



The Immunization Information System (IIS) Baseline Requirements Project

April 2021

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Purpose and description

This document provides an overview of the immunization information system (IIS) requirements project and the approach taken to complete the project deliverables: an **IIS Functional Model** and a corresponding **IIS Baseline Requirements Traceability Matrix (RTM)**.

The IIS requirements project was a collaborative effort among the Centers for Disease Control and Prevention (CDC), the American Immunization Registry Association (AIRA), and the Public Health Informatics Institute (PHII) to develop a set of functional and nonfunctional requirements for public health immunization programs to use in procurement solicitations for IIS technology solutions.

The requirements detailed as part of this effort provide clarity on what IIS technology must do and how it must operate to align with the CDC IIS Functional Standards and programmatic and immunization stakeholder needs. The essential requirements paint a picture of a baseline IIS, with foundational functions, capabilities and attributes necessary to support immunization program activities. As such, the essential system requirements are eligible for support through base federal immunization program funds.

The requirements are intended to aid programs in the procurement and selection of IIS technology to best suit their needs, specifically in:

- Procurement of a new system, a new module and/or enhancements to their current system.
- Provision of a robust and comprehensive foundation from which jurisdiction- and/or program-specific requirements can be further detailed, based on jurisdictional laws and policies.
- Creation of a roadmap for future development efforts, e.g., through the identification of key functionality that may not be currently available but is identified as a high priority for future consideration.
- Support of joint development efforts across programs.

It should be noted that the requirements delivered within the RTM were identified for any IIS regardless of platform. Whether developing an awardee-based system or procuring a commercially available off-the-shelf (COTS) solution, the requirements provide a foundational basis to evaluate and select the system that best meets or exceeds the program's prioritized needs.

IIS Functional Model

In order to develop baseline requirements for IIS, the project team developed an IIS Functional Model to provide an organizing framework to identify the core functions, capabilities and technical attributes of IIS technology. The IIS Functional Model, depicted in Figure 1 below, provides a visual representation of the nine core functions and six core technical attributes of these systems, as well as an organizing framework for functional and nonfunctional requirements. The model also provides a consistent framework and common terminology for conveying and communicating the core IIS functions, capabilities and attributes across the IIS community.

Used in conjunction with the baseline set of IIS requirements within the RTM, programs can assess their current IIS to identify gaps and provide a foundation to accelerate procurement and/or development efforts. A companion **IIS Assessment Workbook** can be used for this purpose.

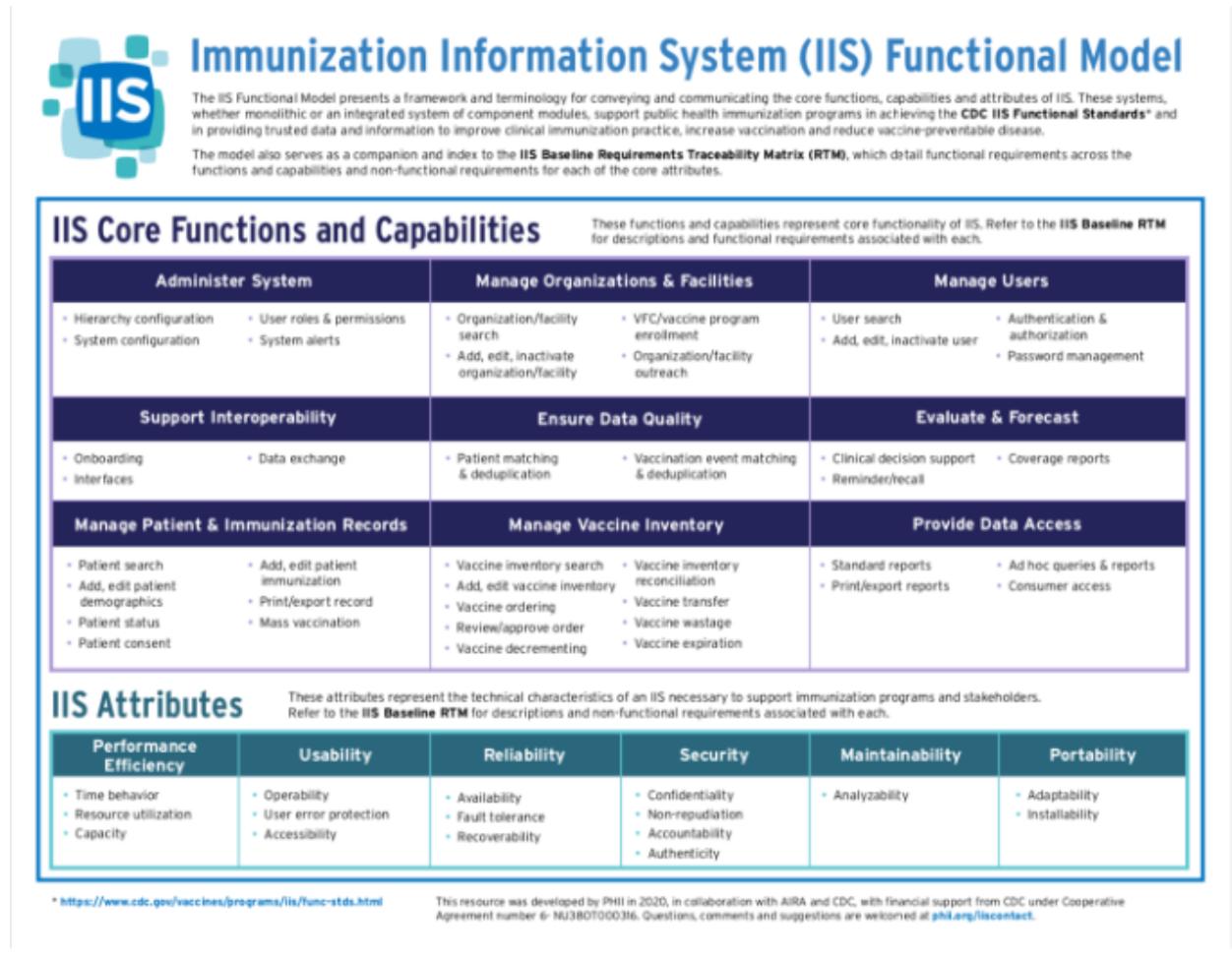


Figure 1. IIS Functional Model

IIS Baseline Requirements Traceability Matrix

Once consensus of the IIS Functional Model was reached, the project team compiled and drafted IIS requirements for each function and capability and technical attribute. The methodology used in the collection and synthesis of the baseline IIS requirements is described in further detail in the next section of this document. However, the requirements were aligned to the CDC IIS Functional Standards, as well as CDC and AIRA guidance documentation and resources. For example, the requirements referenced the CDC Endorsed Data Elements,¹ the current HL7 IIS Interoperability Guide² and the CDC CDSi logic

¹ <https://www.cdc.gov/vaccines/programs/iis/core-data-elements.html>

² <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/hl7.html>

specifications.³ The requirements were also aligned with the high-level needs discussed in the AIRA Modeling of Immunization Registry Workgroup (MIROW) Best Practice Guides.⁴

Following industry best practice, functional and non-functional requirements were listed within a Requirements Traceability Matrix, commonly referred to as a RTM. The **IIS Baseline Requirements Traceability Matrix** includes essential and optional requirements for IIS across the nine IIS functions and six IIS technical attributes.

IIS Functional Model descriptions			Return to Contents tab		
Tab Name	# of Rows	Function	Description	Capability	Description
Admin System	61	Administer System	Management of global system settings and alerts, including set up of user roles and permissions.	Hierarchy Configuration --ability to create hierarchy that informs the association between geographical levels within the jurisdiction and among organizations, facilities, providers and users System Configuration --ability to define system-wide settings, such as management of code tables User Roles and Permissions --ability to define and manage user roles and use role permissions to perform a function, activity or task System Alerts --ability to broadcast communication to IIS users viewable upon logging into the system	Function: Manage Vaccine Inventory Return to Contents tab
Manage Orgs	82	Manage Organizations and Facilities	Management of organizations and facility accounts.	Organization/Facility Search --ability to lock up and retrieve an organization or facility account Add, Edit, Inactivate Organization/Facility --ability to add, edit or inactivate an organization or facility; ability for an organization to initiate enrollment and re-enrollment in the IIS VFC/Vaccine Program Enrollment --ability to enroll and re-enroll a provider organization in VFC and/or other vaccine program(s) Organization/Facility Outreach --ability to communicate with organization/facility representatives	Req # Capability Requirement: The IIS must/should have Reviewer notes Priority: E, O (Essential, Optional) Vendor response: Yes, No with justification*, No *Comment required
Manage Users	34	Manage Users	Management of user accounts.	User Search --ability to define parameters to look up and retrieve a user account Add, Edit, Inactivate User Authentication and Authorization --ability to add, edit or inactivate a user account --ability to validate a user's identity, entity and system permissions Password Management --ability to administer, change and reset user passwords Onboarding --ability to establish/re-establish/modify an interface with another information system for the electronic exchange of demographic and/or immunization data	Vaccine Inventory Search ability to search inventory by user-defined parameters E Vaccine Inventory Search ability to search the inventory by funding source E Vaccine Inventory Search ability to search inventory by vaccine type E Vaccine Inventory Search ability to search inventory by vaccine lot number E Vaccine Inventory Search ability to search inventory by vaccine NDC code E Add, Edit Vaccine Inventory ability to manage vaccine inventory E Add, Edit Vaccine Inventory ability to support visualization of current vaccine inventory E Add, Edit Vaccine Inventory ability to edit inventory funding source at the lot level E Add, Edit Vaccine Inventory ability to edit inventory funding source at the vaccine level E Add, Edit Vaccine Inventory ability to add vaccine information to inventory E Add, Edit Vaccine Inventory ability to add vaccine information to inventory E Mass Vac Add, Edit Vaccine Inventory ability to support barcode scanning system to electronically upload vaccine inventory to the IIS O Add, Edit Vaccine Inventory ability to view current inventory list by facility E Add, Edit Vaccine Inventory ability to view current inventory list by organization E Add, Edit Vaccine Inventory ability for jurisdictional admin to edit organization/facility inventory E Add, Edit Vaccine Inventory ability to borrow vaccine from lots belonging to one funding source to lots belonging to another funding source O Add, Edit Vaccine Inventory ability to reclassify funding source of borrowed vaccine from private to public or vice versa for replacement cases O Add, Edit Vaccine Inventory ability to view refrigeration storage capability E Add, Edit Vaccine Inventory ability to document vaccine storage and handling events such as temperature excursions E Add, Edit Vaccine Inventory ability to store refrigeration storage capability E Vaccine Ordering ability for rule based logic to recommend vaccine order quantity E Vaccine Ordering ability to alert user when "reorder recommendation" inventory level is reached O Vaccine Ordering ability to pre-populate order with recommended quantities based on inventory doses administered and reported to IIS E Vaccine Ordering ability to edit pre-populated order quantity E Vaccine Ordering ability to order vaccines E
Interop	61	Support Interoperability	Manage interfaces to exchange data between the IIS and other systems.	Data Exchange --ability to facilitate electronic data exchange with other information systems, including EHRs, VITCIS, jurisdictional vital records, and the Q Gateway Interfaces --ability to exchange data electronically and monitor and troubleshoot data exchange --ability to identify and manage duplicate and potential duplicate patient records Vaccination Event Matching and Deduplication --ability to identify and manage duplicate and potential duplicate vaccination entries	
Data Quality	30	Ensure Data Quality	Deduplication and consolidation of records.	Patient Matching and Deduplication --ability to identify and manage duplicate and potential duplicate patient records Vaccination Event Matching and Deduplication --ability to identify and manage duplicate and potential duplicate vaccination entries Client Decision Support --ability to evaluate and forecast immunizations for a patient per ACP guidelines and in alignment with CDC specifications Reminder/Recall --ability to identify and notify patients who are due for upcoming immunizations (reminder) and/or are past due (recall) Coverage Reports --ability to create reports to support immunization coverage assessment at the provider and geographic levels including reports for the CDC's VFC provider-level immunization quality improvement program (IQIP) Patient Search --ability to look up and retrieve a patient record Add, Edit Patient Demographics --ability to add, edit or inactivate a patient record Patient Status --ability to manage the assignment of a specific patient to a provider organization or jurisdiction Patient Consent --ability to manage patient agreement to participate in the IIS in accordance with jurisdictional policy Add, Edit Patient Immunization --ability to add, edit an immunization record Print/Export Report --ability to print or export either a patient or immunization record Mass Vaccination --ability to capture a large volume of demographic and immunization data in emergency situations Vaccine Inventory Search --ability to look up and retrieve vaccine doses in inventory Add, Edit Vaccine Inventory --ability to manage vaccine inventory, including ordering, storing and handling, and reconciliation of applying doses	
Eval/Forecast	64	Evaluate and Forecast	Determine the validity of past immunizations administered as a basis for determining immunizations due.		
Manage Pt In Record	82	Manage Patient and Immunization Records	Manage patient demographics and patient immunization record.		
Manage Vaccine Inv	86	Manage Vaccine Inventory	Order publicly-purchased vaccine and manage vaccine inventory.		

Figure 2. Images from the IIS Baseline Requirements Traceability Matrix

Two examples of sheets within the RTM above show detailed descriptions of the functional standards (left) and prioritization of capability within each core function (right).

Methodology

Requirements describe the needed functionality of a system – specifically, *what* the system needs to capture, perform and display, but not the *how*. The purpose of the IIS Requirements Project was to identify a baseline set of requirements that defines the immediate and future organizational needs of IIS. A base set of requirements can assist organizations in defining their specific needs for information systems and can be used in system or module procurement solicitations rather than having each organization recreating the wheel.

There are many approaches to requirements collection of a new system, module or enhancement. These include reviewing help desk tickets to determine system challenges experienced by users and defining requirements that mitigate or resolve these challenges. Another approach is through reengineering existing business processes to optimize the system in streamlining and/or automating various steps.

³ <https://www.cdc.gov/vaccines/programs/iis/cdsi.html>

⁴ <https://www.immregistries.org/mirow>

The following sections describe the methodology used to collect, define and validate the baseline set of IIS requirements.

Project governance

The IIS requirements project was governed by three teams composed of key stakeholders, subject matter experts, informatics analysts, project managers and a business analyst (refer to Table 1 below). A detailed list of the individuals who participated in each team is available in Appendix A.

Table 1. IIS project governance

Team	Key members	Role
Sponsor	CDC	<ul style="list-style-type: none"> ● Provided guidance and direction to the core team regarding project approach. ● Resolved issues and make decisions as needed by the core team, considering core team and reviewer group feedback. ● Participated in messaging to programs/program representatives and vendors/vendor representatives regarding this project. ● Approved external-facing project deliverables.
Core team	Project manager, IIS subject matter experts, business analyst and informatics analysts	<ul style="list-style-type: none"> ● Executed the project, i.e., drafted project deliverables and managed/executed project activities. ● Provided initial quality review of all deliverables before sharing with the extended team for review and feedback. ● Completed revisions based on extended team and sponsor feedback.
Extended team	Core team members, including subject matter experts from CDC and AIRA	<ul style="list-style-type: none"> ● Reviewed and provided feedback on draft materials developed by the core team. ● Suggested refinements in materials in advance of sharing with program and vendor representatives.

The core team utilized a defined set of guiding principles (see Appendix B) to govern the project activities and guide decision-making. The collection phase of the functional and nonfunctional requirements began in February 2020 and included efforts to refine and prioritize the requirements through May 2020. The validation phase encompassed a thorough review and feedback of the functional and nonfunctional requirements by the core team, extended team and IIS programs, which took place from April to July 2020 and culminated in a baseline set of requirements. These phases are illustrated further in Figure 2 below.

Requirements management approach

Figure 3 below depicts the three-phased approach taken by the project team in the collection, refinement and prioritization, and validation of functional and nonfunctional requirements of an IIS. This approach culminated in a baseline set of requirements that were listed within an industry standard requirements management tool, a **Requirements Traceability Matrix (RTM)**. The RTM, also described above, was a key deliverable of the project and enabled system requirements to be documented and usable in subsequent project lifecycle phases including design and testing.

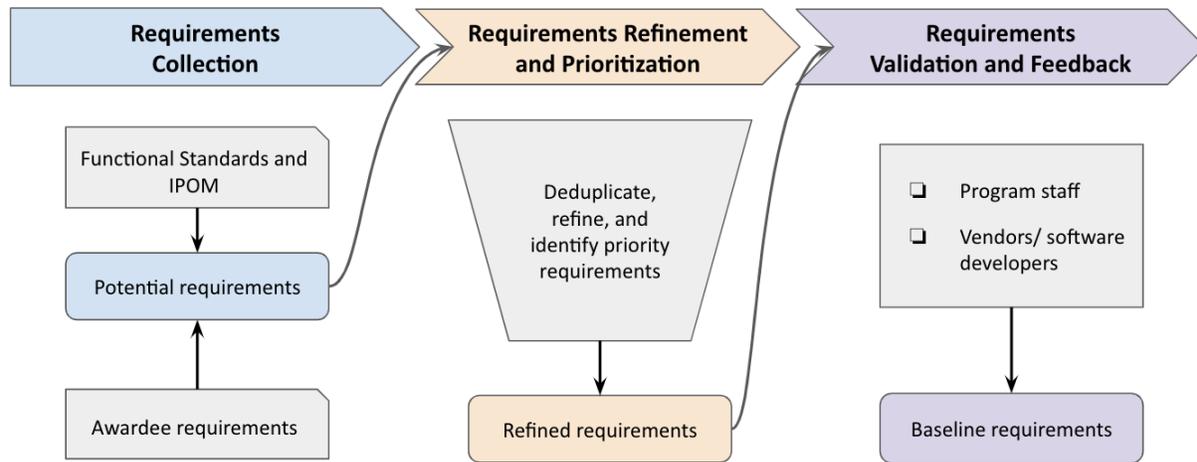


Figure 3. IIS Requirements management approach

How were the requirements identified and collected?

The first phase of the requirements management process involved requirements collection. The majority of the requirements were compiled from earlier IIS procurement solicitations including Tennessee, Oregon, South Carolina and New Hampshire. In addition, the IIS Functional Standards, the CDC Immunization Program Operations Manual, the CDC IIS Data Quality Blueprint, and the International Organization for Standardization (ISO) 25010 Product Quality Model also guided the development and organization of the requirements.

A two-day in-person working session took place in February 2019 to introduce and discuss the draft **IIS Functional Model** deliverable and a proposed initial set of requirements to validate in advance of stakeholder review. Each of the three project teams – sponsor, core and extended – were represented in the session.

Following the working session, the core team reviewed and compared compiled requirements across IIS functions, capabilities and attributes. Iterative development of the IIS Functional Model accompanied this process to provide a common visual framework for grouping the requirements as appropriate.

Approximately 1,300 functional requirements and 300 non-functional requirements were identified from the four state solicitations. These requirements were organized by functional and nonfunctional areas as defined in the IIS Functional Model and documented in the RTM. An industry standard project

artifact, the RTM was used to organize and present the baseline set of functional and non-functional requirements for immunization program use, adaptation or adoption.

How were the requirements refined and prioritized?

In phase two, a subgroup of the core team consisting of the business analyst and two subject matter experts synthesized the myriad of requirements compiled within the RTM to remove duplicates, organize the requirements within their appropriate grouping, and clarify any ambiguous language. This effort resulted in a baseline set of approximately 750 unique functional and 100 nonfunctional requirements within the RTM with each requirement tagged with the originating source for traceability. [Note: As a program utilizes the RTM, the requirements within each tab should be numbered for reference per industry best practices.]

The core team then refined the requirements further to ensure clarity and assess their priority for an immunization program as either essential or optional.

The objectives of the core team review during this phase included:

- Further reduce ambiguity.
- Remove any remaining duplicates.
- Ensure consistency in terminology across and within the RTM.
- Ensure alignment of terminology with the IIS Functional Standards and other resources.
- Identify high-level requirements and organize related detailed requirements underneath with noted priority.

Project reviewers noted their questions, suggestions and potential changes directly in a working version of the RTM, while maintaining the integrity of the original document for reference. Proposed changes were evaluated by the business analyst and SME subgroup prior to incorporation within the master RTM. The outcome of the extensive review and evaluation was a refined draft of the requirements that was ready for IIS program stakeholder review.

Following standard project management discipline, a RAID log was utilized to capture any risks, actions, issues or decisions raised throughout the project lifecycle. In addition, the RTM was expanded into a comprehensive workbook to include tabs for each function and attribute of the IIS Functional Model, instructions for review, guidance for its use/adoption, the various IIS functional and nonfunctional requirements, and a glossary of terms.

How were the requirements validated?

The final phase of the requirements management process was validating the requirements. This began with the extended team reviewing and providing feedback on the IIS Functional Model and corresponding iteration of the functional and nonfunctional requirements. Comments and suggestions for wording and priority changes, as well as deletions, were considered by the core team. Revisions were made to the RTM for further validation by jurisdictions preparing for an upcoming solicitation.

Three jurisdictions – Pennsylvania, Hawaii and Nebraska – in preparation for an upcoming solicitation then reviewed both the functional and nonfunctional requirements for clarity, prioritization and potential additions. Each jurisdiction provided feedback, which was compiled and reviewed by the core team for incorporation into the master RTM. Their feedback was compiled via comments within the RTM and teleconferences while maintaining the integrity of the prior version for reference. Comments

concerning the functional and nonfunctional requirements were evaluated by the project core team to determine if changes or additions of new requirements were needed.

The core team also consulted with three post-solicitation immunization programs – Washington D.C., Tennessee and South Carolina – for validation of the project deliverables. The post-solicitation programs provided input into how the RTM workbook might assist jurisdictions in their solicitations or for other potential uses such as system enhancement requests.

How do the project artifacts fit into the IIS landscape?

Figure 4 below depicts how the requirements project artifacts (in orange) fit within the IIS landscape, nationally and for an individual jurisdiction. At a high level, program operations inform system requirements – specifically, what the system must do, which in turn guide system implementation and system support to reach the primary goal of increasing vaccination rates to reduce vaccine preventable diseases.

Program operations, system requirements, system implementation and system support are influenced by jurisdictional factors stemming from local laws and policies in turquoise, as well as national factors and resources highlighted in dark grey within Figure 4 below. Evaluation and assurance activities are represented in purple and span across program operations and system requirements, implementation and support.

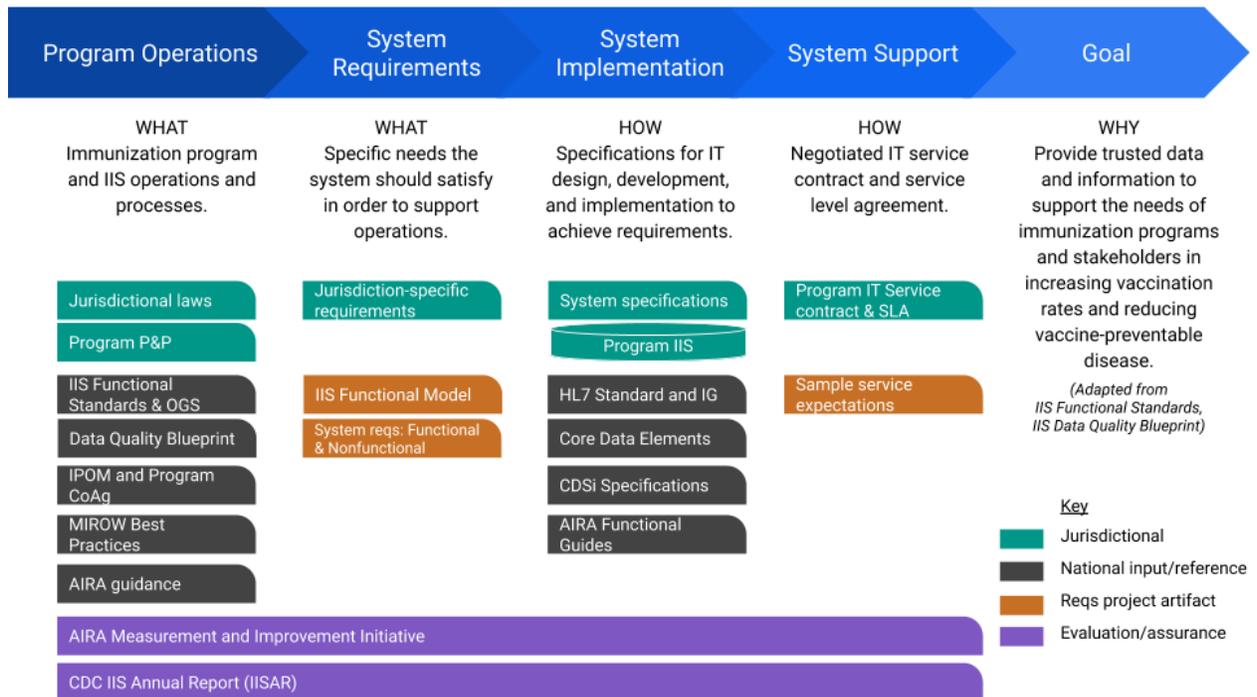


Figure 4. IIS landscape

The artifacts produced by this project will aid programs in procuring and selecting IIS technologies, help ensure great functional consistency and standardization across the IIS community, and provide a common basis for identifying prospective shared services for joint development.

Appendix A: Project team members and additional acknowledgements

Core team members

- Bill Brand, project director
- Erin Roche, project lead
- Sara Sanford, project manager (September 2019 - October 2020)
- Birgit Bolton, project manager (October 2020 - present)
- Kelley Chester, business analyst
- Marcey Propp, SME
- Amy Metroka, SME
- Nosipho Beaufort, SME
- Noam Arzt, SME

Extended team/ reviewers

AIRA

- Kristi Siahaya, Director of Standards and Analytics
- Mary Beth Kurilo, Senior Director of Health Informatics
- Eric Larson, Senior Technical Project Manager
- Elizabeth Abbott, Adult Program Manager

CDC/NCIRD/ISD/IISSB

- Beth Cox, Public Health Analyst
- Janet Fath, Operations Team Lead
- Lynn Gibbs-Scharf, Branch Chief
- LaTrace Harris, Evaluation Team Lead
- Nkenge Jones-Jack, Public Health Analyst
- David Lyalin, Public Health Analyst

CDC Partners

- RTI
- BRS

Additional acknowledgements

This work is the result of input from the project team, identified in Appendix A, as well as numerous additional contributors, listed below, who generously contributed their time and expertise to the project and materials.

Program representatives

Hawaii

- Angela Sorells-Washington, Acting Registry Supervisor
- Ronald Balajadia, Immunization Branch Chief

Pennsylvania

- David Mattiko, Registry Manager
- Thomas McCleaf, Immunization Program Director
- C. Keith Frye, Project Manager
- Frank Caniglia, Director
- Kristine Rosancrans, Registry Specialist Supervisor
- Andrew Noble
- Adam Bingnear, Public Health Program Administrator

- Paul Przewoznik, Information Security Officer
- Janee Bloom, Applications Developer Administrator

Washington D.C.

- Donna Davidson, Immunization Program Manager
- Ousman Jobe, Data Systems Coordinator

Nebraska

- Connie Ganz, Health Section Administrator
- Ernard Klipic, NESIIS Data Exchange Coordinator/NESIIS Training Coordinator

New York City

- Angel Aponte, Computer Software Specialist

South Carolina

- Wendell Gullede, Assistant Director, Immunization Division
- Gary Worrell, Project Manager for IIS Development

Tennessee

- Nathalie Hartert, IIS Director

US Virgin Islands

- Monife Stout, Immunization Program Manager
- Annette Hobson, IIS Manager

IIS vendors/implementers

Optimoz

- Naresh Patel, President
- Bindiya Bhattacharjee, Director of Operations

Appendix B. Guiding principles for the IIS requirements project

Guiding principles are simple rules or value statements that help project teams make decisions when they are faced with a choice or when disagreements arise. Clear, well-written guiding principles aid teams in making directionally-correct decisions more quickly and with greater autonomy. Guiding principles can also help manage scope as they may lead workgroups to exclude certain functionality or to leave a process “as is.”⁵

Purpose: Identify a set of principles to guide us as a project team in decision-making (e.g., does the proposed system requirement represent a “baseline” requirement that is critical for immunization program awardees to have in a viable IIS system?).

Overarching principles

- **Support procurement:** Artifacts should support the effective procurement of IIS products (i.e., platforms or modules) and/or IIS support services. As such, the artifacts should strive for clear requirements articulation for functional and non-functional system requirements and in articulating sample requested support service tasks and expected performance standards.
- **Product and architecture agnostic:** Requirements should be independent of and not indicate a preference for any particular product or technical architecture.
- **Broad engagement across multiple audiences:** The project should engage IIS stakeholders broadly in developing and reviewing its artifacts. Artifacts should be developed that recognize multiple audiences (e.g., immunization program staff, IIS staff, software developers/implementers) who require that material be presented in different levels of detail.
- **Alignment with existing artifacts and efforts:** The project should draw upon and complement the rich foundation of existing IIS artifacts and IIS standardization and improvement efforts. Terminology should be consistent with what is commonly used in the IIS community.
- **Foundational:** Artifacts should provide a solid foundation to promote more uniformity and compatibility in IIS implementation.
- **Flexible:** Where appropriate, artifacts should assist immunization program awardees in further defining their specific jurisdictional IIS *system needs*. Artifacts should also provide flexibility in allowing awardees to pick and choose *support service tasks* that reflect their specific operational needs.
- **Promote efficiency:** Through continuing reuse, artifacts should promote greater efficiency for all stakeholders through greater consistency, less redundancy and increased familiarity.
- **Durability:** As much as possible, requirements should serve IIS/immunization programs at least five years into the future and not just be reflective of past or current needs.

⁵ <https://www.healthcareitleaders.com/blog/guiding-principles-offer-direction-add-clarity-large-hit-projects/>

Identifying in-scope requirements

- **Viability:** Requirements should articulate the minimum or baseline system features and quality attributes needed to develop or support a viable IIS.
- **Program support and funding:** Requirements should directly support IIS/immunization programs in the attainment of the IIS Functional Standards and associated Operational Guidance Statements and required activities described in the Immunization Program Operations Manual. Requirements should also support programs in driving data quality improvement as indicated in the IIS Data Quality Blueprint. As such, baseline system requirements should be able to be supported through base federal immunization program funds (e.g., Section 317 Ops, VFC Operations, VFC Compliance/Quality Improvement [VCQI], etc.).

Glossary of requirements terminology

Attribute: A system technical characteristic; each attribute is further detailed by non-functional requirements.

Capability: A system's ability to execute a particular process in support of a function.

Function: Categorization or logical grouping of capabilities that combine together to produce an output/achieve a desired outcome.

Functional requirement: Statement that describes intended behavior of a system to support business processes and tasks.

Non-functional requirement: Statement that describes how a system must operate. Non-functional requirements are used to indicate technical characteristics of the system.

Requirement: A statement that describes what is needed from an information system in order to achieve a particular objective or support a particular activity. See also: system requirement, functional requirement and non-functional requirement.

Requirements traceability matrix (RTM): An industry-standard tool to document requirements in a format that allows for validation, analysis, and testing of each requirement.

System requirement: A statement that describes either a functional or non-functional requirement.