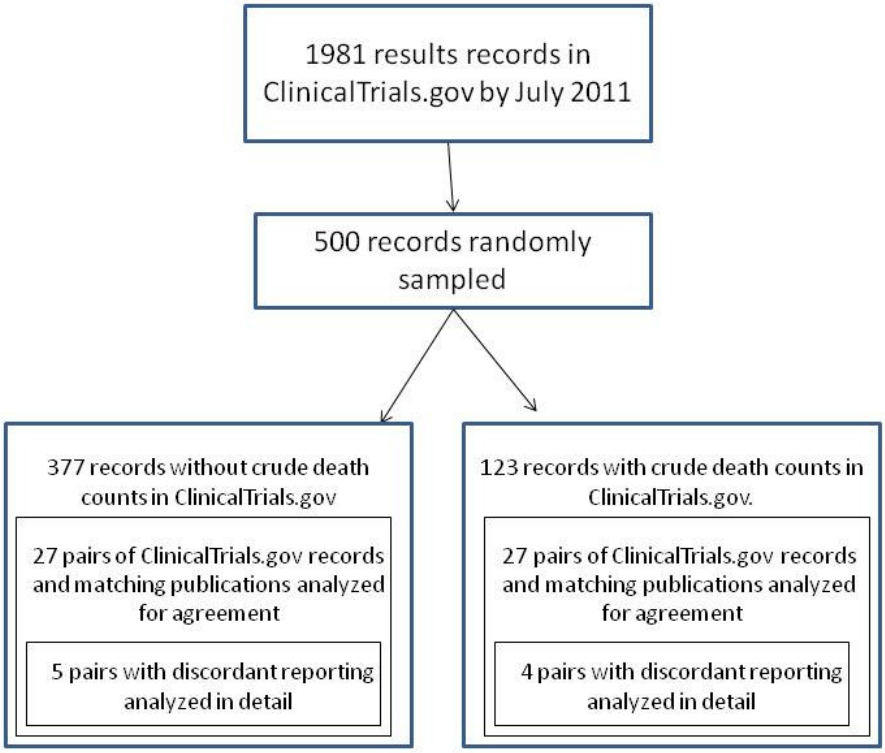
## Appendix Figure 1. Study Flow




## Appendix 2. Examples death counts reported in modules in ClinicalTrials.gov records

**Primary of secondary outcome**

**Measured Values**

| | Evaluable Patients |
|---|---|
| **Number of Participants Analyzed**<br>[units: participants] | 15 |
| **Number of Participants (Patients) Who Died Due to Transplant.**<br>[units: Participants] | 4 |

**No statistical analysis provided for Number of Participants (Patients) Who Died Due to Transplar**

**Serious Adverse Events**

Serious Adverse Events

| | Home Monitoring | Conventional |
|---|---|---|
| **Total, serious adverse events** | | |
| # participants affected / at risk | 124/977 (12.69%) | 74/473 (15.64%) |
| **Cardiac disorders** | | |
| Cardiac related hospitalizations † | | |
| # participants affected / at risk | 45/977 (4.61%) | 31/473 (6.55%) |
| # events | 64 | 35 |
| **General disorders** | | |
| Death † | | |
| # participants affected / at risk | 52/977 (5.32%) | 26/473 (5.50%) |
| # events | 52 | 26 |
| Non-cardiac related hospitalizations † | | |
| # participants affected / at risk | 16/977 (1.64%) | 3/473 (0.63%) |
| # events | 20 | 4 |

**Participant Flow**

**Participant Flow: Overall Study**

| | Docetaxel + Sunitinib | Docetaxel |
|---|---|---|
| STARTED | 296 | 297 |
| Treated | 295 | 293 |
| COMPLETED | 0 | 0 |
| NOT COMPLETED | 296 | 297 |
| Study Ongoing | 19 | 31 |
| Protocol Violation | 1 | 1 |
| Lost to Follow-up | 2 | 5 |
| Death | 10 | 4 |
| Objective Progression or Relapse | 227 | 206 |
| Participant refused | 3 | 7 |
| Unspecified | 34 | 43 |

## Appendix 3. Example of a ClinicalTrials.gov record with an indeterminate total number of deaths

### Module A

**Recruitment Details**

| Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations |
|---|
| Between June 1997 and June 1999, 1491 women from 20 countries were enrolled in the study. The last patient last visit occurred in January 2010. |

**Pre-Assignment Details**

| Significant events and approaches for the overall study following participant enrollment, but prior to group assignment |
|---|
| Eleven women (1 who had been randomly assigned to receive TAC and 10 assigned to receive FAC) did not receive any treatment for the following reasons: 8 withdrew consent, 1 was lost to follow-up, and 2 did not receive treatment for other reasons. In total 1480 patients (744 in the TAC group and 736 in the FAC group) were treated. |

**Reporting Groups**

| | Description |
|---|---|
| TAC (Docetaxel) | docetaxel in combination with doxorubicin and cyclophosphamide |
| FAC (5-fluorouracil) | 5-fluorouracil in combination with doxorubicin and cyclophosphamide |

**Participant Flow: Overall Study**

| | TAC (Docetaxel) | FAC (5-fluorouracil) |
|---|---|---|
| STARTED | 745 | 746 |
| COMPLETED | 679 | 711 |
| NOT COMPLETED | 66 | 35 |
| Adverse Event | 45 | 8 |
| Death | 2 | 2 |
| Lost to Follow-up | 0 | 1 |
| Consent Withdrawn | 17 | 17 |
| Breast Cancer Relapse | 1 | 4 |
| Violation of Inclusion Criteria | 1 | 3 |

### Module B

2. Secondary: Number of Participants With Overall Survival Events [ Time Frame: up to 10 year follow-up ]

Hide Outcome Measure 2

| | |
|---|---|
| **Measure Type** | Secondary |
| **Measure Title** | Number of Participants With Overall Survival Events |
| **Measure Description** | Overall Survival - time from the date of randomization up to the date of death of any cause. |
| **Time Frame** | up to 10 year follow-up |
| **Safety Issue** | No |

**Population Description**

| **Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.** |
|---|
| No text entered. |

**Reporting Groups**

| | **Description** |
|---|---|
| **TAC (Docetaxel)** | docetaxel in combination with doxorubicin and cyclophosphamide |
| **FAC (5-fluorouracil)** | 5-fluorouracil in combination with doxorubicin and cyclophosphamide |

**Measured Values**

| | **TAC (Docetaxel)** | **FAC (5-fluorouracil)** |
|---|---|---|
| **Number of Participants Analyzed [units: participants]** | **745** | **746** |
| **Number of Participants With Overall Survival Events [units: Participants]** | **188** | **241** |