

E5204 Primary Analysis PRO Bowel Function/Uniscale Data Description (for NCT00303628-D3)

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 Bowel function/uniscale 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 Bowel Function/uniscale questionnaire dataset

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
prob_w_bmv_yn	Overall having problem with bowel function	0=no, 1=yes
bmv_grtst_num	Greatest number of bowel movements in a day	Integer (0-24)
bmv_grtst_num_yn	3 or more bowel movements in a day	0=no, 1=yes
prob_night_bmv_yn	Get up at night	0=no, 1=yes
prob_lose_bmv_yn	Lost control of bowel movement	0=no, 1=yes
prob_30min_bmv_yn	Bowel movement within 30 minutes	0=no, 1=yes
cloth_pad_bmv_yn	Wear protective clothing	0=no, 1=yes

prob_stool_gas_yn	Unable to tell stool from gas	0=no, 1=yes
prob_stool_liq_yn	Liquid stool	0=no, 1=yes
urge_bmv_15m_yn	Must do within 15 minutes	0=no, 1=yes
cramp_w_bmv_yn	Cramping with a bowel movement	0=no, 1=yes
if_yes_cramp	Severity of cramping	1=mild, 2=moderate, 3=severe
bld_in_bmv_yn	Blood in bowel movement	0=no, 1=yes
bld_in_bmv	Amount of blood in bowel movement	1=on toilet tissue only, 2=mixed with or coating bowel movement, 3=enough to turn water in toilet bowl red
prob_activ_bmv	Affect normal activities	1=no problem, 2=mild, 3=moderate, 4=severe
prob_activ_bmv_yn	Affect normal activities or not	0=no, 1=yes
qol_uniscale	Patient's quality of life rating during the past week	Integer (0-10)
miss	No. of items with missing value	Integer (0-11)
problem	No. of problems	Integer (0-11)

Notes:

- Unless otherwise specified, blank values indicate missing data.