

This data dictionary is for dataset NCT00433511-D5.

This data submission is intended to add variables to the NCTN/NCORP Data Archive for publication:
PubMed ID:30040523;PMCID:PMC6118403.

Reminders:

- The primary endpoint in E5103 was invasive disease-free survival (IDFS) which was defined as time from registration to Step1 to date of first treatment failure (invasive ipsilateral, invasive local-regional or distant recurrence, invasive contralateral breast cancer, invasive non-breast second primary, or death from any cause, whichever occurred first).
- Per Protocol and case report forms (CRFs), patients were to be followed for documentation of first local-regional and for first distant recurrence: when first local-regional recurrence was documented in absence of a documented first distant recurrence, patients were to continue to be followed for documentation of first distant recurrence; if first distant recurrence was documented in absence of documentation of first local-regional recurrence, no further follow up for documentation of first local-regional recurrence was required (first local-regional recurrence documented 1-2 months after first distant recurrence (within the same visit) was sometimes reported).
- Variables ttlr and ttdr in this dataset (NCT00433511-D5) are time from Step 1 registration to local-regional recurrence and to distant recurrence respectively, regardless if that was the first IDFS event.
- Reminder to consult datasets: NCT00433511-D1 for the dfscns (IDFS indicator variable), dfs (IDFS time variable), and oscns (OS indicator variable), and NCT00433511-D4 for os_2 (OS time variable).

Note 9999=not applicable

Variable name	Variable Description
protocol_number	Protocol Number
groupuid	Unique patient id (blinded)
lrcns	Local-regional recurrence indicator 1=local-regional recurrence
ttlr	Time from Step 1 registration to local-regional recurrence (months)
drcns	Distant recurrence indicator 1=distant recurrence
ttdr	Time from Step 1 registration to distant recurrence (months)