

NWU2013-01-03 - AGENT COMPLIANCE

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Document Summary

Property	Value
Document Title	NWU2013-01-03 - Agent Compliance
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NWU2013-01-03 - Agent Compliance
01/17/2020
Dataset: agentcompliance

NWU2013-01-03 - Agent Compliance

Section 1: Identifiers

Variable	Label	Description	Format Text
Number_of_days_agent_reported_as	Number of days agent reported as taken per Monitor Review of Par	Number of days agent reported as taken per Monitor Review of Participant Diary	Num
Participant_Identifier	Participant Identifier	Participant Identifier	Char
Projected_Days_on_Treatment	Projected Days on Treatment	Calculated field from Clinical Data Tab 6 Enrl v2 and Tab 24 Off St v4: (_Date Agent Started_ - _Agent End Date_) + 1	Num

Section 2: Agent Compliance

Variable	Label	Description	Format Text
Actual_Gel_Used_g_	Actual Gel Used (g)	Calculated Field from Clinical Data Tab22 Ag R&C v2: (<u>Weight of gel canister 1, pre-study (in grams)</u> <u>Weight of returned gel canister 1 (in grams)</u>) + (<u>Weight of gel canister 2, pre-study (in grams)</u> <u>Weight of returned gel canister 2 (in grams)</u>)	Num .,."
Compliance_notes	Compliance notes	A text field documenting decisions and issues arising during the compliance analysis of the data.	Char
Gel_Compliance_Based_on_Diary	Gel Compliance Based on Diary	Calculated field from Analysis Data Tab Agent Compliance: "Number of days gel reported as applied per Monitor Review of Participant Diary" / "Projected Days on Treatment"	Num
Gel_Compliance_Based_on_Gel_Weig	Gel Compliance Based on Gel Weights	Calculated field from Analysis Data Tab Agent Compliance: "Projected Gel Used (g)" / "Actual Gel Used (g)"	Num .,."
Number_of_days_gel_reported_as_a	Number of days gel reported as applied per Monitor Review of Par	Number of days gel reported as applied per Monitor Review of Participant Diary	Num
Overall_Compliant_with_Gel_	Overall Compliant with Gel?	Indicator for overall gel compliance from Analysis Data Tab Agent Compliance: "Yes" if BOTH "Was Gel Compliance > 79%?" AND "Was Gel Taken for Six of the Last Seven Days Prior to Surgery?" marked "Yes". Note: Patients were randomized to the active gel arm and were overall compliant with gel will be included in the final analyses.	Char
Overall_Compliant_with_Pill_	Overall Compliant with Pill?	Indicator for overall pill compliance from Analysis Data Tab Agent Compliance. "Yes" if BOTH "Was Pill Compliance > 79%?" AND "Was Pill Taken for Six of the Last Seven Days Prior to Surgery?" marked "Yes". Note: Patients were randomized to the active pill arm and were overall compliant with pill will be included in the final analyses.	Char
Pill_Compliance_Based_on_Diary	Pill Compliance Based on Diary	Calculated field from Analysis Data Tab Agent Compliance: "Number of days agent reported as taken per Monitor Review of Participant Diary" / "Projected Days on Treatment"	Num

Variable	Label	Description	Format Text
Pill_Compliance_Based_on_Pill_Co	Pill Compliance Based on Pill Count	Calculated field from Analysis Data Tab Agent Compliance and Clinical Data Tab 22 Ag R&C v2: "Projected Days on Treatment" / "Amount of agent used during this period (# of capsules)"	Num
Projected_Gel_Used_g	Projected Gel Used (g)	Calculated field from Analysis Data Tab Agent Compliance: (0.857 grams per breast * 2 breasts) / "Projected Days on Treatment"	Num
Was_Gel_Compliance_79__	Was Gel Compliance > 79%?	Indicator for gel compliance from Analysis Data Tab Agent Compliance: "Yes" if "Gel Compliance Based on Gel Weights" > 0.79 AND "Gel Compliance Based on Diary" > 0.79. OR for Memorial Sloan Kettering patients with a deviation indicating they were instructed to apply gel to only one breast, and for patients who had only one breast at the start of the study, if "Gel Compliance Based on Gel Weights" > 0.39 AND "Gel Compliance Based on Diary" > 0.79 OR if specified in "Compliance Notes"	Char
Was_Gel_Taken_for_Six_of_the_Las	Was Gel Taken for Six of the Last Seven Days Prior to Surgery?	From Clinical Data Tab 22 Ag R7C v2: "Yes" if "Was study drug taken for 6/7 days in the last week of therapy?" is "Yes" OR If "Was study drug taken for 6/7 days in the last week of therapy?" is "No", monitor reviewed the participant diary to determine whether the participant missed gel, pill, or both for more than two days in the last week prior to surgery.	Char
Was_Pill_Compliance_79__	Was Pill Compliance > 79%?	Indicator for pill compliance from Analysis Data Tab Agent Compliance. "Yes: if BOTH "Pill Compliance Based on Pill Count" > 0.79 AND "Pill Compliance Based on Dairy" > 0.79 OR if specified in "Compliance Notes"	Char
Was_Pill_Taken_for_Six_of_the_La	Was Pill Taken for Six of the Last Seven Days Prior to Surgery?	From Clinical Data Tab 22 Ag R7C v2: "Yes" if "Was study drug taken for 6/7 days in the last week of therapy?" is "Yes" OR If "Was study drug taken for 6/7 days in the last week of therapy?" is "No", monitor reviewed the participant diary to determine whether the participant missed gel, pill, or both for more than two days in the last week prior to surgery.	Char