

Summary Table of FDAAA 801 and NIH Policy on Clinical Trials Registration and Reporting

Element of Policy/Rule	Rule	NIH Policy	ICMJE	CMS
Scope/Applicability	<p>Applicable clinical trials of FDA-regulated drug, biological, and device products and pediatric post-market surveillance studies of devices required by the FDA under the FD&C Act. Does not apply to phase 1 trials or small feasibility device studies.</p> <p>Applicable clinical trials are (1) clinical trials of drug and biological products that are controlled, clinical investigations, other than phase 1 investigations, of a product subject to FDA regulation; and (2) prospective clinical studies of health outcomes comparing an intervention with a device product against a control in humans (other than small feasibility studies) or any pediatric post-market surveillance studies required by FDA under the FD&C Act. Applies to public and private sector sponsors and other entities who meet the definition of a responsible party.</p>	<p>All clinical trials funded wholly or partially by NIH. Includes phase 1 clinical trials and trials that do not involve any FDA regulated product such as trials involving only behavioral interventions. Applies to NIH-funded clinical trials where applications or proposals are received by NIH on or after the policy’s effective date. Applies to NIH-conducted clinical trials initiated on or after the policy’s effective date.</p>	<p>Interventional studies (any intervention type, phase, or geographic location). ICMJE adopted the WHO definition of clinical trial as “any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.”</p> <p>*Identifying trials subject to FDAAA and ensuring they are registered in a timely manner does not ensure organization/investigator will meet requirements of ICMJE. The ICMJE policy covers more kinds of trials and intervention types and requires earlier registration.</p>	<p>Under NCD 310.1, “Medicare will cover the routine costs of qualifying trials that either have been deemed to be automatically qualified, have certified that they meet the qualifying criteria, or are required through the NCD process, unless CMS’s Chief Clinical Officer subsequently finds that a clinical trial does not meet the qualifying criteria or jeopardizes the safety or welfare of Medicare beneficiaries.</p> <p>“If the study is registered on ClinicalTrials.gov and is assigned an NCT identifier number, and includes billable charges, the NCT identifier number should be reported on all related claims as long as the patient is a study participant.”</p>
Timeframe for registration on ClinicalTrials.gov	Not later than 21 days after enrollment of the first participant.	Same	Prior to enrollment of first participant	
Registration data elements to be	Elements defined in the final rule. Consists of descriptive information, recruitment	Same	Same	

submitted to ClinicalTrials.gov	information, location and contact information, and administrative data.			
Timeframe for results information submission to ClinicalTrials.gov	Not later than 12 months after primary completion date; possible delay of up to an additional 2 years for trials of unapproved products or of products for which initial FDA marketing approval or clearance is being sought, or approval or clearance of a new use is being sought.	Same	N/A	
Results information data elements to be submitted to ClinicalTrials.gov	Elements defined in the final rule. Includes participant flow, demographic and baseline characteristics, outcomes and statistical analyses, adverse events, the protocol and statistical analysis plan, and administrative information	Same	N/A	
Potential Consequences of non-compliance	Identifying clinical trial record as non-compliant in ClinicalTrials.gov For federally funded trials, grant funding can be withheld if required reporting cannot be verified Civil monetary penalties of up to \$10,000/day (amount to be adjusted going forward)	May lead to suspension or termination of grant or contract funding Can be considered in future funding decisions Identify clinical trial record as non-compliant in ClinicalTrials.gov	Will not be published	
Effective Date	January 18, 2017. Compliance date is 90 days from the effective date.	January 18, 2017		January 1, 2015

References:

<https://www.nih.gov/news-events/summary-table-hhs-nih-initiatives-enhance-availability-clinical-trial-information>

<http://www.nejm.org/doi/full/10.1056/NEJMSr1611785#bt01>

<http://osp.od.nih.gov/sites/default/files/resources/CaseStudies-2015UPDATED.pdf>

<https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission>

<https://www.nih.gov/news-events/summary-hhs-nih-initiatives-enhance-availability-clinical-trial-information>

<http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/>

<http://www.icmje.org/journals-following-the-icmje-recommendations/>

<https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Downloads/Mandatory-Clinical-Trial-Identifier-Number-QsAs.pdf>

Definitions:

A. Applicable Clinical Trial:

Registration is required for trials that meet the FDAAA 801 definition of an "applicable clinical trial" and were either initiated after September 27, 2007, or initiated on or before that date and were still ongoing as of December 26, 2007. Trials that were ongoing as of September 27, 2007, and reached the Completion Date (see Primary Completion Date data element on ClinicalTrials.gov) before December 26, 2007, are excluded. Applicable Clinical Trials include the following:

1. 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
2. Trials of devices (see note): 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 (Note: For Applicable Clinical Trials that include a device not previously approved or cleared by FDA for any use and that need to be registered, full posting of the trial information on ClinicalTrials.gov will be delayed until after the device has been approved or cleared, as required by FDAAA 801. See the Delayed Posting data element on ClinicalTrials.gov.)

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:

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

B. Responsible Party

The Responsible Party for a clinical trial must register the trial and submit results information. The Responsible Party is defined as:

1. The sponsor of the clinical trial or
2. The principal investigator (PI) of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the PI is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of FDAAA's requirements for the submission of clinical trial information

At UCLA, the JCCC is the responsible party for all cancer studies and holds the institutional account. For SOM studies, the PI is the responsible party. The institutional account administration access is held by Elaine Cooperstein (Terra Hughes).

- C. Primary completion date: Results information must be submitted after the primary completion date, defined as the date that the final subject was examined or received an intervention for the purpose of collecting the data for the primary outcome measure. Results information submission may be delayed for as long as two additional years if the responsible party submits a certification to ClinicalTrials.gov that either: 1) a drug, biological, or device product studied in the clinical trial is not yet approved, licensed, or cleared for marketing by the FDA and is still under development by the manufacturer; or 2) that the manufacturer is the sponsor of the clinical trial and has sought or will seek approval, licensure, or clearance for a new use of a product studied in the trial within one year. The Final Rule also permits responsible parties to request extensions to the results information submission deadline for "good cause" (See § 11.44).

- D. Clinical Trial (NIH definition) - The NIH Policy applies to clinical trials defined as "a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes." Therefore, the NIH definition includes all phases of studies, as well as feasibility studies including all types of interventions (not just FDA regulated interventions).