Clinical Trials Results Reporting

OHSU Knight Cancer Institute
Oregon Clinical and Translational Research Institute

JANUARY 17, 2019 PRESENTED BY:

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Summary of Next Steps

- Revise Primary Completion Date and Study Completion Date from “anticipated” to “actual”
- Change study/recruitment status (if needed)
- Revise subject enrollment from “anticipated” to “actual” enrollment count experienced
- Upload IRB-approved informed consent form (in PDF format) to record’s document upload module
  - Redact sensitive information (i.e. PI phone #)
  - Upload anytime after enrollment closes
  - Upload no later than 60 days after last subject last visit (LSLV)

Outline for Results Reporting

- 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 & Tricks
- Additional Resources

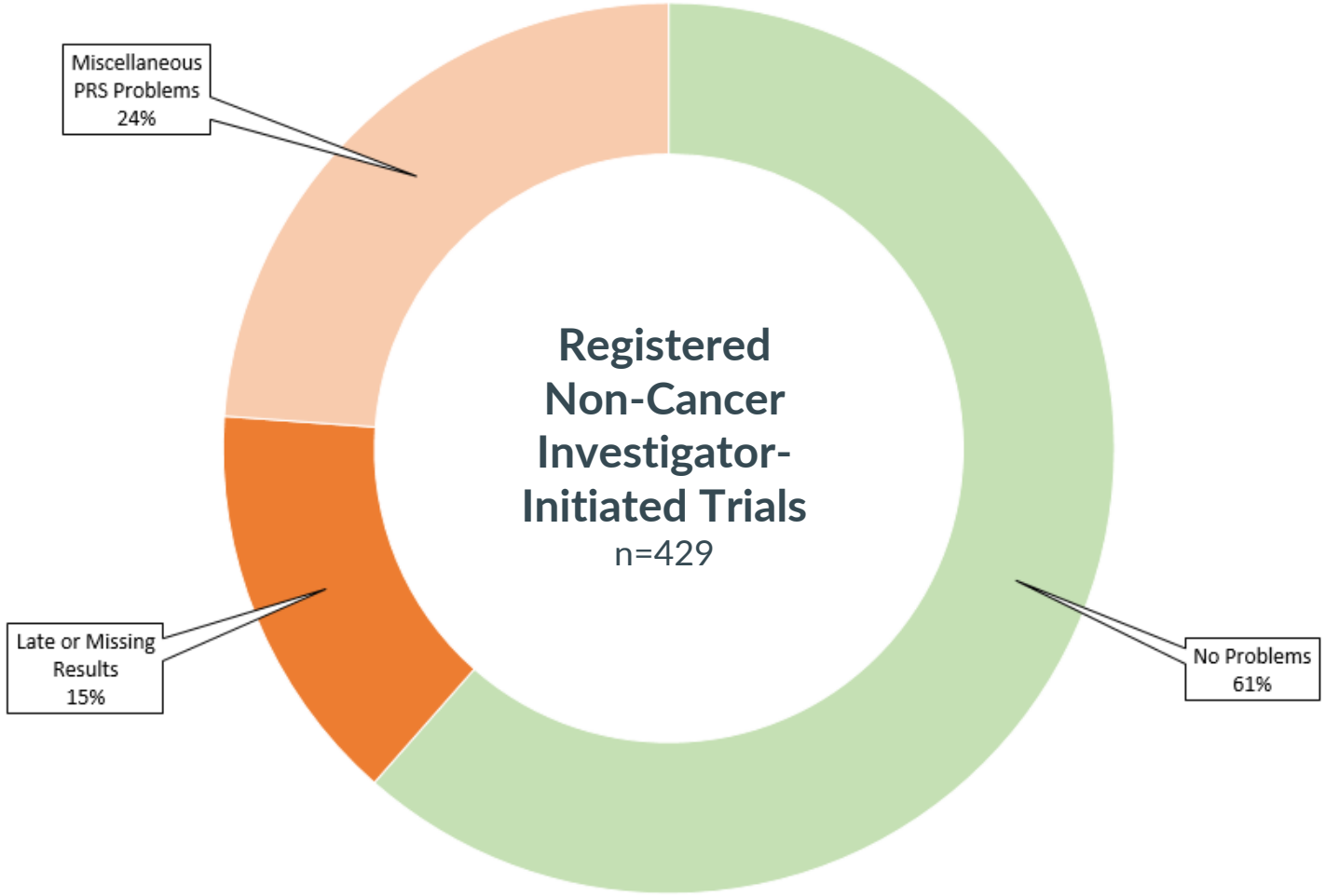
Why Is This Needed?

- 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
  - Final Rule (42 CFR pt 11) of the Food and Drug Administration Amendments Act (FDAAA 801)
  - NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information (NOT-OD-16-149)

What Happens If You Don't Report Results When Required?

- Final Rule (42 CFR Part 11) expands regulatory requirements in accordance with FDAAA 801
  - Establishes penalties including civil monetary penalties ($11,805 per trial per day) and, for federally funded studies, the withholding of federal grant funds **AND**
- Current/future grant funding could be withheld by NIH (NOT-OD-16-149), **AND**
- Current/future OHSU research funding could be frozen

What's Our Status?



Does My Study Require Results?

- If study is an *Applicable Clinical Trial (ACT)*, and thus subject to FDAAA (FDA Amendments Act, Section 801), then IT DOES require results posting
- ACTs are:
  - Controlled clinical investigations involving drugs or prospective studies of health outcomes involving drugs/devices that are or would/will be 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

*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 use the ACT Checklist (PDF): https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf, OR…

Email register@clinicaltrials.gov,
or Knight Cancer Institute via ctrp-admin@ohsu.edu for cancer studies

ACT Checklist for Determining Results Reporting Requirement

- More data elements and elaborations are included in the PDF that are important in determining ACT status
- Please download the ACT Checklist for more information: https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf

Question	Yes	No
1. Is the study interventional (a clinical trial)? *Study Type* data element is "Interventional"	☐	☐
2. Do ANY of the following apply (is the answer "Yes" to at least one of the following sub-questions: 2a, 2b, OR 2c)? **a. Is at least one study facility located in the United States or a U.S. territory?** *Facility Location – Country* data element is "United States," "American Samoa," "Guam," "Northern Mariana Islands," "Puerto Rico," "U.S. Virgin Islands," or other U.S. territory. **b. Is the study conducted under a U.S. FDA Investigational New Drug application (IND) or Investigational Device Exemption (IDE)?** *U.S. Food and Drug Administration IND or IDE Number* data element is "Yes." **c. Does the study involve a drug, biological, or device product that is manufactured in and exported from the U.S. (or a U.S. territory) for study in another country?** *Product Manufactured in and Exported from the U.S.* data element is "Yes."	☐	☐
3. Does the study evaluate at least one drug, biological, or device product regulated by the United States Food and Drug Administration (U.S. FDA)? *Studies a U.S. FDA-regulated Device Product* data element is "Yes" and/or *Studies a U.S. FDA-regulated Drug Product* data element is "Yes."	☐	☐
4. Is the study other than a Phase 1 trial of a drug and/or biological product or is the study other than a device feasibility study? For drug product trials, *Study Phase* data element is NOT "Phase 1" and for device product trials, *Primary Purpose* is NOT "Device Feasibility."	☐	☐

If "Yes" is answered to all 4 questions, and the study was initiated on or after January 18, 2017, the trial would meet the definition of an ACT that is required to be registered under 42 CFR 11.22.

Does My Study Require Results?

- Results posting is required if the human subject research study receives any NIH funding and:
  - Is interventional in study design
  - Has a start date on/after January 18, 2017
    - Ongoing studies with start date prior to January 18, 2017 are SUGGESTED by NIH to recognize the policy:

      *Although the policy does not apply to NIH-funded clinical trials initiated before the effective date, we encourage all ongoing NIH-funded clinical trials to follow it. It is also critical for investigators conducting NIH-funded applicable clinical trials that are subject to the statute and rule to be sure they are in compliance with those requirements.**

*NOT-OD-16-149: NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information. (2016, September 16). Retrieved from https://grants.nih.gov/grants/guide/notice-files/not-od-16-149.html

Preparing for Results Reporting

- **Who enters results?** You! But you can get help.
- **Avoid unpleasant surprises**. Review the requirements for results entry well ahead of study completion.
- **Involve your biostatistician.** PI and biostatistician (ideally) should review record results before submission.

Preparing for Results Reporting

- **Plan early!**
  - Budget ~40hrs (over several months*) for results posting
  - Be continuously thinking about your data and results throughout protocol development, study conduct, and update your registration accordingly.
  - Make sure all key elements are reflected from the protocol and data collection instruments.

    FYI: Protocol upload is required during results posting
  - Registrations that are error-free, clear, descriptive, and kept up-to-date throughout the trial will be easier to report results.

*__Federal Register__ / Vol. 81, No. 183 / Wednesday, September 21, 2016 / Rules and Regulations
Clinical Trials Registration and Results Information Submission

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 receiving 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 ClinicalTrials.gov so they align.
  - In general, FDAAA requires all 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 full study Completion Date.

Preparing For Results Reporting

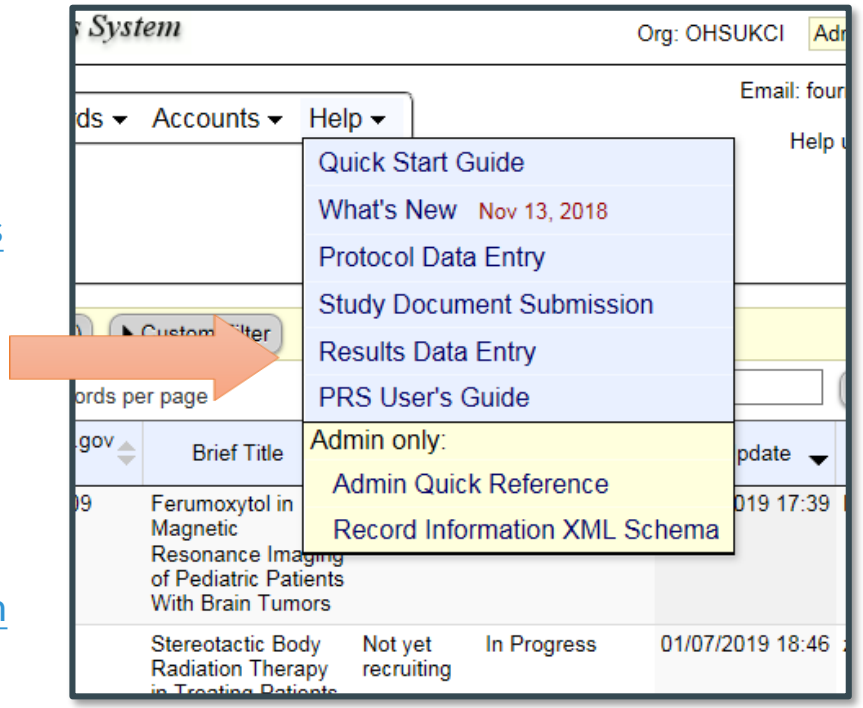
Appendix A: Sample Study Team Work Plan for Study Results

This is an example of how a team might develop a detailed delegation and action plan for accomplishing publication of study results.

#	Task	Assigned Owner	Target Date	Notes
1	Ensure all data submitted into EDC			
2	Clean and prep data for analysis			
3	Data analysis for study endpoints			
4	Review of data analysis/results			
5	Review CT.gov training materials			
6	Entry of data into CT.gov			
7	PI review and release of data in CT.gov			***Must occur by 12 months after primary completion date.
8	Verify CT.gov QA review completed			

Preparing for Results Reporting

- **First Time?** – Check out these links below:
  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
     - Includes templates & checklists
  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.



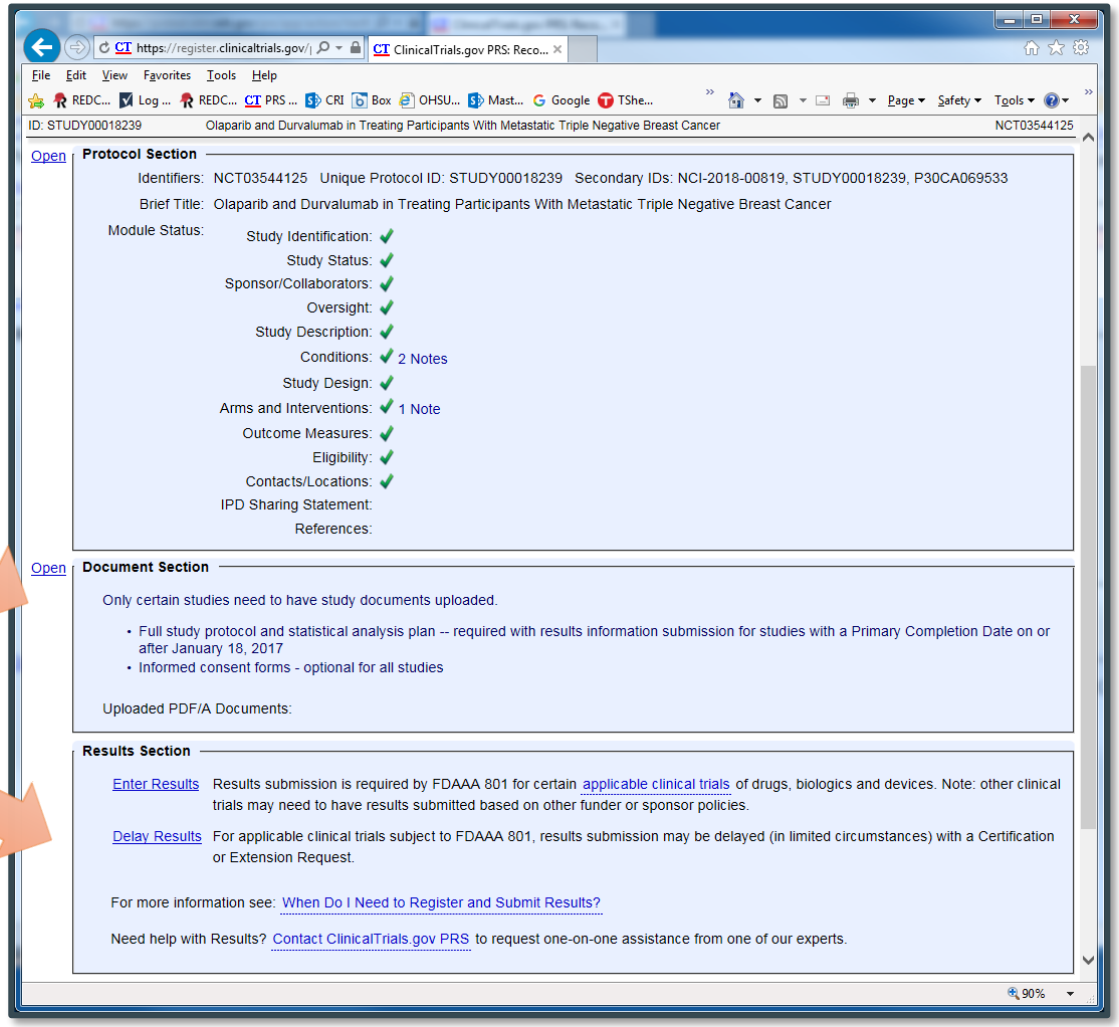
Preparing For Results Reporting

- 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

Getting Started with Results Entry

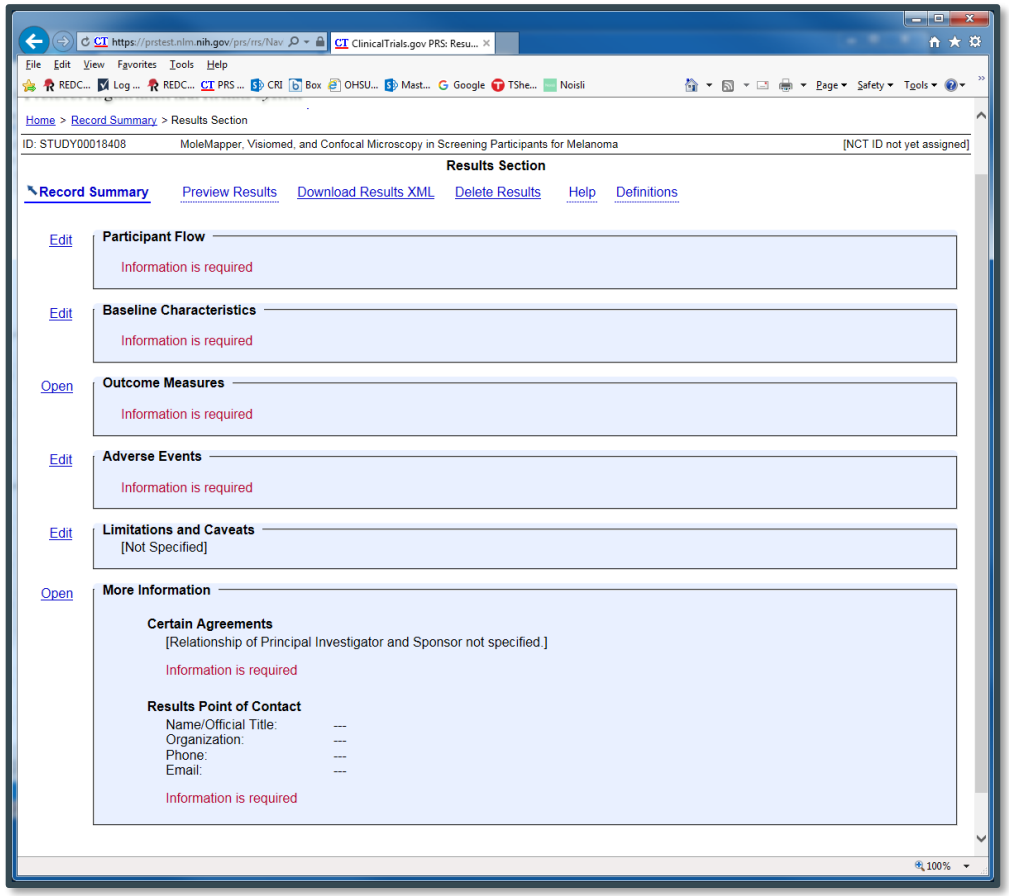
When ready to start…

1. Login to PRS and navigate to your protocol registration
2. **NEW** for studies started after 1/18/17
   - Protocol is required with results
   - Consent may be required soon as well
3. Click **Enter Results**
   - This will set up the full outline of the Results Section for you (next screen)



Getting Started with Results Entry

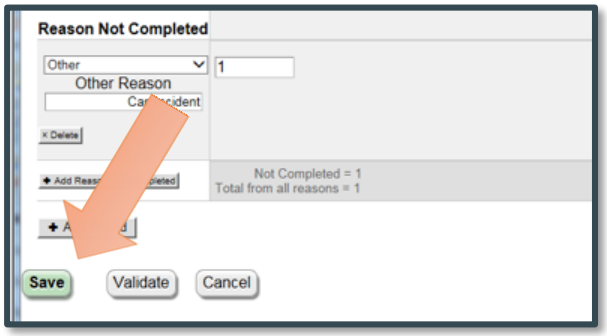
1. Getting started cont…. Click **Edit** to begin entry on the 4 modules
2. When complete with all 4 modules, make sure to complete **Limitations and Caveats** (if applicable), and **Agreements & Contacts**
3. Completing the Limitations section will be *important if there are issues with your results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

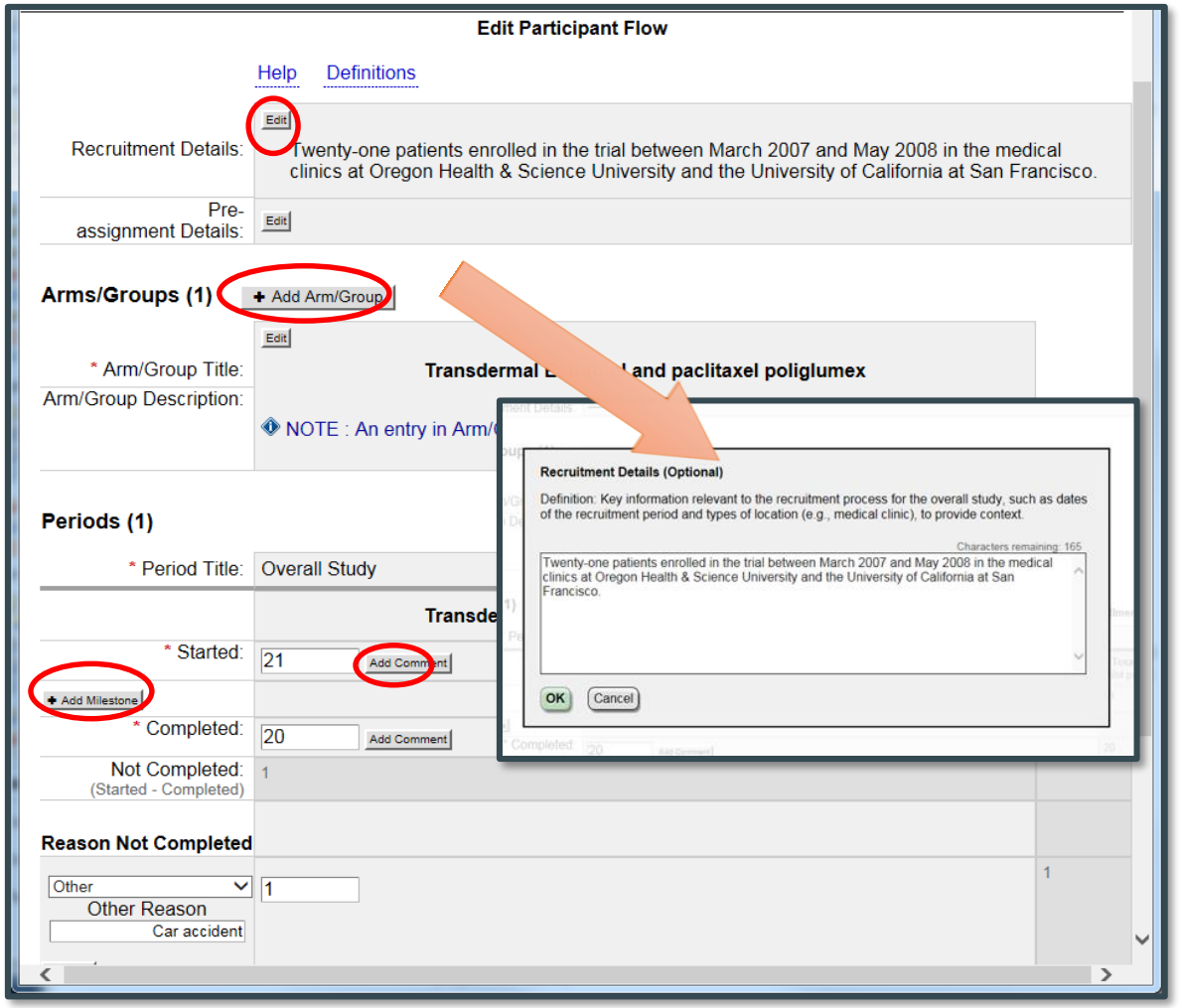


Getting Started with Results Entry

Navigation & Editing Tips

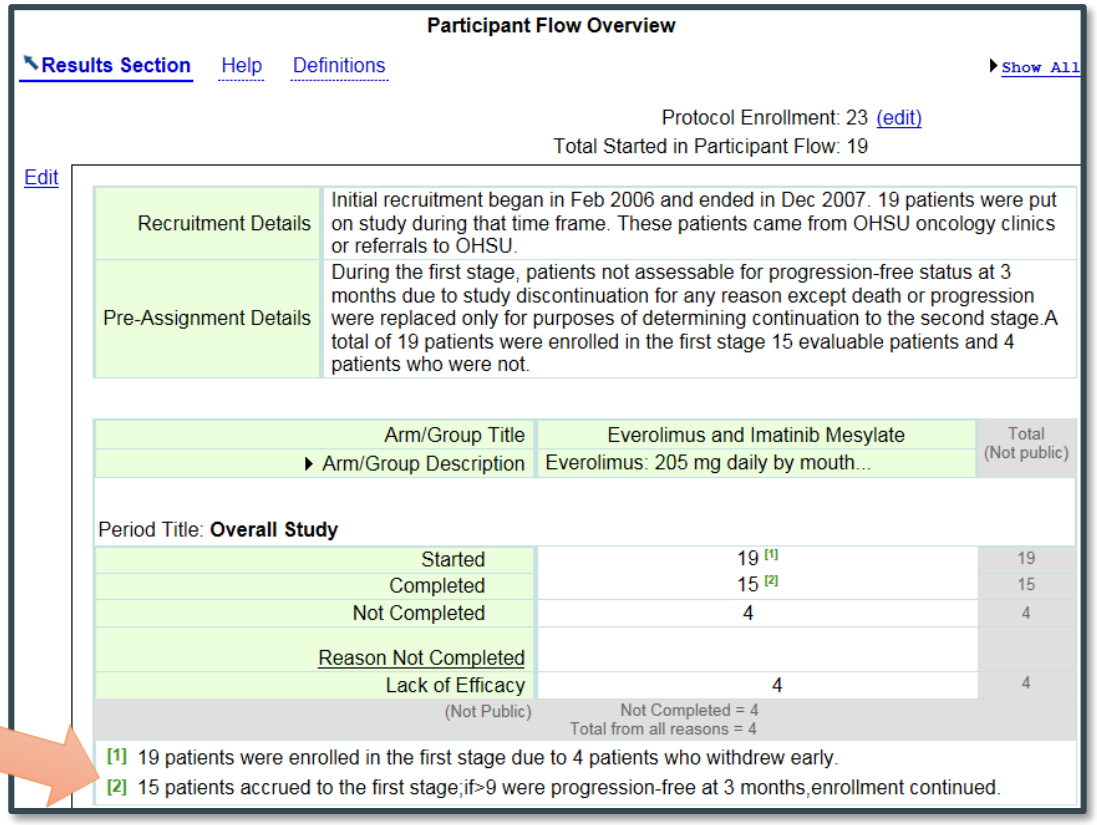
- Be aware, there are lots of nested edit functions & pop-ups
- Take your time, navigation can get confusing
- Don't forget to hit **Save**





Module 1: Participant Flow

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

Refer to template:
http://prsinfo.clinicaltrials.gov/results_table_layout/DataEntryTable_PopFlowForm.pdf

Module 1: Participant Flow

Another example

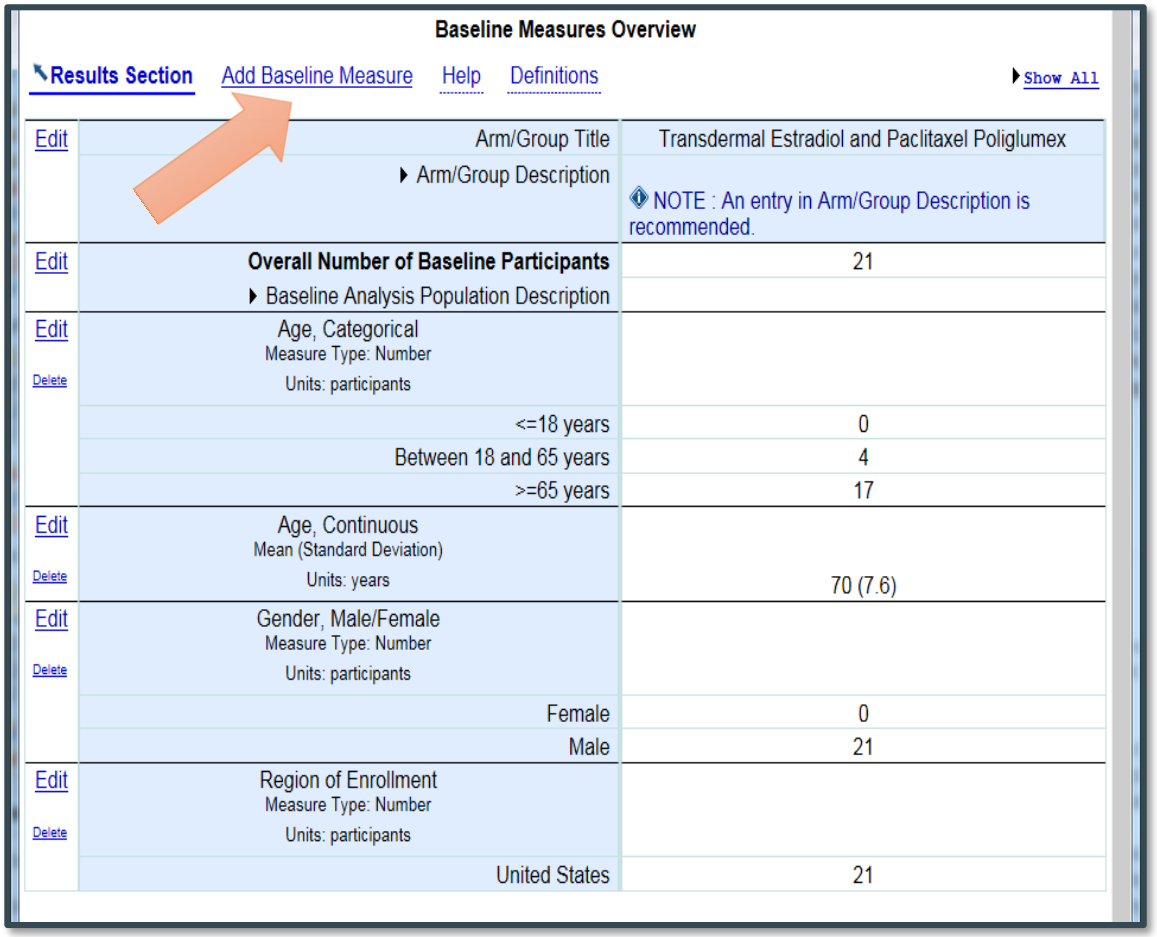
- Study that is reporting multiple periods
- Multiple Arms

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: *A table of demographic and baseline data, similar to Table 1 in a journal article*
- To add another measure, click **Add Baseline Measure**
- continued on next slide…



Baseline Measures Overview

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

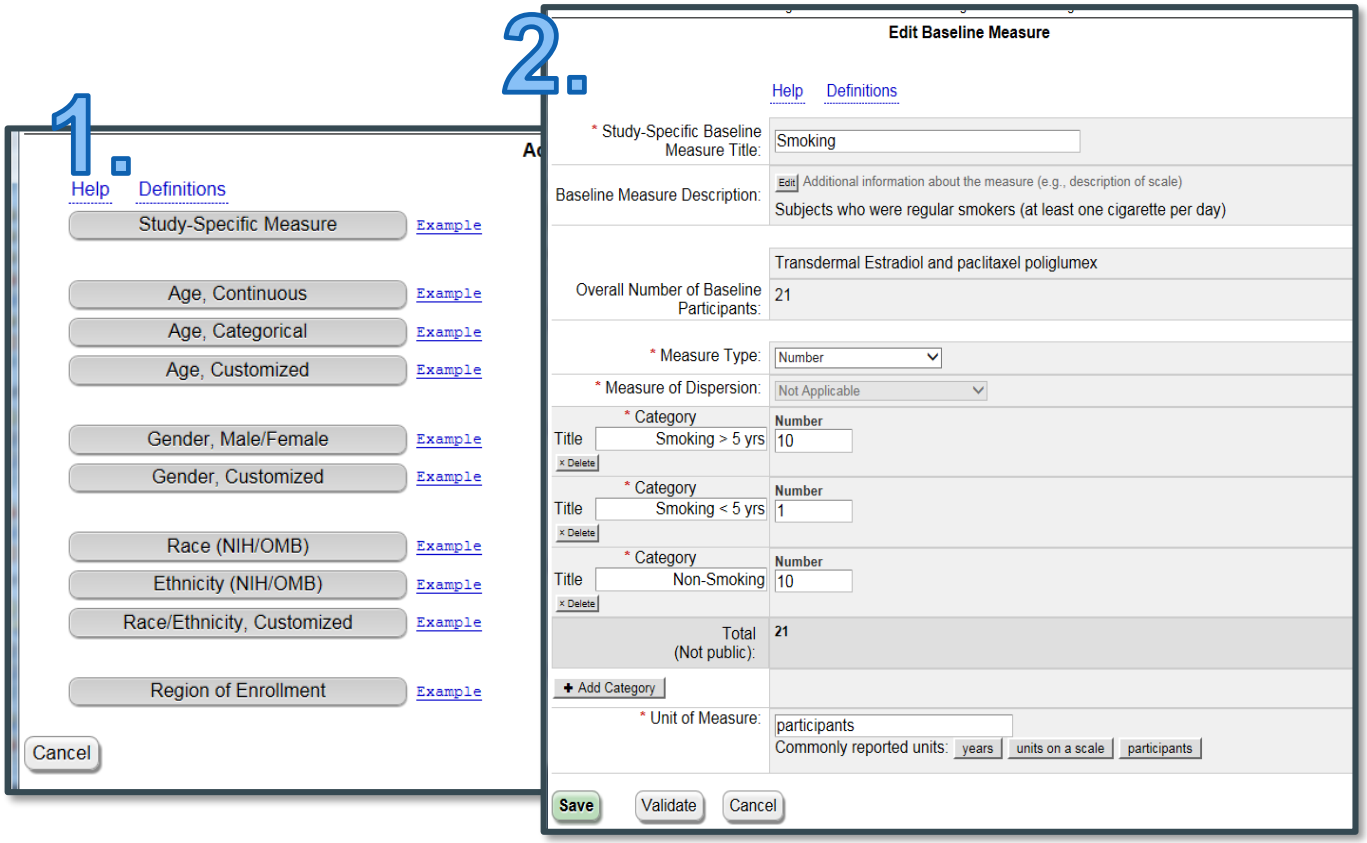
Edit	Arm/Group Title	Transdermal Estradiol and Paclitaxel Poliglumex
	Arm/Group Description	NOTE : An entry in Arm/Group Description is recommended.
Edit	**Overall Number of Baseline Participants**	21
	Baseline Analysis Population Description	
Edit Delete	Age, Categorical Measure Type: Number Units: 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

Refer to template:
http://prsinfo.clinicaltrials.gov/results_table_layout/DataEntryTable_BaselineRegionRaceEthnicityForm.pdf

Module 2: Baseline Characteristics

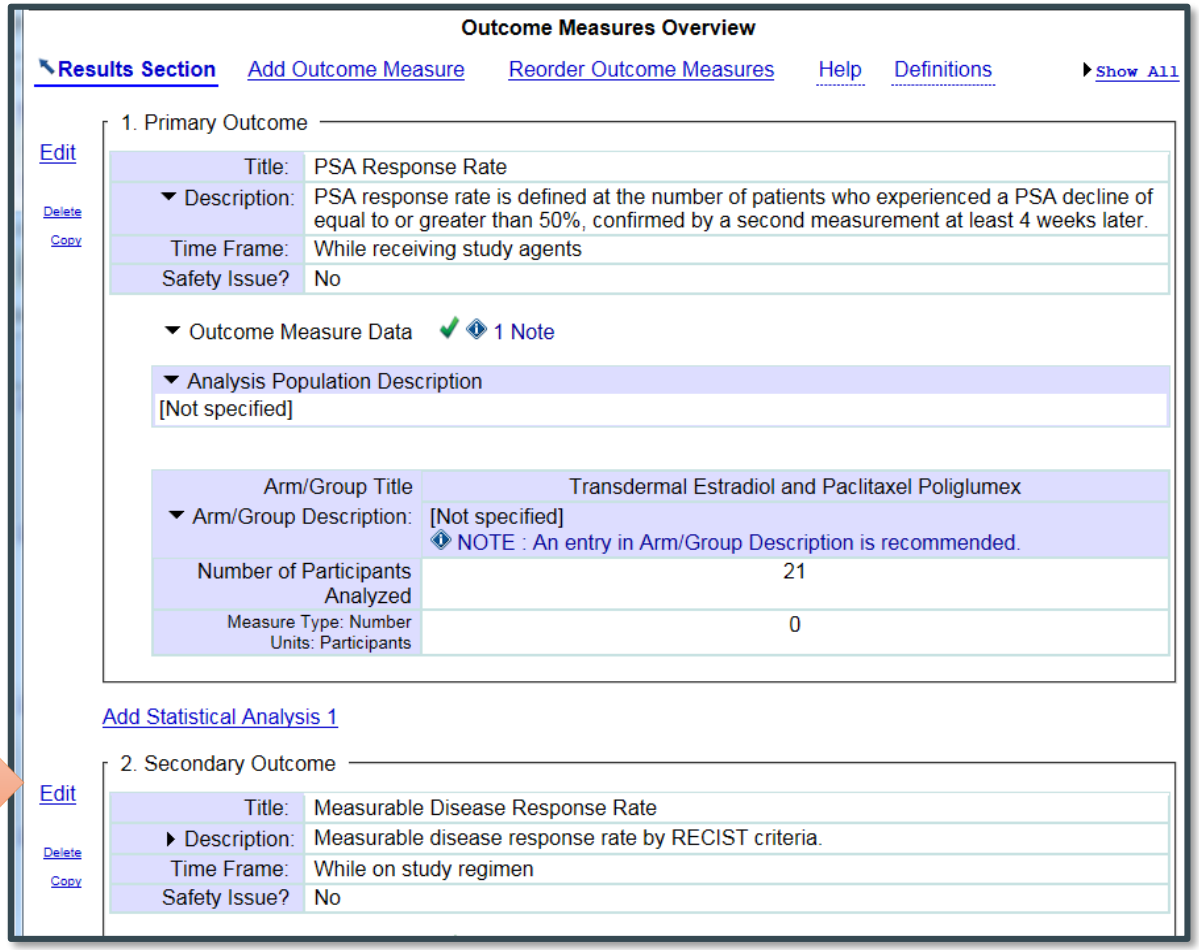
Add Baseline Measure cont.

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

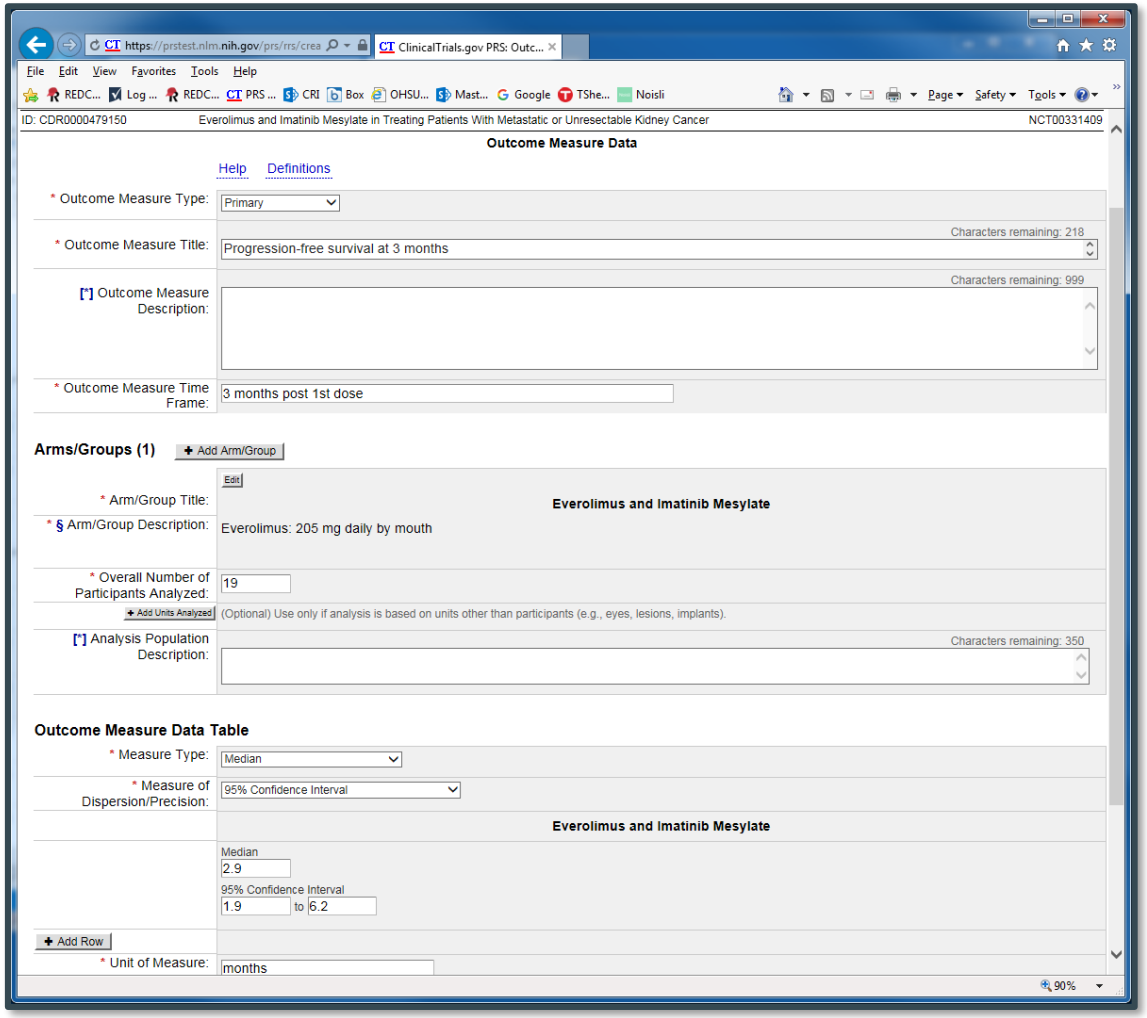


Refer to template:
http://prsinfo.clinicaltrials.gov/results_table_layout/DataEntryTable_OMForm.pdf

Module 3: Outcome Measures & Statistical Analyses

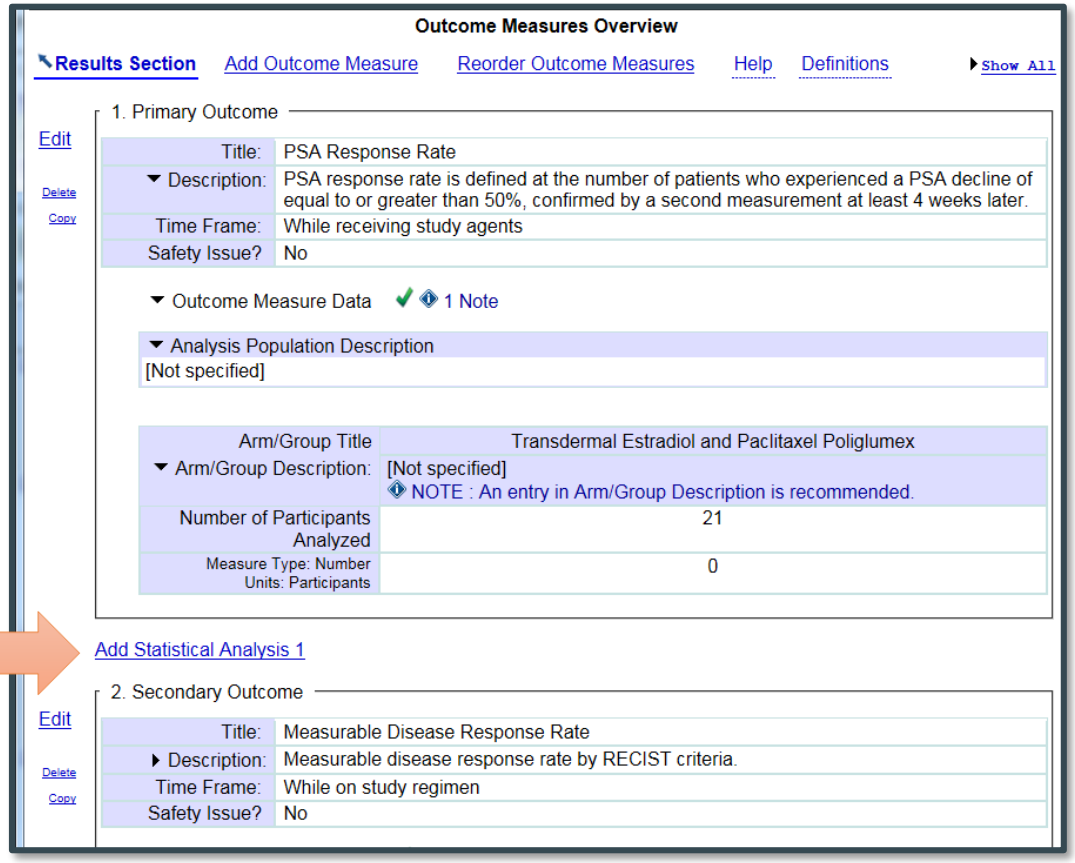
Edit Outcome cont.

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

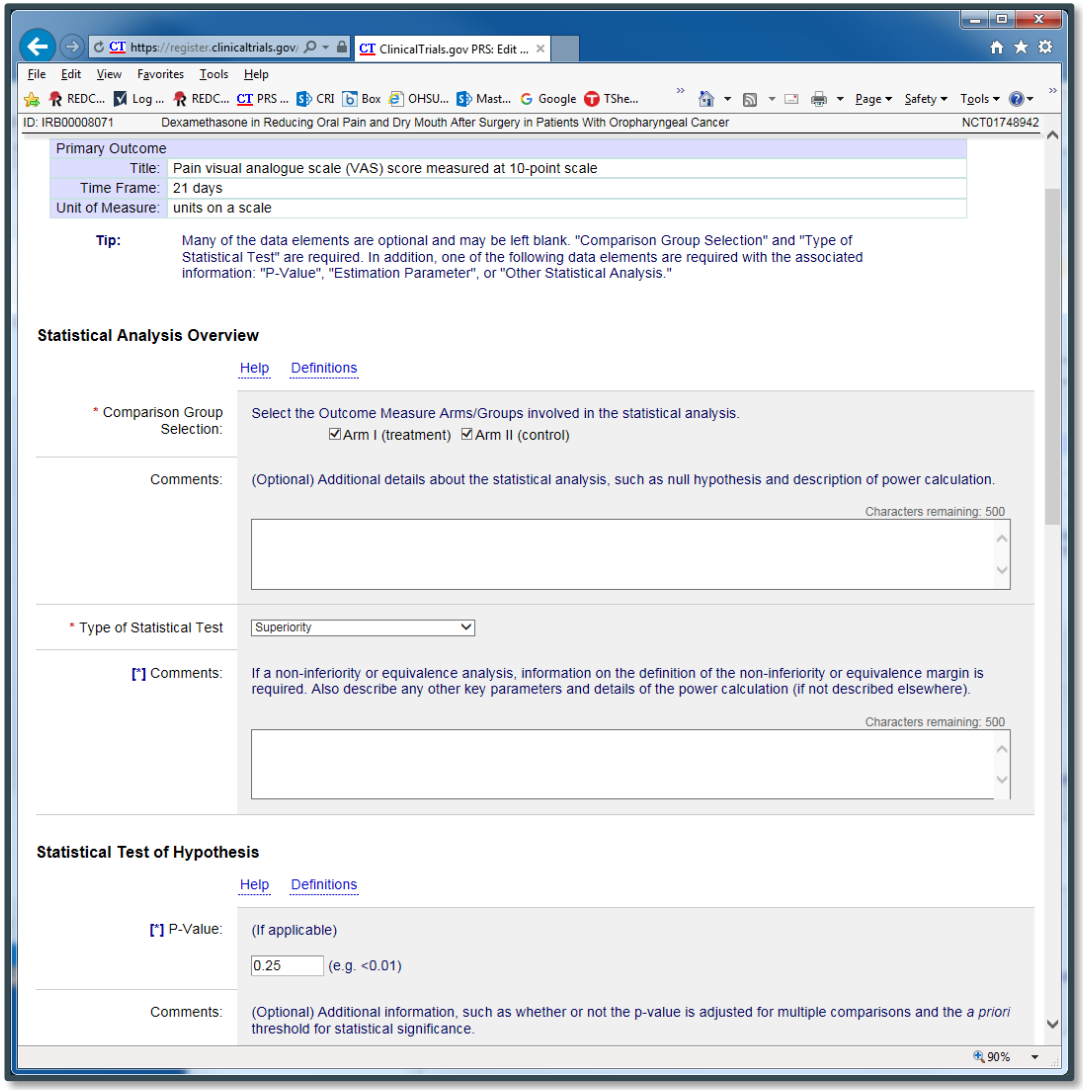
- Once you've finished entering your outcome data
- You'll see a summarized view of the outcome
- To add additional details about the analysis behind the outcome, Click **Add Statistical Analysis**



Module 3: Outcome Measures & Statistical Analyses

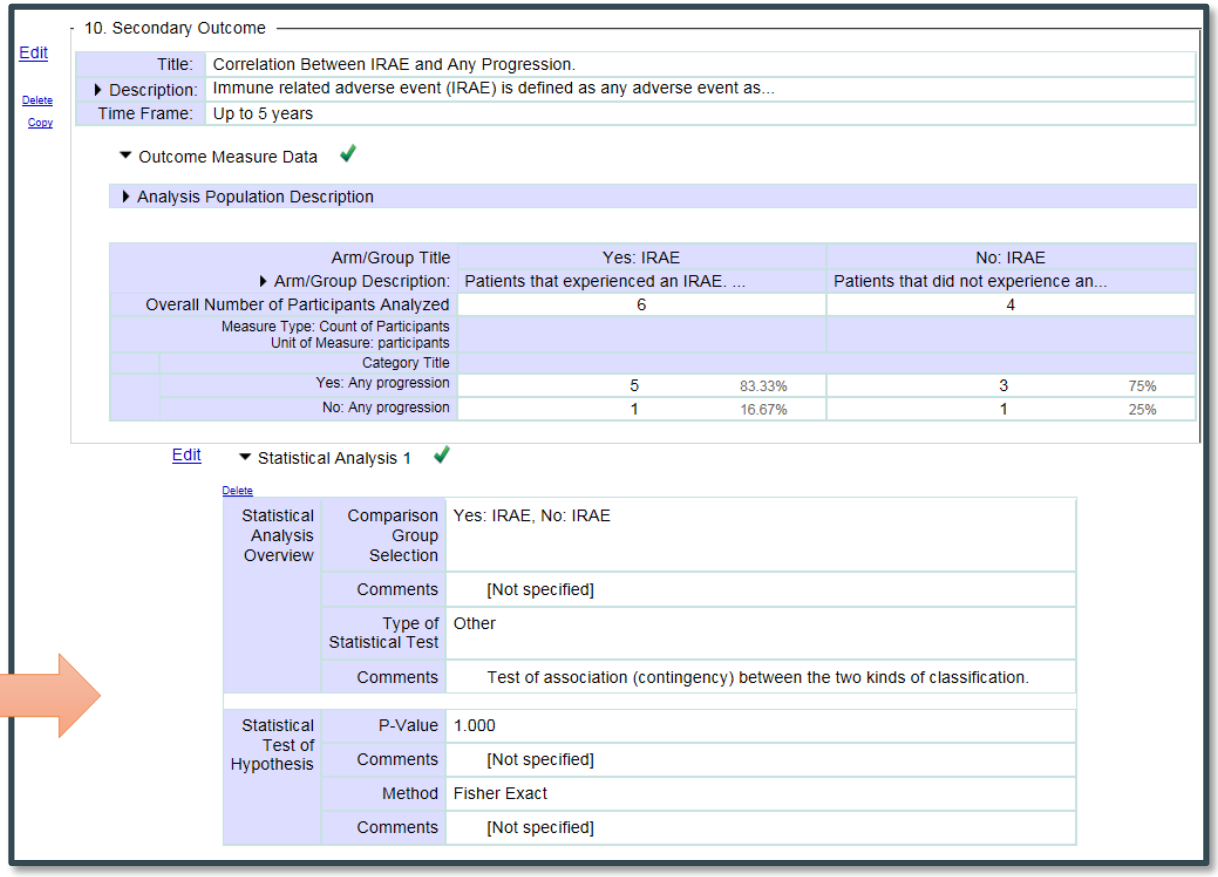
Statistical Analysis cont.

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.)
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.
- After you save, you'll see a summarize view of the analysis
- Display right under the Outcome Data



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."*

- Starts with SAEs first, then Other AEs
- Data is complied by organ system then:
  - Number of subjects affected*
  - Number subjects at risk* *(number that received the intervention)*
  - Number of events (optional)

* There is an upload option….

Adverse Events Overview

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

Edit	Time Frame	Adverse Events were collected from the start of Ipilimumab therapy until off study for progression, adverse event or other reason, an average of one year.
	Adverse Event Reporting Description	Only Adverse Events that are considered possibly related or related to the study procedures or study drug are reported.
	Source Vocabulary Name for Table Default	CTCAE (4.0)
	Collection Approach for Table Default	Non-systematic Assessment
Edit	Arm/Group Title	Treatment (Ipilimumab)
	Arm/Group Description	Patients receive ipilimumab IV over...

All-Cause Mortality

		Treatment (Ipilimumab)
		Affected / at Risk (%)
Edit	Total	2/10 (20%)

Serious Adverse Events

			Treatment (Ipilimumab)	
			Affected / at Risk (%)	# Events
Edit		Total	1/10 (10%)	
Edit	Gastrointes...	Diarrhea * A	1/10 (10%)	1

∗ Indicates events were collected by non-systematic methods.
A Term from vocabulary, CTCAE (4.0)

Add Serious Adverse Event

Other (Not Including Serious) Adverse Events

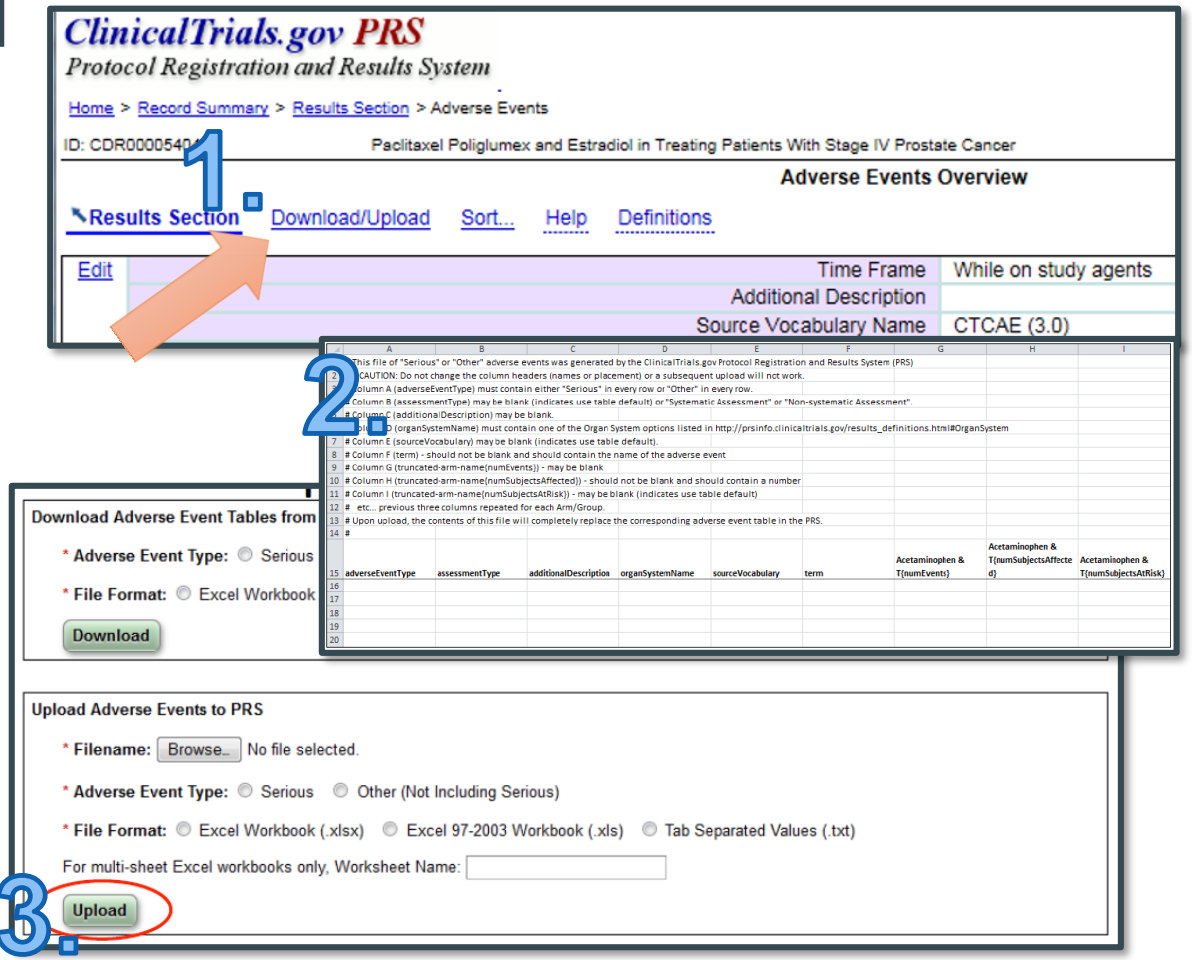
Edit		Frequency Threshold for Reporting Other Adverse Events	5%	
			Treatment (Ipilimumab)	
			Affected / at Risk (%)	# Events
Edit		Total	10/10 (100%)	
Edit	Skin and su...	Pruritus * A	4/10 (40%)	4
	Gastrointes...	Diarrhea * A	6/10 (60%)	11
	Skin and su...	Skin and subcutaneous tissue disorders - Other [1] * A	4/10 (40%)	4
	General dis...	Fatigue * A	4/10 (40%)	4
	General dis...	Fever * A	3/10 (30%)	3
	Musculoskel...	Myalgia * A	3/10 (30%)	5
	Skin and su...	Dry Skin * A	1/10 (10%)	1

Refer to template:
http://prsinfo.clinicaltrials.gov/results_table_layout/DataEntryTable_SAEForm.pdf
http://prsinfo.clinicaltrials.gov/results_table_layout/DataEntryTable_FreqAEForm.pdf

Module 4: Adverse Events

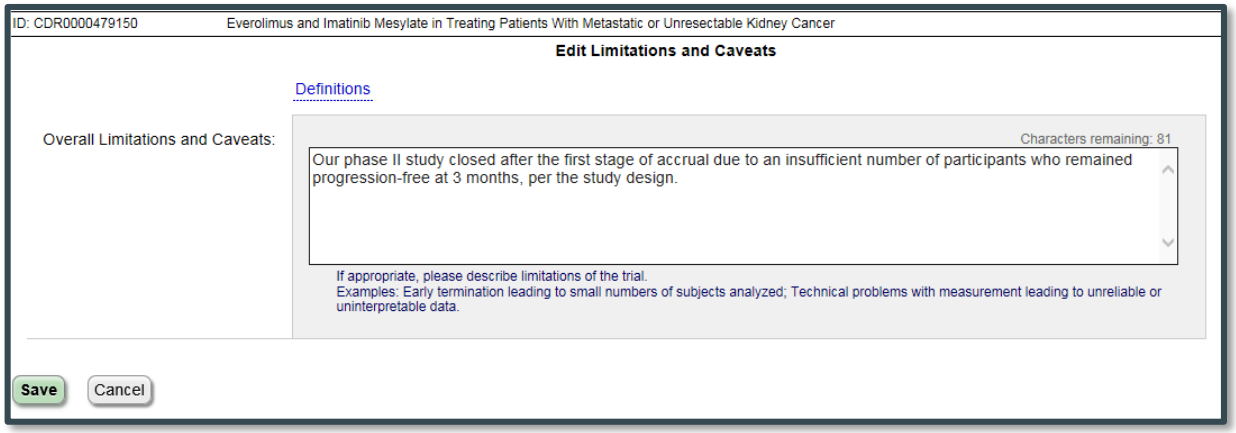
Can bulk upload Adverse Events

1. Click Download /Upload
2. Download Excel template and fill out
3. Click upload
4. Double check results



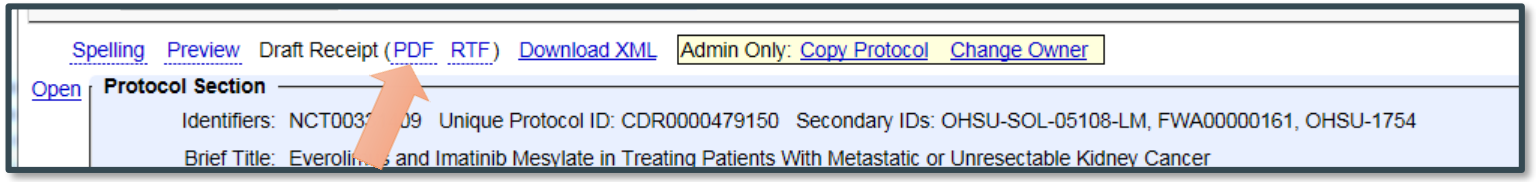
Last Two Sections

- Limitations and Caveats
- More Information
  - Certain agreements
  - Points of Contact



Finished with Results Entry

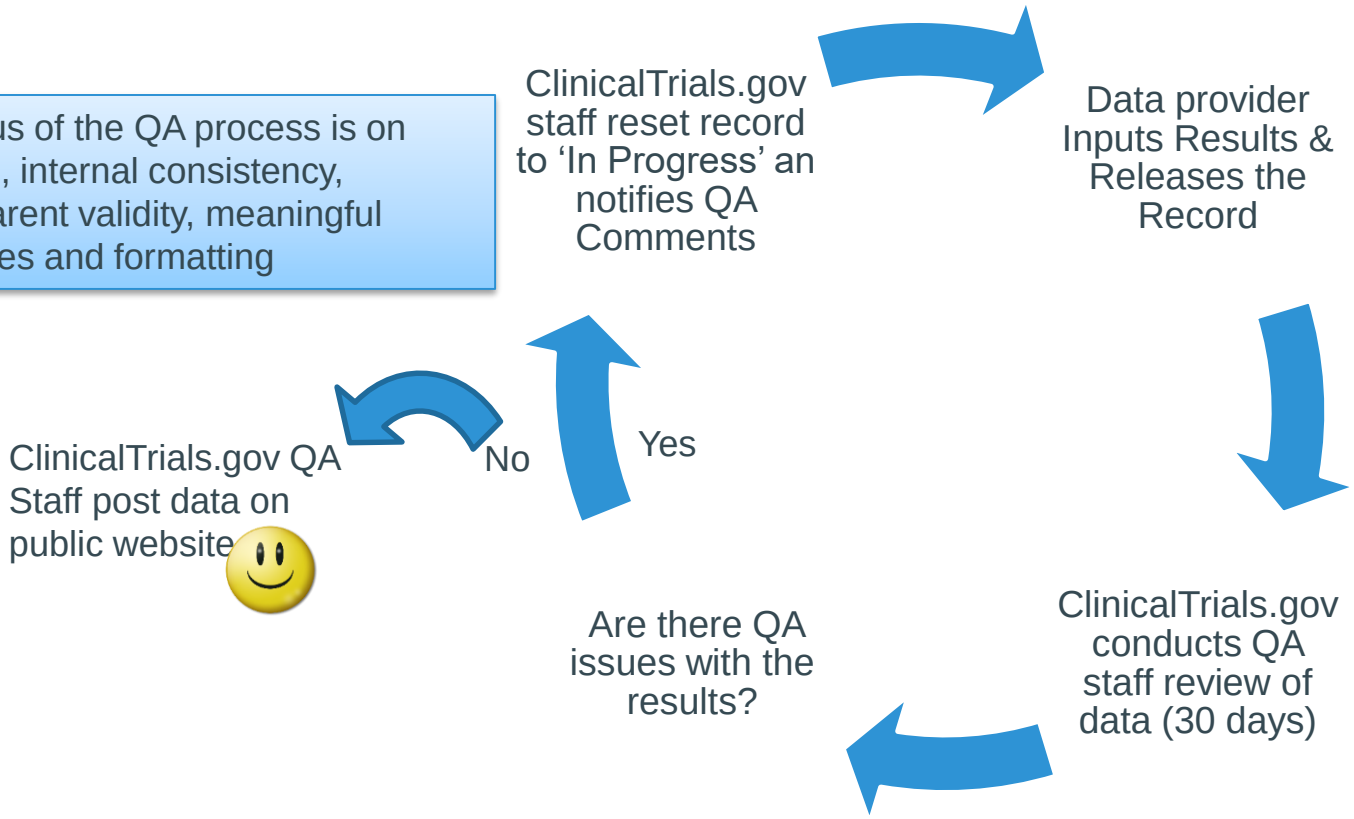
- When you're all finished with results entry we recommend
  - **Have a second person (ideally the PI and/or Biostatistician) review it**
    - Mistakes can be embarrassing
  - You can export a RTF or PDF version of the entire registration & results data if they are not comfortable navigating in CT.gov



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

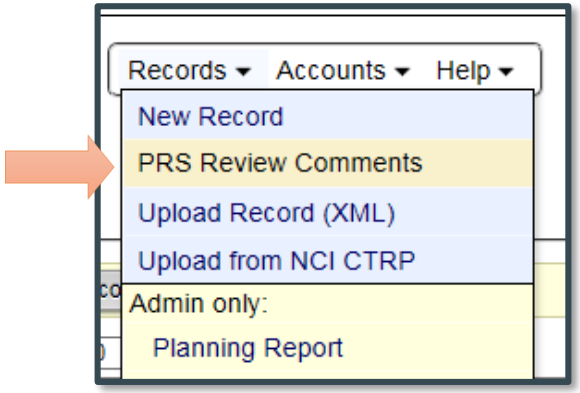
ClinicalTrials.gov PRS QA Process

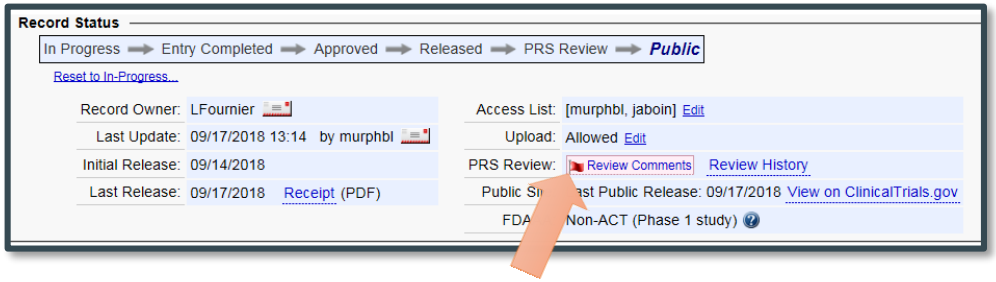
Focus of the QA process is on logic, internal consistency, apparent validity, meaningful entries and formatting



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.
- Or select the study record and there's a red flag with link upper right under Record Status.

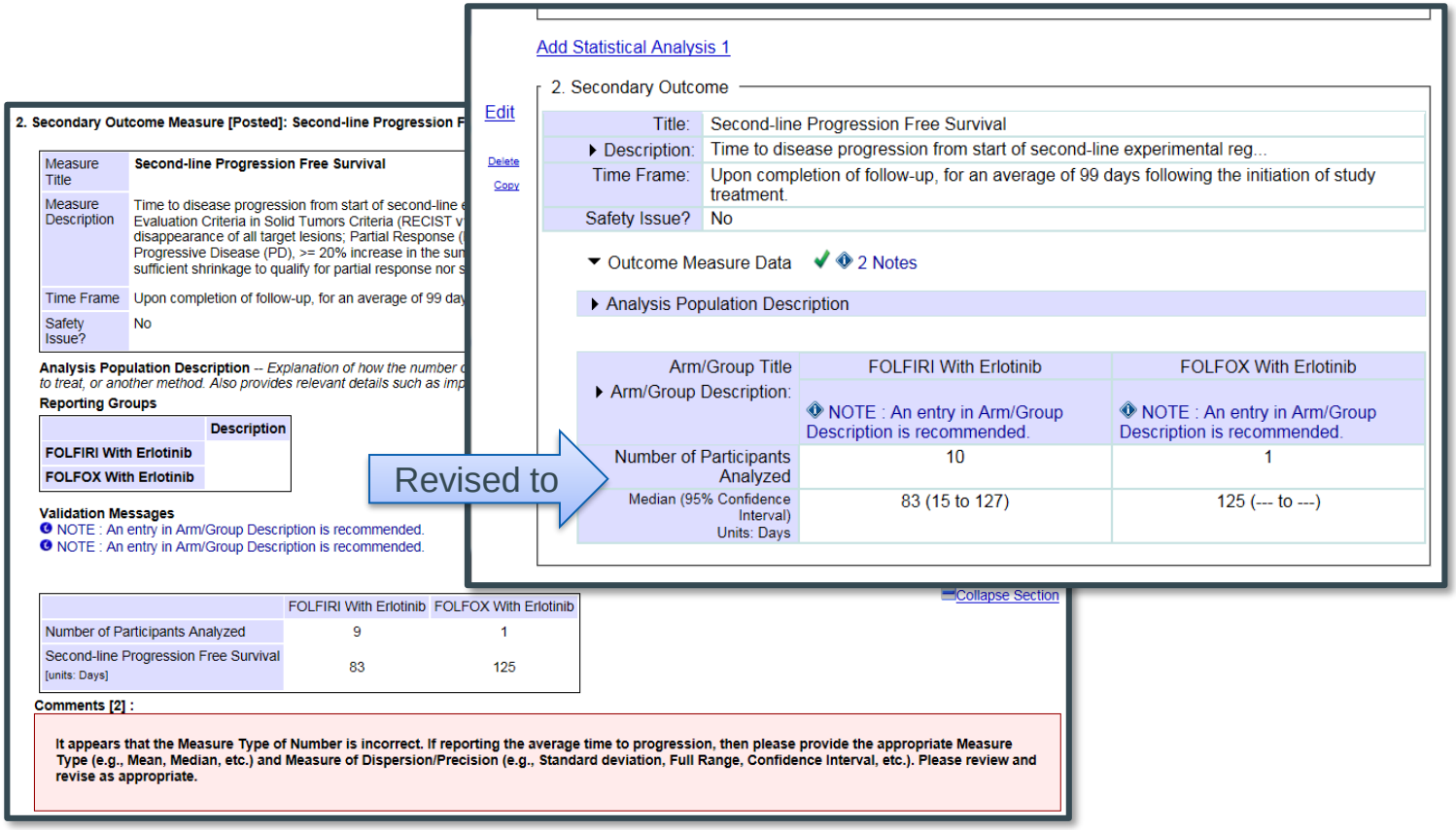




ClinicalTrials.gov PRS QA Process

Example 1:

- Measure Types need to be consistent with outcome description



ClinicalTrials.gov PRS QA Process

- Other common QA issues
  - Totals should match with actual enrollment specified in registration, else explain.
  - Outcome title and/or description need to be very specific to fully understand what is being measured
  - If you have questions regarding your comments, you can email ClinicalTrials.gov register@clinicaltrials.gov

ClinicalTrials.gov PRS QA Process

- 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
  - Secondary outcomes can be posted later (but must be posted within 12 months of overall)
- **Better to post what you have by due date, than be late.**

Overall Tips & Tricks

- Remember to **Save** your work, or **Cancel** if discarding
- Journal publications can be more detailed/expansive than results posted to ClinicalTrials.gov, however…
  - Results should be consistent and congruent across platforms.
  - If publishing *after* posting results, update results in the PRS to ensure they are consistent with publication
- Ensure units and scales are labeled, consistent, understandable
- Use simple outcome titles and avoid using verbs (e.g. "To determine…") in descriptions
  - Focus on what is measured and not why
- You are not required to address all PRS-generated "Notes" before submitting results, however:
  - Warnings, errors, and PRS Review Comments must be addressed
- Expand and define acronyms upon first use within results

Overall Tips & Tricks

- It is OK to disagree with and discuss PRS Review Comments and errors
  - Email register@clinicaltrials.gov and reference the trial NCT#
  - Corresponding analyst can leave notes for the next analyst to review
    - Notes will only be reviewed by next analyst after the record has been released again

Overall Tips & Tricks

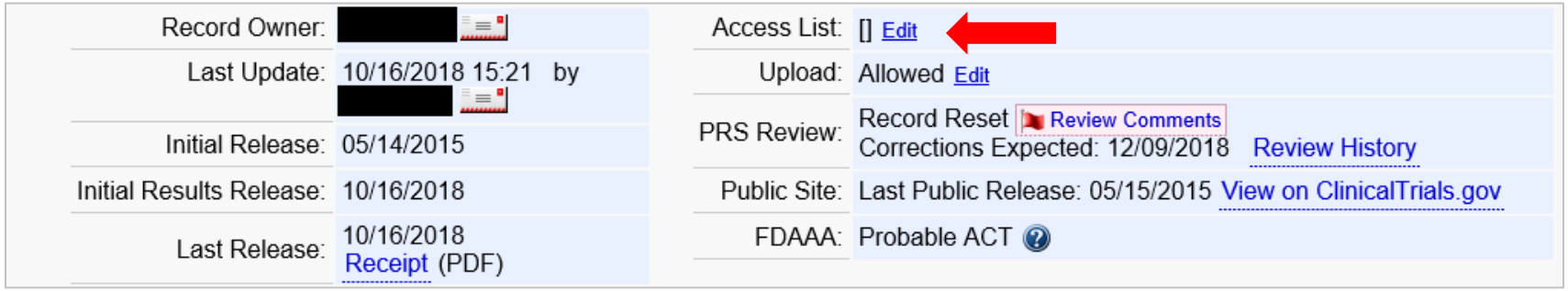
- Editing record data in the PRS does NOT automatically update ClinicalTrials.gov
  - Mark **ENTRY COMPLETE** when changes to data are done
  - Record Owner or Responsible Party has to log in, review, and **APPROVE** the record
  - Responsible Party has to log in, review and **RELEASE** the record
  - PRS analysts have to perform **PRS REVIEW** (minor revisions take 2-5 days) and will push to ClinicalTrials.gov ONLY IF there are no errors, warnings, or PRS Review Comments to issue

Overall Tips & Tricks

- Revise the **Record Verification Date** to help in the release of a record
  - Example: An advisory PRS Review Comment is disagreed upon by the PI and no other data should be altered. Without changes to PRS Review Comments the system won't let you release the record.
    - Modify the Record Verification Date under the Protocol Section → Study Status, then mark data entry complete and release

Overall Tips & Tricks

- Utilize the record **Access List** to delegate PRS maintenance and results reporting
  - Consider adding co-investigators, study team members, partnering biostatisticians
  - Apply for an individual PRS account via https://clinicaltrials.gov/ct2/apply-account-individ?indivAccount=true
  - For cancer-studies, email ctrp-admin@ohsu.edu for a PRS account.

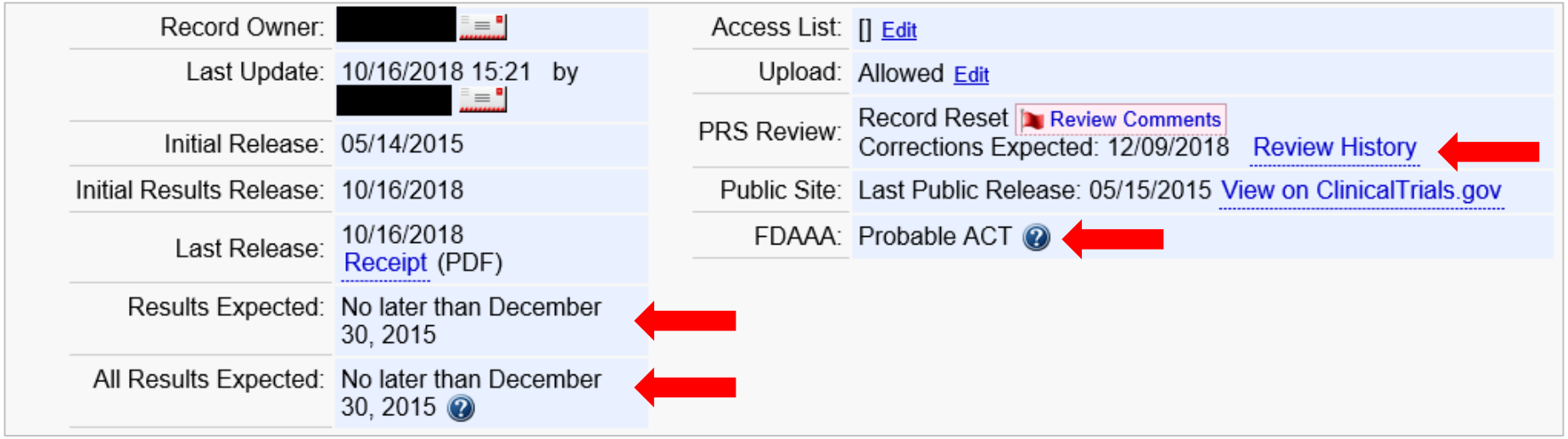


Overall Tips & Tricks

- Make updating of PRS records routine
  - Follow FDA update timeline requirements: https://clinicaltrials.gov/ct2/manage-recs/faq#fr_23
  - Small, consistent updates throughout trial conduct make study completion and results reporting easier
    - If managing multiple PI/department records, consider performing systematic updates across the calendar month
    - Log in to https://register.clinicaltrials.gov and always check PRS “Problems” column (far right)

Overall Tips & Tricks

- Utilize the Record Status dashboard
  - See if analysts consider the study an Applicable Clinical Trial (ACT)
  - See when analysts expect you to make corrections (in response to review comments), submit study results, etc.



Overall Tips & Tricks

- Get support and ask questions!
  - Email John Hicks at hickjo@ohsu.edu if you have questions about an OHSU investigator-initiated trial (IIT) with ClinicalTrials.gov
    - **Coming soon!** Clinical Research Services Office (CRSO) support webpage and resources for ClinicalTrials.gov
  - Email Knight Cancer Institute (ctrp-admin@ohsu.edu) with any questions about cancer studies

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 Definitions: 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 Information Page: https://bridge.ohsu.edu/research/knight/resources/kcto/SitePages/Knight%20Clinical%20Trials%20Study%20Registration.aspx
- Emails: (cancer) Knight CRQA CTRP/CT.gov staff ctrp-admin@ohsu.edu
- Emails: (non-cancer) Non-cancer hickjo@ohsu.edu
- OHSU policy for Non-cancer IIT trial registration https://bridge.ohsu.edu/community/rate/Shared%20Documents/OHSU_Policy_ClinicalTrials_InvestigatorInitiated_RegistrationReporting_20181114.pdf
- OHSU RAIN (Research Administration Information Network): https://o2.ohsu.edu/research-administration-training-education/research-administration-information-network/index.cfm

Some of the slides were adapted with permission from the work of the Clinical and Translational Science Awards (CTSA) program's Clinical Trials Registration Workgroup of the Regulatory Knowledge Key Function Committee. Original slides available at Harvard Catalyst https://catalyst.harvard.edu/programs/regulatory/clinical-trial-reg.html

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Thank You