

Meeting Name	Interim Use Case Committee Meeting
Meeting Date and Time:	August 30-31, 2005
Location:	Arlington, VA
Objectives:	Create preliminary Use Case descriptions for HITSP review during the inaugural HITSP meeting scheduled for September 27-28.

Attendee Name	Org.	Telephone	E-mail Address
See Appendix			

* Indicates the participant attended the meeting via phone

Agenda

1. *Overview ONCHIT 1 proposal, scope, and charge of the Interim Use Case Committee*
2. *Establish criteria for selecting Use Cases*
3. *Review proposed/submitted Use Cases*
4. *Select top five Use Cases*
5. *Develop draft preliminary Use Case descriptions*
6. *Review next steps*

Decisions

- Identified six **high-level criteria** for selecting the first set of use cases for further refinement.
 - **Is Pragmatic:** Implementable, Feasibility – practical application, Affordable. Suitable for a year 1 HITSP project – executable
 - **Adds Value:** Clinical value, Long-term viability, Solves real-world problem (for providers), Federal hotspot – national priority, No exposure to patient privacy
 - **Likelihood for Measurable Outcomes:** non-clinical outcomes, clinical outcomes, Value/ROI
 - **Is Comprehensive:** Span more than one SDO, Span health system and care settings and continuum of care across time, Accessibility – digital divide
 - **Addresses an ONC Program Needs:** Extent to which use-case is likely to integrate with other ONCHIT projects; Compelling story
 - **Pertains to Population/public health Issues**
- Selected the top **four use cases** for further refinements and identified primary points of contact for each Use Case
 - Electronic Prescribing (**Ross Martin, Pfizer Global**)
 - Well Child Care with Immunization (**Alan Zuckerman, ASTM**)
 - Primary Care (**Charles Parisot, EHR VA**)
 - Chronic Disease Management (**Lori Fourquet,)**
- Selected **Maria Rudolph of ACC** to act as the integrator across the five use cases for the purpose of identifying common interoperability-level use cases; with **Lynne Gilbertson from NCPDP**
- Agreed to examine each high-level (what we called Health System Level) use case to identify the specific scenarios or storyboards that can be implemented within the contract timeframe of one year

Actions

AI ID	AI Description	Assigned To	Date Assigned	Due Date	Status
20050 831-01	Develop a draft template for the use case documentation that will standardize and normalize presentation across all five use cases	J. Sensmeier C. Fantaskey	8/31/05	9/10/05	NEW
20050 831-02	Document the results of the meeting and distribute them, along with the materials presented	C. Fantaskey	8/31/05	9/10/05	Done
20050 831-03	Participate in a teleconference with work group leaders to synch preliminary use cases	Project Team Ross Martin Alan Zuckerman Charles Parisot Lori Fourquet Lynne Gilbertson	8/31/05	9/16/05	NEW
20050 831-04	Email next iteration of draft use cases Joyce Sensmeier	Ross Martin Alan Zuckerman Charles Parisot Lori Fourquet Lynne Gilbertson	8/31/05	9/19/05	NEW
20050 831-05	Email next iteration of draft use cases to the full Use Case Committee by September 20th	J. Sensmeier	8/31/05	9/20/05	NEW

Next Planned Meeting of the Use Case Committee

October 4-5, Rosemont, IL near O’Hare airport. Begin to develop the formal contract deliverable. Assuming the contract has been awarded, this will be called the Use Case Committee (dropping the Interim designation). This session will be used to refine the draft use cases that were reviewed and approved by the HITSP at their inaugural session.

Appendix

RANKING OF THE USE CASES BASED UPON THE DEFINED CRITERIA.....7

INTEGRATED APPROACH TO PERFORMING THE 11 TASKS DEFINED BY THE GOVERNMENT7

EXCERPTS FROM THE TECHNICAL PROPOSAL DESCRIBING THE PROPOSED APPROACH TO PERFORMING THE WORK8

- Task 3 – Develop a Minimum of Three Recommended Use Cases 8
- Task 5 – Standards Alignment and Gap Analysis10
 - Baseline Standards..... 11
 - Analyze and Document Gaps and Overlaps 12
 - Initiate and Facilitate Resolutions 12
- Task 6 – Selection, Test and Evaluation of Standards for Individual Use Cases.....13
 - Selection 14
 - Implementation Testing 15
 - Evaluation 16
- Task 7 – Prototype, Test and Evaluate Processes for Change Management and Dissemination of Harmonized Standards17
 - Clarify the Scope and Requirements of the Change Management and Dissemination Processes . 18
 - Conduct a Best Practices Analysis..... 19
 - Design the prototype processes to include governance, operations, public channels, and schedules 20
 - Exercise the processes on one or more of the use cases 22
 - Evaluate the results and recommend changes for next phase 22
- Task 8 – Implementation Guidelines for Standards.....23
 - Prototype Standards Implementation Guidelines 23
 - Test Standards Implementation Guidelines..... 24
 - Evaluate and Refine Standards Implementation Guidelines; Prepare Deliverable 26
 - Collaborate with NIST 26
- Task 9 – Develop Business Plan for Self-Sustaining Standards Harmonization Process.....27
 - Identify Stakeholders Having Input to the Business Plan 27
 - Identify and Review Existing Standards Maintenance Models..... 27
 - Gather Stakeholder Input..... 28
 - Prepare “Straw Man” Model..... 28
 - Engage Stakeholders to Review and Refine Straw Man Model 28

PROPOSED WORK BREAKDOWN STRUCTURE – TO BE UPDATED AFTER AWARD OF ONCHIT 130

PROPOSED ONCHIT 1 CONTRACT MANAGEMENT ORGANIZATION31

August 30-31, 2005 - Attendees

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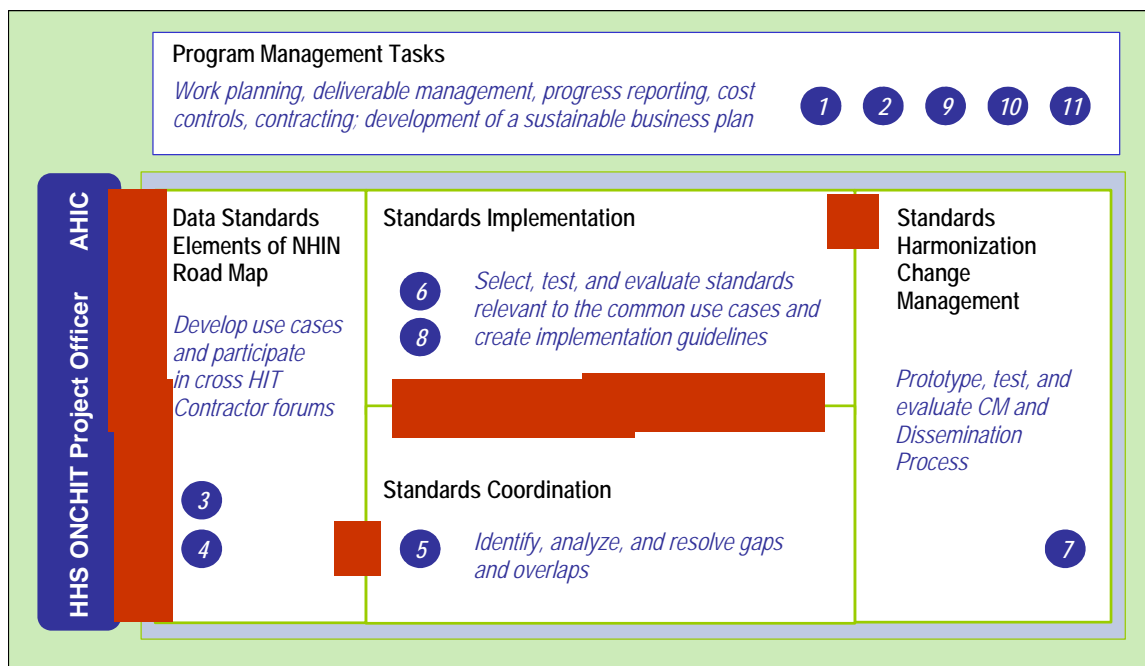
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Ranking of the Use Cases Based Upon the Defined Criteria

Primary Purpose	Other Characteristics A	Other Characteristics B
1. E-prescribing	Formulary	Prior Authorization
2. Chronic disease management	Chronic care/diabetes	Cancer patient survivors/PHR
3. Well child care	Immunization /Newborn D/C summary	Public health
4. Primary care - specialist referral	Infrastructure bundle	XDS
5. Infectious disease	Public Health/flu/lab	DX reporting
6. ER Visit		
7. Health monitoring		
8. OB/Gyn		
9. Meta data		

Integrated Approach to Performing the 11 Tasks Defined by the Government



n Indicates the Statement of Work tasks that are addressed.

Excerpts from the Technical Proposal Describing the Proposed Approach to Performing the Work

Task 3 – Develop a Minimum of Three Recommended Use Cases

The objective of Task 3 is to develop a minimum of three recommended use cases annually illustrating the applicability and business need for all areas of standards for interoperability. As applied in this context, a use case can be a narrative and graphical description (a storyboard with figures and diagrams) of the behaviors of persons or things (actors), and/or a sequence of actions, in a targeted area of interest (domain). For example, a storyboard describing the actions to “place a laboratory order with specimens” might read as follows:

“A physician in a care department prescribes laboratory tests for a patient. The order is entered into the Order Placer with all pertinent information. Using rules established by the laboratory (in the Order Placer’s dictionary), the Order Placer determines what specimens are required to perform the tests, with collection (container type, preservative/ anticoagulant, volume, time and patient status) and transportation conditions. The Order Placer also provides specimen identification labels which can contain a unique specimen ID (usually bar coded), a placer order ID, the patient identification (PID, name, visit number)...”

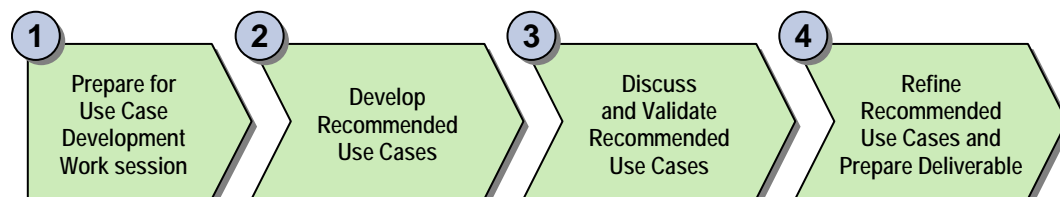
Excerpt from the IHE Laboratory Technical Framework, July 8, 2004
http://www.ihe.net/Technical_Framework/upload/LabTFVol1_v1_1_jul08_FT.pdf

A use case is typically coupled with technical specifications that guide how systems and technology must be implemented to meet the use case requirements. The technical specifications developed for the use case might include, among other things, a data model, process flows, the identification of standards to be used, and criteria to test whether the system can fully support the actions described in the storyboard.

Use cases are a proven tool for effectively linking real-world situations with the technology required to support them. By combining two different perspectives, the user’s and the technology implementer’s, a use case closes the gaps in understanding between the two views. The real-world scenarios described in a use case enable various stakeholders—technical and non-technical alike—to easily understand how the technology (in this case, standards for interoperability) supports common or envisioned behaviors of actors (clinicians, payers, etc.). The clarity and intuitiveness of the use case-driven approach will help establish a clear vision of national interoperability. Moreover, by selecting a use case-driven approach, HHS helps ensure from the start that all the necessary moving parts—from standards to certification to health information exchange—will focus on the same important healthcare transactions.

To develop the first set of recommended use cases in just one month, while achieving the necessary level of stakeholder consensus, we designed a fast track approach that includes focused preparation work, leveraging existing use cases, participation of key stakeholders in the use case workshop, and validation of the recommended use cases by a broader community. The following diagram provides an overview of Task 3 activities.

Exhibit 1. Task 3 Overview



Prepare for Use Case Development Work Session

Use case development must be a collaborative activity to ensure that the best thinking from across the community of interest is brought to light. However, the use cases must be developed, vetted, and ready for cross-HIT contractor review within thirty days. Therefore, the first activity in this task is to lay the foundation for rapid development and definition by leveraging existing use cases as the starting point for identifying those use cases most relevant to current national priorities. A representative Use Case Working Committee will take the actions needed to prepare for a work session where the broader community will complete the use case development activity. We will aggressively engage users (e.g., payers, providers, clinicians, and representatives of consumers of health services) to identify the highest impact use cases. Specifically, the Use Case Working Committee will:

- Identify use case workshop participants from across the stakeholder community.
- Define draft criteria for evaluating and prioritizing use cases based on national priorities for health care interoperability. The first set of criteria will screen for applicability to national priorities and business need. The second screening will address the feasibility of implementation.
- Baseline existing use cases for review and consideration and identify new candidate use cases.
- Apply evaluation criteria to create a prioritized list of baseline use cases.
- Prepare a template for use case definition. The template will provide a clear model for documenting a use case so that the workshop participants will have a structure to follow and can “fill in the blanks.” For example, the template will include elements such as actor list, process flow diagram, concise descriptive text, and high level data definition and data flow among participants.
- Arrange workshop logistics including arranging meeting space and lodging arrangements, identifying facilitator and scribe, preparing formal agenda, confirming attendee list, communicating logistics to participants, and preparing session documentation.

Develop Recommended Use Cases

The Use Case Working Committee will work to identify and define the recommended use cases in a working session. The working session will have a duration of two to three days depending on the final agenda. The tentative agenda for the working session will be as follows:

- Review the use case evaluation criteria that were prepared in advance; validate the criteria and add to or modify the criteria based on input from participants.
- Review the superset of use cases that were prepared in advance; validate each use case and add others to the list as appropriate based on input from participants.
- Apply validated evaluation criteria to the superset of use cases and prioritize the list of baseline use cases. Review the six to nine use cases ranked highest and obtain working committee agreement to designate the recommended use cases.
- Define working groups to prepare high level use case documentation (one use case per working group). The working groups will prepare high level use case documentation using the template defined under Activity One.
- Each working group will present its high level use case documentation to the group and incorporate group comments.

- Wrap up session, including documenting any open items or issues.
- Prepare the session documentation and distribute to participants and other stakeholders.

Discuss and Validate Recommended Use Cases

In Activity Three, the Use Case Working Committee will present the recommended use cases to a broader stakeholder audience including HHS IT contractors to obtain their input and validation. This is a step towards developing broader stakeholder consensus. We will present each of the recommended use cases in a “tabletop exercise” with Use Case Working Committee members representing the various roles and activities defined by each use case. The Use Case Working Committee will:

- Identify and invite participants to the use case review session.
- Prepare formal agenda, prepare session documentation, and arrange logistics, meeting space and lodging arrangements, identifying facilitator and scribe, confirming attendee list, communicating logistics to participants, etc.
- Conduct the review session, presenting each recommended use case to the group with Use Case Working Committee members playing the actor roles and walking through each use case scenario from start to finish.
- Capture comments from attendees during the session.

Refine Recommended Use Cases and Prepare Task 3 Deliverable

The Use Case Working Committee will refine and finalize the documentation for each of the recommended use cases. The Use Case Working Committee will prepare a written deliverable documenting the recommended use cases and provide the deliverable for Government review. Upon acceptance by the Project Officer, the recommended use cases will be ready to be presented to AHIC. After AHIC selects the Common Use Cases, the HITSP Board will organize a Technical Committee to lead subsequent activities for each use case.

Exhibit 2. Task 3 Delivery Schedule

Description	Quantity/Format	Estimated Delivery
TASK 3		
Ref# 3 Recommended Use Cases – Phase 1	Minimum of 3/ electronic	Within 1 month of EDOC
Ref# 11 Recommended Use Cases – Phase 2	Minimum of 3/ electronic	Within 14 months of EDOC
Ref# 17 Recommended Use Cases – Phase 3	Minimum of 3/ electronic	Within 26 months of EDOC
Ref# 23 Recommended Use Cases – Option Period	Minimum of 3/ electronic	Within 38 months of EDOC

Task 3 activities will be repeated for each contract year. Use cases for Years 2, 3, and possibly 4 will be created following a more carefully studied path through the Task 3 activities – not the initial 30 day process. As soon as the Year 1 use case activity is completed, we will charter a technical committee to begin identifying the next set of use cases to recommend to the AHIC for the subsequent year.

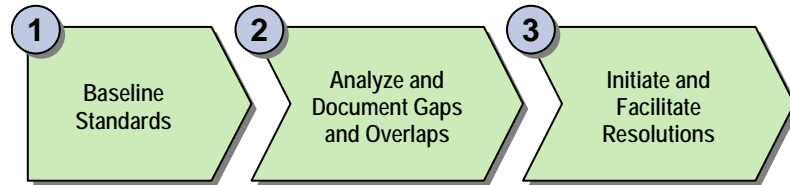
Task 5 – Standards Alignment and Gap Analysis

The goal of Task 5 is to identify the population of existing standards relevant to the Common Use Cases, and, concurrently with Task 6, analyze and document the gaps and overlaps specific to the standards, and

initiate and facilitate a process to resolve the gaps through interactions with the appropriate SDOs, user stakeholders and vendors.

Exhibit 3. Task 5 Overview

Standards coordination activities (Task 5) and standards implementation activities (Task 6) are conducted concurrently and the inputs and outputs of each task iterate between the tasks.



Baseline Standards

The Standards Harmonization Collaborative will begin by reviewing the existing inventories of standards to identify those that are relevant to the common use cases identified in Task 3. Examples include the US Health Information Knowledge Base Demonstration, the Consolidated Health Informatics (CHI) standards, and the ANSI HISB Inventory of Health Care Information Standards. We will aggressively reach out to SDOs, vendors, and other stakeholders to identify the broadest set of standards that are relevant to the use cases. During this effort, relevance will be defined in general terms, that is, the standard is relevant if it applies to most or all of the business events associated with the use case. The Standards Harmonization Collaborative will form a consolidated baseline inventory of the standards relevant to the common use cases, and catalogue information about the standards according to their level of maturity, business and technical characteristics that impact interoperability. Standards characteristics most relevant during Task 5 are venue and business event (defined in the following exhibit). The more detailed and technical characteristics are gathered or refined during the activities in Task 6.

Exhibit 4. Characteristics of a Standard

Characteristic	Description	Examples
Venue ¹	The stakeholder sub-community wherein existing healthcare information standards arose, and the exchange mechanisms and formats in which the standards are currently in use.	<ul style="list-style-type: none"> ▪ X12N messages to exchange administrative information among healthcare providers and payers ▪ DICOM to exchange diagnostic imaging information between modality systems and PACS and between PACS and EHR systems.
Business Event	The specific user action in a healthcare IT system that creates the need to send information to another system	<ul style="list-style-type: none"> ▪ A lab technician signing off that a result is valid and may be transmitted to the provider ▪ A primary care physician instructing his or her EHR system to send referral information to a cardiologist ▪ An emergency department physician asking is EHR system to query a RHIO to see if data on a patient is available from another EHR ▪ A physician asking his EHR to create an adverse event report based on information is has collected during an encounter.
Syntax	The way that data are represented in packages of information for interchange	<ul style="list-style-type: none"> • HL7 version 2 and version 3 syntaxes, including the Clinical Document Architecture, DICOM, NCPDP and X12.
Data Type	The way that an individual datum is represented within a package of information.	<ul style="list-style-type: none"> • Non-negative numbers of a maximum number of digits, • Unbounded integers • A datum that represents the date and time that an event occurred formatted according to ISO or W3C standards

¹ Within a healthcare domain, multiple ‘venues’ can exist.

Characteristic	Description	Examples
Coding	For coded data, the specific sets of values that are permitted in a message.	<ul style="list-style-type: none"> List of values for race Dictionary of medical diagnoses Dictionary of allowable laboratory tests
Information Model	Interrelationships among data within a message	Whether a lab report can be only about a person or also about a thing, or about an animal or about a herd

Analyze and Document Gaps and Overlaps

Once the landscape of relevant standards is known, the Standards Harmonization Collaborative will perform an analysis of the standards to identify duplications, gaps and overlaps related to the common use cases. The focus of this analysis effort will be on business-related interoperability characteristics; that is, venue and business event. The lower-level interoperability characteristics (syntax, data type, coding and information model) will be analyzed in Task 6 during the testing and evaluation activities. Information gathered during the Task 6 activities will be included in the documentation of duplications, gaps and overlaps throughout Task 5.

The Standards Harmonization Collaborative will identify the relevant venues for the common use case domains, and extract the business events involving the need to share information between IT systems from the use cases selected in Tasks 3 and 4. For each venue, the Standards Harmonization Collaborative will catalogue the standards that have been historically applied. Through discussions and information gathering with the HITSP panel, the Standards Harmonization Collaborative will document known duplications and overlaps within these venues. While complete ‘venue gaps’ will be identified during Task 6, business level barriers to implementation will be obtained based on the collective experiences of the HITSP, and recorded as part of the analysis.

The Standards Harmonization Collaborative will list each specific business event associated with a use case, and link the appropriate standards from the consolidated baseline to them. It is expected that multiple gaps and duplications will be identified for individual business events. We will reach to the stakeholders who have experience in standards implementations (including representatives from use and other stakeholder groups) related to the use cases to gather information about duplicative standards for specific business events, and provide insight into the origin of duplication. Similarly, we will highlight the business event for which few or no standards exist. Although the results of this analysis and documentation effort will be relatively high level, it is critical to identify significant standards gaps at the business event level, because it may pose an insurmountable barrier to accomplishing the activities outlined in Tasks 6 and beyond.

Initiate and Facilitate Resolutions

Where existing standards have gaps, or where no standard exists, it will be necessary to propose the refinement or adaptation of an existing standard, or formation of a new one to meet the common use case requirements. The outreach process initiated in Activity One will be extended to communicate with the appropriate SDOs to establish a ‘priority communication channel’ to fast-track a change or establish a new interpretation of an existing standard.

Assessing the Use of LOINC for Test Results

Booz Allen facilitated veterinary diagnostic laboratories’ adoption of LOINC for test results when developing the National Animal Health Laboratory Network. Simply by reviewing the results recorded in their LIMS systems, and comparing them to the LOINC codes for the diseases they tested for, the laboratory diagnosticians were able to identify multiple cases where results recorded in ‘real language’ did not map to LOINC. In some cases, new LOINC codes were requested; in others, the group found that concepts captured by the laboratory diagnosticians weren’t actually ‘results’ – and called for a different standard altogether.

In this activity, it is critical to understand the unique governance and volunteer staffing of the relevant SDOs. The creation of special policies may be required or by-laws may need to be modified for a fast track communication channel to be established. SDOs welcome input on well defined industry requirements. However, SDOs cannot accept dictated changes to their standards. The Standards Harmonization Collaborative will negotiate a successful gap resolution process based on respect for the open, consensus process of the SDOs. In addition – and perhaps of more significance -- most SDOs rely on volunteer experts for even the logistics involved in supporting the standards balloting, review and acceptance processes. The Standards Harmonization Collaborative’s ‘fast track’ gap resolution must include the resources to support ad-hoc meetings or out-of-sequence resolution recommendations to close a standards gap.

There will be cases where fast tracking an adaptation or new interpretation is not possible. Discovering these cases may occur during the higher-level venue and business event analysis of Task 5, or during the lower-level gap analysis conducting during the testing activities in Task 6. As stated above, if a standard does not exist, if it exists but is totally unproven, or there are deep rifts that cannot be resolved through the accelerated process, a longer-term convergence process may be required. If this occurs during the higher level analysis, it may result in a recommendation to AHIC to assign a lower priority to that use case.

The inventory, gap analysis and resolution activities will continue through use case sets in Years 2,3, and potentially Year 4. As the information gathered through these activities expands, and as individual participants providing input to these activities join the process and depart, the need for an automated repository of metadata (information about the standards’ interoperability characteristics) will arise. Indeed, an automated repository is mandatory in the long term given the complexity of clinical data and the long-term challenge of addressing use cases that go beyond direct care giving to supporting public health, clinical research, quality assessment and homeland security. The US Health Information Knowledgebase Demonstration, available through the National Cancer Institute, may be leveraged for this purpose.

Exhibit 5. Task 5 Delivery Schedule

Description	Quantity/Format	Estimated Delivery
TASK 5		
Ref# 6 Standards Gap/Overlap Resolution Strategy – Phase I	1/ electronic	Within 8 months of EDOC
Ref# 13 Standards Gap/Overlap Resolution Strategy – Phase 2	1/ electronic	Within 21 months of EDOC
Ref# 18 Standards Gap/Overlap Resolution Strategy – Phase 3	1/ electronic	Within 33 months of EDOC
Ref# 24 Standards Gap/Overlap Resolution Strategy – Option	1/ electronic	Within 45 months of EDOC

Task 6 – Selection, Test and Evaluation of Standards for Individual Use Cases

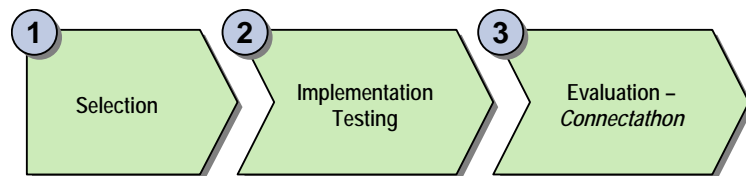
The purpose of Task 6 is to select, test and evaluate the standards identified in the inventory established in Task 5. Selection, testing and evaluation of specific standards that support the Common Use Cases will provide the basis for syntactic and semantic interoperability. The analysis of relevant standards in Task 5 will inform the selection, testing and evaluation processes in Task 6. The results of each step of Task 6 will also enhance the Task 5 analyses by confirming the results and by identifying additional gaps and overlaps. Both of these tasks will also inform the NHIN Road Map as Use Cases are identified and prioritized for subsequent phases and beyond.

The process the Standards Harmonization Collaborative will use to select, test and evaluate appropriate standards is a unique combination of the best features of the successful processes used by the ANSI Healthcare Informatics Standards Board (HISB), the HIMSS Integrating the Healthcare Enterprise (IHE) initiative, the US Health Information Knowledgebase, HL7 and the Federal Consolidated Health Informatics (CHI) program. The Standards Harmonization Collaborative of experts will determine the technical and vocabulary standards needed to support the Common Use Cases. Domain teams will examine the set of standards and tools for each domain and select the most appropriate standard. The CHI experience in selecting domain teams and using these teams to identify standards is an important component of this approach and standards that have already been selected by CHI will be given priority in the selection process for Common Use Cases. In addition, many of the stakeholders in healthcare already use standards specified by such groups as OASIS, DICOM, and HL7, among others. The Standards Harmonization Collaborative will discuss and agree on common standards in collaboration with HHS health IT contractors and appropriate stakeholders such as HHS, VA, DoD, DoC, DHS, EPA, NSF, and GSA, which shall be designated and convened by the Project Officer.

For each Common Use Case and the corresponding set of standards that support the Common Use Case, an Integration Profile will be created that precisely defines how the standards are to be implemented for the test. An Integration Profile is a set of implementation guidelines for the standards used to meet the Use Case and is discussed in more detail below. From this Integration Profile, a specification is developed to provide vendors and system integrators the information they need to implement each standard in their products. The effectiveness of the standard and its implementation is then tested in a live demonstration of prototypes. Live testing provides the true test of the value of a set of standards and is the only way to ensure that an Integration Profile is complete and correct. The end goal is not simply the adoption of standards, but true interoperability. The process the Standards Harmonization Collaborative proposes will provide an accurate method to select and evaluate standards based on the standards applicability to the Common Use Cases and the feasibility of adoption in NHIN prototypes. The process is detailed in the following paragraphs.

Exhibit 6. Task 6 Overview

Standards coordination activities (Task 5) and standards implementation activities (Task 6) are conducted concurrently and the inputs and outputs of each task iterate between the tasks.



Selection

The selection of healthcare standards will be driven by the user needs demonstrated in the Common Use Cases. The use cases will describe a business process composed of a number of sub processes and events, which require the selection and implementation of standards in several domains. A well defined and rigorous process is necessary because the world of standards today offers generality, ambiguity and many alternatives.

The Standards Harmonization Collaborative will convene a Technical Committee of domain experts to conduct a detailed analysis of each Common Use Case to determine the set of standards that will be needed to satisfy the required interoperability characteristics (see Exhibit 4 in Task 5). The Technical Committees will leverage existing standards and processes, such as those used in CHI and the National Library of Medicine’s Unified Medical Language System. Exhibit 7 presents examples of general evaluation criteria that may support the selection decisions.

Exhibit 7. Illustrative Evaluation Criteria for Standard Selection

Evaluation Criteria	Description
Supports the use case	The standard has the necessary codes or values or capability to support the use case. For example, <ul style="list-style-type: none"> ▪ For a vocabulary it must have both depth and breadth ▪ For a messaging standard the specification must support all of the message types and data that will be included in the message
Standard currently used in healthcare	The standard is currently used in a healthcare systems and settings. Widely used standards with a high satisfaction level among all stakeholders are the most desirable using this criteria.
Actively supported	The standard is actively supported by an SDO. The standard is current and regular releases and updates are provided
Widely available	The standard is a national or international standard. It is available to any stakeholder. There may be a license fee involved but there are no restrictions on the use of a properly licensed copy of the standard
Economic implications	The standard should be freely available or available with flexible pricing options to allow implementation by stakeholders ranging from large corporations to small physician practices to non-profit and academic institutions

In situations where more than one standard is identified to meet a requirement of a use care the “best fit” will be determined by the testing and evaluation activities in this task. Throughout this process, the ‘fast track’ communication process described in Task 5 will be leveraged to resolve gaps where possible. At the conclusion of this activity, the Standards Harmonization Collaborative will have selected a group of relevant standards for each of the Common Use Cases, and will have launched gap resolution activities that will allow the testing and evaluation of specific standards to proceed without delay.

Implementation Testing

The Standards Harmonization Collaborative testing activity will focus on both the standards’ ability to support interoperability, as well as feasibility or ease of adoption. The Standards Harmonization Collaborative will leverage the proven IHE process of developing “Integration Profiles” for standards in the context of specific use cases. An Integration Profile is a tool that organizes and leverages the integration capabilities that can be achieved by coordinated implementation of communication standards. Integration profiles provide a precise definition of how standards are implemented. An Integration Profile is written in a format that includes a detailed use case and the specifications for implementation of standards in products or systems. This detailed profile eliminates the ambiguity that is sometime associated with a standard that has been designed to support many situations and environments.

The Integration Profile provides detailed and complete specifications for each one of the standard subsets needed to support a use case, as well as all the linkages needed between the set of standards selected. This response uses the term “Integration Profile” instead of Implementation Guidelines because experience has demonstrated that most use cases require the use of more than one standard, and therefore must specify not only the guidelines for implementing each standard, but also the manner in which they should be used together.

Leveraging Testing Tools

For some domains there are already specific tools that facilitate such testing. For example, MESA is a set of publicly available software tools developed by the Electronic Radiology Laboratory at the Mallinkrodt Institute of Radiology, Washington University of St. Louis. The MESA tools are designed for use by participating companies in implementing standards in accordance with

The IHE experience tells us that in about one third of use cases, “micro gaps” are identified in needed standards when developing detailed Integration Profiles. Again, we will resolve these micro gaps in the standard through the ‘fast track’ collaborative process referenced in Task 5. If rapid resolution of the micro gap is not possible, the appropriate use case committee will consult with the AHIC and other ONCHIT contractors to modify some aspects of the Use Case in order to continue the process. At this stage, it will be critical to ensure the team can proceed with the selected use cases.

specific Integration Profiles and preparing for evaluation of the system interoperability. MESA provides communication partners test data and test plans to perform a baseline level of testing. The latest version of the MESA Test Tools available in the public domain can be found at www.ertl.wustl.edu/mesa/index.html.

The Standards Harmonization Collaborative will provide an opportunity for public comment on the proposed Integration Profiles prior to the actual testing. This will ensure that all interested parties will have the opportunity to provide feedback on the Integration Profile. The comments will be reviewed by the Use Case Committee.

The Standards Harmonization Collaborative will develop specific test cases and test scripts that can be used by system developers and integrators to perform independent testing. This level of testing is akin to “unit testing” in the software development industry and will prepare each system for the evaluation step describe below.

Evaluation

The Standards Harmonization Collaborative evaluation methodology will extend the proven IHE *Connect-a-thon* process, bringing multiple vendors and system integrators together to conduct live testing and evaluation of standards’ ability to be implemented in a multi-vendor environment and satisfy interoperability requirements. The Standards Harmonization Collaborative will organize and facilitate periodic evaluation events to allow software vendors and contractors from the other ONCHIT contracts to test the implementation of the required standards, and interoperability with corresponding systems from industry peers.

During the event, systems exchange information with other systems from multiple vendors, performing all of the transactions required for the roles required by the ONCHIT use cases as detailed in the Integration Profiles. Advantages of this evaluation methodology include:

- Testing in a controlled environment
- Cost-efficient access to testing with industry peers
- Opportunity to build and strengthen business relationships
- A managed process for implementing standards conformance

An example of this evaluation method is the IHE *Connect-a-thon* in January 2005, in Oak Brook, IL. The comprehensive, multi-domain *Connect-a-thon* included systems from cardiology, IT infrastructure, laboratory and radiology. The companies that participated in the 2005 *Connect-a-thon* are listed in Exhibit 8 and demonstrate the level of interest and value of this type of evaluation activity for a wide range of system providers.

IHE *Connect-a-thon*

The proven IHE *Connect-a-thon* process has been operating since 1998. The process tests at two levels: 1) using special software tools to test against the Technical Frameworks/ Integration Profiles, and 2) with other vendors to test actual interoperability. The *Connect-a-thon* culminates in a week-long event that tests vendor systems in a controlled environment. Thousands of cross-vendor tests are performed with tens of thousands of transactions passed among systems. *Connect-a-thons* remove barriers to interoperability and integration that would otherwise have to be dealt with on-site, at the expense of the customer. They also drive vendor awareness and adoption of best-of-breed, standards-based solutions.

Exhibit 8. Companies Participating in the 2005 *Connect-a-thon*

▪ Agfa HealthCare	▪ Hitachi Medical Corporation	▪ Novell, Inc.
▪ Allscripts	▪ Hologic	▪ Philips Medical Systems
▪ Camtronics Medical Systems	▪ IDX Systems Corp.	▪ QRS Diagnostic
▪ Cedara Software Corp.	▪ INFINITT Technology	▪ Quovadx
▪ Cerner Corporation	▪ InSite One, Inc.	▪ St. Jude Medical A.B.
▪ Dictaphone Corporation	▪ Intelrad Medical Systems	▪ Sectra Imtec A.B.
▪ Dynamic Imaging, LLC	▪ InterSystems Corporation	▪ Sentillion
▪ Eastman Kodak Company	▪ Konica-Minolta Medical Imaging, USA, Inc.	▪ Siemens Medical Solutions
▪ Eclipsys	▪ Kryptiq	▪ Stentor
▪ Eimageon	▪ Marotech	▪ Swissray International, Inc.
▪ Epic Systems Corporation	▪ McKesson Information Solutions	▪ Tiani Medgraph A.G.
▪ ETIAM	▪ MedCommons Inc.	▪ Tiani Spirit GmbH
▪ FujiFilm Medical Systems, USA, Inc.	▪ MedCon, Inc.	▪ Toshiba Medical Systems Company
▪ GE Healthcare	▪ Merge eFilm	▪ Vital Images
▪ Heartlab, Inc	▪ Mortara Instrument, Inc.	▪ WebMD Practice Services

The process defined by the Standards Harmonization Collaborative is a comprehensive and proven selection, testing and evaluation process that leverages existing processes and completed work. As a result of the activities described in Task 6, this contract team, in collaborative with the government and contractors identified by the Project Manager, will deliver:

- List of all the standards that satisfy the requirements imposed by the relevant use-cases
- Testing criteria, in the form of test cases and test scripts that shall be used to test the standard to the relevant use-case.
- Results of the interoperability evaluation.

Exhibit 9. Task 6 Delivery Schedule

Description	Quantity/Format	Estimated Delivery
TASK 6		
Ref# 8 Recommended Standards – Phase 1	1/ Electronic	Within 9 months of EDOC
Ref# 15 Recommended Standards – Phase 2	1/ Electronic	Within 22 months of EDOC
Ref# 20 Recommended Standards – Phase 3	1/ Electronic	Within 34 months of EDOC
Ref# 26 Recommended Standards – Option	1/ Electronic	Within 46 months of EDOC

Task 7 – Prototype, Test and Evaluate Processes for Change Management and Dissemination of Harmonized Standards

The purpose of Task 7 is to prototype, test and evaluate a standards change management process, and a process and vehicle for disseminating the information about the standards that are relevant to the use cases. The ability to scale to a nationwide change management process is an imperative for the future. Without effective dissemination channels, the degree of adoption will remain at levels too low to have significant impact. But even when adoption is high, a viable process for attaining commitment and

managing change within the health standards community is required to consistently leverage the full potential of standards toward the goal of national interoperability.

There are three elements to effectively manage changes to standards. First is Change Management, the implementation of specified procedures for controlling, documenting and reporting change. Second is the Dissemination Process, the channel and schedule for conveying the information about implementing health standards in support of use cases. Third is the Road Map, a shared strategy for change that can inform both processes and provide adequate lead time for stakeholders to react to changes disseminated through the process.

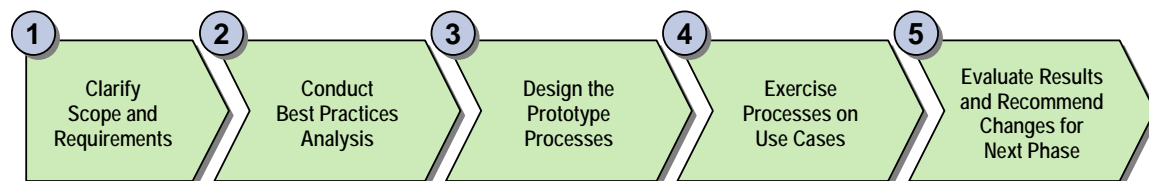
But regardless of how effective our processes are, and no matter how much lead time we provide for vendors, if the user community does not choose to adopt the standards our efforts will have little impact. As we have seen, the health community has historically been slow in adopting new standards, primarily because institutions are using systems that comprise integrated commercial off the shelf software (COTS) and custom applications packages with many and complex interfaces. Upgrading products to stay compliant with changes in standards is not always the top priority – real world experiences teach user’s that “if it is not broken, don’t fix it.” For this reason, contractors across the ONCHIT HIT programs must continue to consider incentives for adoption.

A national strategic roadmap for interoperability and encouraging adoption of HIT are not directly in the scope of Task 7. However, our proposed approach will remain mindful of both.

Our proposed processes for change management and dissemination of harmonized standards will be prototyped, tested and evaluated consistent with the voluntary consensus model for standards -- that is standards that are developed by a standards development body employing a consensus based process. Consensus is defined as general agreement, but not necessarily unanimity, and includes a process for attempting to resolve objections by interested parties, as long as all comments have been fairly considered, each objector is advised of the disposition of his or her objection(s) and the reasons why, and the consensus body members are given an opportunity to change their votes after reviewing the comments.

Our approach to Task 7 is summarized below and described in the following sections.

Exhibit 10. Task 7 Overview



Clarify the Scope and Requirements of the Change Management and Dissemination Processes

The first activity we propose pertains to clearly understanding what is meant by a change management and a dissemination process. Historically, the health standards issue has been characterized as being understood only by the group of intellectuals that shared the same jargon and who were either unable or unwilling to be understood by policy makers and

Interoperability Showcase

The IHE Interoperability Showcase at the HIMSS 2005 Annual Conference is an example of a widely attended and effective information dissemination process. At this show case a demonstration of an interoperable personal health record resulted in:

- 5,772 document entered
- 47,415 requests for documents
- 40,984 individual items queried.
- 2300 attendees participants
- 32 vendors and
- 12 organizations including the DoD and VA

other “outsiders.” This perception, whether earned or not, must be addressed before we can disseminate standards information and manage its changes. For example, do we wish to manage change just to standards that affect the technical aspects of interoperability, or do we also wish to manage changes to clinical languages that is conveyed using the technology? If the Common Use Cases include use of a clinical language, than the quality of the standards harmonization and implementation activities will be enriched by managing changes to the meaning of the interoperable information.

The best way to avoid potential conflicts and ensure maximum benefit from a standard is to participate in its development. If an organization neglects to participate in the change process, there is a risk that the standard will be developed in a way that does not address, or worse, hampers, the organization’s interests. There are a number of ways to participate in standards change as shown in Exhibit 11.

Exhibit 11. Example Modes of Participation in Standards Change Management

Mode of Participation	Description
Track Development	<ul style="list-style-type: none"> Follow the development of a standard or guideline at a high level, for example, by reading summaries and implementation timelines on the developer’s public website. Organizations usually choose this role if they aren’t sure if the standard will affect them, or if they don’t feel they can have much influence on it’s development
Perform Public Reviews	<ul style="list-style-type: none"> Perform public review of drafts of the standard made available by the development organization (submission of comments is optional). Organizations often choose this role when they want advance or deeper level of knowledge of the developing standard but aren’t necessarily interested in altering or influencing the content of the standard.
Perform Formal Review	<ul style="list-style-type: none"> Become a formal reviewer by establishing a relationship with the standards developer and making a commitment to review and provide comments on drafts. The formal reviewer’s comments help to ensure that the standard takes into account the organization’s needs, including the needs of its customers, partners, suppliers or other stakeholders, its technology, market, investments and plans for the future
Develop a Standard	<ul style="list-style-type: none"> Become a member of the standards developer’s organization While standards developers typically solicit and consider comments from public and formal reviewers, it is the members who have the greatest influence on the standard because they actually write the standard.
Drive Development	<ul style="list-style-type: none"> Drive the development of a new standard by investing significant resources and assuming key responsibilities This may be appropriate when producing the standard is part of the organization’s charter or mission, or when the need for the standard is critical.

The Standards Harmonization Collaborative considers each level of participation and creates an evolutionary approach to change management and dissemination that will address the different needs of participants over the course of the contract period of performance.

We propose that Change Management/Dissemination requirements and scope be on the agenda of one of the early cross-HIT contractor forums described in the Statement of work under Task 4. We will draft and propose to the forum a phased high-level concept of operations for change management and dissemination for discussion. As a result of this activity, we will have a shared understanding of the priorities and expectations of the broader HIT community for standards dissemination and change management. Through a shared understanding, we can avoid duplications, omissions, and inefficiencies in our processes.

Conduct a Best Practices Analysis

As our first step, we will conduct a review of national and international SDO and SDO coordinating group Change Management and Dissemination processes to fully understand the processes and to gather

lessons learned. In doing this we will highlight best practices and increase our knowledge of past obstacles to success.

Exhibit 12 presents some of the best practice indicators that we will be looking for during our review.

Exhibit 12. Change Management Best Practice Indicators

Best Practice Indicator	Example
Collaborative	There is a demonstrated inclusive and collaborative process for each step of the standards update and maintenance process. This includes definition of the requirements for change or update to the standard; development of new terms or message structures; public comment; testing; and publication
Consensus	The decision making process provides for adequate discussion and is flexible and open so that decisions based on at least general agreement by all stakeholders is achieved
Rate of adoption	Two of the factors influencing the rate of adoption is the process by which changes are managed and the effectiveness of the publication and dissemination of the standard
Agility	When there is a critical health care business requirement for a change to a standard, the process has flexibility to meet that requirement in a timely manner. This may be through an out of cycle release or an interim / draft standard.
Transparency	The process for change is visible to all stakeholders. Although not every stakeholder will actively participate in the development and maintenance of a standard, every stakeholder should be able to observe each step of the process

One example of an existing practice to provide rapid and transparent response to new business requirements is the ISO process.

“ISO standards are developed according to strict rules to ensure that they are transparent and fair. The reverse side of the coin is that it can take time to develop consensus among the interested parties and for the resulting agreement to go through the public review process in the ISO member countries. For some users of standards, particularly those working in fast-changing technology sectors, it may be more important to agree on a technical specification and publish it quickly, before going through the various checks and balances needed to win the status of a full International Standard. Therefore, to meet such needs, ISO has developed a new range of "deliverables", or different categories of specifications, allowing publication at an intermediate stage of development before full consensus: Publicly Available Specification (PAS), Technical Specification (TS), Technical Report (TR), International Workshop Agreement (IWA).”

Excerpt from the ISO Web Site

<http://www.iso.org/iso/en/aboutiso/introduction/index.html#sixteen>
<http://www.iso.org/iso/en/aboutiso/introduction/index.html - top#top>

Design the prototype processes to include governance, operations, public channels, and schedules





The HITSP Charter defines a governance process for engaging SDOs and coordinating the activities of existing SDOs and standards coordinating and certification organizations. We will use this process to harmonize the changes and updates to the HIT standards. Changes and updates to standards are extensions of development and will follow the same rules for participation, collaboration and achieving consensus. In addition to the HITSP processes that provide an overarching framework for standards harmonization, we propose that each SDO manages its internal process and overall schedule for standard maintenance in recognition of the HITSP plans and schedule.

To promote wide spread public dissemination of each release of a standard, we will establish an HIT Standards Web Site. This web site will provide a single point of contact for information about HIT standards. Through the web site, stakeholders will access information about each of the standards and the

relevant use cases as each of the steps in the standards harmonization process that are described in this proposal are completed. The web site will also provide a master schedule for the release of new and updated standards. Finally, the web site will provide links to the web sites and other public information sources maintained by SDOs and standards coordinating bodies.

We will also leverage existing publication and standards support mechanisms including the examples shown in Exhibit 13. These examples demonstrate both public outreach and support mechanisms. Support for standards includes not only public announcements and schedules but also comprehensive implementation guidelines (from Task 8) and education opportunities. We will leverage both the new (e.g. new implementation guidelines), and the “old” (e.g. education sessions to effectively disseminate information and support for adoption).

Exhibit 13. Example Public Dissemination Channels

Public Communication Channel	Example
Federal Register	<p>The Federal Register is published by the Office of the Federal Register, National Archives and Records Administration (NARA). The Federal Register is the official daily publication for rules, proposed rules, and notices of Federal agencies and organizations, as well as executive orders and other presidential documents. It is a key source of information for all government agencies and stakeholders affected by government proposal, including government sponsored adoption of standards.</p>
NIST Publications and Conferences	<p>NIST publishes a variety of standards related publications including the Federal Information Processing Standards (FIPS). NIST also maintains a publicly available on-line technical publications database which can be leveraged to locate NIST publications.</p> <p>Additional outreach can be accomplished through conferences in collaboration with NIST. NIST conferences are co-sponsored with other federal agencies, academic institutions, professional societies, or industry groups. NIST also co-sponsors conferences with commercial or profit-making organizations provided the conference is not budgeted to make a profit for the organizers or the conference is not used for commercial purposes by the co-sponsor.</p> 
IHE Interoperability Showcase	<p>An interoperability demonstration held as part of the annual HIMSS Conference & Exhibition to demonstrate advancements in technology and standards through an interactive environment. The Showcase provides key information on the latest issues, standards, processes, products and insights.</p> 
HL7 Education Session	<p>The HL7 Educational Summit is a concentrated, schedule of tutorials focused on HL7-specific topics. This is an educational opportunity for the healthcare IT community as it strives for greater interoperability among healthcare information systems. Classes offer information designed to benefit a wide range of HL7 users, from beginner to advanced.</p> 
ANSI	<p>Standards Action is ANSI's key public review vehicle. Published weekly, it provides members and the public with timely, accurate information and enables effective participation in the standards development process - both in this country and internationally.</p> 

This combination of new and existing processes will provide an overall strategic direction to HIT standards harmonization and leverage existing processes to provide an efficient and effective change management process.

Exercise the processes on one or more of the use cases

The initial use of our processes will be for standards for which there are only minor changes such as the “micro-gaps” described in our description of Task 6 and for major releases of existing standards that have already been scheduled for release during the first 8 months of this contract. Limiting testing of the new combination of processes will prevent any negative impact on the current release cycle for any given standard. This an important consideration since predictability is one of the key factors that will enhance adoption rates.

The combination of new and existing change management and public dissemination processes will be well tested through life of the contract as gaps and duplications are resolved for the common use cases. This testing and evaluation will initially occur with relatively small changes and will be refined as larger issues are addressed by major releases of new and updated standards. We believe this incremental approach to implementing and testing the change management process will result in an effective and efficient process while incurring minimum risk.

Over the life of this contract, message and vocabulary standards will be updated through major releases. The Standards Harmonization Collaborative will exercise the HITSP governance process as defined in the HITSP Charter and the dissemination processes defined above.

Evaluate the results and recommend changes for next phase

We will evaluate the Change Management and Dissemination processes in the first year, and continue to evaluate these processes for each of the following years. The primary evaluation criteria we will use are described in Exhibit 14. Other evaluation criteria will be developed as part of the execution of this task.

Exhibit 14. Initial Change Management and Dissemination Evaluation Criteria

Evaluation Factor	Description
Purchase of new standards or downloads from the distribution site	As each new version of a standard is published, the rate at which the latest version is purchased (for fee based standards) or downloaded from an official web site (for publicly available standards) will be measured and tracked against other events such conferences, publications and education sessions
Unique visitors or “hits” on web sites	Record the number of visitors to the ONCHIT Standards Web Site and will work with each standard specific web site sponsor to record visitors to their sites
Feedback on the ONCHIT Web site and on each of the SDO web sites	Monitor feedback from visitors to each web site
Attendance at events	Monitor and record attendance levels at standards showcases, conferences and educational events
Rate of adoption	Monitor and record the rate of adoption of each release of a standard

As a result of Task 7, we will deliver the Dissemination Plan and Release Schedule for Relevant Standards and Publicly Available Dissemination Channel. This deliverable will be refined and updated in Year 2, 3, and possibly 4.

Exhibit 15. Task 7 Delivery Schedule

Description	Quantity/Format	Estimated Delivery
TASK 7		
Ref# 7 Dissemination Plan and Release Schedule for Relevant Standards and Publicly Available Dissemination Channel	1/ Electronic	Within 8 months of EDOC
Ref# 14 Dissemination Plan and Release Schedule for Relevant Standards and Publicly Available Dissemination Channel	1/ Electronic	Within 21 months of EDOC
Ref# 19 Dissemination Plan and Release Schedule for Relevant	1/ Electronic	Within 33 months of EDOC

Standards and Publicly Available Dissemination Channel		
Ref# 25 Dissemination Plan and Release Schedule for Relevant Standards and Publicly Available Dissemination Channel	1/ Electronic	Within 45 months of EDOC

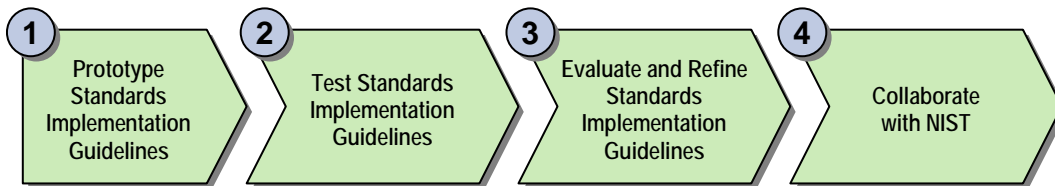
Task 8 – Implementation Guidelines for Standards

The purpose of Task 8 is to prototype, test, and evaluate standards implementation guidelines for each use case that are the tangible artifacts of the work performed in Tasks 3, 5 and 6. The purpose of implementation guidelines is to provide clear, unambiguous instructions to guide various organizations through the process of implementing the standards in their business operations and supporting IT systems. The Implementation Guidelines are the focus of the Change Management and Dissemination processes described in Task 7.

Implementation Guidelines may also serve as a criteria for certifying that HIT products are compliant with national standards. These touch points between ONCHIT1 and ONCHIT2 will be explored after award to ensure that the technical approach for one is consistent with the other.

The following diagram provides an overview of Task 8 activities with their corresponding inputs and outputs.

Exhibit 16. Task 8 Overview



Prototype Standards Implementation Guidelines

In the first activity, the team will review the existing, relevant standards implementation guidelines for best practices. The goal of this effort is to leverage experience of organizations that have experience with standards implementation guidelines.

The team will define a template for standards implementation guidelines. The template will include major elements including:

- Applicability guidance/decision support matrix: Which standards apply to my situation as a specific type of healthcare systems vendor/healthcare provider/payer? How can I evaluate the costs and benefits associate with each applicable standard?
- Detailed implementation instructions: What are the specific steps I need to take to implement the applicable standards? What are the dependencies among the steps? What types of resources will be required to implement the applicable standards? What does a sample project plan for implementing the standards look like? What kind of organizational development/change management activities should I undertake to help ensure successful implementation?
- Implementation quality verification guidance: How can I verify that I’ve implemented the standard correctly? What are the recommended testing methods and scenarios?

- Common implementation issues and solutions: What are the lessons learned? What are common questions standards implementers ask?

Using the template described above, concurrent and in collaboration with the team developing, testing and evaluating the Integration Profiles in Task 6, the team will write draft standards implementation guidelines for the selected standards.

Test Standards Implementation Guidelines

The team will plan and execute tests to verify the effectiveness and accuracy of the standards implementation guidelines. Test preparation activities will include the following steps:

- Identify and engage test participants (actors for the relevant Common Use Cases, such as real world providers, payers, and software vendors).
- Define test scenarios (identify specific systems, transactions, scope, etc.). The team will leverage experience of organizations such as ANSI, IHE, and HIMSS to identify applicable best practices in testing standards implementation guidelines.
- Prepare any necessary materials (test data, interface specifications, implementation plan, etc.).

During the activities of this task, the team will uncover issues related to both adoption as well as the appropriate use of a specified standard in a demonstration of functions described in a use case or set of use cases. A key requirement of this demonstration is interoperability. It is not sufficient to implement a standard in such a way that only demonstrates its use within a single vendor or system solution. The implementation must be interoperable with other solutions that support the same use cases.

Many issues influence the adoption and implementation of interoperability standards in health care; Exhibit 17 below presents several key issues and some examples for possible mitigation strategies. As required under this task, we will develop a thorough description of issues relevant to the standards identified by this effort.

Exhibit 17. Discussion of Standards Adoption Issues

Issue	Description	Mitigation
Lack of agreement on which standard to use	<ul style="list-style-type: none"> ▪ For any given use case there is frequently more than one applicable standard, either for vocabulary or for message structure and exchange that can be used. ▪ For global corporations and in the national public health arena there are conflicts with standards adopted by other countries. For example, a patient identification algorithm in the European Union will not necessarily be interoperable with the method adopted in the United States. ▪ Older versions of a standard that has been implemented in a legacy system are not always fully interoperable with newer versions. 	<ul style="list-style-type: none"> ▪ Our process provides a consensus based selection process using a broad base of stakeholders. It also demonstrates correct use and effectiveness of the standard for a specific use case. ▪ The implementation schedule and process provided by our team will facilitate planning and budgeting for adoption and upgrades to legacy systems.

Issue	Description	Mitigation
Lack of agreement on implementation options	<ul style="list-style-type: none"> ▪ Many standards can be implemented in individual systems in different ways. Standards can be general and ambiguous. Most standards have optional features or implementation options that result in system implementations that are not interoperable. For example, the MedDRA Dictionary has been used to describe drug adverse events by using either Preferred Terms (PT) or Lower Level Terms (LLT). While both PTs and LLTs are valid within the MedDRA dictionary, the used of different coding levels in different systems can make data aggregation and analysis difficult for public health surveillance systems. 	<p>The proposed testing and evaluation process (Task 6) (beginning with the use of specific integration profiles linked to the priority use cases) provides the specificity needed to allow the implementation of standards to ensure interoperability.</p>
Cost of implementation in legacy systems	<p>Implementing a standard in a legacy system can be costly in terms of time and money for both vendors of hardware and software systems and for the users of those systems. For each new standard or version of a standard there are a series of tasks that must be completed:</p> <ul style="list-style-type: none"> ▪ Analysis – an analysis of the message or vocabulary to be implemented versus the existing system must be completed to gain an understanding of the changes needed. ▪ Translation / Mapping – a strategy for mapping terms from one version or vocabulary to the preferred version. ▪ Migration – a strategy for migration to the new standard or technology is required. This could include mapping or translation of terms from one vocabulary to another. ▪ Validation / Certification – many legacy systems are validated or certified to operate correctly, especially those operating in a regulated environment. Upgraded systems must be re-validated or re-certified. 	<p>Through the Connectathon style testing and evaluation sessions (Task 6) our solution provides real world implementation assistance and examples, and experience that can be used to develop proven implementation strategies.</p>
Timing	<p>The timing of the implementation of a new or updated standard is important to ensure continuous interoperability between systems. Depending on the maturity of an information system within an organization, the timing of an implementation of a standard may be linked to:</p> <ul style="list-style-type: none"> ▪ Implementation of a new system and legacy system retirement ▪ An existing system's upgrade cycle ▪ Other priority activities in the organization 	<p>Our approach provides a transparent, clear and predictable time table for the process by which standards are selected, tested, evaluated and disseminated. Organization can utilize this information to assess the value of the use cases and the supporting standards to their operations and thus incorporate the standards development timing in their enterprise IT planning process.</p>
Availability of the standard	<p>This typically is an issue with a proprietary standard such as a dictionary or vocabulary for which there is a license cost.</p>	<p>The approach is to begin standards selection with standards that have been selected by the CHI. The focus on commonly used standards may result in lower costs due to economy of scale discounts or public domain versions of the standard.</p>

Evaluate and Refine Standards Implementation Guidelines; Prepare Deliverable

Following completion of testing, the team will analyze test the results and defects/issues discovered. The team will also interview test participants to gather additional feedback.

Based on the analysis of test results and feedback from participants, the team will first review and update the standards implementation guidelines template itself. With template updates completed, the team will turn to the tasks of reviewing and updating the selected standards implementation guidelines. With these tasks complete, the team will prepare and deliver the Standards Implementation Guidelines deliverable for Government review.

Booz Allen has first hand experience working with NIST to develop implementation guidelines

Booz Allen is currently under contract to develop high quality, time-sensitive, and accurate computer security and information assurance (IA) guidance publications and materials for NIST that reflect the requirements of the latest laws and regulations. In addition, technical support is provided to their IA activities. The purpose of this effort is three-fold: (1) develop tools and techniques that streamline products, services, and security controls development; (2) develop guidance and tools to promote the deployment of products, services, and security controls; and (3) assist NIST in the development and maintenance of Federal Information Processing Standards (FIPS) and Special Publications.

Collaborate with NIST

The team will develop a plan to collaborate with NIST which will provide leverage NIST best practices and will provide NIST with the information needed to adopt relevant standards as Federal Information Processing Standards (FIPS). The team's experience with the NIST mission and operations provide an excellent basis for developing and executing a plan to collaborate with NIST. We understand the NIST culture and requirements for creating, evaluating, publishing and designating Federal Information Processing Standards (FIPS). The ANSI Team is experienced in supporting NIST's rule-making procedures modeled after those established by the Administrative Procedures Act:

- NIST announces the proposed FIPS in the *Federal Register* for public review and comment. At the same time that the proposed FIPS is announced in the Federal Register, it is also announced on NIST's electronic pages. To encourage review by senior information technology officials, the proposed FIPS is announced on the electronic pages of the Chief Information Officers Council. The text and associated specifications, if applicable, of the proposed FIPS are posted on the NIST electronic pages.
- A 30 to 90-day period is provided for review and for submission of comments on the proposed FIPS to NIST.
- Comments received in response to the *Federal Register* notice and to the other notices are reviewed by NIST to determine if modifications to the proposed FIPS are needed.
- A detailed justification document is prepared, analyzing the comments received and explaining whether modifications were made, or explaining why recommended changes were not made.
- NIST submits the recommended FIPS, the detailed justification document, and recommendations as to whether the standard should be compulsory and binding for Federal government use, to the Secretary of Commerce for approval.
- A notice announcing approval of the FIPS by the Secretary of Commerce is published in the Federal Register, and on NIST's electronic pages.
- A copy of the detailed justification document is filed at NIST and is available for public review.

The plan we develop will be completely compatible with the FIPS process. Our open, transparent and consensus-driven standards selection, testing and evaluation process will provide standards which can be inserted directly into the NIST process.

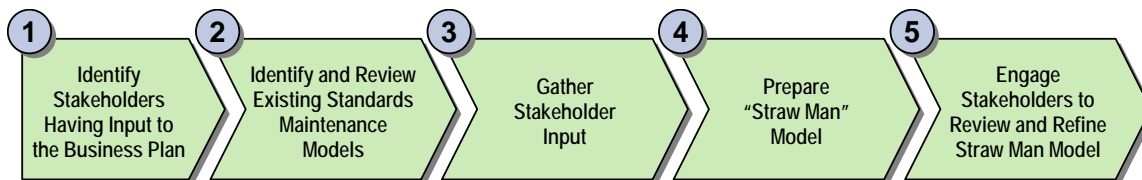
Exhibit 18. Task 8 Delivery Schedule

Description	Quantity/Format	Estimated Delivery
TASK 8		
Ref# 9 Implementation Guidelines (per use case)– Phase 1	1/ Electronic	Within 12 months of EDOC
Ref# 16 Implementation Guidelines (per use case) – Phase 2	1/ Electronic	Within 24 months of EDOC
Ref# 21 Implementation Guidelines (per use case) – Phase 3	1/ Electronic	Within 36 months of EDOC
Ref# 27 Implementation Guidelines (per use case) – Option	1/ Electronic	Within 48 months of EDOC

Task 9 – Develop Business Plan for Self-Sustaining Standards Harmonization Process

The purpose of Task 9 is to design and develop a self-sustaining standards harmonization process to ensure future viability and appropriate evolution of the standards defined by this project. To be successful, the business plan must take into account the inevitable evolution of technology, health care provision models, and development of new or refined government and industry models of operation and collaboration. The ongoing process must include appropriate representation from stakeholder organizations, and must be based on a balanced approach that applies sufficient stewardship and leadership without creating unnecessary overhead or bureaucracy. Our proposal is based on a philosophy of inclusion, as evidenced by the team we have assembled and by the stakeholders identified as targeted participants in the proposed governance process. This philosophy will also guide the development of the business plan.

Exhibit 19. Task 9 Overview



Task 9 will have an elapsed duration of six months and will be complete twelve months from EDOC.

Identify Stakeholders Having Input to the Business Plan

The Standards Harmonization Collaborative will identify the stakeholders whose input and consensus will be needed to define the self-sustaining process. These stakeholders will include Government representatives from numerous agencies identified in RFP Section C.2, representatives from all stakeholder groups. We will identify the core group of stakeholders who will participate in the review process later in this task and invite their participation.

Identify and Review Existing Standards Maintenance Models

Using input from the stakeholders and drawing upon our team’s expertise, we will identify existing standards maintenance models to review as input to defining the new self-sustaining process. The team will document potentially useful elements of the existing models, and also document pros and cons about each model studied. To the extent possible, the team will interview participants and leaders of the existing

maintenance models and solicit their input regarding what works well in their models and what challenges they face.

Gather Stakeholder Input

Standards Harmonization Collaborative will gather stakeholder input through a series of meetings and interviews with all stakeholder groups identified in Activity One above. Data gathering tools may also include a Web-based survey.

A subsequent step for collecting input will be a “town hall” meeting at the HIMSS Annual Conference in February 2006. Nearly 23,000 healthcare professionals with a focus on information technology attended the 2005 HIMSS Annual Conference. HIMSS has previously held similar sessions that provide an open forum opportunity for large numbers of diverse stakeholders to discuss significant issues. This conference is also an excellent opportunity for smaller groups to meet in person to hear updates on activities and provide responses to them. Standards Harmonization Collaborative will also convene stakeholder and other interested groups at this conference for this purpose. We will utilize other associations’ conferences and seminars as appropriate to gain further feedback about the early work of the proposed standards harmonization process and to gain suggestions for organizational and operational constructs of a sustainable business model.

Prepare “Straw Man” Model

Based on ONCHIT requirements and information gathered in the activities described above, the team will define and document a “straw man” model for consideration by ONCHIT stakeholders. Major elements of the model will include:

- Organizational and operational model;
- Strategic and tactical planning model;
- Technical oversight and direction; and,
- Budget estimate for six years of operation; and,
- Sustainable funding model including examination of revenue sources such as membership dues, standards implementation guidelines and other documentation sales, interoperability test suite sales, and other funding sources.

Engage Stakeholders to Review and Refine Straw Man Model

The team will organize a two to three day working session to review and refine the straw man model. Participants will include key stakeholders whose input and consensus are considered essential to definition and adoption of a successful operating model. The tentative session agenda will be as follows:

- Review straw man operating model and capture initial comments and suggestions for revision.
- Organize working groups of session participants to further refine components of the straw man model.
- Working groups conduct their activities, document their work, and report back to the consolidated group.

The Standards Harmonization Collaborative team will refine and finalize the documentation of the self-sustaining process. This activity has a duration of approximately one month. The Standards Harmonization Collaborative will prepare a written deliverable documenting the sustainable process and provide the deliverable for Government review.

As a result of Task 9, we will deliver a business plan that includes cost and revenue projections over a 6-year period, a the proposed organization and concept of operations needed to implement the business model.

Exhibit 20. Task 9 Delivery Schedule

Description	Quantity/Format	Estimated Delivery
TASK 9		
Ref#10 Business Plan	1 electronic	Within 12 months of EDOC

Proposed Work Breakdown Structure – To be updated after award of ONCHIT 1

Task Name	3rd Quarter		4th Quarter			1st Quarter			2nd Quarter			3rd Quarter			4th Quarter	
	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov
ONCHIT1 Base Year Activities	[Gantt chart showing task durations across quarters]															
Task 1: Develop and Maintain a Comprehensive Work Plan	[Gantt chart showing task durations across quarters]															
Prepare WBS and Work Plan	[Gantt chart showing task durations across quarters]															
Align ONCHIT1 Activities with Other Work Streams	[Gantt chart showing task durations across quarters]															
Prepare Earned Value Management Model	[Gantt chart showing task durations across quarters]															
Define Risks and Mitigation Strategies	[Gantt chart showing task durations across quarters]															
Task 2: Conduct Project Start-up Meeting	[Gantt chart showing task durations across quarters]															
Task 3: Develop a Minimum of Three Recommended Use Cases	[Gantt chart showing task durations across quarters]															
Prepare for Use Case Development Worksession	[Gantt chart showing task durations across quarters]															
Develop Recommended Use Cases	[Gantt chart showing task durations across quarters]															
Discuss and Validate Recommended Use Cases	[Gantt chart showing task durations across quarters]															
Refine Recommended Use Cases and Prepare Task 3 Deliverable	[Gantt chart showing task durations across quarters]															
Task 4: Cross HIT Project Coordination	[Gantt chart showing task durations across quarters]															
Task 5: Standards Alignment and Gap Analysis	[Gantt chart showing task durations across quarters]															
Baseline Standards	[Gantt chart showing task durations across quarters]															
Analyze and Document Gaps and Overlaps	[Gantt chart showing task durations across quarters]															
Initiate and Facilitate Resolutions	[Gantt chart showing task durations across quarters]															
Task 6: Selection, Test and Evaluation of Standards for Individual Use Cases	[Gantt chart showing task durations across quarters]															
Selection	[Gantt chart showing task durations across quarters]															
Implementation Testing	[Gantt chart showing task durations across quarters]															
Evaluation	[Gantt chart showing task durations across quarters]															
Task 7: Prototype, Test and Evaluate Processes for Change Management and Dissemination of Harmonized Standards	[Gantt chart showing task durations across quarters]															
Clarify the Scope and Requirements of the Change Management and Dissemination Processes	[Gantt chart showing task durations across quarters]															
Conduct a Best Practices Analysis	[Gantt chart showing task durations across quarters]															
Design the Prototype Processes to include Governance, Operations, Public Channels, and Schedules	[Gantt chart showing task durations across quarters]															
Exercise the Processes on One or More of the Use Cases	[Gantt chart showing task durations across quarters]															
Evaluate the Results and Recommend Changes for Next Phase	[Gantt chart showing task durations across quarters]															
Task 8: Implementation Guidelines for Standards	[Gantt chart showing task durations across quarters]															
Prototype Standards Implementation Guidelines	[Gantt chart showing task durations across quarters]															
Test Standards Implementation Guidelines	[Gantt chart showing task durations across quarters]															
Evaluate and Refine Standards Implementation Guidelines; Prepare Deliverable	[Gantt chart showing task durations across quarters]															
Collaborate with NIST	[Gantt chart showing task durations across quarters]															
Task 9: Develop Business Plan for Self-Sustaining Standards Harmonization Process	[Gantt chart showing task durations across quarters]															
Identify Stakeholders Having Input to Business Plan	[Gantt chart showing task durations across quarters]															
Identify and Review Existing Standards Maintenance Models	[Gantt chart showing task durations across quarters]															
Gather Stakeholder Input	[Gantt chart showing task durations across quarters]															
Prepare "Straw Man" Model	[Gantt chart showing task durations across quarters]															
Engage Stakeholders to Review and Refine Straw Man Model	[Gantt chart showing task durations across quarters]															
Task 10: Submit Written Monthly Status and Financial Reports	[Gantt chart showing task durations across quarters]															
Task 11: Assist ONCHIT1 Project Officer with Internal/External Communications	[Gantt chart showing task durations across quarters]															

Proposed ONCHIT 1 Contract Management Organization

