

Integrating the Healthcare Enterprise

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**IHE IT Infrastructure (ITI)
Technical Framework Supplement**

Retrieve Form for Data Capture
(RFD)

15

**Draft for Trial Implementation
October 10, 2008**

Foreword

20 Integrating the Healthcare Enterprise (IHE) is an initiative designed to stimulate the integration
of the information systems that support modern healthcare institutions. Its fundamental objective
is to ensure that all required information for medical decisions is both accurate and available to
healthcare professionals as they care for patients. The IHE initiative is both a process and a
forum for encouraging integration efforts. It defines a technical framework for the
25 implementation of established messaging standards to achieve specific clinical goals. It includes
a rigorous testing process for the implementation of this framework. And it organizes
educational sessions and exhibits at major meetings of medical professionals to demonstrate the
benefits of this framework and encourage its adoption by industry and users.

The approach employed in the IHE initiative is not to define new integration standards, but rather
30 to support the use of existing standards—HL7, DICOM, IETF, and others—as appropriate in
their respective domains in an integrated manner, defining configuration choices when
necessary. IHE maintains formal relationships with several standards bodies including HL7, and
DICOM and refers recommendations to them when clarifications or extensions to existing
standards are necessary.

35 This initiative has numerous sponsors and supporting organizations in different medical specialty
domains and geographical regions. In North America the primary sponsors are the Healthcare
Information and Management Systems Society (HIMSS) and the Radiological Society of North
America (RSNA). IHE Canada has also been formed. IHE Europe (IHE-EUR) is supported by a
large coalition of organizations including the European Association of Radiology (EAR) and
40 European Congress of Radiologists (ECR), the Coordination Committee of the Radiological and
Electromedical Industries (COCIR), Deutsche Röntgengesellschaft (DRG), the EuroPACS
Association, Groupement pour la Modernisation du Système d'Information Hospitalier
(GMSIH), Société Française de Radiologie (SFR), Società Italiana di Radiologia Medica
(SIRM), the European Institute for health Records (EuroRec), the European Society of
45 Cardiology (ESC) and the Israeli Medical Information Association. In Japan IHE-J is sponsored
by the Ministry of Economy, Trade, and Industry (METI); the Ministry of Health, Labor, and
Welfare; and MEDIS-DC; cooperating organizations include the Japan Industries Association of
Radiological Systems (JIRA), the Japan Association of Healthcare Information Systems Industry
(JAHIS), Japan Radiological Society (JRS), Japan Society of Radiological Technology (JSRT),
50 and the Japan Association of Medical Informatics (JAMI). Other organizations representing
healthcare professionals are invited to join in the expansion of the IHE process across
disciplinary and geographic boundaries.

The IHE Technical Frameworks for the various domains (IT Infrastructure, Cardiology,
Laboratory, Radiology, etc.) define specific implementations of established standards to achieve
55 integration goals that promote appropriate sharing of medical information to support optimal
patient care. It is expanded annually, after a period of public review, and maintained regularly
through the identification and correction of errata. The current version for these Technical
Frameworks may be found at www.ihe.net/Technical_Framework.

60 The IHE Technical Framework identifies a subset of the functional components of the healthcare
enterprise, called IHE Actors, and specifies their interactions in terms of a set of coordinated,
standards-based transactions. It describes this body of transactions in progressively greater
depth. The volume I provides a high-level view of IHE functionality, showing the transactions
organized into functional units called Integration Profiles that highlight their capacity to address
65 specific clinical needs. The subsequent volumes provide detailed technical descriptions of each
IHE transaction.

This IHE IT Infrastructure Technical Framework Supplement is issued for Trial Implementation
through May 2009.

70 Comments and change proposals arising from Trial Implementation may be
submitted to <http://forums.rsna.org> under the forum:

“Integrating the Healthcare Enterprise”

Select the sub-forum:

“IHE IT Infrastructure 2007-2008 Supplement for Trial Implementation”

Comment [LF1]: This forum does not exist yet.

75 The IHE IT Infrastructure Technical Committee will address these comments resulting from
implementation, connectathon testing, and demonstrations such as HIMSS 2008. Final text is
expected to be published in August 2009.

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100 **1 Introduction**

The Retrieve Form for Data Capture Profile (RFD) provides a method for gathering data within a user's current application to meet the requirements of an external system. RFD supports the retrieval of forms from a form source, display and completion of a form, and return of instance data from the display application to the source application.

105 **1.1 Open Issues and Questions**

1. This profile is using W3C XForms 1.1. While XForms 1.1 is in *Last Call for Comments* status, this profile will remain in Trial Implementation.
2. At what point does the investigator verify /sign off on the data?
- 110 3. Digital signatures seem like they might be applicable, but it is not clear what risk they mitigate, and more importantly how they are accomplished within the constraints of the profile.

1.2 Closed Issues

1. Should the Form Manager be broken into two actors: one for supplying and a second for consuming forms? Yes: Form Manager and Form Receiver.
- 115 2. If one application supports Form Manager and Form Receiver, does there need to be an IHE transaction between the two to handle the case of partially completed forms? No: the Form Manager and Form Receiver may be grouped for communication purposes but these communications are internal and are not IHE Transactions.
- 120 3. Should the XForm instance element be allowed to use the src attribute? Yes, this is allowed; this is a change from the public comment version of this document.
4. Should there be other constraints on the XForms that comply with this profile? Yes, see Volume 2, 3.a.4.3.1 XForm Instance Data Constraints and 3.a.4.3.2 XForms supporting the Archive Capability for the existing constraints.
5. Should the Archive Form transaction be a separate transaction ? Yes.
- 125 6. Need a way to summarize the x-forms submission for the audit log, there is no way to identify the transaction.
 - Require forms manager assign an id for each xform transaction.
 - Require forms manager assign a description for each xform transaction
 - Audit log includes both in the audit log
- 130 7. The Security Analysis of Assets, Risks, Threats removed this from the open issues.
8. How are data queries/ data corrections documented? Functionality now included within the profile.

- 135
9. The Domain Use Cases and appendix examples will be removed and placed in another location when this document transitions to Trial Implementation. – it was decided that the Domain Use Case text should remain in place.

2 Profile Abstract

140 The Retrieve Form for Data Capture Profile (RFD) provides a method for gathering data within a user's current application to meet the requirements of an external system. RFD supports the retrieval of forms from a form source, display and completion of a form, and return of instance data from the display application to the source application.

GLOSSARY

form - An area with editable fields into which users and applications insert data

Volume I – Integration Profiles

Changes to Sections 1 – 1.X

145 1.7 History of Annual Changes

Add the following bullet to the end of the bullet list in section 1.7

Retrieve Form for Data Capture (RFD) - provides a means for the retrieval and submission of forms data between physicians/investigators and electronic data capture systems or other data collection agencies.

150 *Add the following new section to section 2.2*

2.2.17 Retrieve Form for Data Capture (RFD)

The Retrieve Form for Data Capture Profile (RFD) provides a method for gathering data within a user's current application to meet the requirements of an external system. RFD supports the retrieval of forms from a form source, display and completion of a form, and return of instance data from the display application to the source application.

Add the following new section 17

17 Retrieve Form for Data Capture

160 The Retrieve Form for Data Capture Profile (RFD) provides a method for gathering data within a user's current application to meet the requirements of an external system. RFD supports the retrieval of a form from a form source, the display and completion of the form, and the return of instance data from the display application to a receiving application. In addition, RFD provides a mechanism to amend data that was previously captured.

165 Consider the case where a healthcare provider site uses an Electronic Health Record (EHR) to document patient care. In this case, the EHR acts as the local home application for the provider's personnel. Suppose an external agency, through some contractual arrangement, requires data from the provider, some of which reside in the EHR's database, the rest requiring data entry by the EHR's users. RFD enables the EHR user to retrieve a data capture form from the external agency, to fill out the form, and to return the data to the external agency without leaving the provider's local home application, the EHR. The profile also permits the external agency to indicate that there is a need to clarify points about the data so captured and provides the mechanisms to allow the data to be modified.

175 Many potential uses of RFD want the form to dynamically pre-populate forms from the host application's database, that is have the form delivered with host application database values filled in to appropriate fields of a form. RFD permits automatic form population and provides a generic mechanism by which this can be accomplished. However, the profile does not speak to the issue of content, remaining silent on normative vocabularies and other enablers of semantic interoperability. Specific domain groups – clinical trials, drug safety, bio-surveillance – will build on RFD by contributing content specifications or by evaluating and recommending existing content standards that will operate within RFD. When RFD, as an infrastructure profile, integrates with domain-specific content standards, a much greater level of interoperability will result.

185 The RFD profile provides a generic polling mechanism to allow an external agency to indicate issues with data that have been captured and enable the healthcare provider to correct the data. The profile does not dictate the mechanism employed or content required to achieve such corrections.

190 In this profile, the external agency provides data capture forms in a schema appropriate to its domain. The profile intends to minimize the work that the displaying application should do, and to bring over fully functional forms that carry with them the instruction necessary to complete the form. The RFD Profile uses XForms technology to support negotiation between the form display and form provider systems, so that iterative exchanges can deal with issues like form selection, completion of a series of forms, partial completion of forms, returning to forms partially filled out in earlier sessions. RFD also supports archiving a copy of the completed form.

195 RFD offers the capability to leverage industry standards that address both the structure and
content of forms used for data capture. HL7's Individual Case Safety Record (ICSR) and
CDISC's Operational Data Model (ODM) provide examples.

200 The infrastructure provided by the RFD profile can be utilized by many domain groups and the
following domain-specific use cases illustrate the wide variety of uses to which RFD can be
made.

17.1 Use Cases

205 The following use cases indicate how this profile might be used by various disciplines. The RFD
profile enables all of these use cases. It does not implement any of them. Actual discipline
specific profiles that specify both the use of RFD and the rules for data objects are expected in
future domain-specific IHE profiles.

17.1.1 Investigational New Drug Clinical Trial Use Case

210 The setting for the clinical trial use case is a physicians' practice where patient care is delivered
side-by-side with clinical research. The site, Holbin Medical Group, is a multi-site physician
practice, employing over 100 physicians in a variety of specialties. Holbin's CEO encourages
the physicians to participate as site investigators for pharmaceutical-sponsored clinical trials;
Holbin provides support for clinical research activities in the form of a Research Department of
twelve dedicated study coordinators, mostly RNs, along with clerical and data-entry support
personnel. Holbin Medical Group uses an Electronic Health Record (EHR) and a number of
215 sponsor-provided Electronic Data Capture (EDC) systems for documenting clinical trial
activities. (For our purposes, an EHR is any application which is the primary site for
documenting patient care, and retrieving patient care information. Thus we include in our span
of interest many systems installed today that are not quite EHRs in the strictest sense, but which
would still benefit from this approach.)

220 Holbin's involvement in a clinical study begins when the Research Department receives a
request for proposal from a study sponsor. A Study Coordinator, Patricia Zone, RN, evaluates
the RFP for business viability and clinical appropriateness, and provides the requested
documentation back to the sponsor. After being selected as a site for the trial, identified as
#1234, and providing the required regulatory documentation to the sponsor, the physician
identified as the Principal Investigator and other study personnel receive protocol-specific
225 training from the sponsor. During the trial set-up period, Patricia ensures that the appropriate
system security is in place for this protocol, recruits patients to participate as subjects according
to inclusion and exclusion criteria described in the study protocol, schedules patient visits,
manages data capture and data entry, and performs all the attendant financial tasks.

230 Patricia contacts Corey Jones, a patient at Holbin, about participating in the trial, and Corey
agrees to participate as a subject. Patricia registers Corey in the EHR as a subject in trial #1234,
using the EHR's patient index. She schedules Corey's study visits using the EHR scheduling
module, and flags the visits as pertaining to the trial #1234. After the set-up stage, the site
initiates clinical trial care and trial-specific documentation.

235 The use case continues with current state and desired state scenarios, which describe data capture
utilizing EDC technology during a patient clinical trial visit before and after the RFD
implementation.

17.1.1.1 Current State

240 Corey Jones arrives at the clinic for a scheduled trial visit and meets with Patricia Zone for a
face-to-face interview. Patricia logs into the EHR and documents the visit with a terse entry:
‘Mrs. Jones comes in for a clinical trial visit associated with study #1234.’ Patricia interviews
Mrs. Jones, makes some observations, and records her observation on a source paper document.
She looks up recent lab results in the EHR and records them in the Case Report Form (CRF).
245 The EHR provides only a portion of the data required to complete the form, the rest comes from
the interview and observations. (Estimates on the percentage of data required for a clinical trial
that would be available in an EHR vary from 5% to 40%. Even in the best case, the EHR
typically captures only a subset of the data required by a study protocol.)

250 The completed source document is forwarded to Bob, the data entry person. Bob identifies the
CRF as belonging to trial #1234, and selects the trial #1234 EDC system, which may be housed
on a dedicated laptop provided by the sponsor or may be accessible via a browser session
connected to the Sponsor’s EDC system via the Internet. He takes a three ring binder off the
shelf and refers to his ‘crib sheet’ to get the instructions for how to use this particular system. He
logs into the EDC application, using a user name and password unique to this system, and enters
the data into the correct electronic case report form (eCRF) for that trial visit. Once the source
document has been processed, Bob files it in a ‘banker’s box’¹ as part of the permanent source
255 record of the trial (in order to meet the requirements of the Federal Code of Regulations 21CFR
312:62).

260 In addition to trial #1234, Bob performs data entry on eight additional EDC systems, five on
dedicated laptops and three that are web-based. The web-based EDC systems save on table
space, but still require entries in the three ring binders where Bob puts his ‘crib sheets’. It is a
chore to make sure that data from a particular trial gets entered into the corresponding laptop
with its unique login ritual and data capture form, so Bob experiences much frustration in dealing
with this unwieldy set of systems. Bob is a conscientious employee, and stays current in his
work. But in many other sites the data entry person holds the CRF for a period of time before
entering the data, perhaps entering data twice a month, or entering the data the week before the
265 monitor visit occurs.

17.1.1.2 Desired State

Mrs. Jones arrives for a visit and Patricia logs into the EHR, pulls up Mrs. Jones’s record, and
identifies the scheduled clinical trial visit. Because of the patient identification and scheduling
steps that took place in the set-up stage, the EHR recognizes Mrs. Jones as a subject in Trial

¹ See the definition: http://www.archivists.org/glossary/term_details.asp?DefinitionKey=1193

270 1234, and requests an electronic case report form from trial #1234's EDC system, using RFD. If
the trial is sufficiently complex, the retrieved form may contain a list of relevant forms from the
EDC system for Patricia to choose from. When the correct context is established between the
EHR and the EDC, Patricia selects the clinical research tab within the EHR application to reveal
275 the appropriate form. The EHR checks Patricia's credentials, confirms that she is empowered to
view the form, and displays the form. The data capture form is essentially the same form that the
EDC system would offer for this visit, and its presentation may take on some of the look and feel
of the EHR's user interface. The use of a crib sheet may still be necessary, although
sophisticated forms should carry with them information on how to fill out the form.

280 Patricia interviews Mrs. Jones and enters data into the clinical trial form. Data from the EHR
database may be pre-populated into the proper data fields (which have built-in edit checks).
Upon completing the form, Patricia hits the submit button, and the EHR returns the complete
form to the EDC system, using RFD. A copy of the document is archived in the site clinical trial
document vault as part of the permanent source record of the trial.

17.1.2 Public Health Reporting Use Cases

285 17.1.2.1 Public Health Scenario 1

17.1.2.1.1 Current State

Mrs. Smith presents to the Emergency Department of the Community Hospital with digestive
complaints. The health care provider sends samples to the lab. The laboratory identifies
cryptosporidium. The laboratory personnel query the laboratory database for weekly required
290 public health reporting. Cases are identified, and information from the laboratory information
system is copied to the public health form, printed, and sent to the public health authority. The
public health officials review the reports submitted from the health care providers in the
jurisdiction and identify that multiple cases of cryptosporidium have been presenting to area
hospitals. Notification of the event is communicated to health care providers in the area to notify
295 them to watch for additional cases. Water supplies servicing the affected areas are tested and
treated accordingly. However, with the delay in the detection process caused by the paper-based
process, numerous additional cases of cryptosporidium infection present for care.

17.1.2.1.2 Desired State

Mrs. Smith presents to the Emergency Department of the Community Hospital with digestive
300 complaints. The health care provider sends samples to the lab. The laboratory identifies
cryptosporidium. The laboratory system identifies this test result as a required public health
report and sends it to the state DOH using PHIN standards as soon as the result is verified in the
laboratory system. In addition or alternatively, a form is retrieved using the RFD profile from the
Biowatch public health system. The case reporting form is presented to the provider, pre-
305 populated with EHR mapped data. The healthcare provider fills out the remaining supplemental
information and submits this data electronically to the public health authority. The public health

310 authority receives numerous electronic reports from laboratories and health care providers in the jurisdiction. Notification is sent to area health care providers and laboratories in the area to notify them to watch for additional cases. Water supplies servicing the area are tested and treated accordingly. With the early detection through process automation, further illness in the community is minimized.

17.1.2.1.3 Anthrax and Avian Influenza Scenarios: Disease Monitoring Based on Presumptive Diagnoses and/or Patient ‘Problems’

315 Anthrax: Patient presents at ED with rapidly progressive respiratory symptoms. Gram stain of sputum reveals gram positive rods, chest X-ray reveals a widened mediastinum, and patient's condition rapidly deteriorates. Culture of sputum in laboratory is suspicious for *Bacillus anthracis*. State DOH contacted and specimens sent for confirmation. Once confirmed, the state DOH notifies appropriate local, regional, state, and federal officials (e.g., CDC, FBI, USAMRID), and notifies local hospitals, providers, and media. (This involves a bioterrorist scenario on the back end after ID confirmation – the influenza scenario below does not, but probably invokes the same pathways.)

320 Once notified of the potential for additional cases, the ED performs STAT Gram stains on sputa and PA/Lateral Chest Xrays for all patients presenting with rapidly progressive respiratory symptoms. Presence of Gram positive rods in sputum is entered directly into the lab system OR
325 by designated ER staff into a specific ADT field on the patient ADT screen in the CIS for internal / external surveillance reporting. Rapid reading of Chest Xray with mediastinal widening is entered in a specific ADT field by designated staff (e.g., Radiology technician) on behalf of physician. Entry of information in these fields creates a transaction of the information to the local public health department biosurveillance system (BIS) as presumptively diagnosed
330 inhalational anthrax. The BIS aggregates information received from multiple sites to present the location, origin and extent of presumptive and defined case presentation.

Influenza: Physicians around hospital and hospital ED get rapidly increasing number of patients with respiratory symptoms suggestive of a viral infection, but no increased prevalence of similar
335 symptoms in surrounding hospitals. Rapid test for influenza A/B is positive in many of the patients and epidemic influenza is circulating in the community. Respiratory culture is negative for bacterial pathogen at 24 hr, but viral culture is positive for influenza A. AH5N1 is suspected due to association of patients with each other and “dead chickens”. All specimens are sent to state DOH ASAP for ID. State lab identifies AH5N1. Follow-up similar to #1 above. The follow-up once notification is disseminated from health department(s) to local providers, is similar to
340 the presumptive diagnosis information transmission to public health BIS. A more robust method for collection of presumptive diagnoses in either scenario (but not near-term) is to use standardized “problem” terms (using SNOMED) for selection of presumptive problems as part of routine operations of a CIS for physician order entry and for physician and nursing documentation.

345 The difference in these two scenarios is that the Anthrax case involves syndromic surveillance (severe respiratory symptoms and a widened mediastinum on X-ray: need radiology surveillance and cross-correlation to ED and Lab – much more complex.)

17.1.3 Pharmaco-vigilance Scenario

350 A community-based physician, Dr. Cramp, sees a patient in an outpatient clinic and accesses the patient's electronic health record which reveals that the patient is on one of the new statin drugs. The physical examination turns up muscle weakness in the patient's calves, which the physician recognizes as a possible adverse reaction to the statin. He orders a total creatinine kinase lab test to help in diagnosing the problem.

17.1.3.1 Current State

355 Dr. Cramp exits the EHR and, using a web browser, goes to <http://www.fda.gov/medwatch/>. He brings up form FDA 3500, for 'voluntary reporting of adverse events noted spontaneously in the course of clinical care'. He navigates through several screens of routing and instructions to arrive at the first screen of the actual form, which requests patient identifier, age at time of event or date of birth, sex, and weight; the second screen requests seven entries: a classification of the event, classification of outcome, event date, report date, description, relevant tests (he notes that
360 a test has been ordered), and other relevant history (the last three fields are text entry); the third and fourth screens ask for details about the product ; and so forth. In actuality, the current state is that this form is seldom completed.

17.1.3.2 Desired State

365 Dr. Cramp sees the patient and accesses the EHR as above. Upon finding the potential problem, he clicks on an 'Adverse Event Reporting' button which brings up FDA form 3500, which has been styled to fit in with the look and feel of the EHR user interface. The form is presented with the demographics already completed. The product name is part of the working context of the EHR session, and is automatically loaded into the appropriate field. Dr. Cramp completes the
370 empty fields of the form and submits directly to the FDA Medwatch site.

RFD takes care of retrieving the form from MedWatch, displaying it, and returning the form to FDA. Note that the profile does not address whether or not the EHR stores a copy of the form or preloads it with EHR data. Simply using the EHR to display, complete, and submit the form is sufficient. The EHR and the site might decide to capture and store the form in the EHR
375 database, which would be a permitted extension of the profile, but not necessary.

17.1.4 Cardiology Research Use Cases

17.1.4.1 Cardiology Use Case 1 - Submission to National, State and Regional Data Registries

380 Several jurisdictions have mandatory requirements for submission of data for particular cardiac
procedures, (e.g., New York State for angioplasty and cardiac surgery, or the US for
implantation of cardioverter defibrillators in Medicare patients). Additionally, many institutions
participate in voluntary regional or national data registries, notably the NCDR™ National
Cardiovascular Data Registry.

385 A single cardiac patient's data may be submitted to multiple registries. It is therefore useful for
data collections for multiple submissions to be done simultaneously, so that the nurse preparing
the data can review the patient medical record once and extract relevant data to each of the
submission forms. Additionally, the patient's "medical record" is in fact spread across several
electronic and paper-based systems, so that repeated access in the preparation of multiple
submissions must be minimized.

390 Most of the cardiac registry submissions require data from several encounters. E.g., the NCDR
gathers data on patients who undergo diagnostic cardiac catheterization followed by a
percutaneous coronary intervention (PCI). If the patient had presented to the Emergency
Department with an ST-elevation infarction, only a small portion of the NCDR-required data is
gathered in association with the catheterization procedure. The following information is needed
395 to complete the NCDR data set: Date of previous CABG, date of previous PCI, time of arrival in
the ER, baseline laboratory data (BUN, creatinine), information from the patient's history
(family history of CAD, history of stroke, pulmonary and renal disease, etc.), measured cardiac
ejection fraction prior to PCI, QCA findings, inventory of the devices used (including bar codes),
and medications administered.

400 Thus, the preparation of the submission must be done incrementally at each encounter, and/or
retrospectively at a time that all the information can be determined. Incremental preparation is
problematic, since at the initial encounters it is not known what procedures the patient will
undergo, and hence what registries' data forms need to be filled in. Purely retrospective data
collection is similarly problematic, as it is better to obtain the data when it is produced, rather
405 than needing to search through the record for it.

Carl Cardiac, a patient, presents at the ED with chest pain, and based on ECG and history is
whisked to the cath lab for a diagnostic and interventional procedure. During the PCI, while
things are slow during the angioplasty balloon inflation, Ted Tech, the cath lab technologist,
calls up the (empty) state and national angioplasty registry forms from the forms repository onto
410 the cath lab logging system, and begins filling in relevant information from the case. During
post-procedure clean-up, he completes as much information as he knows, and stores the partially
filled-in forms back to the forms repository.

At the end of the month, Nancy Nurse is assigned the task of completing the registry data
collection for that month's cath patients. She retrieves a list of cath patients, and for each one

415 pulls up partially completed forms. When she gets to Carl’s name, she pulls up the forms as partially completed by Ted, and accesses Carl’s lab results, cath procedure report, nursing notes from the CCU, and discharge summary report. She fills in the remainder of the registry forms, and stores the completed forms back to the repository.

420 At the end of the quarter, Adele Admin uses a specialized application to retrieve all the completed forms for the national registry for the quarter from the repository, and to prepare the submission. She does a similar task with an application that processes the state registry forms.

17.1.4.2 Cardiology Use Case 2 – Performance Measures

425 A major issue in cardiology is improving the quality of care by monitoring select performance measures. There is a strong collaborative arrangement between the ACC, AHA, CMS, JCAHO, and AHRQ on the development and use of performance measures, such as the new ACC/AHA Clinical Performance Measures for Adults With ST-Elevation and Non–ST-Elevation Myocardial Infarction.

430 These performance measures require data collection, similar to the collection of data for submission to registries. However, after collection of data for a particular time period, further analysis on the total patient population must be applied to obtain an appropriate denominator for the reported measures (i.e., certain patients must be retrospectively excluded from the population data set).

17.1.5 Radiology Use Case – Clinical Impact Registry

435 As part of the effort to assess the impact of PET imaging on cancer patient management, the Centers for Medicare and Medicaid Services have predicated reimbursement, for a number of otherwise non-reimbursed procedures, on the submission of study data to a National Oncologic PET Registry (NOPR) operated by the American College of Radiology at www.cancerpetregistry.org.

440 This use case involves a sequence of forms which must be submitted for a given patient study and includes overlaps with the billing process.

PET Facilities are required to register their site with NOPR. Because access to NOPR is limited to registered facilities and because the facility depends on complete submission to get the reimbursement, the PET Facility has the primary responsibility and direct access for submitting all data. The referring physician does not have access to NOPR.

445 Paul Positron, a patient, presents with indications of stomach cancer (or other indication covered only by participation in the NOPR). His physician, Dr. Jones, refers him to PET-Pros, a participating PET facility. PET-Pros obtains basic demographic information from Dr. Jones and submits this information to NOPR via a Web form, at which time a Registry case number is assigned by NOPR.

450 Once a Registry case number is created, NOPR emails Dr. Jones the Pre-PET Form that must be completed with case specific clinical details and forwarded to PET-Pros for entry into the NOPR database by midnight of the day of the PET scan.

At some time before the PET study, or when Paul arrives for the PET scan, PET-Pros provides Paul with the ACR IRB-approved standard NOPR Patient Information Sheet. Paul can contact
455 the NOPR directly for more information, if necessary. Paul indicates his NOPR consent verbally to staff at the PET facility, either on the day of the PET study or within two working days after the PET study is completed. Written consent is not required. PET-Pros notes in the PET Report Form, if the patient gave or withheld consent for use of his data in future NOPR research.

Once the PET scan has been performed and reported, PET-Pros submits a study completion form and a report form (including the report provided to Dr. Jones) to NOPR.
460

NOPR emails Dr. Jones the Post-PET Form for completion. This form collects information relating to the impact of the scan. It also includes an ACR IRB-approved Referring Physician Information Sheet and indication whether physician consent for use of the response data in future NOPR research has been given or withheld. The Post-PET form must be completed, forwarded
465 to PET-Pros and entered into the NOPR database within 30 days of the PET scan.

The NOPR database notifies PET-Pros when all case data have been entered so that the facility can bill CMS for the study. PET-Pros can check on the case status of their patients at any time using the PET Facility Reporting Tools available on the NOPR Web site.

17.1.6 Data Clarification

470 There is a need for a clarification process that enables a sponsor organization to highlight data that needs to be examined and potentially corrected. These are detected by sponsor-initiated checks (edit checks) that result in sponsor data queries for clarification, correction, or verification relating to previously submitted data. These queries about previously submitted data are provided to the EHR system upon request. Note that there is no automated notification to the
475 EHR that these queries for clarification / correction / verification exist. It is up to the EHR to periodically make requests when working with a sponsor that performs these edit checks. Performing these longitudinal edit checks on submitted data does not apply to all use cases.

17.1.6.1 Current State - query process

480 Edit checks built in to eCRFs can facilitate accurate and complete data capture; however, it is probable that during the course of a trial, some data elements will need to be reviewed by the site for clarification, correction, or verification. As data managers review the data (through manual and/or system-supported validation processes), they identify missing, incomplete, or potentially discrepant data (e.g. a site reports a patient was prescribed penicillin for a headache). Data queries are generated through an EDC system and sent back to the site for clarification/
485 correction/ verification by the research coordinator. For each data query, the coordinator must reference the source record where the data element was originally documented and compare the queried data element to the source. On occasions, the site may need to contact the patient if the

490 source is incomplete (e.g., a stop date on a medication). Clarifications to the data are documented by the coordinator in the source and if it is determined that the source record is in error, corrections are clearly documented in the source per GCP guidelines. The coordinator then responds to the query in the EDC system providing a reason for any updates to the original record which the system captures in the audit trail. The data manager can then review the updates and the response and close the query if no further information is required.

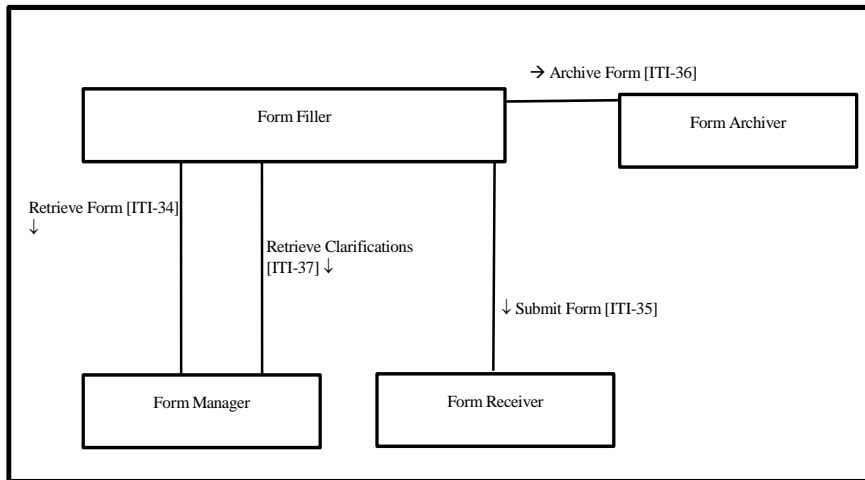
17.1.6.2 Future State - query process

495 Edit checks built in to trial-specific XForms and eCRFs in the EHR system can facilitate accurate and complete data capture; however, it is probable that during the course of a trial, some data elements will need to be reviewed by the site for clarification, correction, or verification.

500 As data managers review the data (through manual and/or system-supported validation processes), they identify missing, incomplete, or potentially discrepant data (e.g. a site reports a patient was prescribed penicillin for a headache). Data queries are generated through the sponsor system and prepared to the site for clarification/ correction/ verification by the research coordinator. The EHR study coordinator accesses and reviews each data query through the EHR system referencing the EHR data in order to respond to the query. On occasions, the site may need to contact the patient if the EHR data is incomplete (e.g., a stop date on a medication).
505 The coordinator documents clarifications to the data in the EHR system if needed and submits a query response as well as any data updates to the sponsor system and to the investigator site archive. The query response includes a reason for any changes made which is included as part of the audit trail in the EHR system, sponsor system, and the investigator's site archive. The data manager of the sponsor can then review the response and the updates in the sponsor system and
510 close the query if no further information is required.

17.2 Actors/ Transactions

Figure 17.2-1 shows the actors directly involved in the Retrieve Form for Data Capture Integration Profile and the relevant transactions between them. Actors that may be indirectly involved due to their participation in other profiles are not shown.



515

Figure 17.2-1. Retrieve Form for Data Capture Actor Diagram

520 Table 17.2-1 lists the transactions for each actor directly involved in the Retrieve Form for Data Capture Profile. In order to claim support of this Integration Profile, an implementation must perform the required transactions (labeled “R”). Transactions labeled “O” are optional. A complete list of options defined by this Integration Profile that the implementations may choose to support is listed in Volume I, Section 17.3.

Table 17.2-1. Retrieve Form for Data Capture Integration Profile - Actors and Transactions

Actors	Transactions	Optionality	Section in Vol. 2
Form Filler	Retrieve Form	R	ITI TF-2:3.34
	Submit Form	R	ITI TF-2:3.35
	Archive Form	O	ITI TF-2:3.36
	Retrieve Clarifications	O	ITI TF-2:3.37
Form Manager	Retrieve Form	R	ITI TF-2:3.34
	Retrieve Clarifications	R	ITI TF-2:3.37
Form Receiver	Submit Form	R	ITI TF-2:3.36
Form Archiver	Archive Form	R	ITI TF-2:3.36

525

17.2.1 Actors

17.2.1.1 Form Manager

530 The Form Manager supplies forms to Form Fillers based upon form retrieval requests. In some cases, the Form Manager may simply return a form from a store of forms, whereas in other cases the returned form may be selected or even constructed based upon context information supplied in the form retrieval request. Additionally, forms from a store may be modified based upon whether or not the Form Filler supplies additional information about a Form Archiver.

17.2.1.2 Form Filler

535 The Form Filler actor retrieves forms from a Form Manager as and when required. When requesting a form, the Form Filler actor can optionally provide context information by providing pre-population xml data in the request for use by the Form Manager.

The Form Filler may also specify a Form Archiver actor. The Form Archiver actor specified by the Form Filler is in addition to any Form Archiver actors specified by the Form Manager.

17.2.1.3 Form Receiver

540 The Form Receiver actor receives and processes completed or partially completed forms instance data from a Form Filler. Form Receiver processing is out of the scope of the profile.

17.2.1.4 Form Archiver

The Form Archiver actor receives completed or partially completed forms instance data and stores these for archival purposes.

545 **17.2.2 Transactions**

17.2.2.1 Retrieve Form

The Retrieve Form transaction carries the form identifier from a Form Filler to a Form Manager. The transaction also allows a Form Filler to optionally specify a Form Archiver actor as well as optionally containing context information in the form of xml data to be used in the selection and pre-population of the requested form prior to the form being returned to the Form Filler.

550

17.2.2.2 Submit Form

The Submit Form transaction allows a Form Filler to submit form instance data to a Form Receiver actor.

17.2.2.3 Archive Form

555 The Archive Form transaction allows a Form Filler to submit form instance data to a Form Archiver actor.

17.2.2.4 Retrieve Clarifications

The Retrieve Clarifications transaction allows a Form Filler to request the set of clarifications for a given organization from a Form Manager.

560 **17.3 Retrieve Form for Data Capture Integration Profile Options**

Options that may be selected for this Integration Profile are listed in the table 17.3-1 along with the Actors to which they apply. Dependencies between options when applicable are specified in notes.

Table 17.3-1 Actors and Options

Actor	Options	Vol & Section
Form Filler	Archive Form	ITI TF-2:3.36
Form Filler	Data Clarifications	ITI TF-2:3.37
Form Filler	SOAP Transport	ITI TF-2:3.34.4.1.3
Form Manager	SOAP Transport	ITI TF-2:3.34.4.1.3
Form Receiver	SOAP Transport	ITI TF-2:3.35.4.1.3
Form Archiver	SOAP Transport	ITI TF-2:3.36.4.1.3

565 **17.3.1 Archive Form Option**

The Archive Form option allows a Form Filler to submit, for archival purposes, the form instance data to a Form Archiver.

17.3.2 Data Clarifications Option

570 The Data Clarifications option allows a Form Filler to retrieve clarifications and submit updates
,to a Form Receiver for data that have been previously submitted.

17.3.3 SOAP Transport

575 In addition to the required HTTP transport for all transactions, an actor may choose to implement
the transactions using the SOAP mechanism defined sections in ITI TF-2:3.34, TF-2:3.35 and
TF-2:3.36.

17.4 Retrieve Forms for Data Capture Process Flow

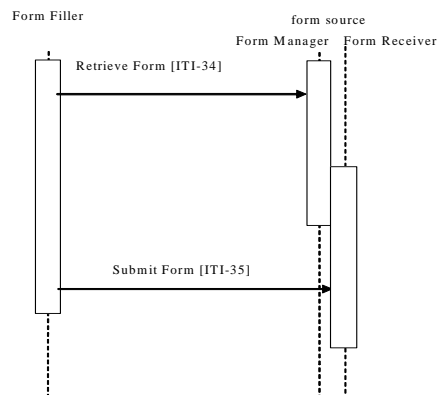
580 This section describes the process and information flow when a form is retrieved for data capture
and subsequently submitted upon partial or full completion. The criteria for determining whether
or not the form is “complete” is outside the scope of this profile.
Five cases are distinguished.

- **Case 1:** This case illustrates a simple, Retrieve Form using a known formID.

585 The identifier of a form, the formID, is known to the Form Filler, such as may happen during the registration process for participation in a Clinical Trial. formID values could also be communicated with by publication of form directories or by personal communications. The method of acquisition of the formID is outside the scope of this profile and is a precondition for the Retrieve Form request.

590 The Form Manager and Form Receiver are grouped on the same system functioning as the form source.

595 The Form Filler makes a Retrieve Form request to a Form Manager. The Form Manager either returns the requested form, or an error indicating no form is available. When a form is returned, the Form Filler will subsequently submit the form instance data to a Form Receiver using the Submit Form transaction. Since the Form Manager and Form Receiver are grouped, there may be communications between the Form Receiver and the Form Manager, as would be necessary to support partially completed forms, but these communications are internal and are not IHE transactions.



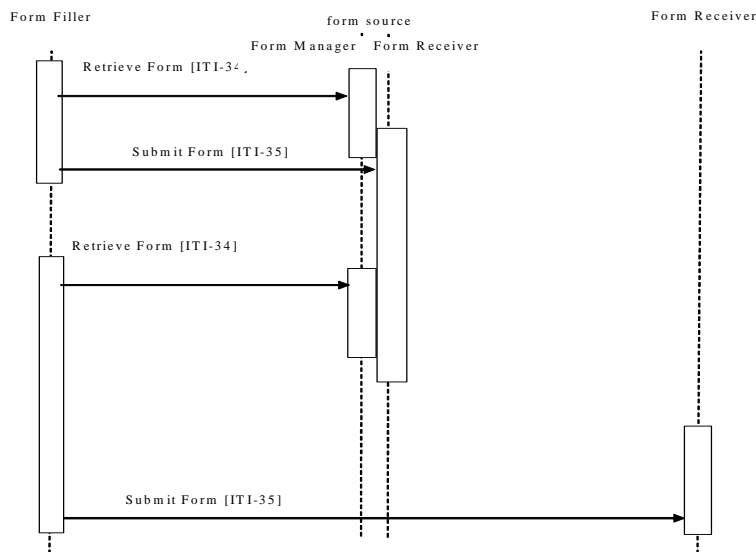
600 **Figure 17.4-1 Case 1: Retrieve Form and Submit Form;
Form Manager grouped with Form Receiver**

- **Case 2:** This case illustrates that a Form Receiver may be standalone (i.e., not grouped with a Form Manager).

605 The identifier of a form, the formID, is known to the Form Filler; there is a grouped Form Manager and Form Receiver on one system supporting intermediate form storage, and a separate Form Receiver on a different system for final storage of form data.

610 The Form Filler makes a Retrieve Form request to a Form Manager. The Form Manager either returns the requested form or an error indicating no form is available. When a form is returned, the Form Filler submits partially complete forms to the intermediate Form Receiver. This partially completed form can be retrieved with another Retrieve Form request to the Form Manager, and final completed form data can be submitted to the final storage, standalone, Form Receiver, such as a national data registry. The action upon submit is controlled by the XForm, hence the Form Manager is responsible for defining the post-submit action by selection of, or generation of, the desired action during the Retrieve Form transaction processing.

615



620

Figure 17.4-2 Case 2: Retrieve Form, Submit Form; Form Manager separate from Form Receiver

- **Case 3:** In this case the Form Filler supports the Archive option.

The Form Filler makes a Retrieve Form request to a Form Manager. The Form Manager either returns the requested form or an error indicating no form is available. When a

625 form is returned and subsequently submitted, form instance data is submitted to the Form Receiver and also to the Form Archiver.

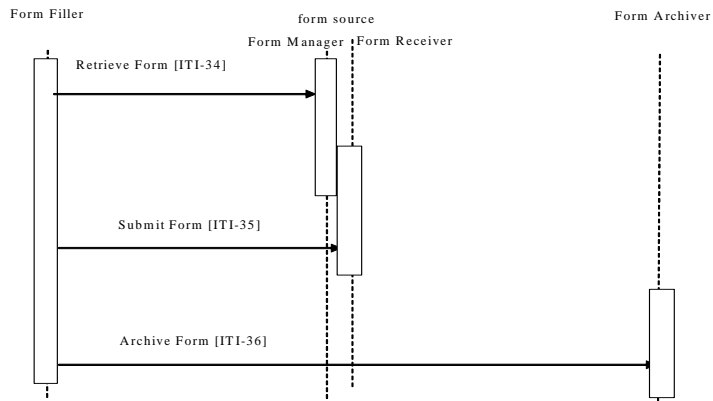


Figure 17.4-3 Case 3: Retrieve Form, Submit Form, Archive Form

- 630 • **Case 4:** This case illustrates one way to use Form design to solve the issue where a formID is not known in advance.

635 The identifier of a form, the formID, is not known to the Form Filler, but a set of context value (name, value) pairs is known. A context form where these values could be entered would have a formID. Information collected by the instance of a context form would be used by the Form Manager to determine the appropriate data capture form to return to the Form Filler.

640 The Form Filler has enough information to request a context form, that is a form collects information that can help the Form Manager determine the actual data capture form. The Form Filler completes the context form, submits this to the Form Receiver which returns either new instance data, or a new form. The action upon submit is controlled by the XForm, hence the Form Manager controls this at the time of XForm selection or creation. This process can be repeated as needed.

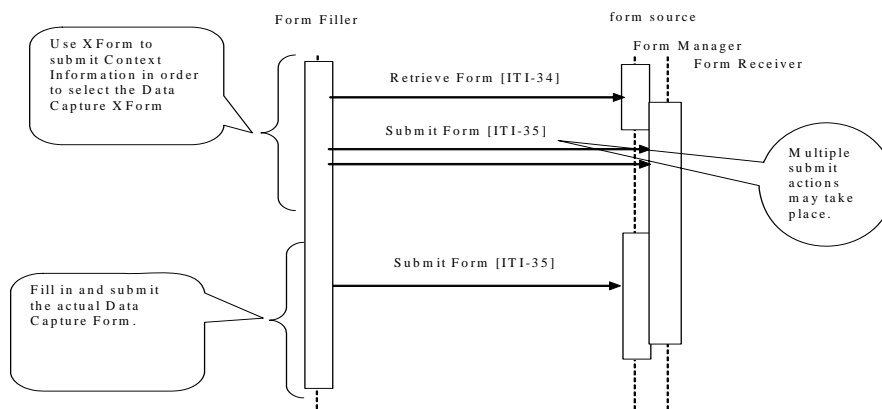


Figure 17.4-4 Case 4: Retrieve Form using an XForm; Submit Form

- 645 • **Case 5:** In this case the Form Filler supports the Data Clarifications option.

650 The Form Filler makes a Retrieve Clarifications request to a Form Manager. The interactions of Form Receiver and Form Manager are outside of the scope of this profile. An example of a solution for providing clarification information to a Form Manager is to group the Form Manager with the Form Receiver, as shown in Figures 17.4-5 and 17.4-6. The request made by the Form Filler contains an organization identifier allowing the Form Manager to return only the set of clarifications relevant to the organization making the request. The Form Manager returns a form containing the necessary information to allow the site or organization making the request to amend the data as required. These Retrieve Clarifications request must be periodically executed by the Form Filler. The

frequency of request is likely based upon some duration as defined or agreed upon by the Form Manager / Form Receiver.

660

The Form Manager can return either a form containing the data to be modified or a form containing a list of references to other forms. In the second case, the references are used to obtain the individual forms using the Retrieve Form transaction. In both cases the data are then modified and submitted to the Form Receiver using the Submit Form transaction. Submitted data may then be evaluated by the data manager of the sponsor for proper handling.

665

The profile does not distinguish between the two responses, the content returned within the form allows the user of the Form Filler to process the form returned in the appropriate manner.

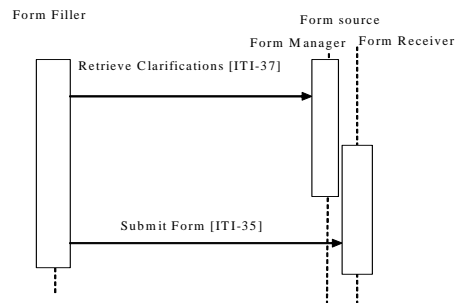
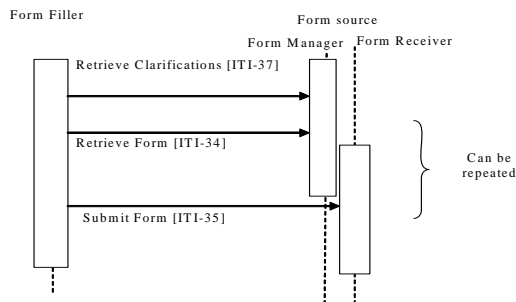


Figure 17.4-5 Case 5: Form Filler supporting Data Clarifications Option



670

Figure 17.4-6 Case 5: Form Filler supporting Data Clarifications Option

17.5 Security Considerations

17.5.1 RFD Risk analysis Risk Assessment

675 The risk analysis for RFD enumerates assets, threats, and mitigations. The complete risk data is stored and available from IHE².

680 The purpose of this risk assessment is to notify vendors of some of the risks that they are advised to consider when implementing RFD actors. For general IHE risks and threats, please see ITI TF-1:Appendix L. The vendor is also advised that many risks cannot be mitigated by the IHE profile and instead responsibility for mitigation is transferred to the vendor, and occasionally to the affinity domains, individual enterprises and implementers. In these instances, IHE fulfills its responsibility to notify affected parties through the use of the following sections.

17.5.2 Recommendations

The high impact risks include: accuracy errors, mismatch between data and schema, disclosure of trade secrets. This profile includes the mitigations:

685 **M1.** If the user notices that the wrong form has been retrieved they will discard the form. Since Form Retrieval is stateless, a discard of the form shall cause no problems.

M2. The XForms model provides for schema validation of the data model. The XForms plugins responsible for processing and displaying XForms, which are outside of this profile, are required to validate forms.

690 **M3.** TLS may be implemented, so that those affinity domains and enterprises that need privacy protection and site authentication can use it. (Implementations must provide the TLS, but the decision to activate it is up to the affinity domain and enterprises.)

M4. Form validations will prevent submission of forms with missing data.

695 **M5.** The RFD Archive Form Transaction for saving source data to a trusted third party is an option that it is available to enterprises. These mitigations are transferred to Vendors and Clients.

700 **T1.** IHE recommends that providers evaluate and review forms as presented before entering data and submitting. Provider review is an essential part of the forms retrieval and submission process to ensure data is entered into the correct form and for the correct patient. Vendors are cautioned not to use RFD for unmediated treatment or diagnosis. A doctor must always intervene prior to treatment or diagnosis to ensure that errors that may occur in transit are checked by a human prior to engaging in any treatment or diagnosis of a patient.

T2. XForms allows for basic data validity checks within the form. It is the responsibility of the XForms designers/implementers to take advantage of this to protect against entry errors, etc.

² The risk analysis data may be found at: ftp://ftp.ihe.net/IT_Infrastructure/iheityr5-2007-2008/Technical_Cmte/Profile_Work/RFD/RFD%20Risk%20Analysis%202007-05-15.xls

- 705 **T3.** The need for partially filled forms identifies this as a workflow issue within the organization(s) supplying the data.
- T4.** Forms and workflow designers should break forms into sequential step forms if possible.
- T5.** Forms Design should facilitate evaluation of workflow and gaps.
- T6.** Access control and security at the client site are important mitigating factors to potential disclosures.
- 710 **T7.** Policy controls are recommended to determine which systems may be used to perform the Form Filler actor.
- T8.** Policy controls are recommended to determine which users may fill out forms.
- T9.** This profile does not require audit logging. An enterprise audit logging process is recommended to reduce errors and track malicious behavior.
- 715 **T10.** An application feature to support roll back of forms data may be needed.
- T11.** Notification of the need to clarify data.
- T13.** Forms Managers, Receivers, Archivers must be on well protected systems.
- T14.** Network and Infrastructure and Systems robustness must be considered, especially for forms applications that are to be used during disasters, epidemics, and other situations where the local infrastructure may be significantly disrupted.
- 720 **T15.** Forms should be designed for high latency, low bandwidth links if they are for applications that are to be used during disasters, epidemics, and other situations where the local infrastructure may be significantly disrupted.
- T16.** Form Fillers should be robust in the face of user error, network failure, and underlying hardware failures.
- 725 **T17.** Workflow must be addressed in the requirements gathering phase. Vendors are advised to discuss investigator workflow with clients.
- T18.** Vendors are advised to consider the implications of their logging and audit repository implementation.

730 **<Appendix A> Actor Summary Definitions**

Add the following Actor Descriptions in Appendix A

- Form Filler:** the actor responsible for retrieving a form from a Form Manager, and for submitting form instance data to a Form Receiver. The Form Filler may optionally be responsible for retrieving clarifications information from a Form Manager.
- 735 **Form Manager:** the actor that supplies a form based upon a request that supplies a form identification. The Form Manager also supplies clarification information.
- Form Receiver:** the actor that receives form instance data.

Form Archiver: the actor responsible for receiving form instance data for archival purposes.

<Appendix B> Transaction Summary Definitions

740 *Add the following Transaction Descriptions in Appendix B*

Retrieve Form: This transaction retrieves the requested form from a Form Manager.

Submit Form: This transaction submits form instance data to a Form Receiver.

Archive Form: This transaction, which is a subclass of the XForms submit, supplies the form instance data to a Form Archiver.

745 **Retrieve Clarifications:** This transaction retrieves a set of clarifications from a Form Manager.

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3 IHE Transactions

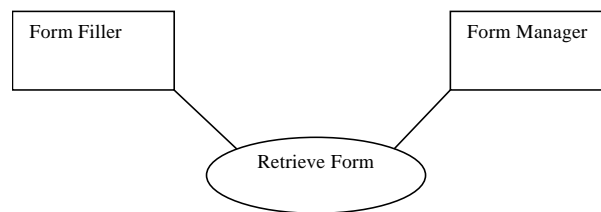
3.34 Retrieve Form

750 This section corresponds to Transaction ITI-34 of the IHE IT Infrastructure Technical Framework. Transaction ITI-34 is used by the Form Filler and Form Manager actors.

3.34.1 Scope

This transaction involves a Form Filler requesting a form from a Form Manager. The Form Filler has a formID, obtained by a means that is outside the scope of this profile, and the Form Manager will either return a form corresponding to the given formID or else it returns an error response. Forms are XForms.

3.34.2 Use Case Roles



Actor: Form Filler

760 **Role:** A forms display and editing system capable of allowing form fields to be completed.

Actor: Form Manager

Role: A system that provides forms based upon requests that provide specific formIDs.

3.34.3 Referenced Standards

Additional educational information may be found on the IHE Wiki.

765 IETF RFC1738, Uniform Resource Locators (URL), December 1994,
<http://www.faqs.org/rfcs/rfc1738.html>

IETF RFC2616 HyperText Transfer Protocol HTTP/1.1

Extensible Markup Language (XML) 1.0 (Second Edition). W3C Recommendation 6 October 2000. <http://www.w3.org/TR/REC-xml>.

770 ITI TF-2: Appendix V Web Services for IHE Transactions

XForms 1.1, W3C Working Draft. <http://www.w3.org/TR/2004/WD-xforms11-20041115/>

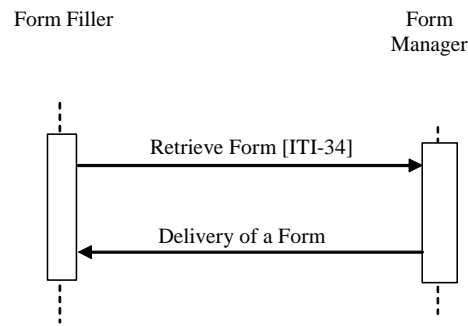


Figure 3.34.4: Interaction Diagram

775 **3.34.4.1 Retrieve Form**

Retrieve Form involves a Form Filler requesting a form from a Form Manager. The Form Filler must supply a formID in order to make a Retrieve Form transaction.

780 If the Form Filler needs to have the returned form submit instance data to a specific Form Archiver, then the Retrieve Form shall include an archiveURL argument, as a URL pointing to the Form Archiver actor. See 3.34.4.1.4 where this is further discussed as an expected action of the Form Manager.

785 If the Form Filler wants to request that Form Filler context information be used in the selection and/or creation of the returned form, then the prepopData argument is supplied with well-formed xml representing the Form Filler context. Specification of the prepopData schema is left to future content profiles.

3.34.4.1.1 Trigger Events

The Retrieve Form is triggered by a Form Filler submitting a formID to a Form Manager actor. The profile does not specify when the Retrieve Form by formID happens, only that this transaction is available when a copy of a form is needed from a Form Manager.

790 **3.34.4.1.2 HTTP Message Semantics**

The HTTP Message Semantics differ depending upon whether the Form Filler needs to provide data to the Form Manager in order to pre-populate a form instance.

When the Form Filler is not pre-populating the form, the Retrieve Form transaction shall be supported by invocation of an HTTP-GET by the Form Filler with the following parameters:

795

Parameter Name	REQ	Description	Value
formID	R	Identifies the form to both actors	This value is a string.
archiveURL	O	Identifies the URL of a Form Archiver.	This value is a URL

Alternatively, when the Form Filler needs to supply the Form Manager with pre-populating, context, information, the Retrieve Form transaction shall be supported by invocation of an HTTP-POST request by the Form Filler with the following parameters:

Parameter Name	REQ	Description	Value
formID	R	Identifies the form to both actors	This value is a string.
archiveURL	O	Identifies the URL of a Form Archiver.	This value is a URL
prepopData	R	The xml context information supplied by a Form Filler for use in pre-populating XForm fields	This value is a well-formed xml document.

800 3.34.4.1.3 SOAP Transport

When the Form Filler and Form Manager support the SOAP Transport option, the RetrieveForm transaction shall comply with all requirements described in ITI TF-2:Appendix V Web Services for IHE Transactions. See Appendix W for a reference to Implementation material, such as WSDL and examples.

805 3.34.4.1.4 Expected Actions

The Form Manager shall return the XForm based on the value of the formID provided by the Form Filler. When the Form Filler provides a valid URL in the archiveURL parameter of the request, the Form Manager shall return an XForm that will perform an Archive Transaction upon form submission, in addition to any predefined actions associated with the form submission. As shown in 3.36 Archive Form, this additional archival transaction is between Form Filler and Form Archiver actors. The Form Manager alters the XForm to enable this additional transaction when the Form Filler supplies a URL value for the archiveURL parameter.

When the Form Filler supplies data in the prepopData parameter, the Form Manager may use this information to determine the form to be returned and to pre-populate the fields of the form. The exact use of the prepopData, and the structure, is deferred to the publication of an IHE content profile.

3.34.4.1.4.1 HTTP- method

Upon reception of the Retrieve Form, the Form Manager shall parse the request and shall return the requested form and the HTTP response code 200 – OK.

820 If no form is available then the return shall be an HTTP response code 404 (not found) with the suggested reason-phrase “Form not found”.

3.34.4.1.4.2 SOAP method

825 When the Form Filler and Form Manager support the SOAP Transport option, the response by
the Form Manager is dependent on the encodedResponse input element (see Appendix W for a
reference to Implementation material, such as WSDL and examples). If encodedResponse is
'true', then the response from the Form Manager shall be either a Structured(XML) or
Unstructured (non-XML) element. If encodedResponse is 'false', then the response from the
Form Manager shall be a URL element that can be used directly by a web browser for retrieval
and operation of the form. When the encodedResponse parameter is 'true' and the response from
830 the Form Manager is either a Structured (XML) or Unstructured (non-XML) element, then all
anchor addresses that are not fragment identifiers shall be composed of absolute URIs.

3.34.4.2 Delivery of a Form

3.34.4.2.1 Trigger Events

835 The Delivery of a Form is triggered by a Form Manager actor responding to a Retrieve Form
request.

3.34.4.2.2 Message Semantics

The XForm is returned in response to the HTTP RetrieveForm, or, as noted in 3.34.4.1.2, a URL
element is returned.

3.34.4.2.3 Expected Actions

840 The Form Filler may display the XForm or navigate to the returned URL to retrieve the XForm.

3.35 Submit Form

This section corresponds to Transaction ITI-35 of the IHE IT Infrastructure Technical
Framework. Transaction ITI-35 is used by the Form Filler and Form Receiver actors.

3.35.1 Scope

845 This transaction involves a Form Filler submitting a form to a Form Receiver.

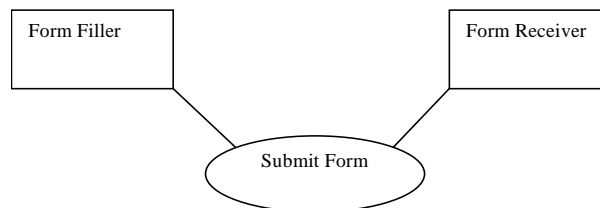


Figure 3.35.2: Use Case Roles

Actor: Form Filler

850 **Role:** A forms display and editing system capable of allowing form fields to be completed.

Actor: Form Receiver

Role: A system that receives submitted forms.

3.35.3 Referenced Standards

855 IETF RFC1738, Uniform Resource Locators (URL), December 1994,
<http://www.faqs.org/rfcs/rfc1738.html>

IETF RFC2616 HyperText Transfer Protocol HTTP/1.1

Extensible Markup Language (XML) 1.0 (Second Edition). W3C Recommendation 6 October 2000. <http://www.w3.org/TR/REC-xml>.

ITI TF-2: Appendix V Web Services for IHE Transactions

860 XForms 1.1, W3C Working Draft. <http://www.w3.org/TR/2004/WD-xforms11-20041115/>

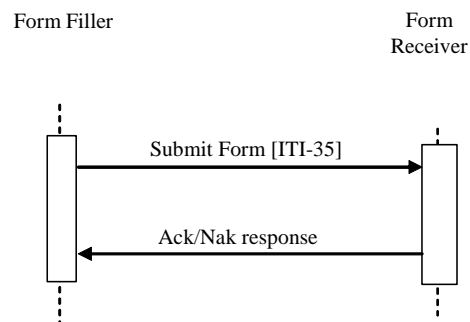


Figure 3.35.4: Interaction Diagram

3.35.4.1 Submit Form

865 This transaction is initiated whenever a Form Filler needs to submit form instance data to a Form Receiver.

3.35.4.1.1 Trigger Events

The Submit Form is triggered by the submission action of the XForm, as defined by an `<xforms:submission>` element within the XForm. An example of this would be the click of a

870 button displayed on the Form. See
http://wiki.ihe.net/index.php?title=Retrieve_Form_for_Data_Capture#XForms_in_General for
more details on XForms.

3.35.4.1.2 HTTP Message Semantics

875 The Submit Form transaction is performed by invocation of an HTTP-POST by the Form Filler,
submitting the XForm instance data (xml) to a Form Receiver.

3.35.4.1.3 SOAP Transport

880 When the Form Filler and Form Receiver support the SOAP Transport option the SubmitForm
transaction shall comply with all requirements described in ITI TF-2:Appendix V Web Services
for IHE Transactions. See Appendix W for a reference to Implementation material, such as
WSDL and examples.

3.35.4.1.4 Expected Actions

885 Upon reception of the Submit Form, the Form Receiver shall parse the request and shall return
the HTTP response code 200 – OK. The xml instance data may be saved by the Form Receiver.
Additionally, the Form Receiver may return new form instance data, or it may return a new
XForm.

If the Form Receiver cannot recognize the posted data, then the Form Receiver shall return the
HTTP response code 400 – Bad Request.

3.36 Archive Form

890 This section corresponds to Transaction ITI-36 of the IHE IT Infrastructure Technical
Framework. Transaction ITI-36 is used by the Form Filler and Form Archiver actors.

3.36.1 Scope

This transaction involves a Form Filler submitting form instance data to a Form Archiver.

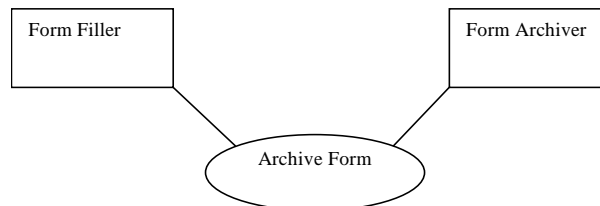


Figure 3.36.2: Use Case Roles

895

Actor: Form Filler

Role: A forms display and editing system capable of allowing form fields to be completed.

Actor: Form Archiver

Role: A system that receives submitted forms for archival purposes.

900 **3.36.3 Referenced Standards**

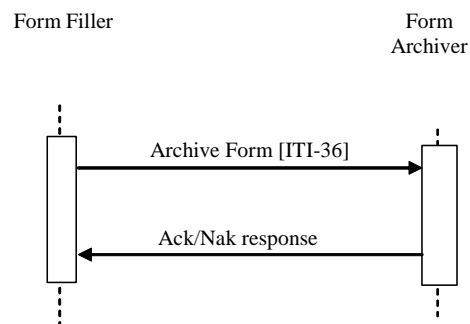
IETF RFC1738, Uniform Resource Locators (URL), December 1994,
<http://www.faqs.org/rfcs/rfc1738.html>

IETF RFC2616 HyperText Transfer Protocol HTTP/1.1

905 Extensible Markup Language (XML) 1.0 (Second Edition). W3C Recommendation 6 October
2000. <http://www.w3.org/TR/REC-xml>.

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XForms 1.1, W3C Working Draft. <http://www.w3.org/TR/2004/WD-xforms11-20041115/>



910 **Figure 3.36.4: Interaction Diagram**

3.36.4.1 Archive Form

This transaction is initiated whenever a Form Filler needs to submit a copy of form instance data to a Form Archiver for archival purposes.

915 **3.36.4.1.1 Trigger Events**

The Archive Form is triggered by the submission action of the XForm, as defined by an <xforms:submission> element within the XForm. This instance of an <xforms:submission>

element is not the same instance used for the Submit Form transaction – the location specified shall differ from that specified by the Submit Form element.

920 **3.36.4.1.2 HTTP Message Semantics**

The Archive Form transaction is performed by invocation of an HTTP-POST by the Form Filler, submitting the XForm instance data (xml) to a Form Archiver.

3.36.4.1.3 SOAP Transport

925 When the Form Filler and Form Archiver support the SOAP Transport option, the Archive Form transaction shall comply with all requirements described in ITI TF-2:Appendix V Web Services for IHE Transactions. See Appendix W for a reference to Implementation material, such as WSDL and examples.

3.36.4.1.4 Expected Actions

930 Upon reception of the Archive Form, the Form Archiver shall parse the request and shall return the HTTP response code 200 – OK. The xml instance data, i.e., the entire xml document, shall be saved by the Form Archiver.

If the Form Archiver fails to save the xml instance data then the Form Archiver shall return the HTTP response code 500 – Internal Server Error.

935 If the Form Archiver cannot recognize the form Submission, then the Form Archiver shall return the HTTP response code 400 – Bad Request.

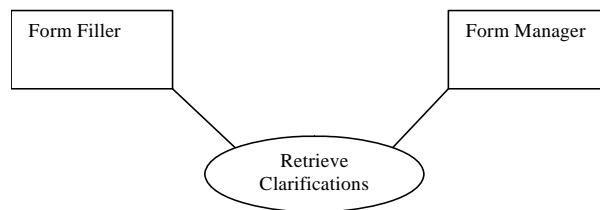
3.37 Retrieve Clarifications

This section corresponds to Transaction ITI-37 of the IHE IT Infrastructure Technical Framework. Transaction ITI-37 is used by the Form Filler and Form Manager actors.

3.37.1 Scope

940 This transaction involves a Form Filler requesting a set of clarifications from a Form Manager. A Form Filler supporting the Retrieve Clarifications option shall perform this request periodically, based upon a duration defined by or agreed upon with the Form Manager / Form Receiver. Note that not all use cases will need to support this option.

945 The Form Filler has an orgID, obtained by a means that is outside the scope of this profile, and the Form Manager will either return a form that contains either the data to be clarified or a set of links to other forms that can be retrieved using the Retrieve Form transaction. The items returned by the Form Manager are Forms that are XForms. All updates / clarifications / new data are submitted to the Form Receiver using the Submit Form transaction.



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Figure 3.37.2: Use Case Roles

Actor: Form Filler

Role: A forms display and editing system capable of allowing form fields to be completed.

Actor: Form Manager

955

Role: A system that provides clarification information based upon requests that provide specific orgIDs.

3.37.3 Referenced Standards

IETF RFC1738, Uniform Resource Locators (URL), December 1994,
<http://www.faqs.org/rfcs/rfc1738.html>

960

IETF RFC2616 HyperText Transfer Protocol HTTP/1.1

Extensible Markup Language (XML) 1.0 (Second Edition). W3C Recommendation 6 October 2000. <http://www.w3.org/TR/REC-xml>.

ITI TF-2: Appendix V Web Services for IHE Transactions

XForms 1.1, W3C Working Draft. <http://www.w3.org/TR/2004/WD-xforms11-20041115/>

965

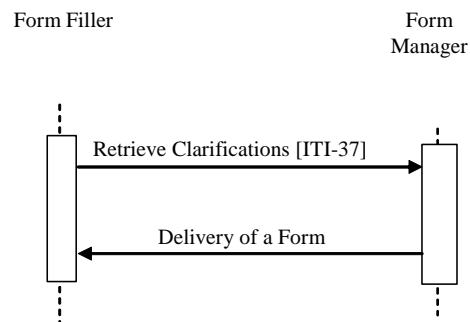


Figure 3.37.4: Interaction Diagram

3.37.4.1 Retrieve Clarifications

970 This transaction is initiated whenever a Form Filler which supports the Retrieve Clarifications option needs to obtain clarification information relevant to the organization or site.

3.37.4.1.1 Trigger Events

975 The Retrieve Clarification event is triggered by the need for information on current clarifications to be made available within an EHR system. The profile does not specify when the Retrieve Clarification happens, only that this transaction is available when information regarding clarifications is needed from a Form Manager. It is the responsibility of the Form Filler that supports this option to periodically execute this transaction.

3.37.4.1.2 HTTP Message Semantics

980 The Retrieve Clarification transaction shall be performed by invocation of an HTTP-GET by the Form Filler. The Form Filler actor generates the request whenever a user needs the set of clarifications from a Form Manager.

The request shall include the following parameters to identify the form to be returned, and the optional Form Archiver.

Parameter Name	REQ	Description	Value
orgID	R	Identifies the organization requiring the clarifications	This value is a string.
archiveURL	O	Identifies the URL of a Form Archiver.	This value is a URL

985 3.37.4.1.3 SOAP Transport

When the Form Filler and Form Manager support the SOAP Transport option, the RetrieveClarification transaction shall comply with all requirements described in ITI TF-2:Appendix V: Web Services for IHE Transactions. See Appendix W for a reference to Implementation material, such as WSDL and examples,.

990 3.37.4.1.4 Expected Actions

The Form Manager returns the set of clarifications that match the given orgID.

3.37.4.1.4.1 HTTP Method

995 Upon reception of the Retrieve Form, the Form Manager shall parse the request and shall return the clarifications which match the orgID provided by the Form Filler and the HTTP response code 200 – OK.

If no clarification information is available then the return shall be a form (with an HTTP response code 200 – OK) indicating that no clarification information is available.

If no form is available for the given orgID then the return shall be an HTTP response code 404 (not found) with the suggested reason-phrase “Form not found”.

1000 3.37.4.1.4.2 SOAP Method

1005 In the case when the SOAP RetrieveClarifications message is used, see Appendix W for a reference to Implementation material, such as WSDL and examples, the response by the Form Manager is dependent on the encodedResponse input element. If encodedResponse is ‘true’, then the response from the Form Manager shall be either a Structured(XML) or Unstructured (non-XML) element. If encodedResponse is ‘false’, then the response from the Form Manager shall be a URL element that can be used directly by a web browser for retrieval and operation of the form. When the encodedResponse parameter is ‘true’ and the response from the Form Manager is either a Structured (XML) or Unstructured (non-XML) element, then all anchor addresses that are not fragment identifiers shall be composed of absolute URIs.

1010 3.37.4.2 Delivery of a Form

3.37.4.2.1 Trigger Events

The Delivery of a Form is triggered by a Form Manager actor providing an XForm based upon the orgID supplied with the Retrieve Clarifications transaction.

3.37.4.2.2 Message Semantics

1015 The XForm is returned in response to the HTTP Retrieve Clarifications, or, as noted in 3.37.4.1.2, a URL element is returned.

3.34.4.2.3 Expected Actions

The Form Filler may display the XForm or navigate to the returned URL to retrieve the XForm.