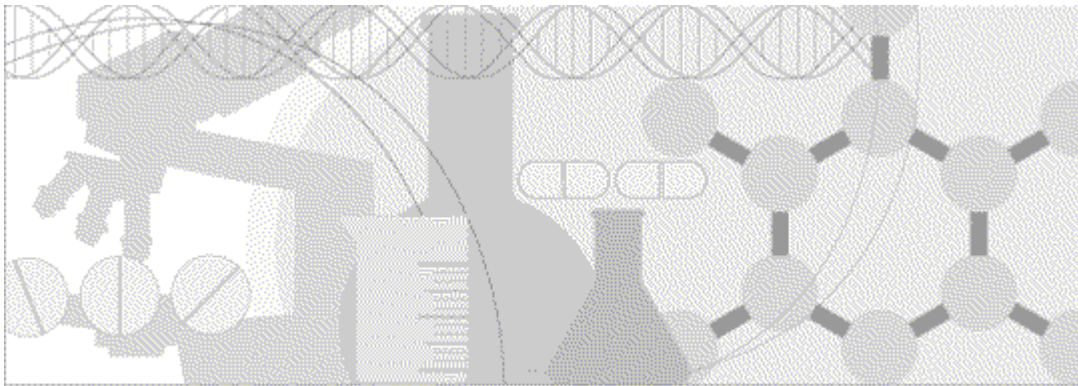


Interfaces Guide

Oracle[®] Health Sciences InForm Adapter
Release 1.3.7



ORACLE[®]

Part Number: E54452-01

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Overview of this guide

This guide provides information on using the interfaces that are included with the InForm Adapter software.

Audience

This guide is for IT administrators and others who are responsible for integrating the InForm software with other applications, including Oracle-provided products, third-party products, and custom client processes.

Documentation

The product documentation is available from the following locations:

- **Oracle Software Delivery Cloud** (<https://edelivery.oracle.com>)—The complete documentation set.
- **My Oracle Support** (<https://support.oracle.com>)—*Release Notes* and *Known Issues*.
- **Oracle Technology Network** (<http://www.oracle.com/technetwork/documentation>)—The most current documentation set, excluding the *Release Notes* and *Known Issues*.

All documents may not be updated for every InForm Adapter release. Therefore, the version numbers for the documents in a release may differ.

Document	Description
<i>Release Notes</i>	The <i>Release Notes</i> document describes hardware and software requirements and describes the new features, enhancements, and fixed issues in this release.
<i>Known Issues</i>	The <i>Known Issues</i> document provides detailed information about the known issues in this release, along with workarounds, if available.
<i>Installation Guide</i>	The <i>Installation Guide</i> provides a brief overview of the InForm Adapter software, step-by-step instructions for installing and uninstalling the software, setting security options, and troubleshooting information.
<i>Interfaces Guide</i>	The <i>Interfaces Guide</i> provides information on using the interfaces that are included with the InForm Adapter software.
<i>Secure Configuration Guide</i>	The <i>Secure Configuration Guide</i> provides an overview of the security features provided with the InForm Adapter application including details about the general principles of application security and how to install, configure, and use the InForm Adapter application securely.
<i>Third Party Licenses and Notices</i>	The <i>Third Party Licenses and Notices</i> document includes licenses and notices for third party technology that may be included with the InForm Adapter software.

Documentation accessibility

For information about Oracle's commitment to accessibility, visit the Oracle Accessibility Program website at <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=docacc>.

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Oracle customers have access to support through My Oracle Support. For information, visit <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=info>, or if you are hearing impaired, visit <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs>.

Finding InForm Adapter information and patches on My Oracle Support

The latest information about the InForm Adapter application is on the Oracle Support self-service website, My Oracle Support. Before you install and use the InForm Adapter application, check My Oracle Support for the latest information, including *Release Notes* and *Known Issues*, alerts, white papers, bulletins, and patches.

Creating a My Oracle Support account

You must register at My Oracle Support to obtain a user name and password before you can enter the site.

- 1 Open a browser to <https://support.oracle.com>.
- 2 Click the **Register** link.
- 3 Follow the instructions on the registration page.

Finding information and articles

- 1 Sign in to My Oracle Support at <https://support.oracle.com>.
- 2 If you know the ID number of the article you need, enter the number in the text box at the top right of any page, and then click the magnifying glass icon or press **Enter**.
- 3 To search the knowledge base, click the **Knowledge** tab, and then use the options on the page to search by:
 - Product name or family.
 - Keywords or exact terms.

Finding patches

You can search for patches by patch ID or number, product, or family.

- 1 Sign in to My Oracle Support at <https://support.oracle.com>.
- 2 Click the **Patches & Updates** tab.
- 3 Enter your search criteria and click **Search**.
- 4 Click the patch ID number.

The system displays details about the patch. You can view the Read Me file before downloading the patch.

- 5 Click **Download**, and then follow the instructions on the screen to download, save, and install the patch files.

Finding Oracle documentation

The Oracle website contains links to Oracle user and reference documentation. You can view or download a single document or an entire product library.

Finding Oracle Health Sciences documentation

For Oracle Health Sciences applications, go to the Oracle Health Sciences Documentation page at <http://www.oracle.com/technetwork/documentation/hsgbu-clinical-407519.html>.

Note: Always check the Oracle Health Sciences Documentation page to ensure you have the most up-to-date documentation.

Finding other Oracle documentation

- 1 Do one of the following:
 - Go to <http://www.oracle.com/technology/documentation/index.html>.
 - Go to <http://www.oracle.com>, point to the **Support** tab, and then click **Product Documentation**.
- 2 Scroll to the product you need, and click the link.

Finding prerequisite software for Oracle Health Sciences applications

Prerequisite software for Oracle Health Sciences applications is available from the following locations:

- Download the latest major or minor release from the Oracle Software Delivery Cloud (<https://edelivery.oracle.com/>).

For information on the credentials that are required for authorized downloads, click **FAQs** on the main page of the Oracle Software Delivery Cloud portal.

- Download subsequent patch sets and patches from My Oracle Support (<https://support.oracle.com>).

To find patch sets or patches, select the **Patches & Updates** tab.

If a previous version of prerequisite software is no longer available on the Oracle Software Delivery Cloud, log a software media request Service Request (SR). Previous versions of prerequisite software are archived and can usually be downloaded. After you open an SR, you can check its status:

- US customers: Call 1-800-223-1711.
- Outside the US: Check www.oracle.com/us/support/contact/index.html for your local Oracle Support phone number.

For more information on logging a media request SR, go to My Oracle Support for Document 1071023.1: Requesting Physical Shipment or Download URL for Software Media (<https://support.oracle.com/epmos/faces/DocumentDisplay?id=1071023.1>).

CHAPTER 1

What is the InForm Adapter software?

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What is the InForm Adapter software?

The InForm Adapter software provides interfaces to web services that support the secure transfer of data between InForm studies and either Oracle products (such as the Clintrial Integration Solution (CIS) and Central Coding applications) or third-party products and custom applications. Each application that can accept queries or updates to its data and metadata from InForm studies requires a specific set of interfaces.

Like application programming interfaces (APIs), the InForm Adapter interfaces use published web services interfaces to allow programmatic access to applications. This allows Oracle products to be tightly integrated with each other and with third-party products.

The InForm Adapter interfaces

The InForm Adapter 1.3.7 release includes the following interfaces that are available for programmatic access.

Interface	Description
Admin	Provides access to information about the location of InForm servers and InForm trials.
Discrepancy	Transmits InForm queries (discrepancies) to and from other systems or modules. This release of the InForm Adapter software includes the Discrepancy Original interface and the Discrepancy Enhanced interface.
ODM Export	Provides access to receive InForm administrative data, clinical data, and metadata in CDISC ODM standard format.

About namespaces

Each InForm Adapter interface has an XML namespace that defines the parameters for each web method that resides in the namespace.

A sample namespace is

`http://www.phaseforward.com/InForm Adapter/ODM`

If you browse to the ASMX page for an interface, you are presented with:

- A list of the web methods that can be used to interact with that interface, including syntax provided for each web method.
- Samples that include the SOAP header and body, but not the request node.

About LSIDs

Life Science Identifiers (LSIDs) provide a way to identify subsystem resources. Some of the InForm Adapter interface web methods (such as QueryData and ReturnData) pass LSIDs as input parameters.

Through a series of scoping mechanisms, LSIDs resolve to a specific location. An Oracle LSID uses the following syntax:

URN:LSID:authorityID:namespaceID:objectID

where:

- *authorityID* is the domain name of the authority managing the content.
- *namespaceID* includes the following components:
 - Subauthority
 - Concept-name
 - Descriptor-type
- *objectID* is the object identifier.

Authority ID

The Authority ID is the domain name for the entity managing the data. This typically is a sponsor site:

URN:LSID:sponsor.com:PhaseForward.com/InForm/pf206/1000/Patient;Name:AAA
 URN:LSID:sponsor.com:PhaseForward.com/InForm/Pf206/Transaction;Guid:9A4A4A51-FB3A-4F4B-9B57-A2912A289769

NamespaceID

The NamespaceID consists of the following components:

- **Subauthority**—References a subsystem within the Oracle domain. For example,
 - **PhaseForward.com/InForm** is a reference to an InForm object.
 - **PhaseForward.com/Clintrace** is a reference to a Clintrace object.
- **Concept name**—Begins with the InForm study name. The following keywords are supported:
 - **Site**—Specifies data related to a site, such as a list of patients. For example, **Trial_Name/Site_ID**.
 - **Patient (Subject)**—Specifies patient data, such as form data. Patient concept name is always after a site ID. For example, **Trial_Name/Site_ID/Patient**.
 - **User**—Specifies user data, such as user attributes. For example, **Trial_Name/User**.
 - **ExecutionPlan**—Specifies data associated with an execution plan. For example, **Trial_Name/ExecutionPlan**.
 - **Transaction**—Specifies an InForm transaction. For example, **Trial_Name/Transaction**.
 - **StudyVersion**—Specifies data under an InForm study version, such as blank forms. For example, **Trial_Name/StudyVersion**.

- **Descriptor-type**—Specifies the NamespaceID by:
 - Name (object refname).
 - DBUID.
 - GUID.

Object ID

The object ID depends on the type of descriptor specified in the namespace ID concept name and descriptor type:

- If the descriptor selects a refname, the object ID is the corresponding text string.
- If the descriptor selects a GUID or DBUID, the object returns the appropriate ID number.

For example, for study pf206, to access a patient AAA enrolled in site 1000, your LSID would include the Object ID that corresponds to the Name descriptor:

```
URN:LSID:sponsor.com:PhaseForward.com/InForm/pf206/1000/Patient;Name:AAA
```

If you were specifying a LSID to access a specific transaction (GUID 9A4A4A51-FB3A-4F4B-9B57-A2912A289769) in study pf206, Object ID would correspond to the GUID descriptor:

```
URN:LSID:sponsor.com:PhaseForward.com/InForm/Pf206/Transaction;Guid:9A4A4A51-FB3A-4F4B-9B57-A2912A289769
```

LSID types

User LSID

Identifies a user in an InForm study.

```
URN:LSID:www.companyabc.com:www.phaseforward.com/InFormAdapter//;Trial=<trial_alias>/User;UserGuidRef:{<user_guid>}
```

Item	Description
www.phaseforward.com	The Authority ID for Oracle LSIDs.
www.phaseforward.com/InFormAdapter//;	The Namespace ID/subauthority reference for the InForm Adapter subsystem.
<trial_alias>	The alias for the InForm trial. This corresponds to the value found in the InForm table: INFORMADAPTER.PF_STUDYINFORMATION.ALIAS
<user_guid>	The user ID. This corresponds to the value in the InForm table: TRIALUSER.PF_DBUID.GUID

The UserLSID element returns the user LSID.

Example—UserLSID

```
<UserLSID>
  URN:LSID:www.phaseforward.com:www.phaseforward.com/InFormAdapter//;Trial=apps
  rv44_pfstevent/User;UserGuidRef:{A3EDB63E-719C-454F-A1D6-F8DC4B97BE2E}
</UserLSID>
```

Item LSID

Identifies an item on an InForm form associated with a patient and study.

```
URN:LSID:www.phaseforward.com:www.phaseforward.com/InFormAdapter//;Trial=<trial_alias>/Site=<site_id>,<site_rev_number>/Subject=<patient_guid>/Formset=<chapter_ref_name>,<chapter_rev_number>,<chapter_index>/Form=<page_ref_name>,<page_rev_number>.000,<page_index>.000/Section=<section_ref_name>/Item;RefNameTuple:<item_ref_name>
```

Item	Description
www.phaseforward.com	The Authority ID for Oracle LSIDs.
www.phaseforward.com/InFormAdapter//;	The Namespace ID/subauthority reference for the InForm Adapter subsystem.
<trial_alias>	The alias for the InForm trial. This corresponds to the value found in the InForm table: INFORMADAPTER.PF_STUDYINFORMATION.ALIAS

Item	Description
<site_id>	The ID for the site. This corresponds to the value found in the InForm table: TRIALUSER.PF_SITE.SITEID
<site_rev_number>	This corresponds to the value found in the InForm table: TRIALUSER.PF_SITE.SITEREVISIONNUMBER (for the specific site id)
<patient_guid>	This corresponds to the value found in the InForm table: TRIALUSER.PF_DBUID.GUID (for the specific patient id)
<chapter_ref_name>	This corresponds to the value found in the InForm table: TRIALUSER.PF_CHAPTER.CHAPTERREFNAME
<chapter_rev_number>	This corresponds to the value found in the InForm table: PF_SUBJECTVECHAPTER.SUBJECTCHAPTERREVISIONNUMBER
<chapter_index>	This corresponds to the value found in the InForm table: PF_SUBJECTVECHAPTER.CHAPTERINDEX
<page_ref_name>	This corresponds to the value found in the InForm table: TRIALUSER.PF_PAGE.PAGEREFNAME
<page_rev_number>	This corresponds to the value found in the InForm table: TRIALUSER.PF_PAGE.PAGEREVISIONNUMBER (for the specific page ref)
<page_index>	This corresponds to the value found in the InForm table: TRIALUSER.PF_ITEMCONTEXT.PAGEINDEX (for the specific subject id, form) Required for repeating forms.
<section_ref_name>	This corresponds to the value found in the InForm table: TRIALUSER.PF_SECTION.SECTIONREFNAME
<item_ref_name>	This corresponds to the value found in the InForm table: TRIALUSER.PF_ITEM.ITEMREFNAME

The item LSID can be returned in these elements:

- ItemLSID
- ItemLSIDPointer
- ReferenceLSID

Example—ItemLSID

```
<ItemLSID>
  URN:LSID:www.phaseforward.com:www.phaseforward.com/InFormAdapter//;Trial=PFST
  45/Site=PhaseForward/Subject={1331E366-DD80-4EED-8759-
  DCAFFB74DC7D}/Formset=vstBASE,,1.000/Form=frmDem,133369290054048.000,1.000/Se
  ction=sctDem/Item;RefName:itmDemGendr
</ItemLSID>
```

Form LSID

Identifies a form associated with an InForm study, site, and patient.

```
URN:LSID:www.phaseforward.com:www.phaseforward.com/InFormAdapter//;Trial=<trial_
alias>/Site=<site_id>,<site_rev_number>/Subject={<subject_guid>}/Formset=<chapte
r_ref_name>,<chapter_rev_number>,<chapter_index>/Form;RefNameTuple:<page_ref_nam
e>,<page_rev_number>,<page_index>
```

Item	Description
www.phaseforward.com	The Authority ID for Oracle LSIDs.
www.phaseforward.com/InFormAd apter//;	The Namespace ID/subauthority reference for the InForm Adapter subsystem.
<trial_alias>	The alias for the InForm trial. This corresponds to the value found in the InForm table: INFORMADAPTER.PF_STUDYINFORMATION.ALIAS
<site_id>	This corresponds to the value found in the InForm table: TRIALUSER.PF_SITE.SITEID
<site_rev_number>	This corresponds to the value found in the InForm table: TRIALUSER.PF_SITE.SITEREVISIONNUMBER
<subject_guid>	This corresponds to the value found in the InForm table: TRIALUSER.PF_DBUID.GUID (for the specific patient id)
<chapter_ref_name>	This corresponds to the value found in the InForm table: TRIALUSER.PF_CHAPTER.CHAPTERREFNAME
<chapter_rev_number>	This corresponds to the value found in the InForm table: PF_SUBJECTVECHAPTER.SUBJECTCHAPTERREVISI ONNUMBER
<chapter_index> (Required for repeating visits)	This corresponds to the value found in the InForm table: PF_SUBJECTVECHAPTER.CHAPTERINDEX
<page_ref_name>	This corresponds to the value found in the InForm table: TRIALUSER.PF_PAGE.PAGEREFNAME
<page_rev_number>	This corresponds to the value found in the InForm table: TRIALUSER.PF_PAGE.PAGEREVISIONNUMBER (for the specific page ref)

Item	Description
<page_index>	This corresponds to the value found in the InForm table: TRIALUSER.PF_ITEMCONTEXT.PAGEINDEX (for the specific subject id, form) Required for repeating forms.

The FormLSID element returns the form LSID.

Example—FormLSID

```
<FormLSID>
  URN:LSID:www.phaseforward.com:www.phaseforward.com/InFormAdapter//;Trial=apps
  rv16_pfstevent/Site={17ee673b-9278-4a69-92a1-af327f775dd7}/Subject={1331E366-
  DD80-4EED-8759-
  DCAFFB74DC7D}/Formset=CommonCRF,,1/Form;RefNameTuple:frmCM,133369314914048.00
  0,133436282531025.000
</FormLSID>
```

Site LSID

Identifies a site in an InForm study.

```
URN:LSID:www.phaseforward.com:www.phaseforward.com/InFormAdapter//;Trial=<trial_
alias>/Site;GuidTuple:{<site_guid>}
```

Item	Description
www.phaseforward.com	The Authority ID for Oracle LSIDs.
www.phaseforward.com/InFormAdapter //;	The Namespace ID/subauthority reference for the InForm Adapter subsystem.
<trial_alias>	The alias for the InForm trial. This corresponds to the value found in the InForm table: INFORMADAPTER.PF_STUDYINFORMATION.A LIAS
<site_guid>	Corresponds to the site ID stored in the TRIALUSER.PF_DBUID.GUID table.

The SiteLSID element returns the site LSID.

Example—SiteLSID

```
<SiteLSID>
  URN:LSID:www.phaseforward.com:www.phaseforward.com/InFormAdapter//;Trial=apps
  rv16_pfstevent/fSite;GuidTuple:{17EE673B-9278-4A69-92A1-
  AF327F775DD7},133369346507048
</SiteLSID>
```

Patient LSID

Identifies a patient in a site and study.

URN:LSID:www.phaseforward.com:www.phaseforward.com/InFormAdapter//;Trial=<trial_alias>/Site={<site_guid>}/Subject;DBUIDTuple:{<subject_guid>,<subject_rev>

Item	Description
www.phaseforward.com	The Authority ID for Oracle LSIDs.
www.phaseforward.com/InFormAdapter//;	The Namespace ID/subauthority reference for the InForm Adapter subsystem.
<trial_alias>	The alias for the InForm trial. This corresponds to the value found in the InForm table: INFORMADAPTER.PF_STUDYINFORMATION.ALIAS
<site_guid>	This corresponds to the value found in the InForm table: TRIALUSER.PF_DBUID.GUID (for the specific site id)
<subject_guid>	This corresponds to the value found in the InForm table: TRIALUSER.PF_DBUID.GUID (for the specific subject id)
<subject_rev>	This corresponds to the value found in the InForm table: TRIALUSER.PF_PATIENT.PATIENTREVISIONNUMBER

The PatientLSID element returns the patient LSID.

Example—PatientLSID

```
<PatientLSID>
  URN:LSID:www.phaseforward.com:www.phaseforward.com/InFormAdapter//;Trial=pfst
  45/Site={8CF36263-64E8-49E7-9355-424AFD6AD434}/Subject;DBUIDTuple:{2C69FFB8-
  DAA4-482F-BB2D-1FB176E4A7C5},193316154218003
</PatientLSID>
```

Discrepancy LSID

Identifies an InForm query for in a study.

URN:LSID:www.phaseforward.com:www.phaseforward.com/InFormAdapter//;Trial=<trial_alias>/Discrepancy;GuidTuple:<discrep_guid>,<discrep_rev>.000

Item	Description
www.phaseforward.com	The Authority ID for Oracle LSIDs.

Item	Description
www.phaseforward.com/InFormAdapter//;	The Namespace ID/subauthority reference for the InForm Adapter subsystem.
<trial_alias>	The alias for the InForm trial. This corresponds to the value found in the InForm table: INFORMADAPTER.PF_STUDYINFORMATION.ALIAS
<discrep_guid>	This corresponds to the value found in the InForm table: TRIALUSER.PF_DBUID.GUID (for the specific query id)
<discrep_rev>	This corresponds to the value found in the InForm table: TRIALUSER.PF_QUERY.QUERYREVISIONNUMBER (for the specific query id)

The DiscrepancyLSID element returns the discrepancy LSID.

Example—DiscrepancyLSID

```
<DiscrepancyLSID>
  URN:LSID:www.phaseforward.com:www.phaseforward.com/InFormAdapter//;Study=pfst
  45/Discrepancy;GuidTuple:c6b358ee-310a-4994-93e2-dba036c8733a,133373414310064
</DiscrepancyLSID>
```

Execution plan LSID

Identifies an execution plan in an InForm study.

```
URN:LSID:www.phaseforward.com:www.phaseforward.com/InFormAdapter//;Trial=<trial_
alias>/ExecutionPlan;RefNameTuple:<ep_name>,<queue_rev_number>.000
```

Item	Description
www.phaseforward.com	The Authority ID for Oracle LSIDs.
www.phaseforward.com/InFormAdapter//;	The Namespace ID/subauthority reference for the InForm Adapter subsystem.
<trial_alias>	The alias for the InForm trial. This corresponds to the value found in the InForm table: INFORMADAPTER_USER.PF_STUDYINFORMATION.ALIAS
<ep_name>	This corresponds to the value found in the InForm table: TRIALUSER.PF_EXECUTIONPLAN.EPREFNAME

Item	Description
<queue_rev_number>	This corresponds to the value found in the InForm table: TRIALUSER.PF_EXECUTIONQUEUE.QUEUEVEV SIONNUMBER (max, for the specific execution plan id from the execution plan table)

The PlanLSID element returns the execution plan LSID.

Example—PlanLSID

```
<PlanLSID>
  URN:LSID:www.phaseforward.com:www.phaseforward.com/InFormAdapter//;Trial=apps
  rv16_pfstevent/ExecutionPlan;RefNameTuple:EPScript,169679664314095.000
</PlanLSID>
```

Transaction LSID

Identifies that a change has occurred in an InForm trial.

```
URN:LSID:www.phaseforward.com:www.phaseforward.com/InFormAdapter//;Trial=<trial_
alias>/Transaction;GUID:<transaction_guid>
```

Item	Description
www.phaseforward.com	The Authority ID for Oracle LSIDs.
www.phaseforward.com/InFormAdapt er//;	The Namespace ID/subauthority reference for the InForm Adapter subsystem.
<trial_alias>	The alias for the InForm trial. This corresponds to the value found in the InForm table: INFORMADAPTER.PF_TRIALINFORMATION.ALI AS
<transaction_guid>	The value for the transaction GUID. This corresponds to the value found in the InForm table: TRIALUSER.PFEX_TRANSACTIONXML.EXTERN ALGUID

The EventID element returns the transaction LSID.

Example—EventID

```
<EventID>
  URN:LSID:www.phaseforward.com:www.phaseforward.com/InFormAdapter//;Trial=apps
  rv44_pfstevent/Transaction;GUID:41945e5d-f454-44c2-92b9-d1ce46486597
</EventID>
```

Location of .xsd files

For each of the following interfaces, the xsd files are located on the InForm Adapter server in the following location:

```
<installation_directory>\InForm Adapter\<interface_name>\bin\xsd
```

For example, the AdapterAdmin.xsd file is located at:

```
<installation_directory>\InForm Adapter\AdapterAdmin\bin\xsd\
```

Interface name	xsd files
AdapterAdmin	AdapterAdmin.xsd
Discrepancy	discrepancyInterface.xsd
ODM Export	ODM1-2-0.xsd ODMParameters.xsd PhaseForward_ODM.xsd
TransactionAdapter	externalMap.xsd InFormTransactionAdapter.xsd MedMLSchema.xsd SyncXMLSchema.xsd

CHAPTER 2

Adapter Admin interface

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Overview: InForm Adapter Admin interface

The InForm Adapter Admin interface receives study information from the InForm Server Adapter (ISA) and stores it in the InForm Adapter database. This connection information can be used by interfaces that may directly access the InForm study database, such as the ODM Export interface.

Input parameters and results

The InForm Adapter Admin web methods take a single XML element as an input parameter, and return a single XML element according to a specific XML schema.

Namespace

All XmlElement parameters are under the following namespace:

`http://www.phaseforward.com/InFormAdapter/AdapterAdmin/1.0`

where

1.0 specifies the version of the schema.

Public web methods

GetTrialList

Returns the list of all studies known to the InForm Adapter.

XmlElement **GetTrialList**(*XmlElement requestParams*)

Input parameters—GetTrialList

Takes a GetTrialList XML element as an input parameter.

Example requestGet—TrialList

```
<GetTrialList xmlns="http://www.phaseforward.com/InFormAdapter/AdapterAdmin/1.0" />
```

ResultsGet—TrialList

Returns an `ArrayOfTrial` XML element that contains a list of trial elements. Each trial element contains the following attributes.

Attribute	Description
ID	An identifier that uniquely identifies the study definition.
trialName	The name of the study, as defined in its InForm installation.
alias	An optional identifier that may be used to uniquely identify a study that has the same name as a study on another InForm server.
connectionString	The Oracle TNS name used to locate the Oracle database where the study resides.
user	An Oracle username used to log in to the study database.
password	The password of the Oracle user.
ServerName	The name of the InForm Adapter server that is used to process InForm transactions for this study.

Example response—GetTrialList

```
<ArrayOfTrial
  <Trial ID="97569ec9-80d7-4a8b-9341-066342b5d7a1" alias="JDIA.jim"
    trialName="JIM"
      connectionString="jdia_dev1" user="configuid" Password="configpid"
      ServerName="JDIA" />
</ArrayOfTrial>
```

SetTrial

Adds a new study to the InForm Adapter configuration, or updates a study if it already exists. If the trial you are registering is for the InForm application version 6.1 or above, the InForm Adapter software registers the trial with Integration Manager, which is part of the InForm 6.1 application. For more information, see the InForm 6.1 documentation.

XmlElement **SetTrial**(*XmlElement requestParams*)

Input parameters—SetTrial

Takes a SetTrial XML element as an input parameter.

Attribute	Description
trialName	The name of the study, as defined in its InForm installation.
alias	An optional identifier that can be used to uniquely identify a study that shares a name with another study on a different server.
oracleConnectionStr	The Oracle TNS name that is used to locate the Oracle database where the study resides.
userID	An Oracle username that may be used to log into the study database.
password	The password of the Oracle user.
Server	The name of the machine hosting the InForm Server Adapter (ISA) that is used to process InForm transactions for this study. Note: You must specify a value if you are using the Coding, Discrepancy, or Transaction interfaces.

Example request—SetTrial

```
<SetTrial xmlns="http://www.phaseforward.com/InFormAdapter/AdapterAdmin/1.0"
  trialName="JIM" alias="appsrv23.JIM" oracleConnectionStr="appsrv23_dev1"
  userID="jimuid" password="jimpid" server="APPSRV23" />
```

Results

Returns a Result XML element that indicates whether the study definition was added or modified successfully. If you are using InForm 6.1 or later, SetTrial registers the InForm Adapter software for this trial with the InForm Integration Manager.

Example response—SetTrial

```
<Result
  xmlns="http://www.phaseforward.com/InFormAdapter/AdapterAdmin/1.0">True</Result>
```


RemoveTrial

Removes an existing study definition from the InForm Adapter configuration.

XmlElement **RemoveTrial**(*XmlElement requestParams*)

Note: RemoveTrial does not affect the InForm study.

Input parameters—RemoveTrial

Takes a RemoveTrial XML element as an input parameter.

Attribute	Description
trial	The name of the study to be removed. If there are multiple studies with this name, the alias of the study must be used.

Example request—RemoveTrial

```
<RemoveTrial xmlns="http://www.phaseforward.com/InFormAdapter/AdapterAdmin/1.0"
  trial="ntahodeueu" />
```

Results

Returns a Result XML element that indicates whether the study was successfully deleted.

Example response—RemoveTrial

```
<Result
  xmlns="http://www.phaseforward.com/InFormAdapter/AdapterAdmin/1.0">True</Result>
```

SetServer

Adds a server definition to the InForm Adapter configuration.

XmlElement **SetServer**(*XmlElement requestParams*)

Input parameters—SetServer

Takes a SetServer XML element as an input parameter.

Attribute	Description
server	A unique name for the server.
url	The URL that can be used to access the InForm Server Adapter web service. On a typical installation, this is <code>http://<i>servername</i>/InFormAdapter/ServerAdapter/ServerAdapter.asmx</code>

Attribute	Description
testURL	<p>Values: true, false.</p> <p>If true, SetServer checks the URL that is entered in the SOAP header of the request. If the syntax is invalid, or if the URL points to an incorrect location, one of the following exceptions is returned in the SOAP exception:</p> <ul style="list-style-type: none"> • The specified Server Adapter URL is invalid. Please check the URL syntax. • The Server Adapter web service does not exist at the specified URL.

Example request—SetServer

```
<SetServer xmlns="http://www.phaseforward.com/InFormAdapter/AdapterAdmin/1.0"
  server="JDIA"
  url="http://servername/InFormAdapter/ServerAdapter/ServerAdapter.asmx"
  testURL="true" />
```

Results—SetServer

Returns a Result XML element that indicates if the server was successfully created.

Example response—SetServer

```
<Result
  xmlns="http://www.phaseforward.com/InFormAdapter/AdapterAdmin/1.0">True</Result>
```

RemoveServer

Removes an existing server definition from the InForm Adapter configuration.

XmlElement **RemoveServer**(*XmlElement requestParams*)

Note: RemoveTrial does not affect the InForm server.

Input parameters—RemoveServer

Takes a RemoveServer XML element as an input parameter.

Attribute	Description
server	The name of the server definition to be removed.

Example request—RemoveServer

```
<RemoveServer xmlns="http://www.phaseforward.com/InFormAdapter/AdapterAdmin/1.0"
  server="JDIA" />
```

Results—RemoveServer

Returns a Result XML element that indicates if the server definition was successfully removed.

Example response—RemoveServer

```
<Result
xmlns="http://www.phaseforward.com/InFormAdapter/AdapterAdmin/1.0">True</Result>
```

GetServerList

Returns the list of all servers known to the InForm Adapter software.

XmlElement **GetServerList**(*XmlElement requestParams*)

Input parameters—GetServerList

Takes a GetServerList XML element as an input parameter.

Example request—GetServerList

```
<GetServerList
xmlns="http://www.phaseforward.com/InFormAdapter/AdapterAdmin/1.0" />
```

Results—GetServerList

Returns an ArrayOfServerAdapter XML element that contains a list of all ServerAdapter elements servers known to the InForm Adapter software. Each ServerAdapter element has the following attributes:

Attribute	Description
ID	An identifier that uniquely identifies the server definition.
Name	The name of the study, as defined in its InForm installation.
Url	The URL of the ServerAdapter web service for the server.

Example response—GetServerList

```
<ArrayOfServerAdapter>
  <ServerAdapter
    ID="167cf837-f996-459e-a27b-5ae115b35c25"
    Name="APPSRV44"
    Url="http://servername/InFormAdapter/ServerAdapter/ServerAdapter.asmx" />
</ArrayOfServerAdapter>
```

GetRequestUsers

Returns a list of the users that are used to authenticate a connection between one InForm Adapter interface and an InForm Server Adapter. The caller can request users by:

- Name.
- Domain.
- Host name of the computer where the InForm Server Adapter is located.

XmlElement **GetRequestUsers**(*XmlElement requestParams*)

Input parameters—GetRequestUsers

Takes a GetRequestUser XML element as an input parameter.

Attribute	Description
SearchMethod	<p>An optional integer attribute that indicates the field to search for, with the following valid values:</p> <ul style="list-style-type: none"> • 0—Search for all users that match the specified user id. • 1—Search for all users in the specified domain. • 2—Search for the user that matches the specified destination. <p>If SearchMethod is not specified, the default user is returned.</p>

The RequestUserInformation XML element contains the search criteria for the GetRequestUser method.

RequestUserInformation has the following attributes.

Attribute	Description
Destination	If the SearchMethod is specified and set to 2, this is the Destination value to search for. Otherwise, this field is ignored.
UserId	If the SearchMethod is specified and set to 0, this is the UserId value to search for. Otherwise, this field is ignored.
Password	For GetRequestUsers(), this field is always ignored.
Domain	If the SearchMethod is specified and set to 1, this is the Domain value to search for. Otherwise, this field is ignored.

Example request—GetRequestUsers

```
<GetRequestUser
xmlns="http://www.phaseforward.com/InFormAdapter/AdapterAdmin/1.0"
  SearchMethod="2" >
  <RequestUserInformation
    Destination="smithxp.north.pf.com"
    UserId=""
    Password=""
    Domain="" />
</GetRequestUser>
```

Results—GetRequestUsers

Returns an `ArrayOfNTSecurity` XML element that lists the `NTSecurity` elements that match the specified search.

Attribute	Description
ID	An identifier that uniquely identifies the user definition.
Destination	The host name of the machine that hosts the InForm Server Adapter.
UserId	A user id that has permissions to connect to the InForm Server Adapter.
Password	The password for the user id.
Domain	The domain to which the user belongs.

Example response—GetRequestUsers

```
<ArrayOfNTSecurity>
  <NTSecurity
    ID="a63de481-a178-480b-b5c1-987c11e4f827"
    Destination="smithxp.north.pf.com"
    UserId="smith"
    Password="whatever"
    Domain="north" />
</ArrayOfNTSecurity>
```

ConfigureRequestUser

Adds or modifies a user to be used to authenticate a connection between one InForm Adapter interface and an InForm Server Adapter.

XmlElement **ConfigureRequestUser**(*XmlElement requestParams*)

Input parameters—ConfigureRequestUser

Takes a `ConfigureRequestUser` XML element as an input parameter.

The `ConfigureRequestUser` element has one child element.

Child	Description
RequestUserInformation	A RequestUserInformation element, which contains the definition of the user to be added or modified.

The RequestUserInformation element has the following attributes:

Attribute	Description
Destination	The unique host name of the computer that hosts an instance of the InForm Server Adapter. If the user calls ConfigureRequestUser() and specifies a destination that exists, that record will be modified with the new values.
UserId	A user id that has permissions to connect to the InForm Server Adapter.
Password	The password for the user ID.
Domain	The domain to which the user belongs.

Example Request—ConfigureRequestuser

```
<ConfigureRequestUser
xmlns="http://www.phaseforward.com/InFormAdapter/AdapterAdmin/1.0">
  <RequestUserInformation
    Destination="smithxp.north.pf.com"
    UserId="smith"
    Password="b3ansNr1ce"
    Domain="north" />
</ConfigureRequestUser>
```

Results—ConfigureRequestUser

Returns a Result XML element that indicates whether the server was successfully created or modified.

Example Response—ConfigureRequestUser

```
<Result
xmlns="http://www.phaseforward.com/InFormAdapter/AdapterAdmin/1.0">True</Result>
```

CHAPTER 3

Discrepancy Enhanced interface

In this chapter

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Overview: Discrepancy Enhanced interface

The Discrepancy Enhanced interface sends discrepancies (clinical queries) and their resolutions between the InForm software and other systems or modules.

- For a study, site, subject, or list of subjects, you can retrieve discrepancies of a specific type, or retrieve a count of discrepancies in the form of [Subject, State, Guid].
- For an item, you can issue a candidate or open discrepancy, retrieve all discrepancies, or retrieve discrepancies of a specific type.
- For a discrepancy, or list of discrepancies identified by a GUID, you can answer or close a discrepancy, delete a candidate discrepancy, reissue an answered discrepancy, and retrieve discrepancy details.
- You can close a set of answered discrepancies in a single transaction.
- The Discrepancy Enhanced interface can determine whether the requested target of a discrepancy maps to another item, and issue the discrepancy against the mapped (target) item.

For more information, see *Use cases* (on page 48).

The Discrepancy Enhanced interface includes the following operations.

Operation	Description
Summary reporting operations	
<i>GetSummaryCounts</i> (on page 29)	Retrieves a count of discrepancies against the requested site, subject, and visit criteria.
Detail reporting operations	
<i>GetByCriteria</i> (on page 31)	Retrieves details for all discrepancies that match the requested criteria.
<i>GetByDiscrepancyGuid</i> (on page 36)	Retrieves the current detail for the requested discrepancies.
<i>GetHistorybyDiscrepancyGuid</i> (on page 39)	Retrieves the revision history for the requested discrepancies, on a per-study basis.
<i>GetByTransactionID</i> (on page 40)	Retrieves the revision of each discrepancy that is associated with the specified TransactionId.
Data modifying operations	
<i>Issue</i> (on page 41)	Issues a new discrepancy in an Open or Candidate state.
<i>Update</i> (on page 45)	Updates a discrepancy for a single study.

Programming model and operations

Writing requests

Each request is enclosed in a SOAP envelope that begins with a SOAP header, followed by a Body statement that includes the operation and field values.

For examples of Body statements, see the individual *Operations* (on page 29).

SOAP header

The SOAP header contains information about the service, the message, and the sender. It must include all of the following fields.

Note: The requirement for requests to contain the `wsu:Timestamp`, `wsse:Username`, and `wsse:Password` elements is defined in the WSDL by `ws-policy`.

If your web service toolkit does not support `ws-policy`, you must manually add these elements to the web service request.

Field	Description	Standard
<code>wsa:Action</code>	SOAP action for the operation. Include this field as part of the summary for each SOAP operation.	WS-Addressing
<code>wsa:MessageID</code>	Unique ID for the message.	WS-Addressing
<code>wsa:ReplyTo</code>	Use the value that is shown in the example.	WS-Addressing
<code>wsa:To</code>	Full URL of the service. Note: The full URL is different for each customer.	WS-Addressing
<code>wsu:Timestamp</code>	Time the message was created and when it expires. Oracle recommends a 5-minute time window. The software allows for five minutes of clock drift between servers. This value can be modified in the <code>web.config</code> file by setting the <code>MaxClockSkew</code> value.	SOAP Message Security 1.0
<code>wsse:Username</code>	User name of the user in the InForm study.	SOAP Message Security 1.0
<code>wsse:Password</code>	Password of the user in the InForm study.	SOAP Message Security 1.0

How requests are processed

Changes that you specify in a single call occur as part of an atomic unit and are applied immediately on successful completion of the call. If one change contains an error, none of the changes are applied. For example, if you attempt to issue five discrepancies, and you specify invalid data for one discrepancy, none of the discrepancies is issued.

Requests are subject to the following constraints:

- **Processing time**—The maximum allowed time for a single request is five minutes. Processing that exceeds the maximum time results in an error.
- **Size of requests**—Requests must be smaller than 5 MB.
- **Case-sensitivity**—The Enhanced Discrepancy interface operations require the same case-sensitivity rule as the InForm application—object references by name are case-sensitive. Objects whose names contain different cases (for example, "cra" and "CRA") are different objects.
- **Sequence of operations**—The caller is responsible for sequencing operations as required for semantic correctness (for example, a discrepancy must exist before it can be updated).

Before the request is processed, the following operations are performed:

- The server logs the request (operation and user name only) to the event log for historical analysis.
- The user name and password are extracted from the SOAP header and are validated against the InForm database. Only requests with valid credentials for active accounts are accepted and processed.

Multiple repeat requests with invalid passwords will disable the account and require administrative action according to existing InForm business logic. The allowed number of failed log-on attempts is set in the InForm application on the System Configuration page.

- Parameters are validated. If the request contains invalid content, an error is returned. For example, schema validation and InForm character restrictions are enforced.

Operations

Operation	Description
Summary reporting operations	
<i>GetSummaryCounts</i> (on page 29)	Retrieves a count of discrepancies against the requested site, subject, and visit criteria.
Detail reporting operations	
<i>GetByCriteria</i> (on page 31)	Retrieves details for all discrepancies that match the requested criteria.
<i>GetByDiscrepancyGuid</i> (on page 36)	Retrieves the current detail for the requested discrepancies.
<i>GetHistorybyDiscrepancyGuid</i> (on page 39)	Retrieves the revision history for the requested discrepancies, on a per-study basis.
<i>GetByTransactionID</i> (on page 40)	Retrieves the revision of each discrepancy that is associated with the specified TransactionId.
Data modifying operations	
<i>Issue</i> (on page 41)	Issues a new discrepancy in an Open or Candidate state.
<i>Update</i> (on page 45)	Updates a discrepancy for a single study.

GetSummaryCounts

Retrieves a count of discrepancies against the requested site, subject, and visit criteria.

For example, for a specified trial, returns the number of discrepancies in each state.

Input parameters—GetSummaryCounts

Takes a SummaryRequest XML element as an input parameter.

SummaryRequest takes a list of study names and study-related criteria as input parameters.

The site, subject, and visit criteria that you specify form an SQL query that uses AND between each item. Criteria items that are not specified are not included in the query.

```
SummaryFilterList / SummaryFilter/<parameters>
```

SummaryRequest	
Parameter	Description
authenticationTrialName	The study in which the discrepancies are issued or updated. If username/password authentication is enabled, the username and password that you specify in the SOAP header are authenticated against this study name.

SummaryRequest	
Parameter	Description
DiscrepancyType	The type of query. Values: Manual or Auto. Optional.
SiteIdList	A list of site IDs. Maximum number of site IDs in a single request: 1000.
SubjectGuidList	A list of subject GUIDs. Maximum number of GUIDs in a single request: 1000.
VisitList	A list of refnametuples. Each refnametuple indicates data related to a visit, such as name, revision, and index. Maximum number of refnametuples in a single request: 1000.

Example request—GetSummaryCounts

The example shows the Body of the request, which is preceded by the *SOAP header* (on page 27).

```
<GetSummaryCounts
xmlns="http://www.phaseforward.com/InForm/2010/01/Discrepancy">
  <SummaryRequest authenticationTrialName="testtrial">
    <SummaryFilterList >
      <SummaryFilter FilterName="My filter 1">
        <TrialName>testtrial</TrialName>
        <DiscrepancyType>Auto</DiscrepancyType>
        <TrialCriteria>
          <SiteIdList>
            <Id>7600</Id>
          </SiteIdList>
          <SubjectGuidList>
            <Guid>{8136950C-7676-4ED6-84AE-AE965E12A6E7}</Guid>
          </SubjectGuidList>
          <VisitList>
            <Visit>
              <Name>vstCORE1</Name>
              <Index>1</Index>
            </Visit>
          </VisitList>
        </TrialCriteria>
      </SummaryFilter>
    </SummaryFilterList>
  </SummaryRequest>
</GetSummaryCounts>
```

Results—GetSummaryCounts

Returns a list of counts by discrepancy state for each study requested.

Example response—GetSummaryCounts

```

GetSummaryCountsResponse
xmlns="http://www.phaseforward.com/InForm/2010/01/Discrepancy">
  <GetSummaryCountsResult>
    <SummaryFilterResultList >
      <SummaryFilterResult FilterName="My filter 1">
        <TrialName>testtrial</TrialName>
        <DiscrepancyStateCountList>
          <DiscrepancyStateCount>
            <State>Answered</State>
            <Count>1</Count>
          </DiscrepancyStateCount>
          <DiscrepancyStateCount>
            <State>Closed</State>
            <Count>2</Count>
          </DiscrepancyStateCount>
        </DiscrepancyStateCountList>
      </SummaryFilterResult>
    </SummaryFilterResultList>
  </GetSummaryCountsResult>
</GetSummaryCountsResponse>

```

GetByCriteria

Retrieves details for all discrepancies that match the requested criteria.

Criteria can be specified in two ways:

- By site, subject, and/or visit.
- By InForm item, specified by any of the following ways:
 - By DBUID or by GUID

The DBUID or GUID is the identifier for the record in the PF_ItemContext table.
 - By populating a structure containing members that hold the data found in an LSID.

Input parameters—GetByCriteria

Takes a DetailByCriteriaRequest XML element as an input parameter.

DetailByCriteriaRequest has the following parameters and child elements.

Note: Some parameters are specific to the encapsulated InFormItem type.

DetailByCriteriaRequest	
Parameter or Child element > parameter	Description
authenticationTrialName	The study in which the discrepancies are issued or updated. If username/password authentication is enabled, the username and password that you specify in the SOAP header are authenticated against this study name.
CurrentStateList	If specified, only the records in the specified states are included in the result set.
StateChangesAfter	If specified, only the records that have changes in state that occur after this date are include in the result set. Date format: YYYY-MM-DD'THH:MM:SS
IncludeHistory	Values: True, False. True: All state changes for the relevant discrepancies are included in the result set. False: Only the most recent (current) state of the discrepancy is included in the result set.
IssuedOrUpdatedByUserNameList	A list of user names. If specified, only discrepancies that were issued or updated by one of the names in the list are included in the result set. Maximum number of usernames in a single request: 1000.
DiscrepancyType	Values: Auto, Manual. If specified, only discrepancies of the specified type are included in the result set. If not specified, both types are returned.
Bookmark	A response includes a bookmark if there are more records that match the requested criteria. The caller passes in this bookmark on a subsequent call to return the remaining records. Absence of a bookmark indicates that the caller wants to receive the first set of records that match the criteria. Note: When using bookmarks, the subsequent requests must be identical to the first request. If you use different parameter values in subsequent calls, errors and unexpected results will occur.
ResultsetSize	The number of records to be retrieved in a single call. Default: 1000. Maximum: 2000.

DetailByCriteriaRequest	
Parameter or Child element > parameter	Description
DetailCriteriaFilter element	<p>Element that contains TrialCriteria or ItemCriteria child elements.</p> <p>Note: A single DetailCriteriaFilter element can contain either TrialCriteria elements or ItemCriteria elements, but not both.</p> <ul style="list-style-type: none"> • TrialCriteria: The site, subject, and visit criteria that you specify form an SQL query that uses AND between each item. Criteria items that are not specified are not included in the query. • ItemCriteria: item-identifying types form a query that uses OR between each item.
TrialCriteria > SiteIdList	<p>A list of site IDs.</p> <p>Maximum number of site IDs in a single request: 1000.</p>
TrialCriteria > SubjectGuidList	<p>A list of subject GUIDs.</p> <p>Maximum number of GUIDs in a single request: 1000.</p>
TrialCriteria > VisitList	<p>A list of refnametuples in which each refnametuple identifies a visit.</p> <p>Maximum number of refnametuples in a single request: 1000.</p>
ItemCriteria > InFormItemDbuidList	<p>A list of DBUIDs that identifies an InForm item.</p> <p>Maximum number of DBUIDs in a single request: 1000.</p>
ItemCriteria > InFormItemGuidList	<p>A list of GUIDs that identifies an InForm item.</p> <p>Maximum number of GUIDs in a single request: 1000.</p>
itemCriteria > InFormItemList	<p>All data that is needed to identify an InForm item. Do not include the study name.</p> <p>Maximum number of InForm items: 1000.</p>

Example request—GetByCriteria

The example shows the Body of the request, which is preceded by the *SOAP header* (on page 27).

```
<GetByCriteria xmlns="http://www.phaseforward.com/InForm/2010/01/Discrepancy">
  <DetailByCriteriaRequest authenticationTrialName="testtrial">
    <ResultsetSize >
      100</ResultsetSize>
    <DetailCriteriaFilterList >
      <DetailCriteriaFilter FilterName="My filter 1">
        <TrialName>testtrial</TrialName>
        <CurrentStateList>
          <State>Answered</State>
        </CurrentStateList>
        <DiscrepancyType>Auto</DiscrepancyType>
        <StateChangesAfter>2006-01-01T00:00:00</StateChangesAfter>
        <IncludeHistory>true</IncludeHistory>
        <IssuedOrUpdatedByUsernameList>
          <Name>system</Name>
        </IssuedOrUpdatedByUsernameList>
        <TrialCriteria>
          <SiteIdList>
            <Id>7600</Id>
          </SiteIdList>
          <SubjectGuidList>
            <Guid>{8136950C-7676-4ED6-84AE-AE965E12A6E7}</Guid>
          </SubjectGuidList>
          <VisitList>
            <Visit>
              <Name>vstCORE1</Name>
              <Index>1</Index>
            </Visit>
          </VisitList>
        </TrialCriteria>
      </DetailCriteriaFilter>
    <DetailCriteriaFilter>
      <TrialName>testtrial</TrialName>
      <ItemCriteria>
        <InFormItemDbuidList>
          <Dbuid>62232</Dbuid>
        </InFormItemDbuidList>
        <InFormItemGuidList>
          <Guid>{2DA84C24-9985-4B72-9FDE-6E643492451F}</Guid>
        </InFormItemGuidList>
        <InFormItemList>
          <InFormItem>
            <SiteId>7600</SiteId>
            <SubjectGuid>
              {860C66AE-6AFE-49CE-A707-35D9F01EC982}</SubjectGuid>
            <Visit>
              <Name>vstBASE</Name>
              <Index>1</Index>
            </Visit>
            <Form>
              <Name>frmDOV</Name>
              <Revision>153925409031062</Revision>
              <Index>1</Index>
            </Form>
            <SectionName>DOV</SectionName>
            <ItemName>DOV</ItemName>
          </InFormItem>
        </InFormItemList>
      </ItemCriteria>
    </DetailCriteriaFilter>
  </DetailCriteriaFilterList>
</DetailByCriteriaRequest>
</GetByCriteria>
```


Results—GetByCriteria

Returns data related to the current state of the discrepancies that meet the criteria.

Example response—GetByCriteria

```
<GetByCriteriaResponse
xmlns="http://www.phaseforward.com/InForm/2010/01/Discrepancy">
  <GetByCriteriaResult>
    <DetailFilterResultList>
      <DetailFilterResult DetailFilterName="My filter 1">
        <TrialName>testtrial</TrialName>
        <DiscrepancyList>
          <Discrepancy>
            <Guid>{EE68BF95-0A90-42A1-B8EA-5B2EB1FA43B2}</Guid>
            <Revision>198749271718028</Revision>
            <State>Answered</State>
            <Type>Auto</Type>
            <Reissued>>false</Reissued>
            <Reason>Original value is correct</Reason>
            <UserName>system</UserName>
            <InFormItem>
              <SiteId>7600</SiteId>
              <SubjectGuid>
                {8136950C-7676-4ED6-84AE-AE965E12A6E7}</SubjectGuid>
              <Visit>
                <Name>vstCORE1</Name>
                <Index>1</Index>
              </Visit>
              <Form>
                <Name>frmVS</Name>
                <Revision>153925473296062</Revision>
                <Index>1</Index>
              </Form>
              <SectionName>sctVS</SectionName>
              <ItemName>itmVSRespRte</ItemName>
            </InFormItem>
          </Discrepancy>
        </DiscrepancyList>
      </DetailFilterResult>
      <DetailFilterResult DetailFilterName="DetailFilter 2">
        <TrialName>testtrial</TrialName>
        <DiscrepancyList>
          <Discrepancy>
            <Guid>{F673B574-02E5-4634-99AF-E233A2F2E412}</Guid>
            <Revision>227438221887048</Revision>
            <State>Opened</State>
            <Type>Auto</Type>
            <Reissued>>false</Reissued>
            <Reason>No was selected, but reason for dose change or
              missed medication was provided; please correct.</Reason>
            <UserName>autoquery</UserName>
            <InFormItem>
              <SiteId>7600</SiteId>
              <SubjectGuid>
                {8136950C-7676-4ED6-84AE-AE965E12A6E7}</SubjectGuid>
              <Visit>
                <Name>CommonCRF</Name>
                <Index>1</Index>
              </Visit>
              <Form>
                <Name>frmDOSE</Name>
                <Revision>153925414734062</Revision>
                <Index>1</Index>
              </Form>
              <SectionName>sctDOSE</SectionName>
              <ItemSet>
                <Name>itsDOSE</Name>
                <Order>227438221778048</Order>
              </ItemSet>
            </InFormItem>
          </Discrepancy>
        </DiscrepancyList>
      </DetailFilterResult>
    </DetailFilterResultList>
  </GetByCriteriaResult>
</GetByCriteriaResponse>
```

```

        <ItemName>itmDOSEMissed</ItemName>
      </InFormItem>
    </Discrepancy>
  </Discrepancy>
  <Guid>{27D7F5CD-A0A8-4131-BCD0-7E5F6D178467}</Guid>
  <Revision>234273542952019</Revision>
  <State>Opened</State>
  <Type>Manual</Type>
  <Reissued>>false</Reissued>
  <Reason>Item incomplete</Reason>
  <UserName>system</UserName>
  <InFormItem>
    <SiteId>7600</SiteId>
    <SubjectGuid>
      {8136950C-7676-4ED6-84AE-AE965E12A6E7}</SubjectGuid>
    <Visit>
      <Name>vstBASE</Name>
      <Index>1</Index>
    </Visit>
    <Form>
      <Name>frmDem</Name>
      <Revision>153925408218062</Revision>
      <Index>1</Index>
    </Form>
    <SectionName>sctFH</SectionName>
    <ItemName>itmFHDep</ItemName>
  </InFormItem>
</Discrepancy>
</DiscrepancyList>
</DetailFilterResult>
</DetailFilterResultList>
</GetByCriteriaResult>
</GetByCriteriaResponse>

```

GetByDiscrepancyGuid

Retrieves the current detail for the requested discrepancies.

Input parameters—GetByDiscrepancyGuid

Takes a DetailByGuidRequest XML element as an input parameter.

DetailByGuidRequest takes one or more study names, each with an associated list of Discrepancy GUIDs.

DetailByGuidRequest	
Parameter	Description
authenticationTrialName	The study in which the discrepancies are issued or updated. If username/password authentication is enabled, the username and password that you specify in the SOAP header are authenticated against this study name.
StateChangesAfter	If specified, only the records that have changes in state that occur after this date are include in the result set. Date format: YYYY-MM-DD'THH:MM:SS
DiscrepancyGuidList	A list of GUIDS associated with the specified study name. Maximum number of GUIDs in a single request: 1000.

DetailByGuidRequest	
Parameter	Description
Bookmark	<p>A response includes a bookmark if there are more records that match the requested criteria.</p> <p>The caller passes in this bookmark on a subsequent call to return the remaining records.</p> <p>Absence of a bookmark indicates that the caller wants to receive the first set of records that match the criteria.</p> <p>Note: When using bookmarks, the subsequent requests must be identical to the first request. If you use different parameter values in subsequent calls, errors and unexpected results will occur.</p>
ResultSetSize	<p>The number of records to be retrieved in a single call.</p> <p>Default: 1000. Maximum: 2000.</p>

Example request—GetByDiscrepancyGuid

The example shows the Body of the request, which is preceded by the *SOAP header* (on page 27).

```
<GetByDiscrepancyGuid
xmlns="http://www.phaseforward.com/InForm/2010/01/Discrepancy">
  <DetailByGuidRequest authenticationTrialName="testtrial">
    <ResultSetSize>
      100</ResultSetSize>
    <DetailGuidFilterList>
      <DetailGuidFilter FilterName="My filter 1">
        <TrialName>testtrial</TrialName>
        <StateChangesAfter>2006-01-01T00:00:00</StateChangesAfter>
        <DiscrepancyGuidList>
          <Guid>{6E50F337-9A64-4ABD-9F13-CD568FA480C1}</Guid>
          <Guid>{F673B574-02E5-4634-99AF-E233A2F2E412}</Guid>
        </DiscrepancyGuidList>
      </DetailGuidFilter>
    </DetailGuidFilterList>
  </DetailByGuidRequest>
</GetByDiscrepancyGuid>
```

Results—GetByDiscrepancyGuid

Response schema and supporting types: uses same response schema as GetByCriteria.

Example response—GetByDiscrepancyGuid

```

<GetByDiscrepancyGuidResponse
xmlns="http://www.phaseforward.com/InForm/2010/01/Discrepancy">
  <GetByDiscrepancyGuidResult>
    <DetailFilterResultList>
      <DetailFilterResult DetailFilterName="My filter 1">
        <TrialName>testtrial</TrialName>
        <DiscrepancyList>
          <Discrepancy>
            <Guid>{6E50F337-9A64-4ABD-9F13-CD568FA480C1}</Guid>
            <Revision>155222540031037</Revision>
            <State>Opened</State>
            <Type>Auto</Type>
            <Reissued>>false</Reissued>
            <Reason>Value is not within the expected range; please
            verify</Reason>
            <UserName>autoquery</UserName>
            <InFormItem>
              <SiteId>7600</SiteId>
              <SubjectGuid>
                {4913C98C-722B-46DE-916E-B62D833CC96E}</SubjectGuid>
              <Visit>
                <Name>vstBASE</Name>
                <Index>1</Index>
              </Visit>
              <Form>
                <Name>frmDem</Name>
                <Revision>153925408218062</Revision>
                <Index>1</Index>
              </Form>
              <SectionName>sctDem</SectionName>
              <ItemName>itmDemHgt</ItemName>
            </InFormItem>
          </Discrepancy>
          <Discrepancy>
            <Guid>{F673B574-02E5-4634-99AF-E233A2F2E412}</Guid>
            <Revision>227438221887048</Revision>
            <State>Opened</State>
            <Type>Auto</Type>
            <Reissued>>false</Reissued>
            <Reason>No was selected, but reason for dose change or
            missed medication was provided; please correct.</Reason>
            <UserName>autoquery</UserName>
            <InFormItem>
              <SiteId>7600</SiteId>
              <SubjectGuid>
                {8136950C-7676-4ED6-84AE-AE965E12A6E7}</SubjectGuid>
              <Visit>
                <Name>CommonCRF</Name>
                <Index>1</Index>
              </Visit>
              <Form>
                <Name>frmDOSE</Name>
                <Revision>153925414734062</Revision>
                <Index>1</Index>
              </Form>
              <SectionName>sctDOSE</SectionName>
              <ItemSet>
                <Name>itsDOSE</Name>
                <Order>227438221778048</Order>
              </ItemSet>
              <ItemName>itmDOSEMissed</ItemName>
            </InFormItem>
          </Discrepancy>
        </DiscrepancyList>
      </DetailFilterResult>
    </DetailFilterResultList>
  </GetByDiscrepancyGuidResult>
</GetByDiscrepancyGuidResponse>

```

GetHistoryByDiscrepancyGuid

Retrieves the revision history for the requested discrepancies, on a per-study basis.

Input parameters—GetHistoryByDiscrepancyGuid

Takes a HistoryByGuidRequest XML element as an input parameter.

HistoryByGuidRequest takes a study name with an associated list of GUID and revision number pairs. The GUID is the unique identifier for a discrepancy.

HistoryByGuidRequest	
Parameter	Description
authenticationTrialName	The study in which the discrepancies are issued or updated. If username/password authentication is enabled, the username and password that you specify in the SOAP header are authenticated against this study name.
DiscrepancyIdentifierList	A list of DiscrepancyIdentifiers that are associated with the specified study name.
DiscrepancyIdentifier	A GUID and revision number pair. Revision number is optional. You can pass in as many GUID and revision number pairs as you like, on a per-study basis. If you specify a revision number, the result set is limited to records that have a revision number greater than the one you specified.

Example request—GetHistoryByDiscrepancyGuid

The example shows the Body of the request, which is preceded by the *SOAP header* (on page 27).

```
<GetHistoryByDiscrepancyGuid
xmlns="http://www.phaseforward.com/InForm/2010/01/Discrepancy">
  <HistoryByGuidRequest authenticationTrialName="testtrial">
    <DiscrepancyIdentifierList>
      <DiscrepancyIdentifier>
        <Guid>{D905028E-48D5-4EEF-AB40-E18B8CFAAF76}</Guid>
        <Revision>234807295233074</Revision>
      </DiscrepancyIdentifier>
    </DiscrepancyIdentifierList>
  </HistoryByGuidRequest>
</GetHistoryByDiscrepancyGuid>
```

Results—GetHistoryByDiscrepancyGuid

The response includes a list of all revisions that meet the specified criteria for the specified discrepancies. Results are listed in order by GUID and then by revision number.

Example response—GetHistoryByDiscrepancyGuid

```
<GetHistoryByDiscrepancyGuidResponse
xmlns="http://www.phaseforward.com/InForm/2010/01/Discrepancy">
  <GetHistoryByDiscrepancyGuidResult>
    <DiscrepancyRevisionInstanceList>
      <DiscrepancyRevisionInstance>
        <Guid>{D905028E-48D5-4EEF-AB40-E18B8CFAAF76}</Guid>
        <Revision>234807447030074</Revision>
        <State>Deleted</State>
        <Type>Manual</Type>
        <Reissued>>false</Reissued>
        <Reason>Deleting this query.</Reason>
        <DateEntered>2008-06-10T21:17:26-04:00</DateEntered>
        <UserName>mroberts</UserName>
      </DiscrepancyRevisionInstance>
    </DiscrepancyRevisionInstanceList>
  </GetHistoryByDiscrepancyGuidResult>
</GetHistoryByDiscrepancyGuidResponse>
```

GetByTransactionId

Retrieves the revision of each discrepancy that is associated with the specified TransactionId.

This operation gives callers of the *Issue* (on page 41) and *Update* (on page 45) operations the means to identify, at a later time, exactly which discrepancies were issued or updated. If an Issue request times out, but commits to the database, the client can use GetByTransactionId to determine the details of the discrepancies that were committed to the database.

Input parameters—GetByTransactionId

Takes a DetailByTransactionIdRequest as an input parameter.

DetailByTransactionIdRequest has the following parameters.

DetailByTransactionIdRequest	
Parameter	Description
authenticationTrialName	The study in which the discrepancies are issued or updated. If username/password authentication is enabled, the username and password that you specify in the SOAP header are authenticated against this study name.
TransactionId	A GUID that is used to identify the particular transaction.

Example request —GetByTransactionId

The example shows the Body of the request, which is preceded by the *SOAP header* (on page 27).

```
<GetByTransactionId
xmlns="http://www.phaseforward.com/InForm/2010/01/Discrepancy">
  <DetailByTransactionIdRequest authenticationTrialName="testtrial">
    <TransactionId>
      {5F03D922-5E8C-4363-94AE-05DF51660D16}</TransactionId>
    </DetailByTransactionIdRequest>
</GetByTransactionId>
```

Results—GetByTransactionId

Example response—GetByTransactionId

```
<GetByTransactionIdResponse
xmlns="http://www.phaseforward.com/InForm/2010/01/Discrepancy">
  <GetByTransactionIdResult>
    <DiscrepancyRevisionInstanceList>
      <DiscrepancyRevisionInstance>
        <Guid>{27D7F5CD-A0A8-4131-BCD0-7E5F6D178467}</Guid>
        <Revision>234273542952019</Revision>
        <State>Opened</State>
        <Type>Manual</Type>
        <Reissued>>false</Reissued>
        <Reason>Item incomplete</Reason>
        <DateEntered>2008-06-04T16:59:02-04:00</DateEntered>
        <UserName>system</UserName>
      </DiscrepancyRevisionInstance>
    </DiscrepancyRevisionInstanceList>
  </GetByTransactionIdResult>
</GetByTransactionIdResponse>
```

Issue

Issues a new discrepancy in an Open or Candidate state.

This functionality equates to the following InForm rights:

- Enter a query in the Candidate state.
- Enter a query in the Open state.

Input parameters—Issue

Takes an issueRequest XML element as a child element.

IssueRequest takes a list of InForm items, referenced by GUID, DBUID, or an InForm item type that allows the specification of data that is found in an LSID.

A request can be made for a single study. A request that contains multiple items is treated as an atomic transaction.

Hidden items

A hidden item is an item that is globally hidden.

A request to issue a discrepancy on a hidden item generates an error.

Issue	
Parameter or child element	Description
authenticationTrialName	The study in which the discrepancies are issued or updated. If username/password authentication is enabled, the username and password that you specify in the SOAP header are authenticated against this study name.

Issue	
Parameter or child element	Description
transactionId	<p>A GUID created by the caller.</p> <p>TransactionID is not case sensitive. It must use one of the formats described in <i>Transaction ID GUID format</i> (on page 42).</p> <p>This parameter prevents a transaction from being submitted multiple times. If you specify a value that was previously submitted and resulted in a successful transaction, an error occurs.</p>
transactionUserName	<p>The user name of the InForm user to associate with this transaction.</p> <p>If using the InForm Adapter with InForm 6.0 or later studies that are configured to work with single sign-on, the OrgID value must be prepended to the trial username to match the tenant-qualified username that is used by the single sign-on application.</p>
InFormItemIdentifier	<p>A unique identifier of an InForm item:</p> <ul style="list-style-type: none"> • GUID. • DBUID. • An InForm item type structure that contains the data found in an LSID.
InitialState	<p>The state in which the query is to be opened.</p> <p>Values: Candidate, Opened.</p>
Reason	<p>The reason for issuing the discrepancy.</p>
ValidateOnly	<p>Values: True, False.</p> <p>If True, both of the following occur:</p> <ul style="list-style-type: none"> • The request is validated, but no data is committed to the database. • The response contains an error list that includes any errors in validation. If all items in the request are validated successfully, the error list is empty.

TransactionID GUID format

The TransactionID is a GUID that must use the following format. In the example, **d** represents a hexadecimal digit whose case is ignored.

- Groups of 8, 4, 4, 4, and 12 digits with hyphens between the groups. The entire GUID can optionally be enclosed in matching braces.

For example:

```
ddddddddd-dddd-dddd-dddd-dddddddddddd
{ddddddddd-dddd-dddd-dddd-dddddddddddd}
```

Example request—Issue

The example shows the Body of the request, which is preceded by the *SOAP header* (on page 27). The transactionUserName value includes an optional OrgID value, which is required only for InForm studies that use single sign-on.

```
<s:Body xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema">
  <Issue xmlns="http://www.phaseforward.com/InForm/2010/01/Discrepancy">
    <IssueRequest authenticationTrialName="testtrial"
transactionId="{4cbc93cc-e024-4836-ac4e-blededea80fa}"
transactionUserName="sampleorg.system">
      <RequestList>
        <DiscrepancyIssueRequest>
          <InFormItemIdentifier>
            <InFormItem>
              <SiteId>7600</SiteId>
              <SubjectGuid>{8136950C-7676-4ED6-84AE-
AE965E12A6E7}</SubjectGuid>
              <Visit>
                <Name>vstBASE</Name>
                <Revision>153925521781062</Revision>
                <Index>1</Index>
              </Visit>
              <Form>
                <Name>frmDem</Name>
                <Revision>153925408218062</Revision>
                <Index>1</Index>
              </Form>
              <SectionName>sctDem</SectionName>
              <ItemName>itmDemHgt</ItemName>
            </InFormItem>
          </InFormItemIdentifier>
          <InitialState>Opened</InitialState>
          <Reason>IA: Unit Test: IssueAgainstItemWithMapping: 12/13/2010
3:23:18 PM</Reason>
        </DiscrepancyIssueRequest>
      </RequestList>
    </IssueRequest>
  </Issue>
</s:Body>
```

Discrepancies issued on mapped items

The Discrepancy Enhanced interface determines whether the requested target of a discrepancy maps to another item and issues the discrepancy against the mapped item.

In some cases, the intended target of the discrepancy is mapped to an item that has been determined, by study design, to be the intended recipient of the discrepancy. In these cases, the response includes the mapped item attribute with a value "true," indicating that the specified target was not the recipient of the discrepancy.

For example:

```
<DiscrepancyResult mappedItem="true">
  <Discrepancy>
    <Guid>{F0C07BFB-238D-4CE7-ABD3-61E6FCE1AA96}</Guid>
    <Revision>290608637760651</Revision>
  </Discrepancy>
  <InFormItemIdentifier>
    <InFormItemDbuid>9034</InFormItemDbuid>
  </InFormItemIdentifier>
</DiscrepancyResult>
```

Results—Issue

Returns one of the following elements:

- **ErrorList**—Returned if an error is encountered.
Error list includes a `DiscrepancyIssueError` for each requested item that has an error.
- **ResultList**—Returned if no errors are encountered and the operation is successful.

The results are atomic; that is, if an error is encountered, no discrepancies are issued.

Example response—Issue

```
<s:Body xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema">
  <IssueResponse
xmlns="http://www.phaseforward.com/InForm/2010/01/Discrepancy">
    <IssueResult>
      <ResultList>
        <DiscrepancyResult mappedItem="true">
          <Discrepancy>
            <Guid>{867CAD53-3B95-4371-B38B-00B1CF7F1CA3}</Guid>
            <Revision>313946605051342</Revision>
          </Discrepancy>
          <InFormItemIdentifier>
            <InFormItem>
              <SiteId>7600</SiteId>
              <SubjectGuid>{8136950C-7676-4ED6-84AE-
AE965E12A6E7}</SubjectGuid>
              <Visit>
                <Name>vstBASE</Name>
                <Revision>153925521781062</Revision>
                <Index>1</Index>
              </Visit>
              <Form>
                <Name>frmDem</Name>
                <Revision>153925408218062</Revision>
                <Index>1</Index>
              </Form>
              <SectionName>sctDem</SectionName>
              <ItemName>itmDemHgt</ItemName>
            </InFormItem>
          </InFormItemIdentifier>
        </DiscrepancyResult>
      </ResultList>
    </IssueResult>
  </IssueResponse>
</s:Body>
```

Update

Updates a discrepancy for a single study.

Update allows a caller to perform any of the following actions for a discrepancy:

- Answer.
- Close.
- Open a candidate discrepancy.
- Delete a candidate discrepancy.
- Reissue a discrepancy.
- Validate a discrepancy.

Input parameters—Update

Update takes a list of discrepancies, in which each discrepancy has an associated GUID, revision number, target state, reason, and optional reissue flag.

A request can be made for a single study. A request that contains multiple items is treated as an atomic transaction.

Update	
Parameter	Description
authenticationTrialName	The study in which the discrepancies are issued or updated. If username/password authentication is enabled, the username and password that you specify in the SOAP header are authenticated against this study name.
transactionID	A GUID created by the caller. TransactionID is not case sensitive. It must use one of the formats described in <i>Transaction ID GUID format</i> (on page 42). This parameter prevents a transaction from being submitted multiple times. If you specify a value that was previously submitted and resulted in a successful transaction, an error occurs.
transactionUserName	The user name of the InForm user to associate with this transaction.
Guid	A GUID that identifies the discrepancy to update.

Update	
Parameter	Description
Revision	<p>The revision number of the discrepancy that is identified by the GUID.</p> <p>If the specified revision number is less than the current revision number, the operation prohibits the update and notifies the caller that the data is stale.</p> <p>If no revision number is specified, the transaction takes effect against the latest (most current) revision.</p>
State	<p>The target state.</p> <p>Values: Candidate, Opened.</p>
Reissue	<p>Values: True, False.</p> <p>If True, the transaction is treated as a reissuing of the discrepancy.</p> <p>Can be specified only when specifying Candidate or Opened as the target state.</p>
Reason	<p>The reason for issuing the discrepancy.</p>
ValidateOnly	<p>Values: True, False.</p> <p>If True, both of the following occur:</p> <ul style="list-style-type: none"> • The request is validated, but no data is committed to the database. • The response contains an error list that includes any errors in validation. If all items in the request are validated successfully, the error list is empty.

Example request—Update

The example shows the Body of the request, which is preceded by the *SOAP header* (on page 27).

```
<Update xmlns="http://www.phaseforward.com/InForm/2010/01/Discrepancy">
  <UpdateRequest authenticationTrialName="testtrial" transactionId="{08a13f1b-
d2bd-4342-93ba-f450cf031bfc}" transactionUserName="system">
    <RequestList>
      <DiscrepancyUpdateRequest>
        <Guid>{63635436-F30C-4B75-89B4-C6D147FB6AAB}</Guid>
        <State>Opened</State>
        <Reason>candidate => open</Reason>
      </DiscrepancyUpdateRequest>
      <DiscrepancyUpdateRequest>
        <Guid>{2E08BD54-0B74-4A94-9884-7F7BAC68984C}</Guid>
        <State>Opened</State>
        <Reason>candidate => open</Reason>
      </DiscrepancyUpdateRequest>
      <DiscrepancyUpdateRequest>
        <Guid>{F0C07BFB-238D-4CE7-ABD3-61E6FCE1AA96}</Guid>
        <State>Opened</State>
        <Reason>candidate => open</Reason>
      </DiscrepancyUpdateRequest>
    </RequestList>
  </UpdateRequest>
</Update>
```

```

    </UpdateRequest>
  </Update>

```

Results—Update

Returns one of the following elements:

- **ErrorList**—Returned if an error is encountered.
Error list includes a `DiscrepancyIssueError` for each requested item that has an error.
- **ResultList**—Returned if no errors are encountered and the operation is successful.

The results are atomic; that is, if an error is encountered, no discrepancies are updated.

Some discrepancies in the request might not allow state changes. For each unsuccessful transaction, a populate `Message` element is included, and the `Result` element has a value of `False`.

Example response—Update

```

<UpdateResponse xmlns="http://www.phaseforward.com/InForm/2010/01/Discrepancy">
  <UpdateResult>
    <ResultList>
      <DiscrepancyUpdateResult>
        <Guid>{63635436-F30C-4B75-89B4-C6D147FB6AAB}</Guid>
        <Revision>290608643214335</Revision>
      </DiscrepancyUpdateResult>
      <DiscrepancyUpdateResult>
        <Guid>{2E08BD54-0B74-4A94-9884-7F7BAC68984C}</Guid>
        <Revision>290608643292468</Revision>
      </DiscrepancyUpdateResult>
      <DiscrepancyUpdateResult>
        <Guid>{F0C07BFB-238D-4CE7-ABD3-61E6FCE1AA96}</Guid>
        <Revision>290608643370601</Revision>
      </DiscrepancyUpdateResult>
    </ResultList>
  </UpdateResult>
</UpdateResponse>

```

Use cases

General use

Area	Use case	Operation
Studies	Retrieve discrepancies of a certain type. For example, find all open discrepancies for a study.	<i>GetByCriteria</i> (on page 31)
	Retrieve counts in the form of [Site, State, Count]. For each of the specified studies, how many discrepancies are in each state.	<i>GetSummaryCounts</i> (on page 29)
Sites	Retrieve discrepancies of a specific type. For example, find all Open discrepancies for the site.	<i>GetByCriteria</i> (on page 31)
	Retrieve counts in the form of [Subject, State, Count]. For example, for specified sites, find the number of discrepancies in each state.	<i>GetSummaryCounts</i> (on page 29)
	Retrieve all the discrepancies for the specified sites.	<i>GetByCriteria</i> (on page 31)
Subjects or lists of subjects	Retrieve discrepancies of a certain type. For example, find all open discrepancies for one or more subjects.	<i>GetByCriteria</i> (on page 31)
	Retrieve counts in the form of [Subject, State, Count].	<i>GetSummaryCounts</i> (on page 29)
Visits	For each of the specified visits, how many discrepancies are in each state.	<i>GetSummaryCounts</i> (on page 29)
Items	Retrieve all discrepancies for an item.	<i>GetByCriteria</i> (on page 31)
	Retrieve discrepancies of a specific type for an item. For example, find all open discrepancies for an item.	<i>GetByCriteria</i> (on page 31)
	Open a discrepancy:	<i>Issue</i> (on page 41)
	<ul style="list-style-type: none"> • Candidate discrepancy. • Non-candidate discrepancy. 	
Discrepancy or list of discrepancies,	Answer a discrepancy.	<i>Update</i> (on page 45).
	Close a discrepancy.	<i>Update</i> (on page 45).

Area	Use case	Operation
each identified by a GUID	Delete a Candidate discrepancy.	<i>Update</i> (on page 45).
	Reissue an Answered discrepancy as Open.	<i>Update</i> (on page 45).
	Reissue an Answered discrepancy as Candidate.	<i>Update</i> (on page 45).
	Retrieve discrepancy details.	<i>GetByDiscrepancyGuid</i> (on page 36)
	Retrieve the revision history of a discrepancy.	<i>GetHistoryByDiscrepancyGuid</i> (on page 39)
In relation to a set of discrepancies	Use a single transaction to close all answered discrepancies.	<i>Update</i> (on page 45)
	Identify the transactions that were committed to the InForm database by the Issue or Update operations.	<i>GetByTransactionId</i> (on page 40)

ODM use

Clients that use an ODM extract determine that certain items need to have associated discrepancies. The client can use the Discrepancy interface to issue the discrepancies, using data from the ODM administrative data, metadata, and clinical data extracts.

Structural representation of LSIDs

LSIDs use a structural-based representation in the Discrepancy Enhanced interface.

String-based representation

In versions of the InForm Adapter software prior to 1.3 SP3, LSIDs used a string-based representation. For example:

```
URN:LSID:www.phaseforward.com:www.phaseforward.com/InFormAdapter//;Trial=test
trial/Site=7600/Subject={A2F60023-E0DA-4497-8E9A-
E1F05A284AAE}/Formset=CommonCRF,245827582062039,1/Form=frmDOSE,15392541473406
2,1/Section=sctDOSE/Itemset=itsDOSE,,153925414515062/Item;RefNameTuple:itmDOS
ETotalCaps
```

Structural representation

LSIDs are now represented structurally. For example, the LSID shown in the string-based representation is now represented like this:

```
<InFormItemIdentifier>
  <InFormItem>
    <TrialName>testtrial</TrialName>
    <SiteId>7600</SiteId>
    <SubjectGuid>{A2F60023-E0DA-4497-8E9A-E1F05A284AAE}</SubjectGuid>
    <Visit>
      <Name>CommonCRF</Name>
      <Revision>245827582062039</Revision>
      <Index>1</Index>
    </Visit>
    <Form>
      <Name>frmDOSE</Name>
      <Revision>153925414734062</Revision>
      <Index>1</Index>
    </Form>
    <SectionName>sctDOSE</SectionName>
    <ItemSet>
      <Name>itsDOSE</Name>
      <Order>153925414515062</Order>
    </ItemSet>
    <ItemName>itmDOSETotalCaps</ItemName>
  </InFormItem>
</InFormItemIdentifier>
```

Location of LSID components in ODM extract files

LSID component	Location in ODM	Notes
Trial	Alias used to register the study with the InForm Adapter software.	
Site ID	AdminData/Location/@OID	
Subject GUID	ClinicalData/SubjectData/@GUID	
Visit name	ClinicalData/SubjectData/StudyEventData/@StudyEventOID	
Visit revision	StudyEventDef/@Revision	The revision of the visit in the study version for which the item has data. This value must be looked up in the metadata.
Visit index	ClinicalData/SubjectData/StudyEventData/@StudyEventRepeatKey	If this attribute is not present, pass the value 1; note that you do not need ".000."
Form name	ClinicalData/SubjectData/StudyEventData/FormData/@FormOID	
Form revision	FormDef/@Revision	The revision of the form in the study version for which the item has data. This value must be looked up in the metadata.

LSID component	Location in ODM	Notes
Form index	ClinicalData/SubjectData/StudyEventData/FormData/@FormRepeatKey	If this attribute is not present, pass the value 1; note that you do not need ".000."
Section name	ItemGroupDef/@Name	Get the ItemGroupOID and look up the name in the metadata for that study version.
Itemset name	ItemGroupDef/@ItemSetRefName	Required only if the item exists in an itemset.

Client dashboard use

A client can create a dashboard application to identify studies or sites that have an excessive number of discrepancies, or unanswered discrepancies.

The client can call the new reporting function `GetSummaryCounts`, which provides multiple filters. For each study, the client specifies a filter. The XML that is returned includes an entry for each state, showing the number of discrepancies in that state.

After seeing the study counts, the user can obtain greater detail by viewing summary counts by site. The client application calls the same operation but submits a filter for each site.

For more information, see *GetSummaryCounts* (on page 29).

CHAPTER 4

Discrepancy Original interface

In this chapter

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Overview: Discrepancy Original interface

The Discrepancy Original interface sends clinical queries and their resolutions between InForm and other systems or modules. It:

- Opens queries between subsystems.
- Routes answers to queries to the appropriate subsystems and modules.
- Routes query close events to the appropriate subsystems and modules.
- Receives information about the query from the other subsystem or module.

This section describes the syntax and functionality of the InForm Adapter Discrepancy Original interface, which can be found at the target host:

`/InFormAdapter/Discrepancy/InFormDiscrepancy.asmx`

Requests—Input parameters

The web methods of the Discrepancy Original interface take a `DiscrepancyRequest` XML element as an input parameter. The `DiscrepancyRequest` element can contain one of the following children to provide more information to the called web method:

- **RetrieveDiscrepancyRequest**—When retrieving a discrepancy from the desired InForm installation.
- **DiscrepancyOpenRequest**—When opening a new discrepancy in the desired InForm installation.
- **DiscrepancyAnswerRequest**—When answering an existing discrepancy in the desired InForm installation.
- **DiscrepancyCloseRequest**—When closing an existing discrepancy in the desired InForm installation.
- **DiscrepancyReissueRequest**—When reissuing a previously answered discrepancy.
- **DiscrepancyOpenCandidateRequest**—When transitioning a Candidate discrepancy to the Open state.
- **DiscrepancyDeleteCandidateRequest**—When transitioning a Candidate query to the Deleted state.

Results

The Discrepancy Original web methods all return a `DiscrepancyResponse` XML element. The `DiscrepancyResponse` element can contain one of the following children when returning information to the caller:

- **DiscrepancyRequestOutputMsg**—Returns the results of an Open, Answer, or Close request to the caller along with any information pertinent to the request.
- **DiscrepancyRetrieveResponse**—Returns the information about the desired Discrepancy to the caller.

Namespace

All XmlElement parameters are under the following namespace:

`http://www.phaseforward.com/AdapterFramework/Discrepancy/1.0`

where

1.0 specifies the version of the schema.

Public web methods

Public Web methods list

The Oracle Discrepancy Original interface provides the following public Web methods.

Method	Description
<i>OpenDiscrepancy</i> (on page 56)	Opens a discrepancy on the specified reference data element.
<i>AnswerDiscrepancy</i> (on page 58)	Answers a specified discrepancy.
<i>CloseDiscrepancy</i> (on page 59)	Closes a Discrepancy.
<i>DiscrepancyRequest</i> (on page 61)	Performs an open, answer, or close action for a discrepancy in the desired InForm system.
<i>RetrieveDiscrepancy</i> (on page 62)	Retrieves the specified discrepancy information from the web service.
<i>ReissueDiscrepancy</i> (on page 64)	Transitions a discrepancy from the Answered state to the Opened state or Candidate state.
<i>OpenCandidateDiscrepancy</i> (on page 65)	Transitions a discrepancy from the Candidate state to the Open state.
<i>DeleteCandidateDiscrepancy</i> (on page 67)	Transitions a discrepancy from the Candidate state to the Deleted state.

OpenDiscrepancy

Opens a discrepancy on the specified reference data element.

`XmlElement OpenDiscrepancy(XmlElement requestParams)`

Note: To reissue an answered discrepancy, use *ReissueDiscrepancy* (on page 64).

Input parameters—OpenDiscrepancy

Takes a DiscrepancyRequest XML element as an input parameter. The DiscrepancyRequest contains a DiscrepancyOpenRequest child element.

DiscrepancyOpenRequest follows the DiscrepancyOpenType XML schema. It has the following attributes.

DiscrepancyOpenRequest	
Attribute	Description

DiscrepancyOpenRequest	
Attribute	Description
MessageLSID	Currently not implemented. Provided for future use.
ReferenceLSID	The LSID that points to the data element in the InForm software with which the discrepancy is associated.
EnteredBy	The InForm user name that is associated with the opening of the discrepancy.
Reason	The reason that the discrepancy is being opened.
InitialState	The state in which the discrepancy is opened. Values: Candidate or Opened.

Example request—OpenDiscrepancy

```
<DiscrepancyRequest xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema"
xmlns="http://www.phaseforward.com/AdapterFramework/Discrepancy/1.0">
  <DiscrepancyOpenRequest>
    <ReferenceLSID>URN:LSID:www.phaseforward.com:www.phaseforward.com/InFormAd
apter//;Trial=TESTTRIAL/Site=7600/Subject={A5DDF3A3-1D8B-4B5A-ADC9-
B7D926F6A761}/Formset=vstCORE2,153925521781062.000,1.000/Form=frmDOV,15392
5409031062.000,1.000/Section=DOV/Item;RefName:DOV</ReferenceLSID>
    <EnteredBy>system</EnteredBy>
    <Reason>Value is not within the expected range; please verify</Reason>
    <InitialState>Opened</InitialState>
  </DiscrepancyOpenRequest>
</DiscrepancyRequest>
```

Results—OpenDiscrepancy

Returns a DiscrepancyResponseXML element. DiscrepancyResponse contains one or more DiscrepancyRequestOutputMsg child elements.

DiscrepancyRequestOutputMsg contains the following elements.

DiscrepancyRequestOutputMsg	
Element	Description
RequestStatus	True or False, depending upon the outcome of the request.
DiscrepancyLSID	Contains an LSID that identifies the discrepancy that results from the request.

Example response—OpenDiscrepancy

```
<OpenDiscrepancyResult
xmlns="http://www.phaseforward.com/AdapterFramework/Discrepancy/1.0">
  <DiscrepancyResponse xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema"
xmlns="http://www.phaseforward.com/AdapterFramework/Discrepancy/1.0">
    <DiscrepancyRequestOutputMsg>
      <RequestStatus>True</RequestStatus>
      <DiscrepancyLSID>URN:LSID:www.phaseforward.com:www.phaseforward.com/InFo
rmAdapter//;Trial%3dTESTTRIAL%2fDiscrepancy;GuidTuple:e0ee0570-ab81-
4b80-a306-878579925489%2c276703605273428</DiscrepancyLSID>
    </DiscrepancyRequestOutputMsg>
  </DiscrepancyResponse>
</OpenDiscrepancyResult>
```

AnswerDiscrepancy

Answers a specified discrepancy. The discrepancy to answer is specified by an LSID that must have the discrepancy GUID as its key.

XmlElement **AnswerDiscrepancy**(*XmlElement requestParams*)

Note: To reissue an answered discrepancy, use *ReIssueDiscrepancy* (on page 64).

Input parameters—AnswerDiscrepancy

Takes a DiscrepancyRequest XML element as an input parameter. The DiscrepancyRequest contains a DiscrepancyAnswerRequest child element.

DiscrepancyAnswerRequest follows the DiscrepancyAnswerType XML element schema. It has the following attributes.

DiscrepancyAnswerRequest	
Attributes	Description
MessageLSID	Currently not implemented.
DiscrepancyLSID	The LSID that points to the discrepancy to answer.
ReferenceLSID	The LSID that points to the data element in the InForm software with which the discrepancy is associated.
Reason	The reason that the discrepancy was answered.
EnteredBy	The InForm username that is associated with the answering of the discrepancy.

Example request—AnswerDiscrepancy

```
<DiscrepancyRequest xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema"
xmlns="http://www.phaseforward.com/AdapterFramework/Discrepancy/1.0">
  <DiscrepancyAnswerRequest>
    <DiscrepancyLSID>URN:LSID:www.phaseforward.com:www.phaseforward.com/InForm
Adapter//;Trial%3dTESTTRIAL%2fDiscrepancy;GuidTuple:656161ce-00c8-46d6-
87bf-bcee2e23fbd5%2c276703630367660</DiscrepancyLSID>
    <ReferenceLSID>URN:LSID:www.phaseforward.com:www.phaseforward.com/InFormAd
apter//;Trial=TESTTRIAL/Site=7600/Subject={A5DDF3A3-1D8B-4B5A-ADC9-
B7D926F6A761}/Formset=vstCORE2,153925521781062.000,1.000/Form=frmDOV,15392
5409031062.000,1.000/Section=DOV/Item;RefName:DOV</ReferenceLSID>
    <Reason>Original value is correct</Reason>
    <EnteredBy>system</EnteredBy>
  </DiscrepancyAnswerRequest>
</DiscrepancyRequest>
```

Results—AnswerDiscrepancy

Returns a DiscrepancyResponseXML element. DiscrepancyResponse contains one or more DiscrepancyRequestOutputMsg child elements.

DiscrepancyRequestOutputMsg contains the following elements.

DiscrepancyRequestOutputMsg	
Element	Description
RequestStatus	True or False, depending upon the outcome of the request.
DiscrepancyLSID	Contains an LSID that identifies the discrepancy that results from the request.

Example response—AnswerDiscrepancy

```
<AnswerDiscrepancyResult
xmlns="http://www.phaseforward.com/AdapterFramework/Discrepancy/1.0">
  <DiscrepancyResponse xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema"
xmlns="http://www.phaseforward.com/AdapterFramework/Discrepancy/1.0">
    <DiscrepancyRequestOutputMsg>
      <RequestStatus>True</RequestStatus>
      <DiscrepancyLSID>URN:LSID:www.phaseforward.com:www.phaseforward.com/InFo
rmAdapter//;Trial%3dTESTTRIAL%2fDiscrepancy;GuidTuple:656161ce-00c8-
46d6-87bf-bcee2e23fbd5%2c276703630727042</DiscrepancyLSID>
    </DiscrepancyRequestOutputMsg>
  </DiscrepancyResponse>
</AnswerDiscrepancyResult>
```

CloseDiscrepancy

Closes a Discrepancy. The discrepancy to close is specified by an LSID that must have the Discrepancy GUID as its key.

XmlElement **CloseDiscrepancy**(*XmlElement requestParams*)

Input parameters—CloseDiscrepancy

Takes a DiscrepancyRequest XML element as an input parameter. The DiscrepancyRequest element contains a DiscrepancyCloseRequest child element.

DiscrepancyCloseRequest follows the DiscrepancyCloseType XML element schema. It has the following attributes.

DiscrepancyCloseRequest	
Attribute	Description
MessageLSID	Currently not implemented.
DiscrepancyLSID	The LSID that points to the discrepancy to close.
ReferenceLSID	The LSID that points to the data element in the InForm software with which the discrepancy is associated.
EnteredBy	The InForm user name that is associated with the closing of the discrepancy.
Reason	The reason that the discrepancy was closed.

Example request—CloseDiscrepancy

```
<DiscrepancyRequest xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema"
xmlns="http://www.phaseforward.com/AdapterFramework/Discrepancy/1.0">
  <DiscrepancyCloseRequest>
    <DiscrepancyLSID>URN:LSID:www.phaseforward.com:www.phaseforward.com/InForm
Adapter//;Trial%3dTESTTRIAL%2fDiscrepancy;GuidTuple:e0ee0570-ab81-4b80-
a306-878579925489%2c276703605273428</DiscrepancyLSID>
    <ReferenceLSID>URN:LSID:www.phaseforward.com:www.phaseforward.com/InFormAd
apter//;Trial=TESTTRIAL/Site=7600/Subject={A5DDF3A3-1D8B-4B5A-ADC9-
B7D926F6A761}/Formset=vstCORE2,153925521781062.000,1.000/Form=frmDOV,15392
5409031062.000,1.000/Section=DOV/Item;RefName:DOV</ReferenceLSID>
    <EnteredBy>system</EnteredBy>
    <Reason>Response satisfies query</Reason>
  </DiscrepancyCloseRequest>
</DiscrepancyRequest>
```

Results—CloseDiscrepancy

Returns a `DiscrepancyResponseXML` element. `DiscrepancyResponse` contains one or more `DiscrepancyRequestOutputMsg` child elements.

`DiscrepancyRequestOutputMsg` contains the following elements.

DiscrepancyRequestOutputMsg	
Element	Description
RequestStatus	True or False, depending upon the outcome of the request.
DiscrepancyLSID	Contains an LSID that identifies the discrepancy that results from the request.

Example response—CloseDiscrepancy

```
<CloseDiscrepancyResult
xmlns="http://www.phaseforward.com/AdapterFramework/Discrepancy/1.0">
  <DiscrepancyResponse xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema"
xmlns="http://www.phaseforward.com/AdapterFramework/Discrepancy/1.0">
    <DiscrepancyRequestOutputMsg>
      <RequestStatus>True</RequestStatus>
      <DiscrepancyLSID>URN:LSID:www.phaseforward.com:www.phaseforward.com/InFo
rmAdapter//;Trial%3dTESTTRIAL%2fDiscrepancy;GuidTuple:e0ee0570-ab81-
4b80-a306-878579925489%2c276703607382843</DiscrepancyLSID>
    </DiscrepancyRequestOutputMsg>
  </DiscrepancyResponse>
</CloseDiscrepancyResult>
```

DiscrepancyRequest

Performs an open, answer, or close action for a discrepancy in the desired InForm system.

XmlElement `DiscrepancyRequest(XmlElement requestParams)`

Input parameters—DiscrepancyRequest

Takes a `DiscrepancyRequest` XML element as an input parameter. Depending on the type of request, the `DiscrepancyRequest` element contains one of the following child elements:

- `DiscrepancyOpenRequest`
For more information, see *OpenDiscrepancy* (on page 56).
- `DiscrepancyAnswerRequest`
For more information, see *AnswerDiscrepancy* (on page 58).
- `DiscrepancyClose`
For more information, see *CloseDiscrepancy* (on page 59).

Results—DiscrepancyRequest

The results of this method are identical to the results specified in the *OpenDiscrepancy* (on page 56), *AnswerDiscrepancy* (on page 58), or *CloseDiscrepancy* (on page 59) sections.

RetrieveDiscrepancy

Retrieves the specified discrepancy information from the web service. The discrepancy is specified by an LSID that can represent either a unique revision of a discrepancy or all revisions of a discrepancy.

XmlElement **RetrieveDiscrepancy**(*XmlElement* requestParams)

Input parameters—RetrieveDiscrepancy

Takes a DiscrepancyRequest XML element as an input parameter. The DiscrepancyRequest element contains a DiscrepancyRetrieveRequest child element.

DiscrepancyRetrieveRequest follows the DiscrepancyRetrieveType XML element schema. It has the following attributes.

DiscrepancyRetrieveRequest	
Attribute	Description
MessageLSID	Currently not implemented.
DiscrepancyLSID	This parameter contains an LSID that points to a particular discrepancy. This parameter can be used in two different ways: <ul style="list-style-type: none"> As a discrepancy identified by a GUID only without any revisions. This results in all discrepancy revisions being returned to the caller. As a discrepancy identified by a GUID and a revision. In this case, the specific revision of the discrepancy is returned to the caller.
Reference	Currently not implemented.

Example request—RetrieveDiscrepancy - Atlanta

```
<DiscrepancyRequest xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema"
xmlns="http://www.phaseforward.com/AdapterFramework/Discrepancy/1.0">
  <DiscrepancyRetrieveRequest>
    <DiscrepancyLSID>URN:LSID:www.phaseforward.com:www.phaseforward.com/InForm
Adapter//;Trial%3dTESTTRIAL%2fDiscrepancy;GuidTuple:e0ee0570-ab81-4b80-
a306-878579925489%2c276703607382843</DiscrepancyLSID>
  </DiscrepancyRetrieveRequest>
</DiscrepancyRequest>
```

Results—RetrieveDiscrepancy

Returns a DiscrepancyResponse XML element. This element contains one or more DiscrepancyRetrieveResponse child elements.

The DiscrepancyRetrieveResponse element contains information about the discrepancies requested.

DiscrepancyRetrieveResponse	
Element	Description
MessageLSID	Not used.
DiscrepancyLSID	The LSID that identifies the retrieved discrepancy. <ul style="list-style-type: none"> If a single discrepancy was requested, the DiscrepancyLSID value is identical to the value was passed in. If all revisions of the discrepancy were requested, each instance of DiscrepancyLSID contains a different LSID that refers to the particular revision.
Reference	The LSID that points to the data element in the InForm software with which the discrepancy is associated. This element will be returned as an LSID.
DateEntered	The date that the LSID revision was entered into the InForm system.
EnteredBy	The InForm user name that is associated with the retrieval of the discrepancy.
Comments	The revision history comment associated with the discrepancy.
State	The state associated with the discrepancy instance that is returned. Value: Candidate, Open, Answered, or Closed.
Data	The reason entered with the discrepancy.

Example response—RetrieveDiscrepancy

```
<RetrieveDiscrepancyResult
xmlns="http://www.phaseforward.com/AdapterFramework/Discrepancy/1.0">
  <DiscrepancyResponse xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema"
xmlns="http://www.phaseforward.com/AdapterFramework/Discrepancy/1.0">
    <DiscrepancyRetrieveResponse>
      <DiscrepancyLSID>URN:LSID:www.phaseforward.com:www.phaseforward.com/InFo
rmAdapter//;Trial%3dTESTTRIAL%2fDiscrepancy;GuidTuple:e0ee0570-ab81-
4b80-a306-878579925489%2c276703607382843</DiscrepancyLSID>
      <ReferenceLSID>URN:LSID:www.phaseforward.com:www.phaseforward.com/InF
ormAdapter//;Trial=TESTTRIAL/Site=7600/Subject={A5DDF3A3-1D8B-4B5A-
ADC9-
B7D926F6A761}/Formset=vstCORE2,245827582062039,1/Form=frmDOV,15392540
9031062,1/Section=DOV/Item;RefNameTuple:DOV</ReferenceLSID>
      <DateEntered>10/8/2009 7:06:47 PM</DateEntered>
      <EnteredBy>system</EnteredBy>
      <Comments>Change query state</Comments>
      <State>Closed</State>
      <Data>Value is not within the expected range; please verify</Data>
    </DiscrepancyRetrieveResponse>
  </DiscrepancyResponse>
</RetrieveDiscrepancyResult>
```

ReissueDiscrepancy

Transitions a discrepancy from the Answered state to the Opened state or Candidate state.

XmlElement **ReissueDiscrepancy**(*XmlElement* requestParams)

Input parameters—ReissueDiscrepancy

Takes a DiscrepancyRequest XML element as an input parameter. The DiscrepancyRequest element contains a DiscrepancyReissueRequest element.

DiscrepancyReissueRequest follows the DiscrepancyReissueType XML schema. It has the following attributes.

DiscrepancyReissueRequest	
Attribute	Description
DiscrepancyLSID	The LSID that points to the discrepancy to reissue.
ReferenceLSID	The LSID that points to the data element in the InForm software with which the discrepancy is associated.
EnteredBy	The InForm user name that is associated with the reissuing of the discrepancy.
Reason	The reason that the discrepancy was reissued.
State	The state of the discrepancy after it is reissued. Value: Opened or Candidate.

Example request—ReissueDiscrepancy

```
<DiscrepancyRequest xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema"
xmlns="http://www.phaseforward.com/AdapterFramework/Discrepancy/1.0">
  <DiscrepancyReissueRequest>
    <DiscrepancyLSID>URN:LSID:www.phaseforward.com:www.phaseforward.com/InForm
Adapter//;Trial%3dTESTTRIAL%2fDiscrepancy;GuidTuple:656161ce-00c8-46d6-
87bf-bcee2e23fbd5%2c276703630367660</DiscrepancyLSID>
    <ReferenceLSID>URN:LSID:www.phaseforward.com:www.phaseforward.com/InFormAd
apter//;Trial=TESTTRIAL/Site=7600/Subject={A5DDF3A3-1D8B-4B5A-ADC9-
B7D926F6A761}/Formset=vstCORE2,153925521781062.000,1.000/Form=frmDOV,15392
5409031062.000,1.000/Section=DOV/Item;RefName:DOV</ReferenceLSID>
    <EnteredBy>system</EnteredBy>
    <Reason>Item incomplete</Reason>
    <State>Opened</State>
  </DiscrepancyReissueRequest>
</DiscrepancyRequest>
```

Results—ReissueDiscrepancy

Returns a `DiscrepancyResponseXML` element. `DiscrepancyResponse` contains one or more `DiscrepancyRequestOutputMsg` child elements.

`DiscrepancyRequestOutputMsg` contains the following elements.

DiscrepancyRequestOutputMsg	
Element	Description
RequestStatus	True or False, depending upon the outcome of the request.
DiscrepancyLSID	Contains an LSID that identifies the discrepancy that results from the request.

Example response—ReissueDiscrepancy

```
<ReissueDiscrepancyResult
xmlns="http://www.phaseforward.com/AdapterFramework/Discrepancy/1.0">
  <DiscrepancyResponse xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema"
xmlns="http://www.phaseforward.com/AdapterFramework/Discrepancy/1.0">
    <DiscrepancyRequestOutputMsg>
      <RequestStatus>True</RequestStatus>
      <DiscrepancyLSID>URN:LSID:www.phaseforward.com:www.phaseforward.com/InFo
rmAdapter//;Trial%3dTESTTRIAL%2fDiscrepancy;GuidTuple:656161ce-00c8-
46d6-87bf-bcee2e23fbd5%2c276703631008297</DiscrepancyLSID>
    </DiscrepancyRequestOutputMsg>
  </DiscrepancyResponse>
</ReissueDiscrepancyResult>
```

OpenCandidateDiscrepancy

Transitions a discrepancy from the Candidate state to the Open state.

XmlElement `OpenCandidateDiscrepancy(XmlElement requestParams)`

Input parameters—OpenCandidateDiscrepancy

Takes a `DiscrepancyRequest` XML element as an input parameter. The `DiscrepancyRequest` contains a `DiscrepancyOpenCandidateRequest` element.

`DiscrepancyOpenCandidateRequest` follows the `DiscrepancyOpenCandidateType` XML schema. It has the following attributes.

DiscrepancyOpenCandidateRequest	
Attribute	Description
MessageLSID	Currently not implemented.
DiscrepancyLSID	The LSID that points to the candidate discrepancy to open.
ReferenceLSID	The LSID that points to the data element in the InForm software with which the discrepancy is associated.

DiscrepancyOpenCandidateRequest	
Attribute	Description
EnteredBy	The InForm user name that is associated with moving the discrepancy to the Open state.
Reason	The reason that the discrepancy was moved to the Open state

Example request—OpenCandidateDiscrepancy

```
<DiscrepancyRequest xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema"
xmlns="http://www.phaseforward.com/AdapterFramework/Discrepancy/1.0">
  <DiscrepancyOpenCandidateRequest>
    <DiscrepancyLSID>URN:LSID:www.phaseforward.com:www.phaseforward.com/InForm
Adapter//;Trial%3dTESTTRIAL%2fDiscrepancy;GuidTuple:19955d23-a0bb-4ea7-
bba-e0b9604e1681%2c276703630055154</DiscrepancyLSID>
    <ReferenceLSID>URN:LSID:www.phaseforward.com:www.phaseforward.com/InFormAd
apter//;Trial=TESTTRIAL/Site=7600/Subject={A5DDF3A3-1D8B-4B5A-ADC9-
B7D926F6A761}/Formset=vstCORE2,153925521781062.000,1.000/Form=frmDOV,15392
5409031062.000,1.000/Section=DOV/Item;RefName:DOV</ReferenceLSID>
    <EnteredBy>system</EnteredBy>
    <Reason>Making this an "opened" discrepancy</Reason>
  </DiscrepancyOpenCandidateRequest>
</DiscrepancyRequest>
```

Results—OpenCandidateDiscrepancy

Returns a DiscrepancyResponseXML element. DiscrepancyResponse contains one or more DiscrepancyRequestOutputMsg child elements.

DiscrepancyRequestOutputMsg contains the following elements.

DiscrepancyRequestOutputMsg	
Element	Description
RequestStatus	True or False, depending upon the outcome of the request.
DiscrepancyLSID	Contains an LSID that identifies the discrepancy that results from the request.

Example response—OpenCandidateDiscrepancy - Atlanta

```
<OpenCandidateDiscrepancyResult
xmlns="http://www.phaseforward.com/AdapterFramework/Discrepancy/1.0">
  <DiscrepancyResponse xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema"
xmlns="http://www.phaseforward.com/AdapterFramework/Discrepancy/1.0">
    <DiscrepancyRequestOutputMsg>
      <RequestStatus>True</RequestStatus>
      <DiscrepancyLSID>URN:LSID:www.phaseforward.com:www.phaseforward.com/InFo
rmAdapter//;Trial%3dTESTTRIAL%2fDiscrepancy;GuidTuple:656161ce-00c8-
46d6-87bf-bcee2e23fbd5%2c276703630367660</DiscrepancyLSID>
    </DiscrepancyRequestOutputMsg>
  </DiscrepancyResponse>
</OpenCandidateDiscrepancyResult>
```


DeleteCandidateDiscrepancy

Transitions a discrepancy from the Candidate state to the Deleted state.

XmlElement **DeleteCandidateDiscrepancy**(*XmlElement* requestParams)

Input parameters—DeleteCandidateDiscrepancy

Takes a DiscrepancyRequest XML element as an input parameter. The DiscrepancyRequest contains a DiscrepancyDeleteCandidateRequest element.

DiscrepancyDeleteCandidateRequest follows the DiscrepancyDeleteCandidateType XML schema. It has the following attributes.

DiscrepancyDeleteCandidateRequest	
Attribute	Description
MessageLSID	Currently not implemented.
DiscrepancyLSID	The LSID that points to the candidate discrepancy to delete.
Reference LSID	The LSID that points to the data element in the InForm software with which the discrepancy is associated.
EnteredBy	The InForm user name that is associated with the deletion of the discrepancy.
Reason	The reason that the discrepancy was deleted.

Example request—DeleteCandidateDiscrepancy

```
<DiscrepancyRequest xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema"
xmlns="http://www.phaseforward.com/AdapterFramework/Discrepancy/1.0">
  <DiscrepancyDeleteCandidateRequest>
    <DiscrepancyLSID>URN:LSID:www.phaseforward.com:www.phaseforward.com/InForm
Adapter//;Trial%3dTESTTRIAL%2fDiscrepancy;GuidTuple:1cc5ab84-4be4-4cd6-
b3ec-c0cc1edb6277%2c276703607679724</DiscrepancyLSID>
    <ReferenceLSID>URN:LSID:www.phaseforward.com:www.phaseforward.com/InFormAd
apter//;Trial=TESTTRIAL/Site=7600/Subject={A5DDF3A3-1D8B-4B5A-ADC9-
B7D926F6A761}/Formset=vstCORE2,153925521781062.000,1.000/Form=frmDOV,15392
5409031062.000,1.000/Section=DOV/Item;RefName:DOV</ReferenceLSID>
    <EnteredBy>system</EnteredBy>
    <Reason>Determined to be invalid for a candidate discrepancy</Reason>
  </DiscrepancyDeleteCandidateRequest>
</DiscrepancyRequest>
```

Results—DeleteCandidateDiscrepancy

Returns a DiscrepancyResponseXML element. DiscrepancyResponse contains one or more DiscrepancyRequestOutputMsg child elements.

DiscrepancyRequestOutputMsg contains the following elements.

DiscrepancyRequestOutputMsg	
Element	Description
RequestStatus	True or False, depending upon the outcome of the request.
DiscrepancyLSID	Contains an LSID that identifies the discrepancy that results from the request.

Example response—DeleteCandidateDiscrepancy

```
<DeleteCandidateDiscrepancyResult
xmlns="http://www.phaseforward.com/AdapterFramework/Discrepancy/1.0">
  <DiscrepancyResponse xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema"
xmlns="http://www.phaseforward.com/AdapterFramework/Discrepancy/1.0">
    <DiscrepancyRequestOutputMsg>
      <RequestStatus>True</RequestStatus>
      <DiscrepancyLSID>URN:LSID:www.phaseforward.com:www.phaseforward.com/InFo
rmAdapter//;Trial%3dTESTTRIAL%2fDiscrepancy;GuidTuple:1cc5ab84-4be4-
4cd6-b3ec-c0cc1edb6277%2c276703607976605</DiscrepancyLSID>
    </DiscrepancyRequestOutputMsg>
  </DiscrepancyResponse>
</DeleteCandidateDiscrepancyResult>
```

CHAPTER 5

ODM Export Interface

In this chapter

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Overview: ODM Export interface

The ODM Export interface is a unidirectional interface that provides a web service for any outside application that needs to retrieve data from an InForm database in CDISC ODM standard format. Both clinical data and metadata are available. Refer to www.cdisc.org for more information on the ODM standard.

The ODM Export interface connects directly to the InForm database. It does not route requests through either the InForm Server Adapter interface or the InForm application server on the InForm server.

This chapter describes the syntax and functionality of the ODM Export interface of the InForm Adapter software, which is located on the InForm Adapter server at **/InFormAdapter/ODM/InFormODM.asmx**. The ODM Export interface focuses on the semantics of the function calls that are published by the interface, and the parameters that the published web methods use. Each section gives examples of XML for both the web method request and response.

ODM Export: XML schema

Writing requests

Each request is enclosed in a SOAP envelope that begins with a SOAP header, followed by a Body statement that contains the public web method and its input parameters and values.

For examples of Body statements, see the individual web methods. For more information, see *Public Web Methods* (on page 77).

SOAP header

The SOAP header contains information about the service, the message, and the sender. It must include all of the following fields.

Note: The requirement for requests to contain the **wsu:Timestamp**, **wsse:Username**, and **wsse:Password** elements are defined in the WSDL by **ws-policy**.

If your web service toolkit does not support **ws-policy**, you must manually add these elements to the web service request.

Field	Description	Standard
wsa:Action	SOAP action for the operation. Include this field as part of the summary for each SOAP operation.	WS-Addressing
wsa:MessageID	Unique ID for the message.	WS-Addressing
wsa:ReplyTo	Use the value that is shown in the example.	WS-Addressing
wsa:To	Full URL of the service. Note: The full URL is different for each customer.	WS-Addressing
wsu:Timestamp	Time the message was created and when it expires. Oracle recommends a 5-minute time window.	SOAP Message Security 1.0
wsse:Username	User name of the integration user in the InForm study.	SOAP Message Security 1.0
wsse:Password	Password of the integration user in the InForm study.	SOAP Message Security 1.0

Security information in the SOAP header

The ODM Export interface uses user/password authentication security.

The SOAP header contains information about the service, the message, and the sender. It also contains a Security element that contains a Username and Password. For example:

```

<wsse:Security>
  <wsse:UsernameToken>
    <wsse:Username>sampleusername</wsse:Username>
    <wsse:Password>samplepassword</wsse:Password>
  </wsse:UsernameToken>
</wsse:Security>

```

The Body of each SOAP request includes the **trial** attribute that contains the name of the InForm study. This value is used with information in the Security element of the SOAP header to authenticate the ODM Export interface against the InForm study.

To configure username/password authentication for the ODM Export interface, you must also define several settings in the ODM web configuration files. For more information, see the *Installation Guide*.

Note: The username/password security is supported for studies in the InForm 4.6 SP2a release, the InForm 5.0 SP1 release, and the InForm 5.5 and above releases. For more information, see the *Installation Guide*.

SOAP header example

This example shows the SOAP header, followed by the SOAP Body for the GetSiteList method.

```

<?xml version="1.0" encoding="utf-8"?>
<soap:Envelope xmlns:soap="http://schemas.xmlsoap.org/soap/envelope/"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema"
xmlns:wsa="http://schemas.xmlsoap.org/ws/2004/03/addressing"
xmlns:wsse="http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-wssecurity-secext-1.0.xsd" xmlns:wsu="http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-wssecurity-utility-1.0.xsd">
  <soap:Header>
    <wsa:Action>http://www.phaseforward.com/InFormAdapter/ODM/1.0/GetSiteList</wsa:Action>
    <wsa:MessageID>uuid:e01ed5cf-c4f5-47e6-bdfa-c3b502fed2be</wsa:MessageID>
    <wsa:ReplyTo>
      <wsa:Address>http://schemas.xmlsoap.org/ws/2004/03/addressing/role/anonymous</wsa:Address>
    </wsa:ReplyTo>
    <wsa:To>http://localhost./informadapter/odm/InformODM.asmx</wsa:To>
    <wsse:Security soap:mustUnderstand="1">
      <wsu:Timestamp wsu:Id="Timestamp-9b483c78-0bb5-4d0c-869a-eef879363b6c">
        <wsu:Created>2010-04-08T18:34:53Z</wsu:Created>
        <wsu:Expires>2010-04-08T18:35:53Z</wsu:Expires>
      </wsu:Timestamp>
      <wsse:UsernameToken xmlns:wsu="http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-wssecurity-utility-1.0.xsd" wsu:Id="SecurityToken-d08c57f6-7036-4245-954e-96e8eddfc188">
        <wsse:Username>system</wsse:Username>
        <wsse:Password Type="http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-username-token-profile-1.0#PasswordText">manager</wsse:Password>
        <wsse:Nonce>XgoBZTHle+zXBFmrfZT2Sw==</wsse:Nonce>
        <wsu:Created>2010-04-08T18:34:53Z</wsu:Created>
      </wsse:UsernameToken>
    </wsse:Security>
  </soap:Header>
  <soap:Body>
    <node xmlns="http://www.phaseforward.com/InFormAdapter/ODM/1.0">
      <GetSiteList xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema" trial="testtrial"
xmlns="http://www.phaseforward.com/InFormAdapter/ODM/1.0" />
    </node>
  </soap:Body>
</soap:Envelope>

```

Input parameters

The ODM web methods take a single XmlElement parameter. Each web method has a specific XML schema to which the input parameter must adhere.

For more information, see *Public Web methods* (on page 77).

Schema files provided with the ODM Export interface

Schema files for requests and response are located in the InForm Adapter installation directory.

```
<installation_directory>\ODM\bin\xsd
```

Validate ODM requests and responses against the following schema files:

Request schemas:

- Top level file: ODMPParameters.xsd
Sub level file: ODMPParameters2.xsd

Response schemas:

- Top level file: ResponseODM.xsd
Sub level files:
 - ODM.xsd
 - ODM1-2-0.xsd
 - PFExtensions.xsd
 - PhaseForward_ODM.xsd

Most web service toolkits can be used to validate XML.

Validation assures that request XML has the correct parameters and is of the right type to be used by the Oracle ODM Export methods, and that responses have valid XML to be used as input in other programs.

Request and Response schema locations

Request directory

```
<installation_directory>\InFormAdapter\ODM\bin\xsd
```

Request version	Filename
Version 2.0	ODMPParameters2.xsd

Response directory

<installation_directory>InformAdapter\ODM\bin\xsd

Response version	Filename
Version 2.0	ResponseODM.xsd

Namespaces

- Request and Response XML
<http://www.phaseforward.com/InformAdapter/ODM/2.0>
where
2.0 is the version of the schema.
- ODM extensions
<http://www.phaseforward.com/InformAdapter/ODM/Extensions/2.0>

Version extensions

The <http://phaseforward.com/InformAdapter/ODM/1.2> schema includes <http://www.phaseforward.com/InformAdapter/ODM/1.1> and extends the types defined there with the new parameters as needed.

ResponseODM

The ODM document is returned as a child of **ResponseODM**, as defined in the schema.

All web methods return an XmlElement. For more information, see *Public Web Methods List* (on page 77).

ODM data that is returned

The ODM Export interface returns three types of ODM data:

- Snapshot.
- Transactional.
- Specific data item.

Retrieving snapshot ODM data

Snapshot returns the current (most recent) study data in ODM format, without audit history.

Version 2 Snapshot mode includes the following changes that are required for CDISC ODM 1.3 compliance:

- AnnotationAuditRecord has been removed.
ODM Snapshot mode does not support audit records, which are included as part of transactional mode.
- Date controls from the InForm application are now emitted as type Text with the optional extension **InFormDateTime="true"** to indicate that the data point stores incomplete date/time values from the InForm software.

The following methods can return ODM Snapshot data:

- *DownloadMetadataODM* (on page 77).
- *DownloadAdminDataODM* (on page 81).
- *GetPatientForms* (on page 91).

Retrieving transactional ODM data

Retrieving transactional data is the recommended, scalable way to retrieve all data in ODM.

Transactional data includes ODM data with the audit history and has the ability to retrieve only items that have changed since the previous call to the **GetTransactions** method.

The following methods can retrieve ODM transactional data:

- *DownloadMetadataODM* (on page 77).
- *DownloadAdminDataODM* (on page 81).
- *GetTransactions* (on page 92).

Retrieving a specific data item

To retrieve a specific data item, use the `RetrieveData` method, specifying an LSID that points to the specific piece of data that is to be retrieved.

For more information, see *RetrieveData* (on page 99).

Error messages from the ODM Export interface

Exception	Description
TRIAL_NOT_FOUND	The requested study cannot be located.
SITE_NOT_FOUND	The requested site cannot be located.
INFORM_SITE_NOTFOUND	The requested site cannot be located.
PATIENT_NOT_FOUND	The requested patient cannot be located.
INFORM_PATIENT_NOTFOUND	The requested patient cannot be located.
VISIT_NOT_FOUND	The requested visit cannot be located.
FORM_NOT_FOUND	The requested form cannot be located.
BOOKMARK_NOT_FOUND	The requested bookmark cannot be located.
GENERAL	A general error has occurred.
Input schema version supported in the trial <trial name> in InForm is <schema version>	Displays when the request.xml is not using V2 schema for a study in the InForm 4.7 software.

Public Web methods

Unless otherwise specified, all element names are in the ODM namespace. The namespace file is included in Adapter ODMPParameters.xsd in the directory

`<installation_directory>\InForm Adapter\ODM\bin\xsd`

Public Web Methods List

The Oracle ODM Export interface provides the following public Web methods.

Method	Description
<i>DownloadMetadaODM</i> (on page 77)	Returns the definitions of all the metadata (for example, study versions, visits, and forms) in a study.
<i>DownloadAdminDataODM</i> (on page 81)	Returns lists of all users, sites, and signature definitions in a study.
<i>DownloadPatientDataODM</i> (on page 87)	Returns the patient data on a form in a study.
<i>GetSiteList</i> (on page 89)	Returns the list of all sites in the specified study.
<i>GetPatientList</i> (on page 90)	Returns the list of all subjects that are associated with a particular site. Archived subjects are not returned.
<i>GetPatientForms</i> (on page 91)	Returns the list of all forms that apply for a subject.
<i>GetTransactions</i> (on page 92)	Returns a list of all the subject-related transactions for a specified study.
<i>GetTransactionStatus</i> (on page 98)	Returns the status of transactions that have been processed.
<i>RetrieveData</i> (on page 99)	Returns the ODM data that matches the specified LSID.

DownloadMetadataODM

Returns the definitions of all the metadata (for example, study versions, visits, and forms) in a study.

XmlElement **DownloadMetadataODM**(*XmlElement* node)

Input parameters—DownloadMetadataODM

Takes an XmlElement of type DownloadMetadataODM that contains the following children.

DownloadMetadataODM input parameters	
Node/Attribute name	Description
trial	<p>The study from which to receive metadata.</p> <p>Specify either the study name, or the study alias value that is used when registering the study through the InForm Adapter Admin interface.</p>
userName	The user ID of the user who is requesting the data.
priorFileOID	<p>Optional reference to the previous file (if one exists) in a series.</p> <p>Type = String</p>
fileType	<p>The type of ODM file data that is to be returned.</p> <p>Type = Enumeration.</p> <p>Enumeration values = Snapshot, Transactional.</p>
mappingVersion	<p>The version of the InForm-to-ODM mapping. Specify 2.0 for the most complete and accurate representation of the InForm data that is returned in ODM format.</p> <p>Type = Enumeration.</p> <p>Enumeration values = 1.0, 2.0.</p> <p>Default = 2.0.</p>
includeExtensions	<p>Specifies whether to include Oracle Phase Forward ODM extensions in the data that is returned from the method.</p> <p>Type = Boolean.</p> <p>Default = True.</p>
complianceMode	<p>Specifies how to handle transactions in the study that are deleted and then undeleted.</p> <p>Type = Enumeration.</p> <p>Enumeration values = Strict, Loose.</p> <p>Default = Strict.</p> <p>Strict uses a Remove transaction to indicate that a form has been deleted. If the form is subsequently undeleted, the returned data includes all the data for the form that was deleted and then undeleted.</p> <p>Loose uses a FormStatus or ItemGroupStatus element with the attribute name of Deleted. Loose compliance mode is more efficient.</p>

DownloadMetadataODM input parameters

Node/Attribute name	Description
studyVersionName	<p>The version of the InForm study for which to download metadata.</p> <p>Type = String</p> <p>Optional.</p> <p>You can specify a single study version. The value for studyVersionName must match the Study Version that is displayed on a site's configuration page in the InForm application.</p> <p>You can specify both studyVersionName and studyVersionCutoff to return only the data from the specified study version that is committed to the InForm application after the specified date.</p>
studyVersionCutoff	<p>The response includes only the study data that is committed to the InForm application after the date you specify. For example, if you specify 2010-12-15T00:00:00 (December 15, 2010), only data that is committed to the study on December 16, 2010 and later will be included.</p> <p>Type = xs:DateTime</p> <p>Optional.</p> <p>Format: YYYY-MM-DDTHH:MM:SS</p> <p>If you specify a DateTime, you must include all components of the format.</p> <p>If you specify a date in the future, no study versions are returned.</p> <p>You can specify both studyVersionName and studyVersionCutoff to return only the data from the specified study version that is committed to the InForm application after the specified date.</p>
studyVersionSummary	<p>If True, returns summary output; that is, a MetaDataVersion element for each study version in the InForm study, without returning child elements of MetaDataVersion.</p> <p>Type=Boolean</p> <p>Default=False</p> <p>studyVersionSummary can be used with either studyVersionName or studyVersionCutoff to return summary output for any study version that meets the criteria you specify.</p> <p>If you set studyVersionSummary=True, skipRevisioningWithoutVersioning is also set to True.</p>

DownloadMetadataODM input parameters

Node/Attribute name	Description
skipRevisingWithoutVersioning	<p>Specifies whether to omit additional processing to detect metadata that was created by the use of the Revising without Versioning technique in the InForm application.</p> <p>Type = Boolean</p> <p>Optional.</p> <p>Default = False</p> <ul style="list-style-type: none"> False—Performs extra processing to determine which metadata resulted from Revising without Versioning. True—Omits extra processing; as a result, performance is improved. <p>Note: If studyVersionSummary=True, skipRevisionWithoutVersioning is automatically set to True.</p>

Example request—DownloadMetadataODM

```
<node xmlns="http://www.phaseforward.com/InFormAdapter/ODM/1.0">
  <DownloadMetadataODM xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
    xmlns:xsd="http://www.w3.org/2001/XMLSchema"
    trial="testtrial"
    userName="system"
    fileType="Transactional"
    mappingVersion="2.0"
    complianceMode="Loose"
    studyVersionName="Study Version 1.0"
    studyVersionCutoff="2010-10-28T00:00:00"
    xmlns="http://www.phaseforward.com/InFormAdapter/ODM/2.0" />
</node>
```

Response—DownloadMetaDataODM

Returns an XmlElement that contains the definitions of all metadata in the study. The definitions are located under the /ODM/STUDY XPath in the returned XML.

For more information, see:

- Transactional data—DownloadMetadataODM example response.
- Snapshot data—DownloadMetadataODM example response* (on page 107).

Internationalization—DownloadMetadataODM response

MeasurementUnit

The MeasurementUnit element includes the TranslatedText for Symbol, and has the optional xml:lang attribute to specify the language used by the translation.

Example

```
<MeasurementUnit OID="Inches" Name="Inches" pf:DBUID="1766"
pf:GUID="{32A95F99-27FF-41AE-809C-F46583001D69}"
pf:Revision="153925075453062">
  <Symbol>
    <TranslatedText>in</TranslatedText>
    <TranslatedText xml:lang="en-US">in</TranslatedText>
    <TranslatedText xml:lang="ja-JP">in</TranslatedText>
  </Symbol>
</MeasurementUnit>
```

For more information, see the mapping information for *MeasurementUnit* (on page 150).

Question

Question is a child element of ItemDef. It contains a TranslatedText element for each study language.

For more information, see the mapping information for *ItemDef* (on page 160).

CodeList

Each CodeListItem of the CodeList element has translations that are based on the study locales.

For more information, see the mapping information for *CodeList* (on page 168).

TranslatedText in Mnemonic element

The elements FormDef and StudyEventDef contain a Mnemonic element, which contains the element TranslatedText.

Example using FormDef

```
<FormDef OID="frmAE" Name="frmAE" Repeating="Yes" pf:DBUID="5761"
pf:GUID="{26FD95F7-1250-4879-B97F-0C58871DE56D}"
pf:Revision="153925387562062">
  <ItemGroupRef ItemGroupOID="frmAE.sctAE" OrderNumber="1" Mandatory="No" />
  <pf:Mnemonic>
    <TranslatedText>AE</TranslatedText>
    <TranslatedText xml:lang="en-US">AE</TranslatedText>
    <TranslatedText xml:lang="ja-JP">AE</TranslatedText>
  </pf:Mnemonic>
</FormDef>
```

DownloadAdminDataODM

Returns lists of all users, sites, and signature definitions in a study.

XmlElement **DownloadAdminDataODM**(*XmlElement* node)

Input parameters—DownloadAdminDataODM

Takes an XmlElement that follows the DownloadAdminDataODM element schema as an input parameter. The DownloadAdminDataODM element has the following children.

DownloadAdminDataODM input parameters	
Node/Attribute name	Description
trial	<p>The study from which to retrieve administrative data.</p> <p>Specify either the study name, or the study alias value that is used when registering the study through the InForm Adapter Admin interface.</p>
userName	The user ID of the user who is requesting the data.
priorFileOID	<p>Optional reference to the previous file (if one exists) in a series.</p> <p>Type = String.</p>
fileType	<p>The type of ODM file data that is to be returned.</p> <p>Type = Enumeration.</p> <p>Enumeration values = Snapshot, Transactional..</p>
mappingVersion	<p>The version of the InForm-to-ODM mapping. Specify 2.0 for the most complete and accurate representation of the InForm data that is returned in ODM format.</p> <p>Type = Enumeration.</p> <p>Enumeration values = 1.0, 2.0.</p> <p>Default = 2.0.</p>
includeExtensions	<p>Specifies whether to include Oracle Phase Forward ODM extensions in the data that is returned from the method.</p> <p>Type = Boolean.</p> <p>Default = True.</p>
complianceMode	<p>Specifies how to handle transactions in the study that are deleted and then undeleted.</p> <p>Type = Enumeration.</p> <p>Enumeration values = Strict, Loose.</p> <p>Default = Strict.</p> <p>Strict uses a Remove transaction to indicate that a form has been deleted. If the form is subsequently undeleted, the returned data includes all the data for the form that was deleted and then undeleted.</p> <p>Loose uses a FormStatus or ItemGroupStatus element with the attribute name of Deleted. Loose compliance mode is more efficient.</p>

DownloadAdminDataODM input parameters

Node/Attribute name	Description
includeUsers	Parameters that specify a section in the admin data to be returned with the response.
includeLocations	
includeSignatures	includeUsers is required if you want to specify userBookmark.
includeGroups	Type=Boolean.
includeLocales	Values=True or False. Default=True (the section is included).
userBookmark	The InForm UserID. You must specify includeUsers if you want to specify a userBookmark. <ul style="list-style-type: none"> • If userBookmark is specified, users are returned beginning with the UserID that immediately follows (greater than) the specified UserID. The number of records returned by the call is equal to the ODMUserBookmark count as defined in the configuration file <code>informAdapter.ODM.config</code>. To return all users in multiple calls, use a bookmark value of zero (0) in the first call. If the userBookmark is greater than zero, only the user section of admin data is returned, regardless of whether you specified any other parameters. • If a userBookmark is not specified, all users are returned in a single response, beginning with the first user in the study.

Example request—DownloadAdminDataODM

```
<node xmlns="http://www.phaseforward.com/InFormAdapter/ODM/1.0">
  <DownloadAdminDataODM
    xmlns="http://www.phaseforward.com/InFormAdapter/ODM/2.0"
    priorFileOID="Depression Study/{25213601-4fd7-4502-bc65-af2fd73d1c3}"
    fileType="Transactional" mappingVersion="2.0"
    include_Extensions="true" complianceMode="Strict"
    trial="pfst45odm" userName="soatest"
    include_Signature = "true" include_users="true" include_locations="true"
    include_groups="false" include_locales="false"
    UserBookmark = "0"/>
</node>
```

Response—DownloadAdminDataODM

Returns an XmlElement that contains the list of all users, sites, and signature definitions in a site in a study.

If you are using bookmarks, the response includes:

- **UserBookmark**—The last UserBookmark that has been processed. If UserBookmark is the same as the request there are no more users.
- **Status**—Optional field that indicates whether there are more users. Status appears only when there are no more users to process. The bookmark will always be that of the last processed user.

For examples of responses, see:

- *Transactional data—DownloadAdminDataODM response* (on page 110).
- *Snapshot data—DownloadAdminDataODM response* (on page 110).

Using a bookmark

To return all user admin data in multiple calls and responses:

- 1 In the first call to DownloadAdminDataODM, obtain the Signature, Locations, and Users sections, but limit the number of users to return by specifying a user bookmark with a value of zero (0).
- 2 In the second call, DownloadAdminDataODM again, this time using the bookmark that was returned by the first method call. This will return only the User section, starting with the first record after the userBookmark.
- 3 Make additional calls with the same parameters. Check to determine whether all users have been returned by either checking for the status node, or determining whether the bookmark node in the response is the same as the userBookmark in the request.

Bookmark example

This is an excerpt from the InFormAdapter.ODM.config file, with an example of ODMUserBookmark count of 100 records.

```
.
.
<AdapterSettings>
  <RootVirtualDirectory>InFormAdapter</RootVirtualDirectory>
  <CustomerURI>www.phaseforward.com</CustomerURI>
  <ApplicationName>CentralServices</ApplicationName>
  <ApplicationId>8833091a-b3e7-4049-b22b-868551c9af32</ApplicationId>
  <MultiInstanceSuffix></MultiInstanceSuffix>
</AdapterSettings>
  <ODMUserBookmark count="100" />
  <ODMTransaction count="500" />
  <!-- Uncomment this empty element to disable the application of ODM data
  reduction post processing. -->
  <!-- <SkipODMReduction /> -->
  <!-- if auditResponse set to true, request will be audited even when
  auditRequest=false -->
  <InFormAdapterAudit auditRequest="true" auditResponse="true" />
.
.
.
```

Internationalization—DownloadAdminDataODM response

Product Locale

The product locale of the InForm software. Used to extract the translations in the InComplete Reasons codelist.

Applies to studies that use InForm 4.7 software, InForm 5.0 software, and subsequent releases.

The consumer of the incomplete reason code list must get the product locale from the admin data, and use one product locale to extract the incomplete reason.

For studies that use the InForm 4.6 software, product locale is not included in the admin data.

Schema

```
<xs:attributeGroup name="ProductLocalAttributeDefinition">
  <xs:attribute ref="xml:lang" />
</xs:attributeGroup>

<xs:element name="ProductLocale">
  <xs:complexType>
    <xs:attributeGroup ref="ProductLocalAttributeDefinition" />
  </xs:complexType>
</xs:element>

<xs:element name="ProductLocaleList">
  <xs:complexType>
    <xs:sequence>
      <xs:element ref="ProductLocale" minOccurs="1" maxOccurs="unbounded" />
    </xs:sequence>
  </xs:complexType>
</xs:element>
```

Example

```
<pf:ProductLocale xml:lang="en-US" />
<pf:ProductLocale xml:lang="ja-JP" />
```

User Study locale

Each User element includes the attribute StudyLocale. User StudyLocale exists only for studies that use InForm 4.7 software (all releases) and InForm 5.0 software (all releases), and InForm 5.5 software and above.

User StudyLocale is retrieved from the study database.

Schema

```
<xs:attribute name="StudyLocale" type="xs:language"></xs:attribute>
```

Example

```
<User OID="amichelle" UserType="Investigator" pf:DBUID="6953"
pf:GUID="{25FD0671-52D9-41B3-B83F-1BB2100E5DFE}" pf:StudyLocale="en-US">
  <LoginName>amichelle</LoginName>
  <DisplayName>Ann Michelle (CRC)</DisplayName>
  <FullName>Ann Michelle (CRC)</FullName>
  <FirstName>Ann</FirstName>
  <LastName>Michelle (CRC)</LastName>
  <Address />
  <LocationRef LocationOID="7600" />
  <LocationRef LocationOID="7628" />
  <LocationRef LocationOID="7660" />
</User>
```

Site Study locale

Specified in the Location element. Includes the attribute Locale in the attribute group for the site.

Schema

```
<xs:attribute name="Locale" type="xs:language"></xs:attribute>
```

Example

```
<Location OID="54312" Name="Marlboro Hospital" LocationType="Site"
pf:SiteCountry="USA" pf:SiteTimezone="(GMT-05:00) Eastern Time (US &
Canada)" pf:GUID="{C769A488-9AF4-4303-802C-C0147AE58396}"
pf:Revision="198749285921028" pf:Locale="en-US">
  <MetaDataVersionRef StudyOID="Depression Study"
  MetaDataVersionOID="Undefined" EffectiveDate="0001-01-01" />
  <pf:Mnemonic>
    <TranslatedText>MARL</TranslatedText>
  </pf:Mnemonic>
</Location>
```

FullName and DisplayName

Not all cultures use FirstName + LastName as the full name. The full name can be derived from FirstName and LastName elements that are available in the same response. The consumer of DownloadAdminDataODM should rely on FirstName and LastName elements to get the full name or display name.

DisplayName and FullName should be skipped, even though they exist in the response to conform to the ODM 1.3 standard.

Example

```
<User OID="UA" UserType="Sponsor" pf:DBUID="4540" pf:GUID="{931DB5AC-47E8-
4E5D-9348-C862F6889238}">
  <LoginName>UA</LoginName>
  <DisplayName>User Admin</DisplayName>
  <FullName>User Administrator</FullName>
  <FirstName>User</FirstName>
  <LastName>Administrator</LastName>
  <Address />
</User>
```

TranslatedText in Mnemonic element

The Location element contains a Mnemonic element, which contains the element TranslatedText.

Note: The site mnemonic can contain any Unicode characters. However, because the InForm 4.7 software does not allow you to specify a locale for the site mnemonic, the translated text does not include the xml:lang attribute.

Example—Location

```

<Location OID="7600" Name="PhaseForward" LocationType="Site"
pf:SiteCountry="USA" pf:SiteTimezone="(GMT-05:00) Eastern Time (US & Canada)"
pf:GUID="{3C07AF5F-E07F-471A-8F7C-AB120A48C1BB}"
pf:Revision="153925498812062">
  <MetaDataVersionRef StudyOID="Depression Study"
  MetaDataVersionOID="Study Version 1.0" EffectiveDate="2000-04-04" />
  <MetaDataVersionRef StudyOID="Depression Study"
  MetaDataVersionOID="Study Version 2.0" EffectiveDate="2008-03-28" />
  <MetaDataVersionRef StudyOID="Depression Study"
  MetaDataVersionOID="Study Version 2.0###1222711396" EffectiveDate="2008-
  03-28" />
  <MetaDataVersionRef StudyOID="Depression Study"
  MetaDataVersionOID="Study Version 2.0###1222711535" EffectiveDate="2008-
  03-28" />
  <pf:Mnemonic>
    <TranslatedText>PF</TranslatedText>
  </pf:Mnemonic>
</Location>

```

Meaning and LegalReason elements

These two elements are child elements of SignatureDef. They contain the language-specific text from the study in InForm 4.7 or InForm 5.5 and above and are driven by the study locales.

Both Meaning and LegalReason include a TranslatedText element, which indicates the available translations.

The translations for Meaning and LegalReason are based on the study locales that are available when the DownloadAdminDataODM method is called.

DownloadPatientDataODM

Returns the patient data on a form in a study.

XmlElement **DownloadPatientDataODM**(*XmlElement node*)

Input parameters—DownloadPatientDataODM

Takes an XmlElement that follows the DownloadPatientDataODM element schema as an input parameter. The DownloadPatientDataODM element has the following children.

DownloadPatientDataODM input parameters	
Node/Attribute name	Description
trial	The study from which to retrieve subject data. Specify either the study name, or the study alias value that is used when registering the study through the InForm Adapter Admin interface.
userName	The user ID of the user who is requesting the data.
patientID	The patient ID of the subject for which the data is retrieved.
visitID	The visit from which the subject data is retrieved.

DownloadPatientDataODM input parameters	
Node/Attribute name	Description
visitIndex	<p>If the visit is not a repeating visit, the index is always 1.</p> <p>For a repeating visit, specify the index for the visit from which to retrieve data. For example, “Unscheduled Patient Visit 2” has an index of 2.</p>
formID	The ID of the form from which subject data is retrieved.
formRevision	The revision number of the form.
priorFileOID	<p>Optional reference to the previous file (if one exists) in a series.</p> <p>Type = String.</p>
mappingVersion	<p>The version of the InForm-to-ODM mapping. Specify 2.0 for the most complete and accurate representation of the InForm data that is returned in ODM format.</p> <p>Type = Enumeration.</p> <p>Enumeration values = 1.0, 2.0.</p> <p>Default = 2.0.</p>
includeExtensions	<p>Specifies whether to include Oracle Phase Forward ODM extensions in the data that is returned from the method.</p> <p>Type = Boolean.</p> <p>Default = True.</p>
skipODMReduction	<p>Specifies whether to disable the ODM data reduction feature.</p> <p>Type = BooleanDefault = False (Data reduction remains enabled.)</p> <p>Optional.</p> <p>ODM data reduction reduces redundancies in ODM output. Items are identified as unique based on their identifying key (OID, repeat key, etc). Contents of items that have the same key are reduced to a single item, in chronological order. The output remains ODM compliant, but is more compact.</p> <p>You can disable reduction for all studies on the server by uncommenting the element <SkipODMReduction /> in the InFormAdapter.ODM.config file. The request parameter value, if specified in the method call, takes precedence over the server-wide element value in the configuration file.</p> <p>For example, if you uncomment <SkipODMReduction /> in the configuration file, and include skipODMReduction=False in the call to the GetTransactions method for study pfst45odm, only the GetTransactions response for that particular request to trial pfst45odm will apply ODM data reduction to the response.</p>

DownloadPatientDataODM input parameters

Node/Attribute name	Description
complianceMode	<p>Specifies how to handle transactions in the study that are deleted and then undeleted.</p> <p>Type = Enumeration.</p> <p>Enumeration values = Strict, Loose.</p> <p>Default = Strict.</p> <p>Strict uses a Remove transaction to indicate that a form has been deleted. If the form is subsequently undeleted, the returned data includes all the data for the form that was deleted and then undeleted.</p> <p>Loose uses a FormStatus or ItemGroupStatus element with the attribute name of Deleted. Loose compliance mode is more efficient.</p>

Note: FileType is set in the internal type to Snapshot.

Example request—DownloadPatientDataODM

```
<node xmlns="http://www.phaseforward.com/InFormAdapter/ODM/1.0">
  <DownloadPatientDataODM
    xmlns="http://www.phaseforward.com/InFormAdapter/ODM/2.0"
    priorFileOID="{30CF7D2D-4824-46D4-BEE2-BBDE2EEA3B67}"
    mappingVersion="2.0" includeExtensions="false"
    complianceMode="Loose" trial="pfst45odm" userName="pjohnson"
    patientID="15272" visitID="10654" visitIndex="1" formID="6442"
    formRevision="241095329541088" >
  </DownloadPatientDataODM>
</node>
```

Response—DownloadPatientDataODM

Returns an XmlElement that contains the subject data on a form for subjects who match the specified patient ID. The subject data is located under the /ODM/ClinicalData XPath in the returned XML.

For more information, see *DownloadPatientDataODM response* (on page 112).

GetSiteList

Returns the list of all sites in the specified study.

XmlElement **GetSiteList**(*XmlElement* node)

Input parameters—GetSiteList

Takes an XmlElement that follows the GetSiteList element schema as an input parameter. The GetSiteList element has the following children.

GetSiteList input parameters	
Node/Attribute name	Description
trial	The study from which to retrieve a list of sites.

Example request—GetSiteList

```
<GetSiteList trial="pfst"
  xmlns="http://www.phaseforward.com/InFormAdapter/ODM/1.0" />
```

Response—GetSiteList

Returns an XmlElement that contains the list of sites in the study. The site list is located under the /CRFSUBMIT/SITELIST XPath in the returned XML.

For more information, see *GetSiteList example response* (on page 112).

Internationalization—GetSiteList response

GetSiteList returns the language for each site for trials that use the InForm 4.7 and InForm 5.0 software and subsequent releases.

Example:

```
<SITELIST>
  <SITEINFO SITEID="54312" SITENAME="Marlboro Hospital" SITEMNEMONIC="MARL"
    SITEGUID="{C769A488-9AF4-4303-802C-C0147AE58396}" LANGUAGECODE="en-US" />
  <SITEINFO SITEID="7628" SITENAME="McLean Hospital" SITEMNEMONIC="MCLEAN"
    SITEGUID="{C966597A-B965-413F-A3B4-7F38449CC23B}" LANGUAGECODE="en-US" />
  <SITEINFO SITEID="7660" SITENAME="Mass General Hospital" SITEMNEMONIC="MGH"
    SITEGUID="{7C9EAD34-BAD3-4E80-BEA9-BAC29E055D08}" LANGUAGECODE="en-US" />
  <SITEINFO SITEID="7600" SITENAME="PhaseForward" SITEMNEMONIC="PF"
    SITEGUID="{3C07AF5F-E07F-471A-8F7C-AB120A48C1BB}" LANGUAGECODE="en-US" />
  <SITEINFO SITEID="7644" SITENAME="Veterans Administration Hospital"
    SITEMNEMONIC="VA" SITEGUID="{867835F8-3F2A-4D9D-81D0-2673703A0999}"
    LANGUAGECODE="en-US" />
</SITELIST>
```

GetPatientList

Returns the list of all subjects that are associated with a particular site. Archived subjects are not returned.

XmlElement GetPatientList(*XmlElement* node)

Input parameters—GetPatientList

Takes an XmlElement that follows the GetPatientList element schema as an input parameter. The GetPatientList element has the following children.

GetPatientList input parameters	
Node/Attribute name	Description
trial	The study from which to retrieve a list of subjects. Specify either the study name, or the study alias value that is used when registering the study through the InForm Adapter Admin interface.
siteID	The DBUID of the site for which the list of subjects is retrieved.

Example request—GetPatientList

```
<GetPatientList trial="pfst" siteID="11210"
  xmlns="http://www.phaseforward.com/InFormAdapter/ODM/1.0"/>
```

Response—GetPatientList

Returns an XmlElement that contains the list all subjects in a site in a study. The subject list is located under the /CRFSUBMIT/PATIENTLIST XPath in the returned XML.

For more information, see *GetPatientList example response* (on page 112).

GetPatientForms

Returns the list of all forms that apply for a subject.

XmlElement **GetPatientForms**(*XmlElement node*)

Input parameters—GetPatientForms

Takes an XmlElement that follows the GetPatientForms element schema as an input parameter. The GetPatientForms element has the following children.

GetPatientForms input parameters	
Node/Attribute name	Description
trial	The study from which to retrieve the subject forms. Specify either the study name, or the study alias value that is used when registering the study through the InForm Adapter Admin interface.
patientID	The patient ID of the subject for which the data is retrieved.

Example request—GetPatientForms

```
<GetPatientForms trial="pfst45" patientID="10769"
  xmlns="http://www.phaseforward.com/InFormAdapter/ODM/1.0" />
```

Response—GetPatientForms

Returns an XmlElement that contains the list of sites located in the study. The XML contains the following element types:

- FORMSETLIST—A list of all of the patient's visits.
- FORMSET—A child of FORMSETLIST. Represents one of the patient's visits.
- FORMLIST—A child of FORMSET. Contains a list of all the forms within a visit.
- FORM—A child of FORMSET. Each form element represents one of the patient's forms.

For more information, see *GetPatientForms example response* (on page 113).

GetTransactions

Returns a list of all the subject-related transactions for a specified study.

XmlElement **GetTransactions**(*XmlElement requestParams*)

Along with the ODM document, the XML element **Status** and a **bookmark** is returned.

Status contains one of the following values:

- **OK** means that the transaction processed normally and another call should be made.
- **END** means that the call ended on the last transaction in the data, and the calls can stop processing.

The **bookmark** returns the record after which processing should start the next time that GetTransactions is called.

Input parameters—GetTransactions

Takes the Xml Element **DownloadTransactionODM** that follows the GetTransactionODM element schema as an input parameter. The DownloadTransactionODM element has the following attributes.

DownloadTransactionODM input parameters	
Node/Attribute name	Description
trial	The study from which to retrieve transaction data. Specify either the study name, or the study alias value that is used when registering the study through the InForm Adapter Admin interface.

DownloadTransactionODM input parameters	
Node/Attribute name	Description
bookmark	<p>The InForm transaction ID.</p> <ul style="list-style-type: none"> • If a bookmark is specified—Transactions are returned beginning with the transaction that follows the specified transaction ID. • If the bookmark is not specified—Transactions are returned beginning from the first transaction in the study. <p>For more information, see <i>Usage—GetTransactions</i> (on page 96).</p>
userName	The user ID of the user who is requesting the data.
priorFileOID	<p>Optional reference to the previous file (if one exists) in a series.</p> <p>Type = String.</p>
mappingVersion	<p>The version of the InForm-to-ODM mapping. Specify 2.0 for the most complete and accurate representation of the InForm data that is returned in ODM format.</p> <p>Type = Enumeration.</p> <p>Enumeration values = 1.0, 2.0.</p> <p>Default = 2.0.</p>
includeExtensions	<p>Specifies whether to include Oracle Phase Forward ODM extensions in the data that is returned from the method.</p> <p>Type = Boolean.</p> <p>Default = True.</p>

DownloadTransactionODM input parameters	
Node/Attribute name	Description
skipODMReduction	<p>Specifies whether to disable the ODM data reduction feature.</p> <p>Type = BooleanDefault = False (Data reduction remains enabled.)</p> <p>Optional.</p> <p>ODM data reduction reduces redundancies in ODM output. Items are identified as unique based on their identifying key (OID, repeat key, etc). Contents of items that have the same key are reduced to a single item, in chronological order. The output remains ODM compliant, but is more compact.</p> <p>You can disable reduction for all studies on the server by uncommenting the element <SkipODMReduction /> in the InFormAdapter.ODM.config file. The request parameter value, if specified in the method call, takes precedence over the server-wide element value in the configuration file.</p> <p>For example, if you uncomment <SkipODMReduction /> in the configuration file, and include skipODMReduction=False in the call to the GetTransactions method for study pfst45odm, only the GetTransactions response for that particular request to trial pfst45odm will apply ODM data reduction to the response.</p>
complianceMode	<p>Specifies how to handle transactions in the study that are deleted and then undeleted.</p> <p>Type = Enumeration.</p> <p>Enumeration values = Strict, Loose.</p> <p>Default = Strict.</p> <p>Strict uses a Remove transaction to indicate that a form has been deleted. If the form is subsequently undeleted, the returned data includes all the data for the form that was deleted and then undeleted.</p> <p>Loose uses a FormStatus or ItemGroupStatus element with the attribute name of Deleted. Loose compliance mode is more efficient.</p>

Example request—GetTransactions

```
<node xmlns="http://www.phaseforward.com/InFormAdapter/ODM/1.0">
  <DownloadTransactionODM xmlns:xsi="http://www.w3.org/2001/XMLSchema-
instance" xmlns:xsd="http://www.w3.org/2001/XMLSchema"
  trial="pfst47odm" bookmark="{CB219A42-F227-43D8-93F7-DF91AED86EC2}"
  userName="system"
  priorFileOID="{CB219A42-F227-43D8-93F7-DF91AED86EC2}"
  mappingVersion="2.0"
  complianceMode="Loose"
  xmlns="http://www.phaseforward.com/InFormAdapter/ODM/2.0" />
</node>
```

Response—GetTransactions

Returns an XmlElement that contains the subject transaction data (such as form submissions) for subjects who match the specified patient ID. The subject data is located under the /ODM/ClinicalData XPath in the returned XML.

GetTransactions response	
Node/Attribute name	Description
Description	The description of the study.
FileType	For InForm data, FileType is always Transactional , indicating that an InForm transaction is returned.
FileOID	A unique identifier for the file. Consists of the study.name followed by a GUID. For example: <code>pfst/{345C8404-9656-425B-BA03-EE92D7E1FE91}</code>
PriorFileOID	An identifier for the transaction that was retrieved by the previous API call.
CreationDateTime	The date and time when the API call was made.
ODMVersion	The version of the ODM schema of the returned data.
Originator	The ID of the user who made the API call.
TransactionsProcessed	Indicates the number of transactions that were considered by the method. Note: This number is not the same as the number of clinical data transactions that are returned. Some transactions do not contain clinical data.
Bookmark	The bookmark that must be passed into the next call to GetTransactions. Indicates the point in the transaction log after which the processing should begin. For more information, see <i>Usage—GetTransactions</i> (on page 96).
MetaDataVersionOID	Identifier for the study version of the form in the InForm system. If the form does not contain a study version, MetaDataVersion is returned with the value "Undefined."

For more information, see:

- *Example returning clinical data* (on page 114).
- *Example returning no clinical data* (on page 114).

Usage—Get Transactions

The GetTransactions web method provides an incremental way to retrieve data from the InForm Adapter interface.

To return all the subject transactions for a study, you call the GetTransactions web method multiple times. With each call, the InForm Adapter software:

- Analyzes 500 transactions and returns all the clinical data transactions that it finds.
- Returns a bookmark that must be passed into the next call to GetTransactions. The bookmark indicates the point in the transaction log after which the processing should begin.

To begin retrieving data from the beginning of the transaction log, the first call to GetTransactions must have an empty bookmark.

Note: Because an InForm study contains administration and metadata transactions as well as patient transactions, the first several calls to GetTransactions typically return an ODM element that does not contain any data (child elements).

To retrieve all the subject transactions for a study:

- 1 Call GetTransactions with an empty bookmark, indicating that you want to retrieve all subject transactions starting at the beginning of your study:

```
<DownloadTransactionODM xmlns:xsd="http://www.w3.org/2001/XMLSchema"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  trial="pfst45" bookmark=""
  userName="mcollins"
  xmlns="http://www.phaseforward.com/InFormAdapter/ODM/2.0" />
```

- 2 Call GetTransactions again, this time using the bookmark that was returned by the first method call:

```
<DownloadTransactionODM xmlns:xsd="http://www.w3.org/2001/XMLSchema"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  trial="pfst45" bookmark="{833A7114-BA90-4494-9E4E-7A9D3446E318}"
  userName="mcollins"
  xmlns="http://www.phaseforward.com/InFormAdapter/ODM/1.0" />
```

- 3 Repeat the process using the FileOID from the previous response as the bookmark for the next call until the results of the call is Status = END, indicating that the process is complete.

What happens after all transactions are processed?

This section includes three scenarios that describe the behavior of GetTransactions when the InForm Adapter software encounters the last transaction to be processed.

For each scenario, the ResponseODM document has been defined to contain the following:

- An ODM element as previously defined.
- The status of the last record that was processed: END or OK.
- A bookmark.

In addition, transactions A, B, C, and D exist.

- **Scenario 1**

In this scenario, transactions A, B, C, and D contain clinical data. In the first call to GetTransactions, A, B, and C are processed, and C is passed as the bookmark. In the next call, processing begins with D.

Because D contains clinical data:

- The ODM element returns transaction data.
- The Status value is "END."
- The bookmark is D.

- **Scenario 2**

In this scenario, A, B, and C contain clinical data, but D does not contain clinical data. In the first call to GetTransactions, A, B, and C are processed, and C is passed as the bookmark. In the next call, processing begins with D.

Because D does not contain clinical data:

- The ODM element returns an empty ODM document.
- The Status value is "END."
- The bookmark is D.

- **Scenario 3**

In this scenario, A, B, C, and D have been processed by the first call, and D is passed as the bookmark.

Because D is the last transaction:

- An ODM element is not returned.
- The Status value is "END."
- The Bookmark is D. You get back the same bookmark you passed in, because processing reached the last transaction.

After you process any of these scenarios, check to see whether ODM exists, and if it does, process it. If the results of subsequent call is Status = END, the download is complete. If Status is a value other than END, you must make another call using the bookmark.

For more information, see *GetTransactions example response* (on page 113).

GetTransactionStatus

Returns the status of transactions that have been processed.

Input parameters

Takes an XmlElement that follows the DownloadTransactionODM element schema as an input parameter.

GetTransactionStatus input parameter	
Node/Attribute name	Description
trial	The study from which to retrieve transaction data.
bookmark	The InForm transaction ID. The bookmark is used when calculating TransactionXmlRemaining. When you pass in the last bookmark, TransactionXmlRemaining returns 0.

Example request—GetTransactionStatus

```
<node xmlns="http://www.phaseforward.com/InFormAdapter/ODM/1.0">
  <DownloadTransactionODM xmlns:xsi="http://www.w3.org/2001/XMLSchema-
instance" xmlns:xsd="http://www.w3.org/2001/XMLSchema"
  trial="testtrial" mappingVersion="2.0"
  xmlns="http://www.phaseforward.com/InFormAdapter/ODM/2.0" />
</node>
```

Response—GetTransactionStatus

Returns an XML element that contains information about the transactions that have been processed.

GetTransactionStatus response	
Node/Attribute name	Description
TotalTransactionCount	The total number of transactions in the system, regardless of how many transactions have been converted into XML.
TransactionXmlCount	The number of transactions that have been converted in to XML. Transaction XMLs are used to generate ODM transactions. If the system is up to date, TotalTransactionCount and TransactionXmlCount will be equal.
TransactionXmlRemaining	The number of transactions that remain in the system after the specified bookmark.

GetTransactionStatus response

Node/Attribute name	Description
LastTransactionXmlTime	The time/date of the most recent transaction. Note: If this time/date is far in the past, it might indicate either of the following: <ul style="list-style-type: none"> • The transaction XML is not being generated. • The study is archived and no new transactions are occurring.

If TransactionsProcessed (as returned by GetTransactions) are summed, you can compare that number with the information that is returned from GetTransactionStatus to verify that you have received everything.

$$\text{SumOfTransactionsprocessed} + \text{TransactionXmlRemaining} = \text{TransactionXmlCount}$$

To find the percentage of transactions completed:

$$1 - \text{TransactionXmlRemaining} / \text{TransactionXmlCount} = \% \text{ complete}$$

For more information, see *GetTransactionStatus example response* (on page 115).

RetrieveData

Returns the ODM data that matches the specified LSID.

XmlElement **RetrieveData**(*XmlElement requestParams*)

Input parameters—RetrieveData

Takes an XmlElement that follows the RetrieveDataInputMsg element schema as an input parameter. The RetrieveDataInputMsg element has the following children.

RetrieveDataInputMsg input parameters

Child Element Name	Description
ContentLSID	The LSID of the data to be retrieved.
XPath	An optional XPath query that returns a subset of the data.
MaxReturnSize	Maximum return size. To indicate that there is no maximum size, enter -1 .
Format	ODM.
PriorFileOID	Optional reference to the previous file (if one exists) in a series. Type = String.

RetrieveDataInputMsg input parameters	
Child Element Name	Description
MappingVersion	<p>The version of the InForm-to-ODM mapping. Specify 2.0 for the most complete and accurate representation of the InForm data that is returned in ODM format.</p> <p>Type = Enumeration.</p> <p>Enumeration values = 1.0, 2.0.</p> <p>Default = 2.0.</p>
IncludeExtensions	<p>Specifies whether to include Oracle Phase Forward ODM extensions in the data that is returned from the method.</p> <p>Type = Boolean.</p> <p>Default = True.</p>
ComplianceMode	<p>Specifies how to handle transactions in the study that are deleted and then undeleted.</p> <p>Type = Enumeration.</p> <p>Enumeration values = Strict, Loose.</p> <p>Default = Strict.</p> <p>Strict uses a Remove transaction to indicate that a form has been deleted. If the form is subsequently undeleted, the returned data includes all the data for the form that was deleted and then undeleted.</p> <p>Loose uses a FormStatus or ItemGroupStatus element with the attribute name of Deleted. Loose compliance mode is more efficient.</p>

Example request—RetrieveData

This request retrieves data for a site.

Note: This sample has lines omitted, which are indicated by comments. For a complete example response, see the ODM Export interface example XML files provided with the product release.

```
<requestParams xmlns="http://www.phaseforward.com/AdapterFramework/Export/1.0">
  <RetrieveDataInputMsg
    xmlns="http://www.phaseforward.com/AdapterFramework/Export/2.0">
    <ContentLSID>URN:LSID:www.phaseforward.com:www.phaseforward.com/InFormAdapter//;Trial%3dpfstodm%2fSite;GuidTuple:{91E00421-3FB4-42AE-96B7-033D58E2F102}</ContentLSID>
    <XPath/>
    <Format>ODM</Format>
    <MaxReturnSize>-1</MaxReturnSize>
    <PriorFileOID>APITesting</ns1:PriorFileOID>
    <MappingVersion>2.0</ns1:MappingVersion>
    <IncludeExtensions>true</ns1:IncludeExtensions>
    <ComplianceMode>Strict</ns1:ComplianceMode>
  </RetrieveDataInputMsg>
</requestParams>
```

Response—RetrieveData

Returns XML that contains the data that was requested. The XML follows the RetrieveDataOutputMsg element schema. The returned data is located in the text of the /RetrieveDataOutputMsg/ReturnData element.

```
<RetrieveDataOutputMsg
xmlns="http://www.phaseforward.com/AdapterFramework/Export/1.0">
  <ReturnData>The return data may be found here.</ReturnData>
</RetrieveDataOutputMsg>
```

Usage—RetrieveData

The RetrieveData method uses LSIDs to specify the data to be returned. LSIDs are returned by different event types from the Eventing interface. For more information, see Eventing interface.

Passing a User LSID

This request returns a list of users for a study.

```
<requestParams xmlns="http://www.phaseforward.com/AdapterFramework/Export/1.0">
  <RetrieveDataInputMsg
xmlns="http://www.phaseforward.com/AdapterFramework/Export/2.0">
    <ContentLSID>URN:LSID:www.phaseforward.com:www.phaseforward.com/InFormAdap
ter//;Trial=PFST45/User;UserGuidRef:{47930B2E-C1BE-4A65-9092-A693CBBC0767}
    </ContentLSID>
    <XPath/>
    <Format>ODM</Format>
    <MaxReturnSize>-1</MaxReturnSize>
    <PriorFileOID>APITesting</ns1:PriorFileOID>
    <MappingVersion>2.0</ns1:MappingVersion>
    <IncludeExtensions>>true</ns1:IncludeExtensions>
    <ComplianceMode>Strict</ns1:ComplianceMode>
  </RetrieveDataInputMsg>
</requestParams>
```

Passing an Item LSID

This request returns data for all items on a single form for a single subject.

```
<requestParams xmlns="http://www.phaseforward.com/AdapterFramework/Export/1.0">
  <RetrieveDataInputMsg
xmlns="http://www.phaseforward.com/AdapterFramework/Export/2.0">
    <ContentLSID>URN:LSID:www.phaseforward.com:www.phaseforward.com/InFormAdap
ter//;Trial=${TRIAL_Alias}/Site=9995,94986885328025/Subject={7DA8FBD4-
2749-4A81-8778-
56481BF072B6}/Formset=vstBASE,,1.000/Form=frmVS,94986819609025.000,1.000/S
ection=sctVS/Item;RefNameTuple:itmVSWeight
    </ContentLSID>
    <XPath/>
    <Format>ODM</Format>
    <MaxReturnSize>-1</MaxReturnSize>
    <PriorFileOID>APITesting</ns1:PriorFileOID>
    <MappingVersion>2.0</ns1:MappingVersion>
    <IncludeExtensions>>true</ns1:IncludeExtensions>
    <ComplianceMode>Strict</ns1:ComplianceMode>
  </RetrieveDataInputMsg>
</requestParams>
```

Passing a Patient LSID

This request returns a list of subjects for a single site.

```
<requestParams xmlns="http://www.phaseforward.com/AdapterFramework/Export/1.0">
  <RetrieveDataInputMsg
    xmlns="http://www.phaseforward.com/AdapterFramework/Export/2.0">
    <ContentLSID>URN:LSID:www.phaseforward.com:www.phaseforward.com/InFormAdap
      ter//;Trial=PFST45/Site={8CF36263-64E8-49E7-9355-
        424AFD6AD434}/Subject;DBUIDTuple:{2C69FFB8-DAA4-482F-BB2D-
        1FB176E4A7C5},193316154218003
    </ContentLSID>
    <XPath/>
    <Format>ODM</Format>
    <MaxReturnSize>-1</MaxReturnSize>
    <PriorFileOID>APITesting</ns1:PriorFileOID>
    <MappingVersion>2.0</ns1:MappingVersion>
    <IncludeExtensions>true</ns1:IncludeExtensions>
    <ComplianceMode>Strict</ns1:ComplianceMode>
  </RetrieveDataInputMsg>
</requestParams>
```

Examples of ODM Responses

DownloadMetadataODM example response

Transactional Data—DownloadMetadataODM response

Note: This sample has lines omitted, which are indicated by comments. For a complete example response, see the ODM Export interface example XML files provided with the sample applications.

```

<DownloadMetadataODMResult
xmlns="http://www.phaseforward.com/InFormAdapter/ODM/1.0">
  <ResponseODM
xmlns:pf="http://www.phaseforward.com/InFormAdapter/ODM/Extensions/2.0"
xmlns="http://www.phaseforward.com/InFormAdapter/ODM/2.0">
    <?xml version="1.0" encoding="UTF-8"?>
      <ODM Description="Depression Study" FileType="Transactional"
FileOID="Depression Study/c3b41e13-3a26-4b50-b17f-5304ae8cedd0"
CreationDateTime="2010-12-29T18:54:40+00:00" ODMVersion="1.3"
Originator="system" pf:MappingVersion="V2" pf:HierarchicalOIDs="Yes"
pf:InFormAdapterVersion="1.0.4014.24733"
xmlns="http://www.cdisc.org/ns/odm/v1.3"
xmlns:pf="http://www.phaseforward.com/InFormAdapter/ODM/Extensions/2.0">
        <Study OID="Depression Study">
          <GlobalVariables>
            <StudyName>Depression Study</StudyName>
            <StudyDescription>Not Defined</StudyDescription>
            <ProtocolName>PF-ST Sample Trial</ProtocolName>
          </GlobalVariables>
          <BasicDefinitions>
            <MeasurementUnit OID="Inches" Name="Inches" pf:DBUID="1766"
pf:GUID="{32A95F99-27FF-41AE-809C-F46583001D69}"
pf:Revision="153925075453062">
              <Symbol>
                <TranslatedText>in</TranslatedText>
              </Symbol>
            </MeasurementUnit>
            <MeasurementUnit OID="Centimeter" Name="Centimeter" pf:DBUID="1770"
pf:GUID="{D625F294-A02D-4A8D-9AFE-D3AF302F718F}"
pf:Revision="153925075671062">
              <Symbol>
                <TranslatedText>cm</TranslatedText>
              </Symbol>
            </MeasurementUnit>
            <!--other MeasurementUnit entries omitted from example-->
          </BasicDefinitions>
          <MetaDataVersion OID="Study Version 1.0" Name="PF-ST Sample Trial"
pf:ApprovalDate="2002-01-17T19:05:46+00:00" pf:DBUID="7987"
pf:GUID="{40B6DEE9-CEF8-435C-9F28-33C5D9EC83B9}"
pf:Revision="153925521781062">
            <Protocol>
              <StudyEventRef StudyEventOID="CommonCRF" OrderNumber="1"
Mandatory="No" />
              <StudyEventRef StudyEventOID="screen" OrderNumber="2" Mandatory="No"
/>
              <!--other StudyEventRef entries omitted from sample-->
            </Protocol>
            <StudyEventDef OID="CommonCRF" Name="CommonCRF" Repeating="No"
Type="Common" Category="CommonCRF" pf:DBUID="7989" pf:GUID="{362E22F5-A2D8-
48F5-84D0-858F3A4B8C83}" pf:Revision="153925521781062" pf:UUID="9D6BBC5D-
5811-11D2-8065-00A0C9AF7674">
              <FormRef FormOID="frmAE" OrderNumber="1" Mandatory="No" />
              <FormRef FormOID="frmCM" OrderNumber="2" Mandatory="No" />
              <FormRef FormOID="frmDOSE" OrderNumber="3" Mandatory="No" />
            <pf:Mnemonic>

```

```

        <TranslatedText>CCRF</TranslatedText>
    </pf:Mnemonic>
</StudyEventDef>
    <StudyEventDef OID="screen" Name="screen" Repeating="No"
Type="Scheduled" Category="Screening" pf:DBUID="7991" pf:GUID="{F3566F50-
9261-4997-B179-58940D72091A}" pf:Revision="153925521781062"
pf:UUID="D882CE38-0F42-11D2-A419-00A0C963E0AC">
    <FormRef FormOID="frmScr" OrderNumber="1" Mandatory="No" />
    <pf:Mnemonic>
        <TranslatedText>Screen</TranslatedText>
    </pf:Mnemonic>
</StudyEventDef>
    <StudyEventDef OID="enroll" Name="enroll" Repeating="No"
Type="Scheduled" Category="Enrollment" pf:DBUID="7994" pf:GUID="{4A6C530B-
904C-4C04-9660-17DC453CBCDB}" pf:Revision="153925521781062"
pf:UUID="D882CE3A-0F42-11D2-A419-00A0C963E0AC">
    <FormRef FormOID="frmEnr" OrderNumber="1" Mandatory="No" />
    <pf:Mnemonic>
        <TranslatedText>Enroll</TranslatedText>
    </pf:Mnemonic>
</StudyEventDef>
    <!--other StudyEventDef entries omitted from example-->
    <FormDef OID="frmAE" Name="frmAE" Repeating="Yes" pf:DBUID="5761"
pf:GUID="{26FD95F7-1250-4879-B97F-0C58871DE56D}"
pf:Revision="153925387562062">
    <ItemGroupRef ItemGroupOID="frmAE.sctAE" OrderNumber="1"
Mandatory="No" />
    <pf:Mnemonic>
        <TranslatedText>AE</TranslatedText>
    </pf:Mnemonic>
</FormDef>
    <FormDef OID="frmCGI" Name="frmCGI" Repeating="No" pf:DBUID="5867"
pf:GUID="{779C186B-FBF9-4CFC-936B-C28AA86B5228}"
pf:Revision="153925395500062">
    <ItemGroupRef ItemGroupOID="frmCGI.sctCGIImp" OrderNumber="1"
Mandatory="No" />
    <ItemGroupRef ItemGroupOID="frmCGI.sctCGISevere" OrderNumber="2"
Mandatory="No" />
    <ItemGroupRef ItemGroupOID="frmCGI.sctCGIVAS" OrderNumber="3"
Mandatory="No" />
    <pf:Mnemonic>
        <TranslatedText>CGI</TranslatedText>
    </pf:Mnemonic>
</FormDef>
    <FormDef OID="frmCM" Name="frmCM" Repeating="Yes" pf:DBUID="6548"
pf:GUID="{2DB5A7C2-87A0-46ED-BFBE-D2E18614108D}"
pf:Revision="153925446500062">
    <ItemGroupRef ItemGroupOID="frmCM.sctCMEntry" OrderNumber="1"
Mandatory="No" />
    <pf:Mnemonic>
        <TranslatedText>CM</TranslatedText>
    </pf:Mnemonic>
</FormDef>
    <!--other FormDef entries omitted from example-->

    <ItemGroupDef OID="frmAE.sctAE" Name="sctAE" Repeating="No"
pf:DBUID="5758" pf:GUID="{E5367F79-5252-48C3-B5C7-FE937E6E76E1}"
pf:Revision="153925387312062">
    <ItemRef ItemOID="frmAE.sctAE.itmAEDdiag.txtAEDdiag" OrderNumber="1"
Mandatory="Yes" />
    <ItemRef ItemOID="frmAE.sctAE.itmAECODEDESC.calAEDDESC"
OrderNumber="2" Mandatory="Yes" />
    <ItemRef
ItemOID="frmAE.sctAE.itmAECODESYS.grpAECODESYSTEM.calAECODE" OrderNumber="3"
Mandatory="No" />
    <ItemRef
ItemOID="frmAE.sctAE.itmAECODESYS.grpAECODESYSTEM.calAESYSTEM"
OrderNumber="4" Mandatory="No" />
    <ItemRef ItemOID="frmAE.sctAE.itmAEOSET.dtmAEOSET" OrderNumber="5"
Mandatory="Yes" />
    <ItemRef ItemOID="frmAE.sctAE.itmAESTOP.rdcAESTOP" OrderNumber="6"

```

```

Mandatory="Yes" />
  <ItemRef ItemOID="frmAE.sctAE.itmAESTop.rdcAESTop.dtmAESTop"
OrderNumber="7" Mandatory="No" />
  <ItemRef ItemOID="frmAE.sctAE.itmAESerious.mrdcYesNo"
OrderNumber="8" Mandatory="Yes" />
  <ItemRef ItemOID="frmAE.sctAE.itmAESeverity.rdcAESeverity"
OrderNumber="9" Mandatory="Yes" />
  <ItemRef ItemOID="frmAE.sctAE.itmAERelat.rdcAERelation"
OrderNumber="10" Mandatory="Yes" />
  <ItemRef ItemOID="frmAE.sctAE.itmAEDrugAction.rdcAEDrugAction"
OrderNumber="11" Mandatory="Yes" />
  <ItemRef ItemOID="frmAE.sctAE.itmAEOutcome.rdcAeOutcome"
OrderNumber="12" Mandatory="Yes" />
  <pf:InFormItemRef InFormItemId="frmAE.sctAE.itmAEDiag"
OrderNumber="1" Mandatory="Yes" />
  <pf:InFormItemRef InFormItemId="frmAE.sctAE.itmAECODEDESC"
OrderNumber="2" Mandatory="Yes" />
  <pf:InFormItemRef InFormItemId="frmAE.sctAE.itmAECODESYS"
OrderNumber="3" Mandatory="Yes" />
  <pf:InFormItemRef InFormItemId="frmAE.sctAE.itMAEOnset"
OrderNumber="4" Mandatory="Yes" />
  <pf:InFormItemRef InFormItemId="frmAE.sctAE.itmAESTop"
OrderNumber="5" Mandatory="Yes" />
  <pf:InFormItemRef InFormItemId="frmAE.sctAE.itMAESerious"
OrderNumber="6" Mandatory="Yes" />
  <pf:InFormItemRef InFormItemId="frmAE.sctAE.itMAESeverity"
OrderNumber="7" Mandatory="Yes" />
  <pf:InFormItemRef InFormItemId="frmAE.sctAE.itMAERelat"
OrderNumber="8" Mandatory="Yes" />
  <pf:InFormItemRef InFormItemId="frmAE.sctAE.itMAEDrugAction"
OrderNumber="9" Mandatory="Yes" />
  <pf:InFormItemRef InFormItemId="frmAE.sctAE.itMAEOutcome"
OrderNumber="10" Mandatory="Yes" />
</ItemGroupDef>
<ItemGroupDef OID="frmCGI.sctCGIImp" Name="sctCGIImp" Repeating="No"
pf:DBUID="5811" pf:GUID="{1ED8ECDC-B926-4E78-9287-1F1A8ECA2073}"
pf:Revision="153925391328062">
  <ItemRef ItemOID="frmCGI.sctCGIImp.itmCGIImp.rdcCGIImp"
OrderNumber="1" Mandatory="Yes" />
  <pf:InFormItemRef InFormItemId="frmCGI.sctCGIImp.itmCGIImp"
OrderNumber="1" Mandatory="Yes" />
</ItemGroupDef>
<ItemGroupDef OID="frmCGI.sctCGISevere" Name="sctCGISevere"
Repeating="No" pf:DBUID="5855" pf:GUID="{D04DD4F2-A8D3-48EC-84E0-
94AC98BB5146}" pf:Revision="153925394546062">
  <ItemRef ItemOID="frmCGI.sctCGISevere.itmCGISevere.rdcCGISeverity"
OrderNumber="1" Mandatory="Yes" />
  <pf:InFormItemRef InFormItemId="frmCGI.sctCGISevere.itmCGISevere"
OrderNumber="1" Mandatory="Yes" />
</ItemGroupDef>
<ItemGroupDef OID="frmCGI.sctCGIVAS" Name="sctCGIVAS" Repeating="No"
pf:DBUID="5863" pf:GUID="{7CAC79FB-9FCA-4ADE-903E-2C44033C9C1E}"
pf:Revision="153925395265062">
  <ItemRef ItemOID="frmCGI.sctCGIVAS.itmCGIMood.txtCGIBrowserSide"
OrderNumber="1" Mandatory="Yes" />
  <pf:InFormItemRef InFormItemId="frmCGI.sctCGIVAS.itmCGIMood"
OrderNumber="1" Mandatory="Yes" />
</ItemGroupDef>
<ItemGroupDef OID="frmCM.sctCMEntry" Name="sctCMEntry" Repeating="No"
pf:DBUID="6545" pf:GUID="{546E6DBF-5CEE-42EF-9C2E-96194C036E94}"
pf:Revision="153925446281062">
  <ItemRef ItemOID="frmCM.sctCMEntry.itmCMMed.txtCMMed"
OrderNumber="1" Mandatory="Yes" />
  <ItemRef ItemOID="frmCM.sctCMEntry.itmCMDose.txtCMDose"
OrderNumber="2" Mandatory="Yes" />
  <ItemRef ItemOID="frmCM.sctCMEntry.itmCMStartDate.dtmCMStartDate"
OrderNumber="3" Mandatory="Yes" />
  <ItemRef ItemOID="frmCM.sctCMEntry.itmCMStopDate.rdcCMStopped"
OrderNumber="4" Mandatory="Yes" />
  <ItemRef
ItemOID="frmCM.sctCMEntry.itmCMStopDate.rdcCMStopped.dtmCMStopDate"

```

```

OrderNumber="5" Mandatory="No" />
  <ItemRef ItemOID="frmCM.sctCMEntry.itmCMReason.rdcCMReason"
OrderNumber="6" Mandatory="Yes" />
  <ItemRef
ItemOID="frmCM.sctCMEntry.itmCMReason.rdcCMReason.pdcCMReason"
OrderNumber="7" Mandatory="No" />
  <ItemRef
ItemOID="frmCM.sctCMEntry.itmCMReason.rdcCMReason.txtCMReasonOther"
OrderNumber="8" Mandatory="No" />
  <pf:InFormItemRef InFormItemOID="frmCM.sctCMEntry.itmCMMed"
OrderNumber="1" Mandatory="Yes" />
  <pf:InFormItemRef InFormItemOID="frmCM.sctCMEntry.itmCMDose"
OrderNumber="2" Mandatory="Yes" />
  <pf:InFormItemRef InFormItemOID="frmCM.sctCMEntry.itmCMStartDate"
OrderNumber="3" Mandatory="Yes" />
  <pf:InFormItemRef InFormItemOID="frmCM.sctCMEntry.itmCMStopDate"
OrderNumber="4" Mandatory="Yes" />
  <pf:InFormItemRef InFormItemOID="frmCM.sctCMEntry.itmCMReason"
OrderNumber="5" Mandatory="Yes" />
</ItemGroupDef>
<!--other ItemGroupDef entries omitted from example-->
  <CodeList OID="frmPE.sctPEFollowup.itmPEFReprod.mrdcPEFStatus"
Name="mrdcPEFStatus" DataType="text">
  <CodeListItem CodedValue="3"
pf:SelectionOID="frmPE.sctPEFollowup.itmPEFReprod.mrdcPEFStatus.3">
  <Decode>
    <TranslatedText>No change since Baseline visit</TranslatedText>
  </Decode>
  </CodeListItem>
  <CodeListItem CodedValue="4"
pf:SelectionOID="frmPE.sctPEFollowup.itmPEFReprod.mrdcPEFStatus.4">
  <Decode>
    <TranslatedText>Change since Baseline visit, please
specify:</TranslatedText>
  </Decode>
  </CodeListItem>
  <CodeListItem CodedValue="9"
pf:SelectionOID="frmPE.sctPEFollowup.itmPEFReprod.mrdcPEFStatus.9">
  <Decode>
    <TranslatedText>Not Examined</TranslatedText>
  </Decode>
  </CodeListItem>
  <CodeListItem CodedValue="">
  <Decode>
    <TranslatedText />
  </Decode>
  </CodeListItem>
</CodeList>
<!--other CodeList entries omitted from sample-->
  <pf:InFormItemDef OID="frmAE.sctAE.itmAEDdiag" Name="itmAEDdiag"
SVRRequired="Yes" pf:DBUID="5615" pf:GUID="{F1751AAA-8B55-4050-917A-
C5D7FA9380C8}" pf:Revision="153925376843062">
  <ItemRef ItemOID="frmAE.sctAE.itmAEDdiag.txtAEDdiag" OrderNumber="1"
Mandatory="Yes" />
  </pf:InFormItemDef>
  <pf:InFormItemDef OID="frmAE.sctAE.itmAECCodeDesc" Name="itmAECCodeDesc"
pf:DBUID="5621" pf:GUID="{FD4FA58A-4F6A-4B98-A0BB-0C814BD76057}"
pf:Revision="153925377265062">
  <ItemRef ItemOID="frmAE.sctAE.itmAECCodeDesc.calAEDescrip"
OrderNumber="2" Mandatory="Yes" />
  </pf:InFormItemDef>
  <pf:InFormItemDef OID="frmAE.sctAE.itmAECCodeSys" Name="itmAECCodeSys"
pf:DBUID="5631" pf:GUID="{4C926B74-B6B7-432C-A601-E2AD69577773}"
pf:Revision="153925378109062">
  <ItemRef
ItemOID="frmAE.sctAE.itmAECCodeSys.grpAECCodeSystem.calAECCode" OrderNumber="3"
Mandatory="No" />
  <ItemRef
ItemOID="frmAE.sctAE.itmAECCodeSys.grpAECCodeSystem.calAESystem"
OrderNumber="4" Mandatory="No" />
  </pf:InFormItemDef>

```



```

        <pf:InFormItemDef OID="frmAE.sctAE.itmAEOnset" Name="itmAEOnset"
SVRequired="Yes" pf:DBUID="5637" pf:GUID="{9A720263-D09D-42EE-B40C-
4491B97660DA}" pf:Revision="153925378531062">
        <ItemRef ItemOID="frmAE.sctAE.itmAEOnset.dtmAEOnset" OrderNumber="5"
Mandatory="Yes" />
        </pf:InFormItemDef>
        <!--other pf:InFormItemDef entries omitted from example-->
    </MetaDataVersion>
    <pf:ReviewState pf:DBUID="14216" RefName="DataReview1" StateValue="1"
Revision="1">
        <pf:ReviewStage RefName="DataReview1.ReviewStage1" StageValue="0"
Activated="1" Revision="1">
            <pf:Name>
                <TranslatedText xml:lang="en-US">Needs Review</TranslatedText>
                <TranslatedText xml:lang="ja-JP">要レビュー</TranslatedText>
            </pf:Name>
            <pf:Mnemonic>
                <TranslatedText xml:lang="en-US">RS1</TranslatedText>
                <TranslatedText xml:lang="ja-JP">レビューS1</TranslatedText>
            </pf:Mnemonic>
        </pf:ReviewStage>
        <pf:ReviewStage RefName="DataReview1.ReviewStage2" StageValue="1"
Activated="1" Revision="1">
            <pf:Name>
                <TranslatedText xml:lang="en-US">Pending</TranslatedText>
                <TranslatedText xml:lang="ja-JP">保留</TranslatedText>
            </pf:Name>
            <pf:Mnemonic>
                <TranslatedText xml:lang="en-US">RS2</TranslatedText>
                <TranslatedText xml:lang="ja-JP">レビューS2</TranslatedText>
            </pf:Mnemonic>
        </pf:ReviewStage>
        <pf:ReviewStage RefName="DataReview1.ReviewStage3" StageValue="2"
Activated="1" Revision="1">
            <pf:Name>
                <TranslatedText xml:lang="en-US">Reviewed</TranslatedText>
                <TranslatedText xml:lang="ja-JP">レビュー済</TranslatedText>
            </pf:Name>
            <pf:Mnemonic>
                <TranslatedText xml:lang="en-US">RS3</TranslatedText>
                <TranslatedText xml:lang="ja-JP">レビューS3</TranslatedText>
            </pf:Mnemonic>
        </pf:ReviewStage>
        <pf:Name>
            <TranslatedText xml:lang="en-US">Data Review</TranslatedText>
            <TranslatedText xml:lang="ja-JP">データレビュー</TranslatedText>
        </pf:Name>
        <pf:Mnemonic>
            <TranslatedText xml:lang="en-US">R1</TranslatedText>
            <TranslatedText xml:lang="ja-JP">レビュー1</TranslatedText>
        </pf:Mnemonic>
    </pf:ReviewState>

    <pf:SubjectPool PoolNumber="0" PoolRefName="Eligible" />
    <pf:SubjectPool PoolNumber="1" PoolRefName="AutoSelect" />
    <pf:SubjectPool PoolNumber="2" PoolRefName="ManualFirstN" />
    <pf:SubjectPool PoolNumber="3" PoolRefName="ManualUISelect" />
    <pf:SubjectPool PoolNumber="4" PoolRefName="ManualImport" />
    <pf:SubjectPool PoolNumber="99" PoolRefName="Excluded" />
</Study>
</ODM>
</ResponseODM>
</DownloadMetadataODMResult>

```

Snapshot data—DownloadMetadataODM response

```

<DownloadMetadataODMResult
  xmlns="http://www.phaseforward.com/InFormAdapter/ODM/1.0">
  <ResponseODM
    xmlns="http://www.phaseforward.com/InFormAdapter/ODM/2.0"
    xmlns:xsd="http://www.w3.org/2001/XMLSchema"
    xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
    <ODM
      CreationDateTime="2008-11-07T14:12:23+00:00"
      Description="Depression Study"
      FileOID="Depression Study/93af6341-a6ff-4b32-86f4-1702cc5f885f"
      FileType="Snapshot" ODMVersion="1.3" Originator="soatest"
      PriorFileOID="ANY_STRING_VALUE" pf:HierarchicalOIDs="Yes"
      pf:InFormAdapterVersion="1.2.3.60" pf:MappingVersion="V2"
      xmlns="http://www.cdisc.org/ns/odm/v1.3"
      xmlns:pf="http://www.phaseforward.com/InFormAdapter/ODM/Extensions/2.0">
      <Study
        OID="Depression Study">
        <GlobalVariables>
          <StudyName>Depression Study</StudyName>
          <StudyDescription>Not Defined</StudyDescription>
          <ProtocolName>PF-ST Sample Trial</ProtocolName>
        </GlobalVariables>
        <BasicDefinitions>
          <MeasurementUnit
            Name="Inches"
            OID="Inches">
            <Symbol>
              <TranslatedText>in</TranslatedText>
            </Symbol>
          </MeasurementUnit>
          <!-- others omitted from sample -->
        </BasicDefinitions>
        <MetaDataVersion
          Name="PF-ST Sample Trial" OID="StudyVersion020108"
          pf:ApprovalDate="4/1/2005 9:00:00 AM">
          <Protocol>
            <StudyEventRef
              Mandatory="No" OrderNumber="1"
              StudyEventOID="CommonCRF"/>
            <!-- others omitted from sample -->
          </Protocol>
          <StudyEventDef
            Category="CommonCRF" Name="CommonCRF" OID="CommonCRF"
            Repeating="No" Type="Common">
            <FormRef FormOID="frmDOSE"
              Mandatory="No"
              OrderNumber="3"/>
            <!-- other FormRefs omitted from sample -->
          </StudyEventDef>
          <!-- other StudyEventDefs omitted from sample -->
          <FormDef
            Name="frmDOSE" OID="frmDOSE"
            Repeating="No">
            <ItemGroupRef ItemGroupOID="sctDOSE"
  
```

```

        Mandatory="No"
        OrderNumber="1"/>
</FormDef>

    <!-- other FormDefs omitted from sample -->

<ItemGroupDef
  Comment="INSTRUCTIONS&lt;br> 1. Enter a new record whenever
  there is a change in dose&lt;br> 2. Enter Stop Date as the last
  date of a specific dose level, or the last date treatment was
  used for the study"
  Name="sctDOSE" OID="sctDOSE" Repeating="Yes">
  <ItemRef
    ItemOID="itmDOSEFromDate" Mandatory="Yes"
    OrderNumber="1"/>
</ItemGroupDef>

<!-- Other ItemGroupDefs omitted from sample -->

<ItemDef
  DataType="text" Length="255" Name="itmDOSEFromDate"
  OID="itmDOSEFromDate"
  pf:InFormDateTime="true">
  <Question>
    <TranslatedText>Start date</TranslatedText>
  </Question>
</ItemDef>

<!-- Other ItemDefs omitted from sample -->

</MetaDataVersion>

<pf:SubjectPool PoolNumber="0" PoolRefName="Eligible" />
<pf:SubjectPool PoolNumber="1" PoolRefName="AutoSelect" />
<pf:SubjectPool PoolNumber="2" PoolRefName="ManualFirstN" />
<pf:SubjectPool PoolNumber="3" PoolRefName="ManualUISelect" />
<pf:SubjectPool PoolNumber="4" PoolRefName="ManualImport" />
<pf:SubjectPool PoolNumber="99" PoolRefName="Excluded" />

  </Study>
</ODM>
</ResponseODM>
</DownloadMetadataODMResult>
</soap:Body>
</soap:Envelope>

```

DownloadAdminDataODM example response

Transactional data—DownladAdminDataODM response

```

<ResponseODM
xmlns:pf="http://www.phaseforward.com/InFormAdapter/ODM/Extensions/2.0"
xmlns="http://www.phaseforward.com/InFormAdapter/ODM/2.0">
  <ODM Description="StudyDesign" FileType="Transactional"
FileOID="StudyDesign/062d51cd-0084-4e3e-982b-6ecf6a4c9c80"
CreationDateTime="2011-10-17T19:31:11+00:00" ODMVersion="1.3"
Originator="" pf:MappingVersion="V2" pf:HierarchicalOIDs="Yes"
pf:InFormAdapterVersion="1.0.4302.18717"
xmlns="http://www.cdisc.org/ns/odm/v1.3">
    <AdminData>
      <User OID="system" UserType="Other" pf:DBUID="1" pf:GUID="System
User" pf:StudyLocale="en-US">
        <!--Additional Users à
        <Location OID="13341" Name="(01) Massachusetts General Hospital"
LocationType="Site" pf:SiteCountry="USA" pf:SiteTimezone="Eastern
Standard Time" pf:GUID="{1120443F-38BA-42CE-97C0-8EA3E1399336}"
pf:Revision="326047546003022" pf:Locale="en-US"
pf:SVAutoSelectRate="10" pf:SVFirstNSubjects="1">
          <!--Additional Locations -->
          <SignatureDef OID="13830" Methodology="Electronic"
pf:GroupName="Investigator Sigs">
            <!--Additional SignatureDef-->
            <pf:GroupDef OID="13830" Name="Investigator Sigs" GroupType="Signature"
/>
          /AdminData>
        /ODM>
      <Status>END</Status>
      <UserBookmark>13298</UserBookmark>
    /ResponseODM>

```

Snapshot data—DownloadAdminData response

```

<DownloadAdminDataODMResult
xmlns="http://www.phaseforward.com/InFormAdapter/ODM/1.0">
  <ResponseODM
xmlns="http://www.phaseforward.com/InFormAdapter/ODM/2.0"
xmlns:xsd="http://www.w3.org/2001/XMLSchema"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
    <ODM
CreationDateTime="2008-11-07T10:40:11+00:00"
Description="Depression Study"
FileOID="Depression Study/4db404af-46cc-46d7-9f50-3254538ac289"
FileType="Snapshot" ODMVersion="1.3" Originator="soatest"
PriorFileOID="ANY_STRING_VALUE" pf:HierarchicalOIDs="Yes"
pf:InFormAdapterVersion="1.2.3.60" pf:MappingVersion="V2"
xmlns="http://www.cdisc.org/ns/odm/v1.3"
xmlns:pf="http://www.phaseforward.com/InFormAdapter/ODM/Extensions/2.0">
      <AdminData>
        <User
OID="mmeyer"
UserType="Investigator">
          <LoginName>mmeyer</LoginName>
          <DisplayName>Marianne Meyer</DisplayName>
          <FullName>Marianne Meyer</FullName>
          <FirstName>Marianne</FirstName>
          <LastName>Meyer</LastName>
          <Address>
            <StreetName>100 Main Street</StreetName>

```

```

        <City>Worcester</City>
        <StateProv>MA</StateProv>
        <Country>USA</Country>
        <PostalCode>10123</PostalCode>
    </Address>
    <Email>email@domain.test</Email>
    <Fax>(555) 555-1212</Fax>
    <Phone>(555) 555-1212</Phone>
    <LocationRef
    LocationOID="10127"/>
    <pf:GroupRef GroupOID="5954" />
</User>

<!-- other Users omitted from sample -->

<pf:GroupDef OID="5954" Name="System Creator Group"
GroupType="Rights">
    <pf:Right Description="Create User"/>
    <pf:Right Description="Terminate User" />
</pf:GroupDef>

<Location
    LocationType="Site" Name="(01) Massachusetts General Hospital"
    OID="10127" pf:SiteCountry="USA"
    pf:SiteTimezone="(GMT-05:00) Eastern Time (US & Canada)">

    <MetaDataVersionRef
        EffectiveDate="2005-04-01T00:00:00+00:00"
        MetaDataVersionOID="StudyVersion020108"
        StudyOID="Depression Study"/>

    <!-- other MetaDataVersionRefs omitted from sample -->

    <Mnemonic
        xmlns="http://www.phaseforward.com/InFormAdapter/ODM/Extensions/2.0">
        <TranslatedText
            xmlns="http://www.cdisc.org/ns/odm/v1.3">01</TranslatedText>
        </Mnemonic>

</Location>

<!-- other Locations omitted from sample -->

<SignatureDef
    Methodology="Electronic" OID="10401"
    pf:GroupName="Investigator Sigs">
    <Meaning>Approval</Meaning>
    <LegalReason>By my dated signature below, I, %s %s, verify that
    this case report form accurately displays the results of the
    examinations, tests, evaluations and treatments noted
    within.<br><br> Pursuant to Section 11.100 of Title 21
    of the Code of Federal Regulations, this is to certify that I
    intend that this electronic signature is to be the legally binding
    equivalent of my handwritten signature.<br><br> To
    this I do attest by supplying my user name and password and
    clicking the button marked <br>Submit<br>
    below.</LegalReason>
    </SignatureDef>

    <!-- other SignatureDefs omitted from sample -->

</AdminData>
</ODM>
</ResponseODM>
</DownloadAdminDataODMResult>

```

DownloadPatientDataODM example response

```

<DownloadPatientDataODMResult
xmlns="http://www.phaseforward.com/InFormAdapter/ODM/1.0">
  <ResponseODM
xmlns:pf="http://www.phaseforward.com/InFormAdapter/ODM/Extensions/2.0"
xmlns="http://www.phaseforward.com/InFormAdapter/ODM/2.0">
    <ODM Description="Depression Study" FileType="Snapshot"
FileOID="Depression Study/404b4c22-4d47-4ebf-a83d-d5bb7afd0294"
CreationDateTime="2008-11-11T19:25:56+00:00" PriorFileOID="Depression
Study/571bdca0-fea3-4263-ba3a-8b96e4196b52" ODMVersion="1.3"
Originator="test" pf:MappingVersion="V2" pf:HierarchicalOIDs="Yes"
pf:InFormAdapterVersion="1.0.3235.41590"
xmlns="http://www.cdisc.org/ns/odm/v1.3">
      <ClinicalData StudyOID="Depression Study"
MetadataVersionOID="StudyVersion1">
        <SubjectData SubjectKey="72511" TransactionType="Insert">
          <StudyEventData StudyEventOID="screen">
            <FormData FormOID="frmScr">
              <ItemGroupData ItemGroupOID="sctScrInfo">
                <ItemData ItemOID="itmScrPatInit" Value="smk" />
                <ItemData ItemOID="itmScrDOB" Value="1968-12-23T-:-:-
+00:00" />
                <ItemData ItemOID="itmScrDate" Value="2006-01-02T-:-:-
+00:00" />
              </ItemGroupData>
            </FormData>
          </StudyEventData>
        </SubjectData>
      </ClinicalData>
    </ODM>
  </ResponseODM>
</DownloadPatientDataODMResult>

```

GetSiteList example response

```

<CRFSUBMIT>
  <SITELIST>
    <SITEINFO SITEID="54312" SITENAME="Marlboro Hospital"
SITEMNEMONIC="MARL" SITEGUID="{C769A488-9AF4-4303-802C-C0147AE58396}"
LANGUAGECODE="en-US" />
    <SITEINFO SITEID="7628" SITENAME="McLean Hospital"
SITEMNEMONIC="MCLEAN" SITEGUID="{C966597A-B965-413F-A3B4-7F38449CC23B}"
LANGUAGECODE="en-US" />
    <SITEINFO SITEID="7660" SITENAME="Mass General Hospital"
SITEMNEMONIC="MGH" SITEGUID="{7C9EAD34-BAD3-4E80-BEA9-BAC29E055D08}"
LANGUAGECODE="en-US" />
    <SITEINFO SITEID="7600" SITENAME="PhaseForward" SITEMNEMONIC="PF"
SITEGUID="{3C07AF5F-E07F-471A-8F7C-AB120A48C1BB}" LANGUAGECODE="en-US" />
    <SITEINFO SITEID="7644" SITENAME="Veterans Administration Hospital"
SITEMNEMONIC="VA" SITEGUID="{867835F8-3F2A-4D9D-81D0-2673703A0999}"
LANGUAGECODE="en-US" />
  </SITELIST>
</CRFSUBMIT>

```

GetPatientList example response

```

<CRFSUBMIT>
  <PATIENTLIST SITEID="8853">
    <PATIENT PATIENTID="11007" PATIENTREVISIONNUMBER="133790109391081"
      SITEID="8853"
      INITIALS="LMM" ENROLLMENTNUMBER="222" SCREENINGNUMBER="SCR-PF-1"
      CRBLOCKED="false" CRBFROZEN="false" PATIENTINDEX="1"
      ARCHIVED="false"/>
    <PATIENT PATIENTID="11015" PATIENTREVISIONNUMBER="133790109391081"
      SITEID="8853"
      INITIALS="JMD" ENROLLMENTNUMBER="224" SCREENINGNUMBER="SCR-PF-2"
      CRBLOCKED "false" CRBFROZEN="false" PATIENTINDEX="1"
      ARCHIVED="false"/>
  </PATIENTLIST>
</CRFSUBMIT>

```

GetPatientForms example response

```

<PATIENTVISITCRFLIST PATIENTID="10769" INITIALS="AAA" PATIENTNO="222" xmlns="">
  <FORMSETLIST>
    <FORMSET FORMSETID="8982" FORMSETMNEMONIC="Base" FORMSETNAME="Baseline"
      FORMSETREFNAME="vstBASE" FORMSETREVISION="133429397696064"
      FORMSETREPEATING="false" FORMSETINDEX="1">
      <FORMLIST>
        <FORM FORMID="6691" FORMMNEMONIC="DOV" FORMNAME="DATE OF VISIT"
          FORMREFNAME="frmDOV" FORMREVISION="133369290882048"
          FORMTYPE="1" FORMSTARTED="true" FORMVERSIONDATE="24-Mar-2005
            15:01"
          FORMHASAUDITTRAIL="true" />
        <FORM FORMID="7591" FORMMNEMONIC="PI" FORMNAME="PATIENT INFORMATION"
          FORMREFNAME="frmPI" FORMREVISION="133369321820048" FORMTYPE="1"
          FORMSTARTED="true" FORMVERSIONDATE="24-Mar-2005 15:02"
          FORMHASAUDITTRAIL="true" />
      </FORMLIST>
    </FORMSET>
    <FORMSET FORMSETID="8985" FORMSETMNEMONIC="Wk 1" FORMSETNAME="Core Week 1"
      FORMSETREFNAME="vstCORE1" FORMSETREVISION="133429397696064"
      FORMSETREPEATING="false" FORMSETINDEX="1">
      <FORMLIST>
        <FORM FORMID="6691" FORMMNEMONIC="DOV" FORMNAME="DATE OF VISIT"
          FORMREFNAME="frmDOV" FORMREVISION="133369290882048"
          FORMTYPE="1" FORMSTARTED="false" FORMVERSIONDATE="24-Mar-2005
            15:01"
          FORMHASAUDITTRAIL="false" />
        <FORM FORMID="7858" FORMMNEMONIC="VS" FORMNAME="VITAL SIGNS"
          FORMREFNAME="frmVS" FORMREVISION="133369332226048"
          FORMTYPE="1" FORMSTARTED="false" FORMVERSIONDATE="24-Mar-2005
            15:02"
          FORMHASAUDITTRAIL="false" />
      </FORMLIST>
    </FORMSET>
  </FORMSETLIST>
</PATIENTVISITLIST>

```

GetTransactions example response

For another example of a GetTransactions request and response, see the ODM Export sample XML files that are provided with the product release.

Example returning clinical data

```
<GetTransactionsResult
xmlns="http://www.phaseforward.com/InFormAdapter/ODM/1.0">
  <ResponseODM
xmlns:pf="http://www.phaseforward.com/InFormAdapter/ODM/Extensions/2.0"
xmlns="http://www.phaseforward.com/InFormAdapter/ODM/2.0">
    <ODM Description="StudyDesign" FileType="Transactional"
FileOID="{DD36F77C-D15B-4CC6-905E-C3FE13028A76}" CreationDateTime="2010-
12-13T20:38:11+00:00" PriorFileOID="{CB219A42-F227-43D8-93F7-
DF91AED86EC2}" ODMVersion="1.3" Originator="system"
pf:MappingVersion="V2" pf:HierarchicalOIDs="Yes"
pf:InFormAdapterVersion="1.0.3999.27031"
xmlns="http://www.cdisc.org/ns/odm/v1.3">
      <ClinicalData StudyOID="StudyDesign" MetaDataVersionOID="Study Design
1.0.0" pf:TransactionGuid="{AB7C93A6-C5F2-49D0-9282-C42A82ED5E14}"
pf:Revision="253647973055083.000">
        <SubjectData SubjectKey="14440" TransactionType="Upsert"
pf:GUID="{44C8BF9B-C32B-4C92-9B4C-51A3C8A72D84}">
          <SiteRef LocationOID="12121" />
          <StudyEventData StudyEventOID="vstCORE8">
            <AuditRecord>
              <UserRef UserOID="mmeyer" />
              <LocationRef LocationOID="Unknown" />
              <DateTimeStamp>2009-01-14T22:46:13+00:00</DateTimeStamp>
              <ReasonForChange>Visit Started</ReasonForChange>
            </AuditRecord>
            <FormData FormOID="frmDOV">
              <ItemGroupData ItemGroupOID="frmDOV.sctVisitDateandTime">
                <ItemData
ItemOID="frmDOV.sctVisitDateandTime.DateandTimeofVisit_DOV.Da
teandTimeofVisit_DOV" Value="2007-09-11T12:25:++00:00"
pf:FormattedDateValue="2007-09-11T12:25:NUL+00:00">
                  <AuditRecord>
                    <UserRef UserOID="mmeyer" />
                    <LocationRef LocationOID="12121" />
                    <DateTimeStamp>2009-01-
14T22:46:13+00:00</DateTimeStamp>
                    <ReasonForChange>Initial Entry</ReasonForChange>
                    <SourceID>rdinformq079</SourceID>
                  </AuditRecord>
                </ItemData>
              </ItemGroupData>
            </FormData>
          </StudyEventData>
        </SubjectData>
      </ClinicalData>
    </ODM>
    <Status>END</Status>
    <Bookmark>{DD36F77C-D15B-4CC6-905E-C3FE13028A76}</Bookmark>
    <TransactionsProcessed>28</TransactionsProcessed>
  </ResponseODM>
</GetTransactionsResult>
```


Example returning no clinical data

```
<GetTransactionsResult
xmlns="http://www.phaseforward.com/InFormAdapter/ODM/1.0">
  <ResponseODM
xmlns:pf="http://www.phaseforward.com/InFormAdapter/ODM/Extensions/2.0"
xmlns="http://www.phaseforward.com/InFormAdapter/ODM/2.0">
    <ODM Description="Depression Study" FileType="Transactional"
FileOID="{2CBDCC47-3557-463E-8FB1-0614B0DFFAF5}" CreationDateTime="2008-
11-11T18:58:54+00:00" PriorFileOID="Depression Study/2f887d08-33f2-4e8f-
9ff0-4c08c4ae188b" ODMVersion="1.3" Originator="system"
pf:MappingVersion="V2" pf:HierarchicalOIDs="Yes"
pf:InFormAdapterVersion="1.0.3235.41590"
xmlns="http://www.cdisc.org/ns/odm/v1.3" />
    <Bookmark>{2CBDCC47-3557-463E-8FB1-0614B0DFFAF5}</Bookmark>
    <TransactionsProcessed>1000</TransactionsProcessed>
  </ResponseODM>
</GetTransactionsResult>
```

GetTransactionStatus example response

```
<GetTransactionStatusResult
xmlns="http://www.phaseforward.com/InFormAdapter/ODM/1.0">
  <TransactionStatus xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema"
xmlns="http://www.phaseforward.com/InFormAdapter/ODM/2.0">
    <TotalTransactionCount>5804</TotalTransactionCount>
    <TransactionXmlCount>5804</TransactionXmlCount>
    <TransactionXmlRemaining>5804</TransactionXmlRemaining>
    <LastTransactionXmlTime>2010-10-
29T13:41:26+00:00</LastTransactionXmlTime>
  </TransactionStatus>
```

RetrieveData example response

This example returns site information.

```
<RetrieveDataResult
xmlns="http://www.phaseforward.com/AdapterFramework/Export/1.0">
  <RetrieveDataOutputMsg
xmlns="http://www.phaseforward.com/AdapterFramework/Export/2.0"
xmlns:xsd="http://www.w3.org/2001/XMLSchema"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
    <ReturnData
xmlns="http://www.phaseforward.com/AdapterFramework/Export/1.0">&lt;CRFSUBMIT
xmlns:xsd="http://www.w3.org/2001/XMLSchema"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-
instance"&gt;&lt;SITELIST&gt;&lt;SITEINFO SITEID="8613" SITENAME="McLean
Hospital" ITEMNEMONIC="MCLEAN" SITEGUID="{BB1D4B6C-D13F-4346-AAE6-
2F03394C8B47}" /&gt;&lt;SITEINFO SITEID="8645" SITENAME="Mass General
Hospital" ITEMNEMONIC="MGH" SITEGUID="{E5F61DA9-2568-4541-A109-
96688C2737BB}" /&gt;&lt;SITEINFO SITEID="8585" SITENAME="PhaseForward"
ITEMNEMONIC="PF" SITEGUID="{17EE673B-9278-4A69-92A1-AF327F775DD7}"
/&gt;&lt;SITEINFO SITEID="9448" SITENAME="Phase Forward 2" ITEMNEMONIC="PF2"
SITEGUID="{24D27B54-AB73-45C0-91AA-838869E2D18E}" /&gt;&lt;SITEINFO
SITEID="8629" SITENAME="Veterans Administration Hospital" ITEMNEMONIC="VA"
SITEGUID="{7B5E9C4E-1B43-4893-A8D8-D895ABD44680}"
/&gt;&lt;/SITELIST&gt;&lt;/CRFSUBMIT&gt;
    </ReturnData>
    <Status>OK</Status>
  </RetrieveDataOutputMsg>
</RetrieveDataResult>
```

Oracle ODM extensions

- *Candidate element* (on page 116)
- *CriticalForm element* (on page 118)
- *FormattedDateValue* (on page 120)
- *FormStatus element* (on page 121)
- *GroupDef element* (on page 122)
- *Right element* (on page 123)
- *GroupRef element* (on page 123)
- *InFormItemData element* (on page 124)
- *InFormItemDef element* (on page 124)
- *InFormItemRef element* (on page 125)
- *ItemStatus element* (on page 126)
- *Query element* (on page 127)
- *QueryStatus element* (on page 127)
- *ReasonIncomplete element* (on page 128)
- *ReviewState element* (on page 128)
- *ReviewStage element* (on page 129)
- *SubjectPool element* (on page 130)
- *SubjectPoolChange element* (on page 131)
- *SubjectStatus element* (on page 132)
- ProductLocale

Candidate element

The Candidate element is returned when a screening or enrollment action is performed in the InForm application.

XPath

ODM/ClinicalData/SubjectData/pf:Candidate

Parent element	Child elements
SubjectData	DOB. ScreeningDate.

Attributes

Attributes/children: Candidate	Description
DOB	Date of birth of the candidate. type=TypeDATE.
ScreeningDate	type=TypeDATE.
PatientGuid	The GUID of the candidate. type=TypeGUID. Required.
Revision	The revision number of the subject type=TypeREVISION. Required.
SiteGUIDREF	The GUID of the site. type=TypeGUID. Required.
Initials	The initials of the subject type=TypeINITIALS. Required.
State	The state of the subject. type=TypePatientSTATE. Optional.
ScreeningNumber	The candidate's screening number. type=xs:String. Required.
EnrollmentNumber	The subject's enrollment number. type=TypeENROLLMENTNUMBER. Required.
ScreeningFailure	The reason for screening failure. type=xs:string. Required.
EnrollmentFailure	The reason for enrollment failure. type=xs:string. Required.

Attributes/children: Candidate	Description
EnrollmentOverride	The reason that the enrollment failure was overridden. type=xs:string. Required.
PatientNumberRevision	The revision number of the patient number. type=TypeREVISION. Optional.

CriticalForm element

The CriticalForm element is returned in any of the following situations:

- In the user interface, a form is selected as a critical form.
- In the user interface, a form that was previously selected as critical is deselected (marked as not critical).
- The form is cooked in with MedML that selects the form as critical.

Forms that have never been selected as critical do not appear.

XPath

ODM/ClinicalData/SubjectData/pf:CriticalForm

Parent element	Child elements
SubjectData	None.

Attributes

Attributes/children: CriticalForm	Description
FormRef	Identifies the form. For more information, see <i>FormRef</i> (on page 152).
LocationOID	The OID of the site. If the site is missing in the InForm application, LocationOID has an empty string ("").
IsCritical	A flag that indicates whether the form is critical type=xs:string. Values: 0—Not critical. 1—Critical. Required.

Example—Criticalform

This example of ODM transactional output indicates that for site 54312, frmDose is set to the critical form while frmDOV is set to non-critical form.

```
<ODM
xmlns:pf="http://PhaseForward.com/InFormAdapter/ODM/PhaseForward_ODM.xsd"
Description="Depression Study" FileType="Transactional" FileOID="**IGNORED**"
CreationDateTime="**IGNORED**" PriorFileOID="{82A6D9DC-2058-43BE-A640-
7FCD9E6C86F8}" ODMVersion="1.2" Originator="system" pf:MappingVersion="V1"
pf:HierarchicalOIDs="No" pf:InFormAdapterVersion="**IGNORED**"
xmlns="http://www.cdisc.org/ns/odm/v1.2">
  <ClinicalData StudyOID="Depression Study" MetaDataVersionOID="Study
Version 1.0" pf:TransactionGuid="{E30DBE60-CCB2-40AA-9A3F-BA7373712C49}">
    <pf:CriticalForm FormRef="frmDose" LocationOID="54312" IsCritical="1">
    <pf:CriticalForm FormRef="frmDOV" LocationOID="54312" IsCritical="0">
      </ClinicalData>
</ODM>
```

CriticalItems

Attributes	Value/Map to InForm
CriticalItems	Includes a separate CriticalItem element for each item-level change that occurs in the InForm application. For more information, see <i>CriticalItem</i> (on page 120).

CriticalItem

Attributes	Value/Map to InForm
CriticalItem	<p>Include a separate CriticalItem element for each item-level change that occurs in the InForm application.</p> <p>Attributes:</p> <ul style="list-style-type: none"> • ItemRefName—Item name. • FormOID—Form name. If blank, applies to all forms that include this item. • LocationOID—Site location. • Critical—Indicates that one of the following override options applies to an item: <ul style="list-style-type: none"> ▪ True—Item is critical on the form(s) specified by the FormOID. ▪ False—Item is not critical on the form(s) specified by the FormOID. ▪ StudyDefault—Item has a study default value on the form(s) that is specified by the FormOID. • ItemRevision—Item revision number.

FormattedDateValue

The FormattedDateValue element returns data that differentiates between null and unknown date values in the InForm software.

XPath

ODM/ClinicalData/ItemData/pf:FormattedDateValue

- UNK indicates an unknown date part.
- NUL indicates a null date part.

To maintain backward compatibility and conform to ODM standard, "-" is still used to express a value of unknown or null in the Value attribute. If differentiation between null and unknown is required, use the pf:FormattedDateValue extension.

For more information, see *ItemData* (on page 184).

FormStatus element

The FormStatus element refers to the state of a form in the InForm software. A FormStatus element is returned if a change has been made to a form's state; for example, if the form was frozen, locked, or marked SV ready.

XPath

ODM/ClinicalData/SubjectData/StudyEventData/FormData/pf:FormStatus

Parent element	Child elements
FormData	odm:AuditRecord.

Attributes

Attributes: FormStatus	Description
Activated	A flag that indicates whether the form has been activated. type=odm:YesOrNo. Optional.
SVPartial	A flag that indicates whether the form has been partially source verified. type=odm:YesOrNo. Optional.
Frozen	A flag that indicates whether the form is frozen. type=odm:YesOrNo. Optional.
Locked	A flag that indicates whether the form is locked. type=odm:YesOrNo. Optional.
Deleted	A flag that indicates whether the form is deleted. This attribute is returned only when complianceMode="Loose." type=odm:YesOrNo Optional.
SVComplete	A flag that indicates whether the form is source verification complete. type=odm:YesOrNo. Optional.

Attributes: FormStatus	Description
SVReady	A flag that indicates whether the form is source verification ready. type=odm:YesOrNo Optional.
SVSelected	A flag that indicates whether partial source verification has been selected for the form. type=odm:YesOrNo Optional.
Signed	A flag that indicates whether the transaction caused the signature status of the form to change. type=odm:YesOrNo Yes —the transaction caused the signature status of the form to change to "signed." No —the transaction caused the signature status of the form to change to "unsigned."

GroupDef element

The GroupDef element defines a user group in an InForm study. AdminData contains a collection of GroupDef elements.

Xpath

ODM/AdminData/pf:GroupDef

Parent element	Child elements
AdminData	pf:Right .

Attributes

Attributes: GroupDef	Description
OID	The refname of the item. type=odm:oid. Required.
Name	The name of the group as displayed in the InForm software. type=odm:text. Required.
GroupType	The type of the group, such as Rights, Reporting, Query, Signature. type=xs:String. Required.

Right element

The pf:Right element is a child element of the pf:GroupDef element. One pf:Right element exists for each right defined in the user group.

Xpath

ODM/AdminData/pf:GroupDef/pf:Right

Parent element	Child elements
pf:GroupDef	None.

Attributes

Attributes: Right	Description
Description	The description of the right. type=xs:string. Required.

GroupRef element

One GroupRef child element exists for each group to which the user belongs. Each GroupRef contains a GroupOID element. GroupRef elements reference GroupDef elements by matching the GroupRef's GroupOID attribute to the GroupDef's OID attribute.

Xpath

ODM/AdminData/User/pf:GroupRef

Parent element	Child elements
User	None.

Attributes

Attributes: GroupRef	Description
GroupOID	The identifier of the group. type=odm:oid. Required.

InFormItemData element

The InFormItemData element represents an item in the InForm software.

In the Oracle implementation of ODM, an ItemData maps to an InForm control (not to an InForm item).

Any time that an Oracle extension that applies to an InForm item (as opposed to a control) is used, the extension is attached to an InFormItemData.

XPath

ODM/ClinicalData/SubjectData/StudyEventData/FormData/ItemGroupData/pf:InFormItemData

Parent element	Child elements
ItemGroupData	<i>Query</i> (on page 127). <i>ItemStatus</i> (on page 126).

Attributes

Attributes: InFormItemData	Description
InFormItemOID	The identifier of the data item. type=odm:oid. Required.
Name	The item RefName. type=string. Required.

InFormItemDef element

The InFormItemDef element is the metadata definition for the InForm item, and explains which controls (ItemRefs) are contained in the item.

In the Oracle implementation, an ItemDef maps to an InForm control.

XPath

ODM/Study/MetaDataVersion/pf:InformItemDef

Parent element	Child elements
MetaDataVersion	odm:ItemRef.

Attributes

Attributes: InFormItemDef	Description
OID	The refname of the item. type=odm:oid. Required.
Name	type=odm:text. Required.
SVRequired	Indicates whether source verification is required. type=odm:YesOrNo. Optional.
DBUID	The location OID.
GUID	Visit identifier.
Revision	Revision.
UUID	UUID.

InFormItemRef element

The InFormItemRef element shows the ordering of the InForm item within a section.

XPath

ODM/Study/MetaDataVersion/ItemGroupDef/pf:InFormItemRef

Parent element	Child elements
ItemGroupDef	None.

Attributes

Attributes: InFormItemRef	Description
InFormItemOid	The refname of the item. type=odm:oid. Required.
OrderNumber	Display order of the item within the section. type=odm:integer. Optional.

Attributes: InFormItemRef	Description
Mandatory	Indicates whether the item is mandatory. type=odm:YesOrNo. Required.

ItemStatus element

The ItemStatus element refers to the status of an item on a form. This element is returned if an item has been source verified or if an itemset has been deleted or undeleted.

XPath

If an item has been source verified:

```
ODM/ClinicalData/SubjectData/StudyEventData/FormData/ItemGroupData/pf:ItemStatus
```

If an itemset has been deleted or undeleted:

```
ODM/ClinicalData/SubjectData/StudyEventData/FormData/ItemGroupData/InFormItemData/pf:ItemStatus
```

Parent element	Child elements
Either of the following: <ul style="list-style-type: none"> InFormItemData (if the item has been source verified). ItemGroupData (if the itemset has been deleted). 	odm:AuditRecord.

Attributes

Attributes: ItemStatus	Description
SourceVerified	A flag that indicates whether the item has been source verified. type=odm:YesOrNo. Optional.
Deleted	A flag that indicates whether the itemset has been deleted. type=odm:YesOrNo. Optional.

Query element

The query element represents a query in the InForm software.

XPath

ODM/ClinicalData/SubjectData/StudyEventData/FormData/ItemGroupData/pf:InFormItemData/pf:Query

Parent element	Child elements
<i>InFormItemData</i> (on page 124).	<i>QueryStatus</i> (on page 127).

Attributes

Attributes: Query	Description
DBUID	The location OID of the query.
OID	The identifier of the query. type=odm:oid. Optional
Text	The text of the query. type=xs:string. Optional
Type	The type of query. type=QueryType. Required.

QueryStatus element

The QueryStatus element represents the state of a query. The element contains an audit record that explains when and why the change of state happened.

XPath

ODM/ClinicalData/SubjectData/StudyEventData/formData/ItemGroupData/InFormItemData/pf:Query/pf:QueryStatus

Parent element	Child elements
pf:Query	odm:AuditRecord.

Attributes

Attributes: QueryStatus	Description
Status	type=QueryState. Required. Values: Open, Answered, closed, Candidate, Reissued, or Deleted.
Text	type=String.

ReasonIncomplete element

The ReasonIncomplete element represents the reason that an item in the InForm software does not have a value.

XPath

ODM/ClinicalData/SubjectData/StudyEventData/FormData/Annotation/pf:ReasonIncomplete

Parent element	Child elements
Annotation	CodeListOID="ReasonIncomplete."

ReasonIncomplete is a hard-coded codelist that defines the options. The code list is returned in the metadata and ItemData.

ReviewState element

The ReviewState element is returned to represent the state and stage of the progress of data review in the InForm application.

Up to five form-level customizable states are permitted to provide flexibility in tracking the progress of reviews.

XPath

ODM/ClinicalData/SubjectData/pf:ReviewState

Parent element	Child elements
SubjectData	<i>pf:ReviewStage</i> (on page 129). Each pf:ReviewState element must have three pf:ReviewStage elements.

Attributes

Attributes/children: ReviewState	Description
pf:DBUID	dbuid.
RefName	Review state ref name.
StateValue	State value. A number from 1 through 5.
Revision	Revision number. For more information, see <i>Revision, DBUID, and GUID attributes</i> . (on page 135)
Name element	Child element: <i>TranslatedText</i> (on page 150).
Mnemonic element	Child element <i>Mnemonic</i> (on page 152).

ReviewStage element

The pf:ReviewStage element represents the review stage for the specific review state.

Each pf:ReviewState element must have three pf:ReviewStage elements. The review state is in one of the three stages at any time. The first stage is the default stage for a defined review state before any reviewer assigns any other review stage.

XPath

ODM/ClinicalData/SubjectData/pf:ReviewState/pf:ReviewStage

Parent element	Child elements
pf:ReviewState	None.

Attributes

Attributes: ReviewStage	Description
RefName	Stage ref name.
StageValue	Stage value.
Activated	0 or 1.
Revision	Revision number.

SubjectPool element

The SubjectPool element is returned to represent the source verification pool in the InForm application.

XPath

ODM/ClinicalData/SubjectData/pf:SubjectPool

Parent element	Child elements
SubjectData	PoolNumber. PoolRefName.

Attributes

Attributes/children: SubjectPool	Description
PoolNumber	<p>The InForm Pool Number.</p> <p>type=xs:string.</p> <p>Required.</p> <p>One of the following values, representing the available pools that are hardcoded in the InForm software:</p> <p>0—PF_SVELIGIBLE_POOL</p> <p>1—PF_SVAUTO_SELECT_POOL</p> <p>2—PF_SVMANUAL_FIRSTN_POOL</p> <p>3—PF_SVMANUAL_UISELECT_POOL</p> <p>4—PF_SVMANUAL_IMPORT_POOL</p> <p>99—PF_SVEXCLUDED_POOL</p>

Attributes/children: SubjectPool	Description
PoolRefName	<p>The ref name of the pool.</p> <p>type=xs:string.</p> <p>Required.</p> <p>One of the following values:</p> <p>Eligible—PoolNumber=0, indicating the pool is SV Eligible.</p> <p>AutoSelect—PoolNumber=1, indicating a pool whose members are automatically selected based on settings determined by the site administrator.</p> <p>ManualFirstN—PoolNumber=2, indicating a pool in which the first <n> number of subjects are automatically selected.</p> <p>ManualUISelect—PoolNumber=3, indicating that the pool members are added by being selected in the UI.</p> <p>ManualImport—PoolNumber=4, indicating an imported file that contains the pool members.</p> <p>Excluded—PoolNumber=99, indicating that the pool is excluded from source verification.</p>

SubjectPoolChange element

The SubjectPoolChange element is returned to represent the changes in the subject pool in the InForm application.

XPath

ODM/ClinicalData/SubjectData/pf:SubjectPoolChange

Parent element	Child elements
SubjectData	SubjectKey.

Attributes

Attributes: SubjectPoolChange	Description
LocationOID	The Site OID.

Attributes: SubjectPoolChange	Description
PoolNumber	The InForm Pool Number. type=xs:string. Required. One of the following values, representing the available pools that are hardcoded in the InForm software: 0—PF_SVELIGIBLE_POOL 1—PF_SVAUTO_SELECT_POOL 2—PF_SVMANUAL_FIRSTN_POOL 3—PF_SVMANUAL_UISELECT_POOL 4—PF_SVMANUAL_IMPORT_POOL 99—PF_SVEXCLUDED_POOL
SubjectData	The subjects placed in the pool, identified by SubjectKey.

SubjectStatus element

The SubjectStatus element indicates that a state change has occurred to a patient, subject, or CRB.

XPath

ODM/ClinicalData/SubjectData/pf:SubjectStatus

Parent element	Child elements
SubjectData	odm:AuditRecord.

Attributes

Attributes: SubjectStatus	Description
Frozen	A flag that indicates whether the subject is frozen. type=odm:YesOrNo. Optional.
Locked	A flag that indicates whether the item is locked. type=odm:YesOrNo. Optional.
SVReady	A flag that indicates whether the item is source verification ready. type=odm:YesOrNo. Optional.

Attributes: SubjectStatus	Description
State	The state of the subject. Values are: Screened, ScreenFailed, Enrolled, EnrollmentFailed, EnrollmentOverride, Randomized, Complete, or DroppedOut. type=SubjectState. Optional.
ScreenFailReason	The reason that the subject failed the screening. type=xs:string. Optional.
EnrollFailReason	The reason that the subject failed to enroll. type=xs:string. Optional.
EnrollOverrideReason	The reason that the enrollment was overridden. type=xs:string. Optional.

ProductLocale element

The ProductLocale element indicates the product locale of the InForm software. It is used to extract the InComplete Reasons code list. ProductLocale applies to studies that use InForm versions 5.5 and above.

XPath

ODM/AdminData/pf:ProductLocale

Parent element	Child elements
ProductLocaleList	None.

Attributes

Attribute: ProductLocale	Description
xml:lang	The language available in the study.

Oracle attributes that are applied to standard ODM elements

The file **PFextensions.xsd** contains the attribute extensions for attributes that are defined in the **PhaseForward_ODM.xsd** file. These schema files are located in the **<Installation_path>/ODM/bin/xsd** directory.

Standard ODM element	Oracle attribute	Type
ClinicalData	TransactionalGuid	xs:string
CodeListItem	SelectionOID	odm:oid
FormDef	UUID	xs:string
FormRef	AltFormOID	xs:string
ItemData	NormalizedValue	odm:value
ItemDef	CheckboxGroupRefName	xs:string
ItemDef	InFormDataTime	xs:boolean
ItemDef	PFVarName	xs:string
ItemDef	ParentOID	odm:oidref
ItemDef	ParentType	pf:ParentType
ItemDef	ItemDefType	pf:ItemDefType
ItemDef	SelectionOwner	odm:oidref
ItemDef	UUID	xs:string
ItemGroupDef	ItemSetRefName	xs:string
ItemGroupDef	SVRequired	odm:YesOrNo
ItemGroupDef	UUID	xs:string
Location	Mnemonic	xs:string
Location	SiteCountry	xs:string
Location	SiteTimezone	xs:string
Location	Locale	xs:language
Location	SVAutoSelectRate	xs:integer Value 1-100
Location	SVFirstNSubjects	xs:integer
MeasurementUnitRef	NormalizationUnit	odm:YesOrNo
MetaDataVersion	ApprovalDate	xs:boolean
ODM	MappingVersion	xs:string
ODM	HierarchicalOIDs	xs:string
ODM	InFormAdapterVersion	xs:string

Standard ODM element	Oracle attribute	Type
SignatureDef	GroupName	xs:string
SignatureDef	Meaning	xs:string
SignatureDef	LegalReason	xs:string
FormDef	Dynamic	odm:YesOrNo
StudyEventDef		
StudyEventDef	Optional	odm:YesOrNo
StudyEventDef	UUID	xs:string
User	StudyLocale	xs:language

Revision, DBUID, and GUID attributes

DBUID, GUID, and Revision attributes are Oracle extension attributes on their respective elements.

Metadata

In metadata, the following elements include the pf:DBUID, pf:GUID, and pf:Revision attributes.

- MetaDataVersion
- StudyEventDef
- FormDef
- ItemGroupDef
- ItemDef
- MeasurementUnit
- InFormItemDef

In metadata, the following elements include the pf:UUID attribute.

- StudyEventDef
- FormDef
- ItemGroupDef
- ItemDef
- InFormItemDef

For more information, see the individual elements listed in *ODM Mapping* (on page 143).

Clinical data and Association data

ODM data elements consist of Clinical data nodes and Association nodes. These nodes contain a new pf:Revision attribute that applies to all the data in the node unless the child node contains a pf:Revision attribute of its own.

The DBUID and GUID attributes for the data items within these nodes are defined in the metadata except as noted:

- **Annotation** (on page 183).
- **Location** (on page 166).
- **Query** (on page 188).
- **SubjectData** (on page 172).
- **MetaData Version** (on page 151).
- **User** (on page 163).
- **Site \ Location** (on page 166).

AdminData

The User element includes pf:DBUID, pf:GUID, pf:Revision, and pf:StudyLocale extensions.

Site \ Location includes the pf:GUID, pf:Revision, and pf:Locale extensions.

- The location OID is the DBUID.
- Location Revision is the same as transaction only if the transaction is revising the location.

For more information, see the individual elements listed in *ODM Mapping* (on page 143).

Extensions that show control hierarchy and type

To define details for controls, the ODM Export interface provides the following extensions to the ODM elements *ItemDef* (on page 160) and *CodeListItem* (on page 168).

Oracle extension to ItemDef	Description
pf:ParentOID	The parent of each ItemDef that is not a top-level ItemDef.
pf:ParentType	Defines the type of parent control. If value of parent type is: <ul style="list-style-type: none"> • ItemDef, then pf:ParentOID refers to the parent ItemDef's OID. • CodeListItem, then pf:ParentOID refers to the parent CodeListItem's pf:SelectionOID.
pf:SelectionOwner	For each ItemDef that is the child of a radio group selection, the OID of the CodeList that contains the codelist selection.
pf:ItemDefType	Indicates the control type. Values: RadioGroup, Checkbox, Text, Calculated, PullDown, Date.

Oracle extension to CodeListItem	Description
pf:SelectionOID	An OID that uniquely identifies the selection in a radio group. The value is a concatenation of the CodeList OID and the CodeListItem CodedValue.

Elements and extensions for subject pools

The *pf:SubjectPool element* (on page 130) represents a collection of subjects in the InForm application that were placed in the source verification pool by automated selection to represent a desired target source verification rate.

DownloadAdminDataODM returns the available pools, the rate of autoselection, first N subjects, and the subject added and/or removed from the pool.

For more information, see:

- *SubjectPool element* (on page 130).
- *SubjectPoolChange element* (on page 131).

Subject pool selection

The *Location element* (on page 166) includes the following attributes for pool selection:

- pf:SVAutoSelectRate
The value of pf:SVAutoSelectRate comes from a query that indicates the number of subjects that are automatically selected for the source verification pool.
Automatic selection is determined by settings made by the site administrator that specify a value for the percentage selection criteria. The percentage determines the rate of subjects that are automatically selected for source verification.
- pf:SVFirstNSubjects
The source verification pool is determined by defining the number of subjects to be included in the pool. The subjects are added to the pool until the defined number is reached.
The value of pf:SVFirstNSubjects comes from a query that indicates the number of subjects in the pool.

Changes in the subject pool

The ODM Export interface tracks changes to the subject pool.

pf:SubjectPoolChange (on page 131) represents the pool change and includes the subjects placed in the pool.

```
<pf:SubjectPoolChange LocationOID="Site OID" PoolNumber="Pool Number" >
  <SubjectData SubjectKey="subject key 1" />
  ...
  <SubjectData SubjectKey="subject key n" />
</pf:SubjectPoolChange>
```

If the site is missing in the InForm application, LocationOID has an empty string ("").

Example of pool change transaction in ODM output:

```
<ResponseODM
xmlns:pf="http://www.phaseforward.com/InFormAdapter/ODM/Extensions/2.0"
xmlns="http://www.phaseforward.com/InFormAdapter/ODM/2.0">
  <ODM Description="Depression Study" FileType="Transactional"
  FileOID="{AA4E2F2E-DA3E-460A-963F-66BEEAEC515F}" CreationDateTime="2009-
  06-01T17:17:26+00:00" PriorFileOID="{20D57F92-8A0A-4749-8272-
  337E48D2DFF0}" ODMVersion="1.3" Originator="system" pf:MappingVersion="V2"
  pf:HierarchicalOIDs="Yes" pf:InFormAdapterVersion="1.0.3439.20859"
  xmlns="http://www.cdisc.org/ns/odm/v1.3">
    <ClinicalData StudyOID="Depression Study" MetaDataVersionOID="Study
    Version 2.1" pf:TransactionGuid="{AA4E2F2E-DA3E-460A-963F-66BEEAEC515F}"
    pf:Revision="227455370337048.000">
      <pf:SubjectPoolChange LocationOID="" PoolNumber="1" >
        <SubjectData SubjectKey="JIMD" />
        <SubjectData SubjectKey="ABC" />
        <SubjectData SubjectKey="JS" />
      </pf:SubjectPoolChange>
    </ClinicalData>
  </ODM>
  <Bookmark>{AA4E2F2E-DA3E-460A-963F-66BEEAEC515F}</Bookmark>
  <TransactionsProcessed>1</TransactionsProcessed>
</ResponseODM>
```

Elements and extensions for review states and stages

The InForm 5.5 SP0 and later software release allows five customizable review states to allow flexibility in tracking review progress. Each review state is in one of its three customizable stages at any time.

- Each pf:ReviewState element must have three pf:ReviewStage elements.
- Each *pf:ReviewState element* (on page 128) contains three *pf:ReviewStage elements* (on page 129).
- The first stage is the default stage for a defined review state before any reviewer assigns other review stages.
- In the InForm application, review states, and stages are cooked in the MedML with available product locales and displayed in the Data Viewer in the user's product locale.
- Each review state can be defined at different times, but each state, including its three stages, must be completely defined at one time. A partially defined state is not allowed.
- Stage includes review stage name, mnemonic, refname, stage value, and revision number.

Rights for review states

DownloadAdminData ODM returns a *pf:GroupDef* (on page 122) for each group, with the definition of the group and a pf:Right element for each right assigned to the group.

For studies using the InForm 5.5 release and subsequent releases, the attribute *pf:Right* (on page 123) contains the following values for Description that pertain to review state and stage information for a subject form:

```
<pf:Right Description="Assign Review States"/>
<pf:Right Description="View Review States"/>
```


How review state and stage information is returned

To obtain complete review stage and state information, you issue several ODM Export methods:

- 1 DownloadAdminDataODM.

The method returns all the permissions that can be assigned in the study.

In the administrative data, each user has a group reference that list the GroupOID of the group to which the user is assigned. The pf:GroupDef that uses that OID lists the permissions for the group. The user has those permissions by virtue of being a member of that group.

- 2 DownloadMetadataODM.

The method returns metadata that includes the elements pf:ReviewState and pf:ReviewStage.

The following metadata excerpt shows a pf:ReviewState element with a StateValue="1", and one of its three pf:ReviewStage child elements. The refname for the review stage includes the review state refname and the review state refname "DataReview1.ReviewStage1".

```
<pf:ReviewState pf:DBUID="14216" RefName="DataReview1" StateValue="1"
Revision="335876530226035">
  <pf:ReviewStage RefName="DataReview1.ReviewStage1" StageValue="0"
Activated="1" Revision="335876530226035">
  <!--other pf:ReviewStage elements omitted from example -->
```

- 3 GetTransactions.

For each form in the InForm application in which the review state and/or stage has been updated, the transaction XML that is returned indicates the review state and stage for each form.

The review state and review stage are each returned as a number; for example, ReviewState="1" ReviewStage="0".

For example:

```
<pf:FormStatus ReviewStageRefName="DataReview5.ReviewStage51"
ReviewState="1" ReviewStage="0" ReviewStateRevision="335876536304035">
.
.
.
</pf:FormStatus>
```

See the *Example* (on page 140).

- 4 Compare the transactional output and the metadata output to determine the review state and stage of the form. For example, the pf:FormStatus element (in Step 3) has ReviewState="1" and ReviewStage="0." The corresponding metadata (in Step 2) shows the RefName of the form as "DataReview1.ReviewStage1."

Example—review state and stage information in administrative data, metadata, and transaction output

In this example,

- DownloadAdminDataODM returns information about the groups to which the user mlynch is a member, and information about the group.
- DownloadMetadataODM returns information about the states and stages that are defined.
- GetTransactions returns information about changes to the status of a form.

DownloadAdminDataODM

In the administrative data, each user has a group reference which points at pf:GroupDef. pf:GroupDef defines the permissions.

The XML data that is returned indicates that user belongs to three groups. pf:GroupRef

```
<User OID="mlynch" UserType="Sponsor" pf:DBUID="12801" pf:GUID="{C651EA0D-B3A3-4DFE-B7E4-22B132D5FAAB}" pf:StudyLocale="en-US">
  <LoginName>mlynch</LoginName>
  <DisplayName>Melissa Lynch</DisplayName>
  <FullName>Melissa Lynch</FullName>
  <FirstName>Melissa</FirstName>
  <LastName>Lynch</LastName>
  <Address>
  <Country>USA</Country>
</Address>
  <Email>email@domain.test</Email>
  <Fax>(555) 555-1212</Fax>
  <Phone>(555) 555-1212</Phone>
  <LocationRef LocationOID="13341" />
  <LocationRef LocationOID="13375" />
  <LocationRef LocationOID="13409" />
  <LocationRef LocationOID="13443" />
  <LocationRef LocationOID="13477" />
  <LocationRef LocationOID="13511" />
  <LocationRef LocationOID="13545" />
  <LocationRef LocationOID="13579" />
  <LocationRef LocationOID="13613" />
  <pf:GroupRef GroupOID="6528" />
  <pf:GroupRef GroupOID="13811" />
  <pf:GroupRef GroupOID="13959" />
</User>
```

The following XML indicates that group CRA with OID 13959 has the permissions to assign and view review state.

```
<pf:GroupDef OID="13959" Name="CRA" GroupType="Rights">
  <pf:Right Description="Print" />
  <pf:Right Description="Monitor" />
  <pf:Right Description="Reports" />
  <pf:Right Description="View CRF" />
  <pf:Right Description="View CRF Signature Information" />
  <pf:Right Description="View Case Book Signature Information" />
  <pf:Right Description="Data Export Listings" />
  <pf:Right Description="Freeze a CRF" />
  <pf:Right Description="Unfreeze a CRF" />
  <pf:Right Description="Mark and Unmark a CRF as SVed" />
  <pf:Right Description="Freeze a Case Book" />
  <pf:Right Description="Unfreeze a Case Book" />
  <pf:Right Description="Change Query State from Candidate to Open" />
  <pf:Right Description="Change Query State from Candidate to Deleted" />
  <pf:Right Description="Change Query State from Answered to Closed" />
  <pf:Right Description="Enter Query in Candidate State" />
  <pf:Right Description="Enter Query in Open State" />
</pf:GroupDef>
```

```

    <pf:Right Description="Re-issue Query in Candidate State" />
    <pf:Right Description="Re-issue Query in Open State" />
    <pf:Right Description="Reordering Of Patients" />
    <pf:Right Description="Change Query State from Open to Closed" />
    <pf:Right Description="Change Query State from Reissued Candidate to
    Closed" />
    <pf:Right Description="Assign Review States" />
    <pf:Right Description="View Review States" />
    <pf:Right Description="Change Site SV Settings" />
  </pf:GroupDef>

```

DownloadMetadataODM

The sample XML shows one review state and its stages

```

<pf:ReviewState pf:DBUID="14216" RefName="DataReview1" StateValue="1"
Revision="335876530226035">
  <pf:ReviewStage RefName="DataReview1.ReviewStage1" StageValue="0"
Activated="1" Revision="335876530226035">
    <pf:Name>
      <TranslatedText xml:lang="en-US">Needs Review-
2ndRevision</TranslatedText>
      <TranslatedText xml:lang="ja-JP">?????</TranslatedText>
    </pf:Name>
    <pf:Mnemonic>
      <TranslatedText xml:lang="en-US">RS1</TranslatedText>
      <TranslatedText xml:lang="ja-JP">????S1</TranslatedText>
    </pf:Mnemonic>
  </pf:ReviewStage>
  <pf:ReviewStage RefName="DataReview1.ReviewStage2" StageValue="1"
Activated="1" Revision="335876530226035">
    <pf:Name>
      <TranslatedText xml:lang="en-US">Pending-2ndRevision</TranslatedText>
      <TranslatedText xml:lang="ja-JP">??</TranslatedText>
    </pf:Name>
    <pf:Mnemonic>
      <TranslatedText xml:lang="en-US">RS2</TranslatedText>
      <TranslatedText xml:lang="ja-JP">????S2</TranslatedText>
    </pf:Mnemonic>
  </pf:ReviewStage>
  <pf:ReviewStage RefName="DataReview1.ReviewStage3" StageValue="2"
Activated="1" Revision="335876530226035">
    <pf:Name>
      <TranslatedText xml:lang="en-US">Reviewed-2ndRevision</TranslatedText>
      <TranslatedText xml:lang="ja-JP">?????</TranslatedText>
    </pf:Name>
    <pf:Mnemonic>
      <TranslatedText xml:lang="en-US">RS3</TranslatedText>
      <TranslatedText xml:lang="ja-JP">????S3</TranslatedText>
    </pf:Mnemonic>
  </pf:ReviewStage>
  <pf:Name>
    <TranslatedText xml:lang="en-US">Data Review-2ndRevision</TranslatedText>
    <TranslatedText xml:lang="ja-JP">???????</TranslatedText>
  </pf:Name>
  <pf:Mnemonic>
    <TranslatedText xml:lang="en-US">R1</TranslatedText>
    <TranslatedText xml:lang="ja-JP">????1</TranslatedText>
  </pf:Mnemonic>
</pf:ReviewState>

```

GetTransactions

The sample XML shows the form status changes for a form.

```
<ResponseODM
xmlns:pf="http://www.phaseforward.com/InFormAdapter/ODM/Extensions/2.0"
xmlns="http://www.phaseforward.com/InFormAdapter/ODM/2.0">
  ODM Description="StudyDesign" FileType="Transactional" FileOID="{A18E6CE1-
11AB-4C6B-A4A8-63E31BD9025F}" CreationDateTime="2011-08-25T19:08:07+00:00"
PriorFileOID="{69262641-61FC-4FA3-AAE8-5D34B8AC8A4E}" ODMVersion="1.3"
Originator="system" pf:MappingVersion="V2" pf:HierarchicalOIDs="Yes"
pf:InFormAdapterVersion="1.0.4254.25287"
xmlns="http://www.cdisc.org/ns/odm/v1.3">
  <ClinicalData StudyOID="StudyDesign" MetaDataVersionOID="Study Design
0.0.2" pf:TransactionGuid="{A18E6CE1-11AB-4C6B-A4A8-63E31BD9025F}"
pf:Revision="335969315181037.000">
    <SubjectData SubjectKey="14336" TransactionType="Upsert"
pf:GUID="{EC5C716F-1AC3-49C0-88FE-A3AA33236EC1}">
      <SiteRef LocationOID="13341" />
      <StudyEventData StudyEventOID="vstCORE1">
        <FormData FormOID="frmDOV">
          <pf:FormStatus ReviewStageRefNchame="DataReview5.ReviewStage51"
ReviewState="5" ReviewStage="0"
ReviewStateRevision="335876536304035">
            <AuditRecord>
              <UserRef UserOID="lhill" />
              <LocationRef LocationOID="Unknown" />
              <DateTimeStamp>2011-08-25T17:48:35+00:00</DateTimeStamp>
              <!--The next line is the comment provided when the review state is
assigned to a subject form -->
              <ReasonForChange>assign review state 5.0</ReasonForChange>
            </AuditRecord>
          </pf:FormStatus>
        </FormData>
      </StudyEventData>
    </SubjectData>
  </ClinicalData>
</ODM>
<Status>END</Status>
<Bookmark>{A18E6CE1-11AB-4C6B-A4A8-63E31BD9025F}</Bookmark>
<TransactionsProcessed>1</TransactionsProcessed>
</ResponseODM>
```

APPENDIX A
ODM Mapping

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About ODM mapping

This appendix shows the ODM to InForm mapping for transactional data (where supported) for Version 2 of the Oracle ODM Export Interface.

For snapshot data, Version 2 Snapshot mode includes the following changes that are required for CDISC ODM 1.3 compliance:

- AnnotationAuditRecord has been removed.
ODM Snapshot mode does not support audit records, which are included as part of transactional mode.
- Date controls from the InForm application are now emitted as type Text with the optional extension **InFormDateTime="true"** to indicate that the data point stores incomplete date/time values from the InForm software.

For more information, see *ODM data that is returned* (on page 75).

Mapping of localized items

The following items are localized in the InForm software. The translation for each item is placed under the TranslatedText element in the ODM that is returned.

Item name	Element name in ODM.xml
The symbol of measurement unit.	MeasurementUnit/Symbol
Item text.	itemDef/Question
Radio button list, dropdown list, list box, control group, or checkbox list that is associated with a control in the InForm software.	CodeList/CodeListItem/Decode
Form mnemonic.	FormDef/pf:Mnemonic
Visit mnemonic.	StudyEventDef/pf:Mnemonic
Legal Reason.	SignatureDef/pf:LegalReason
Meaning.	SignatureDef/pf:Meaning

Site mnemonic is also placed under the TranslatedText element. However, it is not localized in pf_resourcedata in the InForm application. It is returned as the fallback because there is no language associated with it.

ODM

Attributes	Value/Map To InForm
Description	InForm Study Name.
FileType	FileType.Snapshot or FileType.TransactionaI, based on input parameter.
Archival	Yes.
FileOID	InForm Study Name + unique GUID.
CreationDateTIme	Current date time.
PriorFileOID	If present, FileOID of previous file in chain.
ODMVersion	1.3.
Originator	Based on input parameter.
MappingVersion	V1 or V2 to indicate the version of the InForm to ODM mapping definitions that were requested by the caller.
HierarchicalOIDs	No or Yes to indicate whether the ODM OIDs represent the programmatic, hierarchical repath of the metadata.
InFormAdapterVersion	Version of InForm Adapter that was used to generate the response.

Example—ODM

```
<ODM Description="Hypertension Study" FileType="Snapshot" FileOID="Hypertension
Study1/19/2005 11:31:35 AM"
  CreationDateTime="2005-01-19T11:31:35.1930510-05:00" ODMVersion="1.3"
  Originator="test"
  xmlns="http://www.cdisc.org/ns/odm/v1.3" />
```

Study

Attributes	Value/Map To InForm
OID	InForm Study Name.

Example—Study

```
<Study OID="Hypertension Study" />
```

GlobalVariables

Children	Value/Map To InForm
StudyName	InForm Study Name.
StudyDescription	Volume Edition DesignNotes.
ProtocolName	ProtocolVersion.

Example—GlobalVariables

```
<GlobalVariables>  
  <StudyName>Hypertension Study</StudyName>  
  <ProtocolName>Protocol XYZZY</ProtocolName>  
</GlobalVariables>
```

BasicDefinitions

BasicDefinitions contains the InForm measurement unit definitions.

MeasurementUnit

Attributes	Value/Map To InForm
OID	Unit RefName.
Name	Unit Symbol.
DBUID	Entity: Units. Property: DBUID.
GUID	Unit identifier.
Revision	Entity: Units. Property: Revision.

TranslatedText

BasicDefinitions/MeasurementUnit/Symbol/TranslatedText

Attributes	Value/Map to InForm
Body text	Unit Symbol.

TranslatedText specifies the xml:lang for each language, and the element without xml:lang. This value is used when the culture is unspecified or unavailable for a given value.

Example—BasicDefinitions

```
<BasicDefinitions>
  <MeasurementUnit OID="Inches" Name="Inches">
    <Symbol>
      <TranslatedText>in</TranslatedText>
      <TranslatedText xml:lang="en-US">in</TranslatedText>
      <TranslatedText xml:lang="ja-JP">in</TranslatedText>
    </Symbol>
  </MeasurementUnit>
  <MeasurementUnit OID="Centimeter" Name="Centimeter">
    <Symbol>
      <TranslatedText>cm</TranslatedText>
    </Symbol>
  </MeasurementUnit>
</BasicDefinitions>
```

MetaDataVersion

Attributes	Value/Map to InForm
OID	Study version RefName.
Name	Study version display name.
ApprovalDate	Date that the study was approved.
DBUID	Entity:StudyVersion. Property: Revision.
GUID	Study version identifier.
Revision	Entity:StudyVersion. Property: Revision.

StudyEventRef

Attributes	Value/Map to InForm
StudyEventOID	Visit RefName.
OrderNumber	Visit order number (for user interface display).
Mandatory	Always No .

Example—MetaDataVersion

```
<MetaDataVersion OID="Study Version Basic" Name="Protocol XYZZY">
  <Protocol>
    <StudyEventRef StudyEventOID="Visit1" OrderNumber="1" Mandatory="No" />
    <StudyEventRef StudyEventOID="Visit2" OrderNumber="2" Mandatory="No" />
    <StudyEventRef StudyEventOID="Visit3" OrderNumber="3" Mandatory="No" />
    <StudyEventRef StudyEventOID="Visit4" OrderNumber="4" Mandatory="No" />
  </Protocol>
</MetaDataVersion>
```

StudyEventDef

Attributes	Value/Map to InForm
OID	Visit RefName.
Name	Visit RefName.
Repeating	Yes for repeating visits.
Type	Scheduled, Unscheduled, or Common.
Category	PatientVisit, Screening, Enrollment, CommonCRF, or Relation.
DBUID	Entity: Visit. Property: DBUID.
GUID	Visit identifier.
Revision	Entity: Visit. Property: Revision.
UUID	Entity: Visit. Property: UUID.
Dynamic	Visit is a dynamic visit.

Mnemonic

StudyEventDef/Mnemonic

Attributes	Value/Map to InForm
TranslatedText	Display mnemonic for visit.

FormRef

Attributes	Value/Map to InForm
FormOID	Form RefName.
OrderNumber	Form page order (for user interface display).
Mandatory	Always No .
AltFormOID	Specifies the OID of the Alt form for the form that is identified by the current FormOID.

Example—StudyEventDef

```
<StudyEventDef OID="vstFinal" Name="vstFinal" Repeating="No" Type="Scheduled"
Category="Enrollment" pf:DBUID="10057" pf:GUID="{8BA4EB52-CCFD-4567-92CD-
AFFA16947926}" pf:Revision="250599557260035" pf:UUID="D882CE3A-0F42-11D2-A419-
00A0C963E0AC">
  <FormRef FormOID="frmDOV" OrderNumber="1" Mandatory="No" />
  <FormRef FormOID="frmSC" OrderNumber="2" Mandatory="No" />
  <pf:Mnemonic>
    <TranslatedText>Final</TranslatedText>
  </pf:Mnemonic>
</StudyEventDef>
```

FormDef

Attributes	Value/Map to InForm
FormOID	Form RefName.
Name	Form RefName.
Repeating	Yes if the form is a repeating form.
DBUID	Entity: Form. Property: DBUID.
GUID	Form identifier.
Revision	Entity: Form. Property: Revision.
UUID	Entity: Form. Property: UUID.
Dynamic	Yes if the form is a dynamic form.
OrderNumber	The order of the form (for presentation in the user interface).

Mnemonic

FormDef/Mnemonic

Attributes	Value/Map to InForm
TranslatedText	The display mnemonic for the form.

ItemGroupRef

Attributes	Value/Map to InForm
ItemGroupOID	Form-relative RefPath for the section.
OrderNumber	Section Order.
Repeating	Section Repeating, when Yes indicates that the section contains an itemset.

Example—FormDef

```
<FormDef OID="frmDOV" Name="frmDOV" Repeating="No" pf:DBUID="7642"  
pf:GUID="ab9274c1-b46c-4d3d-baf6-a0a8bbcf6a06" pf:Revision="250599336073035"  
pf:UUID="D882CE3B-0F42-11D2-A419-00A0C963E0AC">  
  <ItemGroupRef ItemGroupOID="frmDOV.sctVisitDateandTime" OrderNumber="1"  
    Mandatory="No" />  
  <pf:Mnemonic>  
    <TranslatedText>DOV</TranslatedText>  
  </pf:Mnemonic>  
</FormDef>
```

ItemGroupDef

Attributes	Value/Map to InForm
OID	Form-relative RefPath for the section.
Name	Section RefName.
Repeating	Section Repeating; Yes when the section contains an ItemSet.
ItemSetDBUID	Entity: ItemSet. Property: DBUID.
DBUID	Entity: Section. Property: DBUID.
GUID	Form identifier.
Revision	Entity: Section. Property: Revision.
UUID	Entity: Section/Itemset. Property: UUID.
ItemSetRefName	Present when the section contains an itemset; specifies the RefName of the ItemSet in the section.
ItemSetRevision	Entity: ItemSet. Property: Revision.
SVRequired	Present when the section contains an ItemSet and the ItemSet requires source verification.
RowCount	IsFixedSize—If Yes, the itemset includes only the number of rows specified in RowCount.
SVCritical	Indicates whether an item is marked as source verified critical in the InForm and Central Designer applications.

Example—ItemGroupDef

Sample output

```
<ItemGroupDef OID="frmDOSEVS.SctVitalSigns.SctVitalSigns" Name="SctVitalSigns"
Repeating="Yes" pf:ItemSetRefName="SctVitalSigns" pf:SVRequired="Yes"
pf:DBUID="6822"
pf:GUID="{1D1ECF17-5746-4B62-BC78-429295D32CE3}" pf:Revision="381233343951065"
pf:RowCount="5" pf:IsFixedSize="Yes">
  <ItemRef
ItemOID="frmDOSEVS.SctVitalSigns.SctVitalSigns.itmPlannedTime.itmPlannedTime"
OrderNumber="1" Mandatory="Yes">
  <pf:InFormItemRef
InFormItemOID="frmDOSEVS.SctVitalSigns.SctVitalSigns.itmPlannedTime"
OrderNumber="1" Mandatory="Yes">
    <pf:UsePredefinedValue value="Yes" />
  </pf:InFormItemRef>
</ItemRef>
</ItemGroupDef>
```

InformItemRef

InformItemData/ItemStatus

Attributes	Value/Map to InForm
InFormItemOID	Form-relative RefPath of an item.
Mandatory	Yes if the item is mandatory.
OrderNumber	Display order of the item within the section.
UserPredefinedValue	If Yes , this value is populated from a list of predefined values that is associated with the ItemOID.

Example—InformItemRef

```
<pf:InFormItemRef InFormItemOID="frmCGI.sctCGIImp.itmCGIImp" OrderNumber="1"
Mandatory="Yes" />
```

ItemRef

Attributes	Value/Map to InForm
ItemOID	Form-relative RefPath for a control within an item.
OrderNumber	Control order within an item.
Mandatory	Control is required.

Example—ItemGroupDef

```
<ItemGroupDef OID="frmDOV.sctVisitDateandTime" Name="sctVisitDateandTime"
Repeating="No" pf:DBUID="7639" pf:GUID="{0bf10cac-c53e-4926-8843-9e8fda1569d4}"
pf:Revision="250599335838035" pf:UUID="ABCFA388-223A-11D2-A426-00A0C963E0AC">
  <ItemRef
    ItemOID="frmDOV.sctVisitDateandTime.DateandTimeofVisit_DOV.DateandTimeofVisit
_DOV" OrderNumber="1" Mandatory="Yes" />
  <pf:InFormItemRef
    InFormItemOID="frmDOV.sctVisitDateandTime.DateandTimeofVisit_DOV"
    OrderNumber="1" Mandatory="Yes" />
</ItemGroupDef>
```

InformItemDef

Attributes/Children	Value/Map to InForm
OID	The refname of the item. type=odm:oid. Required.
Name	Form-relative RefPath for the item. type=odm:text. Required.
SVRequired	Yes , if source verification is required for the item. type=odm:YesOrNo. Optional.
DBUID	Entity: Item. Property: DBUID.
GUID	Entity: Item. Property: GUID.
Revision	Entity: Item. Property: Revision.
UUID	Entity: Item. Property: UUID.
SVCritical	Indicates whether an item is marked as source verified critical in the InForm and Central Designer applications.

Example—InformItemDef

```
<pf:InformItemDef OID="frmDOV.sctVisitDateandTime.DateandTimeofVisit_DOV"
Name="DateandTimeofVisit_DOV" SVRequired="Yes" pf:DBUID="7648"
pf:GUID="{005A7BA1-AEA9-42E4-83F3-3E2358F68646}" pf:Revision="250599336526035"
pf:UUID="BD991BBF-B0A4-11D2-80E3-00A0C9AF7674">
  <ItemRef
    ItemOID="frmDOV.sctVisitDateandTime.DateandTimeofVisit_DOV.DateandTimeofVisit
    _DOV" OrderNumber="1" Mandatory="Yes" />
</pf:InformItemDef>
```

ItemDef

Attributes	Value/Map to InForm
OID	Form-relative RefPath for the control.
Name	Item RefName.
DataType	See <i>Data Type Table</i> (on page 161).
Length	See <i>Data Type Table</i> (on page 161).
SignificantDigits	See <i>Data Type Table</i> (on page 161).
Revision	<ul style="list-style-type: none"> Entity: Control. Property: Revision. Entity: Item. Property: Revision.
GUID	Item identifier.
DBUID	<ul style="list-style-type: none"> Entity: Control. Property: DBUID. Entity: Item. Property: DBUID.
UUID	Entity: Control. Property: UUID.
ParentOID	The parent of each ItemDef that is not a top-level ItemDef.
ParentType	Defines the type of parent control. If value of parent type is: <ul style="list-style-type: none"> ItemDef, then pf:ParentOID refers to the parent ItemDef's OID. CodeListItem, then pf:ParentOID refers to the parent CodeListItem's pf:SelectionOID.
SelectionOID	An OID that uniquely identifies the selection in a radio group.
SelectionOwner	For each ItemDef that is the child of a radio group selection, the OID of the CodeList that contains the codelist selection.
ItemDefType	Indicates the control type. Values: RadioGroup, Checkbox, Text, Calculated, PullDown, Date.
Question	Question text for the item that contains the control.
SignificantDigits	See <i>Data Type Table</i> (on page 161).
CheckboxGroupRefName	Present when the control is contained in a checkbox group and contains the RefName of the checkbox group.

Data Type Table

InForm control type	Definition
Simple Control	<ul style="list-style-type: none"> Data Type is defined by the element's type. Length: text 255, integer 10, float 308. <p>Notes:</p> <ul style="list-style-type: none"> Integer is always returned as 10 (the maximum number of digits in a 32-bit integer). Float is always returned as 308 (the maximum exponent for a 64-bit floating-point number). <ul style="list-style-type: none"> Significant Digit: 4.
Pulldown Control	References a codelist with the allowable values.
Text Control	<ul style="list-style-type: none"> Data Type is defined by control data type (Pf_TextControl/DataType). Length: text Pf_TextControl/MaxLength, integer 10, float 308. <p>Notes:</p> <ul style="list-style-type: none"> Integer is always returned as 10 (the maximum number of digits in a 32-bit integer). Float is always returned as 308 (the maximum exponent for a 64-bit floating-point number). <ul style="list-style-type: none"> Significant Digit: Pf_TextControl/PFPrecision.
Radio Control	References a codelist with the allowable values.
Group Control	Represented as an ItemDef per check option with the name of the option included in the form-relative RefPath in the ItemDefOID.
Datetime Control	incompleteDatetime.
Calculated Control	Text type with length = 255.

MeasurementUnitRef

Attributes	Value/Map to InForm
MeasurementUnitOID	Unit RefName.
NormalizationUnit	Yes , if the referenced unit is for normal values.

Question

Children	Value/Map to InForm
TranslatedText	Item question. A TranslatedText element exists for each study language.

Example—ItemDef

```
<ItemDef OID="frmDOSE.sctDOSE.itsDOSE.itmDOSEFromDate.dtmDOSE" Name="dtmDOSE"  
DataType="incompleteDatetime">  
  <Question>  
    <TranslatedText>Start date</TranslatedText>  
  </Question>  
</ItemDef>
```


User

Attributes/Children	Value/Map to InForm
OID	User Name.
UserType	User Type.
LoginName	User Name.
DisplayName	User DisplayName.
FullName	User first name + User last name. Note: Not all cultures use FirstName + LastName as the full name. The full name can be derived from FirstName and LastName elements that are available in the same response. The consumer of DownloadAdminDataODM should rely on FirstName and LastName elements to get the full name or display name.
FirstName	User first name.
LastName	User last name.
Organization	
Address/StreetName	User Address 1. User Address 2.
Address/City	User City.
Address/StateProv	User State Province.
Address/County	User Country.
Address/PostalCode	User postal code.
Address/OtherText	
Email	User email.
Picture	
Pager	User beeper.
Fax	User fax.
Phone	User phone number.
LocationRef/LocationOID	Site Name. Entity: User. Property: Site.
GroupRef	One GroupRef child element exists for each group to which the user belongs. Contains a GroupOID attribute.

Attributes/Children	Value/Map to InForm
DBUID	Entity: User. Property: DBUID.
GUID	User Identifier.
Revision	Entity: User. Property: Revision.
LoginName	Entity: User. Property: Login Name.
UserType	Entity: User. Property: User Type.
StudyLocale	Locale of study. Derived from dcv_thingdata in the study database.
Active	Indicates whether the user state is active.
Terminated	Indicates whether the user state is terminated.
InFormUserType	This type can contain the following values that correspond to the InForm user interface: <ul style="list-style-type: none"> • System • Site • Sponsor • Support • Integration

Example–User - mapping

```

<AdminData>
  <User OID="mmeyer" UserType="Investigator" pf:DBUID="11217"
pf:GUID="{8B980147-0531-4DD5-9B86-68BCA7F1532F}" pf:StudyLocale="en-US"
pf:Active="Yes" pf:Terminated="No" pf:InFormUserType="Site">
  <LoginName>mmeyer</LoginName>
  <DisplayName>Marianne Meyer</DisplayName>
  <FullName>Marianne Meyer</FullName>
  <FirstName>Marianne</FirstName>
  <LastName>Meyer</LastName>
  <Address>
    <Country>USA</Country>
  </Address>
  <Email>email@domain.test</Email>
  <Fax>(555) 555-1212</Fax>
  <Phone>(555) 555-1212</Phone>
  <LocationRef LocationOID="13001" />
  <pf:GroupRef GroupOID="5289" />
  <pf:GroupRef GroupOID="13609" />
</User>

```

GroupDef

GroupRef elements reference GroupDef elements by matching the GroupRef's GroupOID attribute to the GroupDef's OID attribute.

GroupRef is a child of User.

Attributes/Children	Value/Map to InForm
OID	The DBUID of the group.
NAME	Name of group as displayed in the InForm software.
GroupType	Type of group as defined in the InForm software.
Right	List of rights. Contains a list of Right elements, each of which contains a Description.

Right

AdminData/pf:GroupDef/pf:Right

Attributes	Value/Map to InForm
Description	The right defined in the group.

Example—GroupDef

```
<pf:GroupDef OID="5954" Name="System Creator Group" GroupType="Rights">
  <pf:Right Description="Create User"/>
  <pf:Right Description="Terminate User" />
</pf:GroupDef>
```

Location

To ensure that the audit records that are generated by sponsor users comply with the ODM standard, a Location with OID **Unknown** is automatically defined in the ODM that is returned for a study.

Attributes	Value/Map to InForm
OID	Site DBUID.
Name	Site name.
LocationType	Site. Entity: Site. Property: Type.
Revision	Entity: Site. Property: Revision. Note: Location Revision is the same as transaction only if the transaction is revising the location.
GUID	Site identifier.
SiteCountry	Entity: Site. Property: Country.
SiteTimezone	Entity: Site. Property: Timezone.
Locale	Locale of the site.
pf:SVAutoSelectRate	The value comes from a query: For more information, see <i>Subject pool selection</i> (on page 137).
pf:SVFirstNSubjects	The value comes from a query: For more information, see <i>Subject pool selection</i> (on page 137).

Mnemonic

Location/Mnemonic

Attributes	Value/Map to InForm
TranslatedText	The site mnemonic that does not come from the pf_resourcedata. This mnemonic can have any Unicode characters. It should not contain the xml:lang attribute.

Example—Location

```
<Location
  LocationType="Site" Name="(01) Massachusetts General Hospital"
  OID="10127" pf:SiteCountry="USA"
    pf:SiteTimezone="(GMT-05:00) Eastern Time (US & Canada)">
  <MetaDataVersionRef
    EffectiveDate="2005-04-01T00:00:00+00:00"
    MetaDataVersionOID="StudyVersion020108"
    StudyOID="Depression Study"/>
  <Mnemonic
    xmlns="http://www.phaseforward.com/InFormAdapter/ODM/Extensions/2.0">
  <TranslatedText
    xmlns="http://www.cdisc.org/ns/odm/v1.3">01</TranslatedText>
  </Mnemonic>
</Location>
```

CodeList

Attributes	Value/Map to InForm
OID	Control RefName. For example, if an item contains a drop-down list, the RefName of the drop-down list will be used. If file type is Transactional, the ControlRefName is hierarchical: form.section.item.control
Name	<ul style="list-style-type: none"> • If file type is Snapshot, Name is the same as OID. • If file type is Transactional, Name is the same as the ControlRefName without the hierarchical prefixing.
DataType	Type of Control. See <i>Data Type Table</i> (on page 161).

Example—CodeList

File type is Snapshot:

```
<CodeList OID="rdcEXCLC" Name="rdcEXCLC" DataType="text" />
```

File type is Transactional:

```
<CodeList OID="frmPreg.sctPreg.itmPregTest.itmPregTest.rdcPregDone"
Name="rdcPregDone" DataType="text">
```

CodeListItem

Attributes	Value/Map to InForm
CodedValue	Value used to map the CodeListItem to an ItemData value in ODM ClinicalData.
pf:SelectionOID	An OID that uniquely identifies the selection in a radio group. The value is a concatenation of the CodeList OID and the CodeListItem CodedValue.

Example—CodeListItem

```
<CodeListItem CodedValue="2"
pf:SelectionOID="frmPreg.sctPreg.itmPregTest.itmPregTest.rdcPregDone.2">
  <Decode>
    <TranslatedText>Positive</TranslatedText>
  </Decode>
</CodeListItem>
```

MetaDataVersionRef

Attributes	Value/Map to InForm
StudyOID	Study Name. Entity: Site. Property: Study.
MetaDataVersionOID	Volume Edition Description. Entity: Site. Property: Study Version. If the form has no study version, MetaDataVersionOID="Undefined."
EffectiveDate	Site accept date. Entity: Site. Property: Study Version Approval Date.

Example—MetaDataVersionRef

```
<MetaDataVersionRef StudyOID="Hypertension Study"
  MetaDataVersionOID="Study Version Basic" EffectiveDate="1998-06-30" />
```

SignatureDef

Attributes	Value/Map to InForm
OID	Signature DBUID.
Methodology	Electronic.
Meaning	CRB meaning, CRF meaning, or Group Name.
LegalReason	CRB Affidavit, CRF Affidavit, or PF_DEFAULT_CRFAFFADAVIT.

Meaning

CRB meaning, CRF meaning, or Group Name.

SignatureDef/Meaning

Attributes	Value/Map to InForm
TranslatedText	Language-specific text from the study.

LegalReason

CRB Affidavit, CRF Affidavit, or PF_DEFAULT_CRFAFFADAVIT.

SignatureDef/Meaning

Attributes	Value/Map to InForm
TranslatedText	Language-specific text from the study.

Example—SignatureDef

```
<SignatureDef OID="CRA Sigs" Methodology="Electronic">
  <Meaning>Approved</Meaning>
  <LegalReason>
    By my dated signature below, I, %s %s, verify that this case report form
    accurately displays the results of the examinations, tests, evaluations
    and treatments noted within. Pursuant to Section 11.100 of Title 21 of the
    Code of Federal Regulations, this is to certify that I intend that this
    electronic signature is to be the legally binding equivalent of my
    handwritten signature. To this I do attest by supplying my password and
    clicking the button marked Submit below.
  </LegalReason>
</SignatureDef>
```


ClinicalData

Attributes	Value/Map to InForm
StudyOID	Study Name.
MetaDataVersionOID	Study Version. If the form has no study version, MetaDataVersionOID="Undefined."
CriticalItems	Includes a separate <i>CriticalItem</i> element for each item-level change that occurs in the InForm application. For more information, see <i>CriticalItem</i> (on page 120).

Example—ClinicalData

```
<ClinicalData StudyOID="Depression Study Update" MetaDataVersionOID="Study
Version 1.0" />
```

Example—ClinicalData Sample Output

```
<ClinicalData StudyOID="StudyDesign" MetaDataVersionOID="Study Design 0.0.4"
pf:TransactionGuid="{DEEC7341-A41A-426B-93E3-8CFD2A95BEB0}"
pf:Revision="382526547058065.000">
  <pf:CriticalItems>
    <pf:CriticalItem sItemRefName="Gender" FormOID="" LocationOID="13548"
Critical="StudyDefault" ItemRevision="381233328489065" />
    <pf:CriticalItem ItemRefName="Gender" FormOID="frmDem"
LocationOID="13548" Critical="true" ItemRevision="381233328489065" />
    <pf:CriticalItem ItemRefName="MaritalStatus" FormOID="frmDem"
LocationOID="13548" Critical="false" ItemRevision="381233326086065" />
    <AuditRecord>
      <UserRef UserOID="mlynch" />
      <LocationRef LocationOID="Unknown" />
      <DateTimeStamp>2013-02-14T14:22:27+00:00</DateTimeStamp>
    </AuditRecord>
  </pf:CriticalItems>
</ClinicalData>
```

SubjectData

Attributes	Value/Map to InForm
SubjectKey	Patient DBUID.
GUID	Subject identifier.
Revision	Entity: Subject. Property: Revision.
SiteRef	Entity: Patient Move. Property: <i>no property listed.</i>
CriticalItems	Includes a separate <i>CriticalItem</i> element for each item-level change that occurs in the InForm application. For more information, see <i>CriticalItem</i> (on page 120).

Signature

Indicates that the CRB has been signed for the subject.

SiteRef

Site for the subject. In the event of a subject site move, a SubjectData element that contains a new SiteRef and no StudyEventData element is sent.

pf:SubjectPool

Represents the source verification pool in the InForm application.

SubjectData/pf:SubjectPool

Attributes	Value/Map to InForm
PoolNumber	<p>The InForm Pool Number.</p> <p>type=xs:string.</p> <p>Required.</p> <p>One of the following values, representing the available pools that are hardcoded in the InForm software:</p> <p>0—PF_SVELIGIBLE_POOL</p> <p>1—PF_SVAUTO_SELECT_POOL</p> <p>2—PF_SVMANUAL_FIRSTN_POOL</p> <p>3—PF_SVMANUAL_UISELECT_POOL</p> <p>4—PF_SVMANUAL_IMPORT_POOL</p> <p>99—PF_SVEXCLUDED_POOL</p>
PoolRefName	<p>The ref name of the pool.</p> <p>type=xs:string.</p> <p>Required.</p> <p>One of the following values:</p> <p>Eligible—PoolNumber=0, indicating the pool is SV Eligible.</p> <p>AutoSelect—PoolNumber=1, indicating a pool whose members are automatically selected based on settings determined by the site administrator.</p> <p>ManualFirstN—PoolNumber=2, indicating a pool in which the first <n> number of subjects are automatically selected.</p> <p>ManualUISelect—PoolNumber=3, indicating that the pool members are added by being selected in the UI.</p> <p>ManualImport—PoolNumber=4, indicating an imported file that contains the pool members.</p> <p>Excluded—PoolNumber=99, indicating that the pool is excluded from source verification.</p>

pf:SubjectPoolChange

Reflects the change in the subject pool. Includes the subjects placed in the pool

SubjectData/pf:SubjectPoolChange

Attributes	Value/Map to InForm
LocationOID	Includes the subjects placed in the pool.
PoolNumber	Pool number.

pf:CriticalForm

Represents a form that must be source verified.

SubjectData/pf:CriticalForm

Attributes	Value/Map to InForm
FormRef	FORMGUID.
LocationOID	Site OID.
IsCritical	ISCRITICAL.

pf:ReviewState

Represents the state and stage of the progress of data review in the InForm application.

SubjectData/pf:ReviewState

Attributes	Value/Map to InForm
pf:DBUID	dbuid.
RefName	Review state name.
StateValue	State value.
Revision	Revision number.
Name element	Translated text.
Mnemonic element	Mnemonic.

pf:ReviewStage

Represents one of the three review stages of the review state.

SubjectData/pf:CriticalForm

Attributes	Value/Map to InForm
RefName	Stage ref name.
StageValue	Stage value.
Activated	0 or 1.
Revision	Revision number.

Example—SubjectData

```

<ClinicalData StudyOID="StudyDesign" MetaDataVersionOID="Study Design 0.0.2"
pf:TransactionGuid="{6EAEA8C3-68D1-4314-881C-5AA2A5575308}"
pf:Revision="326048162773035.000">
  <SubjectData SubjectKey="14266" TransactionType="Upsert"
pf:GUID="{83A9C428-8475-4AEF-A169-37D4F1E52975}">
    <SiteRef LocationOID="13341" />
    <StudyEventData StudyEventOID="enroll">
      <AuditRecord>
        <UserRef UserOID="enes" />
        <LocationRef LocationOID="Unknown" />
        <DateTimeStamp>2011-05-02T21:56:02+00:00</DateTimeStamp>
        <ReasonForChange>Visit Started</ReasonForChange>
      </AuditRecord>
      <FormData FormOID="frmEnr">
        <ItemGroupData ItemGroupOID="frmEnr.sctSubjectNum">
          <ItemData ItemOID="frmEnr.sctSubjectNum.SubNum_Enr.SubNum_Enr"
Value="AAA">
            <AuditRecord>
              <UserRef UserOID="enes" />
              <LocationRef LocationOID="13341" />
              <DateTimeStamp>2011-05-02T21:56:02+00:00</DateTimeStamp>
              <ReasonForChange>Enrollment Entry</ReasonForChange>
              <SourceID>RDINFAPP261</SourceID>
            </AuditRecord>
          </ItemData>
        </ItemGroupData>
      </FormData>
    </StudyEventData>
  </SubjectData>
</ClinicalData>

```

Candidate

SubjectData/Candidate

Attributes	Value/Map to InForm
DOB	The date of birth of the subject.
ScreeningDate	The date of the screening.
PatientGUID	The GUID of the subject.
Revision	The revision number of the subject.
SiteGUIDREF	The GUID of the site.
Initials	The initials of the subject.
State	The state of the subject.
ScreeningNumber	The subject's screening number.
EnrollmentNumber	The subject's enrollment number.
ScreeningFailure	The reason for screening failure.
EnrollmentFailure	The reason for enrollment failure.
EnrollmentOverride	The reason that the enrollment failure was overridden.
PatientNumberRevision	The revision number of the subject number.

Example—Candidate

```

pf:Candidate SubjectInitials="GMC" EnrollmentNumber="08-002"
ScreeningNumber="SCR-08-1" ScreeningFailure="" EnrollmentFailure=""
EnrollmentOverride="" DateOfBirth="1959-04-18T00:00:00+00:00"
ScreeningDate="2004-01-01T00:00:00+00:00" PatientRevision="94995391031040.000">
  <AuditRecord>
    <UserRef UserOID="msilva" />
    <LocationRef LocationOID="Unknown" />
    <DateTimeStamp>2004-01-05T16:36:31+00:00</DateTimeStamp>
    <ReasonForChange>Screening Log Entry</ReasonForChange>
  </AuditRecord>
</pf:Candidate>

```

SubjectStatus

Attributes	Value/Map to InForm-
State	Screened, ScreenFailed, Enrolled, EnrollmentFailed, EnrollmentOverride, Randomized, Complete, or DroppedOut.
ScreenFailReason	Text that describes the reason for the screening failure.
EnrollFailReason	Text that describes the reason for the enrollment failure.
EnrollOverrideReason	Text that describes the reason for the enrollment override.
SVReady	Source verification ready.
Frozen	Yes , if subject is frozen.
Locked	Yes , if subject is locked.

Example—SubjectStatus

```
<pf:SubjectStatus State="Screened">
  <AuditRecord>
    <UserRef UserOID="msilva" />
    <LocationRef LocationOID="Unknown" />
    <DateTimeStamp>2004-01-05T16:36:31+00:00</DateTimeStamp>
    <ReasonForChange>Screening Log Entry</ReasonForChange>
  </AuditRecord>
</pf:SubjectStatus>
```

StudyEventData

An activated visit is indicated by a StudyEventData element that contains no child FormData element.

Attributes	Value/Map to InForm
StudyEventOID	Form-relative visit refpath.
StudyEventRepeatKey	Visit index (for repeating visits only).
TransactionType	<ul style="list-style-type: none"> • With Loose compliance mode: Upsert. • With Strict compliance mode: Insert, Upsert, or Remove.
DBUID	Entity: Visit. Property: DBUID.
Revision	Entity: Visit. Property: Revision.

Example—StudyEventData

```
<StudyEventData StudyEventOID="vstBASE" />
```


FormData

Attributes	Value/Map to InForm
FormOID	Form RefName.
FormRepeatKey	Form index (for repeating forms only).

Signature

Indicates that the form has been signed for the subject.

Example—FormData

```
<FormData FormOID="LAE1" FormRepeatKey="243960146618003"
TransactionType="Remove">
  <pf:FormStatus Deleted="Yes" >          Yes/No
    <AuditRecord>
      <UserRef UserOID="system" />
      <LocationRef LocationOID="Unknown" />
      <DateTimeStamp>2008-09-24T19:46:51+00:00</DateTimeStamp>
    </AuditRecord>
  </pf:FormStatus>
</FormData>
```

FormStatus

Attributes	Value/Map to InForm
Activated	Yes , when the form has been activated.
SVPartial	Yes , when the form has been partially source verified.
Frozen	Yes , when the form is frozen.
Locked	Yes , when the form is locked.
Deleted	Yes , when the form has been deleted.
SVComplete	Yes , when the form is source verification complete.
SVReady	Yes , when the form is source verification ready.
SVSelected	Yes , when partial source verification has been selected for the form.
Signed	<p>Yes—the transaction caused the signature status of the form to change to "signed."</p> <p>No—the transaction caused the signature status of the form to change to "unsigned."</p> <p>The Signed attribute is not returned for a form that has not yet been signed.</p>

Example—FormStatus

```

<FormData FormOID="frmDOSE">
  <pf:FormStatus SVComplete="No">          Yes/No
    <AuditRecord>
      <UserRef UserOID="system" />
      <LocationRef LocationOID="Unknown" />
      <DateTimeStamp>2008-09-19T21:05:54+00:00</DateTimeStamp>
    </AuditRecord>
  </pf:FormStatus>
</FormData>

```

Signature

Children	Value/Map to InForm
UserRef/UserOID	User Name.
LocationRef/LocationOID	Site Name.
SignatureRef/SignatureOID	Signature Group Name.
DateTimeStamp	Entered date.

Example—Signature

```
<FormData FormOID="DEM" FormRepeatKey="1">
  <Signature>
    <UserRef UserOID="Inform CRA2" />
    <LocationRef LocationOID="PhaseForward" />
    <SignatureRef SignatureOID="CRA CRF Approval" />
    <DateTimeStamp>2005-04-06T19:41:49.0000000-04:00</DateTimeStamp>
  </Signature>
</FormData>
```

ItemGroupData

Attributes	Value/Map to InForm
ItemGroupOID	Form-relative RefPath for the section.
ItemGroupRepeatKey	Present when the section contains an ItemSet and specifies the ItemSet index.

Example—ItemGroupData

```
<ItemGroupData ItemGroupOID="LAB" ItemGroupRepeatKey="134562926897091" />
```

Annotation

FormData/Annotation
ItemData/Annotation

Attributes/Children	Value/Map to InForm
SeqNum	Comment ID.
Comment	Comment text.
Comment/ReasonIncomplete	Reason that the form or item is incomplete.
GUID	Entity: Comment. Property: GUID.
DBUID	Entity: Comment. Property: DBUID.

Example—Annotation

```
<Annotation SeqNum="9985">
  <Comment>test item comment</Comment>
</Annotation>
```

ItemData

Attributes/Children	Value/Map to InForm
ItemOID	Item RefName.
Value	ItemContext/control values.
DBUID	<ul style="list-style-type: none"> Entity: Item. Property: DBUID. Entity: Control. Property: DBUID.
Revision	<ul style="list-style-type: none"> Entity: Item. Property: Revision. Entity: Control Property: Revision.
pf:FormattedDateValue	<p>Indicates a value of null or unknown in the date part.</p> <ul style="list-style-type: none"> UNK indicates an unknown date part. NUL indicates a null date part. <p>Note: To maintain backward compatibility and conform to ODM standard, "-" is still used to express a value of unknown or null in the Value attribute. If differentiation between null and unknown is required, use the pf:FormattedDateValue extension.</p>

Example—ItemData

Example for unknown date part:

```
<ItemData ItemOID="LAE1.LsctAE.LitmAESTDT.LAESTDTTM"Value="2009-04-19T-:-:-+00:00" pf:FormattedDateValue="2009-04-19TUNK:UNK:UNK+00:00" />
```

Example for null date part:

In the example, the hour, minute, and second are null.

```
<ItemData ItemOID="LAE1.LsctAE.LitmAESTDT.LAESTDTTM"Value="2009-04-19T-:-:-+00:00" pf:FormattedDateValue="2009-04-19TNUL:NUL:NUL+00:00" />
```

ItemStatus

If an item has been source verified:

InformItemData/ItemStatus

If an itemset has been deleted or undeleted:

ItemGroupData/ItemStatus

Attributes/Children	Value/Map to InForm
Source Verified	Item has been source verified.
Deleted	Indicates whether the item has been deleted.

Example—ItemStatus

```
<FormData FormOID="frmDOV">
  <ItemGroupData ItemGroupOID="frmDOV.DOV">
    <pf:InformItemData InformItemOID="frmDOV.DOV.DOV" Name="DOV">
      <pf:ItemStatus SourceVerified="Yes"> "> (Yes or No are the 2 values this
      can be)
      <AuditRecord>
        <UserRef UserOID="system" />
        <LocationRef LocationOID="Unknown" />
        <DateTimeStamp>2008-09-17T20:32:49+00:00</DateTimeStamp>
      </AuditRecord>
    </pf:ItemStatus>
  </pf:InformItemData>
</ItemGroupData>
</FormData>
```

InformItemData

InformItemData/ItemStatus

Attributes/Children	Value/Map to InForm
InformItemOID	Form-relative RefPath for the item.
Name	Item RefName.
ItemStatus	Status of the item in the InForm software; for example, SVReady.
Query	Query element against an item in the InForm software.

Example—InformItemData

```
<pf:InformItemData InformItemOID="frmDOSE.sctDOSE.itmDOSE.itmDOSEToDate"
Name="itmDOSEToDate">
  <pf:Query OID="{00E6AD12-0848-4F71-AB61-ED0F845D1404}" Text="Stop Date is
not equal to or after the Start Date; please verify" Type="Autoquery"
pf:DBUID="75369" pf:Revision="244386598500043.000">
  <pf:QueryStatus Status="Open">
    <AuditRecord>
      <UserRef UserOID="autoquery" />
      <LocationRef LocationOID="Unknown" />
      <DateTimeStamp>2008-09-29T18:09:58+00:00</DateTimeStamp>
      <ReasonForChange>Stop Date is not equal to or after the Start
Date; please verify</ReasonForChange>
    </AuditRecord>
  </pf:QueryStatus>
</pf:Query>
</pf:InformItemData>
```


AuditRecord

Attributes/Children	Value/Map to InForm
Edit Point	DataManagement.
UserRef/UserOID	User Name.
LocationRef/LocationOID	Site Name.
DateTimeStamp	Entered date.
ReasonForChange	Reason.
SourceID	Machine Name.

UserRef

AuditRecord/UserRef

Attributes/Children	Value/Map to InForm
UserOID	Entity: Item. Property: Change user.

Example—AuditRecord

```
<ItemData ItemOID="DEMDOB" Value="Apr/5/1968">
  <AuditRecord EditPoint="DataManagement">
    <UserRef UserOID="crc2" />
    <LocationRef LocationOID="PhaseForward" />
    <DateTimeStamp>2005-04-06T12:09:05.0000000-04:00</DateTimeStamp>
    <ReasonForChange>Transcription Error</ReasonForChange>
    <SourceID>APPSRV27</SourceID>
  </AuditRecord>
</ItemData>
```

Query

InformItemData/Query

Attributes/Children	Value/Map to InForm
DBUID	Entity: Query. Property: DBUID.
OID	Query identifier.
Text	The text of the query.
Type	Autoquery or User.
Revision	Revision.
Query/QueryStatus	The status of the query.

Example—Query

```
<pf:Query OID="{08016623-5E3D-417C-93BB-33573CF1E1DC}" Text="Data does not match
source" Type="User">
  <pf:QueryStatus Status="Open">
    <AuditRecord>
      <UserRef UserOID="system" />
      <LocationRef LocationOID="Unknown" />
      <DateTimeStamp>2008-03-17T19:17:22+00:00</DateTimeStamp>
      <ReasonForChange>Data does not match source</ReasonForChange>
    </AuditRecord>
  </pf:QueryStatus>
</pf:Query>
```

QueryStatus

InformItemData/ItemStatus

Attributes/Children	Value/Map to InForm
Status	Open, Answered, Closed, Candidate, Reissued, or Deleted.
Text	Query text.
Query/QueryStatus/AuditRecord/UserRef	Entity: Query. Property: User.
Query/QueryStatus/AuditRecord/DateTimeStamp	Entity: Query. Property: Time.
Query/QueryStatus/AuditRecord/ReasonForChange	Entity: Query. Property: Reason for Change.

Example—QueryStatus

```
<pf:Query OID="{B70FF676-A6B3-4608-8AD0-A32444764F45}" Text="Date of Visit is
prior to Screening Date; please correct" Type="Autoquery">
  <pf:QueryStatus Status="Open">
    <AuditRecord>
      <UserRef UserOID="autoquery" />
      <LocationRef LocationOID="Unknown" />
      <DateTimeStamp>2004-01-08T13:47:01+00:00</DateTimeStamp>
      <ReasonForChange>Date of Visit is prior to Screening Date; please
correct</ReasonForChange>
    </AuditRecord>
  </pf:QueryStatus>
</pf:Query>
```


APPENDIX B

Client programs for determining item completeness

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Introduction

This appendix provides algorithms and pseudocode for writing client programs that evaluate transactional data returned from the ODM Export methods `DownloadMetadataODM` and `GetTransactions` to determine whether items in the InForm application are complete.

Items in the InForm application

In the InForm application, each item contains a single control. If that control is a group control, checkbox group, or radio group, it can contain a number of child controls. The InForm database does not explicitly model the completeness of this hierarchy of controls, although it does come into play when determining the completeness of a form.

This appendix uses the following definitions.

- **Leaf control**—Any control that holds a value and does not have children. Examples include:
 - Pulldown controls
 - Text boxes
- **Group control**—A control that contains children, but does not have its own value.
 - **Radio group**—A control that has a number of options, exactly one of which must be selected.
 - **Checkbox group**—A control that has a number of options, any number of which may be selected.

A group control, checkbox group, and radio group's children might be simple controls with no values, leaf controls, or other group controls, checkbox groups, or radio groups. Although a group control is a container and has no value of its own, checkbox groups and radio groups do have values that indicate their selections.

- **Completeness**—Generally, an item is considered to be complete if either of the following are true:
 - The item's top-level control is complete.
 or
 - The item's top-level control is a simple or calculated control.

Examples of items in the InForm application

Radio and Checkbox groups

The item in the InForm study:

Does anyone in the subject's family have a history of depression? Yes

Parent
 Sibling
 Other _____

No

Unknown

This item is composed of a radio group containing three options:

- A checkbox group with caption **Yes** that contains three options:
 - A simple control **Parent**.
 - A simple control **Sibling**.
 - A text box with caption **Other**.
- A simple control: **No**.
- A simple control: **Unknown**.

Criteria to determine whether an item is complete:

- If nothing is selected, then the item is incomplete.
- If **No** is selected, then the item is complete, because No does not have any children of its own (it is a simple control).
- If **Yes** is selected, but no checkbox options are selected, the item is not complete because at least one checkbox must be selected.
- If **Yes** is selected and **Parent** or **Sibling** is selected, then the item is complete, because Parent and Sibling don't have any children of their own.
- If **Yes** is selected and **Other** is selected, but the text box is not filled in, then the item is incomplete.

Simple group control

This example describes a blood pressure control:



Blood pressure: ___ / ___ mmHg

This item is composed of a group control containing:

- A text control (systolic).
- A simple control with the label /.
- A text control (diastolic).
- A simple control with the label **mmHg**.

Criteria to determine whether an item is complete:

In this example, the item is considered complete if either systolic or diastolic is entered, because the group control is considered complete if at least one of its children is complete.

Note: A typical study design will actually trigger a query if one of the parts of the blood pressure is left blank, but the item is technically complete.

Extensions for showing control hierarchy and type

To define details for controls, the ODM Export interface provides the following extensions to the ODM elements *ItemDef* (on page 160) and *CodeListItem* (on page 168).

Oracle extension to ItemDef	Description
pf:ParentOID	The parent of each ItemDef that is not a top-level ItemDef.
pf:ParentType	Defines the type of parent control. If value of parent type is: <ul style="list-style-type: none"> • ItemDef, then pf:ParentOID refers to the parent ItemDef's OID. • CodeListItem, then pf:ParentOID refers to the parent CodeListItem's pf:SelectionOID.
pf:SelectionOwner	For each ItemDef that is the child of a radio group selection, the OID of the CodeList that contains the codelist selection.
pf:ItemDefType	Indicates the control type. Values: RadioGroup, Checkbox, Text, Calculated, PullDown, Date.
Oracle extension to CodeListItem	Description
pf:SelectionOID	An OID that uniquely identifies the selection in a radio group. The value is a concatenation of the CodeList OID and the CodeListItem CodedValue.

Considerations:

- For each ItemDef, the extension **pf:ParentOID** must be added to show the parent for each data point. For example:


```
<ItemDef OID="frm.sct.itmFamHist.rdcYNUnk.chkFamHist.Other.txtOther"
  pf:ParentOID="frm.sct.itmFamHist.rdcYNUnk.chkFamHist.Other" ... />
```
- A pf:ParentOID is omitted in each root item.
- A pf:InFormItemDef might have multiple root ItemDefs when the root InForm control is a group control, because ItemDefs are not returned for InForm group controls.
- Each ItemDef that has a pf:ParentOID attribute will also contain a pf:ParentType attribute to indicate the type of the ItemDef's parent.
- Each ItemDef that is the child of a radio group selection will also identify the code list that contains the CodeListItem. This is extra information, but will be helpful in linking an item with the code list that contains the radio group selection that is its parent.

```
<ItemDef OID="frm.sct.itmFamHist.rdcYNUnk.chkFamHist.Parent"
  pf:ParentOID="frm.sct.itmFamHist.rdcYNUnk.Y"
  pf:ParentType="CodeListItem"
  pf:SelectionOwner="frm.sct.itmFamHist.rdcYNUnk"... />
```

Example—control hierarchy:

```
<ItemDef OID="frm.sct.itmFamHist.rdcYNUnk.chkFamHist.Other.txtOther"
  pf:ParentOID="frm.sct.itmFamHist.rdcYNUnk.chkFamHist.Other"
  pf:ParentType="ItemDef" ... />
<ItemDef OID="frm.sct.itmFamHist.rdcYNUnk.chkFamHist.Parent"
  pf:ParentOID="frm.sct.itmFamHist.rdcYNUnk.Y"
  pf:ParentType="CodeListItem" ... />
```

Example—control type:

```
<ItemDef OID="frm.sct.itmFamHist.rdcYN.chkFamHist.Other.txtOther"
  pf:ItemDefType="Text" ... />
```

Radio and Checkbox groups, with ODM metadata output

The item in the InForm study:

Does anyone in the subject's family have a history of depression? Yes

Parent
 Sibling
 Other _____

No

Unknown

Issuing the DownloadMetadataODM method on the InForm study produces the following XML output for the item, which includes the extensions to ItemDef and CodeListItem that show control hierarchy and type.

```
<ItemDef OID="frm.sct.itmFamHist.rdcYNUnk"
  pf:ItemDefType="RadioGroup" ... >
  <CodeListRef CodeListOID="frm.sct.itmFamHist.rdcYNUnk" />
</ItemDef>
<ItemDef OID="frm.sct.itmFamHist.rdcYNUnk.chkFamHist.Parent"
  pf:ParentOID="frm.sct.itmFamHist.rdcYNUnk.Y"
  pf:ParentType="CodeListItem"
  pf:SelectionOwner="frm.sct.itmFamHist.rdcYNUnk">
  pf:ItemDefType="Checkbox" ... />
<ItemDef OID="frm.sct.itmFamHist.rdcYNUnk.chkFamHist.Sibling"
  pf:ParentOID="frm.sct.itmFamHist.rdcYNUnk.Y"
  pf:ParentType="CodeListItem"
  pf:SelectionOwner="frm.sct.itmFamHist.rdcYNUnk">
  pf:ItemDefType="Checkbox" ... />
<ItemDef OID="frm.sct.itmFamHist.rdcYNUnk.chkFamHist.Other"
  pf:ParentOID="frm.sct.itmFamHist.rdcYNUnk.Y"
  pf:ParentType="CodeListItem"
  pf:SelectionOwner="frm.sct.itmFamHist.rdcYNUnk">
  pf:ItemDefType="Checkbox" ... />
<ItemDef OID="frm.sct.itmFamHist.rdcYNUnk.chkFamHist.Other.txtOther"
  pf:ParentOID="frm.sct.itmFamHist.rdcYNUnk.chkFamHist.Other"
  pf:ParentType="ItemDef"
  pf:ControlType="Text" ... />
<CodeList OID="frm.sct.itmFamHist.rdcYNUnk"
  <CodeListItem CodedValue="Y"
    pf:SelectionOID="frm.sct.itmFamHist.rdcYNUnk.Y"... />
```

```

<CodeListItem CodedValue="N"
  pf:SelectionOID="frm.sct.itmFamHist.rdcYNUnk.N"... />
CodeListItem CodedValue="Unk"
  pf:SelectionOID="frm.sct.itmFamHist.rdcYNUnk.Unk"... />
</CodeList>

<pf:InFormItemDef OID="frm.sct.itmFamHist" ... >
  <ItemRef ItemOID="frm.sct.itmFamHist.rdcYNUnk" />
  <ItemRef ItemOID="frm.sct.itmFamHist.rdcYNUnk.chkFamHist.Parent" />
  <ItemRef ItemOID="frm.sct.itmFamHist.rdcYNUnk.chkFamHist.Sibling" />
  <ItemRef ItemOID="frm.sct.itmFamHist.rdcYNUnk.chkFamHist.Other" />
  <ItemRef ItemOID="frm.sct.itmFamHist.rdcYNUnk.chkFamHist.Other.txtOther"
  />
</pf:InFormItemDef>

```

Group control, with ODM metadata output

The item in the InForm study:

Walking range as reported (without help or sticks) meters
 Number of minutes:

This example includes a group control (**gp_WalkRange**) that contains two children:

- A radio group (**rd_4Digit_Meters**) with one selection Meters:
 - A text box (**tx_Meters**) with caption "meters."
- A text box (**tx_2DigitMin**) with caption "Number of minutes."

Issuing the DownloadMetadataODM method on the InForm study produces the following XML output for the item, which includes the extensions to ItemDef and CodeListItem that show control hierarchy and type.

```

<ItemDef
  OID="fm_FSS2.sc_Ambulation.it_WalkRange.gp_WalkRange.rd_4Digit_Meters"
  pf:ItemDefType="RadioGroup">
  <CodeListRef
    CodeListOID="fm_FSS2.sc_Ambulation.it_WalkRange.gp_WalkRange.rd_4Digit_Meters" />
</ItemDef>
<ItemDef
  OID="fm_FSS2.sc_Ambulation.it_WalkRange.gp_WalkRange.rd_4Digit_Meters.tx_Meters"
  pf:ParentOID="fm_FSS2.sc_Ambulation.it_WalkRange.gp_WalkRange.rd_4Digit_Meters.Meters"
  pf:ParentType="CodeListItem"
  pf:SelectionOwner="fm_FSS2.sc_Ambulation.it_WalkRange.gp_WalkRange.rd_4Digit_Meters"
  pf:ItemDefType="Text">
</ItemDef>
<ItemDef
  OID="fm_FSS2.sc_Ambulation.it_WalkRange.gp_WalkRange.tx_2DigitMin"
  <!-- No pf:ParentOID or pf:ParentType, because it's at the top -->
  pf:ControlType="Text">
</ItemDef>

<CodeList
  OID="fm_FSS2.sc_Ambulation.it_WalkRange.gp_WalkRange.rd_4Digit_Meters">
  <CodeListItem
    CodedValue="!pf!8829"
    pf:SelectionOID=

```

```

        "fm_FSS2.sc_Ambulation.it_WalkRange.gp_WalkRange.rd_4Digit_Meters.Meters
        "/>
    <CodeListItem
        CodedValue=" "
        pf:SelectionOID=

        "fm_FSS2.sc_Ambulation.it_WalkRange.gp_WalkRange.rd_4Digit_Meters.BLANK"
        />
</CodeList>

<pf:InFormItemDef
    OID="fm_FSS2.sc_Ambulation.it_WalkRange"
    <!-- pf:RootItemOID was removed from the design because items can have
    multiple roots i.e. top level controls in this case
    fm_FSS2.sc_Ambulation.it_WalkRange.gp_WalkRange.tx_2DigitMin and
    fm_FSS2.sc_Ambulation.it_WalkRange.gp_WalkRange.rd_4Digit_Meters -->
    <ItemRef
        ItemOID="fm_FSS2.sc_Ambulation.it_WalkRange.gp_WalkRange.rd_4Digit_Meter
        s" />
    <ItemRef
        ItemOID="fm_FSS2.sc_Ambulation.it_WalkRange.gp_WalkRange.rd_4Digit_Meter
        s.tx_Meters" />
    <ItemRef
        ItemOID="fm_FSS2.sc_Ambulation.it_WalkRange.gp_WalkRange.tx_2DigitMin"
        />
</pf:InFormItemDef>

```

Algorithms for determining completeness

To determine an item's completeness, write a client program that processes the ODM metadata and clinical data that is returned from *DownloadMetadataODM* (on page 77) and *GetTransactions* (on page 92) to evaluate the ItemData elements for each InForm item (pf:InFormItemDef).

Writing a client program to evaluate ItemData elements

To evaluate the ItemData information for each InForm item, your program must find the root ItemDef elements (root controls) for each InForm item, and recursively process them and their child ItemDef elements (child controls) to determine the completeness of each InForm item. Match the ItemDef elements from metadata (from DownloadMetadataODM) to the corresponding ItemData elements from clinical data (from GetTransactions) to get the values of the controls.

To identify the ItemDefs of an InForm item:

An InForm item is represented in metadata by a pf:InFormItemDef element. Each pf:InFormItemDef has a list of ItemRefs, which represent all of the controls associated with the InForm item. The ItemRefs have corresponding ItemDefs.

- If the ItemDef has no pf:ParentType, then it is a root ItemDef.
- If the ItemDef has pf:ParentType of "ItemDef," then find the ItemDef whose OID matches the child's pf:ParentOID.
- If the ItemDef has pf:ParentType of "CodeListItem," then find the CodeListItem whose pf:SelectionOID matches the ItemDef's pf:ParentOID.

To find the root ItemDefs of an InForm item:

- From the InForm item's ItemRefs, find the corresponding ItemDefs that do not have parents. These are the root ItemDefs.

To find the child ItemDefs of an ItemDef:

- 1 If the ItemDef has pf:ControlType of "RadioGroup," then find the child ItemDefs whose pf:ParentOID match the pf:SelectionOID of the RadioGroup's selected CodeListItem. The Clinical Data will determine which CodeListItem is selected from the RadioGroup.
- 2 For ItemDefs that have other pf:ControlType values, find the child ItemDef whose pf:ParentOID matches the ItemDef's OID.

Calculated controls:

Calculated controls are treated specially when determining completeness. When an item contains only a single calculated control, the item is considered complete, even if the calculated control has no value. Also, if a checkbox or radio group selection contains only a calculated control, that selection is considered to be complete. Otherwise, calculated controls are ignored.

An item is complete if:

- It has only calculated controls.
- or
- It has at least one complete control, and no incomplete controls.

Note: Empty is not the same as Incomplete. A radio group or checkbox group is incomplete if it has a selection, and the selection's child control(s) are empty or incomplete.

Algorithms - pseudocode

This pseudocode provides a programmatic explanation of the requirements described in *Writing a client program to evaluate ItemData elements* (on page 199).

```

IsItemComplete(item)
{
    if (item only has calculated controls)
        return true;

    foreach(childControl of item)
    {
        bool completeControlFound = false;

        if (IsControlIncomplete(childControl, completeControlFound))
            return false;
    }
    return completeControlFound;
}

```

```

IsControlIncomplete(control, completeControlFound)
{
    if (control is a calculated control)
        return false;

    if (control is a control type that doesn't have children (text,
        pulldown, etc.))
    {
        if (control has value)
        {
            completeControlFound = true;
        }
        return false;
    }

    if (control is a radio group)
    {
        if (it doesn't have a selection)
            return false;

        selectedOption = the radio group's selected option;
    }
}

```

```

        if (selectedOption doesn't have any child controls OR
            it has exactly one child that is a calculated control)
        {
            completeControlFound = true;
            return false;
        }

        foreach (child of the selected option)
        {
            if (IsChildControlIncomplete(child))
                return true;
        }

        completeControlFound = true;
        return false;
    }

    if (control is a checkbox option)
    {
        if (it isn't checked)
            return false;

        if (it has exactly one child that is a calculated control)
        {
            completeControlFound = true;
            return false;
        }

        foreach (child of the checkbox option)
        {
            if (IsChildControlIncomplete(child))
                return true;
        }

        completeControlFound = true;
        return false;
    }
}

IsChildControlIncomplete(control)
{
    if (control is a calculated control)
        return false;

    if (control is a control type that doesn't have children (text, pulldown,
        etc.))
        Does the control have a value?
        if (yes)
            return false;
        if (no)
            return true;

    if (control is a radio group)
    {
        if (it doesn't have a selection)
            return true;

        selectedOption = the radio group's selected option;

        if (selectedOption doesn't have any child controls OR
            it has exactly one child that is a calculated control)
            return false;

        foreach (child of the selected option)
        {
            if (IsChildControlIncomplete(child))
                return true;
        }

        return false;
    }
}

```

```
    }
    if (control is a checkbox option)
    {
        if (it isn't checked)
            return true;

        if (it has exactly one child that is a calculated control)
            return false;

        foreach (child of the checkbox option)
        {
            if (IsChildControlIncomplete(child))
                return true;
        }
        return false;
    }
}
```


APPENDIX C

Sampler tools

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Discrepancy Sampler tool

The Discrepancy Sampler is a sample application that demonstrates how to use the InForm Adapter Discrepancy Enhanced interface to issue and update discrepancies on an InForm study, and get summary details of discrepancies by using reporting functions.

Download the Sampler tools

- 1 Log on to the Download Center at <https://extranet.phaseforward.com>.
- 2 Download and then extract the InForm AdapterSamples.zip file to the installation directory on the InForm Adapter server.

Both the Discrepancy Sampler and the ODM Sampler tools are extracted from the ZIP file.

Prerequisites for the Discrepancy Sampler tool

Security configuration

By default, the Discrepancy Sampler tool is set to use secure configuration (HTTPS), which is the default for the InForm Adapter Discrepancy Service.

Note: If you use the unsecured configuration for the InForm Adapter Discrepancy Service (HTTP instead of HTTPS) you need to use the same configuration for the Discrepancy Sampler tool.

To set security configuration for the Discrepancy Sampler tool:

- 1 Open the **DiscrepancySampler.exe.config** file at the following location:
`<installation_directory>\InformAdapterSamples\DiscrepancySampler\bin`
- 2 In the **system.serviceModel/client** section, comment out the endpoint that uses **wsHttpBinding** and uncomment the endpoint that uses **customBinding**.

The example shows the default secure configuration (HTTPS) enabled and the unsecure configuration commented out.

```
.
.
.
<client>
  <!-- Use the following endpoint to use the wsHttpBinding. It uses https
  and it supports authentication. -->
  <endpoint
    address="https://localhost./InFormAdapter/DiscrepancyService/Discrepancy
    Service.svc"
    binding="wsHttpBinding" bindingConfiguration="DiscrepancyService"
    contract="DiscrepancyServiceWcf.DiscrepancyService"
    name="DiscrepancyService" />

  <!-- Use the following endpoint to use the customBinding. It uses http
  instead of https
  and it does not support authentication. -->
  <!--
  <endpoint
    address="http://localhost./InFormAdapter/DiscrepancyService/DiscrepancyS
    ervice.svc"
    binding="customBinding" bindingConfiguration="DiscrepancyService"
    contract="DiscrepancyServiceWcf.DiscrepancyService"
    name="DiscrepancyService" />
```

```

-->
</client>
.
.
.

```

Username password authentication and the ODM Export interface

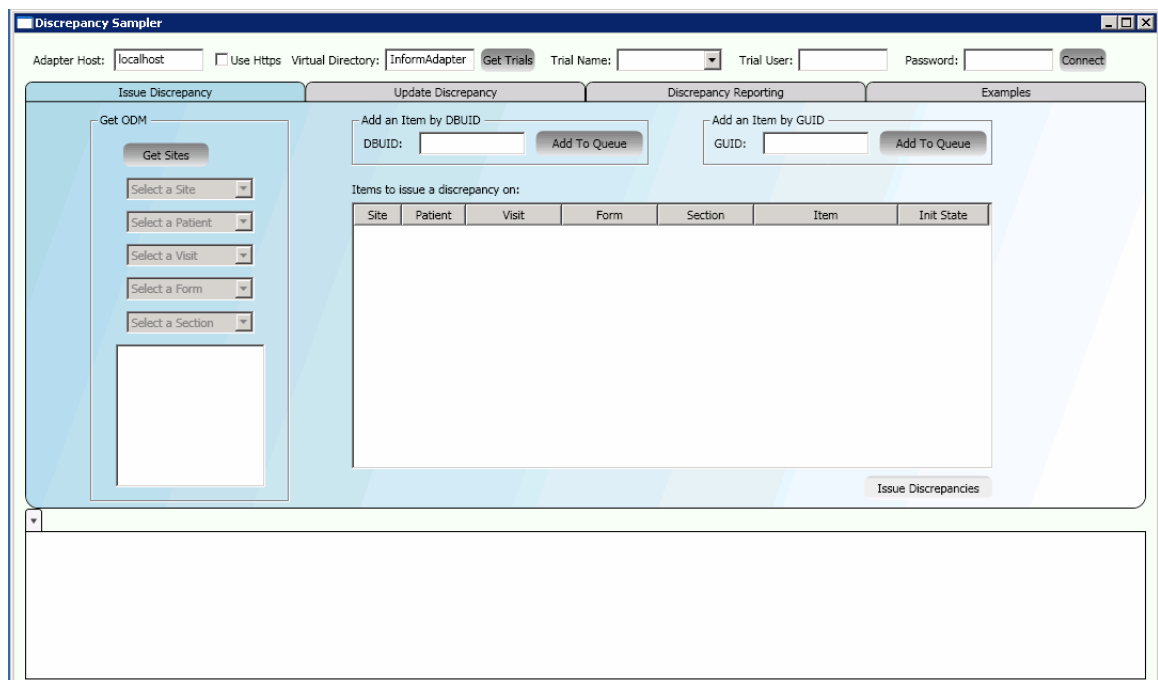
The Discrepancy Sampler uses the ODM Export interface to search the sites, patients, visits, forms, and section, and displays items that have values.

To use Username Password authentication to access studies with the Sampler tools, you must manually set up WSE Username token support. This is required for:

- The ODM Sampler tool.
- Features of the Discrepancy Sampler tool that use the ODM Export interface to search for items and their values.

For more information, see *Adding WSE Username token support for the Samplers*. (on page 222)

Connecting to a study



- 1 To start the Discrepancy Sampler tool, double-click the **DiscrepancySampler.exe** file at the following location:
`<installation_directory>\InformAdapterSamples\DiscrepancySampler\bin`
- 2 In the **Adapter Host** field, provide the name of the InForm Adapter server.
- 3 If you want to use https to connect to the server, select the checkbox.
- 4 In the **Virtual Directory** field, provide the InForm Adapter virtual directory name.
- 5 Click **Get Trials**.

The studies you can access become available from the Trial Name field.

Note: The Trial Name field might appear blank. Click the arrow to display the list of available studies.

- 6 In the **Trial Name** field, select a study name.
- 7 In the **Trial User** and **Password** fields, type your InForm user name and password, and click **Connect**.

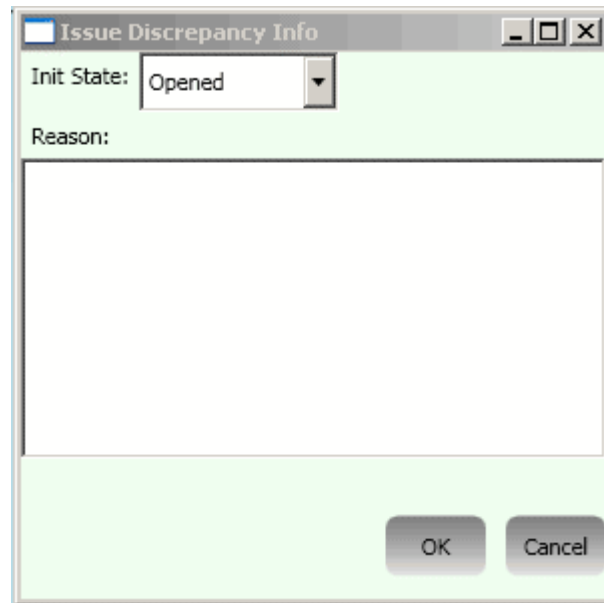
Issuing a discrepancy

The Discrepancy Sampler uses the ODM Export interface to search the sites, patients, visits, forms, and section, and displays items that have values.

- 1 Start the Discrepancy Sampler tool and connect to a study.
For more information, see *Connecting to a study* (on page 205).
- 2 Select the **Issue Discrepancy** tab.
- 3 Click **Get Sites**.
- 4 Select a site.
- 5 Select a subject.
- 6 Select a visit.
- 7 Select a form.
- 8 Select a section.
A list of items and their values appears. Only the items that have values are listed.
- 9 Double-click the item for which you want to issue a discrepancy.

Alternatively, you can provide information in the **Add an Item by DBUID** or **Add and Item by GUID** areas and click **Add to Queue**.

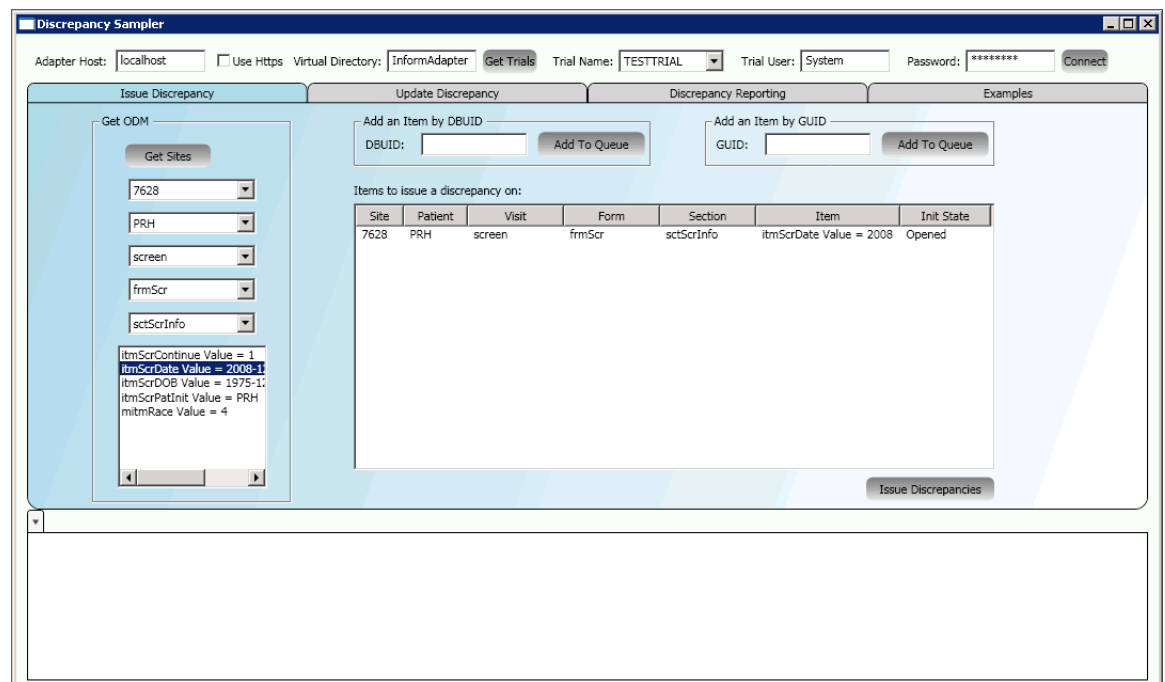
The **Issue Discrepancy Info** window appears.



10 In the **Init State** field, select the state in which to open the discrepancy.

11 Type a reason for the discrepancy, and click **OK**.

The discrepancy appears in the Items to issue a discrepancy on queue.



12 To add more discrepancies to the queue so they can be issued in the same call to the Issue operation, repeat steps 3 through 11.

- 13 For discrepancies in the queue, you can:
 - **Make additional changes to a discrepancy**—Double-click the discrepancy in the queue. The UpdateDiscrepancyInfo window reopens, where you can make your changes.
 - **Remove a discrepancy from the queue**—Right-click the discrepancy in the queue and click **Remove Selected**.
- 14 To issue all the discrepancies in the queue, click **Issue Discrepancies**.
The Issue response XML appears in the results pane. All the results from the queue you processed appear in the same tab. The queue becomes empty.
- 15 To issue additional discrepancies, repeat steps 3 through 9 to create a new queue. When you click **Issue Discrepancies**, the discrepancies in the queue are processed and appear in a new tab in the results pane.
- 16 To enlarge the contents of a tab in the results pane, double-click the tab.

Updating a discrepancy

On the Update Discrepancies tab, you can display all discrepancies in a study, or only those discrepancies that are in a particular state.

- 1 Start the Discrepancy Sampler tool and connect to a study.
For more information, see *Connecting to a study* (on page 205).
- 2 Select the **Update Discrepancy** tab.

- 3 From the list of states, select the state of discrepancies to display, or select **All States**.
- 4 Click **Get Discrepancies**.

A list of discrepancies in the state you specified appears, listed by discrepancy GUID.

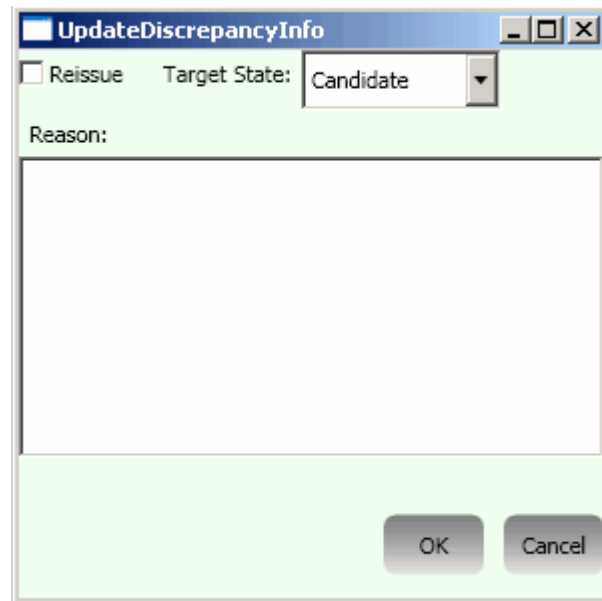
Alternatively, you can use the **Enter Guid** and **Revision** fields to update a specific discrepancy.

- 5 From the list of discrepancies, select a discrepancy GUID.

Information about the item and its discrepancy appears.

- 6 To make changes to the selected discrepancy, click **Add to Queue**.

The **UpdateDiscrepancyInfo** window appears.



- 7 Make the changes you want and provide a reason, then click **OK**.

The discrepancy appears in the **Discrepancies to Update** queue, listed by discrepancy GUID.

- 8 For discrepancies in the queue, you can:

- **Make additional changes to a discrepancy**—Double-click the discrepancy in the queue. The UpdateDiscrepancyInfo window reopens, where you can make your changes.
- **Remove a discrepancy from the queue**—Right-click the discrepancy in the queue and click **Remove Selected**.

- 9 To add more discrepancies to the queue, repeat steps 3 through 8.

- 10 To update all the discrepancies in the queue, click **Update**.

The Update response XML appears in a tab in the results pane, and the Discrepancies to Update queue becomes empty.

- 11 Repeat the procedure to update additional discrepancies. All the discrepancies in the queue are processed and appear in a new tab in the results pane.

Discrepancy reporting

You can generate a summary report, or specify a range of criteria to specify which discrepancies to include in the report.

- 1 Start the Discrepancy Sampler tool and connect to a study.

For more information, see *Connecting to a study* (on page 205).

- 2 Select the **Discrepancy Reporting** tab.

Each of the tabs on the Discrepancy Reporting page tab lets you specify a filter name and criteria for the filter.

Summary reporting

The Discrepancy Enhanced interface operation GetSummaryCounts allows you to specify multiple filters in a single request with different studies.

- 1 Select the **Summary Reporting** tab.

The screenshot shows the 'Discrepancy Sampler' application window. At the top, there are fields for 'Adapter Host' (localhost), 'Use Https' (checkbox), 'Virtual Directory' (InformAdapter), 'Get Trials' (button), 'Trial Name' (TESTTRIAL), 'Trial User' (System), 'Password' (*****), and 'Connect' (button). Below this is a tabbed interface with four tabs: 'Issue Discrepancy', 'Update Discrepancy', 'Discrepancy Reporting' (selected), and 'Examples'. Under the 'Discrepancy Reporting' tab, there are three sub-tabs: 'Summary Reporting' (selected), 'Detail By Criteria Reporting', and 'Detail By Guid Reporting'. The 'Summary Reporting' sub-tab contains a 'Trial' field with 'TESTTRIAL' entered, a 'Filter Name' field, and a 'Trial Criteria' section with 'Site ID', 'Subject Guid', 'Visit', 'Visit Name', and 'Visit Index' fields. There is an 'Add Filter To Request' button. Below these fields is a 'Current Summary Request' text area, a 'Clear Request' button, and a 'Get Summary Counts' button.

- 2 Fill in the fields.

Field	Description
Trial	The study name for which you want to generate summary reports of discrepancies. Required.
Filter Name	Name for the current request filter. Optional. The filter name can be used to decipher the response.

Field	Description
Trial Criteria	<p>Optional criteria on which to filter.</p> <ul style="list-style-type: none"> • Site ID, in the form of a DBUID. • Subject Guid. • Visit Name. • Visit Index. If you specify a visit index, you must also specify a visit name.

3 Click **Add Filter To Request**.

A SummaryFilter is added to the Current Summary Request field, which displays the SummaryRequest XML as you are building it.

You can add multiple filters to the request. In the response, a separate SummaryFilterRequest is returned for each filter, containing summary counts of discrepancies based on that filter.

4 When the request is complete, click **GetSummaryCounts**.

- The GetSummaryCounts response XML displays in the results pane in a single tab.
- The filters remain in the Current Summary Request field until you click **Clear Request**,
- You can repeat the procedure to get additional summary reports.

Detail by criteria reporting

1 Select the **Detail By Criteria Reporting** tab.

The screenshot shows the 'Discrepancy Sampler' application window. At the top, there are fields for 'Adapter Host' (localhost), 'Use Https' (unchecked), 'Virtual Directory' (InformAdapter), 'Get Trials' button, 'Trial Name' (TESTTRIAL), 'Trial User' (System), 'Password' (*****), and 'Connect' button. Below this is a tabbed interface with four tabs: 'Issue Discrepancy', 'Update Discrepancy', 'Discrepancy Reporting' (selected), and 'Examples'. Under 'Discrepancy Reporting', there are three sub-tabs: 'Summary Reporting', 'Detail By Criteria Reporting' (selected), and 'Detail By Guid Reporting'. The 'Detail By Criteria Reporting' sub-tab contains several sections:

- Request Level Parameters:** 'Bookmark' and 'Result Set Size' text boxes with an 'Add Parameters' button below them.
- Detail Filter Parameters:** 'Trial' (TESTTRIAL), 'Filter Name' text boxes, an 'Include History' checkbox, radio buttons for 'Trial Criteria' (selected) and 'Item Criteria', and 'Site ID' and 'Item Dbuid' text boxes. An 'Add Detail Filter' button is at the bottom right of this section.
- Current State List:** A list of checkboxes for 'Candidate', 'Opened', 'Answered', 'Closed', and 'Deleted'.
- Current Detail By Criteria Request:** A large empty text area.
- Buttons for 'Clear Request' and 'Get Discrepancies' are located at the bottom right of the main content area.

 At the bottom of the window, there is a large empty area, likely for displaying the results of the request.

2 In the **Request Level Parameters** section, optionally provide a **Bookmark** and/or a **Result Set Size** for the request.

Result Set Size indicates the maximum number of discrepancies to return in the response. If the maximum is reached and there are more discrepancies to return, the response will contain a bookmark. You can input this bookmark on a subsequent request that uses the same request parameters to get the remaining discrepancies.

For more information, see *Input parameters - GetByCriteria* (on page 31).

- 3 Click **Add Parameters**.

The parameters are added to the Current Detail by Criteria Request field.

- 4 In the **Detail Filter Parameters** section, provide the following information:

Parameter	Description
Trial	The study name for which you want detail by criteria reports of discrepancies. Required.
Filter Name	Name for the current request filter. Optional. The filter name can be used to decipher the response.
Include History	<ul style="list-style-type: none"> • Selected—All the revisions of the discrepancies are returned for this filter. • Unselected—Only the latest revisions of the discrepancies are returned.
Trial Criteria	If selected, you can provide a Site ID on which to filter the results.
Item Criteria	If selected, you can provide an Item Dbuid on which to filter the results.
Current State	Select one or more checkboxes to filter by the state of the discrepancy. If no boxes are checked, all states are returned. <ul style="list-style-type: none"> • Candidate. • Opened. • Answered. • Closed. • Deleted.

- 5 Click **Add Detail Filter**.

The Detail Filter is added to the Current Detail By Request field, which displays the DetailByCriteriaRequest XML as you are building it.

You can add multiple filters to the request.

- 6 When the request is complete, click **Get Discrepancies**.

The sampler calls the Discrepancy Enhanced interface GetDiscrepanciesByCriteria operation, and displays the response XML in the results pane.

Detail by GUID reporting

- 1 Select the **Detail By Guid Reporting** tab.

- 2 In the **Request Level Parameters** section, optionally provide a **Bookmark** and/or a **Result Set Size** for the request.

Result Set Size indicates the maximum number of discrepancies to return in the response. If the maximum is reached and there are more discrepancies to return, the response will contain a bookmark. You can input this bookmark on a subsequent request that uses the same request parameters to get the remaining discrepancies.

For more information, see *Input parameters—GetByDiscrepancyGuid* (on page 36).

- 3 Click **Add Parameters**.
The parameters are added to the Current Detail By Guid Request field.
- 4 In the **Detail Filter Parameters** section, provide the following information:

Parameter	Description
Trial	The study name for which you want detail by criteria reports of discrepancies. Required.
Filter Name	Name for the current request filter. Optional. The filter name can be used to decipher the response.
Discrepancy GUID	Specifies the discrepancy GUIDs to add to the Discrepancy GUIDs in this filter list. Each detail filter can have one or more discrepancy GUIDs.

- 5 Click **Add Detail Filter**.

The GetByDiscrepancyGuid request XML appears in the Current Detail By Guid Request field.

- 6 To add more filters, repeat steps 3 through 6.

- 7 When the request is complete, click **Get Discrepancies**.

The response XML appears in a tab in the results pane.

The request XML remains in the Current Detail By Guid Request field. To remove the XML, click **Clear Request**.

Examples tab

The **Examples** tab of the Discrepancy Sampler has examples of commonly used cases.

ODM Sampler tool

The ODM Sampler tool is a sample application that demonstrates how to use the ODM Export interface to download admin data, metadata, and patient forms, and to download transactions from the study filtered by site, subject, and form.

If you want to use Username authentication to access studies, you must set it up manually before you use the ODM Sampler tool. For more information, see *Adding WSE Username token support for the Sampler tools* (on page 222).

Download the Sampler tools

- 1 Log on to the Download Center at <https://extranet.phaseforward.com>.
- 2 Download and then extract the InForm AdapterSamples.zip file to the installation directory on the InForm Adapter server.

Both the Discrepancy Sampler and the ODM Sampler tools are extracted from the ZIP file.

Connecting to a study

The screenshot shows the ODM Sampler application window. It features several input fields and buttons for configuration. At the top, there are fields for 'Adapter Host' and 'Adapter Virtual Directory', with a 'Use Https' checkbox. Below these is a 'Connect' button and a 'Trial Name' dropdown. A 'Username Authentication' section includes an 'Enabled' checkbox, 'Trial User', and 'Trial Password' fields. Two expandable sections, 'ODM 2.0 Parameters' and 'AdminData Options', are visible. The main area is divided into three columns: 'Download Snapshot ODM', 'GetTransactions', and 'Filter Transactions'. Each column contains specific buttons like 'DownloadAdminData', 'DownloadMetaData', 'GetPatientForms', 'GetSiteList', and 'GetPatientList'. A 'DownloadPatientDataODM' button is located at the bottom right of the main area. At the very bottom, there are 'Enlarge' and 'Save To File' buttons, and a small dropdown menu.

- 1 To start the ODM Sampler tool, double-click the **OdmSampler.exe** file at the following location:

```
<installation_directory>\InformAdapterSamples\OdmSampler\bin
```
- 2 In the **Adapter Host** field, provide the name of the InForm Adapter server.
- 3 If you want to use https to connect to the server, select the checkbox.
- 4 In the **Adapter Virtual Directory** field, provide InForm Adapter virtual directory name.
- 5 If you are using Username authentication, select the **Enabled** checkbox, and fill in the **Trial User** and **Trial Password** fields.
- 6 Click **Connect**.

The studies you can access become available from the Trial Name field.

Note: The Trial Name field might appear blank. Click the arrow to display the list of available studies.

- 7 In the **Trial Name** field, select a study name.

Specifying input parameters

- 1 Expand the ODM 2.0 Parameters window.

- 2 Select the attributes you want to use, then collapse the window.

The table provides a brief description of each option. For more information, see the input parameters for each method in *ODM public Web methods* (on page 77).

Attribute	Description
Mapping Vers.	The version of the InForm-to-ODM mapping. Specify 2.0 for the most complete and accurate representation of the InForm data that is returned in ODM format
Compliance Mode	Specifies how to handle transactions in the study that are deleted and then undeleted.
File Type	The type of ODM file data that is to be returned.
Incl Extensions	Specifies whether to include Oracle ODM extensions in the data that is returned from the method.
PriorFileOID	Optional reference to the previous file (if one exists) in a series.
Request User Name	The user ID of the user who is requesting the data.

Calling ODM Export methods

After you connect to an InForm study, you can use the ODM sampler tool to issue a request for the ODM Export methods.

The response XML for each method appears at the bottom of the sampler window, in a separate tab labeled with the name of the study and the method. You can select a tab and enlarge the view, save the response to a file, or delete the response.

Downloading admin data, metadata, and patient data

- 1 Start the ODM Sampler tool and connect to a study.
For more information, see *Connecting to a study* (on page 216).
- 2 Select the **Download Snapshot ODM** tab. Follow the steps listed in the table for each method.

ODM Export method	Steps
DownloadAdminData	<ul style="list-style-type: none"> • Click DownloadAdminData. <p>In the results pane, response XML for DownloadAdminData appears in a separate tab.</p>
GetSiteList	<ul style="list-style-type: none"> • Click GetSiteList. <p>A list of site numbers and names appears, and in the results pane, response XML for GetSiteList appears in a separate tab.</p>
DownloadMetadata	<ul style="list-style-type: none"> • Click DownloadMetaData. <p>In the results pane, response XML for DownloadMetadata appears in a separate tab.</p>
GetPatientList	<ol style="list-style-type: none"> 1 Click GetSiteList. 2 Select a site. 3 Click GetPatientList. <p>A list of patient initials and numbers appears, and in the results pane, the response XML for GetPatientList appears in a separate tab.</p>
GetPatientForms	<ol style="list-style-type: none"> 1 Click GetSiteList. 2 Select a site. 3 Click GetPatientList. 4 Select a patient. 5 Click GetPatientForms. <p>A list of forms appears, and in the results pane, the response XML for GetPatientForms appears in a separate tab.</p>

ODM Export method	Steps
DownloadPatientDataODM	<ol style="list-style-type: none"> 1 Click GetSiteList. 2 Select a site. 3 Click GetPatientList. 4 Select a patient. 5 Click GetPatientForms. 6 Select a form from which to get data. 7 Click DownloadPatientDataODM. <p>In the results pane, the response XML for GetPatientForms appears in a separate tab.</p>

Get Transactions

- 1 Start the ODM Sampler tool and connect to a study.
For more information, see *Connecting to a study* (on page 216).
- 2 Click the **GetTransactions** tab.
- 3 Set the input parameters for the GetTransactions method. For more information, see Specifying input parameters.
- 4 The table describes the options for selecting Get All Transactions or Get Transactions Once, and how to use Polling.

Button or field	Description/Steps
Bookmark	<p>Indicates the point in the transaction log after which the processing should begin.</p> <p>This field is empty until the first time you click Get Transactions Once.</p> <p>After the first time you click Get Transactions Once, the bookmark field is populated by a bookmark for the last transaction that is returned by the GetTransactions method.</p> <p>For more information, see <i>Usage - Get Transactions</i> (on page 96).</p>
Get All Transactions	<ol style="list-style-type: none"> 1 Click Get All Transactions. 2 Specify a location for the returned transactions. <p>The GetTransactions method returns all transactions in the study, in files that contain 500 transactions each, named 1.xml, 2.xml, and so on.</p>

Button or field	Description/Steps
Get Transactions Once	<p>This button returns clinical data.</p> <ol style="list-style-type: none"> 1 Click Get Transactions Once. <p>The GetTransactions method returns 500 transactions and displays them in the results pane in a separate tab, named <trialname>-Transactions.</p> <p>A bookmark appears, indicating the last transaction that was returned.</p> 2 To return more transactions, click Get Transactions Once. <p>The method returns the next 500 transactions, beginning with the transaction after the bookmark, and displays them in a new tab that includes that bookmark in the tab name.</p> <p>A new bookmark appears in the bookmark field, indicating the last transaction that was returned.</p>
Polling Interval	<p>Used with Get All Transactions.</p> <ol style="list-style-type: none"> 1 You can set a polling interval after you use Get All Transactions, in either of the following situations <ul style="list-style-type: none"> ▪ After you click Get All Transactions, you must remain connected to the study (that is, do not choose a new study from the Trial Name field). The ODM Sampler tool remains open. <p>or</p> <ul style="list-style-type: none"> ▪ If you clicked Get All Transactions and then navigated to a different study, or closed the ODM Sampler, you must open the sampler again and connect to the study. On the GetTransactions tab, click Load Saved Transactions. 2 Select the polling interval and click Set. <p>Polling continues until you do any of the following actions:</p> <ul style="list-style-type: none"> ▪ Click Stop. ▪ Select a different study. ▪ Close the ODM Sampler.

Filter transactions

For a study, you can generate a list of transactions for sites, subjects, or forms.

Before you filter transactions, you must retrieve them.

- Use the **GetTransactions** tab to return transactions for the study. For more information, see *Get Transactions* (on page 219).

If you have closed the ODM Sampler or navigated to a different study since you retrieved transactions:

- 1 Open the sampler and connect to the study.
- 2 Click **Load Saved Transactions** and select the location where you saved the returned transaction files.

To filter transactions:

Transactions for	Steps
A Site	<ol style="list-style-type: none"> 1 Click GetSiteList. 2 Select a site from the list. 3 Click Show Site Transactions. <p>Transactions for the site appear in the results pane in a separate tab. The tab name includes the study name and the site name.</p>
A Subject	<ol style="list-style-type: none"> 1 Click GetSiteList. 2 Select a site from the list. 3 Click GetPatientList. 4 Select a subject. 5 Click Show Patient Transactions. <p>Transactions for the patient appear in the results pane in a separate tab, named with the study name and the patient initials.</p>
A Form	<ol style="list-style-type: none"> 1 Click GetSiteList. 2 Select a site from the list. 3 Click GetPatientList. 4 Select a subject. 5 Click GetPatientForms. 6 Select a form. 7 Click Show Form Transactions. <p>Transactions for the form appear in the results pane in a separate tab, named with the study name, patient initials, and form name.</p>

Adding WSE Username token support for the Samplers

Perform these procedures if you want to access studies with username password authentication when using the ODM Sampler tool and the features of the Discrepancy Sampler tool that use the ODM Export interface.

Microsoft WSE 2.0 SP3:

- Obtain the Microsoft WSE 2.0 SP3 software and install it on the InForm Adapter server.
This installs the Microsoft.Web.Services2.dll at: C:\Program Files\Microsoft WSE\v2.0\Microsoft.Web.Services2.dll .

For the ODM Sampler:

- 1 In the ODMSampler project, add a reference to the Microsoft.Web.Services2.dll assembly.
- 2 In <installation_directory>\InformAdapterSamples\OdmSampler\WebReferences\InFormODMWS, in the Reference.cs file:

At line 30, change the base class of InFormODM from:

```
System.Web.Services.Protocols.SoapHttpClientProtocol
```

to:

```
Microsoft.Web.Services2.WebServicesClientProtocol
```

The result looks like this:

```
public partial class InFormODM :
Microsoft.Web.Services2.WebServicesClientProtocol {
```

- 3 In the OdmWorkerV2.cs file, located at <installation_directory>\InformAdapterSamples\OdmSampler, do the following:

Uncomment lines 5 and 6:

```
using Microsoft.Web.Services2;
using Microsoft.Web.Services2.Security.Tokens;
```

Uncomment lines 55 through 68:

```
if (mainWindow.chkAuth.IsChecked.Value)
{
    if (string.IsNullOrEmpty(mainWindow.txtAuthUser.Text) ||
string.IsNullOrEmpty(mainWindow.txtAuthPswd.Password))
    {
        throw new Exception(MainWindow.NoUserOrPasswordSpecified);
    }

    SoapContext requestSoapContext = odmProxy.RequestSoapContext;

    UsernameToken usernameToken = new
UsernameToken(mainWindow.txtAuthUser.Text,
mainWindow.txtAuthPswd.Password, PasswordOption.SendPlainText);
requestSoapContext.Security.Tokens.Clear();
requestSoapContext.Security.Tokens.Add(usernameToken);
requestSoapContext.Security.Timestamp.TtlInSeconds = 60;
}
```

- 4 Recompile OdmSampler.

For the Discrepancy Sampler:

- 1 In the DiscrepancySampler project, add a reference to the Microsoft.Web.Services2.dll assembly.
- 2 In <installation_directory>\InformAdapterSamples\DiscrepancySampler\WebReferences\OdmWS, in the Reference.cs file:

At line 30, change the base class of InFormODM from:

```
System.Web.Services.Protocols.SoapHttpClientProtocol
```

to:

```
Microsoft.Web.Services2.WebServicesClientProtocol
```

The result looks like this:

```
public partial class InFormODM :
Microsoft.Web.Services2.WebServicesClientProtocol {
```

- 3 In the **OdmWorkerV2.cs** file, located at <installation_directory>\InformAdapterSamples\DiscrepancySampler, do the following.

Uncomment lines 10 and 11:

```
using Microsoft.Web.Services2;
using Microsoft.Web.Services2.Security.Tokens;
```

Uncomment lines 23 through 38:

```
if (string.IsNullOrEmpty(trialUser))
{
    throw new Exception(Properties.Resources.UserInputMessage);
}

if (string.IsNullOrEmpty(trialPassword))
{
    throw new Exception(Properties.Resources.PasswordInputMessage);
}

SoapContext requestSoapContext = odmProxy.RequestSoapContext;

UsernameToken usernameToken = new UsernameToken(trialUser,
trialPassword, PasswordOption.SendPlainText);
requestSoapContext.Security.Tokens.Clear();
requestSoapContext.Security.Tokens.Add(usernameToken);
requestSoapContext.Security.Timestamp.TtlInSeconds = 60;
```

- 4 Recompile DiscrepancySampler.
- 5 Set the ODM Web.config file to use InForm Authentication.

For more information, see the *Installation Guide*.

Source Code for Sampler tools

This release includes the source code for the Discrepancy Sampler tool and the ODM Sampler tool.

You can use Visual Studio 2008 to open the projects and view the code. This allows you to see how the sampler tool is constructing the requests and making the web service calls.

You can also modify the code.

The source code is accessible from the following locations:

- Discrepancy Sampler tool:
 <installation_directory>\InformAdapterSamples\DiscrepancySampler
- ODM Sampler tool:
 <installation_directory>\InformAdapterSamples\OdmSampler

The sampler tools are subject to the following:

Note: The sampler code is provided for your convenience to demonstrate how to use the ODM Transaction Export Interface and the Discrepancy Interface. You may use the sampler code in source form, for internal purposes only, as an aid in developing a web service interface for the discrepancy interface or ODM interface, respectively. The sampler code shall not be sublicensed, copied, or transferred in any manner. The sampler code and all accompanying documentation are provided to you "as is." without any representation that the sampler code will meet your requirements or that its use will be uninterrupted or error-free.

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