



Virginia Information Technologies Agency

HITSAC Genomics Working Group Final Report: Proposed Use Cases & Recommended Health IT Standards

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Presentation to the
Health IT Standards Advisory Committee
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Presentation Agenda

- Use Case #1: Process for Implementing a Clinical-Grade Variant File for Reporting to the Virginia Cancer Registry (VDH) and Integrating into an Electronic Health Record through eHealth Exchange
- Use Case #2: Process for Transmitting Results from Pharmacogenomic Testing across Electronic Health Record Systems
- Recommended health IT standards and implementation guides in clinical genomics for adoption as Commonwealth standards



USE CASE #1 – CLINICAL-GRADE VARIANT FILE



Use Case #1 – Primary Stakeholders

- Virginia Department of Health (VDH)
- ConnectVirginia HIE
- U.S. Centers for Disease Control and Prevention (CDC)
- Healtheway eHealth Exchange



Use Case #1 – Background

- CDC has been facilitating a working group to develop a clinical-grade variant file specification to support the exchange of genomic information in a standardized manner
- CDC working group includes:
 - CDC Divisions
 - College of American Pathologists
 - HL7 Clinical Genomics Working Group



Use Case #1 – Background

- CDC file specification will enable genomic information to be reported to a cancer registry (CR) and integrated into a patient's EHR in a standardized manner
- CDC has leveraged existing synoptic reporting specifications and aligned them with HL7's LOINC-qualified genetic variation model
- Use Case #1 will define the process for implementing the CDC clinical-grade variant file for CR reporting and EHR integration



Use Case #1 – Purpose

To establish a process for implementing the CDC's clinical-grade variant file for the purpose of (a) reporting genomic information to the Virginia Cancer Registry (VDH), using ConnectVirginia's Public Health Reporting Pathway, and (b) integrating into an electronic health record through the eHealth Exchange

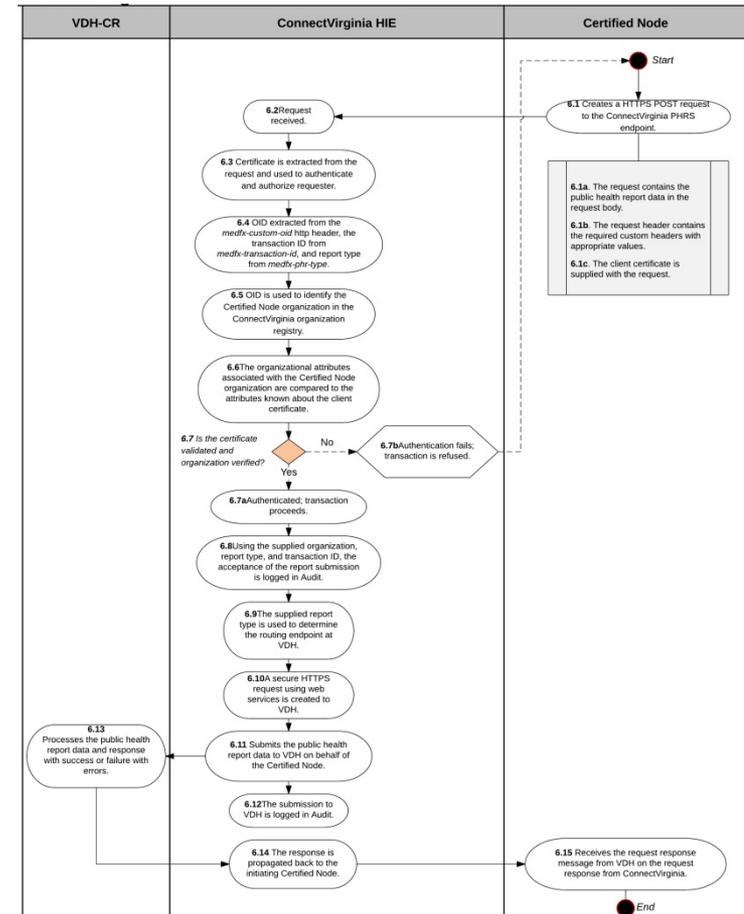
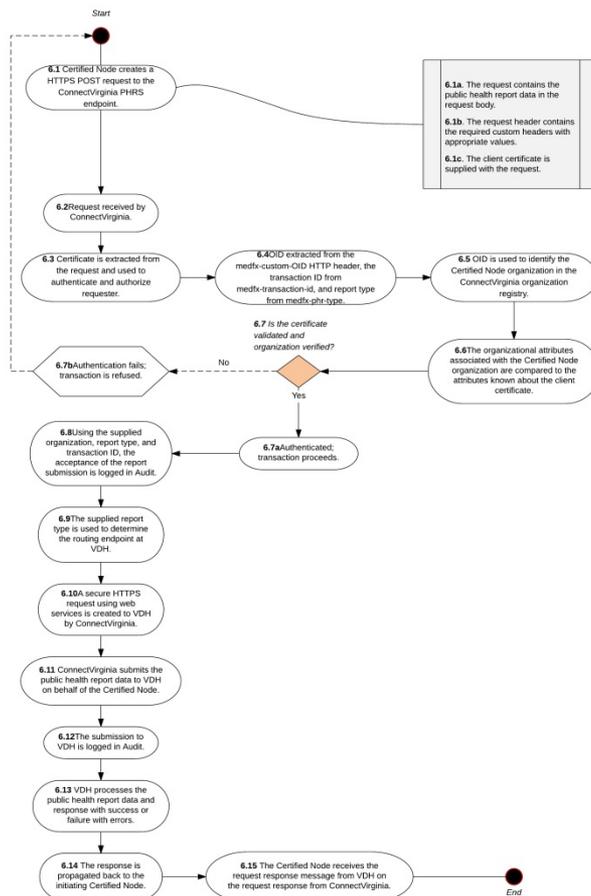


Use Case #1 – Cancer Registry Reporting

VDH-ConnectVirginia Public Health Reporting Pathway

ConnectVirginia PHR WSDL	1.0
Virginia Department of Health Meaningful Use Registration	N/A
Virginia Immunization Information System HL7 Version 2.5.1 Transfer Specification	HL7 v.2.5.1
Syndromic Surveillance Submission Guide: Ambulatory Data	08/12/2013
VDH Syndromic Surveillance Submission Guide: Emergency Department and Urgent Care Data	08/12/2013
HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm)	HL7 v.2.5.1
Electronic Lab Report Submission Guide	12/04/2012
HL7 International OID Registry	N/A

Use Case #1 – Cancer Registry Flows





Use Case #1 – EHR Integration

eHealth Exchange 2011 Specifications

- [CAQH CORE X12 Document Submission Service Interface Specification v 1.0 3/6/2012](#) [PDF - 390 KB]
- [Electronic Submission of Medical Documentation \(esMD\) X12 Profile v 1.0 3/6/2012](#) [PDF - 783 KB]
- [Web Services Registry Web Service Interface Specification v 3.1 3/6/2012](#) [PDF - 405 KB]
- [Messaging Platform v3.0 approved by NTCon 6/27/2011](#) [PDF - 232 KB]
- [Patient Discovery v2.0 approved by NTCon 6/27/2011](#) [PDF - 234 KB]
- [Query for Documents v3.0 approved by NTCon 6/27/2011](#) [PDF - 201 KB]
- [Retrieve Documents v3.0 approved by NTCon 6/27/2011](#) [PDF - 153 KB]
- [Authorization Framework v3.0 approved by NTCon 7/25/2011](#) [PDF - 226 KB]
- [Web Services Registry v3.0 approved by NTCon 7/25/2011](#) [PDF - 376 KB]
- [Electronic Submission of Medical Documentation \(esMD\) XDR Production Specification v1.0](#) [PDF - 324 KB]
- [Administrative Distribution Production Specification v2.0](#) [PDF - 144 KB]
- [Document Submission Production Specification v2.0](#) [PDF - 192 KB]



Use Case #1 – Next Steps

- HITSAC Recommendation to Proceed
- Complete transaction types and flows for the ConnectVirginia Public Health Reporting Pathway
- Present to eHealth Exchange Coordinating Committee
- Complete transaction types and flows for eHealth Exchange



USE CASE #2 – PHARMACOGENOMICS



Use Case #2 – Primary Stakeholders

- Virginia Department of Health
- Inova Translational Medicine Institute (ITMA)
- Virginia Commonwealth University
- ConnectVirginia HIE
- MedVirginia HIE



Use Case #2 – Background

- ITMI has implemented a pharmacogenomic testing protocol for Clopidogrel (Plavix, CYP2C19), a second-generation thienopyridine designed for treatment of patients with coronary artery disease, etc.
- ITMI named the test the “Plavix Genotype Test” and performs the test using a kit approved by the U.S. Food and Drug Administration
- Interpretation of the Plavix Genotype Test has been standardized on the assay and ITMI’s Luminex laboratory equipment



Use Case #2 – Background

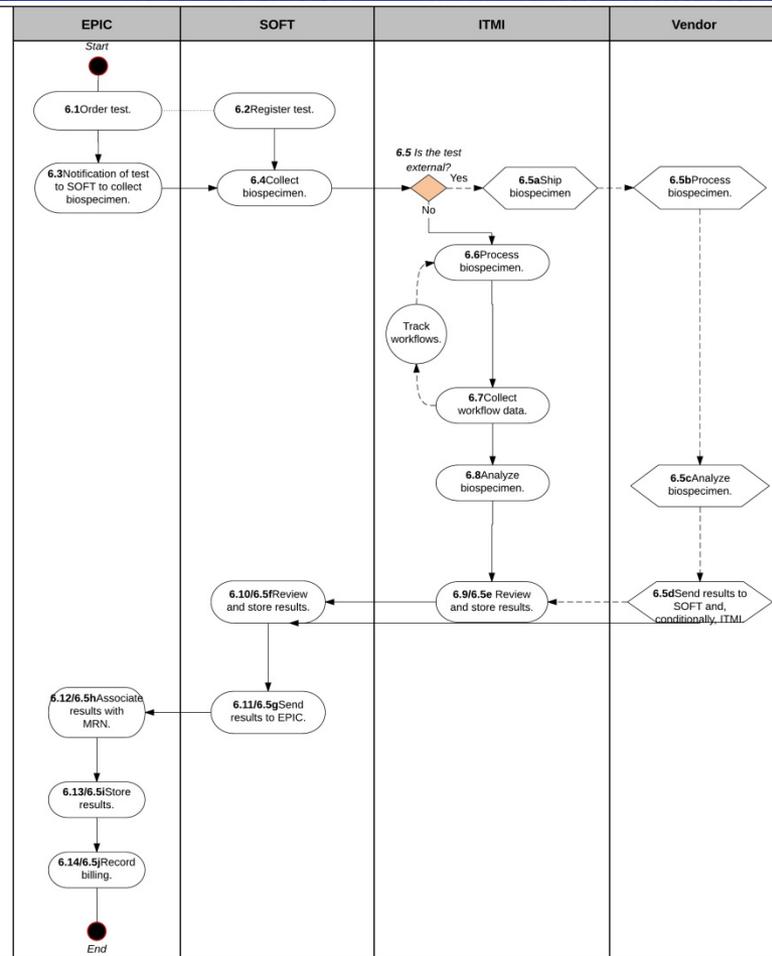
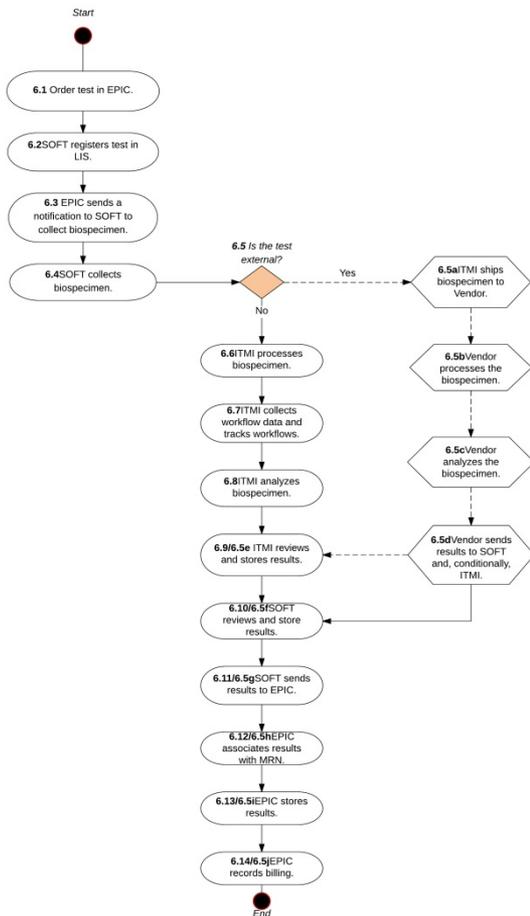
- ITMI has successfully integrated results from the Plavix Genotype Test into Inova's Epic EHR system
- Use Case #2 will define the process for transmitting results from ITMI's Plavix Genotype Test across EHR systems and vendor platforms



Use Case #2 – Purpose

To establish a process for transmitting results from ITMI's Plavix Genotype Test from Inova's Epic EHR system to VCU's Cerner EHR system via ConnectVirginia and MedVirginia

Use Case #2 – ITMI Flows





Use Case #2 – Next Steps

- HITSAC Recommendation to Proceed
- Complete transaction types, specifications and flows for ConnectVirginia and MedVirginia
- Complete transaction types and flows for VCU Cerner EHR System



RECOMMENDED HEALTH IT STANDARDS & IMPLEMENTATION GUIDES



Recommended Health IT Standards

- Clinical Laboratory Improvement Amendments (Public Law 100-578)
<http://www.gpo.gov/fdsys/pkg/CFR-2003-title42-vol3/xml/CFR-2003-title42-vol3-part493.xml>
 - Regulations cover all laboratory testing (except research) performed on humans in the U.S.
 - Administered by the Division of Laboratory Services, Survey and Certification Group, Center for Clinical Standards and Quality (CCSQ), Centers for Medicare & Medicaid Services (CMS)



Recommended HL7 Implementation Guides

- HL7 Implementation Guide for CDA Release 2: Genetic Testing Reports, Release 1
- HL7 Version 2 Implementation Guide: Clinical Genomics; fully LOINC-Qualified Cytogenetic Model, Release 1 (US Realm)
- HL7 Version 2 Implementation Guide: Clinical Genomics; Fully LOINC-Qualified Genetic Variation Model (US Realm)



For More Information

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