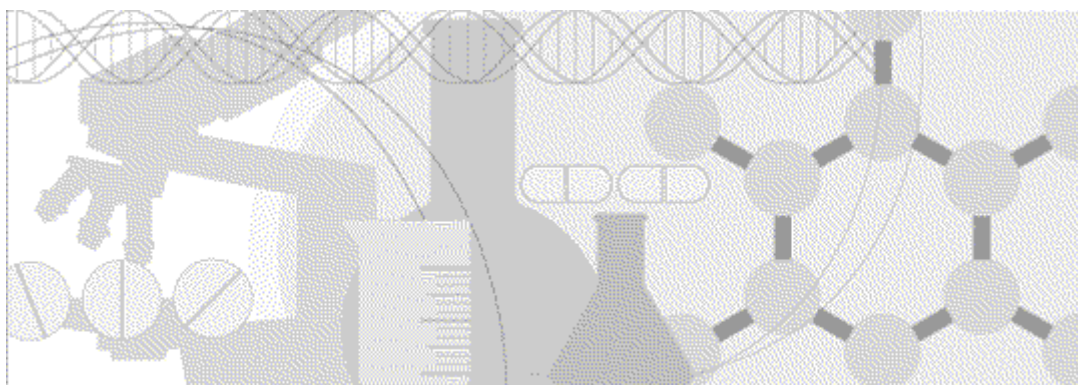


InForm Clinical Data API Guide

Oracle[®] Health Sciences InForm 6.1



ORACLE[®]

Part Number: E51806-01

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About this guide

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Overview of this guide

The *Clinical Data API Guide* provides information about submitting data to the InForm application in InForm ODM format using the following:

- Clinical Data API—Web service interface that allows a remote InForm user to import clinical data using an API.
- ODM Submit utility—Command line tool that allows a local user to execute an import file in ODM format with InForm-specific extensions using the command line.

Audience

This guide is for users who submit clinical data. Remote users; that is, users who do not have access to the physical machine on which the InForm application is installed, can submit clinical data using the Clinical Data API. Local users; that is, users who have access to the physical machine on which the InForm application is installed, can submit clinical data using the ODM Submit utility.

Documentation

The product documentation is available from the following locations:

- **Oracle Software Delivery Cloud** (<https://edelivery.oracle.com>)—The complete documentation set.
- **My Oracle Support** (<https://support.oracle.com>)—*Release Notes* and *Known Issues*.
- **Oracle Technology Network** (<http://www.oracle.com/technetwork/documentation>)—The most current documentation set, excluding the *Release Notes* and *Known Issues*.

All documents may not be updated for every InForm release. Therefore, the version numbers for the documents in a release may differ.

Document	Description
<i>Release Notes</i>	The <i>Release Notes</i> document describes enhancements introduced and problems fixed in the current release, upgrade considerations, release history, and other late-breaking information.
<i>Known Issues</i>	The <i>Known Issues</i> document provides detailed information about the known issues in this release, along with workarounds, if available.
<i>Secure Configuration Guide</i>	The <i>Secure Configuration Guide</i> provides an overview of the security features provided with the Oracle® Health Sciences InForm application, including details about the general principles of application security, and how to install, configure, and use the InForm application securely.
<i>Upgrade and Migration Guide</i>	The <i>Upgrade and Migration Guide</i> provides instructions for upgrading and migrating the InForm software and InForm Portal software to the current InForm release, and for upgrading the Cognos software for use with the Reporting and Analysis module.
<i>Installation Guide</i>	The <i>Installation Guide</i> describes how to install the software and configure the environment for the InForm application and Cognos software.
<i>Study and Reporting Setup Guide</i>	The <i>Study and Reporting Setup Guide</i> describes how to perform the tasks that are required to set up an InForm study and configure the Reporting and Analysis module for the study.
<i>User Guide</i>	The <i>User Guide</i> provides an overview of the InForm application including details on multilingual studies, how to navigate through the user interface, how to manage a study-specific Home page with the InForm Portal application, and how to accomplish typical tasks you perform while running a clinical study.
<i>Reporting and Analysis Guide</i>	The <i>Reporting and Analysis Guide</i> provides an overview of the Reporting and Analysis module. It includes a brief overview of the Reporting and Analysis interface, illustrates how to access the Ad Hoc Reporting feature, and describes the study management and clinical data packages available for Reporting and Analysis. It also provides detailed descriptions of each standard report that is included with your installation.

Document	Description
<i>Reporting Database Schema Guide</i>	The <i>Reporting Database Schema Guide</i> describes the Reporting and Analysis database schema, and provides information on creating Reporting Database Extracts (RDEs).
<i>InForm Utilities Guide</i>	<p>The <i>InForm Utilities Guide</i> provides information about and step-by-step instructions for using the following utilities:</p> <ul style="list-style-type: none"> • PFCConsole utility • MedML Installer utility • InForm Data Import utility • InForm Data Export utility • InForm Performance Monitor utility • InForm Report Folder Maintenance utility <p>This guide also provides reference information for the MedML elements and scripting objects that are used to import and export data to and from the InForm application, as well as sample data import XML.</p>
MedML Installer utility online Help	<p>The MedML Installer utility online Help provides information about, and step-by-step instructions for using, the MedML Installer utility, which is used to load XML that defines study components into the InForm database.</p> <p>This guide also provides reference information for the MedML elements and scripting objects that are used to import and export data to and from the InForm application, as well as sample data import XML.</p> <p>This document is also available from the user interface.</p>
InForm Data Export utility online Help	<p>The InForm Data Export utility online Help provides information about and step-by-step instructions for using the InForm Data Export utility, which is used to export data from the InForm application to the following output formats:</p> <ul style="list-style-type: none"> • Customer-defined database (CDD) • Name value pairs <p>This document is also available from the user interface.</p>
InForm Data Import utility online Help	<p>The InForm Data Import utility online Help provides information about and step-by-step instructions for using the InForm Data Import utility, which is used to import data into the InForm application.</p> <p>This document is also available from the user interface.</p>
<i>Clinical Data API Guide</i>	The <i>Clinical Data API Guide</i> provides information about submitting data to the InForm application in InForm ODM format.
<i>Third Party Licenses and Notices</i>	The <i>Third Party Licenses and Notices</i> document includes third party technology that may be included in or distributed with this product.

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>.

If you need assistance

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

Finding InForm information and patches on My Oracle Support

The latest information about the InForm application is on the Oracle Support self-service website, My Oracle Support. Before you install and use the InForm application, check My Oracle Support for the latest information, including *Release Notes* and *Known Issues*, alerts, white papers, bulletins, and patches.

Creating a My Oracle Support account

You must register at My Oracle Support to obtain a user name and password before you can enter the site.

- 1 Open a browser to <https://support.oracle.com>.
- 2 Click the **Register** link.
- 3 Follow the instructions on the registration page.

Finding information and articles

- 1 Sign in to My Oracle Support at <https://support.oracle.com>.
- 2 If you know the ID number of the article you need, enter the number in the text box at the top right of any page, and then click the magnifying glass icon or press **Enter**.
- 3 To search the knowledge base, click the **Knowledge** tab, and then use the options on the page to search by:
 - Product name or family.
 - Keywords or exact terms.

Finding patches

You can search for patches by patch ID or number, product, or family.

- 1 Sign in to My Oracle Support at <https://support.oracle.com>.
- 2 Click the **Patches & Updates** tab.
- 3 Enter your search criteria and click **Search**.
- 4 Click the patch ID number.

The system displays details about the patch. You can view the Read Me file before downloading the patch.

- 5 Click **Download**, and then follow the instructions on the screen to download, save, and install the patch files.

Finding Oracle documentation

The Oracle website contains links to Oracle user and reference documentation. You can view or download a single document or an entire product library.

Finding Oracle Health Sciences documentation

For Oracle Health Sciences applications, go to the Oracle Health Sciences Documentation page at <http://www.oracle.com/technetwork/documentation/hsgbu-clinical-407519.html>.

Note: Always check the Oracle Health Sciences Documentation page to ensure you have the most up-to-date documentation.

Finding other Oracle documentation

- 1 Do one of the following:
 - Go to <http://www.oracle.com/technology/documentation/index.html>.
 - Go to <http://www.oracle.com>, point to the **Support** tab, and then click **Product Documentation**.
- 2 Scroll to the product you need, and click the link.

Finding prerequisite software for Oracle Health Sciences applications

Prerequisite software for Oracle Health Sciences applications is available from the following locations:

- Download the latest major or minor release from the Oracle Software Delivery Cloud (<https://edelivery.oracle.com/>).

For information on the credentials that are required for authorized downloads, click **FAQs** on the main page of the Oracle Software Delivery Cloud portal.

- Download subsequent patch sets and patches from My Oracle Support (<https://support.oracle.com>).

To find patch sets or patches, select the **Patches & Updates** tab.

If a previous version of prerequisite software is no longer available on the Oracle Software Delivery Cloud, log a software media request Service Request (SR). Previous versions of prerequisite software are archived and can usually be downloaded. After you open an SR, you can check its status:

- US customers: Call 1-800-223-1711.
- Outside the US: Check www.oracle.com/us/support/contact/index.html for your local Oracle Support phone number.

For more information on logging a media request SR, go to My Oracle Support for Document 1071023.1: Requesting Physical Shipment or Download URL for Software Media (<https://support.oracle.com/epmos/faces/DocumentDisplay?id=1071023.1>).

CHAPTER 1

Clinical Data API

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Overview of the Clinical Data API

The Clinical Data API is an application program interface (API) that allows remote users; that is, users who do not have access to the physical machine on which the InForm application is installed, to submit clinical data to the InForm application.

To submit data to the InForm application using the Clinical Data API, you must use an XML format called InForm ODM. InForm ODM is based on the ODM XML schema, and has InForm-specific extensions.

For a description of the supported elements and attributes for InForm ODM, see *ODM Submit elements* (on page 25).

Web service URL

The web service URL must resolve to a study name. Additional study name parameters supplied in the message ensure that the routing is correct.

A web service URL includes the following:

```
http://<fully_qualified_domain_name>:<port>/<study_name>/ws/odmsubmitservice/ODMSubmitService.svc
```

Verifying the installation

- Check IIS to make sure that the Clinical Data API virtual directory was successfully created:
 - a Open the IIS Service Manager.
 - b Navigate to the computer on which the Clinical Data API is installed.
 - c Select **Sites** > **odmsubmitservice_Site**.
 - d In the **Actions** panel, verify that the correct port number is listed under **Browse Web Site**.
- Ensure that you configured the SSL certificate for the Clinical Data API virtual directory.

Using the sample WSDL

To use the WSDL to generate the proxy client code:

- For C#, modify the WSDL in the
<installation_directory>\InForm\ODMSubmitSamplesWebServiceClients\CSClientSample folder by replacing the three instances of **THE_WEB_SERVICE_URL** with a valid URL.
For more information, see *C# example* (on page 5).
- For Java, modify the WSDL in the
<installation_directory>\InForm\ODMSubmitSamplesWebServiceClients\JavaClientSample\META-INF\wsdl folder by replacing the three instances of **THE_WEB_SERVICE_URL** with a valid URL.

For more information, see *Java example* (on page 7).

C# example

```
<?xml version="1.0" encoding="utf-8"?>
<wsdl:definitions xmlns:wsam="http://www.w3.org/2007/05/addressing/metadata"
xmlns:wsap="http://schemas.xmlsoap.org/ws/2004/08/addressing/policy"
xmlns:msc="http://schemas.microsoft.com/ws/2005/12/wsdl/contract"
xmlns:wsp="http://schemas.xmlsoap.org/ws/2004/09/policy"
xmlns:soap="http://schemas.xmlsoap.org/wsdl/soap/" xmlns:wsu="http://docs.oasis-
open.org/wss/2004/01/oasis-200401-wss-wssecurity-utility-1.0.xsd"
xmlns:soap12="http://schemas.xmlsoap.org/wsdl/soap12/"
xmlns:soapenc="http://schemas.xmlsoap.org/soap/encoding/"
xmlns:tns="http://www.phaseforward.com/InForm/ODMSubmit/Extensions/1.0"
xmlns:wsa10="http://www.w3.org/2005/08/addressing"
xmlns:wsaw="http://www.w3.org/2006/05/addressing/wsdl"
xmlns:wsa="http://schemas.xmlsoap.org/ws/2004/08/addressing"
name="ODMSubmitService"
targetNamespace="http://www.phaseforward.com/InForm/ODMSubmit/Extensions/1.0"
xmlns:wsdl="http://schemas.xmlsoap.org/wsdl/">
  <wsp:Policy wsu:Id="ODMSubmitService_policy">
    <wsp:ExactlyOne>
      <wsp:All>
        <sp:TransportBinding
xmlns:sp="http://schemas.xmlsoap.org/ws/2005/07/securitypolicy">
          <wsp:Policy>
            <sp:TransportToken>
              <wsp:Policy>
                <sp:HttpsToken RequireClientCertificate="false" />
              </wsp:Policy>
            </sp:TransportToken>
            <sp:AlgorithmSuite>
              <wsp:Policy>
                <sp:Basic256 />
              </wsp:Policy>
            </sp:AlgorithmSuite>
            <sp:Layout>
              <wsp:Policy>
                <sp:Strict />
              </wsp:Policy>
            </sp:Layout>
            <sp:IncludeTimestamp />
          </wsp:Policy>
        </sp:TransportBinding>
        <sp:SignedSupportingTokens
xmlns:sp="http://schemas.xmlsoap.org/ws/2005/07/securitypolicy">
          <wsp:Policy>
            <sp:UsernameToken
sp:IncludeToken="http://schemas.xmlsoap.org/ws/2005/07/securitypolicy/IncludeTok
en/AlwaysToRecipient">
```

```

        <wsp:Policy>
            <sp:WssUsernameToken10 />
        </wsp:Policy>
    </sp:UsernameToken>
</wsp:Policy>
</sp:SignedSupportingTokens>
<sp:Wss11
xmlns:sp="http://schemas.xmlsoap.org/ws/2005/07/securitypolicy">
    <wsp:Policy />
</sp:Wss11>
<sp:Trust10
xmlns:sp="http://schemas.xmlsoap.org/ws/2005/07/securitypolicy">
    <wsp:Policy>
        <sp:MustSupportIssuedTokens />
        <sp:RequireClientEntropy />
        <sp:RequireServerEntropy />
    </wsp:Policy>
</sp:Trust10>
<wsaw:UsingAddressing />
</wsp:All>
</wsp:ExactlyOne>
</wsp:Policy>
<wsdl:types>
    <schema
targetNamespace="http://www.phaseforward.com/InForm/ODMSubmit/Extensions/1.0/Imp
orts" xmlns="http://www.w3.org/2001/XMLSchema">
        <!-- Specify URL to get XSD for this web service. For example:
https://myvm.mydomain.com:14051/mytrial/ws/odmsubmitservice/ODMSubmitService.svc
?xsd=xsd0 -->
        <import schemaLocation="THE_WEB_SERVICE_URL?xsd=xsd0"
namespace="http://www.phaseforward.com/InForm/ODMSubmit/Extensions/1.0" />
    </schema>
</wsdl:types>
<wsdl:message name="ODMSubmitService_Submit_InputMessage">
    <wsdl:part name="parameters" element="tns:Submit" />
</wsdl:message>
<wsdl:message name="ODMSubmitService_Submit_OutputMessage">
    <wsdl:part name="parameters" element="tns:SubmitResponse" />
</wsdl:message>
<wsdl:message name="ODMSubmitService_Status_InputMessage">
    <wsdl:part name="parameters" element="tns:Status" />
</wsdl:message>
<wsdl:message name="ODMSubmitService_Status_OutputMessage">
    <wsdl:part name="parameters" element="tns:StatusResponse" />
</wsdl:message>
<wsdl:message name="ODMSubmitService_Report_InputMessage">
    <wsdl:part name="parameters" element="tns:Report" />
</wsdl:message>
<wsdl:message name="ODMSubmitService_Report_OutputMessage">
    <wsdl:part name="parameters" element="tns:ReportResponse" />
</wsdl:message>
<wsdl:portType name="ODMSubmitService">
    <wsdl:operation name="Submit">
        <wsdl:input
wsaw:Action="http://www.phaseforward.com/InForm/ODMSubmit/Extensions/1.0/Submit"
message="tns:ODMSubmitService_Submit_InputMessage" />
        <wsdl:output
wsaw:Action="http://www.phaseforward.com/InForm/ODMSubmit/Extensions/1.0/SubmitR
eply" message="tns:ODMSubmitService_Submit_OutputMessage" />
    </wsdl:operation>
    <wsdl:operation name="Status">
        <wsdl:input
wsaw:Action="http://www.phaseforward.com/InForm/ODMSubmit/Extensions/1.0/Status"
message="tns:ODMSubmitService_Status_InputMessage" />
        <wsdl:output
wsaw:Action="http://www.phaseforward.com/InForm/ODMSubmit/Extensions/1.0/StatusR
eply" message="tns:ODMSubmitService_Status_OutputMessage" />
    </wsdl:operation>
    <wsdl:operation name="Report">
        <wsdl:input
wsaw:Action="http://www.phaseforward.com/InForm/ODMSubmit/Extensions/1.0/Report"

```

```

message="tns:ODMSubmitService_Report_InputMessage" />
  <wsdl:output
wsaw:Action="http://www.phaseforward.com/InForm/ODMSubmit/Extensions/1.0/ReportR
eply" message="tns:ODMSubmitService_Report_OutputMessage" />
  </wsdl:operation>
</wsdl:portType>
<wsdl:binding name="ODMSubmitService" type="tns:ODMSubmitService">
  <wsp:PolicyReference URI="#ODMSubmitService_policy" />
  <soap12:binding transport="http://schemas.xmlsoap.org/soap/http" />
  <wsdl:operation name="Submit">
    <soap12:operation
soapAction="http://www.phaseforward.com/InForm/ODMSubmit/Extensions/1.0/Submit"
style="document" />
    <wsdl:input>
      <soap12:body use="literal" />
    </wsdl:input>
    <wsdl:output>
      <soap12:body use="literal" />
    </wsdl:output>
  </wsdl:operation>
  <wsdl:operation name="Status">
    <soap12:operation
soapAction="http://www.phaseforward.com/InForm/ODMSubmit/Extensions/1.0/Status"
style="document" />
    <wsdl:input>
      <soap12:body use="literal" />
    </wsdl:input>
    <wsdl:output>
      <soap12:body use="literal" />
    </wsdl:output>
  </wsdl:operation>
  <wsdl:operation name="Report">
    <soap12:operation
soapAction="http://www.phaseforward.com/InForm/ODMSubmit/Extensions/1.0/Report"
style="document" />
    <wsdl:input>
      <soap12:body use="literal" />
    </wsdl:input>
    <wsdl:output>
      <soap12:body use="literal" />
    </wsdl:output>
  </wsdl:operation>
</wsdl:binding>
<wsdl:service name="ODMSubmitService">
  <wsdl:port name="ODMSubmitService" binding="tns:ODMSubmitService">
    <!-- Specify URL for this web service. For example:
https://myvm.mydomain.com:14051/mytrial/ws/odmsubmitservice/ODMSubmitService.svc
-->
    <soap12:address location="THE_WEB_SERVICE_URL" />
  <wsa10:EndpointReference>
    <!-- Specify URL for this web service. For example:
https://myvm.mydomain.com:14051/mytrial/ws/odmsubmitservice/ODMSubmitService.svc
-->
    <wsa10:Address>THE_WEB_SERVICE_URL</wsa10:Address>
  </wsa10:EndpointReference>
  </wsdl:port>
</wsdl:service>
</wsdl:definitions>

```

Java example

```

<?xml version="1.0" encoding="utf-8"?>
<wsdl:definitions name="ODMSubmitService"
targetNamespace="http://www.phaseforward.com/InForm/ODMSubmit/Extensions/1.0"
xmlns:wsdl="http://schemas.xmlsoap.org/wsdl/"
xmlns:wsa10="http://www.w3.org/2005/08/addressing"
xmlns:tns="http://www.phaseforward.com/InForm/ODMSubmit/Extensions/1.0"
xmlns:wsu="http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-wssecurity-
utility-1.0.xsd" xmlns:wsaw="http://www.w3.org/2006/05/addressing/wsdl"
xmlns:wsp="http://schemas.xmlsoap.org/ws/2004/09/policy"
xmlns:wsap="http://schemas.xmlsoap.org/ws/2004/08/addressing/policy"
xmlns:msc="http://schemas.microsoft.com/ws/2005/12/wsdl/contract"
xmlns:wsam="http://www.w3.org/2007/05/addressing/metadata"
xmlns:wsa="http://schemas.xmlsoap.org/ws/2004/08/addressing"
xmlns:soap="http://schemas.xmlsoap.org/wsdl/soap/"
xmlns:soap12="http://schemas.xmlsoap.org/wsdl/soap12/"
xmlns:soapenc="http://schemas.xmlsoap.org/soap/encoding/">
  <wsp:Policy wsu:Id="ODMSubmitService_policy">
    <wsp:ExactlyOne>
      <wsp:All>
        <sp:SymmetricBinding
xmlns:sp="http://schemas.xmlsoap.org/ws/2005/07/securitypolicy">
          <wsp:Policy>
            <sp:ProtectionToken>
              <wsp:Policy>
                <sp:SecureConversationToken
sp:IncludeToken="http://schemas.xmlsoap.org/ws/2005/07/securitypolicy/IncludeTok
en/AlwaysToRecipient">
                  <wsp:Policy>
                    <sp:RequireDerivedKeys/>
                    <sp:BootstrapPolicy>
                      <wsp:Policy>
                        <sp:SignedParts>
                          <sp:Body/>
                          <sp:Header Name="To"
Namespace="http://www.w3.org/2005/08/addressing"/>
                          <sp:Header Name="From"
Namespace="http://www.w3.org/2005/08/addressing"/>
                          <sp:Header Name="FaultTo"
Namespace="http://www.w3.org/2005/08/addressing"/>
                          <sp:Header Name="ReplyTo"
Namespace="http://www.w3.org/2005/08/addressing"/>
                          <sp:Header Name="MessageID"
Namespace="http://www.w3.org/2005/08/addressing"/>
                          <sp:Header Name="RelatesTo"
Namespace="http://www.w3.org/2005/08/addressing"/>
                          <sp:Header Name="Action"
Namespace="http://www.w3.org/2005/08/addressing"/>
                        </sp:SignedParts>
                        <sp:EncryptedParts>
                          <sp:Body/>
                        </sp:EncryptedParts>
                        <sp:SymmetricBinding>
                          <wsp:Policy>
                            <sp:ProtectionToken>
                              <wsp:Policy>
                                <sp:SpnegoContextToken
sp:IncludeToken="http://schemas.xmlsoap.org/ws/2005/07/securitypolicy/IncludeTok
en/AlwaysToRecipient">
                                  <wsp:Policy>
                                    <sp:RequireDerivedKeys/>
                                  </wsp:Policy>
                                </sp:SpnegoContextToken>
                              </wsp:Policy>
                            </sp:ProtectionToken>
                          <sp:AlgorithmSuite>
                            <wsp:Policy>
                              <sp:Basic256/>
                            </wsp:Policy>
                          </sp:SymmetricBinding>
                        </wsp:Policy>
                      </sp:SecureConversationToken>
                    </wsp:Policy>
                  </sp:IncludeToken>
                </sp:ProtectionToken>
              </wsp:Policy>
            </sp:ProtectionToken>
          </wsp:Policy>
        </sp:SymmetricBinding>
      </wsp:All>
    </wsp:ExactlyOne>
  </wsp:Policy>

```

```

        </wsp:Policy>
      </sp:AlgorithmSuite>
    <sp:Layout>
      <wsp:Policy>
        <sp:Strict/>
      </wsp:Policy>
    </sp:Layout>
    <sp:IncludeTimestamp/>
    <sp:EncryptSignature/>
    <sp:OnlySignEntireHeadersAndBody/>
  </wsp:Policy>
</sp:SymmetricBinding>
<sp:Wss11>
  <wsp:Policy>
    <sp:MustSupportRefKeyIdentifier/>
    <sp:MustSupportRefIssuerSerial/>
    <sp:MustSupportRefThumbprint/>
    <sp:MustSupportRefEncryptedKey/>
  </wsp:Policy>
</sp:Wss11>
<sp:Trust10>
  <wsp:Policy>
    <sp:MustSupportIssuedTokens/>
    <sp:RequireClientEntropy/>
    <sp:RequireServerEntropy/>
  </wsp:Policy>
</sp:Trust10>
</wsp:Policy>
</sp:BootstrapPolicy>
</wsp:Policy>
</sp:SecureConversationToken>
</wsp:Policy>
</sp:ProtectionToken>
<sp:AlgorithmSuite>
  <wsp:Policy>
    <sp:Basic256/>
  </wsp:Policy>
</sp:AlgorithmSuite>
<sp:Layout>
  <wsp:Policy>
    <sp:Strict/>
  </wsp:Policy>
</sp:Layout>
<sp:IncludeTimestamp/>
<sp:EncryptSignature/>
<sp:OnlySignEntireHeadersAndBody/>
</wsp:Policy>
</sp:SymmetricBinding>
<sp:Wss11
xmlns:sp="http://schemas.xmlsoap.org/ws/2005/07/securitypolicy">
  <wsp:Policy>
    <sp:MustSupportRefKeyIdentifier/>
    <sp:MustSupportRefIssuerSerial/>
    <sp:MustSupportRefThumbprint/>
    <sp:MustSupportRefEncryptedKey/>
  </wsp:Policy>
</sp:Wss11>
<sp:Trust10
xmlns:sp="http://schemas.xmlsoap.org/ws/2005/07/securitypolicy">
  <wsp:Policy>
    <sp:MustSupportIssuedTokens/>
    <sp:RequireClientEntropy/>
    <sp:RequireServerEntropy/>
  </wsp:Policy>
</sp:Trust10>
  <wsaw:UsingAddressing/>
</wsp:All>
</wsp:ExactlyOne>
</wsp:Policy>
<wsp:Policy wsu:Id="ODMSubmitService_Submit_Input_policy">
  <wsp:ExactlyOne>

```

```

    <wsp:All>
      <sp:SignedParts
xmlns:sp="http://schemas.xmlsoap.org/ws/2005/07/securitypolicy">
        <sp:Body/>
        <sp:Header Name="To"
Namespace="http://www.w3.org/2005/08/addressing"/>
        <sp:Header Name="From"
Namespace="http://www.w3.org/2005/08/addressing"/>
        <sp:Header Name="FaultTo"
Namespace="http://www.w3.org/2005/08/addressing"/>
        <sp:Header Name="ReplyTo"
Namespace="http://www.w3.org/2005/08/addressing"/>
        <sp:Header Name="MessageID"
Namespace="http://www.w3.org/2005/08/addressing"/>
        <sp:Header Name="RelatesTo"
Namespace="http://www.w3.org/2005/08/addressing"/>
        <sp:Header Name="Action"
Namespace="http://www.w3.org/2005/08/addressing"/>
      </sp:SignedParts>
      <sp:EncryptedParts
xmlns:sp="http://schemas.xmlsoap.org/ws/2005/07/securitypolicy">
        <sp:Body/>
      </sp:EncryptedParts>
    </wsp:All>
  </wsp:ExactlyOne>
</wsp:Policy>
<wsp:Policy wsu:Id="ODMSubmitService_Submit_output_policy">
  <wsp:ExactlyOne>
    <wsp:All>
      <sp:SignedParts
xmlns:sp="http://schemas.xmlsoap.org/ws/2005/07/securitypolicy">
        <sp:Body/>
        <sp:Header Name="To"
Namespace="http://www.w3.org/2005/08/addressing"/>
        <sp:Header Name="From"
Namespace="http://www.w3.org/2005/08/addressing"/>
        <sp:Header Name="FaultTo"
Namespace="http://www.w3.org/2005/08/addressing"/>
        <sp:Header Name="ReplyTo"
Namespace="http://www.w3.org/2005/08/addressing"/>
        <sp:Header Name="MessageID"
Namespace="http://www.w3.org/2005/08/addressing"/>
        <sp:Header Name="RelatesTo"
Namespace="http://www.w3.org/2005/08/addressing"/>
        <sp:Header Name="Action"
Namespace="http://www.w3.org/2005/08/addressing"/>
      </sp:SignedParts>
      <sp:EncryptedParts
xmlns:sp="http://schemas.xmlsoap.org/ws/2005/07/securitypolicy">
        <sp:Body/>
      </sp:EncryptedParts>
    </wsp:All>
  </wsp:ExactlyOne>
</wsp:Policy>
<wsp:Policy wsu:Id="ODMSubmitService_Status_Input_policy">
  <wsp:ExactlyOne>
    <wsp:All>
      <sp:SignedParts
xmlns:sp="http://schemas.xmlsoap.org/ws/2005/07/securitypolicy">
        <sp:Body/>
        <sp:Header Name="To"
Namespace="http://www.w3.org/2005/08/addressing"/>
        <sp:Header Name="From"
Namespace="http://www.w3.org/2005/08/addressing"/>
        <sp:Header Name="FaultTo"
Namespace="http://www.w3.org/2005/08/addressing"/>
        <sp:Header Name="ReplyTo"
Namespace="http://www.w3.org/2005/08/addressing"/>
        <sp:Header Name="MessageID"
Namespace="http://www.w3.org/2005/08/addressing"/>
        <sp:Header Name="RelatesTo"

```

```

Namespace="http://www.w3.org/2005/08/addressing" />
  <sp:Header Name="Action"
Namespace="http://www.w3.org/2005/08/addressing" />
  </sp:SignedParts>
  <sp:EncryptedParts
xmlns:sp="http://schemas.xmlsoap.org/ws/2005/07/securitypolicy">
  <sp:Body/>
  </sp:EncryptedParts>
  </wsp:All>
  </wsp:ExactlyOne>
</wsp:Policy>
<wsp:Policy wsu:Id="ODMSubmitService_Status_output_policy">
  <wsp:ExactlyOne>
  <wsp:All>
  <sp:SignedParts
xmlns:sp="http://schemas.xmlsoap.org/ws/2005/07/securitypolicy">
  <sp:Body/>
  <sp:Header Name="To"
Namespace="http://www.w3.org/2005/08/addressing" />
  <sp:Header Name="From"
Namespace="http://www.w3.org/2005/08/addressing" />
  <sp:Header Name="FaultTo"
Namespace="http://www.w3.org/2005/08/addressing" />
  <sp:Header Name="ReplyTo"
Namespace="http://www.w3.org/2005/08/addressing" />
  <sp:Header Name="MessageID"
Namespace="http://www.w3.org/2005/08/addressing" />
  <sp:Header Name="RelatesTo"
Namespace="http://www.w3.org/2005/08/addressing" />
  <sp:Header Name="Action"
Namespace="http://www.w3.org/2005/08/addressing" />
  </sp:SignedParts>
  <sp:EncryptedParts
xmlns:sp="http://schemas.xmlsoap.org/ws/2005/07/securitypolicy">
  <sp:Body/>
  </sp:EncryptedParts>
  </wsp:All>
  </wsp:ExactlyOne>
</wsp:Policy>
<wsp:Policy wsu:Id="ODMSubmitService_Report_Input_policy">
  <wsp:ExactlyOne>
  <wsp:All>
  <sp:SignedParts
xmlns:sp="http://schemas.xmlsoap.org/ws/2005/07/securitypolicy">
  <sp:Body/>
  <sp:Header Name="To"
Namespace="http://www.w3.org/2005/08/addressing" />
  <sp:Header Name="From"
Namespace="http://www.w3.org/2005/08/addressing" />
  <sp:Header Name="FaultTo"
Namespace="http://www.w3.org/2005/08/addressing" />
  <sp:Header Name="ReplyTo"
Namespace="http://www.w3.org/2005/08/addressing" />
  <sp:Header Name="MessageID"
Namespace="http://www.w3.org/2005/08/addressing" />
  <sp:Header Name="RelatesTo"
Namespace="http://www.w3.org/2005/08/addressing" />
  <sp:Header Name="Action"
Namespace="http://www.w3.org/2005/08/addressing" />
  </sp:SignedParts>
  <sp:EncryptedParts
xmlns:sp="http://schemas.xmlsoap.org/ws/2005/07/securitypolicy">
  <sp:Body/>
  </sp:EncryptedParts>
  </wsp:All>
  </wsp:ExactlyOne>
</wsp:Policy>
<wsp:Policy wsu:Id="ODMSubmitService_Report_output_policy">
  <wsp:ExactlyOne>
  <wsp:All>
  <sp:SignedParts

```

```

xmlns:sp="http://schemas.xmlsoap.org/ws/2005/07/securitypolicy">
  <sp:Body/>
    <sp:Header Name="To"
Namespace="http://www.w3.org/2005/08/addressing"/>
    <sp:Header Name="From"
Namespace="http://www.w3.org/2005/08/addressing"/>
    <sp:Header Name="FaultTo"
Namespace="http://www.w3.org/2005/08/addressing"/>
    <sp:Header Name="ReplyTo"
Namespace="http://www.w3.org/2005/08/addressing"/>
    <sp:Header Name="MessageID"
Namespace="http://www.w3.org/2005/08/addressing"/>
    <sp:Header Name="RelatesTo"
Namespace="http://www.w3.org/2005/08/addressing"/>
    <sp:Header Name="Action"
Namespace="http://www.w3.org/2005/08/addressing"/>
  </sp:SignedParts>
  <sp:EncryptedParts
xmlns:sp="http://schemas.xmlsoap.org/ws/2005/07/securitypolicy">
  <sp:Body/>
  </sp:EncryptedParts>
</wsp:All>
</wsp:ExactlyOne>
</wsp:Policy>
<wsdl:types>
  <schema
targetNamespace="http://www.phaseforward.com/InForm/ODMSubmit/Extensions/1.0/Imp
orts" xmlns="http://www.w3.org/2001/XMLSchema">
  <!-- Specify URL to get XSD for this web service. For example:
https://myvm.mydomain.com:14051/mytrial/ws/odmsubmit/service/ODMSubmitService.svc
?xsd=xsd0 -->
  <import schemaLocation="THE_WEB_SERVICE_URL?xsd=xsd0"
namespace="http://www.phaseforward.com/InForm/ODMSubmit/Extensions/1.0"/>
  </schema>
</wsdl:types>
<wsdl:message name="ODMSubmitService_Submit_InputMessage">
  <wsdl:part name="parameters" element="tns:Submit"/>
</wsdl:message>
<wsdl:message name="ODMSubmitService_Submit_OutputMessage">
  <wsdl:part name="parameters" element="tns:SubmitResponse"/>
</wsdl:message>
<wsdl:message name="ODMSubmitService_Status_InputMessage">
  <wsdl:part name="parameters" element="tns:Status"/>
</wsdl:message>
<wsdl:message name="ODMSubmitService_Status_OutputMessage">
  <wsdl:part name="parameters" element="tns:StatusResponse"/>
</wsdl:message>
<wsdl:message name="ODMSubmitService_Report_InputMessage">
  <wsdl:part name="parameters" element="tns:Report"/>
</wsdl:message>
<wsdl:message name="ODMSubmitService_Report_OutputMessage">
  <wsdl:part name="parameters" element="tns:ReportResponse"/>
</wsdl:message>
<wsdl:portType name="ODMSubmitService">
  <wsdl:operation name="Submit">
    <wsdl:input
wsaw:Action="http://www.phaseforward.com/InForm/ODMSubmit/Extensions/1.0/Submit"
message="tns:ODMSubmitService_Submit_InputMessage"/>
    <wsdl:output
wsaw:Action="http://www.phaseforward.com/InForm/ODMSubmit/Extensions/1.0/SubmitR
eply" message="tns:ODMSubmitService_Submit_OutputMessage"/>
  </wsdl:operation>
  <wsdl:operation name="Status">
    <wsdl:input
wsaw:Action="http://www.phaseforward.com/InForm/ODMSubmit/Extensions/1.0/Status"
message="tns:ODMSubmitService_Status_InputMessage"/>
    <wsdl:output
wsaw:Action="http://www.phaseforward.com/InForm/ODMSubmit/Extensions/1.0/StatusR
eply" message="tns:ODMSubmitService_Status_OutputMessage"/>
  </wsdl:operation>
  <wsdl:operation name="Report">

```



```

        <wsdl:input
wsaw:Action="http://www.phaseforward.com/InForm/ODMSubmit/Extensions/1.0/Report"
message="tns:ODMSubmitService_Report_InputMessage"/>
        <wsdl:output
wsaw:Action="http://www.phaseforward.com/InForm/ODMSubmit/Extensions/1.0/ReportR
eply" message="tns:ODMSubmitService_Report_OutputMessage"/>
        </wsdl:operation>
    </wsdl:portType>
    <wsdl:binding name="ODMSubmitService" type="tns:ODMSubmitService">
        <wsp:PolicyReference URI="#ODMSubmitService_policy"/>
        <soap12:binding transport="http://schemas.xmlsoap.org/soap/http"/>
        <wsdl:operation name="Submit">
            <soap12:operation
soapAction="http://www.phaseforward.com/InForm/ODMSubmit/Extensions/1.0/Submit"
style="document"/>
            <wsdl:input>
                <wsp:PolicyReference URI="#ODMSubmitService_Submit_Input_policy"/>
                <soap12:body use="literal"/>
            </wsdl:input>
            <wsdl:output>
                <wsp:PolicyReference URI="#ODMSubmitService_Submit_output_policy"/>
                <soap12:body use="literal"/>
            </wsdl:output>
        </wsdl:operation>
        <wsdl:operation name="Status">
            <soap12:operation
soapAction="http://www.phaseforward.com/InForm/ODMSubmit/Extensions/1.0/Status"
style="document"/>
            <wsdl:input>
                <wsp:PolicyReference URI="#ODMSubmitService_Status_Input_policy"/>
                <soap12:body use="literal"/>
            </wsdl:input>
            <wsdl:output>
                <wsp:PolicyReference URI="#ODMSubmitService_Status_output_policy"/>
                <soap12:body use="literal"/>
            </wsdl:output>
        </wsdl:operation>
        <wsdl:operation name="Report">
            <soap12:operation
soapAction="http://www.phaseforward.com/InForm/ODMSubmit/Extensions/1.0/Report"
style="document"/>
            <wsdl:input>
                <wsp:PolicyReference URI="#ODMSubmitService_Report_Input_policy"/>
                <soap12:body use="literal"/>
            </wsdl:input>
            <wsdl:output>
                <wsp:PolicyReference URI="#ODMSubmitService_Report_output_policy"/>
                <soap12:body use="literal"/>
            </wsdl:output>
        </wsdl:operation>
    </wsdl:binding>
    <wsdl:service name="ODMSubmitService">
        <wsdl:port name="ODMSubmitService" binding="tns:ODMSubmitService">
            <!-- Specify URL for this web service. For example:
https://myvm.mydomain.com:14051/mytrial/ws/odmsubmitservice/ODMSubmitService.svc
-->
            <soap12:address location="THE_WEB_SERVICE_URL"/>
            <wsa10:EndpointReference>
                <!-- Specify URL for this web service. For example:
https://myvm.mydomain.com:14051/mytrial/ws/odmsubmitservice/ODMSubmitService.svc
-->
                <wsa10:Address>THE_WEB_SERVICE_URL</wsa10:Address>
            <Identity
xmlns="http://schemas.xmlsoap.org/ws/2006/02/addressingidentity">
                <Upn>SLC05GQL\PfUSR_SLC05GQL</Upn>
            </Identity>
            </wsa10:EndpointReference>
        </wsdl:port>
    </wsdl:service>
</wsdl:definitions>

```

Creating the Clinical Data API user

To access the web service interfaces and to use the Clinical Data API, you must be an InForm Integration user with the ODM Submit right.

For more information, see the *User Guide*.

Sample programs for ODM Submit

Sample programs with source for C# and Java are available in the following directory:

- **C# sample programs—**
<installation_directory>\InForm\ODMSubmitSamples\WebServiceClients\CClientSample
- **Java sample programs—**
<installation_directory>\InForm\ODMSubmitSamples\WebServiceClients\JavaClientSample

These programs demonstrate communications with the ODM Submit web service, and can be used as a reference as you create a file to submit using the Clinical Data API.

Message format

Each request is enclosed in a SOAP envelope that begins with a SOAP header, followed by a Body statement that contains the web method, and its input parameters and values.

SOAP header

The SOAP header contains information about the service, the message, and the sender credentials. It must include all the fields in the following table.

Note: The requirement for requests to contain the `wsu:Timestamp`, `wsse:Username`, and `wsse:Password` elements are defined in the WSDL by `ws-policy`. If your web service toolkit does not support `ws-policy`, you must manually add these elements to the web service request.

ODM Submit— SOAP Header		
Field	Description	Standard
<code>wsa:Action</code>	SOAP action for the operation. Include this field as part of the summary for each SOAP operation.	WS-Addressing
<code>wsa:MessageID</code>	Unique ID for the message.	WS-Addressing
<code>wsa:ReplyTo</code>	Specify the following value: <pre><wsa:ReplyTo xmlns:wsa="http://www.w3.org/2005/08/addressing"> <wsa:Address>http://www.w3.org/2005/08/addressing/anonymous</wsa:Address> </wsa:ReplyTo></pre>	WS-Addressing
<code>wsa:To</code>	Full URL of the service.	WS-Addressing
<code>wsu:Timestamp</code>	Time when the message was created and when it expires. Oracle recommends a five minute time window. The software allows for five minutes of clock drift between servers. To modify this value in the <code>web.config</code> file, set the <code>MaxClockSkew</code> value.	SOAP Message Security 1.0
<code>wsse:Username</code>	User name of the user in the InForm study. This user must be assigned the Integration user type.	SOAP Message Security 1.0
<code>wsse:Password</code>	Password of the user in the InForm study. This user must be assigned the Integration user type.	SOAP Message Security 1.0

Web service interface methods

The Clinical Data API has three methods, which support:

- Clinical data submission.
For more information, see *ODM Submit—Submission messages* (on page 17).
- Summary reporting for each ODM Submit document that was processed.
For more information, see *ODM Submit—Document status messages* (on page 19).
- Historical data reporting.
For more information, see *ODM Submit—Report messages* (on page 21).

The web service methods are synchronous for the remote client. Remote clients send request messages, and the web service returns a response message for each request that indicates success or identifies errors that occurred.

ODM Submit—Submission messages

The WSODMXMLSubmit method accepts incoming messages to be processed by the Clinical Data API. It has two formats:

- Request format—For submitting data.
For more information, see *SOAP body for Request message—Submissions* (on page 17).
- Response format—For returning the submit status of the operation.
For more information, see *Response XML format—Submissions* (on page 18).

SOAP body for Request message—Submissions

Request message parameters	
Name	Description
TrialName	Name of the study to which to submit data.
SSOTenant	For Oracle-hosted, single sign-on studies, the customer identifier used to scope the credential in the single sign-on environment to a specific customer.
OrgID	User Organizational ID. <ul style="list-style-type: none"> • For Oracle-hosted, single sign-on studies, this field is required. • For InForm native authentication, this field must be blank..
UserName	User name of the InForm user who is submitting the clinical data.
UserPassword	Password of the InForm user who is submitting the clinical data.

Request message parameters	
Name	Description
RulesEnabled	Specifies whether rules should be executed when processing clinical data. <ul style="list-style-type: none"> • True—Execute rules. • False—Do not execute rules.
StopOnError	Specifies the action to take if a submit operation fails during processing. <ul style="list-style-type: none"> • True—Stop processing. • False—Continue processing the document.
SubmitToLockedOrFrozenForms	Allows data to be submitted to locked or frozen forms.
ODMSubmitDocument	String text for the ODM Submit XML document.
ODMSubmitdocumentID	ODM Submit document unique identifier.
WCFUsername	User name of the InForm user who is submitting the clinical data. This user must be assigned the Integration user type.
WCFPassword	Password of the InForm user who is submitting the clinical data. This user must be assigned the Integration user type.

Response XML format—Submissions

Response message parameters	
Name	Description
WSODMXMLSubmitResult	Top-level element with the PROCESSED attribute, which indicates whether the request was processed. <ul style="list-style-type: none"> • TRUE—Request was processed successfully. The SubmitStatus parameter appears and displays text that indicates that the request was processed. • FALSE—Request was not processed successfully. The Error parameter appears and displays text that indicates why the request was not processed.
Error	Appears if the PROCESSED attribute for WSODMxmlSubmitResult is set to FALSE. Contains information about why the web message could not be processed.

Response message parameters	
Name	Description
SubmitResults	<p>Appears if the PROCESSED attribute for WSODMXmlSubmitResult is set to TRUE.</p> <p>Contains the FileOID, ReceivedDateTime, and ProcessStartDateTime.</p>
SubmitStatus	<p>Appears if the PROCESSED attribute for WSODMXmlSubmitResult is set to TRUE.</p> <p>Contains the FileOID, ReceivedDateTime, and ProcessStartDateTime.</p>
SubmitReport	<p>Appears if the PROCESSED attribute for WSODMXmlSubmitResult is set to TRUE.</p> <p>Contains the FileOID, ReceivedDateTime, and ProcessStartDateTime.</p>
MessageID	<p>HRESULT error code, which can occur at the web service or the Clinical Data API interface.</p> <p>Note: Appears only when the STATUS attribute for SubmitStatus is set to FAILED.</p>
Message	<p>English text of the MessageID.</p> <p>Note: Appears only when the STATUS attribute for SubmitStatus is set to FAILED.</p>
ActivityGUID	<p>Corresponds to the InForm ActivityGUID when an error appears in the event log.</p> <p>Note: Appears only when the STATUS attribute for SubmitStatus is set to FAILED.</p>

ODM Submit—Document status messages

The WSODMXMLSubmitStatus method accepts an ODMSubmitDocumentID (FileOID in ODM terminology) and returns a summary status for the FileOID.

SOAP body for Request messages—Document status

Request message parameters	
Name	Description
TrialName	Name of the study to which to submit data.
SSOTenant	For Oracle-hosted, single sign-on studies, the customer identifier used to scope the credential in the single sign-on environment to a specific customer.
OrgID	User Organizational ID. <ul style="list-style-type: none"> For Oracle-hosted, single sign-on studies, this field is required. For InForm native authentication, this field must be blank.
UserName	User name of the InForm user who is submitting the clinical data.
UserPassword	Password of the InForm user who is submitting the clinical data.
ODMSubmitDocumentID	ODM Submit document unique identifier.
WCFUsername	User name of the InForm user who is submitting the clinical data. This user must be assigned the Integration user type.
WCFPassword	Password of the InForm user who is submitting the clinical data. This user must be assigned the Integration user type.

Response XML format—Document status

Response message parameters	
Name	Description
WSODMXMLSubmitResult	<p>Top-level element with the PROCESSED attribute, which indicates whether the request was processed.</p> <ul style="list-style-type: none"> TRUE—Request was processed successfully. The SubmitStatus parameter appears and displays text that indicates that the request was processed. FALSE—Request was not processed successfully. The Error parameter appears and displays text that indicates why the request was not processed.

Response message parameters

Error	Appears if the PROCESSED attribute for WSODMXmlSubmitResult is set to FALSE. Contains information about why the web message could not be processed.
SubmitStatus	Appears if the PROCESSED attribute for WSODMXmlSubmitResult is set to TRUE. Contains the FileOID, ReceivedDateTime, and ProcessStartDateTime.

ODM Submit—Report messages

The WSODMXMLSubmitSummary method accepts an ODMSubmitDocumentID (FileOID in ODM terminology), and returns a summary status, and if available, a complete list of individual submit statuses.

This method is primarily used for remote clients to diagnose submit operations.

Note: The individual submit commands may not be available if you executed the XmlSubmitPurgeRecords stored procedure to remove the detailed submit records from the logging facility. For more information, see *Removing Clinical Data API records* (on page 22).

SOAP body for Request messages—Reports

Request message parameters

Name	Description
TrialName	Name of the study to which to submit data.
SSOTenant	For Oracle-hosted, single sign-on studies, the customer identifier used to scope the credential in the single sign-on environment to a specific customer.
OrgID	User Organizational ID. <ul style="list-style-type: none"> For Oracle-hosted, single sign-on studies, this field is required. For InForm native authentication, this field must be blank.
UserName	User name of the InForm user who is submitting the clinical data.
UserPassword	Password of the InForm user who is submitting the clinical data.
ODMSubmitDocumentID	ODM Submit document unique identifier.
WCFUsername	User name of the InForm user who is submitting the clinical data. This user must be assigned the Integration user type.

Request message parameters	
Name	Description
WCFPassword	Password of the InForm user who is submitting the clinical data. This user must be assigned the Integration user type.

Response XML format—Reports

Response message parameters	
Name	Description
WSODMXMLSubmitResult	<p>Top-level element with the PROCESSED attribute, which indicates whether the request was processed.</p> <ul style="list-style-type: none"> • TRUE—Request was processed successfully. The SubmitStatus parameter appears and displays text that indicates that the request was processed. • FALSE—Request was not processed successfully. The Error parameter appears and displays text that indicates why the request was not processed.
Error	<p>Appears if the PROCESSED attribute for WSODMXmlSubmitResult is set to FALSE.</p> <p>Contains information about why the web message could not be processed.</p>
SubmitStatus	<p>Appears if the PROCESSED attribute for WSODMXmlSubmitResult is set to TRUE.</p> <p>Contains the FileOID, ReceivedDateTime, and ProcessStartDateTime.</p>

Removing Clinical Data API status records

You can use the `XmlSubmitPurgeRecords` stored procedure, which exists in the study schema, to remove Clinical Data API status records that were submitted prior to a specified date.

- To execute `XmlSubmitPurgeRecords`, use the following syntax:

```
XmlSubmitPurgeRecords (LastProcessingDate IN DATE)
```

where:

- **IN DATE**—Parameter you need to pass the command. Specify a date in the `IN DATE` parameter, and the `XmlSubmitPurgeRecords` procedure removes the status records that were submitted before that date.

The date must use the format `yyyy-mm-dd hh:mm:ss`. For example, to remove status records prior to February 28, 2014 at 12:30 pm, enter **2014-02-28 12:30:00**.

Note: If you run the `XmlSubmitPurgeRecords` stored procedure, you cannot access detailed information regarding individual status records prior to the date you entered in the `IN DATE` parameter. You can access only a summary of submits.

CHAPTER 2

ODM Submit elements

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About ODM Submit schema elements

The ODM Submit utility supports the use of CDISC standard ODM 1.3 elements and ODM elements with InForm-specific extensions. The prefix **pf:** identifies InForm-specific extensions.

Notes:

- You must escape all attributes.
- You must escape element contents or enclose them in a CDATA section.
- The first line of the file must be an XML tag that specifies the file encoding. Only UTF-8 encoding is supported, so the first line of the file must be:

```
<?xml version="1.0" encoding="UTF-8"?>
```
- If an unsupported attribute or element is present, an error message is generated and the ODM is not submitted.

Missing and empty data values

When you submit data for a control, some of the control data might not be available. For a control with missing data, you can do one of the following:

- Exclude the ItemData element for a control for which data was not collected.
- Set the IsNull attribute for the control to Yes if data was collected but then cleared, or to clear data for the control.

Note: If you specify the IsNull attribute, you cannot specify the Value attribute for the control.

Units and normalized values

For a control that contains unit information, you can specify the unit value using the MeasurementUnitRef attribute of the ItemData element. However, you cannot specify a normalized value for the unit.

You can also exclude a unit value for a control that contains unit information. However, if you do not specify a unit the control is marked as incomplete in the InForm application.

Supported elements and attributes

Annotation (Comment)

Use to submit comments and incomplete reasons. The Annotation element can appear as a sub-element of:

- **ItemData**—For an item-level comment.
For an item-level comment, the ItemData element in which you contain the annotation must point to an item, not a control in an item. For more information, see *ItemData* (on page 35).
- **FormData**—For a form-level comment.
- **Association**
For more information, see *Annotation (Sub-element of Association)* (on page 30).

Example

```
<Annotation SeqNum="1" pf:DBUID="30087"
  pf:GUID="{885FAAB2-3997-482E-9179-97560DAA33B2}">
  <Comment>item comment when item has many sub-controls</Comment>
</Annotation>
```

Supported sub-elements

- **Comment**—Optional.
Zero or one instance.
- **pf:ReasonIncomplete**—Optional.
Zero or one instance.

Supported attributes

- **SeqNum**—Required. Must be 1.

Unsupported elements

- **Flag**
- **pf:AnnotationAuditData**
- **pf:AnnotationAuditRecord**

Unsupported attributes

- **TransactionType**
- **pf:DBUID**
- **pf:GUID**

Annotation (Sub-element of Association)

Sub-element of Association.

Example

```
<Annotation SeqNum="33663" pf:DBUID="33663" pf:GUID="{E34262AA-A279-4BA4-
B8BA-DDABE6CC52BB}">
  <Comment>PF Association</Comment>
  <Flag>
    <FlagValue CodeListOID="AssociationAction">Add</FlagValue>
    <FlagType CodeListOID="FlagType">Association</FlagType>
  </Flag>
</Annotation>
```

Supported sub-elements

- Flag—Required.

The Flag sub-element must have the sub-element FlagValue with CodeListOID=AssociationAction. AssociationAction can have a value of Add or Remove.

Association

Used to add or remove associations between repeating forms. The Association element is a sub-element of the top-level ODMSubmit element.

Example

```
<Association StudyOID="Depression Study"
  MetadataVersionOID="StudyVersion_ODMTEST03">
  <KeySet StudyOID="Depression Study"
    SubjectKey="29530"
    StudyEventOID="Visit1" StudyEventRepeatKey="342216927026073"
    FormOID="LAE1" FormRepeatKey="343316719654073" />
  <KeySet StudyOID="Depression Study"
    SubjectKey="29530"
    StudyEventOID="Visit1" StudyEventRepeatKey="342216927026073"
    FormOID="L_ConMeds" FormRepeatKey="343316927026073" />
  <Annotation SeqNum="33663" pf:DBUID="33663" pf:GUID="{E34262AA-A279-4BA4-
B8BA-DDABE6CC52BB}">
    <Comment>PF Association</Comment>
    <Flag>
      <FlagValue CodeListOID="AssociationAction">Add</FlagValue>
      <FlagType CodeListOID="FlagType">Association</FlagType>
    </Flag>
  </Annotation>
</Association>
```

Supported sub-elements

- KeySet—Required.
Exactly two occurrences.
- Annotation—Required.
Exactly one occurrence.

Supported attributes

- StudyOID—Required.
Study name. Must be current and must match the value specified in the STUDYNAME attribute of the STUDYVERSION MedML element.
- MetadataVersionOID—Required.
Study version that is assigned to the site. This does not have to be the current study version.

Unsupported elements and attributes

- None.

pf:Candidate

Allows you to perform an enrollment override for a subject.

Example

```
<pf:Candidate EnrollmentOverride="Date: 11/9/2011 At: 02:03 Monitor: Louise Hill Title: CRA Reason: Subject nearly met criteria" />
```

Supported sub-elements

- None

Supported attributes

- EnrollmentOverride—Required.
Specify the reason for the enrollment override.

Unsupported elements

- AuditRecord

Unsupported attributes

- pf:DateOfBirth
- pf:EnrollmentFailure
- pf:EnrollmentNumber
- pf:PatientNumber
- pf:PatientRevision
- pf:ScreeningDate
- pf:ScreeningFailure
- pf:ScreeningNumber
- pf:SubjectInitials

ClinicalData

Use to submit data for one or more subjects, each in its own SubjectData sub-element.

Example

```
<ClinicalData StudyOID="Depression Study" MetaDataVersionOID="Study Version 1"
  pf:TransactionGuid="{69B04136-0872-464A-8870-A0BDA864943C}">
  <SubjectData ... details omitted
</ClinicalData>
```

Supported sub-elements

- SubjectData—Optional.
Zero or more instances. Each instance corresponds to a subject.

Supported attributes

- StudyOID—Required.
Study name. Must be current and must match the value specified in the STUDYNAME attribute of the STUDYVERSION MedML element.
- MetaDataVersionOID—Required.
Study version that is assigned to the site. This does not have to be the current study version.

Comment

Sub-element of the Annotation element, used to enter or edit item and form comments.

Example

```
<Comment>item comment when item has many sub-controls</Comment>
```

Supported sub-elements

- None.

Supported attributes

- None.

Unsupported elements

- None.

Unsupported attributes

- SponsorOrSite

FormData

Sub-element of the StudyEventData element. Use the FormData element to enter or edit data for one form instance for one subject.

Supported sub-elements

- Annotation—Optional.
Zero or one instance.
- ItemGroupData—Optional.
Zero or more instances.
- pf:FormStatus—Optional.
Zero or one instance.

Supported attributes

- FormOID—Required.
Form RefName.
- FormRepeatKey—Required for repeating forms.
 - For non-repeating forms—Do not use.
 - For repeating forms—Required.
A non-null string that identifies the repeating form instance uniquely within the subject visit instance.

- pf:FormRepeatKeyOrdinal—Optional.
 - For non-repeating forms—Do not use.
 - For repeating forms—Optional.

The 1-based ordinal of the repeating form instance. When computing an ordinal, the calculation counts each instance of the repeating form within a visit instance for a subject, including repeating forms that did not use the pf: FormRepeatKeyOrdinal attribute, and deleted repeating form instances.

Unsupported elements

- ArchiveLayoutRef
- AuditRecord
- Signature
- pf:FormAuditData
- pf:PFFormSignatures

Unsupported attributes

- TransactionType

pf:FormStatus

An InForm-specific sub-element of FormData, used to specify the form status for a single form instance.

Supported sub-elements

- None.

Supported attributes

- Frozen—Optional.
- Locked—Optional.
- Deleted—Optional.
 - Yes—Delete a repeating form.
 - No—Undelete a repeating form.

- SVReady—Optional.

Unsupported elements

- AuditRecord

Unsupported attributes

- pf:Activated
- pf:ReviewStateRevision
- pf:Signed
- pf:SVComplete
- pf:SVPartial
- pf:SVSelected

ItemData

Sub-element of the ItemGroupData element, used to specify an item comment or the value of an item or control.

Example

```
<ItemData ItemOID="frmDOV.DOV.DOV.DOV"
  Value="2011-10-19T09:17">
</ItemData>
```

Supported sub-elements

- MeasurementUnitRef—Optional.
Zero or one instance.
- Annotation—Optional.
Zero or one instance.

Supported attributes

- ItemOID—Required.
The RefName path from the form to the item or control.
 - For a non-repeating item—FORM.SECTION.ITEM.[CONTROL]
 - For an item in an itemset—FORM.SECTION.ITEMSET.ITEM.[CONTROL]

Note: The ItemData element is contained in the ItemGroupData element, which also has a RefName path; the two paths must not conflict.

- Value—Optional.
The value for the item, control, or comment.
- pf:FormattedDateValue—Optional.
Indicates whether a date component without a specified value is empty or is set to Unknown.
If you use both the Value attribute and the pf:FormattedDateValue attribute:
 - The parts of the date that you supply in the Value attribute must exactly match the value in the pf:FormattedDateValue attribute.
 - The parts of the date that are unspecified in the Value attribute must be unspecified in pf:FormattedDateValue. However, in the pf:FormattedDateValue attribute, unspecified date parts are identified as either **No value supplied** or **Date part unknown**.

Unsupported elements

- AuditRecord
- Signature

Unsupported attributes

- IsNull
- pf:ItemAuditData
- pf:NormalizedValue
- pf:ReasonIncomplete
- pf:TransactionType

pf:FormattedDateValue

Indicates whether a date component without a specified value is empty or is set to Unknown.

If you use both the Value attribute and the pf:FormattedDateValue attribute:

- The parts of the date that you supply in the Value attribute must exactly match the value in the pf:FormattedDateValue attribute.
- The parts of the date that are unspecified in the Value attribute must be unspecified in pf:FormattedDateValue. However, in the pf:FormattedDateValue attribute, unspecified date parts are identified as either **No value supplied** or **Date part unknown**.

The following example shows a date/time control where the month and hour are Unknown, and the day and minute are not entered:

```
<ItemData ItemOID="frmA.sctB.itmC.dtcDateD "  
Value="2015----T--:"  
pf:FormattedDateValue="2015-UNK-NULTUNK:NUL:NUL" />
```

The pf:FormattedDateValue element allows you to specify the value UNK for parts that are Unknown and NUL for parts that were not specified.

ItemGroupData

Sub-element of the FormData element. Use the ItemGroupData element to enter data for one section of a form instance.

Example

```
<ItemGroupData ItemGroupOID="frmDOV.DOV">
  <ItemData ItemOID="frmDOV.DOV.DOV.DOV"
    Value="2011-10-19T09:17">
  </ItemData>
</ItemGroupData>
```

Supported sub-elements

- ItemData—Optional.
Zero or many instances, in any order.
- pf:ItemStatus—Optional.
Zero or one instance.

Supported attributes

- ItemGroupOID—Required.

RefName path of the item into which to enter data:

- For a non-repeating item—FORM.SECTION
- For an itemset—FORM.SECTION.ITEMSET

The ItemGroupData element is a sub-element of the FormData element, which specifies the form RefName. The form RefName that you specify in the FormData element must match the form RefName that you specify in the ItemGroupOID attribute.

- ItemGroupRepeatKey—Optional.
 - For a non-repeating item—Not required.
 - For an item in an itemset—Required.
A non-null string that uniquely identifies an itemset row within a form instance.

- pf:ItemGroupRepeatKeyOrdinal—Optional.

The 1-based ordinal value of the itemset row in the form instance. Each row in the itemset is counted when computing an ordinal, including prior rows that did or did not use the pf:ItemGroupRepeatKeyOrdinal attribute, and deleted Add Entry itemset rows.

Unsupported elements

- AuditRecord
- Signature
- TransactionType
- pf:InFormItemData
- pf:Query

pf:ItemStatus

Sub-element of the ItemGroupData element.

Example

```
<pf:ItemStatus Deleted="No">
</pf:ItemStatus>
```

Supported sub-elements

- None

Supported attributes

- Deleted—Required.
 - Yes—Delete an Add Entry itemset row.
 - No—Undelete an Add Entry itemset row.

KeySet

Sub-element of the Association element. One occurrence per form is required.

Example

```
<Association StudyOID="Depression Study"
  MetadataVersionOID="StudyVersion_ODMTEST03">
  <KeySet StudyOID="Depression Study"
    SubjectKey="29530"
    StudyEventOID="Visit1" StudyEventRepeatKey="342216927026073"
    FormOID="LAE1" FormRepeatKey="343316719654073" />
  <KeySet StudyOID="Depression Study"
    SubjectKey="29530"
    StudyEventOID="Visit1" StudyEventRepeatKey="342216927026073"
    FormOID="L_ConMeds" FormRepeatKey="343316927026073" />
  <Annotation SeqNum="33663" pf:DBUID="33663" pf:GUID="{E34262AA-A279-4BA4-
  B8BA-DDABE6CC52BB}">
    <Comment>PF Association</Comment>
    <Flag>
      <FlagValue CodeListOID="AssociationAction">Add</FlagValue>
      <FlagType CodeListOID="FlagType">Association</FlagType>
    </Flag>
  </Annotation>
</Association>
```

Supported attributes

- StudyOID—Required.
- SubjectKey—Required.
- SubjectKeyType—Optional.
GUID (the default) or SubjectNumber.
- StudyEventOID—Required.
Visit RefName.
- StudyEventRepeatKey—Required for repeating visits only.
- FormOID—Required.
Form RefName.
- FormRepeatKey—Required.

ODMSubmit

The top-level element of an ODM document. The ODMSubmit element has several defined sub-elements, but only ClinicalData is supported for the InForm ODM format.

Example

```
<ODMSubmit Description="Depression Study" FileType="Transactional"
  pf:HierarchicalOIDs="Yes"
  xmlns="http://www.cdisc.org/ns/odm/v1.3"
  xmlns:pf="http://www.phaseforward.com/InFormAdapter/ODM/Extensions/2.0">
  <ClinicalData ... details omitted
</ODMSubmit>
```

Supported sub-elements

- ClinicalData—Optional.
Zero or more instances.

Supported attributes

- ODMVersion—Required.
ODM version number. Must be 1.3.1.
- FileType—Required.
Type of the file. Must be Transactional.
- FileOID—Required.
Uniquely identifies each distinct ODM bit.
- PriorFileOID—Optional.
Allows you to uniquely order ODM bits.
The specified PriorFileOID must match the FileOID of an ODM bit that was previously processed. If it does not, the submit action fails.
- CreationDateTime—Required but is not used by the Clinical Data API.
Date and time of creation.
- pf:HierarchicalOIDs—Required.
Must be Yes.

Unsupported elements

- AdminData
- ReferenceData
- Study

Unsupported attributes

- Archival
- AsOfDateTime
- Association
- Description
- Granularity
- Id
- Originator
- SourceSystem
- SourceSystemVersion
- pf:InFormAdapterVersion

- pf:MappingVersion

pf:ReasonIncomplete

Custom InForm sub-element of the Annotation element, used to specify a reason for marking an item or form as incomplete.

To specify a reason for data incompleteness, include the selection value of the incomplete reason control on the form in the body of the pf:ReasonIncomplete element, not as an attribute.

Example

```
<pf:ReasonIncomplete
  CodeListOID="ReasonIncomplete">NAElement</pf:ReasonIncomplete>
```

Supported sub-elements

- None

Supported attributes

- CodeListOID—Required.
Must be ReasonIncomplete.

SiteRef

Identifies a site within the study.

Example

```
<SiteRef LocationOID="BID" />
```

Supported sub-elements

- None

Supported attributes

- LocationOID—Required.
Must be the site mnemonic.

StudyEventData

Sub-element of the SubjectData element, used to specify a single visit instance for one subject.

Example

```
<StudyEventData StudyEventOID="vstUnschVisit1"  
  StudyEventRepeatKey="3">  
  <FormData FormOID="frmDOVRFI">  
    ...Details omitted  
  </FormData>  
</StudyEventData>
```

Supported sub-elements

- FormData—Optional.
Zero or more instances.

Supported attributes

- StudyEventOID—Required.
RefName of the visit.
- StudyEventRepeatKey—Optional.
 - For a non-repeating visit—Do not use.
 - For a repeating visit—Required.
A non-null string that uniquely identifies a given instance of the repeating visit for the subject.
- pf:StudyEventRepeatKeyOrdinal—Optional.
 - For a non-repeating visit—Do not use.
 - For a repeating visit—Required.
The 1-based ordinal index of the repeating visit for the subject.

Unsupported elements

- Annotation
- AuditRecord
- Signature

Unsupported attributes

- TransactionType
- pf:Deleted

SubjectData

Sub-element of the ClinicalData element, used to specify data for one subject.

Example

```
<SubjectData TransactionType="Upsert"
  SubjectKey="{B6E65FC3-0E73-4DA9-898A-8A11D6BCC3B5}">
  <SiteRef LocationOID="BID" />
  <StudyEventData StudyEventOID="vstCORE2" />
</SubjectData>
```

Supported sub-elements

- SiteRef—Required.

Zero or one instance. Defines the site for the subject.

The SiteRef element is optional in the ODM schema, but is required for InForm ODM input.

To transfer a subject to a new site, use the SubjectData element and specify the new site data in the SiteRef sub-element.

- StudyEventData—Optional.

Zero or more instances. Contains data for one visit instance.

- pf:Candidate—Optional.

Zero or one instance.

- pf:SubjectStatus—Optional.

Zero or one instance.

Supported attributes

- SubjectKey—Required.

Unique identifier for the subject. For more information, see *SubjectKey and SubjectKeyType attributes* (on page 44).

- SubjectKeyType—Optional.

Type of key specified in the SubjectKey attribute. For more information, see *SubjectKey and SubjectKeyType attributes* (on page 44).

Unsupported elements

- Annotation
- AuditRecord
- InvestigatorRef
- Signature
- StudyEventStatus

Unsupported attributes

- TransactionType
- pf:GUID

pf:SubjectStatus

Used to set the status for a subject.

Example

```
<pf:SubjectStatus State="Enrolled">  
</pf:SubjectStatus>
```

Supported sub-elements

- None

Supported attributes

- Frozen—Optional.
- Locked —Optional.
- SVReady—Optional.
- EnrollOverrideReason—Optional.
- State—Optional.

Set to Enrolled to enroll a subject.

You cannot use the State attribute to set the subject to the following states, which are set by the InForm application, depending on data entered on a form:

- ScreenFailed
- Screened
- EnrollmentFailed
- Randomized
- Complete
- DroppedOut

SubjectKey

Attribute of the SubjectData element, used to identify a subject. Specify one of the following:

- **GUID**—Unique, unchanging string identifier for a subject in a study. The GUID must be a Unicode string that uses fewer than 255 bytes in the database UTF-8 character set.
 - For an existing subject, use the subject GUID that exists in the InForm database.
 - For a new subject, specify a GUID to use for the subject.
- **Subject Number**—Subject number that appears in the InForm user interface to identify an enrolled subject. You can only specify a SubjectNumber for the SubjectKey attribute if you are entering data for an existing subject.

Note: Ensure that you specify the current Subject Number for the subject.

SubjectKeyType

Attribute of the SubjectData element, used to specify the type of subject identification used in the SubjectKey attribute. The options are:

- GUID (the default)
- InForm Subject Number

Value

Attribute of the ItemData element, used to specify the value for a control.

The value that you specify for the Value attribute must match the data in the ItemData element. The Value attribute is verified against the type of the ItemData, and if it is incorrect, an error occurs.

Value attribute for text controls

Use the Value attribute to specify the text to enter in a text control, using XML escaping if necessary.

When you enter a value for a text control, ensure that the text conforms to the following MedML attributes specified for the control:

- MAXLENGTH
- DATATYPE
- MINVALUE
- MAXVALUE
- PRECISION
- CHARSET

For example, to enter text in the text box sub-controls for checkboxes 1 and 3, use the following:

```
<ItemData ItemOID="frmA.sctB.itmC.MULTICB.SELECT1.TEXT1" Value="text value 1"/>
<ItemData ItemOID="frmA.sctB.itmC.MULTICB.SELECT3.TEXT3" Value="text value 3"/>
```

Value attribute for pulldown controls

Use the Value attribute to specify the value for a pulldown control (drop-down list).

Value attribute for radio controls

Use the Value attribute to select a radio button in a radio control.

For example, to select the sub-control with selection value 2 in a radio control, use the following:

```
<ItemData ItemOID="frmA.sctB.itmC.radioD" Value="2"/>
```

To clear the selection, use the following:

```
<ItemData ItemOID="frmA.sctB.itmC.radioD" IsNull="Yes"/>
```

Value attribute for date/time controls

Use the Value attribute to enter a date and time in a date/time control, if the following is true:

- You know all of the required components in the control.

If you specify an incomplete date and time in the Value attribute, the missing date components are represented with a single dash (-) and are treated as not entered in the InForm application.

- You do not need to distinguish between components that are not entered and that are entered as Unknown.

If you do not know all of the required components, or need to distinguish between components that are not entered and those that are entered as Unknown, use the `pf:FormattedDateValue` attribute instead of the Value attribute. For more information, see *pf:FormattedDateValue* (on page 36).

The value that you enter for a date/time control must conform to the:

- MedML attributes for the control.
- ISO 8601 standard.

For example, to specify the value October 21, 2011 at 12:44, use the following:

```
<ItemData ItemOID="frmA.sctB.itmC.dtcDateD" Value="2011-10-21T12:44" />
```

Value attribute for checkbox controls

Use the Value attribute to select or deselect a checkbox control.

For example, to select checkboxes 1 and 3 in an item with checkbox controls, use the following:

```
<ItemData ItemOID="frmA.sctB.itmC.MULTICB.SELECT1" Value="SELECT1" />
<ItemData ItemOID="frmA.sctB.itmC.MULTICB.SELECT3" Value="SELECT3" />
```

To nullify the selection of checkbox 1 set the IsNull attribute to True for checkbox 1 and use the Value attribute to select checkbox 2:

```
<ItemData ItemOID="frmA.sctB.itmC.MULTICB.SELECT1" IsNull="true" />
<ItemData ItemOID="frmA.sctB.itmC.MULTICB.SELECT2" Value="SELECT2" />
```

Value attribute for group controls

A group control has one or more sub-controls. You can submit data to a sub-control using the ItemData element, but you cannot submit data to the parent control.

For example, to enter data for the first and third text box sub-controls in a group control, use the following:

```
<ItemGroupData ItemGroupOID="frmECG.sctECG">
<ItemData ItemOID="frmECG.sctECG.itml.gc1.txtSample1" Value="xyz" />
<ItemData ItemOID="frmECG.sctECG.itml.gc1.txtSample3" Value="abc" />
</ItemGroupData>
```

To remove the value for the first text box sub-control and add a value to the second text box sub-control, use the following:

```
<ItemGroupData ItemGroupOID="frmECG.sctECG">
<ItemData ItemOID="frmECG.sctECG.itml.gc1.txtSample1" IsNull="true" />
<ItemData ItemOID="frmECG.sctECG.itml.gc1.txtSample2" Value="pqr" />
</ItemGroupData>
```

CHAPTER 3

Running the ODM Submit utility from the command line

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ODM Submit utility command line parameters

Local users can run the ODM Submit utility from the command line to submit clinical data to the InForm application in InForm ODM format. To run the ODM Submit utility from the command line, use the following parameters.

Parameter	Variable	Description
ODMSubmit.exe		Starts the ODM Submit utility.
-trialname	<i>trialname</i>	Full pathname of the study into which you are importing data.
/accountparams "path_to_password_file"		<p>When specified, includes the path to a text file that contains the user name and passwords required to run the command.</p> <p>If the accountparams option is not specified, the command prompts for the required user names and passwords.</p> <p>The format of the parameter file is parameter=value. There is a new line for each parameter, and there are no spaces on a line.</p> <p>Note: Oracle recommends that you do not use this option. The utility prompts you to enter a username and password when you run the utility from the command line. This is the most secure way to provide a password.</p>
-verbose		Write detailed messages as it processes the input file.
-ValidateXML		Check to make sure that all required XML tags exist and the specified control paths can be found, without loading data. Optionally, use this parameter to validate an XML file before importing it.
-StoponError		Stop processing when the utility encounters an error. When errstop is not specified, the tag containing the error is skipped and the import continues with the next data tag in the file.
-RulesDisabled		Do not run rules while submitting data. This parameter is required.
-SubmitToLockedOrFrozenForms		Submit data to a locked or frozen form. If you do not enable this option, an error occurs when you attempt to submit data to a locked or frozen form.
-File	<i>filename</i>	File name for the ODM Submit document.

Parameter	Variable	Description
-FileList	<i>filename</i>	<p>File name for the document that contains a list of ODM Submit file names.</p> <p>For example:</p> <pre><?xml version="1.0" encoding="utf-8"?> <File> <File>firstFileName.xml</File> <File>secondFileName xml</File> </File></pre>
