



Merge eClinical: Process Improvement and Education

## eClinical OS: Study Designer Training

Data Imports / API Services

Authored by: Emily Malok

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# **Version 5.4.7 Highlights**

There were no updates to the Data Imports or API modules in eClinical OS v5.4.7.





# 1 Overview

**Overview** 

Setup

Data Imports

API Services

There are times that subject data is collected outside the EDC application and yet the information needs to be incorporated into the study. This often occurs when using central labs, ECG reader facilities, or other vendors, such as IVRS systems. There are two main ways to incorporate the data:

- ◆ You can keep the data separate from the main EDC data and integrate it after the EDC data is exported.
- You can import the external data into EDC so that it is included in the main study export.

We'll focus on the second option in this module. Imports can be done manually or they can be set up, using the API Services, to be done automatically. If you import data, it must have a CRF page or pages in EDC to be stored in. These pages can be visible to EDC users or hidden -- refer to the Build Tools manual for methods of masking page data.

We'll begin with module setup, then discuss the different options for imports, and finish with the options in the API services -- both interactive and remote.



IMPORTANT: If you plan on using the API services for remote access, especially with an automatic transfer, you must work with your Merge Account Manager and Merge IT to set up the connection initially. If the information for server access does not change, this can be re-used from study to study. If the information changes at any time, you must contact your Account Manager to get the connection updated.





2 Setup

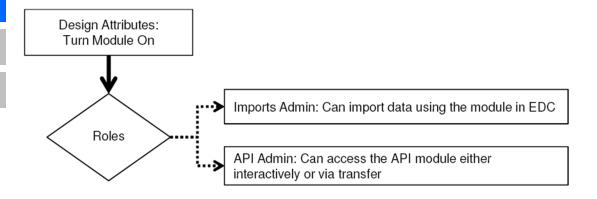
### Overview

Setup

Data Imports

**API Services** 





#### **Basic Steps to Configure:**

- ♦ Turn the module on
- ◆ Provide high level design attributes
- Assign permissions to roles
- Review Page Design and Visit Design for proper mapping of external files



*NOTES: When using Flush/Prepare Study in a design that includes Data Imports and API Services, the flush will:* 

- ♦ DELETE ALL processing logs, records
- ♦ *DELETE ALL physical files that are stored on the server after upload.*





### 2.1

# **Design Attributes**



**LOCATION:** Process → Design Attributes (Optional)

This turns the module on and provides some general format for the module.

Imports / API:			
capand for attribute descriptions			
Attribute	Value	Comment	
Study Using Imports / API Module?	Yes 🔻	ii.	History
Import / API Format	API XML V1.0 ▼	.ti	History
Processing Success Confirmation Emails	emily.malok@merge.com	.ti	History
Processing Failure / Error Emails	emily.malok@merge.com	it.	History
Email Option	Only Error Emails ▼	.ti	History
Internal User ID for External System Transfer (Numeric)		li.	History
Where the import is coming from?	Central Lab	it	History

Attribute	Options	Details
Study Using Imports / API Module?	<ul><li>Yes</li><li>Yes - Currently Halted</li><li>No</li></ul>	This question indicates whether or not the Data Imports/API Services module will be used. The "Yes - Currently Halted" optional allows you to temporarily stop imports or module access once you have started using the module.
Processing Success Confirmation Emails	Free Text	This specifies addresses to receive the successful process email notifications. Use commas to separate multiple email addresses.





### **Design Attributes** 2.1

Attribute	Options	Details
Processing Failure / Error Emails	Free Text	This specifies addresses to receive the failure or error in process email notifications. Use commas to separate multiple email addresses.
Import/API Format	• API XML V1.0	This species the format schema to be used for data import files and API calls. More details are available in the Reference section and in the Data Imports/API Services manual.
Email Option	<ul><li> All</li><li> Only Error Emails</li><li> None</li></ul>	<ul> <li>This specifies if users want to receive processing emails.</li> <li>All: Users specified in the Email fields above will receive all success and failure notifications for an import attempt.</li> <li>Only Error Emails: Users specified in the Email fields above will receive only the failure notifications for an import attempt.</li> <li>None: Users specified in the Email fields above will not receive notifications for an import attempt.</li> </ul>
Internal User ID for External System Transfer	Numeric	This value is the unique internal ID of the user to attribute all actions of files coming to the study using this method. The user must have data imports admin rights, be active in the study, etc. for the file processing to complete.
IMPORTANT: Use this ONLY if files are fed to system from external systems, and NOT using the tab in the study or web services module.		
Where the import is coming from	Free Text	This allows you to specify what actions will be performed using the Imports/API module. This helps identify what to test when using the Study Testing module.





### 2.2 Roles



#### Process → Roles **LOCATION:**

The Data Imports and API administrative roles are separate options when you provide role permissions. A role for automated upload and import will need both permissions.

Add New Role: ②	
Role Name:	*
Abbreviation:	*
Icon:	*
Can Add/Edit Subject Information?	(includes editing revison of a subject)
Can Add/Edit Page Data / Page Links?	
Can Sign Pages?	
Can Add Query?	
Can Edit Query?	
Can Source Doc Verify (SDV)?	
Can Delete/Restore Pages?	
Can Delete/Restore Subjects?	
Can Upload Files to CRFs?	
Can Upload Site Documents?	
Unblinded Role?	(applies to page / site document uploads where blinding indicated, plus randomization/stratification and dispensing)
Data Imports Admin?	(can view/upload data import files)
API Admin?	(can use eClinical OS API web servicing)
Uploads Admin?	(can delete other users site or CRF attachments)
	⊕ Add

Role Permissions	Options	Details
Data Imports Admin?	Checkbox	This permission allows users to access the Imports/API tab in EDC and view or upload data import files.
API Admin?	Checkbox	This permission allows users to access the interactive mode in EDC to review format without producing web services calls on the user's side. It also enables the user to use the API Information Services in true web servicing mode (server to server XML).





### 2.2 Roles

Based on the administration roles selected, the user will have an Import/API tab, Imports tab, or API tab added to their EDC view.

#### DATA IMPORTS ADMIN ONLY



#### API ADMIN ONLY



#### BOTH DATA IMPORTS AND API ADMIN







2

### **Practical Exercise**

**DAISY** 

### Access for Data Imports and API

- 1. Click Design Attributes (Optional) on the Process menu.
- 2. In the Imports/API Module section, enter the following details:

Attribute	Enter This
Study Using Imports/API Module	Yes
Import/API Format	API XML V1.0
Processing Success Confirmation Emails	[ Use Your Email Address ]
Processing Failure/Error Emails	[ Use Your Email Address ]
Email Option	All
Internal User ID for External System Transfer (Numeric)	< leave blank >
Where the import is coming from?	< leave blank >

- 3. Click Update.
- 4. Click Roles on the Process menu.
- 5. For the Administrator role, in the Admin Rights column, check the Data Imports box and the API box.
- 6. Click Save Row.







3

## **Data Imports**

**Overview** 

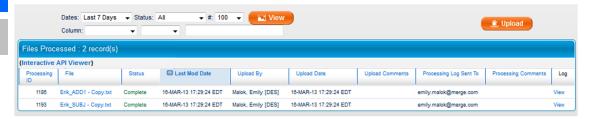
Setup

**Data Imports** 

**API Services** 

On the main screen module screen in EDC, you will be able to do the following:

- ♦ Sort or Filter items recent items. The default display is "Last 7 Days".
- Access an Upload area if you have Data Import Admin permission
- Access the Interactive API area if you have the API Admin permission



The Files Processed table is the main feature on the page. It contains details about each file, such as:

- Unique Processing ID, which is provided by the system when uploaded
- ♦ File Name, which is hyperlinked to view the file
- ♦ Status of Completed (green) or Failed (red)
- ♦ Last Modified Date
- ♦ Upload By
- ♦ Upload Date
- ♦ Upload Comments
- ♦ Email address where the processing log was sent
- ♦ Any processing comments
- ♦ A link to view the processing log





### 3.1 F

### **File View Filters**

You can use the filters to help locate and view import files

Filter	Options
Dates	This specifies a time frame for the import files: <ul> <li>All</li> <li>Last 3 Days</li> <li>Last 7 Days (default)</li> <li>Last 30 Days</li> </ul>
Status	This specifies the status of the file:  • All  • New  • Not Complete  • Complete  • FAILED
#	This is the number of results to display:  • 50  • 100  • 1000  • All
Column	These three fields are used in conjunction to narrow the file list:
Field 1	This is the column that will be filtered by:  • Processing ID  • File
Field 2	This is the operator to set the criteria:  Contains  (equals) (for equals)
Field 3	This is the free text value field for the criteria.



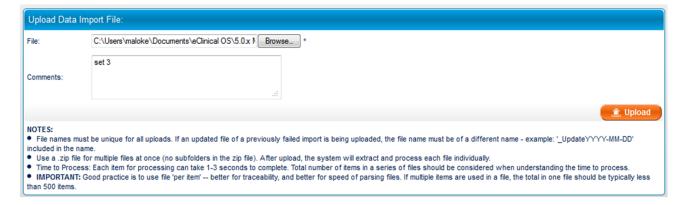


### 3.2

### **Importing Files Manually**

#### To Upload a File for Import:

Step	Details
1	Click the Upload button on the main Import page.
2	Use the Browse button to open the window and locate your file on your local machine.
Optional	Provide a comment or description for the file.
3	Click the Upload button again.





#### NOTES:

- File names must be unique for all uploads. If an updated file of a previously failed import is being uploaded, the file name must be of a different name example: '\_UpdateYYYY-MM-DD' included in the name.
- Use a .zip file for multiple files at once (no subfolders in the zip file). After upload, the system will extract and process each file individually.
- Time to Process: Each item for processing can take 1-3 seconds to complete. Total number of items in a series of files should be considered when understanding the time to process.



IMPORTANT: Good practice is to use file 'per item' -- better for traceability, and better for speed of parsing files. If multiple items are used in a file, the total in one file should be typically less than 500 items.

For details on automatically importing files, see the API section later in this manual.





### 3.3

### **General Tips - All Types**

- Each type of file import has error checking as noted in each section.
- There is one stage of XML parsing checking that takes place first.
- If any of that fails, the issues are reported, with the action aborted.
- Only after all parsing checks succeeds, does additional study design level checking take place.
- ◆ Multiple <item> sections can appear in one file, or users may choose to do 'one item per file' for clarity in reporting / logs at the IMPORTS tab in EDC.
  - ♦ type : The type of item to process (e.g. ADD\_SUBJECT)
  - ♦ studyid: The internal ID within eClinical OS for the study.
- ♦ All processed items will have audit trail that refers to the file name where the source of that data came from.





## **Error Checking**

#### **For ALL TYPES:**

- ♦ Valid XMLformat
- ♦ Missing type
- ♦ Unknown type
- Missing subjected AND subjectidentifier (one is needed, but not both)
- ♦ subjectid given, but not numeric
- subjectidentifier given, but not numeric
- subjectidentifier given, but not matching a subject identifier in the study
- User uploading the file MUST:
  - ♦ Have an active study account
  - ♦ Be associated to a site / organization in the study that is active.
  - ♦ Study must not be Closed







## Single vs. Multiple Records

#### One Item within a file

#### Multiple Items within a file





## ADD\_SUBJECT

#### **Purpose**

Used to add a subject if a subject doesn't previously exist (i.e. the Subject Identifier / Number)

#### Sample File

#### **Field Specifics**

Field	Description /	Error Checking at File	Error Checking After
	Notes	XML Parsing	XML Parse
subjectidentifier	The Subject Number/ Identifier of the added subject	<ul><li>Numeric</li><li>Required</li></ul>	<ul> <li>Doesn't match existing number</li> <li>Must satisfy the length format if design attributes dictate. (non-'Free Text Entry')</li> <li>NOTE: Does NOT validate against the Study Wide or Site Level formatting of the identifier. The creator of this file should be following those rules.</li> </ul>





# 3.6 ADD\_SUBJECT

Field	Description / Notes	Error Checking at File XML Parsing	Error Checking After XML Parse
subjectidentifier2	If used, the 2 <sup>nd</sup> subject identifier		<ul> <li>If used, and Text Field or Date - required</li> <li>If Text Field format, 100 character max</li> <li>Date type: YYYY-MM-DD format</li> <li>Check Box type: 'X' or empty are only valid usages</li> </ul>
subjectidentifier3	If used, the 3 <sup>rd</sup> subject identifier		<ul> <li>If used, and Text Field or Date - required</li> <li>If Text Field format, 100 character max</li> <li>Date type: YYYY-MM-DD format</li> <li>Check Box type: 'X' or empty are only valid usages</li> </ul>
add_ revisionnumber	Revision number for the add	<ul> <li>Numeric</li> <li>Required only if multiple revisions with "Add" exist for the site</li> </ul>	Matches a revision ID from study design
sitenumber	Site the subject is associated with	Numeric     Required	<ul> <li>Matches a site number in the study</li> <li>Site has Can Add rights with the revision</li> <li>Overall Study Cap not met (non-deleted subjects)</li> <li>Site Cap not met (non-deleted subjects)</li> </ul>





# 3.6 ADD\_SUBJECT

Field	Description / Notes	Error Checking at File XML Parsing	Error Checking After XML Parse
statusid	Optional - status of subject after add. If ID nor name are passed, status of subjects takes the first status of study design.		<ul> <li>If passed, numeric</li> <li>If passed, matches an ID from Subject Status design area.</li> </ul>
statusname	Optional – status of subject after add.		If used, matches a status name in the Subject Status design area.
comment	Optional - comment to add to the audit trail as part of the subject add.	If given, 3700 maximum	•
skip_if_exists	Optional – allows import process to continue without a registered error if the subject already exits	• "true" or "false"	"false" is default if missing





### EDIT\_SUBJECT\_INFO

#### **Purpose**

Used to edit a subject's main information, change site, delete, restore, and/or comment. For example, when using a 2nd subject identifier classified as a screening number and 3rd subject identifier classified as an Informed Consent Date.

#### Sample File

#### **Field Specifics**

Field	Description / Notes	Error Checking at File XML Parsing	Error Checking After XML Parse
subjectid	The internal subject ID of the subject. Pass this with a different subject identifier to have a subject number/identifier changed	<ul> <li>Numeric (if passed)</li> <li>One of ID or Identifier Required</li> </ul>	





# EDIT\_SUBJECT\_INFO

Field	Description / Notes	Error Checking at File XML Parsing	Error Checking After XML Parse
subjectidentifier	The Subject Number/ Identifier of the added subject	<ul> <li>Numeric (if passed)</li> <li>One of ID or Identifier Required</li> </ul>	<ul> <li>If passed, must match existing subject number</li> <li>Must satisfy the length format if design attributes dictate. (non-'Free Text Entry')</li> <li>NOTE: Does NOT validate against the Study Wide or Site Level formatting of the identifier. The creator of this file should be</li> </ul>
	nd		following those rules.
subjectidentifier2	If used, the 2 <sup>nd</sup> subject identifier		<ul> <li>If used, and Text Field or Date - required</li> <li>If Text Field format, 100 character max</li> <li>Date type: YYYY-MM-DD format</li> <li>Check Box type: 'X' or empty are only valid usages</li> </ul>
subjectidentifier3	If used, the 3 <sup>rd</sup> subject identifier		<ul> <li>If used, and Text Field or Date - required</li> <li>If Text Field format, 100 character max</li> <li>Date type: YYYY-MM-DD format</li> <li>Check Box type: 'X' or empty are only valid usages</li> </ul>





# EDIT\_SUBJECT\_INFO

### **Field Specifics (continued)**

Field	Description / Notes	Error Checking at File XML Parsing	Error Checking After XML Parse
sitenumber	Site the subject is associated with	<ul><li>Numeric</li><li>Required</li></ul>	<ul> <li>Matches a site number in the study</li> <li>Overall Study Cap not met (non-deleted subjects)</li> <li>Site Cap not met (non-deleted subjects)</li> </ul>
statusid	Optional - status of subject as part of update If ID nor name are passed, no status change is made		<ul> <li>If passed, numeric</li> <li>If passed, matches an ID from Subject Status design area.</li> </ul>
statusname	Optional – status of subject as part of update. Pass empty ID/name for no change.		If passed, matches a status name in the Subject Status design area.
comment	Required - comment to add as part of update	<ul><li>Required</li><li>3700 characters maximum</li></ul>	

(continued on next page)





# EDIT\_SUBJECT\_INFO

Field	Description / Notes	Error Checking at File XML Parsing	Error Checking After XML Parse
edit_subject _deletedvalue	Used to delete or restore a subject. Pass EMPTY to not have this aspect updated.	• Only <b>true</b> or <b>false</b> can be passed, if passed, true = subject is marked deleted in EDC	<ul> <li>If a restore, checks that Study Cap not met</li> <li>If a restore, checks that Site Cap not met</li> </ul>
	IMPORTANT NOTE: The pass of a value to this field results in ONLY that update in the <item>. If other subject level information needs updating, use a second <item> processing section.</item></item>		





## ADD\_QUERY

#### **Purpose**

Used to add a new query to a page/control within a subject's CRF pages.



#### NOTES:

- The subject must be both non-deleted and not in a Subject Status that is 'Data Read Only'
- ♦ Visit ID / Visit Sequence / Page ID / Page Sequence are per the visit schedule design of the subject's current Revision. Visit Sequence and Page Sequence are '0' for non repeating visits or pages and non-zero for repeating visits or pages.
- ♦ The system does NOT halt the add of a query should one of that type already exist at that location.

#### Sample File

```
<ecos-dataprocessitems>
      <item type="ADD_QUERY">
             <subjected></subjected>
             <subjectidentifier>102004</subjectidentifier>
             <visitid>10</visitid>
             <visitseq>0</visitseq>
             <pageid>30</pageid>
             <pageseq>0</pageseq>
             <controlid></controlid>
             <controltablecolumn>DEMO.DOB</controltablecolumn>
             <querytypename>Site Query</querytypename>
             <querystatusname> </querystatusname>
             <add query subject>Subject line should read this text</add query subject>
             <add query details>Some details added</add query details>
       </item>
</ecos-dataprocessitems>
```





# **ADD\_QUERY**

### **Field Specifics**

Field	Description / Notes	Error Checking at File XML Parsing	Error Checking After XML Parse
subjectid	The internal subject ID of the subject.	<ul> <li>Numeric (if passed)</li> <li>One of ID or Identifier Required</li> </ul>	NOTE: Subject MUST be non-deleted and in a Subject Status that is not 'Data Read Only', for this type of update.
subjectidentifier	The Subject Number/ Identifier of the added subject	<ul> <li>Numeric (if passed)</li> <li>One of ID or Identifier Required</li> </ul>	If passed, must match existing subject number
visitid	Visit ID	Numeric     Required	Matches an ID from the subject's current schedule of pages
visitseq	Visit Sequence	<ul><li>Numeric</li><li>Required</li></ul>	<ul> <li>Matches a sequence from the subject's current schedule of pages</li> <li>USE_LAST_VISIT_ SEQUENCE (see 3.14 Details about USE_LAST attributes)</li> </ul>
pageid	Page ID	Numeric     Required	Matches an ID from the subject's current schedule of pages
pageseq	Page Sequence	<ul><li>Numeric</li><li>Required</li></ul>	<ul> <li>Matches a sequence from the subject's current schedule of pages</li> <li>USE_LAST_PAGE_ SEQUENCE (see 3.14 Details about USE_LAST attributes)</li> </ul>





# **ADD\_QUERY**

#### **Field Specifics (continued)**

Field	Description / Notes	Error Checking at File XML Parsing	Error Checking After XML Parse
querytypeid	Type ID of the Query to add	<ul> <li>Numeric (if passed)</li> <li>One of ID or Type required</li> </ul>	<ul> <li>If passed, numeric</li> <li>If passed, matches an ID from Query Types design area.</li> <li>Cannot a type 'System Query' (ID=0), that is reserved for eClinical OS system queries. Suggest using a new Query Type in the study design for imported queries</li> </ul>
querytypename	Type Name of the Query to add	One of ID or Type required	<ul> <li>If passed, must match a type name from Query Types design area.</li> <li>Cannot a type 'System Query' (ID=0), that is reserved for eClinical OS system queries. Suggest using a new Query Type in the study design for imported queries</li> </ul>
statusid	Optional - status ID of query as part of add. If neither ID nor Status passed, first status of query is set on the add.	Numeric (if passed)	If passed, matches a status from that type of Query.

(continued on next page)





# **ADD\_QUERY**

Field	Description / Notes	Error Checking at File XML Parsing	Error Checking After XML Parse
statusname	Optional, status name of query as part of add. If neither ID nor Status passed, first status of query is set on the add.		If passed, matches a status name from that type of Query.
controlid	Which control  — ID from page design — to attach the query to. (pass one of ID or table.column)	<ul> <li>If passed, must be numeric</li> <li>One of controlid or controltable-column must be indicated</li> </ul>	If given, matches a controlID from the page design at the location in the subject's visit schedule
controltablecolumn	Which control -Table.Column from page design – to attach the query to. (pass one of ID or table.column	One of controlid or controltable- column must be indicated	If given, matches a     Table.Column control from     the page design at the     location in the subject's     visit schedule
add_query_subject	The subject line of the query	<ul><li>Required</li><li>Max 250 characters</li></ul>	
add_query_details	The query details	<ul><li>Required</li><li>Max 3700 characters</li></ul>	







# **EDIT\_QUERY**

#### **Purpose**

Used to edit an existing query in the study.



NOTES: The subject must be both non-deleted and not in a Subject Status that is 'Data Read Only'

#### Sample File

#### **Field Specifics**

Field	Description / Notes	Error Checking at File XML Parsing	Error Checking After XML Parse
subjectid	The internal subject ID of the subject.	<ul> <li>Numeric (if passed)</li> <li>One of ID or Identifier Required</li> </ul>	NOTE: Subject MUST be non-deleted and in a Subject Status that is not 'Data Read Only'
subjectidentifier	The Subject Number/ Identifier of the added subject	<ul> <li>Numeric (if passed)</li> <li>One of ID or Identifier Required</li> </ul>	If passed, must match existing subject number





# **EDIT\_QUERY**

Field	Description / Notes	Error Checking at File XML Parsing	Error Checking After XML Parse
querystatusid	Optional - status ID of query as part of add. If neither ID nor Status passed, first status of query is set on the add.	Numeric (if passed)	If passed, matches a status from that type of Query.
querystatusname	Optional, status name of query as part of add. If neither ID nor Status passed, first status of query is set on the add.		If passed, matches a status name from that type of Query.
edit_query_id	The ID in the study of the query	<ul><li>Required</li><li>Numeric</li></ul>	Must match a query on the subject
edit_query _deletedvalue	Optional – pass true, false for deleting or restoring the query	If passed, must be true or false	
edit_query_subject	Optional, the subject line of the query – an update to the existing subject line	If passed, max 250 characters	





# **EDIT\_QUERY**

Field	Description /	Error Checking at	Error Checking After XML
	Notes	File XML Parsing	Parse
edit_query _comments	The query comments as part of the update	<ul><li>Required</li><li>Max 3700 characters</li></ul>	





# 3.10 ADD\_VISIT

#### **Purpose**

Used to add a visit for a subject.



#### NOTES:

- The subject must be both non-deleted and not in a Subject Status that is 'Data Read Only'
- The visit must be available to add: If the visit is repeating, the current visit count must not have met the maximum repeats value. If the visit is not repeating and the visit is already present, the ADD VISIT import will not cause a change.

#### Sample File

```
<ecos-dataprocessitems>
       <item type="ADD_VISIT">
              <subjected></subjected>
              <subjectidentifier>102004</subjectidentifier>
              <visitid>160</visitid>
       </item>
</ecos-dataprocessitems>
```

#### **Field Specifics**

Field subjectid	Description / Notes The internal subject ID of the subject.	<ul> <li>Error Checking at File XML Parsing</li> <li>Numeric (if passed)</li> <li>One of ID or Identifier Required</li> </ul>	<ul> <li>Error Checking After XML</li> <li>Parse</li> <li>NOTE: Subject MUST be non-deleted and in a Subject Status that is not 'Data Read Only'</li> </ul>
subjectidentifier	The Subject Number/ Identifier of the added subject	<ul> <li>Numeric (if passed)</li> <li>One of ID or Identifier Required</li> </ul>	If passed, must match existing subject number





# 3.10 ADD\_VISIT

Field	Description / Notes	Error Checking at File XML Parsing	Error Checking After XML Parse
visitid	Visit ID	<ul><li>Required</li><li>Numeric</li></ul>	<ul> <li>Matches a Visit ID from the subject's Visit Schedule Revision</li> <li>It does not need to be repeating but Add will be limited by the maximum number of visits</li> </ul>





### 3.11 ADD\_PAGE\_DATA

#### **Purpose**

Used to add a new page for a subject.



#### NOTES:

- The subject must be both non-deleted and not in a Subject Status that is 'Data Read Only'
- For a repeating page add controlidrepeatingcheck is STRONGLY suggested. See the table of fields for notes on this field.

#### Sample File

```
<myedc-dataprocessitems>
      <item type="ADD_PAGE_DATA">
             <subjected></subjected>
             <subjectidentifier>102004</subjectidentifier>
             <visitid>10</visitid>
             <visitseq>0</visitseq>
             <pageid>140</pageid>
             <pageseq>0</pageseq>
             <add data addpage>false</add data addpage>
             <ru><round or pad decimalparts>false</ru></ru>
             <controlidrepeatingcheck>1</ controlidrepeatingcheck>
             <controlidrepeatingcheck>2</ controlidrepeatingcheck>
             <datavalues>
                   <control id="" tablecolumn="DEMO.DOB">
                          <value>1973-04-23
                          <reason>A reason for DOB</reason>
                   </control>
                   <control id="" tablecolumn="DEMO.HT">
                          <value>70</value>
                          <reason>height reason</reason>
                   </control>
                                 (continued on next page)
```





## 3.11 ADD\_PAGE\_DATA

```
<control id="" tablecolumn="DEMO.CBTEST">
                          <value>X</value>
                          <reason>checkbox reason</reason>
                    </control>
                    <control id="" tablecolumn="DEMO.GENDER">
                          <value>1</value>
                          <reason>gender reason</reason>
                    </control>
             </datavalues>
      </item>
</myedc-dataprocessitems>
```

### **Field Specifics**

Field	Description / Notes	Error Checking at File XML Parsing	Error Checking After XML Parse
subjectid	The internal subject ID of the subject.	<ul> <li>Numeric (if passed)</li> <li>One of ID or Identifier Required</li> </ul>	NOTE: Subject MUST be non-deleted and in a Subject Status that is not 'Data Read Only', for this type of update.
subjectidentifier	The Subject Number/ Identifier of the added subject	<ul> <li>Numeric (if passed)</li> <li>One of ID or Identifier Required</li> </ul>	If passed, must match existing subject number
visitid	Visit ID	Numeric     Required	Matches an ID from the subject's current schedule of pages
visitseq	Visit Sequence	<ul><li>Numeric</li><li>Required</li></ul>	<ul> <li>Matches a sequence from the subject's current schedule of pages</li> <li>USE_LAST_VISIT_         SEQUENCE (see 3.14 Details about USE_LAST attributes)</li> </ul>





## ADD\_PAGE\_DATA

### **Field Specifics (continued)**

Field	Description / Notes	Error Checking at File XML Parsing	Error Checking After XML Parse
pageid	Page ID	<ul><li>Numeric</li><li>Required</li></ul>	Matches an ID from the subject's current schedule of pages
pageseq	Page Sequence  OPTIONAL  depends of type of data add	If passed,     Numeric	If passed, matches a sequence from the subject's current schedule of pages, where NO data is yet present. If data exists at that location, the processing will fail, and UPDATE_PAGE_DATA file type should be used.  USE_LAST_PAGE_SEQUENCE (see 3.14 Details about USE_LAST attributes)
add_data_addpage	Whether the data adds expect to add a repeating page first.	Required     Must be true or false	<ul> <li>If true, then <i>pageseq</i> must be passed as true and the spot in the visit schedule for the subject must be repeating, and not have violated any max repeats rules.         NOTE: For Max Repeats = -1             File Import adds ARE allowed – the -1 turns off ability in EDC to add pages, but pages may be added through Import Module.     </li> <li>If false, then <i>pageseq</i> must be passed, with that being an existing page with no data on the page. If data exists on that page, then the type UPDATE _PAGE_DATA must be used instead of ADD_PAGE_DATA</li> </ul>





## ADD\_PAGE\_DATA

### **Field Specifics (continued)**

Field Description Notes	/ Error Checking at File XML Parsing	Error Checking After XML Parse
round_or_pad_ decimalparts  How data values should be treated which dealing with page controls type Numeri	false	<ul> <li>When false – the values in the datavalues area must directly match the After Decimal formatting, i.e. After Decimal = 0 -&gt; no decimal usage, and After Decimal = X means X numbers after the decimal</li> <li>When true, the values for decimals are padded or rounded per the After Decimal settings. Example, suppose a control has After Decimal formatting = 2.</li> <li>File 3.456 -&gt; EDC 3.46</li> <li>File 3.4 -&gt; EDC 3.40</li> <li>Regardless of this setting the Before Decimal formatting for a Numeric field is checked to not be more than the allowed places.</li> </ul>





## ADD\_PAGE\_DATA

### **Field Specifics (continued)**

Field	Description / Notes	Error Checking at File XML Parsing	Error Checking After XML Parse
controlidrepeat- ingcheck	Optional – although STRONGLY SUGGESTED. This control ID is used to ensure the subject does not already have a repeating page with that same value at that control slot. This is recommended to prevent duplicate adds by runaway file deliveries.	Numeric (if passed)	<ul> <li>If passed, matches a control id form the page design at that visit schedule location.</li> <li>Multiple can be added to form a multi-part uniqueness check</li> </ul>





## ADD\_PAGE\_DATA

### **Field Specifics (continued)**

Field	Description /	Error Checking at	Error Checking After XML
	Notes	File XML Parsing	Parse
datavalues / control id / control table.column / value / reason	List of data values/reasons.  System Queries WILL execute after the add of data to a page. Not all controls from the page design are required, those not passed simply result in empty values for the page data. For example, a repeating page with ND (Not Done) checked can have a datavalues section of just the one control = 'X', without needing the other controls.	<ul> <li>If passed, control's id attribute must be numeric</li> <li>If passed, control's tablecolumn must contain a period (.)</li> <li>One of id or tablecolumn must be passed for the control element</li> <li>Reason not required, and can be left out of the XML</li> </ul>	<ul> <li>Must have at least one data value for the add action.</li> <li>Each value is checked against the page design at the subject's visit schedule location.</li> <li>Multi / Many Select – must be formatted as value1^value2 ^ delimiting</li> <li>Date format = YYYY-MM-DD</li> <li>Time format = HH:MI – 24 hour clock</li> <li>Not Done / Check Box – must be X or empty</li> <li>Codelist type controls (Dropdown, Radiolist, Multi Select, Many Select) must be valid codes from the codelist</li> <li>Text Field have Max Length enforced</li> <li>Comments have 3700 max length enforced</li> <li>Numeric has Before Decimal value enforced, with the round_or_pad_decimalparts value dictating how After Decimal format is handled.</li> </ul>





### 3.12 UPDATE PAGE DATA

#### **Purpose**

Used to update data on an existing page for a subject.



#### NOTES:

- The subject must be both non-deleted and not in a Subject Status that is 'Data Read Only'
- The spot in the subject's visit schedule MUST already have data residing. If the page spot exists, but no data is yet added, the action will abort. (ADD PAGE DATA should be used)
- ♦ For a repeating page add controlidrepeatingcheck is STRONGLY suggested. See the table of fields for notes on this field.

#### Sample File

```
<ecos-dataprocessitems>
      <item type="UPDATE PAGE DATA">
             <subjectidentifier>102004</subjectidentifier>
             <visitid>100</visitid>
             <visitseq>0</visitseq>
             <pageid>20</pageid>
             <pageseq>1</pageseq>
             <round or pad decimalparts>true</round or pad decimalparts>
             <datavalues>
                    <control id="" tablecolumn="CONMED.GN">
                          <value>The drug name</value>
                          <reason>asdff</reason>
                    </control>
                    <control id="" tablecolumn="CONMED.DOSE">
                          <value>444</value>
                          <reason>height reason</reason>
                    </control>
                    <control id="" tablecolumn="CONMED.FREQ">
                          <value>3</value>
                                 (continued on next page)
```





# 3.12 UPDATE\_PAGE\_DATA

```
<reason>a reason</reason>
                    </control>
                    <control id="" tablecolumn="CONMED.INDIC">
                           <value>3</value>
                           <reason>my reason</reason>
                    </control>
             </datavalues>
      </item>
</ecos-dataprocessitems>
```

### **Field Specifics**

Field	Description / Notes	Error Checking at File XML Parsing	Error Checking After XML Parse
subjectid	The internal subject ID of the subject.	<ul> <li>Numeric (if passed)</li> <li>One of ID or Identifier</li> <li>Required</li> </ul>	NOTE: Subject MUST be non-deleted and in a Subject Status that is not 'Data Read Only', for this type of update.
subjectidentifier	The Subject Number/Identifier of the added subject	<ul> <li>Numeric (if passed)</li> <li>One of ID or Identifier</li> <li>Required</li> </ul>	If passed, must match existing subject number
visitid	Visit ID	Numeric     Required	Matches an ID from the subject's current schedule of pages
visitseq	Visit Sequence	Numeric     Required	<ul> <li>Matches a sequence from the subject's current schedule of pages</li> <li>USE_LAST_VISIT_ SEQUENCE (see 3.14 Details about USE_LAST attributes)</li> </ul>





## UPDATE\_PAGE\_DATA

### **Field Specifics (continued)**

Field	Description / Notes	Error Checking at File XML Parsing	Error Checking After XML Parse
pageid	Page ID	Numeric     Required	Matches an ID from the subject's current schedule of pages
pageseq	Page Sequence	<ul><li>Numeric</li><li>Required</li></ul>	<ul> <li>Matches a sequence from the subject's current schedule of pages</li> <li>USE_LAST_PAGE_ SEQUENCE (see 3.14 Details about USE_LAST attributes)</li> </ul>
round_or_pad_dec imalparts	How data values should be treated when dealing with page controls of type Numeric.	Required     Must be true or false	<ul> <li>When false – the values in the datavalues area must directly match the After Decimal formatting, i.e. After Decimal = 0 -&gt; no decimal usage, and After Decimal = X means X numbers after the decimal</li> <li>When true, the values for decimals are padded or rounded per the After Decimal settings. For Example, suppose a control has After Decimal formatting = 2.</li> <li>File 3.456 -&gt; EDC         <ul> <li>3.46</li> <li>File 3.4 -&gt; EDC</li> <li>3.40</li> </ul> </li> <li>Regardless of this setting the Before Decimal formatting for a Numeric field is checked to not be more than the allowed places.</li> </ul>





## 3.12 UPDATE\_PAGE\_DATA

### **Field Specifics (continued)**

Field	Description / Notes	Error Checking at File XML Parsing	Error Checking After XML Parse
controlidrepeat- ingcheck	Optional – although STRONGLY SUGGESTED. This control ID is used to ensure the subject does not already have a repeating page with that same value at that control slot. This is recommended to prevent duplicate adds by runaway file deliveries.	Numeric (if passed)	<ul> <li>If passed, matches a control id form the page design at that visit schedule location.</li> <li>Multiple can be added to form a multi-part uniqueness check</li> </ul>





## 3.12 UPDATE\_PAGE\_DATA

### **Field Specifics (continued)**

Field	Description / Notes	Error Checking at File XML Parsing	Error Checking After XML Parse
datavalues / control id / control table.column / value / reason	List of data values/reasons.  System Queries WILL execute after the add of data to a page. Not all controls from the page design are required, those not passed simply result in empty values for the page data. For example, a repeating page with ND (Not Done) checked can have a datavalues section of just the one control = 'X', without needing the other controls.	<ul> <li>If passed, control's id attribute must be numeric</li> <li>If passed, control's tablecolumn must contain a period (.)</li> <li>One of id or tablecolumn must be passed for the control element</li> <li>Reason not required, and can be left out of the XML</li> </ul>	<ul> <li>Must have at least one data value for the add action.</li> <li>Each value is checked against the page design at the subject's visit schedule location.</li> <li>Multi / Many Select – must be formatted as value1^value2 ^ delimiting</li> <li>Date format = YYYY-MM-DD</li> <li>Time format = HH:MI – 24 hour clock</li> <li>Not Done / Check Box – must be X or empty</li> <li>Codelist type controls (Dropdown, Radiolist, Multi Select, Many Select) must be valid codes from the codelist</li> <li>Text Field have Max Length enforced</li> <li>Comments have 3700 max length enforced</li> <li>Numeric has Before Decimal value enforced, with the round_or_pad_decimalparts value dictating how After Decimal format is handled.</li> </ul>





### ADD OR UPDATE PAGE DATA

#### **Purpose**

Used to update data on an existing page for a subject or create a new page with the data if one does not already exist.



#### NOTES:

- The subject must be both non-deleted and not in a Subject Status that is 'Data Read Only'
- ♦ For a repeating page add controlidrepeatingcheck is STRONGLY suggested. See the table of fields for notes on this field.
- Adding or updating on a specific page requires that the visitseq and pageseq be specified.
- If updating and visitseq or pageseq is omitted, then controllidrepeatingcheck is used to check the field on the repeating visits/pages to find the page to update. If no match is found, a new visit or page will be created.

#### **Sample Files**

♦ Add or update data on an existing page (all keys known) – include visitseq and pageseq





## 3.13 ADD\_OR\_UPDATE\_PAGE\_DATA

#### **Sample Files (continued)**

♦ Add or update data on an existing page (all keys known) – include visitseq and pageseq (Continued)

```
<reason>A reason for HEENT2</reason>
                     </control>
              </datavalues>
       </item>
</ecos-dataprocessitems>
```

♦ Add a new page – do not specify any controllidrepeatingchecks

```
<ecos-dataprocessitems>
      <item type="ADD OR UPDATE PAGE DATA">
             <subjectidentifier>101001/subjectidentifier>
             <visitid>110</visitid>
             <visitseq>0</visitseq>
             <pageid>20</pageid>
             <round_or_pad_decimalparts>false</round or pad decimalparts>
             <datavalues>
                    <control id="" tablecolumn="AE.SER">
                    <value>1</value>
                    <reason>A reason for AE Serious</reason>
                    </control>
                    <control id="" tablecolumn="AE.EVENT">
                    <value>HEADACHE</value>
                    <reason>A reason for AE Event</reason>
                    </control>
             </datavalues>
      </item>
</ecos-dataprocessitems>
```





### 3.13 ADD OR UPDATE PAGE DATA

#### **Sample Files (continued)**

♦ Update data on an unkown page – exclude visitseq (repeating visits) or pageseq (repeating page), specify the data that identifies the page in the controls tags associated with the ids specified in controllidreaptingcheck. If no controllidrepeatingchecks are provided or no match exists, then a new visit/page will be created.

```
<ecos-dataprocessitems>
      <item type="ADD OR UPDATE PAGE DATA">
             <subjectidentifier>000002</subjectidentifier>
             <visitid>150</visitid>
             <visitseq>0</visitseq>
             <pageid>20</pageid>
             <round or pad decimalparts>false</round or pad decimalparts>
             <controlidrepeatingcheck>2</controlidrepeatingcheck>
             <controlidrepeatingcheck>3</controlidrepeatingcheck>
             <datavalues>
                    <control id="2" tablecolumn="INEX.NU">
                    <value>30</value>
                    <reason>A reason for Inclusion/exclusion Number</reason>
                    </control>
                    <control id="3" tablecolumn="INEX.CRDETAILS">
                    <value>This is a test.</value>
                    <reason>A reason for CR Details</reason>
                    </control>
             </datavalues>
       </item>
</ecos-dataprocessitems>
```





# ADD\_OR\_UPDATE\_PAGE\_DATA

### **Field Specifics**

Field	Description / Notes	Error Checking at File XML Parsing	Error Checking After XML Parse
subjectid	The internal subject ID of the subject.	<ul> <li>Numeric (if passed)</li> <li>One of ID or Identifier Required</li> </ul>	• NOTE: Subject MUST be non-deleted and in a Subject Status that is not 'Data Read Only', for this type of update.
subjectidentifier	The Subject Number/Identifier of the added subject	<ul> <li>Numeric (if passed)</li> <li>One of ID or Identifier Required</li> </ul>	If passed, must match existing subject number
visitid	Visit ID	Numeric     Required	<ul> <li>Matches a sequence from the subject's current schedule of pages</li> <li>If blank, controlidrepeating-check will determine If an existing visit should be updated or a new visit should be created</li> <li>USE_LAST_VISIT_SEQUENCE (see 3.14 Details about USE_LAST attributes)</li> </ul>
visitseq	Visit Sequence – Optional if page sequence is provided and visit is repeating	<ul><li>Numeric</li><li>Required</li></ul>	<ul> <li>Matches a sequence from the subject's current schedule of pages</li> <li>If blank, controlidrepeating-check will determine If an existing visit should be updated or a new visit should be created</li> </ul>
pageid	Page ID	Numeric     Required	Matches an ID from the subject's current schedule of pages





## ADD\_OR\_UPDATE\_PAGE\_DATA

### **Field Specifics (continued)**

Field	Description / Notes	Error Checking at File XML Parsing	Error Checking After XML Parse
pageseq	Page Sequence	Numeric     Required	<ul> <li>Matches a sequence from the subject's current schedule of pages</li> <li>If blank, controlidrepeating-check will determine If an existing page should be updated or a new page should be created.</li> <li>USE_LAST_PAGE_SEQUENCE (see 3.14 Details about USE_LAST attributes)</li> </ul>
round_or_pad_ decimalparts	How data values should be treated when dealing with page controls of type Numeric.	Required     Must be true or false	<ul> <li>When false – the values in the datavalues area must directly match the After Decimal formatting, i.e. After Decimal = 0 -&gt; no decimal usage, and After Decimal = X means X numbers after the decimal</li> <li>When true, the values for decimals are padded or rounded per the After Decimal settings. Example, suppose a control has After Decimal formatting = 2.</li></ul>





# ADD\_OR\_UPDATE\_PAGE\_DATA

### **Field Specifics**

Field	Description / Notes	Error Checking at File XML Parsing	Error Checking After XML Parse
controlidrepeat- ingcheck	Optional for data add, page add, and update to a known page – although STRONGLY SUGGESTED.  For a page add, this control ID is used to ensure the subject does not already have a repeating page with that same value at that control slot. This is recommended to prevent duplicate adds by runaway file deliveries. For an update to an unknown page, the control IDs specified are used identifty the page to be updated.	Numeric (if passed)	<ul> <li>If passed, matches a control id form the page design at that visit schedule location.</li> <li>Multiple can be added to form a multi-part uniqueness check</li> <li>A datavalue (see below) for each controlidrepeating-check must be provided</li> </ul>





# ADD\_OR\_UPDATE\_PAGE\_DATA

### **Field Specifics (continued)**

Field	Description / Notes	Error Checking at File XML Parsing	Error Checking After XML Parse
datavalues / control id / control table.column / value / reason	List of data values / reasons. System Queries WILL execute after the add of data to a page. Not all controls from the page design are required, those not passed simply result in empty values for the page data. For example, a repeating page with ND (Not Done) checked can have a datavalues section of just the one control = 'X', without needing the other controls.	<ul> <li>If passed, control's id attribute must be numeric</li> <li>If passed, control's table.column must contain a period (.)</li> <li>One of <i>id</i> or <i>tablecolumn</i> must be passed for the control element</li> <li>Reason not required, and can be left out of the XML</li> </ul>	<ul> <li>Must have at least one data value for the add action.</li> <li>Each value is checked against the page design at the subject's visit schedule location.</li> <li>Multi / Many Select – must be formatted as value1^value2 ^ delimiting</li> <li>Date format = YYYY-MM-DD</li> <li>Time format = HH:MI – 24 hour clock</li> <li>Not Done / Check Box – must be X or empty</li> <li>Codelist type controls (Dropdown, Radiolist, Multi Select, Many Select) must be valid codes from the codelist</li> <li>Text Field have Max Length enforced</li> <li>Comments have 3700 max length enforced</li> <li>Numeric has Before Decimal value enforced, with the <i>round_or_pad_decimalparts</i> value dictating how After Decimal format is handled.</li> </ul>







### 3.14 Details about USE LAST attributes

#### **USE LAST VISIT SEQUENCE**

For each subject/visit reference in an import file, the import records the visit sequence while processing the file. If USE LAST VISIT SEQUENCE is found in a later block of XML within the import file, replace USE LAST VISIT SEQUENCE with the last visit sequence used for that subject/visit.

#### Scenario:

A repeating visit exists in the study.

Page 1 on the visit contains the unique key(s) for the visit.

Page 2 on the visit does not contain the unique key(s) for the visit.

Page 1 can be added/updated using ADD OR UPDATE SUBJECT DATA by leaving the visit sequence blank and specifying the correct unique keys.

Page 2 cannot be added/updated because it does not contain the unique keys, so there is no way to look up an existing page.

How this change will allow page 2 to be updated:

A block of XML will be put in the import document for that subject.

This block will provide the visit id, page id, and page seq for Page 1 (not visit sequence).

This block will also contain all of the unique keys required to look up the visit sequence but does not need to provide data values for any other field. This essentially turns this block in to a look up function for a visit sequence.

A second block of XML will be included for page 2. It will specify visit id (sames as page 1) visit seq - USE LAST VISIT SEQUENCE page id (page 2 page id) page seq (page 2 page seq, could also be blank to allow lookup)



#### **NOTES:**

- Can only be used to lookup visit sequences for items already processed (sequentially) in the same file
- As each item in the file is processed, the visit sequence will be stored for each subject id and visit id (including ADD VISIT)
- ♦ When USE LAST VISIT SEQUENCE is specified for a visitseq, the import will find the most recent visit sequence used for that subject/visit combination. If found, that will be used as the visitseq. If not found, an error will occur.





# **Study Designer**

### 3.14 Details about USE LAST attributes

#### **USE LAST PAGE SEQUENCE**

USE LAST PAGE SEQUENCE functions exactly the same as USE LAST VISIT SEQUENCE except that it works for page sequence.



#### *NOTES:*

- Stores the last used page sequence for a combination of subject/visit/visitseq/pageid previously found in the file
- ♦ Can be used in conjunction with USE LAST VISIT SEQUENCE
- ♦ Primary purpose for USE LAST PAGE SEQUENCE is adding queries. Most likely this would be used for a complete study migrations (i.e. changing platform / rescue study)





### **Practical Exercise**

**DAISY** 

#### **Using Data Imports in DAISY**



IMPORTANT: You may need the DAISY sample import files from the Additional Materials to complete this exercise. Additional Materials are available in the Training box on the landing page.

We will begin by adding a subject.

- 1. First, you will need to create the XML file or update the one provided in the Additional Materials.
  - FILE NAME: daisy\_samples\_add\_subject\_002101.xml

#### FILE TEXT:

- <ecos-dataprocessitems>
- <item studyid="Use Your DAISY Study ID" type="ADD SUBJECT">
- <subjectidentifier>002101</subjectidentifier>
- <subjectidentifier2>ABC</subjectidentifier2>
- <subjectidentifier3></subjectidentifier3>
- <add revisionnumber>1</add revisionnumber>
- <sitenumber>001</sitenumber>
- <statusid />
- <statusname />
- </item>
- </ecos-dataprocessitems
- 2. In the study EDC, click the Imports/API tab.
- 3. Click the Upload button.
- 4. Click Browse and find the file from step 1.
- 5. In the Comments, enter the text 'DAISY Training'.
- 6. Click the Upload button.





### **Practical Exercise**

**DAISY** 

You are returned to the main Data Imports screen and will see your file on the processed table. It should be in status New. You will not receive an e-mail when it has finished processing unless there is an error.



NOTES: If you receive alert emails when a subject is added to the study (Design Attributes Optional -> Add/Edit Subject Email Alert Mail List), you will receive an email about the add.

The upload should be a success. If you refresh your EDC screen, you will see the status updated to Completed (in green) and see the log file.

Navigate to the Patient List. Click on the Patient ID to open the Patient View. Click on Patient Information. Note the history for the patient shows the addition by import.

Now we will add data to the subject we just added.

- 7. First, you will need to create another XML file or update the one provided in the Additional Materials.
  - ◆ FILE NAME: daisy samples add page data 002101.xml

```
FILE TEXT

<ecos-dataprocessitems>

<item type="ADD_PAGE_DATA" studyid="Use Your DAISY

Study ID">

<subjected></subjected>

<subjected entifier>002101</subjected entifier>

<visitid>10</visitid>

<visitid>10</visitid>

<visitseq>0</visitseq>

<page id>10</page id>

<page seq>0</page seq>

<add_data_addpage>false</add_data_addpage>
```





### **Practical Exercise**

**DAISY** 

#### FILE TEXT CONTINUED

```
<round or pad decimalparts>false</round or pad decimalparts>
             <controlidrepeatingcheck>1</controlidrepeatingcheck>
<datavalues>
                    <control id="1" tablecolumn="IC.ICYN">
                           <value>1</value>
                           <reason>Training data import</reason>
                    </control>
                    <control id="2" tablecolumn="IC.ICDT">
                           <value>2012-03-01</value>
                           <reason>Training data import</reason>
                    </control>
                    <control id="3" tablecolumn="IE.IEYN">
                           <value>1</value>
                           <reason>Training data import</reason>
                    </control>
                    <control id="4" tablecolumn="IE.IETYPE">
                           <value></value>
                           <reason>Training data import</reason>
                    </control>
                    <control id="5" tablecolumn="IE.IEFAIL">
                           <value></value>
                           <reason>Training data import</reason>
                    </control>
             </datavalues>
      </item>
</ecos-dataprocessitems>
```





**Study Designer** 

3

### **Practical Exercise**

#### **DAISY**

- 8. In the study EDC, click the Imports/API tab.
- 9. Click the Upload button.
- 10. Click Browse and find the file from step 1.
- 11. In the Comments, enter the text 'DAISY Training'.
- 12. Click the Upload button.

You are returned to the main Data Imports screen and will see your file on the processed table. It should be in status New. You will only receive an e-mail when it has finished processing if there are errors.

The upload should be a success. If you refresh your EDC screen, you will see the status updated to Completed (in green) and see the log file.

Navigate to the Patient List. Click on the Patient ID for 002101 to open the Patient View. Note the Consent/Criteria page shows the Entered icon. Click on the icon to access the page. The data we imported is present. Click on Full Page Audit Trail (middle of the right panel). You can see the data was added by import and also the comment we had for the "reason" in the import.







### **Self Assessment | Tips and Tricks**

1.	If you attempt to import data to a page using UPDATE_PAGE_DATA but the page does not exist yet, the import process will skip over that part of the file and process any other functions.
	□ True □ False
2.	If you are importing data to a static page (non-repeating), the page sequence will always be zero (0).
	□ True □ False
3.	You can use more than one controlidrepeatingcheck to help identify unique pages when importing data to a repeating page using ADD_OR_UPDATE_PAGE_DATA.
	□ True □ False



### **Tips and Tricks**

- The import file must be in the XML format outlined in this manual, but the actual file extension may be .TXT, .XML, or another format that presents text.
- The controllidrepeatingcheck elements help the system identify whether the page already exists or not.
  - When using ADD OR UPDATE PAGE DATA If all values match, the identified visit/page will be used. If all values match on multiple pages, an error will be provided. If none match, a new visit/page will be created.
  - When using ADD PAGE DATA If any match, an error will be given.
- ◆ The Page Sequence for a static/non-repeating page is always zero (0). The Page Sequence for a repeating page starts at one (1) and increments with each record added.
- The Visit Sequence for a static/non-repeating visit is always zero (0). The Visit Sequence for a repeating visit starts at one (1) and increments with each visit added.
- Page ID can be found on the Visit Details.
- Visit ID can be found on the Visit Schedule: Order.

#### Answers:

1 False 2 True 3 False





**Study Designer** 

### **Self Assessment | Tips and Tricks**



#### **Tips and Tricks (continued)**

- When defining the location of a page, Visit ID and Page ID are required. Page Sequence or Visit Sequence may be left blank under certain circumstances.
  - When adding or updating page data in a repeating visit, if the visit sequence is unknown or the visit is not yet created, the visit sequence should be left blank. (Visit ID, Page ID, and Page Seq required). You can include one or more controllidrepeatingcheck elements to identify unique records.
  - When adding or updating page data in a repeating page, if the page sequence is unknown or the visit is not yet created, the visit sequence should be left blank. (Visit ID, Page ID, and Visit Seq required). You can include one or more controlidrepeatingcheck elements to identify unique records.
  - When all parts of the page key (Visit ID, Page ID, Visit Seq, Page Seq) are known and included, controlidrepeatingcheck elements are ignored.
- An optional element <skip if exists> can be used to skip subjects that already exist when using the ADD SUBJECT function and not cause the entire import to fail. The allowed values are empty, true, and false.
  - True means the system will skip if the subject exists.
  - False means it will not. The default, if not provided, is False.
- If a CRF Revision is not provided in the ADD SUBJECT function, the system will attempt to identify the default revision.
  - If the site for the subject only has one revision with CAN ADD permission, the system will choose that revision to add the subject.
  - If the site has multiple revisions with CAN ADD, an error will be generated and the subject will not be created.





## Study Designer



### **API Services**

**Overview** 

Setup

Application Programming Interface (API) Services are used to interface between systems -- allowing your servers to connect directly to your study in eClinical OS and transfer or retrieve data.

**Data Imports** 

**API Services** 

API can be used interactively in the system to query details about the study and it's data. It can also be set up as a method to automatically import data. Basic details will be covered in this section of the manual. For more in-depth information, please contact your Merge Account Manager or Technical Support.





### **Interactive Mode**

Home	Patient Li	st Reports	Site Docum	ents Chan	ge Requests	Imports/	API Sites	1	
Files	Colum	: Last 7 Days	▼ Status: All	Ac	ers with bo Imin check k on the Fi	ed for the			
(Intera	ctive API Vie	ewer)							
Proce ID	ssing Fi	le		Status		Last Mod Date	•		
4		ples_add_subjects_2 y.xml	012-05-04 -	FAILED	14-M	AY-12 14:47:58	EDT		
only ch study ro			Patient List  Click for Inte	Reports ractive API Vie	Site Docu		Change Re	quests	API
eClinical OS	: API Services (I	nteractive Mode)							
Login User ID: Password:			*					tive AP Screen	I
Study ID:		1122	<b>☆</b> Login						
Raw Server R	eturn Value:								
Notes / Paran	neter Usage:								
Type		Notes		arameter 1		Parameter 2		Parameter 3	
data_mobile_us	ser_pret	Mobile Notification information	• 5	Status of site(s) returned Jse only values of all, ac Default is all if not indicat	tive or inactive	-		-	
data_subjectlis	t	Subject information	• (	Whether to include delete Use only values of yes of Default is yes if not indic	r no	Return subject     Use valid Site #	s from a specific site	Return just a sp     Use valid subjection	ecific subject ct identifier
data_userlist		Users in study	● ( per noe	Filter on return Use only values of all, all Inding, notpending, act edcconnects, or atleas Default is all if not indicat	toneedcconnect	- et,		-	
data_userhisto	•	User access history	-			-		-	
data_userlogin	s	User logins to study	-			-		-	







### **Interactive Mode**

Interactive mode opens in a new tab or window of your browser and required a re-login using your account credentials. This login follows the same rules for a regular eClinical OS login, including a limit of 5 failed attempts.

Each action yields a 'Raw Server Return Value'. This shows what the server would return for a true web service call (after login) for the action performed (login, logout, fetch of information, etc).

Successful logins / information requests / pushes are met with status='ok' returns. An example of the return on a good login and logout:

login:

```
<reply status="ok" type="login"></reply>
```

and logout:

```
<reply status="ok" type="logout"></reply>
```

Any error is met with an XML reply with status attribute = 'error'. Details of the error are contained in the reply (example of a bad login attempt):

<reply status="error" errors="ERROR: Password incorrect for this user. You have 4 more attempts
until your account is locked out."></reply>

Interactive mode cannot be used actively for two different projects at the same time. An attempt on the 2nd project to pull up this mode will be met with an auto-logout.

The page contains a table that summarizes the types of information that can be fetched, complete with parameters that are applicable for each type. The information is also included in the next section.





## **4.2** Information Returns

Information Type	Description / Notes	Parameter 1	Parameter 2	Parameter 3
data_sitelist	Site information	<ul> <li>Status of site(s) returned</li> <li>Use only values of all, active or inactive</li> <li>Default is all if not indicated</li> </ul>	-	-
data_subjectlist	Subject information	<ul> <li>Whether to include deleted subjects in return</li> <li>Use only values of yes or no</li> <li>Default is yes if not indicated</li> </ul>	<ul> <li>Return subjects from a specific site</li> <li>Use valid Site #</li> </ul>	<ul> <li>Return just a specific subject</li> <li>Use valid subject identifier</li> </ul>
data_userlist	Users in study	<ul> <li>Filter on return</li> <li>Use only values of all, all-nonsubject, all-subject, pending, not-pending, active, inactive, noedcconnects, or atleastoneedcconnect</li> <li>Default is all if not indicated</li> </ul>	-	-
data _userhistory	User access history	-	-	-
data_userlogins	User logins to study	-	-	-





# Study Designer

### 4.2 **Information Returns**

Information	Description /	Parameter 1	Parameter 2	Parameter 3
Type	Notes			
data_querylist	Queries in study	<ul> <li>Whether to include deleted subjects in return</li> <li>Use only values of yes or no</li> <li>Default is yes if not indicated</li> </ul>	<ul> <li>Filter on deleted query or page deleted</li> <li>Use only values of all, not-pagedeleted, pagedeleted, notdeleted, deleted, or notdeleted-and-not-pagedeleted</li> <li>Default is all if not indicated</li> </ul>	<ul> <li>Filter on status</li> <li>Use only values of all, answered, notanswered, closed, notclosed, notanswered-ornotclosed, or answered-orclosed</li> <li>Default is all if not indicated</li> </ul>
data_pagelinksa ttachments	Page Attachments, Page Links	<ul> <li>Whether to include deleted subjects in return</li> <li>Use only values of yes or no</li> <li>Default is yes if not indicated</li> </ul>	<ul> <li>Filter the return</li> <li>Use only values of all, links, or attachments</li> <li>Default is all if not indicated</li> </ul>	-
data _pagestatus	Status of all pages in study, including no data pages	<ul> <li>Whether to include deleted subjects in return</li> <li>Use only values of yes or no</li> <li>Default is yes if not indicated</li> </ul>	-	





Information	Description / Notes	Parameter 1	Parameter 2	Parameter 3
Type  data_epro	ePROs in study, completed or incomplete	<ul> <li>Whether to include deleted subjects in return</li> <li>Use only values of yes or no</li> <li>Default is yes if not indicated</li> </ul>	<ul> <li>Filter on finished / not finished</li> <li>Use only values of all, finished, or notfinished</li> <li>Default is all if not indicated</li> </ul>	-
data_rand	Randomization records in study. During live portion of study, blinded information shown per the design attributes settings for exports	-	-	-
data_ dispensebatches	Dispense batches in study	-	-	-
data _dispenseitems	Dispense records in study. During live portion of study, blinded information shown per the design attributes settings for exports	-	_	_





Information Type	Description / Notes	Parameter 1	Parameter 2	Parameter 3
data_dispensesh ipments	Shipments in study	-	-	-
data_dispensesit esettings	Site shipment settings in study	-	-	-
data_datatable	EDC data table. As with other data table export formats, NO deleted subjects or pages are included.	Valid table name (T) from page designs.     Refer to Preview Data Exports for valid tables in the study.	-	-
data_reports_vie w	Report view, the schema of the XML depends on the report type. Run design_reports to gather report ID to pass to this function, and understand type of report from that design information fetch.	<ul> <li>ID of report</li> <li>Only valid ID from study reports is accepted, and the report must be active</li> <li>User site rights and role rights are re-checked on fetch for valid access</li> </ul>	-	-
design _studyattributes	Main study attributes	-	-	-
design_ designattributes	All high level design attributes - required and optional	-	-	-





# Study Designer

### 4.2 Information Returns

Information Type	Description / Notes	Parameter 1	Parameter 2	Parameter 3
design_roles	Role definitions	-	-	-
design _subjectstatus	Subject status definitions, jump permissions	-	-	-
design _pagestatus	Page status definitions, jump permissions	-	-	-
design _querytypes	Query type/ status definitions, jump permissions	-	-	-
design_codelists	Codelist definitions in study, filter to only used, or view all.  NOTE: System level codelists for page statuses, subject statuses, randomization assignments etc. included always	<ul> <li>Filter on return</li> <li>Use only values of all or onlyinusebypage</li> <li>onlyinusebypage yields just codelists that are in use by some page design</li> <li>Default is all if not indicated</li> </ul>	-	





Information	Description /	Parameter 1	Parameter 2	Parameter 3
Type	Notes			
design _pagedefinitions	Page definitions in study, filter to only used, or view all	<ul> <li>Filter on return</li> <li>Use only values of all, onlyinvisitdef or onlyinvisitscheduledef</li> <li>onlyinvisitdef yields</li> </ul>	-	-
		just pages that are used in some visit definition, even if the visit is not in a visit schedule		
		onlyinvisitscheduledef yields just pages that are used in some visit schedule		
		Default is <b>all</b> if not indicated		
design _visitdefinitions	Visit definitions in study, filter to only used, or view all	<ul> <li>Filter on return</li> <li>Use only values of all or onlyinvisitscheduledef</li> </ul>	-	-
		onlyinvisitscheduledef yields just visits that are used in some visit schedule  Default in all if not		
		Default is <b>all</b> if not indicated		
design _visitschedules	Visit schedule definitions in study, filter to only used, or	<ul><li>Filter on return</li><li>Use only values of all or onlyinusebysubject</li></ul>	-	-
	view all	• onlyinusebysubject yields just visit schedules that are currently in use by non-deleted subjects		
		Default is <b>all</b> if not indicated		





Information	Description /	Parameter 1	Parameter 2	Parameter 3
Type	Notes			
design_revisions	Revision definitions, includes basic definition, rules, permissions, and jumps	-	-	-
design _visitschedulepe rmissions	Visit schedule permissions, across all revisions	-	-	-
design _visitscheduleru les	Visit schedule rules, across all revisions	-	-	-
design _systemqueries	System query definitions in study	<ul> <li>Filter on return</li> <li>Use only values of all, onlyinvisitdef or onlyinvisitscheduledef</li> <li>onlyinvisitdef yields just queries from pages that are used in some visit definition, even if the visit is not in a visit schedule</li> <li>onlyinvisitscheduledef yields just queries from pages that are used in some visit schedule</li> <li>Default is all if not indicated</li> </ul>		-
design_reports	Report definitions	<ul> <li>Status of report(s) returned</li> <li>Use only values of all, active or inactive</li> <li>Default is all if not indicated</li> </ul>	-	-





# **Study Designer**

Information Type	Description / Notes	Parameter 1	Parameter 2	Parameter 3
design_ systemmessages	System messages in EDC	<ul> <li>Status of message returned</li> <li>Use only values of all, active or inactive</li> <li>Default is all if not indicated</li> </ul>	-	-
design_strata	Stratification design information	-	-	-
design_rand	Randomization design information	-	-	-
design_ dispensetypes	Dispense types design information	-	-	-
design_ dispensetreat- ments	Dispense treatments design information		-	-
general_ study- list	Studies currently logged in user has access to - general study access (i.e. general user), not with respect to any team.	<ul> <li>Status of study account requests</li> <li>Use only values of all, active, pending, or inactive</li> <li>Default is all if not indicated</li> </ul>		



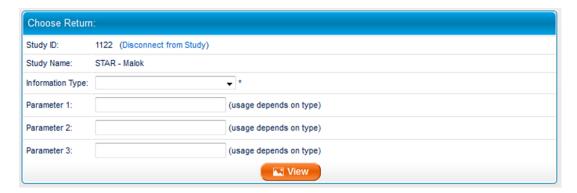


## **Information Returns**

After successful login, the user can fetch any of a number of pieces of information.

Each is available from the 'Information Type' drop down – with data\_\* representing data in the study, and design \* representing study design.

Parameter 1, Parameter 2, and Parameter 3 fields are values sent to an API call, to filter the return in some way. The values (if at all) are dependent on the Information Type used, and the system will reject any bad parameter names with an error reply.







## 4.3 data sitelist

Information Type	Description / Notes	Parameter 1	Parameter 2	Parameter 3
data_sitelist	Site information	• Status of site(s) returned	-	-
		<ul> <li>Use only values of all, active or inactive</li> <li>Default is all if not</li> </ul>		
		indicated		

### Sample Return

```
<reply status="ok" type="data sitelist">
 <sites>
   <site>
     <sitenum>101</sitenum>
    <siteid>512</siteid>
     <sitename>Site 101</sitename>
    <type>Site</type>
    <contact>Joe Primary Contact
    <email>eric.emerton@merge.com</email>
    <alternail>eric.emerton@etrials.com</alternail>
    <phone>123-456-7899</phone>
    <fax>No fax</fax>
     <active>t</active>
    <address>123 Main Street Cary, NC 27513</address>
    <country>USA</country>
     <pi>Dr. Smith</pi>
    <capall>10</capall>
    <caprand>5</caprand>
    <revisions>
        <revision id="1" canadd="t" canmoveto="f" />
    </revisions>
   </site>
   <site>
     <sitenum>102</sitenum>
    <siteid>514</siteid>
    <sitename>Site 102</sitename>
    <type>Site</type>
```

(continued on next page)





## data\_sitelist

### **Sample Return (continued)**

```
<contact></contact>
     <email></email>
     <alternail></alternail>
     <phone></phone>
     <fax></fax>
     <active>t</active>
     <address>An address iwht double quote " and a single quote ' then return and
              END</address>
     <country></country>
     <pi><pi></pi>
     <capall></capall>
     <caprand></caprand>
     <revisions>
        <revision id="1" canadd="t" canmoveto="f" />
     </revisions>
   </site>
 </sites>
</reply>
```

Field	Description / Notes
sitenum	Site # / Identifier
siteid	Internal ecos id (never changes)
sitename	Site Name
type	Type for the organization (Site, Sponsor, CRO, etc), from dropdown in EDC
contact	Primary Contact
email	Email
phone	Phone
fax	Fax
active	Active – t (true) or f (false)
address	Address







# 4.3 data\_sitelist

Field	Description / Notes	
country	Country / Region	
pi	Primary Investigator	
capall	Overall cap (non deleted subjects)	
capprand	Randomization cap (non deleted subjects)	
revisions	Revision rights for the site – using t (true) or f (false) on the permissions 'Can Add' / 'Can Move'	







## 4.4 data\_subjectlist

Information Type	Description / Notes	Parameter 1	Parameter 2	Parameter 3
data_subjectlist	Subject information	<ul> <li>Whether to include deleted subjects in return</li> <li>Use only values of yes or no</li> <li>Default is yes if not indicated</li> </ul>	<ul> <li>Return subjects from a specific site</li> <li>Use valid Site #</li> </ul>	<ul> <li>Return just a specific subject</li> <li>Use valid subject identifier</li> </ul>

### Sample Return

```
<reply status="ok" type="data subjectlist">
 <subjects>
   <subject>
     <siteid>12345</ siteid >
     <sitenum>101</sitenum>
     <subid>5507</subid>
     <subnum>101001</subnum>
     <ident2>Cohort 1</ident2>
     <ident3>2011-04-13</ident3>
     <revnum>1</revnum>
     <statusid>15</statusid>
     <statusname>Screened</statusname>
     <deleted>f</deleted>
   </subject>
   <subject>
     <siteid>12345</ siteid >
     <sitenum>101</sitenum>
     <subid>5508</subid>
     <subnum>101101</subnum>
     <ident2>Cohort 2</ident2>
     <ident3>2011-04-13</ident3>
     <revnum>2</revnum>
     <statusid>15</statusid>
     <statusname>Enrolled</statusname>
     <deleted>t</deleted>
   </subject>
 </ subjects >
</reply>
```









# data\_subjectlist

Field	Description / Notes	
siteid	Internal ecos site id (never changes)	
sitenum	Site # / Identifier	
subid	Internal ecos subject id (never changes)	
subnum	Subject Identifier / Number	
ident2	Identifier 2 for subject – if used. Dates formatted as ISO, Check Box as X / empty	
ident3	Identifier 3 for subject – if used. Dates formatted as ISO, Check Box as X / empty	
revnum	Current CRF Revision for subject.	
statusid	ID of subject status	
statusname	Name of subject status	
deleted	Whether currently marked deleted – t (true) or f (false)	





## data userlist

Information	Description /	Parameter 1	Parameter 2	Parameter 3
Type	Notes			
data_userlist	Users in	Filter on return	-	-
	study	<ul> <li>Use only values of all, all-nonsubject, all-subject, pending, notpending, active, inactive, noedcconnects, or atleastoneedcconnect</li> <li>Default is all if not indicated</li> </ul>		

### Sample Return

```
<reply status="ok" type="data userlist">
 <users>
   <user>
     <internalid>1</internalid>
     <sitenum>101</sitenum>
     <sitename>Site 101</sitename>
     <siteid>512</siteid>
     <first>Eric</first>
     <middle></middle>
     <last>Smith</last>
     login>mylogin
     <email>eric.smith@etrials.com</email>
     <phone>x465</phone>
     <fax>653-3620</fax>
     <desroleid>5</desroleid>
     <desrolename>Primary Investigator</desrolename>
     <allsites>t</allsites>
     <othersitelist></othersitelist>
     <studystatus>Active</studystatus>
     <lastmbyid>1</lastmbyid>
     <lastmby>Smith, Eric</lastmby>
     <lastmdt>2011-04-21 15:34:10</lastmdt>
     <numstudylogins>108</numstudylogins>
     <generalactive>t</generalactive>
     <generalrole>Study Designer/generalrole>
   </user>
 </users>
</reply>
```







# 4.5 data\_userlist

Field	Description / Notes	
internalid	ID of user – never changes	
sitenum	Site # / Identifier for user	
sitename	Site Name for user	
siteid	Internal ecos site id for user	
first	First Name	
middle	Middle Initial / Name	
last	Last name	
login	User Login	
email	Email	
phone	Phone	
fax	Fax	
desroleid	ID of user role in study	
desrolename	Name of user role in study	
allsites	Whether user has all sites access – t (true) or f (false)	
othersitelist	List of other sites – site numbers – listed with comma delimiting, forward and trailing commas	
lastmbyid	Last modified by, internal ID	
lastmby	Last modified by, name	
lastmdt	Last modified date (ISO format)	
numstudylogins	Number of connections to EDC	
generalactive	Whether general account for the user is active	
generalrole	General role within ecos (Study Designer, General, etc.)	





## 4.6 data\_userhistory

Information Type	Description / Notes	Parameter 1	Parameter 2	Parameter 3
data_userhistory	User access	-	-	-

### Sample Return

```
<reply status="ok" type="data userhistory">
 <userhistory>
   <userrevision>
     <userid>1</userid>
     <username>Emerton, Eric</username>
     <siteid>512</siteid>
     <sitenum>101</sitenum>
     <roleid>5</roleid>
     <rolename>Primary Investigator</rolename>
     <status>Active</status>
     <allsites>t</allsites>
     <othersites>,103,111,</othersites>
     <revision>2</revision>
     <lastmbyid>1</lastmbyid>
     <lastmby>Emerton, Eric/lastmby>
     <lastmdt>2011-07-05 19:31:33</lastmdt>
   </userrevision>
 </userhistory >
</reply>
```

Field	Description / Notes	
userid	ID of user – never changes, see internalid of data_userlist	
username	Name of user	
siteid	Site internal ID for primary site of user	
sitenum	Site # / Identifier for primary site of user	
roleid	Design role id	
rolename	Design role name	
status	Status of user – Pending, Active, Inactive	





## **Study Designer**

# 4.6 data\_userhistory

Field	Description / Notes
allsites	Whether user has access to all sites – t or f
othersites	List of other site access – site number, comma delimited. Included leading and trailing comma so that search of , <sitenum>, is not ambigious</sitenum>
revision	Current revision of history of user
lastmbyid	Last modified by, internal ID
lastmby	Last modified by, name
lastmdt	Last modified date (ISO format)





# data\_userlogins

Information Type	Description / Notes	Parameter 1	Parameter 2	Parameter 3
data _userhistory	User logins to study	-	-	-

### Sample Return

Field	Description / Notes	
userid	ID of user – never changes, see internalid of data_userlist	
username	Name of user	
logindt	Datetime (GMT) of connection to the study	





# 4.8 data\_querylist

Information Type	Description / Notes	Parameter 1	Parameter 2	Parameter 3
data_querylist	Queries in study	<ul> <li>Whether to include deleted subjects in return</li> <li>Use only values of yes or no</li> <li>Default is yes if not indicated</li> </ul>	<ul> <li>Filter on deleted query or page deleted</li> <li>Use only values of all, not-pagedeleted, pagedeleted, notdeleted, deleted, or notdeleted-and-not-pagedeleted</li> <li>Default is all if not indicated</li> </ul>	<ul> <li>Filter on status</li> <li>Use only values of all, answered, notanswered, closed, notclosed, notanswered-or-notclosed, or answered-or-closed</li> <li>Default is all if not indicated</li> </ul>

### Sample Return

```
<reply status="ok" type="data_querylist">
 <queries>
   <query>
    <subid>5513</subid>
     <subnum>102001</subnum>
    <visitid>10</visitid>
    <visitseq>0</visitseq>
     <pageid>10</pageid>
     <pageseq>0</pageseq>
     <controlid>1</controlid>
    <id>11</id>
     <typeid>15</typeid>
     <typename>Site Query</typename>
     <statusid>10</statusid>
     <statusname>Site Answered</statusname>
```

(continued on next page)





## data\_querylist

### **Sample Return (continued)**

```
<answered>t</answered>
    <closed>f</closed>
    <sysqname></sysqname>
    <subline>The subject line</subline>
    <lastmbyid>1</lastmbyid>
    <lastmby>Emerton, Eric</lastmby>
    <lastmdt>2011-05-03 18:12:01</lastmdt>
    <deleted>f</deleted>
    <pagedeleted>f</pagedeleted>
    <subjectdeleted>f</subjectdeleted>
     <revision>3</revision>
     <querycomments>
      <querycomment>
        <revision>3</revision>
        <lastmbyid>1480</lastmbyid>
        <lastmby>Emerton, Eric/lastmby>
        <lastmdt>2011-05-03 18:11:58</lastmdt>
        <comment> (marked query restored)</comment>
      </querycomment>
    </querycomments>
   </query>
 </queries>
</reply>
```

Field	Description / Notes	
subid	Internal ID of subject (never changes)	
subnum	Subject # / Identifier	
visitid	Visit ID of the EDC page	
visitseq	Visit Sequence of the EDC page	
pageid	Page ID of the EDC page	
pageseq	Page Sequence of the EDC page	
controlid	ID of control on page where query resides	
Typeid	ID of query type	
typename	Name of query type	





# data\_querylist

Field	Description / Notes		
statusid	ID of query status		
statusname	Name of query status		
answered	Per rules of the query, whether query considered currently answered (t or f)		
closed	Per rules of the query, whether query considered currently closed (t or f)		
sysqname	If a System Query, name of system query		
subline	Subject Line		
lastmbyid	Last modified by, internal ID		
lastmby	Last modified by, name		
lastmdt	Last modified date (ISO format)		
deleted	Whether query itself is marked deleted (t or f)		
pagedeleted	Whether page query resides is currently deleted (t or f)		
subjectdeleted	Whether subject currently deleted (t or f)		
revision	Current revision number of the query		
querycomments	Section of all comments. The revision 1 query comment is the initial details of the query		
querycomments .revision	Revision # of the comment		
querycomments. lastmbyid	Last modified by – for comment - internal ID		
querycomments .lastmby	Last modified by – for comment - name		
querycomments .lastmdt	Last modified date – for comment - (ISO format)		
querycomments .comment	Comment at that revision		



## data\_pagelinksattachments

Information	Description /	Parameter 1	Parameter 2	Parameter 3
Type	Notes			
data_pagelinksa	Page Attachments,	• Whether to include	<ul> <li>Filter the</li> </ul>	-
ttachments	Page Links	deleted subjects in	return	
		return	• Use only	
		• Use only values of	values of all,	
		yes or no	links, or	
		• Default is <b>yes</b> if	attachments	
		not indicated	<ul> <li>Default is</li> </ul>	
			all if not	
			indicated	

### Sample Return

```
<reply status="ok" type="data pagelinksattachments">
 <pagelinksattach>
   linkattach>
     <subid>5507</subid>
     <subnum>101001</subnum>
     <visitid1>10</visitid1>
    <visitseq1>0</visitseq1>
    <pageid1>30</pageid1>
     <pageseq1>0</pageseq1>
    <visitid2></visitid2>
     <visitseq2></visitseq2>
    <pageid2></pageid2>
    <pageseq2></pageseq2>
    <filename>Emerton, Eric.doc</filename>
     <unblind>f</unblind>
     <comments>test</comments>
    <lastmbyid>1</lastmbyid>
    <lastmby>Emerton, Eric</lastmby>
    <lastmdt>2011-05-03 18:54:15</lastmdt>
   linkattach>
   linkattach>
     <subid>5507</subid>
     <subnum>101001</subnum>
     <visitid1>10</visitid1>
```

(continued on next page)





## data\_pagelinksattachments

### **Sample Return (continued)**

```
<visitseq1>0</visitseq1>
     <pageid1>30</pageid1>
     <pageseq1>0</pageseq1>
     <visitid2></visitid2>
     <visitseq2></visitseq2>
     <pageid2></pageid2>
     <pageseq2></pageseq2>
    <filename>documentOutput.doc</filename>
     <unblind>t</unblind>
     <comments>cccc</comments>
     <lastmbyid>1</lastmbyid>
     <lastmby>Emerton, Eric/lastmby>
     <lastmdt>2011-05-03 18:54:08</lastmdt>
   /linkattach>
 </pagelinksattach>
</reply>
```

Field	Description / Notes		
subid	Internal ID of subject (never changes)		
subnum	Subject # / Identifier		
visitid1	Visit ID of the EDC page (1 <sup>st</sup> of link, or where the file attached)		
visitseq1	Visit Sequence of the EDC page (1 <sup>st</sup> of link, or where the file attached)		
pageid1	Page ID of the EDC page (1 <sup>st</sup> of link, or where the file attached)		
pageseq1	Page Sequence of the EDC page (1 <sup>st</sup> of link, or where the file attached)		
visitid2	Visit ID of the EDC page (2nd of link)		
visitseq2	Visit Sequence of the EDC page (2nd of link)		
pageid2	Page ID of the EDC page (2nd of link)		
pageseq2	Page Sequence of the EDC page (2nd of link)		
visitid1	Visit ID of the EDC page (1 <sup>st</sup> of link, or where the file attached)		
filename	If a page attachment, the name of the file attached		
unblind	If a page attachment, whether user chose to indicate the attachment might contain unblinding information (should the question exist per design attributes)		







# data\_pagelinksattachments

Field	Description / Notes
comments	Any comments indicated by the user for the attachment or link
lastmbyid	Last modified by, internal ID
lastmby	Last modified by, name
lastmdt	Last modified date (ISO format)





# 4.10 data\_pagestatus

Information	Description /	Parameter 1	Parameter 2	Parameter 3
Type	Notes			
data _pagestatus	Status of all pages in study, including no data pages	<ul> <li>Whether to include deleted subjects in return</li> <li>Use only values of yes or no</li> </ul>	-	-
		• Default is <b>yes</b> if not indicated		

### Sample Return

```
<reply status="ok" type="data pagestatus">
 <pagestatuses>
   <pagestatus>
     <subid>5507</subid>
     <subnum>101001</subnum>
     <visitid>10</visitid>
     <visitseq>0</visitseq>
     <pageid>10</pageid>
     <pageseq>0</pageseq>
     <statusid>0</statusid>
     <lastmbyid>1</lastmbyid>
     <lastmby>Emerton, Eric/lastmby>
     <lastmdt>2011-04-13 14:12:43</lastmdt>
     <lastmbyidd></lastmbyidd>
     <lastmbyd></lastmbyd>
     <lastmdtd></lastmdtd>
     <deleted>f</deleted>
     <revision>1</revision>
   </pagestatus>
 </pagestatuses>
</reply>
```

Field	Description / Notes
subid	Internal ID of subject (never changes)
subnum	Subject # / Identifier
visitid	Visit ID of the EDC page
visitseq	Visit Sequence of the EDC page





# 4.10 data\_pagestatus

Field	Description / Notes	
pageid	Page ID of the EDC page	
pageseq	Page Sequence of the EDC page	
statusid	ID of the page status	
statusname	Name of the page status	
lastmbyid	Last modified by, internal ID – of the status of page	
lastmby	Last modified by, name – of the status of page	
lastmdt	Last modified date (ISO format) – of the status of page	
lastmbyidd	Last modified by, internal ID – of the data on the page	
lastmbyd	Last modified by, name – of the data on the page	
lastmdtd	Last modified date (ISO format) – of the data on the page	
deleted	Whether page currently marked deleted	
revision	Revision number of the last update	





# 4.11 data\_epro

Information	Description /	Parameter 1	Parameter 2	Parameter 3
Type	Notes			
data_epro	ePROs in study, completed or incomplete	<ul> <li>Whether to include deleted subjects in return</li> <li>Use only values of yes or no</li> <li>Default is yes if not indicated</li> </ul>	<ul> <li>Filter on finished / not finished</li> <li>Use only values of all, finished, or notfinished</li> <li>Default is all if not indicated</li> </ul>	

### Sample Return

```
<reply status="ok" type="data_epro">
 <epros>
   <epro>
    <subid>5405</subid>
     <subnum>101001</subnum>
    <visitid>150</visitid>
    <visitseq>0</visitseq>
    <pageid>10</pageid>
     <pageseq>5</pageseq>
     <started>2011-02-19 04:14:03</started>
     <ended>2011-02-19 04:31:52</ended>
   </epro>
   <epro>
    <subid>5405</subid>
    <subnum>101001</subnum>
     <visitid>150</visitid>
    <visitseq>0</visitseq>
     <pageid>20</pageid>
     <pageseq></pageseq>
     <started>2011-02-19 04:37:36</started>
    <ended></ended>
   </epro>
</epros>
</reply>
```





# 4.11 data\_epro

Field	Description / Notes
subid	Internal ID of subject (never changes)
subnum	Subject # / Identifier
visitid	Visit ID of the EDC page
visitseq	Visit Sequence of the EDC page
pageid	Page ID of the EDC page
pageseq	Page Sequence of the EDC page – empty when epro not finished, i.e. not saved data. Only finished epros become pages in EDC
started	Start datetime of the epro (ISO format)
ended	End datetime of the epro (ISO format) – if finished
status.id	ID of subject status
status.name	Name of subject status
status.imagefile	Image for subject status
status.esignature	Whether status is an signature status – t or f
status.datareadonly	Whether data for page considered read only at the status – t or f





# 4.12 data\_rand

Information	<b>Description / Notes</b>	Parameter 1	Parameter 2	Parameter 3
Type				
data_rand	Randomization	-	-	-
	records in study.			
	During live portion of			
	study, blinded			
	information shown			
	per the design			
	attributes settings for			
	exports			

### Sample Return

```
<reply status="ok" type="data_rand">
 <randlist>
   <rand>
    <randnum>1001</randnum>
     <statusid>3</statusid>
     <statusname>Used</statusname>
     <subid>5507</subid>
     <subnum>101001</subnum>
     <strataid></strataid>
     <assignid></assignid>
     <blookid></blockid>
     <revision>4</revision>
     <sitenum></sitenum>
    <comments>asdf</comments>
     <lastmbyid>1</lastmbyid>
     <lastmby>Emerton, Eric/lastmby>
    <lastmdt>2011-04-20 18:31:03</lastmdt>
   </rand>
 </randlist>
</reply>
```

Field	Description / Notes
randnum	Randomization number
statusid	Current status ID of randomization record
statusname	Current status name of randomization record
subid	Internal ID of subject (never changes) – if assigned





# . . .

# 4.12 data\_rand

Field	Description / Notes
subnum	Subject # / Identifier - if assigned
strataid	ID of stratification of record (from study design) – shows per design attributes export settings
assignid	ID of randomization assignment (from study design) – shows per design attributes for export settings.
blockid	Block ID of record (if used) – shows per design attributes for export settings.
revision	Current revision number of record
sitenum	Number of site the record is associated with (if site based stratification being used – empty if study wide stratify / randomizing)
comments	Latest comments on the record
lastmbyid	Last modified by, internal ID
lastmby	Last modified by, name
lastmdt	Last modified date (ISO format)





# 4.13 data\_dispensebatches

Information Type	Description /	Parameter 1	Parameter 2	Parameter 3
	Notes			
data _dispensebatches	Dispense batches in study	-	-	-

### Sample Return

```
<reply status="ok" type="data dispensebatches">
 <dispensebatches>
   <hatch>
    <id>1</id>
    <typeid>1</typeid>
    <typename>200 mg</typename>
    <statusid>1</statusid>
    <statusname>Active</statusname>
    <shipperid>544</shipperid>
    <shippernum>998</shippernum>
    <shippername>ACME Drug Shipping</shippername>
    <name>200 mg</name>
    <description>Some description on ID 1</description>
    <otherattribute2>Batch 456</otherattribute2>
    <otherattribute3>PMD 454545/otherattribute3>
    <otherattribute4></otherattribute4>
    <expiration>2012-07-27</expiration>
    <comments></comments>
    <counttotal>62</counttotal>
    <countonhold>0</countonhold>
    <countatshipper>14</countatshipper>
    <countordered>17</countordered>
    <countintransit>0</countintransit>
    <countatsite>14</countatsite>
    <countdispensed>6</countdispensed>
    <countquarantined>1</countquarantined>
    <countwasted>10</countwasted>
    <countexpired>0</countexpired>
    <countunblinded>0</countunblinded>
    <lastmbyid>1</lastmbyid>
```

(continued on next page)





# 4.13 data\_dispensebatches

### **Sample Return (continued)**

```
<lastmby>Emerton, Eric</lastmby>
     <lastmdt>2011-07-05 16:00:33</lastmdt>
     <revision>17</revision>
   </batch>
 </dispensebatches>
</reply>
```

Field	Description / Notes
id	ID within the study (not ecos internal unique ID)
typeid	Dispense type id
typename	Dispense Type Name
statusid	ID of status of batch
statusname	Name of status of batch
shipperid	Internal id of shipper associated to batch
shippernum	Site Number of shipper associated to batch
shippername	Site Name of shipper associated to batch
name	Name o f batch
description	Description of batch
otherattribute1	If used (from Design Attributes Optional) – the value for 1st other attribute
otherattribute2	If used (from Design Attributes Optional) – the value for 2nd other attribute
otherattribute3	If used (from Design Attributes Optional) – the value for 3rd other attribute
otherattribute4	If used (from Design Attributes Optional) – the value for 4th other attribute
expiration	Expiration date
comments	Current comments
counttotal	# total in batch
countonhold	# On Hold in batch (currently)
countatshipper	# Available at Shipper in batch (currently)





# 4.13 data\_dispensebatches

Field	Description / Notes
countordered	# Ordered in batch (currently)
countintransit	# In Transit in batch (currently)
countatsite	# At Site in batch (currently)
countdispensed	# Dispensed in batch (currently)
countquarantined	# Quarantined in batch (currently)
countwasted	# Wasted in batch (currently)
countexpired	# Expired in batch (currently)
countunblinded	# Unblinded in batch (currently)
lastmbyid	Last modified by, internal ID
lastmby	Last modified by, name
lastmdt	Last modified date (ISO format)
revision	Current revision number





## Study Designer

# 4.14 data dispenseitems

Information	Description / Notes	Parameter 1	Parameter 2	Parameter 3
Type				
data	Dispense records in study.	-	-	-
_dispenseitems	During live portion of study, blinded information shown per the design attributes settings for exports			

### Sample Return

```
<reply status="ok" type="data dispenseitems">
 <dispenseitems>
   <item>
     <identifier>0172</identifier>
     <statusid>17</statusid>
     <statusname>Wasted</statusname>
     <shipment>1025</shipment>
     <shipmentfromid>544</shipmentfromid>
     <shipmentfromnum>998</shipmentfromnum>
     <shipmentfromname>ACME Drug Shipping</shipmentfromname>
     <shipmenttoid>564</shipmenttoid>
     <shipmenttonum>104</shipmenttonum>
     <shipmenttoname>Site 104</shipmenttoname>
     <typeid>2</typeid>
     <typename>Placebo</typename>
     <dispensebatchid>2</dispensebatchid>
     <dispensebatchname>Placebo</dispensebatchname>
     <sequencenumber>1906</sequencenumber>
     <expiration>2012-06-29</expiration>
     <visitid></visitid>
     <visitseq></visitseq>
     <pageid></pageid>
     <pageseq></pageseq>
     <controlid></controlid>
     <comments>shipment 1025 wasted</comments>
    <lastmbyid>1</lastmbyid>
     <lastmby>Emerton, Eric/lastmby>
     <lastmdt>2011-07-05 15:44:47</lastmdt>
     <revision>7</revision>
```

(continued on next page)





# 4.14 data\_dispenseitems

### **Sample Return (continued)**

</item> </ dispenseitems > </reply>

Field	Description / Notes
identifier	Visible ID for the item, i.e. on the label / packaging
statusid	ID of status of item
statusname	Name of status of item
shipment	Shipment # - if currently part of a shipment
shipmentfromid	ID of site where shipment originates
shipmentfromnum	Site Number of site where shipment originates
shipmentfromname	Site Name of site for destination
shipmenttoid	ID of site for destination
shipmenttonum	Site Number of site for destination
shipmenttoname	Site Name of site for destination
typeid	Dispense type id
typename	Dispense Type Name
dispensebatchid	ID from dispense batches
dispensebatchname	Name from dispense batch
sequencenumber	Sequence Number – against which items are ordered or dispensed
expiration	Expiration date
subid	ID of subject – if dispensed
subnum	Identifier of subject – if dispensed
visitid	If dispensed, visit ID at which dispensed
visitseq	If dispensed, visit sequence at which dispensed
pageid	If dispensed, page ID at which dispensed
pageseq	If dispensed, page sequence at which dispensed
controlid	If dispensed, control ID (on page) at which dispensed
comments	Current comments
lastmbyid	Last modified by, internal ID
lastmby	Last modified by, name
lastmdt	Last modified date (ISO format)
revision	Current revision number





# 4.15 data dispenseshipments

Description /	Parameter 1	Parameter 2	Parameter 3
Notes			
Shipments in study	-	-	-
	Notes	Notes	Notes

### Sample Return

```
<reply status="ok" type="data dispenseshipments">
 <dispenseshipments>
   <shipment>
    <id>1001</id>
     <statusid>3</statusid>
     <statusname>4</statusname>
    <fromid>544</fromid>
    <fromnum>998</fromnum>
     <fromname>ACME Drug Shipping</fromname>
    <toid>512</toid>
    <tonum>101</tonum>
    <toname>Site 101</toname>
     <orderdate>2011-05-26</orderdate>
    <sentdate>2011-05-26</sentdate>
    <receivedate>2011-05-26</receivedate>
     <comments>(confirmed arrived) : OK</comments>
     <counttotal>4</counttotal>
    <countquarantined>0</countquarantined>
    <lastmbyid>1</lastmbyid>
    <lastmby>Emerton, Eric/lastmby>
     <lastmdt>2011-05-26 19:35:50</lastmdt>
     <revision>5</revision>
    <items>
    </items>
   </shipment>
 </ dispenseshipments >
</reply>
```

Field	Description / Notes
id	Shipment number
statusid	ID of status of item
statusname	Name of status of item





# 4.15 data\_dispenseshipments

Field	Description / Notes
fromid	ID of site where shipment originates
fromnum	Site Number of site where shipment originates
fromname	Site Name of site for destination
toid	ID of site for destination
tonum	Site Number of site for destination
toname	Site Name of site for destination
orderdate	Date of order
sentdate	If marked sent, date
receivedate	If marked received, date
comments	Current comments
counttotal	# of items in shipment
countquarantined	# of items currently at Quarantined status
lastmbyid	Last modified by, internal ID
lastmby	Last modified by, name
lastmdt	Last modified date (ISO format)
revision	Current revision number
items	Area with list of dispense items in the shipment
item.identifier	Dispense Item identifier
item.currentstatusid	Current status id of the dispense item
item	Current status name of the dispense item
.currentstatusname	
item.comments	Current comments of the dispense item
item.lastmbyid	Last modified by, internal ID (of dispense item)
item.lastmby	Last modified by, name (of dispense item)
item.lastmdt	Last modified date (ISO format) (of dispense item)
item.revision	Current revision number (of dispense item)





# 4.16 data\_dispensesitesettings

Information Type	Description /	Parameter 1	Parameter 2	Parameter
	Notes			3
data	Site shipment	-	-	-
_dispensesitesettings	settings in study			

### Sample Return

```
<reply status="ok" type="data dispensesitesettings">
 <dispensesitesettings>
   <site>
     <siteid>512</siteid>
     <sitenum>101</sitenum>
     <sitename>Site 101</sitename>
     <shipperid>544</shipperid>
     <shippernum>998</shippernum>
     <shippername>ACME Drug Shipping</shippername>
     <shipperactive>t</shipperactive>
     <siteactive>t</siteactive>
     <siteactiveshipments>t</siteactiveshipments>
     <comments></comments>
     <lastmbyid>1</lastmbyid>
     <lastmby>Emerton, Eric/lastmby>
     <lastmdt>2011-05-25 18:08:24</lastmdt>
     <revision>11</revision>
   </site>
 </dispensesitesettings>
</reply>
```

Field	Description / Notes
siteid	ID of site
sitenum	Site Number
sitename	Site Name
shipperid	ID of shipper the site is associated to
shippernum	Site Number of the shipper the site is associated to
shippername	Site Name of the shipper the site is associated to
shipperactive	Whether the shipper is currently active (t or f)
siteactive	Whether the site is currently active (main status, t or f)





# 4.16 data\_dispensesitesettings

Field	Description / Notes
siteactiveshipments	Whether the site is currently active to receive shipments (t or f)
comments	Current comments
lastmbyid	Last modified by, internal ID
lastmby	Last modified by, name
lastmdt	Last modified date (ISO format)
revision	Current revision number





## 4.17 data datatable

Information	<b>Description / Notes</b>	Parameter 1	Parameter 2	Parameter 3
Type				
data_datatable	EDC data table. As	* Valid table name (T)	-	-
_	with other data table export formats, NO deleted subjects or pages are included.	from page designs. Refer to Preview Data Exports for valid ta- bles in the study.		

### Sample Return

```
<reply status="ok" type="data datatable">
 <data table="AE">
   <datarow>
    <value colname="SUBID">5507</value>
    <value colname="SUBNUM">101001
    <value colname="VISITID">110</value>
    <value colname="VISITSEO">0</value>
    <value colname="PAGEID">20</value>
    <value colname="PAGESEQ">1</value>
    <value colname="STATUSID">5</value>
     <value colname="EVENT">Headache</value>
    <value colname="DTONSET">2011-05-05</value>
    <value colname="DTSTOP"></value>
    <value colname="SEV">2</value>
    <value colname="RELATED">2</value>
    <value colname="ACTION">3</value>
    <value colname="OUTCOME"></value>
   </datarow>
 </data>
</reply
```

Field	Description / Notes
datarow	Row of data
datarow.value	Values – defined by attribute of their column name (per page design).  Note that the data values are per formatting:  Codes for codelist fields  ISO for Dates  HH:MI for Time  X or empty for checkbox





# 4.18 data\_reports\_view

Information Type	Description / Notes	Parameter 1	Parameter 2	Parameter 3
data_reports_view	Report view, the schema of the XMI depends on the report type. Run design_reports to gather report ID to pass to this function, and understand type of report from that design information fetch.	<ul> <li>ID of report</li> <li>Only valid ID from study reports is accepted, and the report must be active</li> <li>User site rights and role rights are re-checked on fetch for valid access</li> </ul>	-	

### Sample Return

```
<reply status="ok" type="data_reports_view">
 <reportview reportid="10" projid="1422">
   <row type="header">
     <val style="">Subject</val>
     <val style="">Patient Initials</val>
     <val style="">Screening Date</val>
     <val style=""></val>
     <val style="">Page</val>
     <val style="">Page Status</val>
     <val style="">Event</val>
     <val style="">Event Start</val>
     <val style="">Event Action</val>
     <val style="">Med Start</val>
     <val style="">Med Name</val>
     <val style="">Med Indication</val>
   </row>
 </reportview>
</reply>
```

Field	Description / Notes	
row type	the type of information being show	
val	the information in that row	





# 4.19 design\_studyattributes

Information Type	Description / Notes	Parameter 1	Parameter 2	Parameter 3
design _studyattributes	Main study attributes	-	-	-

### Sample Return

```
<reply status="ok" type="design studyattributes">
 <studyattributes>
   <studyattribute>
    <section>Required Attributes</section>
    <id>5001</id>
    <name>Study Name</name>
    <description>Name appearing on reports, page headers, etc.</description>
    <value>A Rand Study (CRF Rev Strata)
    <comment>comment here</comment>
    <lastmbyid>1</lastmbyid>
    <lastmby>Emerton, Eric [DES]</lastmby>
    <lastmdt>2011-05-04 20:11:30</lastmdt>
   </studyattribute>
 </studyattributes>
</reply>
```

Field	Description / Notes
section	Name of attribute section
id	Internal ID of the attribute
name	Name of attribute
description	Description of attribute
value	Current value of attribute – ISO for date, X (or empty) for check boxes
comments	Current comments about attribute
lastmbyid	Last modified by, internal ID
lastmby	Last modified by, name
lastmdt	Last modified date (ISO format)





# 4.20 design designattributes

Information	<b>Description / Notes</b>	Parameter 1	Parameter 2	Parameter 3
Type				
design _designattributes	All high level design attributes - required and optional	-	1	-

### Sample Return

```
<reply status="ok" type="design designattributes">
 <designattributes>
   <designattribute>
     <section>Required Design Attributes</section>
     <id>5508</id>
     <name>EDC Date Format</name>
     <description>Format of date control field in EDC study pages.</description>
     <value>DD-MMM-YYYY</value>
     <comment>Imported from other study design (A Rand Study (Site Rand))/comment>
     <lastmbyid>1</lastmbyid>
     <lastmby>Emerton, Eric [DES]</lastmby>
     <lastmdt>2011-04-13 14:07:45</lastmdt>
   </designattribute>
   <designattribute>
     <section>Required Design Attributes/section>
     <id>5510</id>
     <name>Subject Label</name>
     <description>The label for added entities in the study. Examples: Subject, Patient, Device,
              Specimen, Hospital, County.</description>
     <value>Patient</value>
     <comment>Imported from other study design (A Rand Study (Site Rand))/comment>
     <lastmbyid>1</lastmbyid>
     <lastmby>Emerton, Eric [DES]</lastmby>
     <lastmdt>2011-04-13 14:07:45</lastmdt>
   </designattribute>
 </designattributes>
</reply>
```

Field	Description / Notes
section	Name of attribute section







# 4.20 design\_designattributes

Field	Description / Notes
id	Internal ID of the attribute
name	Name of attribute
description	Description of attribute
value	Current value of attribute – ISO for date, X (or empty) for check boxes
comments	Current comments about attribute
lastmbyid	Last modified by, internal ID
lastmby	Last modified by, name
lastmdt	Last modified date (ISO format)





## 4.21 design roles

Information Type	Description / Notes	Parameter 1	Parameter 2	Parameter 3
design_roles	Role definitions	-	-	-

### Sample Return

```
<reply status="ok" type="design roles">
 <roles>
   <role>
< id > 30 < / id >
     <name>Administrator</name>
     <abbrev>ADM</abbrev>
     <imagefile>administrator.png</imagefile>
     <canaddsubject>t</canaddsubject>
     <caneditsubject>t</caneditsubject>
     <canaddeditdata>t</canaddeditdata>
     <cansignpages>t</cansignpages>
     <canaddquery>t</canaddquery>
     <caneditquery>t</caneditquery>
     <cansdv>t</cansdv>
     <candeleterestorepages>t</candeleterestorepages>
     <candeleterestoresubjects>t</candeleterestoresubjects>
     <canuploadpageattachments>t</canuploadpageattachments>
     <canuploadsitedocs>t</canuploadsitedocs>
     <unblinded>t</unblinded>
     <randadmin>t</randadmin>
     <dispenseadmin>t</dispenseadmin>
     <apiadmin>t</apiadmin>
     <importadmin>t</importadmin>
     <uploadsadmin>t</uploadsadmin>
     <candispense>t</candispense>
     <canconfirmshipments>t</canconfirmshipments>
     <caneditshipments>t</caneditshipments>
     <caneditdispenseitems>t</caneditdispenseitems>
     <caneditsiteshipmentsettings>t</caneditsiteshipmentsettings>
     <medcodingid>1201</medcodingid>
     <medcodingname>Browser</medcodingname>
      <canviewshipsettings>t</canviewshipsettings>
```

(continued on next page)





# 4.21 design\_roles

## **Sample Return (continued)**

```
<eamadmin>t</eamadmin>
      <eamreadonly>t</eamreadonly>
      <eamphaseone>t</eamphaseone>
      <eamcoordinator>t</eamcoordinator>
      <eamphasetwo>t</eamphasetwo>
      <eamphasethree>t</eamphasethree>
      <eameditevent>t</eameditevent>
      <eamcreatedossier>t</eamcreatedossier>
      <eamassignadjudicators>t</eamassignadjudicators>
      <eamcreateoutcome>t</eamcreateoutcome>
      <labsedit>t</labsedit>
      <labsview>t</labsview>
      <safetygen>f</safetygen>
      <safetyview>f</safetyview>
 </roles>
</reply>
```

Field	Description / Notes	
id	ID of role	
name	Name of role	
abbrev	Abbreviation of role	
imagefile	Image for role	
canaddsubject	Whether can add subject – t or f	
caneditsubject	Whether can edit subject information – t or f	
cannaddeditdata	Whether can add or edit page data – t or f	
cansignpages	Whether can sign pages – t or f (additional permissions in the page statuses)	
canaddquery	Whether can add queries – t or f (additional permissions in the query types)	
caneditquery	Whether can edit subject – t or f (additional permissions in the query types)	
cansdv	Whether can SDV fields – t or f	





# 4.21 design\_roles

Field	Description / Notes		
candeleterestore- pages	Whether can mark pages deleted or restore them – t or f		
candeleterestoresub- jects	Whether can mark subjects deleted or restore them – t or f		
canuploadpageat- tachments	Whether can upload documents to CRFs – t or f		
canuploadsitedocs	Whether can upload documents to the Site Docs tab – t or f		
unblinded	Whether considered unblinded – t or f		
randadmin	Whether is a role is considered a randomization admin (if module in use)  – t or f		
dispenseadmin	Whether is a role is considered a dispense / item admin (if module in use) – t or f		
apiadmin	Whether is a role that can use the API (if module in use) – t or f		
importadmin	Whether is a role that can use the Data Imports (if module in use) – t or f		
uploadsadmin	Whether is a role that is considered an admin for uploads in EDC - t or f		
candispense	Whether is a role that can dispense items (if module in use) – t or f		
canconfirmshipments	Whether is a role that can confirm a shipment sent or arrived (if module in use) – t or f		
caneditshipments	Whether is a role that can edit a shipment (if module in use) – t or f		
caneditdispenseitems	Whether is a role that can edit dispense items (if module in use) – t or f		
caneditsiteshipment- settings	Whether is a role that can edit site shipment settings (if module in use) – t or f		
canveiwshipsettings	Whether is a role that can view site shipment settings (if module in use)  – t or f		
medcodingid	ID of medical coding role (if module in use)		
medcodingname	Name of medical coding role (if module in use)		
eamadmin	Whether is a role is considered an endpoint adjudication admin (if module in use) – t or f		





# 4.21 design\_roles

Field	Description / Notes		
eamreadonly	Whether is a role that has read only access to the EAM module (if module in use) – t or f		
eamphaseone	Whether is a role that can be assigned as Phase One adjudicator (if module in use) – t or f		
eamcoordinator	Whether is a role that can be assigned as Event Coordinator (if module in use) – t or f		
eamphasetwo	Whether is a role that can be assigned as Phase Two adjudicator (if module in use) – t or f		
eamphasethree	Whether is a role that can be assigned as Phase Three adjudicator (if module in use) – t or f		
eameditevent	Whether is a role that can edit the EAM event (if module in use) – t or f		
eamcreatedossier	Whether is a role that can create an EAM dossier (if module in use) – t or f		
eamassignadjudica- tors	Whether is a role that can assign adjudicators to an event (if module in use) – t or f		
eamcreateoutcome	Whether is a role that can generate the EAM outcome (if module in use) - t or f		
labsedit	Whether is a role that can edit items in the Lab Normals module (if module in use) – t or f		
labsview	Whether is a role that can view items in the Lab Normals module (if module in use) – t or f		
safetygen	Whether is a role that can generate Safety forms (if module in use) – t or f		
safetyview	Whether is a role that can view Safety forms (if module in use) – t or f		





## 4.22 design\_subjectstatus

Information Type	Description / Notes	Parameter 1	Parameter 2	Parameter 3
design_subjectstatus	Subject status definitions, jump permissions	-	-	-

### Sample Return

```
<reply status="ok" type="design_subjectstatus">
 <subjectstatusdefinitions>
   <statuses>
     <status>
      < id > 0 < /id >
      <name>Enrolled</name>
      <imagefile>substatus_added.png</imagefile>
      <datareadonly>f</datareadonly>
     </status>
     <status>
      <id>5</id>
      <name>Completed</name>
      <imagefile>substatus complete.png</imagefile>
      <datareadonly>t</datareadonly>
     </status>
     <permission>
      <statusidfrom>0</statusidfrom>
      <statusnamefrom>Enrolled</statusnamefrom>
      <statusidto>5</statusidto>
      <statusnameto>Completed</statusnameto>
      <roleid>10</roleid>
      <rol><rolename</td>Study Coordinator</rolename</td>
      <randmove>f</randmove>
      <unblindmove>f</unblindmove>
     </permission>
   </permissions>
 </subjectstatusdefinitions>
</reply>
```

Field	Description / Notes
status.id	ID of subject status
status.name	Name of subject status





# 4.22 design\_subjectstatus

Field	Description / Notes		
status.imagefile	Image for subject status		
status.datareadonly	Whether data for subject considered read only at the status – t or f		
permission .statusfromid	For a status move, the status from ID		
permission .statusfromname	For a status move, the status from name		
permission .statusfromid	For a status move, the status to ID		
permission .statusfromname	For a status move, the status to name		
permission.roleid	For a status move, the ID of role		
permission.rolename	For a status move, the name of role		
permission.randmove	Whether considered a randomization move – t or f		
permission .unblindmove	Whether considered a randomization move – t or f		





## 4.23 design\_pagestatus

Information	<b>Description / Notes</b>	Parameter 1	Parameter 2	Parameter 3
Type				
design_pagestatus	Page status definitions, jump permissions	-	-	-

### Sample Return

```
<reply status="ok" type="design subjectstatus">
 <pagestatusdefinitions>
   <statuses>
     <status>
      <id>0</id>
      <name>No Data</name>
      <imagefile>document plain.png</imagefile>
      <esignature>f</esignature>
      <datareadonly>f</datareadonly>
      <revertto>f</revertto>
      <dkde1>f</dkde1>
      <dkde2>f</dkde2>
     </status>
   <permissions>
     <permission>
      <statusidfrom>0</statusidfrom>
      <statusnamefrom>Enrolled</statusnamefrom>
      <statusidto>5</statusidto>
      <statusnameto>Completed</statusnameto>
      <roleid>5</roleid>
      <rol><rolename>Primary Investigator</rolename>
     </permission>
   </permissions>
 </pagestatusdefinitions>
</reply>
```

Field	Description / Notes	
status.id	ID of subject status	
status.name	Name of subject status	
status.imagefile	Image for subject status	





# 4.23 design\_pagestatus

Field	Description / Notes		
status.esignature	Whether status is an signature status – t or f		
status.datareadonly	Whether data for page considered read only at the status – t or f		
status.revertto	Whether status is used to revert to – should a new query be added, and query dictate that page status should revert – t or f		
dkde1	If double key data entry module in use, whether status is considered the first of DKDE statuses		
dkde1	If double key data entry module in use, whether status is considered the second of DKDE statuses		
permis- sion.statusfromid	For a status move, the status from ID		
permis- sion.statusfromname	For a status move, the status from name		
permis- sion.statusfromid	For a status move, the status to ID		
permis- sion.statusfromname	For a status move, the status to name		
permission.roleid	For a status move, the ID of role		
permission.rolename	For a status move, the name of role		





# 4.24 design\_querytypes

Information	<b>Description / Notes</b>	Parameter 1	Parameter 2	Parameter 3
Type				
design_querytypes	Query type/status	-	-	-
	definitions, jump per-			
	missions			

## Sample Return

```
<reply status="ok" type="design_querytypes">
 <querytypedefinitions>
   <querytype>
    <id>15</id>
     <name>Site Query</name>
     <openblockpagepromote>t</openblockpagepromote>
     <openrevertpagestatus>t</openrevertpagestatus>
     <statuses>
      <status>
        <id>0</id>
        <name>Open</name>
        <statusmeansanswered>f</statusmeansanswered>
        <statusmeansclosed>f</statusmeansclosed>
      </status>
     </statuses>
     <permissions>
      <permission>
        <statusidfrom>0</statusidfrom>
        <statusnamefrom>Open</statusnamefrom>
        <statusidto>5</statusidto>
        <statusnameto>Answered</statusnameto>
        <roleid>30</roleid>
        <rolename>Administrator</rolename>
      </permission>
     </permissions>
    <rules>
      <rule>
        <canadd>35</canadd>
        <hidden>Test Role</hidden>
        <canmarkdeleted>f</canmarkdeleted>
        <roleid>35</roleid>
```

(continued on next page)





# 4.24 design\_querytypes

## **Sample Return (continued)**

```
<rolename>Test Role</rolename>
      </rule>
     </rules>
   </querytype>
 </querytypedefinitions>
</reply>
```

Field	Description / Notes
id	ID of query type
name	Name of query type
openblockpagepro-	Whether an open query of this type should block any page statuses
mote	moves
openrevertpages- tatuse	Whether the open of this query type should revert the page status – t or f
statuses	Area of status definitions for the query type
status.id	ID of subject status
status.name	Name of subject status
status.statusmeansan swered	Whether the status should consider the query closed
status.statusmeansclo	Whether the status should consider the query answered (non-open, al-
sed	lows page status moves)
permissions	Area of permissions for the query type
permis-	For a status move, the status from ID
sion.statusfromid	
permis-	For a status move, the status from name
sion.statusfromname	
permis- sion.statusfromid	For a status move, the status to ID
permis-	For a status move, the status to name
sion.statusfromname	1 of a status move, the status to name
permission.roleid	For a status move, the ID of role
permission.rolename	For a status move, the name of role
rules	Area of rules for the query type







# 4.24 design\_querytypes

Field	Description / Notes
rule.canadd	Whether the role can add this query type – t or f
rule.hidden	Whether the role has this type of query hidden – t or f
rule.canmarkdeleted	Whether the role can mark this type of query deleted – t or f
rule.roleid	ID of role for rule
rule.rolename	Name of role for rule





# 4.25 design\_codelists

Information	Description /	Parameter 1	Parameter 2	Parameter 3
Type	Notes			
design_codelists	Codelist definitions in study, filter to only used, or view all. <b>NOTE:</b> System level codelists for page statuses, subject statuses, randomization assignments etc. included always	<ul> <li>Filter on return</li> <li>Use only values of all or onlyinusebypage</li> <li>onlyinusebypage yields just codelists that are in use by some page design</li> <li>Default is all if not indicated</li> </ul>	-	_

### Sample Return

```
<reply status="ok" type="design codelists">
 <codelists>
   <codelist>
     <id>9553</id>
     <name>Gender</name>
     <description></description>
     <items>
      <item code="1" hidden="f">Male</item>
      <item code="2" hidden="f">Female</item>
     </items>
   </codelist>
 </re>
</reply>
```

Field	Description / Notes
id	ID of codelist
name	Name of codelist
description	Description of codelist
items	The codelist items
item.code	Code of codelist item
Item (contents of node)	The display text of item
item.hidden	Whether the item is hidden in EDC – t or f



## 4.26 design\_pagedefinitions

Information	Description /	Parameter 1	Parameter 2	Parameter 3
Type	Notes			
design	Page	• Filter on return		
_pagedefinitions	definitions in study, filter to only used, or view all	• Use only values of all, onlyinvisitdef or only-invisitscheduledef		
		• onlyinvisitdef yields just pages that are used in some visit definition, even if the visit is not in a visit schedule		
		• onlyinvisitscheduledef yields just pages that are used in some visit schedule		
		Default is <b>all</b> if not indicated		

### Sample Return

```
<reply status="ok" type="design_pagedefinitions">
 <pagedefinitions>
   <page>
     <id>9526</id>
     <name>pDEMOG</name>
     <description>-</description>
     <controls>
      <control>
        <id>7</id>
        <displayorder>1</displayorder>
        <questext>Initials/questext>
        <helptext></helptext>
        <questypeid>103</questypeid>
        <questypename>Text Field</questypename>
        <codelistid></codelistid>
        <codelistname></codelistname>
        <br/>beforedec></beforedec>
```

(continued on next page)





# 4.26 design\_pagedefinitions

## **Sample Return (continued)**

```
<afterdec></afterdec>
        <maxlength>3</maxlength>
        <size>3</size>
        <indentlevel>0</indentlevel>
        DEMO
        <column>INITS</column>
        <sdv>f</sdv>
        <medcoding>f</medcoding>
       <medcodingdictionaryid></medcodingdictionaryid>
       <medcodingdictionary></medcodingdictionary>
      </control>
    </controls>
   </page>
</pagedefinitions>
</reply>
```

Field	Description / Notes
id	ID of page design object
name	Name of page
description	Description of page
controls	The page controls items
control.id	ID of control – one of keys in any data export
control.displaytext	Visual display order in the page
control.questext	Question Text
control.helptext	Hover help
control.questypeid	Type ID of the control
control .questypename	Name of control type
control.codelistid	ID of codelist (if codelist type control)
control.codelistname	Name of codelist (if codelist type control)
control.beforedec	Before Decimal formatting (numeric type controls)
control.afterdec	After Decimal formatting (numeric type controls)





# 4.26 design\_pagedefinitions

Field	Description / Notes
control.maxlength	Max Length (text field controls)
control.size	Size visually (text field controls)
control.indentlevel	Control visual indent level
control.table	Table name
control.column	Column name
control.sdv	Whether a SDV field – t or f
control.medcoding	Whether a medical coding field – t or f
control .medcodingdictionary id	ID of medical coding dictionary (if medical coding control)
control .medcodingdictionary name	ID of medical coding dictionary (if medical coding control)





## 4.27

## design\_visitdefinitions

Information	Description /	Parameter 1	Parameter 2	Parameter 3
Type	Notes			
design	Visit definitions in	• Filter on return		
_visitdefinitions	study, filter to only used, or view all	• Use only values of all or onlyinvis-itscheduledef		
		<ul> <li>onlyinvisitscheduledef yields just visits that are used in some visit schedule</li> <li>Default is all if not indicated</li> </ul>		

## Sample Return

```
<reply status="ok" type="design visitdefinitions">
 <visitdefinitions>
   <visit>
     <id>9452</id>
     <name>Screening</name>
     <description>Screening Visit</description>
     <pages>
        <id>30</id>
        <name>MedHx Specify</name>
        <displayorder>3</displayorder>
        <repeats>t</repeats>
        <maxrepeats>0</maxrepeats>
        <repeatshelptext>For each body system abnormal, add a page below</repeatshelptext>
        <re>erepeatingcontrols>1==Value</repeatingcontrols></re>
        <pagedesignobjectid>9530</pagedesignobjectid>
        <pagedesignobjectname>pMHABN</pagedesignobjectname>
       </page>
     </pages>
   </visit>
 </visitdefinitions>
</reply>
```





## 4.27

# $design\_visit definitions$

Field	Description / Notes
id	ID of visit design object (NOT visitid in a visit schedule)
name	Name of visit
description	Description of visit
pages	Page Designs that comprise the visit
page.id	ID of page within the visit – will take on pageid in any data row (visitid/visitseq/pageid/pageseq combination)
page.name	Visual page name in EDC
page.displayorder	Display order in a visit in EDC (left to right)
page.repeats	Whether a repeating page – t or f
page.maxrepeats	If repeats, the maximum allowed – 0 for unlimited, -1 for disabled.
page.repeatshelptext	Text at top of repeating summary grid in EDC
page .repeatingcontrols	Controls / Texts that comprise the header column of a repeating grid in EDC
page .pagedesignobjectid	ID of page design (NOT pageid in data keys)
Page.pagedesignobje ctname	Name of page design



## 4.28 design\_visitschedules

Information Type	Description / Notes	Parameter 1	Parameter 2	Parameter 3
design _visitschedules	Visit schedule definitions in study, filter to only used, or view all	<ul> <li>Filter on return</li> <li>Use only values of all or onlyinusebysubject</li> <li>onlyinusebysubject yields just visit schedules that currently in use by non-deleted subjects</li> <li>Default is all if not indicated</li> </ul>	-	-

### Sample Return

```
<reply status="ok" type="design visitschedules">
 <visitschedules>
   <revision id="1">
      <visit>
        <id>10</id>
        <name>SCREENING</name>
        <abbrev>SCR</abbrev>
        <addwhen>On Add Subject</addwhen>
        <repeats>f</repeats>
        <maxrepeats></maxrepeats>
        <repeatshelptext></repeatshelptext>
        <visitdesignobjectid>9528</visitdesignobjectid>
        <visitdesignobjectname>vSCREEN</visitdesignobjectname>
        <pages>
          <page>
           <id>10</id>
            <name>Incl/Excl</name>
            <repeats>f</repeats>
            <maxrepeats></maxrepeats>
            <repeatshelptext></repeatshelptext>
            <repeatingcontrols></repeatingcontrols>
            <pagedesignobjectid>9465</pagedesignobjectid>
```

(continued on next page)





# 4.28 design\_visitschedules

## **Sample Return (continued)**

```
<pagedesignobjectname>pINCL EXCL H</pagedesignobjectname>
       </pages>
      </visit>
   </revision>
 </visitschedules>
</reply>
```

Field	Description / Notes
revision	ID – the CRF revision ID, for the next section. One section in XML for each revision
visits	Visits in the revision
visit.id	Visit ID – this becomes visitd in any visitid/visitseq/pageid/pageseq combination
visit.name	Visual name of visit in EDC
visit.abbrev	Visit abbreviation – roll-up or status grid headings
visit.addwhen	When visit is added.
visit.repeats	Whether a repeating visit – t or f
visit.maxrepeats	If repeats, the maximum allowed – 0 for unlimited, -1 for disabled.
visit.repeatshelptext	Text when user attempt to add visit in EDC
visit .visitdesignobjectid	ID of visit design (NOT pageid in data keys)
visit.visitdesignobject name	Name of visit design
pages	Pages that comprise the visit
page.id	ID of page within the visit – will take on pageid in any data row (visitid/visitseq/pageid/pageseq combination)
page.name	Visual page name in EDC
page.repeats	Whether a repeating page – t or f
page.maxrepeats	If repeats, the maximum allowed – 0 for unlimited, -1 for disabled.







# 4.28 design\_visitschedules

Field	Description / Notes
page.repeatshelptext	Text at top of repeating summary grid in EDC
page .repeatingcontrols	Controls / Texts that comprise the header column of a repeating grid in EDC
page .pagedesignobjectid	ID of page design (NOT pageid in data keys)



# 4.29 design\_revisions

<b>Information Type</b>	<b>Description / Notes</b>	Parameter 1	Parameter 2	Parameter 3
design_revisions	Revision definitions, includes basic definition, rules, permissions, and jumps	-	-	-

### Sample Return

```
<reply status="ok" type="design revisions">
 <revisiondefinitions>
   <revisions>
    <revision>
      <id>1</id>
      <description>Cohort 1</description>
      <numvisits>16</numvisits>
      <numsubjects>10</numsubjects>
      <numrules>11</numrules>
      <numpagepermissions>2</numpagepermissions>
      <permissions>
        <permission>
         <visitid>10</visitid>
         <pageid>10</pageid>
         <perm>Hide / Live Exports</perm>
         <roleid>25</roleid>
         <rolename>Read Only</rolename>
        </permission>
      </permissions>
      <rules>
        <rule>
         <id>1</id>
         <typeid>1301</typeid>
         <typename>Data Value - Send Alert</typename>
         <visitid>10</visitid>
         <pageid>10</pageid>
         <controlid>2</controlid>
         <active>f</active>
```

(continued on next page)





## 4.29 design\_revisions

## **Sample Return (continued)**

```
<definition>
            <def type="Email User">Yes</def>
            <def type="Email Site Alert">Yes</def>
            <def type="Email List"></def>
            <def type="Subject Line">Inc/Exclusion set to No</def>
            <def type="Body">hello</def>
          </definition>
        </rule>
      </rules>
    </revision>
   </revisions>
   <jumps>
     <jump>
      <idfrom>1</idfrom>
      <idto>2</idto>
     </jump>
   </jumps>
 </revisiondefinitions>
</reply>
```

Field	Description / Notes		
id	ID of revision		
description	Description of revision		
numvisits	Number of visits in the revision's visit schedule		
numsubjects	Current number of subjects at the revision in EDC		
numrules	Number of Visit Schedule Rules for revision		
numpagepermissions	Number of Visit Schedule Permissions for revision		
permissions	Area describing page permissions		
permission.visitid	Visit ID of the permission rule		
permission.pageid	Page ID of the permission rule		
permission.perm	Type of page permission		
permission.roleid	ID of role for permission		
permission.rolename	Name of role for permission		





# 4.29 design\_revisions

Field	Description / Notes		
rules	Area describing visit schedule rules		
rule.id	ID within study of the rule		
rule.typeid	ID of rule type		
rule.typename	Name of rule type		
rule.visitid	Visit ID where the rule resides		
rule.pageid	Page ID where the rule resides		
rule.controlid	Control ID where rule resides (if applicable)		
rule.rulevalue	Value for comparison (e.g. in Data Alert Rule)		
rule.active	Whether the rule is active – t or f		
rule.definition	Series of type / value pairs that describe the rule – depends on the type, which pairs are seen here.		
jumps	All revision jumps		
jump.idfrom	The revision ID from in a From -> To jump		
jump.idto	The revision ID to in a From -> To jump		





## 4.30 design\_visitschedulepermissions

Information Type	Description / Notes	Parameter 1	Parameter 2	Parameter 3
design_ visitschedulepermis-	Visit schedule permissions, across all revisions	-	-	-

## Sample Return

```
<reply status="ok" type="design visitschedulepermissions">
 <visitschedulepermissions>
   <permission>
     <revision>1</revision>
     <visitid>10</visitid>
     <pageid>10</pageid>
     <perm>Hide / Live Exports</perm>
     <roleid>25</roleid>
     <rolename>Read Only</rolename>
   </permission>
 </visitschedulepermissions>
</reply>
```

Field	Description / Notes	
permission.revision	CRF Revision ID for the permission	
permission.visitid	Visit ID of the permission rule	
permission.pageid	Page ID of the permission rule	
permission.perm	Type of page permission	
permission.roleid	ID of role for permission	
permission .rolename	Name of role for permission	





## 4.31 design\_visitschedulerules

Information Type	Description /	Parameter 1	Parameter 2	Parameter 3
	Notes			
design_ visitschedulerules	Visit schedule rules, across all revisions	-		-

### Sample Return

```
<reply status="ok" type="design visitschedulerules">
 <visitschedulerules>
   <rule>
    <revision>1</revision>
    <id>1</id>
    <typeid>1301</typeid>
    <typename>Data Value - Send Alert</typename>
    <visitid>10</visitid>
    <pageid>10</pageid>
    <controlid>2</controlid>
     <active>f</active>
     <definition>
      <def type="Email User">Yes</def>
      <def type="Email Site Alert">Yes</def>
      <def type="Email List"></def>
      <def type="Subject Line">Inc/Exclusion set to No</def>
      <def type="Body">hello</def>
    </definition>
   </rule>
</visitschedulerules>
</reply>
```

Field	Description / Notes	
rule.revision	ID of CRF revision	
rule.id	D within study of the rule	
rule.typeid	ID of rule type	
rule.typename	Name of rule type	
rule.visitid	Visit ID where the rule resides	







# design\_visitschedulerules

Field	Description / Notes		
rule.pageid	Page ID where the rule resides		
rule.controlid	Control ID where rule resides (if applicable)		
rule.rulevalue	Value for comparison (e.g. in Data Alert Rule)		
rule.active	Whether the rule is active – t or f		
rule.definition	Series of type / value pairs that describe the rule – depends on the type, which pairs are seen here.		





## 4.32 design\_systemqueries

Information Type	Description / Notes	Parameter 1	Parameter 2	Parameter 3
designsystemqueries System query definitions in study	<ul> <li>Filter on return</li> <li>Use only values of all, onlyinvisitdef or onlyinvisitscheduledef</li> </ul>	-	-	
	• onlyinvisitdef yields just queries from pages that are used in some visit definition, even if the visit is not in a visit schedule			
	• onlyinvisitscheduledef yields just queries from pages that are used in some visit schedule			
		• Default is <b>all</b> if not indicated		

### Sample Return

```
<reply status="ok" type="design systemqueries">
 <systemqueries>
   <systemquery>
    <internalid>9560</internalid>
     <name>EEMULTI VITALS</name>
     <pagedesignobjectid>9473</pagedesignobjectid>
    <pagedesignobjectname>pPHYSEXAM</pagedesignobjectname>
    <typeid>186</typeid>
    <typename>Other / Cross Page</typename>
    <message>"Date" is not equal to Vitals date at this visit/message>
    <conditions>SAME_VISIT--VTL.DT <> PE.DT ::: </conditions>
    <description></description>
     <controlid>1</controlid>
    <controltablecolumn>PE.DT</controltablecolumn>
     <active>f</active>
    <lastmbyid>1</lastmbyid>
    <lastmby>Emerton, Eric [DES]</lastmby>
```

(continued on next page)





## 4.32 design\_systemqueries

## **Sample Return (continued)**

```
<lastmdt>2011-04-13 14:07:43
```

- <numfiredtotal>0</numfiredtotal>
- <numfiredopen>0</numfiredopen>
- <numfiredanswered>0</numfiredanswered>
- <numfiredclosed>0</numfiredclosed>
- <numfireddeleted>0</numfireddeleted>
- <numfiredorphaned>0</numfiredorphaned>
- </systemquery>
- </systemqueries>
- </reply>

Field	Description / Notes		
internalid	ID of query design object		
name	Name of query		
pagedesignobjectid	Page design ID the query is attached to		
pagedesignobject- name	Name of page design the query is attached to		
typeid	Type ID of the query		
typename	Type name of the query		
message	Message to the user		
conditions	Conditions for the query to fire		
description	Description / notes for the query		
controlid	Control ID the query fires on (within the page design)		
controltablecolumn	Table.Column of the control the query fires on (within the page design)		
active	Whether query is active – t or f		
lastmbyid	Last modified by, internal ID		
lastmby	Last modified by, name		
lastmdt	Last modified date (ISO format)		
numfiredtotal	Currently fired – total		
numfiredopen	Currently fired – and open		







# 4.32 design\_systemqueries

Field	Description / Notes
numfiredanswered	Currently fired – and answered
numfiredclosed	Currently fired – and closed
numfireddeleted	Currently fired – but marked deleted
numfiredorphaned	Currently fired – but part of orphaned data due to a subject revision move





## 4.33 design\_reports

Information	Description /	Parameter 1	Parameter 2	Parameter 3
Type	Notes			
design_reports	Report definitions	Status of report(s) returned	-	-
		<ul> <li>Use only values of all, active or inactive</li> <li>Default is all if not indicated</li> </ul>		

## Sample Return

```
<reply status="ok" type="design reports">
 <reports>
   <report>
    <id>3</id>
    <typeid>609</typeid>
     <typename>Study Standard: SDV Status/Percentages</typename>
     <name>SDV</name>
     <description></description>
     <active>t</active>
     <subjectpdf>f</subjectpdf>
     <showatlanding>f</showatlanding>
     <mobileenabled>f</mobileenabled>
     <lastmbyid>227</lastmbyid>
     <lastmby>Malok, Emily [DES]
     <lastmdt>2013-03-07 19:47:49</lastmdt>
     <definition>
    </definition>
     <roles>
      <role id="-1">ALL</role>
    </roles>
     <sites>
      <site>ALL</site>
    </sites>
   </report>
 </reports>
</reply>
```





# 4.33 design\_reports

Field	Description / Notes		
id	ID of report		
typeid	Type ID of the query		
typename	Type name of the query		
name	Visual name of report		
description	Visual description of report		
active	Whether report is active – t or f		
subjectpdf	Whether the report is to be included in closeout PDFs (subject level reports only) – t or f		
lastmbyid	Last modified by, internal ID		
lastmby	Last modified by, name		
lastmdt	Last modified date (ISO format)		
definition	Area for definition – Label / value pairs – depending on type or report		
roles	Roles that view the report – ID/name pairs. When ALL is used for role selection, ID appears as -1		





## 4.34 design\_systemmessages

Information	Description /	Parameter 1	Parameter 2	Parameter 3
Type	Notes			
design _systemmessages	System messages in EDC	• Status of message(s) returned	-	-
		• Use only values of all, active or inactive		
		• Default is <b>all</b> if not indicated		

## Sample Return

```
<reply status="ok" type="design systemmessages">
 <systemmessages>
   <systemmessage>
     <id>17</id>
     <active>t</active>
     <important>f</important>
     <expiredate>2011-05-05</expiredate>
     <subject>The subject</subject>
     <message>Here is the message</message>
     <lastmbyid>1</lastmbyid>
     <lastmby>Emerton, Eric [DES]</lastmby>
     <lastmdt>2011-05-03 18:39:33</lastmdt>
     <roles>
      <role id="5">Primary Investigator</role>
      <role id="10">Study Coordinator</role>
     </roles>
     <studydocs>
      <studydoc>MyDoc.doc</studydoc>
     </studydocs>
   </systemmessage>
 </systemmessages>
</reply>
```

Field	Description / Notes
id	ID of report
active	Whether message is active – t or f
Important	Whether message is deemed important, and users see it first on entry to the study – t or f







# 4.34 design\_systemmessages

Field	Description / Notes		
expiredate	The date the message should no longer show		
subject	The subject line of message		
message	The full message text		
lastmbyid	Last modified by, internal ID		
lastmby	Last modified by, name		
lastmdt	Last modified date (ISO format)		
roles	Roles that view the report – ID/name pairs. When ALL is used for role selection, ID appears as -1		
studydocs	Names of one or more documents posted as part of the message		





## 4.35 design\_strata

Information Type	<b>Description / Notes</b>	Parameter 1	Parameter 2	Parameter 3
design_strata	Stratification design information	-	-	-

### Sample Return

```
<reply status="ok" type="design strata">
 <stratadefinitions>
   <stratagroup>
     <id>1</id>
     <name>Cohort 1</name>
     <cap></cap>
     <description>Cohort 1</description>
     <factors>
      <factor>
        <id>1</id>
        <typeid>1805</typeid>
        <typename>Subject CRF Revision</typename>
        <description></description>
        <definition>
          <def type="Condition">=</def>
          <def type="Value">1</def>
        </definition>
      </factor>
     </factors>
   </stratagroup>
 </stratadefinitions>
</reply>
```

Field	Description / Notes
stratagroup.id	ID of a strata group
stratagroup.name	Name of strata group
stratagroup.cap	Cap for strata group
stratagroup .description	Description of strata group
stratagroup.factors	Area for factors
stratagroup.factors	Area for factors – which if all true – place a subject in that group





# 4.35 design\_strata

Field	Description / Notes		
factor.id	ID of factor in the study design		
factor.typeid	Type ID for factor		
factor.typename	Type name of factor		
factor.description	Description of factor		
factor.definition	Series of def Type/Value pairs that define the conditions of the factor		





# 4.36 design\_rand

Information Type	Description / Notes	Parameter 1	Parameter 2	Parameter 3
design_rand	Randomization design information	-	-	-

## Sample Return

```
<reply status="ok" type="design_rand">
 <randdefinitions>
   <rand>
     <id>1</id>
     <name>Active</name>
     <cap></cap>
    <description>Active</description>
   </rand>
   <rand>
     <id>2</id>
     <name>Placebo</name>
     <cap></cap>
     <description>Placebo</description>
   </rand>
 </randdefinitions>
</reply>
```

Field	Description / Notes	
rand.id	ID of a randomization assignment	
rand.name	Name of randomization assignment	
rand.cap	Cap for randomization assignment	
rand.description	Description of randomization assignment	





## 4.37 design\_dispensetypes

Information Type	<b>Description / Notes</b>	Parameter 1	Parameter 2	Parameter 3
design _dispensetypes	Dispense types design information	-	1	1

### Sample Return

```
<reply status="ok" type="design dispensetypes">
 <dispensetypedefinitions>
   <dispensetype>
     <id>1</id>
     <name>200 mg</name>
     <defaultinitialship>8</defaultinitialship>
     <defaultfloorship>4</defaultfloorship>
     <defaultceilingship>10</defaultceilingship>
     <description>200 mg Active</description>
   </dispensetype>
   <dispensetype>
     <id>2</id>
     <name>Placebo</name>
     <defaultinitialship>8</defaultinitialship>
     <defaultfloorship>4</defaultfloorship>
     <defaultceilingship>10</defaultceilingship>
     <description>Placebo</description>
   </dispensetype>
 </dispensetypedefinitions>
</reply>
```

Field	Description / Notes
id	ID of dispense type
name	Name of dispense type
defaultinitialship	Should new site shipment settings be added – the initial ship value to use for this type
defaultfloorship	Should new site shipment settings be added – the floor value to use for this type
defaultceilingship	Should new site shipment settings be added – the ceiling ship value to use for this type
description	Description of type





## 4.38 design\_dispensetreatments

Information Type	Description /	Parameter 1	Parameter 2	Parameter 3
	Notes			
design _dispensetreatments	Dispense treatments design information	-	-	-

### Sample Return

```
<reply status="ok" type="design dispensetreatments">
 <dispensetreatmentdefinitions>
   <dispensetreatment>
     < id > 1 < /id >
     <name>One 200 mg</name>
     <dispenseabledays>1</dispenseabledays>
     <description>One 200 mg.. at visit 1</description>
     <factors>
      <factor>
        <id>1</id>
        <typeid>1905</typeid>
        <typename>Current Rand Assignment</typename>
        <description></description>
        <definition>
          <def type="Condition">=</def>
          <def type="Value">1</def>
        </definition>
      </factor>
     </factors>
     <dispensetypes>
      <type>
        <id>1</id>
        <name>200 mg</name>
        <description>200 mg Active</description>
      </type>
     </dispensetypes>
   </dispensetreatment>
 </ dispensetreatmentdefinitions >
</reply>
```





# 4.38 design\_dispensetreatments

Field	Description / Notes
dispensetreatment.id	ID of treatment
dispensetreatment .name	Name of treatment
dispensetreatment .dispenseabledays	Days that the treatment would be dispensed to a subject. Expiration dates of drug back up this many days, to ensure a treatment can be given to a subject.
dispensetreatment .description	Description of treatment
dispensetreatment .factors	Area for factors – which if all true – yields the treatment at dispense time
factor.id	Id of factor
factor.typeid	Type ID of factor
factor.typename	Type name of factor
factor.description	Description of factor
factor.definition	Pairs of def type / value
dispensetreatment .dispensetypes	Mapping of dispense types given when this treatment is selected
dispensetypes.type.id	Id of dispense type
dispensetypes .type.name	Name of dispense type
dispensetypes .type.description	Description of dispense type





## 4.39 general\_studylist

<b>Information Type</b>	Description / Notes	Parameter 1	Parameter 2	Parameter 3
general_ studylist	Studies currently logged in user has access to - general study access (i.e. general user), not with respect to any team.	<ul> <li>Status of study account requests</li> <li>Use only values of all, active, pending, or inactive</li> <li>Default is all if not indicated</li> </ul>	-	-

## Sample Return

```
<reply status="ok" type="general studylist">
 <studyaccesses>
   <studyaccess>
    <studyid>1482</studyid>
    <sponsor>Merge Healthcare/sponsor>
    <name>myEDC 1.6.0 Demonstration Study</name>
    <statusid>853</statusid>
    <status>Inactive</status>
    <studystatus>Live</studystatus>
    <ohref="color: blue;"><oherlanguages>
    <roleid>30</roleid>
    <rolename>Administrator</rolename>
    <allsites>t</allsites>
    <sitelist></sitelist>
    cprimaryorgid>1669</primaryorgid>
    primaryorgname>
    primaryorgnumber>
    primaryorgactive>t</primaryorgactive>
   </studyaccess>
 </studyaccesses>
</reply>
```





# 4.39 general\_studylist

Field	Description / Notes
studyid	the ID of the study whose access is being displayed
sponsor	the sponsor of the study
name	the study name
statusid	the id for the user status
status	the user's status for the study
studystatus	the status of the study
otherlanguages	the languages other than English that are being used in the study
roleid	the id for the role assigned to the user
rolename	the name of the role assigned to the user
allsites	if the user has permission to access all sites – t or f
sitelist	the additional sites the user has access to, if applicable
primaryorgid	the system id of the site that is the user's primary site/organization
primaryorgname	the name of the site that is the user's primary site/organization
primaryorgnumber	the site # of the user's primary site/organization
primaryorgactive	whether or not the user's primary site/organization is active – t or f







## 4.40 Non-Interactive API Mode

For non-interactive usage, users can build an application that can make and receive web service calls.

### LOGIN SAMPLE

https://eclinicalos.com/edc studyservices.jsp?studyid=1234&action=login

..with posts to fields 'login' and 'password' – would login to services

### LOGOUT SAMPLE

https://eclinicalos.com/edc studyservices.jsp?action=logout

..will end the existing web services session

### FETCHING INFORMATION SAMPLE

https://eclinicalos.com/edc studyservices.jsp?action=infoattempt&type=design roles

.. will return the XML for the study's Role design, as seen in the 'Raw Server Return' of interactive Type is the names as seen in the Information Type dropdown in interactive mode. Action must be 'infoattempt'. Action and Type can be field/value pairs posted as opposed to in the URL string itself.

### PASSING PARAMETERS TO THE CALL SAMPLE

&param1=..value..&param2=..value...&param3=..value..

in the URL, or have your application prepare the post to the server with fields / values of those names.

### FILE FOR IMPORT SAMPLE

https://eclinicalos.com/edc studyservices.jsp?action=importfile

... together with a filecontents=.. <the XML file contents>, and filename = <uniquefile name.xml>... will post a file into the Imports queue, just as if it was manually uploaded. eClinical OS batch processes will then act on the file as normal.



NOTE: If no filename value is passed, a unique file name is generated. The system has guidelines for assigning a unique file name. It is strongly suggested that users provide a filename value. This will better describe the files contents for reference from the Imports tab summary table.









## **Practical Exercise**

**DAISY** 

## Generating data\_subjectlist Results

- 1.In the study EDC, click the Imports/API tab.
- 2. Click the Interactive API Viewer link in the table header.
- 3.In the new window/tab, enter your eClinical OS login information and click Login. Your DAISY Study ID should already be in the appropriate field.

Attribute	Details	
Information Type	data_subjectlist	
Parameter 1	no	
Parameter 2	< leave blank >	
Parameter 3	< leave blank >	

- 4.In the Choose Return box at the left, enter the following information:
- 5.Click View.



NOTES: The system will default to the Study ID for the study you access the API from. You can enter a different Study ID to access another study, but you can only access one study at a time.





## Study Designer



# **Self Assessment | Tips and Tricks**

1.	The API Services can be used interactively from EDC or non-interactively from a remote application.			
		$\Box$ True	□ False	
2.		Using the interactive mode, if you call the design_roles in a study that is not using Randomization/Stratification, you will not see the Rand Admin permission in the results.		
		$\Box$ True	□ False	
3.		You will use you log in to a study's	r eClinical OS user name and password in combination with the Study ID to s API Services.	
		□ True	□ False	



## **Tips and Tricks**

◆ You can view the full list of current information types and their parameters on screen when you log in to the interactive API mode.

Answers:

1. True 2. True 3. True







## **Summary Page**



## FINDING HELP

## Merge eClinical OS Technical Support

eclinicalos-support@merge.com

## Merge Healthcare Help Desk

For access to off-hours help, international phone numbers, and Live Chat options

Website: http://www.merge.com/Support/Clinical-Trials.aspx

By Phone: 1.888.500.4247

By Email: <u>eclinicalhelp@merge.com</u>

