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Final Rule Webinar Series – 3 of 3

- The webinar will begin at 1 PM ET
- We will test the audio before we begin
  - All telephone lines are muted
- Use the Q & A panel to ask questions
  - Address questions to "All Panelists"
  - We will aim to address questions not answered today in the next webinar and/or with information on the ClinicalTrials.gov website
- After the webinar, submit questions to: register@clinicaltrials.gov

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Final Rule for Section 801 of the Food and Drug Administration Amendments Act of 2007 (42 CFR Part 11)

Final Rule Webinar Series – 3 of 3
October 11, 2016

Rebecca J. Williams, Assistant Director, ClinicalTrials.gov
National Library of Medicine

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https://ClinicalTrials.gov

Webinar Series – Overview

- Webinar #1 (September 27, 2016) – now available online
  - Overview of the Final Rule
  - Effective Date and Compliance Date
- Webinar #2 (October 5, 2016) – now available online
  - Clinical Trial Registration Information and Update Requirements
- Webinar #3 (October 11, 2016)
  - Clinical Trial Results Information and Update Requirements
  - Posting and Quality Control Review Procedures

https://clinicaltrials.gov/ct2/manage-recs/present#FinalRuleWebinar

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Today's Agenda

A. Overview of Final Rule Requirements

B. Results Submission Requirements

1. Who must submit clinical trial results information?
2. For which applicable clinical trials must clinical trial results information be submitted?
3. When must clinical trial results information be submitted?
4. What constitutes clinical trial results information?
5. When must clinical trial results information be updated?

C. Posting and Quality Control Review Procedures

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A. Overview of Final Rule Requirements

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The NEW ENGLAND JOURNAL of MEDICINE

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 rulemaking. 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-

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DOI:10.1056/NEJMsr1611785

Regulatory Text - Table of Contents

Subpart A – General Provisions

- § 11.2 - What is the purpose of this part?
- § 11.4 - To whom does this part apply?
- § 11.6 - What are the requirements for the submission of truthful information?
- § 11.8 - In what format must clinical trial information be submitted?
- § 11.10 - What definitions apply to this part?

Subpart B – Registration

- § 11.20 - Who must submit clinical trial registration information?
- § 11.22 - Which applicable clinical trials must be registered?
- § 11.24 - When must clinical trial registration information be submitted?
- § 11.28 - What constitutes clinical trial registration information?
- § 11.35 - By when will the NIH Director post clinical trial registration information submitted under § 11.28?

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Regulatory Text - Table of Contents (cont.)

Subpart C – Results Information Submission

- § 11.40 - Who must submit clinical trial results information?
- § 11.42 - For which applicable clinical trials must clinical trial results information be submitted?
- § 11.44 - When must clinical trial results information be submitted for applicable clinical trials subject to § 11.42?
- § 11.48 - What constitutes clinical trial results information?
- § 11.52 - By when will the NIH Director post clinical trial results information submitted under § 11.48?
- § 11.54 - What are the procedures for requesting and obtaining a waiver of the requirements clinical trial results information submission?

Subpart D – Additional Submissions of Clinical Trial Information

- § 11.60 - What requirements apply to the voluntary submission of clinical trial information for clinical trials of FDA-regulated drug products (including biological products) and device products?
- § 11.62 - What requirements apply to applicable clinical trials for which submission of clinical trial information has been determined by the NIH Director to be necessary to protect the public health?
- § 11.64 - When must clinical trial information submitted to ClinicalTrials.gov be updated or corrected?

Subpart E – Potential Legal Consequences of Non-Compliance

- § 11.66 - What are potential legal consequences of not complying with the requirements of this part?

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General Requirements (42 CFR Part 11)

- The responsible party for an applicable clinical trial (ACT) must:
  - **Register** the ACT on ClinicalTrials.gov no later than 21 days after enrollment of the first participant;
  - **Update** the ACT on ClinicalTrials.gov at least once every 12 months with some items requiring update within 15 or 30 days of a change (e.g., Recruitment Status, Primary Completion Date within 30 days)
  - **Submit summary results** (including adverse event information) not later than 1 year after the trial's Primary Completion Date, with delays allowed in some circumstances

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B. Results Submission Requirements
1. Who must submit clinical trial results information?

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Who must submit clinical trial results information? (42 CFR 11.40)

- The **responsible party** for an applicable clinical trial that is specified in 42 CFR 11.42 must submit clinical trial results information for that trial
- See 42 CFR 11.4(c) for determination of responsible party
  - Also described in 2nd webinar on October 5, 2016

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See also Section IV.A.2. To whom does this part apply? - § 11.4 (81 FR 65002 – 05)

2. For which applicable clinical trials must clinical trial results information be submitted?

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Which trials must submit clinical trial results information? (42 CFR 11.42)

- Applicable clinical trials for which the studied product is **approved, licensed, or cleared** by FDA and required to register
  - Primary Completion Date on or after January 18, 2017: 42 CFR 11.48
  - Primary Completion Date before January 18, 2017: STATUTE (FDAAA)
- Applicable clinical trials for which the studied product is **not approved, licensed, or cleared** by FDA and required to register
  - Primary Completion Date on or after January 18, 2017: 42 CFR 11.48
  - Primary Completion Date before January 18, 2017: Not required

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Final Rule Section IV.C.2. For which applicable clinical trials must clinical trial results information be submitted? - § 11.42 (81 FR 65064 – 66)

Primary Completion Date

- Definition of “completion date” (42 CFR 11.10(a))
  - For purposes of this part, “completion date” (term in the statute) referred to as “primary completion date”
  - Date the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome
  - If multiple primary outcome measures, the date on which data collection is completed for all of the primary outcomes
- "Primary completion date” data element (42 CFR 11.10(b)(17))
  - Estimated date updated to actual primary completion date

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Final Rule Section IV.A.5. What definitions apply to this part? - § 11.10 (81 FR 65008 – 29)

3. When must clinical trial results information be submitted?

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When must clinical trial results information be submitted for applicable clinical trials?

- Standard submission deadline (42 CFR 11.44(a))
  - Applies to applicable clinical trials required to have results information submitted under 42 CFR 11.42
  - Results information must be submitted no later than 1 year after the Primary Completion Date
- Delayed submission
  - Seeking approval, licensure, or clearance of a **new use** (42 CFR 11.44(b))
  - Seeking **initial** approval, licensure, or clearance (42 CFR 11.44(c))
  - Extensions for good cause (42 CFR 11.44(e))

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Final Rule Section IV.C.3. When must results information be submitted for applicable clinical trials subject to § 11.42? § 11.44 (81 FR 65066 – 79)

Submitting Partial Results Information (42 CFR 11.44(d))

- Addresses situations in which secondary outcome measure(s) or additional adverse event information are not collected by the primary completion date
  - Secondary outcome measure (SOM) is due no later than one year after the date on which the final subject is examined or receives an intervention for purposes of final collection of data for that SOM
  - Additional adverse event information is due no later than one year after the date of data collection of that information
  - If certification delaying results information is submitted under 42 CFR 11.44(b) or (c), then later of due dates

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Final Rule Section IV.C.3. When must results information be submitted for applicable clinical trials subject to § 11.42? § 11.44 (81 FR 65066 – 79)

Submitting Partial Results Information (42 CFR 11.44(d))

- Study Completion Date (42 CFR 11.10(a))
  - "Date the final subject was examined or received an intervention for purposes of final collection of data for the primary and secondary outcome measures and adverse events (e.g., last subject's last visit), whether the clinical trial concluded according to the pre-specified protocol or was terminated"
  - Helps identify requirements for clinical trial results information and when obligations for updates and corrections are fulfilled
- Responsible party may need to submit partial results information several times
- Obligation to submit results continues until all required results information is submitted – i.e., not later than 1 year following Study Completion Date

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Final Rule Section IV.C.3. When must results information be submitted for applicable clinical trials subject to § 11.42? § 11.44 (81 FR 65066 – 79)

4. What constitutes clinical trial results information?

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What constitutes clinical trial results information? (42 CFR 11.48)

- 42 CFR 11.48(a) applies to applicable clinical trials required to register* and with a Primary Completion Date on or after January 18, 2017 (effective date)
- Results information consists of:
  - (1) Participant Flow
  - (2) Demographic and baseline characteristics
  - (3) Outcomes and statistical analyses
  - (4) Adverse event information
  - (5) Protocol and statistical analysis plan
  - (6) Administrative information
  - (7) Additional clinical trial results information for applicable device clinical trials of unapproved or uncleared device products
- See also "Changes from Current Practice Described in the Final Rule" (https://prsinfo.clinicaltrials.gov/FinalRuleChanges-16Sept2016.pdf)

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* Other than a pediatric postmarket surveillance of a device product that is not a clinical trial (see 42 CFR 11.48(b))

Which Requirements Apply? Final Rule v. Statute

- **Results information** determined by Primary Completion Date
  - Primary Completion Date on or after January 18, 2017: FINAL RULE
  - Primary Completion Date before January 18, 2017: STATUTE (FDAAA)
- Protocol Registration and Results System (PRS) will rely on Primary Completion Date (PCD) to determine which results information requirements apply
- Although we intend to make most results data elements specified in 42 CFR 11.48(a) available in PRS on January 18, 2017, the earliest results information would be due under final rule requirements is January 18, **2018**

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Final Rule, Section IV.F. Table on Applicability of Requirements in 42 CFR Part 11 (81 FR 65121)

Overview of PRS Implementation Plans

- By Late November: Targeting release to PRSTest with the registration and results final rule data elements (except protocols)
  - Data element definition documents and XML schema will be available (new data elements will be additive; intend for "old" XML schema to work indefinitely)
  - For informational purposes; do not use PRSTest as a "staging area" for PRS
- January 18, 2017: Effective Date
  - Release will be operational on PRS; results data elements newly required by final rule will be available and have WARNING if not completed (if PCD $\geq$ Jan 18, 2017)
- April 18, 2017: Compliance Date
  - Results data elements newly required by final rule will have ERRORS if not completed (if PCD $\geq$ Jan 18, 2017)

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PRS Test: https://prstest.nlm.nih.gov

Participant Flow (42 CFR 11.48(a)(1))

- Participant Flow Arm Information (Title and Description *)
- Pre-Assignment Information, if any *
  - Significant events that occur after enrollment and prior to assignment to an arm
- Participant Data
  - Number of human subjects that started and completed the clinical trial, by arm
  - If assignment is based on a unit other than participants, also include a description of the unit of assignment (e.g., eyes, lesions, implants) and number of units that started and completed the clinical trial, by arm * (new)

* Newly required by the final rule
Final Rule Section IV.C.4. What constitutes clinical trial results information? - § 11.48 (81 FR 65079 - 81)

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Demographic and Baseline Characteristics (42 CFR 11.48(a)(2))

- Baseline Characteristics Arm/Group Information (Title and Description *)
- Baseline Analysis Population Information
  - Overall Number of Baseline Participants
  - Overall Number of Units Analyzed * (new)
    - If the analysis is based on a unit other than participants, a description of the unit of analysis (e.g., eyes, lesions)
  - Analysis Population Description *
    - If the Overall Number of Baseline Participants (or units) differs from the number of human subjects (or units) assigned to the arm

* Newly required by the final rule
Final Rule Section IV.C.4. What constitutes clinical trial results information? - § 11.48 (81 FR 65081 - 84)

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Demographic and Baseline Characteristics

- Baseline Measure Information
  - Age
  - Sex/Gender
  - Race and Ethnicity * (if collected under protocol)
  - Other measure(s) that were assessed at baseline and used in the analysis of the primary outcome measure(s) *

* Newly required by the final rule
Final Rule Section IV.C.4. What constitutes clinical trial results information? - § 11.48 (81 FR 65081 - 84)

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Demographic and Baseline Characteristics (cont.)

- Baseline Measure Information
  - Name and Description of Measure, including any categories used to submit Baseline Measure Data
  - Measure Type and Measure of Dispersion
    - Added "count of participants", "count of units," and "geometric least squares mean" to Measure Type options (new)
    - Removed "log mean" as Measure Type option
  - Unit of Measure
- Baseline Measure Data
  - Additional option for specifying when data are mutually exclusive and exhaustive
- Number of Baseline Participants (and Units) * (new)
  - If different from Overall Number of Baseline Participants or Overall Number of Units Analyzed

* Newly required by the final rule
Final Rule Section IV.C.4. What constitutes clinical trial results information? - § 11.48 (81 FR 65081 - 84)

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Outcomes and Statistical Analyses (42 CFR 11.48(a)(3))

- For each primary and secondary outcome measure
- Outcome Measure Arm/Group Information (Title and Description *)
- Analysis Population Information
  - Number of Participants Analyzed
  - Number of Units Analyzed
    - If the analysis is based on a unit other than participants, a description of the unit of analysis (e.g., eyes, lesions, implants)
  - Analysis Population Description *
    - If Number of Participants Analyzed or Number of Units Analyzed differs from number of human subjects or units assigned to the arm

* Newly required by the final rule
Final Rule Section IV.C.4. What constitutes clinical trial results information? - § 11.48 (81 FR 65081 - 84)

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Outcomes and Statistical Analyses

- Outcome Measure Information
  - Name of the specific outcome measure, including any categories in which Outcome Measure Data are aggregated
  - Description of metric used to characterize specific outcome measure *
  - Time point(s) at which the measurement was assessed
  - Outcome Measure Type (Primary, secondary, other pre-specified, post hoc)
  - Measure Type and Measure of Dispersion or Precision
    - Same modifications as described for similar elements in baseline
  - Unit of Measure
- Outcome Measure Data

* Newly required by the final rule
Final Rule Section IV.C.4. What constitutes clinical trial results information? - § 11.48 (81 FR 65084 - 90)

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Outcomes and Statistical Analyses (cont.)

- Result(s) of scientifically appropriate tests of statistical significance of primary and secondary outcome measures (limited to statistical analyses that rely on submitted outcome measure data)
  - Pre-specified in the protocol and/or statistical analysis plan and performed on the outcome measure data (excludes statistical analyses considered exploratory)
  - Made public by the sponsor or responsible party prior to the date on which clinical trial results information is submitted for the primary outcome measure(s)
  - Conducted on a primary outcome measure in response to a request by FDA prior to the date on which clinical trial results information is submitted for the primary outcome measure(s)
- Does not reflect Agency's agreement that analyses are necessarily valid

* Newly required by the final rule

Final Rule Section IV.C.4. What constitutes clinical trial results information? - § 11.48 (81 FR 65084 - 90)

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Statistical Analyses

- Statistical Analysis Overview, including
  - Identification of arms compared
  - Type of statistical test conducted
    - Superiority, non-inferiority, equivalence, or other (appropriate for single-group or other descriptive statistics) (new)
    - For a non-inferiority or equivalence test, a description that includes the power calculation and non-inferiority or equivalence margin
- One of the following, as applicable
  - Statistical Test of Hypothesis (p-value and procedure used)
  - Method of Estimation (estimation parameter, estimated value, and confidence interval (if calculated))
  - General "other" option if information can't be submitted using above options

Final Rule Section IV.C.4. What constitutes clinical trial results information? - § 11.48 (81 FR 65084 - 90)

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Considerations for Terminated Trials

- Trial terminated before data are collected for primary and/or secondary outcome(s)
  - Specify zero ("0") for Number of Participants Analyzed
  - Outcome Measure Data not required to be submitted
  - Must still provide Participant flow, Demographic and baseline characteristics, and Adverse event information
- Outcome measure data collected, but actual enrollment falls well below target
  - Outcome measure information and data must be submitted
  - Statistical analysis information not expected to be submitted
  - If privacy considerations; 42 CFR 11.54 (waiver) may apply
    - Expected to be requested and granted in only a very limited number of situations

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Final Rule Section IV.C.4. What constitutes clinical trial results information? - § 11.48 (81 FR 65084 - 90)

Adverse Event Information (42 CFR 11.48(a)(4))

- Information for completing three tables summarizing anticipated and unanticipated adverse events collected by arm or comparison group

  (1) All serious adverse events

  (2) Adverse events, other than serious adverse events, that exceed a frequency of 5 percent within any arm of the clinical trial

  (3) All-cause mortality * (new)

* Newly required by the final rule

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Final Rule Section IV.C.4. What constitutes clinical trial results information? - § 11.48 (81 FR 65090 - 97)

Adverse Event Information

- Methods for collecting adverse events
  - Time Frame *
  - Adverse Event Reporting Description *
    - If adverse event information collected in the clinical trial is collected based on a different definition of adverse event and/or serious adverse event
  - Collection Approach *
    - The type of approach taken to collect adverse event information, whether systematic or non-systematic

* Newly required by the final rule
Final Rule Section IV.C.4. What constitutes clinical trial results information? - § 11.48 (81 FR 65090 - 97)

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Adverse Event Information (cont.)

- Information for each of the three tables
  - Adverse Event Arm/Group Information (Title and Description *)
  - Total Number (participants) Affected, by arm or comparison group (new; all-cause mortality *)
  - Total Number (participants) at Risk, by arm or comparison group (new; all-cause mortality *)
- Adverse Event Information for each table (except all-cause mortality)
  - Descriptive term for the adverse event
  - Organ system associated with the adverse event
    - Added "Product issues" to list of options (new)
- Adverse Event Data for each table (except all-cause mortality)
  - Number of human subjects affected by adverse event
  - Number of human subjects at risk for adverse event (if different from total)

* Newly required by the final rule
Final Rule Section IV.C.4. What constitutes clinical trial results information? - § 11.48 (81 FR 65090 - 97)

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Protocol and Statistical Analysis Plan (42 CFR 11.48(a)(5))

- A copy of the protocol and statistical analysis plan (if not included in the protocol) * (new)
  - Including all amendments approved by human subjects review board (if applicable) before time of submission that apply to all locations
  - Cover page with Official Title, NCT number, and date of document
  - May redact:
    - Names, addresses, and other personally identifiable information
    - Trade secret and/or confidential commercial information (unless otherwise required to be submitted under this part)
  - Common electronic document format specified at https://prsinfo.clinicaltrials.gov

* Newly required by the final rule
Final Rule Section III.D. Submission of Protocols and Statistical Analysis Plans (81 FR 64999 - 65002)

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Administrative Information (42 CFR 11.48(a)(6))

- Results Point of Contact
  - Name or official title of the point of contact
  - Name of the affiliated organization
  - Telephone number and email address of the point of contact
- Certain Agreements
  - An indication of whether the principal investigator (PI) is an employee of the sponsor and, if not,
  - Whether there is any agreement between the sponsor (or its agent) and the PI restricting the PI's ability, after the PCD, to discuss publicly or publish the clinical trial results
  - Excludes agreements solely to comply with laws protecting the privacy of human subjects participating in the clinical trial

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Final Rule Section IV.C.4. What constitutes clinical trial results information? - § 11.48 (81 FR 65097 - 99)

5. When must clinical trial results information be updated?

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When must clinical trial results information submitted to ClinicalTrials.gov be updated? (42 CFR 11.64(a)(2))

- For trials with a Primary Completion Date on or after January 18, 2017 (i.e., subject to 42 CFR 11.48)
- In general, clinical trial results information must be updated at least **once per year**, except for the protocol and statistical analysis plan and certain agreements

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Final Rule Section IV.D.3. When must clinical trial information submitted to ClinicalTrials.gov be updated or corrected? § 11.64 (81 FR 65108 - 17)

C. Posting and Quality Control Review Procedures

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Posting of Clinical Trial Registration Information

- Applicable drug clinical trials (42 CFR 11.35(a))
  - Post not later than 30 calendar days after the responsible party has submitted registration information (excludes certain admin. data)
- Applicable device clinical trials (42 CFR 11.35(b))
  - Device product previously approved or cleared
    - Post as soon as practicable but not later than 30 calendar days after clinical trial results information is required to be posted, as specified in 42 CFR 11.52
  - Device product that has not been previously approved or cleared
    - Post not earlier than the date of FDA approval or clearance of the device product ("lockbox") and not later than 30 calendar days after the date of that approval or clearance, unless responsible party authorizes posting ("opt-out")

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Final Rule Section IV.B.5. By when will the NIH Director post clinical trial registration information submitted under § 11.28? § 11.35 (81 FR 65062 - 64)

Posting of Clinical Trial Results Information

- By when will the NIH director post clinical trial results information? (42 CFR 11.52)
  - Post not later than 30 calendar days after the responsible party submits the information

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Final Rule Section IV.C.5. By when will the NIH Director post submitted clinical trial results information? § 11.52 (81 FR 65101)

Posting and Quality Control

- Intend to continue a form of quality control (QC) review at time of submission that is similar to procedures we have been using
  - (1) automated system-based check; (2) manual review
- Interpret the statutory posting deadline to be a clearly delineated timeline between submission and posting
  - Information will be posted even if QC review process has not concluded
  - Registration will not receive NCT number until QC review process has concluded
  - Posted record will contain information to make clear process has not concluded
  - Will evaluate ways posted record could specify data element(s) that may contain errors, deficiencies, and/or inconsistencies

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Final Rule Section IV.B.5. (81 FR 65062 – 63), Final Rule Section IV.C.5. (81 FR 65101), Final Rule Section IV.D.3. (81 FR 65108 - 17)

Quality Control (42 CFR 11.64(b)(1))

- Director will establish procedures for quality control review specified at https://prsinfo.clinicaltrials.gov
- Director may provide electronic notification to the responsible party of apparent errors, deficiencies and/or inconsistencies that are identified by quality control review
- The responsible party must correct or address all apparent errors, deficiencies, and/or inconsistencies
  - Within 15 calendar days for clinical trial registration information
  - Within 25 calendar days for clinical trial results information

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Final Rule Section IV.D.3. When must clinical trial information submitted to ClinicalTrials.gov be updated or corrected? § 11.64 (81 FR 65108 - 17)

Other Corrections (42 CFR 11.64(b)(2))

- A responsible party who becomes aware of errors (other than those identified in the quality control process), shall correct or address such errors
  - Within 15 days for clinical trial registration information
  - Within 25 days for clinical trial results information

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Final Rule Section IV.D.3. When must clinical trial information submitted to ClinicalTrials.gov be updated or corrected? (81 FR 65108 - 17)

When Obligation to Submit Updates Ends (42 CFR 11.64(a)(3))

- If clinical trial results information is required to be submitted, obligation to update clinical trial information ends when:
  - All required clinical trial results information has been submitted; and
  - Corrections have been made or addressed in response to any notice received in the quality control process under 42 CFR 11.64(b)(1).
- If no clinical trial results information is required to be submitted, obligation to update clinical trial registration information ends when:
  - All required clinical trial registration information has been submitted; and
  - Corrections have been made or addressed in response to any notice received in the quality control process under 42 CFR 11.64(b)(1).

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Final Rule Section IV.D.3. When must clinical trial information submitted to ClinicalTrials.gov be updated or corrected? (81 FR 65108 - 17)

When Obligation to Correct Ends (42 CFR 11.64(b)(2)(ii))

- Obligation to correct or address errors a responsible party becomes aware of (42 CFR 11.64(b)(2))
- If clinical trial results information is required to be submitted:
  - All required clinical trial results information has been submitted; and
  - Corrections have been made or addressed in response to any notice received in the quality control process under 42 CFR 11.64(b)(1)
- If no clinical trial results information is required to be submitted:
  - All required clinical trial registration information has been submitted; and
  - Corrections have been made or addressed in response to any notice received in the quality control process under 42 CFR 11.64(b)(1).

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Final Rule Section IV.D.3. When must clinical trial information submitted to ClinicalTrials.gov be updated or corrected? (81 FR 65108 - 17)

Additional Resources

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NIH Resources

- NIH News Release on the HHS Final Rule and NIH Policy
  - https://www.nih.gov/news-events/news-releases/hhs-take-steps-provide-more-information-about-clinical-trials-public
- NIH Policy on the Dissemination of Clinical Trial Information
  - NIH Guide Notice: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-149.html
  - Questions: clinicaltrials.disseminationpolicy@mail.nih.gov

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ClinicalTrials.gov Resources

- Submit Studies: https://clinicaltrials.gov/ct2/manage-recs
  - FDAAA 801 Requirements – Regulations Implementing FDAAA 801
    - Changes from Current Practice Described in the Final Rule (PDF)
      - http://prsinfo.clinicaltrials.gov/FinalRuleChanges-16Sept2016.pdf
    - Zarin DA, Tse T, Williams RJ, Carr S. Trial reporting in ClinicalTrials.gov - the final rule. *N Engl J Med*; 2016. DOI: 10.1056/NEJMsr1611785.
      - http://www.nejm.org/doi/full/10.1056/NEJMsr1611785
  - Training Materials – Final Rule Webinar Series (will be archived)
- Final Rule Information: https://prsinfo.clinicaltrials.gov
- Questions: register@clinicaltrials.gov

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