# FDAAA 801 Requirements

*Section 801 of the FDA Amendments Act*

## Who is Responsible?

- Sponsor
- Principal Investigator

## Which Trials Must be Registered?

Either initiated after September 27, 2007, or initiated on or before that date and were still ongoing as of December 26, 2007:

- **Trials of drugs and biologics.** Controlled clinical investigations, other than phase 1 clinical investigations, of drugs or biological products subject to Food and Drug Administration (FDA) regulation
- **Trials of devices.** 1) Controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and 2) pediatric postmarket surveillance required by FDA

## What "Applicable Clinical Trials"?

"Applicable clinical trials" generally include interventional studies (with one or more arms) of **FDA-regulated drugs, biological products, or devices that meet one of the following conditions:**

- The trial has one or more sites in the United States
- The trial is conducted under an FDA investigational new drug application or investigational device exemption
- The trial involves a drug, biologic, or device that is manufactured in the United States or its territories and is exported for research

## Exclusions

The following types of studies are generally excluded from the registration (and results submission) requirements of FDAAA 801. This is not a complete list.

- Phase 1 drug trials including studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes (see note)
- Small clinical trials 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 (see note)
- Trials that do not include drugs, biologics, or devices (such as behavioral interventions)
- Non-interventional (observational) clinical research, such as cohort or case-control studies

## Registration Deadline

The Responsible Party (that is, the sponsor or designated PI) for an Applicable Clinical Trial must submit required clinical trial information not later than 21 days after enrollment of the first participant.

## Results Deadlines

In general, results of an Applicable Clinical Trial of a drug, biologic, or device that is approved, licensed, or cleared by FDA must be submitted by the Responsible Party no later than 12 months after the Completion Date.