



UTIC | **ANMCO**
CLUB |
CRITICAL CARE COMMUNITY

Lo Studio VESALIUS-CV: l'importanza di ridurre il rischio cardiovascolare nei pazienti senza pregresso evento

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Cardiologia Clinica e Riabilitativa

Ospedale S. Filippo Neri, ROMA

FISM

- **LDL-C is a well-established, modifiable CV risk factor**
- **Lowering LDL-C with PCSK9 inhibitors, including evolocumab, ↓ the risk of CV events in patients with a prior, major ASCVD event, such as MI or stroke**
- **Clinical benefit of PCSK9 inhibition in patients without a prior MI or stroke is unknown**

No Known ASCVD

Known ASCVD

Increasing risk for development of ASCVD

Increasing severity of ASCVD

Low-CV Risk
(w/o known ASCVD)

High-CV Risk
(w/o known ASCVD)

Diabetes
+ risk enhancer

Atherosclerosis
w/o Prior Event

Coronary disease,
Cerebrovascular disease, or
Peripheral artery disease,
+ risk enhancer
No MI or Stroke

Major ASCVD
Event

Prior MI
Prior Stroke
Symptomatic PAD
+ risk enhancer

VESALIUS-CV

FOURIER and
ODYSSEY-OUTCOMES

N= 12,257

Stable patients at high-risk for CV events
but no prior MI or stroke*

Event & f/up driven trial:

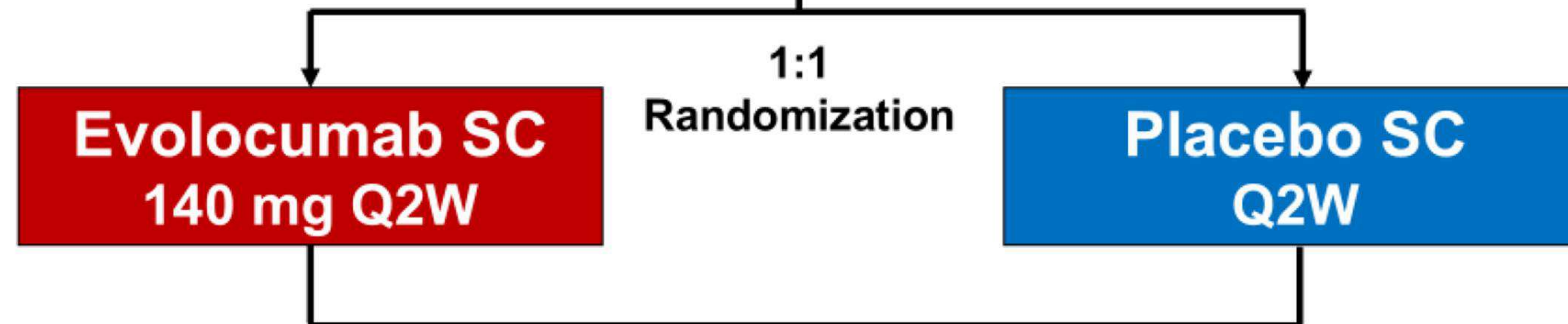
- 3-P MACE \geq 751 events
- 4-P MACE \geq 1,254 events
- Median f/up \geq 4.5yrs

LDL-C \geq 90 mg/dL or
non-HDL-C \geq 120 mg/dL or
ApoB \geq 80mg/dL

On optimized statin therapy (\pm ezetimibe)

***At least one of the following:**

- CAD without MI
- CVD without stroke
- PAD
- High-risk diabetes mellitus



Dual Primary Endpoints:

Time to coronary heart disease death, MI, or ischemic stroke (3-P MACE)
Time to 3-P MACE plus ischemia-driven arterial revascularization (4-P MACE)

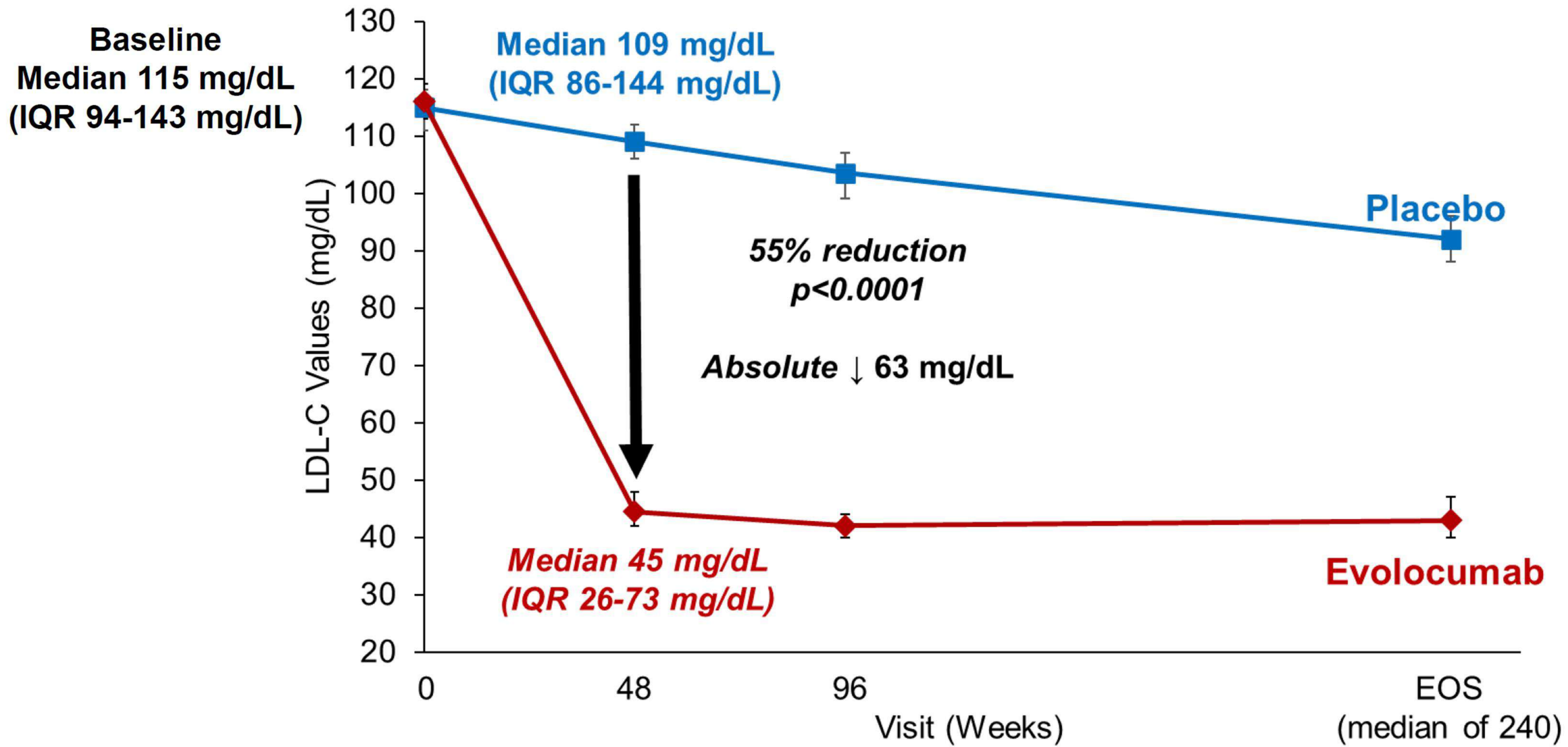
Demographics	N=12,257	Lipid-lowering therapy (LLT)	
Age (years)	66 [60, 71]	Any LLT	92%
Female	43%	High-intensity LLT regimen	72%
White	93%	Any statin	87%
Hispanic	17%	High-intensity statin	68%
Diabetes	58%	Ezetimibe	20%
Qualifying Disease Categories*		Lipid Values (mg/dL)	
Any qualifying atherosclerosis	67%	LDL-C	122 [104, 149]
CAD w/o MI	45%	Non-HDL-C	153 [130, 182]
CVD w/o stroke	10%	Apolipoprotein-B	100 [89, 121]
PAD	17%		
High-risk diabetes	49%		
With no qualifying atherosclerosis	33%		

% or median and interquartile range.

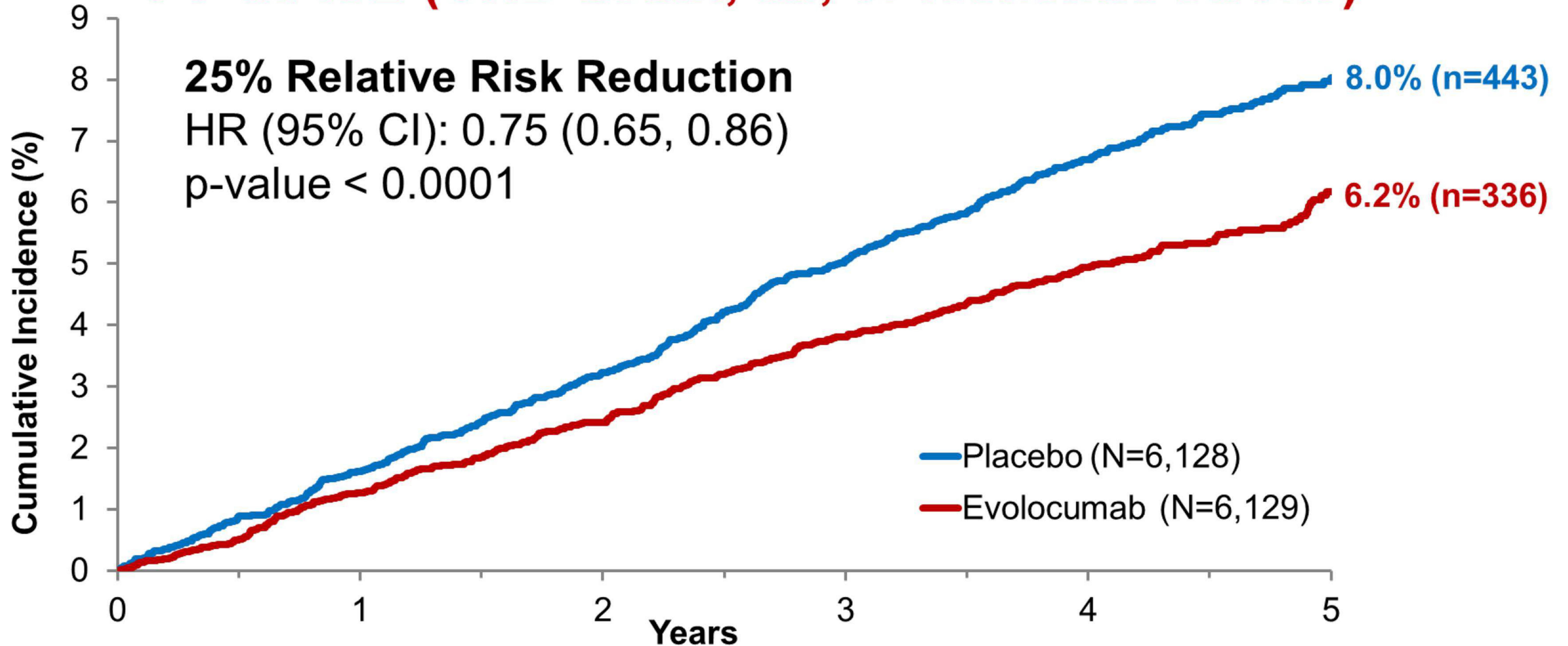
Pooled data; no difference between treatment arms.

**Qualifying disease categories of CAD CVD, PAD and high-risk diabetes are not mutually exclusive*

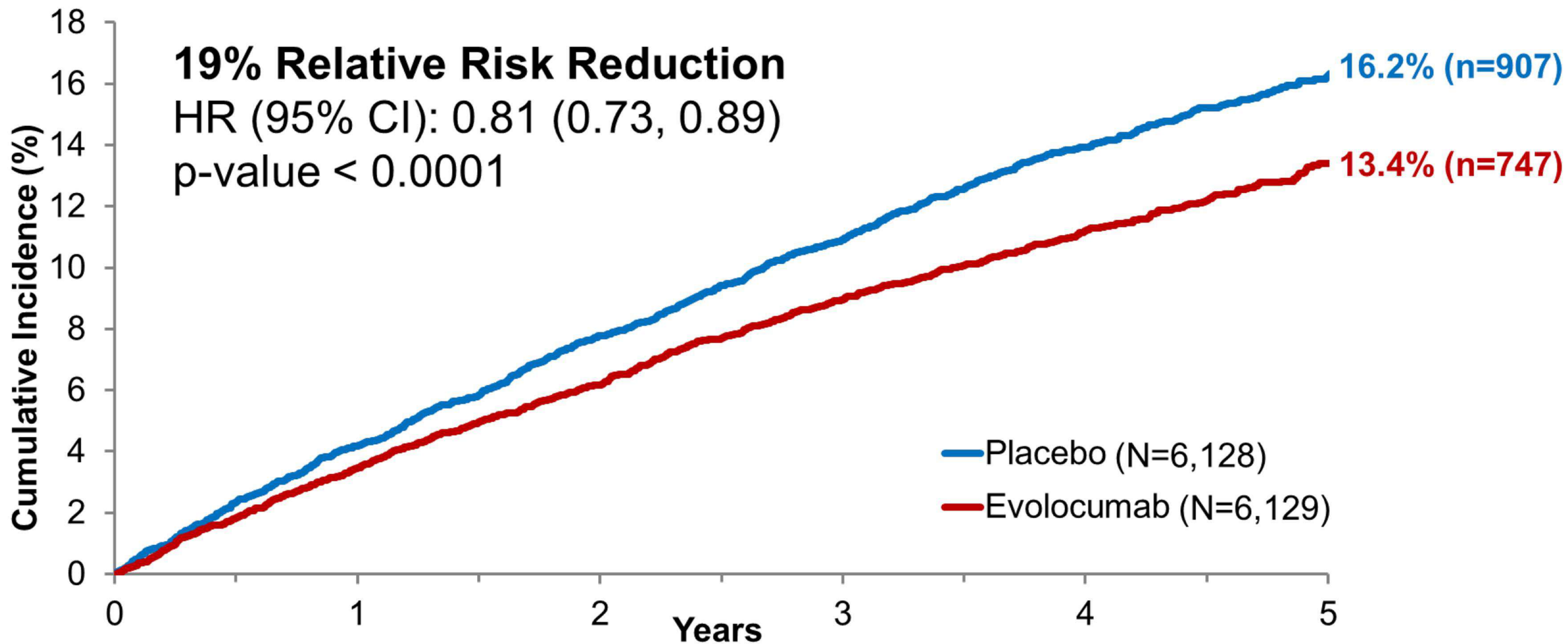
LDL-C Over Time



3-P MACE (CHD death, MI, or ischemic stroke)



4-P MACE (CHD death, MI, ischemic stroke, or IDR)



Dual Primary Endpoints

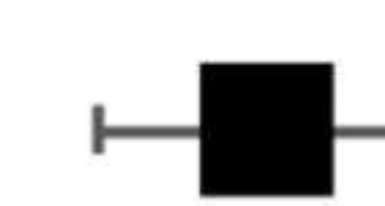
3-P MACE



HR (95% CI)
0.75 (0.65, 0.86)

p-value
<0.0001

4-P MACE



HR (95% CI)
0.81 (0.73, 0.89)

p-value
<0.0001

Key Secondary Endpoints *(in testing order)*

MI, ischemic stroke, or IDR

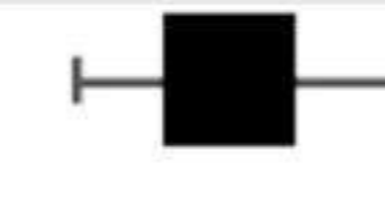


HR (95% CI)
0.79 (0.72, 0.88)

p-value
<0.0001

Composite Endpoints

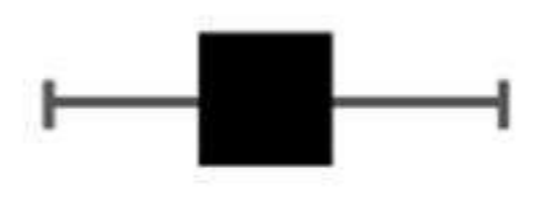
CHD death, MI, or IDR



HR (95% CI)
0.79 (0.72, 0.88)

p-value
<0.0001

CV death, MI, or ischemic stroke



HR (95% CI)
0.73 (0.64, 0.84)

p-value
<0.0001

CHD death or MI



HR (95% CI)
0.73 (0.62, 0.87)

p-value
0.0003

MI



HR (95% CI)
0.64 (0.52, 0.79)

p-value
<0.0001

IDR



HR (95% CI)
0.79 (0.70, 0.88)

p-value
<0.0001

Individual Endpoints

CHD death



HR (95% CI)
0.89 (0.68, 1.16)

p-value
0.39

CV death



HR (95% CI)
0.79 (0.64, 0.98)

p-value
0.032*

All-cause death



HR (95% CI)
0.80 (0.70, 0.91)

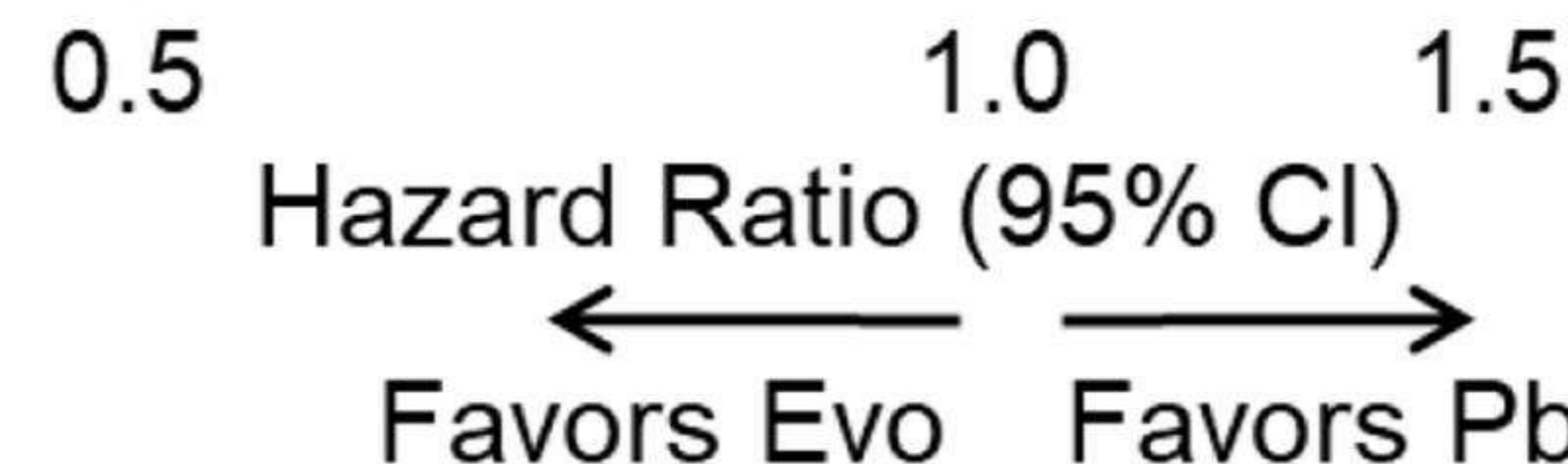
p-value
0.0005*

Ischemic stroke



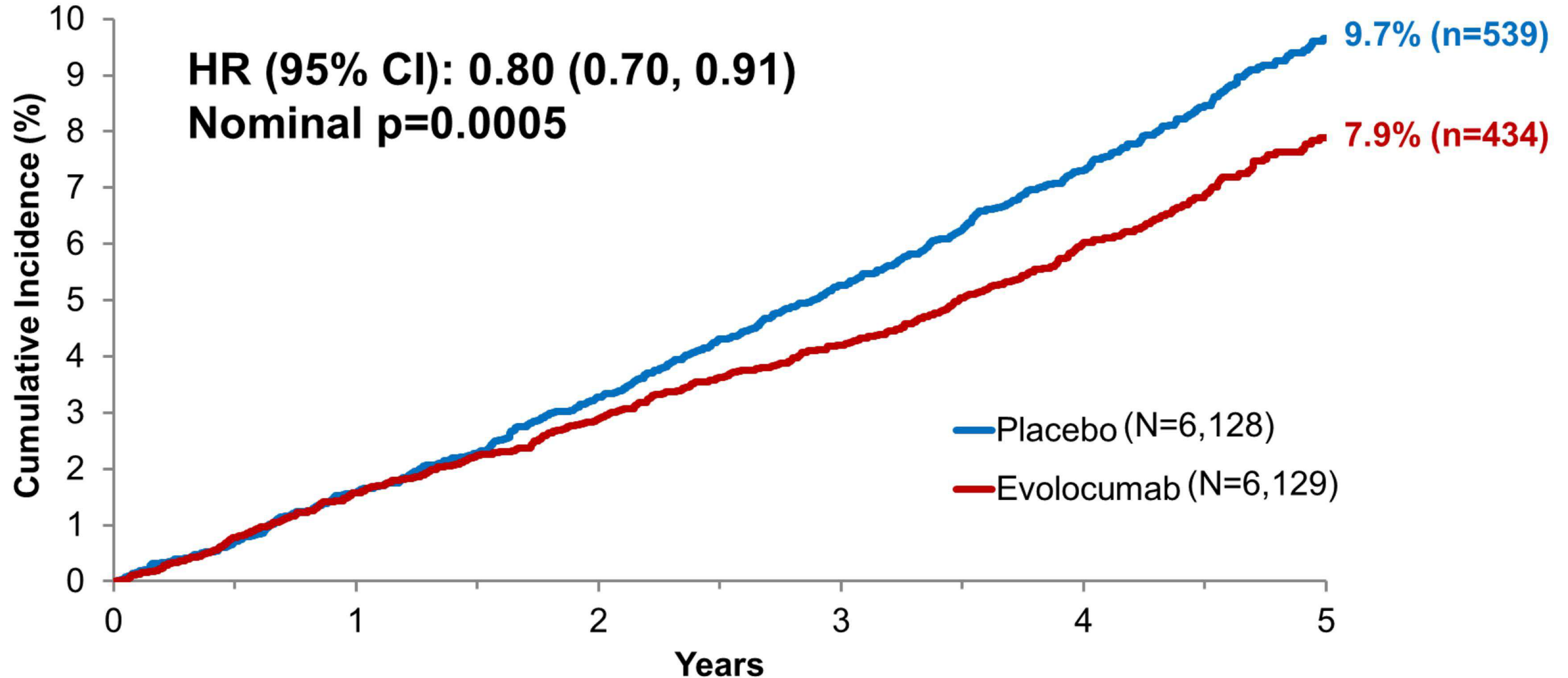
HR (95% CI)
0.79 (0.62, 1.01)

p-value
0.062*

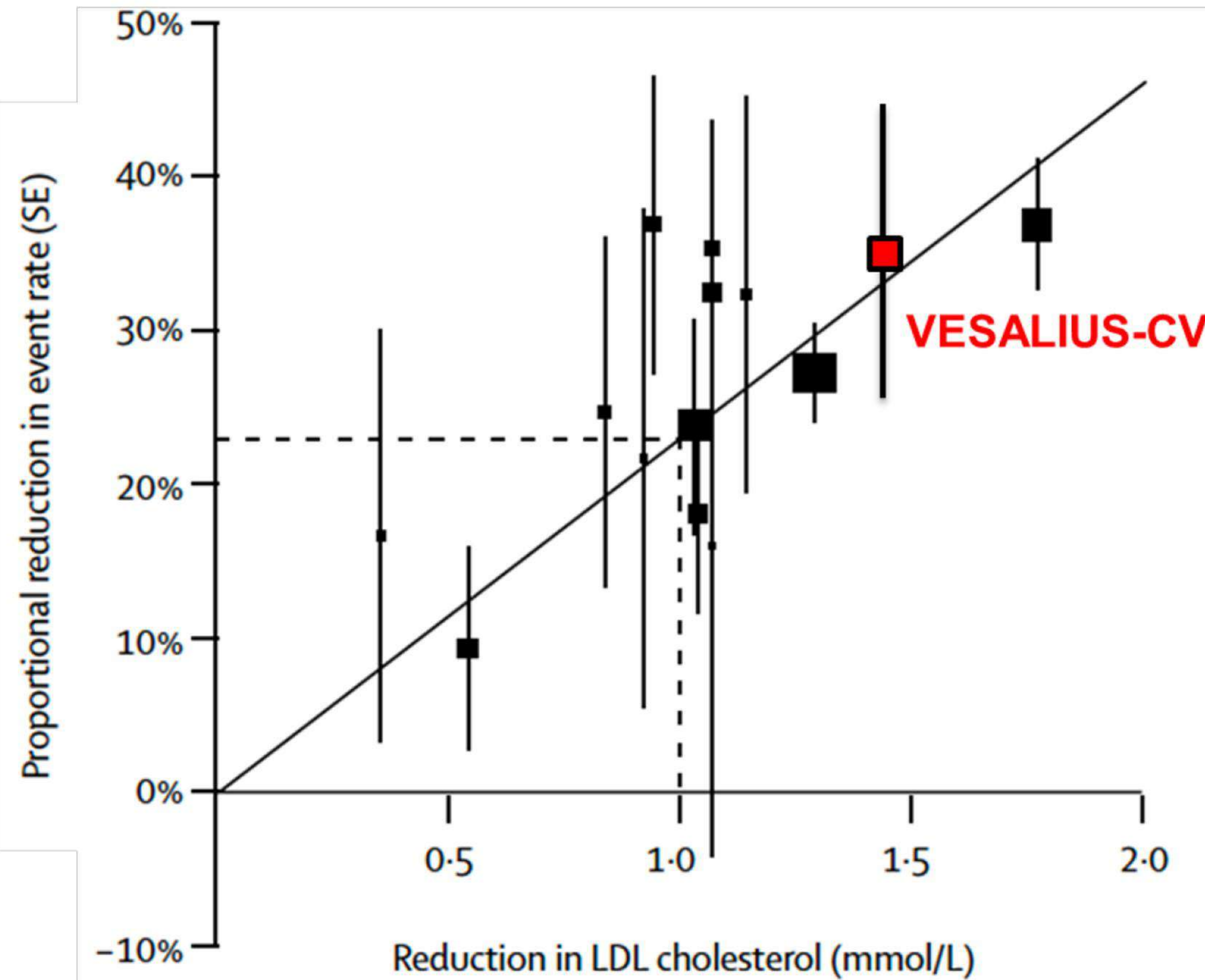


*Nominal p-value

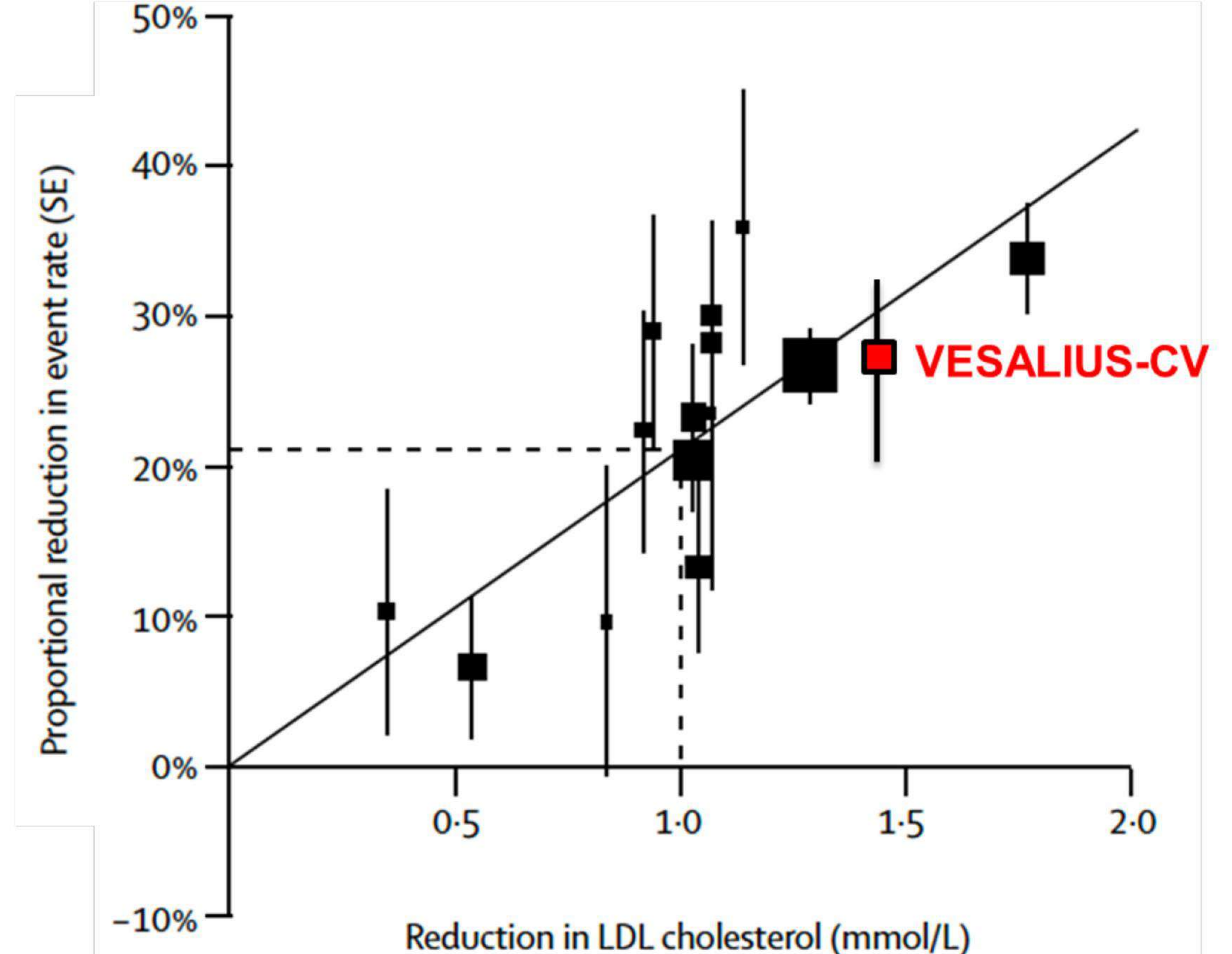
CHD, coronary heart disease
IDR, ischemia-driven arterial revasc



Major Coronary Event [MCE]
(Death due to AMI, MI)



Major Vascular Event [MVE]
(MCE, fatal/non-fatal stroke, cor revasc)



In pts at high CV risk w/o prior MI or stroke, addition of the PCSK9 inhibitor, evolocumab, to baseline LLRx resulted in:

- Median achieved LDL-C of 45 mg/dL (1.16 mmol/L)
- 25% ↓ in 3-P MACE and 19% ↓ in 4-P MACE
- Consistency across subgroups, including in those with diabetes and no qualifying atherosclerosis
- 27% ↓ in CV death, MI or ischemic stroke and 36% ↓ in MI
- Nominally lower rates of CV and all-cause death

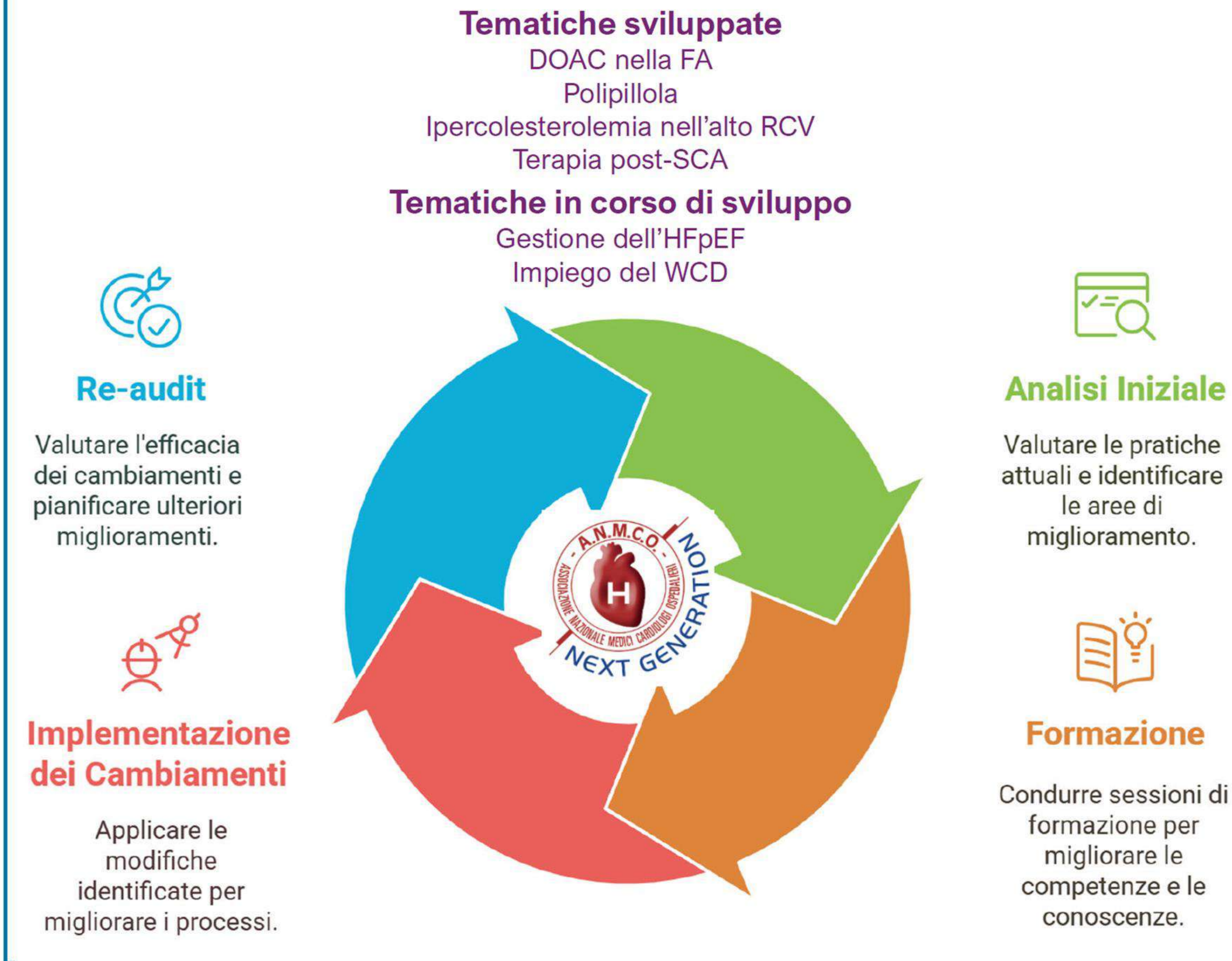
POSITION PAPER

Statement ANMCO – ANMCO National Audit Initiative: una strategia per migliorare la qualità delle cure e promuovere l'eccellenza di prossimità

Furio Colivicchi¹, Stefania Angela Di Fusco¹, Andrea Matteucci¹, Michele Massimo Gulizia², Carmine Riccio³, Pasquale Caldarola⁴, Claudio Bilato⁵, Leonardo De Luca⁶, Giovanna Geraci⁷, Alessandro Navazio⁸, Adriano Murrone⁹, Loris Roncon¹⁰, Stefano Urbinati¹¹, Andrea Di Lenarda¹², Domenico Gabrielli^{13,14}, Federico Nardi¹⁵, Massimo Grimaldi¹⁶, Fabrizio Oliva^{17,18}

G Ital Cardiol 2025;26(12):933-940

GRAPHICAL ABSTRACT



Rappresentazione grafica del ciclo di ciascun progetto dell'ANMCO National Audit Initiative. DOAC, anticoagulanti orali diretti; FA, fibrillazione atriale; HFpEF, scompenso cardiaco con frazione di eiezione preservata; RCV, rischio cardiovascolare; SCA, sindrome coronarica acuta; WCD, defibrillatore indossabile.



- Revisione, sulla base di ***criteri espliciti***, delle attività svolte da operatori interni all'organizzazione, allo scopo di esaminare e valutare ***l'appropriatezza, l'efficacia, l'efficienza nonché la sicurezza delle prestazioni erogate***.
- I report prodotti a seguito di un audit interno si configurano come indicazioni finalizzate al miglioramento della qualità delle cure.

G Ital Cardiol 2025;26(12):933-940

AUDIT VHR - Quali pazienti e quale setting clinico

Pazienti con profilo di rischio cardiovascolare molto elevato senza un precedente evento (LG ESC 2019/2021; Update 2025); Settembre – Dicembre 2025

Criteri di esclusione

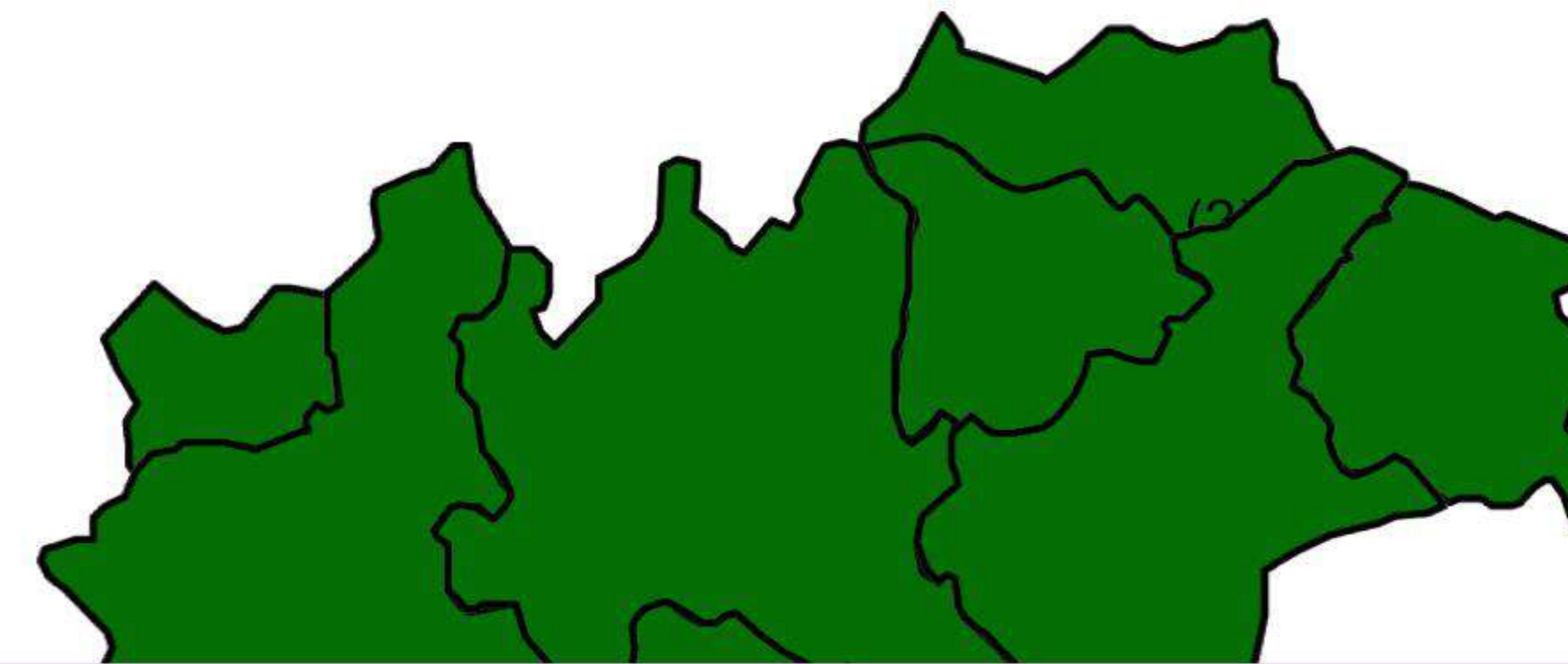
1. Pregresso SCA/IMA,
2. Pregresso Stroke/TIA.
3. Pregresso By-Pass Aorto-Coronarico o altra chirurgia cardiaca.
4. Scompenso Cardiaco.

Setting

1. Ambulatorio
2. Per strutture prive di ambulatorio, pazienti ospedalizzati

CENTRI COINVOLTI

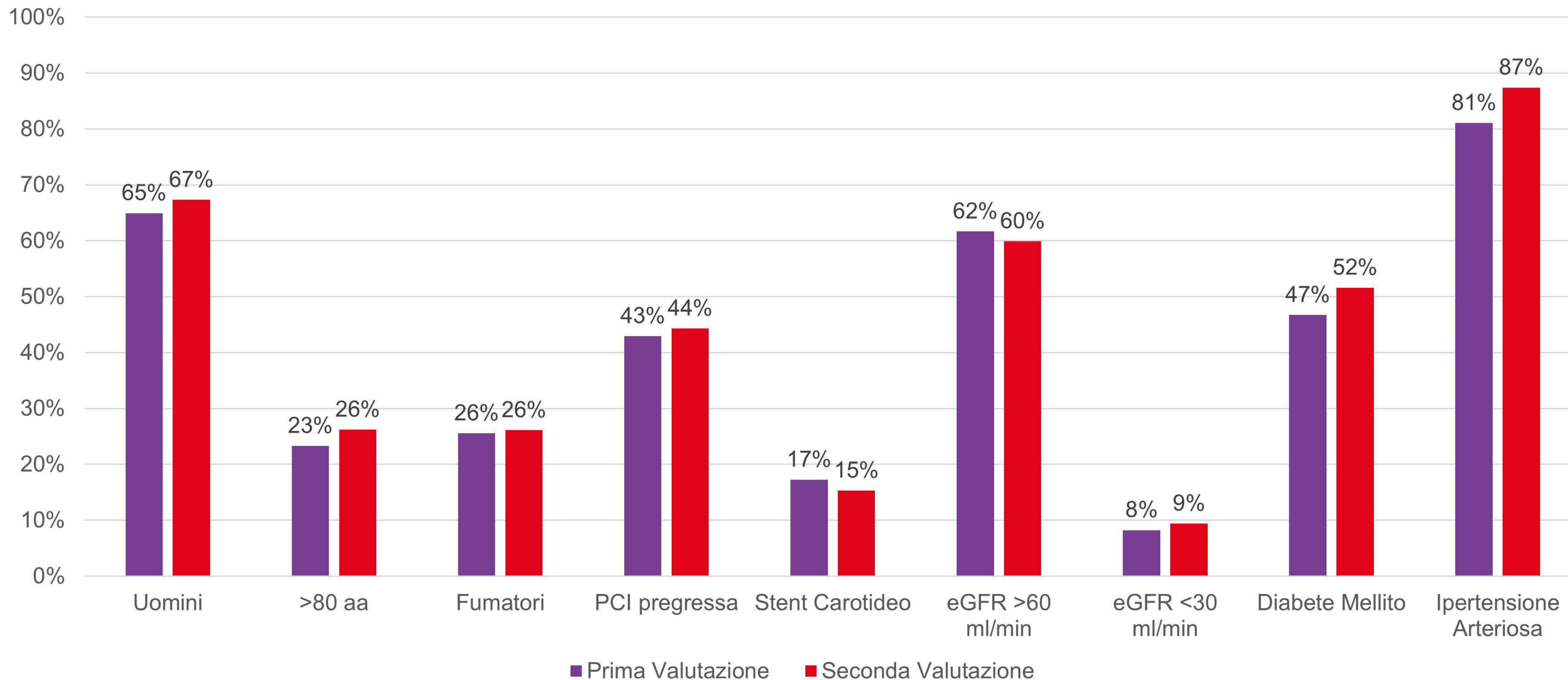
- Abruzzo **1**
- Calabria **1**
- Campania **3**
- Emilia Romagna **1**
- Friuli Venezia Giulia **1**
- Lazio **3**
- Liguria **1**
- Lombardia **4**
- Marche **1**
- Piemonte e Valle d'Aosta **3**
- Puglia **2**
- Sardegna **1**
- Sicilia **2**
- Toscana **1**
- Trentino Alto Adige **0**
- Umbria **0**
- Veneto **1**



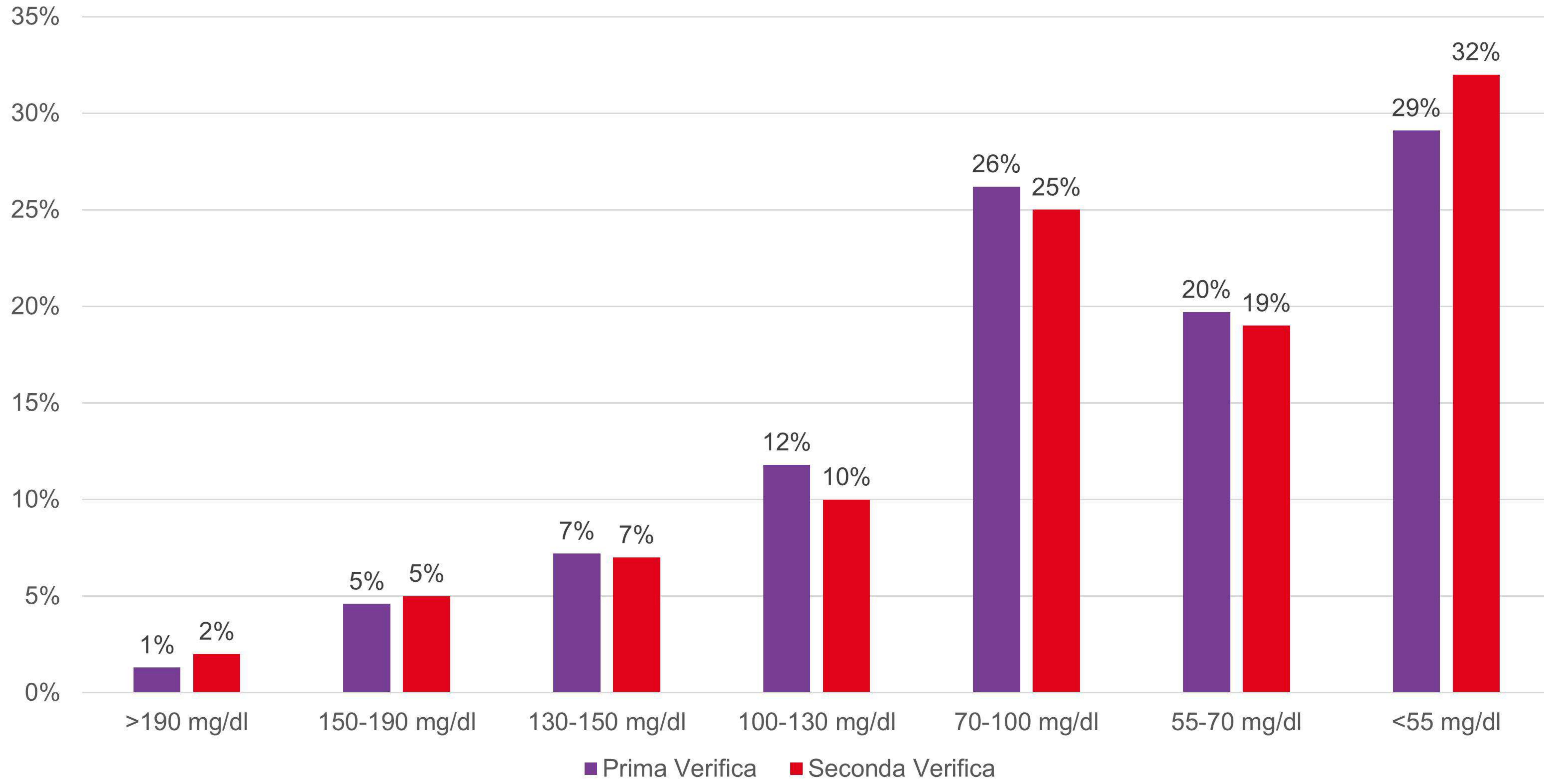
26 CENTRI
ADERENTI
IN TUTTA ITALIA
260 Cardiologi



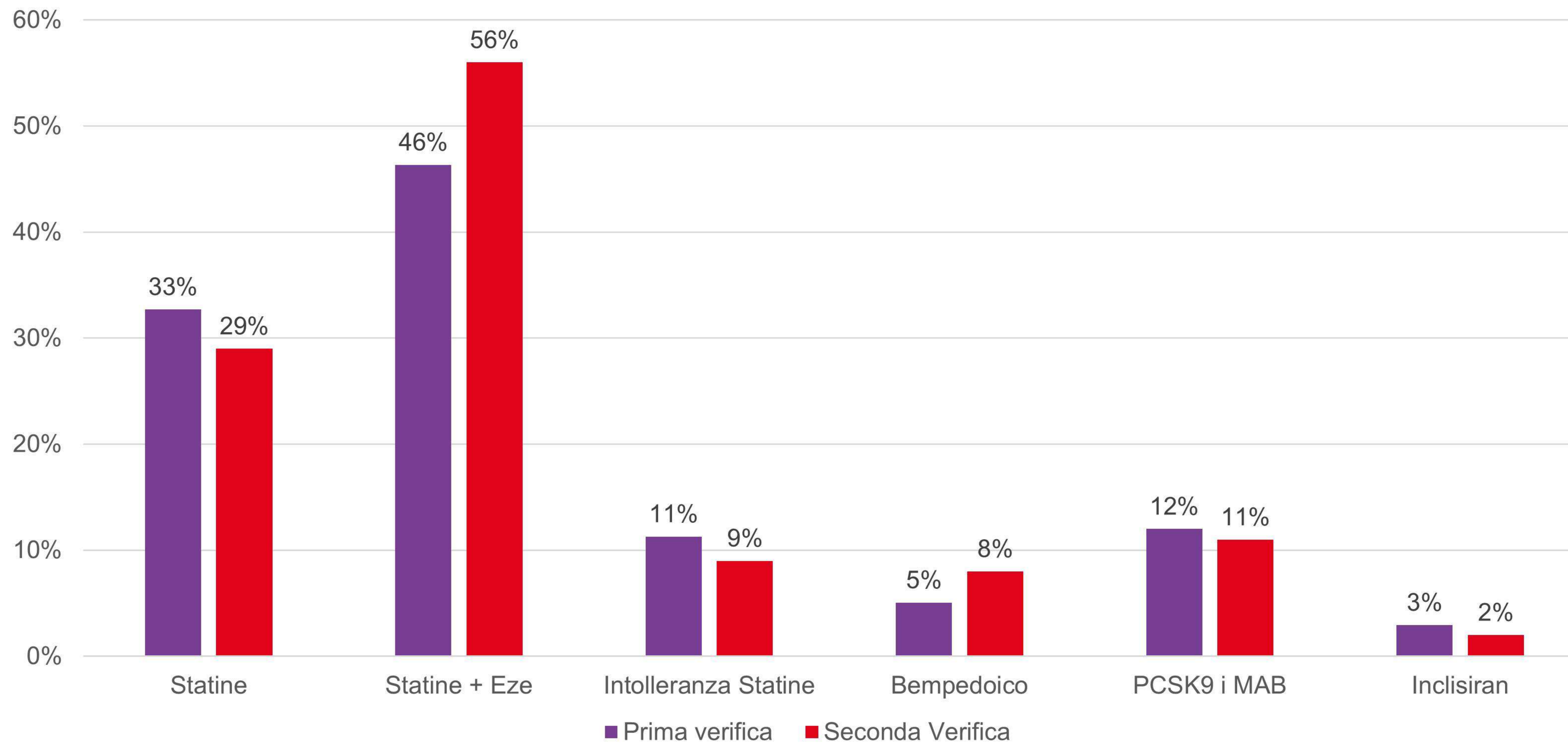
Prima Valutazione su 972 pazienti con Rischio CV Molto Elevato VS Seconda Valutazione su 1047 pazienti



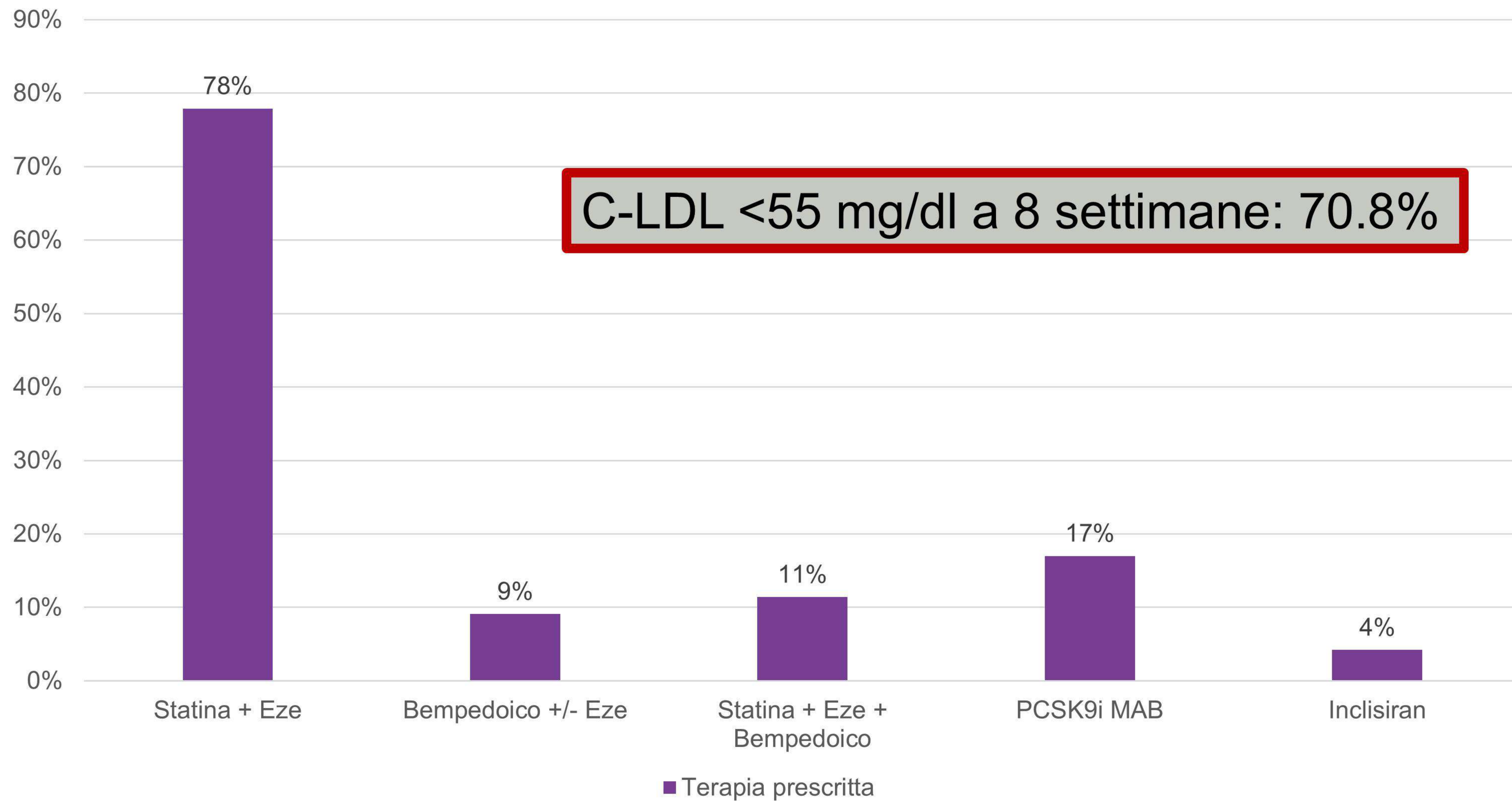
Profilo Lipidico - C-LDL



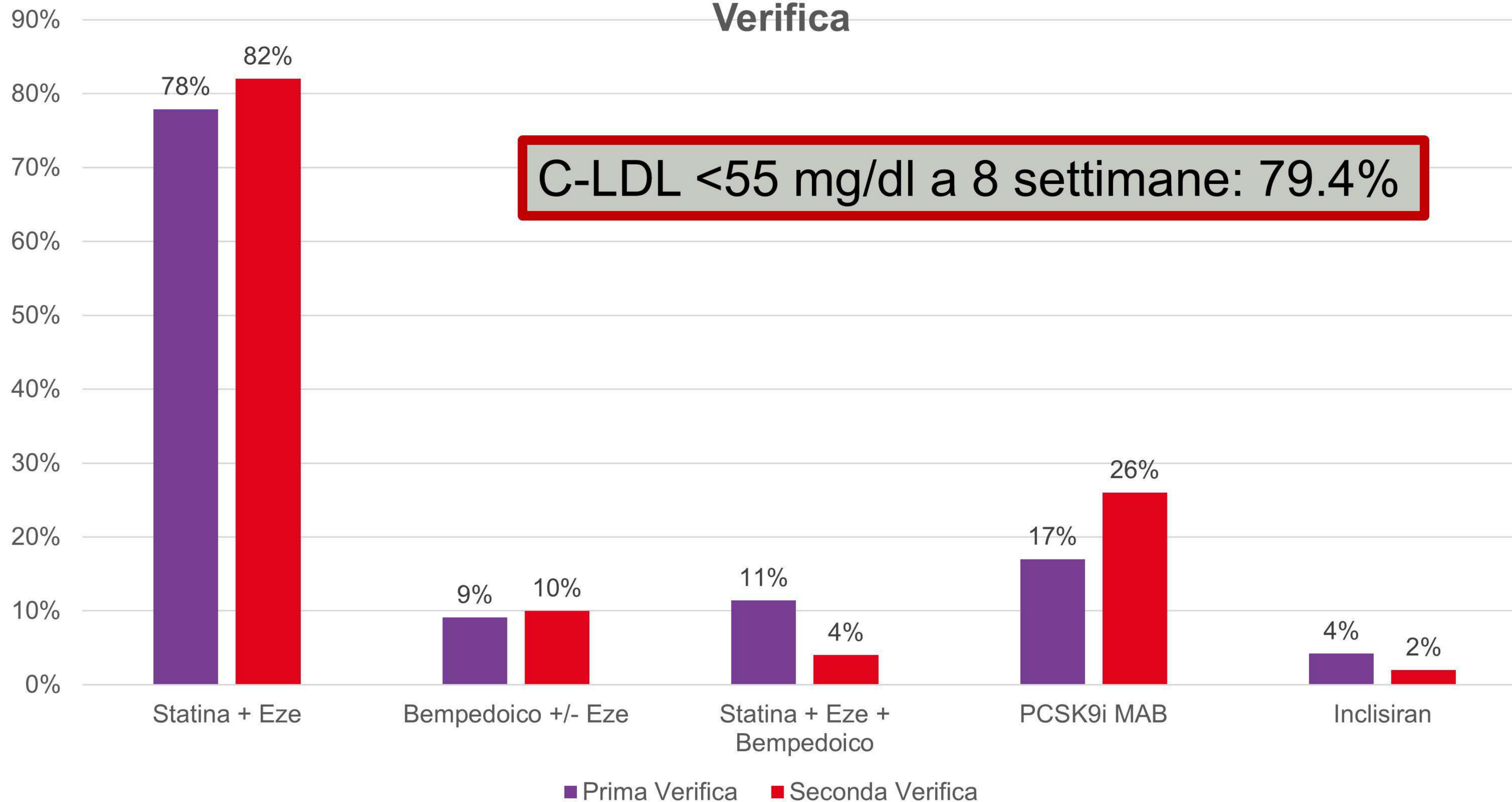
Terapia in corso prima della visita/ricovero Prima VS Seconda verifica



Terapia prescritta dopo visita/ricovero nella Prima Verifica



Terapia prescritta dopo visita/ricovero nella Prima VS nella Seconda Verifica





Next Generation

