E2108 Primary Analysis PRO Data Description

The clinicaltrials.gov protocol identifier: NCT01242800
This data dictionary is for the NCT01242800-D3 dataset.

The data in the spreadsheet are the clinical analysis data for the primary manuscript on E2108 results, published in

> Khan SA, Zhao F, Goldstein LJ, Cella D, Basik M, Golshan M, Julian TB, Pockaj BA, Lee CA, Razaq W, Sparano JA, Babiera GV, Dy IA, Jain S, Silverman P, Fisher CS, Tevaarwerk AJ, Wagner LI, Sledge GW. Early Local Therapy for the Primary Site in De Novo Stage IV Breast Cancer: Results of a Randomized Clinical Trial (E2108). *J Clin Oncol*. 2022 Mar 20;40(9):978-987.PMCID: PMC8937009.

The instrument used in the study was FACT-B (Version 4), which includes FACT-G (27 items about physical well-being, functional well-being, social/family well-being and emotional well-being) plus 10 items about breast cancer specific concerns (ie, breast cancer subscale). In addition, 9 additional exploratory items were written by the study team in this trial, 4 items to assess lymphedema, 1 item to assess worry about tumor growth, 2 items to assess discomfort in the breast and chest wall, and 2 items to assess the effects of tumor nodules and ulcers on functional well-being. The FACT-B instrument was administered at registration (ie, baseline of Step 1, BASELINE_ST1), at randomization (ie, baseline of Step 2, collected prior to randomization, BASELINE_ST2), at 6 months (06_MO_POST_RAND), 18 months (18_MO_POST_RAND) and 30 months (30_MO_POST_RAND) post-randomization in patients on both arms. Arm A patients (alongside a few Arm B patients) also reported FACT-B data at decision for early local therapy (prior to surgery, LOCAL_TX).

All patients who were randomized to Step 2 and answered at least one FACT-B item at one time point were included in the dataset. Standard procedures for FACT instrument administration and scoring were followed.

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
1	uid	Patient identifier	De-identified patient ID
2	trtm	Treatment arm at step 2	A=Continued systemic therapy, B=Early local therapy

Field	Variable Name	Description	Coding
3	visit_time	Assessment time point	String variable
4	gp1	FACT-B Physical Well-being item score for item 1	0=Not at all, 1=A little bit, 2=Somewhat, 3=Quite a bit, 4=Very much
5	gp2	FACT-B Physical Well-being item score for item 2	Same as gp1
6	gp3	FACT-B Physical Well-being item score for item 3	Same as gp1
7	gp4	FACT-B Physical Well-being item score for item 4	Same as gp1
8	gp5	FACT-B Physical Well-being item score for item 5	Same as gp1
9	gp6	FACT-B Physical Well-being item score for item 6	Same as gp1
11	gp7	FACT-B Physical Well-being item score for item 7	Same as gp1
12	gf1	FACT-B Functional Well-being item score for item 1	Same as gp1
13	gf2	FACT-B Functional Well-being item score for item 2	Same as gp1
14	gf3	FACT-B Functional Well-being item score for item 3	Same as gp1
15	gf4	FACT-B Functional Well-being item score for item 4	Same as gp1
16	gf5	FACT-B Functional Well-being item score for item 5	Same as gp1
17	gf6	FACT-B Functional Well-being item score for item 6	Same as gp1
18	gf7	FACT-B Functional Well-being item score for item 7	Same as gp1
19	gs1	FACT-B Social/family Well-being item score for item 1	Same as gp1
20	gs2	FACT-B Social/family Well-being item score for item 2	Same as gp1
21	gs3	FACT-B Social/family Well-being item score for item 3	Same as gp1
22	gs4	FACT-B Social/family Well-being item score for item 4	Same as gp1
23	gs5	FACT-B Social/family Well-being item score for item 5	Same as gp1
24	gs6	FACT-B Social/family Well-being item score for item 6	Same as gp1
25	gs7	FACT-B Social/family Well-being item score for item 7	Same as gp1
26	ge1	FACT-B Emotional Well-being item score for item 1	Same as gp1
27	ge2	FACT-B Emotional Well-being item score for item 2	Same as gp1
28	ge3	FACT-B Emotional Well-being item score for item 3	Same as gp1
29	ge4	FACT-B Emotional Well-being item score for item 4	Same as gp1
30	ge5	FACT-B Emotional Well-being item score for item 5	Same as gp1
31	ge6	FACT-B Emotional Well-being item score for item 6	Same as gp1
32	b1	FACT-B Additional Concerns item score for item 1	Same as gp1
33	b2	FACT-B Additional Concerns item score for item 2	Same as gp1

Field	Variable Name	Description	Coding
34	b3	FACT-B Additional Concerns item score for item 3	Same as gp1
35	b4	FACT-B Additional Concerns item score for item 4	Same as gp1
36	b5	FACT-B Additional Concerns item score for item 5	Same as gp1
37	b6	FACT-B Additional Concerns item score for item 6	Same as gp1
38	b7	FACT-B Additional Concerns item score for item 7	Same as gp1
39	b8	FACT-B Additional Concerns item score for item 8	Same as gp1
40	b9	FACT-B Additional Concerns item score for item 9	Same as gp1
41	p2	FACT-B Additional Concerns item score for item 10	Same as gp1
42	b10	Movement of my arm on the side of breast cancer is painful	Same as gp1; The score values in the publication are recoded so that higher scores indicate less symptoms (i.e., publication score = $4 - b10$)
43	b11	I have a poor range of arm movements on the side of breast cancer	Same as gp1; The score values in the publication are recoded so that higher scores indicate less symptoms (i.e., publication score = $4 - b11$)
44	b12	My arm on the side of breast cancer feels numb	Same as gp1; The score values in the publication are recoded so that higher scores indicate less symptoms (i.e., publication score = $4 - b12$)
45	b13	I have stiffness of my arm on the side of breast cancer	Same as gp1; The score values in the publication are recoded so that higher scores indicate less symptoms (i.e., publication score = $4 - b13$)
46	b15	I worry about the tumor growing in my breast and/or chest wall	Same as gp1; The score values in the publication are recoded so that higher scores indicate less symptoms (i.e., publication score = $4 - b15$)
47	b16	I have pain or discomfort in my breast and/or chest wall	Same as gp1; The score values in the publication are recoded so that higher scores indicate less symptoms (i.e., publication score = $4 - b16$)
48	b17	The pain or discomfort in my breast and/or chest wall has limited my ability to work (including work at home)	Same as gp1; The score values in the publication are recoded so that higher scores indicate less symptoms (i.e., publication score = $4 - b17$)
49	b18	The lumps or open sores in my breast and/or chest wall have limited my ability to work (including work at home)	Same as gp1; The score values in the publication are recoded so that higher scores indicate less symptoms (i.e., publication score = $4 - b18$)

50	b19	The lumps or open sores in my breast and/or chest wall have limited my social activities	Same as gp1; The score values in the publication are recoded so that higher scores indicate less symptoms (i.e., publication score = 4 – *b19*)
51	toitotal	FACT-B TOI score	Numeric values, defined per protocol, including 24 items (7 FACT-G Physical well-being items, 7 FACT-G Functional well-being items, 10 FACT-B Additional Concerns items)
52	gtotal	FACT-G scale score	Numeric values, including FACT-G 27 items
53	btotal	FACT-B Breast Cancer specific item (additional concerns) subscale score	Numeric values, including 10 FACT-B Additional Concerns items
54	totalscore	FACT-B total score	Numeric values, including 37 items (FACT-G 27 items+ 10 Additional Concerns items)

Notes:
- Unless otherwise specified, blank values indicate missing data.