# Oracle® Life Sciences InForm InForm Configuration Guide for InForm Publisher





Oracle Life Sciences InForm InForm Configuration Guide for InForm Publisher, Release 7.0.1

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# **Preface**

This preface contains the following sections:

- · Documentation accessibility
- Related resources
- Access to Oracle Support

# Documentation accessibility

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

### Related resources

All documentation and other supporting materials are available on the Oracle Help Center.

# Access to Oracle Support

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



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# About this guide

In this chapter:

Overview of this guide

# Overview of this guide

This guide provides instructions for configuring the Oracle Life Sciences InForm Publisher feature.

Audience

# **Audience**

This guide is for people who are responsible for configuring the Oracle Life Sciences InForm Publisher feature.



2

# Overview of the Oracle Life Sciences InForm Publisher feature

#### In this chapter:

About the Oracle Life Sciences InForm Publisher feature

### About the Oracle Life Sciences InForm Publisher feature

The Oracle InForm Publisher feature publishes data from Oracle 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 Oracle InForm Publisher feature with an Oracle InForm study you must configure it to work with the study and the target application.

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

- The Oracle Argus Safety Publisher is used by the Oracle InForm to Oracle Argus Safety integration. This option is only supported when Oracle InForm is hosted by Oracle.
- The ODM Extract Publisher can publish data to web service, local directory, FTP, or CTMS endpoints.

#### **Oracle Argus Safety Publisher**

The Oracle Argus Safety Publisher is used to send data for a serious or reportable Adverse Event to the Oracle Life Sciences Clinical One Platform Integration Hub.

#### **ODM Extract Publisher**

If configured for ODM Extract, the Oracle InForm Publisher application provides a way for customers to define events of interest and select the output format for publishing data from Oracle 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 in the ODM Snapshot XML format. The Oracle 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 Oracle 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, and CTMS.

# Configuring the Oracle Life Sciences InForm Publisher application

#### In this chapter:

- About configuring the Oracle Life Sciences InForm Publisher application
- 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 Oracle Life Sciences InForm Publisher software or reset the encryption key.
- Using a proxy server
   The Oracle Life Sciences 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.
- Descriptions of elements in the Oracle Life Sciences InForm Publisher configuration file
   The Subscriber element of the Oracle InForm Publisher configuration file contains the
   configuration settings that define how the Oracle InForm Publisher software communicates
   with the target application. Each instance of the Subscriber element defines the
   communication with one instance of the target application.
- Configuring the Oracle Life Sciences InForm Publisher application using PublisherAdmin
   The PublisherAdmin command allows you to configure the Oracle InForm Publisher
   application from the command line. The PublisherAdmin command line syntax contains the
   following commands, each with its own set of parameters.
- Configuring the Oracle Life Sciences InForm Publisher application using the Publisher configuration tool
   The Publisher configuration tool is a user interface that allows you to modify the Oracle InForm Publisher configuration file.
- Configuring error logging settings
- Updating the InForm Publisher service security descriptor for automated deployments only
- Starting the InForm Publisher service

# About configuring the Oracle Life Sciences InForm Publisher application

You must configure the following parameters for the Oracle 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 Oracle 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 Oracle InForm application.

Include one Subscriber element definition for each instance of the target application to which the Oracle InForm Publisher application publishes data.

As new studies come online on the Oracle InForm application server, or if a study on the Oracle InForm application server sends data to a different instance of the target application from the instance specified during installation, update the Oracle InForm Publisher configuration.



After updating the configuration, restart the Oracle InForm Publisher service for the changes to take effect. For more information, see Starting the InForm Publisher service.

You can configure the Oracle InForm Publisher software from the:

- Command line Use the PublisherAdmin command syntax to configure the Oracle InForm Publisher software from the command line. For more information, see Configuring the Oracle Life Sciences InForm Publisher application using PublisherAdmin.
- **Publisher configuration tool** Use the tool interface to modify the InFormPublisher configuration file. For more information, see Configuring the Oracle Life Sciences InForm Publisher application using the Publisher configuration tool.

For details about the elements in the configuration file, see Descriptions of elements in the Oracle Life Sciences InForm Publisher configuration file.

# 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 Oracle Life Sciences InForm Publisher software or reset the encryption key.

Using the InstallConfiguration.exe command line executable file, you can perform configuration-related tasks for the Oracle 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 Oracle Life Sciences InForm Publisher application allows you to send messages through a proxy server. A .NET specific application configuration file allows you to specify applicationwide proxy behavior using the .NET system.net.defaultProxy configuration element.

The application configuration file for the Oracle InForm Publisher application is installed with the Oracle 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 Oracle Life Sciences InForm Publisher application through port 9044 on 127.0.0.1.
- Example—Using a bypass list
   The following proxy server configuration sends all outgoing traffic from the Oracle Life
   Sciences InForm Publisher application through port 9044 on 127.0.0.1, unless the endpoint
   address matches a regular expression specified in the bypass list.

# Example—Specifying a simple proxy server

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

# Example—Using a bypass list

The following proxy server configuration sends all outgoing traffic from the Oracle Life Sciences 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.



# Descriptions of elements in the Oracle Life Sciences InForm Publisher configuration file

The Subscriber element of the Oracle InForm Publisher configuration file contains the configuration settings that define how the Oracle 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.
- Subscriber
  - Defines a subscriber for each instance of the target application to which the Oracle Life Sciences InForm Publisher application publishes data. You can define one subscriber for each target application to which the Oracle InForm Publisher application publishes data.
- Trials
  - Container for the list of studies that publish to the target application.
- add
- SecureEndpointCredentials
- QueueingPrivilegeGrantor

### **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 Oracle Life Sciences InForm Publisher service is running, but it does not try to publish messages based on the configuration.

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 Oracle Life Sciences InForm Publisher application publishes data. You can define one subscriber for each target application to which the Oracle InForm Publisher application publishes data.

- ODM Extract and Oracle Argus Safety attributes
- ODM Extract only attributes
- Oracle Argus Safety only attributes

#### **ODM Extract and Oracle 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 subscriber. REQUIRED.
  - Oracle Argus Safety
  - ODM Extract
- EndPoint—Web service, local directory, FTP or CTMS endpoint URI that the Oracle InForm Publisher application calls to update data to the subscriber destination. REQUIRED.

Oracle 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.



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 endpoint name defined in Oracle Central Designer.

Required for ODM Extract subscriber.



- EndPointType—Endpoint type to be used for publishing. ODM Extract publisher supports three endpoint types, DIRECTORY, FTP, SOAP, and CTMS.
   Required for ODM Extract subscriber.
- FTPLocalFolderPath—Local folder path where generated files are stored before they are transmitted to remote server.
   ODM Extract Publisher only. Applicable only when the endpoint type is FTP.
- **FTPRemoteFolderPath**—Folder path on remote server to which 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*.

- ScheduledPushInterval—Interval at which the Oracle InForm Publisher software:
  - Retries actions that previously failed due to errors.
  - For Oracle 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 Oracle 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.
- SignatureFilesPath—Not supported.

### ODM Extract only attributes

- 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 manages 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
- Example

#### Child elements

- Trials—Container for the list of studies that publish to the target application.
   REQUIRED. For more information, see Trials.
- SecureEndPointCredentials—Container for the user name and password of the user for the web service endpoint URI that the Oracle 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.

#### Example

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

For example, if the Oracle 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 Oracle 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 Oracle 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 Oracle InForm Publisher application then sends the failed messages.



#### Oracle Argus Safety only attributes

- SafetyEventUpdateInterval—Number of minutes after a safety event is pushed to the Oracle Argus Safety application that the Oracle InForm Publisher application waits to check for updates to the safety event. Specify an integer between 5 and 1400. The default is 120 minutes.
- SafetyEventAutoSendInterval—Number of minutes after a safety event is marked as serious in the Oracle InForm application that the Oracle 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 Safetyy application by indicating that on a form. Specify an integer between 5 and 1400. The default is 120 minutes.
- SafetyErrorMaxAge—Number of hours after an error occurs that the Oracle InForm
   Publisher application retries the action. After the specified number of hours, the Oracle
   InForm Publisher application no longer attempts to retry the action. Specify a number
   between 1 and the value you specify for the SafetyErrorRetryExpiration field. If you do not
   specify a value for the SafetyErrorRetryExpiration field, there is no maximum value for this
   field. The default is 2 hours.
- SafetyErrorRetryExpiration—Number of hours before the Oracle InForm Publisher service is stopped and restarted; this value is used to create a time range to determine the expired errors that the Oracle InForm Publisher application attempts to reactivate and retry the actions associated with them.
   For example, if the SafetyEventRetryExpiration value is set to 7, an expired error that
  - occurred up to 7 hours before the Oracle InForm Publisher service was restarted is reactivated. The Oracle InForm Publisher then retries the action associated with the error for the amount of time specified in the SafetyErrorMaxAge setting.
- SafetyErrorMaxRetries

  —Number of attempts the Oracle InForm Publisher application
  makes to save an error to the database before logging a system error and giving up. The
  default is 3.
- **SafetyErrorRetryInterval**—Amount of time between attempts the Oracle InForm Publisher application makes to save an error to the database. The default value is 120 seconds.
- Example

#### Example

In this example, safety data is transmitted to the Oracle Argus Safety application for study pfst1. The Oracle InForm Publisher application checks for updates in the Oracle Argus Safety application every 60 minutes, and sends serious data every 60 minutes. If an error occurs, the Oracle InForm Publisher application retries the action for 2 hours. If the retries are not successful, the Oracle InForm Publisher application makes 3 attempts to save an error to the database, waiting 120 seconds between attempts.

<Subscriber Name="ArgusSubscriber" EndPoint="http://localhost/AiaListener/
AiaService/" Assembly="InFormPublisher.ArgusSafetyPublisher.dll"
Type="PhaseForward.InFormPublisher.Publishing.ArgusSafetyPublisher.ArgusSafety
Publisher" RequireHeartbeat="false" ScheduledPushInterval="30"
RequireScheduledPush="true" SafetyEventUpdateInterval="60"
SafetyEventAutoSendInterval="60" SafetyErrorMaxAge="2"
SafetyErrorMaxRetries="3" SafetyErrorRetryInterval="120">

<Trials>



```
<add ForTrial="pfst1" ThreadInLowPriority="false"
RunStartupValidation="false" AeRangeStartingOffset="14"
AeRangeEndingOffset="14" LabRangeStartingOffset="14"
LabRangeEndingOffset="14" ConMedRangeStartingOffset="14"
ConMedRangeEndingOffset="14" />
</Trials>
</Subscriber>
```

#### **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.



If you selected the installation options that do not add any Oracle InForm studies to the Oracle InForm Publisher configuration, or if you are adding new studies, use the Trials element to add the studies.

- Attributes
- Child element
- Example

#### **Attributes**

None.

#### Child element

add—Identifies a study that publishes to the target application.
 REQUIRED. For more information, see add.

### 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 Oracle 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.

```
<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">Rs893d1HFp7Ni34WoDOuSNPSbXhsboHGEhrTJiGlF0M=</
InFormAdapterPassword>
</Trials>
```

#### add

Identifies a study that publishes to the target application.

Configure the add element for each study that publishes to the instance of the target application.

- ODM Extract and Oracle Argus Safety attributes
- ODM Extract only attribute
- Oracle Argus Safety only attribute

#### ODM Extract and Oracle Argus Safety attributes

ForTrial—Name of the study (case insensitive).
 REQUIRED.



The ForTrial attribute of each < add > element must be unique across all subscribers.

- 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
  Oracle InForm Publisher startup. If you specify True, the logical schemas/data mappings
  that were configured in the Oracle Central Designer application for use when integrating
  the Oracle InForm application with the Oracle Argus Safety application are validated when
  the Oracle InForm Publisher application is started. This validation identifies missing or



invalid mappings that can cause unexpected results in the data published by the Oracle InForm Publisher application. The default is True.

For ODM Extract Publisher subscribers, always set to False because validation is performed in Oracle Central Designer.

# **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 Oracle InForm Publisher application in the audit table.



By default, this option is set to False.

#### Oracle Argus Safety only attribute

#### AE range starting and ending offsets

If the Oracle InForm site user can choose which AEs are relevant for sending to Oracle Argus Safety, instead of using time frames, the AE Range Starting Offset and AE Range Ending Offset attributes must be set to -1.

AeRangeStartingOffset—Number of days before the onset date of an adverse event that
the Oracle 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 Oracle 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
  Oracle 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 Oracle 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.

#### ConMed range starting and ending offsets

If the Oracle InForm site user can select relevant concomitant medications, the ConMed Range Starting Offset and Ending Offset attributes must be set to -1.

 ConMedRangeStartingOffset—Number of days before the onset date of an adverse event that the Oracle 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 Oracle 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.
- ConMedRangeEndingOffset—Number of days after the onset date of an adverse event that the Oracle 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 Oracle 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.

#### Lab range starting and ending offsets

If the Oracle InForm site user can select relevant labs, the Lab Range Starting Offset and Ending Offset attributes must be set to -1.

- LabRangeStartingOffset—Number of days before the onset date of an adverse event that the Oracle 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 Oracle 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.
- LabRangeEndingOffset—Number of days after the onset date of an adverse event that the Oracle 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 Oracle 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.

#### **Unsupported attributes**

- InFormAdapterUri—Not supported.
- InFormAdapterTransactionUser—Not supported.



#### Example

#### 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 Oracle 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"</pre>
RunStartupValidation="false" AeRangeStartingOffset="14"
AeRangeEndingOffset="14" LabRangeStartingOffset="14"
LabRangeEndingOffset="14" ConMedRangeStartingOffset="14"
ConMedRangeEndingOffset="14" />
<add ForTrial="disjointsample" ThreadInLowPriority="false"</pre>
RunStartupValidation="false" AeRangeStartingOffset="14"
AeRangeEndingOffset="14" LabRangeStartingOffset="14"
LabRangeEndingOffset="14" ConMedRangeStartingOffset="14"
ConMedRangeEndingOffset="14" />
<InFormAdapterUser encrypted="true" salt="1Xayf/IJJ7g="</pre>
cipherAlgorithmVersion="3.0">TmykN8lhpwbv0F0tWw6PI1/7f0182kxAysDtHRo/hy4=</
InFormAdapterUser>
<InFormAdapterPassword encrypted="true" salt="qx00cmyf9Yo="</pre>
cipherAlgorithmVersion="3.0">Rs893d1HFp7Ni34WoDOuSNPSbXhsboHGEhrTJiGlF0M=</
InFormAdapterPassword>
</Trials>
```

### SecureEndpointCredentials

Container for the user name and password of the user for the web service endpoint URI that the Oracle 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.

- Attributes
- Child elements

#### **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.

#### Child elements

None.

# QueueingPrivilegeGrantor

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

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

- Attributes
- Child elements

#### **Attributes**

None.

#### Child elements

- Database—Database that the Oracle 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.

# Configuring the Oracle Life Sciences InForm Publisher application using PublisherAdmin

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



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

EventPublishing

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



#### service

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

#### 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 Oracle Life Sciences InForm Publisher application publishes data.

#### 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.

#### grantor

The grantor command defines the Oracle Life Sciences InForm Publisher Database User that is created by the installer. This database 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.

Example—PublisherAdmin command

#### service

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

Parameter	Description
service start	Starts the Oracle InForm Publisher service.
service stop	Stops the Oracle InForm Publisher service.
service restart	<ul> <li>If the Oracle InForm Publisher service is running, stops the service and restarts it.</li> <li>If the Oracle InForm Publisher service is not running, starts it.</li> </ul>
service status	Displays the current status of the Oracle 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 Oracle Life Sciences InForm Publisher application publishes data.

Parameter	Description
subscriber show	Displays a list of subscribers attributes for the subscribers, and associated studies. Includes the following option:
	[All/subscriberName]
	where
	<ul> <li>All/subscriberName—A specific subscriber. To see a list of all subscribers, specify all.</li> </ul>
subscriber remove	Removes a specified subscriber from the configuration.



Parameter	Description
subscriber set	Configures the attributes for a subscriber. You can add one or more attributes. Includes the following option:
	[subscriberName] [attr1=value1]
	where
	<ul> <li>subscriberName—Name of the subscriber to configure.</li> <li>attr1—Attribute to set for the subscriber.</li> <li>value1—Value for the attribute.</li> </ul>
	For a description of the subscriber attributes, see Subscriber



Parameter	Description
subscriber add	Adds a new subscriber to the configuration. Includes the following options:
	[publishertype] [subscriberName] [endpointType] [endpoint][endpointAlias][FtpLocalFolderPath] [FtpRemoteFolderPath]
	where
	<ul> <li>publishertype—Type of publisher to associate with the subscriber. For example, ArgusSafety, or OdmExtract.</li> </ul>
	<ul> <li>subscriberName—Name of the subscriber to add.</li> </ul>
	<ul> <li>endpointtype—Must be either SOAP, FTP, DIRECTORY, or CTMS.</li> <li>ODM Extract Publisher only.</li> </ul>
	<ul> <li>endpoint—Web service endpoint URI that the Oracle InForm Publisher application calls to update data to the subscriber destination.</li> </ul>
	<ul> <li>endpointalias—String value that must match the destination specified in the custom events to be sent to this endpoint.</li> </ul>
	<ul> <li>ODM Extract Publisher only.</li> <li>ftplocalfolderpath— Local directory name where ODM files are temporarily stored.</li> <li>ODM Extract Publisher only. Applicable only when the endpoint type is FTP.</li> </ul>
	<ul> <li>ftpremotefolderpath—Remote directory name where ODM files are sent.</li> <li>ODM Extract Publisher only. Applicable only when the endpoint type is FTP.</li> </ul>
	Note:

To configure attributes for the subscriber, you must use the subscriber set parameter.



Parameter	Description
subscriber setCredentials	Configures the SecureEndPointCredentials element for a subscriber. Includes the following option:
	[subscriberName] User=[user] [PasswordFile]
	where
	<ul> <li>subscriberName—Name of the subscriber to configure.</li> </ul>
	<ul> <li>user—User name of the web service endpoint URI user.</li> </ul>
	<ul> <li>PasswordFile—Path to a file that contains the password for the web service endpoint URI user.</li> </ul>
	Note:  To clear the existing secure endpoint credentials, set the User value to blank (for example, PublisherAdmin
	subscriber setCredentials MySubscriber User=).
	To enter the password interactively, do not enter a PasswordFile parameter value (for example

# 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	Displays a list of subscribers associated with the study. Includes the following option:
	[trialName]
	where
	<ul> <li>trialName—Name of the study for which to view subscribers.</li> </ul>



PublisherAdmin subscriber setCredentials MySubscriber User=MyUser).

Parameter	Description
trial add	Adds the specified study to the specified subscriber. Includes the following options:
	[subscriberName] [trialName]
	where
	<ul> <li>subscriberName—Name of the subscriber to add the study to.</li> </ul>
	<ul> <li>trialName—Name of the study to add to the subscriber.</li> </ul>
trial remove	Removes the specified study from the specified subscriber. Includes the following options:
	[subscriberName] [trialName]
	where
	<ul> <li>subscriberName—Name of the subscriber</li> </ul>
	from which to remove the study.
	<ul> <li>trialName—Name of the study to remove from the subscriber.</li> </ul>
trial set	Configures the attributes for a study. You can add one or many attributes. Includes the following options:
	[subscriberName] [trialName] [attr1=value1]
	where
	<ul> <li>subscriberName—Name of the subscriber associated with the study.</li> </ul>
	<ul> <li>trialName—Name of the study to configure.</li> </ul>
	<ul> <li>attr1—Name of the attribute to configure for</li> </ul>
	the study. You can specify one or many attributes.
	<ul> <li>value1—Value of the attribute to configure for</li> </ul>
	the study.
	Note:  For a description of
	the study attributes, see Trials.
trial setIA	Not supported.

# grantor

The grantor command defines the Oracle Life Sciences InForm Publisher Database User that is created by the installer. This database 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	Designates a user as the Queuing Privilege Grantor user.
	Includes the following options:
	<ul> <li>[sysuser] [tnsname] [grantoruser]</li> <li>[grantorpwdfile]</li> </ul>
	or • [sysuser] [tnsname] [grantoruser] where
	<ul> <li>sysuser—User name of the Oracle syster user account that can create new Oracle user accounts.</li> </ul>
	Note:  The sysuser is prompted to enter system user password in the command line.
	<ul> <li>tnsname—TNS name of the study with which to associate the Queueing Privilege Grantor user.</li> </ul>
	<ul> <li>grantoruser—User name of the user to designate as the Queueing Privilege Grantor user.</li> </ul>
	<ul> <li>grantorpwdfile—Path for a file that contains the password for the Queueing Privilege Grantor user.</li> <li>To use this option, create a text file that includes the password, and call the grantorpwdfile command. Then, delete the text file.</li> </ul>
	If a grantor password file is not provided, the sysuser is prompted to enter the grantor account password.
grantor remove	Removes a Queueing Privilege Grantor for a study from the configuration. Includes the following option:
	<ul><li>[tnsname] where</li></ul>
	<ul> <li>tnsname—TNS name of the study from which to disassociate the Queueing Privilege Grantor user.</li> </ul>
	Note:
	This command does not remove the user from the database.
grantor show	Displays the Queueing Privilege Grantor for each database associated with the Oracle InForm Publisher instance.
grantor update	



# 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&SWEExtCmd=Execute Service 9



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 Oracle Life Sciences InForm Publisher application using the Publisher configuration tool

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

- Stopping and starting the Oracle Life Sciences InForm Publisher application
- Adding and configuring a subscriber
- Removing a subscriber
- Adding a Queueing Privilege Grantor user
- Adding a study to a subscriber
- Configuring a study
- Removing a study from a subscriber
- Loading the Oracle Life Sciences InForm mapping table for a study

# Stopping and starting the Oracle Life Sciences InForm Publisher application

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



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

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

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

To add an Oracle Argus Safety Publisher subscriber



To add an ODM Extract Publisher subscriber

# To add an Oracle Argus Safety Publisher subscriber

1. In the Add New Oracle 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 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 Oracle InForm Publisher Configuration dialog box appears.

3. After a new Oracle 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 Oracle 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.
Secure Endpoint Password	Password for the web service endpoint URI user. This field is enabled when endpoint type is HTTPS.



Field	Description
Scheduled Push Interval	Interval at which the Oracle InForm Publisher software:
	<ul> <li>Retries actions that previously failed due to errors.</li> <li>Checks to see if SAE Update Interval (mins) has elapsed and, if so, sends any necessary updates for existing safety events.</li> <li>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. This value is calculated by the Oracle 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</li> </ul>
0.1 0: 1 5: 5 1	minutes. The default value is 60 minutes.
Gateway Signature Files Path	Not supported.
Endpoint Type	READ-ONLY
Endpoint Alias	N/A
FTP Local Folder Path	N/A
FTP Remote Folder Path	N/A

Table 3-1 Oracle 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 Oracle InForm application that the Oracle 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 Oracle InForm Publisher application retries the action. After the specified number of hours, the Oracle 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.



Table 3-1 (Cont.) Oracle Argus Safety fields

Field	Description
Expired-Error Reactivation (hours)	Number of hours before the Oracle InForm Publisher service is stopped and restarted; this value is used to create a time range to determine the expired errors that the Oracle InForm Publisher application attempts to reactivate and retry the actions associated with them.
	For example, if the Expired-Error Reactivation (hours) value is set to 7, an error that occurred up to 7 hours before the Oracle InForm Publisher service was restarted is re-activated, and the Oracle InForm Publisher again attempts to save the error for the amount of time specified in the Error Expiration (hours) setting.
Error-DB Failure - Retry Interval (secs)	Amount of time between attempts the Oracle 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 Oracle 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
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 endpoint name specified for the custom event in Oracle Central Designer.
Endpoint Type	Select the endpoint type from the drop-down list.
	Options are:
	<ul> <li>DIRECTORY—Local directory endpoint.</li> </ul>
	<ul> <li>FTP—FTP endpoint.</li> </ul>
	<ul> <li>SOAP—Web services endpoint.</li> </ul>
	<ul> <li>CTMS—Sends data to Siebel CTMS.</li> <li>Your endpoint type choice determines which options you can configure.</li> </ul>
Endpoint Address	The location of the endpoint.
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.



Field	Description
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 Oracle 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.
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	<ul> <li>Interval at which the Oracle InForm Publisher software:</li> <li>Retries actions that previously failed due to errors.</li> <li>Checks if any event triggers have evaluated positive and, if they have, sends event ODM</li> </ul>
	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><li>DIRECTORY—Local directory endpoint.</li><li>FTP—FTP endpoint.</li></ul>
	<ul> <li>SOAP—Web services endpoint</li> </ul>
	<ul> <li>CTMS—Sends data to Siebel CTMS.</li> <li>Your choice of endpoint type determines which options you can configure.</li> </ul>
Endpoint Address	The location of the endpoint.
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.



Table 3-2 ODM Extract fields

Field	Description
Admin/Meta Push	Data type that needs to be pushed. Options are:  NONE ADMIN META ADMINANDMETA
Admin/Meta Frequency (Mins)	Scheduled frequency, in minutes, for the Admin and Meta Data push.
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 Oracle 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.
- 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 Oracle 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:

Table 3-3 Oracle Argus Safety and ODM Extract

Field	Description
Study ID	Not supported.
Low Priority Thread?	True or false, indicating the priority mode of the thread that publishes events:  True—Thread priority is low.  False (default)—Thread priority is normal.
Run Startup Validation?	This value should always be set to False.
Language ID	Not supported.

Table 3-4 ODM Extract only

Field	Description
Enable Audit	If the endpoint type of the ODM Extract Publisher subscriber is CTMS, this option enables or disables storing messages sent from the Oracle InForm Publisher application in the audit table.
	Note:  By default, this option is set to False.



#### Table 3-5 Oracle Argus Safety only

#### Field

#### AE Range Starting Offset (days)

#### Description

Number of days before the onset date of an adverse event that the Oracle 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.

- 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.



#### Note:

If the Oracle InForm site user can choose which AEs are relevant for sending to Oracle Argus Safety, instead of using time frames, the AE Range Staring Offset attribute must be set to -1.

#### AE Range Ending Offset (days)

Number of days after the onset date of an adverse event that the Oracle 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.

- 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.



#### Note:

If the Oracle InForm site user can choose which AEs are relevant for sending to Oracle Argus Safety, instead of using time frames, the AE Range Ending Offset attribute must be set to -1.



Table 3-5 (Cont.) Oracle Argus Safety only

#### Field

#### Lab Range Starting Offset (days)

#### Description

Number of days before the onset date of an adverse event that the Oracle 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.

- 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.



If the Oracle InForm site user can select relevant labs, the Lab Range Starting Offset attribute must be set to -1.

#### Lab Range Ending Offset (days)

Number of days after the onset date of an adverse event that the Oracle 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.

- 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.

#### Note:

If the Oracle InForm site user can select relevant labs, the Lab Range Ending offset attribute must be set to -1.



Table 3-5 (Cont.) Oracle Argus Safety only

#### Field

#### ConMed Range Starting Offset (days)

#### Description

Number of days before the onset date of an adverse event that the Oracle 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.

- 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.



If the Oracle InForm site user can select relevant concomitant medications, the ConMed Range Starting Offset attribute must be set to -1.

#### ConMed Range Ending Offset (days)

Number of days after the onset date of an adverse event that the Oracle 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.

- 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.

#### Note:

If the Oracle InForm site user can select relevant concomitant medications, the ConMed Range Ending Offset attribute must be set to -1.

Oracle InForm Adapter URI

Not supported.



Table 3-5 (Cont.) Oracle Argus Safety only

Field	Description
Oracle InForm user for Adapter	Not supported.
Oracle InForm user pwd for Adapter	Not supported.
Oracle InForm txn user for Adapter	Not supported.

4. Click Save.

# Removing a study from a subscriber

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

## Loading the Oracle Life Sciences InForm mapping table for a study

To load the Oracle InForm mapping table for a study for ODM Extract Publisher subscribers with the CTMS endpoint type:

- In the directory where you extracted the Oracle InForm Publisher product archive, go to the CTMS Mappings folder.
- 2. Copy the mapping.xml file.



Before loading the mapping.xml file, check if you must update it with the Oracle 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 user name] [trial password].

#### For example:

CTMSMapping C:\temp trials demo user id demo password.

# Configuring error logging settings

The Oracle 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 Oracle 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.

# Updating the InForm Publisher service security descriptor - for automated deployments only

If the Oracle InForm application uses automated deployments, you must follow these steps to append the Oracle InForm Users group to the security descriptor of the Oracle InForm Publisher service:

- 1. Log in to the Oracle InForm application server as an administrator and open a command prompt window.
- Get the SID for the Oracle InForm Users group by running the following command:

```
wmic group where (name="InForm Users") get sid
```

The command returns an SID with the following format:

```
SID

S-x-x-xxxxxxxx-xxxxxx-xxxxxx-xxxxxx-xxxx
```

3. Get the current security descriptor for the InForm Publisher service by running the following command:

```
sc sdshow "InForm Publisher Service"
```

The command returns a security descriptor similar to the following:

```
D: (A;;CCLCSWRPWPDTLOCRRC;;;SY) (A;;CCDCLCSWRPWPDTLOCRSDRCWDWO;;;BA) (A;;CCLCSWLOCRRC;;;IU) (A;;CCLCSWLOCRRC;;;SU)
```

4. Add the SID returned in step 2 to the descriptor returned in step 3 by running the following command:

```
sc sdset "InForm Publisher Service" D: (A;;CCLCSWRPWPDTLOCRRC;;;SY)
(A;;CCDCLCSWRPWPDTLOCRSDRCWDWO;;;BA)^

(A;;CCLCSWLOCRRC;;;IU) (A;;CCLCSWLOCRRC;;;SU) (A;;RPWPDTLO;;;S-x-x-xxxxxxxxx-xxxxxxx-xxxxxxx-xxxxxxx)
```

# Starting the InForm Publisher service

Start the Oracle InForm Publisher service after performing the initial installation and configuration. When updating the configuration, restart the service after the update is complete.

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



If the Oracle 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 Oracle InForm application.
- If you attempt to start the Oracle InForm Publisher service before starting the Oracle InForm service after you reboot a server, an error occurs indicating that the dependency service or group failed to start. When this occurs, start the Oracle InForm Publisher service again.
  - To prevent this error, when you reboot a server, always start the InForm service before you start the Oracle InForm Publisher service.
- The configuration XML file was manually modified and 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.

