Safety-Enhanced Design §170.315(g) (3)

EHR Usability Test Report - DrCloudEHR 2020

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

DrCloudEHR 2020

Date of Usability Test: Mar 26 2019

Date of Report: May 28, 2019

Report Prepared by: info@drcloudemr.com

EnSoftek, Inc.

735 SW 158th Ave Beaverton OR 97006

Document Revisions

Date	Version	Author	Comments
2/3/2019	1.0	Balakishore Doddamreddy	Initial Report
2/15/2019	2.0	Balakishore Doddamreddy, Kishore Kumar	Report updated
3/13/2019	2.1	Ramesh Nagul	Sent to Manu Reddy for review
3/25/2019	2.2	Ramesh Nagul	Incorporated changes from feedback
3/27/2019	2.3	Balakishore Doddamreddy	Reviewing and updating results
3/27/2019	2.4	Ramesh Nagul	Incorporated results from team
4/26/2019	2.5	Ramesh Nagul	Incorporated changes from reviewer
5/28/2019	2.6	Ramesh Nagul	Incorporated changes from reviewer

Table of Contents

1. EXECUTIVE SUMMARY

A usability test of **DrCloudEHR 2019** was conducted on Mar 20-21 2019 by members of the EnSoftek Testing and Quality Assurance Team
The usability test followed the NISTIR 7742 User Centered Design approach.[1]
The purpose of this test was to test and validate the usability of the current user interface, and provide evidence of usability in the EHR under Test (EHRUT).

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

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

Task Description	Tasks
Computerized Provider Order Entry (CPOE) – medications	Record Medication Order
CPOE – laboratory	Record Lab Order
CPOE – diagnostic imaging	Record Diagnostic Imaging Order
Enter Medication Allergy	Record Medication Allergy
Drug-drug, Drug-allergy Interaction Checks for CPOE	Trigger a drug-drug interaction alert and explain alert override
Demographics	Record Demographics
Problem List	View patient's chart – Medical Problems
Medication List	View patient's medication history
Medication Allergy List	Enter a medication allergy View a patient's medication allergy list
Clinical Decision Support	Display information links to medication data references
Implantable Device List	Enter an Implantable Device View Patient's Implantable Device List
Clinical Information Reconciliation and Incorporation	Import and Export data from patient's unstructured CCDA

[1] Robert M. Schumacher User Centric. Inc, and Svetlana Z. Lowry Information Access Division Information Technology Laboratory National Institute of Standards and Technology, NISTIR 7741 NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records (November 2010) p. 2-62

Electronic Prescribing	Prescribe a medication

During the 60-minute usability tests, each participant was asked to review and sign an informed consent/release form (included in Appendix 2). Participants had prior experience with the EHRUT from the Health IT Program. Prior to the test, online training was provided to some users along with online documentation and access to videos. The administrator introduced the test, and instructed participants to complete a series of tasks (given one at a time) using the EHRUT. During the testing, the administrator timed the test and, along with the data logger(s) recorded user performance data on paper and electronically. The administrator did not give the participant assistance in how to complete the task.

The following types of data were collected for each participant:

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

All participant data was de-identified – no correspondence could be made from the identity of the participant to the data collected. Following the conclusion of the testing, participants were asked to complete a post- test questionnaire. There was no compensation offered to ensure results are unbiased. Various recommended metrics, in accordance with the examples set forth in the NIST *Guide to the Processes Approach for Improving the Usability of Electronic Health Records*, were used to evaluate the usability of the EHRUT. Following is a summary of the performance and rating data collected on the EHRUT.

The results from the System Usability Scale scored the subjective satisfaction with the system based on performance.[2] ***To be calculated from entire class results***

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

[2] See Tullis, T. & Albert, W. (2008). Measuring the User Experience. Burlington, MA: Morgan Kaufman (p. 149). Broadly interpreted, scores under 60 represent systems with poor usability; scores over 80 would be considered above average.

Major findings & Areas for improvement *Consistency*

- DrFirst is very consistent when adding Medications, Allergic data, Medical problems and Prescriptions.
- DrFirst is very User friendly to the end users and doesn't need any assistance when using the system.

Context

- The 'DrFirst Rcopia is accessible to only users who have the Rcopia user Id created at DrFirst and this cannot be accessed by the patients.

Synchronization

- Medical Problems, Allergies, Medications entered at DrFirst will automatically be synchronized to DrCloudEHR.

Usability

- Reconciliation Process in DrCloudEHR is user friendly. It allows the user to reconcile Medical problems, Allergies and Medications by importing the CCDA file.

2. INTRODUCTION

The EHR Under Test (EHRUT) tested for this study was DrCloudEHR 2019. Designed to present medical information to healthcare providers in ***ambulatory*** settings, the EHRUT serves as a centralized solution that allows providers to document patient health information and facilities' information sharing. The usability testing attempted to represent realistic exercises and conditions.

The purpose of this study was to test and validate the usability of the current user interface, and provide evidence of usability in the EHRUT. To this end, measures of effectiveness, efficiency and user satisfaction, such as task completion time, task success / errors, task efficiency, tester assessment were captured during the usability testing.

3. METHOD

3.1 PARTICIPANTS

A total of 10 participants were tested on the EHRUT. Participants in the test were healthcare providers / healthcare IT students. Participants were recruited by *Columbia University Health IT Certificate Program.* **No compensation was offered**. In addition, participants

had no direct connection to the development of or organization producing the EHRUT. Participants were not from the testing or supplier organization.

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

Participant Identifier	Participant Gender	Participant Age	Participant Education	Participant Occupation/Role	Participant Professional Experience	Participant Computer Experience	Participant Product Experience	Participant Assistive Technology Needs
1	Male	40-45	PostGraduate	Physician	120 months	130 months	36 months	None
2	Male	30-35	PostGraduate	Clinic Admin	120 months	120 months	96 months	None
3	Female	25-30	Graduate	Clinician	84 months	96 months	84 months	None
4	Female	35-40	PostGraduate	Quality Analyst	108 months	120 months	36 months	None
5	Male	30-35	PostGraduate	Quality Analyst	108 months	108 months	96 months	None
6	Male	20-27	Graduate	Quality Analyst	36 months	45 months	24 months	None
7	Male	25-30	Graduate	Quality Analyst	74 months	98 months	30 months	None
8	Male	35-40	Graduate	Quality Analyst	84 months	96 months	72 months	None
9	Female	30-35	Graduate	Clinician	102 months	120 months	84 months	None
10	Male	35-40	PostGraduate	Quality Analyst	120 months	130 months	108 months	None

10 participants (matching the demographics in the section on Participants) were recruited and 10 participated in the usability test. 0 participants failed to show for the study. Participants were scheduled for 1 session of 60 minutes

3.2 STUDY DESIGN

Overall, the objective of this test was to uncover areas where the application performed well – that is, effectively, efficiently, and with satisfaction – and areas where the application failed to meet the needs of the participants. The data from this test may serve as a baseline for future tests with an updated version of the same EHR and/or comparison with other EHRs provided the same tasks are used.

In short, this testing serves as both a means to record or benchmark current usability, but also to identify areas where improvements must be made.

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

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

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

3.3 TASKS

A number of tasks were constructed that would be realistic and representative of the kinds of activities a user might do with this EHR. Tasks were selected based on their frequency of use, criticality of function, and those that may be most troublesome for users.[6].This study collected performance data on 12 tasks typically conducted on an EHR:

Task Description	Tasks
Computerized Provider Order Entry (CPOE) – medications	Record Medication Order
CPOE – laboratory	Record Lab Order
CPOE – diagnostic imaging	Record Diagnostic Imaging Order
Enter Medication Allergy	Record Medication Allergy
Drug-drug, Drug-allergy Interaction Checks for CPOE	Trigger a drug-drug interaction alert and explain alert override
Demographics	Record Demographics
Problem List	View patient's chart – Medical Problems
Medication List	View patient's medication history
Medication Allergy List	Enter a medication allergy View a patient's medication allergy list

Clinical Decision Support	Display information links to medication data references
Implantable Device List	Enter an Implantable Device View Patient's Implantable Device List
Clinical Information Reconciliation and Incorporation	Import and Export data from patient's unstructured CCDA
Electronic Prescribing	Prescribe a medication

3.4 PROCEDURES

Upon arrival, participants were greeted; their identity was verified and matched with a name on the participant schedule. Participants were then assigned a participant ID.[7] Each participant reviewed and signed an informed consent and release form (See Appendix 3). A representative from the test team witnessed the participant's signature.

To ensure that the test ran smoothly, two staff members participated in this test, the usability administrator and the data logger. The usability testing staff conducting the test was experienced usability practitioners with over 10 years of experience, with Bachelor's degree in Computer Science and Commerce.

[6] Constructing appropriate tasks is of critical importance to the validity of a usability test. These are the actual functions, but most tasks contain larger and more fleshed out context that aligns with the sample data sets available in the tested EHR. Please consult usability references for guidance on how to construct appropriate tasks.
[7] All participant data must be de-identified and kept confidential.

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

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

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

Following the session, the administrator gave the participant the post-test questionnaire, the System Usability Scale (see Appendix 4)

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

3.5 TEST LOCATION

Testing was performed remotely using Zoom Video Conferencing. The participant, moderator (Beaverton, Oregon), and data logger all logged in separately to a previously configured Zoom meeting session. Control of the session was passed to the participant logging into the test version of DrCloudEHR 2019 at
(https://qa-win.drcloudemr.com/dc_ehr_qa/interface/login/index.html?rev=1.2&site=muthree) for each of the tasks.

All users were in their own facilities and were able to communicate with each other using the Audio/Video conferencing tools. 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 provided to the participants.

3.6 TEST ENVIRONMENT

The EHRUT would be typically be used in a healthcare office or facility. In this instance, the testing was conducted remotely. The participants used a mouse and keyboard when interacting with the EHRUT.

The EHRUT would be typically be used in a healthcare office or facility. In this instance, the testing was conducted in remotely. For testing, the computer used were desktops running Windows 7 with a 15” monitor, default color settings and a resolution of 1440 x 900. The participants used a mouse and keyboard when interacting with the EHRUT.

The DrCloudEHR 2019 system used a display with a resolution of 1024 x 768. We did not record the display size, but default color settings were used. The application was set up by the EnSoftek according to the vendor's documentation describing the system set-up and preparation. The application itself was running on a Windows 2008 R2 system with IIS and MySQL database backend using a test database on a WAN connection.
Technically, the system performance (i.e., response time) was representative to what actual users would experience in a field implementation. Additionally, participants were instructed not to change any of the default system settings (such as control of font size).

3.7 TEST FORMS AND TOOLS

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

1. Informed Consent
2. Moderator's Guide
3. Usability Testing Closing Comments and Final Questions
4. System Usability Scale Questionnaire

Examples of these documents can be found in Appendices 3-6 respectively. The Moderator's Guide was devised so as to be able to capture required data.

The participant's interaction with the EHRUT was monitored over video/web software running on the moderator machine. Each participant's reactions were monitored and documented.

3.8 PARTICIPANT INSTRUCTIONS

The administrator reads the following instructions aloud to each participant (also see the full moderator's guide in Appendix [B4]):

Thank you for participating in this study. Your input is very important. Our session today will last about 60 minutes. During that time, you will use an instance of an electronic health record system. I will ask you to complete a few tasks using this system and answer some questions. You should complete the tasks as quickly as possible making as few errors as possible. Please try to complete the tasks on your

own following the instructions very closely. Please note that we are not testing you we are testing the system, therefore if you have difficulty all this means is that something needs to be improved in the system. I will be here in case you need specific help, but I am not able to instruct you or provide help in how to use the application.
Overall, we are interested in how easy (or how difficult) this system is to use, what in it would be useful to you, and how we could improve it. I did not have any involvement in its creation, so please be honest with your opinions. All of the information that you provide will be kept confidential and your name will not be associated with your comments at any time.

Following the procedural instructions, participants were shown the EHR and given 10 minutes to explore the system and make comments. Once this task was done the administrator gave the following instructions:

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

Participants should not use a think-aloud protocol during the testing. Excessive verbalization or attempts to converse with the moderator during task performance should be strongly discouraged. Participants will naturally provide commentary, but they should do so, ideally, after the testing. Some verbal commentary may be acceptable between tasks, but again should be minimized by the moderator

Participants were then given the tasks to complete. Tasks are listed in the moderator's guide in Appendix [B4].

3.9 USABILITY METRICS

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

1. Effectiveness of DrCloudEHR 2019 by measuring participant success rates and errors
2. Efficiency of DrCloudEHR 2019 by measuring the average task time and path deviations.

3. Satisfaction with DrCloudEHR 2019 by measuring ease of use ratings

DATA SCORING

The following table details how tasks were scored, errors evaluated, and the time data analyzed. [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, 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 [x] seconds then allotted task time performance was [x * 1.25] seconds. This ratio should be aggregated across tasks and reported with mean and variance scores.
Effectiveness: Task Failures	If the participant abandoned the task, did not reach the correct answer or performed it incorrectly, or reached the end of the allotted time before successful completion, the task was counted as a "Failures." No task times were taken for errors. The total number of errors was calculated for each task and then divided by the total number of times that task was attempted. Not all deviations would be counted as errors.[11] 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.

[3] An excellent resource is Tullis, T. & Albert, W. (2008). Measuring the User Experience. Burlington, MA: Morgan Kaufman. Also see www.measuringusability.com

Efficiency: Task Deviations	The participant's path (i.e., steps) through the application was recorded. Deviations occur if the participant, for example, went to a wrong screen, clicked on an incorrect menu item, followed an incorrect link, or interacted incorrectly with an on-screen control. This path was compared to the optimal path. The number of steps in the observed path is divided by the number of optimal steps to provide a ratio of path deviation. It is strongly recommended that task deviations be reported. Optimal paths (i.e., procedural steps) should be recorded when constructing tasks.
Efficiency: Task Time	Each task was timed from when the administrator said "Begin" until the participant said, "Done." If he or she failed to say "Done," the time was stopped when the participant stopped performing the task. Only task times for tasks that were successfully completed were included in the average task time analysis. Average time per task was calculated for each task. Variance measures (standard deviation and standard error) were also calculated.
Satisfaction: Task Rating	Participant's subjective impression of the ease of use of the application was measured by administering both a simple post-task question as well as a post-session questionnaire. After each task, the participant was asked to rate "Overall, this task was:" on a scale of 1 (Very Difficult) to 5 (Very Easy). These data are averaged across participants. Common convention is that average ratings for systems judged easy to use should be 3.3 or above. To measure participants' confidence in and likeability of DrCloudEHR 2019 overall, the testing team administered the System Usability Scale (SUS) post-test questionnaire. Questions included, "I think I would like to use this system frequently," "I thought the system was easy to use," and "I would imagine that most people would learn to use this system very quickly." See full System Usability Score questionnaire in Appendix 5

Details of how observed data were scored.

4. RESULTS

4.1 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 analysis

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

[12] See Tedesco and Tullis (2006) for a comparison of post-task ratings for usability tests. Tedesco, D. & Tullis, T. (2006) A comparison of methods for eliciting post-task subjective ratings in usability testing. *Usability Professionals Association Conference*, June 12 – 16, Broomfield, CO.

[13] The SUS survey yields a single number that represents a composite measure of the overall perceived usability of the system. SUS scores have a range of 0 to 100 and the score is a relative benchmark that is used against other iterations of the system

Task #	Task Description	Task Success - Mean (%)	Task Success - Standard Deviation (%)	Task Path Deviation - Observed #	Task Path Deviation - Optimal #	Task Time - Mean (seconds)	Task Time - Standard Deviation (seconds)	Task Time Deviation - Mean Observed Seconds	Task Time Deviation - Mean Optimal Seconds	Task Errors Mean(%)	Task Errors - Standard Deviation (%)	Task Rating - Scale Type	Task Rating	Task Rating - Standard Deviation
1	Computerized Provider Order Entry (CPOE) – medications	100	0	10	9	36	9	27	25	0	0	1=Hard, 5=Easy	5	0
2	CPOE – laboratory	100	0	11	10	37	11	26	25	0	0	1=Hard, 5=Easy	5	0
3	CPOE – diagnostic imaging	100	0	12	10	38	13	25	25	0	0	1=Hard, 5=Easy	5	0

4	Enter Medication Allergy	100	0	9	8	34	9	25	25	0	0	1=Hard, 5=Easy	5	0
5	Drug-drug, Drug-allergy Interaction Checks for CPOE	100	0	13	12	44	11	33	30	0	0	1=Hard, 5=Easy	5	0
6	Demographics	100	0	19	17	47	4	43	40	0	0	1=Hard, 5=Easy	5	0
7	Problem List	100	0	8	8	17	0	18	15	0	0	1=Hard, 5=Easy	5	0
8	Medication List	100	0	8	8	18	1	17	15	0	0	1=Hard, 5=Easy	5	0
9	Medication Allergy List	100	0	8	8	18	1	17	15	0	0	1=Hard, 5=Easy	5	0
10	Clinical Decision Support	100	0	10	10	42	7	35	30	0	0	1=Hard, 5=Easy	5	0
11	Implantable Device List	100	0	12	12	26	4	22	20	0	0	1=Hard, 5=Easy	5	0

12	Clinical Information Reconciliation and Incorporation	100	0	19	16	82	0	83	80	0	0	1=Hard, 5=Easy	5	0
13	Electronic Prescribing	100	0	16	15	48	0	48	45	0	0	1=Hard, 5=Easy	5	0

The results scored the subjective satisfaction with the system based on performance.

4.2 DISCUSSION OF THE FINDINGS

EFFECTIVENESS

In general, the EHRUT was found to be effective based on task success of 100%.

EFFICIENCY

We found that average task time for all tasks for 12 of 13 participants was 37 seconds. All participants were able to complete all tasks successfully with a task path deviation ranging from 1-3 clicks. 8% of the tasks took an extra 3 clicks while 15% of the tasks took an extra 2 clicks, 38% took 1 extra click and 39% took 0 (zero) extra clicks. The lowest average Task Path Deviation Percentage (((Observed*100)/Optimal) -100) was 0% and the highest value of 18.75%. With an average Task Path Deviation Percentage of 7.6% all tasks were completed with **92.4%** efficiency.

SATISFACTION

While the tasks were rated as simple there were a number of issues described below that affected user satisfaction.

MAJOR FINDINGS & AREAS FOR IMPROVEMENT

- Consistency
  - Selection. On some screens (e.g. Rx) item selection was shown by a pointer and highlighting. On other screens (e. g. 'Click on Drug / Intolerance') there was no highlighting.
- Icon meaning. On some screens (e.g. 'Allergy / Intolerance') and Rx Drug Stage) the magnifying glass signified a log of activity. On others (e.g. Rx Drug Stage) it signified a review. On others (e.g. Pending Rx) it signified a review AND opportunity for data entry (e.g. Override and notes).
- Context. The 'DrFirst Rcopia Account Status' is an administrative function and not patient specific
- Synchronization
  - Medication & Allergy Data entered in DrFirst Rcopia was synchronized with DrCloudEHR on a timed basis and did not show up immediately when changing context.
- Usability
  - During the Clinical Reconciliation task, the Patient CCDA was displayed in the upper frame. When Immunization was selected in the lower frame, the immunization table was displayed in the upper frame overlaying the Patient CCDA document.

5. APPENDICES

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

1. Participant demographics
2. Non-Disclosure Agreement and Informed Consent
3. Example Moderator's Guide
4. Final Questions & System Usability Scale Questionnaire

Appendix 1: PARTICIPANT DEMOGRAPHICS

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

Gender

Men	[7]
Women	[3]
Total (participants)	[10]

Occupation/Role

Clinicians	[2]
Physician	[1]
Pharmacist	[X]
Admin Staff	[1]
Quality Analysts	[6]
Total (participants)	[10]

Years of Experience

Average Years experience	7 years and 11 months

Facility Use of EHR	
All paper	[X]
Some paper, some	[X] electronic
All electronic	[6 months]
Total (participants)	[X]

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

postgraduate

Computer Expertise *Customize this to reflect what you know about your EHR's audience*

Besides reading email, what professional activities do you do on the computer? [e.g., access EHR, research; reading news; shopping/banking; digital pictures; programming/word processing, etc.] [If no computer use at all, Terminate]

About how many hours per week do you spend on the computer? [Recruit according to the demographics of the intended users, e.g., 0 to 10, 11 to 25,

26+ hours per week]

What computer platform do you usually use? [e.g., Mac, Windows, etc.]
What Internet browser(s) do you usually use? [e.g., Firefox, IE, AOL, etc.] In the last month, how often have you used an electronic health record?
How many years have you used an electronic health record?
How many EHRs do you use or are you familiar with?

How does your work environment patient records? [Recruit according to the demographics of the intended users]

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

Appendix 2: Non-Disclosure Agreement and Informed Consent

Non-Disclosure Agreement

THIS AGREEMENT is entered into as of _____, *2010*, between _____("the Participant") and the testing organization *Test Company* located at *Address*.

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 *Test Company*, 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 *Test Company* 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:** _____

Informed Consent

EnSoftek 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. At the conclusion of the test, you will be compensated for your time.

Agreement

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

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

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

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

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

Please check one of the following:

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

Signature: _____ Date: _____

Appendix 3: EXAMPLE MODERATOR'S GUIDE

Only three tasks are presented here for illustration.

EHRUT Usability Test

Moderator's Guide

Administrator _____

_____

Data Logger **Date** _____ **Time** _____

Participant # _____

Location _____

Prior to testing

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

Prior to each participant:

- Reset application
- Start session recordings with *tool*

Prior to each task:

- Reset application to starting point for next task

After each participant:

- End session recordings with *tool*

After all testing

- Back up all video and data file

Orientation

Thank you for participating in this study. Our session today will last ***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 help you with anything to do with the system itself. Please save your detailed comments until the end of a task or the end of the session as a whole when we can discuss freely.

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

The product you will be using today is a demo version. Some of the data may not make sense as it is placeholder data.

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

Do you have any questions or concerns?

Summative Testing Process for §170.315

Preparatory Workflows:

Log into DrCloudEHR:

1. Browse to DrCloudEHR URL
2. Enter login and password
3. Click 'Login' button to display Home Screen

Select a Patient:

1. At Home Screen:
2. Click in left Nav menu: Patients
3. Select patient name from roster
4. Patient Summary Screen is displayed.

Sign into DrFirst Rcopia eRx:

1. From Patient Summary Screen:
2. Click DrFirst Rcopia MedEntry button 3. At MedEntry screen click 'Compose Rx' tab 4. Compose Rx screen is displayed.

Clinical Workflows: DrCloudEHR with DrFirst Rcopia eRx

The DrFirst Rcopia eRx Medication Order workflow described below fulfills multiple testing objectives; each one is noted as it occurs in the workflow.

DrFirst Rcopia eRx medication order entry:

1. Log into DrCloudEHR
2. Select a patient
3. Sign into eRx
4. Select the Compose Rx tab

   170.315(a)(6) Medication list: the patient's current med list is visible as soon as the provider signs into eRx

   170.315(a)(7) Medication allergy list: the patient's allergy list is visible as soon as the provider signs into eRx

Enter a medication allergy.

1. Click the Allergy/ Intolerance button
2. Enter allergy (here, e.g., morphine)
3. Select from search results list
4. Select the severity
5. Click 'save allergy'

Order a medication.

This workflow addresses the (a)(1) CPOE objective as it relates to medication order entry.

a. Enter drug name in drug search text area - codeine
b. Click Drug Search button
c. New panel contains search results(a)(8) Clinical decision support is provided here by informational links to a few different authoritative literature sources. Which would be accessible in a production environment.
d. Click on drug name to select desired preparation
e. Close alert popup
f. Compose the prescription:
g. Click the items for “1 tablet PRN three times a day for 7 days”
h. Click 'Save Rx'
i. In next panel click pink button to 'Take Complete Rx to Review
    i. Page'
    ii. (a)(2) Drug-drug interaction and allergy alerts are displayed- see along the top of the panel.
    iii. Since the Allergy alert has been triggered, you might explain why it's being overridden.
j. Click magnifying glass at lower right of medication panel
k. In Drug Review screen select override reason from middle dropdown
l. Click 'Save'
m. Click link, 'Close/ Return to previous page'
    i. Return to the 'Compose Rx' screen to print or transmit the prescription
n. Click 'Transmit Rx' electronically which would happen if this were a production site and the prescriber registered with SureScripts.

o. And that fulfills (b)(3) Electronic prescribing (Alternatively, click 'Finish/ Add to meds” button)

Clinical Information Reconciliation

(b)(4) Clinical Information Reconciliation

Must first import the CCDA into the patient's DrCloudEHR documents:

1. In patient's DrCloudEHR summary screen click Document link
2. Click CCDA link
3. Browse to location of CCDA
4. Click Upload
5. Return to pt's summary screen.

Open the CCDA for viewing:

1. Click Documents link
2. Click + sign to expand CCDA
3. Click on desired CCDA (may need to re-select tab)

Prepare display for reconciliation:

1. Change display selector at top left to Bottom
2. In left Nav menu click Summary
3. In Summary screen click Issues link
4. Scroll through the CCDA to each section

Problems

- Corresponds to Medical Problems, with diagnosis.
- Add a new medical problem from the CCDA by clicking the Add button and using the Add New Issue popup dialog.
- Edit an existing medical problem by clicking on the problem name then using the Edit Issue dialog.

Entering Medications from CCDA

1. Click the Add button in Medications section to go to DrFirst Rcopia eRx
2. Enter Ordering prescriber's name in 'Replace current Doctor' text area
3. Select the medication's original start date in dropdown lists to right
4. Enter portion of drug name in Drug Search text area
5. Click pink Drug Search button

6. Click on drug name to select desired preparation
7. Click Edit button to compose the prescription:
8. Enter the sig of the med as specified by the external prescriber
9. Click 'Save Rx'
10. Repeat for all medications to be entered from CCDA.

Medication Reconciliation

In our example the Provider is entering the medications and editing them as needed. When finished with all meds, click button above order, 'Select to Move to Current
Meds'
Entire list will be added to current medications
In left nav menu, click 'Summary'
New and/ or edited meds will be transferred to pt's record.

Allergies

1. In Pt summary screen, click 'Issues' link
2. Scroll through CCDA to Allergy information
3. Click Add button to sign into eRx and add new ones

Allergy Reconciliation

Provider signs into eRx at Med Entry screen; may:

- click Allergy/ Intolerance magnifying glass at right of panel to view new allergy action details
- click allergy name to Return to patient summary screen: it or d/c allergy item.

When finished, return the panel view list to default and click 'Clear Active Patient' button at top left of Summary screen.

Appendix 4: Final Questions & System Usability Scale Questionnaire

Final Questions

What was your overall impression of this system?

- The System is User friendly and can be accessed by users who have access to it . It is designed in such a way that people would learn to use this system very quickly

What aspects of the system did you like most?

- Billing
- Integration of Third-party tools like DrFirst into DrCloudEHR.
- Ability to access the Third-Party tools

What aspects of the system did you like least?

Were there any features that you were surprised to see?

Integrated Golden Thread Quality Management System

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?

Yes

SYSTEM USABILITY SCALE QUESTIONNAIRE [4]

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

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

[16] Brooke, J.: SUS: A "quick and dirty" usability scale. In: Jordan, P. W., Thomas, B., Weerdmeester, B. A., McClelland (eds.) *Usability Evaluation in Industry* pp. 189--194. Taylor & Francis, London, UK (1996). SUS is copyrighted to Digital Equipment Corporation, 1986.

Lewis, J R & Sauro, J. (2009) "The Factor Structure Of The System Usability Scale." in *Proceedings of the Human Computer Interaction International Conference (HCII 2009), San Diego CA, USA*

Safety-Enhanced Design §170.315(b) (11)

EHR Usability Test Report - DrCloudEHR 2025

Report based on NISTIR 7742 Customized Common Industry Format Template for Electronic Health Record Usability Testing, ISO/IEC 25062:2006 Common Industry Format for Usability Test Reports

DrCloudEHR 2025

Date of Usability Test: March 17 2025

Date of Report: March 17 2025

Report Prepared by: info@drcloudemr.com

EnSoftek, Inc.
735 SW 158th Ave Beaverton OR 97006

Document Revisions

Date	Version	Author	Comments
3/10/2025	1.0	Balakishore Doddamreddy	Initial Report
3/10/2025	2.0	Balakishore Doddamreddy, Kishore Kumar	Report updated
3/10/2025	2.1	Ramesh Nagul	Sent to Manu Reddy for review
3/11/2025	2.2	Ramesh Nagul	Incorporated changes from reviewer
3/12/2025	2.0	Balakishore Doddamreddy, Kishore Kumar	Report updated
3/14/2025	2.3	Ramesh Nagul	Incorporated changes from reviews
3/14/2025	2.4	Balakishore Ready	Incorporated changes from Kendra
3/17/2025	2.5	Ramesh Nagul	Reviewed BK changes – send to SLI
3/21/2025	2.6	Ramesh Nagul	Incorporated SLI Feeback - send to SLI

Table of Contents

1. EXECUTIVE SUMMARY

A usability test of DrCloudEHR 2025 was conducted on March 17th 2025 by members of the EnSoftek Testing and Quality Assurance Team

The usability test followed the NISTIR 7741 User Centered Design approach.[4]

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

During the usability test, 10 healthcare providers, matching the target demographic criteria, served as participants and used the EHRUT in simulated, but representative tasks. This study collected performance data on these tasks typically conducted on an EHR for the §170.315(b)(11) functionality:

1. View and update Decision Support Intervention source attribute information.
2. Provide feedback on incorrect Decision Support Intervention rule usage.
3. Review the rules with User's Feedback and Export the results
4. View and update 3rd party Decision Support Intervention source attribute information.

During the 60-minute usability tests, each participant was asked to review and sign an informed consent/release form (included in Appendix 2). Participants had prior experience with the EHRUT from the Health IT Program. Prior to the test, online training was provided to some users along with online documentation and access to videos. The administrator introduced the test, and instructed participants to complete a series of tasks (given one at a time) using the EHRUT. During the testing, the administrator timed the test and, along with the data logger(s) recorded user performance data on paper and electronically. The administrator did not give the

[4] Robert M. Schumacher User Centric. Inc, and Svetlana Z. Lowry Information Access Division Information Technology Laboratory National Institute of Standards and Technology, NISTIR 7741 NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records (November 2010) p. 2-62

participant assistance in how to complete the task.

The following types of data were collected for each participant:

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

All participant data was de-identified – no correspondence could be made from the identity of the participant to the data collected. Following the conclusion of the testing, participants were asked to complete a post- test questionnaire. There was no compensation offered to ensure results are unbiased. Various recommended metrics, in accordance with the examples set forth in the NIST *Guide to the Processes Approach for Improving the Usability of Electronic Health Records*, were used to evaluate the usability of the EHRUT. Following is a summary of the performance and rating data collected on the EHRUT.

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

Major findings: All tasks were completed with few major deviations which determines that DrCloudEHR is a safe and effective and efficient system. Each task had only one user who did not successfully complete the task.

- The user ratings for the viewing, editing, and providing feedback for Decision Support Intervention (DSI) information was all rated highly as easy to accomplish, showing that this functionality of DrCloudEHR meets usability requirements.
- The dashboard is uncluttered and easy to navigate to the actionable areas where clinical decision rules are displayed and editable.

Areas for improvement: Make it easier to find the action trigger for editing or providing feedback by changing both the icon images and the size of the icons to make them appear more like buttons and convey their intent.

- The DSI message saying no source attribute information has been provided should be moved out of the text edit fields and below the message. Color code provides more contrast for users to differentiate between instruction text and user entered values.
- Predictive DSI source attribute information should be grouped into headers and the header texts should have more contrast in both size, weight, and color from the user edit fields.
- Saving an entry in the evidence based DSI should show a successfully saved message and skip the edit screens of the rest of the rule workflow.
- Have the dashboard areas by default be fully expanded to see all information on the screen instead of being closed by default requiring users to expand the DSI screen area and scroll down to the action items.

2. INTRODUCTION

The EHR Under Test (EHRUT) tested for this study was DrCloudEHR 2025.Designed to present medical information to healthcare providers in ***ambulatory*** settings, the EHRUT serves as a centralized solution that allows providers to document patient health information and facilities' information sharing. The usability testing attempted to represent realistic exercises and conditions.

The purpose of this study was to test and validate the usability of the current user interface and provide evidence of usability in the EHRUT. To this end, measures of effectiveness, efficiency and user satisfaction, such as task completion time, task success / errors, task efficiency, tester assessment were captured during the usability testing.

3. METHODS

3.1 PARTICIPANTS

A total of 10 participants were tested on the EHRUT. Participants in the test were healthcare providers / healthcare IT students. Participants were recruited by *Columbia University Health IT Certificate Program.* **No compensation was offered***.* In addition, participants had no direct connection to the development of or organization producing the EHRUT. Participants were not from the testing or supplier organization.

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

Participant ID	Participant Gender	Age	Participant Education	Participant Occupation	Professional Experience (months)	Computer Experience (months)	Product Experience (months)	Assistive Technology Needs
P11	Female	40-49	Doctorate degree (e.g.,MD, DNP, DMD, PhD)	Physician	240	120	36	None
P12	Female	30-39	Bachelor's degree	Nurse practitioner	144	216	96	None
P13	Female	40-49	Doctorate degree (e.g.,MD, DNP, DMD, PhD)	Physician	36	120	84	None
P14	Female	30-39	Trade/technical/vocational training	Quality Analyst	120	120	36	None
P15	Female	30-39	Doctorate degree (e.g.,MD, DNP, DMD, PhD)	Physician	276	180	96	None
P16	Male	40-49	Doctorate degree (e.g.,MD, DNP, DMD, PhD)	Physician	300	180	100	None
P17	Male	50-59	Bachelor's degree	Physician Assistant	156	240	12	None
P18	Male	60-69	Doctorate degree (e.g.,MD, DNP, DMD, PhD)	Physician	408	144	24	None

P20	Female	30-39	Bachelor's Degree	Quality Analyst	108	108	27	None
D10	Female	30-39	Bachelor's degree	Quality Analyst	48	228	27	None

10 participants (matching the demographics in the section on Participants) were recruited and 10 participated in the usability test. 0 participants failed to show up for the study. Participants were scheduled for 1 session of 60 minutes

3.2 STUDY DESIGN

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

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

- Number of tasks successfully completed without assistance
- Time to complete the tasks
- Number and types of errors
- Path deviations
- Participant's verbalizations (comments)
- Participant's satisfaction ratings of the system
- Additional information about the various measures can be found in Section 3.9 on Usability Metrics.

3.3 TASKS

A number of tasks were constructed that are realistic and representative of the activities a user might do with this EHR. Tasks were selected based on their frequency of use, criticality of function, those that may be most troublesome for users, and the tasks were constructed considering the study objectives. This study collected performance data on these tasks typically conducted on an EHR:

1. View and update Decision Support Intervention source attribute information.
   a. § 170.315 (b)(11) Decision Support Interventions
2. Provide feedback on incorrect Decision Support Intervention rule usage.
   a. § 170.315 (b)(11) Decision Support Interventions
3. Review the rules with User's Feedback and Export the results
   a. § 170.315 (b)(11) Decision Support Interventions
4. View and update 3rd party Decision Support Intervention source attribute information.
   a. § 170.315 (b)(11) Decision Support Interventions

3.4 PROCEDURE

Upon arrival, participants were greeted; their identity was verified and matched with a name on the participant schedule. Participants were then assigned a participant ID.[7] Each participant reviewed and signed an informed consent and release form (See Appendix 3). A representative from the test team witnessed the participant's signature.

To ensure that the test ran smoothly, two staff members participated in this test, the usability administrator and the data logger. The usability testing staff conducting the test were experienced usability practitioners with over 10 years of experience, with bachelor's degree in computer science and commerce.

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

Participants were instructed to perform the tasks:

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

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

Following the session, the administrator gave the participant the post-test questionnaire, the System Usability Scale (see Appendix 4)

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

3.5 TEST LOCATION

Testing was performed remotely using Zoom Video Conferencing. The participant, moderator (Beaverton, Oregon), and data logger all logged in separately to a previously configured Zoom meeting session. Control of the session was passed to the participant logging into the test version of DrCloudEHR 2025 at (https://qa-linux-01.drcloudemr.com/ehrQA/interface/login/index.html?rev=1.2&site=muthree) for each of the tasks.

All users were in their own facilities and were able to communicate with each other using the Audio/Video conferencing tools. 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 the safety instruction and evacuation procedures were valid, in place, and provided to the participants

3.6 TEST ENVIRONMENT

The EHRUT would typically be used in a healthcare office or facility. In this instance, the testing was conducted remotely. The participants used a mouse and keyboard when interacting with the EHRUT.

The EHRUT would typically be used in a healthcare office or facility. In this instance, the testing was conducted remotely. For testing, the computer used were desktops running Windows 10 with a 19" monitor, default color settings and a resolution of 1440 x 900. The participants used a mouse and keyboard when interacting with the EHRUT.

The DrCloudEHR 2025 system was set up by EnSoftek according to the documentation describing the system set-up and preparation. The application itself was running on a Ubuntu Linux VM running Apache and MySQL database backend using a test database on a WAN connection.
Technically, the system performance (i.e., response time) was representative to what actual users would experience in a field implementation. Additionally, participants were instructed not to change any of the default system settings (such as control of font size).

3.7 TEST FORMS AND TOOLS

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

- Informed Consent
- Moderator's Guide
- Usability Testing Closing Comments and Final Questions
- System Usability Scale Questionnaire

Examples of these documents can be found in Appendices 3-6 respectively. The Moderator's Guide was devised to be able to capture required data.

The participant's interaction with the EHRUT was monitored over video/web software running on the moderator machine. Each participant's reactions were monitored and documented.

3.8 PARTICIPANT INSTRUCTIONS

The administrator reads the following instructions aloud to each participant (also see the full moderator's guide in Appendix [B4]):

Thank you for participating in this study. Your input is very important. Our session today will last about 60 minutes. During that time, you will use an instance of an electronic health record system. I will ask you to complete a few tasks using this system and answer some questions. You should complete the tasks as quickly as possible, making as few errors as possible. Please try to complete the tasks on your own following the instructions very closely. Please note that we are not testing you we are testing the system, therefore if you have difficulty all this means is that something needs to be improved in the system. I will be here in case you need specific help, but I am not able to instruct you or provide help in how to use the application.
Overall, we are interested in how easy (or how difficult) this system is to use, what in it would be useful to you, and how we could improve it. I did not have any involvement in its creation, so please be honest with your opinions. All of the information that you provide will be kept confidential and your name will not be associated with your comments at any time.

Following the procedural instructions, participants were shown the EHR and given 10 minutes to explore the system and make comments. Once this task was done the administrator gave the following instructions:

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

Participants should not use a think-aloud protocol during the testing. Excessive verbalization or attempts to converse with the moderator during task performance should be strongly discouraged. Participants will naturally provide commentary, but they should do so, ideally, after the testing. Some verbal commentary may be acceptable between tasks, but again should be minimized by the moderator

Participants were then given the tasks to complete. Tasks are listed in the moderator's guide in Appendix [B4].

3.9 USABILITY METRICS

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

during the usability testing. The goals of the test were to assess:

- Effectiveness of DrCloudEHR 2025 by measuring participant success rates and errors
- Efficiency of DrCloudEHR 2025 by measuring the average task time and path deviations.
- Satisfaction with DrCloudEHR 2025 by measuring ease of use ratings

DATA SCORING

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

Measures	Rationale and Scoring
Effectiveness: Task Success	A task was counted as a "Success" if the participant was able to achieve the correct outcome, without assistance, within the time allotted on a per task basis. The total number of successes were calculated for each task and then divided by the total number of times that task was attempted. The results are provided as a percentage. Task times were recorded for successes. Observed task times divided by the optimal time for each task is a measure of optimal efficiency. Optimal task performance time, as benchmarked by expert performance under realistic conditions, is recorded when constructing tasks. 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 [65 seconds] then allotted task time performance was [65 * 1.25 = 81 seconds]. This ratio should be aggregated across tasks and reported with mean and variance scores.

Effectiveness: Task Failures	If the participant abandoned the task, did not reach the correct answer or performed it incorrectly, or reached the end of the allotted time before successful completion, the task was counted as a "Failure". 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.[11] 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. It is strongly recommended that task deviations be reported. Optimal paths (i.e., procedural steps) should be recorded when constructing tasks.
Efficiency: Task Time	Each task was timed from when the administrator said "Begin" until the participant said, "Done." If he or she failed to say "Done," the time was stopped when the participant stopped performing the task. Only task times for tasks that were successfully completed were included in the average task time analysis. Average time per task was calculated for each task. Variance measures (standard deviation and standard error) were also calculated.
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. After each task, the participant was asked to rate "Overall, this task was:" on a scale of 1 (Very Difficult) to 5 (Very Easy). These data are averaged across participants. Common convention is that average ratings for systems judged easy to use should be 3.3 or above.

Details of how observed data were scored.

4. RESULTS

4.1 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 analysis

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

Measure Task	No	Task Success	Path Deviation	Task Time		Errors	Task Ratings 5= Easy
		Mean (SD)	Deviations (Observed/ Optimal)	Mean (SD) seconds	Deviations (Observed/Optimal)	Mean (SD)	Mean (SD)
1. View and update Decision Support Intervention source attribute information.	10	90 (32)	10/8	96 (45)	96/123	2.4(3.2)	4.20(0.08)
2. Provide feedback on incorrect Decision Support Intervention rule usage.	10	90 (32)	7/6	86 (70)	86/72	0.9(1.4)	4.70(0.13)
3. Review the rules with User's Feedback and Export the results.	10	90 (32)	8/8	110 (71)	110/102	0.4(0.7)	4.10(0.08)
4. View and update 3rd party Decision Support Intervention source attribute information	10	90(32)	7/6	86(70)	86/72	0.9(1.4)	4.70(0.13)

The results scored the subjective satisfaction with the system based on performance.

4.2 DISCUSSION OF THE FINDINGS

The goal of EHR usability test is for users to interact with the system effectively, efficiently, and with an acceptable level of satisfaction. To measure these parameters, the data was collected after conducting virtual video recordings and analysis: time taken for each task, task successes, path deviations, task errors, and ease of use ratings were analyzed. Each task was analyzed individually.

EFFECTIVENESS

Based on test results, participants were able to complete the tasks with a success rate of 90%.

EFFICIENCY

Based on the observations, participants found DRCLOUDEHR to be an efficient system to use as most of them completed the tasks in less than the expected time. The average time taken for each task was calculated and compared to the optimal task times. Some observations:

- Task 1 had a higher number of observed path deviations (10/8 clicks) and was completed in ~65 seconds.
- Task 2 took the least amount of time at 46 seconds and had the least number of observed path deviations.
- Task 3 took the longest amount of time (~85 seconds) and had a high number of observed path deviations (8/8 clicks).

SATISFACTION

Participants rated the tasks on the level of ease based on a five point Likert scale, with 1 being difficult and 5 being easy. Satisfaction ratings averaged to 4 or higher which indicates that users did not perceive the tasks as difficult.

MAJOR FINDINGS

Most participants were able to complete tasks within the optimal time range. Nonetheless, there were slight uncertainties which were discovered while testing. Regarding Task 1, when saving the rule participants did not see any success message and instead were taken to the rule interval edit screen. Only upon saving the rule edit screen where they taken back to the rule summary page but still did not see any success message.

While testing Task 2, some participants struggled initially to click on the "?" icon to provide feedback on the rule's incorrect usage. Also, participants would deviate in their path by clicking on the "Edit" rule button because they could not immediately see the Feedback input box on the screen. Participants had to discover that they needed to scroll down to the bottom of the source attribute summary screen in order to provide feedback on the rule.

For both Task 1 and Task 4, participants were confused by the default text message in the text edit fields saying "The source attribute value is unknown or the DSI developer did not provide any information for this field". They struggled to know if the text field already had text or if the field was editable given the message.

Participants reported needing more contrast between the text field and the default empty message.

For Task 4, some participants struggled to find the 3rd party predictive DSI section as it was closed and hidden from view by default.

Overall, the participants noted that despite some of the minor challenges, the tasks were easy to accomplish, the dashboard was easy to navigate and participants were able to find the DSI attribute sections. The general flow of the EHR was easy to follow.

AREAS FOR IMPROVEMENT

Despite the mostly positive comments about DRCLOUDEHR, there are a few design aspects which can be improved. Firstly, making it easier to edit or provide feedback on the DSI source attributes for both evidence and predictive DSI by making the icon images to use a larger "gear" icon. This would convey a sense that the DSI rule is being configured or setup and make it easier for users to see and select it.

Next, the Predictive DSI source attribute information should be grouped into headers grouped by purpose. The current list is very long and made it challenging for participants to find the specific field they needed to edit. On both this screen, and the evidence-based screen, the default missing source attribute information should be moved out of the text box and have greater contrast to show it is a system message. The contrast could be done via size, weight, or color.

In the Evidence Based DSI edit screen, when launched from the patient demographic's dashboard screen, it should return the user to the demographics screen upon successful completion and show a save message to the user. This will avoid user confusion by skipping past the save interval screen.

Lastly, on the patient demographic's dashboard screen, all of the visible selections should have their contents fully visible and expanded by default instead of many of the sections being collapsed by default. This allows first time users to find the 3rd party Predictive DSI source attributes edit area inside the "Smart Enabled Apps" sections. Users can then have the option to collapse the section on future usages, but will be able to know the area exists, enhancing the learnability and usability of the system.

5. APPENDICES

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

1. Participant demographics
2. Non-Disclosure Agreement and Informed Consent
3. Example Moderator's Guide
4. Final Questions & System Usability Scale Questionnaire

Appendix 1: PARTICIPANT DEMOGRAPHICS

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

Gender	Count
Men	3
Women	7
Total (Participants)	10
Occupation	**Count**
Clinicians	2
Physician	1
Quality Analysts	6
Admin Staff	1
Total (Participants)	10
Years of Experience	**Years**
Average Years of Experience	8Years and 10 months

Appendix 2: Non-Disclosure Agreement and Informed Consent

Non-Disclosure Agreement

THIS AGREEMENT is entered into as of __ _, *2025*, between _ ("the Participant") and the testing organization *Test Company* located at *Address*.

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 *Test Company*, 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 *Test Company* 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:**

Informed Consent

EnSoftek 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. At the conclusion of the test, you will be compensated for your time.

Agreement

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

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

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

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

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

Please check one of the following:

☐ YES, I have read the above statement and agree to be a participant.

☐ NO, I choose not to participate in this study.

Signature: _____ Date: _____

Appendix 3: EXAMPLE MODERATOR'S GUIDE

EHRUT Usability Test

Moderator's Guide

Administrator

Data Logger **Date** _____ Time _____

Participant #

Location

Prior to testing

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

Prior to each participant:

- Reset application
- Start session recordings with *tool*

Prior to each task:

- Reset application to starting point for next task

After each participant:

- End session recordings with *tool*

After all testing

- Back up all video and data file

Orientation

Thank you for participating in this study. Our session today will last ***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 help you with anything to do with the system itself. Please save your detailed comments until the end of a task or the end of the session as a whole when we can discuss freely.
I did not have any involvement in its creation, so please be honest with your opinions.

The product you will be using today is a demo version. Some of the data may not make sense as it is placeholder data.

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

Do you have any questions or concerns?

Summative Testing Process for §170.315 (b)(11) Decision Support Interventions

Task 1: View and update Decision Support Intervention source attribute information.

In this scenario, the user will update the Prostate Cancer Screening rule to explain the rule's usage of patient's biological birth sex.

Update the summary text for a rule.

1. Change “Rule usage of Patient`s Sex” field to “This rule uses birth sex to determine if the patient should be screened for prostate cancer”

On a scale of 1 to 5, with 5 being easiest to perform, how would you rate this task?

Success:

- ☐ Easily completed
- ☐ Completed with difficulty or help (Describe)
- ☐ Not completed

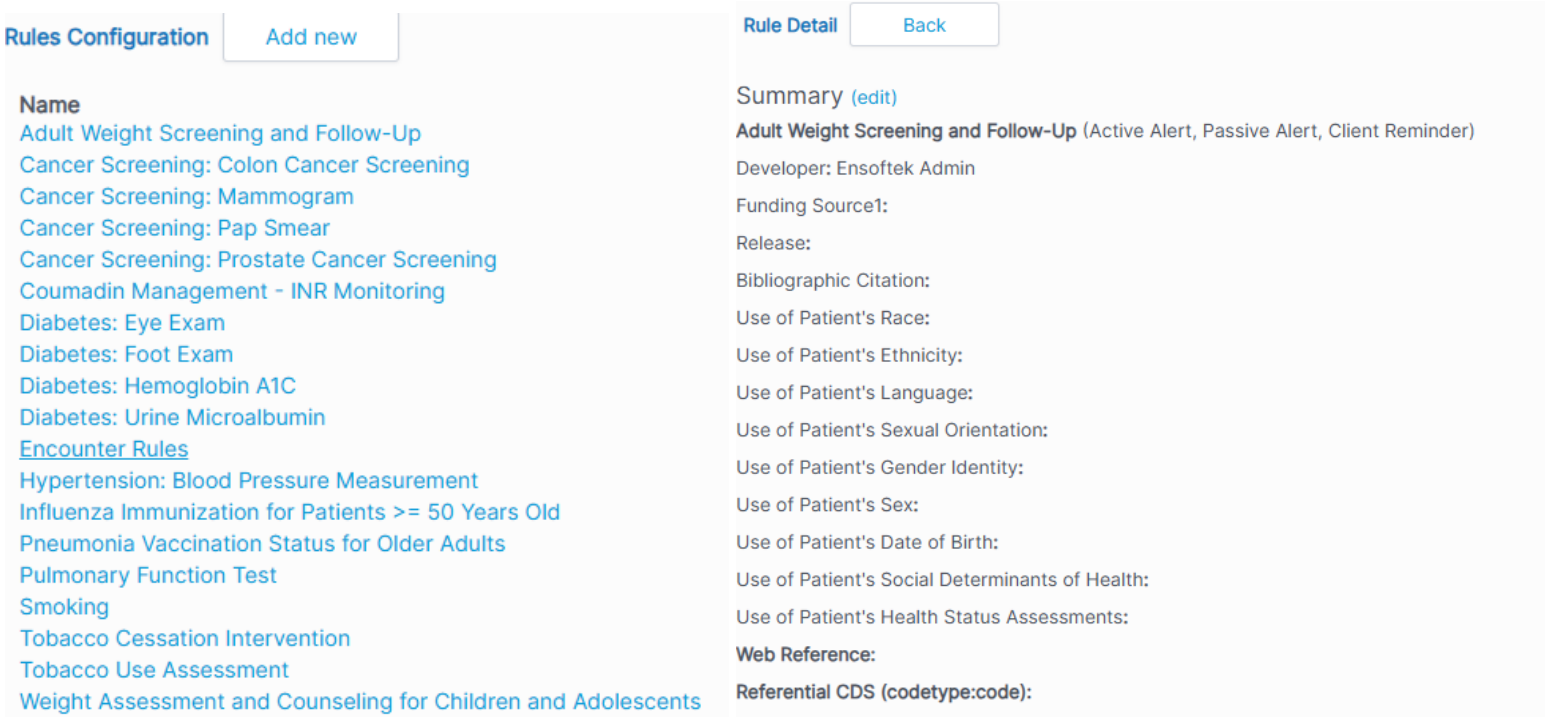
Task Time: _____ seconds

Optimal Path

In this scenario, the user will update the

1. Under Administration -To the left Navigation click on Rules
2. Click the rule you want to edit.
3. Click Edit next to the Summary text and update the field.
4. Click Save

Screenshot showing how to view and update decision support interventions.



- ☐ Correct
- ☐ Minor Deviations / Cycles (Describe)
- ☐ Major Deviations (Describe)

Observed Errors and Verbalizations:

Rating:

Overall this task was: _____

Administrator/Notetaker's Comments:

Task 2: Provide feedback on incorrect Decision Support Intervention rule usage.

In this scenario, the user will provide feedback on a rule that flags a patients for a pap smear.

Provide a Feedback on the rule:

1. Type following in “Rule Feedback” field: “Rule should not have flagged this patient for pap smear as his birth sex is male”

On a scale of 1 to 5, with 5 being easiest to perform, how would you rate this task?

Success:

- ☐ Easily completed
- ☐ Completed with difficulty or help (Describe)
- ☐ Not completed

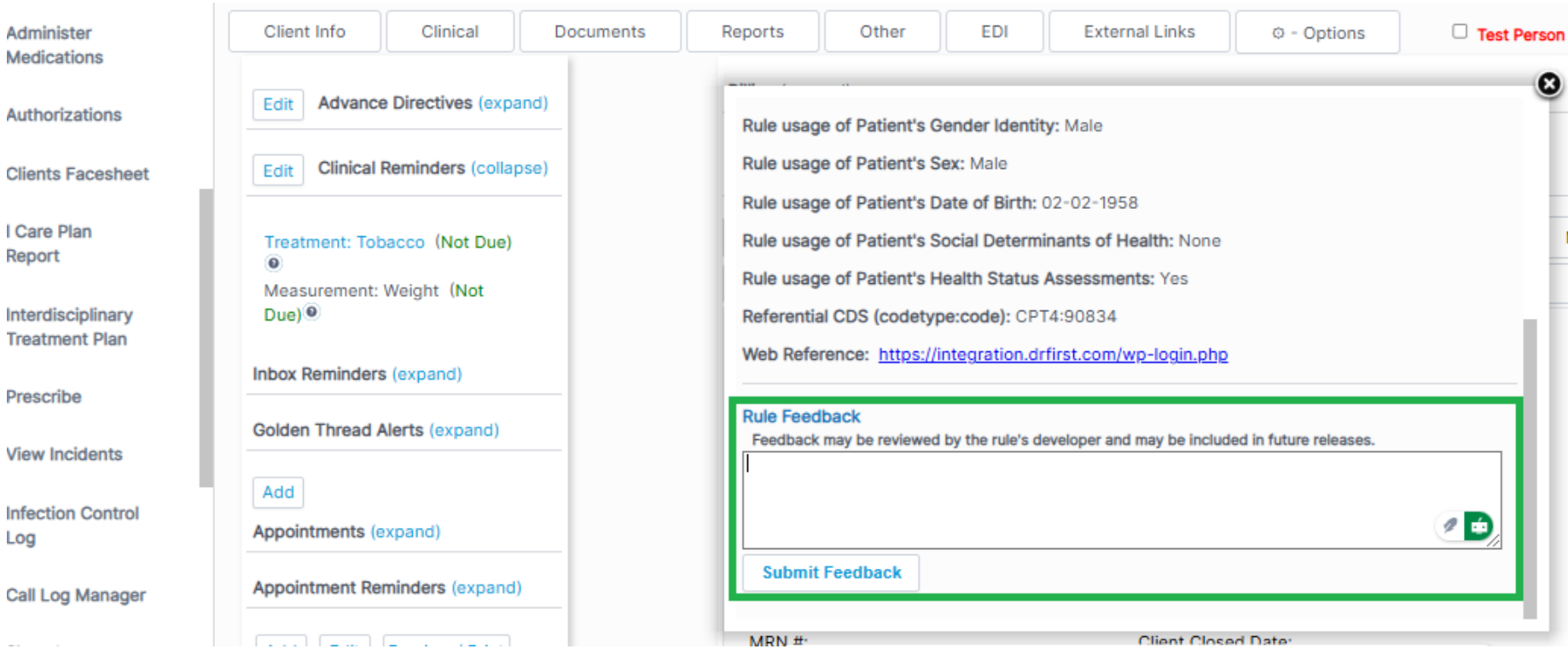
Task Time: _____ seconds

Optimal Path

In this scenario, the user will provide feedback on a rule.

1. Click Search on the top right and type “Clayson” to lookup a client/patient.
2. Pick the client to view their chart summary
3. Locate the clinical reminders section.
4. Under the Clinical reminders section, click on any of the links.
5. Input feedback for the rule and click on the Submit Feedback button.

<u>Screenshot showing how to provide a Feedback for the rules</u>



☐ Correct
☐ Minor Deviations / Cycles (Describe)
☐ Major Deviations (Describe)

Observed Errors and Verbalizations:

Rating:

Overall this task was: _____

Administrator/Notetaker's Comments:

Task 3: Review the rules with User's Feedback and Export the results.

In this scenario, the user will review and export the data in CSV format for further processing.

On a scale of 1 to 5, with 5 being easiest to perform, how would you rate this task?

Success:

- ☐ Easily completed
- ☐ Completed with difficulty or help (Describe)
- ☐ Not completed

Task Time: _____ seconds

Optimal Path

In this scenario, the user will **Review the rules with Feedback and Export the results:**

1. Navigate to the Reports section of DrCloudEHR.
2. To the left navigation, click on MU Reports
3. Click on Alert Log
4. Select the desired date range and click on the search button.
5. To review the feedback, click on the Feedback icon
6. Once the results are displayed on the screen, click on the Download button to export the report.

Screenshots showing the Feedback for the reviews and how to export the results.

Feedback Log

For rules with user's feedback, click on to show feedback

From: 03/16/2025 17:52:00 To: 03/17/2025 18:52:00

Search Download Print

Total Results: 215

Date	Client ID	User ID	Location	Category	Action Taken	Interventions	Feedback	New Alerts
03/17/2025 12:27:24	1004892	1	Chart	Passive Alert	Feedback	Measurement: Weight (Past Due)	This is a citation for Measurment weight	
03/17/2025 12:27:01	1004892	1	Chart	Passive Alert	View	Measurement: Weight (Past Due)		
03/17/2025 12:26:56	1004892	1	Chart	Active Alert		Measurement: Weight (Past Due)		
03/17/2025 12:26:51	1004892	1	Chart	Passive Alert		Measurement: Weight (Past Due)		
03/17/2025 12:25:08	1004880	1	Chart	Active Alert	View	Measurement: Blood Pressure (Not Due)		
03/17/2025 12:25:00	1004880	1	Chart	Active Alert		Treatment: Tobacco (Past Due) Assessment: Penicillin Allergy (Past Due) Measurement: Blood Pressure (Not Due) Measurement: Weight (Past Due)		
03/17/2025 12:24:55	1004880	1	Chart	Passive Alert		Treatment: Tobacco (Past Due) Measurement: Weight (Past Due)		

Task 4: View and update 3rd party Decision Support Intervention source attribute information

In this scenario, the user will view and update 3rd party decision support intervention source attributes.

On a scale of 1 to 5, with 5 being easiest to perform, how would you rate this task?

Success:

- ☐ Easily completed
- ☐ Completed with difficulty or help (Describe)
- ☐ Not completed

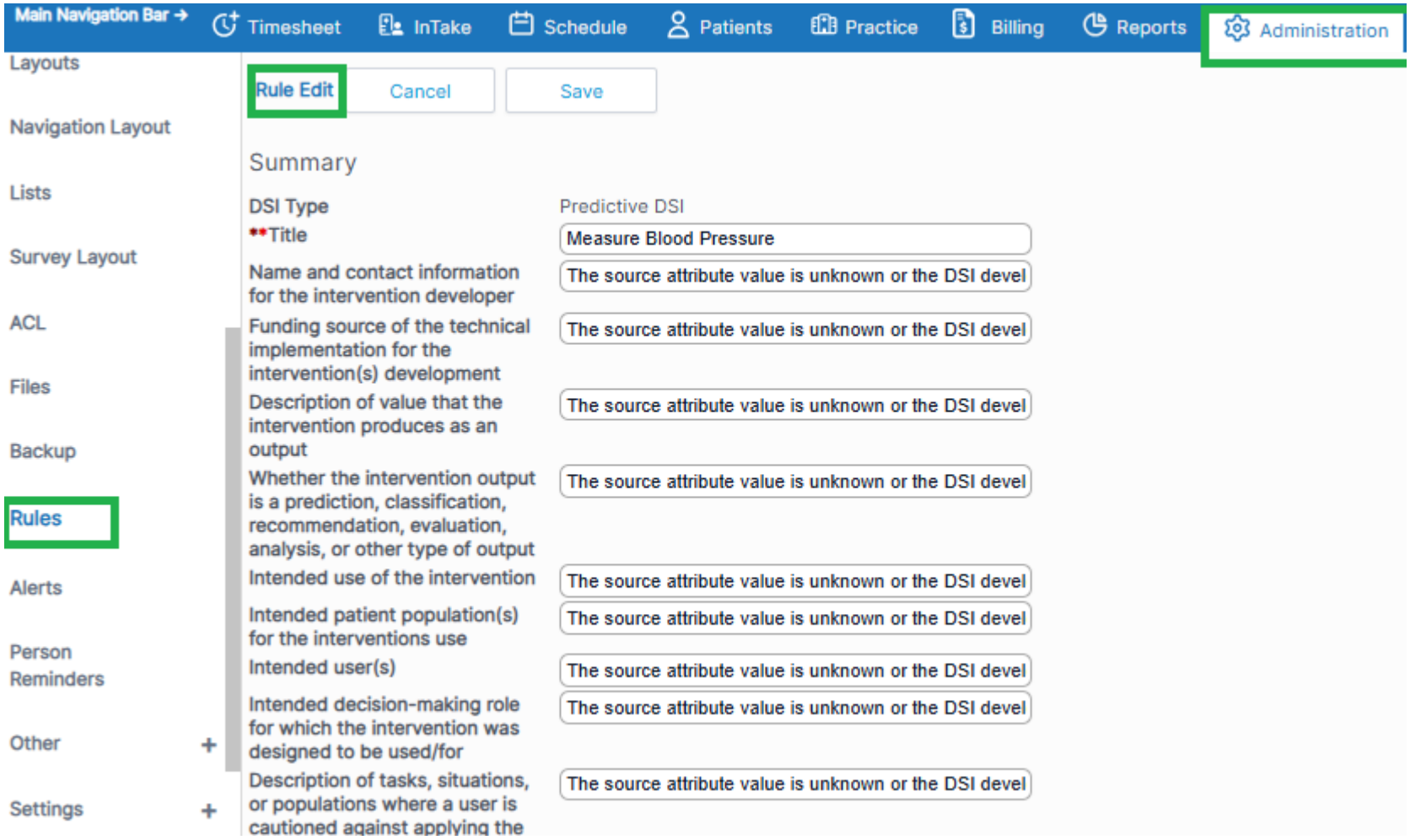
Task Time: _____ seconds

Optimal Path

In this scenario, the user will view and update 3rd party decision support intervention source attributes.

1. Navigate to the Administration section of DrCloudEHR.
2. To the left navigation, click on Rules.
3. Click on Add New
4. Under the Rule Add page, select the DSI Type as 'Predictive DSI'
5. Respective attributes will be displayed.
6. The user can enter the desired value in each of the attributes and click on the Save button.

Updating the Predictive DSI attributes



Viewing the Predictive DSI attributes


DOB: 03/05/1987 Age: 38
Under a legal guardianship:
Encounter History
Chart | New Encounter
Not Provided
Funding Provider: VALUE OPTIONS
Code Status:
BP: 130/70 mmHg Pulse: per min
Ht: 59.06 in Resp: per min
Wt: 165.35 lbs Temp: () °F
BdSA : SqMts BMI: 33.3 (Obesity I) kg/m2
BAC: %
Chief Complaint:
Client Info Banner
March 17, 2025 Ensoftek Ad
Main Navigation Bar
Timesheet
InTake
Schedule
Patients
Practice
Billing
Reports
Administration
Inbox 870
Settings
ADL
Unplug:Server
Main Dashboard
Sidebar Menu
search menu
Portal forms
Administer Medications
l Care Plan
New Incident
Client Search/Add
Clients Facesheet
ABA Tool
Authorizations
Measure Blood Pressure (Active Alert) (Predictive DSI)
Name and contact information for the intervention developer: The source attribute value is unknown or the DSI developer did not provide any information for this field
Funding source of the technical implementation for the intervention(s) development: The source attribute value is unknown or the DSI developer did not provide any information for this field
Description of value that the intervention produces as an output: The source attribute value is unknown or the DSI developer did not provide any information for this field
Whether the intervention output is a prediction, classification, recommendation, evaluation, analysis, or other type of output: The source attribute value is unknown or the DSI developer did not provide any information for this field
Intended use of the intervention: The source attribute value is unknown or the DSI developer did not provide any information for this field
Intended patient population(s) for the interventions use: The source attribute value is unknown or the DSI developer did not provide any information for this field
Intended user(s): The source attribute value is unknown or the DSI developer did not provide any information for this field
Intended decision-making role for which the intervention was designed to be used/for (e.g., informs, augments, replaces clinical management): The source attribute value is unknown or the DSI developer did not provide any information for this field
Description of tasks, situations, or populations where a user is cautioned against applying the intervention: The source attribute value is unknown or the DSI developer did not provide any information for this field
Known risks, inappropriate settings, inappropriate uses, or known limitations: The source attribute value is unknown or the DSI developer did not provide any information for this field
Exclusion and inclusion criteria that influenced the training data set: The source attribute value is unknown or the DSI developer did not provide any information for this field