Integrating the Healthcare Enterprise

IHE Quality, Research and Public Health (QRPH)

Technical Framework

Volume 1

IHE QRPH TF-1

Profiles

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CONTENTS

1 Introduction

This document, Volume 1 of the IHE Quality, Research and Public Health (QRPH) Technical Framework, describes the clinical use cases, actors, content module, and transaction requirements for the Quality, Research and Public Health profiles.

1.1 Introduction to IHE

Integrating the Healthcare Enterprise (IHE) is an international initiative to promote the use of standards to achieve interoperability among health information technology (HIT) systems and effective use of electronic health records (EHRs). IHE provides a forum for care providers, HIT experts and other stakeholders in several clinical and operational domains to reach consensus on standards-based solutions to critical interoperability issues.

The primary output of IHE is system implementation guides, called IHE profiles. IHE publishes each profile through a well-defined process of public review and Trial Implementation and gathers profiles that have reached Final Text status into an IHE Technical Framework, of which this volume is a part.

For general information regarding IHE, refer to www.ihe.net. It is strongly recommended that, prior to reading this volume, the reader familiarizes themselves with the concepts defined in the *IHE Technical Frameworks General Introduction*.

1.2 Introduction to IHE Quality, Research and Public Health (QRPH)

The IHE Quality, Research and Public Health (QRPH) domain addresses the information exchange and electronic health record content standards necessary to share information relevant to quality improvement in patient care, clinical research and public health monitoring.

Clinical, demographic and financial information is routinely gathered and used in the process of providing clinical care. This information has significant value to public health agencies for monitoring disease patterns of known clinical processes (including incidence, prevalence and situational awareness) and for identifying new patterns of disease. Such data may be used to develop population analyses and programs for direct outreach and condition management through registries and locally determined appropriate treatment programs or protocols.

Similarly, information about care processes delivered to patients can be used to identify adherence to expected evidence-based clinical care protocols and to assess outcomes and quality of care provided by individual clinicians or groups of clinicians. Much of the data required for quality analysis exists within the clinical patient record and can be repurposed for analysis. The protocols for subsequent management of clinicians and individual patients with respect to quality data are often addressed as performance improvement or disease management initiatives.

Research and clinical studies, likewise, require identification of patterns of clinical presentation to select patients for inclusion (with consent) in research protocols. Subsequent study execution requires infrastructure and detailed content gathering capabilities similar to those required by quality initiatives and public health.

The QRPH domain addresses specifications for patient selection, individual and aggregate date reporting, and privacy and security constraints for re-use of patient information, enabling experts in health quality, research and public health to collaborate and coordinate their activities.

1.3 Intended Audience

The intended audience of IHE Technical Frameworks Volume 1 (Profiles) is:

- Those interested in integrating healthcare information systems and workflows
- IT departments of healthcare institutions
- Technical staff of vendors participating in the IHE initiative

1.4 Prerequisites and Reference Material

For more general information regarding IHE, refer to www.ihe.net. It is strongly recommended that, prior to reading this volume, the reader familiarizes themselves with the concepts defined in the *IHE Technical Frameworks General Introduction*.

Additional reference material available includes:

1.4.1 Actor Descriptions

Actors are information systems or components of information systems that produce, manage, or act on information associated with operational activities in the enterprise.

A list of actors defined for all domains and their brief descriptions can be found as Appendix A to the *IHE Technical Frameworks General Introduction*.

1.4.2 Transaction Descriptions

Transactions are interactions between actors that transfer the required information through standards-based messages.

A list of transactions defined for all domains, their transactions numbers, and a brief description can be found as Appendix B to the *IHE Technical Frameworks General Introduction*.

1.4.3 Content Modules

Content modules are data and data definitions shared between actors.

In the future, a list of content modules defined for all domains, their reference numbers, and a brief description can be found as Appendix G to the *IHE Technical Frameworks General Introduction*.

1.4.4 IHE Integration Statements

IHE Integration Statements provide a consistent way to document high level IHE implementation status in products between vendors and users.

The instructions and template for IHE Integration Statements can be found as Appendix F to the *IHE Technical Frameworks General Introduction*.

IHE also provides the IHE Product Registry (http://www.ihe.net/IHE_Product_Registry) as a resource for vendors and purchasers of HIT systems to communicate about the IHE compliance of such systems. Vendors can use the Product Registry to generate and register Integration Statements.

1.5 Overview of Technical Framework Volume 1

Volume 1 is comprised of several distinct sections:

- Section 1 provides background and reference material.
- Section 2 presents the conventions used in this volume to define the profiles.
- Sections 3 and beyond define Quality, Research and Public Health profiles, actors, and requirements in detail.

The appendices in Volume 1 provide clarification of uses cases or other details. A glossary of terms and acronyms used in the IHE Technical Framework is provided in Appendix D to the *IHE Technical Frameworks General Introduction*.

1.6 Comment Process

IHE International welcomes comments on this document and the IHE initiative. Comments on the IHE initiative can be submitted by sending an email to the co-chairs and secretary of the Quality, Research and Public Health domain committees at qrph@ihe.net Comments on this document can be submitted at http://ihe.net/QRPH_Public_Comments.

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1.10 History of Document Changes

This section provides a brief summary of changes and additions to this document.

Date	Document Revision	Change Summary
2011-09-02	0.1	Initial Trial Implementation version (no Final Text profiles)
2018-10-19	1.0	Initial Final Text version including CRD and DSC Profiles

[1] HL7 is the registered trademark of Health Level Seven International.

2 Quality, Research and Public Health Integration Profiles

IHE Integration Profiles offer a common language that healthcare professionals and vendors can use to discuss integration needs of healthcare enterprises and the integration capabilities of information systems in precise terms. Integration Profiles specify implementations of standards that are designed to meet identified clinical needs. They enable users and vendors to state which IHE capabilities they require or provide, by reference to the detailed specifications of the IHE Quality, Research and Public Health Technical Framework.

IHE Integration Profiles are defined in terms of IHE actors (defined in Volume 1), transactions (defined in Volume 2), and content modules (defined in Volume 3). Actors are information systems or components of information systems that produce, manage, or act on information associated with clinical and operational activities in healthcare. Transactions are interactions between actors that communicate the required information through standards-based messages. Content modules define how the content used in a transaction is structured. A content module is specified so as to be independent of the transaction in which it appears.

Vendor products support an Integration Profile by implementing the appropriate actor(s) and transactions. A given product may implement more than one actor and more than one integration profile.

IHE profiles which have reached the status of *Final Text* are published as part of the domain's Technical Framework Volumes 1-4. Prior to Final Text status, IHE profiles are published independently as *Profile Supplements* with the status of *Public Comment* or *Trial Implementation*.

For a list and short description of Quality, Research and Public Health profiles, see https://www.ihe.net/ihe_domains/quality_research_and_public_health/. The list includes all of the profiles in this document (Final Text) and may include profiles in the Trial Implementation stage.

2.1 Required Actor Groupings and Bindings

The IHE Technical Framework relies on the concepts of *required actor groupings* and *bindings*.

Required actor groupings may be defined between two or more IHE actors. Actors are grouped to combine the features of existing actors. This allows reuse of features of an existing actor and does not recreate those same features in another actor. Internal communication between grouped actors is not specified by IHE. An example of grouped actors in the IHE Radiology Scheduled Workflow Profile is the grouping between the Image Manager and Image Archive.

Additionally, required actor groupings may cross profile boundaries. For example, an XDS Document Registry Actor is required to be grouped with an ATNA Secure Node Actor. Required actor groupings are defined in each profile definition in Volume 1. To comply with an actor in an IHE profile, a system must perform all transactions required for that actor in that profile. Actors supporting multiple Integration Profiles must support all of the transactions of each profile. (Note: In previous versions of IHE Technical Framework documents, the concept of profile

dependencies existed. For simplification, profile dependencies have been combined with required actor groupings and are enumerated/repeated within each profile in Volume 1.)

Bindings refer to content modules. Bindings map data from a content module to the metadata of a specific transport profile. Bindings for content modules, and the associated concepts, are defined in Volume 3.

2.2 Security Implications

IHE transactions often contain information that must be protected in conformance with privacy laws, regulations and best practices. This protection is documented in the Security Considerations section of each profile, which communicates security/privacy concerns that the implementers need to be aware of, assumptions made about security/privacy pre-conditions and, where appropriate, key elements of a risk mitigation strategy to be applied.

2.3 Integration Profiles Overview

An overview of the profiles is listed at http://www.ihe.net/Profiles.

2.4 Product Implementations

As described in detail in the *IHE Technical Frameworks General Introduction*, an implementer chooses specific profiles, actors, and options to implement for their product. To comply with an actor in an IHE profile, a system must perform all the required transactions required for that actor in that profile.

To communicate the conformance of a product offering with IHE profiles, implementers provide an IHE Integration Statement describing which IHE integration profiles, IHE actors and options are incorporated.

Further discussion about integration statements and a sample form can be found in Appendix F to the *IHE Technical Frameworks General Introduction*. To make consumers aware of the product integration statement, enter it in the IHE Product Registry (http://product-registry.ihe.net/).

3 Clinical Research Document (CRD) Profile

The Clinical Research Document Profile (CRD) specifies a standard way to generate a clinical research document from EHR data provided in the CDA®[2] standard.

While the profile does not mandate the use of the CDASH standard, it provides guidance on how this profile could incorporate transformation of CDA content into CDASH.

The profile uses the transaction framework defined in the IHE ITI Retrieve Form for Data Capture (RFD) Profile. It further constrains the prepopData and workflowData data elements of the Retrieve Form [ITI-34] transaction in order to optimize the pre-population of the form used to collect the data during a patient's visit on an investigation site and an optional functionality is more tightly specified as required.

The CRD Profile uses the Archive Source Documents [QRPH-36] transaction to enable the CRD actors to meet data auditing requirements of the FDA when creating clinical research documents. It enables a Form Filler, which provides a pre-population document and some workflow data when retrieving a form, to archive the pre-population document it supplied.

The profile also enables FDA security requirements by optionally grouping CRD actors with actors in the IHE ITI Consistent Time (CT), Audit Trail and Node Authentication (ATNA), or Cross-Enterprise User Assertion (XUA) Profiles. See Section X.5 Security Considerations.

In summary, the CRD Profile is just like the RFD Profile except it is more specific about the pre-population xml requirements used when retrieving a form, some optional functionality is more tightly specified as required, a new transaction is created and is used to facilitate the archiving of the pre-population data, and other actor's groupings are added to enhance the security of CRD actors.

3.1 CRD Actors, Transactions, and Content Profiles

This section defines the actors, transactions, and/or content modules in this profile. General definitions of actors are given in the Technical Frameworks General Introduction Appendix A at http://ihe.net/Technical_Frameworks.

Figure 3.1-1 shows the actors directly involved in the CRD Profile and the relevant transactions between them. If needed for context, other actors that may be indirectly involved due to their participation in other related profiles are shown in dotted lines. Actors which have a required grouping are shown in conjoined boxes (see Section 3.3).

[2] CDA is the registered trademark of Health Level Seven International.

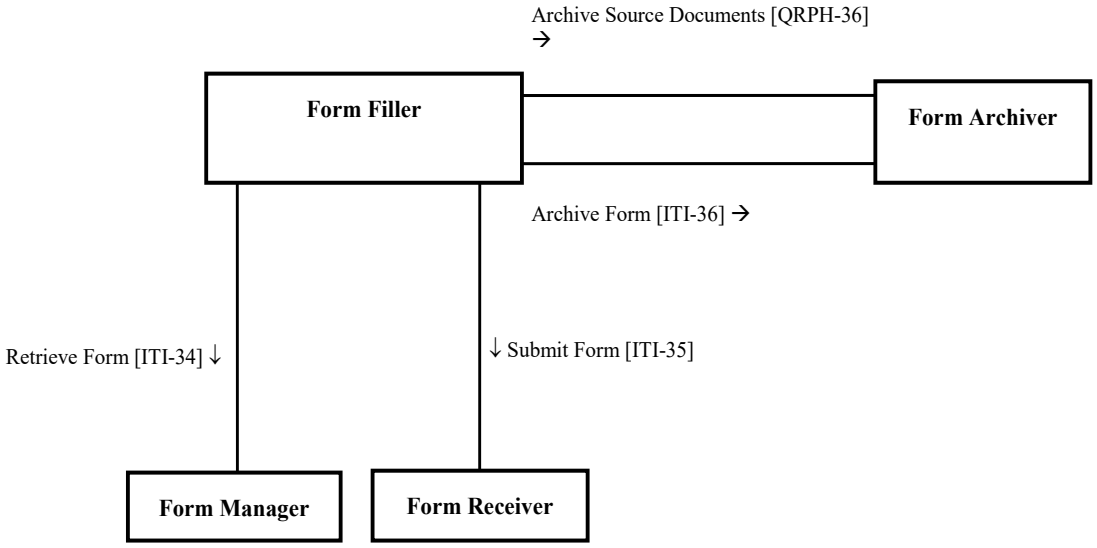

Figure 3.1-1: CRD Actor Diagram

335 Table 3.1-1 lists the transactions for each actor directly involved in the CRD Profile. To claim compliance with this profile, an actor shall support all required transactions (labeled "R") and may support the optional transactions (labeled "O").

Table 3.1-1: CRD Profile - Actors and Transactions

Actors	Transactions	Initiator or Responder	Optionality	Reference
Form Filler	Retrieve Form	Initiator	R	ITI TF-2b: 3.34
	Archive Source Documents	Initiator	O	QRPH TF-2: 3.36
	Submit Form	Initiator	R	ITI TF-2b: 3.35 (See Note 1)
	Archive Form	Initiator	O	ITI TF-2b: 3.36 (See Note 2)
Form Manager	Retrieve Form	Responder	R	ITI TF-2b: 3.34
Form Receiver	Retrieve Form	Responder	R	ITI TF-2b: 3.35
Form Archiver	Archive Source Documents	Responder	R	QRPH TF-2: 3.36
	Archive Form	Responder	R	ITI TF-2b: 3.36

Note 1: This transaction is further constrained in this profile (see QRPH TF-3: 6.3.1.2).

340 Note 2: This transaction is further constrained in this profile (see QRPH TF-3: 6.3.1.2).

Table 3.1-1 lists the content module(s) defined in the CRD Profile. To claim support with this profile, an actor shall support all required content modules (labeled "R") and may support optional content modules (labeled "O").

Table X.1-2: CRD – Actors and Content Modules

Actors	Content Modules	Optionality	Reference
Form Filler	CRD Prepop data document (creator)	R	QRPH TF-3: 6.3.1.D
	CRD Workflow data (creator)	R	QRPH TF-3: 6.3.1.D1
Form Manager	CRD Prepop data document (consumer)	R	QRPH TF-3: 6.3.1.D
	CRD Workflow data (consumer)	R	QRPH TF-3: 6.3.1.D1
Form Archiver	CRD Prepop data document	O	QRPH TF-3: 6.3.1.D
	CRD Workflow data	O	QRPH TF-3: 6.3.1.D1
Form Receiver	CRD Workflow data (creator)	R	QRPH TF-3: 6.3.1.D1

3.1.1 Actor Descriptions and Actor Profile Requirements

Most requirements are documented in Transactions (Volume 2) and Content Modules (Volume 3). This section documents any additional requirements on profile's actors.

3.1.1.1 Form Filler

In addition to its role as defined in the RFD Profile in ITI TF-1:17, the Form Filler SHALL support the generation of the pre-population data in the form of the two content modules hereafter named "CRD prepop data" and "CRD workflow data".

3.1.1.2 Form Manager

In addition to its role as defined in the RFD Profile in ITI TF-1:17, the Form Manager MAY specify mappings between CCD®[3] and CDASH. While the profile does not mandate the use of the CDASH standard, it provides guidance on how this profile could incorporate transformation of CDA content into CDASH.

3.1.1.3 Form Receiver

The role of the Form Receiver in this profile is the one defined in the RFD Profile in ITI TF-1:17.

3.1.1.4 Form Archiver

The role of the Form Archiver in this section is the one defined in the RFD Profile in ITI TF-1:17.

[3] CCD is the registered trademark of Health Level Seven International.

3.2 CRD Actor Options

Options that may be selected for each actor in this profile, if any, are listed in the Table 3.2-1. Dependencies between options, when applicable, are specified in notes.

Table 3.2-1: CRD – Actors and Options

Actor	Option Name	Reference
Form Filler	Archive Source Documents	QRPH TF-2: 3.36
	Archive Form	ITI TF-2b: 3.36
Form Manager	None	
Form Receiver	None	
Form Archiver	None	

Note: In the CRD Profile, the pre-population data is not an option; it is required as the profile is precisely about defining it. The CRD Profile requires that this prepop and workflow data conform to the xml data constrained in QRPH TF-3: 6.3.1.D and 6.3.1.D1. The "Archive Source Documents" Option requires the Form Filler to submit the Prepop and Workflow data to the Form Archiver through the [QRPH-36] transaction. If the Form Filler supports this option, that transaction must be completed first in order to provide the Form Manager with the context id related to the archived CRD (see QRPH TF-3: 6.3.1.D1).

3.3 CRD Required Actor Groupings

An actor from this profile (Column 1) shall implement all of the required transactions and/or content modules in this profile ***in addition to <u>all</u>*** of the requirements for the grouped actor (Column 2).

Table 3.3-1: CRD – Required Actor Groupings

CRD Actor	Actor(s) to be grouped with	Reference	Content Bindings Reference
Form Filler	None	--	--
Form Manager	None	--	--
Form Receiver	None	--	--
Form Archiver	None	--	--

3.4 CRD Overview

3.4.1 Concepts

3.4.2 Use Cases

3.4.2.1 Use Case #1: Clinical Trial Visit

We are in the setting of a clinical study which implies a certain number of visits for all the patients involved. A patient enrolled in a clinical study comes to the Hospital for a visit related to that clinical study.

3.4.2.1.1 Clinical Trial Visit Use Case Description

The setting for the clinical research use case is a physician practice where patient care is delivered side-by-side with clinical research activities. 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 Medical Record (EMR) and a number of sponsor-provided Electronic Data Capture (EDC) systems for documenting clinical trial activities. EDC is a system for documenting clinical trial activities. EDC is a remote data entry system, provided by the research sponsor, which uses either a laptop (thick or thin client) or a web site. For our purposes, an EMR 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 EMRs in the strictest sense, but which would still benefit from this approach.

Holbin's involvement in a clinical study begins when the Research Department receives a request for proposal (RFP) or a request for a feasibility assessment (EU) from a study Sponsor. The Investigator or the Study Coordinator, Patricia Zone, RN, evaluates the RFP to assess if their facility has the required patient population (clinical condition and required numbers required by the study protocol) as specified in the clinical study protocol, as well as the business viability. A major issue that must be addressed is the time needed to perform the clinical study and whether or not the site has the time to perform the study appropriately. Once these concerns are addressed satisfactorily and the site is selected for the trial, the financial aspects are addressed and the site then sends the required regulatory documentation to the Sponsor. The Sponsor then provides Protocol-specific training to the Physician Investigator and other study personnel.

During the trial set-up period, Patricia, together with the Investigator 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, ensures that IRB approval has been obtained, maintains required regulatory documents and performs all the attendant financial tasks.

Patricia, under the supervision of the Investigator 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 EMR as a subject in trial #1234, using the EMR's patient index. She schedules Corey's study visits using the EMR 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.

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.

3.4.2.1.1.1 Current State

Mrs. Corey Jones arrives at the clinic for a scheduled trial visit and meets with Patricia Zone (Registered Nurse) for a face-to-face interview. Patricia logs into the EMR 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 EMR and records them in the Case Report Form (CRF). The EMR 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 EMR vary from 5% to 40%. Even in the best case, the EMR typically captures only a subset of the data required by a study protocol.)

The completed source document is forwarded to Bob Thomas, 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 documents have 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).

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 monitor visit occurs.

3.4.2.1.1.2 Desired State

Mrs. Jones arrives for a visit and Patricia logs into the EMR, 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, and because Mrs. Jones informed consent indicated that it was permissible to do so, the EMR recognizes Mrs. Jones as a subject in Trial 1234 and requests an electronic case report form from trial #1234's, using RFD. If the trial is sufficiently complex, the retrieved form MAY contain a list of relevant forms from the RFD Forms Manager system from which Patricia MAY choose. Patricia selects the appropriate form, the EMR checks Patricia's credentials, confirms that consent to access the EMR data has been obtained and thus confirms that she is empowered to view the form, and displays the form. (The data capture form is essentially the same form that an EDC system would offer for this visit, and its presentation MAY take on some of the look and feel of the EMR's user interface.)

Nurse Patricia interviews Mrs. Jones and enters data into the clinical trial form as presented in the EMR. The clinical site personnel will be well acquainted with the basic data collection variables[4] that appear on the clinical trial form as they are consistently collected in all types/phases of clinical trials. Applicable data from the EMR database are now archived for future regulatory auditing and used to pre-populate some of the clinical trial data fields. Additional data MAY need to be captured interactively via the forms (which MAY have built-in edit checks). Upon completing the form, Patricia hits the submit button, and the EMR 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.

3.4.2.1.2 Clinical Trial Visit Process Flow

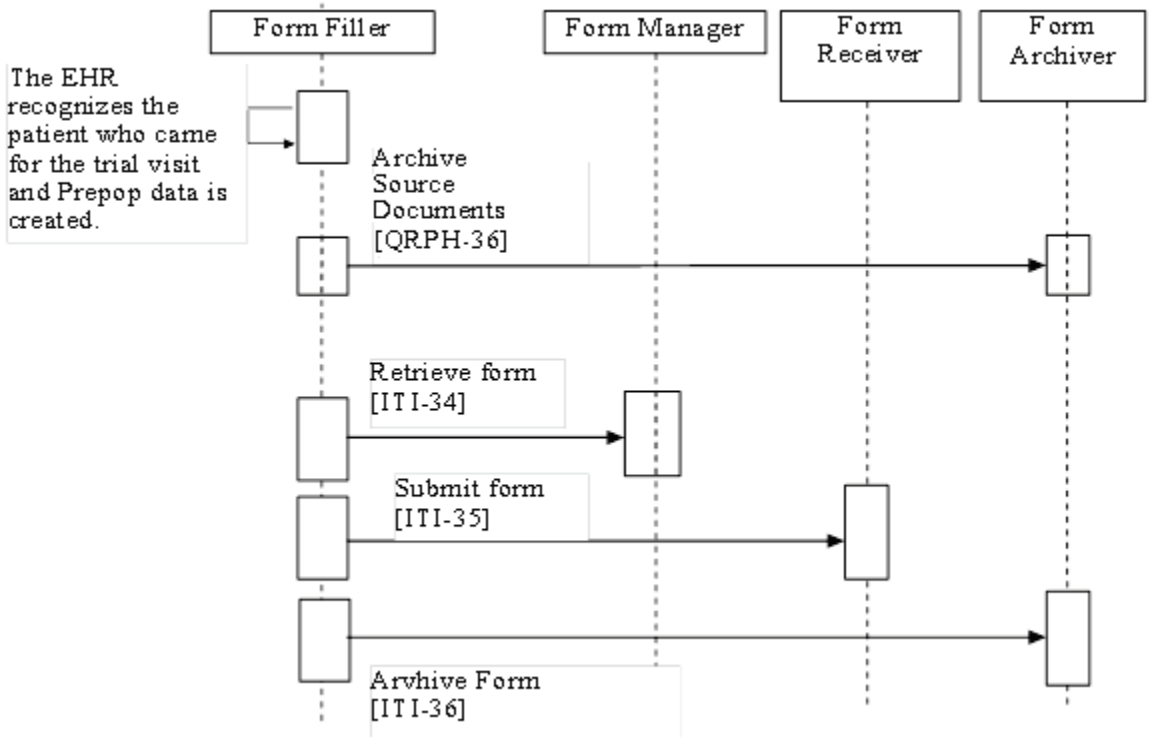

Figure 3.4.2.1.2-1: Basic Process Flow in CRD Profile

In this Process Flow, the Form Filler knows which form it wants to retrieve from the Form Manager. The Form Filler wants to send prepop and workflow data for this form. In addition, the Form Filler wants to archive the prepop and workflow data.

[4] These clinical trial forms or domain modules are comprised of data collection variables identified by the Clinical Data Acquisition Standards Harmonization (CDASH) Initiative. The CDASH initiative identifies data collection fields that are applicable to all clinical trials regardless of therapeutic area or phase of trial. Addition data collection fields will have been added to the CDASH collection variables to capture the required therapeutic area or required fields by the study Sponsor.

3.5 CRD Security Considerations

3.5.1 Consistent Time (CT)

In order to address identified security risks all actors in CRD should be grouped with Consistent Time (CT) Profile – Time Client Actor. This grouping will assure that all systems have a consistent time clock to assure a consistent timestamp for audit logging and form accuracy.

3.5.2 Audit Trail and Node Authentication (ATNA)

In order to address identified security risks all actors in CRD may be grouped with Audit Trail and Node Authentication (ATNA) Profile – Secure Node or Secure Application Actors. This grouping may assure that security related events are recorded in the audit log and that only highly trusted systems can communicate.

3.5.3 Cross Enterprise User Assertion (XUA)

In order to address identified security risks all actors in CRD may be grouped with Cross-Enterprise User Assertion (XUA) Profile actors. The Form Filler would be the XUA X-Service User and the other actors would be the XUA X-Service Provider. These groupings support user-based access control.

3.6 CRD Cross Profile Considerations

Not applicable

4 Drug Safety Content (DSC) Profile

The Drug Safety Content Profile (DSC) specifies a standard way to generate an adverse event document from EMR data provided in the CDA standard.

The profile uses the transaction framework defined in the RFD Profile. It further constrains the prepopData data elements of the RFD Retrieve Form transaction in order to optimize the pre-population of the form used to collect the data during a patient's visit on an investigation site and an optional functionality is more tightly specified as required.

Other FDA requirements which this profile meets are security requirements. This is enabled by the grouping of each of the actors defined in this profile with a CT Time Client, an ATNA Secure Node or Application and an XUA X-Service User.

In Summary, the DSC Profile is just like the RFD Profile except it is more specific about the pre-population xml requirements used when retrieving a form, some optional functionality is more tightly specified as required and other actor's groupings are added to enhance the security of the actors.

4.1 DSC Actors, Transactions and Content Modules

Figure 4.1-1 shows the actors directly involved in the DSC Profile and the relevant transactions between them. If needed for context, other actors that may be indirectly involved due to their participation in other related profiles are shown in dotted lines. Actors which have a mandatory grouping are shown in conjoined boxes.

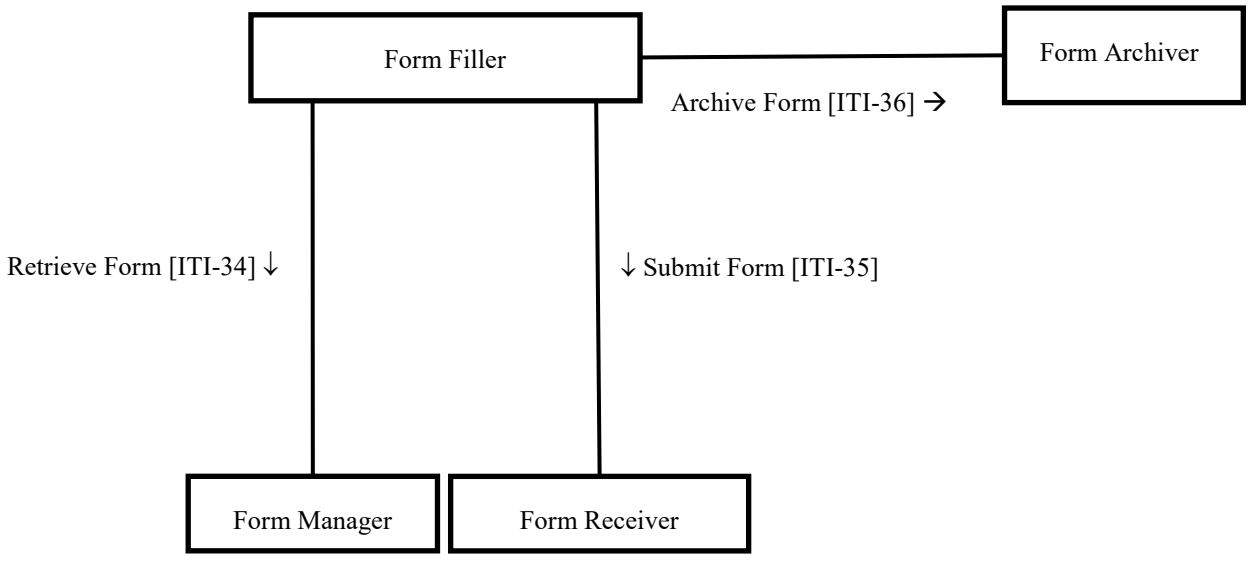

Figure 4.1-1: DSC Actor Diagram

Figure 4.1-1 shows the principal actors described (bold and solid boxes) in the DSC Integration Profile. Here there are no transactions per se between these actors as this profile is a content profile, but if there were some, they would be designed in bold and solid lines. The diagram also

shows actors which are not defined in this profile (dashed Boxes) but which SHALL be grouped with the principal ones.

As explained in the summary and shown in Table 4.3-1, the DSC actors SHALL also be grouped with some CT actors and SHOULD be grouped with some XUA and ATNA actors.. However, for clarity's sake, it was decided not to show them in Figure 4.1-1, as this figure points out the most important features which this profile is about. An exhaustive DSC actor diagram can be found in Appendix A of this volume (see Figure A.1-1).

Table 4.1-1 lists the transactions for each actor directly involved in the DSC Profile. In order to claim support of this Profile, an implementation of an actor must perform the required transactions (labeled "R") and MAY support the optional transactions (labeled "O"). Actor groupings are further described in Section 4.3.

Table 4.1-1: DSC Profile – Actors and Transactions

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

Table 4.1-2: DSC Profile – Actors and Content Modules

Actors	Content Module	Optionality	Section in Vol. 3
Form Filler	Case Report Document (creator)	R	3.Y1
Form Manager	Case Report Document (consumer)	R	3.Y1
Form Receiver	None	N/A	N/A

4.1.1 Actor Descriptions and Actor Profile Requirements

Normative requirements are typically documented in Volume 2 (Transactions) and Volume 3 (Content Modules). Some Integration Profiles, however, contain requirements which link transactions, data, and/or behavior. Those Profile requirements are documented in this section as normative requirements ("shall").

4.1.1.1 Form Filler

In addition to its role as defined in the RFD Profile in ITI TF-1, the Form Filler SHALL support the generation of the pre-population data as defined in Volume 3, content requirements, hereafter named "Case Report Document."

As described in Table 4.3-1, for security enhancing purposes, the Form Filler SHALL also be grouped with a CT Time Client. The Form Filler SHOULD be grouped with an XUA X-Service Provider and an ATNA Secure Node or ATNA Secure Application.

4.1.1.2 Form Manager

As described in Table 4.3-1, for security enhancing purposes, the Form Manager SHALL also be grouped with a CT Time Client. The Form Manager SHOULD be grouped with a XUA X-Service Provider and an ATNA Secure Node or ATNA Secure Application.

4.1.1.3 Form Receiver

The role of the Form Receiver in this profile is the one defined in the RFD Profile in ITI TF-1.

It SHALL also be grouped with a CT Time Client. It SHOULD be grouped with a XUA X-Service Provider, and an ATNA Secure Node or ATNA Secure Application.

4.1.1.4 Form Archiver

The role of the Form Archiver in this section is the one defined in the RFD Profile in ITI TF-1.

It SHALL also be grouped with a CT Time Client. It SHOULD be grouped with a XUA X-Service Provider, and an ATNA Secure Node or ATNA Secure Application.

4.2 DSC Actor Options

Options that may be selected for this profile are listed in the Table 4.2-1 along with the actors to which they apply. Dependencies between options when applicable are specified in notes.

Table 4.2-1: DSC – Actors and Options

Actor	Options	Volume & Section
Form Filler	Archive Form	ITI TF-2b:3.36
Form Manager	None	-
Form Receiver	None	-
Form Archiver	None	-

Note: Considering that we are in the DSC Profile, the pre-population data is not an option anymore; it is required as the profile is precisely about defining it. The DSC Profile requires that this prepop data conforms to the xml data constrained in its volume 3.

4.3 DSC Actor Required Groupings

Actor(s) which are required to be grouped with another actor(s) are listed in this section. The grouped actor may be from this profile or a different domain/profile. These mandatory required groupings, plus further descriptions if necessary, are given in the table below.

An actor from this profile (Column 1) must implement all of the required transactions in this profile in addition to all of the required transactions for the grouped profile/actor listed (Column 2).

Table 4.3-1: DSC – Required Actor Groupings

DSC Actor	Grouping Condition	Actor to be grouped with	Technical Framework Reference
Form Filler	Optional	ATNA Secure Node or ATNA Secure Application	ITI TF- 1: 9.4
	Required	CT Time Client	ITI TF- 1: 7.1
	Optional	XUA X-Service User	ITI TF- 1: 13.4
Form Manager	Optional	ATNA Secure Node or ATNA Secure Application	ITI TF- 1: 9.4
	Required	CT Time Client	ITI TF- 1: 7.1
	Optional	XUA X-Service Provider	ITI TF- 1: 13.4
Form Receiver	Optional	ATNA Secure Node or ATNA Secure Application	ITI TF- 1: 9.4
	Required	CT Time Client	ITI TF- 1: 7.1
	Optional	XUA X-Service Provider	ITI TF- 1: 13.4
Form Archiver	Optional	ATNA Secure Node or ATNA Secure Application	ITI TF- 1: 9.4
	Required	CT Time Client	ITI TF- 1: 7.1
	Optional	XUA X-Service Provider	ITI TF- 1: 13.4

4.4 DSC Overview

4.4.1 Concepts

Not applicable

4.4.2 Use Cases

4.4.2.1 Use Case #1: Clinical Trial Adverse Event (AE) Reporting

This use case demonstrates how the DSC Profile can be used to report an adverse event in the context of a clinical trial.

4.4.2.1.1 Clinical Trial Adverse Event (AE) Reporting Use Case Description

A physician, Dr. Smith, is seeing his first clinical trial patient, Rita Jones, for her trial visit. As he talks to her he is reviewing her clinical data in the clinical trial management software used by his practice. After discussing her progress over the last two weeks on the trial, she describes a pain in her abdomen that wasn't present until she started the trial drug for her heart condition. Dr. Smith notices an unanticipated increase in her amylase level and decides this could be due to the trial drug, as this is the second case with similar symptoms he's seen in the last week.

He chooses a menu item from the software to 'Report AE" and a form appears in which he selects the information to include in the report. Ms. Jones' labs, medications, demographics, physical exam and current complaint information are added into the form automatically. Dr. Smith adds some additional information on his suspicions in a text box on the form and pushes 'Report this AE", and the form disappears from his screen.

Dr. Smith recalls the time prior to using the automated reporting process and remembers how he would want to report an event like this, but after finishing seeing his patients, doing paperwork and getting lunch, he would only remember a few of the case details, and he never remembered where he could find a copy of the form to report the event. If he ran into his study nurse he would tell her the bare details of the case and ask her to report it, but that was as much as he was able to do given his schedule.

With this new system, he was confident that the case had the relevant clinical information, and he could add his interpretation of the case during the patient visit, while the impressions were fresh in his mind. The entire process usually took him only a few minutes to complete and he knew that the report would be complete and of high quality. He also knew that he could call the report up whenever he wished to review it in light of new information or similar cases.

4.4.2.1.2 Clinical Trial Adverse Event Process Flow

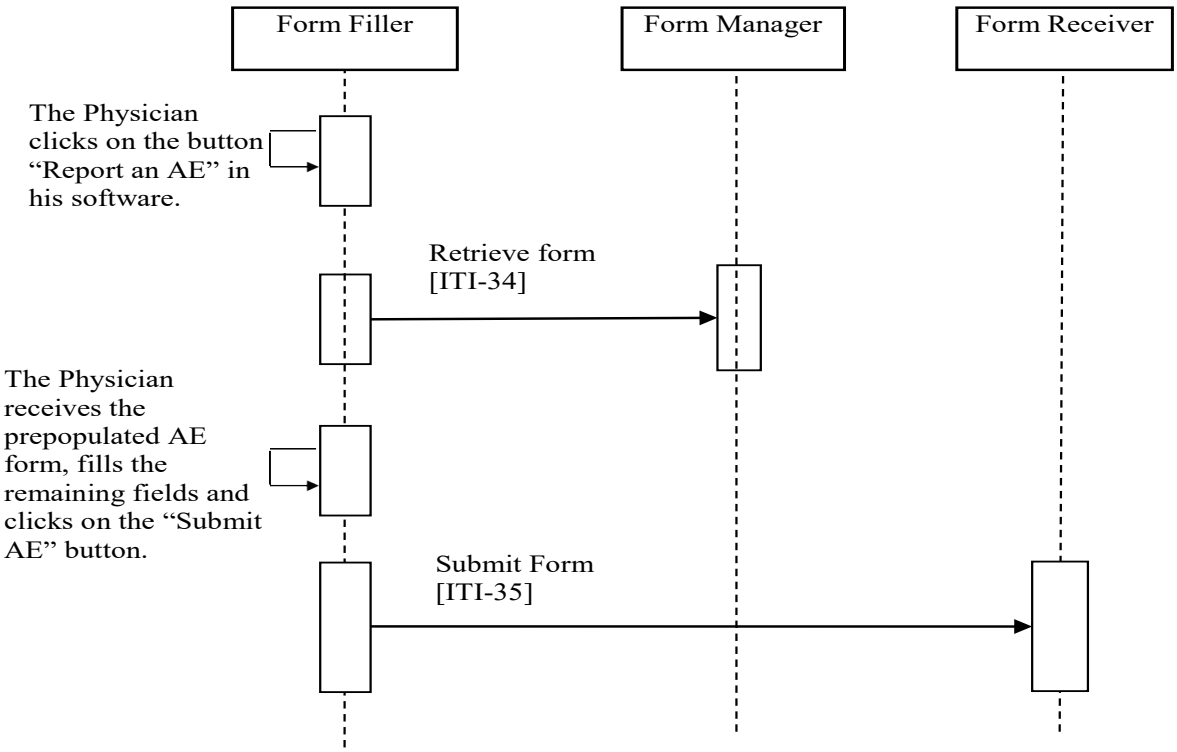

Figure 4.4.2.1.2-1: Basic Process Flow in DSC Profile used in the context of a Clinical Trial Adverse Event Reporting

4.4.2.1.3 Current State

Currently in the U.S., Europe, and Japan, adverse drug events (ADEs) and adverse drug reactions (ADRs), here generally referred to as adverse events (AEs), are collected on drugs (here meant to include both exogenous chemical and endogenous or 'biologics') through all phases of clinical trials and after the drug has been approved for marketing, through to the life of the drug on the market. There are some differences in regulations, practices and systems by geographic region, but certain commonalities remain:

Clinical Trial

- During clinical trial (CT) investigations, objectives include AEs as a safety component, one aspect of which is the reporting out of AEs during the trial. Certain types of AEs, classified as 'serious' by regulatory definition, must be reported according to a strict timeline and cannot wait until the completion of the trial. Data and information on these events must be collected, evaluated and sent to regulatory authorities by the principal investigator in a timely fashion. Currents methods of reporting range from a completion of a simple paper form by the principal investigator or a designee based on data captured in case record forms, visits and phone calls with medical personnel, to initial population

of data directly from trial management systems and electronic medical records (EMRs) used at the trial sites followed by assessment and refining of the information by designated personnel. A significant issue with all AE reporting from clinical trials involves the myriad number of clinical data storage systems, standards and data mappings and translations needed to get the data from the parent system to the regulators in a timely fashion.

Phase IV Trial

- One frequent source of post-marketing AEs comes from trials undertaken once the drug is on the market. These trials can range from Phase IV trials in which there is some type of case control or other means of control and a formal protocol to more loosely controlled trials (commonly referred to as 'marketing trials' in which there is a very general protocol). Phase IV trials are often performed to test the safety and effectiveness of new indications for drugs approved for more limited clinical use. The more well-controlled the trial, the more the data collection and reporting requirements resemble that of pre-marketing CTs. But in marketing trials, data may be collected from various means - through phone interviews, surveys, emails, and from a very large number of consumers/patients. In these trials the quality and amount of data collection can vary tremendously.
- A common thread in all AE reporting is the heterogeneity of the systems and stakeholders in the process. This creates a large number of possible forms, interfaces and data translation requirements which increase the friction between the participants - from the original reporter all the way through to the regulator.

  The current post marketing reporting process in the U.S. is largely paper-based and requires people to track down paper or .pdf forms which take anywhere from 30 to 45 minutes to complete. In Europe some countries have specialized reporting of AEs from, e.g., general practitioners, but there are common technological challenges with maintaining reporting forms and decreasing the burden of producing a report remains problematic. In other countries the process is similar to the U.S., with similar issues. Beyond the initial report, because of the number of handoffs in the process, the different requirements of the various data processing systems involved, and the various requirements for data privacy, a standardized means of defining and moving data through the process is also needed - a commonly recognized format and process can greatly improve how post marketing reports are created and received in the future. Such transmission, privacy and security concerns are not in the direct scope of this profile which specifically addresses the content of the message.

4.4.2.1.4 Desired State

Given the heterogeneous environment for AE collection and reporting, it is highly desirable to provide some more efficient way to move the data through the reporting system so that the act of reporting becomes easier as a routine output of usual clinical care processes, data fidelity can be maintained, reporting can be timely, and the number of translations of data that occur can be reduced to a minimum.

In clinical trials, an investigator should be able to use a single process to report AEs across any CTs and should not have to remember or transcribe data that already exists in the clinical systems. Additionally, to improve the reporting process, maintenance of data required for reporting should be accomplished without modification of each underlying data source system, especially given the large number of systems used in generating the data at the sites, in managing the trials, in processing the data at the manufacturers, and in receiving the data at the regulators Standardization of data collection instruments and avoidance of duplicate data entry and transcription is similarly a desire for post marketing trials.

4.4.2.2 Use Case #2: Post-Market Surveillance AE Reporting

This use case demonstrates how the DSC Profile can be used to report an adverse event in the context of post-market surveillance.

4.4.2.2.1 Post-Market Surveillance AE Reporting Use Case Description

In the afternoon, when he was seeing the ambulatory clinic patients, Dr. Smith discussed with Mr. Brown the muscle weakness and shooting pains in his legs that started a few days after being put on his high dose statin regimen following his angioplasty. Dr. Smith thought it was likely related to the statin and after counseling Mr. Brown, Dr. Smith pulled up his record in the EHR used by his practice, discontinued the statin, and marked reason for discontinuation as “AE”. This brought up a pre-populated form with Mr. Brown’s demographics, current labs, medical history, medications and a text box labeled “Adverse Event”. Dr. Smith typed in ‘myopathy’ and noted that the generic and trade name of the statin was pre-populated in the form. He added a note that he had ordered tests to help confirm the diagnosis and they were pending. He then pressed the “Submit AE” button on the form and it disappeared, and Dr. Smith finished ordering tests and writing his notes on Mr. Brown in the EMR.

Dr. Smith remembered how he never previously considered reporting an AE from one of his patients since it involved finding a reporting form, filling out the information himself and usually being late to see his next patient. And if he would ask a nurse or pharmacist to file a report he knew the report would rarely, if ever, be submitted. With this new process he could complete the report himself and not have to pass along the burden to someone else.

4.4.2.2.2 Clinical Trial Adverse Event Process Flow

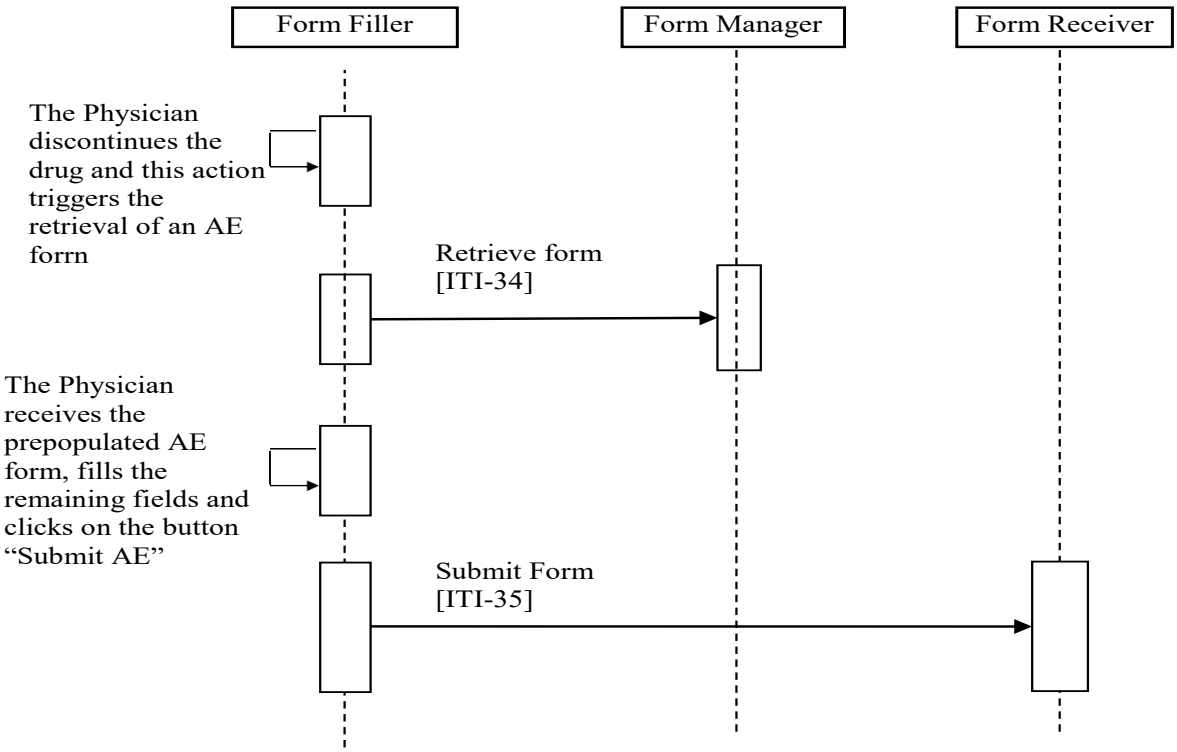

Figure X.4.3.2-1: Basic Process Flow in DSC Profile used in the context of a Post-Marketing Surveillance Adverse Event Reporting

4.4.2.2.3 Current State

Currently in the U.S., Europe, and Japan, adverse drug events (ADEs) and adverse drug reactions (ADRs), here generally referred to as adverse events (AEs), are collected on drugs (here meant to include both exogenous chemical and endogenous or 'biologics') through all phases of clinical trials and after the drug has been approved for marketing, through to the life of the drug on the market. There are some differences in regulations, practices and systems by geographic region, but certain commonalities remain:

> Once a drug is on the market, AEs are collected through various means, but in general the common state of affairs is through a paper-based system of reporting. In some cases, reporting initiates from phone calls to a drug information center sponsored by a drug manufacturer from consumers taking the medication, doctors caring for patients or other healthcare personnel such as pharmacists. The information is transcribed by the call center personnel and forwarded on to the manufacturer. In other situations, the consumer or healthcare practitioner may call the FDA directly or may send in a paper form through the postal service or by fax, to report the event. In the U.S. a MedWatch® form can be used for this purpose. In all cases of post-marketed reporting, getting the data from the system in which it resides (e.g., EMR) into a form which is ready to be received by regulatory authorities is a laborious process and not part of any clinical routine. This

'burden of reporting' likely has a significant role in the number of difficulties seen in post marketing reporting of AEs which include a lack of quality in reports, a small number of reports, and a general difficulty in getting enough information in any one report to make an adequate assessment of the event(s) in question. In some countries this situation is improved through national systems and/or regulatory requirements for reporting, but in all cases the act of reporting can be made easier through a more direct flow of clinical information on the AE to the regulatory authorities and manufacturers.

4.4.2.2.4 Desired State

Given the heterogeneous environment for AE collection and reporting, it is highly desirable to provide some more efficient way to move the data through the reporting system so that the act of reporting becomes easier as a routine output of usual clinical care processes, data fidelity can be maintained, reporting can be timely, and the number of translations of data that occur can be reduced to a minimum.

The desired state for post-marketing reporting is one in which the burden to submit an AE report is very low and is part of the routine of the reporter - especially in the case of the physician or other healthcare practitioner. This same reasoning holds true if the reporter is a consumer or patient using a system to maintain their personal health information such as a Personal Health Record. In such post-marketing AE reporting, integrated reporting solutions should trigger and pre-populate essential information to the extent possible in standard formats. Such solutions should also enable behind the scene mapping of clinical care interface terminology through clinically interoperable formats directly to elements required for surveillance for medications and biologics in an integrated fashion.

4.5 DSC Security Considerations

4.5.1 Consistent Time (CT)

In order to address identified security risks all actors in DSC should be grouped with Consistent Time (CT) Profile – Time Client. This grouping will assure that all systems have a consistent time clock to assure a consistent timestamp for audit logging.

4.5.2 Audit Trail and Node Authentication (ATNA)

In order to address identified security risks all actors in DSC should be grouped with Audit Trail and Node Authentication (ATNA) Profile – Secure Node or ATNA Secure Application. This grouping will assure that only highly trusted systems can communicate and that all changes are recorded in the audit log.

4.5.3 Cross Enterprise User Authentication (XUA)

In order to address identified security risks all actors in DSC should be grouped with Cross Enterprise User Authentication (XUA) Profile actors as appropriate. This grouping will assure that only highly trusted persons can communicate.

4.6 DSC Cross Profile Considerations

Not applicable

Appendices

Appendix A – Further Details on Implementations of the DSC Profile

This appendix is informative.

A.1 Grouped Actors in the DSC Profile

Figure A.1-1 below shows actors involved in the DSC Integration Profile. Actors shown in full black outline are part of the definition of the DSC Profile. Actors shown in dashed orange lines may be grouped with other DSC actors and provide security functions.

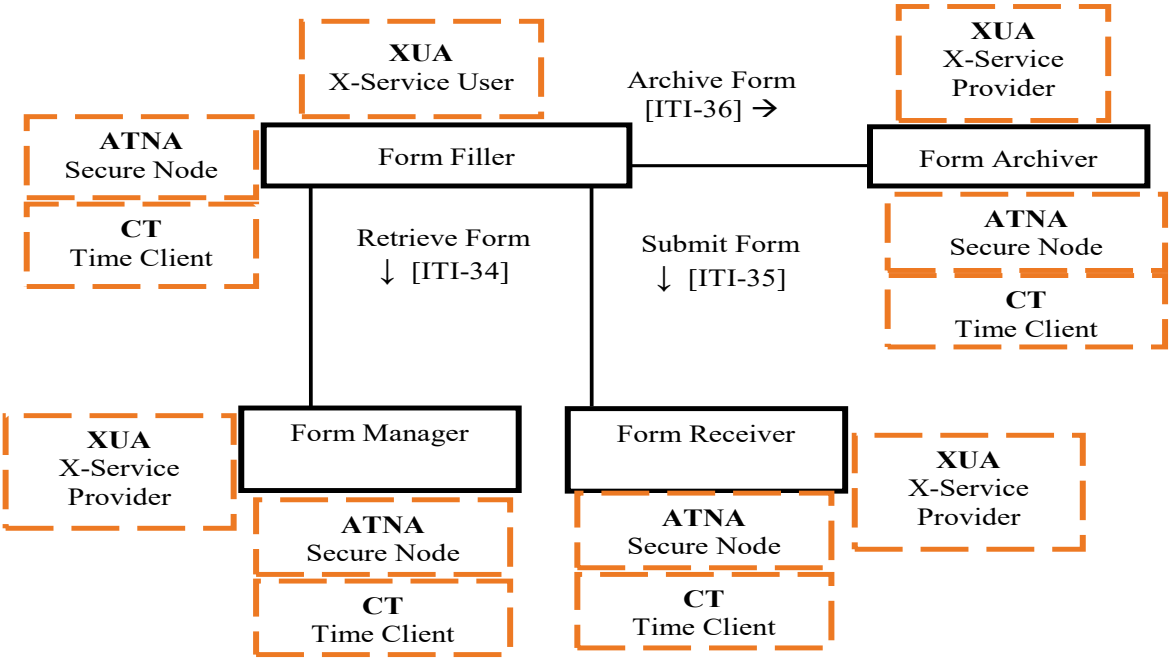

Figure A.1-1: Grouped Actors in the DSC Profile

Glossary

780 The IHE Glossary, an appendix to the *IHE Technical Frameworks General Introduction*, can be found here.

