# UWI2016-08-01 - Exclusion Criteria V4 Data Dictionary

## TABLE OF CONTENTS

# Document Summary

| Property | Value |
|---|---|
| Document Title | UWI2016-08-01 - Exclusion Criteria V4: Data Dictionary |
| Date Created | 01/06/2025 |
| Sections | 3 |
| Entries | 15 |
| Document Filename | dictionary_excl_criteria_v4.rtf |

# UWI2016-08-01 - Exclusion Criteria V4: 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 | | "MN022"="MN022"<br>"WI020"="WI020" |

# Section 3: Exclusion Criteria V4

| Class | Variable | Label | Description | Format Text |
|-------|----------|-------|-------------|-------------|
| 01. Principal | _4_2_10_Evidenc e_or_high_suspi ci | Evidence Or High Suspicion Of Metastatic Disease At Enrollment | | "No"="No" "Yes"="Yes" |
| 01. Principal | _4_2_11_Women _with_severe_bo ne_d | Women With Severe Bone Density Issues/Osteoporosis | | "No"="No" "Yes"="Yes" |
| 01. Principal | _4_2_12_Unwillin g_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_Participa nts_who_had_cu ra | 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_su rgical_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_Receivin g_any_other_inv es | Receiving Any Other Investigational Agents | | "No"="No" "Yes"="Yes" |
| 01. Principal | _4_2_4_Any_gast rointestinal_cond | Any Gastrointestinal Condition Causing Malabsorption Or Obstruction | | "No"="No" "Yes"="Yes" |
| 01. Principal | _4_2_5_Has_bee n_on_any_hormo nal | 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_hor mone_replaceme nt_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_illnes s** | Known Intercurrent Illness Or Psychiatric Illness/Social Situations That Will Limit Compliance With Study Requirements | | "No"="No" "Yes"="Yes" |

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