11/09/07

FACT SHEET (Available at http://prsinfo.clinicaltrials.gov/)

Registration at ClinicalTrials.gov: As required by Public Law 110-85, Title VIII

On September 27, 2007, a U.S. law was enacted that expands the types of clinical trials that must be registered in ClinicalTrials.gov, increases the number of data elements that must be submitted, and also requires submission of results data. There are penalties for non-compliance with the law. This fact sheet addresses the new registration requirements, some of which have reporting deadlines beginning on **December 26, 2007.** Information about the requirement to submit results data will be forthcoming.

1. General Requirements for Registration

A. Clinical Trials That Must be Registered at ClinicalTrials.gov ("Applicable Clinical Trials")

- Trials of Drugs and Biologics: controlled clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation [1]
- Trials of Devices: Controlled trials with heath outcomes of devices subject to FDA regulation, other than small feasibility studies, and pediatric postmarket surveillance [2]

B. Who is Responsible for Trial Registration? ("Responsible Party") [3]

1. The sponsor of the clinical trial [4]; - *OR* -
2. The principal investigator (PI) of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the PI is responsible for conducting the trial and has sufficient data rights.

C. Required Data Elements -

The Responsible Party must submit descriptive, recruitment, location, contact, and administrative information when registering an applicable clinical trial [5]. More data elements are required than under prior U.S. law, and these new requirements include primary and secondary outcome measures, start date, and target number of subjects.

2. Timing of Registration at ClinicalTrials.gov

In general, the Responsible Party for an applicable clinical trial must submit required information by the later of 12/26/**2007** or 21 days after the first patient is enrolled [6].

Exceptions: (a) data for trials "ongoing" as of 9/27/2007 that do ***not*** involve a "serious or life threatening disease or condition" must be submitted by 9/27/**2008** [7], [8];
(b) trials that involve a "serious or life threatening disease or condition", are initiated before 9/27/07, and have a "completion date" prior to 12/26/2007 [9] are not subject to the new requirements, although they may be subject to other laws.

3. Penalties for Failure to Register

Penalties for responsible parties who fail to register applicable clinical trials are significant and may include civil monetary penalties [10] and, for federally-funded trials, the withholding or recovery of grant funds [11]. Starting December 26, 2007, any application or report submitted to FDA under sections 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act or under section 351 of the Public Health Service Act will need to include certification of compliance with any applicable provisions [12].