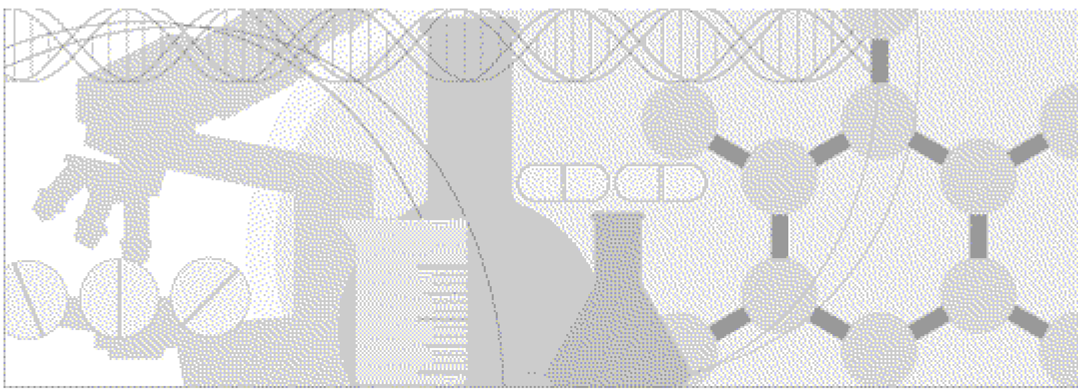
Sampler Guide

Oracle® Health Sciences InForm Adapter
Release 1.3.9



Part Number: E92702-01

Contents

CHAPTER 1

Introduction to the InForm Adapter Sampler tools

In this chapter

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 1.3.9 release includes the following interfaces that are available for programmatic access.

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

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.

This guide, the sampler tools and application, and the source code are accessible in patch 19144206 on My Oracle Support (https://support.oracle.com). Download the archive for this release and unzip it:

- Discrepancy Sampler tool:

  <unzip_directory>\InformAdapterSamples\DiscrepancySampler

- ODM Sampler tool:

  <unzip_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.**

CHAPTER 2

Discrepancy Sampler tool

In this chapter

Overview: Discrepancy interface

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

The Discrepancy 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 interface can determine whether the requested target of a discrepancy maps to another item, and issue the discrepancy against the mapped (target) item.

Prerequisites for the Discrepancy Sampler tool

Security configuration

By default, the Discrepancy Sampler tool uses secure configuration (HTTPS), which is the default for the 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*.

Username password authentication and the ODM Export interface

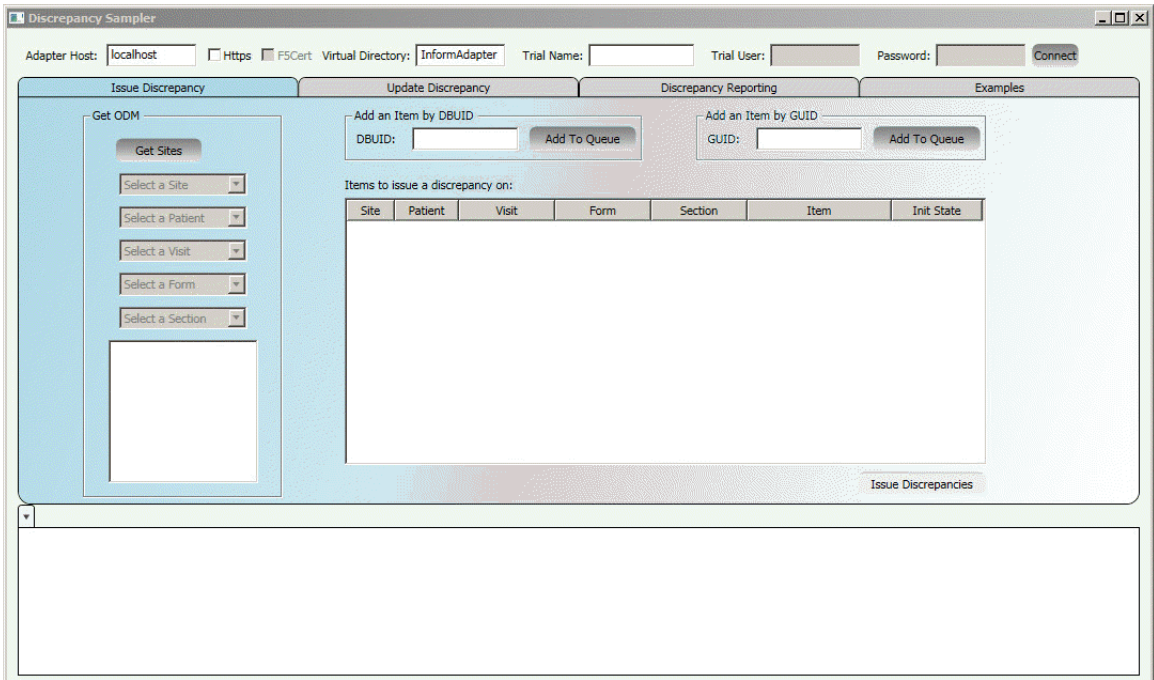
The Discrepancy Sampler uses the ODM Export interface to search the sites, patients, visits, forms, and section, and displays items that have values.

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 30).

Connecting to a study



1 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 either the domain name or the IP address where the resource is located. For example:

```
https://VanityUrl/pfst60/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:

```
pfst60/informadapter
```

6 In the **Trial Name** field, enter the trial name to connect to. For example:

```
pfst60
```

> **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.

7 If the Discrepancy Interface was installed using Secure or F5 mode for the Discrepancy interface, you must specify the username and password of this user.

8 If ODM Export WSE is installed, select the ODMWSE checkbox.

or

If the Discrepancy Interface was installed using F5CERT mode, then only the username needs to be entered. The password field can be left blank.

9 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 8).

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.

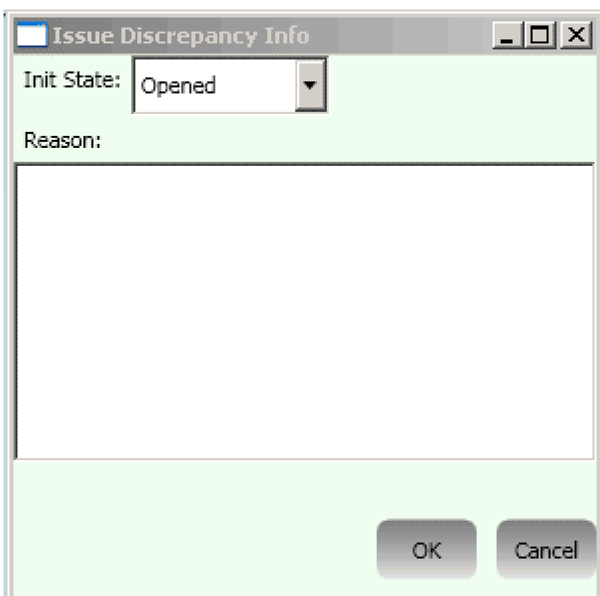
8 Select a section.

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**.

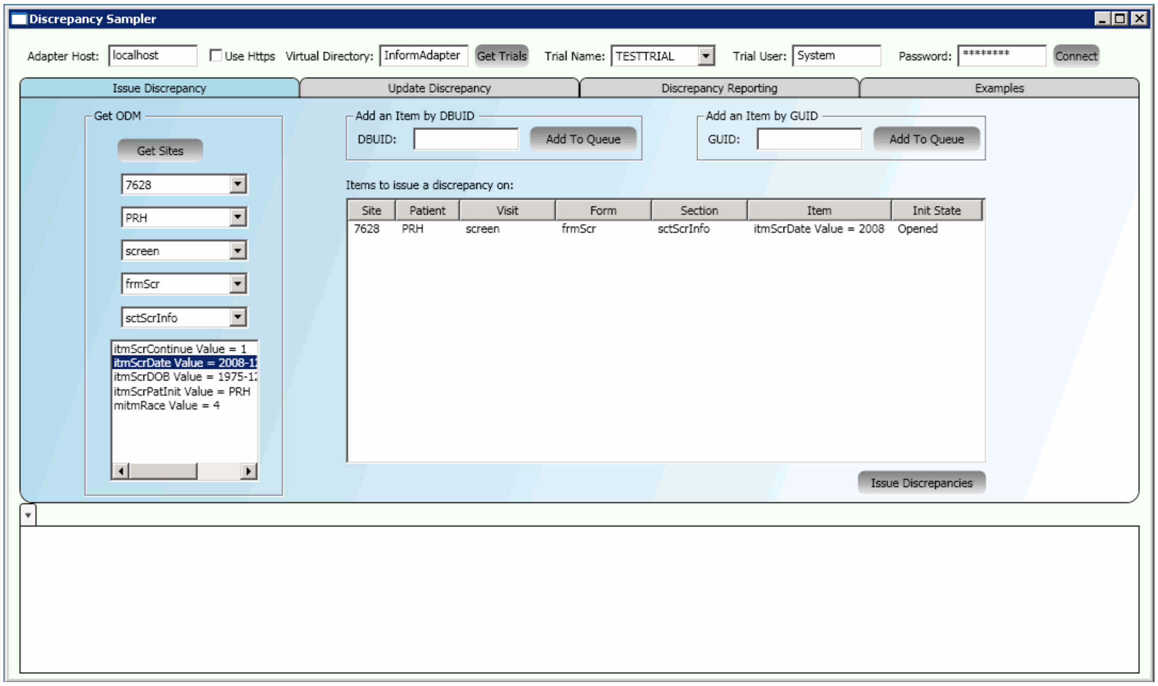
The **Issue Discrepancy Info** window appears.



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.

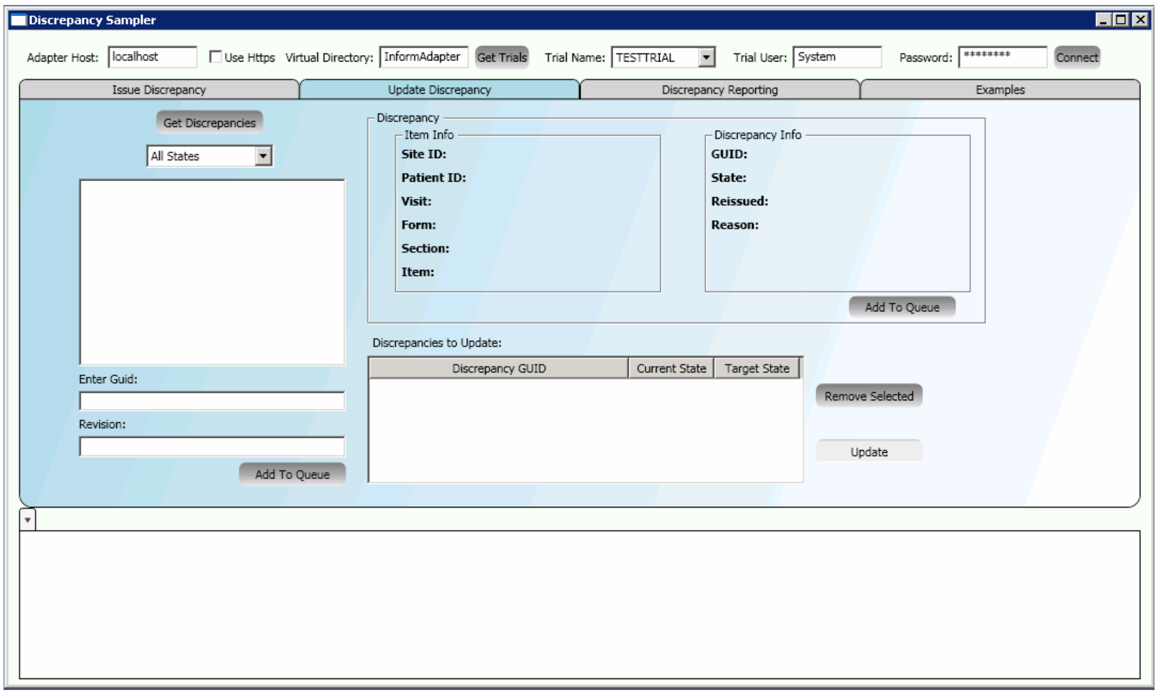
Updating a discrepancy

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 8).

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.

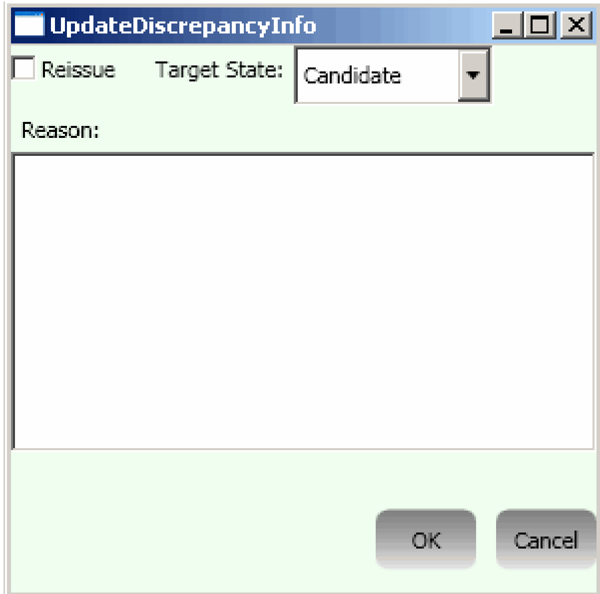
Alternatively, you can use the **Enter Guid** and **Revision** fields to update a specific discrepancy.

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 8).

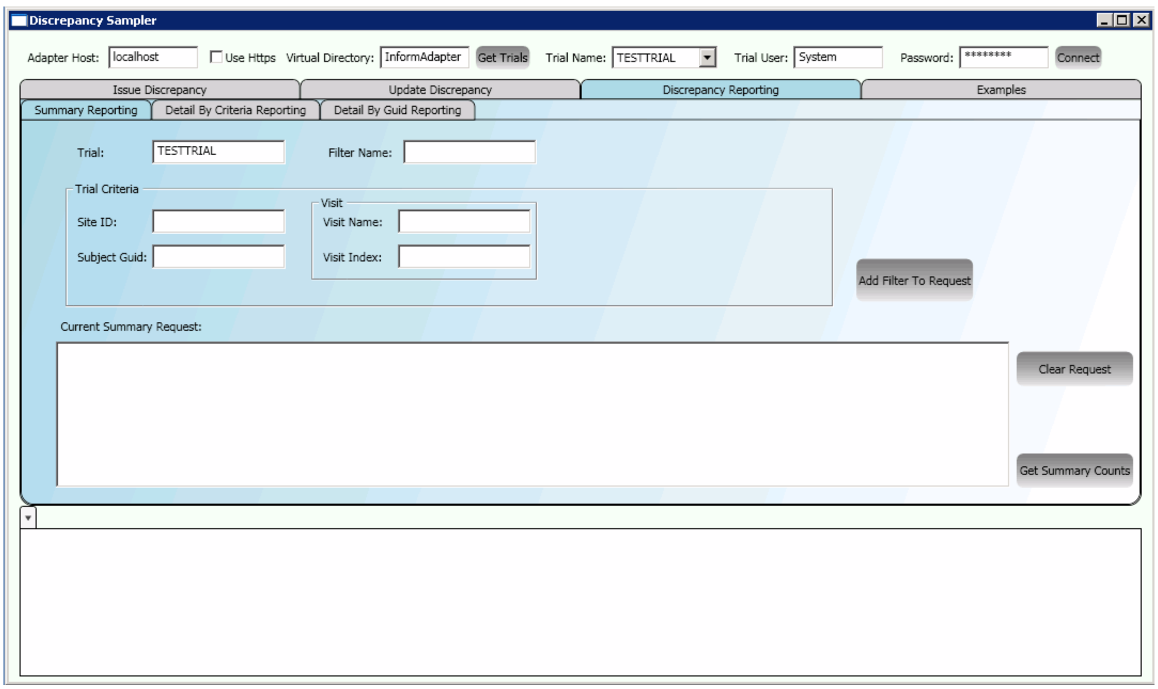
2 Select the **Discrepancy Reporting** tab.

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.



2 Fill in the fields.

Field	Description
Trial	The study name for which you want to generate summary reports of discrepancies. Required.

Field	Description
Filter Name	Name for the current request filter. Optional. The filter name can be used to decipher the response.
Trial Criteria	Optional criteria on which to filter. • **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.

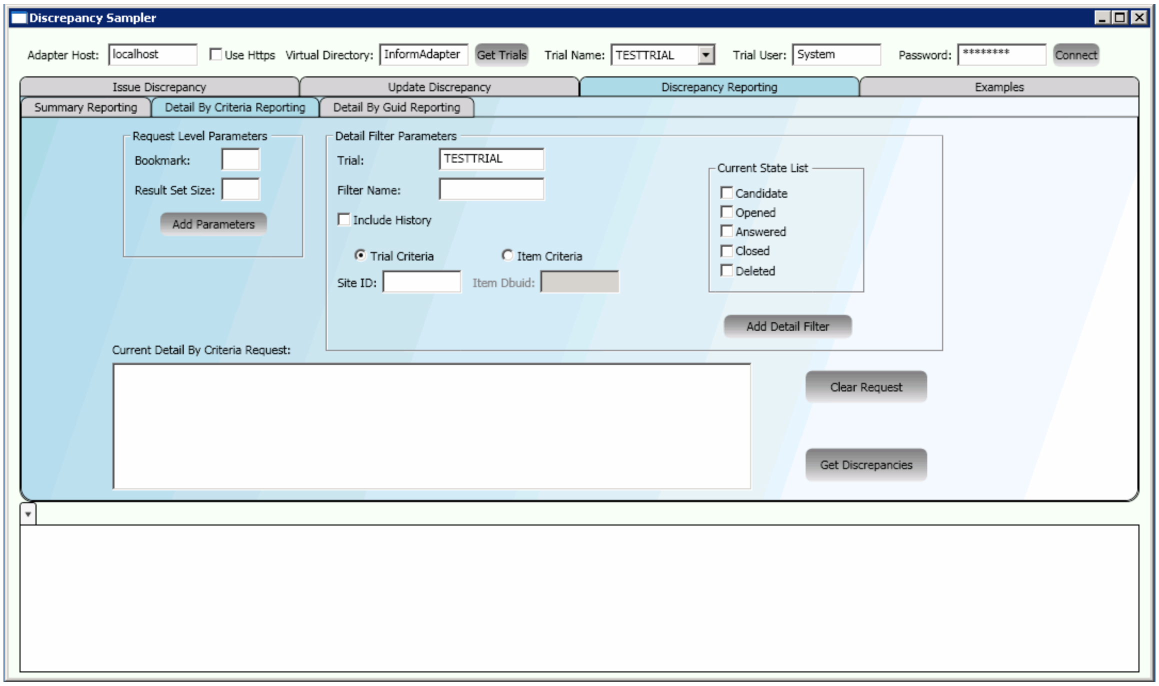
You can add multiple filters to the request. In the response, a separate SummaryFilterRequest is returned for each filter, containing summary counts of discrepancies based on that filter.

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.



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.

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	• 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.

Parameter	Description
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.

1 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.

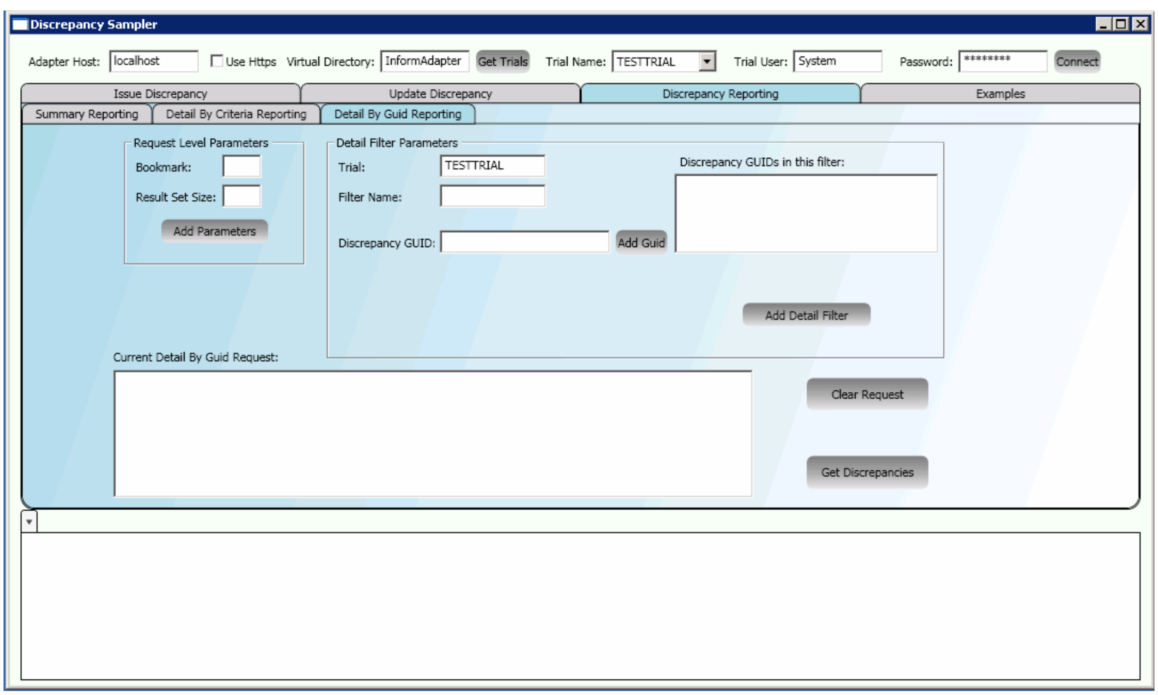
You can add multiple filters to the request.

2 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.

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.

1 Click **Add Detail Filter**.

The GetByDiscrepancyGuid request XML appears in the Current Detail By Guid Request field.

2 To add more filters, repeat steps 3 through 6.

3 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.

CHAPTER 3

ODM Sampler tool

In this chapter

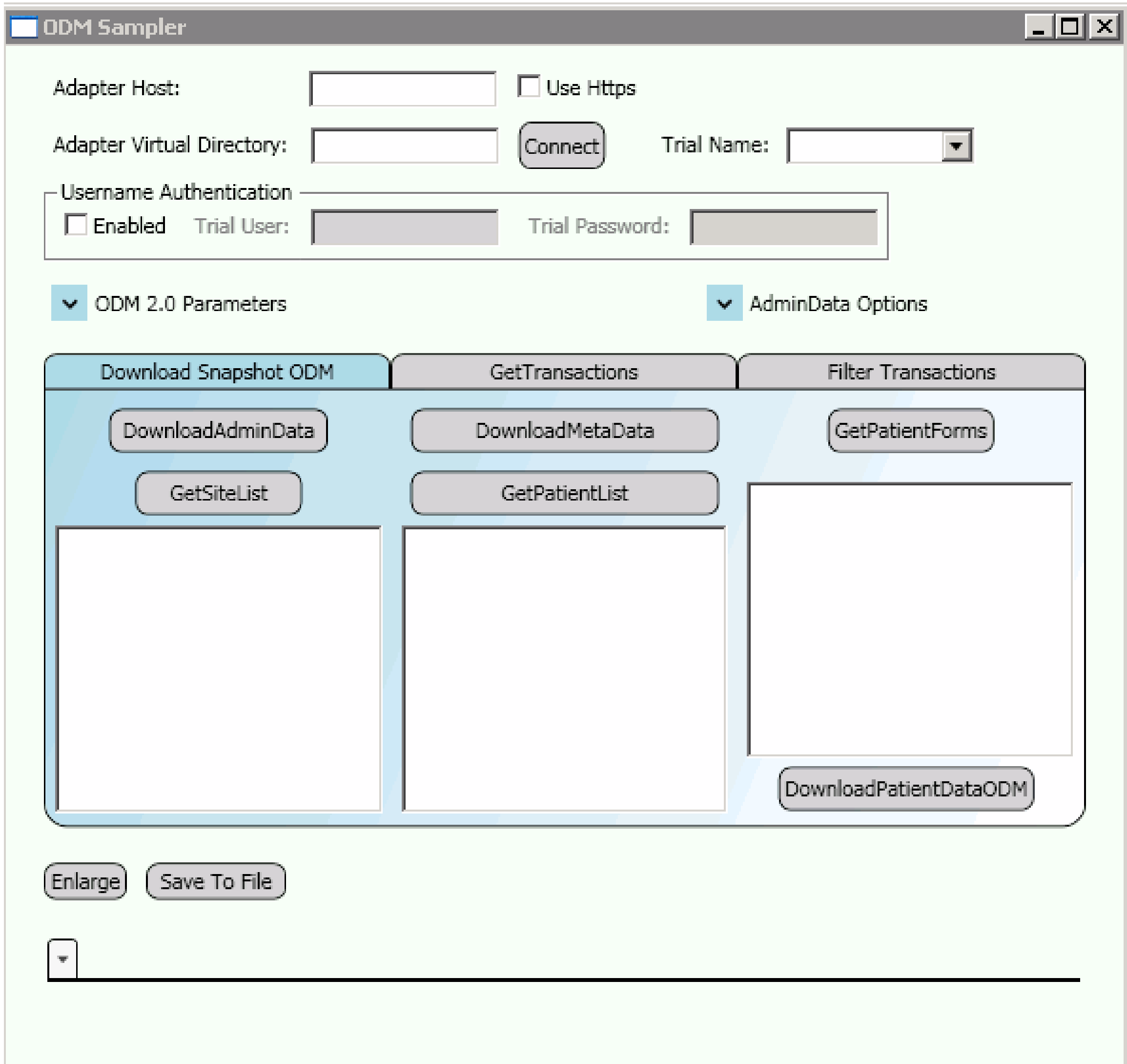
Overview: ODM Export interface

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 InForm database in CDISC ODM standard format. Clinical data, admin data, and metadata are available. Refer to ***http://www.cdisc.org 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



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.

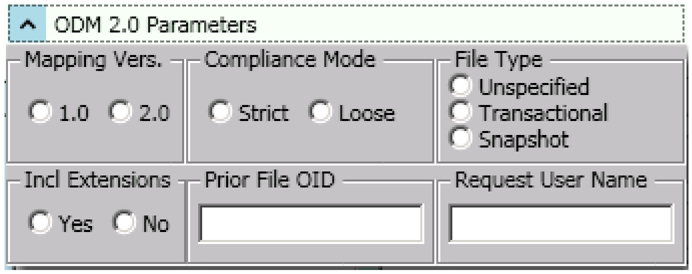
4 In the **Adapter Virtual Directory** field, provide InForm Adapter virtual directory name.

5 If you are using Username authentication, select the **Enabled** checkbox, and fill in the **Trial User** and **Trial Password** fields.

6 In the **Trial Name** field, enter 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 the InForm Adapter *Interfaces Guide*.

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 23).

2. Select the **Download Snapshot ODM** tab. Follow the steps listed in the table for each method.

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.
DownloadMetadata	• Click **DownloadMetaData.** In the results pane, response XML for DownloadMetadata appears in a separate tab.
GetPatientList	1 Click **GetSiteList.** 2 Select a site. 3 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	1 Click **GetSiteList**. 2 Select a site. 3 Click **GetPatientList**. 4 Select a patient. 5 Click **GetPatientForms**. A list of forms appears, and in the results pane, the response XML for GetPatienForms appears in a separate tab.

Note: 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.

For more information, see ***Connecting to a study*** (on page 23).

2 Click the **GetTransactions** tab.

3 Set the input parameters for the GetTransactions method.

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	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	1 Click **Get All Transactions**. 2 Specify a location for the returned transactions. The GetTransactions method returns all transactions in the study, in files that contain 500 transactions each, named 1.xml, 2.xml, and so on.
Get Transactions Once	This button returns clinical data. 1 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. 2 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.

<table>
<tr><th>Button or field</th><th>Description/Steps</th></tr>
<tr><td>Polling Interval</td><td>Used with Get All Transactions.

1 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.

2 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.</td></tr>
</table>

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 27).

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	1 Click **GetSiteList**. 2 Select a site from the list. 3 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	1 Click **GetSiteList**. 2 Select a site from the list. 3 Click **GetPatientList**. 4 Select a subject. 5 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	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**. Transactions for the form appear in the results pane in a separate tab, named with the study name, patient initials, and form name.

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 <unzip_directory>\InformAdapterSamples\OdmSampler\Web References\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 <unzip_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 <unzip_directory>\InformAdapterSamples\DiscrepancySampler\Web References\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 **OdmWorker.cs** file, located at <unzip_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*.

About the documentation

Where to find the product documentation

The product documentation is available from the following locations:

- My Oracle Support (https://support.oracle.com)—Release Notes and Known Issues.
- Oracle Help Center (https://docs.oracle.com)—The most current documentation set.

Documentation accessibility

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

Access to Oracle Support

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