



# SEAS

**Simvastatin + Ezetimibe in Aortic Stenosis**

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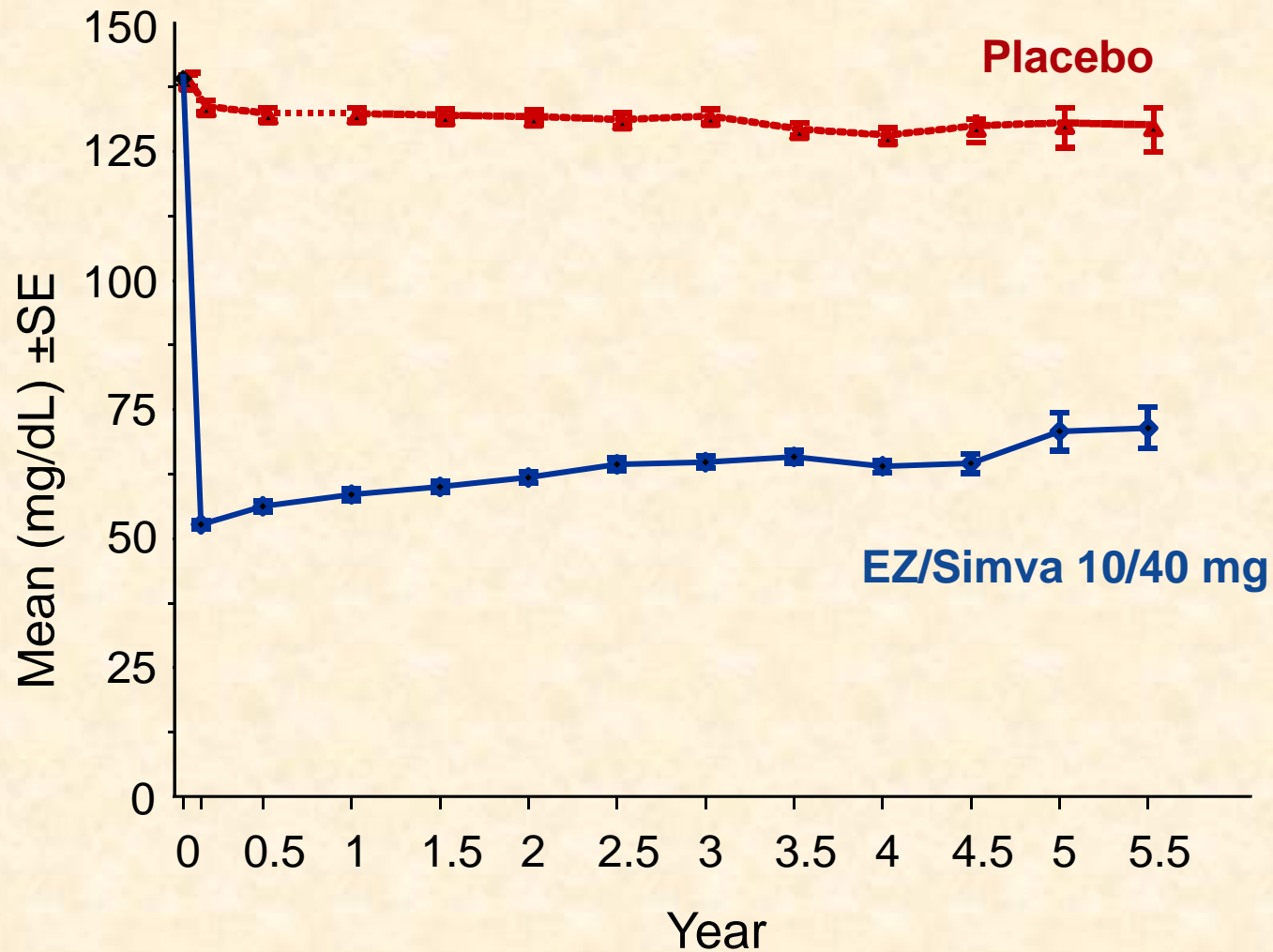
Disclosure:

Research grants and/or speaker- / consulting fees from  
Merck, MSP, Astra-Zeneca, Pfizer

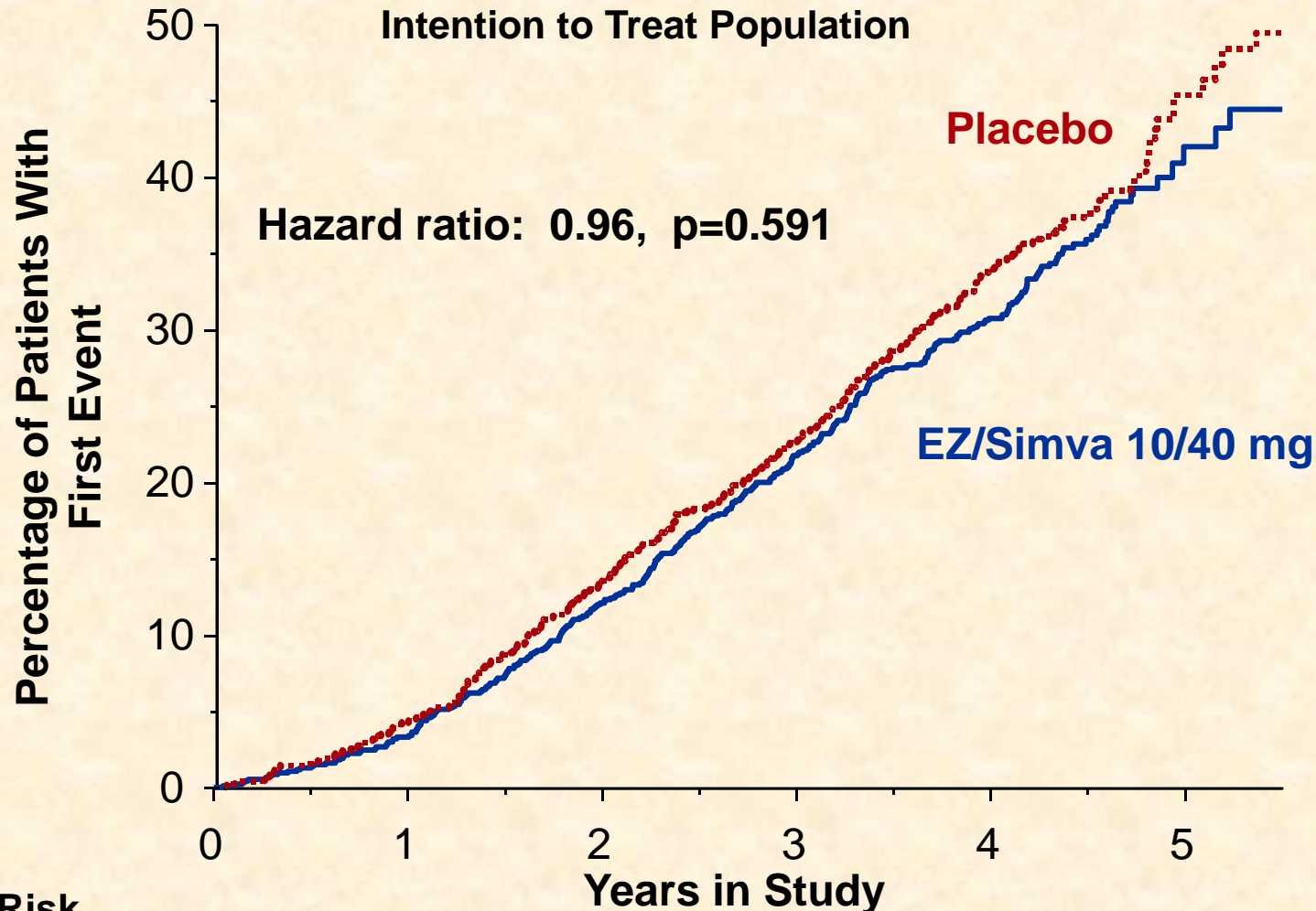
# LDL-Cholesterol



Intention to Treat Population



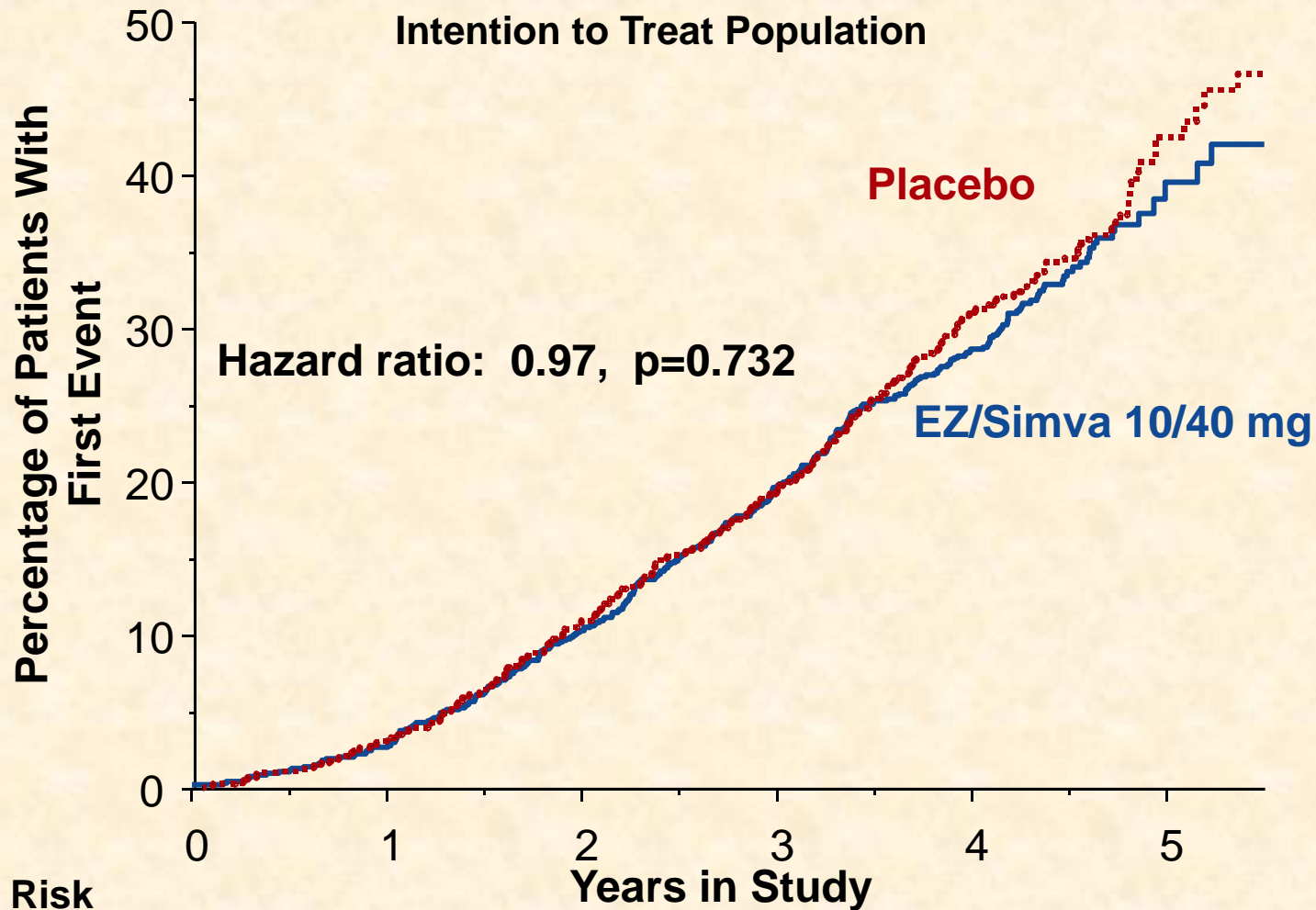
# Primary Endpoint MCE



No. at Risk

EZ/Simva 10/40 mg	906	817	713	618	53
Placebo	884	791	696	586	56

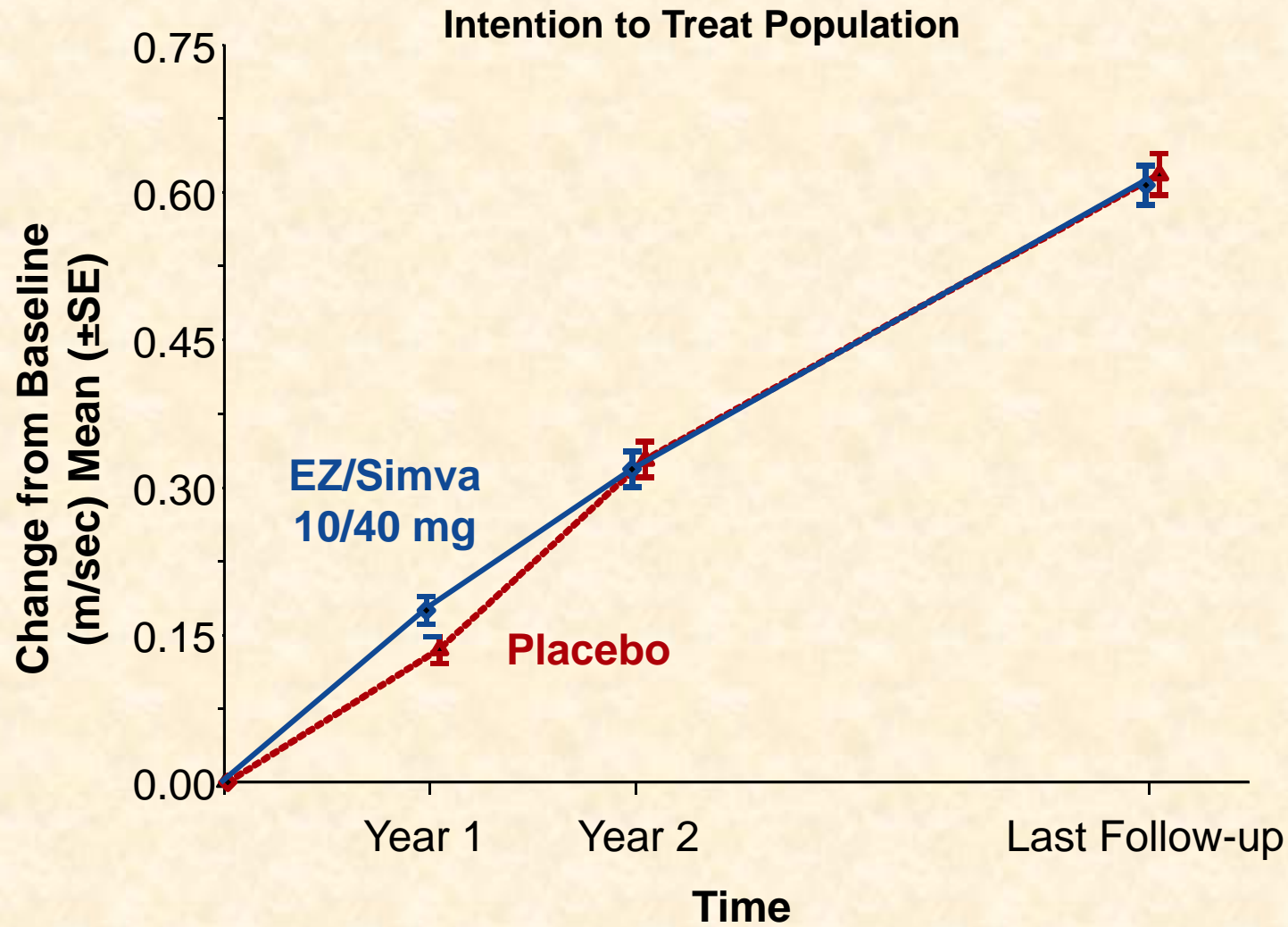
# 2nd EP: Aortic Valve Events



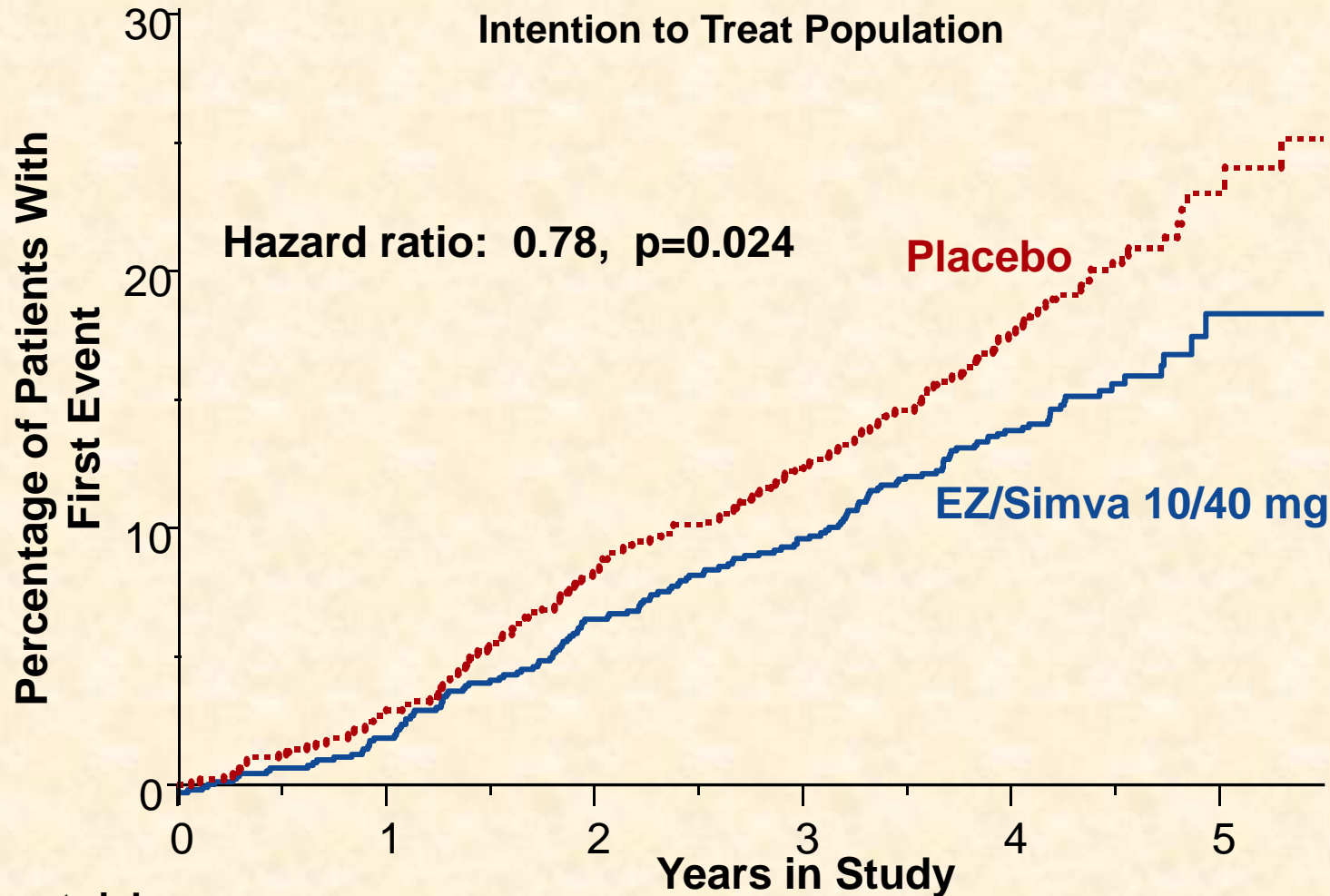
No. at Risk

<b>EZ/Simva 10/40 mg</b>	<b>914</b>	<b>836</b>	<b>732</b>	<b>635</b>	<b>55</b>
<b>Placebo</b>	<b>895</b>	<b>814</b>	<b>725</b>	<b>611</b>	<b>58</b>

# Peak Aortic - Jet Velocity



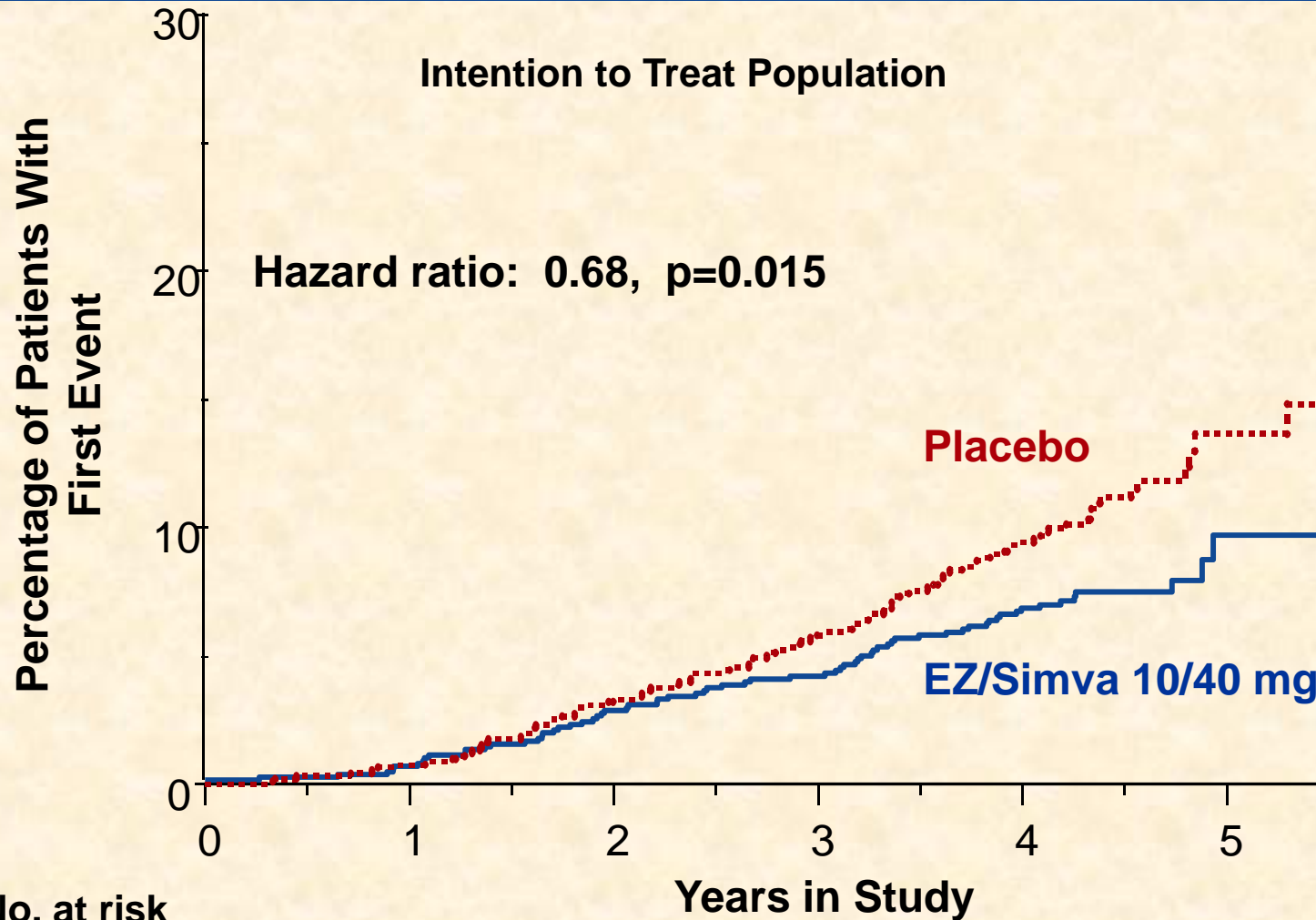
# 2nd EP: Ischemic CV Events



No. at risk

EZ/Simva 10/40 mg	917	867	823	769	76
Placebo	898	838	788	729	76

# Coronary Artery Bypass Grafting (CABG)



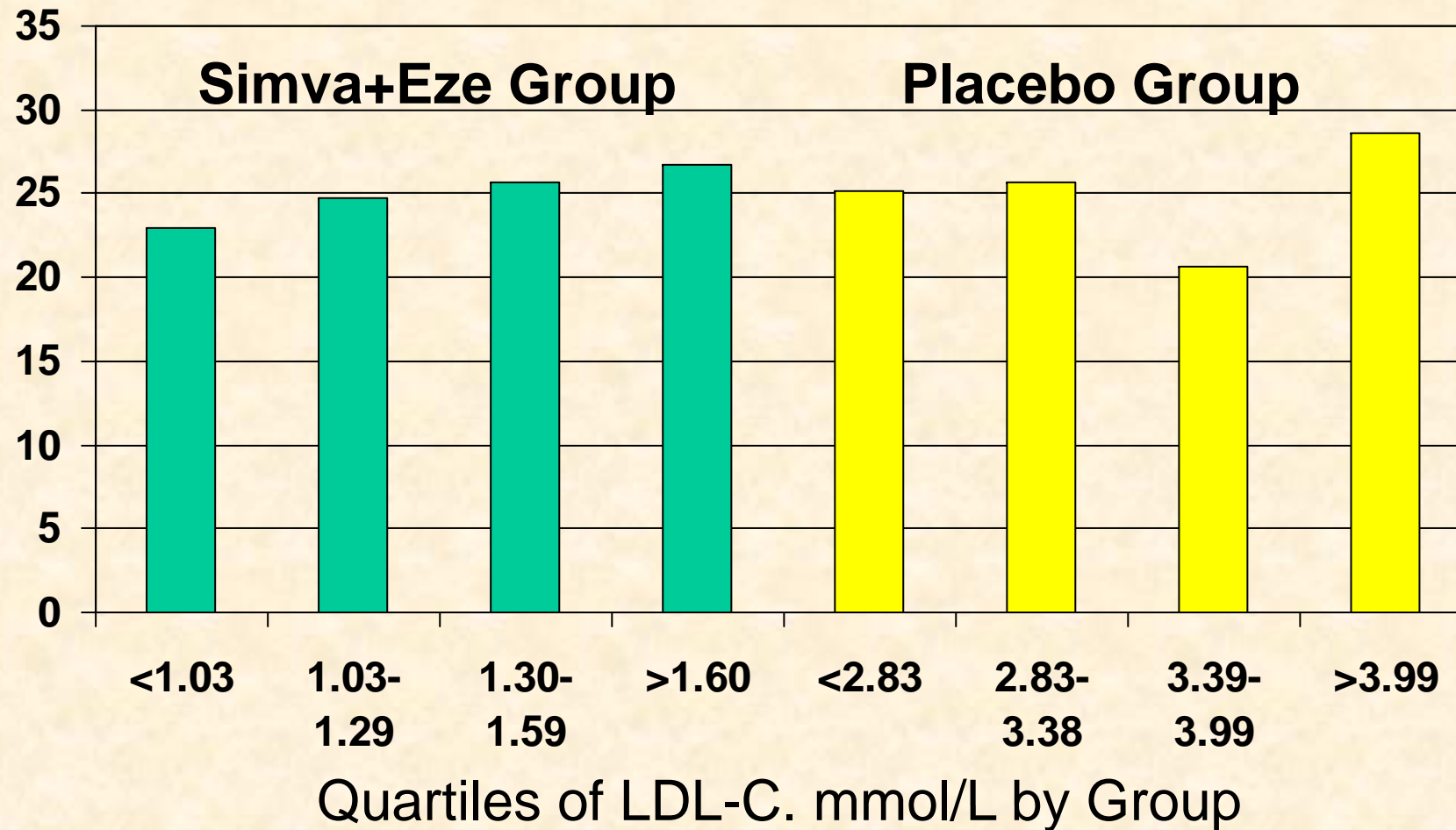
No. at risk

<b>EZ/Simva 10/40 mg</b>	<b>925</b>	<b>887</b>	<b>848</b>	<b>797</b>	<b>80</b>
<b>Placebo</b>	<b>909</b>	<b>862</b>	<b>819</b>	<b>761</b>	<b>80</b>

# Ischemic Endpoints by In-trial LDL-C



LDL-C levels are mean of levels at 8 and 24 weeks





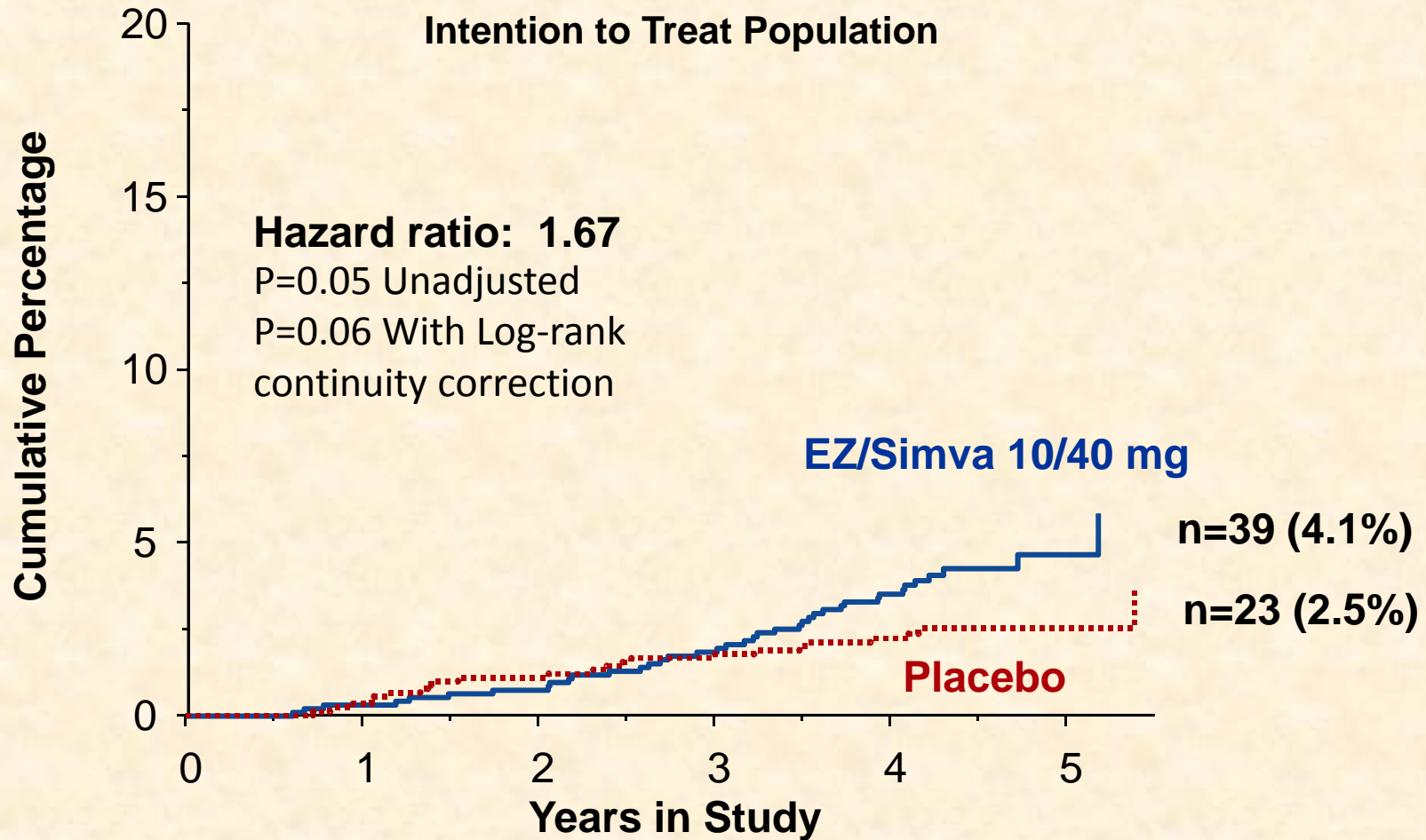
# Clinical Adverse Events (AE)



All Patients as Treated Population

	Placebo N=929 n	EZ/ Simva N=943* n	p=
<b>Any serious AE (SAE)</b>	<b>463</b>	<b>468</b>	
<b>Drug discon. due to SAE</b>	<b>79</b>	<b>77</b>	
<b>Musculoskeletal AE</b>	<b>181</b>	<b>165</b>	<b>0.28</b>
<b>Myopathy / Rhabdo</b>	<b>0</b>	<b>0</b>	
<b>New cancer</b>	<b>65</b>	<b>102</b>	<b>0.01</b>
<b>Recurrent, same site</b>	<b>5</b>	<b>3</b>	
<b>Cancer, total</b>	<b>70</b>	<b>105</b>	<b>0.01</b>

# Fatal Cancer



No. at risk

EZ/Simva 10/40 mg	930	912	884	855	89
Placebo	916	890	865	835	94

# Incident Cancer

All Patients as Treated Population



Site	Placebo (N=929)	EZ/simva (N=943)
	n	n
Lip, oral pharynx, Oesophagus	1	1
Stomach	1	5
Large bowel / intestine	8	9
Pancreas	1	4
Liver gallbladder, bile ducts	3	2
Lung	10	7
Other respiratory	0	1
Skin (any)	8	18
Breast	5	8
Prostate	13	21
Kidney	2	2
Bladder	7	7
Genital	4	4
Hemathological	5	7
Other/unspecified	7	12