



Clinical Trials Results Reporting

OHSU Knight Cancer Institute

Oregon Clinical and Translational Research Institute

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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

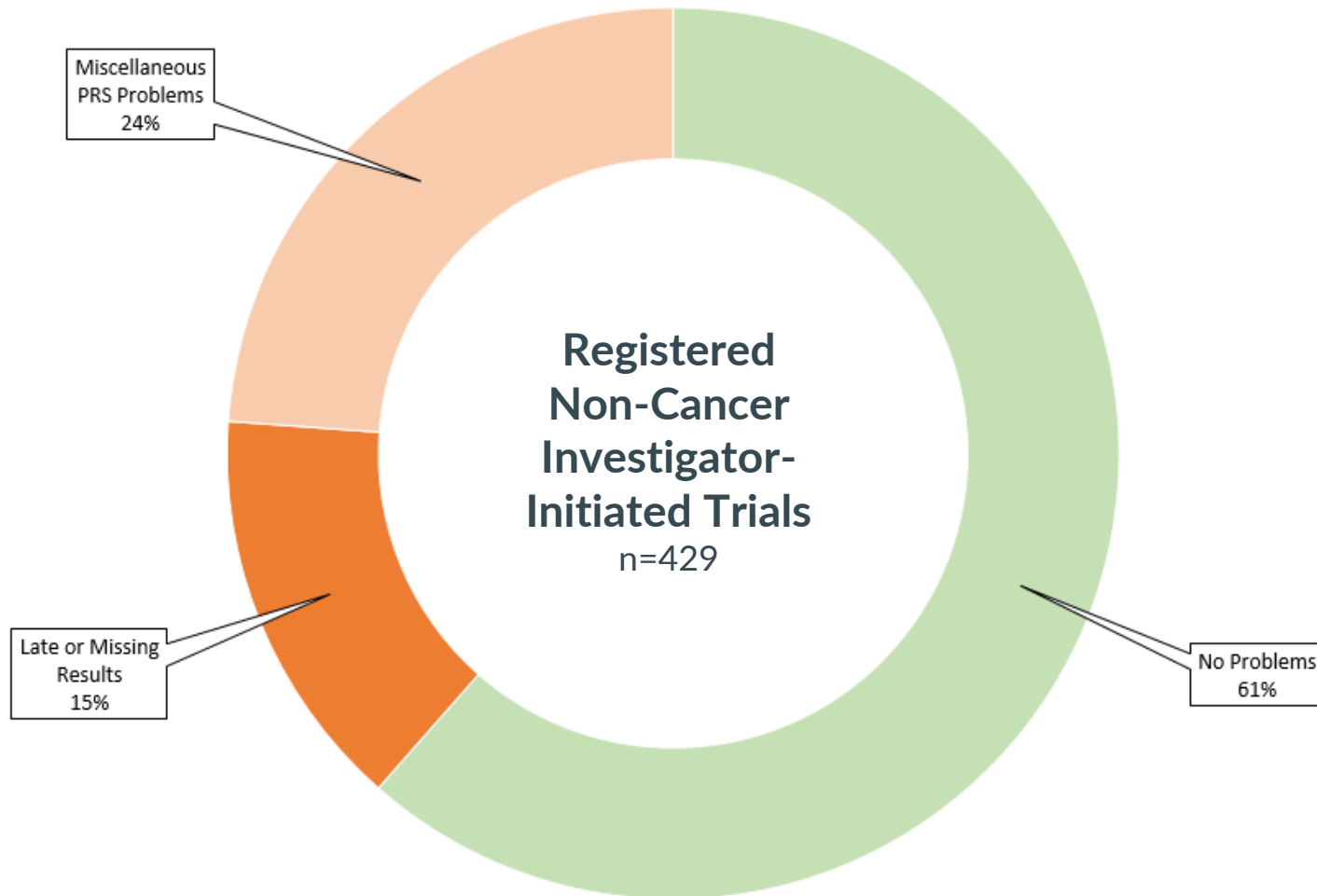
Why Is This Needed?

- 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)? <i>Study Type data element is "Interventional"</i>	<input type="checkbox"/>	<input type="checkbox"/>
2. Do ANY of the following apply (is the answer "Yes" to <u>at least one</u> of the following sub-questions: 2a, 2b, OR 2c)?	<input type="checkbox"/>	<input type="checkbox"/>
a. Is at least one study facility located in the United States or a U.S. territory? <i>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.</i>		
b. Is the study conducted under a U.S. FDA Investigational New Drug application (IND) or Investigational Device Exemption (IDE)? <i>U.S. Food and Drug Administration IND or IDE Number data element is "Yes."</i>		
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? <i>Product Manufactured in and Exported from the U.S. data element is "Yes."</i>		
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)? <i>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."</i>	<input type="checkbox"/>	<input type="checkbox"/>
4. Is the study <u>other than</u> a Phase 1 trial of a drug and/or biological product or is the study <u>other than</u> a device feasibility study? <i>For drug product trials, Study Phase data element is NOT "Phase 1" and for device product trials, Primary Purpose is NOT "Device Feasibility."</i>	<input type="checkbox"/>	<input type="checkbox"/>

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.

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

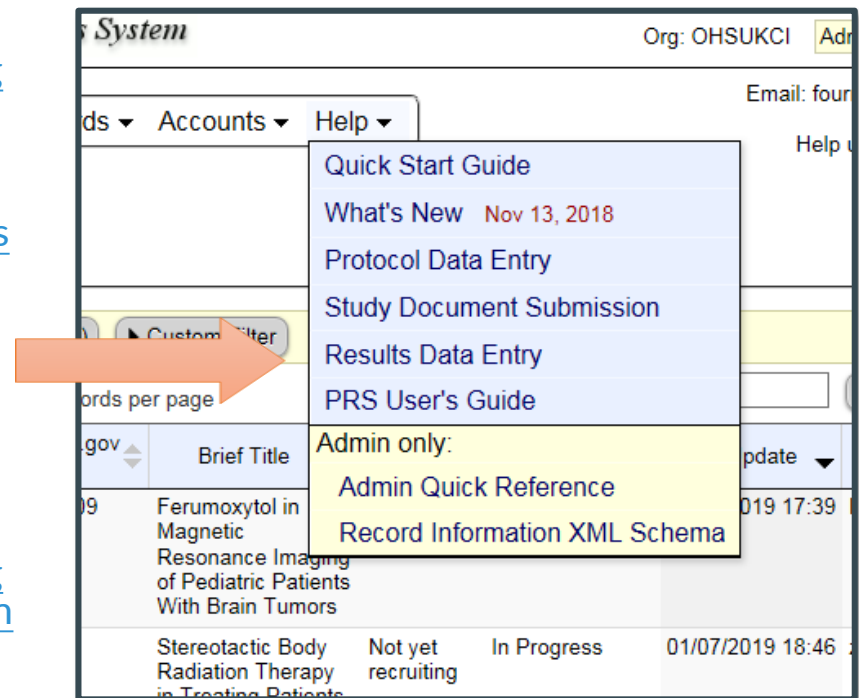
Appendix A: Sample Study Team Work Plan for Study Results

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.



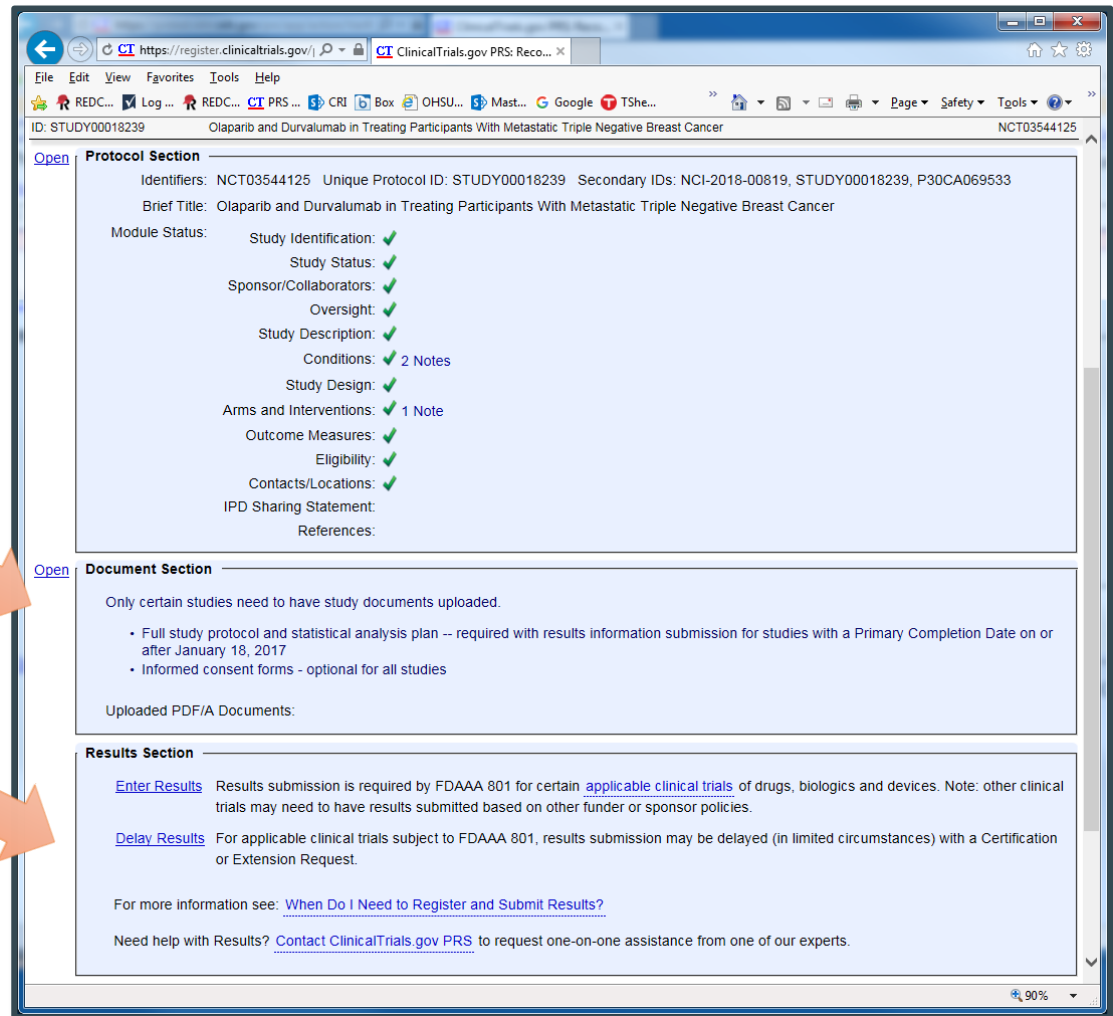
Preparing For Results Reporting

- 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

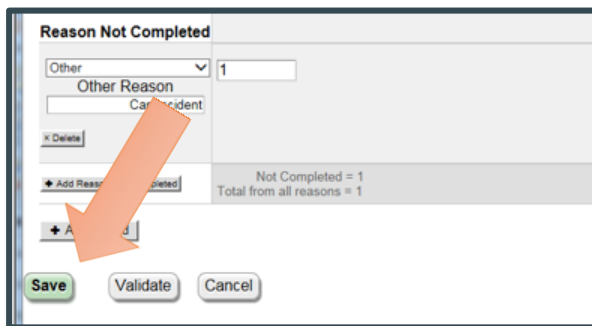
1. Getting started cont....
Click **Edit** to begin entry on the 4 modules
2. When complete with all 4 modules, make sure to complete **Limitations and Caveats** (if applicable), and **Agreements & Contacts**
3. Completing the Limitations section will be *important if there are issues with your results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

A screenshot of a web browser showing the ClinicalTrials.gov Results Section for study ID: STUDY00018408. The browser address bar shows the URL: https://prtest.nlm.nih.gov/prs/rs/Nav. The page title is "ClinicalTrials.gov PRS: Resu...". The page content includes a navigation bar with links: Home, Record Summary, Results Section, and [NCT ID not yet assigned]. Below the navigation bar, there are tabs for Record Summary, Preview Results, Download Results XML, Delete Results, Help, and Definitions. The main content area is divided into sections: Participant Flow, Baseline Characteristics, Outcome Measures, Adverse Events, Limitations and Caveats, and More Information. Each section has an "Edit" or "Open" link and a message "Information is required". The "Limitations and Caveats" section is currently expanded, showing a "Certain Agreements" section with a message "[Relationship of Principal Investigator and Sponsor not specified.] Information is required" and a "Results Point of Contact" section with fields for Name/Official Title, Organization, Phone, and Email, all marked as "Information is required".

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**

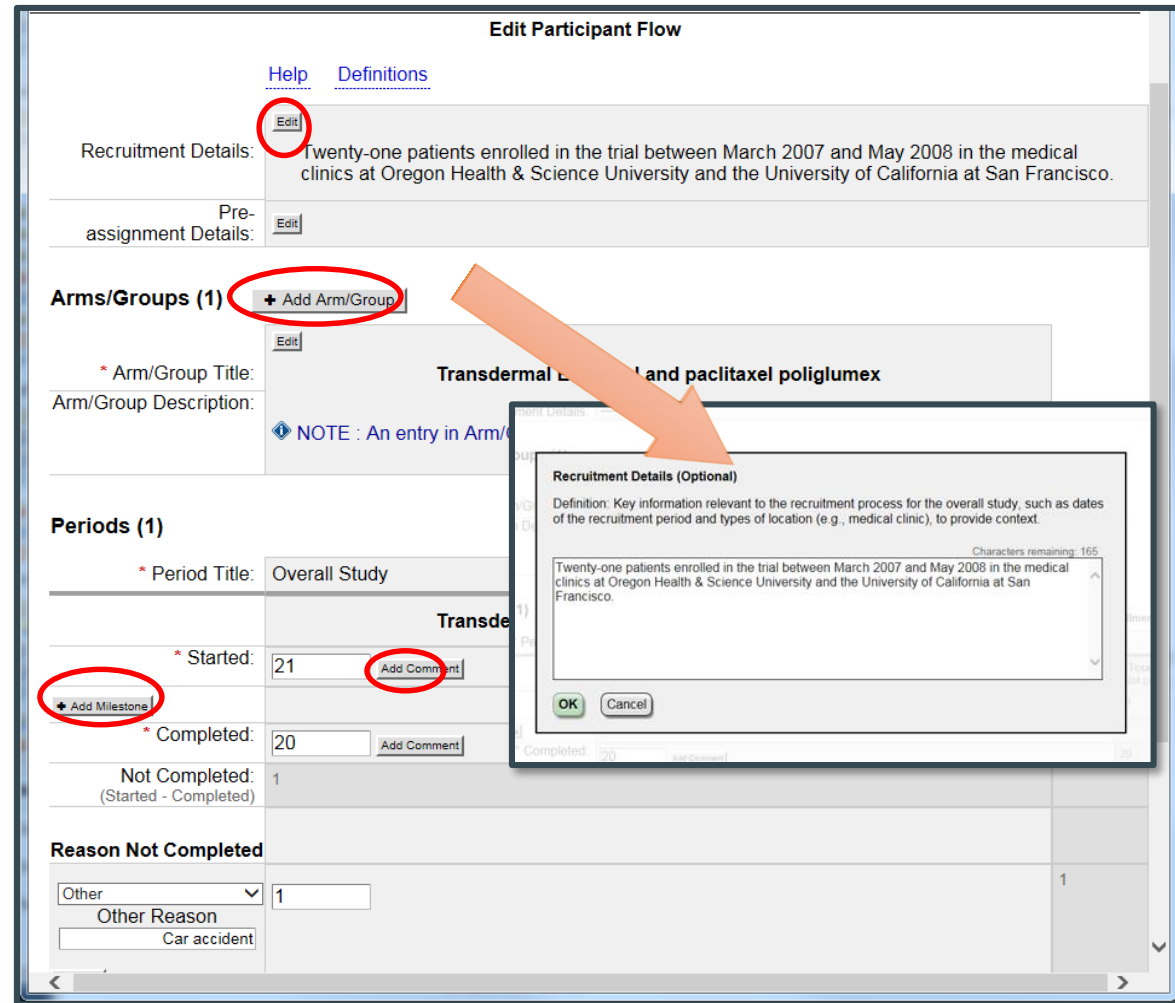


Reason Not Completed

Other Reason: 1
Other Reason: Car accident

Not Completed = 1
Total from all reasons = 1

Save **Validate** **Cancel**



Edit Participant Flow

[Help](#) [Definitions](#)

Recruitment Details: **Edit** Twenty-one patients enrolled in the trial between March 2007 and May 2008 in the medical clinics at Oregon Health & Science University and the University of California at San Francisco.

Pre-assignment Details: **Edit**

Arms/Groups (1) **+ Add Arm/Group**

* Arm/Group Title: Transdermal E and paclitaxel poliglumex

Arm/Group Description: NOTE : An entry in Arm/

Periods (1)

* Period Title: Overall Study

* Started: 21 **Add Comment**

* Completed: 20 **Add Comment**

Not Completed: 1
(Started - Completed)

Reason Not Completed

Other Reason: 1
Other Reason: Car accident

Recruitment Details (Optional)

Definition: Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and types of location (e.g., medical clinic), to provide context.

Twenty-one patients enrolled in the trial between March 2007 and May 2008 in the medical clinics at Oregon Health & Science University and the University of California at San Francisco.

OK **Cancel**

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
<u>Reason Not Completed</u>		
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
<u>Reason Not Completed</u>			
Adverse Event	1	5	6
Withdrawal by Subject	2	3	5
(Not Public)		Not Completed = 8 Total from all reasons = 8	
		Not Completed = 3 Total from all reasons = 3	
Period Title: Follow-up			
Started	24	24	48
		NOTE : The number of participants to start a Period is not equal to the number who completed previous Period.	
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	<div> <div>Arm/Group Title</div> <div>Transdermal Estradiol and Paclitaxel Poliglumex</div> <div> <div>Arm/Group Description</div> <div>NOTE : An entry in Arm/Group Description is recommended.</div> </div> </div>	
Edit	<div> <div>Overall Number of Baseline Participants</div> <div>21</div> <div> <div>Baseline Analysis Population Description</div> </div> </div>	
Edit Delete	<div> <div>Age, Categorical</div> <div>Measure Type: Number</div> <div>Units: participants</div> </div>	
	<=18 years	0
	Between 18 and 65 years	4
	>=65 years	17
Edit Delete	<div> <div>Age, Continuous</div> <div>Mean (Standard Deviation)</div> <div>Units: years</div> </div>	70 (7.6)
Edit Delete	<div> <div>Gender, Male/Female</div> <div>Measure Type: Number</div> <div>Units: participants</div> </div>	
	Female	0
	Male	21
Edit Delete	<div> <div>Region of Enrollment</div> <div>Measure Type: Number</div> <div>Units: participants</div> </div>	
	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

1.

[Help](#) [Definitions](#)

Study-Specific Measure [Example](#)

Age, Continuous [Example](#)

Age, Categorical [Example](#)

Age, Customized [Example](#)

Gender, Male/Female [Example](#)

Gender, Customized [Example](#)

Race (NIH/OMB) [Example](#)

Ethnicity (NIH/OMB) [Example](#)

Race/Ethnicity, Customized [Example](#)

Region of Enrollment [Example](#)

[Cancel](#)

2.

Edit Baseline Measure

[Help](#) [Definitions](#)

* Study-Specific Baseline Measure Title:

Baseline Measure Description: [Edit](#) Additional information about the measure (e.g., description of scale)
Subjects who were regular smokers (at least one cigarette per day)

Overall Number of Baseline Participants:

Transdermal Estradiol and paclitaxel poliglumex

* Measure Type:

* Measure of Dispersion:

* Category Number
[x Delete](#)

* Category Number
[x Delete](#)

* Category Number
[x Delete](#)

Total (Not public): 21

[+ Add Category](#)

* Unit of Measure:
Commonly reported units:

[Save](#) [Validate](#) [Cancel](#)

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

Outcome Measures Overview

[Results Section](#) [Add Outcome Measure](#) [Reorder Outcome Measures](#) [Help](#) [Definitions](#) [Show All](#)

1. Primary Outcome

[Edit](#) [Delete](#) [Copy](#)

Title:	PSA Response Rate
Description:	PSA response rate is defined at the number of patients who experienced a PSA decline of equal to or greater than 50%, confirmed by a second measurement at least 4 weeks later.
Time Frame:	While receiving study agents
Safety Issue?	No

Outcome Measure Data 1 Note

Analysis Population Description

[Not specified]

Arm/Group Title	Transdermal Estradiol and Paclitaxel Poliglumex
Arm/Group Description:	[Not specified] NOTE : An entry in Arm/Group Description is recommended.
Number of Participants Analyzed	21
Measure Type: Number Units: Participants	0

[Add Statistical Analysis 1](#)

2. Secondary Outcome

[Edit](#) [Delete](#) [Copy](#)

Title:	Measurable Disease Response Rate
Description:	Measurable disease response rate by RECIST criteria.
Time Frame:	While on study regimen
Safety Issue?	No

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

The screenshot shows the 'Outcome Measure Data' form for ClinicalTrials.gov study NCT00331409, titled 'Everolimus and Imatinib Mesylate in Treating Patients With Metastatic or Unresectable Kidney Cancer'. The form is divided into several sections:

- Outcome Measure Data:**
 - Outcome Measure Type:** Primary
 - Outcome Measure Title:** Progression-free survival at 3 months (Characters remaining: 218)
 - Outcome Measure Description:** (Characters remaining: 999)
 - Outcome Measure Time Frame:** 3 months post 1st dose
- Arms/Groups (1):**
 - Arm/Group Title:** Everolimus and Imatinib Mesylate
 - Arm/Group Description:** Everolimus: 205 mg daily by mouth
 - Overall Number of Participants Analyzed:** 19
 - Analysis Population Description:** (Characters remaining: 350)
- Outcome Measure Data Table:**
 - Measure Type:** Median
 - Measure of Dispersion/Precision:** 95% Confidence Interval
 - Median:** 2.9
 - 95% Confidence Interval:** 1.9 to 6.2
 - Unit of Measure:** months

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**

Outcome Measures Overview
[Results Section](#) [Add Outcome Measure](#) [Reorder Outcome Measures](#) [Help](#) [Definitions](#) [Show All](#)

[Edit](#)
[Delete](#)
[Copy](#)

1. Primary Outcome

Title:	PSA Response Rate
▼ Description:	PSA response rate is defined as the number of patients who experienced a PSA decline of equal to or greater than 50%, confirmed by a second measurement at least 4 weeks later.
Time Frame:	While receiving study agents
Safety Issue?	No

▼ Outcome Measure Data ✓ 1 Note

▼ Analysis Population Description
[Not specified]

Arm/Group Title	Transdermal Estradiol and Paclitaxel Poliglumex
▼ Arm/Group Description:	[Not specified] NOTE : An entry in Arm/Group Description is recommended.
Number of Participants Analyzed	21
Measure Type: Number Units: Participants	0

[Add Statistical Analysis 1](#)

[Edit](#)
[Delete](#)
[Copy](#)

2. Secondary Outcome

Title:	Measurable Disease Response Rate
► Description:	Measurable disease response rate by RECIST criteria.
Time Frame:	While on study regimen
Safety Issue?	No

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

The screenshot shows the 'ClinicalTrials.gov PRS: Edit' page for trial ID IRB00008071. The primary outcome is 'Pain visual analogue scale (VAS) score measured at 10-point scale' with a time frame of 21 days and units on a scale. A tip indicates that many data elements are optional, but 'Comparison Group Selection' and 'Type of Statistical Test' are required, along with one of 'P-Value', 'Estimation Parameter', or 'Other Statistical Analysis'.

Statistical Analysis Overview

[Help](#) [Definitions](#)

*** Comparison Group Selection:** Select the Outcome Measure Arms/Groups involved in the statistical analysis.
☒ Arm I (treatment) ☒ Arm II (control)

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

*** Type of Statistical Test:** Superiority

[?] Comments: If a non-inferiority or equivalence analysis, information on the definition of the non-inferiority or equivalence margin is required. Also describe any other key parameters and details of the power calculation (if not described elsewhere).
Characters remaining: 500

Statistical Test of Hypothesis

[Help](#) [Definitions](#)

[?] P-Value: (If applicable)
0.25 (e.g. <0.01)

Comments: (Optional) Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the *a priori* threshold for statistical significance.

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

10. Secondary Outcome

[Edit](#)
[Delete](#)
[Copy](#)

Title: Correlation Between IRAE and Any Progression.

► Description: Immune related adverse event (IRAE) is defined as any adverse event as...

Time Frame: Up to 5 years

▼ Outcome Measure Data ✓

► Analysis Population Description

Arm/Group Title	Yes: IRAE	No: IRAE
► Arm/Group Description: Patients that experienced an IRAE. ...	Patients that experienced an IRAE. ...	Patients that did not experience an...
Overall Number of Participants Analyzed	6	4
Measure Type: Count of Participants		
Unit of Measure: participants		
Category Title		
Yes: Any progression	583.33%	375%
No: Any progression	116.67%	125%

[Edit](#) ▼ Statistical Analysis 1 ✓

[Delete](#)

Statistical Analysis Overview	Comparison Group Selection	Yes: IRAE, No: IRAE
	Comments	[Not specified]
	Type of Statistical Test	Other
	Comments	Test of association (contingency) between the two kinds of classification.
Statistical Test of Hypothesis	P-Value	1.000
	Comments	[Not specified]
	Method	Fisher Exact
	Comments	[Not specified]



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 compiled 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
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

ClinicalTrials.gov PRS
Protocol Registration and Results System

[Home](#) > [Record Summary](#) > [Results Section](#) > Adverse Events

ID: CDR00005401 Paclitaxel Poliglumex and Estradiol in Treating Patients With Stage IV Prostate Cancer

Adverse Events Overview

[Results Section](#) [Download/Upload](#) [Sort...](#) [Help](#) [Definitions](#)

[Edit](#) [Time Frame](#) [While on study agents](#)
[Additional Description](#)
[Source Vocabulary Name](#) [CTCAE \(3.0\)](#)

2. [Download Adverse Event Tables from](#)

* **Adverse Event Type:** ☐ Serious

* **File Format:** ☐ Excel Workbook

[Download](#)

Download Adverse Event Tables from PRS

* Adverse Event Type: ☐ Serious
 * File Format: ☐ Excel Workbook

Download

10 # Column H (truncated arm name (numSubjectsAffected)) - should not be blank and should contain a number
 11 # Column I (truncated arm name (numSubjectsAtRisk)) - may be blank (indicates use table default)
 12 # etc... previous three columns repeated for each Arm/Group
 13 # Upon upload, the contents of this file will completely replace the corresponding adverse event table in the PRS.
 14 #

	adverseEventType	assessmentType	additionalDescription	organSystemName	sourceVocabulary	term	Acetaminophen & T(numEvents)	Acetaminophen & T(numSubjectsAffected)	Acetaminophen & T(numSubjectsAtRisk)
15									
16									
17									
18									
19									
20									

Upload Adverse Events to PRS

* Filename: No file selected.
 * Adverse Event Type: ☐ Serious ☐ Other (Not Including Serious)
 * File Format: ☐ Excel Workbook (.xlsx) ☐ Excel 97-2003 Workbook (.xls) ☐ Tab Separated Values (.txt)

For multi-sheet Excel workbooks only, Worksheet Name:

Upload

Last Two Sections

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

ID: CDR0000479150 Everolimus and Imatinib Mesylate in Treating Patients With Metastatic or Unresectable Kidney Cancer

Edit Limitations and Caveats

[Definitions](#)

Overall Limitations and Caveats:

Our phase II study closed after the first stage of accrual due to an insufficient number of participants who remained progression-free at 3 months, per the study design.

Characters remaining: 81

If appropriate, please describe limitations of the trial.
Examples: Early termination leading to small numbers of subjects analyzed; Technical problems with measurement leading to unreliable or uninterpretable data.

[Save](#) [Cancel](#)

More Information

[Results Section](#)

[Edit](#)

Certain Agreements

Principal Investigators are NOT employed by the organization sponsoring the study.

There is NOT an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

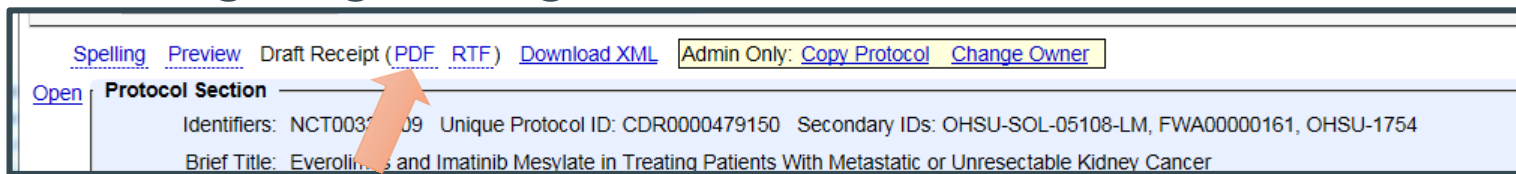
[Edit](#)

Results Point of Contact

Name/Official Title: Christopher W. Ryan
Organization: Oregon Health and Science University
Phone: 503-494-1951
Email: ryanc@ohsu.edu

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



Spelling Preview Draft Receipt (PDF RTF) Download XML Admin Only: Copy Protocol Change Owner

Open Protocol Section

Identifiers: NCT003...09 Unique Protocol ID: CDR0000479150 Secondary IDs: OHSU-SOL-05108-LM, FWA00000161, OHSU-1754

Brief Title: Everolimus and Imatinib Mesylate in Treating Patients With Metastatic or Unresectable Kidney Cancer

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



Record Status

In Progress ➡ Entry Completed ➡ **Approved** ➡ Released ➡ PRS Review ➡ Public

[Reset to In-Progress...](#)

Next Step: Release record **Release...**

ClinicalTrials.gov PRS QA Process

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

ClinicalTrials.gov QA Staff post data on public website



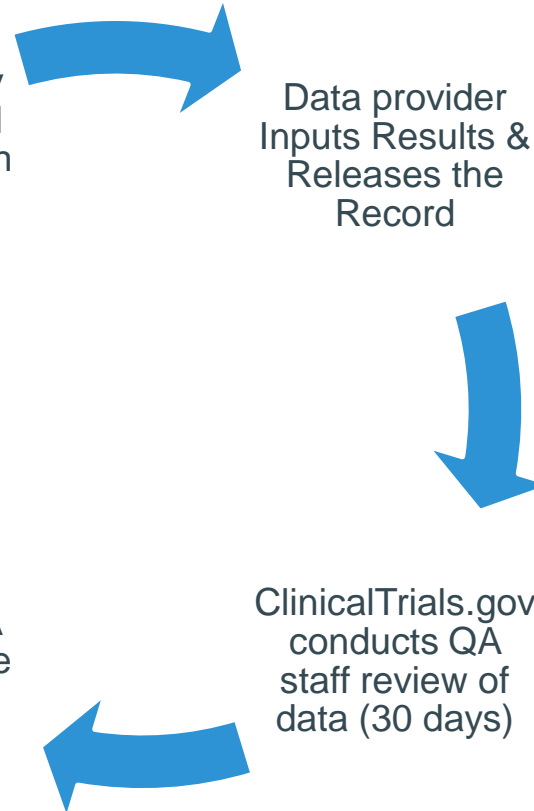
ClinicalTrials.gov staff reset record to 'In Progress' and notifies QA Comments

Data provider Inputs Results & Releases the Record

ClinicalTrials.gov conducts QA staff review of data (30 days)

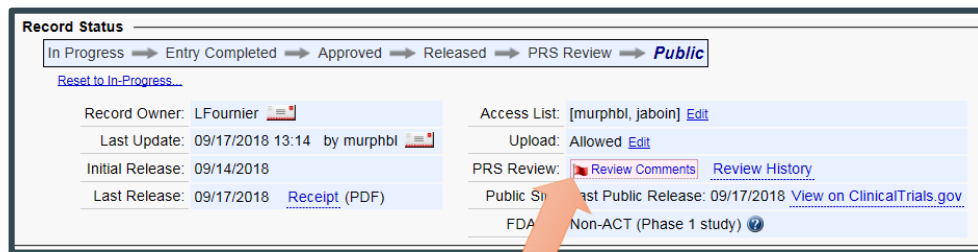
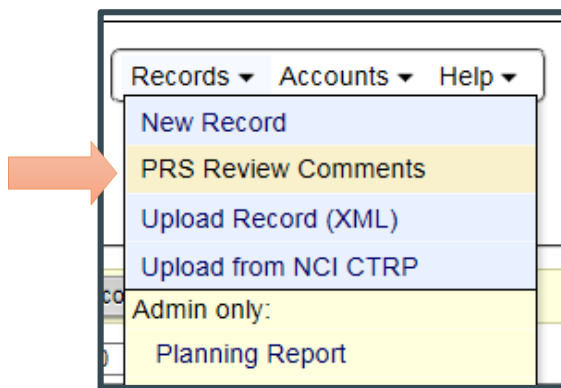
Are there QA issues with the results?

No Yes



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

2. Secondary Outcome Measure [Posted]: Second-line Progression Free Survival

Measure Title	Second-line Progression Free Survival
Measure Description	Time to disease progression from start of second-line experimental reg... Evaluation Criteria in Solid Tumors Criteria (RECIST v... disappearance of all target lesions; Partial Response (P... Progressive Disease (PD), >= 20% increase in the sum... sufficient shrinkage to qualify for partial response nor s...
Time Frame	Upon completion of follow-up, for an average of 99 days
Safety Issue?	No

Analysis Population Description -- Explanation of how the number of participants to treat, or another method. Also provides relevant details such as impact of treatment on progression-free survival.

Reporting Groups

	Description
FOLFIRI With Erlotinib	
FOLFOX With Erlotinib	

Validation Messages

- NOTE : An entry in Arm/Group Description is recommended.
- NOTE : An entry in Arm/Group Description is recommended.

2. Secondary Outcome

[Add Statistical Analysis 1](#)

[Edit](#) [Delete](#) [Copy](#)

Title:	Second-line Progression Free Survival	
Description:	Time to disease progression from start of second-line experimental reg...	
Time Frame:	Upon completion of follow-up, for an average of 99 days following the initiation of study treatment.	
Safety Issue?	No	

▼ Outcome Measure Data ✓ 2 Notes

► Analysis Population Description

Arm/Group Title	FOLFIRI With Erlotinib	FOLFOX With Erlotinib
► Arm/Group Description:	NOTE : An entry in Arm/Group Description is recommended.	NOTE : An entry in Arm/Group Description is recommended.
Number of Participants Analyzed	10	1
Median (95% Confidence Interval) Units: Days	83 (15 to 127)	125 (--- to ---)

[Collapse Section](#)

	FOLFIRI With Erlotinib	FOLFOX With Erlotinib
Number of Participants Analyzed	9	1
Second-line Progression Free Survival [units: Days]	83	125

Comments [2] :

It appears that the Measure Type of Number is incorrect. If reporting the average time to progression, then please provide the appropriate Measure Type (e.g., Mean, Median, etc.) and Measure of Dispersion/Precision (e.g., Standard deviation, Full Range, Confidence Interval, etc.). Please review and revise as appropriate.

Revised to

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

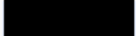



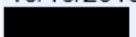



- Editing record data in the PRS does NOT automatically update ClinicalTrials.gov
 - Mark **ENTRY COMPLETE** when changes to data are done
 - Record Owner or Responsible Party has to log in, review, and **APPROVE** the record
 - Responsible Party has to log in, review and **RELEASE** the record
 - PRS 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.











Record Owner:	 	Access List:	 Edit 
Last Update:	10/16/2018 15:21 by  	Upload:	Allowed Edit
Initial Release:	05/14/2015	PRS Review:	Record Reset  Review Comments
Initial Results Release:	10/16/2018		Corrections Expected: 12/09/2018 Review History
Last Release:	10/16/2018 Receipt (PDF)	Public Site:	Last Public Release: 05/15/2015 View on ClinicalTrials.gov
		FDAAA:	Probable ACT 

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/departments 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.

Record Owner:		Access List:	 Edit
Last Update:	10/16/2018 15:21 by 	Upload:	Allowed Edit
Initial Release:	05/14/2015	PRS Review:	Record Reset  Review Comments
Initial Results Release:	10/16/2018		Corrections Expected: 12/09/2018 Review History 
Last Release:	10/16/2018 Receipt (PDF)	Public Site:	Last Public Release: 05/15/2015 View on ClinicalTrials.gov
Results Expected:	No later than December 30, 2015 	FDAAA:	Probable ACT  
All Results Expected:	No later than December 30, 2015  		

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>

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Thank You