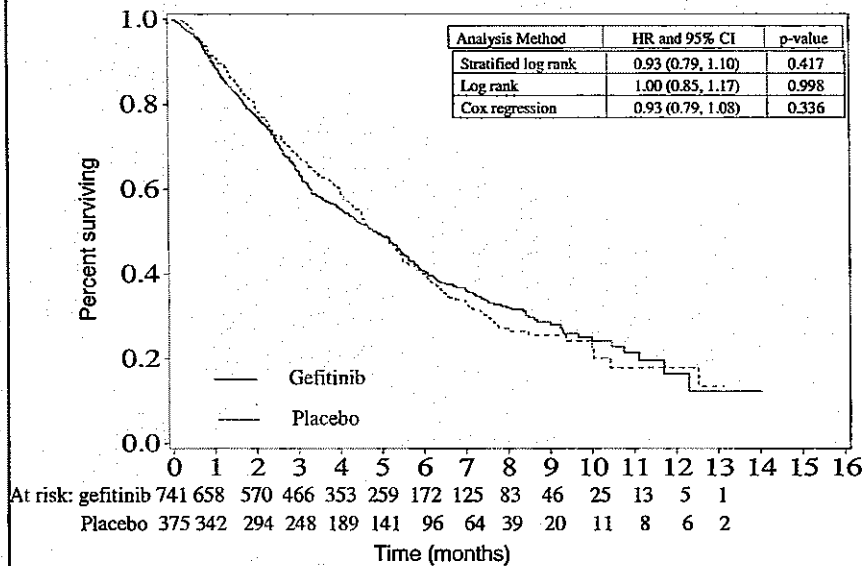
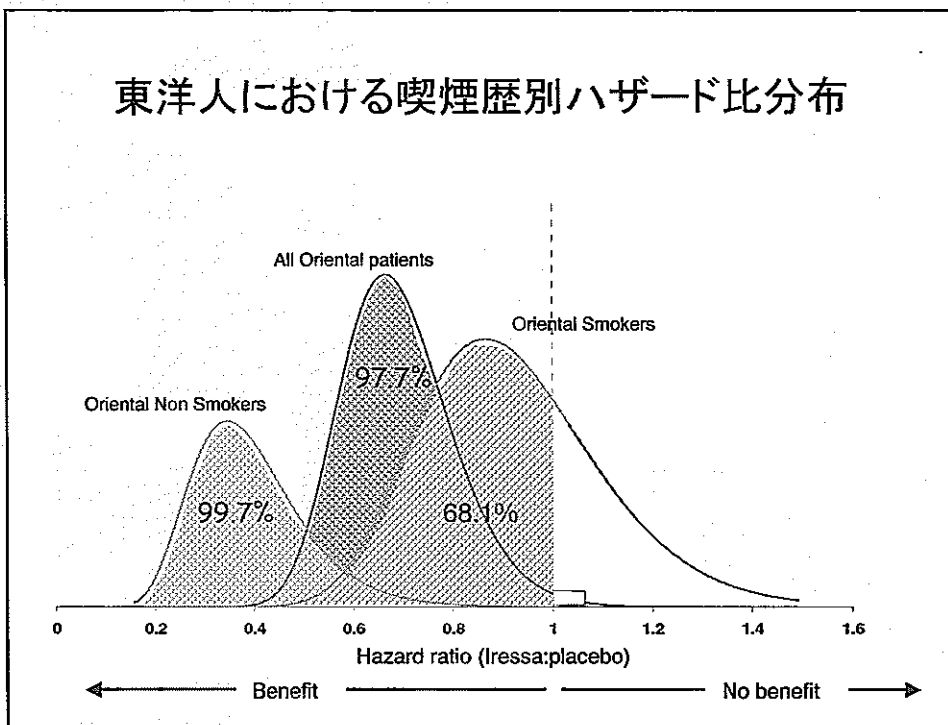


生存期間: 東洋人以外喫煙者



東洋人における喫煙歴別ハザード比分布



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

	All patients		Never smoked		Ever smoked	
	Gefitinib N=894	Placebo N=456	Gefitinib N=153	Placebo N=81	Gefitinib N=741	Placebo 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	
	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 N=209	Placebo N=104	Gefitinib N=839	Placebo 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%