

42 C.F.R. § 11.22

Which applicable clinical trials must be registered?

- (a) *General specification.* (1) Any applicable clinical trial that is initiated after September 27, 2007, must be registered.
- (2) Any applicable clinical trial that is initiated on or before September 27, 2007, and is ongoing on December 26, 2007, must be registered.
- (3) *Determining the date of initiation for an applicable clinical trial.* An applicable clinical trial, other than a pediatric postmarket surveillance of a device product that is not a clinical trial, is considered to be initiated on the date on which the first human subject is enrolled. A pediatric postmarket surveillance of a device product that is not a clinical trial is considered to be initiated on the date on which FDA approves the plan for conducting the surveillance.

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