ClinicalTrials.gov Results Reporting

DATE: January 7, 2016 PRESENTED BY: Lara Fournier and Laura Bradley

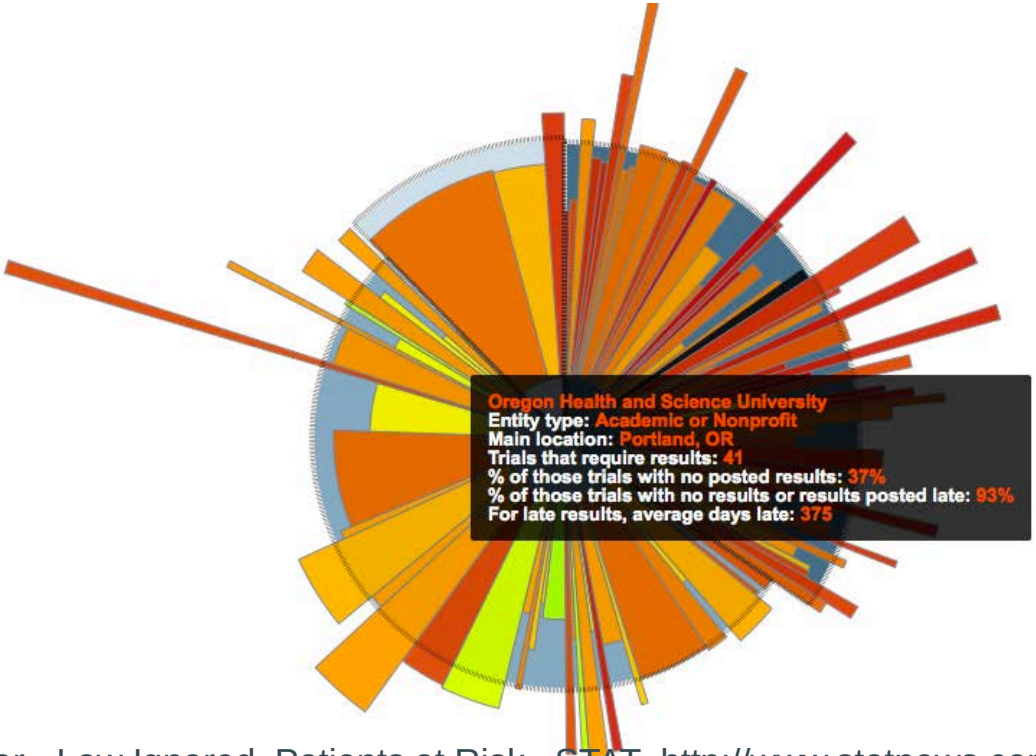
Outline

- Introduction
  - Why is this Needed?
  - Does my study require results?
  - Preparing for Results Entry
  - Broad Overview
- Modules
  - Participant Flow
  - Baseline Characteristics
  - Outcome Measures*
  - Adverse Events
- Getting Started with Results Entry
- ClinicalTrials.gov review process
- Overall Tips & FAQs
- Additional Resources

Why Is This Needed?

- Allows greater transparency in research
  - Provide a public record of basic study results in a standardized format
  - Promote the fulfillment of ethical obligations to participants and the overall contribution to medical knowledge
  - Reduces publication and outcome reporting biases
- It's the Law
  - Criminal and/or civil penalties assessed to responsible parties
  - $10,000 for first event, $10,000 per day its not corrected within 30 days
  - Notices of Non-compliance
  - Withholding of NIH grant funding

Why is This Needed? It's in the news..



2015 Piller - Law Ignored, Patients at Risk. STAT http://www.statnews.com/2015/12/13/clinical-trials-investigation/

Does My Study Require Results Entry?

- If study is an *Applicable Clinical Trial (ACT)*, and thus subject to FDAAA (FDA Amendments Act, Section 801), then IT DOES.
- ACTs are:
  - Controlled clinical investigations involving drugs or prospective studies of health outcomes involving drugs/devices that are subject to FDA regulation (includes IND/IDE)
  - Phase II, III, IV interventional initiated on/after 9/27/2007 or ongoing as of 12/26/2007.
  - Usually* excludes Phase I, Expanded Access studies, pediatric post-market device surveillance.
- *Rules are subject to change so keep checking back to these links:
  - http://grants.nih.gov/clinicaltrials_fdaaa/ACTs_under_FDAAA.htm
  - https://www.clinicaltrials.gov/ct2/manage-recs/fdaaa
- *If unsure if your study is ACT, please ask: register@ct.gov or Knight Cancer: ctrp-admin@ohsu.edu}}

Preparing for Results Reporting

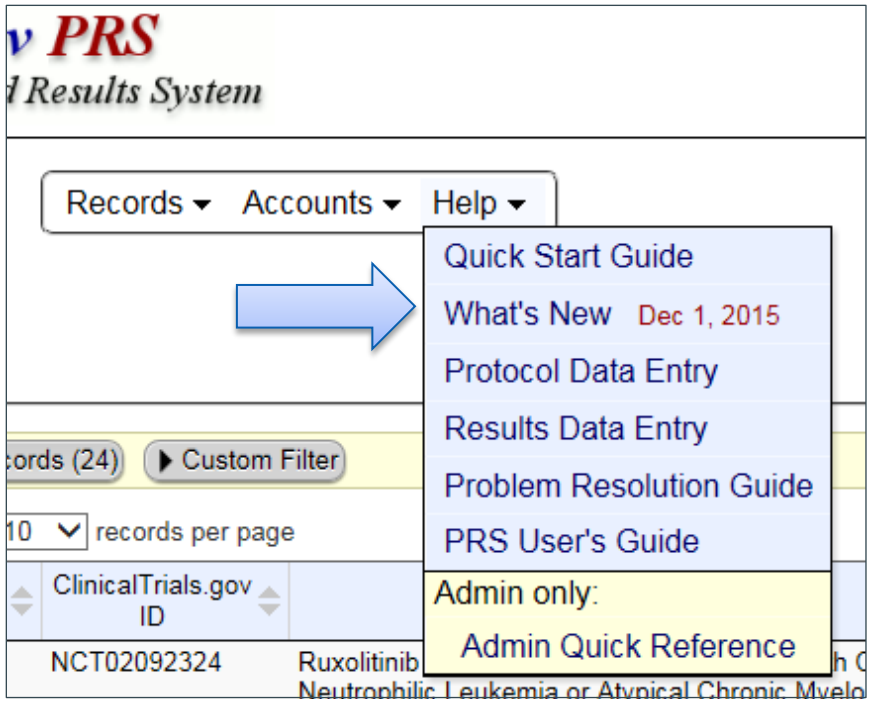
- **Who enters results?** You! But you can get help.
- **Involve your Biostatisticians** (ideally PI and Biostats should sign-off on final posting), or brush up on statistics.
- **Plan Early!** Ideally -start when you're writing your protocol, to make sure all key elements are reflected in the protocol as well as in your data collection instruments
- Be continuously thinking about your data & results throughout the conduct of your study and update your registration accordingly
- The more accurate, error-free, descriptive and clear your arms/outcomes are in the initial registration, the easier it will be for results reporting
- **Avoid Unpleasant Surprises**. Review the requirements for results entry well ahead of study completion.

Preparing For Results Reporting

- When to Report Results?
  - Within 12 months of **Primary Completion Date** (final data collection for primary outcome(s)).
  - If product is not approved by **Primary Completion Date** but approved later, then results due 30 days after approval.
  - Delays are possible under limited circumstances.
    - **Pending publication is NOT considered a good cause for delay**
  - Publishing? If you think you can publish within the timeframe, best to prepare both at the same time. Otherwise, post results first, then publish, then update the results in CT.gov so they align.
  - In general, FDAAA requires all primary and secondary outcomes be reported within 12 months of Primary Completion Date
    - In cases where secondary outcome data has not yet completed at that time, report the primary outcome data in the above timeframe, then report the secondary outcome data as soon as available or no later than 12 months after final, study completion date.

Preparing for Results Reporting

- **First Time?** – Check out these links:
  1. How to submit results: https://clinicaltrials.gov/ct2/manage-recs/how-report
  2. Basic Results Data Element Definitions: https://register.clinicaltrials.gov/prs/html/results_definitions.html
  3. PRS User Guide: Located on the Help menu dropdown, after login
  4. Results Data Entry section on Help Menu dropdown
  5. Webinars and additional training: https://clinicaltrials.gov/ct2/manage-recs/present#ResultsPresentation
- Continue to check for Changes: See **What's New** on the Help Menu dropdown.



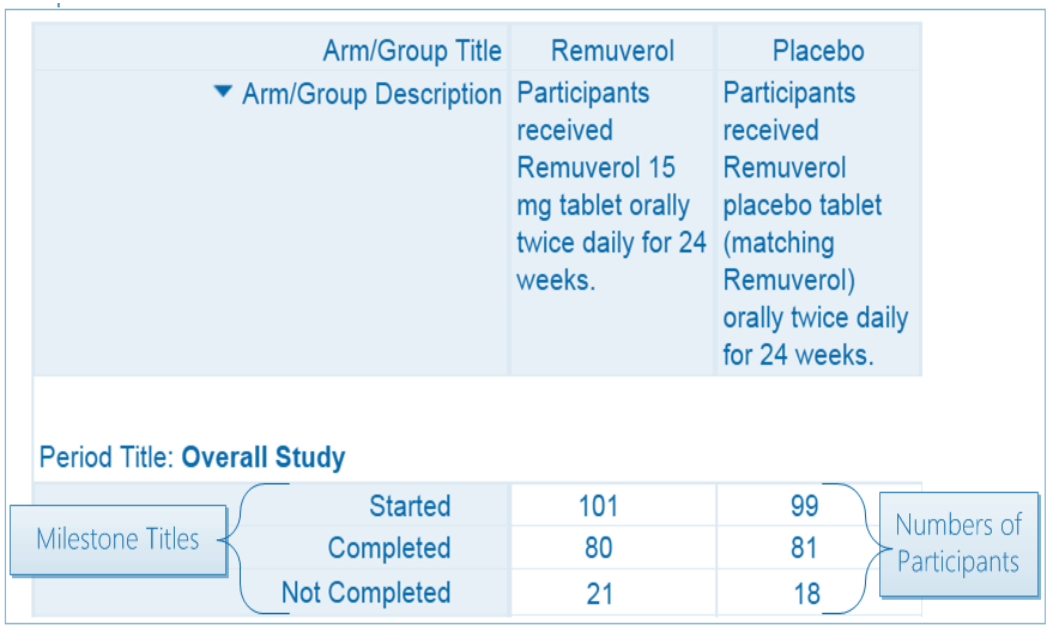
Preparing For Results Reporting

- How Are Results Reported in ClinicalTrials.gov?
- Tables are constructed by data providers (you)
  - Rows are measures
  - Columns are Arm / Groups
- 4 broad categories, each with different structure:
    - Participant Flow
    - Baseline Characteristics
    - Outcomes Measures and Statistical Analyses
    - Adverse Events

Module 1: Participant Flow

Definition:

A Table that shows how participants were assigned to intervention(s) and how they progressed through the study.



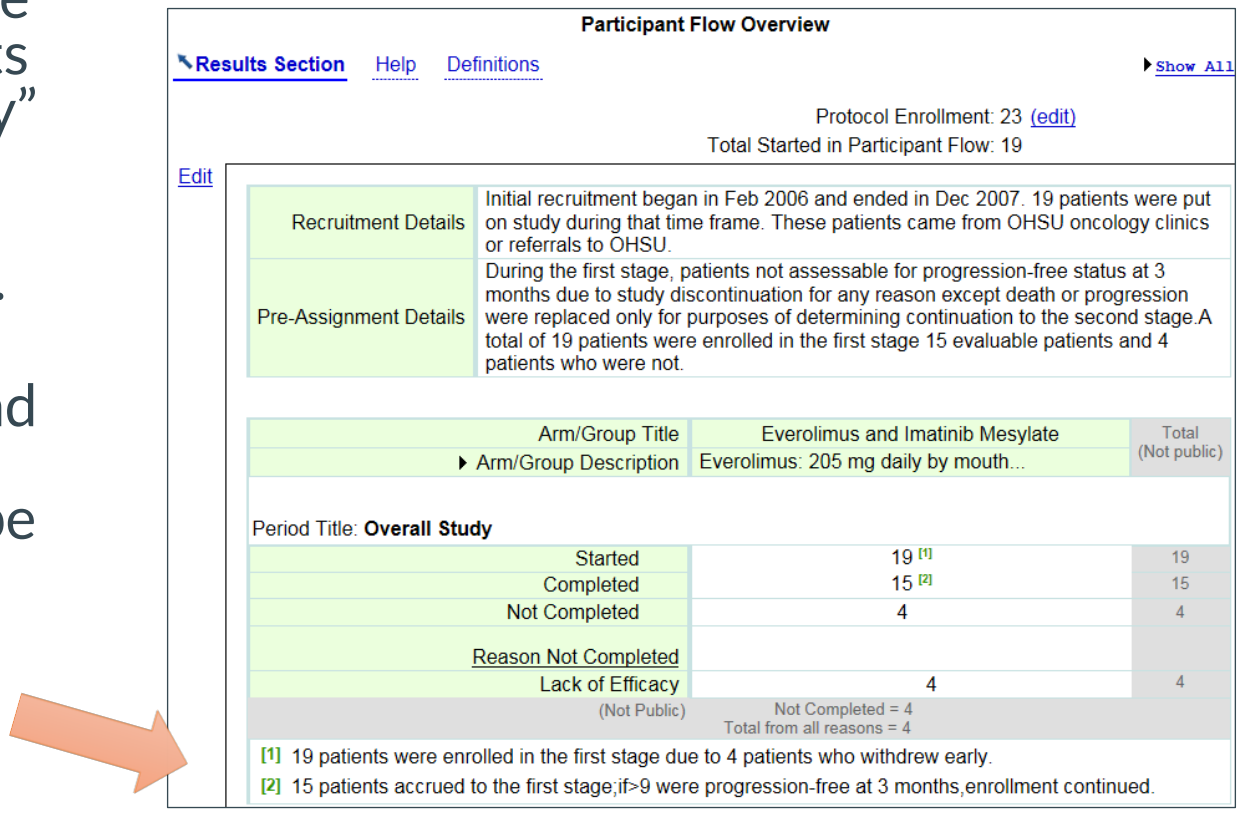
Arm/Group Title	Remuverol	Placebo
▼ Arm/Group Description	Participants received Remuverol 15 mg tablet orally twice daily for 24 weeks.	Participants received Remuverol placebo tablet (matching Remuverol) orally twice daily for 24 weeks.
Period Title: **Overall Study**		
Started	101	99
Completed	80	81
Not Completed	21	18

Module 1: Participant Flow

- Documents the “flow” of participants through different stages of the study
- Should account for all enrolled participants and which were analyzed (or not).
- Elements
  - Recruitment Details (key info related to recruitment process)
  - Pre-assignment Details (details relating to events following enrollment but prior to Arm/Group assignment)
  - Arm/Group (these should pre-populate from your registration)
  - Periods (e.g. “first intervention”, “washout”, “second intervention”), each would be a separate table.
  - Milestones (key events, e.g. “started at least one dose”)
- Overall number “started” should match “Enrollment, Actual” total
- Refer to template: http://prsinfo.clinicaltrials.gov/results_table_layout/DataEntryTable_PopFlowForm.pdf

Module 1: Participant Flow

- Example 1:
- Study with one period, reports "Overall Study" and one table may be all that's needed.
- If protocol enrollment and total started don't match, be sure to add notes



Participant Flow Overview

Results Section | Help | Definitions | Show All

Protocol Enrollment: 23 (edit)
Total Started in Participant Flow: 19

Edit

Recruitment Details	Initial recruitment began in Feb 2006 and ended in Dec 2007. 19 patients were put on study during that time frame. These patients came from OHSU oncology clinics or referrals to OHSU.
Pre-Assignment Details	During the first stage, patients not assessable for progression-free status at 3 months due to study discontinuation for any reason except death or progression were replaced only for purposes of determining continuation to the second stage.A total of 19 patients were enrolled in the first stage 15 evaluable patients and 4 patients who were not.

Arm/Group Title	Everolimus and Imatinib Mesylate	Total (Not public)
Arm/Group Description	Everolimus: 205 mg daily by mouth...	
Period Title: **Overall Study**		
Started	19 [1]	19
Completed	15 [2]	15
Not Completed	4	4
Reason Not Completed		
Lack of Efficacy	4	4
(Not Public)	Not Completed = 4 Total from all reasons = 4	

[1] 19 patients were enrolled in the first stage due to 4 patients who withdrew early.
[2] 15 patients accrued to the first stage;if>9 were progression-free at 3 months,enrollment continued.

Module 1: Participant Flow

- Example 2:
- Study that is reporting multiple periods

Recruitment Details	This clinical trial was conducted between 12/23/2008 to 3/27/2013 at Oregon Health and Science University's (OHSU) Center for Women's Health Breast Center in Portland, OR. English-speaking women were recruited to participate in the study based on the following inclusion criteria: ≥ 21 years, diagnostic mammogram with results that require biopsy.
Pre-Assignment Details	

Arm/Group Title	Sulforaphane Supplement	Placebo	Total (Not public)
▸ Arm/Group Description	Patients receive oral broccoli spro...	Patients receive oral placebo supp...	
Period Title: **Treatment Period**			
Started	27	27	54
Completed	24	19	43
Not Completed	3	8	11
Reason Not Completed			
Adverse Event	1	5	6
Withdrawal by Subject	2	3	5
(Not Public)	Not Completed = 3 Total from all reasons = 3	Not Completed = 8 Total from all reasons = 8	
Period Title: **Follow-up**			
Started	24	24 NOTE : The number of participants to start a Period is not equal to the number who completed previous Period.	48
Completed Final Visit	24	24	48
Completed	24	24	48
Not Completed	0	0	0

Module 2: Baseline Characteristics

Definition:

Baseline Characteristics is a table of demographic and baseline data, similar to *Table 1* in a journal article

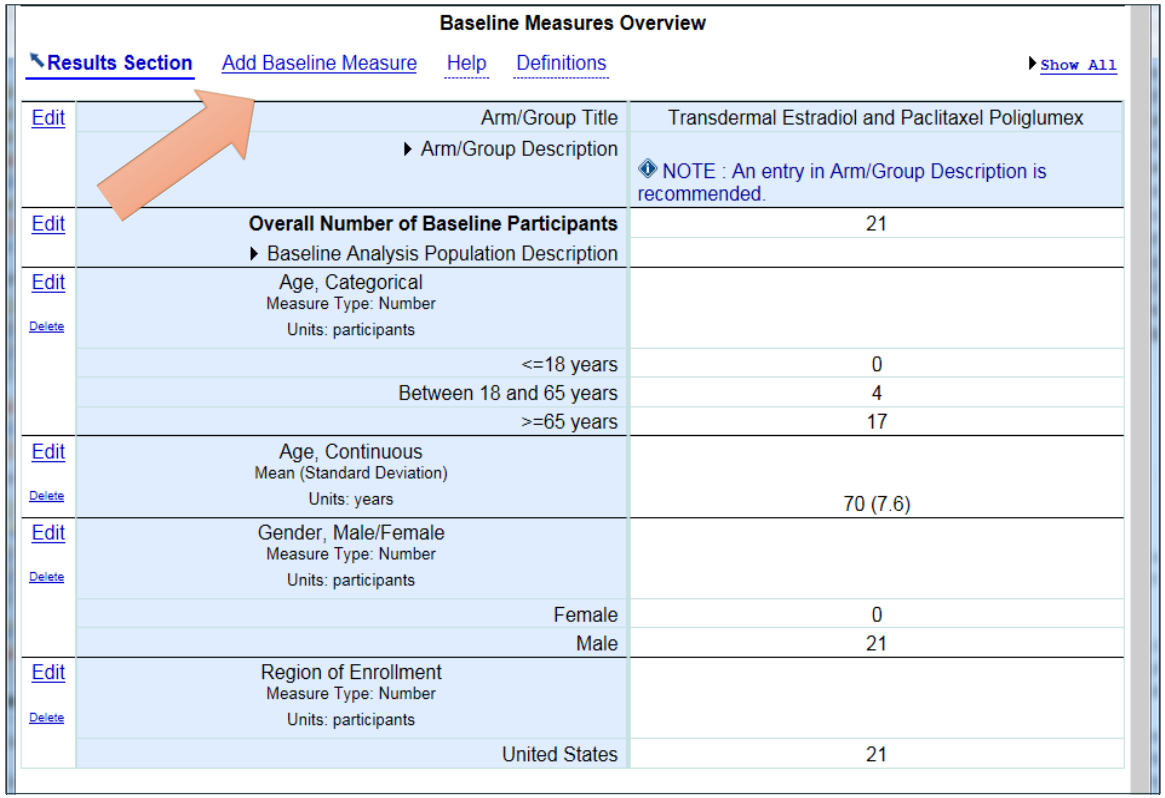
Arm/Group Title	Remuverol	Placebo	Total
▸ Arm/Group Description	Participants received Remuverol 15 ...	Participants received Remuverol pla...	
Overall Number of Baseline Participants	101	99	**200**
▸ Baseline Analysis Population Description			
Age Continuous units: years Mean (Standard Deviation)	34.78 (9.72)	35.34 (10.71)	34.98 (9.89)
Gender, Male/Female units: participants Measure Type: Number			
Female	60	63	123
Male	41	36	77

Module 2: Baseline Characteristics

- Elements:
  - Demographic and baseline data for each Arm or Group
  - Accommodates different data types
    - Continuous: measure of central tendency (e.g. mean) and measure of dispersion (e.g., standard deviation)
    - Categorical: for each category – 1) a count OR 2) measure of central tendency and measure of dispersion.
  - Default (Age, Race, Gender)
  - Study-Specific/User Defined (smoking, viral load, etc) – choose what's applicable to the study
- Refer to templates: http://prsinfo.clinicaltrials.gov/results_table_layout/DataEntryTable_BaselineRegionRaceEthnicityForm.pdf

Module 2: Baseline Characteristics

- Example:
- To add another measure, click Add Baseline Measure



Baseline Measures Overview

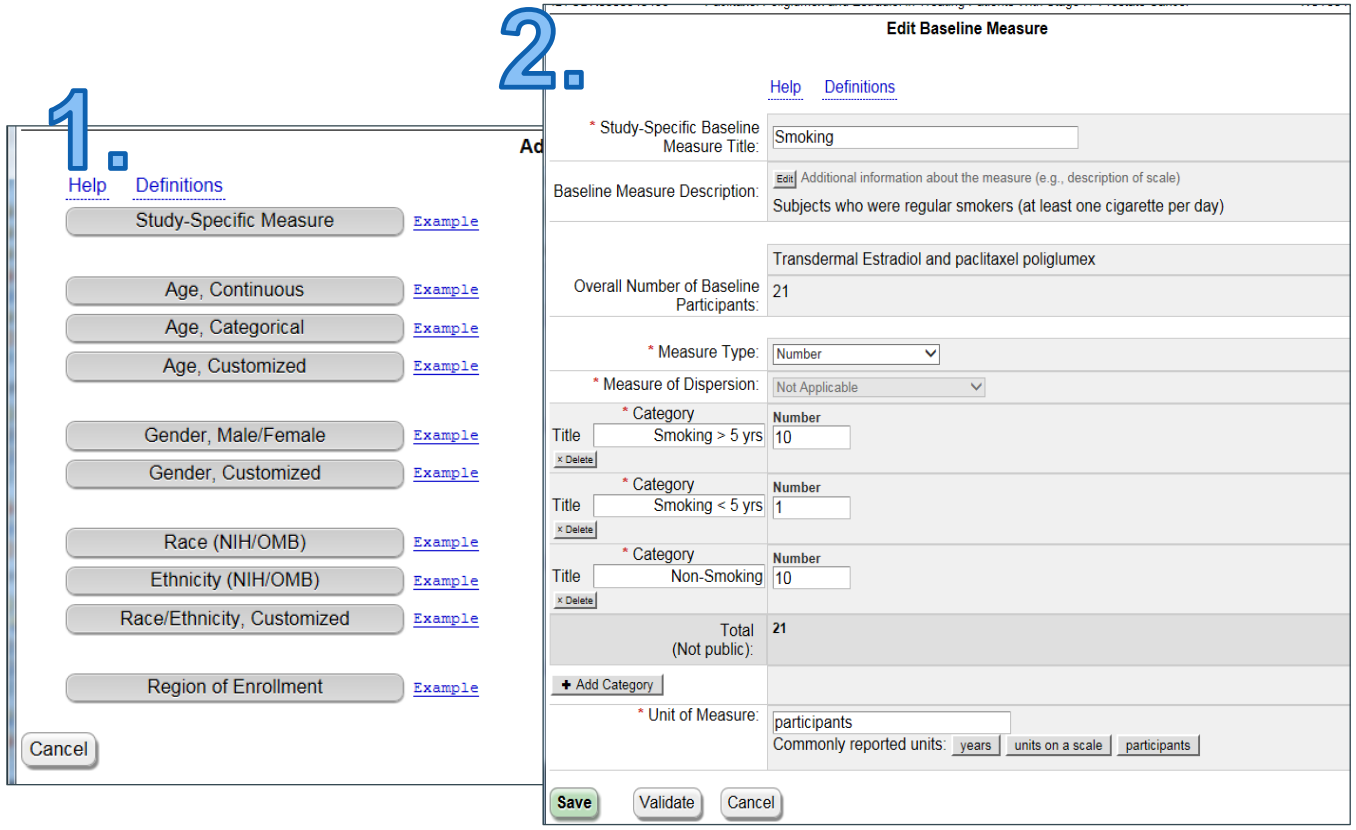
Results Section | Add Baseline Measure | Help | Definitions | Show All

Edit	Arm/Group Title	Transdermal Estradiol and Paclitaxel Poliglumex
	▸ Arm/Group Description	NOTE : An entry in Arm/Group Description is recommended.
Edit	**Overall Number of Baseline Participants**	21
	▸ Baseline Analysis Population Description	
Edit Delete	Age, Categorical Measure Type: Number Units: participants	
	<=18 years	0
	Between 18 and 65 years	4
	>=65 years	17
Edit Delete	Age, Continuous Mean (Standard Deviation) Units: years	70 (7.6)
Edit Delete	Gender, Male/Female Measure Type: Number Units: participants	
	Female	0
	Male	21
Edit Delete	Region of Enrollment Measure Type: Number Units: participants	
	United States	21

Module 2: Baseline Characteristics

Add Baseline Measure cont.

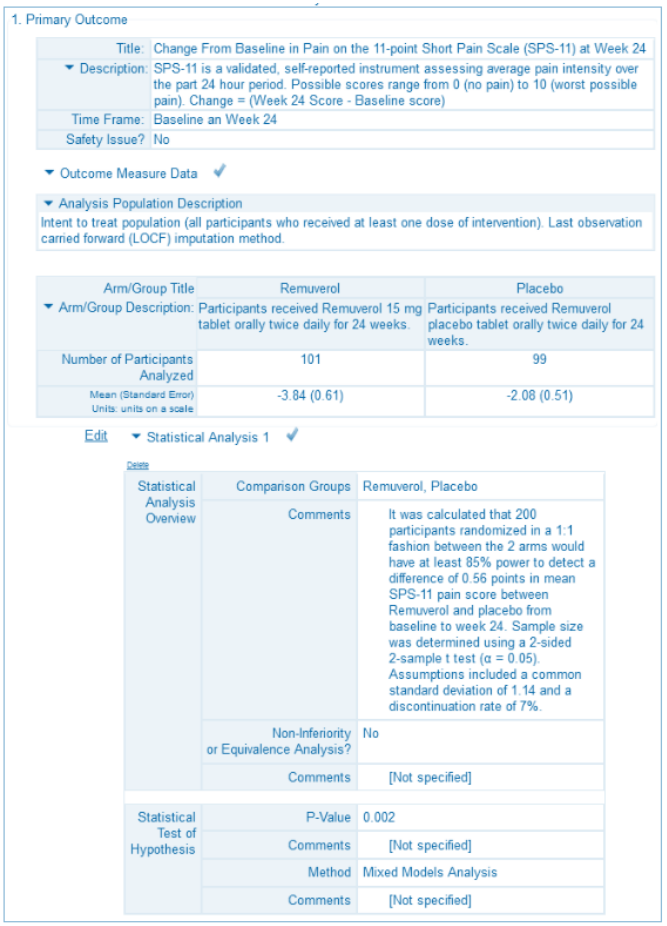
- 1. Select the type (see link examples)
- 2. Enter details and Save



Module 3: Outcome Measures & Statistical Analyses

Definition:

The Outcome Measures module summarizes outcome data using a structured tabular format and for applicable clinical trials includes all pre-specified primary and secondary outcomes. Displays the results and associated analyses.



1. Primary Outcome

Title:	Change From Baseline in Pain on the 11-point Short Pain Scale (SPS-11) at Week 24
Description:	SPS-11 is a validated, self-reported instrument assessing average pain intensity over the part 24 hour period. Possible scores range from 0 (no pain) to 10 (worst possible pain). Change = (Week 24 Score - Baseline score)
Time Frame:	Baseline an Week 24
Safety Issue?	No

Outcome Measure Data

Analysis Population Description

Intent to treat population (all participants who received at least one dose of intervention). Last observation carried forward (LOCF) imputation method.

Arm/Group Title	Remuverol	Placebo
Arm/Group Description:	Participants received Remuverol 15 mg tablet orally twice daily for 24 weeks.	Participants received Remuverol placebo tablet orally twice daily for 24 weeks.
Number of Participants Analyzed	101	99
Mean (Standard Error) Units: units on a scale	-3.84 (0.61)	-2.08 (0.51)

Edit Statistical Analysis 1

Delete

Statistical Analysis Overview	Comparison Groups	Remuverol, Placebo
	Comments	It was calculated that 200 participants randomized in a 1:1 fashion between the 2 arms would have at least 85% power to detect a difference of 0.56 points in mean SPS-11 pain score between Remuverol and placebo from baseline to week 24. Sample size was determined using a 2-sided 2-sample t test (α = 0.05). Assumptions included a common standard deviation of 1.14 and a discontinuation rate of 7%.
	Non-Inferiority or Equivalence Analysis?	No
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.002
	Comments	[Not specified]
	Method	Mixed Models Analysis
	Comments	[Not specified]

Module 3: Outcome Measures & Statistical Analyses

- Elements
  - Measure Type (Primary, Secondary, Other)
  - Tables with Arms/Groups & Number of participants analyzed
  - Descriptive Information
    - Title*
    - Description*
    - Unit of Measure*
    - Outcome Measure Time Frame*
    - Reporting Status
    - Safety Issue*
    - Measure Type
    - Measure of Dispersion/Precision (e.g. Standard Deviation)
  - Data

  **Some data will auto-populate from your registration (titles, descriptions, timeframes, etc).*
- Refer to template: http://prsinfo.clinicaltrials.gov/results_table_layout/DataEntryTable_OMForm.pdf

Module 3: Outcome Measures & Statistical Analyses

Primary Outcome Measure:

Outcome 1

* Title: Dysphagia Questionnaire

* Time Frame: At the end of the study

Description:

(‡) Safety Issue? No

× Delete Outcome

Primary Outcome Measure:

Outcome 1

* Title: Number of Patients with Complete Response to Dysphagia

* Time Frame: Baseline to 6 weeks

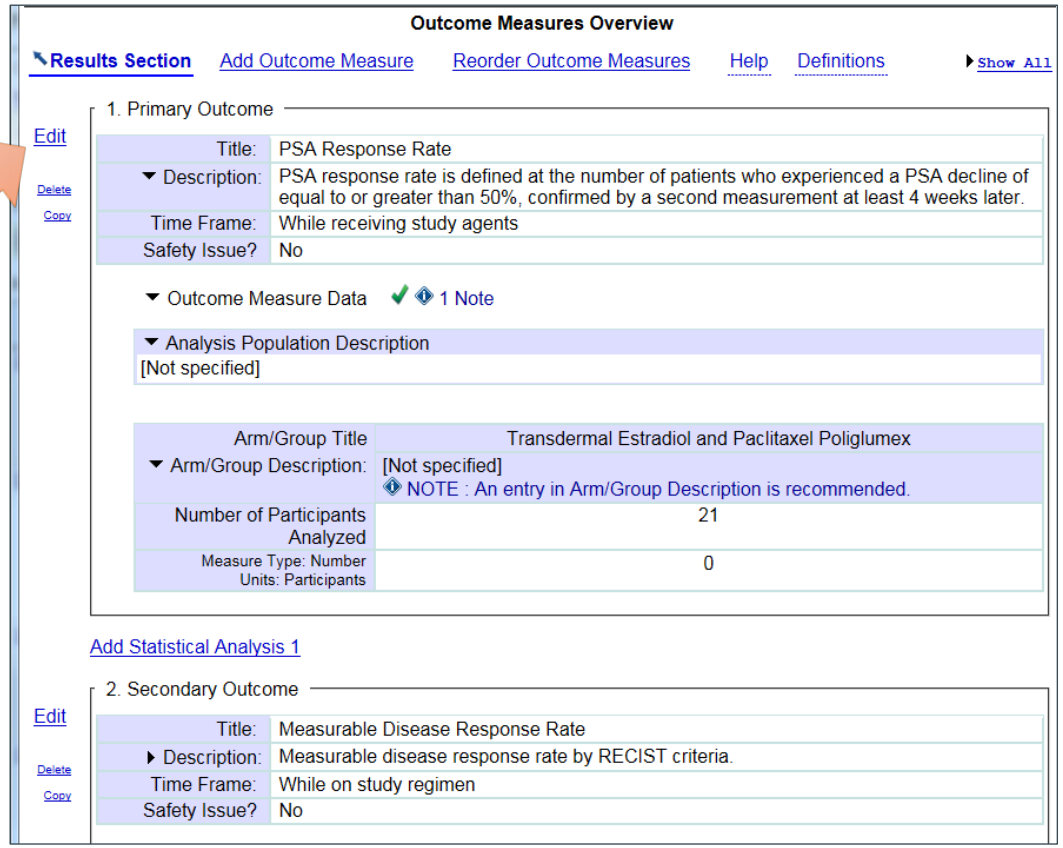
Description:

(‡) Safety Issue? No

× Delete Outcome

Module 3: Outcome Measures & Statistical Analyses

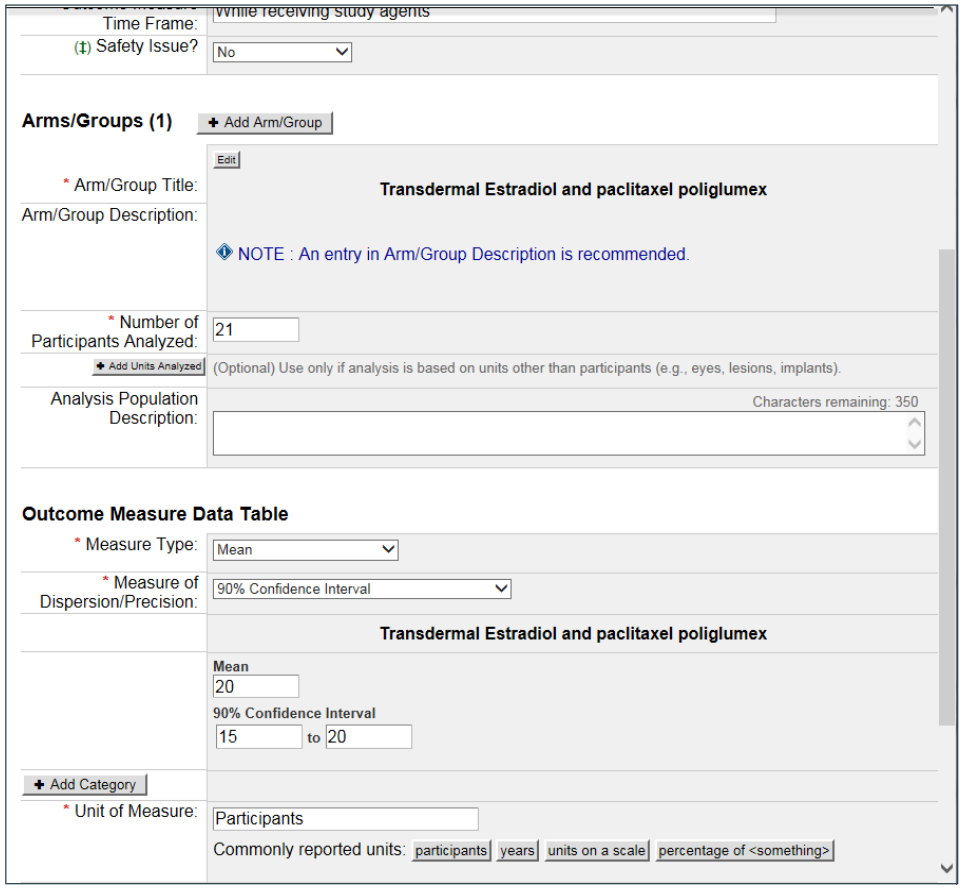
- Example
- Journal articles have similar information, just presented in different format
- To edit outcome, click Edit next to listed outcome



Module 3: Outcome Measures & Statistical Analyses

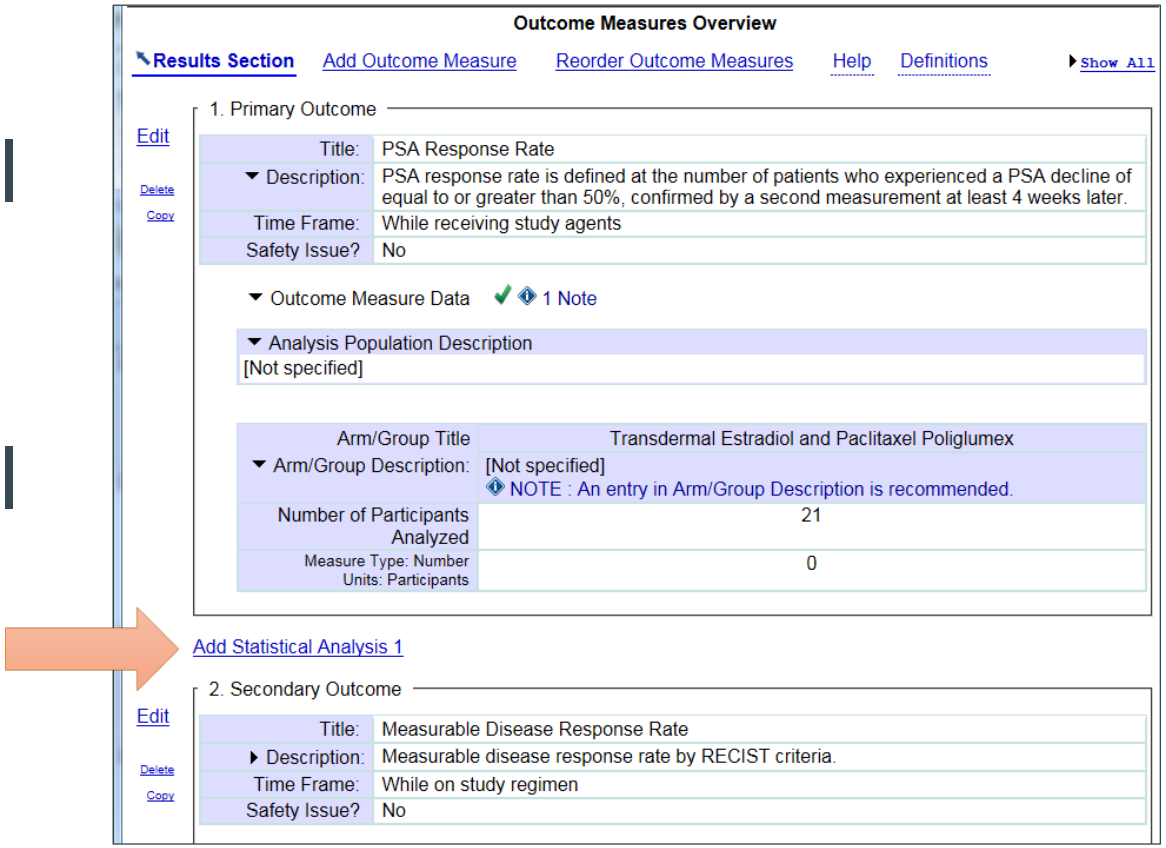
Edit Outcome cont.

1. Make sure all * (required) fields are filled out
2. Completing optional description fields is recommended.
3. Select Measure Type
4. Measure of Dispersion
5. Enter Data
6. Select Units



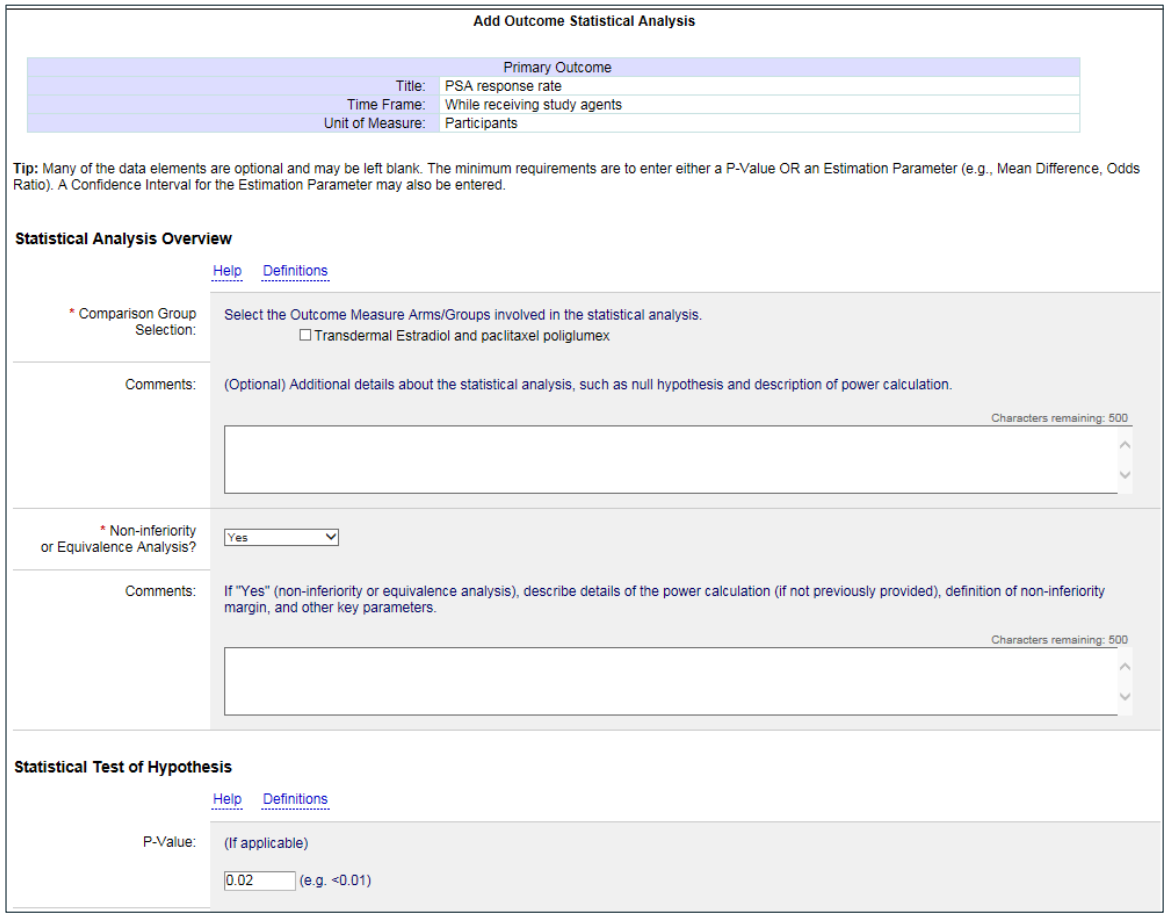
Module 3: Outcome Measures & Statistical Analyses

- To Add a Statistical Analysis, Click Add Statistical Analysis



Module 3: Outcome Measures & Statistical Analyses

- Statistical Analysis cont.
  1. Select the outcome Arm/Group you are adding the analysis for
  2. Add Non-inferiority or Equivalence Analysis
  3. Statistical Test of Hypothesis
  4. Method (ANOVA, Wilcoxon, etc.)



Add Outcome Statistical Analysis

Primary Outcome	
Title:	PSA response rate
Time Frame:	While receiving study agents
Unit of Measure:	Participants

Tip: Many of the data elements are optional and may be left blank. The minimum requirements are to enter either a P-Value OR an Estimation Parameter (e.g., Mean Difference, Odds Ratio). A Confidence Interval for the Estimation Parameter may also be entered.

Statistical Analysis Overview

Help Definitions

* Comparison Group Selection: Select the Outcome Measure Arms/Groups involved in the statistical analysis.
☐ Transdermal Estradiol and paclitaxel poliglumex

Comments: (Optional) Additional details about the statistical analysis, such as null hypothesis and description of power calculation.
Characters remaining: 500

* Non-inferiority or Equivalence Analysis? Yes

Comments: If "Yes" (non-inferiority or equivalence analysis), describe details of the power calculation (if not previously provided), definition of non-inferiority margin, and other key parameters.
Characters remaining: 500

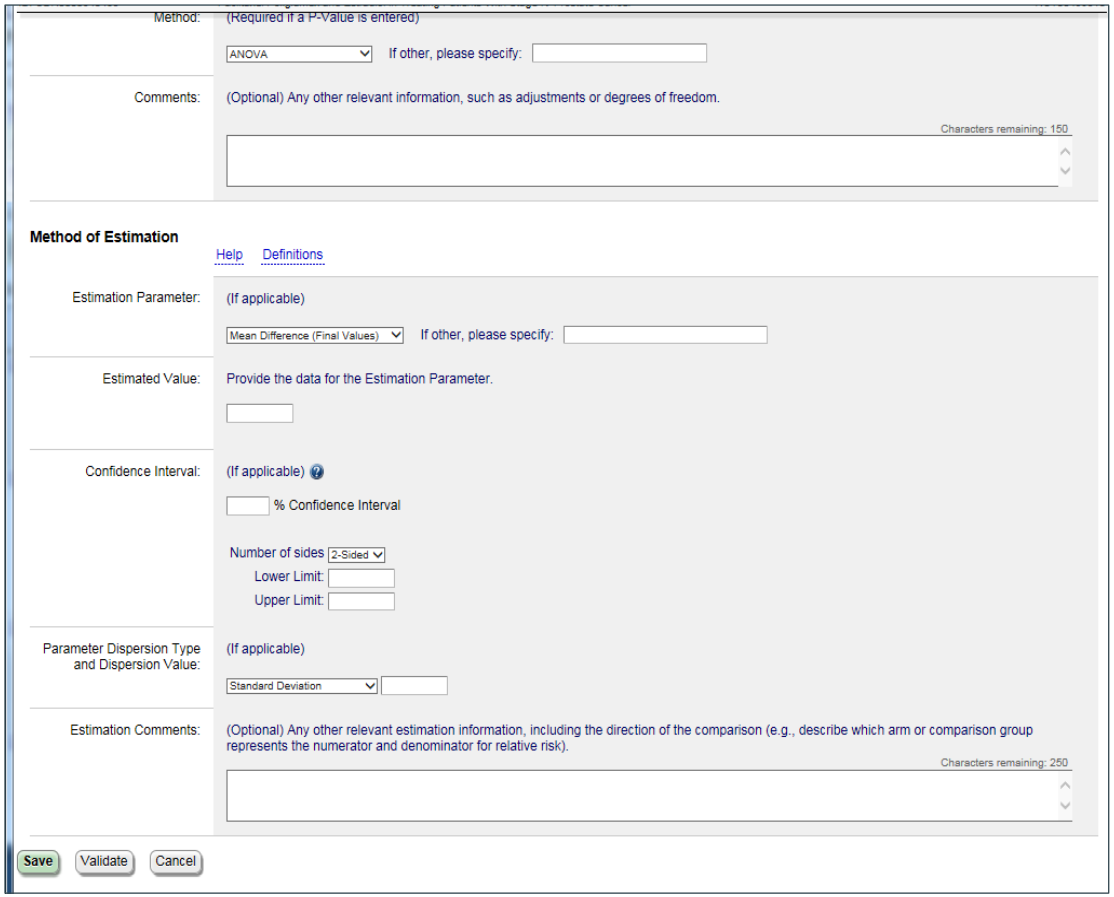
Statistical Test of Hypothesis

Help Definitions

P-Value: (If applicable)
0.02 (e.g. <0.01)

Module 3: Outcome Measures & Statistical Analyses

- Statistical Analysis cont.
  6. Adding comments for greater clarity is encouraged
  7. Enter method of estimation details
  8. Hit Save



Module 3: Outcome Measures & Statistical Analyses

Statistical Analysis cont.

- Example

Measure Type	Primary
Measure Title	Invasive **Breast Cancer** Incidence (**Breast Cancer**-Free Survival)
Measure Description	Invasive breast cancer incidence was estimated from the breast cancer-free survival (BCFS) which was calculated for all women from the day of the randomization to the earliest date of diagnosis for invasive breast cancer. Women who died from other causes were censored at the time of death. If a woman did not develop an invasive breast cancer, or died, BCFS was censored on the date of the last day the woman was known alive (LKA), which was the latest of the date of assessment. Women who had breast cancer before study entry were also censored at the time of randomization.
Time Frame	Over study (median follow-up 35 months)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
intention to treat (ITT)

Reporting Groups

	Description
Exemestane	25 mg of exemestane tablet daily
Placebo	Placebo tablet daily

Measured Values

	Exemestane	Placebo
Number of Participants Analyzed [units: participants]	**2285**	**2275**
Invasive Breast Cancer Incidence (Breast Cancer-Free Survival) [units: percentage of cases/follow-up person-yr] Number (95% Confidence Interval)	**0.19 (0.08 to 0.30)**	**0.55 (0.36 to 0.73)**

Statistical Analysis 1 for Invasive Breast Cancer Incidence (Breast Cancer-Free Survival)

Groups [1]	All groups
Method [2]	Log Rank
P Value [3]	0.002
Hazard Ratio (HR) [4]	0.35
95% Confidence Interval	0.18 to 0.70

Module 4: Adverse Events

Definition:

"Unfavorable changes in health, including abnormal laboratory findings that occur in trial participants during the clinical trial or within a specified period following the trial."

Edit	Time Frame		
	Additional Description		
	Source Vocabulary Name	MedDRA (12.0)	
	Assessment Type	Systematic Assessment	
Edit	Arm/Group Title	Remuverol	Placebo
	▼ Arm/Group Description	Participants received Remuverol 15 mg tablet orally twice daily for 24 weeks.	Participants received Remuverol placebo tablet orally twice daily for 24 weeks.

▼ Serious Adverse Events

		Remuverol Affected / at Risk (%)	Placebo Affected / at Risk (%)
Edit	Total	4/101 (3.96%)	0/99 (0%)
Edit	Blood and l... Anemia Iron Deficiency †	1/101 (0.99%)	0/99 (0%)
	Immune syst... Viral Meningitis †	1/101 (0.99%)	0/99 (0%)
	Skin and su... Psoriasis †	1/101 (0.99%)	0/99 (0%)
	Blood and l... Idiopathic Thrombocytopenic Purpura †	1/101 (0.99%)	0/99 (0%)

† Indicates events were collected by systematic assessment.

Add Serious Adverse Event

▼ Other (Not Including Serious) Adverse Events

Edit	Frequency Threshold for Reporting Other Adverse Events	1%	
		Remuverol Affected / at Risk (%)	**Placebo** Affected / at Risk (%)
Edit	Total	98/101 (97.03%)	46/99 (46.46%)
Edit	Ear and lab... Earache †	35/101 (34.65%)	7/99 (7.07%)
	Endocrine d... Hypothyroidism †	27/101 (26.73%)	25/99 (25.25%)
	Eye disorde... Conjunctivitis †	13/101 (12.87%)	4/99 (4.04%)
	Gastrointes... Nausea †	12/101 (11.88%)	7/99 (7.07%)
	Gastrointes... Stomachache †	10/101 (9.9%)	2/99 (2.02%)
	Gastrointes... Vomiting †	10/101 (9.9%)	3/99 (3.03%)

† Indicates events were collected by systematic assessment.

Add Other (Not Including Serious) Adverse Event

Module 4: Adverse Events

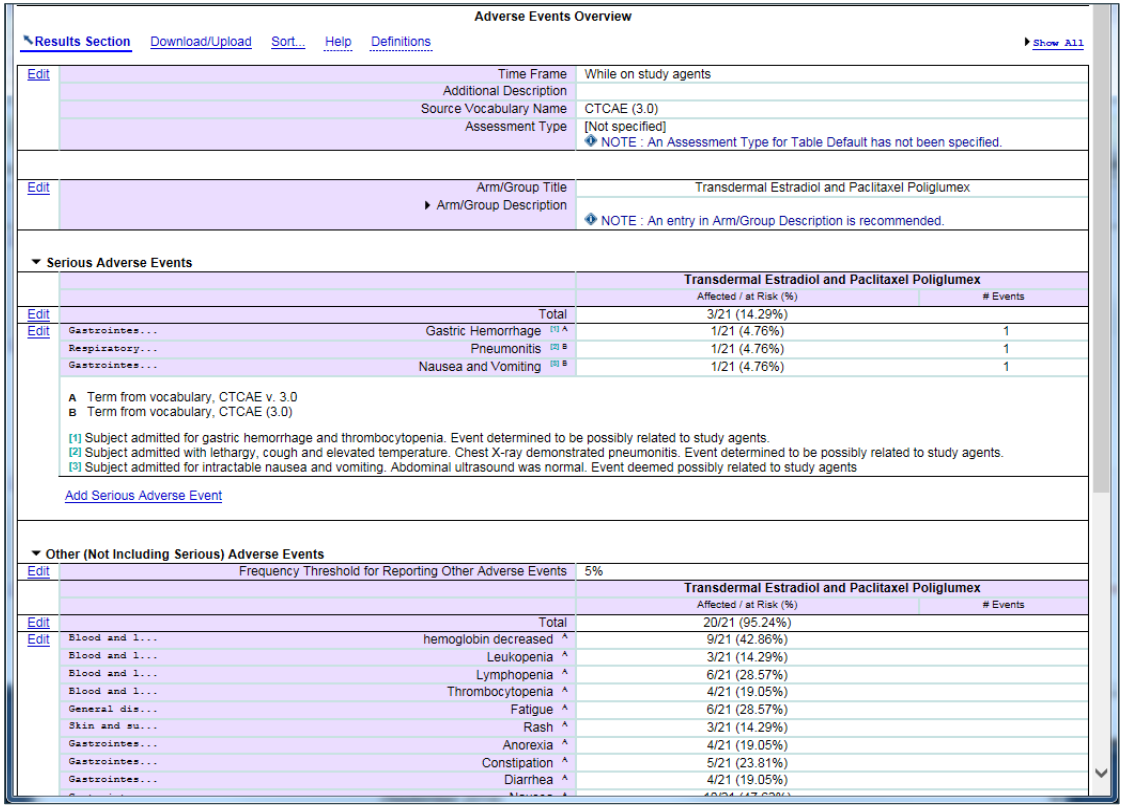
- Elements:
  - Module consists of two tables of summary adverse event data for each Arm/Group.
  - Serious Adverse Events (SAEs)
    - Includes a table of ALL anticipated and unanticipated SAEs grouped by organ system, with number and frequency of such events per Arm/Group
  - Other Adverse Events
    - Includes a table of anticipated and unanticipated adverse events that exceed 5 % frequency within an Arm/Group.
- Refer to templates:
  - http://prsinfo.clinicaltrials.gov/results_table_layout/DataEntryTable_SAEForm.pdf
  - http://prsinfo.clinicaltrials.gov/results_table_layout/DataEntryTable_FreqAEForm.pdf
- You can enter manually or download, then upload a template.

Module 4: Adverse Events

Example:

Data is complied by organ system then:

- Number of subjects affected*
- Number subjects at risk* *(number that received the intervention)*
- Number of events (optional)



Adverse Events Overview

Results Section | Download/Upload | Sort... | Help | Definitions | Show All

Edit	Time Frame	While on study agents
	Additional Description	
	Source Vocabulary Name	CTCAE (3.0)
	Assessment Type	[Not specified]
		NOTE : An Assessment Type for Table Default has not been specified.
Edit	Arm/Group Title	Transdermal Estradiol and Paclitaxel Poliglumex
	Arm/Group Description	
		NOTE : An entry in Arm/Group Description is recommended.

Serious Adverse Events

		Transdermal Estradiol and Paclitaxel Poliglumex	
		Affected / at Risk (%)	# Events
Edit	Total	3/21 (14.29%)	
Edit	Gastrointes... Gastric Hemorrhage [1] A	1/21 (4.76%)	1
	Respiratory... Pneumonitis [2] B	1/21 (4.76%)	1
	Gastrointes... Nausea and Vomiting [3] B	1/21 (4.76%)	1

A Term from vocabulary, CTCAE v. 3.0
B Term from vocabulary, CTCAE (3.0)

[1] Subject admitted for gastric hemorrhage and thrombocytopenia. Event determined to be possibly related to study agents.
[2] Subject admitted with lethargy, cough and elevated temperature. Chest X-ray demonstrated pneumonitis. Event determined to be possibly related to study agents.
[3] Subject admitted for intractable nausea and vomiting. Abdominal ultrasound was normal. Event deemed possibly related to study agents

Add Serious Adverse Event

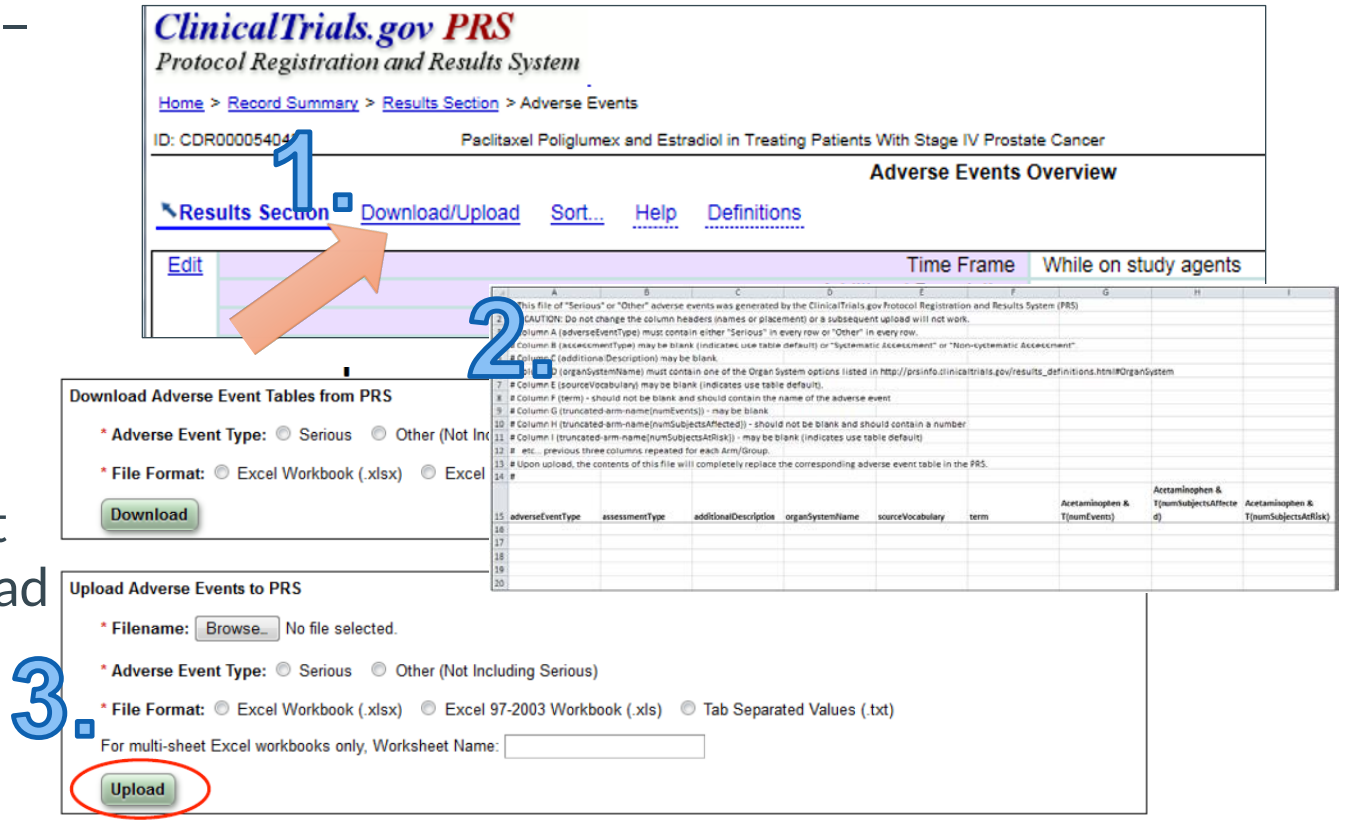
Other (Not Including Serious) Adverse Events

			Transdermal Estradiol and Paclitaxel Poliglumex	
Edit	Frequency Threshold for Reporting Other Adverse Events	5%		
			Affected / at Risk (%)	# Events
Edit	Total		20/21 (95.24%)	
Edit	Blood and l...	hemoglobin decreased A	9/21 (42.86%)	
	Blood and l...	Leukopenia A	3/21 (14.29%)	
	Blood and l...	Lymphopenia A	6/21 (28.57%)	
	Blood and l...	Thrombocytopenia A	4/21 (19.05%)	
	General dis...	Fatigue A	6/21 (28.57%)	
	Skin and su...	Rash A	3/21 (14.29%)	
	Gastrointes...	Anorexia A	4/21 (19.05%)	
	Gastrointes...	Constipation A	5/21 (23.81%)	
	Gastrointes...	Diarrhea A	4/21 (19.05%)	

Module 4: Adverse Events

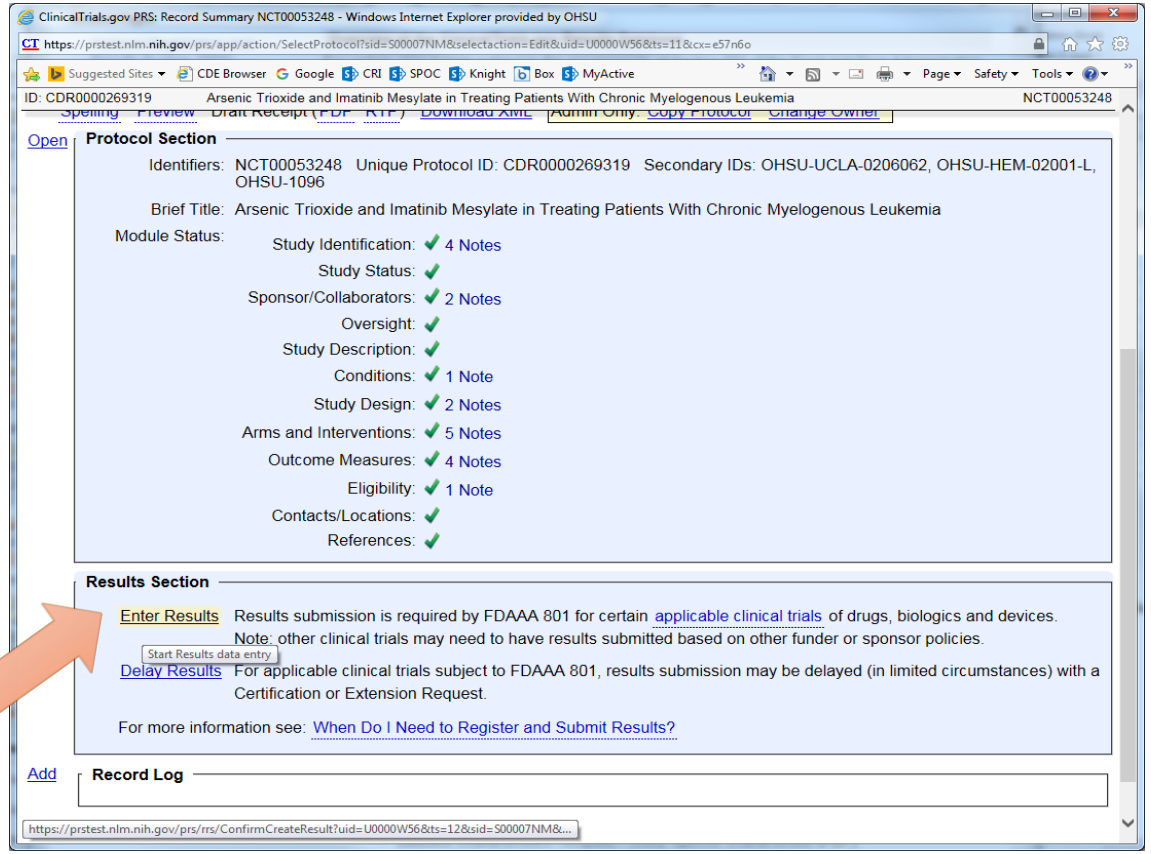
Download/ Upload Option – a likely time saver.

1. Click Download /Upload
2. Download Excel template and fill out
3. Click upload



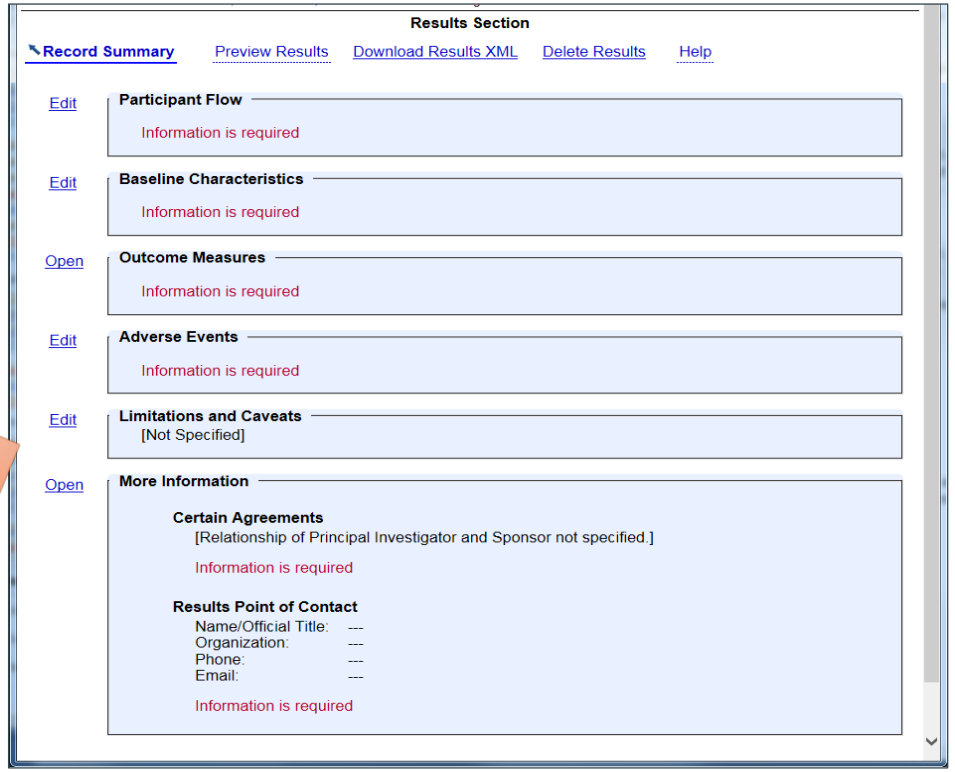
Getting Started with Results Entry

- When ready to start…
  1. Login to PRS and navigate to your protocol registration
  2. Click **Enter Results**
     - This will set up the full outline of the Results Section for you (next screen)



Getting Started with Results Entry

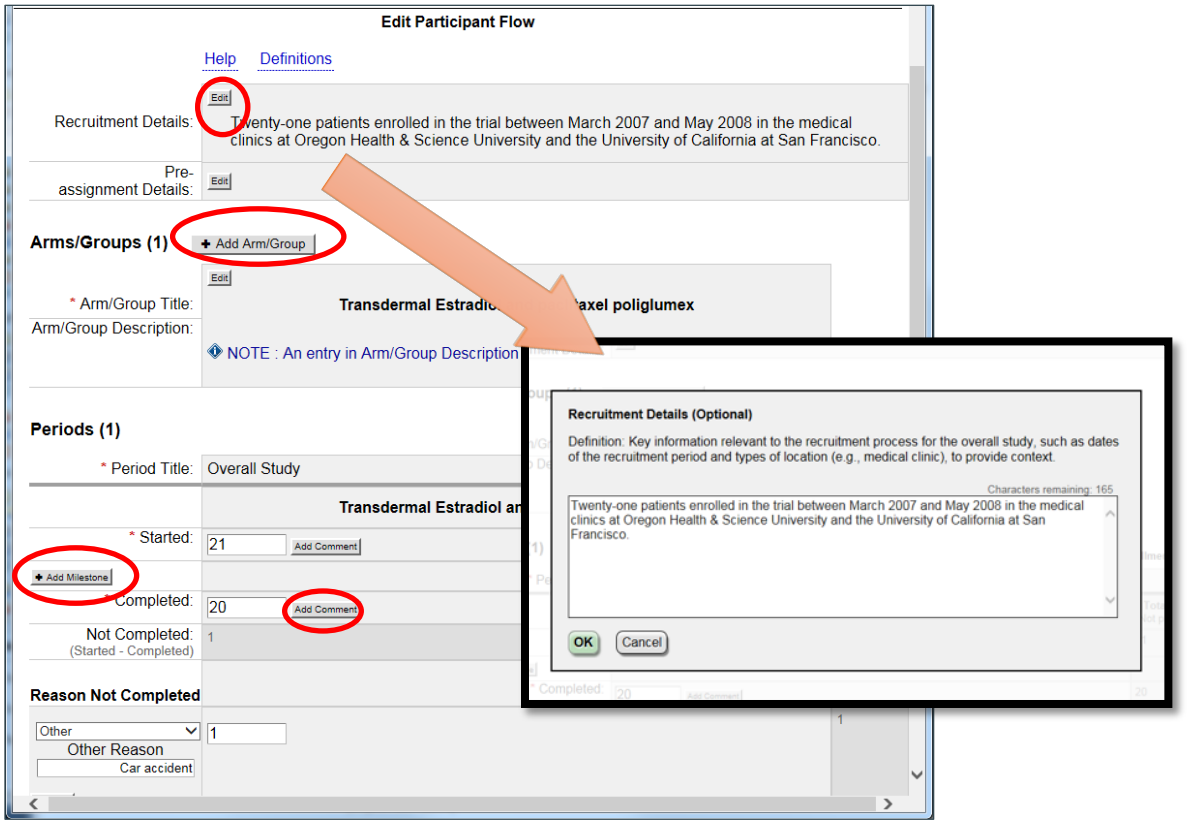
- Getting started cont.
  3. Click **Edit** to begin entry on the 4 modules
  4. When complete with all 4 modules, make sure to complete **Limitations and Caveats** (if applicable), and **Agreements & Contacts**
  5. Completing the Limitations section will be *important if there are issues with your results data* (incomplete data, terminated early, etc)



Getting Started with Results Entry

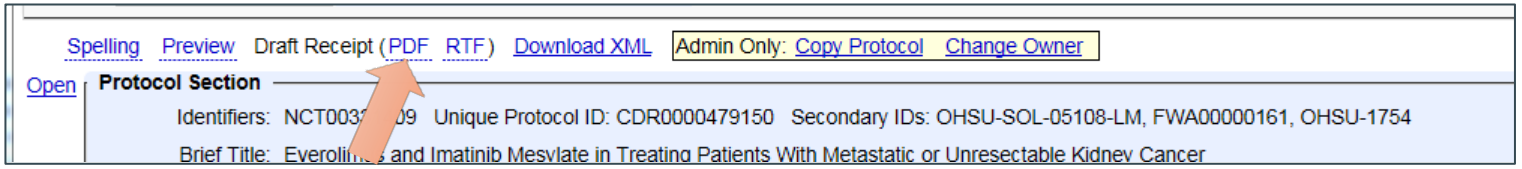
Navigation & Editing Tips

- Be aware, there are lots of nested edit functions & pop-ups
- Take your time, navigation can get confusing
- Don't forget to hit **Save**

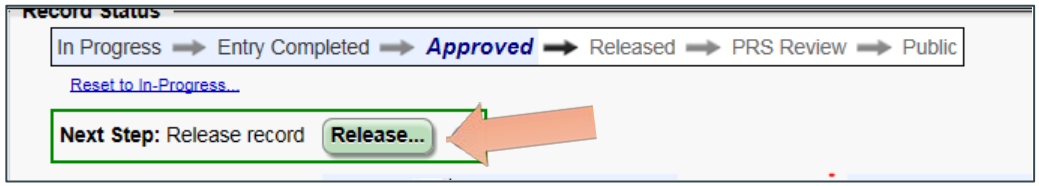


Getting Started with Results Entry

- When you're <u>all finished</u> with results entry we recommend
  - **Have a second person (ideally the PI and/or Biostatistician) review it**
    - Mistakes can be embarrassing
  - You can export a RTF or PDF version of the entire registration & results data if they are not comfortable navigating in CT.gov

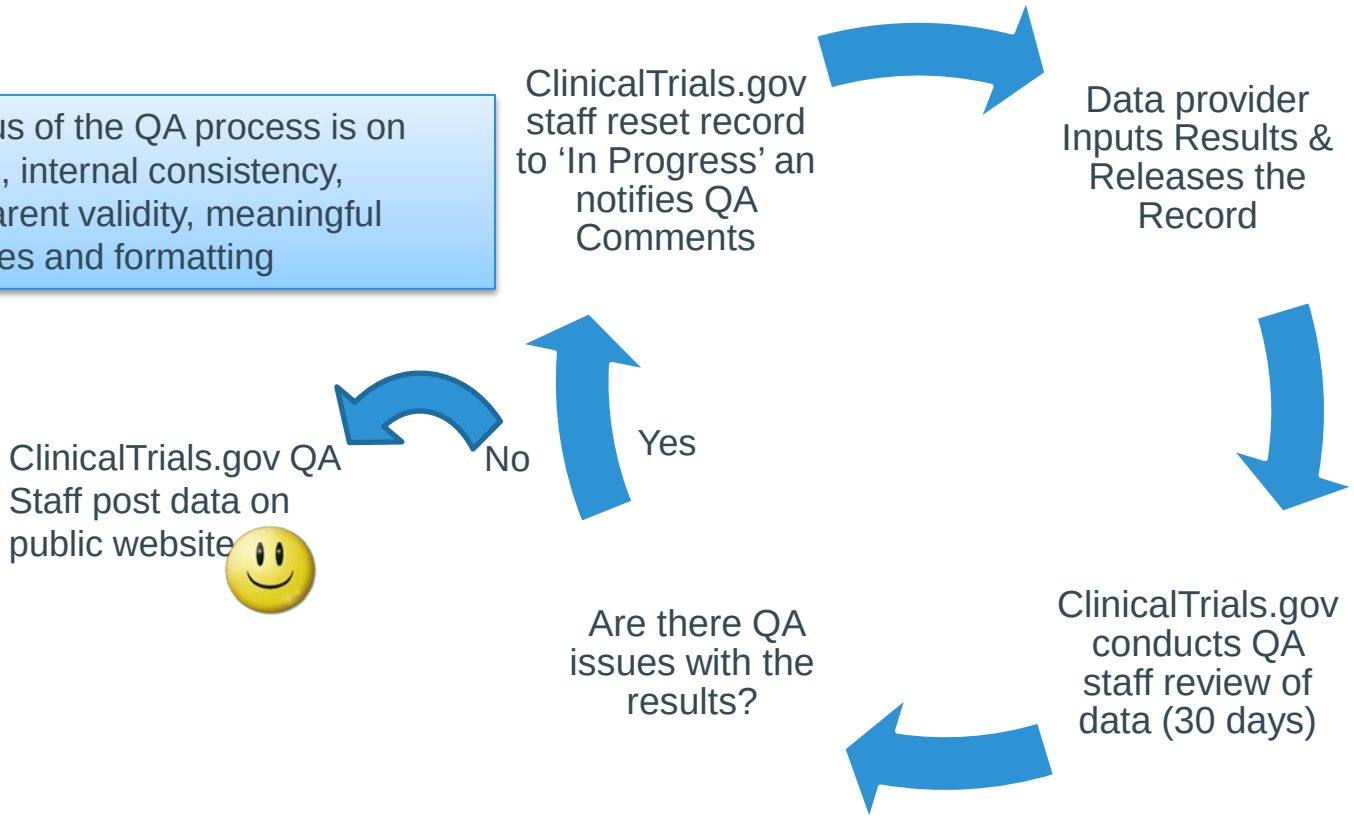


- **Complete**, **Approve** then **Release** the record and it will then go into PRS Review (QA)



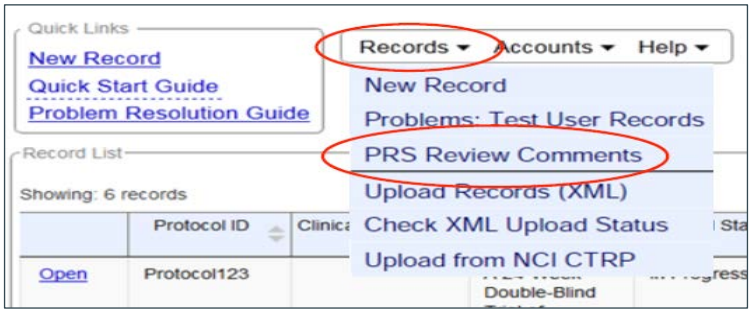
ClinicalTrials.gov PRS QA Process

Focus of the QA process is on logic, internal consistency, apparent validity, meaningful entries and formatting



ClinicalTrials.gov PRS QA Process

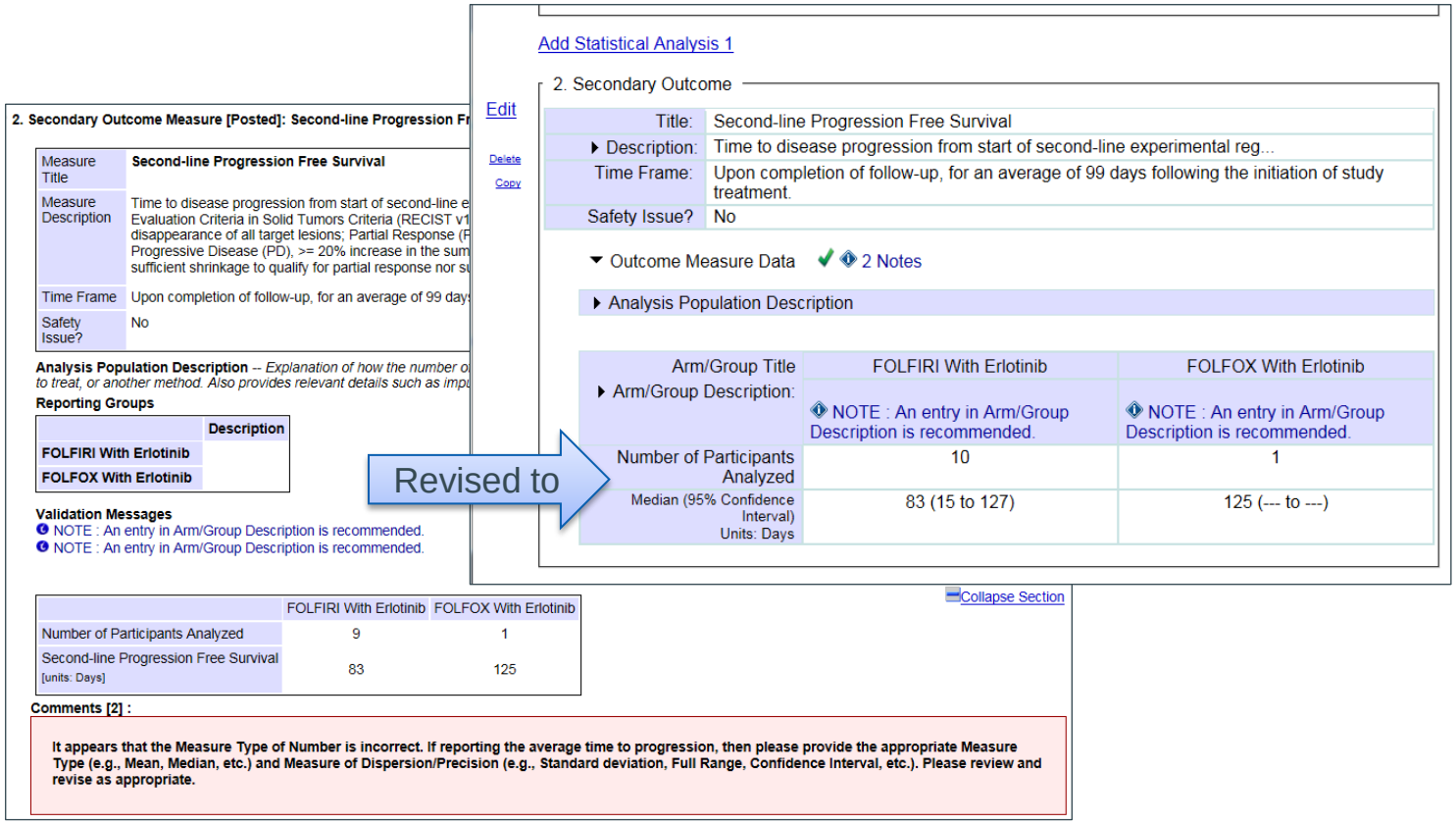
- The QA Process can take a while, especially if it happens multiple times
- The more accurate, complete and specific the results are, the quicker the process will go
- To review the comments, login to PRS and select PRS Review Comments under the Records menu.



ClinicalTrials.gov PRS QA Process

Example 1:

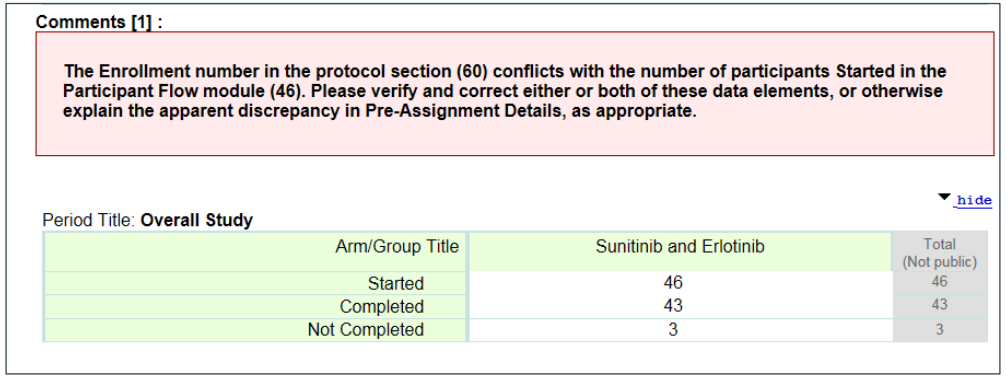
- Measure Types need to be consistent with outcome description



ClinicalTrials.gov PRS QA Process

Example 2 & 3

- Totals should match with enrollment, else explain.
- Outcome title and/or description need to be specific



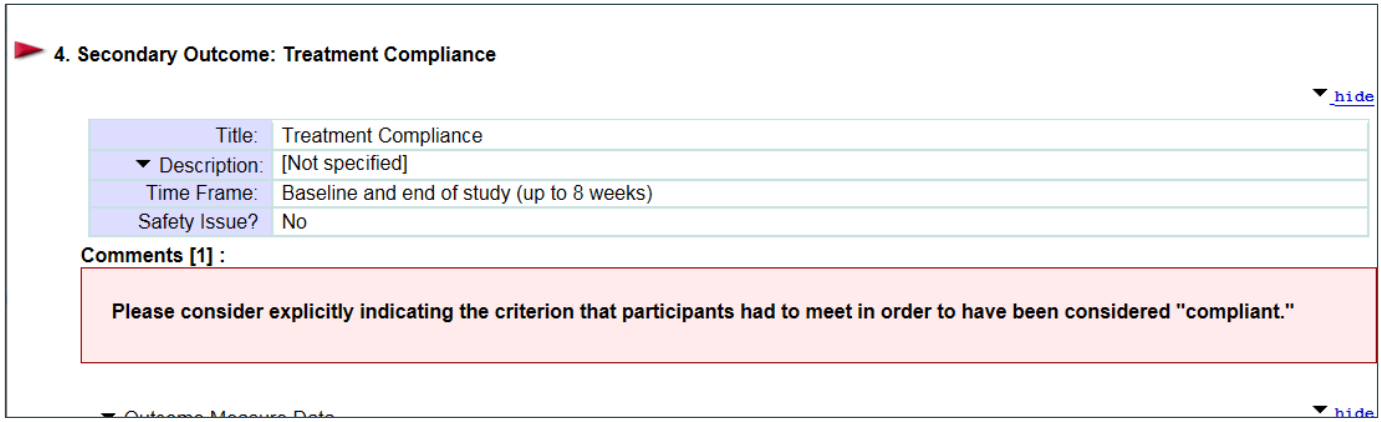
Comments [1] :

The Enrollment number in the protocol section (60) conflicts with the number of participants Started in the Participant Flow module (46). Please verify and correct either or both of these data elements, or otherwise explain the apparent discrepancy in Pre-Assignment Details, as appropriate.

hide

Period Title: **Overall Study**

Arm/Group Title	Sunitinib and Erlotinib	Total (Not public)
Started	46	46
Completed	43	43
Not Completed	3	3



4. Secondary Outcome: Treatment Compliance

hide

Title:	Treatment Compliance
Description:	[Not specified]
Time Frame:	Baseline and end of study (up to 8 weeks)
Safety Issue?	No

Comments [1] :

Please consider explicitly indicating the criterion that participants had to meet in order to have been considered "compliant."

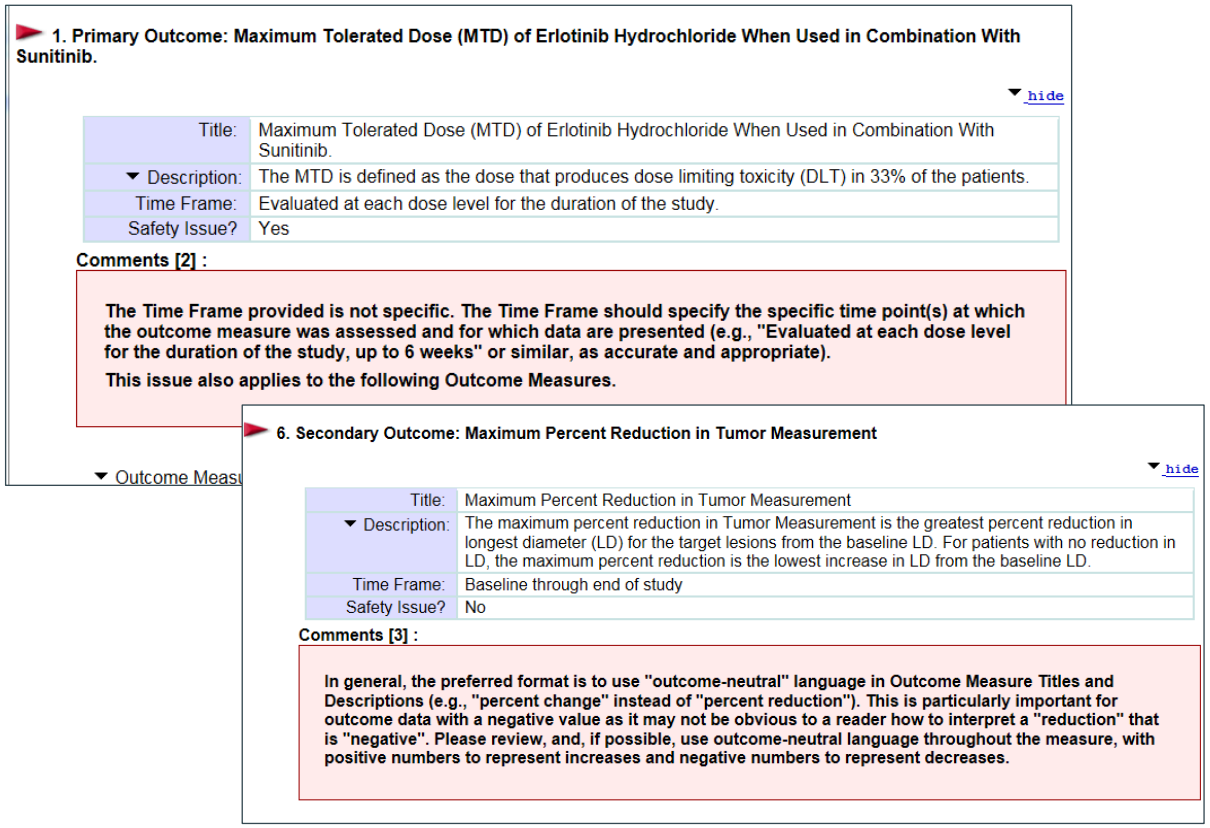
hide

ClinicalTrials.gov PRS QA Process

Example

4 & 5

- Timeframe need to be specific
- Outcome language should be “neutral”



1. Primary Outcome: Maximum Tolerated Dose (MTD) of Erlotinib Hydrochloride When Used in Combination With Sunitinib.

hide

Title:	Maximum Tolerated Dose (MTD) of Erlotinib Hydrochloride When Used in Combination With Sunitinib.
Description:	The MTD is defined as the dose that produces dose limiting toxicity (DLT) in 33% of the patients.
Time Frame:	Evaluated at each dose level for the duration of the study.
Safety Issue?	Yes

Comments [2] :

The Time Frame provided is not specific. The Time Frame should specify the specific time point(s) at which the outcome measure was assessed and for which data are presented (e.g., "Evaluated at each dose level for the duration of the study, up to 6 weeks" or similar, as accurate and appropriate).

This issue also applies to the following Outcome Measures.

Outcome Measu

6. Secondary Outcome: Maximum Percent Reduction in Tumor Measurement

hide

Title:	Maximum Percent Reduction in Tumor Measurement
Description:	The maximum percent reduction in Tumor Measurement is the greatest percent reduction in longest diameter (LD) for the target lesions from the baseline LD. For patients with no reduction in LD, the maximum percent reduction is the lowest increase in LD from the baseline LD.
Time Frame:	Baseline through end of study
Safety Issue?	No

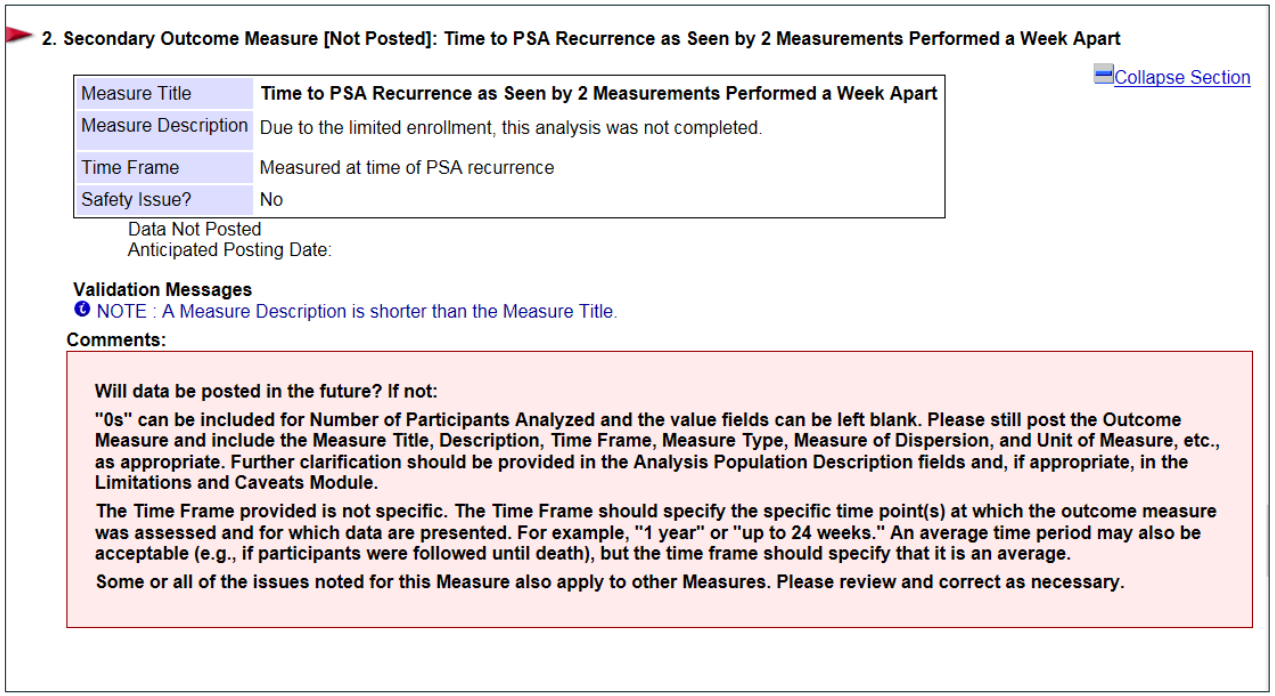
Comments [3] :

In general, the preferred format is to use "outcome-neutral" language in Outcome Measure Titles and Descriptions (e.g., "percent change" instead of "percent reduction"). This is particularly important for outcome data with a negative value as it may not be obvious to a reader how to interpret a "reduction" that is "negative". Please review, and, if possible, use outcome-neutral language throughout the measure, with positive numbers to represent increases and negative numbers to represent decreases.

ClinicalTrials.gov PRS QA Process

Example 6

- What if I don't have the data?
  - Studies that terminated early – can enter '0s'
  - Or – apply for an extension if you think you will get the data
- **Better to post what you have by due date, than be late.**



2. Secondary Outcome Measure [Not Posted]: Time to PSA Recurrence as Seen by 2 Measurements Performed a Week Apart

Collapse Section

Measure Title	**Time to PSA Recurrence as Seen by 2 Measurements Performed a Week Apart**
Measure Description	Due to the limited enrollment, this analysis was not completed.
Time Frame	Measured at time of PSA recurrence
Safety Issue?	No

Data Not Posted
Anticipated Posting Date:

Validation Messages

NOTE : A Measure Description is shorter than the Measure Title.

Comments:

Will data be posted in the future? If not:

"0s" can be included for Number of Participants Analyzed and the value fields can be left blank. Please still post the Outcome Measure and include the Measure Title, Description, Time Frame, Measure Type, Measure of Dispersion, and Unit of Measure, etc., as appropriate. Further clarification should be provided in the Analysis Population Description fields and, if appropriate, in the Limitations and Caveats Module.

The Time Frame provided is not specific. The Time Frame should specify the specific time point(s) at which the outcome measure was assessed and for which data are presented. For example, "1 year" or "up to 24 weeks." An average time period may also be acceptable (e.g., if participants were followed until death), but the time frame should specify that it is an average.

Some or all of the issues noted for this Measure also apply to other Measures. Please review and correct as necessary.

Overall Tips & FAQS

- Remember to hit **Save** to your work, or **Cancel** if you don't want to Save
- Publications can be more detailed and expansive than posted results but they should be consistent & congruent. If publishing *after* posting results, go back and update results to ensure they are consistent
- Make sure units and scales are labeled and understandable
- Outcome titles, avoid using verbs (e.g. "To determine…") – focus on what is measured and not why
- You are not required to address all auto-generated "Notes" before submitting your results, however, warnings and errors should be addressed
- Make sure acronyms are spelled out first time they are used

References and Additional Resources

- Clinicaltrials.gov information general results info: https://www.clinicaltrials.gov/ct2/about-site/results
- Clinicaltrials.gov information detailed results info: https://clinicaltrials.gov/ct2/manage-recs/how-report
- Questions?
  - ClinicalTrials.gov staff - register@clinicaltrials.gov
  - Oncology/Cancer Studies (Knight Cancer Institute) - ctrp-admin@ohsu.edu
  - Non-cancer - OCTRI {Contact??}
- FDAAA & Elaborations of Defintions: https://www.clinicaltrials.gov/ct2/manage-recs/fdaaa
- CMS – Mandatory Reporting of NCT #s on Medicare Claims Q&A https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Downloads/Mandatory-Clinical-Trial-Identifier-Number-QsAs.pdf
- PRS User's Guide XML section (must be logged in to PRS to access) https://register.clinicaltrials.gov/prs/app/template/ReferenceGuide.vm?popup=true&uid=U0000W56&ts=3&cx=-pf1azb#xml
- OHSU Knight Clinical Trial Registration SOPs: CR007, CR013 - https://bridge.ohsu.edu/research/knight/policies/SitePages/Home.aspx
- Knight CTRP staff ctrp-admin@ohsu.edu
- OHSU ClinicalTrials.gov IRB Help Sheet: http://www.ohsu.edu/xd/about/services/integrity/policies/upload/Clinical-Trials-ClinicalTrials-gov-Registration-Requirements-Help-Sheet.pdf

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Thank You