

E5204 Primary Analysis PRO FACT-Diarrhea Data Description (for NCT00303628-D4)

The data in the spreadsheet are the PRO 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.

Three patient-reported outcomes instruments were used in the study: Bowel function/uniscale, FACT-Diarrhea, FACT-GOG Ntx scale. Dataset and dictionary were prepared separately for each of them. This dictionary is for the FACT-Diarrhea data.

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 for FACT-Diarrhea subscale questionnaire dataset (FACT-D (Version 4) Subscale)

Variable Name	Description	Coding
uid	Patient identifier	De-identified patient ID, not ECOG case ID
trtm	Treatment arm	A=Arm A, B=Arm B
time	Assessment time point	String variable
symp_index_1	FACT-D item score for item 1 (C3)	0=Not at all, 1=A little bit, 2=Somewhat, 3=Quite a bit, 4=Very much
symp_index_2	FACT-D item score for item 2 (ITF1)	Same as item 1
symp_index_3	FACT-D item score for item 3 (ITU2)	Same as item 1
symp_index_4	FACT-D item score for item 4 (D1)	Same as item 1
symp_index_5	FACT-D item score for item 5 (D2)	Same as item 1
symp_index_6	FACT-D item score for item 6 (D3)	Same as item 1
symp_index_7	FACT-D item score for item 7 (D4)	Same as item 1

symp_index_8	FACT-D item score for item 8 (D5)	Same as item 1
symp_index_9	FACT-D item score for item 9 (D6)	Same as item 1
symp_index_10	FACT-D item score for item 10 (ITF3)	Same as item 1
symp_index_11	FACT-D item score for item 11 (ITF5)	Same as item 1
miss	No. of items with missing value	Integer (0-11)
factdtotal	Scale total score	Numeric values

Notes:

- Unless otherwise specified, blank values indicate missing data.