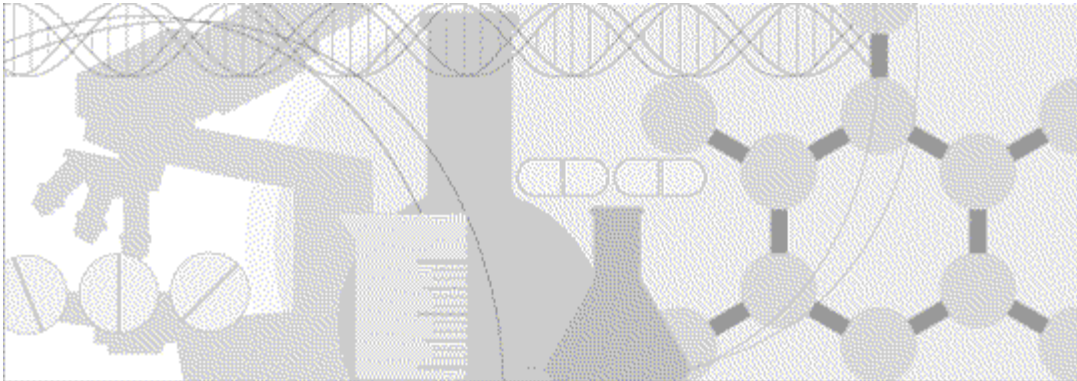


Interfaces Guide

Oracle[®] Health Sciences InForm Adapter
Release 1.3.9



ORACLE[®]

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CHAPTER 1

What is the InForm Adapter software?

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What is the InForm Adapter software?

The InForm Adapter software provides interfaces to web services that support the secure transfer of data between InForm studies and either Oracle products (such as the Clintrial Integration Solution (CIS) and Central Coding applications) or third-party products and custom applications. Each application that can accept queries or updates to its data and metadata from InForm studies requires a specific set of interfaces.

Like application programming interfaces (APIs), the InForm Adapter 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 InForm Adapter interfaces

The InForm Adapter 1.3.9 release includes the following interfaces that are available for programmatic access.

Interface	Description
Discrepancy	Transmits InForm queries (discrepancies) to and from other systems or modules.
ODM Export	Provides access to receive InForm administrative data, clinical data, and metadata in CDISC ODM standard format.

About namespaces

Each InForm Adapter interface has an XML namespace that defines the parameters for each web method that resides in the namespace.

A sample namespace is

`http://www.phaseforward.com/InForm Adapter/ODM`

Note: The information below is available only if documentation is enabled for the web service. For security purposes, web service documentation is disabled by default. For information on how to enable documentation for web services, see the *Secure Configuration Guide*.

If you browse to the ASMX page for an interface, you are presented with:

- A list of the web methods that can be used to interact with that interface, including syntax provided for each web method.
- Samples that include the SOAP header and body, but not the request node.

Location of .xsd files

For each of the following interfaces, the xsd files are located on the InForm Adapter server in the following location:

```
<installation_directory>\InForm Adapter\<interface_name>\bin\xsd
```

For example, the AdapterAdmin.xsd file is located at:

```
<installation_directory>\InForm Adapter\AdapterAdmin\bin\xsd\
```

Interface name	xsd files
Discrepancy	discrepancyInterface.xsd
ODM	ODM1-2-0.xsd
	ODMParameters.xsd
	PhaseForward_ODM.xsd

CHAPTER 2

Discrepancy interface

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Overview: Discrepancy interface

The Discrepancy interface sends discrepancies (clinical queries) and their resolutions between the InForm software and other systems or modules.

- For a study, site, subject, or list of subjects, you can retrieve discrepancies of a specific type, or retrieve a count of discrepancies in the form of [Subject, State, Guid].
- For an item, you can issue a candidate or open discrepancy, retrieve all discrepancies, or retrieve discrepancies of a specific type.
- For a discrepancy, or list of discrepancies identified by a GUID, you can answer or close a discrepancy, delete a candidate discrepancy, reissue an answered discrepancy, and retrieve discrepancy details.
- You can close a set of answered discrepancies in a single transaction.
- The Discrepancy interface can determine whether the requested target of a discrepancy maps to another item, and issue the discrepancy against the mapped (target) item.

For more information, see *Use cases* (on page 32).

The Discrepancy interface includes the following operations.

Operation	Description
Summary reporting operations	
<i>GetSummaryCounts</i> (on page 14)	Retrieves a count of discrepancies against the requested site, subject, and visit criteria.
Detail reporting operations	
<i>GetByCriteria</i> (on page 16)	Retrieves details for all discrepancies that match the requested criteria.
<i>GetByDiscrepancyGuid</i> (on page 21)	Retrieves the current detail for the requested discrepancies.
<i>GetHistorybyDiscrepancyGuid</i> (on page 23)	Retrieves the revision history for the requested discrepancies, on a per-study basis.
<i>GetByTransactionID</i> (on page 24)	Retrieves the revision of each discrepancy that is associated with the specified TransactionId.
Data modifying operations	
<i>Issue</i> (on page 25)	Issues a new discrepancy in an Open or Candidate state.
<i>Update</i> (on page 29)	Updates a discrepancy for a single study.

Programming model and operations

Writing requests

Each request is enclosed in a SOAP envelope that begins with a SOAP header, followed by a Body statement that includes the operation and field values.

For examples of Body statements, see the individual *Operations* (on page 14).

SOAP header

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

Note: The requirement for requests to contain the **wsu:Timestamp**, **wsse:Username**, and **wsse:Password** elements is defined in the WSDL by ws-policy. The URLs to include are:

wsa—<http://www.w3.org/2005/08/addressing> (username/password authentication)

wsu—<http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-wssecurity-utility-1.0.xsd> (username/password authentication)

wsse—<http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-wssecurity-secext-1.0.xsd> (signing in with X.509 cert (F5CERT))

If your web service toolkit does not support ws-policy, you must manually add these elements to the web service request.

Username authentication

Field	Description	Standard
wsa:Action	SOAP action for the operation. Include this field as part of the summary for each SOAP operation.	WS-Addressing
wsa:MessageID	Unique ID for the message.	WS-Addressing
wsa:ReplyTo	Use the value that is shown in the example.	WS-Addressing
wsa:To	Full URL of the service. Note: The full URL is different for each customer.	WS-Addressing

Field	Description	Standard
wsu:Timestamp	Time the message was created and when it expires. Oracle recommends a 5-minute time window. The software allows for five minutes of clock drift between servers. This value can be modified in the web.config file by setting the MaxClockSkew value.	SOAP Message Security 1.0
wsse:Username	User name of the user in the InForm study.	SOAP Message Security 1.0
wsse:Password	Password of the user in the InForm study.	SOAP Message Security 1.0

F5CERT Certificate authentication

Request Headers:

Field	Description	Standard
wsa:Action	SOAP action for the operation. Include this field as part of the summary for each SOAP operation.	WS-Addressing
wsa:MessageID	Unique ID for the message.	WS-Addressing
wsa:ReplyTo	Use the value that is shown in the example.	WS-Addressing
wsa:To	Full URL of the service. Note: The full URL is different for each customer.	WS-Addressing
wsse:Security	Provides the X.509 Certificate Token, time stamp, and the signature.	SOAP Message Security 1.1.1
wsse:Security/wsu:Timestamp	Time the message was created and when it expires. Oracle recommends a 5-minute time window. The software allows for five minutes of clock drift between servers. This value can be modified in the web.config file by setting the MaxClockSkew value.	SOAP Message Security 1.1.1
wsse:Security/BinarySecurityToken	The X.509 certificate referenced within the signature.	SOAP Message Security 1.1.1
wsse:Security/Signature	The signature of the soap body.	XML Signature Syntax and Processing (Second Edition)

Response Header:

Field	Description	Standard
wsse:Security	Provides the signature confirmation.	SOAP Message Security 1.1.1
wsse:Security/wsse11:SignatureConfirmation	Contains the contents of the <ds:SignatureValue> element of the request signature as the value of the @Value attribute of the <wsse11:SignatureConfirmation> element.	SOAP Message Security 1.1.1

SOAP header example

Username authentication

```

<s:Envelope xmlns:s="http://www.w3.org/2003/05/soap-envelope"
xmlns:a="http://www.w3.org/2005/08/addressing" xmlns:u="http://docs.oasis-
open.org/wss/2004/01/oasis-200401-wss-wssecurity-utility-1.0.xsd">
  <s:Header>
    <a:Action
s:mustUnderstand="1">http://www.phaseforward.com/InForm/2010/01/Discrepancy/GetD
iscrepanciesByCriteria</a:Action>
    <a:MessageID>urn:uuid:4c8b041f-fdea-4420-8e7f-f635d8749597</a:MessageID>
    <a:ReplyTo>

<a:Address>http://www.w3.org/2005/08/addressing/anonymous</a:Address>
    </a:ReplyTo>
    <a:To
s:mustUnderstand="1">https://hostaddress/pfst60/informadapter/Discrepancy/Discre
pancyService.svc</a:To>
    <o:Security s:mustUnderstand="1" xmlns:o="http://docs.oasis-
open.org/wss/2004/01/oasis-200401-wss-wssecurity-secext-1.0.xsd">
      <u:Timestamp u:Id="_0">
        <u:Created>2017-09-15T14:49:53.345Z</u:Created>
        <u:Expires>2017-09-15T14:54:53.345Z</u:Expires>
      </u:Timestamp>
      <o:UsernameToken u:Id="uuid-5c7fe557-db6d-4eba-8a34-4da851d07690-1">
        <o:Username>integrationuser</o:Username>
        <o:Password Type="http://docs.oasis-open.org/wss/2004/01/oasis-
200401-wss-username-token-profile-1.0#PasswordText">actualpassword</o:Password>
      </o:UsernameToken>
    </o:Security>
  </s:Header>
  <s:Body xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema">
    <GetByCriteria
xmlns="http://www.phaseforward.com/InForm/2010/01/Discrepancy">
      <DetailByCriteriaRequest authenticationTrialName="pfst60">
        <DetailCriteriaFilterList>
          <DetailCriteriaFilter>
            <TrialName>pfst60</TrialName>
          </DetailCriteriaFilter>
        </DetailCriteriaFilterList>
      </DetailByCriteriaRequest>
    </GetByCriteria>
  </s:Body>
</s:Envelope>

```

F5CERT authentication

Sample SOAP request

```
<s:Envelope xmlns:s="http://www.w3.org/2003/05/soap-envelope">
  <s:Header>
    <Action a:mustUnderstand="1" xmlns="http://www.w3.org/2005/08/addressing"
      xmlns:a="http://www.w3.org/2003/05/soap-envelope">http://www.phaseforward.com/InForm/2010/01/Discrepancy/Issue</Action>
    <MessageID xmlns="http://www.w3.org/2005/08/addressing">urn:uuid:c43bdf5e-da49-4a81-a6c5-0475898e7867</MessageID>
    <ReplyTo xmlns="http://www.w3.org/2005/08/addressing">
      <Address>http://www.w3.org/2005/08/addressing/anonymous</Address>
    </ReplyTo>
    <wsse:Security s:mustUnderstand="1" xmlns:wsse="http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-wssecurity-secext-1.0.xsd">
      <Timestamp xmlns="http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-wssecurity-utility-1.0.xsd">
        <Created>2017-06-12T18:05:07.5696550Z </Created>
        <Expires>2017-06-12T18:10:07.5696550Z </Expires>
      </Timestamp>
      <wsse:BinarySecurityToken wsu:Id="SignatureCert"
        ValueType="http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-x509-token-profile-1.0#X509v3" EncodingType="http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-soap-message-security-1.0#Base64Binary" xmlns:wsu="http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-wssecurity-utility-1.0.xsd">MIIC9zCCAdgAwIBAgIQSQF0GoBgBbdH+iEQSM+ShDANBgkqhkiG9w0BAQsFADAeMRwwGgYDVQQDDBN3d3cuZmFicmlrYW0yNTYuY29tMB4XDTE3MDUxNTA4MzY0N1oXDTE4MDUxNTA4MzY0N1owHjE
cMBOGA1UEAwTd3d3LmZhYnJpa2FtMjU2LmNvbTCCASIwDQYJKoZIhvcNAQEBBQADggEPADCCAQoCggE
BAOEjxHpJ7H6++tcsKtBn+d8W2fjgZSVH/HPAVtExL5t+7z6bhRIBqcvHXslQcHN/XGmPHZR0ogLq7jK
qs9f02AHLHDMjIcz6zyx+ri71tMwaIrkOT19w0iwKLue20j3W/fJU2zgH7Wkhq0IPZD32ULS3EJf5D6
uaRRglU8bPSdgGPqnd9ENL4Y0yOMUAYr090p+Yx3Wp9J33x6lAcYBijsB437Pz+C6ZKNGaIK+cXNovfB
AK3FJwCkyitatXbab/01AnlGBRcihqdBbAsWePJhrZegDY4m0f6LnKBzdHsZtnK8NENrKK3p8j9C2g82
rcTRIEYszRtdWkODjskfQ9XMCaWEAAmXMC8wDgYDVR0PAQH/BAQDAgWgMB0GA1UdDgQWBBSGgzkWSPS
T7DA+P5U5e74MumrIDTANBgkqhkiG9w0BAQsFAA0CAQEAIzIgwslZHTFwq4+Q190k8a605dscZn9wMa/
BE6/LVbUTMeHNDHKJM28lYx1+imhVvXg/s+NG+0p9RtAuTDiuU5n/YX7jGY1DsJwts1EKfBZJWHKsZRq
K2tmJ0r+tfY0/zxvzIp3sPw58m7+EWbwBzFEghIhvbmmMvTPye0tIfmFOF9nEIzfSd1Nl6k4bNb4w3Cu
J97QCg3fX55ZP3Cex7mPmWZCaCIyFGjvuBpPqabHqr7/s1duHkb36kkY4N29qr6aCgxLwB34RyeUvvqR
xfPsrvoc4j1rEEBh8cEdi7cDIPR5JjUknHv0R7iUIra2aSc6Pk06DmxLpmhDuJsD9Sg==</wsse:Bina
rySecurityToken>
      <Signature xmlns="http://www.w3.org/2000/09/xmldsig#">
        <SignedInfo>
          <CanonicalizationMethod Algorithm="http://www.w3.org/2001/10/xml-exc-c14n#"></CanonicalizationMethod>
          <SignatureMethod Algorithm="http://www.w3.org/2001/04/xmldsig-more#rsa-sha256"></SignatureMethod>
          <Reference URI="#Body">
            <Transforms>
              <Transform Algorithm="http://www.w3.org/2001/10/xml-exc-c14n#"></Transform>
            </Transforms>
            <DigestMethod
              Algorithm="http://www.w3.org/2001/04/xmenc#sha256"></DigestMethod>
            <DigestValue>ioIf/7owlT7zrM51l7yx/IE+gDNSTZTdX4US0PUwGZE=</DigestValue>
          </Reference>
        </SignedInfo>
        <SignatureValue>VkaErFdY4Xwh9nkwqtqAN2XI19Z5hFC9uhL38JCQ3uKUPO9VPRANxHW87dQxjKztb
/EwqXI4JThrd/Lb0btjGWU3i1/OoakcNAYdaL2yC3BjHgay+hJ0mT4EYL1iXerNpCZhcpW/WjIq0q1
dwIwH9nMlncuhmejYBMN3JUHddwCeS85XRAEcVhbjyU7R2G58S/RX/nNsD65Mard/1YhGcUg1j5rGc3y
Qt1SJeyckI6QKGN9FXryk8b/ruzbXyiVoi/eBxKKCHbAXChYUvTd9ggaag6mt0bD0NZ0bsRMDRtR1x1
dvmAyuJi2mBwik2X3ZZNhICjtZd+URKSZA/bQA==</SignatureValue>
      <KeyInfo>
        <SecurityTokenReference xmlns="http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-wssecurity-secext-1.0.xsd">
          <Reference URI="#SignatureCert"></Reference>
        </SecurityTokenReference>
      </wsse:Security>
  </s:Header>
  <s:Body>
  </s:Body>
</s:Envelope>
```

```

        </KeyInfo>
        </Signature>
        </wsse:Security>
        <To s:mustUnderstand="1"
xmlns="http://www.w3.org/2005/08/addressing">https://hsgbu-bur-qa-
infws.us.oracle.com/pfst60/informadapter/Discrepancy/DiscrepancyService.svc</To>
        </s:Header>
        <s:Body id="Body">
        <Issue xmlns="http://www.phaseforward.com/InForm/2010/01/Discrepancy">
        <IssueRequest transactionUserName="" transactionId="{2CEF4ECE-0B95-4665-
BAB2-E9819C8A3A85}" authenticationTrialName="PFST60">
        <RequestList>
        <DiscrepancyIssueRequest
xsi:type="DiscrepancyIssueRequestCentralCoding"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
        <InFormItemIdentifier>
        <InFormItemGuid>{066DBC9-E7F9-4E00-BB28-
A840D03AB66B}</InFormItemGuid>
        </InFormItemIdentifier>
        <InitialState>Opened</InitialState>
        <Reason>Make verbatim more specific</Reason>
        <CentralCodingReserved1>{CFA8437E-9F4C-4401-8A90-
6975D1D78FDB}</CentralCodingReserved1>
        <CentralCodingReserved2>bleeding</CentralCodingReserved2>
        </DiscrepancyIssueRequest>
        </RequestList>
        </IssueRequest>
        </Issue>
        </s:Body>
</s:Envelope>

```

Sample SOAP response

```

<s:Envelope xmlns:a="http://www.w3.org/2005/08/addressing"
xmlns:s="http://www.w3.org/2003/05/soap-envelope">
  <s:Header>
    <a:Action
s:mustUnderstand="1">http://www.phaseforward.com/InForm/2010/01/Discrepancy/Issu
eResponse</a:Action>
    <Security s:mustUnderstand="1" xmlns="http://docs.oasis-
open.org/wss/2004/01/oasis-200401-wss-wssecurity-secext-1.0.xsd">
      <SignatureConfirmation b:Id="Body"
Value="VkaErFdY4Xwh9nkwtqAN2XI19Z5hFC9uhL38JCQ3uKUpo9VPRAnxHW87dQxjKZtb/EwqXI4J
Thrd/Lb0btjGWU3Il/OoakcNAYYdaL2yC3BjHgay+hJ0mT4EYL11XerNpCZhcpw/WjIq0qldwIWh9nM1
ncuhmejYBMN3JUHddwCeS85XRAEcVhjbyU7R2G58S/RX/nNsD65Mard/1YhGcUg1j5rGc3yQt1SJeycK
I6QKgWN9FXryk8b/ruzbXyiVoi/eBxKKChbAXChYUvTD9gqaag6mt0bD0NZ0bsRMDRtR1x1dvmAyuJi2
mBWik2X3ZZNhICjtZd+URKSZA/bQA==" xmlns="http://docs.oasis-open.org/wss/oasis-
wss-wssecurity-secext-1.1.xsd" xmlns:b="http://docs.oasis-
open.org/wss/2004/01/oasis-200401-wss-wssecurity-utility-1.0.xsd" />
    </Security>
  </s:Header>
  <s:Body xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema">
    <IssueResponse
xmlns="http://www.phaseforward.com/InForm/2010/01/Discrepancy">
      <IssueResult>
        <ResultList>
          <DiscrepancyResult mappedItem="false">
            <Discrepancy>
              <Guid>{AB345CB3-CF2C-4900-B684-1DB046E7E7B9}</Guid>
              <Revision>518540376280899</Revision>
            </Discrepancy>
            <InFormItemIdentifier>
              <InFormItemGuid>{066DBC9-E7F9-4E00-BB28-
A840D03AB66B}</InFormItemGuid>
            </InFormItemIdentifier>
          </DiscrepancyResult>
        </ResultList>
      </IssueResult>
    </IssueResponse>
  </s:Body>

```

</s:Envelope>

How requests are processed

Changes that you specify in a single call occur as part of an atomic unit and are applied immediately on successful completion of the call. If one change contains an error, none of the changes are applied. For example, if you attempt to issue five discrepancies, and you specify invalid data for one discrepancy, none of the discrepancies is issued.

Requests are subject to the following constraints:

- **Processing time**—The maximum allowed time for a single request is five minutes. Processing that exceeds the maximum time results in an error.
- **Size of requests**—Requests must be smaller than 5 MB.
- **Case-sensitivity**—The Enhanced Discrepancy interface operations require the same case-sensitivity rule as the InForm application—object references by name are case-sensitive. Objects whose names contain different cases (for example, "cra" and "CRA") are different objects.
- **Sequence of operations**—The caller is responsible for sequencing operations as required for semantic correctness (for example, a discrepancy must exist before it can be updated).

Before the request is processed, the following operations are performed:

- The server logs the request (operation and user name only) to the event log for historical analysis.
- The user name and password are extracted from the SOAP header and are validated against the InForm database. Only requests with valid credentials for active accounts are accepted and processed.

Multiple repeat requests with invalid passwords will disable the account and require administrative action according to existing InForm business logic. The allowed number of failed log-on attempts is set in the InForm application on the System Configuration page.

- Parameters are validated. If the request contains invalid content, an error is returned. For example, schema validation and InForm character restrictions are enforced.

Operations

Operation	Description
Summary reporting operations	
<i>GetSummaryCounts</i> (on page 14)	Retrieves a count of discrepancies against the requested site, subject, and visit criteria.
Detail reporting operations	
<i>GetByCriteria</i> (on page 16)	Retrieves details for all discrepancies that match the requested criteria.
<i>GetByDiscrepancyGuid</i> (on page 21)	Retrieves the current detail for the requested discrepancies.
<i>GetHistorybyDiscrepancyGuid</i> (on page 23)	Retrieves the revision history for the requested discrepancies, on a per-study basis.
<i>GetByTransactionID</i> (on page 24)	Retrieves the revision of each discrepancy that is associated with the specified TransactionId.
Data modifying operations	
<i>Issue</i> (on page 25)	Issues a new discrepancy in an Open or Candidate state.
<i>Update</i> (on page 29)	Updates a discrepancy for a single study.

GetSummaryCounts

Retrieves a count of discrepancies against the requested site, subject, and visit criteria.

For example, for a specified trial, returns the number of discrepancies in each state.

Input parameters—GetSummaryCounts

Takes a SummaryRequest XML element as an input parameter.

SummaryRequest takes a list of study names and study-related criteria as input parameters.

The site, subject, and visit criteria that you specify form an SQL query that uses AND between each item. Criteria items that are not specified are not included in the query.

SummaryFilterList / SummaryFilter/<parameters>

SummaryRequest	
Parameter	Description
authenticationTrialName	The study in which the discrepancies are issued or updated. If username/password authentication is enabled, the username and password that you specify in the SOAP header are authenticated against this study name.

SummaryRequest	
Parameter	Description
DiscrepancyType	The type of query. Values: Manual or Auto. Optional.
SiteIdList	A list of site IDs. Maximum number of site IDs in a single request: 1000.
SubjectGuidList	A list of subject GUIDs. Maximum number of GUIDs in a single request: 1000.
VisitList	A list of refnametuples. Each refnametuple indicates data related to a visit, such as name, revision, and index. Maximum number of refnametuples in a single request: 1000.

Example request—GetSummaryCounts

The example shows the Body of the request, which is preceded by the SOAP header.

```
<GetSummaryCounts
xmlns="http://www.phaseforward.com/InForm/2010/01/Discrepancy">
  <SummaryRequest authenticationTrialName="testtrial">
    <SummaryFilterList >
      <SummaryFilter FilterName="My filter 1">
        <TrialName>testtrial</TrialName>
        <DiscrepancyType>Auto</DiscrepancyType>
        <TrialCriteria>
          <SiteIdList>
            <Id>7600</Id>
          </SiteIdList>
          <SubjectGuidList>
            <Guid>{8136950C-7676-4ED6-84AE-AE965E12A6E7}</Guid>
          </SubjectGuidList>
          <VisitList>
            <Visit>
              <Name>vstCORE1</Name>
              <Index>1</Index>
            </Visit>
          </VisitList>
        </TrialCriteria>
      </SummaryFilter>
    </SummaryFilterList>
  </SummaryRequest>
</GetSummaryCounts>
```

Results—GetSummaryCounts

Returns a list of counts by discrepancy state for each study requested.

Example response—GetSummaryCounts

```
GetSummaryCountsResponse
xmlns="http://www.phaseforward.com/InForm/2010/01/Discrepancy">
  <GetSummaryCountsResult>
    <SummaryFilterResultList >
      <SummaryFilterResult FilterName="My filter 1">
        <TrialName>testtrial</TrialName>
        <DiscrepancyStateCountList>
```

```

        <DiscrepancyStateCount>
          <State>Answered</State>
          <Count>1</Count>
        </DiscrepancyStateCount>
        <DiscrepancyStateCount>
          <State>Closed</State>
          <Count>2</Count>
        </DiscrepancyStateCount>
      </DiscrepancyStateCountList>
    </SummaryFilterResult>
  </SummaryFilterResultList>
</GetSummaryCountsResult>
</GetSummaryCountsResponse>

```

GetByCriteria

Retrieves details for all discrepancies that match the requested criteria.

Criteria can be specified in two ways:

- By site, subject, and/or visit.
- By InForm item, specified by any of the following ways:
 - By DBUID or by GUID

The DBUID or GUID is the identifier for the record in the PF_ItemContext table.
 - By populating a structure containing members that hold the data found in an LSID.

Input parameters—GetByCriteria

Takes a DetailByCriteriaRequest XML element as an input parameter.

DetailByCriteriaRequest has the following parameters and child elements.

Note: Some parameters are specific to the encapsulated InFormItem type.

DetailByCriteriaRequest	
Parameter or Child element > parameter	Description
authenticationTrialName	The study in which the discrepancies are issued or updated. If username/password authentication is enabled, the username and password that you specify in the SOAP header are authenticated against this study name.
CurrentStateList	If specified, only the records in the specified states are included in the result set.
StateChangesAfter	If specified, only the records that have changes in state that occur after this date are include in the result set. Date format: YYYY-MM-DDTHH:MM:SS

DetailByCriteriaRequest	
Parameter or Child element > parameter	Description
IncludeHistory	Values: True, False. True: All state changes for the relevant discrepancies are included in the result set. False: Only the most recent (current) state of the discrepancy is included in the result set.
IssuedOrUpdatedByUsernameList	A list of user names. If specified, only discrepancies that were issued or updated by one of the names in the list are included in the result set. Maximum number of usernames in a single request: 1000.
DiscrepancyType	Values: Auto, Manual. If specified, only discrepancies of the specified type are included in the result set. If not specified, both types are returned.
Bookmark	A response includes a bookmark if there are more records that match the requested criteria. The caller passes in this bookmark on a subsequent call to return the remaining records. Absence of a bookmark indicates that the caller wants to receive the first set of records that match the criteria. Note: When using bookmarks, the subsequent requests must be identical to the first request. If you use different parameter values in subsequent calls, errors and unexpected results will occur.
ResultSetSize	The number of records to be retrieved in a single call. Default: 1000. Maximum: 2000.
DetailCriteriaFilter element	Element that contains TrialCriteria or ItemCriteria child elements. Note: A single DetailCriteriaFilter element can contain either TrialCriteria elements or ItemCriteria elements, but not both. • TrialCriteria: The site, subject, and visit criteria that you specify form an SQL query that uses AND between each item. Criteria items that are not specified are not included in the query. • ItemCriteria: item-identifying types form a query that uses OR between each item.

DetailByCriteriaRequest	
Parameter or Child element > parameter	Description
TrialCriteria > SiteIdList	A list of site IDs. Maximum number of site IDs in a single request: 1000.
TrialCriteria > SubjectGuidList	A list of subject GUIDs. Maximum number of GUIDs in a single request: 1000.
TrialCriteria > VisitList	A list of refnametuples in which each refnametuple identifies a visit. Maximum number of refnametuples in a single request: 1000.
ItemCriteria > InFormItemDbuidList	A list of DBUIDs that identifies an InForm item. Maximum number of DBUIDs in a single request: 1000.
ItemCriteria > InFormItemGuidList	A list of GUIDs that identifies an InForm item. Maximum number of GUIDs in a single request: 1000.
itemCriteria > InFormItemList	All data that is needed to identify an InForm item. Do not include the study name. Maximum number of InForm items: 1000.

Example request—GetByCriteria

The example shows the Body of the request, which is preceded by the SOAP header.

```
<GetByCriteria xmlns="http://www.phaseforward.com/InForm/2010/01/Discrepancy">
  <DetailByCriteriaRequest authenticationTrialName="testtrial">
    <ResultsetSize >
      100</ResultsetSize>
    <DetailCriteriaFilterList >
      <DetailCriteriaFilter FilterName="My filter 1">
        <TrialName>testtrial</TrialName>
        <CurrentStateList>
          <State>Answered</State>
        </CurrentStateList>
        <DiscrepancyType>Auto</DiscrepancyType>
        <StateChangesAfter>2006-01-01T00:00:00</StateChangesAfter>
        <IncludeHistory>true</IncludeHistory>
        <IssuedOrUpdatedByUsernameList>
          <Name>system</Name>
        </IssuedOrUpdatedByUsernameList>
        <TrialCriteria>
          <SiteIdList>
            <Id>7600</Id>
          </SiteIdList>
          <SubjectGuidList>
            <Guid>{8136950C-7676-4ED6-84AE-AE965E12A6E7}</Guid>
          </SubjectGuidList>
          <VisitList>
            <Visit>
              <Name>vstCORE1</Name>
              <Index>1</Index>
            </Visit>
          </VisitList>
        </TrialCriteria>
      </DetailCriteriaFilter>
    </DetailCriteriaFilterList>
  </DetailByCriteriaRequest>
</GetByCriteria>
```

```

        </VisitList>
      </TrialCriteria>
    </DetailCriteriaFilter>
  </DetailCriteriaFilterList>
  <DetailByCriteriaRequest>
    <TrialName>testtrial</TrialName>
    <ItemCriteria>
      <InFormItemDbuidList>
        <Dbuid>62232</Dbuid>
      </InFormItemDbuidList>
      <InFormItemGuidList>
        <Guid>{2DA84C24-9985-4B72-9FDE-6E643492451F}</Guid>
      </InFormItemGuidList>
      <InFormItemList>
        <InFormItem>
          <SiteId>7600</SiteId>
          <SubjectGuid>
            {860C66AE-6AFE-49CE-A707-35D9F01EC982}</SubjectGuid>
          <Visit>
            <Name>vstBASE</Name>
            <Index>1</Index>
          </Visit>
          <Form>
            <Name>frmDOV</Name>
            <Revision>153925409031062</Revision>
            <Index>1</Index>
          </Form>
          <SectionName>DOV</SectionName>
          <ItemName>DOV</ItemName>
        </InFormItem>
      </InFormItemList>
    </ItemCriteria>
  </DetailCriteriaFilter>
</DetailByCriteriaRequest>
</GetByCriteria>

```

Results—GetByCriteria

Returns data related to the current state of the discrepancies that meet the criteria.

Example response—GetByCriteria

```

<GetByCriteriaResponse
xmlns="http://www.phaseforward.com/InForm/2010/01/Discrepancy">
  <GetByCriteriaResult>
    <DetailFilterResultList>
      <DetailFilterResult DetailFilterName="My filter 1">
        <TrialName>testtrial</TrialName>
        <DiscrepancyList>
          <Discrepancy>
            <Guid>{EE68BF95-0A90-42A1-B8EA-5B2EB1FA43B2}</Guid>
            <Revision>198749271718028</Revision>
            <State>Answered</State>
            <Type>Auto</Type>
            <Reissued>>false</Reissued>
            <Reason>Original value is correct</Reason>
            <UserName>system</UserName>
            <InFormItem>
              <SiteId>7600</SiteId>
              <SubjectGuid>
                {8136950C-7676-4ED6-84AE-AE965E12A6E7}</SubjectGuid>
              <Visit>
                <Name>vstCORE1</Name>
                <Index>1</Index>
              </Visit>
              <Form>
                <Name>frmVS</Name>
                <Revision>153925473296062</Revision>
                <Index>1</Index>
              </Form>
            </InFormItem>
          </Discrepancy>
        </DiscrepancyList>
      </DetailFilterResult>
    </DetailFilterResultList>
  </GetByCriteriaResult>
</GetByCriteriaResponse>

```

```

        </Form>
        <SectionName>sctVS</SectionName>
        <ItemName>itmVSRespRte</ItemName>
    </InFormItem>
</Discrepancy>
</DiscrepancyList>
</DetailFilterResult>
<DetailFilterResult DetailFilterName="DetailFilter 2">
    <TrialName>testtrial</TrialName>
    <DiscrepancyList>
        <Discrepancy>
            <Guid>{F673B574-02E5-4634-99AF-E233A2F2E412}</Guid>
            <Revision>227438221887048</Revision>
            <State>Opened</State>
            <Type>Auto</Type>
            <Reissued>>false</Reissued>
            <Reason>No was selected, but reason for dose change or
            missed medication was provided; please correct.</Reason>
            <UserName>autoquery</UserName>
            <InFormItem>
                <SiteId>7600</SiteId>
                <SubjectGuid>
                    {8136950C-7676-4ED6-84AE-AE965E12A6E7}</SubjectGuid>
                <Visit>
                    <Name>CommonCRF</Name>
                    <Index>1</Index>
                </Visit>
                <Form>
                    <Name>frmDOSE</Name>
                    <Revision>153925414734062</Revision>
                    <Index>1</Index>
                </Form>
                <SectionName>sctDOSE</SectionName>
                <ItemSet>
                    <Name>itsDOSE</Name>
                    <Order>227438221778048</Order>
                </ItemSet>
                <ItemName>itmDOSEMissed</ItemName>
            </InFormItem>
        </Discrepancy>
    <Discrepancy>
        <Guid>{27D7F5CD-A0A8-4131-BCD0-7E5F6D178467}</Guid>
        <Revision>234273542952019</Revision>
        <State>Opened</State>
        <Type>Manual</Type>
        <Reissued>>false</Reissued>
        <Reason>Item incomplete</Reason>
        <UserName>system</UserName>
        <InFormItem>
            <SiteId>7600</SiteId>
            <SubjectGuid>
                {8136950C-7676-4ED6-84AE-AE965E12A6E7}</SubjectGuid>
            <Visit>
                <Name>vstBASE</Name>
                <Index>1</Index>
            </Visit>
            <Form>
                <Name>frmDem</Name>
                <Revision>153925408218062</Revision>
                <Index>1</Index>
            </Form>
            <SectionName>sctFH</SectionName>
            <ItemName>itmFHDep</ItemName>
        </InFormItem>
    </Discrepancy>
</DiscrepancyList>
</DetailFilterResult>
</DetailFilterResultList>
</GetByCriteriaResult>
</GetByCriteriaResponse>

```

GetByDiscrepancyGuid

Retrieves the current detail for the requested discrepancies.

Input parameters—GetByDiscrepancyGuid

Takes a DetailByGuidRequest XML element as an input parameter.

DetailByGuidRequest takes one or more study names, each with an associated list of Discrepancy GUIDs.

DetailByGuidRequest	
Parameter	Description
authenticationTrialName	The study in which the discrepancies are issued or updated. If username/password authentication is enabled, the username and password that you specify in the SOAP header are authenticated against this study name.
StateChangesAfter	If specified, only the records that have changes in state that occur after this date are include in the result set. Date format: YYYY-MM-DDTHH:MM:SS
DiscrepancyGuidList	A list of GUIDS associated with the specified study name. Maximum number of GUIDs in a single request: 1000.
Bookmark	A response includes a bookmark if there are more records that match the requested criteria. The caller passes in this bookmark on a subsequent call to return the remaining records. Absence of a bookmark indicates that the caller wants to receive the first set of records that match the criteria. Note: When using bookmarks, the subsequent requests must be identical to the first request. If you use different parameter values in subsequent calls, errors and unexpected results will occur.
ResultSetSize	The number of records to be retrieved in a single call. Default: 1000. Maximum: 2000.

Example request—GetByDiscrepancyGuid

The example shows the Body of the request, which is preceded by the SOAP header.

```
<GetByDiscrepancyGuid
xmlns="http://www.phaseforward.com/InForm/2010/01/Discrepancy">
  <DetailByGuidRequest authenticationTrialName="testtrial">
    <ResultSetSize>
      100</ResultSetSize>
    <DetailGuidFilterList>
      <DetailGuidFilter FilterName="My filter 1">
        <TrialName>testtrial</TrialName>
        <StateChangesAfter>2006-01-01T00:00:00</StateChangesAfter>
      </DetailGuidFilter>
    </DetailGuidFilterList>
  </DetailByGuidRequest>
</GetByDiscrepancyGuid>
```

```

    <DiscrepancyGuidList>
      <Guid>{6E50F337-9A64-4ABD-9F13-CD568FA480C1}</Guid>
      <Guid>{F673B574-02E5-4634-99AF-E233A2F2E412}</Guid>
    </DiscrepancyGuidList>
  </DetailGuidFilter>
</DetailGuidFilterList>
</DetailByGuidRequest>
</GetByDiscrepancyGuid>

```

Results—GetByDiscrepancyGuid

Response schema and supporting types: uses same response schema as GetByCriteria.

Example response—GetByDiscrepancyGuid

```

<GetByDiscrepancyGuidResponse
xmlns="http://www.phaseforward.com/InForm/2010/01/Discrepancy">
  <GetByDiscrepancyGuidResult>
    <DetailFilterResultList>
      <DetailFilterResult DetailFilterName="My filter 1">
        <TrialName>testtrial</TrialName>
        <DiscrepancyList>
          <Discrepancy>
            <Guid>{6E50F337-9A64-4ABD-9F13-CD568FA480C1}</Guid>
            <Revision>155222540031037</Revision>
            <State>Opened</State>
            <Type>Auto</Type>
            <Reissued>>false</Reissued>
            <Reason>Value is not within the expected range; please
            verify</Reason>
            <UserName>autoquery</UserName>
            <InFormItem>
              <SiteId>7600</SiteId>
              <SubjectGuid>
                {4913C98C-722B-46DE-916E-B62D833CC96E}</SubjectGuid>
              <Visit>
                <Name>vstBASE</Name>
                <Index>1</Index>
              </Visit>
              <Form>
                <Name>frmDem</Name>
                <Revision>153925408218062</Revision>
                <Index>1</Index>
              </Form>
              <SectionName>sctDem</SectionName>
              <ItemName>itmDemHgt</ItemName>
            </InFormItem>
          </Discrepancy>
          <Discrepancy>
            <Guid>{F673B574-02E5-4634-99AF-E233A2F2E412}</Guid>
            <Revision>227438221887048</Revision>
            <State>Opened</State>
            <Type>Auto</Type>
            <Reissued>>false</Reissued>
            <Reason>No was selected, but reason for dose change or
            missed medication was provided; please correct.</Reason>
            <UserName>autoquery</UserName>
            <InFormItem>
              <SiteId>7600</SiteId>
              <SubjectGuid>
                {8136950C-7676-4ED6-84AE-AE965E12A6E7}</SubjectGuid>
              <Visit>
                <Name>CommonCRF</Name>
                <Index>1</Index>
              </Visit>
              <Form>
                <Name>frmDOSE</Name>
                <Revision>153925414734062</Revision>
                <Index>1</Index>
              </Form>
            </InFormItem>
          </Discrepancy>
        </DiscrepancyList>
      </DetailFilterResult>
    </DetailFilterResultList>
  </GetByDiscrepancyGuidResult>
</GetByDiscrepancyGuidResponse>

```

```

        <SectionName>sctDOSE</SectionName>
        <ItemSet>
            <Name>itsDOSE</Name>
            <Order>227438221778048</Order>
        </ItemSet>
        <ItemName>itmDOSEMissed</ItemName>
    </InFormItem>
</Discrepancy>
</DiscrepancyList>
</DetailFilterResult>
</DetailFilterResultList>
</GetByDiscrepancyGuidResult>
</GetByDiscrepancyGuidResponse>

```

GetHistoryByDiscrepancyGuid

Retrieves the revision history for the requested discrepancies, on a per-study basis.

Input parameters—GetHistoryByDiscrepancyGuid

Takes a HistoryByGuidRequest XML element as an input parameter.

HistoryByGuidRequest takes a study name with an associated list of GUID and revision number pairs. The GUID is the unique identifier for a discrepancy.

HistoryByGuidRequest	
Parameter	Description
authenticationTrialName	The study in which the discrepancies are issued or updated. If username/password authentication is enabled, the username and password that you specify in the SOAP header are authenticated against this study name.
DiscrepancyIdentifierList	A list of DiscrepancyIdentifiers that are associated with the specified study name.
DiscrepancyIdentifier	A GUID and revision number pair. Revision number is optional. You can pass in as many GUID and revision number pairs as you like, on a per-study basis. If you specify a revision number, the result set is limited to records that have a revision number greater than the one you specified.

Example request—GetHistoryByDiscrepancyGuid

The example shows the Body of the request, which is preceded by the SOAP header.

```

<GetHistoryByDiscrepancyGuid
xmlns="http://www.phaseforward.com/InForm/2010/01/Discrepancy">
  <HistoryByGuidRequest authenticationTrialName="testtrial">
    <DiscrepancyIdentifierList>
      <DiscrepancyIdentifier>
        <Guid>{D905028E-48D5-4EEF-AB40-E18B8CFAAF76}</Guid>
        <Revision>234807295233074</Revision>
      </DiscrepancyIdentifier>
    </DiscrepancyIdentifierList>
  </HistoryByGuidRequest>
</GetHistoryByDiscrepancyGuid>

```

```

    </HistoryByGuidRequest>
  </GetHistoryByDiscrepancyGuid>

```

Results—GetHistoryByDiscrepancyGuid

The response includes a list of all revisions that meet the specified criteria for the specified discrepancies. Results are listed in order by GUID and then by revision number.

Example response—GetHistoryByDiscrepancyGuid

```

<GetHistoryByDiscrepancyGuidResponse
  xmlns="http://www.phaseforward.com/InForm/2010/01/Discrepancy">
  <GetHistoryByDiscrepancyGuidResult>
    <DiscrepancyRevisionInstanceList>
      <DiscrepancyRevisionInstance>
        <Guid>{D905028E-48D5-4EEF-AB40-E18B8CFAAF76}</Guid>
        <Revision>234807447030074</Revision>
        <State>Deleted</State>
        <Type>Manual</Type>
        <Reissued>false</Reissued>
        <Reason>Deleting this query.</Reason>
        <DateEntered>2008-06-10T21:17:26-04:00</DateEntered>
        <UserName>mroberts</UserName>
      </DiscrepancyRevisionInstance>
    </DiscrepancyRevisionInstanceList>
  </GetHistoryByDiscrepancyGuidResult>
</GetHistoryByDiscrepancyGuidResponse>

```

GetByTransactionId

Retrieves the revision of each discrepancy that is associated with the specified TransactionId.

This operation gives callers of the **Issue** (on page 25) and **Update** (on page 29) operations the means to identify, at a later time, exactly which discrepancies were issued or updated. If an Issue request times out, but commits to the database, the client can use GetByTransactionId to determine the details of the discrepancies that were committed to the database.

Input parameters—GetByTransactionId

Takes a DetailByTransactionIdRequest as an input parameter.

DetailByTransactionIdRequest has the following parameters.

DetailByTransactionIdRequest	
Parameter	Description
authenticationTrialName	The study in which the discrepancies are issued or updated. If username/password authentication is enabled, the username and password that you specify in the SOAP header are authenticated against this study name.
TransactionId	A GUID that is used to identify the particular transaction.

Example request —GetByTransactionId

The example shows the Body of the request, which is preceded by the SOAP header.

```

<GetByTransactionId

```

```

xmlns="http://www.phaseforward.com/InForm/2010/01/Discrepancy">
  <DetailByTransactionIdRequest authenticationTrialName="testtrial">
    <TransactionId>
      {5F03D922-5E8C-4363-94AE-05DF51660D16}</TransactionId>
    </DetailByTransactionIdRequest>
  </GetByTransactionId>

```

Results—GetByTransactionId

Example response—GetByTransactionId

```

<GetByTransactionIdResponse
xmlns="http://www.phaseforward.com/InForm/2010/01/Discrepancy">
  <GetByTransactionIdResult>
    <DiscrepancyRevisionInstanceList>
      <DiscrepancyRevisionInstance>
        <Guid>{27D7F5CD-A0A8-4131-BCD0-7E5F6D178467}</Guid>
        <Revision>234273542952019</Revision>
        <State>Opened</State>
        <Type>Manual</Type>
        <Reissued>false</Reissued>
        <Reason>Item incomplete</Reason>
        <DateEntered>2008-06-04T16:59:02-04:00</DateEntered>
        <UserName>system</UserName>
      </DiscrepancyRevisionInstance>
    </DiscrepancyRevisionInstanceList>
  </GetByTransactionIdResult>
</GetByTransactionIdResponse>

```

Issue

Issues a new discrepancy in an Open or Candidate state.

This functionality equates to the following InForm rights:

- Enter a query in the Candidate state.
- Enter a query in the Open state.

Input parameters—Issue

Takes an issueRequest XML element as a child element.

IssueRequest takes a list of InForm items, referenced by GUID, DBUID, or an InForm item type that allows the specification of data that is found in an LSID.

A request can be made for a single study. A request that contains multiple items is treated as an atomic transaction.

Hidden items

A hidden item is an item that is globally hidden.

A request to issue a discrepancy on a hidden item generates an error.

Issue	
Parameter or child element	Description

Issue	
Parameter or child element	Description
authenticationTrialName	The study in which the discrepancies are issued or updated. If username/password authentication is enabled, the username and password that you specify in the SOAP header are authenticated against this study name.
transactionId	A GUID created by the caller. TransactionID is not case sensitive. It must use one of the formats described in <i>Transaction ID GUID format</i> (on page 27). This parameter prevents a transaction from being submitted multiple times. If you specify a value that was previously submitted and resulted in a successful transaction, an error occurs.
transactionUserName	The user name of the InForm user to associate with this transaction. If using the InForm Adapter with InForm 6.0 or later studies that are configured to work with single sign-on, the OrgID value must be prepended to the trial username to match the tenant-qualified username that is used by the single sign-on application.
InFormItemIdentifier	A unique identifier of an InForm item: • GUID. • DBUID. • An InForm item type structure that contains the data found in an LSID.
InitialState	The state in which the query is to be opened. Values: Candidate, Opened.
Reason	The reason for issuing the discrepancy.
ValidateOnly	Values: True, False. If True, both of the following occur: • The request is validated, but no data is committed to the database. • The response contains an error list that includes any errors in validation. If all items in the request are validated successfully, the error list is empty.

TransactionID GUID format

The TransactionID is a GUID that must use the following format. In the example, **d** represents a hexadecimal digit whose case is ignored.

- Groups of 8, 4, 4, 4, and 12 digits with hyphens between the groups. The entire GUID can optionally be enclosed in matching braces.

For example:

```
dddddddd-dddd-dddd-dddd-dddddddddddd
{dddddddd-dddd-dddd-dddd-dddddddddddd}
```

Example request—Issue

The example shows the Body of the request, which is preceded by the SOAP header. The transactionUserName value includes an optional OrgID value, which is required only for InForm studies that use single sign-on.

```
<s:Body xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema">
  <Issue xmlns="http://www.phaseforward.com/InForm/2010/01/Discrepancy">
    <IssueRequest authenticationTrialName="testtrial"
transactionId="{4cbc93cc-e024-4836-ac4e-b1ededea80fa}"
transactionUserName="sampleorg.system">
      <RequestList>
        <DiscrepancyIssueRequest>
          <InFormItemIdentifier>
            <InFormItem>
              <SiteId>7600</SiteId>
              <SubjectGuid>{8136950C-7676-4ED6-84AE-AE965E12A6E7}</SubjectGuid>
              <Visit>
                <Name>vstBASE</Name>
                <Revision>153925521781062</Revision>
                <Index>1</Index>
              </Visit>
              <Form>
                <Name>frmDem</Name>
                <Revision>153925408218062</Revision>
                <Index>1</Index>
              </Form>
              <SectionName>sctDem</SectionName>
              <ItemName>itmDemHgt</ItemName>
            </InFormItem>
          </InFormItemIdentifier>
          <InitialState>Opened</InitialState>
          <Reason>IA: Unit Test: IssueAgainstItemWithMapping: 12/13/2010
3:23:18 PM</Reason>
        </DiscrepancyIssueRequest>
      </RequestList>
    </IssueRequest>
  </Issue>
</s:Body>
```

Discrepancies issued on mapped items

The Discrepancy interface determines whether the requested target of a discrepancy maps to another item and issues the discrepancy against the mapped item.

In some cases, the intended target of the discrepancy is mapped to an item that has been determined, by study design, to be the intended recipient of the discrepancy. In these cases, the response includes the mapped item attribute with a value "true," indicating that the specified target was not the

recipient of the discrepancy.

For example:

```
<DiscrepancyResult mappedItem="true">
  <Discrepancy>
    <Guid>{F0C07BFB-238D-4CE7-ABD3-61E6FCE1AA96}</Guid>
    <Revision>290608637760651</Revision>
  </Discrepancy>
  <InFormItemIdentifier>
    <InFormItemDbuid>9034</InFormItemDbuid>
  </InFormItemIdentifier>
</DiscrepancyResult>
```

Results—Issue

Returns one of the following elements:

- **ErrorList**—Returned if an error is encountered.
Error list includes a **DiscrepancyIssueError** for each requested item that has an error.
- **ResultList**—Returned if no errors are encountered and the operation is successful.

The results are atomic; that is, if an error is encountered, no discrepancies are issued.

Example response—Issue

```
<s:Body xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema">
  <IssueResponse
    xmlns="http://www.phaseforward.com/InForm/2010/01/Discrepancy">
    <IssueResult>
      <ResultList>
        <DiscrepancyResult mappedItem="true">
          <Discrepancy>
            <Guid>{867CAD53-3B95-4371-B38B-00B1CF7F1CA3}</Guid>
            <Revision>313946605051342</Revision>
          </Discrepancy>
          <InFormItemIdentifier>
            <InFormItem>
              <SiteId>7600</SiteId>
              <SubjectGuid>{8136950C-7676-4ED6-84AE-AE965E12A6E7}</SubjectGuid>
              <Visit>
                <Name>vstBASE</Name>
                <Revision>153925521781062</Revision>
                <Index>1</Index>
              </Visit>
              <Form>
                <Name>frmDem</Name>
                <Revision>153925408218062</Revision>
                <Index>1</Index>
              </Form>
              <SectionName>sctDem</SectionName>
              <ItemName>itmDemHgt</ItemName>
            </InFormItem>
          </InFormItemIdentifier>
        </DiscrepancyResult>
      </ResultList>
    </IssueResult>
  </IssueResponse>
</s:Body>
```

Update

Updates a discrepancy for a single study.

Update allows a caller to perform any of the following actions for a discrepancy:

- Answer.
- Close.
- Open a candidate discrepancy.
- Delete a candidate discrepancy.
- Reissue a discrepancy.
- Validate a discrepancy.

Input parameters—Update

Update takes a list of discrepancies, in which each discrepancy has an associated GUID, revision number, target state, reason, and optional reissue flag.

A request can be made for a single study. A request that contains multiple items is treated as an atomic transaction.

Update	
Parameter	Description
authenticationTrialName	The study in which the discrepancies are issued or updated. If username/password authentication is enabled, the username and password that you specify in the SOAP header are authenticated against this study name.
transactionID	A GUID created by the caller. TransactionID is not case sensitive. It must use one of the formats described in <i>Transaction ID GUID format</i> (on page 27). This parameter prevents a transaction from being submitted multiple times. If you specify a value that was previously submitted and resulted in a successful transaction, an error occurs.
transactionUserName	The user name of the InForm user to associate with this transaction.
Guid	A GUID that identifies the discrepancy to update.

Update	
Parameter	Description
Revision	The revision number of the discrepancy that is identified by the GUID. If the specified revision number is less than the current revision number, the operation prohibits the update and notifies the caller that the data is stale. If no revision number is specified, the transaction takes effect against the latest (most current) revision.
State	The target state. Values: Candidate, Opened.
Reissue	Values: True, False. If True, the transaction is treated as a reissuing of the discrepancy. Can be specified only when specifying Candidate or Opened as the target state.
Reason	The reason for issuing the discrepancy.
ValidateOnly	Values: True, False. If True, both of the following occur: • The request is validated, but no data is committed to the database. • The response contains an error list that includes any errors in validation. If all items in the request are validated successfully, the error list is empty.

Example request—Update

The example shows the Body of the request, which is preceded by the SOAP header.

```
<Update xmlns="http://www.phaseforward.com/InForm/2010/01/Discrepancy">
  <UpdateRequest authenticationTrialName="testtrial" transactionId="{08a13f1b-
    d2bd-4342-93ba-f450cf031bfc}" transactionUserName="system">
    <RequestList>
      <DiscrepancyUpdateRequest>
        <Guid>{63635436-F30C-4B75-89B4-C6D147FB6AAB}</Guid>
        <State>Opened</State>
        <Reason>candidate => open</Reason>
      </DiscrepancyUpdateRequest>
      <DiscrepancyUpdateRequest>
        <Guid>{2E08BD54-0B74-4A94-9884-7F7BAC68984C}</Guid>
        <State>Opened</State>
        <Reason>candidate => open</Reason>
      </DiscrepancyUpdateRequest>
      <DiscrepancyUpdateRequest>
        <Guid>{F0C07BFB-238D-4CE7-ABD3-61E6FCE1AA96}</Guid>
        <State>Opened</State>
        <Reason>candidate => open</Reason>
      </DiscrepancyUpdateRequest>
    </RequestList>
  </UpdateRequest>
</Update>
```

```
</UpdateRequest>
</Update>
```

Results—Update

Returns one of the following elements:

- **ErrorList**—Returned if an error is encountered.
Error list includes a **DiscrepancyIssueError** for each requested item that has an error.
- **ResultList**—Returned if no errors are encountered and the operation is successful.

The results are atomic; that is, if an error is encountered, no discrepancies are updated.

Some discrepancies in the request might not allow state changes. For each unsuccessful transaction, a populate **Message** element is included, and the **Result** element has a value of **False**.

Example response—Update

```
<UpdateResponse xmlns="http://www.phaseforward.com/InForm/2010/01/Discrepancy">
  <UpdateResult>
    <ResultList>
      <DiscrepancyUpdateResult>
        <Guid>{63635436-F30C-4B75-89B4-C6D147FB6AAB}</Guid>
        <Revision>290608643214335</Revision>
      </DiscrepancyUpdateResult>
      <DiscrepancyUpdateResult>
        <Guid>{2E08BD54-0B74-4A94-9884-7F7BAC68984C}</Guid>
        <Revision>290608643292468</Revision>
      </DiscrepancyUpdateResult>
      <DiscrepancyUpdateResult>
        <Guid>{F0C07BFB-238D-4CE7-ABD3-61E6FCE1AA96}</Guid>
        <Revision>290608643370601</Revision>
      </DiscrepancyUpdateResult>
    </ResultList>
  </UpdateResult>
</UpdateResponse>
```

Use cases

General use

Area	Use case	Operation
Studies	Retrieve discrepancies of a certain type. For example, find all open discrepancies for a study.	<i>GetByCriteria</i> (on page 16)
	Retrieve counts in the form of [Site, State, Count]. For each of the specified studies, how many discrepancies are in each state.	<i>GetSummaryCounts</i> (on page 14)
Sites	Retrieve discrepancies of a specific type. For example, find all Open discrepancies for the site.	<i>GetByCriteria</i> (on page 16)
	Retrieve counts in the form of [Subject, State, Count]. For example, for specified sites, find the number of discrepancies in each state.	<i>GetSummaryCounts</i> (on page 14)
	Retrieve all the discrepancies for the specified sites.	<i>GetByCriteria</i> (on page 16)
Subjects or lists of subjects	Retrieve discrepancies of a certain type. For example, find all open discrepancies for one or more subjects.	<i>GetByCriteria</i> (on page 16)
	Retrieve counts in the form of [Subject, State, Count].	<i>GetSummaryCounts</i> (on page 14)
Visits	For each of the specified visits, how many discrepancies are in each state.	<i>GetSummaryCounts</i> (on page 14)
Items	Retrieve all discrepancies for an item.	<i>GetByCriteria</i> (on page 16)
	Retrieve discrepancies of a specific type for an item. For example, find all open discrepancies for an item.	<i>GetByCriteria</i> (on page 16)
	Open a discrepancy:	<i>Issue</i> (on page 25)
	• Candidate discrepancy. • Non-candidate discrepancy.	
Discrepancy or list of discrepancies,	Answer a discrepancy.	<i>Update</i> (on page 29).
	Close a discrepancy.	<i>Update</i> (on page 29).

Area	Use case	Operation
each identified by a GUID	Delete a Candidate discrepancy.	<i>Update</i> (on page 29).
	Reissue an Answered discrepancy as Open.	<i>Update</i> (on page 29).
	Reissue an Answered discrepancy as Candidate.	<i>Update</i> (on page 29).
	Retrieve discrepancy details.	<i>GetByDiscrepancyGuid</i> (on page 21)
	Retrieve the revision history of a discrepancy.	<i>GetHistoryByDiscrepancyGuid</i> (on page 23)
In relation to a set of discrepancies	Use a single transaction to close all answered discrepancies.	<i>Update</i> (on page 29)
	Identify the transactions that were committed to the InForm database by the Issue or Update operations.	<i>GetByTransactionId</i> (on page 24)

ODM use

Clients that use an ODM extract determine that certain items need to have associated discrepancies. The client can use the Discrepancy interface to issue the discrepancies, using data from the ODM administrative data, metadata, and clinical data extracts.

Structural representation of LSIDs

Life Science Identifiers (LSIDs) provide a way to identify subsystem resources. LSIDs use a structural-based representation in the Discrepancy interface. For example:

```

<InFormItemIdentifier>
  <InFormItem>
    <TrialName>testtrial</TrialName>
    <SiteId>7600</SiteId>
    <SubjectGuid>{A2F60023-E0DA-4497-8E9A-E1F05A284AAE}</SubjectGuid>
    <Visit>
      <Name>CommonCRF</Name>
      <Revision>245827582062039</Revision>
      <Index>1</Index>
    </Visit>
    <Form>
      <Name>frmDOSE</Name>
      <Revision>153925414734062</Revision>
      <Index>1</Index>
    </Form>
    <SectionName>sctDOSE</SectionName>
    <ItemSet>
      <Name>itsDOSE</Name>
      <Order>153925414515062</Order>
    </ItemSet>
    <ItemName>itmDOSETotalCaps</ItemName>
  </InFormItem>
</InFormItemIdentifier>

```

Location of LSID components in ODM extract files

LSID component	Location in ODM	Notes
Trial	Alias used to register the study with the InForm Adapter software.	
Site ID	AdminData/Location/@OID	
Subject GUID	ClinicalData/SubjectData/@GUID	
Visit name	ClinicalData/SubjectData/StudyEventData/@StudyEventOID	
Visit revision	StudyEventDef/@Revision	The revision of the visit in the study version for which the item has data. This value must be looked up in the metadata.
Visit index	ClinicalData/SubjectData/StudyEventData/@StudyEventRepeatKey	If this attribute is not present, pass the value 1; note that you do not need ".000."
Form name	ClinicalData/SubjectData/StudyEventData/FormData/@FormOID	
Form revision	FormDef/@Revision	The revision of the form in the study version for which the item has data. This value must be looked up in the metadata.
Form index	ClinicalData/SubjectData/StudyEventData/FormData/@FormRepeatKey	If this attribute is not present, pass the value 1; note that you do not need ".000."
Section name	ItemGroupDef/@Name	Get the ItemGroupOID and look up the name in the metadata for that study version.
Itemset name	ItemGroupDef/@ItemSetRefName	Required only if the item exists in an itemset.

Client dashboard use

A client can create a dashboard application to identify studies or sites that have an excessive number of discrepancies, or unanswered discrepancies.

The client can call the reporting function `GetSummaryCounts`, which provides multiple filters. For each study, the client specifies a filter. The XML that is returned includes an entry for each state, showing the number of discrepancies in that state.

After seeing the study counts, the user can obtain greater detail by viewing summary counts by site.

The client application calls the same operation but submits a filter for each site.

For more information, see ***GetSummaryCounts*** (on page 14).

Error messages from the Discrepancy interface

Error Code/MessageID	Operation	Error
TRANSACTION_PROCESSING_ERROR		An error occurred processing a transaction {0}.
DISCREPANCY_AGAINST_CALCULATED_ITEM	Issue	Cannot issue a discrepancy against a calculated item.
INFORM_FORM_REPEATING_NO_DATA	Issue	Cannot issue a discrepancy against a repeating form that has no data.
DISCREPANCY_AGAINST_ITEMSET_ROW	Issue	Cannot issue a discrepancy against an itemset row. Must issue against an item in the itemset.
DISCREPANCY_TRANGEN_NOT_CREATED		Could not create an instance of the transaction generator.
DISCREPANCY_ELEMENT_NOT_CREATED		Could not create element.
DISCREPANCY_DBUID_NOT_FOUND	GetByCriteria, Issue	Could not find an item associated with the requested Dbuid: {0}.
DISCREPANCY_GUID_NOT_FOUND	GetHistory, Update	Could not find an item associated with the requested Guid: {0}.
INFORM_FORM_NOTFOUND_DETAIL		Form not found: {0}.
MAPPEDITEM_ENTRY_BLANK		Found a mapped item entry for item {0} but it is blank.
DISCREPANCY_INVALID_USER		Invalid user specified.
PATIENT_GUID_NOTFOUND		Patient with GUID {0} not found.
INFORM_DISCREPANCY_STATE_CHANGE_NOTALLOWED		State change not allowed from {0} to {1}.
MAPPEDITEM_PATH_CHAPTER_NOTSPECIFIED		The chapter is not specified in the mapped item path: {0}.
INFORM_FORM_DELETED		The Form is deleted. InForm does not allow query management on a deleted form.
INFORM_FORM_LOCKED		The Form or Visit is locked. InForm does not allow query management on a locked form.
TRANSACTIONID_INVALIDFORMAT		The format of the requested TransactionId is invalid {0}.
MAPPEDITEM_PATH_ITEM_NOTSPECIFIED		The item is not specified in the mapped item path: {0}.

Error Code/MessageID	Operation	Error
TRANSACTION_PROCESSING_ERROR		An error occurred processing a transaction {0}.
MAPPEDITEM_CHAPTER_MISMATCH		The mapped item's chapter '{0}' must match the requested item's chapter '{1}'.
MAPPEDITEM_ITEMSET_MISMATCH		The mapped item's itemset '{0}' must match the requested item's itemset '{1}'.
MAPPEDITEM_PAGE_MISMATCH		The mapped item's page '{0}' must match the requested item's page '{1}'.
MAPPEDITEM_FORMAT_INVALID		The mapped item's path is invalid: {0}.
MAPPEDITEM_SECTION_MISMATCH		The mapped item's section '{0}' must match the requested item's section '{1}' since the item resides in an itemset.
MAPPEDITEM_PATH_PAGE_NOTSPECIFIED		The page is not specified in the mapped item path: {0}.
DISCREPANCY_REQUEST_CRITERIA_INPUT_LIMIT_EXCEEDED		The request contained {0} values for {1}. The limit is {2}.
TRANSACTIONID_INVALID		The request must contain a valid TransactionId.
INFORM_ITEM_HIDDEN		The requested InForm item is hidden.
REQUEST_LIST_EMPTY		The requested list is empty.
TRANSACTIONID_DUPLICATE		The requested TransactionId {0} is a duplicate.
MAPPEDITEM_PATH_SECTION_NOTSPECIFIED		The section is not specified in the mapped item path: {0}.
DISCREPANCY_BOOKMARK_INVALID		The specified bookmark "{0}" is invalid for the current request. If a request includes a bookmark, it should be a bookmark that was returned in the response from the matching request.
DISCREPANCY_INVALID_REVISION		The specified discrepancy revision number {0} does not match the latest revision number {1}.
INFORM_FORM_INDEX_INVALID		The specified form index {0} is invalid.
INFORM_FORM_REVISION_STALE		The specified form revision {0} is not the most recent.
DISCREPANCY_INVALID_SITE		The specified site {0} is invalid for patient {1}.

Error Code/MessageID	Operation	Error
TRANSACTION_PROCESSING_ERROR		An error occurred processing a transaction {0}.
DISCREPANCY_INVALID_STATE		The specified state is invalid: {0}.
INFORM_VISIT_INDEX_INVALID		The specified visit index {0} is invalid.
INFORM_TRIALCONN_NOTFOUND_TRIAL		Trial Connection for trial {0} was not found.
INFORM_TRIALCONN_NOTFOUND		Trial Connection not found.
INFORM_USER_NOTFOUND		Trial User not found.
DISCREPANCY_LSID_NOTCREATED		Unable to construct an LSID.
INFORM_ITEM_PARSE_ERROR		Unable to extract an InForm item from the requested XML.
INFORM_VISIT_NOTFOUND_DETAIL		Visit not found: {0}.

CHAPTER 3

ODM Export Interface

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Overview: ODM Export interface

The ODM Export interface is a unidirectional interface that provides a web service for any outside application that needs to retrieve data from an InForm database in CDISC ODM 1.3.0 standard format. Clinical data, admin data, and metadata are available. Refer to www.cdisc.org for more information on the ODM standard.

The ODM Export interface connects directly to the InForm database. It does not route requests through either the InForm Server Adapter interface or the InForm application server on the InForm server.

This chapter describes the syntax and functionality of the ODM Export interface of the InForm Adapter software. The interface is located on the InForm Adapter server at **/InFormAdapter/ODM/InFormODM.asmx** (for the WSE version) or **/inFormAdapter/ODM/ODMservice.svc** (for the WCF version). The ODM Export interface focuses on the semantics of the function calls that are published by the interface, and the parameters that the published web methods use. Each section gives examples of XML for both the web method request and response.

ODM Export: XML schema

Writing requests

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

For examples of Body statements, see the individual web methods. For more information, see *Public Web Methods* (on page 48).

SOAP header

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

Note: The requirement for requests to contain the **wsu:Timestamp**, **wsse:Username**, and **wsse:Password** elements are defined in the WSDL by ws-policy.

If your web service toolkit does not support ws-policy, you must manually add these elements to the web service request.

Field	Description	Standard
wsa:Action	SOAP action for the operation. Include this field as part of the summary for each SOAP operation.	WS-Addressing
wsa:MessageID	Unique ID for the message.	WS-Addressing
wsa:ReplyTo	Use the value that is shown in the example.	WS-Addressing
wsa:To	Full URL of the service. Note: The full URL is different for each customer.	WS-Addressing
wsu:Timestamp	Time the message was created and when it expires. Oracle recommends a 5-minute time window.	SOAP Message Security 1.0
wsse:Username	User name of the integration user in the InForm study.	SOAP Message Security 1.0
wsse:Password	Password of the integration user in the InForm study.	SOAP Message Security 1.0

Security information in the SOAP header

The ODM Export interface uses user/password authentication security and X.509 certificate authentication.

The SOAP header contains information about the service, the message, the sender, and a security element.

The Body of each SOAP request includes the **trial** attribute that contains the name of the InForm study. This value is used with information in the Security element of the SOAP header to

authenticate the ODM Export interface against the InForm study.

To configure username/password authentication for the ODM Export interface, you must also define several settings in the ODM web configuration files. For more information, see the *Installation Guide*.

SOAP header example

Username authentication

Sample SOAP request

```
http://docs.oasis-open.org/wss/2004/01/oasis-200401-wss-wssecurity-utility-1.0.xsd">
  <s:Header>
    <a:Action
s:mustUnderstand="1">http://www.oracle.com/InFormAdapter/2011/10/ODM/GetTransact
ions</a:Action>
    <a:MessageID>urn:uuid:561ac131-b74d-4cfc-ac13-58296724dd28</a:MessageID>
    <a:ReplyTo>

<a:Address>http://www.w3.org/2005/08/addressing/anonymous</a:Address>
    </a:ReplyTo>
    <a:To s:mustUnderstand="1">https://hsgbu-bur-qa-
infws.us.oracle.com/pfst60/informadapter/ODM/ODMService.svc</a:To>
    <o:Security s:mustUnderstand="1" xmlns:o="http://docs.oasis-
open.org/wss/2004/01/oasis-200401-wss-wssecurity-secext-1.0.xsd">
      <u:Timestamp u:Id="_0">
        <u:Created>2017-08-16T16:26:55.128Z</u:Created>
        <u:Expires>2017-08-16T16:31:55.128Z</u:Expires>
      </u:Timestamp>
      <o:UsernameToken u:Id="uuid-a97e3c57-65c9-4604-94d7-d316841f17ea-3">
        <o:Username>mmeyer</o:Username>
        <o:Password Type="http://docs.oasis-open.org/wss/2004/01/oasis-
200401-wss-username-token-profile-1.0#PasswordText">Manager1</o:Password>
      </o:UsernameToken>
    </o:Security>
  </s:Header>
  <s:Body>
    <GetTransactions xmlns="http://www.oracle.com/InFormAdapter/2011/10/ODM"
xmlns:i="http://www.w3.org/2001/XMLSchema-instance">
      <node>
        <DownloadTransactionODM trial="pfst60" bookmark="{1CBDB979-5DD9-
41B2-9D26-50CB73B65024}" userName="" skipODMReduction="false" priorFileOID=""
mappingVersion="2.0" xmlns="http://www.phaseforward.com/InFormAdapter/ODM/2.0"
xmlns:xsd="http://www.w3.org/2001/XMLSchema"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"/>
      </node>
    </GetTransactions>
  </s:Body>
</s:Envelope>
```

Sample SOAP response

```
<s:Envelope xmlns:s="http://www.w3.org/2003/05/soap-envelope"
xmlns:a="http://www.w3.org/2005/08/addressing" xmlns:u="http://docs.oasis-
open.org/wss/2004/01/oasis-200401-wss-wssecurity-utility-1.0.xsd">
  <s:Header>
    <a:Action
s:mustUnderstand="1">http://www.oracle.com/InFormAdapter/2011/10/ODM/GetTransact
ionsResponse</a:Action>
    <a:RelatesTo>urn:uuid:561ac131-b74d-4cfc-ac13-58296724dd28</a:RelatesTo>
    <o:Security s:mustUnderstand="1" xmlns:o="http://docs.oasis-
open.org/wss/2004/01/oasis-200401-wss-wssecurity-secext-1.0.xsd">
```



```

2ZambsNWSJDJ0AJjRaIdGb/d6y77W0h6kNPjcpoSdgheX2vsiUPQNiv2+mkrDqwhpbTp9H5SGxmrdgWED
5caFhVC/FHVMlobiMUXCgIsYntMayavNWT9s3+Q0LhoaS8BxBxZ+CcA2o4zc+/kFb5MqcSxd8Ky4lR6I
GGLI1ziDI8i3/xQ8n7zFDIjpvYkJOc00J2vaWw1/H628BEbNEzhVdEM0eDSyWVMhZuv2doLb3mHJRAR
PDPLFC5uKKA==</wsse:BinarySecurityToken>
  <Signature xmlns="http://www.w3.org/2000/09/xmldsig#">
    <SignedInfo>
      <CanonicalizationMethod
Algorithm="http://www.w3.org/2001/10/xml-exc-c14n#" />
      <SignatureMethod
Algorithm="http://www.w3.org/2001/04/xmldsig-more#rsa-sha256" />
      <Reference URI="#Body">
        <Transforms>
          <Transform Algorithm="http://www.w3.org/2001/10/xml-
exc-c14n#" />
        </Transforms>
      <DigestMethod
Algorithm="http://www.w3.org/2001/04/xmlenc-sha256" />
    </SignedInfo>
    <DigestValue>qyHowb8v8J0+mAiUpakQ49PTMwaKtPEWioAaR0MujG8=</DigestValue>
  </Signature>
</wsse:Security>
  <To s:mustUnderstand="1"
xmlns="http://www.w3.org/2005/08/addressing">https://VanityUrlBehindf5/pfst60/in
formadapter/ODM/ODMService.svc</To>
</s:Header>
<s:Body id="Body">
  <GetTransactions xmlns="http://www.oracle.com/InFormAdapter/2011/10/ODM"
xmlns:i="http://www.w3.org/2001/XMLSchema-instance">
    <node>
      <DownloadTransactionODM mappingVersion="2.0" priorFileOID=""
skipODMReduction="false" userName="" bookmark="{1CBDB979-5DD9-41B2-9D26-
50CB73B65024}" trial="pfst60"
xmlns="http://www.phaseforward.com/InFormAdapter/ODM/2.0"
xmlns:xsd="http://www.w3.org/2001/XMLSchema"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" />
    </node>
  </GetTransactions>
</s:Body>
</s:Envelope>

```

Sample SOAP response

```

<s:Envelope xmlns:s="http://www.w3.org/2003/05/soap-envelope"
xmlns:a="http://www.w3.org/2005/08/addressing">
  <s:Header>
    <a:Action
s:mustUnderstand="1">http://www.oracle.com/InFormAdapter/2011/10/ODM/GetTransact
ionsResponse</a:Action>
    <a:RelatesTo>urn:uuid:40753a0b-97e3-4a04-bd5f-99d78487f517</a:RelatesTo>
  </s:Header>
  <s:Body>
    <Security s:mustUnderstand="1" xmlns="http://docs.oasis-
open.org/wss/2004/01/oasis-200401-wss-wssecurity-secext-1.0.xsd">
      <SignatureConfirmation
Value="NXi3DGzn4f8FNfkvn6X0kwlpP9CnM4/8rfpty5q1UZunj1pcGa/ulQu+P8VatS5yXgeDutAq03
uyhraG1BrQqWYGijTAB4L9sWszZqW2Uw5SG2tprKYAiVcmC0oM2ICnRe9VLzYgjkQ1+QIGHjysPH523Y
HfnyKEgIOsXn349tB7K2k3UaoyiixBIM9q13V27yq5fYt54QG0iARrHBfsGDJi/OVS6Gm1Enlb712GP9
mvQEZb3fYZYjCsQK0SRBpbKcYdlCHD5WymT0d49/Ve+FD7utCvNfKATzqhTqAprW95W6lv+iujMHxWEP

```

```

FG4/a2laowK0d7Wxi1wRY1M+U9XVg==" b:Id="Body" xmlns="http://docs.oasis-
open.org/wss/oasis-wss-wssecurity-secext-1.1.xsd" xmlns:b="http://docs.oasis-
open.org/wss/2004/01/oasis-200401-wss-wssecurity-utility-1.0.xsd"/>
  </Security>
</s:Header>
  <s:Body xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema">
    <GetTransactionsResponse
xmlns="http://www.oracle.com/InFormAdapter/2011/10/ODM">
      <GetTransactionsResult>
        <ResponseODM
xmlns="http://www.phaseforward.com/InFormAdapter/ODM/2.0"
xmlns:pf="http://www.phaseforward.com/InFormAdapter/ODM/Extensions/3.0">
          <ODM Description="StudyDesign" FileType="Transactional"
FileOID="{07AD01F0-C26E-45E2-890D-C9FC04BC8CBE}" CreationDateTime="2017-08-
16T15:41:37+00:00" PriorFileOID="{1CBDB979-5DD9-41B2-9D26-50CB73B65024}"
ODMVersion="1.3.1" Originator="" pf:MappingVersion="V2"
pf:HierarchicalOIDs="Yes" pf:InFormAdapterVersion="1.3.9.0"
xmlns="http://www.cdsc.org/ns/odm/v1.3"/>
            <Bookmark>{07AD01F0-C26E-45E2-890D-C9FC04BC8CBE}</Bookmark>
            <TransactionsProcessed>500</TransactionsProcessed>
          </ResponseODM>
        </GetTransactionsResult>
      </GetTransactionsResponse>
    </s:Body>
  </s:Envelope>

```

Input parameters

The ODM web methods take a single XmlElement parameter. Each web method has a specific XML schema to which the input parameter must adhere.

For more information, see *Public Web methods* (on page 48).

Schema files provided with the ODM Export interface

Schema files for requests and response are located in the InForm Adapter installation directory.

```
<installation_directory>\ODM\bin\xsd
```

Validate ODM requests and responses against the following schema files:

Request schemas:

- Top level file: ODMPParameters.xsd
- Sub level file: ODMPParameters2.xsd

Response schemas:

- Top level file: ResponseODM.xsd
- Sub level files:
 - ODM.xsd
 - ODM1-2-0.xsd
 - PFExtensions.xsd
 - PhaseForward_ODM.xsd

Most web service toolkits can be used to validate XML.

Validation assures that request XML has the correct parameters and is of the right type to be used by

the Oracle ODM Export methods, and that responses have valid XML to be used as input in other programs.

Request and Response schema locations

Request directory

`<installation_directory>\InFormAdapter\ODM\bin\xsd`

Request version	Filename
Version 2.0	ODMParameters2.xsd

Response directory

`<installation_directory>InformAdapter\ODM\bin\xsd`

Response version	Filename
Version 2.0	ResponseODM.xsd

Namespaces

- Request and Response XML
`http://www.phaseforward.com/InFormAdapter/ODM/2.0`
where
2.0 is the version of the schema.
- ODM extensions
`http://www.phaseforward.com/InFormAdapter/ODM/Extensions/2.0`

Version extensions

The `http://phaseforward.com/InFormAdapter/ODM/1.2` schema includes `http://www.phaseforward.com/InFormAdapter/ODM/1.1` and extends the types defined there with the new parameters as needed.

ResponseODM

The ODM Export interface returns transactional ODM data. The ODM document is returned as a child of **ResponseODM**, as defined in the schema.

All web methods return an XmlElement. For more information, see *Public Web Methods List* (on page 48).

Error messages from the ODM Export interface

Exception	Description
TRIAL_NOT_FOUND	The requested study cannot be located.
SITE_NOT_FOUND	The requested site cannot be located.
INFORM_SITE_NOTFOUND	The requested site cannot be located.
PATIENT_NOT_FOUND	The requested patient cannot be located.
INFORM_PATIENT_NOTFOUND	The requested patient cannot be located.
VISIT_NOT_FOUND	The requested visit cannot be located.
FORM_NOT_FOUND	The requested form cannot be located.
BOOKMARK_NOT_FOUND	The requested bookmark cannot be located.
GENERAL	A general error has occurred.
Input schema version supported in the trial <trial name> in InForm is <schema version>	Displays when the request.xml is not using V2 schema for a study in the InForm 4.7 software.

Public Web methods

Unless otherwise specified, all element names are in the ODM namespace. The namespace file is included in Adapter ODMPParameters.xsd in the directory

<installation_directory>\InForm Adapter\ODM\bin\xsd

Public Web Methods List

The Oracle ODM Export interface provides the following public Web methods.

Method	Description
<i>DownloadMetadataODM</i> (on page 48)	Returns the definitions of all the metadata (for example, study versions, visits, and forms) in a study.
<i>DownloadAdminDataODM</i> (on page 52)	Returns lists of all users, sites, and signature definitions in a study.
<i>GetSiteList</i> (on page 58)	Returns the list of all sites in the specified study.
<i>GetPatientList</i> (on page 58)	Returns the list of all subjects that are associated with a particular site. Archived subjects are not returned.
<i>GetPatientForms</i> (on page 59)	Returns the list of all forms that apply for a subject.
<i>GetTransactions</i> (on page 60)	Returns a list of all the subject-related transactions for a specified study.
<i>GetTransactionStatus</i> (on page 66)	Returns the status of transactions that have been processed.

DownloadMetadataODM

Returns the definitions of all the metadata (for example, study versions, visits, and forms) in a study.

XmlElement **DownloadMetadataODM**(*XmlElement node*)

Input parameters—DownloadMetadataODM

Takes an XmlElement of type DownloadMetadataODM that contains the following children.

DownloadMetadataODM input parameters	
Node/Attribute name	Description
trial	The study from which to receive metadata. Specify either the study name, or the study alias value that is used when registering the study through the InForm Adapter Admin interface.
userName	The user ID of the user who is requesting the data.

DownloadMetadataODM input parameters	
Node/Attribute name	Description
priorFileOID	Optional reference to the previous file (if one exists) in a series. Type = String
fileType	The type of ODM file data that is to be returned. Type = Enumeration. Enumeration values = Transactional.
mappingVersion	The version of the InForm-to-ODM mapping. Specify 2.0 for the most complete and accurate representation of the InForm data that is returned in ODM format. Type = Enumeration. Enumeration values = 1.0, 2.0. Default = 2.0.
includeExtensions	Specifies whether to include Oracle Phase Forward ODM extensions in the data that is returned from the method. Type = Boolean. Default = True.
complianceMode	Specifies how to handle transactions in the study that are deleted and then undeleted. Type = Enumeration. Enumeration values = Strict, Loose. Default = Strict. Strict uses a Remove transaction to indicate that a form has been deleted. If the form is subsequently undeleted, the returned data includes all the data for the form that was deleted and then undeleted. Loose uses a FormStatus or ItemGroupStatus element with the attribute name of Deleted . Loose compliance mode is more efficient.

DownloadMetadataODM input parameters	
Node/Attribute name	Description
studyVersionName	The version of the InForm study for which to download metadata. Type = String Optional. You can specify a single study version. The value for studyVersionName must match the Study Version that is displayed on a site's configuration page in the InForm application. You can specify both studyVersionName and studyVersionCutoff to return only the data from the specified study version that is committed to the InForm application after the specified date.
studyVersionCutoff	The response includes only the study data that is committed to the InForm application after the date you specify. For example, if you specify 2010-12-15T00:00:00 (December 15, 2010), only data that is committed to the study on December 16, 2010 and later will be included. Type = xs:DateTime Optional. Format: YYYY-MM-DDTHH:MM:SS If you specify a DateTime, you must include all components of the format. If you specify a date in the future, no study versions are returned. You can specify both studyVersionName and studyVersionCutoff to return only the data from the specified study version that is committed to the InForm application after the specified date.
studyVersionSummary	If True, returns summary output; that is, a MetaDataVersion element for each study version in the InForm study, without returning child elements of MetaDataVersion. Type=Boolean Default=False studyVersionSummary can be used with either studyVersionName or studyVersionCutoff to return summary output for any study version that meets the criteria you specify. If you set studyVersionSummary=True, skipRevisioningWithoutVersioning is also set to True.

DownloadMetadataODM input parameters

Node/Attribute name	Description
skipRevisioningWithoutVersioning	Specifies whether to omit additional processing to detect metadata that was created by the use of the Revising without Versioning technique in the InForm application. Type = Boolean Optional. Default = False - False—Performs extra processing to determine which metadata resulted from Revising without Versioning. - True—Omits extra processing; as a result, performance is improved. Note: If studyVersionSummary=True, skipRevisionWithoutVersioning is automatically set to True.

Example request—DownloadMetadataODM

```
<node xmlns="http://www.phaseforward.com/InFormAdapter/ODM/1.0">
  <DownloadMetadataODM xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
    xmlns:xsd="http://www.w3.org/2001/XMLSchema"
    trial="testtrial"
    userName="system"
    fileType="Transactional"
    mappingVersion="2.0"
    complianceMode="Loose"
    studyVersionName="Study Version 1.0"
    studyVersionCutoff="2010-10-28T00:00:00"
    xmlns="http://www.phaseforward.com/InFormAdapter/ODM/2.0" />
</node>
```

Response—DownloadMetaDataODM

Returns an XmlElement that contains the definitions of all metadata in the study. The definitions are located under the /ODM/STUDY XPath in the returned XML.

Internationalization—DownloadMetadataODM response

MeasurementUnit

The MeasurementUnit element includes the TranslatedText for Symbol, and has the optional xml:lang attribute to specify the language used by the translation.

Example

```
<MeasurementUnit OID="Inches" Name="Inches" pf:DBUID="1766"
  pf:GUID="{32A95F99-27FF-41AE-809C-F46583001D69}"
  pf:Revision="153925075453062">
  <Symbol>
    <TranslatedText>in</TranslatedText>
    <TranslatedText xml:lang="en-US">in</TranslatedText>
    <TranslatedText xml:lang="ja-JP">in</TranslatedText>
  </Symbol>
```

```
</MeasurementUnit>
```

For more information, see the mapping information for *MeasurementUnit* (on page 113).

Question

Question is a child element of ItemDef. It contains a TranslatedText element for each study language.

For more information, see the mapping information for *ItemDef* (on page 122).

CodeList

Each CodeListItem of the CodeList element has translations that are based on the study locales.

For more information, see the mapping information for *CodeList* (on page 130).

TranslatedText in Mnemonic element

The elements FormDef and StudyEventDef contain a Mnemonic element, which contains the element TranslatedText.

Example using FormDef

```
<FormDef OID="frmAE" Name="frmAE" Repeating="Yes" pf:DBUID="5761"
pf:GUID="{26FD95F7-1250-4879-B97F-0C58871DE56D}"
pf:Revision="153925387562062">
  <ItemGroupRef ItemGroupOID="frmAE.sctAE" OrderNumber="1" Mandatory="No" />
  <pf:Mnemonic>
    <TranslatedText>AE</TranslatedText>
    <TranslatedText xml:lang="en-US">AE</TranslatedText>
    <TranslatedText xml:lang="ja-JP">AE</TranslatedText>
  </pf:Mnemonic>
</FormDef>
```

DownloadAdminDataODM

Returns lists of all users, sites, and signature definitions in a study.

XmlElement **DownloadAdminDataODM**(*XmlElement node*)

Input parameters—DownloadAdminDataODM

Takes an XmlElement that follows the DownloadAdminDataODM element schema as an input parameter. The DownloadAdminDataODM element has the following children.

DownloadAdminDataODM input parameters	
Node/Attribute name	Description
trial	The study from which to retrieve administrative data. Specify either the study name, or the study alias value that is used when registering the study through the InForm Adapter Admin interface.
userName	The user ID of the user who is requesting the data.

DownloadAdminDataODM input parameters	
Node/Attribute name	Description
priorFileOID	Optional reference to the previous file (if one exists) in a series. Type = String.
fileType	The type of ODM file data that is to be returned. Type = Enumeration. Enumeration values = Transactional.
mappingVersion	The version of the InForm-to-ODM mapping. Specify 2.0 for the most complete and accurate representation of the InForm data that is returned in ODM format. Type = Enumeration. Enumeration values = 1.0, 2.0. Default = 2.0.
includeExtensions	Specifies whether to include Oracle Phase Forward ODM extensions in the data that is returned from the method. Type = Boolean. Default = True.
complianceMode	Specifies how to handle transactions in the study that are deleted and then undeleted. Type = Enumeration. Enumeration values = Strict, Loose. Default = Strict. Strict uses a Remove transaction to indicate that a form has been deleted. If the form is subsequently undeleted, the returned data includes all the data for the form that was deleted and then undeleted. Loose uses a FormStatus or ItemGroupStatus element with the attribute name of Deleted . Loose compliance mode is more efficient.
includeUsers includeLocations includeSignatures includeGroups includeLocales	Parameters that specify a section in the admin data to be returned with the response. includeUsers is required if you want to specify userBookmark. Type=Boolean. Values=True or False. Default=True (the section is included).

DownloadAdminDataODM input parameters	
Node/Attribute name	Description
userBookmark	The InForm UserID. You must specify includeUsers if you want to specify a userBookmark. • If userBookmark is specified, users are returned beginning with the UserID that immediately follows (greater than) the specified UserID. The number of records returned by the call is equal to the ODMUserBookmark count as defined in the configuration file <code>informAdapter.ODM.config</code>. To return all users in multiple calls, use a bookmark value of zero (0) in the first call. If the userBookmark is greater than zero, only the user section of admin data is returned, regardless of whether you specified any other parameters. • If a userBookmark is not specified, all users are returned in a single response, beginning with the first user in the study.

Example request—DownloadAdminDataODM

```
<node xmlns="http://www.phaseforward.com/InFormAdapter/ODM/1.0">
  <DownloadAdminDataODM
    xmlns="http://www.phaseforward.com/InFormAdapter/ODM/2.0"
    priorFileOID="Depression Study/{25213601-4fd7-4502-bc65-af2fd73d1c3}"
    fileType="Transactional" mappingVersion="2.0"
    includeExtensions="true" complianceMode="Strict"
    trial="pfst45odm" userName="soatest"
    includeSignature = "true" includeUsers="true" includeLocations="true"
    includeGroups="false" includeLocales="false"
    UserBookmark ="0"/>
</node>
```

Response—DownloadAdminDataODM

Returns an XmlElement that contains the list of all users, sites, and signature definitions in a site in a study.

If you are using bookmarks, the response includes:

- **UserBookmark**—The last UserBookmark that has been processed. If UserBookmark is the same as the request there are no more users.
- **Status**—Optional field that indicates whether there are more users. Status appears only when there are no more users to process. The bookmark will always be that of the last processed user.

For examples of responses, see: *Transactional data—DownloadAdminDataODM response* (on page 72).

Using a bookmark

To return all user admin data in multiple calls and responses:

- 1 In the first call to DownloadAdminDataODM, obtain the Signature, Locations, and Users sections, but limit the number of users to return by specifying a user bookmark with a value of zero (0).
- 2 In the second call, DownloadAdminDataODM again, this time using the bookmark that was returned by the first method call. This will return only the User section, starting with the first record after the userBookmark.
- 3 Make additional calls with the same parameters. Check to determine whether all users have been returned by either checking for the status node, or determining whether the bookmark node in the response is the same as the userBookmark in the request.

Bookmark example

This is an excerpt from the InFormAdapter.ODM.config file, with an example of ODMUserBookmark count of 100 records.

```
.
.
<AdapterSettings>
  <RootVirtualDirectory>InFormAdapter</RootVirtualDirectory>
  <CustomerURI>www.phaseforward.com</CustomerURI>
  <ApplicationName>CentralServices</ApplicationName>
  <ApplicationId>8833091a-b3e7-4049-b22b-868551c9af32</ApplicationId>
  <MultiInstanceSuffix></MultiInstanceSuffix>
</AdapterSettings>
  <ODMUserBookmark count="100" />
  <ODMTransaction count="500" />
  <!-- Uncomment this empty element to disable the application of ODM data
  reduction post processing. -->
  <!-- <SkipODMReduction /> -->
  <!-- if auditResponse set to true, request will be audited even when
  auditRequest=false -->
  <InFormAdapterAudit auditRequest="true" auditResponse="true" />
.
.
.
```

Internationalization—DownloadAdminDataODM response

Product Locale

The product locale of the InForm software. Used to extract the translations in the InComplete Reasons codelist.

Applies to studies that use InForm 4.7 software, InForm 5.0 software, and subsequent releases.

The consumer of the incomplete reason code list must get the product locale from the admin data, and use one product locale to extract the incomplete reason.

For studies that use the InForm 4.6 software, product locale is not included in the admin data.

Schema

```
<xs:attributeGroup name="ProductLocalAttributeDefinition">
  <xs:attribute ref="xml:lang"/>
</xs:attributeGroup>
```

```

<xs:element name="ProductLocale">
  <xs:complexType>
    <xs:attributeGroup ref="ProductLocalAttributeDefinition"/>
  </xs:complexType>
</xs:element>

<xs:element name="ProductLocaleList">
  <xs:complexType>
    <xs:sequence>
      <xs:element ref="ProductLocale" minOccurs="1" maxOccurs="unbounded" />
    </xs:sequence>
  </xs:complexType>
</xs:element>

```

Example

```

<pf:ProductLocale xml:lang="en-US" />
<pf:ProductLocale xml:lang="ja-JP" />

```

User Study locale

Each User element includes the attribute StudyLocale. User StudyLocale exists only for studies that use InForm 4.7 software (all releases) and InForm 5.0 software (all releases), and InForm 5.5 software and above.

User StudyLocale is retrieved from the study database.

Schema

```

<xs:attribute name="StudyLocale" type="xs:language"></xs:attribute>

```

Example

```

<User OID="amichelle" UserType="Investigator" pf:DBUID="6953"
pf:GUID="{25FD0671-52D9-41B3-B83F-1BB2100E5DFE}" pf:StudyLocale="en-US">
  <LoginName>amichelle</LoginName>
  <DisplayName>Ann Michelle (CRC)</DisplayName>
  <FullName>Ann Michelle (CRC)</FullName>
  <FirstName>Ann</FirstName>
  <LastName>Michelle (CRC)</LastName>
  <Address />
  <LocationRef LocationOID="7600" />
  <LocationRef LocationOID="7628" />
  <LocationRef LocationOID="7660" />
</User>

```

Site Study locale

Specified in the Location element. Includes the attribute Locale in the attribute group for the site.

Schema

```

<xs:attribute name="Locale" type="xs:language"></xs:attribute>

```

Example

```

<Location OID="54312" Name="Marlboro Hospital" LocationType="Site"
pf:SiteCountry="USA" pf:SiteTimezone="(GMT-05:00) Eastern Time (US &
Canada)" pf:GUID="{C769A488-9AF4-4303-802C-C0147AE58396}"
pf:Revision="198749285921028" pf:Locale="en-US">
  <MetaDataVersionRef StudyOID="Depression Study"
  MetaDataVersionOID="Undefined" EffectiveDate="0001-01-01" />
  <pf:Mnemonic>
    <TranslatedText>MARL</TranslatedText>
  </pf:Mnemonic>
</Location>

```

FullName and DisplayName

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 DownloadAdminDataODM should rely on FirstName and LastName elements to get the full name or display name.

DisplayName and FullName should be skipped, even though they exist in the response to conform to the ODM 1.3 standard.

Example

```
<User OID="UA" UserType="Sponsor" pf:DBUID="4540" pf:GUID="{931DB5AC-47E8-4E5D-9348-C862F6889238}">
  <LoginName>UA</LoginName>
  <DisplayName>User Admin</DisplayName>
  <FullName>User Administrator</FullName>
  <FirstName>User</FirstName>
  <LastName>Administrator</LastName>
  <Address />
</User>
```

TranslatedText in Mnemonic element

The Location element contains a Mnemonic element, which contains the element TranslatedText.

Note: The site mnemonic can contain any Unicode characters. However, because the InForm 4.7 software does not allow you to specify a locale for the site mnemonic, the translated text does not include the xml:lang attribute.

Example—Location

```
<Location OID="7600" Name="PhaseForward" LocationType="Site"
pf:SiteCountry="USA" pf:SiteTimezone="(GMT-05:00) Eastern Time (US & Canada)"
pf:GUID="{3C07AF5F-E07F-471A-8F7C-AB120A48C1BB}"
pf:Revision="153925498812062">
  <MetaDataVersionRef StudyOID="Depression Study"
  MetaDataVersionOID="Study Version 1.0" EffectiveDate="2000-04-04" />
  <MetaDataVersionRef StudyOID="Depression Study"
  MetaDataVersionOID="Study Version 2.0" EffectiveDate="2008-03-28" />
  <MetaDataVersionRef StudyOID="Depression Study"
  MetaDataVersionOID="Study Version 2.0##1222711396" EffectiveDate="2008-03-28" />
  <MetaDataVersionRef StudyOID="Depression Study"
  MetaDataVersionOID="Study Version 2.0##1222711535" EffectiveDate="2008-03-28" />
  <pf:Mnemonic>
    <TranslatedText>PF</TranslatedText>
  </pf:Mnemonic>
</Location>
```

Meaning and LegalReason elements

These two elements are child elements of SignatureDef. They contain the language-specific text from the study in InForm 4.7 or InForm 5.5 and above and are driven by the study locales.

Both Meaning and LegalReason include a TranslatedText element, which indicates the available translations.

The translations for Meaning and LegalReason are based on the study locales that are available when

the DownloadAdminDataODM method is called.

GetSiteList

Returns the list of all sites in the specified study.

XmlElement **GetSiteList**(*XmlElement node*)

Input parameters—GetSiteList

Takes an XmlElement that follows the GetSiteList element schema as an input parameter. The GetSiteList element has the following children.

GetSiteList input parameters	
Node/Attribute name	Description
trial	The study from which to retrieve a list of sites.

Example request—GetSiteList

```
<GetSiteList trial="pfst"
  xmlns="http://www.phaseforward.com/InFormAdapter/ODM/1.0" />
```

Response—GetSiteList

Returns an XmlElement that contains the list of sites in the study. The site list is located under the /CRFSUBMIT/SITELIST XPath in the returned XML.

For more information, see *GetSiteList example response* (on page 73).

Internationalization—GetSiteList response

GetSiteList returns the language for each site for trials that use the InForm 4.7 and InForm 5.0 software and subsequent releases.

Example:

```
<SITELIST>
  <SITEINFO SITEID="54312" SITENAME="Marlboro Hospital" SITEMNEMONIC="MARL"
    SITEGUID="{C769A488-9AF4-4303-802C-C0147AE58396}" LANGUAGECODE="en-US" />
  <SITEINFO SITEID="7628" SITENAME="McLean Hospital" SITEMNEMONIC="MCLEAN"
    SITEGUID="{C966597A-B965-413F-A3B4-7F38449CC23B}" LANGUAGECODE="en-US" />
  <SITEINFO SITEID="7660" SITENAME="Mass General Hospital" SITEMNEMONIC="MGH"
    SITEGUID="{7C9EAD34-BAD3-4E80-BEA9-BAC29E055D08}" LANGUAGECODE="en-US" />
  <SITEINFO SITEID="7600" SITENAME="PhaseForward" SITEMNEMONIC="PF"
    SITEGUID="{3C07AF5F-E07F-471A-8F7C-AB120A48C1BB}" LANGUAGECODE="en-US" />
  <SITEINFO SITEID="7644" SITENAME="Veterans Administration Hospital"
    SITEMNEMONIC="VA" SITEGUID="{867835F8-3F2A-4D9D-81D0-2673703A0999}"
    LANGUAGECODE="en-US" />
</SITELIST>
```

GetPatientList

Returns the list of all subjects that are associated with a particular site. Archived subjects are not

returned.

XmlElement **GetPatientList**(*XmlElement node*)

Input parameters—GetPatientList

Takes an *XmlElement* that follows the *GetPatientList* element schema as an input parameter. The *GetPatientList* element has the following children.

GetPatientList input parameters	
Node/Attribute name	Description
trial	The study from which to retrieve a list of subjects. Specify either the study name, or the study alias value that is used when registering the study through the InForm Adapter Admin interface.
siteID	The DBUID of the site for which the list of subjects is retrieved.

Example request—GetPatientList

```
<GetPatientList trial="pfst" siteID="11210"
  xmlns="http://www.phaseforward.com/InFormAdapter/ODM/1.0"/>
```

Response—GetPatientList

Returns an *XmlElement* that contains the list all subjects in a site in a study. The subject list is located under the */CRFSUBMIT/PATIENTLIST* XPath in the returned XML.

For more information, see *GetPatientList example response* (on page 73).

GetPatientForms

Returns the list of all forms that apply for a subject.

XmlElement **GetPatientForms**(*XmlElement node*)

Input parameters—GetPatientForms

Takes an *XmlElement* that follows the *GetPatientForms* element schema as an input parameter. The *GetPatientForms* element has the following children.

GetPatientForms input parameters	
Node/Attribute name	Description
trial	The study from which to retrieve the subject forms. Specify either the study name, or the study alias value that is used when registering the study through the InForm Adapter Admin interface.

GetPatientForms input parameters

Node/Attribute name	Description
patientID	The patient ID of the subject for which the data is retrieved.

Example request—GetPatientForms

```
<GetPatientForms trial="pfst45" patientID="10769"
  xmlns="http://www.phaseforward.com/InFormAdapter/ODM/1.0" />
```

Response—GetPatientForms

Returns an XmlElement that contains the list of sites located in the study. The XML contains the following element types:

- FORMSETLIST—A list of all of the patient's visits.
- FORMSET—A child of FORMSETLIST. Represents one of the patient's visits.
- FORMLIST—A child of FORMSET. Contains a list of all the forms within a visit.
- FORM—A child of FORMSET. Each form element represents one of the patient's forms.

For more information, see *GetPatientForms example response* (on page 74).

GetTransactions

Returns a list of all the subject-related transactions for a specified study.

XmlElement **GetTransactions**(*XmlElement requestParams*)

Along with the ODM document, the XML element **Status** and a **bookmark** is returned.

Status contains one of the following values:

- **OK** means that the transaction processed normally and another call should be made.
- **END** means that the call ended on the last transaction in the data, and the calls can stop processing.

The **bookmark** returns the record after which processing should start the next time that GetTransactions is called.

Input parameters—GetTransactions

Takes the Xml Element **DownloadTransactionODM** that follows the GetTransactionODM element schema as an input parameter. The DownloadTransactionODM element has the following attributes.

DownloadTransactionODM input parameters

Node/Attribute name	Description
---------------------	-------------

DownloadTransactionODM input parameters	
Node/Attribute name	Description
trial	The study from which to retrieve transaction data. Specify either the study name, or the study alias value that is used when registering the study through the InForm Adapter Admin interface.
bookmark	The InForm transaction ID. • If a bookmark is specified—Transactions are returned beginning with the transaction that follows the specified transaction ID. • If the bookmark is not specified—Transactions are returned beginning from the first transaction in the study. For more information, see <i>Usage—GetTransactions</i> (on page 64).
userName	The user ID of the user who is requesting the data.
priorFileOID	Optional reference to the previous file (if one exists) in a series. Type = String.
mappingVersion	The version of the InForm-to-ODM mapping. Specify 2.0 for the most complete and accurate representation of the InForm data that is returned in ODM format. Type = Enumeration. Enumeration values = 1.0, 2.0. Default = 2.0.
includeExtensions	Specifies whether to include Oracle Phase Forward ODM extensions in the data that is returned from the method. Type = Boolean. Default = True.

DownloadTransactionODM input parameters	
Node/Attribute name	Description
skipODMReduction	Specifies whether to disable the ODM data reduction feature. Type = BooleanDefault = False (Data reduction remains enabled.) Optional. ODM data reduction reduces redundancies in ODM output. Items are identified as unique based on their identifying key (OID, repeat key, etc). Contents of items that have the same key are reduced to a single item, in chronological order. The output remains ODM compliant, but is more compact. You can disable reduction for all studies on the server by uncommenting the element <SkipODMReduction /> in the InFormAdapter.ODM.config file. The request parameter value, if specified in the method call, takes precedence over the server-wide element value in the configuration file. For example, if you uncomment <SkipODMReduction /> in the configuration file, and include skipODMReduction=False in the call to the GetTransactions method for study pfst45odm, only the GetTransactions response for that particular request to trial pfst45odm will apply ODM data reduction to the response.
complianceMode	Specifies how to handle transactions in the study that are deleted and then undeleted. Type = Enumeration. Enumeration values = Strict, Loose. Default = Strict. Strict uses a Remove transaction to indicate that a form has been deleted. If the form is subsequently undeleted, the returned data includes all the data for the form that was deleted and then undeleted. Loose uses a FormStatus or ItemGroupStatus element with the attribute name of Deleted. Loose compliance mode is more efficient.

Example request—GetTransactions

```
<node xmlns="http://www.phaseforward.com/InFormAdapter/ODM/1.0">
  <DownloadTransactionODM xmlns:xsi="http://www.w3.org/2001/XMLSchema-
instance" xmlns:xsd="http://www.w3.org/2001/XMLSchema"
    trial="pfst47odm" bookmark="{CB219A42-F227-43D8-93F7-DF91AED86EC2}"
    userName="system"
    priorFileOID="{CB219A42-F227-43D8-93F7-DF91AED86EC2}"
    mappingVersion="2.0"
    complianceMode="Loose"
    xmlns="http://www.phaseforward.com/InFormAdapter/ODM/2.0" />
</node>
```

Response—GetTransactions

Returns an XmlElement that contains the subject transaction data (such as form submissions) for subjects who match the specified patient ID. The subject data is located under the /ODM/ClinicalData XPath in the returned XML.

GetTransactions response	
Node/Attribute name	Description
Description	The description of the study.
FileType	For InForm data, FileType is always Transactional , indicating that an InForm transaction is returned.
FileOID	A unique identifier for the file. Consists of the study.name followed by a GUID. For example: <code>pfst/{345C8404-9656-425B-BA03-EE92D7E1FE91}</code>
PriorFileOID	An identifier for the transaction that was retrieved by the previous API call.
CreationDateTime	The date and time when the API call was made.
ODMVersion	The version of the ODM schema of the returned data.
Originator	The ID of the user who made the API call.
TransactionsProcessed	Indicates the number of transactions that were considered by the method. Note: This number is not the same as the number of clinical data transactions that are returned. Some transactions do not contain clinical data.
Bookmark	The bookmark that must be passed into the next call to GetTransactions. Indicates the point in the transaction log after which the processing should begin. For more information, see <i>Usage—GetTransactions</i> (on page 64).
MetaDataVersionOID	Identifier for the study version of the form in the InForm system. If the form does not contain a study version, MetaDataVersion is returned with the value "Undefined."

For more information, see:

- *Example returning clinical data* (on page 74).
- *Example returning no clinical data* (on page 75).

Usage—Get Transactions

The GetTransactions web method provides an incremental way to retrieve data from the InForm Adapter interface.

To return all the subject transactions for a study, you call the GetTransactions web method multiple times. With each call, the InForm Adapter software:

- Analyzes 500 transactions and returns all the clinical data transactions that it finds.
- Returns a bookmark that must be passed into the next call to GetTransactions. The bookmark indicates the point in the transaction log after which the processing should begin.

To begin retrieving data from the beginning of the transaction log, the first call to GetTransactions must have an empty bookmark.

Note: Because an InForm study contains administration and metadata transactions as well as patient transactions, the first several calls to GetTransactions typically return an ODM element that does not contain any data (child elements).

To retrieve all the subject transactions for a study:

- 1 Call GetTransactions with an empty bookmark, indicating that you want to retrieve all subject transactions starting at the beginning of your study:

```
<DownloadTransactionODM xmlns:xsd="http://www.w3.org/2001/XMLSchema"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  trial="pfst45" bookmark=""
  userName="mcollins"
  xmlns="http://www.phaseforward.com/InFormAdapter/ODM/2.0" />
```

- 2 Call GetTransactions again, this time using the bookmark that was returned by the first method call:

```
<DownloadTransactionODM xmlns:xsd="http://www.w3.org/2001/XMLSchema"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  trial="pfst45" bookmark="{833A7114-BA90-4494-9E4E-7A9D3446E318}"
  userName="mcollins"
  xmlns="http://www.phaseforward.com/InFormAdapter/ODM/1.0" />
```

- 3 Repeat the process using the FileOID from the previous response as the bookmark for the next call until the results of the call is Status = END, indicating that the process is complete.

What happens after all transactions are processed?

This section includes three scenarios that describe the behavior of GetTransactions when the InForm Adapter software encounters the last transaction to be processed.

For each scenario, the ResponseODM document has been defined to contain the following:

- An ODM element as previously defined.
- The status of the last record that was processed: END or OK.
- A bookmark.

In addition, transactions A, B, C, and D exist.

• Scenario 1

In this scenario, transactions A, B, C, and D contain clinical data. In the first call to GetTransactions, A, B, and C are processed, and C is passed as the bookmark. In the next call, processing begins with D.

Because D contains clinical data:

- The OMD element returns transaction data.
- The Status value is "END."
- The bookmark is D.

• Scenario 2

In this scenario, A, B, and C contain clinical data, but D does not contain clinical data. In the first call to GetTransactions, A, B, and C are processed, and C is passed as the bookmark. In the next call, processing begins with D.

Because D does not contain clinical data:

- The ODM element returns an empty ODM document.
- The Status value is "END."
- The bookmark is D.

• Scenario 3

In this scenario, A, B, C, and D have been processed by the first call, and D is passed as the bookmark.

Because D is the last transaction:

- An ODM element is not returned.
- The Status value is "END."
- The Bookmark is D. You get back the same bookmark you passed in, because processing reached the last transaction.

After you process any of these scenarios, check to see whether ODM exists, and if it does, process it. If the results of subsequent call is Status = END, the download is complete. If Status is a value other than END, you must make another call using the bookmark.

For more information, see *GetTransactions example response* (on page 74).

GetTransactionStatus

Returns the status of transactions that have been processed.

Input parameters

Takes an XmlElement that follows the DownloadTransactionODM element schema as an input parameter.

GetTransactionStatus input parameter	
Node/Attribute name	Description
trial	The study from which to retrieve transaction data.
bookmark	The InForm transaction ID. The bookmark is used when calculating TransactionXmlRemaining. When you pass in the last bookmark, TransactionXmlRemaining returns 0.

Example request—GetTransactionStatus

```
<node xmlns="http://www.phaseforward.com/InFormAdapter/ODM/1.0">
  <DownloadTransactionODM xmlns:xsi="http://www.w3.org/2001/XMLSchema-
    instance" xmlns:xsd="http://www.w3.org/2001/XMLSchema"
    trial="testtrial" mappingVersion="2.0"
    xmlns="http://www.phaseforward.com/InFormAdapter/ODM/2.0" />
</node>
```

Response—GetTransactionStatus

Returns an XML element that contains information about the transactions that have been processed.

GetTransactionStatus response	
Node/Attribute name	Description
TotalTransactionCount	The total number of transactions in the system, regardless of how many transactions have been converted into XML.
TransactionXmlCount	The number of transactions that have been converted in to XML. Transaction XMLs are used to generate ODM transactions. If the system is up to date, TotalTransactionCount and TransactionXmlCount will be equal.
TransactionXmlRemaining	The number of transactions that remain in the system after the specified bookmark.

GetTransactionStatus response	
Node/Attribute name	Description
LastTransactionXmlTime	The time/date of the most recent transaction. Note: If this time/date is far in the past, it might indicate either of the following: • The transaction XML is not being generated. • The study is archived and no new transactions are occurring.

If TransactionsProcessed (as returned by GetTransactions) are summed, you can compare that number with the information that is returned from GetTransactionStatus to verify that you have received everything.

$$\text{SumOfTransactionsprocessed} + \text{TransactionXmlRemaining} = \text{TransactionXmlCount}$$

To find the percentage of transactions completed:

$$1 - \text{TransactionXmlRemaining} / \text{TransactionXmlCount} = \% \text{ complete}$$

For more information, see *GetTransactionStatus example response* (on page 75).

Examples of ODM Responses

Transactional Data—DownloadMetadataODM response

Note: This sample has lines omitted, which are indicated by comments. For a complete example response, see the ODM Export interface example XML files provided with the sample applications.

```
<DownloadMetadataODMResult
xmlns="http://www.phaseforward.com/InFormAdapter/ODM/1.0">
  <ResponseODM xmlns="http://www.phaseforward.com/InFormAdapter/ODM/2.0"
xmlns:pf="http://www.phaseforward.com/InFormAdapter/ODM/Extensions/2.0">
    <ODM Description="StudyDesign" FileType="Transactional"
FileOID="StudyDesign/d5e69373-f6c2-474a-bfe9-23acaad34db4"
CreationDateTime="2018-01-29T20:31:41+00:00" ODMVersion="1.3" Originator=""
pf:MappingVersion="V2" pf:HierarchicalOIDs="Yes"
pf:InFormAdapterVersion="1.3.9.126" xmlns="http://www.cdisc.org/ns/odm/v1.3">
      <Study OID="StudyDesign">
        <GlobalVariables>
          <StudyName>StudyDesign</StudyName>
          <StudyDescription>Not Defined</StudyDescription>
          <ProtocolName>StudyDesign</ProtocolName>
        </GlobalVariables>
        <BasicDefinitions>
          <MeasurementUnit OID="cm" Name="cm" pf:DBUID="7857"
pf:GUID="{8DE8B7AD-42B9-45E7-9AEE-FE2D6582F301}"
pf:Revision="469037475352001">
            <Symbol>
              <TranslatedText>cm</TranslatedText>
              <TranslatedText xml:lang="en-US">cm</TranslatedText>
            </Symbol>
          </MeasurementUnit>
          <MeasurementUnit OID="in" Name="in" pf:DBUID="7862"
pf:GUID="{849BF66E-A002-48A8-AF9C-A79AD1659DC5}"
pf:Revision="469037475417001">
            <Symbol>
              <TranslatedText>in</TranslatedText>
              <TranslatedText xml:lang="en-US">in</TranslatedText>
            </Symbol>
          </MeasurementUnit>
          <!--other MeasurementUnit entries omitted from example-->
        </BasicDefinitions>
        <MetaDataVersion OID="Study Design 0.0.131" Name="StudyDesign"
pf:ApprovalDate="2015-11-12T21:11:20+00:00" pf:DBUID="21177"
pf:GUID="{6C148104-92D4-43DA-BDD9-4588A592714D}"
pf:Revision="469037480021001">
          <Protocol>
            <StudyEventRef StudyEventOID="screen" OrderNumber="1"
Mandatory="No" />
            <StudyEventRef StudyEventOID="enroll" OrderNumber="2"
Mandatory="No" />
            <!--other StudyEventRef entries omitted from sample-->
          </Protocol>
          <StudyEventDef OID="screen" Name="screen" Repeating="No"
Type="Scheduled" Category="Screening" pf:DBUID="9716" pf:GUID="{BD5E333F-
D4ED-41DB-B5A8-6E9DAA4ADEF9}" pf:Revision="469037480021001"
pf:UUID="D882CE38-0F42-11D2-A419-00A0C963E0AC" pf:VisitStartHours="0">
            <FormRef FormOID="frmScr" OrderNumber="1" Mandatory="No"
/>
            <pf:Mnemonic>
              <TranslatedText>Screen</TranslatedText>
              <TranslatedText xml:lang="en-
US">Screen</TranslatedText>
            </pf:Mnemonic>
          </StudyEventDef>
          <StudyEventDef OID="enroll" Name="enroll" Repeating="No"
```

```

Type="Scheduled" Category="Enrollment" pf:DBUID="9717" pf:GUID="{5930A2F6-
52E3-4AAA-82FC-5FBCB1B7777C}" pf:Revision="469037483222001"
pf:UUID="D882CE3A-0F42-11D2-A419-00A0C963E0AC" pf:VisitStartHours="0">
    <FormRef FormOID="frmEnr" OrderNumber="1" Mandatory="No"
/>
    <pf:Mnemonic>
        <TranslatedText>Enroll</TranslatedText>
        <TranslatedText xml:lang="en-
US">Enroll</TranslatedText>
    </pf:Mnemonic>
</StudyEventDef>
<StudyEventDef OID="vstBASE" Name="vstBASE" Repeating="No"
Type="Scheduled" Category="PatientVisit" pf:DBUID="9718" pf:GUID="{DE604FC0-
5B13-4FCF-B63B-51EB0C16222F}" pf:Revision="469037483239001"
pf:UUID="03B0D5D8-7F2C-11D2-A728-00A0C977C64B" pf:VisitStartHours="0">

    <FormRef FormOID="frmDOV" OrderNumber="1" Mandatory="No"
/>
    <FormRef FormOID="frmPI" OrderNumber="2" Mandatory="No" />
    <FormRef FormOID="frmDem" OrderNumber="3" Mandatory="No"
/>
    <FormRef FormOID="MEDHIST" OrderNumber="4" Mandatory="No"
/>
    <FormRef FormOID="frmINCEXC" OrderNumber="5"
Mandatory="No" />
    <pf:Mnemonic>
        <TranslatedText>Base</TranslatedText>
        <TranslatedText xml:lang="en-
US">Base</TranslatedText>
    </pf:Mnemonic>
</StudyEventDef>
<!--other StudyEventDef entries omitted from example-->
<FormDef OID="LAE1" Name="LAE1" Repeating="Yes"
pf:DBUID="8983" pf:GUID="{99E452E7-3245-4D05-8C96-10DDE7E4AC64}"
pf:Revision="469037400214001">
    <ItemGroupRef ItemGroupOID="LAE1.LAE1" OrderNumber="1"
Mandatory="No" />
    <pf:Mnemonic>
        <TranslatedText>AE</TranslatedText>
        <TranslatedText xml:lang="en-US">AE</TranslatedText>
    </pf:Mnemonic>
</FormDef>
<FormDef OID="L_ConMeds" Name="L_ConMeds" Repeating="Yes"
pf:DBUID="9632" pf:GUID="{84C4994C-6150-4BCE-871F-0EA8463B9EC0}"
pf:Revision="469037467611001">
    <ItemGroupRef ItemGroupOID="L_ConMeds.L_ConMeds"
OrderNumber="1" Mandatory="No" />
    <pf:Mnemonic>
        <TranslatedText>CM</TranslatedText>
        <TranslatedText xml:lang="en-US">CM</TranslatedText>
    </pf:Mnemonic>
</FormDef>
<FormDef OID="MEDHIST" Name="MEDHIST" Repeating="No"
pf:DBUID="8550" pf:GUID="{B004EB9E-7CE5-4E87-A7A6-AFD34C017A88}"
pf:Revision="469037440605001">
    <ItemGroupRef ItemGroupOID="MEDHIST.MEDHIST"
OrderNumber="1" Mandatory="No" />
    <pf:Mnemonic>
        <TranslatedText>MHx</TranslatedText>
        <TranslatedText xml:lang="en-US">MHx</TranslatedText>
    </pf:Mnemonic>
</FormDef>
<!--other FormDef entries omitted from example-->
<ItemGroupDef OID="frmCGI.sctImprovement"
Name="sctImprovement" Repeating="No" pf:DBUID="7320" pf:GUID="{0C2EC8F6-E634-
45A9-B73F-5F5EEB2DFCD3}" pf:Revision="469037390572001">
    <ItemRef
ItemOID="frmCGI.sctImprovement.Subjectdescribefeeeling.Subjectdescribefeeeling"
OrderNumber="1" Mandatory="Yes" />
    <pf:InFormItemRef
InFormItemOID="frmCGI.sctImprovement.Subjectdescribefeeeling" OrderNumber="1"

```

```

Mandatory="Yes" />
    </ItemGroupDef>
    <ItemGroupDef OID="frmCGI.sctSeverity" Name="sctSeverity"
Repeating="No" pf:DBUID="7271" pf:GUID="{7B408A91-C0FA-48C1-8CFA-
9F848F641D1F}" pf:Revision="469037389510001">
        <ItemRef
ItemOID="frmCGI.sctSeverity.Investigatordepressionopinion.Investigatordepress
ionopinion" OrderNumber="1" Mandatory="Yes" />
        <pf:InFormItemRef
InFormItemOID="frmCGI.sctSeverity.Investigatordepressionopinion"
OrderNumber="1" Mandatory="Yes" />
    </ItemGroupDef>
    <ItemGroupDef OID="frmDem.sctDemographics"
Name="sctDemographics" Repeating="No" pf:DBUID="7930" pf:GUID="{D342749D-
35FD-4868-A09D-26BB0FCB4B4E}" pf:Revision="449057806440086">
        <ItemRef ItemOID="frmDem.sctDemographics.Gender.Gender"
OrderNumber="1" Mandatory="Yes" />
        <ItemRef
ItemOID="frmDem.sctDemographics.DateofBirth_DEM.DateofBirth_DEM"
OrderNumber="2" Mandatory="Yes" />
        <ItemRef ItemOID="frmDem.sctDemographics.Race.Race"
OrderNumber="3" Mandatory="Yes" />
        <ItemRef
ItemOID="frmDem.sctDemographics.ScreeningDate_DEM.ScreeningDate_DEM"
OrderNumber="4" Mandatory="Yes" />
        <ItemRef ItemOID="frmDem.sctDemographics.Height.Height"
OrderNumber="5" Mandatory="Yes" />
        <pf:InFormItemRef
InFormItemOID="frmDem.sctDemographics.Gender" OrderNumber="1" Mandatory="Yes"
/>
        <pf:InFormItemRef
InFormItemOID="frmDem.sctDemographics.DateofBirth_DEM" OrderNumber="2"
Mandatory="Yes" />
        <pf:InFormItemRef
InFormItemOID="frmDem.sctDemographics.Race" OrderNumber="3" Mandatory="Yes"
/>
        <pf:InFormItemRef
InFormItemOID="frmDem.sctDemographics.ScreeningDate_DEM" OrderNumber="4"
Mandatory="Yes" />
        <pf:InFormItemRef
InFormItemOID="frmDem.sctDemographics.Height" OrderNumber="5" Mandatory="Yes"
/>
    </ItemGroupDef>
    <!--other ItemGroupDef entries omitted from example-->
    <ItemDef OID="LAE1.LAE1.AEHiddenE.AEHiddenE"
Name="AEHiddenE" DataType="text" Length="128" pf:DBUID="8654"
pf:GUID="{63244987-07A9-4E19-92C4-8ED3358CF727}"
pf:Revision="469037390967001" pf:ItemDefType="Text">
        <Question>
            <TranslatedText>AEHiddenE</TranslatedText>
            <TranslatedText xml:lang="en-
US">AEHiddenE</TranslatedText>
        </Question>
    </ItemDef>
    <ItemDef OID="LAE1.LAE1.AEHiddenJ.AEHiddenJ"
Name="AEHiddenJ" DataType="text" Length="128" pf:DBUID="8649"
pf:GUID="{D21DCD18-7851-460C-A01B-3F7DA89080D9}"
pf:Revision="469037390843001" pf:ItemDefType="Text">
        <Question>
            <TranslatedText>AEHiddenJ</TranslatedText>
            <TranslatedText xml:lang="en-
US">AEHiddenJ</TranslatedText>
        </Question>
    </ItemDef>
    <ItemDef OID="LAE1.LAE1.AESeqNo.AESeqNo" Name="AESeqNo"
DataType="integer" Length="10" pf:DBUID="8977" pf:GUID="{1A5EAF7-F67E-40FE-
9658-B428A7BA192F}" pf:Revision="469037400021001" pf:ItemDefType="Text">
        <Question>
            <TranslatedText>Sequence Number</TranslatedText>
            <TranslatedText xml:lang="en-US">Sequence
Number</TranslatedText>

```

```

        </Question>
    </ItemDef>
    <!--other ItemDef entries omitted from sample-->
    <CodeList
OID="frmECG.sctChangefromBaselineElectrocardiogram.ChangefromBase.ChangefromB
ase.Changespecify" Name="Changespecify" DataType="text">
        <CodeListItem CodedValue="2"
pf:SelectionOID="frmECG.sctChangefromBaselineElectrocardiogram.ChangefromBase
.ChangefromBase.Changespecify.2">
            <Decode>
                <TranslatedText>Abnormal, not clinically
significant</TranslatedText>
                <TranslatedText xml:lang="en-US">Abnormal, not
clinically significant</TranslatedText>
                <TranslatedText xml:lang="ja-JP">異常
臨床的に深刻ではない。</TranslatedText>
            </Decode>
        </CodeListItem>
        <CodeListItem CodedValue="3"
pf:SelectionOID="frmECG.sctChangefromBaselineElectrocardiogram.ChangefromBase
.ChangefromBase.Changespecify.3">
            <Decode>
                <TranslatedText>Abnormal, clinically significant;
please comment:</TranslatedText>
                <TranslatedText xml:lang="en-US">Abnormal,
clinically significant; please comment:</TranslatedText>
                <TranslatedText xml:lang="ja-JP">異常
臨床的に深刻である。コメントを入力して下さい。</TranslatedText>
            </Decode>
        </CodeListItem>
        <CodeListItem CodedValue="">
            <Decode>
                <TranslatedText />
            </Decode>
        </CodeListItem>
    </CodeList>
    <!--other CodeList entries omitted from sample-->
    <pf:InFormItemDef OID="LAE1.LAE1.EventDiagnosis"
Name="EventDiagnosis" SVRequired="Yes" SVCritical="No" pf:DBUID="8971"
pf:GUID="{CC36A649-6374-4787-8E15-09ABC10719E4}"
pf:Revision="469037399889001">
        <ItemRef ItemOID="LAE1.LAE1.EventDiagnosis.EventDiagnosis"
OrderNumber="2" Mandatory="Yes" />
    </pf:InFormItemDef>
    <pf:InFormItemDef OID="LAE1.LAE1.EventDiagnosisJ"
Name="EventDiagnosisJ" SVCritical="No" pf:DBUID="8965" pf:GUID="{8619A337-
B3A3-450D-990A-7446FA2DB9D6}" pf:Revision="469037399763001">
        <ItemRef
ItemOID="LAE1.LAE1.EventDiagnosisJ.EventDiagnosisJ" OrderNumber="3"
Mandatory="No" />
    </pf:InFormItemDef>
    <pf:InFormItemDef OID="LAE1.LAE1.Modifiedterm"
Name="Modifiedterm" SVCritical="No" pf:DBUID="8960" pf:GUID="{79F65302-7CCB-
469D-B3CA-80F26E91E24B}" pf:Revision="469037399650001">
        <ItemRef ItemOID="LAE1.LAE1.Modifiedterm.Modifiedterm"
OrderNumber="4" Mandatory="No" />
    </pf:InFormItemDef>
    <pf:InFormItemDef OID="LAE1.LAE1.MedDRA" Name="MedDRA"
SVCritical="No" pf:DBUID="8955" pf:GUID="{0B62512C-72BA-4609-9D60-
C9D2AE4BF6B8}" pf:Revision="469037399529001">
        <ItemRef ItemOID="LAE1.LAE1.MedDRA.MedDRA" OrderNumber="5"
Mandatory="No" />
    </pf:InFormItemDef>
    <!--other pf:InFormItemDef entries omitted from example-->
    </MetaDataVersion>
    <pf:ReviewState pf:DBUID="13906" RefName="DataReview1"
StateValue="1" Revision="1">
        <pf:ReviewStage RefName="DataReview1.ReviewStage1"
StageValue="0" Activated="1" Revision="1">
            <pf:Name>

```

```

        <TranslatedText xml:lang="en-US">Needs
Review</TranslatedText>
        <TranslatedText xml:lang="ja-
JP">要レビュー</TranslatedText>
        </pf:Name>
        <pf:Mnemonic>
        <TranslatedText xml:lang="en-US">RS1</TranslatedText>
        <TranslatedText xml:lang="ja-
JP">レビューS1</TranslatedText>
        </pf:Mnemonic>
        </pf:ReviewStage>
        <pf:ReviewStage RefName="DataReview1.ReviewStage2"
StageValue="1" Activated="1" Revision="1">
        <pf:Name>
        <TranslatedText xml:lang="en-
US">Pending</TranslatedText>
        <TranslatedText xml:lang="ja-JP">保留</TranslatedText>
        </pf:Name>
        <pf:Mnemonic>
        <TranslatedText xml:lang="en-US">RS2</TranslatedText>
        <TranslatedText xml:lang="ja-
JP">レビューS2</TranslatedText>
        </pf:Mnemonic>
        </pf:ReviewStage>
        <pf:ReviewStage RefName="DataReview1.ReviewStage3"
StageValue="2" Activated="1" Revision="1">
        <pf:Name>
        <TranslatedText xml:lang="en-
US">Reviewed</TranslatedText>
        <TranslatedText xml:lang="ja-
JP">レビュー済</TranslatedText>
        </pf:Name>
        <pf:Mnemonic>
        <TranslatedText xml:lang="en-US">RS3</TranslatedText>
        <TranslatedText xml:lang="ja-
JP">レビューS3</TranslatedText>
        </pf:Mnemonic>
        </pf:ReviewStage>
        <pf:Name>
        <TranslatedText xml:lang="en-US">Data
Review</TranslatedText>
        <TranslatedText xml:lang="ja-
JP">データレビュー</TranslatedText>
        </pf:Name>
        <pf:Mnemonic>
        <TranslatedText xml:lang="en-US">R1</TranslatedText>
        <TranslatedText xml:lang="ja-JP">レビュー1</TranslatedText>
        </pf:Mnemonic>
        </pf:ReviewState>
        <pf:SubjectPool PoolNumber="0" PoolRefName="Eligible" />
        <pf:SubjectPool PoolNumber="1" PoolRefName="AutoSelect" />
        <pf:SubjectPool PoolNumber="2" PoolRefName="ManualFirstN" />
        <pf:SubjectPool PoolNumber="3" PoolRefName="ManualUISelect" />
        <pf:SubjectPool PoolNumber="4" PoolRefName="ManualImport" />
        <pf:SubjectPool PoolNumber="99" PoolRefName="Excluded" />
        </Study>
    </ODM>
</ResponseODM>
</DownloadMetadataODMResult>

```

Transactional data—DownladAdminDataODM response

```

<ResponseODM
xmlns:pf="http://www.phaseforward.com/InFormAdapter/ODM/Extensions/2.0"
xmlns="http://www.phaseforward.com/InFormAdapter/ODM/2.0">
    <ODM Description="StudyDesign" FileType="Transactional"
FileOID="StudyDesign/062d51cd-0084-4e3e-982b-6ecf6a4c9c80"

```

```

CreationDateTime="2011-10-17T19:31:11+00:00" ODMVersion="1.3"
Originator="" pf:MappingVersion="V2" pf:HierarchicalOIDs="Yes"
pf:InFormAdapterVersion="1.0.4302.18717"
xmlns="http://www.cdisc.org/ns/odm/v1.3">
  <AdminData>
    <User OID="system" UserType="Other" pf:DBUID="1" pf:GUID="System
    User" pf:StudyLocale="en-US">
      <!--Additional Users à
      <Location OID="13341" Name="(01) Massachusetts General Hospital"
      LocationType="Site" pf:SiteCountry="USA" pf:SiteTimezone="Eastern
      Standard Time" pf:GUID="{1120443F-38BA-42CE-97C0-8EA3E1399336}"
      pf:Revision="326047546003022" pf:Locale="en-US"
      pf:SVAutoSelectRate="10" pf:SVFirstNSubjects="1">
        <!--Additional Locations -->
      <SignatureDef OID="13830" Methodology="Electronic"
      pf:GroupName="Investigator Sigs">
        <!--Additional SignatureDef-->
      <pf:GroupDef OID="13830" Name="Investigator Sigs" GroupType="Signature"
      />
    </User>
  </AdminData>
</ODM>
<Status>END</Status>
<UserBookmark>13298</UserBookmark>
</ResponseODM>

```

GetSiteList example response

```

<CRFSUBMIT>
  <SITELIST>
    <SITEINFO SITEID="54312" SITENAME="Marlboro Hospital"
    ITEMNEMONIC="MARL" SITEGUID="{C769A488-9AF4-4303-802C-C0147AE58396}"
    LANGUAGECODE="en-US" />
    <SITEINFO SITEID="7628" SITENAME="McLean Hospital"
    ITEMNEMONIC="MCLEAN" SITEGUID="{C966597A-B965-413F-A3B4-7F38449CC23B}"
    LANGUAGECODE="en-US" />
    <SITEINFO SITEID="7660" SITENAME="Mass General Hospital"
    ITEMNEMONIC="MGH" SITEGUID="{7C9EAD34-BAD3-4E80-BEA9-BAC29E055D08}"
    LANGUAGECODE="en-US" />
    <SITEINFO SITEID="7600" SITENAME="PhaseForward" ITEMNEMONIC="PF"
    SITEGUID="{3C07AF5F-E07F-471A-8F7C-AB120A48C1BB}" LANGUAGECODE="en-US" />
    <SITEINFO SITEID="7644" SITENAME="Veterans Administration Hospital"
    ITEMNEMONIC="VA" SITEGUID="{867835F8-3F2A-4D9D-81D0-2673703A0999}"
    LANGUAGECODE="en-US" />
  </SITELIST>
</CRFSUBMIT>

```

GetPatientList example response

```

<CRFSUBMIT>
  <PATIENTLIST SITEID="8853">
    <PATIENT PATIENTID="11007" PATIENTREVISIONNUMBER="133790109391081"
    SITEID="8853"
      INITIALS="LMM" ENROLLMENTNUMBER="222" SCREENINGNUMBER="SCR-PF-1"
      CRBLOCKED="false" CRBFROZEN="false" PATIENTINDEX="1"
      ARCHIVED="false"/>
    <PATIENT PATIENTID="11015" PATIENTREVISIONNUMBER="133790109391081"
    SITEID="8853"
      INITIALS="JMD" ENROLLMENTNUMBER="224" SCREENINGNUMBER="SCR-PF-2"
      CRBLOCKED "false" CRBFROZEN="false" PATIENTINDEX="1"
      ARCHIVED="false"/>
  </PATIENTLIST>
</CRFSUBMIT>

```

GetPatientForms example response

```
<PATIENTVISITCRFLIST PATIENTID="10769" INITIALS="AAA" PATIENTNO="222" xmlns="">
  <FORMSETLIST>
    <FORMSET FORMSETID="8982" FORMSETMNEMONIC="Base" FORMSETNAME="Baseline"
      FORMSETREFNAME="vstBASE" FORMSETREVISION="133429397696064"
      FORMSETREPEATING="false" FORMSETINDEX="1">
      <FORMLIST>
        <FORM FORMID="6691" FORMMNEMONIC="DOV" FORMNAME="DATE OF VISIT"
          FORMREFNAME="frmDOV" FORMREVISION="133369290882048"
          FORMTYPE="1" FORMSTARTED="true" FORMVERSIONDATE="24-Mar-2005
            15:01"
          FORMHASAUDITTRAIL="true" />
        <FORM FORMID="7591" FORMMNEMONIC="PI" FORMNAME="PATIENT INFORMATION"
          FORMREFNAME="frmPI" FORMREVISION="133369321820048" FORMTYPE="1"
          FORMSTARTED="true" FORMVERSIONDATE="24-Mar-2005 15:02"
          FORMHASAUDITTRAIL="true" />
      </FORMLIST>
    </FORMSET>
    <FORMSET FORMSETID="8985" FORMSETMNEMONIC="Wk 1" FORMSETNAME="Core Week 1"
      FORMSETREFNAME="vstCORE1" FORMSETREVISION="133429397696064"
      FORMSETREPEATING="false" FORMSETINDEX="1">
      <FORMLIST>
        <FORM FORMID="6691" FORMMNEMONIC="DOV" FORMNAME="DATE OF VISIT"
          FORMREFNAME="frmDOV" FORMREVISION="133369290882048"
          FORMTYPE="1" FORMSTARTED="false" FORMVERSIONDATE="24-Mar-2005
            15:01"
          FORMHASAUDITTRAIL="false" />
        <FORM FORMID="7858" FORMMNEMONIC="VS" FORMNAME="VITAL SIGNS"
          FORMREFNAME="frmVS" FORMREVISION="133369332226048"
          FORMTYPE="1" FORMSTARTED="false" FORMVERSIONDATE="24-Mar-2005
            15:02"
          FORMHASAUDITTRAIL="false" />
      </FORMLIST>
    </FORMSET>
  </FORMSETLIST>
</PATIENTVISITLIST>
```

GetTransactions example response

For another example of a GetTransactions request and response, see the ODM Export sample XML files that are provided with the product release.

Example returning clinical data

```
<GetTransactionsResult
  xmlns="http://www.phaseforward.com/InFormAdapter/ODM/1.0">
  <ResponseODM
    xmlns:pf="http://www.phaseforward.com/InFormAdapter/ODM/Extensions/2.0"
    xmlns="http://www.phaseforward.com/InFormAdapter/ODM/2.0">
    <ODM Description="StudyDesign" FileType="Transactional"
      FileOID="{DD36F77C-D15B-4CC6-905E-C3FE13028A76}" CreationDateTime="2010-
        12-13T20:38:11+00:00" PriorFileOID="{CB219A42-F227-43D8-93F7-
        DF91AED86EC2}" ODMVersion="1.3" Originator="system"
      pf:MappingVersion="V2" pf:HierarchicalOIDs="Yes"
      pf:InFormAdapterVersion="1.0.3999.27031"
      xmlns="http://www.cdisc.org/ns/odm/v1.3">
      <ClinicalData StudyOID="StudyDesign" MetaDataVersionOID="Study Design
        1.0.0" pf:TransactionGuid="{AB7C93A6-C5F2-49D0-9282-C42A82ED5E14}"
        pf:Revision="253647973055083.000">
        <SubjectData SubjectKey="14440" TransactionType="Upsert"
          pf:GUID="{44C8BF9B-C32B-4C92-9B4C-51A3C8A72D84}">
          <SiteRef LocationOID="12121" />
        </SubjectData>
      </ClinicalData>
    </ODM>
  </ResponseODM>
</GetTransactionsResult>
```

```

<StudyEventData StudyEventOID="vstCORE8">
  <AuditRecord>
    <UserRef UserOID="mmeyer" />
    <LocationRef LocationOID="Unknown" />
    <DateTimeStamp>2009-01-14T22:46:13+00:00</DateTimeStamp>
    <ReasonForChange>Visit Started</ReasonForChange>
  </AuditRecord>
  <FormData FormOID="frmDOV">
    <ItemGroupData ItemGroupOID="frmDOV.sctVisitDateandTime">
      <ItemData
        ItemOID="frmDOV.sctVisitDateandTime.DateandTimeofVisit_DOV.DateandTimeofVisit_DOV" Value="2007-09-11T12:25:--+00:00"
        pf:FormattedDateValue="2007-09-11T12:25:NUL+00:00">
        <AuditRecord>
          <UserRef UserOID="mmeyer" />
          <LocationRef LocationOID="12121" />
          <DateTimeStamp>2009-01-14T22:46:13+00:00</DateTimeStamp>
          <ReasonForChange>Initial Entry</ReasonForChange>
          <SourceID>rdinformq079</SourceID>
        </AuditRecord>
      </ItemData>
    </ItemGroupData>
  </FormData>
</StudyEventData>
</SubjectData>
</ClinicalData>
</ODM>
<Status>END</Status>
<Bookmark>{DD36F77C-D15B-4CC6-905E-C3FE13028A76}</Bookmark>
<TransactionsProcessed>28</TransactionsProcessed>
</ResponseODM>
</GetTransactionsResult>

```

Example returning no clinical data

```

<GetTransactionsResult
  xmlns="http://www.phaseforward.com/InFormAdapter/ODM/1.0">
  <ResponseODM
    xmlns:pf="http://www.phaseforward.com/InFormAdapter/ODM/Extensions/2.0"
    xmlns="http://www.phaseforward.com/InFormAdapter/ODM/2.0">
    <ODM Description="Depression Study" FileType="Transactional"
      FileOID="{2CBDCC47-3557-463E-8FB1-0614B0DFFAF5}" CreationDateTime="2008-11-11T18:58:54+00:00" PriorFileOID="Depression Study/2f887d08-33f2-4e8f-9ff0-4c08c4ae188b" ODMVersion="1.3" Originator="system"
      pf:MappingVersion="V2" pf:HierarchicalOIDs="Yes"
      pf:InFormAdapterVersion="1.0.3235.41590"
      xmlns="http://www.cdisc.org/ns/odm/v1.3" />
    <Bookmark>{2CBDCC47-3557-463E-8FB1-0614B0DFFAF5}</Bookmark>
    <TransactionsProcessed>1000</TransactionsProcessed>
  </ResponseODM>
</GetTransactionsResult>

```

GetTransactionStatus example response

```

<GetTransactionStatusResult
  xmlns="http://www.phaseforward.com/InFormAdapter/ODM/1.0">
  <TransactionStatus xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
    xmlns:xsd="http://www.w3.org/2001/XMLSchema"
    xmlns="http://www.phaseforward.com/InFormAdapter/ODM/2.0">
    <TotalTransactionCount>5804</TotalTransactionCount>
    <TransactionXmlCount>5804</TransactionXmlCount>
    <TransactionXmlRemaining>5804</TransactionXmlRemaining>
    <LastTransactionXmlTime>2010-10-29T13:41:26+00:00</LastTransactionXmlTime>
  </TransactionStatus>
</GetTransactionStatusResult>

```

</TransactionStatus>

Oracle ODM extensions

- *Candidate element* (on page 77)
- *CriticalForm element* (on page 79)
- *FormattedDate Value* (on page 81)
- *FormStatus element* (on page 81)
- *GroupDef element* (on page 83)
- *Right element* (on page 83)
- *GroupRef element* (on page 84)
- *InFormItemData element* (on page 84)
- *InFormItemDef element* (on page 85)
- *InFormItemRef element* (on page 86)
- *ItemStatus element* (on page 86)
- *Query element* (on page 87)
- *QueryStatus element* (on page 88)
- *ReasonIncomplete element* (on page 88)
- *ReviewState element* (on page 89)
- *ReviewStage element* (on page 89)
- *SubjectPool element* (on page 90)
- *SubjectPoolChange element* (on page 91)
- *SubjectStatus element* (on page 92)
- ProductLocale

Candidate element

The Candidate element is returned when a screening or enrollment action is performed in the InForm application.

XPath

ODM/ClinicalData/SubjectData/pf:Candidate

Parent element	Child elements
SubjectData	DOB. ScreeningDate.

Attributes

Attributes/children: Candidate	Description
--------------------------------	-------------

Attributes/children: Candidate	Description
DOB	Date of birth of the candidate. type=TypeDATE.
ScreeningDate	type=TypeDATE.
PatientGuid	The GUID of the candidate. type=TypeGUID. Required.
Revision	The revision number of the subject type=TypeREVISION. Required.
SiteGUIDREF	The GUID of the site. type=TypeGUID. Required.
Initials	The initials of the subject type=TypeINITIALS. Required.
State	The state of the subject. type=TypePatientSTATE. Optional.
ScreeningNumber	The candidate's screening number. type=xs:String. Required.
EnrollmentNumber	The subject's enrollment number. type=TypeENROLLMENTNUMBER. Required.
ScreeningFailure	The reason for screening failure. type=xs:string. Required.
EnrollmentFailure	The reason for enrollment failure. type=xs:string. Required.
EnrollmentOverride	The reason that the enrollment failure was overridden. type=xs:string. Required.

Attributes/children: Candidate	Description
PatientNumberRevision	The revision number of the patient number. type=TypeREVISION. Optional.

CriticalForm element

The CriticalForm element is returned in any of the following situations:

- In the user interface, a form is selected as a critical form.
- In the user interface, a form that was previously selected as critical is deselected (marked as not critical).
- The form is cooked in with MedML that selects the form as critical.

Forms that have never been selected as critical do not appear.

XPath

ODM/ClinicalData/SubjectData/pf:CriticalForm

Parent element	Child elements
SubjectData	None.

Attributes

Attributes/children: CriticalForm	Description
FormRef	Identifies the form. For more information, see <i>FormRef</i> (on page 115).
LocationOID	The OID of the site. If the site is missing in the InForm application, LocationOID has an empty string ("").
IsCritical	A flag that indicates whether the form is critical type=xs:string. Values: 0—Not critical. 1—Critical. Required.

Example—Criticalform

This example of ODM transactional output indicates that for site 54312, frmDose is set to the critical form while frmDOV is set to non-critical form.

```
<ODM
xmlns:pf="http://PhaseForward.com/InFormAdapter/ODM/PhaseForward_ODM.xsd"
Description="Depression Study" FileType="Transactional" FileOID="**IGNORED**"
CreationDateTime="**IGNORED**" PriorFileOID="{82A6D9DC-2058-43BE-A640-
7FCD9E6C86F8}" ODMVersion="1.2" Originator="system" pf:MappingVersion="V1"
pf:HierarchicalOIDs="No" pf:InFormAdapterVersion="**IGNORED**"
xmlns="http://www.cdisc.org/ns/odm/v1.2">
  <ClinicalData StudyOID="Depression Study" MetaDataVersionOID="Study
    Version 1.0" pf:TransactionGuid="{E30DBE60-CCB2-40AA-9A3F-BA7373712C49}">
    <pf:CriticalForm FormRef="frmDose" LocationOID="54312" IsCritical="1">
    <pf:CriticalForm FormRef="frmDOV" LocationOID="54312" IsCritical="0">
      </ClinicalData>
    </ODM>
```

CriticalItems

Attributes	Value/Map to InForm
CriticalItems	Includes a separate <i>CriticalItem</i> element for each item-level change that occurs in the InForm application. For more information, see <i>CriticalItem</i> (on page 80).

CriticalItem

Attributes	Value/Map to InForm
------------	---------------------

Attributes	Value/Map to InForm
CriticalItem	Include a separate CriticalItem element for each item-level change that occurs in the InForm application. Attributes: • ItemRefName—Item name. • FormOID—Form name. If blank, applies to all forms that include this item. • LocationOID—Site location. • Critical—Indicates that one of the following override options applies to an item: ▪ True—Item is critical on the form(s) specified by the FormOID. ▪ False—Item is not critical on the form(s) specified by the FormOID. ▪ StudyDefault—Item has a study default value on the form(s) that is specified by the FormOID. • ItemRevision—Item revision number.

FormattedDateValue

The FormattedDateValue element returns data that differentiates between null and unknown date values in the 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* (on page 147).

FormStatus element

The FormStatus element refers to the state of a form in the 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

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

Parent element	Child element
FormData	odm:AuditRecord.

Attributes

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.

Attribute	Description
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."

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 elements
AdminData	pf:Right .

Attributes

Attributes: GroupDef	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.

Attributes

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

GroupRef element

One GroupRef child element exists for each group to which the user belongs. Each GroupRef contains a GroupOID element. GroupRef elements reference GroupDef elements by matching the GroupRef's GroupOID attribute to the GroupDef's OID attribute.

Xpath

ODM/AdminData/User/pf:GroupRef

Parent element	Child elements
User	None.

Attributes

Attributes: GroupRef	Description
GroupOID	The identifier of the group. type=odm:oid. Required.

InFormItemData element

The InFormItemData element represents an item in the InForm software.

In the Oracle implementation of ODM, an ItemData maps to an InForm control (not to an InForm item).

Any time that an Oracle extension that applies to an InForm item (as opposed to a control) is used, the extension is attached to an InFormItemData.

XPath

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

Parent element	Child elements
ItemGroupData	<i>Query</i> (on page 87). <i>ItemStatus</i> (on page 86).

Attributes

Attributes: InFormItemData	Description
InFormItemOID	The identifier of the data item. type=odm:oid. Required.
Name	The item RefName. type=string. Required.

InFormItemDef element

The InFormItemDef element is the metadata definition for the 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.

Attributes

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.

Attribute	Description
GUID	Visit identifier.
Revision	Revision.
UUID	UUID.

InFormItemRef element

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

XPath

ODM/Study/MetaDataVersion/ItemGroupDef/pf:InFormItemRef

Parent element	Child element
ItemGroupDef	None.

Attributes

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

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:	odm:AuditRecord.
- InFormItemData (if the item has been source verified). - ItemGroupData (if the itemset has been deleted).	

Attributes

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 InForm software.

XPath

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

Parent element	Child element
<i>InFormItemData</i> (on page 84).	<i>QueryStatus</i> (on page 88).

Attributes

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

Attributes	Description
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.

Attributes

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 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.

ReviewState element

The ReviewState element is returned to represent the state and stage of the progress of data review in the InForm application.

Up to five form-level customizable states are permitted to provide flexibility in tracking the progress of reviews.

XPath

ODM/ClinicalData/SubjectData/pf:ReviewState

Parent element	Child elements
SubjectData	<i>pf:ReviewStage</i> (on page 89). Each pf:ReviewState element must have three pf:ReviewStage elements.

Attributes

Attributes/children: ReviewState	Description
pf:DBUID	dbuid.
RefName	Review state ref name.
StateValue	State value. A number from 1 through 5.
Revision	Revision number. For more information, see <i>Revision, DBUID, and GUID attributes</i> . (on page 95)
Name element	Child element: <i>TranslatedText</i> (on page 113).
Mnemonic element	Child element <i>Mnemonic</i> (on page 115).

ReviewStage element

The pf:ReviewStage element represents the review stage for the specific review state.

Each pf:ReviewState element must have three pf:ReviewStage elements. The review state is in one of the three stages at any time. The first stage is the default stage for a defined review state before any reviewer assigns any other review stage.

XPath

ODM/ClinicalData/SubjectData/pf:ReviewState/pf:ReviewStage

Parent element	Child elements
pf:ReviewState	None.

Attributes

Attributes: ReviewStage	Description
RefName	Stage ref name.
StageValue	Stage value.
Activated	0 or 1.
Revision	Revision number.

SubjectPool element

The SubjectPool element is returned to represent the source verification pool in the InForm application.

XPath

ODM/ClinicalData/SubjectData/pf:SubjectPool

Parent element	Child elements
SubjectData	PoolNumber. PoolRefName.

Attributes

Attributes/children: SubjectPool	Description
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

Attributes/children: SubjectPool	Description
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.

SubjectPoolChange element

The SubjectPoolChange element is returned to represent the changes in the subject pool in the InForm application.

XPath

ODM/ClinicalData/SubjectData/pf:SubjectPoolChange

Parent element	Child elements
SubjectData	SubjectKey.

Attributes

Attributes: SubjectPoolChange	Description
LocationOID	The Site OID.

Attributes: SubjectPoolChange Description	
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
SubjectData	The subjects placed in the pool, identified by SubjectKey.

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.

Attribute	Description
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.

ProductLocale element

The ProductLocale element indicates the product locale of the InForm software. It is used to extract the InComplete Reasons code list. ProductLocale applies to studies that use InForm versions 5.5 and above.

XPath

ODM/AdminData/pf:ProductLocale

Parent element	Child elements
ProductLocaleList	None.

Attributes

Attribute: ProductLocale	Description
xml:lang	The language available in the study.

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
----------------------	------------------	------

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	InFormDataTime	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

Standard ODM element	Oracle attribute	Type
FormDef	Dynamic	odm:YesOrNo
StudyEventDef		
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

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

For more information, see the individual elements listed in *ODM Mapping* (on page 105).

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** (on page 146).
- **Location** (on page 128).
- **Query** (on page 151).
- **SubjectData** (on page 135).
- **MetaData Version** (on page 114).
- **User** (on page 125).
- **Site \ Location** (on page 128).

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* (on page 105).

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** (on page 122) and **CodeListItem** (on page 130).

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.
pf:SelectionOwner	For each ItemDef that is the child of a radio group selection, the OID of the CodeList that contains the codelist selection.

Oracle extension to ItemDef	Description
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.

Elements and extensions for subject pools

The *pf:SubjectPool element* (on page 90) represents a collection of subjects in the InForm application that were placed in the source verification pool by automated selection to represent a desired target source verification rate.

DownloadAdminDataODM returns the available pools, the rate of autoselection, first N subjects, and the subject added and/or removed from the pool.

For more information, see:

- *SubjectPool element* (on page 90).
- *SubjectPoolChange element* (on page 91).

Subject pool selection

The *Location element* (on page 128) includes the following attributes for pool selection:

- pf:SVAutoSelectRate
The value of pf:SVAutoSelectRate comes from a query that indicates the number of subjects that are automatically selected for the source verification pool.
Automatic selection is determined by settings made by the site administrator that specify a value for the percentage selection criteria. The percentage determines the rate of subjects that are automatically selected for source verification.
- pf:SVFirstNSubjects
The source verification pool is determined by defining the number of subjects to be included in the pool. The subjects are added to the pool until the defined number is reached.
The value of pf:SVFirstNSubjects comes from a query that indicates the number of subjects in the pool.

Changes in the subject pool

The ODM Export interface tracks changes to the subject pool.

pf:SubjectPoolChange (on page 91) represents the pool change and includes the subjects placed in the pool.

```
<pf:SubjectPoolChange LocationOID="Site OID" PoolNumber="Pool Number" >
  <SubjectData SubjectKey="subject key 1" />
  ...
  <SubjectData SubjectKey="subject key n" />
</pf:SubjectPoolChange>
```

If the site is missing in the InForm application, LocationOID has an empty string ("").

Example of pool change transaction in ODM output:

```
<ResponseODM
xmlns:pf="http://www.phaseforward.com/InFormAdapter/ODM/Extensions/2.0"
xmlns="http://www.phaseforward.com/InFormAdapter/ODM/2.0">
  <ODM Description="Depression Study" FileType="Transactional"
    FileOID="{AA4E2F2E-DA3E-460A-963F-66BEEAEC515F}" CreationDateTime="2009-
    06-01T17:17:26+00:00" PriorFileOID="{20D57F92-8A0A-4749-8272-
    337E48D2DFF0}" ODMVersion="1.3" Originator="system" pf:MappingVersion="V2"
    pf:HierarchicalOIDs="Yes" pf:InFormAdapterVersion="1.0.3439.20859"
    xmlns="http://www.cdisc.org/ns/odm/v1.3">
    <ClinicalData StudyOID="Depression Study" MetaDataVersionOID="Study
    Version 2.1" pf:TransactionGuid="{AA4E2F2E-DA3E-460A-963F-66BEEAEC515F}"
    pf:Revision="227455370337048.000">
      <pf:SubjectPoolChange LocationOID="54312" PoolNumber="1" >
        <SubjectData SubjectKey="JIMD" />
        <SubjectData SubjectKey="ABC" />
        <SubjectData SubjectKey="JS" />
      </pf:SubjectPoolChange>
    </ClinicalData>
  </ODM>
  <Bookmark>{AA4E2F2E-DA3E-460A-963F-66BEEAEC515F}</Bookmark>
  <TransactionsProcessed>1</TransactionsProcessed>
</ResponseODM>
```

Elements and extensions for review states and stages

The InForm 5.5 SP0 and later software release allows five customizable review states to allow flexibility in tracking review progress. Each review state is in one of its three customizable stages at any time.

- Each *pf:ReviewState* element must have three *pf:ReviewStage* elements.
- Each *pf:ReviewState element* (on page 89) contains three *pf:ReviewStage elements* (on page 89).
- The first stage is the default stage for a defined review state before any reviewer assigns other review stages.
- Review states and stages are defined in Central Designer and deployed into the InForm study with available product locales, and displayed in the Data Viewer in the user's product locale.
- Each review state can be defined at different times, but each state, including its three stages, must be completely defined at one time. A partially defined state is not allowed.
- Stage includes review stage name, mnemonic, refname, stage value, and revision number.

Rights for review states

DownloadAdminData ODM returns a *pf:GroupDef* (on page 83) for each group, with the definition of the group and a *pf:Right* element for each right assigned to the group.

For studies using the InForm 5.5 release and subsequent releases, the attribute *pf:Right* (on page 83) contains the following values for Description that pertain to review state and stage information for a subject form:

```
<pf:Right Description="Assign Review States"/>
<pf:Right Description="View Review States"/>
```

How review state and stage information is returned

To obtain complete review stage and state information, you issue several ODM Export methods:

- 1 DownloadAdminDataODM.

The method returns all the permissions that can be assigned in the study.

In the administrative data, each user has a group reference that list the GroupOID of the group to which the user is assigned. The *pf:GroupDef* that uses that OID lists the permissions for the group. The user has those permissions by virtue of being a member of that group.

- 2 DownloadMetadataODM.

The method returns metadata that includes the elements *pf:ReviewState* and *pf:ReviewStage*.

The following metadata excerpt shows a *pf:ReviewState* element with a *StateValue*="1", and one of its three *pf:ReviewStage* child elements. The *refname* for the review stage includes the review state *refname* and the review state *refname* "DataReview1.ReviewStage1".

```
<pf:ReviewState pf:DBUID="14216" RefName="DataReview1" StateValue="1"
Revision="335876530226035">
  <pf:ReviewStage RefName="DataReview1.ReviewStage1" StageValue="0"
Activated="1" Revision="335876530226035">
    <!--other pf:ReviewStage elements omitted from example -->
```

- 3 GetTransactions.

For each form in the InForm application in which the review state and/or stage has been updated, the transaction XML that is returned indicates the review state and stage for each form.

The review state and review stage are each returned as a number; for example, *ReviewState*="1" *ReviewStage*="0".

For example:

```
<pf:FormStatus ReviewStageRefName="DataReview5.ReviewStage51"
ReviewState="1" ReviewStage="0" ReviewStateRevision="335876536304035">
  .
  .
  .
</pf:FormStatus>
```

See the *Example* (on page 99).

- 4 Compare the transactional output and the metadata output to determine the review state and stage of the form. For example, the *pf:FormStatus* element (in Step 3) has *ReviewState*="1" and *ReviewStage*="0." The corresponding metadata (in Step 2) shows the *RefName* of the form as "DataReview1.ReviewStage1."

Example—review state and stage information in administrative data,

metadata, and transaction output

In this example,

- DownloadAdminDataODM returns information about the groups to which the user mlynch is a member, and information about the group.
- DownloadMetadataODM returns information about the states and stages that are defined.
- GetTransactions returns information about changes to the status of a form.

DownloadAdminDataODM

In the administrative data, each user has a group reference which points at pf:GroupDef. pf:GroupDef defines the permissions.

The XML data that is returned indicates that user belongs to three groups. pf:GroupRef

```
<User OID="mlynch" UserType="Sponsor" pf:DBUID="12801" pf:GUID="{C651EA0D-B3A3-4DFE-B7E4-22B132D5FAAB}" pf:StudyLocale="en-US">
  <LoginName>mlynch</LoginName>
  <DisplayName>Melissa Lynch</DisplayName>
  <FullName>Melissa Lynch</FullName>
  <FirstName>Melissa</FirstName>
  <LastName>Lynch</LastName>
  <Address>
  <Country>USA</Country>
</Address>
  <Email>email@domain.test</Email>
  <Fax>(555) 555-1212</Fax>
  <Phone>(555) 555-1212</Phone>
  <LocationRef LocationOID="13341" />
  <LocationRef LocationOID="13375" />
  <LocationRef LocationOID="13409" />
  <LocationRef LocationOID="13443" />
  <LocationRef LocationOID="13477" />
  <LocationRef LocationOID="13511" />
  <LocationRef LocationOID="13545" />
  <LocationRef LocationOID="13579" />
  <LocationRef LocationOID="13613" />
  <pf:GroupRef GroupOID="6528" />
  <pf:GroupRef GroupOID="13811" />
  <pf:GroupRef GroupOID="13959" />
</User>
```

The following XML indicates that group CRA with OID 13959 has the permissions to assign and view review state.

```
<pf:GroupDef OID="13959" Name="CRA" GroupType="Rights">
  <pf:Right Description="Print" />
  <pf:Right Description="Monitor" />
  <pf:Right Description="Reports" />
  <pf:Right Description="View CRF" />
  <pf:Right Description="View CRF Signature Information" />
  <pf:Right Description="View Case Book Signature Information" />
  <pf:Right Description="Data Export Listings" />
  <pf:Right Description="Freeze a CRF" />
  <pf:Right Description="Unfreeze a CRF" />
  <pf:Right Description="Mark and Unmark a CRF as SVed" />
  <pf:Right Description="Freeze a Case Book" />
  <pf:Right Description="Unfreeze a Case Book" />
  <pf:Right Description="Change Query State from Candidate to Open" />
  <pf:Right Description="Change Query State from Candidate to Deleted" />
  <pf:Right Description="Change Query State from Answered to Closed" />
  <pf:Right Description="Enter Query in Candidate State" />
  <pf:Right Description="Enter Query in Open State" />
  <pf:Right Description="Re-issue Query in Candidate State" />
  <pf:Right Description="Re-issue Query in Open State" />
</pf:GroupDef>
```

```

    <pf:Right Description="Reordering Of Patients" />
    <pf:Right Description="Change Query State from Open to Closed" />
    <pf:Right Description="Change Query State from Reissued Candidate to
    Closed" />
    <pf:Right Description="Assign Review States" />
    <pf:Right Description="View Review States" />
    <pf:Right Description="Change Site SV Settings" />
  </pf:GroupDef>

```

DownloadMetadataODM

The sample XML shows one review state and its stages

```

<pf:ReviewState pf:DBUID="14216" RefName="DataReview1" StateValue="1"
Revision="335876530226035">
  <pf:ReviewStage RefName="DataReview1.ReviewStage1" StageValue="0"
Activated="1" Revision="335876530226035">
    <pf:Name>
      <TranslatedText xml:lang="en-US">Needs Review-
      2ndRevision</TranslatedText>
      <TranslatedText xml:lang="ja-JP">????</TranslatedText>
    </pf:Name>
    <pf:Mnemonic>
      <TranslatedText xml:lang="en-US">RS1</TranslatedText>
      <TranslatedText xml:lang="ja-JP">???S1</TranslatedText>
    </pf:Mnemonic>
  </pf:ReviewStage>
  <pf:ReviewStage RefName="DataReview1.ReviewStage2" StageValue="1"
Activated="1" Revision="335876530226035">
    <pf:Name>
      <TranslatedText xml:lang="en-US">Pending-2ndRevision</TranslatedText>
      <TranslatedText xml:lang="ja-JP">??</TranslatedText>
    </pf:Name>
    <pf:Mnemonic>
      <TranslatedText xml:lang="en-US">RS2</TranslatedText>
      <TranslatedText xml:lang="ja-JP">???S2</TranslatedText>
    </pf:Mnemonic>
  </pf:ReviewStage>
  <pf:ReviewStage RefName="DataReview1.ReviewStage3" StageValue="2"
Activated="1" Revision="335876530226035">
    <pf:Name>
      <TranslatedText xml:lang="en-US">Reviewed-2ndRevision</TranslatedText>
      <TranslatedText xml:lang="ja-JP">????</TranslatedText>
    </pf:Name>
    <pf:Mnemonic>
      <TranslatedText xml:lang="en-US">RS3</TranslatedText>
      <TranslatedText xml:lang="ja-JP">???S3</TranslatedText>
    </pf:Mnemonic>
  </pf:ReviewStage>
  <pf:Name>
    <TranslatedText xml:lang="en-US">Data Review-2ndRevision</TranslatedText>
    <TranslatedText xml:lang="ja-JP">??????</TranslatedText>
  </pf:Name>
  <pf:Mnemonic>
    <TranslatedText xml:lang="en-US">R1</TranslatedText>
    <TranslatedText xml:lang="ja-JP">???1</TranslatedText>
  </pf:Mnemonic>
</pf:ReviewState>

```

GetTransactions

The sample XML shows the form status changes for a form.

```

<ResponseODM
xmlns:pf="http://www.phaseforward.com/InFormAdapter/ODM/Extensions/2.0"
xmlns="http://www.phaseforward.com/InFormAdapter/ODM/2.0">
  ODM Description="StudyDesign" FileType="Transactional" FileOID="{A18E6CE1-
11AB-4C6B-A4A8-63E31BD9025F}" CreationDateTime="2011-08-25T19:08:07+00:00"
PriorFileOID="{69262641-61FC-4FA3-AAE8-5D34B8AC8A4E}" ODMVersion="1.3"
Originator="system" pf:MappingVersion="V2" pf:HierarchicalOIDs="Yes"

```

```

pf:InFormAdapterVersion="1.0.4254.25287"
xmlns="http://www.cdisc.org/ns/odm/v1.3">
  <ClinicalData StudyOID="StudyDesign" MetaDataVersionOID="Study Design
0.0.2" pf:TransactionGuid="{A18E6CE1-11AB-4C6B-A4A8-63E31BD9025F}"
pf:Revision="335969315181037.000">
    <SubjectData SubjectKey="14336" TransactionType="Upsert"
pf:GUID="{EC5C716F-1AC3-49C0-88FE-A3AA33236EC1}">
      <SiteRef LocationOID="13341" />
      <StudyEventData StudyEventOID="vstCORE1">
        <FormData FormOID="frmDOV">
          <pf:FormStatus ReviewStageRefNchame="DataReview5.ReviewStage51"
ReviewState="5" ReviewStage="0"
ReviewStateRevision="335876536304035">
            <AuditRecord>
              <UserRef UserOID="lhill" />
              <LocationRef LocationOID="Unknown" />
              <DateTimeStamp>2011-08-25T17:48:35+00:00</DateTimeStamp>
              <!--The next line is the comment provided when the review state is
assigned to a subject form -->
              <ReasonForChange>assign review state 5.0</ReasonForChange>
            </AuditRecord>
          </pf:FormStatus>
        </FormData>
      </StudyEventData>
    </SubjectData>
  </ClinicalData>
</ODM>
<Status>END</Status>
<Bookmark>{A18E6CE1-11AB-4C6B-A4A8-63E31BD9025F}</Bookmark>
<TransactionsProcessed>1</TransactionsProcessed>
</ResponseODM>

```

Elements and extensions change history

The following table contains a history changes to elements and extensions and the InForm Adapter release when they were introduced.

Release	Change details	InForm compatibility notes
1.3.9	StudyEventDef element—pf:VisitStartHours attribute added.	Compatible with all studies designed in Central Designer.
1.3.7.3	The way in which ReviewState and ReviewStage are represented under the SubjectData element was changed.	
1.3.7	User element—pf:InFormUserType element added.	

Release	Change details	InForm compatibility notes
1.3.6.1	- ItemGroupDef element—The following attributes were added: - pf:RowCount - pf:IsFixedStatus - pf:UsePredefinedValue - ClinicalData element—pf:CriticalItems attribute added. - InFormItemDef element—pf:SVCritical attribute added. - ItemGroupDef element—pf:SVCritical attribute added.	No values for InForm releases prior to 6.0.
1.3.6	User element—pf:Active and pf:Terminated attributes added.	
1.3 SP5	- FormStatus element—pf:SVSelected attribute added. - New elements added: - pf:ReviewState - pf:ReviewStage - pf:SubjectPool - pf:SubjectPoolChange	No values for InForm releases prior to 5.5.

APPENDIX A

ODM Mapping

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About ODM mapping

This chapter shows the ODM to InForm mapping for transactional data (where supported) for Version 2 of the Oracle ODM Export Interface.

Mapping of localized items

The following items are localized in the 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 InForm application. It is returned as the fallback because there is no language associated with it.

ODM

Attributes	Value/Map To InForm
Description	InForm Study Name.
FileType	FileType.Transactiona1
Archival	Yes.
FileOID	InForm Study Name + unique GUID.
CreationDateTime	Current date time.
PriorFileOID	If present, FileOID of previous file in chain.
ODMVersion	1.3.
Originator	Based on input parameter.
MappingVersion	V1 or V2 to indicate the version of the InForm to ODM mapping definitions that were requested by the caller.
HierarchicalOIDs	No or Yes to indicate whether the ODM OIDs represent the programmatic, hierarchical repath of the metadata.
InFormAdapterVersion	Version of InForm Adapter that was used to generate the response.

Example—ODM

```
<ODM Description="Hypertension Study" FileType="Transactional"
FileOID="Hypertension Study1/19/2005 11:31:35 AM"
CreationDateTime="2005-01-19T11:31:35.1930510-05:00" ODMVersion="1.3"
Originator="test"
xmlns="http://www.cdisc.org/ns/odm/v1.3" />
```

Study

Attributes	Value/Map To InForm
OID	InForm Study Name.

Example—Study

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

GlobalVariables

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

Example—GlobalVariables

```
<GlobalVariables>  
  <StudyName>Hypertension Study</StudyName>  
  <ProtocolName>Protocol XYZZY</ProtocolName>  
</GlobalVariables>
```

BasicDefinitions

BasicDefinitions contains the InForm measurement unit definitions.

MeasurementUnit

Attribute	Value/Map to 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 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 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

Attribute	Value/Map to 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 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 Central Designer. For example, if the value for visit 2 is 8, visit 2 should occur one day after visit 1.

Mnemonic

StudyEventDef/Mnemonic

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

FormRef

Attribute	Value/Map to 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" pf:VisitStartHours="0">
  <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 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

FormDef/Mnemonic

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

ItemGroupRef

Attribute	Value/Map to InForm
ItemGroupOID	Form-relative RefPath for the section.
OrderNumber	Section Order.
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" />
</FormDef>
```

```
<pf:Mnemonic>  
  <TranslatedText>DOV</TranslatedText>  
</pf:Mnemonic>  
</FormDef>
```

ItemGroupDef

Attributes	Value/Map to 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.
RowCount	IsFixedSize—If Yes, the itemset includes only the number of rows specified in RowCount.
SVCritical	Indicates whether an item is marked as source verified critical in the InForm and Central Designer applications.

Example—ItemGroupDef

Sample output

```
<ItemGroupDef OID="frmDOSEVS.SctVitalSigns.SctVitalSigns" Name="SctVitalSigns"
Repeating="Yes" pf:ItemSetRefName="SctVitalSigns" pf:SVRequired="Yes"
pf:DBUID="6822"
pf:GUID="{1D1ECF17-5746-4B62-BC78-429295D32CE3}" pf:Revision="381233343951065"
pf:RowCount="5" pf:IsFixedSize="Yes">
  <ItemRef
ItemOID="frmDOSEVS.SctVitalSigns.SctVitalSigns.itmPlannedTime.itmPlannedTime"
OrderNumber="1" Mandatory="Yes">
    <pf:InFormItemRef
InFormItemOID="frmDOSEVS.SctVitalSigns.SctVitalSigns.itmPlannedTime"
OrderNumber="1" Mandatory="Yes">
      <pf:UsePredefinedValue value="Yes" />
    </pf:InFormItemRef>
  </ItemRef>
</ItemGroupDef>
```

```
</ItemGroupDef>
```

InformItemRef

InformItemData/ItemStatus

Attributes	Value/Map to InForm
InFormOID	Form-relative RefPath of an item.
Mandatory	Yes , if the item is mandatory.
OrderNumber	Display order of the item within the section.
UserPredefinedValue	If Yes, this value is populated from a list of predefined values that is associated with the ItemOID.

Example—InformItemRef

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

ItemRef

Attribute	Value/Map to 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

Attributes/Children	Value/Map to InForm
OID	The refname of the item. type=odm:oid. Required.
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.
SVCritical	Indicates whether an item is marked as source verified critical in the InForm and Central Designer applications.

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 InForm
OID	Form-relative RefPath for the control.
Name	Item RefName.
DataType	See <i>Data Type Table</i> (on page 123).
Length	See <i>Data Type Table</i> (on page 123).
SignificantDigits	See <i>Data Type Table</i> (on page 123).
Revision	- Entity: Control. Property: Revision. - Entity: Item. Property: Revision.
GUID	Item identifier.
DBUID	- Entity: Control. Property: DBUID. - Entity: Item. Property: DBUID.
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 <i>Data Type Table</i> (on page 123).
CheckboxGroupRefName	Present when the control is contained in a checkbox group and contains the RefName of the checkbox group.

Data Type Table

InForm control type	Definition
Simple Control	- Data Type is defined by the element's type. - Length: text 255, integer 10, float 308. Notes: - 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.
Text Control	- Data Type is defined by control data type (Pf_TextControl/DataType). - Length: text Pf_TextControl/MaxLength, integer 10, float 308. Notes: - 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 InForm
MeasurementUnitOID	Unit RefName.
NormalizationUnit	Yes , if the referenced unit is for normal values.

Question

Child	Value/Map to 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>
```

User

Attributes/Children	Value/Map to InForm
OID	User Name.
UserType	User Type.
LoginName	User Name.
DisplayName	User DisplayName.
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 DownloadAdminDataODM should rely on FirstName and LastName elements to get the full name or display name.
FirstName	User first name.
LastName	User last name.
Organization	
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	
Email	User email.
Picture	
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.

Attributes/Children	Value/Map to InForm
DBUID	Entity: User. Property: DBUID.
GUID	User Identifier.
Revision	Entity: User. Property: Revision.
LoginName	Entity: User. Property: Login Name.
UserType	Entity: User. Property: User Type.
StudyLocale	Locale of study. Derived from dc_v_thingdata in the study database.
Active	Indicates whether the user state is active.
Terminated	Indicates whether the user state is terminated.
InFormUserType	This type can contain the following values that correspond to the InForm user interface: • System • Site • Sponsor • Support • Integration

Example–User - mapping

```

<AdminData>
  <User OID="mmeyer" UserType="Investigator" pf:DBUID="11217"
pf:GUID="{8B980147-0531-4DD5-9B86-68BCA7F1532F}" pf:StudyLocale="en-US"
pf:Active="Yes" pf:Terminated="No" pf:InFormUserType="Site">
    <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="13001" />
    <pf:GroupRef GroupOID="5289" />
    <pf:GroupRef GroupOID="13609" />
  </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 InForm
OID	The DBUID of the group.
NAME	Name of group as displayed in the InForm software.
GroupType	Type of group as defined in the InForm software.
Right	List of rights. Contains a list of Right elements, each of which contains a Description.

Right

AdminData/pf:GroupDef/pf:Right

Attribute	Value/Map to 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.

Attributes	Value/Map to 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.
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 <i>Subject pool selection</i> (on page 97).
pf:SVFirstNSubjects	The value comes from a query: For more information, see <i>Subject pool selection</i> (on page 97).

Mnemonic

Location/Mnemonic

Attribute	Value/Map to 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 & 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>
```

CodeList

Attribute	Value/Map to InForm
OID	Control RefName. For example, if an item contains a drop-down list, the RefName of the drop-down list will be used. The ControlRefName is hierarchical: form.section.item.control
Name	ControlRefName without the hierarchical prefixing.
DataType	Type of Control. See <i>Data Type Table</i> (on page 123).

Example—CodeList

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

CodeListItem

Attribute	Value/Map to 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

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

MetaDataVersionRef

Attribute	Value/Map to 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

```
<MetaDataVersionRef StudyOID="Hypertension Study"
  MetaDataVersionOID="Study Version Basic" EffectiveDate="1998-06-30" />
```

SignatureDef

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

Meaning

CRB meaning, CRF meaning, or Group Name.

SignatureDef/Meaning

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

LegalReason

CRB Affidavit, CRF Affidavit, or PF_DEFAULT_CRFAFFADAVIT.

SignatureDef/Meaning

Attribute	Value/Map to 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>
```

ClinicalData

Attributes	Value/Map to InForm
StudyOID	Study Name.
MetaDataVersionOID	Study Version. If the form has no study version, MetaDataVersionOID="Undefined."
CriticalItems	Includes a separate CriticalItem element for each item-level change that occurs in the InForm application. For more information, see <i>CriticalItem</i> (on page 80).

How study versions are populated

Study versions are populated in the MetaDataVersionOID field of the ClinicalData element. Per ODM Standard, the Study Version for a form is the study version where the metadata was defined for that form. InForm Adapter follows that standard.

When data is entered on a revision of a form, InForm Adapter retrieves the Study Version where that revision of the form was made. This means that a particular transaction that contains updates to multiple forms, where one was modified in Study Version 2 and another in Study Version 3, may return more than one ClinicalData entry in the same transaction.

For example:

- In Study Version 1, you have Form A, Form B, and Form C.
- In Study Version 2, you create revision 2 of Form B because you added an item.
- In Study Version 3, you create revision 2 of Form C because you added a new item group.

These changes result, as follows:

- Subject 1 is assigned to Site 1, which is using Study Version 3.
- Rules are defined that cause Form B and Form C to be updated when data is entered on Form A.
- Form A is submitted for Subject 1 and a transaction is created that updates forms A, B and C.

There will be three ClinicalData sections. Because data was entered into revision 1 of Form A, which was created in Study Version 1 and never changed in 2 or 3, Form A will appear in its own ClinicalData element with MetaDataVersionOID of Study Version 1.

Form B will appear in a separate ClinicalData element with MetaDataVersionOID of Study Version 2.

Form C will appear in a separate ClinicalData element with MetaDataVersionOID of Study Version 3.

The purpose of the MetaDataVersionOID in the ClinicalData element of the transactional ODM is to give you a reference into the Metadata XML so that you can find the correct definition of the form. Therefore, in each of these cases you are given the correct MetaDataVersionOID for the

correct study version that contains the definition of what items, etc., are in that revision of the form.

Example—ClinicalData

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

Example—ClinicalData Sample Output

```
<ClinicalData StudyOID="StudyDesign" MetaDataVersionOID="Study Design 0.0.4"  
pf:TransactionGuid="{DEEC7341-A41A-426B-93E3-8CFD2A95BEB0}"  
pf:Revision="382526547058065.000">  
  <pf:CriticalItems>  
    <pf:CriticalItem sItemRefName="Gender" FormOID="" LocationOID="13548"  
Critical="StudyDefault" ItemRevision="381233328489065" />  
    <pf:CriticalItem ItemRefName="Gender" FormOID="frmDem"  
LocationOID="13548" Critical="true" ItemRevision="381233328489065" />  
    <pf:CriticalItem ItemRefName="MaritalStatus" FormOID="frmDem"  
LocationOID="13548" Critical="false" ItemRevision="381233326086065" />  
    <AuditRecord>  
      <UserRef UserOID="mlynch" />  
      <LocationRef LocationOID="Unknown" />  
      <DateTimeStamp>2013-02-14T14:22:27+00:00</DateTimeStamp>  
    </AuditRecord>  
  </pf:CriticalItems>  
</ClinicalData>
```

SubjectData

Attributes	Value/Map to InForm
SubjectKey	Patient DBUID.
GUID	Subject identifier.
Revision	Entity: Subject. Property: Revision.
SiteRef	Entity: Patient Move. Property: <i>no property listed</i> .
CriticalItems	Includes a separate CriticalItem element for each item-level change that occurs in the InForm application. For more information, see <i>CriticalItem</i> (on page 80).

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 InForm application.

SubjectData/pf:SubjectPool

Attributes	Value/Map to InForm
------------	---------------------

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

pf:ReviewState

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

SubjectData/pf:ReviewState

Attributes	Value/Map to 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 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 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

```

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>

```

SubjectStatus

Attributes	Value/Map to InForm-
State	Screened, ScreenFailed, Enrolled, EnrollmentFailed, EnrollmentOverride, Randomized, Complete, or DroppedOut.
ScreenFailReason	Text that describes the reason for the screening failure.
EnrollFailReason	Text that describes the reason for the enrollment failure.
EnrollOverrideReason	Text that describes the reason for the enrollment override.
SVReady	Source verification ready.
Frozen	Yes , if subject is frozen.
Locked	Yes , if subject is locked.

Example—SubjectStatus

```
<pf:SubjectStatus State="Screened">
  <AuditRecord>
    <UserRef UserOID="msilva" />
    <LocationRef LocationOID="Unknown" />
    <DateTimeStamp>2004-01-05T16:36:31+00:00</DateTimeStamp>
    <ReasonForChange>Screening Log Entry</ReasonForChange>
  </AuditRecord>
</pf:SubjectStatus>
```

StudyEventData

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

Attribute	Value/Map to 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

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

FormData

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

Signature

Indicates that the form 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>
```

FormStatus

Attributes	Value/Map to InForm
Activated	Yes , when the form has been activated.
SVPartial	Yes , when the form has been partially source verified.
Frozen	Yes , when the form is frozen.
Locked	Yes , when the form is locked.
Deleted	Yes , when the form has been deleted.
SVComplete	Yes , when the form is source verification complete.
SVReady	Yes , when the form is source verification ready.
SVSelected	Yes , when partial source verification has been selected for the form.
Signed	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." The Signed attribute is not returned for a form that has not yet been signed.

Example—FormStatus

```

<FormData FormOID="frmDOSE">
  <pf:FormStatus SVComplete="No">          Yes/No
    <AuditRecord>
      <UserRef UserOID="system" />
      <LocationRef LocationOID="Unknown" />
      <DateTimeStamp>2008-09-19T21:05:54+00:00</DateTimeStamp>
    </AuditRecord>
  </pf:FormStatus>
</FormData>

```

Signature

Children	Value/Map to InForm
UserRef/UserOID	User Name.
LocationRef/LocationOID	Site Name.
SignatureRef/SignatureOID	Signature Group Name.
DateTimeStamp	Entered date.

Example—Signature

```

<FormData FormOID="DEM" FormRepeatKey="1">
  <Signature>
    <UserRef UserOID="Inform CRA2" />
    <LocationRef LocationOID="PhaseForward" />
    <SignatureRef SignatureOID="CRA CRF Approval" />
    <DateTimeStamp>2005-04-06T19:41:49.0000000-04:00</DateTimeStamp>
  </Signature>
</FormData>

```

ItemGroupData

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

Example—ItemGroupData

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

Annotation

FormData/Annotation
ItemData/Annotation

Attribute/Child	Value/Map to 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

```
<Annotation SeqNum="9985">
  <Comment>test item comment</Comment>
</Annotation>
```

ItemData

Attribute/Child	Value/Map to InForm
ItemOID	Item RefName.
Value	ItemContext/control values.
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 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 InForm
Source Verified	Item has been source verified.
Deleted	Indicates whether the item has been deleted.

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 InForm
InFormItemOID	Form-relative RefPath for the item.
Name	Item RefName.
ItemStatus	Status of the item in the InForm software; for example, Source Verified or Deleted.
Query	Query element against an item in the InForm software.

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>
```

AuditRecord

Attributes/Children	Value/Map to InForm
Edit Point	DataManagement.
UserRef/UserOID	User Name.
LocationRef/LocationOID	Site Name.
DateTimeStamp	Entered date.
ReasonForChange	Reason.
SourceID	Machine Name.

UserRef

AuditRecord/UserRef

Attributes/Children	Value/Map to InForm
UserOID	Entity: Item. Property: Change user.

Example—AuditRecord

```
<ItemData ItemOID="DEMD0B" Value="Apr/5/1968">
  <AuditRecord EditPoint="DataManagement">
    <UserRef UserOID="crc2" />
    <LocationRef LocationOID="PhaseForward" />
    <DateTimeStamp>2005-04-06T12:09:05.0000000-04:00</DateTimeStamp>
    <ReasonForChange>Transcription Error</ReasonForChange>
    <SourceID>APPSRV27</SourceID>
  </AuditRecord>
</ItemData>
```

Query

InformItemData/Query

Attribute/Child	Value/Map to InForm
DBUID	Entity: Query. Property: DBUID.
OID	Query identifier.
Text	The text of the query.
Type	Autoquery or User.
Revision	Revision.
Query/QueryStatus	The status of the 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>
```

QueryStatus

InformItemData/ItemStatus

Attributes/Children	Value/Map to InForm
Status	Open, Answered, Closed, Candidate, Reissued, or Deleted.
Text	Query text.
Query/QueryStatus/AuditRecord/UserRef	Entity: Query. Property: User.
Query/QueryStatus/AuditRecord/DateTimeStamp	Entity: Query. Property: Time.
Query/QueryStatus/AuditRecord/ReasonForChange	Entity: Query. Property: Reason for Change.

Example—QueryStatus

```

<pf:Query OID="{B70FF676-A6B3-4608-8AD0-A32444764F45}" Text="Date of Visit is
prior to Screening Date; please correct" Type="Autoquery">
  <pf:QueryStatus Status="Open">
    <AuditRecord>
      <UserRef UserOID="autoquery" />
      <LocationRef LocationOID="Unknown" />
      <DateTimeStamp>2004-01-08T13:47:01+00:00</DateTimeStamp>
      <ReasonForChange>Date of Visit is prior to Screening Date; please
correct</ReasonForChange>
    </AuditRecord>
  </pf:QueryStatus>
</pf:Query>

```

APPENDIX B

Client programs for determining item completeness

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Introduction

This appendix provides algorithms and pseudocode for writing client programs that evaluate transactional data returned from the ODM Export methods `DownloadMetadataODM` and `GetTransactions` to determine whether items in the InForm application are complete.

Items in the InForm application

In the InForm application, each item contains a single control. If that control is a group control, checkbox group, or radio group, it can contain a number of child controls. The InForm database does not explicitly model the completeness of this hierarchy of controls, although it does come into play when determining the completeness of a form.

This appendix uses the following definitions.

- **Leaf control**—Any control that holds a value and does not have children. Examples include:
 - Pulldown controls
 - Text boxes
- **Group control**—A control that contains children, but does not have its own value.
 - **Radio group**—A control that has a number of options, exactly one of which must be selected.
 - **Checkbox group**—A control that has a number of options, any number of which may be selected.

A group control, checkbox group, and radio group's children might be simple controls with no values, leaf controls, or other group controls, checkbox groups, or radio groups. Although a group control is a container and has no value of its own, checkbox groups and radio groups do have values that indicate their selections.

- **Completeness**—Generally, an item is considered to be complete if either of the following are true:
 - The item's top-level control is complete.
 or
 - The item's top-level control is a simple or calculated control.

Examples of items in the InForm application

Radio and Checkbox groups

The item in the InForm study:

Does anyone in the subject's family have a history of depression? ☐ Yes

☐ Parent
☐ Sibling
☐ Other _____

☐ No

☐ Unknown

This item is composed of a radio group containing three options:

- A checkbox group with caption **Yes** that contains three options:
 - A simple control **Parent**.
 - A simple control **Sibling**.
 - A text box with caption **Other**.
- A simple control: **No**.
- A simple control: **Unknown**.

Criteria to determine whether an item is complete:

- If nothing is selected, then the item is incomplete.
- If **No** is selected, then the item is complete, because No does not have any children of its own (it is a simple control).
- If **Yes** is selected, but no checkbox options are selected, the item is not complete because at least one checkbox must be selected.
- If **Yes** is selected and **Parent** or **Sibling** is selected, then the item is complete, because Parent and Sibling don't have any children of their own.
- If **Yes** is selected and **Other** is selected, but the text box is not filled in, then the item is incomplete.

Simple group control

This example describes a blood pressure control:



This item is composed of a group control containing:

- A text control (systolic).
- A simple control with the label **/**.
- A text control (diastolic).
- A simple control with the label **mmHg**.

Criteria to determine whether an item is complete:

In this example, the item is considered complete if either systolic or diastolic is entered, because the group control is considered complete if at least one of its children is complete.

Note: A typical study design will actually trigger a query if one of the parts of the blood pressure is left blank, but the item is technically complete.

Extensions for showing control hierarchy and type

To define details for controls, the ODM Export interface provides the following extensions to the ODM elements *ItemDef* (on page 122) and *CodeListItem* (on page 130).

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.
pf: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.

Considerations:

- For each ItemDef, the extension **pf:ParentOID** must be added to show the parent for each data point. For example:

```
<ItemDef OID="frm.sct.itmFamHist.rdcYNUnk.chkFamHist.Other.txtOther"
  pf:ParentOID="frm.sct.itmFamHist.rdcYNUnk.chkFamHist.Other" ... />
```

- A pf:ParentOID is omitted in each root item.
- A pf:InFormItemDef might have multiple root ItemDefs when the root InForm control is a group control, because ItemDefs are not returned for InForm group controls.
- Each ItemDef that has a pf:ParentOID attribute will also contain a pf:ParentType attribute to indicate the type of the ItemDef's parent.
- Each ItemDef that is the child of a radio group selection will also identify the code list that contains the CodeListItem. This is extra information, but will be helpful in linking an item with the code list that contains the radio group selection that is its parent.

```
<ItemDef OID="frm.sct.itmFamHist.rdcYNUnk.chkFamHist.Parent"
  pf:ParentOID="frm.sct.itmFamHist.rdcYNUnk.Y"
  pf:ParentType="CodeListItem"
```

```
pf:SelectionOwner="frm.sct.itmFamHist.rdcYNUnk"... />
```

Example—control hierarchy:

```
<ItemDef OID="frm.sct.itmFamHist.rdcYNUnk.chkFamHist.Other.txtOther"
  pf:ParentOID="frm.sct.itmFamHist.rdcYNUnk.chkFamHist.Other"
  pf:ParentType="ItemDef" ... />
<ItemDef OID="frm.sct.itmFamHist.rdcYNUnk.chkFamHist.Parent"
  pf:ParentOID="frm.sct.itmFamHist.rdcYNUnk.Y"
  pf:ParentType="CodeListItem" ... />
```

Example—control type:

```
<ItemDef OID="frm.sct.itmFamHist.rdcYN.chkFamHist.Other.txtOther"
  pf:ItemDefType="Text" ... />
```

Radio and Checkbox groups, with ODM metadata output

The item in the InForm study:

Does anyone in the subject's family have a history of depression? ☐ Yes ☐ No ☐ Unknown

☐ Parent ☐ Sibling ☐ Other _____

Issuing the DownloadMetadataODM method on the InForm study produces the following XML output for the item, which includes the extensions to ItemDef and CodeListItem that show control hierarchy and type.

```
<ItemDef OID="frm.sct.itmFamHist.rdcYNUnk"
  pf:ItemDefType="RadioGroup" ... >
  <CodeListRef CodeListOID="frm.sct.itmFamHist.rdcYNUnk" />
</ItemDef>
<ItemDef OID="frm.sct.itmFamHist.rdcYNUnk.chkFamHist.Parent"
  pf:ParentOID="frm.sct.itmFamHist.rdcYNUnk.Y"
  pf:ParentType="CodeListItem"
  pf:SelectionOwner="frm.sct.itmFamHist.rdcYNUnk">
  pf:ItemDefType="Checkbox" ... />
<ItemDef OID="frm.sct.itmFamHist.rdcYNUnk.chkFamHist.Sibling"
  pf:ParentOID="frm.sct.itmFamHist.rdcYNUnk.Y"
  pf:ParentType="CodeListItem"
  pf:SelectionOwner="frm.sct.itmFamHist.rdcYNUnk">
  pf:ItemDefType="Checkbox" ... />
<ItemDef OID="frm.sct.itmFamHist.rdcYNUnk.chkFamHist.Other"
  pf:ParentOID="frm.sct.itmFamHist.rdcYNUnk.Y"
  pf:ParentType="CodeListItem"
  pf:SelectionOwner="frm.sct.itmFamHist.rdcYNUnk">
  pf:ItemDefType="Checkbox" ... />
<ItemDef OID="frm.sct.itmFamHist.rdcYNUnk.chkFamHist.Other.txtOther"
  pf:ParentOID="frm.sct.itmFamHist.rdcYNUnk.chkFamHist.Other"
  pf:ParentType="ItemDef"
  pf:ControlType="Text" ... />
<CodeList OID="frm.sct.itmFamHist.rdcYNUnk"
  <CodeListItem CodedValue="Y"
    pf:SelectionOID="frm.sct.itmFamHist.rdcYNUnk.Y"... />
  <CodeListItem CodedValue="N"
    pf:SelectionOID="frm.sct.itmFamHist.rdcYNUnk.N"... />
  CodeListItem CodedValue="Unk"
```

```

        pf:SelectionOID="frm.sct.itmFamHist.rdcYNUnk.Unk"... />
</CodeList>

<pf:InFormItemDef OID="frm.sct.itmFamHist" ... >
  <ItemRef ItemOID="frm.sct.itmFamHist.rdcYNUnk" />
  <ItemRef ItemOID="frm.sct.itmFamHist.rdcYNUnk.chkFamHist.Parent" />
  <ItemRef ItemOID="frm.sct.itmFamHist.rdcYNUnk.chkFamHist.Sibling" />
  <ItemRef ItemOID="frm.sct.itmFamHist.rdcYNUnk.chkFamHist.Other" />
  <ItemRef ItemOID="frm.sct.itmFamHist.rdcYNUnk.chkFamHist.Other.txtOther"
  />
</pf:InFormItemDef>

```

Group control, with ODM metadata output

The item in the InForm study:

This example includes a group control (**gp_WalkRange**) that contains two children:

- A radio group (**rd_4Digit_Meters**) with one selection Meters:
 - A text box (**tx_Meters**) with caption "meters."
- A text box (**tx_2DigitMin**) with caption "Number of minutes."

Issuing the DownloadMetadataODM method on the InForm study produces the following XML output for the item, which includes the extensions to ItemDef and CodeListItem that show control hierarchy and type.

```

<ItemDef
  OID="fm_FSS2.sc_Ambulation.it_WalkRange.gp_WalkRange.rd_4Digit_Meters"
  pf:ItemDefType="RadioGroup">
  <CodeListRef
    CodeListOID="fm_FSS2.sc_Ambulation.it_WalkRange.gp_WalkRange.rd_4Digit_Meters" />
</ItemDef>
<ItemDef
  OID="fm_FSS2.sc_Ambulation.it_WalkRange.gp_WalkRange.rd_4Digit_Meters.tx_Meters"
  pf:ParentOID="fm_FSS2.sc_Ambulation.it_WalkRange.gp_WalkRange.rd_4Digit_Meters.Meters"
  pf:ParentType="CodeListItem"
  pf:SelectionOwner="fm_FSS2.sc_Ambulation.it_WalkRange.gp_WalkRange.rd_4Digit_Meters"
  pf:ItemDefType="Text">
</ItemDef>
<ItemDef
  OID="fm_FSS2.sc_Ambulation.it_WalkRange.gp_WalkRange.tx_2DigitMin"
  <!-- No pf:ParentOID or pf:ParentType, because it's at the top -->
  pf:ControlType="Text">
</ItemDef>

<CodeList
  OID="fm_FSS2.sc_Ambulation.it_WalkRange.gp_WalkRange.rd_4Digit_Meters">
  <CodeListItem
    CodedValue="!pf!8829"
    pf:SelectionOID="fm_FSS2.sc_Ambulation.it_WalkRange.gp_WalkRange.rd_4Digit_Meters.Meters"
  />

```

```
<CodeListItem
  CodedValue=""
  pf:SelectionOID=
    "fm_FSS2.sc_Ambulation.it_WalkRange.gp_WalkRange.rd_4Digit_Meters.BLANK"
  />
</CodeList>

<pf:InFormItemDef
  OID="fm_FSS2.sc_Ambulation.it_WalkRange"
  <!-- pf:RootItemOID was removed from the design because items can have
  multiple roots i.e. top level controls in this case
  fm_FSS2.sc_Ambulation.it_WalkRange.gp_WalkRange.tx_2DigitMin and
  fm_FSS2.sc_Ambulation.it_WalkRange.gp_WalkRange.rd_4Digit_Meters -->
  <ItemRef
    ItemOID="fm_FSS2.sc_Ambulation.it_WalkRange.gp_WalkRange.rd_4Digit_Meter
    s" />
  <ItemRef
    ItemOID="fm_FSS2.sc_Ambulation.it_WalkRange.gp_WalkRange.rd_4Digit_Meter
    s.tx_Meters" />
  <ItemRef
    ItemOID="fm_FSS2.sc_Ambulation.it_WalkRange.gp_WalkRange.tx_2DigitMin"
    />
</pf:InFormItemDef>
```

Algorithms for determining completeness

To determine an item's completeness, write a client program that processes the ODM metadata and clinical data that is returned from *DownloadMetadataODM* (on page 48) and *GetTransactions* (on page 60) to evaluate the ItemData elements for each InForm item (pf:InFormItemDef).

Writing a client program to evaluate ItemData elements

To evaluate the ItemData information for each InForm item, your program must find the root ItemDef elements (root controls) for each InForm item, and recursively process them and their child ItemDef elements (child controls) to determine the completeness of each InForm item. Match the ItemDef elements from metadata (from DownloadMetadataODM) to the corresponding ItemData elements from clinical data (from GetTransactions) to get the values of the controls.

To identify the ItemDefs of an InForm item:

An InForm item is represented in metadata by a pf:InFormItemDef element. Each pf:InFormItemDef has a list of ItemRefs, which represent all of the controls associated with the InForm item. The ItemRefs have corresponding ItemDefs.

- If the ItemDef has no pf:ParentType, then it is a root ItemDef.
- If the ItemDef has pf:ParentType of "ItemDef," then find the ItemDef whose OID matches the child's pf:ParentOID.
- If the ItemDef has pf:ParentType of "CodeListItem," then find the CodeListItem whose pf:SelectionOID matches the ItemDef's pf:ParentOID.

To find the root ItemDefs of an InForm item:

- From the InForm item's ItemRefs, find the corresponding ItemDefs that do not have parents. These are the root ItemDefs.

To find the child ItemDefs of an ItemDef:

- 1 If the ItemDef has pf:ControlType of "RadioGroup," then find the child ItemDefs whose pf:ParentOID match the pf:SelectionOID of the RadioGroup's selected CodeListItem. The Clinical Data will determine which CodeListItem is selected from the RadioGroup.
- 2 For ItemDefs that have other pf:ControlType values, find the child ItemDef whose pf:ParentOID matches the ItemDef's OID.

Calculated controls:

Calculated controls are treated specially when determining completeness. When an item contains only a single calculated control, the item is considered complete, even if the calculated control has no value. Also, if a checkbox or radio group selection contains only a calculated control, that selection is considered to be complete. Otherwise, calculated controls are ignored.

An item is complete if:

- It has only calculated controls.
- or
- It has at least one complete control, and no incomplete controls.

Note: Empty is not the same as Incomplete. A radio group or checkbox group is incomplete if it has a selection, and the selection's child control(s) are empty or incomplete.

Algorithms - pseudocode

This pseudocode provides a programmatic explanation of the requirements described in *Writing a client program to evaluate ItemData elements* (on page 161).

```
IsItemComplete(item)
{
    if (item only has calculated controls)
        return true;

    foreach(childControl of item)
    {
        bool completeControlFound = false;

        if (IsControlIncomplete(childControl, completeControlFound))
            return false;
    }
    return completeControlFound;
}
```

```
IsControlIncomplete(control, completeControlFound)
{
    if (control is a calculated control)
        return false;

    if (control is a control type that doesn't have children (text,
        pulldown, etc.))
    {
        if (control has value)
        {
            completeControlFound = true;
        }
        return false;
    }

    if (control is a radio group)
    {
        if (it doesn't have a selection)
            return false;

        selectedOption = the radio group's selected option;
```

```

        if (selectedOption doesn't have any child controls OR
            it has exactly one child that is a calculated control)
        {
            completeControlFound = true;
            return false;
        }

        foreach (child of the selected option)
        {
            if (IsChildControlIncomplete(child))
                return true;
        }

        completeControlFound = true;
        return false;
    }

    if (control is a checkbox option)
    {
        if (it isn't checked)
            return false;

        if (it has exactly one child that is a calculated control)
        {
            completeControlFound = true;
            return false;
        }

        foreach (child of the checkbox option)
        {
            if (IsChildControlIncomplete(child))
                return true;
        }

        completeControlFound = true;
        return false;
    }
}

IsChildControlIncomplete(control)
{
    if (control is a calculated control)
        return false;

    if (control is a control type that doesn't have children (text, pulldown,
        etc.))
        Does the control have a value?
        if (yes)
            return false;
        if (no)
            return true;

    if (control is a radio group)
    {
        if (it doesn't have a selection)
            return true;

        selectedOption = the radio group's selected option;

        if (selectedOption doesn't have any child controls OR
            it has exactly one child that is a calculated control)
            return false;

        foreach (child of the selected option)
        {
            if (IsChildControlIncomplete(child))
                return true;
        }

        return false;
    }
}

```

```
    }  
    if (control is a checkbox option)  
    {  
        if (it isn't checked)  
            return true;  
  
        if (it has exactly one child that is a calculated control)  
            return false;  
  
        foreach (child of the checkbox option)  
        {  
            if (IsChildControlIncomplete(child))  
                return true;  
        }  
        return false;  
    }  
}
```

About the documentation

Where to find the product documentation

The product documentation is available from the following locations:

- My Oracle Support (<https://support.oracle.com>)—Release Notes and Known Issues.
- Oracle Help Center (<https://docs.oracle.com>)—The most current documentation set.

Documentation accessibility

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

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