

2005-2017 Clinical Laboratory Improvement Advisory Committee (CLIAC)

Discussions Related to Laboratory Interoperability

CLIAC Meeting Summaries available at: <https://www.cdc.gov/cliac/Meetings/PastMeetings.aspx>

CLIAC Recommendation Table available at: https://ftp.cdc.gov/pub/CLIAC_meeting_presentations/pdf/Recommendations/CLIAC_Recommendations.pdf

Meeting Date	Presentations, Discussion Summaries, and Activity Updates
September 7-8, 2005	<p><u>Presentation: Centers for Disease Control and Prevention (CDC) Update</u></p> <ul style="list-style-type: none"> • Challenged laboratories to be leaders in exchange of national health data for communicating laboratory results and other patient data. • Noted that messaging requires using three standards: Logical Observation Identifier Names and Codes (LOINC®), Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT®), and Health Level Seven (HL7) coding. • Proposed that wide adoption of these IT standards within the U.S. would expedite the flow of critical information among federal, state, local, and private sector laboratories during emergencies. • Showed that in Nebraska, laboratory report delays dropped from 26 to 2 days after adopting these standards. • Indicated that 26 states can handle an HL7 message including laboratory results. • Stated that The Laboratory Response Network needs to be able to communicate with the Food and Drug Administration (FDA), Federal Bureau of Investigation, and Environmental Protection Agency. • Noted that The Public Health Information Network (PHIN) requires secure communications to carry out early event detection, outbreak management, and countermeasure efforts.
September 20-21, 2006	<p><u>Presentation: Challenges in Clinical Communication</u></p> <ul style="list-style-type: none"> • Provided an overview of the evolution of clinical information systems and laboratory information systems (LIS) and their limitations. • Reviewed the communication of laboratory data aggregation and summarization so clinicians will be able to find the needed information. • Described the need for user-friendly display and ability to segment data to represent the patient. • Noted that LISs are not structured to provide population data, nor are laboratories usually staffed to support extraction of such data for research or for clinical quality assurance efforts.
February 9-10, 2010	<p><u>Presentation: Introduction: Electronic Health Records and Electronic Transmission of Lab Information</u></p> <ul style="list-style-type: none"> • Provided an introduction to Health Information Technology (HIT) including: <ul style="list-style-type: none"> ○ Background on the Title 4 American Recovery and Reinvestment Act (ARRA) - February 17, 2009. ○ Office of the National Coordinator for Health (ONC), HIT Committee, Centers for Medicare & Medicaid Services (CMS) and Office of E-Health Standards and Services are working on issues that currently hinder electronic transmission of laboratory information. <p><u>Presentation: Office of the National Coordinator for Health (ONC) Update - Electronic Health Records</u></p> <ul style="list-style-type: none"> • Described an ONC supported study on state laws concerning persons authorized to order tests and receive results. • Noted that 23 states did not identify who could be considered an authorized person while others were prescriptive in their definition of an “authorized person,” with no uniform standard applied by all states. • Presented the ONC reported findings of a hearing convened on October 20, 2009 with Electronic Health Record (EHR) stakeholders to discuss issues surrounding the electronic exchange of laboratory data. The hearing identified impediments to this exchange of information that fell into three major categories: standards/technological, business, and perceived regulatory impediments. • Reviewed longer term next step items including: <ul style="list-style-type: none"> ○ HIT Standards Committee recommending standards, certification criteria, and implementation specifications. ○ ONC and CMS will monitor feedback from the Survey and Certification letter and consider possible regulatory changes if issues cannot be resolved through the ONC standards or CLIA interpretive guidelines. <p><u>Presentation: EHRs CLIA Myths and Facts</u></p> <ul style="list-style-type: none"> • Provided an overview of Clinical Laboratory Improvements Amendments (CLIA) of 1988 and EHRs. • Noted the regulations for test ordering (§493.1105), test request (§493.1241) and results reporting (§493.1291) are applicable.

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	<ul style="list-style-type: none"> • Stated that several systems for transmitting electronic health information already in use and issues outside of the CLIA purview, such as terminology, standardization, and complexity, may create challenges in the future. • Announced that a newly clarified CLIA interpretive guidance for EHRs is imminent. • Provided a list of CLIA misconceptions and clarification relating to EHRs. <p><u>Presentation: EHRs Brookings Institution</u></p> <ul style="list-style-type: none"> • Described high-value health care laboratory data integration project. • Noted that the barriers identified by Brookings included: <ul style="list-style-type: none"> ○ CLIA definition of "authorized person" should include other non-ordering providers, EHR, and other Health Insurance Portability and Accountability Act (HIPAA) covered entities. ○ CMS should explicitly describe the verification process for appropriate laboratory data display in the EHRs when there is no electronic verification and said laboratory data transmitted to an EHR in the endorsed messaging format should be deemed compliant, provided the EHR system has been certified to display laboratory result data in compliance with the CLIA requirements. ○ CMS should amend the CLIA regulations to align with meaningful use requirements and set a target date for achieving them. <p><u>Presentation: CDC Perspective: Electronic Transmission of Laboratory Information and Oversight of Laboratory Information Systems</u></p> <ul style="list-style-type: none"> • Provided an overview of the Public Health Laboratory Interoperability Project (PHLIP), a LIS used by CDC to transmit data to 50 state public health laboratories, including challenges encountered and lessons learned from the project. • CDC established a harmonized vocabulary team for common terms. • Noted that SNOMED CT® was insufficient, so CDC developed its own test and report codes. <p><u>Presentation: FDA Perspective: Electronic Transmission of Laboratory Information and Oversight of Laboratory Information Systems</u></p> <ul style="list-style-type: none"> • Explained that LISs fall under 201(h) of the Federal Food Drug and Cosmetic Act (FDCA) and are considered a component part or accessory of a medical device, further classified as calculator/data processing module. • Noted that in Subpart C - Clinical Laboratory Instruments, section 862.2100, LISs fall under class 1, exempt from pre-market approval, but must be registered and the manufacturer must follow good manufacturing practices, report device failures, have an inventory of tests/software on the market, and have a system for remedying device failures. • Described a proposed rule for Medical Device Data Systems which discusses software and the electronic storage, retrieval, transfer, display, and conversion of medical device data. • Suggested that laboratories report discrepancies found in laboratory data transmission resulting from a software malfunction to FDA anonymously via FDA's MedWatch https://www.fda.gov/safety/MedWatch/default.htm. <p><u>Presentation: Vendor Perspective: Electronic Transmission of Laboratory Information and Oversight of Laboratory Information Systems</u></p> <ul style="list-style-type: none"> • Described that for clients using Sunquest Information Systems: <ul style="list-style-type: none"> ○ Greater than 75% of laboratory testing is performed by hospitals and the majority of results are delivered via paper to the ordering physician. ○ Several variations of HL7 standards are being used by LIS vendors and the latest version of HL7 is rarely being utilized. • Provided reasons why providers of laboratory data (e.g., hospitals, laboratories) are resistant to adopting an LIS: <ul style="list-style-type: none"> ○ Cost ○ Personnel issues ○ Lack of interoperability between other LIS products ○ Non-standard results management and display by ordering physicians • Suggested that CLIA regulations should be aligned with new and current EHR practices, laboratory interfaces should be standardized, and standards should be implemented to translate test codes. •

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	<p>Activity Update:</p> <ul style="list-style-type: none"> • ARRA established an incentive program for the meaningful use of certified EHR technology by eligible professionals. • CMS published a Notice of Proposed Rulemaking (NPRM) on the incentive program's meaningful use of certified EHR technology. • ONC published an Interim Final Rule (IFR) on standards and certification criteria. • CMS issued a Survey and Certification letter for laboratory surveyors, to facilitate the electronic exchange of laboratory information. • The CLIA interpretive guidelines were updated to reflect changes to facilitate the electronic exchange of laboratory information
September 1-2, 2010	<p>Presentation: Electronic Health Records and CLIA</p> <ul style="list-style-type: none"> • Reported on an HHS group (CMS, ONC, HIT Policy, Office of General Counsel, Office of the E-Health Standards and Services) that addressed issues thought to hinder the electronic exchange of laboratory information including the following CLIA issues: <ul style="list-style-type: none"> ○ Final report destination for laboratory results ○ The accuracy, reliability, confidentiality and timeliness of laboratory test reports ○ Ensuring proper laboratory report content ○ Limitations on the disclosure of laboratory results to the "authorized person" and those persons responsible for using results • Reviewed the steps taken to address CLIA Issues including: <ul style="list-style-type: none"> ○ Revised Interpretive Guidelines ○ Survey and Certification Letter ○ List of Frequently Asked Questions • Provided explanation that CLIA does not regulate EHR systems or vendors. • Noted that EHRs not required to develop products that are CLIA compliant <ul style="list-style-type: none"> ○ Laboratory determines if the EHR product meets all applicable facility needs and regulatory requirements ○ If laboratory uses an EHR system, the laboratory and not the vendor makes sure their staff are trained on EHR systems ○ Future of CLIA and EHR <p>Activity Update:</p> <ul style="list-style-type: none"> • Discussions with ONC, OCR, and CMS began on ways the CLIA regulations can help facilitate a patient's access to their personal laboratory results. • 45 CFR Part 164 ; CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports; Final Rule published February 6, 2014 https://www.gpo.gov/fdsys/pkg/FR-2014-02-06/pdf/2014-02280.pdf
August 31 – September 1, 2011	<p>Presentation: The Laboratory's Role in the Development and Use of Electronic Health Records (EHRs) and Electronic Laboratory Reporting (ELR) of Public Health Information for Notifiable Diseases and Meaningful Use (MU)</p> <ul style="list-style-type: none"> • Provided an overview and background of the Health Information Technology for Economic and Clinical Health (HITECH) Act. • Provided an overview and background of the ONC-Health Information Technology Advisory Committees: <ul style="list-style-type: none"> ○ HIT Policy Committee (HITPC) ○ HIT Standards Committee (HITSC) <p>Presentation: Office of the National Coordinator for Health (ONC) Update - Overview of Regulations Relevant to Patient Laboratory Testing in the Electronic Health Record</p> <ul style="list-style-type: none"> • Provided an overview of HIT regulations and MU. • Stated that the goal is to promote adoption and utilization of HIT as a mechanism for improving health outcomes, increasing transparency, increasing efficiency and improving healthcare delivery. • Noted the importance of laboratory interoperability with State HIE's by providing short and long term objectives for this effort • Presented that Regional Extension Center (REC) functional interoperability community of practice tasked with aligning RECs with Lab MU requirements. • Described two roles for laboratory data described in the Meaningful Use or Incentive rule: <ul style="list-style-type: none"> ○ incorporate clinical laboratory test results in the EHR as structured data ○ capability to electronically submit reportable laboratory results to public health agencies

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	<p><u>Presentation: Office of the National Coordinator for Health (ONC) Update - S&I Framework Laboratory Results Interface (LRI) Initiative Update</u></p> <ul style="list-style-type: none"> • Defined the Standards of Interoperability (S&I) Framework approach to create a collaborative, coordinated process to create harmonized health information technology specifications for use throughout the United States • Defined the mission and focus of the S&I framework: to establish a nationwide implementation guide for electronic submission of laboratory results. • Noted that Laboratory Results Interface (LRI) Initiative objectives are to have EHR and laboratory information systems (LIS) vendors agree that they can use the implementation guide while minimizing intermediaries, customization, and translation, thereby enabling easier implementation for providers who adopt EHRs. • Presented S&I Framework and LRI Initiative key challenges, outcomes and next steps. <p><u>Presentation: The Laboratory's Perspective on the Development and Use of Electronic Health Records</u></p> <ul style="list-style-type: none"> • Stated that the laboratory supplies the largest volume of clinical actionable data to the EHR and needs data back from the EHR. • Suggested that poor integration of EHR with the laboratory could defeat the purpose of the EHR. • Emphasized six problem areas: <ul style="list-style-type: none"> ○ laboratory/pathology results display ○ order entry ○ clinical decision support ○ structured data ○ accreditation impact ○ EHR certification • Emphasized the importance of involving pathologists and laboratory personnel in the design, implementation and use of EHRs. <p><u>Presentation: Overview of CDC's Electronic Laboratory Reporting (ELR) and Meaningful Use (MU) Activities</u></p> <ul style="list-style-type: none"> • Provided an overview of Electronic Laboratory Reporting (ELR) to public health. • Diagrammed the different paths laboratory information can take in a person based investigation. • Discussed how laboratories could support eligible hospitals and help providers meet the public health objectives. • Described the elements of the laboratory report needed for public health ELR. • Provided a list of issues related to public health ELR not addressed by MU regulations. • Discussed the purpose of the HL7 Version 2.5.1 Implementation Guide. <p><u>Activity Update:</u></p> <ul style="list-style-type: none"> • DLS convened the Communication in Informatics (CII) Workgroup Meeting, July 11-12, 2012. • CII Workgroup published the white paper <i>The Essential Role of Laboratory Professionals, Ensuring the Safety and Effectiveness of Laboratory Data in Electronic Health Record Systems</i> in May 2014 https://www.cdc.gov/labhit/paper/laboratory_data_in_ehrs_2014.pdf • DLS LabHIT participated in the S&I Framework discussions on Laboratory Orders Interface, Laboratory Results Interface, and the electronics Directory of Services to ensure the guides included capture of the CLIA elements for test ordering and test reporting • DLS led the S&I Framework aLOINC® Order Code Initiative • List of order codes developed by aLOINC® Order Code and published at https://loinc.org/ June 2016.
February 14 - 15, 2012	<p><u>Presentation: Communication and Electronic Health Records</u></p> <ul style="list-style-type: none"> • Provided background and overview of CDC CII Workgroup • Overviewed the Institute of Medicine Report - Health IT and Patient Safety: Building safer Systems for Better Care. • Emphasized the need for reporting adverse events related to the EHR.
August 29-30, 2012	<p><u>Presentation: Introduction to Laboratory Informatics and Electronic Health Records (EHRs) Topics to be Discussed at this Meeting.</u></p> <ul style="list-style-type: none"> • Emphasized that laboratories need to be included in the rapidly evolving and widespread use of electronic health information exchange • Raised awareness regarding EHR issues

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	<p><u>Presentation: CDC Informatics Team Activities Update</u></p> <ul style="list-style-type: none"> • Provided background and update on the CDC Laboratory Healthcare Information Technology (LabHIT) Team. • Described the emerging EHR regulatory landscape and agency involvement. • Presented the Communication in Informatics logic model for the project. <p><u>Presentation: Communication in Informatics Workgroup Meeting Update</u></p> <ul style="list-style-type: none"> • Provided an update on the 2012 Communication in Informatics Workgroup meeting. • Provided examples of laboratory-related errors in electronic reporting. <p><u>Presentation: ONC's Laboratory Reporting Workgroup</u></p> <ul style="list-style-type: none"> • Provided an overview of the ONC's Direct Laboratory Workgroup (Direct). • Defined "Direct" as a project to create the set of standards and services that, with a policy framework, enable simple, directed, routed, scalable transport of laboratory results over the Internet used for secure and meaningful exchange between known participants in support of the EHR incentive program. Direct uses a secure email-messaging system to transmit information, such as laboratory test results. • Provided an update on the Laboratory Reporting Tiger Team convened to reduce the time and cost to implement and verify (e.g. visual verification) laboratory result reporting interfaces, in the ambulatory environment, while maintaining the accuracy, completeness and usability of laboratory test result information viewed by the authorized person for safe and effective interpretation. <p><u>Presentation: Measuring, Evaluating and Improving the Usability of Electronic Health Records - NIST Update</u></p> <ul style="list-style-type: none"> • Provided an overview on how to measure, evaluate and improve the usability of EHRs. • Described usability as "the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use" - ISO9241. • Explained of how technical guidance provided by NIST would improve usability of EHRs. <p><u>Presentation: Unique Usability Challenges in Designing EHR's Used for the Care of Children</u></p> <ul style="list-style-type: none"> • Provided an overview of the challenges faced when designing EHRs for pediatric medical care. • Reviewed usability guidelines and variables that affect patient care such as the special requirements, human factor solutions, and critical functions found in pediatric charts. • Discussed pediatric patient care variables, the EHR, and the difference between patient care usability guidelines for adults and newborns. <p><u>Activity Update:</u></p> <ul style="list-style-type: none"> • ONC formed the Laboratory Reporting Workgroup Tiger Team. • The Laboratory Tiger Team developed the following documents for ONC's use: <ul style="list-style-type: none"> ○ Guidelines for display of test results that led to an S&I Framework Initiative that became an Implementation Guide (HL7 EHR-S Functional Requirements: S&I Framework Laboratory Results Messages, Release 1 - US Realm) ○ Standard for Trial Use, May 2016) ○ Business rules for patient/provider friendly names, which were applied to the top 2000 results codes and presented to the LOINC® Laboratory meeting December 2015 ○ Use cases for the NIST validation suite (NIST HL7 V2 LRI Validation Tool, Release 2, December 2016)
March 6-7, 2013	<p><u>Presentation: Introduction - Harmonization of Clinical Laboratory Results</u></p> <ul style="list-style-type: none"> • Provided an introduction on harmonization including interoperability of terminology and harmonization of data or numerical values • Provided a LabHIT Team update. • Noted the letter expressing August 2012 CLIAC recommendations was sent to the HHS Secretary on September 26, 2012. <p><u>Presentation: Issues in the Standardization of Clinical Laboratory Results</u></p> <ul style="list-style-type: none"> • Provided an overview of the National Library of Medicine (NLM) supported vocabulary standards: <ul style="list-style-type: none"> ○ LOINC®

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	<ul style="list-style-type: none"> ○ RxNorm - Pharmacy (clinical drugs) Normalized Naming System ○ SNOMED CT® - ● Discussed challenges associated with codes. <p><u>Presentation: FDA Semantic Interoperability of Laboratory Results for Public Health</u></p> <ul style="list-style-type: none"> ● Provided examples of where laboratory data is not interoperable. ● Discussed available tools for interoperability of laboratory data: <ul style="list-style-type: none"> ○ LOINC® (question) ○ SNOMED® (answer) ○ HL7 message ○ UDI (unique device identifier) ○ GMDN (global medical device nomenclature - what the test does) ○ SPL (structured product labeling - wrapper) <p>Activity Update:</p> <ul style="list-style-type: none"> ● FDA, CDC, and NLM formed a taskforce on Semantic Interoperability called SHIELD - Systemic Harmonization and Interoperability Enhancement for Laboratory Data. ● FDA/CDC/NLM Public Workshop on Promoting Semantic Interoperability of Laboratory Data held at FDA on September 28, 2015. ● Medical Device Innovation Consortium (MDIC) held a meeting to clarify regulatory issues and discuss development of a white paper for the technical component, July 22, 2016. ● IVD Industry Connectivity Consortium (IICC) published the Digital Format for Publication of LOINC® to Vendor IVD Test Results, June 1, 2017. ● CDC/FDA/NLM/ONC/CMS Public Workshop Promoting Semantic Interoperability of Laboratory Data held at NLM November 8, 2016. ● HL7 began LOINC® IVD Devices (LIVD) a Fast Healthcare Interoperability Resources (FHIR) component of the Digital Format for Publication of LOINC® to Vendor IVD Test Results, January 2017.
August 21-22, 2013	<p><u>Presentation: Introduction and CDC LabHIT Update</u></p> <ul style="list-style-type: none"> ● Provided the background of HITECH. ● Described the EHR Incentive Rule and Meaningful Use. ● Provided an overview of the laboratory data related to the two rules. <p><u>Presentation: Office of the National Coordinator for Health Information Technology (ONC)</u></p> <ul style="list-style-type: none"> ● Provided an overview of the Office of Science and Technology, and Office of the National Coordinator for Health Information Technology (ONC). ● Defined the Standards and Interoperability (S&I) lifecycle, operating metrics, and initiative list. ● Presented a snapshot of the S&I portfolio and pilot sites. ● Thanked CLIAC for thoughtful recommendations in the letter of 2012 and provided a report of the ONC action taken as a result of this letter. ● Encouraged future involvement with S&I framework <p><u>Presentation: Office of the National Coordinator for Health (ONC) Update - Laboratory Reporting Tiger Team</u></p> <ul style="list-style-type: none"> ● Provided an overview of ONC's laboratory reporting workgroup tiger team and activities for each sub-team: <ul style="list-style-type: none"> ○ Policy team ○ Standards team ○ Testing and Certification team ○ LOI/LRI Regulatory Issues team ● Reviewed the revised CLIA guidance issued March 2010 and the current verification process of a typical EHR system. ● Noted the Tiger Team successes and description of a laboratory test report for EHR certification including: Test report definition, CLIA required elements and best practice elements, and EHR behaviors for certification

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	<ul style="list-style-type: none"> • Discussed preliminary recommendations and next steps for the Tiger Team • Summarized the teams activities and introduced the new LOINC® order efforts <p><u>Presentation: Clinician Experience in Health IT Policy and Standards Development</u></p> <ul style="list-style-type: none"> • Stated that by setting and using appropriate standards, medical errors can be prevented thereby ensuring patient safety. • Stressed importance of having laboratory experts in the decision making process. • Described concerns about the display of laboratory results and what patients should be able to see in their patient portal. <p><u>Presentation: Public Health Information Network Vocabulary Access and Distribution System (PHIN VADS) - Application & Content Overview</u></p> <ul style="list-style-type: none"> • Described the following: <ul style="list-style-type: none"> ○ PHIN VADS a public web-based enterprise vocabulary system for accessing, searching, and distributing Health Level 7 (HL7) messaging value sets ○ Vocabulary definitions and examples ○ Standard Vocabulary Organization (SDO) tools ○ Standards adopted by PHIN VADS ○ Overview and background of PHIN VADS ○ Purpose and usage of VADS: ○ Laboratory content in PHIN VADS ○ Reportable Condition Mapping Table (RCMT) introduction and overview • Provided an overview of CDC Public Health Vocabulary Community of Practice. <p><u>Presentation: CDC LabHIT Team and Specimen Test Vocabulary LabCoP</u></p> <ul style="list-style-type: none"> • Provided an overview of the specimen cross mapping table project started in 2009. • Described the Laboratory Messaging Community of Practice (LabCoP) workgroup that includes CDC and APHL. • Provided the APHL Informatics team history and overview. • Noted the definitions of HL7 codes, LOINC® and Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT®) • Presented the specimen cross mapping table - a tool, codes, gaps, and solutions.
March 5-6, 2014	<p><u>Presentation: aLOINC® Project Update</u></p> <ul style="list-style-type: none"> • Explained the ability to receive electronic messages using LOINC® is required for EHRs to achieve the objectives of the CMS incentive program referred to as Meaningful Use (MU). • Stated the widespread usage of non-standardized local codes among clinical laboratories across the United States is a significant challenge to interoperability of laboratory data in health information exchange. • Discussed the need to provide standardized terminology for laboratory test names so that computers can “talk” to each other across multiple organizations and platforms. • Discussed CDC’s involvement in both the S&I Framework’s “aLOINC®” Initiative to develop a list of the most frequently ordered laboratory tests and corresponding LOINC® codes. • Concluded by outlining a planned approach and timeline for the CDC Public Health intra-agency workgroup activities and identifying potential stakeholders.
April 15-16, 2015	<p><u>Presentation: Laboratory Information Exchange in Health Information Technology (IT) Introduction</u></p> <ul style="list-style-type: none"> • Explained why we need interoperability. • Outlined barriers to interoperability. <p><u>Presentation: Laboratory Interoperability Plan</u></p> <ul style="list-style-type: none"> • Provided an overview of the ONC’s draft action plan for laboratory interoperability. • Noted that CMS and CDC brought into the workgroup after the plan was developed. • Reviewed the five building blocks that make up the laboratory interoperability plan.

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	<ul style="list-style-type: none"> • Discussed CMS's concerns about the plan. • Suggested strategies for implementing the plan. • Noted that there is no regulatory requirements for laboratories to implement. • Stated that CMS, CDC, and FDA began conversations aimed towards revision of the laboratory interoperability action plan. <p><u>Presentation: aLOINC® Order Code Initiative Update</u></p> <ul style="list-style-type: none"> • Provided a demonstration on using LOINC®. • Reviewed the Standards and interoperability (S&I) framework initiative. • Reviewed the aLOINC® order code key deliverables: <ul style="list-style-type: none"> ○ aLOINC® Common Order Codes Value Set ○ Input to Regenstrief on user panels and coding ○ Recommendations of use of LOINC® for ordering ○ Recommendation to Regenstrief on content updates • Discussed the data reviewed and process for analysis. • Summarized preliminary recommendations.
November 18-19, 2015	<p><u>Presentation: FDA's Perspective on Laboratory Interoperability</u></p> <ul style="list-style-type: none"> • Described value of laboratory interoperability to the laboratory, patients, providers, and the nation. • Noted the challenges interoperability is encountering. <p><u>Presentation: Promoting Semantic Interoperability of Laboratory Data: Public Workshop Update</u></p> <ul style="list-style-type: none"> • Provided an overview of the Promoting Semantic Interoperability of Laboratory Data; Public Workshop. • Noted that the meetings focus was on: <ul style="list-style-type: none"> ○ Logical Observation Identifiers Names and Codes (LOINC®) ○ Systematized Nomenclature of Medicine (SNOMED CT®) ○ Unified code for Units of Measure (UCUM), and ○ Unique Device Identifiers (UDI) • Stated that more than 250 participants in person or via web including National Library of Medicine (NLM), Regenstrief, CDC, FDA, CMS, and Office of National Coordinator (ONC). • Reviewed background and key issues discussed at the meeting as well as come comments that were received after the meeting. • Stated that the workgroup concurred that the focus should be on LOINC®, which is most pivotal coding scheme. • Reviewed the FDA's considerations including how to integrate industry into the workgroup. <p><u>Laboratory Interoperability Update Presentation:</u></p> <ul style="list-style-type: none"> • Provided an update on the Laboratory Interoperability Action Plan • Identified areas where CMS, CDC, and FDA agreed to work to promote interoperability that were included in the ONC Interoperability Roadmap published October 2015. <p><u>Activity Update:</u></p> <ul style="list-style-type: none"> • ONC Interoperability Roadmap published October 2015 included 4 bullets related to the Laboratory Interoperability Plan <ul style="list-style-type: none"> ○ NLM, FDA, CDC, CMS and other stakeholders should collaborate regarding approaches to promoting laboratory information exchange (especially through the use of LOINC®, SNOMED-CT®, UCUM and UDIs) between in vitro diagnostic devices and database systems, including laboratory information systems and electronic health records. ○ ONC, NIST, CMS, CDC and FDA should collaborate to advance laboratory data interoperability, including specifications to ensure compliance with CLIA, state and local quality laboratory regulations. ○ ONC, NIST, CMS, CDC and FDA should collaborate to advance laboratory data interoperability, including the establishment of requirements for common application programming interfaces (APIs) that meet CLIA requirements for laboratory test ordering and reporting.

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	<ul style="list-style-type: none"> ○ CDC should encourage development of training aids to help laboratories use LOINC® for laboratory test ordering and reporting in a structured format that includes data elements necessary to meet CLIA requirements. ● ONC published Interoperability Standards Advisory (updated annually) https://www.healthit.gov/isa/historical-isa-publications
April 13-14, 2016	<p><u>Presentation: Laboratory Interoperability: ONC policies and Engagement with Clinical Laboratories</u></p> <ul style="list-style-type: none"> ● Summarized ONC's work to drive the adoption of interoperability of IT systems in health care. ● Showed that EHR usage has expanded to include 2/3 of POLS and 95% of hospitals. ● Described the Federal Health IT Strategic Plan. ● Highlighted goal four: Implement the shared nationwide interoperability roadmap. ● Discussed Interoperability Standards Advisory (ISA). ● Reviewed the ISA process and timeline.
November 1-2, 2017	<p><u>Presentation: The Quest for Interoperability</u></p> <ul style="list-style-type: none"> ● Provided an overview of health information technology including: <ul style="list-style-type: none"> ○ Tools for Interoperability standards ○ Federal Health IT ○ IOM Report recommendations ○ HL7, LOINC®, ICD, SNOMED-CT®