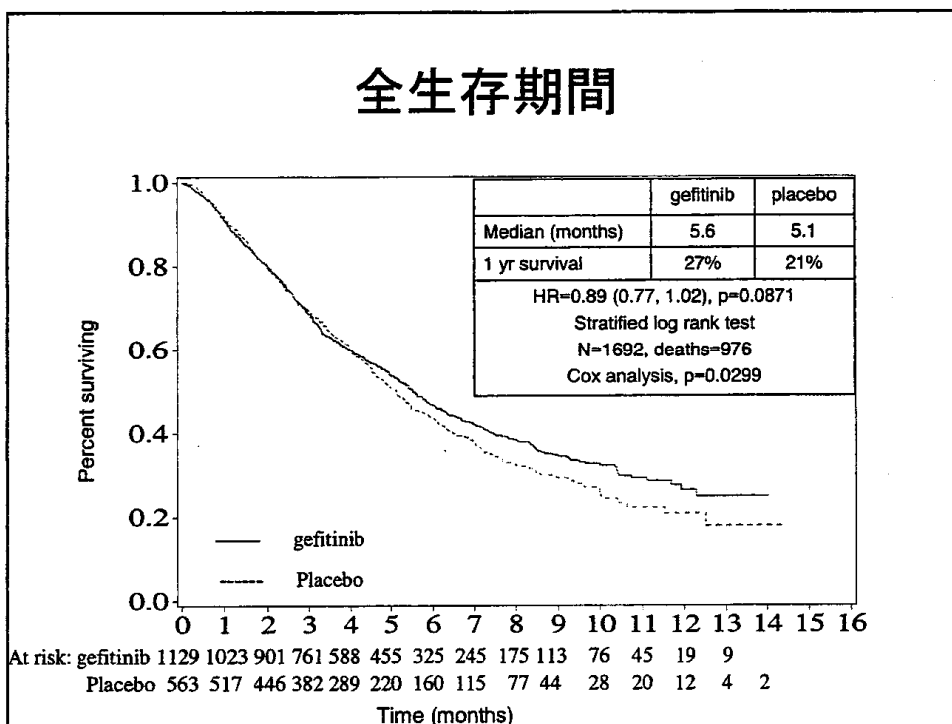
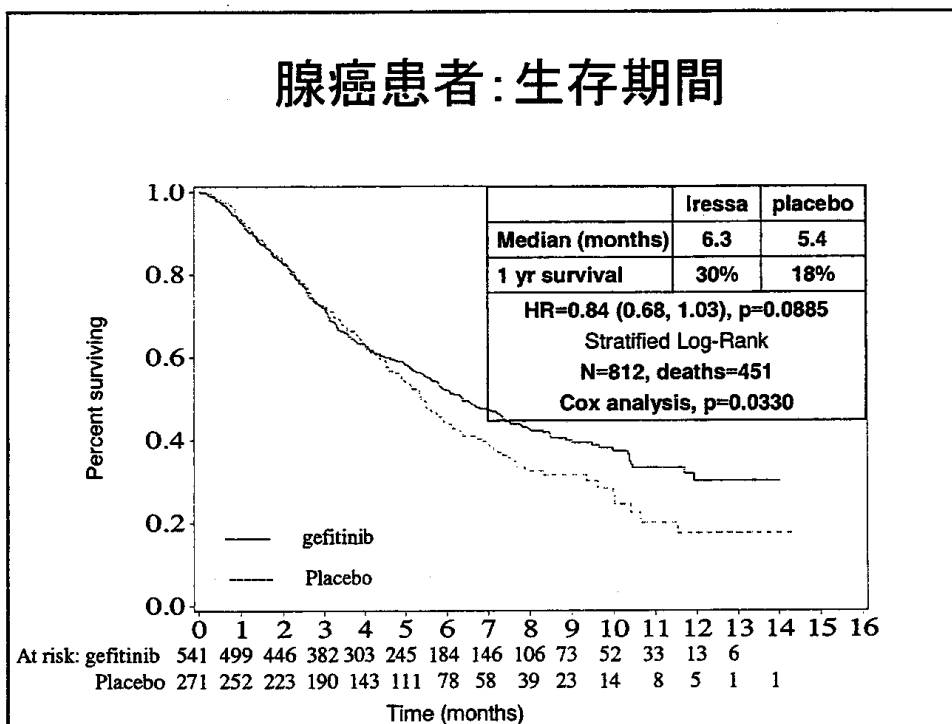


**第 2 回及び第 3 回検討会資料の抜粋
(生存曲線、患者背景に関する資料)**

全生存期間



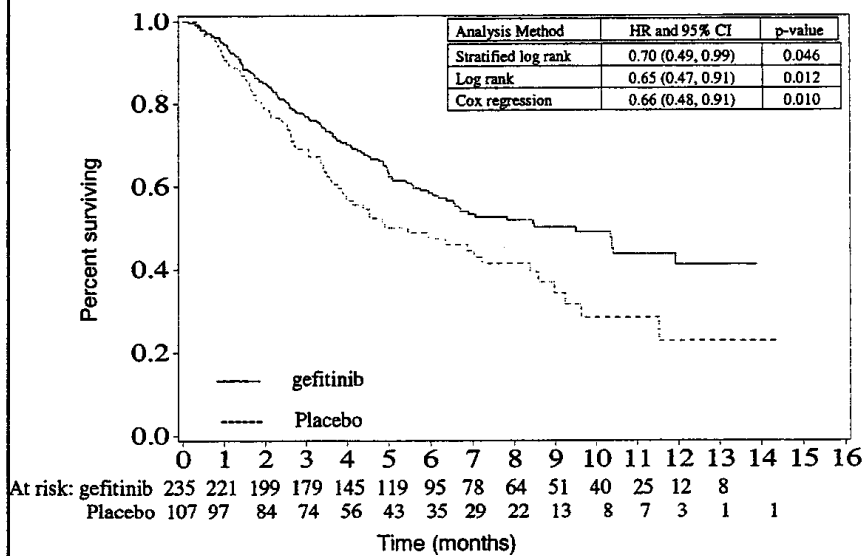
腺癌患者:生存期間



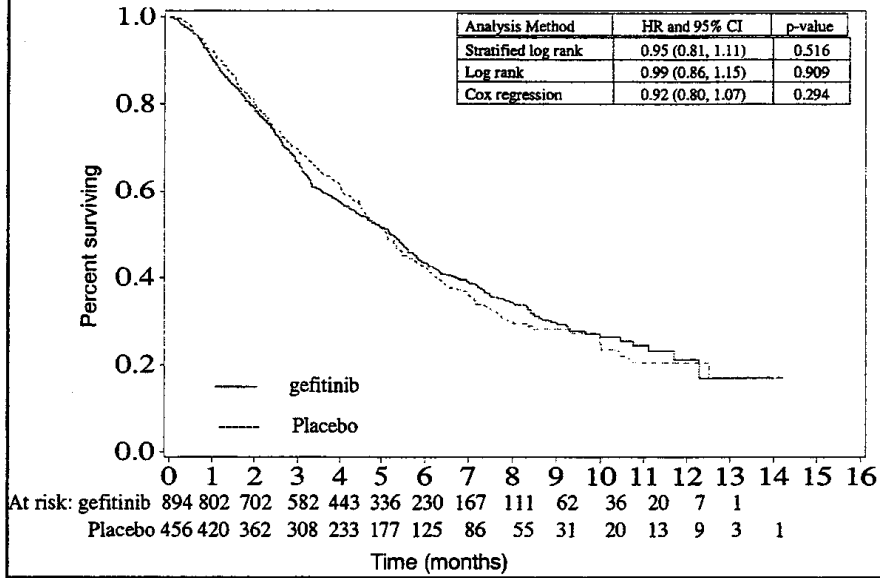
東洋人の患者背景

		ゲフィチニブ N=235	プラセボ N=107
年齢 (中央値)		61 歳	61 歳
男性		60%	60%
PS 0-1		72%	72%
非喫煙者		41%	41%
2次治療		54%	65%
組織型	腺癌	64%	64%
診断から無作為化までの期間	< 6カ月	25%	32%
	6-12カ月	40%	38%
前化学療法における最良総合効果	CR/PR	21%	21%
	SD	35%	32%
	PD/NE	44%	48%

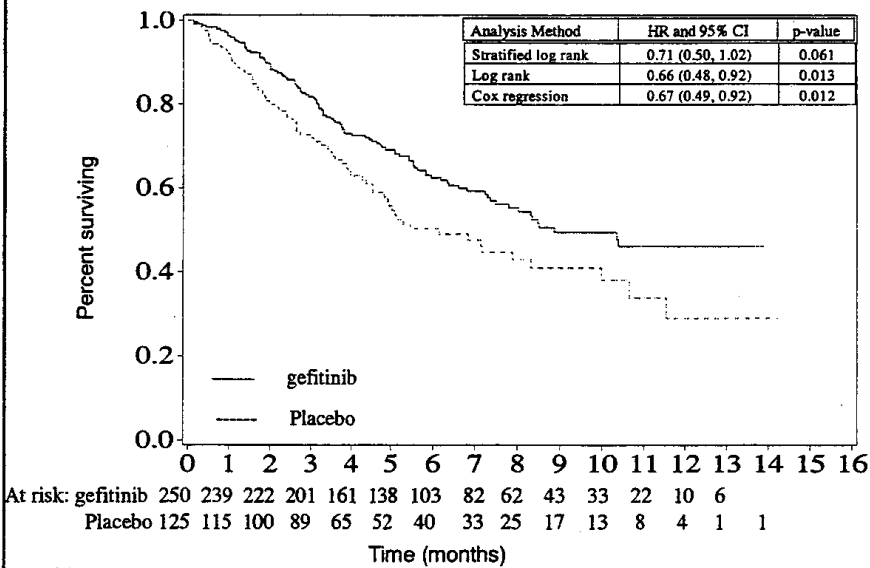
生存期間: 東洋人



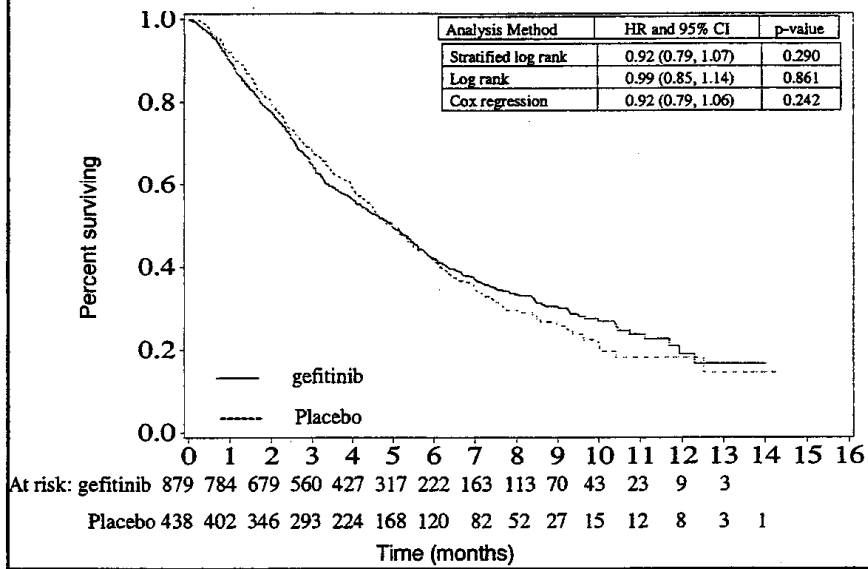
生存期間: 東洋人以外



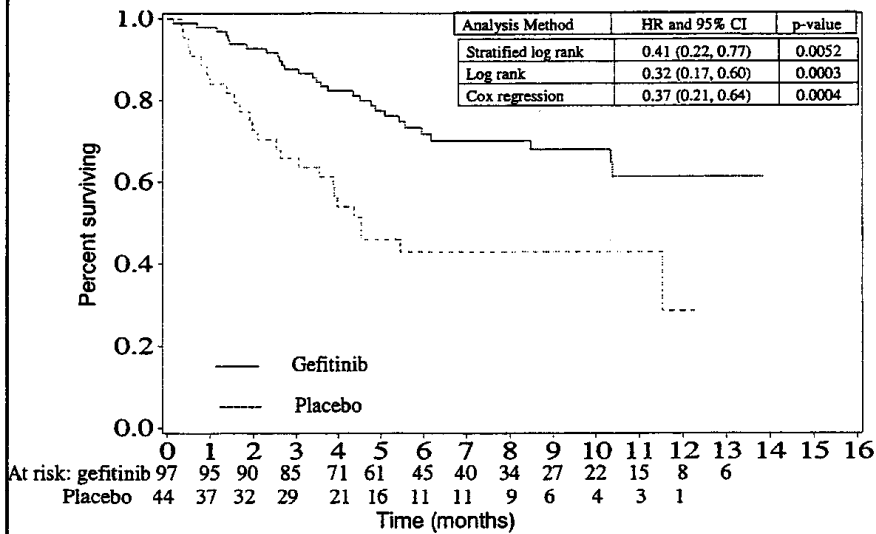
生存期間: 非喫煙者



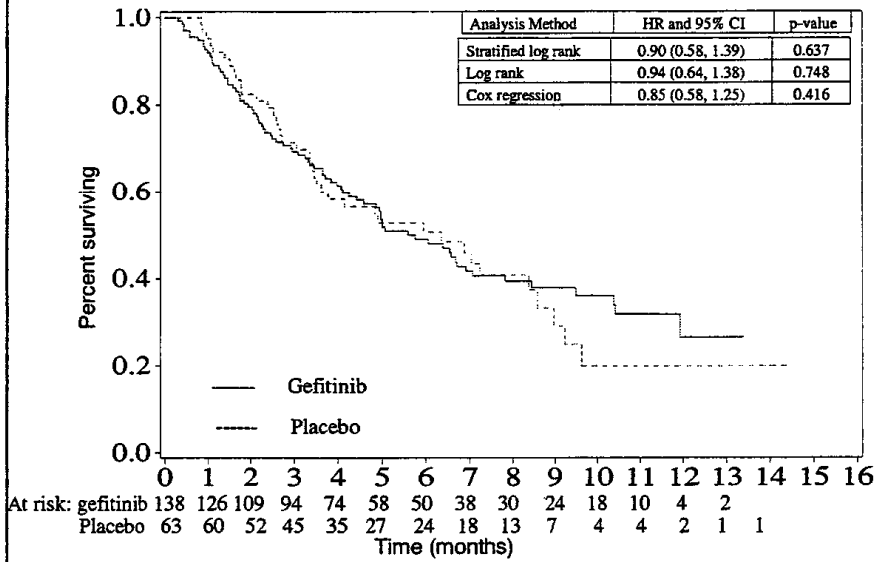
生存期間：喫煙者



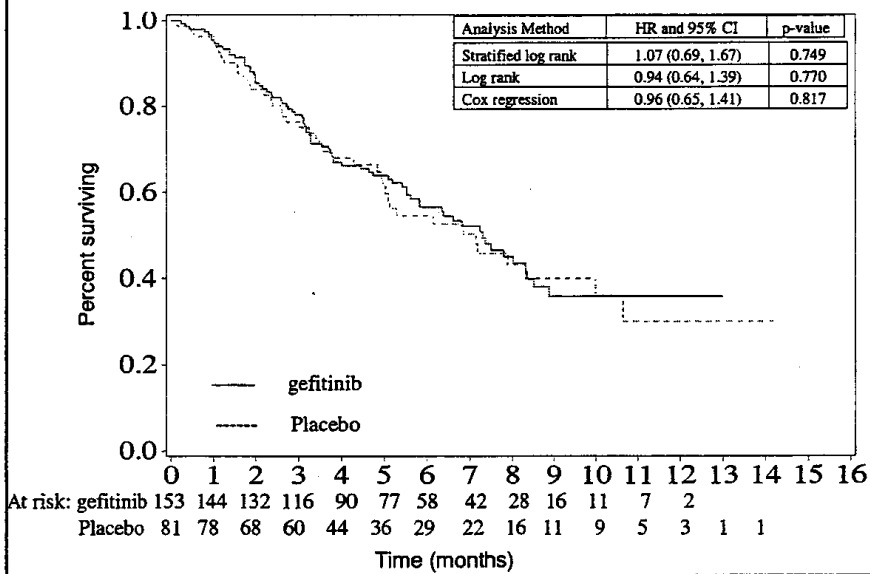
生存期間：東洋人非喫煙者



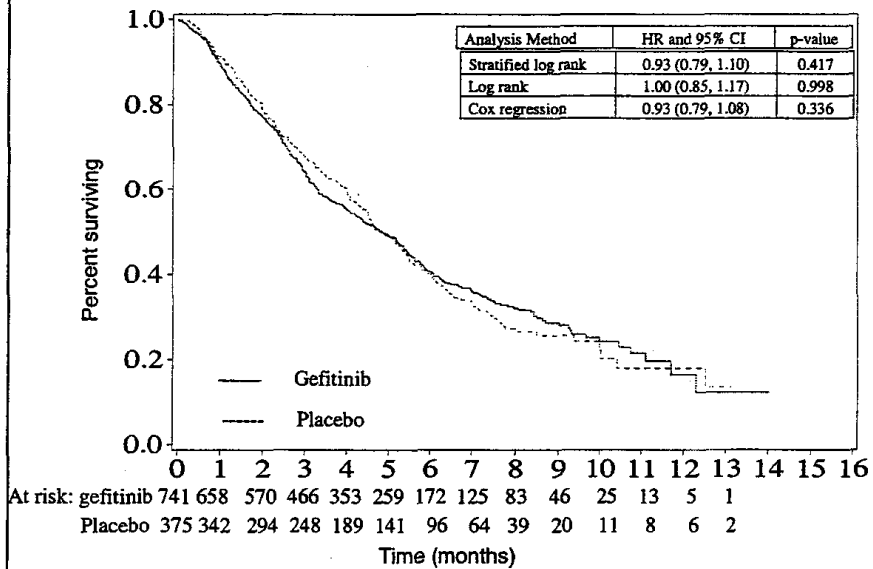
生存期間: 東洋人喫煙者



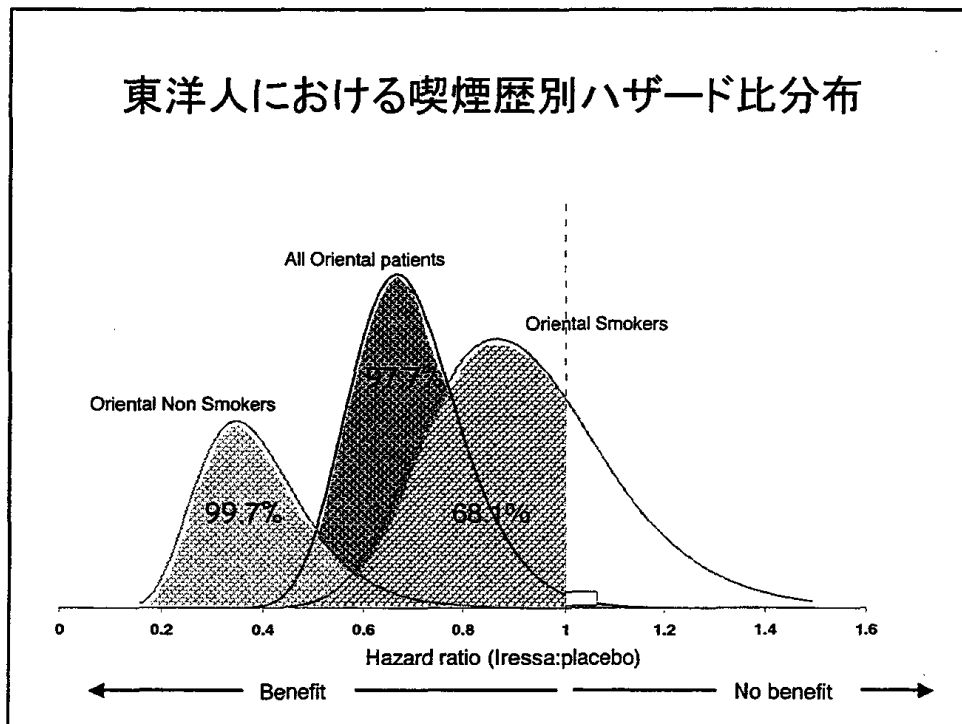
生存期間: 東洋人以外非喫煙者



生存期間: 東洋人以外喫煙者



東洋人における喫煙歴別ハザード比分布



東洋人及び非喫煙者の患者背景に関する資料

Within the Non Oriental patient subset, demography was well balanced at baseline

	All patients		Never smoked		Ever smoked		
	Gefitinib	Placebo	Gefitinib	Placebo	Gefitinib	Placebo	
	N=894	N=456	N=153	N=81	N=741	N=375	
Age (median)	62 years	61 years	62 years	63 years	62 years	61 years	
Age < 65 years	61%	62%	56%	54%	62%	64%	
Age ≥ 65 years	39%	38%	44%	46%	38%	36%	
Male	69%	69%	34%	37%	77%	76%	
PS 0-1	64%	68%	66%	64%	63%	69%	
Never smoked	17%	18%	100%	100%	0	0	
2nd line	47%	45%	48%	52%	47%	44%	
Refractory	89%	90%	86%	85%	89%	90%	
Intolerant	11%	10%	13%	12%	11%	9%	
Adenocarcinoma histology	44%	45%	71%	62%	38%	41%	
Time from diagnosis to randomisation	<6 months	26%	23%	35%	21%	24%	24%
	6-12 months	36%	40%	29%	42%	38%	39%
	> 12 months	37%	37%	35%	37%	38%	37%
Best response to prior chemotherapy	CR/PR	17%	19%	11%	24%	18%	18%
	SD	37%	38%	42%	39%	36%	38%
	PD/NE	46%	43%	46%	33%	45%	44%

Within the Oriental patient subset, demography was well balanced at baseline.

	All patients		Never smoked		Ever smoked		
	Gefitinib	Placebo	Gefitinib	Placebo	Gefitinib	Placebo	
	N=235	N=107	N=97	N=44	N=138	N=63	
Age (median)	61 years	61 years	58 years	55 years	64 years	64 years	
Age < 65 years	59%	64%	68%	82%	53%	52%	
Age ≥ 65 years	41%	36%	32%	18%	47%	48%	
Male	60%	60%	21%	27%	87%	83%	
PS 0-1	72%	72%	72%	70%	72%	73%	
Never smoked	41%	41%	100%	100%	0	0	
2nd line	54%	65%	52%	64%	55%	65%	
Refractory	93%	97%	94%	100%	93%	95%	
Intolerant	7%	3%	6%	0	7%	5%	
Adenocarcinoma histology	64%	64%	77%	84%	55%	49%	
Time from diagnosis to randomisation	<6 months	25%	32%	22%	41%	27%	25%
	6-12 months	40%	38%	38%	34%	41%	41%
	> 12 months	35%	30%	40%	25%	32%	33%
Best response to prior chemotherapy	CR/PR	21%	21%	22%	16%	21%	24%
	SD	34%	32%	35%	32%	34%	32%
	PD/NE	44%	48%	43%	52%	45%	44%

第2回検討会における
アストラゼネカ社への質問に対する回答

ISEL試験 患者背景－奏効しなかった患者 (東洋人及び東洋人以外)

		Oriental		Non-Oriental	
		Gefitinib	Placebo	Gefitinib	Placebo
		N=209	N=104	N=839	N=452
Age (median)		62 years	61 years	62 years	61 years
Male		61%	59%	71%	69%
PS 0-1		73%	71%	63%	68%
Never smoked		39%	42%	15%	18%
2nd line		55%	64%	47%	45%
Refractory		93%	97%	89%	89%
Intolerant		7%	3%	11%	11%
Adenocarcinoma histology		60%	62%	40%	42%
Time from diagnosis to randomisation	<6 months	25%	32%	27%	23%
	6-12 months	40%	39%	37%	40%
	> 12 months	34%	30%	37%	37%
Best response to prior chemotherapy	CR/PR	21%	21%	17%	19%
	SD	34%	31%	38%	38%
	PD/NE	45%	48%	45%	43%

ISEL試験 患者背景－奏効しなかった非喫煙者 (東洋人及び東洋人以外)

		Oriental		Non-Oriental	
		Gefitinib N=82	Placebo N=44	Gefitinib N=128	Placebo N=81
Age (median)		59 years	55 years	62 years	63 years
Male		21%	27%	34%	37%
PS 0-1		76%	71%	66%	64%
Never smoked		100%	100%	100%	100%
2nd line		54%	64%	48%	52%
Refractory		93%	100%	86%	85%
Intolerant		7%	0%	14%	15%
Adenocarcinoma histology		74%	80%	62%	53%
Time from diagnosis to randomisation	<6 months	23%	41%	38%	21%
	6-12 months	38%	34%	31%	42%
	> 12 months	39%	25%	32%	37%
Best response to prior chemotherapy	CR/PR	20%	16%	12%	22%
	SD	35%	32%	43%	38%
	PD/NE	45%	52%	45%	38%