

E5204 Primary Analysis Adverse Events Data Description (for NCT00303628-D2)

The data in the spreadsheet are the adverse events 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. Only the 347 patients who started protocol therapy 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

Variable Name	Description	Coding	Note
uid	Patient identifier	De-identified patient ID, not ECOG case ID	Only the 347 patients who were treated were included in the database
trtm	Treatment arm	A=Arm A B=Arm B	119 patients on arm A and 123 patients on arm B reported grade 3 or higher toxicity
toxlabel	Toxicity name	String variable	per CTCAE v3.0
grade	Toxicity grade	1-5	per CTCAE v3.0, the worst degree
txrel	Attribution to treatment	3=possibly, 4=probably, 5=definitely	Events with missing information about treatment relations were included as events when treatment-related AEs were calculated.

Notes:

- Unless otherwise specified, blank values indicate missing data
- All treatment-related AEs were included in the database, and only the worst degree was reported in the paper.