PACCT-1 Additional Clinical Data Description

This data submission (NCT00310180-D4) contains the additional clinical data 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. The clinical data presented there were also used in the analysis for this manuscript, but are not included in this submission to avoid duplication. For convenience, this submission also includes several variables that were not used in this manuscript and were not part of the original submission. Data in this submission, together with that from the primary manuscript, can be used to approximate published study findings, but exact reproduction of previous manuscripts may not be possible in some cases.

PRO data used in this paper are in separate submissions (NCT00310180-D5 and NCT00310180-D6).

The data reflect the study database as of March 2, 2018. PACCT-1 included a pre-registration for OncoType Recurrence Score (RS) evaluation, followed by a registration onto one of the arms of the study (assignment of patients with RS 11-25 to arms B and C was by randomization). All patients who were registered to one of the arms are included.

Data File Description

Field	Name	Description	Coding
1	blindid	Case ID number	numeric code, up to 7 digits (same blinded id used in NCT00310180-D1)
2	racegp	Grouped Race as used in Albain et al	1 = White 3 = Black 4 = Asian 97 = Other/Unknown
3	insur	Insurance status at study entry	'1Pri' = Private '2Mcare' = Medicare '3Mcaid' = Medicaid '5Non' = None '6Int' = Patient from outside US '7O/N' = Other or unknown
4	hypertension	Hypertension at baseline	1 = No 2 = Yes

5	hyperlipidemia	hyperlipidemia at baseline	1 = No 2 = Yes
6	depression	depression at baseline	1 = No 2 = Yes
7	diabetes	diabetes at baseline	1 = No 2 = Yes
8	osteoarthritis	osteoarthritis at baseline	1 = No 2 = Yes
9	osteoporosis	osteoporosis at baseline	1 = No 2 = Yes
10	pulmonary	pulmonary at baseline	1 = No 2 = Yes
11	otherarthritis	other arthritis at baseline	1 = No 2 = Yes
12	cardiovascular	cardiovascular at baseline	1 = No 2 = Yes
13	bmi	Patient body mass index (weight divided by height squared)	Numeric kg/m^2
14	weight	Patient weight in kg	Numeric
15	height	Patient height in cm	Numeric

16	ERquant	Quantitative ER gene expression by PCR	Rounded to 1 decimal place and truncated above and below at 12.5 and 3.6
17	PRquant	Quantitative PR gene expression by PCR	Rounded to 1 decimal place and truncated above and below at 10.0 and 3.1
18	HER2quant	Quantitative HER2 gene expression by PCR	Rounded to 1 decimal place and truncated above and below at 13.0 and 7.5.
19	ERStatusPCR	ER status as determined by gene expression	'Positive' if ERquant >=6.5 'Negative' if ERquant <=6.4
20	PRStatusPCR	PR status as determined by gene expression	'Positive' if PRquant >=5.5 'Negative' if PRquant <=5.4
21	HER2StatusPCR	HER2 status as determined by gene expression	'Positive' if HER2quant >=11.5 'Negative' if HER2quant <=10.6 'Equivocal' if HER2quant between 10.7 and 11.3
22	possibleqol	Indicator of whether the patient was enrolled while the PRO study was active at the enrolling site	Logical variable (values TRUE and FALSE)
23	pprot	Indicator of whether the patient was treated per protocol (can be derived from rxarm and RecChemo)	TRUE if rxarm=A or B and RecChem=0 or rxarm=C or D and RecChem=1 FALSE otherwise
24	firstET	First type of endocrine therapy given	Character, with values 'AI' 'OFS' 'Tam' 'Tam & AI' 'YOth' = Other 'ZNone' = None reported

Notes:
- Missing and not applicable values coded NA, except where noted otherwise.
- In the analysis, months were calculated as days/30.4375
- In the data set from the primary publication (NCT00310180-D1), Endocrine therapy type 'OFS' includes patients who received ovarian function suppression with or without tamoxifen. Patients with TypeEndocrine=OFS there may have firstET=Tam here if it was clear that tamoxifen was started first.
- Change in endocrine therapy can be obtained from firstET (in this dataset) and TypeEndocrine (from D1): Tam to AI is firstET=Tam and TypeEndocrine=Tam & AI, and AI to Tam is firstET=AI and TypeEndocrin=Tam & AI.
- The population of patients included in the PRO substudy are a subset of the patients in the primary analysis for disease-free survival (see InAnalysis in NCT00310180-D1).