Update on Registration of Clinical Trials in ClinicalTrials.gov

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Abbreviations: FDAAA = Food and Drug Administration Amendments Act; ICMJE = International Commitee of Medical Journal Editors; PIs = principal investigators

This brief note is an update to the "Medical Writing Tip of the Month" article on clinical trial registration in *CHEST* (March 2007).[1] ClinicalTrials.gov (http://clinicaltrials.gov/), which currently contains > 73,000 registered trials, is operated by the National Institutes of Health. Although ClinicalTrials.gov continues to support a wide range of trial registration policies, including that of the International Committee of Medical Journal Editors (ICMJE),[2] we want to call your attention to a new US law. On September 27, 2007, Congress enacted the Food and Drug Administration Amendments Act (FDAAA) [United States Public Law 110-85], which expands the legal requirements for registration beyond previous US law and mandates results reporting.[3] Violations are subject to penalties. While the information presented previously on how to register at ClinicalTrials.gov continues to apply, we briefly describe changes to the registration requirements under FDAAA (see http://prsinfo.clinicaltrials.gov/fdaaa.html for more information). Reporting results at ClinicalTrials.gov is addressed in the companion "Medical Writing Tip of the Month" article in this issue of *CHEST*.[4]

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In general, section 801 of FDAAA (FDAAA 801) covers clinical trials (called "applicable clinical trials"

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in the law) that generally meet the following criteria:

- Phase 2 to 4 interventional studies;
- Studies that involve drugs, biological products, and medical devices (other than small feasibility studies) regulated by the US Food and Drug Administration;
- Studies that have at least one site in the United States or are conducted under an investigational new drug application or investigational device exemption; and
- Studies initiated or ongoing as of September 27, 2007, or later (those completed as of September 27, 2007, are excluded).

Study sponsors or principal investigators (PIs) designated by the sponsor (called "responsible parties" in FDAAA 801) must register applicable clinical trials no later than 21 days after enrollment of the first participant. They must also provide information not previously mandated under US law but required by other registration policies (*eg*, ICMJE[2]), including all prespecified primary and secondary outcome measures (see http://prsinfo.clinicaltrials.gov/definitions.html for more details regarding the registration data element requirements).

As previously described,[1] ClinicalTrials.gov staff review submissions prior to public posting and may request the sponsor or PI to clarify or correct information. Most registered trials will be available publicly within 2 to 5 business days. However, currently, under FDAAA 801, registered information for trials of investigational devices "not previously cleared or approved" by the US Food and Drug Administration may not be posted on the public site prior to approval or clearance of the device(s) involved in the trial. Responsible parties of device trials who wish to comply with the journal editors' policy should consult the ICMJE site for guidance (http://www.icmje.org/faq.pdf). Further, while FDAAA requires sponsors or PIs to update the recruitment status within 30 days of a change and all other registered information no less

frequently than once a year, we continue to recommend that records be amended as soon as recruitment status or other aspects of a protocol change to ensure that up-to-date information is available to the public.

References

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3 Tse T, Zarin DA. Clinical trial registration and results reporting: ClinicalTrials.gov and FDAAA. FDLI Update 2009; 1:18–22

4 Tse T, Williams RJ, Zarin DA. Reporting "basic results" in ClinicalTrials.gov. Chest 2009; 136:295–303