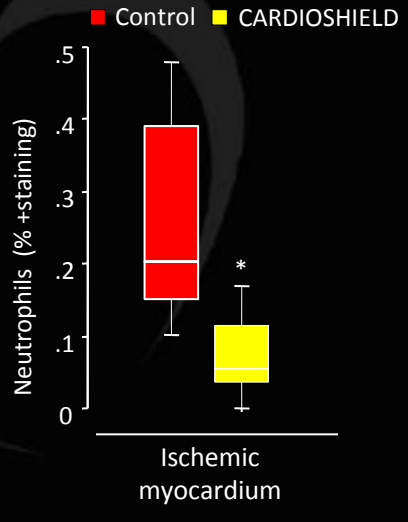
OXIDATIVE DAMAGE



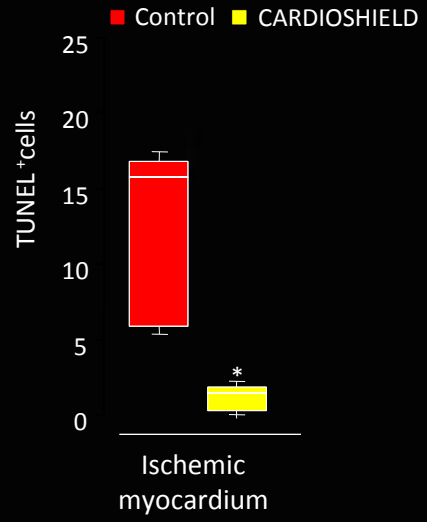
MITOCHONDRIAL FUNCTION



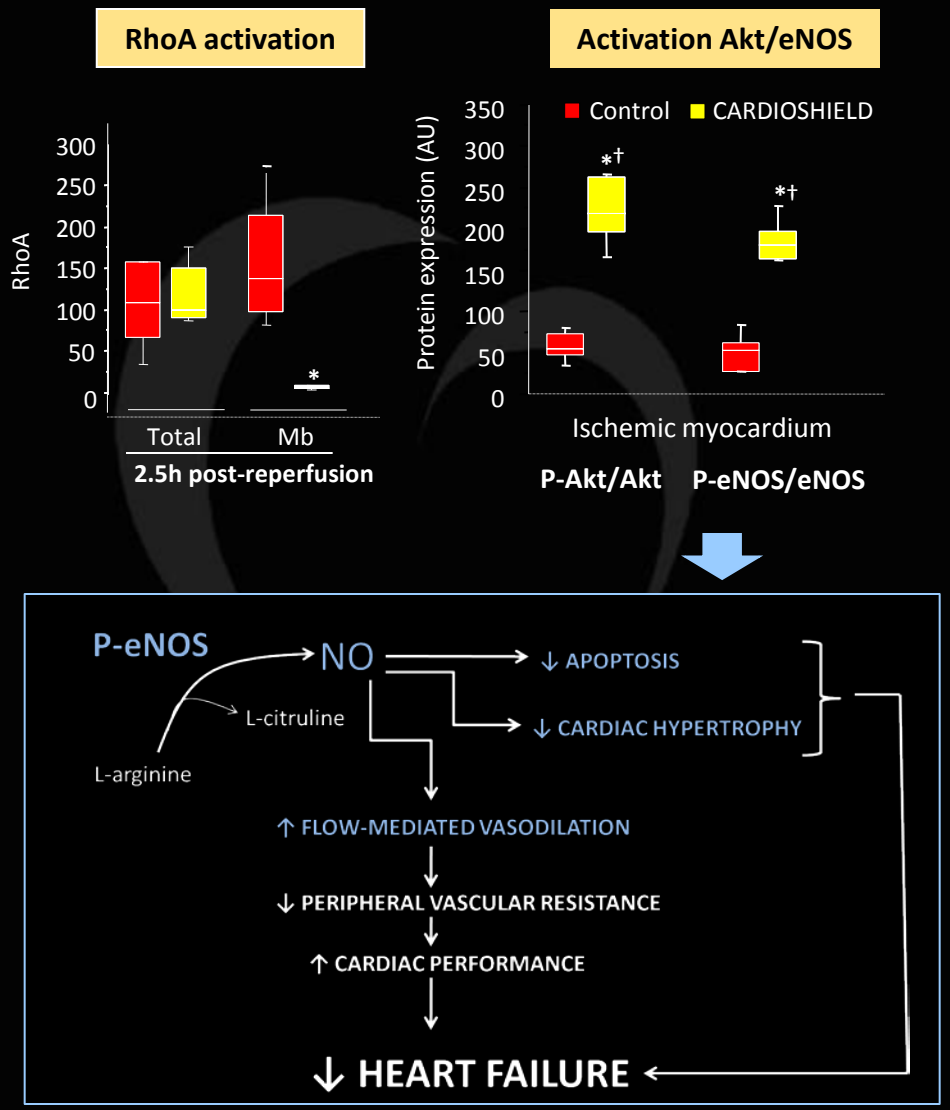
NEUTROPHILE INFILTRATION



APOPTOSIS EXECUTION



CARDIOSHIELD increases CELL SURVIVAL

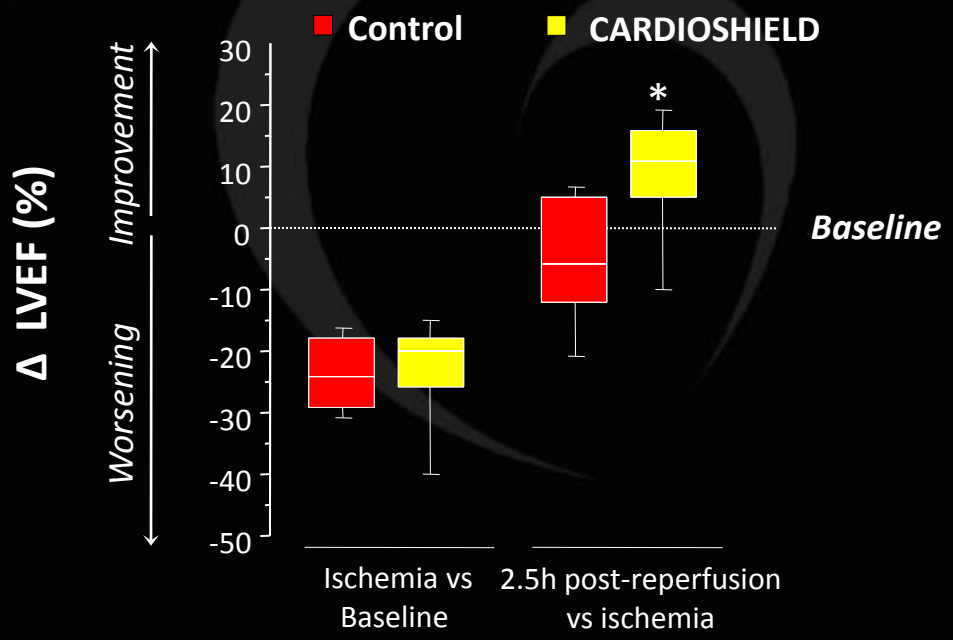


G. Vilahur, L. Casaní, E. Peña, G.Mendieta, L.Badimon. Int J Cardiol 2014

CARDIOSHIELD IMPROVES CARDIAC PERFORMANCE

G. Vilahur, L. Casaní, E. Peña, G.Mendieta, L.Badimon. *Int J Cardiol 2014*

LEFT VENTRICLE EJECTION FRACTION



ON-GOING PRECLINICAL STUDIES: Comorbidities

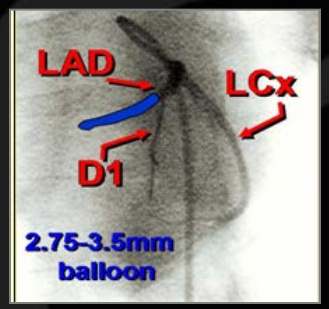
Hypercholesterolemic pigs

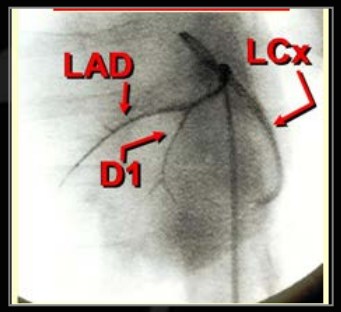
CARDIOSHIELD (intravenous)

REPERFUSION

LD post-MI

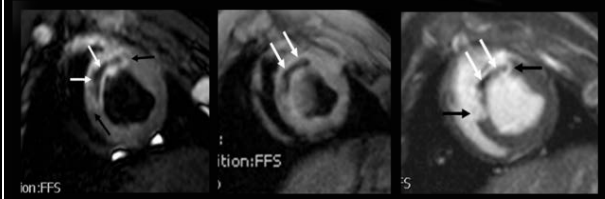
75 min | 15 min | 150 min



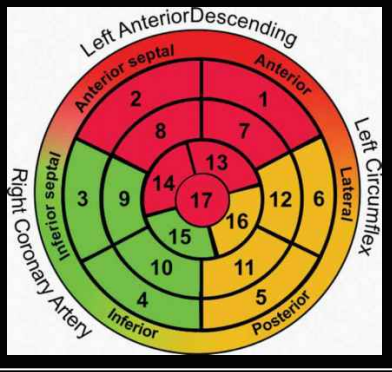


CMR analysis at 3days and 42 days

Global analysis

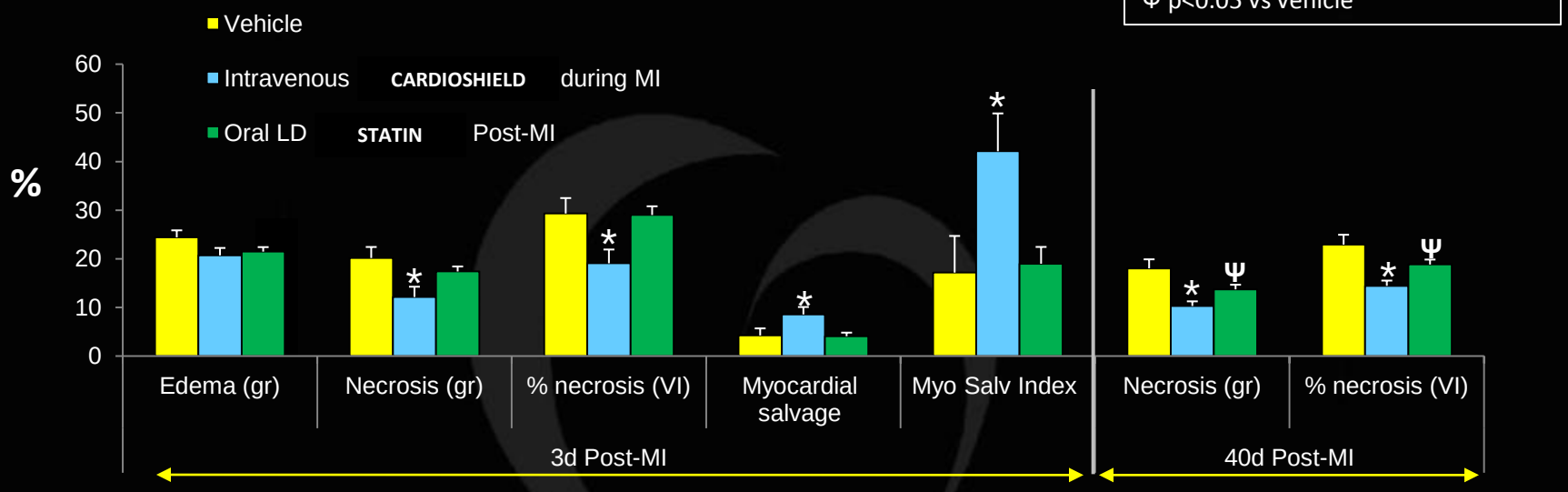


Regional analysis



ON-GOING PRECLINICAL STUDIES

Global analysis



Regional analysis

TREATMENT	Dysfunctional segments day3 post-MI	Wall thickening day40 post-MI (mm)	Viable segments
Vehicle	24 (67%)	1,5±0,3	33%
Intravenous CARDIOSHIELD during MI	20 (56%)	2,1±0,4	58%
Oral LD STATIN Post-MI	21 (58%)	1,3±0,3	33%

CHRONOGRAM

Preclinical phase – 2 years

Phase I – PoC- First in man trial – 1 year

Phase IIb - PoC-1 year

DIFFERENTIAL FEATURES FACING THE MARKET

- **Market target**

  Any pharmaceutical company interested in exploiting the development of a new formulation for **intravenous administration**.

- **Advantages**

  As far as we know, at present, there is no agent in the market like this that in preclinical phase reduces the size of infarction more than 30%.

IPR PROTECTION

Cardioshield

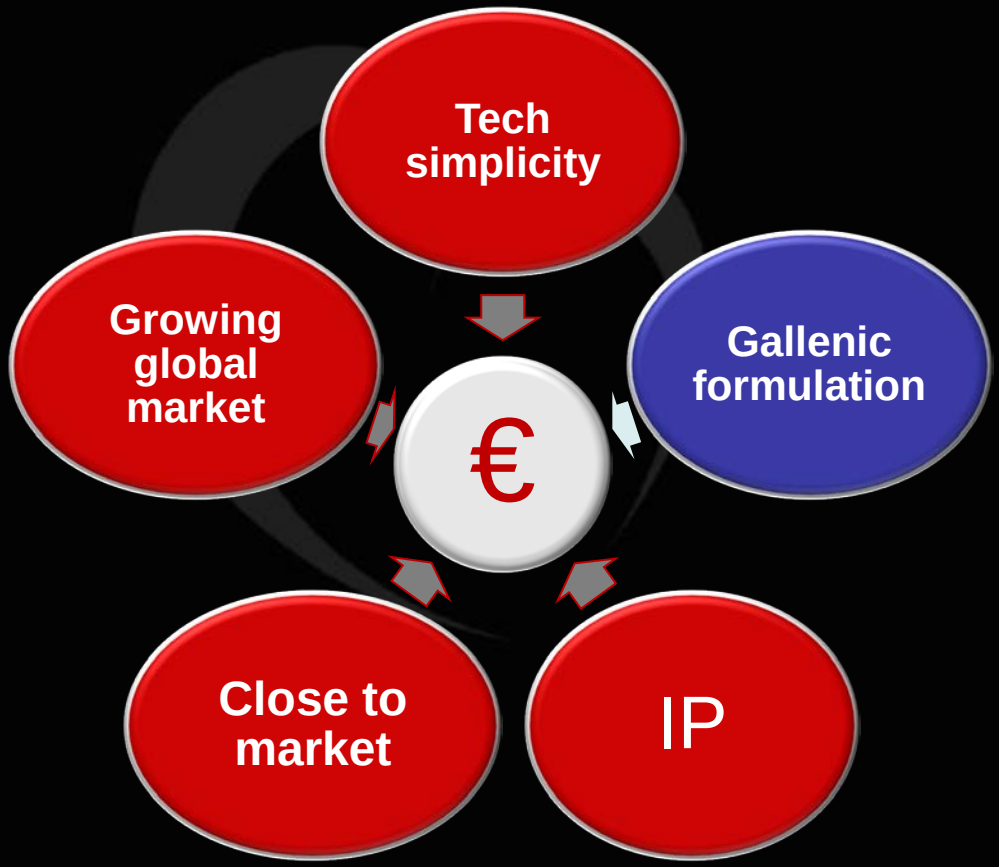
IP: 27/5/2014 European patent application nº EP14382190.8 for "PREVENTION AND/OR TREATMENT OF ISCHEMIA/REPERFUSION INJURY" issued to CONSORCI INSTITUT CATALÀ DE CIÈNCIES CARDIOVASCULARS

INVENTORS *(in order of authorship):* ***Lina Badimon & Gemma Vilahur***
APPLICATION FORM *No: 1438219.8-1464*
PRIORITY COUNTRY*: Spain* *PRIORITY DATE: 27/5/2014*
HOLDER ENTITY*: Instituto Catalan de Ciencias Cardiovasculares (ICCC)*
OTHER COUNTRIES WHICH THE PATENT HAS BEEN EXTENDED TO*: AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE IS, IT IL, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT RO, RS SE, SI, SK, SM TR.*

PITFALLS AND RISKS TO BE CONSIDERED

None foreseen

PARTNERING OPPORTUNITIES




Thank you