

ACC, HIMSS and RSNA  
Integrating the Healthcare Enterprise



5 **IHE IT Infrastructure Technical Framework  
Supplement 2006-2007**

10 **Retrieve Form for Data Capture  
(RFD)**

15 **Trial Implementation Version**

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65 **Foreword**

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 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.

70  
75 The approach employed in the IHE initiative is not to define new integration standards, but rather 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.

80  
85 This initiative has numerous sponsors and supporting organizations in different medical specialty domains and geographical regions. In North America the primary sponsors are the American College of Cardiology (ACC), 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 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 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), 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.

95  
100 The IHE Technical Frameworks for the various domains (IT Infrastructure, Cardiology, Laboratory, Radiology, etc.) define specific implementations of established standards to achieve 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](http://www.ihe.net/Technical_Framework).

105 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  
110 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 March 2007.

115 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 2006 Supplement for Trial Implementation”***

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The IHE IT Infrastructure Technical Committee will address these comments resulting from implementation, connect-a-thon testing, and demonstrations such as HIMSS 2007. Final text is expected to be published in June 2007.

## **1 Introduction**

125 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.

### **1.1 Open Issues and Questions**

- 130 1) This profile is using XForms 1.0. The long-term goal for this profile is to use XForms 1.1; however, that is not yet available. Until such time as XForms 1.1 is available, this will remain in Trial Implementation.
- 2) How are data queries/ data corrections documented?
- 3) At what point does the investigator verify /sign off on the data?
- 135 4) Should the Archive Form transaction be a separate transaction ?
- 5) 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 a unique id for each xform transaction.

- Require forms manager assign a description for each xform transaction
- 140 ○ Audit log includes both in the audit log
- 6) 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.
- 7) Workflow and definition of using XForms by multiple authors should be explored.
- 145 8) Workflow and definition of pushing XForms should be explored.
- 9) Controls for distributed contributors should be explored.

## 1.2 Closed Issues

- 150 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.
- 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.
- 155 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.

## 160 2 Profile Abstract

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.

## 165 3 GLOSSARY

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

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# Volume I – Integration Profiles

## 170 Changes to Sections 1 – 1.X

### 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.

175

*Add the following section to Table 2-1 Integration Profiles Dependencies in section 2.1*

Retrieve Form for Data Capture	ATNA		
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*Add the following new section to section 2.2*

### 180 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.

185

*Add the following new section 17*

## 17 Retrieve Form for Data Capture Integration Profile

190 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.

195 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 site's personnel. Suppose an external agency, through some contractual arrangement, requires data from the site, 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 site's local home application, the EHR

200 Many potential uses of RFD want the form filler to dynamically pre-populate forms from the host application's database. While RFD permits automatic form population, it does not speak to the means of so doing. RFD neither forbids nor encourages such content transfers, but ignores them as out of scope. In fact, RFD avoids dealing with content issues altogether, 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.

210 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 profile supports 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.

215 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. Future extensions to the profile will enable semantic specificity that will in turn allow for more automatic population of data from the host system.

### 17.1 Use Cases

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

225 specific profiles that specify both the use of RFD and the rules for data objects will be in the  
discipline specific IHE Frameworks.

### **17.1.1 Investigational New Drug Clinical Trial Use Case**

230 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  
235 personnel. Holbin Medical Group uses an Electronic Health Record (EHR) and a number of  
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.)

240 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  
245 identified as the Principal Investigator and other study personnel receive protocol-specific  
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.

250 Patricia contacts Corey Jones, a patient at Holbin, about participating in the trial, and Corey  
agrees to participate as a subject. Patricia registers Corey 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.

255 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**

260 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 document. She  
looks up recent lab results in the EHR and records them in the CRF. The EHR provides only a

265 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.)

270 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  
275 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' as part of the permanent source  
record of the trial (in order to meet the requirements of the Federal Code of Regulations 21CFR  
312:62).

280 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  
285 entering the data, perhaps entering data twice a month, or entering the data the week before the  
monitor visit occurs.

### 17.1.1.2 Desired State

290 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  
1234, and requests an electronic case report form from trial #1234's EDC system, using RFD. If  
the trial is sufficiently complex, the RFD profile provides a transaction to retrieve a list of  
relevant forms from the EDC system and display the list for Patricia to choose from. When the  
correct context is established between the EHR and the EDC, Patricia selects the clinical  
295 research tab within the EHR application to reveal 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  
300 information on how to fill out the form.

Patricia interviews Mrs. Jones and enters data into the clinical trial form. Data from the EHR  
database is re-entered or cut and pasted into the proper data fields (which have built-in edit  
checks). (In further stages of evolution, the form will launch automatic data extraction directly  
from the EHR database.) Upon completing the form, Patricia hits the submit button, and the

305 EHR returns the complete form to the EDC system, using RFD. (Note that at this early stage of  
the evolution of RFD, no data are automatically extracted from or posted to the EHR database.  
As the content profile is completed and integrated into the implementation, this situation will  
improve and EHR data will be re-used automatically. In the meantime, RFD provides beneficial  
occupancy for EDC forms within an EHR, and takes an important first step that has, in and of  
310 itself, value.) At the same time, a copy of the document is archived in the site clinical trial  
document vault as part of the permanent source record of the trial.

There has been persistent interest in adding more automatic data capture process to the profile.  
One version of this idea is stated by Steven Schwartz of Allscripts:

315 “Rather than not committing the data to the EHR or merely leveraging existing data from the  
EHR, the form should be designated as a clinical trial form and should be saved as a document in  
that patient’s record with restricted rights. Access would only be provided to the study  
coordinator or other authorized study personnel that are designated within the rights management  
features of the EHR application. That way if an audit of the source record is ever needed, a  
320 monitor can be given access to the original form in which the data were collected, or can be  
taken back via an audit trail to see where and when any of the pre-populated fields were  
collected. Also, the physician would be able to see that the patient came in for a study visit even  
though they would not have authorization to view the data unless they break glass or are given  
rights.”

## **17.1.2 Public Health Reporting Use Cases**

### **325 17.1.2.1 Public Health Scenario 1**

#### **17.1.2.2 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  
330 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  
335 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.

#### **17.1.2.3 Desired State**

340 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 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-populated with EHR mapped data. The health care provider fills out the remaining supplemental information and submits this data electronically to the public health authority. The public health 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.

#### **17.1.2.4 Anthrax & Avian Influenza Scenarios: disease monitoring based on presumptive diagnoses and/or patient ‘problems.’**

355 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, 360 USAMRID), and notifies local hospitals, providers, and media. (This involves a bioterrorist scenario on the back end after ID confirmation – the influenza one below does not, but probably invokes the same pathways.)

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 365 symptoms. Presence of Gram positive rods in sputum is entered directly into the lab system OR 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 370 to the local public health department biosurveillance system (BIS) as presumptively diagnosed 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 375 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- 380 up once notification is disseminated from health department(s) to local providers, is similar to 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

385 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.

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

390 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.

#### 395 17.1.3.1 Current state

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 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.

#### 405 17.1.3.2 Desired state

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 empty fields of the form and submits directly to the FDA Medwatch site.

415 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 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

420 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.

425 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  
430 submissions must be minimized. There should be no assumption in the RFD Profile that there is a unitary “EHR” that is the focal application from which the forms will be filled.

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  
435 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 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  
440 ejection fraction prior to PCI, QCA findings, inventory of the devices used (including bar codes), and medications administered.

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  
445 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 than needing to search through the record for it. The RFD Profile must therefore accommodate both incremental and retrospective preparation models.

Carl Cardiac, a patient, presents at the ED with chest pain, and based on ECG and history is  
450 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 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  
455 filled-in forms back to the forms repository.

460 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 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.

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.

#### 465 **17.1.4.2 Cardiology Use Case 2 – performance measures**

470 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.

475 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**

480 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 re-imbursement, 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](http://www.cancerpetregistry.org).

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

485 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.

490 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.

495 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.

500 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 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.

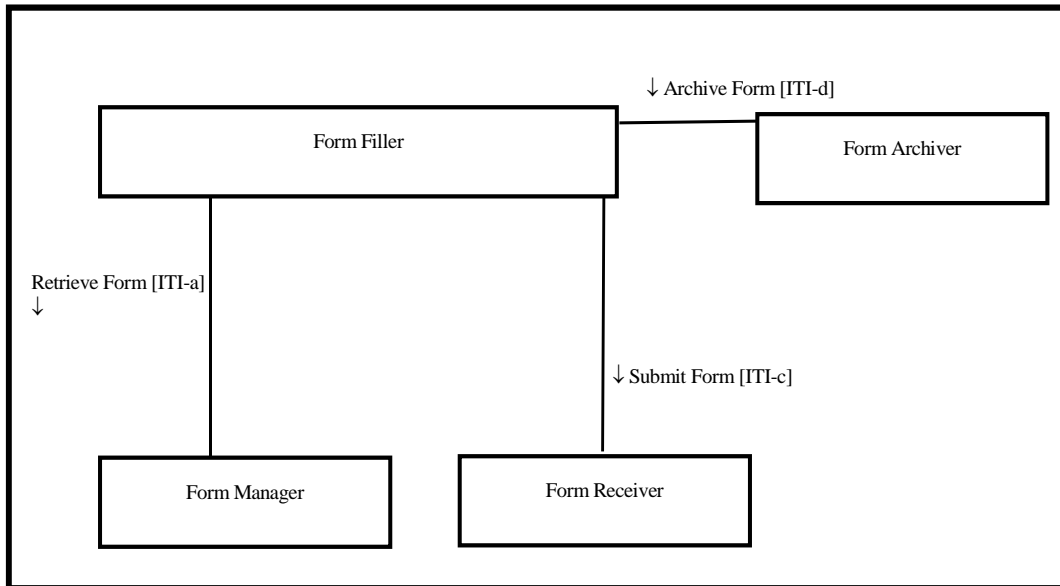
Once the PET scan has been performed and reported, PET-Pros submits a study completion form and a report form (including the report provided to Dr. Jones) to NOPR.

505 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 to PET-Pros and entered into the NOPR database within 30 days of the PET scan.

510 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.

## 17.2 Actors/ Transactions

515 Figure 6.2-1 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.



**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.

525

**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	7.1
	Submit Form	R	7.2
	Archive Form	O	7.3
Form Manager	Retrieve Form	R	7.1
Form Receiver	Submit Form	R	7.2
Form Archiver	Archive Form	R	7.3

530

## 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.

535

**Table 17.3-1 Actors and Options**

Actor	Options	Vol & Section
Form Filler	<i>Archive Form</i>	Vol 2. 7.3

### 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.

## 17.4 XForms Features of Interest

540

XForms are: standards based, open and non-proprietary, platform independent.

Several of the requirements and options of this profile are based upon features of XForms. The following is a list of features that XForms authors and designers may need to consider in the design of XForms, or that XForms consumers may need to understand.

545

- XForms Instance Data is an XML element within the XForm package.
- Advanced branching logic, data element value checking, and consistency may be provided by the design of an XForm.
- Optional and acceptable values may be specified to allow for “partially complete forms”, however care must be taken in the form design and data instance schema.

550

- The XForms Submit Protocol specifies where and how instance data is to be submitted. It also defines how the information returned after submit is to be applied. The default behavior is to replace the form, but another action is replacement of instance data. In the examples shown in the next section, use of these two actions is noted as they are integral to achieving the desired functionality.

555

- Retrieval of partially complete forms, and submission of incremental updates to form instance data is possible but requires care in forms design.
- Capturing author information as a part of instance data may be useful to provide information about the person submitting the form.
- Information on how to fill out a form may be designed into an XForm

560

- XForms features may allow for sponsor branding.
- Pre-population of information into instance data will rely upon the constraint in this profile that the instance data will have an id attribute value of “RFDInstanceData”. The xml of the

instance data will need to be parsed and updated inline into the xml of the XForm before the XForm is passed to the plug-in in order for pre-population to work.

- 565 • There are many more features of XForms to consider; see <http://www.w3.org/TR/2006/REC-xforms-20060314/>

## 17.5 Retrieve Forms for Data Capture Process Flow

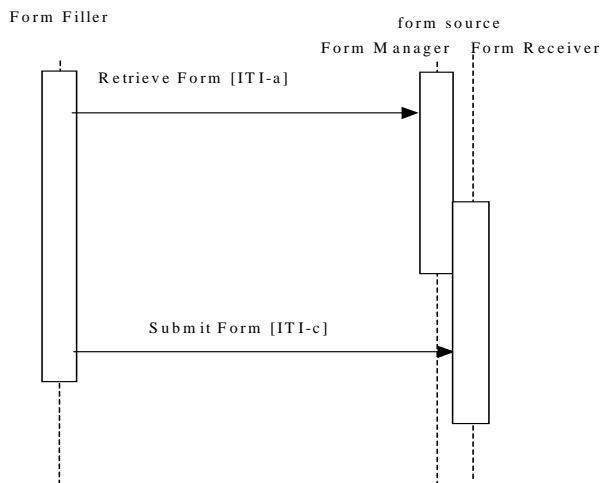
570 This section describes the process and information flow when a form is retrieved for data capture and subsequently submitted upon partial or full completion. Whether or not the form is “complete” is outside the scope of this profile.

Four cases are distinguished.

- 575 • Case 1: The identity of a unique form 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. Acquisition of the FormID is outside the scope of this profile and is a precondition for the Retrieve Form request.

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

585 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 that these communications are internal and are not IHE Transactions.

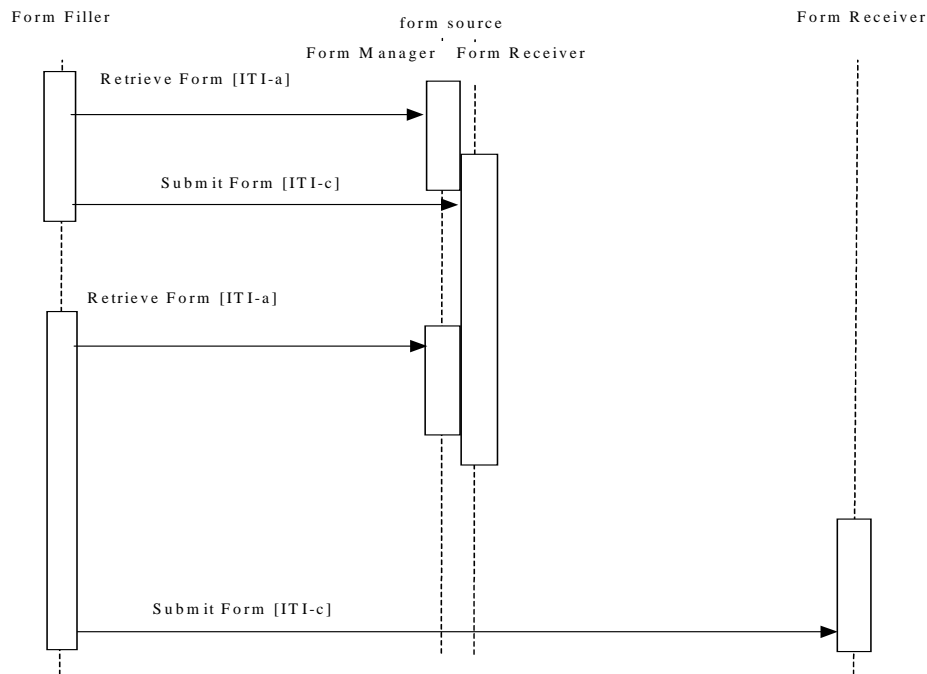


**Figure 17.4-1 Case 1: Retrieve Form and Submit Form**

- 590
- Case 2: The identity of a unique form 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.

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 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 controls this at the time of XForm selection or creation..

600



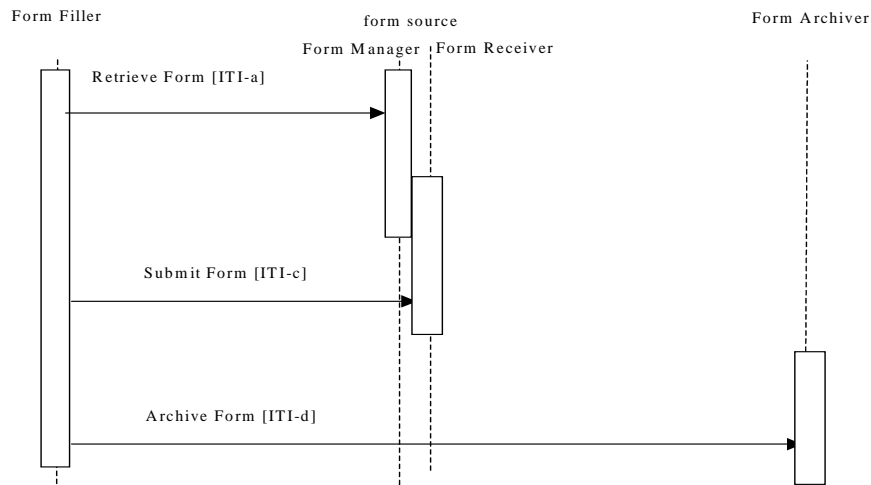
**Figure 17.4-2 Case 2: Retrieve Form, Submit Form**

- Case 3: This case simply includes the Archive option.

605

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 exercise one of the techniques that enables the ability to Archive as an additional XForm save option. When the form is subsequently submitted, form instance data is submitted to the Form Receiver and also to the Form Archiver.

610



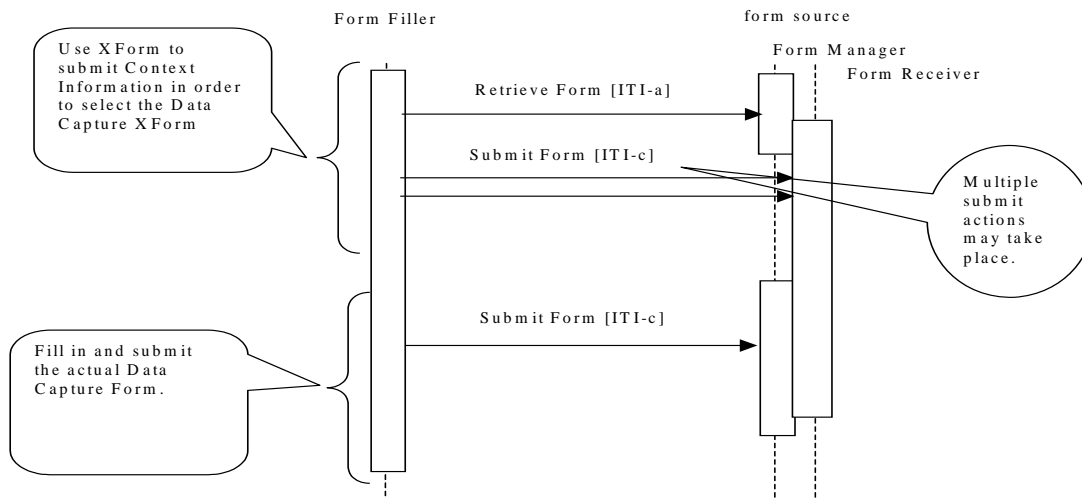
615

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

- Case 4: The identity of a unique form is not known to the Form Filler, but a set of context value (name,value) pairs is known. A context form would have a unique FormID. Information collected by the instance of a context form would be used by the Form Manager to determine the appropriate data collection form.

620

Form Filler knows enough to request a context form that can determine the actual data capture form. The Form Filler completes the context form, submits this to the Form Receiver and is returned 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.



625

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

## 17.6 Security Considerations

### 630 17.6.1 RFD Risk analysis Risk Assessment

The following table is a summary of the risk analysis for RFD. Public comment on the assets, threats, and mitigations are requested. In the trial implementation version this will be replaced by the specified threats, importance ratings, and mitigations. The complete risk data will be stored and maintained in a central location.

635 The purpose of this risk assessment is to notify vendors of some of the risks that they are advised to consider in implementing RFD actors. For general IHE risks and threats, please see appendix L. The vendor is also advised that many risks can not be mitigated by the IHE profile and instead responsibility for mitigation is transferred to the vendor, and occasionally to the client. Especially those identified below. In these instances, IHE fulfills its responsibility to notify affected parties through the use of the following table.

RFD specific information assets	Description/Scenario	Related threats	Likelihood (H, M, L, VL)	Impact (H, M, L, VL)	Importance (Risk level)	Related mitigation activity (Current or proposed) (M# means a risk mitigated in implantation, T# means that the responsibility of mitigation must be transferred to the Vendor or Client, I# recommends improvements to a profile)
Partially filled forms	Workflow requires that forms be able to be completed at a later time, either when information becomes more available (eg: when the patient is available for discussion) or when time becomes available. This creates concerns for the accuracy, integrity, and completeness of the data.	Corruption threats to the integrity and accuracy of the form data such as: <ul style="list-style-type: none"> <li>• completion of the wrong form</li> <li>• patient data mismatch</li> <li>• mismatch between data and schema</li> <li>• accuracy errors</li> <li>• gaps in the data if forms are not properly completed</li> <li>• random corruption (eg: in transit)</li> </ul> Threat of inappropriate disclosure:	H	H	H	<b>M1.</b> TLS for content integrity (Currently available) <b>M2.</b> ATNA audit (Somewhat available) <b>M3.</b> XForms Data validations (Somewhat available) <b>M4.</b> Consistent Time (CT) profile mitigates some corruption and delay threats by establishing consistent time parameters for communication. <b>M5.</b> TCP/IP: using TCP/IP instead of UDP provides some mitigation for transit integrity errors. <b>T1.</b> Education and awareness at the healthcare provider can lead to the early discovery of errors.



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RFD specific information assets	Description/Scenario	Related threats	Likelihood (H, M, L, VL)	Impact (H, M, L, VL)	Importance (Risk level)	Related mitigation activity (Current or proposed) (M# means a risk mitigated in implantation, T# means that the responsibility of mitigation must be transferred to the Vendor or Client, I# recommends improvements to a profile)
		<ul style="list-style-type: none"> <li>random corruption (eg: in transit)</li> </ul> Threat of inappropriate disclosure: <ul style="list-style-type: none"> <li>to competitors</li> <li>to generic hostiles (eg: worms) to hostile individuals</li> </ul>				
Blank Form	Blank forms may contain information pertaining to trade secrets (eg: information about experimental medications not ready for release) or be subject to specific corruption errors.	<ul style="list-style-type: none"> <li>Threat of disclosure of trade secret but not PHI:</li> <li>Disclosure to competitors, intentional or accidental</li> <li>Threat of corruption of data:</li> <li>Getting the wrong form to fill out, causing a collection of the wrong data</li> <li>falsified data because partially complete form is mistaken for blank form</li> </ul>	M	H	H	M1, M2, M3, M4, M5, T1, T2, I1, I2
Patient Safety and Privacy	A corrupt form may affect the safety of the patient by resulting in erroneous prescriptions, or missing or incorrect information upon which a diagnosis is based. There is also a confidentiality risk of disclosure of patient health information to malicious individuals (eg: paparazzi,	Patient safety / corruption threat: <ul style="list-style-type: none"> <li>accuracy of information in forms</li> <li>integrity</li> </ul> Patient confidentiality/disclosure threat: <ul style="list-style-type: none"> <li>Threatens patient trust in healthcare provider</li> </ul>	L	M	L	M1, M2, T1, T2, T3, I1, I2 <b>T7.</b> Vendors are cautioned not to use RFD for unmediated treatment or diagnosis. Ie: 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.
			L	M	M	

IHE IT Infrastructure Technical Framework Supplement – RFD Supplement

RFD specific information assets	Description/Scenario	Related threats	Likelihood (H, M, L, VL)	Impact (H, M, L, VL)	Importance (Risk level)	Related mitigation activity (Current or proposed) (M# means a risk mitigated in implantation, T# means that the responsibility of mitigation must be transferred to the Vendor or Client, I# recommends improvements to a profile)
	hackers, etc)	<ul style="list-style-type: none"> <li>Clinical trial disclosures are more sensitive</li> <li>May have negative impact on patient</li> </ul>				
Relationship between forms manager and forms filler in a double blind study	Clinical trials require that the relationship between the clinic and the trial not be discoverable. Sub-assets: Alias tables as well as other identifying information must be protected	Threat of disclosure of partial information that can lead to the identification of a party participating in the blind study.	VL	M	L	M1, M2, T2, T3
Aggregate data in the forms archive and the forms manager	The collection of multiple patients’ PHI in the forms archive or potentially a forms manager is also susceptible to inappropriate disclosure. Disclosures of multiple patients’ information cause a larger impact than a single patient’s PHI, by definition.	Threat of disclosure of multiple PHI: <ul style="list-style-type: none"> <li>If poorly segregated</li> <li>If poorly protected</li> </ul>	L	H	M	M1, M2, T2, T3
Service delivery timelines	Excessive delays in such as: <ul style="list-style-type: none"> <li>Delay in accessing the form in the filler</li> <li>Delay in receiving the filled form</li> </ul> Can lead to adverse impacts on patient health and safety <b>if the delay is significant</b> . (Minor delays are not considered in this discussion.)	Threat of delayed reception of form to fill out. Threat of delay in reception of filled form. <ul style="list-style-type: none"> <li>Improper routing</li> <li>Denial of Service attack</li> <li>Digital signature/encryption delays</li> <li>Inappropriately difficult access</li> </ul>	M  M	M  H	M	I2  T2. The purpose of identifying this risk in this document is to <b>inform the vendor</b> that network and processor delays must be taken into account in the design phase.

RFD specific information assets	Description/Scenario	Related threats	Likelihood (H, M, L, VL)	Impact (H, M, L, VL)	Importance (Risk level)	Related mitigation activity (Current or proposed) (M# means a risk mitigated in implantation, T# means that the responsibility of mitigation must be transferred to the Vendor or Client, I# recommends improvements to a profile)
		controls (too hard to log in, or too short session timeout)				
Investigator time	Investigators in clinical trials have finite time to dedicate to investigations.	Delay causing threats: <ul style="list-style-type: none"> <li>Multiple data entry systems</li> <li>Time spent on non-productive work</li> </ul>	M	M	M	T4: Workflow must be addressed in the requirements gathering phase. Vendors are advised to discuss investigator workflow with clients.
Auditor time	In the event of a disclosure or other incident, incident investigation can become prohibitively long.	Delay causing threats: <ul style="list-style-type: none"> <li>Incomplete logging</li> <li>Difficult to parse audit trail (poor UI)</li> </ul>	M	M	M	M2, I1 T5: Vendors are advised to consider the implications of their logging and audit repository implementation.
Physical computer assets	Malicious software, and/or malicious individuals can threaten the physical integrity of the hardware used to perform all form functions.	There are related threats to patient safety as well as confidentiality: <ul style="list-style-type: none"> <li>If healthcare can not be provided due to missing forms</li> <li>If stolen hardware contains PHI</li> </ul>	VL	M	L	T6: Healthcare providers/clients of vendors must arrange for appropriate physical security within their operational environment.

640 **17.6.1.1 Recommendations (Analysis conclusions?)**

From this table it becomes clear that most high level risks are consistently mitigated by the implementation of mitigations M1-M5. As a result, vendors must put priority to ensuring strong implementations of CT, ATNA, Xforms.

All other risk mitigations must be addressed in product design or operational implementation.

645

## <Appendix A> Actor Summary Definitions

*Add the following Actor Descriptions in Appendix A*

650 **Form Filler:** the actor responsible for retrieving a form from a Form Manager, and for submitting form instance data to a Form Receiver. The mechanism by which a unique identification of a form is obtained is outside the scope of the Retrieve Form for Data Capture profile.

**Form Manager:** the actor that supplies a form based upon a request that supplies a unique form identification.

**Form Receiver:** the actor that receives form instance data.

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

## <Appendix B> Transaction Summary Definitions

*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.

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

## Volume 2 - Transactions

### 3 IHE Transactions

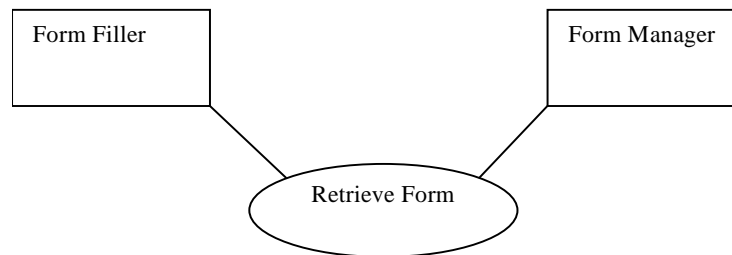
#### 665 3.a. Retrieve Form

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

##### 3.a.1 Scope

670 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. An XForm instance may include the Archive Capability. See Appendix U.2 and U.3 for details and code samples for one way to exercise the Archive Capability.

##### 675 3.a.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

680 **Role:** A system that provides forms based upon requests that provide specific FormIDs.

##### 3.a.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

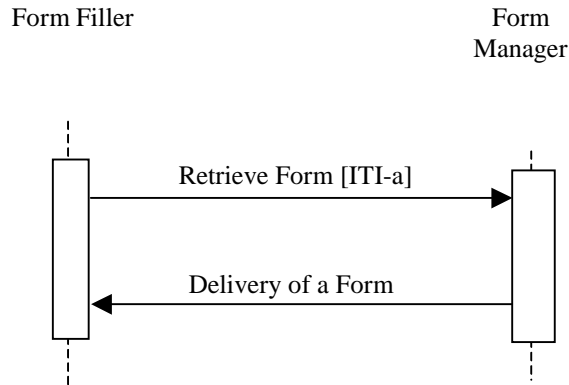
685 Extensible Markup Language (XML) 1.0 (Second Edition). W3C Recommendation 6 October 2000. <http://www.w3.org/TR/REC-xml>.

Web Services Description Language (WSDL) 1.1. W3C Note 15 March 2001.  
<http://www.w3.org/TR/wsdl>.

XForms 1.0 (Second Edition)

690 <http://www.w3.org/TR/2006/REC-xforms-20060314/>

### 3.a.4 Interaction Diagram



#### 3.a.4.1 Retrieve Form

695 This transaction is initiated whenever a Form Filler needs a copy of a form based upon a known FormID. A sample WSDL is provided in Appendix U.1.

#### 3.a.4.2 Trigger Events

700 The Retrieve Form is triggered by the need for some information to be passed from an EHR system to an EDC or other data collection agency as in the use cases discussed in Vol 1. 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.

#### 3.a.4.3 Message Semantics

The Retrieve Form transaction is performed by HTTP-GET. The Form Filler Actor generates the request whenever a user needs a copy of a form from a Form Manager.

705 The request shall include the following parameter to identify the form to be returned.

Parameter Name	REQ	Description	Value
formID	R	Identifies the form to both actors	This value is a string.

The only binding required for both the Form Filler Actor and the Form Manager Actor is the binding to HTTP-GET. In this binding a sample message will be formatted as follows:

710 <http://<location>/RetrieveForm?formID=1.2.3>

### 3.a.4.3.1 XForm Instance Data Constraints

715 The id attribute of the xforms:instance element shall have a value of “RFDInstanceData”. This provides FormFillers a known handle to the instance data, both for adding additional submission elements as well as for the pre-population of instance data elements.

### 3.a.4.3.2 XForms supporting the Archive Capability

Every XForm that provides the Archive Capability shall have the id attribute of an action element assigned the value of “RFDSUBMIT”. This provides Form Fillers with a handle to the submit trigger.

720 See Appendix U.2 for details on the Archive Capability.

### 3.a.4.4 Expected Actions

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.

725 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”.

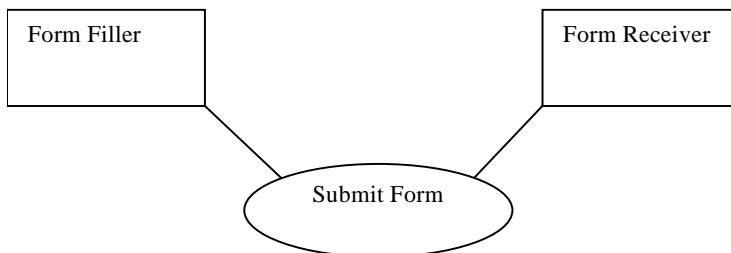
## 3.c Submit Form

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

### 3.c.1 Scope

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

### 3.c.2 Use Case Roles



**Actor:** Form Filler

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

735 **Actor:** Form Receiver

**Role:** A system that receives submitted forms.

### 3.c.3 Referenced Standards

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

740 IETF RFC2616 HyperText Transfer Protocol HTTP/1.1

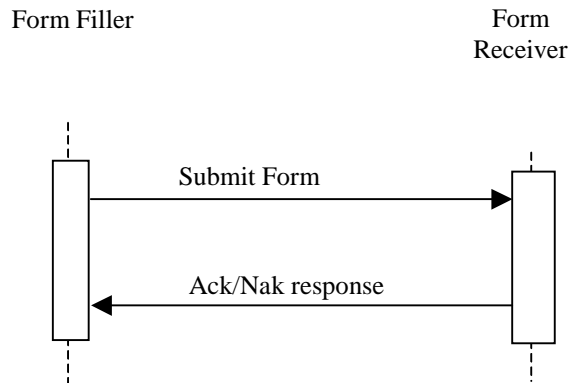
Extensible Markup Language (XML) 1.0 (Second Edition). W3C Recommendation 6 October 2000. <http://www.w3.org/TR/REC-xml>.

Web Services Description Language (WSDL) 1.1. W3C Note 15 March 2001.  
<http://www.w3.org/TR/wsdl>.

745 XForms 1.0 (Second Edition)

<http://www.w3.org/TR/2006/REC-xforms-20060314/>

### 3.c.4 Interaction Diagram



#### 3.c.4.1 Submit Form

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

##### 3.c.4.1.1 Trigger Events

The Submit Form is triggered by the submission action of the XForm.

### 3.c.4.1.2 Message Semantics

755 The Submit Form transaction is performed by invocation an HTTP-POST, submitting the XForm instance data (xml) to a Form Receiver. XForms 1.0 does not currently bind to SOAP.

### 3.c.4.1.3 Expected Actions

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 is saved by the Form Receiver.

760 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.

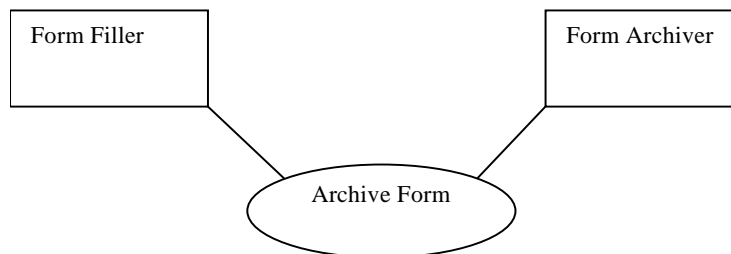
## 3.d Archive Form

765 This section corresponds to Transaction ITI-d of the IHE Technical Framework. Transaction ITI-d is used by the Form Filler and Form Archiver actors.

### 3.d.1 Scope

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

### 3.d.2 Use Case Roles



770

**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.

### 775 3.d.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

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

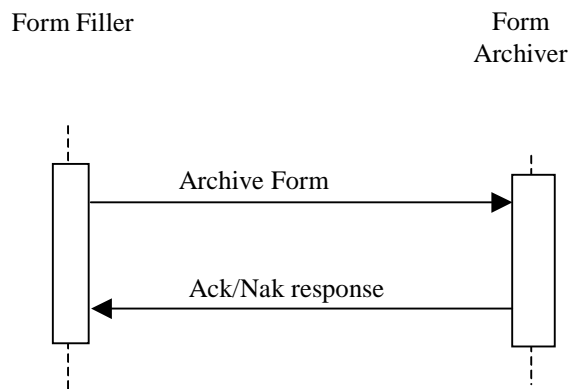
Web Services Description Language (WSDL) 1.1. W3C Note 15 March 2001. <http://www.w3.org/TR/wsdl>.

XForms 1.0 (Second Edition)

<http://www.w3.org/TR/2006/REC-xforms-20060314/>

785

### 3.d.4 Interaction Diagram



#### 3.d.4.1 Archive Form

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

##### 3.d.4.1.1 Trigger Events

The Archive Form is triggered by the submission action within the XForm, where a second save has been assigned to the XForm submission.

##### 3.d.4.1.2 Message Semantics

795 The Archive Form transaction is performed by invocation an HTTP-POST, submitting the XForm instance data (xml) to a Form Archiver. XForms 1.0 does not currently bind to SOAP.

##### 3.d.4.1.3 Expected Actions

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 is saved by the Form Archiver.

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

## U Appendix U: RFD Examples

### U.1 WSDL

805 The WSDL definition of web services will be supplied in a separate file. This code is provided as an example and is not intended to replace the format specification of the transactions in Volume 2.

### U.2 XForms Example: Archive Capability

810 **This section illustrates one method for a Form Manager to support the capability to enable archiving by the Form Filler and the Form Filler to activate the archival**

To support the Archival option, the Form Manager supplies an XForm which includes the following:

- A template for a dynamically built submission definition.

```
<xforms:action ev:event="DOMActivate" id="RFDSSubmit">
```

- 815
- An id attribute value of “RFDInstanceData” on the xforms:instance element

- Script to build the XForms submission for the Submit transaction and the Archive transaction.

```
<script type="">
```

```
    buildSubmits();
```

820

- A separate xforms:model that looks for a data file and a schema file as:

```
<xforms:model id="submitModel" schema="theSubmits.xsd">
```

```
    <xforms:instance id="submitInstance" src="theSubmits.xml"/>
```

```
</xforms:model>
```

- 825
- The script that will create the XForms – see the following example

To exercise the Archival option, the Form Filler supplies:

- The Submit Options Schema file: theSubmits.xsd
- The Submit Options data file: theSubmits.xml

## 830 U.3 Example of XForm with Archive Option

### U.3.1 Sample submit options file: theSubmits.xml

```
835 <?xml version="1.0" encoding="UTF-8"?>
    <theSubmits xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
        xsi:noNamespaceSchemaLocation="theSubmits.xsd">
        <theSubmitList>
            <theAction theMethod="post" theId="one">http://submission.org/cgi-
bin/submitinstance.sh</theAction>
            <theAction theMethod="post" theId="two">http://thearchive.org/cgi-bin/archiveinstance.sh</theAction>
840 </theSubmitList>
    </theSubmits>
```

### U.3.2 Schema for theSubmits.xml

```
845 <?xml version="1.0" encoding="UTF-8"?>
<xs:schema xmlns:xs="http://www.w3.org/2001/XMLSchema"
    elementFormDefault="qualified"
    attributeFormDefault="unqualified">
    <xs:simpleType name="methodType">
    <xs:restriction base="xs:string">
850 <xs:enumeration value="put" />
        <xs:enumeration value="post" />
    </xs:restriction>
    </xs:simpleType>
    <xs:complexType name="actionType">
855 <xs:simpleContent>
        <xs:extension base="xs:string">
            <xs:attribute name="theMethod" type="methodType" />
            <xs:attribute name="theId" type="xs:string" />
        </xs:extension>
    </xs:simpleContent>
860 </xs:complexType>
    <xs:complexType name="submitListType" >
        <xs:sequence minOccurs="0" maxOccurs="unbounded">
            <xs:element name="theAction" type="actionType" />
865 </xs:sequence>
    </xs:complexType>

    <xs:complexType name="submitType">
        <xs:sequence>
870 <xs:element name="theSubmitList" type="submitListType" maxOccurs="1" />
        </xs:sequence>
    </xs:complexType>
    <xs:element name="theSubmits" type="submitType"/>
</xs:schema>
875
```

### U.3.3 XForm as delivered to Form Filler

```
<?xml version="1.0" encoding="ASCII"?>
<html xmlns="http://www.w3.org/1999/xhtml"
  880   xmlns:ev="http://www.w3.org/2001/xml-events"
      xmlns:xforms="http://www.w3.org/2002/xforms"
      xmlns:xml="http://www.w3.org/XML/1998/namespace"
      xmlns:v="http://www.cdisc.org/ns/odm/v1.3">

  <head>
  885   <title>OMD 1.3 Sample</title>

      <xforms:model id="submitModel" schema="theSubmits.xsd">
        <xforms:instance id="submitInstance" src="theSubmits.xml"/>
      </xforms:model>
  890

      <xforms:model id="model_ODM">
        <xforms:instance id="RFDInstanceData"> <!--xform instance data goes here --></xforms:instance>
      </xforms:model>

  895     <script type="">
        function buildSubmits()
        {
          var oModel = document.getElementById("submitModel");
          var oInstance = oModel.getInstanceDocument("submitInstance");
  900
          var pModel = document.getElementById("model_ODM");
          var pInstance = pModel.getInstanceDocument("instance_model_ODM");

          var theSubmits = oInstance.getElementsByTagName("theSubmits");
  905          var theSubmitList = theSubmits[0].getElementsByTagName("theSubmitList");
          var theAction = theSubmitList[0].getElementsByTagName("theAction");

          var submitTrigger = document.getElementById("RFDSubmit");

  910          for(var i = 0; i < theAction.length ;i++) {
            n = document.createElementNS("http://www.w3.org/2002/xforms", "submission");
            n.setAttribute("id" , theAction[i].getAttribute("theId"));
            n.setAttribute("method" , theAction[i].getAttribute("theMethod"));
            n.setAttribute("action" , theAction[i].textContent);
  915            pModel.appendChild(n);

            m = document.createElementNS("http://www.w3.org/2002/xforms", "send");
            m.setAttribute("submission" , theAction[i].getAttribute("theId"));
            submitTrigger.appendChild(m);
  920          }
        }
      </script>

      <link href="gen_Black_and_White.css" rel="stylesheet"/>
  925   </head>
   <body>
```

```
930 <xforms:group>
    <xforms:label>OMD 1.3 Sample</xforms:label>
</xforms:group>
    <xforms:input ref="/v:ODM/@AsOfDateTime" model="model_ODM">
    <xforms:label>As Of Date Time</xforms:label>
    <xforms:hint>Enter a value for AsOfDateTime of type dateTime</xforms:hint>
</xforms:input>
935 <xforms:input ref="/v:ODM/@CreationDateTime" model="model_ODM">
    <xforms:label>Creation Date Time</xforms:label>
    <xforms:hint>Enter a value for CreationDateTime of type dateTime</xforms:hint>
</xforms:input>

940 <xforms:trigger>
    <xforms:label>Submit</xforms:label>
    <xforms:action ev:event="DOMActivate" id="RFDSSubmit">
    </xforms:action>
</xforms:trigger>
945 <script type="">
    buildSubmits();
</script>
</body>
</html>

950
```

### U.3.4 XForm as Transformed Upon Load

```

<?xml version="1.0" encoding="ASCII"?>
<html xmlns="http://www.w3.org/1999/xhtml"
  955   xmlns:ev="http://www.w3.org/2001/xml-events"
      xmlns:xforms="http://www.w3.org/2002/xforms"
      xmlns:xml="http://www.w3.org/XML/1998/namespace"
      xmlns:v="http://www.cdsc.org/ns/odm/v1.3">

  <head>
  960   <title>OMD 1.3 Sample</title>

      <xforms:model id="submitModel" schema="theSubmits.xsd">
          <xforms:instance id="submitInstance" src="theSubmits.xml"/>
      </xforms:model>

  965   <xforms:model id="model_ODM">
      <xforms:instance id="RFDInstanceData"> <!--the xform instance data is here → </xforms:instance>
          <submission id="one" method="post" action="http://submissionsite.org/cgi-bin/submitinstance.sh"/>
          <submission id="two" method="post" action="http://thearchive.org/cgi-bin/archiveinstance.sh"/>
  970   </xforms:instance>

      <script type="">
          function buildSubmits()
          {
  975             var oModel = document.getElementById("submitModel");
              var oInstance = oModel.getInstanceDocument("submitInstance");

              var pModel = document.getElementById("model_ODM");
              var pInstance = pModel.getInstanceDocument("instance_model_ODM");
  980

              var theSubmits = oInstance.getElementsByTagName("theSubmits");
              var theSubmitList = theSubmits[0].getElementsByTagName("theSubmitList");
              var theAction = theSubmitList[0].getElementsByTagName("theAction");

  985             var submitTrigger = document.getElementById("RFDSUBMIT");

              for(var i = 0; i < theAction.length ;i++) {
                  n = document.createElementNS("http://www.w3.org/2002/xforms", "submission");
                  n.setAttribute("id", theAction[i].getAttribute("theId"));
  990                  n.setAttribute("method", theAction[i].getAttribute("theMethod"));
                  n.setAttribute("action", theAction[i].textContent);
                  pModel.appendChild(n);

                  m = document.createElementNS("http://www.w3.org/2002/xforms", "send");
  995                  m.setAttribute("submission", theAction[i].getAttribute("theId"));
                  submitTrigger.appendChild(m);
              }
          }
  1000 </script>

```

```
<link href="gen_Black_and_White.css" rel="stylesheet"/>
</head>
<body>

1005   <xforms:group>
        <xforms:label>OMD 1.3 Sample</xforms:label>
    </xforms:group>
    <xforms:input ref="/v:ODM/@AsOfDateTime" model="model_ODM">
1010   <xforms:label>As Of Date Time</xforms:label>
        <xforms:hint>Enter a value for AsOfDateTime of type dateTime</xforms:hint>
    </xforms:input>
    <xforms:input ref="/v:ODM/@CreationDateTime" model="model_ODM">
1015   <xforms:label>Creation Date Time</xforms:label>
        <xforms:hint>Enter a value for CreationDateTime of type dateTime</xforms:hint>
    </xforms:input>

    <xforms:trigger>
        <xforms:label>Submit</xforms:label>
1020   <xforms:action ev:event="DOMActivate" id="RFDSSubmit">
        <send submission="one"/>
        <send submission="two"/>
    </xforms:action>
    </xforms:trigger>
    <script type="">
1025   buildSubmits();
    </script>
</body>
</html>
```