

E5204 Primary Analysis PRO FACT/GOG-Ntx Data Description (for NCT00303628-D5)

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/GOG-Ntx 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/GOG-Ntx scale questionnaire dataset

Variable Name	Description	Coding	Note
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_index1		0=Not at all, 1=A little bit, 2=Somewhat, 3=Quite a bit, 4=Very much	This item was added to the FACT/GOG-Ntx form by the study team, it was worded as "I have pain in hands or feet when I am exposed to cold temperatures".
symp_index2		0=Not at all, 1=A little bit, 2=Somewhat, 3=Quite a bit, 4=Very much	This item was added to the FACT/GOG-Ntx form by the study team, it was worded as

			"I have difficulty breathing when I am exposed to cold temperatures".
symp_index_1	FACT-Ntx item score for item 1 (NTX1)	0=Not at all, 1=A little bit, 2=Somewhat, 3=Quite a bit, 4=Very much	
symp_index_2	FACT-Ntx item score for item 2 (NTX2)	Same as FACT-Ntx item 1	
symp_index_3	FACT-Ntx item score for item 3 (NTX3)	Same as FACT-Ntx item 1	
symp_index_4	FACT-Ntx item score for item 4 (NTX4)	Same as FACT-Ntx item 1	
symp_index_5	FACT-Ntx item score for item 5 (NTX5)	Same as FACT-Ntx item 1	
symp_index_6	FACT-Ntx item score for item 6 (HI12)	Same as FACT-Ntx item 1	
symp_index_7	FACT-Ntx item score for item 7 (NTX6)	Same as FACT-Ntx item 1	
symp_index_8	FACT-Ntx item score for item 8 (NTX7)	Same as FACT-Ntx item 1	
symp_index_9	FACT-Ntx item score for item 9 (NTX8)	Same as FACT-Ntx item 1	
symp_index_10	FACT-Ntx item score for item 10 (NTX9)	Same as FACT-Ntx item 1	
symp_index_11	FACT-Ntx item score for item 11 (An6)	Same as FACT-Ntx item 1	
miss	No. of items with missing value	Integer (0-11)	Only included the 11 items from the FACT/GOG-Ntx form
ntxtotal	FACT-Ntx total score for the 11 items	Numeric value	Only included the 11 items from the FACT/GOG-Ntx form

Notes:

- Unless otherwise specified, blank values indicate missing data.