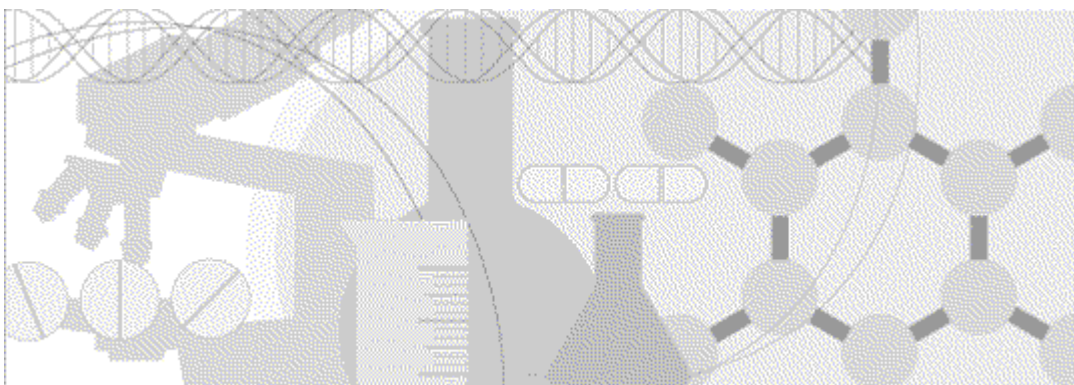


Installation Guide

Oracle[®] Health Sciences InForm Publisher
Release 2.1.1



ORACLE[®]

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CHAPTER 1

Installing the InForm Publisher software

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About the InForm Publisher software

The InForm Publisher software publishes data from InForm studies that can be imported to a target application.

The data is published from a transaction queue, on a configurable schedule.

To use the InForm Publisher software with an InForm study, you must:

- 1 Install the InForm Publisher software on the InForm application server.
- 2 Configure the software to work with the study and the target application.

About the InForm Publisher application publishing options

InForm Publisher offers two publishing options, the Argus Safety Publisher and the ODM Extract Publisher:

- The Argus Safety Publisher can publish data from InForm studies to web service endpoints.
- The ODM Extract Publisher can publish data to web service, local directory, FTP, or CTMS endpoints.

Argus Safety Publisher

The Argus Safety Publisher sends the message about the serious adverse event to a web service that transforms the message to E2B+.

ODM Extract Publisher

If configured for ODM Extract, the InForm Publisher application provides a way for customers to define events of interest and select the output format for publishing data from InForm studies. Transactions are based on study events (for example, data added to a subject's study data or changes in subject status). The ODM Extract event output is the ODM Snapshot XML format. The InForm Publisher application can publish the XML to web service, local directory, FTP, or CTMS endpoints.

ODM Extract data can serve as input for applications that require InForm data or status as needed by the requirements of the customer receiving application. This data can be sent to a variety of customer applications, including metric reporting, clinical coding, clinical repositories, IRT, and CTMS.

System requirements

Install the InForm Publisher software on the InForm application server. Its hardware and software requirements are identical to those for the InForm application server.

In addition, the InForm Publisher software requires the following:

- ODP.Net version 2.102.3.3 or later.
- Microsoft Framework .NET version 4.0, 4.5.2, or 4.6.

Installing a certificate for the InForm Publisher software

If the endpoint that the InForm Publisher application calls to update data to the subscriber destination requires a client certificate, you must set up a client certificate for the InForm Publisher Service to call the endpoint.

This is performed through the Certificates MMC snap-in in Microsoft Windows. Because the InForm Publisher Service runs as the local service user, you must add the certificate to the certificate store for the local computer for the InForm Publisher Service.

Installing the InForm Publisher software with the installer wizard

Install the InForm Publisher software on the InForm application server after installing the InForm software.

Note: Before installing the InForm Publisher software, run the InForm Publisher database script on the database server to set up the InForm Publisher application account. This step is recommended to ensure the system administrator password is not exposed at the InForm Publisher application level.

To install the InForm Publisher software:

- 1 Download the InForm Publisher software and extract the ISO image.
- 2 In the InForm Publisher directory in the ISO, go to the Custom Event SQL directory.
- 3 Run the CreateIPUser.sql script.

Note: The script needs to be run by a database user that has the rights to create users.

The script prompts you for the user name and password. The user name is used to grant the trial schema user privileges to queues read by the InForm Publisher application (Queueing Privilege Grantor user).

- 4 Navigate to the location of the InForm Publisher installation files on the downloaded ISO image, and double-click **setup.exe**.

The Welcome page appears.

- 5 Click **Next**.

The Required System Components page lists the components and version numbers and indicates if any required components are missing.

- 6 If all required components are present, click **Next**.

or

If not all components are present, click **Next** and **Finish** on the next page to exit the InForm Publisher installation. In this case:

- a Install the missing components on the server.
- b Restart the InForm Publisher installation, go through the steps above, and click **Next**.

Note: If the installation of the InForm core software was successful, all required components should be present.

The Choose Destination Location page appears.

- 7 Accept the default location, or click **Change**, and browse to a desired location.
- 8 Click **Next**.

The User Rights Assignment page appears.

- 9 Click **Next**.

The installer grants the InForm Publisher application the right to log on to Windows as a service. The Ready to Install the Program page appears.

10 Click **Install**.

The installer copies the files to the location specified on the Choose Destination Location page and then displays the Database Configuration page. This page lists the connection string to the InForm database instance.

11 Select the **TNS Alias Name** from the drop-down list.

12 To use a Queuing Privilege Grantor user account created by the script on the database server, select the **Skip Account Creation** checkbox.

- In the **InForm Publisher Database User Account** field, enter the credentials used to grant privileges to the trial user to access queues read by the InForm Publisher application (Queuing Privilege Grantor user credentials).
- Click **Test Connection**.
 - If a green check appears, the connection is valid.
 - If a red X appears, the connection is invalid.

If the connection is invalid, delete and re-enter the Queuing Privilege Grantor user account credentials, and click **Test Connection**.

or

To create a new InForm Publisher database account, leave the **Skip Account Creation** checkbox unchecked.

- In the **InForm Publisher Database User Account** field, enter a new user name and password for the Queuing Privilege Grantor user.
- In the **Oracle account with creation privileges** field, enter the name of an Oracle system user account that can create new Oracle user accounts.

This user is used to create the Queuing Privilege Grantor user, which is an Oracle account that grants privileges to the trial schema user.

- In the **Password** field, enter the password for the Oracle account for creating users.

Note: If the InForm application is configured to use multiple database servers, the installer detects each one and prompts you to specify a Queuing Privilege Grantor user and its password for each database instance.

- Click **Test Connection**.
 - If a green check appears, the connection is valid.
 - If a red X appears, the connection is invalid.

If the connection is invalid, delete and re-enter the Oracle system user account credentials, and click **Test Connection**.

13 Click **Next**.

When the installation is complete, the InstallShield Wizard Complete page appears.

14 To launch the InForm Publisher configuration tool to configure the application, select **Launch the Publisher configuration tool**. By default, this checkbox is selected.

For more information about using the Publisher configuration tool, see *Configuring the InForm Publisher application using the Publisher configuration tool* (on page 37).

- 15 Click **Finish**.

Installing the InForm Publisher software with the unattended installation option

Install the InForm Publisher software on the InForm application server after installing the InForm software.

- 1 In the folder where you extracted the InForm Publisher installation files, edit the installation variables in the setup.iss file. For more information, see **setup.iss file variables** (on page 9).
- 2 Run the SilentInstallInFormPublisher.bat file. The SilentInstallInFormPublisher.bat file is also located in the folder where you extracted the InForm Publisher installation files.

Note: The unattended installation option supports installing on only one InForm database per installation.

setup.iss file variables

Note: If you select the options that do not configure the InForm Publisher software to publish to any studies, you must add the studies manually after completing the installation. For more information, see **Configuring the InForm Publisher application** (on page 15).

Variable	Description
szDir	Path name to the InForm Publisher software installation location.
Sel-0	Not supported.
Sel-1	Not supported.
TNS_Name	TNS alias of the instance containing the InForm studies that are to be published to the target application.
SystemUserName	Name of an Oracle system user account that can grant privileges to the Oracle user accounts for the InForm studies (for example, system). Note: The system user name and password are not needed if you ran the script on the database before running the unattended installation.
SystemPassword	Password for the privilege-granting Oracle account.
PublisherUserName	Name of the user who has the rights to grant privileges to the queue read by the InForm Publisher application (Queueing Privilege Grantor user).
PublisherUserPwd	Password for user who has the rights to grant privileges to the queue read by the InForm Publisher application.
SkipAccountCreation	Option to skip the creation of a new Queueing Privilege Grantor user. Note: The default value for the SkipAccountCreation variable is False.

Sample setup.iss file

Variables that you can set appear in bold type.

```
[InstallShield Silent]
Version=v7.00
File=Response File
[File Transfer]
OverwrittenReadOnly=NoToAll
[ {E3CCDC00-716F-4178-B046-D75E2DB63E29}-DlgOrder]
Dlg0={E3CCDC00-716F-4178-B046-D75E2DB63E29}-SdWelcome-0
Count=7
Dlg1={E3CCDC00-716F-4178-B046-D75E2DB63E29}-SdShowInfoList-0
Dlg2={E3CCDC00-716F-4178-B046-D75E2DB63E29}-SdAskDestPath2-0
Dlg3={E3CCDC00-716F-4178-B046-D75E2DB63E29}-AskOptions-0
Dlg4={E3CCDC00-716F-4178-B046-D75E2DB63E29}-SdDisplayTopics-0
Dlg5={E3CCDC00-716F-4178-B046-D75E2DB63E29}-SdStartCopy2-0
Dlg6={E3CCDC00-716F-4178-B046-D75E2DB63E29}-QueueingPrivilegeGrantorSetup-0
[ {E3CCDC00-716F-4178-B046-D75E2DB63E29}-SdWelcome-0]
Result=1
[ {E3CCDC00-716F-4178-B046-D75E2DB63E29}-SdShowInfoList-0]
Result=1
[ {E3CCDC00-716F-4178-B046-D75E2DB63E29}-SdAskDestPath2-0]
szDir=C:\Program Files\Oracle\InForm Publisher
Result=1
[ {E3CCDC00-716F-4178-B046-D75E2DB63E29}-AskOptions-0]
Result=1
Sel-0=1
Sel-1=0
[ {E3CCDC00-716F-4178-B046-D75E2DB63E29}-SdDisplayTopics-0]
Result=1
[ {E3CCDC00-716F-4178-B046-D75E2DB63E29}-SdStartCopy2-0]
Result=1
[Application]
Name=InForm Publisher
Version=1.00.0000
Company=Oracle
Lang=0009
[ {E3CCDC00-716F-4178-B046-D75E2DB63E29}-QueueingPrivilegeGrantorSetup-0]
TNS_Name=trial1
SystemUserName=systemUserName
SystemPassword=systemPassword
PublisherUserName=publisherUserName
PublisherUserPwd=publisherPassword
SkipAccountCreation=false
```

Upgrading to the latest version of the InForm Publisher software

To upgrade to the latest version of the InForm Publisher software, follow the upgrade instructions in the InForm Publisher *Release Notes*.

Uninstalling the InForm Publisher software

To uninstall the InForm Publisher software:

- Rerun the installer wizard and select the **Uninstall** option.
- or
- Run the SilentUnInstallInFormPublisher.bat file located in the folder where you extracted the InForm Publisher installation files.

Either method allows you to drop the Queuing Privilege Grantor user. The Queuing Privilege Grantor user can also be dropped by the database administrator.

Uninstalling the InForm Publisher software with the installer wizard

- 1 From the Windows Control Panel, open either the Add/Remove program or Programs and Features program, depending on your Windows operating system version.
- 2 Double-click InForm Publisher.
The Preparing Setup page appears. A message asks you to confirm that you want to remove the InForm Publisher files.
- 3 Click **Yes**.
The Database Configuration page appears and lists:
 - The TNS name of the instance where the InForm Publisher software is installed.
 - The Name of the Queuing Privilege Grantor user.
- 4 To drop the Queuing Privilege Grantor user, select **Yes**, then:
 - a In the **Oracle System User Name** field, enter the name of the Oracle system user account.
 - b In the **Oracle System User Password** field, enter the password for the Oracle system user.
 - c Click **Next**.
- 5 To uninstall without dropping the Queuing Privilege Grantor user, select **No**, and then click **Next**.
The installer uninstalls the InForm Publisher software and drops or leaves the Queuing Privilege Grantor user according to your selection. The Uninstall Complete page appears.
- 6 Click **Finish**.

Uninstalling the InForm Publisher software with the unattended uninstallation option

- 1 In the location where you extracted the InForm Publisher installation files, edit the uninstallation variables in the uninstall.iss file. For more information, see *uninstall.iss file variables* (on page 13).
- 2 Run the SilentUnInstallInFormPublisher.bat file. The SilentUnInstallInFormPublisher.bat file is also located in the folder where you extracted the InForm Publisher installation files.

uninstall.iss file variables

Variable	Description
DropUser	TRUE or FALSE (case insensitive), indicating whether to drop the Queuing Privilege Grantor user. Default is TRUE.
SystemUserName	Name of an Oracle system user account that can drop the Queuing Privilege Grantor user.
SystemPassword	Password for the Oracle account.

Sample uninstall.iss file

Variables that you can set appear in bold type.

```
[InstallShield Silent]
Version=v7.00
File=Response File
[File Transfer]
OverwrittenReadOnly=NoToAll
[{E3CCDC00-716F-4178-B046-D75E2DB63E29}-DlgOrder]
Dlg0={E3CCDC00-716F-4178-B046-D75E2DB63E29}-MessageBox-0
Count=3
Dlg1={E3CCDC00-716F-4178-B046-D75E2DB63E29}-DropQueueingPrivilegeGrantor-0
Dlg2={E3CCDC00-716F-4178-B046-D75E2DB63E29}-SdFinish-0
[{E3CCDC00-716F-4178-B046-D75E2DB63E29}-MessageBox-0]
Result=6
[{E3CCDC00-716F-4178-B046-D75E2DB63E29}-DropQueueingPrivilegeGrantor-0]
DropUser=TRUE
SystemUserName=systemUserName
SystemPassword=systemPassword
[Application]
Name=InForm Publisher
Version=1.00.0000
Company=Oracle
Lang=0009
[{E3CCDC00-716F-4178-B046-D75E2DB63E29}-SdFinish-0]
Result=1
bOpt1=0
bOpt2=0
```


CHAPTER 2

Configuring the InForm Publisher application

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About configuring the InForm Publisher application

You must configure the following parameters for the InForm Publisher software to work with an endpoint and the target application for integration.

- **Subscriber**—Target application settings including name, assembly, and publisher type.
- **Study**—Settings for the study from which data is published using the InForm Publisher application.
- **Queueing Privilege Grantor user**—Database user that grants privileges to the study database user.
- **Endpoint settings**—Authentication settings for the endpoint used in integration. For example, the user name and password used by the application receiving messages from the InForm application.

You can configure the InForm Publisher software from the:

- **Command line**—Use the PublisherAdmin command syntax to configure the InForm Publisher software from the command line. For more information, see *Configuring InForm Publisher using PublisherAdmin* (on page 30).
- **Publisher configuration tool**—Use the tool interface to modify the InFormPublisher.config XML file. For more information, see *Configuring the InForm Publisher application using the Publisher configuration tool* (on page 37).

Descriptions of elements in the InForm Publisher configuration file

The **Subscriber** element of the InForm Publisher configuration file contains the configuration settings that define how the InForm Publisher software communicates with the target application. Each instance of the **Subscriber** element defines the communication with one instance of the target application.

The **Subscriber** element is a child of the **Subscribers** element, which is a child of the **EventPublishing** element.

EventPublishing

The **EventPublishing** command allows you to start or stop publishing events.

The **Enabled** attribute of the **EventPublishing** command is set to **false** by default. When this is **false**, the InForm Publisher service is running, but it does not try to publish messages based on the configuration in the `InFormPublisher.config` file.

When you have finished making configuration changes, set the attribute to `PublisherAdmin EventPublishing Enabled="true"` and restart the service.

Subscriber

Defines a subscriber for each instance of the target application to which the InForm Publisher application publishes data. You can define one subscriber for each target application to which the InForm Publisher application publishes data.

ODM Extract and Argus Safety attributes

- **Name**—Name for an instance of the target application. The name must be unique across all subscribers.

REQUIRED.

- **Type**—Publisher type for the specified assembly.
 - Choose **Argus Safety** to define communication between InForm and Argus Safety.
 - Choose **ODM Extract** if you are using custom events.

REQUIRED.

- **EndPoint**—Web service, local directory, FTP or CTMS endpoint URI (Uniform Resource Identifier) that the InForm Publisher application calls to update data to the subscriber destination.

REQUIRED.

Argus Safety subscribers support only web service URIs. ODM Extract subscribers support web service, local directory, FTP, or CTMS type endpoints.

The endpoint format is dependent on the endpoint type:

- If the endpoint type is **FTP**, the `EndPointAddress` hostname should be in the format:

ftp://<hostname><:portnumber>.

- If the endpoint type is SOAP, the EndPointAddress hostname should be in the format:
http://<hostname><:portnumber> or https://<hostname><:portnumber>.
- If the endpoint type is DIRECTORY, the EndPointAddress hostname should be in the format:
<Drive>:\<directory_name>.
- If the endpoint type is CTMS, the EndPointAddress hostname should be in the format:
https://<hostname><:portnumber>/eai_enu/start.swe?SWEExtSource=SecureWebService&;SWEExtCmd=Execute&;WSSOAP=1.

- **EndPointAlias**—String value which must match the destination specified for custom events to be sent to this endpoint.

Required for ODM Extract subscriber.

Note: When custom events are defined, a destination is specified to control where the result output for the event will be delivered. The EndPointAlias must match the destination specified for custom events to be sent to this endpoint.

- **EndPointType**—Endpoint type to be used for publishing. ODM Extract publisher supports these endpoint types, DIRECTORY, FTP, SOAP, and CTMS.
Required for ODM Extract subscriber.
- **HeartbeatInterval**—Not supported.
- **ScheduledPushInterval**—Interval at which the InForm Publisher software:
 - Retries actions that previously failed due to errors.
 - For Argus Safety Publisher:
 - Checks if the SafetyEventUpdateInterval has elapsed, and, if so, sends any necessary updates for existing safety events.
 - Checks if the SafetyEventAutoSendInterval has elapsed for any existing serious safety events that have not been sent, and, if so, sends those safety events.
 - This value is calculated by the InForm Publisher application and is not directly configurable. The value is set to one half of the lesser value specified for the SafetyEventUpdateInterval or SafetyEventAutoSendInterval, rounded down to the nearest whole number, up to a maximum of 60 minutes. The default value is 60 minutes.
 - For ODM Extract Publisher:
 - Checks if any event triggers have evaluated positive, and if they have, sends event ODM data to subscriber endpoint. The default value is 30 minutes.
- **SignatureFilePath**—Not supported.
- **IntervalBetweenRetryAction**—Not supported.
- **IntervalAfterFailedAction**—Not supported.
- **MaxNumberRetryFailedAction**—Not supported.
- **SecureEndPointCredentials**—Container for the user name and password of the user for the

web service endpoint URI that the InForm Publisher application calls to update data to the subscriber destination. The `SecureEndpointCredentials` attributes are used only if the endpoint uses the HTTPS or sFTP protocol and user authentication is enabled on the endpoint.

ODM Extract only attributes

- **FtpTimeout**—Scheduled durations for the FTP connection timeout, in seconds.
ODM Extract Publisher only. Applicable only when the endpoint type is FTP.
- **FtpLocalFolderPath**—Local folder path where generated files are stored before they are transmitted to the remote server.
ODM Extract Publisher only. Applicable only when the endpoint type is FTP.
- **FtpRemoteFolderPath**—Folder path on remote server to which the publisher writes files.
ODM Extract Publisher only. Applicable only when the endpoint type is FTP.

Note: When the endpoint type is FTP, use a property file (`OdmConfig.properties`) to specify the type of data to be pushed. For more information, see the *Integration Guide*.

- **OdmAdminAndMetaPushInterval**—Scheduled frequency, in minutes, for the ADMIN and META Data push.
- **OdmAdminAndMetaType**—Data type that needs to be pushed. Options are NONE, ADMIN, META, and ADMINANDMETA.
- **OdmExtractErrorMaxAge**—Number of hours since the error activation time for which the error manager retries saving the error. The default value is 2 hours.
- **OdmErrorRetryExpiration**—Number of hours since the error creation time that the error manager should activate the errors that have been given up. This setting is read during the startup of ODM Extract publisher and removed after it is read. This value cannot be less than the `OdmExtractErrorMaxAge` value, but if that is the case, the code defensively uses this value as the `OdmExtractErrorMaxAge` value to ensure correct reactivation and expiration logic. The default value is 0.
- **OdmExtractSuppressErrorPeriod**—Number of hours that ODM Extract Publisher does not report the error for retry. The ODM Extract Publisher reads this value at the start-up time and removes this attribute from the configuration file after the start-up. At run time, the ODM Extract Publisher generates the date and time when the period of suppressing errors should end after this value is read. Any error occurring before this date is only logged as a warning and not retried automatically by the error manager. The default value is 0.
- **OdmExtractRetryInterval**—Interval, in minutes, between error retries. The default value is 1 minute.
- **OdmExtractSaveErrorMaxRetries**—Maximum number of times for the error manager to retry saving an error. The default value is 3.
- **OdmExtractSaveErrorRetryInterval**—Interval in seconds that the error manager should wait to retry saving the error. The default value is 120 seconds.

Child elements

- **Trials**—Container for the list of studies that publish to the target application.
REQUIRED. For more information, see Trials.

Example

If there is an error in sending the ODM to the endpoint, the InForm Publisher application saves the error to the database and writes a warning to the Event Log. Based on the `ODMExtractRetryInterval` setting, the InForm Publisher application does not retry to send the ODM for the respective number of push instances.

For example, if the InForm Publisher application runs every two hours and you specify 3 as the `ODMExtractRetryInterval`, the application only retries to send the error every six hours.

Once you reach the `ODMExtractErrorMaxAge`, the InForm Publisher application stops retrying the error.

If you know the endpoint will be down for one day, you can set the `ODMExtractSuppressErrorPeriod` to 24 hours. The first time the InForm Publisher application receives an error, it does not save the error to the database and it stops trying to send any output to the endpoint for the number of hours specified in the `ODMExtractSuppressErrorPeriod`. After that interval has passed, it goes back and sends all the events that fired during the `ODMExtractSuppressErrorPeriod` interval.

If you need to resend messages because the `ODMExtractErrorMaxAge` has already passed, you can specify the `ODMErrorRetryExpiration` to reactivate the errors that occurred previously. Any error that is still in the error queue because the message was not sent and that was created the number of hours before specified by the `ODMErrorRetryExpiration` parameter is retried when you restart the Subscriber.

For example, if you have resolved an issue with the endpoint and need to resend messages that failed a week before, you can set `ODMErrorRetryExpiration` to 168 hours and restart the subscriber. The InForm Publisher application then sends the failed messages.

Argus Safety only attributes

These attributes are for Argus Safety only. For more information, see *Oracle® Health Sciences InForm to Argus Integration Study Design Requirements*.

- **AeRangeStartingOffset**—Number of days before the onset date of an adverse event that the InForm Publisher application should consider when determining which Adverse Event (AE) forms (in addition to the AE form on which the adverse event was reported) are associated with the adverse event. If an instance of a related AE form has a start date within the range specified in the `AeRangeStartingOffset` and `AeRangeEndingOffset` settings, the safety event data from the related form is transmitted to the Oracle Argus Safety application. The default value is 14.

This attribute is for Argus Safety type subscribers only. It is not required for trials added to ODM Extract type subscribers.

- To include all AE forms that were started before the AE onset date, enter -1.
- To include no AE forms that were started before the AE onset date, enter 0.
- **AeRangeEndingOffset**—Number of days after the onset date of an adverse event that the InForm Publisher should consider when determining which Adverse Event (AE) forms are

associated with the adverse event. If an instance of a related AE form has a start date within the range specified in the `AeRangeStartingOffset` and `AeRangeEndingOffset` settings, the safety event data from the related form is transmitted to the Oracle Argus Safety application. The default value is 14.

This attribute is for Argus Safety type subscribers only. It is not required for trials added to ODM Extract type subscribers.

- To include all AE forms that were started after the AE onset date, enter -1.
- To include no AE forms that were started after the AE onset date, enter 0.
- **ConMedRangeStartingOffset**—Number of days before the onset date of an adverse event that the InForm Publisher application should consider when determining which Concomitant Medication (ConMed) forms are associated with the adverse event. If an instance of a related ConMed form has a start date within the range specified in the `ConMedRangeStartingOffset` and `ConMedRangeEndingOffset` settings, the safety event data from the related form is transmitted to the Oracle Argus Safety application. The default value is 14.

This attribute is for Argus Safety type subscribers only. It is not required for trials added to ODM Extract type subscribers.

- To include all ConMed forms that were started before the AE onset date, enter -1.
- To include no ConMed forms that were started before the AE onset date, enter 0.
- For more information, see *Oracle® Health Sciences InForm to Argus Integration Study Design Requirements*.
- **ConMedRangeEndingOffset**—Number of days after the onset date of an adverse event that the InForm Publisher application should consider when determining which Concomitant Medication (ConMed) forms are associated with the adverse event. If an instance of a related ConMed form has a start date within the range specified in the `ConMedRangeStartingOffset` and `ConMedRangeEndingOffset` settings, the safety event data from the related form is transmitted to the Oracle Argus Safety application. The default value is 14.

This attribute is for Argus Safety type subscribers only. It is not required for trials added to ODM Extract type subscribers.

- To include all ConMed forms that were started after the AE onset date, enter -1.
- To include no ConMed forms that were started after the AE onset date, enter 0.
- For more information, see *Oracle® Health Sciences InForm to Argus Integration Study Design Requirements*.
- **LabRangeStartingOffset**—Number of days before the onset date of an adverse event that the InForm Publisher application should consider when determining which Lab forms are associated with the adverse event. If an instance of a related Lab form has a start date within the range specified in the `LabRangeStartingOffset` and `LabRangeEndingOffset` settings, the safety event data from the related form is transmitted to the Oracle Argus Safety application. The default value is 14.

This attribute is for Argus Safety type subscribers only. It is not required for trials added to ODM Extract type subscribers.

- To include all Lab forms that were started before the AE onset date, enter -1.
- To include no Lab forms that were started before the AE onset date, enter 0.
- For more information, see *Oracle® Health Sciences InForm to Argus Integration Study Design Requirements*.

Requirements.

- **LabRangeEndingOffset**—Number of days after the onset date of an adverse event that the InForm Publisher application should consider when determining which Lab forms are associated with the adverse event. If an instance of a related Lab form has a start date within the range specified in the LabRangeStartingOffset and LabRangeEndingOffset settings, the safety event data from the related form is transmitted to the Oracle Argus Safety application. The default value is 14.

This attribute is for Argus Safety type subscribers only. It is not required for trials added to ODM Extract type subscribers.

- To include all Lab forms that were started after the AE onset date, enter -1.
- To include no Lab forms that were started after the AE onset date, enter 0.
- For more information, see *Oracle® Health Sciences InForm to Argus Integration Study Design Requirements*.
- **InFormAdapterUri**—URI of the web service endpoint for the InForm Adapter Safety interface.
Not supported.
- **InFormAdapterTransactionUser**—User name of the InForm user to associate with the transactions created by the InForm Adapter Safety interface.
Not supported.

Trials

Container for the list of studies that publish to the target application.

Use the Trials element to define the list of studies that publish to the target application. Review the Trials element for each Subscriber element.

ODM Extract and Argus Safety attributes

- **ForTrial**—Name of the study (case insensitive).

REQUIRED.

In the ODM subscriber, this is the trial name that is sent in the description using the exact case as in the config file.

Note: The ForTrial attribute of each < add > element must be unique in a subscriber trial list.

- **StudyId**—Unique study identifier.
READ-ONLY.
- **ThreadInLowPriority**—True or false, indicating the priority mode of the thread that publishes events:
OPTIONAL.
 - **True**—Thread priority is low.

- **False (default)**—Thread priority is normal.
- **BacklogStartTransactionId**—Not supported.
- **RunStartupValidation**—True or false, indicating whether to run validation checks during InForm Publisher startup. If you specify True, the logical schemas/data mappings that were configured in the Central Designer application for use when integrating the InForm application with the Oracle Argus Safety application are validated when the InForm Publisher application is started. This validation identifies missing or invalid mappings that can cause unexpected results in the data published by the InForm Publisher application. The default is True.

For ODM Extract Publisher subscribers:

- If validation on a custom event fails, the custom event is inactivated and the InForm Publisher application can still start.
- RunStartupValidation should not be set to true.

ODM Extract only attribute

- **Enable Audit**—If the endpoint type of the ODM Extract Publisher subscriber is CTMS, this option enables or disables storing messages sent from the InForm Publisher application in the audit table.

Note: By default, this option is set to False.

Argus Safety only attributes

These attributes are for Argus Safety only. For more information, see *Oracle® Health Sciences InForm to Argus Integration Study Design Requirements*.

- **AeRangeStartingOffset**—Number of days before the onset date of an adverse event that the InForm Publisher application should consider when determining which Adverse Event (AE) forms (in addition to the AE form on which the adverse event was reported) are associated with the adverse event. If an instance of a related AE form has a start date within the range specified in the AeRangeStartingOffset and AeRangeEndingOffset settings, the safety event data from the related form is transmitted to the Oracle Argus Safety application. The default value is 14.

This attribute is for Argus Safety type subscribers only. It is not required for trials added to ODM Extract type subscribers.

- To include all AE forms that were started before the AE onset date, enter -1.
- To include no AE forms that were started before the AE onset date, enter 0.
- **AeRangeEndingOffset**—Number of days after the onset date of an adverse event that the InForm Publisher should consider when determining which Adverse Event (AE) forms are associated with the adverse event. If an instance of a related AE form has a start date within the range specified in the AeRangeStartingOffset and AeRangeEndingOffset settings, the safety event data from the related form is transmitted to the Oracle Argus Safety application. The default value is 14.

This attribute is for Argus Safety type subscribers only. It is not required for trials added to ODM Extract type subscribers.

- To include all AE forms that were started after the AE onset date, enter -1.

- To include no AE forms that were started after the AE onset date, enter 0.
- **ConMedRangeStartingOffset**—Number of days before the onset date of an adverse event that the InForm Publisher application should consider when determining which Concomitant Medication (ConMed) forms are associated with the adverse event. If an instance of a related ConMed form has a start date within the range specified in the ConMedRangeStartingOffset and ConMedRangeEndingOffset settings, the safety event data from the related form is transmitted to the Oracle Argus Safety application. The default value is 14.

This attribute is for Argus Safety type subscribers only. It is not required for trials added to ODM Extract type subscribers.

- To include all ConMed forms that were started before the AE onset date, enter -1.
- To include no ConMed forms that were started before the AE onset date, enter 0.
- For more information, see *Oracle® Health Sciences InForm to Argus Integration Study Design Requirements*.
- **ConMedRangeEndingOffset**—Number of days after the onset date of an adverse event that the InForm Publisher application should consider when determining which Concomitant Medication (ConMed) forms are associated with the adverse event. If an instance of a related ConMed form has a start date within the range specified in the ConMedRangeStartingOffset and ConMedRangeEndingOffset settings, the safety event data from the related form is transmitted to the Oracle Argus Safety application. The default value is 14.

This attribute is for Argus Safety type subscribers only. It is not required for trials added to ODM Extract type subscribers.

- To include all ConMed forms that were started after the AE onset date, enter -1.
- To include no ConMed forms that were started after the AE onset date, enter 0.
- For more information, see *Oracle® Health Sciences InForm to Argus Integration Study Design Requirements*.
- **LabRangeStartingOffset**—Number of days before the onset date of an adverse event that the InForm Publisher application should consider when determining which Lab forms are associated with the adverse event. If an instance of a related Lab form has a start date within the range specified in the LabRangeStartingOffset and LabRangeEndingOffset settings, the safety event data from the related form is transmitted to the Oracle Argus Safety application. The default value is 14.

This attribute is for Argus Safety type subscribers only. It is not required for trials added to ODM Extract type subscribers.

- To include all Lab forms that were started before the AE onset date, enter -1.
- To include no Lab forms that were started before the AE onset date, enter 0.
- For more information, see *Oracle® Health Sciences InForm to Argus Integration Study Design Requirements*.

- **LabRangeEndingOffset**—Number of days after the onset date of an adverse event that the InForm Publisher application should consider when determining which Lab forms are associated with the adverse event. If an instance of a related Lab form has a start date within the range specified in the LabRangeStartingOffset and LabRangeEndingOffset settings, the safety event data from the related form is transmitted to the Oracle Argus Safety application. The default value is 14.

This attribute is for Argus Safety type subscribers only. It is not required for trials added to ODM Extract type subscribers.

- To include all Lab forms that were started after the AE onset date, enter -1.
- To include no Lab forms that were started after the AE onset date, enter 0.
- For more information, see *Oracle® Health Sciences InForm to Argus Integration Study Design Requirements*.
- **InFormAdapterUri**—URI of the web service endpoint for the InForm Adapter Safety interface.
Not supported.
- **InFormAdapterTransactionUser**—User name of the InForm user to associate with the transactions created by the InForm Adapter Safety interface.
Not supported.

Child elements

- **InForm Adapter User**—If the InForm Adapter URI uses HTTPS with user authentication, user name of the InForm user to use for authentication.
Not supported.
- **InForm Adapter Password**—If the InForm Adapter URI uses HTTPS with user authentication, password for the InForm Adapter user.
Not supported.

Example

In this example, safety data is transmitted to the Oracle Argus Safety application for study combosample. In the study, validation is not performed on startup, and the InForm Publisher application considers AE, ConMed, and Lab forms that are started 14 days before or 14 days after the onset date of an adverse event. In addition, the example indicates that the thread priority is normal.

```
<Trials>
  <add ForTrial="combosample" ThreadInLowPriority="false"
    RunStartupValidation="false" AeRangeStartingOffset="14"
    AeRangeEndingOffset="14" LabRangeStartingOffset="14"
    LabRangeEndingOffset="14" ConMedRangeStartingOffset="14"
    ConMedRangeEndingOffset="14" />
  <add ForTrial="disjointsample" ThreadInLowPriority="false"
    RunStartupValidation="false" AeRangeStartingOffset="14"
    AeRangeEndingOffset="14" LabRangeStartingOffset="14"
    LabRangeEndingOffset="14" ConMedRangeStartingOffset="14"
    ConMedRangeEndingOffset="14" />
  <InFormAdapterUser encrypted="true" salt="1Xayf/IJJ7g="
    cipherAlgorithmVersion="3.0">TmykN8lhpwbv0F0tWw6PI1/7f0182kxAysDtHRO/hy4=<
  /InFormAdapterUser>
  <InFormAdapterPassword encrypted="true" salt="qx00cmyf9Yo="
    cipherAlgorithmVersion="3.0">Rs893d1HFp7Ni34WoDOuSNPsbXhsboHGehrTJiG1F0M=<
```

```
    /InFormAdapterPassword>  
</Trials>
```

SecureEndpointCredentials

Container for the user name and password of the user for the web service endpoint URI that the InForm Publisher application calls to update data to the subscriber destination.

SecureEndpointCredentials attributes are used only if the endpoint uses HTTPS, sFTP or SSH protocols and user authentication is enabled on the endpoint.

Note: You can change the user name and password attributes by using the `PublisherAdmin` command or the Publisher configuration tool. You cannot change the user name and password manually in the configuration XML file, because they are encrypted. For more information, see *Adding and configuring a subscriber* (on page 37).

Attributes

- **username**—User name of the web service endpoint URI user. This attribute corresponds to the Secure Endpoint User Name field in the Publisher configuration tool.
- **password**—Password for the web service endpoint URI user. This attribute corresponds to the Secure Endpoint Password field in the Publisher configuration tool.

QueueingPrivilegeGrantor

Defines the InForm Publisher Database User that is created by the installer. This database user can grant privileges to the study database user.

One QueueingPrivilegeGrantor element exists for each study database instance detected by the installer. The database, the privilege-granting user account, and the password for that user account are encrypted using internal encryption specifications.

You should not have to change the values of the QueueingPrivilegeGrantor element generated by the installer.

Attributes

None.

Child elements

- **Database**—Database that the InForm Publisher software connects to containing the database account that can grant privileges to the study database user. This value is encrypted.
REQUIRED.
- **Username**—User name of the database account that can grant privileges to the study database user. This value is encrypted.
REQUIRED.
- **Password**—Password for the database account that can grant privileges to the study database user. This value is encrypted.
REQUIRED.

Example

In this example, an encrypted Queueing Privilege Grantor user is defined.

```
<QueueingPrivilegeGrantor>
  <Database encrypted="true" salt="vTogKAvXYKY="
    cipherAlgorithmVersion="2.0">LKeYSNY9DHY=</Database>
  <UserName encrypted="true" salt="+HgMIxmX0bQ="
    cipherAlgorithmVersion="2.0">1q3RUVexhzHZ8wnBFhb+Ug==</UserName>
  <Password encrypted="true" salt="fZflM49n9o4="
    cipherAlgorithmVersion="2.0">whc9OJRNomU6wHC3qewwtA==</Password>
</QueueingPrivilegeGrantor>
```

Regenerating the encryption key file

The encryption key file is used to decrypt encrypted data at run time. The encryption key is generated once per installation. If the encryption key is corrupted or deleted, you can either reinstall the InForm Publisher software or reset the encryption key.

Using the InstallConfiguration.exe command line executable file, you can perform configuration-related tasks for the InForm Publisher application. The /changeEncryptionKey switch in the InstallConfiguration command allows you to generate or reset the encryption key, as follows:

- If the configuration file contains no encrypted data and no encryption key file exists, the switch generates an encryption key file, and encrypts the relevant data in the configuration file.
- If the configuration file contains encrypted data and an encryption key file already exists, the switch generates a new encryption key file, and encrypts the relevant data in the configuration file.
- If the configuration file contains encrypted data and no encryption key file exists, the InstallConfiguration command returns an error message and does not load the configuration file because a valid encryption key file is required to load the configuration file.

Using a proxy server

The InForm Publisher application allows you to send messages through a proxy server. A .NET specific application configuration file allows you to specify application-wide proxy behavior using the .NET `system.net.defaultProxy` configuration element.

The application configuration file for the InForm Publisher application is installed with the InForm Publisher software and is located in the `/Bin` directory under the installation location. The application configuration file is called `InFormPublisher.exe.config`.

Example—Specifying a simple proxy server

The following proxy server configuration sends all outgoing traffic from the InForm Publisher application through port 9044 on 127.0.0.1.

```
<?xml version="1.0" encoding="utf-8" ?>
<configuration>
  <system.net>
    <defaultProxy>
      <proxy proxyaddress="http://127.0.0.1:9044" />
    </defaultProxy>
  </system.net>
</configuration>
```

Example—Using a bypass list

The following proxy server configuration sends all outgoing traffic from the InForm Publisher application through port 9044 on 127.0.0.1, unless the endpoint address matches a regular expression specified in the bypass list.

If the endpoint address includes `.oracle.com`, it bypasses the proxy.

```
<?xml version="1.0" encoding="utf-8" ?>
<configuration>
  <system.net>
    <defaultProxy>
      <proxy proxyaddress="http://127.0.0.1:9044" />
      <bypasslist>
        <add address="[a-z]+\\.oracle\.com" />
      </bypasslist>
    </defaultProxy>
  </system.net>
</configuration>
```

Configuring the InForm Publisher application using PublisherAdmin

The PublisherAdmin command allows you to configure the InForm Publisher application from the command line. The PublisherAdmin command line syntax contains the following commands, each with its own set of parameters:

- **service** (on page 30)
- **subscriber** (on page 30)
- trial
- EventPublishing
- **grantor** (on page 34)

The command line executable file, PublisherAdmin.exe, is available in the \Bin folder of the location where you installed the InForm Publisher software.

service

The service command allows you to view the status of the InForm Publisher service, and to start, stop, or restart it.

Parameter	Description
service start	Starts the InForm Publisher service.
service stop	Stops the InForm Publisher service.
service restart	<ul style="list-style-type: none"> • If the InForm Publisher service is running, stops the service and restarts it. • If the InForm Publisher service is not running, starts it.
service status	Displays the current status of the InForm Publisher service.

subscriber

The subscriber command allows you to view and modify subscriber settings. You can define a subscriber for each instance of the target application to which the InForm Publisher application publishes data.

Parameter	Description
-----------	-------------

Parameter	Description
subscriber show	<p>Displays a list of subscribers attributes for the subscribers, and associated studies. Includes the following option:</p> <p>[All/subscriberName]</p> <p>where</p> <ul style="list-style-type: none">• All/subscriberName—A specific subscriber. To see a list of all subscribers, specify all.
subscriber remove	<p>Removes a specified subscriber from the configuration.</p>
subscriber set	<p>Configures the attributes for a subscriber. You can add one or more attributes. Includes the following option:</p> <p>[subscriberName] [attr1=value1]</p> <p>where</p> <ul style="list-style-type: none">• subscriberName—Name of the subscriber to configure.• attr1—Attribute to set for the subscriber.• value1—Value for the attribute. <p>Note: For a description of the subscriber attributes, see <i>Subscriber</i> (on page 17).</p>

Parameter	Description
subscriber add	<p>Adds a new subscriber to the configuration. Includes the following options:</p> <p>[publishertype] [subscriberName] [endpointType][endpoint][endpointAlias][FtpTimeOut][FtpLocal FolderPath] [FtpRemoteFolderPath]</p> <p>where</p> <ul style="list-style-type: none"> • publishertype—Type of publisher to associate with the subscriber. For example, ArgusSafety, or OdmExtract. • subscriberName—Name of the subscriber to add. • endpointtype—Must be either SOAP, FTP, DIRECTORY, or CTMS. ODM Extract Publisher only. • endpoint—Web service endpoint URI that the InForm Publisher application calls to update data to the subscriber destination. • endpointalias—String value that must match the destination specified in the custom events to be sent to this endpoint. ODM Extract Publisher only. • ftptimeout—Numeric value for the number of seconds before the FTP service disconnects the subscriber. ODM Extract Publisher only. Applicable only when the endpoint type is FTP. • ftplocalfolderpath— Local directory name where ODM files are temporarily stored. ODM Extract Publisher only. Applicable only when the endpoint type is FTP. • ftpremotefolderpath—Remote directory name where ODM files are sent. ODM Extract Publisher only. Applicable only when the endpoint type is FTP. <p>Note: To configure attributes for the subscriber, you must use the subscriber set parameter.</p>

Parameter	Description
subscriber setCredentials	<p>Configures the SecureEndPointCredentials element for a subscriber. Includes the following option:</p> <p>[subscriberName] User=[user]</p> <p>where</p> <ul style="list-style-type: none"> subscriberName—Name of the subscriber to configure. user—User name of the web service endpoint URI user. <p>Note: To clear the existing secure endpoint credentials, set the User value to blank (for example, PublisherAdmin subscriber setCredentials MySubscriber User=).</p> <p>You are prompted to enter the password for the URI user.</p>

trial

The trial command allows you to view and modify study attributes. Use the trial command to define the list of studies that publish to the target application.

Parameter	Description
trial show	<p>Displays a list of subscribers associated with the study. Includes the following option:</p> <p>[trialName]</p> <p>where</p> <ul style="list-style-type: none"> trialName—Name of the study for which to view subscribers.
trial add	<p>Adds the specified study to the specified subscriber. Includes the following options:</p> <p>[subscriberName] [trialName]</p> <p>where</p> <ul style="list-style-type: none"> subscriberName—Name of the subscriber to add the study to. trialName—Name of the study to add to the subscriber.
trial remove	<p>Removes the specified study from the specified subscriber. Includes the following options:</p> <p>[subscriberName] [trialName]</p> <p>where</p> <ul style="list-style-type: none"> subscriberName—Name of the subscriber from which to remove the study. trialName—Name of the study to remove from the subscriber.

Parameter	Description
trial set	<p>Configures the attributes for a study. You can add one or many attributes. Includes the following options:</p> <p>[subscriberName] [trialName] [attr1=value1]</p> <p>where</p> <ul style="list-style-type: none"> • subscriberName—Name of the subscriber associated with the study. • trialName—Name of the study to configure. • attr1—Name of the attribute to configure for the study. You can specify one or many attributes. • value1—Value of the attribute to configure for the study. <p>Note: For a description of the study attributes, see Trials.</p>

grantor

The grantor command defines the InForm Publisher database user that is created by the installer. This user can grant privileges to the study database user. The database, the privilege-granting user account, and the password for that user account are encrypted using internal encryption specifications.

Parameter	Description
grantor set	<p>Designates a user as the Queueing Privilege Grantor user.</p> <p>Includes the following options:</p> <p>[sysuser] [tnsname] [grantoruser]</p> <p>where</p> <ul style="list-style-type: none"> ▪ sysuser—User name of the Oracle system user account that can create new Oracle user accounts. <p>Note: You are prompted to enter the password of the sysuser.</p> <ul style="list-style-type: none"> ▪ tnsname—TNS name of the database instance the InForm Publisher application is installed in. ▪ grantoruser—User name of the database account that can grant privileges to access the queue to the study database user. <p>Note: You are prompted to enter the password for the Queueing Privilege Grantor user.</p>

Parameter	Description
grantor remove	<p>Removes a Queueing Privilege Grantor for a study from the configuration file. Includes the following option:</p> <ul style="list-style-type: none"> • [tnsname] <p>where</p> <ul style="list-style-type: none"> ▪ tnsname—TNS name of the database instance the InForm Publisher application is installed in. <p>Note: This command does not remove the user from the database.</p>
grantor show	<p>Displays the Queueing Privilege Grantor for each database associated with the InForm Publisher instance.</p>
grantor update	<p>Updates the username and password for the Queueing Privilege Grantor user in the config file only.</p> <p>The grantor user must already be created using the SQL script.</p> <p>Includes the following option:</p> <ul style="list-style-type: none"> • [tnsname] [grantoruser] <p>where</p> <ul style="list-style-type: none"> • tnsname—TNS name of the database instance the InForm Publisher application is installed in. • grantoruser—User name of the user to designate as the Queueing Privilege Grantor user. <p>Note: You are prompted to enter the password for the Queueing Privilege Grantor user.</p>

Example—PublisherAdmin command

Add an Argus Safety subscriber

```
PublisherAdmin subscriber add ArgusSafety MySafetySubscriber
http://localhost/endpoint
PublisherAdmin subscriber set MySafetySubscriber SafetyEventUpdateInterval=60
SafetyEventExpirationInterval=60
```

Add an ODM subscriber with SOAP endpoint

```
PublisherAdmin Subscriber add OdmExtract OESubscriber9 SOAP
http://yourhost:yourport /ODMTest-GenericReceiverService-context-
root/ODMProcessorService?wsdl Service_9
```

Add an ODM subscriber with FTP endpoint

```
PublisherAdmin Subscriber add OdmExtract OESubscriber9 FTP
ftp://yourhost:yourport Service_9 C:\CustomEventOut /destination
```

Add an ODM subscriber with DIRECTORY endpoint

```
PublisherAdmin Subscriber add OdmExtract OESubscriber9 DIRECTORY C:\Odm\Out
Service_9
```

Add an ODM subscriber with CTMS endpoint

```
PublisherAdmin Subscriber add OdmExtract OESubscriber9 CTMS
https://yourhost:yourport/eai_enu/start.swe?SWEExtSource=SecureWebService&SWE
ExtCmd=Execute Service_9
```

Note: If the endpoint contains special characters such as ampersand (&), use escape character (^) before the special character.

Set Subscriber properties

```
PublisherAdmin Subscriber set OESubscriber9
OdmAdminAndMetaType=ADMINANDMETA OdmAdminAndMetaPushInterval=30
```

Add trial to a subscriber

```
PublisherAdmin trial add OESubscriber9 combo
```

Set trial properties

```
PublisherAdmin trial set MySafetySubscriber MyTrial123
RunStartupValidation=false
```

```
PublisherAdmin service start
```


Configuring the InForm Publisher application using the Publisher configuration tool

The Publisher configuration tool is a user interface that allows you to modify the InForm Publisher configuration file.

The Publisher configuration tool appears when you click the Launch Config tool checkbox in the installer wizard. In addition, the tool, which is named PublisherConfigUI, is also located in the \Bin folder of the location where you installed the InForm Publisher software.

Stopping and starting the InForm Publisher application

Click the **Start** or **Stop** button in the upper-right corner of the InForm Publisher Configuration dialog box.

Note: You can enable or disable event publishing by selecting the Event Publishing Enabled checkbox. If you disable event publishing and have subscribers defined, events will not be transmitted to subscribers.

Adding and configuring a subscriber

- 1 Select the **Subscribers** tab.
- 2 In the **Add New Subscriber** drop-down list, select the publisher type for the subscriber: Argus Safety or ODM Extract.
- 3 Click **Add**.

The Add Subscriber dialog box appears for the selected publisher type.

To add an Argus Safety Publisher subscriber

- 1 In the **Add New Argus Safety Publisher Type Subscriber** dialog box, enter the information for the new subscriber:

Field	Description
Subscriber Name	Name for the subscriber.
Endpoint Alias	N/A
Endpoint Type	N/A
Endpoint Address	The location of the endpoint.
FTP Time Out	N/A
FTP Local Folder Path	N/A
FTP Remote Folder Path	N/A
Select trials to add to this subscriber	One or more trials to associate with the subscriber.

- 2 Click **Ok**.
The InForm Publisher Configuration dialog box appears.
- 3 After a new Argus Safety subscriber is created, you can view or edit the following configuration information.

Field	Description
Subscriber Type	Type of subscriber, which specifies the target application associated with the subscriber. This field is populated based on your selection in the Add New Subscriber drop-down list. READ-ONLY
Subscriber Name	Subscriber name.
Endpoint	Web service endpoint URI that the InForm Publisher application calls to update data to the subscriber destination.
Secure Endpoint User Name	User name of the web service endpoint URI user. This field is enabled when endpoint type is HTTPS or FTP.
Secure Endpoint Password	Password for the web service endpoint URI user. This field is enabled when endpoint type is HTTPS or FTP.
Scheduled Push Interval	Interval at which the InForm Publisher software: <ul style="list-style-type: none"> • Retries actions that previously failed due to errors. • Checks to see if SAE Update Interval (mins) has elapsed and, if so, sends any necessary updates for existing safety events. • Checks to see if SAE Auto-Send Interval (mins) has elapsed for any existing serious safety events that have not been sent yet and, if so, sends those safety events. <p>This value is calculated by the InForm Publisher software and is not directly configurable. The value is set to one half of the lesser value specified for the SAE Update Interval (mins) or SAE Auto-Send Interval (mins), rounded down to the nearest whole number, up to a maximum of 60 minutes. The default value is 60 minutes.</p>
Gateway Signature Files Path	Not supported.
Endpoint Type	READ-ONLY
Endpoint Alias	N/A
FTP Time Out	N/A
FTP Local Folder Path	N/A
FTP Remote Folder Path	N/A
Argus Safety fields	

Field	Description
SAE Update Interval (mins)	Number of minutes after a safety event is pushed to the Oracle Argus Safety application that the InForm Publisher application waits to check for updates to the safety event. Specify an integer between 5 and 1400. The default is 120 minutes.
SAE Auto-Send Interval (mins)	Number of minutes after a safety event is marked as serious in the InForm application that the InForm Publisher application waits before sending the data to the Oracle Argus Safety application. This setting applies only if the study is designed so that a user must choose to send a serious adverse event to the Oracle Argus Safety application by indicating that on a form. Specify an integer between 5 and 1400. The default is 120 minutes.
Error Expiration (hours)	Number of hours after an error occurs that the InForm Publisher application retries the action. After the specified number of hours, the InForm Publisher application no longer attempts to retry the action. Specify a number between 1 and the value you specify for the Expired-Error Reactivation (hours) field. If you do not specify a value for the Expired-Error Reactivation (hours) field, there is no maximum value for this field. The default is 2 hours.
Expired-Error Reactivation (hours)	<p>Number of hours before the InForm Publisher service is stopped and restarted; this value is used to create a time range to determine the expired errors that the InForm Publisher application attempts to reactivate and retry the actions associated with them.</p> <p>For example, if the Expired-Error Reactivation (hours) value is set to 7, an error that occurred up to 7 hours before the InForm Publisher service was restarted is re-activated, and the InForm Publisher again attempts to save the error for the amount of time specified in the Error Expiration (hours) setting.</p>
Error-DB Failure - Retry Interval (secs)	Amount of time between attempts the InForm Publisher application makes to save an error to the database. The default is 120 seconds.
Error-DB Failure - Max Retries	Number of attempts the InForm Publisher application makes to save an error to the database before logging a system error and giving up. The default is 3.

- 4 Click **Save**.

To add an ODM Extract Publisher subscriber

- 1 In the **Add New OdmExtract Publisher Type Subscriber** dialog box, enter the information for the new subscriber.

Field	Description
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Field	Description
Subscriber Name	Name for the subscriber.
Endpoint Alias	Enter a string value. When custom events are defined, a destination is specified to control where the result output for the event will be delivered. The EndPointAlias must match the destination specified for custom events to be sent to this endpoint.
Endpoint Type	Select the endpoint type from the drop-down list. Options are: <ul style="list-style-type: none"> • DIRECTORY—Local directory endpoint. • FTP—FTP endpoint. • SOAP—Web services endpoint. • CTMS—Sends data to Siebel CTMS. Your endpoint type choice determines which options you can configure.
Endpoint Address	The location of the endpoint.
FTP Time Out	The scheduled duration for the FTP connection timeout, in seconds.
FTP Local Folder Path	The access path to the local FTP folder path.
FTP Remote Folder Path	The access path to the remote FTP folder path.
Secure Endpoint User Name	User name of the web service endpoint URI user. This field is enabled when endpoint type is HTTPS or FTP.
Secure Endpoint Password	Password for the web service endpoint URI user. This field is enabled when endpoint type is HTTPS or FTP.
Select trials to add to this subscriber	One or more trials to associate with the subscriber.

- 2 Click **Ok**.

The InForm Publisher Configuration dialog box appears.

- 3 After a new ODM Extract subscriber is created, you can view or edit the following configuration information.

Field	Description
Subscriber Type	Type of subscriber, which specifies the target application associated with the subscriber. This field is populated based on your selection in the Add New Subscriber drop-down list. READ-ONLY
Subscriber Name	Name for the subscriber.

Field	Description
Endpoint	Web service, local directory, FTP, or CTMS endpoint URI that the InForm Publisher application calls to update data to the subscriber destination.
Secure Endpoint User Name	User name of the web service endpoint URI user. This field is enabled when endpoint type is HTTPS or FTP.
Secure Endpoint Password	Password for the web service endpoint URI user. This field is enabled when endpoint type is HTTPS or FTP.
Scheduled Push Interval	Interval at which the InForm Publisher software: <ul style="list-style-type: none"> Retries actions that previously failed due to errors. Checks if any event triggers have evaluated positive and, if they have, sends event ODM data to the subscriber endpoint.
Gateway Signature Files Path	Not supported.
Endpoint Type	Select the endpoint type from the drop-down list. Options are : <ul style="list-style-type: none"> DIRECTORY—Local directory endpoint. FTP—FTP endpoint. SOAP—Web services endpoint. CTMS—Sends data to Siebel CTMS. Your choice of endpoint type determines which options you can configure.
Endpoint Address	The location of the endpoint.
FTP Time Out	The scheduled duration for the FTP connection timeout, in seconds.
FTP Local Folder Path	The access path to the local FTP folder path.
FTP Remote Folder Path	The access path to the remote FTP folder path.
ODM Extract fields	
Admin/Meta Push	Data type that needs to be pushed. Options are: <ul style="list-style-type: none"> NONE ADMIN META ADMINANDMETA
Admin/Meta Frequency (Mins)	Scheduled frequency, in minutes, for the Admin and Meta Data push.

Field	Description
Error Max Age (Hrs)	Number of hours since the error activation time for which the error manager retries saving the error.
Error Retry Expiration (Hrs)	Number of the hours since the error creation time that the error manager should activate the errors that have been given up. The default value is 0. This setting is read during the startup of ODM Extract publisher and removed after it is read. This value cannot be less than the OdmExtractErrorMaxAge value, but if that is the case, the code defensively uses this value as the OdmExtractErrorMaxAge value to ensure correct reactivation and expiration logic.
Error Suppress Error Period (Hrs)	Number of hours that ODM Extract Publisher does not report the error for retry. The ODM Extract Publisher reads this value at the start-up time and removes this attribute from the configuration file after the start-up. At run time, the ODM Extract Publisher generates the date and time when the period of suppressing errors should end after this value is read. Any error occurring before this date is only logged as a warning and not retried automatically by the error manager.
Error Retry Interval (Mins)	Interval, in minutes, between error retries.
Save Error Max Retries	Maximum number of attempts for the error manages to retry saving an error.
Save Error Retry Interval (Secs)	Interval in seconds that the error manager should wait to retry saving the error.

- 4 Click **Save**.

Removing a subscriber

- 1 On the InForm Publisher Configuration dialog box, in the **Subscribers** tab, select a subscriber.
- 2 Click **Remove Subscriber**.

Adding a Queueing Privilege Grantor user

- 1 Select the **Queueing Grantor** tab.
- 2 In the **Queueing Privilege Grantor Not Configured** field, select the Queueing Privilege Grantor user to configure.
- 3 Enter the user name and password for the Oracle System account.
- 4 For the Queueing Privilege Grantor user, enter a user name and password.

Adding a study to a subscriber

On the Add New Subscriber dialog box, from the **Select trials to add to this subscriber** drop-down list, select the study name and click **Add**.

or

On the InForm Publisher Configuration dialog box, in the **Subscribers** tab, click a subscriber and select a trial from the Trial to Subscriber drop-down list, then click **Add**.

Configuring a study

- 1 Select the **Subscribers** tab.
- 2 In the tree, select the study to configure.
The available configuration settings for the study appear on the right.
- 3 Provide the following for the study:

Field	Description
Argus Safety and ODM Extract	
Study ID	Not supported.
Low Priority Thread?	<p>True or false, indicating the priority mode of the thread that publishes events:</p> <ul style="list-style-type: none"> • True—Thread priority is low. • False (default)—Thread priority is normal.
Run Startup Validation?	<p>True or false, indicating whether to run validation checks during InForm Publisher startup. If you specify True, the logical schemas/data mappings that were configured in the Central Designer application for use when integrating the InForm application with the Oracle Argus Safety application are validated when the InForm Publisher application is started. This validation identifies missing or invalid mappings that can cause unexpected results in the data published by the InForm Publisher application. The default is True.</p> <p>For ODM Extract Publisher subscribers, if validation on a custom event fails, the custom event is inactivated and the InForm Publisher application can still start.</p> <p>Note: Do not set Run Startup Validation to True for ODM Extract Publisher subscriber.</p>
ODM Extract Only	

Field	Description
Enable Audit	<p>If the endpoint type of the ODM Extract Publisher subscriber is CTMS, this option enables or disables storing messages sent from the InForm Publisher application in the audit table.</p> <p>Note: By default, this option is set to False.</p>
Argus Safety Only	
AE Range Starting Offset (days)	<p>Number of days before the onset date of an adverse event that the InForm Publisher application should consider when determining which Adverse Event (AE) forms (in addition to the AE form on which the adverse event was reported) are associated with the adverse event. If an instance of a related AE form has a start date within the range specified in the AeRangeStartingOffset and AeRangeEndingOffset settings, the safety event data from the related form is transmitted to the Oracle Argus Safety application. The default value is 14.</p> <ul style="list-style-type: none"> To include all AE forms that were started before the AE onset date, enter -1. To include no AE forms that were started before the AE onset date, enter 0.
AE Range Ending Offset (days)	<p>Number of days after the onset date of an adverse event that the InForm Publisher should consider when determining which Adverse Event (AE) forms are associated with the adverse event. If an instance of a related AE form has a start date within the range specified in the AeRangeStartingOffset and AeRangeEndingOffset settings, the safety event data from the related form is transmitted to the Oracle Argus Safety application. The default value is 14.</p> <ul style="list-style-type: none"> To include all AE forms that were started after the AE onset date, enter -1. To include no AE forms that were started after the AE onset date, enter 0.

Field	Description
Lab Range Starting Offset (days)	<p>Number of days before the onset date of an adverse event that the InForm Publisher application should consider when determining which Lab forms are associated with the adverse event. If an instance of a related Lab form has a start date within the range specified in the LabRangeStartingOffset and LabRangeEndingOffset settings, the safety event data from the related form is transmitted to the Oracle Argus Safety application. The default value is 14.</p> <ul style="list-style-type: none"> To include all Lab forms that were started before the AE onset date, enter -1. To include no Lab forms that were started before the AE onset date, enter 0. For more information, see <i>Oracle® Health Sciences InForm to Argus Integration Study Design Requirements</i>.
Lab Range Ending Offset (days)	<p>Number of days after the onset date of an adverse event that the InForm Publisher application should consider when determining which Lab forms are associated with the adverse event. If an instance of a related Lab form has a start date within the range specified in the LabRangeStartingOffset and LabRangeEndingOffset settings, the safety event data from the related form is transmitted to the Oracle Argus Safety application. The default value is 14.</p> <ul style="list-style-type: none"> To include all Lab forms that were started after the AE onset date, enter -1. To include no Lab forms that were started after the AE onset date, enter 0. For more information, see <i>Oracle® Health Sciences InForm to Argus Integration Study Design Requirements</i>.
ConMed Range Starting Offset (days)	<p>Number of days before the onset date of an adverse event that the InForm Publisher application should consider when determining which Concomitant Medication (ConMed) forms are associated with the adverse event. If an instance of a related ConMed form has a start date within the range specified in the ConMedRangeStartingOffset and ConMedRangeEndingOffset settings, the safety event data from the related form is transmitted to the Oracle Argus Safety application. The default value is 14.</p> <ul style="list-style-type: none"> To include all ConMed forms that were started before the AE onset date, enter -1. To include no ConMed forms that were started before the AE onset date, enter 0. For more information, see <i>Oracle® Health Sciences InForm to Argus Integration Study Design Requirements</i>.

Field	Description
ConMed Range Ending Offset (days)	<p>Number of days after the onset date of an adverse event that the InForm Publisher application should consider when determining which Concomitant Medication (ConMed) forms are associated with the adverse event. If an instance of a related ConMed form has a start date within the range specified in the ConMedRangeStartingOffset and ConMedRangeEndingOffset settings, the safety event data from the related form is transmitted to the Oracle Argus Safety application. The default value is 14.</p> <ul style="list-style-type: none"> To include all ConMed forms that were started after the AE onset date, enter -1. To include no ConMed forms that were started after the AE onset date, enter 0. For more information, see <i>Oracle® Health Sciences InForm to Argus Integration Study Design Requirements</i>.
InForm Adapter URI	<p>URI of the web service endpoint for the InForm Adapter Safety interface.</p> <p>Not supported.</p>
InForm user for Adapter	<p>If the InForm Adapter URI uses HTTPS with user authentication, user name of the InForm user to use for authentication.</p> <p>Not supported.</p>
InForm user pwd for Adapter	<p>If the InForm Adapter URI uses HTTPS with user authentication, password for the InForm Adapter user.</p> <p>Not supported.</p>
InForm txn user for Adapter	<p>User name of the InForm user to associate with the transactions created by the InForm Adapter Safety interface.</p>

- 4 Click **Save**.

Removing a study from a subscriber

- 1 On the InForm Publisher Configuration dialog box, in the **Subscribers** tab, select a study.
- 2 Click **Remove Trial From Subscriber**.

Creating custom event definition tables

Before you configure a trial for an ODM Extract Publisher subscriber, the custom event definition tables must be created in that trial. To create an ODM Extract event table for ODM Extract Publisher subscribers:

- 1 Log into the trial database with the trial user credentials (trialnameuid/trialnamepid).
- 2 In the directory where you extracted the ISO files, go to the Custom Event SQL folder.
- 3 Execute the `CREATE_ALL_ODM_EXTRACT_EVENT_TABLES.sql` command.

Loading the InForm mapping table for a study

To load the InForm mapping table for a study for ODM Extract Publisher subscribers with the CTMS endpoint type, you can place the mapping.xml file on the application server.

- 1 In the folder where you extracted the ISO files, go to the CTMS Mappings subfolder.
- 2 Copy the mapping.xml file.

Note: Before loading the mapping.xml file, check if you must update it with the InForm codelist values. For more information, see the *Integration Guide*.

- 3 Open the command prompt window and navigate to <InFormPublisher Installation Directory>/Bin.

- 4 Run the following command:

```
CTMSMapping [path of mapping xml file] [tnsname] [trial database user  
name]
```

For example:

```
CTMSMapping C:\temp trials demo_user_id.
```

You are prompted to enter the password for the trial database user.

- 5 Enter the password for the trial database user.

Configuring error logging settings

The InForm Publisher software uses the open source Log4Net component (<http://logging.apache.org/log4net/>) to perform error logging to a configurable location.

By default, the InForm Publisher software is configured to log all warnings and errors that occur to the event viewer. However, it can be configured to log additional information to a log file or some other location.

For more information, see <http://logging.apache.org/log4net/release/config-examples.html>.

Starting the InForm Publisher service

Start the InForm Publisher service after performing the initial installation and configuration. When updating the configuration by editing the InFormPublisher.config file, stop the InForm Publisher service before performing the update, and restart the service after the update is complete.

- 1 On the InForm application server where the InForm Publisher module is installed, click **Start > Administrative Tools > Services**.
- 2 Select the **InForm Publisher Service**, and click **Start**.

If the InForm Publisher service encounters an error, error messages are written to the Event Log. Error messages could occur in the following situations:

- The InFormPublisher.config file refers to a study that does not exist in the InForm application.
- You attempt to start the InForm Publisher service before starting the InForm service after you reboot a server. When you reboot a server, you must start the InForm service and then start the InForm Publisher service.
- The XML in the configuration XML file is not well-formed.
- The endpoint URL is in an invalid format in the configuration XML file.
- One of the configuration XML file attributes has an invalid value or a value that is outside of its minimum or maximum boundary.

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/en/industries/health-sciences/inform-publisher/index.html>)—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=info> if you are hearing impaired.