

Key ClinicalTrials.gov Reporting Requirements

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<http://ClinicalTrials.gov>

DISCLAIMER

Views are mine and do not necessarily
represent views of NIH or HHS

ClinicalTrials.gov Background

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ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.

Search (all fields optional)

Condition / Disease:

Keyword:

Country: ▾

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The database currently lists 245,188 studies with locations in all 50 States and in 200 countries.

Recruiting Study Locations



42,772 recruiting studies (May 18, 2017)

More Information

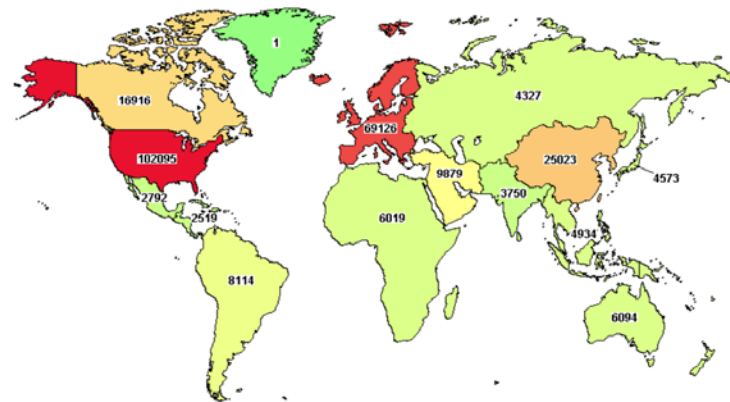
[For Patients and Families](#)

[For Researchers](#)

[For Study Record Managers](#)

About ClinicalTrials.gov

- Clinical studies registry and results database
 - >245,000 studies (trials, observational studies, & expanded access)
 - Studies with locations in all 50 states and 200 countries
 - Privately and publicly funded studies involving humans
 - Study information submitted by study sponsors or investigators
- Website & registry launched in February 2000
 - Results database, in September 2008
 - >26,000 studies with posted results
- Intended Audience
 - Registry: Public
 - Results Database: Readers of the medical literature
 - Both: Downloaders for other content analysis
- Usage
 - 76,000 unique visitors per day



Colors indicate the number of studies with locations in that region
Least Most
Labels give the exact number of studies.

Source: <https://ClinicalTrials.gov>

Content of a Study Record

(Minimum Information Requirements)

- **Registration section**

- Submitted **at** trial initiation
- Summarizes information from trial protocol: e.g.,
 - Condition
 - Interventions
 - Study Design
- Includes recruitment information (e.g., eligibility, locations)

- **Results section**

- Submitted **after** trial completion
- Summarizes trial results
 - Participant flow
 - Baseline characteristics
 - Outcome measures (including statistical analyses)
 - Adverse events
 - All cause Mortality
- Full Protocols & SAPs

ClinicalTrials.gov Reporting Volume

(as of 22 May 2017)

- Registration
 - 245,000 study records
 - 600 submissions/week
 - 16,500 data providers (sponsors and investigators)
- Summary Results Reporting
 - 26,000 records with results posted
 - 140 submissions/week
 - 2,800 data providers
- Usage Stats
 - 199+ million page views/month
 - 1.1M+ unique visitors/month

ClinicalTrials.gov Statistics

(as of May 22, 2017)

	<u>Registration</u>	<u>Results</u>
Total*	245,188	26,354
Type of Trial		
Observational	47,815 (20%)	1,695 (6%)
Interventional**	196,214 (80%)	24,659 (93%)
– Drug & Biologic	118,353	19,811
– Behavioral, Other	58,401	4,192
– Surgical Procedure	21,132	1,312
– Device***	23,273	2,886
Study Sites (200 countries)		
US only	88,536 (36%)	13,464 (51%)
Non-US only	114,559 (47%)	6,632 (25%)
US & Non-US mixed	13,559 (6%)	3,621 (14%)
Not Specified	28,534 (12%)	2,637 (10%)

*Includes 433 expanded access programs

**A study record may include more than one type of intervention

***Does not include 726 applicable device clinical trials submitted, but qualify for “delayed posting” under FDAAA

ClinicalTrials.gov Reporting Requirements

ClinicalTrials.gov – Milestones

- 1997 – FDA Modernization Act (FDAMA)
- 2000 - ClinicalTrials.gov launched
- 2005 - International Committee of Medical Journal Editors (ICMJE) trial registration policy
- 2007 - FDAAA 801* (Title VIII of Public Law 110-85)
 - Expanded clinical trial registration requirement and imposed new results submission requirements
 - Added enforcement provisions including up to \$10,000/day in civil monetary penalties and withholding remaining or future grant funds
- 2016 – FDAAA 801 Final Rule (42 CFR Part 11) & NIH Clinical Trials Disclosure Policy

Enhancing Clinical Trial Transparency

ClinicalTrials.gov

Under the law, it says you must report. If you don't report, the law says you shouldn't get funding. I'm going to find out if it's true [that the research centers aren't reporting the results] and if it's true, I'm going to cut funding. That's a promise.

Vice President Joe Biden
June 29, 2016



Key Clinical Trial Reporting Requirements

Reporting Requirement	ICMJE Policy (Effective in 2005)	FDAAA Final Rule (Issued in 2016)	Final NIH Policy (Issued in 2016)
Scope	Registration	Registration & Results Reporting	Registration & Results Reporting
Funding Source	Any	Any	NIH
Intervention Type	All	Drugs, Biologics, & Devices regulated by the FDA (Except Phase 1)	All (e.g., including Phase 1, behavioral interventions)
Submission Timing	Before enrollment of first participant	<u>Registration</u> : Within 21 days after first participant <u>Results</u> : Not later than 1 year after Primary Completion Date (some Delays permitted)	<u>Registration</u> : Within 21 days after first participant <u>Results</u> : Not later than 1 year after Primary Completion Date (some Delays permitted)
Enforcement	Refusal to publish	Criminal proceedings and civil penalties (up to \$10,000/day); Loss of HHS funding to grantee institution	Loss of NIH funding (term and condition of award)

ICMJE Trial Registration Policy

- **Scope** – All clinical trials, regardless of intervention type, phase, or sponsor
- **Reporting Due Date** – Registration before enrollment of the first participant
- **Potential Consequences of Non-Compliance** – Editor's refusal to publish trial results

FDAAA/Final Rule Overview

- **Scope –**
 - **Applicable Clinical Trials:** Include non-phase 1 trials of drugs, devices, and biologicals (including IND/IDE exempt trials)
 - **Responsible Party:** Study sponsor or designated PI
- **Reporting Due Dates –**
 - **Registration:** No later than 21 days after enrollment of the first participant
 - **Results Reporting:** No later than 1 year after the “primary completion date,”* with delayed submission for limited circumstances
- **Potential Consequences of Non-Compliance –**
 - **FDA:** Criminal proceedings and civil penalties (up to \$10,000/day)
 - **HHS:** Loss of HHS funding to grantee institution

- **Scope –**
 - **NIH-funded Trials:** Funded in whole or in part, including phase 1 trials and non-drug/device trials (e.g., behavioral, dietary supplements)
 - **Responsible Party:** NIH-funded awardees and investigators, as part of terms and conditions
- **Reporting Due Dates –**
 - **Registration:** No later than 21 days after enrollment of the first participant
 - **Results Reporting:** No later than 1 year after the “primary completion date”*
- **Potential Consequences of Non-Compliance –**
 - Loss of NIH funding to grantee institution

*Date final participant was examined or received intervention for the primary outcome as specified in the protocol

What's New in the FDAAA Final Rule

42 CFR Part 11

SPECIAL REPORT

Trial Reporting in ClinicalTrials.gov — The Final Rule

Deborah A. Zarin, M.D., Tony Tse, Ph.D., Rebecca J. Williams, Pharm.D., M.P.H.,
and Sarah Carr, B.A.

Title VIII of the Food and Drug Administration (FDA) Amendments Act of 2007 (FDAAA) expanded the legal mandate for sponsors and others responsible for certain clinical trials of FDA-regulated drug, biologic, and device products to register their studies and report summary results information to ClinicalTrials.gov,¹ which is managed by the National Library of Medicine at the National Institutes of Health (NIH). The statute expanded registration requirements and provided a legally defined timeline with specific requirements for the systematic reporting of summary trial results. Although statutory components took effect before 2010, the FDAAA directed the Department of Health and Human Services (HHS) to issue regulations regarding certain statutory provisions and to consider possible expansion of the requirements through rule-making.

developed the final rule, which was made publicly available on September 16, 2016. Simultaneously, the NIH issued a complementary final policy, under which NIH-funded awardees and investigators will be expected to submit registration and results information for all NIH-funded clinical trials, whether or not the trials are covered by the FDAAA requirements.⁶

Here, we summarize and highlight key points about the final rule (see box).

BACKGROUND

The FDAAA established legal requirements for sponsors and designated principal investigators (i.e., responsible parties) to report specified clinical trial information for certain applicable clinical trials to ClinicalTrials.gov. In addition to registration, the statute established a system and man-

Key Points about the Final Rule.

Clarifies the statutory language

Provides objective, structured criteria for evaluating whether a study is an “applicable clinical trial” (ACT)

Clarifies that for purposes of the final rule, all multigroup studies and all single-group interventional studies with prespecified outcome measures are considered “controlled”

Clarifies distinction between “secondary” and other prespecified outcome measures

Expands transparency beyond the basic statutory requirements

Requires submission of results information for ACTs of unapproved products

Requires submission of baseline information on race or ethnic group, if collected during the clinical trial, and other characteristics associated with primary outcome measures

Defines required levels of specification for outcome measures

Requires submission of information about adverse-event timeframe and collection method, as well as all-cause mortality

Requires submission of full protocol and statistical analysis plan at the same time as submission of results information

Other issues

NIH will post submitted records within a specified time frame, even if the records do not meet quality-control criteria; these records will include a disclaimer and, possibly, notation of the identified concerns

NIH will post registration information for trials of unapproved devices if authorized by responsible party

HHS declined requiring submission of narrative summaries

Goals of Final Rule

- **Clarifies** terms and provisions in the statute (FDAAA): e.g.,
 - ACT determination approach
- **Expands** basic requirements
 - Results information required for ACTs of unapproved products
 - Full protocol and statistical analysis plan required with results (will be made public)
- **Addresses** other Issues
 - Narrative summaries not required

New Final Rule Reporting Requirements

- All interventional studies are “in scope,” e.g.,
 - Single arm studies
 - Studies of imaging devices
 - Studies of IVDs
- Results submission required for trials regardless of FDA product approval status
- Full protocol (and SAP) required with results submission
- Posting at ClinicalTrials.gov within 30 days, even if does not meet QC criteria

Other New Requirements under Final Rule

- Can “opt out” of device lockbox
- Additional baseline measures required
 - Race/ethnicity
 - Measures associated with outcome measures

New Requirements: Adverse Event Information

- **Time Frame** - specific period over which adverse event information was collected
- **Adverse-Event Reporting Description** - if the adverse-event information collected in the clinical trial is collected on the basis of a different definition of “adverse event” from that used in the final rule
- **Collection Approach** - used for adverse events during the study: systematic or nonsystematic),
- **All-Cause Mortality Table** – shows the number and frequency of deaths due to any cause by treatment group or comparison group

New Requirements: Submission of Protocols and SAPs

- Full protocol documents (and statistical analysis plans) required as Final Rule results submission
- Document upload feature to be available in June
 - Format: Portable Document Format Archival (PDF/A)
 - Mockup of study record display

▶ **Study Documents (Full Text) Available at ClinicalTrials.gov**

Documents provided by National Cancer Institute (NCI)

[Study Protocol](#) (PDF, May 1, 2017)

[Statistical Analysis Plan](#) (PDF, May 1, 2017)

[Informed Consent Form – Child](#) (PDF, May 1, 2017)

[Informed Consent Form – Parent](#) (PDF, May 1, 2017)

Effective Date: January 18, 2017

- FDAAA Final Rule Requirements
 - Registration: Study Start Date \geq January 18, 2017
 - Summary Results: Primary Completion Date \geq January 18, 2017
 - Compliance Date: April 18, 2017
- NIH Policy Requirements
 - Study Start Date \geq January 18, 2017AND
 - Funding application (e.g., grants, other transactions, contracts) first submitted \geq January 18, 2017

COGR Comments on the NPRM and the Final Rule

NIH-2011-0003-0873 submitted on 23 March 2015 by
Anthony P. DeCrappeo, President, COGR

<https://www.regulations.gov/document?D=NIH-2011-0003-0873>

COGR

an organization of research universities

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March 23, 2015

Jerry Moore
NIH Regulations Officer
Office of Management and Assessment
6011 Executive Boulevard
Suite 601, MSC 7669
Rockville, MD 20852-7669

Re: Notice of Proposed Rulemaking (NPRM) for Clinical Trials Registration and Results Submission (RIN 0925-AA52), Docket Number NIH-2011-0003

Dear Mr. Moore:

The Council on Governmental Relations (COGR) is an association of 190 research universities and their affiliated academic medical centers and research institutes. COGR concerns itself with the influence of federal regulations, policies, and practices on the performance of research conducted at its member institutions. We and our members appreciate the opportunity to comment on the Department of Health and Human Services (DHHS) NPRM entitled, "Clinical Trials Registration and Results Submission."

We support the interest of the DHHS to expand results reporting to the general public, medical and researcher communities ("stakeholders") through ClinicalTrials.gov. We also recognize that transparency of information concerning clinical trials is critical to all stakeholders in order to reduce bias, avoid duplication, and expedite scientific discoveries. However, we are alarmed after hearing from our COGR members that the NPRM as currently written will generate concerns surrounding privacy protection with the potential that de-identified data can eventually be traced to a human being. Other concerns include the fear of non-compliance and stricter penalties within the short timeframes imposed, inadequate resources to provide the volume of data and

Summary of COGR Comments on NPRM

- **Overall:** “We support the interest of the DHHS to expand results reporting to the general public, medical and researcher communities (“stakeholders”) through ClinicalTrials.gov.”
- **Specific Concerns:**
 1. De-identified Data and Data Sharing Plan
 2. Quality Control Review Timeframes Too Short
 3. Burden of Update Timeframes
 4. Transparency and Harmonization

1. De-identified Data and Sharing Plans

- **Comment Excerpt:** “...we are alarmed after hearing from our COGR members that the NPRM as currently written will generate concerns surrounding privacy protection with the potential that de-identified data can eventually be traced to a human being.”
- Neither the Final Rule nor the NIH Policy requires submission of a data sharing plan or individual participant-level data (IPD)
 - “No patient-specific data are required to be submitted by this rule or by the law this rule is intended to implement.” (81 FR 64982)
 - “In those situations in which a responsible party believes results information could not be submitted in a way that is consistent with this proposed rule without risk of re-identification, the responsible party could alternatively request a waiver of results submission requirements...” (79 FR 69591)

Optional Data Sharing Data Elements

- ClinicalTrials.gov provides two sets of **optional** data elements to accommodate other IPD-sharing policies (e.g., NAS, ICMJE)

Plan to Share Individual Participant Data (IPD) Data Element - **Current**

- **At Time of Registration (Oversight module)**
 - **Plan to Share IPD**
 - Definition: Indicate whether there is a plan to make individual participant data (IPD) collected in this study available to other researchers (typically after the end of the study). Select Yes/No/Undecided.
 - **Plan Description**
 - Definition: If IPD collected in this study are to be made available to other researchers (typically after the end of the study), briefly describe what participant data sets and/or documents are to be shared, when data will be available, and how the data may be obtained. An explanation may be provided for why IPD will not be shared.

Individual Participant Data (IPD) Sharing Statement - **Planned**

- Plan to Share IPD (Yes/No/Undecided)
 - **IPD-Sharing Description:** specific participant data sets to be shared
 - **IPD-Sharing Additional Information Type**
 - Study Protocol
 - Statistical Analysis Plan
 - Informed Consent Form
 - Clinical Study Report
 - Analytic Code
 - **IPD-Sharing Time Frame:** when IPD and supporting information will become available and for how long
 - **IPD-Sharing Access Criteria:** with whom, for what types of analyses, and by what mechanism IPD will be shared
 - **URL:** web address used to find additional plan information

Plan to Share Individual Participant Data (IPD) Data Element - **Current**

- **At Time of Registration (Oversight module)**
 - **Plan to Share IPD**
 - Definition: Indicate whether there is a plan to make individual participant data (IPD) collected in this study available to other researchers (typically after the end of the study). Select Yes/No/Undecided.
 - **Plan Description**
 - Definition: If IPD collected in this study are to be made available to other researchers (typically after the end of the study), briefly describe what participant data sets and/or documents are to be shared, when data will be available, and how the data may be obtained. An explanation may be provided for why IPD will not be shared.

Available Study Data/Documents

Data Element -- Current

- **Available Study Data/Documents**

Definition: Study data sets and documents that are being shared. Provide the following information for each:

- **Type**

Definition: The type of data set or document being shared.

- Individual Participant Data Set
- Study Protocol
- Statistical Analysis Plan
- Informed Consent Form
- Clinical Study Report
- Analytic Code
- Other (specify)

- **URL**

Definition: The Web address used to request or access the data set or document.

References Module: Available Study Data/Documents Data Element

- **Available Study Data/Documents (cont.)**

- **Identifier**

Definition: The unique identifier used by a data repository for the data set or document.

- **Comments**

Definition: Additional information including the name of the data repository or other location where the data set or document is available. Provide any additional explanations about the data set or document and instructions for obtaining access, particularly if a URL is not provided.

2. QC Review Timeframes Too Short

- **Comment Excerpt:** “we ask that [NLM] not publicly post data that has not been through its own Quality Assurance process completely and successfully just for the sake of meeting 30 day posting goals. Bad data shared publicly is worse than delayed data...”
- **Final Rule:**
 - 42 CFR 11.35: “NIH will post publicly... registration information ... not later than 30 calendar days after the responsible party has submitted such information...”
 - 42 CFR 11.52: “The Director will post publicly... results information... not later than 30 calendar days after the date of submission.”

42 CFR 11.64(b)(1) Corrections— *Quality control*

- “...the Director may provide electronic notification to the responsible party of apparent errors, deficiencies, and/or inconsistencies in the submitted information identified during procedures for quality control review... as specified at <https://prsinfo.clinicaltrials.gov>.”
- “The responsible party must correct or address all apparent errors, deficiencies, and/or inconsistencies identified in the notification
 - not later than 15 calendar days for clinical trial registration information, or
 - 25 calendar days for clinical trial results information, after the date of the electronic notification sent to the responsible party.”

What Do the QC Review Criteria Address?

- Tables should convey study design, conduct, and analysis
- Data must make sense
 - Measure name, units, and data must match
 - Use words precisely (e.g., incidence, rate)
 - No invalid entries
 - E.g., 823 hours/day; “time to survival”
 - No missing parameters or data
- Results record must be logical and internally consistent

Examples of Errors

- “Time to survival” listed as an outcome measure, without understanding that it is an illogical entry;
- More participants analyzed for an outcome measure than started the study (and no recognition that this was a problem);
- P-value reported, but investigator denied that it was based on a “statistical test”;
- Confidence interval reported, but no parameter listed (and investigator denied that there was a parameter)

Posted Records for which QC Review Has Not Concluded – Final Rule Preamble

- “The quality control review process will continue even after submitted information is posted, with a notice that the quality control review process has not concluded.” (81 FR 65116)
- **For Registration only:** “...we will not assign an NCT number until the quality control review process has concluded.” (81 FR 65064)
- “...the clinical trial record will contain information that will be visible to those viewing the record on *ClinicalTrials.gov* to make it clear that the quality control review process has not concluded for the posted registration information.” (81 FR 65064)
- “...we will evaluate whether there are ways in which the notices for each record could specify the data element(s) identified by the Agency that may contain errors, deficiencies, and/or inconsistencies, and aim to employ other measures to ensure that the notice is clear and limited to the relevant sections.” (81 FR 65111-2)

Posted Records for which QC Review Has Not Concluded – Plans

- QC review comments made on study records after April 18, 2017, will be labeled as either “Major Comments” or “Advisory Comments” within the PRS data entry system
 - **Major issues** identified in the comments must be corrected or addressed
 - **Advisory issues** are suggestions to help improve the clarity of the record
- More information on the remaining steps to fully implement the quality control review criteria and process will be available soon.

What is our Goal?

1. Make it as straightforward as possible for the motivated person with the requisite knowledge to enter results
2. Make it as clear as possible what the requisite knowledge is:
 - a) Clinical research knowledge and skills
 - b) Understanding of specific trial, and access to summary data

Upgrades from ClinicalTrials.gov

- User-focused improvements to data entry system
- 12 PhD level quality reviewers are available for 1:1 assistance at any stage in process
 - “navigator” process available to walk you through complete data entry
- Reports within the system to help organizational administrators keep track of the status of their records
- Email and other warning system in place to alert Responsible Parties when there are problems that require attention

Requesting One-on-One Help with Results

Results Section

[Enter Results](#) Results submission is required by FDAAA 801 for certain [applicable clinical trials](#) of drugs, biologics and devices. Note: other clinical trials may need to have results submitted based on other funder or sponsor policies.

For more information see: [When Do I Need to Register and Submit Results?](#)

Need help with Results? Contact ClinicalTrials.gov PRS to request one-on-one assistance from one of our experts.

Message to ClinicalTrials.gov Staff

Requesting one-on-one assistance with Results.

* Your Email Address:

* Message: Let us know if you have specific questions about your record or if you need general help with Results.

If you would like to speak with someone by phone, please complete the following information:

Phone Number:

Best Dates/Times (with time zone):

* Required fields

Reactions to 1-to-1 Results Navigation

- “The session with clinicaltrials.gov was highly effective, and indeed we worked out methods for reporting side effects for crossover studies.”
- “I've been very impressed with how responsive the PRS team has been with my questions. Additionally, the quality and completeness of the answers has been fantastic.”
- “We so appreciate the time and the discussion yesterday and especially your continued interest in helping us seek the best possible resolution with our challenges with the results section of this study.”
- “Thank you so much for your clear explanation. It helps me a lot.”
- “I cannot thank you enough for helping me work through this. ... I have learned a lot, and have saved all the informational links for future use with the site.”

3. Burden of Update Timeframes

- **Comment Excerpt:** ““we recommend that you expand the time frames ... to the maximal reasonable choices. ... Urgent updates could uniformly face a 30 day requirement, non-urgent updates could be done annually....”

Data Element	Deadline for Updating (i.e., not later than the specified date)
Study Start Date	30 calendar days after the first subject is enrolled (if the first human subject was not enrolled at the time of registration).
Intervention Name(s)	30 calendar days after a nonproprietary name is established.
Availability of Expanded Access	30 calendar days after expanded access becomes available (if available after registration); and 30 calendar days after an NCT number is assigned to a newly created expanded access record. [1]
Expanded Access Status	30 calendar days after a change in the availability of expanded access.
Expanded Access Type	30 calendar days after a change in the type(s) of available expanded access.
Overall Recruitment Status	30 calendar days after a change in overall recruitment status. [2]
Individual Site Status	30 calendar days after a change in status of any individual site.
Human Subjects Protection Review Board Status	30 calendar days after a change in status.
Primary Completion Date	30 calendar days after the clinical trial reaches its actual primary completion date.
Enrollment	At the time the primary completion date is changed to “actual,” the actual number of participants enrolled must be submitted.
Study Completion Date	30 calendar days after the clinical trial reaches its actual study completion date.
Responsible Party, by Official Title	30 calendar days after a change in the responsible party or the official title of the responsible party.
Responsible Party Contact Information	30 calendar days after a change in the responsible party or the contact information for the responsible party.
Device Product Not Approved or Cleared by U.S. FDA	15 calendar days after a change in approval or clearance status has occurred.
Record Verification Date	Any time the responsible party reviews the complete set of submitted clinical trial information for accuracy and not less than every 12 months, even if no other updated information is submitted at that time.

4. Transparency and Harmonization

- **Comment Excerpt:** “We ask that you harmonize with other agencies and acknowledge efforts currently underway to promote public awareness and transparency ensuring efforts aren’t duplicated unnecessarily.”

Other Relevant Policies Leveraging ClinicalTrials.gov Infrastructure

- **WHO** – Registration of all interventional studies
- **Declaration of Helsinki** – Registration of all human studies
- **EMA** – Registration and summary results reporting for all EU drug trials
- **CMS** – Registration of trials used for Coverage with Evidence Development (CED) and summary results reporting (or publication)
- **VA** – Registration and summary results reporting for all Office of Research and Development-funded clinical trials
- **PCORI** – Registration and summary results reporting for all PCORI-funded clinical studies

The Need for Institutional Leadership: Improving the CRE

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Potential Actions for Stakeholders

- Funders
 - Identify gaps and potential overlaps before funding new research
 - Hold awardees accountable for accurate, timely and complete reporting
- Institutional Review Boards
 - Identify past and ongoing trials that may inform potential risks and benefits of proposed trials
- Academic Medical Centers
 - Provide scientific leadership and institutional resources to support trial reporting by investigators
 - Take responsibility for ensuring all sponsored trials are reported
 - Create educational resources to support quality trial documentation as part of training and provide incentives for high-quality reporting

Potential Actions for Stakeholders - continued

- Trialists
 - Search for similar trials (landscape analysis) before starting a trial
 - Register and report results with specificity and accuracy
- Journal Editors/Peer Reviewers
 - Ensure prospective and complete trial registration occurred before publishing trial results
 - Verify that data submitted in manuscript are consistent with prespecified registration and/or discrepancies are explained
- Meta-Researchers
 - Continue characterizing and monitoring the clinical research enterprise
- ClinicalTrials.gov & Other Databases
 - Continue to improve user interfaces and enhance resource materials available to users
 - Continue to improve search interfaces

Questions?