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FEBRUARY 23–27, 2014
ORLANDO, FLORIDA

INNOVATION. IMPACT. OUTCOMES.
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NIST Tooling and Test Procedures in Support of Meaningful Use

February 27, 2014

Robert Snelick and John J. Garguilo

NIST
National Institute of Standards and Technology
U.S. Department of Commerce

Conflict of Interest Disclosure

Robert Snelick, MS Computer Science
John J. Garguilo, MS Computer Science

Has no real or apparent conflicts of interest to report.

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Learning Objectives

- Identify software tooling used in Meaningful Use testing
- Explain the development of the Meaningful Use test procedures
- Explain the Meaningful Use test process
- Demonstrate test tool functionality
- Develop understanding of Meaningful Use testing

Session Topics (Part 1, John Garguilo)

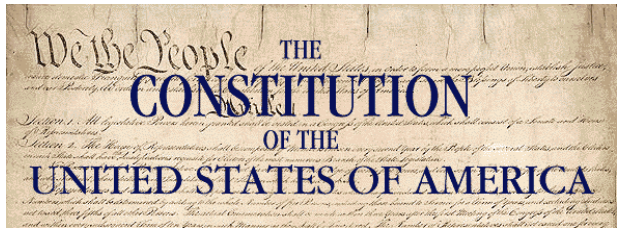
- A little about Department of Commerce's NIST
- The Importance of Standards
  - And the need of standards, profiles, and constraints
- What does NIST do? Why does NIST do it?
- Conformance and Interoperability Testing
- NIST Meaningful Use Stage 2 Tooling Inventory
- NIST Meaningful Use Stage 3 Tooling Plans
- Certification Results

Session Topics (Part 2, Rob Snelick)

- Meaningful Use Process (and where NIST Fits in)
- NIST HL7 V2 Testing Infrastructure and Framework Overview
- Testing and Profiling Concepts
- Testing Process
- HL7 V2 Test Tool Overview
- Case Study – MU-2 Lab Results Interface Tool
  - Sending System (Creation)
  - Receiving System (Incorporation)
- Future Direction

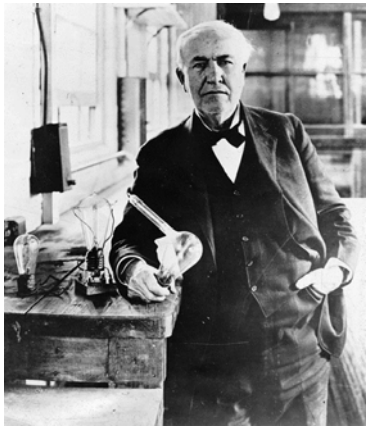
NIST and the Importance of Standards

Measurements, testing, and standards are the basis for developing and deploying technology.



Article 1, Section 8: The Congress shall have the power to . . . *fix the standard of weights and measures*

- National Bureau of Standards established by Congress in 1901
- Eight different "authoritative" values for the gallon
- Electrical industry needed standards
- American instruments sent abroad for calibration
- Consumer products and construction materials uneven in quality and unreliable

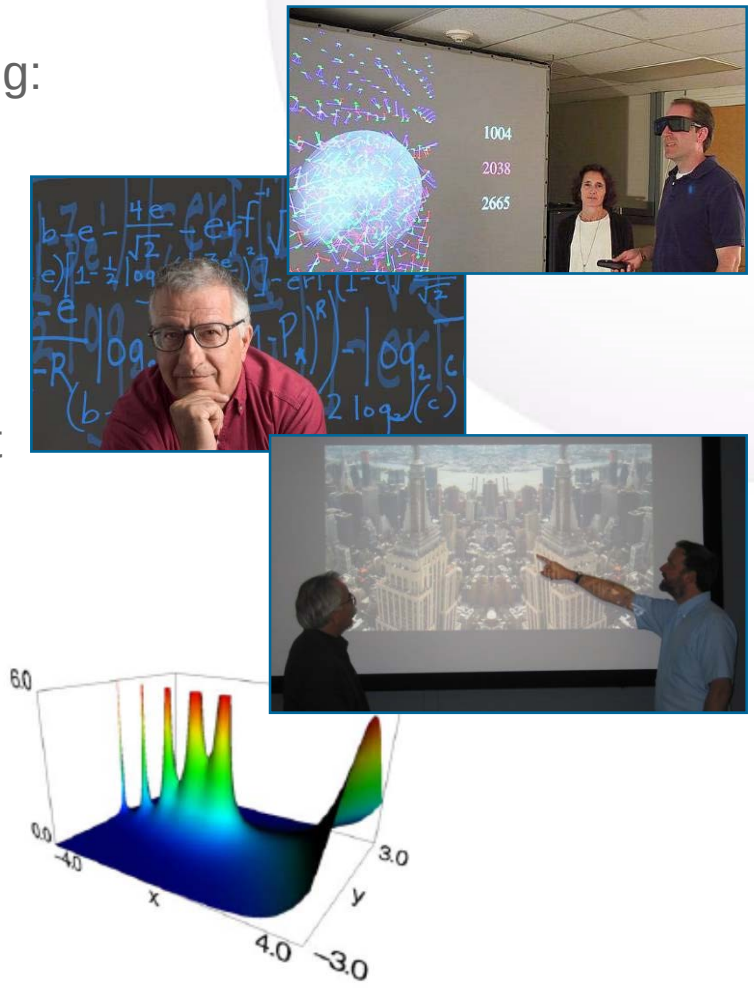


Estimated that 80% of global merchandise trade is influenced by testing and other measurement-related requirements of regulations and standards.

Information Technology Laboratory Mission

- To promote U.S. innovation and industrial competitiveness by advancing:
  - Measurement science;
  - Standards; and
  - Technology.

  through the research and development in:
  - Information technology;
  - Mathematics; and
  - Statistics.



Setting the stage. . . A few premises

- Premise that **standards** are essential to achieving conformance and interoperability

- Premise that ***rigorous*** testing is critical to achieving **conformance** and enabling **interoperability**.

- Enabling people to manage their own health independently as well as to supporting the clinician decision to manage the patient (in both acute and personal settings) in a safe, timely, and effective manner.

Standards are Necessary! Why?

- Value of Standards
  - Common and repeatable use
  - Consensus established by recognized body
    - Common, definition, meaning, and attributes
- Provide use, rules, guidelines for activities of their results
- Aimed at the achievement of the optimum degree of order in a given context

Standards Perspective

- Why is NIST involved?
  - Trusted industry neutral entity
  - Help write better (and better) standards
  - Iterative feedback to standards bodies and domain groups
  - Healthcare Information Technology ‘Test Infrastructure’
    - Need at once (for testing)
    - Re-usable component with common interfaces for consistent usage
  - Interoperability ‘Test Bed’
    - To execute testing over a variety of domains / test events
    - Enable ‘users’ to quickly devise test tooling to meet needs
      - Get away from one development effort needed for each test event
      - Enable users with domain knowledge to drive testing

Standards Perspective, continued

- Great, but aren't standards intentionally **open ended**?
  - Often vague?
- How do we enable semantic interoperability?
  - (i.e., convey consistency meaning)
- How do standards help with/address conformance and interoperability?

- **. . . Standards alone are not the answer**

What's Needed to Test. . .

- So, how might one narrow this 'open-endedness' to achieve an appropriate level of constraints?

- **Constraining** Standards
  - Need to constrain the scope to be realistic, 'usable', 'implementable', 'testable', and therefore "**Conformant**" - The assessment of an implementation to determine if its behavior is consistent with the requirements for behavior defined in a standard or other reference document.
- One way is via ***Profiling*** – Constraints placed on Standards
  - *Integration* Profiles (realistic use cases of business/clinical process being addressed)
  - *Implementation* Profiles (requirements that implementers build to…)
  - *Conformance* Profiles (ideally no optionality, able to be rigorously tested)

Conformance and Interoperability

- **Conformance**: Conformance is defined as the fulfillment of a product, process, or service of specified requirements [1,2]. The concept of conformance is essential to any standard for *providing an objective measure of how closely implementations satisfy the requirements* defined in the standard.

- **Semantic Interoperability**: Beyond the ability of two or more computer systems to exchange information (**syntactic Interoperability**), semantic interoperability is the ability to automatically communicate information and have that information *correctly interpreted* by the receiving system.

[1] ISO Reference - ISO/IEC 17000 Conformity assessment - Vocabulary and general principles, first edition 2004-11-02.

[2] Glossary of Conformance Terminology, Interoperability and Conformance Technical Committee, OASIS. http://www.oasis-open.org/committees/ioc/glossary.htm

Conformance and Interoperability, continued

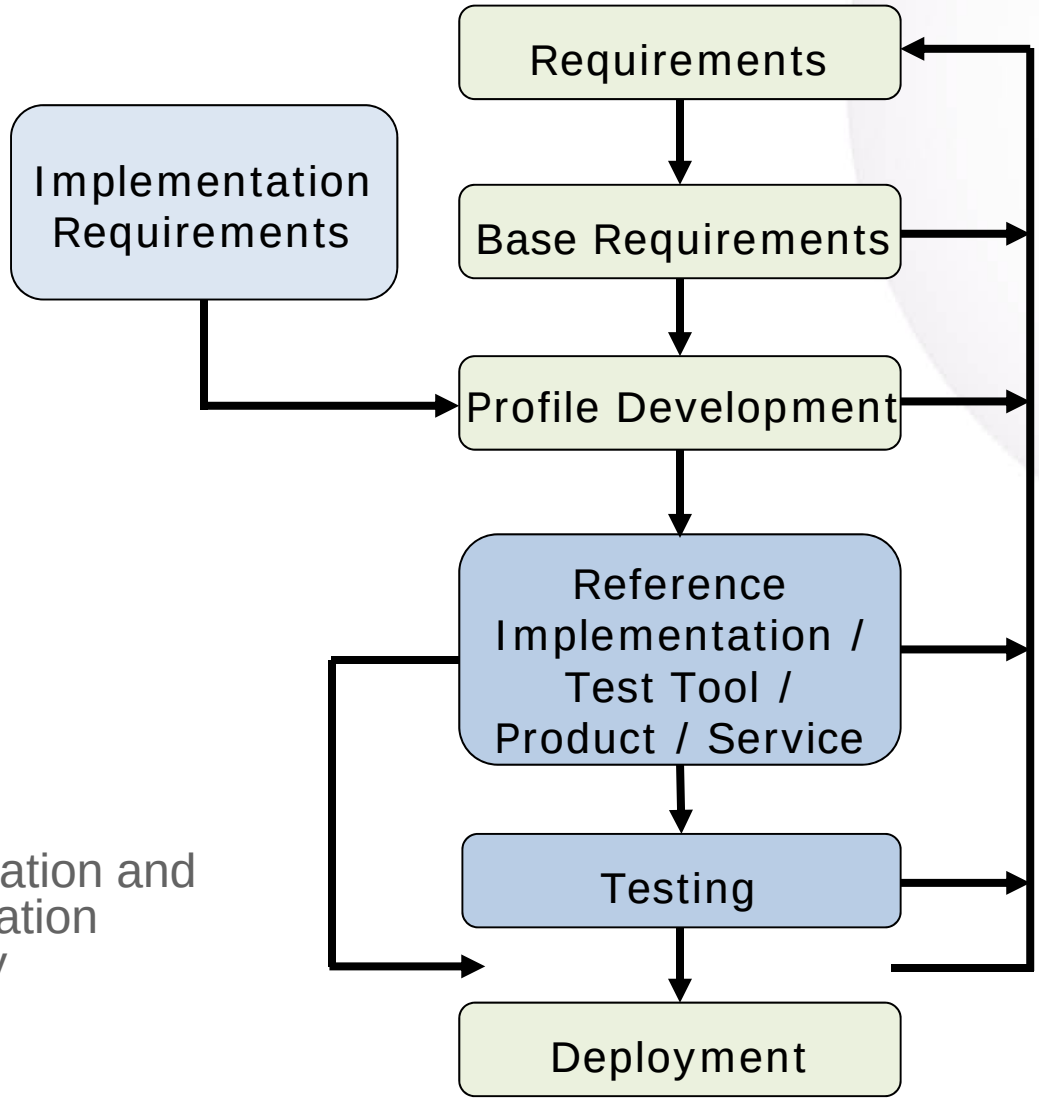
- Conformance CAN NOT be definitively determined* - but gives a level of confidence based on quality and quantity of test(s) performed
  - (*unless specification is very basic)

- Conformance  Interoperability

  - A is Conformant, B is Conformant
    - The above does not say anything about interoperability between A and B

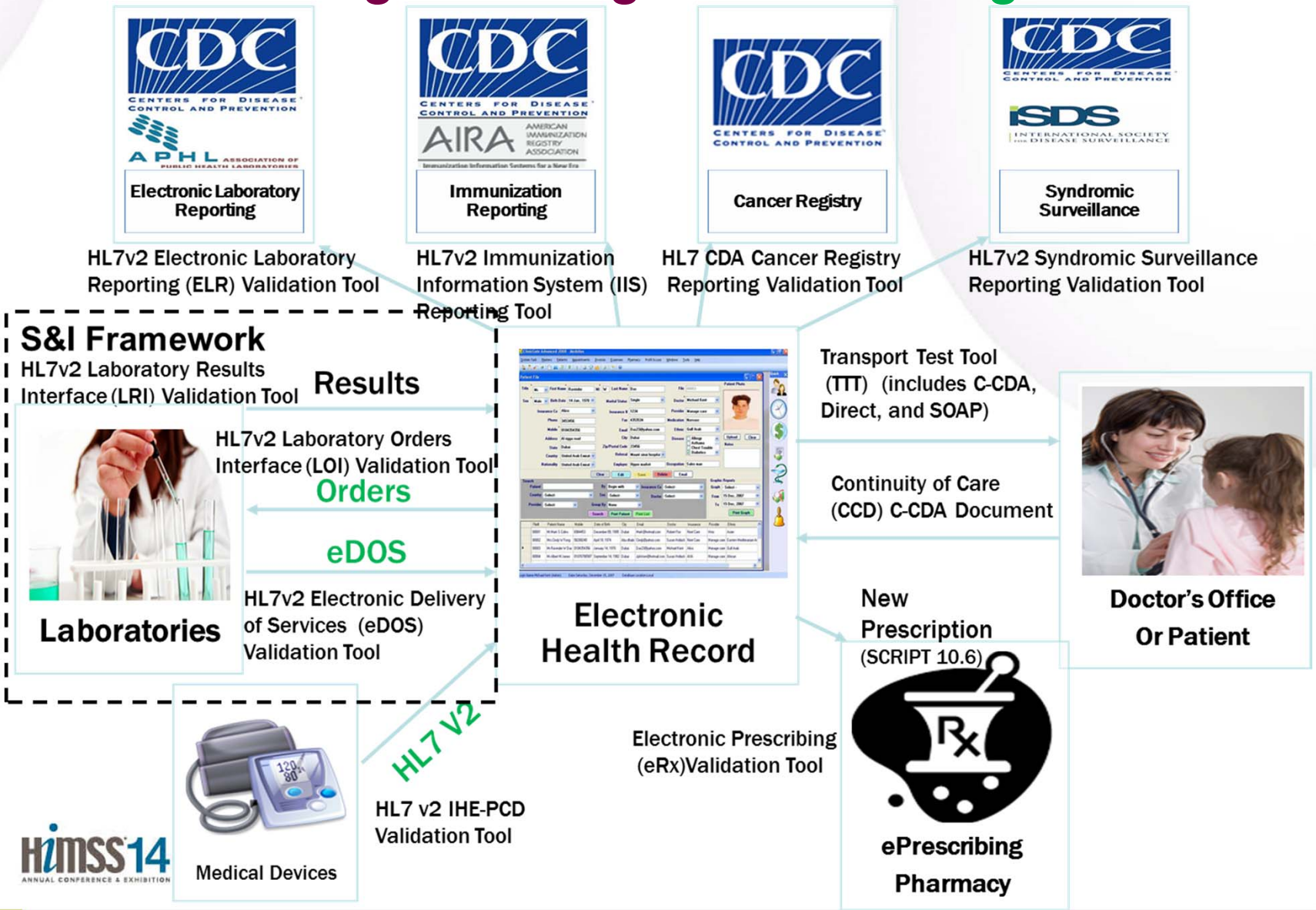
ICT Standards Life Cycle

NIST Special Publication 500-291



- ICT: Information and Communication Technology

NIST Tooling for Stage II and Stage III



Certification Results

- Tally of EHR technology vendors with one or more products ONC certified for Edition 2014 as of the end of February 2014
  - 90 using the NIST Syndromic Surveillance Validation Tool
  - 32 using the NIST ELR Validation Tool
  - 91 using the NIST Immunization Messaging Validation Tool
  - 97 using the NIST LRI-EHR Validation Tool
  - 24 using the NIST LRI-LIS Validation Tool
  - 80 using the NIST ePrescribing Validation Tool
  - 11 using the NIST Cancer Registry Validation Tool
  - 85 using the NIST Transport Validation Tool

Part 2:
Testing Concepts and NIST Tools: HL7 V2

Robert Snelick

February 27, 2014

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Meaningful Use Certification Process Overview

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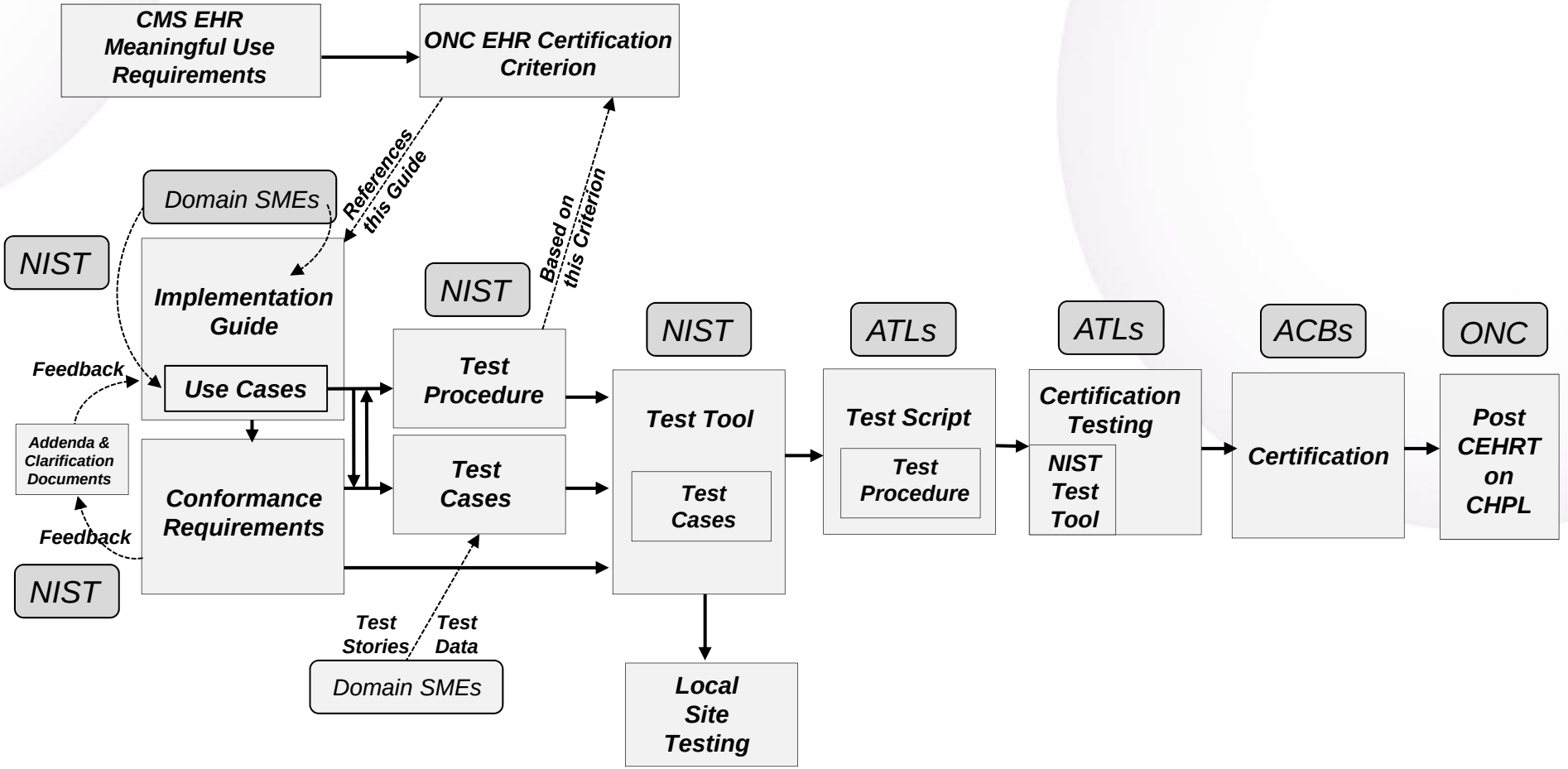
Overview: Meaningful Use Certification Process



NIST – National Institute of Standards and Technology
ACB – Authorized Certification Body
SME – Subject Matter Expert
CHPL – Certified Health IT Product List
EHR – Electronic Health Record

ATL – Accredited Testing Laboratory
ONC – Office of the National Coordinator for Health Information Technology
CEHRT – Certified Electronic Health Record Technology
CMS – Centers for Medicare and Medicaid Services

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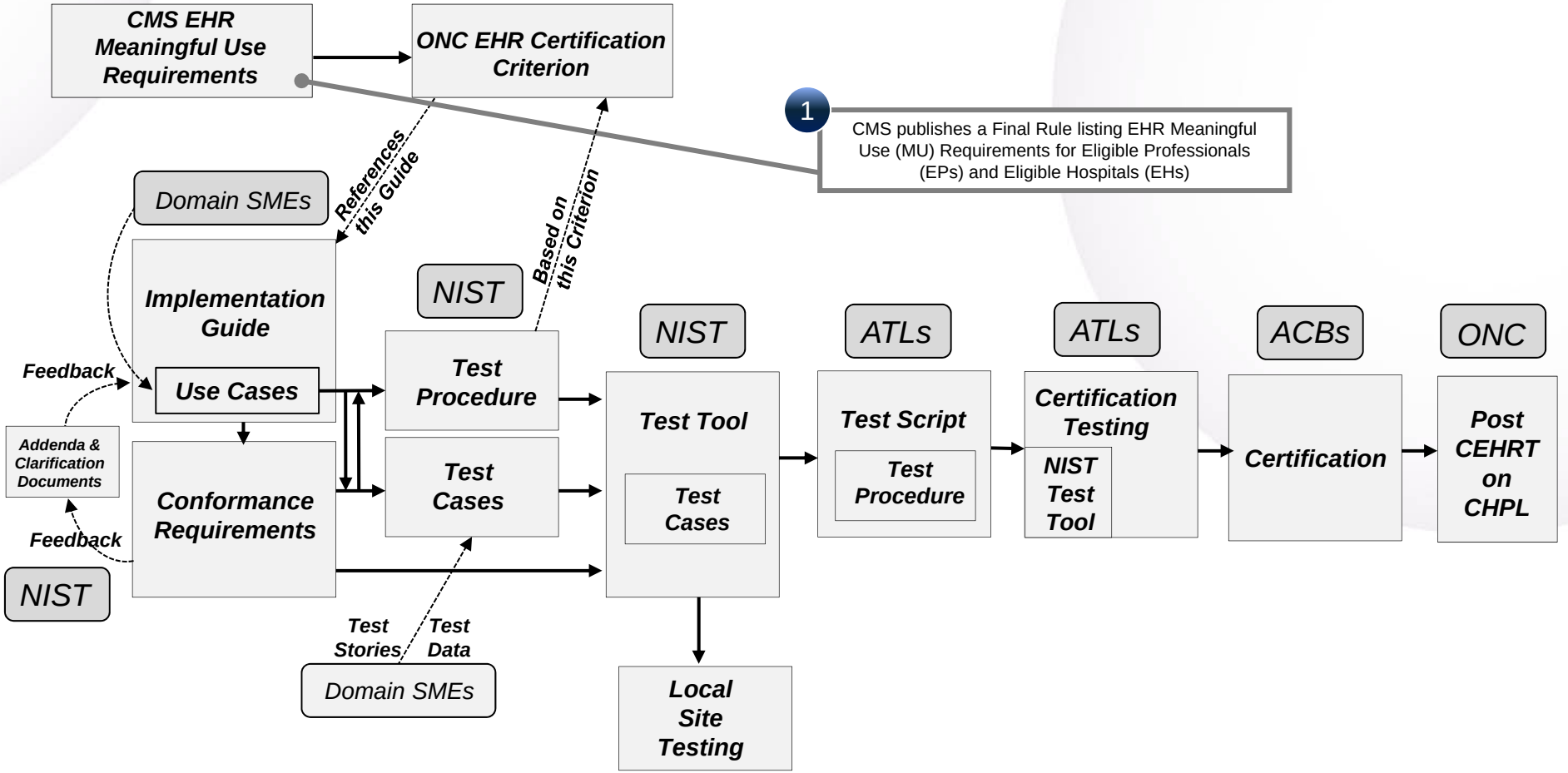

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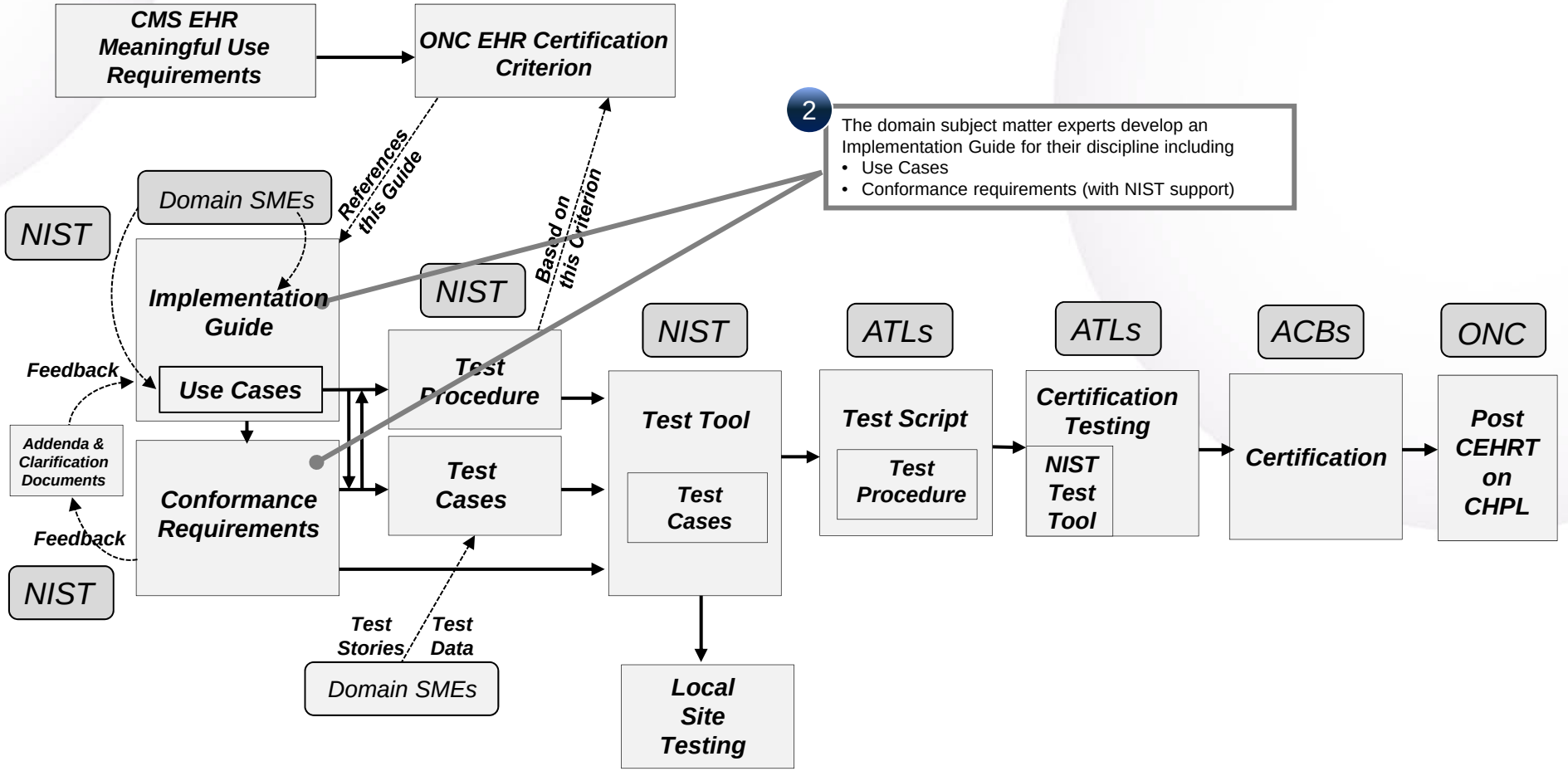

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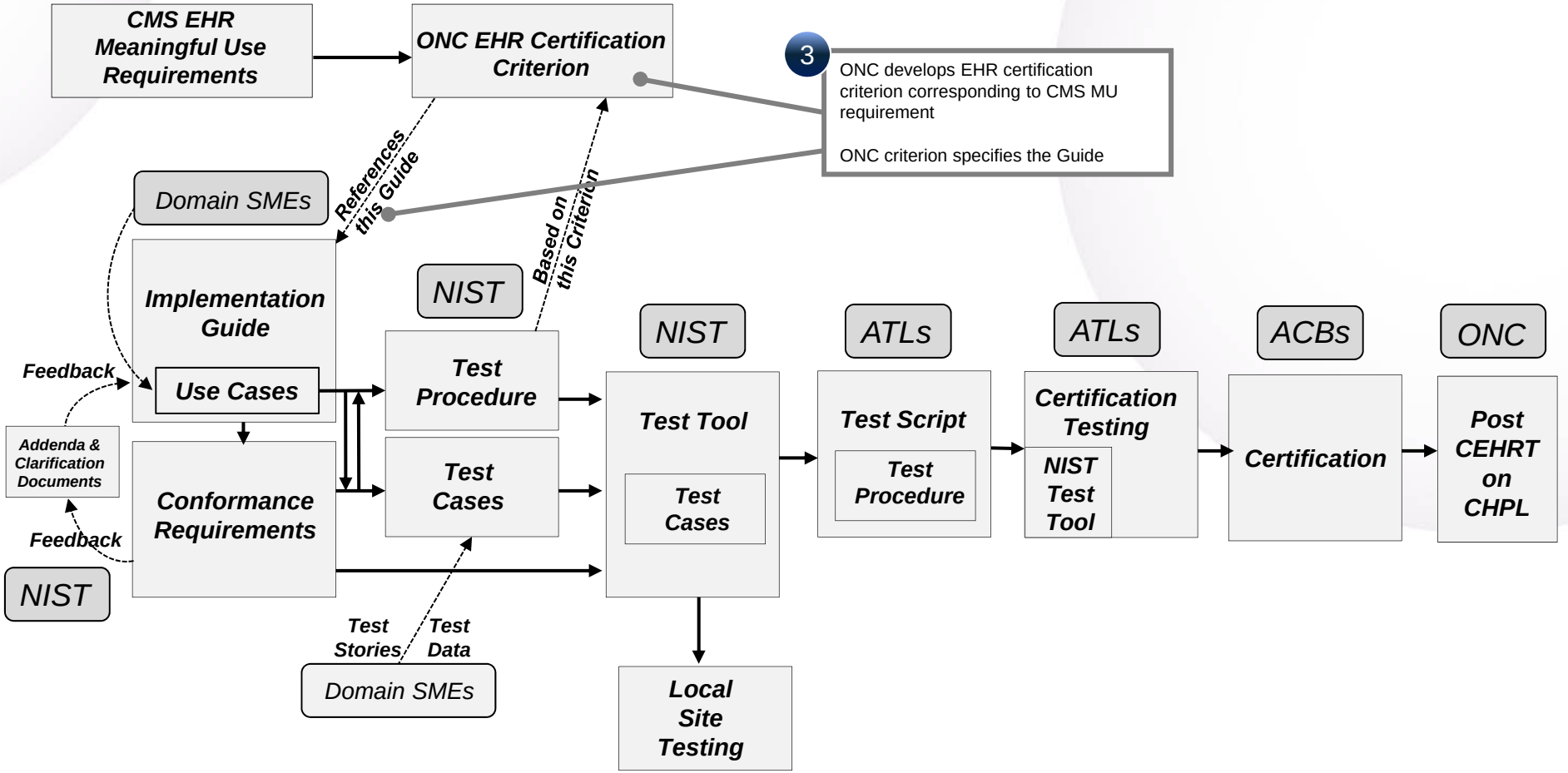

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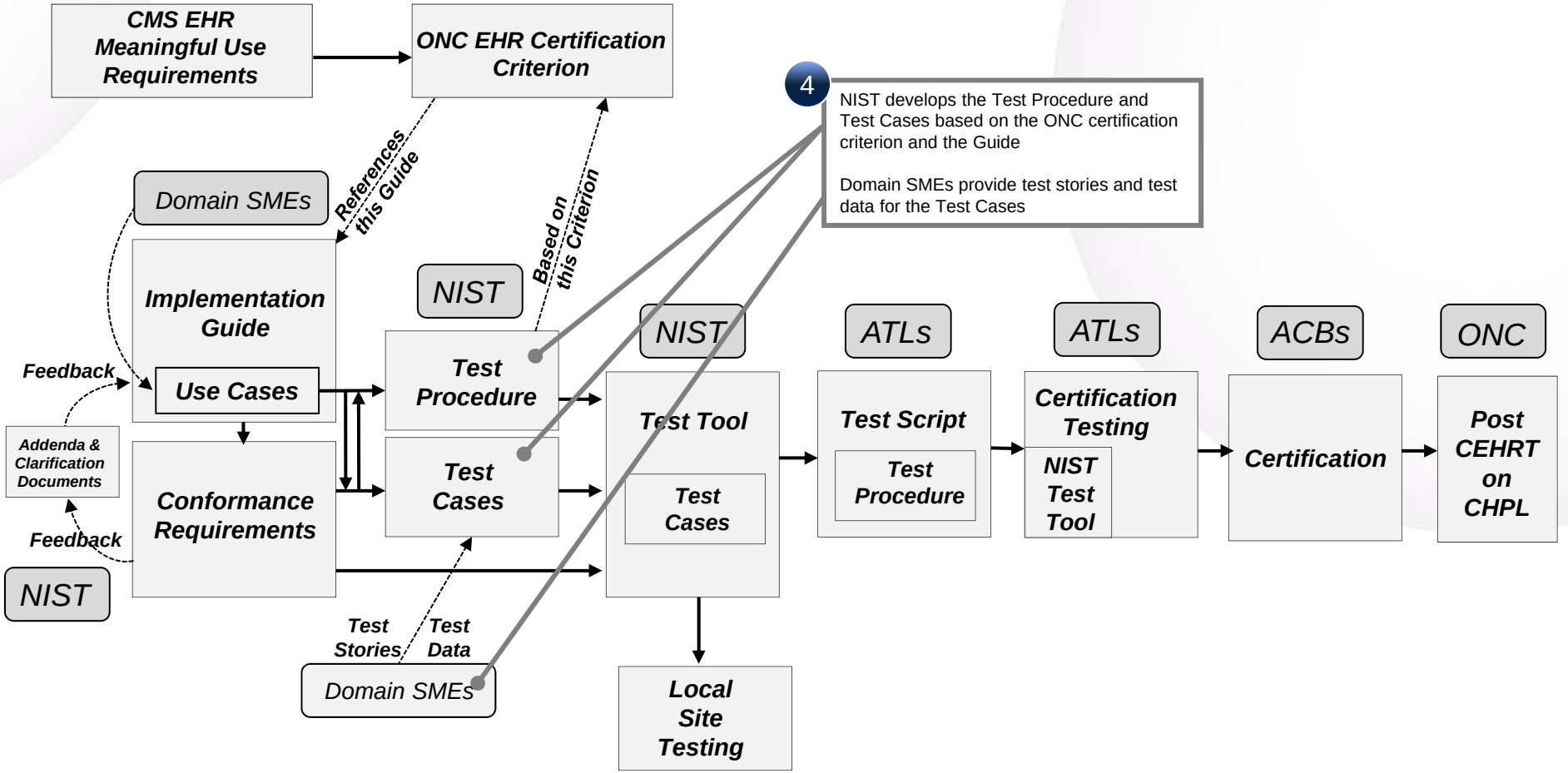

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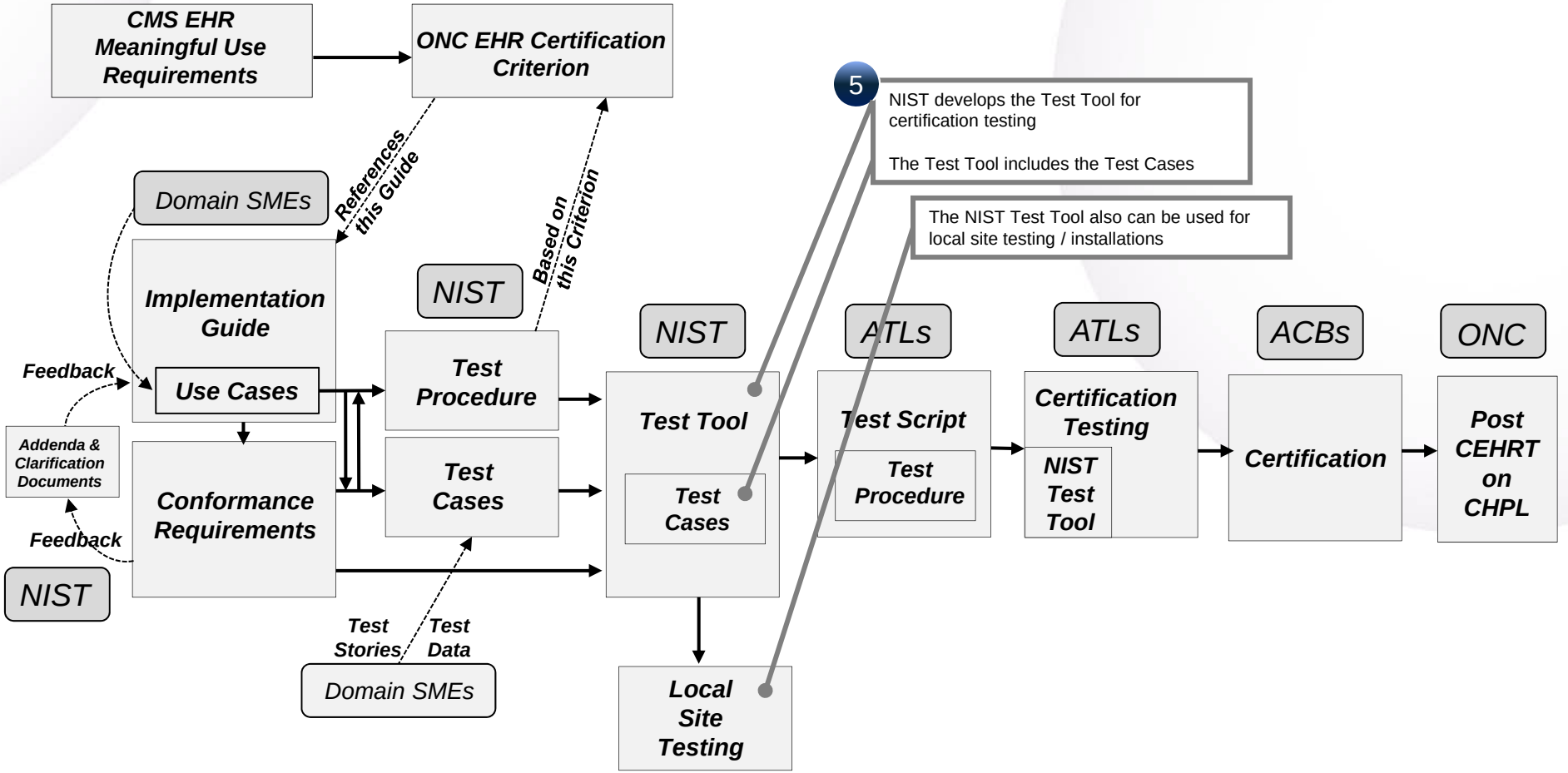

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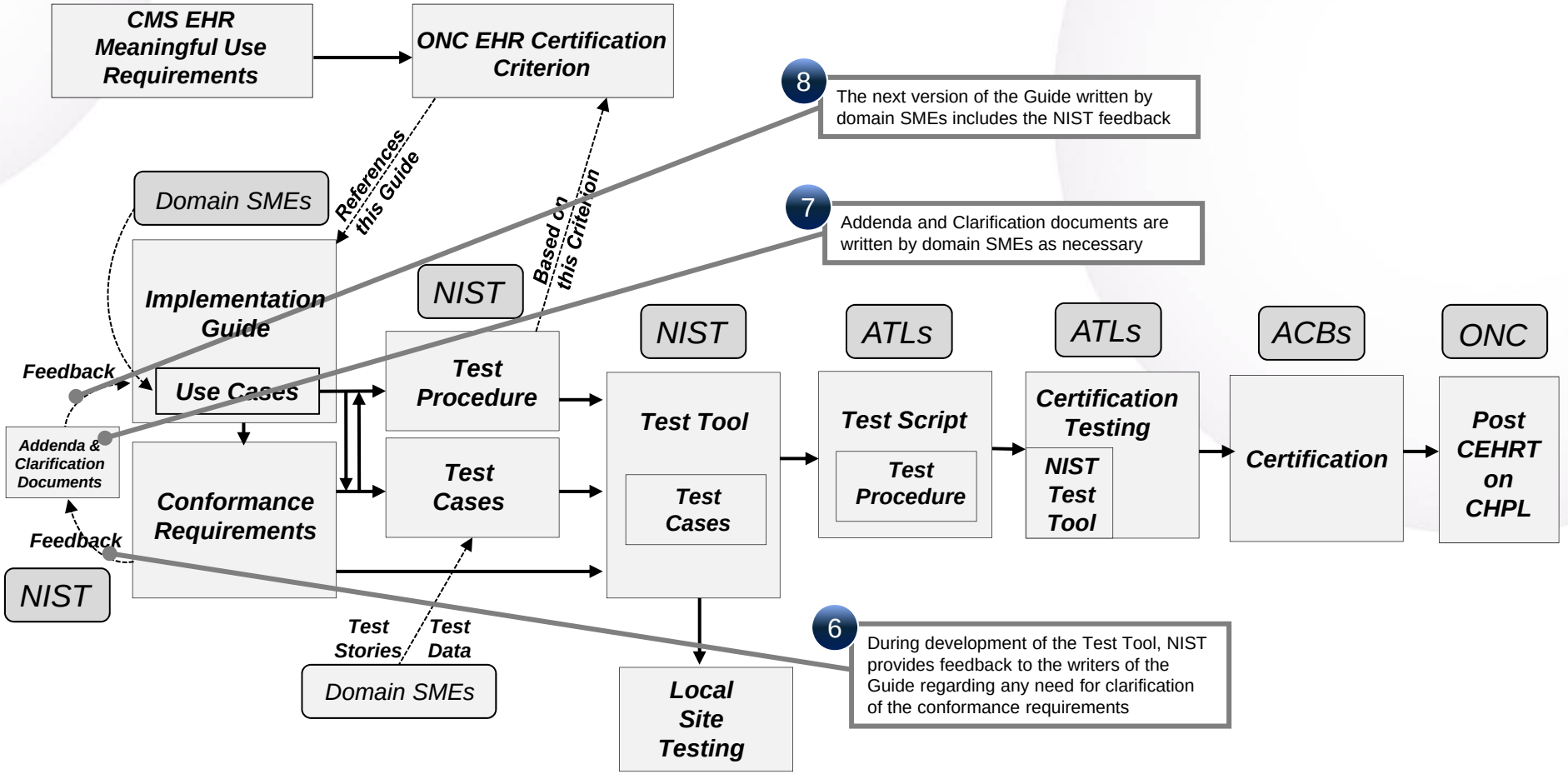

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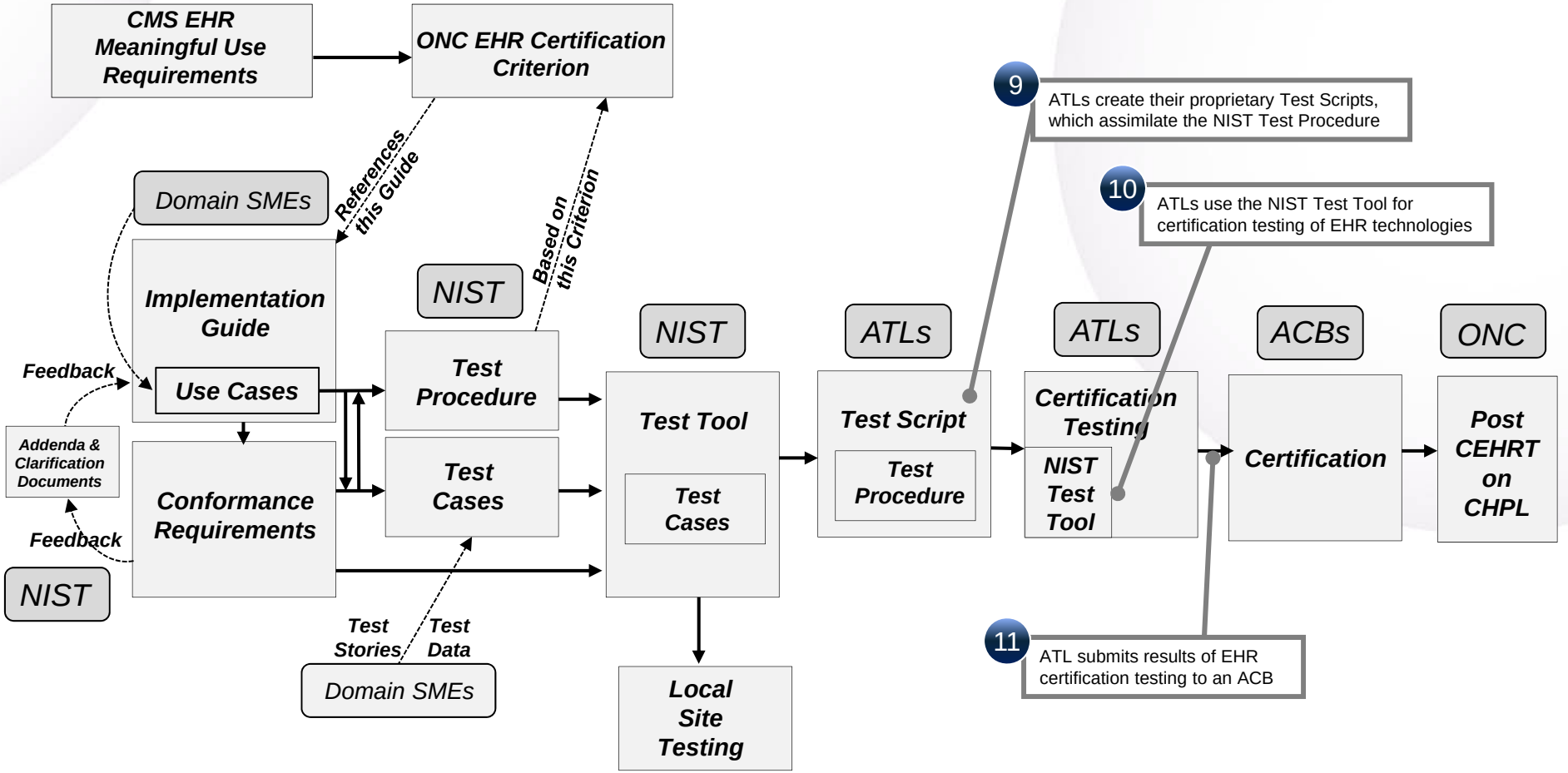

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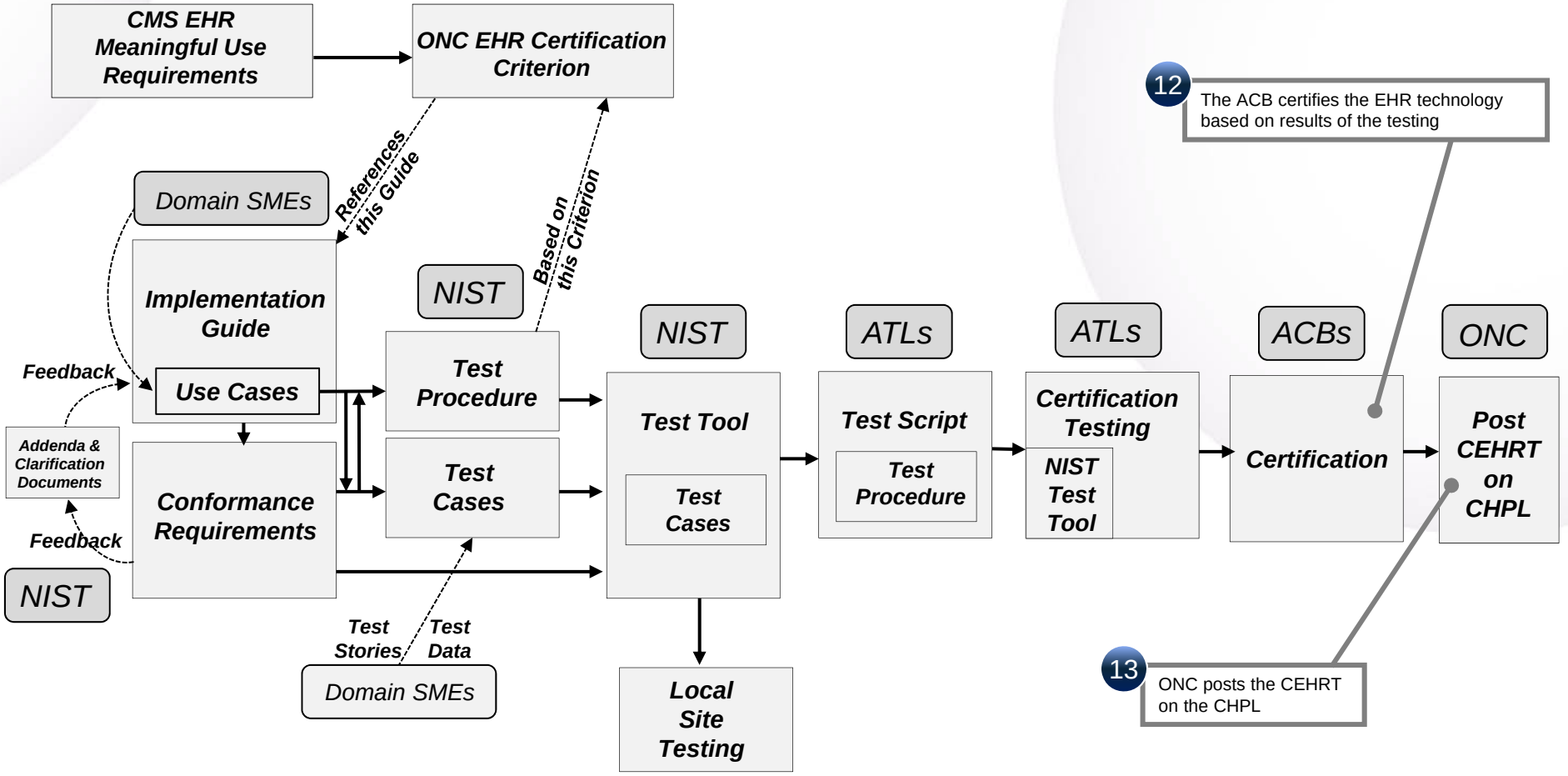

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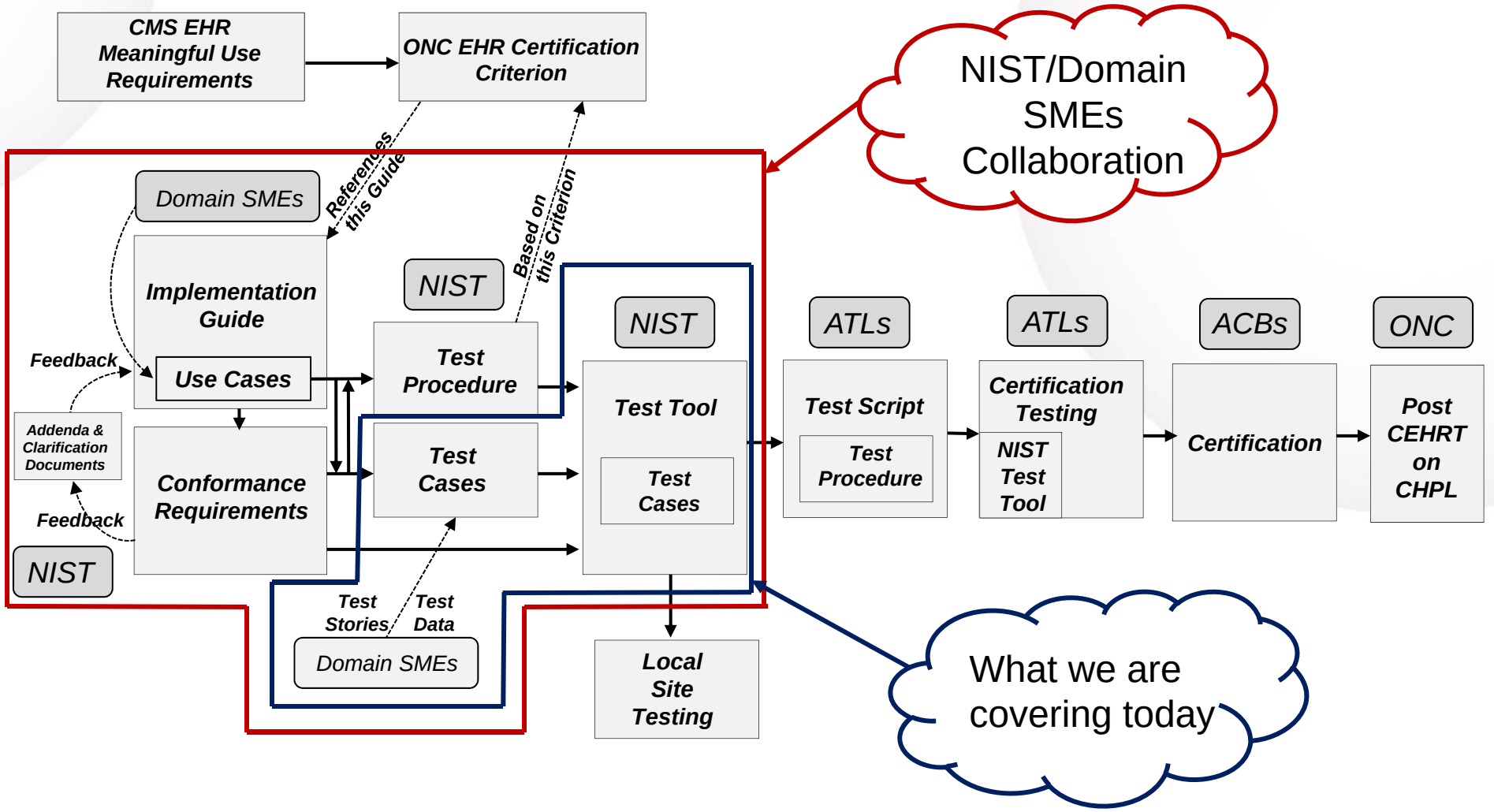

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Testing and Profiling Concepts

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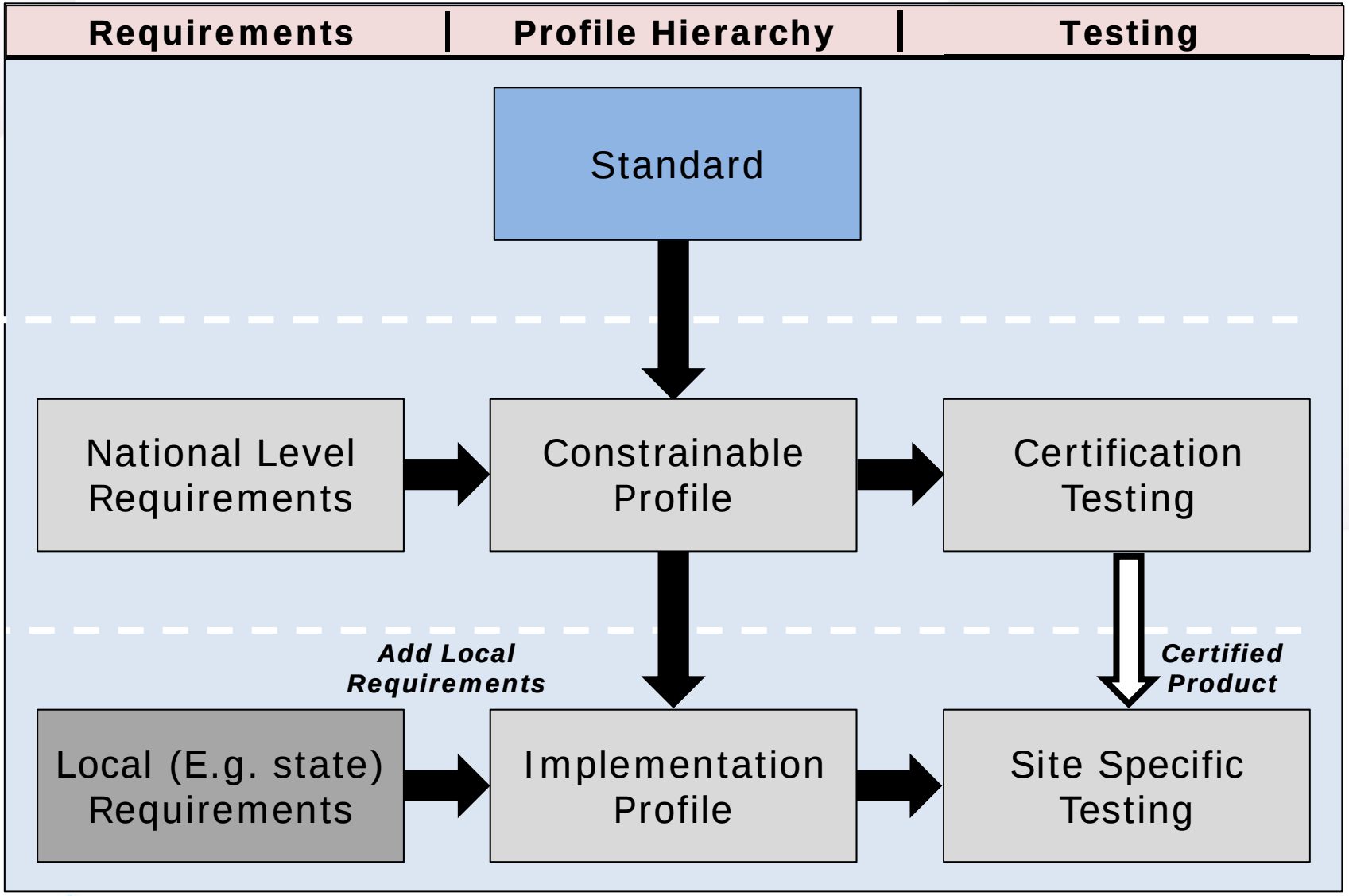
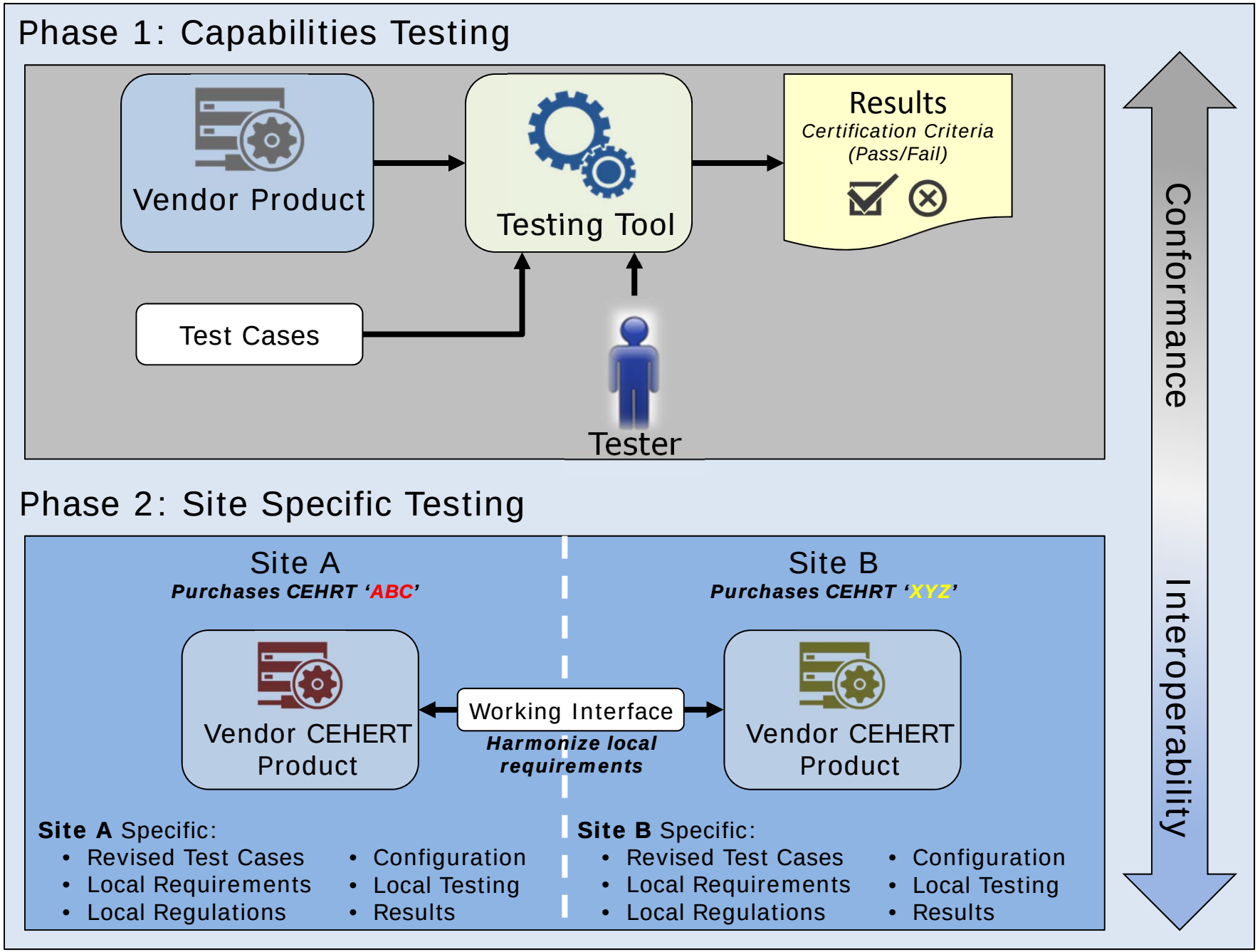
Certification Testing

- What Certification Testing Is
  - Focus is on assessing the system's capability (phase 1)
  - Critical step towards achieving interoperability for exchanging healthcare information, but it is not the end-all
  - Purchasing a certified EHR system provides a degree of certainty that the buyer has obtained a product that meets a level of capabilities established by the ONC
  - Although the ONC HIT Certification Program by design does not extend to installation bases, it provides the foundation and a shorter pathway to achieving site-specific interoperability
- What Certification Testing is not
  - It is not directed at site-specific installations
  - End users of certified EHR products will need to configure their products according to their local requirements and test (phase 2)

Standards, Profiles, and Testing

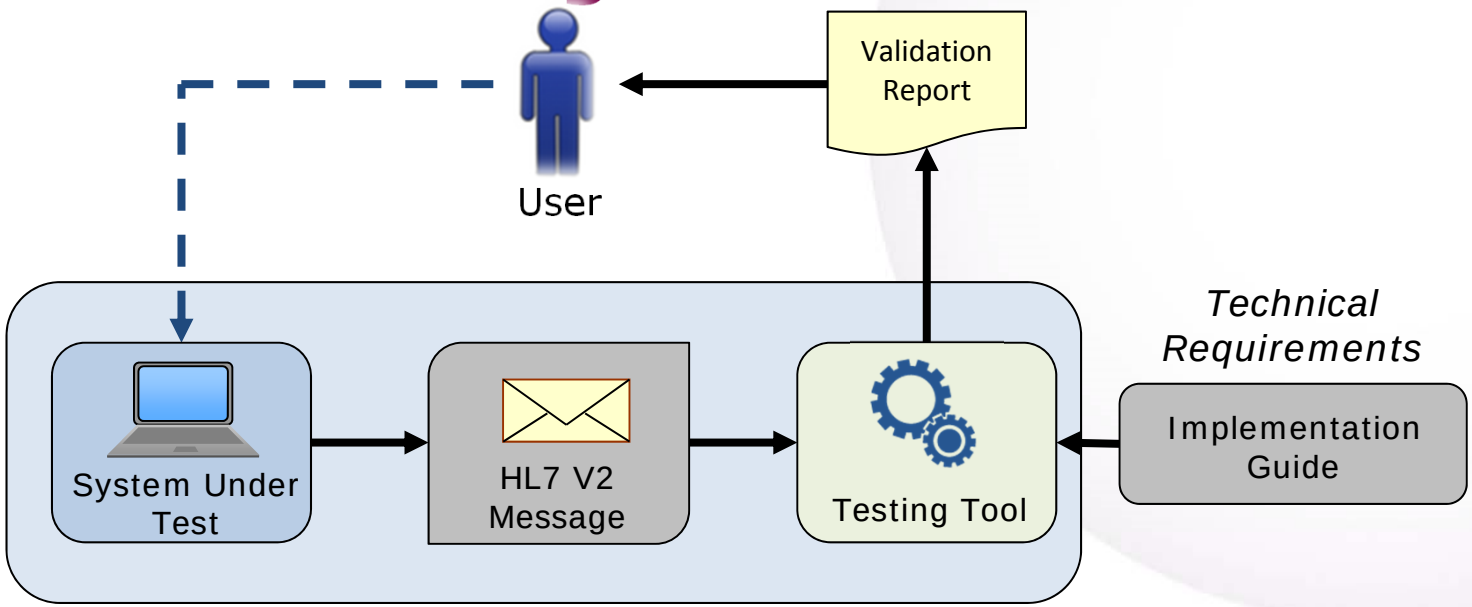



Phase 1: Capabilities Testing
Vendor Product
Testing Tool
Results
Certification Criteria
(Pass/Fail)
Test Cases
Tester
Conformance
Interoperability
Phase 2: Site Specific Testing
Site A
Purchases CEHRT 'ABC'
Site B
Purchases CEHRT 'XYZ'
Vendor CEHERT Product
Working Interface
Harmonize local requirements
Vendor CEHERT Product
Site A Specific:
Revised Test Cases
Local Requirements
Local Regulations
Configuration
Local Testing
Results
Site B Specific:
Revised Test Cases
Local Requirements
Local Regulations
Configuration
Local Testing
Results

Test Tool Operation Modes

- Testing the Sender (Message Creation)
  - Context-free Testing
    - Provides a simple and convenient method for testing message structure and most vocabulary
    - The context-free operational mode validates any message created by the EHR
    - It is disassociated from a test script, test case, or specific content (test data)
  - Context-based Testing
    - Test Cases provided
    - Context (specific Test Scenario, etc.) is known to validation tool
    - Expands the scope of testing
- Testing the Receiver (Incorporation)
  - Incorporation of message and associated functional requirements
  - Employs inspection testing (Juror Document)

Context-free Testing

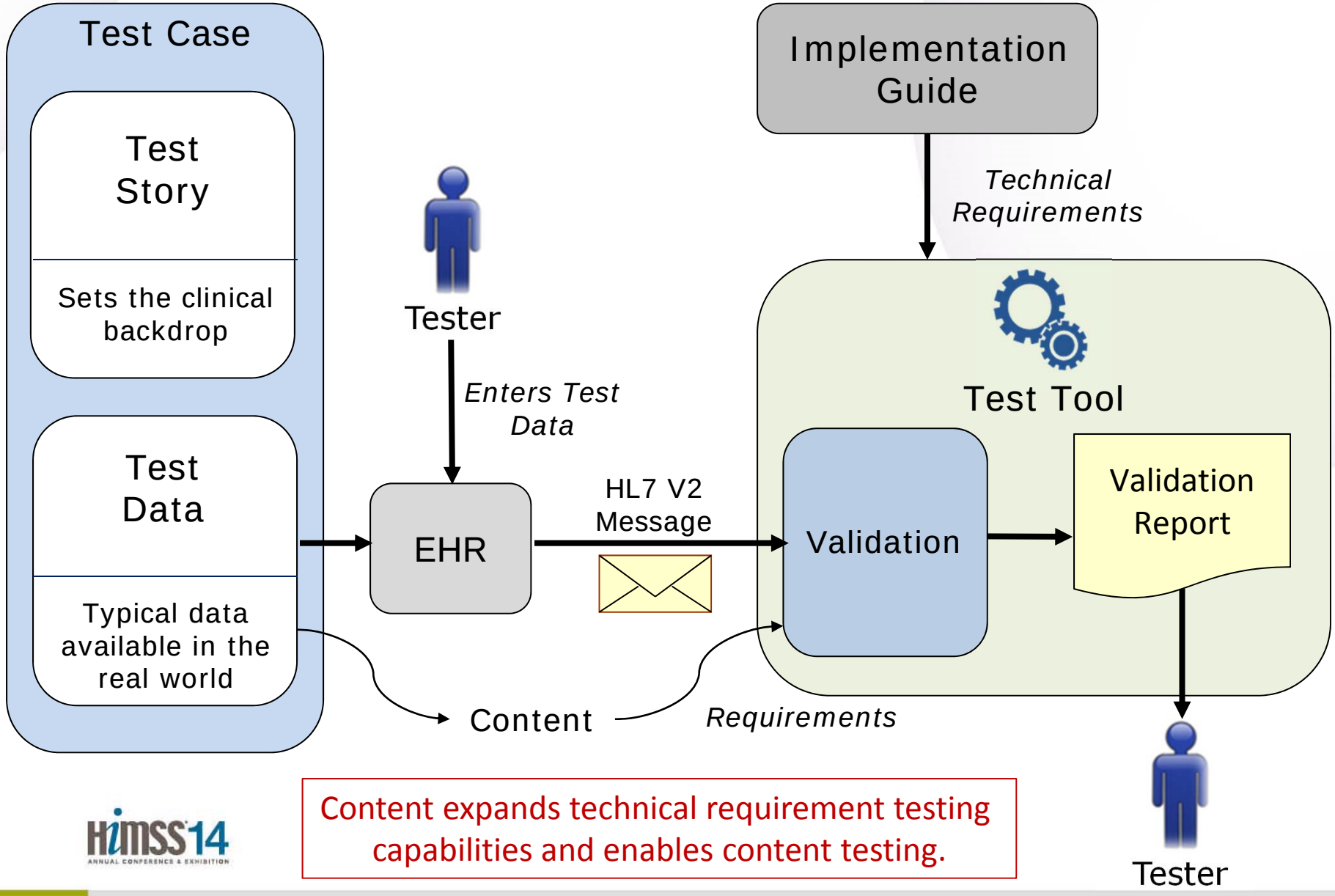


- No Test Cases provided
- Context (Test Scenario, etc.) is unknown to validation tool
- May be used to test any message created by an EHR
- Provides a simple and convenient method for testing message *structure* and most *vocabulary*
- Typically is not used for certifying EHR technologies for the ONC certification criteria, but may be used for certification testing in specific instances (the Tester must perform visual inspection to validate content of message)

Context-based Testing

- The context-based operational mode validates messages associated with a given test script that includes data for a specific test scenario
  - The EHR creates a message that corresponds to the test data provided in the test script
  - Testing will include the technical requirements and content-specific requirements specified in the test case
- Context (specific Test Scenario, etc.) is known to validation tool
- Provides a method for testing/assessing a message for all conformance requirements of an Implementation Guide
- Is used for certifying EHR technologies for the ONC certification criteria
- **Significantly expands the scope of testing**
  - Usage: Required, but may be empty (RE), Conditionals (C)
  - Cardinality: Ranges
  - Length: Ranges
  - Vocabulary
- **Helps Interpretation and Use of the Standards**

Context-based Testing (Sending Application)



Content expands technical requirement testing capabilities and enables content testing.

Test Story

Description

Following treatment, the patient's vital signs gradually return to normal. At 2 PM, the patient's laboratory and radiology tests results are provided to the attending physician. The tests indicate that the infant has influenza and pneumonia. The patient's mother is provided with treatment information and prescriptions for her infant son. The working diagnosis (ICD-9 CM 487.1) is resolved/inactivated, and at 5 PM the patient is discharged home with a final primary diagnosis of pneumonia, and secondary diagnosis of influenza. Big City Children's Urgent Care routinely sends electronic syndromic surveillance data to the Big City Health Department (BCHD) in accordance with a city regulation. At 6:00 PM on February 20, 2010, the facility's electronic health record module for syndromic surveillance data assembles and transmits a Discharge ADT message about this patient encounter to BCHD.

Comments

This Test Case provides an example of clinical encounter that could take place in either an urgent care or emergency clinical setting. It is therefore applicable to EHR technology used in some ambulatory settings. Dates and times are provided in this test case to illustrate the sequence of clinical and messaging events. Since the exact dates and times are not reproducible when modeling the test case with EHR technology, only date and time format will be validated within tester submitted test data. ICD 9 CM diagnosis codes are acceptable with or without decimals.

TestObjectives

Output an ADT A03 discharge message in HL7 2.5.1 containing the syndromic surveillance data for the patient encounter.

Notes to Testers

This Test Case does not prescribe the method used by the EHR to change a Working diagnosis to a Final diagnosis. The Test Case only validates a specific ADT message type. Although the other units of measure for patient age are acceptable in general (and the Context-free validation accepts any of the valid units of measure for age), the SS_1_1_UC_Visit Test Case specifies that "a" for years be used in this message for the Context-based validation. Certain health departments mandate that the patient age be sent in years only, and the EHR must be able to support sending "0 years".

Test Data

Patient Information

Element Name	Data
Name	Coded Pseudo-Name to ensure anonymity
Gender	Male
Race	Native Hawaiian or Other Pacific Islander
Ethnic Group	Not Hispanic or Latino
Zip Code	02130
County/Parish Code	25025

Visit Information

Element Name	Data
Admit Date and Time	02/20/2010 8:30 AM
Discharge Disposition	Discharged to home or self care (routine discharge)
Diagnosis Type	Final
Diagnosis	Pneumococcal pneumonia [Streptococcus pneumoniae pneumonia]
Diagnosis Type	Final
Diagnosis	Influenza

Observation Results Information

Element Name	Data
Observation Identifier	Chief complaint:Find:Pt:Patient:Nom:Reported
Observation Value	Fever, cough
Units	
Observation Results Status	Final results; Can only be changed with a corrected result.

Message Content

PID : Patient Identification Segment

Location	Data Element	Data	Categorization
PID.1	**Set ID - PID**	1	IG Fixed Data
PID.3	**Patient Identifier List**		
PID.3.1	ID Number	3333	Changeable Data
PID.3.5	Identifier Type Code	MR	Changeable Data
PID.5[1]	**Patient Name**		
PID.5[1].7	Name Type Code		
PID.5[2]	**Patient Name**		
PID.5[2].7	Name Type Code	S	Test Case Fixed Data
PID.8	**Administrative Sex**	M	Test Case Fixed Data

DG1 : Diagnosis Segment

Location	Data Element	Data	Categorization
DG1.1	**Set ID - DG1**	1	IG Fixed Data
DG1.3	**Diagnosis Code - DG1**		
DG1.3.1	Identifier	481	Test Case Fixed Data
DG1.3.2	Text	Pneumococcal pneumonia [Streptococcus pneumoniae pneumonia]	Changeable Data
DG1.3.3	Name of Coding System	I9CDX	IG Fixed Data
DG1.6	**Diagnosis Type**	F	Test Case Fixed Data

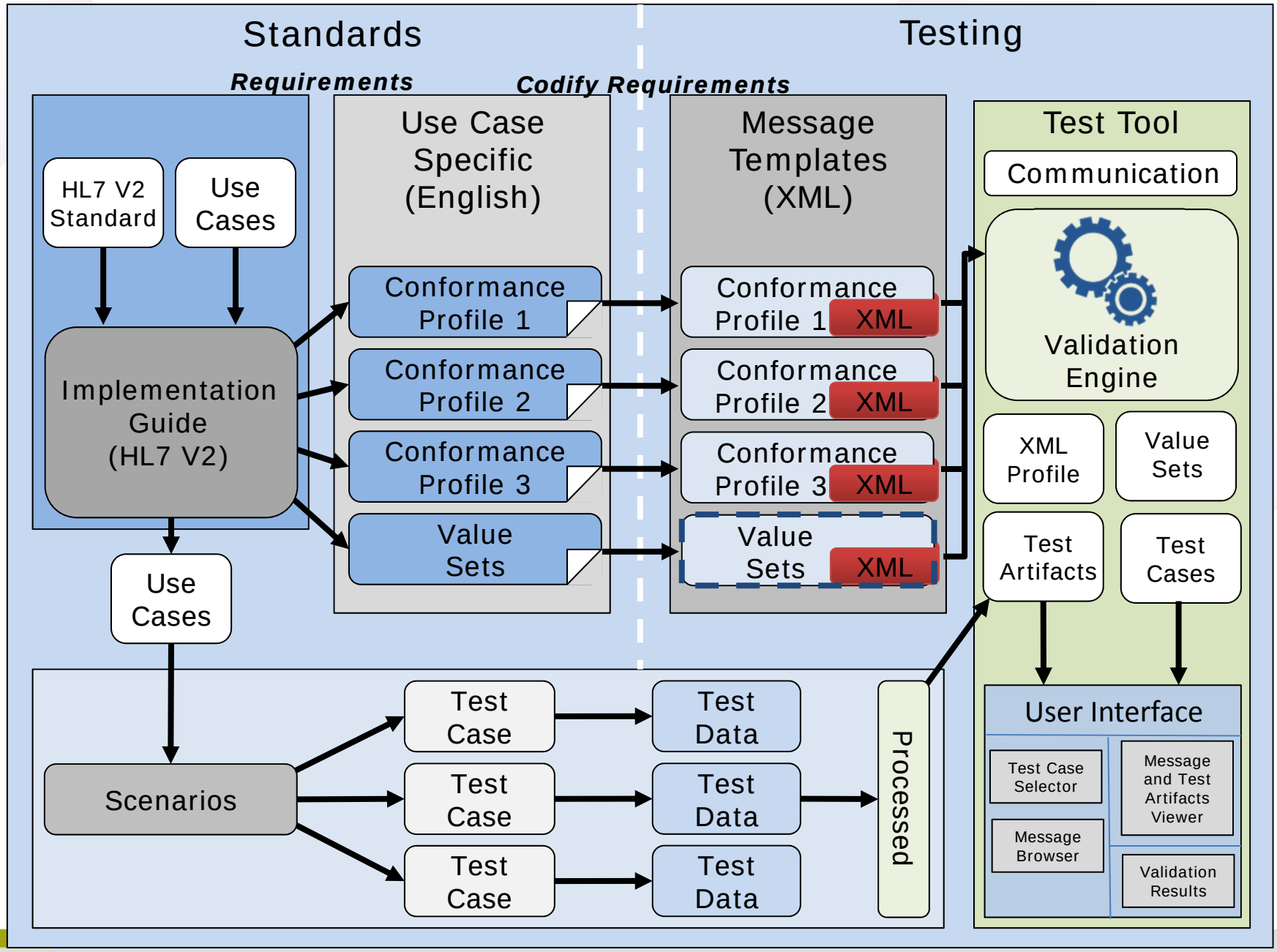
DG1 : Diagnosis Segment

Location	Data Element	Data	Categorization
DG1.1	**Set ID - DG1**	2	IG Fixed Data
DG1.3	**Diagnosis Code - DG1**		
DG1.3.1	Identifier	487	Test Case Fixed Data
DG1.3.2	Text	Influenza	Changeable Data
DG1.3.3	Name of Coding System	I9CDX	IG Fixed Data
DG1.6	**Diagnosis Type**	F	Test Case Fixed Data

OBX : Observation/Result Segment

Location	Data Element	Data	Categorization
OBX.1	**Set ID**	1	IG Fixed Data
OBX.2	**Value Type**	CWE	Test Case Fixed Data
OBX.3	**Observation Identifier**		
OBX.3.1	Identifier	SS003	Test Case Fixed Data
OBX.3.3	Name of Coding System	PHINQUESTION	Test Case Fixed Data
OBX.5-CWE	**Observation Value**		
OBX.5-CWE.1	Identifier	261QU0200X	Test Case Fixed Data
OBX.5-CWE.2	Text	Urgent Care	Changeable Data
OBX.5-CWE.3	Name of Coding System	NUCC	Test Case Fixed Data

Tool Development and Framework



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Test Tool Overview

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Meaning Validation Suite Overview

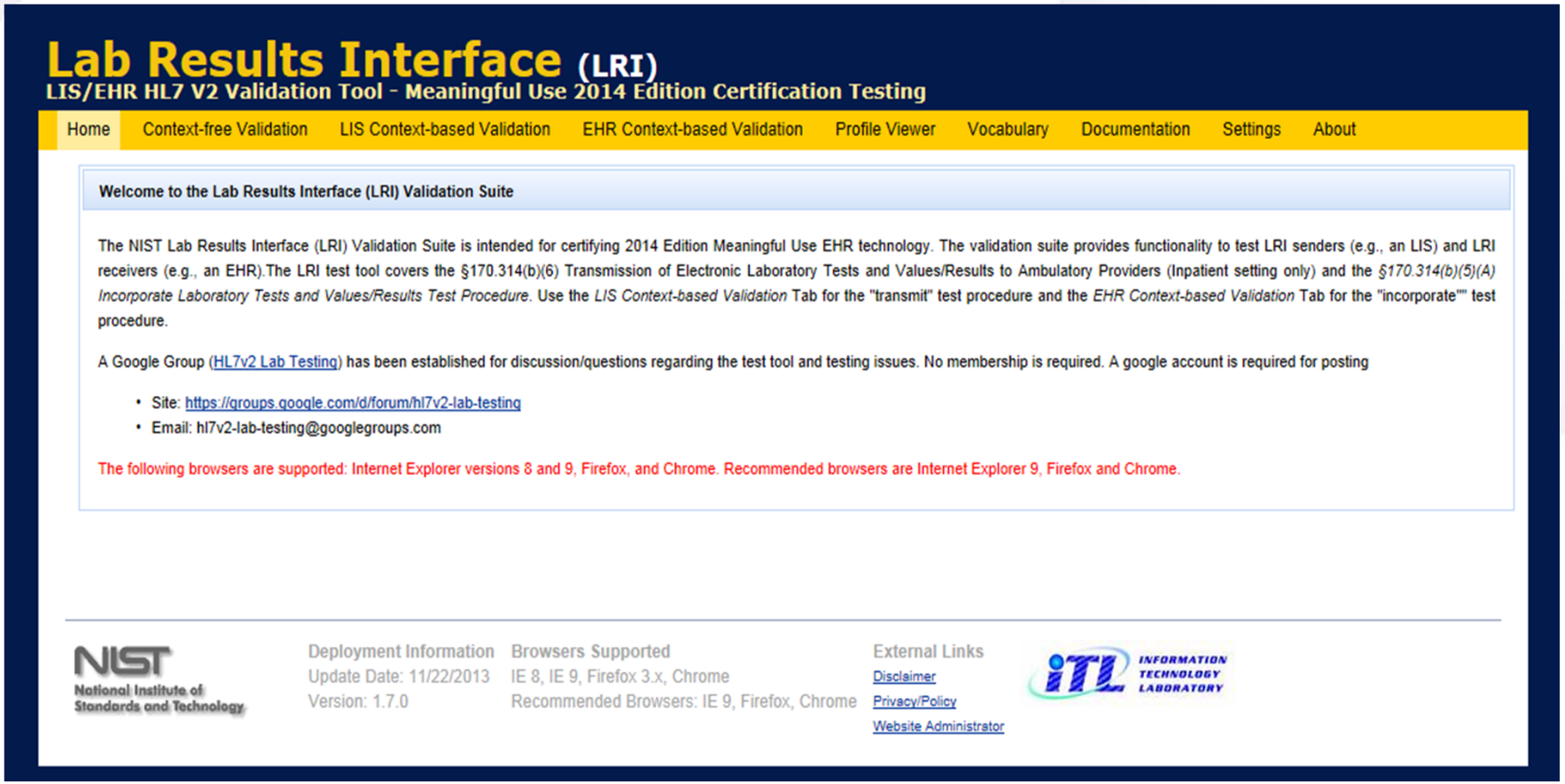
Purpose: The tool validates:

- Lab result messages created by hospital laboratory information systems (LIS) technology according to specific requirements captured in a conformance profile
- Lab result messages received/incorporated by electronic health record systems (EHR) technology according to specific requirements captured in a conformance profile

Tool Key Capabilities	
LIS Context-free Testing	**(No Test Cases - Test any LRI message created by LRI senders (e.g. an LIS)** • Context (e.g. type and results of lab test) is unknown to validation tool • Provides a simple and convenient method for testing message structure and most vocabulary
LIS Context-based Testing	**(Generated Data sheets from Test Cases)** • Context (e.g. type and results of lab test) is known to validation tool • All conformance requirements of LRI implementation guide can be assessed • Used for certifying 2014 Edition Meaningful Use EHR technology
EHR Context-based Testing	**(Generated Data Sheets and Juror Documents from Test Cases)** • Validates EHR systems that receive messages in accordance with the ONC S&I Framework Lab Results Interface (LRI) implementation guide (IG) • Creates Juror document for inspection testing • Used for certifying 2014 Edition Meaningful Use EHR technology
Profile Viewer	Provides a browsable version of the conformance profile which encapsulates the requirements. Can be used to assist in the interpretation of errors.
Vocabulary Browser	Provides a browsable view of the vocabulary requirements. Can be used to assist in the interpretation of value set errors.
Documentation	Provides access to documents which will assist in using the tool (including test plans, data sheet and juror document supplements.

Test Tool Home Page

Web Application allows for easy access and no installation.



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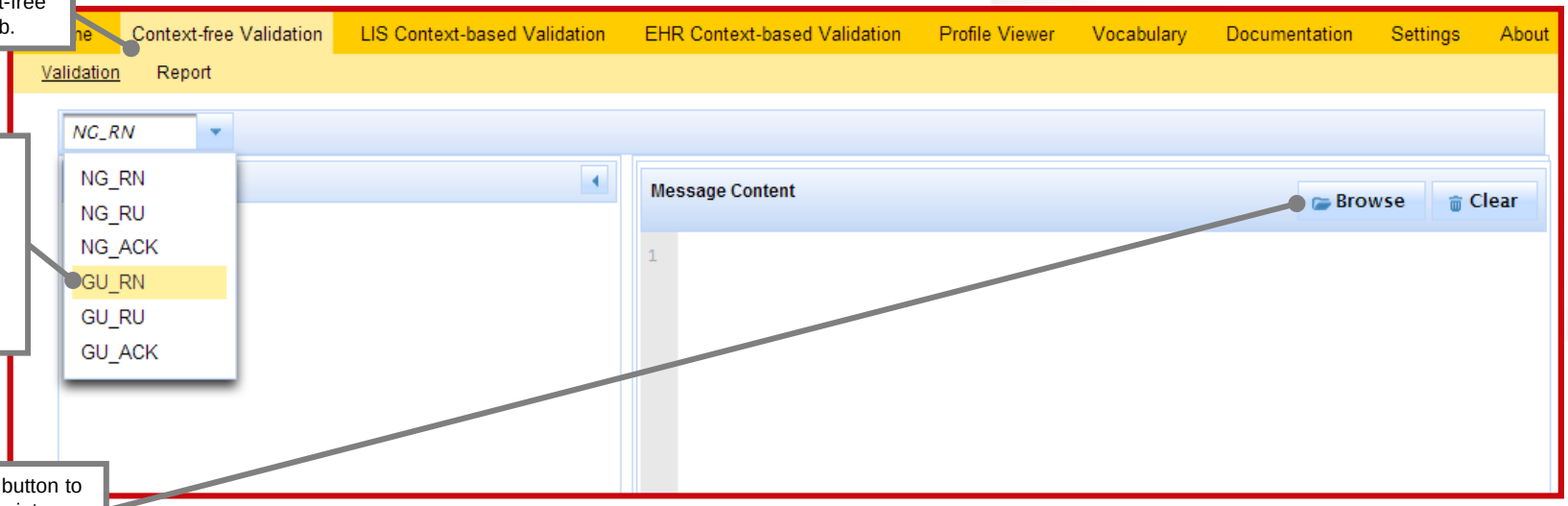
1) Import test message (Context-Free)

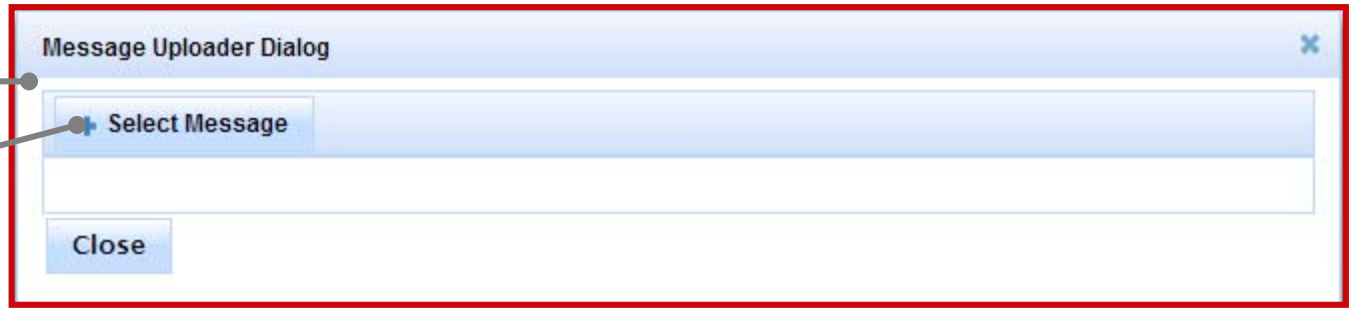
Context-free Validation page

This page validates any LIS message. It is disassociated from a test script, test case, or specific content. Testing will include the technical requirements and content-specific requirements specified in the selected profile.

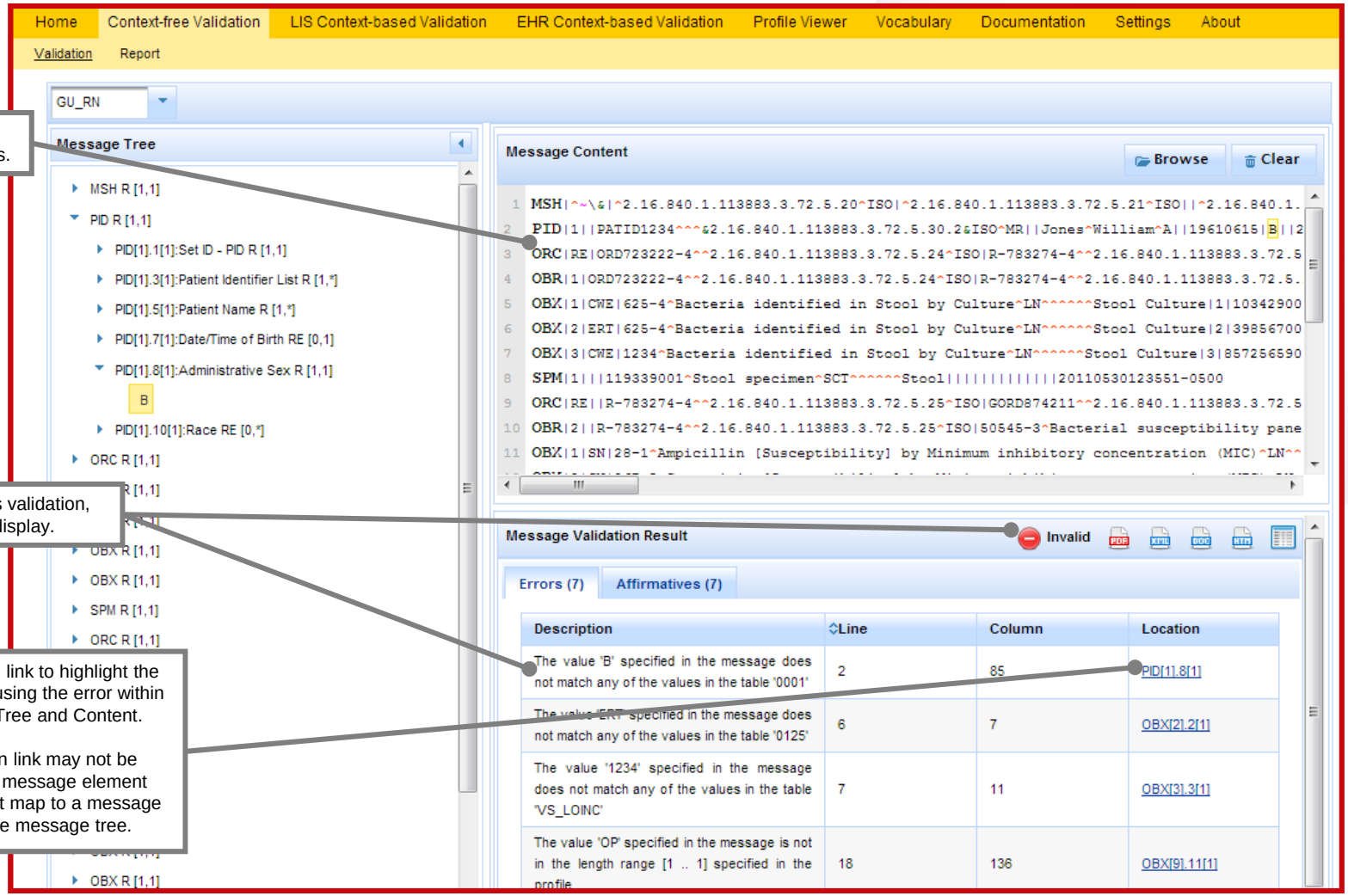
1. Open LRI Validation tool using link: http://hl7v2-lab-testing.nist.gov.
2. Click on Context-free Validation tab.
3. Select conformance profile to use to validate the message.

   For this tutorial, select GU_RN.
4. Click on Browse button to load message into Message Content window.
5. Message Uploader Dialog window displays.
6. Click on Select Message button.
7. Open test message file to upload it.





2) Validate test message and review message validation errors



1 Uploaded test message displays.

2 If message fails validation, errors will display.

3 Click on location link to highlight the data element causing the error within the Message Tree and Content.

Note: Location link may not be available if the message element location does not map to a message element in the message tree.

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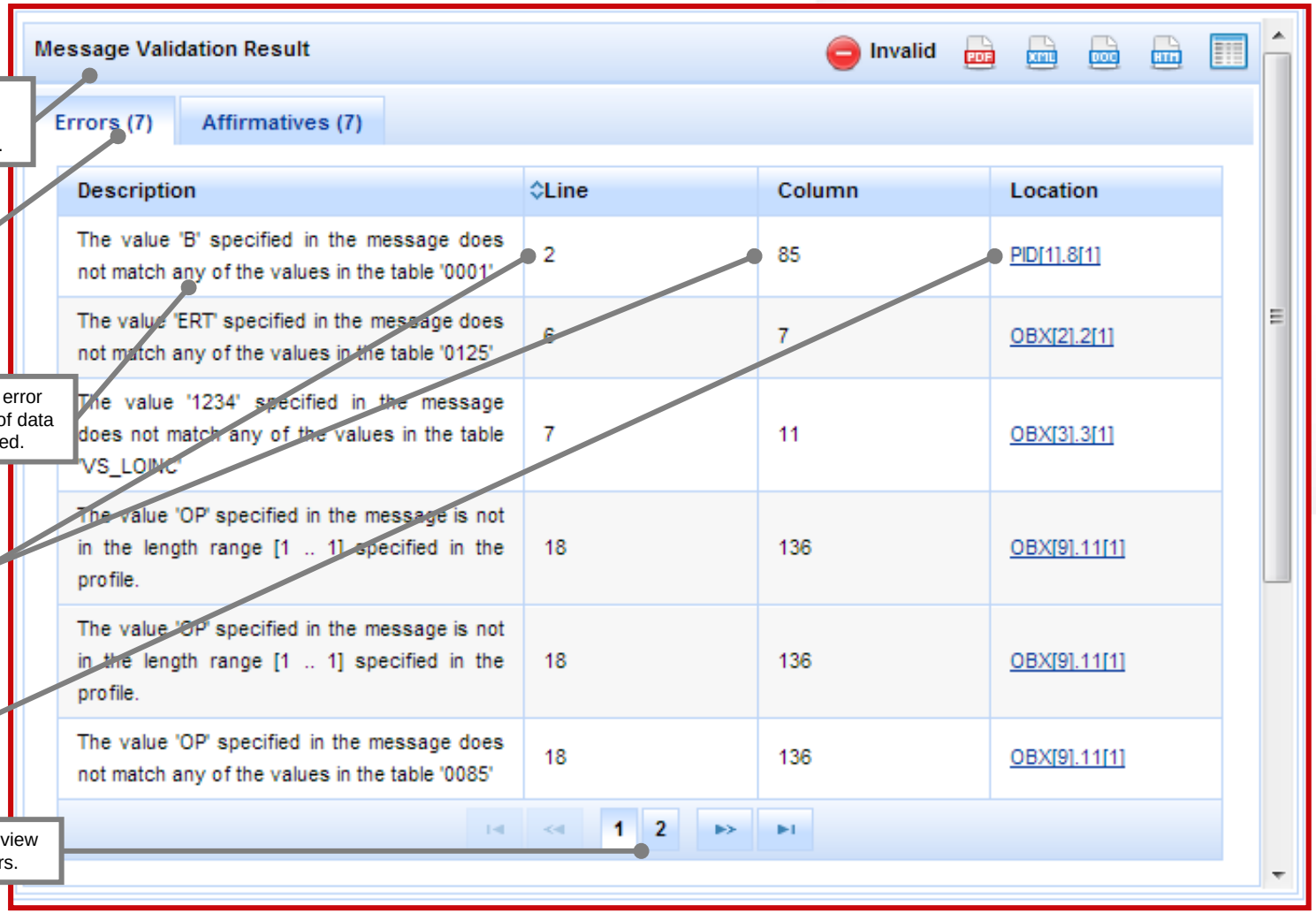
2) Validate test message and review message validation errors, continued



4 Review error information provided in the Message Validation Result section.

5 Total number of errors displays.

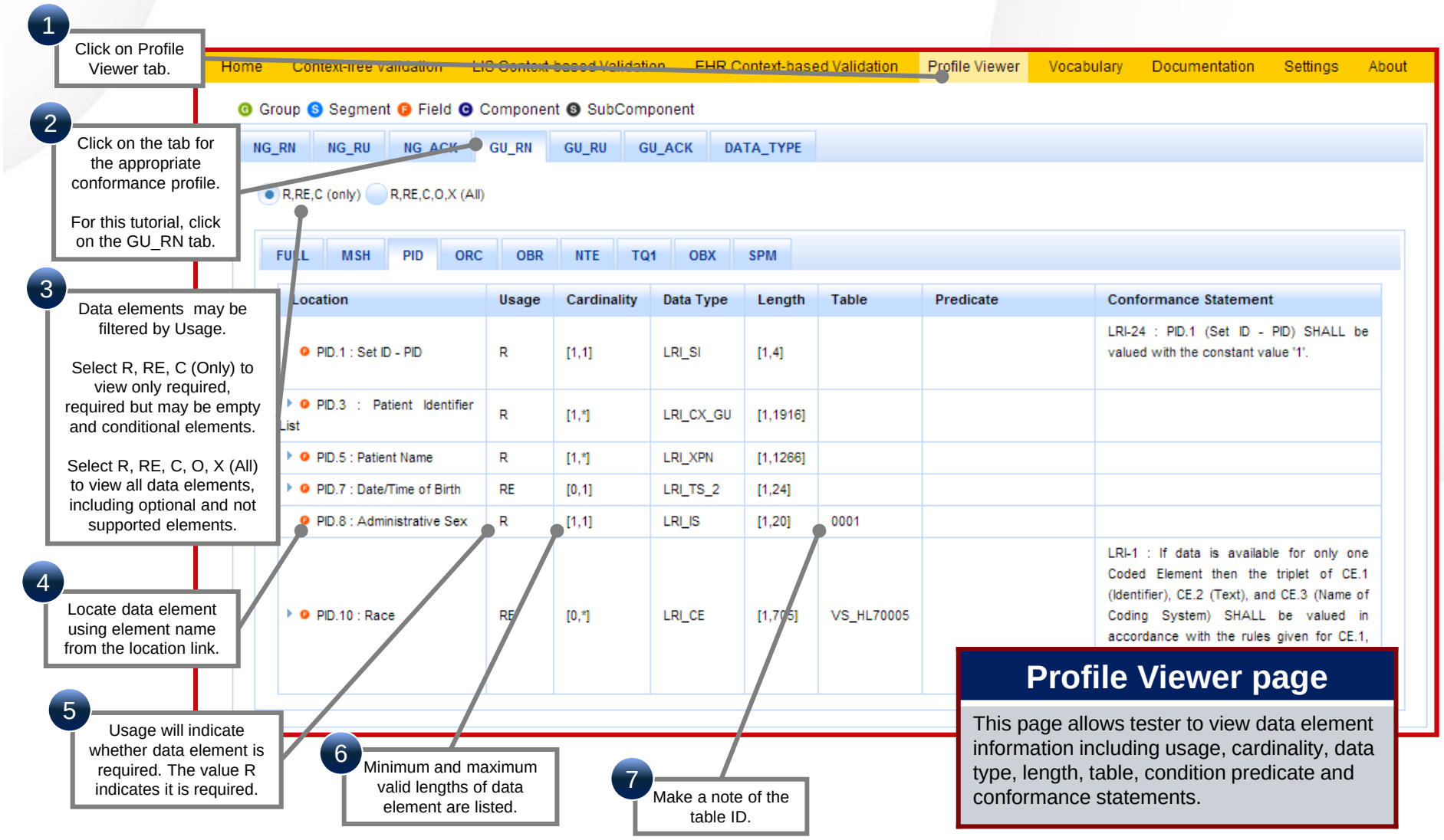
6 Description explains why error occurred. Format or table of data element may be provided.

7 Line number and column of errors are provided.

8 Location link displays the location of the data element.

9 Click on page numbers to view additional pages of errors.

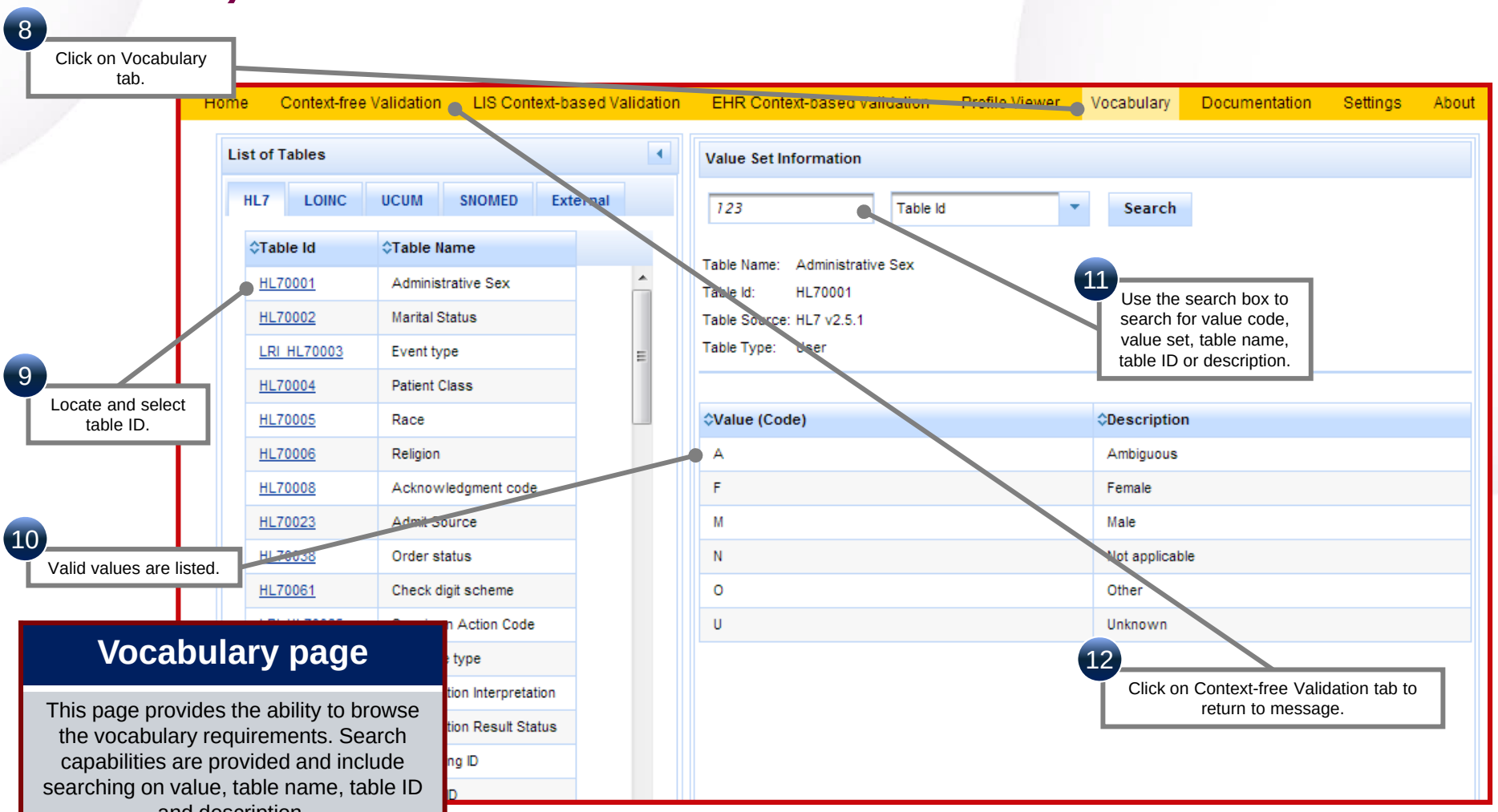
3) Look up valid data element values and tables



Profile Viewer page

This page allows tester to view data element information including usage, cardinality, data type, length, table, condition predicate and conformance statements.

3) Look up valid data element values and tables, continued



Vocabulary page

This page provides the ability to browse the vocabulary requirements. Search capabilities are provided and include searching on value, table name, table ID and description.

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ONWARD

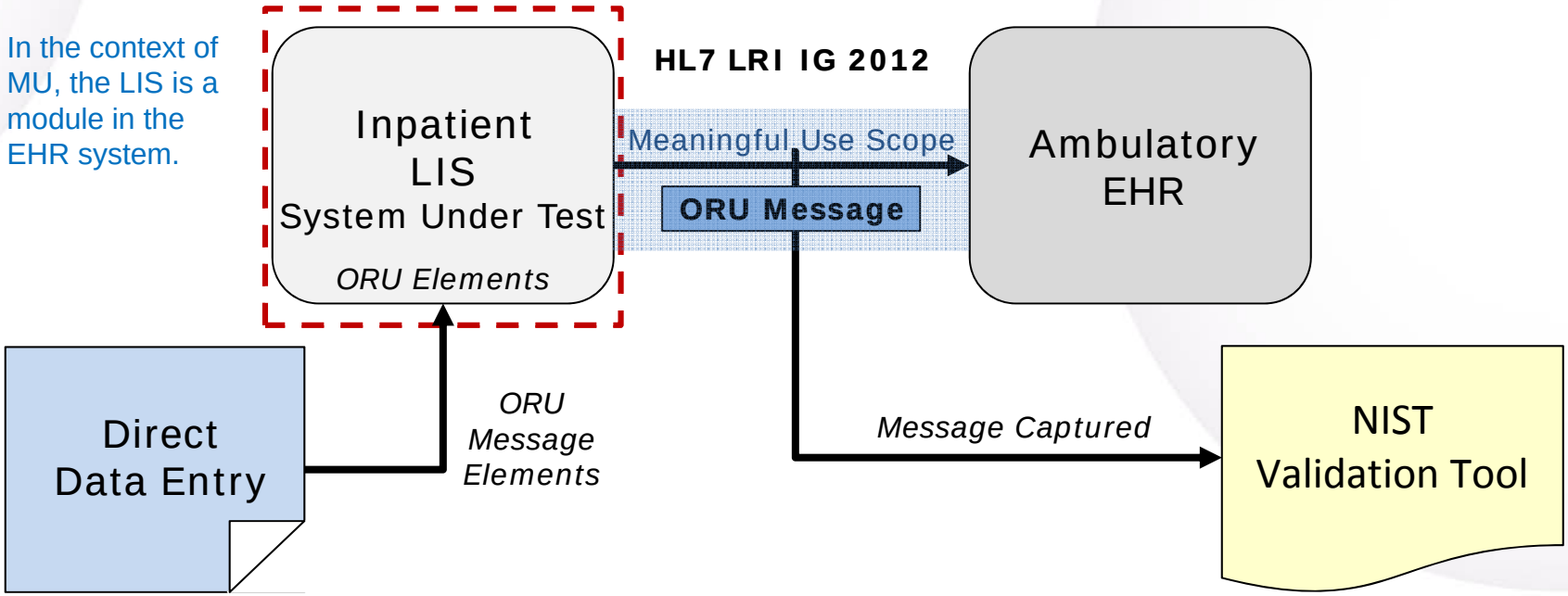
Test Tool Overview
Case Study: Lab Results Interface

Testing the Message Created by the Sender (Context-Based)

NIST
National Institute of Standards and Technology
U.S. Department of Commerce

LIS Test Process and Scope

In the context of MU, the LIS is a module in the EHR system.



- The LIS is the system being tested. The LIS system is required to create messages that conforms to the referenced standards.
- Test data can be entered into LIS directly via the LIS's user interface or be imported via an incoming message. The LIS is expected to process the test data to create a message. This message is captured and uploaded into the testing tool for validation.
- Test data are available through the Test Tool via the Test Cases. Each Test Case includes a Test Story that provides the context, a Test Data Specification that lists the test data, and a Message Content Data Sheet that shows a conformant message.

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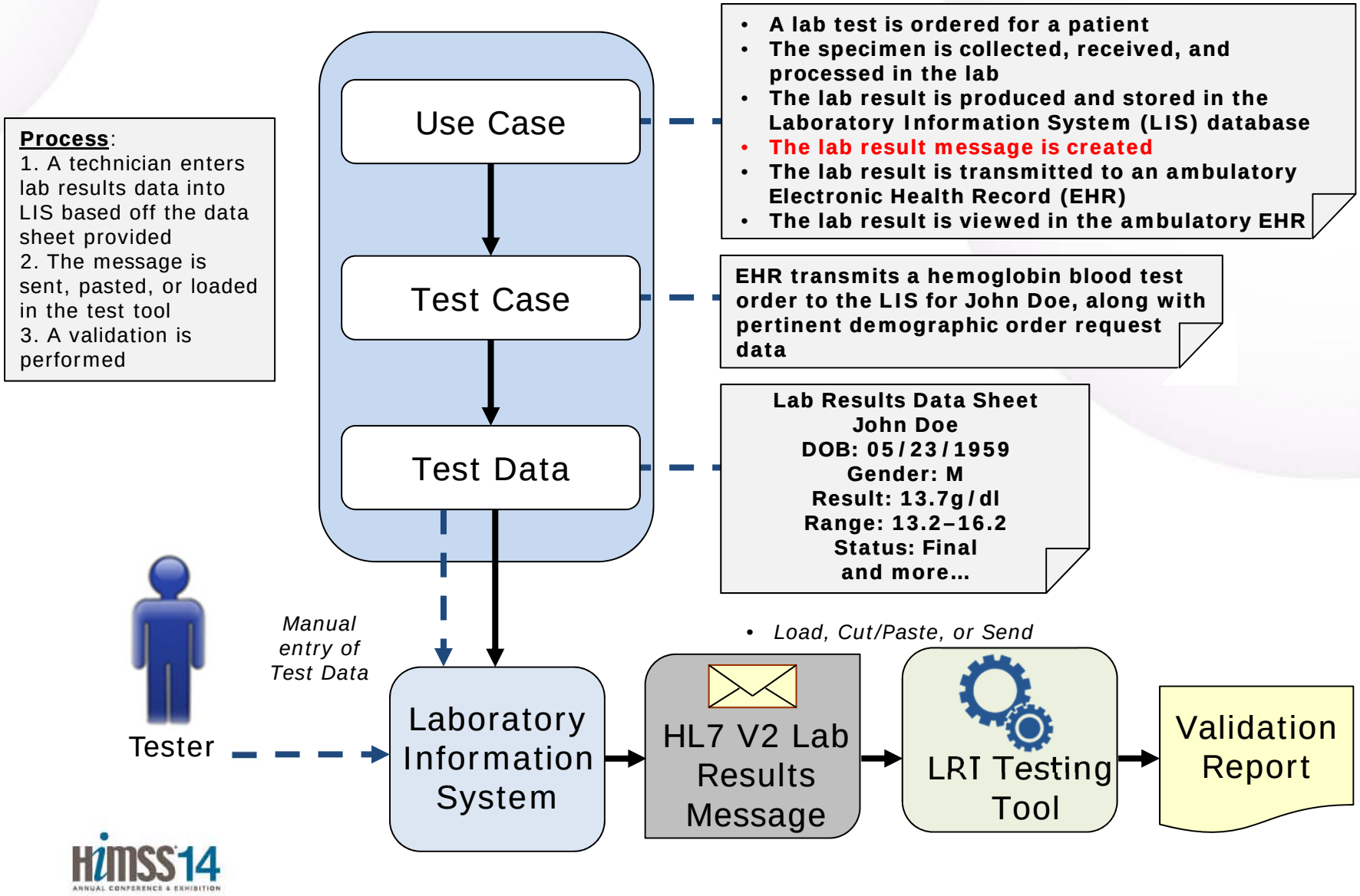
LIS Context-based Testing Overview



Test Case Summary (Create)

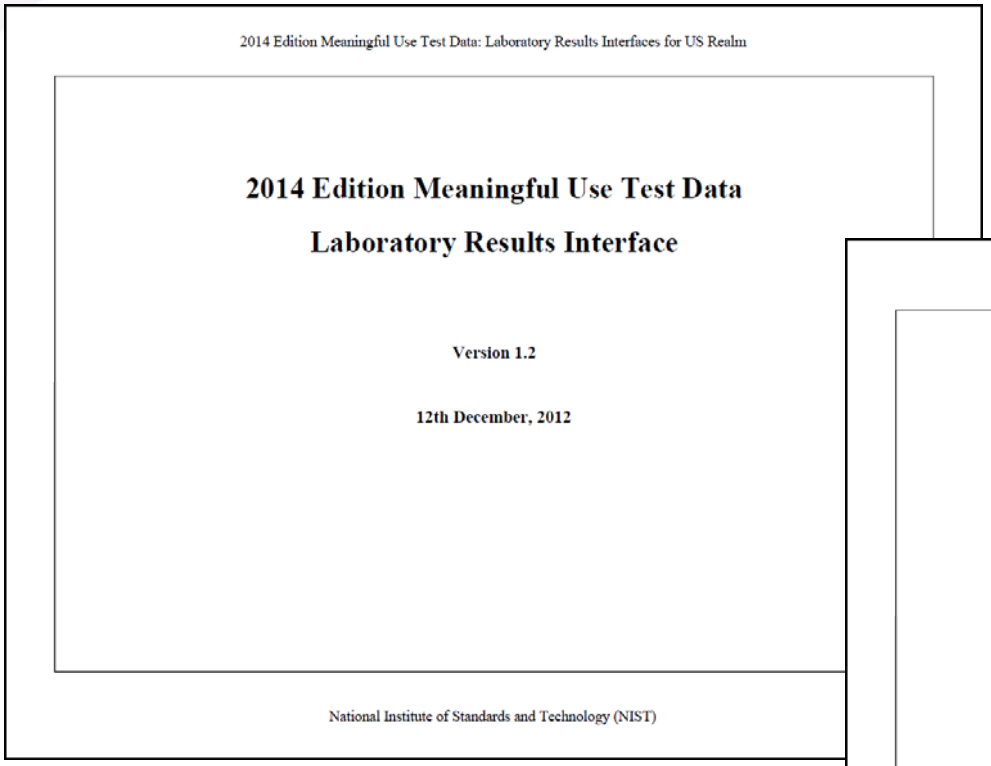
- A Test Case contains of
  - Narrative Test Story
    - Provides the context for the test case (real-world scenario)
  - Test Data Specification
    - Provides the data associated with the Test Story
    - Consists of typically available information in the clinical setting
  - Test Story and Test Data Specification together
    - Provide sufficient information to be entered into the EHR for generating the test message using Vendor-identified EHR function(s)
  - Message Content Data Sheet
    - Shows a conformant message instance for each Test Case
    - Organizes the message content in a table format that provides the HL7 V2 message elements and the data associated with the message elements for each Test Case
    - Provides the “answer” to the Test Case (“question”) articulated by the Test Story and the Test Data Specification.

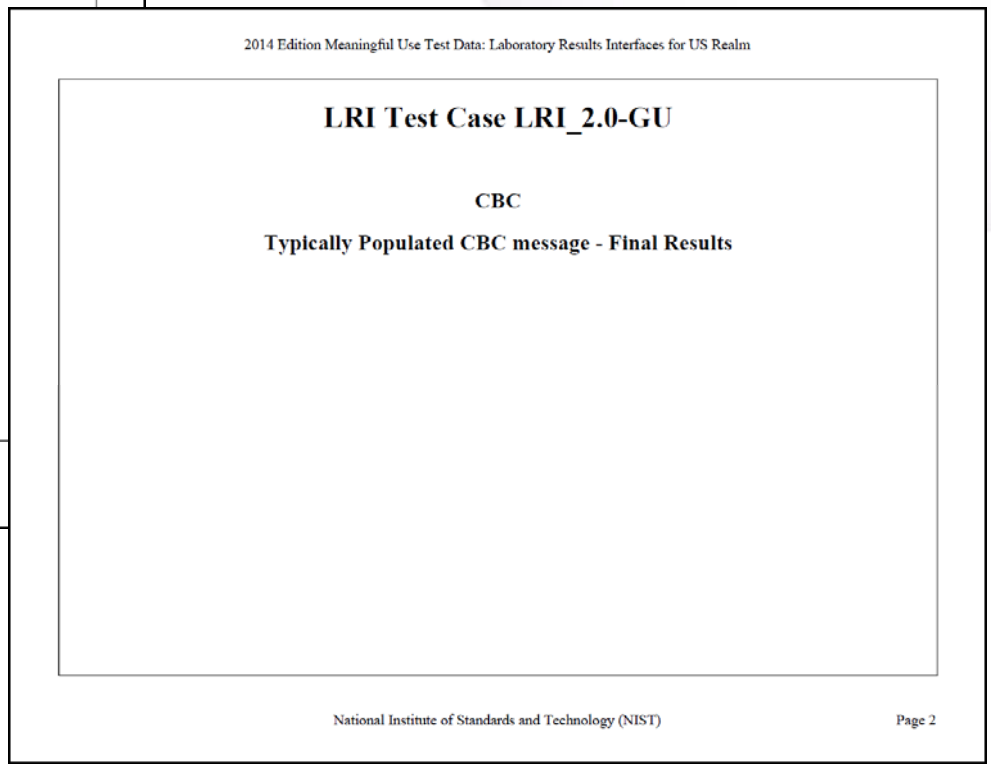
LRI Test Cases

Lab Results Interface Test Stories and Associated Test Cases

Test Stories	NG Test Cases	GU Test Cases
1. Maximally Populated SED Rate message - Final Results	LRI_1.0-NG	LRI_1.0-GU
2. Maximally Populated SED Rate message - Corrected Results	LRI_1.1-NG	LRI_1.1-GU
3. Rejected SED Rate Message (No OBX segment; OBR.25 = X)	LRI_1.2-NG	LRI_1.2-GU
4. Typically Populated CBC message - Final Results	LRI_2.0-NG	LRI_2.0-GU
5. Typically Populated Lipid Panel message - Final Results	LRI_3.0-NG	LRI_3.0-GU
6. Culture-Escherichia coli, Salmonella, Shigella - Parent – Preliminary	LRI_4.0-NG	LRI_4.0-GU
7. Culture-Escherichia coli, Salmonella, Shigella - Parent/Child Susceptibility – Final	LRI_4.1-NG-RU OR LRI_4.2-NG-RN	LRI_4.1-GU-RU OR LRI-4.2-GU-RN
8. Reflex - Hepatitis	LRI_5.0-NG-RU OR LRI_5.1-NG-RN	LRI_5.0-GU-RU OR LRI-5.1-GU-RN

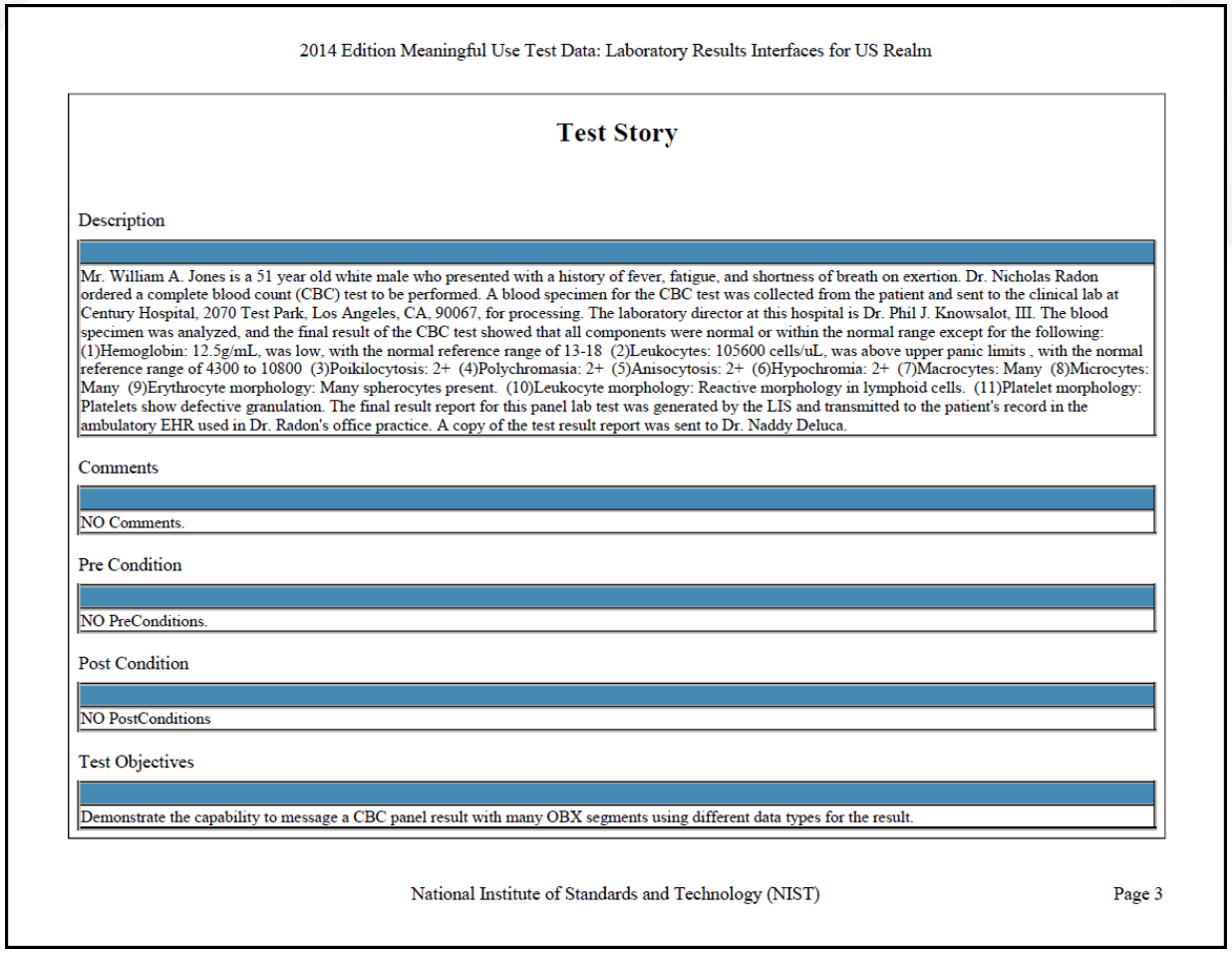
Test Package





Provide complete documentation of the Test Case.

Test Story



2014 Edition Meaningful Use Test Data: Laboratory Results Interfaces for US Realm

Test Story

Description

Mr. William A. Jones is a 51 year old white male who presented with a history of fever, fatigue, and shortness of breath on exertion. Dr. Nicholas Radon ordered a complete blood count (CBC) test to be performed. A blood specimen for the CBC test was collected from the patient and sent to the clinical lab at Century Hospital, 2070 Test Park, Los Angeles, CA, 90067, for processing. The laboratory director at this hospital is Dr. Phil J. Knowsalot, III. The blood specimen was analyzed, and the final result of the CBC test showed that all components were normal or within the normal range except for the following: (1)Hemoglobin: 12.5g/mL, was low, with the normal reference range of 13-18 (2)Leukocytes: 105600 cells/uL, was above upper panic limits , with the normal reference range of 4300 to 10800 (3)Poikilocytosis: 2+ (4)Polychromasia: 2+ (5)Anisocytosis: 2+ (6)Hypochromia: 2+ (7)Macrocytes: Many (8)Microcytes: Many (9)Erythrocyte morphology: Many spherocytes present. (10)Leukocyte morphology: Reactive morphology in lymphoid cells. (11)Platelet morphology: Platelets show defective granulation. The final result report for this panel lab test was generated by the LIS and transmitted to the patient's record in the ambulatory EHR used in Dr. Radon's office practice. A copy of the test result report was sent to Dr. Naddy Deluca.

Comments

NO Comments.

Pre Condition

NO PreConditions.

Post Condition

NO PostConditions

Test Objectives

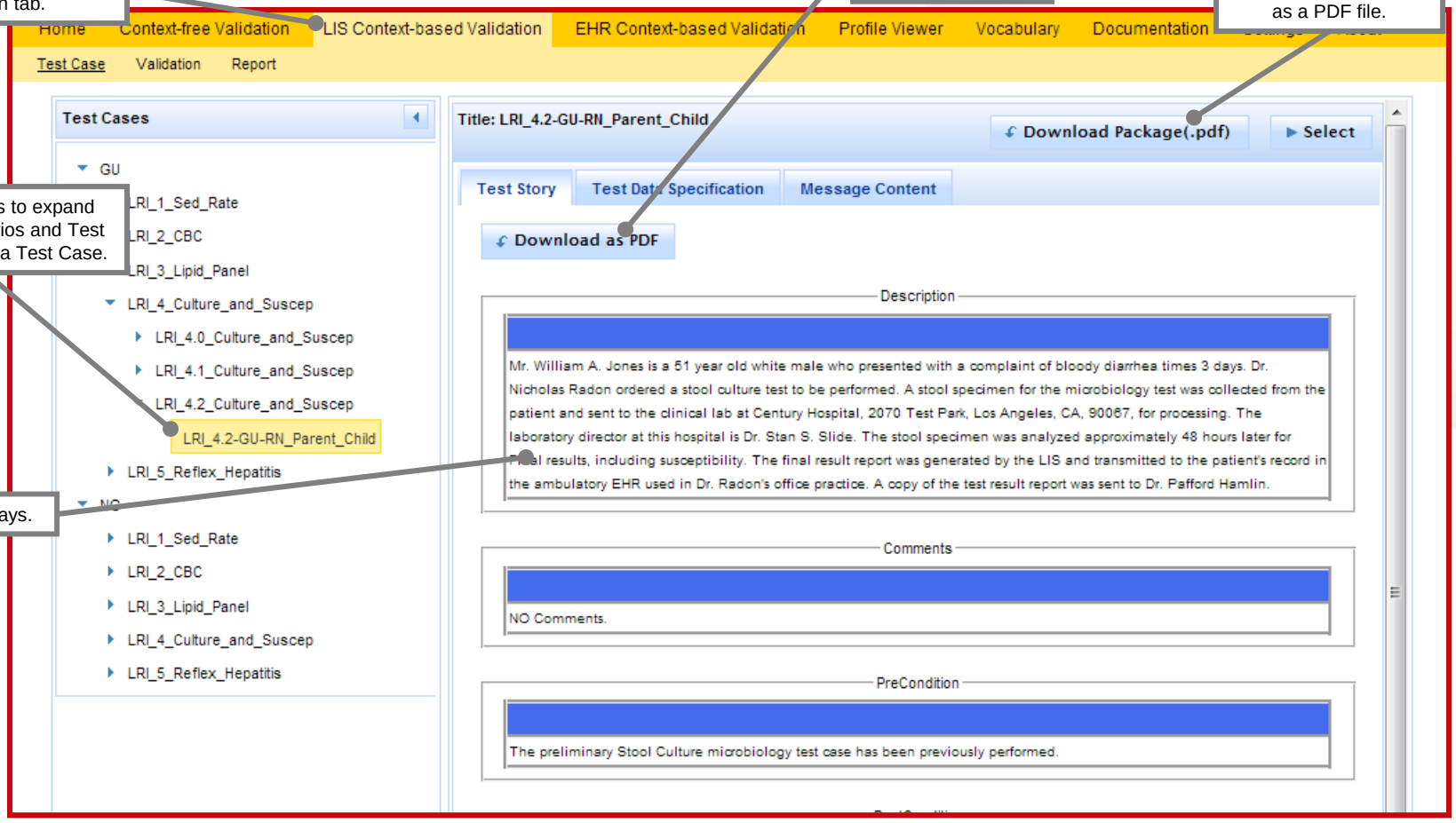
Demonstrate the capability to message a CBC panel result with many OBX segments using different data types for the result.

National Institute of Standards and Technology (NIST) Page 3

Description of real world scenario.

1) Select Test Case and review Test Story

1. Open LRI Validation tool using link: http://hl7v2-lab-testing.nist.gov.
2. Click on LIS Context-based Validation tab.
3. Click on arrows to expand the Test Scenarios and Test Cases. Click on a Test Case.
4. Test Story displays.
5. Test Story may be downloaded as a PDF file.
6. Test Case Package may be downloaded as a PDF file.



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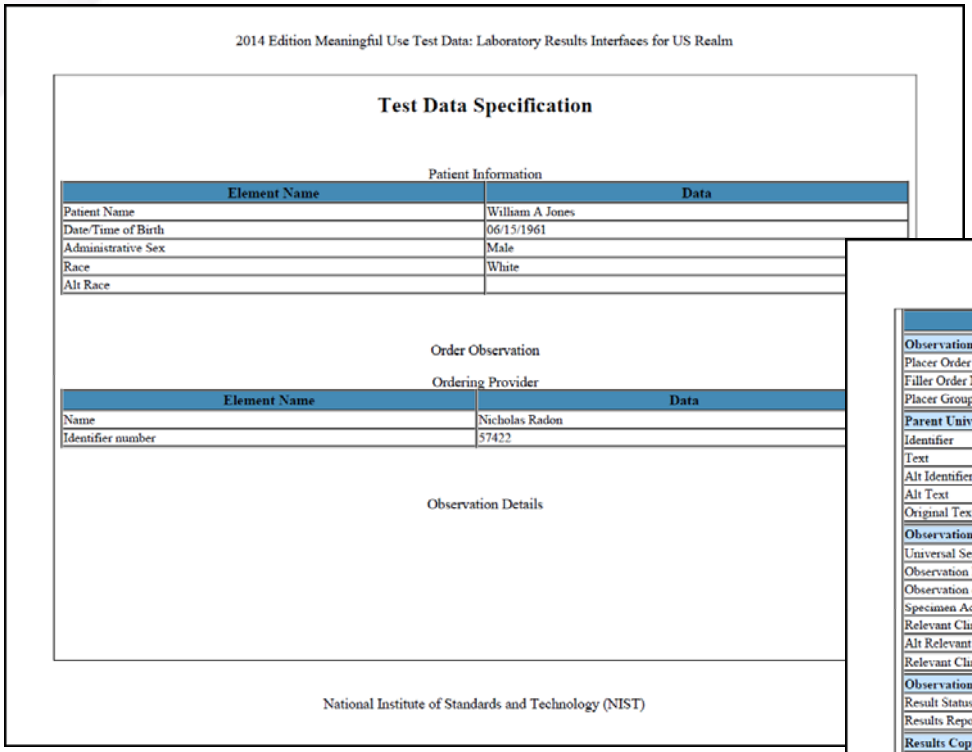
Test Data Specification



2014 Edition Meaningful Use Test Data: Laboratory Results Interfaces for US Realm

Test Data Specification

Patient Information

Element Name	Data
Patient Name	William A Jones
Date/Time of Birth	06/15/1961
Administrative Sex	Male
Race	White
Alt Race	

Order Observation

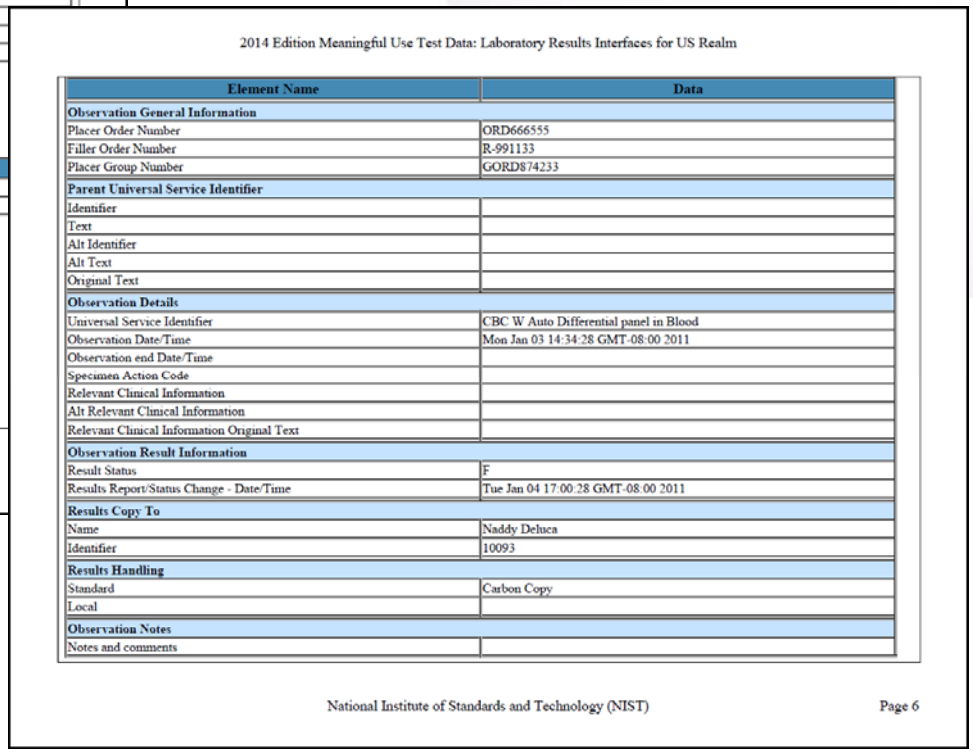
Ordering Provider

Element Name	Data
Name	Nicholas Radon
Identifier number	57422

Observation Details

National Institute of Standards and Technology (NIST)

Provides data typically available in the clinical setting.



2014 Edition Meaningful Use Test Data: Laboratory Results Interfaces for US Realm

Element Name	Data
Observation General Information	
Placer Order Number	ORD666555
Filler Order Number	R-991133
Placer Group Number	GORD874233
Parent Universal Service Identifier	
Identifier	
Text	
Alt Identifier	
Alt Text	
Original Text	
Observation Details	
Universal Service Identifier	CBC W Auto Differential panel in Blood
Observation Date/Time	Mon Jan 03 14:34:28 GMT-08:00 2011
Observation end Date/Time	
Specimen Action Code	
Relevant Clinical Information	
Alt Relevant Clinical Information	
Relevant Clinical Information Original Text	
Observation Result Information	
Result Status	F
Results Report/Status Change - Date/Time	Tue Jan 04 17:00:28 GMT-08:00 2011
Results Copy To	
Name	Naddy Deluca
Identifier	10093
Results Handling	
Standard	Carbon Copy
Local	
Observation Notes	
Notes and comments	

National Institute of Standards and Technology (NIST) Page 6

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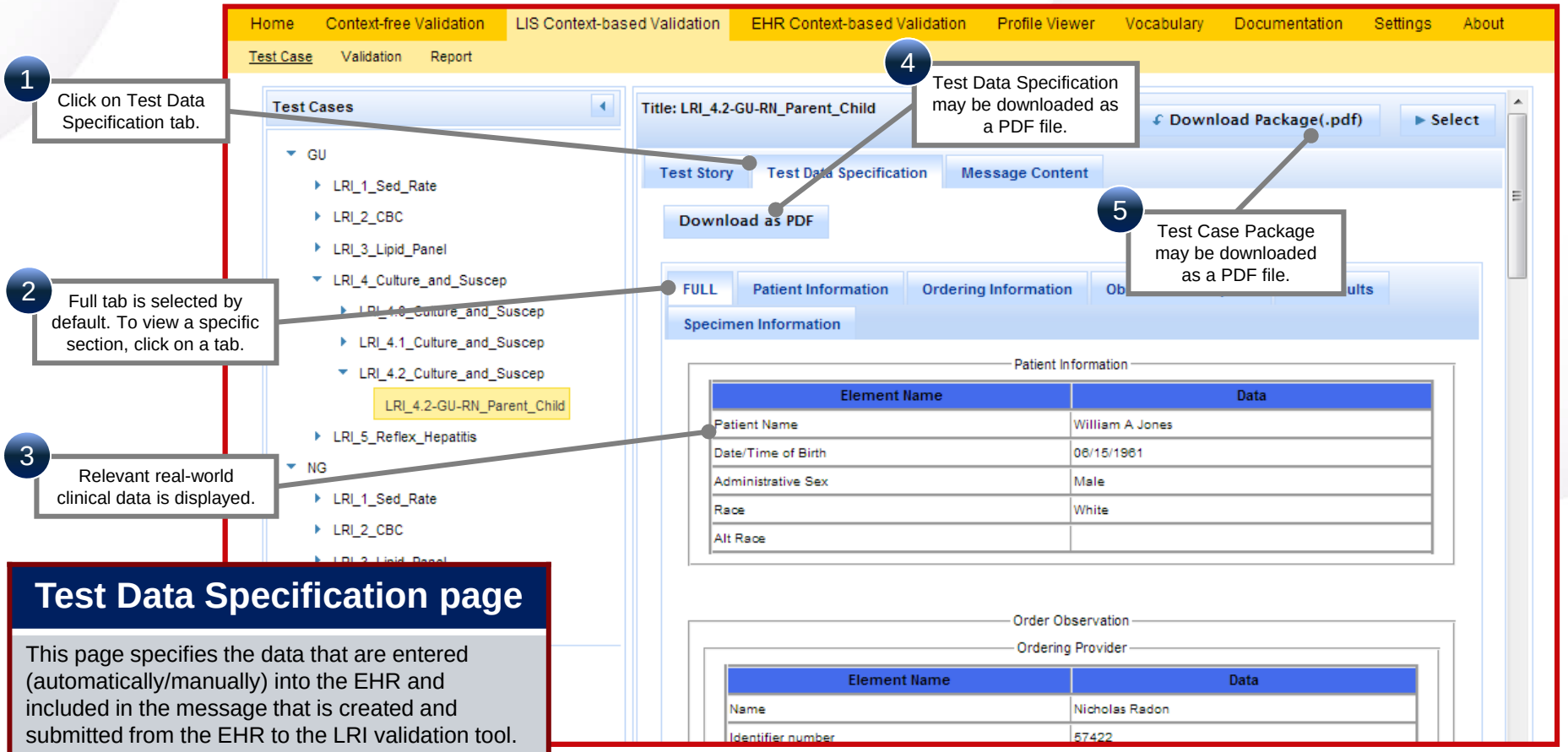
2) Review the Test Data Specification



Test Data Specification page

This page specifies the data that are entered (automatically/manually) into the EHR and included in the message that is created and submitted from the EHR to the LRI validation tool. The tester shall identify an existing patient record in the EHR or shall create a patient record in the EHR using the data in the Data Sheet associated with the Test Case.

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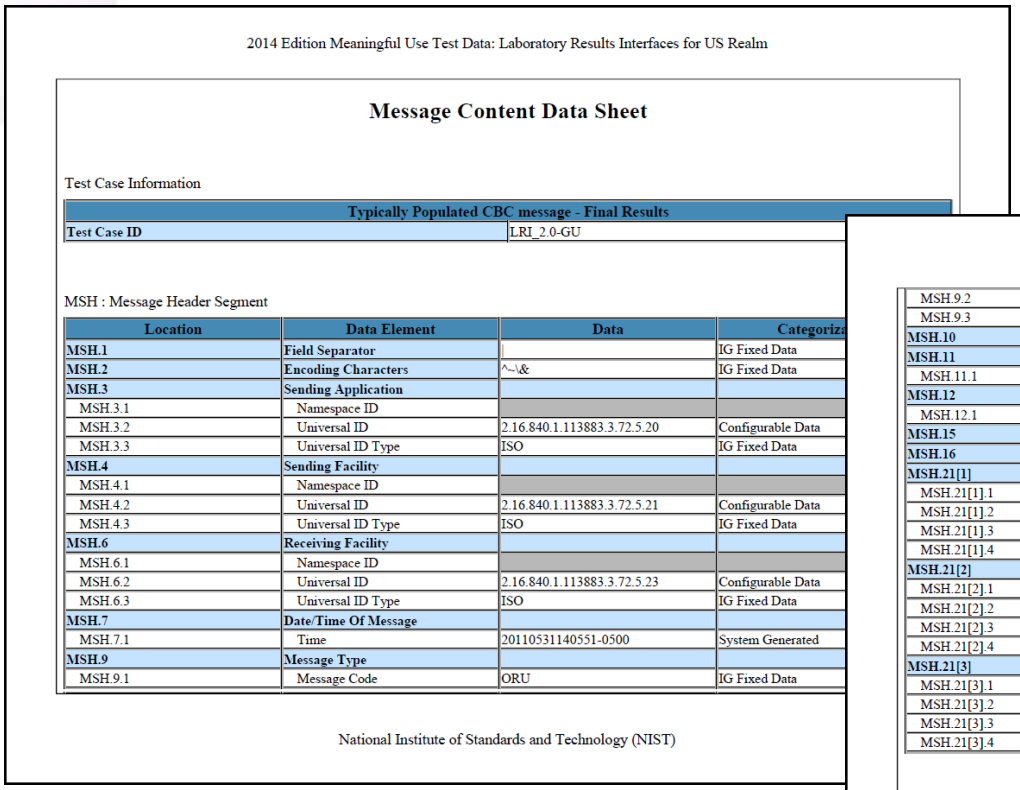
Message Content



2014 Edition Meaningful Use Test Data: Laboratory Results Interfaces for US Realm

Message Content Data Sheet

Test Case Information

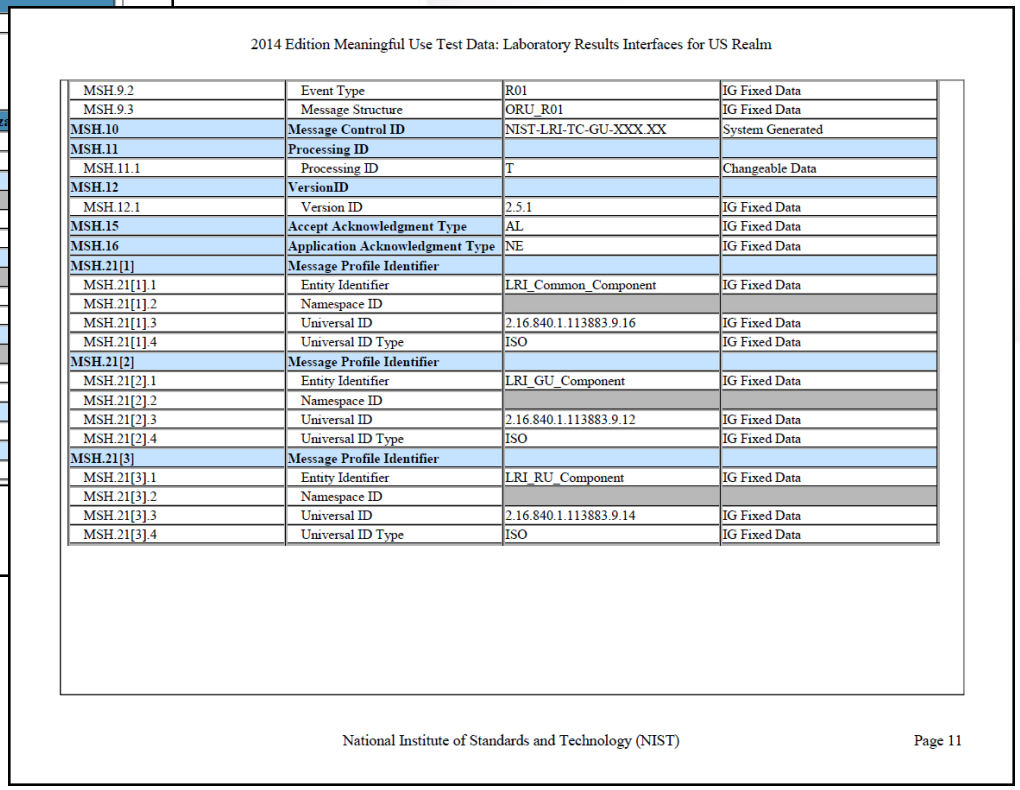
Typically Populated CBC message - Final Results	
Test Case ID	LRI_2.0-GU

MSH : Message Header Segment

Location	Data Element	Data	Categoriz
MSH.1	**Field Separator**	|	IG Fixed Data
MSH.2	**Encoding Characters**	^~\&	IG Fixed Data
MSH.3	**Sending Application**		
MSH.3.1	Namespace ID		
MSH.3.2	Universal ID	2.16.840.1.113883.3.72.5.20	Configurable Data
MSH.3.3	Universal ID Type	ISO	IG Fixed Data
MSH.4	**Sending Facility**		
MSH.4.1	Namespace ID		
MSH.4.2	Universal ID	2.16.840.1.113883.3.72.5.21	Configurable Data
MSH.4.3	Universal ID Type	ISO	IG Fixed Data
MSH.6	**Receiving Facility**		
MSH.6.1	Namespace ID		
MSH.6.2	Universal ID	2.16.840.1.113883.3.72.5.23	Configurable Data
MSH.6.3	Universal ID Type	ISO	IG Fixed Data
MSH.7	**Date/Time Of Message**		
MSH.7.1	Time	20110531140551-0500	System Generated
MSH.9	**Message Type**		
MSH.9.1	Message Code	ORU	IG Fixed Data

National Institute of Standards and Technology (NIST)

Provides the expected results for message element

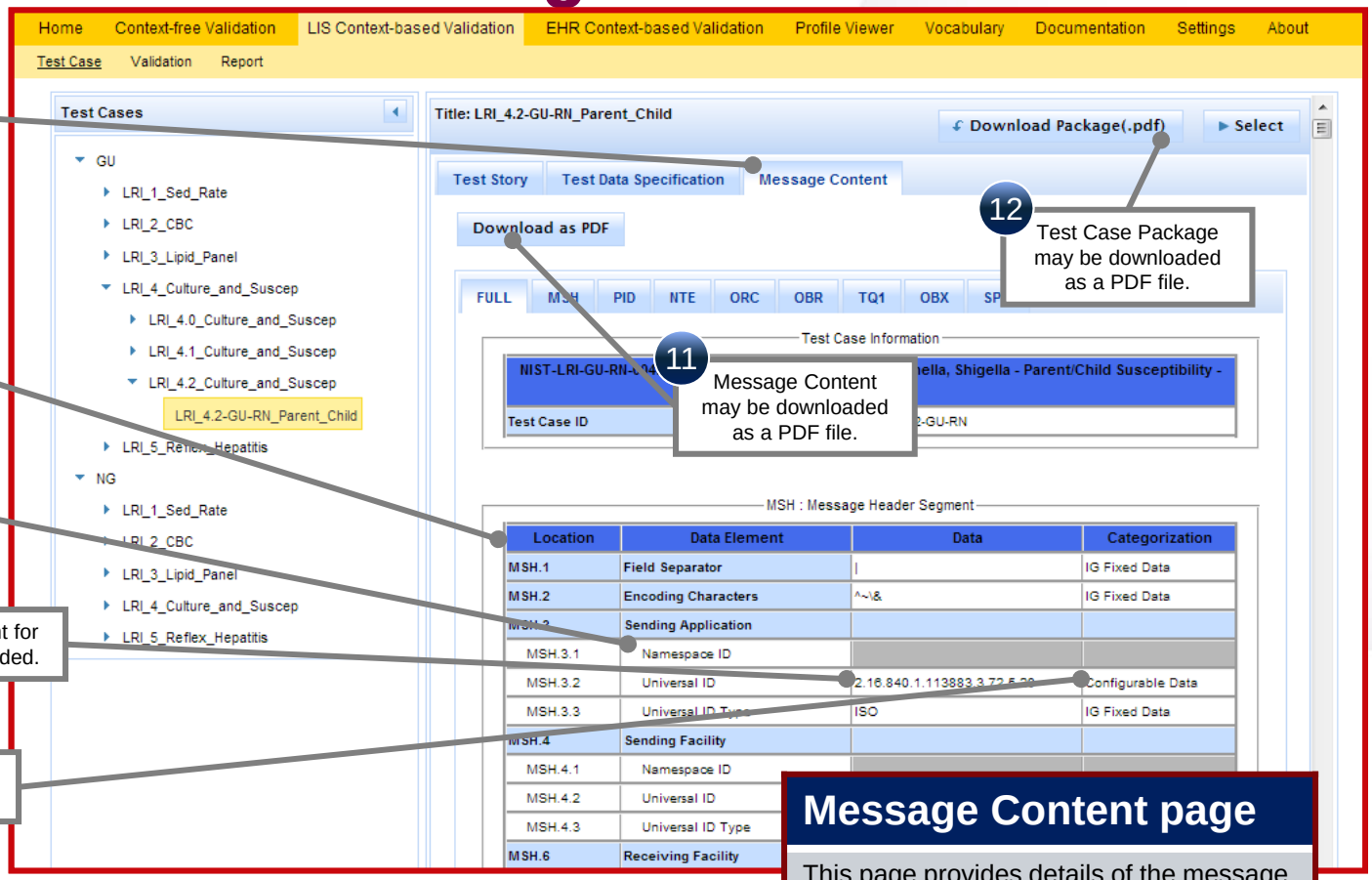


2014 Edition Meaningful Use Test Data: Laboratory Results Interfaces for US Realm

MSH.9.2	Event Type	R01	IG Fixed Data
MSH.9.3	Message Structure	ORU_R01	IG Fixed Data
MSH.10	**Message Control ID**	NIST-LRI-TC-GU-XXX.XX	System Generated
MSH.11	**Processing ID**		
MSH.11.1	Processing ID	T	Changeable Data
MSH.12	**VersionID**		
MSH.12.1	Version ID	2.5.1	IG Fixed Data
MSH.15	**Accept Acknowledgment Type**	AL	IG Fixed Data
MSH.16	**Application Acknowledgment Type**	NE	IG Fixed Data
MSH.21[1]	**Message Profile Identifier**		
MSH.21[1].1	Entity Identifier	LRI_Common_Component	IG Fixed Data
MSH.21[1].2	Namespace ID		
MSH.21[1].3	Universal ID	2.16.840.1.113883.9.16	IG Fixed Data
MSH.21[1].4	Universal ID Type	ISO	IG Fixed Data
MSH.21[2]	**Message Profile Identifier**		
MSH.21[2].1	Entity Identifier	LRI_GU_Component	IG Fixed Data
MSH.21[2].2	Namespace ID		
MSH.21[2].3	Universal ID	2.16.840.1.113883.9.12	IG Fixed Data
MSH.21[2].4	Universal ID Type	ISO	IG Fixed Data
MSH.21[3]	**Message Profile Identifier**		
MSH.21[3].1	Entity Identifier	LRI_RU_Component	IG Fixed Data
MSH.21[3].2	Namespace ID		
MSH.21[3].3	Universal ID	2.16.840.1.113883.9.14	IG Fixed Data
MSH.21[3].4	Universal ID Type	ISO	IG Fixed Data

National Institute of Standards and Technology (NIST) Page 11

2a) Review the Message Content



6 Click on Message Content tab.

7 Location specifies the location of a data element within the message.

8 Name of data element is provided.

9 Exact value of the data element for the selected Test Case is provided.

10 Categorization indicates if the data is fixed or can be changed.

11 Message Content may be downloaded as a PDF file.

12 Test Case Package may be downloaded as a PDF file.

Message Content page

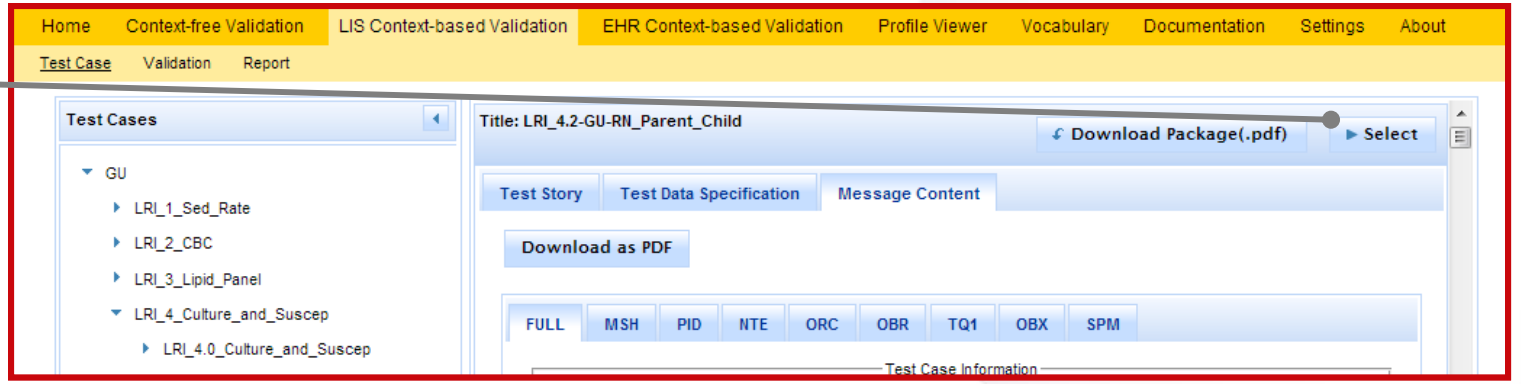
This page provides details of the message segment, as well as an example of a valid instance of each data element.

3) Create test message

1 Using the EHR technology, create the LRI test message with the test data provided for the selected Test Case (step 2).

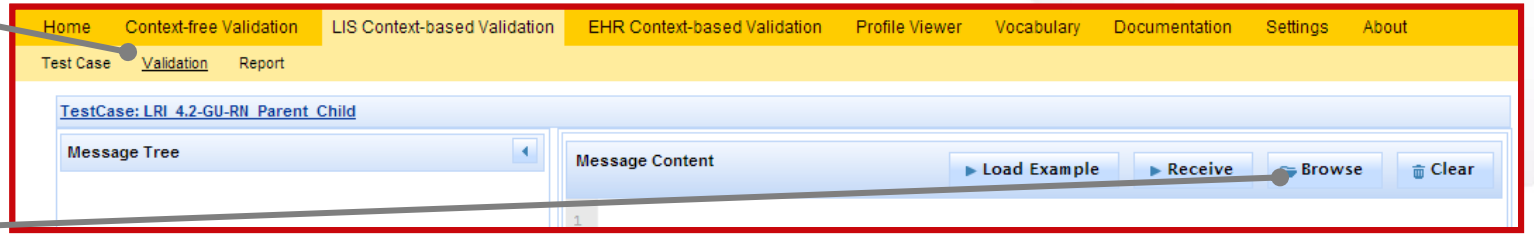
4) Load Test Case and import test message

1. Click on Select button to load the Test Case.



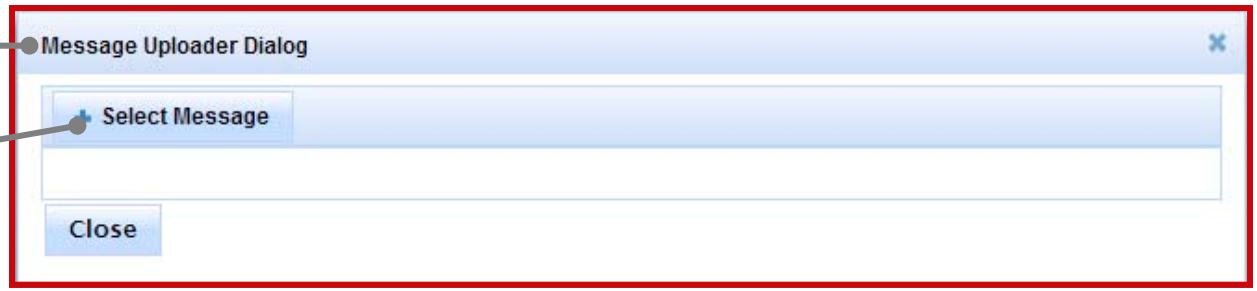
2. Validation page displays.

3. Click on Browse button.



4. Message Uploader Dialog window displays.

5. Click on Select Message button.



6. Open test message file created in step 3 to upload it.

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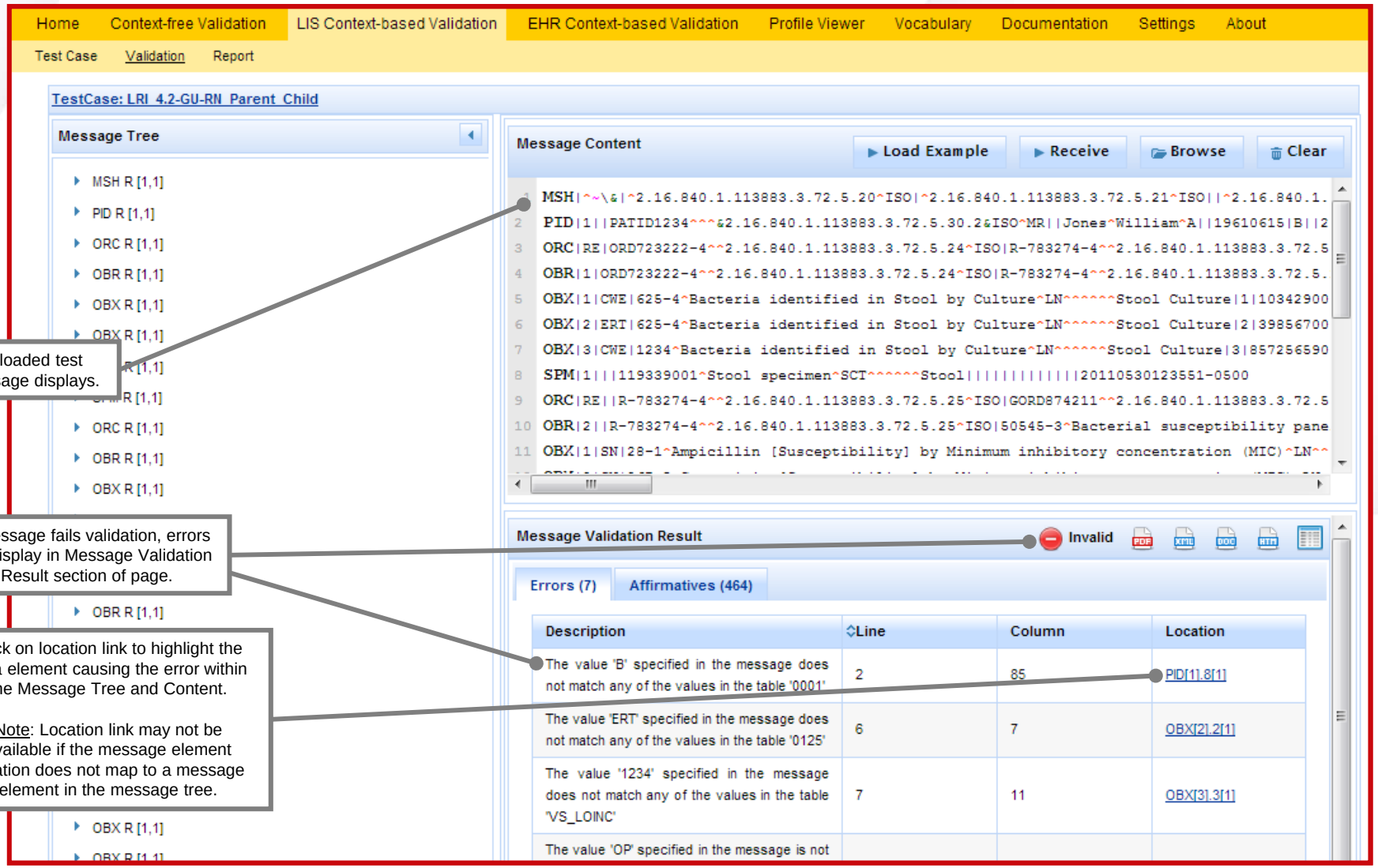
5) Validate message and review report



1 Uploaded test message displays.

2 If message fails validation, errors will display in Message Validation Result section of page.

3 Click on location link to highlight the data element causing the error within the Message Tree and Content.

Note: Location link may not be available if the message element location does not map to a message element in the message tree.

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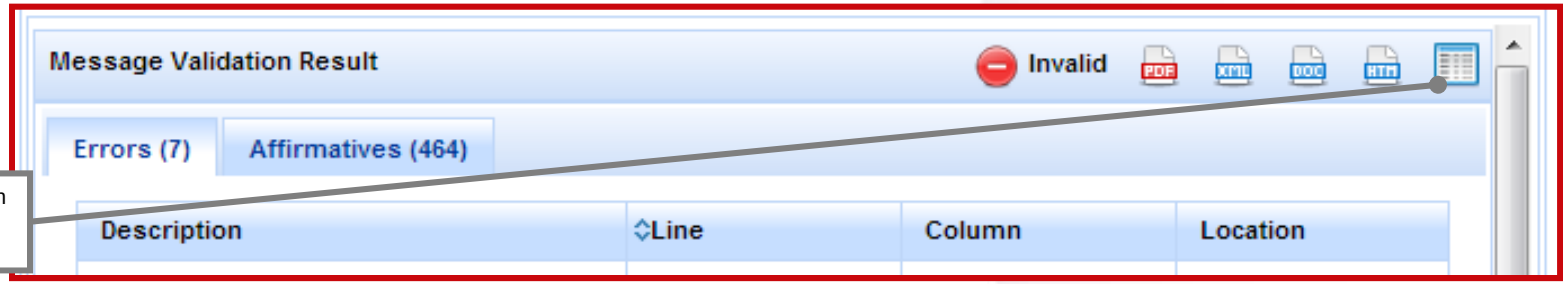
6) Save and Print Report

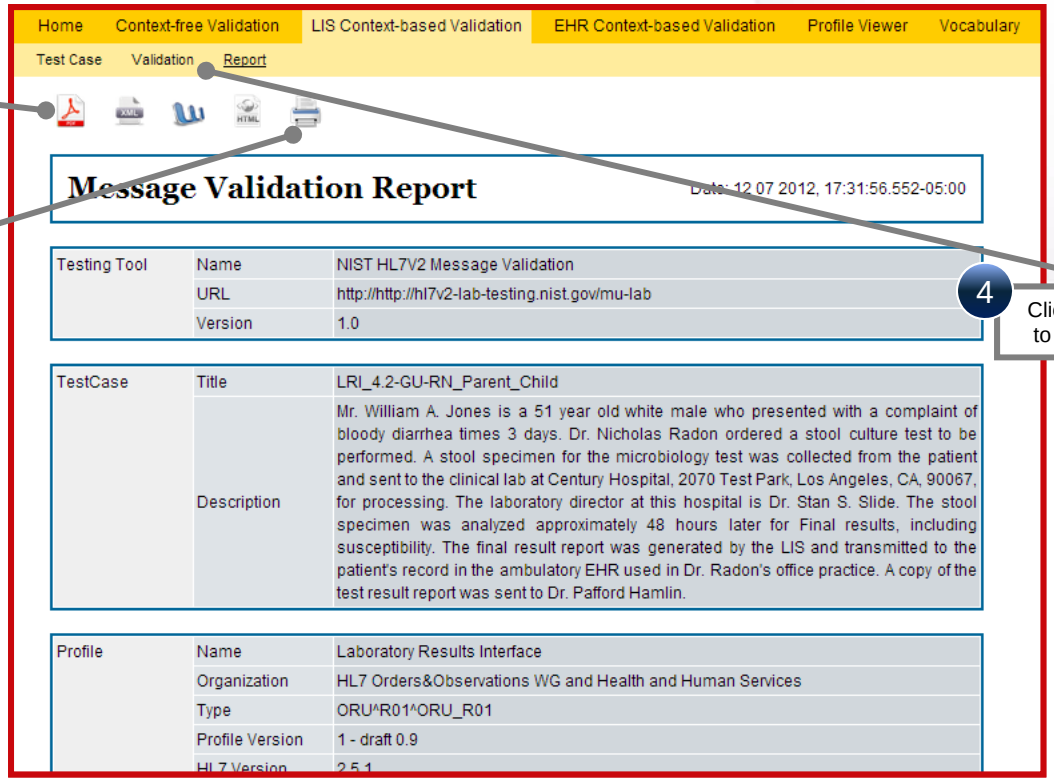


1 Click Report Details icon to display Message Validation Report.

2 Message Validation Report may be downloaded as a PDF, XML, Word doc or HTML file.

3 Message Validation Report may be printed.

4 Click on Validation link to return to message.



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ORLANDO, FLORIDA

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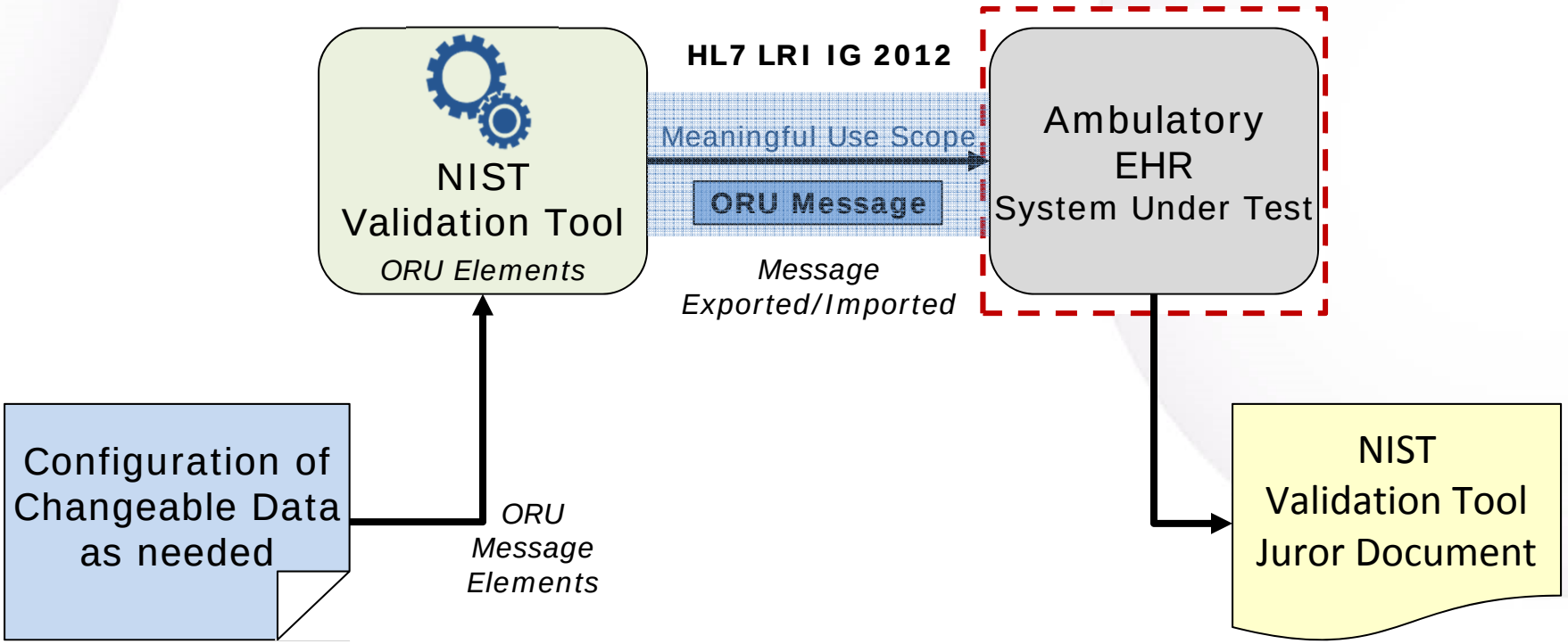
Test Tool Overview
Case Study: Lab Results Interface

Testing Incorporation of Message by the Receiver

NIST
National Institute of Standards and Technology
U.S. Department of Commerce

Lab Incorporation Test Process and Scope



- The ambulatory EHR is the system being tested. The EHR system is required to receive and incorporate messages that conform to the referenced standards .
- The ambulatory EHR is expected to process the test data received in a message. This message is exported from the NIST Test Tool and imported into the EHR for validation by the Tester/Inspector using the Test Case-specific Juror Document.
- Test data are available through the Test Tool via the Test Cases. Each Test Case includes a Test Story that provides the context, a Test Data Specification that lists the data that are typically available in the clinical setting , a Message Content Data Sheet that shows a conformant message (in a table format), a Test Message, and a Juror Document.

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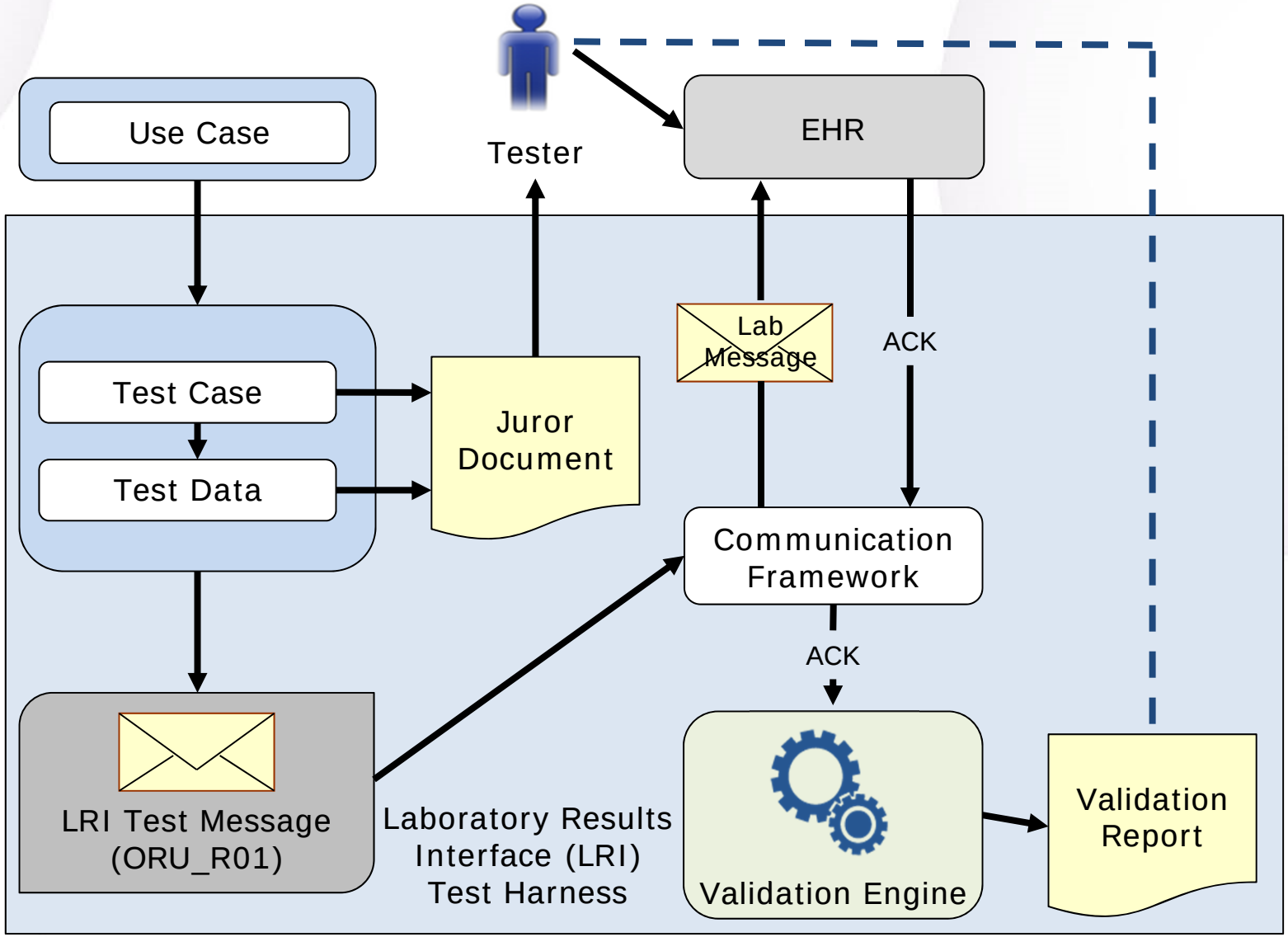
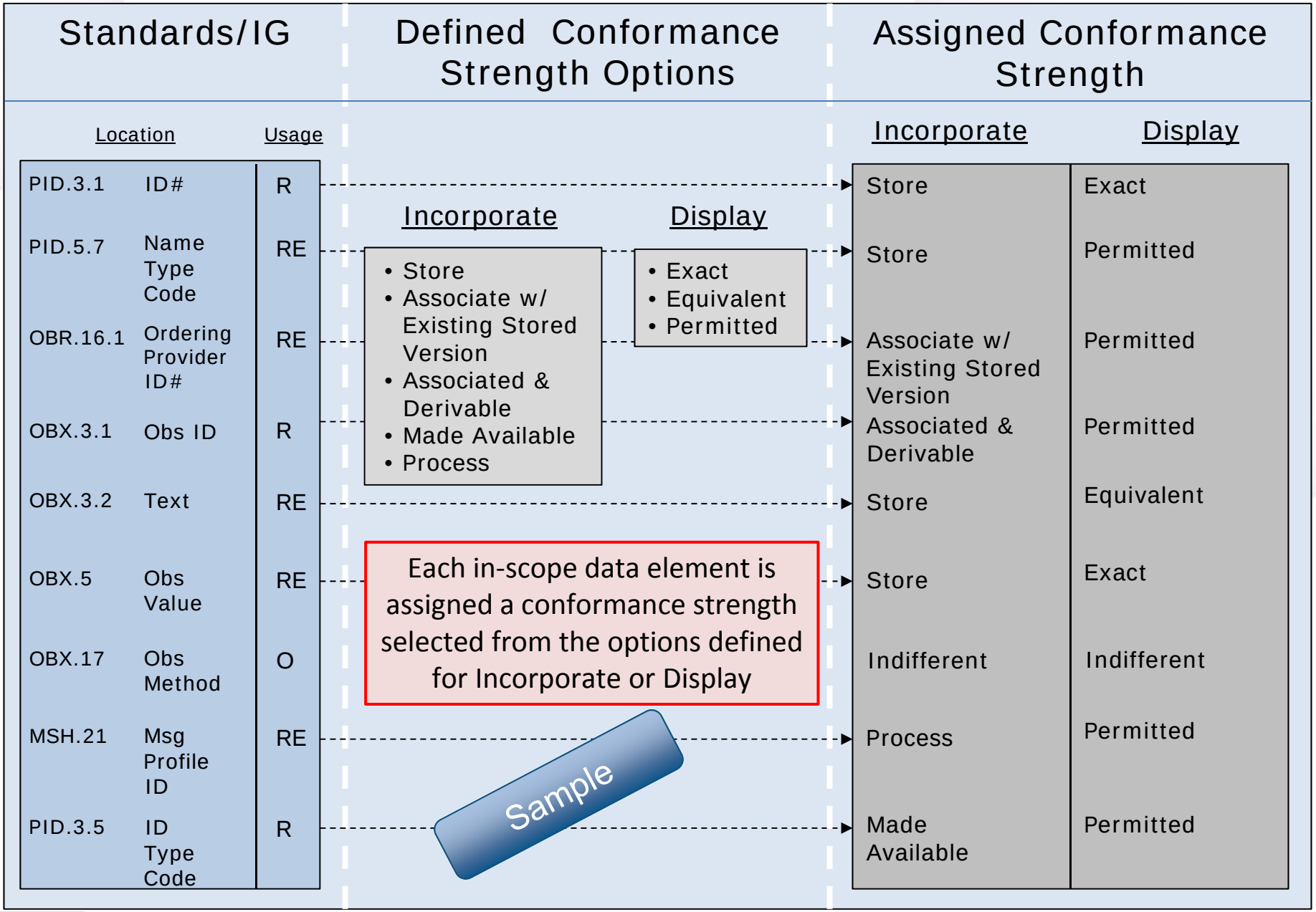
LRI Lab Incorporation Test Process



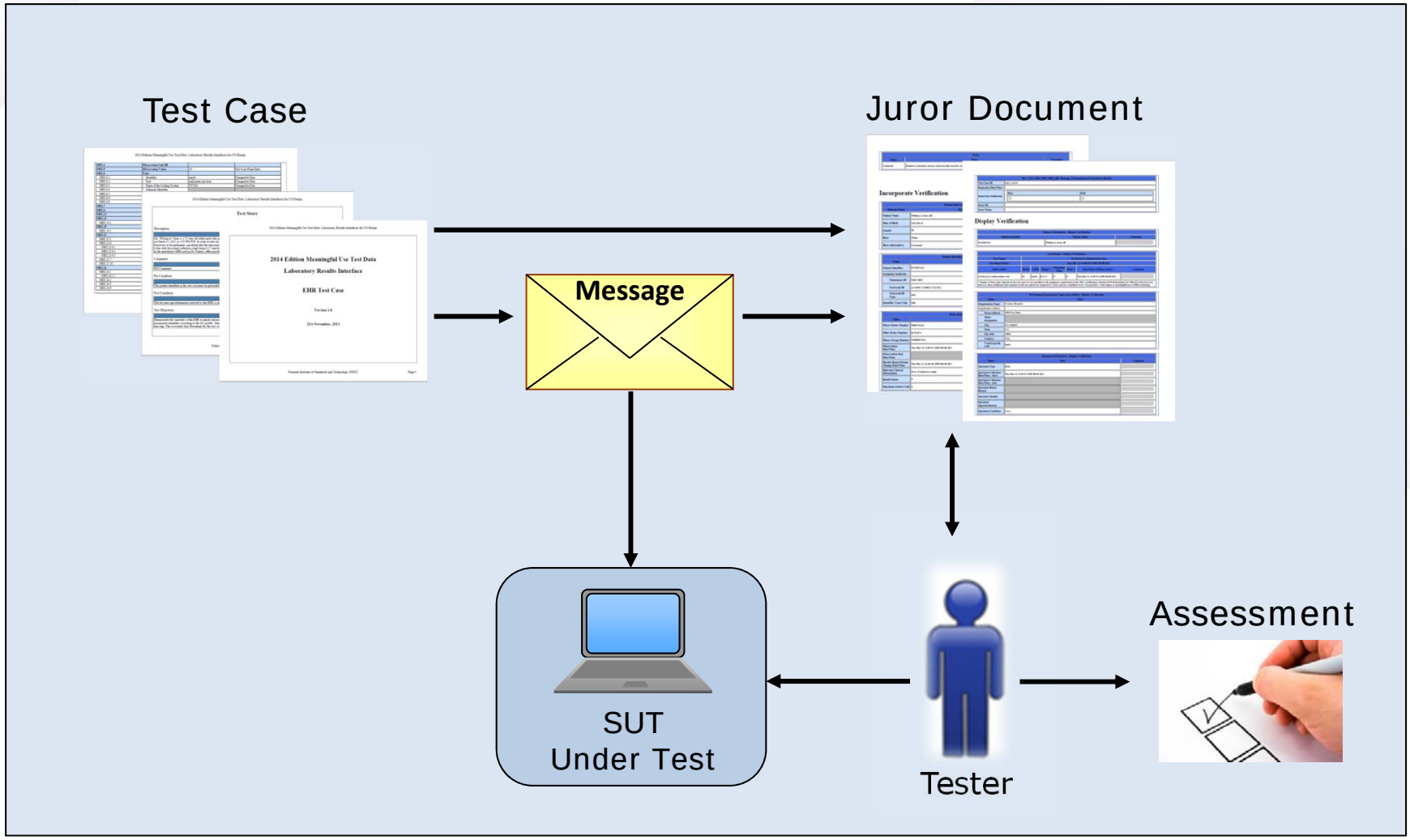
Test Case Summary (Incorporation)

- A Test Case contains of
  - Narrative Test Story
    - Provides the context for the test case (real-world scenario)
  - Test Data Specification
    - Provides the data associated with the Test Story
    - Consists of typically available information in the clinical setting
  - Test Story and Test Data Specification together
    - Provide sufficient information for generating the test message to be imported (e.g., sent) to the EHR technology being tested
  - Juror Document
    - Provides a Test Case-specific checklist the Tester uses to assess and record that the test message is correctly incorporated into the EHR
    - Utilizes a process where an inspector ascertains if the lab results sent in the test message are incorporated appropriately in the EHR technology
    - Guides the inspector through the assessment process – a visual inspection where verification may include viewing the EHR display or an extended (e.g., data base view) inspection

Determining Incorporation Requirements

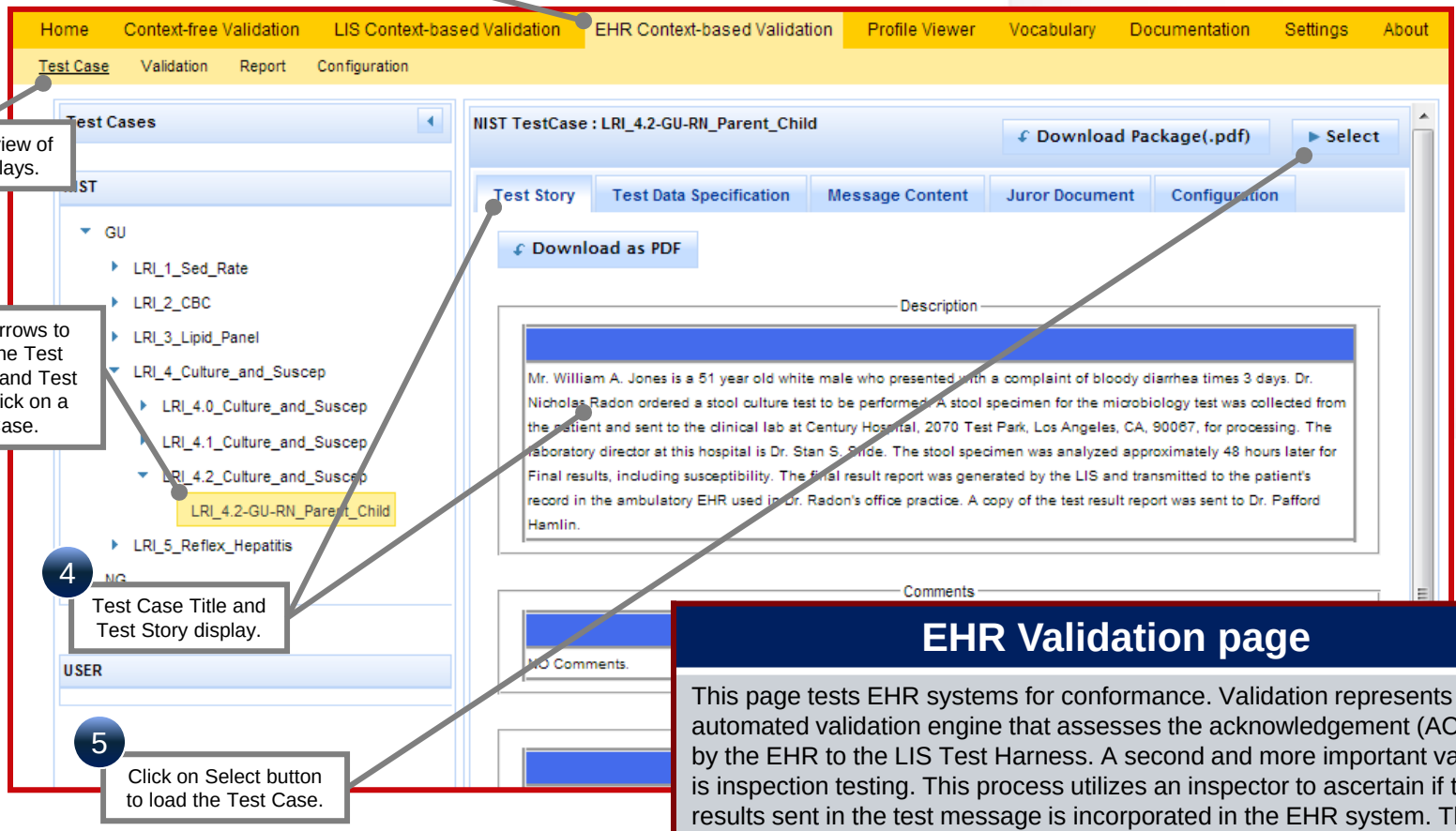


Assessing Incorporation Requirements



1) Select Test Case and load LRI test message

1. Open LRI Validation tool using link: http://hl7v2-lab-testing.nist.gov and click on EHR Context-based Validation tab.
2. Test case view of page displays.
3. Click on arrows to expand the Test Scenarios and Test Cases. Click on a Test Case.
4. Test Case Title and Test Story display.
5. Click on Select button to load the Test Case.



EHR Validation page

This page tests EHR systems for conformance. Validation represents the automated validation engine that assesses the acknowledgement (ACK) sent by the EHR to the LIS Test Harness. A second and more important validation is inspection testing. This process utilizes an inspector to ascertain if the lab results sent in the test message is incorporated in the EHR system. The Juror Document guides the inspector through the assessment process.

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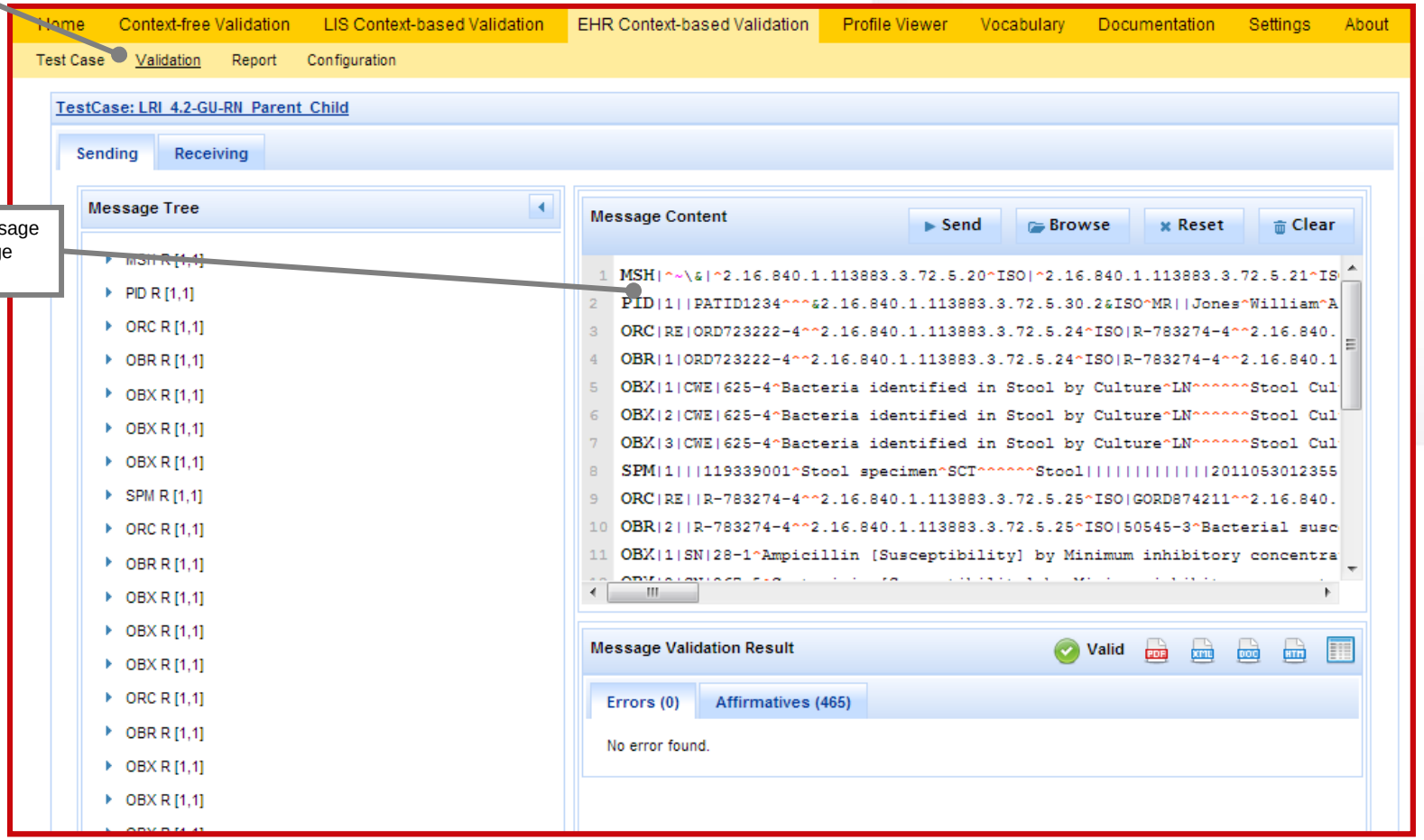
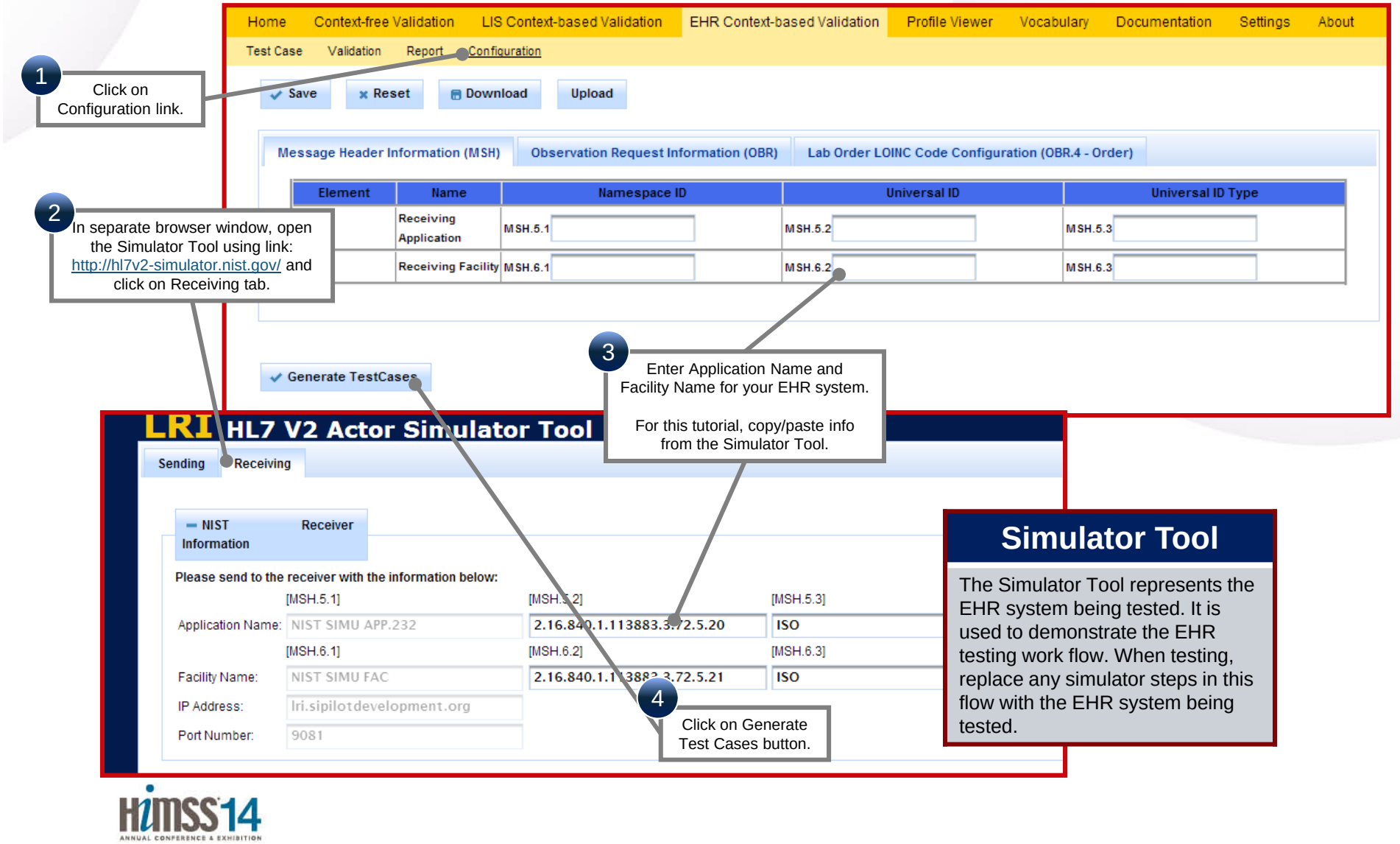
1a) Select Test Case and load LRI test message

6 Validation view of page displays with Sending tab defaulted.

7 Loaded example message displays in Message Content section.



2) Configure Test Cases with Receiver Information



Simulator Tool

The Simulator Tool represents the EHR system being tested. It is used to demonstrate the EHR testing work flow. When testing, replace any simulator steps in this flow with the EHR system being tested.

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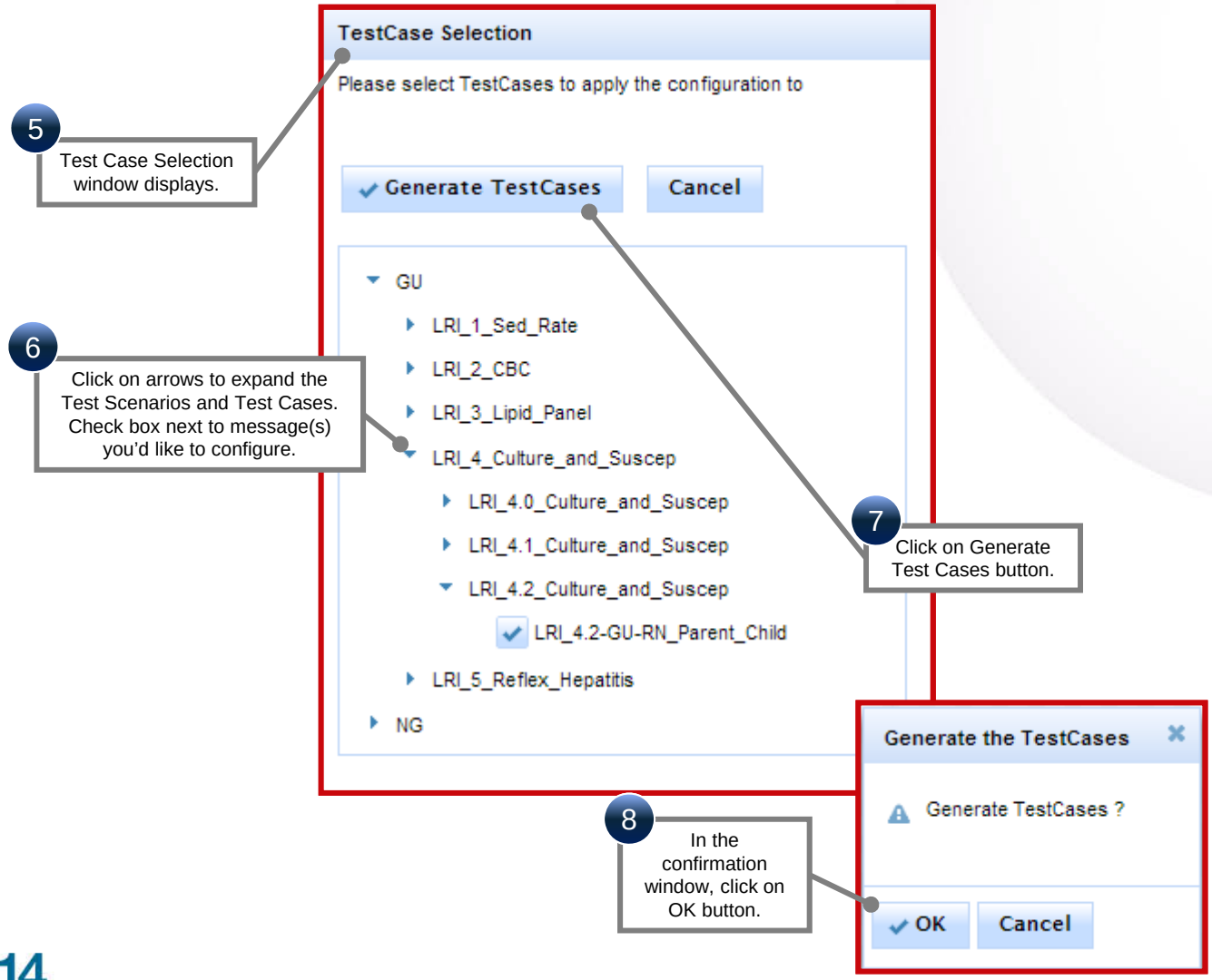
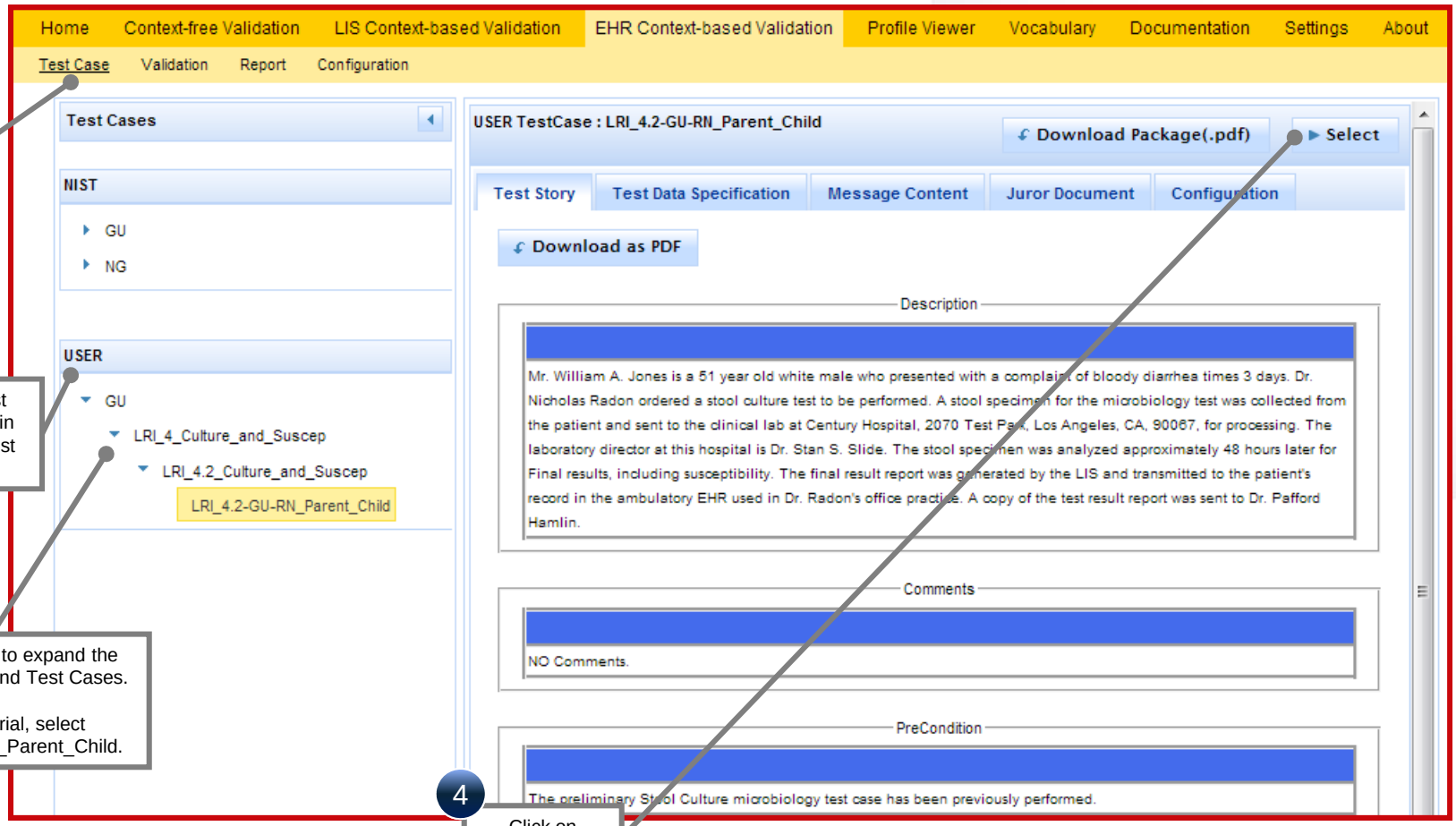
2) Configure Test Cases with Receiver Info, continued



3) Load LRI Test Message



1. Test Case view of page will display.
2. Configured Test Case(s) display in User Defined Test Cases section.
3. Click on arrows to expand the Test Scenarios and Test Cases.

   For this tutorial, select LRI_4.2-GU-RN_Parent_Child.
4. Click on Select button.

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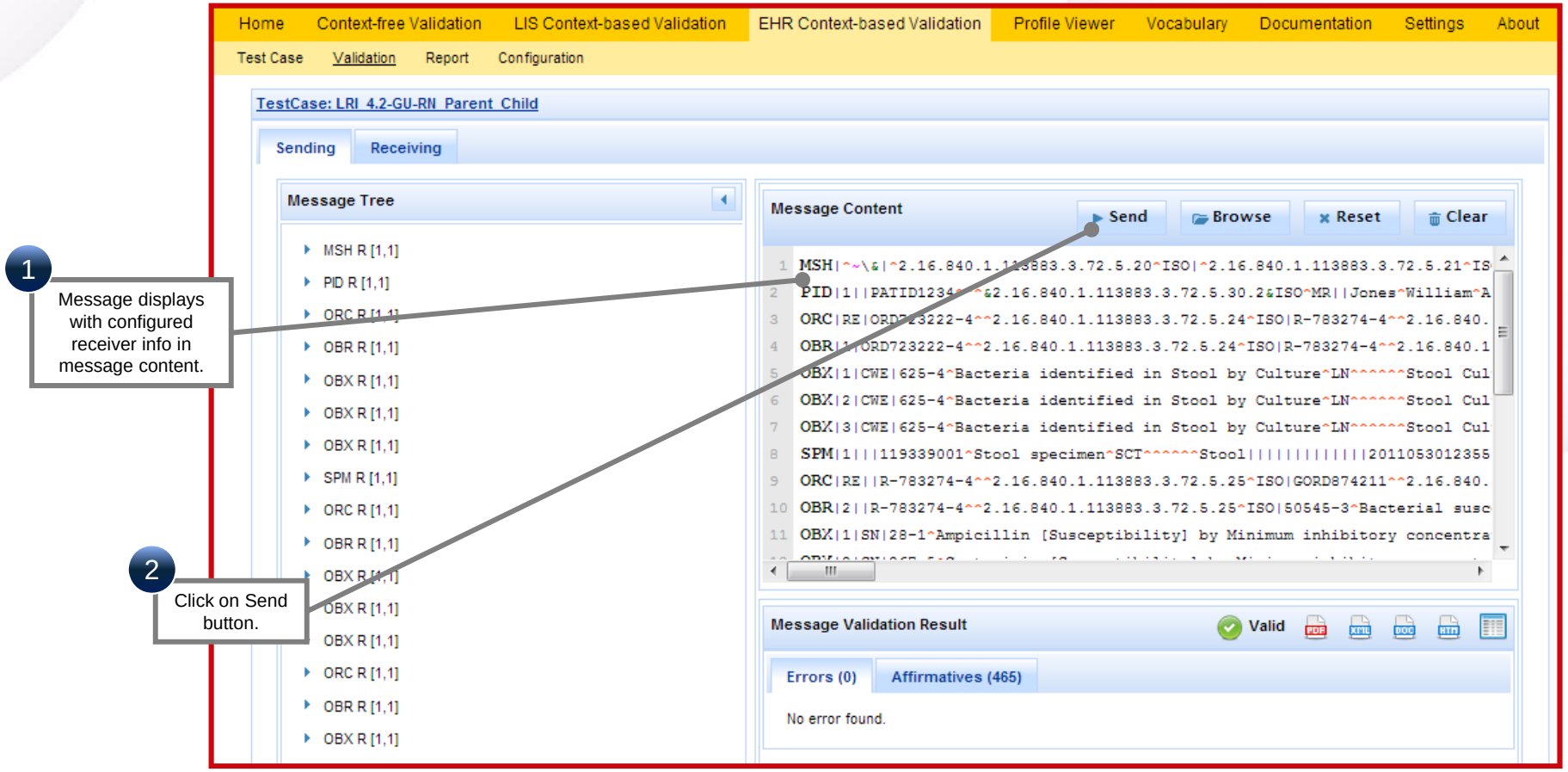
4) Send LRI Test Message to your EHR system



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4) Send LRI Test Message to your EHR system, continued

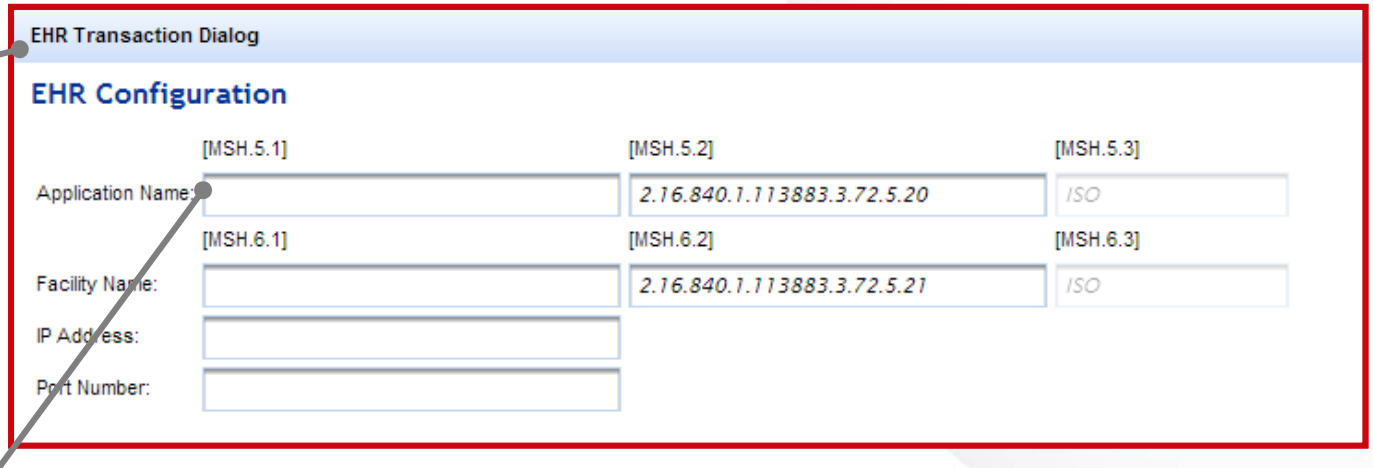
3 EHR Transaction Dialog window displays.

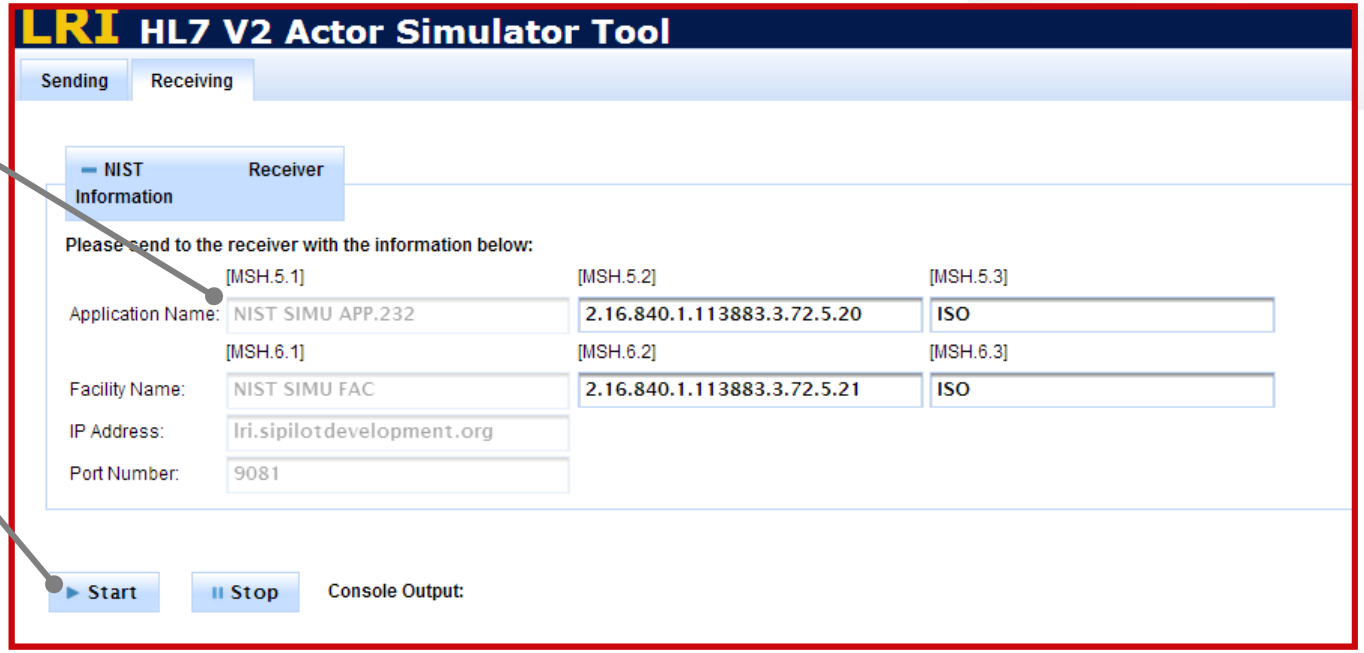
4 Enter Application Name, Facility Name, IP Address and Port Number for EHR system being tested.

For this tutorial, the simulator is taking the place of your EHR system. Copy/paste info from the Simulator Tool.

5 Make sure your EHR system is ready to receive an LIS message.

For this tutorial, click Start button on the Simulator Tool.





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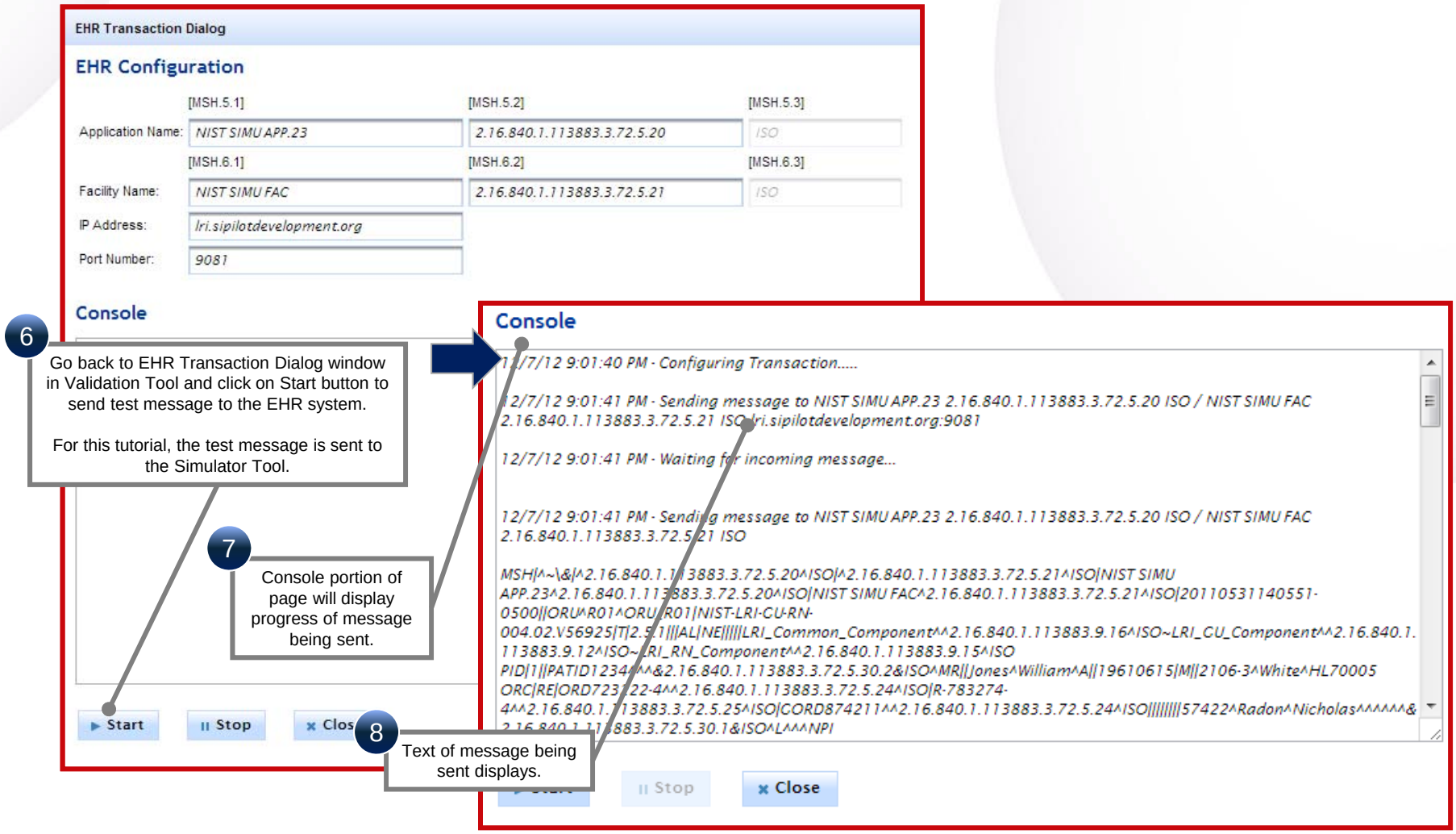
4a) Send LRI Test Message to your EHR system



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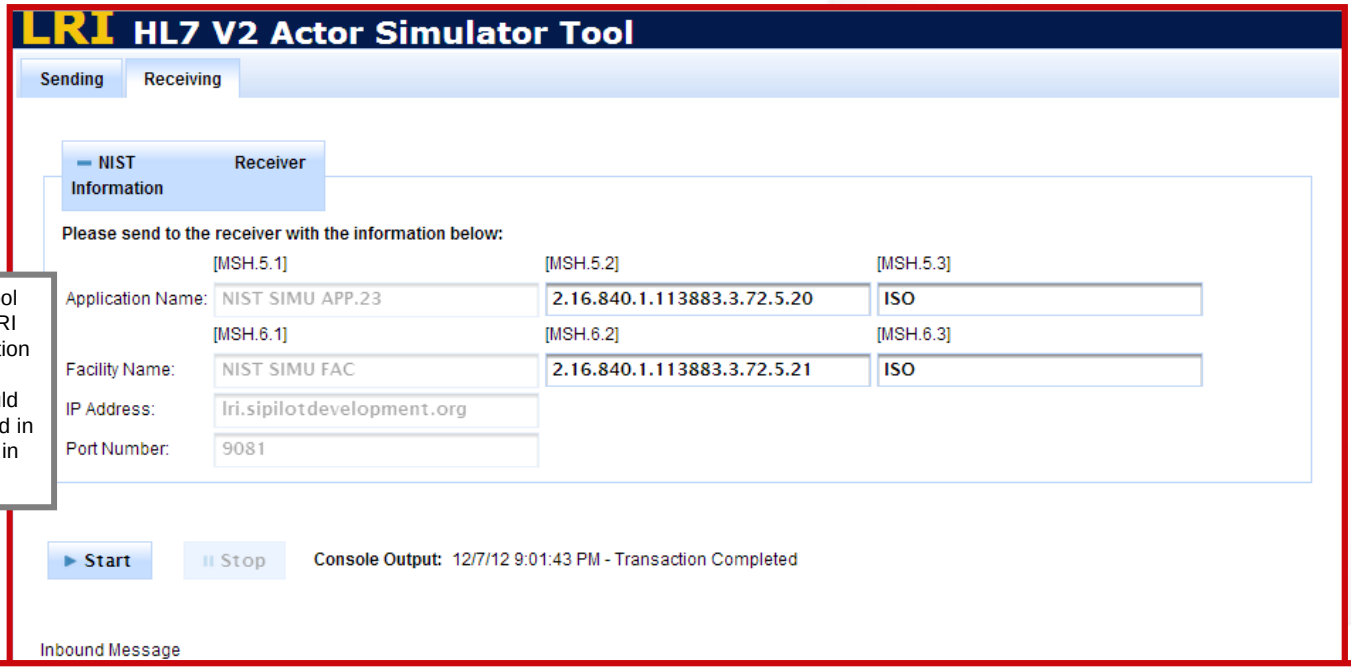
5) Verify message was received by EHR System / Simulator

1

For this tutorial, the Simulator Tool displays test message sent by LRI Validation tool from EHR Transaction Dialog window in the Inbound Message section. Message should match message sent and displayed in EHR Transaction Dialog window in previous slide.



Inbound Message

MSH|^~\&|^2.16.840.1.113883.3.72.5.20^ISO|^2.16.840.1.113883.3.72.5.21^ISO|NIST SIMU APP.23^2.16.840.1.113883.3.72.5.20^ISO|NIST SIMU FAC^2.16.840.1.113883.3.72.5.21^ISO|20110531140551-0500||ORU^R01^ORU_R01|NIST-LRI-GU-RN-004.02.V56925|T|2.5.1|||AL|NE|||||LRI_Common_Component^^2.16.840.1.113883.9.16^ISO~LRI_GU_Component^^2.16.840.1.113883.9.12^ISO~LRI_RN_Component^^2.16.840.1.113883.9.15^ISO
PID|1||PATID1234^^^&2.16.840.1.113883.3.72.5.30.2&ISO^MR||Jones^William^A||19610615|M||2106-3^White^HL70005
ORC|RE|ORD723222-4^^2.16.840.1.113883.3.72.5.24^ISO|R-783274-4^^2.16.840.1.113883.3.72.5.25^ISO|GORD874211^^2.16.840.1.113883.3.72.5.24^ISO|||||||57422^Radon^Nicholas^^^^^^&2.16.840.1.113883.3.72.5.30.1&ISO^L^^^NPI
OBR|1|ORD723222-4^^2.16.840.1.113883.3.72.5.24^ISO|R-783274-4^^2.16.840.1.113883.3.72.5.25^ISO|625-4^Bacteria identified in Stool by Culture^LN^3456543^CULTURE STOOL^99USI^^^Stool Culture|||20110530123551-0500||||||787.91^DIARRHEA^I9CDX^^^^^^DIARRHEA|||57422^Radon^Nicholas^^^^^^&2.16.840.1.113883.3.72.5.30.1&ISO^L^^^NPI||||||20110531140428-0500|||F

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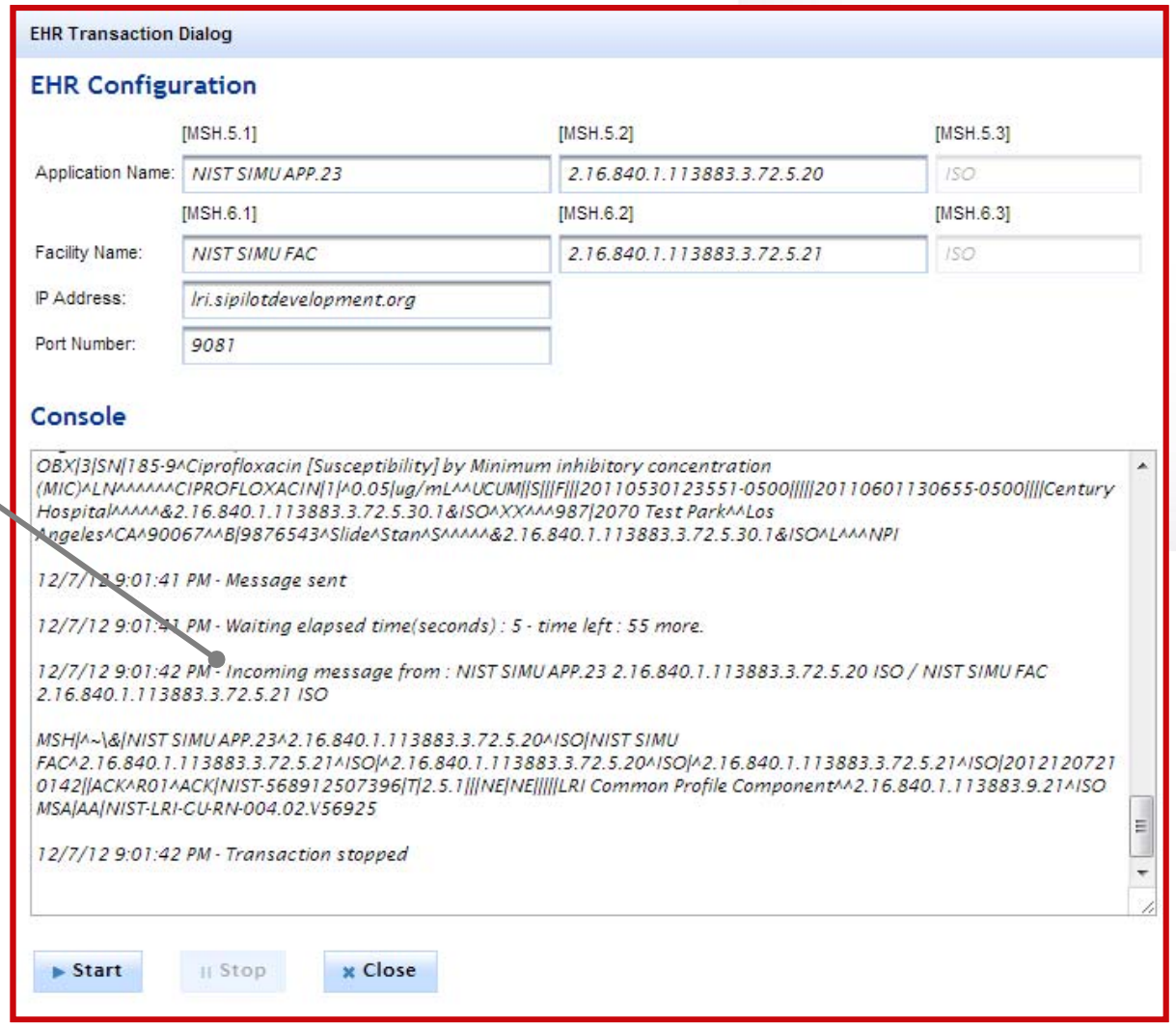
5) Verify message was received by HER System / Simulator, continued

2

Acknowledgment message sent by your EHR displays.

For this tutorial, the message is sent by the Simulator Tool.



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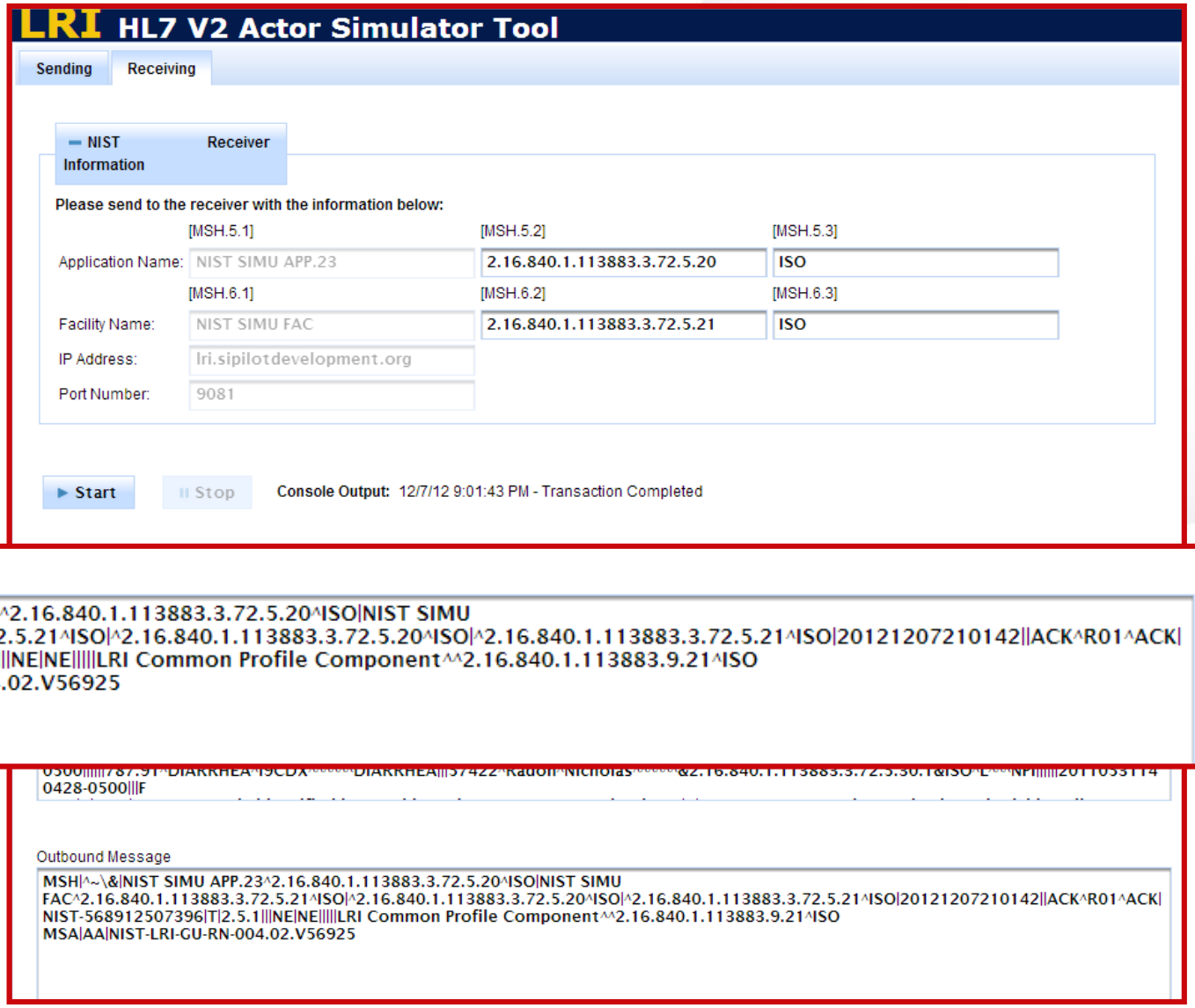
5) Verify message was received by HER System / Simulator, continued

3

For this tutorial, the Simulator Tool displays acknowledgment message it sent in the Outbound Message section.



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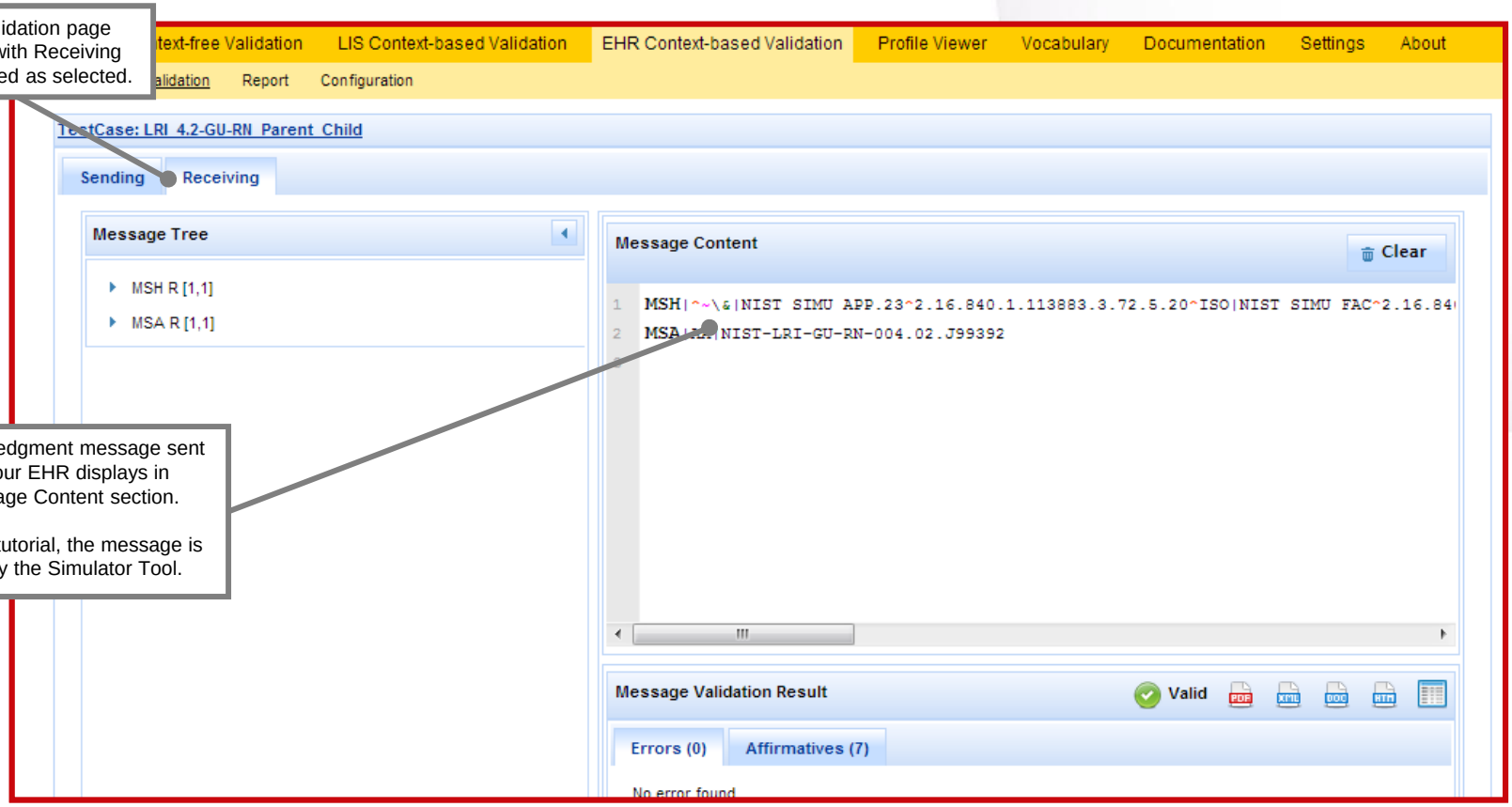
5) Verify message was received by HER System / Simulator, continued

4 Close EHR Transaction Dialog window.

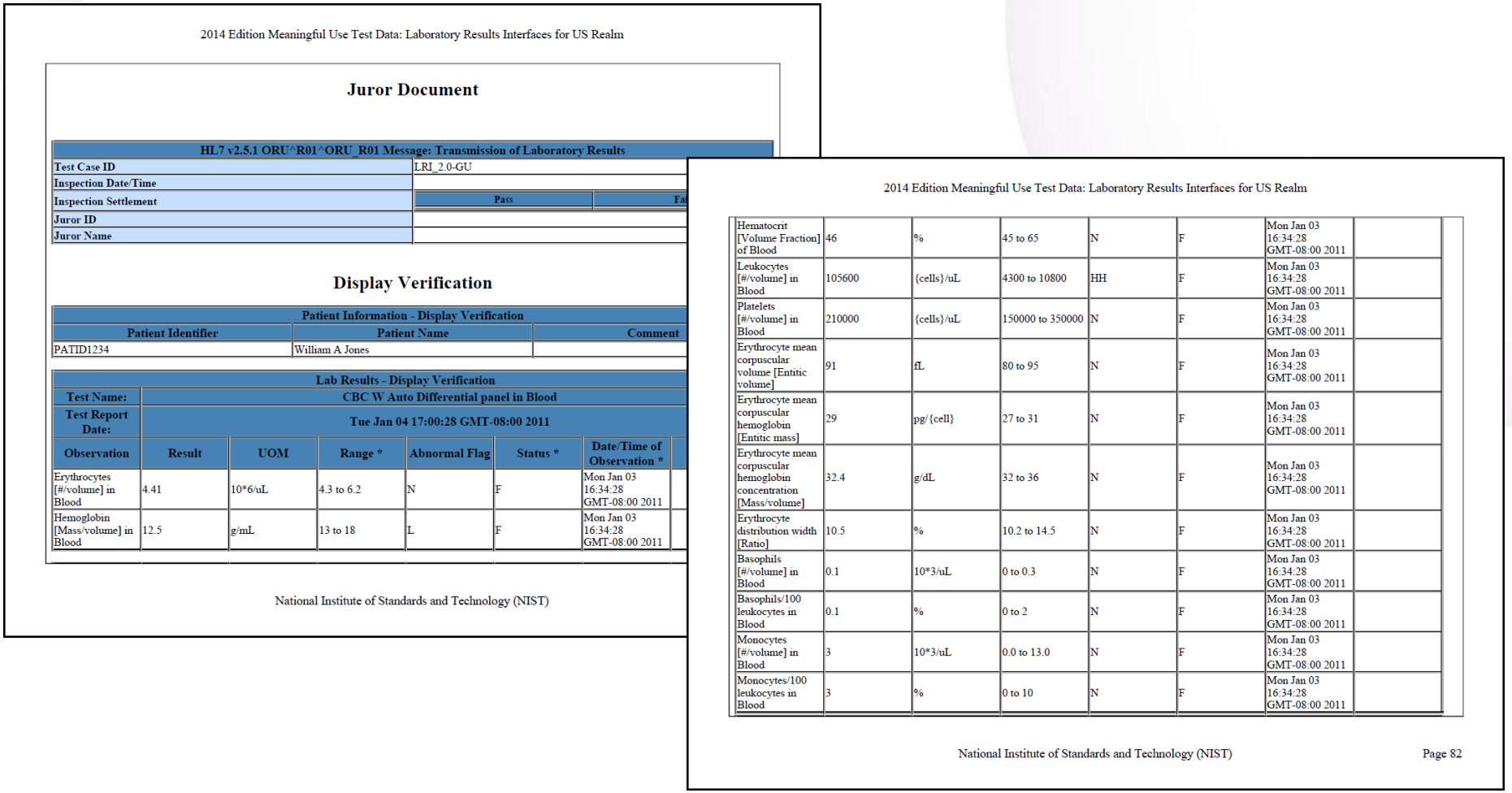
5 EHR Validation page displays with Receiving tab defaulted as selected.

6 Acknowledgment message sent by your EHR displays in Message Content section.

For this tutorial, the message is sent by the Simulator Tool.



The Test Data documents provide the actual test data – EHR, continued



2014 Edition Meaningful Use Test Data: Laboratory Results Interfaces for US Realm

Juror Document

HL7 v2.5.1 ORU^R01^ORU_R01 Message: Transmission of Laboratory Results		
Test Case ID	LRI_2.0-GU	
Inspection Date/Time		
Inspection Settlement	Pass	Fa
Juror ID		
Juror Name		

Display Verification

Patient Information - Display Verification		
Patient Identifier	Patient Name	Comment
PATID1234	William A Jones	

Lab Results - Display Verification						
Test Name:	CBC W Auto Differential panel in Blood					
Test Report Date:	Tue Jan 04 17:00:28 GMT-08:00 2011					
Observation	Result	UOM	Range *	Abnormal Flag	Status *	Date/Time of Observation *
Erythrocytes [#/volume] in Blood	4.41	10*6/uL	4.3 to 6.2	N	F	Mon Jan 03 16:34:28 GMT-08:00 2011
Hemoglobin [Mass/volume] in Blood	12.5	g/mL	13 to 18	L	F	Mon Jan 03 16:34:28 GMT-08:00 2011

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Hematocrit [Volume Fraction] of Blood	46	%	45 to 65	N	F	Mon Jan 03 16:34:28 GMT-08:00 2011	
Leukocytes [#/volume] in Blood	105600	{cells}/uL	4300 to 10800	HH	F	Mon Jan 03 16:34:28 GMT-08:00 2011	
Platelets [#/volume] in Blood	210000	{cells}/uL	150000 to 350000	N	F	Mon Jan 03 16:34:28 GMT-08:00 2011	
Erythrocyte mean corpuscular volume [Entitic volume]	91	fL	80 to 95	N	F	Mon Jan 03 16:34:28 GMT-08:00 2011	
Erythrocyte mean corpuscular hemoglobin [Entitic mass]	29	pg/{cell}	27 to 31	N	F	Mon Jan 03 16:34:28 GMT-08:00 2011	
Erythrocyte mean corpuscular hemoglobin concentration [Mass/volume]	32.4	g/dL	32 to 36	N	F	Mon Jan 03 16:34:28 GMT-08:00 2011	
Erythrocyte distribution width [Ratio]	10.5	%	10.2 to 14.5	N	F	Mon Jan 03 16:34:28 GMT-08:00 2011	
Basophils [#/volume] in Blood	0.1	10*3/uL	0 to 0.3	N	F	Mon Jan 03 16:34:28 GMT-08:00 2011	
Basophils/100 leukocytes in Blood	0.1	%	0 to 2	N	F	Mon Jan 03 16:34:28 GMT-08:00 2011	
Monocytes [#/volume] in Blood	3	10*3/uL	0.0 to 13.0	N	F	Mon Jan 03 16:34:28 GMT-08:00 2011	
Monocytes/100 leukocytes in Blood	3	%	0 to 10	N	F	Mon Jan 03 16:34:28 GMT-08:00 2011	

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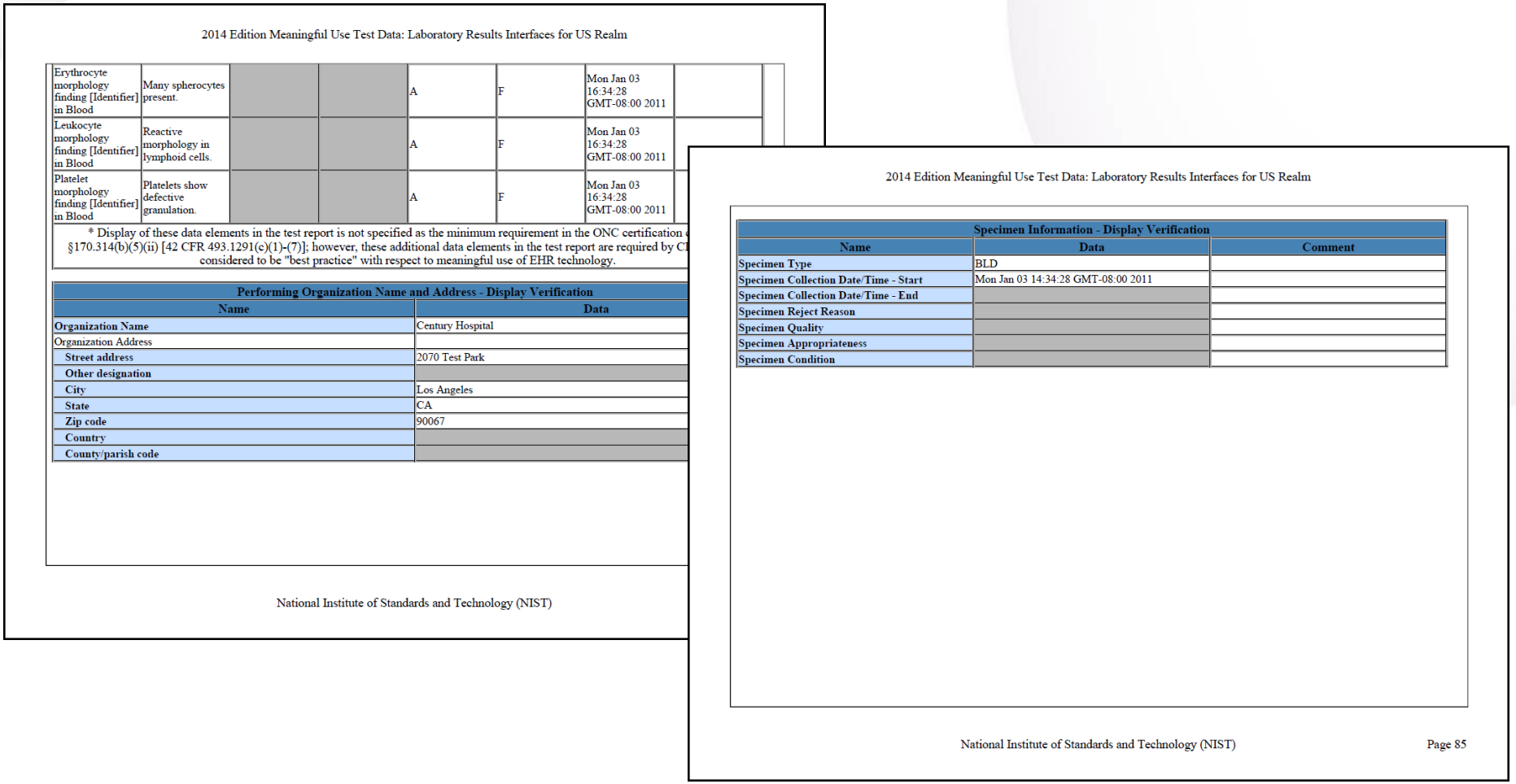
The Test Data documents provide the actual test data – EHR, continued



2014 Edition Meaningful Use Test Data: Laboratory Results Interfaces for US Realm

Erythrocyte morphology finding [Identifier] in Blood	Many spherocytes present.			A	F	Mon Jan 03 16:34:28 GMT-08:00 2011	
Leukocyte morphology finding [Identifier] in Blood	Reactive morphology in lymphoid cells.			A	F	Mon Jan 03 16:34:28 GMT-08:00 2011	
Platelet morphology finding [Identifier] in Blood	Platelets show defective granulation.			A	F	Mon Jan 03 16:34:28 GMT-08:00 2011	

* Display of these data elements in the test report is not specified as the minimum requirement in the ONC certification
§170.314(b)(5)(ii) [42 CFR 493.1291(c)(1)-(7)]; however, these additional data elements in the test report are required by C
considered to be "best practice" with respect to meaningful use of EHR technology.

Performing Organization Name and Address - Display Verification	
Name	**Data**
Organization Name	Century Hospital
Organization Address	
Street address	2070 Test Park
Other designation	
City	Los Angeles
State	CA
Zip code	90067
Country	
County/parish code	

National Institute of Standards and Technology (NIST)

2014 Edition Meaningful Use Test Data: Laboratory Results Interfaces for US Realm

Specimen Information - Display Verification		
Name	**Data**	**Comment**
Specimen Type	BLD	
Specimen Collection Date/Time - Start	Mon Jan 03 14:34:28 GMT-08:00 2011	
Specimen Collection Date/Time - End		
Specimen Reject Reason		
Specimen Quality		
Specimen Appropriateness		
Specimen Condition		

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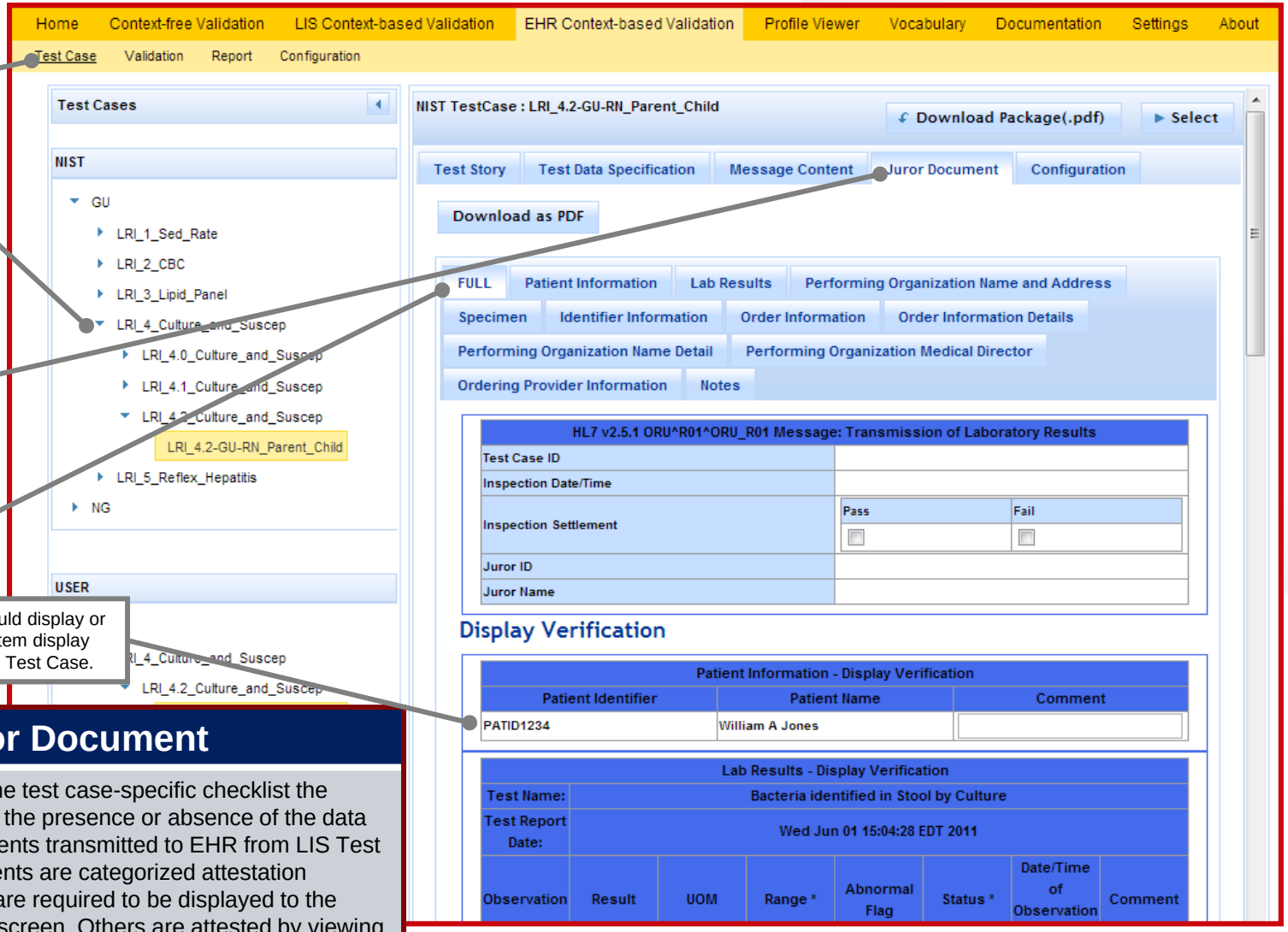
6) Review Juror Document for Test Case

1. Click on Test Case tab.
2. Click on arrows to expand the Test Scenarios and Test Cases under NIST. Click on a Test Case.
3. Click on Juror Document tab.
4. Full version of Juror Document will display.
5. Data elements that should display or be stored in EHR system display based on the selected Test Case.



Juror Document

The Juror Document is the test case-specific checklist the Tester uses to document the presence or absence of the data in the EHR for data elements transmitted to EHR from LIS Test Harness. The data elements are categorized attestation criteria. Some elements are required to be displayed to the clinical user on the EHR screen. Others are attested by viewing database records or configuration files.

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LRI EHR Conformance Test Tool – Juror Document (CBC)

Lab Results - Display Verification							
Test Name:	CBC W Auto Differential panel in Blood						
Test Report Date:	Tue Jan 04 20:00:28 EST 2011						
Observation	Result	UOM	Range *	Abnormal Flag	Status *	Date/Time of Observation *	Comment
Erythrocytes [#/volume] in Blood	4.41	10*6/uL	4.3 to 6.2	N	F	Mon Jan 03 19:34:28 EST 2011	
Hemoglobin [Mass/volume] in Blood	12.5	g/mL	13 to 18	L	F	Mon Jan 03 19:34:28 EST 2011	
Hematocrit [Volume Fraction] of Blood	46	%	45 to 65	N	F	Mon Jan 03 19:34:28 EST 2011	
Leukocytes [#/volume] in Blood	105600	{cells}/uL	4300 to 10800	HH	F	Mon Jan 03 19:34:28 EST 2011	
Platelets [#/volume] in Blood	210000	{cells}/uL	150000 to 350000	N	F	Mon Jan 03 19:34:28 EST 2011	
Erythrocyte mean corpuscular volume [Entitic volume]	91	fL	80 to 95	N	F	Mon Jan 03 19:34:28 EST 2011	
Erythrocyte mean corpuscular hemoglobin [Entitic mass]	29	pg/{cell}	27 to 31	N	F	Mon Jan 03 19:34:28 EST 2011	
Erythrocyte mean corpuscular hemoglobin concentration [Mass/volume]	32.4	g/dL	32 to 36	N	F	Mon Jan 03 19:34:28 EST 2011	
Erythrocyte distribution width [Ratio]	10.5	%	10.2 to 14.5	N	F	Mon Jan 03 19:34:28 EST 2011	
Basophils [#/volume] in Blood	0.1	10*3/uL	0 to 0.3	N	F	Mon Jan 03 19:34:28 EST 2011	
Basophils/100 leukocytes in Blood	0.1	%	0 to 2	N	F	Mon Jan 03 19:34:28 EST 2011	
Monocytes [#/volume] in Blood	3	10*3/uL	0.0 to 13.0	N	F	Mon Jan 03 19:34:28 EST 2011	
Monocytes/100 leukocytes in Blood	3	%	0 to 10	N	F	Mon Jan 03 19:34:28 EST 2011	
Eosinophils [#/volume] in Blood	0.25	10*3/uL	0.0 to 0.45	N	F	Mon Jan 03 19:34:28 EST 2011	

Summary

- Standards are necessary for Interoperability
- Conformance Testing is Essential
  - Seeks to verify that systems are implemented correctly
  - Testing improves standards via feedback loop
  - Test case and examples help in the interpretation of the standard and reinforces concepts in the standard
- Certified systems is the foundation for achieving interoperable in practice
- Realistic and Relevant Test Cases are helpful to end users
- NIST has developed a Methodology and Framework for Testing
  - Reusable framework
  - Modular
  - Allows for quicker development of test tools

NIST Meaningful Use Tools Overview

MU-2 Conformance Tools	
Name	URL
MU-2014 HL7v2 Immunization Messaging Validation Tool	http://hl7v2-iz-testing.nist.gov/mu-immunization/
MU-2014 HL7v2 Syndromic Surveillance Reporting Validation Tool	http://hl7v2-ss-testing.nist.gov/mu-syndromic/
MU-2014 HL7v2 Electronic Laboratory Reporting (ELR) Validation Tool	http://hl7v2-elr-testing.nist.gov/mu-elr/
MU-2014 HL7v2 Laboratory Results Interface (LRI) Validation Tool	http://hl7v2-lab-testing.nist.gov/mu-lab/
MU-2014 Cancer Registry Report Validation	http://hit-testing.nist.gov/cda-validation/muCr.html
MU-2014 ePrescribing NCPDP SCRIPT 10.6 Validation Tool	http://erx-testing.nist.gov/
MU-2014 Transport Test Tool (TTT) (includes C-CDA, Direct, and SOAP)	http://transport-testing.nist.gov/ttt/
NIST EHR-Randomizer Application	https://ehr-randomizer.nist.gov:14081/ehr-randomizer-app/#/home
Anticipated Additional MU-3 Conformance Tools	
NIST HL7v2 Laboratory Orders Interface (LOI) Validation Tool	In Development
NIST HL7v2 Electronic Delivery of Services (eDOS) Validation Tool	In Development
NIST HL7v2 Immunization Messaging (EHR & IIS) Validation Tool	In Development
NIST HL7v2 Medical Devices (PCD) Validation Tool	In Development

Questions / Discussion?

Thank you for your attention and attendance of this session!

- Speakers:
  - Robert Snelick, robert.snelick@nist.gov
  - John J. Garguilo, john.garguilo@nist.gov

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