

E5204 Primary Analysis Clinical Data Description (for NCT00303628-D1)

The data in the spreadsheet are the clinical analysis data for the primary manuscript on E5204 results, published in

Chakravarthy AB, Zhao F, Meropol NJ, Flynn PJ, Wagner LI, Sloan J, Diasio RB, Mitchell EP, Catalano P, Giantonio BJ, Catalano RB, Haller DG, Awan RA, Mulcahy MF, O'Brien TE, Santala R, Cripps C, Weis JR, Atkins JN, Leichman CG, Petrelli NJ, Sinicrope FA, Brierley JD, Tepper JE, O'Dwyer PJ, Sigurdson ER, Hamilton SR, Cella D, Benson AB 3rd. Intergroup Randomized Phase III Study of Postoperative Oxaliplatin, 5-Fluorouracil and Leucovorin vs Oxaliplatin, 5-Fluorouracil, Leucovorin and Bevacizumab for Patients with Stage II or III Rectal Cancer Receiving Preoperative Chemoradiation: A trial of the ECOG-ACRIN Research Group (E5204). *The Oncologist*. 2020 May;25(5):e798-e807. doi: 10.1634/theoncologist.2019-0437. Epub 2019 Dec 18.

The data reflect the study database as of April 8, 2015. All patients who were randomized to one of the arms are included.

Data can be used to approximate published study findings, but exact reproduction of previous manuscripts may not be possible in some cases (e.g., when data must be modified for de-identification purposes or have undergone further data cleaning).

Data File Description

Field	Variable Name	Description	Coding	Note
1	uid	Patient identifier	De-identified patient ID, not ECOG case ID	
2	indicator	Whether the case was included in the primary analysis	0=no, 1=yes	
3	trtm	Treatment arm	A=Arm A, B=Arm B	
4	elig	Eligibility	0=no, 1=yes	
5	treated	Received protocol therapy	0=no, 1=yes	
6	surv_s	OS status	0=censor, 1=died	As of database on 4/8/2015
7	surv_m	OS time in months	Continuous variable	As of database on 4/8/2015
8	recur	Disease recurrence	0=no, 1=yes	
9	dfs_s	DFS status	0=censor, 1=DFS event	As of database on 4/8/2015
10	dfs_m	DFS time in months	Continuous variable	As of database on 4/8/2015

Field	Variable Name	Description	Coding	Note
11	strt1	Stratification factor- ECOG performance status	1=0, 2=1	
12	strt2	Stratification factor- Clinical staging	1=high risk, 2=low risk	
13	strt3	Stratification factor- Pre-operative oxaliplatin	1=no, 2=yes	
14	strt4	Stratification factor- Pre-operative radiation dose	1=40-50 Gy 2=50-55.8 Gy 3=Not applicable - patient participated on NSABP R-04	The stratification factor had the first two options only when the trial first activated. The third option was added to the stratification factor for a short period of time during the study, and it was removed later. There were only the two first options in the latest version of the protocol. All three options were used in the primary paper.
15	age	Age at study entry (years)	Continuous variable	
16	sex	Sex	1=male, 2=female	
17	race	Race	1=White, 2=Black, 3=other	
18	ethnicity	Ethnicity	1=Hispanic, 2=Non-Hispanic, 3=unknown	
19	ecogps	ECOG performance status	0=0, 1=1	
20	clin_t_stage_num	Clinical T stage	1=T1, 2=T2, 3=T3, 4=T4	
21	clin_n_stage_num	Clinical N stage	0=N0, 1=N1, 2=N2	
22	clin_m_stage_num	Clinical M stage	0=M0	
23	bowel_obstrc_yn	Present with clinical bowel obstruction	1=no, 2=yes	
24	bowel_perfrt_yn	Bowel perforation	1=no, 2=yes	
25	histol_grade	Histologic grade	1=Grade I, 2=Grade II, 3=Grade III, 4=Grade IV	
26	prior_chemo_yn	Prior oxaliplatin	1=no, 2=yes	
27	prior_oth_tx_yn1	Prior capecitabine	1=no, 2=yes	

Field	Variable Name	Description	Coding	Note
28	prior_oth_tx_yn2	Prior continuous 5-FU infusion	1=no, 2=yes	
29	prior_oth_tx_yn3	Prior 5-FU+leucovorin	1=no, 2=yes	
30	rt_total_dose	Prior RT total dose (Gy)	Continuous variable	
31	prim_surg_type	Prior surgery type	1=Low anterior resection 2=Abdominal perineal resection 3=Low anterior resection/coloanal anastomosis 9=other	
32	compl_resct_yn	Complete resection done	1=no, 2=yes	
33	ostomy_yn	Ostomy created	1=no, 2=yes, colostomy; 3=yes, ileostomy	
34	spnct_prsrv_yn	Sphincter preserved	1=no, 2=yes	
35	total_cyc_num1	Total number of cycles of protocol treatment	Integer	347 patients received protocol therapy and had a value for the variable
36	total_cyc_num2	Number of cycles of oxaliplatin	Integer	347 patients received protocol therapy and had a value for the variable
37	bev_cycle	Number of cycles of bevacizumab	Integer	174 patients received treatment on arm B and had a value for the variable
38	off_tx_reas	Reason for discontinuing protocol therapy	1=Treatment completed per protocol criteria, 2=Disease progression, relapse during active treatment, 3=Adverse events/side effects/complications, 4=Death on study, 5=Patient withdrawal/refusal after beginning protocol therapy, 6=Alternative therapy,	Only patients who started protocol therapy answered the question.

Field	Variable Name	Description	Coding	Note
			7=Patient off treatment for other complicating disease, 99=other	
39	second	Indicator for second primary cancer	1=yes	
40	second_inv	Indicator for second invasive primary cancer	1=yes	
41	prim2_site	Site of second primary cancer	String variable	19 patients developed second primary cancer and had a value for this variable
42	clinicalrisk	Pre-treatment clinical stage risk	0=T1-3, node negative 1=T4 and/or node positive	
43	ypCR	Indicator for pathological pCR	1=yes	

Notes:

- Unless otherwise specified, blank values indicate missing data.
- In the analysis, months were calculated as days/30.4375