

UWI2016-08-01 - Exclusion Criteria V3 Data Dictionary

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Document Summary

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UWI2016-08-01 - Exclusion Criteria V3: Data Dictionary

Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	Sequence_No_	Participant ID		Char

Section 2: Study-wide

Class	Variable	Label	Description	Format Text
01. Principal	DCP_Protocol_Number	DCP Protocol Number		"UWI2016-08-01"="UWI2016-08-01"
01. Principal	Registering_Institution	Registering Institution		"WI020"="WI020"

Section 3: Exclusion Criteria V3

Class	Variable	Label	Description	Format Text
01. Principal	_4_2_10_Evidence_or_high_suspect	Evidence Or High Suspicion Of Metastatic Disease At Enrollment		"No"="No" "Yes"="Yes"
01. Principal	_4_2_11_Women_with_severe_bone_d	Women With Severe Bone Density Issues/Osteoporosis		"No"="No" "Yes"="Yes"
01. Principal	_4_2_12_Unwilling_or_unable_to_u	Unwilling Or Unable To Undergo Research Biopsy During The Baseline (Pre-Surgical) Clinic Visit, Or Inadequate Research Biopsy Obtained During The Baseline (Pre-Surgical) Clinic Visit		"No"="No" "Yes"="Yes"
01. Principal	_4_2_1_Participants_who_had_cura	Participants Who Had Curatively Treated Invasive Malignancies For Which All Treatments Ended Within 1 Year Prior To The Study		"No"="No" "Yes"="Yes"
01. Principal	_4_2_2_Not_a_surgical_candidate	Not A Surgical Candidate Or Surgery Is Not Scheduled Within 43 Days From Starting The Study Drug.		"No"="No" "Yes"="Yes"
01. Principal	_4_2_3_Receiving_any_other_inves	Receiving Any Other Investigational Agents		"No"="No" "Yes"="Yes"
01. Principal	_4_2_4_Any_gastrointestinal_cond	Any Gastrointestinal Condition Causing Malabsorption Or Obstruction		"No"="No" "Yes"="Yes"
01. Principal	_4_2_5_Has_been_on_any_hormonal	Has Been On Any Hormonal Treatment For CAH/EIN Or Grade 1 Endometrial Carcinoma In Last 3 Months		"No"="No" "Yes"="Yes"
01. Principal	_4_2_6_Use_hormone_replacement_t	Use Hormone Replacement Therapy, Phytoestrogen Supplements, Progestin, Tamoxifen Or Aromatase Inhibitor Within The Prior 3 Months		"No"="No" "Yes"="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	_4_2_7_Concomitant_use_of_strong	Concomitant Use Of Strong CYP3A4 Inducers		"No"="No" "Yes"="Yes"
01. Principal	_4_2_8_Known_hypersensitivity_to	Known Hypersensitivity To Exemestane Or Its Excipients		"No"="No" "Yes"="Yes"
01. Principal	_4_2_9_Known_intercurrent_illnesses	Known Intercurrent Illness Or Psychiatric Illness/Social Situations That Will Limit Compliance With Study Requirements		"No"="No" "Yes"="Yes"