Clinical Trials Results Reporting
OHSU Knight Cancer Institute
Oregon Clinical and Translational Research Institute

JANUARY 17, 2019 PRESENTED BY:
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JOHN HICKS, Clinical Research Compliance Specialist
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?

Registered Non-Cancer Investigator-Initiated Trials
n=429

- No Problems: 61%
- Late or Missing Results: 15%
- Miscellaneous PRS Problems: 24%
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).

*Rules are subject to change so keep checking back to these links:
- [http://grants.nih.gov/clinicaltrials_fdaaa/ACTs_under_FDAAA.htm](http://grants.nih.gov/clinicaltrials_fdaaa/ACTs_under_FDAAA.htm)
- [https://www.clinicaltrials.gov/ct2/manage-recons/fdaraa](https://www.clinicaltrials.gov/ct2/manage-recons/fdaraa)

If unsure if your study is ACT, please use the ACT Checklist (PDF): [https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf](https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf), OR...

Email [register@clinicaltrials.gov](mailto:register@clinicaltrials.gov), or Knight Cancer Institute via [ctrp-admin@ohsu.edu](mailto: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

<table>
<thead>
<tr>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Is the study interventional (a clinical trial)?</td>
</tr>
<tr>
<td>Study Type data element is “Interventional”</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>2. Do ANY of the following apply (is the answer “Yes” to at least one of the following sub-questions: 2a, 2b, OR 2c)?</td>
</tr>
<tr>
<td>a. Is at least one study facility located in the United States or a U.S. territory?</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td>b. Is the study conducted under a U.S. FDA Investigational New Drug application (IND) or Investigational Device Exemption (IDE)?</td>
</tr>
<tr>
<td>U.S. Food and Drug Administration IND or IDE Number data element is “Yes.”</td>
</tr>
<tr>
<td>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?</td>
</tr>
<tr>
<td>Product Manufactured in and Exported from the U.S. data element is “Yes.”</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>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)?</td>
</tr>
<tr>
<td>Studies a U.S. FDA-regulated Device Product data element is “Yes” and/or</td>
</tr>
<tr>
<td>Studies a U.S. FDA-regulated Drug Product data element is “Yes.”</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>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?</td>
</tr>
<tr>
<td>For drug product trials, Study Phase data element is NOT “Phase 1” and for device product trials, Primary Purpose is NOT “Device Feasibility.”</td>
</tr>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

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.*

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.
## 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.

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

• **First Time?** – Check out these links below:
  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](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.

Refer to template:
[http://prsinfo.clinicaltrials.gov/results_table_layout/DataEntryTable_PopFlowForm.pdf](http://prsinfo.clinicaltrials.gov/results_table_layout/DataEntryTable_PopFlowForm.pdf)
Module 1: Participant Flow

Another example

- Study that is reporting multiple periods
- Multiple Arms

This clinical trial was conducted between 12/23/2006 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.

<table>
<thead>
<tr>
<th>Arm/Group Title</th>
<th>Sulfuraphane Supplement</th>
<th>Placebo</th>
<th>Total (Not public)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arm/Group Description</td>
<td>Patients receive oral broccoli supplement</td>
<td>Patients receive oral placebo supplement</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Period Title: Treatment Period</th>
<th>Started</th>
<th>Completed</th>
<th>Not Completed</th>
<th>Started</th>
<th>Completed</th>
<th>Not Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Started</td>
<td>27</td>
<td>24</td>
<td>3</td>
<td>27</td>
<td>19</td>
<td>8</td>
</tr>
<tr>
<td>Completed</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not Completed</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reason Not Completed</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adverse Event</td>
<td>1</td>
<td></td>
<td></td>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Withdrawal by Subject</td>
<td>2</td>
<td></td>
<td></td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5</td>
<td></td>
<td></td>
<td>11</td>
<td></td>
<td>11</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Period Title: Follow-up</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Started</td>
<td>24</td>
<td></td>
<td></td>
<td>24</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Completed</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not Completed</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NOTE: The number of participants to start a Period is not equal to the number who completed previous Period.
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...

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....

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 QA staff review of data (30 days)

Are there QA issues with the results?

Yes

Data provider Inputs Results & Releases the Record

No

ClinicalTrials.gov QA staff reset record to ‘In Progress’ and notifies QA

Comments

ClinicalTrials.gov QA staff post data on public website.
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.
Example 1:

- **Measure Types need to be consistent with outcome description.**

Revised to:

- **Measure**
  - **Time to disease progression from start of second-line experimental regimen**
  - **Upon completion of follow-up, for an average of 99 days following the initiation of study treatment.**

**Outcome Measure Data**

<table>
<thead>
<tr>
<th>Arm/Group Title</th>
<th>FOLFOX With Erlotinib</th>
<th>FOLFOX With Erlotinib</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of Participants Analyzed</strong></td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td><strong>Median (95% Confidence Interval)</strong></td>
<td>83 (15 to 127)</td>
<td>125 (--- to ---)</td>
</tr>
<tr>
<td><strong>Comments</strong></td>
<td>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.</td>
<td></td>
</tr>
</tbody>
</table>
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
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
  – For cancer-studies, email ctmp-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.

<table>
<thead>
<tr>
<th>Record Owner:</th>
<th></th>
<th>Access List:</th>
<th>[]</th>
<th>Edit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last Update:</td>
<td>10/16/2018 15:21</td>
<td>Upload:</td>
<td>Allowed</td>
<td>Edit</td>
</tr>
<tr>
<td>Initial Release:</td>
<td>05/14/2015</td>
<td>PRS Review:</td>
<td>Record Reset Corrections Expected: 12/09/2018</td>
<td>Review History</td>
</tr>
<tr>
<td>Initial Results Release:</td>
<td>10/16/2018</td>
<td>Public Site:</td>
<td>Last Public Release: 05/15/2015</td>
<td>View on ClinicalTrials.gov</td>
</tr>
<tr>
<td>Last Release:</td>
<td>10/16/2018 Receipt (PDF)</td>
<td>FDAAA:</td>
<td>Probable ACT</td>
<td></td>
</tr>
<tr>
<td>Results Expected:</td>
<td>No later than December 30, 2015</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| 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](https://www.clinicaltrials.gov/ct2/about-site/results)
- 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](https://www.clinicaltrials.gov/ct2/manage-recs/fdaaa)
- 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](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](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_RegistrationReport20181114.pdf](https://bridge.ohsu.edu/community/rate/Shared%20Documents/OHSU_Policy_ClinicalTrials_InvestigatorInitiated_RegistrationReport20181114.pdf)
- OHSU RAIN (Research Administration Information Network): [https://o2.ohsu.edu/research-administration-training-education/research-administration-information-network/index.cfm](https://o2.ohsu.edu/research-administration-training-education/research-administration-information-network/index.cfm)

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Thank You