

The Office of the National Coordinator for Health Information Technology

State HIE Bright Spots **Synthesis** Lab Exchange

Themes and Lessons from Lab Exchange Bright Spots

October 2013

About this Document

The Bright Spots initiative is designed to help identify and disseminate successful implementation practices and approaches that are worth spreading. Check out more detailed implementation briefs at http://statehieresources.org/bright-spots/.

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Executive Summary

The exchange of clinical laboratory data plays an important role in the functioning and improvement of America's health care system. Studies estimate that U.S. laboratories (labs) conduct ten billion clinical and diagnostic tests per year.¹ While lab services account for less than 3 percent of annual health care spending, the results of lab tests affect an estimated 70 percent of medical decisions,² highlighting the potential influence of laboratory medicine on the quality, efficiency, and cost of health care.

Accessing lab data in a timely manner and in a format that allows for clinical decision support, trending analyses, and population health management is essential to delivering efficient and effective patient care. For these reasons, the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) targeted the exchange of lab data among providers in meaningful use stage 1 & 2 criteria and in Program Information Notice (PIN) priorities for State HIE Cooperative Agreement Program grantees. Even with this level of priority and visibility, achieving these requirements has been a challenging task for third partyⁱ HIE entities.

This document explores the primary approaches used by successful third party entities to enable lab exchange and illustrates that there is no one "secret formula" for success. While the final formula for lab exchange may differ among third party entities, we have identified several common factors linked to successful exchange:

A clear understanding of the local lab market dynamics, economic incentives, and local policy levers to both identify technology and tailor service options to meet the needs of stakeholders, deliver business value, and foster adoption. The maturity and competitive nature of a given market will influence the value that third parties are able to offer for lab exchange and the specific role they may be able to play. This is especially true for entities offering lab result delivery services (See page 12 for details)

¹ The term third party is used throughout this document to describe organizations that facilitate the exchange of lab information, but are not clinical laboratories or ordering providers/final users of the laboratory information.

- **Organizational and technical maturity** are important for supporting largely automated processes/data flows whether results delivery or translation services are the third party's focus. Organizational maturity also helps build confidence in services among data trading partners. (See <u>pages 5-7</u> for details)
- **Application of the Pareto principle** helps focus attention and make several aspects of lab exchange more manageable, particularly LOINC and SNOMED coding. (See <u>page 15</u> for details)
- Attention to critical operational factors such as, (1) ensuring staff and management resources are commensurate with the work at hand, whether supported via employees or contractors (see page 6 for details); (2) dedicated project management tools and resources across all data trading partners (see page 14 for more details); (3) strategic executive support across stakeholders (see page 15 for more details)

Proactively addressing these factors during planning and implementation phases and learning from the experience of seasoned third party HIE entities will help ensure a successful approach that is aligned to the specific needs of each local market.

Structure of this document

To navigate this resource, we have organized the synthesis into three sections with respective subsections.

- 1. <u>A HISP or HIE Entity's Role in Lab Exchange</u>, including:
 - Approach #1: Lab results delivery
 - Approach #2: Lab results storage
 - Approach #3: Technical assistance
- 2. Principles That Guide Successful Approaches, including:
 - o Know your environment
 - Establish a value proposition
- 3. <u>Tactics that Move the Needle on Lab Exchange</u>, including:
 - o Employ strong project management
 - o Obtain executive champion support
 - Follow the 80/20 rule for LOINC mapping
 - Ease the financial burden

We explore each of these three areas in the sections that follow. For a complete list of interviewees, please see <u>Appendix A</u>.

General Lab Exchange Process

The steps that occur between the time a patient has a specimen taken to when a provider reviews the results of the patient's test include both a *lab ordering* and *results delivery* process. The process often looks like this:

A provider orders a test or multiple tests from a chosen lab (*lab ordering*); the lab then processes the order (when and where specimens are drawn varies greatly, thus this component is not represented here), completes the test, produces the results, and sends the test results back to the ordering provider (*lab results delivery*).

Today, the sophistication of this information exchange can vary greatly, as labs and providers use both electronic and non-electronic methods to order tests and deliver results. For example, some providers send orders to labs on paper and receive the results by mail or fax.

Other providers place orders within their electronic health record (EHR) system and receive results back into the same system, where the data can be directly integrated into their patients' records. True lab exchange involves system-to-system electronic communication where EHR systems, lab information systems (LIS), and (at times) third party systems, such as health information exchange (HIE) infrastructure, seamlessly interact to exchange and use timely lab information.

Some labs have direct connections to provider systems for integrated ordering and results delivery; however, many labs and providers need to rely on a third party integrator to help information flow between their systems. In this bright spots synthesis, we focus on the latter – lab information exchange facilitated by third parties, such as Health Information Service Provider (HISP)² or HIE entities. Generally, these entities have legal agreements (i.e., a business associate agreement and/or service level agreement) in place to receive lab results and route them to providers. **Figure 1** illustrates a basic lab exchange process where a third party is involved – from the moment a provider places a lab orderⁱⁱ to when he or she accesses the test results.





The following steps are illustrated in Figure 1 above.

• Lab ordering. The provider fills out an electronic lab order—including patient name, unique identifying number (i.e., medical record number), date and time, diagnosis code(s), and test(s) ordered—using an EHR or web-based portal application. Simultaneously, specimens marked with the same information may be sent to the lab for testing (unless the specimen will be drawn at the lab).

[&]quot;Though the lab ordering process is important, this synthesis focuses on lab results delivery.

- Lab information system receipt and processing. The LIS receives the electronic order. After tests are processed using lab testing tools, the LIS creates the test results, prepares them for dissemination, and sends the results to a third party system.
- Routing. A third party (whether a HISP or HIE entity) receives the test results and routes the results to the provider's receiving system. If the results are routed using Direct protocols, the results are encapsulated in a Direct message before routing.
- Lab results delivery. The provider's receiving system (whether an EHR, portal, or email client) receives the results (or Direct message containing the results). If the results are in a structured format³, an integrated EHR system can extract the result and associate the data with information such as patient name, lab order number, and medical record number to ensure the correct test result is matched to the corresponding order before storing discrete data in the patient's record. Providers who receive results via web-based portals or email clients may require that staff open the results, match the results to the order, and manually save the results to an EHR system (if one is available).
- Provider access. The provider accesses the test results in an EHR system, a webbased portal, or an email client application.

A HISP or HIE Entity's Role in Lab Exchange

Our research identified three main approaches that successful third parties are taking to increase electronic exchange of lab information:

Lessons Learned from a Lab Results Delivery Veteran – Delaware Health Information Network (DHIN)

Since 2007, DHIN has served as the "report of record" for most lab results in the state. The organization attributes its success to achieving critical provider mass (with over 90 percent of the state's providers signed up and using the network) and partnering with all the major hospitals and commercial lab vendors (LabCorp and Quest) early on. DHIN noted several potential issues to be aware of regarding lab results delivery and/or ordering:

Provider workflow issues. Former DHIN Executive Director Gina Bianco (Perez) cited an issue DHIN found when HIE entities act as a "clearinghouse" for lab ordering. Bianco said, "When providers go to order a lab test, they don't want to go through the steps to choose a lab. When an HIE entity works with multiple labs, there are generally several listed in a provider's EHR. Providers have complained about the extra steps it takes to choose a lab from a list in a drop down menu. On the flip side, labs we've worked with become concerned when they are no longer the "default" lab that automatically populates when the provider places an order in his/her EHR." Accordingly, an important balance should be struck between how lab stakeholders make information both available and easily useable within a provider's workflow.

Patient matching concerns. Bianco noted that because of the way labs collect data in an order, they often provide lab results with missing patient demographic information. Missing demographic data on a lab result can create challenges for HIE infrastructure to accurately match the result to the right person in the system. This can result in two entries or records for the same patient in the HIE system, causing manual work de-dup the duplicative entry. Bianco further noted that this issue is helped when the HIE entity supports both ordering and results delivery; the HIE entity can "complete the loop" and match order with result, based on the unique order number and patient demographics.

- **Approach #1** Lab results delivery, which includes the facilitation of electronic lab information between a lab's LIS and a provider's system (whether web-based portal, EHR, or email client)
- **Approach #2** Storing lab results in a repository for later retrieval (third party receives a copy of lab results from a lab and stores them in a repository so that providers can query (i.e., search and retrieve) them as needed
- **Approach #3** Technical assistance services, such as translation from local lab codes to LOINC, outreach and education to providers, and more

Approach #1 – Lab Results Delivery

Some third parties deliver lab results directly as the report of record⁴ or official lab result to ordering providers (i.e., not a copy of the original result). Further, some organizations also provide lab ordering capabilities, offering a one-stop shop for providers to submit orders and receive the results back via a single entity. Third parties that have demonstrated success with this approach exhibit the following characteristics:

- 1. A very clear understanding of the local or regional lab environment and early entry into the market (before a plethora of point-to-point lab connections are established)
- 2. Operational technical infrastructure that is trusted, known, and used by a critical mass of health care providers (organizational and technical maturity)
- 3. Adequate staffing (whether in-house or contracted)
- 4. A deep understanding of the policy and regulatory requirements that govern labs and their delivery of results to providers

We explore these factors in further detail below.

Existing lab environment. Organizations successfully delivering electronic lab results to providers cited the importance of knowing the state or region's existing lab (and overall HIT) environment, including the range and reach of hospital, commercial, or independent labs that already deliver lab results electronically or allow/facilitate electronic ordering. Generally, third party organizations that provide widespread results delivery today were early to enter their state or region's lab market (i.e., before national or larger regional labs had point-to-point interfaces with providers). For example, **Delaware Health Information Network** (**DHIN**) attributes its success in delivering lab results to a majority of the state's providers to the absence of direct interfaces between labs and providers when the organization entered the market. Approximately 98 percent of Delaware providers who make lab orders (and therefore receive results) are enrolled as users of DHIN. Around 75 percent of these providers have "signed off" on accepting DHIN as the report of record and are subsequently shutting off all other methods of results delivery. Former DHIN Executive Director Gina Bianco (Perez), said, "*Nowadays, as EHR adoption has grown, reference labs have made it a part of their business to build lab interfaces to providers' EHRs quickly. Where there is an absence of HIE, it is done point-to-point and very few HIE entities provide the report of record."*

HIE organizational and technical maturity. To successfully deliver electronic lab results, third parties must have relatively advanced organizational maturity. That means an established technical infrastructure that enables a largely automated flow of electronic lab data from an ordering provider to the lab, and back to the ordering provider. It also means an established reputation among data trading partners, in terms of trust and confidence, that the third party's system can securely and safely provide what trading partners need. Finally, it means having a critical mass of providers already signed up and using the third party's services. The organizations we interviewed that have experienced ongoing success delivering lab results to providers achieved this success only once they had operational infrastructure in place—including interfaces with labs, hospitals, and providers—as well as a substantial number of providers on-boarded and ready to receive results (either via a web-based portal or directly into their EHR systems).

Vermont Information Technology Leaders, Inc. (VITL), which processes approximately two million messages per month (lab orders/results as well as other types of transactions), credited its success in this space to organizational maturity. VITL's Sandy McDowell said, *"The hospitals have tremendous trust in VITL. They recognize our strength and capabilities as an organization."* J. Marc Overhage, former CEO of the Indiana Health Information Exchange (IHIE), said that critical mass is "hugely important." Once IHIE had a critical mass of providers signed up, the organization could tout the same value proposition as more established hospital labs in terms of results delivery.

Staffing and management. Success also appears to be associated with investments in staffing commensurate with the scope of lab results delivery services offered. IHIE offers a robust set of lab services including building interfaces from provider EHRs to the HIE infrastructure, providing downtime support for hospitals, and running a help desk to assist providers who may not have received a result or received

incorrect data. The organization estimated its capital costs for this initiative to be in the hundreds of thousands of dollars and originally budgeted to employ one full-time equivalent (FTE) staff position per one thousand providers. Today, IHIE employs over 70 individuals and its network delivers more than 11 million clinical results a month to more than 25,000 physicians in Indiana and 16 other states, including approximately 2,000 in the Chicago area. The organizations we interviewed also indicated that building the necessary interfaces for results delivery requires a high degree of coordination and communication, and dedicated project managers are essential to keeping implementations on time and on budget.

Taking Incremental Steps to Structured Lab Results Delivery

Many third parties may not have the human or financial resources necessary to proceed with full-scale lab results delivery right away. J. Marc Overhage, former CEO of the Indiana Health Information Exchange (IHIE), suggests starting in a more controlled environment: "...agree to do a trial run with a lab for six months or find a 'big brother,' – a more mature organization that could help get you started and then turn over operations when you are ready."

Policy and regulatory requirements. Organizations should review and be prepared to comply with the various policy and regulatory requirements that pertain to sending electronic lab data from laboratories to ordering providers. The <u>Clinical Laboratory Improvement Amendments</u> (CLIA) and the <u>Health Insurance</u> <u>Portability and Accountability Act of 1996</u> (HIPAA) regulate the release of lab results and require labs to have adequate mechanisms in place to ensure results are accurately sent to the right location in a timely fashion (42 C.F.R. § 493.1291).⁵ Furthermore, some states have greater restrictions in place around the release of lab data. Ken McCaslin of **Quest Diagnostics** explained that failure to meet certain CLIA regulations can result in big financial penalties for labs; thus, some labs are hesitant to lose control of how lab data gets from their system to that of the ordering provider. Former IHIE CEO J. Marc Overhage recalled his experience working with certain lab directors to validate CLIA compliance of an interface from the lab to a provider: "Some labs will say, 'we delivered a well formed message to the HIE infrastructure, so we feel confident.' Other labs feel compelled to see the interface all the way through and want to see how the result is displayed on the other side."

It is important to note that most of the organizations we interviewed that offer lab results delivery services use the same infrastructure to send other types of clinical information. DOCS4DOCS®, the electronic results delivery service built by the Regenstrief Institute nearly 10 years ago and managed by IHIE since 2004, is not only the single source of clinical lab results for thousands of providers across multiple states, the service also delivers transcriptions, radiology reports, pathology reports, and discharge and transfer reports.

John Kansky, IHIE's current Vice President for Strategy and Planning said, "As an organization, IHIE offers myriad services including a clinical data repository, a clinical quality program, and automated ADT alerting. However, our DOCS4DOCS® service was our first and continues to be our 'bread and butter.' We've found many other uses for this pipeline over the years. For example, we've recently started using the service to send automated alerts to physicians for public health related events/information."

Approach # 2 – Lab Results Storage

Some third party entities receive copies of lab results and store them in repositories so that providers can query (i.e., search and retrieve) results as needed. For third parties located in environments where labs have already established connections with hospitals and providers for results delivery and ordering, obtaining copies of lab results may prove valuable when treating providers need to view a patient's medical history and previous tests ordered elsewhere.

Lab Results Storage Benefits

The benefits of sending lab results electronically to an ordering provider may seem more obvious than storing lab result "copies" in repositories for future view. However, one study found that, after the introduction of a community HIE entity, the number of lab tests performed after encounters involving recent off-site lab tests fell 49 percent. The researchers argued access to previous lab tests made a positive impact in the decision process to order additional tests and had some significant financial savings implications.¹³

- Maryland's Chesapeake Regional Information System for Our Patients (CRISP) receives over 500,000 lab results in an average 10-day period from 32 of 46 acute care hospitals⁶ across the state. This equates to approximately 28 million results now available for query in its repository. The lab results enter CRISP's HIE infrastructure as HL7 V2.x messages, flowing over VPN connections and through CRISP's interface engines. CRISP transforms the inbound lab messages so they conform to the organization's lab specification. CRISP determined that LOINC mapping is not critical for the organization to provide because the HIE entity is not delivering results to an end-point system. CRISP maintains the source system result codes and displays them to end users who search for and retrieve the information.
- In addition to its lab results delivery services, VITL receives clinical data in a structured Continuity of Care Document (CCD) format from practices that participate in Vermont's <u>Blueprint</u> program, which maintains a reporting registry for chronic diseases and health maintenance. Practices that participate in Blueprint can receive per patient per month quality-related incentive payments for sending electronic results to the registry through VITL.
- In the case of Maine's HealthInfoNet (HIN), the organization has developed direct connections to local reference and hospital labs. Anytime HIN's lab partners deliver a result to a provider, they also send a copy of those messages to HIN for inclusion in the organization's Centralized Data Repository (CDR). Unlike CRISP, HIN maps these results to LOINC and SNOMED-CT codes as part of their HIE services described in the following section.

Entities exploring this type of service should consider the necessary legal requirements, including obtaining business associate agreements (BAAs), service level agreements (SLAs), or other types of participation agreements with various lab partners and providers. For example, CRISP has both a BAA and a <u>participation agreement</u> in place with each lab from which it receives results. CRISP's national lab partners—including LabCorp and Quest—require ordering providers to fill out a form that explicitly requests that results are sent to the CRISP repository. The provider must include details such as the practice name, LabCorp or Quest account number, and contract information.

Figure 2 below highlights a general example of a lab's connection to a third party system for results storage purposes.



Figure 2: Lab copy sent to third party for storage

Approach # 3 – Technical Assistance

Other organizations are providing services that support the lab exchange process, either in addition to the services listed above or independently.

LOINC Translation Services

A common technical assistance example involves an HIE entity offering the initial or ongoing mapping of a lab's local codes to standardized LOINC so that data can more easily move between LIS and provider EHR systems. Today, most labs deliver results electronically via HL7 messages and use unique local codes to identify key pieces of information such as what test was run. For example, one hospital lab might identify serum sodium with the code "C1231" while another lab identifies it with the code "SNA".⁷ The degrees of variation make exchange between systems difficult. The Logical Observation Identifiers Names and Codes (LOINC) is one standard designed to solve this problem. Developed in 1994 by a group of researchers at the Regenstrief Institute, LOINC is a universal standard for identifying medical laboratory observations.⁸ In essence, entities that provide such services, often called "translation," map a lab's unique coding compendium to the standardized LOINC compendium so that it can be understood across multiple information systems. **Figure 3** below illustrates an example of LOINC mapping.

Figure 3: LOINC mapping example



Several HIE entities we interviewed provide LOINC translation services. In anticipation of a state statute that will require hospitals and practices to send lab data to the state's public health department using LOINC, the **New Mexico Health Information Collaborative (NMHIC)** offers translation services. NMHIC receives (mostly in HL7 v.2.3 format) and translates to LOINC approximately 1,000 lab results for notifiable conditions every week from 18 different hospitals before sending them to the public health department. As mentioned previously, Maine's HealthInfoNet (HIN) connects directly to the two state reference labs and all the hospital labs (and through them, national labs such as Quest) and receives copies of results for inclusion in its Centralized Data Repository (CDR). As a service, HIN maps the hospitals' and labs' local compendiums to LOINC and SNOMED-CT (Systematized Nomenclature of Medicine Clinical Terms) before storing the results in its repository. HIN then provides these mapped catalogues out to the labs and provider organizations for future use as part of their paid HIE subscription.

These and other organizations identified the following factors as key to successful LOINC translation services:

Adequate time and resources. Interviewees expressed that while mapping local codes to LOINC is a worthwhile effort, it involves significant time and resource investment. Typical estimates to map all tests in an LIS ranged from 6 to 12 weeks, although most organizations focus on mapping only the most commonly used lab tests first, which can decrease dependence on staff and shorten timelines. We explore this tactic—called the 80/20 rule—in the "Tactics that Move the Needle on Lab Exchange" section below. Though VITL previously provided LOINC translation to labs, the organization has ceased providing these services directly due to the amount of overhead involved. The organization previously monitored results coming back from participating hospitals, mapped them to LOINC codes, and sent the results (in LOINC) back to the ordering provider. To maintain and manage this process for less than a dozen practices required approximately one FTE. VITL is now focused on getting hospitals to include LOINC codes as a secondary field in the HL7 messages they send to VITL. VITL now funds a separate service provider to maintain a map of local to LOINC codes at each hospital.

- **Regular maintenance.** Beyond the initial mapping from local to LOINC codes, ongoing maintenance is required. Two to three times a year, the Regenstrief Institute releases updates to the LOINC standard. In addition, labs frequently make changes to their own compendiums, including the addition of new lab codes or updates to existing codes. Changes in the LOINC compendium and local compendiums must be updated in a timely manner to ensure accuracy and maintain interoperability.
- Human interaction. There are some technical tools available that assist in mapping lab codes, but human interaction and communication between the organization mapping the codes and the lab is still necessary. For example, HealthInfoNet uses a semi-automated system and software tool for its translation services. The tool automatically maps codes where units and definitions are clearly defined. Other codes, however, require some human intervention: some codes flow into an error queue where an HIN staff member, who monitors the queue, manually maps these codes to LOINC. In addition, HIN requires—as part of its participation agreement and policies—that participating labs notify the HIE entity when they change a code. This can entail HIN staff reaching out to lab managers directly when codes are changed or when HIN identifies a possible communication gap.

Other Examples of Technical Assistance

For organizations that may not want to directly handle lab data, there are other examples of successful technical assistance, such as providing education, outreach, and guidance about LOINC and/or lab exchange.

In January 2012, the **Ohio Health Information Partnership (The Partnership)**, in collaboration with the <u>Lab Interoperability Cooperative</u> (LIC)⁹, conducted a series of full-day LOINC workshops for hospital lab managers, directors, and hospital-based HIT professionals. In addition to general information about LOINC and its importance to meaningful use and public health reporting, the workshops provided hands-on guidance for mapping LOINC codes to hospitals' local data dictionaries. The two workshops were offered free of charge and also provided tools for



attendees to use after the class, such as a LOINC best practice guide and mapping template. A total of 58 hospitals attended the workshops, or about 33 percent of the 172 meaningful use-eligible hospitals in Ohio. Based on a "before and after" survey that each participant completed, The Partnership reported that attendees left the training with more knowledge about LOINC and increased confidence to perform the mapping process. In a 2013 survey, The Partnership found that 12 percent of its hospital participants were currently using LOINC codes to send results to providers.

As of April 2013, the LIC has engaged more than 960 hospital labs across the country through more than 30 in-person and virtual education workshops. In addition to training lab personnel, attendees at these sessions have included staff from public health agencies, HIE entities, and Regional Extension Centers (RECs). The initiative is still actively providing regionally-based LOINC education in-person and virtual workshops through September 2013.

The lowa Department of Public Health (IDPH) recently released the <u>IDPH Implementation Guide and ELR</u> <u>Constrained Profile V1.04.01</u>, which helps providers and hospitals confirm that reportable lab results sent to the public health department will meet meaningful use requirements. Defining the standard structure and content for electronic laboratory reporting (ELR), the guide details how hospitals and laboratories must construct lab messages, as well as how to go about submitting test messages, using a tool called the <u>National Institutes of Standards and Technology (NIST) ELR Validation Too</u>l. Providers and hospitals submit test messages to IDPH for review. Once reviewed, IDPH sends a letter affirming that the entity has met the Stage 1 meaningful use measure for electronic lab reporting.

Principles That Guide Successful Approaches

Regardless of the approaches they take or the services they offer, we found third parties that achieved some success advancing lab exchange typically adopted the guiding principles described below.

Know Your Environment

Every lab exchange strategy should take into account the current lab environment and market—including what proportion of labs (hospital, national, or regional) already deliver results electronically—and the general appetite for HIT adoption. Having a firm grasp on the landscape helps focus energy on providing services where there are gaps and capitalizes on existing lab capabilities in the state. Conducting regular monitoring and outreach to update environmental scans can help HIE entities stay on top of the changing market.

The Pennsylvania eHealth Partnership Authority, for example, conducted a <u>survey</u> of 516 labs in the state (response rate of 93 percent). The survey asked about the rate of electronic exchange, method of electronic delivery, and use of the LOINC classification system. This information gave the Pennsylvania team a better understanding of the state's lab market and where the organization can deliver the most value. Through the survey, the team discovered that some labs—though listed as "independent" in the <u>Centers for Medicare & Medicaid Services (CMS) OSCAR database</u>¹⁰—were in fact affiliated with national labs such as LabCorp or Quest Diagnostics. The survey also revealed pockets of LIS concentration – 40 percent of the state's lab population used the same two LISs, while the remainder was fairly stratified among other systems.

This detailed information helped Pennsylvania to better understand and encourage the market forces that were already driving labs to go electronic. It also allowed Pennsylvania to identify those labs that were not electronically enabled for some valid business reason (i.e., they are not really labs but rather specimen collection points). Pennsylvania has conducted repeat surveys with labs that were not electronically exchanging information and worked with the state's certified HISP community to connect these labs with programs and services that can help them advance their electronic exchange capability.

ONC, in partnership with the <u>National Opinion</u> <u>Research Center</u> (NORC) is currently surveying 14,000 clinical labs, including approximately 2,700 hospital-based labs, to determine their capabilities relative to electronic lab exchange. ONC hopes to use the information to provide targeted assistance as State HIE grantees continue to develop strategies for the exchange of clinical lab data and develop policies that will promote the exchange of structured lab results between labs and providers.

State HIE grantees have also used information about their landscape to determine the gaps that exist in their state and to map (or adjust) their lab strategy to fulfill priority needs.

For example:

- Two large reference labs comprise 90 percent of Hawai'i's lab market. Rather than building competing services, the Hawai'i Health Information Exchange (HHIE) is collaborating with both organizations to offer LOINC translation services.
- Maine's HealthInfoNet used information it learned about the lab landscape in the state to focus energy in areas besides lab results delivery. When the organization launched in 2007, the two large state-based reference labs- owned by two area health systemsrepresented approximately 65-70 percent of Maine's lab market. Shaun Alfreds, HIN's COO, recalls, "We found to date there has been little appetite for HIN to do results delivery. Most providers have direct connections with local and national reference laboratories, so we focused our energies elsewhere, including getting copies of lab results for our HIE repository and providing LOINC translation services. Moving forward, we are beginning to see some demand for these services in the ambulatory specialty practices and are assessing if there is a business reason for HIN to provide these services in these settings." In addition to the services described above, HIN provides automated lab reporting of standardized laboratory results to the State Department of Public Health to support public and population health monitoring.

Establish a Value Proposition

As with any HIE venture, stakeholders want to know the benefits, costs, and value before getting involved; thus, it is critical for third parties considering any type of lab service to understand what "value" means to a

CRISP's Value Proposition Analysis

Not every exchange entity is well-suited to provide lab results routing or delivery services. In deciding to focus on exchange services *other than* lab results delivery, the leadership of Maryland's statewide HIE entity, CRISP, asked itself the following questions:

- Can we assist *hospital* labs in delivering results more efficiently than they can on their own?
- Can we assist *independent* labs in delivering results more efficiently than they can on their own?
- Can we be more cost effective in producing interfaces than a lab or hospital?
- What are providers willing to pay and can we break even or profit at that level given the specific number of customers we currently have or anticipate in the future?
- Given our HIE infrastructure costs, what level of participation from results delivery customers would we require?

For CRISP, the answer to many of these questions was "no," suggesting the organization was not in a strong position to offer results delivery services more efficiently than alternative service providers or the labs directly. To compete, CRISP would have needed to subsidize the lab connection, which would not have been scalable or have served the market well in the mid- to long-term. Their alternative approach is described under "Approach #2" on page 7.

lab, to a provider, or any other relevant stakeholder. This is critical to driving adoption and use of the third party's services.

Interviewees pointed to several factors that influence value based on their experience:

• **Economics.** Whether it is increasing a lab's profit margins or saving providers money by reducing interface costs, money matters for many health care stakeholders in the lab exchange space.

If there is not some financial gain or cost savings, promoting adoption can be challenging. IHIE was successful in gaining lab participation by demonstrating it could provide results delivery services for hospital labs more cost effectively than if the labs created one-off interfaces to provider organizations. IHIE conducted cost analyses with potential hospital lab partners to highlight cost savings. J. Marc Overhage explained how one hospital lab was spending \$0.81 on average to deliver a single lab result: *"IHIE came and did it for \$0.11. The hospital lab took time lapse photos of their mail room and after nine months, the mail room was a patient lounge."* John Kansky, IHIE's current Vice President of Strategy and Planning said, *"Don't launch [lab results delivery or other services] without knowing the services are going to solve a business problem for your stakeholders. Getting customer economic belief and buy-in is critical before moving forward."*

Halfpenny Technologies, a secure, cloud-based, vendor-neutral clinical data exchange platform for labs, hospitals, health plans, ACOs, and EHR vendors, has implemented approximately 4,000 interfaces between LIS and EHR systems around the country. Gai Elhanan of Halfpenny said, "Labs seek our assistance because of the potential cost-savings and return on investment they will receive by using Halfpenny's interoperable infrastructure and LOINC mapping services, rather than implementing interfaces or offering the lab services themselves."

Market share. Competition in the lab marketplace, like most of the HIT market, is fierce. Providing partnerships or services that help labs edge out competition has proven to be a successful strategy for some third parties. Trudi Matthews of HealthBridge recalls how her organization was able to deliver value to some of the smaller hospital labs: "HealthBridge was in the lab space before some of the national players had an electronic solution. We proved valuable to the hospitals as a lab results delivery mechanism because they wanted to retain lab business and didn't want revenues going to large companies." Two HIE entities-including DHIN and HINhave attracted national labs to their infrastructures because they already have a large portion of providers connected to their infrastructure. HIE infrastructure that has a large proportion of a given market's providers already connected can be appealing to labs looking to capture more market share quickly.

The Ohio Health Information Partnership – Helping rural labs compete with urban counterparts

LOINC! LOINC! The Sky Is Not Falling-a whitepaper written by The Partnership's COO, Fred Richards—provides an overview of the issues that rural labs face and presents various examples of why they should adopt LOINC. One compelling point Richards found in talking to these labs is the prospect of an increasingly competitive landscape. Richards said, "Rural hospitals know their patients travel to Cleveland or Columbus for treatment. So, they try hard to keep their patients at their hospitals. It's not surprising that rural hospitals are hungry to learn about LOINC because they want to compete with their urban counterparts." The whitepaper describes how the use of LOINC will help rural hospitals compete on a level playing field with larger regional or national labs and increase rural hospitals' capabilities to connect to community provider's electronic health records (EHRs), improving the chance that providers will order labs through their local hospitals. The enhanced communication and interoperability between rural hospitals and ambulatory providers will help keep patients (and business) within the local community.

- Regulatory pressures. Another way to show value is helping stakeholders adapt and thrive in a dynamic health care environment, including helping them align with and responding to new health care regulations. In 2010, the New Mexico Health Information Collaborative (NMHIC) was approached by the state's Department of Health to assist providers in meeting the meaningful use requirement for sending electronic reportable lab results to the public health department. After agreeing to become certified under ONC's processes for the public health reporting measure, the organization worked with an Authorized Testing and Certification Body (ATCB) to understand certification costs, processes, etc. On April 6, 2012, after going through rigorous testing processes, NMHIC received modular certification for Stage 1 meaningful use public health measures (electronic lab results reporting, syndromic surveillance, and immunization reporting). The certification ensures that the organization's partners can attest to meeting public health reporting meaningful use requirements via NMHIC, which enhances the organization's value to providers and labs as well as improves NMHIC's ability to expand across the state. NMHIC's new capabilities prepare the organization to further assist stakeholders in meeting future regulatory requirements like these.
- **Provider demand.** Interviewees cited provider demand as significant to the advancement of lab • exchange. According to Quest Diagnostics, lab vendors have traditionally been "cautious" to follow market trends, but usually respond to customer (i.e., provider) demand for new services and functionality. The Ohio Health Information Partnership has seen providers spur hospital labs to send lab results directly into their EHRs by appealing to the lab's market competitiveness. The Partnership's COO Fred Richards said, "Providers have gone to hospitals in the area and said, 'This national lab delivers my results directly into my EHR, and I'd like you to make it easier for me to get results on a local level." Some third parties have employed successful strategies to organize providers to communicate a common 'ask' that helps accelerate lab exchange. For example, J. Marc Overhage recalled that it was provider demand that finally helped convince some national labs to let IHIE deliver lab results via their HIE infrastructure. Rather than pleading with the labs for their participation, IHIE communicated the value of lab results delivery directly to various provider organizations. The organization also developed an automated form letter that was sent from the IHIE system on behalf of the provider to the lab requesting the provider's lab results be delivered via the HIE entity. IHIE was able to secure the participation of these labs by allowing the providers to drive demand.

Tactics that Move the Needle on Lab Exchange

Across a variety of lab environments, HIE maturity levels, and service offerings, our research uncovered several consistent tactics that contribute to successful lab exchange outcomes.

Employ Strong Project Management

Like any HIT project, lab exchange implementations involve many players—including lab directors, hospital CIOs, IT staff, EHR vendors, clinicians—and systems. Strong project management is critical to ensure the implementation is on time, on task, and on budget, and that it satisfies the expectations of various stakeholders. VITL attributes some of its success to a skilled staff with strong project management capabilities. VITL's Sandy McDowell commented, "*There needs to be a project manager on all sides*—*the lab, practice, and EHR vendor.*" The Hawai'i HIE uses a highly structured approach to implementing interfaces between labs and the HIE infrastructure. In addition to drafting a customized project plan with each entity involved, Hawai'i HIE and its partners sign a memorandum of understanding (MOU) at each project's outset detailing activities to be completed, the anticipated timeline, and delineated roles and responsibilities. **Table 1** highlights sample responsibilities specified in a Hawai'i HIE MOU, specifically related to a lab implementation using Direct standards and specifications:

Table 1: Hawai'i HIE sample lab vs. HIE entity responsibilities – Direct implementation

Hawaii HIE responsibilities	Lab responsibilities
Hawai'i HIE shall use its best efforts to enroll physicians into the β eta Direct pilot project to meet the needs of LAB	LAB shall name people in LAB to contact for Hawai'i HIE on communications needs
Hawai'i HIE shall name people in Hawai'i HIE as contacts for LAB and their programmer/designee on mapping, development and communications	LAB shall maintain the infrastructure and equipment needed to use Direct electronic exchange in its office
Hawai'i HIE shall use its best efforts to ensure that data transmitted through the β eta Direct pilot is not tampered with or altered in the transmission process	LAB shall maintain programming and technical resources to troubleshoot issues related to accessing the Hawai'i HIE Direct platform, and the underlying software that is used in its office
Hawai'i HIE shall assist LAB in troubleshooting problems related to Direct and facilitate communications between LAB and providers participating in the βeta Direct pilot	LAB shall notify Hawai'i HIE of issues related to Direct, and devote resources to work toward resolving those issues
Hawai'i HIE shall provide the transmission data summary to LAB in mutually agreed to formats, but shall not be responsible for the accuracy and completeness of the data provided to LAB for this βeta Direct pilot	LAB shall work with Hawai'i HIE in the validation process
	LAB shall be responsible for the final formatting, display and appearance of any electronic attachments transmitted via Direct to its clients

Obtain Executive Champion Support

The ever-changing health care and HIT environment means that there are competing, and sometimes conflicting, priorities across various stakeholders, sometimes making it difficult for all parties to focus the same amount of energy on an issue. A top-level executive (e.g., a Chief Information Officer [CIO]) may be able to cut through bureaucracy, focus attention on a particular need, and ultimately, speed project completion. When speaking about one of IHIE's most successful lab interfaces with a hospital, J. Marc Overhage said, *"The interface took 30 days start to finish because the CIO was committed to making it happen. He had credibility and presence in the organization."* Interviewees relayed that it helps to do targeted education and outreach to executives to garner their support. ATLAS, a lab hub vendor said, *"It's really helpful to increase awareness at the C-level and educate these leaders on any decisions that could potentially affect their ability to be successful in the market."* The organizations we interviewed identified the following roles and actions of an effective executive champion:

- Legitimizes vision and goals. The executive champion should provide leadership and strategic direction on mission, goals, and objectives. He or she should provide a convincing business case (supporting goals, etc.) that fosters early and sustaining support from stakeholders.
- **Mobilizes resources.** The executive champion should obtain any necessary resources (financial, human capital, etc.) to support the initiative.
- Acts as a cheerleader. The executive champion should motivate stakeholders to drive the initiative forward.
- **Removes barriers.** When things go wrong, the executive champion should step in to resolve matters quickly to avoid implementation delays and other possible issues.

Follow the 80/20 Rule for LOINC Mapping

As mentioned previously, converting local lab compendiums to LOINC is an arduous task that requires time, money, and resources. Several interviewees indicated that focusing mapping efforts on only a subset of LOINC codes that represent a significant portion of lab tests makes the process far more manageable for hospitals and labs than if they try to take on an entire compendium at once. This focused approach to the mapping process is commonly referred to as the 80/20 rule. According to studies, a small fraction of lab codes (20 percent) represent the majority (80 percent) of results. For example, the Regenstrief Institute conducted a study that concluded that approximately 800 lab codes (out of thousands) could account for 99 percent of the test results stored in the clinical databases of institutions with which Regenstrief collaborates¹¹. Fred Richards of the Ohio Health Information Partnership commented, *"I sat down with a lab manager a few months ago and saw the worry on his face as he thought about mapping over 5,000 codes in his compendium. I told him to focus on his top 100—the ones that are reportable to public health—and gradually deal with the others later. Immediately, he relaxed and said 'I can do that.' When communicating about LOINC, you need to break things down and make them palatable." Many of the organizations engaged in LOINC translation services—including DHIN, Hawai'i HIE, and IHIE use a similar process of focusing on a small set of the most commonly used codes first.*

Ease the Financial Burden

Building electronic interfaces can be expensive for stakeholders that want to engage in electronic lab results exchange. Third parties may help spur adoption by negotiating rates with vendors or offering financial incentives. The Ohio Health Information Partnership negotiated fees with large vendors so that it could provide interfaces to hospitals at a very low cost – 50 percent or greater discounts than what a vendor would normally charge. The Partnership worked with one hospital that had received a \$12K interface price from a vendor to do one lab interface. With a negotiated fee structure, The Partnership was able to offer the same interface for \$2K. Similarly, DHIN worked directly with EHR vendors to negotiate rates for interfaces from upwards of \$60K for some vendors, down to approximately \$3K.

Looking Forward

Our research highlights some of the common success factors across third party entities that have had success increasing lab exchange at both state and regional levels. While we celebrate achievements to date, there is significant room for growth. To that end, there are several initiatives that are expected to further advance lab exchange in the near future.

Lab Results Initiative Implementation Guide

Addressing the time and financial constraints that arise from building custom interfaces between lab information systems and EHRs, the ONC Standards and Interoperability (S&I) Framework convened a community of approximately 90 volunteers from industry, and state and federal government to develop the Lab Results Initiative Implementation Guide (LRI IG). The LRI IG defines technical specifications (such as necessary content, format, and vocabulary standards) for organizations implementing structured lab information exchange between a LIS and an ambulatory EHR system from a different organization. The use of the guide will significantly decrease the need for mapping local lab codes to a standardized code set such as LOINC or implementing completely unique configurations between lab and EHR systems. The LRI guide is available on the <u>S&I Framework Wiki</u>.

Stage 2 Meaningful Use Implications for Lab Exchange

<u>Stage 2 meaningful use</u> (released in August 2012 and set to go into effect in early 2014) will raise the bar for lab exchange, requiring tighter integration between LISs and EHRs and the adherence to nationally recognized technology standards. The following list includes highlights of the Stage 2 meaningful use measures related to lab exchange:

- The incorporation of structured lab results into certified EHRs moves from a menu item to a core item, requiring physicians to meet a threshold of at least 55 percent of all clinical lab test results ordered.
- Certified EHRs must be able to consume lab results in accordance with the LRI guide, including meeting the LRI specification using LOINC and SNOMED-CT (for certain results).

With these new provisions, we can expect increased demand for the exchange of normalized, discrete data that can be consumed via EHRs, increased connectivity between EHRs and LISs, and the expanded use of LOINC.

Use of Direct for Lab Results Delivery

As mentioned previously, the Direct Project protocol is one way to securely exchange data between labs and providers over the internet. In May 2012, ONC convened a group of public and private sector stakeholders (including state HIE grantees and HIE/HISP vendors) in Washington, DC for a Lab Summit to jumpstart pilots that would, by working through many key considerations, demonstrate simple and costeffective lab results reporting services using Direct secure messaging. Pilot teams from **Alaska**, **Florida**, **Guam**, **Hawai'i**, **North Carolina**, and **West Virginia** used the working meeting to map out plans to use the protocol to deliver lab results to ambulatory providers and have continued to meet over the past year to collectively track progress, share lessons learned, and distribute useful artifacts that can be reused to accelerate lab exchange progress in other states. Examples of work plans, subscription agreements, and participation terms and conditions are listed on the <u>Direct Project wiki</u>. In addition, the ONC State HIE Lab Interoperability Community of Practice has released the <u>Labs over Direct Toolkit</u>, which includes a summary of experiences and lessons learned from participating pilot states, as well as reusable documents and templates.

These initial implementations will serve as a catalyst for the wider scale deployment of Direct as a scalable, standardized, and valuable means of exchange for laboratory transactions.

Themes and Lessons

Through our research, we uncovered a few overarching themes and lessons:

• One approach may not work for all. From performing structured lab results delivery on behalf of a lab, to storing copies of lab results in a repository, to providing lab education and outreach to hospitals and providers – there are a variety of approaches third parties are taking to increase the flow of electronic lab results to ambulatory providers and adoption of the LOINC standard. However, an approach that makes sense for one organization might not be feasible for another. The success of an organization's lab strategy greatly depends on a variety of factors, including the state and local lab environment, the maturity of organizations engaged in lab exchange, and the demands physicians place on labs. Every interviewee had its own unique environment and mix of factors that required a slightly different approach to advancing lab exchange.

Success depends on finding and filling the gaps. Through its Program Information Notices and other guidance, ONC has continually stressed the importance of adopting gap-filling approaches to exchange. This strategy focuses on getting essential exchange services to providers and data trading partners currently without (or with limited) HIE capabilities (by expanding existing exchange services and assets or building only those services needed to address the gap). We found that the gapfilling approach is critical to success in the lab environment, which is often saturated with community, regional, or national labs that have long-established connections with providers to perform lab results delivery and ordering. Organizations should think creatively about how they can engage in *value-driven* activities that help fill a void or supplement existing services, without duplicating existing exchange services/activity. These efforts may not always be technical in nature and may involve activities like mobilizing the provider community to increase demand, educating stakeholders on the importance of lab exchange.

Alaska – Poised to Launch Direct for Lab Results Delivery

The State of Alaska, in partnership with the Alaska eHealth Network and Orion Health (as the state HISP), is in the process of launching a Direct pilot involving two main scenarios. One includes a hospital lab sending results to a provider group's EHR system. The other is a state lab sending results to a pediatric provider group's EHR system. As of late January 2013, the team has been establishing service level agreements between partners and preparing systems for necessary CLIA testing. When asked about challenges and lessons learned so far, Paul Cartland stated that workflow is top of mind for the state's providers: "Providers don't want another system (such as a portal) to check results. They want interfaces directly into their EHR systems. Sending electronic data via Direct is not enough. You need a way to make the results delivery process viable with existing workflow."

• Finding the lab services "sweet spot" is difficult. Finding the right role for third parties to play in lab exchange can be challenging. Many interviewees mentioned the difficulty of competing in a crowded market with regional and commercial lab vendors or the low return on investment they experienced when offering more technically-oriented lab services. The reality for many health information organizations is that lab results are a critical piece of the patient information puzzle, but providing traditional delivery services may be too expensive to maintain and may not be needed given the advancement of point-to-point connections between labs and providers. Finding the sweet spots where third parties can truly make an impact in advancing lab exchange may take a few attempts (and potentially result in a few failures). The two guiding principles previously mentioned in this synthesis—knowing your environment and establishing a value proposition—are good guideposts to finding the right role for a given organization.

Appendix A – Interview List

The State of Alaska / Alaska eHealth Network ATLAS Chesapeake Regional Information System for Our Patients (CRISP) **Delaware Health Information Network (DHIN)** Halfpenny Technologies Hawai'i Health Information Exchange **HealthBridge HealthInfoNet** Indiana Health Information Exchange (IHIE) Kentucky Health Information Exchange (KHIE) Keystone Health Information Exchange (KeyHIE) / Geisinger Health System New Mexico Health Information Collaborative (NMHIC) Ohio Health Information Partnership (OHIP) The Pennsylvania eHealth Partnership Authority **Quest Diagnostics** Surescripts / Lab Interoperability Cooperative Vermont Information Technology Leaders, Inc. (VITL)

Appendix B – Lab Results Delivery Key Considerations

There are a variety of factors third parties should consider when making the decision to offer lab results delivery. The use of Direct specifications to deliver lab results also has its own unique considerations.

Key considerations	Applicable to lab exchange efforts in general	Applicable to lab exchange facilitated via the Direct specification
Format of results: There are a variety of structured, semi-structured, and unstructured formats that labs use to send results, including Health Level Seven (HL7) v2.3, HL7 v2.5, Consolidated Clinical Document Architecture (C-CDA), and Portable Document Format (PDF). The format that the lab information system (LIS) produces affects an EHR's ability to integrate data on the receiving end. The Office of the National Coordinator for Health Information Technology's (ONC) <u>Standards & Interoperability Lab Results Interface (LRI)</u> initiative created a common content standard to better support the incorporation of lab results into EHRs as structured data and to align with meaningful use requirements.	¥	¥
System enablement for Direct: The LIS must be enabled to associate the ordering provider with a destination (i.e., the provider's Direct address) to send results. This process may be automated or semi- automated, but is unlikely to fit laboratory workflows as a manual process. Recipients' systems (i.e., EHR, portal, or email client) must be able to receive information over the Direct protocol, but must also be able to receive, display, and in some cases parse and consume the attached information, in this case a lab result. If a provider wants to receive lab results via Direct in their EHR, it is important to work directly with the EHR vendor to determine how technical integration will work and what the workflow is for the provider. Alternatively, some providers may choose to receive results via Direct in a web-based portal or existing email client.		¥
Message Delivery Notification: In accordance with the Direct Project's Applicability Statement for Secure Health Transport, HISPs must issue a Message Disposition Notification (MDN, RFC3798) upon successful receipt, decryption, and trust validation of a Direct message. By sending this MDN, the third party is taking custodianship of the message and is indicating that it will deliver the message to its final destination. In addition, HISPs must be compliant with the Implementation Guide for Delivery Notification in Direct v1.0, which provides a sufficiently high level of assurance (as required by CLIA) that a message has arrived successfully at its final destination.		¥
Certificate exchange: It is possible that a given lab may use a health information service provider (HISP) other than the HISP used by providers. In order for a lab to send results via Direct to ordering providers that use a different HISP, the HISPs would generally have to exchange their respective trust anchor certificates either directly with one another or through participation in a common trust community/trust bundle.		~

Key considerations	Applicable to lab exchange efforts in general	Applicable to lab exchange facilitated via the Direct specification
Routing: Routing methods define how electronic results are sent from the lab's LIS to a third party (if used) and on to the final destination (i.e., EHR, portal, or email client). Direct messages are routed via the internet standard, Simple Mail Transfer Protocol (SMTP)+ / Multipurpose Internet Mail Extensions (MIME). HIE entities often use Simple Object Access Protocol (SOAP) and/or Virtual Private Network (VPN) connections for routing lab data.	¥	4
Patient matching: The lab result must include patient demographics and a unique identifier. Using this data, the system receiving the lab result must match the result to the original lab order and the rest of the patient's health record. In electronic systems, results are often easier to match to the correct patient record when lab orders are submitted electronically, as the unique identifier from the electronic order can be stored and used to improve matching accuracy beyond demographic data alone.	V	✓
Delivery: The format of the results determines the receiving system's ability to integrate the results into a patient's record. For example, results in an HL7 format are more easily integrated into an EHR. Unstructured formats such as PDF may be viewable through an email or web client or portal, as well as an EHR system. However, the EHR system will be unable to absorb the PDF-formatted results as discrete data. The PDF must be attached to the patient's record or someone must manually transfer the data from the PDF into the patient's record.	✓	¥
Access: Providers can view lab results within an EHR, via a web-based portal, or via email client depending on capabilities of the receiving system.	~	v
CLIA & Lab certification: <u>Clinical Laboratory Improvement</u> <u>Amendments</u> (CLIA) requires entities sending lab results as the report of record to rigorously test their processes to assure timely, predictable, and positive/negative acknowledgement of delivery of lab results (through delivery notification and service level agreements (SLAs)) and to certify that results are not altered during the transport process. Visual verification is one technique that lab stakeholders may use to validate that results were not altered during transmission. Accreditation organizations, including <u>The College of American Pathologists</u> (CAP), <u>The Joint Commission</u> , <u>American Osteopathic Association</u> , <u>American Society of Histocompatibility Immungenetics</u> , Commission on Office Laboratory Accreditation (<u>COLA</u>), and American Association of Blood Banks (<u>AABB</u>), enforce these standards within the lab community. If using Direct protocols, delivery notification requirements as specified in the Implementation Guide for Delivery Notification must be implemented in order to be CLIA compliant.	¥	¥

¹ "Laboratory Medicine: A National Status Report," Centers for Disease Control and Prevention (CDC) (2007), <u>http://wwwn.cdc.gov/dls/bestpractices/</u>.

² "The Value of Clinical Laboratory Services," American Clinical Lab Association (2011), <u>http://www.acla.com/node/355</u>.

³ A HISP is in charge of performing a number of services required for the exchange of health information as defined by the Direct Project (<u>http://nwhin.siframework.org/HISP</u>).

⁴ ONC defines the term structured as "documentation of discrete data using controlled vocabulary, creating fixed fields within a record or file, or another method that provides clear structure to information (is not completely free text)." Examples of structured data are those in HL7 formats. An unstructured data example includes PDF documents.

⁵ The Report of Record is the set of all preliminary, partial, final and corrected lab reports delivered to the Authorized provider or a third party (on the authorized provider's behalf).

⁶ "Privacy and Security Solutions for Interoperable Health Information Exchange," RTI International. (2009), <u>http://www.healthit.gov/sites/default/files/rules-regulation/290-05-0015-final-508-state-clia-law-report.pdf.</u>

⁷ Does not include long term, religious non-medical health care institutions, psychiatric, rehabilitation, and children's' hospitals.

⁸ McDonald C et al., LOINC, A Universal Standard for Identifying Laboratory Observations: A 5-Year Update. *Clinical Chemistry* 49:4 (2003): 624-633, <u>http://www.clinchem.org/content/49/4/624.full.pdf</u>.

⁹ "LOINC Background." Logical Observation Identifiers Names and Codes (LOINC) (2013), <u>http://loinc.org/background.</u>

¹⁰ Funded by CDC, the Lab Interoperability Cooperative (LIC) is a two-year funded grant initiative to connect hospital laboratories with their related public health agencies and enable reportable laboratory results to be transmitted electronically. The LIC is a consortium of partners that includes the American Hospital Association (AHA), the College of American Pathologists (CAP) and Surescripts Network for Clinical Interoperability.

¹¹ The Online Survey, Certification, and Reporting (OSCAR) database is maintained by the Centers for Medicare & Medicaid Services (CMS) and contains facility-level data on the operations, patient census, and regulatory compliance of nursing facilities.

¹² Vreeman DJ et al., "A rationale for parsimonious laboratory term mapping by frequency." AMIA Annual Symposium Proceedings (2007), <u>http://www.ncbi.nlm.nih.gov/pubmed/18693941</u>.

¹³ Hebel, Esteban and B. Middleton, M. Shubina, & A.Turchin. "Bridging the Chasm: Effect of Health Information Exchange on Volume of Laboratory Testing." JAMA Archives of Internal Medicine, 2012;172 (6):517-519.

About the State HIE Bright Spots Initiative: Bright spots are successful implementation efforts worth emulating. The State HIE Program will continuously identify, collect and share solutions-focused approached grantees can replicate in their own environments to accelerate HIE progress and share State HIE progress with various internal and external audiences. For more information, contact Erica Galvez at <u>erica.galvez@hhs.gov</u> or Meredith Lewis Blum at <u>meblum@deloitte.com</u>.