EHR Usability Test Report of MedicusEHR 1.0

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

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Table of Contents

1 Executive Summary

Medicus staff conducted a usability study for MedicusEHR v1.0, on November 2019 on different healthcare organizations. MedicusEHR is an ambulatory electronic health record cloud-based application from Medicus Clinical, LLC. The usability test was a part of completing the Safety - Enhanced Design (SED) requirements in the certification criteria identified in 45 CFR Part 170 Subpart C of the Health Information Technology: 2015 Edition Health Information Technology (Health IT) Certification Criteria. The purpose of this study was to test and validate the usability of the current user interface and provide evidence of the usability and functionalities of MedicusEHR under test. During the usability test, a total of ten (10) healthcare professionals used MedicusEHR in a testing environment of the application, representative task.

A Usability Test on selected features and task of the MedicusEHR v1.0, were evaluated in person, in ten (10) clinician's locations. For the usability test, a total of ten (10) users, with work experience of Nurse, Physician and Medical Assistance, matching the target demographic criteria served as participants and used MedicusEHR in simulated, but representative tasks.

During this test, a total of six (6) tasks typically conducted on an EHR were evaluated. The tasks were associated with one (1) certification criteria in 45 CFR Part 170 Subpart C of the Health Information Technology: 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications:

- **170.315(b)(3) Electronic Prescribing**

The usability test duration ranged from 20 minutes, depending on the number of tasks assigned to the criteria. During the one-on-one usability test, each participant was greeted by the instructor, briefed on testing protocols, asked to review and sign a non-disclosure, and informed consent form (included in **Appendix 6**); and were instructed they could withdraw at any time. The instructor introduced the test and provided the guidelines to the participants to complete the expected tasks using the EHR. Test participants had prior experience with electronic health records, but not necessarily with the tasks being tested, no additional training was provided for the usability test. During the test, the instructor timed the test and, along with the data logger(s), recorded user performance data on paper and electronically. The instructor did not assist participants during the test.

The design and product development process for this usability test is based on the User-Centered Design Process (UCD) and in accordance with various recommended metrics and examples outlined in the NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records (NISTIR 7741).

Following the examples in the *NIST 7742 Customized Common Industry Format Template for Electronic Health Record Usability Testing (NISTIR 7742),* various recommended metrics were used to evaluate the usability of the software. 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 verbalizations**
- **System Usability Scale (SUS)**

In addition, results include documentation of the following observations:

- Major findings
- Areas of improvement

All participant data was de-identified – no correspondence could be made from the identity of the participant to the data collected. After finishing the test, participants were asked to complete a System Usability Scale Questionnaire (sampler include included in **Appendix 8**).

The results from the System Usability Scale (SUS) scored the subjective satisfaction with the system based on performance with these tasks to be: 97.10%. The average Confidence ratings was 4.8 out of 5 when asked **"How confident was it to use the product being tested to complete the given task:"** on a scale of 1 (Strongly Disagree) to 5 (Strongly Agree). When asked "The system was easy to use?", the average rating was 4.8 out of 5 on a scale of 1 (Strongly Disagree) to 5 (Strongly Agree). The participants were very satisfied with the system. Results are detailed in the Results section of this report, which includes a subsection for each of the ten CEHRT 2015 Ed. criteria.

2 Introduction

The EHR used for this usability test was MedicusEHR v1.0. This cloud-based application platform is designed to provide a healthcare professional with a technology method of recording and tracking patient healthcare records. MedicusEHR supports many healthcare professional roles; e.g. Physician, Nurse, Medical Assistant, Front Desk, through a diversity of healthcare specialties, e.g. Internal Medicine, ENT, Endocrinology, Geriatric, Cardiology. MedicusEHR has a variety of features to facilitate healthcare professionals to manage a daily workflow in an ambulatory outpatient practice to record and manage patient charts, as well as the ability to manage, schedule, reconcile and incorporate clinical information and billing.

The purpose and objective of this study were to test and validate the usability of MedicusEHR user interface and provide evidence of the usability of the EHR by representing realistic exercises. To this end, measures of effectiveness, efficiency and user satisfaction, such as ease of use and completion of tasks on time, were captured during the usability testing. Satisfaction and user confidence were assessed using the System Usability Scale (SUS) satisfaction questionnaire.

The design is based upon an explicit understanding of users, tasks, and environments, such as the locations, exam room, patient interactions, and the different scenarios faced both by the clinician and the back office or front desk staff. With this mind, the context in the UCD was carefully considered, and users were involved throughout the design and development, assessments, conceptualization, and specifications by pilot groups, client visits, and industry events.

For each feature Medicus Clinical LLC, identified needs, regulatory requirements, safety best practices, and our company's experience to develop a user-friendly, agile, and innovative way to integrate technology into the daily operation of any practice.

2.1 Design and Development

Development projects are selected and prioritized based on feedback from selected users of MedicusEHR. Following that input, the EHR specialist, developers, physicians, nurse, and operational staff, documents the needs/recommendations of the users. From mockups to prototype-based formative usability testing, users are involved in all process of the design process. Internal user experience experts evaluate designs based on industry-standard.

2.2 User Testing

MedicusEHR performs unit testing and integrated testing. Unit testing early in the cycle informs broad design decisions. Integrated testing on pre-release and released development quantifies usability and identifies major areas for future focus and improvement.

3 Method

3.1 Participant

A total of ten (10) participants were tested on the EHRUT(s). Participants in the test were physicians (MD), nurses, and medical assistants. The EHR specialist team from Medicus Clinical, LLC, recruited participants. Participants had no direct connection to the development of or the organization producing the EHRUT(s). Participants we're not members of Medicus Clinical LLC. Participants were given the opportunity to have the same orientation and level of training as the actual end-users would have received.

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 1.**

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, computing experience, and user needs for assistive technology. Participant names were replaced with Participant ID's so that an individual's data cannot be tied back to individual identities.

Table 1 Participant

N	Part ID	Gender	Age	Education	Occupation/ Role	Professional Experience	Computer Experience	Product Experience	Technology Needs
1	ID01	Male	60-69	Doctorate degree (e.g., MD, DNP, DMD, PhD)	Physician	458	86	8	No
2	ID02	Female	30-39	Bachelor's Degree	Nurse	50	194	7	No
3	ID03	Female	20-29	Bachelor's Degree	Nurse	14	12	8	No
4	ID04	Female	20-29	Bachelor's Degree	Nurse	13	50	8	No
5	ID05	Male	20-29	Bachelor's Degree	Nurse	12	170	8	No
6	ID06	Female	40-49	Some college credit, no degree	Medical Assistance	242	242	7	No
7	ID07	Male	70-79	Doctorate degree (e.g., MD, DNP, DMD, PhD)	Physician	602	182	7	No
8	ID08	Male	30-39	Doctorate degree (e.g., MD, DNP, DMD, PhD)	Physician	158	326	7	No
9	ID09	Female	40-49	Doctorate degree (e.g., MD, DNP, DMD, PhD)	Physician	170	374	6	No
10	ID10	Male	50-59	Doctorate degree (e.g., MD, DNP, DMD, PhD)	Physician	398	362	7	No

Ten (10) participants (matching the demographics in the section on Participants) were recruited and participated in the usability test. Participants were scheduled for 20 minutes sessions. Outlook email and calendar platform was used to keep track of the participant schedule and include each participant's demographic characteristics. The participant also received an email and appointment with the details of the usability test date and time.

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 with the same tasks were 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 a control area in their daily work 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:

- The number of tasks 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 usability measures can be found in Section 3.9 on Usability Metrics.

3.3 Task

A few tasks were constructed that would be realistic and representative of the kinds of activities a user might do with this EHR. Please refer to Table 2 to review the Tasks that were requested to be completed by the user. Tasks were selected based on their frequency of use, the criticality of the function, and those that may be most troublesome for users. Tasks were constructed in light of the study objectives.

Table 2 Task

SED Criteria	Criteria Name	Task	Objective
170.315.b.3	**Electronic Prescribing**	b3.1 Create new prescription	Create e-prescribe to treat high blood pressure (tablet)
170.315.b.3	**Electronic Prescribing**	b3.2 Change prescription (dosage or duration)	Approved a prescription change request
170.315.b.3	**Electronic Prescribing**	b3.3 Cancel prescription	Provider send to pharmacist the cancellation of a medication
170.315.b.3	**Electronic Prescribing**	b3.4 Refill prescription	Approved a refill prescription request
170.315.b.3	**Electronic Prescribing**	b3.5 Receive fill status notification	Review fill status from the pharmacy
170.315.b.3	**Electronic Prescribing**	b3.6 Request and receive medication history information	Request and review from Pharmacy a patient medication history

3.4 Risk Assessment

MedicusEHR assessed the risk level to patients of all workflows included in this usability test. These workflows were evaluated based on the potential risk for adverse events to the patient and assigned a risk category of high, moderate, or low risk. Tasks which are related to record information and clinical documentation of the patient, were determined to be of high risk. While basic functions were considering moderate and accessing reference information was determined to be low.

High risk items were prioritized in terms of development changes as a result of success and/or failure during testing. A summary of the user tasks prioritization ranking based on the risk associated with user errors and patient safety is shown in the Table 3.

Table 3 Patient Risk Assessments

SED Criteria	Task	Risk	Pre reason for risk	Post test risk
170.315.b.3	b3.1 Create new prescription	High	User can create a wrong prescription	No error observed during the test
170.315.b.3	b3.2 Change prescription (dosage or duration)	High	User can receive a wrong dosage request	No error observed during the test
170.315.b.3	b3.3 Cancel prescription	Low	There is no risk of human error	No error observed during the test
170.315.b.3	b3.4 Refill prescription	Low	There is no risk of human error	No error observed during the test
170.315.b.3	b3.5 Receive fill status notification	Low	There is no risk of human error	No error observed during the test
170.315.b.3	b3.6 Request and receive medication history information	Low	There is no risk of human error	No error observed during the test

3.5 Procedure

MedicusEHR Specialist team administered all test sessions in face to face interactions in the work environment facilities of each participant. To ensure that the test ran smoothly, two MedicusEHR Specialists participated in each session; one as the usability instructor, and the other one as the data logger. The staff conducting the test was experienced usability practitioners and had a combined 20 years of experience in EHR management and design.

Before MedicusEHR Specialist arrival Participants were advised to choose a quiet room in their facility to complete the test, upon the MedicusEHR Specialist team arrival at participant's clinical facilities, they presented themselves and greeted the Participants. Their identity was verified and matched with the name on the participant schedule. The MedicusEHR Specialist prepared the selected area with a computer property of Medicus Clinical, LLC and then requested the participant to initiate the test process. Participants were assigned a participant ID number. Before starting the usability test, the participants received the Participant Guide (see **Appendix 4**), and a Participant Screening (see **Appendix 1**). Also, the participant reviewed and signed a Non-Disclosure and Informed Consent Form (see **Appendix 6**) and a Recording Consent Form (see **Appendix 7**). A representative from the test team witnessed the participant's signature.

Participants were instructed to:

- Complete the tasks as quickly as possible, using their normal workflow (Participants were not advised to think aloud)
- Complete the tasks without assistance except to clarify task details.
- Complete the task without using a think-aloud technique.

The instructor could give immaterial guidance and clarification on tasks, but no instructions on use. Participants were then given instructions on how to interact with the task instructions. Task timing began once the moderator finished reading the question. The task time was stopped once the participant indicated they had completed the task. All test sessions were recorded and analyzed using ***gotoTraining*** application. While participants completed the tasks, the instructor monitored task times, obtained post-task rating data and took notes on participant comments. One additional observer served as the data logger and took notes on task success, path deviations, number and type of errors, and comments.

Following the completion of each task, the instructor gave the participant the System Usability Questionnaire (e.g., the System Usability Scale, see **Appendix 8)**. In addition, participants were able to ask questions about the EHR tested and could also describe any aspects of the EHR product they currently use.

Participants' demographic information, task success rate, time on task, errors, deviations, verbal responses, and post-test questionnaires were recorded into a spreadsheet. Once the test session concluded, participants were thanked for their time and feedback.

3.6 Test Location

Test were given in the clinical work facility of the participants, in a quiet room that could accommodate, the two (2) MedicusEHR resource that will administer the test, and the participant. The room has an office desk and that could allow connectivity of a computer property of Medicus Clinical, LLC. Only the participant, test instructor and data logger were in the test room. The testing product was already installed on the computer property of Medicus Clinical, LLC. To ensure that the environment was comfortable for users, noise levels were kept to a minimum with the ambient temperature within a normal range.

3.7 Test Environment

The EHR would typically be used in a healthcare office or facility. In this instance, the testing was conducted in the participant facilities. For testing, the participant used a 13-inch Microsoft Surface Book 2 (Model 1832, 1834), on a 2.6 GHz Intel Core™ i5-7300U CPU processor, a property of Medicus Clinical, LLC. The participants used a keyboard and mouse when interacting with MedicusEHR. The application used 1920 x 1080 x59 hertz resolution on the screen for better performance. The application was set up by the MedicusEHR team according to the documentation describing the system set-up and preparation. The application itself was running on Windows 10 Pro using a test database on a wireless connection. Technically, the system performance (i.e., response time) was somewhat slower than what actual users would experience in field implementation. Additionally, participants were instructed not to change any of the default system settings (such as control of font size).

3.8 Test Form and Tools

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

Table 4 Test form and tools

Tool	Detail
Screening participant evaluation	Paper print out
Non-Disclosure and Informed Consent Form	Paper print out
Moderator Guide	Paper print out
Participant Guide	Paper print out
Usability test questionnaire	Paper print out
Recording Consent Form	Paper print out
Virtual meeting	GoToTraining

Examples of these documents can be found in Appendices, respectively. The Instructor Guide was devised to be able to capture the required data.

The participant's interaction with the EHRUT was captured and recorded in the GoToTraining application. The video was storage locally in a secure folder in the Assertus server.

3.9 Participant Instructions

The moderator reads the following instructions aloud to each participant.

Thank you for participating in this usability study. Your input is very important. Our session today will last about 20 minutes. During that time, you will look at MedicusEHR v1.0 to perform specific tasks. I will ask you to complete a few tasks using the system and answer some questions. You will be asked to complete these tasks on your own, trying to do them as quickly as possible, with the fewest possible errors or deviations. 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 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 support, but I am not able to guide you or provide additional help in how to use the application. Please be honest with your opinions, and if it's possible, save your detailed comments until the end of a task or the end of the session when we can discuss it deeply.

Remember that the product you will be using today is MedicusEHR v1.0. Also, don't forget, as explained before, we are recording the audio and screenshots of our session today. All the information that you provide will be kept confidential, and your name will not be associated with your comments at any time. If you feel it necessary, you can withdraw at any time during the testing.

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 completed the task. If you have any questions or concerns, feel free to ask.

3.10 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:

1. MedicusEHR by measuring participant success rates and errors
2. MedicusEHR by measuring the average task time and path deviations
3. MedicusEHR by measuring ease-of-use ratings

Data Scoring

The following Table (Table 5 Rating) details how metrics measuring efficiency, effectiveness, and satisfaction were scored.

Table 5 Usability metrics

Measures	Rational and Scoring
Effectiveness: Task Success	- A task was counted as a "Success" if the participant was able to achieve the correct outcome, including if the participant was able to achieve the correct outcome with unnecessary steps and additional time. A success score for each task was calculated by averaging the scores for each task. The results are provided as a percentage. -Task times were recorded for successes. Observed task times divided by the optimal time for each task were calculated as a measure of optimal efficiency. -Optimal task performance time, as benchmarked by expert performance under realistic conditions, was recorded when constructing tasks. Target task times were operationally derived by multiplying a benchmarked expert performance by a factor of 2.0, allowing for some time buffer because (1) participants were not trained to expert performance, (2) some features were new, and (3) some tasks had multiple valid paths to a successful outcome. Thus, if an expert, optimal performance on a task was 10 seconds, then allotted task time performance was [10 * 2.0] seconds. This ratio was aggregated across tasks and reported with mean and variance scores.
Effectiveness: Task Failures	If the participant abandoned the task, did not reach the correct answer, performed it incorrectly, or reached the end of the allotted time before successful completion, the task was counted as a Failure. No task times for failed tasks or tasks that exceeded the target task time were used in calculations.
Efficiency: Task Deviations	The participant's navigation 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 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. Path deviations are reported on a qualitative level for use in recommendations for improvement.
Efficiency: Task Time	Each task was timed from when the administrator said "Begin" until the participant said "Done." If the participant failed to say "Done," the time was stopped when the participant ceased performing the task. Only task times for tasks that were completed and tasks that were completed at or under the target time were included in the average task time analysis. Average time per task and variance measures were calculated for each task for use in the analysis of the results.
Satisfaction: Task Rating	Participant's subjective impression of the ease of use of the application was measured by administering both a simple question on the completion of each scenario and a post-session questionnaire. After each scenario, the participant was asked to rate "Overall, these tasks were:" on a scale of 1 (Very Difficult) to 5 (Very Easy). These data were averaged across participants. To measure participants' confidence in and likeability of MedicusEHR overall, the testing team administered the System Usability Scale (SUS) usability questionnaire. Questions included; I thought the system was easy to use system. See the full System Usability Score questionnaire in Appendix 8 System Usability Test Questionnaire

4 Results

4.1 - 170.315(b)(3) Electronic Prescribing

Data Analysis and Reporting

Table 6 Electronic Prescribing task results

		Effectiveness		Efficiency						Satisfaction	
	N	Task Success		Path Deviation		Task Time		Error		Rating	
Task	#	Mean %	(SD %)	Deviations Observed/Optimal	(SD)	Mean	(SD)	Mean%	(SD%)	Mean	(SD)
Create new prescription	10	100	0	5/5	1	19	1	0	0	4.9	0.08
Change prescription (dosage or duration)	10	100	0	5/5	1	12	1	0	0	4.9	0.08
Cancel prescription	10	100	0	3/3	1	6	1	0	0	5	0
Refill prescription	10	100	0	5/5	1	13	1	0	0	4.8	.2
Receive fill status notification	10	100	0	3/3	1	3	1	0	0	4.7	.34
Request and receive medication history information	10	100	0	4/4	1	17	1	0	0	4.6	.53

Discussion of the Findings

Physician, Nurse, and Medical Assistant were given six Electronic Prescribing tasks:

- b3.1 Create new prescription
- b3.2 Change prescription (dosage or duration)
- b3.3 Cancel prescription
- b3.4 Refill prescription
- b3.5 Receive fill status notification
- b3.6 Request and receive medication history information

Effectiveness

The success score for the six tasks related to electronic prescribing, tasks b3.1 to b3.6 was 100%.

Efficiency

Create new prescription b3.1, took 19 seconds on average. In the task b3.2, approved a prescription change took 12 seconds on average. In task b3.3, cancel a prescription took 6 seconds. Approved a refill request, b3.4, took 13 seconds on average. Review fill status from pharmacy, b3.5 took 3 seconds on average, and request and review from Pharmacy a patient medication history, b3.6 took 17 seconds on average.

Most participants completed the tasks with the same number of steps as expert users and within the optimal time for each task, as suggested by expert timings.

Satisfaction

Most participants rated tasks b3.1 and b3.2, as easy or very easy, with a result of 4.9 out of 5 points on a Likert scale. Task b3.3 was rated as very easy, with a result of 5 out of 5 points on a Likert scale. Task b3.4 rated as easy or very easy, with a result of 4.8 out of 5 points on a Likert scale. Task b3.5 rated as easy and very easy, with a result of 4.7 out of 5 points on a Likert scale. Task b3.6 rated as easy and very easy, with a result of 4.6 out of 5 points on a Linkert scale. Most participants were familiar with these tasks and found them straightforward and easy to complete.

The prescription is one of the favorite modules for our provider, because include in the same screen all the information they need to create a prescription, it's easy, simple an intuitive, It was considered the patient safety.

Major Findings

Some participants stated that the size of the letter in the prescription module is small. Improve the messages that are received from the Pharmacy, refill request and change request, with a note of the Pharmacist.

Areas of Improvement

Some participant takes additional time, they mention the size of the letter is small in the prescription module.

Due to the usability results in these criteria, we are going to reinforce the implementation process and focus on the functionalities that improve the workflow of the users. Also, include in the screen a functionality near to the field with the definition, to facilitate user's adoption, specifically in the messages that are received from the pharmacy.

4.2– Overall results

Areas for improvement include:

- Training tips

  Evaluating implementation process, focus on the automatic functionalities that improve the workflow of the users. This usability study identified areas where traditional training tips can be improved or expanded to help users become comfortable with the functionality more quickly. With that in mind we incorporate recurrent webinars. Also, in our plan we will introduce just-in-time training, the users will access information when they need it.

- Common satisfaction features:

  The overall results from the SUS (System Usability Scale) scored the subjective satisfaction with the system based on performance with these tasks to be 97.10 percent.

  Participants repeatedly mention that the performance of their systems were different from the test system. They stated the performance is one of the best capabilities of the system. Also, the ability to access all features from multiple locations in the system, its accessible, intuitive and even if the participant don't' use the functionality daily can completed the tasks.

In overall the user-centered design and usability testing, gave us the opportunities to refine and enhance the user experience. Some of these enhancements have been prioritized for release in upcoming MedicusEHR updates. Still others will be revisited in more depth in future studies.

5 Appendices

Appendix 1: Participant Screening

Appendix 2: Participant Demographics

Appendix 3: Testing dates and locations

Appendix 4: Participant Guide

Appendix 5: Instructor Guide

Appendix 6: Non- Disclosure and Informed Consent Form

Appendix 7: Recording Consent Form

Appendix 8: System Usability Scale Questionnaire

Appendix 1: Participant Screening

Name:
Date:
Location:

1. **What is your gender?**
   a. Male
   b. Female
2. **Which of these bests describes your current age?**
   a. 0-9
   b. 10-19
   c. 20-29
   d. 30-39
   e. 40-49
   f. 50-59
   g. 60-69
   h. 70-79
   i. 80-89
   j. 90-99
   k. 100+
3. **Highest Level of Education:**
   a. High school graduate/GED
   b. Some college credit, no degree
   c. Trade/technical/vocational training
   d. Associate degree
   e. Bachelor's degree
   f. Master's degree (MSN, MS)
   g. Doctorate (MD, DNP, DO, Ph.D.)
4. **What is your current role?**
   a. Medical Assistant (MA)
   b. Nurse
   c. Office Manager
   d. Physician
   e. Front Desk
   f. Other (please specify)
5. **What is your specialty?**
6. **How many years have you been working in your field?**
7. **How many years of experience do you have using computers?**
8. **How long have you been using MedicusEHR?**
9. **Do you require any assistive technologies to use a computer?**
   a. Yes
   b. No

Appendix 2: Participant Demographics

Gender	
Female	5
Male	5
Total participant	**10**

Occupation/Role	
Medical Assistance	1
Nurse	4
Physician	5
Total participant	**10**

Education	
Doctorate degree (e.g., MD, DNP, DMD, PhD)	5
Bachelor's Degree	4
Some college credit, no degree	1
Total participant	**10**

Experience (month)	
Experience with MedicusEHR (month)	8 (average)

Appendix 3: Testing dates and locations

Testing Dates and Locations

	Test Dates	Locations
1	4-Nov-19	Bayamon, PR
2	6-Nov-19	Bayamon, PR
3	6-Nov-19	Bayamon, PR
4	7-Nov-19	San Juan, PR
5	12-Nov-19	San Juan, PR
6	12-Nov-19	San Juan, PR
7	13-Nov-19	Guaynabo, PR
8	14-Nov-19	Guaynabo, PR
9	15-Nov-19	Bayamon, PR
10	15-Sep-19	Guaynabo, PR

Appendix 4: Participant Guide

Participant guide (sampler)

Thank you for participating in this usability study. Our session today will last about 20 minutes. During that time, you will look at MedicusEHR to perform specific tasks. I will ask you to complete a few tasks using the system and answer some questions. You will be asked to complete these tasks on your own, trying to do them as quickly as possible with the fewest possible errors or deviations. 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 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. Do not do anything more than asked. Please save your detailed comments until the end of a task or the end of the session when we can discuss it deeply. Please be honest with your opinions. The product you will be using today is MedicusEHR. We are recording the audio and screenshots of our session today. All 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 can withdraw at any time during the testing. 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 completed the task. If you have any questions or concerns, feel free to ask.

170.315.b.3 Electronic Prescribing

Task 1: Create new prescription
In a new encounter, create a e-prescription of Zestril 10mg Tablet once a day, the patient have a diagnosis of high blood pressure.

Task 2: Change prescription (dosage or duration)
The Pharmacist send a change request Captopril 25mg tablet once a day. Please Approve the change to the Pharmacy

Task 3: Cancel prescription
Send a cancellation electronically of a prescription Zestril 10mg tablet

Task4: Refill prescription
The Pharmacist send a refill request of 1 refill for Pataday 0.2% Ophthalmic Solution, please Approve the refill request.

Task 5: Receive fill status notification
Review fill status of Captopril 25mg

Task 6: Request and receive medication history information
Request to TX Pharmacy 10.6MU a medication history of the patient Spencer Hocking
Review a medication history of Spencer Hocking

Appendix 5: Instructor Guide

Instructor guide (sampler)

Instructor:
Data Logger
Date
Time:
Participant ID
Location:

Thank you for participating in this usability study. Our session today will last about 20 minutes. During that time, you will look at MedicusEHR to perform specific tasks. I will ask you to complete a few tasks using the system and answer some questions. You will be asked to complete these tasks on your own, trying to do them as quickly as possible with the fewest possible errors or deviations. 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 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. Do not do anything more than asked. Please save your detailed comments until the end of a task or the end of the session when we can discuss it deeply. Please be honest with your opinions. The product you will be using today is MedicusEHR. We are recording the audio and screenshots of our session today. All 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 can withdraw at any time during the testing. 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 completed the task. If you have any questions or concerns, feel free to ask.

170.315.b.3 Electronic Prescribing
Task 1: Create new prescription
Directions to the Instructor:
Instruct Participant to create new prescription in a progress note
Success:
☐ Easily completed
☐ Not completed
____Steps
Comments:
Optimal Time: 25 seconds
Task Time: _____seconds. (Task starts when the participant is asked to begin. The task ends after create a prescription of Zestril 10mg or participant say Done).
Optimal Steps (5 steps): Prescription Builder/Create Blank Prescription----Add New---Search Medication name—Select medication and sig etc.---Add to prescription---- Send Prescription
☐ Correct
☐ Minor Deviation
☐ Major Deviations (describe below in Comments)
____Steps

Observed Errors and Verbalizations:

Participant Rating Scale, overall, this task was:
☐ 1 Very Difficult. ☐ 2. Difficult ☐ 3. Neither Easy nor Difficult, ☐ 4. Easy ☐ 5. Very Easy

Instructor note:

Task 2: Change prescription (dosage or duration)
Directions to the Instructor:
Approve a change request from Pharmacy
Success:
☐ Easily completed
☐ Not completed
____Steps
Comments:

Optimal Time: 12 seconds
Task Time: _____seconds. (Task starts when the participant is asked to begin. The task ends when approve a change request or participant say Done)
Optimal Steps (5 steps): Message center--- Select Change request message--- select prescription---- select approve option--- select submit
☐ Correct
☐ Minor Deviation
☐ Major Deviations (describe below in Comments)

Observed Errors and Verbalizations:

Participant Rating Scale, overall, this task was:
☐ 1 Very Difficult. ☐ 2. Difficult ☐ 3. Neither Easy nor Difficult, ☐ 4. Easy ☐ 5. Very Easy

Instructor note:

Task 3: Cancel prescription
Directions to the Instructor:
Instruct participants to send a cancellation electronically of Zestril 10mg tablet
Success:
☐ Easily completed
☐ Not completed
____Steps
Comments:
Optimal Time: 7 seconds
Task Time: _____seconds. (Task starts when the participant is asked to begin. The task ends when identified the medication change or participant say Done).

Optimal Steps (3 steps): Chronology----Select action in the prescription----View details----Select Cancel Prescription

☐ Correct
☐ Minor Deviation
☐ Major Deviations (describe below in Comments)

Observed Errors and Verbalizations:
Participant Rating Scale, overall, this task was:
☐ 1 Very Difficult. ☐ 2. Difficult ☐ 3. Neither Easy nor Difficult, ☐ 4. Easy ☐ 5. Very Easy

Instructor note:

Task 4: Refill prescription
Directions to the Instructor:
Instruct participants to Approve a refill request of Pataday 0.2% Ophthalmic Solution
Success:
☐ Easily completed
☐ Not completed
____Steps
Comments:
Optimal Time: 15 seconds
Task Time: _____seconds. (Task starts when the participant is asked to begin. The task ends when approve the refill request or participant say Done).

Optimal Steps (5 steps): Message center--- Select Refill request message--- select prescription---- select approve option--- select submit

☐ Correct
☐ Minor Deviation
☐ Major Deviations (describe below in Comments)

Observed Errors and Verbalizations:
Participant Rating Scale, overall, this task was:
☐ 1 Very Difficult. ☐ 2. Difficult ☐ 3. Neither Easy nor Difficult, ☐ 4. Easy ☐ 5. Very Easy

Instructor note:

Task 5: Receive fill status notification
Directions to the Instructor:
Instruct participants to Review fill status of Captopril 25mg
Success:
☐ Easily completed
☐ Not completed
____Steps

Comments:
Optimal Time: 5 seconds
Task Time: _____seconds. (Task starts when the participant is asked to begin. The task ends when identify the fill status or participant say Done).

Optimal Steps (3 steps): Select Chronology--- Look for the medication--- see the column with the status
☐ Correct
☐ Minor Deviation
☐ Major Deviations (describe below in Comments)

Observed Errors and Verbalizations:
Participant Rating Scale, overall, this task was:
☐ 1 Very Difficult. ☐ 2. Difficult ☐ 3. Neither Easy nor Difficult, ☐ 4. Easy ☐ 5. Very Easy

Instructor note:

Task 6: Request and receive medication history information
Directions to the Instructor:
Instruct participants to request and then review a medication history of the patient Spencer Hocking
Success:
☐ Easily completed
☐ Not completed
____Steps
Comments:
Optimal Time: 15 seconds
Task Time: _____seconds. (Task starts when the participant is asked to begin. The task ends when identify the fill status or participant say Done).

Optimal Steps (4 steps): Action----- Select Medication history option--- Select the Pharmacy--- Push get hx----Review medication history
☐ Correct
☐ Minor Deviation
☐ Major Deviations (describe below in Comments)

Observed Errors and Verbalizations:
Participant Rating Scale, overall, this task was:
☐ 1 Very Difficult. ☐ 2. Difficult ☐ 3. Neither Easy nor Difficult, ☐ 4. Easy ☐ 5. Very Easy

Instructor note:

Appendix 6: Non- Disclosure and Informed Consent Form

Non- Disclosure and Informed Consent Form

This AGREEMENT is entered as of _____, 2019 between _____ (**Participant)** and Assertus Holdings, LLC. (**Testing Company**) located at Corporate Office Park Suite 102, San Juan Puerto Rico.

The participant agrees to take part in an evaluation being conducted by the Testing Company. This evaluation is about configuring the MedicusEHR (EHR) system. The purpose of this study is to gather feedback about the effectiveness and efficiency of the EHR in the test.

The Participant acknowledges their voluntary participation in the usability study may bring the Participant into possession of Confidential Information. The term "Confidential Information" means all technical and commercial information of a proprietary or confidential nature which is disclosed by the Testing Company, or otherwise acquired by the Participant, during the study.

By way of illustration, but not limitation, Confidential Information includes trade secrets, processes, formulas, data, know-how, products, designs, drawings, computer-aided design files and other computer files, computer software, ideas, improvements, inventions, training methods and materials, marketing techniques, plans, strategies, budgets, financial information, and/or forecasts.

Any information the Participant acquires relating to this product during this study is confidential and proprietary to the Testing Company and is being disclosed solely for the purposes of the Participant's contribution to the usability study. By signing this form, the Participant acknowledges treating all Confidential Information received during the study in accordance with this nondisclosure agreement. Accordingly, the Participant will not disclose any of the Confidential Information obtained during this study to anyone else or any other organization.

Print Name: _____

Signature: _____

Date Signed: _____

Appendix 7: Recording Consent Form

Recording Consent Form

Assertus would like to thank you for participating in this study. The purpose of this study is to evaluate the usability of the Medicus EHR system. If you decide to participate, you will be asked to perform several tasks within Medicus EHR; and completing a short survey and provide your feedback. The study should take approximately 20 minutes. We will be recording your session to allow Assertus Holdings, LLC., staff members who are unable to be present today to observe your session and benefit from your comments and feedback. Your participation in this study is voluntary, and you are free to withdraw at any point during the study.

Please read the statement below and verbally indicate you accept and consent.

I understand and agree that as a voluntary participant in the present study conducted by Assertus Holdings, LLC. (Testing Company) and I am free to withdraw consent or discontinue my participation at any time.

I understand and agree that the Testing Company will record my test session. I grant the Testing Company permission to use and release the recording of my test session. I understand and agree that the data collected from this study may be shared outside of the Testing Company, and I relinquish any rights to the record. I understand and agree that my recorded session may be copied and used by the Testing Company without further permission.

I understand and agree that the purpose of this study is for the improvement of the product and the features being tested. I agree to immediately raise any concerns or areas in order to fulfill the objective of the study.

I have read and understood the above statement and agree to be a voluntary participant in this study.

Print Name: _____

Signature: _____

Date Signed: _____

Appendix 8: System Usability Scale Questionnaire

System Usability Scale Questionnaire

1. **I think that I would like to use this system frequently**
   (1) Strongly Disagree (2) Disagree (3) Neither agreed or disagreed (4) Agree (5) Strongly Agree

2. **I found the system unnecessarily complex**
   (1) Strongly Disagree (2) Disagree (3) Neither agreed or disagreed (4) Agree (5) Strongly Agree

3. **I thought that the system was easy to use**
   (1) Strongly Disagree (2) Disagree (3) Neither agreed or disagreed (4) Agree (5) Strongly Agree

4. **I think that I would need the support of a technical person to be able to use this system**
   (1) Strongly Disagree (2) Disagree (3) Neither agreed or disagreed (4) Agree (5) Strongly Agree

5. **I found the various functions in this system were well integrated**
   (1) Strongly Disagree (2) Disagree (3) Neither agreed or disagreed (4) Agree (5) Strongly Agree

6. **I thought there was too much inconsistency in this system**
   (1) Strongly Disagree (2) Disagree (3) Neither agreed or disagreed (4) Agree (5) Strongly Agree

7. **I would imagine that most people would learn to use this system very quickly**
   (1) Strongly Disagree (2) Disagree (3) Neither agreed or disagreed (4) Agree (5) Strongly Agree

8. **I found the system very cumbersome to use**
   (1) Strongly Disagree (2) Disagree (3) Neither agreed or disagreed (4) Agree (5) Strongly Agree

9. **I felt very confident using the system**
   (1) Strongly Disagree (2) Disagree (3) Neither agreed or disagreed (4) Agree (5) Strongly Agree

10. **I needed to learn a lot of things before I could get going with this system**
    (1) Strongly Disagree (2) Disagree (3) Neither agreed or disagreed (4) Agree (5) Strongly Agree

EHR Usability Test Report of MedicusEHR 1.0

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

Date of Usability Test: Aug 2019 – Sept 2019

Date of Report: October 10, 2019

Report Prepared by: MedicusEHR

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Table of Contents

1 Executive Summary

Medicus staff conducted a usability study for MedicusEHR v1.0, between August 2019 and September 2019 on different healthcare organizations. Medicus EHR is an ambulatory electronic health record cloud-based application from Medicus Clinical, LLC. The usability test was a part of completing the Safety -Enhanced Design (SED) requirements in the certification criteria identified in 45 CFR Part 170 Subpart C of the Health Information Technology: 2015 Edition Health Information Technology (Health IT) Certification Criteria. The purpose of this study was to test and validate the usability of the current user interface and provide evidence of the usability and functionalities of MedicusEHR under test. During the usability test, a total of ten (10) healthcare professionals used MedicusEHR in a testing environment of the application, representative task.

A Usability Test on selected features and task of the MedicusEHR v1.0, were evaluated in person, in ten (10) clinician's locations. For the usability test, a total of ten (10) users, with work experience of Nurse, Physician and Medical Assistance, matching the target demographic criteria served as participants and used MedicusEHR in simulated, but representative tasks.

During this test, a total of thirty (30) tasks typically conducted on an EHR were evaluated. The tasks were associated with nine (9) certification criteria in 45 CFR Part 170 Subpart C of the Health Information Technology: 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications:

- **170.315(a)(1) CPOE – Medications**
- **170.315(a)(2) CPOE – Laboratory**
- **170.315(a)(3) CPOE – Diagnostic Imaging**
- **170.315(a)(4) Drug-drug, Drug-allergy Interaction Checks**
- **170.315(a)(5) Demographics**
- **170.315(a)(6) Problem List**
- **170.315(a)(7) Medication List**
- **170.315(a)(8) Medication Allergy List**
- **170.315(a)(14) Implantable Device List**

The usability test duration ranged from 60 minutes, depending on the number of tasks assigned to the criteria. During the one-on-one usability test, each participant was greeted by the instructor, briefed on testing protocols, asked to review and sign a non-disclosure, and informed consent form (included in **Appendix 6**); and were instructed they could withdraw at any time. The instructor introduced the test and provided the guidelines to the participants to complete the expected tasks using the EHR. Test participants had prior experience with electronic health records, but not necessarily with the tasks being tested, no additional training was provided for the usability test. During the test, the instructor timed the test and, along with the data logger(s), recorded user performance data on paper and electronically. The instructor did not assist participants during the test.

The design and product development process for this usability test is based on the User-Centered Design Process (UCD) and in accordance with various recommended metrics and examples outlined in the NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records (NISTIR 7741).

Following the examples in the *NIST 7742 Customized Common Industry Format Template for Electronic Health Record Usability Testing (NISTIR 7742),* various recommended metrics were used to evaluate the usability of the software. 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 verbalizations**
- **System Usability Scale (SUS)**

In addition, results include documentation of the following observations:

- Major findings
- Areas of improvement

All participant data was de-identified – no correspondence could be made from the identity of the participant to the data collected. After finishing the test, participants were asked to complete a System Usability Scale Questionnaire (sampler include included in **Appendix 8**).

The results from the System Usability Scale (SUS) scored the subjective satisfaction with the system based on performance with these tasks to be: 95.15%. The average Confidence ratings was 4.74 out of 5 when asked **"How confident was it to use the product being tested to complete the given task:"** on a scale of 1 (Strongly Disagree) to 5 (Strongly Agree). When asked "The system was easy to use?", the average rating was 4.55 out of 5 on a scale of 1 (Strongly Disagree) to 5 (Strongly Agree). The participants were very satisfied with the system. Results are detailed in the Results section of this report, which includes a subsection for each of the ten CEHRT 2015 Ed. criteria.

2 Introduction

The EHR used for this usability test was MedicusEHR v1.0. This cloud-based application platform is designed to provide a healthcare professional with a technology method of recording and tracking patient healthcare records. MedicusEHR supports many healthcare professional roles; e.g. Physician, Nurse, Medical Assistant, Front Desk, through a diversity of healthcare specialties, e.g. Internal Medicine, ENT, Endocrinology, Geriatric, Cardiology. MedicusEHR has a variety of features to facilitate healthcare professionals to manage a daily workflow in an ambulatory outpatient practice to record and manage patient charts, as well as the ability to manage, schedule, reconcile and incorporate clinical information and billing.

The purpose and objective of this study were to test and validate the usability of MedicusEHR user interface and provide evidence of the usability of the EHR by representing realistic exercises. To this end, measures of effectiveness, efficiency and user satisfaction, such as ease of use and completion of tasks on time, were captured during the usability testing. Satisfaction and user confidence were assessed using the System Usability Scale (SUS) satisfaction questionnaire.

The design is based upon an explicit understanding of users, tasks, and environments, such as the locations, exam room, patient interactions, and the different scenarios faced both by the clinician and the back office or front desk staff. With this mind, the context in the UCD was carefully considered, and users were involved throughout the design and development, assessments, conceptualization, and specifications by pilot groups, client visits, and industry events.

For each feature Medicus Clinical LLC, identified needs, regulatory requirements, safety best practices, and our company's experience to develop a user-friendly, agile, and innovative way to integrate technology into the daily operation of any practice.

2.1 Design and Development

Development projects are selected and prioritized based on feedback from selected users of MedicusEHR. Following that input, the EHR specialist, developers, physicians, nurse, and operational staff, documents the needs/recommendations of the users. From mockups to prototype-based formative usability testing, users are involved in all process of the design process. Internal user experience experts evaluate designs based on industry-standard.

2.2 User Testing

MedicusEHR performs unit testing and integrated testing. Unit testing early in the cycle informs broad design decisions. Integrated testing on pre-release and released development quantifies usability and identifies major areas for future focus and improvement.

3 Method

3.1 Participant

A total of ten (10) participants were tested on the EHRUT(s). Participants in the test were physicians (MD), nurses, and medical assistants. The EHR specialist team from Medicus Clinical, LLC, recruited participants. Participants had no direct connection to the development of or the organization producing the EHRUT(s). Participants we're not members of Medicus Clinical LLC. Participants were given the opportunity to have the same orientation and level of training as the actual end-users would have received.

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 1.**

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, computing experience, and user needs for assistive technology. Participant names were replaced with Participant ID's so that an individual's data cannot be tied back to individual identities.

Table 1 Participant

N	Part ID	Gender	Age	Education	Occupation/ Role	Professional Experience	Computer Experience	Product Experience	Technology Needs
1	ID01	Male	60-69	Doctorate degree (e.g., MD, DNP, DMD, PhD)	Physician	456	84	6	No
2	ID02	Female	30-39	Bachelor's Degree	Nurse	48	192	5	No
3	ID03	Female	20-29	Bachelor's Degree	Nurse	12	10	6	No
4	ID04	Female	20-29	Bachelor's Degree	Nurse	11	48	6	No
5	ID05	Male	20-29	Bachelor's Degree	Nurse	10	168	6	No
6	ID06	Female	40-49	Some college credit, no degree	Medical Assistance	240	240	5	No
7	ID07	Male	70-79	Doctorate degree (e.g., MD, DNP, DMD, PhD)	Physician	600	180	5	No
8	ID08	Male	30-39	Doctorate degree (e.g., MD, DNP, DMD, PhD)	Physician	156	324	5	No
9	ID09	Female	40-49	Doctorate degree (e.g., MD, DNP, DMD, PhD)	Physician	168	372	4	No
10	ID10	Male	50-59	Doctorate degree (e.g., MD, DNP, DMD, PhD)	Physician	396	360	5	No

Ten (10) participants (matching the demographics in the section on Participants) were recruited and participated in the usability test. Participants were scheduled for 60 minutes sessions. Outlook email and calendar platform was used to keep track of the participant schedule and include each participant's demographic characteristics. The participant also received an email and appointment with the details of the usability test date and time.

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 with the same tasks were 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 a control area in their daily work 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:

- The number of tasks 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 usability measures can be found in Section 3.9 on Usability Metrics.

3.3 Task

A few tasks were constructed that would be realistic and representative of the kinds of activities a user might do with this EHR. Please refer to Table 2 to review the Tasks that were requested to be completed by the user. Tasks were selected based on their frequency of use, the criticality of the function, and those that may be most troublesome for users. Tasks were constructed in light of the study objectives.

Table 2 Task

SED Criteria	Criteria Name	Task	Objective
170.315.a.1	**CPOE Medication**	a1.1 Record medication via CPOE	Add a new medication to be ordered in an existing patient
170.315.a.1	**CPOE Medication**	a1.2 Change medication via CPOE	Update the sig information to be customized in a different way
170.315.a.1	**CPOE Medication**	a1.3 Display changed CPOE medication order	Review a change made in a medication order
170.315.a.2	**CPOE Labs**	a2.1 Record Lab order via CPOE	Place lab order in an existing patient
170.315.a.2	**CPOE Labs**	a2.2 Change Lab order via CPOE	Update a lab order date
170.315.a.2	**CPOE Labs**	a2.3 Display changed CPOE Lab order	Review the lab order changes
170.315.a.3	**CPOE Imaging**	a3.1 Record Imaging order via CPOE	Place diagnostic test order in an existing patient
170.315.a.3	**CPOE Imaging**	a3.2 Change Imaging order via CPOE	Update a diagnostic imaging order to change the test type.
170.315.a.3	**CPOE Imaging**	a3.3 Display changed CPOE Imaging order	Review the diagnostic imaging changes
170.315.a.4	**Drug-drug, Drug-allergy Interactions Check**	a4.1 Using CPOE, trigger a drug-drug interaction by entering a new medication order	While selecting a Medication, a drug-drug alert appears, cancel the order to protect the patient's safety

170.315.a.4	**Drug-drug, Drug-allergy Interactions Check**	a4.2 Using CPOE, trigger a drug-allergy interaction by entering a new medication order	While selecting a Medication, a drug-allergy alert appears, cancel the order to protect the patient's safety
170.315.a.4	**Drug-drug, Drug-allergy Interactions Check**	a4.3 Adjust the severity level of a displayed drug-drug interaction	User adjust the drug-drug interaction severity level
170.315.a.5	**Demographic**	a5.1 Record a patient's preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity.	Add a new patient with the requirement field
170.315.a.5	**Demographic**	a5.2 Change the patient's preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity.	Change demographic information; preferred language, race, ethnicity in an existing patient
170.315.a.5	**Demographic**	a5.3 Display the patient's changed preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity	Review demographic in the patient that the participant made changes
170.315.a.6	**Problem List**	a6.1 Record a problem to the problem list	Add a new health problem in an existing patient
170.315.a.6	**Problem List**	a6.2 Change a problem on the problem list	Update the status of a problem
170.315.a.6	**Problem List**	a6.3 Display the active problem list	Review the active problems in the problem list
170.315.a.6	**Problem List**	a6.4 Display the historical problem list	Review history problem list
170.315.a.7	**Medication List**	a7.1 Record a medication to the medication list	Add new medication in an existing patient
170.315.a.7	**Medication List**	a7.2 Change a medication on the medication list	Discontinue a medication that the patient is no longer taking.
170.315.a.7	**Medication List**	a7.3 Display the active medication list	Review the active medication in the medication list
170.315.a.7	**Medication List**	a7.4 Display the historical medication list	Review history medication list
170.315.a.8	**Medication Allergy List**	a8.1 Record a medication allergy	Add a new allergy to the allergy list.
170.315.a.8	**Medication Allergy List**	a8.2 Change a medication allergy	Change status allergy to an existing allergy
170.315.a.8	**Medication Allergy List**	a8.3 Display the active medication allergy list	Review the active allergies in the allergy list.
170.315.a.8	**Medication Allergy List**	a8.4 Display the historical medication list	Review history allergy list
170.315.a14	**Implantable Device List**	a14.1 Record UDI	Add a new UDI in an existing patient
170.315.a14	**Implantable Device List**	a14.2 Change UDI Status	Update an UDI status
170.315.a14	**Implantable Device List**	a14.3 Access UDI, device description, identifiers, and attributes	Review the device identifier information for the implantable device

3.4 Risk Assessment

MedicusEHR assessed the risk level to patients of all workflows included in this usability test. These workflows were evaluated based on the potential risk for adverse events to the patient and assigned a risk category of high, moderate, or low risk. Tasks which are related to record information and clinical documentation of the patient, were determined to be of high risk. While basic functions were considering moderate and accessing reference information was determined to be low.

High risk items were prioritized in terms of development changes as a result of success and/or failure during testing. A summary of the user tasks prioritization ranking based on the risk associated with user errors and patient safety is shown in the Table 3.

Table 3 Patient Risk Assessments

SED Criteria	Task	Risk	Pre reason for risk	Post test risk
170.315.a.1	a1.1 Record medication via CPOE	High	User can add the wrong medication	No error observed during the test
170.315.a.1	a1.2 Change medication via CPOE	Moderate	User has knowledge and is just updating information	No error observed during the test
170.315.a.1	a1.3 Display changed CPOE medication order	Low	There is no risk of human error, is a read only chart	Error observed, for details see section 4.1 major findings
170.315.a.2	a2.1 Record Lab order via CPOE	High	User could find themselves in the wrong patient clinical profile	Error observed, for details see section 4.2 major findings
170.315.a.2	a2.2 Change Lab order via CPOE	Moderate	User has knowledge and is just updating information	No error observed during the test
170.315.a.2	a2.3 Display changed CPOE Lab order	Low	There is no risk of human error, is a read only chart	No error observed during the test
170.315.a.3	a3.1 Record Imaging order via CPOE	High	User could find themselves in the wrong patient clinical profile	No error observed during the test
170.315.a.3	a3.2 Change Imaging order via CPOE	Moderate	User has knowledge and is just updating information	Error observed, for details see section 4.3 major findings
170.315.a.3	a3.3 Display changed CPOE Imaging order	Low	There is no risk of human error, is a read only chart	No error observed during the test
170.315.a.4	a4.1 Using CPOE, trigger a drug-drug interaction by entering a new medication order	High	User may have an incomplete list	No error observed during the test
170.315.a.4	a4.2 Using CPOE, trigger a drug-allergy interaction by entering a new medication order	High	Allergy must be present before drug selection	No error observed during the test
170.315.a.4	a4.3 Adjust the severity level of a displayed drug-drug interaction	High	Adjust interaction of a drug-drug, Alert that could be important for the patient	No error observed during the test

170.315.a.5	a5.1 Record a patient's preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity.	Moderate	User can make incorrect typos	Error observed, for details see section 4.5 major findings
170.315.a.5	a5.2 Change the patient's preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity.	Moderate	User can make incorrect typos	Error observed, for details see section 4.5 major findings
170.315.a.5	a5.3 Display the patient's changed preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity	Low	There is no risk of human error, is a read only chart	Error observed, for details see section 4.5 major findings
170.315.a.6	a6.1 Record a problem to the problem list	High	User could find themselves in the wrong patient clinical profile	No error observed during the test
170.315.a.6	a6.2 Change a problem on the problem list	Moderate	User has knowledge and is just updating information	No error observed during the test
170.315.a.6	a6.3 Display the active problem list	Low	There is no risk of human error, is a read only chart	No error observed during the test
170.315.a.6	a6.4 Display the historical problem list	Low	There is no risk of human error, is a read only chart	No error observed during the test
170.315.a.7	a7.1 Record a medication to the medication list	High	User could find themselves in the wrong patient clinical profile	Error observed, for details see section 4.7 major findings
170.315.a.7	a7.2 Change a medication on the medication list	Moderate	User has knowledge and is just updating information	Error observed, for details see section 4.7 major findings
170.315.a.7	a7.3 Display the active medication list	Low	There is no risk of human error, is a read only chart	No error observed during the test
170.315.a.7	a7.4 Display the historical medication list	Low	There is no risk of human error, is a read only chart	No error observed during the test
170.315.a.8	a8.1 Record a medication allergy	High	Patient may not have knowledge of allergies	Error observed, for details see section 4.8 major findings
170.315.a.8	a8.2 Change a medication allergy	Moderate	User has knowledge and is just updating information	Error observed, for details see section 4.8 major findings
170.315.a.8	a8.3 Display the active medication allergy list	Low	There is no risk of human error, is a read only chart	Error observed, for details see section 4.8 major findings
170.315.a.8	a8.4 Display the historical medication list	Low	There is no risk of human error, is a read only chart	No error observed during the test

170.315.a14	a14.1 Record UDI	High	Recording of UDI can present human error into the record keeping as current version does not have a scanner recorder	No error observed during the test
170.315.a14	a14.2 Change UDI Status	Moderate	Is a new module, but there is no risk	No error observed during the test
170.315.a14	a14.3 Access UDI, device description, identifiers, and attributes	Low	There is no risk of human error, is a read only chart	No error observed during the test

3.5 Procedure

MedicusEHR Specialist team administered all test sessions in face to face interactions in the work environment facilities of each participant. To ensure that the test ran smoothly, two MedicusEHR Specialists participated in each session; one as the usability instructor, and the other one as the data logger. The staff conducting the test was experienced usability practitioners and had a combined 20 years of experience in EHR management and design.

Before MedicusEHR Specialist arrival Participants were advised to choose a quiet room in their facility to complete the test, upon the MedicusEHR Specialist team arrival at participant's clinical facilities, they presented themselves and greeted the Participants. Their identity was verified and matched with the name on the participant schedule. The MedicusEHR Specialist prepared the selected area with a computer property of Medicus Clinical, LLC and then requested the participant to initiate the test process. Participants were assigned a participant ID number. Before starting the usability test, the participants received the Participant Guide (see **Appendix 4**), and a Participant Screening (see **Appendix 1**). Also, the participant reviewed and signed a Non-Disclosure and Informed Consent Form (see **Appendix 6**) and a Recording Consent Form (see **Appendix 7**). A representative from the test team witnessed the participant's signature.

Participants were instructed to:

- Complete the tasks as quickly as possible, using their normal workflow (Participants were not advised to think aloud)
- Complete the tasks without assistance except to clarify task details.
- Complete the task without using a think-aloud technique.

The instructor could give immaterial guidance and clarification on tasks, but no instructions on use. Participants were then given instructions on how to interact with the task instructions. Task timing began once the moderator finished reading the question. The task time was stopped once the participant indicated they had completed the task. All test sessions were recorded and analyzed using ***gotoTraining*** application. While participants completed the tasks, the instructor monitored task times, obtained post-task rating data and took notes on participant comments. One additional observer served as the data logger and took notes on task success, path deviations, number and type of errors, and comments.

Following the completion of each task, the instructor gave the participant the System Usability Questionnaire (e.g., the System Usability Scale, see **Appendix 8)**. In addition, participants were able to ask questions about the EHR tested and could also describe any aspects of the EHR product they currently use.

Participants' demographic information, task success rate, time on task, errors, deviations, verbal responses, and post-test questionnaires were recorded into a spreadsheet. Once the test session concluded, participants were thanked for their time and feedback.

3.6 Test Location

Test were given in the clinical work facility of the participants, in a quiet room that could accommodate, the two (2) MedicusEHR resource that will administer the test, and the participant. The room has an office desk and that could allow connectivity of a computer property of Medicus Clinical, LLC. Only the participant, test instructor and data logger were in the test room. The testing product was already installed on the computer property of Medicus Clinical, LLC. To ensure that the environment was comfortable for users, noise levels were kept to a minimum with the ambient temperature within a normal range.

3.7 Test Environment

The EHR would typically be used in a healthcare office or facility. In this instance, the testing was conducted in the participant facilities. For testing, the participant used a 13-inch Microsoft Surface Book 2 (Model 1832, 1834), on a 2.6 GHz Intel Core™ i5-7300U CPU processor, a property of Medicus

Clinical, LLC. The participants used a keyboard and mouse when interacting with MedicusEHR. The application used 1920 x 1080 x59 hertz resolution on the screen for better performance. The application was set up by the MedicusEHR team according to the documentation describing the system set-up and preparation. The application itself was running on Windows 10 Pro using a test database on a wireless connection. Technically, the system performance (i.e., response time) was somewhat slower than what actual users would experience in field implementation. Additionally, participants were instructed not to change any of the default system settings (such as control of font size).

3.8 Test Form and Tools

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

Table 4 Test form and tools

Tool	Detail
Screening participant evaluation	Paper print out
Non-Disclosure and Informed Consent Form	Paper print out
Moderator Guide	Paper print out
Participant Guide	Paper print out
Usability test questionnaire	Paper print out
Recording Consent Form	Paper print out
Virtual meeting	GoToTraining

Examples of these documents can be found in Appendices, respectively. The Instructor Guide was devised to be able to capture the required data.

The participant's interaction with the EHRUT was captured and recorded in the GoToTraining application. The video was storage locally in a secure folder in the Assertus server.

3.9 Participant Instructions

The moderator reads the following instructions aloud to each participant.

Thank you for participating in this usability study. Your input is very important. Our session today will last about 60 minutes. During that time, you will look at MedicusEHR v1.0 to perform specific tasks. I will ask you to complete a few tasks using the system and answer some questions. You will be asked to complete these tasks on your own, trying to do them as quickly as possible, with the fewest possible

errors or deviations. 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 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 support, but I am not able to guide you or provide additional help in how to use the application. Please be honest with your opinions, and if it's possible, save your detailed comments until the end of a task or the end of the session when we can discuss it deeply.

Remember that the product you will be using today is MedicusEHR v1.0 Also, don't forget, as explained before, we are recording the audio and screenshots of our session today. All the information that you provide will be kept confidential, and your name will not be associated with your comments at any time. If you feel it necessary, you can withdraw at any time during the testing.

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 completed the task. If you have any questions or concerns, feel free to ask.

3.10 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:

1. MedicusEHR by measuring participant success rates and errors
2. MedicusEHR by measuring the average task time and path deviations
3. MedicusEHR by measuring ease-of-use ratings

Data Scoring

The following Table (Table 5 Rating) details how metrics measuring efficiency, effectiveness, and satisfaction were scored.

Table 5 Usability metrics

Measures	Rational and Scoring
Effectiveness: Task Success	- A task was counted as a "Success" if the participant was able to achieve the correct outcome, including if the participant was able to achieve the correct outcome with unnecessary steps and additional time. A success score for each task was calculated by averaging the scores for each task. The results are provided as a percentage. -Task times were recorded for successes. Observed task times divided by the optimal time for each task were calculated as a measure of optimal efficiency. -Optimal task performance time, as benchmarked by expert performance under realistic conditions, was recorded when constructing tasks. Target task times were operationally derived by multiplying a benchmarked expert performance by a factor of 2.0, allowing for some time buffer because (1) participants were not trained to expert performance, (2) some features were new, and (3) some tasks had multiple valid paths to a successful outcome. Thus, if an expert, optimal performance on a task was 10 seconds, then allotted task time performance was [10 * 2.0] seconds. This ratio was aggregated across tasks and reported with mean and variance scores.
Effectiveness: Task Failures	If the participant abandoned the task, did not reach the correct answer, performed it incorrectly, or reached the end of the allotted time before successful completion, the task was counted as a Failure. No task times for failed tasks or tasks that exceeded the target task time were used in calculations.
Efficiency: Task Deviations	The participant's navigation 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 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. Path deviations are reported on a qualitative level for use in recommendations for improvement.
Efficiency: Task Time	Each task was timed from when the administrator said "Begin" until the participant said "Done." If the participant failed to say "Done," the time was stopped when the participant ceased performing the task. Only task times for tasks that were completed and tasks that were completed at or under the target time were included in the average task time analysis. Average time per task and variance measures were calculated for each task for use in the analysis of the results.
Satisfaction: Task Rating	Participant's subjective impression of the ease of use of the application was measured by administering both a simple question on the completion of each scenario and a post-session questionnaire. After each scenario, the participant was asked to rate "Overall, these tasks were:" on a scale of 1 (Very Difficult) to 5 (Very Easy). These data were averaged across participants. To measure participants' confidence in and likeability of MedicusEHR overall, the testing team administered the System Usability Scale (SUS) usability questionnaire. Questions included; I thought the system was easy to use system. See the full System Usability Score questionnaire in Appendix 8 System Usability Test Questionnaire

4 Results

4.1 - 170.315(a)(1)- Computerized Provider Order Entry- Medication

Data Analysis and Reporting

Table 6 Computerized Provider Order Entry Medication task results

		Effectiveness		Efficiency						Satisfaction	
	N	Task Success		Path Deviation		Task Time		Error		Rating	
Task	#	Mean %	(SD %)	Deviations Observed/Optimal	(SD)	Mean	(SD)	Mean%	(SD%)	Mean	(SD)
Record medication via CPOE	10	100	0	6/6	1	56	1	0	0	4.6	0.53
Change medication via CPOE	10	100	0	4/4	1	17	1	0	0	4.6	0.53
Display changed CPOE medication order	10	100	0	2/1	2	9	3	30	43	4.5	0.8

Discussion of the Findings

Physician, Nurse, and Medical Assistant were given three Computerized provider order entry medications tasks:

- a1.1 Record medication via CPOE
- a1.2 Change medication via CPOE
- a1.3 Display changed CPOE medication order

Effectiveness

The success score for add a new medication, task a1.1 was 100%, to display the change in medication, task a1.3 was 100%, both tasks were easy for the participant that work daily with this functionality but take time and extra step to the participant that doesn't work daily with that module. The success score to change CPOE medication, a1.2, was 100%, after creating a new medication order is easier for the participant without experience.

Efficiency

Record a new CPOE medication a1.1 in an existing patient, took 56 seconds on average. In the task a1.2, change a sig took 17 seconds. In task a1.3, review the change of the dose took 9 seconds.

Most participants completed the tasks with the same number of steps as expert users and within the optimal time for each task, as suggested by expert timings.

Satisfaction

Most participants rated task a1.1 as easy or very easy, with a result of 4.6 out of 5 points on a Likert scale. Task a1.2 rated as easy or very easy, with a result of 4.6 out of 5 points on a Likert scale. Task a1.3 rated as easy or very easy, with a result of 4.5 out of 5 points on a Likert scale. Most participants were familiar with these tasks and found them straightforward and easy to complete.

Major Findings

Post- usability test, task a1.3 was categorized as patient safety low risk because, some participant made a different workflow to complete, they were made unnecessary steps and selected additional screens.

One participant state: "The CPOE medication module is simple and has everything that I need to reference, it is one of the most used in my office."

Areas of Improvement

The unnecessary steps were the workflow the participant selected to complete the tasks. Due to the results of task a1.3 categorized as patient safety low risk, we are going to reinforce the implementation process, focus on the automatic functionalities that improve the workflow of the MedicusEHR users.

4.2 - 170.315(a)(2)- CPOE- Laboratory

Data Analysis and Reporting

Table 7 Computerized Provider Order Entry Laboratory task results

		Effectiveness		Efficiency						Satisfaction	
	N	Task Success		Path Deviation		Task Time		Error		Rating	
Task	#	Mean %	(SD%)	Deviations Observed/Optimal	(SD)	Mean	(SD)	Mean %	(SD%)	Mean	(SD)
Record Lab order via CPOE	10	100	0	7 / 6	1	49	2	10	11	4.5	0.34
Change Lab order via CPOE	10	100	0	6 /6	0	31	2	0	0	4.5	0.34
Display changed CPOE Lab order	10	100	0	1 / 1	1	7	2	0	0	4.8	0.2

Discussion of the Findings

Physician, Nurse, and Medical Assistant were given three Computerized provider order entry laboratory tasks:

- a2.1 Record Lab order via CPOE
- a2.2 Change Lab order via CPOE
- a2.3 Display changed CPOE Lab order
-

Effectiveness

The success score for the record a new laboratory order, task a2.1 was 100%, to change a lab order, task a2.3 was 100%, and for display a change in lab order, task a2.3 was 100%. All tasks for CPOE Laboratory were easy for them.

Efficiency

Record a new lab order a2.1 in an existing patient, took 49 seconds on average. In task a2.2, change an order lab date took 31 seconds. In the task a2.3, review the change took 7 seconds.

Most participants completed the tasks with the same number of steps as expert users and within the optimal time for each task, as suggested by expert timings.

Satisfaction

Most participants rated task a2.1 as easy or very easy, with a result of 4.5 out of 5 points on a Likert scale. Task a2.2 rated as easy or very easy, with a result of 4.5 out of 5 points on a Likert scale. Task a2.3 rated as easy or very easy, with a result of 4.8 out of 5 points on a Likert scale. Most participants were familiar with these tasks and found them straightforward and easy to complete.

Major Findings

As result of task a2.1, was rating as patient safety high risk because, some participant state that the size of the letter in the lab order module is small, this made it difficult to search the labs in the "general search" area. However, some participants mention: "The lab order search is easy with the frequent list and labs panel functionalities."
The participants who have no experience making lab order changes, confused the name of the icon, where it displays the details of the order. For that reason, some participants take more time to complete task a2.2.
Participants were easily able to record a new laboratory order. This task was easy to complete as the frequent lab lists for this task were clearly defined.

Areas of Improvement

Most of the extra seconds in task a2.3, were additional time taken by participants attempting to access the previous ordering tool location. One potential way to facilitate faster learning would be to guide the user on how to access the previous lab order. The task a2.1 rating as patient safety high risk, due to this result we improve the size of the letter since it makes the user feel comfortable while searching the lab order.

4.3 - 170.315(a)(3)- CPOE- Diagnostic Imaging

Data Analysis and Reporting

Table 8 CPOE Imaging task results

		Effectiveness		Efficiency						Satisfaction	
	N	Task Success		Path Deviation		Task Time		Error		Rating	
Task	#	Mean %	(SD %)	Deviations Observed/Optimal	(SD)	Mean	(SD)	Mean	(SD)	Mean	(SD)
Record Imaging order via CPOE	10	100	0	7 / 7	1	47	2	0	0	4.7	0.34
Change Imaging order via CPOE	10	100	0	7 / 5	1	54	3	30	43	4.1	0.64
Display changed CPOE Imaging order	10	100	0	1 / 1	1	5	2	0	0	4.6	0.31

Discussion of the Findings

Physician, Nurse, and Medical Assistant were given three CPOE imaging tasks:

- a3.1 Record Imaging order via CPOE
- a3.2 Change Imaging order via CPOE
- a3.3 Display changed CPOE Imaging order

Effectiveness

The success score for the record a new imaging order, task a3.1 was 100%, for display a change in imaging order, task a3.3 was 100%, both tasks were easy for the participant. The success score for change an imaging order, task a3.2 was 100%. Some participants completed the task with difficulty.

Efficiency

Record a new imaging order a3.1 in an existing patient, took 47 seconds on average. In the task a3.2, change an imaging order diagnosis took 54 seconds. In the task a3.3, review the change took 5 seconds.

Some participants completed the tasks a3.1 and a3.3 with the same number of steps as expert users and within the optimal time for each task, as suggested by expert timings. In task a3.2, some participants made an extra step to complete the task. Most of the extra steps taken involved typing errors that were corrected before filling information to the patient's note.

Satisfaction

Most participants rated the task a3.1 as easy or very easy, with a result of 4.7 out of 5 points on a Likert scale. Task a3.2 rated as easy or very easy, with a result of 4.5 out of 5 points on a Likert scale. Task a3.3 rated as easy or very easy, with a result of 4.8 out of 5 points on a Likert scale. Most participants were familiar with these tasks and found them straightforward and easy to complete.

Major Findings

Participants were easily able to record a new imaging order. These tasks were easy to complete as the frequent imaging lists for this task were clearly defined. Some participants stated that the size of the letter in the imaging order module is small.

Some participants take more time to complete task a3.2, because of this result was rating, patient safety risk moderate. Participants who have no experience making imaging order changes confused the name of the icon where it displays the details of the imaging order and searching imaging order by descriptive.

Areas of Improvement

Most of the extra seconds in task a3.2 categorized as patient safety risk moderate, were additional time taken by participants attempting to access the previous ordering tool location. One potential way to facilitate faster learning would be to guide the user on how to access the previous imaging order. Due to this result we are going to reinforce the implementation process and focus on automatic functionalities. The size of the letter will increase for a better user experience, it makes the user feel comfortable while searching the imaging order. Participant state the frequent list made the imaging order an easier functionality, but the general search needs improvement to facilitate the searching of the imaging order. The size of the letter will increase for a better user experience in medication module

4.4 - 170.315(a)(4)- Drug-drug, Drug-allergy Interaction Checks

Data Analysis and Reporting

Table 9 Drug-drug, Drug-allergy interaction checks task results

		Effectiveness		Efficiency						Satisfaction	
	N	Task Success		Path Deviation		Task Time		Error		Rating	
Task	#	Mean %	(SD%)	Deviations Observed/Optimal	(SD)	Mean	(SD)	Mean%	(SD%)	Mean	(SD)
Using CPOE, trigger a drug-drug interaction by entering a new medication order	10	100	0	4 / 4	1	20	1	0	0	4.6	0.53
Using CPOE, trigger a drug-allergy interaction by entering a new medication order	10	100	0	4 / 4	1	20	1	0	0	4.6	0.53
Adjust the severity level of a displayed drug-drug interaction	10	100	0	3 / 3	1	11	1	0	0	4.8	0.2

Discussion of the Findings

Physician, Nurse and Medical Assistant were given three drug-drug, drug-allergy Interaction checks tasks:

- a4.1 Trigger a drug-drug interaction
- a4.2 Trigger a drug-allergy interaction
- a4.3 Adjust the severity level of a displayed drug-drug interaction

Effectiveness

The tasks related with interaction were completed with a 100% completion rate and a few extra steps.

Efficiency

Participants completed the task a4.1 in an average of 20 seconds, task a4.2 in an average of 20 seconds, and a task a4.3 in an average of 11 seconds. Most extra steps performed during these tasks involved participants navigating to find additional details about the interaction.

Satisfaction

Most participants rated the task a4.1 as easy or very easy, with a result of 4.6 out of 5 points on a Likert scale. Task a4.2 rated as easy or very easy, with a result of 4.6 out of 5 points on a Likert scale. Task a4.3 rated as easy or very easy, with a result of 4.8 out of 5 point on a Linker scale. Most participants were familiar with these tasks and found them straightforward and easy to complete.

Major Findings

The drug-drug interaction task and drug-allergy interaction task, both tasks were performed with a perfect completion rate. Some participants completed extra steps to investigate the drug interaction in other areas of the prescription builder, viewing information such as additional details about patient allergies or health problems. While these extra steps increased the average task time somewhat.

Areas of Improvement

The longer task completion times for Task a4.1 and a4.2 were partially due to participants searching for alternate medications. Some improvements could include in further studies and integration, or tools that recommend replacement medications for certain interactions.

4.5 - 170.315(a)(5)- Demographics

Data Analysis and Reporting

Table 10 Demographics task results

		Effectiveness		Efficiency						Satisfaction	
	N	Task Success		Path Deviation		Task Time		Error		Rating	
Task	#	Mean%	(SD%)	Deviations Observed/Optimal	(SD)	Mean	(SD)	Mean%	(SD%)	Mean	(SD)
Record a patient's preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity	10	100	0	5 / 4	1	84	2	10	11	4.1	1.73
Change a patient's preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity	10	100	0	5 / 4	1	54	2	20	25	4.6	0.53
Display the patient's changed preferred language, date of birth, birth sex, race, ethnicity, sexual orientation	10	100	0	2 / 1	2	5	2	30	43	4.5	0.5

Discussion of the Findings

Physician, Nurse, and Medical Assistant were given three Computerized provider order entry imaging tasks:

- a5.1 Record a patient's preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity
- a5.2 Change a patient's preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity
- a5.3 Display the patient's changed preferred language, date of birth, birth sex, race, ethnicity, sexual orientation

Effectiveness

The success score for task a5.1 and a5.2 was 100%. Both tasks were easy for the participant that works daily with this functionality but takes time and extra step to the participant that doesn't work daily with that module. Task a5.3 has a success score of 100%.

Efficiency

Some of the participants exceeded the target time and made an extra step for the task a5.1 and 5.2, due to unfamiliarity. Five of the ten participants state that front desk staff or nurses, perform demographics tasks. Participants could complete the task because the required fields are identified on the demographics screen.

Satisfaction

Most participants rated the task a5.1 as easy or very easy, with a result of 4.1 out of 5 points on a Likert scale. Task a5.2 rated as easy or very easy, with a result of 4.6 out of 5 points on a Likert scale. Task a5.3 rated as easy or very easy, with a result of 4.5 out of 5 points on a Likert scale. Most participants were familiar with these tasks and found them straightforward and easy to complete.

Major Findings

Front Desk or Nurse staff typically perform demographic data entry tasks. In the task a5.1, a5.2 and a5.3 some participant was confused with the selection in the fields; race, ethnicity, sexual orientation, gender identity. The finding of this usability study indicates, that the terminology of that required fields is not familiar for some of the participants. Post usability test the tasks a5.1 and 5.2 was categorized patient safety moderate risk, the rating of the task a5.3 was patient safety low risk.

Areas of Improvement

For some of the participant, the terminology of sexual orientation, gender identity, ethnicity, and race are new for them. The findings in the tasks a5.1, a5.2 categorized as patient safety risk moderate and a5.3 categorized as patient safety risk low, shows us how important is educating the staff in that terminology before start MedicusEHR implementation. Also, include in the screen a functionality near to the field with the definition, to facilitate user's adoption.

4.6 - 170.315(a)(6)- Problem list

Data Analysis and Reporting

Table 11 Problem list task results

		Effectiveness		Efficiency						Satisfaction	
	N	Task Success		Path Deviation		Task Time		Error		Rating	
Task	#	Mean%	(SD%)	Deviations Observed/Optimal	(SD)	Mean	(SD)	Mean%	(SD%)	Mean	(SD)
Record a problem to the problem list	10	100	0	5 / 5	1	39	1	0	0	4.5	0.8
Change a problem on the problem list	10	100	0	4 / 3	1	17	1	0	0	4.9	0.08
Display the active problem list	10	100	0	2 / 2	1	4	1	0	0	5	0
Display the historical problem list	10	100	0	1 / 1	1	2	1	0	0	5	0

Discussion of the Findings

Physician, Nurse, and Medical Assistant were given four problem list tasks:

- a6.1 Record a problem to the problem list
- a6.2 Change a problem on the problem list
- a6.3 Display the active problem list
- a6.4 Display the historical problem list

Effectiveness

The success score for tasks in the problem list was 100%. All the tasks were easy for the participant.

Efficiency

Participant completed the task a6.1 in an average of 39 seconds, task a6.2 in an average of 17 seconds, task a6.3 in an average of 4 seconds, and a6.4 in an average of 2 seconds. Nine of ten participants completed the tasks a6.1, a6.3 and a6.4 with either fewer steps or the same number of steps as expert users.

Some of the participants in the task a6.2 complete the task but do not use the optimal step.

Satisfaction

Participants rated the task a6.1 as easy or very easy, with a result of 4.5 out of 5 points on a Likert scale. Task a6.2 rated as easy or very easy, with a result of 4.9 out of 5 points on a Likert scale. Task a6.3 and a6.4, both were rated as very easy, with a result of 5 out of 5 points on a Likert scale. Most participants were familiar with these tasks and found them straightforward and very easy to complete.

Major Findings

Most participants in task a6.2 use a different workflow to change status in a health problem. The health problem module has an option to change a status easier with unnecessary steps, but they were unfamiliar to an easier workflow.

Areas of Improvement

Due to the results of task a6.2, we are going to reinforce the implementation process and focus on the functionalities that improve the workflow of the users.

4.7 - 170.315(a)(7)- Medication list

Data Analysis and Reporting

Table 12 Medication list task results

		Effectiveness		Efficiency						Satisfaction	
	N	Task Success		Path Deviation		Task Time		Error		Rating	
Task	#	Mean%	(SD%)	Deviations Observed/Optimal	(SD)	Mean	(SD)	Mean%	(SD%)	Mean	(SD)
Record a medication to the medication list	10	100	0	5 / 5	1	35	1	10	11	4.5	0.8
Change a medication on the medication list	10	100	0	4 / 3	1	24	2	30	43	4.5	0.8
Display the active medication list	10	100	0	2 / 2	1	4	1	0	0	4.8	0.2
Display the historical; medication list	10	100	0	1 / 1	1	3	1	0	0	4.8	0.2

Discussion of the Findings

Physician, Nurse, and Medical Assistant were given four medication list tasks:

- a7.1 Record a medication to the medication list
- a7.2 Change a medication on the medication list
- a7.3 Display the active medication list
- a7.4 Display the historical medication list

Effectiveness

The success score for the four tasks in the medication list was 100%; all the tasks were easy for the participant.

Efficiency

Participant completed the task a7.1 in an average of 35 seconds, task a7.2 in an average of 24 seconds, task a7.3 in an average of 4 seconds, and a7.4 in an average of 3 seconds. Ten of ten participants completed the tasks a7.3 and a7.4 with either fewer steps or the same number of steps as expert users.

Some of the participants in the task a7.2 complete the task but do not use the optimal step.

Satisfaction

Participants rated the task a7.1 and a7.2 as easy or very easy, with a result of 4.5 out of 5 points on a Likert scale. Task a7.3 and a7.4 rated as easy or very easy, with a result of 4.8 out of 5 points on a Likert scale. Most participants were familiar with these tasks and found them straightforward and very easy to complete.

Major Findings

Most participants in the tasks a7.1 rating as patient safety high risk and a7.2 rating as patient safety moderate risk, use a different workflow to change status in medication area. The medication module has an option to record and change status easier with unnecessary steps, but they were unfamiliar to an easier workflow. Some participants mention that the size of the letter in medication area is small.

Areas of Improvement

Due to the results of the tasks a7.1(moderate risk) and a7.2(low risk), we are going to reinforce the implementation process and focus on the automatic functionalities that improve the workflow of the users. The size of the letter will increase for a better user experience in medication module.

4.8 - 170.315(a)(8)- Medication Allergy list

Data Analysis and Reporting

Table 13 Medication allergy list task results

		Effectiveness		Efficiency						Satisfaction	
	N	Task Success		Path Deviation		Task Time		Error		Rating	
Task	#	Mean%	(SD%)	Deviations Observed/Optimal	(SD)	Mean	(SD)	Mean%	(SD%)	Mean	(SD)
Record a medication allergy	10	100	0	6 / 5	1	31	2	10	11	4.6	.53
Change a medication allergy	10	100	0	4 / 3	1	15	1	20	25	4.6	.53
Display the active medication allergy list	10	100	0	2 / 2	1	6	1	20	25	4.3	.72
Display the historical medication allergy list	10	100	0	1 / 1	1	2	1	0	0	4.8	0.2

Discussion of the Findings

Physician, Nurse, and Medical Assistant were given four medication allergy list tasks:

- a8.1 Record a medication allergy
- a8.2 Change a medication allergy
- a8.3 Display the active medication allergy list
- a8.4 Display the historical medication allergy list

Effectiveness

The success score for tasks a8.1 and a8.3 in the medication allergy was 100%. Task a8.2 was completed with 100%, with unnecessary steps. Task a8.4 was completed with 100%.

Efficiency

Participant completed the task a8.1 in an average of 31 seconds, task a8.2 in an average of 15 seconds, task a8.3 in an average of 6 seconds, and a8.4 in an average of 2 seconds. Some participants completed the tasks a8.3 and a8.4 with either fewer steps or the same number of steps as expert users.

Some of the participant in the tasks a8.1 and a8.2 complete the task, but do not use the optimal step.

Satisfaction

Participants rated the tasks a8.1, a8.2, and a8.4 as easy or very easy, with a result between 4.6 and 4.8 out of 5 points on a Likert scale. Task a8.3 was rated as easy, very easy, and neither easy or difficult, with a result of 4.3 out of 5 points on a Likert scale. Most participants were familiar with these tasks and found them straightforward and very easy to complete.

Major Findings

Most participants in tasks a8.1, a8.2 and a8.3 use a different workflow to complete the task with additional steps and or consuming more time. Post usability test the task a8.1 was categorized as patient safety high risk, a8.2 patient safety moderate risk and a8.3 patient safety low risk. The medication module has an automatics and easier functionalities to record, change status and display medications, but they were unfamiliar to an easier workflow.

Areas of Improvement

Due to the results of the task a8.1(high risk), a8.2(moderate risk) and a8.3(low risk), we are going to reinforce the implementation process and focus on the automatic functionalities that improve the workflow of the users.

4.9 - 170.315(a)(14)- Implantable device list

Data Analysis and Reporting

Table 14 Implantable device list

		Effectiveness		Efficiency						Satisfaction	
	N	Task Success		Path Deviation		Task Time		Error		Rating	
Task	#	Mean%	(SD%)	Deviations Observed/Optimal	(SD)	Mean	(SD)	Mean%	(SD%)	Mean	(SD)
Record UDI	10	100	0	8 / 7	1	20	1	0	0	4.7	0.34
Change UDI Status	10	100	0	5 / 5	1	10	1	0	0	4.6	0.53
Access UDI, device description, identifiers, and attributes	10	100	0	1 / 1	1	3	1	0	0	4.6	0.53

Discussion of the Findings

Physician, Nurse and Medical Assistant were given three Implantable device list tasks:

- a14.1 Record UDI
- a14.2 Change UDI Status
- a14.3 Access UDI, device description, identifiers, and attributes

Effectiveness

Task a14.2 and a14.3 were both completed with a 100% completion rate and a few extra steps. Task a14.1 were completed with 100%.

Efficiency

Participants completed the task a14.1 in an average of 20 seconds, task a14 in an average of 10 seconds, and task a14.3 in an average of 2 seconds. Most extra steps performed during these tasks involved participants navigating to find additional details about device.

Satisfaction

Most participants rated the task a14.1 as easy or very easy, with a result of 4.7 out of 5 points on a Likert scale. Tasks a14.2 and a14.3 both were rated as easy or very easy, with a result of 4.6 out of 5 points on a Likert scale. Most participants were familiar with these tasks and found them straightforward and easy to complete.

Major Findings

Part of the success with using this new feature may be attributable to the training provided to participants.

Areas of Improvement

Participant recommend the alternative to record a note in implantable device in patient when the device ID is not available

4.9 – Overall results

Areas for improvement include:

- Training tips

  Low familiarity ratings with certain functionality, along with participant's lack of knowledge of the existence of some functionality and were unfamiliar with the optimal path workflow, may indicate a need for training and documentation that is accessible within common workflows and provided in formats that are easily consumable by busy user with multiple task in their clinicals facilities.

  Evaluating implementation process, focus on the automatic functionalities that improve the workflow of the users. This usability study identified areas where traditional training tips can be improved or expanded to help users become comfortable with the functionality more quickly. With that in mind we incorporate recurrent webinars. Also, in our plan we will introduce just-in-time training, the users will access information when they need it.

- Identifying additional options to minimized data entry

  The usability test results of CPOE labs and diagnostic imaging bring us the opportunities to make refinements to the workflow and the look and feel of the system. See sections 4.2 and 4.3 for more details. This usability study identified methods, such as auto-completion, which can impact efficiency for specific tasks. Recent and ongoing technological improvements might also introduce ways to streamline data entry. Further research in these areas can yield innovative methods to boost clinician efficiency.

- Common satisfaction features:

  The overall results from the SUS (System Usability Scale) scored the subjective satisfaction with the system based on performance with these tasks to be 95.15 percent.

  Participants repeatedly mention that the performance of their systems were different from the test system. They stated the performance is one of the best capabilities of the system. Also, the ability to access all features from multiple locations in the system, its accessible, intuitive and even if the participant don't' use the functionality daily can completed the tasks.

In overall the user-centered design and usability testing, gave us the opportunities to refine and enhance the user experience. Some of these enhancements have been prioritized for release in upcoming MedicusEHR updates. Still others will be revisited in more depth in future studies.

5 Appendices

Appendix 1: Participant Screening

Appendix 2: Participant Demographics

Appendix 3: Testing dates and locations

Appendix 4: Participant Guide

Appendix 5: Instructor Guide

Appendix 6: Non- Disclosure and Informed Consent Form

Appendix 7: Recording Consent Form

Appendix 8: System Usability Scale Questionnaire

Appendix 1: Participant Screening

Name:
Date:
Location:

1. **What is your gender?**
   a. Male
   b. Female
2. **Which of these bests describes your current age?**
   a. 0-9
   b. 10-19
   c. 20-29
   d. 30-39
   e. 40-49
   f. 50-59
   g. 60-69
   h. 70-79
   i. 80-89
   j. 90-99
   k. 100+
3. **Highest Level of Education:**
   a. High school graduate/GED
   b. Some college credit, no degree
   c. Trade/technical/vocational training
   d. Associate degree
   e. Bachelor's degree
   f. Master's degree (MSN, MS)
   g. Doctorate (MD, DNP, DO, Ph.D.)
4. **What is your current role?**
   a. Medical Assistant (MA)
   b. Nurse
   c. Office Manager
   d. Physician
   e. Front Desk
   f. Other (please specify)
5. **What is your specialty?**
6. **How many years have you been working in your field?**
7. **How many years of experience do you have using computers?**
8. **How long have you been using MedicusEHR?**
9. **Do you require any assistive technologies to use a computer?**
   a. Yes
   b. No

Appendix 2: Participant Demographics

Gender	
Female	5
Male	5
Total participant	**10**

Occupation/Role	
Medical Assistance	1
Nurse	4
Physician	5
Total participant	**10**

Education	
Doctorate degree (e.g., MD, DNP, DMD, PhD)	5
Bachelor's Degree	4
Some college credit, no degree	1
Total participant	**10**

Experience (month)	
Experience with MedicusEHR (month)	5.1 (average)

Appendix 3: Testing dates and locations

Testing Dates and Locations

	Test Dates	Locations
1	6-Aug-19	Bayamon, PR
2	13-Aug-19	Bayamon, PR
3	15-Aug-19	Bayamon, PR
4	19-Aug-19	San Juan, PR
5	20-Aug-19	San Juan, PR
6	30-Aug-19	San Juan, PR
7	11-Sep-19	Guaynabo, PR
8	17-Sep-19	Guaynabo, PR
9	23-Sep-19	Bayamon, PR
10	27-Sep-19	Guaynabo, PR

Appendix 4: Participant Guide

Participant guide (sampler)

Thank you for participating in this usability study. Our session today will last about 60 minutes. During that time, you will look at MedicusEHR to perform specific tasks. I will ask you to complete a few tasks using the system and answer some questions. You will be asked to complete these tasks on your own, trying to do them as quickly as possible with the fewest possible errors or deviations. 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 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. Do not do anything more than asked. Please save your detailed comments until the end of a task or the end of the session when we can discuss it deeply. Please be honest with your opinions. The product you will be using today is MedicusEHR. We are recording the audio and screenshots of our session today. All 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 can withdraw at any time during the testing. 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 completed the task. If you have any questions or concerns, feel free to ask.

170.315.a.1 CPOE – Medications

Task 1: Record Medication Order via CPOE:

In a new encounter, create a medication **Xarelto**. Search for medication presentation **Xarelto 10mg tablet**. Once the medication is selected, complete the required fields (*). When you are ready, please begin

Task 2: Change the Medication Order via CPOE:

Update the prescription sig (instruction dosage) for **Xarelto 10mg tablet**. When you are ready, please begin

Task 3: Display Changed CPOE Medication Order:

Review the prescription list in the progress note and identify the changes in the medication **Xarelto 10mg tablet**. When you are ready, please begin

170.315.a.2 Computerized Provider Order Entry (CPOE) Laboratory Order

Task 1: Record's a clinical laboratory order:

In a new encounter, create a new order for a clinical lab test, search Lipid **1996- Panel Serum or Plasma, or CPT code 80061**. When finished, click Submit. When you are ready, please begin

Task 2: Change patient's clinical laboratory order:

In the open encounter, direct your attention to the Order helper area (Previous Order) to change the order priority to STAT. When you are ready, please begin

Task 3: Display the patient's changed type of clinical laboratory order:

In the open note, review the information updated in the clinical lab test for **Lipid 1996- Panel Serum or Plasma.** When you are ready, please begin

170.315.a.3 Computerized Provider Order Entry (CPOE) Diagnostic Imaging

Task 1: Record's CPOE Imaging order:

In a new encounter, create a new diagnostic imaging order, search for **Magnetic resonance (e.g., proton) imaging chest (e.g., for evaluation of hilar and mediastinal lymphadenopathy); w/o contrast material** or **CPT code 71550.** When finished, click Submit. When you are ready, please begin

Task 2: Change patient's imaging order:

In the open encounter, direct your attention to the Order helper area (Previous Order), change the **Diagnosis** to any of your choosing. When finished, click Submit. When you are ready, please begin

Task 3: Display the patient's changed type of imaging order:

In the open note review, the information updated in the diagnostic imaging order for: **Magnetic resonance (e.g., proton) imaging chest (e.g., for evaluation of hilar and mediastinal lymphadenopathy); w/o contrast material.** When finished, click Submit. When you are ready, please begin

170.315.a.4 Drug-Drug, Drug-Allergy Interaction Checks for CPOE

Task 1: Trigger a Drug-Drug Interaction by Entering a New Medication Order

Add new medication order **Diclofenac Sodium 75 MG Delayed-Release Oral Tablet**, and the patient already takes **Xarelto. T**his medication interacts severely with the new medication. The test is considered complete when the alert on the screen is displayed. When you are ready, please begin

Task 2: Trigger a Drug-Allergy Interaction by Entering a New Medication Order

Add new medication order **Diclofenac Sodium 75 MG Delayed-Release Oral Tablet**, and the patient already takes **Ibuprofen. T**his medication interacts severely with the new medication. The test is considered complete when the alert on the screen is displayed. When you are ready, please begin

Task 3: Adjust the severity level of a displayed drug-drug interaction

In user maintenance edit doctor.ortiz , and select high level interaction option to adjust the severity. The test is considered complete when select accept. When you are ready, please begin.

170.315.a.5 Demographics

Task 1: Record a patient's preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity

Add a new Patient, include the following information in the appropriately labeled fields. When you are ready, please begin

- Date of birth as 9/30/1977
- Enter Sex as Female
- Enter Race as Asian Indian
- Enter Ethnicity as Not- Hispanic or Latino
- Enter Sexual orientation as Straight or heterosexual
- Enter Gender identity; identifies as Female
- Record a patient's preferred language as English

Task 2: Change a patient's preferred language, dob, birth sex, race, ethnicity, sexual orientation, gender identity.

Update patient demographic information, change the following details in the appropriately labeled fields. When you are ready, please begin

- Change date of birth as 9/30/1975
- Change the patient's race to Asian
- Change the Ethnicity to Hispanic or Latino
- Change Sexual orientation to Bisexual
- Change the preferred language to a Spanish

Task 3: Display the patient's changed preferred language, date of birth, birth sex, race, ethnicity, sexual orientation

Review the demographic information, previously edited.

170.315.a.6 Problem List

Task 1: Record a Problem List

In the clinical profile, select the Health Problems module, search **Benign hypertension**. When you are ready, please begin

Task 2: Change a Problem on the Health Problem List

In the clinical profile, select the Health Problems module. Select any of the patient's active problems and update the status to resolve, include the reason. When you are ready, please begin.

Task 3: Access the Active Health Problem List

In the clinical profile, select Health Problems view details. Identify the status filter to display the active health problem list. When you are ready, please begin.

Task 4: Access the Health Problem List History

In the clinical profile, select Health Problems view details. Identify the status filter to display the health problem history. When you are ready, please begin.

315.a.7 Medication List

Task 1: Record a Medication to the Medication List

In the clinical profile select Medication module, search **Flexeril 10mg** with dose instructions of your choice When you are ready, please begin

Task 2: Change a Medication on the Medication List

In the clinical profile, select the Medication module. Select any of the patient medication and update the status to discontinue a reason to change treatment. When you are ready, please begin

Task 3: Display the Active Medication List

In the clinical profile, select Medications view details. Identify the status filter to display the active medication list. When you are ready, please begin.

Task 4: Medication List/Display the Historical Medication List

In the clinical profile, select Medications view details. Identify the status filter to display the medication history. When you are ready, please begin

315.a.8 Medication Allergy List

Task 1: Record a Medication Allergy

In the clinical profile select the Allergy module, search **Ibuprofen**. When you are ready, please begin

Task 2: Change a Medication Allergy

In the clinical profile, select the Allergy module. Update the status to inactive to any of the allergy included in the patient allergy list

Task 3: Display the Active Medication Allergy List

In the clinical profile, select Allergy view details. Identify the status filter to display the active medication list. When you are ready, please begin.

Task 4: Display the Historical Medication Allergy List

In the clinical profile, select Medications view details. Identify the status filter to display the medication history. When you are ready, please begin

315.a.14 Implantable Device List

Task 1: Record UDI

Add cardiopulmonary bypass to the device list. Use the Unique Device Identifier; +B066000325011NS1/$$420020216LOT123456789012345/SXYZ456789012345678/16D20130202C1 Add an implant date of 9/12/2018. When you are ready, please begin

Task 2: Change UDI Status

Change device status from active to inactive to a cardiopulmonary bypass. When you are ready, please begin

Task 3: Access UDI, device description, identifiers, and attributes

Review the implantable device details in the device list

Appendix 5: Instructor Guide

Instructor guide (sampler)

Instructor:
Data Logger
Date
Time:
Participant ID
Location:

Thank you for participating in this usability study. Our session today will last about 60 minutes. During that time, you will look at MedicusEHR to perform specific tasks. I will ask you to complete a few tasks using the system and answer some questions. You will be asked to complete these tasks on your own, trying to do them as quickly as possible with the fewest possible errors or deviations. 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 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. Do not do anything more than asked. Please save your detailed comments until the end of a task or the end of the session when we can discuss it deeply. Please be honest with your opinions. The product you will be using today is MedicusEHR. We are recording the audio and screenshots of our session today. All 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 can withdraw at any time during the testing. 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 completed the task. If you have any questions or concerns, feel free to ask.

170.315.a.1 CPOE – Medications
Task 1: Record Medication Order via CPOE
Directions to the Instructor:
Instruct Participant to create new medication order in the progress note
Success:
☐ Easily completed
☐ Completed with difficulty (describe below in Comments)
☐ Not completed
____Steps
Comments:

Optimal Time: 60 seconds
Task Time: _____seconds. (Task starts when the participant is asked to begin. The task ends after Xarelto 10mg tablet is documented or participant say Done).
Optimal Steps (6 steps): New Visit Note----Select Prescription----Prescription Order Builder/Create Blank Prescription----Add New---Search Medication name—Select medication and sig etc.---Add to prescription
☐ Correct

☐ Minor Deviation
☐ Major Deviations (describe below in Comments)
____Steps
Observed Errors and Verbalizations:

Participant Rating Scale, overall, this task was:
☐ 1 Very Difficult. ☐ 2. Difficult ☐ 3. Neither Easy nor Difficult, ☐ 4. Easy ☐ 5. Very Easy

Instructor note:

Task 2: Change Medication Order via CPOE
Instruct Participant to go to Prescription order builder to change medication order
Success:
☐ Easily completed
☐ Completed with difficulty (describe below in Comments)
☐ Not completed
____Steps
Comments:

Optimal Time: 17 seconds
Task Time: _____seconds. (Task starts when the participant is asked to begin. The task ends when prescription sig(instruction) was changed or participant say Done)
Optimal Steps (4 steps): Prescription Order Builder--- Prescription/Select Edit---Change the medication instruction(sig)---Add to prescription
☐ Correct
☐ Minor Deviation
☐ Major Deviations (describe below in Comments)

Observed Errors and Verbalizations:

Participant Rating Scale, overall, this task was:
☐ 1 Very Difficult. ☐ 2. Difficult ☐ 3. Neither Easy nor Difficult, ☐ 4. Easy ☐ 5. Very Easy

Instructor note:

Task 3: Display Changed CPOE Medication Order
Directions to the Instructor:
Instruct participants to go to the Progress Note/ Prescription area.
Success:
☐ Easily completed
☐ Completed with difficulty (describe below in Comments)
☐ Not completed
____Steps
Comments:

Optimal Time: 3 seconds
Task Time: _____seconds. (Task starts when the participant is asked to begin. The task ends when identified the medication change or participant say Done).

Optimal Steps (1 steps): Prescription Order Builder----Select Send/Print All pending prescription----Close the prescription order builder---Progress Note
☐ Correct
☐ Minor Deviation
☐ Major Deviations (describe below in Comments)

Observed Errors and Verbalizations:
Participant Rating Scale, overall, this task was:
☐ 1 Very Difficult. ☐ 2. Difficult ☐ 3. Neither Easy nor Difficult, ☐ 4. Easy ☐ 5. Very Easy

Instructor note:

170.315.a.2 Computerized Provider Order Entry (CPOE) Laboratory Order
Task 1: Record's Clinical Laboratory Order
Directions to the Instructor:
Instruct Participant to create new clinical laboratory order in the open progress note
Success:
☐ Easily completed
☐ Completed with difficulty (describe below in Comments)
☐ Not completed
____Steps
Comments:

Optimal Time: 25 seconds
Task Time: _____seconds. (Task starts when the participant is asked to begin. The task ends when participant create a lab order or participant say Done).
Optimal Steps (6 steps): Open Progress Note----Orders Module---Create Blank Order---- Clinical Lab Test/ General Search----Type the Clinical Lab Order Name or CPT Code----Add Description----Add Dx--- Submit
☐ Correct
☐ Minor Deviation
☐ Major Deviations (describe below in Comments)
____Steps
Observed Errors and Verbalizations:

Participant Rating Scale, overall, this task was:
☐ 1 Very Difficult. ☐ 2. Difficult ☐ 3. Neither Easy nor Difficult, ☐ 4. Easy ☐ 5. Very Easy

Instructor note:

Task 2: Change patit's clinical Laboratory Order

Directions to the Instructor:

Instruct Participant to edit a clinical laboratory order in the open progress note

Success:

☐ Easily completed

☐ Completed with difficulty (describe below in Comments)

☐ Not completed

____Steps

Comments:

Optimal Time: 20 seconds

Task Time: _____seconds. (Task starts when the participant is asked to begin. The task ends when the participant change the order date or participant say Done).

Optimal Steps (6 steps): Open Progress Note----Click Detail Icon---- Select Test Order----Create Order----Add Description----Add Dx--- Submit

☐ Correct

☐ Minor Deviation

☐ Major Deviations (describe below in Comments)

____Steps

Observed Errors and Verbalizations:

Participant Rating Scale, overall, this task was:

☐ 1 Very Difficult. ☐ 2. Difficult ☐ 3. Neither Easy nor Difficult, ☐ 4. Easy ☐ 5. Very Easy

Instructor note:

Task 3: Display patient's changed type clinical Laboratory Order

Directions to the Instructor:

Instruct Participant to display changed clinical laboratory order in the open progress note

Success:

☐ Easily completed

☐ Completed with difficulty (describe below in Comments)

☐ Not completed

____Steps

Comments:

Optimal Time: 3 seconds

Task Time: _____seconds. (Task starts when the participant is asked to begin. The task ends participant identify the lab order changes or participant say Done).

Optimal Steps (1 step): Open Progress Note----Previous Orders / Detail Icon

☐ Correct

☐ Minor Deviation

☐ Major Deviations (describe below in Comments)

____Steps

Observed Errors and Verbalizations:

Participant Rating Scale, overall, this task was:
☐ 1 Very Difficult. ☐ 2. Difficult ☐ 3. Neither Easy nor Difficult, ☐ 4. Easy ☐ 5. Very Easy
Instructor note:

---

170 315.a.3 Computerized Provider Order Entry (CPOE) Diagnosis Imaging
Task 1: Record's Diagnosis Imaging Order
Directions to the Instructor:
Instruct Participant to create new diagnosis imaging order in the open progress note
Success:
☐ Easily completed
☐ Completed with difficulty (describe below in Comments)
☐ Not completed
____Steps
Comments:

Optimal Time: 25 seconds
Task Time: _____seconds. (Task starts when the participant is asked to begin. The task ends when participant create an imaging order or participant say Done).
Optimal Steps (7 steps): Open Progress Note----Orders Module---Create Blank Order---- Imaging/ General Search----Type the Imaging Order Name or CPT Code----Add Description----Add Dx--- Submit
☐ Correct
☐ Minor Deviation
☐ Major Deviations (describe below in Comments)
____Steps

Observed Errors and Verbalizations:

Participant Rating Scale, overall, this task was:
☐ 1 Very Difficult. ☐ 2. Difficult ☐ 3. Neither Easy nor Difficult, ☐ 4. Easy ☐ 5. Very Easy

Instructor note:

Task 2: Change patient's Imaging Order
Directions to the Instructor:
Instruct Participant to edit an imaging order in the open progress note
Success:
☐ Easily completed
☐ Completed with difficulty (describe below in Comments)
☐ Not completed
____Steps
Comments:

Optimal Time: 20 seconds
Task Time: _____seconds. (Task starts when the participant is asked to begin. The task ends when participant change diagnosis in the imaging order or participant say Done).
Optimal Steps (5 steps): Open Progress Note----Click Detail Icon---- Select Type Imaging Test---- Create Order----Add Description----Add Dx--- Submit
☐ Correct
☐ Minor Deviation
☐ Major Deviations (describe below in Comments)
____Steps
Observed Errors and Verbalizations:

Participant Rating Scale, overall, this task was:
☐ 1 Very Difficult. ☐ 2. Difficult ☐ 3. Neither Easy nor Difficult, ☐ 4. Easy ☐ 5. Very Easy
Instructor note:

Task 3: Display patient's changed type imaging Order
Directions to the Instructor:
Instruct Participant to display changed clinical laboratory order in the open progress note
Success:
☐ Easily completed
☐ Completed with difficulty (describe below in Comments)
☐ Not completed
____Steps
Comments:

Optimal Time: 3 seconds
Task Time: _____seconds. (Task starts when the participant is asked to begin. The task ended when the participant identified the imaging order changes or participant say Done).
Optimal Steps (1 step): Open Progress Note----Previous Orders/**Detail Icon**
☐ Correct
☐ Minor Deviation
☐ Major Deviations (describe below in Comments)
____Steps
Observed Errors and Verbalizations:

Participant Rating Scale, overall, this task was:
☐ 1 Very Difficult. ☐ 2. Difficult ☐ 3. Neither Easy nor Difficult, ☐ 4. Easy ☐ 5. Very Easy
Instructor note:

170.315.a.4 Drug-Drug, Drug-Allergy Interaction Checks for CPOE

Task 1: Trigger a Drug-Drug Interaction by Entering a New Medication Order

Directions to Instructor:

Instruct the Participant to add a new medication order

Success:

☐ Easily completed

☐ Completed with difficulty (describe below in Comments)

☐ Not completed

Comments:

Optimal Time: 20 seconds

Task Time: _____ (Task starts when the participant is asked to begin. Task ends when the drug interaction alert appears on the screen or participant say Done).

Optimal Steps (4 steps): New Visit Note----Select Prescription----Prescription Order Builder/Create Blank Prescription----Add New---Search Medication name/the interaction will display in the screen

☐ Correct

☐ Minor Deviation

☐ Major Deviations (describe below in Comments)

____Steps

Observed Errors and Verbalizations:

Participant Rating Scale, overall, this task was:

☐ 1 Very Difficult. ☐ 2. Difficult ☐ 3. Neither Easy nor Difficult, ☐ 4. Easy ☐ 5. Very Easy

Instructor note:

Task 2: Trigger a Drug-Allergy Interaction by Entering a New Medication Order

Directions to Instructor:

Instruct the Participant to add a new medication order

Success:

☐ Easily completed

☐ Completed with difficulty (describe below in Comments)

☐ Not completed

____Steps

Comments:

Optimal Time: 20 seconds

Task Time: _____seconds. (Task starts when the participant is asked to begin. The task ends when the drug interaction alert appears on the screen or participant say Done).

Optimal Steps (4 steps): New Visit Note----Select Prescription----Prescription Order Builder/Create Blank Prescription----Add New---Search Medication name/the interaction will display in the screen

☐ Correct

☐ Minor Deviation

☐ Major Deviations (describe below in Comments)

Observed Errors and Verbalizations:

Participant Rating Scale, overall, this task was:
☐ 1 Very Difficult. ☐ 2. Difficult ☐ 3. Neither Easy nor Difficult, ☐ 4. Easy ☐ 5. Very Easy

Instructor notes

Task 3: Adjust the severity level of a displayed drug-drug interaction

Directions to Instructor:

Instruct the Participant to adjust the severity level for drug-drug interaction
Success:
☐ Easily completed
☐ Completed with difficulty (describe below in Comments)
☐ Not completed
____Steps
Comments:

Optimal Time: 11 seconds
Task Time: _____seconds. (Task starts when the participant is asked to begin. The task ends when select accept button or participant say Done).
Optimal Steps (3 steps): User center- Edit- Select high level interaction option- Accept
☐ Correct
☐ Minor Deviation
☐ Major Deviations (describe below in Comments)
Observed Errors and Verbalizations:

Participant Rating Scale, overall, this task was:
☐ 1 Very Difficult. ☐ 2. Difficult ☐ 3. Neither Easy nor Difficult, ☐ 4. Easy ☐ 5. Very Easy

Instructor note:

170.315.a.5 Demographics
Task 1: Record a patient's preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity
Directions to Instructor:
Instruct the Participant to go to Patient Center Lookup
Success:
☐ Easily completed
☐ Completed with difficulty (describe below in Comments)
☐ Not completed
____Steps
Comments:

Optimal Time: 50 seconds
Test Task Time: _____ Seconds. (Task starts when the Participant is asked to start. The task is completed when participant selects accept or participant say Done).
Optimal Steps (4 steps): Patient Center Lookup/Add New---Patient Maintenance Information/Edit---Complete the red fields---Select Accept
☐ Correct
☐ Minor Deviation
☐ Major Deviations (describe below in Comments)
Observed Errors and Verbalizations:

Participant Rating Scale, overall, this task was:
☐ 1 Very Difficult. ☐ 2. Difficult ☐ 3. Neither Easy nor Difficult, ☐ 4. Easy ☐ 5. Very Easy

Instructor note:

Task 2: Change the patient's preferred language, date of birth, birth sex, race, ethnicity, sexual orientation, gender identity.
Directions to Instructor:
Instruct the Participant to search the patient previously created, to edit the record.
Success:
☐ Easily completed
☐ Completed with difficulty (describe below in Comments)
☐ Not completed
____Steps
Comments:

Optimal Time: 30 seconds
Test Task Time: ____ Seconds (Task starts when Participant is asked to start. Task is completed when changing patient information and select accept or participant say Done).
Optimal Steps (4 Steps): General Information/Select details----- Patient Maintenance Information/Select edit button---Change the patient information-------Select Accept
☐ Correct
☐ Minor Deviation
☐ Major Deviations (describe below in Comments)
Observed Errors and Verbalizations:

Participant Rating Scale, overall, this task was:
☐ 1 Very Difficult. ☐ 2. Difficult ☐ 3. Neither Easy nor Difficult, ☐ 4. Easy ☐ 5. Very Easy
Instructor note:

Task 3: Display the patient's changed preferred language, date of birth, birth sex, race, ethnicity, sexual orientation
Directions to Instructor:
Instruct the participant to search previously edited patient, to display the changes

Success:
☐ Easily completed
☐ Completed with difficulty (describe below in Comments)
☐ Not completed
____Steps
Comments:
Optimal Time: 3 seconds
Test Task Time: _____Seconds. (Task starts when the Participant is asked to start. The task is completed when displaying the demographic screen with the changes or participant say Done).
Optimal Steps (1 steps): Patient Center/General Information tab
☐ Correct
☐ Minor Deviation
☐ Major Deviations (describe below in Comments)
Observed Errors and Verbalizations:

Participant Rating Scale, overall, this task was:
☐ 1 Very Difficult. ☐ 2. Difficult ☐ 3. Neither Easy nor Difficult, ☐ 4. Easy ☐ 5. Very Easy
Instructor note:

170.315.a.6 Problem List

Task 1: Record a Problem List
Directions to the Instructor:
Instruct the Participant to access the Patient Center/ Clinical Profile, Health Problems Module.
Success:
☐ Easily completed
☐ Completed with difficulty (describe below in Comments)
☐ Not completed
____Steps
Comments:

Optimal Time: 30 seconds
Test Task Time: _____seconds. (Task starts when the participant is asked to begin. The task ends when selecting the accept button or participant say Done).
Optimal Steps (5 steps): Clinical Profile/Health Problem Module---Add New button--- Select Problem ------Add Chronicity---Star Day--Accept
☐ Correct
☐ Minor Deviation
☐ Major Deviations (describe below in Comments)
Observed Errors and Verbalizations:

Participant Rating Scale, overall, this task was:
☐ 1 Very Difficult. ☐ 2. Difficult ☐ 3. Neither Easy nor Difficult, ☐ 4. Easy ☐ 5. Very Easy

Instructor Note:

Task 2: Change a Problem on the Health Problems list
Directions to the Instructor:
Instruct the participant to access the Clinical Profile, Health Problem Module, to edit Problem status.
Success:
☐ Easily completed
☐ Completed with difficulty (describe below in Comments)
☐ Not completed
____Steps
Comments:

Optimal Time: 15 seconds

Test Task Time: ____seconds. (Task starts when the participant is asked to begin. The task ends when the Accept button is selected or participant say Done).

Optimal Steps (3 steps): Clinical Profile/Health Problems List---- Chose any active Health Problem---- Right-click functionality/ Select Resolve
☐ Correct
☐ Minor Deviation
☐ Major Deviations (describe below in Comments)
Observed Errors and Verbalizations:

Participant Rating Scale, overall, this task was:
☐ 1 Very Difficult. ☐ 2. Difficult ☐ 3. Neither Easy nor Difficult, ☐ 4. Easy ☐ 5. Very Easy

Instructor note:

Task 3: Access the Active Health Problem List

Directions to the Instructor:
Instruct participants to look for the Clinical Profile, Health Problems module, and filter by active status.
Success:
☐ Easily completed
☐ Completed with difficulty (describe below in Comments)
☐ Not completed
____Steps

Comments:

Optimal Time: 5 seconds

Test Task Time: _____seconds. (Task starts when the participant is asked to begin. The task ends when the Participant identifies the list of activities or participant say Done).
Optimal Steps (2 steps): Clinical Profile/Health Problem Module--- Filter by status (highlighted in bold.)/Select active
☐ Correct
☐ Minor Deviation
☐ Major Deviations (describe below in Comments)
Observed Errors and Verbalizations:

Participant Rating Scale, overall, this task was:
☐ 1 Very Difficult. ☐ 2. Difficult ☐ 3. Neither Easy nor Difficult, ☐ 4. Easy ☐ 5. Very Easy

Instructor Note:

Task 4: Access Health Problem List History
Directions to the Instructor:
Instruct Participant to go to the Clinical Profile, Health Problem List to display by default all Health Problems list
Success:
☐ Easily completed
☐ Completed with difficulty (describe below in Comments)
☐ Not completed
____Steps
Comments:

Optimal Time: 3 seconds
Test Task Time: _____seconds. (Task starts when the participant is asked to begin. The task ends when the Participant identifies the list of all allergies or participant say Done).
Optimal Steps (1 steps): Clinical Profile/Health Problem Module--- Filter by status (highlighted in bold.)/Select all
☐ Correct
☐ Minor Deviation
☐ Major Deviations (describe below in Comments)
Observed Errors and Verbalizations:

Participant Rating Scale, overall, this task was:
☐ 1 Very Difficult. ☐ 2. Difficult ☐ 3. Neither Easy nor Difficult, ☐ 4. Easy ☐ 5. Very Easy
Instructor Note:

315.a.7 Medication List

Task 1: Record a Medication to the Medication List

Directions to the Instructor:

Instruct Participant to the Clinical Profile/ Medications, to add a new medication.

Success:

☐ Easily completed

☐ Completed with difficulty (describe below in Comments)

☐ Not completed

____Steps

Comments:

Optimal Time: 30 seconds

Task Time: _____seconds. (Task starts when the participant is asked to begin. The task ends when selecting the medication and click accept or participant say Done).

Optimal Steps (5 steps): Clinical Profile/Medication Module---- Add New--- Search medication— Select Medication and complete the sig, etc.--- Select Accept.

☐ Correct

☐ Minor Deviation

☐ Major Deviations (describe below in Comments)

Observed Errors and Verbalizations:

Participant Rating Scale, overall, this task was:

☐ 1 Very Difficult. ☐ 2. Difficult ☐ 3. Neither Easy nor Difficult, ☐ 4. Easy ☐ 5. Very Easy

Instructor note:

Task 2: Change a Medication on the Medication List

Directions to the Instructor:

Instruct Participant to the Clinical Profile/ Medications, to change medication.

Success:

☐ Easily completed

☐ Completed with difficulty (describe below in Comments)

☐ Not completed

____Steps

Comments:

Optimal Time: 15 seconds

Task Time: _____seconds. (Task starts when the participant is asked to begin. The task ends when medication status is changed, or participant say Done).

Optimal Steps (3 steps): Clinical Profile/Medication module--- select View Details---- Select the medication/Right Click---Discontinue and reason

☐ Correct

☐ Minor Deviation

☐ Major Deviations (describe below in Comments)

Observed Errors and Verbalizations:

Participant Rating Scale, overall, this task was:

☐ 1 Very Difficult. ☐ 2. Difficult ☐ 3. Neither Easy nor Difficult, ☐ 4. Easy ☐ 5. Very Easy

Instructor note:

Task 3: Display the Active Medication List

Directions to the Instructor:

Instruct participants to go to the Clinical Profile/ Medications and filter by active status.

Success:

☐ Easily completed

☐ Completed with difficulty (describe below in Comments)

☐ Not completed ____Steps

Optimal Time: 5 seconds

Task Time: ____ seconds. (Task starts when the participant is asked to begin. The task ends when filtered by active status).

Optimal Steps (2 steps): Clinical Profile/Medication Module--- select View Details---- Filter by status (highlighted in bold.)/select active

☐ Correct

☐ Minor Deviation

☐ Major Deviations (describe below in Comments)

Observed Errors and Verbalizations:

Participant Rating Scale, overall, this task was:

☐ 1 Very Difficult. ☐ 2. Difficult ☐ 3. Neither Easy nor Difficult, ☐ 4. Easy ☐ 5. Very Easy

Instructor note:

Task 4: Medication List/Display the Historical Medication List

Directions to the Instructor:

Instruct Participant to go to the Clinical Profile & Medications display by default all medication list

Success:

☐ Easily completed

☐ Completed with difficulty(describe below in Comments)

☐ Not completed

____Steps

Comments:

Optimal Time: 3 seconds

Task Time: _____seconds. (Task starts when the participant is asked to begin. The task ends when select view detail, the list displays all medication list or participant say Done).

Optimal Steps (1 steps): Clinical Profile/Medication Module---select View Details (the screen will display all medications list (active and discontinue)

☐ Correct

☐ Minor Deviation

☐ Major Deviations (describe below in Comments)

Observed Errors and Verbalizations:

Participant Rating Scale, overall, this task was:
☐ 1 Very Difficult. ☐ 2. Difficult ☐ 3. Neither Easy nor Difficult, ☐ 4. Easy ☐ 5. Very Easy
Instructor note:
315.a.8 Medication Allergy List
Task 1: Record a Medication Allergy
Directions to the Instructor:
Instruct the Participant to access the Patient Center/ Clinical Profile, Allergies/Intolerance Module.
Success:
☐ Easily completed
☐ Completed with difficulty (describe below in Comments)
☐ Not completed
____Steps

Comments:

Optimal Time: 20 seconds
Test Task Time: _____seconds. (Task starts when the participant is asked to begin. The task ends when selecting the accept button or participant say Done).
Optimal Steps (5 steps): Clinical Profile/Allergies/Intolerance Module---Add New button- Select drug type/Allergic to/Reaction-- Accept
☐ Correct
☐ Minor Deviation
☐ Major Deviations (describe below in Comments)
Observed Errors and Verbalizations:

Participant Rating Scale, overall, this task was:
☐ 1 Very Difficult. ☐ 2. Difficult ☐ 3. Neither Easy nor Difficult, ☐ 4. Easy ☐ 5. Very Easy

Instructor note:

Task 2: Change a Medication Allergy
Directions to the Instructor:
Instruct the participant to access the Clinical Profile, Allergies/Intolerance Module to edit allergy status.
Success:
☐ Easily completed
☐ Completed with difficulty (describe below in Comments)
☐ Not completed
____Steps
Comments:

Optimal Time: 10 seconds
Test Task Time: ____seconds. (Task starts when the participant is asked to begin. The task ends when the Accept button is selected or participant say Done).

Optimal Steps (3 steps): Clinical Profile/Allergies/Intolerance Module---- View detail option----Using the mouse right-click functionality/ Select inactively

☐ Correct

☐ Minor Deviation

☐ Major Deviations (describe below in Comments)

Observed Errors and Verbalizations:

Participant Rating Scale, overall, this task was:

☐ 1 Very Difficult. ☐ 2. Difficult ☐ 3. Neither Easy nor Difficult, ☐ 4. Easy ☐ 5. Very Easy

Instructor note:

Task 3: Display the Active Medication Allergy List

Directions to the Instructor:

Instruct Participant to go to the Clinical Profile, Allergies/Intolerance module, and filter by active status.

Success:

☐ Easily completed

☐ Completed with difficulty (describe below in Comments)

☐ Not completed

____Steps

Comments:

Optimal Time: 5 seconds

Test Task Time: _____seconds. (Task starts when the participant is asked to begin. The task ends when the Participant identifies the list of active allergies or say Done).

Optimal Steps (2 steps): Clinical Profile/Medication Module--- select View Details---- Filter by status (highlighted in bold.)/select active

☐ Correct

☐ Minor Deviation

☐ Major Deviations (describe below in Comments)

Observed Errors and Verbalizations:

Participant Rating Scale, overall, this task was:

☐ 1 Very Difficult. ☐ 2. Difficult ☐ 3. Neither Easy nor Difficult, ☐ 4. Easy ☐ 5. Very Easy

Instructor note:

Task 4: Display the Historical Medication Allergy List

Directions to the Instructor:

Instruct Participant to go to the Clinical Profile, Allergies/Intolerance display by default all allergies list

Success:

☐ Easily completed

☐ Completed with difficulty (describe below in Comments)

☐ Not completed

____Steps

Comments

Optimal Time: 3 seconds
Test Task Time: _____seconds. (Task starts when the participant is asked to begin. The task ends when the Participant identifies the list of all allergies)
Optimal Steps (1 steps): Clinical Profile/Allergies Module--- select View Details (by default display all allergies; active and inactive)
☐ Correct
☐ Minor Deviation
☐ Major Deviations (describe below in Comments)
Observed Errors and Verbalizations:

Participant Rating Scale, overall, this task was:
☐ 1 Very Difficult. ☐ 2. Difficult ☐ 3. Neither Easy nor Difficult, ☐ 4. Easy ☐ 5. Very Easy
Instructor note:

315.a.14 Implantable device List
Task 1: Record UDI
Directions to the Instructor:
Instruct the Participant to access the Patient Center/ Clinical Profile, Implantable device module.
Success:
☐ Easily completed
☐ Completed with difficulty (describe below in Comments)
☐ Not completed
____Steps
Comments:

Optimal Time: 19 seconds
Test Task Time: _____seconds. (Task starts when the participant is asked to begin. The task ends when selecting the accept button.)
Optimal Steps (7 steps): Clinical Profile/Implantable device module---Add New button- Add UDI- Select parse button- Add status- Date- -- Accept
☐ Correct
☐ Minor Deviation
☐ Major Deviations (describe below in Comments)
Observed Errors and Verbalizations:

Participant Rating Scale, overall, this task was:
☐ 1 Very Difficult. ☐ 2. Difficult ☐ 3. Neither Easy nor Difficult, ☐ 4. Easy ☐ 5. Very Easy
Instructor note:

Task 2: Change UDI Status
Directions to the Instructor:
Instruct the participant to access the Clinical Profile, Implantable device Module to change the status.

Success:
☐ Easily completed
☐ Completed with difficulty (describe below in Comments)
☐ Not completed
____Steps
Comments:

Optimal Time: 9.5 seconds
Test Task Time: ____seconds. (Task starts when the participant is asked to begin. The task ends when the Accept button is selected.)
Optimal Steps (5 steps): Clinical Profile/Implantable device module---- View detail option----select the device- Edit- Change status- Select accept
☐ Correct
☐ Minor Deviation
☐ Major Deviations (describe below in Comments)
Observed Errors and Verbalizations:

Participant Rating Scale, overall, this task was:
☐ 1 Very Difficult. ☐ 2. Difficult ☐ 3. Neither Easy nor Difficult, ☐ 4. Easy ☐ 5. Very Easy
Instructor note:

Task 3: Access UDI, device description, identifiers, and attributes

Directions to the Instructor:
Instruct Participant to go to the Clinical Profile, implantable device view device details
Success:
☐ Easily completed
☐ Completed with difficulty (describe below in Comments)
☐ Not completed
____Steps
Comments:

Optimal Time: 3 seconds
Test Task Time: _____seconds. (Task starts when the participant is asked to begin. The task ends when the Participant identifies the device details).
Optimal Steps (1 steps): Clinical Profile/implantable device--- select View Details
☐ Correct
☐ Minor Deviation
☐ Major Deviations (describe below in Comments) Comments: Click or tap here to enter text.
Observed Errors and Verbalizations:
Participant Rating Scale, overall, this task was:
☐ 1 Very Difficult. ☐ 2. Difficult ☐ 3. Neither Easy nor Difficult, ☐ 4. Easy ☐ 5. Very Easy
Instructor note:

Appendix 6: Non- Disclosure and Informed Consent Form

Non- Disclosure and Informed Consent Form

This AGREEMENT is entered as of _____, 2019 between _____ (**Participant)** and Assertus Holdings, LLC. (**Testing Company**) located at Corporate Office Park Suite 102, San Juan Puerto Rico.

The participant agrees to take part in an evaluation being conducted by the Testing Company. This evaluation is about configuring the MedicusEHR (EHR) system. The purpose of this study is to gather feedback about the effectiveness and efficiency of the EHR in the test.

The Participant acknowledges their voluntary participation in the usability study may bring the Participant into possession of Confidential Information. The term "Confidential Information" means all technical and commercial information of a proprietary or confidential nature which is disclosed by the Testing Company, or otherwise acquired by the Participant, during the study.

By way of illustration, but not limitation, Confidential Information includes trade secrets, processes, formulas, data, know-how, products, designs, drawings, computer-aided design files and other computer files, computer software, ideas, improvements, inventions, training methods and materials, marketing techniques, plans, strategies, budgets, financial information, and/or forecasts.

Any information the Participant acquires relating to this product during this study is confidential and proprietary to the Testing Company and is being disclosed solely for the purposes of the Participant's contribution to the usability study. By signing this form, the Participant acknowledges treating all Confidential Information received during the study in accordance with this nondisclosure agreement. Accordingly, the Participant will not disclose any of the Confidential Information obtained during this study to anyone else or any other organization.

Print Name: _____

Signature: _____

Date Signed: _____

Appendix 7: Recording Consent Form

Recording Consent Form

Assertus would like to thank you for participating in this study. The purpose of this study is to evaluate the usability of the Medicus EHR system. If you decide to participate, you will be asked to perform several tasks within Medicus EHR; and completing a short survey and provide your feedback. The study should take approximately 60 -90 minutes. We will be recording your session to allow Assertus Holdings, LLC., staff members who are unable to be present today to observe your session and benefit from your comments and feedback. Your participation in this study is voluntary, and you are free to withdraw at any point during the study.

Please read the statement below and verbally indicate you accept and consent.

I understand and agree that as a voluntary participant in the present study conducted by Assertus Holdings, LLC. (Testing Company) and I am free to withdraw consent or discontinue my participation at any time.

I understand and agree that the Testing Company will record my test session. I grant the Testing Company permission to use and release the recording of my test session. I understand and agree that the data collected from this study may be shared outside of the Testing Company, and I relinquish any rights to the record. I understand and agree that my recorded session may be copied and used by the Testing Company without further permission.

I understand and agree that the purpose of this study is for the improvement of the product and the features being tested. I agree to immediately raise any concerns or areas in order to fulfill the objective of the study.

I have read and understood the above statement and agree to be a voluntary participant in this study.

Print Name: _____

Signature: _____

Date Signed: _____

Appendix 8: System Usability Scale Questionnaire

System Usability Scale Questionnaire

1. **I think that I would like to use this system frequently**
   (1) Strongly Disagree (2) Disagree (3) Neither agreed or disagreed (4) Agree (5) Strongly Agree

2. **I found the system unnecessarily complex**
   (1) Strongly Disagree (2) Disagree (3) Neither agreed or disagreed (4) Agree (5) Strongly Agree

3. **I thought that the system was easy to use**
   (1) Strongly Disagree (2) Disagree (3) Neither agreed or disagreed (4) Agree (5) Strongly Agree

4. **I think that I would need the support of a technical person to be able to use this system**
   (1) Strongly Disagree (2) Disagree (3) Neither agreed or disagreed (4) Agree (5) Strongly Agree

5. **I found the various functions in this system were well integrated**
   (1) Strongly Disagree (2) Disagree (3) Neither agreed or disagreed (4) Agree (5) Strongly Agree

6. **I thought there was too much inconsistency in this system**
   (1) Strongly Disagree (2) Disagree (3) Neither agreed or disagreed (4) Agree (5) Strongly Agree

7. **I would imagine that most people would learn to use this system very quickly**
   (1) Strongly Disagree (2) Disagree (3) Neither agreed or disagreed (4) Agree (5) Strongly Agree

8. **I found the system very cumbersome to use**
   (1) Strongly Disagree (2) Disagree (3) Neither agreed or disagreed (4) Agree (5) Strongly Agree

9. **I felt very confident using the system**
   (1) Strongly Disagree (2) Disagree (3) Neither agreed or disagreed (4) Agree (5) Strongly Agree

10. **I needed to learn a lot of things before I could get going with this system**
    (1) Strongly Disagree (2) Disagree (3) Neither agreed or disagreed (4) Agree (5) Strongly Agree