

# Outcome Measure Template Example 1

(Units=Participants; Measure Type=Number;  
Measure of Dispersion=NA)

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<b>Outcome Measure Type*</b>	(Circle One) <b>Primary</b> Secondary    Other Pre-specified    Post-Hoc	<b>Safety Issue?</b>	(Circle One) <b>Yes</b> No			
<b>Outcome Measure Title*</b>	<b>Number of Participants With Myocardial Infarction, Stroke or Death From Cardiovascular Causes</b> *					
<b>Outcome Measure Description</b>	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.					
<b>Outcome Measure Time Frame*</b>	Up to 2 years *					
<b>Arm/Group Title*</b>	<b>Low-dose Aspirin Therapy</b> *	<b>Beta Blocker Therapy</b> *	*			
<b>Arm/Group Description ①</b>	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				
<b>Number of Participants Analyzed*</b>	1545 *	1524 *	*			
<b>Analysis Population Description</b>	All participants who received at least one dose of treatment.					
<b>Unit of Measure *</b>	<b>Measure Type*</b>	<b>Dispersion/Precision Type *</b>	<b>Measure Type</b>	<b>Dispersion/ Precision Type</b>	<b>Measure Type</b>	<b>Dispersion/ Precision Type</b>
	(Circle One) <b>Number</b> Mean Median Least Squares Mean Geometric Mean Log Mean	(Circle One) ② <b>Not Applicable</b> Standard Deviation Inter-Quartile Range Full Range Standard Error 95% Confidence Interval 90% Confidence Interval Geometric Coefficient of Variation				
<b>Category Title ④</b>	[*] 277 *	③ *	246 *	③ *	*	③ *
<b>Category Title ④</b>	[*] [*]	③ [*]	[*]	③ [*]	[*]	③ [*]

\* Required by ClinicalTrials.gov

[\*] Conditionally required by ClinicalTrials.gov

- ① Arm/Group Description describes details about the interventions administered (e.g., dosage, dosage form, frequency of administration) or groups evaluated.
- ② "Not Applicable" Dispersion/Precision Type should be used only when Measure Type is "Number". "Standard Deviation", "Standard Error", "Inter-quartile Range", and "Full Range" should NOT be used when Measure Type is "Number". "Geometric Coefficient of Variation" should be used only when Measure Type is "Geometric Mean".
- ③ No Dispersion/Precision value is needed when Dispersion/Precision Type is "Not Applicable". Numeric Lower and Upper Limits should be entered when Dispersion Precision Type is any kind of "Range" or "Interval". A single number should be entered for all other Dispersion/Precision Types.
- ④ [Optional] Add as many Categories as needed. When more than one Category is entered, a Category Title and Outcome Measure Data are required for each row. Outcome Measure data is required in at least one row. Category Titles are only required if more than one row.

# Outcome Measure Template Example 2

(NCT00444457 Units=Percentage of Participants; Measure Type=Number; Measure of Dispersion=95% CI)

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<b>Outcome Measure Type*</b>	(Circle One) <b>Primary</b> Secondary    Other Pre-specified    Post-Hoc	<b>Safety Issue?</b> (Circle One)    Yes <b>No</b>
<b>Outcome Measure Title*</b>	Percentage of Participants Achieving Predefined Antibody Level $\geq 0.1$ International Units Per Milliliter (IU/mL) for Tetanus Toxoid*	
<b>Outcome Measure Description</b>	Percentage of participants achieving predefined antibody threshold $\geq 0.1$ 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.	
<b>Outcome Measure Time Frame*</b>	1 month after the infant series (7 months of age) <span style="float: right;">*</span>	

Arm/Group Title*	41 $\alpha$ Fv1 <span style="float: right;">*</span>	34 $\alpha$ Fv1 <span style="float: right;">*</span>	<span style="float: right;">*</span>			
<b>Arm/Group Description</b> ①	Participants received 1 single 0.5 milliliter (mL) dose of 41 $\alpha$ -Strain Fluvococcal 1 conjugate vaccine (41 $\alpha$ Fv1) 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 34 $\alpha$ -Strain Fluvococcal 1 conjugate vaccine (34 $\alpha$ Fv1) at 2, 4, and 6 months of age (infant series) and 12 months of age (toddler dose)				
<b>Number of Participants Analyzed*</b>	184 <span style="float: right;">*</span>	196 <span style="float: right;">*</span>	* <span style="float: right;">*</span>			
<b>Analysis Population Description</b>	Immunogenicity population: N=number of participants analyzed with a determinate post-third dose IgG antibody concentration to the given vaccine component.					
<b>Unit of Measure</b> *	Measure Type*	Dispersion/Precision Type *	Measure Type	Dispersion/Precision Type	Measure Type	Dispersion/Precision Type
	(Circle One) <b>Number</b> Mean Median Least Squares Mean Geometric Mean Log Mean	(Circle One) ② Not Applicable Standard Deviation Inter-Quartile Range Full Range Standard Error <b>95% Confidence Interval</b> 90% Confidence Interval Geometric Coefficient of Variation				
<b>Category Title</b> ④	[*] <b>98.4</b> <span style="float: right;">*</span>	<b>95.3 to 99.7</b> ③*	<b>98.5</b> <span style="float: right;">*</span>	<b>95.6 to 99.7</b> ③*	<span style="float: right;">*</span>	③*
<b>Category Title</b> ④	[*] <span style="float: right;">*</span>	③ [*]	[*]	③ [*]	[*]	③ [*]

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① Arm/Group Description describes details about the interventions administered (e.g., dosage, dosage form, frequency of administration) or groups evaluated.

② "Not Applicable" Dispersion/Precision Type should be used only when Measure Type is "Number". "Standard Deviation", "Standard Error", "Inter-quartile Range", and "Full Range" should NOT be used when Measure Type is "Number". "Geometric Coefficient of Variation" should be used only when Measure Type is "Geometric Mean".

③ No Dispersion/Precision value is needed when Dispersion/Precision Type is "Not Applicable". Numeric Lower and Upper Limits should be entered when Dispersion Precision Type is any kind of "Range" or "Interval". A single number should be entered for all other Dispersion/Precision Types.

④ [Optional] Add as many Categories as needed. When more than one Category is entered, a Category Title and Outcome Measure Data are required for each row. Outcome Measure data is required in at least one row. Category Titles are only required if more than one row.

### Outcome Measure Template Example 3

(Change Outcome Measure with more than 2 Arms, Including mean and standard deviation)

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<b>Outcome Measure Type*</b>	(Circle One) <b>Primary</b> Secondary    Other Pre-specified    Post-Hoc	<b>Safety Issue?</b>	(Circle One) Yes <b>No</b>
<b>Outcome Measure Title*</b>	Change in Low-density Lipoprotein (LDL) Cholesterol *		
<b>Outcome Measure Description</b>			
<b>Outcome Measure Time Frame*</b>	Baseline, 3 months *		

<b>Arm/Group Title*</b>	<b>Statin Drug 5 mg</b> *	<b>Statin Drug 80 mg</b> *	<b>Omega-3 Supplement</b> *			
<b>Arm/Group Description</b> 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.			
<b>Number of Participants Analyzed*</b>	28 *	32 *	31 *			
<b>Analysis Population Description</b>	All participants for whom LDL measurements were recorded at Baseline and 3 months.					
<b>Unit of Measure *</b>	<b>Measure Type*</b>	<b>Dispersion/Precision Type *</b>	<b>Measure Type</b>	<b>Dispersion/Precision Type</b>	<b>Measure Type</b>	<b>Dispersion/Precision Type</b>
	(Circle One) <b>Mean</b> Number Median Least Squares Mean Geometric Mean Log Mean	(Circle One) ② <b>Standard Deviation</b> Not Applicable Inter-Quartile Range Full Range Standard Error 95% Confidence Interval 90% Confidence Interval Geometric Coefficient of Variation				
<b>Category Title</b> ④	[*] -55.4 *	5.2 ③ *	-78.1 *	4.8 ③ *	-32.3 *	10.6 ③ *
<b>Category Title</b> ④	[*] [*]	③ [*]	[*]	③ [*]	[*]	③ [*]

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① Arm/Group Description describes details about the interventions administered (e.g., dosage, dosage form, frequency of administration) or groups evaluated.

② "Not Applicable" Dispersion/Precision Type should be used only when Measure Type is "Number". "Standard Deviation", "Standard Error", "Inter-quartile Range", and "Full Range" should NOT be used when Measure Type is "Number". "Geometric Coefficient of Variation" should be used only when Measure Type is "Geometric Mean".

③ No Dispersion/Precision value is needed when Dispersion/Precision Type is "Not Applicable". Numeric Lower and Upper Limits should be entered when Dispersion Precision Type is any kind of "Range" or "Interval". A single number should be entered for all other Dispersion/Precision Types.

④ [Optional] Add as many Categories as needed. When more than one Category is entered, a Category Title and Outcome Measure Data are required for each row. Outcome Measure data is required in at least one row. Category Titles are only required if more than one row.

**Outcome Measure Template Example 4** (to illustrate appropriate use of NA feature)

<b>Outcome Measure Type*</b>	(Circle One) <b>Primary</b> Secondary Other Pre-specified Post-Hoc			<b>Safety Issue?</b>	(Circle One) Yes <b>No</b>	
<b>Outcome Measure Title*</b>	<b>Median Time to Response of Target Lesions using RECIST Criteria</b> *					
<b>Outcome Measure Description</b>	Median Time from 1 <sup>st</sup> 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).					
<b>Outcome Measure Time Frame*</b>	Up to 24 months *					
<b>Arm/Group Title*</b>	<b>37.5 mg INX123</b> *		<b>75.0 mg INX123</b> *		*	
<b>Arm/Group Description</b> 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.			
<b>Number of Participants Analyzed*</b>	<b>29</b> *		<b>25</b> *		*	
<b>Analysis Population Description</b>	All participants with Baseline and at least one post-baseline target lesion measurement.					
<b>Unit of Measure *</b>	Months *	<b>Measure Type*</b>	<b>Dispersion/Precision Type *</b>	<b>Measure Type</b>	<b>Dispersion/Precision Type</b>	<b>Measure Type</b>
		(Circle One) <b>Median</b> Number Mean Least Squares Mean Geometric Mean Log Mean	(Circle One) ② Not Applicable Standard Deviation Inter-Quartile Range Full Range Standard Error <b>95% Confidence Interval</b> 90% Confidence Interval Geometric Coefficient of Variation			
<b>Category Title</b> ④	[*]	<b>10</b> *	Not enough participants achieved response to calculate upper 95% CI ③ *	<b>15</b> *	Not enough participants achieved response to calculate upper 95% CI ③ *	[*]
<b>Category Title</b> ④	[*]	[*]	③ [*]	[*]	③ [*]	③ [*]

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 ① Arm/Group Description describes details about the interventions administered (e.g., dosage, dosage form, frequency of administration) or groups evaluated.  
 ② "Not Applicable" Dispersion/Precision Type should be used only when Measure Type is "Number". "Standard Deviation", "Standard Error", "Inter-quartile Range", and "Full Range" should NOT be used when Measure Type is "Number". "Geometric Coefficient of Variation" should be used only when Measure Type is "Geometric Mean".  
 ③ No Dispersion/Precision value is needed when Dispersion/Precision Type is "Not Applicable". Numeric Lower and Upper Limits should be entered when Dispersion Precision Type is any kind of "Range" or "Interval". A single number should be entered for all other Dispersion/Precision Types.  
 ④ [Optional] Add as many Categories as needed. When more than one Category is entered, a Category Title and Outcome Measure Data are required for each row. Outcome Measure data is required in at least one row. Category Titles are only required if more than one row.