Table 18 Primary Outcome Measure: IRF-Assessed Objective Response Rate per RECIST v1.1 Compared with Pre-Specified Historical Control Rate Tested in Seven Subpopulations, Treated Patients

	Historical Rate	Number of Responders	N	Observed Rate	Lower CI	Upper CI	p-value
TC3 or IC3 in Cohort3	5%	31	115	27.0%	19.1%	36.0%	<0.0001
TC3 or IC3 in Cohorts 2 and 3	7%	60	237	25.3%	19.9%	31.4%	<0.0001
TC3 or IC2/3 in Cohort 3	5%	43	236	18.2%	13.5%	23.7%	<0.0001
TC2/3 or IC2/3 in Cohort 3	5%	44	253	17.4%	12.9%	22.6%	<0.0001
TC3 or IC2/3 in Cohorts 2 and 3	7%	86	483	17.8%	14.5%	21.5%	<0.0001
TC2/3 or IC2/3 in Cohorts 2 and 3	7%	90	520	17.3%	14.2%	20.8%	<0.0001
TC3 or IC3 in all patients	15%	77	302	25.5%	20.7%	30.8%	<0.0001

P-value presented is two-sided and from the exact test.
Clinical cut-off date: 28-MAY-2015; Final RAVE extraction date: 07-AUG-2015

Program: /opt/BIOSTAT/prod/cdt7692d/s28754e/t_test_binomial.sas
Output: /opt/BIOSTAT/prod/cdt7692d/s28754e/reports/t_test_binomial.out
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