

Comparison of Clinical Trials Registry Legislation in the Senate and House

Prepared by Tannaz Rasouli, AAMC Office of Governmental Relations

Clinical Trials Registry

	S. 1082 (Title II, Subtitle C)	H.R. 1561 (Title III)
Sponsors	Sen. Kennedy (D-Mass.), introduced 4/10/07 (adapted from S. 484 with Sen. Enzi (R-Wyo.))	Reps. Waxman (D-Calif.) & Markey (D-Mass.), introduced 3/19/07
Status	Approved, 93-1, by Senate 5/9/07	Referred to Committee on Energy & Commerce
Inclusion of Devices	Applies to both drug and device clinical trials.	Same.
Scope	Late Phase II, Phase III, and Phase IV trials must be registered in the database. Publicly available information (including FDA's action package on a drug) on results will be included. Device clinical trials to support FDA approval or clearance also are included, as well as pediatric postmarket surveillance. FDA will be given regulatory authority to require inclusion of results for trials not covered by publicly available information.	Late Phase II, Phase III, and Phase IV trials must be registered. A results database shall house results of all Phase III and Phase IV trials.
Searchable Categories within Clinical Trial Registry	NIH Director shall expand the existing Clinical Trial Registry data bank and shall ensure that registry data is made publicly available through the Internet. Director shall ensure that the data bank is easily used by the public, that entries are easily compared, and that the public may search entries by one or more of the following criteria: <ul style="list-style-type: none"> ▪ Disease or condition being studied, using Medical Subject Headers (MeSH) ▪ Treatment being studied ▪ Recruitment status of the trial ▪ Source of support for the trial, which may be NIH or another Federal agency, a private 	NIH Director shall establish a clinical trial database that is made publicly available through the Internet. Director shall ensure that the public may search entries by one or more of the following criteria: <ul style="list-style-type: none"> ▪ Indication being studied, using MeSH descriptors ▪ Safety issue being studied ▪ Enrollment status of the trial ▪ Sponsor of the trial

	<p>industry source, or university or other organization</p> <ul style="list-style-type: none"> ▪ Location of the clinical trial ▪ Age group studied, including pediatric subpopulations ▪ Study phase of the clinical trial ▪ National Clinical Trial number or other study identification of the clinical trial 	
Data Submission for Inclusion in Clinical Trial Registry	Responsible party shall submit to NIH Director clinical trial information not later than 21 days after first patient enrolled. Party also shall submit updates on enrollment status and completion within 30 days of such changes. A responsible party for a clinical trial that is not a drug or device trial may submit trial information for voluntary inclusion in the registry data bank.	Responsible party shall submit to NIH Director clinical trial information not later than 14 days after first patient enrolled. Party also shall submit updates on enrollment status and completion within 30 days of such changes, as well as periodic updates not less than once every six months until results of the trial are submitted.
Expansion of Clinical Trial Data Bank to Include Results	Expands the existing Clinical Trial Registry Data Bank to require links to results information.	Establishes a separate database for clinical trials results that links to corresponding entries in the registry database.
Searchable Categories within Clinical Trial Results Database	N/A	<p>NIH Director shall ensure the public may search entries by one or more of the following:</p> <ul style="list-style-type: none"> ▪ Indication studied, using MeSH descriptors ▪ Safety issue studied ▪ Approval status of application for the tested indication ▪ Phase of the clinical trial ▪ Name of the drug that is subject of trial ▪ Sponsor/Financial sponsor, as applicable

<p>A(ii)</p>	<p>Required Information</p>	<p>Secretary shall ensure the registry data bank includes links to:</p> <p>(I) FDA Information</p> <ul style="list-style-type: none"> ▪ Posted FDA summaries of advisory committee meetings on any drug or device clinical trial in the registry data bank. ▪ Posted FDA assessment of results of any drug trial in the registry data bank. ▪ FDA public health advisories regarding drugs/devices in the registry data bank. ▪ FDA action package for approval document for any drug in the data bank. ▪ Summary of safety and effectiveness information/data for device clinical trials. <p>(II) NIH Information</p> <ul style="list-style-type: none"> ▪ Medline citations to any publications regarding drug/device clinical trials in the data bank. ▪ The entry for the drug in the National Library of Medicine database of structured product labels, if available. 	<p>Responsible party shall submit above information, as well as:</p> <ol style="list-style-type: none"> 1) Two non-promotional summary documents; one that is technical and one that is non-technical in nature. The documents should include: <ul style="list-style-type: none"> ▪ Purpose of the trial ▪ Sponsor/financial sponsor of the trial ▪ Point of contact for information ▪ Description of patient population being tested ▪ General description of trial & results and the reason for changes in design ▪ (Technical summary only) Summary data of results including whether primary endpoint achieved, assessment of secondary endpoints, significant safety information, links to available peer-reviewed publications based on the trial, completion date, and link to web postings of adverse regulatory actions taken by FDA 2) Information on the percentage of individuals who ceased participation as subjects and their reasons for ceasing participation 3) Information of any agreement that the responsible party and/or manufacturer has entered, that restricts discussion or publication of the results at scientific meetings, public forums, or in scientific and academic journals
---------------------	------------------------------------	--	--

			<p>4) Link to available peer-reviewed publications based on the trial results</p> <p>5) Completion date of the trial</p> <p>6) Link to listing of any adverse FDA actions</p>
B	NIH Feasibility Study	Directs NIH to conduct a study within 18 months to determine the best methods of making results of clinical trials publicly available after drug approval.	None.
C	Negotiated Rulemaking	<p>Directs Secretary to establish a negotiated rulemaking process to determine which trials to include results information for in the data bank. The regulations shall establish which elements to include, a standard format and procedure for submission, a standard procedure for verification, and an implementation plan.</p> <p>Committee shall include members representing FDA, NIH, other Federal agencies as appropriate, patient advocacy and provider groups, pharmaceutical industry, contract clinical research organizations, International Committee of Medical Journal Editors, and other interested parties.</p>	None.
F	Waivers for Certain Clinical Trial Results	Secretary may waive any applicable requirements upon written request from the responsible person; Secretary must inform Congress of the waiver within 30 days of issuance.	None.
Coordination & Compliance		No Federal agency may release funds under a research grant to an awardee who has not submitted the required information for applicable clinical trials. The Secretary shall consult with other agencies that	Same.

	conduct human subject research to determine if such studies should be included in the data bank and to develop a procedure for submission of information.	
Retroactivity	The Secretary may include links to results information for entries submitted to the database prior to enactment, as available.	Secretary shall establish procedures and mechanisms to allow voluntary submission to the registry and results databases of information for clinical trials initiated before the date of enactment.
Authorization of Appropriations	\$10 million for each fiscal year	Same.
Timing and Public Availability	<p>Negotiated rulemaking process (described above) to determine timing of submissions.</p> <p>Negotiated rulemaking process (described above) to determine timing of posting results information.</p>	<p>Except in the case of extensions, results information to be submitted not later than 1 year after the earlier of (a) the estimated completion date of the trial, or (b) the actual date of completion or termination. Responsible party shall provide updates to information not less frequently than once every six months during the 10-year period after such information is originally due.</p> <p>Results of pre-approval studies to be made public not later than 30 days after the drug or device is approved or licensed or the Secretary deems the drug or device non-approvable. Summarized results of medical and clinical pharmacology reviews of pre-approval studies shall be made publicly available not later than 90 days after approval/non-approval. Results of post-approval studies to be made public not later than 30 days after submission.</p>

		If regulatory action or publication is pending, results would not be published until resolved. An investigator must notify NIH of publication not later than 15 days after and results will be made publicly available not later than 30 days after publication. If manuscript still not published within 2 years of trial completion, results will be made public.
Monetary Penalties for Non-Compliance	Penalty of \$10,000 imposed for first violation, and not more than \$20,000 for each subsequent violation.	Monetary penalties imposed if not corrected within 30 days. Penalty shall not be more than a total of \$15,000 for all violations adjudicated in a single proceeding in the case of an individual, and not more than \$10,000 per day until the violation is corrected in the case of any other person; the penalty for a nonprofit entity may not exceed a total of \$15,000 for all violations adjudicated in a single proceeding.
Content Review	Negotiated rulemaking process (described above) shall establish a standard procedure for verification.	Secretary shall compare submitted summary documents to results data for a representative sample of clinical trials to verify that the information is non-promotional, and not false or misleading.
Clinicaltrials.gov		Directs Secretary to publish in the Federal Register a notice determining the more efficient approach to establishing the registry database: (a) expanding and building upon the <clinicaltrials.gov> website, or (b) supplanting the website.