

Statistical Analyses 1 for Objective Response (OR)

Statistical analysis title	Statistical analysis 1- Objective Response (OR)		Analysis Type	Equivalence	
			Comment		
Statistical analysis description	Null hypothesis: "True probability p of objective tumor response does not exceed p0, p0=0.4." H0: p<=0.4 One-sided type I error probability of alpha=10%				
Comparison groups or subject analysis sets	Regorafenib + Oxaliplatin/Folinic Acid/5-FU (mFOLFOX6)				
Number of subjects in this analysis	41				
Analysis specification	Pre-specified				
Statistical hypothesis test					
P-value	=	Value: <u>0.36</u>	Comment		
Method [Required if P-value provided]	Other method name: (specify) One-sample exact binomial test				
Parameter Estimate					
Parameter type	Other effect estimate: Percentage of Subjects				
Point estimate	43.90				

Confidence interval	Level	Other: 80 %	Sides	2	Lower limit	33.19	Upper limit	55.09
Variability estimate	Choose an item.			Dispersion Value				