Oracle® Life Sciences InForm Sampler Guide for InForm Adapter





Oracle Life Sciences InForm Sampler Guide for InForm Adapter, 7.0.1

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Preface

This preface contains the following sections:

- Documentation accessibility
- · Diversity and Inclusion
- Related resources
- Access to Oracle Support
- Additional copyright information

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Contact our Oracle Customer Support Services team by logging requests in one of the following locations:

- English interface Customer Support Portal (https://hsgbu.custhelp.com/)
- Japanese interface Customer Support Portal (https://hsgbu-jp.custhelp.com/)

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Introduction to the Oracle Life Sciences InForm Adapter Sampler tools

In this section:

- What is the Oracle Life Sciences InForm Adapter feature?
 - The Oracle InForm Adapter feature provides interfaces to web services that support the secure transfer of data between Oracle InForm studies and either Oracle products (such as the Oracle Life Sciences Central Coding application) or third-party products and custom applications.
- The Oracle Life Sciences InForm Adapter interfaces
- Source Code for Sampler tools

You can use Visual Studio 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.

What is the Oracle Life Sciences InForm Adapter feature?

The Oracle InForm Adapter feature provides interfaces to web services that support the secure transfer of data between Oracle InForm studies and either Oracle products (such as the Oracle Life Sciences Central Coding application) or third-party products and custom applications.

Each application that can accept queries or updates to its data and metadata from Oracle InForm studies requires a specific set of interfaces.

Like application programming interfaces (APIs), the Oracle 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 Oracle Life Sciences InForm Adapter interfaces

The Oracle InForm Adapter feature for the Oracle InForm 7.0 release includes the following interfaces that are available for programmatic access:

Interface	Description
Discrepancy	Transmits Oracle InForm queries (discrepancies) to and from other systems or modules.
ODM Export	Provides access to receive Oracle InForm administrative data, clinical data, and metadata in CDISC ODM standard format.

Source Code for Sampler tools

You can use Visual Studio 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.

This guide, the sampler tools and application, and the source code are accessible from (https://support.oracle.com). Search for "Oracle Life Sciences InForm Adapter" and select the latest versions. Download the source code and unzip it to your personal computer at your choice of location. For example:

- Discrepancy Sampler tool: <unzip_directory>\InformAdapterSamples\DiscrepancySampler

The sampler tools are subject to the following:



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 sub-licensed, 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.



Discrepancy Sampler tool

In this section:

Overview: Discrepancy interface

The Discrepancy Sampler is a sample application that demonstrates how to use the Oracle Life Sciences InForm Adapter Discrepancy interface to issue and update discrepancies on an Oracle Life Sciences InForm study, and get summary details of discrepancies by using reporting functions.

Security configuration

By default, the Discrepancy Sampler tool uses secure configuration (HTTPS), which is the default for the Oracle Life Sciences InForm Adapter Discrepancy Service.

User name 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.

- Connecting to a study
- 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.

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.

Discrepancy reporting

You can generate a summary report, or specify a range of criteria to specify which discrepancies to include in the report.

Examples tab

Overview: Discrepancy interface

The Discrepancy Sampler is a sample application that demonstrates how to use the Oracle Life Sciences InForm Adapter Discrepancy interface to issue and update discrepancies on an Oracle Life Sciences InForm study, and get summary details of discrepancies by using reporting functions.

The Discrepancy interface sends discrepancies (clinical queries) and their resolutions between the Oracle 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 interface can determine whether the requested target of a discrepancy maps to another item, and issue the discrepancy against the mapped (target) item.

Security configuration

By default, the Discrepancy Sampler tool uses secure configuration (HTTPS), which is the default for the Oracle Life Sciences InForm Adapter Discrepancy Service.

If you set up a different security configuration for the Discrepancy Service, use the same configuration in the Discrepancy Sampler tool. For more information about configuring security for the Discrepancy Service, see the *Installation Guide*.

User name 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 User Name Password authentication to access studies with the Sampler tools, when you connect to the study, select the **Use Https** checkbox.

Connecting to a study

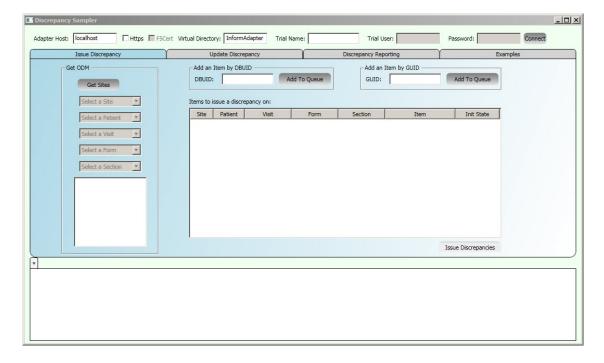


Figure 2-1 Discrepancy Sampler

 To start the Discrepancy Sampler tool, double-click the DiscrepancySampler.exe file at the following location:

<unzip_directory>\InformAdapterSamples\DiscrepancySampler\bin

2. In the **Adapter Host** field, provide the name of either the IP address or domain name where the resource is located. For example:

https://VanityUrl/pfst62/informadapter/ODM/ODMService.svc

- 3. If you want to use https to connect to the server, select the **Use Https** checkbox.
- **4.** Select **f5cert** if you want to use f5cert. The certificate must be installed on your local machine and you must provide the certificate subject in the application configuration file.

<add key="IACertName" value="the subject name of the certificate to
sign the soap message" />

5. In the Virtual Directory field, provide the path or directory on the server. For example: pfst62/informadapter

Note:

To use the discrepancy interface, you must create a user for your integration that belongs to a query group in InForm. This username will be stored in the InForm audit trail when creating a discrepancy.

- 6. If the Discrepancy Interface was installed using Secure or F5 mode for the Discrepancy interface, you must specify the user name and password of this user. If the Discrepancy Interface was installed using F5CERT mode, then only the user name needs to be entered. The password field can be left blank.
- 7. 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.
- 2. Select the Issue Discrepancy tab.
- Click Get Sites.
- 4. Select a site.
- 5. Select a subject.
- 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.

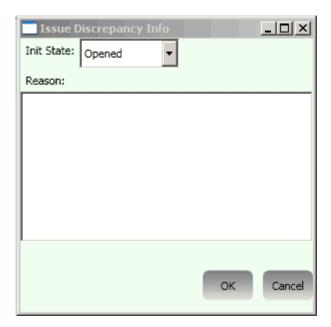
9. Double-click the item for which you want to issue a discrepancy.

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.



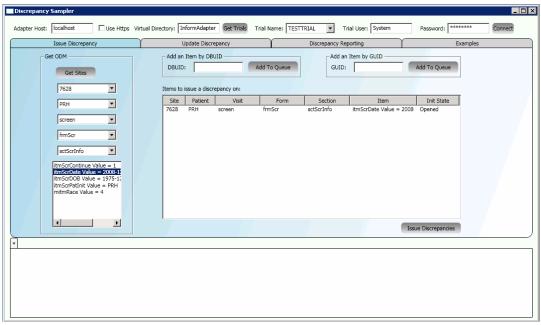
Figure 2-2 Issue Discrepancy Info



- **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.

Figure 2-3 Discrepancy Sampler - Issue added to 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:



Option	Description
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.

(Optional) Enter the result of the procedure here.

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.
- 2. Select the **Update Discrepancy** tab.

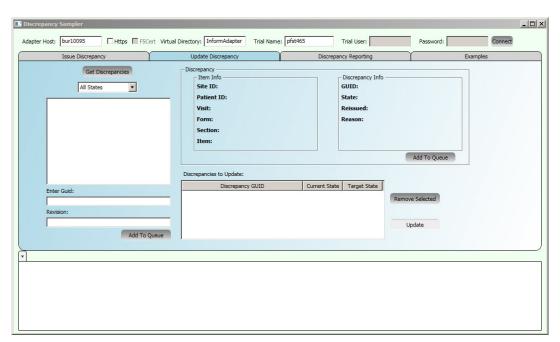


Figure 2-4 Update Discrepancy

- 3. From the list of states, select the state of discrepancies to display, or select All States.
- 4. Click Get Discrepancies.

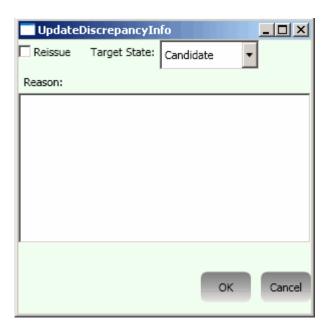
A list of discrepancies in the state you specified appears, listed by discrepancy GUID.



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.

Figure 2-5 UpdateDiscrepancyInfo window



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:

Option	Description
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.

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 interface operation GetSummaryCounts allows you to specify multiple filters in a single request with different studies.

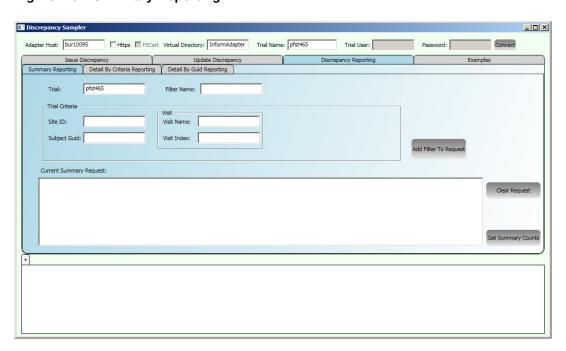
- Detail by criteria reporting
- Detail by GUID reporting

Summary reporting

The Discrepancy interface operation GetSummaryCounts allows you to specify multiple filters in a single request with different studies.

Select the Summary Reporting tab.

Figure 2-6 Summary Reporting



- 2. Fill in the fields:
 - Trial (Required) The study name for which you want to generate summary reports of discrepancies.
 - **Filter Name** (Optional) Name for the current request filter. The filter name can be used to decipher the response.



- Trial Criteria:
 - 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.

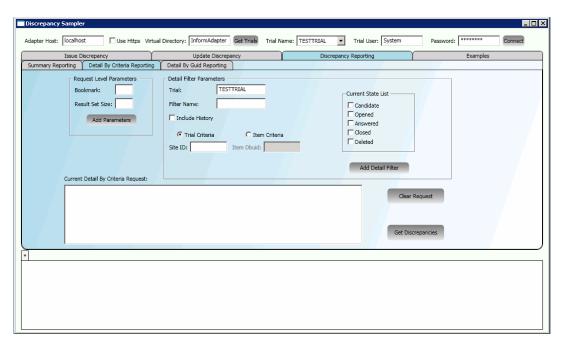


Figure 2-7 Detail By Criteria Reporting

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.



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:
 - Trial (Required) The study name for which you want detail by criteria reports of discrepancies.
 - **Filter Name** (Optional) Name for the current request filter. The filter name can be used to decipher the response.
 - Include History -
 - 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 avSite 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:
 - 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.

When the request is complete, click Get Discrepancies.

The sampler calls the Discrepancy interface GetDiscrepanciesByCriteria operation, and displays the response XML in the results pane.

Detail by GUID reporting

1. Select the **Detail By Guid Reporting** tab.



Figure 2-8 Detail By Guid Reporting

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.

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:
 - Trial (Required) The study name for which you want detail by criteria reports of discrepancies.
 - **Filter Name** (Optional) Name for the current request filter. 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.
- 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

In this section:

Overview: ODM Export interface

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.

- Connecting to a study
- Using the ODM Java Sampler tool

The ODM Java Sampler tool utility is an ODM Java Client with Object classes generated using ODM WSDL and XSD that you can use to write your own Client using Java language.

- Specifying input parameters
- Calling ODM Export methods

After you connect to an Oracle Life Sciences InForm study, you can use the ODM sampler tool to issue a request for the ODM Export methods.

- Downloading admin data, metadata, and patient data
- Get Transactions
- Filter transactions

For a study, you can generate a list of transactions for sites, subjects, or forms.

Overview: ODM Export interface

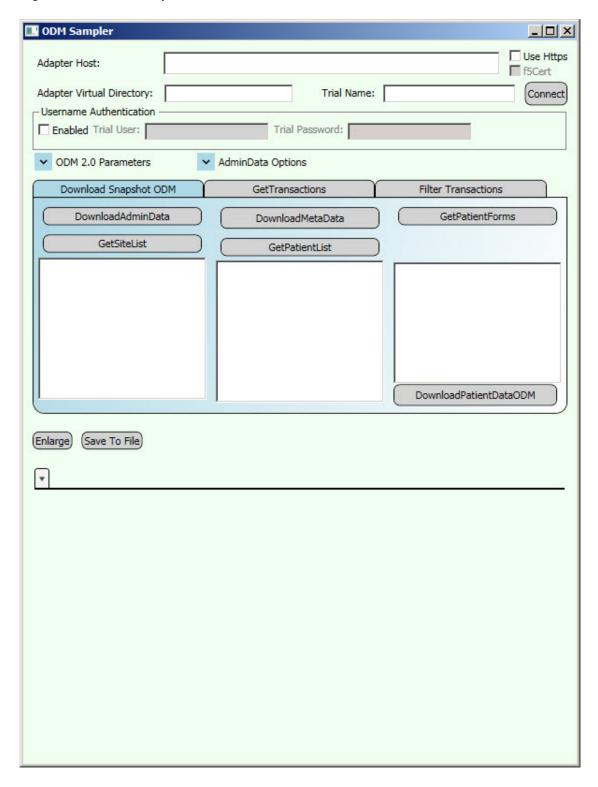
The ODM Sampler tool is a sample application that demonstrates how to use the ODM Export interface to download admin data, metadata, and patient forms, and to download transactions from the study filtered by site, subject, and form.

The ODM Export interface 1.3.0 is a unidirectional interface that provides a web service for any outside application that needs to retrieve data from an Oracle Life Sciences InForm database in CDISC ODM standard format. Clinical data, admin data, and metadata are available. Refer to http://www.cdisc.org for more information on the ODM standard.

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.

Connecting to a study

Figure 3-1 ODM Sampler





 To start the ODM Sampler tool, double-click the OdmSampler.exe file at the following location:

```
<unzip directory>\InformAdapterSamples\OdmSampler\bin
```

2. In the **Adapter Host** field, provide the name of either the IP address or domain name where the resource is located. For example:

```
https://VanityUrl/pfst62/informadapter/ODM/ODMService.svc
```

- 3. If you want to use https to connect to the server, select the **Use Https** checkbox.
- 4. Select **f5cert** if you want to use f5cert. The certificate must be installed on your local machine and you must provide the certificate subject in the application configuration file.

```
<add key="IACertName" value="the subject name of the certificate to
sign the soap message" />
```

5. In the Virtual Directory field, provide the path or directory on the server. For example:

```
pfst62/informadapter
```

- If you are using Username authentication, select the Enabled checkbox, and fill in the Trial User and Trial Password fields. Skip this step if you are using f5cert.
- 7. In the Trial Name field, enter the trial to connect to. For example: pfst62
- Click Connect.

Using the ODM Java Sampler tool

The ODM Java Sampler tool utility is an ODM Java Client with Object classes generated using ODM WSDL and XSD that you can use to write your own Client using Java language.

This utility provides:

- The ability to perform a call to single Oracle Life Sciences InForm Adapter method, for example, GetSiteList, using Certificate based Authentication. You can also use the utility as a reference to call other Oracle InForm Adapter methods using Java language.
- · A file for compilation (Build.bat) of this tool.

Usage

```
java -jar ODMJavaSampler.jar <Adapter_Host> <Virtual_Dir> <trial_Name>
<Certificate_JKS_FILE> <Cert_Alias> <Cert_Password> <Method Name>
```

Example

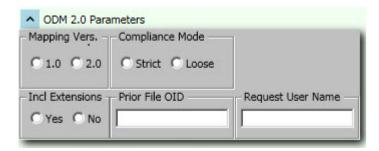
java -jar ODMJavaSampler.jar example.us.examplelink.com/qapfst InFormAdapter qapfst cert.jks te-a8192283-ac72-4b7a-b305-9b71fb3afbbe password GetSiteList

Specifying input parameters

Expand the ODM 2.0 Parameters window.



Figure 3-2 ODM 2.0 Parameters



2. Select the attributes you want to use, and then collapse the window.

The table provides a brief description of each option. For more information, see the input parameters for each method in the *Oracle Life Sciences InForm Adapter Interfaces Guide*.

Option	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. 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.
	Loose uses a FormStatus or ItemGroupStatus element with the attribute name of Deleted. Loose compliance mode is more efficient.
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.

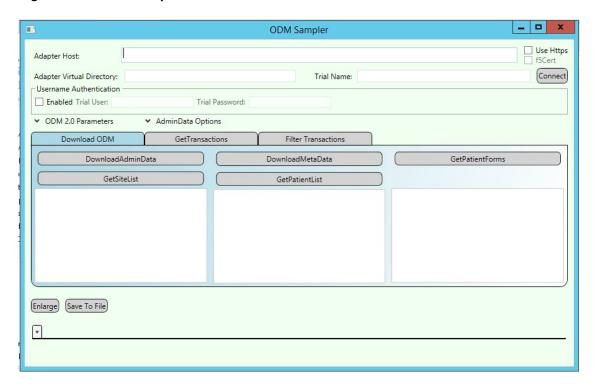
Calling ODM Export methods

After you connect to an Oracle Life Sciences 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.



Figure 3-3 ODM Sampler



Downloading admin data, metadata, and patient data

1.

2.

ODM Export method	Steps
DownloadAdminData	Click DownloadAdminData . In the results pane, response XML for DownloadAdminData appears in a separate tab.
GetSiteList	Click GetSiteList . A list of site numbers and names appears, and in the results pane, response XML for GetSiteList appears in a separate tab.
	Note: The calls using F5 with certificates are provided to prove that the calls to Oracle Life Sciences InForm Adapter are successful.
DownloadMetadata	Click DownloadMetadata . In the results pane, response XML for DownloadMetadata appears in a separate tab.



ODM Export method	Steps
GetPatientList	a. Click GetSiteList.
	b. Select a site.
	c. Click GetPatientList.
	A list of patient initials and numbers appears, and in the results pane, the response XML for GetPatientList appears in a separate tab.
GetPatientForms	a. Click GetSiteList.
	b. Select a site.
	c. Click GetPatientList.
	d. Select a patient.
	e. Click GetPatientForms.
	A list of forms appears, and in the results pane, the response XML for GetPatientForms appears in a separate tab.



This sample application does not handle transactions that don't satisfy the client-side filters, such as SV subject pool transactions.

Get Transactions

- 1. Start the ODM Sampler tool and connect to a study.
- 2. Click the **GetTransactions** tab.
- 3. Set the input parameters for the GetTransactions method.

The table describes the options for selecting Get All Transactions or Get Transactions Once, and how to use Polling.

Option	Description	
Bookmark	Indicates the point in the transaction log after which the processing should begin. This field is empty until the first time you click Get Transactions Once .	
	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.	
Get All Transactions	a. Click Get All Transactions.	
	 Specify a location for the returned transactions. 	



Option

Description

The GetTransactions method returns all transactions in the study, in files that contain 500 transactions each, named

1.xml, 2.xml, and so on.

This button returns clinical data.

a. Click Get Transactions Once.
 The GetTransactions method returns
 500 transactions and displays them in the results pane in a separate tab, named <trialname>-Transactions.

A bookmark appears, indicating the last transaction that was returned.

b. To return more transactions, click **Get Transactions Once**.

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.

A new bookmark appears in the bookmark field, indicating the last transaction that was returned.

Used with Get All Transactions. You can set a polling interval after you use Get All Transactions, in either of the following situations:

- 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. or
- 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.

Select the polling interval and click Set.

Polling continues until you do any of the following actions:

- Click Stop.
- Select a different study.
- Close the ODM Sampler.

Get Transactions Once

Polling Interval



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.

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.
- Click Load Saved Transactions and select the location where you saved the returned transaction files.

Transactions for:	Steps:
A Site	a. Click GetSiteList.
	b. Select a site from the list.
	c. Click Show Site Transactions. Transactions for the site appear in the results pane in a separate tab. The tab name includes the study name and the site name.
A Subject	a. Click GetSiteList.
	b. Select a site from the list.
	c. Click GetPatientList.
	d. Select a subject.
	e. Click Show Patient Transactions . Transactions for the patient appear in the results pane in a separate tab, named with the study name and the patient initials.
A Form	a. Click GetSiteList.
	b. Select a site from the list.
	c. Click GetPatientList.
	d. Select a subject.
	e. Click GetPatientForms.
	f. Select a form.
	g. Click Show Form Transactions. Transactions for the form appear in the results pane in a separate tab, named with the study name, patient initials, and form name.

