

STATISTICAL ANALYSIS PLAN: INDV-6000-405

Addendum

Protocol Title: A Single-Dose Study to Evaluate the Relative Bioavailability, Safety, and Tolerability of SUBLOCADE at Alternative Injection Locations in Adults

Final Version: 19 Mar 2024

NCT: NCT05704543

Statistical Analysis Plan Addendum

Protocol ID: INDV-6000-405

[REDACTED]

Date: 19MAR2024

Description:

After database lock, it was noted that the appendix of the SAP the following definition was used to derive medications prior to SUBLOCADE injection.

End Date of Non-Study Medication	Start Date of Non-Study Medication		
	Missing	< Start date of SUBOXONE	≥ Start date of SUBOXONE and ≤ end date of SUBOXONE
Missing (includes flagged as "Ongoing")	Prior Concomitant (Run-In)	Prior Concomitant (Run-In)	Concomitant (Run-In)
< Start date of SUBOXONE	Prior	Prior	Data Error
≥ Start date of SUBOXONE and ≤ end date of SUBOXONE	Prior Concomitant (Run-In)	Prior Concomitant (Run-In)	Concomitant (Run-In)

However, in the last row of this table, it implies that prior medications and Run-In concomitant medications do not include a medication started before injection and ended after last dose of SUBOXONE. The first column last row should not include the clause "and ≤ end date of SUBOXONE".

In addition, medications should be considered run-in concomitant as long as its start date is between start of SUBOXONE and SUBLOCADE injection date (if injection took place). Therefore, the last column should be split into two situations, with and without injection.

After modification, the definition should read the following:

End Date of Non-Study Medication	Start Date of Non-Study Medication			
	Missing	< Start date of SUBOXONE	≥ Start date of SUBOXONE if no injection	≥ Start date of SUBOXONE and ≤ SUBLOCADE injection date if there is SUBLOCADE injection
Missing (includes flagged as "Ongoing")	Prior Concomitant (Run-In)	Prior Concomitant (Run-In)	Concomitant (Run-In)	Concomitant (Run-In)
< Start date of SUBOXONE	Prior	Prior	Data Error	Data Error

≥ Start date of SUBOXONE	Prior Concomitant (Run-In)	Prior Concomitant (Run-In)	Concomitant (Run-In)	Concomitant (Run-In)
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Implications:

Run-In concomitant medications flag and consequently, Table 14.1.5.2 will be updated.