# The ISEL (IRESSA Survival Evaluation in Lung Cancer) Study
Summary of Overall Survival data and analysis of Oriental subset

Objective of meeting

- To appraise MHLW of preliminary data from the ISEL study, and in particular, the results in Oriental patients.

ISEL (IRESSA Survival Evaluation in Lung Cancer): Clinical Trial Design

A double blind Phase III survival study comparing IRESSA (250mg) plus BSC vs. placebo plus BSC in patients with advanced NSCLC who have received 1–2 prior chemotherapy regimens and are refractory or intolerant to their most recent regimen
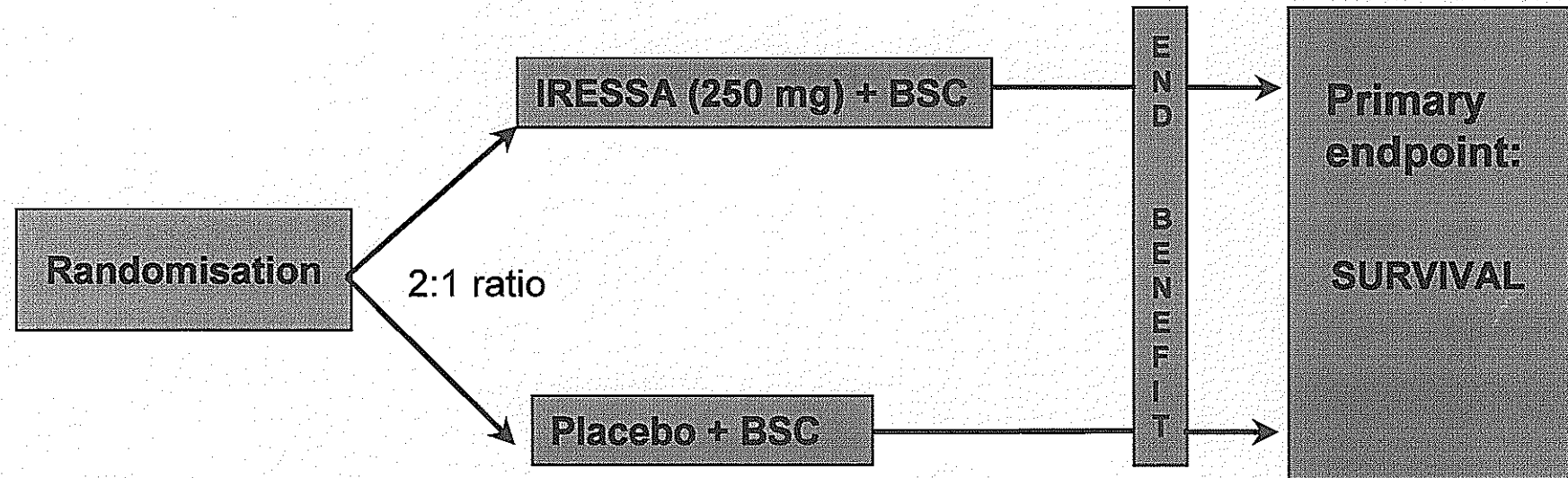
1692 patients in 210 centres across 28 countries
Stratified for histology, gender, intolerant/refractory and smoking history
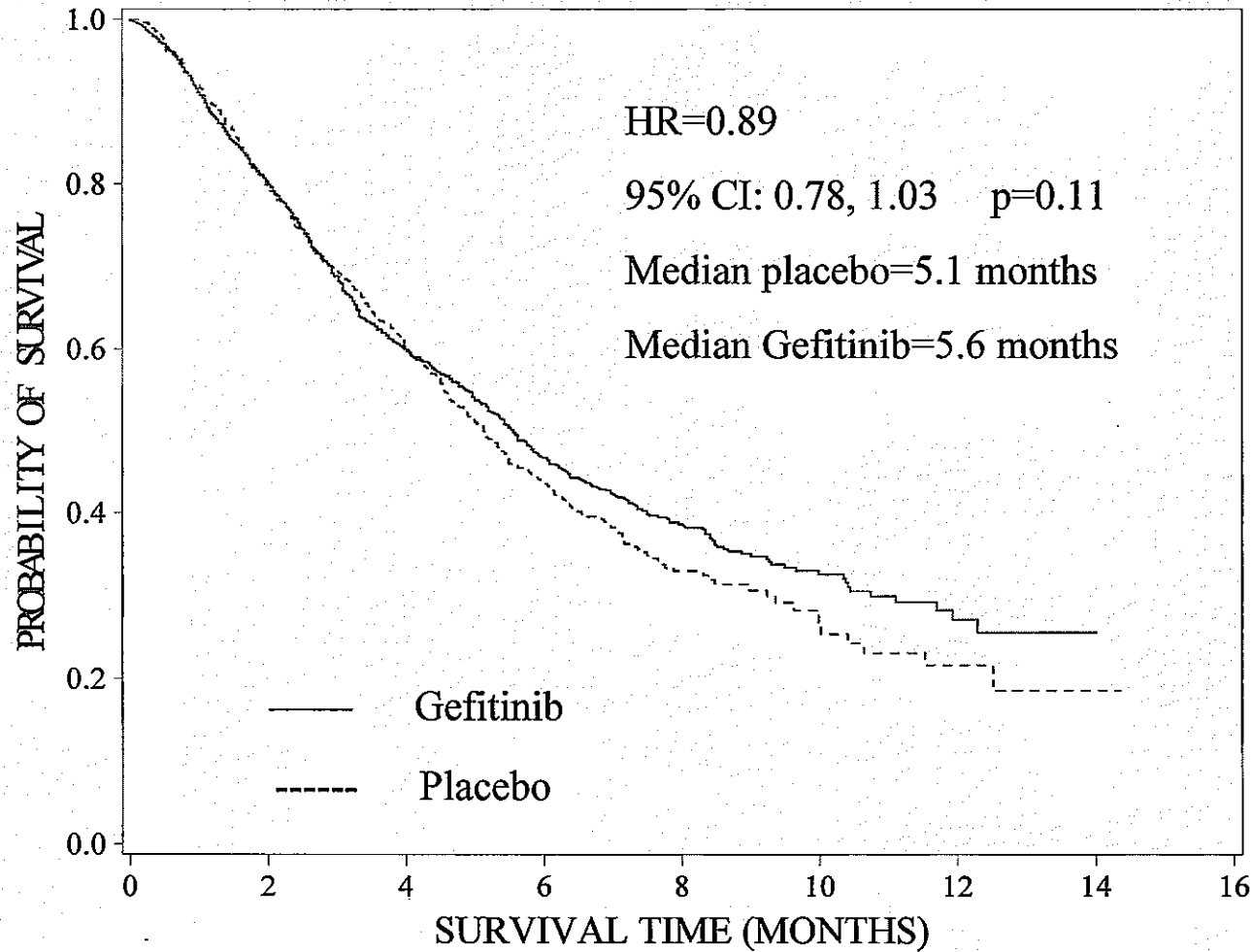342 patients of oriental origin
No Japanese sites

Endpoints and Methods

- Primary endpoint overall survival
  - Stratified log rank test.
  - Overall and adenocarincoma patient subsets co-primary populations for analysis.
- Secondary endpoints (Time to treatment failure, objective response and QoL) and safety available February 2005.
- Pre-planned subgroup analyses including patients of Oriental origin.
  - Cox regression analysis.

- 969 (59%) deaths at time of analysis.
- Median follow-up 7 months.
- Randomised treatment groups well balanced at baseline

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Summary of Survival Data

	All Histologies		Adenocarcinoma	
	Gefitinib N=1129	Placebo N=563	Gefitinib N=541	Placebo N=272
Number died (%)	632 (56%)	337 (60%)	287 (53%)	162 (60%)
Median (months)	5.6	5.1	6.3	5.4
1year survival rate (%)	27%	22%	31%	17%
Log Rank HR (95% CI)	0.89 (0.78, 1.03) P = 0.11		0.83 (0.67, 1.02) P = 0.07	
Cox analysis HR (95% CI)	0.87 (0.76, 0.995) P = 0.042		0.81 (0.66, 0.98) P = 0.030	

Survival in the overall population

HR=0.89
95% CI: 0.78, 1.03   p=0.11
Median placebo=5.1 months
Median Gefitinib=5.6 months

PROBABILITY OF SURVIVAL

SURVIVAL TIME (MONTHS)

MONTHS :	0	2	4	6	8	10	12
AT RISK :	1692	1348	876	484	252	103	31

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