

MDA2014-04-01 - Exclusion Criteria prev10a2 Data Dictionary

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Document Summary

Property	Value
Document Title	MDA2014-04-01 - Exclusion Criteria prev10a2: Data Dictionary
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MDA2014-04-01 - Exclusion Criteria prev10a2: 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		"Exclusion Criteria Pre v10A2"="Exclusion Criteria Pre v10A2"
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" "Month 1"="Month 1"
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: Exclusion Criteria prev10a2

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"="BMI <18.5 Kg/m2" "10"="Use of any chemopreventive agents (SERM) in the last 3 months" "11"="Concomitant use of CYP3A4 inducer medication (rifampicin, phenytonin, carbamazepine, phenobarbital, and St. John's wort)" "2"="Previous treatment for breast cancer including chemotherapy and endocrine therapy" "3"="Women who are planned to receive neoadjuvant therapy" "4"="Receiving investigational agents" "5"="History of allergic reactions attributed to compounds of similar chemical or biologic composition to Exemestane" "6"="Uncontrolled intercurrent illness including, but not limited to, ongoing or active infection, symptomatic congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements" "7"="Other co-existing malignancies (with the exclusion of basal cell carcinoma or skin squamous cell carcinoma) diagnosed during the last 2 years before randomization " "8"="History of severe osteoporosis (T score <= -4 either spine or hip), or presence of vertebral fracture" "9"="Use of HRT in the last 30 days prior to the randomization"
01. Principal	_448_9944_visit_date	Visit Date		Char