ONC HIT Certification Program
Test Results Summary for 2014 Edition EHR Certification

Part 1: Product and Developer Information

1.1 Certified Product Information

Product Name:	Supra
Product Version:	FiEHR
Domain:	Ambulatory
Test Type:	Complete EHR

1.2 Developer/Vendor Information

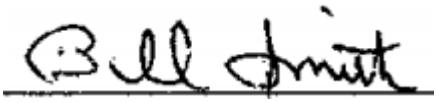
Developer/Vendor Name:	ADS Technologies, Inc.
Address:	174 Waterfront Street, Suite 330 National Harbor MD 20745
Website:	www.SupraEHR.com
Email:	info@supraehr.com
Phone:	866-721-8460
Developer/Vendor Contact:	Parag Shah

Part 2: ONC-Authorized Certification Body Information

2.1 ONC-Authorized Certification Body Information

ONC-ACB Name:	Drummond Group
Address:	13359 North Hwy 183, Ste B-406-238, Austin, TX 78750
Website:	www.drummondgroup.com
Email:	ehr@drummondgroup.com
Phone:	817-294-7339
ONC-ACB Contact:	Bill Smith

This test results summary is approved for public release by the following ONC-Authorized Certification Body Representative:

Bill Smith	Certification Committee Chair
ONC-ACB Authorized Representative	**Function/Title**
 10/5/2014	
Signature and Date	

2.2 Gap Certification

The following identifies criterion or criteria certified via gap certification

§170.314			
[x] (a)(1)	[ ] (a)(17)	[x] (d)(5)	[ ] (d)(9)
[x] (a)(6)	[ ] (b)(5)*	[x] (d)(6)	[x] (f)(1)
[x] (a)(7)	[x] (d)(1)	[x] (d)(8)	

*Gap certification allowed for Inpatient setting only

[ ] No gap certification

2.3 Inherited Certification

The following identifies criterion or criteria certified via inherited certification

§170.314			
☐ (a)(1)	☐ (a)(14)	☐ (c)(3)	☐ (f)(1)
☐ (a)(2)	☐ (a)(15)	☐ (d)(1)	☐ (f)(2)
☐ (a)(3)	☐ (a)(16) *Inpt. only*	☐ (d)(2)	☐ (f)(3)
☐ (a)(4)	☐ (a)(17) *Inpt. only*	☐ (d)(3)	☐ (f)(4) *Inpt. only*
☐ (a)(5)	☐ (b)(1)	☐ (d)(4)	☐ (f)(5) *Optional & Amb. only*
☐ (a)(6)	☐ (b)(2)	☐ (d)(5)	
☐ (a)(7)	☐ (b)(3)	☐ (d)(6)	☐ (f)(6) *Optional & Amb. only*
☐ (a)(8)	☐ (b)(4)	☐ (d)(7)	
☐ (a)(9)	☐ (b)(5)	☐ (d)(8)	☐ (g)(1)
☐ (a)(10)	☐ (b)(6) *Inpt. only*	☐ (d)(9) *Optional*	☐ (g)(2)
☐ (a)(11)	☐ (b)(7)	☐ (e)(1)	☐ (g)(3)
☐ (a)(12)	☐ (c)(1)	☐ (e)(2) *Amb. only*	☐ (g)(4)
☐ (a)(13)	☐ (c)(2)	☐ (e)(3) *Amb. only*	

☒ No inherited certification

Part 3: NVLAP-Accredited Testing Laboratory Information

Report Number: TEB-03112014-2498

Test Date(s): 2/5/2014, 2/16/2014, 3/11/2014

3.1 NVLAP-Accredited Testing Laboratory Information

ATL Name:	Drummond Group EHR Test Lab
Accreditation Number:	NVLAP Lab Code 200979-0
Address:	13359 North Hwy 183, Ste B-406-238, Austin, TX 78750
Website:	www.drummondgroup.com
Email:	ehr@drummondgroup.com
Phone:	512-335-5606
ATL Contact:	Beth Morrow

For more information on scope of accreditation, please reference NVLAP Lab Code 200979-0.

Part 3 of this test results summary is approved for public release by the following Accredited Testing Laboratory Representative:

Timothy Bennett	Test Proctor
ATL Authorized Representative	**Function/Title**
 10/5/2014	Nashville, TN
Signature and Date	**Location Where Test Conducted**

3.2 Test Information

3.2.1 Additional Software Relied Upon for Certification

Additional Software	Applicable Criteria	Functionality provided by Additional Software

[x] No additional software required

3.2.2 Test Tools

Test Tool	Version
[x] Cypress	2.4.1
[x] ePrescribing Validation Tool	1.0.3
[ ] HL7 CDA Cancer Registry Reporting Validation Tool	1.0.3
[ ] HL7 v2 Electronic Laboratory Reporting (ELR) Validation Tool	1.8
[x] HL7 v2 Immunization Information System (IIS) Reporting Validation Tool	1.7.1
[x] HL7 v2 Laboratory Results Interface (LRI) Validation Tool	1.7
[x] HL7 v2 Syndromic Surveillance Reporting Validation Tool	1.7
[x] Transport Testing Tool	174
[x] Direct Certificate Discovery Tool	2.1

[ ] No test tools required

3.2.3 Test Data

[ ] Alteration (customization) to the test data was necessary and is described in Appendix [*insert appendix letter*]

[☒] No alteration (customization) to the test data was necessary

3.2.4 Standards

3.2.4.1 Multiple Standards Permitted

The following identifies the standard(s) that has been successfully tested where more than one standard is permitted

Criterion #	Standard Successfully Tested	
(a)(8)(ii)(A)(2)	[ ] §170.204(b)(1) HL7 Version 3 Implementation Guide: URL-Based Implementations of the Context-Aware Information Retrieval (Infobutton) Domain	[ ] §170.204(b)(2) HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton) Service-Oriented Architecture Implementation Guide
(a)(13)	[x] §170.207(a)(3) IHTSDO SNOMED CT® International Release July 2012 and US Extension to SNOMED CT® March 2012 Release	[ ] §170.207(j) HL7 Version 3 Standard: Clinical Genomics; Pedigree

Criterion #	Standard Successfully Tested	
(a)(15)(i)	[x] §170.204(b)(1) HL7 Version 3 Implementation Guide: URL-Based Implementations of the Context-Aware Information Retrieval (Infobutton) Domain	[ ] §170.204(b)(2) HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton) Service-Oriented Architecture Implementation Guide
(a)(16)(ii)	[ ] §170.210(g) Network Time Protocol Version 3 (RFC 1305)	[ ] §170. 210(g) Network Time Protocol Version 4 (RFC 5905)
(b)(2)(i)(A)	[ ] §170.207(i) The code set specified at 45 CFR 162.1002(c)(2) (ICD-10-CM) for the indicated conditions	[x] §170.207(a)(3) IHTSDO SNOMED CT® International Release July 2012 and US Extension to SNOMED CT® March 2012 Release
(b)(7)(i)	[ ] §170.207(i) The code set specified at 45 CFR 162.1002(c)(2) (ICD-10-CM) for the indicated conditions	[x] §170.207(a)(3) IHTSDO SNOMED CT® International Release July 2012 and US Extension to SNOMED CT® March 2012 Release
(e)(1)(i)	Annex A of the FIPS Publication 140-2 [*list encryption and hashing algorithms*] AES SHA1	
(e)(1)(ii)(A)(2)	[x] §170.210(g) Network Time Protocol Version 3 (RFC 1305)	[ ] §170. 210(g) Network Time Protocol Version 4 (RFC 5905)
(e)(3)(ii)	Annex A of the FIPS Publication 140-2 [*list encryption and hashing algorithms*] AES SHA1	
Common MU Data Set (15)	[x] §170.207(a)(3) IHTSDO SNOMED CT® International Release July 2012 and US Extension to SNOMED CT® March 2012 Release	[ ] §170.207(b)(2) The code set specified at 45 CFR 162.1002(a)(5) (HCPCS and CPT-4)

[ ] None of the criteria and corresponding standards listed above are applicable

3.2.4.2 Newer Versions of Standards

The following identifies the newer version of a minimum standard(s) that has been successfully tested

Newer Version	Applicable Criteria

☒ No newer version of a minimum standard was tested

3.2.5 Optional Functionality

Criterion #	Optional Functionality Successfully Tested
☒ (a)(4)(iii)	Plot and display growth charts
☐ (b)(1)(i)(B)	Receive summary care record using the standards specified at §170.202(a) and (b) (Direct and XDM Validation)
☐ (b)(1)(i)(C)	Receive summary care record using the standards specified at §170.202(b) and (c) (SOAP Protocols)
☐ (b)(2)(ii)(B)	Transmit health information to a Third Party using the standards specified at §170.202(a) and (b) (Direct and XDM Validation)
☐ (b)(2)(ii)(C)	Transmit health information to a Third Party using the standards specified at §170.202(b) and (c) (SOAP Protocols)
☐ (f)(3)	Ambulatory setting only – Create syndrome-based public health surveillance information for transmission using the standard specified at §170.205(d)(3) (urgent care visit scenario)
☐ Common MU Data Set (15)	Express Procedures according to the standard specified at §170.207(b)(3) (45 CFR162.1002(a)(4): Code on Dental Procedures and Nomenclature)
☐ Common MU Data Set (15)	Express Procedures according to the standard specified at §170.207(b)(4) (45 CFR162.1002(c)(3): ICD-10-PCS)

☐ No optional functionality tested

3.2.6 2014 Edition Certification Criteria* Successfully Tested

Criteria #	Version		Criteria #	Version	
	TP**	TD***		TP	TD
☐ (a)(1)	1.2	1.5	☒ (c)(3)	1.6	1.6
☒ (a)(2)	1.2		☐ (d)(1)	1.2	
☒ (a)(3)	1.2	1.4	☒ (d)(2)	1.5	
☒ (a)(4)	1.4	1.3	☒ (d)(3)	1.3	
☒ (a)(5)	1.4	1.3	☒ (d)(4)	1.3	
☐ (a)(6)	1.3	1.4	☐ (d)(5)	1.2	
☐ (a)(7)	1.3	1.3	☐ (d)(6)	1.2	
☒ (a)(8)	1.2		☒ (d)(7)	1.2	
☒ (a)(9)	1.3	1.3	☐ (d)(8)	1.2	
☒ (a)(10)	1.2	1.4	☐ (d)(9) *Optional*	1.2	
☒ (a)(11)	1.3		☒ (e)(1)	1.8	1.5
☒ (a)(12)	1.3		☒ (e)(2) *Amb. only*	1.2	1.6
☒ (a)(13)	1.2		☒ (e)(3) *Amb. only*	1.3	
☒ (a)(14)	1.2		☐ (f)(1)	1.2	1.2
☒ (a)(15)	1.5		☒ (f)(2)	1.3	1.7.1
☐ (a)(16) *Inpt. only*	1.3	1.2	☒ (f)(3)	1.3	1.7
☐ (a)(17) *Inpt. only*	1.2		☐ (f)(4) *Inpt. only*	1.3	1.7
☒ (b)(1)	1.7	1.4	☐ (f)(5) *Optional & Amb. only*	1.2	1.2
☒ (b)(2)	1.4	1.6			
☒ (b)(3)	1.4	1.2	☐ (f)(6) *Optional & Amb. only*	1.3	1.0.3
☒ (b)(4)	1.3	1.4			
☒ (b)(5)	1.4	1.7	☐ (g)(1)	1.7	1.9
☐ (b)(6) *Inpt. only*	1.3	1.7	☒ (g)(2)	1.7	1.9
☒ (b)(7)	1.4	1.6	☒ (g)(3)	1.3	
☒ (c)(1)	1.6	1.6	☒ (g)(4)	1.2	
☒ (c)(2)	1.6	1.6			

☐ No criteria tested

*For a list of the 2014 Edition Certification Criteria, please reference http://www.healthit.gov/certification (navigation: 2014 Edition Test Method)

**Indicates the version number for the Test Procedure (TP)

***Indicates the version number for the Test Data (TD)

3.2.7 2014 Clinical Quality Measures*

Type of Clinical Quality Measures Successfully Tested:

- [x] Ambulatory
- [ ] Inpatient
- [ ] No CQMs tested

*For a list of the 2014 Clinical Quality Measures, please reference http://www.cms.gov (navigation: 2014 Clinical Quality Measures)

Ambulatory CQMs							
CMS ID	Version	CMS ID	Version	CMS ID	Version	CMS ID	Version
[x] 2	v3	[x] 90	v3	[x] 136	v3	[x] 155	v2
[x] 22	v2	[x] 117	v2	[ ] 137		[x] 156	v2
[x] 50	v2	[ ] 122		[x] 138	v2	[ ] 157	
[ ] 52		[ ] 123		[ ] 139		[ ] 158	
[ ] 56		[ ] 124		[ ] 140		[ ] 159	
[ ] 61		[ ] 125		[ ] 141		[ ] 160	
[ ] 62		[x] 126	v2	[ ] 142		[ ] 161	
[ ] 64		[ ] 127		[ ] 143		[ ] 163	
[ ] 65		[ ] 128		[ ] 144		[ ] 164	
[ ] 66		[ ] 129		[ ] 145		[x] 165	v2
[x] 68	v3	[ ] 130		[x] 146	v2	[x] 166	v3
[x] 69	v2	[ ] 131		[ ] 147		[ ] 167	
[ ] 74		[ ] 132		[ ] 148		[ ] 169	
[x] 75	v2	[ ] 133		[ ] 149		[ ] 177	
[ ] 77		[ ] 134		[x] 153	v2	[ ] 179	
[ ] 82		[ ] 135		[x] 154	v2	[ ] 182	

Inpatient CQMs							
CMS ID	Version	CMS ID	Version	CMS ID	Version	CMS ID	Version
[ ] 9		[ ] 71		[ ] 107		[ ] 172	
[ ] 26		[ ] 72		[ ] 108		[ ] 178	
[ ] 30		[ ] 73		[ ] 109		[ ] 185	
[ ] 31		[ ] 91		[ ] 110		[ ] 188	
[ ] 32		[ ] 100		[ ] 111		[ ] 190	
[ ] 53		[ ] 102		[ ] 113			
[ ] 55		[ ] 104		[ ] 114			
[ ] 60		[ ] 105		[ ] 171			

3.2.8 Automated Numerator Recording and Measure Calculation

3.2.8.1 Automated Numerator Recording

Automated Numerator Recording Successfully Tested			
☐ (a)(1)	☐ (a)(9)	☐ (a)(16)	☐ (b)(6)
☐ (a)(3)	☐ (a)(11)	☐ (a)(17)	☐ (e)(1)
☐ (a)(4)	☐ (a)(12)	☐ (b)(2)	☐ (e)(2)
☐ (a)(5)	☐ (a)(13)	☐ (b)(3)	☐ (e)(3)
☐ (a)(6)	☐ (a)(14)	☐ (b)(4)	
☐ (a)(7)	☐ (a)(15)	☐ (b)(5)	

☒ Automated Numerator Recording was not tested

3.2.8.2 Automated Measure Calculation

Automated Measure Calculation Successfully Tested			
☒ (a)(1)	☒ (a)(9)	☐ (a)(16)	☐ (b)(6)
☒ (a)(3)	☒ (a)(11)	☐ (a)(17)	☒ (e)(1)
☒ (a)(4)	☒ (a)(12)	☒ (b)(2)	☒ (e)(2)
☒ (a)(5)	☒ (a)(13)	☒ (b)(3)	☒ (e)(3)
☒ (a)(6)	☒ (a)(14)	☒ (b)(4)	
☒ (a)(7)	☒ (a)(15)	☒ (b)(5)	

☐ Automated Measure Calculation was not tested

3.2.9 Attestation

Attestation Forms (as applicable)	Appendix
☒ Safety-Enhanced Design*	A
☒ Quality Management System**	B
☒ Privacy and Security	C

*Required if any of the following were tested: (a)(1), (a)(2), (a)(6), (a)(7), (a)(8), (a)(16), (b)(3), (b)(4)

**Required for every EHR product

3.3 Appendices

Attached below.

Test Results Summary Change History

Test Report ID	Description of Change	Date

2014 Edition Test Report Summary

ADS Technologies, Inc.
174 Waterfront Street
National Harbor, MD 20745
Tel 443-325-7660 Fax 443-367-0149

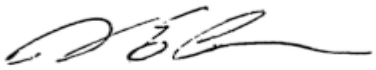
Monday, September 29, 2014

To Whom It May Concern:

This letter is provided to serve as attestation to the veracity and authneticity of the EHR Usability Report.

If you have any further questions please contact at the information provided on www.supraehr.com.

Thank you,



John McDonough, COO

User Centered Design Process

Contents

User Centered Design Process

1. Overview

This document describes in detail the UCD (User-Centered Design) process followed during the development of FiEHR (Fully integrated Electronic Health Records) software application.

2. User-Centered Design Process

The following UCD Process is followed for development of FiEHR software application.

2.1 Analysis

Analysis and design of the software developed is done before start of software development process. Users were involved at all levels of Software Development Life Cycle (SDLC) of software development.

2.1.1 Objective

The main objective behind development of FiEHR software application is to computerize and speed up the process of storing and tracking of Electronic Health Records of patients and also taking care of Billing part and there by assisting the end users to complete the billing process.

2.1.2 User Analysis

A list of users were identified so as to provide the software development team with information related to Electronic Health Records and Billing. These users were identified as Subject Matter Experts (SME).

Regular meetings are held with the users and the product is demonstrated based on the releases. As the software development is done using the Iterative method, any new feature or functionality added to the software is demonstrated to the SME's and regular feed- back is taken into taken from the users enabling the software development team to build user friendly software.

2.1.3 Task Analysis

Task List are prepared and maintained for software development team and users too. The items mentioned in the task list is discussed in detail and status of the task is recorded and tracked for timelines and functionalities.

2.1.4 Workflow Analysis

Analysis of Workflow is done before start of development of software by the software development team and users. Users appraise the software development team of the workflow involved in the software.

The workflow scenario for a new patient is as follows:

1. Recording New Patient's information along with Demographics.
2. Recording of Patient's Appointment with the Doctor.
3. Recording of Patient's Check In Information post Appointment.
4. Visit to Doctor.
5. Recording of Patient's Profile like Problem List, Allergy, Medication, Family History, Social History, Procedure, Alert, Vital Signs, Care Plan, Cognitive, Diagnosis, Appointment Procedure, Vaccine, Drug Administered, Lab Order, Screen Order and Assessment details are captured.
6. Patient Billing Information with an option for Insurance Payment and copay.

2.2 Design

The software design process is divided into three main sections. They are Presentations, Interactions and conceptual Model. The ratio is 10% presentation, 40% Interaction and 50% Conceptual Model.

Paper Prototypes are prepared before the start of the development for user interfaces and analyzed for ease of use for the end users.

Mockup sessions are also conducted with users where in the design of the user interfaces are discussed and finalized.

2.3 Evaluation

Walk through sessions are regularly conducted with the users for effective evaluation of the software and regular feed-back is taken from the users.

2.4 Implementation

Subsequent to the approval of user interfaces from the end users, implementation or development of software commences. Software is developed using iterative process where in after each iteration and testing, the users are given a live demonstration of the software and the users review are taking into account and managed.

FiEHR software is developed using latest Microsoft Software Development Platform with excellent user interfaces and search options where in applicable.
Usability testing is also done in detail with regards to screen design, capturing all data elements, functionalities, validations and various other software functions. Extensive testing of the software is done and Test Cases and Test Results are maintained on a regular basis enabling the software developer to look into the issues and fix the bugs or errors as reported by the Tester. Test cases contains Test Case name, Description, Expected Results, Actual Result, Pass/Fail.

2.5 Deployment

Deployment of the software application is done on a shared network using 2x software. Multiple users can access and operate on the software simultaneously.

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EHR Usability Test Report of FiEHR (Fully integrated Electronic Health Records) Build-1

Date of Usability Test:

4/12/2014

Location of Usability Test:

ADS Corporate Office

Date of Report:

4/25/2014

ADS Technologies, Inc.
174 Waterfront Street, Suite 330
National Harbor, MD 20745
Tel 443-325-7660 Fax 443-367-0149

Contents

ADS Technologies, Inc.
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EHR Usability Test

1. Executive Summary

This is a report on the usability test of FiEHR(Build-1) software application, a complete ambulatory EHR which was conducted on 04/12/2014.

The purpose of the testing was to validate the usability of the EHR application and provide evidence of usability in the EHR under Test (EHRUT). EHR Usability Test is bifurcated into 8 different sections. The sections covered are

- Find the correct patient within the System - Login in to the EHRUT using the login name and password as per Login Information Provided and as mentioned in the Test Sheet. Find the Correct Patient within the system as per the data provided in the test sheet and check the patient's date of birth, age and Sex and confirm the same.
- §170.314(a)(1)-CPOE (Computerized Provider Order Entry)
  - Record, change and access Medication.
  - Record, Change and access Lab Orders.
  - Record, Change and access Screen Orders.
- §170.314(a)(2)-InteractionCheck
  - Create drug-drug and drug-allergy interventions prior to CPOE and adjustment of severity levels of drug-drug interventions.
- §170.314(a)(6)-MedicationList
  - Record, change, access and Print Patient's medication list.
- §170.314(a)(7)-Medication Allergy
  - Record, change and access patient's allergy list.
- §170.314(a)(8) - Clinical Decision Support
- §170.314(b)(3)- Electronic Prescription
- §170.314(b)(4) - Clinical Information Reconciliation and Medication Prior to Transition Care

For the usability test, nine participants were identified and the use of EHRUT in real world tasks. The test collected performance data in the following tasks typically performed with the EHR application.

Duration of the usability test was **60 minutes**. Participants had prior experience of working on an EHR software application and also have gone through the standard training program on FiEHR software application. Please note that prior to the start of the Test Application Login Information &Patient's Demographic information is provided beforehand to the respective participants. CDS Rules were configured for Allergy against a Problem List entry in the Admin Module.

The proctor introduced each task one at a time to the participant and along with the data loggers recorded the user's performance electronically and did not provide any assistance about how to complete the task.

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EHR Usability Test

The following data was collected from each participant during the course of test:

- The number of tasks completed in the allotted time, successfully measured as Yes/No.
- Any task failures measured as Yes/No including deviation from the path to complete the task.
- The amount time each task took to complete successfully measured in minutes and seconds.
- Any usability issues that the participant encountered during the course of task completion.
- Task ratings on a scale of 1 – 5 where 1 = Difficult and 5 = Easy.
- Allotted time to complete the task measured in seconds.

At the end of the Usability Test, a questionnaire was given to each participant to be filled in with regards to overall impression of the software application, aspects most liked, aspects not liked, surprising features in the new software application, features expected to be encountered by the participant but were not present, comparison with other EHR software applications, recommendations from the participant to other colleagues with regards to the usage of the EHR software application.

The following is the summary of metrics of the EHR Usability Test. Note that the values for “Task Time Taken” are calculated by taking the average of minutes and seconds for completing the task for nine participants.

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1.1 Data Scoring

#	Task Description	Task Success/ Failure	Task Deviations (Yes/No) or errors	Task Time	Task Ratings (5=Easy)
1	Find the correct Patient within the system and check Date of Birth, Age and Sex.	9	0	Mean : 2:66 SD : 1.13	Mean : 5
2	Record, change and access Medication.	9	0	Mean : 1:4 SD :1.14	Mean : 5
3	Record, change and access Lab Orders.	9	0	Mean : 8:02 SD : 7.11	Mean : 4.8
4	Record, change and access Screen Orders.	9	0	Mean : 10:06 SD :6.1	Mean : 4.68
5	Create drug-drug and drug-allergy interventions prior to CPOE and adjustment of severity levels of drug-drug interventions.	9	0	Mean : 3:03 SD : 2.17	Mean : 4.84
6	Record, change, access and print Patient's medication list.	9	0	Mean : 5:03 SD : 2.27	Mean : 4.87
7	Record, change and access patient's allergy list.	9	0	Mean : 5:01 SD : 3.21	Mean : 4.82
8	Encountering CDS (Clinical Decision Support) rules for problem list and allergy list.	9	0	Mean : 2:04 SD : 1.15	Mean : 5
9	Electronic Prescription of Medication.	9	0	Mean : 2:04 SD : 1.13	Mean : 5
10	Clinical Information Reconciliation prior to Transition Care.	8/1	1	Mean : 3:01 SD : 3.18	Mean : 4.44

In addition to the data above, the following observations were noted:

1.2 Major Findings

Participants had experience working on the EHR application. They were fluent and comfortable enough to operate the EHR. The testing highlighted ease of use, user friendliness and simplicity in navigation.

Participants found the Medication Module to be the best feature in the application.

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1.3 Areas of Improvement

The following improvements will increase satisfaction and enhance usability:

- Better system response times
- Further simplification of some tasks

1.4 Overall Risk Analysis

- **None**

2. Introduction

The EHRUT tested in this study is Supra FiEHR. The software application is a complete ambulatory EHR specializing in Radiology/Screening, Lab Orders and Patient Management. This system was tested in real world conditions using simulated data.

The study was designed to test the usability of the current user interface and provide feedback on the usability of the EHR Under Test (EHRUT). This study employs metrics designed to measure the effectiveness, efficiency and user satisfaction, which are derived from the data captured during the usability testing.

3. Method

3.1 Participants

A total of nine participants were used in the testing of EHRUT. The participants were not from the testing or the supplier organization. They received basic training that all new users of the EHRUT would receive prior to the actual clinical use

Participant Breakdown

#	Gender	Age	Role	Professional Experience	Computer Experience	EHR Experience
1	Male	42	Physician	12 years	12 years	10 years
2	Male	72	Physician	42 years	5 years	2 years

3	Male	36	Administrative	10 years	10 years	1 year
4	Female	38	Physician	10 years	10 years	8 years
5	Male	32	Physician Assistant	2 years	10 years	5 years
6	Female	44	Registered Nurse	20 years	10 years	10 years
7	Female	27	Medical Assistant	3 years	7 years	10 months
8	Male	51	Physician	18 years	6 years	None
9	Female	22	Medical Assistant	1 year	7 years	None

3.2 Study Design

The objective of the study was to examine the usability of the system as it relates to the user interface and other key features when attempting to access, change and record various types of patient information. The goal of collecting the information was both to serve as a baseline benchmark for future usability and to help identify critical areas of improvement

3.3 Tasks

A representative sample of tasks that are typically performed within the EHR was chosen to include all of the requirements for criteria for certification: §170.314(a)(1)_Computerized Provider Order Entry, §170.314(a)(2)_InteractionCheck, §170.314(a)(6)_MedicationList, §170.314(a)(7)_Medication Allergy, §170.314(a)(8) Clinical Decision Support, §170.314(b)(3) Electronic Prescription, §170.314(b)(4) Clinical Information Reconciliation and Medication Prior to Transition Care.

- Find the correct patient within the system and check for Date of Birth, Age and Sex.
- Record, change and access Medication.
- Record, change and access Lab Orders.
- Record, change and access Screen Orders.

- Create drug-drug and drug-allergy interventions prior to CPOE and adjustment of severity levels of drug-drug interventions.
- Record, change, access and print Patient's medication list.
- Record, change and access Patient's allergy list.
- Encountering CDS (Clinical Decision Support) rules for problem list and allergy list.
- Electronic Prescription of Medication.
- Clinical Information Reconciliation prior to Transition of Care.

3.4 Procedure

The procedure for the study included greeting the participants as they arrived by the test Proctor. At that point the proctor verified their identity as well as their demographic information and assigned each a participant ID. They reviewed and consented to the study and were informed that they could withdraw from the study at any time. Participants did not have prior experience with the FIEHR software application. The proctor introduced the test and instructed participants to complete a series of tasks (given one at a time) using the EHRUT. During the test, the proctor timed the test and along with the data logger recorded user performance data electronically. The proctor did not give the participants assistance in how to complete the tasks.

Participants were instructed to perform each task effectively and efficiently with as few deviations as possible. The participants were also informed that guidance will not be given as to the usage of the application but clarifications on tasks would be given.

3.5 Test Location, Environment, Forms and Tools

The test location was in an enclosed room where all the computers with required Microsoft Windows software (i.e. Windows 7 Professional) were already installed. The EHRUT software application was loaded on a server and a short cut of the application was configured on the participants' desktops.

Documentation used during the test included the consent form for participants, the printed instruction sheets for each task, the post-test questionnaire.

3.6 Participant Instructions

The proctor used the following as a guide in walking each participant through the testing process:

"Thank you for your participation today, we value your input as a clinical user of various systems, it is our goal to collect information on the usability of FIEHR (Fully Integrated Electronic Health Records). Our session today is scheduled for 60 minutes of testing followed by a number of questions after we have completed the test. I will ask you to complete some basic tasks within the system, which I'd like you to do effectively and efficiently with as few deviations as possible. During the test, I will not be able to assist with any of the tasks. I will provide and read a written copy of the instructions of each task. From that point on, immaterial guidance or clarification on tasks would be given but no instructions on the use of the system."

After those instructions, each participant was shown the first task. At the start of each task before reading the instructions for that task the proctor said:

"I will read the description of this task to you and say "Begin." You should then perform the task and once you believe you've completed the task successfully, say "Done."

From that point, in order, the participants were given each of the tasks to complete. At the end of the study, the test proctor gave the participants the post-test satisfaction survey and thanked them for their time and comments.

3.7 Usability Metrics

The metrics used in this study were designed to test both the effectiveness and efficiency of the EHRUT as well as overall satisfaction with the ease of use.
Table 7 from the *NIST Guide to the Process Approach for Improving the Usability of Electronic Health Records* provides a template for these metrics:

Measure	Rational and Scoring
Effectiveness: Task Success	A task is counted as a "Success" if the participant was able to achieve the correct outcome, without assistance, within the time allotted on a per task basis. The total number of successes are calculated for each task and then divided by the total number of times that task was attempted. The results are provided as a percentage.
Effectiveness: Task Failures	If the participant abandons the task, does not reach the correct answer or performs it incorrectly, or reaches the end of the allotted time before successful completion, the task is counted as a "Failure." No task times are taken for errors. The total number of errors is calculated for each task and then divided by the total number of times that task was attempted. Not all deviations would be counted as errors. This should also be expressed as the mean number of failed tasks per participant. On a qualitative level, an enumeration of errors and error types should be collected.

Efficiency: Task Deviations	The participant's path (i.e., steps) through the application is recorded. Deviations occur if the participant, for example, visits an incorrect screen, clicks on an incorrect menu item, follows an incorrect link, or interacts incorrectly with an onscreen control. This path is 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. Deviations do not necessarily mean failure – simply a less efficient method through the interface. It is strongly recommended that task deviations be reported. Optimal paths (i.e., procedural steps) should be recorded when constructing tasks.
Efficiency: Task Time	Each task is timed from when the administrator says "Begin" until the participant says "Done." If he or she fails to say "Done," the time is stopped when the participant stopped performing the task. Only task times for tasks that are successfully completed are included in the average task time analysis. Average time per task is calculated for each task. Variance measures (standard deviation and standard error) are also calculated. Task times are recorded for successes. Observed task times divided by the optimal time for each task is a measure of optimal efficiency. Optimal task performance time, as benchmarked by expert performance under realistic conditions, is recorded when constructing tasks. Target task times used for task times in the Moderator's Guide must be operationally defined by taking multiple measures of optimal performance and multiplying by some factor (e.g., 1.25) that allows some time buffer because the participants are presumably not trained to expert performance. Thus, if expert, optimal performance on a task was 100 seconds then allotted task time performance would be 125 seconds. This ratio should be aggregated across tasks and reported with mean and variance scores.
Satisfaction: Task Rating	Participant's subjective impression of the ease of use of the application is measured by administering both a simple post-task question as well as a post-session questionnaire.
Risk of User Error: Task Rating	Risk of participant making an error when completing the task based on a scale of 1 -10, with 10 being very risky.

4. Results

4.1 Data Analysis and Reporting

As described for each metric above, the results of the test were calculated based on the recommendation of the NIST guide to the process approach for improving the Usability of Electronic Health Records.

	Participant #	Task Success/ Failure	Task Deviations	Task Errors	Task Time (MM:SS)	Task Rating (5 - Easy)
Find the correct patient within the system and check the date of birth, age and sex.	1	S	0	0	0:16	5
	2	S	0	0	0:14	5
	3	S	0	0	0:16	5

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EHR Usability Test

	Participant #	Task Success/ Failure	Task Deviations	Task Errors	Task Time (MM:SS)	Task Rating (5 - Easy)
	4	S	0	0	0:13	5
	5	S	0	0	0:16	5
	6	S	0	0	0:16	5
	7	S	0	0	0:16	5
	8	S	0	0	0:16	5
	9	S	0	0	0:16	5
Record, change and access Medication.	1	S	0	0	1:35	5
	2	S	0	0	1:22	5
	3	S	0	0	2:10	5
	4	S	0	0	0:40	5
	5	S	0	0	1:07	5
	6	S	0	0	0:30	5
	7	S	0	0	2:08	5
	8	S	0	0	1:38	5
	9	S	0	0	2:03	5
Record, change and access Lab Orders.	1	S	0	0	10:01	5
	2	S	0	0	5:01	5
	3	S	0	0	8:02	5
	4	S	0	0	6:11	5
	5	S	0	0	8:06	5
	6	S	0	0	5:25	5
	7	S	0	0	12:02	5
	8	S	0	0	7:31	5
	9	S	0	0	13:01	5
Record, change and access Screen Orders.	1	S	0	0	10:01	5
	2	S	0	0	6:01	5
	3	S	0	0	7:02	5
	4	S	0	0	14:01	5
	5	S	0	0	8:26	5
	6	S	0	0	11:02	5

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EHR Usability Test

	Participant #	Task Success/ Failure	Task Deviations	Task Errors	Task Time (MM:SS)	Task Rating (5 - Easy)
	7	S	0	0	13:02	5
	8	S	0	0	10:01	5
	9	S	0	0	15:01	5
Create drug-drug and drug-allergy interventions prior to CPOE and adjustment of severity levels of drug-drug interventions.	1	S	0	0	4:22	5
	2	S	0	0	1:54	5
	3	S	0	0	1:52	5
	4	S	0	0	4:41	5
	5	S	0	0	3:37	5
	6	S	0	0	2:14	5
	7	S	0	0	4:10	5
	8	S	0	0	2:13	5
	9	S	0	0	3:09	5
Record, change, access and print Patient's medication list.	1	S	0	0	7:06	5
	2	S	0	0	4:28	5
	3	S	0	0	4:17	5
	4	S	0	0	9:07	5
	5	S	0	0	4:02	5
	6	S	0	0	5:12	5
	7	S	0	0	5:12	5
	8	S	0	0	3:34	5
	9	S	0	0	6:04	5
Record, change and access patient's allergy list.	1	S	0	0	6:18	5
	2	S	0	0	3:31	5
	3	S	0	0	5:08	5
	4	S	0	0	7:52	5

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EHR Usability Test

	Participant #	Task Success/ Failure	Task Deviations	Task Errors	Task Time (MM:SS)	Task Rating (5 - Easy)
	5	S	0	0	6:33	5
	6	S	0	0	4:18	5
	7	S	0	0	3:13	5
	8	S	0	0	4:29	5
	9	S	0	0	7:02	5
Encountering CDS (Clinical Decision Support) rules for problem list and allergy list.	1	S	0	0	2:32	5
	2	S	0	0	1:40	5
	3	S	0	0	1:36	5
	4	S	0	0	1:33	5
	5	S	0	0	1:48	5
	6	S	0	0	1:20	5
	7	S	0	0	1:34	5
	8	S	0	0	2:12	5
	9	S	0	0	4:06	5
Electronic Prescription of Medication.	1	S	0	0	3:02	5
	2	S	0	0	2:32	5
	3	S	0	0	1:08	5
	4	S	0	0	1:05	5
	5	S	0	0	2:02	5
	6	S	0	0	1:38	5
	7	S	0	0	3:03	5
	8	S	0	0	1:33	5
	9	S	0	0	3:02	5
Clinical Information Reconciliation prior to Transition Care.	1	S	0	0	7:01	5
	2	S	0	0	3:51	5
	3	S	0	0	7:02	5
	4	F	1	0	_	1

	Participant #	Task Success/ Failure	Task Deviations	Task Errors	Task Time (MM:SS)	Task Rating (5 - Easy)
	5	S	0	0	3:02	5
	6	S	0	0	3:08	5
	7	S	0	0	7:00	5
	8	S	0	0	4:02	5
	9	S	0	0	6:01	5

4.2 Discussion of the Findings

4.2.1 Effectiveness

The absence of error or failures with the system demonstrates the usability and effectiveness of the system.

4.2.2 Efficiency

The lack of significant deviations from the optimal path to complete tasks prove that the EHRUT has been developed with a user centric design that is intuitive and efficient for clinical use.

4.2.3 Satisfaction

The overall satisfaction level of the participants is within the normal limits.

4.2.4 Major Findings

Participants had experience working on the EHR application. They were fluent and comfortable enough to operate the EHR. The testing highlighted ease of use, user friendliness and simplicity in navigation.

Participants found the Medication Module to be the best feature in the application.

4.2.5 Areas of Improvement

The following improvements will increase satisfaction and enhance usability:

- Better system response times
- Further simplification of some tasks

4.2.6 Overall Risk Analysis

The overall study has a risk rating of 1 on a scale of 1 – 10. This low error rating indicates that a typical user is unlikely to have errors when completing tasks.

5. Appendices

5.1 Appendix 2 – Hardware Requirements

The hardware requirements can be bifurcated into two parts. They are Hardware requirements for Client Side and Server Side. The software will be installed on the server and the application will be accessed by the client side computer.

5.1.1 Client-Side

For installation of the FiEHR software application, the following configurations on user's machine are required:

- **Operating System (O/S):** Any Windows O/S above MS Windows 7®.
- **MS Dot Net Framework:** 4.5v®

5.1.2 Server-Side

The following software will be required on the Server.

- **Operating System:** Windows Server 2008® and above.
- **MS Dot Net Framework:** 4.5v®
- **Database:** SQL Server 2008 R2® OR MySQL®

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Date: March 11, 2014

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Phone: 817-294-7339

RE: 107.304.d.7 Quality Management System Letter of Attestation

Supra FiEHR uses the software development lifecycle (SDLC) process for all analysis, design, development, testing, implementation and maintenance of Supra FiEHR software.
A high-level description of Supra FiEHR implementation for each stage of the SDLC is listed below:

Analysis - Supra FiEHR employs business analysts responsible for documenting requirements for each new version of Supra FiEHR software. The requirements are based on feedback from internal and external stakeholders and industry research.

Design - Supra FiEHR employs system architects responsible for designing and documenting the technology required to build the software features defined in the analysis stage. Architects are responsible for ensuring all Supra FiEHR software products meet the following characteristics: scalability, maintainability, reliability, availability, extensibility, manageability, performance and security.

Development - Supra FiEHR employs development resources responsible for coding the technology defined by the architects in the design stage. Development resources are also responsible for code changes required from issues discovered during the maintenance stage.

Testing - Supra FiEHR employs resources responsible for testing the requirements defined in the analysis stage against the code developed during the development stage. Testing resources are also responsible for load/stress testing and testing issues discovered during the maintenance stage.

Implementation - Supra FiEHR employs implementation resources responsible for configuring and deploying Supra FiEHR software to a production environment.

Maintenance - Supra FiEHR employs maintenance resource responsible for ensuring each component of the software platform is operational. During the maintenance stage resource capture valuable stakeholder feedback about the system and feed this information to the business analysts who incorporate the feedback into future version of Supra FiEHR software.

Attested By,

Parag Shah

_____

Signature

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Date: March 3, 2014

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RE: 170.314.d.2-4 Protect Audit Log
170.314. d.2-5 Detection of Audit Log Alteration Attestation

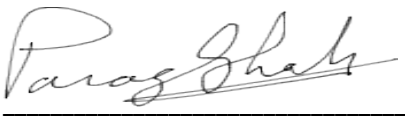
170.314. d.2-4: Protect Audit Log:
The audit log data is stored in a protected database. The database is protected by database user level security that prevents unauthorized users from accessing, modifying or deleting data within the secured database. All database and operating system permissions are accessible to system administrators only and cannot be added / modified / deleted by Supra FiEHR Platform users.

Auditable events can be toggled on or off only by those with Security Administrator rights. These events are also logged.

170.314.d.2-5: Detection of Audit Log Alteration:
Supra FiEHR does not allow any alteration of the audit log. The application has been written to only allow inserts and updates to audit log tables. For detection, Database row checksums are calculated and compared. Using reporting mechanisms built in the product, any such alterations can be detected.

Attested By,

Parag Shah



Signature

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RE: 107.304.d.7 Encryption of Data at Rest Letter of Attestation

Supra FiEHR does not store any electronic health information locally on end-user devices.

Attested By,

Parag Shah

_____
Signature