

MDA2014-04-01 - Inclusion Criteria 10a2_8_9_2017 Data Dictionary

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Document Summary

Property	Value
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MDA2014-04-01 - Inclusion Criteria 10a2_8_9_2017: Data Dictionary

Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	mrno	Participant Id		Char

Section 2: Study-wide

Class	Variable	Label	Description	Format Text
01. Principal	accession	Accession		Numeric
01. Principal	form	Form		"Inclusion Criteria v10A2 8/9/2017"="Inclusion Criteria v10A2 8/9/2017"
01. Principal	institution	Institution		"Columbia University Medical Center"="Columbia University Medical Center" "EUROPEAN INSTITUTE OF ONCOLOGY"="EUROPEAN INSTITUTE OF ONCOLOGY" "Galliera Hospital"="Galliera Hospital" "M. D. Anderson Cancer Center"="M. D. Anderson Cancer Center" "Moffitt Cancer Center"="Moffitt Cancer Center"
01. Principal	interval	Interval		"Baseline"="Baseline" "Event Interval not available"="Event Interval not available"
01. Principal	interval_date	Interval Date		SAS Date
01. Principal	reg_date	Registration Date		Char
01. Principal	trial	Trial		"MDA2014-04-01"="MDA2014-04-01"

Section 3: Inclusion Criteria 10a2_8_9_2017

Class	Variable	Label	Description	Format Text
01. Principal	_447_9596_y_n	Criteria Eligibility Answer - Yes/No		"No"="No" "Yes"="Yes"
01. Principal	_447_9597_eligibility_question	Criteria Eligibility Question		Char
01. Principal	_447_9598_no	Criteria Number		"1"="Postmenopausal women (* postmenopausal: age >= 60 years, or amenorrhea >= 12 months, or bilateral oophorectomy, or - in women with hysterectomy only- FSH in the menopausal levels as per local institutional guidelines 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" "2"="ECOG performance status <=1 (Karnofsky >=70%; see protocol Appendix A)" "3"="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 <=1.5 x institutional ULN" "4"="Ability to understand and the willingness to sign a written informed consent document"
01. Principal	_448_9944_visit_date	Visit Date		Char