**Trial Registration Service – Use Cases**

Contents

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# Document History

|  |  |  |  |
| --- | --- | --- | --- |
| **Date** | **New Version #.** | **Summary of changes** | **Editor** |
| Mar 17, 2016 | V 0.1 | Original – Only Protocol Trial Registration requirements are included. | Hemant Undale |
| Mar 23, 2016 | V 0.2 | Update and Amendment methods included | Hemant Undale |
| May 4, 2016 | V 0.4 | XML payload save requirement added | Hemant Undale |
| June 13, 2016 | V1.0 | Import of a trial | Hemant Undale |
| Aug 10, 2016 | V1.0 | One additional change | Hemant Undale |

# Overview

This document describes the submission of a trial registration for a Protocol trial, updates and amendments to the Protocol trial via RESTful service interface into the ‘CTRP Registry’. Protocol trial category is defined by the trial Summary 4 Funding Sponsor type that includes ‘National’, ‘Externally Peer-Reviewed’ and ‘Institutional’. Submitting Complete document and other trial related documents allows full trial abstraction with generating XML file suitable for submission (updating) trial to ClinicalTrials.gov, generating other type of reports and exchanging trial information between various trial-related applications.

Trials with ‘Industrial’ Summary 4 Funding Sponsor Type belong to the Imported category.

This document also describes initiating the import trial primarily funded by Industry from the ClinicalTrials.gov repository using RESTful service. This document also describes updating certain data elements of an Imported trial using RESTful service.

# 2. Use Cases

## Register a Protocol Trial

The RESTful service provides a capability to register a Protocol trial into the CTRP Repository.

CTRP maintains a repository of Organizations and Persons and assigns them unique identifiers. CTRP also maintains CTEP’s identifiers for the Organizations and Persons. CTRP and CTEPs repositories for Organizations and Persons are harmonized. One prerequisite for calling this service is that the calling system has CTRP’s internal identifiers for Organizations and Persons. Registering a Protocol trial includes providing information about the Sponsor and Lead Organization and the service requires use of CTRP’s identifiers for verifying them.

The xsd (<https://github.com/CBIIT/ctrp/blob/develop/ws5x.xsd> ) specifies the data elements, associated data types and permissible values.

When the service is called, it verifies the well formedness of the xml against the xsd. It also validates the data elements against permissible values. After successful validation, it processes the payload and registers the trial in CTRP repository. XSD validations are enumerated in Appendix A.

Upon successful registration, Service returns NCI assigned trial id.

API Specification:

|  |  |
| --- | --- |
| Use case | Register a ProtocolTrial |
| Description | Service to Register a Protocol trial in CTRP repository. |
| URL | <url-for-tier>/ctrp/ws/api/v1/trials/complete  <http://ctrp-ci.nci.nih.gov/ctrp/ws/api/v1/trials/complete> |
| http method | POST |
| Request Body | XML document with CompleteTrialRegistration  MIME type: application/xml |
| Response Body | XML document with TrialRegistrationConfirmation  MIME type: application/xml |
| HTTP Response Code | **200**. Success  **400**. Validation error  **401**. Invalid username/password or insufficient permissions to access the service.  **404**. One of the Persons/Organizations acting on the trial was not found in PO  **500**. Internal server error |
| Business Rules and Validations | 1. The service will only use Organizations (lead organization, sponsor) and Persons (Principal investigator) curated in CTRP and should be currently ‘Active’. If a user needs an Organization or Person that has not been curated, user will need to send a request to CTRO.  2. Duplicate trials are not allowed and are defined by the combination of lead organization (id) and lead organization trial identifier OR lead organization and official title. The duplicate check is conducted against active, non-rejected trial records. The combination of Lead org and Lead org trial id needs to be unique. Separately, the combination of Lead org and official title needs to be unique.  A trial previously registered successfully and not rejected in CTRP cannot be re-registered.  4. Responsible Party, Regulatory Information, Sponsor is only applicable to trials that need to be updated by CTRP to ClinicalTrials.gov.  5. Funding mechanism and Serial number needs to exist in the NIH grant database. A grant that has been awarded will typically exist in the NIH grant database.  If IND or IDE information is provided:  a. Grantor for IND can be CDER or CBER; Grantor for IDE can be CDRH or CBER  If IND holder type is NIH, then a valid NIH Institution should be provided.  If IND holder type is NCI, then a valid NCI Division (or Program) code should be provided.  6. If Current Trial Status is ‘Active’, Trial Start Date must be the same or before the Current Trial Status Date and have ‘actual’ type.  7. If Current Trial Status is ‘In Review’ or ‘Approved’, Trial Start Date must have ‘anticipated’ type. Trial Start Date must have ‘actual’ type for any other Current Trial Status value besides ‘In Review’ and ‘Approved’.  8. Primary Completion Date must be the same or bigger that the date of the current trial status preceded Completed or Administratively Completed status.  9. If Current Trial Status is ‘Complete’ or ‘Administratively Complete’, Primary Completion Date must have ‘actual’ type. Primary Completion Date must have ‘anticipated’ type for any other Current Trial Status value besides ‘Complete’ and ‘Administratively Compete’.  10. Trial Start Date must be same/smaller than Primary Completion Date.  Primary Completion Date must be current/past if ‘actual’ primary completion date type is provided and must be future if ‘anticipated’ trial primary completion date type is provided.  11. Trial owner must have been previously registered in CTRP and the email address must be known to CTRP. If the trial owner’s email address is not known to CTRP and does not have trial submitter privilege, the trial registration should be rejected.  12. Accepted document format includes: PDF, WORD, Excel, and Word Perfect  (file type extensions - pdf, doc, docx, docm, xls, xlsx, xlsm, xlsb, rtf, txt)  13. Save the XML payload in a file system with the name <source><transaction\_type><datetimestamp>. |
| Link to xsd | <<https://github.com/CBIIT/ctrp/blob/develop/ws5x.xsd>> |

## Update a Complete Trial

The RESTful service provides a capability to update a Protocol trial already existing in the CTRP Repository.

To update a Protocol trial, the Protocol trial must have previously been successfully registered in CTRP and an NCI Identifier is available. The update service call will need to reference the registered trial using the NCI identifier.

The xsd (<https://github.com/CBIIT/ctrp/blob/develop/ws5x.xsd> ) specifies the data elements, associated data types and permissible values.

When the service is called, it verifies the well formedness of the xml against the xsd. It also validates the data elements against permissible values. After successful validation, it processes the payload and registers the trial in CTRP repository. XSD validations are enumerated in Appendix B.

Upon successful update, Service returns a success message.

API Specification:

|  |  |
| --- | --- |
| Use case | Update a Protocol Trial |
| Description | Service to Update a Protocol trial in CTRP repository. |
| URL | <url for tier>/services/v1/trials/Complete/nci/<nci-id> post |
| http method | POST |
| Request Body | XML document with CompleteTrialUpdate  MIME type: application/xml |
| Response Body | XML document with TrialRegistrationConfirmation  MIME type: application/xml |
| HTTP Response Code | **200**. Success  **400**. Validation error  **401**. Invalid username/password or insufficient permissions to access the service.  **500**. Internal server error |
| Business Rules and Validations | Only a trial owner can update the trial data. The user account executing the RESTful service should be the trial owner of the trial. If not, the update should be rejected.  The update can add certain data to the existing trial or update existing data.  ClinicalTrials.gov identifier can be added, if not already existing in CTRP.  Obsolete ClinicalTrials.gov identifier can be added, if not already existing in CTRP.  Other identifiers can be added, if not already existing in CTRP.  Accrual Disease coding set can be updated for the trial, only if there are no existing accruals for the trial.  Funding mechanisms can be added. If the trial in CTRP already has the grant number being provided, the update will fail. Funding mechanism and Serial number needs to exist in the NIH grant database. A grant that has been awarded will typically exist in the NIH grant database.  Trial status can be added along with the date. If a status has previously been recorded with CTRP, the update will fail. Please see the valid status and their transitions in <<User Guide link>>.  Trial Start Date, Primary completion date and completion date can be updated. If Current Trial Status is ‘Active’, Trial Start Date must be the same or before the Current Trial Status Date and have ‘actual’ type.  7. If Current Trial Status is ‘In Review’ or ‘Approved’, Trial Start Date must have ‘anticipated’ type. Trial Start Date must have ‘actual’ type for any other Current Trial Status value besides ‘In Review’ and ‘Approved’.  8. Primary Completion Date must be the same or bigger that the date of the current trial status preceded Completed or Administratively Completed status.  9. If Current Trial Status is ‘Complete’ or ‘Administratively Complete’, Primary Completion Date must have ‘actual’ type. Primary Completion Date must have ‘anticipated’ type for any other Current Trial Status value besides ‘Complete’ and ‘Administratively Compete’.  10. Trial Start Date must be same/smaller than Primary Completion Date.  Primary Completion Date must be current/past if ‘actual’ primary completion date type is provided and must be future if ‘anticipated’ trial primary completion date type is provided.  11. Additional trial related documents can be provided. If a document already exists in CTRP, it will be replaced. Accepted document format includes: PDF, WORD, Excel, and Word Perfect  (file type extensions - pdf, doc, docx, docm, xls, xlsx, xlsm, xlsb, rtf, txt)  12. Save the XML payload in a file system with the name <source><transaction\_type><datetimestamp>. |
| Link to xsd | <<https://github.com/CBIIT/ctrp/blob/develop/ws5x.xsd>> |

## Amend a Complete Trial

The RESTful service provides a capability to amend a Protocol trial already existing in the CTRP Repository.

To amend a Protocol trial, the Protocol trial must have previously been successfully registered in CTRP and an NCI Identifier is available. The amend service call will need to reference the registered trial using the NCI identifier.

The xsd (<https://github.com/CBIIT/ctrp/blob/develop/ws5x.xsd> ) specifies the data elements, associated data types and permissible values.

When the service is called, it verifies the well formedness of the xml against the xsd. It also validates the data elements against permissible values. After successful validation, it processes the payload and registers the trial in CTRP repository. XSD validations are enumerated in Appendix C.

Upon successful amendment of the trial, Service returns a success message.

API Specification:

|  |  |
| --- | --- |
| Use case | Amend a Protocol Trial |
| Description | Service to Amend a Protocol trial in CTRP repository. |
| URL | <url for tier>/services/v1/trials/Complete/nci/<nci-id> put |
| http method | POST |
| Request Body | XML document with CompleteTrialAmendment  MIME type: application/xml |
| Response Body | XML document with TrialRegistrationConfirmation  MIME type: application/xml |
| HTTP Response Code | **200**. Success  **400**. Validation error  **401**. Invalid username/password or insufficient permissions to access the service.  **500**. Internal server error |
| Business Rules and Validations | Only a trial owner can amend the trial data. The user account executing the RESTful service should be the trial owner of the trial. If not, the amendment should be rejected.  A trial can be amended only if the previously submitted trial registration or amendment has been abstracted and the current processing status ‘Abstracted Verified-Response’ or ‘Abstracted Verified-No Response’.  XSD validations are enumerated in Appendix A.   1. The following amendment-specific data must be provided for completing abstraction submission: NCT number (optional), amendment number (optional), amendment date, change memo document, amended protocol, IRB approval for the amended protocol, ‘protocol highlight’ (optional), participating sites document (if changes to participating sites/investigators, contact, status occurred, optional), Informed Consent (if new Informed Consent exists and is not attached to the amendment protocol, optional). 2. The service will only use Organizations (lead organization, sponsor) and Persons (Principal investigator) curated in CTRP and should be currently ‘Active’. If a user needs an Organization or Person that has not been curated, user will need to send a request to CTRO. 3. Study Source cannot be modified. 4. Lead organization trial identifier can be changed. However, it will be checked for duplicates to enforce the unique Lead Organization and Lead Organization Trial Identifier constraint as well as lead organization and official title constraint. 5. Accrual Disease coding set can be updated for the trial, only if there are no existing accruals for the trial. 6. ClinicalTrials.gov identifier can be added, if not already existing in CTRP. 7. Obsolete ClinicalTrials.gov identifier can be added, if not already existing in CTRP. 8. Other identifiers can be added, if not already existing in CTRP. 9. Responsible Party, Regulatory Information, Sponsor is only applicable to trials that need to be updated by CTRP to ClinicalTrials.gov. 10. Existing grant and IND/IDE can be inactivated. Grant and IND/IDE inactivation implies setting ‘inactive’ status and date of inactivation to grant and IND/IDE records.   If IND or IDE information is provided:  a. Grantor for IND can be CDER or CBER; Grantor for IDE can be CDRH or CBER  If IND holder type is NIH, then a valid NIH Institution should be provided.  If IND holder type is NCI, then a valid NCI Division (or Program) code should be provided.   1. No IND/IDE duplication should be allowed at submission (same Type, Grantor, and Number). Only active IND/IDE records are used for duplicates check. 2. When an IND/IDE record is recorded this IND/IDE status must be set to ‘active’ and IND/IDE status activation date be set to the current date. 3. Grant can be added if all grant elements (Funding Mechanism, NIH Institution Code, Serial Number and NCI Division/Program) are not NULL. 4. No grant duplication should be allowed at submission (same Funding Mechanism, NIH Institution Code and Serial Number). Only active grants are used for duplicates check. 5. Grant Serial Number must be 5 or 6 digits long. 6. Current Trial Status Date must be current or past. 7. Trial Start Date must be current/past if ‘actual’ trial start date type is selected and must be future if ‘anticipated’ trial start date type is selected. 8. Primary Completion Date must be current/past if ‘actual’ primary completion date type is selected and must be future if ‘anticipated’ trial primary completion date type is selected. 9. If Current Trial Status is ‘Approved’ or ‘In-Review’ Trial Start Date must have ‘anticipated’ type. Trial Start Date and type should not have correlation with Current Trial Status ‘Withdrawn’ date. Trial Start Date must have ‘actual’ type for any other Current Trial Status value besides ‘Approved’, ‘In-Review’ and ‘Withdrawn’. Note that submission of amendment for study with ‘In-Review’ status will be rejected according to business rules during submission validation. 10. If Current Trial Status is ‘Completed’, Primary Completion Date must have ‘actual’ type and be same or bigger that the date of the preceding current status is such status exists. 11. If Current Trial Status is ‘Completed’ or ‘Administratively Completed’, Primary Completion Date must have ‘actual’ type. Primary Completion Date must have ‘anticipated’ type for any other Current Trial Status value besides ‘Completed’, ‘Administratively Completed’ or ‘Withdrawn’. There should be no correlation between Current Trial Status ‘Withdrawn’ date and Primary Completion Date and type. 12. Trial Start Date must be same/smaller than Primary Completion Date. 13. Reason for trial withdrawal, suspension and termination should be added to the trial registration screen. It is mandatory for the following current trial statuses: ‘Withdrawn’, ‘Temporary Closed to Accrual’, ‘Temporary Closed to Accrual and Intervention’ and ‘Administratively Complete’. It should not be saved in the DB if the current trial status is not in the above list. 14. Only valid current trial status transition is allowed if current trial status is changed 15. Sponsor and Responsible Party related elements are not required if ClinicalTrials.gov XML is not required but are mandatory otherwise. 16. Regulatory Information related elements are not required if ClinicalTrials.gov XML is not required but are mandatory otherwise. 17. Data Table 4 Funding Source data is mandatory for submitting amendment. 18. No existing document update/deletion is allowed. Additional trial related documents can be provided. Accepted document format includes: PDF, WORD, Excel, and Word Perfect   (file type extensions - pdf, doc, docx, docm, xls, xlsx, xlsm, xlsb, rtf,txt)   1. Trial status and status date must not replace the existing data if values are not changed at submitting amendment. New values must be added to the set of trial statuses if values are changed at submitting amendment. Overall recruitment status and date are derived in the latter case and are added to the existing set of overall recruitment statuses/dates. 2. Submission number value equal to the most current trial submission incremented by one (submission order) is assigned to the trial for distinguishing various submissions (StudyProtocol. submissionNumber). 3. ‘Amendment Submitted’ processing status and submission date value are assigned to the added trial (amended). 4. ‘Submission Received Date’ milestone and submission date are added to trial milestones set at successful submission. 5. Acknowledgment of submitting an amendment along with NCI trial ID is displayed upon successful submission. 6. Acknowledgment of amendment submitting along with NCI trial ID and amendment date is emailed to the trial submitter. 7. Amendment date must be current or past. 8. Amendment submission must not be allowed if study status is ‘Withdrawn’, ‘Completed’, ‘Administratively Completed’ or ‘Disapproved’ (no amend link in the search trial result). 9. Save the XML payload in a file system with the name <source><transaction\_type><datetimestamp>. |
| Link to xsd | <<https://github.com/CBIIT/ctrp/blob/develop/ws5x.xsd>> |

## Register (Import) an Abbreviated Trial

The RESTful service provides a capability to import an Abbreviated trial from ClinicalTrials.gov repository.

Upon successful import of the trial, Service returns a success message.

API Specification:

|  |  |
| --- | --- |
| Use case | Register (Import) an Abbreviated Trial |
| Description | Service to Register an Abbreviated trial in CTRP repository by importing the specified trial from ClinicalTrials.gov. |
| URL | <url for tier>/services/v1/trials/import/<nct-id> put |
| http method | POST |
| Request Body | Empty |
| Response Body | XML document with TrialRegistrationConfirmation  MIME type: application/xml |
| HTTP Response Code | **200**. Success  **400**. Validation error  **401**. Invalid username/password or insufficient permissions to access the service.  **412**. A trial with the given identifier already exists  **500**. Internal server error |
| Business Rules and Validations | 1. The service will only use Organizations (lead organization, sponsor) and Persons (Principal investigator) curated in CTRP and should be currently ‘Active’. If a user needs an Organization or Person that has not been curated, user will need to send a request to CTRO.  2. Validate that the NCT ID does not exist in CTRP.The check is conducted against active, non-rejected trial records.  3. Validate that the NCT ID is available in clinicaltrials.gov.  4. Upon parsing the XML provided by Clinicaltrials.gov, check for duplicate trial. Duplicate trials are not allowed and are defined by the combination of lead organization (id) and lead organization trial identifier OR lead organization and official title. The duplicate check is conducted against active, non-rejected trial records. The combination of Lead org and Lead org trial id needs to be unique. Separately, the combination of Lead org and official title needs to be unique.  A trial previously registered successfully and not rejected in CTRP cannot be re-registered. |
| Link to xsd | <<https://github.com/CBIIT/ctrp/blob/develop/ws5x.xsd>> |

Appendix A

XSD validations for Registering a Protocol Trial. Document encryption is base64binary.

|  |  |  |  |
| --- | --- | --- | --- |
| **Element Name** | **Validation** | **Mandatory(M)/**  **Optional(O)/**  **Conditional(C)** | **Field Length** |
| clinicalTrialsDotGovXmlRequired | Boolean – True or False | M |  |
| leadOrgTrialID | Identifier assigned by the Lead organization to the trial. Typically, this uniquely identifies the trial in the lead organization. | M | 255 |
| clinicalTrialsDotGovTrialID | Trial NCT Identifier – up to 50 character string, must start with ‘NCT’ followed by digits only (e.g. NCT12345678). | O | 255 |
| otherTrialID | Other Trial Identifiers (multiple entries OK) | O | 255 |
| Title | Official title | M |  |
| Phase | Trial phase – Allowable values are (one of) ‘0’,’I’,’I/II’,’II’,’II/III’,’III’, ’IV’, ’NA’. | M |  |
| Pilot | Boolean – True or False | M |  |
| accrualDiseaseTerminology | Disease coding system that will be used to identify disease for patient when submitting accrual. One of ‘SDC’,’ICD9’,’ICD10’,  ’ICD-O-3’. | M |  |
| primaryPurpose | Primary Purpose - Allowable values are ‘Treatment’, ‘Prevention’, ‘Supportive Care’, ‘Screening’, ‘Diagnostic’, ‘Health Services Research’, ‘Basic Science’, ‘Other’ | M |  |
| primaryPurposeOtherDescription | If the primarypurpose is ‘Other’, then the description of the primary purpose is needed. | C |  |
| interventionalDesign | Composite field | M |  |
| * secondaryPurpose |  | M |  |
| * secondaryPurposeOtherDescription |  |  |  |
| leadOrganization | Identifies Organization leading the trial. | M |  |
| * existingOrganization |  | M |  |
| * + poID | PO Identifier is a number and identifies the internal identifier in CTRP for Organization. | M |  |
| Pi | Identifies Principal Investigator for the trial. | M |  |
| * existingPerson |  | M |  |
| * + poID | PO Identifier is a number and identifies the internal identifier in CTRP for Person. | M |  |
| Sponsor | Funding Sponsor of the trial. Should not be specified if clinicalTrialsDotGovXmlRequired flag is false. | C |  |
| * existingOrganization |  | C |  |
| * + poID | PO Identifier is a number and identifies the internal identifier in CTRP for Organization. | C |  |
| responsibleParty | Responsible Party should not be specified if clinicalTrialsDotGovXmlRequired flag is false. | C |  |
| * ExistingOrganization |  | C |  |
| * + poID | PO Identifier is a number and identifies the internal identifier in CTRP for Organization | C |  |
| summary4FundingSponsor | Summary 4 (Data Table 4) funding sponsor. | M |  |
| * ExistingOrganization |  | M |  |
| * + poID | PO Identifier is a number and identifies the internal identifier in CTRP for Organization | M |  |
| programCode | ?? |  |  |
| fundedByNciGrant | Boolean – True or False | M |  |
| Grant | Only if fundedByNciGrant is True | C |  |
| * fundingMechanism | NIH funding mechanism unique identifier, a 3-character code used to identify areas of extramural research activity applied to funding mechanisms. | C |  |
| * nihInstitutionCode | Two-letter code identifying the first major-level subdivision, the organization that supports an NIH grant, contract, or inter-agency agreement. The support may be financial or administrative. | C |  |
| * serialNumber | Number generally assigned sequentially to a series within an Institute, Center, or Division. | C |  |
| * nciDivisionProgramCode | NCI organizational unit that provides funding for the study. | C |  |
| * fundingPercentage | Value from 1 – 100 identifying % of the total funding funded by grant. | C |  |
| trialStatus | Trial status codes – Allowable values are In Review, Approved, Active, Enrolling By Invitation, Closed to Accrual, Closed to Accrual and Intervention, Temporarily Closed to Accrual, Temporarily Closed to Accrual and Intervention, Withdrawn, Administratively Complete, Complete | M |  |
| WhyStopped | If the trial is Administratively Complete, Withdrawn, or Temporarily Closed, enter the reason that the study stopped. | O |  |
| trialStatusDate | Date the trial entered the identified trialStatus | M |  |
| trialStartDate | Trial Start Date | O |  |
| * Date | Date field | O |  |
| * Type | Allowable values are ‘Actual’, ‘Anticipated’, ‘N/A’ | O |  |
| primaryCompletionDate | Primary Completion Date | O |  |
| * Date | Date field | O |  |
| * Type | Allowable values are ‘Actual’, ‘Anticipated’, ‘N/A’ | O |  |
| completionDate | Completion Date | O |  |
| * Date | Date field | O |  |
| * Type | Allowable values are ‘Actual’, ‘Anticipated’, ‘N/A’ | O |  |
| Ind | Investigation Drug info | C |  |
| * Number | Investigational Drug number | C |  |
| * Grantor | Grantor for IND can be CDER or CBER; Grantor for IDE can be CDRH or CBER | C |  |
| * holderType | Allowable values are ‘Investigator’,’ Organization’,’ Industry’,’NIH’,’NCI’ | C |  |
| * nihInstitution | Allowable values are NEI, NHLBI, NHGRI, NIA, NIAAA, NIAID, NIAMS, NIBIB, NICHD, NIDCD, NIDCR, NIDDK, NIDA, NIEHS, NIGMS, NIMH, NINDS, NINR, NLM, CIT, CSR, FIC, NCCAM, NCMHD, NCRR, CC, OD | C |  |
| * expandedAccess?? |  | C |  |
| * expandedAccessType?? |  | C |  |
| * Exempt | Indicates whether or not the trial is associated with the U.S. FDA and does not require IRB approval. | C |  |
| IDE | Investigation Device info | C |  |
| * Number | Investigational Device number | C |  |
| * Grantor | Grantor for IDE can be CDER or CBER; Grantor for IDE can be CDRH or CBER | C |  |
| * holderType | Allowable values are ‘Investigator’,’ Organization’,’ Industry’,’NIH’,’NCI’ | C |  |
| * nihInstitution | Allowable values are NEI, NHLBI, NHGRI, NIA, NIAAA, NIAID, NIAMS, NIBIB, NICHD, NIDCD, NIDCR, NIDDK, NIDA, NIEHS, NIGMS, NIMH, NINDS, NINR, NLM, CIT, CSR, FIC, NCCAM, NCMHD, NCRR, CC, OD | C |  |
| * expandedAccess?? |  | C |  |
| * expandedAccessType?? |  | C |  |
| * Exempt | Indicates whether or not the trial is associated with the U.S. FDA and does not require IRB approval. | C |  |
| regulatoryInformation | Trial Regulatory Information. Required only for trials that require uploads into ClinicalTrials.gov. | O |  |
| * Country | Specify the country in which the Trial Oversight Authority is located. Use country's 3-digit ISO code. | O |  |
| * authorityName | Name of each national or international health organization with authority over the protocol. Authority name must be known to CTRP. | O |  |
| * fdaRegulated | Indicate whether this trial includes an intervention subject to US Food and Drug Administration regulation – True or False | O |  |
| * section801 | Indicate whether this is an 'applicable clinical trial' as defined in US Public Law 110-85, Title VIII, Section 801 – True or False. | O |  |
| * delayedPosting | Indicate whether this trial includes a device NOT previously approved or cleared by the US FDA – True or False | O |  |
| * dataMonitoringCommitteeAppointed | Indicate whether a data monitoring committee has been appointed for this study – True or False. | O |  |
| protocolDocument | Encrypted protocol document to upload | M |  |
| irbApprovalDocument | Encrypted IRB Approval document to upload | M |  |
| participatingSitesDocument | Encrypted Participating Sites document to upload | O |  |
| informedConsentDocument | Encrypted Informed Consent document to upload | M |  |
| otherDocument | Any other documents encrypted to upload | O |  |
| Category | Trial Category – either of National, Externally Peer-Review or ‘Institutional’ | M |  |
| trialOwner | Identifies an owner of this trial by an email address. Email address must be known to CTRP in order for the ownership to be established. | M |  |

Appendix B

XSD validations for Updating a Protocol Trial. Document encryption is base64binary.

|  |  |  |  |
| --- | --- | --- | --- |
| **Element Name** | **Validation** | **Mandatory(M)/**  **Optional(O)/**  **Conditional(C)** | Field Length |
| clinicalTrialsDotGovTrialID | Boolean – True or False | M |  |
| otherTrialID | Other Trial Identifiers (multiple entries OK) | O | 255 |
| accrualDiseaseTerminology | Disease coding system that will be used to identify disease for patient when submitting accrual. One of ‘SDC’,’ICD9’,’ICD10’,  ’ICD-O-3’. | M |  |
| Grant |  | O |  |
| * fundingMechanism | NIH funding mechanism unique identifier, a 3-character code used to identify areas of extramural research activity applied to funding mechanisms. | O |  |
| * nihInstitutionCode | Two-letter code identifying the first major-level subdivision, the organization that supports an NIH grant, contract, or inter-agency agreement. The support may be financial or administrative. | O |  |
| * serialNumber | Number generally assigned sequentially to a series within an Institute, Center, or Division. | O |  |
| * nciDivisionProgramCode | NCI organizational unit that provides funding for the study. | O |  |
| * fundingPercentage | Value from 1 – 100 identifying % of the total funding funded by grant. | O |  |
| trialStatus | Trial status codes – Allowable values are In Review, Approved, Active, Enrolling By Invitation, Closed to Accrual, Closed to Accrual and Intervention, Temporarily Closed to Accrual, Temporarily Closed to Accrual and Intervention, Withdrawn, Administratively Complete, Complete | O |  |
| WhyStopped | If the trial is Administratively Complete, Withdrawn, or Temporarily Closed, enter the reason that the study stopped. | O |  |
| trialStatusDate | Date the trial entered the identified trialStatus | O |  |
| trialStartDate | Trial Start Date | O |  |
| * Date | Date field | O |  |
| * Type | Allowable values are ‘Actual’, ‘Anticipated’, ‘N/A’ | O |  |
| primaryCompletionDate | Primary Completion Date | O |  |
| * Date | Date field | O |  |
| * Type | Allowable values are ‘Actual’, ‘Anticipated’, ‘N/A’ | O |  |
| completionDate | Completion Date | O |  |
| * Date | Date field | O |  |
| * Type | Allowable values are ‘Actual’, ‘Anticipated’, ‘N/A’ | O |  |
| protocolDocument | Encrypted protocol document to upload | M |  |
| irbApprovalDocument | Encrypted IRB Approval document to upload | M |  |
| participatingSitesDocument | Encrypted Participating Sites document to upload | O |  |
| informedConsentDocument | Encrypted Informed Consent document to upload | M |  |
| otherDocument | Any other documents encrypted to upload | O |  |

Appendix C

XSD validations for submitting an Amendment to a Protocol Trial. Document encryption is base64binary.

|  |  |  |  |
| --- | --- | --- | --- |
| **Element Name** | **Validation** | **Mandatory(M)/**  **Optional(O)/**  **Conditional(C)** | **Field Length** |
|  |  |  |  |
| clinicalTrialsDotGovXmlRequired | Boolean – True or False | M |  |
| leadOrgTrialID | Identifier assigned by the Lead organization to the trial. Typically, this uniquely identifies the trial in the lead organization. | M | 255 |
| clinicalTrialsDotGovTrialID | Trial NCT Identifier – up to 50 character string, must start with ‘NCT’ followed by digits only (e.g. NCT12345678). | O | 255 |
| otherTrialID | Other Trial Identifiers (multiple entries OK) | O | 255 |
| Title | Official title | M |  |
| Phase | Trial phase – Allowable values are (one of) ‘0’,’I’,’I/II’,’II’,’II/III’,’III’, ’IV’, ’NA’. | M |  |
| Pilot | Boolean – True or False | M |  |
| accrualDiseaseTerminology | Disease coding system that will be used to identify disease for patient when submitting accrual. One of ‘SDC’,’ICD9’,’ICD10’,  ’ICD-O-3’. | M |  |
| primaryPurpose | Primary Purpose - Allowable values are ‘Treatment’, ‘Prevention’, ‘Supportive Care’, ‘Screening’, ‘Diagnostic’, ‘Health Services Research’, ‘Basic Science’, ‘Other’ | M |  |
| primaryPurposeOtherDescription | If the primarypurpose is ‘Other’, then the description of the primary purpose is needed. | C |  |
| interventionalDesign | Composite field | M |  |
| * secondaryPurpose |  | M |  |
| * secondaryPurposeOtherDescription |  |  |  |
| leadOrganization | Identifies Organization leading the trial. | M |  |
| * existingOrganization |  | M |  |
| * + poID | PO Identifier is a number and identifies the internal identifier in CTRP for Organization. | M |  |
| Pi | Identifies Principal Investigator for the trial. | M |  |
| * existingPerson |  | M |  |
| * + poID | PO Identifier is a number and identifies the internal identifier in CTRP for Person. | M |  |
| Sponsor | Funding Sponsor of the trial. Should not be specified if clinicalTrialsDotGovXmlRequired flag is false. | C |  |
| * existingOrganization |  | C |  |
| * + poID | PO Identifier is a number and identifies the internal identifier in CTRP for Organization. | C |  |
| responsibleParty | Responsible Party should not be specified if clinicalTrialsDotGovXmlRequired flag is false. | C |  |
| * ExistingOrganization |  | C |  |
| * + poID | PO Identifier is a number and identifies the internal identifier in CTRP for Organization | C |  |
| summary4FundingSponsor | Summary 4 (Data Table 4) funding sponsor. | M |  |
| * ExistingOrganization |  | M |  |
| * + poID | PO Identifier is a number and identifies the internal identifier in CTRP for Organization | M |  |
| programCode | ?? |  |  |
| fundedByNciGrant | Boolean – True or False | M |  |
| Grant | Only if fundedByNciGrant is True | C |  |
| * fundingMechanism | NIH funding mechanism unique identifier, a 3-character code used to identify areas of extramural research activity applied to funding mechanisms. | C |  |
| * nihInstitutionCode | Two-letter code identifying the first major-level subdivision, the organization that supports an NIH grant, contract, or inter-agency agreement. The support may be financial or administrative. | C |  |
| * serialNumber | Number generally assigned sequentially to a series within an Institute, Center, or Division. | C |  |
| * nciDivisionProgramCode | NCI organizational unit that provides funding for the study. | C |  |
| * fundingPercentage | Value from 1 – 100 identifying % of the total funding funded by grant. | C |  |
| trialStatus | Trial status codes – Allowable values are In Review, Approved, Active, Enrolling By Invitation, Closed to Accrual, Closed to Accrual and Intervention, Temporarily Closed to Accrual, Temporarily Closed to Accrual and Intervention, Withdrawn, Administratively Complete, Complete | M |  |
| WhyStopped | If the trial is Administratively Complete, Withdrawn, or Temporarily Closed, enter the reason that the study stopped. | O |  |
| trialStatusDate | Date the trial entered the identified trialStatus | M |  |
| trialStartDate | Trial Start Date | O |  |
| * Date | Date field | O |  |
| * Type | Allowable values are ‘Actual’, ‘Anticipated’, ‘N/A’ | O |  |
| primaryCompletionDate | Primary Completion Date | O |  |
| * Date | Date field | O |  |
| * Type | Allowable values are ‘Actual’, ‘Anticipated’, ‘N/A’ | O |  |
| completionDate | Completion Date | O |  |
| * Date | Date field | O |  |
| * Type | Allowable values are ‘Actual’, ‘Anticipated’, ‘N/A’ | O |  |
| Ind | Investigation Drug info | C |  |
| * Number | Investigational Drug number | C |  |
| * Grantor | Grantor for IND can be CDER or CBER; Grantor for IDE can be CDRH or CBER | C |  |
| * holderType | Allowable values are ‘Investigator’,’ Organization’,’ Industry’,’NIH’,’NCI’ | C |  |
| * nihInstitution | Allowable values are NEI, NHLBI, NHGRI, NIA, NIAAA, NIAID, NIAMS, NIBIB, NICHD, NIDCD, NIDCR, NIDDK, NIDA, NIEHS, NIGMS, NIMH, NINDS, NINR, NLM, CIT, CSR, FIC, NCCAM, NCMHD, NCRR, CC, OD | C |  |
| * expandedAccess?? |  | C |  |
| * expandedAccessType?? |  | C |  |
| * Exempt | Indicates whether or not the trial is associated with the U.S. FDA and does not require IRB approval. | C |  |
| IDE | Investigation Device info | C |  |
| * Number | Investigational Device number | C |  |
| * Grantor | Grantor for IDE can be CDER or CBER; Grantor for IDE can be CDRH or CBER | C |  |
| * holderType | Allowable values are ‘Investigator’,’ Organization’,’ Industry’,’NIH’,’NCI’ | C |  |
| * nihInstitution | Allowable values are NEI, NHLBI, NHGRI, NIA, NIAAA, NIAID, NIAMS, NIBIB, NICHD, NIDCD, NIDCR, NIDDK, NIDA, NIEHS, NIGMS, NIMH, NINDS, NINR, NLM, CIT, CSR, FIC, NCCAM, NCMHD, NCRR, CC, OD | C |  |
| * expandedAccess?? |  | C |  |
| * expandedAccessType?? |  | C |  |
| * Exempt | Indicates whether or not the trial is associated with the U.S. FDA and does not require IRB approval. | C |  |
| regulatoryInformation | Trial Regulatory Information. Required only for trials that require uploads into ClinicalTrials.gov. | O |  |
| * Country | Specify the country in which the Trial Oversight Authority is located. Use country's 3-digit ISO code. | O |  |
| * authorityName | Name of each national or international health organization with authority over the protocol. Authority name must be known to CTRP. | O |  |
| * fdaRegulated | Indicate whether this trial includes an intervention subject to US Food and Drug Administration regulation – True or False | O |  |
| * section801 | Indicate whether this is an 'applicable clinical trial' as defined in US Public Law 110-85, Title VIII, Section 801 – True or False. | O |  |
| * delayedPosting | Indicate whether this trial includes a device NOT previously approved or cleared by the US FDA – True or False | O |  |
| * dataMonitoringCommitteeAppointed | Indicate whether a data monitoring committee has been appointed for this study – True or False. | O |  |
| protocolDocument | Encrypted protocol document to upload | M |  |
| irbApprovalDocument | Encrypted IRB Approval document to upload | M |  |
| participatingSitesDocument | Encrypted Participating Sites document to upload | O |  |
| informedConsentDocument | Encrypted Informed Consent document to upload | M |  |
| otherDocument | Any other documents encrypted to upload | O |  |
| amendmentNumber | Amendment number | O | 200 |
| amendmentDate | Date | M |  |
| ctepIdentifier | CTEP’s Trial Identifier for CTEP trials | O |  |
| dcpIdentifier | DCP’s Trial Identifier for DCP trials | O |  |
| changeMemoDocument | Contains a summary of changes to the original, or last amended, trial submission. One or the other of the Change Memo and Protocol Highlight documents is required. You do not have to submit both of these documents. | O |  |
| protocolHighlightDocument | Marked up protocol document highlighting the amendments. One or the other of the Change Memo and Protocol Highlight documents is required. You do not have to submit both of these documents. | O |  |