

Statistical Analysis 1 for Patient Reported Outcomes: Functional Assessment of Cancer Therapy-Breast Symptom Index (8 item) (FBSI-8)

Statistical analysis title	Statistical analysis for FBSI-8			Analysis Type	Superiority			
				Comment				
Statistical analysis description	Estimate of Difference (least squares mean [LSM] difference) = (Sorafenib + Capecitabine) - (Placebo + Capecitabine). The difference between the two treatment groups was evaluated with an analysis of covariance model using the baseline score and the same stratification factors as used for randomization (IVRS) as covariates.							
Comparison groups or subject analysis sets	Sorafenib (Nexavar, BAY43-9006) + Capecitabine versus Placebo + Capecitabine							
Number of subjects in this analysis	476							
Analysis specification	Pre-specified							
Parameter Estimate								
Parameter type	Other effect estimate: LSM Difference							
Point estimate	-0.441							
Confidence interval	Level	95%	Sides	2	Lower limit	-0.967	Upper limit	0.086
Variability estimate	Choose an item.			Dispersion Value				