
Immunization Information Systems Joint Development

Practical guidance for collaborative IIS projects

July 2014

Acknowledgements

The Public Health Informatics Institute (PHII) thanks the following individuals for sharing their time and expertise as part of the project work group. We also acknowledge their agencies, corporations and team members for making it possible for the work group members to participate in a face-to-face meeting.

Angel Aponte
New York City Dept. of Health

Rebecca Coyle
AIRA

Heather Shull
Colorado Dept. of Public Health

Belinda Baker
Washington State Dept. of Health

Joe Gibson
Marion County Public Health

Bob Swanson
Michigan Immunization Program,
AIM representative

Nathan Bunker
Dandelion Software and Research

Mary Beth Kurilo
Oregon Immunization ALERT

Gary Urquhart
Centers for Disease Control and
Prevention

Frank Caniglia
Pennsylvania Statewide IIS

Dan Martin
Centers for Disease Control and
Prevention

Warren Williams
Centers for Disease Control and
Prevention

PHII also thanks the following members of the vendor community for sharing their time, expertise and feedback through webinars and interviews.

Noam Arzt
HLN Consulting, LLC

Kevin Garnett
Crystal Lightning

Shane Speciale
Avanza Systems

Brandy Altstadter
Scientific Technologies Corporation

Nichole Lambrecht
Envision Technology

Mike Suralik
HLN Consulting, LLC

Gordon Chamberlin
Oak Forest Tech Consulting

Steve Murchie
Envision Technology

Gary Wheeler
Hewlett Packard

Erich Daub
Scientific Technologies Corporation

Katie Reed
Hewlett Packard

This report was made possible through cooperative agreement no. HM08-080502CONT12 from the Centers for Disease Control and Prevention (CDC) National Center for Immunization and Respiratory Diseases.

Table of contents

Introduction 1

Part I: System level changes needed to support joint development 3

Part II: Key elements in planning and executing effective joint development projects..... 5

 Stakeholder engagement 5

 Planning for effective governance..... 5

 Transparency and accountability 8

 Legal and contractual considerations..... 8

 Project management 10

 Requirements development/lifecycle planning 10

 Adherence to standards 11

Part III: Selecting joint development projects..... 13

 The value of joint development 14

 Selecting joint development projects..... 13

 Opportunities, challenges and strategies 15

Appendix A: Key elements for successful joint development projects

Appendix B: Stakeholder analysis template

Appendix C: Sample RACI chart

Appendix D: Overview of open source software for public health

Introduction

The immunization information systems (IIS) community has been called to respond to ever-increasing expectations, whether in supporting immunization delivery in the private sector or immunization programs in the public sector. National health information technology (HIT) initiatives such as Meaningful Use (MU) increase pressure on all entities involved in electronic health information exchange, including public health, for more standardization in practices, policies, legislation and systems requirements. These pressures are occurring even as financial and staffing resources across public health are increasingly constrained.

To address these challenges, IIS managers must look to innovative ways to enhance system functionality through collaboration, leverage funding where possible, and apply the intellectual and technical capabilities of their peers from across the IIS community. To address these needs, the Centers for Disease Control and Prevention's (CDC) Immunization Information Systems Support Branch (the Branch) engaged¹ the Public Health Informatics Institute (PHII) to support the launch of an initiative on IIS joint development. This guidance document is the result of an initial meeting of the Branch and American Immunization Registry Association (AIRA) representatives, facilitated by PHII in July 2013. It also incorporates input from IIS implementers obtained through two webinars and subsequent phone interviews, as well as guidance researched or developed by PHII.

Note: The term "implementers" is used here to connote software vendors for commercially available or open source products, IT companies who develop and/or support a government-developed system used by one or more agencies, and agency IT staff who develop and support a system used only in their agency. Given the range of IT organizations and staff supporting IIS programs today, the word "vendor" is clearly too limiting. PHII and its partners involved implementers in these discussions and in the development of this paper because of their expertise and their current support of joint development efforts. The implementers' participation also provided first-hand knowledge of the initiative, which could help inform their own future business strategies/models.

The intent of this document is to help guide the IIS community in identifying the risks and benefits of joint development, and to provide practical information about the governance and management aspects of such collaborative projects. It is intended to stimulate and inform ongoing conversations and aid in the planning and execution of joint development projects. While it distills lessons learned to date, it should not constrain how joint development evolves in the future.

For purposes of this initiative, "joint development" is any collaborative effort of IIS programs, with or without their implementers, that involves collectively contributing expertise, staff time, software tools and/or other resources to develop a product that could be used by multiple IIS or other public health programs.

Products of joint development can include collaborative development of standards, business requirements, functional or system requirements, design specifications, or production of actual software tools or applications. Joint development can be done through formal and informal arrangements, including various contracting and procurement strategies. The product may be deployed by individual programs or collectively as an open source or other shared resource.

Because the IIS community has a long history of joint development in areas of standards (the HL7 implementation guide) and best practice guidelines (MIROW), this report will focus on what would be

¹ Through cooperative agreement no. HM08-080502CONT12

required to extend joint development efforts toward collaboratively defining requirements and developing shared solutions.

The guidance in this report is presented in three main sections:

- **Part I: Moving toward a culture of joint development**
This section highlights system level changes needed to create a supportive environment for joint development approaches.
- **Part II: Key elements in planning and executing effective joint development projects**
This section provides practical guidance on factors that can make or break a collaborative project between IIS programs.
- **Part III: Selecting a joint development project**
This section reports on the discussion and results of the initial face-to-face meeting on joint development, held at PHII on July 24-25, 2013.

The three sections and supporting appendices address such topics as:

- The value proposition for joint development in the current environment
- Selecting a joint development project, including criteria and considerations for which IIS functions are most amendable to joint development
- Critical success factors for a joint development project
- Legal and contractual issues
- Understanding different models of fiscal relationships
- Open source solutions and licensing

Part I: Moving toward a culture of joint development

An overarching challenge for joint development is transitioning from a historical culture of every agency “doing its own thing” to a culture that acknowledges that common needs should result in common solutions. This transition begins with a recognition that the needs and requirements for agency programs are much more similar than not. Without a widespread acceptance of that reality, there is unlikely to be sufficient motivation to pursue and support joint development efforts.

Creating a nationwide culture of effective joint development requires paying attention to several key factors, including:

- Engaging a broad set of stakeholders early and often. This is particularly important for implementers who ideally are working with their customers to help define/clarify system requirements, estimate budgets, and create realistic project plans and timelines.
- Ensuring awardees have sufficient lead time between when a CDC-driven funding announcement or new set of requirements is issued, and when the response is due to CDC. This allows time for joint development collaboratives to be negotiated and more precise budgets to be created. The National Center for Immunization and Respiratory Diseases (NCIRD) doesn’t always have control over this, but it is an ideal to aim for.
- Reducing variability in local system requirements to an absolute minimum. This helps to reduce costs for the IIS programs and potentially for others, such as Electronic Health Record (EHR) vendors. Greater, more consistent reliance on national standards can facilitate this process. (Note that state variability in procurement and EHR requirements is likely to continue regardless of how harmonized IIS operational policies and requirements become.)
- Ensuring that every project, whether done singly or jointly, is paying attention to the “triple constraints” of time, quality and money. Joint development projects may require more upfront time because of the need to set up a joint governance structure, legal, EHR or other research. However, joint projects may save time in later phases and lead to better products with fewer changes needed after testing, etc. With growing experience, joint development could increasingly lead to reduced cost for the community, but forcing implementers to rush the time table will invariably result in a reduction of quality and perhaps higher costs.
- Ensuring that part of due diligence in a new joint development project is to see if any implementer or others have a similar product in R&D, development or pending release. There should be ways to manage overlapping endeavors so that resources are not wasted and so that efforts are coordinated when and where possible.
- Ensuring that joint development projects have structured debriefings afterwards to evaluate successes, lessons learned, and how to share and build on the lessons learned.
- Establishing governance, fiscal and funding mechanisms to create ways of supporting joint IT development efforts.

Supporting and sustaining such a cultural shift will require new activities and changing processes in old activities. The following informal recommendations came out of a joint development meeting held at the 2013 AIRA meeting in Denver:

1. The IIS community should agree to a common set of core system requirements. The requirements could build on the 2013-2017 Functional Standards, collaborative requirements development facilitated by PHII, as well as the Modeling Immunization Registry Operations Workgroup (MIROW) and other best practice documentation. These requirements could support simplified and more consistent requests for proposals when an agency is making a major system migration, help ensure more consistent policies and practices across IIS, and contribute to any certification efforts. This system may require a technical support strategy, ideally involving both AIRA and the Branch, to ensure any awardee entering a Request for

Proposal (RFP) process is receiving the encouragement and support needed to adhere to the core standards.

2. A central repository of requirements and best practice documentation needs to be created and curated. This could be performed by AIRA or another organization. Knowledge management repositories comprise a range of strategies and practices used in an organization or community to identify, create, represent, distribute and enable adoption of insights and experiences. Many nonprofit organizations have resources dedicated to knowledge management repository efforts, often as a part of their business strategy. AIRA's knowledge management efforts could focus on organizational objectives such as improved IIS performance, best practice, requests for proposals documents, requirements documentation, project plans, testing documents, training documents, lessons learned, and integration and continuous improvement of IIS.
3. AIRA should explore alternative governance structures and processes, such as a joint development steering committee to oversee joint development activities, including how to ensure rapid decisions when needed. Overall governance for an ongoing joint development initiative will be critical to its success over time. All parties—funders, IIS programs, implementer—should agree to this structure, since it must represent all of those interests while also keeping end users' interests in mind.
4. Ensure that the same CDC announcements received by awardees are also delivered to IIS implementers. CDC or AIRA could provide a mechanism to achieve this consistency in messaging. Immunization programs and implementers have developed strong partnerships over the past 15 years. Awardees depend on an open relationship with their implementers to assist with cost estimates for immunization program funding opportunities. Most funding opportunities are from CDC, and the implementer community is dependent on receiving this information from each of the immunization programs with which they partner. In many situations, awardees interpret the messaging from CDC in different ways. Implementers would like to be included on the main messaging from CDC about new initiatives, and even the dialogue leading up to a funding announcement, to help with workflows and cost estimates for their IIS partners and to minimize developing business rules in isolation with each awardee. Since this is a complex area with legal implications for CDC, a separate workgroup may need to be formed to explore the implications and to recommend a defensible strategy.
5. AIRA, the Association of Immunization Managers (AIM) and the IIS Support Branch could develop a mechanism to ensure that all IIS implementers have the ability to communicate with each other. An email list² or work group structure would be a good resource for this community to share lessons learned, participate in developing best practices and participate in joint development efforts. This community of practice could reduce the variability in local requirements to an absolute minimum if organized and staffed appropriately to meet its needs.

² Note: AIRA created this list on November 1, 2013.

Part II: Key elements in planning and executing effective joint development projects

Solid planning is a prerequisite for project success. These elements are likely to be critical to the success of a joint development project:

- Stakeholder engagement
- Planning for effective governance
- Transparency and accountability
- Legal and contractual considerations
- Project management
- Requirements development/lifecycle planning
- Adherence to standards
- Mechanisms of support for both initial efforts and for long-term maintenance

Each factor contributes a unique but synergistic aspect to an effective collaborative project. The following narrative describes common issues for each factor (see Appendix A for a one-page checklist).

Stakeholder engagement

One of the most common mistakes made in technology projects is failing to consider which stakeholders need to be involved in the project, in what way and at what times. Too often, projects fail not because of technology issues, but because people critical to the project were unclear about the goal, scope or details, or were not sufficiently engaged to ensure input at the appropriate levels at the right time.

People considered critical to a project—the stakeholders—are those who are affected by a project, have influence over it, or have an interest in its success or failure. This includes the leadership team within an agency, program managers, users of the information system, central IT, etc. As part of every project, project leaders should conduct a stakeholder analysis to identify everyone who needs to be engaged and prioritize them according to their level of interest and influence on the project (see Appendix B for a stakeholder analysis template).

Planning for effective governance

Participating partners

Each IIS program, governmental agency, private company or other entity with a direct stake in the joint development project—that is, who will have defined duties and responsibilities with respect to others within the project—should be identified as a *participating partner*. While various other stakeholders may have an interest in a project, participating partners have obligations to each other that are ideally formalized in a signed agreement such as a project charter and/or memorandum of understanding (MOU).

Some partners will be easy to identify. Entities that contribute funding, staff time or other in-kind contributions (e.g., software) are partners. Other partners may be less apparent. A jurisdiction that does not contribute to the joint development product but uses the product and participates in an ongoing user group could also, as an example, be a partner. A third party that has a fiscal relationship with

Stakeholder engagement

- ✓ Stakeholders have been identified and engaged.
 - IIS staff
 - IIS implementers
 - EHR vendors (if appropriate)
 - End users (if different than IIS staff)
 - Division/bureau leadership
 - Agency attorneys
 - CIO/central IT
 - Financial management
 - Human resources
- ✓ The audience, key message(s), timing and call to action for each communication are documented.

respect to the joint development project may also be a partner, as might federal or state agencies with oversight or regulatory powers.

Each partner in a joint development project may have multiple internal departments that have an interest in the project (e.g., IT, human resources, procurement and legal). Such groups could be considered stakeholders (to distinguish from the more ongoing involvement of partners), and should be consulted as necessary during the course of the joint development project. Consulting early with stakeholders is recommended to prevent unwelcome surprises later in the project.

Roles and responsibilities

The roles and responsibilities of each partner should be clearly understood by all partners. A key organizing element is a project charter, a document that lists the purpose, scope, goals, objectives, milestones, deliverables and stakeholders of a project, and delineates roles and responsibilities of each member of the project team. A RACI chart (see Appendix C) can also help define the roles and responsibilities prior to beginning the joint development project. Development and execution of a project charter upfront may initially slow the process; however, having such a written agreement may save time and resources later, especially if there is turnover of personnel or management.

Governance structure

The structure to support effective governance is critical to a successful joint development project; in fact, failing to establish a structure that is appropriate to the size and complexity of the project presents a serious risk.

Examples of governance structures include the following:

- One person or an entity makes all decisions that are binding on all participants. This type of governance might be appropriate for production of limited open source code based on well-defined standards.
- Each partner appoints one representative to a governing body. Each representative has one vote. Voting rules and threshold are established, e.g., simple majority, 2/3 majority, whether silence is assent, etc.
- One body, e.g., the board of a 501(c)(3), makes decisions on priority for joint development projects and fiscal matters. Jurisdictions who wish to participate in a particular project sign an MOU for that specific project. The MOU establishes a governing board for the project that is empowered to make binding decisions for the single project. The project governing board would have representatives from all participating jurisdictions. Decisions of even more limited scope could be made by one designated person or group of people.
- An ongoing governance structure, perhaps provided by AIRA or another entity, under which all joint developments projects fall, ensures adherence to joint development standards that were collaboratively developed.

Other governance decisions include setting regular meetings, designating the project leader or manager, and establishing required vendor support and funding. These governance decisions can determine which laws and policies apply to your project—see “legal and contractual considerations” on page 8.

Governance

- ✓ A project charter is developed and approved by all participating partners.
- ✓ A governance structure has been established and approved by all participating partners.
- ✓ Partners agree to regular meetings.
- ✓ A champion exists, in or outside the project team, who keeps the team focused on the project vision and goals.
- ✓ Support from implementers, agency IT staff, and any other required source has been identified and formalized through a charter, MOU, contract or other instrument.
- ✓ A funding mechanism is in place that enables adequate financial support for the project.

Understanding fiscal relationships

A key aspect of joint development projects is deciding how funds will be sought and/or managed. Whether IIS programs are each contributing funds to a shared “pot,” or CDC or another organization provides funding to a single entity to manage on behalf of others, the funding model has important financial and legal implications. Two basic models are fiscal sponsor and fiscal agent³. Each has its advantages, depending on the nature of the project and the funding mechanism.

Fiscal sponsor	Fiscal agent
An entity—usually a nonprofit organization—accepts financial and legal responsibility for a grant/contract beneficiary (in IIS joint development projects, two or more immunization programs).	An entity accepts fiscal duties with respect to funds, but the grant/contract recipient retains legal responsibility.
Differences	
The fiscal sponsor has more responsibility—both legal and financial duties—and is likely to have authority to accept deliverables and make payments.	The fiscal agent accepts fiscal duties only. The grant/contract recipient retains more discretion and control, and is likely to retain authority to accept deliverables and authorize payments.
Funds are subject to the laws and policies of the funder and fiscal sponsor, but are not subject to the laws and policies of the grant/contract recipient, such as a state health department. If structured properly, the funds would not be subject to laws pertaining to public agency legal authority, procurement or human resources.	Funds are subject to the laws and policies of the funder <i>and</i> the jurisdiction accepting the funds, usually a state (and possibly the laws of the agent).
Examples	
For many years, Public Health Solutions in New York City served as the fiscal sponsor for AIRA, receiving and dispensing the cooperative agreement funds, including payroll. AIRA abided by its policies and procedures. AIRA was not a 501(c)(3) at the time.	AIRA currently contracts with an organization that provides administrative support for AIRA, including accounting and payroll. However, AIRA sets its own policies and procedures based on its own governance preferences. Various IIS programs join a joint development project, and they agree on one jurisdiction serving as fiscal agent, receiving and managing the funds from each member of the collaborative.

³ There are no standard definitions for these terms, so they can have different meanings in different situations. For instance, a fiscal agent can at times have all the responsibilities of a fiscal sponsor, and a fiscal sponsor can also be known as a bona fide fiscal agent or fiscal intermediary for a CDC grant or contract. This report has defined the terms for the purposes of this report only. Regardless of the term used, the responsibilities and authorities of the entity must be clearly defined in each relationship.

Other financial structures

Other possibilities exist for financially supporting a joint development project, such as a number of IIS programs entering into simultaneous or sequential contracts with an implementer to develop a solution that each will use. Alternatively, a funder could contract directly with implementers to support joint development projects or implementation of shared solutions.

Transparency and accountability

Because joint development projects inherently involve collaboration and may involve expenditures of public funds, the need for transparency and accountability is particularly critical. The participating partners need to hold each other accountable to the terms agreed upon in the project charter. Fiscal sponsor(s) or agent(s) must be transparent and forthcoming about the management and disbursement of funds. The project governing body must openly communicate about its oversight activities over any project manager, vendor(s) or fiscal agent. Implementer(s) developing actual solutions must have regular communications on progress to all of the participating partners. Also, participating partners must be transparent and accountable to the financial management and legal offices within their agency.

Legal and contractual considerations

Before beginning any joint development project, the project sponsor or team needs to clearly conceptualize and articulate each aspect of the project. Laws and policies apply to specific situations. The structure of each joint development project will trigger application of specific laws and policies. For example, is the purpose of the joint development project to produce a requirements document or other written artifact using only existing personnel? Or is the purpose to produce a new application or application module? What will be the source of the funding, and what entity will be responsible for oversight of funding and governance? These and similar questions should be addressed upfront, ideally in the governance stage.

Authority to be a partner in a joint development project

Each partner in a joint development project must have authority to enter into the project. The type of authority needed will depend on the type of participant (e.g., governmental agency, corporation, etc.), the details of each joint development project, and what is being undertaken by each partner. In many cases, authority to enter into a joint development project will be implicit in general public health or corporate powers. A clear statement of the specific benefit of the joint development project to a partner will assist senior leaders in determining whether the partner has legal authority to enter into the project.

If a partner is contributing or paying funds as a part of the joint development project, it must have the legal authority to use the funds for that purpose, which will likely depend upon the source of the funds. For state or federal funds, general or specific appropriation language should be consulted for authority to expend the funds and required timing of the expenditure. If the source of funds is a grant or a contract, the grant or contract terms for authority to use the funds should be examined, in addition to general federal and state laws. If in doubt, check with the funder.

Legal Considerations

- ✓ Policies and regulations that might be barriers to implementation have been identified and mitigated.
- ✓ Any licensing issues have been identified and addressed.

Transparency and accountability

- ✓ All participating partners are fully informed throughout the project.
- ✓ Expenditures are routinely reported.
- ✓ Project documentation is readily available.

Any private nonprofit or for-profit entity will usually have authority to be a participating partner in a joint development project under general corporate or other powers. Nonprofit or public entities will need to ensure that responsibilities under the joint development project are a good fit for the entity and its mission.

Contractual issues

Contractual issues arise in joint development projects in two basic ways:

- **Constraints on use of funds, personnel and in-kind contributions**

Review any contract or grant that funds personnel or products that will be used for the joint development project, ensuring that the joint development project is consistent with the provisions of the grant or contract. For example, if computer code will be contributed to a development project, is that use permitted by the funding source that originally paid for the code development and by any license for that code? Is there an existing contract with a vendor that limits use of any code that would be modified by the joint development project? Existing contracts with implementers should be examined to determine if they need to be amended to accomplish the purpose of the joint development project, and to ensure the project will meet any contractual requirements and standards for systems development. Existing contracts may say that the implementer owns or has licensed code that uses the implementer's application. Any collaborative that involves multiple implementers and jurisdictions may require new implementers based on funding sources and other factors.

- **Joint development project agreement**

Consult with contracts experts to determine if there are competitive bidding/sole source requirements that apply to any agreement involved in the joint development project. Explore and address as needed the following issues:

- Authority to enter into the agreement
- Benefit of the joint development project to each partner
- Roles and responsibilities of each partner
- Governance of joint development project
- Ownership of the product of the joint development project
- Responsibility to obtain any copyright or licensing (see Appendix D).
- Responsibility for maintaining any product of the joint development project
- Any cost implications (increase or decrease) due to the new functionality and changes in any established contractual service level agreement
- Limitation of liability of each partner from the others (if appropriate) and from third parties who use any product of the joint development project (if appropriate)
- Term and termination
- Payment of funds, by whom and to whom; controls to ensure that payments are appropriate
- Duties of any fiscal relationship

Procurement and human resources issues

Each partner in a joint development project should consult with its own procurement and human resources experts to determine if there are requirements that must be met, such as competitive bidding or hiring, and exceptions that may apply for smaller dollar amounts or sole source contracting. In

general, procurement policies apply to acquisition of goods, and human resources rules apply to services, but there may not be a clear line between goods and services in a joint development project. For example, if the purpose of a joint development project is to produce open source code, is the project to acquire the services of the programmers or the code itself? There may also be constraints on the length of any consultant contract that is not competitively bid or posted.

Project management

Good project management can help ensure your project is executed effectively and efficiently. Project management is the discipline of applying knowledge, tools and skills to meet project goals. All projects require some level of project management, with larger projects likely requiring more formalized tools and processes in order to deliver results on time and on budget⁴.

Requirements development/lifecycle planning

A critical factor in the success of any information system project is to first clearly define the *information need* that must be met, then to concretely define what the *information system* must do to support meeting that information need. Coming to a clear agreement on the system requirements is perhaps even more important in a joint development project to ensure that all partners have a full and clear understanding of what the output will be and how it will work in their setting. Some jointly-developed products may require refinements in the specifications for any given agency to implement in its environment. Such “tweaking” would likely occur outside the scope of the joint development project itself, unless other agencies have to make similar refinements and the “tweaked” product is shared.

Different approaches can be used to collaboratively define requirements. Two examples of approaches used are the MIROW guides⁵ and PHII's Collaborative Requirements Development Methodology^{TM6}. While those approaches may be too involved for smaller joint development projects, the basic principles are the same: engage the partners in clearly understanding the information needs, document the actors and their roles as part of

Project Management

- ✓ A project manager is assigned to the project.
- ✓ A project plan is created that aligns with the project charter.
- ✓ The project manager manages project budget and contracts.
- ✓ The project manager ensures necessary resources are identified and effectively managed.
- ✓ The project plan is regularly reviewed and revised as necessary.

Lifecycle Planning

- ✓ The need for the project has been documented in the project charter.
- ✓ Information needs are identified and documented.
- ✓ System requirements are identified by the stakeholders/end users.
- ✓ Detailed system design specifications are developed, as appropriate.
- ✓ A plan for system testing and acceptance is developed.
- ✓ The system is tested to ensure that it meets design specifications.
- ✓ Training, system support and maintenance are in place.
- ✓ A plan for disposition is in place.

⁴ The consensus of the July 2013 work group (see Section III) was that project management duties are likely too extensive for most joint development projects, and can be performed best by a person who is dedicated to the project, rather than a staff person from a participating IIS program or an implementer. An independent entity, such as AIRA, could serve as the employer/contractor of joint development project management staff or services.

⁵ See <http://www.cdc.gov/vaccines/programs/iis/activities/mirow.html>

⁶ See <http://phii.org/crdm/>

that information need, diagram the workflows to be clear which actor is performing what task in what sequence, and then define the information system requirements to support all of that activity. The requirements then form the basis for a statement of work for the implementers.

Once the detailed work is begun, a traditional waterfall method can be used to work through the steps of design, construction, testing, implementation and maintenance. Alternatively, the Agile method⁷ could be more appropriate, allowing coders to take an incremental and iterative approach to software design, responding to changes in requirements as they arise.

Adherence to standards

A major challenge in sharing health information is ensuring the information has the same meaning to both the sender and the receiver. Both in the U.S. and globally, major efforts are underway to standardize how health information is captured, coded and exchanged so that semantic interoperability can be achieved and healthcare outcomes improved. The IIS community has been a leader within public health in moving to standards-based semantics and coding with the early development of the core data set, HL7 implementation guides and minimum functional standards.

Meaningful Use and other e-health trends, however, are putting increased pressure on public health agencies to harmonize operations and policies across programs within an agency and across agencies nationally. The overall intention is for jointly developed products to be implemented in multiple settings, across multiple platforms, and for costs to be reduced for individual programs and the IIS community overall. Over time, these products may be jointly maintained and supported, so it is possible that participating programs may elect to restrict or even disallow local customizations. If so, this should be thoroughly discussed at project inception and be included in the project charter.

Any jointly developed requirements and/or product should adhere to existing immunization standards. But partners must also be aware of and incorporate other standards used in the healthcare arena, open source communities or other relevant domains.

Adherence to Standards

- ✓ Solutions align with relevant immunization, health care, open source or other standards.
- ✓ If appropriate, agreement exists across project partners to restrict/disallow jurisdictional customizations/variability.

Mechanisms of support for initial efforts and long-term maintenance

This factor is most appropriate for software or module/tools that are developed jointly. It would be tempting to consider a joint software development project done when the work group has disbanded and the solution is tested. But, in reality, that is only the beginning. There must be a plan for how the shared solution will be deployed, whether locally or in the cloud. Depending upon the nature of the solution, other software might need to be configured to interoperate

Initial and long-term maintenance

- ✓ A plan is in place to ensure the solution is deployed and configured appropriately
- ✓ Support is available to configure any other system that needs to interoperate with the solution
- ✓ Ongoing maintenance is provided to keep the solution functioning and responsive to evolving needs
- ✓ The community of users is disciplined about not undermining the benefits of joint development through unique customizations

⁷ See <http://agilemethodology.org/>

with it, which will require testing and support. And, perhaps most importantly, the mechanism(s) must be in place to ensure ongoing support and maintenance so the solution functions optimally and remains responsive to ongoing needs. Lastly, the system requires a disciplined community of users so the shared solutions don't become customized for each user (unless it was designed to be customized, such as with an CDSi service) in a way that diminishes the cost-savings or other intended benefit that drive the joint development effort in the first place.

Part III: Selecting joint development projects

The value of joint development

Common needs should drive common solutions. Public health programs across the country have more in common than not, yet historically, they have largely pursued solutions independently. This status quo is beginning to change with increases in both budgetary pressures and calls for public health to function more consistently with the health care sector. Public health is increasingly looking to enhance program impact and information system functionality by leveraging the intellectual and technical capabilities of others.

Such joint development approaches are not new to the IIS community. Collaborative approaches for developing best practices and requirements artifacts to actual software have yielded important lessons that can be built upon. These projects highlight a key value of joint development: when several IIS programs have a similar need, a better outcome can be achieved when people come together and contribute to collective thinking and planning. Developing projects "by committee" may seem inefficient, but considering the alternative, which is IIS programs duplicating efforts by creating similar products in isolation, collaboration clearly represents the better value.

Joint development can also lead to greater harmonized and consistent implementation of standards across IIS programs. The emerging eHealth environment relies on standards and reduced product variability across both health care and public health environments. Such variability is costly for everyone in both dollars and inefficient processes.

Selecting joint development projects

The first step in launching a joint development project is to come to an agreement on what that project will be. The work group that convened in July 2013 developed the following criteria as a guide to identify and select a suitable project. No one candidate project could be expected to meet all the criteria, but the more criteria a project meets, the stronger the value proposition.

Core criteria (All three should apply.)

- The proposed product is needed by more than one IIS.
- The project addresses an immunization program priority.
- The project risks are manageable. These could include financial, legal, contractual or other risks.

Secondary criteria and considerations (One or more may apply depending upon the situation. Some criteria/considerations relate to software development; however, all joint projects may not involve developing software.)

- Development time is likely to be shortened due to combined contributions/expertise.
- More functionality is likely to be developed for the same amount of money.
- Standards or other guidance exists (or can be developed) for necessary interfaces between the new product and other IIS modules.
- The project addresses a funded mandate.
- The solution is compatible across multiple implementers and/or platforms.
- The project leads to greater compatibility across IIS programs and/or between IIS and EHRs.
- The deadline for availability of required functionality is acceptable to all the project stakeholders.

- The project does not require contractual or service level agreement changes for ongoing support of the IIS.
- The project adds to the IIS knowledgebase, community stability and/or continuity.
- Testing tools and test data are available.
- The solution is politically feasible.
- The project does not require immunization policy change.

The work group identified a number of potential joint development projects, and voted for their top candidates⁸. The leading candidate projects identified at the face-to-face meeting were:

- Meaningful use Web-based registration system (ten votes)
- AFIX⁹ reporting (seven votes)
- Immunization forecaster (seven votes)
- Data quality tools (six votes)
- Patient matching algorithms for de-duplication (six votes)
- Consumer access (six votes)

The list below contains the remaining candidate projects, each of which received less than six votes. The workgroup believed that both the projects listed above and those on the next page meet all three core criteria, as well as several of the secondary criteria/considerations.

Other possible joint development projects identified by the work group

- Future HL7 upgrades and implementations
- SMS text-based reminder recall notifications
- IIS dashboards that allow users to view clinic coverage reports compared to local, state, and national, as well as low inventory warnings, and last reminder/recall notification date
- 2D barcoding implementation
- Perinatal Hepatitis B case module
- Address cleansing and geocoding features for an IIS
- Vaccine de-duplication algorithms
- WSDL for HL7 interfaces
- Population-based coverage reports
- Record locator service for national consumer access or a service that allows IIS to locate records in other IIS
- Child health integration
- Interface with SNS tracking systems
- Influenza public health preparedness initiatives

⁸ Joint development may already be occurring in some of the candidate projects, which would need to be leveraged.

⁹ AFIX (Assessment-Feedback-Incentives-Exchange) is a quality improvement program used by awardees to raise immunization coverage levels, reduce missed opportunities to vaccinate, and improve standards of practices at the provider level. See <http://www.cdc.gov/vaccines/programs/afix/index.html>

Example of applying the criteria

To illustrate how the criteria could be applied in the future, an example using AFIX (neither developed nor discussed by the workgroup) is included below.

Criteria	How/why criteria is met
Core criteria	
The proposed product is needed by more than one IIS.	With the future decommissioning of CoCASA, all IIS programs will need to develop the functionality needed to support the assessment aspect of AFIX.
The project addresses an immunization program priority.	AFIX has been a NCIRD/Section 317 priority for many years
The project risks are manageable.	The requirements are being collaboratively defined, CDC has funded the initial collaborative meeting (May 2014), there are no legal considerations, and work done through CDSi can be leveraged.
Secondary criteria and other considerations	
Development time is likely to be shortened due to combined contributions/expertise.	A collaborative approach to defining the requirements, and perhaps overseeing development of a shared solution, will likely be considerably less costly in terms of time and money than 54 IIS programs developing independently.
The project addresses a funded mandate.	AFIX has been a 317 requirement for many years. What's new is the IIS role in the program.
The project leads to greater compatibility across IIS programs and/or between IIS and EHRs.	A collaborative approach to defining the requirements, and perhaps overseeing development of a shared solution, will likely yield more standardized use of CDSi, MOGE and other rules, as well as report format and other features.
The deadline for availability of required functionality is acceptable to all the project stakeholders.	The initial AFIX workgroup has established 2017 as the transition date from CoCASA to IIS.

Opportunities, challenges and strategies

The table below identifies joint development opportunities, related challenges and barriers, and possible strategies to address challenges for the top six candidate projects. This table is meant to help focus conversation around the value proposition for each project. It may not list every opportunity or solution. Various joint development projects, formal and informal, are likely occurring in these areas already.

Opportunity	Challenges and barriers	Strategies to address challenges
<p>Meaningful use registration system</p> <p>Stage 2 of MU EHR incentive program requires health care providers to register with the public health agencies (PHAs) to which they will be submitting data. Many PHAs need to acquire a logging application to register providers/hospitals and manage the on-boarding process.</p> <p><i>Note:</i> Since this candidate project was identified in July, a nationwide task force collaboratively developed requirements for an on-boarding tool, and many agencies developed or adopted tools.</p>	<ul style="list-style-type: none"> ▪ Should be operational by October 1, 2013 ▪ Current variability in processes, requirements across states ▪ Includes ELR, syndromic surveillance, cancer communities ▪ Needs coordination within an agency (IIS, ELR, syndromic, cancer) and across agencies/jurisdictions ▪ Needs guidance on how to migrate existing, homegrown tools to shared or open source tools (general challenge) ▪ Integration of registration system with IIS or contact management system ▪ Changes in PHA’s MU readiness over time 	<ul style="list-style-type: none"> ▪ Leverage requirements created by the CDC-sponsored Stage 2 MU Readiness Task Force, available at phConnect.org. ▪ Leverage work of public health informatics fellows in several states who are working on this in collaboration with the Stage 2 MU Readiness Task Force (phConnect.org). ▪ Leverage existing systems (create mechanism to enable sharing of existing applications or inform agencies of commercially available applications). ▪ Build solutions that could have longer-term benefits (future MU stages, improved management of public health and clinical health relationships).
<p>AFIX reporting¹⁰</p> <p>With the announcement that CDC will be ceasing support of Co-CASA¹¹ within the next few years, IIS must replicate the AFIX reporting capabilities of Co-CASA. Since the programmatic requirements and the business logic will be largely the same across the country, working on a single or limited number of solutions is ideal. The Co-CASA source code is available in the public domain.</p>	<ul style="list-style-type: none"> ▪ Need business rules, specifications, requirements, outputs for AFIX reports (measures) ▪ No sustained funding ▪ Policy issues regarding implementation (relate to maturity of IIS) ▪ No standardized implementation of current MOGE¹² rules (2005) ▪ No standardized import rules (shot record) ▪ Need immunization forecaster interface first, need consistent clinical decision support (CDS) logic (implemented in IZ forecaster, not AFIX module) 	<ul style="list-style-type: none"> ▪ Jointly identify requirements and rules (involve AIM and VFC staff). ▪ Fund a limited number of widely used solutions. ▪ Explore open source solutions as a strategy. ▪ Explore using Direct Assistance–Other funding mechanism to minimize financial/contractual complexities. ▪ Ensure solution meets both clinical and immunization program needs.

¹⁰ An initial meeting on IIS roles in AFIX was held May 2014.

¹¹ See <http://www.cdc.gov/vaccines/programs/cocasa/index.html>

¹² See <http://www.inclentrust.org/uploadedbyfck/file/CDC%20Immunization%20works%20Learning%20CD/MIROW-Chapter%201-MOGE.pdf>. CDC and AIRA re-commissioned a MIROW work group on MOGE rules in 2014 with an emphasis on new perspectives that were not addressed in the 2005 guide: AFIX coverage assessments and electronic data exchange.

Opportunity	Challenges and barriers	Strategies to address challenges
<p>Immunization forecaster</p> <p>Forecasters already exist as Web services from a number of implementers, but more work is needed on interfacing IIS with these services and improving testing procedures.</p>	<ul style="list-style-type: none"> ▪ Ambiguity of the rules ▪ Variability across jurisdictions ▪ Need simple, standardized interfaces between IIS and forecaster and EHR and forecaster ▪ Standardization of forecast results versus message format ▪ Technical issues regarding de-coupling existing/embedded forecast engines 	<ul style="list-style-type: none"> ▪ Build on/support existing products (including open source). ▪ Build on/support existing testing and rules management tools (including open source). ▪ Create a technical working group to develop interface standards. ▪ Focus on child immunizations initially. ▪ Incorporate CDC CDSi¹³ logic guidance. ▪ Long term, certify/validate forecasters.
<p>Data quality tools</p> <p>As volume and velocity of data increase over time, there will be a greater need to automate processes as much as possible, including data quality checks. This could include data quality checking when on-boarding a new provider, or ongoing data quality routines/processes.</p>	<ul style="list-style-type: none"> ▪ Variability in processes across IIS programs ▪ No current standardized metrics 	<ul style="list-style-type: none"> ▪ Review current tools used by the IIS community. ▪ Develop consensus on metrics needed for data quality measures. ▪ Collaboratively define business rules, building on existing MIROW and other work.
<p>Patient matching</p> <p>Record de-duplication is one of the core functionalities and challenges for IIS, one which could benefit from collective analysis and documentation.</p>	<ul style="list-style-type: none"> ▪ Variability in processes across jurisdictions ▪ Electronic messaging can increase duplicate records. 	<ul style="list-style-type: none"> ▪ Develop a framework for describing detailed approaches to patient matching, including technology, human resources and workflow, as needed. ▪ Develop consistent approaches to evaluating and disseminating the accuracy of various matching strategies, including those that employ human review. ▪ Use test cases developed by CDC's Patient De-duplication project. ▪ Develop criteria/metrics for a certification/validation process.

¹³ See <http://www.cdc.gov/vaccines/programs/iis/interop-proj/cds.html>

Opportunity	Challenges and barriers	Strategies to address challenges
<p>Consumer access</p> <p>Demand for consumer access to health information is sweeping the country, but the accompanying privacy and security issues are not trivial. IIS, and public health generally, could benefit from consistent approaches to authentication and auditing. There are several consumer access projects being piloted across the country whose lessons could be built upon.</p>	<ul style="list-style-type: none"> ▪ Variability in state health data privacy laws ▪ Variability in IIS privacy and confidentiality policies ▪ IIS policies on consumer access ▪ Need for authenticating users and auditing consumer access 	<ul style="list-style-type: none"> ▪ Share policies and approaches for allowing consumer access to IIS data. ▪ Leverage existing approaches for consumer access to their EHR data (e.g., patient portals, PHR and EHR interoperability, etc.).

Appendices

Appendix A: Key elements for successful joint development projects

Appendix B: Stakeholder analysis template

Appendix C: Sample RACI chart

Appendix D: Overview of open source software for public health

Appendix A: Key elements for successful joint development projects

<p>Governance</p> <ul style="list-style-type: none"> ✓ A project charter is developed and approved by all partners. ✓ A governance structure has been established. ✓ Partners agree to regular meetings. ✓ A champion exists, in or outside the project team, who keeps the team focused on the project vision and goals. ✓ Vendor support, IT staffing and any other required support have been established. ✓ A funding mechanism is in place that enables adequate financial support to the project 	<p>Transparency/accountability</p> <ul style="list-style-type: none"> ✓ All participants are fully informed throughout project. ✓ Expenditures are routinely reported. ✓ Project documentation is readily available. 	<p>Stakeholder engagement</p> <ul style="list-style-type: none"> ✓ Stakeholders have been identified and engaged. <ul style="list-style-type: none"> ○ IIS staff ○ Implementers ○ End users (if different than IIS staff) ○ Funder(s) ✓ The audience, key message, timing and call to action for each communication are documented. ✓ The delivery vehicles for the communications are documented.
<p>Lifecycle planning</p> <ul style="list-style-type: none"> ✓ The need for the project has been documented in the project charter. ✓ Information needs are identified and documented. ✓ System requirements are identified by the stakeholders/end users. ✓ Detailed system design specifications are developed, as appropriate. ✓ System is tested to ensure that it meets design specifications. ✓ Training, system support and maintenance are in place. ✓ A plan for disposition is in place. ✓ Modularity (functionality can be incorporated into different IIS platforms). 	<p>Legal considerations</p> <ul style="list-style-type: none"> ✓ Policies and regulations that might be barriers to implementation have been identified and mitigated. ✓ Any licensing issues have been identified and addressed. <p>Adherence to standards</p> <ul style="list-style-type: none"> ✓ Solutions align with relevant immunization, health care, open source or other standards. ✓ If appropriate, an agreement exists across project partners to restrict/disallow jurisdictional customizations/variability. 	<p>Project management</p> <ul style="list-style-type: none"> ✓ A project manager is assigned to the project. ✓ The project manager creates a project plan that aligns with the project charter. ✓ The project manager manages project budget and contracts. ✓ Project manager identifies and effectively manages necessary resources. ✓ The project plan is regularly reviewed and revised as necessary.
	<p>Initial and long-term maintenance</p> <ul style="list-style-type: none"> ✓ A plan is in place to ensure the solution is deployed and configured appropriately. ✓ Support is available to configure any other system that needs to interoperate with the solution. ✓ Ongoing maintenance is provided to keep the solution functioning and responsive to evolving needs. ✓ The community of users is disciplined about not undermining the benefits of joint development through unique customizations. 	

Appendix B: Stakeholder analysis template

Stakeholder analysis is used to manage projects and inform communications planning. The goal of stakeholder analysis is to identify all stakeholder groups, as well as each group's current beliefs about key issues, including their interest in and power to influence the issues, and potential role(s) in the project. Stakeholder analysis also identifies the individual contacts within organizations to help make it an actionable project tool. Elements of the analysis include the following:

1. Identify all the stakeholders that reflect the project's goal and objectives (e.g., if one project objective is to influence policy, a stakeholder group would be policymakers in that domain).
2. Complete the stakeholder analysis matrix.
 - a. Considering the project's objectives and the stakeholder groups identified in Step 1, expand this list to include all possible organizations that have a stake in the project. A "stake" means that the project may affect them positively or negatively. Also consider the mission/interests for each stakeholder organization, based on current knowledge or research.
 - b. Assess each stakeholder organization's level of interest in each key issue and power to influence the issue. The different points of view on where stakeholders fall can be very informative.
 - c. Prioritize each stakeholder organization into a two-by-two interest-influence matrix in light of the project's objectives. (E.g., if a project objective is to influence policy, are the right organizations in the high-high quadrant?)
3. If possible, ask key project staff/participants to complete the stakeholder analysis worksheet by adding the names of key individuals and their contact information for all stakeholder organizations listed. This step also involves documenting each stakeholder's role in the project (if known, or potential role if not yet known). This information provides the basis for planning approaches to communication.
4. Use the stakeholder analysis matrix and worksheet information to inform the project plan and communications plan. For example, if a high-high stakeholder is identified who is not actively engaged, should he/she have a different role in the project? What communications strategy can be used? If a stakeholder is high influence but low interest, do you want to use a strategy to increase their interest?
5. On completion of the analysis, a comprehensive stakeholder analysis worksheet should be maintained for the project. As new stakeholders are identified, add to the stakeholder analysis matrix and worksheet. Re-evaluate organizations' interest-influence placement in the matrix and their roles as new information becomes available. Maintain the list of stakeholder organizations on the worksheet in groups according to their quadrant placement on the stakeholder matrix.

Stakeholder analysis matrix

STAKEHOLDER *POTENTIAL INFLUENCE* LEVEL

STAKEHOLDER *INTEREST* LEVEL

		High	Low
High	<p>↑ High influence</p> <p>&</p> <p>↑ High interest</p> <p>Strategy: Maintain support, refine communications to align with project goals, leverage stakeholder influence</p>	<p>↓ Low influence</p> <p>&</p> <p>↑ High interest</p> <p>Strategy: Provide information, status updates</p>	
Low	<p>↑ High influence</p> <p>&</p> <p>↓ Low interest</p> <p>Strategy: Actively engage, target communications to align with project goals, leverage stakeholder influence</p>	<p>↓ Low influence</p> <p>&</p> <p>↓ Low interest</p> <p>Strategy: Passive relationship management</p>	

Appendix C: Sample RACI chart

A RACI chart describes the roles of various participants/stakeholders in completing tasks or deliverables for a project. The more complex a project, and the more stakeholders involved, the more useful a RACI can be to forge agreements on roles and responsibilities before launching project activities.

RACI is an acronym for the four key project responsibilities:

- **Responsible:** “The doer”

Those who actually perform the project work and achieve tasks. Depending upon the task, this could be committee members, a developer, project manager or other participants.

- **Accountable:** “The buck stops here.”

The one (and typically *only* one) ultimately answerable for the correct completion of a task or deliverable. This person is often the one who delegates the work to those *responsible*.

- **Consulted:** “Subject matter expert”

Those whose opinions are sought or who are otherwise active in various phases of the project, particularly in developing key artifacts or reviewing drafts. The level of active participation may vary, but it is usually characterized by two-way communication.

- **Informed:** “Kept in the loop”

Those who are kept up-to-date on progress, typically upon completion of a task or deliverable. This may involve only one-way communication.

Sample RACI chart

Task/position	Project Director	Funder	Project manager	Team members	Etc.
Develop and approve project charter	A	C	R	C	
Etc.					
Etc.					
Etc.					

Appendix D: Overview of open source software for public health¹⁴

While joint development projects can result in many products other than new software, this section is included as a primer because open source software is still a fairly novel concept in the public health community. It can be tempting to see open source solutions as a panacea, but, as with any information technology project, the solution must fit the project's needs and requirements. In addition, any solution will likely need to meet state IT, security and other standards to be viable for a given jurisdiction. This appendix is intended as an educational resource only, and is not meant to imply that joint development projects will or ought to result in open source solutions.

While definitions of open source software vary, there are integral characteristics to any true open source software. In general, open source software is software that end users have the right to use, study, modify and distribute. While these “four freedoms” signify open source software, the specifics can vary with different licensing approaches.

Sometimes open source software is associated with free software. Open source software is free in the sense that there are no licensing fees; however, that does not mean that it comes at no cost, and other restrictions may apply. Like any software product, open source tools have costs associated with acquisition, implementation, end-user support and maintenance. These costs can be in the form of in-house staff or IT overhead to provide those services, or in contractual costs to a third-party vendor that specializes in providing support for open source products.

Most software, including open source software, is protected via copyright. The creator of the software holds the copyright for that product. The copyright holder can specify the terms under which the software may be used or modified.

With proprietary software, the copyright holder typically seeks to restrict how software will be used by others to maximize the commercial viability of the software product, and sometimes to protect trade secrets. These restrictions are articulated in the terms of the proprietary software's end user license agreement. Those terms typically forbid the end user from distributing copies of or making alterations to the software, and may prohibit analysis or “reverse engineering” of software algorithms and technology.

Like proprietary software, open source software is also licensed by its copyright holder. However, unlike proprietary software, the licensees of open source software are granted the freedoms to use, study, modify and distribute the software, though usually within specific constraints identified in the open source license.

A leading rationale for adopting open source software is avoidance of the licensing fees associated with proprietary software. Yet, as licensing costs are reduced, an agency's development and maintenance costs may rise with its open source implementations. Without an external vendor, public health agencies must rely on internal resources to assess, integrate, troubleshoot and maintain open source tools. This requires a relatively high degree of information technology sophistication, particularly for a system as critical to the public health enterprise as an IIS.

An additional rationale for open source is the benefit of the agency retaining rights to the source code. Holding these rights preserves the agency's access to data, code and ability to modify/maintain the software even if the relationship between the agency and its implementers changes or ends. This benefit is not only available in open source, as some for-profit implementers have agreed to place their code in escrow that only becomes available to the agency upon termination or default.

¹⁴ While the topics of intellectual property and copyright are addressed here, this section is only intended to inform the reader about software licensing options, not to serve as legal advice.

Recognizing that some organizations want to adopt open source tools, but lack resources to support them, implementers and consultants have come forward with various business models to generate revenue from open source software implementation. These include implementers that offer consulting or support services to implement or maintain open source tools. In addition, “dual-licensing” describes a strategy where a vendor offers an open source product as a way to introduce customers to a more feature-rich proprietary product.

As with proprietary or in-house developed software, ongoing modifications and enhancements will likely be necessary. One way to reduce these costs is to use standardized software across multiple jurisdictions. Implementers have learned to do this with their proprietary software by using strict version control. For open source software to be cost effective, a similar versioning control plan with some type of governing oversight needs to be considered.

Open source solutions could increase the availability of low-cost applications for public health purposes. As public health agencies take more sophisticated approaches to information management, strategies that encourage modular, configurable and reusable components become more viable.