

# MDA2014-04-01 - Inclusion Criteria prev10a2 Data Dictionary

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## Document Summary

| Property          | Value  |
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# MDA2014-04-01 - Inclusion Criteria prev10a2: Data Dictionary

## Section 1: Identifiers

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| Class         | Variable    | Label          | Description | Format Text |
|---------------|-------------|----------------|-------------|-------------|
| 01. Principal | <b>mrno</b> | Participant Id |             | Char        |

## Section 2: Study-wide

| Class         | Variable             | Label             | Description | Format Text   |
|---------------|----------------------|-------------------|-------------|---|
| 01. Principal | <b>accession</b>     | Accession         |             | Numeric   |
| 01. Principal | <b>form</b>          | Form              |             | "Inclusion Criteria Pre v10A2"="Inclusion Criteria Pre v10A2"   |
| 01. Principal | <b>institution</b>   | Institution       |             | "Columbia University Medical Center"="Columbia University Medical Center"<br>"EUROPEAN INSTITUTE OF ONCOLOGY"="EUROPEAN INSTITUTE OF ONCOLOGY"<br>"Galliera Hospital"="Galliera Hospital"<br>"M. D. Anderson Cancer Center"="M. D. Anderson Cancer Center"<br>"Moffitt Cancer Center"="Moffitt Cancer Center" |
| 01. Principal | <b>interval</b>      | Interval          |             | "Baseline"="Baseline"<br>"Event Interval not available"="Event Interval not available"<br>"Month 1"="Month 1"   |
| 01. Principal | <b>interval_date</b> | Interval Date     |             | SAS Date  |
| 01. Principal | <b>reg_date</b>      | Registration Date |             | Char  |
| 01. Principal | <b>trial</b>         | Trial             |             | "MDA2014-04-01"="MDA2014-04-01"   |

## Section 3: Inclusion Criteria prev10a2

| Class         | Variable                              | Label                                | Description | Format Text   |
|---------------|---------------------------------------|--------------------------------------|-------------|---|
| 01. Principal | <b>_447_9596_y_n</b>                  | Criteria Eligibility Answer - Yes/No |             | "No"="No"<br>"Yes"="Yes"  |
| 01. Principal | <b>_447_9597_eligibility_question</b> | Criteria Eligibility Question        |             | Char  |
| 01. Principal | <b>_447_9598_no</b>                   | Criteria Number                      |             | "1"="Postmenopausal women (* postmenopausal: age >= 60 years, or amenorrhea >= 12 months, or bilateral oophorectomy, or - in women with hysterectomy only- FSH > 30 IU/L if < 60 years old) with histologically-confirmed ER positive (>= 10%) primary breast cancer stage T0-2, N0-1, Mx. Women with larger tumors who refuse chemo and/or endocrine neoadjuvant therapy can be eligible"<br>"2"="Age <= 75 (prev10a2 version only)"<br>"3"="ECOG performance status <=1 (Karnofsky >=70%; see protocol Appendix A)"<br>"4"="Participants must have normal organ and marrow function as defined below: Leukocytes >=3,000/microliter, Absolute neutrophil count >=1,500/microliter, Platelets >=100,000/microliter, Total bilirubin <= 2 x institutional ULN, AST (SGOT)/ALT (SGPT) <=1.5 x institutional ULN, Creatinine within normal institutional limits"<br>"5"="Ability to understand and the willingness to sign a written informed consent document" |
| 01. Principal | <b>_448_9944_visit_date</b>           | Visit Date                           |             | Char  |