

softserve



CGM CLINICAL 8.3 SAFETY ENHANCED DESIGN USER TESTING REPORT SUMMARY

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1 EXECUTIVE SUMMARY

A usability test of CGM CLINICAL, version 8.3 was completed on December 9, 2019 by SoftServe Inc for CompuGroup Medical. The remote video sessions were conducted. The purpose of this test was to test and validate the usability of the current user interface, and provide evidence of usability in the EHR Under Test (EHRUT). During the usability test, 12 healthcare providers matching the target demographic criteria served as participants and used the EHRUT in simulated, but representative tasks.

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

Certification criteria	Task	Wave of testing
Criteria 170.315(a)(1) - CPOE medications	A1a - A record and save a medication order A1b - Change medication order A1c - Access medication order	1
Criteria 170.315(a)(2) - CPOE laboratory	A2a - Record and save laboratory order A2b - Change laboratory order A2c - Access laboratory order	1
Criteria 170.315(a)(3) - CPOE radiology	A3a - Record and save a radiology order A3b - Change radiology order A3c - Access radiology order	1
Criteria 170.315(a)(4) - Drug-drug, drug-allergy interaction checks	A4a - Create a drug-drug interaction A4b - Create a drug- allergy interaction A4c - Adjust the drug to drug severity level A4d - Create and view only major drug-drug interaction A4e - Adjust the drug to drug severity level	2
Criteria 170.315(a)(5) - Demographics	A5a - View patient demographics A5b - Change patient sex A5c - Change patient's gender identity A5d - Change patient's sexual orientation A5e - Change patient date of birth A5f - Change patient's ethnicity A5g - Change patient's race A5h - Change patient's preferred language	1
Criteria 170.315(a)(6) - Problem list	A6a - View patient's problem list A6b - Mark problem inactive A6c - Filter the patient's problem list by inactive problems only A6d - Add a new problem A6e - Filter the patient's problem list by active problems only	2

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Certification criteria	Task	Wave of testing
Criteria 170.315(a)(7) - Medication list	A7a - Enter a medication A7b - Change medication strength/dosage A7c - Discontinue a medication A7d - View the patient's medication history A7e - Mark that patient is currently not taking any medications	1
Criteria 170.315(a)(8) - Medication allergy list	A8a - Enter a new medication allergy A8b - Change patient medication allergy A8c - Deactivate medication allergy A8d - Indicate no known medication allergies	1
Criteria 170.315(a)(9) - clinical Decision support	A9a - Trigger and review decision support details based on problem list A9b - Trigger and review decision support details based on medication list A9c - Trigger and review decision support details based on medication allergy list A9d - Trigger and review decision support details based on demographics A9e - Trigger and review decision support details based on laboratory tests A9f - Trigger and review decision support details based on vital signs A9g - Trigger and review decision support details based on a combination of demographics and problem list A9h - Review CDS source attributes A9i - Trigger and review decision support details based on information incorporated from transition of care document A9j - Review demographic infobutton resources A9k - Review problem infobutton resources A9l - Review medication infobutton resources	2
Criteria 170.315(a)(14) - Implantable device list	A14a - View patient's implantable device list A14b - Add implantable device to patient's list A14c - Mark implantable device as inactive A14d - View active and inactive devices	1
Criteria 170.315(b)(2) - clinical information reconciliation and incorporation	B2a - Reconcile a patient's problem, medication and medication allergy list from another source B2b - Generate a new CCDA with reconciled	1

Certification criteria	Task	Wave of testing
Criteria 170.315(b)(3) - E-prescribing	B3a - Create a prescription B3b - Approve a change request from pharmacy B3c - Discontinue a prescription B3d - Approve a renewal request from pharmacy B3e - Receive rxfill status notification B3f - Request and receive medication history information	1

During the two-hour one-on-one usability test, each participant was greeted by the administrator and then instructed that they could withdraw at any time. Participants did not have prior experience with the EHR. Prior to testing sessions, training video materials were provided to participants. The moderator introduced the test, and instructed participants to complete a series of tasks (given one at a time) using the EHRUT. During the testing, the moderator, recorded user performance data on paper and electronically. The moderator did not give the participant assistance in how to complete the task, unless they asked because they were unable to do so. Participant screens and audio were recorded for subsequent analysis. The following types of data were 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 satisfaction ratings of the system

All participant data was de-identified – no correspondence could be made from the identity of the participant to the data collected. Following the conclusion of the testing, participants were compensated with \$250.00 for their time. Various recommended metrics, in accordance with the examples set forth in the NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records, were used to evaluate the usability of the EHRUT. Following is a summary of the performance and rating data collected on the EHRUT.

The results from the System Usability Scale scored the subjective satisfaction with the system based on performance with these tasks to be: 60.75¹

¹ - See Tullis, T. & Albert, W. (2008). *Measuring the User Experience*. Burlington, MA: Morgan Kaufman (p. 149). Broadly interpreted, scores under 60 represent systems with poor usability; scores over 80 would be considered above average.

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

MAJOR FINDINGS:

Generally, participants in the usability study said that they liked the functionality of CGM CLINICAL™. The majority of the tasks were rated between “very easy” and “easy”.

Participants in the usability study did not have that much to say in the way of commentary on the specific areas of the software.

Based on the quantitative data, the stronger areas of the software are the Demographics, Implantable Device List, Problem List, Clinical Decision Support.

Electronic Prescribing, Clinical Information Reconciliation, CPOE Medications, CPOE Laboratory, CPOE Diagnostic Imaging areas were challenging for majority of user test participants and CPOE Medications, CPOE Laboratory have the lowest satisfaction rating.

Judging by the quantitative data, many of the issues were caused by busy screens or extra drop-downs, which lead to less stream-lined workflows, also some errors were caused by not clear naming of some actions – participants were sure that task is completed successfully, but final action selected lead to wrong final result. Additionally, lower success rate is most likely a result of unfamiliarity with flows, process and requirements.

2 INTRODUCTION

The EHRUT tested for this study was CGM CLINICAL™, Version 8.2. This product is designed to present medical information to healthcare providers in an ambulatory setting. The EHRUT is an easily adaptable integrated PM and EHR solution intended to support a broad range of specialties that allows providers to document patient health information and facilitates information sharing across multiple settings. The usability testing attempted to represent realistic exercises and conditions.

The purpose of this study was to test and validate the usability of the current user interface, and provide evidence of usability in the EHRUT. To this end, measures of effectiveness, efficiency and user satisfaction, such as task time and number of clicks per task, were captured during the usability testing.

The purpose of this study was to test and validate the usability of the current user interface, and provide evidence of usability in the EHR Under Test (EHRUT). To this end, measures of effectiveness, efficiency and user satisfaction, were captured during the usability testing.

3 METHOD

3.1 PARTICIPANTS

A total of 20 participants were tested on the EHRUT(s) (10 per each wave). Participants in the test were Registered Nurses. Participants were recruited by SoftServe Inc. (with support of Schlesinger Group for wave 1 and L&E Research for wave 2) and were compensated \$250 for their time. In addition, participants had no direct connection to the development of or organization producing the EHRUT(s). Participants were not from the testing or supplier organization. Participants were provided with training materials prior to testing sessions.

For the test purposes, end-user characteristics were identified and translated into a recruitment screener used to solicit potential participants; an example of a screener is provided in Appendix.

Recruited participants had a mix of backgrounds and demographic characteristics conforming to the recruitment screener. The following is a table of participants by characteristics, including demographics, professional experience and computing experience. Participant names were replaced with Participant IDs so that an individual's data cannot be tied back to individual identities.

ID	Participant Gender	Participant Age	Participant Education	Participant Occupation/Role	Participant Professional Experience (years)	Participant Computer Experience (years)
1	Female	30-39	Bachelor's Degree	Registered nurse	11	25
2	Female	40-49	Bachelor's Degree	Registered nurse	13	20
3	Female	30-39	Bachelor's Degree	Registered nurse	7	20
4	Female	40-49	Bachelor's Degree	Registered nurse	20	15
5	Female	30-39	Bachelor's Degree	Registered nurse	9	20
6	Female	30-39	Bachelor's Degree	Registered nurse	8	20
7	Female	40-49	Bachelor's Degree	Registered nurse	10	15
8	Female	30-39	Bachelor's Degree	Registered nurse	9	15
9	Female	60-69	Bachelor's Degree	Registered nurse	15	20
10	Female	40-49	Bachelor's Degree	Registered nurse	15	15
11	Female	40-49	Master's Degree	Registered nurse	2.5	25
12	Female	50-59	Associate degree	Registered nurse	32	20
13	Female	30-39	Bachelor's Degree	Registered nurse	8	20

ID	Participant Gender	Participant Age	Participant Education	Participant Occupation/Role	Participant Professional Experience (years)	Participant Computer Experience (years)
14	Female	30-39	Master's Degree	Registered nurse	6	15
15	Female	50-59	Bachelor's Degree	Registered nurse	21	20
16	Female	40-49	Bachelor's Degree	Registered nurse	17	20
17	Female	50-59	Bachelor's Degree	Registered nurse	15	15
18	Female	20-29	Bachelor's Degree	Registered nurse	4	15
19	Female	40-49	Master's Degree	Registered nurse	26	20
20	Female	30-39	Associate degree	Registered nurse	11	15

Participants were scheduled for up to 3 hours sessions with at least one hour in between each session to reset systems to proper test conditions. A spreadsheet was used to keep track of the participant schedule, and included each participant's demographic characteristics as provided by the recruiting firm.

3.2 STUDY DESIGN

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

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

- 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

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

3.3 TASKS

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

Task	Risk Rating
A1a - A record and save a medication order	2
A1b - Change medication order	2
A1c - Access medication order	4
A2a - Record and save laboratory order	2
A2b - Change laboratory order	3
A2c - Access laboratory order	4
A3a - Record and save a radiology order	2
A3b - Change radiology order	3
A3c - Access radiology order	4
A4a - Create a drug-drug interaction	3
A4b - Create a drug- allergy interaction	3
A4c - Adjust the drug to drug severity level	3
A4d - Create and view only major drug-drug interaction	3
A4e - Adjust the drug to drug severity level	3
A5a - View patient demographics	5
A5b - Change patient sex	5
A5c - Change patient's gender identity	4
A5d - Change patient's sexual orientation	4
A5e - Change patient date of birth	5
A5f - Change patient's ethnicity	4
A5g - Change patient's race	4
A5h - Change patient's preferred language	4
A6a - View patient's problem list	5
A6b - Mark problem inactive	3
A6c - Filter the patient's problem list by inactive problems only	4
A6d - Add a new problem	3
A6e - Filter the patient's problem list by active problems only	4
A7a - Enter a medication	3

Task	Risk Rating
A7b - Change medication strength/dosage	3
A7c - Discontinue a medication	3
A7d - View the patient's medication history	4
A7e - Mark that patient is currently not taking any medications	4
A8a - Enter a new medication allergy	3
A8b - Change patient medication allergy	3
A8c - Deactivate medication allergy	3
A8d - Indicate no known medication allergies	4
A9a - Trigger and review decision support details based on problem list	4
A9b - Trigger and review decision support details based on medication list	4
A9c - Trigger and review decision support details based on medication allergy list	4
A9d - Trigger and review decision support details based on demographics	4
A9e - Trigger and review decision support details based on laboratory tests	4
A9f - Trigger and review decision support details based on vital signs	4
A9g - Trigger and review decision support details based on a combination of demographics and problem list	4
A9h - Review CDS source attributes	5
A9i - Trigger and review decision support details based on information incorporated from transition of care document	4
A9j - Review demographic infobutton resources	5
A9k - Review problem infobutton resources	5
A9l - Review medication infobutton resources	5
A14a - View patient's implantable device list	4
A14b - Add implantable device to patient's list	2
A14c - Mark implantable device as inactive	4
A14d - View active and inactive devices	4
B2a - Reconcile a patient's problem, medication and medication allergy list from another source	3
B2b - Generate a new CCDA with reconciled	3
B3a - Create a prescription	3
B3b - Approve a change request from pharmacy	3
B3c - Discontinue a prescription	3
B3d - Approve a renewal request from pharmacy	3
B3e - Receive rxfill status notification	4
B3f - Request and receive medication history information	3

Risk scale: On a scale of 1-5 with 1 being riskiest and 5 being least risky

Tasks were selected based on their frequency of use, criticality of function, and those that may be most troublesome for users. Tasks should always be constructed in light of the study objectives.

3.4 PROCEDURE

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

To ensure that the test ran smoothly, two staff members participated in this test, moderator and the data logger.

The moderator moderated the session including administering instructions and tasks. The moderator also monitored task times, obtained post-task rating data, and took notes on participant comments. A second person served as the data logger and took notes on task success, path deviations, number and type of errors, and comments.

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

- As quickly as possible making as few errors and deviations as possible.
- Without assistance; administrators were allowed to give immaterial guidance and clarification on tasks, but not instructions on use unless they were unable to complete the task.
- Without using a think aloud technique.

Task timing began once the administrator finished reading the question. The task time was stopped once the participant indicated they had successfully completed the task. Scoring is discussed below in Section 3.9.

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

Participants were thanked for their time and compensated.

3.5 TEST LOCATION

The testing was all completed via a remote session, using the Zoom Meeting tool. Only the participant, the moderator and a data logger were present during the testing session.

3.6 TEST ENVIRONMENT

The EHRUT would be typically be used in a healthcare office or facility. In this instance, the testing was conducted via a remote session. For testing, the participants used personal computers and were given the remote control to use EHRUT. The participants used a trackpad and/or mouse and keyboard when interacting with the EHRUT.

The CGM CLINICAL 8.3 application was set up by CompuGroup Medical according to their environment. The application itself was running on a VPN platform using a training/test database.

Technically, the system performance (i.e., response time) was representative to what actual users would experience in a field implementation.

3.7 TEST FORMS AND TOOLS

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

- Informed Consent
- Moderator's Guide
- Post-test Questionnaire

Examples of these documents can be found in Appendices. The Moderator's Guide was devised so as to be able to capture required data.

The participant's interaction with the EHRUT was captured and recorded digitally with screen capture software running on the administrator's machine. Verbal comments were recorded with a microphone. The test sessions were electronically recorded, so the data logger could process the test session. Each participant gave consent to record the session and use it for analysis purposes.

3.8 PARTICIPANT INSTRUCTIONS

The administrator reads the following instructions aloud to the participant:

Hi, my name is Brian and I work for a company called SoftServe. I am going to be conducting this usability session today. The usability testing I am conducting today is on an Ambulatory patient management system. I am going to have you run through a set of steps in the system, and let you go at your own pace so that you can give us feedback. We will be recording today's session but be assured that the recording will only be used for analysis purposes to improve our application. Your name will not be used for any purpose beyond this session. Please note that we are not testing you, we are testing the system, therefore if you have difficulty all this means is that something needs to be improved in the system. I will be here in case you need specific help, but I am not able to instruct you or provide help in how to use the application.

Overall, we are interested in how easy (or how difficult) this system is to use, what in it would be useful to you, and how we could improve it. I did not have any involvement in its creation, so please be honest with your opinions. All of the information that you provide will be kept confidential and your name will not be associated with your comments at any time. Should you feel it necessary, you are able to withdraw at any time during the testing.

Do you have any questions that I can answer for you before we begin?

Following the procedural instructions, participants were given access to the EHR and their first task. Once this task was complete, the administrator gave the following instructions:

Thank you for completing this task. On a scale of 1 to 5, 1 being very easy and 5 being rather difficult, how would you rate this task?

Participants were then given additional tasks to complete. Tasks are listed above.

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 test were to assess:

- Effectiveness of CGM CLINICAL 8.3 by measuring participant success rates and errors
- Efficiency of CGM CLINICAL 8.3 by measuring the average task time and path deviations
- Satisfaction with CGM CLINICAL 8.3 by measuring ease of use ratings

3.10 DATA SCORING

The following table details how tasks were scored, errors evaluated, and the time data analyzed.

Measures	Rationale and Scoring
<p>Effectiveness: Task Success</p>	<p>A task was counted as a "Success" if the participant was able to achieve the correct outcome, without assistance, within the time allotted on a per task basis. The total number of successes were calculated for each task and then divided by the total number of times that task was attempted. The results are provided as a percentage.</p> <p>Task times were recorded for successes. Observed task times divided by the optimal time for each task is a measure of optimal efficiency.</p> <p>Optimal task performance time, as benchmarked by expert performance under realistic conditions, is recorded when constructing tasks. Target task times used for task times was operationally defined by taking multiple measures of optimal performance and multiplying by 2 that allows time buffer because the participants had no prior experience with CGM CLINICAL 8.3 and just received video training materials. Thus, if expert, optimal performance on a task was 20 seconds then allotted task time performance was 40 seconds. This ratio was aggregated across tasks and reported with mean and variance scores.</p>
<p>Effectiveness: Task Failures and Errors</p>	<p>If the participant 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 an "Failures." No task times were taken for errors.</p>

Measures	Rationale and Scoring
	<p>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. Error was counted when participant did not reach the correct answer or performed it incorrectly, and desired outcome was not reached.</p>
<p>Efficiency: Task Deviations</p>	<p>The participant's path (i.e., steps) through the application was recorded. Deviations occur if the participant, for example, went to a wrong screen, clicked on an incorrect menu item, followed an incorrect link. This path was compared to the optimal path. The number of steps in the observed path is divided by the number of optimal steps to provide a ratio of path deviation.</p>
<p>Efficiency: Task Time</p>	<p>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.</p>
<p>Satisfaction: Task Rating</p>	<p>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 to rate "Overall, this task was:" on a scale of 1 (Very Easy) to 5 (Very Difficult). These data are averaged across participants.</p> <p>Common convention is that average ratings for systems judged easy to use should be 2.7 or below.</p> <p>To measure participants' confidence in and likeability of the CGM CLINICAL 8.3 overall, 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." See full System Usability Score questionnaire in Appendix.</p>

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.

The usability testing results for the EHRUT are detailed in SED Checklist file. The results should be seen in light of the objectives and goals outlined in Section 3.2 Study Design. The data should yield actionable results that, if corrected, yield material, positive impact on user performance.

The results from the SUS (System Usability Scale) scored the subjective satisfaction with the system based on performance with these tasks were 60.75. Broadly interpreted, scores under 60 represent systems with poor usability; scores over 80 would be considered above average.

The summary of usability testing results for the EHRUT are detailed below:

Task	Task Success		Path Deviation		Errors Mean	Task Ratings 1=Easy
	Mean	STD	Mean	Optimal		
Criteria 170.315(a)(1) - CPOE medications						
A1a - A record and save a medication order	11	0.94	30	12	56	3.1
A1b - Change medication order	13	0.94	21	14	63	2.9
A1c - Access medication order	57	1.56	5	2	14	2.3
Criteria 170.315(a)(2) - CPOE laboratory						
A2a - Record and save laboratory order	40	1.55	13	10	50	2.3
A2b - Change laboratory order	33	1.41	5	8	56	1.6
A2c - Access laboratory order	44	1.49	8	5	11	2.8
Criteria 170.315(a)(3) - CPOE radiology						
A3a - Record and save a radiology order	50	1.58	8	4	10	2.1
A3b - Change radiology order	50	1.58	13	8	10	2.3
A3c - Access radiology order	90	0.95	6	6	0	2.0
Criteria 170.315(a)(4) - Drug-drug, drug-allergy interaction checks						
A4a - Create a drug-drug interaction	30	1.45	10	7	30	1.9
A4b - Create a drug- allergy interaction	70	1.45	7	7	0	1.6
A4c - Adjust the drug to drug severity level	40	1.55	6	5	50	2.6

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A4d - Create and view only major drug-drug interaction	80	1.26	7	7	0	1.4
A4e - Adjust the drug to drug severity level	70	1.45	3	1	0	2.0
Criteria 170.315(a)(5) - Demographics						
A5a - View patient demographics	60	1.55	5	3	20	1.9
A5b - Change patient sex	90	0.95	2	2	0	1.0
A5c - Change patient's gender identity	80	1.26	4	4	10	1.0
A5d - Change patient's sexual orientation	90	0.95	4	4	0	1.0
A5e - Change patient date of birth	100	0.00	2	2	0	1.2
A5f - Change patient's ethnicity	100	0.00	1	2	0	1.0
A5g - Change patient's race	100	0.00	1	2	0	1.0
A5h - Change patient's preferred language	100	0.00	2	2	0	1.0
Criteria 170.315(a)(6) - Problem list						
A6a - View patient's problem list	100	0.00	2	1	0	1.2
A6b - Mark problem inactive	90	0.95	2	2	10	1.5
A6c - Filter the patient's problem list by inactive problems only	100	0.00	2	3	0	1.0
A6d - Add a new problem	90	0.95	6	5	10	1.7
A6e - Filter the patient's problem list by active problems only	100	0.00	3	2	0	1.1
Criteria 170.315(a)(7) - Medication list						
A7a - Enter a medication	80	1.26	11	9	10	1.6
A7b - Change medication strength/dosage	60	1.55	10	5	20	1.8
A7c - Discontinue a medication	40	1.55	5	4	30	1.4
A7d - View the patient's medication history	50	1.58	5	2	30	1.1
A7e - Mark that patient is currently not taking any medications	40	1.55	4	5	40	1.4
Criteria 170.315(a)(8) - Medication allergy list						
A8a - Enter a new medication allergy	89	0.94	7	6	11	1.0

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A8b - Change patient medication allergy	56	1.49	6	6	22	1.2
A8c - Deactivate medication allergy	89	0.94	6	6	11	1.0
A8d - Indicate No Known Medication Allergies	89	0.94	10	9	0	1.1
Criteria 170.315(a)(9) - clinical Decision support						
A9a - Trigger and review decision support details based on problem list	70	1.45	4	3	20	2.7
A9b - Trigger and review decision support details based on medication list	80	1.26	4	3	10	2.1
A9c - Trigger and review decision support details based on medication allergy list	100	0.00	3	3	0	1.9
A9d - Trigger and review decision support details based on demographics	100	0.00	3	3	0	2.1
A9e - Trigger and review decision support details based on laboratory tests	90	0.95	3	3	0	1.8
A9f - Trigger and review decision support details based on vital signs	89	0.94	3	3	0	1.8
A9g - Trigger and review decision support details based on a combination of demographics and problem list	100	0.00	3	3	0	1.7
A9h - Review CDS source attributes	90	0.95	2	2	10	1.7
A9i - Trigger and review decision support details based on information incorporated from transition of care document	100	0.00	3	3	0	1.8
A9j - Review demographic infobutton resources	60	1.55	3	3	30	2.1
A9k - Review problem infobutton resources	90	0.95	4	4	10	1.6
A9l - Review medication infobutton resources	100	0.00	4	4	0	1.4
Criteria 170.315(a)(14) - Implantable device list						
A14a - View patient's implantable device list	100	0.00	1	1	0	1.4
A14b - Add implantable device to patient's list	40	1.55	6	4	40	2.2
A14c - Mark implantable device as inactive	100	0.00	5	4	0	1.3
A14d - View active and inactive devices	100	0.00	2	2	0	1.0

Criteria 170.315(b)(2) - clinical information reconciliation and incorporation						
B2a - Reconcile a patient's problem, medication and medication allergy list from another source	30	1.45	15	7	40	2.8
B2b - Generate a new CCDA with reconciled	50	1.58	7	5	10	3.0
Criteria 170.315(b)(3) - E-prescribing						
B3a - Create a prescription	40	1.55	14	9	20	2.0
B3b - Approve a change request from pharmacy	40	1.55	10	8	0	2.4
B3c - Discontinue a prescription	90	0.95	5	4	10	1.5
B3d - Approve a renewal request from pharmacy	10	0.95	7	7	40	2.3
B3e - Receive RXFILL status notification	60	1.55	6	4	0	2.0
B3f - Request and receive medication history information	60	1.55	8	4	10	2.4

Please see full results of testing in SED Checklist Excel Spreadsheet for CGM CLINICAL 8.3.

EFFECTIVENESS

The areas of CGM CLINICAL™ with the highest level of success were Demographics, Problem List, Medication Allergy List, Clinical Decision Support, Implantable Device List.

Test participants were able to succeed in average of 68% of the attempted tasks (average for all tasks). 15 tasks were completed with 100% success and 32 tasks scored above 80%.

The areas of CGM CLINICAL™ not reaching the highest level of success were CPOE Medications, CPOE Laboratory, Medication List, Electronic Prescribing. In about 50% of cases, the low success rate for those areas was often caused by participants going over the allotted time. Another frequent reason of failure were technical issues (app freezing, scrolling issues) and misinterpreting actions labeling (for example, deleting medication instead of discontinuing it).

EFFICIENCY

As all participants had no prior experience with CGM Clinical 8.3, x2 of optimal time was allotted. Overall, users who were able to complete the usability tasks did so with decent task time efficiency scores. The strongest area in this respect were Demographics and Clinical Decision Support.

The Drug-Drug, Drug Allergy Interaction Checks tasks had a high failure rate due to participants going over the allotted task time, but overall users were very efficient when it came to these tasks. All of them did not require assistance and would be successful with those tasks having more experience with application.

Also, the same as in Effectiveness section, participants had challenges efficiently completing the CPOE tasks, especially those for lab and medication orders due to busy screens and unclear workflows.

SATISFACTION

The results from the SUS (System Usability Scale) scored the subjective satisfaction with the system based on performance with these tasks to be: 60.75. Broadly interpreted, scores under 60 represent systems with poor usability; scores over 80 would be considered above average.

On an individual task level, users ranked, on average, most tasks 1-2 (between "very easy" and "easy").

The tasks lists slightly outside this ranking were:

- Clinical Information Reconciliation
- CPOE Medications
- CPOE Laboratory

The task ranking scores support the previously discussed quantitative data in these cases.

5 APPENDICES

5.1 SAMPLE RECRUITING SCREENER

SCRIPT

We are conducting a Usability test on an Ambulatory patient's management system. The usability test session will include a short 15 minutes' interview after which you will be asked to use the website following given scenario and provide comments and feedback about the site and how it functions.

First, I would like to ask you a few brief qualifying questions.

What is your current job title?

RECORD	
	IF NOT REGISTERED NURSE, THANK & TERMINATE

What is your current employment (practice type and name)?

RECORD	
	IF NOT OUTPATIENT/AMBULATORY CARE, THANK & TERMINATE

Are you currently working with ambulatory patients?

<input type="radio"/>	Yes...CONTINUE
<input type="radio"/>	No...THANK & TERMINATE

How many years of experience do you have?

RECORD	
<input type="radio"/>	2+ ... CONTINUE
<input type="radio"/>	Less than 2 ... THANK & TERMINATE

Roughly what percentage of your professional time is spent on direct patient care?

RECORD	
<input type="radio"/>	IF <50% ... THANK & TERMINATE

Do you currently use any patient management system(s)? If yes, what exactly?

<input type="radio"/>	Yes ... CONTINUE
<input type="radio"/>	No ... THANK & TERMINATE
RECORD	(If candidate knows exactly what system(s) he/she uses.)

What is your current address? State and city only, no street details.

RECORD	
---------------	--

RECRUIT A MIX of different regions (west coast, east coast etc)

What is your education level?

RECORD	
<input type="radio"/>	No high school degree
<input type="radio"/>	High school graduate, diploma or the equivalent (for example: GED)
<input type="radio"/>	Some college credit, no degree
<input type="radio"/>	Trade/technical/vocational training
<input type="radio"/>	Associate degree
<input type="radio"/>	Bachelor's Degree
<input type="radio"/>	Master's Degree
<input type="radio"/>	Doctorate Degree (e.g., MD, DNP, DMD, PhD)

What are your main job responsibilities?

RECORD	
---------------	--

Be sure the respondent is easy to talk to and that you can clearly understand him/her.

If the respondent has an accent that is difficult to understand, **DO NOT RECRUIT**.

Do you have a computer with access to Internet that you can use to participate in user testing?

<input type="radio"/>	Yes...CONTINUE
<input type="radio"/>	No...THANK & TERMINATE

How old are you?

RECORD	
<input type="radio"/>	19 and less
<input type="radio"/>	20 - 29
<input type="radio"/>	30 - 39
<input type="radio"/>	40 - 49
<input type="radio"/>	50 - 59
<input type="radio"/>	60+ THANK & TERMINATE

How much general computer experience do you have? (years)

RECORD	
---------------	--

Record Gender

RECORD	
<input type="radio"/>	Male
<input type="radio"/>	Female
<input type="radio"/>	Decline to specify

Be sure to recruit a mix.

INVITATION FOR PARTICIPATION

We would like to invite you to participate in a remote usability testing session for patient management system, during which you will be asked to use the website following given scenario and provide comments and feedback about the site and how it functions.

You will be compensated for your participation in the usability testing. Is this something you might be interested in?

IF YES, SAY:

Your interview will take place [SCHEDULE DATE] at [TIME]. The conversation will last 1-2 hours, and you will receive an honorarium of \$__ for your time.

If, for any reason, your plans change, please call me at [INSERT NUMBER].

5.2 EXAMPLE MODERATOR'S GUIDE

CGM CLINICAL

SUMMATIVE TESTING PROCESS FOR §170.315(A)(5) DEMOGRAPHICS

[Moderator]

"During these tasks we will ask you to make decisions that may differ from how you would practice. Please follow the tasks as we have outlined them because we have designed them to test the usability of specific workflows."

[Moderator]

**"Please take a few moments to review Task A and let me know when you are ready. Please don't begin any task until I ask you to begin."
PAUSE and wait for the participant to say they are ready.**

TASK A: VIEW PATIENT DEMOGRAPHICS

Patient:

Jack Durrett

Start Point:

Navigate to *Jack Durrett's* Facesheet → Demographics - Identity card

[Moderator]

You are seeing Patient Jack Durrett. During your interview with him he provides you with changes to his demographic information.

View Jack Durrett's current demographic data:

Sex: Unknown

Gender Identity: {blank}

Sexual Orientation: {blank}

Date of birth: 06/28/1962

Gender Identity: Choose not to disclose

Sexual Orientation: Choose not to disclose

Language: English

[Moderator]

***"Once you have completed the task please say Stop to indicate you are finished".
"Please Begin"***

[Participant]

"STOP"

[Moderator]

"Thank you for completing Task A"

"On a scale of 1 to 5, one being simple and 5 being difficult, how would you rate this task? "

Optimal Path:

START

Start Facesheet → Demographics pane → Identity card

1. **Click the right arrow on the Identity title bar**
2. **Click on the Gender Identity/Sexual Orientation link**
3. **View demographic information on Personal tab and Gender Identity/Sexual Orientation window.**

STOP

[Moderator]

Please take a few moments to review Task B and let me know when you are ready and we will begin.

PAUSE and wait for the participant to say they are ready.

TASK B: CHANGE PATIENT SEX

Patient:

Jack Durrett

Start Point:

Navigate to *Jack Durrett's* Facesheet → Demographics pane → Identity

[Moderator]

"You have noticed that Jack Durrett's Sex is incorrectly listed as Unknown. Change Jack's sex to Male."

[Moderator]

*"Once you have completed the task please say Stop to indicate you are finished".
"Please Begin"*

[Participant]

STOP

[Moderator]

"Thank you for completing Task B"

"On a scale of 1 to 5, one being simple and 5 being difficult, how would you rate this task? "

Optimal Path:

START

Start Facesheet → Demographics pane → Identity card

1. **Change sex to Male**
2. **Click OK**

STOP

[Moderator]

"Please take a few moments to review Task C and let me know when you are ready and we will begin".

PAUSE and wait for the participant to say they are ready.

TASK C CHANGE PATIENT'S GENDER IDENTITY

Patient:

Jack Durrett

Start Point:

Navigate to *Jack Durrett's* Facesheet-→ Demographics pane → Identity

[Moderator]

"Jack Durrett informs you that the gender he identifies with is Male. Change the Gender Identity to Identifies as Male"

Make the appropriate changes".

[Moderator]

*"Once you have completed the task please say Stop to indicate you are finished".
"Please Begin"*

[Participant]

STOP

[Moderator]

"Thank you for completing Task C"

"On a scale of 1 to 5, one being simple and 5 being difficult, how would you rate this task?"

Optimal Path:

START

Start Facesheet → Demographics pane → Identity card

1. Click **Gender Identity/Sexual Orientation** link
2. Select **Identifies as Male** from the **Gender Identity** drop-down list
3. Click **OK** on **Gender Identity/Sexual Orientation** window
4. Click **OK** on **Edit Patient Demographics** window

STOP

[Moderator]

"Please take a few moments to review Task D and let me know when you are ready and we will begin".

PAUSE and wait for the participant to say they are ready.

TASK D CHANGE PATIENT'S SEXUAL ORIENTATION

Patient:

Jack Durrett

Start Point:

Navigate to *Jack Durrett's* Facesheet-→ Demographics pane → Identity

[Moderator]

"Jack Durrett informs you that his sexual orientation is straight/heterosexual. Change the Sexual Orientation to Straight or heterosexual"

Make the appropriate changes".

[Moderator]

"Once you have completed the task please say Stop to indicate you are finished".

"Please Begin"

[Participant]

STOP

[Moderator]

"Thank you for completing Task D"

"On a scale of 1 to 5, one being simple and 5 being difficult, how would you rate this task?"

Optimal Path:

START

Start Facesheet → Demographics pane → Identity card

1. **Click Gender Identity/Sexual Orientation link**
2. **Select Straight or heterosexual from the Sexual Orientation drop-down list**
3. **Click OK on Gender Identity/Sexual Orientation window**
4. **Click OK on Edit Patient Demographics window**

STOP

[Moderator]

"Please take a few moments to review Task E and let me know when you are ready and we will begin".

PAUSE and wait for the participant to say they are ready.

TASK E CHANGE PATIENT DATE OF BIRTH

Patient:

Jack Durrett

Start Point:

Navigate to *Jack Durrett's* Facesheet-→ Demographics pane → Identity

[Moderator]

"Jack Durrett informs you that the date of birth you have notated is incorrect. Change the date of birth to 06/28/1963"

Make the appropriate changes".

[Moderator]

"Once you have completed the task please say Stop to indicate you are finished".

"Please Begin"

[Participant]

STOP

[Moderator]

"Thank you for completing Task E"

"On a scale of 1 to 5, one being simple and 5 being difficult, how would you rate this task?"

Optimal Path:

START

Start Facesheet → Demographics pane → Identity card

1. **Change date of birth to 06/28/1963**
2. **Click OK**

STOP

[Moderator]

"Please take a few moments to review Task F and let me know when you are ready and we will begin".

PAUSE and wait for the participant to say they are ready.

TASK F: CHANGE PATIENT'S ETHNICITY

Patient:

Jack Durrett

Start Point:

Navigate to *Jack Durrett's* Facesheet-→ Demographics pane → Identity

[Moderator]

"Jack Durrett notifies you that he does not want to disclose his ethnicity. Change Jack's ethnicity to Declined to specify."

[Moderator]

*"Once you have completed the task please say Stop to indicate you are finished".
"Please Begin"*

[Participant]

STOP

[Moderator]

"Thank you for completing Task F.

"On a scale of 1 to 5, one being simple and 5 being difficult, how would you rate this task?"

Optimal Path:

START

Start Facesheet → Demographics pane → Identity card

1. **Select Declined to specify checkbox for Ethnicity**
2. **Click OK**

STOP

[Moderator]

"Please take a few moments to review Task G and let me know when you are ready and we will begin".

PAUSE and wait for the participant to say they are ready.

TASK G: CHANGE PATIENT'S RACE

Patient:

Jack Durrett

Start Point:

Navigate to *Jack Durrett's* Facesheet-→ Demographics pane → Identity

[Moderator]

"Jack Durrett notifies you that he does not want to disclose his race. Change Jack's Race to Declined to specify."

[Moderator]

*"Once you have completed the task please say Stop to indicate you are finished".
"Please Begin"*

[Participant]

STOP

[Moderator]

"Thank you for completing Task G.

"On a scale of 1 to 5, one being simple and 5 being difficult, how would you rate this task?"

Optimal Path:

START

Start Facesheet → Demographics pane → Identity card

1. **Select Declined to specify checkbox for Race**
2. **Click OK**

STOP

[Moderator]

"Please take a few moments to review Task H and let me know when you are ready and we will begin".

PAUSE and wait for the participant to say they are ready.

TASK H: CHANGE PATIENT'S PREFERRED LANGUAGE

Patient:

Jack Durrett

Start Point:

Navigate to *Jack Durrett's* Facesheet-→ Demographics pane → Identity

[Moderator]

"Jack Durrett notifies you that his preferred language is Spanish. Change Jack's Language selection to Spanish"

[Moderator]

***"Once you have completed the task please say Stop to indicate you are finished".
"Please Begin"***

[Participant]

STOP

[Moderator]

"Thank you for completing Task H.

"On a scale of 1 to 5, one being simple and 5 being difficult, how would you rate this task?"

Optimal Path:

START

Start Facesheet → Demographics pane → Identity card

1. **Select Spanish from the Language drop-down list**
2. **Click OK**

STOP

[Moderator]

This concludes the Demographics Usability Test. We will now move on to Implantable Device List.

5.3 SYSTEM USABILITY SCALE QUESTIONNAIRE

In 1996, Brooke published a “low-cost usability scale that can be used for global assessments of systems usability” known as the System Usability Scale or SUS. Lewis and Sauro (2009) and others have elaborated on the SUS over the years. Computation of the SUS score can be found in Brooke’s paper, in at <http://www.usabilitynet.org/trump/documents/Suschapt.doc> or in Tullis and Albert (2008).

	Strongly disagree				Strongly agree
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 that I would need the support of a technical person to be able to use this system	1	2	3	4	5
5. I found the various functions in this system were well integrated	1	2	3	4	5
6. I thought there was too much inconsistency in this system	1	2	3	4	5
7. I would imagine that most people would learn to use this system very quickly	1	2	3	4	5
8. I found the system very 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 this system	1	2	3	4	5