

Process for Integrating Results from Pharmacogenomic Testing into an Electronic Health Record

Version 1.0

DRAFT

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Developed in Partnership with
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HL7 Clinical Genomics Working Group

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General Information

1. Use Case ID

HITSAC Genomics Working Group Use Case #3 (HITSACGWG3)

2. Use Case Title

Process for Integrating Results from Pharmacogenomic Testing into an Electronic Health Record

3. Abstract

The HITSAC Genomics Working Group Use Case #2 defines the process for integrating results from pharmacogenomic testing into a patient's electronic health record.

4. Description

Pharmacogenomics explores the role of genetics in drug response, focusing in particular on the influence of genetic variation on drug response in patients by correlating gene expression or single-nucleotide polymorphisms with drug absorption, distribution, metabolism and elimination and drug receptor target effects. Pharmacogenomics concentrates on single drug-gene interactions and encompasses a more genome-wide association approach, incorporating genomics and proteomics while exploring the effects of multiple genes on drug response.

Results from pharmacogenomic testing require a designated location, standardized structure and nomenclature and dedicated persistence within the electronic health record (EHR). Unlike other laboratory tests, such as for cholesterol or glucose level, results from pharmacogenomic testing do not change. Therefore, pharmacogenomic test results must remain with the patient and be clearly discoverable by healthcare providers to inform appropriate pharmacological treatment. Specific requirements for pharmacogenomic test results returned to the EHR are as follows:

- A clinical report with the results described in narrative form
 - Actions and recommendations signed off by the certified clinical and or molecular geneticists
 - Understandable information for both clinician and patient
- A discrete result of the allele variation for the specific loci being tested
 - Allows for interoperability and data sharing based on a standard set understandable across the genetic community
 - Enables alerts – both active and passive – to be generated based on the results
 - Provides for statistical and outcomes-based reporting from the results
 - Supports future reporting and alerts based on discovery of validated drug/gene interactions
- A discrete, more descriptive result of the test in the context of the test order
 - Provides for statistical and outcomes-based reporting for non-genetic purposes
 - Gives clear indication result interpretation in the context of patient point of care

The Inova Translational Medicine Institute (ITMI) is a research center established by Inova Health System, to conduct genomic research and translate findings into a clinical setting to improve quality of patient care. ITMI has implemented a pharmacogenomic testing protocol for Clopidogrel (Plavix, CYP2C19), a second-generation thienopyridine that inhibits platelet aggregation and has been designed for treatment of patients with coronary artery disease, acute coronary syndromes (ACS), and/or after percutaneous coronary interventions (PCI). ITMI has named the test “Plavix Genotype Test” and performs the test using a kit approved by the U.S. Food and Drug Administration (FDA).

The interpretation of the Plavix Genotype Test has been standardized on the assay and ITMI’s Luminex laboratory equipment. ITMI initiated its implementation of the clinical genetic/genomics tests on these standard set FDA approved pharmacogenomics tests, as these tests have been validated and are mostly reimbursable. As the testing progresses, ITMI will implement genetic panels, targeting specific genetic markers for conditions such as cancer or supplements to standard tests such as newborn screening.

The following use case has been developed by the Commonwealth of Virginia’s HITSAC Genomics Working Group (HITSAC-GWG) to define the process for integrating results from pharmacogenomic testing into a patient’s electronic health record. The use case leverages the workflow, testing protocols and reporting capability currently being implemented by Inova/ITMI as the Plavix Genotype Test. The ITMI Plavix Genotype Test specification has been provided in Appendix A. Specifications and requirements for integration of pharmacogenomic test results into Inova’s EPIC EHR have been provided in Appendix B.

The use case has been constrained to focus on reporting of pharmacogenomic test results – the Plavix Genotype Test – within the Inova Health System laboratory and EHR environment. Future use cases identified by the HITSAC-GWG will concentrate on generalizing from the Inova/ITMI-centric system to pharmacogenomic tests conducted on other laboratory and EHR platforms.

5. Stakeholders

- Inova/ITMI Pharmacogenomic Laboratory Testing
 - ITMI Laboratory Software
 - ITMI Laboratory Staff

- Inova Health System Electronic Health Record (EHR) System
 - Inova EHR System (EPIC)
 - Inova Clinical Staff

6. Definitions

Pharmacogenomic Test: A laboratory test that measures the influence of genetic variation on drug response in patients.

Electronic Health Record (EHR): A digital version of a patient's medical chart structured based on the Health Level 7 (HL7) Clinical Document Architecture (CDA) and Continuity of Care Document (CCD) Standards.

7. Version Control

The following table contains a history of revisions to this publication.

Version	Date	Revision Description	Contact
1.0	9/23/2014	Initial Use Case Document	Joe Grubbs

Identifying Changes in This Document

- See the latest entry in the revision table above
- Vertical lines in the left margin indicate the paragraph has changes or additions. Specific changes in wording are noted using italics and underlines; with italics only indicating new/added language and italics that is underlined indicating language that has changed.

The following examples demonstrate how the reader may identify updates and changes:

Example with No Change – The text is the same. The text is the same.

Example with Revision – The text is the same. *A wording change, update or clarification is made in this text.*

Example of New Text – *This text is new.*

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Pharmacogenomic Test Result – Plavix Genotype Test

1. Plavix Genotype Test Description

Note: The ITMI Plavix Genotype Test specification has been provided in Appendix A.

The ITMI Plavix Genotype Test XXXXXXXX

[ADDITIONAL INFORMATION FOR THIS SECTION WILL BE PROVIDED BY ITMI/Aaron Black]

2. Alignment with Existing Health IT Standards

The process for integrating pharmacogenomic test results into an electronic health record has been developed to align with the following health IT standards, as required by the Commonwealth of Virginia:

ID	TITLE	VERSION	NOTES

[ADDITIONAL INFORMATION FOR THIS SECTION WILL BE PROVIDED BY ITMI/Aaron Black]

Integrating Results from Pharmacogenomic Testing into the Electronic Health Record

Note: Diagrams of the work flow and data flow of the integration of the ITMI Plavix Genotype Test results into Inova's EPIC EHR system have been provided in this document as Appendix D and Appendix E.

1.0 Preconditions

A set of conditions that must be met before the activities described in the use case can begin.

1. The Inova/ITMI has conducted the Plavix Genotype Test.
2. The result from the ITMI Plavix Genotype Test has been transmitted to the patient's EHR in Inova's EPIC EHR system.
3. The ITMI Plavix Genotype Test result has been integrated into the patient's EHR in Inova's EPIC EHR system.

2.0 Post Condition

A set of conditions that must be met after the activities described in the use case have been completed.

The received ITMI Plavix Genotype Test becomes integrated into the patient's EHR in Inova's EPIC EHR system.

3.0 Priority

Describes the importance and sequence of the use case in the overall activities of the cancer registry.

This is a high-priority use case and the HITSAC Genomics Working Group decided it should be developed first.

4.0 Frequency of Use

Describes how often the activities in the use case take place.

The activities in this use case will take place each time a new or resubmitted ITMI Plavix Genotype Test result becomes transmitted into the patient's EHR in Inova's EPIC EHR system.

5.0 Inova Health System EHR System – EPIC Specifications

Describes the specifications required for integration with Inova Health System's EPIC EHR System.

XXXX.

[ADDITIONAL INFORMATION FOR THIS SECTION WILL BE PROVIDED BY ITMI/Aaron Black]

6.0 Transaction Workflow

Describes the specific steps in the workflow taken to integrate the results from the ITMI Plavix Genotype Test into the Inova EPIC EHR system.

- 6.1 Order test in EPIC
- 6.2 SOFT registers test in LIS
- 6.3 EPIC sends a notification to SOFT to collect biospecimen
- 6.4 SOFT collects biospecimen
- 6.5 If test is external, the following steps occur:
 - 6.5a. ITMI ships biospecimen to vendor
 - 6.5b. Vendor processes the biospecimen
 - 6.5c. Vendor analyzes the biospecimen
 - 6.5d. Vendor sends results to SOFT
 - 6.5e. ITMI reviews and stores results
 - 6.5f. SOFT reviews and stores results
 - 6.5g. SOFT sends results to EPIC
 - 6.5h. EPIC associates results with MRN
 - 6.5i. EPIC stores results
 - 6.5j. EPIC records billing

If the test is not external, the workflow continues

- 6.6 ITMI processes biospecimen
- 6.7 ITMI collects workflow data and tracks workflows
- 6.8 ITMI analyzes biospecimen
- 6.9 ITMI reviews and stores results
- 6.10 SOFT reviews and stores results
- 6.11 SOFT sends results to EPIC
- 6.12 EPIC associates results with MRN
- 6.13 EPIC stores results
- 6.14 EPIC records billing

7.0 Exceptions

None.

8.0 Includes

None.

9.0 Special Requirements

None.

10.0 Assumptions

1. The ITMI has implemented the Plavix Genotype Test.
2. The ITMI Plavix Genotype Test results are in electronic format.
3. The ITMI Plavix Genotype Test results are encrypted pursuant to Commonwealth of Virginia standards.
4. The collection, management and transmittal of the ITMI Plavix Genotype Test results comply with applicable law.

11.0 Pilot Project Recommendation

The findings from this use case will be used to frame a pilot project to test the process for integrating pharmacogenomic test results into a patient's electronic health record. The proposed pilot project has been documented in the white paper, *HITSAC Genomics Working Group Pilot Project Recommendation: Process for Integrating Results from Pharmacogenomic Testing into an Electronic Health Record*. The purpose of the pilot project will be to develop and implement a process to support integration of pharmacogenomic test results into a patient's EHR to enhance quality of patient care.

12.0 References

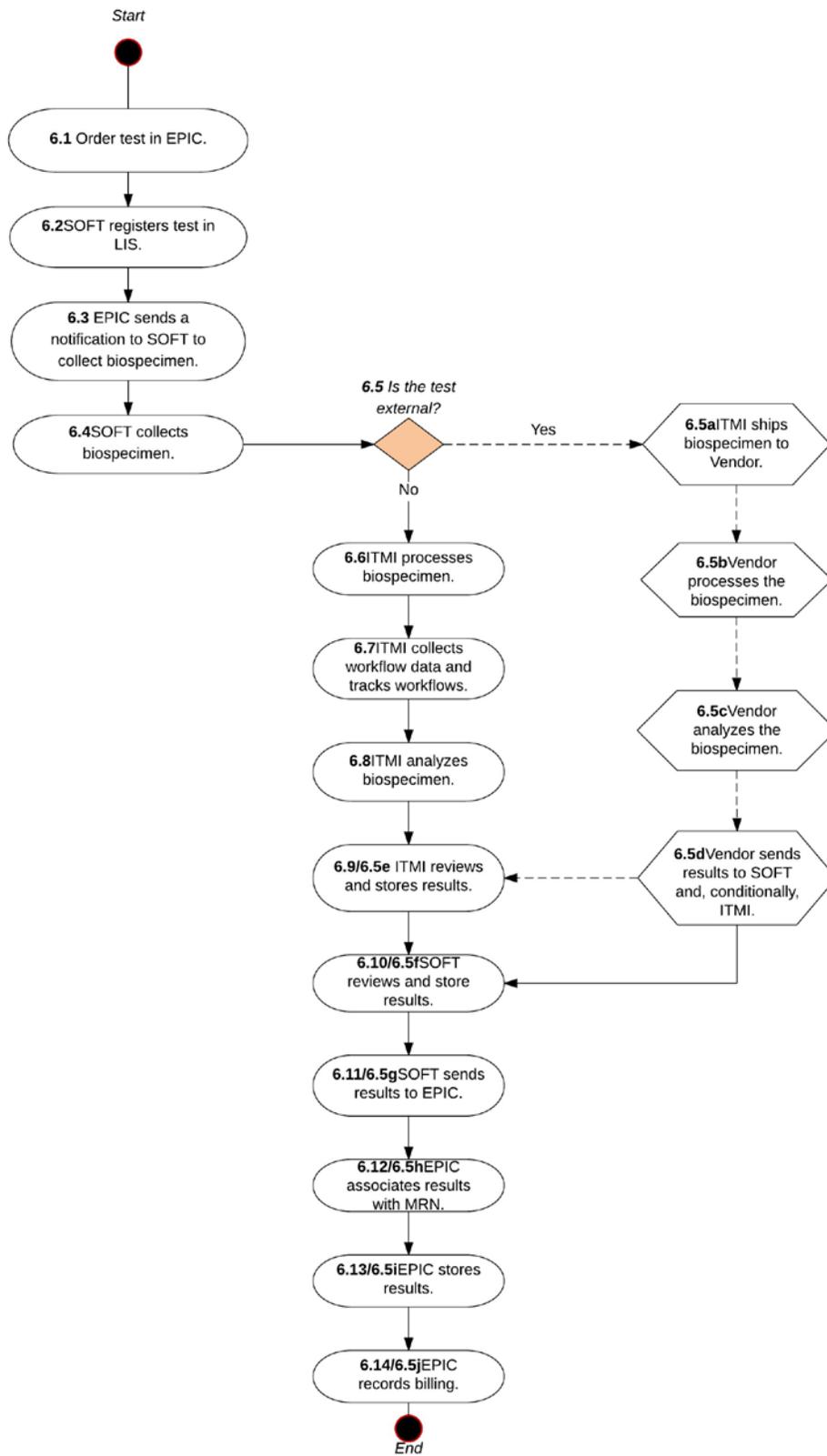
1. XXXX.
2. XXXX.
3. XXXX.
4. XXXX.

[ADDITIONAL INFORMATION FOR THIS SECTION WILL BE PROVIDED BY ITMI/Aaron Black]

NOTE: FULL SET OF APPENDICES WILL BE ADDED IN PRODUCTION VERSION

**Appendix D: Pharmacogenomic Test Result-EHR Integration Transaction
Workflow Diagram**

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Appendix E: Pharmacogenomic Test Result-EHR Integration Data Flow

