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:	Welligent Integrated System
Product Version:	8^{MU}
Domain:	Ambulatory
Test Type:	Modular EHR

1.2 Developer/Vendor Information

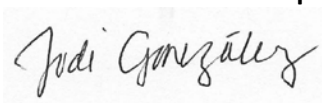
Developer/Vendor Name:	Welligent, Inc.
Address:	5205 Colley Avenue Norfolk Virginia 23508
Website:	www.welligent.com
Email:	csutelan@welligent.com
Phone:	757-213-5970
Developer/Vendor Contact:	Charles Sutelan

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:	(512) 599-1817
ONC-ACB Contact:	Jodi Gonzalez

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

Jodi Gonzalez	Certification Body Manager
ONC-ACB Authorized Representative	**Function/Title**
 10/26/2015	
Signature and Date	

2.2 Gap Certification

The following identifies criterion or criteria certified via gap certification

§170.314			
☐ (a)(1)	☐ (a)(19)	☐ (d)(6)	☐ (h)(1)
☐ (a)(6)	☐ (a)(20)	☐ (d)(8)	☐ (h)(2)
☐ (a)(7)	☐ (b)(5)*	☐ (d)(9)	☐ (h)(3)
☐ (a)(17)	☐ (d)(1)	☐ (f)(1)	
☐ (a)(18)	☐ (d)(5)	☐ (f)(7)**	

*Gap certification allowed for Inpatient setting only
**Gap certification allowed for Ambulatory setting only

☒ No gap certification

2.3 Inherited Certification

The following identifies criterion or criteria certified via inherited certification

§170.314			
[x] (a)(1)	[ ] (a)(16) *Inpt. only*	[ ] (c)(2)	[ ] (f)(2)
[x] (a)(2)	[ ] (a)(17) *Inpt. only*	[ ] (c)(3)	[ ] (f)(3)
[x] (a)(3)	[ ] (a)(18)	[x] (d)(1)	[ ] (f)(4) *Inpt. only*
[x] (a)(4)	[ ] (a)(19)	[x] (d)(2)	[ ] (f)(5) *Amb. only*
[x] (a)(5)	[ ] (a)(20)	[x] (d)(3)	
[x] (a)(6)	[ ] (b)(1)	[x] (d)(4)	[ ] (f)(6) *Amb. only*
[x] (a)(7)	[ ] (b)(2)	[x] (d)(5)	
[x] (a)(8)	[x] (b)(3)	[x] (d)(6)	[ ] (f)(7)
[x] (a)(9)	[x] (b)(4)	[x] (d)(7)	[ ] (g)(1)
[x] (a)(10)	[ ] (b)(5)	[x] (d)(8)	[ ] (g)(2)
[x] (a)(11)	[ ] (b)(6) *Inpt. only*	[x] (d)(9) *Optional*	[x] (g)(3)
[x] (a)(12)	[ ] (b)(7)	[ ] (e)(1)	[x] (g)(4)
[x] (a)(13)	[ ] (b)(8)	[ ] (e)(2) *Amb. only*	[ ] (h)(1)
[x] (a)(14)	[ ] (b)(9)	[ ] (e)(3) *Amb. only*	[ ] (h)(2)
[x] (a)(15)	[ ] (c)(1)	[x] (f)(1)	[ ] (h)(3)

[ ] No inherited certification

Part 3: NVLAP-Accredited Testing Laboratory Information

Report Number: GI-10222015-3005

Test Date(s): 10/22/2015

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:	817-709-1627
ATL Contact:	Kyle Meadors

For more information on scope of accreditation, please reference NVLAP site.

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

Gary Isaac	Test Proctor
ATL Authorized Representative	**Function/Title**
GARY ISAAC 10/26/2015	Sarasota, FL
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
Emdeon eClinician	170.314.a.2, a.10; b.3	eRx related functionality
eTransX eTXChange; eTransX eTX HEMI	170.314.b.1, b.2	DIRECT transport
CQMSolution	170.314.c.1, c.2, c.3	CQM calculation and QRDA generation

☐ No additional software required

3.2.2 Test Tools

Test Tool	Version
[x] Cypress	2.6.1
[x] ePrescribing Validation Tool	1.0.5
[ ] HL7 CDA Cancer Registry Reporting Validation Tool	1.0.3
[ ] HL7 v2 Electronic Laboratory Reporting (ELR) Validation Tool	1.8.2
[ ] HL7 v2 Immunization Information System (IIS) Reporting Validation Tool	1.8.2
[x] HL7 v2 Laboratory Results Interface (LRI) Validation Tool	1.7.2
[ ] HL7 v2 Syndromic Surveillance Reporting Validation Tool	1.7.2
[x] Transport Testing Tool	181
[x] Direct Certificate Discovery Tool	3.0.4
[ ] Edge Testing Tool	0.0.5

[ ] 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*]

[x] 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)	[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)(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
(b)(8)(i)	[ ] §170.207(i) The code set specified at 45 CFR 162.1002(c)(2) (ICD-10-CM) for the indicated conditions	[ ] §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*]	
(e)(1)(ii)(A)(2)	[ ] §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*]	
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)

Criterion #	Standard Successfully Tested

☐ 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)
☐ (e)(1)	View, download and transmit data to a third party utilizing the Edge Protocol IG version 1.1
☐ (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)
☐ (f)(7)	Ambulatory setting only – transmission to public health agencies – syndromic surveillance - Create Data Elements
☐ 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)	1.3	1.5	☒ (c)(3)	1.11	1.11
☐ (a)(2)	1.2		☐ (d)(1)	1.2	
☐ (a)(3)	1.2	1.4	☐ (d)(2)	1.6	
☐ (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)	1.3		☐ (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)	1.11	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	1.3
☐ (a)(16) *Inpt. only*	1.3	1.2	☐ (f)(3)	1.3	1.3
☐ (a)(17) *Inpt. only*	1.2		☐ (f)(4) *Inpt. only*	1.3	1.3
☐ (a)(18)	1.1	1.5	☐ (f)(5) *Amb. only*	1.2	1.2
☐ (a)(19)	1.1	1.5			
☐ (a)(20)	1.1	1.5	☐ (f)(6) *Amb. only*	1.4	1.4
☒ (b)(1)	1.7	1.4			
☒ (b)(2)	1.4	1.6	☐ (f)(7) *Amb. only*	1.1	
☐ (b)(3)	1.4	1.4	☐ (g)(1)	2.0	2.0
☐ (b)(4)	1.3	1.4	☒ (g)(2)	2.0	2.0
☒ (b)(5)	1.4	1.2	☐ (g)(3)	1.4	
☐ (b)(6) *Inpt. only*	1.3	1.3	☐ (g)(4)	1.2	
☒ (b)(7)	1.4	1.7	☐ (h)(1)	1.1	
☐ (b)(8)	1.2	1.2	☐ (h)(2)	1.1	
☐ (b)(9)	1.1	1.1	☐ (h)(3)	1.1	
☒ (c)(1)	1.11	1.11			
☒ (c)(2)	1.11	1.11			

Criteria #	Version		Criteria #	Version	
	TP**	TD***		TP	TD

☐ 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 the CMS eCQM Library (Navigation: June 2014 and April 2014 Updates)

Ambulatory CQMs							
CMS ID	Version	CMS ID	Version	CMS ID	Version	CMS ID	Version
[x] 2	v4	[ ] 90		[x] 136	v4	[x] 155	v3
[ ] 22		[ ] 117		[x] 137	v3	[ ] 156	
[ ] 50		[ ] 122		[x] 138	v3	[ ] 157	
[ ] 52		[ ] 123		[ ] 139		[ ] 158	
[ ] 56		[ ] 124		[ ] 140		[x] 159	v3
[ ] 61		[ ] 125		[ ] 141		[x] 160	v3
[ ] 62		[ ] 126		[ ] 142		[x] 161	v3
[ ] 64		[ ] 127		[ ] 143		[ ] 163	
[ ] 65		[ ] 128		[ ] 144		[ ] 164	
[ ] 66		[ ] 129		[ ] 145		[ ] 165	
[x] 68	v4	[ ] 130		[ ] 146		[ ] 166	
[x] 69	v3	[ ] 131		[ ] 147		[ ] 167	
[ ] 74		[ ] 132		[ ] 148		[x] 169	v3
[ ] 75		[ ] 133		[ ] 149		[x] 177	v3
[ ] 77		[ ] 134		[ ] 153		[ ] 179	
[x] 82	v2	[ ] 135		[ ] 154		[ ] 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)(11)	☐ (a)(18)	☐ (b)(6)
☐ (a)(3)	☐ (a)(12)	☐ (a)(19)	☐ (b)(8)
☐ (a)(4)	☐ (a)(13)	☐ (a)(20)	☐ (b)(9)
☐ (a)(5)	☐ (a)(14)	☐ (b)(2)	☐ (e)(1)
☐ (a)(6)	☐ (a)(15)	☐ (b)(3)	☐ (e)(2)
☐ (a)(7)	☐ (a)(16)	☐ (b)(4)	☐ (e)(3)
☐ (a)(9)	☐ (a)(17)	☐ (b)(5)	

☒ Automated Numerator Recording was not tested

3.2.8.2 Automated Measure Calculation

Automated Measure Calculation Successfully Tested			
☒ (a)(1)	☒ (a)(11)	☐ (a)(18)	☐ (b)(6)
☒ (a)(3)	☒ (a)(12)	☐ (a)(19)	☐ (b)(8)
☒ (a)(4)	☒ (a)(13)	☐ (a)(20)	☐ (b)(9)
☒ (a)(5)	☒ (a)(14)	☒ (b)(2)	☐ (e)(1)
☒ (a)(6)	☒ (a)(15)	☒ (b)(3)	☐ (e)(2)
☒ (a)(7)	☐ (a)(16)	☒ (b)(4)	☐ (e)(3)
☒ (a)(9)	☐ (a)(17)	☒ (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), (a)(18), (a)(19), (a)(20), (b)(3), (b)(4), (b)(9).

**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

5205 Colley Ave.

Norfolk, VA 23508

(757) 213-5960

www.welligent.com

Subject: Usability Testing

October 22, 2015, 2015

To Whom It May Concern.

For the usability testing related to our Stage 2 Meaningful Use Certification, we followed the NIST-7741 standard.

Oct 22, 2015

Charles P. Sutelan, CEO

Welligent Inc.

welligent
Wherever You Are.

The Drummond Group

To Whom It May Concern:

May 14, 2015

Attached is our ONC-ATL- EHR Testing report – 'MU2_Usability_CheckList_and_Report_May142015.'

I attest to the veracity and authenticity of the usability report.

Barbara Klear

May 14, 2015

Barbara Klear
Director of Quality Assurance

EHR Usability Test Report of Welligent 8(c) Interim Release: Q1

EHR:	Welligent
Version:	8(c) Interim Release: Q1
Date of Usability Test:	May 4-6, 2015
Date of Report:	May 14, 2015
Report Prepared By:	Barbara Klear, Director of Quality Assurance Welligent, Inc 757-231-5960, x5946 5205 Colley Avenue Norfolk, VA 23508

Usability Report Checklist

Requirement *(Please also indicate if any of the requirements are separate appendices to the report)*	**Indicated page(s) or section**
Name and version of the product	Page: 1
User-Centered Design Process explained or cited (can be in separate document/letter; see **Error! Reference source not found.** section above)	Page: 5
Date and location of the usability test	Page: 1
Test Environment	Pages: 8-9
Description of intended users	Page: 7

Total number of participants (How many overall, or how many per given task if each is different, ensuring minimum is met. Ensure it is indicated if they are 'Admin Only' users) NOTE: Minimum number of participants is 5 for all tests except admin tasks of configuration of clinical decision support interventions and drug-drug severity settings. For configuration of clinical decision support interventions and drug-drug severity settings, minimum number of participants is 2	Page: 7
Description of participants - Indicate their experience and demographic characteristics.	Page: 7 & 15
All selected participants match the previously stated description of the intended users (clearly indicated)	Page: 7
Description of the user tasks that were tested (Including some level of detail on the expected user path in the EHR not just a list of the ONC criteria task names. This can also be provided with including blank task evaluation sheets with detailed user path descriptions) ***IMPORTANT*** *– EACH of the criteria noted in this checklist MUST be tested for criteria to which you are seeking certification. For example, all six of the CDS interventions must be individually tested along with testing of accessing diagnostic resources and CDS configuration*	Pages: 21-38 See each below in the blank test evaluation sheets.
Selection of user path for tasks is prioritized in accordance with identifying the risk associated with any possible user errors (should be indicated clearly)	Pages: 21-38 See each below in the blank test evaluation sheets.
EVALUATED TASKS CPOE (314.a.1) • 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	 Page: 21 Page: 21 Page: 21 Page: 22 Page: 22 Page: 22 Page: 23 Page: 23 Page: 23

Drug-drug, drug-allergy interactions checks (314.a.2) • Create drug-drug and drug-allergy interventions prior to CPOE completion • Adjustment of severity level of drug-drug interventions (may be an admin type function)	Page: 25 Page: 25
Medication list (314.a.6) • Record Medication List • Change Medication List • Access Medication List	Page: 26 Page: 26 Page: 26
Medication allergy list (314.a.7) • Record Medication Allergy List • Change Medication Allergy List • Access Medication Allergy List	Page: 24 Page: 24 Page: 24
Clinical decision support (314.a.8) • 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)	Page: 27 Page: 28 Page: 28 Page: 29 Page: 30 Page: 31 Page: 32 Page: 33 Page: 34
eMAR (314.a.16) Inpatient Only • Using assistive technology, verify the right patient, medication, dose, route and time.	Page: N/A
Electronic prescribing (314.b.3) • Create prescriptions	Page: 35

Clinical information reconciliation (314.b.4) • 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	Page: 36 Page: 37 Page: 38
List of the specific metrics captured during the testing for effectiveness, efficiency and satisfaction	Page: 6
CONFIRM: Effectiveness and efficiency were evaluated and provided results match metrics indicated	Page: 10-11
Data scoring section	Page: 13-14
Results of the test and data analysis	Page: 13-14
Test results section(s) provide an analysis of the • Use • Tested performance • Error rates	Page: 13-14
User tasks employed in the study are prioritized in accordance with the risk associated with user. NOTE – This is a common error. If the word 'risk' is not in usability report, it is likely that the tasks are not prioritized in accordance with error risk.	Pages: 21-38 See each below in the blank test evaluation sheets.
Major test findings	Page: 14
Identified area(s) of improvement(s)	Page: 14

EXECUTIVE SUMMARY

A usability test of Welligent, Version 8(c), Interim Release Q1, a behavioral health electronic health system, was conducted on May 4-6, 2005 in Norfolk, VA and administered by Barbara Klear, Welligent Director of Quality Assurance. 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). The user-centered design process and the report based on ISO/IEC 25062:2006 Common Industry Format for Usability Test Reports.

During the usability test, five users matching the target demographic criteria served as participants and used the EHRUT in simulated, but representative tasks. The e-prescribe task require the participants to use another application – Emdeon's E-Prescribe. The E-Prescribe application interacted with the Welligent database.

This study collected performance data on seven tasks:

1. CPOE - § 170.314.(a)(1)
2. Drug-drug, drug-allergy interactions checks - § 170.314.(a)(2)
3. Medication List – § 170.314.(a)(6)
4. Medication Allergy List - § 170.314.(a)(7)
5. Clinical Decision Support - § 170.314.(a)(8)
6. Electronic prescribing - § 170.314.(b)(3)
7. Clinical information reconciliation - MU §170.314 (b) (4)

During the timed, one-on-one usability test, each participant was greeted by the administrator and asked to review and sign an informed consent (Appendix 3) and non-disclosure (Appendix 4) forms. Participants had varying degrees of prior experience with EHRs.

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 recorded user performance data on paper and electronically. The administrator did not give the participant assistance in how to complete the task.

The following types of data were collected for each participant:

1. Number of tasks successfully completed within the allotted time without assistance
2. Time to complete the tasks
3. Number and types of errors
4. Path deviations
5. Participant's verbalizations
6. 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. There was no compensation for their time.

Specific Metrics
The following metrics were recorded during the testing:

1. Effectiveness - tasks were evaluated for how accurately they were completed, and how often they produce errors. Each task was assigned a number of steps and each step was rated as to whether the user successfully completed it or produced an error.
2. Efficiency - each task was timed based on use of the system by other staff. The amount of time was then multiplied by a factor of 1.5 to account with the testing participant's unfamiliarity of the new modules and screens.
3. Satisfaction - a post survey (System Usability Scale) was given to each user where they rated each item from Strongly Disagree to Strongly Agree.

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

Major findings

Users were familiar with the system, but not with most of the screens used for the test. Users followed the workflow with ease. There was some variation with providing the date asked for. Most users had problems using the Emdeon screens for the actual e-prescribe task. The Emdeon screen had an entirely different look and feel than the Welligent screens. All participants completed their assigned tasks. There were no failures or 'not completed.'

Areas for improvement
The template used for this study suggested that the participants not think aloud. We believe that commenting as they moved through the task could turn into actionable redesign recommendations.

INTRODUCTION

The EHRUT tested for this study was the Welligent Version $8^{(c)}$, Interim Release Q1, behavioral health software. Designed to chart assessments, treatment plans, and progress notes for behavioral health providers in community-based behavioral health and institutional facilities, the EHRUT is a web-based application consisting primarily of clinical documentation and billing functions. The usability testing attempted to represent realistic exercises and conditions.

The Emdeon E-Prescribe module was also accessed. The version or release is not known.

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 User Test (EHRUT). . To this end, measures of effectiveness, efficiency and user satisfaction, such as specific tasks and time on tasks, were captured during the usability testing.

PARTICIPANTS

A total of five participants were tested on the EHRUT. Participants in the test were a variety of non-health care providers with varying degrees of EHR experience. Participants are employees of Welligent, Inc., but have had no involvement with the development of the application. Most of the tasks involved new components that have not yet been released. The participants were not compensated for their time.

The recruited participants had a mix of backgrounds. 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. Participants were recruited based on EHR familiarity, but not with the screens/tasks used.

Table 1

Participant	*Gender*	*Age*	*Occupation*	*Admin User?*
001	Female	40-50	Project Manager Director	Yes
002	Female	40-50	Project Manager	Yes
003	Female	40-50	Customer Support Manager	No
004	Female	40-50	Product Support Manager	No
005	Female	40-50	Billing Specialist	No

All participants recruited participated. There were no no-shows.

Participants were scheduled for 60 minute sessions with a minimum of 20 minutes between each session for the administrator to reset systems to proper test conditions. A calendar was used to keep track of the participant schedule, and a Word document for each participant's demographic characteristics .

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 the EHR being tested for Meaningful Use Stage 2. 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:

1. Number of tasks successfully completed within the allotted time without assistance
2. Time to complete the tasks
3. Number and types of errors
4. Path deviations
5. Participant's verbalizations (comments)
6. Participant's satisfaction ratings of the system

A number of tasks were constructed that would be realistic and representative of the kinds of activities a user might do with this EHR for Meaningful Use. Tasks were selected based on Meaningful Use testing criteria.

PROCEDURES

Upon arrival, participants were greeted and assigned a participant ID. Each participant reviewed and signed informed consent and non-disclosure forms.

The usability testing staff conducting the test was an experienced administrator with 17 years of EHR training experience and Masters-level courses in Statistics and Tests & Measurements.

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.

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.

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.

Following the session, the administrator gave the participant the post-test questionnaire (e.g., the System Usability Scale, see Appendix 2), 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.

TEST LOCATION

The test facility was a room at the Welligent headquarters. Each participant had a scheduled time and arrived at that time. Only the participant and administrator were in the test room. 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.

TEST ENVIRONMENT

The EHRUT would typically be used in a behavioral health community or institutional setting.

In this instance, the testing was conducted in an office in the Welligent headquarters. For testing, the computer used was a Dell PC running Windows 7 OS.

The participants used a mouse and keyboard when interacting with the EHRUT.

The monitor was set to a default Windows theme used a 1366 x 768 resolution with standard color settings. The application was set up by the administrator.

The application itself used a test database in a development environment on a LAN 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).

TEST FORMS AND TOOLS

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

- Informed Consent
- Non-disclosure form
- Moderator's Guide
- Post-test Questionnaire

Examples of these documents can be found in Appendices 2-5 respectively. The Moderator's Guide was devised so as to be able to capture required data.

PARTICIPANT INSTRUCTIONS

The administrator reads the following instructions aloud to the each participant (also see the full moderator's guide in Appendix 5:

> *Thank you for participating in this study. Our session today will last less than 60 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 or 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 am not a developer for this system, so please be honest with your opinions.*
>
> *The product you will be using today is a behavioral health electronic health record being modified to meet Meaningful Use requirements. Some of the data may not make sense as it is placeholder data.*
>
> *Do you have any questions or concerns?*

Following the procedural instructions, participants were shown the EHR and as their first task, were given time to review 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 task. I will ask you your impressions about the task when Participants were then given five tasks to complete. Tasks are listed in the moderator's guide in Appendix 5.

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

DATA SCORING

The following table (Table 3) details how tasks were scored, errors evaluated, and the time data analyzed.

Table 3

Measures	Rationale and Scoring
Effectiveness: Task Success	A task was counted as a 'Success' if the participant was able to achieve the correct outcome, without assistance, within the time allotted on a per task basis. The total number of successes were calculated for each task and then divided by the total number of times that task was attempted. The results are provided as a percentage. Task times were recorded for successes. Observed task times divided by the optimal time for each task is a measure of optimal efficiency. Optimal task performance time, as benchmarked by expert performance under realistic conditions, was recorded when constructing tasks. Target task times in the Moderator's Guide were developed by using the mean time of the optional performance of three users familiar with the path and screens and multiplying by 1.25 to allow for a time buffer because the participants are presumably not trained to expert performance.

Effectiveness: Task Failures	If the participant abandoned the task, did not reach the correct answer or performed it incorrectly, or reached the end of the allotted time before successful completion, the task was counted as 'Not Completed.' No task times were taken for errors. The total number of errors was calculated for each task and then divided by the total number of times that task was attempted. Not all deviations would be counted as errors. This should also be expressed as the mean number of failed tasks per participant. On a qualitative level, an enumeration of errors and error types should be collected.
Efficiency: Task Deviations	The participant's path (i.e., steps) through the application was recorded. Deviations occur if the participant, for example, went to a wrong screen, clicked on an incorrect menu item, followed an incorrect link, or interacted incorrectly with an on-screen control. This path was compared to the optimal path. The number of steps in the observed path is divided by the number of optimal steps to provide a ratio of path deviation.
Efficiency: Task Time	Each task was timed from when the administrator said 'Begin' until the participant said, 'Done.' If he or she failed to say 'Done,' the time was stopped when the participant stopped performing the task. Only task times for tasks that were successfully completed were included in the average task time analysis. Average time per task was calculated for each task. Variance measures (standard deviation and standard error) were also calculated.
Satisfaction: Task Rating	Participant's subjective impression of the ease of use of the application was measured by administering both a simple post-task question as well as a post-session questionnaire. After each task, the participant was asked to rate 'Overall, this task was:' on a scale of 1 (Very Difficult) to 5 (Very Easy). Common convention is that average ratings for systems judged easy to use should be 3.3 or above. To measure participants' confidence in and likeability of the Welligent EHR overall, the testing team administered the System Usability Scale (SUS) post-test questionnaire. Questions included, 'I think I would like to use this system frequently,' 'I thought the system was easy to use,' and 'I would imagine that most people would learn to use this system very quickly.' See full System Usability Score questionnaire in Appendix 2.

RESULTS

DATA ANALYSIS AND REPORTING

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. There were no exclusions. There were no testing irregularities or issues that affected data collection or interpretation of results.

The usability (effectiveness and efficiency) testing results for the EHRUT are detailed below (see Table 4).

Table 4

Measure	N	Task Success	Path Deviation	Task Time (Seconds)	Errors
	#	Mean (SD)	Deviations (Observed/Optimal)	Optimal/ Mean (SD)	Mean (SD)
1. CPOE					
• Medication Order	5	5	.375/8	180/131	.375
• Lab Order	5	5	.08/12	180/135	.08
• Radiology/ Imaging Order	5	5	.17/12	180/124	.17
2. Medication Allergy	5	5	.45/11	220/174	.45
2. Drug-drug, drug-allergy interaction checks	5	5	.5/6	120/103	.5
					.22
3. Medication List	5	5	.22/18	220/190	
4. Clinical Decision Support	5	5			
• Problem List	5	5	.09/11	180/144	.09
• Medication List	5	5	.15/20	240/192	.15
• Medication Allergy List	5	5	.00/6	90/74	.00
• Demographics	5	5	.12/17	150/112	.12
• Lab Tests and Results	5	5	.47/19	120/119	.47
• Vital Signs	5	5	.31/13	120/102	.31
• Identify User Diagnostic and Therapeutic Reference Information	5	5	.00/5	90/76	.00
• Configuration of CDS Interventions by user	2	2	.33/21	240/215	.33
5. E-Prescribing	5	4	.46/24	360/320	.46
6. Clinical Information Reconciliation	5	5	.31/13	120/98	.31

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

Table 4

Item	1-Strongly Disagree	2	3	4	5-Strongly Agree	Mean
1. I think I would like to use this system frequently.				1	4	4.8
2. I found this system unnecessarily complex.	3	2				1.4
3. I thought the system was easy to use.	3	1	1			1.0
4. I think I would need the support of a technical person to use this system.	3	1	1			1.0
5. I found the various functions in this system were well integrated.					5	5.0
6. I thought there was too much inconsistency in this system.	4	1				1.0
7. I imagine that most people would learn to use this system.					5	5.0
8. I found the system very cumbersome to use.	4	1				1.0
9. I felt very confident using the system.			1		4	4.8
10. I needed to learn a lot of things before I could get going with this system.	3	2				1.4

DISCUSSION OF THE FINDINGS

EFFECTIVENESS

All participants found success. Participants did not have antipsychotic drug knowledge which led to some hesitation in prescribing.

EFFICIENCY

The participants commented that the system was easy intuitive and easy to navigate. No participant failed to complete a task. In a few cases, the participant realized a incorrect response and corrected before the task time was up.

SATISFACTION

Participants reported a most positive overall impression of the system.

AREAS OF IMPROVEMENT

We could not identify any system design areas that needed significant of major improvement. Users familiar with entering data into a computer and with knowledge of the subject area should have no difficulty in navigating the system.

APPENDICES

The following appendices include supplemental data for this usability test report. Following is a list of the appendices provided:

1. Participant demographics
2. System Usability Scale Questionnaire
3. Informed Consent Form
4. Non-Disclosure Agreement (NDA)
5. Example Moderator's Guide

Appendix 1: Participant Demographics

Following is an overview of the participants in this study.

Gender

Men	0
Women	5
Total	5

Age

40-50	5
Total	5

Occupation/Role

Project Manager	2
Training Manager	1
Support Manager	1
Billing Specialist	1
Total	5

Years of Experience Using EHR

4	2
10	2
15	1
Total	5

Appendix 2: System Usability Scale Questionnaire

Welligent Meaningful Use EHR Usability Study

Participant # _____

Date: _____

SYSTEM USABILITY SCALE QUESTIONNAIRE

Circle your answer.

	Strong Disagree				Strong Agree
1. I think I would like to use this system frequently.	1	2	3	4	5
2. I found this system unnecessarily complex.	1	2	3	4	5
3. I thought the system was easy to use.	1	2	3	4	5
4. I think I would need the support of a technical person to use this system.	1	2	3	4	5
5. I found the various functions in this system were well integrated.	1	2	3	4	5
6. I thought there was too much inconsistency in this system.	1	2	3	4	5
7. I imagine that most people would learn to use this system.	1	2	3	4	5
8. I found the system very cumbersome to use.	1	2	3	4	5
9. I felt very confident using the system.	1	2	3	4	5
10. I needed to learn a lot of things before I could get going with this system.	1	2	3	4	5

Appendix 3: Informed Consent Form

Informed Consent – Welligent EHR Meaningful Use Usability Study

Welligent, Inc. 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 60 minutes.

Agreement

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

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 Welligent, Inc. 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.

Participant's printed name: _____

Signature: _____ **Date:** _____

Appendix 4: Non-Disclosure Agreement

Welligent Meaningful Use EHR Usability Study

Non-Disclosure Agreement

THIS AGREEMENT is entered into as of _____between

_____('the Participant') and the testing organization

Welligent, Inc. located at 5205 Colley Ave, Norfolk, VA 23505.

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 Welligent, Inc., 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 Welligent, Inc. 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 receive monetary compensation for feedback and will not disclose this confidential information obtained today to anyone else or any other organizations.

Participant's printed name: _____

Signature: _____ **Date:** _____

Appendix 5: Administrator's/Moderator's Guide

Participant # _____

Welligent Meaningful Use EHR Usability Study

***EHR* Usability Test**

Administrator _____

Date _____ Time _____ Location _____

Thank you for participating in this study. Our session today will last less than 60 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 or 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 am not a developer for this system, so please be honest with your opinions.

The product you will be using today is a behavioral health electronic health record being modified to meet Meaningful Use requirements. Some of the data may not make sense as it is placeholder data.

Do you have any questions or concerns?

Preliminary Questions

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.

Task 1: CPOE - § 170.314.(a)(1)

Take the participant to the starting point for the task.

A. *Task 1A - Medication Order*

Task Risk Priority: 5

1. The patient has Tylenol prescribed as PRN.
    a. Access: Locate this prescription and review the 'Special Instructions.'
    b. Change: Modify the order by entering and potential side effects. ***Save*** and ***Close***.

Optimal Path: *Open patient chart>Click Medications> Click the 'edit' icon to open Tylenol. Review 'Special Instructions.'* Enter 'Potential Side Effects.' ***Save*** and ***Close***.

Task Time: 180 seconds

Success:
___ Easily completed
___ Completed with difficulty or help (Describe below)
___ Not completed

Time to Complete: _____

Number of Steps: ____8____ Correct: _____ Errors: _____

Participant Comments:

Administrator / Note taker Comments:

B. *Task 2B - Laboratory Order*

Task Risk Priority: 4

1. On her last visit, you sent patient to get a colonscopy.
    a. Access: Locate these results and review the notes of the results.
    b. Change: Modify the order by entering the number of days that the patient needs to be retest. Save and Close.
2. Enter: Close this record and enter a new Lab by clicking New.
    - Select 'Test Type' = Lab. ***Search***.
    - Select a Lab. ***Next***.
    - Enter 'Fasting Instructions.' ***Save***.

Optimal Path:

- *Patient chart is open>Click Labs> Click the 'edit' icon to open the colonscopy test. Review 'Results' and 'Results Details'*
- *Patient chart is open>Click Labs> Click the **New**. Select a Lab Test as 'Test Type.' Select a Lab and click **Next**. Enter 'Fasting Instructions' and click **Save**.*

Task Time: 225 seconds

Success:
___ Easily completed
___ Completed with difficulty or help (Describe below)
___ Not completed

Time to Complete: _____

Number of Steps: ___12_____ Correct: _____ Errors: _____

Participant Comments:

Administrator / Note taker Comments:

C. *Task 2C – Radiology/Imaging Order*

Task Risk Priority: 4

1. Last November, you sent *Patient* to get an X-Ray of the right ankle.
    a. Access: Locate these results and review the notes of the results.
    b. Change: Modify the order by entering 'Special Instructions' for the patient. ***Save*** and ***Close***.
2. Enter: Close this record and enter a new Radiology event by clicking New.
    - Select 'Test Type' = Radiology. ***Search***.
    - Select what is to be reviewed. ***Next***.
    - Enter that is 'Entered as CPOE.' ***Save***.

Optimal Path:

- *Patient chart is open>Click Labs> Click the 'edit' icon to open the right ankle X-Ray. Review 'Results' and 'Results Details'*
- *Patient chart is open>Click Labs> Click the **New**. Select a Lab Test as 'Radiology.' Select what is to be X-Rayed and click **Next**. Enter by checking 'Entered as CPOE ' and click **Save**.*

Task Time: 180 seconds

Success:
___ Easily completed
___ Completed with difficulty or help (Describe below)
___ Not completed

Time to Complete: _____

Number of Steps: ____12____ Correct: _____ Errors: _____

Participant Comments:

Administrator / Note taker Comments:

Task 2: Medication Allergy - § 170.314.(a)(7) and Drug-drug, drug-allergy interactions checks - §170.314.(a)(7)

Go to the patient's Allergies.

A. Task 2A – Medication Allergy:

Task Risk Priority: 5

1. Allergies
    a. Access: Review the list of allergies and open quetiapine.
    b. Change: Modify the allergy changing the severity from moderate to severe. ***Save*** and ***Close***.
2. Record: Enter a new allergy based on the medication Seroquel.
    - Select 'Drug/Medication' as type. Search for Seroquel. Select 'Severe' for Severity. ***Save*** and ***Close***.

Optimal Path:

- *The patient chart is open>Click the 'edit icon' to select Quetiapine>'Severity' – change from Moderate to Severe.* ***Save*** and ***Close.***
- *The patient chart is open>Click* ***New****>Select 'Allergy Type' as 'Drug/Medication'>search for Seroquel>'Severity' – select 'Severe.'* ***Save*** and ***Close.***

Task Time: 220 seconds

Success:
___ Easily completed
___ Completed with difficulty or help (Describe below)
___ Not completed

Time to Complete: _____

Number of Steps: ____11____ Correct: _____ Errors: _____

Participant Comments:

Administrator / Note taker Comments:

B. Task 2B: Drug-drug, drug-allergy interaction check

Task Risk Priority: 5

1. Create: Task 2A.2 - Review patient's allergies using the Alerts icon. Note there are allergies for the brand name Seroquel and for the drug quetiapine.
2. Adjustment of severity: Task 2A.1.b –

Optimal Path: *The patient chart is open>Observe patient's alert icons. Review the patient's allergies (Record Navigator>Allergies) Click the 'edit' icon to open Quetiapine. Change the 'Severity' from Moderate to Severe.* ***Save*** *and* ***Close****.*

Task Time: 120 seconds

Success:
___ Easily completed
___ Completed with difficulty or help (Describe below)
___ Not completed

Time to Complete: _____

Number of Steps: ___6_____ Correct: _____ Errors: _____

Participant Comments:

Administrator / Note taker Comments:

Task 3: Medication List - § 170.314.(a)(6)

Go to the patient's Medications.

A. Task 1A – Medication List:

Task Risk Priority: 4

1. Medications
    a. Access: Review the list of medications and open Ventolin.
    b. Change: Modify the prescription order by entering the number of refills allowed. ***Save*** and ***Close***.
2. Enter: Enter a new Medication that is prescribed by another physician.
    - Enter 'Restasis.' Enter that this medication is to be reconciled.
    - ***Save*** and ***Close***

Optimal Path:

- *The patient chart is open> Go to 'Medications'>click the 'edit icon' to Select Ventolin>Enter '# of Refills'.* ***Save*** and ***Close.***
- *The patient char is open>Go to 'Medications'>Click* ***New****>Search for Restasis>Complete required fields>Check 'Medication Reconciled.'*

Task Time: 220 seconds

Success:

___ Easily completed
___ Completed with difficulty or help (Describe below)
___ Not completed

Time to Complete: _____

Number of Steps: ___18_____ Correct: _____ Errors: _____

Participant Comments:

Administrator / Note taker Comments:

Task 4: Clinical Decision Support - § 170.314.(a)(8)

Take the participant to the starting point for the task.

A. Task 3A: Problem List Interventions

Task Risk Priority: 4

Clinical Decision Support Rule: Patients 18 or older with a diagnosis of major depressive disorder should have an assessment for suicide risk.

Patients ages 6 through 17 who has a diagnosis of any form of depressive condition need to be given a Suicide Risk Assessment. Search for Suzy Drummond and open her chart. What do you notice about Suzy's reminders? Click the 'edit' icon to review the rule details. Close. Go to 'Problems/Conditions' in Suzy's chart to review her diagnosis. Is there a diagnosis for a depressive condition? Go to 'Assessment Instruments.' Does Suzy have a Suicide Risk Assessment? Does one need to be completed?

Optimal Path: *Patient Search>Review Reminders>Review due reminder>Go to 'Problems/Conditions'>Look for a depressive condition>Go to 'Assessment Instruments'>Review list*

Task Time: 180 seconds

Success:
___ Easily completed
___ Completed with difficulty or help (Describe below)
___ Not completed

Time to Complete: _____

Number of Steps: ___11_____ Correct: _____ Errors: _____

Participant Comments:

Administrator / Note taker Comments:

B. Task 3B: Medication List Interventions

Task Risk Priority: 4

Clinical Decision Support Rule: Patients on Seroquel Should have Blood Sugar Level Monitored. High blood sugar can happen if you have diabetes already or if you have never had diabetes.

Open the patient's chart. If the patient has diabetes and is on Seroquel, there will be a reminder to take a glucose screen.

Optimal Path: *Open chart>Review 'Reminders' to see if one for a glucose test> Go to Lab Tests>Click **New**>Select Lab Test as 'Type'>Select the type of glucose screen to be performed>Click **Next**>Conduct screen and chart results>**Save*** and ***Close***

Task Time: 240 seconds

Success:
___ Easily completed
___ Completed with difficulty or help (Describe below)
___ Not completed

Time to Complete: _____

Number of Steps: ___20_____ Correct: _____ Errors: _____

Participant Comments:

Administrator / Note taker Comments:

C. Task 3C: Medication Allergy List Interventions

Task Risk Priority: 4

Clinical Decision Support Rule: Medication Allergies Should be Evaluated Every Six Months

When the user opens the patient chart, the reminder rule will display the date of the 6-month test. The user will then review the allergy as needed and enter the date of the review.

Optimal Path: *Open chart>Review reminder for Allergy Retest and the date of the retest>Go to Allergies and enter the date of the retest>* ***Save*** and ***Close****.*

Task Time: 90 seconds

Success:
___ Easily completed
___ Completed with difficulty or help (Describe below)
___ Not completed

Time to Complete: _____

Number of Steps: ___6_____ Correct: _____ Errors: _____

Participant Comments:

Administrator / Note taker Comments:

D. Task 3D: Demographics List Interventions

Task Risk Priority: 3

Clinical Decision Support Rule: Males over the age of 50 who are at average risk of prostate cancer and are expected to live at least 10 more years should have the PSA Test Yearly

Male patients over 50 need to have a PSA yearly test. When the user opens the patient's chart, there will be a reminder if the test is due.

Optimal Path: *Open chart>Review reminder for New Lab Work for PSA>Go to Lab Tests>Click* ***New****>Select Lab Test as 'Type'>Select the type of PSA screen to be performed>Click* ***Next****>Conduct PSA and chart results>* ***Save*** and ***Close***

Task Time: 150 seconds

Success:
___ Easily completed
___ Completed with difficulty or help (Describe below)
___ Not completed

Time to Complete: _____

Number of Steps: _____ Correct: _____ Errors: _____

Participant Comments:

Administrator / Note taker Comments:

E. Task 3E: Lab Tests and Results Interventions

Task Risk Priority: 4

Clinical Decision Support Rule: Screening should be done yearly for men whose PSA level is 2.5 ng/mL or higher.

Patient has had a PSA screen and had an abnormal PSI (2.5 ng/mL or higher). Patient needs to have an annual screen. When opening chart, user is reminded that the follow-up screen is to be conducted (Lab Work Retest) due to a results of 2.7 ng/mL for the previous screen.

Optimal Path: *Open patient's chart>Review reminders>Note need for follow-up PSA >Go to Labs>**New**>Select Lab Test and **Search**>Select colonoscopy>Complete and **Save** and **Close.***

Task Time: 112 seconds

Success:
___ Easily completed
___ Completed with difficulty or help (Describe below)
___ Not completed

Time to Complete: _____

Number of Steps: ____19____ Correct: _____ Errors: _____

Participant Comments:

Administrator / Note taker Comments:

F. Task 3F: Vital Signs Interventions

Task Risk Priority: 2

Clinical Decision Support Rule: Adult body mass index (BMI) assessment: percentage of patients 18 to 74 years of age who had an outpatient visit and whose BMI was documented during the measurement year or the year prior to the measurement year.

The adult Body Mass Index (BMI) should be calculated each year. An active Clinical Decision Support (CDS) Rule is entered for patients ages 18 to 74. When the user opens the patient chart, the reminder rule will display if the patient has not had height and weight recorded in the past year. The users will then take and chart the height and weight in order to obtain the BMI.

Optimal Path: *Open Chart>Review Reminders>Note CDS Alert for patients needing a BMI>Go to Vitals Monitoring and chart the patient's height and weight.*

Task Time: 120 seconds

Success:
___ Easily completed
___ Completed with difficulty or help (Describe below)
___ Not completed

Time to Complete: _____

Number of Steps: ____13____ Correct: _____ Errors: _____

Participant Comments:

Administrator / Note taker Comments:

G. Task 3G: Identify User Diagnostic and Therapeutic Reference Information

Task Risk Priority: 2

The user will be able to access additional information about the diagnosis. The user will review the patient's Problems/Conditions and be able to review additional information from a website selected by the agency. (Requires admin configuration of the selected website.)

Optimal Path: *Go to Problems/Conditions in the patient's chart>Click the 'edit' icon to open a 'Problem/Dx'>Click the yellow 'info' icon to the right of the 'Problem/Dx' field>View the material.*

Task Time: 90 seconds

Success:
___ Easily completed
___ Completed with difficulty or help (Describe below)
___ Not completed

Time to Complete: _____

Number of Steps: ____5____ Correct: _____ Errors: _____

Participant Comments:

Administrator / Note taker Comments:

H. Task 3H: Configuration of CDS interventions by user

Task Risk Priority: 2

Provide instructions to the user to configure the alert for the Suicide Risk assessment.
Instructions:

- Click on Admin>Clinical Decision Support Setup
- Click ***New Rule***
- Enter the rule name and appropriate fields
- ***Save***
- Assign Roles who should have access to this CDS rule
- ***Save*** and ***Close***

Optimal Path: *Go to Admin>Clinical Decision Support Setup>Click **New**>Enter the CDS rule name and fields appropriate to the rule>**Save**>Click on 'Assigned Roles'>Select the Roles that will implement this rule>**Save** and **Close**.*

Task Time: 240 seconds

Success:
___ Easily completed
___ Completed with difficulty or help (Describe below)
___ Not completed

Time to Complete: _____

Number of Steps: ___21_____ Correct: _____ Errors: _____

Participant Comments:

Administrator / Note taker Comments:

Task 5: Electronic prescribing - § 170.314.(b)(3)]

Task Risk Priority: 5

You have decided to put this patient on the antipsychotic – Seroquel. Patient has an allergy to Seroquel and you will need to change to another medication.

Optimal Path: *The patient chart is open>Click 'Medications'>Click **E-Prescribe**> Click a formulary>Select a prescriber>Enter an Effective Date>Search for a Drug> Enter Seroquel> Find Seroquel>Review the medication list and select a dosage and route>Click View DUR Warnings>Note allergy>Search for Risperdal>Note no allergies>Issue the prescription.*

Task Time: 360 seconds

Success:
___ Easily completed
___ Completed with difficulty or help (Describe below)
___ Not completed

Time to Complete: _____

Number of Steps: ____24____ Correct: _____ Errors: _____

Participant Comments:

Administrator / Note taker Comments:

Task 6: Clinical Information Reconciliation - § 170.314.(b)(4)

A. Task 6A – Reconcile Active Medication List

Risk Priority: 2

This is a new patient. Intake has charted the patient's current medications. New medications need to be prescribed, and the medications need to be reconciled. Do a search for Sally and open her chart. Open Medications. Click ***Reconcile***. Describe what you see.

Optimal Path: *Patient Search>Click* **Search***>>Click 'Medications'> Review the list of medications prescribed during this visit> Click* ***Reconcile****>Click the green plus sign to reconcile the medications>****Save*** *and* ***Close***

Task Time: 120 seconds

Success:
___ Easily completed
___ Completed with difficulty or help (Describe below)
___ Not completed

Time to Complete: _____

Number of Steps: ____13____ Correct: _____ Errors: _____

Participant Comments:

Administrator / Note taker Comments:

B. Task 6A – Reconcile Active Problem List

Risk Priority: 2

This is a new patient. Intake has charted the patient's current problems and conditions. These need to be reconciled with the chart. Do a patient search and open her chart. Open Problems/Conditins. Click ***Reconcile***. Describe what you see.

Optimal Path: *Patient Search>Click* **Search***>>Click 'Problems/Conditions> Review the list of problems and conditions charted during this visit> Click* ***Reconcile****>Click the green plus sign to reconcile >****Save*** *and* ***Close***

C. Task 6A – Reconcile Active Medication Allergy List

Risk Priority: 2

This is a new patient. Intake has charted the patient's current medication allergies. New medications need to be prescribed, and the medication allergies need to be reconciled. Do a patient search and open the chart. Allergies. Click ***Reconcile***. Describe what you see.

Optimal Path: *Patient Search>Click* **Search***>>Click 'Allergies'> Review the list of medication allergies charted> Click* ***Reconcile****>Click the green plus sign to reconcile >****Save*** *and* ***Close***

Task Time: 240 seconds

Success:
___ Easily completed
___ Completed with difficulty or help (Describe below)
___ Not completed

Time to Complete: _____

Number of Steps: ____21____ Correct: _____ Errors: _____

Participant Comments:

Administrator / Note taker Comments:

Final Questions:

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?

Electronic Health Records. Delivered.

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Norfolk, VA 23508

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February 19, 2015

Welligent's Quality Management System Overview

Welligent is following the general structure of an ISO-9001:2008 Quality Management System. We have a solid framework in place that is clearly laid out in Appendix A of this letter. Welligent is following the common business workflow laid out in ISO-9001.

Welligent's executive management has implemented a business process management and implementation review process. There is clearly designed documentation requirements for all projects and implementations. Records are clearly controlled through managed process on Welligent's databases and Welligent's corporate records implementation.

Welligent has implemented a process that focuses on our client and their patient interaction with Welligent application and product implementations. We have designed a process that clearly manages the client's and their constituent's objectives. Additionally, Welligent has a clearly defined method for planning in the following area: configuration, information technology, traceability, contract administration, business planning, vendor planning, and logistics. There are clearly defined roles for responsibilities and authority.

There are detailed steps to control Welligent's resource management. We have in place a procedure for annual planning to assess what business activities and resources are needed to determine and meet Customer requirements. We assess and provide the equipment needed to operate the Welligent's core business operations as part of our capital equipment planning. We plan out our facilities configuration, communication procedures, and data processing capabilities as part of our annual planning process. Further, we Apply appropriate

education, training, skills, and experience to work affecting Welligent's core application and products in accordance with ISO-9001 Quality Management System procedures.

Welligent has in place procedures for managing superior product and service realization. Beginning with a marketing requirements/business plan aimed at determining the requirements and objectives of our core application and products. We apply risk analysis profiles to appropriately analyze the impact of any planned changes or additions to applications and products under development. We manage product development to meet marketing requirements and business plan requirements for each project. Based on these requirements a design for implementing the project is put together. Each design has rigorous methods applied to ensure the product meets specification, is accepted by the customer or modified to enhance the product or application to meet the customer's expectations. This is part of the design review procedure and customer communication. Welligent ensures adequate resources are in place to meet customer demand and Welligent's product deliverables. Welligent has procedures in place to ensure customers expectations with application delivery and performance are constantly assessed and customer feedback or issues are remediated in a timely fashion. The procedures Welligent has incorporated into their Quality Management System insures the accuracy and speed of their delivered application and products.

Welligent applies a significant amount of resources to ensure that design specifications are achieved, that significant amount of time goes into the analysis of current projects and delivered products. Additionally, that there is an emphasis put on the evolution and continual improvement of Welligent's core application and delivered products. We ensure that all products and applications meet the expectations of our customers through ongoing customer engagement. Welligent has an internal auditing process to assess the conformity and effectiveness of the Quality Management System processes on Welligent application and product delivery. Welligent has ongoing processes in place to monitor the conformity of applications and services delivered. Through Welligent's procedures there are steps in place for detection, handling and disposition of nonconforming applications and products. There are procedures in place for the prevention of unauthorized access, processing, or delivery of nonconforming applications and products. Once nonconforming applications are detected there is a rigorous process in place for remediating the issue. Finally, Welligent's most important goal is to ensure that our customers and their patients are happy with our core application or product, so procedures are in place that ensure an ongoing line of communication is in place for delivering on this goal.

Charles P. Sutelan, CEO

Welligent Inc.

welligent
Electronic Health Records. Delivered.

Charles P. Sutelan
CEO
5205 Colley Avenue
Norfolk, Virginia 23508

February 19, 2015

Dear Mr. Isaac,

1. **Are default settings for audit log and audit log status record are enabled by default?**
   Yes. Demographic and clinical fields are all audited by default. Changes made either by users through the software's graphical user interface or by administrators using structured query language are automatically logged using Oracle database triggers. Triggers are linked to tables and fire whenever an insert, update or delete transaction is executed. The Welligent software then automatically logs the name/id of the user making the change, the date/time of the change, the pre-change (before) value and the post-change (after) value. Users are unable to manipulate this audit function or disable it in any way.
   [IN170.314(d)(2)-1.01-1.02]

2. **Is encryption of electronic health information on end-user devices is enabled by default?**
   No. The Welligent EHR is web-based on runs within a standard web-browser. Our software does not store data of any kind on our end-users' computers. In fact, we apply a special pragma ("no-cache") to tell the browser not to store or cache any data on our users' workstations.
   [IN170.314(d)(2)-1.03]

3. **Does the EHR SUT allow a user to disable the following?**
   - audit log
   - audit log status
   - encryption status

   No. Users are unable to disable the audit log features of the system or change the status of any logged transactions. Additionally, users cannot alter or prevent any of the logged data from being encrypted by the database. Encryption is ensured using Oracle's Advanced Security features.

   [IN170.314(d)(2)-2.02 / IN170.314(d)(2)-2.09]

4. **Does the EHR SUT permit any users to delete electronic health information?**
   No. While there are some functions where users may perceive that they are deleting information, these deletions are being written to audit logs. Users are not allowed to permanently delete any demographics or clinical data.
   [IN170.314(d)(2)-3.04]

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5. **Describe how the audit logs are protected from being changed, overwritten or deleted by the EHR technology.**
   The audit logs are protected from modification or deletion through the application logic. Additionally, the audit logs are backed up both to disk and to tape and maintained for an indefinite period.
   [IN170.314(d)(2)-4.01]

6. **Describe how the EHR is capable of detecting whether the audit logs have been altered.**
   Audit logs are monitored by the Oracle database as well as by our database administrators. Any attempts to modify or delete this data results in our security staff being notified. Audit logs can also be compared against backup copies to determine if changes were made.
   [IN170.314(d)(2)-5.01]

Sincerely,

Charles P. Sutelan

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