

The FDAA Act of 2007 and Mandatory Registration of Clinical Trials

Author: Darin J. Weber, Ph.D

Contact: dweber@bcg-usa.com; phone: 206-940-3923

Acknowledgement: The author gratefully acknowledges Dr. Kimberly Benton, FDA/CBER/OCT-GT for her comments and insights on this article.

On September 27, 2007, Public Law 110-85, referred to as “The Food and Drug Administration Amendments Act of 2007” (FDAAA) was enacted (<http://www.fda.gov/oc/initiatives/HR3580.pdf>). This Act, in Title VIII “Clinical Trials Databases,” stipulates that all controlled clinical trials, other than Phase I or device feasibility studies, of drugs, biologics and medical devices subject to FDA regulation are to be registered on clinicaltrials.gov.

The deadline for submission of the required information for ongoing controlled clinical studies was December 26, 2007 and for studies initiated after this date, no later than 21 days after the first patient is enrolled. An ongoing clinical trial is considered to be a study in which at least one subject is enrolled and is not completed by the implementation date.

Exception

Ongoing clinical trials for serious or life threatening conditions that were initiated before September 27, 2007 and have a completion date prior to December 26, 2007 are not subject to the new requirements.

Delayed Implementation for Some Types of Studies

If a clinical trial was ongoing as of September 27, 2007 and does not involve a serious or life threatening disease or condition, registration is not required until September 27, 2008 (see table below).

Summary of Required Registration Dates

Status of Study	Indication	Phase of Development	Required Registration Date
Ongoing before 12/27/2007	Serious or life threatening disease or condition	Other than Phase I or feasibility (medical devices)	December 26, 2007; no later than 21 days after 1st patient is enrolled
Ongoing before 12/27/2007	Not for serious or life threatening disease or condition	Other than Phase I or feasibility (medical devices)	September 27, 2008
Completed by 12/26/2007	Serious or life threatening disease or condition	Other than Phase I or feasibility (medical devices)	Not subject to new requirements
Initiated after 12/26/2007	Any clinical indication	Other than Phase I or feasibility (medical devices)	No later than 21 days after 1st patient is enrolled

Consequences of Failing to Register

If you are the sponsor of a ongoing Phase II, Phase III or post marketing clinical trial, or have been delegated responsibility for conduct of the clinical trial it is critical that you ensure that you have registered with clinicaltrials.gov. There are significant monetary penalties for failing to register. Sponsors or designates who fail to register may be subject to a civil monetary penalty of not more than \$10,000. If false or misleading information is submitted and not corrected within 30 days of notification, civil monetary penalties of not more than \$10,000 per day until the violation is corrected can be levied.

Additionally, if you receive funding from the Agencies within the Department of Health and Human Services, including the NIH, FDA and HRSA, remaining grant funds and future grant funds will be withheld until certification of registration has been provided.

Required Data Elements

In addition to the descriptive, recruitment, location, contact, and administrative information that was previously required for registration on clinicaltrials.gov, there are new data elements that must be provided. These new data elements include information concerning primary and secondary outcome measures, start date, and target number of subjects. The exact information required is available at: <http://prsinfo.clinicaltrials.gov>.

How to Register

Registration of a clinical trial can be accomplished by entry of required data into the Protocol Registration System (PRS) available at www.clinicaltrials.gov.

Certification

One new FDAAA provision requires that a certification that all applicable requirements of Title VIII have been met must accompany all human drug, biological, and device product submission made to FDA. At the time of submission of a new IND, IND amendment, 510(k), BLA, PMA, NDA or other regulatory submission to the FDA, such application or submission must be accompanied by a certification that all applicable requirements for registration at clinicaltrials.gov has been made. The certification form must be provided every time a regulatory submission is made, similar to how the FDA Form 1571 is provided for all IND amendments. To facilitate in complying with the certification process, the FDA has developed FDA Form 3674 (<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf>) to cover essentially all regulatory submissions made to the Agency. This form is to be submitted to the FDA for applicable clinical studies, beginning no later than December 26, 2007.

As of this writing the FDA is working on a process to communicate to sponsors their obligations to submit the certification form. Further advice on this will be forthcoming from FDA and posted on the FDA website. If you have additional questions about certification please contact CBER's Office of Communication, Training and Manufacturers Assistance. or send an email to FDAAAclinicaltrials@fda.dhhs.gov.

Summary

With the enactment of the Food and Drug Administration Amendments Act of 2007, clinical trial sponsors and designates, must take on additional responsibilities for mandatory submission of clinical study information to clinicaltrials.gov and provision of certification in all FDA regulatory submissions. It is envisioned that the new information to be included in the databank such as primary and secondary outcome measures will provide improved access to information for potential research subjects as well as assist others in the design of future clinical studies.

International Society for Cellular Therapy

ISCT

