Common Errors

ClinicalTrials.gov
"Basic Results" Database

Principles for Using the Basic Results Database

- Submitted data are used to develop basic tables for the public display
- Tables must be interpretable by people not familiar with each particular study
- Labels for rows, columns, and units of measure must be meaningful and precise

How to Avoid Common Errors

- The following slides illustrate common types of errors that we have identified thus far in submitted records
- We have anonymized the data to avoid identification of Responsible Party
- We have omitted actual drug/intervention names and instead use “Experimental Drug X” or similar titles. This would not be acceptable in an actual record.

Language and Formatting Tips

- Spell out term when first used, acronym in parentheses
- Use precise language
  - Do not use “proportion” unless providing a ratio
  - Do not use “rate” unless providing a quantity in relation to another unit (e.g., participants per unit time)
  - If simply reporting the number of participants, use “number” for Measure Type
- In general, spell out symbols such as
  - “Percentage” rather than “%”
  - “Number” rather than “No.” or “#”
- Use decimal points (not commas) for the “decimal separator” and commas (not periods) for the “thousands separator”

Types of Errors Covered

- Participant Flow
- Reporting Measures
  - Reporting Scales
  - Defining Categories
  - Reporting Time-to-Event Data
- Baseline Measures
- Outcome Measures
- Statistical Analyses
- Adverse Events

Participant Flow

Lack of Internal Consistency

Participant Flow

- Number STARTED should be consistent with “Enrollment, Actual” in protocol section
  - Correct “Enrollment, Actual” (or explain inconsistencies in Pre-Assignment Details)
- If more than one Period, number COMPLETED for each Period should equal number STARTED for next Period (or explain loss or addition of participants)
- If “Milestones” are defined, number for each “Milestone” must be
  - Less than or equal to number STARTED Period (or number that achieved previous Milestone)
  - Greater than or equal to number COMPLETED Period (or number that achieved subsequent Milestone)

BEFORE Revision (Public View)

Actual enrollment (229) displayed in the protocol section does not match total number started in the basic results section (220 + 211 = 431)

Summary Protocol Section:

Actual Enrollment: 229
Study Start Date: June 2006
Study Completion Date: October 2007
Primary Completion Date: October 2007 (Final data collection date for primary outcome measure)

Basic Results Section:

Participant Flow: Initial Treatment

	Placebo	Drug X
STARTED	220	211
COMPLETED	218	210
NOT COMPLETED	2	1

BEFORE Revision (Public View)

Participant Flow: Overall Study

	Placebo	Drug X
STARTED	301	299
Received First Dose	300	280
COMPLETED	298	295
NOT COMPLETED	3	4

Number of participants in a milestone ("Received First Dose") within a period cannot be less than the number COMPLETED (or greater than the number STARTED)

BEFORE Revision (Public View)

Participant Flow: First Period

	Placebo	Drug X
STARTED	301	299
COMPLETED	291	285
NOT COMPLETED	10	14

Participant Flow: Second Period

	Placebo	Drug X
STARTED	298	290
COMPLETED	288	278
NOT COMPLETED	10	12

Number of participants STARTED in second period of Participant Flow needs to be the same as number COMPLETED in the first period

EXAMPLE: Dose Escalation – Different Participants Receive Each Dose (Public View)

Arms/Groups represent 3 dose levels

Number of participants in each dose-level cohort

Participant Flow: Overall Study

	Drug X (5 mg)	Drug X (50 mg)	Drug X (100 mg)	Placebo
STARTED	4	4[1]	4[2]	6[3]
COMPLETED	4	4	4	6
NOT COMPLETED	0	0	0	0

[1] Dose level given only after lower dose was successfully administered

[2] Dose level given only after lower dose was successfully administered

[3] 2 participants were paired with each dose level of Drug X

EXAMPLE: Dose Escalation– Same Participants Receive Each Dose (Public View)

Participant Flow: Overall Study

	Drug X	Placebo
STARTED	4	2
Low Dose (5 mg)	4	2
Medium Dose (50 mg)	4	2
High Dose (100 mg)	4	2
COMPLETED	4	2
NOT COMPLETED	0	0

Total number of participants exposed to Drug X and placebo in the study

Milestones represent 3 dose levels

Reporting Measures

Reporting Scales
Defining Categories
Reporting Time-to-Event Data

Reporting Scales

How to Report a Scale: Helpful Hints

- Measure Title
  - Specific name of scale
    - Spell out acronym, add acronym in parentheses
- Measure Description
  - Construct/Domain if not clear from Measure Title
    - e.g., pain, quality of life
  - Range and direction of scores (e.g., 0 is best; 10 is worst)
  - Optional: Type of scale
    - e.g., continuous, ordinal
- Unit of Measure
  - Use “participants,” if applicable (i.e., for categorical data)
  - Use “units on a scale” or “scores on a scale,” if no other units (i.e., for continuous data)

BEFORE Revision (Public View)

Need information about this scale
- Full Name
- Construct/domain
- Range and directionality

Need information about these values (e.g., is “0” better or worse than “2”?)

Baseline Measures

	Investigational Drug X
GOG Performance Status [units: participants]	
0	48
1	27
2	4

Are these the only possible scores?

Correct: Values within each scale category represent number of “participants”

BEFORE Revision (Data Entry View)

Study-Specific Baseline Measure Title & Baseline Measure Description

BEFORE Revision

Baseline Measure Description information ***not*** provided.

Baseline Measure Title:*	Study Specific Characteristic
Study-Specific Baseline Measure Title:	If the Baseline Measure Title is "Study-Specific", please enter a brief descriptive name for the measure. GOG Peformance Status
Baseline Measure Description:	Additional information such as details about the collection method or participant population, if different from Overall Number of Baseline Participants. [No Text Entered]
Measure Type:*	Number
Measure of Dispersion:*	Please select "Not Applicable" if the Measure Type is "Number". Please do NOT select "Not Applicable" for other measure types. Not Applicable
Unit of Measure:*	Participants

OK Cancel Delete

AFTER Revision (Data Entry View)

Baseline Measure Description

Acronym (“GOG”) expanded

AFTER Revision

Baseline Measure Title:*	Study Specific Characteristic
Study-Specific Baseline Measure Title:	If the Baseline Measure Title is "Study-Specific", please enter a brief descriptive name for the measure. Gynecological Oncology Group (GOG) Performance Status
Baseline Measure Description:	Additional information such as details about the collection method or participant population, if different from Overall Number of Baseline Participants. 5-point, ordinal scale specifying patient's ability to perform activities from 0 (fully active) to 4 (completely disabled, no self-care).
Measure Type:*	Number
Measure of Dispersion:*	Please select "Not Applicable" if the Measure Type is "Number". Please do NOT select "Not Applicable" for other measure types. Not Applicable
Unit of Measure:*	Participants

OK Cancel Delete

Added text about the scale

- Range: “5-point, ordinal”
- Directionality: “0 (fully active) to 4 (completely disabled…)”
- Construct/Domain: “patient’s ability to perform activities”

BEFORE & AFTER Revision (Data Entry View)

Category Title

BEFORE Revision

Baseline Measure: Study Specific Characteristic[GOG Peformance Status]

Please enter category titles and click "OK". If more categories are needed, please click "Create Category" on the next screen.
Category Title is required ONLY when reporting categorical data (i.e., more than one category or row of data per measure).

Category Title*	0
Category Title*	1
Category Title*	2

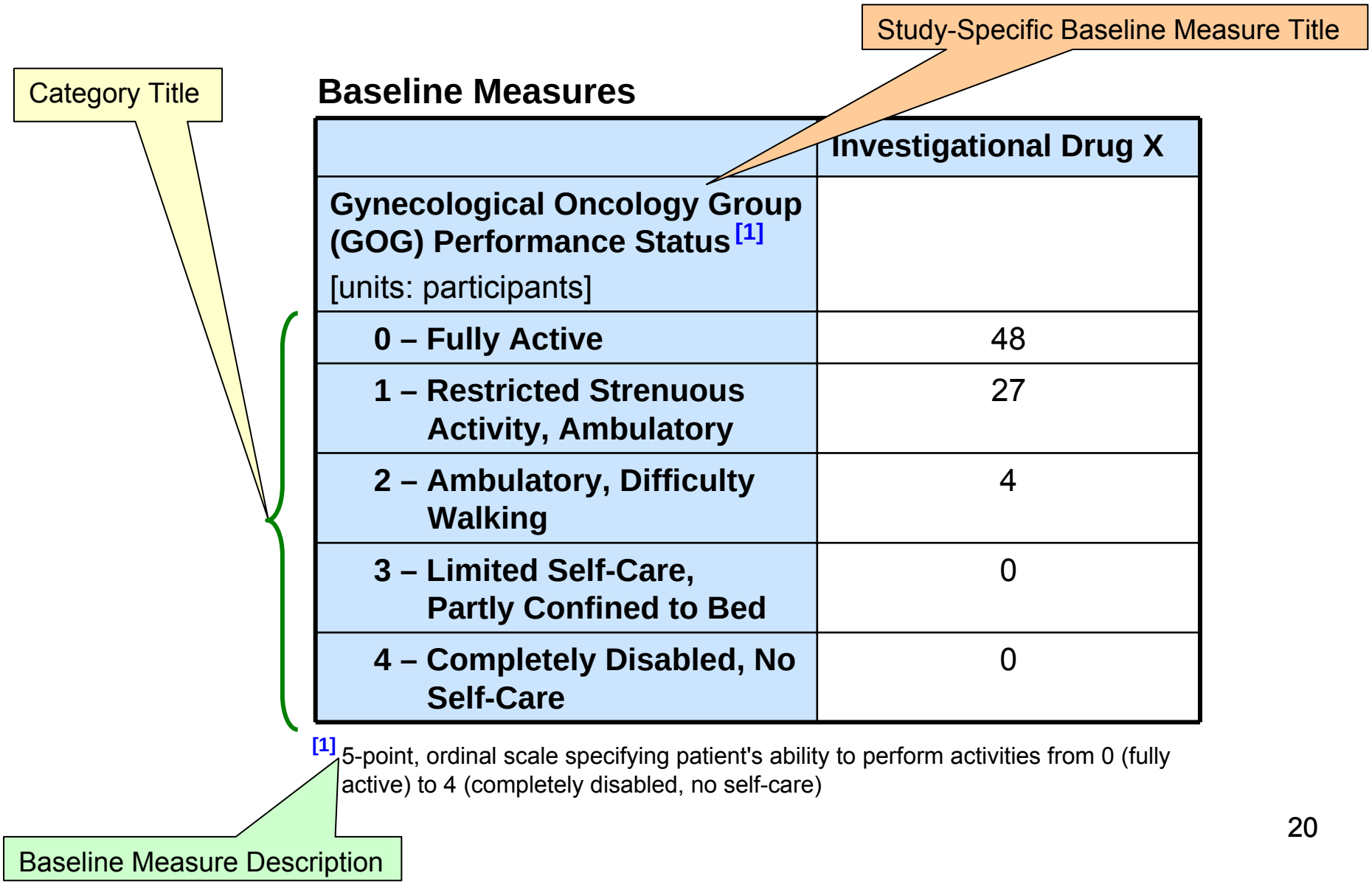
AFTER Revision

Category Title*	0 - Fully Active
Category Title*	1 - Restricted Strenuous Activity, Ambulator
Category Title*	2 - Ambulatory, Difficulty Walking
Category Title*	3 - Limited Self-Care, Partly Confined to Bec
Category Title*	4 - Completely Disabled, No Self-Care

Brief description added to indicate “directionality”

Added 2 categories to represent full range

AFTER Revision (Public View)



Defining Categories

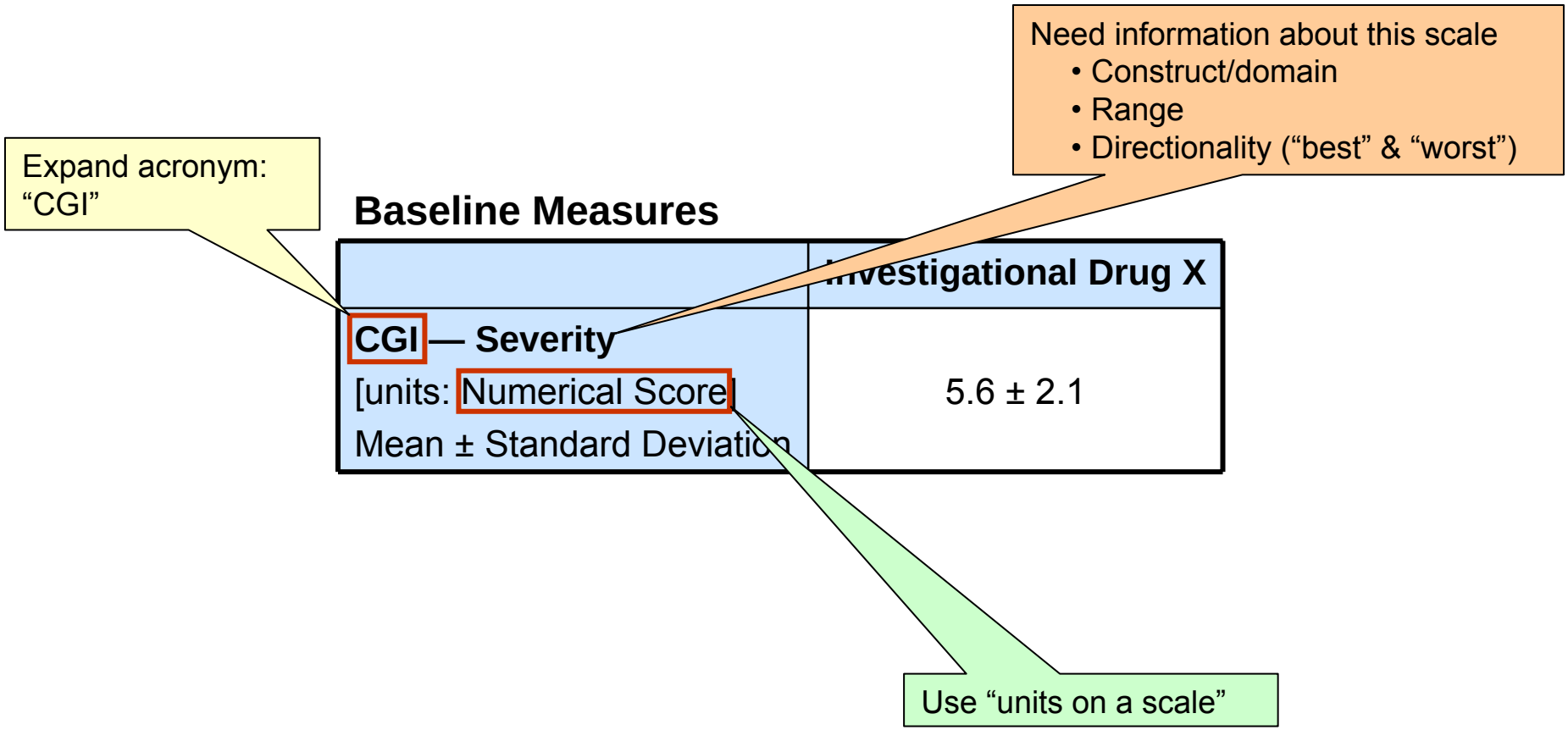
How to Define a Category: Helpful Hints

- Provide informative Category Titles
- Typical characteristics
  - Mutually exclusive (non-overlapping) categories
  - Comprehensive categories, covering the full range of possible results
- For categories based on continuous measures, provide thresholds when possible
  - Especially for 2 categories (i.e., dichotomous measures)

How to Define a Category: Helpful Hints (continued)

- If multichotomous or continuous data are converted to dichotomous, explain the algorithm
- Outcomes such as “improved” and “responders” are actually implied dichotomous categories that represent change over time
  - Best to report *both* possible outcomes (e.g., “improved” and “not improved”)
  - Explain the derivation of data in Measure Description
    - Provide time period of assessment
      e.g., baseline & 6 weeks
    - E.g., How was it determined who was “improved” and “not improved”?

BEFORE Revision (Public View)



BEFORE Revision (Public View)

Need to explain the scale:
- Range
- Directionality

Primary Outcome Measure: Nausea

Measure Type	Primary
Measure Name	Nausea
Measure Description	Nausea scale
Time Frame	8 Weeks
Safety Issue	No

"Improved" is not a measurable unit

Measured Values

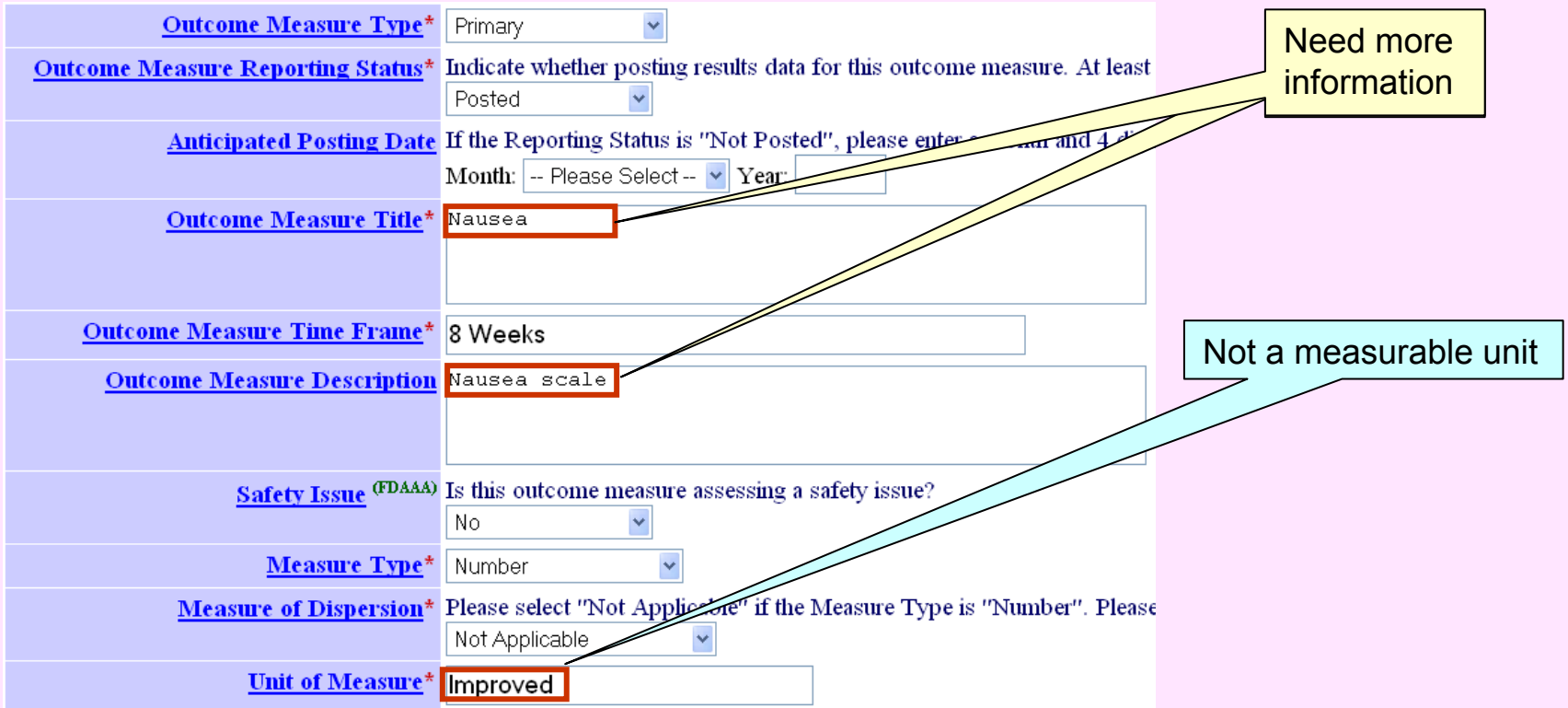
	Placebo	Investigational Drug X
Number of Participants	100	100
Nausea [units: Improved]	40	70

Report both possible outcomes as dichotomous categories: "improved" and "not improved"

BEFORE Revision (Data Entry View)

Unit of Measure

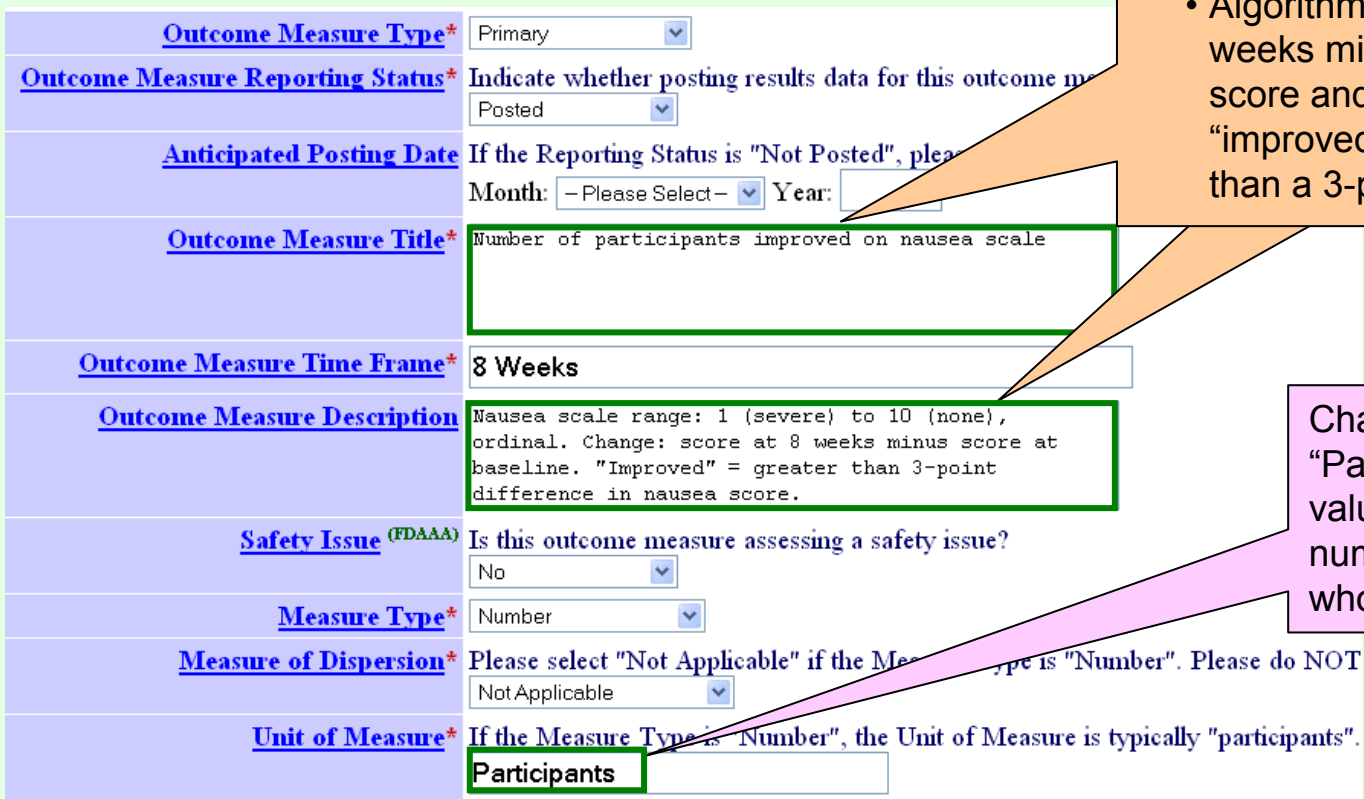
BEFORE Revision



AFTER Revision (Data Entry View)

Unit of Measure

AFTER Revision



Specified:

- Range (1-10)
- Directionality (1 = severe)
- Algorithm (score at 8 weeks minus baseline score and defined “improved” as greater than a 3-point difference)

Changed to “Participants” – values represent number of participants who “improved”

BEFORE & AFTER Revision (Data Entry View)

Outcome Data

BEFORE Revision

Posted — **Primary Outcome: Nausea** *; Units: Improved [8 Weeks]*

Nausea *	Placebo	Investigational Drug X
	Number	Number
Units: Improved	40	70

AFTER Revision

Posted — **Primary Outcome: Number of participants improv… …nausea scale** *; Units: Participants [8 Weeks]*

Number of participants improved on nausea scale *	Placebo	Investigational Drug X
	Number	Number
Improved *Units: Participants*	40	70
Not Improved *Units: Participants*	60	30

Added "Not Improved" category and data for number of participants

AFTER Revision (Public View)

Outcome Measure Name and Measure Description

Primary Outcome Measure: Nausea

Measure Type	Primary
Measure Name	Number of participants improved on nausea scale
Measure Description	Nausea scale range: 1 (severe) to 10 (none), ordinal. Change: score at 8 weeks minus score at baseline. "Improved" = greater than 3-point difference in score.
Time Frame	8 Weeks
Safety Issue	No

Measured Values

Unit of Measure

Category Title

Data

	Placebo	Investigational Drug X
Number of Participants	100	100
Number of participants improved on nausea scale [units: participants]		
Improved	40	70
Not Improved	60	30

BEFORE Revision (Public View)

Secondary Outcome Measure: Pain Assessment by Patient

Measure Type	Secondary
Measure Name	Pain Assessment by Patient
Measure Description	Mean change in pain assessment: Mean of last 5 assessments by patient while on study drug using a 5-point scale (0=no pain; 4 = worst pain).
Time Frame	15 weeks
Safety Issue	No

Incomplete description: How was "mean change" calculated? (e.g.,15 week mean minus baseline mean")

Measured Values

	Drug X, Low Dose	**Drug X, High Dose**
Number of Participants Analyzed	207	210
Pain Assessment by Patient [units: units on a scale] Mean ± Standard Error	-0.53 ± 0.07	-0.71 ± 0.08

AFTER Revision (Public View)

Secondary Outcome Measure: Pain Assessment by Patient

Measure Type	Secondary
Measure Name	Pain Assessment by Patient
Measure Description	Mean of last 5 assessments by patient while on study drug minus assessment at baseline, using the 5-point NIH Pain-P Scale (0=no pain; 4 = worst pain).
Time Frame	Baseline and 15 weeks
Safety Issue	No

Updated Measure Description

Updated Time Frame

Measured Values

	Drug X, Low Dose	Drug X, High Dose
Number of Participants Analyzed	207	210
Pain Assessment by Patient [units: units on a scale] Mean ± Standard Error	-0.53 ± 0.07	-0.71 ± 0.08
Baseline Pain Assessment [units: units on a scale] Mean ± Standard Error	3.75 ± 0.09	3.78 ± 0.09
Mean of Last 5 Pain Assessments [units: units on a scale] Mean ± Standard Error	3.22 ± 0.06	3.07 ± 0.07

Added Categories for context

Reporting Time-to-Event Data

How to Report Time-to-Event Data: Helpful Hints

- Data can be reported as continuous (e.g., median survival) or as categorical (e.g., 5-year survival)
- If data collection is incomplete, a possible approach:
  - At a minimum, report number who reached the “event”
  - Report time of last measurement (use the Outcome Measure Time Frame data element)
    - E.g., Median length of follow up with range
  - Report preferred descriptive statistic for those who achieved the “event” (e.g., median time to event)
    - Do not use a statistic that cannot be computed (e.g., if median cannot be computed, report a different percentile or choose another metric)

BEFORE Revision (Public View)

Secondary Outcome Measure: Progression-Free Survival

Measure Type	Secondary
Measure Name	Progression-Free Survival
Time Frame	Time of initial response to documented tumor progression
Safety Issue	No

Measured Values

	Investigational Drug X
Number of Participants	48
Progression-Free Survival [units: months] Median (Full Range)	3.0+ (1.0 to 33.1)

Invalid entry: “Median” needs to be numerical (cannot include “+”)

AFTER Revision (Public View)

Time Frame: Added time of assessment

Secondary Outcome Measure: Time to Tumor Progression

Measure Type	Secondary
Measure Name	Time to Tumor Progression
Time Frame	Time of initial tumor progression up to 36 months
Safety Issue	No

Analysis Population Description describes results at 36 months

Population Description

36 of the 48 total participants had documented tumor progression by the 36-month assessment.

Measured Values

Changed Units

Created categories for progression-free survival ranges by month

	Investigational Drug X
Number of Participants Analyzed	48
Time to Tumor Progression [units: participants]	
0 – 6 months	22
7 – 12 months	8
13 – 23 months	5
24 – 36 months	1
> 36 months	12

BEFORE Revision (Public View)

Needs description

Secondary Outcome Measure: Time to Relapse of a Mood Episode

Measure Type	Secondary
Measure Name	Time to Relapse of a Mood Episode
Measure Description	
Time Frame	24 months
Safety Issue	No

Invalid entry

Invalid entry

Measured Values

	Placebo	**Investigational Drug X**
Number of Participants Analyzed	148	153
Time to Relapse of a Mood Episode [units: days] Median (Inter-Quartile Range)	219 (83 to NA)	NA (173 to NA)

Baseline Measures

Invalid Data in Total Column

BEFORE Revision (Public View)

Invalid entry: e.g., provide values for the “mean” and “standard deviation” for all participants

Baseline Measures

	Drug X	Drug Y	Total
Heart Rate at Rest [units: beats per minute] Mean ± Standard Deviation	72.3 ± 2.7	71.9 ± 3.1	0 ± 0

Outcome Measures

Logic of Tables

Precision of Information

Logic of Outcome Measure Tables

- Define rows (measures or counts) and columns (arms or comparison groups) to be logically consistent
- Cells (data) represent measures or counts derived from participants within arms or groups
  - Measure Type (and Measure of Dispersion) needs to be consistent with data being reported
  - Unit of Measure must be consistent with values
  - Absolute values are preferable to percentages

BEFORE Revision (Public View)

Measured Values

	Drug X, Week 10	Drug X, Change from Week 10 to 18
Number of Participants Analyzed	88	80
Treatment Satisfaction Questionnaire After 18 Weeks of Treatment [units: scores on a scale] Mean ± Standard Deviation	81 ± 17.46	7.9 ± 12.16

Inconsistency between columns and rows: Measure at week 10 and Measure "after 18 weeks of treatment"

BEFORE Revision (Public View)

Not informative

Primary Outcome Measure: Pharmacokinetics

Measure Type	Primary
Measure Name	Pharmacokinetics
Measure Description	
Time Frame	6 Weeks
Safety Issue	No

Not clear how to interpret this Outcome Measure table
- Time Frame: 6 Weeks
- Units: Weeks
- Outcome Data: 6

Measured Values

	Investigational Drug X
Number of Participants Analyzed	1
Pharmacokinetics [units: weeks]	6

BEFORE Revision (Public View)

Measured Values

	Intervention X	Control
Number of Participants Analyzed	28	27
Hours Per Day of Sleep [units: average hours per day] Mean ± Standard Deviation	823 ± 92	864 ± 106

Inconsistency between Units of Measure, "average hours per day," and Measure Data: value provided is greater than the total number of hours in a day

BEFORE Revision (Public View)

Measured Values

	Drug X, 20 mg	Drug X, 40 mg
Number of Participants Analyzed [units: participants]	175	179
Number of Participants with ADHD [units: participants]	50	12
Percentage of Participants with ADHD [units: participants]	0.257	0.062

Inconsistent units – should be "Percentage"

Is this 0.257 percent or 25.7 percent?

BEFORE Revision (Public View)

Incorrect Outcome Measure Title: Units and Measure Data provide values for “number of relapses,” not “rate” (or a quantity in relation to another unit, e.g., “relapses per unit time”)

Measured Values

	Drug X, 20 mg	Drug X, 40 mg
Number of Participants Analyzed [units: participants]	175	179
Relapse Rate [units: number of relapses]	86	91

Alternatively, if Outcome Measure Title and Measure Data provide values for numbers of participants that “relapsed,” then the Units should be “participants”

Precision of Outcome Measure Information

- Outcome Measure Title, Description
  - Name and description of measure must be informative to people not familiar with study
  - If categorized, need description of categories
  - Use *neutral* words in Title (e.g., “treatment response” rather than “improvement” or “increased response”)
- Units should directly reflect data in the table
- Viewers of the table should be able to understand what the numbers represent

BEFORE Revision (Public View)

Secondary Outcome Measure: Potentially Clinically Significant Heart Rate

Measure Type	Secondary
Measure Name	New 24-Hour Holter Monitoring Alerts
Measure Description	New Holter monitoring alerts are defined as those alerts that occurred post-randomization and were not present at baseline
Time Frame	Visit 3 (Week 15)
Issue	Yes

Indicates measure is "number of alerts"

22 of what?
- Alerts -or-
- Participants

Indicates "number of participants"

Measured Values

	Drug X	Drug Y, Low Dose	Drug Y, High Dose
Number of Participants Analyzed	174	194	174
New 24-Hour Holter Monitoring Alerts [units: participants]	22	19	16

AFTER Revision (Public View)

Secondary Outcome Measure: Potentially Clinically Significant Heart Rate

Measure Type	Secondary
Measure Name	New 24-Hour Holter Monitoring Alerts
Measure Description	Number of participants with 1 or more alerts. New Holter monitoring alerts are defined as those alerts that occurred post-randomization and were not present at baseline
Time Frame	Visit 3 (Week 15)
Safety Issue	Yes

Outcome Measure Description updated with specific information

Unit of Measure

Indicates 22 "participants" had at least 1 alert

Measured Values

	Drug X	Drug Y, Low Dose	Drug Y, High Dose
Number of Participants Analyzed	174	194	174
New 24-Hour Holter Monitoring Alerts [units: participants]	22	19	16

BEFORE Revision (Public View)

Secondary Outcome Measure: Use of Community Health Resources

Measure Type	Secondary
Measure Name	Use of Community Health Resources
Measure Description	Evaluation of visits to primary care pediatrician, hospital emergency and re-hospitalization
Time Fr[illegible]e	Up to 3 months after discharge
S[illegible]y Issue	No

Implies number of health resources used – how was it measured?

- Data are inconsistent: percentages of what?
- Invalid entry: needs to be numerical (cannot include "%")

[illegible]red Values

	Early Discharge	Standard Discharge
Nu[illegible]ber of Participants Analyzed	90	86
Use [illegible]f Community Health Resources [units: Number]	4.4%	10.5%

AFTER Revision (Public View)

Secondary Outcome Measure: Use of Community Health Resources

Measure Type	Secondary
Measure Name	Use of Community Health Resources
Measure Description	Number of participants with 2 or more visits to primary care pediatrician, hospital emergency and re-hospitalization
Time Fra e	Up to 3 months after discharge
Sa y Issue	No

Outcome Measure Description updated

Indicates 4 participants (of 90 or 4.4%) in the "Early Discharge" group used the specified level of resources

M ured Values

	Early Discharge	Standard Discharge
Nu ber of Participants Analyzed	90	86
Use f Community Health Resources [units: participants]	4	9

BEFORE Revision (Public View)

Secondary Outcome Measure: Frequency and Magnitude of Antibody Response

Measure Type	Secondary
Measure Name	Frequency and Magnitude of Antibody Response
Measure Description	Nasal secretions to Virus A/12 and B/14. Antibody Response: Three-fold increase after immunization
Time Frame	Visit 3 (Week 15)
[illegible]sue	Yes

Same unit cannot represent measures of "frequency" *and* "magnitude"

May mean "three-fold or greater increase"

M[illegible]ured Values

	[illegible]accine, [illegible]w Dose	Vaccine, High Dose
Num[illegible]er of Participants Analyzed	[illegible]35	34
Freq[illegible]ency and Magnitude of Antibody Response [units: participants]	[illegible]7	21

"Participants" is not a unit of measure for "frequency" or "magnitude"

Best to provide both categories for a dichotomous measure:
- < 3x increase
- ≥ 3x increase

BEFORE Revision (Public View)

1. Name should be shorter than Description.
2. Inconsistent information in Name (e.g., "Severe Toxicity and Disease Progression") and Description ("Disease Progression" only).

Secondary Outcome Measure: Assess

Measure Type	Secondary
Measure Name	Assessment of Safety of 10 Dose Levels of Drug X Following 5 Cycles, Consisting of a 2-Week Exposure Period Followed by a 1-Week Rest Period, as Measured by Severe Toxicity and Disease Progression
Measure Description	Number of Participants with Disease Progression
Time Frame	Any time during 5 cycles and 30 days thereafter
Safety Issue	Yes

Clarify how "disease progression" is measured.

BEFORE Revision (Public View)

Primary Outcome Measure: Maximum Tolerated Dose (MTD)

Measure Type	Primary
Measure Name	Maximum Tolerated Dose (MTD)
Measure Description	MTD, as measured by unacceptable toxicity, is exceeded if >33% participants experienced Dose Limiting Toxicities (DLT)
Time Frame	15 Weeks
Safety Issu	Yes

Mismatch among Measure Name, Description, and Data

	Dose Level 1	Dose Level 2	Dose Level 3	Dose Level 4	Dose Level 5
mber of Participants Analyzed	9	4	9	9	9
ximum Tolerated Dose (MTD) [its: participants]					
Experienced DLT	1	0	3	2	5
Dose Level <MTD	0	4	0	9	0
Dose Level =MTD	9	0	0	0	0
Dose Level >MTD	0	0	9	0	9

Statistical Analyses

BEFORE Revision (Public View)

Measured Values

	Investigational Drug
Number of Participants Analyzed	96
Response to Drug X [units: participants]	
Complete Response	2
Partial Response	18
Stable Disease	34
Increasing Disease	
Unevaluable	6

Outcome Measure reported as categorical data (five categories of "response") but Statistical Analysis provided as dichotomous data ("Overall Response Rate = Number Responded / Total Participants")

Need information on how the 5 categories were "collapsed" into 2 (i.e., Which of 5 response categories were used in calculating the "Overall Response Rate"?).

Statistical Analysis 1 for Response to Drug X

Groups	Investigational Drug X
Overall Response Rate	0.21
95% Confidence Interval	0.12 to 0.33

BEFORE Revision (Public View)

Groups compared ("week 10" vs. "change from week 10 to 18") not a logical t-test

Measured Values

	Drug X, Week 10	Drug X, Change from Week 10 to 18
Number of Participants Analyzed	88	80
Treatment Satisfaction Questionnaire After 18 Weeks of Treatment [units: scores on a scale] Mean ± Standard Deviation	81 ± 17.46	7.9 ± 12.16

Statistical Analysis 1 for Treatment Satisfaction Questionnaire After 18 Weeks

Groups	Drug X, Week 10 vs. Drug X, Change from Week 10 to 18
Method	Paired t-test
P-Value	0.0018
na	4.684
95% Confidence Interval	2.080 to 7.730

Confidence Interval is not meaningful without an Estimation Parameter (e.g., mean difference, hazard ratio)

BEFORE Revision (Public View)

Measured Values

	Early Discharge	Standard Discharge
Number of Participants Analyzed	100	100
Parental Stress [units: points on a Likert scale] Mean ± Standard Deviation	9.3 ± 1.2	7.8 ± 2.1

Inconsistency between Measure Data and Method of Estimation
- Reported Mean Difference: "9"
- By Inspection: 9.3 – 7.8 = 1.5

Statistical Analysis [illegible] Parental Stress

Groups	Ea[illegible]ischarge vs. Standard Discharge
Method	ANOVA
P-Value	0.05
Mean Difference (Net)	9

BEFORE Revision (Public View)

Measured Values

	Drug X	Placebo
Number of Participants Analyzed	125	120
Visual Analogue Scale (VAS) Pain Assessment at 1.5 Hours [units: scores on a scale] Least Squares Mean ± Standard Error	0.57 ± 0.08	1.12 ± 0.10

Statistical Analysis 1 for Visual Analogue Scale (VAS) P

Groups [1]	Drug X vs. Placebo
Method [2]	Linear mixed model
P-Value [3]	<0.01

Reported Statistical Test not directly related to reported Outcome Measure

[1] Additional details about the analysis, such as null hypothesis and power calculation:

Effect onset is defined as half the time between initial assessment time indicating statistical significance and the previous assessment time.

[2] Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold of significance:

2-sided statistical tests at 0.05 significance level

Adverse Events

How to Report Adverse Events: Helpful Hints

- Report two different tables – Serious and Other
  - Do not report any serious adverse events in the Other Adverse Events table
  - Note that a single type of Adverse Event Term (e.g., “asthma”) may appear in both the Serious and Other tables
    - If possible indicate the level of severity to distinguish “serious” from “other” adverse events (e.g., “asthma – mild and moderate” in the Other table; “asthma – severe” in the Serious table)
- If no adverse events occurred, enter “0” for the Total Number Affected data elements
  - Do not enter 0 if you do not mean to imply that no adverse events occurred