EHR Usability Test Report of AXEIUM EHR
MU3 version

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

AXEIUM EHR, MU3 version

Date of Usability Test: August 12, 2019

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Executive Summary

Usability tests of the MU3 version of the AXEIUM EHR were conducted at various times during the development cycle, the last session for which was held on August 12, 2019. The purpose of these tests was to test and validate the usability of the current user interface, and provide evidence of usability of the EHR Under Test (EHRUT).

During the usability test, 12 active clinicians matching the target demographic criteria served as participants and used the EHRUT in simulated, but representative tasks.

This study collected performance data on 13 tasks typically conducted in the EHR:

Computerized Provider Order Entry
Record lab order
Access lab order
Change lab order

Record radiology order
Access radiology order
Change radiology order

Demographics
Record demographics
Access and modify demographics

Problem List
View Update problem list

Clinical decision support
View CDS Alert
Record historical result

Implantable Device
Add Change implantable device

Clinical information reconciliation
Clinical Info Reconciliation of active
medications, problems, and med allergies

During the 45 minute, one-on-one, remote usability test, each participant was greeted by the administrator and asked to review and sign an informed consent/release form. Participants were advised that they could withdraw at any time. Participants all had prior experience with the AXEIUM EHR.

The administrator introduced the test, and instructed the participant to complete a series of tasks (given one at a time) using the EHRUT. 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.

The test session, including participant screens, user workflow, and audio, was 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 verbal feedback
- Participant's satisfaction ratings of the system using a Likert Scale

All participant data was de-identified so that no correlation could be made from the identity of the participant to the data collected. Following the conclusion of the testing, participants were asked to complete a post-test questionnaire. Participants were not compensated for their time.

The results from the System Usability Scale scored the subjective satisfaction with the system based on performance with these tasks to be 88.

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

Task	Measure Task Success Mean (SD)	Path Deviation Observed /Optimal	Time (sec) Mean (SD)	Time (sec) Observed /Optimal	Errors Mean (SD)	Effort 5=Low Mean (SD)
Computerized Provider Order Entry (CPOE)						
a2.1 Record lab order	100%	11/11	93.0/18.7	27.0/120.0	0/0	3.1/0.5
a2.2 Access lab order	100%	7/6	29.6/14.1	30.4/60.0	0/0	3.1/0.5
a2.3 Change lab order	100%	11/10	52.7/14.1	22.3/75.0	0/0	2.1/0.5

a3.1 Record radiology order	100%	11/11	53.3/5.3	21.7/75.0	10/0.3	2.3/0.5
a3.2 Access radiology order	100%	6/5	44.1/8.8	25.9/70.0	0/0	2.3/1.0
a3.3 Change radiology order	100%	8/4	88.8/19.5	21.2/110.0	10/0.3	1.6/0.8
Demographics						
a5.1 Record demographics	100%	8/7	79.7/9.4	20.3/100.0	0/0	4.3/0.6
a5.2 Access and modify demographics	100%	8/7	77.8/12.2	22.2/100.0	0/0	4.1/0.8
Problem List						
a6.1 View Update problem list	100%	12/10	58.9/6.8	31.1/90.0	10/0.3	3.0/0.8
Clinical decision support						
a9.1 View CDS Alert	100%	12/8	96.6/10.3	23.4/120.0	20/0.4	1.4/0.7
a9.2 Record historical result	100%	18/12	143.3/15.6	16.7/160.0	20/0.4	1.4/0.7
Implantable Device						
a14.1 Add Change implantable device	100%	23/17	151.5/7.5	48.5/200.0	30/0.4582	1.0/0.0
Clinical information reconciliation						
b2.1 Clinical Info Reconciliation - Active medications, problems and med allergies	100%	28/24	102.1/7.9	77.9/180.0	0/0	1.5/0.5

Introduction

This study is the result of usability testing performed on the MU3 version of the AXEIUM EHR, which is designed to collect, track, and report medical information collected from healthcare providers in an ambulatory setting. The application consists of solutions for a range of services including medical, dental, vision, and behavior allowing practices to provide patient care for all their services.

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 to support certification according to criteria outlined in Safety Enhanced Design §170.315(g)(3), specifically:

§ 170.315 (a)(2) Computerized provider order entry – laboratory

§ 170.315 (a)(3) Computerized provider order entry – diagnostic imaging

§ 170.315 (a)(5) Demographics

§ 170.315 (a)(6) Problem list

§ 170.315 (a)(9) Clinical decision support

§ 170.315 (a)(14) Implantable device list

§ 170.315 (b)(2) Clinical information reconciliation and incorporation

Method

Participants

A total of 12 participants were tested on the AXEIUM EHR. Participants in the test included doctors, nurses, medical assistants, and clinic managers. Volunteer participants were recruited by Brilogy and were not compensated for their time.

Participants had no direct connection to the development of or organization producing the EHR, and they were not from or affiliated with Brilogy, and did not need any orientation or training as they all were experienced AXEIUM EHR users.

For test purposes, end-user characteristics were identified and translated into a recruitment screener used to solicit potential participants.

Participants had a mix of backgrounds and demographic characteristics. The following is a table of participants by characteristics, including demographics, professional experience, computing experience, and user needs for assistive technology. Participant names were replaced with Participant IDs so that an individual's data cannot be tied back to his or her identity.

Part ID	Sex	Age	Education	Occupation /Role	Professional Experience	Computer Experience	Product Experience	Assistive Technology
1	Male	60-69	Doctorate degree	Clinic Director	Family Medicine	240	48	No
2	Female	40-49	Doctorate degree	Clinic Director	Family Medicine	180	48	No
3	Female	40-49	Bachelor's degree	Provider	Family Medicine	192	84	No
4	Female	40-49	Bachelor's degree	Provider	Family Medicine	168	84	No
5	Female	50-59	Doctorate degree	Provider	Family Medicine	216	84	No
6	Female	40-49	Bachelor's degree	Provider	Family Medicine	180	84	No
7	Male	40-49	Doctorate degree	Provider	Family Medicine	204	84	No
8	Male	50-59	Doctorate degree	Provider	Family Medicine	240	84	No
9	Female	30-39	Associate degree	Medical Assistant	Family Medicine	156	108	No
10	Female	20-29	Associate degree	Medical Assistant	Family Medicine	132	108	No
11	Female	30-39	Bachelor's degree	Case Manager	Family Medicine	156	108	No
12	Female	30-39	Some college credit, no degree	Clinic Manager	Family Medicine	168	108	No

12 participants participated in the usability test. 0 participants failed to show for the study. Participants were scheduled for 45 minute sessions with 5 minutes in between each session for debrief by the administrator and data logger, and 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 participant.

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 development environment, 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 the Section on Usability Metrics.

Tasks

In support certification according to criteria outlined in Safety Enhanced Design §170.315(g)(3), 13 tasks were constructed that would be realistic and representative of the kinds of activities a user might conduct with the EHR, in the following categories:

- Computerized provider order entry (Labs and Diagnostic Imaging)
- Clinical decision support
- Clinical information reconciliation
- Implantable Device
- Problem List
- Demographics

Tasks were selected based on their frequency of use, criticality of function, and those that may be most troublesome for users. Tasks were designed to meet the study objectives. A detailed list of the tasks provided is included in Appendix B.

Procedures

Remote testing was conducted via a WebEx session by a proctor with 10+ years' experience with the EHRUT. A Remote testing methodology was selected to both for convenience to accommodate the

volunteer participants but also because that technology includes recording of the screen-sharing and audio for subsequent review and analysis.

Participants were advised to choose a quiet location to participate in the study using their own computers, and to:
- Complete the tasks as quickly as possible, using their normal workflow

- Complete the tasks without assistance except to clarify task details, if necessary

All test sessions were recorded by WebEx and subsequently analyzed. While participants completed the tasks, an observer monitored task times, obtained post-task rating data, and took notes on participant comments, and the data logger and took notes on task success, path deviations, number and type of errors, and comments.

Participants' demographic information, 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.

Test Location

Test sessions were conducted remotely via a WebEx meeting. The test administrator, observers, and participant logged into the session from their various locations. All observers and the data logger could see the participant's screen, and listen to the audio of the session.

Test Environment

The EHRUT would be typically be used in a healthcare office or facility. In this instance, the testing was conducted remotely via a WebEx meeting. For testing, the proctor hosted the EHRUT as a Microsoft Remote Desktop Application running on Windows Server 2016

The participants used their own computer, keyboard, and mouse when testing.

Test Forms and Tools

During the usability test, various documents and instruments were used, including:
- Proctor Guide
- Participant Guide

The Proctor's Guide was devised to be able to capture required data. The participant's interaction with the AXEIUM EHR application was captured and recorded via the WebEx meeting technology.\

Participant Instructions

The proctor read the following instructions to the each participant:

> *Thank you for participating in this study. Your input is very important. Our session today will last about 45 minutes. During this time, you will be using the MU3 version of the AXEIUM EHR. I will ask you to complete a few tasks using this system and answer some questions. You should complete the tasks as quickly as possible, making as few errors as possible. Please try to complete the tasks on your own following the instructions very closely. Please note that we are not testing you, rather, 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.*
>
> *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.*

Following the procedural instructions, participants were logged into the EHRUT and then given six or 10 tasks to complete based on their role, and the administrator gave the following instructions:

> *For each task, I will read the description to you and say, "Begin." At that point, please perform the task and say, "Done," once you believe you have successfully completed the task. I will ask you your impressions about the task once you are done.*

Participants were then given their tasks to complete.

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 AXEIUM EHR MU3 by measuring participant success rates and errors
- Efficiency of AXEIUM EHR MU3 by measuring the average task time and path deviations
- Satisfaction with AXEIUM EHR MU3 by measuring ease of use ratings

Data Scoring

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

Measures	Rationale and Scoring
Effectiveness: Task Success	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. 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.
Effectiveness: Task Failures	If the participant abandoned the task, did not reach the correct answer or performed it incorrectly, or reached the end of the allotted time before successful completion, the task was counted as an "Failures." No task times were taken for errors. The total number of errors was calculated for each task and then divided by the total number of times that task was attempted. Not all deviations 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.

Measures	Rationale and Scoring
Efficiency: Task Deviations	The participant's path, i.e., steps through the application, was recorded. Deviations occur if the participant, for example, went to a wrong screen, clicked on an incorrect menu item, followed an incorrect link, or interacted incorrectly with an on-screen control. This path was compared to the optimal path. The number of steps in the observed path is divided by the number of optimal steps to provide a ratio of path deviation. It is strongly recommended that task deviations be reported. Optimal paths (i.e., 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.

Measures	Rationale and Scoring
Satisfaction: Task Rating	Participant's subjective impression of the ease of use of the application was measured by administering both a simple post-task question as well as a post-session questionnaire. After each task, the participant was asked to rate "Overall, this task was:" on a scale of 1 (Very Difficult) to 5 (Very Easy). These data are averaged across participants. Common convention is that average ratings for systems judged easy to use should be 3.3 or above. To measure participants' confidence in and likeability of the MU3 version of the AXEIUM EHR 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 C.

Results

The results of the usability test were calculated according to the methods specified in the Usability Metrics section. Participants who failed to follow session and task instructions had their data excluded from the analysis. There were no testing irregularities recorded.

The usability testing results for the EHRUT are detailed below. The results should be seen in light of the objectives and goals outlined in section on 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 to be 88. Broadly interpreted, scores under 60 represent systems with poor usability; scores over 80 would be considered above average.

§170.315 (a)(2) Computerized Physician Order Entry - Labs

Data Analysis and Reporting

Task \ Measure	Task Success Mean (SD)	Path Deviation Observed /Optimal	Time (sec) Mean (SD)	Observed /Optimal	Errors Mean (SD)	Effort 5=Low Mean (SD)
Computerized Provider Order Entry (CPOE)						
a2.1 Record lab order	100%	11/11	93.0/18.7	27.0/120.0	0/0	3.1/0.5
a2.2 Access lab order	100%	7/6	29.6/14.1	30.4/60.0	0/0	3.1/0.5
a2.3 Change lab order	100%	11/10	52.7/14.1	22.3/75.0	0/0	2.1/0.5

Discussion of Findings

Efficiency

Overall the efficiency of participants completing the ordering and modifying of lab orders was near the optimal path and the deviation in time. This is understandable because the user interface for this feature did not change since MU2..

Effectiveness

Participants were successful 100% of the time when completing the tasks for ordering and modifying lab orders.

Satisfaction

Participant consensus rated the task between Strongly Agree and Agree that the tasks were easy to perform.

Major findings

Task is performing as designed.

Areas for improvement

None identified, or requested.

§170.315 (a)(3) Computerized Physician Order Entry – Diagnostic

Data Analysis and Reporting

Task	Task Success Mean (SD)	Path Deviation Observed /Optimal	Time (sec) Mean (SD)	Observed /Optimal	Errors Mean (SD)	Effort 5=Low Mean (SD)
Computerized Provider Order Entry (CPOE)						
a3.1 Record radiology order	100%	11/11	53.3/5.3	21.7/75.0	10/0.3	2.3/0.5
a3.2 Access radiology order	100%	6/5	44.1/8.8	25.9/70.0	0/0	2.3/1.0
a3.3 Change radiology order	100%	8/4	88.8/19.5	21.2/110.0	10/0.3	1.6/0.8

Discussion of Findings

Efficiency

Overall the efficiency of participants completing the radiology orders was near the optimal path and the deviation in time. This is understandable because the user interface for this feature did not change since MU2..

Effectiveness

Participants were successful 100% of the time when completing the tasks for ordering and modifying referral orders.

Satisfaction

Participant consensus rated the task between Strongly Agree and Agree that the tasks were easy to perform.

Major findings

Task is performing as designed.

Areas for improvement

None identified, or requested.

§170.315 (a)(5) Demographics

Data Analysis and Reporting

Task	Measure	Task Success	Path Deviation	Time (sec)		Errors	Effort 5=Low
		Mean (SD)	Observed /Optimal	Mean (SD)	Observed /Optimal	Mean (SD)	Mean (SD)
Demographics							
a5.1 Record demographics		100%	8/7	79.7/9.4	20.3/100.0	0/0	4.3/0.6
a5.2 Access and modify demographics		100%	8/7	77.8/12.2	22.2/100.0	0/0	4.1/0.8

Discussion of Findings

Efficiency

Overall the efficiency of participants completing demographics add, change and access was within the optimal path and the deviation in time. This is understandable because the user interface for this feature has not changed since MU2..

Effectiveness

Participants were successful about 100% of the time when completing the tasks for demographics add, change and access. No failures. Process was easy to use.

Satisfaction

Participant consensus rated the task between Strongly Agree and Agree that the tasks were very easy to perform.

Major findings

Task is performing as designed..

Areas for improvement

None identified, or requested.

§170.315 (a)(6) Problem List

Discussion of Findings

Task	Measure	Task Success	Path Deviation	Time (sec)		Errors	Effort 5=Low
		Mean (SD)	Observed /Optimal	Mean (SD)	Observed /Optimal	Mean (SD)	Mean (SD)
Problem List							
a6.1 View Update problem list		100%	12/10	58.9/6.8	31.1/90.0	10/0.3	3.0/0.8

Discussion of Findings

Efficiency

Overall the efficiency of participants completing the problem list tasks was near the optimal path and the deviation in time. This is understandable because the user interface for this feature did not change since MU2..

Effectiveness

Participants were successful 100% of the time when completing the tasks for adding, changing and updating the problem list.

Satisfaction

Participant consensus rated the task between Strongly Agree and Agree that the tasks were easy to perform.

Major findings

Task is performing as designed.

Areas for improvement

None identified, or requested.

§170.315 (a)(9) Clinical Decision Support

Data Analysis and Reporting

Task	Task Success Mean (SD)	Path Deviation Observed /Optimal	Time (sec) Mean (SD)	Observed /Optimal	Errors Mean (SD)	Effort 5=Low Mean (SD)
Clinical decision support						
a9.1 View CDS Alert	100%	12/8	96.6/10.3	23.4/120.0	20/0.4	1.4/0.7
a9.2 Record historical result	100%	18/12	143.3/15.6	16.7/160.0	20/0.4	1.4/0.7

Discussion of Findings

Efficiency

Overall the efficiency of participants completing the clinical decision support was within the optimal path and the deviation in time.

Effectiveness

Participants were successful about 100% (average) of the time when completing the tasks for performing the clinical decision support. Task failures were about 20%. Process was moderately difficult to use.

Satisfaction

Participant consensus rated the task between Strongly Agree and Agree that the tasks were moderately difficult to perform.

Major findings

Task is performing as designed. But the users had issues performing the tasks in an efficient manner. Workflow process has been scheduled for a JAD session toward the goal of process simplification.

Areas for improvement

Changes to the user interface to improve the workflow would be beneficial.

§170.315 (a)(14) Implantable Device List

Measure	Task Success	Path Deviation	Time (sec)		Errors	Effort 5=Low
Task	Mean (SD)	Observed /Optimal	Mean (SD)	Observed /Optimal	Mean (SD)	Mean (SD)
Implantable Device						
a14.1 Add Change implantable device	100%	23/17	151.5/7.5	48.5/200.0	30/0.4582	1.0/0.0

Discussion of Findings

Efficiency

Overall the efficiency of participants completing the adding and changing of the implantable devices was outside the optimal path and the deviation in time. This is understandable because the user interface is brand new, and the providers have virtually no use of this feature in their practice.

Effectiveness

Participants were successful 100% of the time when completing the tasks for performing the implantable device process.

Satisfaction

Participant consensus rated the task between Strongly Agree and Agree that the tasks were very difficult to perform.

Major findings

Task could use some changes in the interface, but the usage is so small (almost non-existent) that priority is low.

Areas for improvement

User interface has been flagged for redesign to improve the process.

§170.315 (b)(2) Clinical Information Reconciliation and Incorporation

Data Analysis and Reporting

Task \ Measure	Task Success Mean (SD)	Path Deviation Observed /Optimal	Time (sec) Mean (SD)	Time (sec) Observed /Optimal	Errors Mean (SD)	Effort 5=Low Mean (SD)
Clinical information reconciliation						
b2.1 Clinical Info Reconciliation - Active medications, problems and med allergies	100%	28/24	102.1/7.9	77.9/180.0	0/0	1.5/0.5

Discussion of Findings

Efficiency

Overall the efficiency of participants completing the clinical information reconciliation support was within the optimal path and the deviation in time. This is understandable because the user interface for this feature has not changed since MU2.

Effectiveness

Participants were successful 100% of the time when completing the tasks for performing the clinical reconciliation.

Satisfaction

Participant consensus rated the tasks between Strongly Agree and Agree on the ease of use of the system.

Major findings

Task is performing as designed. And the users had no issues performing the tasks in an efficient manner.

Areas for improvement

None were identified or requested.

Appendices

Appendix A - Trademarks

AXEIUM® is a registered trademark of Brilogy Corporation

All other trademarks or service marks contained herein are the property of their respective owners.

Appendix B - Tasks

170.315 (a)(2) - CPOE Labs

Task No.	Description
a2.1	**CPOE - Record a Lab Order** *(Review and/or consult the lab entry process overview document, if necessary)*

Actor
Provider

Steps

1. Select a patient
2. Open patient Enter Lab Order screen
   Path: Labs > Enter Lab Order
3. Select Lab (e.g., Quest)
4. Enter order code (e.g., 496 – HbA1c)
5. Enter Dx code
6. Click Save Lab Entry button *(but do not 'Print and Send')*

Observations

Task Success	Path Deviations	Errors	Effort: (1) v. high, (5) v. low	Time to Complete
☒ Pass ☐ Fail	☒ No ☐ Yes	☒ No ☐ Yes	☐1 ☐2 ☒3 ☐4 ☐5	66 secs

Comments

Click here

Task No.	Description
a2.2	**CPOE - Access a Lab Order** *(Review and/or consult the lab entry process overview document, if necessary)*

Actor
Provider, MA

Steps

1. Select a patient
2. Open patient View Lab Orders screen

   Path: Labs > View Lab Orders
3. Verify date range
4. double click order header row to see items on order

Observations

Task Success	Path Deviations	Errors	Effort: (1) v. high, (5) v. low	Time to Complete
☒ Pass ☐ Fail	☒ No ☐ Yes	☒ No ☐ Yes	☐1 ☒2 ☐3 ☐4 ☐5	10 secs

Comments

Click here

Task No.	Description
a2.3	**CPOE - Change a Lab Order**

(Review and/or consult the lab entry process overview document, if necessary)

Note that lab order can only be edited before it is sent. To change a lab order that has already been sent, you must delete and reorder with changes.

Actor

Provider

Steps

1. Select a patient
2. Open patient View Lab Orders screen

   Path: Labs > View Lab Orders
3. Verify date range
4. double click order header row to see items on order
5. double click item to load into Lab Detail Entry
6. change Order Code
7. Click Save Lab Entry button

Observations

Task Success	Path Deviations	Errors	Effort: (1) v. high, (5) v. low	Time to Complete
☒ Pass ☐ Fail	☒ No ☐ Yes	☒ No ☐ Yes	☐1 ☐2 ☐3 ☒4 ☐5	32 secs

Comments

Click here

170.315 (a)(3) - CPOE DX Imaging

Task No.	Description
a3.1	**CPOE - Record a Radiology Order** *(Review and/or consult the Referrals and Radiology Orders process overview document, if necessary)*

Actor
Provider

Steps
1. Select a patient
2. Open patient Enter Referral screen   **Path**: Referrals > Enter Referral
3. Set specialty = "Diagnostic Radiology"
4. Pick facility (e.g., SJO Radiology
5. Enter Service Requested
6. Click ⬚Save⬚ button

Observations

Task Success	Path Deviations	Errors	Effort: (1) v. high, (5) v. low	Time to Complete
☒ Pass ☐ Fail	☒ No ☐ Yes	☒ No ☐ Yes	☐1 ☐2 ☐3 ☒4 ☐5	43 secs

Comments
Click here

Task No.	Description
a3.2	**CPOE - Access a Radiology Order** *(Review and/or consult the Referrals and Radiology Orders process overview document, if necessary)*

Actor
Provider, MA, Case Manager

Steps
1. Select a patient
2. Open patient Referral screen   **Path**: Referrals > Outbound Referral
3. Double-click referral to open
4. Click ⬚Close⬚ button

Observations

Task Success	Path Deviations	Errors	Effort: (1) v. high, (5) v. low	Time to Complete
☒ Pass ☐ Fail	☒ No ☐ Yes	☒ No ☐ Yes	☐1 ☐2 ☐3 ☐4 ☒5	24 secs

Comments
Click here

Task No.	Description
a3.3	**CPOE - Change a Radiology Order** *(Review and/or consult the Referrals and Radiology Orders process overview document, if necessary)*

Actor
Provider, MA, Case Manager

Steps
1. Select a patient 2. Open patient Referral screen   **Path**: Referrals > Outbound Referral 3. Double-click referral to open 4. Change referral, add notes, etc. 5. Click ⬚Save⬚ button

Observations				
Task Success	**Path Deviations**	**Errors**	**Effort: (1) v. high, (5) v. low**	**Time to Complete**
☒ Pass ☐ Fail	☒ No ☐ Yes	☒ No ☐ Yes	☐1 ☐2 ☐3 ☒4 ☐5	54 secs
Comments				
Click here				

170.315 (a)(5) - Demographics

Task No.	Description
a5.1	**Record demographics** *(Review, add, change demographic information, if necessary)*

Actor

Provider

Steps

7. Select a patient
8. Open patient update screen

   Path: Patients > Update Patients
9. Add sexual orientation
10. Add mulitple ethnicities.
11. Click Save button

Observations

Task Success	Path Deviations	Errors	Effort: (1) v. high, (5) v. low	Time to Complete
☒ Pass ☐ Fail	☒ No ☐ Yes	☒ No ☐ Yes	☐1 ☒2 ☐3 ☐4 ☐5	63 secs

Comments

Click here

Task No.	Description
a5.2	**Access and modify demographics** *(Access and modify demographic information, if necessary)*

Actor

Provider, MA, Case Manager

Steps

5. Select a patient
6. Open patient update screen

   Path: Patients > Update Patients
7. Change sexual orientation
8. Change ethnicities.
9. Click Save button

Observations

Task Success	Path Deviations	Errors	Effort: (1) v. high, (5) v. low	Time to Complete
☒ Pass ☐ Fail	☒ No ☐ Yes	☒ No ☐ Yes	☐1 ☐2 ☒3 ☐4 ☐5	59 secs

Comments

Click here

170.315 (a)(6) - Problem List

Task No.	Description
A6.1	**View, Update Problem List** *(View and update the problem list, if necessary)*

Actor
Provider, MA, Case Manager

Steps

10. Select a patient

11. Open patient Problem List screen

    Path: Bubble help > Problem list

12. Click on existing problem.

13. Update the problem notes.

14. Add a new problem

15. Click ⎡Save⎤ button

Observations				
Task Success	**Path Deviations**	**Errors**	**Effort: (1) v. high, (5) v. low**	**Time to Complete**
☒ Pass ☐ Fail	☒ No ☐ Yes	☒ No ☐ Yes	☐1 ☐2 ☒3 ☐4 ☒5	46 secs

Comments
Click here

§170.314 (a)(9) – Clinical Decision Support

Overview
Validate ability to configure clinical decision support interventions for Problems, Med List, Med Allergy List, Demographics, Lab Tests and values/results, Vital Signs, and combinations thereof, for a user.

Task No.	Description
A9.1	**View CDS Alert** *(Review and/or consult the CDS Setup & Administration process overview document, if necessary)*

Actor
Clinic Manager (Admin)

Steps
1. Open user-role security screen   **Path**: System Admin > Security > User-Role   2. Tip: Filter the role list with Contains 'CDS'   3. Select a user   4. Check on (or off) one or more CDS roles to configure that intervention for the selected user   5. Click **Save** button

Observations

Task Success	Path Deviations	Errors	Effort: (1) v. high, (5) v. low	Time to Complete
☒ Pass ☐ Fail	☒ No ☐ Yes	☒ No ☐ Yes	☐1 ☐2 ☐3 ☐4 ☒5	77 secs

Comments
Click here

Task No.	Description
A9.2	**Record historical result** *(Review and/or consult the CDS Setup & Administration process overview document, if necessary)*

Actor
Clinic Manager (Admin)

Steps
1. Open reports   **Path**: Reporting Reports   2. Select System Setup   3. Select Security   4. Click **Run** button

Observations

Task Success	Path Deviations	Errors	Effort: (1) v. high, (5) v. low	Time to Complete
☒ Pass ☐ Fail	☒ No ☐ Yes	☒ No ☐ Yes	☐1 ☐2 ☐3 ☐4 ☒5	111 secs

Comments
Click here

170.315 (a)(14) - Implantable Device

Overview
Validate ability to add and change implantable devices).

Task No.	Description
A14.1	**– Add. Change implamtable device** *(Review and update/change implantable device, if necessary)*

Actor	
Clinic Manager (Admin)	

Steps

1. Select a patient.
2. Open the notes tab.
3. Click on add new note.
4. Select medical equipment.
5. Click browse UDI medical equipment link
6. Select UDI medical equipment and copy paste into the note
7. Click **SAVE** button to save the information.

Observations

Task Success	Path Deviations	Errors	Effort: (1) v. high, (5) v. low	Time to Complete
⊠ Pass ☐ Fail	⊠ No ☐ Yes	⊠ No ☐ Yes	☐1 ☐2 ☐3 ☐4 ⊠5	135 secs

Comments

Click here

§170.314 (b)(2) – Clinical Info Reconciliation

Overview
Validate ability to reconcile patient's active medications, problems, and med allergies, to an externally provided electronic list.

Task No.	Description
b2.1	**Clinical Info Reconciliation – Active Medications, Problems & Med Allergies** *(Use the CCD.XSL document that has been loaded to the network share, IncomingCCD folder)*

Actor
Provider, MA

Steps

1. Select a patient
2. Open the CCDA Import Screen

    Path: CMD Box > CCDImport
3. Click Import CCD button
4. Navigate to CCD.XML on network share
5. Medication Tab
    a. Check items in Inbound pane, and Active Med pane – that you want to keep
    b. Review proposed reconciled list
    c. Click Save button
6. Problems Tab
    a. Check items in Inbound pane, and Active Problems pane – that you want to keep
    b. Review proposed reconciled list
    c. Click Save button
7. Med Allergies Tab
    a. Check items in Inbound pane, and Active Med Allergies pane – that you want to keep
    b. Review proposed reconciled list
    c. Click Save button

Observations

Task Success	Path Deviations	Errors	Effort: (1) v. high, (5) v. low	Time to Complete
☒ Pass ☐ Fail	☒ No ☐ Yes	☒ No ☐ Yes	☐1 ☐2 ☐3 ☒4 ☐5	85 secs

Comments

Click here

Appendix C - System Usability Scale

	Strongly disagree				Strongly agree
	1	2	3	4	5
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					

Consent Form: Remote Usability Test (Adult)

Please read and sign this form.

During this usability test I agree to participate in an online session using my computer and telephone. During the session I will be interviewed about the site, asked to find information or complete tasks using the site and asked to complete an online questionnaires about the experience.

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

I understand that participation is voluntary and I agree to immediately raise any concerns I might have.

If you have any questions after today, please contact legal@brilogy.com

Please sign below to indicate that you have read and understand the information on this form and that any questions you might have about the session have been answered.

Date:_____

Please print your name: _____

Please sign your name: _____
Participant's Signature or eSignature

Thank you!

We appreciate your participation.

Please return the signed document to:
  Email: legal@brilogy.com
  Fax: 714.662.6001

Test: (Site name)   __/__/__ to __/__/__

EHR Usability Test Report
AXEIUM EHR MU3 version
(b)(11)

This EHR Usability Test Report is based on:

The Software engineering Software product Quality Requirements and Evaluation (SQuaRE)
Common Industry Format (CIF) for usability test reports (ISO/IEC 25062:2006

This version of the CIF has been customized for use in usability testing of Electronic Health Records (EHRs).
The intention of the CIF is to help vendors demonstrate evidence of usability in their final product in a format that allows both independent evaluation of a single product and comparison across multiple products.

Citation
NIST Interagency/Internal Report (NISTIR) - 7741

Report Number
7741

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Date of Usability Test: December 20, 2024

Date of Report: December 20, 2024

Report Prepared By: Brilogy Corporation
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Table of Contents

Executive Summary

Usability tests of the MU3 - § 170.315 (b)(11) Decision Support Interventions version of the AXEIUM EHR were conducted at various times during the development cycle, the last session for which was held on December 20, 2024. The purpose of these tests was to test and validate the usability of the current user interface, and provide evidence of usability of the EHR Under Test (EHRUT).

During the usability test, 10 active clinicians, providers and medical assistants matching the target demographic criteria served as participants and used the EHRUT in simulated, but representative tasks.

This study collected performance data on 11 tasks typically conducted in the EHR:

Decision Support Interventions
Show DSI electronic feedback appears when user is adding CPT and ICD codes
Show DSI electronic feedback appears when user is adding allergies
Confirm that the system supports the required set of 13 source attributes for evidence-based DSIs and 31 source attributes for predictive DSIs
Test the ability to provide clear documentation of training data
Make available to users DSI model documentation
Log DSI model activity for auditing
Ability to review DSI key performance metrics
Allow users to add new clinical guidelines or evidence to train the model
Allow users to mark DSI electronic feedback as incorrect
Allow users to avoid / disregard triggered DSI workflow on demand
Review DSI metrics and logs

During the 45 minute, one-on-one, remote usability test, each participant was greeted by the administrator and asked to review and sign an informed consent/release form. Participants were advised that they could withdraw at any time. Participants all had prior experience with the AXEIUM EHR.

The administrator introduced the test, and instructed the participant to complete a series of tasks (given one at a time) using the EHRUT. 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.

The test session, including participant screens, user workflow, and audio, was 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 verbal feedback
- Participant's satisfaction ratings of the system using a Likert Scale

All participant data was de-identified so that no correlation could be made from the identity of the participant to the data collected. Following the conclusion of the testing, participants were asked to complete a post-test questionnaire. Participants were not compensated for their time.

The results from the System Usability Scale scored the subjective satisfaction with the system based on performance with these tasks to be 85.

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

Task	Task Success Mean (SD)	Path Deviation Observed /Optimal	Time (sec) Mean (SD)	Time (sec) Observed /Optimal	Errors Mean (SD)	Effort 5=Low Mean (SD)
Decision Support Intervention						
B11.1 Show DSI electronic feedback appears when user is adding CPT and ICD codes	100%	17/15	95.0/35.0	46.0/105.0	5.0/0.2	4.0/0.4
B11.2 Show DSI electronic feedback appears when user is adding allergies	100%	17/15	95.0/22.0	45.0/107.0	7.0/0.25	4.0/0.3
B11.3 Confirm that the system supports the required set of 13 source attributes for evidence-based DSIs and 31 source attributes for predictive DSIs	100%	20/17	120.0/32.0	68.0/145.0	7.0/0.3	4.0/0.4
B11.4 Test the ability to provide clear documentation of training data	100%	10/8	40.0/12.0	65.0/65.0	5.0/0.3	4.0/0.5
B11.5 Make available to users DSI model documentation	100%	5/4	250.0/60.0	88.0/265.0	0.0/0.0	2.0/0.2
B11.6 Log DSI model activity for auditing	100%	5/4	40.0/12.0	25.0/66.0	15.0/0.10	4.0/0.3
B11.7 Ability to review DSI key performance metrics	100%	2/1	20.0/7.0	16.0/32.0	0.0/0.0	4.0/0.7
B11.8 Allow user to add new clinical guidelines or evidence to train the model	100%	10/8	45.0/12.0	27.0/57.0	7.0/0.15	3.0/0.5
B11.9 Allow user to mark DSI electronic feedback as incorrect	100%	18/16	98.0/22.0	42.0/114.0	12.0/0.25	3.0/0.65
B11.10 Allow users to avoid / disregard triggered DSI workflow on demand	100%	20/15	105.0/32.0	35.0/136.0	5.0/0.12	3.0/0.2
B11.11 Review DSI metrics and logs	100%	25/20	90.0/20.0	52/180	7.0/0.23	4.0/0.2

Introduction

This study is the result of usability testing performed on the MU3 - § 170.315 (b)(11) Decision Support Interventions version of the AXEIUM EHR, which is provide electronic feedback data for evidence-based decision support interventions, track audit logs and activity, provide documentation as well as KPI indicators, ability to use or not electronic feedback as well as mark electronic feedback as incorrect and confirm required 13 source attributes. The application consists of solutions for a range of services including medical, dental, vision, and behavior allowing practices to use decision support interventions for all their services.

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 to support certification according to criteria outlined in Safety Enhanced Design §170.315(b)(11), specifically:

§ 170.315 (b)(11) Decision Support Interventions

Method

Participants

A total of 10 participants were tested on the AXEIUM EHR. Participants in the test included doctors, medical assistants, and clinic managers. Volunteer participants were recruited by Brilogy and were not compensated for their time.

Participants had no direct connection to the development of or organization producing the EHR, and they were not from or affiliated with Brilogy, and did not need any orientation or training as they all were experienced AXEIUM EHR users.

For test purposes, end-user characteristics were identified and translated into a recruitment screener used to solicit potential participants.

Participants had a mix of backgrounds and demographic characteristics. The following is a table of participants by characteristics, including demographics, professional experience, computing experience, and user needs for assistive technology. Participant names were replaced with Participant IDs so that an individual's data cannot be tied back to his or her identity.

Part ID	Sex	Age	Education	Occupation /Role	Professional Experience	Computer Experience	Product Experience	Assistive Technology
13	Male	60-69	Doctorate degree	Clinic Director	432	240	48	No
14	Female	40-49	Doctorate degree	Clinic Director	240	180	48	No
15	Female	40-49	Bachelor's degree	Provider	264	192	84	No
16	Female	40-49	Bachelor's degree	Provider	228	168	84	No
17	Female	50-59	Doctorate degree	Provider	360	216	84	No
18	Female	40-49	Bachelor's degree	Provider	252	180	84	No
19	Male	40-49	Doctorate degree	Provider	264	204	84	No
20	Male	50-59	Doctorate degree	Provider	300	240	84	No
21	Female	30-39	Associate degree	Medical Assistant	72	156	108	No
22	Female	20-29	Associate degree	Medical Assistant	48	132	108	No

10 participants participated in the usability test. 0 participants failed to show for the study.

Participants were scheduled for 45 minute sessions with 5 minutes in between each session for debrief by the administrator and data logger, and 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 participant.

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 development environment, 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 the Section on Usability Metrics.

Tasks

In support certification according to criteria outlined in Safety Enhanced Design §170.315(b)(11), 11 tasks were constructed that would be realistic and representative of the kinds of activities a user might conduct with the EHR, in the following categories:

- Decision Support Interventions
- Source Attributes
- Source Attributes Access and Modifications
- Risk Management

Tasks were selected based on their frequency of use, criticality of function, and those that may be most troublesome for users. Tasks were designed to meet the study objectives. A detailed list of the tasks provided is

included in Appendix B.

Procedures

Remote testing was conducted via a WebEx session by a proctor with 10+ years' experience with the EHRUT. A Remote testing methodology was selected to both for convenience to accommodate the volunteer participants but also because that technology includes recording of the screen-sharing and audio for subsequent review and analysis.

Participants were advised to choose a quiet location to participate in the study using their own computers, and to:

- Complete the tasks as quickly as possible, using their normal workflow

- Complete the tasks without assistance except to clarify task details, if necessary

All test sessions were recorded by WebEx and subsequently analyzed. While participants completed the tasks, an observer monitored task times, obtained post-task rating data, and took notes on participant comments, and the data logger and took notes on task success, path deviations, number and type of errors, and comments.

Participants' demographic information, 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.

Test Location

Test sessions were conducted remotely via a WebEx meeting. The test administrator, observers, and participant logged into the session from their various locations. All observers and the data logger could see the participant's screen, and listen to the audio of the session.

Test Environment

The EHRUT would be typically be used in a healthcare office or facility. In this instance, the testing was conducted remotely via a WebEx meeting. For testing, the proctor hosted the EHRUT as a Microsoft Remote Desktop Application running on Windows Server 2016

The participants used their own computer, keyboard, and mouse when testing.

Test Forms and Tools

During the usability test, various documents and instruments were used, including:
- Proctor Guide
- Participant Guide

The Proctor's Guide was devised to be able to capture required data. The participant's interaction with the AXEIUM EHR application was captured and recorded via the WebEx meeting technology.

Participant Instructions

The proctor read the following instructions to the each participant:

> *Thank you for participating in this study. Your input is very important. Our session today will last about 45 minutes. During this time, you will be using the MU3 version of the AXEIUM EHR. I will ask you to complete a few tasks using this system and answer some questions. You should complete the tasks as quickly as possible, making as few errors as possible. Please try to complete the tasks on your own following the instructions very closely. Please note that we are not testing you, rather, 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.*

> *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.*

Following the procedural instructions, participants were logged into the EHRUT and then given six or 10 tasks to complete based on their role, and the administrator gave the following instructions:

> *For each task, I will read the description to you and say, "Begin." At that point, please perform the task and say, "Done," once you believe you have successfully completed the task. I will ask you your impressions about the task once you are done.*

Participants were then given their tasks to complete.

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 AXEIUM EHR MU3 by measuring participant success rates and errors

- Efficiency of AXEIUM EHR MU3 by measuring the average task time and path deviations
- Satisfaction with AXEIUM EHR MU3 by measuring ease of use ratings

Data Scoring

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

Measures	Rationale and Scoring
Effectiveness: Task Success	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. 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.
Effectiveness: Task Failures	If the participant abandoned the task, did not reach the correct answer or performed it incorrectly, or reached the end of the allotted time before successful completion, the task was counted as an "Failures." No task times were taken for errors. The total number of errors was calculated for each task and then divided by the total number of times that task was attempted. Not all deviations 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.

Measures	Rationale and Scoring
Efficiency: Task Deviations	The participant's path, i.e., steps through the application, was recorded. Deviations occur if the participant, for example, went to a wrong screen, clicked on an incorrect menu item, followed an incorrect link, or interacted incorrectly with an on-screen control. This path was compared to the optimal path. The number of steps in the observed path is divided by the number of optimal steps to provide a ratio of path deviation. It is strongly recommended that task deviations be reported. Optimal paths (i.e., 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.

Measures	Rationale and Scoring
Satisfaction: Task Rating	Participant's subjective impression of the ease of use of the application was measured by administering both a simple post-task question as well as a post-session questionnaire. After each task, the participant was asked to rate "Overall, this task was:" on a scale of 1 (Very Difficult) to 5 (Very Easy). These data are averaged across participants. Common convention is that average ratings for systems judged easy to use should be 3.3 or above. To measure participants' confidence in and likeability of the MU3 version of the AXEIUM EHR 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 C.

Results

The results of the usability test were calculated according to the methods specified in the Usability Metrics section. Participants who failed to follow session and task instructions had their data excluded from the analysis. There were no testing irregularities recorded.

The usability testing results for the EHRUT are detailed below. The results should be seen in light of the objectives and goals outlined in section on 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 to be 85. Broadly interpreted, scores under 60 represent systems with poor usability; scores over 80 would be considered above average.

§170.315 (b)(11) Decision Support Interventions

Measure / Task	Task Success Mean (SD)	Path Deviation Observed /Optimal	Time (sec) Mean (SD)	Time (sec) Observed /Optimal	Errors Mean (SD)	Effort 5=Low Mean (SD)
Decision Support Interventions (DSI)						
B11.1 Show DSI electronic feedback appears when user is adding CPT and ICD codes	100%	17/15	95.0/35.0	46.0/105.0	5.0/0.2	4.0/0.4
B11.2 Show DSI electronic feedback appears when user is adding allergies	100%	17/15	95.0/22.0	45.0/107.0	7.0/0.25	4.0/0.3
B11.3 Confirm that the system supports the required set of 13 source attributes for evidence-based DSIs and 31 source attributes for predictive DSIs	100%	20/17	120.0/32.0	68.0/145.0	7.0/0.3	4.0/0.4
B11.4 Test the ability to provide clear documentation of training data	100%	10/8	40.0/12.0	65.0/65.0	5.0/0.3	4.0/0.5
B11.5 Make available to users DSI model documentation	100%	5/4	250.0/60.0	88.0/265.0	0.0/0.0	2.0/0.2
B11.6 Log DSI model activity for auditing	100%	5/4	40.0/12.0	25.0/66.0	15.0/0.10	4.0/0.3
B11.7 Ability to review DSI key performance metrics	100%	2/1	20.0/7.0	16.0/32.0	0.0/0.0	4.0/0.7
B11.8 Allow user to add new clinical guidelines or evidence to train the model	100%	10/8	45.0/12.0	27.0/57.0	7.0/0.15	3.0/0.5
B11.9 Allow user to mark DSI electronic feedback as incorrect	100%	18/16	98.0/22.0	42.0/114.0	12.0/0.25	3.0/0.65
B11.10 Allow users to avoid / disregard triggered DSI workflow on demand	100%	20/15	105.0/32.0	35.0/136.0	5.0/0.12	3.0/0.2
B11.11 Review DSI metrics and logs	100%	25/20	90.0/20.0	52/180	7.0/0.23	4.0/0.2

Discussion of Findings

Efficiency

Overall the efficiency of participants using predictive electronic feedback was near the optimal path and the deviation in time. This is understandable because the interface had to add new DSI features and this was quite disruptive for them.

Effectiveness

Participants were successful 100% of the time when completing the tasks for accessing model and training data documentation, as well to accessing KPI and Audit logs reports.

Satisfaction

Participant consensus rated the task between Strongly Agree and Agree that the tasks were easy to perform.

Major findings

Task is performing as designed.

Areas for improvement

None identified, or requested.

Appendices

Appendix A - Trademarks

AXEIUM® is a registered trademark of Brilogy Corporation

All other trademarks or service marks contained herein are the property of their respective owners.

Appendix B - Tasks

§170.315 (b)(11) – Decision Support Interventions

Overview

Enable users to select evidence-based and predictive DSIs. It also enables users to deploy self-developed predictive DSIs. Support "source attributes" and provide documentation related to trained models and predictive models. Predictive metrics and audit logs are part of this requirement.

Task No.	Description
b11.1	**DSI - Show DSI electronic feedback appears when user is adding CPT and ICD codes** *(Review and/or consult the lab entry process overview document, if necessary)*

Actor
Provider

Steps

1. Select a patient
2. Open patient Enter Exam
    Path: Today Schedule > Exam
3. Select ICD R10.84(abdominal pain) and ICD K29.70 (Gastritis)
4. Select CPT 80076 (Hepatic function panel) and 83013 or 83014: H. pylori testing
5. DSI section appears showing. Recommendations:
    Imaging
    76705: Abdominal ultrasound (to evaluate abdominal pain).
    74246: Upper GI study with contrast (to evaluate for gastritis).

    Endoscopy Procedures:
    43239: Esophagogastroduodenoscopy (EGD) with biopsy.
    43235: Esophagogastroduodenoscopy (EGD) without biopsy.
6. User add recommended CPTs
7. Click Save Exam

Observations

Task Success	Path Deviations	Errors	Effort: (1) v. high, (5) v. low	Time to Complete
☒ Pass ☐	☒ No ☐	☒ No ☐	☐1 ☐2 ☐3 ☒4 ☐5	95 secs

Fail	Yes	Yes		

Comments	
Click here	

Task No.	Description
b11.2	**DSI - Show DSI electronic feedback appears when user is adding allergies** *(Review and/or consult the lab entry process overview document, if necessary)*

Actor
Provider, MA

Steps

1. Select a patient
2. Open patient Enter Exam

    Path: Today Schedule > Exam
3. Go to Allergies and Select Lactose Intolerance
4. DSI section appears showing. Recommendations:

    Dietary Modifications: The primary treatment for lactose intolerance is lactose-restricted diet. This includes avoiding milk and dairy products or consuming lactose-free alternatives. Some people can tolerate small amounts of lactose, so individualized adjustments may be necessary.

    Lactase Supplements: Over-the-counter lactase enzyme supplements (such as Lactaid) can help some people digest lactose-containing foods.

    Probiotics: Some studies suggest that probiotics may help in managing symptoms of lactose intolerance by improving gut health and lactose digestion.

    Alternative Dairy Products: Patients may be advised to consume lactose-free dairy products or plant-based dairy alternatives (e.g., almond milk, soy milk, coconut milk).

5. User add recommended CPTs
6. Click Save Exam

Observations				
Task Success	**Path Deviations**	**Errors**	**Effort: (1) v. high, (5) v. low**	**Time to Complete**
☒ Pass ☐ Fail	☒ No ☐ Yes	☒ No ☐ Yes	☐1 ☐2 ☐3 ☒4 ☐5	95 secs
Comments				
Click here				

Task No.	Description
b11.3	**DSI - Confirm that the system supports the required set of 13 source attributes for evidence-based DSIs and 31 source attributes for predictive DSIs** *(Review and/or consult the lab entry process overview document, if necessary)*

Actor				
Clinic Director, Provider				

Steps

1. Open System Tables

    Path: System Admin > Table Editor

2. Go to DSI Attributes table
3. Verify attributes

Observations

Task Success	Path Deviations	Errors	Effort: (1) v. high, (5) v. low	Time to Complete
☒ Pass ☐ Fail	☒ No ☐ Yes	☒ No ☐ Yes	☐1 ☐2 ☒3 ☐4 ☐5	200 secs

Comments

Click here

Task No.	Description
b11.4	**DSI - Test the ability to provide clear documentation of training data** *(Review and/or consult the lab entry process overview document, if necessary)*

Actor				
Clinical Director, Provider, MA				

Steps

1. Go to HelpOpen patient View Lab Orders screen

    Path: Help > DSI

2. Open Training data documentation

Observations

Task Success	Path Deviations	Errors	Effort: (1) v. high, (5) v. low	Time to Complete
☒ Pass ☐ Fail	☒ No ☐ Yes	☒ No ☐ Yes	☐1 ☐2 ☐3 ☒4 ☐5	40 secs

Comments

Click here

Task No.	Description
b11.5	**DSI - Make available to users DSI model documentation** *(Review and/or consult the lab entry process overview document, if necessary)*

Actor				
Clinical Director, Provider, MA				

Steps

1. Go to Help

    Path: Help > DSI

2. Open DSI AI Model documentation

Observations

Task Success	Path Deviations	Errors	Effort: (1) v. high, (5) v.	Time to Complete

		low	
⊠ Pass ☐ Fail	⊠ No ☐ Yes	⊠ No ☐ Yes	☐1 ☐2 ☐3 ⊠4 ☐5	40 secs

Comments
Click here

Task No.	Description
b11.6	**DSI - Log DSI model activity for auditing** *(Review and/or consult the lab entry process overview document, if necessary)*

Actor
Provider

Steps
1. Select a patient 2. Trigger DSI workflow following steps in b11.1 or b11.2 3. Open Reports screen   **Path**: Reports > DSI > Activity Model 4. View activity data for steps 1 and 2

Observations				
Task Success	**Path Deviations**	**Errors**	**Effort: (1) v. high, (5) v. low**	**Time to Complete**
⊠ Pass ☐ Fail	⊠ No ☐ Yes	⊠ No ☐ Yes	☐1 ☐2 ☐3 ⊠4 ☐5	20 secs

Comments
Click here

Task No.	Description
b11.7	**DSI - Ability to review DSI key performance metrics** *(Review and/or consult the lab entry process overview document, if necessary)*

Actor
Clinical Director, Provider

Steps

1. Open Reports screen
    Path: Reports > DSI > KPI
2. Select open dashboards
3. Read available KPI metrics like
    a. **Accuracy**: Percentage of correct predictions.
    b. **Precision**: Ratio of true positives to all positive predictions.
    c. **Recall**: Ratio of true positives to all actual positives.
    d. **F1 Score**: Harmonic mean of precision and recall.

Observations				
Task Success	**Path Deviations**	**Errors**	**Effort: (1) v. high, (5) v. low**	**Time to Complete**
⊠ Pass ☐ Fail	⊠ No ☐ Yes	⊠ No ☐ Yes	☐1 ☐2 ⊠3 ☐4 ☐5	45 secs

Comments

Click here	

Task No.	Description
b11.8	**DSI - Allow user to add new clinical guidelines or evidence to train the model** *(Review and/or consult the lab entry process overview document, if necessary)*
	Actor
	Provider
	Steps
	1. Select a patient 2. Open patient Enter Exam **Path**: Today Schedule > Exam 3. Select ICD R10.84(abdominal pain) and ICD K29.70 (Gastritis) 4. Select CPT 80076 (Hepatic function panel) and 83013 or 83014: H. pylori testing 5. DSI section appears showing. Recommendations: Imaging 76705: Abdominal ultrasound (to evaluate abdominal pain). 74246: Upper GI study with contrast (to evaluate for gastritis). Endoscopy Procedures: 43239: Esophagogastroduodenoscopy (EGD) with biopsy. 43235: Esophagogastroduodenoscopy (EGD) without biopsy. 6. Select under DSI section Add new Clinical Guidance or Evidence. 7. Enter text 8. Click Save 9. Choose between existing recommendations or new added one 10. Click Save

Observations				
Task Success	**Path Deviations**	**Errors**	**Effort: (1) v. high, (5) v. low**	**Time to Complete**
☒ Pass ☐ Fail	☒ No ☐ Yes	☒ No ☐ Yes	☐1 ☐2 ☒3 ☐4 ☐5	98 secs

Comments
Click here

Task No.	Description
b11.9	**DSI - Allow user to mark DSI electronic feedback as incorrect** *(Review and/or consult the lab entry process overview document, if necessary)*
	Actor
	Provider
	Steps
	1. Open DSI Clinical Guidance and Evidence screen **Path**: System Admin > DSI Clinical Guidance and Evidence 2. Search the record 3. Open the record to verify information 4. Click Review or Disable

5. Click Save button

Observations	

Task Success	Path Deviations	Errors	Effort: (1) v. high, (5) v. low	Time to Complete
☒ Pass ☐ Fail	☒ No ☐ Yes	☒ No ☐ Yes	☐1 ☐2 ☒3 ☐4 ☐5	105 secs

Comments	
Click here	

Task No.	Description
b11.10	**DSI - Allow users to avoid / disregard triggered DSI workflow on demand** *(Review and/or consult the lab entry process overview document, if necessary)*
	Actor
	Provider
	Steps

7. Select a patient
8. Open patient Enter Exam

    Path: Today Schedule > Exam
9. Go to Allergies and Select Lactose Intolerance
10. DSI section appears showing. Recommendations:

    Dietary Modifications: The primary treatment for lactose intolerance is lactose-restricted diet. This includes avoiding milk and dairy products or consuming lactose-free alternatives. Some people can tolerate small amounts of lactose, so individualized adjustments may be necessary.

    Lactase Supplements: Over-the-counter lactase enzyme supplements (such as Lactaid) can help some people digest lactose-containing foods.

    Probiotics: Some studies suggest that probiotics may help in managing symptoms of lactose intolerance by improving gut health and lactose digestion.

    Alternative Dairy Products: Patients may be advised to consume lactose-free dairy products or plant-based dairy alternatives (e.g., almond milk, soy milk, coconut milk).

11. User click hide DSI. He also can mark a checkbox to avoid DSI for this exam.
12. User continue with regular exam without using DSI

Observations	

Task Success	Path Deviations	Errors	Effort: (1) v. high, (5) v. low	Time to Complete
☒ Pass ☐ Fail	☒ No ☐ Yes	☒ No ☐ Yes	☐1 ☐2 ☐3 ☒4 ☐5	5 secs

Comments	
Click here	

Task No.	Description
b11.11	**DSI - Review DSI Audit logs** *(Review and/or consult the lab entry process overview document, if necessary)*

Actor				
Clinical Director				
Steps				
1. Open Reports screen **Path**: Reports > DSI > Audit and Logs 2. User can filter audits and logs using column filters				
Observations				
Task Success	**Path Deviations**	**Errors**	**Effort: (1) v. high, (5) v. low**	**Time to Complete**
☒ Pass ☐ Fail	☒ No ☐ Yes	☒ No ☐ Yes	☐1 ☐2 ☐3 ☒4 ☐5	60 secs
Comments				
Click here				

Appendix C - System Usability Scale

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	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					

Consent Form: Remote Usability Test (Adult)

Please read and sign this form.

During this usability test I agree to participate in an online session using my computer and telephone. During the session I will be interviewed about the site, asked to find information or complete tasks using the site and asked to complete an online questionnaires about the experience.

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

I understand that participation is voluntary and I agree to immediately raise any concerns I might have.

If you have any questions after today, please contact legal@brilogy.com

Please sign below to indicate that you have read and understand the information on this form and that any questions you might have about the session have been answered.

Date:_____

Please print your name: _____

Please sign your name: _____
                               Participant's Signature or eSignature

Thank you!

We appreciate your participation.

Please return the signed document to:
  Email: legal@brilogy.com
  Fax: 714.662.6001

Test: (Site name)   __/__/__ to __/__/__