ClinicalTrials.gov
Fact Sheet

Registration Requirement
The Food and Drug Administration Amendments Act or FDAAA (Public Law 110-85, Title VIII, Section 801) was enacted on September 27, 2007 and mandates the types of trials that need be registered regardless of the study funding source including the data elements submitted and results reported for posting on ClinicalTrials.gov. The International Committee of Medical Journal Editors (ICMJE) also mandates clinical trial registration and updates.

Applicable Trials & Registration Requirements
FDAAA requires registration of all trials for drugs, devices and biologics excluding Phase I drugs studies and small device feasibility studies no later than 21 days after the first participant is enrolled. ICMJE requires registration of all human research projects that prospectively assign human participants to an intervention or comparison group to examine the relationship between a medical intervention and a health outcome before the first participant is enrolled. As of 7/1/2008 this includes Phase I and pharmacokinetic trials. It can take up to five working days for a record to post. To meet FDAAA and ICMJE requirements, UC recommends registering applicable trials at least 30 days prior to study start up.

FDAAA requires registered trial records to be updated at least once every 12 months and changes in recruitment status or study completion within 30 days of occurrence. Results must be registered upon the completion of the primary aim. ICMJE requires information to be updated every six months. Records containing results may take up to 30 days to become available. To meet FDAAA and ICMJE requirements, UC recommends updating records every six months (including date of change) and updating recruitment status and/or study completion within 30 days of the given time point.

Responsibility for Registration
The person or organization responsible (i.e., responsible party) for registering the trial is the sponsor of the trial or the principal investigator as designated by the sponsor, grantee, contractor or awardee.

Failure to Register
Penalties for responsible parties who do not register applicable trials may include notices of noncompliance, monetary sanctions (up to $10,000 per day), withholding or recovery of grant funds for federally funded trials as well as difficulties publishing.

How to Register
The University of Cincinnati maintains an institutional account and individual investigators should not attempt to set up their own account. Investigators should contact the UC Office of Research Integrity for access to an account (researchcompliance@uc.edu).

UC Resources
Guides through initial posting, updating and reporting basic results are available online (link below). http://researchcompliance.uc.edu/HSR/ClinicalTrials.gov.aspx
Identifying an “Applicable Clinical Trial” under FDAAA

- This flowchart presents basic guidance on determining if a trial is considered an “applicable clinical trial” under FDAAA. It maps out the guidance provided in the “Elaboration of Definitions of Responsible Party and Applicable Clinical Trial”, and is also available as an interactive flowchart at: http://grants.nih.gov/ClinicalTrials_fdaaa/index.htm

- This flowchart may not address every situation. The grantee’s sponsored research office, general counsel, or other similar official should be involved in determining whether or not the grant supports an applicable clinical trial that needs to be registered under FDAAA.

Does the trial include a drug, biologic or device?

Yes, a drug or biologic.

Does the trial meet all of the following 4 criteria?

1. It is a clinical investigation;
2. It is a controlled clinical investigation;
3. It is other than a Phase 1 clinical investigation; and
4. It investigates a drug (including a biological product) subject to section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA) or section 351 of the Public Health Service Act.

Yes

The trial would generally be considered an applicable clinical trial.

No

The trial would not generally be considered an applicable clinical trial.

Yes, a device.

Does the device trial meet all of the following 4 criteria?

1. It is a prospective clinical study of health outcomes;
2. It compares an intervention with a device against a control in human subjects;
3. The studied device is subject to section 510(k), 515, or 520(m) of the FDCA; and
4. It is other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes.

Yes

The trial would generally be considered an applicable device clinical trial.

No

The trial would not generally be considered an applicable clinical trial.

Is it pediatric postmarket surveillance as required under section 522 of the FDC Act?

Yes

The trial must be registered by 12/26/2007.

No

The trial is not subject to FDAAA.

Review the following criteria to determine if the applicable clinical trial (ACT) needs to be registered under FDAAA:

If the trial was initiated after 9/27/2007...

... then the ACT must be registered not later than 21 days after the first patient is enrolled, or by 12/26/2007, whichever is later.

If the trial was initiated on or before 9/27/2007 and ongoing as of 12/26/2007 and involves a serious or life threatening disease or condition...

... then the ACT must be registered by 12/26/2007.

If the trial was initiated on or before 9/27/2007 and ongoing as of 12/26/2007 and does not involve a serious or life threatening disease or condition...

... then the ACT must be registered by 9/27/2008.

If the trial was ongoing as of 9/27/2007, did involve a serious or life threatening disease or condition and was completed (meaning, not ongoing) by 12/26/2007...

... then the ACT is not subject to FDAAA, although if it is a drug clinical trial, it may be subject to pre-existing registration requirements under the Food and Drug Administration Modernization Act (FDAMA) of 1997.

If the trial was ongoing as of 9/27/2007, did not involve a serious or life threatening disease or condition and was completed (meaning, not ongoing) by 12/26/2007...

... then the ACT is not subject to FDAAA, and even if it is a drug clinical trial, it is also not subject to pre-existing registration requirements under FDAMA.