Posting Study Results to ClinicalTrials.gov: Effective Tools and Lessons Learned

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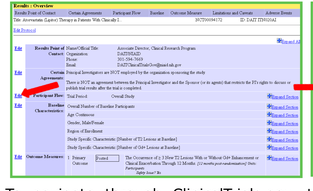
Overview

The Food and Drug Administration Amendments Act of 2007 requires the Sponsor of applicable clinical trials (Phase II-IV drug/biologic/device trials initiated or ongoing as of 27Sep2007 and not completed by 26Dec2007) to post basic results to ClinicalTrials.gov within 12 months of the primary outcome completion date or actual trial completion date for the primary outcome (whichever is earlier). Although the Sponsor is responsible for ensuring results are posted to ClinicalTrials.gov, the Statistical and Data Coordinating Center (SDCC) assigned to the trial can be a pivotal partner in this process.

Novice users may find ClinicalTrials.gov difficult to navigate. Often users are unsure of what information is required or allowable. Additionally, there may be an internal review and approval process prior to a trial's results being cleared for posting to the ClinicalTrials.gov database. In an effort to help both the staff developing/posting results and the reviewer(s), Rho created a fillable Word template. This template provides instruction and structure for individuals developing/posting results. The template also informs the user of character limits, field selection options, required versus optional data elements, and guidance on typical results entries. For the reviewer(s), the template provides a means to review the results without login-access to ClinicalTrials.gov. Additionally, the reviewer can see the system limitations and what options are available, which can aide in constructive feedback.

Part of posting study results to ClinicalTrials.gov is to post adverse events. Hand-entering adverse events can be a tedious task prone to error. ClinicalTrials.gov allows results to be uploaded in a prescribed XML format. Software developers at Rho created a program that converts a SAS® data table into an XML file that is compatible with the structure provided by

The ClinicalTrials.gov Entry System



To navigate through ClinicalTrials.gov, there are multiple basic results table screens with several locations where you need to enter information. In the above screenshot, everything in blue underlined font leads to a new screen with new links to fill in information. For an inexperienced user, it is easy to miss necessary information that can result in error messages requiring correction.

Until the user reaches a results table entry field, it is hard to know what information is required and the types of limitations that may be encountered (i.e. character limits). As a result, a new user could be caught unprepared when entering results. When data is entered into the system, the only way to have others review your results entries prior to their submission to ClinicalTrials.gov quality assurance team is to provide log-in access, which is not preferred.

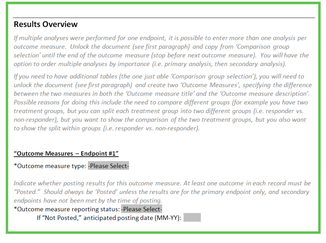
Reasons for a Solution

After Rho, as the SDCC for NIAID networks, embarked on developing/posting results for applicable trials in ClinicalTrials.gov, we realized we needed the following to be effective:

- Ability to see all of the results requiring entry on one scrolling page
- Knowledge of possible options (i.e. drop-down items) and limitations (i.e. character limits)
- A way to show the results to reviewers without losing the security of log-in access

Fillable Word Template

In an effort to solve the first three bullets above, we created a fillable Word template. The template follows the order in which the user would enter data into ClinicalTrials.gov, but you can scroll through the document to see what is needed to optimize gathering all of the necessary data prior to filling it out.



Results Overview

If multiple analyses were performed for one endpoint, it is possible to enter more than one analysis per outcome measure. Unlock the document [see first paragraph] and copy from "Comparison group selection" until the end of the outcome measure (stop before next outcome measure). You will have the option to order multiple analyses by importance (i.e. primary analysis, then secondary analysis).

If you need to have additional tables (the one just able 'Comparison group selection'), you will need to unlock the document (see first paragraph) and create two 'Outcome Measures', specifying the difference between the two measures in both the 'Outcome measure title' and the 'Outcome measure description'. Possible reasons for doing this include the need to compare different groups (for example you have two treatment groups, but you can split each treatment group into two different groups (i.e. responder vs. non-responder), but you want to show the comparison of the two treatment groups, but you also want to show the split within groups (i.e. responder vs. non-responder).

"Outcome Measures – Endpoint #1"

*Outcome measure type: Please Select

Indicate whether posting results for this outcome measure. At least one outcome in each record must be "Posted." Should always be "Posted" unless the results are for the primary endpoint only, and secondary endpoints have not been met by the time of posting.

*Outcome measure reporting status: Please Select

If "Not Posted," anticipated posting date [MM-YY]:

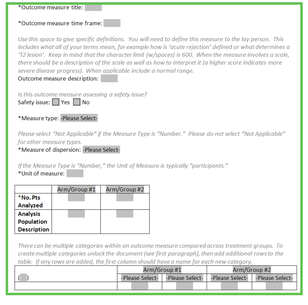
The template also provides information that is not included in ClinicalTrials.gov results table. Seen in the picture to the left in gray italicized text, descriptive information provides instruction and tips for successful data entry.

The gray field labeled "Please Select" can be clicked on to select from a drop-down menu.

The template:

- specifies which information is required vs. optional by having an "*" prior to the text.
- allows for simple check-box entry.

Each gray field that is not a drop-down menu or a check-box is coded to allow for the ClinicalTrials.gov specified space limitations and character or numeric entry for required basic results tables.



*Outcome measure title:

*Outcome measure time frame:

Use this space to give specific definitions. You will need to define this measure to the lay person. This includes what all of your terms mean, for example how is 'acute rejection' defined or what determines a "12 lesion". Keep in mind that the character limit (w/spaces) is 600. When the measure involves a scale, there should be a description of the scale as well as how to interpret it (a higher score indicates more severe disease progress). When applicable include a normal range.

Outcome measure description:

Is this outcome measure assessing a safety issue?

Safety Issue: Yes No

*Measure type: Please Select

Please select "Not Applicable" if the Measure Type is "Number." Please do not select "Not Applicable" for other measure types.

*Measure of dispersion: Please Select

If the Measure Type is "Number," the Unit of Measure is typically "participants."

*Unit of measure:

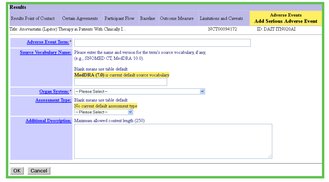
	Arm/Group #1	Arm/Group #2
*No. Pts Analyzed		
Analysis Population Description		

There can be multiple categories within an outcome measure compared across treatment groups. To create multiple categories unlock the document (see first paragraph) then add additional rows to the table. If any rows are added, the first column should have a name for each new category.

	Arm/Group #1	Arm/Group #2
	Please Select	Please Select	Please Select	Please Select

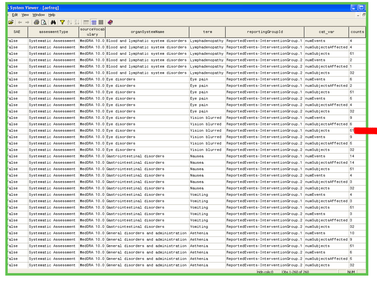
Once a template has been filled out for a particular study, it can be distributed to necessary parties for review. Since this is a Word document, reviewers can make and track changes and leave comments to assist in the results creation process while alleviating the need for reviewers to have ClinicalTrials.gov log-in information.

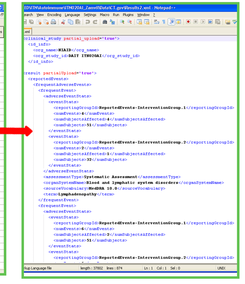
Adverse Event XML Creation



For all adverse events required in the ClinicalTrials.gov database, there are several items that need to be entered as seen in the screenshot to the left. For many studies there are hundreds of adverse events. Hand entering every event is tedious and prone to human error.

ClinicalTrials.gov does allow for the upload of results in an XML file. Our software programmers developed a program that converts a SAS® data table (which is the format Rho uses for data collection) into an XML file that conforms to the structure provided by ClinicalTrials.gov results database.





The above screenshot on the left shows a SAS® data table that has the adverse event data sorted the way ClinicalTrials.gov structure requires. The program we created takes the SAS® data table and outputs an XML file, pictured above on the right. The XML file can then be uploaded directly to ClinicalTrials.gov and save the user from hand entry of adverse events.

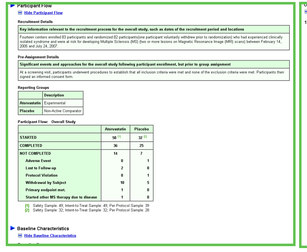
Lessons Learned

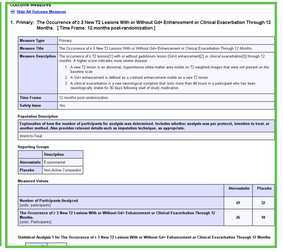
As with every new process there is some trial and error as we determine optimal solutions. Below are observations we would like to share with new users:

- To ensure release of results in a timely manner, begin preparing results 4-5 months prior to the deadline set by ClinicalTrials.gov (one year after the last patient's last visit for primary endpoint, or the actual trial completion date for the primary outcome, whichever is earlier)
- Ensuring results are error free prior to submission will reduce the likelihood of revisions as quality assurance by ClinicalTrials.gov personnel is thorough.
- As you learn the nuances of ClinicalTrials.gov, record tips and solutions so they will be available to you and your colleagues for future entries.

Successfully Posting Results on ClinicalTrials.gov

Once the fillable Word template and adverse events are reviewed/approved, the user must enter and upload the results. The results entered in the Word template can be copy and pasted into ClinicalTrials.gov and the adverse event's XML file can simply be uploaded. Then the user will submit the entries to ClinicalTrials.gov to begin their quality assurance. They will provide comments for revision or they will make your entries public. The screenshots below indicate what the public will see once the results are completed:





Future Directions

We are continuing to improve our process for developing and entering results to ClinicalTrials.gov. We are currently exploring the possibility of creating a faux website that closely mimics ClinicalTrials.gov. With this faux website, the user can enter all of the results in a secure environment. Then the user would be able to create an output that could be sent to reviewers or an XML file output thereby allowing all results to be uploaded instead of just the adverse events.

Summary

Entering results into ClinicalTrials.gov does not require special equipment. However certain tools such as the fillable Word template and the program to create an XML file can greatly improve efficiencies and reduce errors. The screenshots presented in this poster correspond to the protocol ID: DAIT ITN020AI, ClinicalTrials.gov ID: NCT00094172.

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