

Reporting Results on Clinicaltrials.gov

All studies, other than Phase I studies, that are interventional*, include a drug, device, or biologic, have at least 1 site in the U.S., and were ongoing after 9/27/07 MUST report results of the trial on clinicaltrials.gov.

Investigators are required to report results within 12 months of the primary completion date** of the study of APPROVED (for any use, not just the use under investigation in your study) drugs and devices. Posting of results for investigational drug/device studies is not required until a New Drug Application (NDA) is approved, but investigators must access the record for the study in clinicaltrials.gov and report that there is an NDA pending.

Reporting of results is a cognitive, not an administrative, task. A member of the research team who is very familiar with all aspects of the study should complete the reporting requirements. It is recommended that the PI or the statistician complete this task.

The legal requirements for reporting Basic Results include:

- Demographic & baseline characteristics
 - Table of values, overall and for each arm
 - # of patients dropped out & excluded from analysis

- Primary and secondary outcomes
 - Table of values for each primary & secondary outcome measure, by arm
 - Scientifically appropriate tests of statistical significance

- Point of contact (for scientific information)

- Certain agreements (e.g., restrictions on PI to discuss or publish results after trial completion date)

The requirement for reporting results for Adverse Events is effective beginning September of 2009.

- SERIOUS ADVERSE EVENTS

- Table of anticipated & unanticipated serious adverse events
- Grouped by organ system
- Number and frequency of event in each clinical trial arm

- FREQUENT (other) ADVERSE EVENTS

- Table of anticipated & unanticipated adverse events
- Exceed a frequency of 5 percent within any trial arm
- Grouped by organ system
- Number and frequency of event in each trial arm

***Clinicaltrials.gov does offer individual consultations as needed. Click on the Send a Message to PRS button at the top of the registration and write an e-mail requesting a conference call for this purpose.

*Interventional is defined as a study in which the PI assigns a subject to one arm or another. If the study is observing behaviors associated with two different situations and the subject is assigned into that situation, this is an interventional study.

The primary completion date is defined as the date the data collection was complete for the **primary outcome measure.