

## Registration of Clinical Trial Results: New Requirements for ClinicalTrials.gov

This communication is being distributed to inform you of a new requirement to register the results of clinical trials on [ClinicalTrials.gov](http://ClinicalTrials.gov). Please note that ClinicalTrials.gov will be providing additional information about this new requirement in 2008-2009. To stay informed and ensure that your clinical trials are properly registered, please follow the steps at the end of this memo.

**Effective September 27, 2008, results of clinical trials of FDA approved drugs, biologics, and devices must be reported on ClinicalTrials.gov within 12 months of the estimated or actual completion date of the trial, whichever date is earlier.**

### Background:

Section 801 of the Food and Drug Administration Amendments Act of 2007 (FDAAA, [Public Law 110-85](#)) mandates the establishment of a database for clinical trial results, as well as other requirements for the registration of clinical trials. The ClinicalTrials.gov registration system (the [Protocol Registration System](#), or “PRS”) has recently been expanded to collect results data. Effective September 27, 2008, completion of the “Results” section in the PRS will be a legal requirement for clinical trials that meet certain criteria (defined below). As with all other requirements for the registration of clinical trials, failure to report results on ClinicalTrials.gov may result in loss of funding and/or the inability to publish in a journal that is a member of the International Committee of Medical Journal Editors (ICMJE). Investigators are responsible for ensuring that the information they provide is correct, complete, readily understood by the public, and that it is updated in a timely manner.

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*If you are not familiar with the requirement to register clinical trials on ClinicalTrials.gov, please review the [May 2008 Memo on Clinical Trial Registration](#) available on the Industry Contracts Division (ICD) Website at [www.research.ucsf.edu/icd/](http://www.research.ucsf.edu/icd/).*

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### For Which Clinical Trials do I Need to Register Results?

Clinical trial results must be registered for (1) all clinical trials studying FDA-approved drugs, biologics and devices that started *on* or *after* September 27, 2008, (2) all “ongoing clinical trials” studying FDA-approved drugs/biologics/devices that were started *before* September 27, 2008, where an “ongoing clinical trial” is defined as a clinical trial with one or more enrolled patients that did not reach its “completion date” (defined below) prior to September 27, 2008, and (3) all clinical trials of drugs/biologics/devices that are *not yet FDA-approved*; however, the requirements of when registration is required differs from that of FDA-approved drugs/biologics/devices.

### How is the “Completion Date” Defined?

The “completion date” is the date on which the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol, or was terminated early.

### Who is Responsible for Registering Clinical Trial Results?

By law, the “responsible party” must register the results of a clinical trial on ClinicalTrials.gov. The responsible party for registering results of investigator-initiated clinical trials is the

investigator. The responsible party for sponsor-initiated clinical trials is the sponsor or the sponsor's designated investigator. For more information about determining who the responsible party is for a clinical trial, please see the [May 2008 Memo on Clinical Trial Registration](#).

### **When Must Clinical Trial Results be Registered?**

The timing of when results must be registered on ClinicalTrials.gov depends on whether the drug/biologic/device being studied has already been approved by the FDA.

- For clinical trials studying FDA-approved drugs/biologics/devices, results must be registered within 12 months of the estimated or actual study completion date, whichever is earlier.
- If the responsible party certifies that initial FDA approval or approval of a new use for the drug/biologic/device is being sought, the deadline for registration of clinical trial results may be extended to no later than 30 days after FDA action (approval or non-approval). For more information, including instructions on such certification, please see the [Delayed Submission of Results](#) page inside the PRS.
- An extension of the deadline for registration of results may be granted if the responsible party submits a written request that demonstrates good cause for an extension and provides an estimate of the date results will be registered. For more information, including instructions for requesting an extension, please see the [Delayed Submission of Results](#) page inside the PRS.

### **What Types of Results Data Must be Registered?**

Investigators will be responsible for registering results data as specified by ClinicalTrials.gov. Data may include published and unpublished results as outlined below.

1. **Results Point of Contact**: A point of contact (name or title, organization, phone and email) for scientific information about the registered clinical trial results.
2. **Certain Agreements**: Information certifying whether an agreement exists between the sponsor and UCSF that restricts or delays the ability of the investigator and UCSF to discuss or publish results after the clinical trial completion date. For questions about specific clinical trial agreements, and whether they contain such a restriction or delay, investigators will need to review the applicable study award and/or agreement. If an investigator has questions about a particular award, they should contact the appropriate Office of Sponsored Research unit as follows:
  - For studies sponsored by a governmental or non-profit sponsor please contact [Contracts and Grants \(C&G\)](#) at [CGAwardTeam@ucsf.edu](mailto:CGAwardTeam@ucsf.edu).
  - For studies sponsored by a for-profit sponsor please contact the [Industry Contracts Division \(ICD\)](#) at [industrycontracts@ucsf.edu](mailto:industrycontracts@ucsf.edu).
3. **Participant Flow**: Progress of research participants through each stage of a clinical trial in a tabular format, including the number of participants who dropped out of the clinical trial.
4. **Baseline Characteristics**: A table of demographic and baseline data for the entire clinical trial population and for each arm or comparison group.
5. **Outcome Measures**: A table of values for each of the outcome measures by arm or comparison group.

6. Overall Limitations and Caveats: If appropriate, describe significant limitations of the clinical trial.
7. OPTIONAL - Adverse Events: Adverse event data are divided into categories, serious adverse events and other (non-serious) adverse events.

Additional information concerning the required results data is available on the PRS Main Menu under [“Results Data Element Definitions”](#).

### **What Steps Should I Take to Ensure that My Clinical Trial Results are Properly Registered?**

<b>Step 1</b>	If you have not already done so, please review the <a href="#">May 2008 Memo on Clinical Trial Registration</a> available on the Industry Contracts Division of the Office of Sponsored Research (ICD) website at <a href="http://www.research.ucsf.edu/icd/">www.research.ucsf.edu/icd/</a> .
<b>Step 2</b>	If you do not already have one, please obtain a PRS User Account. To obtain an account and complete the initial registration of a clinical trial, please follow the detailed instructions on the last page of the <a href="#">May 2008 Memo on Clinical Trial Registration</a> .
<b>Step 3</b>	Login to the <a href="#">PRS</a> and review the <a href="#">“About Results Data Entry”</a> page. The link is located near the top of the Main Menu. Also, review the <a href="#">“Results Data Element Definitions”</a> page, which is accessible from the PRS Main Menu under “Help”.
<b>Step 4</b>	Join the <a href="#">NIH FDAAA Update LISTSERV</a> to receive important email announcements regarding US Public Law 110-85.
<b>Step 5</b>	Visit the <a href="#">PRS Results Data Entry Test System</a> and familiarize yourself with the procedure for entering results data into the PRS. Creating or modifying records in this system will have no effect on the operational PRS or ClinicalTrials.gov. While exploring the Test System, you may find it useful to follow the <a href="#">ClinicalTrials.gov Basic Results Data Entry Test System: Step-by-Step Guide for Entering Data [PDF]</a> (August 2008).

### **Who do I Contact with Questions about the Initial Registration of a Clinical Trial or Subsequent Registration of Clinical Trial Results?**

If you have questions regarding registration of a clinical trial, please contact PRS directly at [register@clinicaltrials.gov](mailto:register@clinicaltrials.gov). You may also contact the Industry Contracts Division (ICD) of the Office of Sponsored Research at UCSF at [industrycontracts@ucsf.edu](mailto:industrycontracts@ucsf.edu).