**Participating Site Registration Service – Use Cases**

Contents

[Table of Contents 1](#_Toc444766899)

# Document History

|  |  |  |  |
| --- | --- | --- | --- |
| **Date** | **New Version #.** | **Summary of changes** | **Editor** |
| June 21, 2016 | V 0.1 | Original – Participating Site registration | Hemant Undale |

# Overview

This document describes the submission of a participating site for a 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’.

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

This document also describes updating an existing Participating Site for a protocol trial.

This document also describes obtaining a list of existing Participating Sites for a protocol trial.

# 2. Use Cases

## Register a Participating Site for a Protocol Trial

The RESTful service provides a capability to register a Participating Site for a Protocol trial into the CTRP Repository. Please see Reg F22 Register Participating Site feature.

There are 2 flavors being supported. One in which **CTEP Identifier** is used to identify the organization that is the participating site and the investigator information. The other in which **PO identifier (aka CTRP identifier)** is being used.

Please see Reg F22 Register Participating Site feature.

API Specification:

|  |  |
| --- | --- |
| Use case | Register a Participating Site for a Protocol Trial (addSite) |
| Description | Service to Register a Participating Site for a Protocol trial in CTRP repository. |
| URL | <url-for-tier>/trials/{idType}/{trialID}/sites  [http://ctrp-ci.nci.nih.gov/ctrp/ws/api/v1/trials/NCI/{trialID}/sites](http://ctrp-ci.nci.nih.gov/ctrp/ws/api/v1/trials/NCI/%7btrialID%7d/sites)  Parameters  **{idType}:**Type of identifier you want to use to identify a trial in CTRP. Possible values: *NCI, NCT, CTEP*.  **{trialID}:**Trial identifier value itself  Example URL (for 4.x):  https://trials-dev.nci.nih.gov/services/trials/nci/NCI-2014-00496/sites |
| http method | POST |
| Request Body | XML document with  ParticipatingSite  **MIME Type:** application/xml |
| Response Body | CTRP Identifier of the site  **MIME Type**: text/plain |
| HTTP Response Code | * **200**. Success * **400**. Validation error * **401.** Invalid username/password or insufficient permissions to access the service. * **404**. Trial not found * **500**. Internal server error (includes the condition when the caller does not own the trial) |
| Business Rules and Validations | public Response addSite(@PathParam("idType") String idType,  @PathParam("trialID") String trialID,  @Validate ParticipatingSite reg)  The trial identified by idType and trialID must exist in CTRP and should be accepted and should not be a rejected and should not be a draft version.  Site is identified as Organization  The attributes specified in the BaseParticipatingSite element in xsd needs to be created in the database.  If the organization is identified by ctep\_id, then lookup the organization with that id in the ctep context and then navigate to corresponding ctrp organization.  The organization in CTRP identified by the organization identifier ctep\_id needs to  The contact email needs to meet the email format requirements.  The phone contact needs to meet the phone format requirements.  Create a Participating site with following information:   * Site id = Organization identifier of the organization provided as parameter * Local trial identifier * the site recruitment status and the corresponding date. * the open for accrual date, if provided. * the closed for accrual date, if provided. * the site specific program code, if provided. * the Target accrual number, if provided. * One to many Site Investigator information with following:   + Set Primary flag for Principal Investigator. All other investigators are Co-investigators and primary flag will not be set.   + Add the contact email or phone as provided for each investigator. * If site contact is not provided, that is contact email or phone is not provided, then the PI’s phone and email is to be used as site phone and email contact. |
| Link to xsd | <<https://github.com/CBIIT/ctrp/blob/develop/ws5x.xsd>> |

## Update an existing Participating Site for a Protocol Trial

There are 2 flavors being supported. One in which **CTEP Identifier** is used to identify the organization that is the participating site and the investigator information. The other in which **PO identifier (aka CTRP identifier)** is being used.

Please see Reg F22 Register Participating Site feature.

API Specification:

|  |  |
| --- | --- |
| Use case | Update a Participating Site for a Protocol Trial |
| Description | Service to Update a Participating Site for a Protocol trial in CTRP repository. |
| URL | <url-for-tier>/trials/{idType}/{trialID}/sites/po/{id}  [http://ctrp-ci.nci.nih.gov/ctrp/ws/api/v1/trials//{idType}/{trialID}/sites/po/{id}](http://ctrp-ci.nci.nih.gov/ctrp/ws/api/v1/trials/complete)  Parameters  /trials/{idType}/{trialID}/sites/po/{id}  **Parameters**  **{idType}.**Type of identifier used to identify a trial in CTRP. Possible values: *nct*, *nci*, *ctep*.  **{trialID}.**Trial identifier value itself  **{id}.** PO identifier of the organization that is the site on the trial  /trials/{idType}/{trialID}/sites/ctep/{id}  **Parameters**  **{idType}.**Type of identifier used to identify a trial in CTRP. Possible values: *nct*, *nci*, *ctep*.  **{trialID}.**Trial identifier value itself  **{id}.** CTEP identifier of the organization that is the site on the trial  Example URL for 4.x: https://trials-dev.nci.nih.gov/services/trials/nci/NCI-2014-00496/sites/po/34758686 |
| http method | PUT |
| Request Body | XML document with  ParticipatingSiteUpdate  **MIME Type:** application/xml |
| Response Body | CTRP Identifier of the site.  MIME Type: text/plain |
| HTTP Response Code | **200**. Success  **400**. Validation error  **401.** Invalid username/password or insufficient permissions to access the service.  **404**. Site not found  **500**. Internal server error (includes the condition when the caller does not own the trial) |
| Business Rules and Validations | The participating site specified with the parameters must exist in CTRP.  The attributes specified in the BaseParticipatingSite element in xsd needs to be updated in the database.  The contact email needs to meet the email format requirements.  The phone contact needs to meet the phone format requirements.  Update the site recruitment status and the corresponding date.  Update the open for accrual date, if provided.  Update the closed for accrual date, if provided.  Update program code, if provided.  Update the Target accrual number, if provided.  Site PI information – Update Primary flag for Principal Investigator. All other investigators are Co-investigators and primary flag will not be set.  Update the contact email or phone as provided for each investigator. |
| Link to xsd | <<https://github.com/CBIIT/ctrp/blob/develop/ws5x.xsd>> |

## Obtain a list of Participating Sites for a Protocol Trial

Retrieves a list of participating sites on a trial

API Specification:

|  |  |
| --- | --- |
| Use case | Retrieves a list of participating sites on a trial |
| Description | Service to retrieve a list of Participating Sites for a trial in CTRP repository. |
| URL | /trials/{idType}/{trialID}/sites  **Parameters**  **{idType}.**Type of identifier you want to use to identify a trial in CTRP. Possible values: pa, nci, ctep.  **{trialID}.**Trial identifier value itself.  [http://ctrp-ci.nci.nih.gov/ctrp/ws/api/v1/trials//{idType}/{trialID}/sites](http://ctrp-ci.nci.nih.gov/ctrp/ws/api/v1/trials/complete)  **example url for 4.x:**<https://trials-dev.nci.nih.gov/services/trials/nci/NCI-2014-00496/sites> |
| http method | GET |
| Request Body | None |
| Response Body | XML Document with sites |
| HTTP Response Code | **200**. Success  **401.** Invalid username/password or insufficient permissions to access the service.  **404**. Trial not found  **500**. Internal server error |
| Business Rules and Validations | The trial identified by idType and trialID must exist in CTRP and should be accepted and should not be a rejected trial and should not be a draft version. |
| Link to xsd | <<https://github.com/CBIIT/ctrp/blob/develop/ws5x.xsd>> |

Appendix A

XSD validations for Registering a Participating site for a Protocol Trial. Document encryption is base64binary. One of Site PI contact email or phone number must be provided.

|  |  |  |  |
| --- | --- | --- | --- |
| **Element Name** | **Validation** | **Mandatory(M)/**  **Optional(O)/**  **Conditional(C)** | **Field Length** |
| Recruitment Status | Must be one of the values...  ‘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’, ‘Completed’ | M |  |
| Recruitment Status Date | Valid past date (cannot be a future date) | M |  |
| Localtrialidentifier | String | M |  |
| Program code |  | O |  |
| Opened for accrual | Valid Date. Date when the site was opened for accrual. Needed if recruitment status is active or beyond. | C |  |
| Closed for accrual | Valid Date. Date when the site was closed for accrual. Needed if recruitment status is ‘Closed to Accrual’, ‘Closed to Accrual and Intervention’, ‘Completed’. | C |  |
| Target Accrual number | Non negative number | O |  |
| Investigator | 1 to many occurrences | M |  |
| * Existing person |  |  |  |
| * PO id OR * Ctep id | Identifier for the investigator (person). Must be a valid Person id in the CTRP Person repository and associated with the Site | M |  |
| * Role | ‘Principal Investigator’,  ‘Sub Investigator’  (Need to restrict to types allowed for Principal Investigator and Sub Investigator) | M |  |
| * Primary contact | Boolean – True or False | M |  |
|  |  |  |  |
| Organization | 1 occurrence |  |  |
| * Existing Organization |  | M |  |
| * PO Id or CTEP | Identifier for the organization (participating site). Must be a valid Organization id in the CTRP Organization repository and associated with the Site (Need to restrict to types allowed for Participating sites) | M |  |
| **For Updating Participating site** |  |  |  |
| Site PA site id | Site id generated in CTRP for updates to Participating Site |  |  |

Recruitment (Participating Site) Status:

‘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’, ‘Completed’