GE Centricity EMR
Version 9.8
Meaningful Use 2014 Edition
User Centered Design Report

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GE Centricity EMR Version 9.8

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User Centered Design Report

Report based on NIST 7742 Customized Common Industry Format Template for Electronic Health Record Usability Testing

GE Centricity EMR Version 9.8

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1 EXECUTIVE SUMMARY

User centered design (UCD) was integrated into the design and development of GE Centricity EMR Version 9.8 including both clinical (licensed and credentialed providers and clinical ancillary staff facing) and configuration (configuration specialist facing) user interfaces. The UCD process used during the design and development of these prioritized certification criteria is identified in the corresponding chapters.

§170.314(a)(1) Computerized provider order entry

§170.314(a)(2) Drug-drug, drug-allergy interaction checks

§170 314(a)(6) Medication list

§170 314(a)(7) Medication allergy list

§170.314(a)(8) Clinical decision support (CDS)

§170.314(a)(16) Electronic medication administration record

§170.314(b)(3) Electronic prescribing

§170.314(b)(4) Clinical information reconciliation

User-Centered Design Goals

According to the National Institute of Standards and Technology (NIST) Guide to the Processes Approach for Improving the Usability of Electronic Health Records, EHRs should support a process that provides a high level of usability for all users. The goals are for users to interact with the system safely, effectively, efficiently, and with an acceptable level of satisfaction. To this end, design to optimize for safety, effectiveness, efficiency and user satisfaction was utilized throughout the design and development cycle.

2 USER-CENTERED DESIGN METHODS

This section of the report presents a separate chapter for each EHR technology capability submitted for testing. Each chapter provides:

- Certification Criteria
- Identification of UCD process and activities employed
- Reference

2.1 Chapter §170.314(a)(1) Computerized Provider Order Entry

2.1.1 Computerized Provider Order Entry

Table 1 provides the Computerized Provider Order Entry (CPOE) criteria to aid verification that a UCD process was applied to each EHR technology capability.

Table 1. Computerized Provider Order Entry Criteria.

§170.314(a)(1) Computerized provider order entry Enable a user to electronically record, change, and access the following order types (i) Medications; (ii) Laboratory; and (iii) Radiology/imaging.

2.1.2 UCD Process Employed

The EMR MU UX Usability Plan, the GE Usability Work Instruction, and ISO 62366 were utilized in the design and development of the features associated with this criteria. No changes in the CPOE feature were identified as part of the Meaningful Use 2014 Edition development activities. As such, the Usability Work Instruction for Legacy products was applied based on the process described in ISO 62366. A Usability Analysis to identify and control use errors and misuse that might lead to a hazardous situation was conducted. The GE team designed and developed the legacy feature based on the understanding of specific user groups' needs, workflows, and environments. The team gathered requirements and solicited feedback from end users and subject matter experts from the Clinical Advisory Group, customer workgroups, Product Management, and consultants from various roles. Requirements and feedback from sessions were incorporated into the design for subsequent reviews.

2.1.3 Reference

National Institute of Standards and Technology. (2010). *NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records* (NISTIR 7741). Gaithersburg, MD: ://www.nist.gov/manuscript-publication-search.cfm?pub_id=907313.

ISO/IEC 62366:2007, Medical devices – Application of usability engineering to medical devices. Geneva , International Electrotechnical Commission.

2.2 Chapter §170.314(a)(2) Drug-Drug, Drug-Allergy Interaction Checks - Interventions

2.2.1 Drug-Drug, Drug-Allergy Interaction Checks - Interventions

Table 2 provides the Drug-Drug, Drug-Allergy Interaction Checks - Interventions criteria to aid verification that a UCD process was applied to each EHR technology capability.

Table 2. Drug-Drug, Drug-Allergy Interaction Checks - Interventions Criteria.

§170.314 (a)(2) Drug-drug, drug-allergy interaction checks (i) Interventions. Before a medication order is completed and acted upon during computerized

provider order entry (CPOE), interventions must automatically and electronically indicate to a user drug-drug and drug-allergy contraindications based on a patient's medication list and medication allergy list.
(ii) Adjustments.
(A) Enable the severity level of interventions provided for drug-drug interaction checks to be adjusted.
(B) Limit the ability to adjust severity levels to an identified set of users or available as a system administrative function.

2.2.2 UCD Process Employed

The EMR MU UX Usability Plan, the GE Usability Work Instruction, and ISO 62366 were utilized in the design and development of the features associated with this criteria. No changes in the drug-drug, drug-allergy interaction checks - interventions feature were identified as part of the Meaningful Use 2014 Edition development activities. As such, the Usability Work Instruction for Legacy products was applied based on the process described in ISO 62366. A Usability Analysis to identify and control use errors and misuse that might lead to a hazardous situation was conducted. The GE team designed and developed the legacy feature based on the understanding of specific user groups' needs, workflows, and environments. The team gathered requirements and solicited feedback from end users and subject matter experts from the Clinical Advisory Group, customer workgroups, Product Management, and consultants from various roles. Requirements and feedback from sessions were incorporated into the design for subsequent reviews.

2.2.3 Reference

National Institute of Standards and Technology. (2010). *NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records* (NISTIR 7741). Gaithersburg, MD: ://www.nist.gov/manuscript-publication-search.cfm?pub_id=907313.

ISO/IEC 62366:2007, Medical devices – Application of usability engineering to medical devices. Geneva , International Electrotechnical Commission.

2.3 Chapter §170.314(b)(4) Clinical Information Reconciliation (CDS)

2.3.1 Clinical Information Reconciliation

Table 3 provides the Clinical Information Reconciliation criteria to aid verification that a UCD process was applied to each EHR technology capability.

Table 3. Clinical Information Reconciliation

§ 170.314(b)(4) Clinical information reconciliation (CDS) Enable a user to electronically reconcile the data that represent a patient's active medication, problem, and medication allergy list as follows. For each list type:

(i) Electronically and simultaneously display (i.e., in a single view) the data from at least two list sources in a manner that allows a user to view the data and their attributes, which must include, at a minimum, the source and last modification date.
(ii) Enable a user to create a single reconciled list of medications, medication allergies, or problems.
(iii) Enable a user to review and validate the accuracy of a final set of data and, upon a user's confirmation, automatically update the list.

2.3.2 UCD Process Employed

The EMR MU UX Usability Plan, the GE Usability Work Instruction, and ISO 62366 were utilized in the design and development of the features associated with this criteria. Changes in the Clinical Information Reconciliation feature were identified as part of the Meaningful Use 2014 Edition development activities. As such, the Usability Work Instruction for Changes to Legacy Functionality/New functionality Added to Existing Product was applied based on the process described in ISO 62366.

A Failure Modes and Effects Analysis (FMEA) was conducted. Formative and summative usability analyses were carried out to ensure changes do not introduce new use errors or methods of misuse that can cause or contribute to a hazardous situation or negatively affect control measures that mitigate potentially hazardous situations. The GE team designed and developed the clinical information reconciliation feature based on the understanding of specific user groups' needs, workflows, and environments. The team solicited and gathered requirements and solicited feedback from end users and subject matter experts from the Clinical Advisory Board, Product Management, and consultants from various roles. Requirements and feedback from sessions were incorporated into the design for subsequent reviews and Formative Usability testing. Formative Usability testing was conducted with users at the Centricity Healthcare User Group meeting in October, 2012.

2.3.3 Reference

National Institute of Standards and Technology. (2010). NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records (NISTIR 7741). Gaithersburg, MD: ://www.nist.gov/manuscript-publication-search.cfm?pub_id=907313.

ISO/IEC 62366:2007, Medical devices – Application of usability engineering to medical devices. Geneva , International Electrotechnical Commission.

2.4 Chapter §170.314(a)(6) Medication List

2.4.1 Medication List

Table 4 provides the Medication List criteria to aid verification that a UCD process was applied to each EHR technology capability.

Table 4. Medication List Criteria.

§ 170.314(a)(6) Medication List Enable a user to electronically record, change, and access a patient's active medication list as well as medication history: (i) Ambulatory setting. Over multiple encounters; or (ii) Inpatient setting. For the duration of entire hospitalization

2.4.2 UCD Process Employed

The EMR MU UX Usability Plan, the GE Usability Work Instruction, and ISO 62366 were utilized in the design and development of the features associated with this criteria. No changes in the Medication List feature were identified as part of the Meaningful Use 2014 Edition development activities. As such, the Usability Work Instruction for Legacy products was applied based on the process described in ISO 62366. A Usability Analysis to identify and control use errors and misuse that might lead to a hazardous situation was conducted. The GE team designed and developed the legacy feature based on the understanding of specific user groups' needs, workflows, and environments. The team gathered requirements and solicited feedback from end users and subject matter experts from the Clinical Advisory Group, customer workgroups, Product Management, and consultants from various roles. Requirements and feedback from sessions were incorporated into the design for subsequent reviews.

2.4.3 Reference

National Institute of Standards and Technology. (2010). *NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records* (NISTIR 7741). Gaithersburg, MD: ://www.nist.gov/manuscript-publication-search.cfm?pub_id=907313.

ISO/IEC 62366:2007, Medical devices – Application of usability engineering to medical devices. Geneva , International Electrotechnical Commission.

2.5 Chapter §170 314(a)(7) Medication Allergy List

2.5.1 Medication Allergy List

Table 5 provides the Medication Allergy List criteria to aid verification that a UCD process was applied to each EHR technology capability.

Table 5. Medication Allergy List Criteria.

§170.314(a)(7) Medication Allergy List Enable a user to electronically record, change, and access a patient's active medication allergy list as well as medication allergy history:

(i) Ambulatory setting. Over multiple encounters; or (ii) Inpatient setting. For the duration of an entire hospitalization.

2.5.2 UCD Process Employed

The EMR MU UX Usability Plan, the GE Usability Work Instruction, and ISO 62366 were utilized in the design and development of the features associated with this criteria. No changes in the Medication Allergy List feature were identified as part of the Meaningful Use 2014 Edition development activities. As such, the Usability Work Instruction for Legacy products was applied based on the process described in ISO 62366. A Usability Analysis to identify and control use errors and misuse that might lead to a hazardous situation was conducted. The GE team designed and developed the legacy feature based on the understanding of specific user groups' needs, workflows, and environments. The team gathered requirements and solicited feedback from end users and subject matter experts from the Clinical Advisory Group, customer workgroups, Product Management, and consultants from various roles. Requirements and feedback from sessions were incorporated into the design for subsequent reviews.

2.5.3 Reference

National Institute of Standards and Technology. (2010). *NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records* (NISTIR 7741). Gaithersburg, MD: ://www.nist.gov/manuscript-publication-search.cfm?pub_id=907313.

ISO/IEC 62366:2007, Medical devices – Application of usability engineering to medical devices. Geneva , International Electrotechnical Commission.

2.6 Chapter §170.314(a)(8) Clinical Decision Support (CDS) - Clinical

2.6.1 Clinical Decision Support (CDS)

Table 6 provides the Clinical Decision Support (CDS) criteria to aid verification that a UCD process was applied to each EHR technology capability.

Table 6. Clinical Decision Support (CDS) Criteria.

§170.314(a)(8) Clinical decision support (CDS) (i) Evidence-based decision support interventions. Enable a limited set of identified users to select (i.e., activate) one or more electronic clinical decision support interventions (in addition to drug-drug and drug-allergy contraindication checking) based on each one and at least one combination of the following data: (A) Problem list; (B) Medication list; (C) Medication allergy list;

(D) Demographics;
(E) Laboratory tests and values/results; and
(F) Vital signs.

(ii) Linked referential clinical decision support.
(A) EHR technology must be able to:
(1) Electronically identify for a user diagnostic and therapeutic reference information; or
(2) Electronically identify for a user diagnostic and therapeutic reference information in accordance with the standard specified at §170.204(b)(1). <InfoButton>
(B) For paragraph (a)(8)(ii)(A) of this section, EHR technology must be able to electronically identify for a user diagnostic or therapeutic reference information based on each one and at least one combination of the following data referenced in paragraphs (a)(8)(i)(A) through (F) of this section

(iii) Clinical decision support configuration.
(A) Enable interventions and reference resources specified in paragraphs (a)(8)(i) and (ii) of this section to be configured by a limited set of identified users (e.g., system administrator) based on a user's role.
(B) EHR technology must enable interventions to be electronically triggered:
(1) Based on the data referenced in paragraphs (a)(8)(i)(A) through (F) of this section;
(2) When a patient's medications, medication allergies, and problems are incorporated from a transition of care/referral summary received pursuant to paragraph (b)(1)(iii) of this section.
(3) Ambulatory setting only. When a patient's laboratory tests and values/results are incorporated pursuant to paragraph (b)(5)(i)(A)(1) of this section. (no scenario created for this bullet point)

(iv) Automatically and electronically interact. Interventions triggered in accordance with paragraphs (a)(8)(i) through (iii) of this section must automatically and electronically occur when a user is interacting with EHR technology.

(v) Source attributes. Enable a user to review the attributes as indicated for all clinical decision support resources:
(A) For evidence-based decision support interventions under paragraph (a)(8)(i) of this section:
(1) Bibliographic citation of the intervention (clinical research/guideline);
(2) Developer of the intervention (translation from clinical research/guideline);
(3) Funding source of the intervention development technical implementation; and
(4) Release and, if applicable, revision date(s) of the intervention or reference source.
(B) For linked referential clinical decision support in paragraph (a)(8)(ii) of this section and drug-drug, drug-allergy interaction checks in paragraph(a)(2) of this section, the developer of the intervention, and where clinically indicated, the bibliographic citation of the intervention (clinical research/guideline).

2.6.2 UCD Process Employed

The EMR MU UX Usability Plan, the GE Usability Work Instruction, and ISO 62366 were utilized in the design and development of the features associated with this criteria. Changes in the Clinical Decision Support (CDS) feature were identified as part of the Meaningful Use 2014

Edition development activities. As such, the Usability Work Instruction for Changes to Legacy Functionality/New functionality Added to Existing Product was applied based on the process described in ISO 62366.

A Failure Modes and Effects Analysis (FMEA) was conducted. Formative and summative usability analyses were carried out to ensure changes do not introduce new use errors or methods of misuse that can cause or contribute to a hazardous situation or negatively affect control measures that mitigate potentially hazardous situations.

The GE team designed and developed the clinical Decision Support (CDS) feature based on the understanding of specific user groups' needs, workflows, and environments. The team solicited and gathered requirements and solicited feedback from end users and subject matter experts from the Clinical Advisory Board, customer workgroups , Product Management, and consultants from various roles. Requirements and feedback from sessions were incorporated into the design for subsequent reviews. Formative usability analysis via pluralistic walkthroughs of prototypes and expert reviews were conducted throughout the design and development process.

2.6.3 Reference

National Institute of Standards and Technology. (2010). *NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records* (NISTIR 7741). Gaithersburg, MD: ://www.nist.gov/manuscript-publication-search.cfm?pub_id=907313.

ISO/IEC 62366:2007, Medical devices – Application of usability engineering to medical devices. Geneva , International Electrotechnical Commission.

2.7 Chapter §170.314(a)(16) Electronic Medication Administration Record – NA

2.8 Chapter §170.314(b)(3) Electronic Prescribing

2.8.1 §170.314(b)(3) Electronic prescribing

Table 8 provides the electronic medication administration record criteria to aid verification that a UCD process was applied to each EHR technology capability.

Table 7. Electronic Prescribing

§170.314(b)(3) Electronic prescribing Enable a user to electronically create prescriptions and prescription-related information for electronic transmission in accordance with: (i) The standard specified in §170.205(b)(2); and (ii) At a minimum, the version of the standard specified in §170.207(d)(2).

2.8.2 UCD Process Employed

The EMR MU UX Usability Plan, the GE Usability Work Instruction, and ISO 62366 were utilized in the design and development of the features associated with this criteria. No changes in the Electronic Prescribing feature were identified as part of the Meaningful Use 2014 Edition development activities. As such, the Usability Work Instruction for Legacy products was applied based on the process described in ISO 62366. A Usability Analysis to identify and control use errors and misuse that might lead to a hazardous situation was conducted. The GE team designed and developed the legacy feature based on the understanding of specific user groups' needs, workflows, and environments. The team gathered requirements and solicited feedback from end users and subject matter experts from the Clinical Advisory Group, customer workgroups, Product Management, and consultants from various roles. Working in conjunction with Kryptiq, the electronic prescribing screen was designed so as to meet requirements for Surescripts certification. Requirements and feedback from sessions were incorporated into the design for subsequent reviews.

2.8.3 Reference

National Institute of Standards and Technology. (2010). *NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records* (NISTIR 7741). Gaithersburg, MD: ://www.nist.gov/manuscript-publication-search.cfm?pub_id=907313.

ISO/IEC 62366:2007, Medical devices – Application of usability engineering to medical devices. Geneva , International Electrotechnical Commission.

2.9 Chapter – Configuration Criteria

Information regarding UCD process applied to Drug-Drug, Drug-Allergy Interaction Checks - Adjustments and Clinical Decision Support – Configuration are presented in this chapter.

Table 8 provides the Drug-Drug, Drug-Allergy Interaction Checks - Adjustments criteria (§170.314 (a)(2)) and as well as the Clinical Decision Support – Configuration criteria (§170.314(a)(8)) to aid verification that a UCD process was applied to each EHR technology capability.

Table 8. Drug-Drug, Drug-Allergy Interaction Checks - Adjustments Criteria and Clinical Decision Support (CDS) – Configuration Criteria.

§170.314 (a)(2) Drug-drug, drug-allergy interaction checks (Configuration) (i) Interventions. Before a medication order is completed and acted upon during computerized provider order entry (CPOE), interventions must automatically and electronically indicate to a user drug-drug and drug-allergy contraindications based on a patient's medication list and medication allergy list. (ii) Adjustments. (A) Enable the severity level of interventions provided for drug-drug interaction checks to be adjusted. (B) Limit the ability to adjust severity levels to an identified set of users or available as a system administrative function.

§170.314(a)(8) Clinical decision support (CDS) - Configuration

(iii) Clinical decision support configuration.
(A) Enable interventions and reference resources specified in paragraphs (a)(8)(i) and (ii) of this section to be configured by a limited set of identified users (e.g., system administrator) based on a user's role.
(B) EHR technology must enable interventions to be electronically triggered:
(1) Based on the data referenced in paragraphs (a)(8)(i)(A) through (F) of this section;
(2) When a patient's medications, medication allergies, and problems are incorporated from a transition of care/referral summary received pursuant to paragraph (b)(1)(iii) of this section.
(3) Ambulatory setting only. When a patient's laboratory tests and values/results are incorporated pursuant to paragraph (b)(5)(i)(A)(1) of this section. (no scenario created for this bullet point)

2.9.1 UCD Process Employed

The EMR MU UX Usability Plan, the GE Usability Work Instruction, and ISO 62366 were utilized in the design and development of the features associated with this criteria. No substantial changes in configuration features were identified as part of the Meaningful Use 2014 Edition development activities. As such, the Usability Work Instruction for Legacy products was applied based on the process described in ISO 62366. A Usability Analysis to identify and control use errors and misuse that might lead to a hazardous situation was conducted. The GE team designed and developed the legacy feature based on the understanding of specific user groups' needs, workflows, and environments. The team gathered requirements and solicited feedback from end users and subject matter experts from the Clinical Advisory Group, customer workgroups, Product Management, and consultants from various roles. Requirements and feedback from sessions were incorporated into the design for subsequent reviews.

2.9.2 Reference

National Institute of Standards and Technology. (2010). *NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records* (NISTIR 7741). Gaithersburg, MD: ://www.nist.gov/manuscript-publication-search.cfm?pub_id=907313.

ISO/IEC 62366:2007, Medical devices – Application of usability engineering to medical devices. Geneva , International Electrotechnical Commission.

GE Centricity EMR Version 9.8

Meaningful Use 2014 Edition Usability Test Report

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EHR Usability Test Report of GE Centricity EMR Version 9.8

Report based on NIST 7742 Customized Common Industry Format Template for Electronic Health Record Usability Testing

GE Centricity EMR Version 9.8

Dates of Usability Testing:	7/23/2013 to 8/19/2013
Date of Report:	8/26/2013
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Contents

1. Executive Summary

A usability test of the GE Centricity EMR Version 9.8 was conducted from 7/23/2013 to 8/19/2013 by User-View, Inc. All sessions (clinical and configuration) took place remotely. The primary purpose of this summative usability test was to provide objective evidence that the Electronic Health Record Under Test (EHRUT) including both clinical (Licensed, credentialed providers and clinical ancillary staff facing) and configuration (configuration specialist facing) user interfaces can be used in a safe, efficient, and effective manner with regard to seven (applicable to Eligible Professionals) of the eight prioritized certification criteria:

§170.314(a)(1) Computerized provider order entry

§170.314(a)(2) Drug-drug, drug-allergy interaction checks

§170.314(a)(6) Medication list

§170.314(a)(7) Medication allergy list

§170.314(a)(8) Clinical decision support

§170.314(a)(16) Inpatient setting only – electronic medication administration record – NA

§170.314(b)(3) Electronic prescribing

§170.314(b)(4) Clinical information reconciliation

Twelve (12) licensed or credentialed providers and four (4) clinical ancillary staff participated in the clinical usability testing. Fifteen (15) configuration specialists participated in the configuration usability testing. All participants were current users of the EHR. Each participant performed simulated but representative tasks specific to their user role.

The studies collected performance data on tasks typically conducted on the system. Tasks were created and mapped to the prioritized Meaningful Use Certification Criteria. The general clinical scenarios were:

1. Review medications and make updates based on the information provided.
2. Review allergies and make updates based on the information provided.
3. Review and act on Drug-Drug and Drug-Allergy interactions alerts that displayed during the test.
4. Order specific labs, diagnostic imaging and medications from an order set based on the information provided.
5. Change labs, imaging and medications that were ordered.
6. Send prescriptions electronically to the pharmacy (electronic prescribing).
7. Review and act on Clinical Decision Support.
8. Reconcile clinical information.

The configuration scenarios were:

1. Change the severity threshold of drug-drug interaction alerts to be displayed.
2. Limit the user role that can change the severity threshold of drug-drug interactions to be displayed.
3. Configure Clinical Decision Support alerts for drug – age contraindications.

During each 1 hour clinical one-on-one usability test session, each participant was greeted by the administrator and asked to review and sign an informed consent/release form (included in Appendix 16.1 Volunteer, Non-Disclosure, and Video Informed Consent); each was instructed that s/he could withdraw at any time. All participants (clinical and configuration specialists) had prior experience with the system. The administrator introduced the test, and instructed participants to complete a series of tasks (given one at a time) using the EHRUT. During the session, the administrator and data logger recorded user performance data on paper and electronically. The administrator did not give the participant assistance in completing the task unless the participant stated that s/he was done with the task, the participant asked for help, or the participant was not making progress to complete the task after 30 seconds.

Sessions were recorded using Morae Recorder for subsequent analysis.

The following types of data were collected for each participant:

- Effectiveness
    - Percentage of tasks successfully completed within the allotted time without assistance (Pass)
    - Percentage of tasks successfully completed with one assist from the moderator (Pass with help)
    - Percentage of task failures (Fail)
    - Types of errors
- Efficiency
    - Task Time
    - Click Path Notes
    - Types of errors
- System Satisfaction
    - Participant's satisfaction rating of the system
    - Participant's verbalizations

All participant data was de-identified. Following the conclusion of the testing, participants were asked to rate their experience with the system based on the System Usability Scale (SUS) which is provided in Appendix 16.4 System Satisfaction.

Various recommended metrics, in accordance with the examples set forth in the *NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records*, were used to evaluate the usability of the system. Performance data for the clinical tasks is summarized in Table 1. Note that the number of participants completing tasks varies; this is due to both session timing and data requirements.

Table 1. Clinical Performance Data.

Clinical Participants	n	Pass	Pass with help	Fail	% Pass + Pass with help
Computerized Physician Order Entry					
Change Metoprolol	13	85%	8%	8%	93%
Order a diuretic	9	100%	0%	0%	100%
Order Services (labs) that are now due.	10	100%	0%	0%	100%
Order Services (images) that are now due.	10	100%	0%	0%	100%
Add instructions to the Lipid Panel	9	67%	33%	0%	100%
Change the mammogram service provider	9	100%	0%	0%	100%
Drug-Drug and Drug-Allergy Interaction Checks					
Review and act upon drug-drug interaction alert	13	31%	15%	54%	46%
Review and act upon drug-allergy interaction alert	13	31%	15%	54%	46%
Medication List					
Access patient's medication list	13	100%	0%	0%	100%
Change Metoprolol	13	85%	8%	8%	92%
Add New Prescription – Paxil	13	92%	8%	0%	100%

Clinical Participants	n	Pass	Pass with help	Fail	% Pass + Pass with help
Discontinue St. John's Wort	13	100%	0%	0%	100%
Review patient's active and inactive medications in meds list	9	78%	0%	22%	78%
Medication Allergies List					
Access the patient's allergies	11	100%	0%	0%	100%
Change existing patient's drug allergies – (Ibuprofen + severe rash)	11	91%	0%	9%	91%
Add New drug allergy information – (Lisinopril (Ace Inhibitor) + cough)	11	100%	0%	0%	100%
Access patient's active and inactive medication allergies.	10	20%	40%	40%	60%
Clinical Decision Support					
CDS Medication List Advisory (ACE –I)	10	90%	0%	10%	90%
CDS Allergy Alert Advisory – Aspirin - Act upon advisory to record Aspirin contraindication	10	Participants were able to successfully complete the mechanics of this CDS subtask. The expectation of the CDS screen flow did not match participant's expectation. See Discussion.			
		60%	0%	40%	60%
CDS Laboratory Tests & Services Due Advisory	11	82%	0%	18%	82%
CDS Problem Advisory (Renal Dysfunction)	11	91%	0%	9%	91%
Order age based tests and services due (CPOE – preventative health – Demographics CDS)	10	100%	0%	0%	100%
CDS Vital Signs: (abnormal result indicator)	12	Participants were able to successfully complete the mechanics of this CDS subtask. The expectation of the CDS screen flow did not match participant's expectation. See Discussion.			

Clinical Participants	n	Pass	Pass with help	Fail	% Pass + Pass with help
		58%	8%	33%	66%*
Combination: CDS HTN Assessment	11	100%	0%	0%	100%
Find normal range information about LDL (second exposure)	11	64%	18%	18%	82%**
Source: Identify Source of CDS guidance – source of vitals	11	100%	0%	0%	100%**
Electronic Prescribing					
Send the medications electronically	12	92%	0%	8%	92%
Clinical Information Reconciliation					
Access and Reconcile Medication Allergies was used as guided familiarization for this new feature	15	0%	100%	0%	100%
Reconciled Problems	15	100%	0%	0%	100%
Reconcile Medications	15	100%	0%	0%	100%
Confirm that your Problems Allergies and Medications are Reconciled	15	100%	0%	0%	100%

* sum impacted by rounding error

** First attempts to identify the Reference Information and Source of CDS content were considered exposure to the feature. Second attempt success rates are reported.

Table 2 provides a summary of the performance data collected from the Configuration Tool tasks.

Table 2. Configuration Performance Data.

Configuration Participants	n	Pass	Pass with help	Fail	% Pass + Pass with help
Drug-Drug and Drug - Allergy Adjustment					
Change the severity level of the drug-drug interaction requiring acknowledgement	15	13%	13%	73%	26%
Change drug-allergy interaction criticality	15	33%	13%	53%	46%
Limit the ability for group of users to adjust drug interaction warnings	15	73%	13%	13%	86%
Clinical Decision Support Configuration					
Limit the ability for group of users to access clinical decision support	15	100%	0%	0%	100%

* sum impacted by rounding error

The SUS is a reliable and valid measure of system satisfaction. Sauro (http://www.measuringusability.com/sus.php accessed 3/14/2013) reports, the average SUS score from 500 studies across various products e.g., websites, cell phones, enterprise systems and across different industries is a 68. A SUS score above a 68 is considered above average and anything below 68 is below average. User-View encourages teams not to focus on the comparison to the cross industry average SUS of 68 reported by Sauro. Instead, we encouraged teams to use the SUS as a measure to compare their own usability improvement in the application as changes are made.

Eight (8) licensed or credentialed providers and three (3) clinical ancillary staff completed the SUS questionnaire at the end of their session. Four (4) providers and one (1) clinical ancillary staff did not complete the SUS due to time. The EHRUT scored an average of 64 (SD=14).

In addition to the performance data, the following qualitative observations were made regarding the EHRUT.

- Major findings and Areas for Improvement
    - Computerized Physician Order Entry:

- No critical issues were identified as part of the CPOE task. Performance of all subtasks was above the 95% success criterion.
- No additional areas for improvement related to effectiveness and efficiency were identified.

o Drug-Drug and Drug-Allergy Interaction Checks:

- No critical issues were identified as part of the Drug-Drug and Drug-Allergy Interaction Checks task. Performance of all subtasks was below the 95% success criterion.
- Additional areas for improvement related to effectiveness include consider rewording application message to clear, plain and precise description of the interaction. No additional areas for improvement related to efficiency were identified.

o Medication List:

- No critical issues were identified as part of the Medication List task. Performance of two subtasks fell below the 95% success criterion: change Metoprolol and change the display of active and inactive medications.
- Both issues are attributed to an artifact of testing. No additional areas for improvement related to effectiveness and efficiency were identified.

o Medication Allergies:

- No critical issues were identified as part of the Medication Allergies usability task. Performance of two subtasks fell below 95% success criterion: change medication allergy reaction and change the display of active/inactive allergies.
- Both findings are attributed to an artifact of the usability test. No additional areas for improvement related to effectiveness and efficiency were identified.

o Clinical Decision Support

- No critical issues were identified as part of the CDS tasks. Performance of the following subtasks fell below the 95% criteria: review and act upon the Medication List CDS Advisory, review and act upon the Medication Allergy CDS Advisory, review and act upon the Laboratory Tests & Services Due CDS, review and act upon the CDS Problem Advisory, review and act upon Vitals CDS, and locate the Diagnostic and Therapeutic Reference.
- Participants were able to successfully complete the mechanics of all CDS subtasks. The majority of the errors were due to the participants' lack

of familiarity with the specific CDS implemented for testing, and so, their expectations did not match the tested CDS intervention.

- Additional areas for improvement related to effectiveness and efficiency are discussed.

- Electronic Prescribing
  - No critical issues were identified as part of the Electronic Prescribing tasks. Performance of all subtasks was above the 95% success criterion.
  - No additional areas for improvement related to effectiveness and efficiency were identified.
- Clinical Information Reconciliation
  - No critical issues were identified as part of the Clinical Information Reconciliation tasks. Performance of all subtasks was above the 95% success criterion.
  - Additional areas for improvement related to effectiveness are discussed.

Configuration specialists completed the SUS questionnaire at the end of their session. Four (4) configuration specialists had incomplete questionnaire responses and were no included in the calculation of this SUS score. Based on eleven (11) configuration specialists, the ERHUT configuration module scored an average of 68 (SD=20).

- Major findings
  - Drug-Drug and Drug-Allergy Interaction Checks: Adjustments
    - Task failures were due to unfamiliarity with this part of the system (infrequent use of this part of the system) and lack of typical workflow supporting documentation that would typically be used during configuration.
    - Participants described a verification process used when making configuration changes that serves to identify use errors. Opportunities for improvement are discussed.
    - Opportunities to improve usability include assuring screens and screen section titles are sufficiently descriptive enough to support recognition and comprehension for infrequent tasks.
  - Clinical Decision Support – Configuration
    - No usage errors were observed during the CDS Configuration scenario.
    - No additional areas for improvement related to effectiveness and efficiency were identified.

2. Introduction

The EHR tested for this study was GE Centricity EMR Version 9.8. This product provides clinical (licensed and credentialed providers and clinical ancillary staff facing) and configuration (configuration specialist facing) user interfaces. Designed to present medical information to healthcare providers and clinical ancillary in ambulatory settings, the EHRUT consists of a clinical and an administration module to support end user workflow.

The primary purpose of this summative usability test is to provide objective evidence that the EHRUT (including both the clinical facing and configuration facing user interfaces) can be used in a safe, efficient, and effective manner with regard to seven (applicable to Eligible Professionals) of the eight (8) prioritized certification criteria. Specifically the aim of this usability test is to validate that use errors identified from formative usability activities have been effectively mitigated via improvements to the user interface design and/or feature functionality. To this end, measures of effectiveness, efficiency and satisfaction, such as pass/fail rates, errors and error types, task time and System Usability Scores (SUS) were captured during the usability testing and are reported here.

3. Method

3.1 Participants

A total of 31 participants took part in the clinical and configuration usability testing. Twelve (12) licensed or credentialed providers and four (4) clinical ancillary staff participated in the clinical usability testing. Participants were recruited at their own sites by administrators working in collaboration with GE. End-user roles were identified and communicated to site administrators who identified and scheduled participants.

Participants in the clinical usability testing were licensed or credentialed providers and clinical ancillary staff. Clinical participants had to be current users of the system. No clinical participant was employed by GE. Recruited participants had a mix of backgrounds and demographic characteristics. Table 3 provides information regarding clinical test participants by user characteristics and identification of the test environment in which each participated. Participant names were replaced with Participant IDs (PID) so that an individual's data cannot be linked to individual identities.

Table 3. Clinical Participant Characteristics.

PID	Participant Role	Site	Specialty
EMR1	Licensed or credentialed provider	Site 1	Pulmonary and Sleep
EMR2	Licensed or credentialed provider	Site 1	General surgeon
EMR3	Licensed or credentialed provider	Site 1	Gastroenterology

PID	Participant Role	Site	Specialty
EMR4	Licensed or credentialed provider	Site 1	Ear, Nose and Throat
EMR5	Licensed or credentialed provider	Site 1	Pulmonary Critical Care
EMR6	Licensed or credentialed provider	Site 1	Gastroenterology
EMR7	Licensed or credentialed provider	Site 2	Orthopedic
EMR8	Clinical Ancillary Staff	Site 2	Physical Therapy
EMR9	Clinical Ancillary Staff	Site 2	Physical Therapy
EMR10	Licensed or credentialed provider	Site 2	Orthopedic
EMR11	Clinical Ancillary Staff	Site 2	Orthopedic
EMR12	Clinical Ancillary Staff	Site 2	Orthopedic
EMR13	Licensed or credentialed provider	Site 2	Orthopedic
EMR14	Licensed or credentialed provider	Remote	Clinical supervisor at Vein Specialty center
EMR15	Licensed or credentialed provider	Remote	Family Medicine
EMR16	Licensed or credentialed provider	Remote	Family Medicine

Fifteen (15) configuration specialists participated in the configuration usability test. Recruited participants had a mix of backgrounds and demographic characteristics. Table 4 provides information regarding configuration test participants by user characteristics and identification of the test environment in which each participated. Configuration participants were GE employees (3) and customer site employees (12). GE configuration specialist employees were not involved with the design or development of the system. Participant names were replaced with Participant IDs (PID) so that an individual's data cannot be linked to individual identities.

Table 4. Configuration Specialists Characteristics.

Participant's ID	GE Employee?	Test Environment	Job Title
EMR-P1	No	Remote	Ambulatory Systems Manager
EMR-P2	No	Remote	Lead Systems Analyst
EMR-P3	No	Remote	Application Analyst
EMR-P4	No	Remote	Program Manager
EMR-P5	No	Remote	Clinical Application Specialist
EMR-P6	No	Remote	Physician Analyst Supervisor
EMR-P7	No	Remote	Medical Billing
EMR-P8	Yes	Remote	Clinical Team
EMR-P9	Yes	Remote	Support Team
EMR-P10	No	Remote	Clinical Applications Technician
EMR-P11	No	Remote	Clinical Applications Technician
EMR-P12	Yes	Remote	Senior Solutions Specialist
EMR-P13	No	Remote	Senior Clinical Analyst
EMR-P14	No	Remote	Quality Manager
EMR-P15	No	Remote	Provider Consultant

Participants were recruited and participated in the study. A training package was distributed to the clinical sites the week before clinical usability testing. Site administers were asked to have potential clinical test participants review the training material the day before coming to the clinical usability test session. A spreadsheet was used to keep track of the participant schedule and included basic information about each participant.

3.2 Study Design

Overall, the objective of this test was to uncover areas where the application performed well – that is, effectively, efficiently, and with satisfaction – and areas where the application failed to meet the needs of the participants. The data from this test may serve as a baseline for future tests with an updated version of the same EHR and/or comparison with other EHRs provided the same tasks are used. In short, this testing serves as both a means to record or benchmark current usability, but also to identify areas where improvements must be made.

During the usability test, participants interacted with the application. Each participant was provided with the same instructions. The system was evaluated for effectiveness, efficiency and satisfaction as defined by measures collected and analyzed for each participant.

The following measures were collected and analyzed for each participant:

- Effectiveness
  - Percentage of tasks successfully completed within the allotted time without assistance (Pass)
  - Percentage of tasks successfully completed with one assist from the moderator (Pass with help)
  - Percentage of task failures (Fail)
  - Types of errors
- Efficiency
  - Task Time
  - Click Path Notes
  - Types of errors
- System Satisfaction
  - Participant's satisfaction rating of the system
  - Participant's verbalizations

Additional information about the various measures can be found in Section 3.9 on Usability Metrics.

3.3 Tasks

A number of tasks were constructed that would be realistic and representative of the kinds of activities a user might do with this EHR, including:

Clinical Tasks

1. Review medications and make updates based on the information provided.*
2. Electronically order lab, diagnostic imaging and medication based on the information provided.*
3. Change medication order.*
4. Review and act on drug-drug and drug-allergy interaction alerts.*
5. Reconcile clinical information. *
6. Review and act on Clinical Decision Support. *
7. Review allergies and make updates based on the information provided.
8. Change lab and image orders.

Configuration Tasks

1. Change the minimum threshold of severity level to display for drug-drug interactions.*
2. Limit the privilege to change drug-drug interaction settings based on user role.*

3. Set a new security permission to access Clinical Decision Support by user role.

Tasks were constructed that would sufficiently evaluate the Meaningful Use 2014 prioritized Certification Criteria. Tasks were selected based on their frequency of use, criticality of function, and those that may be most troublesome for users. Tasks should always be constructed in light of the study objectives. As part of the task construction, tasks were prioritized in accordance with the risk associated with use errors. As part of the task construction we used NISTIR 7804; Form for Expert Review Items 1A through 1H to create and prioritize tasks based on design areas related to known use errors. Tasks with an "*" in the list above were identified to be highest priority related to risks based on this exercise.

Task details are provided in chapter sections for each certification criteria. Chapter sections include Task Mappings to the certification criteria, high level task descriptions, and steps for successful task completion. Highlighting (**green** colored font) is used within the task mapping tables to aid verification that the usability test tasks address the details of the specified criteria.

3.4 Study Procedure

Upon arrival to the session, participants were greeted; their identity was verified and matched with a name on the participant schedule. Participants were then assigned a participant ID.

Each participant reviewed an informed consent and release form (Appendix 16.1 Volunteer, Non-Disclosure, and Video Informed Consent).

To ensure that the clinical test sessions ran smoothly, two human factors specialists, the administrator and the data logger, conducted each test session. All human factors specialists are experienced human factors professionals holding advanced degrees in human factors or a related degree (e.g., Cognitive Psychology); each has more than 10 years of experience, and each is well versed in planning and performing usability testing of EHRs.

The administrator for the clinical test sessions moderated the session which included administering instructions and tasks, as well as recording task time and participant comments on paper. The data logger recorded task success, click paths, number and type of errors, comments, and post-session ratings in an electronic data collection file. Participants were provided an introduction thanking them for participating, clarifying the purpose of the study, outlining the session and its flow, and what to expect when performing tasks.

Participants were instructed to perform the tasks (see specific instructions below):

1. As they would as part of their everyday activities.
2. Without assistance; asking for help as needed.
3. Without interacting with the moderator until the participant felt he/she was "done" with the task.

For each task, the participants were given access to an outline of the task which was meant to serve as a memory aid for the details of the task (e.g., prescription details). See Section 16.3 Memory Aid. Participants were asked to indicate when they were done so it was clear when

they completed the task, when they got to a point where they couldn't go any further without receiving help, or when they gave up and were not going to try anything else. If participants navigated away from the correct path to complete the task and were still attempting to perform the task after 30 seconds, the moderator would intervene and tell them the next single step in the task to get them back on the correct click path. Thirty seconds was selected based on previous test activities and the constraints of the session length. Tasks where the moderator assisted with one step and the participant successfully completed the task were considered passing with help. More detail on pass/fail task performance and criteria can be referenced in Section 3.10 Data Scoring. Task timing began once the administrator and participant acknowledged the participant knew what was being asked of him/her and the moderator gave the instruction, "you can start when you are ready." Task timing ended when the participant stated, "I'm done." After each task, any errors were discussed and clarified with the participants before moving forward.

Participants were instructed to talk aloud as they were completing the task. They were to say what they were doing and where they were clicking. For example, "I am reviewing the allergies so I am clicking the allergy icon." Participants were told that although they were talking out loud, the administrator would not interact with the participant until the participant said "Done". The talk aloud methodology used was not meant to be the type of talk aloud protocol where the moderator interacts with probing questions during the task. Instead, because of the complexity of the system and multiple click paths available to complete a task, the talk aloud was intended to aid data collection.

Following the session, the moderator gave the participant the post-test questionnaire (e.g., See Section 16.4 System Satisfaction) and thanked each individual for their participation.

Participants' demographic information, task success rate, time on task, errors, deviations, verbal responses, and post-test questionnaire were recorded into a spreadsheet.

3.5 Test Location

Two healthcare clinical systems were used as test locations for face-to-face usability test sessions. The clinics were both located in the northwest. At each location the participant, administrator, and data logger sat at a conference room table. The participant sat in front of a laptop computer equipped with Morae Recorder (TechSmith Corporation, Okemos, MI) and performed usability test tasks. The moderator worked from paper materials. The data logger used a second laptop computer to observe screens and screen interactions via Webex and a third laptop computer to log data.

During remote testing sessions, the moderator was at her personal office, the data-logger documented the data from her personal office, and each participant was at his/her location. WebEx and a teleconference line were used for each test session.

3.6 Test Environment

The EHRUT is used in an ambulatory care facility. All participants completed usability tasks using a Dell laptop with Microsoft Windows operating system. The participants had access to a

Logitech mouse and the laptop's keyboard and trackpad. All participants interacted using the keyboard and the mouse. The Dell laptop has a 14 inch display with 1366 x 768 resolution.

The application was set up by GE. The application itself was running on a Microsoft Windows platform using a certification test system and certification database on a WAN connection. The usability test system consisted of a generic configuration aimed to provide functionality across the usability test sites. The GE EHRUT is a highly configurable system. This generic configuration is not an implementation used at customer sites.

3.7 Test Forms and Tools

During the usability test, various documents and instruments were used, including:

1. Informed Consent Form
2. Moderator Guide
3. Task Outline Memory Aid
4. System Usability Scale (SUS) Questionnaire

Examples of these documents can be found in the Appendices.

Informed Consent Forms were used to inform participants about the study objectives and obtain permission to collect data; as well as to audio and video record the sessions.

The Moderator Guides were devised to conduct the sessions in an organized, efficient, and repeatable manner.

Task Outlines with details as needed served as a memory aid for participants regarding the details of the clinical scenarios.

The SUS questionnaire was used to collect system satisfaction data.

Participant interactions with the system were captured and recorded digitally with screen capture software running on the test machine (WebEx and Morae Recorder).

3.8 Participant Instructions

The administrator read the following study instructions aloud to the each participant (also see the full moderator guides in the appendices).

Hello. My name is _____ and this is _____. Thank you again for coming to evaluate this application today. We will be here with you throughout the session today. Our understanding is that you can stay for 1 hour, until _____.

The first/next thing I would like to do is to show you this consent form to participate. <<moderator provides consent and participant reviews and signs>>

I am going to read this introduction to you because we want to be sure that we don't miss anything.

We are from an independent consulting company. We are not employed at GE. We spend our days doing just this. Companies hire us to conduct activities with people like you that use their products, services, and websites. This is a great chance for you. Not all organizations take the time to get feedback from the folks who actually use their products. So please take advantage of this opportunity to give the GE team critical feedback about the application we are going to look at today.

Remember we are not here to test you. We are testing the application. We are trying to learn what is easy and what is hard to do with the application.

Throughout the session I will ask you to try very specific activities. Some activities might seem simple to you. Other activities might seem difficult. And there will be some activities that you will not able to complete. I am telling you this because I want you to remember that we are not testing you. We are testing the application.

When you are doing these activities, I am not going to interact or talk to you while you are completing the activity. I do want you to talk aloud about what you are doing and where you are clicking. You will say things like I am doing <say what you are doing> and I am clicking <say the place you clicked>. Both _____ and I will be taking notes about what you are doing.

Because I am not going to be talking with you while you do the activities, I want you to make it clear to me when you are done with an activity by saying "I'm done." There are a number of reasons you might be done.

(1) You might say "I'm done" because you completed the activity. You know you completed the activity.

(2) You might say "I'm done" because you have tried, you know you have not completed the activity, but you are not going to try anything else.

(3) You might say "I'm done" because you feel like if you got a hint or asked a question you could finish the activity.

Do you have any questions before we begin?

Details regarding each task will be discussed in the specific Chapter sections. All tasks can be referenced within the Clinical Moderator Guides found in the Appendices.

3.9 Usability Metrics

According to the National Institute of Standards and Technology (NIST) Guide to the Processes Approach for Improving the Usability of Electronic Health Records, EHRs should support a process that provides a high level of usability for all users. The goal is for users to interact with the system safely, effectively, efficiently, and with an acceptable level of satisfaction. To this end, metrics for safety, effectiveness, efficiency and user satisfaction were captured during the usability testing.

The goals of the test were to assess:

- Effectiveness by measuring participant success rates (pass/pass with help, fail) and usage errors. Criteria include:
  - Identification and explanation of the root cause of any potential patient safety risks resulting from usage errors in usability task performance.
  - Identification of potential mitigations for any newly identified usage errors in usability task performance.
- Efficiency by measuring participant task time and task click path notes including identification for potential solutions for identified inefficiencies observed in usability task performance.
- System satisfaction by administering the System Usability Scale (SUS).

3.10 Data Scoring

Table 5 details how tasks were scored and errors evaluated.

Table 5. Data Measure Details.

Measures	Rationale and Scoring
Effectiveness: Task Success	A task was counted as a "Pass" if the participant was able to achieve the correct outcome, without assistance. A task was counted as a "Pass with help" if the participant was able to achieve the correct outcome with one assist from the moderator. "Pass" and "Pass with help" were combined to be Task Success.
Effectiveness: Task Failures	A task was counted as "Fail" if the participant abandoned the task, did not complete the task goal, or needed more than one assist from the moderator. Failed tasks were discussed with participants at the end of each task. An enumeration of usage errors and usage error types was collected to help better understand the source of the usage errors and possible mitigations.
Efficiency: Task Deviation	The participant's path (i.e., steps) through the application was recorded. Deviations occur if the participant, for example, went to a wrong screen, clicked on an incorrect menu item, followed an incorrect link, or interacted incorrectly with an on-screen control. This path was compared to the optimal path. Task deviations were recorded and reported. Optimal paths (i.e., procedural steps) were recorded when constructing tasks.

Efficiency: Task Time	Task times were collected. However, caution is urged if the reader is comparing task times across tasks, features, and/or products. Because the industry has not standardized usability test tasks and protocols for measuring task times, the usability test team feels others might misunderstand and/or misuse reported task times. Industry usability specialists should educate stakeholders about task time (e.g., the many variables that make up the time i.e., multiple tasks in a scenario, clinical "thinking" time, software "thinking" time, etc. and ways to measure task time and identification of tasks that should be fast compared to tasks where slower times represent safe performance). In addition, industry usability specialists should develop a standard method for collecting and reporting task time so that stakeholders can make meaningful comparisons and decisions. In this study, task time was taken with the stop watch on an iPhone. Min:sec was recorded with paper/pen. Task time started when the moderator instructed the participant he/she could begin the task whenever he/she was ready. Task time ended when the participant said "Done" or the participant completed a task and did not say "Done" but exhibited a behavior indicating "Done" and the moderator confirmed by asking, "Are you done?" Tasks in which a subtask failure occurred were excluded from task time calculations. In addition data loss occurred due to manual task time data collection errors.
Satisfaction: Task Rating	To measure participants' satisfaction with the system, the testing team administered the System Usability Scale (SUS) post-test questionnaire. The SUS is a reliable and valid measure of system satisfaction. In order to access system level satisfaction as opposed to feature level satisfaction and as in common practice with the use of the SUS, we administered the questionnaire at the end of the session. See Section 16.4 System Satisfaction.

4. Clinical Test Results

Each Clinical Results chapter of the report presents the results associated with usability test activities conducted with physician and nurse participants. The primary purpose of this summative usability test is to provide objective evidence that the EHRUT user interface can be used in a safe, efficient, and effective manner with regard to seven (applicable to Eligible Professional) of the eight prioritized certification criteria. As such this section of the report presents a separate chapter for each EHR technology capability submitted for testing related to clinical activities.

5. Chapter §170.314(a)(1) Computerized Provider Order Entry Results

5.1 Task Mapping

Table 6 maps the Computerized Provider Order Entry (CPOE) criteria to usability test tasks to aid verification that the report contains all required test scenarios for this EHR capability submitted for testing. **Green** colored font is used within the certification criteria and within the steps for successful task completion to aid verification that the usability test tasks address the details of the specified criteria.

Table 6. Computerized Provider Order Entry Criteria Mapped to Usability Test Tasks

§170.314(a)(1) Computerized provider order entry Enable a user to electronically **record**, **change**, and **access** the following order types **(i) Medications;** (ii) **Laboratory**; and **(iii) Radiology/imaging.**
Tasks: **Change medication** based on the information provided. **Order medication** based on the information provided. Electronically **record** your plan for of preventive care. **Update** the clinical lists and **place orders (Laboratory and Radiology / Imaging)** as needed. **Change the lab order** based on the information provided. **Change the imaging order** based on the information provided. Combined with: § 170.314(a)(6) Medication List §170.314(a)(8) Clinical decision support (CDS)
To successfully complete this task, participants were required to complete each of the following subtasks. Only activities related to §170.314(a)(1) Computerized provider order entry will be discussed in this chapter. Subtask 2.2: Change Metoprolol Subtask 5.3: Order a diuretic. Subtask 7.1: Assess Preventative Care CDS* Subtask 7.2: Order Services (labs and imaging) that are now due Subtask 7.3: Add instructions to the Lipid Panel order Subtask 7.4: Change the mammogram to Westfall Imaging

* See associated chapters for results and discussion § 170.314(a)(6) Medication List §170.314(a)(8) Clinical decision support (CDS)

5.2 Task Participants and Instruction

Based on user characteristics, typical workflow, and tasks performed as part of their daily work, providers and clinical ancillary staff attempted this task. Physician and nurse data were combined based on the fact that neither the task nor the user characteristics differ based on these user roles.

Participants were given the following instruction:

Change Metoprolol from 50 mg to 100mg
Use the Hypertension Q&E form. Order medications as needed to treat the patient's hypertension.
Use the CPOE form to record your assessment preventive care. Update the clinical lists and place orders as needed.
After participants reviewed and ordered the services that were due, the following instruction was given:
Add instructions to the Lipid Panel. Add "fast for 12 hours before the test (no food only water)"
Change the mammogram to Westfall Imaging.

5.3 Data Analysis and Reporting

The Computerized Provider Order Entry (CPOE) criteria were accessed within the context of the clinical scenario described in the instructions above. The subtasks of the scenario are listed below. Only activities (**bolded**) associated with the §170.314(a)(1) Computerized Provider Order Entry will be discussed in this chapter. See associated chapters for results and discussion that were combined with this test scenario. Each of the following subtasks was used to assess task performance:

- Subtask 2.2: **Change Metoprolol**
- Subtask 5.3: **Order a diuretic**.
- Subtask 7.2: **Order** Services (**labs and imaging**) that are now due
- Subtask 7.3: Add instructions to the Lipid Panel order (**change lab**)
- Subtask 7.4: **Change the mammogram** to Westfall Imaging

*See associated chapters for results and discussion
§ 170.314(a)(6) Medication List
§170.314(a)(8) Clinical decision support (CDS)

The results should be seen in light of the objectives and goals outlined in Section 3.2 Study Design. The data should yield actionable results that, if corrected, yield material, positive impact on user performance. Table 7 provides the usability test results for each subtask in the Computerized Provider Order Entry task.

Table 7. Usability Test Results for Each Subtask in the Computerized Provider Order Entry Task.

Measure / Subtask	N that Attempted Task	Task Success				Task Time (sec)	
	#	% Pass	% Pass with Help	% Fail	% Pass + Pass with Help	Mean (SD) n Contributing to Mean	Click Path Notes: Areas Impacting Efficiency
Change Metoprolol	13	85%	8%	8%	93%	Times for these subtasks are incorporated with in associated tasks	Additional opportunities to improve efficiency were not observed.
Order a diuretic	9	100%	0%	0%	100%		
Order Services (labs) that are now due.	10	100%	0%	0%	100%		
Order Services (images) that are now due.	10	100%	0%	0%	100%		
Add instructions to the Lipid Panel	9	67%	33%	0%	100%		
Change the mammogram service provider	9	100%	0%	0%	100%		

As indicated in the table:

- 93% (13 of 13) of participants successfully (Pass + Pass with help) changed Metoprolol.
- 100% (9 of 9) of participants successfully (Pass + Pass with help) ordered a diuretic.
- 100% (10 of 10) of participants successfully (Pass + Pass with help) ordered services that were due (lab and imaging).
- 100% (9 of 9) of participants successfully (Pass + Pass with help) added instructions to the Lipid Panel.
- 100% (9 of 9) of participants successfully (Pass + Pass with help) changed service provider.

5.4 Discussion of the Findings

The following sections discuss the results organized around a risk analysis of use, test performance and error rates. The risk analysis of use includes identification of use errors and

user interface design issues as well as classification of severity based on the consequence of the error. Use errors and user interface design issues that resulted in subtask failures, that are known industry risk issues, and errors and issues related to aspects of the user interface that are configured per customer site are considered more severe compared to noncritical system usability issues related to efficiency. As such the discussion of more serious errors and issues is provided in the Risk Analysis section and the associated mitigation strategy is provided in the Areas for Improvement section.

Based on our definition of effectiveness metrics, performance, use errors and issues stemming for task failures are also discussed in the Effectiveness section as effectiveness was measured with task success and failure. Associated recommendations are provided in the Areas for Improvement section.

Noncritical system usability issues related to efficiency are discussed in the Efficiency section. Associated recommendations are provided in the Areas for Improvement section.

Satisfaction was assessed at the system level. Section 15 System Satisfaction Results for the results of the System Usability Scale (SUS).

The Major Findings section provides a brief summary of the findings related to identified use errors, effectiveness, and efficiency.

5.4.1 Risk Analysis

No critical issues were identified as part of the CPOE task.

5.4.2 Effectiveness

Performance of all subtasks was above the 95% success criterion.

5.4.3 Efficiency

No additional opportunities to improve efficiency were observed.

5.4.4 Satisfaction

Satisfaction was assessed at the system level. Section 15 System Satisfaction Results for the results of the System Usability Scale (SUS).

5.4.5 Major Findings

No critical issues were identified as part of the CPOE task. Performance of all subtasks was above the 95% success criterion.

5.4.6 Areas for Improvement

No additional opportunities to improve effectiveness and efficiency were observed.

6. Chapter §170.314(a)(2) Drug-Drug, Drug-Allergy Interaction Checks – Interventions Results

6.1 Task Mapping

Table 8 maps the Drug-Drug, Drug-Allergy Interaction Checks - Interventions criteria to usability test tasks to aid verification that the report contains all required test scenarios for this EHR capability submitted for testing. **Green** colored font is used within the certification criteria and within the steps for successful task completion to aid verification that the usability test tasks address the details of the specified criteria.

Table 8. Drug-Drug, Drug-Allergy Interaction Checks - Interventions Criteria Mapped to Usability Test Tasks.

§170.314 (a)(2) Drug-drug, drug-allergy interaction checks (i) **Interventions**. Before a medication order is completed and acted upon during computerized provider order entry (CPOE), interventions must automatically and electronically indicate to a user drug-drug and drug-allergy contraindications based on a patient's medication list and medication allergy list. (ii) Adjustments. (A) Enable the severity level of interventions provided for drug-drug interaction checks to be adjusted. (B) Limit the ability to adjust severity levels to an identified set of users or available as a system administrative function.
The assessment of the drug-drug and drug-allergy interaction criteria was combined with § 170.314(a)(6) Medication List §170.314(a)(7) Medication Allergy List To successfully complete this task, participants were required to complete each of the following subtasks. Only activities related to § 170.314 (a)(2) drug-drug, drug-allergy interaction checks will be discussed in this chapter. Subtask 2.1: Access patient's medications Subtask 2.2: Discontinue Lisinopril* Subtask 2.3: Change Metoprolol dose (ePrescribe)* Subtask 2.4: Add New Prescription – Paxil (ePrescribe)* **Subtask 2.5: Review and act upon drug-drug conflicts** Subtask 2.6: Discontinue St. John's Wort* Subtask 2.7: Send the medications electronically to the pharmacy* Subtask 2.8: Access patient's active and inactive medications in meds list* To successfully complete this task, participants were required to complete each of the following subtasks. Only

activities related to § 170.314 (a)(2) drug-drug, drug-allergy interaction checks will be discussed in this chapter.
Subtask 1.1: Access patient's allergies*
Subtask 1.2: Change existing patient's drug allergies – Ibuprofen*
Subtask 1.3: Add New drug allergy information – Ace Inhibitor (Lisinopril)*
Subtask 1.4: **Review and act upon drug-allergy conflict**
Subtask 1.5: Review active and inactive medication allergies*

* See the associated chapter for results and discussion
§ 170.314(a)(6) Medication List
§170.314(a)(7) Medication Allergy List
§170.314(b)(3) Electronic Prescribing

6.2 Task Participants and Instruction

Based on user characteristics, typical workflow, and tasks performed as part of their daily work, providers and clinical ancillary staff attempted this task. The data were combined based on the fact that neither the task nor the user characteristics differ based on these user roles.

Participants were not given instructions related to Drug-Drug or Drug-Allergy alerts.

6.3 Data Analysis and Reporting

The results of the usability test were calculated according to the methods specified in the Usability Metrics section above. Only activities associated with the drug-drug and drug-allergy criterion are reported in this chapter. See associated chapters for results and discussion that were combined with this test scenario.

The results should be seen in light of the objectives and goals outlined in Section 3.2 Study Design. The data should yield actionable results that, if corrected, yield material, positive impact on user performance. Task performance did not differ by user characteristics. Therefore, the data was not separated by user role. Table 9 provides usability test results for each subtask associated Drug-Drug and Drug-Allergy interaction checks.

Table 9. Usability Test Results for Subtasks associated with Drug-Drug and Drug-Allergy Interaction Checks.

Measure / Subtask	N that Attempted Task	Task Success				Task Time (sec)	
	#	% Pass	% Pass with Help	% Fail	% Pass + Pass with Help	Mean (SD) n Contributing to Mean	Click Path Notes: Areas Impacting Efficiency
Review and act upon drug-drug interaction alert	13	31%	15%	54%	46%	Task Times are included in Medication List task's performance measures and Medication Allergies task's performance measures.	Additional opportunities to improve efficiency were not observed.
Review and act upon drug-allergy interaction alert	13	31%	15%	54%	46%		

As indicated in the table:

- 46% (6 of 13) of participants successfully (Pass + Pass with Help) reviewed and acted upon the drug-drug interaction alert.
- 46% (6 of 13) of participants successfully (Pass + Pass with Help) reviewed and acted upon the drug-allergy interaction alert.

6.4 Discussion of the Findings

The following sections discuss the results organized around a risk analysis of use, test performance and error rates. The risk analysis of use includes identification of use errors and user interface design issues as well as classification of severity based on the consequence of the error. Use errors and user interface design issues that resulted in subtask failures, that are known industry risk issues, and errors and issues related to aspects of the user interface that are configured per customer site are considered more severe compared to noncritical system usability issues related to efficiency. As such the discussion of more serious errors and issues is provided in the Risk Analysis section and the associated mitigation strategy is provided in the Areas for Improvement section.

Based on our definition of effectiveness metrics, performance, use errors and issues stemming for task failures are also discussed in the Effectiveness section as effectiveness was measured

with task success and failure. Associated recommendations are provided in the Areas for Improvement section.

Noncritical system usability issues related to efficiency are discussed in the Efficiency section. Associated recommendations are provided in the Areas for Improvement section.

Satisfaction was assessed at the system level. Section 15 System Satisfaction Results for the results of the System Usability Scale (SUS).

The Major Findings section provides a brief summary of the findings related to identified use errors, effectiveness, and efficiency.

6.4.1 Risk Analysis

Most participants did not review interactions until prompted by alert when signing off the note or when prompted by moderator. In the workflow where the moderator prompted the user to review the interactions, these participants had put the note on hold and a follow up user would see the alert when signing off the note.

Some participants did not immediately understand the summary message indicating a Drug-Allergy reaction. This resulted in participants taking additional time to think about the meaning of the summary message and resulted in participants clicking to see the detailed information associated with the alert.

6.4.2 Effectiveness

Performance of all subtasks fell below the 95% success criterion. Participants did not review interaction until prompted and some participants did not understand the summary message indicating a Drug-Allergy reaction.

6.4.3 Efficiency

No additional areas for improvement related to efficiency were identified.

6.4.4 Satisfaction

Satisfaction was assessed at the system level. Section 15 System Satisfaction Results for the results of the System Usability Scale (SUS).

6.4.5 Major Findings

Performance of all subtasks was below the 95% success criterion. Areas for improvement related to effectiveness are discussed below. No additional opportunities for improvement to efficiency were identified.

6.4.6 Areas for Improvement

Additional areas for improvement related to effectiveness include consider rewording application message to clear, plain and precise description of the interaction.

7. Chapter §170.314(a)(6) Medication List Results

7.1 Task Mapping

Table 10 maps the Medication List criteria to usability test tasks to aid verification that the report contains all required test scenarios for this EHR capability submitted for testing. **Green** colored font is used within the certification criteria and within the steps for successful task completion to aid verification that the usability test tasks address the details of the specified criteria.

Table 10. Medication List Criteria Mapped to Usability Test Tasks.

§ 170.314(a)(6) Medication List Enable a user to electronically **record**, **change**, and **access** a patient's **active** medication list as well as medication **history**: (i) Ambulatory setting. Over **multiple encounters**; or (ii) Inpatient setting. For the duration of entire hospitalization
Task: Review medications and make updates based on the information provided.
To successfully complete the task, participants were required to complete each of the following Subtasks. Only activities related to §170.314(a)(6) Medication List will be discussed in this chapter. Subtask 2.1: **Access** patient's medication list Subtask 2.2: **Change** Metoprolol Subtask 2.3: **Add** New Prescription – Paxil Subtask 2.4: Review and act upon drug- drug conflict* Subtask 2.5: **Discontinue** St. John's Wort Subtask 2.6: Send the medications electronically to the pharmacy* Subtask 2.7: **Review** active and inactive medications * See the associated chapter for results and discussion §170.314(b)(3) Electronic Prescribing §170.314(a)(2) Drug-Drug, Drug-Allergy Interaction Checks – Interventions Results

7.2 Task Participants and Instruction

Based on user characteristics, typical workflow, and tasks performed as part of their daily work, providers and clinical ancillary staff attempted this task. The data were combined based on the fact that neither the task nor the user characteristics differ based on these user roles.

Participants were given the following instruction:

Now I am going to have you review and update the medications:
Change Metoprolol <dose from 50mg tablet to the 100mg, tablet. Qty: 90, Refills x2>

Add Paxil <20MG tabs, Qty: 90, Refills x1>
Discontinue St John's Wort
Electronically send the medications to the patient's pharmacy.
Review the patient's existing medications and make updates based on the information provided.

After the participant completed the steps above, s/he was instructed:
Confirm you are viewing patient's active and inactive medications in medication list.

7.3 Data Analysis and Reporting

The results of the usability test were calculated according to the methods specified in the Usability Metrics section above. Only activities related to § 170.314(a)(6) Medication List will be discussed in this chapter. Each of the following subtasks was used to assess task performance.

- Subtask 2.1: Access patient's medication list
- Subtask 2.2: Change Metoprolol
- Subtask 2.3: Add New Prescription – Paxil
- Subtask 2.5: Discontinue St. John's Wort

The results should be seen in light of the objectives and goals outlined in Section 3.2 Study Design. The data should yield actionable results that, if corrected, yield material, positive impact on user performance. Table 11 provides usability test results for each subtask in the Medication List task.

Table 11. Usability Test Results for Each Subtask in the Medication List Task.

Measure / Subtask	N that Attempted Task	Task Success				Task Time (sec)	
Subtask	#	% Pass	% Pass with Help	% Fail	% Pass + Pass with Help	Mean (SD) n Contributing to Mean	Click Path Notes: Areas Impacting Efficiency
Access patient's medication list	13	100%	0%	0%	100%	358 (156) 8	Additional opportunities to improve efficiency were not observed.
Change Metoprolol	13	85%	8%	8%	92%*		
Add New Prescription – Paxil	13	92%	8%	0%	100%		
Discontinue St. John's Wort	13	100%	0%	0%	100%		
Review patient's active and inactive medications in meds list	9	78%	0%	22%	78%		

* sum impacted by rounding error

As indicated in the table:

- 100% (13 of 13) of participants successfully accessed the patient's medication list (Pass + Pass with help).
- 92% (10 of 13) participants successfully (Pass + Pass with help) changed the dose for Metoprolol from 50 mg tablet to 100 mg tablet
- 100% (12 of 13) participants successfully (Pass + Pass with help) added 10 mg tablet Paxil to the patient's medications
- 100% (13 of 13) participants successfully (Pass + Pass with help) discontinued St John's Wort from the patient's medications
- 78% (9 of 9) participants successfully (Pass + Pass with help) confirmed they were viewing the patient's active and inactive medications.

7.4 Discussion of the Findings

The following sections discuss the results organized around a risk analysis of use, test performance and error rates. The risk analysis of use includes identification of use errors and user interface design issues as well as classification of severity based on the consequence of the error. Use errors and user interface design issues that resulted in subtask failures, that are known industry risk issues, and errors and issues related to aspects of the user interface that are configured per customer site are considered more severe compared to noncritical system usability issues related to efficiency. As such the discussion of more serious errors and issues is provided in the Risk Analysis section and the associated mitigation strategy is provided in the Areas for Improvement section.

Based on our definition of effectiveness metrics, performance, use errors and issues stemming for task failures are also discussed in the Effectiveness section as effectiveness was measured with task success and failure. Associated recommendations are provided in the Areas for Improvement section.

Noncritical system usability issues related to efficiency are discussed in the Efficiency section. Associated recommendations are provided in the Areas for Improvement section.

Satisfaction was assessed at the system level. Section 15 System Satisfaction Results for the results of the System Usability Scale (SUS).

The Major Findings section provides a brief summary of the findings related to identified use errors, effectiveness, and efficiency.

7.4.1 Risk Analysis

No critical use errors were identified as part of this usability task. One participant required multiple helps to complete the subtask; thus, marked as a failed subtask. This failure is attributed to an artifact of testing. The participant stated s/he does not order medications often.

Failures when reviewing active and inactive medications by changing the items displayed in the medication list are attributed to the usability test system configuration and are considered an artifact of the usability test environment. Many participants were not familiar with and stated they do not change how items (active, inactive) are displayed in the medication orders list.

7.4.2 Effectiveness

Performance of two subtasks fell below the 95% success criterion: change Metoprolol and change the display of active and inactive medications. Both issues are attributed to an artifact of testing. No additional areas for improvement related to effectiveness were identified.

7.4.3 Efficiency

No additional areas for improvement related to efficiency were identified.

7.4.4 Satisfaction

Satisfaction was assessed at the system level. Section 15 System Satisfaction Results for the results of the System Usability Scale (SUS).

7.4.5 Major Findings

Performance of two subtasks fell below 95% success criterion. Both are attributed to an artifact of testing. Additional areas for improvement related to effectiveness and efficiency were not identified.

7.4.6 Areas for Improvement

No additional areas for improvement related to effectiveness and efficiency were identified.

8. Chapter §170 314(a)(7) Medication Allergy List Results

8.1 Task Mapping

Table 12 maps the Medication Allergy List criteria to usability test tasks to aid verification that the report contains all required test scenarios for this EHR capability submitted for testing. **Green** colored font is used within the certification criteria and within the steps for successful task completion to aid verification that the usability test tasks address the details of the specified criteria.

Table 12. Medication Allergy List Criteria Mapped to Usability Test Tasks.

§170.314(a)(7) Medication Allergy List Enable a user to electronically **record**, **change**, and **access** a patient's active medication allergy list as well as medication allergy history: (i) Ambulatory setting. **Over multiple encounters**; or (ii) Inpatient setting. For the duration of an entire hospitalization.
Task: Review allergies and make updates based on the information provided.
Only activities (bolded) associated with criteria will be discussed in this chapter. To successfully complete the task, participants were required to: Subtask 1.1: **Access** patient's allergies Subtask 1.2: **Change** existing patient's drug allergies – (Ibuprofen + severe rash) Subtask 1.3: **Add** New drug allergy information – (Ace Inhibitor (Lisinopril) + cough) Subtask 1.4: Review and act upon drug-allergy conflict Subtask 1.5: **Review active and inactive** medication allergies

8.2 Task Participants and Instruction

Based on user characteristics, typical workflow, and tasks performed as part of their daily work, physicians and nurses attempted this task. Physician and nurse data were combined based on the fact that neither the task nor the user characteristics differ based on these user roles.

Participants were read the following instruction:

The patient has come in for a blood pressure follow-up. The patient reports:

- *his blood pressure is not entirely under control, and*
- *he has a persistent cough which started around the same time he started Lisinopril*
- *In addition, the patient tells you that his/her reaction to Ibuprofen has gotten worse since he/she was here last. He used to have a mild rash but now it is a severe rash.*

Review the patient's existing allergies and make updates based on the information provided.
After the participant completed the steps in the scenario above, he/she was instructed:
Confirm that you are viewing active and inactive

8.3 Data Analysis and Reporting

The results of the usability test were calculated according to the methods specified in the Usability Metrics section above. Each of the following subtasks was used to assess task performance:

- Subtask 1.1: **Access** patient's allergies
- Subtask 1.2: **Change** existing patient's drug allergies – Ibuprofen
- Subtask 1.3: **Add New** drug allergy information – Ace Inhibitor (Lisinopril)
- Subtask 1.5: **Review active and inactive** medication allergies

The results should be seen in light of the objectives and goals outlined in Section 3.2 Study Design. The data should yield actionable results that, if corrected, yield material, positive impact on user performance. Task performance did not differ by user characteristics . Therefore, the data was not separated by user role. Table 13 provides the usability test results for each subtask in the Medication Allergy List task.

Table 13. Usability Test results for Each Subtask in the Medication Allergy Task.

Measure / Subtask	N that Attempted Task	Task Success				Task Time (sec)	
	#	% Pass	% Pass with Help	% Fail	% Pass + Pass with Help	Mean (SD) n Contributing to Mean	Click Path Notes: Areas Impacting Efficiency
Access the patient's allergies	11	100%	0%	0%	100%	201 (76) 8	Additional opportunities for improvement related to the efficiency were not identified.
Change existing patient's drug allergies – (Ibuprofen + severe rash)	11	91%	0%	9%	91%		
Add New drug allergy information – (Lisinopril (Ace Inhibitor) + cough)	11	100%	0%	0%	100%		
Access patient's active and inactive medication allergies.	10	20%	40%	40%	60%		

As indicated in the table:

- 100% (11 of 11) of the participants successfully accessed the patient's allergies (Pass + Pass with help).
- 91% (10 of 11) of participants successfully (Pass + Pass with help) changed the criticality of reaction from mild to severe.
- 100% (11 of 11) of participants successfully (Pass + Pass with help) added a new drug allergy to Ace Inhibitors (Lisinopril) with severe reaction criticality and symptom of cough.
- 60% (6 of 10) of participants successfully (Pass + Pass with help) confirmed they were viewing the patient's active and inactive medication allergies.

8.4 Discussion of the Findings

The following sections discuss the results organized around a risk analysis of use, test performance and error rates. The risk analysis of use includes identification of use errors and user interface design issues as well as classification of severity based on the consequence of the error. Use errors and user interface design issues that resulted in subtask failures, that are known industry risk issues, and errors and issues related to aspects of the user interface that are configured per customer site are considered more severe compared to noncritical system usability issues related to efficiency. As such the discussion of more serious errors and issues is provided in the Risk Analysis section and the associated mitigation strategy is provided in the Areas for Improvement section.

Based on our definition of effectiveness metrics, performance, use errors and issues stemming from task failures are also discussed in the Effectiveness section as effectiveness was measured with task success and failure. Associated recommendations are provided in the Areas for Improvement section.

Noncritical system usability issues related to efficiency are discussed in the Efficiency section. Associated recommendations are provided in the Areas for Improvement section.

Satisfaction was assessed at the system level. Section 15 System Satisfaction Results for the results of the System Usability Scale (SUS).

The Major Findings section provides a brief summary of the findings related to identified use errors, effectiveness, and efficiency.

8.4.1 Risk Analysis

No critical use errors were identified as part of this usability task. One participant required multiple helps to complete the subtask; thus, marked as a failed subtask. This failure is attributed to an artifact of testing. The participant stated s/he does not often enter medication allergies.

Failures when reviewing active and inactive medications by changing the items displayed in the medication allergy list are attributed to an artifact of the usability test. Many participants were not familiar with and stated they do not change how items (active, inactive) are displayed in the medication allergy list.

8.4.2 Effectiveness

Performance of two subtasks fell below 95% success criterion: change medication allergy reaction and change the display of active/inactive allergies. Both findings are attributed to an artifact of the usability test.

8.4.3 Efficiency

No additional opportunities for improvement related to the efficiency were identified.

8.4.4 Satisfaction

Satisfaction was assessed at the system level. Section 15 System Satisfaction Results for the results of the System Usability Scale (SUS).

8.4.5 Major Findings

No critical issues were identified as part of the Medication Allergies usability task. Performance of two subtasks fell below 95% success criterion: change medication allergy reaction and change the display of active/inactive allergies. Both findings are attributed to an artifact of the usability test.

8.4.6 Areas for Improvement

No additional opportunities for improvement related to the effectiveness and efficiency were identified.

9. Chapter §170.314(a)(8) Clinical Decision Support (CDS) Results

9.1 Task Mapping

Table 14 maps the Clinical Decision Support (CDS) criteria to usability test tasks to aid verification that the report contains all required test scenarios for this EHR capability submitted for testing. **Green** colored font is used within the certification criteria and within the steps for successful task completion to aid verification that the usability test tasks address the details of the specified criteria.

Table 14. Clinical Decision Support (CDS) Criteria Mapped to Usability Test Tasks.

§170.314(a)(8) Clinical decision support (CDS) (i) Evidence-based decision support interventions. **Enable a limited set of identified users** to select (i.e., activate) one or more electronic clinical decision support interventions (in addition to drug-drug and drug-allergy contraindication checking) based on each one and at least **one combination** of the following data: (A) Problem list; (B) Medication list; (C) Medication allergy list; (D) Demographics; (E) Laboratory tests and values/results; and

(F) Vital signs.

(ii) Linked referential clinical decision support.
(A) EHR technology must be able to:
(1) Electronically identify for a user diagnostic and therapeutic reference information; or
(2) Electronically identify for a user diagnostic and therapeutic reference information in accordance with the standard specified at §170.204(b)(1).
(B) For paragraph (a)(8)(ii)(A) of this section, EHR technology must be able to electronically identify for a user diagnostic or therapeutic reference information based on each one and at least one combination of the following data referenced in paragraphs (a)(8)(i)(A) through (F) of this section

(iii) Clinical decision support configuration.
(A) **Enable interventions and reference resources** specified in paragraphs (a)(8)(i) and (ii) of this section to be configured by a limited set of identified users (e.g., system administrator) based on a user's role.
(B) EHR technology must enable interventions to be electronically triggered**:**
(1) Based on the data referenced in paragraphs (a)(8)(i)(A) through (F) of this section;
(2) When a patient's medications, medication allergies, and problems are incorporated from a transition of care/referral summary received pursuant to paragraph (b)(1)(iii) of this section.
(3) Ambulatory setting only. When a patient's laboratory tests and values/results are incorporated pursuant to paragraph (b)(5)(i)(A)(1) of this section. (no scenario created for this bullet point)

(iv) **Automatically and electronically interact**. Interventions triggered in accordance with paragraphs (a)(8)(i) through (iii) of this section must automatically and electronically occur when a user is interacting with EHR technology.

(v) Source attributes. **Enable a user to review the attributes** as indicated for all clinical decision support resources:
(A) For evidence-based decision support interventions under paragraph (a)(8)(i) of this section:
(1) **Bibliographic citation** of the intervention (clinical research/guideline);
(2) Developer of the intervention (translation from clinical research/guideline);
(3) Funding source of the intervention development technical implementation; and
(4) Release and, if applicable, revision date(s) of the intervention or reference source.
(B) For linked referential clinical decision support in paragraph (a)(8)(ii) of this section and drug-drug, drug-allergy interaction checks in paragraph(a)(2) of this section, the **developer of the intervention, and where clinically indicated, the bibliographic citation** of the intervention (clinical research/guideline).

CDS criteria were evaluated through several tasks. Below are the general tasks:

Problem list:	CDS Problem Advisory (Renal Dysfunction) recommendation update
Medications list:	CDS Medication List Advisory (ACE –I)
Medication allergy list:	CDS Medication Allergy Advisory (Aspirin)
Demographics:	CDS Age based Order (colonoscopy) - Preventative Health
Laboratory tests and values/results:	CDS Tests & Services Due Advisory (Hgba1c)
Vital signs:	Vitals Abnormal Range Indicator
Combination:	CDS HTN Assessment
Diagnostic and Therapeutic Reference:	Clinical Reference Button
Source:	Vitals, Problem

The CDS requirement was evaluated with several tasks. CDS criteria was assessed with the subtasks marked in

green font below:

Vitals, Combination, Source
Task 5. Vitals and Hypertension Risk Assessment
Subtask 5.1 Check Vital Signs.
Subtask 5.1(a) Review and active upon **Vitals Abnormal Range Indicator**.
Subtask 5.1 (b) Identify **the source** of the vitals CDS guidance.
Subtask 5.2 Open the Hypertension Form, complete the **Hypertension Risk Assessment (CDS)**
Subtask 5.2(a) What is the risk category for the patient
Subtask 5.2(b) Change the smoking status and describe the impact on the risk calculation
Subtask 5.2 (c) What formula is used to calculate the risk category (Identify the **source of the clinical guidance**).
Subtask 5.3 On the treatment tab, order a diuretic

Problem List, Medication List, Medication Allergy List, Laboratory Tests and Values/Results
Task 6. Diabetes clinical lists and orders for diabetes
Subtask 6.1 Review and act upon **Medication List CDS Advisory**
Subtask 6.2 Prescribe ACE Inhibitor
Subtask 6.3 Review and act upon Medication List CDS Advisory
Subtask 6.4 Review upon **Medication Allergy CDS Advisory**
Subtask 6.5 Review indications for Tests & Services Due
Subtask 6.6 Act on recommendations in **Tests & Services Due CDS Advisory**
Subtask 6.7 Review **CDS Problem Advisory**
Subtask 6.8 Record updates by Commit Assessment
Subtask 6.9 Document contraindication (**CDS Allergy Advisory continued)**

Task 7. Preventative Health Age-Based Orders
Subtask 7.1 Review act upon (order) recommended tests and orders (**Age based Order**)
Subtask 7.3: Add instructions to the Lipid Panel*
Subtask 7.4: Change the mammogram to Westfall Imaging*

Diagnostic and Therapeutic Reference:
Task 4. Clinical Reference Information: Medication dosage and adverse reaction, LDL normal range.
Subtask 4.1 **Find dosing information** about the patient's current medications and potential adverse effects.
Subtask 4.2 **Find normal range information** about LDL

Source (Ref Button):
Subtask 5.1 (b) Identify **the source** of the vitals CDS guidance. (Vitals)
Subtask 5.2 (c) What formula is used to calculate the risk category (Identify the **source of the clinical guidance**).

* See associated chapters for results and discussion
§170.314(a)(1) Computerized provider order entry

9.2 Task Participants and Instruction

Based on user characteristics, typical workflow, and tasks performed as part of their daily work, providers and clinical ancillary staff attempted this task. Physician and nurse data were

combined based on the fact that neither the task nor the user characteristics differ based on these user roles.

There were several types of CDS. Depending on the CDS, either no instructions were provided because the CDS interrupted the workflow or specific instructions were provided which would lead the user to review and act of CDS.

Medications dosing, adverse reaction and lab results reference information:

The patient is returning for hypertension follow-up.
Review the chart before seeing the patient.
Find dosing information about the patient's current medications and potential adverse effects.

Vital signs, risk category and prescribe medication:

The MA has recorded vital signs and reason for visit. Use the document on hold for you and go to Vital Signs CCC.
Where can you find the citation for the source of the clinical guidance?
On the Hypertension (Q&E-CCC) form, complete the assessment tab to calculate the risk category.

Source:

What formula is being used to calculate this risk category?

Medications list:

On the treatment tab, prescribe an ace inhibitor for the Hypertension Treatment.

Medication Allergy and Problem Lists:

Use the CPOE form to record your assessment and plan for Diabetes. Update the clinical lists and place orders as needed.
Specific instruction was not provided because the advisory interrupted the workflow.
Each CDS popup was followed by the subsequent question: What do you expect happens when you click Yes/No?

Laboratory tests and values/results and Diagnosis:

Use the CPOE form to record your assessment preventive care. Update the clinical lists and place orders as needed.
Specific instruction was not provided because the advisory interrupted the workflow.
Each CDS popup was followed by the subsequent question: What do you expect happens when you click Yes/No?

9.3 Data Analysis and Reporting

The results of the usability test were calculated according to the methods specified in the Usability Metrics section above. Each of the following subtasks (**bolded**) was used to assess task performance.

Task 6. Diabetes clinical lists and orders for diabetes

- Subtask 6.1 Review and act upon **Medication List CDS Advisory**
- Subtask 6.4 Review upon **Medication Allergy CDS Advisory**
- Subtask 6.5 Review indications for **Tests & Services Due CDS**
- Subtask 6.6 Act on recommendations in **Tests & Services Due CDS Advisory**
- Subtask 6.7 Review **CDS Problem Advisory**
- Subtask 6.9 Document contraindication (**CDS Allergy Advisory continued**)

Task 5. Vitals and Hypertension Risk Assessment

- Subtask 5.1(a) Review and active upon Vitals Abnormal Range Indicator (**Vitals CDS**).
- Subtask 5.1 (b) Identify the **source of the vitals CDS guidance**.
- Subtask 5.2 Complete the **Hypertension Risk Assessment (CDS)**
- Subtask 5.2 (c) What formula is used to calculate the risk category (**Identify the source** of the clinical guidance).

Task 7. Preventative Health Age-Based Orders

- Subtask 7.1 Review act upon (order) recommended tests and orders (Age-Based Order-**Demographics CDS**)

Diagnostic and Therapeutic Reference:

Task 4. Clinical Reference Information: Medication dosage and adverse reaction, LDL normal range.

- Subtask 4.2 **Find normal range information** about LDL

Source (Ref Button):

- Subtask 5.1 (b) **Identify the source** of the vitals CDS guidance. (Vitals)
- Subtask 5.2 (c) What formula is used to calculate the risk category (**Identify the source** of the clinical guidance).

The results should be seen in light of the objectives and goals outlined in Section 3.2 Study Design. The data should yield actionable results that, if corrected, yield material, positive impact on user performance. Table 15 provides the usability test results for Clinical Decision Support tasks.

Table 15. Usability Test Results associated with reviewing and acting upon Clinical Decision Support

Measure / Subtask	N that Attempted Task	Task Success				Task Time (sec)	
	#	% Pass	% Pass with Help	% Fail	% Pass + Pass with Help	Mean (SD) n Contributing to Mean	Click Path Notes: Areas Impacting Efficiency
CDS Medication List Advisory (ACE –I)	10	90%	0%	10%	90%	NA	Some participants expressed frustration with the number of clicks to review and act on some CDS advisory flows.
CDS Allergy Alert Advisory – Aspirin - Act upon advisory to record Aspirin contraindication	10	All participants were able to successfully complete the mechanics of this CDS subtasks. The expectation of this CDS screen flow did not match participant's expectation. See Discussion.					
		60%	0%	40%	60%		
CDS Laboratory Tests & Services Due Advisory	11	82%	0%	18%	82%		
CDS Problem Advisory (Renal Dysfunction)	11	91%	0%	9%	91%		
Order age based tests and services due (CPOE – preventative health – Demographics CDS)	10	100%	0%	0%	100%		Additional opportunities to improve efficiency were not observed.
CDS Vital Signs: (abnormal result indicator)	12	All participants were able to successfully complete the mechanics of this CDS subtasks. The expectation of this CDS screen flow did not match participant's expectation. See Discussion.					Spatial location of abnormal vital sign indicator caused some participants increased thinking time to associate indicator with the associated field.
		58%	8%	33%	66%*		
Combination: CDS HTN Assessment	11	100%	0%	0%	100%		

Find normal range information about LDL (Diagnostic and Therapeutic Reference)	11	64%	18%	18%	82%**	Time included in associated scenario time.	Additional opportunities to improve efficiency were not observed.
Source: Identify Source of CDS guidance – (Source of vitals)	11	100%	0%	0%	100%**	Time included in associated scenario time.	Additional opportunities to improve efficiency were not observed.

* sum impacted by rounding error

** First attempts to identify the Reference Information and Source of CDS content were considered exposure to the feature. Second attempt success rates are reported.

As indicated in the table:

- 90% (10 of 10) of participants successfully (Pass + Pass with help) reviewed and acted upon the Medication List CDS Advisory.
- 60% (6 of 10) of participants successfully (Pass + Pass with help) reviewed and acted upon the Medication Allergy CDS Advisory. All participants were able to successfully complete the mechanics of this CDS subtasks. The expectation of this CDS screen flow did not match participant's expectation. See Discussion.
- 82% (9 of 11) of participants successfully (Pass + Pass with help) reviewed and acted upon the Laboratory Tests & Services Due CDS.
- 91% (10 of 11) of participants successfully (Pass + Pass with help) reviewed and acted upon the CDS Problem Advisory.
- 100% (10 of 10) of participants successfully (Pass + Pass with help) reviewed and acted upon the Demographics CDS.
- 66% (8 of 12) of participants successfully (Pass + Pass with help) reviewed and acted upon the Vitals CDS. All participants were able to successfully complete the mechanics of this CDS subtasks. The expectation of this CDS screen flow did not match participant's expectation. See Discussion.
- 100% (11 of 11) of participants successfully (Pass + Pass with help) reviewed and acted upon the HTN Assessment (Combination CDS).
- 82% (9 of 11) of participants successfully (Pass + Pass with help) located the Diagnostic and Therapeutic Reference (Find normal range information).

- 100% (11 of 11) of participants successfully (Pass + Pass with help) located the Source of CDS guidance (source of vitals guidance).

9.4 Discussion of the Findings

The following sections discuss the results organized around a risk analysis of use, test performance and error rates. The risk analysis of use includes identification of use errors and user interface design issues as well as classification of severity based on the consequence of the error. Use errors and user interface design issues that resulted in subtask failures, that are known industry risk issues, and errors and issues related to aspects of the user interface that are configured per customer site are considered more severe compared to noncritical system usability issues related to efficiency. As such the discussion of more serious errors and issues is provided in the Risk Analysis section and the associated mitigation strategy is provided in the Areas for Improvement section.

Based on our definition of effectiveness metrics, performance, use errors and issues stemming for task failures are also discussed in the Effectiveness section as effectiveness was measured with task success and failure. Associated recommendations are provided in the Areas for Improvement section.

Noncritical system usability issues related to efficiency are discussed in the Efficiency section. Associated recommendations are provided in the Areas for Improvement section.

Satisfaction was assessed at the system level. Section 15 System Satisfaction Results for the results of the System Usability Scale (SUS).

The Major Findings section provides a brief summary of the findings related to identified use errors, effectiveness, and efficiency.

9.4.1 Risk Analysis

No critical issues were identified as part of the CDS tasks. Participants were able to successfully complete the mechanics of all CDS subtasks. Failures resulted from participants' expectation of flow through multiple CDS features and the actual flow through multiple features. One solution approach to handling multiple CDS features is to group the review of CDS followed by grouping the actions. An alternative approach is to pair review and action of each associated CDS. Both alternatives offer safe and effective CDS solutions. In the current usability test, participants' expectation did not match the solution evaluated.

9.4.2 Effectiveness

Performance of the following subtasks fell below the 95% criteria: review and act upon the Medication List CDS Advisory, Medication Allergy CDS Advisory, review and act upon the Laboratory Tests & Services Due CDS, review and act upon the CDS Problem Advisory, review and act upon Vitals CDS, and located the Diagnostic and Therapeutic Reference.

Participants were able to successfully complete the mechanics of all CDS subtasks. The majority of the errors were due to the participants' lack of familiarity with the specific CDS implemented

for testing, and so, their expectations did not match the tested CDS intervention. Errors in the Vitals CDS task were a result of some participants' expectations not matching the indicator with the associated field.

The Diagnostic and Therapeutic Reference is a new feature. Participant's failures are attributed to lack of familiarity with the feature. Participants provided positive feedback about the feature.

Many participants expressed frustration during the CDS tasks. It is known in the industry that CDS that interrupts the workflow can frustrate end users. Many of the Meaningful Use 2014 Safety Enhanced Design CDS features involved solutions that interrupt the workflow. As such, much of the frustration experienced during the usability test session was an artifact of testing. Configuration purposely was set to review CDS features. Depending on the scenario, some CDS features were carefully reviewed. Other CDS features were routinely dismissed. Participants expressed frustration regarding over-use of CDS in the usability test session and expressed they would not want over use of CDS in their daily practice.

9.4.3 Efficiency

Opportunities for improvements related to the effectiveness of the CDS alerts were identified. Participants expressed frustration with the number of clicks to review and act on some CDS advisory flows. Spatial location of abnormal vital sign indicator caused some participants increased thinking time to associate indicator with the associated field. The finding that CDS screen flow did not match participants' expectations, highlights the need for predictable button labels on CDS screens that create the CDS screen flow.

9.4.4 Satisfaction

Satisfaction was assessed at the system level. Section 15 System Satisfaction Results for the results of the System Usability Scale (SUS).

9.4.5 Major Findings

Performance of the following subtasks fell below the 95% criteria: review and act upon the Medication Allergy CDS Advisory, review and act upon the Laboratory Tests & Services Due CDS, review and act upon the CDS Problem Advisory, review and act upon Vitals CDS, and located the Diagnostic and Therapeutic Reference. Participants were able to successfully complete the mechanics of all CDS subtasks. The majority of the errors were due to the participants' lack of familiarity with the specific CDS implemented for testing, and so, their expectations did not match the tested CDS intervention.

9.4.6 Areas for Improvement

The GE team is well aware of the industry's known issues regarding physician's reaction to CDS features. The team currently addresses CDS by working with customer sites to configure CDS solutions to match the needs of providers at each customer site and is exploring alternative

solutions that might allow for alternative CDS screen flows so as to match differing physician expectations. Opportunities for improvements related to the effectiveness and efficiency of the CDS alerts include:

- Consider consolidation of some CDS advisories.
- Assure action button labels to navigate CDS screen flow are descriptive so as to aid predictability.
- Consider spatial location of abnormal vital sign indicators to optimize visual scanning.

10. Chapter §170.314(b)(3) Electronic Prescribing Results

10.1 Task Mapping

Table 16 maps the Electronic Prescribing criteria to usability test tasks to aid verification that the report contains all required test scenarios for this EHR capability submitted for testing. **Green** colored font is used within the certification criteria and within the steps for successful task completion to aid verification that the usability test tasks address the details of the specified criteria.

Table 16. Electronic Prescribing Criteria Mapped to Usability Test Tasks.

§170.314(b)(3) Electronic Prescribing. **Enable** a user to electronically create prescriptions and prescription-related information for electronic transmission in accordance with: (i) The standard specified in §170.205(b)(2); and (ii) At a minimum, the version of the standard specified in § 170.207(d)(2).
Electronic Prescribing was evaluated as part of the following task: Review medications and make updates based on the information provided.
To successfully complete the task, participants were required to complete each of the following Subtasks. Only activities related to §170.314(b)(3) Electronic Prescribing will be discussed in this chapter. Subtask 2.1: Access patient's medications Subtask 2.2: Change Metoprolol Subtask 2.3: Add New Prescription – Paxil Subtask 2.4: Review and act upon drug- drug conflict Subtask 2.5: Discontinue St. John's Wort Subtask 2.6: **Send the medications electronically** to the pharmacy Subtask 2.7: Review active and inactive medications * See the associated chapter for results and discussion §170.314(a)(2) Chapter §170.314(a)(2) Drug-Drug, Drug-Allergy Interaction Checks – Interventions Results, § 170.314(a)(6) Medication List Results

10.2 Task Participants and Instruction

Participants were given the following instruction:

Now I am going to have you review and update the medications:
Discontinue Lisinopril
Change Metoprolol <dose from 50mg tablet to the 100mg, tablet. Qty: 90, Refills x2>
Add Paxil <20MG tabs, Qty: 90, Refills x1>
Discontinue St John's Wort
Electronically send the medications to the patient's pharmacy.
Review the patient's existing medications and make updates based on the information provided.
Confirm you are viewing patient's active and inactive medications in meds list.

10.3 Date Analysis and Reporting

The results of the usability test were calculated according to the methods specified in the Usability Metrics section above. Only activities related to §170.314(b)(3) Electronic Prescribing will be discussed in this chapter. Each of the following subtasks was used to assess task performance.

- Subtask 2.6: Send the medications electronically to the pharmacy

The results should be seen in light of the objectives and goals outlined in Section 3.2 Study Design. The data should yield actionable results that, if corrected, yield material, positive impact on user performance. Table 17 provides the usability test results for the ePrescribe subtask.

Table 17. Usability Test Results Associated with the Electronic Prescribing Task.

Measure / Subtask	N that Attempted Task	Task Success				Task Time (sec)	
	#	% Pass	% Pass with Help	% Fail	% Pass + Pass with Help	Mean (SD) n Contributing to Mean	Click Path Notes: Areas Impacting Efficiency
Send the medications electronically	12	92%	0%	8%	92%	Task Time is part of Medication List task performance measure	Additional opportunities to improve efficiency were not observed.

As indicated in the table:

- 92% (11 of 12) of participants successfully (Pass + Pass with help) sent the medication information electronically to the pharmacy.

10.4 Discussion of the Findings

The following sections discuss the results organized around a risk analysis of use, test performance and error rates. The risk analysis of use includes identification of use errors and user interface design issues as well as classification of severity based on the consequence of the error. Use errors and user interface design issues that resulted in subtask failures, that are known industry risk issues, and errors and issues related to aspects of the user interface that are configured per customer site are considered more severe compared to noncritical system usability issues related to efficiency. As such the discussion of more serious errors and issues is provided in the Risk Analysis section and the associated mitigation strategy is provided in the Areas for Improvement section.

Based on our definition of effectiveness metrics, performance, use errors and issues stemming for task failures are also discussed in the Effectiveness section as effectiveness was measured with task success and failure. Associated recommendations are provided in the Areas for Improvement section.

Noncritical system usability issues related to efficiency are discussed in the Efficiency section. Associated recommendations are provided in the Areas for Improvement section.

Satisfaction was assessed at the system level. Section 15 System Satisfaction Results for the results of the System Usability Scale (SUS).

The Major Findings section provides a brief summary of the findings related to identified use errors, effectiveness, and efficiency.

10.4.1 Risk Analysis

No critical issues were identified related to electronic prescribing. One participant did not correctly confirm that the prescription had been sent to the pharmacy.

10.4.2 Effectiveness

Performance of the subtask fell below the 95% success criterion. One participant did not correctly confirm that the prescription had been sent to the pharmacy. No additional areas for improvement related to effectiveness were identified.

10.4.3 Efficiency

No additional areas for improvement related to effectiveness were identified.

10.4.4 Satisfaction

Satisfaction was assessed at the system level. Section 15 System Satisfaction Results for the results of the System Usability Scale (SUS).

10.4.5 Major Findings

Performance of the subtask fell below the 95% success criterion. No additional areas for improvement related to effectiveness and efficiency were identified.

10.4.6 Areas for Improvement

No additional areas for improvement related to effectiveness and efficiency were identified.

11. Chapter §170.314(b)(4) Clinical Information Reconciliation Results

11.1 Task Mapping

Table 18 maps Clinical Information Reconciliation criteria to usability test tasks to aid verification that the report contains all required test scenarios for this EHR capability submitted for testing. **Green** colored font is used within the certification criteria and within the steps for successful task completion to aid verification that the usability test tasks address the details of the specified criteria.

Table 18. Clinical Information Reconciliation Criteria Mapped to Usability Test Tasks

§ 170.314(b)(4) Clinical Information Reconciliation Enable a user to electronically reconcile the data that represent a patient's active **medication**, **problem**, and medication allergy list as follows. For each list type: (i) **Electronically** and **simultaneously** display (i.e., in a single view) the data from at least **two list sources** in a manner that allows a user to view the **data** and their **attributes**, which must include, at a minimum, the **source** and **last modification date**. (ii) Enable a user to **create** a single reconciled list of **medications**, **medication allergies**, or **problems**. (iii) Enable a user to **review and validate** the accuracy of a **final set of data** and, upon a user's confirmation, **automatically update** the list.
Task: Reconcile specific clinical information based on the information provided.
Only activities (**bolded**) associated with criteria will be discussed in this chapter. To successfully complete this Task, participants were required to complete each of the following subtasks. **Accessing and reconciling medication allergies** were used as part of guided familiarization to this new feature. Subtask 3.1: **Access** Problems information form **external source and** information form **Centricity EHR**. Subtask 3.2: **Update** Centricity EHR by bringing the **problem** from the external system into Centricity EHR (includes activity and onset date). Subtask 3.3: **Access** Medications information form **external source and** information form **Centricity EHR**. Subtask 3.4: Import Lisinopril - **update the record in the chart with the all the information from the External source** (includes activity, start date, instructions and **last modification date**).

Subtask 3.5: Import Lorazepam - **update the record in the chart with the all the information from the External source** (includes activity, start date, instructions and **last modification date**).

Subtask 3.6: Import Furosemide - **update the record in the chart with the all the information from the External source** (includes activity, start date, instructions and **last modification date**).

Subtask 3.7: **Review** and remove duplicates.

Subtask 3.6: **Confirm** that your Problems, Allergies and Medications are Reconciled

11.2 Task Participants and Instruction

Based on user characteristics, typical workflow, and tasks performed as part of their daily work, providers and clinical ancillary staff attempted this task. Physician and nurse data were combined based on the fact that neither the task nor the user characteristics differ based on these user roles.

Participants were given the following instruction:

There is a new feature in the EHR that is used to reconcile clinical information from an external source with information in this EHR. For example, let's say the patient had a hospital visit. The hospital will send your practice the clinical information from the hospital visit and your team can reconcile that information with the information in your EHR.

Are you familiar with this new feature?

I am going to work with you as we reconcile Allergies. Then I am going to have you reconcile the Problems and the Medications. Just so we are on the same page, for some of these activities I am going to ask you to do things that you would not do if you were using you clinical judgment.

Note: Furosemide and Congestive Heart Failure were already in the chart. Participants were asked to move Furosemide in to the chart to create duplicate and consequently to remove it.

11.3 Data Analysis and Reporting

Each of the following subtasks was used to assess task performance:

- Subtask 3.1: Access Problems information from external source and information from Centricity EHR.
- Subtask 3.2: Update Centricity EHR by bringing the problem from the external system into Centricity EHR .
- Subtask 3.3: Access Medications information from external source and information from Centricity EHR.
- Subtask 3.4: Import Lisinopril - update the record in the chart with the all the information from the External source.

- Subtask 3.5: Import Lorazepam - update the record in the chart with the all the information from the External source.
- Subtask 3.6: Import Furosemide - update the record in the chart with the all the information from the External source.
- Subtask 3.7: Review and remove duplicates.
- Subtask 3.6: Confirm that your Problems, Allergies and Medications are reconciled.

The results should be seen in light of the objectives and goals outlined in Section 3.2 Study Design. The data should yield actionable results that, if corrected, yield material, positive impact on user performance. Based on user characteristics, typical workflow, and tasks performed as part of their daily work, physicians and nurses attempted this task. Physician and nurse data were combined based on the fact that neither the task nor the user characteristics differ based on these user roles.

Table 19 provides the usability task results for each subtask of the Clinical Information Reconciliation task.

Table 19. Usability Test Results Associated with Clinical Information Reconciliation.

Measure / Subtask	N that Attempted Task	Task Success				Task Time (sec)	
	#	% Pass	% Pass with Help	% Fail	% Pass + Pass with Help	Mean (SD) n Contributing to Mean	Click Path Notes: Areas Impacting Efficiency
Access and Reconcile medication allergies was used as guided familiarization to this new feature	15	0%	100%	0%	100%		Labeling, grouping and sorting of data can be improved to support more efficient visual scanning.
Access Problems information form external source and information form Centricity EHR	15	100%	0%	0%	100%		
Update Centricity EHR by bringing the problem from the external system into Centricity	15	100%	0%	0%	100%		
Do not bring in the	15	100%	0%	0%	100%		

duplicate problem to Centricity							
Access Medications information form external source and information form Centricity EHR	15	100%	0%	0%	100%		
Update the Centricity EHR with Lisinopril	15	100%	0%	0%	100%		
Update the Centricity EHR with Lorazepam	15	100%	0%	0%	100%		
Update Centricity EHR with Furosemide	13	100%	0%	0%	100%		
Remove duplicate	15	100%	0%	0%	100%		
Confirm that your Problems Allergies and Medications are Reconciled	15	100%	0%	0%	100%		

As indicated in the table:

- 100% (15 of 15) of participants successfully completed all reconciliation (Pass + Pass with help).

11.4 Discussion of the Findings

The following sections discuss the results organized around a risk analysis of use, test performance and error rates. The risk analysis of use includes identification of use errors and user interface design issues as well as classification of severity based on the consequence of the error. Use errors and user interface design issues that resulted in subtask failures, that are known industry risk issues, and errors and issues related to aspects of the user interface that are configured per customer site are considered more severe compared to noncritical system usability issues related to efficiency. As such the discussion of more serious errors and issues is provided in the Risk Analysis section and the associate mitigation strategy is provided in the Areas for Improvement section.

Based on our definition of effectiveness metrics, performance, use errors and issues stemming for task failures are also discussed in the Effectiveness section as effectiveness was measured with task success and failure.

Noncritical system usability issues related to efficiency are discussed in the Efficiency section. Associated recommendations are provided in the Areas for Improvement section.

Satisfaction was assessed at the system level. Section 15 System Satisfaction Results for the results of the System Usability Scale (SUS).

The Major Findings section provides a brief summary of the findings related to identified use errors, effectiveness, and efficiency.

11.4.1 Risk Analysis

No critical issues were identified as part of the clinical information reconciliation task.

11.4.2 Effectiveness

Performance of all subtasks was above the 95% success criterion. Additional areas for improvement related to effectiveness are described below.

11.4.3 Efficiency

Labeling, grouping and sorting of data can be improved to support more efficient visual scanning.

11.4.4 Satisfaction

Satisfaction was assessed at the system level. Section 15 System Satisfaction Results for the results of the System Usability Scale (SUS).

11.4.5 Major Findings

All participants were able to correctly perform the mechanics of the reconciliation task when they were told what medications and problems needed to be reconciled. Participants had a clear mental model of the feature. Consider improvements to labeling, grouping and sorting of data to support more efficient visual scanning.

11.4.6 Areas for Improvement

Consider providing aid in making decisions about what information is already in the patient's chart versus what information is coming from another source to be reconciled, namely: in case of duplicate medications, when generic and brand names of the medication are compared, consider warning/indicating users of possible duplicates.

Opportunities to improve effectiveness and efficiency include:

- Consider improvements to labeling, grouping and sorting of data to support more efficient visual scanning.

12. Configuration Test Results

Each Configuration Results chapter of the report presents the results associated with usability test activities conducted with configuration specialist participants. The primary purpose of this summative usability test is to provide objective evidence that the system configuration user interface can be used in a safe, efficient, and effective manner with regard to the certification criteria associated with configuration.

13. Chapter §170.314(a)(2)(ii)(A) Drug-Drug, Drug-Allergy Interaction Checks – Adjustments Results

13.1 Task Mapping

Table 20 maps the Drug-Drug, Drug-Allergy Interaction Checks – Adjustments criteria to usability test tasks to aid verification that the report contains all required test scenarios for this EHR capability submitted for testing. **Green** colored font is used within the certification criteria and within the steps for successful task completion to aid verification that the usability test tasks address the details of the specified criteria.

Table 20. Drug-Drug, Drug-Allergy Interaction Checks - Adjustments Criteria Mapped to Usability Test Tasks

§ 170.314(a)(2)(ii) Drug-Drug, Drug-Allergy Interaction Checks – Adjustments (A) Enable the severity level of interventions provided for drug-drug interaction checks to be **adjusted**. (B) **Limit** the ability to adjust severity levels to an identified set of users or available as a system administrative function.
Drug-Drug, Drug-Allergy Interaction Check – Adjustments criteria were evaluated through several tasks. Task 1 Locate and **change the current drug-drug interaction severity threshold**. Task 2 **Change drug-allergy interaction criticality threshold**. Task 3 **Limit** the ability for group of users to adjust drug interaction warnings thresholds.
Only activities (**bolded**) associated with criteria will be discussed in this chapter. To successfully complete the tasks, participants were required to: Subtask 1.1: **Set the system** so that only Major drug-drug interaction warnings display to the users but Moderate and Minor drug-drug interactions do not display. Subtask 1.2: Now **set the system** so that only Severe and Critical drug-allergy interaction warnings display to the users. Task 2: **Set the system** so that those assigned to the physician security group are able to suppress severity levels. Task 3: There is a new security permission under Chart security for "Access to Clinical Decision Support". You need to **ensure that the users in group "Nurses" have permission to access CDS**.

Each task will be examined in full before proceeding to the next task.

13.2 Task Participants and Instruction: Change Severity Level Thresholds

Based on user characteristics, typical workflow, and tasks performed as part of their daily work, participants attempted this task. Participants were given the following instruction:

Scenario & Task 1:

Set the system so that only Major drug-drug interaction warnings display to the users but Moderate and Minor drug-drug interactions do not display.

Now set the system so that only Severe and Critical drug-allergy interaction warnings display to the users.

13.3 Data Analysis and Reporting: Change Severity Level Thresholds

The results of the usability test were calculated according to the methods specified in the Usability Metrics section above. The following subtasks were used to assess task performance:

- Locate and change the severity level of drug-drug interaction intervention.
- Locate and change the criticality level of drug-allergy interaction intervention.

The results should be seen in light of the objectives and goals outlined in Section 3.2 Study Design. The data should yield actionable results that, if corrected, yield material, positive impact on user performance. Table 21 provides usability test results associated with the task, Change Drug-Drug Severity Levels and Change Drug-Allergy Criticality Levels.

Table 21. Usability Test Results for Change Severity Level Thresholds of Drug-Drug and Drug-Allergy Interaction Interventions.

Measure / Subtask	N that Attempted Task	Task Success				Task Time (sec)	
	#	% Pass	% Pass with Help	% Fail	% Pass + Pass with Help	Mean (SD) n Contributing to Mean	Click Path Notes: Areas Impacting Efficiency
Locate and change the current drug-drug interaction severity	15	13%	13%	73%	26%		Similarities in labels referring to different options contributed to the confusion. Ambiguity of labels made it hard to interpret.
Change drug-allergy interaction criticality	15	33%	13%	53%	46%		

As indicated in the table:

- 26% (4 of 15) of participants successfully changed drug-drug intervention severity level requiring acknowledgement (Pass + Pass with help).
- 46% (7 of 15) of participants successfully changed drug-allergy intervention severity level requiring acknowledgement (Pass + Pass with help).

13.4 Discussion of the Findings: Change Severity Level Thresholds

The following sections discuss the results organized around a risk analysis of use, test performance and error rates. The risk analysis of use includes identification of use errors and user interface design issues as well as classification of severity based on the consequence of the error. Use errors and user interface design issues that resulted in subtask failures, that are known industry risk issues, and errors and issues related to aspects of the user interface that are configured per customer site are considered more severe compared to noncritical system usability issues related to efficiency. As such the discussion of more serious errors and issues is provided in the Risk Analysis section and the associated mitigation strategy is provided in the Areas for Improvement section.

Based on our definition of effectiveness metrics, performance, use errors and issues stemming for task failures are also discussed in the Effectiveness section as effectiveness was measured with task success and failure. Associated recommendations are provided in the Areas for Improvement section.

Noncritical system usability issues related to efficiency are discussed in the Efficiency section. Associated recommendations are provided in the Areas for Improvement section.

Satisfaction was assessed at the system level. Section 15 System Satisfaction Results for the results of the System Usability Scale (SUS).

The Major Findings section provides a brief summary of the findings related to identified use errors, effectiveness, and efficiency.

13.4.1 Risk Analysis

Task failures were associated with unfamiliarity with the system for completing this task and lack of supporting documentation typically used during configuration. Configuring settings associated with drug-drug and drug-allergy interactions is an infrequent activity, generally only conducted as part of the initial implementation.

Some participants described that after performing a configuration task they verify that the system change was performed correctly by using the system to check their configuration work. Due to limited time during the usability test session, participants were not able to verify that their system changes were performed correctly. A verification practice like the one described serves to identify use errors during actual configuration and serves as mitigation for errors described in this report.

13.4.2 Effectiveness

Performance of the subtask fell below 95% criterion; locate and change the Drug-Drug and Drug-Allergy interaction warning levels. Recommendations to improve effectiveness are described below.

13.4.3 Efficiency

No additional areas for improvement related to efficiency were identified.

13.4.4 Satisfaction

Satisfaction was assessed at the system level. Section 15 System Satisfaction Results for the results of the System Usability Scale (SUS).

13.4.5 Major Findings

Performance of all subtasks fell below the 95% criterion. Task failures were associated to unfamiliarity with the system for completing this task and lack of supporting documentation that would typically be used during configuration. Participants described a verification process used when making configuration changes that serves to identify use errors. Opportunities for improvement are provided below.

13.4.6 Areas for Improvements

Opportunities to improve usability include assuring screens and screen section titles are sufficiently descriptive enough to support recognition and comprehension for infrequent tasks.

13.5 Task Participants and Instructions: Limit Access to Adjust Severity Level Thresholds

Based on user characteristics, typical workflow, and tasks performed as part of their daily work, participants attempted this task. Participants were given the following instruction:

Scenario & Task 2:
Set the system so that those assigned to the physician security group are able to suppress severity levels.

13.6 Data Analysis and Reporting: Limit Access to Adjust Severity Level Thresholds

The results of the usability test were calculated according to the methods specified in the Usability Metrics section above. The following task was used to assess task performance

- Show me how you can assign or take away the privilege to change drug-drug interaction settings from the doctor's role.

The results should be seen in light of the objectives and goals outlined in Section 3.2 Study Design. The data should yield actionable results that, if corrected, yield material, positive impact on user performance. Table 22 provides usability test results associated with the task, Limit Access.

Table 22. Usability Test Results Associated with Limit Access to Adjust Severity Levels.

Measure / Subtask	N that Attempted Task	Task Success				Task Time (sec)	Click Path Notes: Areas Impacting Efficiency
	#	% Pass	% Pass with Help	% Fail	% Pass + Pass with Help	Mean (SD) n Contributing to Mean	
Limit the ability for group of users to adjust drug interaction warnings	15	73%	13%	13%	86%*		Additional opportunities to improve efficiency were not observed.

* sum impacted by rounding error

As indicated in the table:

- 86% (13 of 15) of participants successfully located and limited access to adjust interaction severity levels to Physician role (Pass + Pass with help).

13.7 Discussion of the Findings: Limit Access to Adjust Severity Level Thresholds

The following sections discuss the results organized around a risk analysis of use, test performance and error rates. The risk analysis of use includes identification of use errors and user interface design issues as well as classification of severity based on the consequence of the error. Use errors and user interface design issues that resulted in subtask failures, that are known industry risk issues, and errors and issues related to aspects of the user interface that are configured per customer site are considered more severe compared to noncritical system usability issues related to efficiency. As such the discussion of more serious errors and issues is provided in the Risk Analysis section and the associated mitigation strategy is provided in the Areas for Improvement section.

Based on our definition of effectiveness metrics, performance, use errors and issues stemming for task failures are also discussed in the Effectiveness section as effectiveness was measured with task success and failure. Associated recommendations are provided in the Areas for Improvement section.

Noncritical system usability issues related to efficiency are discussed in the Efficiency section. Associated recommendations are provided in the Areas for Improvement section.

Satisfaction was assessed at the system level. Section 15 System Satisfaction Results for the results of the System Usability Scale (SUS).

The Major Findings section provides a brief summary of the findings related to identified use errors, effectiveness, and efficiency.

13.7.1 Risk Assessment

The task failures were associated with unfamiliarity with the system for completing this task. In addition, users described the use of supporting documentation during this type of configuration. Test participants did not have access to their supporting documentation during the usability testing. Configuring settings associated with clinical decision support is an infrequent activity, generally only conducted as part of the initial implementation.

Most participants described they were unclear how to complete this task and would consult their help documents and/or articles (on-line or hard-copy), and would call support, if needed.

Some participants described that after performing a configuration task they verify that the system change was performed correctly by using the system to check their configuration work. Due to limited time during the usability test session, participants were not able to verify that their system changes were performed correctly. A verification practice like the one described serves to identify use errors during actual configuration and serves as mitigation for errors described in this report.

13.7.2 Effectiveness

Performance fell below 95% success criterion. Participants had trouble locating the screen to make changes as well as trouble completing the configuration when they were on the screen.

13.7.3 Efficiency

No additional areas for improvement related to efficiency were identified.

13.7.4 Satisfaction

Satisfaction was assessed at the system level. Section 15 System Satisfaction Results for the results of the System Usability Scale (SUS).

13.7.5 Major Findings

Task failures were associated to unfamiliarity with the system for completing this task and lack of supporting documentation that would typically be used during configuration. Participants described a verification process used when making configuration changes that serves to identify use errors. Opportunities for improvement are provided below.

13.7.6 Areas for Improvement

Opportunities to improve usability include assuring screens and screen section titles are sufficiently descriptive enough to support recognition and comprehension for infrequent tasks.

14. Chapter §170.314(a)(8) Clinical Decision Support (CDS) Configuration

14.1 Task Mapping

Table 23 maps the Clinical Decision Support (CDS) Configuration criteria to usability test tasks to aid verification that the report contains all required test scenarios for this EHR capability submitted for testing. **Green** colored font is used within the certification criteria and within the steps for successful task completion to aid verification that the usability test tasks address the details of the specified criteria.

Table 23 –Clinical Decision Support (CDS) Configuration Criteria Mapped to Usability Test Tasks

§170.314(a)(8) Clinical decision support (CDS) - Configuration (iii) Clinical decision support configuration. (A) Enable interventions and reference resources specified in paragraphs (a)(8)(i) and (ii) of this section to be configured by a limited set of identified users (e.g., system administrator) based on a user's role. (B) EHR technology must enable interventions to be electronically triggered: (1) Based on the data referenced in paragraphs (a)(8)(i)(A) through (F) of this section; (2) When a patient's medications, medication allergies, and problems are incorporated from a transition of care/referral summary received pursuant to paragraph (b)(1)(iii) of this section. (3) Ambulatory setting only. When a patient's laboratory tests and values/results are incorporated pursuant to paragraph (b)(5)(i)(A)(1) of this section. (no scenario created for this bullet point)
CDS Configuration criteria were evaluated through the following task. Task 3 Set the system so that those **assigned to the group** "Nurses" have permission to **access CDS**.
To successfully complete the tasks, participants were required to: Task 3: Ensure that the users in group "Nurses" have permission to access CDS.

Each task will be examined in full before proceeding to the next task.

14.2 Task Participants and Instruction: CDS Configuration

Based on user characteristics, typical workflow, and tasks performed as part of their daily work, administrators and implementation consultants attempted this task. GE configuration specialists and non GE configuration specialists' data were combined based on the fact that

neither the task nor the user characteristics differ based on the source of the participants. Participants were given the following instruction:

Scenario & Task 3:

There is a new security permission under Chart security for "Access to Clinical Decision Support". You need to ensure that the users in group "Nurses" have permission to access CDS.

14.3 Data Analysis and Reporting: CDS Configuration

The following subtask was used to assess task performance:

- Task 3: You need to ensure that the users in group "Nurses" have permission to access CDS.

The results should be seen in light of the objectives and goals outlined in Section 3.2 Study Design. The data should yield actionable results that, if corrected, yield material, positive impact on user performance. Table 24 provides usability test results associated with the task, Limit Access.

Table 24. Usability Test Results Associated with CDS Configuration.

Measure / Subtask	N that Attempted Task	Task Success				Task Time (sec)	
	#	% Pass	% Pass with Help	% Fail	% Pass + Pass with Help	Mean (SD) n Contributing to Mean	Click Path Notes: Areas Impacting Efficiency
Limit the ability for group of users to access clinical decision support	15	100%	0%	0%	100%		Additional opportunities to improve efficiency were not observed.

As indicated in the table:

- 100% (15 of 15) of participants successfully limited access to CDS (Pass + Pass with help).

14.4 Discussion of the Findings: Configure CDS

The following sections discuss the results organized around a risk analysis of use, test performance and error rates. The risk analysis of use includes identification of use errors and user interface design issues as well as classification of severity based on the consequence of the error. Use errors and user interface design issues that resulted in subtask failures, that are known industry risk issues, and errors and issues related to aspects of the user interface that are

configured per customer site are considered more severe compared to noncritical system usability issues related to efficiency. As such the discussion of more serious errors and issues is provided in the Risk Analysis section and the associated mitigation strategy is provided in the Areas for Improvement section.

Based on our definition of effectiveness metrics, performance, use errors and issues stemming for task failures are also discussed in the Effectiveness section as effectiveness was measured with task success and failure.

Noncritical system usability issues related to efficiency are discussed in the Efficiency section. Associated recommendations are provided in the Areas for Improvement section.

Satisfaction was assessed at the system level. Section 15 System Satisfaction Results for the results of the System Usability Scale (SUS).

The Major Findings section provides a brief summary of the findings related to identified use errors, effectiveness, and efficiency.

14.4.1 Risk Assessment

No critical use errors were identified or observed as part of this scenario.

14.4.2 Effectiveness

Performance of the subtask was above 95% success criterion. No additional findings regarding effectiveness were identified.

14.4.3 Efficiency

No additional findings regarding efficiency were identified.

14.4.4 Satisfaction

Satisfaction was assessed at the system level. Section 15 System Satisfaction Results for the results of the System Usability Scale (SUS).

14.4.5 Major Findings

No critical errors were identified as part of this scenario.

14.4.6 Areas for Improvement

No additional findings regarding effectiveness and efficiency were identified.

15. System Satisfaction Results

15.1 About System Usability Scale SUS Scores

Participants completed the System Usability Scale (SUS) questionnaire at the end of their session. The SUS is a reliable and valid measure of system satisfaction. Sauro (http://www.measuringusability.com/sus.php accessed 3/14/2013) reports, the average SUS score from 500 studies across various products e.g., websites, cell phones, enterprise systems and across different industries is a 68. SUS scores range from 0 – 100. A SUS score above a 68 is considered above average and anything below 68 is below average.

User-View encourages teams not to focus on the comparison to the cross industry average SUS of 68 reported by Sauro. Instead, we encouraged teams to use the SUS as a measure to compare their own usability improvement in the application as changes are made.

15.2 Clinical System Satisfaction Results

Eight (8) licensed or credentialed providers and three (3) clinical ancillary staff completed the SUS questionnaire at the end of their session. Four (4) providers and one (1) clinical ancillary staff did not complete the SUS due to time. The EHRUT scored an average of 64 (SD=14).

15.3 Configuration System Satisfaction Results

Configuration specialists completed the SUS questionnaire at the end of their session. Four (4) configuration specialists had incomplete questionnaire responses and were no included in the calculation of this SUS score. Based on eleven (11) configuration specialists, the ERHUT configuration module scored an average of 68 (SD=20).

16. Appendices

The following appendices include supplemental data for this usability test report. Following is a list of the appendices provided:

1. Non-Disclosure Agreement (NDA) and Informed Consent Form
2. Moderator Guides
3. Test Detail Memory Aids
4. System Usability Scale Questionnaire

16.1 Volunteer, Non-Disclosure, and Video Informed Consent

Volunteer, Non-Disclosure, and Video Consent Form

I voluntarily agree to participate in an evaluation being conducted by User-View, Inc. of Raleigh, North Carolina. This evaluation is designed to provide feedback regarding a GE EHR.

During the evaluation, I understand that I may learn information that is confidential to User-View or their client. I agree to treat all confidential information received during this evaluation in accordance with this non-disclosure agreement. Accordingly, I will not disclose confidential information to any third parties.

I authorize User-View and their client to keep, preserve, use in any manner and dispose of the findings from this evaluation, including my feedback and opinions expressed. User-View will not associate my name or company name with the results of this evaluation.

I give my permission for User-View and their client to make video and audio records of me during this evaluation. I understand that these recordings can be used only for evaluation purposes and can be used for no other purpose without my knowledge and consent.

I understand that my participation is completely voluntary and that I may leave at any time.

_____	_____	_____
Name (Please Print)	Signature	Date

16.2 Moderator Guides

16.2.1 Clinical Moderator Guide

MODERATOR GUIDE	Summative

Participant:	_____	#:	_____
Location:	_____	Date:	_____
Specialty:	_____	Time:	_____

INTRODUCTION	All User Groups

Hello. My name is _____ and this is _____. Thank you again for coming to evaluate this application today. We will be here with you throughout the session today. Our understanding is that you can stay for 1 hour, until _____.

The first/next thing I would like to do is to show you this consent form to participate. <<moderator provides consent and P signs>>

I am going to read this introduction to you because we want to be sure that we don't miss anything.

I am from an independent consulting company. I am not employed at GE. I spend my days doing just this. Companies hire my company to conduct activities with people like you that use their products, services, and websites. This is a great chance to give the GE team feedback about the application we are going to look at today.

Remember we are not here to test you. We are testing the application. We are trying to learn what is efficient / inefficient and what is easy / hard to do with the application.

Throughout the session I will ask you to try very specific activities. Some activities might seem simple to you. Other activities might seem difficult. And there will be some activities that you will not able to complete. I am telling you this because I want you to remember that we are not testing you. We are testing the application.

The way the session will work is; I will describe a clinical scenario. Once we both agree you understand what I am asking you to do, you will start the activity. I am not going to interact or talk to you while you are completing the activity. I do want you to talk aloud about what you are doing. You will say things like I am clicking <say the place you clicked>. Both _____ and I will be taking notes about what you are doing.

Because I am not going to be talking with you while you do the activities, I want you to make it clear to me when you are done with an activity by saying "I'm done." There are a number of reasons you might be done.

1) Done because you completed the activity, you know you have completed the activity. And you are done.
2) Done because you have tried, you know you have not completed the activity, but you are not going to try anything else.
3) Done because you feel like if you asked a question you could finish the activity.

Do you have any questions before we begin?

Medication Allergy List

Patient is _____ Andersen

The patient has come in for a blood pressure follow-up. The patient reports:

- his blood pressure is not entirely under control, and
- he has a persistent cough which started around the same time he started Lisinopril
- In addition, the patient tells you that his/her reaction to Ibuprofen has gotten worse since he/she was here last. He used to have a mild rash but now it is a severe rash.

Review the patient's existing allergies and make updates based on the information provided.

Here is your cheat sheet.
Do you have any questions about what I am asking you to do?
Remember to talk out loud as you complete the task and tell me when you are done.

Task	*Path*	*Errors*	*Pass/PasswHelp/Fail*
START CLOCK			
Task 1.1: Select patient and go to Allergies module Additional Details Added:			
Task 1.2: Change existing patient's drug allergies – Ibuprofen Click OK			
Task 1.3: Add New drug allergy information – Ace Inhibitor (Lisinopril) Click OK			
Task 1.4 Review and act on drug x allergy interaction alert Please note where reviewed: • View via mouse over			

• View by click and show • View at sign off Did they Override?			
Task 1.5: Confirm you are viewing patient's active and inactive medication allergies.			
STOP CLOCK			

Error Discussion
<<moderator probes on tasks that the participant did not successfully pass, walk them through golden path>>

Medication List

We are still doing activities with _____ Andersen

Now I am going to have you review and update the medications:

Change Metoprolol and eprescribe> <For reference only - dose from 50mg tablet to the 100mg, tablet. Qty: 90, Refills x2
Add Paxil < For reference only - 20MG tabs, Qty: 90, Refills x1>
Discontinue St. John's Wort because patient is no longer taking.
Electronically send the medications to the patient's pharmacy.
Review the patient's existing medications and make updates based on the information provided.

Here is your cheat sheet.
Do you have any questions about what I am asking you to do?
Remember to talk out loud as you complete the task and tell me when you are done.

Task	*Path*	*Errors*	*Pass/PasswHelp/Fail*
START CLOCK			
Task 2.1 Go to Medication module			
Task 2.2: Change Metoprolol dose from 50 mg tablet to 100 mg tablet. ePrescribe OK			
Task 2.3: Add Paxil 20mg tablets *ePrescribe* *OK*			

Task	*Path*	*Errors*	*Pass/PasswHelp/Fail*
Task 2.4 Review and act on drug x drug interaction alerts Drug x Drug Paxil and St. John's Wort, Paxil and Metoprolol Caution alert (Paxil for patient over 65)			
Task 2.5: Discontinue St. John's Wort Discontinued St. John's Wort			
Task 2.6: Confirm you are viewing patient's active and inactive medications in meds list.			
Task 2.7 Sign off on the Note Confirm ePrescribe			

Clinical Information Reconciliation

Patient is _____ Young

Moderator says:

There is a new feature in the EHR that is used to reconcile clinical information from an external source with information in this EHR. For example, let's say the patient had a hospital visit. The hospital will send your practice the clinical information from the hospital visit and your team can reconcile that information with the information in your EHR.

Are you familiar with this new feature?

I am going to work with you as we reconcile Allergies. Then I am going to have you reconcile the Problems and the Medications. Just so we are on the same page, for some of these activities I am going to ask you to do things that you would not do if you were using you clinical judgment. So we are going to use the cheat sheet to decide how to reconcile each item.

Here is the cheat sheet.
<point to the cheat sheet>
You can see we are going to reconcile Allergies, Problems and Meds. We will get to the details when we reconcile.
To start this task: open the patient < patient > there is a document on hold.

Task	Path	Errors	Pass/PasswHelp/Fail
Let's start with reconciling the allergies			
HPI			

You start by clicking the Reconciliation Button. We are going to do Allergies, so click the allergies tab at the top. As you orient yourself to the screen, the left side is information from the external source; like the hospital. The right side is the information currently in your system. You see the patient currently has no Allergies documented in your EHR. See the Drop Down at the top left (open Document to Reconcile. This is where there might be documents from different places that need to be reconciled for this patient. For example, the document from the hospital, from the surgeon, etc. Let's just do the one that is selected. As you finish reconciling the information from one document e.g., the one from the hospital, then the information from the next document e.g., from the surgeon, automatically fills in. Because we are only with you an hour, we are only going to do one document from the list. Next to this drop down is a button to mark as reviewed. You should not click that until you have reconciled your allergies, problems and meds. Once you click mark as reviewed, you do not have access to the information from the other place. Look at the cheat sheet. It says update your EHR with the Augmentin allergy information from the other place. So you click to check off Augmentin. And you click the Add to List button. See how the Augmentin now shows on the right side. Once you have the allergy on the right side you can Edit it. Click the check box and click the Edit button. If you needed to remove it for some reason, you can click the check box and click the Remove button.			
Any questions before I have you Reconcile the Problems?			

Remember to use the cheat sheet. Talk out loud and tell me when you are done.			
START CLOCK			
Task 3.1 Click Problems Tab			
As you orient yourself to the screen, *Tell me what is the information showing on the left side?* Task 3.2 Response to Left Side *What is the information showing on the right side?* Task 3.3 Response to Right Side *Ok use the Cheat Sheet and reconcile the Problems.*			
If participant is not using the cheat sheet – point and read: *Task 3.2 Update Centricity EHR by bringing the problem, Hypertension, from the external system into Centricity*			
Task 3.3: If participant is not using the cheat sheet – point and read: *Do not bring in the Problem, Congestive Heart Failure, to Centricity* No action – say Done			
Meds			
Task 3.4: As you orient yourself to the screen, *Tell me what is the information showing on the left side?* Task 3.5 Response to Left Side *What is the information showing on the right side?* Task 3.6 Response to Right Side *Ok use the Cheat Sheet and reconcile the Problems.*			
Use the Cheat sheet and reconciled the Meds.			
Task 3.5: If participant is not using the cheat sheet – point and read: *Update the Centricity EHR with Lisinopril from the other place*			
Task 3.6: If participant is not using the cheat sheet – point and read: *Update the Centricity EHR with the Centricity EHR with*			

Lorazepam from the external list			
Task 3.7: If participant is not using the cheat sheet – point and read: *Update the Centricity EHR with the Centricity EHR with Furosemide from the external list*			
Task 3.8: Show me how you will get rid of the duplicates Done			
Task 3.9: Let's say you have what you want from the outside place. How do you confirm that your Problems, Allergies, and Meds are Reconciled? Mark as Reviewed			
STOP CLOCK			

Error Discussion
<<moderator probes on tasks that the participant did not successfully pass, walk them through golden path>>

Clinical Decision Support

Patient is _____ Blackwell
The patient is returning for hypertension follow-up.
Review the chart before seeing the patient.
Find dosing information about the patient's current medications and potential adverse effects.
Do you have any questions about what I am asking you to do?
Remember to talk out loud as you complete the task and tell me when you are done.

Task	Path	Errors	Pass/Pass w Help/Fail
START CLOCK			
Task 4.1 Find dosing information about the patient's current medications and potential adverse effects. Get to med list Did they Click ref green button? P F			
Task 4.2 *Find normal range information about LDL* *(hint – Can get to micro Micromedex information)* Did they click Ref button P F See Micromedix			
STOP CLOCK			

Step 2: The MA has recorded vital signs and reason for visit. Use the document on hold for you and go to Vital Signs CCC.
Review vital signs.
Do you have any questions about what I am asking you to do?
Remember to talk out loud as you complete the task and tell me when you are done.

Task	Path	Errors	Pass/PasswHelp/Fail
START CLOCK			
Task 5.1 Click the Vital Signs CCC. *There are a number of CDS features on this page.* *Is the yellow indicator meaningful/not meaningful to you?* Do they see Yellow indicator P F *Where can you find the citation for the source of the clinical guidance?* Did they click Ref Button - P F			
Task 5.2 *On the Hypertension(Q&E-CCC) form, complete the assessment tab to calculate the risk category.* Did they click Hypertension Q&E- CCC Did they click HTN Assessment Tab *What is their category?* *What formula is being used to calculate this risk category?* Did they click Ref button P F			
Task 5.3 *On the treatment tab, prescribe an diuretic .* Did they click the diuretic Button? P F Understand Act			
STOP CLOCK			

Step 3: Continuing with this visit, use the Test Management.
On the test management form order tests and labs based on guidance for Diabetes.
Do you have any questions about what I am asking you to do?
Remember to talk out loud as you complete the task and tell me when you are done.

Task	Path	Errors	Pass/PasswHelp/Fail
START CLOCK			
Record Assessment and Plan for Diabetes CDS **Test Management form**			

Select Diabetes-non-insulin dependent The following Services are now due… P F Understand Act Commit Orders **Use the CPOE form** to record your assessment CDS: Medication list Understand Act CDS: Benefit from Aspirin Understand Act CDS: Document Contraindication to Aspirin Understand Act CDS: Test and Services Due Understand Act CDS: Review Understand Act CDS: Order Tests and Services Understand Act CDS: problem list… P F Understand Act Click Yellow Commit button Click “Load documentation” – record that the patient has had a prior adverse reaction Record Contraindication			
STOP CLOCK			

Use the CPOE form to record your assessment preventive care. Update the clinical lists and place orders as needed.

Task	Path	Errors	Pass/PasswHelp/Fail
START CLOCK			
Task 7.1 Assess Preventative Care CPOE form On Assessment # 2 drop down > Select Preventative Health Care Task 7.2 CDS: The following Services are now due… P F • Click Yes – See items that are due - click OK for more – Order? o Yes o No • Click No - Task 7.3 CDS: Diagnosis : ICD-V70.0… P F • Click Yes – order colonoscopy now? • Click No - Task 7.4 Commit Assessment • They get a pop up saying since the problem being assessed in not in the problem list… Click OK			
Task 7.5 *Add instructions to the Lipid Panel. Add "fast for 12 hours before the test (no food only water)" <pointing to cheat sheet)* Did they click the Orders Button. P F Did they Click Lipid Profile P F Did they enter text in Instructions P F			
Task 7.6 *Change the mammogram to Westfall Imaging.* Did they Click mammo (on that same Update Orders screen) P F Did they click "…" in Test Provider Westfall is selected by default Did they click OK			
STOP CLOCK			

16.2.2 Configuration Moderator Guide

EMR MODERATOR GUIDE	Summative

Participant:	_____	**#:**	_____
Location:	**Remote** _____	**Date:**	_____
Specialty:	_____	**Time:**	_____

INTRODUCTION

<<show welcome PPT Slide 1>>
Hello. My name is < >. Thank you again for coming to evaluate this application today. Our understanding is that you can stay for 30 minutes. Is this still the case?
Just so we are all on the same page... We have you here today to evaluate the extent to which the application meets Meaningful Use certification criteria related to configuration.
The first thing I would like to do is to show you this **consent form** to participate.
<<show consent form – provide highlights of form >>
While you're reading this, let me just give you the highlights. This is saying that you're a volunteer. As a volunteer you need to know that you can leave the session at any time. We'd like to collect data from you. The data includes our conversation, all the screens that you go to, and all of your mouse clicks. We'd like to audio and video record the session today. The recording will include our conversation, all the screens you go to and all of your mouse clicks. Do you have any questions or concerns?
Please read it and let me know if you agree to participate.
Just a reminder, everything is being audio and video recorded now.
<<start recording - shows welcome PPT Slide 2>>
This is what you agreed to on the consent form – I want it to be the first thing on the video recording form now on.

I am going to read this introduction to you because I want to be sure that I don't miss anything and I want to say the same thing to everyone.
I am from an independent consulting company. I am not employed at GE. Please take advantage of this opportunity to give the GE team feedback about the application we are going to look at today.
Remember we are not here to test you. We are testing the application. We are trying to learn what is easy and what is hard; what is efficient and inefficient to do with the application.
Throughout the session I will ask you to do very specific activities. Some activities might seem simple to you. Other activities might seem difficult. And there will be some activities that you will not able to complete. I am telling you this because I want you to remember that we are not testing you. We are testing the application.
When you are doing these activities, I want you to talk aloud about what you are doing and where you are clicking. You will say things like I am changing the such and such so I am clicking <say the place you clicked>. I will be taking notes about what you are doing.
Because we are using a test environment that others are also using we are not actually going to make any changes, so please do not ever click the Save or Update button. I will remind you about this a lot.

Do you have any questions before we begin?

<<moderator passes control to participant>>
Ok, you have control of the keyboard and the mouse....
Few questions before we begin the task:

- Are you a GE employee?
- Describe to me a bit about your role:
  - What is your Job title?
  - Please provide me with a quick description about what you do.
  - How long have you been doing EHR configuration work?
- Do you have clinical, pharmacy and/or IT experience? You know how sometimes there are nurses who become a computer person, I just wanted to know what your background is. *(We want to find out if they have a clinical or pharmacist background, or are just a computer person who happens to do work in the system)*
- When you are doing the configuration of a system, do you have anything that you use so you know where to click? Something that tells you shortcuts in the system? Anything like that?
- *If only survey:* Do you use documentation to find commands and settings? *(they may have information to use the system, and also information specific to a user to make configuration changes, probe)*

TASK 1
§ 170.314(a)(2) Drug-drug, drug-allergy interaction checks- (ii)(A) Adjustment
Enable the severity level of interventions provided for drug-drug interaction checks to be adjusted.

Scenario & Tasks
Set the system so that major drug-drug interactions display but moderate drug-drug interaction alerts do not display.
Do you have any questions about what I am asking you to do?
Remember to talk out loud as you complete the task.
Start when you are ready.

Task	***Observations***	***Errors***	***Pass/ Fail***
Start Time			
GO menu			
Navigation			
Change Severity of Drug/drug interaction to 'Major'			
With the severity drop down open Moderator ask: What drugxdrug interaction alerts will show if you select None:			

Minor: Moderate: Major:			
Moderator ask: Now set the system so that all drug-allergy interaction warnings display to the users.			
Stop Time			

TASK 2
§ 170.314(a)(2) Drug-drug, drug-allergy interaction checks- (ii)(B) Adjustment

Scenario & Tasks

Update the system so that those assigned to the physician role are able to set drug interaction severity levels.

Do you have any questions about what I am asking you to do?
Remember to talk out loud as you complete the task.
Start when you are ready.

Task	***Observations***	***Errors***	***Pass/ Fail***
Start Time			
Administration module			
Navigation			
Checks the permission, "Change interactions preferences"			
Stop Time			

TASK 3

§ 170.314(a)(8) Clinical decision support (CDS)

Enable interventions and reference resources specified in paragraphs (a)(8)(i) and (ii) of this section to be configured by a limited set of identified users (e.g., system administrator) based on a user's role.

Scenario & Tasks

There is a new privilege under Chart which enables a user or role to "Access to Clinical Decision Support". You need to ensure that the users with the Role "Nurse" have this privilege selected.

Do you have any questions about what I am asking you to do?
Remember to talk out loud as you complete the task.
Start when you are ready.

.

Task	*Observations*	*Errors*	*Pass/ Fail*
Start Time			
GO menu			
Setup			
Navigation			
User clicks on the privilege "Access Clinical Decision Support"			
Stop Time			

Let's go to the Home Screen.
(After cancelled out of all windows) If you were doing these configuration changes as part of your job with your system, would you be done after you saved these kinds of changes or would there be additional steps before you were done?
(If participant does not describe verification) Do you have a process to verify that configuration changes are working in the clinical application or do you just know they work because you made the changes in the configuration area of the application?

EXIT QUESTIONS & SUS

That is all the tasks we have for you to go through today. We have one final questionnaire for you. Please base your responses on today's experiences.
<<moderator administers SUS >>

16.3 Memory Aid

Clinical

Medication Allergy List

Change Ibuprofen
- from mild rash to severe rash

Add New drug allergy Lisinopril
- Severe Cough

Medication List

Change Metoprolol dose from 50mg tablet to the 100mg, tablet.
- Qty: 90, Refills x2 and eprescribe.

Add Paxil 20MG tabs
- Qty: 90, Refills x1

Discontinue Drug St. John's Wort
Electronically send the medications to the patient's pharmacy.

Clinical Information Reconciliation

Reconcile Problems:
- Update Centricity EHR by bringing the problem, Hypertension, from the external system into Centricity
- Do not bring in the Problem, Congestive Heart Failure, to Centricity

Reconcile Medication Allergies:
- Augmentin, mild, skin rash – update the Centricity EHR with all the information from the External source

Reconcile Medications:
- Update the Centricity EHR with Lisinopril from the external list
- Update the Centricity EHR with Lorazepam from the external list

Clinical Decision Support

Review and act on each CDS advisory

Configuration

Task 1:
Set the system so that major drug-drug interactions display but moderate and minor drug-drug interaction alerts do not display to the users.

Now set the system so that only Severe and Critical drug-allergy interaction warnings display to the users.

Task 2:
Update the system so that those assigned to the physician role are able to set drug interaction severity levels.

Task 3:
There is a new privilege under Chart which enables a user or role to “Access to Clinical Decision Support.” You need to ensure that the users with the Role “Nurse” have this privilege selected.

16.4 System Satisfaction

Date: _____ Participant #:_____

The System Usability Scale (SUS)

1.) I think that I would like to use this system frequently

1	2	3	4	5
Strongly Disagree		Neither Disagree nor Agree		Strongly Agree

2.) I found the system unnecessarily complex

1	2	3	4	5
Strongly Disagree		Neither Disagree nor Agree		Strongly Agree

3.) I thought the system was easy to use

1	2	3	4	5
Strongly Disagree		Neither Disagree nor Agree		Strongly Agree

4.) I think that I would need the support of a technical person to be able to use this system

1	2	3	4	5
Strongly Disagree		Neither Disagree nor Agree		Strongly Agree

5. I found the various functions in this system were well integrated

1	2	3	4	5
Strongly Disagree		Neither Disagree nor Agree		Strongly Agree

6. I thought there was too much inconsistency in this system

1	2	3	4	5
Strongly Disagree		Neither Disagree nor Agree		Strongly Agree

7. I would imagine that most people would learn to use this system very quickly

1	2	3	4	5
Strongly Disagree		Neither Disagree nor Agree		Strongly Agree

8. I found the system very cumbersome to use

1	2	3	4	5
Strongly Disagree		Neither Disagree nor Agree		Strongly Agree

9. I felt very confident using the system

1	2	3	4	5
Strongly Disagree		Neither Disagree nor Agree		Strongly Agree

10. I needed to learn a lot of things before I could get going with this system

1	2	3	4	5
Strongly Disagree		Neither Disagree nor Agree		Strongly Agree

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Supporting the Meaningful Use 2014 edition certification of Centricity Practice Solution v12 and Centricity EMR v9.8, we offer the following attestation regarding certification criterion 170.314(g)(4) – Quality Management System.

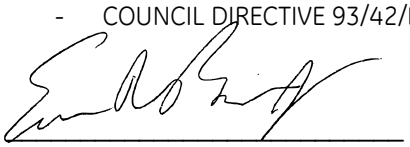
The GE Quality Management System (QMS) was in place during the development of Centricity Practice Solution v12 and Centricity EMR v9.8, supporting the criteria for which we are applying for certification.

Details of the QMS are detailed in the provided document, "CPS 12 IDP M1.doc", specifically Sections:

- Sec. 4: PRD rev 6 and Site Quality plans
- Sec. 7: DHF
- Sec. 8: Design Input Strategy
- Sec. 9: Design Output Strategy
- Sec. 10: Traceability Strategy
- Sec. 12: Risk Management Strategy
- Sec. 15: Design Reviews
- Sec. 16: Defect Management Strategy
- Sec. 20: Design Verification Strategy
- Sec. 21: Design Validation Strategy

The quality standards and regulations that apply to the QMS are:

- ISO 13485:2003 Quality Management System for Medical Devices
- ISO 9001:2008 Quality Management System
- 21 CFR Part 820 Quality System Requirements
- 21 CFR Part 11 Electronic Records and Signatures
- Canadian Medical Devices Regulations including Canadian Medical Device Conformity Assessment System (CMDCAS)
- COUNCIL DIRECTIVE 93/42/EEC concerning medical devices



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Supporting the Meaningful Use 2014 edition certification of Centricity Practice Solution v12 and Centricity EMR v9.8, we offer the following attestation regarding certification criterion 170.314(d)(2) – Auditable Events and Tamper Resistance.

Regarding the ability to disable audit logs:
Typical users cannot disable audit logging, only a very limited number of system administrators that are granted the proper security permissions have the access to disable audit events and/or logs.

Regarding the ability to disable audit log status:
Users cannot disable the audit log status.

Regarding the ability to disable encryption status:
Typical users cannot disable encryption. Encryption of the audit log occurs at the database-level, and by design, cannot be disabled. Encryption of the end user device is not required as no PHI is stored on the end user device.

Regarding deletions related to electronic health information:
Users cannot permanently delete any electronic health information, historical clinical records are retained in the database.

Regarding methods of protecting 1) recording of actions related to electronic health information, 2) recording of audit log status, and 3) recording of encryption status) from being changed, overwritten, or deleted by the EHR technology:
The system has logging capability related to Creating, Modifying and Removing electronic health information (Clinical Health information is not deleted from the EHR). This is achieved by selecting "audit events" which record actions based on event type. A limited set of users with the proper administrative security privileges select or de-select the audit events to be recorded that pertain to electronic health information.

The system by default and design will record the status and/or any changes to the audit event logging. This is achieved through a pre-identified audit event that will log any and all changes that occur to the audit event logging. This capability cannot be disabled.

The system, at the database-level, will record the status and/or any changes to the encryption status. This capability cannot be disabled

Regarding detection of audit log alteration:
The system, at the database-level, will record the status and/or any changes to the encryption status. This capability cannot be disabled.

We have a secondary audit table for tracking changes to our main audit table. In the secondary table we only log malicious changes to the primary table which are updates or deletes of records. A trigger in the database detects the event and logs both the original state of the data, the new state (to identify data that was deleted or altered), and the user who made the change.

To make changes to the audit table, a user must have been granted “update” permission to the table; the only user who would have access is a system administrator (An application user, including "superuser", does not have the ability to make updates to this table) who has full access to the database; this is very closely controlled. Normal operation doesn’t include updates or deletes to log tables, so any entry in the secondary audit table makes it very visible if tampering occurs. The secondary table does get updated when specific patient charts are merged or deleted from the system, but those are infrequent and known events that are easy to reconcile.

If an entry is created/altered/deleted in the secondary audit table (which tracks changes to our main audit table), a “flag” (system message that displays immediately after login, on a specific “dashboard” used for alerts) is sent to the designated system administrator.

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