

ClinicalTrials.gov Webinar Series, March 2011

Protocol Registration System (PRS): Accounts and Registration

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National Library of Medicine

Hi. Today, I am going to talk to you about PRS accounts and protocol registration. Here is our typical data flow for ClinicalTrials.gov—there are three things you need to do to receive a NCT number: 1) you need to apply for an account, 2) you need to enter your study data, and 3) you need to receive the NCT number.

First, you need to apply for an account. You need to go to our PRS information page, determine what kind of account you need to apply for, get your account information, and log into the PRS.

We have two types of PRS users. We have a regular user, normal user, who enters studies and is able to modify those studies. We also have a PRS administrator, who reviews data and errors and they also release records to ClinicalTrials.gov and they also serve as a contact point for ClinicalTrials.gov.

The next thing you need to do is enter your protocol data into ClinicalTrials.gov. So once you receive your login information, you go to our PRS Login page. You enter your login information and you will come to a menu—this is the Standard Function menu for ClinicalTrials.gov. Before you start, you are going to need to change your password, you are going to need to read the Quick Start Guide, and read the User's Guide.

Items to consider before registering a protocol. Studies that are subject to FDAAA must be registered by the responsible party. We only want each protocol once, so please discuss amongst your group who is going to register the protocol. Also, we would like you to review the protocol detail review items. It gives you information about what and how to enter into ClinicalTrials.gov.

So now you want to enter your data into ClinicalTrials.gov. Click on “Create.”

This is a sample of the data entry screen. It is a Web-based entry system, and you would just enter your data and click “Continue” to keep going to the next screen. Here are some of the key registration data elements that we require in ClinicalTrials.gov.

After you have entered your data in ClinicalTrials.gov, review the information. Make sure there are no errors. Also, there are warnings and notes that are messages that may need to be addressed or helpful hints. Review the protocol for consistency, and when you are done with your data, click on “Next Action Complete.”

Once your data entry is finished, your PRS administrator will approve and release the record. After the record is released, the ClinicalTrials.gov QA staff will review the record for consistency and minimum quality review criteria.

So here is a sample of the PRS edit record screen, after you are done. Notice the “Next Action Complete,” at the top left. And then once you hit “Complete,” your administrator will receive an email, and they will approve and release your record.

So next you need to make sure, before you release your record, that the protocol record must be clear and informative. Review focuses on logic, internal consistency, apparent validity,

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meaningful entries, and formatting. Once our QA team reviews it, it gets published, and you receive an NCT number.

There are three ways to get your NCT number: 1) the owner of the record will receive it by email. 2) you can go back into the PRS account and look at the ClinicalTrials.gov ID, or 3) you can search for it on ClinicalTrials.gov with your protocol ID.

After your record has been in ClinicalTrials.gov and you want to modify it, log back into the PRS, and click on “Modify.” When you click on “Modify,” make sure you go to each edit section, and when you are finished, click on “OK.” Please review your record for errors and warnings, and update the record verification date. Once you are done, click on “Next Action Complete.” Here is a sample of the edit protocol record screen.

So when we are reviewing records in our QA system, there are a couple of things that we look at. We want to make sure that the record is in English, that all acronyms and abbreviations are expanded, there are no spelling errors, and that it is formatted properly. Please make sure that the brief title is in lay language and includes condition and interventions evaluated in this study. We also review for internal consistency. We look at the overall recruiting status and we compare it to the study start date, the primary completion date, and the study completion date listed.

When you are entering outcome measures into ClinicalTrials.gov, please make sure that you are entering what it will be measuring, not why it will be measured. We want specific measures. (Note: Such general terms as “safety,” “tolerability,” or “feasibility” are not sufficient.)

For outcome measure time frame, please be specific also: “At Follow up” or “end of study” is not specific. Also, most outcome measures have one time point. So each unique combination outcome measure and time frame should be entered separately.

For outcome measure time frame for change of outcome measure, time frames indicate time period over which change occurred— generally two points should be entered. Time-to-event should include a time over which the event will be assessed.

Also, when you are entering data in ClinicalTrials.gov, there are entering arms and intervention. So when you are entering this section into ClinicalTrials.gov, please specify each study arm first. Next, specify each intervention. Assign each intervention to one or more study arms. This is how it will show up on ClinicalTrials.gov.

So, for additional information, please go to these Web sites, or, if you have questions, please send an email to register@clinicaltrials.gov.