

PACCT-1 FACT-COG Data Description

This data submission (NCT00310180-D5) contains the FACT-COG scales used to generate the results in the PACCT-1 Cognitive Function paper:

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Data from this trial's primary publication can be found in NCT00310180-D1 and additional clinical data in NCT00310180-D4, and additional PRO data in NCT00310180-D6. Data in these submissions can be used to approximate published study findings, but exact reproduction of previous manuscripts may not be possible in some cases.

The data reflect the study database as of March 2, 2018. There is one record for each assessment for each patient.

Data File Description

Field	Name	Description	Coding
1	blindid	Case ID number	numeric code, up to 7 digits (same ids as other data sets)
2	PROvisit	The closest planned PRO assessment time to the actual assessment time	Character '00mth' = baseline '03mth' = 3-month follow-up '06mth' = 6-month follow-up '12mth' = 12-month follow-up '24mth' = 24-month follow-up '36mth' = 36-month follow-up
3	tassmntcog	Days from registration date to assessment date	Integer
4	inwindow	Indicator of whether the assessment occurred within the time window allowed in the analysis for the planned assessment time (see below)	Logical: TRUE if in window FALSE if not in window
5	closestcog	Indicator of which assessment in a PROvisit was closest to the planned data	Numeric: 0 = not closest 1 = closest
6	inPCI	Indicator of whether cases were included in the analysis of the PCI scale by Wagner et al (see eg Table A2)	Logical: TRUE if in analysis FALSE if not in analysis
7	cogpci	FACT-COG Perceived Cognitive Impairment Scale	Numeric 0-80
8	cogpca	FACT-COG Perceived Cognitive Abilities Scale	Numeric 0-36

9	cogoth	FACT-COG Comments from Others Scale	Numeric 0-16
10	cogqol	FACT-COG Impact on Quality of Life Scale	Numeric 0-16

Notes:

- Missing and not applicable values coded NA, except where noted otherwise.
- In the analysis, months were calculated as days/30.4375
- The time windows allowed for the inwindow variable were -100 to +21 days for baseline (also required to be no more than 7 days after start of chemo), +/- 35 days for 3-month, -49 to +70 for 6-month, and +/-91 days for 12-, 24-, and 36-month assessments.
- inPCI requires both inwindow and closesteog, as well as inAnalysis, pprot, and rxarm='B' or 'C' from the clinical data sets
- In Table A2 in the Supplement to the published Wagner et al paper, the summary statistics in the 3rd (FACT-COG Impact on Quality of Life) and 4th (FACT-COG Comments from Others) were transposed (that is, Impact on Quality of Life is in the 4th row and Comments from Others is in the 3rd).