Outcome Measure Template Example 1

(Units=Participants; Measure Type=Count of Participants; Measure of Dispersion/Precision=Not Applicable) ClinicalTrials.gov

* Outcome Measure Type	(Select One) (Primary) Secondary Other Pre-specified Post-Hoc
* Outcome Measure Title	**Number of Participants With Myocardial Infarction, Stroke or Death From Cardiovascular Causes**
[*] Outcome Measure Description	Participants were monitored for up to 2 years. This is the number of participants who have had at least one myocardial infarction or stroke, or if they died from cardiovascular causes during the time of observation.
* Outcome Measure Time Frame	Up to 2 years

* Arm/Group Title		**Low-dose Aspirin Therapy**		**Beta Blocker Therapy**		
*§ Arm/Group Description ①		Participants with familial history of cardiovascular disease received 81 mg Aspirin once daily		Participants with familial history of cardiovascular disease received 100 mg Beta Blocker once daily		
* Overall Number of Participants Analyzed		**1,545**		**1,524**		
[*] Analysis Population Description		All participants who received at least one dose of treatment.				
* Measure Type	* Measure of Dispersion/Precision					
(Select One) (Count of Participants ②) Mean Median Least Squares Mean (LSM) Geometric Mean Geometric LSM Number Count of Units	(Select One) (Not Applicable ③) Standard Deviation Standard Error Inter-Quartile Range Full Range _____ % Confidence Interval Geometric Coefficient of Variation	**277**	② ③	**246**	② ③	② ③
* Unit of Measure	Participants					

* Required *§ Required if Primary Completion Date is on or after January 18, 2017 [*] Conditionally required

① Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.

② If Measure Type is Count of Participants, percentage of participants is automatically calculated from Overall Number of Participants Analyzed. The percentage can be hidden (display is optional).

③ Not Applicable should be used only if Measure Type is Number, Count of Participants, or Count of Units. No dispersion/precision value is needed if Measure of Dispersion is Not Applicable.

Outcome Measure Template Example 2

(NCT00444457 Adapted: Units=Percentage of Participants; Measure Type=Number; Measure of Precision=95% CI) ClinicalTrials.gov

* Outcome Measure Type	(Select One) (Primary) Secondary Other Pre-specified Post-Hoc
* Outcome Measure Title	**Percentage of Participants Achieving Predefined Antibody Level ≥0.1 International Units Per Milliliter (IU/mL) for Tetanus Toxoid**
[*] Outcome Measure Description	Percentage of participants achieving predefined antibody threshold ≥0.1 IU/ mL along with the corresponding 95% CI for concomitant antigen tetanus toxoid are presented. Exact 2-sided CI was based on the observed proportion of participants.
* Outcome Measure Time Frame	1 month after the infant series (7 months of age)

* Arm/Group Title	**41αFv1**	**34αFv1**	
*§ Arm/Group Description ①	Participants received 1 single 0.5 milliliter (mL) dose of 41α-Strain Fluvococcal 1 conjugate vaccine (41αFv1) at 2, 4, and 6 months of age (infant series) and 12 months of age (toddler dose)	Participants received 1 single 0.5 milliliter (mL) dose of 34α-Strain Fluvococcal 1 conjugate vaccine (34αFv1) at 2, 4, and 6 months of age (infant series) and 12 months of age (toddler dose)	
* Overall Number of Participants Analyzed	**184**	**196**	
[*] Analysis Population Description	Immunogenicity population: N=number of participants analyzed with a determinate post-third dose IgG antibody concentration to the given vaccine component.		

* Measure Type	* Measure of Dispersion/Precision					
(Select One)	(Select One)					
Count of Participants	Not Applicable					
Mean	Standard Deviation					
Median	Standard Error					
Least Squares Mean (LSM)	Inter-Quartile Range					
Geometric Mean	Full Range					
Geometric LSM	95 % Confidence Interval					
(Number)	Geometric Coefficient of Variation					
Count of Units		**98.4**	**95.3 to 99.7**	**98.5**	**95.6 to 99.7**		
* Unit of Measure	Percentage of Participants					

* Required *§ Required if Primary Completion Date is on or after January 18, 2017 [*] Conditionally required

① Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.

Outcome Measure Template Example 3

("Change" Outcome Measure with > 2 Arms; Measure Type=Mean; Measure of Dispersion=SD)

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* Outcome Measure Type	(Select One) (Primary) Secondary Other Pre-specified Post-Hoc
* Outcome Measure Title	**Change in Low-density Lipoprotein (LDL) Cholesterol**
[*] Outcome Measure Description	Change was calculated as the value at 3 months minus the value at baseline.
* Outcome Measure Time Frame	Baseline, 3 months

* Arm/Group Title	Statin Drug 5 mg		Statin Drug 80 mg		Omega-3 Supplement	
*§ Arm/Group Description ①	All participants received 5 mg Statin Drug once daily.		All participants received 80 mg Statin Drug once daily.		All participants received Omega-3 Supplement containing 900 mg EPA and 5 g DHA once daily.	
* Overall Number of Participants Analyzed	28		32		31	
[*] Analysis Population Description	All participants for whom LDL measurements were recorded at Baseline and 3 months.					
* Measure Type: (Select One) Count of Participants, (Mean), Median, Least Squares Mean (LSM), Geometric Mean, Geometric LSM, Number, Count of Units						
* Measure of Dispersion/Precision: (Select One) Not Applicable, (Standard Deviation), Standard Error, Inter-Quartile Range, Full Range, _____ % Confidence Interval, Geometric Coefficient of Variation						
	-55.4	5.2	-78.1	4.8	-32.3	10.6
* Unit of Measure	mg/dL					

* Required *§ Required if Primary Completion Date is on or after January 18, 2017 [*] Conditionally required

① Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.

Outcome Measure Template Example 4

(To illustrate appropriate use of data are NA (Not Available))

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* Outcome Measure Type	(Select One) (Primary) Secondary Other Pre-specified Post-Hoc
* Outcome Measure Title	**Median Time to Response of Target Lesions using RECIST Criteria**
[*] Outcome Measure Description	Median Time from 1st dose of treatment to Complete or Partial Response. Target lesions are scanned via MRI to determine dimensions. Response Evaluation Criteria In Solid Tumors (RECIST) Complete Response is defined to be a disappearance of all target lesion(s). RECIST Partial Response is defined to be at least a 30% decrease in the sum of the target lesion longest diameters (LDs).
* Outcome Measure Time Frame	Up to 24 months

* Arm/Group Title	**37.5 mg INX123**	**75.0 mg INX123**	
*§ Arm/Group Description ①	INX123 37.5 mg once daily on a continuous daily dosing schedule. Study medication continued as long as patient was obtaining clinical benefit, or until significant toxicity, or withdrawal of consent, for up to 24 months.	INX123 75.0 mg once daily on a continuous daily dosing schedule. Study medication continued as long as patient was obtaining clinical benefit, or until significant toxicity, or withdrawal of consent, for up to 24 months.	
* Overall Number of Participants Analyzed	**29**	**25**	
[*] Analysis Population Description	All participants with Baseline and at least one post-baseline target lesion measurement.		

* Measure Type	* Measure of Dispersion/Precision					
(Select One) Count of Participants Mean (Median) Least Squares Mean (LSM) Geometric Mean Geometric LSM Number Count of Units	**(Select One)** Not Applicable Standard Deviation Standard Error Inter-Quartile Range Full Range (95 % Confidence Interval) Geometric Coefficient of Variation					
		10	**4 to NA.** Not enough participants achieved response to calculate upper 95% CI	**15**	**9 to NA.** Not enough participants achieved response to calculate upper 95% CI		
* Unit of Measure	Months					

* Required *§ Required if Primary Completion Date is on or after January 18, 2017 [*] Conditionally required

① Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.