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Integration Guide for InForm Publisher

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Preface

This preface contains the following sections:

- Documentation accessibility
- Diversity and Inclusion
- Related resources
- Access to Oracle Support
- Additional copyright information

Documentation accessibility

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- English interface Customer Support Portal (https://hsgbu.custhelp.com/)
- Japanese interface Customer Support Portal (https://hsgbu-jp.custhelp.com/)

You can also call our 24x7 help desk. For information, visit https://www.oracle.com/life-sciences/support/ or visit https://www.oracle.com/corporate/accessibility/learning-support.html#support-tab if you are hearing impaired.

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1

Oracle InForm Publisher integration overview

In this chapter:

- About the Oracle Life Sciences InForm Publisher feature
- The Oracle Life Sciences InForm Publisher interfaces

About the Oracle Life Sciences InForm Publisher feature

The Oracle InForm Publisher feature is an application programming interface (API) for the Oracle Life Sciences InForm application. It supports integrations with Oracle and third-party applications by pulling selected data from the Oracle InForm application when triggered by specific data entered for a subject in the Oracle InForm application.

Like other APIs, the Oracle InForm Publisher interfaces use published web services interfaces to allow programmatic access to applications. This allows Oracle products to be tightly integrated with each other and with third-party products.

The data is published from a transaction queue, on a configurable schedule. To use the Oracle InForm Publisher software with an Oracle InForm study, you must:

1. Install the Oracle InForm software, which includes the Oracle InForm Publisher feature.
2. Configure the software to work with the study and the target application.

For more information, see the *Oracle Life Sciences InForm Publisher Installation Guide*.

The Oracle Life Sciences InForm Publisher interfaces

The Oracle InForm Publisher release includes the following interfaces that are available for programmatic access.

Interface	Description	For more information
Argus Safety Publisher	Publishes adverse event data for a study in the Oracle Life Sciences InForm application to the Oracle Argus Safety application, based on a data mapping in the study design that is configured in the Oracle Life Sciences Central Designer application. You can configure settings in the Oracle InForm Publisher application related to number of attempts and frequency of data publishing, and error logging.	Oracle Life Sciences Central Designer User Guide Oracle Life Sciences InForm Configuration Guide for Oracle InForm Publisher.

Interface	Description	For more information
ODM Extract Publisher	Provides access to receive Oracle InForm clinical data and metadata in CDISC ODM standard format. The ODM Extract Publisher can publish data to web services, local directory, FTP, or CTMS endpoints. 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 custom events (for example, data added to a subject's study data or changes in subject status). A custom event is set up to provide input for applications requiring Oracle InForm data or status, and to provide the specific information needed as determined by customer receiving application requirements. The output adheres to the ODM Snapshot format.	Oracle Life Sciences InForm Configuration Guide for Oracle InForm Publisher. Refer to the Oracle Life Sciences Central Designer documentation on the Oracle Help Center for information on creating custom events.

2

Defining how the receiving application receives ODM extract data

In this chapter:

- Using the web service
- WSDL documentation
- FTP option
- Local Directory option

Using the web service

Custom event data is sent by Oracle Life Sciences InForm Publisher and received by target applications using web service transactions. The custom event is fired by Oracle InForm Publisher when the triggering conditions are met. The event is sent to the particular destination driven by the endpoint name defined in Oracle Life Sciences Central Designer. The destination URL and event alias are stored in Oracle InForm Publisher's config file.

You can download a sample WSDL file from My Oracle Support.

- Writing the web service
- High-level summary of the web service API
- Sample web service request and response

Writing the web service

ODMProcessorService Web Services Description Language (WSDL) defines how a receiving application receives ODM extract data from Oracle Life Sciences InForm Publisher. A receiving application must implement the web service using the WSDL provided. The web service defines a single operation, called receiveODMData.

The receiving application should provide implementation logic to receive ODM data and process it based on the application's requirements. Further processing might involve validating ODM data, storing the data in its database or file system, or transforming and sending the data to downstream applications.

High-level summary of the web service API

The following is a high-level summary of the web service API.

- Service
- Operation—receive ODMdata

Service

Service	Operation
ODMProcessorService	receiveODMData

Operation—receive ODMdata

Service	Operation
ODMProcessorService	receiveODMData

Item	Description
Input	The Oracle Life Sciences InForm Publisher application sends ODM extract data XML in string format to the web service.
Output	The web service sends one of the following return codes to the Oracle InForm Publisher application:
SUCCESS*	After receiving ODM extract data, the receiving application sends a SUCCESS response.
ODMMETAREQUIRED	The receiving application can request ODM metadata.
ODMADMINREQUIRED	The receiving application can request ODM administrative data.
ODMMETAANDADMINREQUIRED	The receiving application can request ODM metadata and administrative data.
Fault	If the web service is unable to process data for any reason, it returns a fault.

> **Note:**
>
> The web service should return a success code after receiving either ODM extract data or ODM metadata and administrative data. The remaining codes should be used only when the receiving application needs administrative data, metadata, or both.

Sample web service request and response

Sample Request

```
<soap:Envelope xmlns:soap="http://www.w3.org/2003/05/soap-envelope"
xmlns:test="http://test.odmextract.informpublisher.hsgbu.oracle.com/"
xmlns:s="s" xmlns:u="u">

   <soap:Body>

      <test:receiveODMData>

         <arg0><![CDATA[<ResponseODM xmlns:pf="http://www.phaseforward.com/
InFormAdapter/ODM/Extensions/3.0" xmlns="http://www.phaseforward.com/
```

```
InFormAdapter/ODM/3.0">

  <ODM Description="combo" FileType="Snapshot"
CreationDateTime="2013-09-16T18:37:54.0535222Z" ODMVersion="1.3.1"
Originator="Oracle HSGBU" SourceSystem="InForm" SourceSystemVersion="6.0"
pf:MappingVersion="V3" pf:HierarchicalOIDs="Yes"
pf:Generator="InFormPublisher  v2.0.50727" xmlns="http://www.cdisc.org/ns/odm/
v1.3">

    <ClinicalData StudyOID="StudyDesign" MetaDataVersionOID="Study Design
0.0.4">

      <SubjectData SubjectKey="17647" pf:GUID="{4ABEE1F2-839F-44CC-
B5FD-81720BEE5A9A}">

        <SiteRef LocationOID="01" />

        <pf:SubjectStatus State="Enrolled" />

      </SubjectData>

      <pf:CustomEvent Name="TC100000027e" Destination="Service_1"
StudyVersion="Study Design 0.0.4" EventID="1" EventRev="1" />

    </ClinicalData>

  </ODM>

  <Status>OK</Status>

</ResponseODM>]]></arg0>

      </test:receiveODMData>

   </soap:Body>

</soap:Envelope>
```

Sample Response

```
<S:Envelope xmlns:S="http://www.w3.org/2003/05/soap-envelope">

  <S:Header>

    <To xmlns="http://www.w3.org/2005/08/addressing">http://www.w3.org/
2005/08/addressing/anonymous</To>

    <Action xmlns="http://www.w3.org/2005/08/addressing">http://
test.odmextract.informpublisher.hsgbu.oracle.com/ODMProcessor/
receiveODMDataResponse</Action>

    <MessageID xmlns="http://www.w3.org/2005/08/addressing">uuid:bfba08fd-
ed9a-4649-aa68-cddc94ed43a3</MessageID>

    <RelatesTo xmlns="http://www.w3.org/2005/08/addressing">urn:uuid:621b1526-
```

```
a917-4a8f-b27c-9d979683852c</RelatesTo>

  </S:Header>

  <S:Body>

    <ns2:receiveODMDataResponse xmlns:ns2="http://
test.odmextract.informpublisher.hsgbu.oracle.com/">

      <return>SUCCESS</return>

    </ns2:receiveODMDataResponse>

  </S:Body>

</S:Envelope>
```

WSDL documentation

In this section:

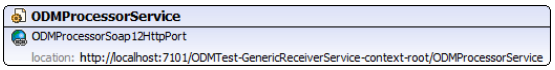
- Services
- Bindings
- Porttypes
- Messages
- Types
- Elements
- Complex types
- Simple types

Services

In this section:

- ODMProcessorService

ODMProcessorService

Item	Description
Diagram	
Ports	ODMProcessorSoap12HttpPort
Binding	tns:ODMProcessorSoapHttp
Extensibility	<soap12:address location="http://localhost:7101/ ODMTest- GenericReceiverService-context-root/ ODMProcessorService"/>

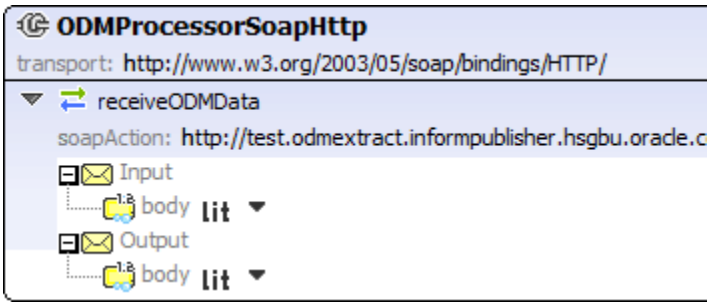
Item	Description
Source	<wsdl:service name="ODMProcessorService"> <wsdl:port name="ODMProcessorSoap12HttpPort" binding="tns:ODMProcessorSoapHttp"> <soap12:address location="http://localhost:7101/ODMTest-GenericReceiverService-context-root/ODMProcessorService"/> </wsdl:port> </wsdl:service>

Bindings

In this section:

- ODMProcessorSoapHttp

ODMProcessorSoapHttp

Item	Description
Diagram	
Type	tns:ODMProcessor
Extensibility	<soap12:binding style="document" transport="http://www.w3.org/2003/05/soap/bindings/HTTP/"/>
Operations	receiveODMData
Extensibility:	<soap12:operation soapAction="http://test.odmextract.informpublisher.hsgbu.oracle.com/receiveODMData" soapActionRequired="false"/>
Input:	<soap12:body use="literal"/>
Output:	<soap12:body use="literal"/>
Used by	Port ODMProcessorSoap12HttpPort in Service ODMProcessorService

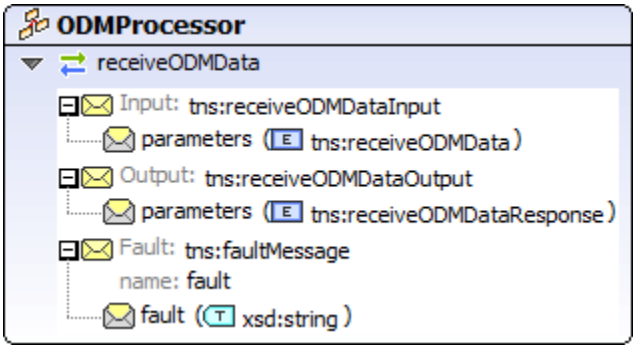
Item	Description
Source	<wsdl:binding name="ODMProcessorSoapHttp" type="tns:ODMProcessor"> <soap12:binding style="document" transport="http://www.w3.org/2003/05/soap/bindings/HTTP/"/> <wsdl:operation name="receiveODMData"> <soap12:operation soapAction="http://test.odmextract.informpublisher.hsgbu.oracle.com/receiveODMData" soapActionRequired="false"/> <wsdl:input> <soap12:body use="literal"/> </wsdl:input> <wsdl:output> <soap12:body use="literal"/> </wsdl:output> </wsdl:operation> </wsdl:binding>

Porttypes

In this section:

- ODMProcessor

ODMProcessor

Item	Description
Diagram	
Operation	receiveODMData
Input	tns:receiveODMDataInput
Output	tns:receiveODMDataOutput
Fault	tns:faultMessage
Used by:	--
Binding	ODMProcessorSoapHttp

Item	Description
Source	<wsdl:portType name="ODMProcessor"> <wsdl:operation name="receiveODMData"> <wsdl:input message="tns:receiveODMDataInput" xmlns:ns2="http://www.w3.org/2006/05/ addressing/wsdl" ns2:action="http:// test.odmextract.informpublisher.hsgbu .oracle.com/receiveODMData"/> <wsdl:output message="tns:receiveODMDataOutput" xmlns:ns2="http://www.w3.org/2006/05/ addressing/wsdl" ns2:action="http:// test.odmextract.informpublisher.hsgbu .oracle.com/receiveODMDataResponse"/> <wsdl:fault name="fault" message="tns:faultMessage"/> </wsdl:operation> </wsdl:portType>

Messages

In this section:

- faultMessage
- receiveODMDataInput
- receiveODMDataOutput

faultMessage

Item	Description
Parts	fault
Type	xsd:string
Used by	--
Operation	receiveODMData
in PortType	ODMProcessor
Source	<wsdl:message name="faultMessage"> <wsdl:part name="fault" type="xsd:string"/> </wsdl:message>

receiveODMDataInput

Item	Description
Parts	parameters
Element:	tns:receiveODMData
Used by	--
Operation	receiveODMData
in PortType	ODMProcessor
Source	<wsdl:message name="receiveODMDataInput"> <wsdl:part name="parameters" element="tns:receiveODMData"/> </wsdl:message>

receiveODMDataOutput

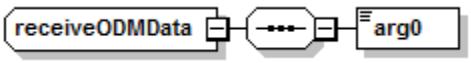
Item	Description
Parts	parameters
Element	tns:receiveODMDataResponse
Used by:	--
Operation	receiveODMData
in PortType	ODMProcessor
Source	<wsdl:message name="receiveODMDataOutput"> <wsdl:part name="parameters" element="tns:receiveODMDataResponse"/ > </wsdl:message>

Types

In this section:

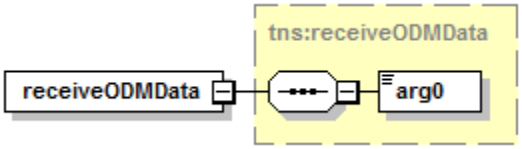
- receiveODMData (Types and ComplexTypes)
- receiveODMData (Types and Elements)
- receiveODMDataResponse (Types and ComplexTypes)
- receiveODMDataResponse (Types and Elements)
- ReturnCodes

receiveODMData (Types and ComplexTypes)

Item	Description
Diagram	
Namespace	http:// test.odmextract.informpublisher.hsgbu.oracle.com/
Children	arg0
Used by	--
Element	receiveODMData

Source	
	`<complexType name="receiveODMData">`
	`  <sequence>`
	`  <element name="arg0"`
	`type="xsd:string"/>`
	`  </sequence>`
	`</complexType>`

receiveODMData (Types and Elements)

Item	Description
Diagram	
Namespace	http:// test.odmextract.informpublisher.hsgbu.oracle.com/
Type	tns:receiveODMData
Properties	--
Content	complex
Children	arg0

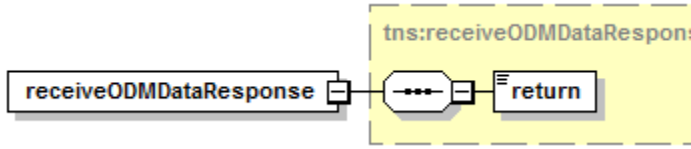
Source	
	`<element name="receiveODMData"`
	`type="tns:receiveODMData"/>`

receiveODMDataResponse (Types and ComplexTypes)

Item	Description
Diagram	
Namespace	http:// test.odmextract.informpublisher.hsgbu.oracle.com/

Item	Description
Children	return
Used by	--
Element	receiveODMDataResponse
Source	<complexType name="receiveODMDataResponse"> <sequence> <element name="return" type="tns:ReturnCodes"/> </sequence> </complexType>

receiveODMDataResponse (Types and Elements)

Item	Description
Diagram	
Namespace	http://test.odmextract.informpublisher.hsgbu.oracle.com/
Type	tns:receiveODMDataResponse
Properties	--
Content	complex
Children	return
Source	<element name="receiveODMDataResponse" type="tns:receiveODMDataResponse"/>

ReturnCodes

Item	Description
Namespace	http://test.odmextract.informpublisher.hsgbu.oracle.com/
Type	restriction of string
Properties	--
Base	xsd:string
Used by	--
Element	receiveODMDataResponse/return
Facets	--

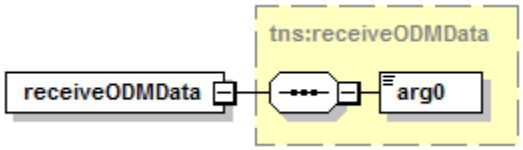
Item	Description
Kind	enumeration
Value	SUCCESS
Annotation	After receiving ODM extract data, the receiving application should send a SUCCESS response back to InForm Publisher by sending this return code.
Kind	enumeration
Value	ODMMETAREQUIRED
Annotation	After receiving ODM extract data, the receiving application can request ODM metadata from InForm Publisher by sending this return code.
Kind	enumeration
Value	ODMADMINREQUIRED
Annotation	After receiving ODM extract data, the receiving application can request ODM administrative data from InForm Publisher by sending this return code.
Kind	enumeration
Value	ODMMETAANDADMINREQUIRED
Annotation	After receiving ODM extract data, the receiving application can request ODM metadata and administrative data from Oracle Life Sciences InForm Publisher by sending this return code.
Source	<simpleType name="ReturnCodes"> <restriction base="xsd:string"> <enumeration value="SUCCESS"/> <enumeration value="ODMMETAREQUIRED"/> <enumeration value="ODMADMINREQUIRED"/> <enumeration value="ODMMETAANDADMINREQUIRED"/> </restriction> </simpleType>

Elements

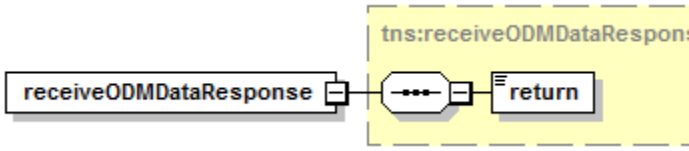
In this section:

- receiveODMData (Types and Elements)
- receiveODMDataResponse (Elements)
- receiveODMDataResponse/return
- receiveODMData/arg0 (Element)

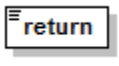
receiveODMData (Types and Elements)

Item	Description
Diagram	
Namespace	http://test.odmextract.informpublisher.hsgbu.oracle.com/
Type	tns:receiveODMData
Properties	--
Content	complex
Children	arg0
Source	`<element name="receiveODMData" type="tns:receiveODMData"/>`

receiveODMDataResponse (Elements)

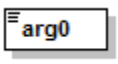
Item	Description
Diagram	
Namespace	http://test.odmextract.informpublisher.hsgbu.oracle.com/
Type	tns:receiveODMData
Properties	--
Content	complex
Children	return
Source	`<element name="receiveODMDataResponse" type="tns:receiveODMDataResponse"/>`

receiveODMDataResponse/return

Item	Description
Diagram	

Item	Description
Type	tns:ReturnCodes
Properties	--
Content	simple
Facets	--
Kind	enumeration
Value	SUCCESS
Annotation	After receiving ODM extract data, the receiving application should send SUCCESS response back to Oracle Life Sciences InForm Publisher by sending this return code.
Kind	enumeration
Value	ODMMETAREQUIRED
Annotation	After receiving ODM extract data, the receiving application can request ODM metadata from Oracle InForm Publisher by sending this return code.
Kind	enumeration
Value	ODMADMINREQUIRED
Annotation	After receiving ODM extract data, the receiving application can request ODM administrative data from Oracle InForm Publisher by sending this return code.
Kind	enumeration
Value	ODMMETAANDADMINREQUIRED
Annotation	After receiving ODM extract data, the receiving application can request ODM metadata and administrative data from Oracle InForm Publisher by sending this return code.
Source	`<element name="return" type="tns:ReturnCodes"/>`

receiveODMData/arg0 (Element)

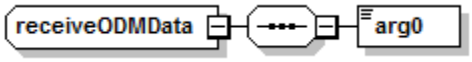
Item	Description
Diagram	
Type	string
Properties	--
Content	simple
Source	`<element name="arg0" type="xsd:string"/>`

Complex types

In this section:

- receiveODMData (Types and ComplexTypes)
- receiveODMDataResponse (Types and ComplexTypes)

receiveODMData (Types and ComplexTypes)

Item	Description
Diagram	
Namespace	http:// test.odmextract.informpublisher.hsgbu.oracle.com/
Children	arg0
Used by	--
Element	receiveODMData
Source	<pre><complexType name="receiveODMData"> <sequence> <element name="arg0" type="xsd:string"/> </sequence> </complexType></pre>

receiveODMDataResponse (Types and ComplexTypes)

Item	Description
Diagram	
Namespace	http:// test.odmextract.informpublisher.hsgbu.oracle.com/
Children	return
Used by	--
Element	receiveODMDataResponse
Source	<pre><complexType name="receiveODMDataResponse"> <sequence> <element name="return" type="tns:ReturnCodes"/> </sequence> </complexType></pre>

Simple types

In this section:

- ReturnCodes

ReturnCodes

Item	Description
Namespace	http://test.odmextract.informpublisher.hsgbu.oracle.com/
Type	restriction of string
Properties	--
Base	xsd:string
Used by	--
Element	receiveODMDataResponse/return
Facets	--
Kind	enumeration
Value	SUCCESS
Annotation	After receiving ODM extract data, the receiving application should send a SUCCESS response back to InForm Publisher by sending this return code.
Kind	enumeration
Value	ODMMETAREQUIRED
Annotation	After receiving ODM extract data, the receiving application can request ODM metadata from InForm Publisher by sending this return code.
Kind	enumeration
Value	ODMADMINREQUIRED
Annotation	After receiving ODM extract data, the receiving application can request ODM administrative data from InForm Publisher by sending this return code.
Kind	enumeration
Value	ODMMETAANDADMINREQUIRED
Annotation	After receiving ODM extract data, the receiving application can request ODM metadata and administrative data from Oracle Life Sciences InForm Publisher by sending this return code.

Item	Description
Source	<simpleType name="ReturnCodes"> <restriction base="xsd:string"> <enumeration value="SUCCESS"/> <enumeration value="ODMMETAREQUIRED"/> <enumeration value="ODMADMINREQUIRED"/> <enumeration value="ODMMETAANDADMINREQUIRED"/> </restriction> </simpleType>

FTP option

To enable FTP publishing for ODM extract type subscriber, configure the following in the InFormPublisher.config file:

- EndPointType = "FTP"
- EndPoint—IP or hostname address for remote host.
- Username—Login credential for remote host.
- Password—Login credential for remote host.
- Local folder—Folder name (FtpLocalFolderPath) from which local files are picked up by ODM Extract SFTP transmitter.
- Remote folder—Folder name (RemoteFolder) on the remote host, where files will be sent.

FTP Attributes

```
.\PublisherAdmin.exe Subscriber set OESubcriber9 EndPoint=ftp://
<hostname>:<portnumber> EndPointType=FTP FtpLocalFolderPath=< local folder
path> FtpRemoteFolderPath=<Remote folder path>
```

SecureEndPointCredentials

```
.\PublisherAdmin.exe Subscriber setCredentials OESubcriber9 User=<username>

<Enter password when prompted>
```

Requesting admin data and metadata

To write admin data or metadata to the Remote Folder, add a file called OdmConfig.properties to the local folder.

- f the file contains ReturnCode=1, the Oracle InForm Publisher application will send admin data during the next push interval.

- If the file contains ReturnCode=2, Oracle InForm Publisher application will send metadata during the next push interval.
- If the file contains ReturnCode=3, the Oracle InForm Publisher application will send both admin data and metadata during the next push interval.
- If the file contains ReturnCode=4 or the ODMConfig.properties file does not exist, the Oracle InForm Publisher application will not sent either admin data or metadata during the next push interval.

Local Directory option

The Oracle Life Sciences InForm Publisher application can publish ODM Snapshot output files to a directory.

3

Export formats

In this chapter:

- ODM Snapshot format
- Oracle extensions for ODM Snapshot

ODM Snapshot format

The format of the ODM custom event extract XML conforms to ODM 1.3.1 with new extensions that do not exist in the ODM XML from Oracle Life Sciences InForm Adapter. The ODM XML is in the Snapshot format and compatible with the transactional output. The custom events extract is in CDISC ODM Snapshot format. Oracle InForm ODM extensions designed for Oracle InForm Adapter ODM transactional output are also supported and have been incorporated into this guide. Audit trails are not included in the ODM Snapshot format.

Oracle extensions for ODM Snapshot

The ODM Extract Publisher is a unidirectional push of information that calls a web service, which a customer must implement to receive the CDISC ODM 1.3.1 Snapshot format. Refer to http:\\www.cdisc.org for more information on the ODM standard.

This section describes the Oracle extensions to the syntax and functionality of the ODM Extract Publisher of the Oracle Life Sciences InForm Publisher software. The ODM Extract Publisher focuses on the semantics of the function calls that are published by the interface, and the parameters that the published web methods use. Elements are included for:

- Custom events
- Clinical data
- Administrative data
- Metadata

Each section gives examples of XML for both the web method request and response.

- ODM structure for custom event output
- Elements for clinical data
- Elements for admin data
- Elements for metadata
- Oracle attributes that are applied to standard ODM elements
- Revision, DBUID, and GUID attributes
- Extensions that show control hierarchy and type

ODM structure for custom event output

In this chapter:

- ODM element
- pf:CustomEvent element
- pf:Alias attribute
- pf:StudyEventStatus
- MeasurementUnitRef
- pf:NormalizedValue of ItemData
- Annotation
- pf:ItemGroupStatus
- pf:ReasonIncomplete
- Critical attribute of ItemStatus
- CustomData
- Association
- IsNull

ODM element

The ODM element has the following attribute set for the predefined value in ODM Custom Event Extract output:

- pf:MappingVersion attribute is set to V3.
- ODMVersion attribute value is 1.3.1.
- FileType is set to Snapshot.
- FileOID is set to the new guid.
- Originator is set to "Oracle HSGBU".
- SourceSystem is set to "InForm".
- SourceSystemVersion is set to the Oracle InForm version of the Oracle InForm study for which the custom event extract is published.
- pf:Generator is set to "InFormPublisher 6.2.0.0.XXX".
- ODM element example

ODM element example

```
<ODM Description="combosample" FileType="Snapshot" CreationDateTime="ignored"
ODMVersion="1.3.1" Originator="Oracle HSGBU" FileOID="" SourceSystem="InForm"
SourceSystemVersion="6.0" pf:MappingVersion="V3" pf:HierarchicalOIDs="Yes"
pf:Generator="InForm Publisher"

xmlns="http://www.cdisc.org/ns/odm/v1.3">
```

pf:CustomEvent element

This extension denotes the custom event for which the ODM XML is published.

XPath

```
ODM/ClinicalData/pf:CustomEvent
```

Attributes

Attribute	Description
Name	This attribute is the custom event destination name that is defined in Oracle Life Sciences Central Designer. This name can be meaningful to the receiving application.
Destination	Name of the destination that the Oracle Life Sciences InForm Publisher application uses to locate the endpoint to which it sends the custom event XML.
StudyVersion	Study version to which this custom event is assigned.
EventID	Internal numeric identifier of the custom event.
EventRef	Revision number of the custom event.

- pf:CustomEvent example

pf:CustomEvent example

```
<pf:CustomEvent Name="DataChangeTest" Destination="FrancaEndpoint"
StudyVersion="Study Design 0.0.9" EventID="18" EventRev="1" />
```

pf:Alias attribute

For pf:Alias element, this is the value defined as the Map To value for result field in Oracle Life Sciences Central Designer.

XPath

```
ODM/ClinicalData/SubjectData/StudyEventData/FormData/ItemGroupData/ItemData/
@pf:Alias

ODM/ClinicalData/SubjectData/StudyEventData/FormData/@pf:Alias

ODM/ClinicalData/SubjectData/pf:StudyEventStatus/@pf:Alias

ODM/ClinicalData/SubjectData/pf:SubjectStatus/@pf:Alias

ODM/ClinicalData/SubjectData/StudyEventData/FormData/ItemGroupData/
ItemGroupStatus/pf:Alias

ODM/ClinicalData/SubjectData/StudyEventStatus/pf:FormStatus/pf:Alias

ODM/ClinicalData/SubjectData/StudyEventData/FormData/ItemGroupData/ItemData/
ItemStatus/pf:Alias
```

pf:StudyEventStatus

This element reflects the visit status and includes the pf:FormStatus element for the form started in the visit.

XPath

```
ODM/ClinicalData/SubjectData/pf:StudyEventStatus
```

Attributes

Attribute	Description
StudyEventOID	Visit refname in the Oracle Life Sciences InForm application.
StudyEventRepeatKey	Visit index for the repeating visit. If the visit is not repeating, this attribute is not generated.
Complete	Yes=Visit is complete. No=Visit is incomplete.
Frozen	Yes=Visit is frozen. No=Visit is not frozen.
Lock	Yes=Visit is locked. No=Visit is unlocked.
SDV	Yes=Visit is source verified. No=Visit is not source verified.
Activated	Yes=Form is activated. No=Other status attributes, such as Complete, Frozen, and so on, are not generated.

- pf:StudyEventStatus example

pf:StudyEventStatus example

```
<pf:StudyEventStatus Complete="No" Frozen="No" Lock="No" SDV="No"
StudyEventOID="vstUnschVisit" StudyEventRepeatKey="393232473548079">

          <pf:FormStatus Activated="Yes" Frozen="No" Locked="No" Deleted="No"
SVReady="No" SVPartial="No" SVComplete="No" SVSelected="Yes" Signed="No"
Completed="No" FormOID="frmCGI" />

          <pf:FormStatus Activated="Yes" Frozen="No" Locked="No" Deleted="No"
SVReady="No" SVPartial="No" SVComplete="No" SVSelected="Yes" Signed="No"
Completed="No" FormOID="frmECG" FormRepeatKey="393232471708079" />

          <pf:FormStatus Activated="Yes" Frozen="No" Locked="No" Deleted="No"
SVReady="No" SVPartial="No" SVComplete="No" SVSelected="Yes" Signed="No"
Completed="No" FormOID="frmHamD" />

          <pf:FormStatus Activated="Yes" Frozen="No" Locked="No" Deleted="No"
SVReady="No" SVPartial="No" SVComplete="No" SVSelected="Yes" Signed="No"
Completed="No" FormOID="frmVS" />

          <pf:FormStatus Activated="Yes" Frozen="No" Locked="No" Deleted="No"
```

```
SVReady="No" SVPartial="No" SVComplete="No" SVSelected="Yes" Signed="No"
Completed="No" FormOID="frmPE" />

          <pf:FormStatus Activated="Yes" Frozen="No" Locked="No" Deleted="No"
SVReady="No" SVPartial="No" SVComplete="No" SVSelected="Yes" Signed="No"
Completed="Yes" FormOID="frmDOV2" />

          <pf:FormStatus Activated="Yes" Frozen="No" Locked="No" Deleted="No"
SVReady="No" SVPartial="No" SVComplete="No" SVSelected="Yes" Signed="No"
Completed="No" FormOID="frmECG" FormRepeatKey="393232474285079" />

          <pf:CustomData Name="CTMSElementName" Value="VisitStatus" />

        </pf:StudyEventStatus>
```

MeasurementUnitRef

This element exists in the item data output and will be populated for the item data if applicable.

XPath

```
ODM/ClinicalData/SubjectData/StudyEventData/FormData/ItemGroupData/ItemData/
MeasurementUnitRef
```

pf:NormalizedValue of ItemData

This extension attribute will be populated if there is a normalized value.

XPath

```
ODM/ClinicalData/SubjectData/StudyEventData/FormData/ItemGroupData/ItemData/
@NormalizedValue
```

Annotation

This element is either the form or item comment and is populated when there is a comment.

XPath for the Item comment

```
ODM/ClinicalData/SubjectData/StudyEventData/FormData/ItemGroupData/ItemData/
Annotation
```

XPath for the form comment

```
ODM/ClinicalData/SubjectData/StudyEventData/FormData/ItemGroupData/ItemData/
Annotation
```

pf:ItemGroupStatus

This extension element reflects the item group status.

XPath

```
ODM/ClinicalData/SubjectData/StudyEventData/FormData/ItemGroupData/
ItemGroupStatus
```

Attributes

Attribute	Description
SVComplete	Yes=Itemset is source verified. No=Itemset is not source verified.
Deleted	Yes=Itemset is deleted. No=Itemset is not deleted.

- pf:ItemGroupStatus example

pf:ItemGroupStatus example

```
<pf:ItemGroupStatus SVComplete="No" Deleted="No" />
```

pf:ReasonIncomplete

This extension element already exists in the transactional output. It will be populated in the custom event extract if the reason incomplete.

Form Reason Incomplete XPath

```
ODM/ClinicalData/SubjectData/StudyEventData/FormData/Annotation/
pf:ReasonIncomplete
```

Item Reason Incomplete XPath

```
ODM/ClinicalData/SubjectData/StudyEventData/FormData/ItemGroupData/ItemData/
Annotation/pf:ReasonIncomplete
```

Critical attribute of ItemStatus

This element tells whether or not the item is SV critical in the Oracle Life Sciences InForm application. The value is True when the item is SV critical and False when it is not. Otherwise, it is StudyDefault.

XPath

```
ODM/ClinicalData/SubjectData/StudyEventData/FormData/ItemGroupData/ItemData/
ItemStatus/@Critical
```

CustomData

This is the extension element to include a name, value pair attached to an element in the custom event XML.

XPath

```
ODM/ClinicalData/SubjectData/pf:SubjectStatus/pf:CustomData
```

Example

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

          <pf:CustomData Name="CustomDataName" Value="CustomDataValue" />

        </pf:SubjectStatus>
```

XPath

```
ODM/ClinicalData/SubjectData/pf:StudyEventStatus/pf:CustomData
```

Example

```
<pf:StudyEventStatus Complete="No" Frozen="No" Lock="No" SDV="No"
StudyEventOID="vstBASE">

          <pf:FormStatus Activated="Yes" Frozen="No" Locked="No" Deleted="No"
SVReady="No" SVPartial="No" SVComplete="No" SVSelected="Yes" Signed="No"
Completed="Yes" FormOID="MEDHISTiSet" />

          <pf:FormStatus Activated="Yes" Frozen="No" Locked="No" Deleted="No"
SVReady="No" SVPartial="No" SVComplete="No" SVSelected="Yes" Signed="No"
Completed="Yes" FormOID="frmCGI" />

          <pf:FormStatus Activated="Yes" Frozen="No" Locked="No" Deleted="No"
SVReady="No" SVPartial="No" SVComplete="No" SVSelected="Yes" Signed="No"
Completed="Yes" FormOID="frmDOV" />

          <pf:FormStatus Activated="Yes" Frozen="No" Locked="No" Deleted="No"
SVReady="No" SVPartial="No" SVComplete="No" SVSelected="Yes" Signed="No"
Completed="No" FormOID="frmPEBase" />

          <pf:FormStatus Activated="Yes" Frozen="No" Locked="No" Deleted="No"
SVReady="No" SVPartial="No" SVComplete="No" SVSelected="Yes" Signed="No"
Completed="No" FormOID="frmHamD" />

          <pf:FormStatus Activated="Yes" Frozen="No" Locked="No" Deleted="No"
SVReady="No" SVPartial="No" SVComplete="No" SVSelected="Yes" Signed="No"
Completed="Yes" FormOID="frmDem" />

          <pf:FormStatus Activated="Yes" Frozen="No" Locked="No" Deleted="No"
SVReady="No" SVPartial="No" SVComplete="No" SVSelected="Yes" Signed="No"
Completed="Yes" FormOID="frmINCEXC" />

          <pf:FormStatus Activated="Yes" Frozen="No" Locked="No" Deleted="No"
SVReady="No" SVPartial="No" SVComplete="No" SVSelected="Yes" Signed="No"
Completed="No" FormOID="frmRAND" />
```

```
          <pf:FormStatus Activated="Yes" Frozen="No" Locked="No" Deleted="No"
SVReady="No" SVPartial="No" SVComplete="No" SVSelected="Yes" Signed="No"
Completed="No" FormOID="frmVS" />

          <pf:FormStatus Activated="Yes" Frozen="No" Locked="No" Deleted="No"
SVReady="No" SVPartial="No" SVComplete="No" SVSelected="Yes" Signed="No"
Completed="No" FormOID="frmPI" />

          <pf:FormStatus Activated="Yes" Frozen="No" Locked="No" Deleted="No"
SVReady="No" SVPartial="No" SVComplete="No" SVSelected="Yes" Signed="No"
Completed="Yes" FormOID="frmECGBase" />

          <pf:FormStatus Activated="Yes" Frozen="No" Locked="No" Deleted="No"
SVReady="No" SVPartial="No" SVComplete="No" SVSelected="Yes" Signed="No"
Completed="Yes" FormOID="frmPM" />

          <pf:FormStatus Activated="Yes" Frozen="No" Locked="No" Deleted="No"
SVReady="No" SVPartial="No" SVComplete="No" SVSelected="Yes" Signed="No"
Completed="No" FormOID="frmPreg" />

          <pf:CustomData Name="CTMSElementName" Value="VisitStatus" />

        </pf:StudyEventStatus>
```

XPath

```
ODM/ClinicalData/SubjectData/StudyEventData/FormData/pf:CustomData
```

Example

```
<FormData FormOID="frmDem">

            <ItemGroupData ItemGroupOID="frmDem.sctDemographics">

              <ItemData
ItemOID="frmDem.sctDemographics.DateofBirth_DEM.DateofBirth_DEM"
Value="1975-12-25T-:-:-+00:00"
pf:FormattedDateValue="1975-12-25TUNK:UNK:UNK+00:00"
pf:Alias="vstBase.frmDem" />

              <ItemData ItemOID="frmDem.sctDemographics.Race.Race" Value="3"
pf:Alias="vstBase.frmDem" />

              <ItemData
ItemOID="frmDem.sctDemographics.ScreeningDate_DEM.ScreeningDate_DEM"
Value="2011-10-26T-:-:-+00:00"
pf:FormattedDateValue="2011-10-26TUNK:UNK:UNK+00:00"
pf:Alias="vstBase.frmDem" />

              <ItemData ItemOID="frmDem.sctDemographics.Height.Height"
Value="153.0" pf:NormalizedValue="153" pf:Alias="vstBase.frmDem">

                <MeasurementUnitRef MeasurementUnitOID="cm" />

                <Annotation SeqNum="1" pf:DBUID="20401"
```

```
pf:GUID="{7725F52A-204D-4A07-A4D9-1980F0D41C97}">

                  <Comment>2nd comment</Comment>

                </Annotation>

              </ItemData>

              <ItemData ItemOID="frmDem.sctDemographics.OnsetAge.OnsetAge"
Value="37.0" pf:Alias="vstBase.frmDem" />

              <ItemData ItemOID="frmDem.sctDemographics.Age.Age" Value="46"
pf:Alias="vstBase.frmDem" />

              <ItemData ItemOID="frmDem.sctDemographics.Gender.Gender"
Value="2" pf:Alias="vstBase.frmDem" />

              <ItemData ItemOID="frmDem.sctDemographics.AgeGroup.AgeGroup"
Value="4" pf:Alias="vstBase.frmDem" />

              <pf:InFormItemData
InFormItemOID="frmDem.sctDemographics.DateofBirth_DEM" Name="DateofBirth_DEM">

                <pf:ItemStatus SourceVerified="No" Critical="StudyDefault" />

              </pf:InFormItemData>

              <pf:InFormItemData InFormItemOID="frmDem.sctDemographics.Race"
Name="Race">

                <pf:ItemStatus SourceVerified="No" Critical="StudyDefault" />

              </pf:InFormItemData>

              <pf:InFormItemData
InFormItemOID="frmDem.sctDemographics.ScreeningDate_DEM"
Name="ScreeningDate_DEM">

                <pf:ItemStatus SourceVerified="No" Critical="StudyDefault" />

              </pf:InFormItemData>

              <pf:InFormItemData
InFormItemOID="frmDem.sctDemographics.Height" Name="Height">

                <pf:ItemStatus SourceVerified="No" Critical="StudyDefault" />

              </pf:InFormItemData>

              <pf:InFormItemData
InFormItemOID="frmDem.sctDemographics.OnsetAge" Name="OnsetAge">

                <pf:ItemStatus SourceVerified="No" Critical="StudyDefault" />

              </pf:InFormItemData>
```

```
              <pf:InFormItemData InFormItemOID="frmDem.sctDemographics.Age"
Name="Age">

                <pf:ItemStatus SourceVerified="No" Critical="StudyDefault" />

              </pf:InFormItemData>

              <pf:InFormItemData
InFormItemOID="frmDem.sctDemographics.Gender" Name="Gender">

                <pf:ItemStatus SourceVerified="No" Critical="StudyDefault" />

              </pf:InFormItemData>

              <pf:InFormItemData
InFormItemOID="frmDem.sctDemographics.AgeGroup" Name="AgeGroup">

                <pf:ItemStatus SourceVerified="No" Critical="StudyDefault" />

              </pf:InFormItemData>

            </ItemGroupData>

            <ItemGroupData ItemGroupOID="frmDem.PatientMedicalHistory">

              <ItemData
ItemOID="frmDem.PatientMedicalHistory.MedicalHistory.MedicalHistory" Value="A
brief summary of the medical history here." pf:Alias="vstBase.frmDem" />

              <pf:InFormItemData
InFormItemOID="frmDem.PatientMedicalHistory.MedicalHistory"
Name="MedicalHistory">

                <pf:ItemStatus SourceVerified="No" Critical="StudyDefault" />

              </pf:InFormItemData>

            </ItemGroupData>

            <ItemGroupData ItemGroupOID="frmDem.sctFamilyHistoy">

              <ItemData
ItemOID="frmDem.sctFamilyHistoy.MaritalStatus.MaritalStatus.NeverMarried"
IsNull="Yes" pf:Alias="vstBase.frmDem" />

              <ItemData
ItemOID="frmDem.sctFamilyHistoy.MaritalStatus.MaritalStatus.Married"
Value="Married" pf:Alias="vstBase.frmDem" />

              <ItemData
ItemOID="frmDem.sctFamilyHistoy.MaritalStatus.MaritalStatus.Separated"
IsNull="Yes" pf:Alias="vstBase.frmDem" />

              <ItemData
ItemOID="frmDem.sctFamilyHistoy.MaritalStatus.MaritalStatus.Divorced"
IsNull="Yes" pf:Alias="vstBase.frmDem" />
```

```
              <ItemData
ItemOID="frmDem.sctFamilyHistoy.MaritalStatus.MaritalStatus.Widowed"
IsNull="Yes" pf:Alias="vstBase.frmDem" />

              <ItemData ItemOID="frmDem.sctFamilyHistoy.Children.Children"
Value="1" pf:Alias="vstBase.frmDem" />

              <ItemData
ItemOID="frmDem.sctFamilyHistoy.FamilyHistoryofDepression.FamilyHistoryofDepre
ssion.1" Value="1" pf:Alias="vstBase.frmDem">

                <Annotation SeqNum="1" pf:DBUID="20567"
pf:GUID="{06673504-7BD4-4505-A87C-A52406327D2F}">

                  <Comment>test comment</Comment>

                </Annotation>

              </ItemData>

              <ItemData
ItemOID="frmDem.sctFamilyHistoy.FamilyHistoryofDepression.FamilyHistoryofDepre
ssion.2" Value="2" pf:Alias="vstBase.frmDem">

                <Annotation SeqNum="1" pf:DBUID="20567"
pf:GUID="{06673504-7BD4-4505-A87C-A52406327D2F}">

                  <Comment>test comment</Comment>

                </Annotation>

              </ItemData>

              <ItemData
ItemOID="frmDem.sctFamilyHistoy.FamilyHistoryofDepression.FamilyHistoryofDepre
ssion.3" Value="3" pf:Alias="vstBase.frmDem">

                <Annotation SeqNum="1" pf:DBUID="20567"
pf:GUID="{06673504-7BD4-4505-A87C-A52406327D2F}">

                  <Comment>test comment</Comment>

                </Annotation>

              </ItemData>

              <ItemData
ItemOID="frmDem.sctFamilyHistoy.FamilyHistoryofDepression.FamilyHistoryofDepre
ssion.1.FamilyHistoryYes.Grandparent" IsNull="Yes" pf:Alias="vstBase.frmDem">

                <Annotation SeqNum="1" pf:DBUID="20567"
pf:GUID="{06673504-7BD4-4505-A87C-A52406327D2F}">

                  <Comment>test comment</Comment>
```

```
                </Annotation>

              </ItemData>

              <ItemData
ItemOID="frmDem.sctFamilyHistoy.FamilyHistoryofDepression.FamilyHistoryofDepre
ssion.1.FamilyHistoryYes.Parent" IsNull="Yes" pf:Alias="vstBase.frmDem">

                <Annotation SeqNum="1" pf:DBUID="20567"
pf:GUID="{06673504-7BD4-4505-A87C-A52406327D2F}">

                  <Comment>test comment</Comment>

                </Annotation>

              </ItemData>

              <ItemData
ItemOID="frmDem.sctFamilyHistoy.FamilyHistoryofDepression.FamilyHistoryofDepre
ssion.1.FamilyHistoryYes.Parent_Sibling" Value="Parent_Sibling"
pf:Alias="vstBase.frmDem">

                <Annotation SeqNum="1" pf:DBUID="20567"
pf:GUID="{06673504-7BD4-4505-A87C-A52406327D2F}">

                  <Comment>test comment</Comment>

                </Annotation>

              </ItemData>

              <ItemData
ItemOID="frmDem.sctFamilyHistoy.FamilyHistoryofDepression.FamilyHistoryofDepre
ssion.1.FamilyHistoryYes.Sibling" Value="Sibling" pf:Alias="vstBase.frmDem">

                <Annotation SeqNum="1" pf:DBUID="20567"
pf:GUID="{06673504-7BD4-4505-A87C-A52406327D2F}">

                  <Comment>test comment</Comment>

                </Annotation>

              </ItemData>

              <ItemData
ItemOID="frmDem.sctFamilyHistoy.FamilyHistoryofDepression.FamilyHistoryofDepre
ssion.1.FamilyHistoryYes.Other" Value="Other" pf:Alias="vstBase.frmDem">

                <Annotation SeqNum="1" pf:DBUID="20567"
pf:GUID="{06673504-7BD4-4505-A87C-A52406327D2F}">

                  <Comment>test comment</Comment>

                </Annotation>

              </ItemData>
```

```
              <ItemData
ItemOID="frmDem.sctFamilyHistoy.FamilyHistoryofDepression.FamilyHistoryofDepre
ssion.1.FamilyHistoryYes.Other.OtherSpecify" Value="What is this"
pf:Alias="vstBase.frmDem">

                <Annotation SeqNum="1" pf:DBUID="20567"
pf:GUID="{06673504-7BD4-4505-A87C-A52406327D2F}">

                  <Comment>test comment</Comment>

                </Annotation>

              </ItemData>

              <pf:InFormItemData
InFormItemOID="frmDem.sctFamilyHistoy.MaritalStatus" Name="MaritalStatus">

                <pf:ItemStatus SourceVerified="No" Critical="StudyDefault" />

              </pf:InFormItemData>

              <pf:InFormItemData
InFormItemOID="frmDem.sctFamilyHistoy.Children" Name="Children">

                <pf:ItemStatus SourceVerified="No" Critical="StudyDefault" />

              </pf:InFormItemData>

              <pf:InFormItemData
InFormItemOID="frmDem.sctFamilyHistoy.FamilyHistoryofDepression"
Name="FamilyHistoryofDepression">

                <pf:ItemStatus SourceVerified="No" Critical="StudyDefault" />

              </pf:InFormItemData>

            </ItemGroupData>

            <ItemGroupData ItemGroupOID="frmDem.EmploymentInfo">

              <ItemData ItemOID="frmDem.EmploymentInfo.Employed.Employed"
Value="1" pf:Alias="vstBase.frmDem" />

              <ItemData ItemOID="frmDem.EmploymentInfo.Occupation.Occupation"
Value="5" pf:Alias="vstBase.frmDem" />

              <ItemData ItemOID="frmDem.EmploymentInfo.AutoFileName"
IsNull="Yes" />

              <pf:InFormItemData
InFormItemOID="frmDem.EmploymentInfo.Employed" Name="Employed">

                <pf:ItemStatus SourceVerified="No" Critical="StudyDefault" />

              </pf:InFormItemData>
```

```
              <pf:InFormItemData
InFormItemOID="frmDem.EmploymentInfo.Occupation" Name="Occupation">

                <pf:ItemStatus SourceVerified="No" Critical="StudyDefault" />

              </pf:InFormItemData>

            </ItemGroupData>

            <pf:FormStatus Activated="Yes" Frozen="No" Locked="No"
Deleted="No" SVReady="No" SVPartial="No" SVComplete="No" SVSelected="Yes"
Signed="No" Completed="Yes" />

            <pf:CustomData Name="CTMSElementName" Value="FormDemData" />

          </FormData>
```

XPath

```
ODM/ClinicalData/SubjectData/StudyEventData/FormData/pf:FormStatus/
pf:CustomData
```

Example

```
<FormData FormOID="frmDem">

            <pf:FormStatus Activated="Yes" Frozen="No" Locked="No"
Deleted="No" SVReady="No" SVPartial="No" SVComplete="No" SVSelected="Yes"
Signed="No" Completed="Yes">

              <pf:CustomData Name="CTMSElementName" Value="DemFormStatus" />

            </pf:FormStatus>

          </FormData>
```

XPath

```
ODM/ClinicalData/SubjectData/StudyEventData/FormData/ItemGroupData/
pf:CustomData
```

Example

```
<ItemGroupData
ItemGroupOID="frmDOSE.sctDosingRecordEntry.sctDosingRecordEntry"
ItemGroupRepeatKey="404831346876015">

              <pf:ItemGroupStatus SVComplete="Yes" Deleted="No" />

              <pf:CustomData Name="CTMSElementName" Value="ItemsetStatus" />

            </ItemGroupData>
```

XPath

```
ODM/ClinicalData/SubjectData/StudyEventData/FormData/ItemGroupData/ItemData/
pf:CustomData\
```

Example

```
<ItemData
ItemOID="frmDOV2.sctFormstobecompleted.Checkallforms.Checkallforms.ECG"
IsNull="Yes" pf:Alias="CheckBoxGroup">

                <pf:CustomData Name="CTMSElementName" Value="ItemData" />

              </ItemData>
```

Association

This element exists in the transactional output. The custom event extract populates it when there is an association between the two forms.

IsNull

This element indicates whether or not the item or form is null. The value is Yes when the form or item does not have any data. Otherwise, the element is not generated.

XPath

```
ODM/ClinicalData/SubjectData/StudyEventData/FormData/ItemGroupData/ItemData/
@IsNull
```

- IsNull example

IsNull example

```
<ItemData ItemOID="frmPE.sctPhysicalExamination_PE.Respiratory"
IsNull="Yes" />

<FormData FormOID="frmVS" pf:IsNull="Yes" />
```

Elements for clinical data

In this section:

- FormattedDateValue
- FormStatus element
- ItemStatus element
- Query element
- QueryStatus element
- ReasonIncomplete element

- SubjectStatus element
- MetaDataVersionRef
- ClinicalData
- SubjectData
- Candidate
- StudyEventData
- FormData
- ItemGroupData
- Annotation
- ItemData
- ItemStatus
- InFormItemData
- Query

FormattedDateValue

The FormattedDateValue element returns data that differentiates between null and unknown date values in the Oracle Life Sciences InForm software.

XPath

```
ODM/ClinicalData/ItemData/pf:FormattedDateValue
```

- UNK indicates an unknown date part.
- NUL indicates a null date part.

To maintain backward compatibility and conform to ODM standard, "-" is still used to express a value of unknown or null in the Value attribute. If differentiation between null and unknown is required, use the pf:FormattedDateValue extension.

For more information, see ItemData.

FormStatus element

The FormStatus element refers to the state of a form in the Oracle Life Sciences InForm software. A FormStatus element is returned if a change has been made to a form's state; for example, if the form was frozen, locked, or marked SV ready.

XPath

If an item has been source verified:

```
ODM/ClinicalData/SubjectData/StudyEventData/FormData/pf:FormStatus
```

Parent element	Child element
FormData	odm:AuditRecord.

Attribute	Description
Activated	A flag that indicates whether the form has been activated. type=odm:YesOrNo. Optional.
SVPartial	A flag that indicates whether the form has been partially source verified. type=odm:YesOrNo. Optional.
Frozen	A flag that indicates whether the form is frozen. type=odm:YesOrNo. Optional.
Locked	A flag that indicates whether the form is locked. type=odm:YesOrNo. Optional.
Deleted	A flag that indicates whether the form is deleted. This attribute is returned only when complianceMode="Loose." type=odm:YesOrNo Optional.
SVComplete	A flag that indicates whether the form is source verification complete. type=odm:YesOrNo. Optional.
SVReady	A flag that indicates whether the form is source verification ready. type=odm:YesOrNo Optional.
SVSelected	A flag that indicates whether partial source verification has been selected for the form. type=odm:YesOrNo Optional.
Signed	A flag that indicates whether the transaction caused the signature status of the form to change. type=odm:YesOrNo **Yes**—the transaction caused the signature status of the form to change to "signed." **No**—the transaction caused the signature status of the form to change to "unsigned."

ItemStatus element

The ItemStatus element refers to the status of an item on a form. This element is returned if an item has been source verified or if an itemset has been deleted or undeleted.

XPath

If an item has been source verified:

```
ODM/ClinicalData/SubjectData/StudyEventData/FormData/ItemGroupData/
pf:ItemStatus
```

If an itemset has been deleted or undeleted:

```
ODM/ClinicalData/SubjectData/StudyEventData/FormData/ItemGroupData/
InformItemData/pf:ItemStatus
```

Parent elements	Child element
Either of the following: • InFormItemData (if the item has been source verified). • ItemGroupData (if the itemset has been deleted).	odm:AuditRecord.

Attribute	Description
SourceVerified	A flag that indicates whether the item has been source verified. type=odm:YesOrNo. Optional.
Deleted	A flag that indicates whether the itemset has been deleted. type=odm:YesOrNo. Optional.

Query element

The query element represents a query in the Oracle Life Sciences InForm software.

XPath

```
ODM/ClinicalData/SubjectData/StudyEventData/FormData/ItemGroupData/
pf:InFormItemData/pf:Query
```

Parent element	Child element
InFormItemData.	QueryStatus element

Attributes	Description
DBUID	The location OID of the query.
OID	The identifier of the query. type=odm:oid. Optional
Text	The text of the query. type=xs:string. Optional
Type	The type of query. type=QueryType. Required.

QueryStatus element

The QueryStatus element represents the state of a query. The element contains an audit record that explains when and why the change of state happened.

XPath

```
ODM/ClinicalData/SubjectData/StudyEventData/formData/ItemGroupData/
InFormItemData/pf:Query/pf:QueryStatus
```

Parent element	Child element
pf:Query	odm:AuditRecord.

Attribute	Description
Status	type=QueryState. Required. Values: Open, Answered, closed, Candidate, Reissued, or Deleted.
Text	type=String.

ReasonIncomplete element

The ReasonIncomplete element represents the reason that an item in the Oracle Life Sciences InForm software does not have a value.

XPath

```
ODM/ClinicalData/SubjectData/StudyEventData/FormData/Annotation/
pf:ReasonIncomplete
```

Parent element	Child element
Annotation	CodeListOID="ReasonIncomplete."

ReasonIncomplete is a hard-coded codelist that defines the options. The code list is returned in the metadata and ItemData.

SubjectStatus element

The SubjectStatus element indicates that a state change has occurred to a patient, subject, or CRB.

XPath

```
ODM/ClinicalData/SubjectData/pf:SubjectStatus
```

Parent element	Child element
SubjectData	odm:AuditRecord.

Attributes

Attribute	Description
Frozen	A flag that indicates whether the subject is frozen. type=odm:YesOrNo. Optional.
Locked	A flag that indicates whether the item is locked. type=odm:YesOrNo. Optional.
SVReady	A flag that indicates whether the item is source verification ready. type=odm:YesOrNo. Optional.
State	The state of the subject. Values are: Screened, ScreenFailed, Enrolled, EnrollmentFailed, EnrollmentOverride, Randomized, Complete, or DroppedOut. type=SubjectState. Optional.
ScreenFailReason	The reason that the subject failed the screening. type=xs:string. Optional.
EnrollFailReason	The reason that the subject failed to enroll. type=xs:string. Optional.
EnrollOverrideReason	The reason that the enrollment was overridden. type:xs:string. Optional.

MetaDataVersionRef

Attribute	Value/Map to Oracle Life Sciences InForm
StudyOID	Study Name. Entity: Site. Property: Study.
MetaDataVersionOID	Volume Edition Description. Entity: Site. Property: Study Version. If the form has no study version, MetaDataVersionOID="Undefined."
EffectiveDate	Site accept date. Entity: Site. Property: Study Version Approval Date.

- Example—MetaDataVersionRef

Example—MetaDataVersionRef

```
<MetaDataVersionRef StudyOID="Hypertension Study"

MetaDataVersionOID="Study Version Basic" EffectiveDate="1998-06-30" />
```

ClinicalData

Attribute	Value/Map to Oracle Life Sciences InForm
StudyOID	Study Name.
MetaDataVersionOID	Study Version. If the form has no study version, MetaDataVersionOID="Undefined."

- Example—ClinicalData

Example—ClinicalData

```
<ClinicalData StudyOID="Depression Study Update" MetaDataVersionOID="Study
Version 1.0" />
```

SubjectData

Attribute	Value/Map to Oracle Life Sciences InForm
SubjectKey	Patient DBUID.
GUID	Subject identifier.
Revision	Entity: Subject. Property: Revision.
SiteRef	Entity: Patient Move. Property: *no property listed*.

- Signature
- SiteRef
- pf:SubjectPool
- pf:SubjectPoolChange
- pf:CriticalForm
- pf:ReviewState
- pf:ReviewStage
- Example—SubjectData

Signature

Indicates that the CRB has been signed for the subject.

SiteRef

Site for the subject. In the event of a subject site move, a SubjectData element that contains a new SiteRef and no StudyEventData element is sent.

pf:SubjectPool

Represents the source verification pool in the Oracle Life Sciences InForm application.

`SubjectData/pf:SubjectPool`

Attributes	Value/Map to Oracle Life Sciences InForm
PoolNumber	The InForm Pool Number. type=xs:string. Required. One of the following values, representing the available pools that are hardcoded in the InForm software: 0—PF_SVELIGIBLE_POOL 1—PF_SVAUTO_SELECT_POOL 2—PF_SVMANUAL_FIRSTN_POOL 3—PF_SVMANUAL_UISELECT_POOL 4—PF_SVMANUAL_IMPORT_POOL 99—PF_SVEXCLUDED_POOL
PoolRefName	The ref name of the pool. type=xs:string. Required. One of the following values: **Eligible**—PoolNumber=0, indicating the pool is SV Eligible. **AutoSelect**—PoolNumber=1, indicating a pool whose members are automatically selected based on settings determined by the site administrator. **ManualFirstN**—PoolNumber=2, indicating a pool in which the first <n> number of subjects are automatically selected. **ManualUISelect**—PoolNumber=3, indicating that the pool members are added by being selected in the UI. **ManualImport**—PoolNumber=4, indicating an imported file that contains the pool members. **Excluded**—PoolNumber=99, indicating that the pool is excluded from source verification.

pf:SubjectPoolChange

Reflects the change in the subject pool. Includes the subjects placed in the pool.

`SubjectData/pf:SubjectPoolChange`

Attributes	Value/Map to Oracle Life Sciences InForm
LocationOID	Includes the subjects placed in the pool.
PoolNumber	Pool number.

pf:CriticalForm

Represents a form that must be source verified.

```
SubjectData/pf:CriticalForm
```

Attributes	Value/Map to Oracle Life Sciences InForm
FormRef	FORMGUID.
LocationOID	Site OID.
IsCritical	ISCRITICAL

pf:ReviewState

Represents the state and stage of the progress of data review in the Oracle Life Sciences InForm application.

```
SubjectData/pf:ReviewState
```

Attributes	Value/Map to Oracle Life Sciences InForm
pf:DBUID	dbuid.
RefName	Review state name.
StateValue	State value.
Revision	Revision number.
Name element	Translated text.
Mnemonic element	Mnemonic.

pf:ReviewStage

Represents one of the three review stages of the review state.

```
SubjectData/pf:CriticalForm
```

Attributes	Value/Map to Oracle Life Sciences InForm
RefName	Stage ref name.
StageValue	Stage value.
Activated	0 or 1.
Revision	Revision number.

Example—SubjectData

```
<ClinicalData StudyOID="StudyDesign" MetaDataVersionOID="Study Design 0.0.2"
pf:TransactionGuid="{6EAEA8C3-68D1-4314-881C-5AA2A5575308}"
```

```
pf:Revision="326048162773035.000">

<SubjectData SubjectKey="14266" TransactionType="Upsert"
pf:GUID="{83A9C428-8475-4AEF-A169-37D4F1E52975}">

<SiteRef LocationOID="13341" />

<StudyEventData StudyEventOID="enroll">

<AuditRecord>

<UserRef UserOID="enes" />

<LocationRef LocationOID="Unknown" />

<DateTimeStamp>2011-05-02T21:56:02+00:00</DateTimeStamp>

<ReasonForChange>Visit Started</ReasonForChange>

</AuditRecord>

<FormData FormOID="frmEnr">

<ItemGroupData ItemGroupOID="frmEnr.sctSubjectNum">

<ItemData ItemOID="frmEnr.sctSubjectNum.SubNum_Enr.SubNum_Enr" Value="AAA">

<AuditRecord>

<UserRef UserOID="enes" />

<LocationRef LocationOID="13341" />

<DateTimeStamp>2011-05-02T21:56:02+00:00</DateTimeStamp>

<ReasonForChange>Enrollment Entry</ReasonForChange>

<SourceID>RDINFAPP261</SourceID>

</AuditRecord>

</ItemData>

</ItemGroupData>

</FormData>

</StudyEventData>

</SubjectData>

</ClinicalData>
```

Candidate

`SubjectData/Candidate`

Attribute	Value/Map to Oracle Life Sciences InForm
DOB	The date of birth of the subject.
ScreeningDate	The date of the screening.
PatientGUID	The GUID of the subject.
Revision	The revision number of the subject.
SiteGUIDREF	The GUID of the site.
Initials	The initials of the subject.
State	The state of the subject.
ScreeningNumber	The subject's screening number.
EnrollmentNumber	The subject's enrollment number.
ScreeningFailure	The reason for screening failure.
EnrollmentFailure	The reason for enrollment failure.
EnrollmentOverride	The reason that the enrollment failure was overridden.
PatientNumberRevision	The revision number of the subject number.

- Example—Candidate

Example—Candidate

```
pf:Candidate SubjectInitials="GMC" EnrollmentNumber="08-002"
ScreeningNumber="SCR-08-1" ScreeningFailure="" EnrollmentFailure=""
EnrollmentOverride="" DateOfBirth="1959-04-18T00:00:00+00:00"
ScreeningDate="2004-01-01T00:00:00+00:00"
PatientRevision="94995391031040.000">

<AuditRecord>

<UserRef UserOID="msilva" />

<LocationRef LocationOID="Unknown" />

<DateTimeStamp>2004-01-05T16:36:31+00:00</DateTimeStamp>

<ReasonForChange>Screening Log Entry</ReasonForChange>

</AuditRecord>

</pf:Candidate>
```

StudyEventData

An activated visit is indicated by a StudyEventData element that contains no child FormData element.

Attribute	Value/Map to Oracle Life Sciences InForm
StudyEventOID	Form-relative visit refpath.
StudyEventRepeatKey	Visit index (for repeating visits only).
TransactionType	• With Loose compliance mode: Upsert. • With Strict compliance mode: Insert, Upsert, or Remove.
DBUID	Entity: Visit. Property: DBUID.
Revision	Entity: Visit. Property: Revision.

• Example—StudyEventData

Example—StudyEventData

```
<StudyEventData StudyEventOID="vstBASE" />
```

FormData

Attribute	Value/Map to Oracle Life Sciences InForm
FormOID	Form RefName.
FormRepeatKey	Form index (for repeating forms only).

• Signature
• Example—FormData

Signature

Indicates that the CRB has been signed for the subject.

Example—FormData

```
<FormData FormOID="LAE1" FormRepeatKey="243960146618003"
TransactionType="Remove">

<pf:FormStatus Deleted="Yes">        Yes/No

<AuditRecord>

<UserRef UserOID="system" />

<LocationRef LocationOID="Unknown" />

<DateTimeStamp>2008-09-24T19:46:51+00:00</DateTimeStamp>

</AuditRecord>

</pf:FormStatus>
```

```
</FormData>
```

ItemGroupData

Attribute	Value/Map to Oracle Life Sciences InForm
ItemGroupOID	Form-relative RefPath for the section.
ItemGroupRepeatKey	Present when the section contains an ItemSet and specifies the ItemSet index.

- Example—ItemGroupData

Example—ItemGroupData

```
<ItemGroupData ItemGroupOID="LAB" ItemGroupRepeatKey="134562926897091" />
```

Annotation

```
FormData/Annotation

ItemData/Annotation
```

Attribute/Child	Value/Map to Oracle Life Sciences InForm
SeqNum	Comment ID.
Comment	Comment text.
Comment/ReasonIncomplete	Reason that the form or item is incomplete.
GUID	Entity: Comment. Property: GUID.
DBUID	Entity: Comment. Property: DBUID.

- Example—Annotation

Example—Annotation

```
<Annotation SeqNum="9985">

<Comment>test item comment</Comment>

</Annotation>
```

ItemData

Attribute/Child	Value/Map to Oracle Life Sciences InForm
ItemOID	Item RefName.
Value	ItemContext/control values.

Attribute/Child	Value/Map to Oracle Life Sciences InForm
DBUID	• Entity: Item. Property:DBUID. • Entity: Control. Property: DBUID.
Revision	• Entity: Item. Property: Revision. • Entity: Control Property: Revision.
pf:FormattedDateValue	Indicates a value of null or unknown in the date part. • UNK indicates an unknown date part. • NUL indicates a null date part.

Note:

To maintain backward compatibility and conform to ODM standard, "-" is still used to express a value of unknown or null in the Value attribute. If differentiation between null and unknown is required, use the pf:FormattedDateValue extension.

- Example—ItemData

Example—ItemData

Example for unknown date part:

```
<ItemData ItemOID="LAE1.LsctAE.LitmAESTDT.LAESTDTTM"Value="2009-04-19T-:-:-
+00:00" pf:FormattedDateValue="2009-04-19TUNK:UNK:UNK+00:00" />
```

Example for null date part:

In the example, the hour, minute, and second are null.

```
<ItemData ItemOID="LAE1.LsctAE.LitmAESTDT.LAESTDTTM"Value="2009-04-19T-:-:-
+00:00" pf:FormattedDateValue="2009-04-19TNUL:NUL:NUL+00:00" />
```

ItemStatus

If an item has been source verified:

```
InformItemData/ItemStatus
```

If an itemset has been deleted or undeleted:

```
ItemGroupData/ItemStatus
```

Attribute/Child	Value/Map to Oracle Life Sciences InForm
Source Verified	Item has been source verified.
Deleted	Indicates whether the item has been deleted.

- Example—ItemStatus

Example—ItemStatus

```
<FormData FormOID="frmDOV">

    <ItemGroupData ItemGroupOID="frmDOV.DOV">

        <pf:InFormItemData InFormItemOID="frmDOV.DOV.DOV" Name="DOV">

            <pf:ItemStatus SourceVerified="Yes"> "> (Yes or No are the 2
values this can be)

                <AuditRecord>

                    <UserRef UserOID="system" />

                    <LocationRef LocationOID="Unknown" />

                    <DateTimeStamp>2008-09-17T20:32:49+00:00</DateTimeStamp>

                </AuditRecord>

            </pf:ItemStatus>

        </pf:InFormItemData>

    </ItemGroupData>

</FormData>
```

InFormItemData

```
InformItemData/ItemStatus
```

Attribute/Child	Value/Map to Oracle Life Sciences InForm
InformItemOID	Form-relative RefPath for the item.
Name	Item RefName.
ItemStatus	Status of the item in the Oracle InForm software; for example, SVReady.
Query	Query element against an item in the InForm software.

- Example—InformItemData

Example—InformItemData

```
<pf:InFormItemData InFormItemOID="frmDOSE.sctDOSE.itsDOSE.itmDOSEToDate"
Name="itmDOSEToDate">

    <pf:Query OID="{00E6AD12-0848-4F71-AB61-ED0F845D1404}" Text="Stop Date is
not equal to or after the Start Date; please verify" Type="Autoquery"
pf:DBUID="75369" pf:Revision="244386598500043.000">

        <pf:QueryStatus Status="Open">

            <AuditRecord>

                <UserRef UserOID="autoquery" />

                <LocationRef LocationOID="Unknown" />

                <DateTimeStamp>2008-09-29T18:09:58+00:00</DateTimeStamp>

                <ReasonForChange>Stop Date is not equal to or after the Start
Date; please verify</ReasonForChange>

            </AuditRecord>

        </pf:QueryStatus>

    </pf:Query>

</pf:InFormItemData>
```

Query

```
InformItemData/Query
```

Attribute/Child	Value/Map to Oracle Life Sciences InForm
DBUID	Entity: Query. Property: DBUID.
OID	Query identifier.
Text	The text of the query.
Type	Autoquery or User.

Attribute/Child	Value/Map to Oracle Life Sciences InForm
Revision	Revision.
Query/QueryStatus	The status of the query.

- Example—Query

Example—Query

```
<pf:Query OID="{08016623-5E3D-417C-93BB-33573CF1E1DC}" Text="Data does not
match source" Type="User">

    <pf:QueryStatus Status="Open">

        <AuditRecord>

            <UserRef UserOID="system" />

            <LocationRef LocationOID="Unknown" />

            <DateTimeStamp>2008-03-17T19:17:22+00:00</DateTimeStamp>

            <ReasonForChange>Data does not match source</ReasonForChange>

        </AuditRecord>

    </pf:QueryStatus>

</pf:Query>
```

Elements for admin data

In this section:

- GroupDef element
- Right element
- User
- GroupDef
- Location
- SignatureDef

GroupDef element

The GroupDef element defines a user group in an InForm study. AdminData contains a collection of GroupDef elements.

Xpath

```
ODM/AdminData/pf:GroupDef
```

Parent element	Child element
AdminData	pf:Right.

Attributes

Attribute	Description
OID	The refname of the item. type=odm:oid. Required.
Name	The name of the group as displayed in the InForm software. type=odm:text. Required.
GroupType	The type of the group, such as Rights, Reporting, Query, Signature. type=xs:String. Required.

Right element

The pf:Right element is a child element of the pf:GroupDef element. One pf:Right element exists for each right defined in the user group.

Xpath

```
ODM/AdminData/pf:GroupDef/pf:Right
```

Parent element	Child element
pf:GroupDef	None.

Attribute	Description
Description	The description of the right. type=xs:string. Required.

User

Attribute/Child	Value/Map to Oracle Life Sciences InForm
OID	User Name.
UserType	User Type.
LoginName	User Name.
DisplayName	User DisplayName.

Attribute/Child	Value/Map to Oracle Life Sciences InForm
FullName	User first name + User last name.

> **Note:**
>
> Not all cultures use FirstName + LastName as the full name. The full name can be derived from FirstName and LastName elements that are available in the same response. The consumer of DownloadAdminData ODM should rely on FirstName and LastName elements to get the full name or display name.

FirstName	User first name.
LastName	User last name.
Organization	N/A
Address/StreetName	User Address 1. User Address 2
Address/City	User City.
Address/StateProv	User State Province.
Address/County	User Country.
Address/PostalCode	User postal code.
Address/OtherText	N/A
Email	User email.
Picture	N/A
Pager	User beeper.
Fax	User fax.
Phone	User phone number.
LocationRef/LocationOID	Site Name. Entity: User. Property: Site.
GroupRef	One GroupRef child element exists for each group to which the user belongs. Contains a GroupOID attribute.
DBUID	Entity: User. Property: DBUID.
GUID	User Identifier.
Revision	Entity: User. Property: Revision.

Attribute/Child	Value/Map to Oracle Life Sciences InForm
LoginName	Entity: User. Property: Login Name.
UserType	Entity: User. Property: User Type.
StudyLocale	Locale of study. Derived from dcv_thingdata in the study database.
Active	Indicates whether the user state is active.
Terminated	Indicates whether the user state is terminated.

- Example—User

Example—User

```
<User OID="mmeyer" UserType="Investigator" pf:DBUID="11816"
pf:GUID="{09379D50-EB2B-46B1-8BDC-F2F7F6A6363D}" pf:StudyLocale="en-US"
pf:Active="Yes" pf:Terminated="No">

        <LoginName>mmeyer</LoginName>

        <DisplayName>Marianne Meyer</DisplayName>

        <FullName>Marianne Meyer</FullName>

        <FirstName>Marianne</FirstName>

        <LastName>Meyer</LastName>

        <Address>

          <Country>USA</Country>

        </Address>

        <Email>email@domain.test</Email>

        <Fax>(555) 555-1212</Fax>

        <Phone>(555) 555-1212</Phone>

        <LocationRef LocationOID="13341" />

        <pf:GroupRef GroupOID="6536" />

        <pf:GroupRef GroupOID="13940" />

      </User>
```

GroupDef

GroupRef elements reference GroupDef elements by matching the GroupRef GroupOID attribute to the GroupDef OID attribute.

GroupRef is a child of User.

Attribute/Child	Value/Map to Oracle Life Sciences InForm
OID	The DBUID of the group.
NAME	Name of group as displayed in the Oracle InForm software.
GroupType	Type of group as defined in the Oracle InForm software.
Right	List of rights. Contains a list of Right elements, each of which contains a Description.

- Right
- Example—GroupDef

Right

```
AdminData/pf:GroupDef/pf:Right
```

Attribute	Value/Map to Oracle Life Sciences InForm
Description	The right defined in the group.

Example—GroupDef

```
<pf:GroupDef OID="5954" Name="System Creator Group" GroupType="Rights">

    <pf:Right Description="Create User"/>

    <pf:Right Description="Terminate User" />

</pf:GroupDef>
```

Location

To ensure that the audit records that are generated by sponsor users comply with the ODM standard, a Location with OID **Unknown** is automatically defined in the ODM that is returned for a study.

Attribute	Value/Map to Oracle Life Sciences InForm
OID	Site DBUID.
Name	Site name.
LocationType	Site. Entity: Site. Property: Type.
Revision	Entity: Site. Property: Revision. Note: Location Revision is the same as transaction only if the transaction is revising the location.
GUID	Site identifier.

Attribute	Value/Map to Oracle Life Sciences InForm
SiteCountry	Entity: Site. Property: Country.
SiteTimezone	Entity: Site. Property: Timezone.
Locale	Locale of the site.
pf:SVAutoSelectRate	The value comes from a query: For more information, see Subject pool selection.
pf:SVFirstNSubjects	The value comes from a query: For more information, see Subject pool selection.

- Mnemonic
- Example—Location

Mnemonic

```
Location/Mnemonic
```

Attribute	Value/Map to Oracle Life Sciences InForm
TranslatedText	The site mnemonic that does not come from the pf_resourcedata. This mnemonic can have any Unicode characters. It should not contain the xml:lang attribute.

Example—Location

```
<Location

    LocationType="Site" Name="(01) Massachusetts General Hospital"

    OID="10127" pf:SiteCountry="USA"

        pf:SiteTimezone="(GMT-05:00) Eastern Time (US &amp;amp; Canada)">

    <MetaDataVersionRef

        EffectiveDate="2005-04-01T00:00:00+00:00"

        MetaDataVersionOID="StudyVersion020108"

        StudyOID="Depression Study"/>

    <Mnemonic

        xmlns="http://www.phaseforward.com/InFormAdapter/ODM/Extensions/2.0">

    <TranslatedText

        xmlns="http://www.cdisc.org/ns/odm/v1.3">01</TranslatedText>
```

```
    </Mnemonic>

</Location>
```

SignatureDef

Attribute	Value/Map to Oracle Life Sciences InForm
OID	Signature DBUID.
Methodology	Electronic.
Meaning	CRB meaning, CRF meaning, or Group Name.
LegalReason	CRB Affidavit, CRF Affidavit, or PF_DEFAULT_CRFAFFADAVIT.

- Meaning
- LegalReason
- Example—SignatureDef

Meaning

CRB meaning, CRF meaning, or Group Name.

```
SignatureDef/Meaning
```

Attribute	Value/Map to Oracle Life Sciences InForm
TranslatedText	Language-specific text from the study.

LegalReason

CRB Affidavit, CRF Affidavit, or PF_DEFAULT_CRFAFFADAVIT.

```
SignatureDef/Meaning
```

Attribute	Value/Map to Oracle Life Sciences InForm
TranslatedText	Language-specific text from the study.

Example—SignatureDef

```
<SignatureDef OID="CRA Sigs" Methodology="Electronic">

    <Meaning>Approved</Meaning>

    <LegalReason>

        By my dated signature below, I, %s %s, verify that this case report
form accurately displays the results of the examinations, tests, evaluations
and treatments noted within. Pursuant to Section 11.100 of Title 21 of the
Code of Federal Regulations, this is to certify that I intend that this
electronic signature is to be the legally binding equivalent of my
handwritten signature. To this I do attest by supplying my password and
```

```
clicking the button marked Submit below.

    </LegalReason>

</SignatureDef>
```

Elements for metadata

In this section:

- Mapping of localized items
- InFormItemDef element
- InFormItemRef element
- Study
- GlobalVariables
- BasicDefinitions
- MetaDataVersion
- StudyEventDef
- FormDef
- ItemGroupDef
- InFormItemDef
- ItemDef
- CodeList

Mapping of localized items

The following items are localized in the Oracle Life Sciences InForm software. The translation for each item is placed under the TranslatedText element in the ODM that is returned.

Item name	Element name in ODM.xml
The symbol of measurement unit.	MeasurementUnit/Symbol
Item text.	itemDef/Question
Radio button list, dropdown list, list box, control group, or checkbox list that is associated with a control in the InForm software.	CodeList/CodeListItem/Decode
Form mnemonic.	FormDef/pf:Mnemonic
Visit mnemonic.	StudyEventDef/pf:Mnemonic
Legal Reason.	SignatureDef/pf:LegalReason
Meaning.	SignatureDef/pf:Meaning

Site mnemonic is also placed under the TranslatedText element. However, it is not localized in pf_resourcedata in the Oracle InForm application. It is returned as the fallback because there is no language associated with it.

InFormItemDef element

The InFormItemDef element is the metadata definition for the Oracle Life Sciences InForm item, and explains which controls (ItemRefs) are contained in the item.

In the Oracle implementation, an ItemDef maps to an InForm control.

XPath

```
ODM/Study/MetaDataVersion/pf:InformItemDef
```

Parent element	Child element
MetaDataVersion	odm:ItemRef.

Attribute	Description
OID	The refname of the item. type=odm:oid. Required.
Name	type=odm:text. Required.
SVRequired	Indicates whether source verification is required. type=odm:YesOrNo. Optional.
DBUID	The location OID.
GUID	Visit identifier.
Revision	Revision.
UUID	UUID.

InFormItemRef element

The InFormItemRef element shows the ordering of the Oracle Life Sciences InForm item within a section.

XPath

```
ODM/Study/MetaDataVersion/ItemGroupDef/pf:InFormItemRef
```

Parent element	Child element
ItemGroupDef	None.

Attribute	Description
InFormItemOid	The refname of the item. type=odm:oid. Required.
OrderNumber	Display order of the item within the section. type=odm:integer. Optional.

Attribute	Description
Mandatory	Indicates whether the item is mandatory. type=odm:YesOrNo. Required.

Study

Attribute	Value/Map to Oracle Life Sciences InForm
OID	Oracle InForm Study Name.

- Example—Study

Example—Study

```
<Study OID="Hypertension Study" />
```

GlobalVariables

Child	Value/Map to Oracle Life Sciences InForm
StudyName	Oracle InForm Study Name.
StudyDescription	Volume Edition DesignNotes.
ProtocolName	ProtocolVersion.

- Example—GlobalVariables

Example—GlobalVariables

```
<GlobalVariables>

    <StudyName>Hypertension Study</StudyName>

    <ProtocolName>Protocol XYZZY</ProtocolName>

</GlobalVariables>
```

BasicDefinitions

BasicDefinitions contains the Oracle Life Sciences InForm measurement unit definitions.

- MeasurementUnit
- TranslatedText
- Example—BasicDefinitions

MeasurementUnit

Attribute	Value/Map to Oracle Life Sciences InForm
OID	Unit RefName.
Name	Unit Symbol.
DBUID	Entity: Units. Property: DBUID.
GUID	Unit identifier.
Revision	Entity: Units. Property: Revision.

TranslatedText

```
BasicDefinitions/MeasurementUnit/Symbol/TranslatedText
```

Attribute	Value/Map to Oracle Life Sciences InForm
Body text	Unit Symbol.

TranslatedText specifies the xml:lang for each language, and the element without xml:lang. This value is used when the culture is unspecified or unavailable for a given value.

Example—BasicDefinitions

```
<BasicDefinitions>

    <MeasurementUnit OID="Inches" Name="Inches">

    <Symbol>

            <TranslatedText>in</TranslatedText>

            <TranslatedText xml:lang="en-US">in</TranslatedText>

            <TranslatedText xml:lang="ja-JP">in</TranslatedText>

    </Symbol>

    </MeasurementUnit>

    <MeasurementUnit OID="Centimeter" Name="Centimeter">

        <Symbol>

            <TranslatedText>cm</TranslatedText>

        </Symbol>

    </MeasurementUnit>

</BasicDefinitions>
```

MetaDataVersion

Attribute	Value/Map to Oracle Life Sciences InForm
OID	Study version RefName.
Name	Study version display name.
ApprovalDate	Date that the study was approved.
DBUID	Entity:StudyVersion. Property: Revision.
GUID	Study version identifier.
Revision	Entity:StudyVersion. Property: Revision.

- StudyEventRef
- Example—MetaDataVersion

StudyEventRef

Attribute	Value/Map to Oracle Life Sciences InForm
StudyEventOID	Visit RefName.
OrderNumber	Visit order number (for user interface display).
Mandatory	Always **No**.

Example—MetaDataVersion

```
<MetaDataVersion OID="Study Version Basic" Name="Protocol XYZZY">

    <Protocol>

        <StudyEventRef StudyEventOID="Visit1" OrderNumber="1"
Mandatory="No" />

        <StudyEventRef StudyEventOID="Visit2" OrderNumber="2"
Mandatory="No" />

        <StudyEventRef StudyEventOID="Visit3" OrderNumber="3"
Mandatory="No" />

        <StudyEventRef StudyEventOID="Visit4" OrderNumber="4"
Mandatory="No" />

    </Protocol>

</MetaDataVersion>
```

StudyEventDef

Attribute	Value/Map to Oracle Life Sciences InForm
OID	Visit RefName.
Name	Visit RefName.
Repeating	**Yes** for repeating visits.
Type	Scheduled, Unscheduled, or Common.
Category	PatientVisit, Screening, Enrollment, CommonCRF, or Relation.
DBUID	Entity: Visit. Property: DBUID.
GUID	Visit identifier.
Revision	Entity: Visit. Property: Revision.
UUID	Entity: Visit. Property: UUID.
Dynamic	Visit is a dynamic visit.
VisitStartHours	Visit start hours set in Oracle Life Sciences Central Designer. For example, if the value for visit 2 is 8, visit 2 should occur one day after visit 1.

- Mnemonic
- FormRef
- Example—StudyEventDef

Mnemonic

```
StudyEventDef/Mnemonic
```

Attribute	Value/Map to Oracle Life Sciences InForm
TranslatedText	Display mnemonic for visit.

FormRef

Attribute	Value/Map to Oracle Life Sciences InForm
FormOID	Form RefName.
OrderNumber	Form page order (for user interface display).
Mandatory	Always **No**.
AltFormOID	Specifies the OID of the Alt form for the form that is identified by the current FormOID.

Example—StudyEventDef

```
<StudyEventDef OID="vstFinal" Name="vstFinal" Repeating="No" Type="Scheduled"
Category="Enrollment" pf:DBUID="10057" pf:GUID="{8BA4EB52-CCFD-4567-92CD-
```

```
AFFA16947926}" pf:Revision="250599557260035" pf:UUID="D882CE3A-0F42-11D2-
A419-00A0C963E0AC">

    <FormRef FormOID="frmDOV" OrderNumber="1" Mandatory="No" />

    <FormRef FormOID="frmSC" OrderNumber="2" Mandatory="No" />

        <pf:Mnemonic>

            <TranslatedText>Final</TranslatedText>

        </pf:Mnemonic>

</StudyEventDef>
```

FormDef

Attribute	Value/Map to Oracle Life Sciences InForm
FormOID	Form RefName.
Name	Form RefName.
Repeating	**Yes** if the form is a repeating form.
DBUID	Entity: Form. Property: DBUID.
GUID	Form identifier.
Revision	Entity: Form. Property: Revision.
UUID	Entity: Form. Property: UUID.
Dynamic	**Yes** if the form is a dynamic form.
OrderNumber	The order of the form (for presentation in the user interface).

- Mnemonic
- ItemGroupRef
- Example—FormDef

Mnemonic

```
FormDef/Mnemonic
```

Attribute	Value/Map to Oracle Life Sciences InForm
TranslatedText	The display mnemonic for the form.

ItemGroupRef

Attribute	Value/Map to Oracle Life Sciences InForm
ItemGroupOID	Form-relative RefPath for the section.
OrderNumber	Section Order.

Attribute	Value/Map to Oracle Life Sciences InForm
Repeating	Section Repeating, when **Yes** indicates that the section contains an itemset.

Example—FormDef

```
<FormDef OID="frmDOV" Name="frmDOV" Repeating="No" pf:DBUID="7642"
pf:GUID="ab9274c1-b46c-4d3d-baf6-a0a8bbcf6a06" pf:Revision="250599336073035"
pf:UUID="D882CE3B-0F42-11D2-A419-00A0C963E0AC">

    <ItemGroupRef ItemGroupOID="frmDOV.sctVisitDateandTime" OrderNumber="1"
Mandatory="No" />

    <pf:Mnemonic>

        <TranslatedText>DOV</TranslatedText>

    </pf:Mnemonic>

</FormDef>
```

ItemGroupDef

Attribute	Value/Map to Oracle Life Sciences InForm
OID	Form-relative RefPath for the section.
Name	Section RefName.
Repeating	Section Repeating; **Yes** when the section contains an ItemSet.
ItemSetDBUID	Entity: ItemSet. Property: DBUID.
DBUID	Entity: Section. Property: DBUID.
GUID	Form identifier.
Revision	Entity: Section. Property: Revision.
UUID	Entity: Section/Itemset. Property: UUID.
ItemSetRefName	Present when the section contains an itemset; specifies the RefName of the ItemSet in the section.
ItemSetRevision	Entity: ItemSet. Property: Revision.
SVRequired	Present when the section contains an ItemSet and the ItemSet requires source verification.

- InFormItemRef
- ItemRef
- Example—ItemGroupDef

InFormItemRef

```
InformItemData/ItemStatus
```

Attribute	Value/Map to Oracle Life Sciences InForm
InFormOID	Form-relative RefPath of an item.
Mandatory	**Yes**, if the item is mandatory.
OrderNumber	Display order of the item within the section.

- Example—InformItemRef

Example—InformItemRef

```
<pf:InFormItemRef InFormItemOId="frmCGI.sctCGIImp.itmCGIImp" OrderNumber="1"
Mandatory="Yes" />
```

ItemRef

Attribute	Value/Map to Oracle Life Sciences InForm
ItemOID	Form-relative RefPath for a control within an item.
OrderNumber	Control order within an item.
Mandatory	Control is required.

Example—ItemGroupDef

```
<ItemGroupDef OID="frmDOV.sctVisitDateandTime" Name="sctVisitDateandTime"
Repeating="No" pf:DBUID="7639" pf:GUID="{0bf10cac-
c53e-4926-8843-9e8fda1569d4}" pf:Revision="250599335838035"
pf:UUID="ABCFA388-223A-11D2-A426-00A0C963E0AC">

    <ItemRef
ItemOID="frmDOV.sctVisitDateandTime.DateandTimeofVisit_DOV.DateandTimeofVisit_
DOV" OrderNumber="1" Mandatory="Yes" />

    <pf:InFormItemRef
InFormItemOId="frmDOV.sctVisitDateandTime.DateandTimeofVisit_DOV"
OrderNumber="1" Mandatory="Yes" />

</ItemGroupDef>
```

InFormItemDef

Attribute/Child	Value/Map to Oracle Life Sciences InForm
OID	The refname of the item. type=odm:oid. Required.

Attribute/Child	Value/Map to Oracle Life Sciences InForm
Name	Form-relative RefPath for the item. type=odm:text. Required.
SVRequired	**Yes**, if source verification is required for the item. type=odm:YesOrNo. Optional.
DBUID	Entity: Item. Property: DBUID.
GUID	Entity: Item. Property: GUID.
Revision	Entity: Item. Property: Revision.
UUID	Entity: Item. Property: UUID.

- Example—InformItemDef

Example—InformItemDef

```
<pf:InFormItemDef OID="frmDOV.sctVisitDateandTime.DateandTimeofVisit_DOV"
Name="DateandTimeofVisit_DOV" SVRequired="Yes" pf:DBUID="7648"
pf:GUID="{005A7BA1-AEA9-42E4-83F3-3E2358F68646}"
pf:Revision="250599336526035" pf:UUID="BD991BBF-B0A4-11D2-80E3-00A0C9AF7674">

    <ItemRef
ItemOID="frmDOV.sctVisitDateandTime.DateandTimeofVisit_DOV.DateandTimeofVisit_
DOV" OrderNumber="1" Mandatory="Yes" />

</pf:InFormItemDef>
```

ItemDef

Attribute	Value/Map to Oracle Life Sciences InForm
OID	Form-relative RefPath for the control.
Name	Item RefName.
DataType	See Data Type Table.
Length	See Data Type Table.
SignificantDigits	See Data Type Table.
Revision	• Entity: Control. Property: Revision. • Entity: Item. Property: Revision.
GUID	Item identifier.
DBUID	• Entity: Control. Property: DBUID. • Entity: Item. Property: DBUID.

Attribute	Value/Map to Oracle Life Sciences InForm
UUID	Entity: Control. Property: UUID.
ParentOID	The parent of each ItemDef that is not a top-level ItemDef.
ParentType	Defines the type of parent control. If value of parent type is: • **ItemDef**, then pf:ParentOID refers to the parent ItemDef's OID. • **CodeListItem**, then pf:ParentOID refers to the parent CodeListItem's pf:SelectionOID.
SelectionOID	An OID that uniquely identifies the selection in a radio group.
SelectionOwner	For each ItemDef that is the child of a radio group selection, the OID of the CodeList that contains the codelist selection.
ItemDefType	Indicates the control type. Values: RadioGroup, Checkbox, Text, Calculated, PullDown, Date.
Question	Question text for the item that contains the control.
SignificantDigits	See Data Type Table.
CheckboxGroupRefName	Present when the control is contained in a checkbox group and contains the RefName of the checkbox group.

- Data Type Table
- MeasurementUnitRef
- Question
- Example—ItemDef

Data Type Table

Oracle Life Sciences InForm control type	Definition
Simple Control	• Data Type is defined by the element's type. • Length: text 255, integer 10, float 308. **Note:** – Integer is always returned as 10 (the maximum number of digits in a 32-bit integer). – Float is always returned as 308 (the maximum exponent for a 64-bit floating-point number). • Significant Digit: 4.
Pulldown Control	References a codelist with the allowable values.

Oracle Life Sciences InForm control type	Definition
Text Control	• Data Type is defined by control data type (Pf_TextControl/DataType). • Length: text Pf_TextControl/MaxLength, integer 10, float 308. **Note:** – Integer is always returned as 10 (the maximum number of digits in a 32-bit integer). – Float is always returned as 308 (the maximum exponent for a 64-bit floating-point number). • Significant Digit: Pf_TextControl/PFPrecision.
Radio Control	References a codelist with the allowable values.
Group Control	Represented as an ItemDef per check option with the name of the option included in the form-relative RefPath in the ItemDefOID.
Datetime Control	incompleteDatetime.
Calculated Control	Text type with length = 255.

MeasurementUnitRef

Attribute	Value/Map to Oracle Life Sciences InForm
MeasurementUnitOID	Unit RefName.
NormalizationUnit	**Yes**, if the referenced unit is for normal values.

Question

Child	Value/Map to Oracle Life Sciences InForm
TranslatedText	Item question. A TranslatedText element exists for each study language.

Example—ItemDef

```
<ItemDef OID="frmDOSE.sctDOSE.itsDOSE.itmDOSEFromDate.dtmDOSE" Name="dtmDOSE"
DataType="incompleteDatetime">

    <Question>

        <TranslatedText>Start date</TranslatedText>

    </Question>

</ItemDef>
```

CodeList

Attribute	Value/Map to Oracle Life Sciences InForm
OID	Control RefName. For example, if an item contains a drop-down list, the RefName of the drop-down list will be used. If file type is Transactional, the ConrolRefName is hierarchical: form.section.item.control
Name	• If file type is Snapshot, Name is the same as OID. • If file type is Transactional, Name is the same as the ControlRefName without the hierarchical prefixing.
DataType	Type of Control. See Data Type Table.

- Example—CodeList
- CodeListItem

Example—CodeList

File type is Snapshot:

```
<CodeList OID="rdcEXCLC" Name="rdcEXCLC" DataType="text"/>
```

File type is Transactional:

```
<CodeList OID="frmPreg.sctPreg.itmPregTest.itmPregTest.rdcPregDone"
Name="rdcPregDone" DataType="text">
```

CodeListItem

Attribute	Value/Map to Oracle Life Sciences InForm
CodedValue	Value used to map the CodeListItem to an ItemData value in ODM ClinicalData.
pf:SelectionOID	An OID that uniquely identifies the selection in a radio group. The value is a concatenation of the CodeList OID and the CodeListItem CodedValue.

- Example—CodeListItem

Example—CodeListItem

```
<CodeListItem CodedValue="2"
pf:SelectionOID="frmPreg.sctPreg.itmPregTest.itmPregTest.rdcPregDone.2">

    <Decode>

        <TranslatedText>Positive</TranslatedText>
```

```
    </Decode>

</CodeListItem>
```

Oracle attributes that are applied to standard ODM elements

The file **PFextensions.xsd** contains the attribute extensions for attributes that are defined in the **PhaseForward_ODM.xsd** file. These schema files are located in the *<Installation_path>/ODM/bin/xsd* directory.

Standard ODM element	Oracle attribute	Type
ClinicalData	TransactionalGuid	xs:string
CodeListItem	SelectionOID	odm:oid
FormDef	UUID	xs:string
FormRef	AltFormOID	xs:string
ItemData	NormalizedValue	odm:value
ItemDef	CheckboxGroupRefName	xs:string
ItemDef	InFormDateTime	xs:boolean
ItemDef	PFVarName	xs:string
ItemDef	ParentOID	odm:oidref
ItemDef	ParentType	pf:ParentType
ItemDef	ItemDefType	pf:ItemDefType
ItemDef	SelectionOwner	odm:oidref
ItemDef	UUID	xs:string
ItemGroupDef	ItemSetRefName	xs:string
ItemGroupDef	SVRequired	odm:YesOrNo
ItemGroupDef	UUID	xs:string
Location	Mnemonic	xs:string
Location	SiteCountry	xs:string
Location	SiteTimezone	xs:string
Location	Locale	xs:language
Location	SVAutoSelectRate	xs:integer Value 1-100
Location	SVFirstNSubjects	xs:integer
MeasurementUnitRef	NormalizationUnit	odm:YesOrNo
MetaDataVersion	ApprovalDate	xs:boolean
ODM	MappingVersion	xs:string
ODM	HierarchicalOIDs	xs:string
ODM	InFormAdapterVersion	xs:string
SignatureDef	GroupName	xs:string
SignatureDef	Meaning	xs:string
SignatureDef	LegalReason	xs:string
FormDef StudyEventDef	Dynamic	odm:YesOrNo
StudyEventDef	Optional	odm:YesOrNo
StudyEventDef	UUID	xs:string
User	StudyLocale	xs:language

Revision, DBUID, and GUID attributes

DBUID, GUID, and Revision attributes are Oracle extension attributes on their respective elements.

- Metadata
- Clinical data and Association data
- AdminData

Metadata

In metadata, the following elements include the pf:DBUID, pf:GUID, and pf:Revision attributes.

- MetaDataVersion
- StudyEventDef
- FormDef
- ItemGroupDef
- ItemDef
- MeasurementUnit
- InFormItemDef

In metadata, the following elements include the pf:UUID attribute.

- StudyEventDef
- FormDef
- ItemGroupDef
- ItemDef
- InFormItemDef

Clinical data and Association data

ODM data elements consist of Clinical data nodes and Association nodes. These nodes contain a new pf:Revision attribute that applies to all the data in the node unless the child node contains a pf:Revision attribute of its own.

The DBUID and GUID attributes for the data items within these nodes are defined in the metadata except as noted:

- Annotation.
- Location.
- Query.
- SubjectData.
- MetaDataVersion.
- User.
- Location.

AdminData

The User element includes pf:DBUID, pf:GUID, pf:Revision, and pf:StudyLocale extensions.

Site\Location includes the pf:GUID, pf:Revision, and pf:Locale extensions.

- The location OID is the DBUID.
- Location Revision is the same as transaction only if the transaction is revising the location.

For more information, see the individual elements listed in ODM Mapping.

Extensions that show control hierarchy and type

To define details for controls, the ODM Export interface provides the following extensions to the ODM elements ItemDef and CodeListItem.

Oracle extension to ItemDef	Description
pf:ParentOID	The parent of each ItemDef that is not a top-level ItemDef.
pf:ParentType	Defines the type of parent control. If value of parent type is: • **ItemDef**, then pf:ParentOID refers to the parent ItemDef's OID. • **CodeListItem**, then pf:ParentOID refers to the parent CodeListItem's pf:SelectionOID.
SelectionOwner	For each ItemDef that is the child of a radio group selection, the OID of the CodeList that contains the codelist selection.
pf:ItemDefType	Indicates the control type. Values: RadioGroup, Checkbox, Text, Calculated, PullDown, Date.

Oracle extension to CodeListItem	Description
pf:SelectionOID	An OID that uniquely identifies the selection in a radio group. The value is a concatenation of the CodeList OID and the CodeListItem CodedValue.