UNIVERSITY OF MIAMI

CLINICALTRIALS.GOV RESULT REPORTING CHECKLIST

This checklist provides an overview of the required elements for Result Reporting in clinicaltrials.gov.

Section	Information to have available	
Participant Flow	Relevant stages or periods of activity in the study	☐
	Number of participants per arm that started and completed each period in the study	☐
	Number of participants per study arm for each period that did not complete and reason(s) they did not complete	☐
Baseline Characteristics	All baseline characteristics and baseline assessment(s) used in the analysis of the Primary Outcome • *Age, Sex/Gender, Race and Ethnicity demographics are required to be reported. If applicable, include all other baseline characteristic data needed to facilitate the interpretation of any Outcome Measure Data.*	☐
	Number of participants per arm and in the entire study population from which data were collected and summarized	☐
	Method used to summarize baseline data • *For example: Count or Percentage of participants, Mean, Median, etc.*	☐
	Measure for the spread of the data (Applies for Additional Baseline Characteristics & Age, Continuous) • *For example: Standard Deviation, Inter-Quartile Range, etc.*	☐
	Unit of measure associated with the numerical data • *For example: participants, mg/dL, etc.*	☐
Outcome Measures	List all outcome measures assessed in the study • *Include all primary and secondary outcomes (required).*	☐
	Title for each outcome indicating specifically what was measured and will be reported in the data • *A precise and clear title that describes the data that will be reported.*	☐
	Description for each outcome explaining how the measure was taken, criteria used, any methods of assessment, and/or details about calculations that were performed to summarize the data • *All measures that uses a scale, grading or staging approach must provide criteria for any categories or provide the range and direction of possible scores needed to interpret the recorded values.*	☐
	Time point over which a participant was assessed for the measure, and for which the data are reported • *Time frame will be the longest duration over which a participant was observed. For a change value, the multiple times points wherein the data was analyzed will be noted.*	☐

	Number of participants in each arm from which data were collected and summarized	☐
	Detailed explanation for the participants in each arm not included in the data summary	☐
	Method used to summarize the outcome measure(s) data • *For example: Count of Participants, Percentage, Mean, Median, etc.*	☐
	Measure for the spread of the data • *For example: Standard Deviation, Confidence Interval, etc.*	☐
	Numerical data for each arm for every outcome(s)	☐
	Specific unit of measure associated with the numerical data • *For example: participants, mg/dL, etc.*	☐
Adverse Events	Specific Time period over which Adverse Events were assessed/collected	☐
	Definition of adverse events data collection or reporting method • *If different from ClinicalTrials.gov definition of an AE which include all AEs whether or not considered related to participation in the research study.*	☐
	Method of adverse events assessment • *Systematic or Non-Systematic Assessment.*	☐
	Number of participants for each arm that died due to any cause during study participation	☐
	Name of Serious Adverse Event (SAE) reported and its organ system	☐
	Number of participants affected for each arm for each SAE(s) reported	☐
	Frequency Threshold of Adverse Events (AE) reporting • *Frequency Threshold will be reported between 0-5%.*	☐
	Name of Adverse Event(s) reported and its organ system	☐
	Number of participants affected for each arm for each AE(s) reported	☐
Documents	Most recent IRB approved protocol • *Document(s) must have a cover page with the official title, NCT number and document date that's consistent with IRB approved version date in PDF/A (Archive) format.*	☐
	Statistical Analysis Plan (*if applicable*) • *If SAP is a separate document from the study protocol. The document(s) must have a cover page with the official title, NCT number and document date in PDF/A (Archive) format.*	☐