



White Paper

Assure Health IT Standards for Public Health

Part II: A Roadmap on HIT Standardization for Public Health Laboratories

2012

Baltimore, Maryland

The **Public Health Data Standards Consortium** (PHDSC, The Consortium) is a national non-profit membership-based organization of federal, state and local health agencies, professional associations, academia, public and private sector organizations, international members, and individuals.

The Consortium is committed to bringing a common voice from the public health community to the national efforts of standardization of health information technology and population health data in order to improve individual and community health.

To fulfill its mission the Consortium:

Identifies priorities for new national standards for population health data;

Promotes integrating health-related information systems to meet the needs of public and private organizations, agencies and individuals;

Participates in national and international efforts to standardize health-related information;

Represents public health interests in standards development organizations, data content committees and standards harmonization entities; and

Educates the public health community about health information technology standards and the health information technology community about public health.



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The **Association of Public Health Laboratories** (APHL) is the national nonprofit representing governmental laboratories that protect the public's health by detecting and monitoring health threats. Members include state, territorial and local public health labs; state environmental testing labs; state agricultural and food safety labs; and individual scientists, public health officials and academicians.

APHL's mission is to promote the role of public health laboratories in shaping national and global health objectives, and to promote policies, programs, and technologies which assure continuous improvement in the quality of laboratory practice and health outcomes.

To fulfill its mission, APHL's focuses on the following areas:

Workforce: Advance the training, leadership development, recruitment & retention of a competent workforce to meet the needs of the public health laboratory system;

Advocacy and Outreach: Enhance the visibility, status & influence of the public health laboratory community through effective advocacy, strategic communications & public relations;

Networking and Community Building: Act as a focal point for the collection and dissemination of information throughout the public health community and to external partners;

Informatics: Improve the informatics capabilities of APHL & its members; and

Laboratory Science, Standards and Practices: Advance the development, use, and evaluation of technologies, quality systems and practices



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Executive Summary

Public Health Laboratories (PHLs) provide specialized testing for clinical care, surveillance and surge capacity during disasters. “Laboratories are key stakeholders in providing critical data to local, state, tribal and federal public health agencies to investigate individual cases of communicable and chronic diseases as well as to characterize and mitigate population-based public health threats.”¹

Health information technology (HIT) standards are the key to enabling electronic information exchanges (i.e., interoperability) between senders and receivers of laboratory information. A survey conducted by the Association of Public Health Laboratories (APHL) revealed tremendous variability, despite of the efforts for implementation of messaging standards at the partner labs,² which rendered data sharing almost impossible, without additional effort to agree on a standard representation of the data across the laboratories. On the national level several efforts are under way to improve data exchange capabilities with a focus on the clinical domain. Integration of that domain with the work of public health laboratories needs to be improved upon.

The Public Health Data Standards Consortium (PHDSC) and APHL partnered (1) to document and analyze the state of HIT standards available for laboratory practices and in use in information exchanges to date; and (2) to develop an implementation strategy (a Roadmap) for HIT standardization of laboratory data exchanges to support public health laboratory business practices, their integration with clinical partners and preparedness activities.

The outcomes of these efforts are presented in this White Paper “*Assure HIT Standards for Public Health*” that includes two documents as follows:

Part 1: HIT Standards in Public Health Laboratory Domain – an overview of HIT standards and their implementation efforts by public health laboratories and national organizations to date, i.e., *Where Are We Now*, and

Part 2: A Roadmap on HIT Standardization for Public Health Laboratories – a proposed implementation strategy and a roadmap to improve laboratory information management systems (LIMS) interoperability with all its partners and suggestions for future PHDSC-APHL projects, i.e., *Where Are We Going*.

Part 1 of the White Paper serves as an informational resource about HIT standards available for PHL data exchanges focused on testing of mostly human samples. Part 2 describes activities with various HIT standardization entities related to the laboratory HIT standards based on the respective phase of HIT standardization in question. The proposed PHDSC-APHL HIT standards implementation strategy and near future (2012-2013) roadmap for PHLs are focused on addressing incomplete and inconsistent adoption of the existing standards and absence of a sustainable approach for standardization of information systems in public health by **operationalizing** HIT standards that already exist for laboratory information exchanges and developing new standards that meet PHL business needs.

¹ Zarcone P, Nordenberg D, Meigs M, Merrick U, Jernigan D, Hinrichs SH. Community-Driven Standards-Based Electronic Laboratory Data-Sharing Networks. Public Health Reports. 2010. Suppl 2; Vol. 125: 47-56. URL: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2846802/>

² Public Health Data Standards Consortium (PHDSC). Business Case: The Role of Public Health in National HIT Standardization. URL: http://www.phdsc.org/standards/business_case.asp

The White Paper is targeted to the following three audiences:

- 1 – *Leadership* - public health leadership and decision-makers at the local, state and federal levels; national HIT leaders; and leadership of State Health Information Exchanges (HIEs) including State Chief Information Officers (CIOs). The goal is to communicate to them the challenges and possible solutions for enabling adoption of interoperable HIT solutions for public health laboratory data exchanges
- 2 – *Health professionals involved in laboratory data exchanges* – directors and staff of public health laboratories, directors and staff at partner organizations of the public health laboratory such as providers, public health preparedness programs and other programs involved in laboratory data exchanges at the local, state and federal levels to engage them in HIT standardization activities (standards development, harmonization and testing; standard-based products certification; and selection of standard-based HIT products for their agencies/programs)
- 3 – *IT professionals involved in HIT standardization* – vendors of electronic health record systems (EHR-S), laboratory information systems (LIS) and LIMS products involved in HIT standardization activities (standards development, harmonization and testing; and standard-based products certification and deployment) to address business needs of public health laboratories and programs in HIT standards to support laboratory health information exchanges.

This document represents *Part 2: A Roadmap on HIT Standardization for Public Health Laboratories* of the White Paper *Assure HIT Standards for Public Health*.

Section

1

Introduction

In 2006, members of the APHL Informatics Committee reviewed the need for and obstacles to building national interoperability of information systems in healthcare and public health.³ With regards to HIT standards they identified the need to:

- harmonize the adoption of technical interoperability standards to support PHL electronic data exchange
- share best practices in the adoption of LIMSs
- work more effectively with HIT vendors of public health LIMS products and
- increase the effectiveness of identifying and propagating the adoption of new methodologies and technologies, including HIT standards-based information management technologies.

The PHDSC and APHL analysis of use of HIT standards by PHLs identified the following barriers to effective electronic laboratory information exchange (not in the order of priority):

Barrier I - The incomplete and inconsistent adoption of existing standards by the wide array of laboratories responsible for reporting laboratory results as well as by the EHR-S and the public health information systems they report to.

Barrier II - The lack of adoption of EHR-S⁴ in clinical settings (i.e., test order senders and result receivers) preventing electronic communication between providers and LIMS.

Barrier III - The use of proprietary, non-standardized information systems in public health preventing electronic communication between LIMS and public health programs (i.e., receivers of test results on public health threat conditions).

Barrier IV - The absence of a sustainable approach and funding to support the development of laboratory standards and their testing; and of certification and adoption of standards-based IT products in clinical, laboratory and public health settings.

Barrier V – The need for informatics-savvy personnel in PHLs to operate in a new HIT and information communication environment

Part 2 of the White Paper is focused to address Barrier I (incomplete and inconsistent adoption of existing standards), Barrier III (use of proprietary, non-standardized information systems), and Barrier IV (absence of a sustainable approach for standardization) by **operationalizing** HIT standards that already exist (see Part 1 of the White Paper) for laboratory information exchanges. The proposed PHDSC-APHL HIT standards implementation strategy and 2012-2013 roadmap for PHLs are focused on addressing incomplete and inconsistent adoption of the existing standards and the absence of a sustainable approach for standardization of information systems in public health. Sections that follow describe (1) activities of various HIT standardization entities on multiple standardization phases related to the laboratory HIT standards; (2) the role that PHDSC and APHL could play to assure the development and deployment of interoperability standards for PHLs; and (3) the 2012-2013 Roadmap on HIT standardization for PHLs.

³Zarcone P, Nordenberg D, Meigs M, Merrick U, Jernigan D, Hinrichs SH. Community-Driven Standards-Based Electronic Laboratory Data-Sharing Networks. Public Health Reports. 2010. Suppl 2; Vol. 125: 47-56. URL: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2846802/>.

⁴Office of National Coordinator for Health IT. DHHS, Health IT Adoption. URL: http://healthit.hhs.gov/portal/server.pt?open=512&objID=1152&parentname=CommunityPage&parentid=28&mode=2&in_hi_userid=11113&cached=true

**Section
2**

The PHDSC HIT Standards Implementation Strategy – Operationalizing HIT Standards for Public Health Laboratories

By **operationalizing** HIT standards for a particular public health domain (program) we mean:

1. **Use existing standards** to develop interoperability specifications (implementation guides, integration profiles, content profiles) or to enhance existing interoperability specifications at the national and international standards harmonization initiatives, e.g., Integrating the Healthcare Enterprise (IHE),⁵ Office of National Coordinator for Health IT (ONC) Standards and Interoperability (S&I) Framework Initiatives,⁶ and others
2. **Test** these specifications at the IHE Connectathon and demonstrate interoperability solutions at the national and international forums
3. **Develop certification criteria** for standards-based HIT solutions and enable certification of public health information systems
4. **Provide technical assistance** to support deployment of standards-based HIT solutions and
5. **Evaluate the effectiveness** of standards-based HIT solutions.

If the need for a new standard is identified, we will work with domain experts and the standards development organizations to develop this standard.

Operationalizing HIT standards for PHLs contributes to the overall PHDSC effort to build a **Coordinated Voice of Public Health on HIT Standards**. Building this **Voice** is the focus in the PHDSC methodology outlined in the *PHDSC Business Case: Role of Public Health in HIT Standardization*,⁷ so that data collected at the point of care can be used and re-used across public health programs (domains) at all levels of government. Of importance in this work is the immediate engagement of all stakeholders in all HIT standardization phases (from the need analysis stage all the way through the deployment stage) via participation in the national standardization entities (**Table 1**).

Outreach through professional organizations of all stakeholders is critical as is the participation of the right subject matter experts for each standardization phase -- needs assessment, definition of the functional requirements and the information exchange content, development and testing standards and so on having access to the laboratory expertise is essential. It is just as important to have a good understanding of the technical expertise and abilities at each stakeholder for the implementation to be successful. Being able to provide standards knowledge as well as the tools that can help facilitate implementations as part of the technical assistance team is key to successful deployment beyond just the early adopters and IT savvy partners.

⁵ Integrating the Healthcare Enterprise. URL: <http://www.ihe.net>

⁶ Office of National Coordinator for Health IT (ONC). Standards & Interoperability Framework. URL:

http://healthit.hhs.gov/portal/server.pt?CommunityID=1206&spaceID=399&parentname=&control=SetCommunity&parentid=&PageID=0&space=CommunityPage&in_hi_totalgroups=1&in_hi_req_ddfolder=6652&in_ra_topoperator=or&in_hi_depth_1=0&in_hi_req_page=20&control=advancedstart&in_hi_req_obitype=18&in_hi_req_obitype=512&in_hi_req_obitype=514&in_hi_req_apps=1&in_hi_revealed_1=0&in_hi_userid=8969&in_hi_groupoperator_1=or&in_hi_model_mode=browse&cached=false&in_ra_groupoperator_1=or&in_tx_fulltext=S%26I+Framework

⁷ Public Health Data Standards Consortium (PHDSC). Business Case: The Role of Public Health in National HIT Standardization. URL: http://www.phdsc.org/standards/business_case.asp

The PHDSC implements this methodology by working with representatives from a particular domain (domain experts, public health professional association(s)) on various phases of HIT standardization by participating in various HIT standardization entities (**Table 1**).

Table 1. HIT Standardization Phases and Entities

<u>HIT Standardization Phase (Products)</u>	<u>HIT Standardization Entity Examples</u>
I - Identify HIT Interoperability Needs and Priorities (<i>Business Cases, Use Cases</i>)	HIT Policy Committee ⁸ and HIT Standards Committee ⁹ <i>Formerly American Health Information Community (AHIC)</i> ¹⁰
II - Develop and Maintain Standards (<i>Standard Specifications</i>)	HL7, ¹¹ IHTSDO, former SNOMED, ¹² LOINC, ¹³ ASC X12, ¹⁴ ISO TC 215 ¹⁵
III -Select and Harmonize Standards (<i>Functional Requirements Assessment; Standards Gap Identification & Harmonization; Dataset & Value Set Development; Interoperability Specification Development</i>)	IHE, ONC S&I Framework Initiatives, <i>Formerly Health Information Technology Standards Panel (HITSP)</i> ¹⁶
IV -Test Standards Interoperability (<i>Software Instantiation, Conformance Testing</i>)	IHE, National Institute of Standards (NIST), ¹⁷ Public Health Information Network (PHIN) ¹⁸
V - Certify Standards-Based Products (<i>Compliance Testing</i>)	ONC Authorized Testing and Certifying Bodies (ATCB), ¹⁹ PHIN
VI- Deploy Certified HIT Products (<i>Deployment Reports</i>)	Future IHE-PHDSC Deployment Workshops

The PHDSC has been using outreach activities for engaging stakeholders and achieving collaboration in HIT standardization since 2005 by working with several public health domains (programs) at standardization entities (ASC X12, HITSP, HL7, IHE, ISO TC 215) as follows:

HITSP 2005-2009

- Biosurveillance
- Immunization
- Electronic Laboratory Reporting
- Public Health Case Reporting
- Newborn Screening

ASC X12, HL7, IHE, ISO 2009-2012

- Early Hearing Detection and Intervention (EHDI)
- Vital Records
- Electronic Laboratory Reporting
- Public Health Case Reporting
- Administrative Data Reporting

⁸ Health Information Technology Policy Committee. URL: http://healthit.hhs.gov/portal/server.pt?open=512&objID=1269&parentname=CommunityPage&parentid=0&mode=2&in_hi_userid=10741&cached=true

⁹ Health Information Technology Standards Committee. URL: http://healthit.hhs.gov/portal/server.pt?open=512&objID=1271&parentname=CommunityPage&parentid=4&mode=2&in_hi_userid=10741&cached=true

¹⁰ American Health Information Community (AHIC). URL: http://www.phdsc.org/health_info/american-health-info.asp

¹¹ Health Level Seven (HL7). URL: <http://www.hl7.org>

¹² International Health Terminology Standards Development Organization (IHTSDO), former SNOMED-Systematized Nomenclature of Medicine – Clinical Terminology. URL: <http://www.ihtsdo.org/snomed-ct>

¹³ Logical Observation Identifiers Names and Codes (LOINC). URL: <http://loinc.org/>

¹⁴ Accredited Standards Committee X12. URL: <http://www.x12.org>

¹⁵ International Organizations for Standardization (ISO). URL: http://www.iso.org/iso/iso_technical_committee.html?commid=54960

¹⁶ Health Information Technology Standards Panel (HITSP). URL: <http://www.hitsp.org>

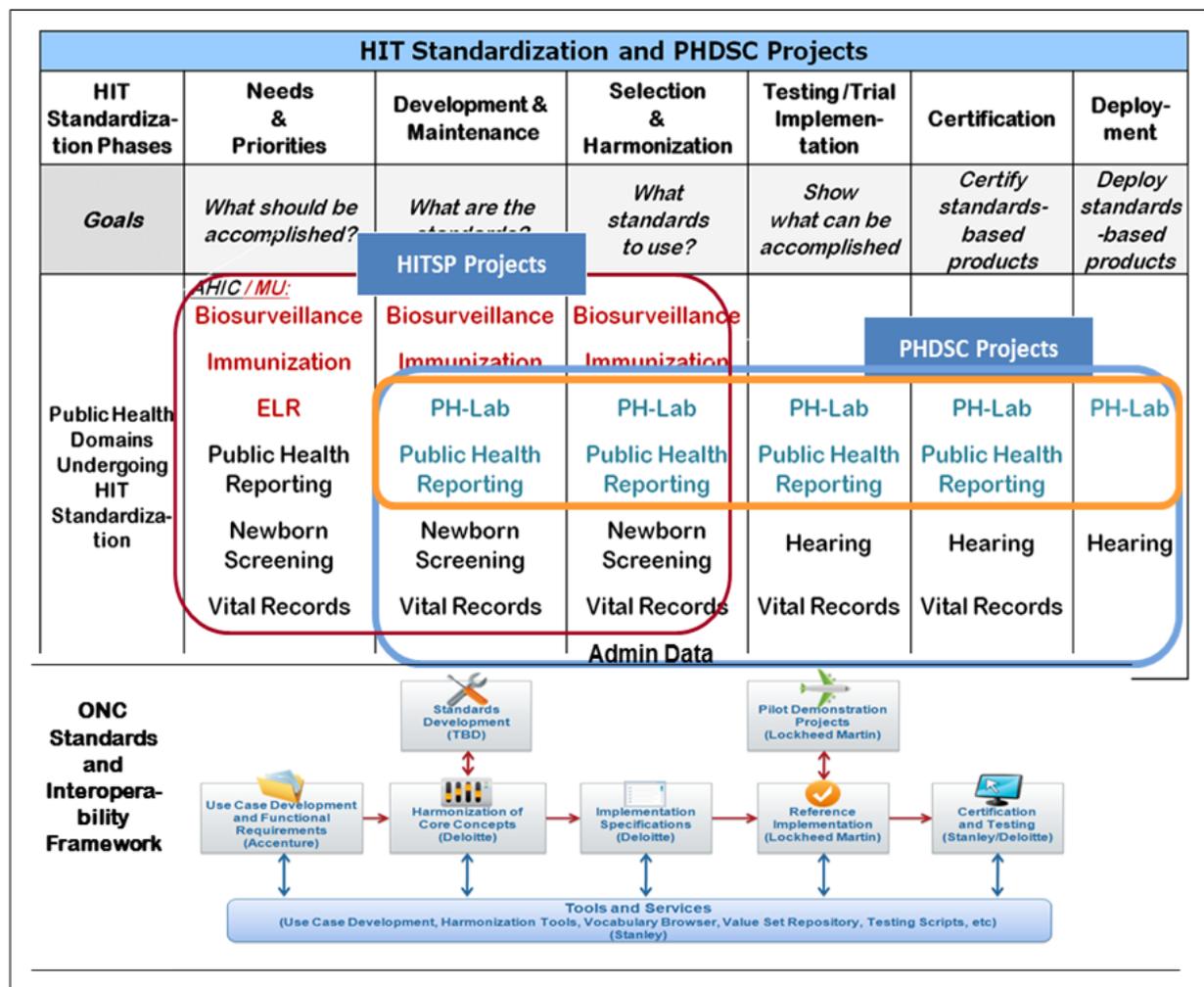
¹⁷ National Institute of Standards and Technology (NIST). URL: <http://www.nist.gov/index.html>

¹⁸ Centers for Disease Control and Prevention (CDC). Public Health Information Network (PHIN). URL: <http://www.cdc.gov/phn/index.html>

¹⁹ ONC-Authorized Testing and Certification Bodies (ATCB). URL: <http://healthit.hhs.gov/portal/server.pt?open=512&mode=2&objID=3120>

- Child Health (Vital Records)

Figure 1 depicts PHDSC efforts in relation to the national HIT standardization initiatives including the Standards and Interoperability Framework developed by the Office of National Coordinator for HIT.



- ♦ PHDSC Projects at the Health Information Technology Standards Panel (HITSP), 2005-2009. ELR – Electronic Laboratory Reporting.
- ♦ PHDSC Projects on HIT Standardization, 2008-2011
 - Early Hearing Detection and Intervention (EHDI)
 - Vital Records
 - Administrative Data reporting
- ♦ PHDSC Public Health Laboratory Project, 2011-2013

Figure. 1. PHDSC HIT Standardization Framework, On-going Projects and ONC S&I Framework

The PHDSC and APHL will collaborate to **operationalize** laboratory standards developed to date by the PHL community by enabling their validation through standards harmonization, testing and certification processes as it was done in the PHDSC projects for the other domains (EHDI, Vital Records and Administrative Data Reporting and Public Health Case Reporting).

After review of existing standards and current initiatives showcasing successful implementations of standards related to PHLs (see Part 1 of the White Paper) we summarized the steps needed to **operationalize** HIT standards in the PH Laboratory domain in **Table 2**. These steps further discussed in details in Section 3 below.

Table 2. Operationalizing HIT Standardizations for PHLs²⁰

Standardization Phase	Activities and Products	Entity (Examples)
Identify HIT Interoperability Needs and Priorities	After the review of business processes, use cases the functional requirements are described and compared to the existing standards. The subject matter expert need to be involved at this level to help identify any gaps in existing standards	HIT Policy Committee HIT Standards Committee ONC S&I Framework CDC and APHL Laboratory Initiatives Laboratory Community of Practice CSTE PHDSC
Develop and Maintain Standards	Based on the functional requirements identified the standard development organizations (SDOs) create new or alter existing standards to meet the identified needs	IHTSDO, former SNOMED, LOINC HL7 ASC X12 ISO
Select and Harmonize Standards	Based on the functional requirements identified these groups gather stakeholders for the respective use cases and review and select the best suited existing standards and provide feedback to the SDOs, if needed	IHE ONC S&I Framework Public Health Reporting Initiative ²¹
Test Standards	The selected standards are being pilot tested to demonstrate usability and provide feedback to the SDOs and standards selection entities	IHE NIST
Certify Standards-based HIT Product	Develop conformance criteria and enable HIT products to be tested and certified as being compliant with the selected standards to ensure a higher level of interoperability between partner systems	Authorized Testing and Certification Bodies. e.g., Certification Commissions for Health IT (CCHIT)
Deploy Standards-based HIT Product	Encourage and provide support for the widespread implementation of the selected, tested and certified standards	IHE PHDSC APHL
Outreach to Assure HIT Standardization for PHLs	Ensure that the users of the standards provide feedback and have a voice at all levels of the HIT development – at the development level, the selection level (both technical and political) and the certification level.	PHDSC APHL

²⁰ Public Health Data Standards Consortium (PHDSC). Assuring HIT Standard for Public Health. Public Health Case Reporting & Laboratory Data Exchanges (PH-Lab) for Preparedness. Project Wiki Pages. URL: <https://wiki.phdsc.org/index.php/PH-Lab>.

²¹ Office of the National Coordinator (ONC) Standards and Interoperability (S&I) Framework Public Health Reporting Initiative. URL: <http://wiki.siframework.org/Public+Health+Reporting+Initiative>

By engaging PHLs stakeholders in the national HIT standardization activities, this project will serve the business needs of public health laboratories, their clinical partners and other public health programs involved in these initiatives and leverage this key data source in a standardized way so that information can be quickly, reliably and economically shared, analyzed, and acted upon to improve clinical care, prevention, surveillance and management of communicable and

Section 3

PHDSC-APHL Partnership Activities on HIT Standardization of Public Health Laboratory Data Exchanges

chronic diseases.

Our approach is to execute PHDSC methodology described in Section 2 by working with APHL and other PHL stakeholders in various HIT standardization phases and entities to develop, harmonize, test HIT interoperability standards; and certify and deploy standards-based HIT products.

This section describes:

- *What* needs to be accomplished to **operationalize** existing HIT standards for public health laboratory data exchanges, highlighting PHDSC partnerships with APHL, and
- *How* to assure public health participation in the HIT standardization and desired outcomes.

WHAT – What needs to be accomplished?

We will **operationalize** existing HIT standards for public health laboratory data exchanges by working with APHL in several national and international initiatives on various phases of HIT standardization as follows:

- Needs and Priorities
- Standards Development
- Standards Harmonization
- Standards Testing
- Certification of Standards-based HIT products
- Deployment of Certified HIT Products.

Through specific activities under this project (**Table 3**), PHDSC will work with APHL and other PHL data exchange stakeholders to enable participation of representatives from PHLs in various HIT standardization entities such as HL7, IHE, ONC S&I Framework and others. PHDSC will also work with APHL to define strategies to increase PHL participation in HIT standardization to develop standards responsive to their needs as described in sections that follow.

Table 3. PHDSC-APHL Roadmap on PH-Lab HIT Standardization 2012-2013:
Specific Projects and Deliverables²²

Standardization Phase	Entity	Products (Project Deliverables)
Identify HIT Interoperability Needs and Priorities	Various CDC and APHL Laboratory Initiatives	<ol style="list-style-type: none"> White Paper: Assure Health IT Standards for Public Health: <i>Part 1: Review of HIT Standards Use in Public Health Laboratory Domain and</i> <i>Part 2: A Roadmap on HIT Standardization for Public Health Laboratories</i> User Story on Communicable Disease Reporting including Laboratory Orders/Result for the ONC S&I Framework Public Health Reporting Initiative
Develop and Maintain Standards	HL7 PHDSC	<ol style="list-style-type: none"> HL7 Public Health Reporting Requirements Standard Clinical Document Architecture (CDA) Templates for Laboratory Reports for selected conditions to be developed using Model Driven Health Tool (MDHT)²³
Select and Harmonize Standards	IHE ONC S&I Public Health Reporting Initiative	IHE Public Health Reporting Integration Profile
Test Standards	IHE HIMSS ²⁴	<ol style="list-style-type: none"> Testing laboratory reports exchanges at IHE Connectathon Demonstration of laboratory reports exchanges the HIMSS Interoperability Showcase
Certify Standards-based HIT Product	CCHIT ²⁵ PHIN	<ol style="list-style-type: none"> HL7 Public Health Functional Profile – Public Health Laboratory Extension Certification Criteria for Laboratory HIT Products Established Certification Process for Public Health Laboratory HIT Products at CCHIT and PHIN
Deploy Standards-based HIT Product	IHE PHDSC APHL	<ol style="list-style-type: none"> Methodology and instruments for conducting deployment workshops for public health laboratory stakeholders on technical assistance to deploy certified HIT products Participation in the design and development of the CDA for Public Health Pilot project in two states
Outreach to Assure HIT Standardization for PHLs	PHDSC APHL AHIMA	<ol style="list-style-type: none"> Representation of PHL interests at HL7, IHE, ONC S&I Framework Initiatives and ONC-ATCBs Strategies to increase PHL participation in HIT standardization to develop standards that are responsive to their needs A metric for assuring that PHL participation in HIT standardization produces the desired outcomes from enabling electronic information exchanges across PHL partners Work with the survey teams from APHL and CAP (American College of Pathologists) to add additional questions to their survey to collect data on the PHL participation in HIT standardization and the impact of this participation

²² Public Health Data Standards Consortium (PHDSC). Assuring HIT Standard for Public Health. Public Health Case Reporting & Laboratory Data Exchanges (PH-Lab) for Preparedness. Project Wiki Pages. URL: <https://wiki.phdsc.org/index.php/PH-Lab>

²³ Open Health Tools. Model-Driven Health Tool (MDHT). Release 1.0. URL: <https://mdht.projects.openhealthtools.org>

²⁴ Healthcare Information and Management Systems Society (HIMSS). URL: <http://www.himss.org>

²⁵ Certification Commission for Health Information Technology (CCHIT). URL: <http://www.cchit.org>

Advocate for PHL in National Needs and Priorities for Standards

National health information exchange priorities²⁶ are defined by the Federal Advisory Committees. These committees established under the Federal Advisory Committees Act (FACA), provide advice on health IT issues to the National Coordinator for Health Information Technology.

The Health Information Technology Policy Committee (**HIT Policy Committee**) was established by the Department of Health and Human Services (HHS) under the American Recovery and Reinvestment Act (ARRA) of 2009. The HIT Policy Committee makes recommendations to the HHS National Coordinator for Health Information Technology on a policy framework for the development and adoption of a nationwide health information infrastructure.

The Health Information Technology Standards Committee (**HIT Standards Committee**) also established by the HHS under ARRA of 2009 makes recommendations to the HHS National Coordinator for Health Information Technology on HIT standards, implementation specifications, and certification criteria for the electronic exchange and use of health information. The HIT Policy and Standards Committees contributed to establishing the Meaningful Use of HIT regulation²⁷ that specified objectives for EHR-S adoption in 2011-2016 (**Figure 2**).²⁸

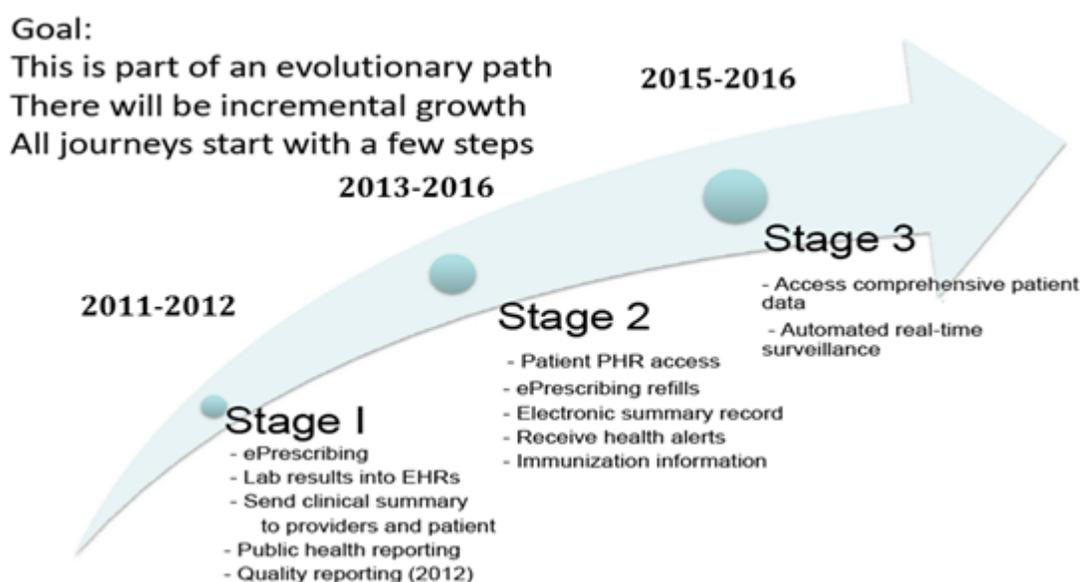


Figure 2. EHR-S Adoption in Meaningful Use of HIT

Laboratory result submission to EHR-Ss and the “capability to submit **electronic data on reportable** (as required by state or local law) **lab results** to public health agencies and actual submission in accordance with applicable law and practice” are included in the MU Stage 1 objectives (**Figure 2**).

²⁶ Public Health Data Standards Consortium (PHDSC). Public Health in HIT Standardization Resource Center. Health Information Exchange Priorities. URL: http://phdsc.org/standards/health-information/HIE_Priorities.asp

²⁷ Meaningful Use Stage 1 Final Rule; Federal Registrar. URL: <http://edocket.access.gpo.gov/2010/pdf/E9-31217.pdf>

²⁸ W. Suarez, et.al. Review of CMS Meaningful Use NPRM and ONC Standards and Certification IFR: Implications for Public Health. Presentation at JPHIT-PHDSC Webinar, February 4, 2010.

During 2005-2009 the **American Health Information Community (AHIC)**²⁹ - a federally-chartered advisory body - served in the capacity of the HIT Policy & Standards Committees to advance efforts on the development of a Nationwide Health Information Network. AHIC has defined priority areas (breakthroughs) and developed National Use Cases³⁰ (**Figure 3**).

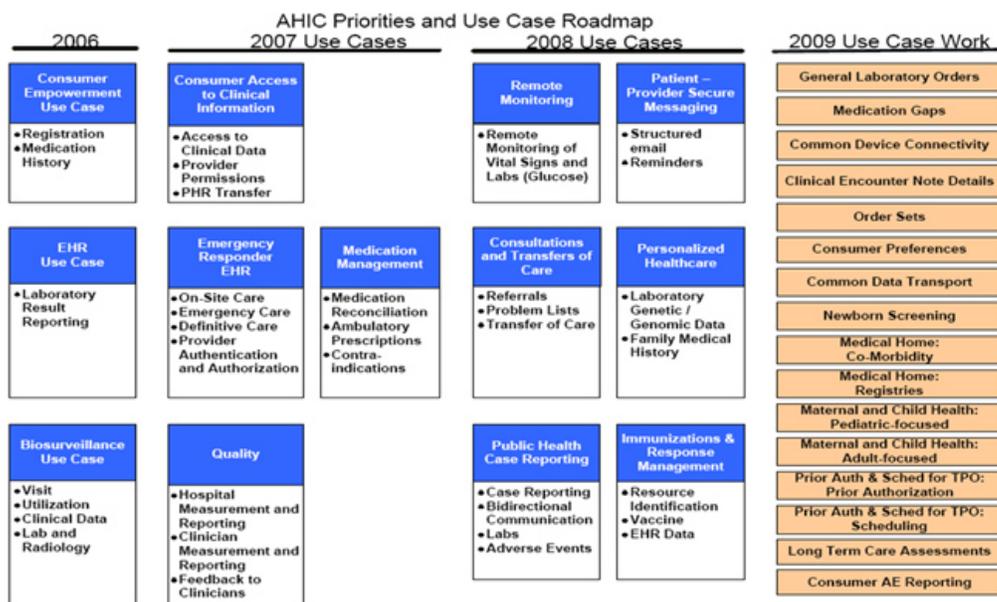


Figure 3. AHIC Priorities and Use Case Roadmap, 2006-2009

In the AHIC Use Cases laboratory orders submission from EHR-S to LIMS were addressed in Biosurveillance, 2006 and Newborn Screening, 2009; laboratory results reporting was addressed in the Laboratory Results Reporting to EHR, 2006 and Public Health Case Reporting, 2008.

PHDSC-APHL Partnership Activities
PHDSC will support APHL in its advocacy efforts to assure that PHLs needs for HIT standardization are included in the national HIT agenda.
The Public Health Reporting Initiative ³¹ is under development to define the scope for a potential public health initiative at the ONC S&I Framework based on the needs of the public health community. This Initiative is aimed at developing a unified approach for integrating siloed public health information systems using harmonized HIT standards. The Initiative will entail harmonization of business processes, functional requirements for information systems, data needs and HIT standards across public health programs to inform the development of interoperable standards-based HIT solutions.
In 2011-2012, the Initiative will focus on the <u>Initial Public Health Report Use Case</u> with multiple User Stories under the following public health domains (programs): <ul style="list-style-type: none"> • Child Health

²⁹ American Health Information Community (AHIC). URL: <http://www.hhs.gov/healthit/community/background/>

³⁰ American Health Information Community (AHIC). AHIC Use Cases and Extensions/Gaps. URL: <http://www.hhs.gov/healthit/usecases/>

³¹ Office of National Coordinator for Health IT (ONC). Standards & Interoperability Framework. Public Health Reporting Initiative. URL <http://wiki.siframework.org/Public+Health+Reporting+Initiative>

- Communicable Diseases
- Chronic Diseases
- Adverse Event Reporting and Other

The PHDSC-APHL team developed a User Story that describe laboratory orders/result data exchanges under these domains (programs) and will further work on developing the implementation guide to support this User Story (**Table 3**).

Participate in Standards Development

Standards development,³² according to the International Organization of Standardization (ISO),³³ is conducted according to the following three principles:

- **Consensus** - the interests of all stakeholders are taken into account: manufacturers, users, vendors, consumer groups, testing laboratories, governments, engineering professions and research organizations
- **Industry wide** - standards solutions have to satisfy industries and customers worldwide
- **Voluntary** - international standardization is market driven and therefore based on voluntary involvement of all stakeholders in the market-place.

HIT standards are developed and maintained by Standards Development Organizations, Data Content Committees, Standards Setting Organizations, and Designated Standard Maintenance Organizations as follows:

- **Standards Development Organizations (SDOs)** are entities that develop, coordinate, promulgate, revise, amend, reissue, interpret, or otherwise maintain standards that address the interests of users outside the SDO. In the United States there are several hundred SDOs that are coordinated by the central National Standards Body (NSB) – the American National Standards Institute (ANSI).³⁴ SDOs accredited by ANSI develop standards using open and transparent processes.
- **Data Content Committees (DCCs) and Standards Setting Organizations (SSOs)**³⁵ are industry consortia or community-driven associations formed to expedite the standard development process or to develop standards for particular software solutions.
- **Designated Standard Maintenance Organizations (DSMOs)**³⁶ are entities designated by the DHHS Secretary to maintain the national standards adopted by the Secretary under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

³² Public Health Data Standards Consortium (PHDSC). Public Health in HIT Standardization Resource Center. HIT Standards. URL: http://phdsc.org/standards/health-information/S_Development.asp

³³ International Organization of Standardization (ISO). URL: http://www.iso.org/iso/standards_development.htm

³⁴ American National Standards Institute (ANSI). URL: <http://www.ansi.org/>

³⁵ Public Health Data Standards Consortium (PHDSC). Public Health in HIT Standardization Resource Center. HIT Standards. DCC. URL: http://phdsc.org/standards/health-information/D_Standards.asp#List of Organizations

³⁶ Health Insurance Portability and Accountability Act (HIPAA). Designated Standard Maintenance Organizations (DSMOs). 1996. URL: <http://www.hipaa-dsmo.org/>

PHDSC-APHL Partnership Activities

If the need for a new standard is identified we will work with APHL subject matter experts and the standards development organizations to develop this standard.

In this project the PHDSC-APHL team will develop a new **HL7 Public Health Reporting Requirements Standard**. This standard will be based on the HL7 Healthcare Quality Measure Framework (HQMF) standard. Originally defined to support the specification of quality measures (eMeasures), the standards will also support the expression of public health reporting requirements. As a structured document specification, this will allow for both a human readable expression as well as a machine-readable expression of the jurisdiction-specific reporting requirements. This standard will support the capability of a system to consume the requirements, and process those requirements against CDA-expressed content. It will determine whether a report should be made to public health, what to report, to whom to send the report, how to report, and when to report. We anticipate balloting the new standard in August 2012 (**Table 3**).

Using the **Model Driven Health Tool (MDHT)** the PHDSC-APHL team will develop CDA R2 Templates for Laboratory Reports for selected conditions including *Anthrax*, *Tularemia*, *Hepatitis-B*, *Tuberculosis* and *Influenza*. We will use the input from the CDC RCMT project on LOINC/SNOMED data mapping for notifiable conditions and APHL PHLIP project data definitions for *Influenza* to define a CDA R2 Content for these conditions (**Table 3**).

Participate in Standards Harmonization

Standards harmonization³⁷ is a process to ensure applicability of various standards for a Use Case that describes the use of a software application. Standards harmonization includes the following steps:

- Use Case development
- Use Case's functional requirements analysis
- Identification of candidate standards
- Resolution of standards gaps, duplications and overlaps through the work with the standards development organizations
- Standards selection
- Construction of the Use Case's Implementation Guide (Interoperability Specification)
- Implementation Guide's inspection test
- Interoperability Specification release and dissemination.

In the United States, HIT standards harmonization activities have been carried out by several organizations described below.

³⁷ Public Health Data Standards Consortium (PHDSC). Public Health in HIT Standardization Resource Center. Standards Harmonization. URL: http://www.phdsc.org/standards/health-information/S_Harmonization.asp

In 2005-2009, **Health Information Technology Standards Panel**³⁸ was established as a cooperative partnership between the public and private sectors to achieve a broadly accepted set of standards to enable widespread interoperability among healthcare software applications, as they will interact in local and regional health information exchanges and in the Nationwide Health Information Network. The Panel's purpose was to:

- Harmonize and integrate diverse standards that will meet clinical and business needs for sharing information among organizations and systems
- Establish HITSP interoperability specifications and promote their acceptance
- Support the implementation of HITSP interoperability specifications across the health care enterprise and
- Facilitate the efforts of standards development organizations to maintain, revise, or develop new standards as required to support the HITSP Interoperability specifications

Supported by the contract from ONC to ANSI, HITSP develops interoperability specifications for the AHIC National Use Cases (**Figure 3**). Both HITSP methodology and interoperability specifications are widely used to enable standards-based information exchanges at the ONC S&I Framework initiatives and IHE.

In 2007 PHDSC has been invited by IHE to start a Public Health Domain at IHE that resulted in formation of the **IHE Quality, Research and Public Health Committee**.³⁹ PHDSC and IHE are collaborating to enable interoperability across clinical and public health enterprises. This includes the development of interoperability standards (Integration Profiles and Content Profiles) for information systems in several public health domains (programs) including *child health (newborn screening, immunization, vital records), chronic diseases (diabetes, cancer), and laboratory*; and work on information infrastructure issues such as *service-oriented architecture (SOA) for public health*. PHDSC member organizations, APHL, American Immunization Registry Association (AIRA), North-American Association of Central Cancer Registries (NAACCR), Software Partners, OZ Systems, Atlas Public Health, Scientific Technology Corporation and Greenway Medical Technology have been working on various public health projects at IHE.

ONC Standards and Interoperability (S&I) Framework⁴⁰ was launched on January 7th, 2011 as a forum to collaborate on interoperability challenges critical to meeting Meaningful Use objectives for 2011. The ONC S&I Framework initiatives utilize the standard harmonization process established by HITSP. The 2011 S&I Framework Initiatives include *Certificate Interoperability (CI) Initiative; Data Segmentation Initiative; Lab Results Interface (LRI) Initiative; Laboratory Orders Initiative; Provider Directories Initiative; Transitions of Care (ToC) Initiative; Query Health Initiative; esMD Initiative and others*.

The **ONC Standards & Interoperability Framework Lab Results Interface (LRI) Initiative**⁴¹ was created to support the Meaningful Use objective to send laboratory data to ordering

³⁸ Health Information Technology Standards Panel. URL: <http://www.hitsp.org>

³⁹ Integrating the Healthcare Enterprise (IHE). Quality Research and Public Health Committee. URL: http://www.ihe.net/Technical_Framework/index.cfm#quality

⁴⁰ Office of the National Coordinator (ONC) Standards and Interoperability (S&I) Framework Public Health Reporting Initiative. URL: <http://wiki.siframework.org/>

⁴¹ Office of National Coordinator for Health IT (ONC). Standards & Interoperability Framework. Lab Results Interface (LRI) Initiative. URL: <http://wiki.siframework.org/Lab+Results+Interface+%28LRI%29+Initiative>

providers. The LRI Initiative is focused on harmonizing two standard specifications for ambulatory laboratory reporting, neither of which are adopted universally across the industry. The cost and time to initiate new electronic laboratory results interfaces hampers broad adoption of such interfaces. The field by field details of HL7 v2 implementation guides used by clinical laboratories and EHR-Ss vary, creating a need for mapping or configuration per interface. The prevalence of core subsets of LOINC codes for common tests and analytes also varies, causing downstream issues in decision support and quality reporting. The LRI Initiative developed the *Laboratory Results Interface Initiative Implementation Guide* based on the HL7 version 2.5.1 message-based standard that will be recommended as an information exchange standard for laboratory data under Meaningful Use.

The Public Health Laboratory Results Workgroup⁴² was created under the LRI Initiative to ensure that the LRI Implementation Guide does not contradict the current MU stage 1 standard for reporting lab results to Public Health Agencies. A strategy for harmonization in the long-term has been discussed in that group, but could not be included in the first release of the LRI guide.

The Public Health Reporting Initiative⁴³ described above is the public health community-led activity at ONC that focuses on standards harmonization process for public health. In 2012 the Initiative's participants will develop the Implementation Guide for the *Initial Public Health Report Use Case* that will specify HIT standards for laboratory test order/test result data exchanges between EHR-S, LIMSs and PH-ISs.

While most of these initiatives are focused on the laboratory functions revolving around testing of human samples, PHLs work is more varied than that and includes testing of non-human samples – specifically animal and environmental samples like soil, water, food, medical devices etc. APHL is working on a toolkit document aimed at the PHL leadership that will expand on the standards described in part 1 of this paper, especially as they pertain to the testing of non-human samples.

PHDSC-APHL Partnership Activities
<p>The PHDSC and APHL team will work on representing PHL interests in the national HIT standards harmonization activities as follows.</p> <p><u>Working with IHE</u> The PHDSC-APHL team will harmonize the workflow and data requirements for data exchanges for the selected conditions (<i>Anthrax, Tularemia, Hepatitis-B, Tuberculosis and Influenza</i>) with the IHE Laboratory Technical Framework⁴⁴ profiles including the Sharing Laboratory Reports (XD-Lab) Integration Profile.</p> <p>Using the Laboratory domain as an example the PHDSC-APHL team will develop the IHE Public Health Reporting Integration Profile that will serve as an overarching HIT Standardization Framework for Public Health (Table 3).</p> <p><u>Working with ONC S&I Public Health Reporting Initiative</u> The PHDSC-APHL team will participate in the development of the Implementation</p>

⁴² Office of National Coordinator for Health IT (ONC). Standards & Interoperability Framework. Lab Results Interface (LRI) Initiative. Public Health Laboratory Results Workgroup. URL:<http://wiki.siframework.org/LRI+Public+Health+Lab+Results+WG>

⁴³ Office of National Coordinator for Health IT (ONC). Standards & Interoperability Framework. Public Health Reporting Initiative. URL <http://wiki.siframework.org/Public+Health+Reporting+Initiative>

⁴⁴ Integrating the Healthcare Enterprise (IHE). Laboratory Committee. URL: http://www.ihe.net/Technical_Framework/index.cfm#laboratory

Guide for the *Initial Public Health Report Use Case* to specify HIT standards for laboratory test order/test result data exchanges between EHR-S, LIMSs and PH-ISs (**Table 3**).

Participate in Standards Testing

Standards testing (reference implementation)⁴⁵ is a process of demonstrating the use of standards in an information technology application.

IHE Connectathon⁴⁶ is the HIT industry's largest interoperability testing event. The initial IHE Connectathon was held in 1999. The North American Connectathon has been held annually ever since and has grown steadily in the level and scope of participation. In 2012 more than 100 leading HIT companies and research organizations will participate to test more than 180 HIT systems for interoperability and compliance with IHE Profiles. This represents an increase of more than 20% over the 2011 event and indicates both the growing recognition in the HIT community of the need for standards-based interoperability and the growing embrace of IHE profiles as a practical means of attaining this goal.

The 2012 Connectathon will test HIT systems from across the spectrum of care. Profiles from eight of the 13 clinical and operational domains represented in IHE will be tested at the event including Anatomic Pathology, Cardiology, IT Infrastructure, Laboratory, Patient Care Coordination, Patient Care Device, Quality, Research and Public Health and Radiology. Separate annual Connectathon events are conducted in the Eye Care and Radiation Oncology domains. A parallel event in Europe was established in 2001 and has followed a similar trajectory. The next IHE Europe Connectathon will be held May 21-25, 2012 in Bern, Switzerland. Connectathons have also been held in Australia, China, Japan and Korea.

A technical project management team develops detailed test plans for each role (actor) being tested at the Connectathon and organizes the process to maximize interoperability testing between corresponding systems from different vendors. The team uses a suite of test tools for thousands of transactions among Connectathon participants, to monitor and record test results and simulate the functions of corresponding systems to enable rapid testing and debugging. Independent monitors observe and record test results, which are published in the Connectathon results database (<http://connectathon-results.ihe.net/>).

The **HIMSS Interoperability Showcase**⁴⁷ follows the IHE Connectathon to demonstrate to the healthcare community available HIT products that support systems interoperability. Organized in collaboration with IHE, the Interoperability Showcase exhibit provides a full landscape of health IT solutions, live demonstrations of interoperability, and educational opportunities that connect thousands of HIT end-users and buyers.

⁴⁵ Public Health Data Standards Consortium (PHDSC). Public Health in HIT Standardization Resource Center. Implementation of Standards-based Specifications. URL: http://www.phdsc.org/standards/health-information/ISB_Specifcions.asp

⁴⁶ Integrating the Healthcare Enterprise (IHE). Connectathon. URL: http://www.ihe.net/News/connectathon_2012_na_registration.cfm

⁴⁷ Health Information management and Systems Society (HIMSS) Interoperability Showcase. URL: <http://www.himssconference.org/exhibition/interop.aspx>

In 2005 PHDSC participated in the 1st HIMSS Interoperability Showcase demonstrating interoperability solutions for child health domains (programs).⁴⁸ In 2011 PHDSC and its members returned to the HIMSS Interoperability Showcase demonstrating HIT solutions based on the IHE Profiles for vital records, newborn hearing screening and immunization.

PHDSC-APHL Partnership Activities
<p>The PHDSC and APHL team will work on testing HIT interoperability standards for laboratory data exchanges as follows.</p> <p><u>Participate in the IHE Connectathon</u> In 2012 the PHDSC-APHL team will work with LIMS vendors to test CDA templates for laboratory reports developed for the selected conditions (<i>Anthrax, Tularemia, Hepatitis-B, Tuberculosis and Influenza</i>) in the Sharing Laboratory Reports (XD-Lab) Integration Profile of the IHE Laboratory Technical Framework.⁴⁹ This testing may be held at the North American IHE Connectathon in January 2012 and/or European IHE Connectathon in May 2012 (Table 3).</p> <p><u>Participate in the HIMSS Interoperability Showcase</u> The PHDSC-APHL team will work with HIT vendors to demonstrate interoperability solutions for exchanging CDA laboratory reports for the selected conditions at the HIMSS Interoperability Showcase in February 2012 (Table 3).</p>

Participate in Certification of Standards-based Products

The Office of the National Coordinator has named the FACA HIT Policy and the HIT Standards Committees as the organizations that survey the landscape and offer recommendations for types of systems that ought to be certified.⁵⁰ The ONC often accepts these recommendations and then instructs National Institute of Standards and Technology (NIST)⁵¹ to develop test scripts accordingly. NIST then develops and offers those scripts to the **Authorized Testing and Certifying Bodies (ATCBs)**. The ONC-ATCBs are required to test and certify EHRs to the applicable certification criteria adopted by the Secretary under subpart C of Part 170 Part II and Part III as stipulated in the Standards and Certification Criteria Final Rule.⁵² This ensures that an EHR technology has the capabilities to meet the goals and objectives of Meaningful Use regulation.

The following organizations have been selected as ONC- ATCBs to perform Complete EHR and/or EHR Module testing and certification:

- ICSA Labs - Mechanicsburg, PA
- SLI Global Solutions - Denver, CO

⁴⁸ Orlova AO, Dunnagan M, Finitzo T, Higgins M, Watkins T, Tien A, Beales S. An Electronic Health Record-Public Health (EHR-PH) System Prototype for Interoperability in 21st Century Healthcare Systems. Am Med Inform Assoc. (AMIA), Annual Symposium, Proc., 2005: 575-579.

⁴⁹ Integrating the Healthcare Enterprise (IHE). Laboratory Committee. URL: http://www.ihe.net/Technical_Framework/index.cfm#laboratory

⁵⁰ Public Health Data Standards Consortium (PHDSC). Public Health in HIT Standardization Resource Center. Certification of Standards-based HIT Products. URL: http://www.phdsc.org/standards/health-information/CSBHIT_Products.asp

⁵¹ National Institute of Standards and Technology (NIST). URL: <http://www.nist.gov/index.html>

⁵² Office of National Coordinator for HIT (ONC). Standards & Certification Criteria Final Rule. URL:

http://healthit.hhs.gov/portal/server.pt?open=512&objID=1195&parentname=CommunityPage&parentid=97&mode=2&in_hi_userid=11673&cached=true

- InfoGard Laboratories, Inc. – San Luis Obispo, CA
- Certification Commission for Health Information Technology (CCHIT) - Chicago, IL
- Drummond Group, Inc. (DGI) - Austin, TX and
- Surescripts LLC - Arlington, VA

Scope of authorization: EHR Modules: E-Prescribing, Privacy and Security.

Based on the NIST test scripts, the ATCBs developed testing and certification programs to certify EHR-S vendors capabilities in support of MU Stage 1.

Some ATCBs offer “additional” testing and certification services (for testing and certifying systems beyond the MU list). These ATCBs are interested in receiving documentation by which they can develop certification scripts for systems that have not yet been identified by ONC as targets for certification.

The **HL7 Public Health Functional Profile (PHFP)** project of the PHDSC, CDC NCHS and the public health community at large⁵³ (described above under the Functional Standards section) defines a set of functional requirements of the HL7 EHR-S Functional Model for information exchanges with public health programs’ information systems including Vital Records, Early Hearing Detection and Intervention (EHDI), Birth Defects, Cancer, NCHS National Surveys, Public Health Laboratories, Birth Defects and Occupational Health.

Based on the approach developed by the HL7 Child Health Workgroup using its Child Health Functional Profile for certifying EHR-S for pediatric care at the Certification Commission for HIT - CCHIT -, the PHFP will be used for developing certification criteria for EHR-S to support information exchanges between clinical EHR-S and public health information systems.

PHDSC-APHL Partnership Activities

The PHDSC and APHL team will work on representing PHL interests in the national process of certifying standard-based HIT products as follows:

Working with HL7

Via participation in the development of the **HL7 Public Health Functional Profile**, PHDSC-APHL team have been working on reviewing the HL7 EHR Functional Model (direct care, supportive and infrastructure functions and conformance criteria) for bi-directional data exchanges between EHR-Ss and PHL LIMSs on laboratory test orders/results The Profile will be balloted in April 2012 (**Table 3**).

Working with ONC ACTBs

PHDSC-APHL team will further **develop certification criteria** for EHR-Ss and PHL LIMS to support data exchanges and will work with the ONC-ACTBs to **enable certification** of EHR-Ss for sending laboratory test orders and receiving test results from LIMS. We will also work with the ONC-ACTBs and CDC PHIN to establish certification processes for PHL LIMSs for receiving laboratory test orders and sending test results to EHR-Ss (**Table 3**).

⁵³ Public Health Data Standards Consortium (PHDSC).Public Health Functional Profile Project. HL7 Public Health Functional Profile. Overview Chapter. 2011. URL: https://wiki.phdsc.org/index.php/EHR-PH_APY3

Deploy Certified HIT Solutions

Deployment of certified standards-based HIT solutions is the most critical component of enabling interoperability between clinical and public health information systems. All HIT standardization efforts are for naught unless legacy information systems are upgraded to utilize interoperability standards. Today, barriers for deploying interoperability standards in public health include:

- The lack of funding
- The lack of technical knowledge and
- The lack of coordinated/unified public health approach for adoption of interoperable HIT solutions across various public health programs at all levels of government.

Addressing the Lack of Funding

HITECH programs provide funding for EHR-S adoption in healthcare, i.e., supporting data sending systems. However, they provide very limited resources mostly via HIE programs for upgrading data receiving systems, e.g., laboratories, pharmacies, public health agencies. In public health, only immunization information systems received significant funding from CDC under HITECH.⁵⁴

There is a need to advocate for resources that will enable transition in Public Health from siloed, customized information systems to interoperable standards-based applications. The resources are needed for both developing the standards-based HIT solutions as well as for the deployment of certified applications. PHDSC estimated that the cost of participation of one subject matter expert in one standardization entity (e.g. IHE, HL7) is \$39,500/year.⁵⁵

There is a need to estimate cost for deployment of certified HIT application in a public health program. The estimate should include costs associated with participation of a public health vendor and/or program staff in

- (1) testing of standards-based solutions, e.g., at IHE Connectathon, to assure that interoperability standards serves program-specific needs
- (2) certification of the standards-based public health application at ONC-ATCBs and
- (3) deployment of the certified HIT application.

Addressing the Lack of Technical Knowledge

The APHL *LTIAPH project* - Laboratory Technical Implementation Assistance for Public Health, as described above, provides guidance and technical assistance to state/territorial public health laboratories and health departments to upgrade LIMs to support interoperable data exchanges with clinical EHR-Ss and public health agencies' PH-ISs.

The LTIAPH identifies data exchange strategies and feasible models of technical assistance that can help develop an approach for delivering technical assistance to upgrade legacy systems for PHL as well as for other public health domains (programs).

⁵⁴ Centers for Medicaid and Medicare Services (CMS). HITECH, Meaningful Use, and Public Health: Funding Opportunities for State Immunization Registries. URL: <http://www.medicaidhitechta.org/Portals/0/Users/011/11/11/ImmunRegWhitePaper.pdf>

⁵⁵ Public Health Data Standards Consortium (PHDSC). Public Health in HIT Standardization Resource Center. How much participation will cost and how it should be funded. URL: <http://www.phdsc.org/standards/public-health-participation-hit-how-much.asp>

IHE has been organizing the Deployment Workshops for users (program staff) to solicit their feedback on utilization of standards-based applications. PHDSC-APHL team is working to organize these workshops for PHL staff.

A new PHDSC-APHL-CSTE project on developing a **Public Health Reporting Resource Repository** of HIT standardization resources and tools is aimed to help public health professionals to participate in HIT standardization process. The Repository will be based on the PHDSC Web-based Resource Center⁵⁶ that contains several Modules aimed to support the implementation of the PHDSC's *Coordinated Public Health Action Plan on HIT Standards* developed as a part of the PHDSC Business Case: Role of Public Health in National HIT.⁵⁷

The *HIT Standards Resources* Module⁵⁸ is an informational resource that describes HIT standardization phases (Needs and Priorities for Standards, Standards Development, Standards Harmonization, Standards Testing, Standards-based HIT Product Certification, and Deployment); standardization entities and their products.

The *Public Health Participation in Health IT Standardization* Module⁵⁹ is designed to address barriers for public health participation in the national HIT standardization efforts and help navigate through and participate in the standardization entities and their activities.

The *HIT Adoption Stories* Module⁶⁰ is a searchable database on the varied uses of and activities related to health information technology in public health. The stories cover local, state, federal and international public health agencies, public health research, public health interoperability and standards development, and HIT resources, as well as broader HIT activities that affect public health.

Addressing the Lack of Coordinated/Unified Public Health Approach for Adoption of Interoperable HIT Solutions across Various Public Health Programs at All Levels of Government

There is an urgent need to assure coordination across programs and agencies with regard to the deployment of standard-based HIT solutions. Upgrades of public health information systems today should be conducted to assure interoperability of those systems with others within the agency to prevent additional re-development in the future. It is critical for public health programs to participate in the regional HIE initiatives. However, HIT upgrades related the MU Stage 1 public health objectives (laboratory reporting, immunization and syndromic surveillance) has to be conducted by taking into the account the needs for interoperability for other public health programs' information systems in the agency.

PHDSC-APHL Team in partnership with the Council of State and Territorial Epidemiologists (CSTE) will be conducting a pilot project on deploying CDA-based HIT solutions for laboratory reports and case reports data exchanges in two states (**CDA for Public Health Pilot Project**). There is a need to engage the broader public health community in the design and development

⁵⁶ Public Health Data Standards Consortium (PHDSC). Public Health in HIT Standardization Resource Center. URL: <http://phdsc.org/standards/resource-center.asp>

⁵⁷ Public Health Data Standards Consortium (PHDSC). Business Case: Role of Public Health in National HIT. URL: http://phdsc.org/standards/business_case.asp

⁵⁸ Public Health Data Standards Consortium (PHDSC). Public Health in HIT Standardization Resource Center. HIT Standards Resources. URL: <http://phdsc.org/standards/health-information-tech-standards.asp>

⁵⁹ Public Health Data Standards Consortium (PHDSC). Public Health in HIT Standardization Resource Center Public Health Participation in Health IT Standardization Web-based Module. URL: <http://phdsc.org/standards/public-health-participation-hit.asp>

⁶⁰ Public Health Data Standards Consortium (PHDSC). Public Health in HIT Standardization Resource Center. HIRT Adoption Story Web-based Module. URL: <https://hitstories.phdsc.org/HITStories/main.htm>

of this Pilot project, so the lessons learned and experience can be shared, thus enabling replication of these pilots in other states and/or programs. The APHL LTIAPH teams could contribute their expertise into working with the selected states for this Pilot project.

PHDSC-APHL Partnership Activities
<p>The PHDSC and APHL team will work to address challenges related to deployment of certified HIT products as follows:</p> <p><u>Addressing the Lack of Funding</u> We will develop estimates for the costs associated with participation of a public health vendor and/or program staff in (1) standards testing, (2) certification of the public health application at one of the ONC-ATCBs, and (3) deployment of the certified HIT application (Table 1).</p> <p><u>Addressing the Lack of Technical Knowledge</u> PHDSC will work with APHL LTIAPH teams to learn from, document and expand on their experience in providing technical assistance to PHLs to support deployment of interoperable solutions (Table 1).</p> <p>PHDSC will also work with APHL to develop IHE-PHDSC-APHL Deployment Workshops. These workshops will target users, (i.e. public health laboratory personnel and program staff) to get their feedback on the standards-based HIT products that were developed using IHE interoperability standards. This will help to understand what improvements, if any, are needed to support business processes of the laboratories and programs. This is the outreach component of the project (Table 3).</p> <p>PHDSC will also work with APHL to develop a metric for <i>evaluating the effectiveness</i> of standard-based HIT solutions to support laboratory data exchanges (Table 3).</p> <p><u>Addressing the Lack of Coordination for Deployment</u> PHDSC-APHL-CSTE team will work with APHL LTIAPH teams to learn from their experience to design and develop the CDA for Public Health Pilot Project (Table 3).</p>

HOW – How to assure public health participation in the HIT standardization and desired outcomes

There is a need to develop metrics for assuring that PHL participation in HIT standardization produces the desired outcomes of enabling electronic information exchanges across PHL partners. To measure the HIT standardization impact, these metrics should include both quantitative measures (e.g., number of PHLs experts participating in HIT standardization entities; number and types of standards developed/used; number of orders/reports exchanged electronically; change in timeliness of reporting) and qualitative measures (e.g., change in completeness/correctness of orders/reports; change in duplicative testing; change in time for completing/sending the report).

Data on the use of HIT standards is presented in Section 3 derived from the APHL surveys of PHLs^{61,62} and the annual CAP Survey of LIS vendors.⁶³ There is a need to better align these surveys to generate a more comprehensive view on the level of HIT standards adoption and the impact of this adoption on PHLs.

PHDSC-APHL Partnership Activities
<p>PHDSC will work with APHL to develop a metric for assuring that PHL participation in HIT standardization produces the desired outcomes of enabling electronic information exchanges across PHL partners.</p>
<p>The PHDSC-APHL team will use data on the use of various standards described in Part 1 of the White Paper as indicators of the current use of HIT standards in PHL information systems to build <i>before-after</i> comparison.</p>
<p>The PHDSC-APHL team will work with the survey teams from APHL and CAP (American College of Pathologists) to add additional questions to their survey to collect data on the PHL participation in HIT standardization and the impact of this participation (Table 3).</p>

⁶¹ 2010 National Electronic Laboratory Reporting (ELR) Snapshot Survey - Summary of Results – National ELR Taskforce May 2011

⁶² PHLIP Influenza ELSM - Messaging Capabilities Assessment Survey (and follow up conversations) – APHL March 2011

⁶³ College of American Pathologists (CAP). An Interactive Guide to Laboratory Software and Instrumentation. Annual Survey of Laboratory Information Systems (LIS). URL: <http://www.captodayonline.com/productguides/software-systems/laboratory-information-systems-cap-today-november-2010.html>

**Section
4**

PHDSC-APHL Roadmap on HIT Standardization for Public Health Laboratories: 2012-2013

This section contains the summary of the specific activities described above to assure that PHL interests are represented in the various national HIT standardization efforts. We present this as the PHDSC-APHL Roadmap on HIT Standardization for PHLs for the period of 2012-2013.

PHDSC-APHL Roadmap on HIT Standardization for PHLs: 2012-2013	
<i>Identify Need and Priorities for HIT Standards</i>	
<p>PHDSC will support APHL in its advocacy efforts to assure that PHLs needs for HIT standardization are included in the national HIT agenda.</p> <p>The Public Health Reporting Initiative⁶⁴ is under development to define the scope for a potential public health initiative at the ONC S&I Framework based on the needs of the public health community. This Initiative is aimed at developing a unified approach for integrating siloed public health information systems using harmonized HIT standards. The Initiative will entail harmonization of business processes, functional requirements for information systems, data needs and HIT standards across public health programs to inform the development of interoperable standards-based HIT solutions.</p> <p>In 2011-2012, the Initiative will focus on the <u>Initial Public Health Report Use Case</u> with multiple User Stories under the following public health domains (programs):</p> <ul style="list-style-type: none"> • Child Health • Communicable Diseases • Chronic Diseases • Adverse Event Reporting and Other <p>The PHDSC-APHL team developed a User Story that describe laboratory orders/result data exchanges under these domains (programs) and will further work on developing the implementation guide to support this User Story (Table 3).</p>	
<i>Develop HIT Standards</i>	
<p>If the need for a new standard is identified we will work with APHL subject matter experts and the standards development organizations to develop this standard.</p> <p>In this project the PHDSC-APHL team will develop a new HL7 Public Health Reporting Requirements Standard. This standard will be based on the HL7 Healthcare Quality Measure Framework (HQMF) standard. Originally defined to support the specification of quality measures (eMeasures), the standards will also support the expression of public health reporting requirements. As a structured document specification, this will allow for both a human readable expression as well as a machine-readable expression of the jurisdiction-specific reporting requirements. This standard will support the capability of a system to consume the requirements, and process those requirements against CDA-expressed content. It will determine whether a report should be made to public health, what to report, to whom to send</p>	

⁶⁴ Office of National Coordinator for Health IT (ONC). Standards & Interoperability Framework. Public Health Reporting Initiative. URL <http://wiki.siframework.org/Public+Health+Reporting+Initiative>

the report, how to report, and when to report. We anticipate balloting the new standard in August 2012 (**Table 3**).

Using the **Model Driven Health Tool (MDHT)** the PHDSC-APHL team will develop CDA R2 Templates for Laboratory Reports for selected conditions including *Anthrax*, *Tularemia*, *Hepatitis-B*, *Tuberculosis* and *Influenza*. We will use the input from the CDC RCMT project on LOINC/SNOMED data mapping for notifiable conditions and APHL PHLIP project data definitions for *Influenza* to define a CDA R2 Content for these conditions (**Table 3**).

Harmonize HIT Standards

The PHDSC and APHL team will work on representing PHL interests in the national HIT standards harmonization activities as follows.

Working with IHE

The PHDSC-APHL team will harmonize the workflow and data requirements for data exchanges for the selected conditions (*Anthrax*, *Tularemia*, *Hepatitis-B*, *Tuberculosis* and *Influenza*) with the **IHE Laboratory Technical Framework**⁶⁵ profiles including the Sharing Laboratory Reports (XD-Lab) Integration Profile.

Using the Laboratory domain as an example the PHDSC-APHL team will develop the **IHE Public Health Reporting Integration Profile** that will serve as an overarching HIT Standardization Framework for Public Health (**Table 3**).

Working with ONC S&I Public Health Reporting Initiative

The PHDSC-APHL team will participate in the development of the Implementation Guide for the *Initial Public Health Report Use Case* to specify HIT standards for laboratory test order/test result data exchanges between EHR-S, LIMSs and PH-ISs (**Table 3**).

Test HIT Standards

The PHDSC and APHL team will work on testing HIT interoperability standards for laboratory data exchanges as follows.

Participate in the IHE Connectathon

In 2012 the PHDSC-APHL team will work with LIMS vendors to test CDA templates for laboratory reports developed for the selected conditions (*Anthrax*, *Tularemia*, *Hepatitis-B*, *Tuberculosis* and *Influenza*) in the Sharing Laboratory Reports (XD-Lab) Integration Profile of the **IHE Laboratory Technical Framework**.⁶⁶ This testing may be held at the North American IHE Connectathon in January 2012 and/or European IHE Connectathon in May 2012 (**Table 3**).

Participate in the HIMSS Interoperability Showcase

The PHDSC-APHL team will work with HIT vendors to demonstrate interoperability solutions for exchanging CDA laboratory reports for the selected conditions at the HIMSS Interoperability Showcase in February 2012 (**Table 3**).

⁶⁵ Integrating the Healthcare Enterprise (IHE). Laboratory Committee. URL: http://www.ihe.net/Technical_Framework/index.cfm#laboratory

⁶⁶ Integrating the Healthcare Enterprise (IHE). Laboratory Committee. URL: http://www.ihe.net/Technical_Framework/index.cfm#laboratory

Certify Standards-based HIT Products

The PHDSC and APHL team will work on representing PHL interests in the national process of certifying standard-based HIT products as follows:

Working with HL7

Via participation in the development of the **HL7 Public Health Functional Profile**, PHDSC-APHL team have been working on reviewing the HL7 EHR Functional Model (direct care, supportive and infrastructure functions and conformance criteria) for bi-directional data exchanges between EHR-Ss and PHL LIMSs on laboratory test orders/results. The Profile will be balloted in April 2012 (**Table 3**).

Working with ONC ACTBs

PHDSC-APHL team will further **develop certification criteria** for EHR-Ss and PHL LIMS to support data exchanges and will work with the ONC-ACTBs to **enable certification** of EHR-Ss for sending laboratory test orders and receiving test results from LIMS. We will also work with the ONC-ACTBs and CDC PHIN to establish certification processes for PHL LIMSs for receiving laboratory test orders and sending test results to EHR-Ss (**Table 3**).

Deploy Standards-based HIT Products

The PHDSC and APHL team will work to address challenges related to deployment of certified HIT products as follows:

Addressing the Lack of Funding

We will develop estimates for the costs associated with participation of a public health vendor and/or program staff in (1) standards testing, (2) certification of the public health application at one of the ONC-ACTBs, and (3) deployment of the certified HIT application (**Table 1**).

Addressing the Lack of Technical Knowledge

PHDSC will work with APHL LTIAPH teams to learn from, document and expand on their experience in providing technical assistance to PHLs to support deployment of interoperable solutions (**Table 1**).

PHDSC will also work with APHL to develop IHE-PHDSC-APHL Deployment Workshops. These workshops will target users, (i.e. public health laboratory personnel and program staff) to get their feedback on the standards-based HIT products that were developed using IHE interoperability standards. This will help to understand what improvements, if any, are needed to support business processes of the laboratories and programs. This is the outreach component of the project (**Table 3**).

PHDSC will also work with APHL to develop a metric for **evaluating the effectiveness** of standard-based HIT solutions to support PHL data exchanges (**Table 3**).

Addressing the Lack of Coordination for Deployment

PHDSC-APHL-CSTE team will work with APHL LTIAPH teams to learn from their experience to design and develop the CDA for Public Health Pilot Project (**Table 3**).

Assure Desired Outcomes from Participation in HIT Standardization

PHDSC will work with APHL to develop a metric for assuring that PHL participation in HIT standardization produces the desired outcomes of enabling electronic infor-

mation exchanges across PHL partners.

The PHDSC-APHL team will use data on the use of various standards included in Section 5 of this document as indicators of the current use of HIT standards in PHL information systems to build *before-after* comparison.

The PHDSC-APHL team will work with the survey teams from APHL and CAP (American College of Pathologists) to add additional questions to their survey to collect data on the PHL participation in HIT standardization and the impact of this participation (**Table 3**).