EHR USABILITY TEST REPORT

Simplify EMR, Version 4.0

Report based on: ISO/IEC 25062:2006 Common Industry Format for Usability Test Report

1. EXECUTIVE SUMMARY

A usability test of Simplify EMR v4.0 was conducted on July 2019 at Genensys headquarters, 7269 Winding Lake Circle, Oviedo FL 32765. The purpose of this study was to test and validate the usability of the current user interface and provide evidence of it in the EHR Under Test (EHRUT).

During the test, a total of 12 healthcare personnel including physicians and administrative staff members matching the target demographic criteria served as participants and used Simplify EMR v4.0 in simulated, but representative tasks.

This study collected performance data for 14 tasks conducted on the EHR including:

1. Record, review and modify medication orders
2. Record, review and modify lab orders
3. Record, review and modify radiology orders
4. Record, review and modify medication allergy list
5. Record medication order and drug-drug interaction
6. Record medication order and drug-allergy interaction
7. Record and modify demographics information
8. Record, review and modify problems
9. Record and modify a clinical decision support rule
10. Trigger and override a clinical decision support rule
11. Add an implantable device
12. Inactivate an implantable device
13. Clinical information reconciliation and incorporation
14. E-prescribe a medication

During the 50 minutes of one-on-one usability test, every participant was welcomed by the overseer. They were requested by the administrator to review and sign an informed consent. Also, they were told that they can withdraw at any time. The majority of the participants had prior knowledge of the system. After the introduction, the participants were requested to complete a series of tasks (one at a time) using the EHRUT. The administrator timed the test and recorded the participants performance electronically. No assistance was given to the participants to complete their tasks.

Below are the types 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's verbalizations
- Participant's system satisfaction ratings

Since it was a voluntary activity, no participant was compensated. After the successful completion of testing, participants were requested to rate their respective tasks and the application. Each participant's privacy was ensured, none of them could be identified from the data collected. Evaluation was done on

the basis of examples in NIST guide to the process approach for improving the usability of electronic health records.

Based on the participants' performance, the system's subjective satisfaction is scaled as 88.92%. Moreover, below the qualitative observations were made:

1.1 Major Findings

Participants for the most part observed the Simplify EMR to be instinctive. They were satisfied with the design and technology which led them to complete their tasks efficiently and quickly.

1.2 Areas for Improvement

Feedback provided by the participants was extremely appreciated and helped us to evaluate the application through their perspective. Some participants suggested front-end improvements which we have taken into consideration.

2. INTRODUCTION

The EHRUT tested for this study was Simplify EMR, Version 4.0. The EHRUT is designed to provide services including Electronic Health Records, Practice Management System, Scheduling, Billing, Patient Portal, Chronic Care Management, Medical Transcription, Communications and Transitional Care Management. The usability test represented realistic scenarios and practices.

The purpose of this study was to evaluate the system's current user interface and provide an evidence of usability of EHRUT. System's interface should be designed and contain the functionalities as per the usability standard of NISTIR 7741.

Task success, task time, path deviation, time deviation, task errors and ratings were recorded during the usability testing. The goal was to assess the product's efficiency, level of user satisfaction and system's potency.

3. METHOD

3.1 Participants

A total of 12 participants were tested on the EHRUT. Most of the participants were clinical employees and configuration specialists. Participants did not belong to the testing or supplier organization, neither had any direct connection with the development of the EHRUT. Participants were given the same level of system exposure and training that is given to the end users.

All of the participants were chosen according to the demographic and background criteria defined in NISTIR 7741 guidelines and instructions. Below is the table of participant characteristics, including their demographics, professional experience and user needs for assistive technology etc. Names were replaced with participant IDs in order to ensure the individual privacy.

ID	Gender	Age	Education	Occupation/ Role	Professional Experience (months)	Computer Experience (months)	Product Experience (months)	Assistive Technology Needs
P1	Male	40-49	Trade/Technical/ Vocational Training	Clinical Informatics Coordinator	90	240	36	No
P2	Male	30-39	Master's Degree	Office/ IT Manager	60	240	24	No
P3	Male	30-39	Doctorate Degree (e.g. MD-DNP-DMD-PhD)	Internal Medicine	55	180	48	No
P4	Male	20-29	Trade/Technical/ Vocational Training	Medical Assistant	60	96	8	Yes
P5	Female	50-59	Master's Degree	EHR Analyst	144	204	40	No
P6	Female	40-49	Doctorate Degree (e.g. MD-DNP-DMD-PhD)	Pediatrician	120	170	20	No
P7	Male	30-39	Master's Degree	EMR Coordinator	132	155	18	No
P8	Male	50-59	Associate Degree	LPN	180	265	30	No
P9	Male	20-29	Bachelor's Degree	RN	35	90	12	No
P10	Female	20-29	High School graduate-diploma or equivalent e.g. GED	Medical Assistant	6	96	15	No
P11	Female	30-39	Bachelor's Degree	RN	120	228	72	No
P12	Female	30-39	Doctorate Degree (e.g. MD-DNP-DMD-PhD)	Physician	72	240	48	No

The test was scheduled to be 50 minutes long with short breaks of 5-10 minutes for debriefing.

3.2 Study Design

The goal was to explore the positive and negatives of the application; where the system performed well and the participants were able to execute their tasks smoothly and without requiring any assistance or confusions on the application side. As well as the areas where the participants faced hurdles due to some reason. The participants only used Simplify EMR which helped the administrator to record and benchmark the current usability of the system. Participant satisfaction with the application was analyzed on the basis of below the measures:

- Number of tasks successfully completed within the allotted time without assistance: 128
- Time to complete the tasks: 32
- Number and types of errors: 20
- Path deviations (Average): 1.32
- Participant satisfaction ratings of the system: 88.92%

3.3 Tasks

Below is the list of tasks that were performed by the participants:

Task 1: Access John's current medication list that contains Amoxicillin 500MG. Update this medication with another antibiotic. The details are given below:

Drug Name	Ceftriaxone 250 MG
Frequency	Daily
Dose	2 tablets
Route	Oral

Task 2: Create a lab order to investigate blood culture with below tests:

- CBC with Ordered Manual Differential Panel – Blood (57782-5)
- Tobacco IgE Ab RAST class [Presence] in Serum (16056-4)

Modify the Tobacco Serum test with below changes:

Diet: Fasting

Task 3: Create a radiology order to investigate a cardiovascular condition with below test:

- ELECTROCARDIOGRAM COMPLETE – (93000)

Task 4: Add Mandol medication allergy to John's current allergies list:

Allergy	Mandol
Reaction	Stomach cramps
Medication	Mandol 100 MG

Task 5: Prescribe Mandol to John and view alert.

Task 6: An alert of drug-drug interaction should appear upon creating a prescription of below. Override the alert as “Can be overridden” and prescribe the medication:

Drug Name	Augmentin 125 MG
Frequency	3
Dose	1 tablet
Route	Oral

Task 7: Modify John’s DOB, Marital Status, Preferred Language and Race:

Date of Birth	10/10/1988
Marital Status	Married
Preferred Language	English
Race	White

Task 8: Review John’s current problem list that contains spiking fever and insomnia. John confirms that he no longer has spiking fever. Therefore, remove it from the list and mark it as resolved. Add another problem, throat irritation.

Task 9: Create a new clinical decision support rule based on the table below:

Title	Rule MU3
Rule Type	Medications
Medications	Ibuprofen 200 MG
Race	White
Gender	Male
Alert Note	Patient counselling advised

Task 10: Trigger the created rule by adding the respective details to John’s profile. Alert should be overridden by marking it as done.

Task 11: Add a ‘pacemaker’ implantable device in the patient’s chart.

Task 12: Mark the added implantable device as inactive.

Task 13: Import the patient’s CCDA in the application and reconcile his medications, allergies and problems.

Task 14: Review clinical decision support alert and e-prescribe the required medication of John.

All the tasks were selected from the study by NIST.

3.4 Procedures

As the participants arrived, they were welcomed by the Genensys management. Their identity check was ran and IDs were allocated.

All participants reviewed and signed an informed consent. A delegate from the test group verified the signatures.

In order to make sure that the test ran smoothly, two individuals from the test team participated in the test, the usability administrator and the data logger. The staff had prior experience of usability practice for 5 to 30 years, with educational backgrounds of medical and post-graduation. The administrator who conducted the session took notes on task times, post-task rating data, participant comments as well as giving instructions and administering tasks. Whereas the data logger took notes on task success, path deviations, number and type of errors and comments.

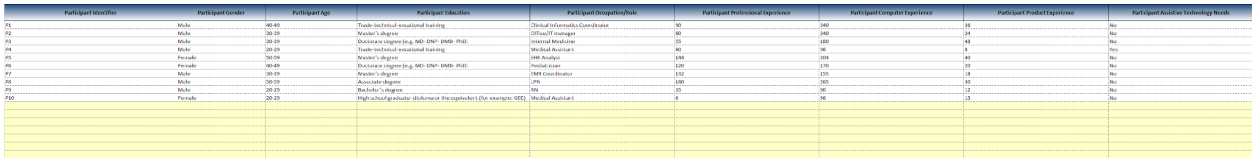
Below is the manner in which participants were required to perform their tasks:

- Without using a think aloud technique.
- As quickly as possible making minimum errors and deviations as possible.
- Without assistance; administrators were allowed to provide immaterial guidance and clarification on tasks, but not instructions on use.

Participants were handed a hard copy of the tasks. Administrator read the instructions and questions to the participants and began to calculate the time, timer was stopped after a participant indicated of completing their task.

Participant demographic information, task success rate, time, errors and deviations were logged in an excel spreadsheet provided by SLI compliance.

Below the screenshot depicts how demographics for the participants were recorded:



Participant Identifier	Participant Gender	Participant Age	Participant Education	Participant Occupation/Role	Participant Professional Experience	Participant Computer Experience	Participant Product Experience	Participant Assistive Technology Needs
P1	Male	40-49	Trade-technical-vocational training	Clinical InformaticsCoordinator	90	240	36	No
P2	Male	30-39	Master's degree	Office/IT manager	80	240	24	No
P3	Male	30-39	Doctorate degree (e.g., MD- DNP- DMD- PhD)	Internal Medicine	55	180	48	No
P4	Male	20-29	Trade-technical-vocational training	Medical Assistant	60	96	6	Yes
P5	Female	50-59	Master's degree	HMI Analyst	144	204	60	No
P6	Female	40-49	Doctorate degree (e.g., MD- DNP- DMD- PhD)	Pediatrician	120	170	70	No
P7	Male	30-39	Master's degree	EMR Coordinator	132	155	18	No
P8	Male	50-59	Associate degree	LPN	180	265	30	No
P9	Male	20-29	Bachelor's degree	RN	15	90	12	No
P10	Female	20-29	High school graduate- diploma- the equivalent (for example- GED)	Medical Assistant	8	96	15	No

Image 1: Participant demographic data

Below the screenshot depicts how characteristics for each measure was recorded and calculated:

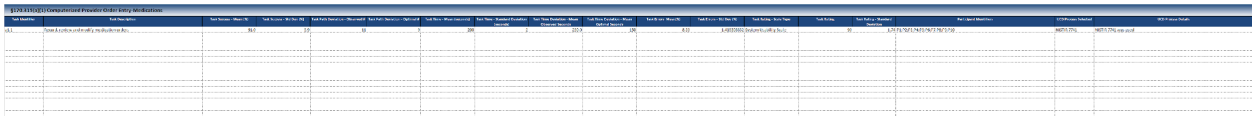


Image 2: CPOE Medications task recording

Participants were given post-test questionnaire to record their ratings of the tasks and system. Also, they were thanked individually for their participation.

3.5 Test Location

The testing facility had a waiting area and a quiet room with a table and computer system assigned for each participant. It also had a separate computer for the administrator to record the session. No other

person was allowed in the test room other than the administrator and the participants. Other observers and the data logger worked from a separate room where they could see the participant's screen. Safety instructions and evacuation plans were in place and were made visible to the participants.

3.6 Test Environment

The EHRUT is typically used in a healthcare office or facility. In this case, the testing was performed at Genensys headquarters. The testing was conducted on Intel® Core i7 desktop computers with operating system as Windows 10. The participants used a mouse and a keyboard to interact with the system. Every system had a 21" screen size with the resolution of 1920x1080. The application was prepared by Genensys staff as per the documentation describing the system set-up and preparation. The application itself was running on Genensys Cloud, using a demo database on LAN connection. The system response time was the same as to what actual users would experience in a field implementation. Participants were also instructed not to change the system's default settings (such as control of font size).

3.7 Test Forms and Tools

Below are the documents used during the usability test:

- Informed consent
- Participant instructions sheet
- System Usability Scale (SUS) questionnaire
- Excel spreadsheet (Data Logging)

3.8 Participant Instructions

Below are the instructions that the administrator read aloud to all the participants:

Thank you all for your time and for participating in this study today. Your input is highly valuable. This session is going to last 50 to 55 minutes. During this time, you will be using an instance of the EHR. I'd like to request you to complete a few tasks using this system and answer some questions. You should try to complete the tasks as quickly as possible and with minimum errors. Please follow the instructions closely and complete the tasks on your own. Please be sure that our goal is not to test you, but our system. This means that if you face some sort of difficulty in completing your task, it is an indication that something needs to be improved in the system. I will be here if you need specific help but I won't be able to assist you in using the application or completing your task.

Through this study, we are exploring how easy or difficult our system is, how is it useful to our users and the margins of improvement in it. The information you share will be kept confidential and your name will not be associated with your comments at any time. Any participant is free to withdraw at any time during the test if necessary.

After the procedural instructions, participants were introduced with the EHR. As their first task, they were given 10 minutes to explore the application and make comments. Once the task was completed, the administrator gave below the instructions:

For each task, I will be reading the instructions to everyone and raise poll which will end as per time associated with task. After the task completion, another poll will be raised to collect data and feedback for each participant. I'd like to request that you not talk aloud or verbalize while you are doing the tasks.

Participants were then given 14 tasks to complete.

3.9 Usability Metrics

According to the NIST guidelines, EHR should contain a process that provides a high level of usability for all users. The goal is for the users to be able to use the system to their ease in an efficient and satisfactory manner. Metrics for effectiveness, efficiency and user satisfaction were captured during the usability testing. The goals of the test were to analyze the below:

- Effectiveness of Simplify EMR v4.0 by measuring participant success rates and errors
- Efficiency of Simplify EMR v4.0 by measuring the average task time and path deviations
- Satisfaction with Simplify EMR v4.0 by measuring ease of use ratings

3.10 Data Scoring

Below is a table detailing how tasks, errors and time were analyzed:

Measures	Rationale and Scoring
Effectiveness (Task Success)	When a participant completed their task within the allotted time, achieved the expected outcome and did not require assistance, it was considered as 'Success'. Total number of successes were recorded for each task and divided with 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 divided by the optimal time for each task is a measure of optimal efficiency. Optimal task performance time, as benchmarked by expert performance under realistic conditions, is recorded when constructing tasks. Target task times used for task times in the Moderator's Guide must be operationally defined by taking multiple measures of optimal performance and multiplying by some factor (1.3) that allows some time buffer because the participants are presumably not trained to expert performance. Thus, if expert, optimal performance on a task was "60" seconds then allotted task time performance was "60*1.3=78" seconds. This ratio should be aggregated across tasks and reported with mean and variance scores.
Effectiveness (Task Failures)	If the participant quit the task, could not complete, performed incorrectly or reached the end of allotted time before successful completion, the task was counted as 'Failure'. Total number of errors were calculated for each task and divided with the total number of times the task was attempted. Not all deviations would be counted as errors. This should also be expressed as the mean number of failed tasks per participant. On a qualitative level, an enumeration of errors and error types should be collected.
Efficiency (Task Deviations)	Participant's workflow (steps) while performing a task was recorded. Deviations occurred in cases such as going on 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. Total number of steps in the observed path is divided with the total number of optimal steps to provide a ratio of path deviation. It is highly recommended that task deviations be reported. Optimal paths (procedural steps) should be recorded when constructing tasks.
Efficiency (Task Time)	Each task 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. Average time per task was calculated for each task. Variance measures (standard deviation and standard error) were also calculated.

Satisfaction (Task Rating)	Participant's subjective impression of the ease of use of the application was measured by post-task questions and post-session questionnaire. After each task, the participants were requested to rate the task on a scale of 1 (very difficult) to 5 (very easy). These data are averaged across participants. Common convention is that average ratings for system's easy to use should be 3.3 and above. To measure participants' likeability of Simplify EMR v4.0, the testing team administered the System Usability Scale (SUS) post-test 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'.

4. RESULTS

4.1 Data Analysis and Reporting

The results of the usability test were calculated according to the methods specified in the Usability Metrics section above. Data for the participants who failed to follow the session or task instructions was excluded from the analysis.

The data should produce actionable results that, if corrected, should produce positive impact on user performance. The usability testing results for the EHRUT are detailed below:

Task	**Task Success** (Mean)	**Path Deviations** (Observed/Optimal)	**Time Deviations** (Observed/Optimal)	**Task Errors** (Mean)	**Task Rating** (Mean)
Record, review and modify medication orders	91	1.22	1.6	8.33	90
Record, review and modify lab orders	100	1.2	1.25	0	85
Record, review and modify radiology orders	91	1.33	1.19	0	85
Record, review and modify allergy list	83.3	1.18	1.33	16.3	75
Record medication order and drug-drug interaction	91	1.16	1.25	8.33	90
Record medication order and drug-allergy interaction	91	1.08	1.33	8.33	75

Record and modify demographics information	100	1.25	1.20	0	95
Record, review and modify problems	100	1.12	1.28	0	95
Record and modify a clinical decision support rule	83.3	1.11	1.1	16.3	85
Trigger and override CDS rule	91	1.25	1.2	8.33	90
Add an implantable device	91	1.11	1.13	8.33	85
Inactivate an implantable device	100	1.2	1.18	0	100
Clinical information reconciliation and incorporation	83.3	1.18	1.21	16.3	85
e-prescribe a medicine	75	1.12	1.11	25	70

Task time deviation was calculated as: Observed time taken by 12 participants/ Optimal time taken by 12 participants

Task path deviation was calculated as: Number of observed steps taken by 12 participants/ Number of optimal steps taken by 12 participants

The result of SUS (system usability scale) measured the participants' satisfaction with the system. For a task whose performance score is 83.3 is considered as broadly interpreted, scores under 65 represented the system's poor usability and scores over 85 were considered as above average.

Effectiveness

Based on the task success for all the 14 tasks, effectiveness of Simplify EMR v4.0 was calculated as 90.12%.

Efficiency

Most of the participants were able to complete their tasks within the allotted time, whereas some were not able to do so. Those who could not complete their tasks, stated that it was because of their wrong interpretation of instructions. Efficiency of Simplify EMR v4.0 was measured based on the average path deviation i.e. 1.2 and average time deviation i.e. 1.31.

Satisfaction

In terms of satisfaction, Simplify EMR v4.0 was rated by the participants as 89%.

4.2 Discussion of Findings

4.2.1 Task 1: Record, review and modify medication orders

Participants had to add a new medication, review patient's current medications and update one of the added medications from the chart.

Major Findings

Participants were able to complete the task within the allotted time without requiring any assistance.

Areas for Improvement

No major suggestions were given as the participants found the task quick and easy.

4.2.2 Task 2: Record, review and modify lab orders

Participants were asked to add a specific lab order and update a pending lab order.

Major Findings

Some of the participants had trouble adding details but most of them completed the task successfully.

Areas for Improvement

No major suggestions other than interface improvement were suggested.

4.2.3 Task 3: Record, review and modify radiology orders

Participants were asked to add a new radiology order to investigate cardiovascular condition and review the current radiology orders.

Major Findings

Due to the workflow's similarity between lab and radiology orders, some of the participants had difficulty adding details.

Areas for Improvement

No major suggestions other than interface improvement were suggested.

4.2.4 Task 4: Record, review and modify allergy list

Participants were asked to add a new medication allergy, review the existing allergies and update one.

Major Findings

Due to the workflow's similarity between medications and allergies component, participants found it easy and completed the task in a very short time.

Areas for Improvement

No major suggestions were given as the participants found the task to be quick and easy.

4.2.5 Task 5: Record medication order and drug-drug interaction

Participants were asked to create a medication order, review drug-drug interaction alert and override it after entering specified comments.

Major Findings

Since the alert notification is quite visible and the user cannot proceed without taking care of it, therefore the participants were able to execute the task quite easily.

Areas for Improvement

No major suggestions were given as the participants found the task to be quick and easy.

4.2.6 Task 6: Record medication order and drug-allergy interaction

Participants were asked to create a medication order, review drug-allergy interaction alerts and override it after entering specified comments.

Major Findings

Due to the similarity between the previous task and this, participants were able to execute it easily.

Areas for Improvement

No major suggestions were given as the participants found the task to be quick and easy.

4.2.7 Task 7: Record and Modify Demographics

Participants were asked to update demographics for a specific patient.

Major Findings

All the participants were able to complete this task within the allotted time.

Areas for Improvement

No major suggestions were given as the participants found the task to be quick and easy.

4.2.8 Task 8: Record, review and modify problems

Participants were asked to add a specific problem in patient's record, review the existing problem list and update one of them.

Major Findings

Most of the participants completed the task in a very short time.

Areas for Improvement

No major suggestions were given as the participants found the task to be quick and easy.

4.2.9 Task 9: Record and modify a clinical decision support rule

Participants were asked to create a new clinical decision support rule with specific information.

Major Findings

Most of the participants were able to complete the task within the allotted time. Whereas, some found it slightly difficult to create a clinical decision support rule.

Areas for Improvement

Some of the participants who had difficulty completing the task were those who did not or had less experience with the product, they were convinced that if they had sufficient experience, they could have completed the task easily. They suggested addition of tooltips in the user interface to be able to understand the terms more easily.

4.2.10 Task 10: Trigger a clinical decision support rule

Participants were asked to review CDS alert for the patient and override it by adding specific comments.

Major Findings

Participants found this task comparatively easier than creating a clinical decision support rule.

Areas for Improvement

No major suggestions were given as the participants found the task to be quick and easy.

4.2.11 Task 11: Add an implantable device

Participants were asked to add an implantable device for a patient.

Major Findings

Almost all of the participants found the task straightforward and completed it within the allotted time.

Areas for Improvement

No major suggestions were given for improvement.

4.2.12 Task 12: Inactivate an implantable device

Participants were asked to inactivate the previously added implantable device for the patient.

Major Findings

Participants found this task extremely easy and completed it in a very short time.

Areas for Improvement

No suggestions for improvement were given.

4.2.13 Task 13: Clinical information reconciliation and incorporation

Participants were asked to import a CCDA file for an existing patient and then reconcile its medications, problems and allergies.

Major Findings

Some of the participants found this task to be difficult as they were not able to complete it in the allotted time.

Areas for improvement

Suggestions were given to improve the workflow for reconciliation.

4.2.14 Task 14: E-prescribe a medicine

Participants were asked to prescribe a medicine according to the CDS alert.

Major Findings

Those who were unable to identify the CDS alerts found the task to be tricky. Most of the participants were able to execute it without any troubles.

Areas for Improvement

Participants suggested that alert notification needs to be more easily visible.

5. APPENDICES

Below is the list of the appendices provided:

1. Sample recruiter screener
2. Participant demographics
3. Non-disclosure agreement (NDA) and informed consent form
4. System usability scale questionnaire

5.1 Appendix 1: Recruiter form

The purpose of a recruiter form is to ensure that the participants selected belong to the target population as closely as possible.

Recruiting Script

Hello, my name is _____, calling from Simplify EMR. We are recruiting individuals to participate in a usability study for our electronic health record. We would like to ask you a few questions to see if you qualify and would like to participate. This should not take more than a couple of minutes. This is strictly for research purposes and would be a voluntary act from your side. Can I ask a few questions?

1. Have you participated in Simplify EMR usability testing previously?
   a. Yes
   b. No

If yes, please describe.

2. Do you or anyone in your home, have a commercial interest in electronic health record software or usability research? (if yes, disqualified)
   a. Yes
   b. No
3. What age group do you belong to?
   a. <20
   b. 20-29
   c. 30-39
   d. 40-49
   e. 50-59
   f. 60-69
   g. 70-79
   h. ≥80
4. Do you require any assistive technologies to use a computer? (if yes, disqualified)
   a. Yes
   b. No

5.2 Appendix 2: Participant demographics

Name _____

Gender _____

Address _____

Phone # _____

Email _____

Organization _____

1. What is your current role?
    a. Analyst
    b. Application Coordinator
    c. Certified Nursing Assistant (CNA)
    d. CEO, CMIO, CIO, etc.
    e. Consultant
    f. Director
    g. Information Technology
    h. Licensed Practical Nurse (LPN)
    i. Marketing/Communications
    j. Medical Assistant (MA)
    k. Nurse
    l. Nurse Practitioner (NP)
    m. Office Manager
    n. Pharmacist
    o. Physician
    p. Physician Assistant (PA)
    q. Project Manager
    r. SVP, AVP, VP, etc.
    s. Trainer
    t. Other (please specify)
2. How long have you held this position?
    a. <5 years
    b. 5-10 years
    c. 10-20 years
    d. >20 years
3. What environment do you work in? (if inpatient or emergency department, disqualified)
    a. Inpatient
    b. Emergency Department

    c. Ambulatory
4. What is your highest level of education?
    a. High school graduate/GED
    b. Some college
    c. College graduate
    d. Postgraduate
    e. Other
5. How many years of experience do you have using computers for personal and professional activities (e.g. reading news, shopping/banking, programming/word processing, research, access EHR etc.)
    a. <5 years
    b. 5-10 years
    c. 10-20 years
    d. >20 years
6. How do you capture patient data in your organization? (if primarily on paper, disqualify)
    a. Primarily on paper
    b. Primarily electronically
7. What is your specialty? (if physician and specialty is Radiology, Ophthalmology and Pathology, disqualify)
8. Are you a fluent English speaker?
    a. Yes
    b. No

5.3 Appendix 3: Non-disclosure agreement and informed consent form

Non-Disclosure Agreement (NDA)

The participant acknowledges his/her voluntary participation in today's usability study may bring the participant into possession of confidential information. The term 'Confidential Information' means all technical and commercial information of a proprietary or confidential nature which is disclosed by Simplify EMR, or otherwise acquired by the participant, in the course of today's study.

By way of illustration, but no limitation, confidential information includes trade secrets, possesses, formulae, data, know-how, products, designs, drawings, computer aided design files and other computer files, computer software, ideas, improvements, inventions, training methods and materials, marketing techniques, plans, strategies, budgets, financial information, or forecasts.

Any information the participant acquires relating to this product during this study is confidential and proprietary to Simplify EMR and is being disclosed solely for the purposes of the participant's participation in today's usability study. By signing this form, the participant acknowledges that s/he will not receive any compensation for feedback as this is a voluntary act and will not disclose this confidential information obtained today to anyone else or any other organizations.

Participant name: _____

Signature: _____ Date: _____

Informed Consent

Genensys would like to thank you for participating in this study. The purpose of this study is to evaluate an electronic health record. If you decide to participate, you will be asked to perform several tasks using the prototype and give your feedback. The study will last about 60 minutes.

Agreement

I understand and agree that as a voluntary participant in the present study conducted by Genensys I am free to withdraw consent or discontinue participation at any time. I understand and agree to participate in the study conducted and videotaped by the Genensys.

I understand and consent to the use and release of the videotaped by Genensys. I understand that the information and videotape is for research purposes only and that my name and image will not be used for any purpose other than research. I relinquish any rights to the videotape and understand the videotape may be copied and used by Genensys without further permission.

I understand and agree that the purpose of this study is to make software applications more useful and usable in the future.

I understand and agree that the data collected from this study may be shared with outside of Genensys and its client. I understand and agree that data confidentiality is assured, because only de-identified data i.e. identification numbers not names – will be used in analysis and reporting of the results.

I agree to immediately raise any concerns or areas of discomfort with the study administrator. I understand that I can leave at any time.

Please check one of the following:

☐ YES, I have read the above statement and agree to be a participant.

☐ NO, I choose not to participate in this study.

Signature: _____ Date: _____

5.4 Appendix 4: System usability scale questionnaire

Strongly Disagree				Strongly Agree
1	2	3	4	5

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

1	2	3	4	5

2. I found the system unnecessarily complex

1	2	3	4	5

3. I thought the system was easy to use

1	2	3	4	5

4. I think I would need the support to be able to use this system

1	2	3	4	5

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

1	2	3	4	5

6. I thought there was too much Inconsistency in the system

1	2	3	4	5

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

1	2	3	4	5

8. I found the system cumbersome to use

1	2	3	4	5

9. I felt very confident using the system

1	2	3	4	5

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


Genensys

EHR Usability Test Report

Simplify EMR v4.0

Report Based on NISTIR 7742 Common Industry Format

Document Information

Date of Usability Test	December 01, 2024 - December 10, 2024
Date of Report	December 10, 2024
Report Prepared By	Genensys LLC Farhan Shamsi, 7269 Winding Lake Cir, Oviedo, FL 32765, United States

Executive Summary

A usability test of Simplify EMR v4.0 was conducted between December 01, 2024 and December 10, 2024. The purpose of this test was to test and validate the decision support intervention (DSI) and Clinical decision support (CDS) functionality, and provide evidence of usability in the Simplify EMR v4.0 Under Test (EHR) during the usability test, 10 healthcare providers matching the target demographic criteria served as participants and used the EHR in simulated, but representative tasks.

This study collected performance data on 4 tasks typically conducted on an EHR:

- Add Clinical Decision Support Intervention
- Admin User Selects Evidence-based DSI and Access / Record / Change Source Attributes
- User Triggers Evidence-based DSI and Provides User Feedback
- Admin User Exports User Feedback

During the 30 minutes one-on-one usability test, each participant was greeted by the administrator and asked to review and sign an informed consent/release form (included in Appendix 3); they were instructed that they could withdraw at any time. Participants had prior experience with the EHR. The administrator introduced the test, and instructed participants to complete a series of tasks (given one at a time) using the EHR. During the testing, the administrator timed the test and, along with the data logger(s) recorded

user performance data on paper and electronically. The administrator did not give the participant assistance in how to complete the task.

All participant data was anonymized to ensure privacy, with no identifiable information linked to the collected data. After the test, participants completed a post-test questionnaire. The usability evaluation followed recommended metrics from the NISTIR 7741 Guide to the Processes Approach for Improving the Usability of Electronic Health Records. Below is a summary of the performance and user satisfaction data gathered during the study. Industry Standard Used

- **Name**: NISTIR 7741
- **Description**: NISTIR 7741 provides guidelines to improve product usability through a process-oriented approach. This standard focuses on enhancing user experience, minimizing user error, and increasing efficiency and satisfaction by establishing clear usability processes.
- **Citation**: National Institute of Standards and Technology. (2010). NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records (NISTIR 7741).

Measure	N.	Task Success	Path Deviation	Task Time		Errors	Task Ratings (5=Easy)
Task	#	Mean	Deviations	Mean (SD)	Deviations	Mean (SD)	Mean (SD)

		(SD)	(Observed / Optimal)		(Observed / Optimal)		
Add Clinical Decision Support Intervention	10	100% (0%)	11 / 11	78 (3)	11 / 8	0% (0%)	5.0
Admin User Selects Evidence-based DSI and Access / Record / Change Source Attributes	10	100% (0%)	10 / 9	62 (4)	14 / 12	5% (15%)	4.9 (0.17)
User Triggers Evidence-based DSI and Provides User Feedback	10	90% (30%)	10 / 7	38 (5)	8 / 4	10% (30%)	4.6 (0.39)
Admin User Exports User Feedback	10	100% (0%)	6 / 5	15 (3)	5 / 2	0% (0%)	5.0

System Usability Score

The System Usability Scale (SUS) was used to measure users' subjective satisfaction with the system based on their task performance. The system received a score of 81.73 In addition to the performance metrics, several qualitative observations were noted:

Major Findings

Participants found Simplify EMR v4.0 to be highly effective and user-friendly, enhancing workflow efficiency and providing easy access to key functions. Positive feedback focused on the following aspects:

- **DSI Accessibility**: Users found it easy to view and access DSIs, appreciating the system's organization in aiding decision-making.
- **Feedback Functionality**: Many participants highlighted the simplicity of providing feedback on DSIs, noting the system's ability to gather valuable user insights.
- **Intuitive Navigation**: The navigation was described as intuitive, especially for administrative tasks and DSI management.
- **Responsive Interface**: The interface's responsiveness and clear prompts allowed participants to complete tasks accurately and with confidence.

Areas for Improvement

Participants shared constructive feedback with suggestions that reflect their positive experience and offer insights for further improvement:

- **Improved Click Efficiency**: While users appreciated the design, some recommended reducing the number of clicks required for common actions to boost workflow efficiency.
- **Better Icon Visibility**: Although the interface was mostly intuitive, a few participants suggested increasing the visibility of the source attributes icon to enhance accessibility.

Introduction

This study presents the comprehensive usability testing conducted for Simplify EMR v4.0, a sophisticated electronic health record system designed to assist healthcare professionals in accurately recording, managing, and tracking patient health data. The Simplify EMR v4.0 is built to support a wide range of healthcare roles, including nurses, medical assistants, physicians, and other medical personnel, across various healthcare settings, from clinics to hospitals. This versatility ensures that the system is adaptable to the diverse needs of healthcare environments, enhancing the delivery of patient care through streamlined processes.

The primary aim of this study was to rigorously evaluate and validate the usability of the Simplify EMR v4.0 user interface. A key focus was to demonstrate how the system adheres to established user-centered design principles, ensuring that the system is intuitive, efficient, and effective for its intended users. In addition to evaluating usability, the study also aimed to ensure that the system meets the specific certification requirements for functionality as outlined in the Health IT Certification Criteria, including §170.315(g)(3) Safety Enhanced Design and §170.315(b)(11) Decision Support Intervention (DSI). These criteria are crucial in ensuring that the system contributes to both patient safety and the quality of clinical decision-making.

The usability testing methodology involved simulating real-world tasks and clinical conditions to assess the system's performance in terms of effectiveness, efficiency, and overall user satisfaction. The tasks were designed to mirror those commonly performed by healthcare professionals, allowing the participants to engage with the system in a manner that reflects their typical workflows. Key metrics were collected during the testing phase to provide a comprehensive assessment of the system's usability. These metrics included task completion rates, time spent on each task, deviations from expected task paths, frequency and types of errors encountered, and participant post-task ratings.

In addition, a System Usability Scale (SUS) score was obtained from participants to quantify the overall user satisfaction and perceived ease of use of the system. This multi-faceted approach provided valuable insights into the strengths of the Simplify EMR v4.0 and identified areas where further optimization may be necessary to enhance user experience and support clinical efficiency. By leveraging these findings, the study aims to provide actionable recommendations for refining the system, ensuring that it fully meets the needs of its users while also aligning with industry standards for safety and decision support.

Method

PARTICIPANTS

A total of 10 participants were involved in the usability testing of the Simplify EMR system. The participants represented a range of healthcare professionals, including Physicians (MD/DO), Nurse Practitioners, RN Managers, and Physician Assistants. Importantly, none of the participants had any direct involvement in the development of the organization producing the EHR, ensuring that the testing results were unbiased and independent. Additionally, the participants were not affiliated with the testing or supplier organization, further mitigating potential conflicts of interest.

To ensure that the test closely mirrored the experience of actual end-users, participants were provided with the same orientation and training that would be given to typical users of the system. For the purposes of the test, the characteristics of the end-users were carefully identified and used to develop a recruitment screener to solicit potential participants. An example of this screener can be found in Appendix [1].

The recruited participants were selected based on a mix of professional backgrounds, demographics, computing experience, and user needs for assistive technology. This diversity in participant profiles allowed for a broad range of perspectives on the usability of the system. The following table summarizes the participants' characteristics, including their professional experience, demographic information, computing skills, and any specific assistive technology requirements. To ensure participant privacy and confidentiality, participant names were anonymized using Participant IDs, preventing any link between the data collected and individual identities.

ID	Gender	Age	Education	Occupation / Role	Professional Experience (months)	Computer Experience (months)	Product Experience (months)	Assistive Technology Needs
1	Male	30-39	Doctorate	Physician	60	147	48	None
2	Female	40-49	Master's Degree	Registered Nurse	120	248	72	None
3	Female	40-49	Master's Degree	Registered Nurse	144	200	98	None
4	Male	50-59	Doctorate	Physician	216	249	125	None
5	Female	20-29	Bachelor's degree	Registered Nurse	24	115	12	None
6	Female	30-39	Master's Degree	Physician Assistant	48	110	10	None
7	Male	40-49	Master's Degree	RN Manager	84	170	70	None
8	Male	50-59	Doctorate	Physician	150	225	140	None
9	Female	40-49	Doctorate	Physician	100	208	67	None
10	Male	30-39	Master's Degree	Registered Nurse	60	207	28	None

STUDY DESIGN

The primary objective of this usability test was to identify both the strengths and weaknesses of the Simplify EMR system in terms of its effectiveness, efficiency, and user satisfaction. By uncovering areas where the application excelled and areas where it fell short, the test provided valuable insights into how well the system meets the needs of its users. The data gathered during this test can serve as a baseline for future usability evaluations, whether they involve updated versions of the same EHR system or a comparison with other EHR systems, provided that the same tasks are used in each case. In essence, this testing functions as both a benchmarking tool for current usability and a means to identify specific areas that require improvement.

Throughout the usability test, all participants interacted with the same version of the Simplify EMR. Each participant was asked to perform the tasks in the same environment, with consistent instructions provided to ensure uniformity across all sessions. The system was evaluated based on several key criteria—effectiveness, efficiency, and satisfaction—which were measured using a combination of metrics collected and analyzed for each participant:

- **Number of tasks successfully completed**: This measure assessed the percentage of tasks completed within the allotted time, without the need for assistance, to evaluate the system's effectiveness in supporting user goals.
- **Time to complete tasks**: The amount of time each participant took to complete the tasks was recorded to evaluate the efficiency of the system.
- **Errors**: The number and types of errors encountered during task completion were tracked to identify potential usability issues and areas where the system could be improved.
- **Path deviations**: Any deviations from the expected or recommended task paths were noted to understand how users navigated the system and where they might have encountered challenges.
- **Participant verbalizations**: During the test, participants were encouraged to provide verbal feedback on their experience, which was recorded to gather insights into their thought processes, frustrations, and overall impressions of the system.
- **Satisfaction ratings**: After completing the tasks, participants provided satisfaction ratings of the system, offering valuable feedback on their overall experience and their perception of the system's usability.

By analyzing these measures, the usability test aimed to provide a comprehensive understanding of how well the Simplify EMR system performed in a real-world setting, helping to highlight both its strengths and areas in need of improvement.

TASKS

A series of tasks were designed for the usability test to simulate realistic scenarios and represent the kinds of activities users would typically perform when using the Simplify EMR system. These tasks were specifically chosen to address a functionality gap between the previously tested criterion §170.315(a)(9) Clinical Decision Support and the new criterion §170.315(b)(11) Decision Support Intervention. The selected tasks were as follows:

1. **Add Clinical Decision Support Intervention (Medium Risk)**: This task involved the addition of a clinical decision support intervention that addresses medium-risk scenarios, allowing users to experience the process of integrating decision support tools into the system for patient care.
2. **Admin User Selects Evidence-based DSI and Accesses/Records/Changes Source Attributes (Low Risk)**: In this task, the admin user was required to select an evidence-based Decision Support Intervention (DSI), and then access, record, or modify the source attributes associated with it. This task was classified as low-risk and aimed to assess the ease of use and effectiveness of accessing and modifying important data in the system.
3. **User Triggers Evidence-based DSI and Provides User Feedback (Low Risk)**: This task focused on how a user could trigger an evidence-based DSI and then provide feedback based on the intervention. The goal was to evaluate how well the system captures user input and how feedback is integrated into the workflow.
4. **Admin User Exports User Feedback (Low Risk)**: In this task, the admin user was asked to export the feedback provided by users, ensuring that the system could effectively handle feedback data and make it available for further review or analysis.

These tasks were designed to assess the system's ability to handle key features associated with Decision Support Interventions as required by the new certification criteria, while also highlighting any potential usability gaps or areas where improvements were needed to meet user needs.

PROCEDURE

Upon arrival, participants were greeted, and their identity was verified against the participant schedule. Each participant was then assigned a unique participant ID. Participants were provided with an informed consent and release form, which they reviewed and signed. A representative from the test team witnessed the signing of the form to ensure transparency and understanding of the testing process.

To ensure the test ran smoothly, two staff members were present: the usability administrator and the data logger. Both were experienced usability practitioners with over five years of experience in conducting usability evaluations. The usability administrator moderated the session, delivering instructions, overseeing task completion, monitoring task times, and collecting post-task rating data. The administrator also recorded participant comments. Meanwhile, the data logger tracked key metrics, including task success rates, path deviations, error counts, and participant feedback.

Participants were given the following instructions:

- Complete the tasks as quickly as possible while minimizing errors and deviations.
- Perform the tasks independently without assistance. Administrators could provide clarifications or general guidance but could not offer instructions on how to use the system.
- Do not use a think-aloud approach; the focus was on task completion, not verbalizing thoughts.

Each participant received a written task description for each activity. The task timing began once the administrator finished reading the task instructions and stopped when the participant indicated that they had successfully completed the task. Task performance was scored based on the success of completion, the time taken, and the number of errors and deviations (see Section 3.9 for detailed scoring methods).

Once the tasks were completed, participants were asked to fill out the System Usability Scale (SUS) questionnaire to assess their overall satisfaction with the system. Data, including demographic information, task success rates, time spent on each task, errors, deviations, verbal responses, and post-test ratings, were recorded in a spreadsheet for later analysis. At the conclusion of the session, participants were thanked for their time and participation in the usability testing process.

TEST LOCATION

For these remote testing sessions, the administrator conducted the sessions from their personal office, while the data logger documented the relevant data from their own office. Each participant was located at their respective location, ensuring that all testing was done remotely. The sessions were facilitated using Microsoft Teams video conferencing software, which allowed for real-time communication and task monitoring while maintaining a secure and efficient testing environment. This virtual setup enabled seamless interaction between the testing team and participants, while also ensuring that the tasks were completed and data was collected in an organized and consistent manner.

TEST ENVIRONMENT

The usability testing for the EHR system was conducted using a remote testing procedure, as the system is typically used in a healthcare office or facility. During the remote sessions, no system data was collected from the participants, ensuring privacy and confidentiality. Participants interacted with the EHR using a keyboard and mouse.

Participants were instructed to log in to a Microsoft Teams meeting via the desktop application, with audio connected and their camera turned off. Control of the administrator's computer was then transferred to the participant, allowing them to interact with the system directly. The sessions were moderated using the same materials and methods as would be employed in an in-person session, ensuring consistency in the testing process. All sessions were audio and video recorded for documentation and analysis purposes.

The study was run from a Lenovo Yoga 7i laptop, with a screen resolution set to 1920 x 1080. Participants, however, used their own devices, which varied in screen size. The screen size of the Lenovo Yoga 7i used for the test was 14 inches, with the operating system running on Windows 11 Home. All participants interacted with the application using their own keyboard and mouse.

In terms of system performance, the response time during the testing sessions was generally similar to what users would experience in a real-world, field implementation of the EHR system. Participants did not alter any of the default system settings, such as font size control, ensuring that the testing environment remained standardized across all sessions.

TEST FORMS AND TOOLS

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

1. Demographic Information Questionnaire
2. Participant Briefing and Debriefing Document
3. Usability Task Monitoring Document
4. Post-Test Survey (System Usability Scale)

Examples of these documents can be found in the Appendices section.

PARTICIPANT INSTRUCTIONS

The administrator reads the following instructions aloud to each participant:

"Thank you for joining today's study. This session will last about 30 minutes. During this time, you'll be exploring our EHR system and completing tasks that align with ONC certification requirements. Our goal is to observe how you complete these tasks to help inform our efforts in certifying this product under the ONC Health IT Certification Program.

I will walk you through a series of tasks using the system. Afterward, I'll ask for your feedback. We are particularly interested in your experience with the system's usability, its potential value for you, and any areas where we could make improvements. We ask that you complete each task on your own, aiming to perform them as efficiently and accurately as possible. If you encounter any issues or get stuck, please continue on your own, as I won't be able to assist with using the system directly. We'd appreciate it if you save any detailed feedback until after each task or at the end of the session, when we can discuss your thoughts more freely."

(See the full Participant Briefing in Appendix 4)

USABILITY METRICS

According to the NISTIR 7741 Guide to the Processes Approach for Improving the Usability of Electronic Health Records, EHR systems must ensure a high level of usability for all users. The goal is for users to interact with the system in a manner that is effective, efficient, and provides a satisfactory experience. To meet these goals, key metrics related to effectiveness, efficiency, and user satisfaction were collected during the usability testing process. The specific objectives of the test were to evaluate:

- **Effectiveness of Simplify EMR v4.0** by measuring participant success rates and identifying errors encountered during task completion.
- **Efficiency of Simplify EMR v4.0** by assessing the average time taken to complete tasks and the frequency of path deviations.
- **Satisfaction with Simplify EMR v4.0** by gathering ease-of-use ratings and qualitative feedback from participants on their experience with the system.

DATA SCORING

The following table details how tasks were scored, errors evaluated, and the time data analyzed and is taken directly from NISTIR 7742 Customized Common Industry Format Template for Electronic Health Record Usability Testing.

Measures	**Rationale and Scoring**
Effectiveness: Task Success	A task was considered a "Success" if the participant was able to achieve the correct outcome, without assistance, within the time allotted for that particular task. The total number of successes was then calculated for each task and divided by the total number of attempts made for that task. The results were expressed as a percentage. Task times were recorded for successful completions. To measure efficiency, observed task times were compared to the optimal time for each task, which serves as a benchmark for optimal efficiency. The optimal task performance time is determined based on expert performance under realistic conditions, and this benchmark is established when the tasks are designed.
Effectiveness: Task Failures	If the participant abandoned the task, failed to reach the correct outcome, performed the task incorrectly, or exceeded the allotted time without completing the task successfully, it was counted as a "Failure." No task times were recorded for failed attempts. The total number of failures was calculated for each task and divided by the total number of attempts for that task. The results were expressed as a percentage and also represented as the mean number of failed tasks per participant. Not all deviations were categorized as errors. On a qualitative level, an enumeration of the types of errors encountered was collected, providing further insight into the nature of the failures.
Efficiency: Task Deviations	The participant's path, or sequence of steps, through the application was recorded during the usability test. Deviations were identified if the participant, for instance, navigated to the wrong screen, selected an incorrect menu item, followed an incorrect link, or interacted incorrectly with an on-screen control. These deviations were then compared to the optimal path, which represents the most efficient and correct sequence of actions for completing the task. To measure the degree of path deviation, the number of steps in the observed participant’s path was divided by the number of optimal steps. This calculation provides a ratio of path deviation, offering insight into how closely the participant’s navigation aligned with the

	ideal task flow.
Efficiency: Task Time	Each task was timed from when the administrator said "Begin" until the participant indicated "Done." If the participant did not say "Done," the timing was stopped when they ceased performing the task. Only the task times for successfully completed tasks were included in the analysis of average task time. The average time per task was calculated for each task based on the successful completions. Additionally, variance measures, including standard deviation and standard error, were also calculated to assess the consistency and variability in task completion times across participants.
Satisfaction: Task Rating	The participant's subjective impression of the ease of use of the application was assessed through both a post-task question and a post-session questionnaire. After completing each task, participants were asked to rate, “Overall, this task was:” on a scale from 1 (Very Difficult) to 5 (Very Easy). The data from these ratings were then averaged across all participants. It is generally accepted that systems judged to be easy to use should have an average rating of 3.3 or above. To assess participants' overall confidence in and likeability of the EHR system, the testing team administered the System Usability Scale (SUS) post-test questionnaire. Some of the questions included were: “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.”

RESULTS

DATA ANALYSIS AND REPORTING

The results of the usability test for Simplify EMR v4.0 were calculated based on the methods outlined in the Usability Metrics section above. Data from participants who did not follow session and task instructions were excluded from the analysis to ensure accuracy and consistency.

The detailed results of the usability testing for the EHR are presented below. These results should be interpreted in the context of the objectives and goals set forth in the Study Design. The data gathered from this testing provides valuable insights and actionable findings, which, when addressed, could lead to significant improvements in user performance and overall system usability.

Measure	N.	Task Success	Path Deviation	Task Time		Errors	Task Ratings (5=Easy)
Task	#	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Mean (SD)
Add Clinical Decision Support Intervention	10	100% (0%)	11 / 11	78 (3)	11 / 8	0% (0%)	5.0
Admin User Selects Evidence-based DSI and Access / Record / Change Source Attributes	10	100% (0%)	10 / 9	62 (4)	14 / 12	5% (15%)	4.9 (0.17)
User Triggers Evidence-based DSI and Provides User Feedback	10	90% (30%)	10 / 7	38 (5)	8 / 4	10% (30%)	4.6 (0.39)
Admin User Exports User Feedback	10	100% (0%)	6 / 5	15 (3)	5 / 2	0% (0%)	5.0

The SUS (System Usability Scale) results scored the subjective satisfaction with the system based on performance with these tasks to be: 81.73.

DISCUSSION OF THE FINDINGS

Effectiveness

The analysis of success rates, failure incidences, and path deviations indicates that the system was well-designed, achieving high task performance scores. The results suggest that users were able to complete tasks effectively, with minimal errors or deviations from the optimal path, highlighting the system's overall efficiency and ease of use.

Efficiency

Efficiency was assessed by comparing participants' time on task with established benchmark times and evaluating clicks per task against benchmark values. Most users completed tasks within or close to the optimal time. However, a few participants

encountered delays, primarily due to the need to switch between open browser tabs to input the correct information, which slightly impacted overall efficiency. Despite these minor delays, the system demonstrated good performance in terms of task completion time.

Satisfaction

Task ratings indicated that all participants found the tasks intuitive and easy to complete. The System Usability Scale (SUS) score for the system was 81.73, with scores ranging from a low of 70 to a high of 100. This suggests a generally positive user experience, with most participants expressing satisfaction with the system's usability.

Major Findings

Participants rated the system highly, describing it as user-friendly, intuitive, and appreciating its simplicity. The ability to provide feedback on the Decision Support Intervention (DSI) was a new feature for most participants and was met with positive responses. Additionally, accessing user feedback as an administrative user was seen as straightforward and efficient, further enhancing the overall user experience.

Areas for Improvement

Despite the overall positive feedback, some users noted that the system required more “clicking” than necessary and suggested that it could be further streamlined for greater efficiency. While the design was generally praised for being clean and uncluttered, a few participants highlighted the need for improved visibility when viewing source attributes to enhance accessibility and usability.

APPENDICES

APPENDIX 1: SAMPLE RECRUITING SCREENER

The purpose of a screener is to ensure that participants selected for the usability test closely represent the target user population. Recruiters were instructed that clinical participants must meet the following criteria:

- Must have experience working directly with patients
- Must be familiar with Enterprise EHR

In addition to these criteria, the following pre-session survey (screener) was used to further assess the eligibility of clinical participants.

#	Question	Options
1	What is your name?	
2	What is your gender?	Female, Male
3	What is your age bracket?	Teens, 20-29, 30-39, 40-49, 50-59, 60-69, 70+
4	What is your highest educational degree earned?	LPN, RN, NP, PA, MD, Other
5	What is your occupation or role title?	
6	How many months of professional experience do you have in this role?	
7	How many months of computer experience do you have (all computer experience)?	
8	How many years have you worked with Genensys?	
9	Do you have any assistive technology needs?	e.g., screen reader, etc.

Appendix 2: PARTICIPANT DEMOGRAPHICS

Gender	Count
Men	5
Women	5
Total (participants)	10
Age Range	**Count**
20-29	1
30-39	3
40-49	4
50-59	2
60+	0

Total (participants)	10	
Education Range	**Count**	
High school graduate	0	
Some college credit	0	
Associate degree	0	
Bachelor's degree	1	
Master's degree	5	
Doctorate degree	4	
Total (participants)	10	
Occupation/Role	**Count**	
RN/LPN/MA	5	
Prescribers	4	
Analysts/Administration Staff	1	
Total (participants)	10	
Years of Experience	**Range**	**Participants**
Professional Experience	12-60	4
	72-120	3
	132-180	2
	180+	1
Computer Experience	12-60	0
	72-120	2
	132-180	2
	180+	6
EHR Experience	12-60	5
	72-120	3
	132-180	2
	180+	0

Appendix 3: NON-DISCLOSURE AGREEMENT AND INFORMED CONSENT FORM

INFORMED CONSENT

Genensys would like to express our sincere gratitude for your participation in this study. The goal of this study is to evaluate an electronic health records system. If you choose to participate, you will be asked to perform several tasks using the prototype and provide feedback on your experience. The study is expected to take approximately 30 minutes to complete.

AGREEMENT

I understand and voluntarily agree to participate in the study conducted by Genensys. I am aware that my participation is entirely voluntary, and I have the right to withdraw my consent or discontinue my involvement at any time without consequence. I acknowledge and consent to my participation in the study conducted by Genensys.
I understand and consent to the use and release of my recorded responses by Genensys. I acknowledge that the information collected will be used solely for research purposes, and my name and image will not be used for any purpose other than the study.

I understand that the objective of this study is to improve the usability and functionality of software applications for future use.

I also understand and agree that the data collected from this study may be shared outside of Genensys and its clients. However, I am assured that data confidentiality will be maintained, as only de-identified data (i.e., identification numbers, not names) will be used for analysis and reporting of the results.

I agree to raise any concerns or discomfort with the study administrator immediately, and I understand that I can withdraw from the study at any time.

Please check one of the following:

- ☐ YES, I have read the above statement and agree to be a participant.
- ☐ NO, I choose not to participate in this study

NON-DISCLOSURE AGREEMENT

This Agreement is made as of December 01, 2024, between (“the Participant”) and the testing organization, Genensys, located at 7269 Winding Lake Cir, Oviedo, FL 32765, United States.

The Participant acknowledges that their voluntary participation in today’s usability study may result in the acquisition of Confidential Information. The term "Confidential Information" refers to all technical and commercial information of a proprietary or confidential nature that is disclosed by Genensys or otherwise acquired by the Participant during the course of today’s study.

Examples of Confidential Information include, but are not limited to, trade secrets, processes, formulae, data, know-how, products, designs, drawings, computer-aided design files, computer files, computer software, ideas, improvements, inventions, training methods

and materials, marketing techniques, plans, strategies, budgets, financial information, and forecasts.

Any information the Participant acquires related to this product during the study is confidential and proprietary to Genensys, and is being disclosed solely for the purpose of the Participant's involvement in today's usability study. By signing this form, the Participant agrees not to disclose any confidential information obtained during the study to any other individuals or organizations.

Participant's Name: _____

Signature: _____ Date: _____

Appendix 4: PARTICIPANT BRIEFING

Thank you for joining today's study. This session will last about 30 minutes. During this time, you'll be exploring our EHR system and completing tasks that align with ONC certification requirements. Our goal is to observe how you complete these tasks to help inform our efforts in certifying this product under the ONC Health IT Certification Program.

I will walk you through a series of tasks using the system. Afterward, I'll ask for your feedback. We are particularly interested in your experience with the system's usability, its potential value for you, and any areas where we could make improvements. We ask that you complete each task on your own, aiming to perform them as efficiently and accurately as possible. If you encounter any issues or get stuck, please continue on your own, as I won't be able to assist with using the system directly. We'd appreciate it if you save any detailed feedback until after each task or at the end of the session, when we can discuss your thoughts more freely.

This session will be recorded using web conferencing software. All information you share will remain confidential, and your feedback will not be tied to your identity.

Do you have any questions or concerns before we begin?

Appendix 5: TASKS

TASK 1 : Add Clinical Decision Support Intervention Test Data Requirements

1. CDS Intervention Title
    - "High Blood Pressure Alert"
2. Clinical Criteria
    - Patient's blood pressure (BP) ≥ 140/90 mmHg
    - Patient age ≥ 18 years
3. Supporting Reference
    - National Heart, Lung, and Blood Institute (NHLBI) Guidelines

- Publication: "Hypertension Guidelines 2020"

4. Patient Population
    - Adults aged 18 years and older
5. Intervention and Suggestion Description
    - "Alert the clinician when the patient's blood pressure is equal to or exceeds 140/90 mmHg, recommending that the patient be considered for hypertension management."
    - Suggest medication review if the patient is on antihypertensive therapy.
    - Recommend lifestyle modification counselling
6. Expected Outcome
    - Clinical Decision Intervention is saved in the system
7. **Rating:** Overall, this task was: _____
    - Show participant written scale: "Very Difficult" (1) to "Very Easy" (5)

TASK 2 : Admin User Selects Evidence-Based DSI and Accesses / Records / Changes Source Attributes

1. Admin User Credentials:
    - Username: Enter Username
    - Password: Enter Password
    - Role: User role (with permissions to access, record, and modify DSIs and attributes)
2. DSI (Clinical Decision Support Intervention) Selection:
    - DSI Title: "Diabetes Management Alert"
    - Evidence Source: American Diabetes Association (ADA) Guidelines 2023
3. Source Attributes:
    - Attribute : Population Criteria
    - Current Value: "Adults 18 years and older with a diagnosis of Type 2 diabetes"
    - New Value: "All patients with Type 2 diabetes, regardless of age"
4. Access & Record Actions:
    - Action 1: View and verify current DSI attributes.
    - Action 2: Record initial values of the DSI attributes before making changes.
    - Action 3: Document all modifications to source attributes in the system log.

5. Expected Changes & Verification:
    - Change Log Verification: Confirm that all changes are recorded in the change log, with timestamps, previous values, and updated values.
    - Permissions Check: Verify that only users with admin privileges can access and edit these attributes.
6. DSI Update Confirmation:
    - Update Status: Verify that after changes are made, the DSI status is "Updated" and that the system confirms successful changes.
7. **Rating:** Overall, this task was: _____
    - Show participant written scale: “Very Difficult” (1) to “Very Easy” (5)

Here's sample test data for Task 3 in the SED Document testing, which involves a user triggering an evidence-based Clinical Decision Support Intervention (DSI) and providing feedback. This data helps ensure that the DSI responds correctly to user actions and that the feedback mechanism functions as expected

TASK 3 : User Triggers Evidence-Based DSI and Provides User Feedback

1. User Credentials
    - Username: Enter Username
    - Password: Enter Password
    - Role: Physician (with permissions to view and respond to DSIs and submit feedback)
2. Clinical Decision Support Intervention (DSI) Details:
    - DSI Title: "Diabetes Blood Sugar Control Alert"
    - Trigger Condition: Blood glucose levels > 180 mg/dL for a patient diagnosed with diabetes
    - Suggested Action: Review current medication and consider insulin adjustment or additional lifestyle counselling.
3. Patient Information (for triggering DSI):
    - Age: 65 years
    - Diagnosis: Type 2 Diabetes
    - Current Blood Glucose Level: 195 mg/dL
    - Current Medications: Metformin 500 mg, once daily
4. Expected DSI Trigger Event

- Scenario: During a routine check-up, the clinician records the patient's latest blood glucose level (195 mg/dL).
- System Response: The DSI triggers an alert for the clinician recommending a review of the patient's diabetes management.

5. User Feedback Data:
   - Feedback Comment: "The alert was helpful"
6. Feedback Submission Process:
   - Action 1: Clinician selects the feedback option within the DSI alert.
   - Action 2: Clinician enters a comment and submits feedback.
   - Action 3: System confirms that feedback was successfully submitted.
7. Expected Outcome:
   - The system logs the feedback entry.
   - The feedback is accessible to the system administrators for review.
   - The user receives a confirmation message indicating that feedback was recorded.
8. **Rating:** Overall, this task was: _____
   - Show participant written scale: "Very Difficult" (1) to "Very Easy" (5)

TASK 4 : Admin User Exports User Feedback

1. Admin User Credentials
   - Username: Enter Username
   - Password: Enter Password
   - Role: User role (permissions to view, manage, and export user feedback)
2. Expected Export Functionality:
   - Action 1: Admin navigates to the user feedback section and selects "DSI Feedback Report."
   - Action 2: Admin applies filters for a specific date range and DSI.
   - Action 3: CSV format and initiates the export.
3. Expected Outcome:
   - The system generates a CSV file containing the filtered feedback records.
   - The exported file includes all specified data fields in the correct format.
   - The export completes successfully without errors.
4. **Rating:** Overall, this task was: _____

- Show participant written scale: “Very Difficult” (1) to “Very Easy” (5)

Appendix 6: SYSTEM USABILITY SCALE QUESTIONNAIRE

#	Question	1 (Strongly disagree)	2	3	4	5 (Strongly agree)
1	I think that I would like to use this system frequently					
2	I found the system unnecessarily complex					
3	I thought the system was easy to use					
4	I think that I would need the support of a technical person to be able to use this system					
5	I found the various functions in this system were well integrated					
6	I thought there was too much inconsistency in this system					
7	I would imagine that most people would learn to use this system very quickly					
8	I found the system very cumbersome to use					
9	I felt very confident using the system					
10	I needed to learn a lot of things before I could get going with this system					