

Data Element Definitions

September 2006

1. Titles and Background Information

Organization's Unique Protocol ID

Definition: Unique identification assigned to the protocol by the sponsoring organization, usually an accession number or a variation of a grant number. Multiple studies conducted under the same grant must each have a unique number.

Examples: CC-99-H-0020; R01-123456-1; R01-123456-2

Brief Title

Definition: Protocol title intended for the lay public.

Example: Safety Study of Recombinant Vaccinia Virus Vaccine to Treat Prostate Cancer

2. Investigational New Drug Application (IND)/Investigational Device Exemption (IDE)

Information: Complete the following only if the protocol involves an Investigational New Drug Application (IND) or Investigational Device Exemption (IDE) under US Food and Drug Administration regulations. (*Will not be made public - for administrative purposes only.*)

IND/IDE Protocol?

Definition: Indicate if the protocol involves an Investigational New Drug Application (IND) or Investigational Device Exemption (IDE) under US Food and Drug Administration regulations (*Will not be made public - for administrative purposes only.*)

IND/IDE Grantor

Definition: FDA center to which the IND or IDE was submitted, i.e., Center for Drug Evaluation and Research (CDER) or Center for Biologics Evaluation and Research (CBER) for INDs; Center for Devices and Radiological Health (CDRH) for IDEs. Select one. (*Will not be made public - for administrative purposes only.*)

IND/IDE Number

Definition: Number assigned to an Investigational New Drug Application (IND) or Investigational Device Exemption (IDE). (*Will not be made public - for administrative purposes only.*)

Examples: 22,333; BB1234

IND/IDE Serial Number

Definition: Use the serial number from the first submission of the protocol to the IND or IDE. (*Will not be made public - for administrative purposes only.*)

3. Human Subjects Review Submitted studies must have approval from a human subjects review board (Board), such as an Institutional Review Board, ethics committee, or equivalent group that is responsible for reviewing and monitoring of human subjects in this protocol.

Review board information is not required for trials associated with U.S. FDA Investigational New Drug (IND) or Investigational Device Exemption (IDE) applications.

Review board information is required for internal administrative use and is not revealed to the public.

Board Approval

Board Approval Status

Definition: Human subjects review board approval status. Select one.

- Request not yet submitted: review board approval is required but has not yet been requested
- Submitted, pending: review board approval has been requested but not yet granted
- Submitted, approved: review board approval has been requested and obtained
- Submitted, exempt: review board has granted an exemption in response to the approval request
- Submitted, denied: review board has denied the approval request
- Submission not required: the study does not require human subjects review

Board Approval Number

Definition: Number assigned by the human subjects review board upon approval of the protocol. May be omitted if status is anything other than approved.

Board Name

Definition: Full name of the approving human subjects review board.

Example: National Institutes of Health - NCI - IRB #1

Board Affiliation

Definition: Official name of organizational affiliation of the approving human subjects review board.

Example: US National Institutes of Health

Board Contact

Definition: Contact information for the human subjects review board.

- Phone: Use the format 123-456-7890 within the United States and Canada. Otherwise, provide the country code.
- Ext: Phone extension, if needed
- Email: Electronic mail address.
- Address: Mailing address for the board, including street address, city, state or province, postal code, and country.

Oversight authority information is displayed on ClinicalTrials.gov.

Oversight Authorities

Definition: The name of each national or international health organization with authority over the protocol. Use the following format for each authority:

country: organization name

Examples:

United States: Institutional Review Board

United States: Food and Drug Administration

Germany: Federal Institute for Drugs and Medical Devices

Australia: Therapeutic Goods Administration

4. Sponsors

Sponsor

Definition: Name of sponsoring organization that takes responsibility for and initiates a clinical investigation.

Examples: National Institute of Allergy and Infectious Diseases, Bristol-Myers Squibb

5. Study Description

Brief Summary

Definition: Short description of the primary purpose of the protocol intended for the lay public. Include a brief statement of the study hypothesis.

Example: The purpose of this study is to determine whether prednisone, methotrexate, and cyclophosphamide are effective in the treatment of rapidly progressive hearing loss in both ears due to autoimmune inner ear disease (AIED).

Detailed Description

Definition: Extended description of the protocol, including information not already contained in other fields, such as comparison(s) studied.

Example:

Sudden out-of-hospital cardiac arrest (OOH-CA) remains a significant cause of death, in spite of recent declines in overall mortality from cardiovascular disease. Existing methods of emergency resuscitation are inadequate due to time delays inherent in the transport of a trained responder with defibrillation capabilities to the side of the OOH-CA victim. Existing Emergency Medical Services (EMS) systems typically combine paramedic Emergency Medical Technician (EMT) services with some level of community involvement, such as bystander cardiopulmonary resuscitation (CPR) training. Some communities include automated external defibrillators (AEDs) at isolated sites or in mobile police or fire vehicles. A comprehensive, integrated community approach to treatment with AEDs would have community units served by these volunteer non-medical responders who can quickly identify and treat a patient with OOH-CA. Such an approach is termed Public Access Defibrillation (PAD).

Comparison(s): Community units trained and equipped to provide public access defibrillation in addition to optimal standard care, compared to community units trained to provide optimal standard care (recognition of out-of-hospital cardiac arrest, 911 access, cardiopulmonary resuscitation).

6. Status

Study Phase

Definition: Phase of investigation, [as defined by the US FDA](#) for trials involving investigational new drugs. Select only one.

N/A: for trials without phases, such as observational trials or expanded access trials.

Phase 0: exploratory trials, involving very limited human exposure, with no therapeutic or diagnostic intent (e.g., screening studies, microdose studies). See [FDA guidance on exploratory IND studies](#) for more information.

Phase 1: includes initial studies to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness; may include healthy participants and/or patients

Phase 1/Phase 2: for trials that are a combination of phases 1 and 2

Phase 2: includes controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks

Phase 2/Phase 3: for trials that are a combination of phases 2 and 3

Phase 3: includes expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide an adequate basis for physician labeling

Phase 4: post-marketing studies to delineate additional information including the drug's risks, benefits, and optimal use

Study Type

Definition: Nature of the investigation. Select one.

- **Interventional:** studies in human beings in which individuals are assigned to receive specific interventions. Subjects may receive diagnostic, therapeutic or other types of interventions. The assignment of the intervention may or may not be random. The individuals are then followed and biomedical and/or health outcomes are assessed.
- **Observational:** studies in human beings in which biomedical and/or health outcomes are assessed in a pre-defined group of individuals. Subjects in the study may receive diagnostic, therapeutic, or other interventions, but the investigator does not assign specific interventions to the subjects of the study.

Overall Recruitment Status

Definition: Overall protocol accrual activity for the protocol. Select one.

- Not yet recruiting: participants are not yet being recruited or enrolled
- Recruiting: participants are currently being recruited and enrolled
- No longer recruiting: participants are no longer being recruited or enrolled
- Completed: participants are no longer being recruited; data analysis is complete
- Suspended: recruiting or enrolling participants has halted but potentially will resume
- Terminated: recruiting or enrolling participants has halted and will not resume
- Withdrawn: study terminated prior to enrollment of first participant

Record Verification Date

Definition: Date the protocol information was last verified. Verification date is shown along with organization name on ClinicalTrials.gov to indicate to the public whether the information is being kept current, particularly recruiting status and contact information.

7. Study Design

Study Type (Interventional)

Definition: Primary investigative techniques used in the protocol. Select the most appropriate term describing the protocol from each of the six categories: Purpose, Allocation, Masking, Control, Assignment, and Endpoint.

Purpose - reason for the protocol

- Treatment: protocol designed to evaluate one or more interventions for treating a disease, syndrome or condition
- Prevention: protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition
- Diagnosis: protocol designed to evaluate one or more interventions aimed at identifying a disease or health condition
- Educational/Counseling/Training: protocol designed to assess one or more interventions in an educational, counseling or training environment
- Supportive Care: protocol designed to evaluation interventions where the primary intent is to maximize comfort, minimize side effects or mitigate against a decline in the subject's health or function. In general, supportive care interventions are not intended to cure a disease.
- Screening: protocol designed to assess or examine methods of identifying a condition (or risk factors for a condition) in people who are not yet known to have the condition (or risk factor).
- Health Services Research: protocol design to evaluate the delivery, processes, management, organization or financing of health care.

Allocation - participant selection

- Randomized Controlled Trial: participants are assigned to intervention groups by chance
- Nonrandomized Trial: participants are expressly assigned to intervention groups

Masking - knowledge of intervention assignments

- Open: no masking is used. All involved know the identity of the intervention assignment.
- Single Blind: one party, either the investigator or participant, is unaware of the intervention assignment; also called single-masked study.
- Double Blind: both participants and investigators are unaware of the intervention assignment

Control - nature of the intervention control

- Placebo: participants may receive only placebo throughout the course of the protocol
- Active: participants may receive some form of treatment (e.g., standard treatment) in place of the intervention under investigation
- Uncontrolled: no controls are used
- Historical: the control consists of results from past studies
- Dose Comparison: participants may receive one of several doses of the intervention

Assignment - intervention assignments

- Single Group: all participants receive the same intervention throughout the protocol
- Parallel: participants receive an intervention throughout the protocol
- Cross-over: participants may receive different interventions sequentially during the protocol
- Factorial: participants may receive no intervention, some intervention or multiple interventions simultaneously
- Expanded Access: includes treatment IND protocols

Endpoint - overall outcome that the protocol is designed to evaluate. Select one.

- Safety: show if the drug is safe under conditions of proposed use
- Efficacy: measure of an intervention's influence on a disease or health condition
- Safety/Efficacy
- Bio-equivalence: scientific basis for comparing generic and brand name drugs
- Bio-availability: rate and extent to which a drug is absorbed or otherwise available to the treatment site in the body
- Pharmacokinetics: the action of a drug in the body over a period of time including the process of absorption, distribution and localization in tissue, biotransformation, and excretion of the compound
- Pharmacodynamics: action of drugs in living systems
- Pharmacokinetics/dynamics

Study Type (Observational)

Definition: Primary investigative techniques used in an observational protocol. Select the most appropriate term describing the protocol from each of the four categories: Purpose, Duration, Selection, and Timing.

Purpose - reason for the protocol

- Natural History: protocol designed to investigate a disease or condition through observation under natural conditions (i.e., without intervention)
- Screening: protocol designed to assess or examine persons or groups in a systematic way to identify specific markers or characteristics (e.g., for eligibility for further evaluation)
- Psychosocial: protocol designed to observe the psychosocial impact of natural events

Duration - length of protocol

- Longitudinal: studies in which participants are evaluated over long periods of time, typically months or years
- Cross-sectional: studies in which participants are evaluated over short periods of time, typically up to 10 weeks

Selection - sample selection

- Convenience Sample: participants or populations are selected due to ease of recruitment

- **Defined Population:** participants or populations are selected based on predefined criteria
- **Random Sample:** participants or populations are selected by chance
- **Case Control:** participants or populations are selected to match the control participants or populations in all relevant factors except for the disease; only the case participants or populations have the disease

Timing - time of protocol

- **Retrospective:** a protocol that observes events in the past
- **Prospective:** a protocol that observes events in real time (may occur in the future)
- **Both:** a protocol that combines retrospective and prospective observation

8. Interventions

Definition: Primary interventions being studied. Provide specific name and type for each intervention (up to 10 items).

Intervention Type - select one per intervention

- Drug
- Gene Transfer - *including gene transfer and recombinant DNA* (e.g., Human nerve growth factor)
- Vaccine
- Behavior (e.g., Protein and calorie controlled diet; Self-hypnotic relaxation)
- Device (e.g., Defibrillators, implantable; Electronic medication reminder system)
- Procedure (e.g., Adenoidectomy; Bronchoalveolar lavage)

Intervention Name - generic name of the precise intervention being studied

Examples:

Zidovudine (drug)

Self-hypnotic relaxation (behavior)

9. Conditions and Keywords

Conditions

Definition: Primary disease or condition being studied, using the National Library of Medicine's Medical Subject Headings (MeSH) controlled vocabulary. The condition field is used to index studies in ClinicalTrials.gov.

Keywords

Definition: Words or phrases that best describe the protocol. Keywords help users find studies in the database. Use NLM's Medical Subject Heading (MeSH) controlled vocabulary terms where appropriate. Be as specific and precise as possible. Avoid acronyms and abbreviations.

10. Eligibility

Eligibility Criteria

Definition: Summary criteria for participant selection

Example:

Inclusion Criteria:

- Clinical diagnosis of Alzheimer's Disease
- Must be able to swallow tablets

Exclusion Criteria:

- Insulin dependent diabetes
- Thyroid disease

Gender

Definition: Physical gender of individuals who may participate in the protocol. Select one.

- Both: both female and male participants are being studied
- Female: only female participants are being studied
- Male: only male participants are being studied

Age Limits

Minimum Age

Definition: Minimum age of participants. Provide a number and select a unit of time (years, months, weeks, days, hours or minutes). Select "N/A (No limit)" if no minimum age is indicated.

Maximum Age

Definition: Maximum age of participants. Provide a number and a unit of time (years, months, weeks, days, hours or minutes). Select "N/A (No limit)" if no maximum age is indicated.

Acceptable Participants

Accepts Healthy Volunteers?

Definition: Indicate if persons who have not had the condition(s) being studied or otherwise related conditions or symptoms, as specified in the eligibility requirements, may participate in the study. Select Yes/No.

11. Protocol Location, Contact and Investigator Information

Multiple locations may be specified. Location is composed of the following fields.

Facility

- Name: Full name of the organization where the protocol is being conducted.
Examples: UCLA Eye Institute; Springfield Memorial Hospital

- City
- State/Province
- Postal Code
- Country

Recruitment Status - protocol accrual activity at a facility. Select one.

- Not yet recruiting: participants are not yet being recruited or enrolled
- Recruiting: participants are currently being recruited and enrolled
- No longer recruiting: participants are no longer being recruited or enrolled
- Completed: participants are no longer being recruited; data analysis is complete
- Suspended: recruiting or enrolling participants has halted but potentially will resume
- Terminated: recruiting or enrolling participants has halted and will not resume
- Withdrawn: recruitment terminated prior to enrollment of first participant

Tip: When a trial's overall status changes to "No longer recruiting," it is not necessary to change recruitment status for each location. Location recruitment status is only shown on ClinicalTrials.gov when Overall Status is "Recruiting".

Facility Contact

- First Name
- Middle Initial
- Last Name
- Degree
- Phone: office phone of the facility contact person. Use the format 123-456-7890 within the United States and Canada. Otherwise, provide the country code.
- Ext: phone extension, if needed
- Email: electronic mail address of the facility contact person

Facility Contact Backup

Person to contact if Facility Contact is not available (i.e., a second contact person).

Investigators (at the protocol location)

- First Name

- Middle Initial
- Last Name
- Degrees
- Role: Site Principal Investigator or Site Sub-Investigator (pick one)

Central Contact

Definition: Person providing centralized, coordinated recruitment information for the entire study.

- First Name
- Middle Initial
- Last Name
- Degree
- Phone: Office phone of the central contact person. Use the format 123-456-7890 within the United States and Canada. Otherwise, provide the country code.
- Ext: phone extension, if needed
- Email: electronic mail address of the central contact person

Central Contact Backup

Person to contact if Central Contact is not available.

Overall Study Officials

Study official information is not required for trials associated with U.S. FDA Investigational New Drug (IND) or Investigational Device Exemption (IDE) applications.

Definition: Person(s) responsible for the overall scientific leadership of the protocol, including study principal investigator.

- First Name
- Middle Initial
- Last Name
- Degree
- Official's Role: Position or function of the official. Select one (Study Chair/Study Director/Study Principal Investigator).

- Organizational Affiliation: Full name of the official's organization. If none, specify Unaffiliated.

12. Related Information

References

Definition: Citations to publications related to the protocol: background and/or results. Provide either the unique PubMed Identifier (PMID) of an article or enter the full bibliographic citation.

MEDLINE Identifier

Definition: unique PubMed Identifier (PMID) for the citation in MEDLINE

Example: PMID: 10987815

Citation

Definition: bibliographic reference in NLM's MEDLINE format

Example: Barza M; Pavan PR; Doft BH; Wisniewski SR; Wilson LA; Han DP; Kelsey SF. Evaluation of microbiological diagnostic techniques in postoperative endophthalmitis in the Endophthalmitis Vitrectomy Study. Arch Ophthalmol 1997 Sep;115(9):1142-50

Results Reference?

Definition: Indicate if the reference provided reports on results from this clinical research study.

Links

Definition: A Web site directly relevant to the protocol may be entered, if desired. Do not include sites whose primary goal is to advertise or sell commercial products or services.

Links to educational, research, government, and other non-profit Web pages are acceptable. All submitted links are subject to review by ClinicalTrials.gov.

URL

Definition: complete URL, including http://

Example: <http://www.alzheimers.org/>

Description

Definition: title or brief description of the linked page. If the page being linked is the protocol's home page on the sponsor's Web site, include the words "Click here for more information about this study:" and provide the name of the protocol.

Examples:

Click here for more information about this study: Clinical Trial of Eye Prophylaxis in the Newborn

The Alzheimer's Disease Education and Referral (ADEAR) Center is a service of the National Institute on Aging

Attachment 5

PRS User's Guide

Section	Audience
Overview	All PRS Users
Procedures for Users	All PRS Users
Procedures for Administrators	PRS Administrators
XML File Transfer	PRS Administrators

Overview

The *ClinicalTrials.gov* Protocol Registration System (PRS) is a web-based tool developed for submitting clinical trials information to *ClinicalTrials.gov*. This document provides step-by-step instructions for entering, modifying, and releasing protocol records using the PRS. Records submitted through the PRS (<http://register.clinicaltrials.gov>) are available to the public at *ClinicalTrials.gov* (<http://clinicaltrials.gov>). A guided tour of the PRS and account application information are available at <http://prsinfo.clinicaltrials.gov/>

PRS users enter information about their clinical trials, ensuring that the information is correct, readily understood by members of the public, and updated in a timely manner.

PRS Administrators are responsible for the process by which clinical trial information is released to *ClinicalTrials.gov* on behalf of their organization. This process includes creating accounts for

PRS users and editing and approving clinical trial records prior to initial release and after record updates. They serve as points of contact for the *ClinicalTrials.gov* team and resolve questions associated with the information that is provided.

The ClinicalTrials.gov team maintains the PRS and the ClinicalTrials.gov site and may make minor corrections to records.

Procedures for Users

[A. Log In to PRS](#)

[B. Create a *ClinicalTrials.gov* Record](#)

[C. Submit Record to Your Administrator](#)

[D. Modify Record](#)

[E. View Record](#)

[F. Preview Record as it Appears on *ClinicalTrials.gov*](#)

[G. Delete Record](#)

[H. Change Your Password](#)

A. Log In to PRS

1. Go to <http://register.clinicaltrials.gov>.
2. Complete the three fields on the **Login** screen:
 - Organization: organization login name
 - Username: user login name
 - Password: (case-sensitive)
3. Click [Login] and the **Main Menu** of the PRS appears.
4. To log out of the PRS, select [Logout] from the **Main Menu** screen.

B. Create a *ClinicalTrials.gov* Record

A record may be created at a single session or created and saved for completion at later sessions. To create a record during a single session:

1. Click [Create] from the **Main Menu** screen.
2. Enter the Unique Protocol ID and Brief Title for your record on the **Create New Protocol Record** screen.
3. Click [Continue] to save data and proceed to the next screen. Repeat data entry and [Continue] for successive screens.
4. After clicking [Continue] on the final data entry screen (**Links**), click [OK] on the **Study Completed** screen.

To create a record and save for completion at later sessions, after step 2. (above) or any successive screen, click [Quit] to stop data entry

- Click [Save Protocol Record] to keep your data. The record is saved for later sessions.
- Click [Delete Protocol Record] to erase the record.

Data entry tips:

Use language that is easily understood in Brief Summary.

Paragraph separation: leave a blank line between paragraphs (press enter twice).

Create lists:

- Keep each item on a separate line (press return after entering text for each line)
- Bullet items by starting each line with two spaces, a hyphen, and a space before entering the text
- Press return after text for each item

All of the data screens are clustered into 11 groups (by topic).

Click on any data entry field name to obtain a description of the field.

All fields may be modified at a later date.

Protocol records progress through the PRS with record status values as explained in the table below.

Description	Record Status
User is creating (or modifying) the record.	In Progress
User has finished - record is ready for review.	Completed
Administrator has reviewed record and has made any necessary changes.	Approved
Administrator has released the record to ClinicalTrials.gov.	Released

C. Submit Record to Your Administrator

1. Click [Modify] from the Main Menu.
2. Click [Edit] next to the record you wish to submit.
3. Review and make any necessary changes indicated by messages below the data fields on the

Edit Protocol Record screen:

ERROR messages indicate items that **MUST** be corrected. All errors must be resolved before a record may be released to *ClinicalTrials.gov*.

NOTE messages should be reviewed and corrected as needed.

4. After data entry for a record has been completed, enter any comments about the record for the Administrator and click [Complete] in the Record Status area of screen. This generates automatic e-mail notification to the Administrator that the record is complete.

Your Administrator will review the record. Approved records are released to ClinicalTrials.gov.

D. Modify Record

1. Click [Modify] on the **Main Menu**.
2. Click [Edit] next to the record to be modified on the **Select Protocol Record - Edit** screen
3. Locate the data field to be modified on the **Edit Protocol Record** screen.
4. Click on the corresponding [Edit] for that field.
5. Make changes on the data entry screen.
6. Click [OK] to save the changes and return to **Edit Protocol Record**.
7. Update Verification Date.

E. View Record

1. Click [View] on the **Main Menu**.
2. Click [View] next to record to be displayed on the **Select Protocol Record - View** screen.
3. **View Protocol Record** is *read-only*. To edit records see [D. Modify Record](#).

F. Preview Record as it Appears on *ClinicalTrials.gov*

1. Click [Modify] on the **Main Menu**.
2. Click [Edit] next to the record to be previewed.
3. Click [Preview] to see the record displayed similar to how it appears on *ClinicalTrials.gov*.
4. Click [Continue] to return to the **Edit Protocol Record** screen.

G. Delete Record

1. Click [Modify] on the **Main Menu**.
 2. Click [Edit] next to the record to be deleted.
 3. Click [Delete].
 4. Click [OK] on the **Delete Protocol** screen or click [Cancel] to return to the **Edit Protocol Record** screen without deleting the record.
- A deleted record can be recovered via the [Undelete] option on the **Main Menu**.

H. Change Your Password

1. Click [Change password] on the **Main Menu**.
2. Enter:
 - old password
 - new password
 - new password again for verification
3. Click [Change Password] to save the new password.

Contact your Administrator if you forget your password.

Procedures for Administrators

[I. Create User Accounts](#)

[J. View and Select Organization Records](#)

[K. Review, Perform Quality Check, and Approve Completed *ClinicalTrials.gov* Record](#)

[L. Release Record to *ClinicalTrials.gov*](#)

[M. Release a Batch of Records to *ClinicalTrials.gov*](#)

[N. Change Ownership of Record.](#)

[O. Updating Records](#)

[P. Edit User Information](#)

[Q. Reset Existing User Password](#)

[R. Disable/Enable User Account](#)

[S. Review Organization Account](#)

[T. Contact PRS System Administrator](#)

I. Create User Accounts

1. Click [Create] under User Accounts/Administrative Functions on the **Main Menu**
2. Complete the fields on the **User Registration** screen:
 - Access Level: "Normal" for Users (or "Administrator" for Administrators)
 - Enter User Login Name: (e.g., last name, first initial)
 - Full User Name:(e.g., full first name followed by last name)
 - User Password: (e.g., changeme)
 - Other User Information: (optional)
 - User E-mail: (e-mail address of user)
3. Click [Create] to accept account information and generate automatic e-mail notification to the user of the new account.
To view existing User account information:
 1. Click [Modify] under User Accounts/Administrative Functions on the **Main Menu**.
 2. Click [Login] next to the User name to see account information.

J. View and Select Organization Records

The first time any selection under Protocol Records on the **Main Menu** is made, you will see a **Protocol Record Selection Criteria** screen:

1. Determine the type of record to be viewed (In Progress, Completed, Approved, or Released). All record types are checked by default.
2. Option: Find particular records using **Search**:
 - Select a record field to search (Brief Title, NCT ID, Condition, Intervention Name or Phase) using the drop-down menu.
 - Enter a word or phrase in the text box.

3. Select Advanced Options if desired.
4. Click [OK].

K. Review, Perform Quality Check, and Approve Completed *ClinicalTrials.gov* Record

1. After Users create and submit records to their Administrators for approval, an automatic e-mail notification is sent to the Administrator (see [B. Create a ClinicalTrials.gov record](#) and [C. Submit a modified record to your Administrator](#)).
2. Check for system-generated e-mail notification of Completed records.
3. Click [Modify] under Protocol Records/Standard Functions on the Main Menu.
4. Select type of record to review on Protocol Record Selection Criteria screen and click [OK].
5. Click [Edit] next to the record to be reviewed on the Select Protocol Record - Edit screen.

Check for and resolve any typos and data errors such as:

ERROR: Verification Date is a required field.

ERROR: Phase is a required field.

ERROR: At least one Intervention must be specified for Interventional studies.

All ERROR messages must be resolved. (See [D. Modify Record](#) for instructions on editing records.)

To Perform Quality Check:

1. Click [Preview] on the Edit Protocol Record screen.
2. On the Protocol Registration Preview screen examine data for accuracy. Review the Brief Summary and Eligibility Criteria to see if language is easily understood by website users. Check that formatting in Brief Summary and Eligibility Criteria allows for ease of reading.
3. Click [Continue] to return to Edit Protocol Record screen. Make any changes that are needed.

Formatting can be improved as follows:

- Paragraph separation: leave a blank line between paragraphs (press enter twice).
- Create lists:
 - Keep each item on a separate line (press return after entering text for each line)
 - Bullet items by starting each line with two spaces, a hyphen, and a space before entering the text
 - Press return after text entry for each item

To Approve:

1. Update Verification Date.
2. Click [Approved] on the Protocol Record Status screen
3. Click [OK].

L. Release Record to ClinicalTrials.gov

1. Click [Modify] under Protocol Records/Standard Functions on the Main Menu.
2. Click [Edit] next to record to be previewed on the Select Protocol Record ? Edit screen.
3. Click [Release] on the Edit Protocol Record screen.

4. Click [OK] to submit the record to ClinicalTrials.gov. (Once a record is released, it cannot be retrieved.)

If an Administrator changes an Approved record, it does not need to be Approved again. The record must still be Released.

Upon release of a record, the protocol information appears on the ClinicalTrials.gov web site within 2-5 days.

M. Release a Batch of Records to ClinicalTrials.gov

1. Click [Release all] under Protocol Records/Administrative Functions on the Main Menu.
2. Click [Release Protocols]. All checked and approved records are submitted to ClinicalTrials.gov.

N. Change Ownership of Record

PRS Users may only edit and view records they created. Users "own" these records. Administrators may edit and view all records in their Organizations. If needed, Administrators may change record ownership among Users.

1. Click [Change owner] under Protocol Records/Administrative Functions on the Main Menu.
2. Click [Ownership] next to the record you wish to change.
3. Enter the Login Name of the new owner.
4. Click [OK]. To find a User Login Name, click [Modify] under User Accounts/Administrative Functions on the Main Menu.

O. Updating Records

1. Update records whenever information is added or changed or at a minimum every six months for all active trials (not yet recruiting, recruiting, and no longer recruiting trials). Generally, Users should be instructed to update records using [D. Modify a record](#), under "Procedures for Users."

- Update the Verification Date when approving any modifications.
- For six months review of active protocols, Verification Date may or may not be the only change needed.

2. Automatic e-mail notification to the Administrator is generated by the following actions:

- The status of a record is changed to Completed.
- Data in any field of a record is changed by the User.
- A record is reset to In-Progress by a User.

Each time a record is modified, it again must be Released by the Administrator for the changes to take effect in ClinicalTrials.gov.

P. Edit User Information

1. Click [Modify] in User Accounts/Administrative Functions on the Main Menu.
2. Click on the selected Login name.
3. Enter changes on the User Information screen.
4. Click [Modify].

Q. Reset Existing User Password

1. Click [Modify] under User Accounts/Administrative Functions on the Main Menu.
2. Click on a Login name.
3. Enter the new password two times. Passwords must contain at least 6 characters and are case sensitive.
4. Click [Change Password].

R. Disable/Enable User Account

1. Click [Enable/disable] under User Accounts/Administrative Functions on the Main Menu.
2. Click on a Login name.
3. Click [Enabled] checkbox:
 - Enabled (box checked): User account is active
 - Disabled (box unchecked): Users cannot access the PRS
4. Click [Modify].

If a user is disabled, ownership of his/her record(s) should be changed.

S. Review Organization Account

1. Click [View] under Organization Account/Administrative Functions on the Main Menu.
2. Review the fields on the Organization Information screen:
 - Organization Login Name
 - Full Organization Name
 - Other Organization Information
 - Administrator Email
3. Click [Send a message to ClinicalTrials.gov Administration].
4. Enter changes.
5. Click [Send].

T. Contact PRS System Administrator

1. Click [Send message to PRS] from Help/Administrative Functions on the Main Menu.
 2. Enter a message in the text area.
 3. Click [Send].
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XML File Transfer

The XML file transfer (upload/download) capability is provided to facilitate the transfer of data between *ClinicalTrials.gov* and data providers' computer systems. This capability is not required for most organizations.

[U. XML Upload](#)

[V. Release of Uploaded Protocol Records](#)

[W. XML Download](#)

U. XML Upload

XML files containing protocol information to be uploaded into the PRS are subject to the same validation process as protocol records created using the PRS web interface.

The PRS Document Type Definition (DTD), available via the PRS main menu, defines the specific required and optional tags associated with a protocol record. The DTD also contains comments outlining some of the key validation rules which cannot be expressed in the form of a DTD. For more details on what constitutes valid content, refer to the PRS Data Element Definitions, also accessible via the main menu.

Multiple records can be uploaded from a single file by simply concatenating the XML for the records and placing the concatenated XML within a "" tag.

Once the XML file is prepared, upload is accomplished by selecting the "Upload protocols" option from the main menu and following the instructions provided on that screen.

V. Release of Uploaded Protocol Records

Protocol records which are uploaded are not automatically released for publication on the *ClinicalTrials.gov* web site. An explicit "release" action is required (see [M. Release a Batch of Records to ClinicalTrials.gov](#)).

Records which pass validation without any errors are given a record status of "Approved", while records with errors are given "Completed" record status. Errors may be corrected either by repeating the upload or via the PRS web interface. When using the latter method, each corrected

record must be approved (using the "Approve" link on the Edit Protocol screen), as only approved records can be released to *ClinicalTrials.gov*.

Note that when a record is uploaded it replaces the previous version of the record, if any exists. However, the previously released version will continue to be published on the *ClinicalTrials.gov* web site until 2-5 days after the new version has been released from the PRS.

W. XML Download

Data from one or more protocol records can be downloaded from the PRS into an XML file on the data provider's computer. To download a single file, use the Download XML link on the Edit Protocol screen.

Multiple protocol records may be downloaded into a single XML file, via the Select Protocol Record screen's Download XML link. It may be necessary to change selection criteria to get the desired list of protocol records before downloading.

