

# MDA2014-04-01 - Inclusion Criteria 11a3\_2\_10\_2018 Data Dictionary

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## Document Summary

Property	Value
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# MDA2014-04-01 - Inclusion Criteria 11a3\_2\_10\_2018: 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

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Class	Variable	Label	Description	Format Text
01. Principal	<b>accession</b>	Accession		Numeric
01. Principal	<b>form</b>	Form		"Inclusion Criteria V11 A3 2/10/2018"="Inclusion Criteria V11 A3 2/10/2018"
01. Principal	<b>institution</b>	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	<b>interval</b>	Interval		"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: Inclusion Criteria 11a3\_2\_10\_2018

Class	Variable	Label	Description	Format Text
01. Principal	<b>_447_9596_y_n</b>	Criteria Eligibility Answer - Yes/No		"No"="No" "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 in the menopausal levels as per local institutional guidelines if < 60 years old) with histologically-confirmed ER-positive (>= 10%) primary breast cancer stage cT0-2, cN0-1, 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	<b>_448_9944_visit_date</b>	Visit Date		Char