



# Multisite Evaluation Plan

Digital Bridge eCR Implementations

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## Acronyms

AIMS	APHL Informatics Messaging Services
APHL	Association of Public Health Laboratories
ASTHO	Association of State and Territorial Health Officials
CCD	Continuity of Care Document
C-CDA	Consolidated Clinical Document Architecture
CDA	Clinical Document Architecture
CDC	Centers for Disease Control and Prevention
CFIR	Consolidated Framework for Implementation Research
CSTE	Council of State and Territorial Epidemiologists
eCR	Electronic Case Reporting
EHR	Electronic Health Record
eICR	Electronic Initial Case Report
ELR	Electronic Laboratory Reporting
HIE	Health Information Exchange
HL7	Health Level Seven
ICD-10	International Statistical Classification of Diseases and Related Health Problems, 10 <sup>th</sup> Revision
IT	Information Technology
IRB	Institutional Review Board
KII	Key Informant Interviews
LOINC	Logical Observation Identifiers Names and Codes
NACCHO	National Association of County and City Health Officials
PHA	Public Health Agency
PHII	Public Health Informatics Institute
PII	Personally Identifiable Information
PMO	Project Management Office
QI	Quality Improvement
RCKMS	Reportable Conditions Knowledge Management System
RCTC	Reportable Conditions Trigger Codes
ROI	Return on Investment
RR	Reportability Response
SNOMED CT	Systematized Nomenclature of Medicine – Clinical Terms

## Glossary

Multisite Evaluator	The individual or team that conducts the multisite evaluation of Digital Bridge eCR implementations. Responsible for implementing the evaluation plan, including data collection, analyses, and facilitating interpretation of results across and with the Implementation Sites.
Case finding	The process of identifying all cases of a disease eligible to be included in the registry database for a defined population, such as patients of a hospital or residents of a state. It is also called case ascertainment. ( <a href="https://www.cdc.gov/cancer/npcr/informatics/aerro2/hospitals/cf/">https://www.cdc.gov/cancer/npcr/informatics/aerro2/hospitals/cf/</a> )
Consumed	The health IT product or public health surveillance system receives, consumes, and makes the information from the case report or reportability response available for use by the clinician or public health staff.
Digital Bridge	A first-of-its-kind collaborative bringing public health, health care, and health IT together to identify better ways to electronically share information between public health and health care organizations.
Digital Bridge eCR approach	Electronic case reporting implemented according to the technical documentation developed by the Digital Bridge collaborators. This documentation is available at <a href="https://digitalbridge.us/resources/">digitalbridge.us/resources/</a>
eICR	The C-CDA-based electronic case report form created for the purposes of electronic case reporting by health care practices to public health agencies. The intent of this document is to provide the minimum amount of information that public health agencies needs to initiate a public health case investigation.
Evaluation questions	Questions that define the issues that the evaluation will investigate and are stated in terms such that they can be answered in a way useful to stakeholders using methods available to the evaluator. (Rossi, Freeman, and Lipsey, 1999, p. 78)
Implementation sites	A partnership of three types of stakeholders: public health, health care, and health IT. Each implementation site is identified by the jurisdiction in which the public health and health care organization are located. Some stakeholder types may have multiple representatives (e.g., New York City and New York State public health representatives or Health Information Exchange and EHR developers representing health IT).



## Implementation stages

Three stages identified by the evaluation committee as relevant for distinctly different evaluation activities.

- **Start-up** – Preparation for electronically sharing production data. Includes development, testing, and onboarding activities.
- **Production** – Go-live; production data sharing begins. May involve additional testing and validation and adjustments to address unanticipated issues. Manual case reporting continues as a parallel process.
- **Maintenance** – Post-production; stable electronic data sharing continues with minor adjustments as needed. Routine manual case reporting for selected conditions is discontinued.

## Manual reporting

Case reporting processes involving a notification by phone, fax, or mail from health care providers to the relevant public health agency.

## Reportability response

The electronic document created to confirm receipt of the eICR, which (if any) conditions were reportable in the eICR and to which public health agency(ies). It provides suggestions for clinical follow-up, other relevant condition information, and additional reporting needs.

## Executive Summary

Current public health case reporting processes require health care providers to remember, during their clinical duties, what is reportable relative to the local jurisdiction and the patient to whom they are providing care. As a result, health care providers have historically underreported disease cases. As its first use case, the Digital Bridge collaborative defined a multi-jurisdictional approach to electronic case reporting (eCR) to reduce the burden of public health reporting of infectious diseases while improving the timeliness, accuracy, and completeness of the data.

This document describes the plan for evaluating the Digital Bridge eCR pilot implementations and reflects input from various stakeholders—including the Digital Bridge governance body, evaluation committee, implementation sites, and other organizations participating in the Digital Bridge effort.

This plan is designed to accommodate the evaluation of implementations that vary in *strategy* yet are consistent in *concept*. Four evaluation goals inform the development and implementation of the plan:

1. Identify and describe the overall processes by which the sites initiated and implemented eCR and the various factors that influenced the processes
2. Determine eCR functioning and performance in terms of:
  - a. System/core component functionality and performance
  - b. Case reporting quality and performance (completeness, accuracy, timeliness)
3. Identify the resources needed to initiate and implement an eCR system
4. Identify the potential value and benefits of eCR to stakeholders

The multisite evaluation plan is designed to address these goals and provide the governance body—as well as other individuals or organizations interested in the implementation of eCR—with reliable information to inform decision-making related to the continued development of the Digital Bridge eCR approach.

This plan leverages key concepts from several types of evaluations including multisite evaluations, public health surveillance system evaluations and health IT implementation evaluations. This document references and summarizes previous evaluation studies to serve as best practices during pending indicator refinement and evaluation tool design by the evaluator and committee.

This largely formative evaluation anticipates using a mixed methods approach to both data collection and analysis and will leverage both qualitative data using primary data collection methods and quantitative analyses that take advantage of secondary data sources as available. The importance of lessons learned during the implementation process is one of the foci of this evaluation, which will be collected via key informant interviews.

Due to the newness of the Digital Bridge eCR approach and the fact that many implementation sites have not had prior experience with eCR, there are many unknowns that must be addressed during tool development or later stages of the evaluation. As a result, this evaluation plan should be viewed as an initial draft and may need to be adjusted as the sites and technical infrastructure teams better understand the nuances of the Digital Bridge eCR approach. Continued, strong stakeholder engagement will be critical to the success of this multisite evaluation.

## Introduction

The Digital Bridge is a multi-organization collaborative with a shared vision of ensuring a healthy nation by establishing effective bidirectional data exchange between health care and public health stakeholders. As its first use case, the Digital Bridge collaborative defined a multi-jurisdictional approach to electronic case reporting (eCR) to reduce the burden of public health reporting of infectious diseases while improving the timeliness, accuracy, and completeness of the data. This document describes the plan for evaluating of the Digital Bridge pilot implementations.

Pilot implementation sites will implement the Digital Bridge eCR approach and technical infrastructure in a phased roll-out beginning in 2018. Each site includes a public health agency, a health care organization, and a health information technology (IT) developer. They will test the eCR approach with data related to five conditions: pertussis, gonorrhea, chlamydia, salmonellosis, and Zika virus infection.

This evaluation plan includes information needed to guide the multisite evaluation of these implementations. The plan sections include background and program description of the Digital Bridge eCR approach; identification of the evaluation stakeholders; a description of the evaluation purpose, approach, and questions; identification of the data sources and methods to be employed for the evaluation; recommendations regarding the management of the evaluation; and how the evaluation findings should be reported and disseminated. The needs and recommendations of various stakeholders—including the Digital Bridge governance body, evaluation committee, implementation sites, and other organizations participating in the Digital Bridge effort—informed plan development.

## Program Description

Established in 2016, the Digital Bridge is a unique collaborative of representatives from health IT developers, public health agencies, and health care organizations working together toward a common goal of “effective information sharing between clinicians and public health professionals” (Digital Bridge, 2017a). The principals behind the Digital Bridge are to identify a unified approach that minimizes burden and costs for all stakeholder groups, advances standards-based information exchange, and ultimately improves bidirectional exchange between public health and health care organizations. The Digital Bridge is managed by the Digital Bridge project management office (PMO) staffed by the Public Health Informatics Institute and Deloitte Consulting. Digital Bridge activities are funded by the Robert Wood Johnson Foundation and the deBeaumont Foundation.

Connecting public health and health care partners electronically should improve the timeliness and completeness of disease reporting, while simultaneously facilitating bidirectional communication through which public health may provide additional health information to the health care community about emerging diseases and treatment options. Similar efforts around electronic immunization reporting, syndromic surveillance, and electronic laboratory reporting (ELR) have yielded improvements in the timeliness, completeness, and quality of reporting to public health organizations. (Overhage, Grannis & McDonald, 2008; Johnson, Williams & Bradley, 2014; Samoff, Fangman, Fleischauer, Waller & MacDonald, 2013). Automation of manual processes also reduced reporting burdens on the health care community.

Current case reporting processes involve a manual notification (e.g., phone, fax, or mail) from the health care community by a facility’s infection control practitioner or astute provider. Across all public health jurisdictions in the United States, there are more than 200 reportable conditions—inclusive of nationally notifiable conditions to the Centers for Disease Control and Prevention (CDC) and conditions that are reportable to local public health jurisdictions but not nationally notifiable. Current processes require health care providers to remember, during their clinical duties, what is reportable relative to the local jurisdiction and the patient to whom they are providing care. As a result, health care providers have historically underreported disease cases.

The Digital Bridge, therefore, selected electronic case reporting as its first use case to improve bidirectional exchange between public health and health care organizations. Appendix A details the major milestones associated with automating the case reporting process. The Digital Bridge approach to eCR leverages a set of trigger codes that should apply across the U.S., new Health Level 7 (HL7) Consolidated Clinical Data Architecture (C-CDA)-based electronic documents, and a decision support intermediary that identifies reportable events based on jurisdictional-specific reporting requirements. Outside the scope of the Digital Bridge eCR approach are how clinicians enter data into the eICR, specifics on how and when the eICR is created in the health IT product, how and whether public health

agencies integrate and use the information in the eICR into their surveillance systems, and how and whether participants integrate and use the information in the reportability response in their IT products.

In 2016, stakeholders representing public health, health care, and health IT agreed upon high-level objectives and a governance approach to conduct an eCR proof of concept (Digital Bridge, 2016). Next, the Digital Bridge governance body created several workgroups whose function was to describe and document the business processes, task flows, technical architecture, functional requirements, and trigger sequencing that would encompass the Digital Bridge eCR approach, all of which are available on the Digital Bridge website, [digitalbridge.us](https://digitalbridge.us) (Digital Bridge, 2017b). Because there are other approaches to eCR that leverage different standards and documents (CDC, 2016; Klompas, et al., 2008; Tseng, Raketich, & Simmons, 2017; Dixon, et al., 2017; Calderwood, et al., 2010), this plan references eCR-based activities as the “Digital Bridge eCR approach” to differentiate it from those other forms of eCR.

In February 2017, the Digital Bridge project began the implementation site selection process. Each site included a set of at least one public health agency, one health care organization, and one health IT developer identified by the jurisdiction in which the public health agency and health care organization are located. These implementation sites, which agreed to implement the Digital Bridge eCR approach (Digital Bridge, 2017c). At a high level, the implementation sites agreed to:

- Implement new eCR standards (the C-CDA-based Electronic Initial Case Report [eICR] and Reportability Response [RR] documents)
- Match local and standardized codes in the health care organizations’ electronic health record (EHR) system to those in the Reportable Conditions Trigger Codes (RCTC) list
- Use the decision support intermediary, the Reportable Conditions Knowledge Management System (RCKMS), to document reporting requirements and adjudicate eICRs for reportable conditions

The eICR, RR, RCTC, and RCKMS are new standards and infrastructure that, prior to these implementation sites going live, have not been used for eCR. Figure 1 displays and defines the critical components of the Digital Bridge eCR approach that will be evaluated. The core components are higher-level functions that will be the focus of the evaluation and are different from the more detailed functions and processes identified by the Digital Bridge technical and business process documentation. The intent of identifying these core components was to focus the evaluation around the primary activities that each implementation site should be completing. It should be noted, however, that the process by which the core components are implemented may vary across implementation sites.

The Digital Bridge implementation sites will demonstrate this eCR approach for five conditions: chlamydia, gonorrhea, pertussis, salmonellosis, and Zika virus infection. The Association of Public Health Laboratories (APHL) maintains APHL’s Informatics Messaging Services (AIMS) platform, and the Council of State and Territorial Epidemiologists (CSTE) developed both RCKMS and the RCTC list.

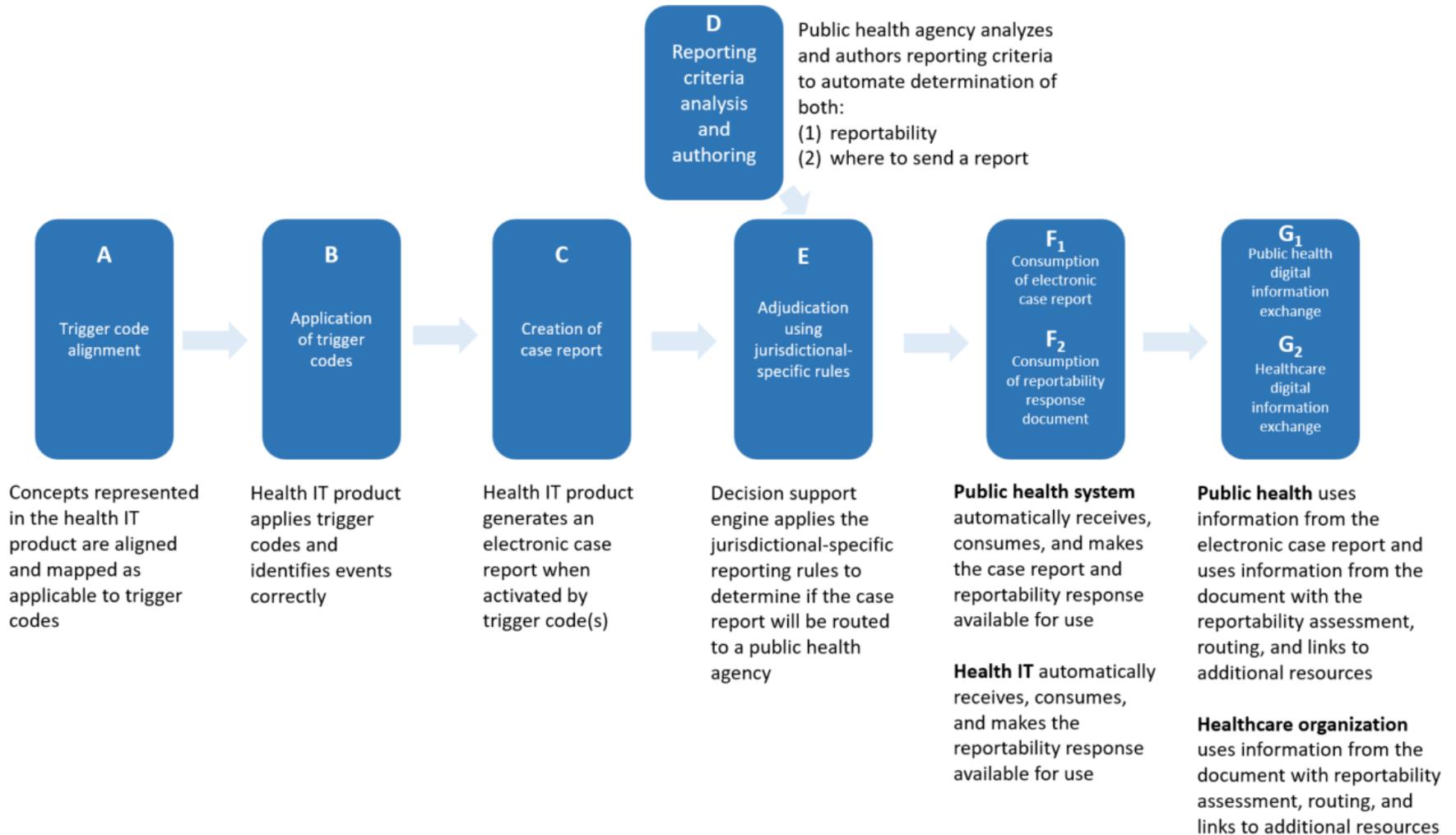


Figure 1. Core Components of Digital Bridge eCR Approach

## Evaluation Background

The governance body approved the formation of the Digital Bridge evaluation committee (committee) on April 6, 2017. On behalf of the governance body, the committee is charged with overseeing, coordinating, and advising on the evaluation approach of the implementation activities. The committee, chaired by Dr. Jeff Engel, includes six primary members, one subject matter expert, six alternates, and fifteen observers (Appendix B). Public health, health care, health IT, and federal government stakeholders are represented on the committee, which also includes members of the infrastructure development team (APHL, CSTE) and implementation sites. Meeting facilitation and support to develop the plan was provided by the MITRE team (a collaboration between the MITRE Corporation and Battelle).

The governance body charged the committee with the task of producing four deliverables, of which this document constitutes the first deliverable. The full list of deliverables assigned to the committee include:

- **Evaluation plan:** written document describing the evaluation approach, roles, and responsibilities for all participants, timelines to complete, and the resources needed for the evaluation activities
- **Evaluation tools:** surveys, guides, and protocols to collect evaluation data
- **Interim evaluation results:** at least one verbal report to the Governance Body of the results
- **Final evaluation report:** at least one written document and presentation of the findings

A multisite evaluator (evaluator) will conduct the evaluation. In the context of this evaluation, the evaluator is an individual or team that facilitates centralized data collection, analysis, and interpretation across the implementation sites. The Digital Bridge PMO will identify the evaluator(s).

To facilitate development of the evaluation plan, the committee identified critical components of the Digital Bridge eCR approach that will be evaluated. Figure 1 displays and defines these seven core components of the Digital Bridge eCR approach. The intent of identifying these core components was to focus the evaluation around the primary activities that each implementation site should be completing. It should be noted, however, that the process by which the core components are implemented may vary.

In addition, and because of the newness associated with this approach, the committee identified three implementation stages relevant for this evaluation. These stages are described below.

- **Start-up:** preparation for electronically sharing production data. Includes development, testing, and onboarding activities. This concept may also be known as implementation or adoption (Cresswell & Sheikh, 2013).
- **Production:** go-live; production data sharing begins. May involve additional testing and validation and adjustments to address unanticipated issues. Manual case reporting continues as a parallel process. This concept may alternately be labeled deployment (Cresswell & Sheikh, 2013).
- **Maintenance:** post-production; stable electronic data sharing continues with minor adjustments as needed. Routine manual case reporting for selected conditions is discontinued. This concept is alternatively called normalization or routinization (Cresswell & Sheikh, 2013).

The core components and stages will be referenced throughout this plan.

## Related Evaluations, Studies, and Frameworks

Committee members referenced several types of evaluations when developing this plan, which are listed below. This plan leverages key concepts from each of these areas.

- Multisite evaluations from which the concepts of stakeholder engagement and a multisite evaluator were derived.
- Evaluations of public health surveillance systems, including ELR and other eCR implementations. These were the basis of the evaluation outcomes measurements for completeness, timeliness, and accuracy.
- Health IT implementation evaluations, which provided the impetus for the implementation stage-based phased evaluation approach and the need to identify best practices and lessons learned through interviews.

### Multisite Evaluations

Frequently during the evaluation planning sessions, it was noted that multisite evaluations, such as those intended for the Digital Bridge implementation sites, have their own unique challenges. Multisite evaluations involve assessment—at more than one site—of program processes or outcome achievement associated with a program or policy (Rog, 2015). The sites included in the evaluation may be implementing programs or policies that are the same, or vary in implementation strategy but are consistent in concept.

Multisite evaluations are typically coordinated by an evaluator who facilitates data collection, analysis, and interpretation in collaboration with the sites. One such multisite evaluation referenced frequently during evaluation planning examined 10 field epidemiology training programs across multiple countries (Jones, MacDonald, Volkov, & Herrera-Guibert, 2014). This evaluation highlighted the importance of strong stakeholder engagement and the development of indicators that could be operationalized in a consistent manner across all sites.

Throughout the development of the evaluation plan, feedback was solicited from the implementation sites. Committee members represented potential end-users of the evaluation results and these individuals were engaged frequently during the planning and drafting of the evaluation plan. Finally, this evaluation plan is premised on the existence of an evaluator who will coordinate the evaluation activities conducted by the implementation sites.

### Evaluations of Public Health Surveillance Systems

The basis for this type of evaluation rests on the work published by German and colleagues (2001) that describes the tasks associated with public health surveillance systems evaluation. As described, the process should include stakeholder engagement; a description of the surveillance system(s) to be evaluated, including the importance of the condition to be surveilled, surveillance system purpose, and

resources to operate the system; focused evaluation activities that ensure appropriate use of resources; and identification of appropriate system performance measurements. The latter includes:

- **Simplicity:** structure and ease of operation
- **Flexibility:** adaptability of infrastructure to changing needs or operating conditions
- **Data quality:** completeness and validity of information shared
- **Acceptability:** willingness of people to use system
- **Sensitivity:** proportion of cases detected
- **Predictive value positive:** proportion of reported cases that truly have condition in question
- **Representativeness:** accuracy of health event detection over time and by populations
- **Timeliness:** speed with which events are identified and reported
- **Stability:** ability of the system to function when it is needed and to do so free of failures

This evaluation will draw on the concepts of data quality, acceptability, sensitivity, predictive value positive and timeliness. There are many published articles describing studies that leverage these performance measures when evaluating public health surveillance systems, including several specific to eCR. Table 1 lists several prominent or recently published studies evaluating different eCR programs and describes their performance measures and data collection processes. In addition, a systematic review conducted by Cresswell and Sheikh (2013) highlighted several studies that noted that any new IT system must be at least as quick as the previously operational system, which helps justify the comparators for eCR timeliness measures to be the existing manual reporting methods, ELR, and other eCR processes in place at the implementation sites.

Indicators for this evaluation are modeled to a certain degree on these studies. When the committee and evaluator develop the evaluation tools, these studies could serve as references on best practices.

**Table 1. Selected eCR Evaluations' Performance Measures and Data Collection Processes**

Authors/Studies	Conditions	Performance Measures	Data Collection Methodology
Tseng, et al. (2017) Evaluation of chlamydia and gonorrhea electronic provider reports data quality	<ul style="list-style-type: none"> <li>Chlamydia</li> <li>Gonorrhea</li> </ul>	<ul style="list-style-type: none"> <li>Predictive value positive</li> <li>Data quality (information accuracy and completeness)</li> <li>Sensitivity</li> </ul>	<ul style="list-style-type: none"> <li>Medical chart review</li> <li>System audit trails</li> <li>Historic case review</li> </ul>
Dixon, et al. (2017) Completeness and timeliness of notifiable disease reporting: A comparison of laboratory and provider reports submitted to a large county health department.	<ul style="list-style-type: none"> <li>Salmonellosis</li> <li>Hepatitis C</li> <li>Hepatitis B</li> <li>Chlamydia</li> <li>Gonorrhea</li> <li>Syphilis</li> <li>Histoplasmosis</li> </ul>	<ul style="list-style-type: none"> <li>Sensitivity</li> <li>Timeliness</li> <li>Data quality (information completeness)</li> </ul>	<ul style="list-style-type: none"> <li>Compilation of all reports received during selected time periods from provider-initiated manual reports, faxed and electronically-received laboratory reports, and electronic Continuity of Care Documents (CCDs)</li> <li>Compilation of timestamps on paper and electronic documents</li> <li>Manual extraction of information from reports' selected fields</li> </ul>
Calderwood, et al. (2010) Real-time surveillance for tuberculosis using electronic health record data from an ambulatory practice in Eastern Massachusetts	<ul style="list-style-type: none"> <li>Tuberculosis</li> </ul>	<ul style="list-style-type: none"> <li>Predictive value positive</li> <li>Sensitivity</li> </ul>	<ul style="list-style-type: none"> <li>Medical chart review</li> <li>Review of public health surveillance system records</li> </ul>
Klompas, et al. (2008a) Automated detection and reporting of notifiable diseases using electronic medical records versus passive surveillance --- Massachusetts, June 2006-July 2007	<ul style="list-style-type: none"> <li>Chlamydia</li> <li>Gonorrhea</li> <li>Pelvic inflammatory disease</li> <li>Acute hepatitis A</li> </ul>	<ul style="list-style-type: none"> <li>Predictive value positive</li> <li>Sensitivity</li> </ul>	<ul style="list-style-type: none"> <li>Medical chart review</li> <li>Manual review of public health surveillance system records</li> </ul>
Klompas, et al. (2008b) Automated identification of acute hepatitis B using electronic medical record data to facilitate public health surveillance	<ul style="list-style-type: none"> <li>Hepatitis B</li> </ul>	<ul style="list-style-type: none"> <li>Predictive value positive</li> <li>Sensitivity</li> </ul>	<ul style="list-style-type: none"> <li>Compared annual acute hepatitis B incidence-density from study period to that in preceding three years</li> <li>Manual review of public health surveillance system records</li> <li>Medical chart review of random sample of patients with selected ICD-9<sup>1</sup> code</li> </ul>

<sup>1</sup> The International Classification of Diseases, Ninth Revision

### Health IT Implementation Evaluations

The Consolidated Framework for Implementation Research (CFIR), developed by the Department of Veterans Affairs Center for Clinical Management Research, identifies concepts upon which an evaluation can be based, as well as specific categories of evaluation relevant to implementation of health information systems (CFIR, n.d.). Table 2 lists the CFIR constructs and aligns them with constructs identified through a systematic review conducted by Rippen and colleagues (2013). These constructs have many similarities to the components of public health surveillance system evaluations.

**Table 2. Constructs from the Consolidated Framework for Implementation Research**

CFIR Constructs	Similar Constructs Used in Other Studies <sup>2</sup>	Relevance to Current Evaluation <sup>3</sup>
<b>Intervention characteristics</b> , including the source of the intervention, stakeholders’ perception of the validity and advantages of the evidence supporting the intervention, ability of the intervention to adapt to sites’ needs, testability on a small scale, complexity of the implementation, and cost	<ul style="list-style-type: none"> <li>• Time to implement or temporality</li> <li>• Functionality</li> <li>• End user attitudes and perceptions</li> <li>• Outcome lifecycle (e.g., when an intervention could expect to achieve a given outcome)</li> <li>• Financial considerations</li> </ul>	<ul style="list-style-type: none"> <li>• Time to implement</li> <li>• Functionality (how core components are implemented at each site)</li> <li>• Implementation stages</li> <li>• Costs</li> </ul>
<b>Outer setting</b> , including patient needs and facilitators and barriers to meeting those needs, the degree to which the organization is networked with other organizations, peer pressure, and external policy and incentives	<ul style="list-style-type: none"> <li>• Social factors (e.g., inter-professional role support, peer attitudes)</li> <li>• Legal concerns</li> <li>• Governance</li> <li>• Environment</li> </ul>	<ul style="list-style-type: none"> <li>• N/A (applicable to work by other Digital Bridge workgroups)</li> </ul>
<b>Inner setting</b> , including the organization’s structure (e.g., size, maturity, age), social and communication networks, culture, and receptivity to change	<ul style="list-style-type: none"> <li>• Organization characteristics</li> <li>• Leadership</li> <li>• Environment</li> </ul>	<ul style="list-style-type: none"> <li>• Implementation site characteristics</li> </ul>

<sup>2</sup> Based on systematic reviews published by Cresswell & Sheikh (2013), Rippen, et al. (2013), and Nguyen, Bellucci, & Nguyen (2013).

<sup>3</sup> See Section 6.3 for additional detail.

CFIR Constructs	Similar Constructs Used in Other Studies <sup>2</sup>	Relevance to Current Evaluation <sup>3</sup>
<b>Characteristics of individuals</b> , including their knowledge and beliefs around the intervention, their ability to implement the intervention, their stage of change, and other personal attributes	<ul style="list-style-type: none"> <li>• Technical skills</li> <li>• Psychological, including readiness for change and willingness to adopt</li> <li>• Stakeholder involvement</li> </ul>	<ul style="list-style-type: none"> <li>• Implementation site characteristics</li> </ul>
<b>Process</b> , including the planning, engagement of appropriate individuals throughout the implementation, execution, and evaluation	<ul style="list-style-type: none"> <li>• Change process</li> <li>• Use of data/system</li> <li>• Workflow redesign</li> <li>• Implementation cycle (e.g., planning, implementation, evaluation, optimization)</li> </ul>	<ul style="list-style-type: none"> <li>• How eICR/RRs are used</li> <li>• How core components are implemented at each site</li> <li>• Implementation stages</li> </ul>

Each of these constructs have components within them that could be considered facilitators or barriers to an implementation. Many of the constructs identified in the CFIR will be measured, including the intervention characteristics, the inner setting (e.g., organization’s prior experience with eCR), and the implementation process for each implementation site (see Section 6.3). These factors, considered both facilitators and barriers to the implementation process, are the basis for evaluation questions 2 and 3 (see Section 6.2).

One study cited frequently during the evaluation planning explored the implementation of a clinical decision support service across multiple sites (Wright, et al., 2015). This qualitative research identified lessons learned over the course of the implementation across several dimensions, including challenges related to the hardware, infrastructure, clinical content, and user interface; the benefits of peer-to-peer communication; and the impact of the organization’s internal policies, procedures, culture, and environment. The importance of lessons learned during the implementation process is one of the foci of this evaluation (evaluation questions 1, 3, 4, and 9). In addition, the researchers conducted baseline interviews in-person with a variety of clinical and IT staff. Follow-up interviews were primarily conducted via webinar after the implementation was complete.

The Wright study is not alone in its use of interviews to evaluate health IT implementations. A systematic review of 98 health IT evaluations found that the most common methods of data collection were questionnaires, interviews, and focus groups (Nguyen, Belluci, & Nguyen; 2014). Consistent with published research, this evaluation will use interviews to gather information.

While the primary method of analysis for the majority of reviewed papers was quantitative, roughly a third used qualitative analysis (Nguyen, et al.; 2014). Over 80 percent of reviewed papers reported either qualitative or quantitative analyses of individuals’ subjective perception when using the health IT

product; fewer than 10 percent relied solely on objective data collected through observation, use of secondary data, or review of existing documentation. This evaluation anticipates using a mixed methods approach to both data collection and analysis and will leverage both qualitative data using primary data collection methods and quantitative analyses that take advantage of secondary data sources as available (see Section 6.3).

Outcomes frequently evaluated in health IT implementations include impacts to quality, efficiency, costs, time, and user satisfaction (Rippen, Pan, Russell, et al., 2013; Nguyen, et al., 2014), some of which correlate to the evaluations of public health surveillance systems (data quality, timeliness, and acceptability). Included in this evaluation will be examination of data quality, time, costs, and user satisfaction (evaluation questions 2, 5, 6, and 7).

## Evaluation Stakeholders

Interest in this evaluation ranges across several stakeholder groups<sup>4</sup>. Each group has a specific perspective, set of needs, and evaluation role (Table 3). The evaluator will engage these stakeholder groups throughout the evaluation to ensure that their needs are met.

**Table 3. Stakeholder Assessment and Engagement Plan**

Stakeholder	Primary Intended Users of the Evaluation?	Participation in and Uses of the Evaluation
Digital Bridge Governance Body	Yes	<ul style="list-style-type: none"> <li>• Approve the evaluation plan</li> <li>• Receive and disseminate the evaluation report and recommendations for action</li> </ul>
Digital Bridge Evaluation Committee	Yes	<ul style="list-style-type: none"> <li>• Contribute to development of the evaluation plan and instrumentation</li> <li>• Present updates and interim results to the governance body</li> <li>• Work with the evaluators to develop a final report</li> <li>• Aid in selection of an evaluation team</li> <li>• Support implementation sites and evaluation team during evaluation planning and implementation</li> </ul>
Digital Bridge Implementation Sites	Yes	<ul style="list-style-type: none"> <li>• Provide input and feedback on the development of the evaluation plan</li> <li>• Provide data needed for the multisite evaluation</li> <li>• Contribute to the interpretation of results</li> <li>• Review final report</li> </ul>
Digital Bridge member organizations	Yes	<ul style="list-style-type: none"> <li>• Use evaluation results to support ongoing development of the Digital Bridge eCR approach</li> </ul>
State and local public health departments	No	<ul style="list-style-type: none"> <li>• Use evaluation results to inform future initiation and implementation of eCR in relevant jurisdictions</li> <li>• Does not include those affiliated with the implementation sites</li> </ul>
Health care organizations	No	<ul style="list-style-type: none"> <li>• Use evaluation results to inform future initiation and implementation of eCR in relevant jurisdictions</li> <li>• Does not include those affiliated with the implementation sites</li> </ul>

<sup>4</sup> As Rossi, Freeman, and Lipsey explain (1999, p. 2), Stakeholders are “individuals, groups, or organization having a significant interest in how well a program functions, for instance, those with decision-making authority over it, funders and sponsors, administrators and personnel, and clients or intended beneficiaries.”

Stakeholder	Primary Intended Users of the Evaluation?	Participation in and Uses of the Evaluation
Health IT developers	No	<ul style="list-style-type: none"> <li>• Use evaluation results to inform future initiation and implementation of eCR in relevant jurisdictions</li> <li>• Does not include those affiliated with the implementation sites</li> </ul>
Evaluator	No	<ul style="list-style-type: none"> <li>• Evaluation plan and tool development; data collection and analysis in collaboration with the implementation; results synthesis; interim and final report development</li> </ul>

## Evaluation Purpose and Goals

The Digital Bridge governance body requested that an evaluation be conducted of the Digital Bridge eCR approach across participating implementation sites. The governance body's key goals were to 1) assess implementation site satisfaction with the Digital Bridge eCR approach and 2) estimate resources needed to implement the approach. An evaluation committee was formed and charged with overseeing, coordinating, and advising evaluation activities of the Digital Bridge eCR approach (Digital Bridge, 2017d). One committee objective is to advise the development of an integrated plan for evaluation activities that will inform Digital Bridge governance body decisions.

In keeping with the governance body's goals for the evaluation, the committee identified and approved the following evaluation goals informing the development and implementation of the evaluation plan:

1. Identify and describe the overall processes by which the sites initiated and implemented eCR and the various factors that influenced the processes
2. Determine eCR functioning and performance in terms of:
  - a. System/core component functionality and performance
  - b. Case reporting quality and performance (completeness, accuracy, timeliness)
3. Identify the resources needed to initiate and implement an eCR system
4. Identify the potential value and benefits of eCR to stakeholders

The multisite evaluation plan is designed to address these goals and provide the governance body—as well as other individuals or organizations interested in the implementation of eCR—with reliable information to inform decision-making related to the continued development of the Digital Bridge eCR approach.

## Evaluation Methods

### Evaluation Approach

This evaluation plan is based on a formative and process-oriented approach. When a new program or activity is being developed, the goal of a formative evaluation is to clarify program logic or change theory, identify internal and external influential factors, and improve design and performance before broader dissemination and implementation of the program occurs (Rossi, Freeman, Lipsey, 1999). The goals of process evaluation are to illuminate and understand the processes of, and relationships among, the component parts of a program or system, and to determine if the program or system is working as intended or expected (Linnan and Steckler, 2002; Patton, 1990).

Formative evaluations that include a focus on process provide useful information to stakeholders who need to understand how a program or system operates to make informed decisions for further development and improvements. As the Digital Bridge continues to develop its eCR approach, the evaluation is designed to utilize the experiences of the implementation sites to inform that ongoing development. This evaluation plan and its development were guided by the CDC Framework for Program Evaluation (1999).

### Evaluation Questions

There are 10 evaluation questions<sup>5</sup> guiding the multisite evaluation of the Digital Bridge eCR implementations. Each is linked to one of the evaluation goals (Table 4).

1. How are core components of eCR initiated and implemented in participating sites?
2. What were the facilitating and inhibiting factors related to eCR initiation and implementation?
3. How were the inhibiting factors addressed?
4. To what extent were the sites able to successfully develop and implement the core components to completely apply the Digital Bridge eCR approach?
5. To what extent is eCR case finding complete, accurate, and timely?
6. To what extent is the information in the eICR complete and accurate?
7. What were the costs associated with the initiation and implementation of eCR in the sites?
8. To what extent did eCR improve (or hinder) surveillance functions in implementation sites?
9. What are the strengths and weaknesses of the Digital Bridge eCR approach(es) for digital information exchange and use?
10. To what extent does eCR add value to health care and public health practice in implementation sites?

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<sup>5</sup> As Rossi, Freeman, and Lipsey explain (1999, p. 78), "Evaluation questions define the issues that the evaluation will investigate and are stated in terms such that they can be answered in a way useful to stakeholders using methods available to the evaluator."

These evaluation questions were identified and developed by the committee, along with review and input from the implementation sites. An initial draft of the evaluation questions and related indicators was shared with the implementation sites. Based on feedback from the sites on those draft questions and indicators, plus additional follow-up meetings with the implementation sites, the questions were revised and finalized by the committee.

Each evaluation question is associated with one or more indicators, i.e., the concepts that will be measured to answer the evaluation questions (Wingate, 2017). Appendix C provides an evaluation planning matrix listing the indicators for each evaluation question, along with the associated data sources and data collection and analysis methods. If deemed necessary and acceptable by the committee, the evaluator can modify these questions or add new questions in consultation with the committee. The committee will review and approve all changes.

Evaluation questions 1-3 are linked to goal 1 and address the implementation processes employed by the implementation sites during the start-up and production stages as they apply the Digital Bridge eCR approach. These questions are intended to elicit information that can help refine and further develop that approach. Question 2 is intended to identify the factors that facilitated and inhibited initiation and implementation of eCR across the sites. These factors can include contextual features (technical, social, political, organizational, and economic) within and outside each site. Question 3 is related to question 2 and is intended to identify the ways stakeholders attempted to overcome inhibiting factors (i.e., barriers and challenges) identified during start-up and production stages, including those that were successful and unsuccessful. The indicators associated with these questions will rely on qualitative research methods to explicate the development and implementation processes relative to each of the core components of the Digital Bridge eCR approach.

Evaluation questions 4-6 are linked to goal 2 and address the functioning and performance of eCR in each of the implementation sites at the end of the start-up stage and throughout the production stage. These questions are intended to elicit information that can help determine the extent to which the implementation sites (1) successfully develop and implement the core components to completely apply the Digital Bridge eCR approach for each of the five conditions, and (2) produce valid and useful information to support surveillance for those conditions. The indicators associated with these questions include those intended to measure the functioning and performance of the core components and the associated IT systems (goal 2a, question 4), and how eCR provides complete, accurate, and timely information that successfully supports case investigations (goal 2b, questions 5-6).

Evaluation question 7 is linked to goal 3 and addresses the resources needed to establish eCR throughout the start-up and production stages. This question is intended to elicit information directly related to the governance body's interest in understanding resources needed to implement the Digital Bridge eCR approach. This question can also inform individuals and organizations interested in implementing eCR understanding of the potential range of associated costs, dependent on-site

characteristics, the conditions being reported on, and the challenges encountered. The indicators associated with these questions include those intended to measure labor and technology costs at baseline and during the start-up and production stages.

Evaluation questions 8-10 are linked to goal 4 and address the perceived value and benefits of eCR. These are overall, summative questions and are intended to address the governance body’s interest in understanding implementation site satisfaction with the Digital Bridge eCR approach. The answers for these questions will be based on the findings and conclusions drawn for the other evaluation questions, and will be developed using a collaborative interpretation process involving the implementation sites and committee (see Section 6.4).

Analyses of the data collected for these questions will be based in part on comparisons across the implementation sites, between sites grouped by shared characteristics (e.g., whether sites had previous experience with eCR), and across the five reported disease conditions (e.g., whether establishing eCR for a specific condition proved to be more challenging and costly than others). The implementation sites will be characterized in terms of key features and factors relevant to eCR using all available data sources.

**Table 4. Evaluation Questions, Data Sources, and Methods**

Evaluation Goals	Evaluation Questions	Data Sources/Methods
1. Identify and describe the overall processes by which the sites initiated and implemented eCR, and the various factors that influenced the processes.	1. How were Core Components of eCR initiated and implemented in participating sites? 2. What were the facilitating and inhibiting factors related to initiation and implementation? 3. How were the inhibiting factors addressed?	Key informant interviews: Stakeholders from the three main stakeholder groups in each site.
2. Determine eCR functioning and performance:		
a. System/Core Component functionality and performance	4. To what extent were the sites able to successfully develop and implement each of the Core Components to completely apply the Digital Bridge eCR approach?	<b>eCR validation and auditing:</b> Site documentation of validation and audit trails (e.g., eICR validator, RR constructor, AIMS Dashboard, CSTE evaluation documentation, on-boarding documentation)

Evaluation Goals	Evaluation Questions	Data Sources/Methods
<p>b. Case reporting quality and performance (completeness, accuracy, timeliness)</p>	<p>5. To what extent is eCR case finding complete, accurate, and timely?</p> <p>6. To what extent is the information in the eCR complete and accurate?</p>	<p><b>Case Reporting Quality and Performance Assessment:</b> eICRs received by the public health agencies compared to existing case records, including ELRs and pre-existing case reporting, to determine completeness, accuracy, and timeliness of the eCR</p>
<p>3. Identify the resources needed to initiate and implement an eCR system</p>	<p>7. What were the costs associated with the initiation and implementation of eCR in the sites?</p>	<p><b>Documenting costs:</b> labor and technology cost data obtained from participating organizations</p> <p>Use Association of State and Territorial Health Officials (ASTHO) Return on Investment (ROI) tool to document and sum all relevant costs per site (planning, development, and routine operating) (ASTHO, n.d.)</p>
<p>4. Identify the potential value and benefits of eCR to stakeholders</p>	<p>8. To what extent did eCR improve (or hinder) surveillance functions in implementation sites?</p> <p>9. What are the strengths and weaknesses of the Digital Bridge eCR approach(es) for digital information exchange and use?</p> <p>10. To what extent does eCR add value to health care and public health practice in implementation sites?</p>	<p>Overall, summative questions to be answered using findings from all other evaluation questions using a collaborative process involving implementation sites and the evaluation committee.</p>

## Data Sources and Collection Methods

The evaluation plan is based on a mixed-methods design consisting of several distinct components—each with its own data sources and methods—aimed at addressing the evaluation goals and questions.

- **Key informant interviews (KII):** qualitative interviews with stakeholders in each site, focused on addressing evaluation questions 1-3 (Section 6.3.1)
- **eCR validation and auditing:** review of documented results of eCR validation checks and audit trails (Section 6.3.2)
- **Case reporting quality and performance assessment:** comparison of eICRs to existing records (Section 6.3.3)
- **Documenting costs:** documentation of the costs of initiating and implementing the Digital Bridge eCR approach in each implementation site from start-up to production stages, including labor and technology investments (Section 6.3.4)
- **Identifying site characteristics:** documentation and assessment of implementation site characteristics relevant to initiating and implementing the Digital Bridge eCR approach from start-up to production stages (Section 6.3.5)

### Key Informant Interviews

With the evaluation approach being primarily formative, the evaluator will use qualitative research methods to collect and analyze data to address evaluation goal 1 (evaluation questions 1-3). Given that the Digital Bridge eCR approach uses new infrastructure and standards, much of which have not yet been tested or piloted, the evaluation of the implementation sites' eCR activities represents an opportunity to inform that ongoing development. Qualitative methods provide the necessary flexibility and detail to address the evaluation goals and questions. The evaluator will document processes as they unfold at each site and highlight potential best practices and lessons learned that would not be discovered with other methods.

The evaluator will use **key informant interviews** (KIIs) as the qualitative data collection method for this component of the plan. In-depth, semi-structured interviews with site leaders (key informants) at each implementation site will allow the evaluator to learn about the Digital Bridge eCR process. These may be conducted twice for maximum benefit.

#### ***Purpose***

The evaluator will conduct semi-structured interviews with individual stakeholders knowledgeable about the processes by which each site initiated and implemented the Digital Bridge eCR approach. The purpose of the KIIs is to collect and analyze data that facilitates an understanding of the eCR initiation and implementation processes employed by the implementation sites (evaluation goal 1, questions 1-3), including unintended or unexpected processes, outcomes, and side effects of the Digital Bridge eCR approach.

### ***Timing***

If resources allow, the KIIs should be conducted at two time points during the evaluation:

- **End of Start-up Stage.** As each site reaches the end of the start-up stage and transitions to the exchange of live digital information, the evaluator will initiate the first round of participant recruitment and data collection. By querying participants about their implementation activities closer in time to when they were conducted, recall bias should be limited. It is also a useful point to understand participant expectations about what will happen during the production stage.
- **End of Production Stage.** There may be some ongoing refinement of how eCR core components are implemented at each site during the production stage. To capture any new changes, as well as participants' perspective on the value and impacts of eCR, KIIs should be conducted at a pre-determined time point in this stage.

If resources do not allow data collection at two time points, then the evaluator will conduct the KIIs at a single time point, i.e., during the early to middle part of the production stage, or approximately 3-5 months after the end of the start-up stage. This will minimize recall bias by keeping data collection relatively close to the start-up stage, while allowing sufficient time to pass during the production stage to capture the continued refinements that may be needed.

### ***Participants and sampling***

The evaluator will conduct the KIIs with individuals representing the three stakeholder groups involved in eCR implementation at each of the sites (public health agencies, health care organizations, and health IT developers). Each implementation site has designated site leaders from each of the stakeholder groups and the minimum goal will be to conduct interviews with all the site leaders. Some jurisdictions have more than one site leader per stakeholder group (e.g., state and local public health organization site leaders; EHR and health information exchange [HIE] developers). During recruitment of KII participants, the evaluator will also ask site leaders for recommendations on who within their team could also be interviewed to develop a more complete picture of the Digital Bridge eCR implementation processes. If there are recommendations, these additional staff will be included in the recruitment process.

The minimum number of KIIs per site is three, assuming only three site leaders and no additional stakeholders are recommended for participation. The actual number of KIIs for a given site could be higher, depending on the number of site leaders and their recommendations for other participants.

### ***Recruitment***

The evaluator will develop email invitations, informed consent materials, and other recruitment materials in consultation with the committee. The initial email invitation will explain the purpose of the overall evaluation and about the interview. Prior to issuing invitations, site leaders will be asked to

notify their recommended individual(s) about nomination for the study. The evaluator will conduct follow-up with invitees who did not respond to the initial invitations to ensure all potential participants received the invitation. This follow-up may include at least one additional email invitation. Because email is not always sufficient for successful recruitment, telephone calls may be necessary to fully determine willingness to participate.

### ***Data collection***

One-hour KIIs will be conducted over the telephone by a two-person team: (1) an interviewer with extensive experience in qualitative interviewing and (2) an assistant with experience supporting qualitative data collection. Each KII will be digitally recorded and the assistant's notes will serve as back-up documentation (or primary documentation if a participant does not agree to audio recording). The assistant will manage the audio recordings (using two recorders to prevent loss of data due to equipment malfunction) and document the main ideas and key themes in the responses. If there is more than one interview team, all team members will be trained by a lead evaluator to ensure consistent implementation of study procedures and interview guides.

The KIIs will be conducted using a semi-structured master interview guide that includes largely open-ended questions and probes aligned with the evaluation goals, questions, and related indicators (see Appendix C). This type of interview guide ensures important questions and topics are fully addressed, while providing flexibility in the depth and breadth of information gathered. The interview guide facilitates information probing on important topics and learning about and discussing unanticipated impacts or activities. If necessary, separate interview guides can be developed for each stakeholder group based on the relevant questions in the master guide.

Within 24 hours of the KII, the interview team will debrief using the assistant's notes as a reference. An initial version of the qualitative analysis codebook will be developed from these initial key theme impressions and may serve as the basis for stakeholder briefings on preliminary results.

### ***Human Subject Protections and Informed Consent***

The evaluator and committee will work with the Digital Bridge PMO to ascertain if Institutional Review Board (IRB) approval is necessary for the evaluation.

Prior to the start of each KII, the interviewer will read the introduction and the informed consent statement (provided during recruitment and scheduling). The informed consent statement will explain how participant confidentiality will be protected and how data will be managed and reported. Participants will be asked if they have any questions, and if so, those questions will be answered before the KII is conducted. Participants will be asked to provide verbal consent for participation after the statement has been read and their questions answered. Participants will also be asked for permission to audio record the interviews.

The interview transcripts will not reference participants' names, though they may contain other forms of personally identifiable information (PII) discussed during the sessions. These other forms of PII will not be edited as they may be needed to provide sufficient contextual information for data analysis and interpretation. Access to the audio recordings and transcripts will be limited to the evaluator who will be involved with data collection, management, and analysis.

### ***Data Management***

The audio recordings of the KIIs will be used to prepare verbatim transcriptions. All transcripts will be structured and formatted in a consistent manner to facilitate data management and analysis. Questions in the transcripts will link to the appropriate interview guide questions using a reference number provided in the guides. Speakers will be clearly identified using generic labels (e.g., "interviewer" and "respondent"). The transcriptionist will be instructed to clearly mark places where speakers' statements are not clear or where the identity of a speaker is not clear.

To ensure accuracy and completeness of the transcripts, members of the interview team will review each KII transcript. For the places marked unclear by the transcriptionist, or for sections where the transcriptionist may have made an error, they will review the relevant audio recording sections and make corrections as needed.

Audio recordings and transcripts will be stored electronically on an access-restricted, password-protected data storage site. Only authorized evaluation team members will be allowed access to the storage location. Recordings and transcripts will not be released to anyone outside the evaluation team. Study participants' PII will not be released or included in any reports or presentations.

### ***Data Analysis***

The evaluator will use qualitative analysis methods to identify and describe the themes and patterns in the data for each indicator across individuals, stakeholder groups, and implementation sites. While there are *a priori* concepts guiding the questions being asked, the evaluator will apply an inductive approach to identify unanticipated or emergent themes and look for similarities and differences among participants, groups, and sites relative to the evaluation goals and questions.

The evaluator will develop a systematic coding scheme to categorize the KII data relative to the appropriate indicators. As noted, team debriefings immediately following each interview will be used to document preliminary ideas for general themes and specific codes. The debriefing notes will form the basis of a preliminary codebook that will serve as the starting point for analysis of all transcripts. New themes will be added to the preliminary codebook as they emerge during the data review and analysis process, and all data sources will be coded appropriately according to the final coding scheme. This

coding approach will allow the evaluator to identify both anticipated and emergent themes, accounting for all relevant categories found in the data.

The evaluator will use qualitative analysis software (e.g., NVivo®, Atlas/ti®, Dedoose®) to facilitate data management and analysis and to maintain documentation of analyses performed.

The evaluator will take steps to ensure that the results of the qualitative analyses are trustworthy. First, several steps will be taken to ensure that the coding of site visit data is credible and as consistent as possible.

- Training for the analysts will include a review of the analytical procedures, including a discussion of codebook development to ensure that codes are well-specified in a common format.
- Prior to analysis of the complete data set, the analysts will independently code the same set of transcripts (3-5). A comparison of coding patterns across the analysts will highlight differences or inconsistencies in coding practices. The analysts will jointly review the coding results, discuss and reconcile those differences, and update code definitions to ensure consensus on meanings before analysis begins. The lead evaluator will assist with the reviews and arbitrate disagreements or discrepancies. Periodic double-coding and review will help ensure that the analysts maintain consistency over time.
- As new themes and codes are identified, analysts will add those codes and their definitions to the codebook, and will discuss the new codes with the other analysts through regular analysis meetings to ensure that similar codes are used consistently across the cases and can be applied to the multiple case analyses.

Second, the evaluator will take steps to ensure that the findings accurately reflect the processes and experiences of the implementation sites.

- Data collection team members not involved with analysis will review and confirm draft findings and provide feedback
- Site leaders from each of the implementation sites will be invited to review and provide feedback on the draft findings as an added check on information accuracy

### **eCR Validation and Auditing**

The indicators presented in this section relate to evaluation goal 2a (question 4), which address whether the eCR infrastructure and standards are working as intended. Because the program being evaluated involves electronic exchange of information, there are existing data sources that can inform the evaluation of system and core component functionality and performance (evaluation goal 2a, question 4). Many of these consist of audit trails, system validators, and other system records that measure

movement of information and data processing activities. Table 5 lists indicators for each core component that will leverage system validation and auditing documentation. Core components G1 and G2 (Figure 1) are excluded here because they are addressed in the key informant interview and case reporting quality and performance assessment sections of this document.

Further description of the data sources and collection methods are in Table 5 organized by core component. All data identified in this section will be reported to the evaluator by the implementation sites following a guidance document developed by the evaluator and approved by the committee. That guidance document will define the structure and format of the data file. The frequency of data aggregation and submission—described below as “regular intervals”—must be determined prior to the beginning of the production stage and should be consistent for all implementation sites. Indicators for which measurement is taken twice (baseline and at the end of the study period) are deemed potentially too burdensome to measure more frequently.

**Table 5. System Performance Indicators that will Leverage IT Validation and Auditing Documentation**

Core Component <sup>6</sup>	Indicators	Data Sources/Methods
<b>Trigger code alignment</b>	<ul style="list-style-type: none"> <li>• Proportion of trigger code concepts represented by standard codes</li> <li>• Proportion of local codes identified during the alignment analysis that were mapped to codes in RCTC</li> </ul>	<ul style="list-style-type: none"> <li>• Extract from health IT product</li> </ul>
<b>Application of trigger codes</b>	<ul style="list-style-type: none"> <li>• Proportion of encounters for which an eICR was sent to AIMS platform</li> </ul>	<ul style="list-style-type: none"> <li>• Extract from health IT product, aggregated at regular intervals</li> </ul>
<b>Creation of case report</b>	<ul style="list-style-type: none"> <li>• Proportion of eICRs received by AIMS that were error-free</li> </ul>	<ul style="list-style-type: none"> <li>• Extract from AIMS dashboards</li> </ul>
<b>Reporting criteria analysis and authoring</b>	<ul style="list-style-type: none"> <li>• Proportion of each condition’s default criteria used</li> <li>• Proportion of RCKMS criteria that match across sites</li> <li>• Number of refinements made to criteria</li> <li>• Number of new criteria added</li> </ul>	<ul style="list-style-type: none"> <li>• Extract from RCKMS</li> </ul>
<b>Adjudication using jurisdictional-specific rules</b>	<ul style="list-style-type: none"> <li>• Proportion of eICRs received by RCKMS that were determined to include a reportable condition</li> </ul>	<ul style="list-style-type: none"> <li>• Extract from AIMS dashboards</li> </ul>

<sup>6</sup> See Figure 1 for definitions of each Core Component.

Core Component <sup>6</sup>	Indicators	Data Sources/Methods
<b>(F1) Consumption of electronic case report</b>	<ul style="list-style-type: none"> <li>Proportion of eICRs sent to public health agencies that were consumed by the public health surveillance system</li> </ul>	<ul style="list-style-type: none"> <li>Numerator data will be extracted from public health surveillance system</li> <li>Denominator data will be extracted from the AIMS platform</li> </ul>
<b>(F2) Consumption of reportability response document</b>	<ul style="list-style-type: none"> <li>Proportion of Reportability Response documents sent to public health agencies that were consumed by the public health surveillance system</li> <li>Proportion of Reportability Response documents sent to health care organizations that were consumed by the health IT product</li> </ul>	<ul style="list-style-type: none"> <li>Numerator data will be extracted from public health surveillance system</li> <li>Denominator data will be extracted from the AIMS platform</li> </ul>

**Trigger code alignment.** The trigger code alignment indicators are intended to demonstrate that standard or local codes in the health IT products were mapped or matched to codes in the RCTC list. While the ideal performance measures would include a complete system audit to determine if any codes in the health IT product were missed during the alignment process, the committee deemed this to be too burdensome.

By taking these measurements at baseline (during start-up stage) and at the end of the study period (during production stage or at a time to be determined by the committee and evaluator), a comparison can be made as to the efficacy of the initial alignment process. A delta of zero could indicate that the initial alignment process was sufficient, while a non-zero number would be indicative of some post-production modification to the initial alignment process. These data will be provided by the health IT developers at each site and should be retrievable from their system audit trails or validation processes.

**Application of trigger codes.** The application of trigger codes indicator is a proxy measure for whether the health IT system is identifying RCTC matches. Note that the term “encounters” may be interpreted differently by health IT developers and it will be important during the tool development phase to identify a definition that can be used consistently across sites to allow for comparability. Use of a percentage measure for this indicator provides context of the frequency of matches given the number of encounters in the system during the study period. Data collection should be aggregated at regular intervals or reported at the conclusion of the study period aggregated for those intervals.

Measurement over time provides information on rate changes and can be matched alongside any site-reported changes in the trigger code alignment process, as well as comparisons across sites in conjunction with information collected for other indicators (e.g., evaluation questions 1, 2b, and 3).

These data will be provided by health IT developers based on audit logs that identify which encounters created during the study period have record of at least one associated eICR.

**Creation of case report.** Although the ideal measurement for this component would be an audit of health IT product data to determine if all information from the health IT product were included appropriately in the eICR, the committee determined early on that would be too burdensome. As a proxy measure, data from the AIMS platform will be leveraged to evaluate the rate with which the eICRs created by the submitting health IT product have formatting errors. Refinement of this indicator may be necessary during the tool development phase because APHL was unable to validate this indicator during the evaluation planning stage.

The AIMS platform has a dashboard that tracks the receipt and status of electronic documents. Before routing eICRs to RCKMS for adjudication, AIMS validates each document to confirm that it is formatted correctly. The indicator presented for this core component is premised on the assumption that data collection could be aggregated from the AIMS dashboard at regular intervals or reported at the conclusion of the study period aggregated for those intervals. Measurement over time provides information on changes in the error rate and can be correlated to any site-reported modifications in their system associated with eICR creation. These data may also be used to compare across sites when used in conjunction with information collected for other indicators (e.g., evaluation questions 1, 2b, and 3). It is also assumed—but must be validated by APHL during the tool development stage—that data will be reported separately for each implementation site by APHL and should be retrievable from their AIMS dashboards.

**Reporting criteria analysis and authoring.** The indicator associated with reporting criteria analysis and authoring will provide proxy information on the how well the RCKMS default criteria meet public health agencies' requirements and what changes are being requested and made to RCKMS to accommodate different public health agencies requirements. RCKMS' default criteria were developed by CSTE for each condition based on the position statements and refinements through public health community input. Refinements to the default criteria may entail addition of more specific requirements (e.g., a time element to the default criteria). The findings from these indicators should be paired with qualitative information learned through the KIIs about what the requested changes were made and why they were requested.

While the first two indicators in this section (beginning with “proportion”) would be measured twice—once before the production stage starts and again at the end of the study—the last two (beginning with “number”) would be measured at the end of the study period. It is also expected that these indicators would be stratified by some combination of condition, code type (e.g., diagnosis, lab order, lab test, organism name), or refinement category. The indicator that examines the proportion of RCKMS criteria

that match across states could be reported out in a correlation matrix or heatmap view. These data would be provided by CSTE for each public health agency.

**Adjudication using jurisdictional-specific rules.** The indicator for adjudication using jurisdictional-specific rules will also rely on data from the AIMS dashboards, although refinement may be necessary during the tool development phase because APHL was unable to provide validation of this indicator during the evaluation planning stage. The proportion will include the total eICRs that were error-free and could therefore be adjudicated by RCKMS and of those, the number of eICRs that were sent to the public health agency. Data collection should be aggregated at regular intervals across the study period or reported at the conclusion of the study period aggregated for those intervals.

Measurement over time provides information on rate changes that may be matched alongside any site-reported changes in the preceding core component steps for context. Stratification for this indicator must be defined based on data availability and burden of data compilation efforts during the tool development phase. This indicator should be measured separately for each implementation site. APHL will use the existing data from their AIMS dashboards for these measurements.

**Consumption of electronic case report and reportability response documents.** The definition of “consumed” for these indicators is in accordance with the definition for the core component (see Figure 1). The indicators for core components F1 and F2 may rely on data from three different sources. Data on the denominator (number of documents sent to the public health agency or health care organization) should be available through the AIMS dashboards. The numerator (number of documents consumed by the public health surveillance system or health IT system) would be provided by the receiving entity.

These data should be collected on regular intervals throughout the study period or reported at the conclusion of the study period aggregated for those intervals. These measurements will provide information on whether and how many electronic documents were consumed by the receiving IT systems (public health surveillance system or health IT product) and whether those rates change over time in response to other changes in the eCR process. Comparisons across sites may also be possible, especially when used in conjunction with information collected relative to evaluation questions 1, 2b, and 3. The receiving IT systems’ audit trails should provide sufficient documentation for these measures.

### Case Reporting Quality and Performance Assessment

Sections 3.2 and 3.3 describe standard indicators used in evaluations of public health surveillance systems and health IT implementations. The evaluation will address how well the Digital Bridge eCR approach fulfills public health surveillance functions by assessing the timeliness, completeness, and accuracy of electronic case reports and their components.

- **Completeness and accuracy** pertain to both the case report and to information elements within the case report. These indicators should be specified in a manner that ensures they can be used to quantify the extent to which electronic case reports serve the needs of public health agencies (see Section 6.3.1).
  - **Case finding completeness and accuracy:** the ability of the system to maximize the number of reportable cases identified while minimizing false reports.
  - **Information completeness and accuracy:** the ability of the system to produce case reports that are valid and reliable for initiating case investigation.
- **Timeliness** refers to the ability of the Digital Bridge eCR approach to produce reports that meet regulatory requirements and perform at least as well as the manual case reporting process.

Each of the indicators discussed in this section requires a comparator, usually another data source, with which to assess the performance of the Digital Bridge eCR approach. This section describes the indicators developed for questions 5 and 6, discusses options for operationalizing them, and the potential limitations related to data accessibility identified by the sites.

To evaluate performance of the Digital Bridge eCR approach at each implementation site and for each of the five targeted reportable conditions, case findings through the Digital Bridge eCR approach will be compared against existing records including ELRs; cases reported by phone, mail, fax or other manual modalities, hereafter identified as “manual reporting;” other eCR processes; and medical chart reviews. Across all events, the measures should consider only those events for which the individual had an encounter at the implementation health care organization.

Indicators addressing the performance and quality objectives for evaluation goal 2b, questions 5 and 6, are defined below. These indicators are also summarized in Appendix C. Where data type, collection, and quality are consistent across sites, the information from these indicators may be used to draw comparisons based on site characteristics (see Section 6.3.5). In addition, specific findings for each indicator can be aligned with information learned during the interviews (see Section 6.3.1); this would provide context for cross-site differences and help to identify best practices and lessons learned. Each indicator is given a high or low priority based on importance, and feasibility or burden associated with the approach.

- **High-priority indicators:** central to surveillance functions; have accessible, relatively low-burden options for comparator data with which to assess performance; and can be clearly specified based on input received from stakeholders to date.
- **Low-priority indicators:** cannot be clearly specified based on the current understanding of public health needs related to information completeness and accuracy, require highly burdensome data collection to accomplish, or both. In these cases, while importance might be high, feasibility and definitional issues could outweigh the value of the information obtained.

More detail about the priority status is provided in the indicator descriptions and in Section 6.3.3.3.

### ***Data Collection and Analysis***

Most data will be readily accessible as extracts from electronic sources. Manual review and data collection would only be needed for indicators requiring chart review. Sampling will not be required for most indicators since eCR and comparison data in the surveillance data systems can be extracted in their entirety (i.e., a census), and no additional burden is associated with analyzing all data versus a sample. Exceptions would be indicators that rely on medical chart review (i.e., indicator 6.2).

Manual chart review for data collection is a high-burden activity, and for conditions where cases reported are high in number, sampling could be more efficient than using a census. Sampling should be stratified by condition and preliminary criteria for sampling within conditions include the health system where the patient sought care (including EHR system in use), provider type, and basic patient characteristics such as age, sex, and perhaps area of residence.

Quantitative data analysis will be used for all indicators, with proportions or mean differences calculated for each. A radar (spider) chart may be utilized to show overall performance for most, if not all, indicators in this section.

For each of these indicators, there is value in defining regular intervals in extracted data (as opposed to analyzing data aggregated across the entire study period) so that any rate changes could be evaluated directly as a function of time (e.g., time since production stage started), as well as matched against information learned from the key informant interviews (see Section 6.3.1) about changes in processes, thereby identifying potential impacts from those process changes. The frequency of “regular intervals” must be determined prior to the production stage and should be consistent for all implementation sites. More discussion with sites is needed to define specific timeframes for data collection, and these would be determined in part by when each site is ready for production. However, it is anticipated that most data required for these indicators could be extracted retrospectively at any time from data systems or medical records.

In addition, there is value in obtaining individual records (rather than data aggregated across an entire site) whenever possible, as this allows for flexibility in defining the indicators and performing analysis. However, more discussion is required with implementation sites to determine feasibility of this approach, since providing individual records might impose additional burden related to de-identification of records before they are shared with the evaluator.

### ***Indicators Associated with eCR Case Finding Completeness, Accuracy and Timeliness (Evaluation Question 5)***

#### ***Proportion of reportable events that should have been identified that were reported through eCR (i.e., true positives) (Indicator 5.1)***

- **Numerator:** events received by public health agencies via the Digital Bridge eCR approach that met reporting regulations
- **Denominator:** all reportable events for which the individual had an encounter at the implementation health care sites that met reporting regulations

This **high priority** indicator measures the ability of the eCR process to accurately identify and transmit an eICR with reportable conditions to the appropriate public health agency. A proportion close to 100 percent indicates that most reportable events were identified.

While the numerator of this indicator will remain consistent (reportable events identified by eCR), how the denominator is operationalized depends on the accessibility of suitable data, balancing feasibility with rigor and generalizability (i.e., the ability of an approach to support comparisons across sites). Additional discussions are necessary with implementation sites to determine the specificity with which they can identify reporting sources (e.g., distinguish between ELR, manual, and eCR and can identify the submitting organization for each). Options for consideration for the universe of all reportable events (considering that only those events in which the case had an encounter at the implementation health care organization), in order from potentially least to most burdensome for data collection, are:

- All reportable events identified through ELR and eCR.
- All reportable events identified in the public health surveillance system, which would include all events reported to public health that were identified through any of the reporting mechanisms mentioned previously.
- All reportable events as identified at the implementation health care organization through a medical chart review. This option was noted by many implementation sites to be very burdensome (even using a sample) and could take significant time to establish appropriate permissions and IRB approval.

***Proportion of eICRs received by public health via the Digital Bridge eCR approach that did not contain an event requested by public health (i.e., false positives) (Indicator 5.2)***

- **Numerator:** events reported through eCR that were revoked following a case investigation, as recorded in the public health surveillance system
- **Denominator:** events reported through eCR

This **high priority** indicator measures the accuracy of case finding through the Digital Bridge eCR approach and is intended to measure the rate at which false positive events—those events that public health should not be notified about—are occurring. These false positives might be the result of failures at any one of several eCR core components. For this indicator, values close to zero are desirable since low values indicate the occurrence of few false positives. Comparisons across sites (assuming data type, collection, and quality are similar) may facilitate an understanding of how implementation differences can impact the false positive proportions.

These data would be identified solely through records extracted from the public health surveillance system. The extract would include aggregated counts of events identified through the Digital Bridge eCR approach, by condition, and include aggregated counts by case status (i.e., confirmed, probable, suspect, revoked, or each jurisdiction's equivalent). Using aggregated counts should minimize identifiability of the information used for this evaluation.

***Proportion of reportable events that were not received by public health through the Digital Bridge eCR approach (i.e., false negatives) (Indicator 5.3)***

- **Numerator:** reportable events not received by public health via the Digital Bridge eCR approach
- **Denominator:** all reportable events for which the individual had an encounter at the implementation health care sites

This **high priority** indicator measures the ability of the Digital Bridge eCR approach to successfully identify and transmit all reportable events to public health agencies; a proportion close to 0 percent is desirable as it indicates few false negatives.

There was considerable discussion by the committee and implementation sites about the best strategy for data to address the numerator. As with indicator 5.1, a systematic review of EHR data is likely not feasible for most sites due to the associated high burden of data collection as well as anticipated challenges with gaining permission to access the records. Because the five conditions primarily rely on laboratory diagnosis for confirmation, the committee and implementation sites believe ELR would be a sufficient comparator and would balance feasibility with accuracy. In this option, the numerator would be operationalized as the events identified by ELR that were not also reported through eCR. As with indicators 5.1 and 5.2, the data would be extracted from the public health surveillance system

Finally, the options for operationalizing the denominator are the same as those specified for indicator 5.1. The first and second options listed may be feasible for sites, while the third option (chart review) would likely be beyond the capacity of most sites.

***Proportion of reportable events that were received by public health agencies in a timely fashion (Indicator 5.4)***

- **Numerator:** reportable events received through the Digital Bridge eCR approach within a defined timeframe, as indicated by receipt of a specified eICR
- **Denominator:** events reported through the Digital Bridge eCR approach

This **high priority** indicator measures the ability of the Digital Bridge eCR approach to successfully transmit initial case reports to a public health agency in a timely fashion; a proportion close to 100 percent indicates that most events transmitted through the approach were received in a timely fashion. The time of eICR receipt is determined by comparing the system timestamp logs of the date and time the eICR was received in the surveillance system to an encounter-relevant date and time (e.g., diagnosis date, encounter date, laboratory date). More discussion with implementation sites is needed to determine which eICR would be the most appropriate marker for timeliness.

There are several comparisons that could be made to evaluate timeliness and the numerator can be operationalized as needed to address the comparison of interest.

1. Timeliness with respect to the regulatory requirement for each condition: each public health jurisdiction has regulations specifying when each condition should be reported to a public health agency. Using surveillance system timestamps to identify when each eICR was received, the

time to report could be calculated as the time difference between an event-relevant date (e.g., diagnosis or laboratory date) and when the report was received in the public health surveillance system. The event-relevant date must still be determined based on additional discussions with the implementation sites about the feasibility and accuracy of the available options. Ideally the event-relevant date would be consistently used across implementation sites. This difference between the dates could be expressed as the proportion of reports meeting the regulatory timeframe, or as the mean difference between the time to receipt of the reports and the regulatory time frame. If the latter metric is employed, a negative mean difference would indicate that eICRs, on average, are received within the required timeframe. If the mean difference is used, a mean difference closer to zero would be preferable as it indicates a shorter time between a patient event and a report to a public health agency.

2. Timeliness with respect to other reporting mechanisms: for events in the public health system that have reports from multiple sources (i.e., ELR, manual reporting, other eCR mechanisms) comparing the difference in receipt times across each reporting source would permit an understanding of how the Digital Bridge eCR approach's timeliness compares to that of other reporting mechanisms. As with option one, this could be expressed as the proportion of cases for which the eICR for a case is received prior to a report received through a comparison mechanism (or the fastest of all comparison reports). It could also be expressed as the mean difference between the time to receipt of the eICR and time to receipt of the comparison report(s). In the latter example, a negative mean difference or one that is close to zero would be desirable as it indicates that eCR, on average, is notifying public health agencies at least as fast, if not faster, than current reporting mechanisms.

Further discussion with implementation sites is needed to determine the feasibility of option two; most implementation sites indicated during discussions that versions of option one are currently in use.

### ***Indicators Associated with eICR completeness and accuracy (Evaluation Question 6)***

#### ***Proportion of eICRs that were missing information from selected fields (Indicator 6.1)***

- **Numerator:** eICRs received by public health that are missing information from selected fields
- **Denominator:** specified eICRs received through eCR

This **low priority** indicator measures the ability of the Digital Bridge eCR approach to generate a case report containing complete information. A proportion close to 0 percent indicates that for most reportable events, the eCR system generates a report that contains all available data. This is a low priority indicator because of concerns related to feasibility, as well as the need for additional work to define it.

Implementation sites and committee members noted concern that this measure may be counter to the original concept of the eICR, which is that it is designed to send the minimal information necessary to initiate an investigation. In addition, the Digital Bridge approach is designed to create a longitudinal record as eICRs may be sent multiple times over a patient's illness event as new information is entered

into the health IT product that matches with RCTCs. As such, there is an expectation that data will be missing, some of which may be populated in subsequent eICRs.

Further discussion with sites is needed to determine the appropriate set of eICRs to include in the universe (i.e., the denominator), balanced with the feasibility of extracting data on all eICRs received. With respect to the appropriate universe for the denominator, choices could include all eICRs received, a random sample of eICRs, or the first or last eICR received for each reportable event (the last eICR is defined as the final eICR received prior to the case being closed). The numerator in each situation would include the eICRs that are missing data from at least one of the selected eICR fields. The committee, in partnership with the implementation sites, must develop consensus on which fields from the eICR should be examined for this evaluation, and what level of sensitivity to missing fields is relevant (e.g., is missing any one field important? Are certain fields so critical that they should never be missing?).

#### ***Proportion of eICRs with selected fields that were not the same as the source data (Indicator 6.2)***

- **Numerator:** eICRs received by public health agencies that contain information from selected fields that varies from the medical record
- **Denominator:** specified eICRs received through the Digital Bridge eCR approach

This **low priority** indicator measures the ability of the Digital Bridge eCR approach to generate a case report containing accurate information. A proportion close to 0 percent indicates that for most reportable events, the eCR process generates a report that contains only accurate data, i.e., the case report accurately reflects the source information. This is a low priority indicator because of concerns related to feasibility, as well as the need for additional work to define it.

As with indicator 6.1, further discussion with sites is needed to determine the appropriate set of eICRs to include in the universe (i.e., the denominator), balanced with the feasibility of extracting data on all eICRs received. Similarly, further discussion is needed to define the critical fields for which accuracy is essential, and the appropriate level of sensitivity to inaccurate data.

There are additional concerns with this indicator. The broad agreement among implementation sites was that the only valid means of checking the accuracy of eICR data would be to perform a chart review for at least a sample of eICRs. As noted above, chart review presents considerable challenges related to gaining access to EHRs and the burden of data collection, and as such may be infeasible for most sites. To the extent that the needed fields are readily available from an existing clinical data repository that sites can access, these barriers may be reduced. Additional discussion with implementation sites would be required to determine whether this is an option.

#### ***Refining Selected Indicators Through Formative Evaluation***

Several important definitional gaps for case reporting quality and performance indicators are documented above, especially for indicators 5.4, 6.1, and 6.2. These reflect gaps in understanding for some of the fundamental informational needs of implementation sites and public health agencies. The risk of operationalizing an indicator without this understanding is that the indicator, once calculated, adds no value to the targeted stakeholders. A full specification of these indicators requires additional

information; however, filling these gaps extends beyond the scope of the evaluability assessment performed to support this evaluation plan.

This evaluation will take the opportunity to use information gleaned while working with sites to inform and improve the ongoing evaluation. This formative evaluation will therefore be employed to investigate the informational needs. Once public health needs are better understood, this information can be used to operationalize several of the indicators outlined in this section. Better specification of indicators will allow performance to be quantified in a way that helps public health agencies make decisions.

Information relevant to definitional issues, such as determining which set of eICRs received for a case should be considered when determining timeliness, speaks directly to whether the product meets the needs of public health users. For example, can a case report that is missing critical fields meet the criterion for timeliness just because it comes quickly? What fields are critical for use? KIIs and collaborative interpretation for evaluation questions 8-10 are the recommended means for gathering this information.

### **Documenting Costs**

This evaluation will quantify the costs associated with initiation and implementation of the eCR Digital Bridge approach in each site (evaluation goal 3, question 7). Findings from this analysis may help other public health agencies determine whether they can support adoption of the Digital Bridge eCR approach. Documenting costs will provide the foundation for several sets of analyses for this and future evaluations. Data analyses for this evaluation will calculate:

- Labor- and technology-related costs of the implementation, with comparisons based on site characteristics, e.g., existing technology at each site (see Section 6.3.5)
- Changes in costs over time, including by implementation stage

The analyses that can be performed will depend on the granularity of available data, the availability of reliable estimates (if actual cost data are not accessible), and the timeframes for which cost data can be obtained or estimated. Limitations identified by the sites were the unavailability of labor costs for certain groups (e.g., health care providers). Therefore, this analysis will include labor costs for members of the eCR team and technology costs associated with needed infrastructure investments, but will not address costs associated with clinical teams. Sites were also concerned with potential difficulties in compiling cost data retrospectively; for this reason, estimates based on documentary sources (e.g., grant budgets), if available, may be utilized in lieu of actual costs. Data sources are discussed briefly below.

Formal ROI analyses including cost savings or other outcomes is beyond the scope of this evaluation for several reasons. With respect to costs savings, implementation sites noted that these would not be observed until the maintenance stage, which is when costs would be expected to normalize as processes become routine. With respect to outcomes such as public health impacts, these are not expected to be realized during the evaluation timeframe. Furthermore, substantial additional work would be needed to

identify the likely public health impacts and determine how these impacts should be quantified to support an ROI analysis.

That said, collecting cost data for the startup and production stages provides a foundation for future analyses that may be of interest to public health agencies and other stakeholders. Future analyses that this foundation could support include ROI analyses that link investments (costs) with benefits to demonstrate positive returns on investment. Examples of positive ROIs of interest to public health agencies are:

- **Greater efficiency:** a calculation showing whether investments resulted in lower costs overall relative to baseline
- **Greater reach:** a larger number of reportable events being captured than previously
- **Public health impact:** faster identification of cases or decreased number of avoidable adverse health outcomes

An ROI tool developed by ASTHO to help public health agencies conduct ROI analysis could be helpful for systematically documenting data, performing certain analyses (such as changes in costs over time), and planning for future analyses (ASTHO, 2013). For documenting data specifically, this tool could potentially be used by sites directly with appropriate technical support from the evaluator. Alternatively, the evaluator could use the tool to compile cost data with the guidance of a fiscal specialist or similar person at each site. Analyses for the evaluation would be conducted by the evaluator but sites could have the option of retaining data in the tool to support future analyses of interest to them. Additional information about the tool and the link to the instructional guide are provided in Appendix D. Indicators used to conduct the cost analysis are summarized in Table 6. Additional information is provided in Appendix C. The rows are further defined below the table.

**Table 6. Indicator Groups to Support Cost Analyses**

	Pre-start-up	Start-up Stage	Production Stage
<b>Timeframe</b>	For each site, define appropriate comparison period	For each site, define beginning and ending dates	For each site, define beginning and ending dates
<b>Labor costs (Indicators 7.1, 7.2)</b>	Planning costs  “Baseline” labor costs – associated with routine operation	Labor costs by team member for eCR team: for core components overall, or within defined dates	Labor costs by team member for eCR team: for core components overall, or within defined dates

	Pre-start-up	Start-up Stage	Production Stage
<b>Technology costs (Indicator 7.3)</b>	Costs associated with maintaining existing technology	Technology investments needed: for core components overall or within defined dates	Technology investments needed: for core components overall or within defined dates

**Timeframe.** Will define broad comparison groups for costs and enable future ROI analyses. The presumption is that cost data could be matched to the timeframes for each stage, but this should be confirmed with implementation sites.

**Labor Costs.** Potential data sources for labor costs include:

- Staff time cards, especially for organizations that track time by project code
- Estimates based on budgets developed for grant proposals

Clinical team labor costs are not considered here for three main reasons. First, the feedback received from implementation sites indicated that health care organizations would likely not provide data. Second, much of the effort relevant to the clinical team is in reference to the reportability response document and feedback from implementation sites indicated that there were no plans currently to use this document. As such, information about health care provider labor was not a priority for inclusion. Finally, there is an expectation that manual reporting will persist through much, if not all, of the production stage, making any savings associated with switching to an automated reporting mechanism challenging to assess.

**Technology Costs.** Additional discussion with sites is needed to identify potential data sources for technology costs specific to implementation stages. One challenge to defining these technology costs is that sites may vary in terms of the technology they had available at the time planning began, and therefore the needed investments may vary as well. An understanding of technology investments in light of a site’s existing technology will be essential for appropriate analysis and interpretation of these costs.

**Leveraging Secondary Data Sources to Characterize Sites**

Table 7 lists site characteristics that will provide context to the evaluation findings and support the interpretation of findings to answer evaluation question 2. Much of these data are available in the sites’ Digital Bridge applications. Information not available in the applications can be retrieved from notes from meetings between the Digital Bridge PMO and each implementation site.

These characteristics are derived from several concepts:

- **Applicability.** Information related to product names, end user types, volume of cases, and IT services delivery will allow individuals reviewing the evaluation findings to identify the implementation site that shares characteristics with their infrastructure. Finding degrees of relatability in the evaluation findings will permit future implementers to better understand what it might take to adopt the Digital Bridge eCR approach.
- **Prior experience with relevant eCR infrastructure and standards.** Sites with prior experience with the infrastructure or standards used in the Digital Bridge eCR approach may find it easier to implement the approach, either because they have more experience in anticipating or identifying problems or they have processes already developed that support the implementation.
- **Legal status affecting eCR implementation.** The process of establishing legal agreements can be time-consuming. Understanding whether relationships exist prior to the eCR implementation may provide context about challenges associated with finalizing those agreements.

**Table 7. Characteristics Relevant for the Evaluation, by Stakeholder Type**

Characteristic Concept	Stakeholder Type		
	Health IT Products	Health care Organizations	Public Health Agencies
<b>Applicability</b>	<ul style="list-style-type: none"> <li>EHR product name</li> <li>Health IT product end user type (e.g., health care or public health)</li> <li>HIE role in information exchange</li> <li>Transport mechanism used to send messages to AIMS platform</li> </ul>	<ul style="list-style-type: none"> <li>IT services delivery (e.g., centralized, independent)</li> <li>Clinicians' awareness of eCR implementation</li> <li>Facility type(s) involved in implementation (e.g., single hospital, single or multisite ambulatory practices)</li> <li>Average cases treated per month for each of the five conditions</li> </ul>	<ul style="list-style-type: none"> <li>Public health surveillance system(s); if different for the five conditions, identify all systems involved in the eCR implementation</li> <li>IT services delivery (e.g., centralized, independent)</li> <li>Type of jurisdiction (e.g., state, regional, county, or municipal)</li> </ul>
<b>Prior experience</b>	<ul style="list-style-type: none"> <li>Prior/existing AIMS interface</li> <li>Prior experience using RCTC list or standardized codes (ICD-10<sup>7</sup>, LOINC, SNOMED) to identify reportable conditions</li> </ul>	<ul style="list-style-type: none"> <li>Prior eCR experience</li> <li>Prior/existing AIMS interface</li> <li>Prior experience using RCTC list or standardized codes (ICD-10, LOINC, SNOMED) to identify reportable conditions</li> <li>Length of experience with current EHR</li> </ul>	<ul style="list-style-type: none"> <li>Prior experience using RCTC list or standardized codes (ICD-10, LOINC, SNOMED) to identify reportable conditions</li> <li>Length of experience with public health surveillance system</li> <li>Experience integrating/using clinical document architecture (CDA)-based documents in public health surveillance system</li> <li>Prior eCR experience</li> <li>Prior/existing AIMS interface</li> <li>Prior experience testing or</li> </ul>

<sup>7</sup> International Statistical Classification of Diseases and Related Health Problems, 10th Revision

Characteristic Concept	Stakeholder Type		
	Health IT Products	Health care Organizations	Public Health Agencies
			implementing RCKMS or similar logic sets
<b>Legal landscape</b>	<ul style="list-style-type: none"> <li>• Presence of existing legal agreements with health care and public health partners</li> <li>• Presence of existing legal agreement with APHL</li> </ul>	<ul style="list-style-type: none"> <li>• Presence of existing legal agreements with public health agencies</li> <li>• Presence of existing legal agreement with APHL</li> </ul>	<ul style="list-style-type: none"> <li>• Presence of existing legal agreement with APHL</li> <li>• Presence of existing legal agreements with health care partners</li> </ul>

### Interpreting Findings and Drawing Conclusions

After data collection and analyses are completed for the evaluation components described above, the evaluator will engage the implementation sites and committee in a collaborative process to interpret the findings, develop answers to the evaluation questions, and reach overall conclusions about the value of the Digital Bridge eCR approach. In addition, this process will be an opportunity to identify and report on unintended or unexpected processes, outcomes, and side effects of the eCR approach. The process will consist of a series of meetings, first with the implementation sites and secondly with the committee, organized around the four evaluation goals.

For example, the evaluator will facilitate a set of web meetings (e.g., GoToMeeting, WebEx, etc.) to share and present the findings for evaluation goal 1 and questions 1-3. A summary of the relevant findings will be shared in written form (e.g., text, tables, and charts) in advance of each meeting. During the meetings, findings will be presented on-screen through the web meeting platform.

- The first set of web meetings will be with site leaders from all implementation sites. Multiple meetings may need to be held to accommodate site leaders’ schedules and to ensure a high level of participation across the sites. The evaluator will facilitate and document discussions about the interpretations of the findings and answers to the evaluation questions.
- The second set of web meetings will be with the committee, following the same steps used with the site leaders.
- The evaluator will prepare a summary of the discussions by evaluation question, share the summary with the site leaders and committee for review and feedback. The evaluator will revise

the summary based on the feedback, and then share the final summary with the site leaders and committee.

The same process will be repeated for the other evaluation goals. However, the process for goal 4 will differ because of the summative nature of its related evaluation questions (8-10). Instead of a summary of findings specific to a particular evaluation goal and related questions, the participants in the goal 4 meetings will rely primarily on the discussion summaries from the other goal meetings. From the goal 4 meetings, the evaluator will document and summarize discussions about the answers to evaluation questions 8-10, and overall conclusions regarding the value and benefits of eCR to stakeholders. Site leaders and the committee will review the goal 4 meetings summary and provide feedback. The evaluator will revise the summary based on the feedback, and share the final summary with the site leaders and committee. The discussion summaries from all the meetings will then provide the basis for the preparation of the final evaluation report.

## Evaluation Management

In this section is a summary of the required and preferred expertise and capabilities of the evaluator team chosen to execute this plan. The roles and responsibilities of all evaluation stakeholders, including the evaluator team, the committee, and the implementation sites, are listed and briefly described.

### Budget

A budget has not been determined yet for the evaluation. The evaluation plan will need to be revisited to address needed changes in the evaluation scope and methods, and the roles and responsibilities of stakeholders, based on the budget that is established.

### Evaluation Documentation

All evaluation materials, including plans, data collection tools, data, and reports, should be maintained in a secure, password protected environment accessible to evaluation staff. Paper records are to be maintained in a secure setting in compliance with IRB requirements. A plan for providing access to electronic and paper materials, including appropriate levels of access by role, should be developed and reviewed with evaluation staff and stakeholders, as appropriate.

Tracking tools will be developed to manage quantitative and qualitative data collection and compilation across sites. These tools should include database applications to store quantitative data in a systematic manner and processes for developing and storing qualitative data (e.g., audio files and transcripts). In addition, a plan for maintaining version control of all evaluation records—including raw data, analytic files, analytic syntax, and reports—should be developed and reviewed with evaluation staff. Finally, a process for documenting decisions should be implemented.

### Managing Sources of Bias

Several measures can be taken to reduce the likelihood that conflicts of interest or scientific bias will affect evaluation findings. Committee members and others responsible for making decisions about how the evaluation is conducted should complete and sign forms where they disclose relationships or holdings relevant to the Digital Bridge eCR approach. An independent, expert panel of reviewers unaffiliated with Digital Bridge can be used to provide a disinterested review of evaluation procedures and findings.

### Evaluator Team Expertise and Capabilities

The **evaluator** team will need to have the following expertise and capabilities to successfully conduct the study.

- Multisite, mixed-methods evaluations
- Formative and process evaluations

- Evaluation of public health programs, preferably those involving surveillance and/or health IT innovations
- American Evaluation Association Evaluation Guidelines
- Stakeholder engagement and facilitation
- Qualitative research methods, including coding and analysis of textual data and key informant interviews (if appropriate)
- Statistical analysis, preferably including development of performance measures
- Cost and financial analyses; although ROI analyses are not part of this evaluation some knowledge of ROI analysis will be helpful for compiling and documenting costs appropriately
- Management of quantitative data, including data cleaning and preparation of analytic files from raw data

### Evaluation Roles and Responsibilities

The **evaluation committee** will:

- Ensure adequate resources are available for the finalization and implementation of the evaluation plan, in collaboration with the governance body
- Identify an evaluator to conduct the evaluation
- Provide routine and ad hoc consultations to evaluators as data are collected and analyzed
- Support the evaluator in identifying other relevant activities and reports to inform data collection, analysis, or interpretation
- Review evaluation conclusions and/or recommendations drawn by evaluators for appropriateness and credibility
- Review and approve interim and final reports
- The committee chair will present interim progress as appropriate and final reports to the governance body
- Advise the governance body in using evaluation findings for decisions that regard outcomes of future eCR implementations

The **evaluator** will:

- Implement the evaluation according to the approved plan, adjusting the plan and protocols as necessary in consultation with the committee
- Complete any necessary data use agreements for authorized use of identifiable data
- Ensure security of project data
- Collect information from the sites during the evaluation period and provide technical support for data compilation activities shouldered by the implementation sites
- Provide regular progress reports to the committee and implementation sites
- Conduct data analyses
- Facilitate interpretation of findings with stakeholders from each site and the committee
- Prepare interim and final evaluation reports

- Adhere to relevant professional standards of practice (e.g., program evaluation standards, protection of human subjects)

The **implementation sites** (including public health agencies, health care organizations, health IT developers, APHL, CSTE) have appropriate roles and responsibilities:

- Implementation organizations will provide feedback on the draft evaluation plan
- Each stakeholder representative within an implementation site is responsible, in collaboration with the evaluator, to extract or collect the appropriate data using the tools provided
- Each implementation site will identify a coordinating entity to collate the data and provide it to the evaluator; data providers will verify the data they submitted
- Each implementation site's coordinating entity will assist the evaluator in identifying and contacting appropriate interview participants
- Individuals representing the three stakeholder groups involved in eCR implementation at each site will participate in KIIs
- Each implementation site's coordinating entity will provide progress updates to the evaluator in accordance with a pre-determined schedule
- Implementation sites must actively participate in the validation and interpretation of data

## Reporting and Dissemination

This section provides guidance for sharing the evaluation results with stakeholders and other relevant users. Requirements and expectations regarding primary reporting to funder(s) are also provided here. Table 8 provides a summary of the target audiences, their informational needs, the strategies that will be used to reach each audience, and the relative timing of the dissemination efforts.

The evaluator will prepare a final evaluation report for the governance body. This report will provide background on the Digital Bridge and its eCR approach, a description of the evaluation methods used, findings related to each evaluation question, discussion of the findings relative to the evaluation purpose and goals, and recommendations for improvements to the Digital Bridge eCR approach and technical infrastructure.<sup>8</sup>

In addition to the final report, the evaluator will work with the committee to prepare a presentation for the governance body on the findings and recommendations. It is expected that this presentation will be delivered to the governance body by the committee chair or designated committee member with support from the evaluator. The governance body will have final editorial and dissemination authority for the evaluation report. It is also expected that the Digital Bridge project management office will assist in disseminating and distributing evaluation findings to a broader stakeholder audience.

**Table 8. Evaluation Reporting and Dissemination by Target Audience**

Audience	Audience’s Informational Needs	Dissemination Strategies
Digital Bridge Governance Body	<ul style="list-style-type: none"> <li>Main findings related to purpose and goals of the evaluation</li> <li>Information on evaluation execution and preliminary findings</li> </ul>	<ul style="list-style-type: none"> <li>Final evaluation report at the conclusion of the study</li> <li>Periodic updates as requested on progress and preliminary findings</li> </ul>
Digital Bridge Evaluation Committee	<ul style="list-style-type: none"> <li>All evaluation findings</li> <li>Information on evaluation execution and preliminary findings</li> </ul>	<ul style="list-style-type: none"> <li>Interim and draft reports on evaluation findings as available</li> <li>Periodic updates on progress and preliminary findings (biweekly)</li> </ul>

<sup>8</sup> See the Checklist for Program Evaluation Report Content developed by Kelly Robertson and Lori Wingate as a guide for the development of the final evaluation report: [https://wmich.edu/sites/default/files/attachments/u350/2017/eval-report-content-checklist\\_0.pdf](https://wmich.edu/sites/default/files/attachments/u350/2017/eval-report-content-checklist_0.pdf).

Audience	Audience’s Informational Needs	Dissemination Strategies
Implementation Sites	<ul style="list-style-type: none"> <li>Lessons learned and best practices from all implementation sites</li> </ul>	<ul style="list-style-type: none"> <li>Digital Bridge PMO-led conference call briefings with slides, leveraging existing meetings as possible</li> <li>Evaluation fact sheet or brief</li> </ul>
Other stakeholders not currently involved in Digital Bridge eCR implementation (public health agencies, health care providers, health IT developers)	<ul style="list-style-type: none"> <li>All evaluation findings, with emphasis on costs, lessons learned, and best practices identified from the evaluation</li> </ul>	<ul style="list-style-type: none"> <li>Digital Bridge PMO-led conference presentations, webinars</li> <li>Governance body member presentations to specific stakeholder groups</li> <li>Evaluation fact sheet or brief</li> </ul>

## Limitations

The budget for the evaluation is not included in this version of the evaluation plan. It is not known who the evaluator will be and estimated costs will depend in part on who is selected to implement the study. In addition, the resources that are allotted for the evaluation will partially determine whether the evaluation plan can be executed in its current form. Substantial changes may be needed to stay within budget.

Due to the evolving nature of the Digital Bridge eCR implementations, there are limits to the degree of specificity in the evaluation timeline.

- The timing for implementation sites' start-up stage and transition to production stage is unknown.
- Staggered start dates for each stage across individual implementation sites could result in significantly extended due dates for the final evaluation report.

Due to the newness of the Digital Bridge eCR approach and the fact that many implementation sites have not had prior experience with eCR, there are many unknowns that must be addressed during tool development or later stages of the evaluation. As a result, this evaluation plan should be viewed as an initial draft and may need to be adjusted as the sites and technical infrastructure teams better understand the nuances of the Digital Bridge eCR approach.

- There is a lack of clarity on the burden required to extract data from health IT and public health surveillance systems. It is therefore difficult to determine at this stage how frequently data should be abstracted from systems. The ideal data extraction frequencies may need to be determined through trial-and-error evaluation based on early implementation sites and standard intervals implemented with later sites.
- Related to burden, it is not clear whether sites will be able to provide individual-level data or will be restricted to providing aggregate data, due to the possible burden associated with de-identifying individual records and data sharing limitations imposed by regulation or IRB.
- Several indicators addressing case reporting quality and performance assessment (goal 2b) require additional formative work to fully specify.

There are limits to the evaluator's ability to rely on written documentation of the sites' implementation processes in relation to evaluation question 1 (How were core components of eCR initiated and implemented in participating sites?). The use of written documentation would reduce data collection burden on sites (i.e., reducing or eliminating reliance on the key informant interviews). However, it became clear from communications with the implementation sites (as part of the development of the plan) that such written documentation would likely not be available or complete enough to fully address the evaluation questions.

There are limits to the methods and data sources that can be used to address evaluation goal 2 (determine eCR functioning and performance).

- Proxies were used for the validation/auditing indicators (goal 2a) as the ideal measurement approach (i.e., intensive chart reviews) was deemed too burdensome by the committee and implementation sites.
- Total case finding is approximated using ELR (goal 2b). It is anticipated that ELR should identify most reportable events but there may be some that are missed. The only way to ensure 100 percent capture would be to conduct a chart review, which was deemed to be too burdensome by the committee and implementation sites. Another potential barrier to utilizing chart review is establishing data use agreements with health care organizations.

The last indicators (for core components F1 and F2) rely on different data sources for the numerator and denominator data. The traditional challenges that arise when merging datasets may be present here. Mitigation strategies may involve ensuring clear extraction protocols that detail specific date and time ranges and definitions for what constitutes a counted event by site.

There are limits to the extent to which the evaluator will be able to document costs as part of evaluation question 7 (What were the costs associated with the initiation and implementation of eCR in the sites?). Cost data may not be available with the level of granularity required to perform the outlined analyses (Section 6.3.4). In addition, the evaluation time frame precludes conducting ROI analyses, including calculation of cost savings.

Generalizability of cost findings may be low; e.g., early adopters may experience more challenges than later adopters, who may reap the benefits of lessons learned.

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## Appendices

### A. Major Milestones Around eCR Development: 2012–2016

Year	Milestone
2012	CSTE assessed states' electronic disease surveillance capacity through the National Electronic Disease Surveillance System assessment
	Initial work for RCKMS began
	Public Health Reporting Initiative selected eCR as use case
2013	National Committee on Vital and Health Statistics held hearing on public health data standards
	Public Health Informatics Institute (PHII) convened workgroup to establish a consensus approach for bidirectional query exchange
	CSTE published position statement in support of HL7 CDA as primary data exchange option for case reporting
	ASTHO Public Health Community Platform (PHCP) initiative launched
2014	PHII and CDC Division of STD Prevention (DSTDP) examined existing eCR approaches in Colorado, Massachusetts, and Utah
	ASTHO published eHealth Policy Statement
	ASTHO and National Association of County and City Health Officials (NACCHO) assessed state/territorial health agency and local health department activities and capacity through first annual Forces of Change Surveys
	RCKMS Feasibility Pilots initiated
2015	CSTE Task Force identified common set of initial data to be used for all conditions and jurisdictions
	PHII and CDC DSTDP held sexually transmitted infection (STI) surveillance expert panel for eCR technical guidance
	ASTHO outlined scope of eCR project using its PHCP
	Office of National Coordinator for Health IT published eCR certification requirements in the 2015 Edition Health IT Certification Criteria rule
	RCKMS Phase II work began
2016	CSTE published eCR position statement
	CDC established funding for eCR standards advancement
	HIMSS16 hosted Epic demonstration of eCR bidirectional information exchange using Structured Data Capture (SDC)
	RCTC list published in Public Health Information Network Vocabulary and Distribution System (PHIN VADS)
	Digital Bridge collaboration began
	HL7 published the eICR STU 1.0

Year	Milestone
	ASTHO pilot projects began
	PHII and CDC DSTDP coordinated pilot test with Alliance of Chicago, health IT, and public health partners
	ASTHO conducted eCR Pilot Review and Legal Meeting
	ASTHO published eCR communications strategy and economic analysis
	PHII and CDC DSTDP launched Advancing eCR of STI Project
	PHI Conference hosted interoperability demonstration of Epic sending CDA-based case report to MAVEN system and bidirectional exchange using SDC
	RCKMS Phase III work began
	Digital Bridge published eCR business process workflow
	Digital Bridge published communications plan

## B. Evaluation Committee Members

Committee Member	Organization	Stakeholder Representation	Role
Jeff Engel	CSTE	<ul style="list-style-type: none"> <li>Public Health</li> <li>Infrastructure Owner</li> </ul>	<ul style="list-style-type: none"> <li>Committee Chair</li> </ul>
Christopher Alban	Epic	<ul style="list-style-type: none"> <li>Health IT</li> <li>Implementation Site</li> </ul>	<ul style="list-style-type: none"> <li>Primary</li> </ul>
Dan Chaput	Office of the National Coordinator for Health IT	<ul style="list-style-type: none"> <li>Federal Government</li> <li>Health IT</li> </ul>	<ul style="list-style-type: none"> <li>Primary</li> </ul>
Shan He	Intermountain Healthcare	<ul style="list-style-type: none"> <li>Health IT Developer</li> <li>Implementation Site</li> </ul>	<ul style="list-style-type: none"> <li>Primary</li> </ul>
Donald Kauerauf	Illinois Department of Public Health	<ul style="list-style-type: none"> <li>Public Health</li> </ul>	<ul style="list-style-type: none"> <li>Primary</li> </ul>
Goldie MacDonald	CDC	<ul style="list-style-type: none"> <li>Federal Government</li> <li>Public Health</li> </ul>	<ul style="list-style-type: none"> <li>Primary</li> </ul>
Indu Ramachandran	Kaiser Permanente	<ul style="list-style-type: none"> <li>Health care</li> </ul>	<ul style="list-style-type: none"> <li>Primary</li> </ul>
Patina Zarcone	APHL	<ul style="list-style-type: none"> <li>Public Health</li> <li>Infrastructure Owner</li> </ul>	<ul style="list-style-type: none"> <li>Primary</li> </ul>
John Beltrami	CDC	<ul style="list-style-type: none"> <li>Federal Government</li> <li>Public Health</li> </ul>	<ul style="list-style-type: none"> <li>Alternate</li> </ul>
Laura Conn	CDC	<ul style="list-style-type: none"> <li>Federal Government</li> <li>Public Health</li> </ul>	<ul style="list-style-type: none"> <li>Alternate</li> </ul>
Sherri Davidson	Alabama Department of Public Health	<ul style="list-style-type: none"> <li>Public Health</li> </ul>	<ul style="list-style-type: none"> <li>Alternate</li> </ul>
James Doyle	Epic	<ul style="list-style-type: none"> <li>Health IT</li> <li>Implementation Site</li> </ul>	<ul style="list-style-type: none"> <li>Alternate</li> </ul>
Myra Lowe	Louisiana Department of Health	<ul style="list-style-type: none"> <li>Public Health</li> </ul>	<ul style="list-style-type: none"> <li>Alternate</li> </ul>
Michelle Meigs	APHL	<ul style="list-style-type: none"> <li>Public Health</li> <li>Infrastructure Owner</li> </ul>	<ul style="list-style-type: none"> <li>Alternate</li> </ul>
Catherine Staes	University of Utah	<ul style="list-style-type: none"> <li>Infrastructure Development</li> </ul>	<ul style="list-style-type: none"> <li>Subject Matter Expert</li> </ul>
Patricia Araki	NACCHO	<ul style="list-style-type: none"> <li>Public Health</li> </ul>	<ul style="list-style-type: none"> <li>Observer</li> </ul>
Tim Carney	ASTHO	<ul style="list-style-type: none"> <li>Public Health</li> </ul>	<ul style="list-style-type: none"> <li>Observer</li> </ul>
Alana Cheeks-Lomax	Digital Bridge PMO	<ul style="list-style-type: none"> <li>Digital Bridge</li> </ul>	<ul style="list-style-type: none"> <li>Observer</li> </ul>
Jessica Cook	Digital Bridge PMO	<ul style="list-style-type: none"> <li>Digital Bridge</li> </ul>	<ul style="list-style-type: none"> <li>Observer</li> </ul>
Joel Hartsell	Utah Department of Health	<ul style="list-style-type: none"> <li>Public Health</li> </ul>	<ul style="list-style-type: none"> <li>Observer</li> </ul>

Committee Member	Organization	Stakeholder Representation	Role
		<ul style="list-style-type: none"> <li>Implementation Site</li> </ul>	
<b>Janet Hui</b>	CSTE	<ul style="list-style-type: none"> <li>Public Health</li> <li>Infrastructure Owner</li> </ul>	<ul style="list-style-type: none"> <li>Observer</li> </ul>
<b>Charlie Ishikawa</b>	Digital Bridge PMO	<ul style="list-style-type: none"> <li>Digital Bridge</li> </ul>	<ul style="list-style-type: none"> <li>Observer</li> </ul>
<b>Jim Jellison</b>	Digital Bridge PMO	<ul style="list-style-type: none"> <li>Digital Bridge</li> </ul>	<ul style="list-style-type: none"> <li>Observer</li> </ul>
<b>Lilly Kan</b>	NACCHO	<ul style="list-style-type: none"> <li>Public Health</li> </ul>	<ul style="list-style-type: none"> <li>Observer</li> </ul>
<b>Shaily Krishan</b>	CSTE	<ul style="list-style-type: none"> <li>Public Health</li> <li>Infrastructure Owner</li> </ul>	<ul style="list-style-type: none"> <li>Observer</li> </ul>
<b>Meredith Lichtenstein</b>	CSTE	<ul style="list-style-type: none"> <li>Public Health</li> <li>Infrastructure Owner</li> </ul>	<ul style="list-style-type: none"> <li>Observer</li> </ul>
<b>Elandis Miller</b>	CSTE	<ul style="list-style-type: none"> <li>Public Health</li> <li>Infrastructure Owner</li> </ul>	<ul style="list-style-type: none"> <li>Observer</li> </ul>
<b>Ben Stratton</b>	Digital Bridge PMO	<ul style="list-style-type: none"> <li>Digital Bridge</li> </ul>	<ul style="list-style-type: none"> <li>Observer</li> </ul>
<b>Kathy Turner</b>	Idaho Division of Public Health	<ul style="list-style-type: none"> <li>Public Health</li> </ul>	<ul style="list-style-type: none"> <li>Observer</li> </ul>
<b>Natalie Viator</b>	Digital Bridge PMO	<ul style="list-style-type: none"> <li>Digital Bridge</li> </ul>	<ul style="list-style-type: none"> <li>Observer</li> </ul>

### C. Evaluation planning Matrix

EQ1: How are core elements of eCR initiated and implemented in participating sites?

Indicator	EC- and Site-Identified Data Sources & Methods	Responsible Party	Timing (Stages)	Analysis Plan	Interpretation
1.1 Trigger code alignment and application processes (Core Components A and B)	Key informant interviews with health care organization IT representative(s) and health IT developers	Multisite evaluator	Start-up	Thematic coding to identify processes for aligning and applying trigger codes. Coding comparisons by sites, site characteristics, and conditions.	Identify similarities and differences among sites and conditions in the trigger code alignment and application processes.
1.2 Processes to ensure the health IT products generate electronic case reports when activated by trigger codes (Core Component C)	Key informant interviews with health care organization IT representative(s) and health IT developers	Multisite evaluator	Start-up	Thematic coding to identify processes for ensuring health IT products generate electronic case reports. Coding comparisons by sites, site characteristics, and conditions.	Identify similarities and differences among sites and conditions in case report creation processes.
1.3 Processes for analyzing and authoring case reporting criteria (Core Component D)	Key informant interviews with public health agency representatives	Multisite evaluator	Start-up and Production	Thematic coding to identify processes for analyzing and authoring case reporting criteria. Coding comparisons by sites, site characteristics, and conditions.	Identify similarities and differences among sites and conditions in the processes used for analyzing and authoring case reporting criteria.

Indicator	EC- and Site-Identified Data Sources & Methods	Responsible Party	Timing (Stages)	Analysis Plan	Interpretation
1.4 Processes to ensure public health and health IT systems can automatically receive, consume, and make electronic reports available for use (Core Components F1 and F2).	Key informant interviews with public health agency representatives and health care organization IT representatives.	Multisite evaluator	Start-up and Production	Thematic coding to identify processes to ensure public health and health IT systems can automatically receive, consume, and make electronic reports available for use. Coding comparisons by sites, site characteristics, and conditions.	Identify how electronic case report and reportability response document use varied among sites and conditions.
1.5 Public health agency staff use of the information from eICRs and reportability response documents (Core Component G1).	Key informant interviews with public health agency staff who use case reports to conduct case investigations.	Multisite evaluator	Production	Coding to determine whether electronic reports were used by public health agency staff. Thematic coding to identify how information from electronic reports were used by public health agency staff. Coding comparisons by sites, site characteristics, and conditions.	Identify similarities and differences among sites and conditions in use of information from electronic case reports and reportability response documents.

Indicator	EC- and Site-Identified Data Sources & Methods	Responsible Party	Timing (Stages)	Analysis Plan	Interpretation
1.6 Health care organization staff use of the information from reportability response documents (Core Component G2).	Key informant interviews with health care organization staff in a position to use reportability response documents.	Multisite evaluator	Production	Coding to determine whether electronic reports were used by health care organization staff. Thematic coding to identify how information from electronic reports were used by health care organization staff. Coding comparisons by sites, site characteristics, and conditions.	Identify similarities and differences among sites and conditions in use of information from reportability response documents.

**EQ2: What were the facilitating and inhibiting factors related to initiation and implementation?**

Indicator	EC- and Site-Identified Data Sources & Methods	Responsible Party	Timing (Stages)	Analysis Plan	Interpretation
2.1 Factors <b>facilitating</b> the initiation and implementation of the eCR Core Components	<p>Key informant interviews with public health agencies, health care organization IT representatives, and health IT developers</p> <p>Site characteristics data from Digital Bridge applications and meeting notes</p>	Multisite evaluator	Start-up and Production	<p>Thematic coding to identify factors that facilitated initiation and implementation of Core Components. Coding comparisons by sites, site characteristics, and conditions.</p>	<p>Identify similarities and differences among sites and conditions in the factors facilitating initiation and implementation of Core Components at each site.</p>
2.2 Factors <b>inhibiting</b> the initiation and implementation of the eCR Core Components	<p>Key informant interviews with public health agencies, health care organization IT representatives, and health IT developers</p> <p>Site characteristics data from Digital Bridge applications and meeting notes</p>	Multisite evaluator	Start-up and Production	<p>Thematic coding to identify factors that inhibited initiation and implementation of Core Components. Coding comparisons by sites, site characteristics, and conditions.</p>	<p>Identify similarities and differences among sites and conditions in the factors inhibiting initiation and implementation of Core Components at each site.</p>

Indicator	EC- and Site-Identified Data Sources & Methods	Responsible Party	Timing (Stages)	Analysis Plan	Interpretation
2.3 Degree to which received electronic case reports meet the needs of public health staff to initiate an investigation	Key informant interviews with public health program agencies	Multisite evaluator	Production	Thematic coding to identify surveillance needs that were met or not met by using eCR. Coding comparisons by sites, site characteristics, and conditions.	Identify similarities and differences among sites and conditions in public health staff needs met by electronic case reporting.
2.4 Stakeholder perceptions of improvements or diminishment in surveillance function	Key informant interviews with public health program agencies	Multisite evaluator	Production	Thematic coding to identify factors that changed surveillance function at Implementation Sites. Coding comparisons by sites, site characteristics, and conditions.	Identify factors that changed surveillance function among Implementation Sites.
2.5 Site leader identification of <b>strengths</b> of each of the Core Components	Key informant interviews with public health agencies and health IT developers	Multisite evaluator	Production	Thematic coding to identify strengths and weaknesses of Digital Bridge approaches. Coding comparisons by sites, site characteristics, and conditions.	Identify similarities and differences among sites and conditions in their reported strengths of each Core Component.
2.6 Site leader identification of <b>weaknesses</b> of each of the Core Components	Key informant interviews with public health agencies and health IT developers	Multisite evaluator	Production	Thematic coding to identify strengths and weaknesses of Digital Bridge approaches. Coding comparisons by sites, site characteristics, and conditions.	Identify similarities and differences among sites and conditions in their reported weaknesses of each Core Component.

Indicator	EC- and Site-Identified Data Sources & Methods	Responsible Party	Timing (Stages)	Analysis Plan	Interpretation
2.7 Site leader's identification of benefits to implementing eCR in health care organizations and public health practice	Key informant interviews with public health agencies and health care organizations	Multisite evaluator	Production	Thematic coding to determine factors that increased efficiency in reportability. Coding comparisons by sites, site characteristics, and conditions.	Identify similarities and differences among sites and conditions in reported benefits to implementing eCR.

**EQ3: How were the inhibiting factors addressed?**

Indicator	EC- and Site-Identified Data Sources & Methods	Responsible Party	Timing (Stages)	Analysis Plan	Interpretation
3.1 Strategies and solutions used to address factors inhibiting initiation and implementation of eCR Core Components	Key informant interviews with public health agencies, health care organization IT representatives, and health IT developers	Multisite evaluator	Start-up and Production	Thematic coding to identify strategies and solutions used to address factors inhibiting initiation and implementation of eCR Core Components. Coding to capture stakeholder perceptions of the effectiveness of the strategies and solutions. Coding comparisons by sites, site characteristics, and conditions.	Identify strategies and solutions used to address inhibiting factors, and which ones were effective.

**EQ4: To what extent were the sites able to successfully develop and implement the Core Components to completely apply the Digital Bridge eCR approach?**

Indicator	EC- and Site-Identified Data Sources & Methods	Responsible Party	Timing (Stages)	Analysis Plan	Interpretation
4.1 Standard codes available, by domain (Yes/No)  <i>There are five possible domains for trigger codes: ICD-10, LOINC for laboratory test orders and laboratory test results, and SNOMED for problem and organism codes.</i>	Stakeholder interviews CSTE questionnaire for trigger code implementation	CSTE	Start-up	Qualitative synthesis to facilitate identification of lessons learned, best practices, and understanding differences across sites.	Provide information on implementation processes and challenges.
4.2 Proportion of local codes identified in alignment analysis that were mapped to codes in the RCTC	Extract from health IT product	Health IT developer extracts data and provides to Evaluator for analysis following approved guidance document	Start-up (baseline measure)  Production	Counts	Comparison can be made as to the efficacy of the initial alignment process; a delta of zero could indicate that the initial alignment process was sufficient, while a non-zero number would be indicative of some post-production modification to the initial alignment process.

Indicator	EC- and Site-Identified Data Sources & Methods	Responsible Party	Timing (Stages)	Analysis Plan	Interpretation
4.3 Proportion of concepts represented by standard codes	Extract from health IT product	Health IT developer extracts data and provides to Evaluator for analysis following approved guidance document	Start-up (baseline measure) Production	Descriptive statistic	Comparison can be made as to the efficacy of the initial alignment process; a delta of zero could indicate that the initial alignment process was sufficient, while a non-zero number would be indicative of some post-production modification to the initial alignment process.
4.4 Proportion of encounters for which an eCR was sent to the AIMS platform	Extract from health IT product, aggregated at regular intervals	Health IT developer extracts data and provides to Evaluator for analysis following approved guidance document	Production	Descriptive statistic	Use of a percentage measure provides context of the frequency of matches given the number of encounters in the system during the study period. Measurement over time provides information on rate changes and can be matched alongside any site-reported changes in the trigger code alignment process.

Indicator	EC- and Site-Identified Data Sources & Methods	Responsible Party	Timing (Stages)	Analysis Plan	Interpretation
4.5 Proportion of eICRs received by AIMS that were passed validation	Extract from AIMS dashboards	APHL extracts data and provides to Evaluator for analysis following approved guidance document	Production	Descriptive statistic	The records from that validation process can be used to evaluate the rate with which the eICRs created by the submitting health IT product have formatting errors. Measurement over time provides information on changes in the error rate and can be correlated to any site-reported modifications in their system associated with eICR creation.
4.6 Proportion of default criteria used by public health agency	Extract from RCKMS or collected from Public Health Agencies (PHAs)	PHAs will extract data and provide to Evaluator for analysis following approved guidance document or CSTE would collect data and provide to Evaluator for analysis following approved guidance document	Start-up (baseline measure) Production	Descriptive statistic	The proportion of default criteria used by PHAs reflects the utility of the existing RCKMS default and potential need for refinements.

Indicator	EC- and Site-Identified Data Sources & Methods	Responsible Party	Timing (Stages)	Analysis Plan	Interpretation
4.7 Proportion of RCKMS criteria that match across sites	Extract from RCKMS	CSTE would collect data and provide to Evaluator for analysis following approved guidance document	Start-up (baseline measure) Production	Descriptive statistic	The proportion of RCKMS criteria that match across sites can be used in conjunction with other indicators to infer potential enhancements needed to RCKMS default.
4.8 Number of new criteria added	Extract from RCKMS	CSTE would collect data and provide to Evaluator for analysis following approved guidance document	Start-up (baseline measure) Production	Descriptive statistic	The number of new criteria added reflect the number of new criteria that need to be added in response to data received through the eCR process.
4.9 Number of refinements made to RCKMS criteria	Extract from RCKMS	CSTE would collect data and provide to Evaluator for analysis following approved guidance document	Start-up (baseline measure) Production	Descriptive statistic	

Indicator	EC- and Site-Identified Data Sources & Methods	Responsible Party	Timing (Stages)	Analysis Plan	Interpretation
4.10 Proportion of eICRs received by RCKMS that were determined to include a reportable condition	Extract from AIMS dashboards	APHL extracts data and provides to Evaluator for analysis following approved guidance document	Production	Descriptive statistic	The proportion will include the total eICRs that were error-free and could therefore be adjudicated by RCKMS and of those, the number of eICRs that were sent to the public health agency. Measurement over time provides information on rate changes which may be matched alongside any site-reported changes in the preceding core component steps for context.
4.11 Proportion of eICRs sent to public health agencies that were consumed by the public health surveillance system	Numerator data will be extracted from public health surveillance system Denominator data will be extracted from the AIMS platform	APHL and public health agency extracts data and provides to Evaluator for analysis following approved guidance document	Production	Descriptive statistic	These measurements will provide information on whether and how many electronic documents were consumed by the receiving IT systems (public health surveillance system or health IT product) and whether those rates change over time in response to other changes in the Core Components process.

Indicator	EC- and Site-Identified Data Sources & Methods	Responsible Party	Timing (Stages)	Analysis Plan	Interpretation
4.12 Proportion of Reportability Response documents sent to public health agencies that were consumed by the public health surveillance system	Numerator data will be extracted from public health surveillance system Denominator data will be extracted from the AIMS platform	APHL and public health agency extracts data and provides to Evaluator for analysis following approved guidance document	Production	Descriptive statistic	These measurements will provide information on whether and how many electronic documents were consumed by the receiving IT systems (public health surveillance system or health IT product) and whether those rates change over time in response to other changes in the Core Components process.
4.13 Proportion of Reportability Response documents sent to health care organizations that were consumed by the health IT product	Numerator data will be extracted from health IT system Denominator data will be extracted from the AIMS platform	APHL and health IT developer or health care organization IT staff extracts data and provides to Evaluator for analysis following approved guidance document	Production	Descriptive statistic	These measurements will provide information on whether and how many electronic documents were consumed by the receiving IT systems (public health surveillance system or health IT product) and whether those rates change over time in response to other changes in the Core Components process.

**EQ5: To what extent is eCR case finding complete, accurate and timely?**

Indicator	EC- and Site-Identified Data Sources & Methods	Responsible Party	Timing (Stages)	Analysis Plan	Interpretation
5.1 Proportion of reportable events that should have been identified that were reported through electronic case reporting (i.e., true positives)	Public health surveillance system	Public health	Production Maintenance	Events that were reported through eCR expressed as a proportion of events that were reported through all existing mechanisms for those who had health care encounters associated with the implementation health care site.	A performance measure assessing completeness of case reporting = true positives.  Provides contextual information to the sites' assessment of the ECR approach to meet its goals, produce sustainable change, and improve surveillance.
5.2 Proportion of eCRs received by public health via the Digital Bridge eCR approach that did not contain an event requested by public health (i.e., false positives)	Public health surveillance system	Public health APHL CSTE Primarily done by public health, CSTE can help facilitate if needed	Production Maintenance	Events that were revoked (determined to not include a reportable event) following public health case investigation expressed as a proportion of all events reported through eCR.	A performance measure assessing accuracy of case reporting, i.e., false positives; the expectation is that the false positive rate will be low.  Provides contextual information to the sites' assessment of the ECR approach to meet its goals, produce sustainable change, and improve surveillance.

Indicator	EC- and Site-Identified Data Sources & Methods	Responsible Party	Timing (Stages)	Analysis Plan	Interpretation
5.3 Proportion of reportable events that were not received by public health through the Digital Bridge eCR approach (i.e., false negatives)	Public health surveillance system AIMS platform	Public health APHL CSTE Primarily done by public health, CSTE can help facilitate if needed	Production  Maintenance	Events that were not reported through eCR expressed as a proportion of events that were reported through ELR for those who had health care encounters associated with the implementation health care site.	A performance measure assessing accuracy of case reporting, i.e., false negatives; the expectation is that the false negative rate will be low.  Provides contextual information to the sites' assessment of the ECR approach to meet its goals, produce sustainable change, and improve surveillance.
5.4 Proportion of reportable events that were received by public health in a timely fashion	Public health surveillance system	Public health	Production  Maintenance	Determine time to receipt of eICR using system timestamp logs to compare date/time eICR was received in surveillance system to date/time patient encounter occurred or date of diagnosis; calculate mean difference in time to receipt of other reports, and proportion of eICRs that are more timely than the comparator.	A performance measure assessing timeliness of eICR relative to: <ul style="list-style-type: none"> <li>• The regulatory requirement for the condition and jurisdiction</li> <li>• Timeliness of ELR and/or manual reports</li> </ul> Provides contextual information to the sites' assessment of the ECR approach to meet its goals, produce sustainable change, and improve surveillance.

**EQ6: To what extent is the information in the eICR complete and accurate?**

Indicator	EC- and Site-Identified Data Sources & Methods	Responsible Party	Timing (Stages)	Analysis Plan	Interpretation
6.1 Proportion of eICRs that were missing information from selected fields	Public health surveillance system	Public health APHL	Production Maintenance	Number of case reports that are missing critical fields expressed as a proportion of case reports with complete information.	A performance measure assessing the completeness of information contained in the eICR.  Provides contextual information to the sites' assessment of the ECR approach to meet its goals, produce sustainable change, and improve surveillance.
6.2 Proportion of eICRs with selected fields that were not the same as the source data	Public health surveillance system Chart review	Health IT	Production Maintenance	Number of case reports that have incorrect data for critical fields expressed as a proportion of case reports with correct data; based on a probability sample of case reports checked against electronic health records.	A performance measure assessing the accuracy of information contained in the eICR.  Provides contextual information to the sites' assessment of the ECR approach to meet its goals, produce sustainable change, and improve surveillance.

**EQ7: What were the costs associated with the initiation and implementation of eCR in the sites?**

Indicator	EC- and Site-Identified Data Sources & Methods	Responsible Party	Timing (Stages)	Analysis Plan	Interpretation
7.1 Total labor hours and eCR team composition by Implementation Stage (to be determined by Core Component activities or established timeframe, as possible or appropriate)	Time cards Estimates based on grant staffing  One option for compiling and analyzing data is the ASTHO ROI tool	Public health Health care org Health IT	Start-up  Production	Sum across team and by team member Sum across all site costs Component of comparison of costs in other timeframes, stages	Comparison across sites of labor hours, team composition, and overall site cost, in relation to key site characteristics.  May provide contextual information related to findings associated with EQs 8-11 (value to stakeholders) and provide insights into best practices and lessons learned.
7.2 Total labor hours and eCR team composition to implement eCR (estimated and actual)	Time cards Estimates based on grant staffing One option for compiling and analyzing data is the ASTHO ROI tool	Public health Health care org Health IT	Start-up	Sum across team and by team member Sum across all site costs Component of comparison of costs in other timeframes, stages	Comparison across sites of labor hours, team composition, and overall site cost, in relation to key site characteristics.  May provide contextual information related to findings associated with EQs 8-11 (value to stakeholders) and provide insights into best practices and lessons learned.

Indicator	EC- and Site-Identified Data Sources & Methods	Responsible Party	Timing (Stages)	Analysis Plan	Interpretation
7.3 Total technology cost by Implementation Stage (to be determined by Core Component activities or established timeframe, as possible or appropriate)	KIIIs Existing site reports Estimates based on grant budget One option for compiling and analyzing data is the ASTHO ROI tool	Health IT	Start-up  Production	Sum across all technology costs Sum across all site costs Component of comparison of costs in other timeframes, stages	Comparison across sites of technology costs related to core component, in relation to key site characteristics.

#### D. Cost Accounting Components of the ASTHO ROI Tool

This appendix contains excerpts and summaries from the ASTHO Instructional Guide for Web-Based ROI Tool (2013). This web-based tool was created to estimate the ROI for improvement efforts undertaken within public health agencies.

To paraphrase the instructional guide, ROI analysis is a form of cost analysis that compares the net costs of an intervention with its net benefits in financial or monetary terms. The tool can be used prospectively as a decision-making tool for new projects or initiatives, during quality improvement (QI) implementation to track ROI, and retrospectively to show economic returns of investments already made. The ROI tool makes comparisons over time, e.g., across a project's implementation stages, and provides several ways to define a positive ROI.

The five steps covered in this appendix are 1) define phases, 2) define cost categories, 3) enter investment costs, 4) enter routine operating costs, and 5) ROI analysis. While the focus of the evaluation plan is on assessing costs, the tool also provides for the specification and analysis of processes and outcomes.

The following pages provide screen shots of key functionalities of the ROI tool:

- Define phases
- Define cost categories
- Enter investment costs
- Enter routine operating costs
- ROI analysis

**Define Phases.** The ASTHO ROI tool uses the QI method of Plan-Do-Study-Act to define each phase of a project. The tool structures the analysis into the following four phases: 1) pre-implementation (Plan), 2) implementation period 1 (Do), 3) implementation period 2 (Study), and 4) implementation period 3 (Act). During each of the phases, the tool can make comparisons for the investment costs, routine operating costs, and outputs or outcomes achieved during each time period.

**Define Cost Categories.** The ROI tool provides a list of pre-populated cost categories to select from. Costs that are constant (i.e., some facility costs) or not directly attached to the intervention do not need to be included. Direct costs such as contracted services, supplies, travel, rental space costs, training costs, or any equipment such as computers or software should be considered when adding your cost categories. In general, personnel cost are the largest costs to a project.

**Enter Investment Costs.** Each cost category requires an investment cost. Investment costs include labor and other costs required to implement the intervention, including the planning activities. Generally, investment costs are higher in the beginning phases of a project.

**Enter Routine Operating Costs.** Routine operating costs are ongoing costs of maintaining and operating the project or program that is implemented or altered. Generally, routine costs are lower in the beginning phases of a project and then increase to a steady state.

**ROI Analysis.** After inputting your costs, you will see the cumulative ROI for your project or initiative in bold. You can see a more detailed analysis and view your ROI analysis including or excluding the output/outcome measures as well. There is also an area to include a discount rate (the tool automatically defaults to a 3 percent discount rate), which refers to the interest rate and helps determine the present value of future cash flows.