**Office of the National Coordinator (ONC)**

**For Health IT**

**Federal Health Architecture (FHA)**

**Information Modeling (IM) Project and Federal Health Information Model (FHIM)**

**Open Development of the FHIM**

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# Executive Summary

Health Information Technology (IT) standards are foundational in providing quality care, increased access to care, reducing healthcare costs, and ultimately improving population health. The Federal Health Architecture (FHA) Standards Program/Federal Health Interoperability Modeling and Standards (FHIMS) Work Group (WG) leads and supports health information technology standards activities across the Federal partners. The primary goal is to develop a comprehensive, integrated set of standards that fully support health information semantic interoperability.[[1]](#footnote-1)

The IM Project/Federal Health Information Model (FHIM) is managed by the FHIMS WG and participation is restricted to the Federal partners and their contractors. The goal of this white paper is to propose an approach to open up participation in development of the FHIM to everyone. The proposed approach consists of three phases and a rebranding of the new information model that would be developed to the National Health Information Model (NHIM). The proposed approach leverages a truly open body and process, the HIT Standards Committee, to support open development of the NHIM.

# Introduction

The Federal partners exchange a lot of health care information among themselves. In order to support collaboration and cooperation, the Federal Health Architecture efforts bringing the Federal partners together in defining their information requirements enabling sharing in a standardized way.

As participation in the IM Project was limited to the Federal partners the goal now is to extend the scope to harmonizing health information requirements to support information exchange across the entire health care industry.

As a result of the research conducted, the following assumptions have been made:

1. The FHIM will be the information model that is the basis for all S&I information exchange implementations.
2. The information requirements for all S&I initiatives will be captured and stored in the FHIM.
3. The FHIM and its processes will be used to support information harmonization.
4. The FHIM will be leveraged for engaging SDOs with current concrete information requirements.
5. The exiting FHA Information Modeling (IM) Project / FHIM effort will continue to develop a harmonized information model for the Federal Partners. This model will represent the Federal Partner requirements and be their input to the National Health Information Model (NHIM).

This white paper describes a three phased integrated, open engagement approach for FHIM. The first phase will implement a more open FHIM process by fully engaging with the S&I Initiatives; the second phase will see the FHIM and the associated terminology models and value sets, fully integrated into the S&I Framework. The third phase will implement an open environment for all stakeholders to participate in FHIM development, by leveraging the Health Information Technology Standards Committee, which is an oversight body for all the SDOs. A rebranding may be appropriate e.g. the National Health Information Model, reflecting a truly open model/tool for all stakeholders with processes that are collaborative and transparent.

Phase 1: ***FHIM as a Harmonization Enabler – Broader Stakeholder Engagement***

This phase will achieve a standing presence and full integration of the FHIM with the S&I Framework initiatives. The governance will include well defined communication lines between the Federal Partners and the S&I initiatives to ensure harmonization across all requirements.

Phase 2*:* ***FHIM as Model Enabler - Integral Part of the Backbone***

This phase will achieve integration of the FHIM with the Model-Driven Health Tools (MDHT) and the S&I Framework Tools and Services, including the repository (SIR). The benefits of the FHIM in this phase would be to identify not only the information and terminology bindings, but also support traceability starting with use cases and continuing through implementation specifications and certification.

Phase 3: ***FHIM as a National Model –ONC Health Information Technology Program***

This phase will achieve a fully open and rebranded National Health Information Model (NHIM) open to all stakeholders, a virtual environment enabling collaboration and transparency. It will leverage the Health Information Technology Standards Committee, which is an oversight body for all the SDOs, to support open NHIM development.

# Background Research

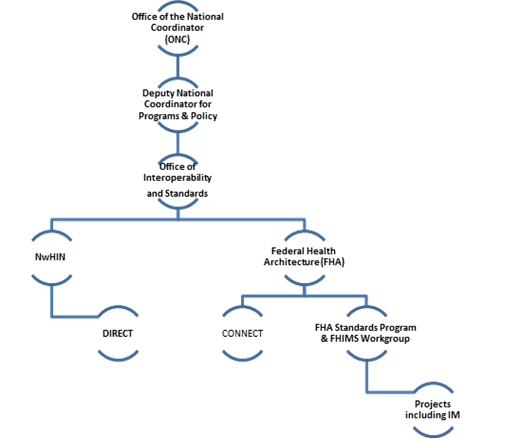
In order to understand how to open this process and to best serve all stakeholders we need to look at current governance and determine the best opportunities for a collaborative process. We need to identify clear lines of communication with stakeholders at both the Federal partner level as well with the entire health care industry.The goal is to resolve how best to incorporate health information requirements into all the S&I Framework efforts, including all relevant stakeholders in the communication loop. Finally we will explore a truly open environment for the FHIM. The following chart reflects the research conducted for this document:

|  |  |
| --- | --- |
| Open Government Initiative (OpenGov) | <http://www.whitehouse.gov/open> |
| Department of Health and Human Services (DHHS) | <http://www.hhs.gov/> |
| Office of the National Coordinator (for Health Information Technology (HIT)) (ONC) | <http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__home/1204> |
| Federal Health Architecture Program (FHA) | <http://healthit.hhs.gov/portal/server.pt?open=512&objID=1181&parentname=CommunityPage&parentid=26&mode=2&in_hi_userid=11113&cached=true> |
| Nationwide Health Information Network (NHIN) | <http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__nhin_resources/1194> |
| Vocabulary Task Force | <http://healthit.hhs.gov/portal/server.pt?open=512&mode=2&objID=3004&PageID=20394> |
| Standards and Interoperablity Framework  (S&I Framework) | <http://jira.siframework.org/wiki/pages/viewpage.action?pageId=5605554> |
| Transition of Care (ToC) | [http://jira.siframework.org/wiki/display/SIF/Transition+of+Care+%28ToC%29+Initiative](http://jira.siframework.org/wiki/display/SIF/Transition+of+Care+%2528ToC%2529+Initiative) |
| Lab Results Interface (LRI) | [http://jira.siframework.org/wiki/display/SIF/Lab+Results+Interface+%28LRI%29+Initiative](http://jira.siframework.org/wiki/display/SIF/Lab+Results+Interface+%2528LRI%2529+Initiative) |
| CDA Consolidation Project | <http://jira.siframework.org/wiki/display/SIF/CDA+Consolidation+Project> |
| CONNECT | <http://www.connectopensource.org/about/what-is-CONNECT> |
| DIRECT | <http://directproject.org/> |

Additionally, research was done by participating in various Standards & Interoperability Framework Working Groups e.g. Use Case & Requirements as well as the Harmonization working group, which provided an awareness of the gaps that exist and key issues that need to be addressed in order to meet meaningful use Stage 2 timelines.

# Governance

The **Office of the National Coordinator for Health Information Technology** (ONC) coordinates a variety of programs to implement HITECH. The ONC also supports related initiatives to facilitate nationwide adoption of health IT.[[2]](#footnote-2) The FHIM, which is of particular interest to this discussion, could in Phase 3 of the approach be considered a program for ONC HITECH.



S&I Framework

Federal Health Information Model (FHIM)

HIT Standards Committee

National Health Information Model (NHIM)

Figure 1: Governance

The Office of Interoperability and Standards (OIS) is responsible for advancing the development, adoption and implementation of health information technology standards nationally through public and private collaboration. It is responsible for the Standards and Interoperability Framework and also manages the Federal Health Architecture (FHA).

The **Federal Health Architecture** (FHA) is responsible to deploy health IT standards ensuring interoperability between the Federal agencies, all levels of government and the private sector.The FHA is responsible for supporting these federal efforts to deploy health IT standards for the **CONNECT** project and the FHIM.

The **FHA Standards Program** coordinates Federal Partner organizations with respect to information and terminology standards, which includes coordination with relevant Standards Development Organizations (SDOs). The **FHIMS Workgroup** is responsible for carrying out activities of the Standards Program e.g. management related to the IM Project, which is developing the FHIM.

# Standards and Interoperability Framework

The S&I Framework is the responsibility of the Office of Interoperability and Standards, it was launched on Jan. 7, 2011.

In order to deliver consistency across standards the S&I Framework makes available a set of integrated functions, processes, and tools being guided by the healthcare and technology industry to achieve harmonized interoperability for healthcare information exchange.[[3]](#footnote-3)

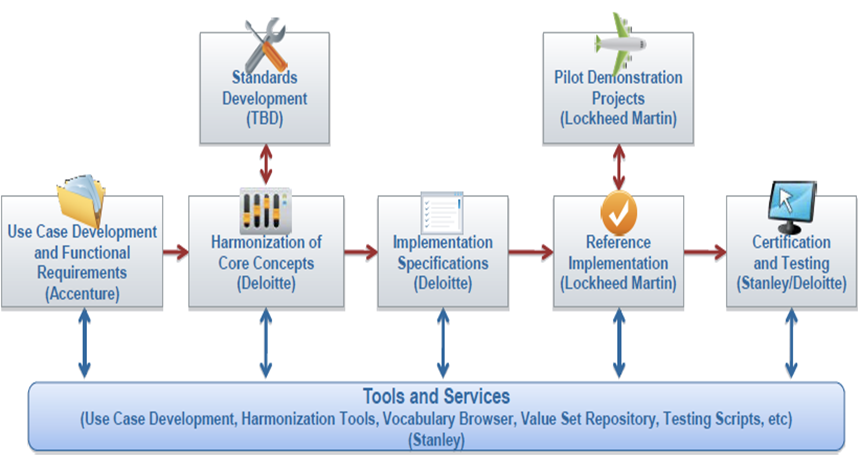


Figure 2: The Standards & Interoperability Framework

The framework is intended to provide governance, organization, communication and coordination for the initiatives that are appropriated.

## Current Initiatives

Current initiatives within the S&I Framework, work in progress, are:

#### Transition of Care Initiative (ToC)

The requirement is for information to be exchanged in transition of care, namely a summary of care for Eligible Provider, Eligible Hospital, and Critical Access Hospital.

#### Lab Results Interface Initiative (LRI)

The requirement is to align at least two standard specifications for ambulatory laboratory reporting, driven primarily by the needs of internal medicine, family practice and pediatrics.

#### Consolidation Project

The requirement is to consolidate Implementation Guides by providing a comprehensive library of reusable data elements based on "Templated CDA".

# What FHIM Provides

The major role and responsibility for FHIM within the S&I Framework is to harmonize core concepts and to determine if there are any gaps in the standards chosen for adoption. If so the FHIM would become the basis for defining new requirements and the development of standards that would feed into the SDOs. The highlights of the FHIM roles in the S&I lifecycle are:

* **Use Case Development and Functional Requirements**: FHIM will capture the interoperability Health Information requirements derived from use case analysis. FHIM can also support information requirements for exchange information.
* **Harmonization of Core Concepts**: The FHIM can be used to determine if there are any gaps in the standards chosen for adoption or if information needs to be harmonized across standards.
* **Standards Development:** FHIM can become the basis for gaps or new requirements that would feed into the SDOs.
* **Implementation Specifications:** FHIM can become the basis on which information is constrained to create implementation specifications.
* **Pilot Demonstration Projects / Reference Implementation:** FHIM can support reference implementations by providing the information that goes into the schema.
* **Certification and Testing:** FHIM will provide information to the MDHT, which will in turn generate certification criteria that support the testing of a Conformance Information Profile.
* **Release Management:** The FHIM models will be released along with any implementation artifacts/specifications that are created from it. The latest version of the FHIM with the latest requirements will always be available and will be updated on a regular basis.

There are two major points of integration of the FHIM into the S&I Framework: 1) The FHIM will integrate with the Use Case Development and Functional Requirements roles of the framework on one side; and 2) on the other side it will integrate with the Implementation Specification role.

## Use Case Development and Functional Requirements

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This is the point of contact for current and future initiatives; the current initiatives are Transition of Care, Lab Result Interface and the CDA Consolidation. The issues expressed by these initiatives underscore the need to formalize a process within the S&I Framework to ensure they have the appropriate feedback and oversight necessary and that all gaps are addressed. These initiatives have requested an endorsement as to the relevancy of their work by ensuring future reuse of their with other initiatives in the S&I Framework e.g. doing the work of; looking up, mapping, creating spreadsheets should only have to be done once. There was also lack of information regarding whether their efforts would become part of a larger body of knowledge e.g. a suggestion to elevate a particular initiative model as an ‘S&I Model’.

FHIM can provide a solution to the challenges identified:

1. The current initiatives e.g. Transition of Care has provided the superset of information and reported the need for more detailed definition to be put into the domain specific models.
2. The initiatives also expressed (e.g. Lab Results Interface) the importance in linking the data element definition and code sets / terminology value sets to the requirements. Traceability will allow for future initiatives that may come across a requirement for a historical lab result; they can be pointed to a section / data element in the matrix to see how it was defined and fulfilled.

## Harmonization of Core Concepts and Standards Development

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The primary role of the FHIM with initiatives would be harmonization. Basically FHIM through its modeling process supports the harmonization of core concepts and identification of gaps that require new standards development. The integration points into the S&I Framework would see the FHIM integrating with use case development and functional requirements by capturing the interoperability Health Information requirements derived from use case analysis. To ensure seamless integration, processes would need to be clearly defined in order to meet the challenges expressed by the current initiatives.

FHIM can provide a solution to challenges identified:

1. The need for a clear path in going through a consensus process.
2. The need to understand the ‘hand off’ to harmonization, e.g. the use case team appears to be separate from other work of the initiatives.
3. The need for an initiative to have access to the latest scenarios of ToC, LRI, CDA Consolidation and their data content as the ‘inter / intra’ alignment occurs.

Currently the burden falls on the initiatives to determine what the next steps are and to ensure that their work is available to other initiatives, the issues surrounding this need to be further explored to ensure communication lines are open and processes are set in place. FHIM roles and responsibilities will need to be clearly defined in order for members to declare commitment. This will promote openness and facilitate participation (e.g. responsible person and contact information readily available, clear instructions of when updates will be done and where to send requests, find artifacts, etc).

## Implementation Specification

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The OMG Prototypical Driven Architecture™ (MDA) supports interoperability from business modeling to system design, to component construction, to assembly, integration, deployment, management, and evolution. It is based on a language that has a well-defined form (“syntax”), meaning (“semantics”). The Model-Driven Health Tools (MDHT) provides the S&I Initiatives a unified set of modeling tools for standards organizations and standards implementers to design, publish, and implement standards driven from a UML model.

An initiative mines the information in the FHIM to meet their specific use cases and produce domain specific implementation guides driven by the MDHT. This approach ensures traceability to the initiative’s specific use case requirements as well as testability to conformance criteria.

|  |
| --- |
| C:\Users\Mary Ann Juurlink\Pictures\everything else.png |

Finally, the FHIM supports the continuum of the S&I Framework lifecycle by providing the information for the MDHT, enabling it to generate platform specific models and certification criteria. Essentially the FHIM as the harmonizer of core concepts and standards development integrates with use case requirements analysis and the creation of the implementation specification and by doing this it perfunctorily supports the reference implementation as well as certification testing.

See [Appendix A](#Appendix_A_) for a larger list of identified gaps and integration points that the S&I Framework will need to address.

# Phased Approach - Integration and Open Participation

Currently the IM Project/FHIM is under FHA. In order to fully integrate it into the S&I Framework we are proposing a phased approach. The following recommendations are for consideration going forward:

1. Make FHIM an official and integral part of the S&I Framework.
2. Definition of specific FHIM working groups e.g. modeling /harmonization, terminology and implementation.
3. Fully identify gaps in the integration of FHIM in the S&I Framework through a formal questionnaire.
4. Further define best practices for the initiatives based on feedback from the DIRECT Project e.g. Best Practices WG, Communications WG etc.
5. The FHIM contribution is broader than just information; it could include vocabulary bindings and information exchange integrations that includes services and protocols that would be required.
6. Rebranding the name FHIM to the National Health Information Model for the new information model. The name Federal Health Information Model suggests limited participation.

The 3 Phased Approach is illustrated by the following diagram:

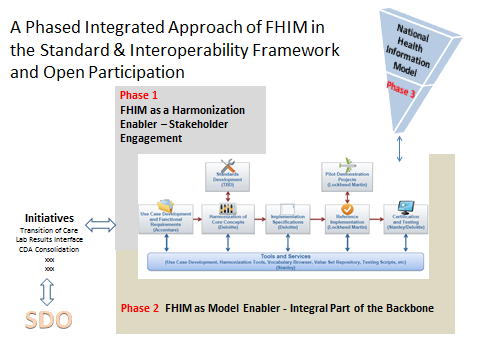


Figure 3: A Phased Integrated Approach and Open Participation

## Phase 1:FHIM as Harmonization Enabler – Stakeholder Engagement

As described in the sections above (the Use Case Development and Functional Requirements, and the Harmonization of Core Concepts and Standards Development) the existing FHIM body is primarily integrating with S&I Framework initiatives and is open to a degree. The openness is mainly through the broad participation of the SDOs. In this first phase, continued participation with the initiatives occurs by providing them with theFHIM model as well as harmonizes their health information requirements. The FHIM can be considered an adjunct to all the initiatives as well as the harmonization function of the S&I Framework. It is also important to note that the Federal Partners will continue to come together and leverage the FHIM and its processes to harmonize their information.

Harmonization, however, is just one function of the FHIM. The goal is to fully integrate the FHIM into use case analysis and behavior definition and thereby support the continuum of the S&I Framework in order to make it a more useful tool. Also the FHIM development needs to be more fully opened up from a stakeholder engagement perspective.

## Phase 2: FHIM as Model Enabler - Integral Part of the Backbone

FHIM becomes fully integrated with the implementation specification that identifies not only the information but the use cases and behavior and also provides vocabulary bindings. By having FHIM as part of the S&I Framework backbone (integration with the continuum of the S&I Framework) it will have permanent standing for integrating into all the initiatives. It will gather and manage requirements for all the initiatives and support all future initiatives.

Similarly the FHIM could become part of the Tools and Services, which is continually managed and maintained with well-defined processes linking all the different phases. FHIM would be the glue that holds, what looks like silos, together. It would support the continuum of the S&I Framework by providing the information for the MDHT, enabling it to generate xml schema and certification criteria.

As the FHIM repository, consists of derived artefacts e.g. models, it would therefore make sense that the repository, which is part of Tools and Services, also include the FHIM. When we say repository we need to remember it means a set of artifacts based on the models.

This phase would see the initiatives using the S&I Framework as part of their work and FHIM is part of that. The consultative bodies are the initiatives and they sit between the S&I Framework and the SDOs. In other words the initiatives are not only using the Standards Development Organizations. Basically the S&I Framework will provide the initiatives with clear deliverables and provide them with processes and tools and services and they go out and do the work. This phase sees the FHIM fully integrated in the S&I Framework, while Phase 3 explores the possibility of a truly open FHIM process.

## Phase 3: Rebranding FHIM

This phase examines the possibilities to further open FHIM making it accessible to everyone. After examining four possibilities it was concluded that neither CONNECT nor the NwHIN are fully open at this time and therefore do not offer a process to follow. We also looked at the S&I Initiatives as they are open in the way they engage stakeholders. Finally we examined leveraging the HIT Standards Committee, which is already working with all the SDOs, as an oversight body.

FHA **CONNECT** is governed by the Federal partners and currently it is in a state of transition. It is still undecided if the ongoing participation will be limited to the Federal partners or if CONNECT will be moved to a more pubic collaborative forum. Regarding the **NwHIN**, until a ruling from ONC is finalized only federal entities and non-federal entities that are part of a federally-sponsored contract that pertains to the NwHIN implementation, can participate. The S&I **initiatives** are open, so far as in that they interact with the standards community which is highly committed with broad participation. However, initiatives are only meant to exist for a limited time frame. The FHIM needs to be a continuous project.

Therefore we propose introducing a standing work group for information modeling under the HIT Standards Committee. This would establish the FHIM with a body and process that is fully open. By placing the FHIM under the HIT Standards Committee it would be supporting ONC in the adoption and implementation of health information technology standards nationally through public and private collaboration.

Furthermore as the FHIM is still in its infancy (e.g., not yet considered the source of information for the S&I Framework), rebranding the FHIM at this point is probably well-timed. The National Health Information Model (NHIM) is a suggested name.

# Communications

Communications about FHIM, to stakeholders, can take many forms, including outreach during conferences, directed materials to specific audiences, engagement in standards development, release management and other activities.

A Communication Strategy must be put in place internally, to realize the vision, governance and benefits of the FHIM. Initially it will serve as a vehicle to gather feedback within the S&I Framework organization and with its stakeholder communities. It will also act as a communications vehicle with external stakeholder groups to help deliver the message and education that may be necessary in order to create an open and collaborative forum. It will provide services to raise awareness and interest in the FHIM; to foster relationship with SDO stakeholders; to promote FHIM adoption; and to develop regular, consistent and credible communication channels with other key stakeholders. It will also need to identify what communication channels can be leveraged and how to provide guidance on educating stakeholders on the value, implementation and support of FHIM.

The communications strategy is intended to ensure broad and appropriate communications are planned, executed and followed up and that general communication objectives are being met.

# Appendix A: Integration Gaps with S&I Framework

As part of the research of the S&I Initiatives, gaps and integration points were identified that the S&I Framework will need to address.

It is important that the issues / gaps be addressed so the initiatives can meet their deliverables in a timely manner providing the value expected from the Office of Interoperability and Standards.

1. The need to have interactions with the Steering Committee. The initiatives don’t see the interactions between those who are on top of the S&I Framework and question how information is filtering down to the initiatives.
2. The need to have a home for the output of the consolidation process e.g. artifacts. A comment was made by an initiative: ‘as Stakeholders infiltrate harmonization we bring this spreadsheet along'.
3. The need to know what the opportunities (connection points) are to introduce their work to others.
4. The governing bodies of the S&I Framework need to share their vision as the initiatives questioned what the next steps are post submission of their deliverables.
5. The need to understand how their work is introduced to the architecture team.
6. The need for education

* To share vision and provide information generally
* Related to the S&I repository which would be the home for artifacts

# Appendix B: The S&I FHIM Template – Phase 1 and Phase 2

#### FHIM Charter

Meaningful Use requires complete and accurate information for providers. With the widespread use of electronic health records providers are enabled by having access to the information they need, when they need it in order to provide the best possible care. In order to better support coordination of care; provider requirements are collected and the health information exchange is harmonized, resulting in information that can be shared more easily among doctor’s offices, hospitals and across the health system. The Federal Health Information Model (FHIM) is producing a logical health information model that supports this semantic interoperability. It is being developed by harmonizing information from the individual Federal partners, Standards Development Organizations (SDO) and the general public.

#### Purpose and Goals

The goal of FHIM is to enable health information interoperability by participating in the development and implementation of a comprehensive, integrated set of health information standards that support semantic interoperability. Accomplishing this goal will require significant modeling efforts related to information and terminologies. Currently the engagement strategy, which is limited to the Federal partners, will be opened to everyone through the SDO’s and the general public with defined requirements.

#### Scope

The scope of this initiative is to build on the work done by the FHA Information Modeling (IM) Project related to information models, terminology models and value sets. The processes that are being set in place will support all health information requirements to support information exchange defined by the S&I Framework projects and the general public. The requirements will be harmonized across projects within the S&I Framework and concurrently with the Standards Development Organizations. The nature of working with SDOs will subsequently include requirements defined and harmonized with the international community. This broad representation will provide the richness needed to support semantic interoperability.

Deliverables of the FHIM include the:

1. Integration of the FHIM (and related terminology models/value sets) with the Model Driven Health Tools (MDHT).
2. Development of a methodology to map the FHIM (and related terminology models/value sets) to the use cases/business models in the S&I Framework and to the HL7 EHR-S Functional Model.
3. Updating and revising of the NIEM process to incorporate the FHIM (and related terminology models/value sets) making it a more model driven process.
4. Participation in the development of an S&I Framework repository process for all S&I Framework artifacts (including the FHIM and related terminology models/value sets).
5. Opening up the modeling process to everyone by developing and implementing a plan that supports open participation in the development of the FHIM.

#### Success Metrics

Measurements and evaluation to be developed, milestones could include:

Process Measures:

Milestone: FHIM governance fully integrated into the S&I Framework

Milestone: Harmonization Work Group meetings planned and occur

Milestone: FHIM Resource Management Plan for 2011 and beyond

Milestone: Identify Strategies e.g. Communication Strategy

Milestone: Action plan for 2011 and beyond

Outcome Measures:

Milestone: Results of Harmonization meetings will include the definition, mappings and harmonized FHIM

Milestone: FHIM model supported by all Federal partners

Milestone: The Federal partners participate in the initiatives and provide requirements.

#### Members

In phases 1 and 2, membership is limited

1. Federal partners
2. Federal partner contractors

S&I Initiatives would participate indirectly through the Federal partners who participate in the initiatives

#### How to get involved

A similar process followed by the other S&I Projects will be followed, for example:

1. Keep me Informed

* To be notified about significant events and announcements from the project, follow this site

1. How can I contribute?

* Visit the "Getting Started as a Volunteer" page
* Review the existing FHIM project's work groups to see where you can contribute
* Refrain from defacement, abuse, commercial promotion, or other content that violates our Wiki Use Guidelines

#### Child Pages

1. FHIM - Initiative Members
2. FHIM - Deliverables Tracker
3. FHIM - Harmonization Work Group
4. FHIM - Model Work Group
5. FHIM - Terminology Work Group
6. FHIM - Agendas and Minutes
7. FHIM - Reference Materials
8. Submit an Issue

# Appendix C: The NHIM Template – Phase 3

**The following is based on Phase 3: Rebranding of FHIM**

The NHIM could fit under the HIT Standards Committee as a standing work group. It would be directly connected to the all the SDOs, and fully open to everyone including the possibility for vendor input / feedback. This would allow all the SDO’s to leverage the model as they are actually developing the standards. The HIT Standards Committee would be responsible to make recommendations to ONC concerning the NHIM.

In planning the NHIM as a public domain model, there is a need to look at the implications of leveraging the HIT Standards Committee making the NHIM a standard that is national in scope. We would need to consider all concerns.

Next steps would include

* Seek approval for a standing work group as part of the HIT Standards Committee.
* Detail how the HIT Standards Committee work group would be organized (level of integration / level of openness).
* Establish a charter, purpose and goals of the NHIM.
* Establish a governance process.
* Detail the working relationship between the FHIM in the S&I Framework and the NHIM.
* Outline key things that need to be done in Phase 3.

1. Federal Health Interoperability Modeling and Standards (FHIMS) Work Group - Standards Engagement Strategy [↑](#footnote-ref-1)
2. <http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__onc_initiatives/1497> [↑](#footnote-ref-2)
3. http://jira.siframework.org/wiki/display/SIF/Introduction+and+Overview [↑](#footnote-ref-3)