

Policies and Procedures

SECTION: Sponsored Programs Administration	NUMBER: 21	
CHAPTER: Sponsored Programs Administration	ISSUED: 10/2011	REVISED: 3/2013; 5/2017
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1. POLICY

ClinicalTrials.gov is a databank established under section 113 of the U.S. Food and Drug Administration (FDA) Modernization Act of 1997 (Modernization Act). The Modernization Act required the creation of a public resource for information on studies of drugs, including biological drug products, to treat serious or life-threatening diseases and conditions conducted under the FDA's investigational new drug (IND) regulations (21 CFR part 312). Section 113 of the Modernization Act amends section 402 of the Public Health Service Act (42 U.S.C. 282). It directs the Secretary of Health and Human Services, acting through the Director of the National Institutes of Health (NIH), to establish, maintain, and operate a databank of information on clinical trials for drugs to treat serious or life-threatening diseases and conditions.

Specifically, section 113 of the Modernization Act requires that ClinicalTrials.gov contain (1) information about Federally and privately funded clinical trials for experimental treatments (drug and biological products) for patients with serious or life-threatening diseases or conditions, (2) a description of the purpose of each experimental drug, (3) patient eligibility criteria, (4) a description of the location of clinical trial sites, and (5) a point of contact for patients wanting to enroll in the trial. Section 113 of the Modernization Act requires that information provided through ClinicalTrials.gov be in a form that can be readily understood by the public. 42 U.S.C. 282(j)(3)(A).

Section 113 of the Modernization Act requires all investigators to submit information to ClinicalTrials.gov about a clinical trial conducted under an investigational new drug (IND) application if it is for a drug to treat a serious or life-threatening disease or condition and it is a trial to test effectiveness (42 U.S.C. 282(j)(3)(A)). The investigator can also provide information on non-effectiveness trials or for drugs to treat conditions not considered serious or life-threatening.

Section 113 of the Modernization Act requires that investigators submit a description of the purpose of each experimental drug, patient eligibility criteria for participation in the trial, a description of the location of clinical trial sites, and a point of contact for those wanting to enroll in the trial.

For more information on registering a clinical trial in ClinicalTrials.gov, see IRB Policy 125, "[Registering Clinical Trials.](#)"