PACT1 Primary Analysis Clinical Data Description

The data in the spreadsheet are the analysis data for the primary manuscript on PACT1 (TAILORx) results, published in

> Sparano, J.A., Gray, R.J., Makower, D.F., Pritchard, K.I., Albain, K.S., Hayes, D.F., Geyer, C.E., Dees, E.C., Goetz, M.P., Olson, J.A., Lively, T., Badve, S.S., Saphner, T.J., Wagner, L.I., Whelan, T.J., Ellis, M.C., Paik, S., Wood, W.C., Radvin, P., Keane, M.M., Gomez Moreno, H.L., Reddy, P.S., Goggins, T.F., Mayer, I.A., Brufsky, A.M., Toppmeyer, D.L., Kaklamani, V.G., Berenberg, J.L., Abrams, J.S., Sledge, G.W.: Adjuvant chemotherapy guided by a 21-gene expression assay in breast cancer. N Engl J Med 2018;379(2):111-121.

The data reflect the study database as of March 2, 2018. PACT1 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
2	rxarm	Assigned Treatment Arm	'A' = RS 0-10, assigned endocrine therapy alone 'B' = RS 11-25, randomized to endocrine therapy alone 'C' = RS 11-25, randomized to chemo + endocrine therapy 'D' = RS > 25, assigned to chemo + endocrine therapy
3	InAnalysis	Indicator variable of whether the patient was in the primary analysis set for the publication	FALSE=no, TRUE=yes
4	osind	Indicator variable of whether the TAILORx On-Study case report form (baseline data) was submitted	0=no, 1=yes
5	inel	Indicator for patients excluded because they were not eligible	0=no, 1=yes
6	StratTumorSize	Tumor Size Stratification (reported during registration)	1 is <= 2.0 cm 2 is > 2.0 cm
7	StratMeno	Menopausal Status Stratification (reported during registration)	1 = Postmenopausal 2 = Pre/Peri Menopausal
8	StratPlannedChemo	Type of Planned Chemo Stratification (reported during registration)	1 = taxane containing regimen 2 = non-taxane regimen 3 = not applicable
9	StratPlannedRT	Type of Planned RT (reported during registration)	1 = Whole breast, no boost 2 = Whole breast with boost 3 = partial breast 4 = none planned
10	RSgp	Grouped RS (derived from RS) Used as a stratification factor	1 = 0-5 2 = 6-10

		for randomizations during the later portion of the study, and included as a stratification factor for all randomized cases for stratified analyses in the paper	3 = 11-15 4 = 16-20 5 = 21-25 6 = 26-30 7 = 31-35 8 = 36-40 9 = 41-50 10 = 51-100
11	Strat	Combined stratification variable used for stratified comparison of randomized arms	codes 1 – 120 (interpretation can be identified by tabulating against the stratification variables above
12	RS	Recurrence Score	Integer 0-100 (max observed value is 87)
13	age	Age at registration on PACT1	In years; ages 23-89 are given as the actual value; ages 90 or older have the value ">=90"
14	meno	Menopausal status at registration on PACT1 (reported on On-Study CRF)	'Pre' = premenopausal 'Post' = postmenopausal
15	race	Patient's race	1 = White 3 = Black 4 = Asian 5 = Native Hawaiian or Pacific Islander 6 = Native American 98 = Multirace 99 = Not reported
16	ethnicity	Patient's ethnicity	1 = Hispanic 2 = Not Hispanic 99 = Not reported
17	TumorSize	Maximum diameter of the primary tumor	value in millimeters (integer)
18	TumorSizeGp	Tumor size category	Character: '<=1' is less than or equal to 1cm '(1,2]' is >1cm and <=2cm '(2,3]' is >2cm and <=3cm '(3,4]' is >3cm and <=4cm '>4' is >4 cm
19	Grade	Histologic Grade (as reported by local site)	'Low' 'Med' 'High'
20	NucGrade	Nuclear Grade (as reported by local site) [not used in publication]	'Low' 'Med' 'High'
21	ERStatus	Estrogen Receptor Status	'Neg' = Negative 'Pos' = Positive
22	PRStatus	Progesterone Receptor Status	'Neg' = Negative 'Pos' = Positive
23	PrimSurg	Primary surgical procedure	'Mx' = mastectomy 'Tx' = tumorectomy
24	RecChemo	Indicator of whether patients	0 = No

		were treated with chemotherapy (cases with no follow-up data are coded as 0)	1 = Yes
25	ChemRegGp	Chemotherapy regimen given (grouped as reported in manuscript)	'1CMF' '2Anthracycline w/o Taxane' '3Anthracycline and Taxane' '4TC and variations' '5Other or Not Specified' '6None'
26	ChemReg	Chemotherapy regimen given (more granular classification than previous variable)	1 = oral CMF (4 week cycles) 2 = IV CMF (3 week cycles) 3 = standard AC (3 week cycles) 4 = dose dense AC (2 week cycles) 5 = standard AC followed by a taxane 6 = dose dense AC followed by a taxane 7 = FEC (3 week cycles) 8 = TAC (3 week cycles) 9 = TC (3 week cycles – includes any taxane with cyclophosphamide) 10 = Other treatment given as part of a CTSU protocol 11 = Other 12 = None 13 = other anthracycline with no taxane 14 = taxane only 15 = other anthracycline with a taxane
27	TypeEndocrine	Type of endocrine therapy	Character, with values 'AI' 'OFS' 'OFS & AI' 'Tam' 'Tam & AI' 'Other' 'None'
28	ttfET	Days from registration to first endocrine therapy (see notes)	Integer (days)
29	ttlET	Days from registration to last endocrine therapy (see notes)	Integer (days)
30	durET	Duration of endocrine therapy (ttlET – ttfET)	Integer (days)
31	endET	Indicator of whether all endocrine therapy had been stopped (used as event indicator for duration analysis)	1 = All endocrine therapy stopped at ttlET 0 = Endocrine therapy continuing at ttlET (censored duration)
32	dfs	Disease-free survival: Days from registration to first dfs event or last disease evaluation	Integer (days)
33	dfsind	DFS event indicator	1 = DFS event reported (dfs is time

			of first DFS event) 0 = no DFS event
34	drfi	Distant recurrence-free interval: Days from registration to first distant recurrence or last disease evaluation	Integer (days)
35	drfiind	Distant recurrence indicator	1 = distant recurrence (drfi is time of distant recurrence) 0 = no distant recurrence
36	rfi	Recurrence-free interval: days from registration to first recurrence or to last disease evaluation	Integer (days)
37	rfiind	Recurrence indicator	1 = recurrence (rfi is time of recurrence) 0 = no recurrence
38	survtime	Days from registration to death or date last known alive	Integer (days)
39	survstat	Survival status	1 = dead 0 = alive
40	WithdrawConsent	Indicator of whether patient withdrew consent for further follow-up	1 = yes 0 = no
41	LostFU	Indicator of whether the patient is lost to follow-up	1 = lost to follow-up 0 = not lost to follow-up
42	typefdfs	Type of first DFS event	1 = ipsilateral breast recurrence 2 = recurrence at local-regional site 3 = recurrence at distant site (includes concurrent distant and local-regional) 4 = new cancer of the opposite breast 5 = new primary cancer at other than breast or non-melanoma skin cancer 6 = death without another event reported
43	typefrec	Type of first recurrence	1 = ipsilateral breast recurrence 2 = recurrence at local-regional site 3 = recurrence at distant site (includes concurrent distant and local-regional)
44	cause	Cause of death	1 = Protocol treatment 2 = Breast cancer 3 = Cardiovascular disease 4 = Other chronic disease 5 = Other cancer 6 = Other 99 = Unknown

Notes:

- Missing and not applicable values coded NA, except where noted otherwise.
- In the analysis, months were calculated as days/30.4375
- The # at risk tables under the Kaplan-Meier plots in the paper were inadvertently given as the number at risk just after the indicated times, rather than the standard convention of just before. This only matters at 48 and 96 months, since those are the only times where exact equality occurs.
- The data set here reflects some additional cleanup of endocrine therapy data since the published analysis. In Table S2, this shifts one premenopausal patient on arm C from AI to none reported, and one postmenopausal patient on arm B from Tam and AI to Tam. There are also some minor changes in the estimated distribution of duration of Endocrine Therapy (Figure S1).
- Start and stop dates of endocrine therapy are often approximate (obtained from follow-up reporting period beginning and end dates). This leads to some cases having a duration of 0 days, which should be interpreted as a short duration that cannot be more precisely determined from the available information.