

Oracle® Life Sciences InForm

Configuration guide for Standard File-Based Integration



Release 7.0.1.1
G25125-02
June 2025

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About this guide

This guide provides instructions to configure the Standard File-Based Integration (SFBI, formerly known as IVRS) for Oracle InForm.



Note:

Though the integration is officially known as SFBI, some user interface elements in the Oracle InForm application might still use the IVRS legacy name.

2

Configure rights and rights groups

Users

When the following users and rights groups are present in Oracle InForm, the application installation process assigns the following default SFBI rights:

User	Default associated rights
sollVRS<study name><Vendor> system	None. • Log Viewer • Email Config • App Config • App Admin

 **Note:**
System users are deactivated in live studies.

Rights groups

Rights Group	Default associated rights
sollVRS<study name><Vendor> (or any rights group assigned prior to installation) PF View Only	None. • Log Viewer • Error Recovery • App Config • Email Config
View Only	• Log Viewer
sollAdmin	• Log Viewer • Error Recovery • Email Config • App Config • App Admin
User Activator RG	• App Admin
User Manager RG	• App Admin

- [Assign rights to users](#)
- [Assign rights to right groups](#)

Assign rights to users

1. Log in to Oracle InForm.
2. Go to **IVRS-<Vendor>**.
3. Go to **Application Administration**.

4. Under the **User Access** tab, assign the desired rights to the users listed in the first column by selecting or deselecting the appropriate right check box.

Assign rights to right groups

1. Log in to Oracle InForm.
2. Go to **IVRS-<Vendor>**.
3. Go to **Application Administration**.
4. Under the **Rights Group Access** tab, assign the desired rights to the users listed in the first column by selecting or deselecting the appropriate right check box.

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Enable the Inbound module

The Inbound module is not enabled by default after the initial Oracle InForm installation. To enable the Inbound module:

1. Log in to Oracle InForm.
2. Go to **IVRS-<Vendor>**.
3. Go to **Application Configuration**.
4. Under **Trial Information**, select the **Enable Inbound Module** check box.
5. In the **Zip File Threshold Limit** field, enter the file size limit before converting them to zip files. The default value is 10 kb.
6. In the **SFTP Downtime Interval (in minutes)** field, enter the desired interval to receive error reports when the sFTP is down. The default value is 15.

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Configure the study import process flow

The SFBI module study data import process must be set up to provide a clear pathway for study data to be imported into Oracle InForm.

At minimum, the SFBI module requires valid values to be populated for **Import User Password**, **Inbound Path**, and **Time Interval between consecutive PFIImport runs** to perform successful study data imports.

To set up the study import process flow:

- [Synchronize the password for the import user](#)
- [Set up sFTP username and password](#)
- [Configure pre-processors](#)
- [Configure email preferences](#)

Synchronize the password for the import user

You must perform the **Reset Password** operation after the initial Oracle InForm installation to synchronize the password for the import user. This is required for both native and SSO authentication modes.

In native authentication mode, the SFBI module will reset the password automatically after clicking on the **Reset Password** link.

In SSO authentication mode, the SFBI module will attempt to reset the password automatically when clicking the **Reset Password** link. If it fails, the tenant administrator credentials are required to continue.

To reset the password:

1. Log in to Oracle InForm.
2. Go to **IVRS-<Vendor>**.
3. Go to **Application Configuration**.
4. Under **Inbound Settings**, go to **Import User Password** and click **Reset Password**.

Set up sFTP username and password



Note:

When using a local path for the inbound process flow, the username and password are not needed. The SFBI module will then require overriding the default file monitoring mechanism in the configuration file. This also requires prior OCI approval and the SFBI windows service to be restarted.

1. Log in to Oracle InForm.

2. Go to **IVRS-<Vendor>**.
3. Go to **Application Configuration**.
4. Under **Inbound Settings**, go to **Inbound sFTP Username** and enter a valid user name.
5. Go to **Inbound sFTP Password** and enter the password for the user.

Configure pre-processors

In this section:

- [Pre-processors overview](#)
- [Pre-processor descriptions](#)
- [Customize pre-processors](#)

Pre-processors overview

The SFBI module includes pre-processors for incoming files. This functionality is **only available** for unzipped PATIENTDATA and EDITPATIENTDATA MedML and DAT files. All other files are imported without pre-processing.

The SFBI pre-processors:

- Validate incoming files.
- Import data into locked and frozen forms.
- Import data into forms where a form-level reason incomplete comment (pre-defined comment) is attached.
- Import data for items where an item-level reason incomplete comment (pre-defined comment) is attached. This functionality is added as part of the FormComment pre-processor.
- Eliminate duplicate records, records with incorrect number of data points, and records with empty key fields or match fields.

Pre-processor descriptions

The SFBI module includes the following pre-processors:

Pre-processor	Description
FormComment	Changes the MedML tag in the item based on item state and removes any current pre-defined comment, if any, to allow data import.
FormFrozen	Allows data import to frozen forms.
FormLocked	Allows data import to locked forms.
DataConstraintChecker	Validate the .DAT file and splits the data in manageable chunks prior to importing.

Customize pre-processors

You can add and customize new pre-processors for the SFBI module. These custom pre-processors should be tested completely and appropriate approval process should be completed before deploying them in production.

To add and customize new pre-processors:

1. Create a new .NET 4.6.2 class library project.
2. Copy the following DLLs from the SFBI deployment package and add a reference to the .NET project created in the previous step:
 - PhaseForward.ServicesSolutions.IIE.PreProcessors
 - PhaseForward.ServicesSolutions.IIE.Utilities
 - PhaseForward.ServicesSolutions.InFormImportExport
3. Create a new class that implements the "IPreProcessor" interface or inherits from the "PreProcessorBase" class.

In the following example, the new class name is "MyCustomPreProc".

```
using System;
using System.Collections.Generic;
using System.Linq;
using System.Text;

namespace PhaseForward.ServicesSolutions.InFormImportExport
{
    public class MyCustomPreProc : PreProcessorBase
    {
        public MyCustomPreProc(string name, string rootFolder) :
        base(name) { }

        public override MyCustomPreProc Process(PreProcessorParams
        preProcParams)
        {
            //Set mandatory properties using method from base class
            SetupProcessing(preProcParams);
            //curParams.FileType = File Type
            //curParams.InboundFile = Full File Path
            //curParams.InboundFileName = File Name
            //curParams.InboundFileExtension = File Extension
            //curParams.MedMLPatientData = MedML datastructure
            return curParams;
        }
    }
}
```

4. Copy the compiled DLL file to <Installed Path>\IvrsIntegration\bin directory.
5. Update the ObjectFactory configuration file located in <Installed Path>\IvrsIntegration\bin directory as follows:

```
<object type=" MyCustomPreProc"
class="PhaseForward.ServicesSolutions.InFormImportExport. MyCustomPreProc"
assembly=" PhaseForward.ServicesSolutions.IIE.Preprocessors"/>
```

6. Add the pre-processor to the configuration file in <Installed Path>\IvrsIntegration\<VendorName>\<ConfigName>\Configuration as follows:

```
<PreProcessors>
  <PreProcessor Name="Dispatcher" />
```

```

    <PreProcessor Name="FormFrozen" />
    <PreProcessor Name="FormLocked" />
    <PreProcessor Name="FormComment" />
    <PreProcessor Name="DataConstraintChecker" />
    <PreProcessor Name="MyCustomPreProc" />
    <PreProcessor Name="FileGenerator" />
  </PreProcessors>

```

7. Restart the SFBI windows service and application pool.

Note:

: If the newly added pre-processor is still not visible, add the pre-processor to the configuration file (Inform_IVRS_<trial>_<VendorName>_<ConfigName>.config) in <Installed Path>\IvrsIntegration\<Website> as follows:

```

<PreProcessors>
  <PreProcessor Name="Dispatcher" />
  <PreProcessor Name="FormFrozen" />
  <PreProcessor Name="FormLocked" />
  <PreProcessor Name="FormComment" />
  <PreProcessor Name="DataConstraintChecker" />
  <PreProcessor Name="MyCustomPreProc" />
  <PreProcessor Name="FileGenerator" />
</PreProcessors>

```

Configure email preferences

Email recipients, subject and content can be configured for each email type.

To configure email preferences:

1. Log in to Oracle InForm.
2. Go to **IVRS-<Vendor>**.
3. Go to **Application Configuration**.
4. Under **E-mail Settings**, select **Enable Sending Emails**.
5. In **SMTP Server**, enter a valid SMTP server name.
6. Under **IVRS-<Vendor>**, go to **Email Configuration** and modify the desired parameters.
 - [Success email settings](#)
 - [Configuration email settings](#)
 - [Application emails settings](#)
 - [Import emails settings](#)

Success email settings

Category "Success" emails are sent when data file is imported successfully.

**Note:**

Oracle recommends that “Success” emails are sent to Sponsor users only.

Success email settings	Description
Send Mail for Messages	Enables or disables the sending of Success emails.
Mail From	Determines the sender email address.
Mail To	Determines the recipient email address.
Mail CC	Determines additional email recipients. Must be separated by comma.
Mail Subject (Solution name, Trial Name and Vendor name will be appended to the configured value)	Determines the email subject line for the emails.
Message Body for Success Error(s) (Tokens: {TRIAL}, {VENDOR})	Determines the main body for the emails.

Configuration email settings

Category “Configuration” emails are sent when an error occurs due to application configuration or email configuration errors.

**Note:**

Oracle recommends that “Configuration” emails are sent to Oracle users only.

Configuration email settings	Description
Send Mail for Messages	Enables or disables the sending of Configuration emails.
Mail From	Determines the sender email address.
Mail To	Determines the recipient email address.
Mail CC	Determines additional email recipients. Must be separated by comma.
Mail Subject (Solution name, Trial Name and Vendor name will be appended to the configured value)	Determines the email subject line for the emails.
Message Body for Success Error(s) (Tokens: {TRIAL}, {VENDOR})	Determines the main body for the emails.

Application emails settings

Category “Application” emails are sent when an error is caused by the SFBI module.

**Note:**

Oracle recommends that “Application” emails are sent to Oracle users only.

Applicaition email settings	Description
Send Mail for Messages	Enables or disables the sending of Application emails.
Mail From	Determines the sender email address.
Mail To	Determines the recipient email address.
Mail CC	Determines additional email recipients. Must be separated by comma.
Mail Subject (Solution name, Trial Name and Vendor name will be appended to the configured value)	Determines the email subject line for the emails.
Message Body for Success Error(s) (Tokens: {TRIAL}, {VENDOR})	Determines the main body for the emails.

Import emails settings

Category “Application” emails are sent when pre-processing of import data or importing data results into an error.

**Note:**

Oracle recommends that “Application” emails are sent to sponsor users only.

Import email settings	Description
Send Mail for Messages	Enables or disables the sending of Import emails.
Mail From	Determines the sender email address.
Mail To	Determines the recipient email address.
Mail CC	Determines additional email recipients. Must be separated by comma.
Mail Subject (Solution name, Trial Name and Vendor name will be appended to the configured value)	Determines the email subject line for the emails.
Message Body for Success Error(s) (Tokens: {TRIAL}, {VENDOR})	Determines the main body for the emails.