Prepared for ClinicalTrials.gov

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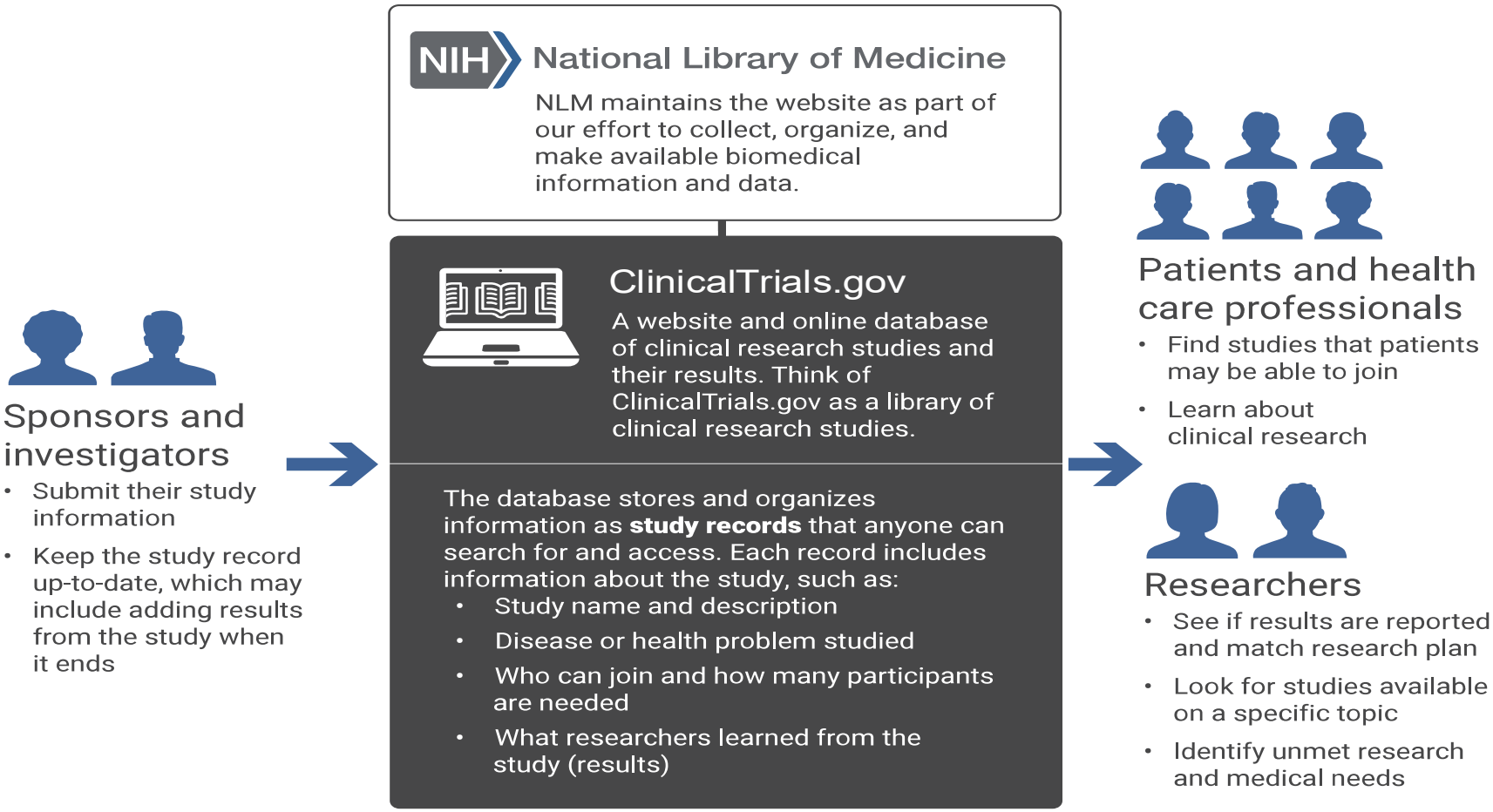
CarilionClinic

Learning Objectives:

1. Recognize which research projects are defined as an Applicable Clinical Trial.
2. Release and maintain a record on ClinicalTrials.gov.

ClinicalTrials.gov Refresher

What is ClinicalTrials.gov?

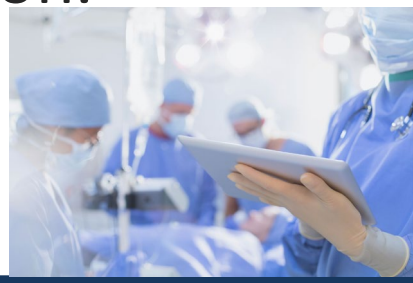



ClinicalTrials.gov and the FDA

- The ClinicalTrials.gov (CT.gov) website first launched in 2000 to comply with the Food and Drug Administration Modernization Act (FDAMA) of 1997
  - This act required the National Institutes of Health (NIH) to create a database of clinical trials that applied to test investigational drugs for serious and life-threatening diseases under an investigational new drug (IND) application.


10 Years Later…

- The FDA Amendments Act of 2007 (FDAAA) expanded the information that sponsors and investigators must submit to CT.gov, including:
  - Different types of trials
  - Additional information about the trials
  - A results database for certain trials, which includes descriptions of participants and study findings, including safety information.



Another 10 Years Later…

FDAAA 801 becomes effective and coincides with the Final Rule for Clinical Trials Registration and Results Information Submission (42 CFR Part 11).

-Effective on January 18, 2017 and responsible parties have been required to be in compliance since April 18, 2017.

-Provided additional information on what trials may be considered an Applicable Clinical Trial (ACT) that must be registered on CT.gov:

*Controlled clinical investigations of any FDA regulated drug or biological product for any disease or condition.

*Certain studies of FDA-regulated medical devices, including pediatric postmarket surveillances of a device product.

Exclusions:

Phase 1 drug or biological product trials

Small trials to determine device feasibility or testing a device prototype

Question	Yes	No
1. Is the study interventional (a clinical trial)? *Study Type* data element is "Interventional"	☐	☐
2. Do ANY of the following apply (is the answer "Yes" to <u>at least one</u> of the following sub-questions: 2a, 2b, OR 2c)?	☐	☐
a. Is at least one study facility located in the United States or a U.S. territory? *Facility Location – Country* data element is "United States," "American Samoa," "Guam," "Northern Mariana Islands," "Puerto Rico," "U.S. Virgin Islands," or other U.S. territory.		
b. Is the study conducted under a U.S. FDA Investigational New Drug application (IND) or Investigational Device Exemption (IDE)? *U.S. Food and Drug Administration IND or IDE Number* data element is "Yes."		
c. Does the study involve a drug, biological, or device product that is manufactured in and exported from the U.S. (or a U.S. territory) for study in another country? *Product Manufactured in and Exported from the U.S.* data element is "Yes."		
3. Does the study evaluate at least one drug, biological, or device product regulated by the United States Food and Drug Administration (U.S. FDA)? *Studies a U.S. FDA-regulated Device Product* data element is "Yes" and/or *Studies a U.S. FDA-regulated Drug Product* data element is "Yes."	☐	☐
4. Is the study <u>other than</u> a Phase 1 trial of a drug and/or biological product or is the study <u>other than</u> a device feasibility study? For drug product trials, *Study Phase* data element is NOT "Phase 1" and for device product trials, *Primary Purpose* is NOT "Device Feasibility."	☐	☐

If "Yes" is answered to all 4 questions, and the study was initiated on or after January 18, 2017, the trial would meet the definition of an ACT that is required to be registered under 42 CFR 11.22.

Non-ACT – do I need to submit?

NIH funded?

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 were received by NIH on or after the policy's effective date (Jan. 18, 2017). Applies to NIH-conducted clinical trials initiated on or after the policy's effective date.

Not an ACT, not NIH funded, so, I'm in the clear, right?

ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

Looking to publish?

- Any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the cause-and-effect relationship between a health-related intervention and a health outcome. Health-related interventions are those used to modify a biomedical or health-related outcome; examples include drugs, surgical procedures, devices, behavioral treatments, educational programs, dietary interventions, quality improvement interventions, and process-of-care changes. Health outcomes are any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events.

Determining the Responsible Party

Under an IND/IDE? The IND/IDE holder is considered the sponsor as defined in 42 CFR 11.10(a), regardless of how the clinical trial is being funded.

Not under an IND/IDE but funded by grant? The funding recipient is generally considered the sponsor for initiating the funding proposal and designing the study.

Under a sponsored contract? The funder of the study.

No funding? The person or entity who initiated the clinical trial.

Can a PI be the responsible party?

- Yes, if the principal investigator 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 can meet all the requirements under the regulation for submitting and updating of clinical trial information.
- The sponsor must designate the PI as the responsible party and have the PI submit via the sponsor's Protocol Registration and Results System (PRS) organizational account.

PRIS3M Application

15.0 Applicable Regulations for ClinicalTrials.gov Registration

15.1 Is this study FDA-regulated?

(●) Yes ( ) No

15.2 Is this research funded wholly or in part by NIH?

( ) Yes (●) No

15.3 Is this study a Clinical Trial, as defined by FDA or NIH, and therefore needing registration on ClinicalTrials.gov? Click the help button to the right to learn more about the definition of a clinical trial.

( ) Yes (●) No

15.4 This study does not require registration on ClinicalTrials.gov per your above responses. Click on the Help bubble to the right for more information about registering. Do you plan to register the study on ClinicalTrials.gov anyway, or have you already?

( ) Yes (●) No

Even though not required, registering clinical trials fulfills a number of purposes and benefits a variety of people. In addition, some journals, including the International Committee of Medical Journal Editors (ICMJE) requires trial registration before enrollment begins as a condition of the publication of research results generated by a clinical trial.

15.6 Who is responsible for registering this trial in ClinicalTrials.gov and ensuring information is updated, as necessary? Please provide a name if the person is at Carilion or listed on the research team, or state the sponsor or lead site if the sponsor or lead site will register the trial.

The responsible party for an applicable clinical trial (ACT) must register the trial and submit results information. The responsible party is defined as:

- ***The sponsor of the clinical trial, as defined in 21 CFR 50.3; or***
- ***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 the requirements for the submission of clinical trial information***

The responsible party for an ACT must submit the required clinical trial information **no later than 21 days** after enrollment of the first participant, but registration is highly recommended before enrollment begins due to some journal requirements.

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Where to find the responsible party

In the contract

- **Clinical Study Registries and Clinical Results Databases**. Sponsor is responsible for, and agrees to, register the Study and post the results information in accordance with the requirements of the Public Service Act, 42 U.S.C. § 282(j)(1)(A), if applicable, as determined by Sponsor. Institution agrees that it will not register the Study.
- Sponsor shall register the Study on www.clinicaltrials.gov in accordance with the requirements described in Section 801 of the Food and Drug Administration Amendment Act.

ClinicalTrials.gov website

Study Trial

ClinicalTrials.gov ID NCTxxxxxxx

Sponsor

Information provided by (Responsible Party)

Last Update Posted

Regulatory Body

- IRB of record
- Grant awardee
- Sponsor
- Contractor
- IND/IDE holder
- Funding organization
- Institution

How will I know my study needs to be registered?

Carilion Clinic IRB Outcome Letter:

Clinicaltrials.gov: The study meets requirements to be registered on Clinicaltrials.gov. Please ensure you are familiar with all the requirements of Section 801 of the Food and Drug Administration Amendments Act (https://clinicaltrials.gov/ct2/manage-recs/fdaaa), as there are consequences for not registering, including potential fines. You must register this clinical trial prior to enrollment of the first participant. Please contact research@carilionclinic.org for assistance with the ClinicalTrials.gov Protocol Registration and Results System (PRS).

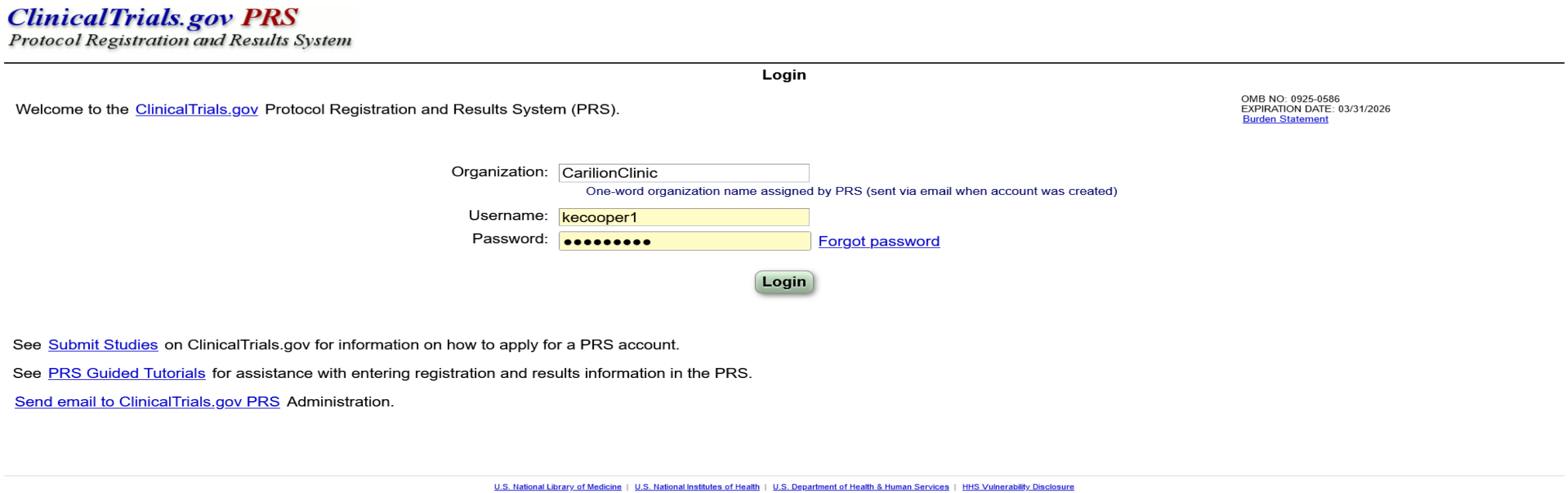
Clinicaltrials.gov Website:
https://www.clinicaltrials.gov

Publisher Guidelines

Funding agency requirements

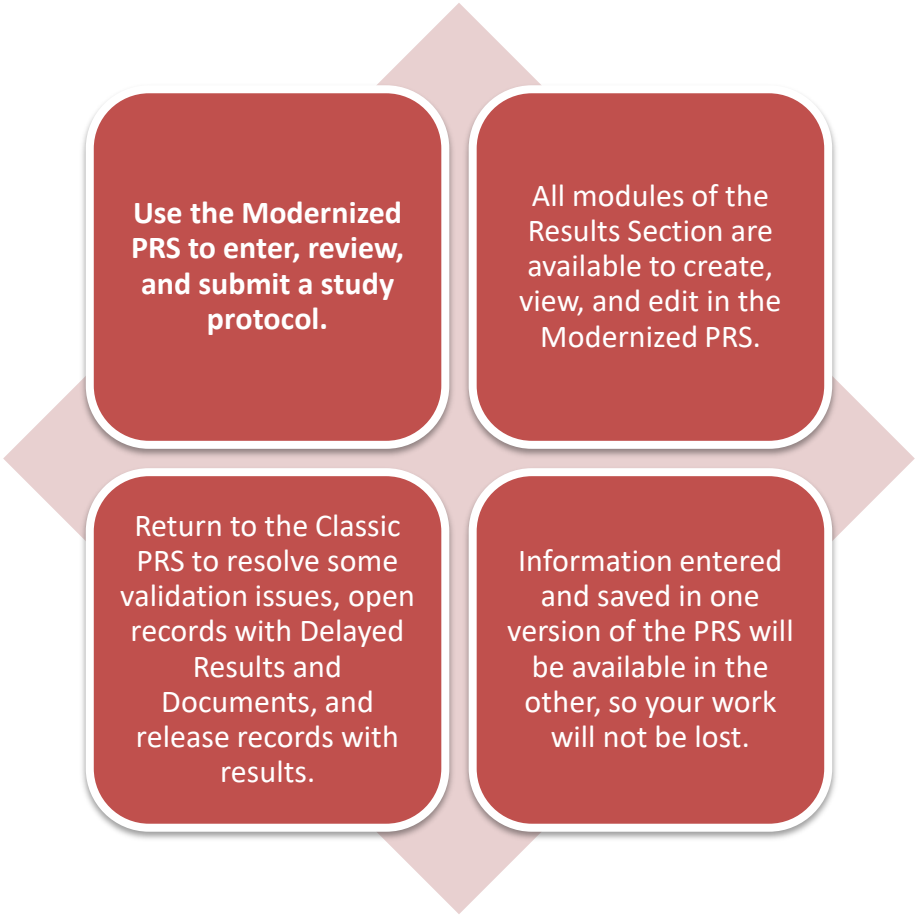
How to Register

Log in to https://register.clinicaltrials.gov/



Modernized or Classic?

https://register.clinicaltrials.gov



Quick Start Guide

1. **Change your password** - If you have not already done so, select Change Password from the Accounts menu on the Home page and complete the form.
2. **Create a record** - A study is registered in the ClinicalTrials.gov system by creating a protocol record. Select New Record on the Home page (either from Quick Links or the Records menu). Fill in a series of data entry pages.

Tip: Data is saved as each page is filled in, so that you can "Quit" at any time, saving the record for later completion using the "Modify a record" instructions provided below.

3. **Mark the record as Entry Completed** - After filling in the last data entry page, the Protocol Section page appears with all of the information provided. Review the information for accuracy and completeness, and use the Edit links to address ERROR messages, if any.

Return to the Record Summary page to see current status of the record. Follow instructions in the Next Step box to finish the registration process, using the Entry Complete button to indicate that data entry is done. Your organization's PRS Administrator will Approve and Release the record for PRS Review and processing by ClinicalTrials.gov. **The record should be available on the public site within 2-5 business days of Release by the administrator.**

EXCEPTION: If you are designated as the Investigator and Responsible Party for a record, you have the authority (and responsibility) to Approve and Release the record even if you are not an administrator. Open the record and follow instructions in the Next Step box on the Record Summary page to perform these steps at the appropriate times. More information on Responsible Party is accessible from the Edit Sponsor/Collaborators page.

4. Modify a record - After initial registration, a record can be modified at any time (except when the record is locked for PRS Review). The Record List on the Home page lists all of your records along with status information for each record. Open the record that you wish to update. The Record Summary page for that record appears. Use the Edit link(s) on the left to modify the desired section of the record.

When a record's status is Entry Completed, Approved, Released or Public, and the record is modified, the record status is automatically reset to In Progress. Remember to mark the record as Entry Completed when finished editing. Your organization's PRS Administrator will Approve and Release the modified record as described above.

5. Keep records up to date - Study records for active studies should be reviewed and modified, as needed, at least once every 12 months. Some data elements must be updated sooner (e.g., within 30 days of a change) based on the requirements in Section 801 of FDAAA and 42 CFR 11.64. **Pay special attention to recruitment statuses, location, and contact information**, as the accuracy and timeliness of this information is extremely important to patients and health care professionals. Update the Record's Verification Date (in the Protocol section, Study Status module) to confirm that the record has been reviewed.

6. Check for problems - The Record List on the Home page includes a Problems column listing issues for each record. To address problems open the record and make the necessary changes, following the instructions in the Next Step box near the top of the Record Summary page.

Record Information Requested

- Study Identification
- Study Status
- Sponsor/Collaborators
- Oversight
- Study Description
- Conditions
- Study Design
- Arms & Interventions
- Outcome Measures
- Eligibility
- Contacts/Locations
- IPD Sharing Statement
- References

When to update record

If there are changes to the study, the changes must be updated on the ClinicalTrials.gov website within 30 days.

- These changes include:
  - Protocol amendment
  - Change in contact information
  - Change in status of recruitment or enrollment

– Even if there are no changes, the study record must go through verification at least every 12 months – this will require the Responsible Party to confirm the accuracy of the record and resubmit for PRS review.

– Record can be edited at any time by clicking on the “Modify” button & re-releasing the record for PRS review and publishing changes to the website.

Results Reporting

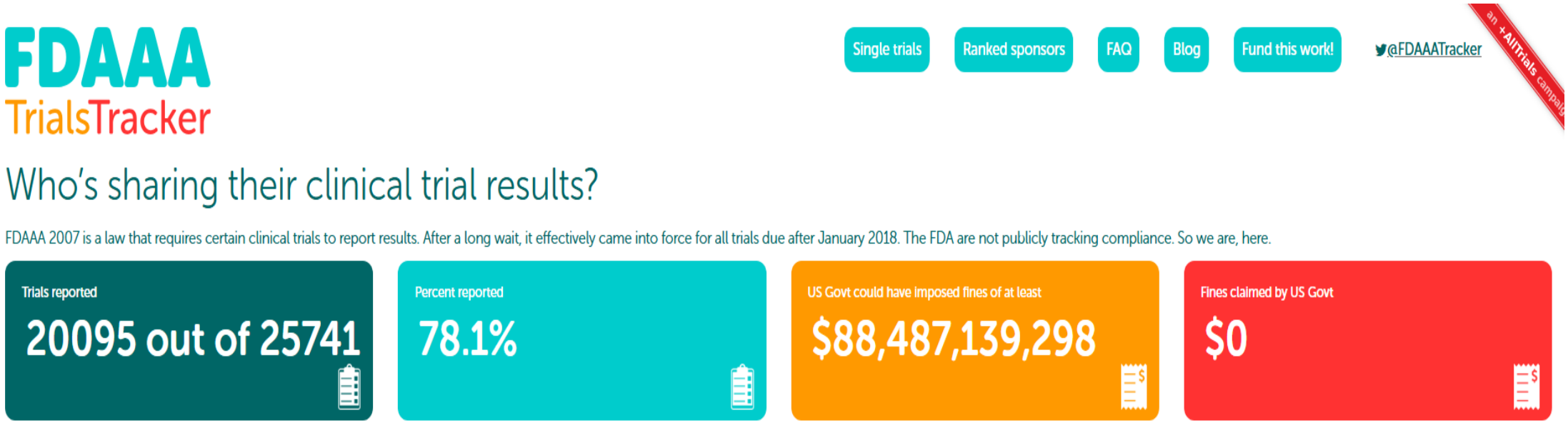
Generally, the results of an Applicable Clinical Trial must be submitted by the Responsible Party no later than 12 months after the study completion date – the date the final subject completed their participation/final collection of data.

Under the final rule, results information submission could be delayed for up to 2 additional years from the date of submission of a certification that either (1) an unapproved, unlicensed, or uncleared product studied in the trial is still under development by the manufacturer or (2) that approval will be sought within 1 year after the primary completion date of the trial for a new use of an approved, licensed, or cleared product that is being studied in the trial (81 FR 64983).

Scientific Results Reporting

- Participant Flow
- Baseline Characteristics
- Outcome Measures and Statistical Analyses
- Adverse Events
- Administrative Information

Why submit results?



#1 It is the right thing to do!
#2 Penalties can be assessed at any time.

Prepared for FDA Audit

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CarilionClinic

Learning Objectives

1. Describe key components of FDA inspection preparation.
2. Organize essential regulatory documents per FDA standards.
3. Develop preventative strategies for common findings.

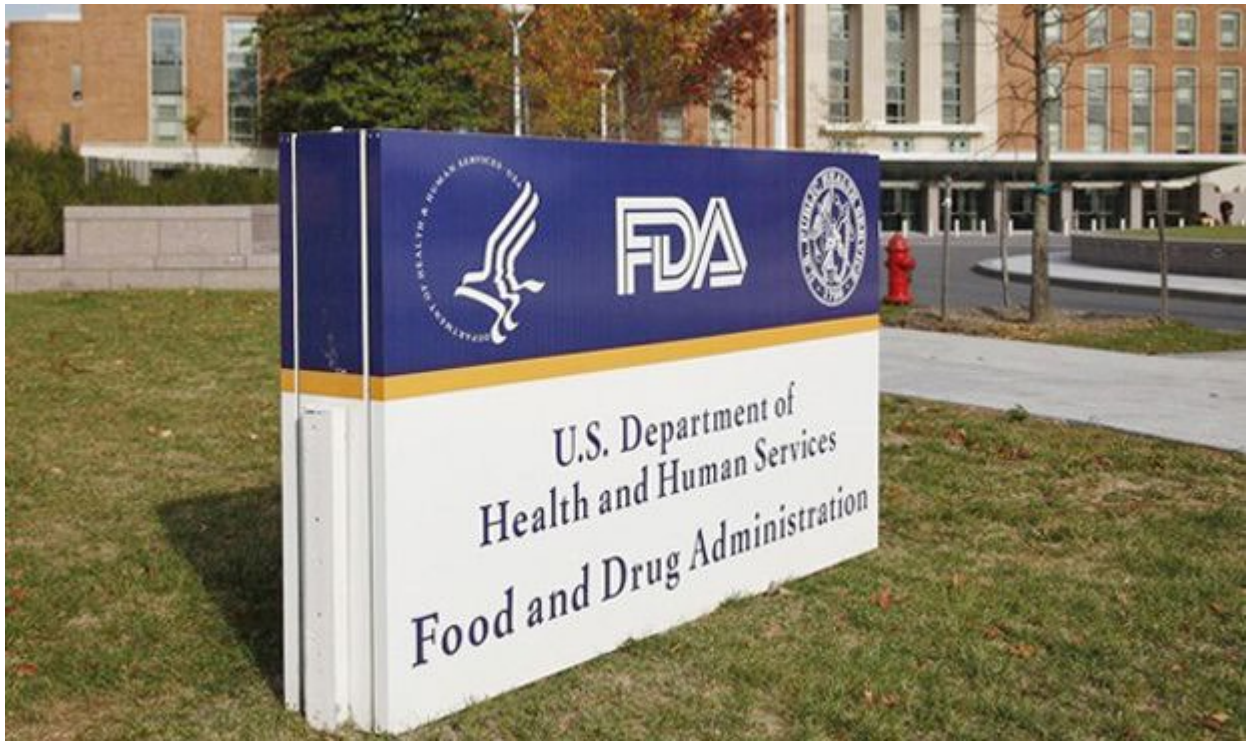
Core Skills Development:

- Professional communication
- Document management
- Issue prevention and resolution
- Inspection response techniques

Setting mindset

What do you <u>actively</u> do to *feel* prepared?

BACKGROUND


FDA
U.S. Department of
Health and Human Services
Food and Drug Administration

Current State: FDA Initiative

ICH E6(R3): Good Clinical Practice

- Intended to provide a flexible and modern framework to support innovate approaches
  - Clinical trials should be designed to protect the rights, safety and well-being of participants and assure reliability of results
  - Clinical trial designs and conduct should be proportionate to the risks and the importance of the data being collected
  - Trial designs and conduct should minimize unnecessary complexity and burden

Goal of Revision

- ✓ **Advance medical research through innovative approaches and ensuring participant protection and data quality.**
- ✓ **Aim is to create a framework that is adaptable while maintaining core ethical and scientific standards.**

New FDA Guidance: Electronic Systems, Records, and Signatures in Clinical Investigations

Key points from the guidance include:

1. **Compliance with** 21 CFR Part 11: Electronic systems and records used in clinical investigations must comply with Part 11 requirements. This ensures that electronic records and signatures are considered trustworthy, reliable, and generally equivalent to paper records and handwritten signatures. Regulated entities must understand these requirements and implement them appropriately in their electronic systems.

2. **Electronic Records Management**: Certified copies of electronic records should be maintained, complete with date and time stamps, and retained for the required period. These records must be readily available for FDA inspection. Proper backup and recovery procedures should be in place to protect against data loss, and the meaning of the record should be preserved throughout its lifecycle.

3. **System Validation and Security**: A risk-based approach should be used to validate electronic systems, with robust security safeguards implemented. This includes assessing the intended use of the system, the importance of the data it handles, and its potential impact on participant safety and trial results. Logical and physical access controls should be integral to these systems, limiting access to authorized users.

4. **Audit Trails**: Systems must have comprehensive audit trails that capture all changes to electronic records. These trails should record who made changes, when they were made, and the reasons for the changes. Audit trails should be protected from modification and should be retained in a searchable and sortable format when practical.

5. **Electronic Signatures**: If used, electronic signatures must comply with Part 11 requirements, including proper identity verification. They must be linked to their respective electronic records in a manner that prevents the signatures from being excised, copied, or transferred to falsify electronic records. Various methods can be used to create valid electronic signatures, including biometrics and username/password combinations.

6. **Training**: Adequate training should be provided to all individuals using these electronic systems. This training should occur before an individual uses the system, during the study as needed, and when changes are made to the electronic system that impact the user. Training should be documented, and current training materials should be available for reference.

7. **IT Service Providers**: When external IT services are used, written agreements should detail how these services meet regulatory requirements. These agreements should address data integrity and security safeguards, roles and responsibilities, and plans for data access throughout the regulatory retention period. Regulated entities should maintain documentation of their oversight of IT services throughout the conduct of the trial.

8. **Inspection Readiness**: Regulated entities should be prepared for FDA inspections of their electronic systems and records. This includes maintaining documentation of system validation, change control procedures, user access controls, and data management plans. During inspections, FDA may review staff training records, system access procedures, and audit trails.

9. **Data Integrity and Security**: Ensuring the authenticity, integrity, and when appropriate, confidentiality of electronic records is crucial. This involves implementing appropriate security measures, such as encryption for data in transit and at rest. Processes should be in place to detect, document, report, and remedy security protocol breaches.

10. **Non-Repudiation**: Users of electronic signatures must submit a letter to the FDA, certifying that their electronic signature is legally binding. This letter, known as a letter of non-repudiation, can be submitted once to cover all electronic signatures used by an organization. The FDA provides specific instructions for submitting these letters either electronically or by mail.

This guidance underscores the FDA's commitment to maintaining high standards in clinical investigations while embracing the rapid digitalization of research processes. As we move further into the digital age, the FDA recognizes that electronic systems, records, and signatures are becoming the primary tools for conducting and managing clinical investigations. By providing these detailed recommendations, the FDA is paving the way for a future where digital technologies are seamlessly integrated into every aspect of clinical research, ensuring that as new technologies emerge, they can be adopted swiftly and securely.

Source: FDA Comprehensive Guidance Document on Electronic Systems

New FDA Guidance: Electronic Systems, Records, and Signatures in Clinical Investigations

- Audit Trails: Systems must have comprehensive audit trails that capture all changes to electronic records. These trails should record who made changes, when they were made, and the reasons for the changes. Audit trails should be protected from modification and should be retained in a searchable and sortable format when practical.
- Inspection Readiness: Regulated entities should be prepared for FDA inspections of their electronic systems and records. This includes maintaining documentation of system validation, change control procedures, user access controls, and data management plans. During inspections, FDA review staff training records, system access procedures, and audit trails.

FINDINGS & COMMONALITIES

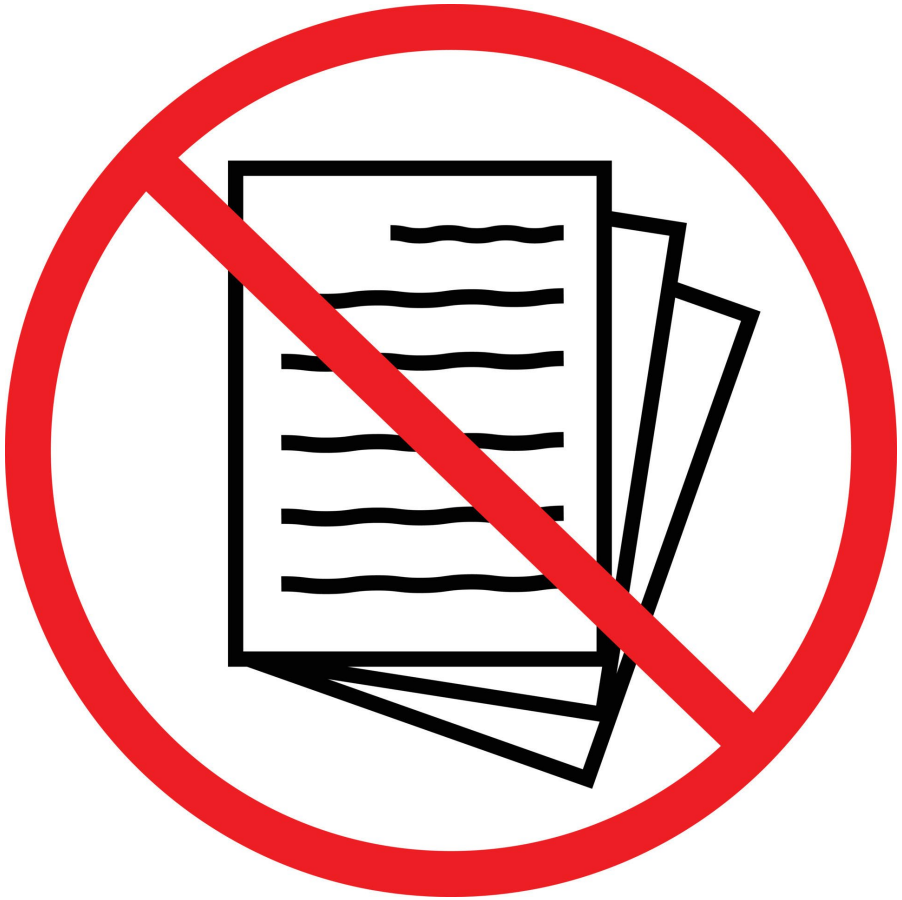
Background on FDA warning letters

In 2010, FDA issued 10 warning letters to clinical investigators—6 out of 10 letters cited the following:

"Failure to maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual administered the investigational drug or employed as control in the investigation" (Bargaje, 2011).

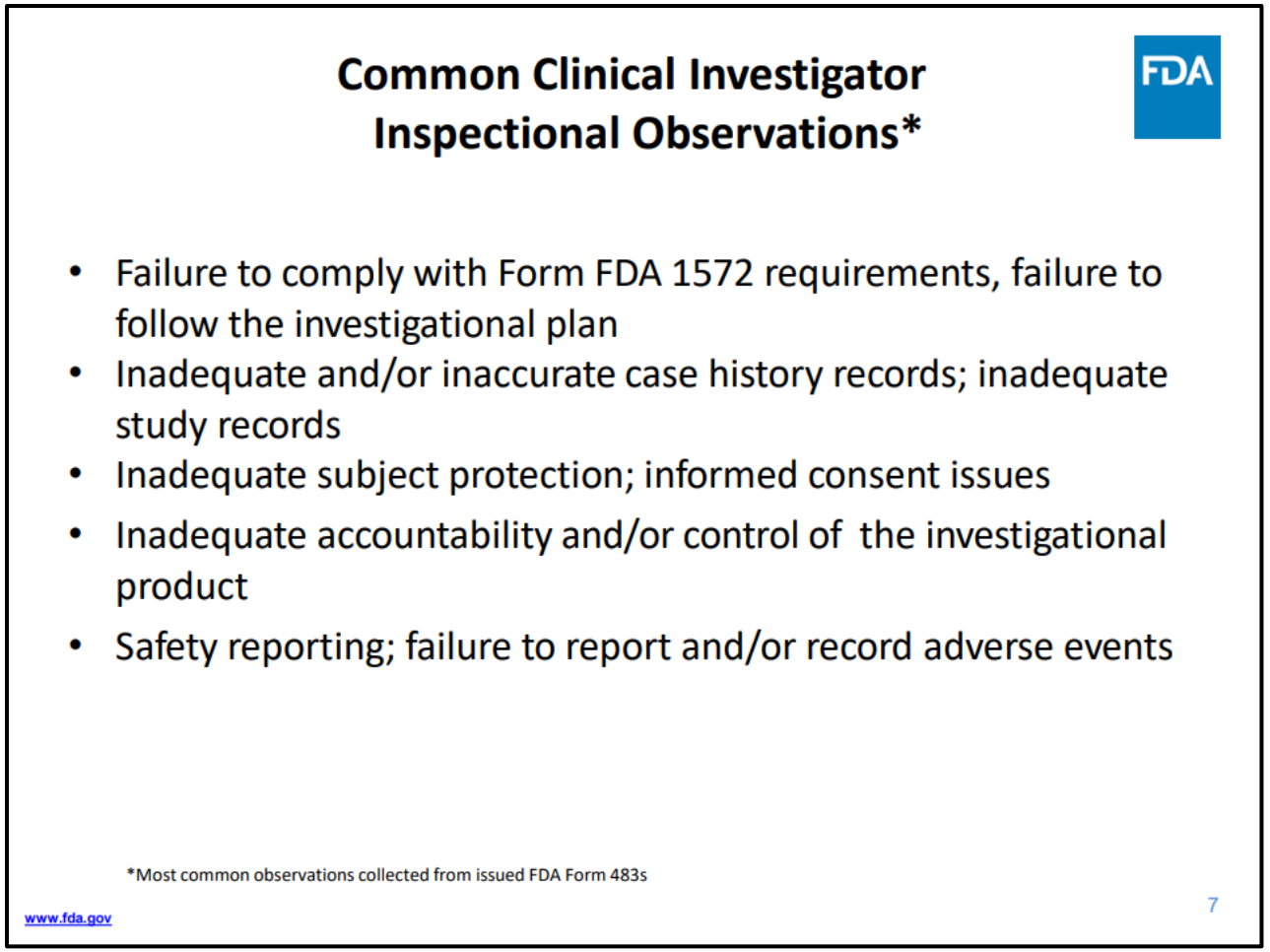
Note: FDA publishes warning letters on their website monthly.

Common Documentation Issues



- Incomplete eligibility criteria documentation
- Multiple conflicting records for the same data points
- Discrepancies between source documents and Case Report Forms (CRFs)
- Missing or incomplete adverse event reporting
- Incorrect/incomplete drug accountability records

FDA Bioresearch Monitoring (BIMO) Metrics-FY23



Source: [BIMO Inspection Metrics | FDA]

Carilion Example: Document Organization Checklist

Carilion Clinic Institutional Review Board
RESEARCH DOCUMENTS ORGANIZATION CHECKLIST

In order to comply with Good Clinical Practice recommendations and to maintain appropriate study documentation, investigators or coordinators must create and maintain the following documents for all studies, **regardless of level of IRB review or funding source**:

1) **Regulatory Binder that includes the following:**

☐ IRB Application
Maintain accessible versions (secure electronic or hard copies) as well as all previously **IRB-approved** versions. You do not need to keep draft versions. If possible, also note the file name and location of the electronic version of the most recently approved application.

☐ Protocol
If there is protocol (for many studies, the IRB application will serve as the protocol), provide secure electronic or hard copies of the current version as well as all previous versions.

☐ Informed Consent Forms
All IRB-approved versions, including the current IRB-approved informed consent. *(File all signed and dated informed consent documents in the research subject files. See below.)* This section should also include IRB-approved assent forms, LAR forms, and/or consent to continue participation in a study (to be signed by minors who come of age during the study). When signed consent has been waived and an information sheet is mandated, all IRB-approved versions of the information sheet should be included in this section.

☐ Other IRB Approved Materials
All approved versions of recruitment materials such as scripts, flyers, brochures; Case Report Forms (CRFs); Data Collection Forms (if applicable.) Maintain originals of all IRB approved versions. *(Maintain completed and signed copies of CRFs or completed data collection forms for each study subject in separate subject study file/binder. See below.)*

☐ Curriculum Vitae (CV)
File a current copy of the CV of each IRB approved research team member and other study personnel.

☐ Professional license
File a copy of the current license for each licensed professional involved in the conduct of the study. Keep all versions on file.

☐ Financial Disclosures
File a copy of the signed financial disclosures for all research team members involved in the conduct of the study.

☐ Miscellaneous
Keep all audit reports, monitoring reports, grant applications, contractual agreements, Certificates of Confidentiality, CITI Training Certificates, Data Safety Monitoring Plans, Package Inserts, Investigator Brochures (drug study), and FDA Form 1572, if applicable. If your study involves an external laboratory, keep a copy of the lab certificate (CLIA), reference lab values, and CV of the lab supervisor. If your study involves distribution of a study drug, keep a drug accountability log for tracking purposes.

2) **Correspondence Binder that includes the following:**

☐ All pertinent and key communication and correspondence with investigators, research team members, Research and Development, and funding agencies/foundations.

☐ Correspondence with sponsor/monitors including but not limited to information such as formal letters, pertinent email messages, study updates, progress reports, safety updates/reports, amendments to protocol, reports of adverse events and protocol deviations, requests for protocol exceptions, if applicable.

☐ Correspondence with data safety monitoring boards/committees including but not limited to regularly scheduled reports and interim findings, if applicable.

3) **IRB Documentation:**

☐ Initial submission packet
IRB application, including supporting documents such as grant applications, recruitment materials, informed consent document, any surveys or questionnaires, etc.

☐ IRB correspondence
All IRB correspondence received from and submitted to IRB including formal letters such as approval letters and pertinent e-mail messages.

☐ Change/Update Forms
All modifications/clarifications submitted for IRB approval

☐ Evidence of student training about how to obtain informed consent if students are assigned and approved to do so and the Principal Investigator has affirmed on the IRB Application that such training has taken place.

☐ Continuing Review Forms
All continuing review applications and supporting materials submitted to the IRB.

☐ Promptly Reportable Information forms
All promptly reportable events, corrective action plan, and any follow-up documentation and/or communication

☐ Conclusion
Conclusion report after completion of study

4) **Research Subject Files:**

☐ Case Report Forms or Data Collection Forms
Maintain completed and signed copies of forms for each study subject in a subject specific study file or binder.

☐ Informed Consent Forms
File all signed and dated informed consent documents in the subject study file or binder or provide access to electronic records.

☐ Checklist for documenting Informed Consent process
An example can be found at https://www.carilionclinic.org/irb/forms

☐ Completed and signed Inclusion/Exclusion Checklist, with notations of the location of the source documentation for the criteria or Screening Forms (if applicable)

☐ Notes to File
Maintain notes to file for each subject in the subject study file or binder as needed.

☐ Research subject specific correspondence, including emails or telephone logs

5) **Other Logs/Tracking Records:**

☐ Enrollment Log. The enrollment log should give an overview of all subjects enrolled if this is appropriate to your study. List all enrolled subjects and/or study ID numbers, including dates of enrollment and any important information such as randomization group, as appropriate. Some studies also may need a screening log to track screening or screen fails prior to enrollment.

☐ Delegation of Duties Log and Study Staff Signature Log for the research team. The Delegation of Duties Log should describe the role of each team member and particularly which members may consent subjects. Make sure this log does not contradict your protocol or IRB Application. The Study Staff Signature Log should show the signatures of all study team members. These logs may be kept in the regulatory binder.

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FDA INSPECTION

Understanding FDA Inspections

Purpose:

- Protect rights, safety, and welfare of subjects
- Verify data accuracy and reliability
- Assess compliance with FDA's regulations

Inspections can be:

- Announced or unannounced
- Routine or for-cause
- On studies that are open or closed
- Study-specific or investigator-specific
- Single study or multiple studies

Reasons for FDA inspection may include:

- Standard monitoring checks
- High participant enrollment
- Marketing application review
- Active public health concerns
- Response to complaints
- Reports of violations
- Sponsor-raised issues
- Follow-up on corrective actions

Pre-Inspection Preparation

- Team Organization
  - Essential Steps:
    - Identify Form FDA 482 recipient
      -Start inspection request tracking log (estimated date & duration, inspector contact information, purpose & scope details)
    - Coordinate team review meeting
      -Create inspection readiness checklist weeks before expected inspection date
    - Review protocol and procedures
      -Prepare summaries of complex protocols
      -Create flowcharts of key processes
      -Compile reports for adverse events and CAPA
    - Prepare staff for interviews
      -Conduct mock inspections with experienced staff

Inspection Request Tracking Log

Principal Investigator: _____ Study #: _____ Page ___ of ___

Study Title: _____

Inspection Date(s): _____

#	Inspector Request/Question	Date/Time Requested	Received By	Status	Date/Time Provided	Provided By	Added to Shadow Binder?	Comments
1								
2								
3								
4								
5								
6								
7								
8								
9								

Required Notifications

Internal Team	Oversight	Support Services
• Study investigators • Research staff • Department Leadership	• IRB Office • External IRB (if applicable) • Office for Sponsored Research/Research & Development (if applicable)	• Investigational Pharmacy • Laboratories • Clinical facilities

Pre-Inspection Planning

Review
- Investigator obligations
- Protocol & SOPs
- Study records

Designate
- Inspection coordinator
- Inspection assistant(s)
- Document runners

Organize
- Study documentation
- Participant files
- Regulatory documents

Prepare
- Inspection room
- Document staging area
- Staff training

Research teams keeping documents organized and procedures in place make these two sections seamless (or already done).

Pre-Inspection Preparation: Documentation Preparation

Required Documentation:

- Site organizational chart
- Reporting structure
- Standard operating procedure (SOP) index
- Study documentation with overview of organization
- Form 1572s and curriculum vitae (CV)
- Financial disclosures

Commonly requested documents:

- Protocol and amendment training
- Delegation of responsibilities
- Screening and enrollment logs
- Informed consent forms—including ICFs for screenings, process documentation, and approvals

Document Readiness Checklist:

- ❑ All documents accessible
- ❑ Electronic systems functional
- ❑ Archived records available
- ❑ Version control verified

During Inspection

Interview Guidelines:

- Introduce yourself with name and position
  -Designate single point of contact for inspector questions
- Confirm study and responsibilities
- Understand questions fully
- Answer within your role scope
- Don’t volunteer information
  -Create response templates for common questions
- Maintain silence after answering
  -Set up daily debriefing schedule for study team
  -Maintain communication log with time stamps

Document Management

Best practices:

- Provide only requested documents
- Review before submission
- Maintain organized workspace
- Have designated copier/printer
- Track document requests

Error Management:

- Prepare explanation for known issues
- Document root cause analysis for past problems
- Create timeline of corrective actions taken
- Compile evidence of improvements

Post-Inspection Actions

Form 483 Response
- Deadline=15 working days
- Address each observation
- Include corrective actions
- Submit securely

Required Notifications
- IRB
- Study sponsor
- External IRBs
- Department leadership

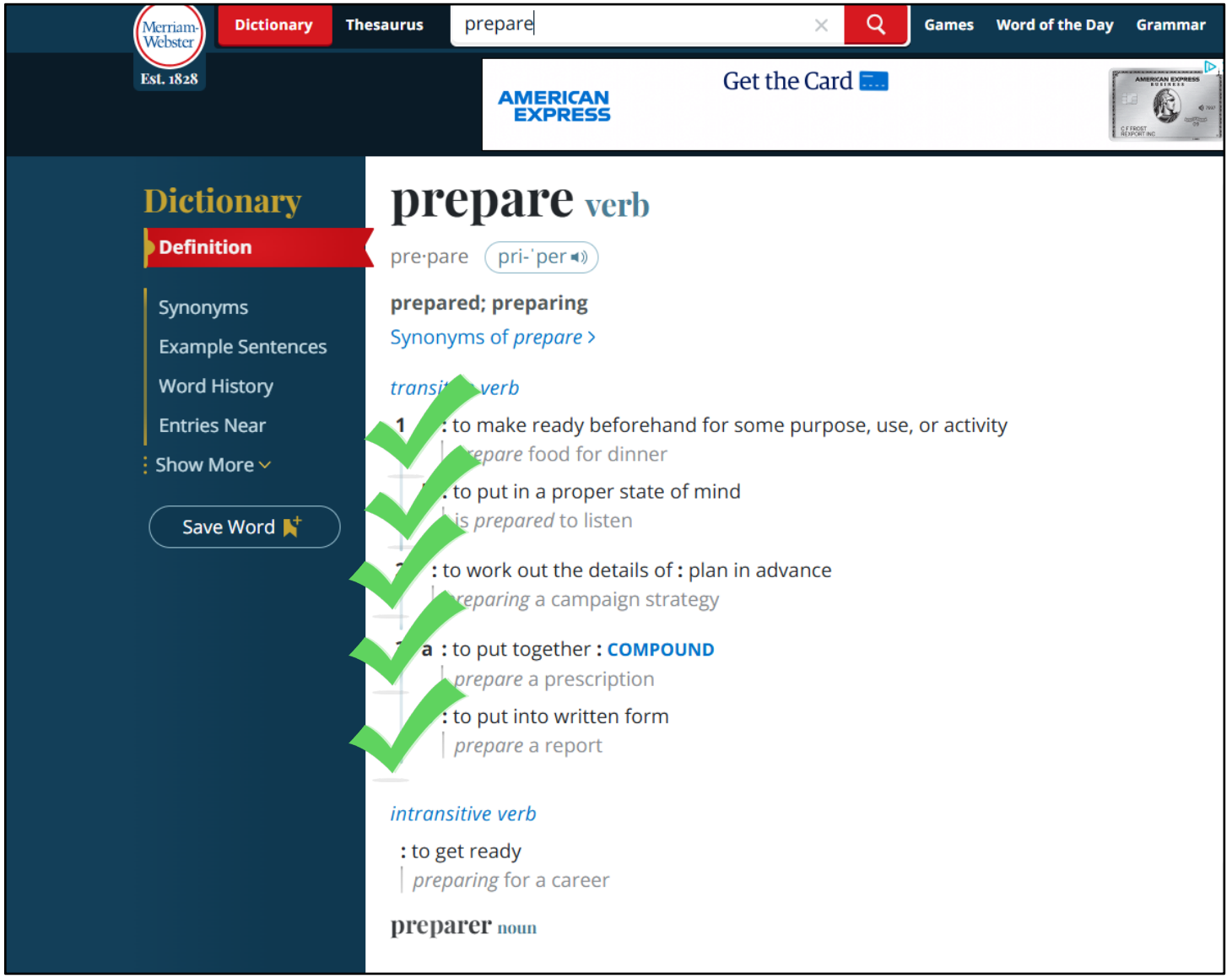
Documentation
- Draft summary report
- File all correspondence
- Update study records
- Maintain inspection file

Warning Letter Response
- Deadline=30 days to respond
- Notify IRB immediately
- Written response
- Monitor FDA website

Keys to Success, Daily

- Stay calm and confident
- Maintain cooperation with all stakeholders
- Address issues promptly
- Keep organized documentation

Summary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Definition
Synonyms
Example Sentences
Word History
Entries Near
Show More
Save Word
prepare verb
pre·pare
pri-ˈper
prepared; preparing
Synonyms of prepare
transitive verb
1 : to make ready beforehand for some purpose, use, or activity
prepare food for dinner
: to put in a proper state of mind
is prepared to listen
: to work out the details of : plan in advance
preparing a campaign strategy
a : to put together : COMPOUND
prepare a prescription
: to put into written form
prepare a report
intransitive verb
: to get ready
preparing for a career
preparer noun

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