

USER-CENTERED DESIGN (UCD) PROCESS

The SmartEMR software was developed with an underlying principle that a User-centered design must first of all seek to serve the user. Our success has been measured not in the context of the technology or programming achievement, but rather in the extent to which the needs of the users are reflected in the interface. At SmartEMR, UCD represents “an iterative process whose goal is the development of usable systems, achieved through involvement of potential users of a system in system design” (Karat, 1996). We have been driven by the principle which states that “the needs of the users should dominate the design of the interface, and the needs of the interface should dominate the design of the rest of the system,” (Norman, 1986).

SmartEMR utilizes a user-centered design process based on the principles of the ISO 9241-210 standards, and in conjunction with the principles and strategies described in this report.

SmartEMR has been steadily governed by the following principles: (Gulliksen and Goöransson 2001).

1. The work practices of the users control the development. Early focus on users and tasks.
2. Active user participation throughout the project, in analysis, design, development and evaluation.
3. Early prototyping to evaluate and develop design solutions and to gradually build a shared understanding of the needs of the users as well as their future work practices.
4. Continuous iteration of design solutions. A cyclic process of design, evaluation and redesign should be repeated as often as necessary.
5. Multidisciplinary design teams achieved by building a design team consisting of programmers, implementation specialists, Sales, Customer Service/Help Desk, etc.
6. Integrated design. The system, the work practices, on-line help, training, organization, etc. should be developed in parallel.

The **Plan-Do-Study-Cycle** [PDSA] (refer to figure 1) has been a staple of our Continuous Quality Improvement process from the very beginning. The PDSA is a never-ending improvement cycle aimed at improving usability and achieving the goals of UCD.

PLAN: Define the problem, Collect data to analyze the causes of the problem, Search for possible solutions, Evaluate the solutions, Make recommendation for action. This steps requires a substantial level of research aimed at understanding the needs, wants, and expectations of our users. We also seek to capture demographic variables that would enhance our overall understanding of the environment in which our clients/users work. On the basis of the data, we are

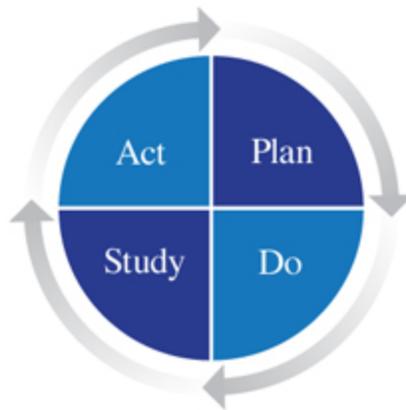
able to design a comprehensive PLAN for mitigating user barriers, addressing user needs, and exceeding user expectations.

DO: Pilot-test the solution with user participation on a limited basis. Using the research data from the PLAN, we implement a comprehensive strategy driven by an interdisciplinary team. Adequate care is taken so as not to disrupt the aspects of the system that are unaffected or the routine work flow.

STUDY: Determine if the solution is working by comparing the before and after performance data. If it is not working, tweak the solution or modify the relevant parameters until the solution can be validated. The goal of this process is continuous refinement and re-testing. During this phase, user involvement and feedback are indispensable.

ACT: Once validated, take action to preserve the gains. Continue to monitor performance via customer complaints, help desk inquiries, etc., to ensure that the problem does not recur.

Figure 1: The PDSA Cycle.





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EHR Usability Test Report of smartEMR v6.0

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EHR Usability Test Report of smartEMR v6.0

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

24/7 smartEMR version 6.0

Date of Usability Test: February 3-4, 2014
Date of Report: April 27, 2014
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1. Executive Summary

A usability test of smartEMR version 6.0 ambulatory EHR was conducted from February 3-4 in Miami, Florida by Vintex International, Inc. The purpose of this test was to test and validate the usability of the current user interface, and provide evidence of usability in the EHR Under Test (EHRUT).

During the usability test, 9 healthcare providers, medical assistants, and administrators matching the target demographic criteria served as participants and used the EHRUT in simulated, but representative tasks.

This study collected performance data on 7 tasks typically conducted on an EHR:

- Allergy Module
- Medication List, CPOE –Medication orders, and e-Prescribing Module
- Drug-to-Drug / Drug-to-allergy Intervention
- Clinical Decision Support Intervention
- Clinical Information Reconciliation
- CPOE Labs and Radiology / Imaging Orders
- Admin Configuration of CDS and Drug-to-Drug

During the 30-minute one-on-one usability test, each participant was greeted by the administrator and asked to review and sign an informed consent/release form (included in Appendix 3). Participants were instructed that they could withdraw at any time. Participants had prior experience with the EHR system. The administrator introduced the test, and instructed participants to complete a series of tasks (given one at a time) using the EHRUT. During the testing, the administrator timed the test and, along with the data logger(s) recorded user performance data on paper and electronically. The administrator did not give the participants assistance on how to complete the task.

The EHRUT(s) tested for this study was smartEMR version 6.0 Designed to present medical information to healthcare providers in ambulatory setting. EHRUT consists of several modules to capture patient medical records, exchange health information between stakeholders and suggested quality improvement based on patient specific information. The test was limited to the tasks explained above. The usability testing attempted to represent realistic exercises and conditions.

The purpose of this study was to test and validate the usability of the current user interface, and provide evidence of usability in the EHR Under Test (EHRUT).

To this end, measures of effectiveness, efficiency and user satisfaction, such as time on task, ability to locate information, and ease of executing the task were captured during the usability testing.

Participant screens, head shots and audio were recorded for subsequent analysis.

The following types of data were collected for each participant:

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

All participant data was de-identified – no correspondence could be made from the identity of the participant to the data collected. Following the conclusion of the testing, participants were asked to complete a post-test questionnaire; participants were not compensated for their time, as participation was voluntary. Various recommended metrics, in accordance with the examples set forth in the NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records, were used to evaluate the usability of the EHRUT. Following is a summary of the performance and rating data collected on the EHRUT.

Table 1

TASK LIST	N	Task Time (success)	Path Deviation	Task Time		Errors	Task Ratings 1=Easy
	#			Mean (SD)	Deviations (Observed / Optimal)		
Medication Allergy Module	7	100%	1.00	24.86	1.04	0.0000	1.00
e-Prescribe Module	7	75%	1.02	112.29	1.34	0.5345	1.43
Drug-to-drug/drug-to-allergy	7	100%	1.00	10.57	2.11	0.0000	1.00
Clinical Decision support	7	78%	1.04	212.14	1.48	0.7868	1.57
Clinical Reconciliation	7	70%	1.06	68.43	1.32	0.8997	1.86
CPOE - Meds	7	75%	1.02	131.00	2.38	0.5345	1.43
Medication Module	7	100%	1.02	70.71	1.61	0.5345	1.43
CPOE - Labs	7	88%	1.02	66.14	2.00	0.7868	1.57
CPOE - Radiology/Imaging	7	88%	1.00	75.57	1.80	0.4880	1.29

Table 2

TASK LIST (Admin)	N	Task Time (success)	Path Deviation	Task Time		Errors	Task Ratings 1=Easy
	#		Deviations (Observed / Optimal)	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Mean (SD)
CDS Admin	4	100%	1.00	22.00	1.29	0.0000	1.00
Drug to Drug Configuration	4	100%	1.00	25.75	1.03	0.0000	1.00

The results from the System Usability Scale scored the subjective satisfaction with the system based on performance with these tasks to be: **87.64**

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

- Major findings

- During initial discussions, we found that participants had some general concerns about the industry itself and concerns about the EHRUT in particular. Some participants were not able to distinguish clearly between the two.
- A high-risk concern for physicians was writing the SIG for medications that are not prescribe in a pill or capsule, like insulin or creams. One way to mitigate this risk was to override the 'structure' SIG and type the instructions under 'notes' section.
- The time spent by the physician in documenting information in the patient's chart was also a major concern.
- Most participants were highly satisfied with the layout of the EHR, and the way information is presented and displayed.
- Participants' experience with Allergies and Drug-to-Drug/Drug-to-Allergy modules produced the most consistent results.

Areas for improvement

- Reduce the numbers of clicks for specific tasks.
- Direct links to reduce path deviation for specific tasks.
- Auto-refresh function that without user-input will always display the most current information in the patient's chart.

2. Introduction

The EHRUT(s) tested for this study was smartEMR version 6.0 Designed to present medical information to healthcare providers in ambulatory setting. EHRUT consists of several modules to record patient health information and acknowledgement of alerts and interventions. The usability testing attempted to represent realistic exercises and conditions.

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

3. Method

3.1 Participants

A total of 7 participants were tested on the EHRUT(s). Participants in the test were doctors, medical assistants and administrators. Participants were recruited by Vintex International, Inc., and were not compensated for their time. In addition, participants had no direct connection to the development of or organization producing the EHRUT(s). Participants were not from the testing or supplier organization. Participants were 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 IDs so that an individual’s data cannot be tied back to individual identities.

Table 3

ID	GENDER	OCCUPATIONAL ROLE	AGE RANGE	YEARS OF EHR EXPERIENCE	PLACE OF BUSINESS	TEST DATE	TEST TIME	ASSISTIVE NEEDS
P1	F	Medical Assistant	23-39	3	Private Practice	3-Feb	13:30	none
P2	F	Administrator	40-59	4	Private Practice	3-Feb	14:15	none
P3	F	Medical Assistant	23-39	2	Private Practice	3-Feb	15:00	none
P4	M	Doctor	40-59	10	Private Practice	3-Feb	15:45	none
P5	F	Medical Assistant	23-39	3	Private Practice	3-Feb	16:30	none
P6	M	Doctor	60-74	3	Private Practice	3-Feb	17:15	none
P7	F	Nurse	23-39	5	Inpatient Facility	3-Feb	18:00	none

Nine (9) participants (matching the demographics in the section on Participants) were recruited and 7 participated in the usability test (see Appendix 2). Two participants failed to show up for the study.

Participants were scheduled for one, 30 minutes sessions with 15 minutes in between each session for debrief by the administrator(s) and data logger(s), and to reset systems to proper test conditions. A spreadsheet was used to keep track of the participant schedule, and included each participant's demographic characteristics as provided by the recruiting firm.

3.2 Study Design

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

During the usability test, participants interacted with one (1) EHR, smartEMR v6.0. Each participant used the system in the same location, and was provided with the same instructions. The system was evaluated for effectiveness, efficiency and satisfaction as defined by measures collected and analyzed for each participant:

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

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

3.3 Tasks

A number of tasks and scenarios were constructed that would be realistic and representative of the kinds of activities a user might do with this EHR. (See Appendix 6)

- CPOE
 - Record Medication Order
 - Change Medication Order
 - Access Medication Order

 - Record Laboratory Order
 - Change Laboratory Order
 - Access Laboratory Order

 - Record Radiology/imaging Order
 - Change Radiology/imaging Order
 - Access Radiology/imaging Order

- Allergy Module
 - Access Medication Allergy Module
 - Record New Medication Allergy
 - Change Medication Allergy

- Medication Module
 - Access Current Medication List
 - Prescribe New Medication
 - Submit Electronically to pharmacy

- e-Prescribing Module
 - Create Prescriptions

- Drug to drug and drug to allergy interaction check
 - Create intervention prior to CPOE completion
 - Adjustment of severity level of drug-drug interventions (may be an admin type function)

- Clinical Decision Support Intervention
 - Problem List Interventions
 - Medication List Interventions
 - Medication Allergy List Interventions
 - Demographics Interventions
 - Lab Tests and Results Interventions
 - Vital Signs Interventions
 - Identify User Diagnostic and Therapeutic Reference Information
 - Configuration of CDS interventions by user (may be an admin type function)

- Clinical Information Reconciliation
 - Reconcile patient's active medication list with another source
 - Reconcile patient's active problem list with another source
 - Reconcile patient's active medication allergy list with another source

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

3.4 Procedures

Upon arrival, participants were greeted; their identity was verified and matched with a name on the participant schedule. Participants were then assigned a participant ID. Each participant reviewed and signed an informed consent and release form (See Appendix 3). A representative from the test team witnessed the participant's signature.

To ensure that the test ran smoothly, two staff members participated in this test, the usability administrator and the data logger. The usability testing staff conducting the test was experienced usability practitioners.

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

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

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

For each task, the participants were given a written copy of the task. Task timing began once the administrator finished reading the question. The task time was stopped once the participant indicated they had successfully completed the task. Scoring is discussed below in Section 3.9.

Following the session, the administrator gave the participant the post-test questionnaire (see Appendix 5), and thanked each individual for their participation.

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

3.5 Test Location

The test facility included a waiting area and a quiet testing room with a table, computer for the participant, and recording computer for the administrator. Only the participant and administrator were in the test room. All observers and the data logger worked from a separate room where they could see the participant's screen and face shot, and listen to the audio of the session. To ensure that the environment was comfortable for users, noise levels were kept to a minimum with the ambient temperature within a normal range. All of the safety instruction and evacuation procedures were valid, in place, and visible to the participants.

3.6 Test Environment

The EHRUT would be typically be used in a healthcare office or facility. In this instance, the testing was conducted in a conference room. For testing, the computer used was a Laptop running OS X 10.9.2. The participants used a mouse and keyboard when interacting with the EHRUT.

SmartEMR v6.0 was displayed on an 18 inches screen on 1920x1200 screen in full color. The application was set up by the vendor according to the vendor's documentation describing the system set-up and preparation. The application itself was running on Mozilla

Firefox using a test database and a WLAN connection. Technically, the system performance (i.e., response time) was representative to what actual users would experience in a field implementation. Additionally, participants were instructed not to change any of the default system settings (such as control of font size).

3.7 Test Forms and Tools

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

1. Informed Consent
2. Moderator's Guide
3. Post-test Questionnaire

Examples of these documents can be found in Appendices 3-5 respectively. The Moderator's Guide was devised so as to be able to capture required data.

The participant's interaction with the EHRUT was captured and recorded digitally with screen capture software running on the test machine. A web camera recorded each participant's facial expressions synced with the screen capture, and verbal comments were recorded with a microphone. The test session was electronically transmitted to a nearby observation room where the data logger observed the test session.

3.8 Participant Instructions

The administrator reads the following instructions aloud to the each participant (also see the full moderator's guide in Appendix 4):

Thank you for participating in this study. Your input is very important. Our session today will last about 35 minutes. During that time you will use an instance of an electronic health record.

I will ask you to complete a few tasks using this system and answer some questions. You should complete the tasks as quickly as possible making as few errors as possible. Please try to complete the tasks on your own following the instructions very closely. Please note that we are not testing you, we are testing the system, therefore if you have difficulty all this means is that something needs to be improved in the system. I will be here in case you need specific help, but I am not able to instruct you or provide help in how to use the application.

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

Following the procedural instructions, participants were shown the EHR and as their first task, were given time (5 minutes) to explore the system and make comments. Once this task was complete, the administrator gave the following instructions:

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

All Participants were then given 6 clinical tasks to complete. 4 Participants were given 2 administrative tasks. Tasks are listed in detailed in Appendix 6.

3.9 Usability Metrics

According to the NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records, EHRs should support a process that provides a high level of usability for all users. The goal is for users to interact with the system effectively, efficiently, and with an acceptable level of satisfaction. To this end, metrics for effectiveness, efficiency and user satisfaction were captured during the usability testing.

The goals of the test were to assess:

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

4. Data Scoring

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

Rationale and Scoring	
Effectiveness: Task Success	<p>A task was counted as a “Success” if the participant was able to achieve the correct outcome, without assistance, within the time allotted on a per task basis.</p> <p>The total number of successes were calculated for each task and then divided by the total number of times that task was attempted. The results are provided as a percentage.</p> <p>Task times were recorded for successes. Observed task times divided by the optimal time for each task is a measure of optimal efficiency.</p> <p>Optimal task performance time, as benchmarked by expert performance under realistic conditions, is recorded when constructing tasks. Target task times used for task times in the Moderator’s Guide must be operationally defined by taking multiple measures of optimal performance and multiplying by some factor [e.g., 1.5] that allows some time buffer because the participants are presumably not trained to expert performance. Thus, if expert, optimal performance on a task was 24 seconds then allotted task time performance was 36 seconds. This ratio should be aggregated across tasks and reported with mean and variance scores.</p>
Effectiveness: Task Failures	<p>If the participant abandoned the task, did not reach the correct answer or performed it incorrectly, or reached the end of the allotted time before successful completion, the task was counted as an “Failures.” No task times were taken for errors.</p> <p>The total number of errors was calculated for each task and then divided by the total number of times that task was attempted. Not all deviations would be counted as errors. This should also be expressed as the mean number of failed tasks per participant.</p> <p>On a qualitative level, an enumeration of errors and error types should be collected.</p>

<p>Efficiency: Task Deviations</p>	<p>The participant's path (i.e., steps) through the application was recorded. Deviations occur if the participant, for example, went to a wrong screen, clicked on an incorrect menu item, followed an incorrect link, or interacted incorrectly with an on-screen control. This path was compared to the optimal path. The number of steps in the observed path is divided by the number of optimal steps to provide a ratio of path deviation.</p> <p>It is strongly recommended that task deviations be reported. Optimal paths (i.e., procedural steps) should be recorded when constructing tasks.</p>
<p>Efficiency: Task Time</p>	<p>Each task was timed from when the administrator said "Begin" until the participant said, "Done." If he or she failed to say "Done," the time was stopped when the participant stopped performing the task. Only task times for tasks that were successfully completed were included in the average task time analysis. Average time per task was calculated for each task. Variance measures (standard deviation and standard error) were also calculated.</p>
<p>Satisfaction: Task Rating</p>	<p>Participant's subjective impression of the ease of use of the application was measured by administering both a simple post-task question as well as a post-session questionnaire. After each task, the participant was asked to rate "Overall, this task was:" on a scale of 1 (Very Easy) to 5 (Very Difficult). These data are averaged across participants.</p> <p>Common convention is that average ratings for systems judged easy to use should be 3.3 or above.</p> <p>To measure participants' confidence in and likeability of smartEMR v6.0 overall, the testing team administered the System Usability Scale (SUS) post-test questionnaire. Questions included, "I think I would like to use this system frequently," "I thought the system was easy to use," and "I would imagine that most people would learn to use this system very quickly." See full System Usability Score questionnaire in Appendix 5</p>

5. Results

5.1 Data Analysis and Reports

The results of the usability test were calculated according to the methods specified in the Usability Metrics section above. Participants who failed to follow session and task instructions had their data excluded from the analyses.

The usability testing results for the EHRUT are detailed below (see Table 4 and 5). The results should be seen in light of the objectives and goals outlined in Section 3.2 Study Design. The data should yield actionable results that, if corrected, yield material, positive impact on user performance.

Table 4

TASK LIST	N	Task Time (success)	Path Deviation	Task Time		Errors	Task Ratings 1=Easy
	#		Deviations (Observed / Optimal)	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Mean (SD)
Medication Allergy Module	7	100%	1.00	24.86	1.04	0.0000	1.00
e-Prescribe Module	7	75%	1.02	112.29	1.34	0.5345	1.43
Drug-to-drug/drug-to-allergy	7	100%	1.00	10.57	2.11	0.0000	1.00
Clinical Decision support	7	78%	1.04	212.14	1.48	0.7868	1.57
Clinical Reconciliation	7	70%	1.06	68.43	1.32	0.8997	1.86
CPOE - Meds	7	75%	1.02	131.00	2.38	0.5345	1.43
Medication Module	7	100%	1.02	70.71	1.61	0.5345	1.43
CPOE - Labs	7	88%	1.02	66.14	2.00	0.7868	1.57
CPOE - Radiology/Imaging	7	88%	1.00	75.57	1.80	0.4880	1.29

Table 5

TASK LIST (Admin)	N	Task Time (success)	Path Deviation	Task Time		Errors	Task Ratings 1=Easy
	#		Deviations (Observed / Optimal)	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Mean (SD)
CDS Admin	4	100%	1.00	22.00	1.29	0.0000	1.00
Drug to Drug Configuration	4	100%	1.00	25.75	1.03	0.0000	1.00

The results from the SUS (System Usability Scale) scored the subjective satisfaction with the system based on performance with these tasks to be: **87.64**. Broadly interpreted, scores under 60 represent systems with poor usability; scores over 80 would be considered above average.

5.2 Discussion of findings

- During the initial discussions, we found some general concerns about the industry itself and concerns about the EHRUT in specific. Some participants were not able to distinguish clearly between the two.
- A high-risk concern for physicians was writing the SIG for medications that are not prescribe in a pill or capsule, like insulin or creams. One way to mitigate this risk was to override the 'structure' SIG and type the instructions under 'notes' section.
- Physician time documenting information in the patient's chart was also a major concern.
- Most participants were highly satisfied with the layout of the EHR, and the way information is presented.

- Participant's experience with Allergies and Drug-to-drug/Drug-to-allergy modules obtained the most consistent results.

5.3 Effectiveness

Participants were able to complete all task with one exception. The one task that was not completed was due to the fact that the participant was an administrator who usually did not prescribe a medication and therefore did not find it useful to complete the task.

Table 6

TASK LIST	SUCCESS	FAILURE	% SUCCESS (SUCCESS/ATTEMPTS)	# OF ATTEMPTS
Medication Allergy Module	7	0	100%	7
e-Prescribe Module	6	1	75%	8
Drug-to-drug/ drug-to-allergy Interaction check	7	0	100%	7
Clinical Decision support Intervention	7	0	78%	9
Clinical Reconciliation	7	0	70%	10
CPOE - Meds	6	1	75%	8
Medication List	7	0	100%	7
CPOE Labs	7	0	88%	8
CPOE Radiology/Imaging	7	0	88%	8

Table 7

TASK LIST (Admin)	SUCCESS	FAILURE	% SUCCESS (SUCCESS/ATTEMPTS)	# OF ATTEMPTS
CDS Admin	4	0	100%	4
Drug to Drug Configuration	4	0	100%	4

5.4 Efficiency

Participants completed all tasks in a timely manner. Some participants clicked on different links but were able to find their way back to the original task. In all, participants were able to complete all tasks successfully with additional clicks.

Table 8

TASK LIST	Optimal (seconds)	Targeted Time (seconds)(x 1.5)	Optimal Efficiency	Average	Median	STDEV	Path (obs/opt)	Time (obs/opt)
Medication Allergy Module	24	36	1.04	24.86	27	4.4508	1.00	1.04
e-Prescribe Module	84	126	1.34	112.29	64	110.3641	1.02	1.34
Drug-to-drug/ drug-to-allergy Interaction	5	7.5	2.11	10.57	10	3.0472	1.00	2.11
Clinical Decision support Intervention	143	214.5	1.48	212.14	218	54.0229	1.04	1.48
Clinical Reconciliation	52	78	1.32	68.43	61	17.0280	1.06	1.32
CPOE - Meds	55	82.5	2.38	131.00	64	110.3641	1.02	2.38
Medication List	44	66	1.28	70.71	65	12.0515	1.02	1.61
CPOE - Labs	33	49.5	1.98	66.14	65	3.7607	1.02	2.00
CPOE - Radiology/Imaging	42	63	1.80	75.57	76	7.9552	1.00	1.80

Table 9

TASK LIST (Admin)	Optimal (seconds)	Targeted Time (seconds)(x 1.5)	Optimal Efficiency	Average	Median	STDEV	Path (obs/opt)	Time (obs/opt)
CDS Admin	17	25.5	1.38	22.00	22.5	2.9439	1.00	1.29
Drug to Drug Configuration	25	37.5	1.02	25.75	26.5	1.8930	1.00	1.03

5.5 Satisfaction

When asked to rate the EHRUT on a scale of 1 to 5; where 1= very easy; 5=very difficult, most users answered with a “1” (very easy), even when they did not perform in the most optimal time or when they did not pick the most optimal path.

Table 10

Task List	STDEV	Task Rating Avg.
Medication Allergy Module	0.0000	1.00
e-Prescribe Module	0.5345	1.43
Drug-to-drug/ drug-to-allergy Interaction	0.0000	1.00
Clinical Decision support Intervention	0.7868	1.57
Clinical Reconciliation	0.8997	1.86
CPOE - Meds	0.5345	1.43
Medication List	0.5345	1.43
CPOE Labs	0.7868	1.57
CPOE Radiology/Imaging	0.4880	1.29

Table 11

TASK LIST (Admin)	STDEV	Task Rating Avg.
CDS Admin	0.0000	1.00
Drug to Drug Configuration	0.0000	1.00

5.6 System Usability Scale Results

Table 12

QUESTION	SUM	AVERAGE	STDEV	MEDIAN
I think I would like to use this system frequently	30	4.29	0.9512	5
I found the system unnecessarily complex	10	1.43	0.7868	1
I thought the system was easy to use	32	4.57	0.7868	5
I think that I would need the support of a technical person to be able to use this system	14	2.00	1.4142	2
I found the various functions in this system were well integrated	30	4.29	1.1127	5
I thought there was too much inconsistency in this system	10	1.43	0.7868	1
I would imagine that most people would learn to use this system very quickly	33	4.71	0.7559	5
I found the system very cumbersome to use	12	1.71	1.4960	1
I felt very confident using the system	31	4.43	0.9759	5
I needed to learn a lot of things before I could get going with this system	13	1.86	1.5736	1
SYSTEM USABILITY SCALE TOTALS	614	87.64	7.7797	86.48

6. Major Findings

Medication-Allergy: Participants found this module to be easy to use. It was consistent with the training received, easy to visualize and easy to update information contained within. No major findings were encountered.

Medication Module and CPOE: Participants found that the module worked well when they needed to prescribe medication in pills or capsules; however, when they had to prescribe insulin or a medication that is administered in a different dosage every day, they experienced difficulty in writing the SIG. Another concern was the number of clicks associated with this task.

Drug-to-drug and drug-to-allergy interventions: Participants found the intervention easy to detect and instructions were easy to follow. However, the use of a color-contrast background to accentuate the information being provided was suggested.

Clinical decision support: Most participants found this module to be the most difficult. The intervention is displayed when the data criteria for the rule matches the information of the patient. For example: if the patient is a 32 years old female and has a BMI of 28, the rule for

'Adult Weight Screening' will be automatically triggered. A BMI treating plan will be suggested and user input will be required (user input can be a referral to a dietician). In order for the user to successfully input information, the user would have to go to the 'Plan of Care' section and then write a referral for a dietician. Participants suggested a direct link to the referral section, next to rule intervention, so as to enhance ease of access. A common error encountered by participants was the clicking on the incorrect link. Also, some participants forgot to record remediation for all rules and would close the tab before they finish documenting a plan of care for all rules. This incident made the users to go back to the 'Plan of Care' section, resulting in additional clicks.

Clinical reconciliation: A major concern for participants was the accuracy of the external reconciliation list. Participants expressed concern and skepticism over the source of the list that was about to be integrated into the patient's medical record. Another concern was that the reconciliation might lead to duplicate and unnecessary information. For example, if in the problem list they have a specific diagnosis for the patient and the external list has the same diagnosis, but in a non-specified format, the user might have two instances of the same problem in the patient's medical record. This was a concern with physicians that see patients with multiple chronic conditions. The Usability of the module was overall well accepted. A common error was forgetting to refresh the screen, thus, preventing users from accessing the latest information. Participants found the module to be easy to follow and an auto-refresh action was suggested so that users will not have to click on the refresh button in order to bring the most current information of the module to display.

7. Areas for Improvement

- Provide users additional education material, about EHR related issues and requirements for Meaningful Use
- Modules related to Meaningful-Use need to be incorporated into the workflow efficiently.
- Instructions or a how-to section for commonly used medications that are not pills, tablets, capsule or are taken/administered the same way every day were deemed to be necessary. This is especially important for medications for common chronic conditions.
- A color-contrast background was determined to be potentially useful in making the alerts stand out.
- In order to improve the ease of access in CDS module, the placement of a direct link to Plan of care next to the alert was vitally important.
- Auto refresh button to display the latest information.
- System feedback upon completing reconciliation.

8. Appendices

The following appendices include supplemental data for this usability test report. Following

is a list of the appendices provided:

1. Sample Recruiting screener
2. Participant demographics
3. Non-Disclosure Agreement (NDA) and Informed Consent Form
4. Moderator's Guide
5. System Usability Scale Questionnaire
6. Evaluated Tasks

Appendix 1: RECRUITING SCREENER

The purpose of a screener is to ensure that the participants selected represent the target user population as closely as possible. (Portions of this sample screener are taken from www.usability.gov/templates/index.html#Usability and adapted for use.)

Recruiting Script for Recruiting Firm

Hello, my name is _____, calling from Vintex International. We are recruiting individuals to participate in a usability study for an electronic health record. We would like to ask you a few questions to see if you qualify and if you would like to participate. This should only take a few minutes of your time. This is strictly for research purposes. If you are interested and qualify for the study, you will be paid to participate. Can I ask you a few questions?

1. Are you male or female?
2. Have you participated in a focus group or usability test in the past 12 months?
3. Do you, or does anyone in your home, work in marketing research, usability research, web design [...etc.]?
4. Do you, or does anyone in your home, have a commercial or research interest in an electronic health record software or consulting company?
5. Which of the following best describes your age? [23 to 39; 40 to 59; 60 to 74; 75 and older]
6. Which of the following best describes your race or ethnic group? [e.g., Caucasian, Asian, Black/African-American, Latino/a or Hispanic, etc.]
7. Do you require any assistive technologies to use a computer? [If so, please describe]

Professional Demographics

8. What is your current position and title? (Must be healthcare provider)
 - RN: Specialty: _____
 - Physician: Specialty: _____
 - Resident: Specialty: _____
 - Administrative Staff: _____
 - Other: _____
9. How long have you held this position?

10. Describe your work location (or affiliation) and environment? [e.g., private practice, health system, government clinic, etc.]

11. Which of the following describes your highest level of education? [e.g., high school graduate/GED, some college, college graduate (RN, BSN), postgraduate (MD/PhD), other (explain)]

Computer Expertise

12. Besides reading email, what professional activities do you do on the computer? [e.g., access EHR, research; reading news; shopping/banking; digital pictures; programming/word processing, etc.]

13. About how many hours per week do you spend on the computer? [e.g., 0 to 10, 11 to 25, 26+ hours per week]

14. What computer platform do you usually use? [e.g., Mac, Windows, etc.]

15. What Internet browser(s) do you usually use? [e.g., Firefox, IE, AOL, etc.]

16. In the last month, how often have you used an electronic health record?

17. How many years have you used an electronic health record?

18. How many EHRs do you use or are you familiar with?

19. How does your work environment patient records?

- On paper
- Some paper, some electronic
- All electronic

Contact Information

Those are all the questions I have for you. Your background matches the people we're looking for.

Would you be able to participate on April 24?

May I get your contact information?

- Name of participant:
- Address:
- City, State, Zip:
- Daytime phone number:
- Evening phone number:
- Alternate [cell] phone number:
- Email address:

Before your session starts, we will ask you to sign a release form allowing us to videotape your session. The videotape will only be used internally for further study if needed. Will you consent to be videotaped?

This study will take place at Ambulatory Practice. I will confirm your appointment a couple of days before your session and provide you with directions to our office. What time is the best time to reach you?

Appendix 2: PARTICIPANT DEMOGRAPHICS

Following is a high-level overview of the participants in this study.

Gender

Men	[2]
Women	[5]
Total (participants)	[7]

Occupation/Role

RN/BSN	[1]
Physician	[2]
Admin Staff	[1]
Medical Assistant	[3]
Total (participants)	[7]

Years of Experience

Years experience	[X]
Facility Use of EHR	
All paper	[0]
Some paper, some electronic	[6]
All electronic	[1]
Total (participants)	[7]

Appendix 3: NON-DISCLOSURE AGREEMENT AND INFORMED CONSENT FORM

Non-Disclosure Agreement

THIS AGREEMENT is entered into as of _____, 2014, between _____
("the Participant") and the testing organization *smartEMR* located at 8000 SW 117 Ave. Miami, FL 33183.

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

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

Any information the Participant acquires relating to this product during this study is confidential and proprietary to *smartEMR* and is being disclosed solely for the purposes of the Participant's participation in today's usability study. By signing this form the Participant acknowledges that s/he will not disclose this confidential information obtained today to anyone else or any other organizations.

Participant's printed name: _____

Signature: _____ Date: _____

Informed Consent

smartEMR would like to thank you for participating in this study. The purpose of this study is to evaluate an electronic health records system. If you decide to participate, you will be asked to perform several tasks using the prototype and give your feedback. The study will last about 15 minutes.

Agreement

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

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

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

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

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

Please check one of the following:

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

Signature: _____

Date: _____

***EHRUT* Usability Test** **Moderator's Guide**

Administrator _____

Data Logger _____

Date _____ Time _____

Participant # _____

Location _____

Prior to testing

- Confirm schedule with Participants
- Ensure EHRUT lab environment is running properly
- Ensure lab and data recording equipment is running properly

Prior to each participant:

- Reset application
- Start session recordings with *tool*

Prior to each task:

- Reset application to starting point for next task

After each participant:

- End session recordings with *tool*

After all testing

- Back up all video and data files
-

Orientation (5 minutes)

Thank you for participating in this study. Our session today will last **15 minutes**. During that time you will take a look at an electronic health record system.

I will ask you to complete a few tasks using this system and answer some questions. 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. 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. Do not do anything more than asked. If you get lost or have difficulty I cannot answer help you with anything to do with the system itself. Please save your detailed comments until the end of a task or the end of the session as a whole when we can discuss freely.

I did not have any involvement in its creation, so please be honest with your opinions.

The product you will be using today is smartEMR's new version – Version 6.0. Some of the data may not make sense as it is placeholder data.

We are recording the audio and screenshots of our session today. All of the information that you provide will be kept confidential and your name will not be associated with your comments at any time.

Do you have any questions or concerns?

Preliminary Questions (5 minutes)

What is your job title / appointment?

How long have you been working in this role?

What are some of your main responsibilities?

Tell me about your experience with electronic health records.

Preliminary Task: First Impressions (120 Seconds)

This is the application you will be working with. Have you heard of it? Yes No

If so, tell me what you know about it.

- *Show test participant the EHRUT.*
- Please don't click on anything just yet.
- What do you notice? What are you able to do here?
Please be specific.

Notes / Comments:

Rating:

Overall, this task was: _____

Show participant written scale: "Very Easy" (1) to "Very Difficult" (5)

Administrator / Notetaker Comments:

Task 1: Allergies Modules (36 Seconds)

Take the participant to the starting point for the task.

Please go to *Patient's* Medication Allergy Module.

Success:

- Easily completed
- Completed with difficulty or help: Describe below
- Not completed

Comments:

Task Time: _____ Seconds

Optimal Path:

Patient's Chart → Go to 'Allergies' → Document new allergy → Go to Patient chart (exit current screen) → Go to 'Allergies' → Delete Aspirin from list → Go to Patient's Chart

- Correct
- Minor Deviations / Cycles: Describe below
- Major Deviations: Describe below

Comments:

Observed Errors and Verbalizations:

Comments:

Rating:

Overall, this task was: _____

Show participant written scale: "Very Easy" (1) to "Very Difficult" (5)

Administrator / Notetaker Comments:

Task 2.1: Medication list (66 Seconds)

Take the participant to the starting point for the task.

Please go to medication module.

Success:

- Easily completed
- Completed with difficulty or help: Describe below
- Not completed

Comments:

Task Time: _____ Seconds

Optimal Path:

Patient's Chart → Click 'Go to medications' link → Click "Document" tab → Add Lisinopril 20 mg tablet → Click on 'Patient's Chart' (Exit current Module) → Click 'Go to medications' link → Click on 'Delete' tropicamide drops 1 % → Click on 'Patient's Chart' (Exit current Module) → Click 'Go to medications' link

- Correct
- Minor Deviations / Cycles: Describe below
- Major Deviations: Describe below

Comments:

Observed Errors and Verbalizations:

Comments:

Rating:

Overall, this task was: _____

Show participant written scale: "Very Easy" (1) to "Very Difficult" (5)

Administrator / Notetaker Comments:

Task 2.2: CPOE – Meds (83 Seconds)

Take the participant to the starting point for the task.

Ensure that this patient has a drug-drug and a drug- allergy to the drug chosen. This will force the participant to find other drugs and use other elements of the application.

Success:

- Easily completed
- Completed with difficulty or help: Describe below
- Not completed

Comments:

Task Time: _____Seconds

Optimal Path:

Patient's Chart → Click 'Go to medications' link → Click 'Prescribe' tab → Add Coumadin table 1mg → Acknowledge DDI/DAI → Click on 'Active' tab → Click on 'Adjust' Aspirin 81mg → Adjust dosage by selecting 'Aspirin 500 mg' from dropdown → 'OK' button → Click on 'Patient's Chart' (Exit current Module)

- Correct
- Minor Deviations / Cycles: Describe below
- Major Deviations: Describe below

Comments:

Observed Errors and Verbalizations:

Comments:

Rating:

Overall, this task was: _____

Show participant written scale: "Very Easy" (1) to "Very Difficult" (5)

Administrator / Notetaker Comments:

Task 2.3: e-Prescriptions (126 Seconds)

Take the participant to the starting point for the task.

After examining *Patient*, you have decided to put this patient on – *Coumadin*. Check for any interactions and generate a prescription for this medication.

Success:

- Easily completed
- Completed with difficulty or help: Describe below
- Not completed

Comments:

Task Time: _____ Seconds

Optimal Path:

Patient Chart → Click on ‘Go to Medications’ → Click ‘Prescribe’ tab → Select medication from list → Select from previously save SIG list → ‘Ok’ button → Click ‘Active medication’ tab → Check medication box → Select pharmacy → ‘Send’ button

- Correct
- Minor Deviations / Cycles: Describe below
- Major Deviations: Describe below

Comments:

Observed Errors and Verbalizations:

Comments:

Rating:

Overall, this task was: _____

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

Administrator / Notetaker Comments:

Task 3: Drug to Drug and Drug to Allergy (8 Seconds)

Take the participant to the starting point for the task.

While prescribing the medication, notice any notifications or interventions.

Success:

- Easily completed
- Completed with difficulty or help: Describe below
- Not completed

Comments:

Task Time: _____Seconds

Optimal Path: *e-prescribing module → Check severity*

- Correct
- Minor Deviations / Cycles: Describe below
- Major Deviations: Describe below

Comments:

Observed Errors and Verbalizations:

Comments:

Rating:

Overall, this task was: _____

Show participant written scale: "Very Easy" (1) to "Very Difficult" (5)

Administrator / Notetaker Comments:

Task 4: Clinical Decision Support (215 Seconds)

Take the participant to Summary Page for today's follow up visit.

Participant should address all clinical decision support interventions.

Success:

- Easily completed
- Completed with difficulty or help: Describe below
- Not completed

Comments:

Task Time: _____Seconds

Optimal Path:

On Summary Page, Acknowledge 7 CDS Interventions → Click on 'Info' link for Smoking → Click on 'Infobutton' for Low-back pain → Click on 'Infobutton' for HbA1c labs → Click on medications 'Info' link → Click on "Plan Of care" → Click on 'Referral to dietician' → Click on 'documentation of current medications' → Continue present regimen → Click on "Self reported lab results" → Click on 'x' to exit and save

- Correct
- Minor Deviations / Cycles: Describe below
- Major Deviations: Describe below

Comments:

Observed Errors and Verbalizations:

Comments:

Rating:

Overall, this task was: _____

Show participant written scale: "Very Easy" (1) to "Very Difficult" (5)

Administrator / Notetaker Comments:

Task 5: Clinical Information Reconciliation (78 Seconds)

Take the participant to the starting point for the task.

While updating patient' clinical information (problem list, medication list or allergy list) you realize there is a list to be reconcile from a different physician. Please proceed to reconcile external list.

Success:

- Easily completed
- Completed with difficulty or help: Describe below
- Not completed

Comments:

Task Time: _____Seconds

Optimal Path:

Patient's Chart → Click on 'Allergies' → Click on 'Reconcile' → Select List from dr. Joe Smith → Select all allergens by clicking on each → "Reconcile" button → "x" to exit → click "Allergies" to refresh

Patient's Chart → Click on 'Problem List' → Click on 'Reconcile' → Select List from dr. Joe Smith → Select all problems by clicking on each → "Reconcile" button → "x" to exit → click "go to problem list" to refresh → Click on "Active problem list"

Patient's Chart → Click on 'Medication List' → Click on 'Reconcile' → Select List from dr. Joe Smith → Select all medications by clicking on each → "Reconcile" button → "x" to exit → click "go to medications" to refresh → Click on "Current medications"

- Correct
- Minor Deviations / Cycles: Describe below
- Major Deviations: Describe below

Comments:

Observed Errors and Verbalizations:

Comments:

Rating:

Overall, this task was: _____

Show participant written scale: "Very Easy" (1) to "Very Difficult" (5)

Administrator / Notetaker Comments:

Task 6: CPOE –Labs and Radiology/Imaging (50 Seconds and 63 Seconds)

Take the participant to Summary Page for today's follow up visit.

While documenting Plan of care section of today's follow-up visit, record a new order for labs and EKG Change Orders to include missing information, and Access final Order.

Success:

- Easily completed
- Completed with difficulty or help: Describe below
- Not completed

Comments:

Task Time: _____Seconds

Optimal Path:

Summary Page → Click 'Orders' → Create new lab order by clicking on CMP → Add CBC → 'Send' Button → Click on 'X' to Exit → Click 'Orders' → Add a lipid profile to current order → 'Send' Button → Click on 'X' to Exit

Summary Page → Click 'Orders' → Create new radiology/imaging order by clicking on EKG → 'Send' Button → Click on 'X' to Exit → Click 'Orders' → Click on "medical necessity" → Select 'Chest Pain' → 'Send' Button → Click on 'X' to Exit

- Correct
- Minor Deviations / Cycles: Describe below
- Major Deviations: Describe below

Comments:

Observed Errors and Verbalizations:

Comments:

Rating:

Overall, this task was: _____

Show participant written scale: "Very Easy" (1) to "Very Difficult" (5)

Administrator / Notetaker Comments:

Task 7: Admin Configuration of CDS and Drug-to-Drug (26 Seconds & 38 Seconds)

Take the participant to Admin Console.

Instruct the participant to adjust functionality for drug to drug and clinical decision support.

Success:

- Easily completed
- Completed with difficulty or help: Describe below
- Not completed

Comments:

Task Time: _____Seconds

Optimal Path:

Admin Console → CDS configuration → Activate all CDS Core rules → Activate All rules to 'show therapeutic' info → Activate All rules to display 'Source' info → Click 'Admin Console Home'

Admin Console → Under Warnings Configuration click 'See Utility' → under DDI dropdown menu select "Up to 2" → "ok" button → Click 'Admin Console Home' → Under Warnings Configuration click 'See Utility' → under DDI dropdown menu select "ALL" → Click 'Admin Console Home'

- Correct
- Minor Deviations / Cycles: Describe below
- Major Deviations: Describe below

Comments:

Observed Errors and Verbalizations:

Comments:

Rating:

Overall, this task was: _____

Show participant written scale: "Very Easy" (1) to "Very Difficult" (5)

Administrator / Notetaker Comments:

Final Questions (5 Minutes)

What was your overall impression of this system?

What aspects of the system did you like most?

What aspects of the system did you like least?

Were there any features that you were surprised to see?

What features did you expect to encounter but did not see? That is, is there anything that is missing in this application?

Compare this system to other systems you have used. Would you recommend this system to your colleagues?

Appendix 5: SYSTEM USABILITY SCALE QUESTIONNAIRE

In 1996, Brooke published a “low-cost usability scale that can be used for global assessments of systems usability” known as the *System Usability Scale* or *SUS*.¹⁶ Lewis and Sauro (2009) and others have elaborated on the *SUS* over the years. Computation of the *SUS* score can be found in Brooke’s paper, in at <http://www.usabilitynet.org/trump/documents/Suschapt.doc> or in Tullis and Albert (2008).

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

Appendix 6: Evaluated Tasks

Medication allergy list (314.a.7)

Scenario

Patient has Aspirin in his current medication-allergy list, add Coumadin to the list, then exit module and go back to Patient's chart. Go back to Allergies module and delete aspirin from list. At the end, the patient should only have Coumadin in the list.

-Medication-Allergy List | Risk: Medium

Patient's Chart > Go to Allergies > Document new allergy > Go to Patient chart (exit current screen) > Go to 'Allergies' > Delete Aspirin from list > Go to Patient's Chart

Task Description	Task	Criteria	EHRUT Module	Equivalent EHRUT action
Record Medication Allergy List	Med-Allergy List	(314.a.7)	Allergy Module	Document new allergy
Change Medication Allergy List	Med-Allergy List	(314.a.7)	Allergy Module	Delete Aspirin
Access Medication Allergy List	Med-Allergy List	(314.a.7)	Allergy Module	Go to Allergy

Medication List (314.a.6), CPOE-Meds (314.a.1), Drug-to-drug/drug-to-allergy interactions (314.a.2) and Electronic Prescribing (314.b.3)

Scenario

Patient has aspirin 81 mg capsule and tropicamide drops 1 % in his current medication list. Patient has brought his list of current medications and he is also taking lisinopril 20 mg tablet for his condition of hypertension prescribed by Dr. Smith. Dr Smith has also discontinued tropicamide drops 1 %. After examining the patient history, physician has decided to start the patient in a Coumadin regimen. This scenario will force Drug to drug interactions (Aspirin and Coumadin) and allergy interaction (Coumadin). Physician decides to continue the patient in aspirin therapy, physician adjust the dosage re-prescribes the medication.

-Medication List | Risk: Medium

Patient's Chart > Click Go to medications link > Click "Document" tab > Add Lisinopril 20 mg tablet > Click on Patient's Chart (Exit current Module) > Click Go to medications link > On Active tab Delete: tropicamide drops 1 % > Click on Patient's Chart (Exit current Module) > Click Go to medications link

-CPOE-Meds | Risk: High

Patient's Chart > Go to medications' link > Click "Prescribe" tab > Add Coumadin table 1mg > Acknowledge DDI/DAI > Active medication tab > Click on 'Adjust' Aspirin 81mg > Adjust dosage by selecting 'Aspirin 500 mg' from dropdown > 'OK' button > Click on Patient's Chart (Exit current Module)

-Drug-drug, drug-allergy | Risk: High

e-prescribing module > Check severity

-e-Prescribing | Risk: High

Patient Chart > Click "Go to Medications > click "Prescribe" tab > Select medication from list > Select

“previously save SIG” > “ok” button > Click “Active medication” tab > click on medication’s check box > Select pharmacy > “Send” button

Task Description	Task	Criteria	EHRUT Module	Equivalent EHRUT action
Record Medication List	Medication List	(314.a.6)	Medication Module	Document new medication
Change Medication List	Medication List	(314.a.6)	Medication Module	Delete: <i>tropicamide drops 1 %</i>
Access Medication List	Medication List	(314.a.6)	Medication Module	Active tab
Record Medication Order	CPOE	(314.a.1)	Medication Module	Add new medication
Change Medication Order	CPOE	(314.a.1)	Medication Module	Adjust medication dosage
Access Medication Order	CPOE	(314.a.1)	Medication Module	Go to medications
Create drug-drug and drug-allergy interventions prior to CPOE completion	Drug-drug, drug-allergy	(314.a.2)	Medication Module	Acknowledge intervention and take an action
Create prescriptions	Electronic prescribing	(314.b.3)	Medication Module	Select medication to generate prescription click on 'send' Button

Clinical Decision Support (314.a.8)

Scenario

Patient came to the office complaining of low back pain. Patient has active diagnoses of diabetes, hypertension and Postmyocardial infarction syndrome. After evaluating the patient today, you notice the following:

1. Patient is not a smoker
2. BMI is outside parameters and no treatment plan has been documented.
3. Current medications has not been checked
4. BP is high, 140/90
5. Patient has an active diagnosis of IVD and no documentation of use of aspirin is found in patient records.
6. There is no recent lab results for HbA1c
7. An x-ray for low-back pain has not been order.

Physician checks source information for smoking rule intervention, since patient isn't a smoker, physician decides there is not need to document a smoking cessation plan. For BMI treatment plan physician decides to refer patient to a dietician. While performing the documentation of current medications, physician notices Lisinopril and Coumadin in patient list of active medications and decides to continue the regimen (acknowledging high BP and Use of Aspirin or other antithrombotic rule). Since today is the first day the patient is complaining of low-back pain, physician decides not to order an x-ray of the lower back. Patient has brought his lab results and it includes HbA1c, physician documents lab results in medical record.

-Clinical Decision Support| Risk: High

On Summary Page, Acknowledge 7 CDS Interventions > Click smoking Info > Click on 'Infobutton' for Low-back pain > Click on 'infobutton' for HbA1c labs > Click on medications Info link > Click on "Plan Of care" > click on "referral to dietician" > click on "documentation of current medications" > continue present regimen > click on "Self reported lab results" > Click on 'x' to exit and save

Task Description	Task	Criteria	EHRUT Module	Equivalent EHRUT action
Problem List Interventions	CDS	(314.a.8)	Visit Summary	Acknowledge Low-Back Pain intervention and document Plan of Care
Medication List Interventions	CDS	(314.a.8)	Visit Summary	Acknowledge missing documentation of current medications and document Plan of Care
Medication Allergy List Interventions	CDS	(314.a.8)	Visit Summary	Acknowledge Aspirin Therapy Rule and document Plan of Care
Demographics Interventions	CDS	(314.a.8)	Visit Summary	Acknowledge Tobacco Assessment intervention and document Plan of Care
Lab Tests and Results Interventions	CDS	(314.a.8)	Visit Summary	Acknowledge missing labs intervention and document Plan of Care
Vital Signs Interventions	CDS	(314.a.8)	Visit Summary	Acknowledge BMI intervention and document Plan of Care
Identify User Diagnostic and Therapeutic Reference Information	CDS	(314.a.8)	Visit Summary	<i>Infobutton</i> , Source link

Clinical information reconciliation (314.b.4)

Scenario

While updating patient's clinical information (problem list, medication list or allergy list) physician realizes there is a list to be reconcile from a different physician. Please proceed to reconcile external list.

-Clinical Reconciliation | Risk: Medium

Patient's Chart >Click on 'Allergies' > Click on 'Reconcile' > Select List from dr. Joe Smith > Select all allergens by clicking on each > "Reconcile" button > "x" to exit > click "Allergies" to refresh

Patient's Chart>Click on 'Problem List'>Click on 'Reconcile'>Select List from dr. Joe Smith>Select all problems by clicking on each >"Reconcile" button>"x" to exit > click "go to problem list" to refresh>Click on "Active problem list"

Patient's Chart>Click on 'Medication List'>Click on 'Reconcile'>Select List from dr. Joe Smith>Select all medications by clicking on each>"Reconcile" button>"x" to exit>click "go to medications" to refresh>Click on "Current medications"

Task Description	Task	Criteria	EHRUT Module	Equivalent EHRUT action
Reconcile patient's active medication list with another source	Reconciliation	(314.b.4)	Medication Module	Go to Medication List and Reconcile external List
Reconcile patient's active problem list with another source	Reconciliation	(314.b.4)	Problem List Module	Go to Problem List and Reconcile external List
Reconcile patient's active medication allergy list with another source	Reconciliation	(314.b.4)	Allergy Module	Go to Allergies and Reconcile external List

CPOE (314.a.1)

Scenario

Patient came to the office complaining of chest pain. Patient has active diagnoses of diabetes, hypertension and Postmyocardial infarction syndrome. After evaluating the patient, physician has decided to order routine blood work (CMP, CBC), after the order is completed, physician realizes that lipid panel needs to be included in the lab test order. Go back to Lab orders and modified current order to include lipid profile. Also Physician decides to order an EKG, after the order is completed,

physician decides to include a medical necessity for the procedure.

-CPOE | Risk: High

Summary Page > Click 'Orders'> Create new lab order by clicking on CMP > Add CBC > 'Send' Button > Click on 'X' to Exit > Click 'Orders'> Add a lipid profile to current order >'Send' Button > Click on 'X' to Exit

Summary Page > Click 'Orders'> Create new radiology/imaging order by clicking on EKG > 'Send' Button > Click on 'X' to Exit > Click 'Orders'> Click on "medical necessity" > Select 'Chest Pain' > 'Send' Button > Click on 'X' to Exit

Task Description	Task	Criteria	EHRUT Module	Equivalent EHRUT action
Record Laboratory Order	CPOE	(314.a.1)	Visit Summary	Create new order for lab
Change Laboratory Order	CPOE	(314.a.1)	Visit Summary	Add new test to current order
Access Laboratory Order	CPOE	(314.a.1)	Visit Summary	Go to orders
Record Radiology/imaging Order	CPOE	(314.a.1)	Visit Summary	Create new order for radiology (EKG)
Change Radiology/imaging Order	CPOE	(314.a.1)	Visit Summary	Add a medical necessity to current order (chest pain)
Access Radiology/imaging Order	CPOE	(314.a.1)	Visit Summary	Go to orders

Admin Console

Scenario

Proceed to activate all core rules for CDS including CDS for Problem List, Medication List, Allergy List, demographics, Labs, and Vital signs. Also make sure that when intervention is introduced into the workflow, it displays Source and therapeutic information. As a second task go to the warning configuration utility tool and select the severity level of drug to drug interaction to be up to 2, exit the screen and go back to the tool and configure the tool to display ALL severity levels warnings.

Configuration of CDS interventions by user | Risk: Low

Admin Console >CDS configuration > Activate all CDS Core rules > Activate All rules to 'show therapeutic' info> Activate All rules to display 'Source' info > Click 'Admin Console Home'

Adjustment of severity level of drug-drug interventions | Risk: Low

Admin Console >Under Warnings Configuration click 'See Utility'> under DDI dropdown menu select "Up to 2"> "ok" button > Click 'Admin Console Home' > Under Warnings Configuration click 'See Utility'> under DDI dropdown menu select "ALL"> Click 'Admin Console Home'

Task Description	Task	Criteria	EHRUT Module	Equivalent EHRUT action
Configuration of CDS interventions by user	CDS configuration	(314.a.8)	Admin Console	CDS configuration
Adjustment of severity level of drug-drug interventions	Drug-drug configuration	(314.a.2)	Admin Console	Warnings configuration Utility



April 29, 2014

Drummond Group, Inc.

To whom it may concern,

By this letter, Vipa Health, LLC confirms the following information is true in relations the attached reports for Safety-Enhanced Design and User Center Design. The smartEMR usability report is being submitted as part of the EHR certification requirements outlined in 170.314(g)(3) – Safety Enhanced Design.

Sincerely

smartEMR

By: Ruben Garcia, CEO

Date: 05/01/2014

Signature: 



April 28, 2014

Drummond Group, Inc.
13359 North Hwy 183
Austin, Texas 78750

RE: 170.314.g.4 – Quality Management Systems

Smart EMR hereby attests to the fact that it is utilizing an internally developed Quality Management System known as Continuous Quality Improvement (CQI). This system incorporates the principles of LEAN (increasing speed and reducing waste), and Total Quality Management (TQM) which is built on the principles of Plan-Do-Study-Act (PDSA) cycle. The ability to blend these quality concepts and methodologies into an agile product development process is what sets *smartEMR* apart.

The blending of the concepts has been documented by various reference sources including the ones below:

1. Omachonu, V and J. Ross, 2005. Principles of Total Quality, CRC Press,
2. Omachonu, V. 1999. Health Care Performance Improvement, Institute of Industrial Engineers, IIE Press.
3. George, M. L. 2002. Lean Six Sigma. McGraw-Hill, New York
4. Stalhane, Tor, and Geir Kjetil Hanssen. "The application of ISO 9001 to agile software development." Product-Focused Software Process Improvement. Springer Berlin Heidelberg, 2008.
5. Sy, D. (2007). Adapting Usability Investigations for Agile User-Centered Design. Journal of Usability Studies, pages 112-132.
6. Juran, J. and De Feo, J. A. 2014. Juran's Quality Handbook, 6th edition. McGraw-Hill, New York.

Our reliance on the CQI methodology has helped us achieve a user-centered design mindset in all of our product development endeavors to date.

smartEMR

By: Ruben Garcia, CEO

Date: 04/17/2014

Signature: _____



To whom it may concern,

170.314 (d) (2) Audit log

- Default setting: smartEMR confirms that the default setting for the audit log is enabled and no user can disable the audit log.
- End-users have no access to the log database table: end-users can only view the report in html format in the admin console of the application. SmartEMR confirms that the our system does not allow any user to perform the following actions:
 - Audit log disabling
 - Changes in the setting of audit logs
 - Changes to audit log status
 - Changes of encryption status
- Methods by which smartEMR detect alteration of audit logs:
End-users don't have the ability to directly access the Audit Logs and no ability to change or alter them. All logs are indexed in a database table with a sequential primary key and hash code. Encryption is generated using SHA-1 algorithm for each row.

170.314 (d) (7) prevent data storage in local devices

smartEMR confirms that Electronic Health Information is not stored on end-user devices.

smartEMR

By: Ruben Garcia, CEO

Date: 04/17/2014

Signature: 