

# MDA2014-04-01 - Exclusion Criteria 10a2\_8\_9\_2017 Data Dictionary

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## Document Summary

Property	Value
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# MDA2014-04-01 - Exclusion Criteria 10a2\_8\_9\_2017: 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		"Exclusion Criteria v10A2 8/9/2017"="Exclusion Criteria v10A2 8/9/2017"
01. Principal	<b>institution</b>	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	<b>interval</b>	Interval		"Baseline"="Baseline" "Event Interval not available"="Event Interval not available"
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: Exclusion Criteria 10a2\_8\_9\_2017

Class	Variable	Label	Description	Format Text
01. Principal	<u>_447_9596_y_n</u>	Criteria Eligibility Answer - Yes/No		"No"="No"
01. Principal	<u>_447_9597_eligibility_question</u>	Criteria Eligibility Question		Char
01. Principal	<u>_447_9598_no</u>	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 invasive 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 systemic Hormone Replacement Therapy (HRT) in the last 30 days prior to the randomization. The use of non-systemic estrogen (such as vaginal estrogen use) is allowed."
01. Principal	<u>_448_9944_visit_date</u>	Visit Date		Char