MDA2014-04-01 - Exclusion Criteria 11a3_2_10_2018 Data Dictionary

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MDA2014-04-01 - Exclusion Criteria 11a3_2_10_2018: 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 V11 A3 2/10/2018"="Exclusion Criteria V11 A3 2/10/2018"
01. Principal	**institution**	Institution		"Columbia University Medical Center"="Columbia University Medical Center" "M. D. Anderson Cancer Center"="M. D. Anderson Cancer Center" "Moffitt Cancer Center"="Moffitt Cancer Center"
01. Principal	**interval**	Interval		"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: Exclusion Criteria 11a3_2_10_2018

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 endocrine therapy, and radiotherapy. Women with prior DCIS who were treated with surgery only and whose treatment ended >2 years prior to enrollment are eligible for the trial." "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	**_448_9944_visit_date**	Visit Date		Char