CliniComp, Intl.

Usability Testing Report of *CliniComp| EHR®* v.213.03

Criteria Covered:
170.315 (a)(1) Computerized Provider Order Entry (CPOE) – medications
170.315 (a)(2) CPOE laboratory
170.315 (a)(3) CPOE diagnostic imaging
170.315 (a)(4) Drug-drug, Drug-allergy Interaction Checks for CPOE
170.315 (a)(5) Demographics
170.315 (a)(6) Problem List
170.315 (a)(7) Medication List
170.315 (a)(8) Medication Allergy List
170.315 (a)(9) Clinical Decision Support
170.315 (a)(14) Implantable Device List
170.315 (b)(2) Clinical Information Reconciliation and Incorporation
170.315 (b)(3) Electronic Prescribing
170.315 (b)(11) Decision Support Interventions

P/N: 250-70027 – Revision 2
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REVISION HISTORY

LEVEL	DATE	REVISION DESCRIPTION	ORIGINATOR	REVISION
1.0	22-May-2020	Initial Version	M. Nater	Original
2.0	25-Nov-2024	Updated to include 170.315 (b)(11) Decision Support Intervention tasks, starting at section 6.	S. Smith	Revision 2

Contents

Preface

DOCUMENT PURPOSE

This document provides information regarding the Safety-Enhanced Design Testing of *CliniComp|EHR* modules v213.03. This document reflects the results from two usability tests. The initial usability testing was performed in 2016, and the results are reflected in sections 1-5. Additional usability testing was performed in 2024 for the 170.315(b)(11) Decision Support Interventions (DSI) certification criteria, and the results are reflected in sections 6-10.

INITIAL TESTING INFORMATION	
Date of Usability Test:	December 7 – 8, 2016
Date of Report:	
Report Prepared By:	CliniComp, Intl.
Study Moderator:	Sheryl Crisologo, Clinical Analyst Study Moderator sheryl.crislogo@clinicomp.com
Quality and Regulatory Affairs:	Dessi Lyakov-Stinger, Manager Dessi.lyakov@clinicomp.com
Testing Location:	(800) 350-8202 9655 Towne Centre Drive San Diego, CA 92121-1964
170.315(B)(11) TESTING INFORMATION	
Date of Usability Test:	November 21, 2024
Date of Report:	November 25, 2024
Report Prepared By:	CliniComp, Intl.
Study Moderator:	Sharlie Smith, SVP Product Study Moderator sharlie.smith@clinicomp.com
Quality and Regulatory Affairs:	Dessi Lyakov-Stinger, Manager Dessi.lyakov@clinicomp.com
Testing Location:	(800) 350-8202 9655 Towne Centre Drive San Diego, CA 92121-1964

DOCUMENT AUDIENCE

This guide is intended for users of *CliniComp|EHR* v213.03.

INDUSTRY STANDARD UCD REFERENCES

NAME	DESCRIPTION
NISTIR 7741	This document provides NIST guidance for those developing electronic health record (EHR) applications who need to know more about processes of user-centered design (UCD). An established UCD process ensures that designed EHRs are efficient, effective, and satisfying to the user.
Citation	NIST Guide to the Process Approach for Improving the Usability of Electronic Health Records

TERMS AND ACRONYMS

TERM	DEFINITION
CCI	CliniComp Intl.
CPOE	Computerized Provider Order Entry
EHRUT	Electronic Health Record Under Test
ID	Participant Identification
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
MD	Doctor of Medicine
NIST	National Institute of Standards and Technology
RN	Registered Nurse
SUS	System Usability Scale

1 Executive Summary

The CliniComp Intl. (CCI) Clinical Analyst group conducted a usability test of the *CliniComp|EHR* on December 7-8, 2016, in San Diego, California. The purpose of the testing was to validate the usability of the current user interface and provide evidence of the usability of the Electronic Health Record Under Test (EHRUT). Eleven healthcare clinicians matching the target demographic criteria served as participants (*see* Appendix 2) using the EHRUT module in simulated, but representative tasks.

This study collected performance data on twelve tasks typically performed in an EHR

- Utilizing patient demographic information
- Utilizing Clinical Decision Support
- Medication allergy list reconciliation
- Medication list reconciliation
- Using Computerized Provider Order Entry (CPOE) for diagnostic imaging orders
- Using CPOE for medical orders
- Using CPOE drug-drug, drug-allergy interaction checks
- Using CPOE for laboratory orders
- Utilizing an implantable device list
- Problem list reconciliation
- Clinical information reconciliation and incorporation
- Electronic Prescribing

At the start of the two-day study, an administrator greeted participants and asked each to review and sign an informed consent and non-disclosure agreement (*see* Appendix 3 and Appendix 4). The administrator informed the participants they could withdraw at any time. All but one participant had prior experience with the EHRUT. The administrator introduced the test and instructed participants to complete the series of tasks, given one at a time, using the EHRUT. A brief overview was provided on how to navigate the *Patient Control* screen and access a patient record. This overview did not include further instruction on features or functionality of the tasks to be tested. During testing, the administrator timed each test and, along with data loggers, recorded user performance data on paper and electronically. The administrator and data loggers did not provide direction to participants on how to complete tasks.

The following lists the type of data collected for each participant:

- Number of tasks successfully completed within the allotted time without assistance
- Time to complete the tasks
- Number and types of errors
- Path deviations
- Participant verbalizations
- Participant satisfaction ratings of the system
- Participant commentary

All participant data was de-identified to eliminate connection from participant identity to the data collected. Following the conclusion of the testing, participants completed the System Usability Scale Questionnaire and were compensated with payment at an hourly rate through a contracted payroll agency. In accordance with the examples set forth in the NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records, various recommended metrics were used to evaluate the usability of the *CliniComp|EHR*. Table 1 summarizes the performance and rating data collected. For further descriptions of the measures, rationale, and scoring, *see* section 3.10 Data Scoring.

Table 1: Summary of Test Results

MEASURE	N	TASK SUCCESS	PATH DEVIATION	TASK TIME (SEC)		ERRORS	TASK RATING* 1=EASY
Task	#	Mean (SD)	Deviations (Observed/ Optimal)	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Mean (SD)
Utilizing patient demographic information	2	97% (5.2%)	1.0	25.3 (4.2)	0.4	0 (0)	1.1 (0.1)
Utilizing Clinical Decision Support	3	76% (26%)	1.0	36.5 (7.1)	0.4	0 (0)	1.3 (0.3)
Medication allergy list and reconciliation	4	85% (21%)	1.0	94.5 (20.1)	0.6	0.1 (0.1)	2.1 (0.3)
Medication list and reconciliation	5	94% (10.5%)	1.0	120.9 (16.2)	0.7	0.1 (0.1)	2.0 (0.3)
Using Computerized Provider Order Entry (CPOE) for diagnostic imaging	6	73% (36.7%)	1.0	66 (12.4)	0.5	0.03 (0.07)	1.6 (0.5)
Using CPOE for medication orders	7	100% (0%)	1.1	56 (14.3)	0.5	0.03 (0.07)	1.2 (0.2)
Using CPOE drug-drug, drug-allergy interaction checks	8	97% (5.2%)	1.0	7.0 (4.2)	0.3	0 (0.0)	1.2 (0.1)
Using CPOE for laboratory orders	9	100% (0%)	1.0	29.2 (8.0)	0.5	0.1 (0.1)	1.3 (0.2)
Utilizing the implantable device list	10	100% (0%)	1.0	21.5 (7.2)	0.4	0.0 (0.1)	1.3 (0.3)
Problem list reconciliation	11	73% (21%)	1.0	111.7 (20.1)	0.6	0.1 (0.1)	2.0 (0.7)
Clinical information reconciliation and incorporation**	12	71% (36.1%)	0.9	71 (410)	0.5	0.1 (0.1)	2.2 (0.6)
Electronic Prescribing	13	91% (10.5%)	1.0	101 (30.8)	0.6	0.0 (0.0)	1.4 (0.5)

*Task rating 1-5; where 1 is “Very Easy” and 5 is “Very Difficult.”

**The clinical information reconciliation and incorporation tasks include the Medication Allergy List Reconciliation, Problem List Reconciliation, and Medication Reconciliation.

1.1 Summary of Results

The EHRUT received a score of **72.5** for subjective satisfaction based on the System Usability Scale (SUS) Questionnaire (*see* Appendix 7). Broadly interpreted, scores under 60 represent systems with poor usability, and scores over 80 are considered above average. [1]

In addition to the performance data, qualitative observations were found:

1.1.1 Major Findings

- Participants excelled in using the CPOE module for six out of the seven tasks.
- During the CPOE tests, 57% of the users appeared to have a preference to use standard order sets instead of using the search or browse feature for single orders, which resulted in decreased steps compared to our defined path.
- Users with previous experience using the system were measured to be more satisfied, contributing to a 100% success rate for several tasks. This result was due to the participant taking a different path (used in their current workflow at their hospital inpatient setting) in the CPOE related task. This experience resulted in a lower number of steps as compared to the test's defined path.
- Participants preferred using the right-click File Menu feature for navigation.

1.1.2 Areas for Improvement

- Participants suggested that CCI provide functionality for a user to redisplay the *Clinical Decision Support* screen once the registered nurse (RN) or the doctor of medicine (MD) has acknowledged the warning. Currently, there is no way to revisit the *Clinical Decision Support Warning* screen.
- In the Clinical Information Reconciliation module, participants requested an enhancement to allow display of two notes side-by-side for review during use of the *Order Entry* screen. Also, they requested notes include the "date of last dose taken."
- The clinical information reconciliation feature for problem lists produced the lowest success rate. Feedback indicated that over 60% of our participants found the feature difficult to use.

1 See Tullis, T. & Albert, W. (2008). Measuring the User Experience. Burlington, MA: Morgan Kaufman (p. 149).

2 Introduction

Designed to facilitate clinician duties in both the outpatient and inpatient healthcare settings, the EHRUT consisted of the following applications within *CliniComp|EHR* v.213.03: CPOE, Implantable Devices, Clinical Decision Support, Clinical Information Reconciliation, and Electronic Prescribing. Each application included a user interface for the charting, viewing, modifying, and secure transmission of health information. The testing attempted to represent realistic exercises and conditions to validate the usability of the user interfaces and provide evidence of usability of the *CliniComp|EHR*. Measures of effectiveness, efficiency, and user satisfaction, such as task time and task success, were captured during the usability test.

3 Method

3.1 Participants

A total of eleven participated in usability testing. Participants included nine registered nurses and two nurse practitioners. Participant clinical expertise encompassed a variety of healthcare settings, including cardiothoracic surgery, emergency medicine, neonatal intensive care, and obstetrics. The participants were recruited by CCI's Clinical Analyst group and compensated for their time at an hourly rate established by a contracted payroll agency (*see* Appendix 9). Additionally, participants had no direct connection to the development or the organization producing the EHRUT, and participants were not from the vendor/testing organization. After the completion of all tasks, participants were given a demonstration of the system, similar to what end-users would receive from CCI during commercial implementation.

For test purposes, end-user characteristics were identified and translated into a participant questionnaire used to ensure that prospective participants met the criteria for the usability test (*see* Appendix 1). Recruited participants had a mix of backgrounds and demographic characteristics conforming to the recruitment screening criteria. Table 2 displays participant characteristics, including demographics, professional experience and specialty, computing experience, and user needs for assistive technology. Participant names were replaced with Participant Identification (ID) codes, so identifying data could not be correlated to individual participants.

Table 2: Participant Demographics and Characteristics

N	PART ID	GENDER	AGE	EDUCATION	OCCUPATION / ROLE	PROFESSIONAL EXPERIENCE (MONTHS)	COMPUTER EXPERIENCE (MONTHS)	PRODUCT EXPERIENCE (MONTHS)	ASSISTIVE TECHNOLOGY NEEDS
1	UT01	Male	30-39	Master's degree	RN	36	180	36	No
2	02	Male	30-39	Bachelor's degree	RN	120	240	120	No
3	03	Male	50-59	Bachelor's degree	RN	120	240	120	No
4	04	Female	60-69	Master's degree	RN	120	180	120	No
5	05	Female	60-69	Master's degree	NP	120	180	120	No
6	06	Male	50-59	Master's degree	RN	120	240	120	No
7	07	Female	30-39	Bachelor's degree	RN	36	180	96	No
8	8	Female	30-39	Bachelor's degree	RN	96	180	96	No
9	09	Female	30-39	Bachelor's degree	RN	96	240	96	No
10	10	Female	50-59	Master's degree	NP	120	240	120	No
11	11	Female	50-59	Bachelor's degree	RN	120	240	120	No

Eleven participants, matching the demographics in Table 2, were recruited, and all eleven participated in the usability test. No participants failed to report for the study. Participants were scheduled for two 8-hour sessions during standard working hours (8:30 am to 4:30 pm) in which they were allowed three cycles to perform the tasks. A spreadsheet was used to track the participant schedule and included each participant's demographic characteristics (*see* Appendix 2).

3.2 Study Design

The objectives of this test were to determine areas where the application performed well (effectively, efficiently, and with satisfaction) and where the application failed to meet participant needs. For specific objectives, see the Moderator's Guide (Appendix 5). The data from this usability test may serve as a baseline for future testing with an updated version of the *CliniComp|EHR* and/or comparison with other EHRs.

During the usability test, participants interacted with the *CliniComp|EHR*. Each participant used the EHRUT in the same location and was provided with the same instruction. The system was evaluated for effectiveness, efficiency, and satisfaction as defined by measures collected and analyzed for each participant:

- Number of tasks successfully completed within the allotted time without assistance
- Time to complete the tasks
- Number and types of errors
- Path deviations
- Participant's verbalizations (comments)
- Participant's satisfaction ratings of the system

For additional information about the various measures, *see* 3.9 Usability Metrics.

3.3 Tasks

Tasks were constructed to be realistic and representative of activities a user might perform with each *CliniComp|EHR* module, based on study objectives. Tasks were selected based on the frequency of use within the application, the criticality of the function, and the most troublesome for users.

TASK	TASK DETAIL	2015 ONC CRITERION TESTED
2	Utilizing patient demographic information	170.315 (a)(5) Demographics
3	Utilizing Clinical Decision Support	170.315 (a)(9) Clinical Decision Support
4	Medication allergy list and reconciliation	170.315 (a)(7) Medication Allergy List 170.315 (b)(2) Clinical Information Reconciliation and Incorporation
5	Medication list and reconciliation	170.315 (a)(8) Medication List 170.315 (b)(2) Clinical Information Reconciliation and Incorporation
6	Using Computerized Provider Order Entry (CPOE) for diagnostic imaging orders	170.315 (a)(3) CPOE- diagnostic imaging
7	Using CPOE for medical orders and drug-drug, drug-allergy interaction checks	170.315 (a)(3) CPOE- medications 170.315 (a)(4) CPOE- Drug-drug, Drug-allergy Interaction Checks for CPOE
8	Using CPOE for laboratory orders	170.315 (a)(2) CPOE- laboratory
9	Utilizing the implantable device list	170.315 (a)(14) Implantable Device List
10	Problem list and reconciliation	170.315 (a)(6) Problem List 170.315 (b)(2) Clinical Information Reconciliation and Incorporation
11	Medication Reconciliation	170.315 (b)(2) Clinical Information Reconciliation and Incorporation
12	Electronic Prescribing	170.315 (b)(3) Electronic Prescribing

3.4 Procedures

Upon arrival, participants were greeted, and their identity was verified and matched with a name on the participant schedule. Participants were then assigned a participant ID and introduced to their assigned data logger. Each participant reviewed and signed informed consent and release forms (*see* Appendix 3 and 4). The moderator witnessed the participant's signature and date.

To ensure that the test ran smoothly, 13 staff members participated in this test, including the usability moderator and 11 data loggers. The usability testing staff were experienced healthcare informaticists with a cumulative health information technology experience extending over 20 years in clinical, administrative, executive, and vendor settings.

The moderator administered the session, including instructions and task descriptions, monitored task times, and took notes on participant comments. One data logger was assigned to each participant to record task success, path deviations, number and type of errors, task times, obtain post-task rating data, and participant comments.

The moderator instructed the participants to perform the test tasks in the following ways:

- As quickly as possible
- Without assistance (administrators could give immaterial guidance and clarification on tasks, but no instructions on use)
- Without using a think-aloud technique

Participants were given a written copy of the tasks for each test. After the moderator described the scenario, task objective, and instruction to begin, the task timer started. The data logger stopped the task time once the participant indicated he or she completed the task. The moderator monitored the maximum allotted time per task, and data loggers captured all study data during the task process and after completion (*see 3.10* Data Scoring).

After all tests concluded, the following occurred:

- The moderator gave participants System Usability Scale Questionnaire (*see* Appendix 7), confirmed enrollment with the contracted payroll agency to ensure compensation, and thanked everyone for their participation.
- Participant demographics, testing success rates, time spent on each test, errors, deviations, verbal responses, and post-test questionnaires were recorded by the data logger in a spreadsheet for each test and participant.
- Participant time was captured on the payroll agency's timesheet by the data logger. All participants signed a receipt with the agency, indicating that they had received accurate compensation.

3.5 Test Location

The testing took place at CCI headquarters in San Diego, California. The testing facility included a waiting area and a quiet testing room with a table and a computer for each participant. Only participants, data loggers, and the moderator were present in the test room. To ensure that the environment was comfortable for users, noise levels were kept to a minimum and the ambient temperature within a normal office range. All safety instruction and evacuation procedures were valid, in place, and visible to participants.

3.6 Test Environment

The EHRUT would typically be used in a healthcare office or facility. For usability testing, the effort was conducted in a testing and training computer lab at CCI. The participants used Hewlett Packard® computers running Windows 8.1, which were connected to CCI's local network. The computers were equipped with 15-inch - 1280x1024 pixel resolution displays.

The application was set up on a test server by the CCI Service Support group according to EHRUT documentation describing the system set-up and preparation. Technically, the system performance (i.e., response time) was representative of what actual users would experience in field implementation. Additionally, participants were instructed not to change any of the default system settings (such as control of font size).

3.7 Test Forms and Tools

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

- Informed Consent
- Non-Disclosure Agreement
- Participant Questionnaire
- Moderator's Guide
- System Usability Scale Questionnaire

Examples of these documents are found in the Appendices. The Moderator's Guide (*see* Appendix 5) was devised to capture the required data. The data loggers captured participants' input and responses using digital timers and hand-written documentation.

3.8 Participant Instructions

The moderator read the following instructions aloud to all participants prior to the start of the usability testing (see Appendix 5):

> *Thank you for participating in this test. Your input is very important to us. Our session today will last approximately two working days. During that time, you will use an instance of an electronic health record.*
>
> *There will be a number of tasks that will need to be completed as well as a few questions that will need to be answered. Each task will need to be completed on your own, at your own pace with minimal possible errors or deviations. We ask that you do them as quickly and efficiently as possible with the instructions that we have provided. Please complete the task and do not attempt to do more than what is instructed.*
>
> *We must emphasize that we are not testing you or your ability to use the system- we are evaluating the usability of the system. We are not able to instruct or provide you with help on how to use the application beyond the provided instructions, but we may be able to provide help on other related issues. Please save your detailed comments until the end of the task or at the end of the session when we can discuss freely as a group.*
>
> *Overall, we are interested in how easy (or how difficult) this system is to use, what features, or functionality are useful to you, and how we could improve it. Please be honest with your opinions.*
>
> *The information you provide us will be kept confidential. Your name and any other identifying information will be omitted and not be associated with your comments. Should you feel it necessary, you are able to withdraw your participation at any time during the testing.*
>
> *The product you will be testing today includes the following applications within the CliniComp EHR: CPOE, Implantable Devices, Clinical Decision Support, Clinical Information Reconciliation, and Electronic Prescribing. Since we are testing specific functionality, the workflow many not seem complete, or the data may not make sense compared to your normal work processes.*
>
> *To access the system, you will be using a demo user and test patient record that correlate with your assigned participant number.*

Following the procedural instructions, participants were shown the *CliniComp|EHR*, and the first task given was to explore the system and make comments (10 minutes). Once this task was complete, the moderator gave the following instructions:

> *For each task, I will read the description to you and say, "Begin." At that point, please perform the task and say "Done" once you believe you have successfully completed the task. I would like to request that you not talk aloud or verbalize while you are doing the tasks. I will ask you your impressions about the task once you are done.*
>
> *Do you have any questions or concerns?*

Participants were then given 11 tasks to complete in three cycles over the course of two testing days. To view the list of tasks, see the Moderator's Guide (Appendix 5).

3.9 Usability Metrics

According to the 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 effectively, efficiently, and with an acceptable level of satisfaction. To this end, metrics for effectiveness, efficiency, and user satisfaction were captured during the usability testing. The goals of the tests were to assess:

1. Effectiveness of *CliniComp|EHR* by measuring participant success rates and errors
2. Efficiency of *CliniComp|EHR* by measuring the average task time and path deviations
3. Satisfaction with *CliniComp|EHR* module by measuring ease of use ratings

3.10 Data Scoring

Table 3 details how tests were scored and the time data analyzed.

Table 3: Data Scoring

MEASURES	RATIONALE AND SCORING
Effectiveness: Test Success	▪ A task was counted as a "Success" if the participant was able to achieve the correct outcome, without assistance, and within the time allotted on a per-task basis. ▪ The total number of successes was calculated for each task and then divided by the total number of times that task was attempted. The results are provided as a percentage. ▪ Task times were recorded for successes. Observed task times were divided by the optimal time for each task as a measure of optimal efficiency. ▪ Optimal task performance time, as benchmarked by expert performance under realistic conditions, were recorded when constructing tasks. For target task time information, see the Moderator's Guide (Appendix 5).
Effectiveness: Test Failures	▪ If the participant abandoned the test or task, did not reach the correct answer or performed it incorrectly, or reached the end of the allotted time before successful completion, the task was counted as "Failures." No task times were taken for errors. ▪ The total number of errors was calculated for each task and then divided by the total number of times that task was attempted. Not all deviations were counted as errors. This was expressed as the mean number of failed tasks per participant. ▪ On a qualitative level, an enumeration of errors and error types were collected.
Efficiency: Test Deviations	▪ The participant's path (i.e., steps) through the application was recorded. Deviations occurred 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. ▪ The number of steps in the observed path was divided by the number of optimal steps to provide a ratio of path deviation.
Efficiency: Test Time	▪ Each test was timed from when the administrator said "Begin" until the participant said, "Done." If he or she failed to say "Done," the time was stopped when the participant stopped performing the task. ▪ Only task times for tasks that were successfully completed were included in the average task time analysis. ▪ The average time per task was calculated for each task. Variance measures (standard deviation and standard error) were also calculated.
Satisfaction: Test Rating	▪ Participant's subjective impression of the ease of use of the application was measured by administering both a simple post-task question as well as a post-session questionnaire. After each task, the participant was asked "overall, on a scale of 1 to 5, where 1 is "Very Easy" and 5 is "Very Difficult," this task was ___." This data was averaged across participants. ▪ Common convention dictates that average ratings for systems judged easy to use are 3.7 or lower. ▪ To measure participants' confidence in and likeability of the *CliniComp|EHR* overall, the testing team administered the post-test SUS Questionnaire. Questions included, "I think I would like to use this system frequently," "I thought the system was easy to use," and "I would imagine that most people would learn to use this system very quickly." *See* Appendix 7).

4 Results

4.1 Data analysis and reporting

The results of the usability tests were calculated according to the methods specified in the Usability Metrics section above. All participants of this study followed the instructions, and no data were excluded.

The usability testing results for the EHRUT are detailed in Table 4 in accordance with the objectives and goals outlined in Section 3.2: Study Design.

Table 4: Test Results

MEASURE	N	TASK SUCCESS	PATH DEVIATION	TASK TIME (SEC)		ERRORS	TASK RATING * 1=EASY
Task	#	Mean (SD)	Deviations (Observed/ Optimal)	Mean (SD)	Deviations (Observed/ Optimal)	Mean (SD)	Mean (SD)
Utilizing patient demographic information	2	97% (5.2%)	1.0	25.3 (4.2)	0.4	0 (0)	1.1 (0.1)
Utilizing Clinical Decision Support	3	76% (26%)	1.0	36.5 (7.1)	0.4	0 (0)	1.3 (0.3)
Medication allergy list and reconciliation	4	85% (21%)	1.0	94.5 (20.1)	0.6	0.1 (0.1)	2.1 (0.3)
Medication list and reconciliation	5	94% (10.5%)	1.0	120.9 (16.2)	0.7	0.1 (0.1)	2.0 (0.3)
Using Computerized Provider Order Entry (CPOE) for diagnostic imaging	6	73% (36.7%)	1.0	66 (12.4)	0.5	0.03 (0.07)	1.6 (0.5)
Using CPOE for medication orders	7	100% (0%)	1.1	56 (14.3)	0.5	0.03 (0.07)	1.2 (0.2)
Using CPOE drug-drug, drug-allergy interaction checks	8	97% (5.2%)	1.0	7.0 (4.2)	0.3	0 (0.0)	1.2 (0.1)
Using CPOE for laboratory orders	9	100% (0%)	1.0	29.2 (8.0)	0.5	0.1 (0.1)	1.3 (0.2)
Utilizing the implantable device list	10	100% (0%)	1.0	21.5 (7.2)	0.4	0.0 (0.1)	1.3 (0.3)
Problem list reconciliation	11	73% (21%)	1.0	111.7 (20.1)	0.6	0.1 (0.1)	2.0 (0.7)
Clinical information reconciliation and incorporation**	12	71% (36.1%)	0.9	71 (410)	0.5	0.1 (0.1)	2.2 (0.6)
Electronic Prescribing	13	91% (10.5%)	1.0	101 (30.8)	0.6	0.0 (0.0)	1.4 (0.5)

*Task rating 1-5; where 1 is “Very Easy” and 5 is “Very Difficult.”

**The clinical information reconciliation and incorporation tasks include the Medication Allergy List and Reconciliation, Problem List Reconciliation, and Medication Reconciliation.

4.2 System Usability Scale

The EHRUT received a score of **72.5** for subjective satisfaction based on the SUS Questionnaire. Broadly interpreted, scores under 60 represent systems with poor usability; scores over 80 would be considered above average.[2] A summary of the SUS Questionnaire results per task or application tested within the EHRUT are included below:

DEMOGRAPHICS
1. 91% of the participants thought they would like to use this system frequently.
2. 91% of the participants found this system was NOT unnecessarily complex.
3. 82% of the participants found the system easy to use.
4. 91% of the participants thought a technical support person would NOT be needed to use this system.
5. 82% of the participants found the system to be well integrated.
6. 91% of the participants did NOT think there was too much inconsistency with the system.
7. 82% of the participants felt most people would learn to use the system very quickly.
8. 91% of the participants did NOT find the system to be cumbersome.
9. 82% of the participants felt very confident using the system.
10. 91% of the participants felt they did NOT need to learn a lot before they could get going with the system.

CLINICAL DECISION SUPPORT
1. 82% of the participants thought they would like to use this system frequently.
2. 82% of the participants found this system was NOT unnecessarily complex.
3. 82% of the participants found the system easy to use.
4. 100% of the participants thought a technical support person would NOT be needed to use this system.
5. 64% of the participants found the system to be well integrated.
6. 91% of the participants did NOT think there was too much inconsistency with the system.
7. 91% of the participants felt most people would learn to use the system very quickly.
8. 100% of the participants did NOT find the system to be cumbersome.
9. 91% of the participants felt very confident using the system.
10. 100% of the participants felt they did NOT need to learn a lot before they could get going with the system.

MEDICATION ALLERGY LIST AND RECONCILIATION
1. 100% of the participants thought they would like to use this system frequently.
2. 55% of the participants found this system was NOT unnecessarily complex.
3. 55% of the participants found the system easy to use.
4. 91% of the participants thought a technical support person would NOT be needed to use this system.
5. 73% of the participants found the system to be well integrated.
6. 82% of the participants did NOT think there was too much inconsistency with the system.
7. 73% of the participants felt most people would learn to use the system very quickly.
8. 73% of the participants did NOT find the system to be cumbersome.
9. 73% of the participants felt very confident using the system.
10. 91% of the participants felt they did NOT need to learn a lot before they could get going with the system.

2 See Tullis, T. & Albert, W. (2008). Measuring the User Experience. Burlington, MA: Morgan Kaufman (p. 149).

MEDICATION RECONCILIATION
1. 82% of the participants thought they would like to use this system frequently.
2. 45% of the participants found this system was NOT unnecessarily complex.
3. 36% of the participants found the system easy to use.
4. 100% of the participants thought a technical support person would NOT be needed to use this system.
5. 55% of the participants found the system to be well integrated.
6. 82% of the participants did NOT think there was too much inconsistency with the system.
7. 73% of the participants felt most people would learn to use the system very quickly.
8. 55% of the participants did NOT find the system to be cumbersome.
9. 45% of the participants felt very confident using the system.
10. 82% of the participants felt they did NOT need to learn a lot before they could get going with the system.

CPOE
1. 91% of the participants thought they would like to use this system frequently.
2. 91% of the participants found this system was NOT unnecessarily complex.
3. 82% of the participants found the system easy to use.
4. 100% of the participants thought a technical support person would NOT be needed to use this system.
5. 64% of the participants found the system to be well integrated.
6. 91% of the participants did NOT think there was too much inconsistency with the system.
7. 100% of the participants felt most people would learn to use the system very quickly.
8. 100% of the participants did NOT find the system to be cumbersome.
9. 91% of the participants felt very confident using the system.
10. 100% of the participants felt they did NOT need to learn a lot before they could get going with the system.

IMPLANTABLE DEVICES
1. 45% of the participants thought they would like to use this system frequently.
2. 82% of the participants found this system was NOT unnecessarily complex.
3. 82% of the participants found the system easy to use.
4. 100% of the participants thought a technical support person would NOT be needed to use this system.
5. 55% of the participants found the system to be well integrated.
6. 91% of the participants did NOT think there was too much inconsistency with the system.
7. 82% of the participants felt most people would learn to use the system very quickly.
8. 73% of the participants did NOT find the system to be cumbersome.
9. 82% of the participants felt very confident using the system.
10. 100% of the participants felt they did NOT need to learn a lot before they could get going with the system.

PROBLEM LIST
1. 64% of the participants thought they would like to use this system frequently.
2. 64% of the participants found this system was NOT unnecessarily complex.
3. 36% of the participants found the system easy to use.
4. 82% of the participants thought a technical support person would NOT be needed to use this system.
5. 36% of the participants found the system to be well integrated.
6. 82% of the participants did NOT think there was too much inconsistency with the system.
7. 64% of the participants felt most people would learn to use the system very quickly.
8. 55% of the participants did NOT find the system to be cumbersome.
9. 73% of the participants felt very confident using the system.
10. 82% of the participants felt they did NOT need to learn a lot before they could get going with the system.

CLINICAL INFORMATION RECONCILIATION
1. 82% of the participants thought they would like to use this system frequently.
2. 55% of the participants found this system was NOT unnecessarily complex.
3. 42% of the participants found the system easy to use.
4. 91% of the participants thought a technical support person would NOT be needed to use this system.
5. 55% of the participants found the system to be well integrated.
6. 82% of the participants did NOT think there was too much inconsistency with the system.
7. 70% of the participants felt most people would learn to use the system very quickly.
8. 61% of the participants did NOT find the system to be cumbersome.
9. 64% of the participants felt very confident using the system.
10. 85% of the participants felt they did NOT need to learn a lot before they could get going with the system.

ELECTRONIC PRESCRIBING
1. 73% of the participants thought they would like to use this system frequently.
2. 82% of the participants found this system was NOT unnecessarily complex.
3. 91% of the participants found the system easy to use.
4. 100% of the participants thought a technical support person would NOT be needed to use this system.
5. 73% of the participants found the system to be well integrated.
6. 91% of the participants did NOT think there was too much inconsistency with the system.
7. 82% of the participants felt most people would learn to use the system very quickly.
8. 100% of the participants did NOT find the system to be cumbersome.
9. 100% of the participants felt very confident using the system.
10. 100% of the participants felt they did NOT need to learn a lot before they could get going with the system.

4.3 Effectiveness

The effectiveness of the *CliniComp|EHR* was defined by the measurement of participant success rates. Most tasks were successfully completed at rates greater than 80% with seven tasks completed with rates greater than 90%. Problem list generated the lowest rate of completion at 73%. Only 36% of the users found this task easy to use, with participants indicating that it could be improved. To improve effective use in the future, the problem list display will be enhanced, and users will be provided improved training on the feature.

4.4 Efficiency

The efficiency of the *CliniComp|EHR* was defined by comparing the participant task performance times to a predefined optimal time. Optimal times ranged from 60-180 seconds, and the calculated grand mean for each task indicated that most tasks were completed efficiently. For the most part, participants followed the optimal path to complete each assigned task, but there were minor path deviations for some tasks. Overall, path deviations were minimal as illustrated by deviation ratios between 0.9-1.1 for all tasks. The one task that was determined to be least effective was the problem list and reconciliation of clinical information.

4.5 Satisfaction

Satisfaction with the *CliniComp|EHR* was measured as a subjective impression of the ease of use of the application. This was acquired by soliciting as an ease-of-use score for each task. The participants were asked to fill in the blank in the following statement: "On a scale from 1-5, where 1 is "very easy' and 5 is "very difficult, this task was____." The ease of use ratings for all tasks were between 1.1-2.0. Common convention dictates average ratings for systems judged "easy to use" as 3.7 or lower. EHRUT data revealed that the *CliniComp|EHR* was relatively easy to use.

To measure participants' confidence in and likeability of the *CliniComp|EHR*, the testing team administered the post-test SUS Questionnaire. The scores captured by this questionnaire resulted in a mean score of 72.5, which is interpreted as average usability for the *CliniComp|EHR*. Broadly interpreted, scores under 60 represent systems with poor usability, and systems with scores over 80 would be considered above average.

Participant commentary further clarified the SUS scoring and identified the areas for improvement.

4.6 Major Findings

The usability study indicated that our intended audience found most of the *CliniComp|EHR* easy to use. User satisfaction ratings were high, and task times fell into acceptable ranges for most of the task features. Participants expressed their satisfaction with the *CliniComp|EHR*, stating the system's ease of navigation and the likelihood of using it frequently.

The problem list and clinical information reconciliation task had the lowest completion rate. Only 36% of the participants found the problem list feature well-integrated with the *CliniComp|EHR*. Participants who completed these tasks did so in less time or steps than the optimal path, which contributed to a lower path deviation result. Participants who did not complete the tasks, expressed their frustration with this specific feature, as it was less intuitive compared to other parts of the *CliniComp|EHR*. This study confirmed that additional training or education is needed with the clinical information reconciliation feature in order to reduce frustration, improve performance times, and achieve task results within the optimal path.

Those who used the system frequently or had more experience with the system were more satisfied users. Several participants had over three years of experience using *Essentris* prior to this usability testing. This strong previous experience resulted in a 100% success rate for three tasks and shorter pathways, which were based on participant clinical workflows. With a few tasks, there were a couple of participants with little or no prior experience who achieved the specific task but not by the optimal method for completing the task.

Participant feedback indicated that user training and education has the potential for minimizing these concerns and can be addressed by a client training team.

5 Conclusion

5.1 Areas for Improvement

Participants made the following recommendations:

- Participants suggested that CCI provide functionality for a user to redisplay the *Clinical Decision Support* screen once the RN or the MD has acknowledged the warning. Currently, there is no way to revisit the *Clinical Decision Support Warning* screen.
- In the Clinical Information Reconciliation module, participants requested an enhancement to allow display of two notes side-by-side for review during use of the *Order Entry* screen. Also, they requested the notes should include the "date of last dose taken."
- Although some of the clinical information reconciliation tasks were within or below optimal times, the study confirmed the need for user training in clinical information reconciliation and the incorporation of features to make optimal tasks paths more obvious and to minimize frustration.

6 Executive Summary - Decision Support Interventions: 170.315 (b)(11)

The CliniComp Intl. (CCI) Clinical Analyst group conducted a usability test of the *CliniComp|EHR* on November 21, 2024, in San Diego, California. The purpose of the testing was to validate the usability of the current user interface and provide evidence of the usability of the Electronic Health Record Under Test (EHRUT). Ten healthcare clinicians matching the target demographic criteria served as participants (*see* Appendix 2) using the EHRUT module in simulated, but representative tasks.

This study collected performance data on the decision support intervention tasks typically performed in an EHR:

- Activate evidence based DSI when reviewing ordering a procedure
- Activate user-supplied predictive DSI when ordering a procedure
- Access plain language description for evidence based DSI
- Access plain language description for user-supplied predictive DSI
- Access, record and change source attributes for evidence based DSI
- Access, record and change source attributes for user-supplied predictive DSI
- Provide feedback/intervention response for evidence based DSI - Implantable Device Interaction

At the start of the one-day study, an administrator greeted participants and asked each to review and sign an informed consent and non-disclosure agreement (*see* Appendix 3 and Appendix 4). The administrator informed the participants they could withdraw at any time. All participants had prior experience with the EHRUT. The administrator introduced the test and instructed participants to complete the series of tasks, given one at a time, using the EHRUT. A brief overview was provided on how to navigate and access a patient record. This overview did not include further instruction on features or functionality of the tasks to be tested. During testing, the administrator timed each test and, along with data loggers, recorded user performance data on paper and electronically. The administrator and data loggers did not provide direction to participants on how to complete tasks.

The following lists the type of data collected for each participant:

Number of tasks successfully completed within the allotted time without assistance

Time to complete the tasks

Number and types of errors

Path deviations

Participant verbalizations

Participant satisfaction ratings of the system

Participant commentary

All participant data was de-identified to eliminate connection from participant identity to the data collected. Following the conclusion of the testing, participants completed the System Usability Scale Questionnaire. The participants volunteered their time and were not compensated. In accordance with the examples set forth in the NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records, various recommended metrics were used to evaluate the usability of the *CliniComp|EHR*. Table 5 summarizes the performance and rating data collected. For further descriptions of the measures, rationale, and scoring, *see* section 8.10 Data Scoring.

Table 5: Summary of Test Results

MEASURE	N	TASK SUCCESS	PATH DEVIATION	TASK TIME (SEC)		ERRORS	TASK RATING* 1=EASY
Task	#	Mean (SD)	Deviations (Observed/ Optimal)	Mean (SD)	Deviations (Observed/ Optimal)	Mean (SD)	Mean (SD)
Activate evidence based DSI when reviewing ordering a procedure	15	100% (0.00)	1.2	67.5 (3.34)	1.03	0.1 (0.23)	1.4 (0.4)
Activate user-supplied predictive DSI when ordering a procedure	16	90% (0.17)	1.4	68.1 (2.81)	1.04	0.2 (0.25)	1.6 (0.7)
Access plain language description for evidence based DSI	17	100% (0.00)	1.0	15.7 (1.10)	1.04	0 (0)	1.0 (0)
Access plain language description for user-supplied predictive DSI	18	100% (0.00)	1.1	15.2 (1.04)	1.01	0 (0)	1.1 (0.1)
Access, record and change source attributes for evidence based DSI	19	80% (0.34)	1.1	78.1 (2.78)	1.04	0.3 (0.46)	1.5 (0.6)
Access, record and change source attributes for user-supplied predictive DSI	20	97% (0.05)	1.1	75.7 (1.00)	1.02	0 (0.05)	1 (0.1)
Provide feedback/intervention response for evidence based DSI - Implantable Device Interaction	21	100% (0.00)	1.1	62.3 (1.67)	1.03	0 (0)	1 (0)

*Task rating 1-5; where 1 is "Very Easy" and 5 is "Very Difficult."

6.1 Summary of Results

The EHRUT received a score of 77.0 for subjective satisfaction based on the System Usability Scale (SUS) Questionnaire (*see* Appendix 7). Broadly interpreted, scores under 60 represent systems with poor usability, and scores over 80 are considered above average. [3]

In addition to the performance data, qualitative observations were found:

6.1.1 Major Findings

The usability study indicated that our intended audience found most of the CliniComp|EHR Decision Support Intervention application easy to use. User satisfaction ratings were high, and task times fell into

3 See Tullis, T. & Albert, W. (2008). Measuring the User Experience. Burlington, MA: Morgan Kaufman (p. 149).

acceptable ranges for most of the task features. Participants expressed their satisfaction with the CliniComp|EHR, stating the system's ease of navigation and the likelihood of using it frequently.

The ability to activate user-supplied predictive DSI and the ability to access, record and change source attributes tasks had the lowest completion rates. Participants who did not complete the tasks, expressed their frustration with this specific feature, as it was less intuitive compared to other parts of the CliniComp|EHR. This study confirmed that additional training or education is needed with the ability to activate user-supplied predictive DSI and the ability to access, record and change source attributes features in order to reduce frustration, improve performance times, and achieve task results within the optimal path.

6.1.2 Areas for Improvement

Participants made the following recommendations:

Participants suggested that CCI improve the ability to access, record and change source attributes for both evidence based and predictive DSI. The participants felt that the user interface could be more intuitive with clear guidance and less clicks.

7 Introduction

Designed to facilitate clinician duties in both the outpatient and inpatient healthcare settings, the EHRUT consisted of the Decision Support Intervention application within *CliniComp|EHR* v.213.03. The application included a user interface for the activation, access, ability to record/modify and provide feedback for decision support interventions. The testing attempted to represent realistic exercises and conditions to validate the usability of the user interfaces and provide evidence of usability of the *CliniComp|EHR*. Measures of effectiveness, efficiency, and user satisfaction, such as task time and task success, were captured during the usability test.

8 Method

8.1 Participants

A total of ten participants participated in usability testing. Participants included eight registered nurses and two nurse practitioners. Participant clinical expertise encompassed a variety of healthcare settings, including cardiothoracic surgery, emergency medicine, neonatal intensive care, general medicine and PACU. The participants were recruited by CCI's Clinical Analyst group. The participants volunteered their time and were not compensated.

For test purposes, end-user characteristics were identified and translated into a participant questionnaire used to ensure that prospective participants met the criteria for the usability test (*see* Appendix 1). Recruited participants had a mix of backgrounds and demographic characteristics conforming to the recruitment screening criteria. Table 6 displays participant characteristics, including demographics, professional experience and specialty, computing experience, and user needs for assistive technology. Participant names were replaced with Participant Identification (ID) codes, so identifying data could not be correlated to individual participants.

Table 6: Participant Demographics and Characteristics

P ID	GENDER	AGE	EDUCATION	OCCUPATION / ROLE	PROFESSIONAL EXPERIENCE (MONTHS)	COMPUTER EXPERIENCE (MONTHS)	PRODUCT EXPERIENCE (MONTHS)	ASSISTIVE TECHNOLOGY NEEDS
12	Female	30-39	Master's degree	RN	108	300	60	No
13	Female	40-49	Master's degree	RN	144	360	108	No
14	Female	40-49	Bachelor's degree	RN	144	360	96	No
15	Male	20-29	Bachelor's degree	RN	48	180	24	No
16	Female	30-39	Bachelor's degree	RN	66	300	36	No
17	Female	40-49	Master's degree	RN	252	360	60	No
18	Male	40-49	Bachelor's degree	RN	276	360	36	No
19	Female	50-59	Master's degree	NP	300	384	144	No
20	Female	30-39	Master's degree	NP	120	360	60	No
21	Female	30-39	Master's degree	RN	132	360	60	No

Ten participants, matching the demographics in Table 6, were recruited, and all ten participated in the usability test. No participants failed to report for the study. Participants were scheduled for one 4-hour session during standard working hours (8:30 am to 4:30 pm) in which they were allowed three cycles to perform the tasks. A spreadsheet was used to track the participant schedule and included each participant's demographic characteristics (*see* Appendix 2).

8.2 Study Design

The objectives of this test were to determine areas where the application performed well (effectively, efficiently, and with satisfaction) and where the application failed to meet participant needs. For specific objectives, see the Moderator's Guide b(11) (Appendix 5). The data from this usability test may serve as a baseline for future testing with an updated version of the *CliniComp|EHR* and/or comparison with other EHRs.

During the usability test, participants interacted with the *CliniComp|EHR*. Each participant used the EHRUT in the same location and was provided with the same instruction. The system was evaluated for effectiveness, efficiency, and satisfaction as defined by measures collected and analyzed for each participant:

- Number of tasks successfully completed within the allotted time without assistance
- Time to complete the tasks
- Number and types of errors
- Path deviations
- Participant's verbalizations (comments)
- Participant's satisfaction ratings of the system

For additional information about the various measures, *see* 8.9 Usability Metrics.

8.3 Tasks

Tasks were constructed to be realistic and representative of activities a user might perform with the *CliniComp|EHR* Decision Support Intervention module, based on study objectives. Tasks were selected based on the frequency of use within the application, the criticality of the function, and the most troublesome for users.

TASK	TASK DETAIL	ONC CRITERION TESTED
15	Activate evidence based DSI when reviewing ordering a procedure	170.315 (b)(11) Decision Support Interventions
16	Activate user-supplied predictive DSI when ordering a procedure	170.315 (b)(11) Decision Support Interventions
17	Access plain language description for evidence based DSI	170.315 (b)(11) Decision Support Interventions
18	Access plain language description for user-supplied predictive DSI	170.315 (b)(11) Decision Support Interventions
19	Access, record and change source attributes for evidence based DSI	170.315 (b)(11) Decision Support Interventions
20	Access, record and change source attributes for user-supplied predictive DSI	170.315 (b)(11) Decision Support Interventions
21	Provide feedback/intervention response for evidence based DSI - Implantable Device Interaction	170.315 (b)(11) Decision Support Interventions

8.4 Procedures

Upon arrival, participants were greeted, and their identity was verified and matched with a name on the participant schedule. Participants were then assigned a participant ID and introduced to their assigned data logger. Each participant reviewed and signed informed consent and release forms (*see* Appendix 3 and 4). The moderator witnessed the participant's signature and date.

The moderator administered the session, including instructions and task descriptions, monitored task times, and took notes on participant comments. One data logger was assigned to each participant to record task success, path deviations, number and type of errors, task times, obtain post-task rating data, and participant comments.

The moderator instructed the participants to perform the test tasks in the following ways:

As quickly as possible

Without assistance (administrators could give immaterial guidance and clarification on tasks, but no instructions on use)

Without using a think-aloud technique

Participants were given a written copy of the tasks for each test. After the moderator described the scenario, task objective, and instruction to begin, the task timer started. The data logger stopped the task time once the participant indicated he or she completed the task. The moderator monitored the maximum allotted time per task, and data loggers captured all study data during the task process and after completion (*see 8.10* Data Scoring).

After all tests concluded, the following occurred:

The moderator gave participants System Usability Scale Questionnaire (*see* Appendix 7) and thanked everyone for their participation.

Participant demographics, testing success rates, time spent on each test, errors, deviations, verbal responses, and post-test questionnaires were recorded by the data logger in a spreadsheet for each test and participant.

8.5 Test Location

The testing took place at CCI headquarters in San Diego, California. The testing facility included a waiting area and a quiet testing room with a table and a computer for each participant. Only participants, data loggers, and the moderator were present in the test room. To ensure that the environment was comfortable for users, noise levels were kept to a minimum and the ambient temperature within a normal office range. All safety instruction and evacuation procedures were valid, in place, and visible to participants.

8.6 Test Environment

The EHRUT would typically be used in a healthcare office or facility. For usability testing, the effort was conducted in a testing and training computer lab at CCI. The participants used Lenovo® computers running Windows 10 Pro, which were connected to CCI's local network. The computers were equipped with 32-inch - 1280x1024 pixel resolution monitors.

The application was set up on a test server by the CCI Service Support group according to EHRUT documentation describing the system set-up and preparation. Technically, the system performance (i.e., response time) was representative of what actual users would experience in field implementation. Additionally, participants were instructed not to change any of the default system settings (such as control of font size).

8.7 Test Forms and Tools

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

Informed Consent

Non-Disclosure Agreement

Participant Questionnaire

Moderator's Guide

System Usability Scale Questionnaire

Examples of these documents are found in the Appendices. The Moderator's Guide b(11) (*see* Appendix 5) was devised to capture the required data. The data loggers captured participants' input and responses using digital timers and hand-written documentation.

8.8 Participant Instructions

The moderator read the following instructions aloud to all participants prior to the start of the usability testing (see Appendix 5):

Thank you for participating in this test. Your input is very important to us. Our session today will last approximately four hours. During that time, you will use an instance of an electronic health record.

There will be a number of tasks that will need to be completed as well as a few questions that will need to be answered. Each task will need to be completed on your own, at your own pace with minimal possible errors or deviations. We ask that you do them as quickly and efficiently as possible with the instructions that we have provided. Please complete the task and do not attempt to do more than what is instructed.

We must emphasize that we are not testing you or your ability to use the system- we are evaluating the usability of the system. We are not able to instruct or provide you with help on how to use the application beyond the provided instructions, but we may be able to provide help on other related issues. Please save your detailed comments until the end of the task or at the end of the session when we can discuss freely as a group.

Overall, we are interested in how easy (or how difficult) this system is to use, what features, or functionality are useful to you, and how we could improve it. Please be honest with your opinions.

The information you provide us will be kept confidential. Your name and any other identifying information will be omitted and not be associated with your comments. Should you feel it necessary, you are able to withdraw your participation at any time during the testing.

The product you will be testing today includes the Decision Support Intervention application within the CliniComp EHR.. Since we are testing specific functionality, the workflow many not seem complete, or the data may not make sense compared to your normal work processes.

To access the system, you will be using a demo user and test patient record that correlate with your assigned participant number.

Following the procedural instructions, participants were shown the *CliniComp|EHR*, and the first task given was to explore the system and make comments (10 minutes). Once this task was complete, the moderator gave the following instructions:

For each task, I will read the description to you and say, "Begin." At that point, please perform the task and say "Done" once you believe you have successfully completed the task. I would like to request that you not talk aloud or verbalize while you are doing the tasks. I will ask you your impressions about the task once you are done.

Do you have any questions or concerns?

Participants were then given 7 tasks to complete in three cycles over the course of four hours. To view the list of tasks, see the Moderator's Guide b(11) (Appendix 5).

8.9 Usability Metrics

According to the 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 effectively, efficiently, and with an acceptable level of satisfaction. To this end, metrics for effectiveness, efficiency, and user satisfaction were captured during the usability testing. The goals of the tests were to assess:

Effectiveness of *CliniComp|EHR* by measuring participant success rates and errors

Efficiency of *CliniComp|EHR* by measuring the average task time and path deviations

Satisfaction with *CliniComp|EHR* module by measuring ease of use ratings

8.10 Data Scoring

Table 7 details how tests were scored and the time data analyzed.

Table 7: Data Scoring

MEASURES	RATIONALE AND SCORING
Effectiveness: Test Success	A task was counted as a "Success" if the participant was able to achieve the correct outcome, without assistance, and within the time allotted on a per-task basis. The total number of successes was calculated for each task and then divided by the total number of times that task was attempted. The results are provided as a percentage. Task times were recorded for successes. Observed task times were divided by the optimal time for each task as a measure of optimal efficiency.

	Optimal task performance time, as benchmarked by expert performance under realistic conditions, were recorded when constructing tasks. For target task time information, see the Moderator's Guide (Appendix 5).
Effectiveness: Test Failures	If the participant abandoned the test or task, did not reach the correct answer or performed it incorrectly, or reached the end of the allotted time before successful completion, the task was counted as "Failures." No task times were taken for errors. The total number of errors was calculated for each task and then divided by the total number of times that task was attempted. Not all deviations were counted as errors. This was expressed as the mean number of failed tasks per participant. On a qualitative level, an enumeration of errors and error types were collected.
Efficiency: Test Deviations	The participant's path (i.e., steps) through the application was recorded. Deviations occurred 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. The number of steps in the observed path was divided by the number of optimal steps to provide a ratio of path deviation.
Efficiency: Test Time	Each test was timed from when the administrator said "Begin" until the participant said, "Done." If he or she failed to say "Done," the time was stopped when the participant stopped performing the task. Only task times for tasks that were successfully completed were included in the average task time analysis. The average time per task was calculated for each task. Variance measures (standard deviation and standard error) were also calculated.
Satisfaction: Test Rating	Participant's subjective impression of the ease of use of the application was measured by administering both a simple post-task question as well as a post-session questionnaire. After each task, the participant was asked "overall, on a scale of 1 to 5, where 1 is "Very Easy" and 5 is "Very Difficult," this task was ___." This data was averaged across participants. Common convention dictates that average ratings for systems judged easy to use are 3.7 or lower. To measure participants' confidence in and likeability of the *CliniComp|EHR* overall, the testing team administered the post-test SUS Questionnaire. Questions included, "I think I would like to use this system frequently," "I thought the system was easy to use," and "I would imagine that most people would learn to use this system very quickly." *See* Appendix 7).

9 Results

9.1 Data analysis and reporting

The results of the usability tests were calculated according to the methods specified in the Usability Metrics section above. All participants of this study followed the instructions, and no data were excluded.

The usability testing results for the EHRUT are detailed in Table 8 in accordance with the objectives and goals outlined in Section 8.2: Study Design.

Table 8: Test Results

TASK	TASK #	TASK SUCCESS	PATH DEVIATION	TASK TIME (SEC)		ERRORS	TASK RATING * 1=EASY
Activate evidence based DSI when reviewing ordering a procedure	15	100% (0.00)	1.2	67.5 (3.34)	1.03	0.1 (0.23)	1.4 (0.4)
Activate user-supplied predictive DSI when ordering a procedure	16	90% (0.17)	1.4	68.1 (2.81)	1.04	0.2 (0.25)	1.6 (0.7)
Access plain language description for evidence based DSI	17	100% (0.00)	1.0	15.7 (1.10)	1.04	0 (0)	1.0 (0)
Access plain language description for user-supplied predictive DSI	18	100% (0.00)	1.1	15.2 (1.04)	1.01	0 (0)	1.1 (0.1)
Access, record and change source attributes for evidence based DSI	19	80% (0.34)	1.1	78.1 (2.78)	1.04	0.3 (0.46)	1.5 (0.6)
Access, record and change source attributes for user-supplied predictive DSI	20	97% (0.05)	1.1	75.7 (1.00)	1.02	0 (0.05)	1 (0.1)
Provide feedback/intervention response for evidence based DSI - Implantable Device Interaction	21	100% (0.00)	1.1	62.3 (1.67)	1.03	0 (0)	1 (0)

*Task rating 1-5; where 1 is “Very Easy” and 5 is “Very Difficult.”

9.2 System Usability Scale

The EHRUT received a score of 77.0 for subjective satisfaction based on the SUS Questionnaire. Broadly interpreted, scores under 60 represent systems with poor usability; scores over 80 would be considered

above average.[4] A summary of the SUS Questionnaire results per task or application tested within the EHRUT are included below:

DECISION SUPPORT INTERVENTIONS
1. 70% of the participants thought they would like to use this system frequently.
2. 70% of the participants found this system was NOT unnecessarily complex.
3. 80% of the participants found the system easy to use.
4. 90% of the participants thought a technical support person would NOT be needed to use this system.
5. 80% of the participants found the system to be well integrated.
6. 90% of the participants did NOT think there was too much inconsistency with the system.
7. 70% of the participants felt most people would learn to use the system very quickly.
8. 70% of the participants did NOT find the system to be cumbersome.
9. 70% of the participants felt very confident using the system.
10. 80% of the participants felt they did NOT need to learn a lot before they could get going with the system.

9.3 Effectiveness

The effectiveness of the *CliniComp|EHR* was defined by the measurement of participant success rates. Most tasks were successfully completed at rates greater than 80% with six tasks completed with rates greater than 90%. Access, record and change source attributes for evidence based DSI generated the lowest rate of completion at 80%. To improve effective use in the future, the display for modifying source attributes will be enhanced, and users will be provided improved training on the feature.

9.4 Efficiency

The efficiency of the *CliniComp|EHR* was defined by comparing the participant task performance times to a predefined optimal time. Optimal times ranged from 15-75 seconds, and the calculated grand mean for each task indicated that most tasks were completed efficiently. For the most part, participants followed the optimal path to complete each assigned task, but there were path deviations for some tasks. Overall, path deviations were minimal as illustrated by deviation ratios between 1.0-1.4 for all tasks. The one task that was determined to be least effective was the ability to activate a user-supplied predictive DSI when reviewing the problem list.

9.5 Satisfaction

Satisfaction with the *CliniComp|EHR* was measured as a subjective impression of the ease of use of the application. This was acquired by soliciting as an ease-of-use score for each task. The participants were asked to fill in the blank in the following statement: "On a scale from 1-5, where 1 is "very easy' and 5 is "very difficult, this task was____." The ease of use ratings for all tasks were between 1.0-1.6. Common convention dictates average ratings for systems judged "easy to use" as 3.7 or lower. EHRUT data revealed that the *CliniComp|EHR* was relatively easy to use.

To measure participants' confidence in and likeability of the *CliniComp|EHR*, the testing team administered the post-test SUS Questionnaire. The scores captured by this questionnaire resulted in a mean score of 77.0, which is interpreted as average usability for the *CliniComp|EHR*. Broadly interpreted, scores under

4 See Tullis, T. & Albert, W. (2008). Measuring the User Experience. Burlington, MA: Morgan Kaufman (p. 149).

60 represent systems with poor usability, and systems with scores over 80 would be considered above average.

Participant commentary further clarified the SUS scoring and identified the areas for improvement.

9.6 Major Findings

The usability study indicated that our intended audience found most of the *CliniComp|EHR* Decision Support Intervention application easy to use. User satisfaction ratings were high, and task times fell into acceptable ranges for most of the task features. Participants expressed their satisfaction with the *CliniComp|EHR*, stating the system's ease of navigation and the likelihood of using it frequently.

The ability to activate user-supplied predictive DSI and the ability to access, record and change source attributes tasks had the lowest completion rates. Participants who did not complete the tasks, expressed their frustration with this specific feature, as it was less intuitive compared to other parts of the *CliniComp|EHR*. This study confirmed that additional training or education is needed with the ability to activate user-supplied predictive DSI and the ability to access, record and change source attributes features in order to reduce frustration, improve performance times, and achieve task results within the optimal path.

Those who used the system frequently or had more experience with the system were more satisfied users. Several participants had over three years of experience using the *CliniComp|EHR* prior to this usability testing. This strong previous experience resulted in a 100% success rate for three tasks and shorter pathways, which were based on participant clinical workflows. With a few tasks, there were a couple of participants with little or no prior experience who achieved the specific task but not by the optimal method for completing the task.

Participant feedback indicated that user training and education has the potential for minimizing these concerns and can be addressed by a client training team.

10 Conclusion

10.1 Areas for Improvement

Participants made the following recommendations:

Participants suggested that CCI improve the ability to access, record and change source attributes for both evidence based and predictive DSI. The participants felt that the user interface could be more intuitive with clear guidance and less clicks.

11 Appendix

The following appendices include supplemental data for this usability test report:

1. Participant Questionnaire
2. Participant Demographics
3. Informed Consent Form
4. Non-Disclosure Agreement
5. Moderator's Guide
6. System Usability Scale Questionnaire
7. Participant Instruction
8. Exit Questionnaire
9. Incentive Receipt and Acknowledgment *(*Not applicable for participants in the b(11) SED testing as time was volunteered.)*

11.1 Appendix 1: Participant Questionnaire

MU EHR Usability Test_Participant Ques

11.2 Appendix 2: Participant Demographics

GENDER	#
Men	4
Women	7
Total (participants)	11

EDUCATION	#
High school graduate/ General Educational Development	0
College Graduate	6
Postgraduate	5
Total (participants)	11

AGE RANGES	#
20 to 29	0
30 to 39	5
50 to 59	4
60 to 69	2
70 and older	0
Total (participants)	11

YEARS OF EXPERIENCE	#
Less than a year	0
1-5	2
5-10	2
More than 10	7
Total (participants)	11

OCCUPATION/ROLE	#
RN/BSN	9
Physician	0
Nurse Practitioner	2
Total (participants)	11

FACILITY USE OF CURRENT EHR	#
All paper	0
Some paper, some electronic	8
All electronic	3
Total (participants)	11

Participant Demographics for b(11) Testing

P ID	GENDER	AGE	EDUCATION	OCCUPATION / ROLE	PROFESSIONAL EXPERIENCE (MONTHS)	COMPUTER EXPERIENCE (MONTHS)	PRODUCT EXPERIENCE (MONTHS)	ASSISTIVE TECHNOLOGY NEEDS
12	Female	30-39	Master's degree	RN	108	300	60	No
13	Female	40-49	Master's degree	RN	144	360	108	No
14	Female	40-49	Bachelor's degree	RN	144	360	96	No
15	Male	20-29	Bachelor's degree	RN	48	180	24	No
16	Female	30-39	Bachelor's degree	RN	66	300	36	No
17	Female	40-49	Master's degree	RN	252	360	60	No
18	Male	40-49	Bachelor's degree	RN	276	360	36	No
19	Female	50-59	Master's degree	NP	300	384	144	No
20	Female	30-39	Master's degree	NP	120	360	60	No
21	Female	30-39	Master's degree	RN	132	360	60	No

11.3 Appendix 3: Informed Consent

MU EHR Usability Test_Informed Conse

11.4 Appendix 4: Non-Disclosure Agreement

MU Usability NDA Form

11.5 Appendix 5: Moderator's Guide

MU EHR Usability Test_Moderator's Gui

MU EHR Usabiliy Test b(11) Moderators Gui

11.6 Appendix 6: Participant Instructions


MU EHR Usability Test_Participant Instru


MU EHR Participant Instructions b11.pdf

11.7 Appendix 7: System Usability Scale Questionnaire


MU EHR SUS Questionnaire.pdf

11.8 Appendix 8: Exit Questionnaire


MU EHR Usability Tes Exit Questionnaire.pdf

11.9 Appendix 9: Incentive Receipt and Acknowledgment

CliniComp, Intl. has an agreement with the following agency who manages payroll processing for contractors:

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**Not applicable for participants in the b(11) SED testing as their time was volunteered.*