

16 How and When to Use APIs

OpenClinica has a highly capable [RESTful web services](#) API that enables you to interchange data programmatically with other systems, as well as carry out bulk actions such as importing data, scheduling events, or creating study participants.

The following pages are designed to help you understand how to use this API. We also provide an API toolset, called [Swagger](#), that enables you to better understand and interact with various API endpoints.

To Access the Swagger Interface for your OpenClinica Domain:

1. Click the **User** menu.
2. Select **Administration**.
3. Select **Web Services Information**.

API users of OpenClinica will need an authentication token in order to access the API endpoints.

To Obtain an Authentication Token Call the Following Endpoint:

URL:

POST to `https://{subdomain}.build.openclinica.io/user-service/api/oauth/token` replacing the **{subdomain}** with your instance subdomain.

For example: `https://xyz.build.openclinica.io/user-service/api/oauth/token`

Request Header:

- Content-Type: application/json

Request Body:

```
{
  "username": " ",
  "password": " "
}
```

Response Body:

Response body will contain the authentication token.

Supply this Authentication Token in the Authorization Header as a Bearer Token When Accessing Other Endpoints:

Authorization: Bearer "*authentication token*";

Important Note:

The rate limit for authentication token retrieval is 2 calls per minute per IP address.

Authentication tokens are valid for 4 hours. To avoid unnecessary load on the system, tokens should be reused and not refreshed until the expiration is approaching. When tokens are needed for multiple processes, initial retrieval of the tokens should be staggered so that the rate limit is not exceeded when the process is started.

Excessive calls to the authentication API will be blocked with a 429 status code. If this occurs, your script should retry a short time later (for example, wait 30 seconds or 1 minute and then retry). The aforementioned guidelines will ensure that the rate limit on retrieving tokens is not exceeded.

For Information on APIs, See the Following Sections:

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16.1 CDISC ODM XML

The Clinical Data Interchange Standards Consortium (CDISC) is a clinical research standards body formed to encourage maximum sharing of information and minimum duplication of efforts. One of the standards CDISC has created and endorsed is the Operational Data Model (ODM), which facilitates the archive and interchange of the metadata and data for clinical research. ODM is represented in XML format and is designed to collect data from many different sources into one document.

Purpose of This Document

OpenClinica provides and/or consumes CDISC ODM XML representations in its Extract Data and Import Data modules and other parts of the software. This document describes how OpenClinica represents study metadata and data that is stored in its internal database as CDISC ODM XML documents. It assumes a working knowledge of CDISC ODM 1.3 and of OpenClinica, and attempts to describe how each OpenClinica field or element is represented in ODM, and under what conditions. The document is best read when accompanied by the CDISC ODM standard. It is geared towards developers, but is also intended for data managers who want to know more about the capabilities of ODM XML export in OpenClinica. Additionally, parts of this document will find its way into the online documentation, for all end users. OpenClinicas ODM representation has changed iteratively from version to version of OpenClinica, and the appendix to this document charts these changes since version 2.5 and the addition of the custom extension to the ODM, introduced with OpenClinica 3.0.

Scope of This Document

This document provides a detailed specification of the OpenClinica [CDISC ODM XML version 1.3](#) with OpenClinica Extensions as implemented in the OpenClinica 3.1 and later releases.

Definitions and Acronyms

- CDISC [Clinical Data Interchange Standards Consortium](#)
- DOM Document Object Model
- ODM CDISC [Operational Data Model](#)
- XML Extensible Markup Language
- XSL Extensible Stylesheet Language, a language for displaying an XML file as a given type.

General Issues

CDISC defines its Operational Data Model, version 1.3, as a vendor neutral, platform independent format for interchange and archive of clinical trials data. The model includes the clinical data along with its associated metadata, administrative data, reference data and audit information. All of the information that needs to be shared among different software systems during the setup, operation, analysis, submission or for long term retention as part of an archive is included in the model. An XML document must meet certain basic criteria to be considered conformant to the ODM standard. These are briefly discussed below:

Syntactic Constraints

The syntactic constraints defined by the ODM standard are:

1. The ODM file must be a well-formed XML file. See the [XML standard](#) for details.
2. The ODM file must conform to the XML Namespace standard. See the [XML Namespace standard](#) for details.
3. The ODM file must contain only elements and attributes defined in the ODM standard schema or in a valid vendor extension schema, and must satisfy the rules about element nesting and the formats of attribute values and element bodies.
4. The ODM file must contain a prolog and a single (top-level) ODM element.
5. The namespace for version 1.3 of the ODM is <http://www.cdisc.org/ns/odm/v1.3>.

Currently, the ODM study definition file (available from the View Study page at the URL /DownloadStudyMetadata?studyId=#) does not meet these requirements for the following reasons:

1. The file generated from the View Study page is only a fragment of XML, and does not contain the initial tag which defines the character set and version, i.e. `<?xml version="1.0" encoding="UTF-8"?>`.
2. The file generated does not contain references to any XML Namespaces, including the namespace for version 1.3 of the ODM itself.
3. The file generated does contain elements defined in the ODM standard schema, but lacks the single top-level ODM element.
4. The files suffix is txt instead of xml.

OpenClinica ODM Data Import meets the above constraints, but note that OpenClinica parses everything within the ClinicalData element only, and it does not read anything in the Study element, and, as such, cannot import Study metadata at this time.

Entities and Elements

Entities and elements in OpenClinica use the same names as their counterparts in ODM. For example, the ODM definitions for study event and Study Event Definition are valid for the entities of the same name in OpenClinica (see Section 2.6, Entities and Elements, of the ODM specification):

- A *study event* is a reusable package of forms usually corresponding to a study data-collection

event.

- A *Study Event Definition* describes a particular type of study event (mostly by listing the types of forms it can contain).
- The clinical data of a study will typically have many actual study events corresponding to each StudyEventDef,

Where the usage of these entity names in OpenClinica diverges from the ODM definition, it will be noted in this document.

Clinical Data Keys

The ODM standard uses the concept of Internal Clinical Data Keys to uniquely address clinical data entities within the model. The following table details the key, or combination of entity identifiers, that you would need to uniquely and specifically address a clinical data entity.

[table id=63 /]

For example, an XPath query to retrieve a specific item data value in an OpenClinica ODM Extract would be of the form:

```
/odm:ODM/odm:ClinicalData[@StudyOID='S_P12345_2818']/odm:SubjectData[@SubjectKey='SS_101']/odm:StudyEventData[@StudyEventOID='SE_INITIALT' and @StudyEventRepeatKey='1']/odm:FormData[@FormOID='F_AGEN_V10']/odm:ItemGroupData[@ItemGroupOID='IG_AGEN_DOSETABLE-F_AGEN_V10' and @ItemGroupRepeatKey='1']/odm:ItemData[@ItemOID='I_AGEN_AGENT_NAME']/@Value
```

In the image below you can see that the latter half of the XML file (the part contained in the <ClinicalData> tags) links to specific tables in the OpenClinica database. We then link back to the Study metadata through those OIDs. Internally we don't use OIDs in those tables, but instead the conventional methods of primary keys and foreign keys in the database is good enough. For more on how ODM, OIDs, and Clinical Data Keys are implemented in OpenClinica see the blog post, ["Thoughts on Code: OpenClinica and Open Standards with CDISC"](#).

Data Representations in ODM XML (Extract)

When OpenClinica outputs ODM XML, the five basic XML entities (gt, lt, quot, amp, apos) are escaped using XML Entity notation (For example: "bread" & "butter" => "bread" & "butter"). Whitespace is represented literally linebreaks and tabs in ItemData values and other fields will be preserved. Note that, while tabs and carriage returns are limited in the data entry side of the application, (tabs will automatically shift focus from one Item to the next, for example) all spaces and linebreaks are saved to the database, and will export into ODM XML. Items saved in the database with non-ASCII characters will be extracted to XML entities using their ASCII decimal value equivalents; please see the next section, ["OpenClinica Data Representations in ODM XML \(Extract\)"](#) for an example of this.

Item Data Types

OpenClinica supports a subset of the Item Data Types defined in ODM. The data type mapping is shown below, along with the allowed string pattern used to validate item values for a given data type. Note that a listing of no definition in the table below means that the data type is not supported in OpenClinica.

Item Data Types

[table id=64 /]

Mapping of OpenClinica Elements to ODM

[table id=65 /]

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16.2 Clinicaldata (Import and Retrieve Clinical Data)

The Clinicaldata Endpoint is Used to:

- Import clinical data to the study.
- Retrieve clinical data in JSON or CDISC XML format.

The user must be authenticated prior to calling this service. The operation is allowed based on the user's privileges.

To Import Clinical Data to the Study:

This endpoint imports clinical data into the OpenClinica system using a CDISC ODM XML file format. The structure of that XML file is a combination of CDISC ODM v1.3.2 and some OpenClinica-specific tags.

Below is the Sample CDISC ODM XML Import Template for Reference.

(To use this template, copy the following text, paste it into an XML file, and update the OIDs as needed):

```
<?xml version="1.0" encoding="UTF-8"?>
<ODM xmlns="http://www.cdisc.org/ns/odm/v1.3"
xmlns:OpenClinica="http://www.openclinica.org/ns/odm_ext_v130/v3.1"
ODMVersion="1.3" FileOID="1D20080412202420" FileType="Snapshot"
Description="Demographics Import" CreationDateTime="2008-04-12T20:24:20" >

  <!-- StudyOID represents either the Study OID (if a study-level user is
importing data) or the Site OID (if a site-level user is importing data). -->
  <ClinicalData StudyOID="S_OID" MetaDataVersionOID="null">
    <!--SubjectKey (optional) is the Participant OID. If not used, remove the
entire text 'SubjectKey="SS_OID"'.
    OpenClinica:StudySubjectID (required) represents the Participant ID.
-->
    <SubjectData SubjectKey="SS_OID" OpenClinica:StudySubjectID="PID-001">
      <!--StudyEventOID (required): The OID for the event into which you
are importing data.
```

StudyEventRepeatKey (optional): The ordinal for a repeating event. If removed, a new study event ordinal is automatically generated. For a visit-based event **OpenClinica:StartDate** is required. If the **StudyEventRepeatKey** value is provided and the specified repeat is already in the database, then the system updates the form data for that study event repeat on import.

OpenClinica:EndDate (optional): If the event has a scheduled end date, you can provide that here. Otherwise, delete it or leave it same as start date.-->

```
<StudyEventData StudyEventOID="SE_OID"
OpenClinica:StartDate="2017-09-29" OpenClinica:EndDate="2017-09-29"
StudyEventRepeatKey="1">
```

<!--FormOID (required): The OID for the form into which you are importing data.

OpenClinica:FormLayoutOID (optional): If no value is provided then the system assigns the default form version to the participant event form.

OpenClinica:Status (optional): Possible values for **OpenClinica:Status** are: 'initial data entry' or 'complete'.

If no value is provided, then the system assigns the status 'initial data entry' to the participant event form on import. -->

```
<FormData FormOID="F_OID" OpenClinica:FormLayoutOID="1.1"
OpenClinica:Status="initial data entry">
```

<!--ItemGroupOID (required): The OID for the item group into which you are importing data.

ItemGroupRepeatKey (optional): If not provided, a new repeat key is auto-generated on import.

If a value is provided and the provided repeat key already exists in the database,

then the associated item data is updated in that item group repeat upon import. -->

```
<ItemGroupData ItemGroupOID="IG_OID"
ItemGroupRepeatKey="1">
```

<!--ItemOID and Value (required): The OID of the item into which you are importing data and the data value to be imported into that item.

Any issues with the value of the item will be reported in the log file with an appropriate errorCode. -->

```
<ItemData ItemOID="I_OID" Value="2017-09-13"/>
<ItemData ItemOID="I_OID" Value="1"/>
<ItemData ItemOID="I_OID" Value="Headache"/>
```

```
</ItemGroupData>
```

```
</FormData>
```

```
</StudyEventData>
```

<!--To import data for more than one Study event, repeat the **StudyEventData** tag and everything within the opening and closing tags.

For a visit-based event with multiple forms, all forms belonging to one repeat of that event should be combined under the same **StudyEventData** tag.

For common events, each FORM should be provided with a SEPARATE

pair of StudyEventData tags.-->

```
</SubjectData>
```

<!-- To import data for more than one Subject, copy and paste the opening and closing SubjectData tags, and everything between those tags. Then update OIDs and values as needed.-->

```
</ClinicalData>
```

```
</ODM>
```

Import is a Two Step Process:

- Create a job to import data using your CDISC ODM XML file.
- Once the job completes, download the log file to review the results.

Below is the Endpoint to Create the Import Job Using Your CDISC ODM XML File:

POST {serverName}/pages/auth/api/clinicaldata/import Where {serverName} is your study URL.
For example: <https://studyxyz.eu.openclinica.io/OpenClinica>

Sample cURL Request:

```
curl -X POST
  {{serverName}}/pages/auth/api/clinicaldata/
  -H 'Authorization: bearer {{authentication token}}'
  -H 'content-type: multipart/form-data; boundary=----
WebKitFormBoundary7MA4YWxkTrZu0gW'
  -F 'file=@{{fileName}}'
```

{{fileName}} references the full path of the ODM XML file that contains the clinical data to import.

Sample Response Body on Success:

```
job uuid: 6c325687-c3c3-41f6-hj98-154ef3352cb1
```

Sample Response Body on Failure:

When there is a failure in starting the import job then an appropriate error code is returned:

```
errorCode.noRoleSetUp
```

Below is the List of all the Error Codes and their Descriptions:

- **errorCode.fileFormatNotSupported:** File is not an XML file.
- **errorCode.invalidXMLFile:** XML file has syntax issues or is not a valid CDISC ODM XML.
- **errorCode.missingStudyOID:** No studyOID provided in the XML.
- **errorCode.studyOIDNotFound:** the Study OID specified in the request is not found.
- **errorCode.studyOIDNotAvailable:** the Study OID specified in the request is in status other than Available.
- **errorCode.noRoleSetup:** the authenticated user has no role defined for the given Study/Site.
- **errorCode.noSufficientPrivileges:** The user does not have sufficient privileges to perform this operation.

Below is the Endpoint to Download the Logfile Once the Job has Completed:

GET {serverName}/pages/auth/api/jobs/{jobUuid}/downloadFile where {serverName} is your study URL. For example: <https://studyxyz.eu.openclinica.io/OpenClinica>

Sample cURL request:

```
curl -X GET
{{serverName}}/pages/auth/api/jobs/{{jobUuid}}/downloadFile
-H 'Authorization: bearer {{authentication token}}'
```

Sample XML Import File Content:

```
SubjectKey,ParticipantID,StudyEventOID,StudyEventRepeatKey,FormOID,ItemGroupO
ID,ItemGroupRepeatKey,ItemOID,Status,Timestamp,Message
SS_LA6,LA-6,SE_STUDYDISCONTINUATION,1,F_TERMINATION,IG_TERMI_GROUP1,1,I_TERMI
_DSSTDAT,Inserted,2019-06-07T23:20:32.690Z,
SS_LA6,LA-6,SE_STUDYDISCONTINUATION,1,F_TERMINATION,IG_TERMI_GROUP1,1,I_TERMI
_DSAENO,Inserted,2019-06-07T23:20:32.708Z,
SS_LA6,LA-6,SE_BASELINE,1,F_TERMINATION,,,Failed,,errorCode.formOIDNotFound
SS_LA6,LA-6,SE_CONMEDS,1,F_CONMEDS,IG_CONME_GROUP1,1,I_CONME_MED,Inserted,201
9-06-07T23:20:32.825Z,
```

If there is a failure in returning the job file, then an appropriate error code is returned.

Below is the list of all the errorCodes with their descriptions:

- **errorCode.invalidUuid:** The Job Uuid specified in the request is not found.
- **errorCode.jobInProgress:** The Job represented by the specified job Uuid has not completed.

Get Clinical Data in JSON or XML Format:

This endpoint retrieves participant clinical data in CDISC ODM XML file or in JSON file format from a given study. Asterisks and wild cards can be used in place of OIDs and Participant ID in the request parameters. This endpoint can also be used to retrieve ONLY the study metadata and/or clinical data including audit logs, discrepancy notes (queries), and the clinical data in the archived forms. The response from the endpoint will be as per the user's access level. For example, a user with ONLY site A access will receive metadata and clinical data only for site A study, users, and participants.

Usage:

```
GET
{serverName}/pages/auth/api/clinicaldata/{studyOID}/{studySubjectIdentifier}/{studyEventOID}/{f
ormOID} where {serverName} is your study URL. For example: https://studyxyz.eu.openclinica.io/OpenClinica
```

Sample cURL request:

```
curl -X GET
'{{serverName}}/pages/auth/api/clinicaldata/{{studyOID}}/{{participantOID}}?c
linicalData=y&includeMetadata=y&includeDN=n&includeAudits=n&showArchived=n'
-H 'Accept: application/xml'
```


-H 'Authorization: bearer {{authentication token}}'

Request Parameters:

- **studyOID:** Required
 - Valid studyOID or siteOID.
- **studySubjectIdentifier:** Required
 - Valid studySubjectOID
 - * **(Asterisk)** can be used to retrieve data for all Participants in the study.
- **studyEventOID:** Required
 - Valid studyEventOID
 - * **(Asterisk)** can be used to retrieve data for all Event OIDs for the given Participant.
- **formOID:** Required
 - Valid formOID
 - * **(Asterisk)** can be used to retrieve data for all Form OIDs for the given Study Event OID of the given participant.
- **includeMetadata:** Optional
 - Whether or not to include the study metadata in the response. (For a large study, including metadata can slow down performance).
 - Possible values: **y** or **n**
 - Default is **n**
- **includeAudits:** Optional
 - Whether or not to include audit trail information in the response.
 - Possible values: **y** or **n**
 - Default is **n**
- **includeDNs:** Optional
 - Whether or not to include the discrepancy notes (Queries) in the response.
 - Possible values: **y** or **n**
 - Default is **n**
- **showArchived:** Optional
 - Whether or not to include the clinical data for the archived forms and form versions.
 - Possible values: **y** or **n**
 - Default is **n**

Response Content Type:

- application/xml
- application/json

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16.3 Participants (Add or Update a Participant)

This Endpoint can be Called to Perform the Following Tasks:

- Add a participant to a given site.
- Update participant contact information like first name, last name, email address or phone number.
- Register the participant to access OpenClinica Participate dashboard.

Stipulations:

- Participants can be registered for OpenClinica Participate ONLY when the Participate module is Active for the given study.
- Study-level participants can't be added to Participate or have contact data entered for them.
 - CRCs and Investigators cannot see Study-level participants, so it is best practice to always add participants to a site.
- Site-level Participants cannot be reassigned to the study-level (only reassigning to a site is possible).
- This endpoint can be called either when the study has the Participant ID Method set to "Manual Entry" or "System-generated"

Access Control:

- User roles **authorized** to call this endpoint and perform the specified operations:
 - Data Managers
 - Clinical Research Coordinators
 - Investigators
- Site level roles can perform this operation only on their site's participants.
- User roles **NOT authorized** to call this endpoint:
 - Monitors (study level and site level)
 - Viewers (study level and site level)

URL:

POST {customerName}/pages/auth/api/clinicaldata/studies/{studyOID}/sites/{siteOID}/participants (Site-level)

POST {customerName}/pages/auth/api/clinicaldata/studies/{studyOID}/participants (Study-level)

where {customerName} is your study URL. For example:
<https://studyxyz.openclinica.io/OpenClinica>.

Sample cURL Request:

```
curl -X POST \
'{{serverName}}/pages/auth/api/clinicaldata/studies/S_JUNO%28PROD%29/sites/S_OHIO%28TEST%29/participants?register=y' \
-H 'Authorization: bearer {{authentication token}}' \
-H 'Content-Type: application/json' \
-d '{
  "subjectKey": "OHIO-5",
  "firstName": "OHIO-5",
  "lastName": "OHIO",
  "emailAddress": "OHIO5@openclinica.com",
  "phoneNumber": "+12582235452"
  "identifier": "ABC-35452"
}'
```

Request Parameters:

- register: Optional
 - Whether or not to register the participant for OpenClinica Participate
 - Possible values: **y** or **n**
 - Default is **n**

Response Body on Success:

```
{
  "subjectKey": "OHIO-6",
  "subjectOid": "SS_OHIO6",
  "status": "Available",
  "participateStatus": "Created"
}
```

Response Body on Failure:

```
{
  "message": [
    "errorCode.noRoleSetUp"
  ],
  "params": [
    "studyOID S_JUNO(TEST)",
    "siteOID S_OHIO(TEST)"
  ]
}
```

Below is the List of errorCodes with their Descriptions:

- **errorCode.studyNotExist:** The study OID specified in the request is not found.
- **errorCode.studyNotAvailable:** The study OID specified in the request is not in 'Available' status.
- **errorCode.siteNotExist:** The site OID specified in the request is not found.
- **errorCode.siteNotAvailable:** The site OID specified in the request is not in 'Available' status.
- **errorCode.noRoleSetUp:** The user has no role assigned for the given study/site.
- **errorCode.noSufficientPrivileges:** The user does not have sufficient privileges to perform this operation.
- **errorCode.participateNotEnabled:** OpenClinica Participate module is not active for the given Study and therefore, the operation is NOT allowed.
- **errorCode.participantIDContainsUnsupportedHTMLCharacter:** The Participant ID contains unsupported HTML (<, >) characters.

- **errorCode.participantIDLongerThan30Characters:** The Participant ID exceeds the 30 character limit.
- **errorCode.participantsEnrollmentCapReached:** The pre-set Participant enrollment limit has reached. No new participants can be added to this study.
- **errorCode.invalidPhoneNumber:** The phone number in the specified request is invalid.
- **errorCode.invalidEmailAddress:** The email address in the specified request is invalid.
- **errorCode.emailAddressTooLong:** The email address in the specified request is too long.

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16.4 Participants/Bulk (Add or Update Bulk List of Participants)

Access the participant endpoint on a list of participant IDs in bulk. The functionality, stipulations, and the access control all apply as per the participants endpoint.

Functionality:

- Create/Update participants in bulk for a given site.
- Update participant contact information like first name, last name, email address, or mobile number.
- Register the participant to access OpenClinica Participate dashboard.

Stipulations:

- Participants can be registered for OpenClinica Participate ONLY when the Participate module is Active for the given study.
- This endpoint can be called either when the study has the Participant ID Method set to "Manual Entry" or "System-generated"

Access Control:

- User roles **authorized** to call this endpoint and perform the specified operations:
 - Data Managers
 - Clinical Research Coordinators
 - Investigators
- Site level roles can perform this operation only on their site's participants.
- User roles **NOT authorized** to call this endpoint:
 - Monitors (study level and site level)
 - Viewers (study level and site level)

Before calling the API, you will need to be authenticated and you will need to get access based on your user roles permissions.

Study-level participants can't be created in bulk via API. (Participants will need to be assigned to a site).

URL:

POST

{customerName}/pages/auth/api/clinicaldata/studies/{studyOID}/sites/{siteOID}/**participants/bulk**

where {customerName} is your customer URL. For example:

https://customerxyz.openclinica.io/OpenClinica

Sample cURL Request:

```
curl -X POST
```

```
{{customerName}}/pages/auth/api/clinicaldata/studies/S_JU0%28TEST%29/sites/S_BOSTON_7642%28TEST%29/participants/bulk?register=y
```

```
-H 'Authorization: bearer {{authentication token}}'
```

```
-H 'content-type: multipart/form-data; boundary=-----
```

```
WebKitFormBoundary7MA4YWxkTrZu0gW'
```

```
-F 'file=@C:directoryfile.csv'
```

Request Parameters:

- register: Possible values: **y** or **n**.
 - When set to **n**, participants will NOT be registered for OpenClinica Participate Module
 - When set to **y**, the system generates an access code for each participant and registers them for OpenClinica Participate Module

This endpoint also requires a CSV file with list of participant IDs and their corresponding contact information, if desired.

Below Are the Requirements for the CSV File Content:

- File must have ONE column with header as 'ParticipantID'. This column must contain the Participant ID.
- File can have either of the following columns: (They are all optional)
 - firstName
 - lastName
 - emailAddress
 - phoneNumber
 - identifier
- File columns can be in any order.
- The following restrictions pertain to the values in these columns:
 - firstName and lastName -- Must be less than or equal to 35 characters in length
 - emailAddress -- Must be an email address and must be less than 255 characters in length
 - phoneNumber -- Must be in the format of +# #####
 - Starts with +
 - Up to 3 digits after + for the country code
 - A space after the country code
 - Up to 14 digits after space for the area code and local code

- No other characters permitted
- Up to 17 characters total
- identifier -- Must be less than or equal to **35** characters in length

participantList.csv should be replaced with a CSV file that contains the list of participant IDs that need to be added to the study.

Here's a [sample CSV file](#) for adding two participant IDs: **JUNO-005** and **JUNO-006**

Response Body on Success:

```
job uuid: d2dbdc07-c0f9-4e4d-9ae2-81f5bfaed1c9
```

Response Body on Failure:

```
errorCode.invalidSiteIdentifier
```

Below is the List of Error Codes with their Descriptions:

- **errorCode.studyNotExist:** The study OID specified in the request is not found.
- **errorCode.invalidSiteIdentifier:** The site OID specified in the request is not found.
- **errorCode.notSupportedFileFormat:** The file format is not supported. Only CSV files are accepted.
- **errorCode.noRoleSetUp:** The user has no role assigned for the given study/site.
- **errorCode.noSufficientPrivileges:** The user does not have sufficient privileges to perform this operation.
- **errorCode.participateInactive:** Participate module is not active for the given study and register flag is set as y in the request.

Once the job has completed, you can access job's log file in the OpenClinica UI via **Tasks** and **Bulk Actions Log**.

If the system encounters a problem processing any particular record in the file, an appropriate error code will be returned for that record and displayed within the log file.

Here are the Possible Error Codes and their Descriptions:

- **errorCode.participantIDContainsUnsupportedHTMLCharacter:** Participant ID contains unsupported HTML (<, >) characters.
- **errorCode.participantIDLongerThan30Characters:** Participant ID exceeds 30 characters limit.
- **errorCode.participantsEnrollmentCapReached:** Participant enrollment limit has reached. No new participants can be added.
- **errorCode.firstNameTooLong:** First name value supplied in the record exceeds 35 character limit.
- **errorCode.emailAddressTooLong:** Email address value supplied in the record exceeds 255 character limit.
- **errorCode.mobileNumberTooLong:** Mobile number value supplied in the record exceeds 17 character limit.
- **errorCode.invalidMobileNumber:** Mobile number value supplied in the record not a valid mobile number.
- **errorCode.invalidEmailAddress:** Email address value supplied in the record not a valid

email address.

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16.5 Retrieve Participant Contact Information

Participant contact information comprises any participant contact details captured in the reserved fields within the study as well as the participant access code generated for accessing OpenClinica Participate.

The following endpoint is used to retrieve participant contact information. This may be helpful, for example, if you want to generate a mailing list of all participants, or integrating with a CTMS system, which may utilize this information.

Only users with site-level CRC and Investigator roles (or derivatives thereof) can call this endpoint to retrieve participant contact information. Removed participants are not included in the results.

Retrieving Contact Information is a Two Step Process:

1. An authorized user submits the request for retrieving participant information
2. Once the job completes, the same user calls the download file endpoint to get the file containing extracted participant information

Below are the Details About the Two Endpoints:

Submit the Request:

POST

`{serverName}/pages/auth/api/clinicaldata/studies/{studyOID}/sites/{siteOID}/participants/extractParticipantsInfo`

where `{serverName}` is your study URL. For example: `https://studyxyz.eu.openclinica.io/OpenClinica`

Request Parameters:

Register: (Optional)

- Possible values **y** or **n**. (The default is **n**.)

When the value **y** is passed, participant contact information includes the Participant's access code for OpenClinica Participate application as well as the Status of the participant on Participate

application. However, when register is passed as n then the access code and participate status is excluded.

Sample cURL Request:

```
curl -X POST
'{{serverName}}/pages/auth/api/clinicaldata/studies/{{studyOID}}/sites/{{site
OID}}/participants/extractPartcipantsInfo?register=y'
-H 'Authorization: bearer {{authentication token}}'
```

Response Body on Success:

The endpoint submits the job in the background and returns a unique job UUID. This job UUID can be used to download the file which contains the retrieved participant information.

Alternatively, the information can be accessed via the OpenClinica UI via **Tasks** and **Bulk Actions Log**.

job uuid: hi12345j-2b02-482f-3h7s-286d54555f25

Response Body on Operation Failure:

```
{
  "message": "errorCode.studyNotExist",
  "params": {
    "siteOid": "sdgsg",
    "studyOid": "sdgsd"
  }
}
```

Here are the Possible Error Codes with their Descriptions:

- **errorCode.studyNotExist:** The study OID specified in the request is not found.
- **errorCode.siteNotExist:** The site OID specified in the request is not found.
- **errorCode.noRoleSetUp:** The user has no role assigned for the given Study/Site.
- **errorCode.noSufficientPrivileges:** The user does not have sufficient privileges to perform this operation.
- **errorCode.participateInactive:** The study does not have an enabled Participate module.

Download the File:

GET {serverName}/pages/auth/api/jobs/{jobUuid}/downloadFile

where {serverName} is your study URL. For
example: <https://studyxyz.eu.openclinica.io/OpenClinica>

Sample cURL Request:

```
curl -X GET
{{serverName}}/pages/auth/api/jobs/{{jobUuid}}/downloadFile
-H 'Authorization: bearer {{authentication token}}'
```

Here are the possible error codes with their descriptions:

- **errorCode.invalidUuid:** The Job UUID specified in the request is not found.

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16.6 Events (Create and Update Single Study Event)

Study Event Endpoints are Used to:

- Create a new study event repeat for a given participant
- Update the properties of a given study event repeat

The user must be authenticated prior to calling this service. The operation is allowed based on the user's privileges.

Create New Study Event Repeat:

This endpoint creates a new repeat of a visit-based study event for a given participant. The Endpoint requires at a minimum: participant ID, study event OID, and a start date. Using these attributes, the system creates either a new study event repeat with the given start date or returns an error as outlined below:

POST {serverName}/pages/auth/api/clinicaldata/studies/{studyOID}/sites/{siteOID}/events Where {serverName} is your study URL. For example: <https://studyxyz.eu.openclinica.io/OpenClinica>

Sample cURL Request:

```
curl -X POST
{{serverName}}/pages/auth/api/clinicaldata/studies/{studyOID}/sites/{siteOID}
/events
-H 'Authorization: bearer {{authentication token}}'
-H 'content-type: application/json'
-d '{
  "subjectKey": "MGH-001",
  "studyEventOID": "SE_DEMOGRAPHICS",
  "startDate": "2000-01-01",
  "endDate": "2000-01-01"
}'
```

Sample Response Body When Success:

```
{
  "subjectKey": "MGH-001",
```

```

"studyEventOID": "SE_DEMOGRAPHICS",
"studyEventRepeatKey": "1",
"startDate": "2000-01-01",
"endDate": "2000-01-01",
"eventStatus": "scheduled"
}

```

Sample Response Body When Failure:

When there is a failure to create new study event repeat then an errorCode is returned. Plan the follow-up steps based on the returned errorCode.

```

{
  "message": "errorCode.endDateBeforeStartDate",
  "params": {
    "siteOid": "S_OHIO(TEST)",
    "studyOid": "S_JUNO(TEST)"
  }
}

```

Here is a List of the Error Codes and their Descriptions:

- **errorCode.studyNotExist:** The Study OID specified in the request is not found.
- **errorCode.studyNotAvailable:** The Study OID specified in the request is in Design, Frozen or Locked status.
- **errorCode.siteNotExist:** The Site OID specified in the request is not found.
- **errorCode.siteNotAvailable:** The Study OID specified in the request is in Design, Frozen or Locked status.
- **errorCode.noRoleSetUp:** The authenticated user has no role defined for the given Study/Site.
- **errorCode.noSufficientPrivileges:** The user does not have sufficient privileges to perform this operation.
- **errorCode.missingParticipantID:** The Participant ID (SubjectKey) [participantID] is not present in the request body.
- **errorCode.participantNotFound:** The Participant ID (SubjectKey) [participantID] specified in the request is not found under the given Study and/or Site OID.
- **errorCode.missingStudyEventOID:** Study event OID is not present in the request body.
- **errorCode.invalidStudyEventOID:** Study event OID specified in the request is not valid and/or found in the given Study and/or Site OID.
- **errorCode.commonEventCannotBeScheduled:** Returned when the study event OID specified in the request is a common event. This endpoint can be called only for visit based events.
- **errorCode.missingStartDate:** Start date is required in order to create a new visit based study event repeat. When start date is missing this error code is returned.
- **errorCode.invalidStartDate:** Start date specified in the request is not in valid format. Supported format: yyyy-MM-dd (or 'yyyy-MM-dd hh:mm' format if including time)
- **errorCode.invalidEndDate:** End date specified in the request is not in valid format. Supported format: yyyy-MM-dd (or 'yyyy-MM-dd hh:mm' format if including time)
- **errorCode.endDateBeforeStartDate:** End date of a visit based study event can be either same as start date or greater than start date. This error code is returned when end date value passed is less than start date.
- **errorCode.eventAlreadyExists:** Study event OID specified in the request is a non-repeating

event and that repeat 1 is already when this endpoint is called.

Update Properties of a Study Event Repeat:

This endpoint updates the properties of a given study event for a given participant. For a visit-based event, properties are Start date, end date, and status. For a common event, properties include only the status of the event. This endpoint requires participant ID, study event OID, and study event repeatKey in order to lookup the appropriate study event. When a match is found, the properties of that event repeat are updated with the values of start date, end date, and/or status passed in the request. **Note:**

- *Status of an event follows a strict transition path.*
- *If no update is required for a given property, remove that property from the request body. An empty value will not be accepted.*

PUT {serverName}/pages/auth/api/clinicaldata/studies/{studyOID}/sites/{siteOID}/events

Where {serverName} is your study URL. For example: https:

//**studyxyz**.eu.openclinica.io/OpenClinica

Sample cURL Request:

```
curl -X POST
{{serverName}}/pages/auth/api/clinicaldata/studies/{studyOID}/sites/{siteOID}
/events
-H 'Authorization: bearer {{authentication token}}'
-H 'content-type: application/json'
-d '{
"subjectKey": "participantID",
"studyEventOID": "studyEventOID",
"studyEventRepeatKey": "1",
"startDate": "YYYY-MM-DD",
"endDate": "YYYY-MM-DD",
"eventStatus": "data entry started"
}'
```

Sample Response Body When Success:

```
{
  "subjectKey": "participantID",
  "studyEventOID": "studyEventOID",
  "studyEventRepeatKey": "1",
  "startDate": "2000-01-01",
  "endDate": "2000-01-01",
  "eventStatus": "scheduled"
}
```

Sample Response Body When Failure:

When there is a failure to update the study event repeat properties, an error code is returned.

```
{
  "message": "errorCode.endDateBeforeStartDate",
```

```

"params": {
  "siteOid": "S_OHIO(TEST)",
  "studyOid": "S_JUNO(TEST)"
}
}

```

Here is the List of the Error Codes and their Descriptions for this Endpoint:

- **errorCode.studyNotExist:** The Study OID specified in the request is not found.
- **errorCode.studyNotAvailable:** The Study OID specified in the request is in Design, Frozen or Locked status.
- **errorCode.siteNotExist:** The Site OID specified in the request is not found.
- **errorCode.siteNotAvailable:** The Study OID specified in the request is in Design, Frozen or Locked status.
- **errorCode.noRoleSetUp:** The authenticated user has no role defined for the given Study/Site.
- **errorCode.noSufficientPrivileges:** The user does not have sufficient privileges to perform this operation.
- **errorCode.missingParticipantID:** The Participant ID (SubjectKey) [participantID] is not present in the request body.
- **errorCode.participantNotFound:** The Participant ID (SubjectKey) [participantID] specified in the request is not found under the given Study and/or Site OID.
- **errorCode.missingStudyEventOID:** Study event OID is not present in the request body.
- **errorCode.invalidStudyEventOID:** Study event OID specified in the request is not valid and/or found in the given Study and/or Site OID.
- **errorCode.missingStudyEventRepeatKey:** Study event repeatKey is required for the lookup. When its not present in the request then this error code is returned.
- **errorCode.invalidStudyEventRepeatKey:** When repeatKey specified in the request is not a valid integer.
- **errorCode.studyEventRepeatNotFound:** When no results are found for the given participant ID, study event OID, and study event repeatKey.
- **errorCode.invalidStartDate:** Start date specified in the request is not in valid format. Supported format: yyyy-MM-dd (or 'yyyy-MM-dd hh:mm' format if including time)
- **errorCode.invalidEndDate:** End date specified in the request is not in valid format. Supported format: yyyy-MM-dd (or 'yyyy-MM-dd hh:mm' format if including time)
- **errorCode.endDateBeforeStartDate:** The end date of a visit based study event can be either the same as start date or greater than start date. This error code is returned when end date value passed is less than start date.
- **errorCode.invalidStatus:** Status specified in the request body is not a valid status.
- **errorCode.eventStatusTransitionNotAllowed:** The status of the given study event repeat is not allowed to be moved to the status that's specified in the request body then this error code is returned.
- **errorCode.eventStatusTransitionNotAvailable:** The status of the given study event repeat cannot be moved to the status that's specified in the request body because there are other conditions that must be met before it is possible. When those conditions are not satisfied at the time of request then this error code is returned. For example: event status can move from data entry started to completed only when all the forms in that event are completed. In this case, if one of the forms is in initial data entry started when user made a request to update the study event status to be completed then this error code will be returned.

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16.7 Bulk Create and Update Study Events

The bulk study event endpoint is used to create or update multiple study events for a list of participant IDs.

The functionality, stipulations and access control for this endpoint is the same as per the single create and update study event endpoint.

The user must be authenticated prior to calling this service. The operation is allowed based on the user's privileges.

URL:

POST {serverName}/pages/auth/api/clinicaldata/studies/{studyOID}/sites/{siteOID}/events/bulk
where {serverName} is your customer URL. For example: https://customerxyz.openclinica.io/OpenClinica

Sample cURL Request:

```
curl -X POST
{{serverName}}/pages/auth/api/clinicaldata/studies/S_JUN0%28PROD%29/sites/S_B
OSTON_3152%28PROD/events/bulk
-H 'Authorization: bearer {{authentication token}}'
-H 'content-type: multipart/form-data; boundary=----
WebKitFormBoundary7MA4YWxkTrZu0gW'
-F 'file=@C:directoryfile.csv'
```

Request Parameters:

This endpoint requires a CSV file with list of Participant IDs, and the Study Event related information. The CSV file must adhere to the following:

- File must have ONE column with header as 'ParticipantID'. This column must contain the Participant ID.
- File must have a column for StudyEventOID
- The following additional columns are required based on the action to be performed on the given StudyEventOID:
 - To Create a new Study Event
 - StudyEventRepeatKey must be EMPTY
 - StartDate must be present (time is optional)
 - EndDate is optional (time is optional)
 - StudyEventStatus is not used
 - To Update the Study Event
 - StudyEventRepeatKey must be present and a valid integer

- StartDate is optional (time is optional)
- EndDate is optional (time is optional)
- StudyEventStatus is optional
- File columns can be in any order.
- Below are the restrictions on the values in these columns:
 - ParticipantID and StudyEventOID must be valid identifiers under the given study site
 - StudyEventRepeatKey must be an integer value
 - StartDate and EndDate must be in 'yyyy-MM-dd' format (or 'yyyy-MM-dd hh:mm' format if including time)
 - StudyEventStatus may include the values: 'data entry started', 'stopped', 'skipped', 'locked' and 'completed'.

Here's a [sample CSV file](#) for creating study event and modifying the study events for the given participants.

Response Body on Success:

Endpoint will submit the job in the background and will return the unique job uuid.

job uuid: ddbadff4-f015-4a2d-81e0-e3daf507bbfc

Response Body on Failure to Submit the Job:

```
{
  "message": "errorCode.siteNotExist",
  "params": {
    "site0id": "S_OHIO(PRD)",
    "study0id": "S_JUNO(PROD)"
  }
}
```

Below is the List of Error Codes with their Descriptions:

- **errorCode.studyNotExist:** The Study OID specified in the request is not found.
- **errorCode.siteNotExist:** The Site OID specified in the request is not found.
- **errorCode.notSupportedFileFormat:** The file format is not supported. Only CSV files are accepted.
- **errorCode.noRoleSetUp:** The user has no role assigned for the given Study/Site.
- **errorCode.noSufficientPrivileges:** The user does not have sufficient privileges to perform this operation.

Once the job has completed you can access the job's log file in the OpenClinica UI via **Tasks** and **Bulk Actions Log** In case of in processing any particular record in the file, an appropriate errorCode will be returned for that record within the logfile.

Here is the List of Possible Error Codes with their Descriptions:

- **errorCode.participantNotFound:** No participant record was found for the given Participant ID value.
- **errorCode.missingParticipantID:** Participant ID value is missing in the record.
- **errorCode.missingStudyEventOID:** Study event OID value is missing in the record.
- **errorCode.invalidStudyEventOID:** Study event OID value in the record is not a valid study event OID.

- **errorCode.CommonEventCannotBeScheduled:** Study event OID in the record is a common event and hence cannot be scheduled.
- **errorCode.missingStartDate:** Start date is missing and therefore study event cannot be scheduled.
- **errorCode.invalidStartDate:** Start date in the record is invalid.
- **errorCode.endDateBeforeStartDate:** End date is before the start date.
- **errorCode.invalidEndDate:** End date in the record is invalid.
- **errorCode.studyEventRepeatNotFound:** Study event repeat key in the record is not found for the given participant.
- **errorCode.invalidEventStatus:** Status in the record is not a valid status.
- **errorCode.invalidEventTransitionStatus:** When the study event transition status from the current status of the given study event repeat to the status provided in the record is not allowed.

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16.8 Bulk Actions Log

OpenClinica Supports Following Bulk Actions Using the Web Services Interface:

1. Bulk add participants.
2. Bulk create study events for given participants.
3. Import using CDISC ODM XML file.
4. Retrieve participants contact information.

Each of the above bulk actions generate a logfile that can be viewed when you click the **Tasks** menu and select **Bulk Actions Log**.

Each Bulk Action Record on the Bulk Actions Log screen is Comprised of the Following Information:

- Source file name
 - Name of the file that was used to execute the bulk action
- Job type
 - Job type describes the bulk action that was executed on the given source file
- Site name
 - This column contains either the name of the site or the study for which the given bulk action was executed.
- Job status
 - Status of the bulk action job at the time of the page load
- Start time
 - Date and time when the bulk action was submitted
- Submitted by
 - Username of the user who submitted the bulk action job
- Completion time

- Date and time when the bulk action job completed
- Actions
 - No actions are available for the bulk action jobs that are in 'In Progress' status
 - Once the bulk action job completed, then following three actions are available:
 - View - User can view the results of the logfile within OpenClinica
 - Download - User can download the logfile on their local system for viewing in offline mode
 - Delete - User can delete the logfile from the system

Accessibility:

Bulk actions log page is accessible to all users. Bulk action jobs listed on the page are based on the user who submitted the job and the user's logged in study or site.

- Study level user, when logged in at the Study level, can view all the bulk action jobs that user submitted either at the Study level or at the Site level for the given study.
- Study level user, when logged in at the Site level, can view all the bulk action jobs that user submitted at the given Site of the given study.
- Site level user can view all the bulk action jobs that user submitted at the logged in site of the given study.

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16.9 Participants (Get Participants at Study Level or Site Level)

This endpoint is used to retrieve a list of study level or site level Participants.

Access Control:

- User roles **authorized** to call this endpoint and perform the specified operations:
 - Data Manager
 - Clinical Research Coordinators (CRC)
 - Investigators
- Site level roles can perform this operation only on their site's participants.
- User roles **NOT authorized** to call this endpoint:
 - Monitors (study level and site level)

The user must be authenticated prior to calling this service. The operation is allowed based on the user's privileges.

At Study Level:

GET {serverName}/pages/auth/api/clinicaldata/studies/{studyOID}/participants where {serverName} is your study URL. For example: <https://studyxyz.eu.openclinica.io/OpenClinica>

At Site Level:

GET {serverName}/pages/auth/api/clinicaldata/studies/{studyOID}/sites/{siteOID}/participants
where {serverName} is your study URL. For example: https:
//studyxyz.eu.openclinica.io/OpenClinica

Sample cURL Request to Site Level Participants:

```
curl -X GET \  
{{serverName}}/pages/auth/api/clinicaldata/studies/{{studyOID}}/sites/{{siteOID}}/participants \  
-H 'Authorization: bearer {{authentication token}}' \  

```

Response Body:

```
{  
  "studyParticipants": [  
    {  
      "subjectKey": "LA-1",  
      "subjectOid": "SS_LA1",  
      "status": "Available",  
      "createdBy": "testuser",  
      "createdAt": "Apr 26, 2019 12:00:00 AM",  
      "lastModified": "Apr 26, 2019 12:00:00 AM",  
      "lastModifiedBy": "testuser"  
    },  
    {  
      "subjectKey": "LA-2",  
      "subjectOid": "SS_LA2",  
      "status": "Available",  
      "createdBy": "testuser",  
      "createdAt": "Apr 26, 2019 12:00:00 AM",  
      "lastModified": "Apr 26, 2019 12:00:00 AM",  
      "lastModifiedBy": "testuser"  
    }  
  ]  
}
```

If the operation fails to get the list of participant IDs, the system returns an appropriate error code.

Below is a List of Error Codes and their Descriptions.

- **errorCode.studyNotExist:** The study OID specified in the request is not found.
- **errorCode.invalidSiteIdentifier:** The site OID specified in the request is not found.
- **errorCode.noRoleSetUp:** Authenticated user does not have a role assigned for the given Study/Site.
- **errorCode.noSufficientPrivileges:** The user does not have sufficient privileges to perform this operation.

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