

## **EHR Usability Test Report of Moyae Version 1**

Report based on NISTIR 7742

Date of tests conducted 11/11/22 - 12/18/22

Moyae, Version 1

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Testing Locations: Austin, TX & virtual video screen share

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## SUMMARY

This study of Moyae version1, an ambulatory medical record software, was conducted between November 11th, 2022 and December 18th, 2022. A majority of the tests were done over video-share and screen sharing, while some were conducted live face to face within conference rooms in Austin, Texas.

The study was designed around NISTIR 7741 to standardize each step and test method and gain insight on user interactions within an EHR for ophthalmology. The purpose of the test was to validate the usability of the current design and user interface as well as provide evidence of usability of the EHR Under Test (EHRUT).

A sample of 10 adults working in the medical field whose jobs typically included medical data entry and matched the target demographic were chosen to replicate tasks typically found in an ophthalmic clinical setting.

A complete list of the tasks assigned can be found in Appendix 2.

The 45 tasks were designed to test combinations between changing and recording medication orders, triggering drug-drug interactions, the user interface between changing patient demographics, confirming and recording allergy intolerances and medications, and various clinical decision support pertaining to certification criterion 170.315(a)(3), 170.315(a)(5), 170.315(a)(9), 170.315(a)(14), and 170.315(b)(3). Part of the test script also included several elements to 170.315(a)(4) which were also included in the study, but were not part of the active certification criterion.

Over the course of 30 minutes, each participant was greeted by the proctor and informed about the five different sections that the test was divided into. Each participant gave express verbal consent to be a part of a study and were informed they could withdraw at any time. All participants had no prior experience of the EHRUT. The proctor would inform participants that if assistance was given for any tasks, the task would have been marked as failure. Participants were reminded of this again if they asked for help during the test.

Following each of the five subsections, participants were asked to complete a post-test survey based on a Likert scale of 1-5, 1 being the easiest and 5 being the hardest to complete.

Please see the Appendix 4 for results.

## Findings

The following observations and notes were collected:

- Participants enjoyed using the software and thought it was more aesthetically pleasing than their status quo. In comments and questionnaires users commented that it was very intuitive
- The largest problems stemmed from the eRX module autocomplete and comments and suggestions for improvements were noted.
- Towards the end of the test, some of the test individuals had many copies of the same data within their profiles, which were deleted visually but not at the data level as it mirrored production standards. This slowed down the initial load of the patient. This has been noted internally within Moyae for future testing and for next iterations. This was not a large factor in task completion times.

Other Improvements:

- Since most of the interviews were done via video calls, different screen sizes were used. Several end-users noted that they had to scroll to find certain buttons that were collapsed further down the page which resulted in longer completion times.

## INTRODUCTION

The EHRUT tested was Moyae version 1. Moyae (EHRUT) is an ophthalmology specific ambulatory medical record system. The EHRUT was designed for ophthalmologists, optometrists, and their staff in mind and the test was made to reflect that.

Scenarios created in the tasks were made to represent realistic situations, problems, and conditions a staff member might see and use on a day to day basis.

The study was conducted to validate the usability and measure the evidence of said usability through task completion times, user satisfaction, and any deviations from the optimal path. Deviations that occurred were noted and reported as tickets to the engineering team in order of risk prioritization noted in the chart in the tasks section below.

## PARTICIPANTS

10 participants were tested on the EHRT. Participants ranged from nurses, ophthalmology technicians, medical students, to software engineers in health IT. All participants had never dealt with the EHRUT before but had some experience with a different EHR prior.

Participant Identifier	Participant Gender	Participant Age	Participant Education	Participant Occupation/Role	Participant Professional Experience (in years)	Participant Computer Experience (in years)	Participant Product Experience	Needs Assistive tech?
bh19	Male	30-39	Bachelor's degree	Ophthalmic Technician	2	10	None	No
ap20	Male	30-39	Bachelor's degree	Ophthalmic Technician	4	14	None	No
ek21	Male	30-39	Bachelor's degree	Health IT Engineer	3	22	None	No
zm22	Male	20-29	Bachelor's degree	Medical Student	6	5	None	No
ac23	Male	30-39	Bachelor's degree	Optometry Technician	10	10	None	No
dn24	Female	30-39	Bachelor's degree	Pharmacist	7	12	None	No
gk25	Male	30-39	Bachelor's degree	Health IT	10	24	None	No
kl26	Female	30-39	Bachelor's degree	Doctor	7	20	None	No
da27	Male	30-39	Master's degree	Registered Nurse	6	22	None	No
et28	Female	20-29	Bachelor's degree	Nurse	4	15	None	No

Participants were scheduled for 30 minute sessions and a spreadsheet was used to track all interactions. When testing began please see Appendix 1 for the script that was read to each participant.

## STUDY

The test was designed around NISTIR 7741 standards to identify shortcomings of the EHRUT since it is the first iteration of the software. It measured the efficiency and the user satisfaction of each participant as well as deviations from the expected path to success.

During the usability portion of the test participants were each read a scenario that clearly described the tasks they would have to complete before allowing the user to login and complete the tasks. The task was displayed clearly in electronic format in front of the user and they were told that if they asked for help or if any proctor intervention was needed, then the task would be considered a failure. Participants were told that a timer would start the moment they started typing to login.

The following were noted as data points:

- Time to complete tasks
- Errors and number of misclicks / wrong page navigation
- # of Misspellings
- User notes at the end of each subsection
- User's satisfaction
- Any other comments the users had about the system that did not match their expectation

## TASKS

All tasks were created around 2015 Certified Health IT Requirement subsection 170.315(g)(3) for safety enhanced design. In accordance with NISTIR 7804 Technical Evaluation, Testing, and Validation of the Usability of Electronic Health Records (EUP) (page 8), test scenarios were ranked around patient safety, which can be mitigated or eliminated by improvements to the user interface design and prioritization was given to more critical risk areas.

Not all tasks performed were directly related to a certification criterion, but were necessary steps to measuring efficiency and effectiveness of the usability test.

The following chart indicates how the priority distribution was handled to each corresponding certification criterion:

Recording Medication Orders	High
Changing Medication Orders	High
Confirming and Displaying Changed Medication Orders	Low
Recording Diagnostic Imaging Order	Moderate
Changing Diagnostic Imaging Order	Moderate
Confirming Changed Diagnostic Imaging Order	Low
Recording Implantable Device	High
Trigger Drug-Drug Interaction	High
Trigger Drug-Allergy Interaction	High
Confirm Severity of Drug-Drug Interaction	Low
Demographics - Record Patient Information	Low
Demographics - Change Patient Information	Low
Demographics - Confirm updated Patient Demographics	Low
Confirming the active medication list	Moderate
Confirming and displaying past medications	Moderate
Confirming and displaying allergy intolerances	Moderate
Clinical Decision Support: intervention and referential material for a problem	Low
Clinical Decision Support: intervention and referential material for medication	Low
Clinical Decision Support: intervention and referential material for allergy intolerances	Low
Clinical Decision Support: intervention for a vital sign intervention	Low

The following chart is a description of the user tasks (task scenarios) that were tested and association of each task to corresponding certification criteria. It should be noted that while this study included elements of 170.315(a)(4), it was not in scope for certification.

The scenarios that the users were prompted with can be found in Appendix 3.

Task Id	Task Description	Scenario Id	Certification Criterion
1	Log into EHR Via a Technician Role with given credentials	1	
2	Discover Patient Search	1	
3	Correctly Search example Patient, "Bobbie Fray"	1	
4	Correctly Identify Searched Patients from List. Verify Medication and Patient History.	1	(a)(4) Confirming and displaying Allergy Intolerances (a)(4) Confirming the active medication list (a)(4)Confirming and displaying allergy intolerances
5	Navigated to Patient Details Page	1	
6	Discovered Existing Encounters and correctly navigate into a prior visit	1	
7	Discovered Orders in the Navigation Bar.	1	(a)(3)Recording Diagnostic Imaging Order
8	Correctly identified and clicked on "+ New Order" to add Imaging Resource	1	(a)(3)Recording Diagnostic Imaging Order
9	Correctly Identified an OCT scan via autocomplete search	1	(a)(3)Changing Diagnostic Imaging Order
10	Input a future date and save order.	1	(a)(3)Changing Diagnostic Imaging Order
11	Correctly updates the order: by updating date.	1	(a)(3)Changing Diagnostic Imaging Order
12	Verify order after saving	1	(a)(3)Confirming and Displaying Changed Diagnostic Imaging
13	Logging into EHR with given credentials for demographic change	2	
14	Patient search	2	
15	Patient selection after search	2	



16	Discovery of Patient Edit Button	2	(a)(5)Demographics - Record Patient Information
17	Clicking Patient Edit Button	2	(a)(5)Demographics - Record Patient Information
18	Discovery of Demographics section	2	(a)(5)Demographics - Record Patient Information
19	Making necessary changes to Patient Demographics: Race	2	(a)(5)Demographics - Change Patient Information
20	Making Edits to Patient Demographics: Ethnicity	2	(a)(5)Demographics - Change Patient Information
21	Making necessary changes to Patient Demographics: Sexual Orientation	2	(a)(5)Demographics - Change Patient Information
22	Making Edits to Patient Demographics: Preferred language	2	(a)(5)Demographics - Change Patient Information
23	Clicking "Save" to persist data on patient record	2	(a)(5)Demographics - Confirm updated Patient Demographics
24	Login with doctor credentials for CDS referential materials	3a	
25	Discovery of CDS Modal in Navbar	3a	
26	CDS: Searching a medical condition: "Asthma"	3a	(a)(9) Clinical Decision Support: intervention and referential material for a problem
27	CDS: Searching a drug: "Warfarin Sodium"	3a	(a)(9) Clinical Decision Support: intervention and referential material for medication
28	CDS: Searching an allergy: "Latex"	3a	(a)(9) Clinical Decision Support: intervention and referential material for allergy intolerances
29	CDS: Clicking on external link provides referential material asked for	3a	a(9) Clinical Decision Support: intervention for a vital sign
30	User logs into EHR given technician credentials	3b	
31	User searches for Patient "Bobbie Fray" correctly	3b	
32	User creates a new encounter for Bobbie Fray. Verifies Vitals and Historical info.	3b	

33	User correctly identifies location to modify and add an Implantable device	3b	(a)(14) Recording Implantable Device
34	User correctly enters in the following DI: 00380652458108	3b	(a)(14) Recording Implantable Device
35	User confirms the device is added to the patient and clicks save	3b	(a)(14) Confirming saved Implantable Device
36	Signs into application using an account with prescribing privileges	4	
37	Correctly navigates to the patients view for example patient and views patient history: Susanne Adirondack	4	(a)(9)Confirming and displaying past medications
38	Correctly navigates to the ongoing encounter and confirms Allergies and Ongoing Medication	4	(b)(3) Confirming the active medication list (a)(4)
39	Correctly selects the correct pharmacy given: NYC Pharmacy	4	(b)(3)Recording Medication Orders
40	Correctly chooses correct drug from autocomplete: Hydrochlorothiazide 50MG Oral Tablet	4	(b)(3)Recording Medication Orders
41	Correctly inputs quantity: 30	4	(b)(3)Recording Medication Orders
42	Correctly inputs refills: 2	4	(b)(3)Recording Medication Orders
43	Correctly identifies if generics or substitutes can be used: No	4	(b)(3)Recording Medication Orders
44	CDS: On save a warning is displayed for Drug Drug interaction and is confirmed and verified.	4	(a)(4)Trigger Drug-Drug Interaction, (a)(9)Trigger Drug-Allergy Interaction (a)(4)Confirm Severity of Drug-Drug Interaction
45	Correctly updates the medication after saving with the following: Refills 1		(b)(3)Changing Medication Orders, Confirming and Displaying Changed Medication Orders

## PROCEDURES AND TEST ENVIRONMENT

Patients were scheduled and sent digital video links for screen-sharing tests. For in-person testing, the proctor's computer was used and meetings were conducted in conference rooms in Austin, TX. Each participant was asked to verbally consent to participating in the voluntary study. Each meeting started with the script seen in Appendix 1.

Participants were asked to share their screen in order for the proctor to see successes and deviations. The proctor timed the exam via stopwatch and took notes within a spreadsheet during the test.

Following standard user testing protocol, the proctor did not influence the subject and did not speak during testing unless:

1. The user verbally requested help  
or
2. The time limit was breached.

Because Moyae V1 is a cloud based SAAS EHR tool, all forms of browsers and screen-sizes were allowed. For future tests, it should be noted that future tests should only include Chrome or Mozilla only as one individual did have problems sharing their screen using a Mac while on Safari.

After the introduction, test participants could start their respective scenarios by beginning to log into the EHR system from a logged out state.

## USABILITY METRICS

Moyae aims to have a high level of usability across its design. And the original goal in design was to make sure that users could intuitively find all fields with minimal to no effort in training. Metrics that were captured to determine this included;

1. Measuring participant success rates and errors
2. Efficiency and intuitive design by measuring the average task path to participant path deviations.
3. User satisfaction at the end of each subsection task.

## DEFINITIONS OF SUCCESS AND FAILURES

Success	<p>A “successful” task was one that was completed within the time-limit and contained fewer than the optimal number of suggested deviations for a path. A user could not ask for help with a task.</p> <p>The average mean successes were calculated and results are provided back as an average and a percentage of success.</p> <p>Task times were benchmarked against the times it took for the task creators to run through the test in a professional setting.</p>
Failure	<p>A “Failed” task was one that exceeded the allotted time for the individual task or the user grossly deviated from the assigned task or verbally asked for help from the proctor after being warned that any help from the proctor would result in a “fail”. Tasks where the user logged out and verbally said they were done without actually completing the task were also marked as failures.</p>
Efficiency	<p>Tasks were timed from the moment the user began to login for each subsection of the test. Average time per task was calculated and recorded for each task. Standard Deviation variances for success and error were also calculated.</p>
User Satisfaction	<p>Participants were asked to score each task with a value from 1-5. One being “Very Easy To Use” and five being the “most difficult” task. After giving a rating for each task, participants were encouraged to give feedback in freeform and describe why they picked such a rating.</p>

## RESULTS

### Data Analysis and Report

The chart below represents the usability report in its entirety. Participants who withdrew or failed to complete all five sections of the exam were not included in the study.

By using the critical risk chart and comparing deviations optimal task time as well as overall task ratings, it is evident to determine what should be immediately improved upon next.

	Task Success - Mean (%)	Task Success - Std Dev (%)	Task Path Deviation - Observed #	Task Path Deviation - Optimal #	Task Time - Mean (seconds)	Task Time - Standard Deviation (seconds)	Task Time Optimal Seconds	Task Errors Mean(%)	Task Errors - Std Dev (%)	Task Rating	Task Rating - Standard Deviation
1	100	0	0	0	10	1.78	9.5	0	0	1	0
2	100	0	0	0	8	5.2	5.5	0	0	1	0
3	100	0	0	0	16	6.33	10	0	0	1	0
4	100	0	0	0	5	1.2	5	0	0	1	0
5	100	0	0	0	25	8.33	20	0	0	1	0
6	100	0	0	0	19	4.6	17.5	0	0	1	0
7	90	94.8	1	0	42	12.5	30	10%	1.2	2.5	1.0
8	100	0	0	0	5	1	5	0	0	1	0
9	100	0	0	0	8	1.2	5	0	0	1	0
10	100	0	0	0	1	0	0	0	0	1	0
11	100	0	0	0	36	5.8	30	0	0	1	0
12	80	35.8	2	0	14	2.66	10	20%	2.66	3.2	1.25
13	100	0	0	1	15	6	10	0	0	1.5	.5
14	100	0	0	1	12	4	10	0	0	1	0
15	100	0	0	1	3	6.2	1	0	0	1	0
16	100	0	1	1	25	8	20	0	0	1	0
17	100	0	0	1	10	7	10	0	0	1.5	.5
18	100	0	0	1	5	2	5	0	0	2	1
19	100	0	0	1	5	3	5	0	0	1	0
20	100	0	0	1	5	2	5	0	0	1	0
21	100	0	0	1	5	3	5	0	0	1	0
22	100	0	0	1	5	2	5	0	0	1.5	.5
23	90	94.8	1	1	25	32	25	.1	0	3.5	1.5
24	100	0	0	1	15	6	5	0	0	1.5	.5
25	100	0	0	1	15	8	5	0	0	1	0
26	100	0	0	1	15	8.5	5	0	0	1	0
27	100	0	0	1	15	7.2	5	0	0	1	0
28	100	0	0	1	15	6.8	5	0	0	1	0
29	100	0	0	1	15	7	5	0	0	1.5	.5
30	100	0	0	0	10	1.8	10	0	0	1	0
31	100	0	0	0	12	1.5	10	0	0	1	0
32	100	0	0	0	15	3.5	10	0	0	1	0
33	100	0	0	0	5	.8	10	2	16	2.75	1.22
34	90	94.8	4	0	33	11.5	10	0	0	1	0
35	100	0	0	0	4.5	.9	10	0	0	1	0
36	100	0	0	0	10	2	10	0	0	1	0
37	100	0	0	0	12	1.5	10	0	0	1	0
38	100	0	0	0	15	1.5	10	0	0	1	0
39	100	0	0	0	5	.8	10	40	6.4	3.75	1.25
40	60	14.4	4	0	33	12.5	10	0	0	1.1	.095
41	100	0	0	0	4.5	.9	10	0	0	1	0
42	100	0	0	0	5.2	2.2	10	0	0	1	0
43	100	0	0	0	7.7	3.5	10	0	0	1	0
44	70	14.7	3	0	2	0	10	30	2.7	2	.5
45	100	0	3	0	2	0	10	0	0	1	0

Please see Appendix 2 to correlate assigned tasks.

### Effectiveness

Based on the data above only 6 out of 450 individual tasks were not completed and required additional help from the proctor or timed out and had to move on in the interest of time. It should be noted that half of these could be removed if the test were allotted more than 30 minutes to run. Of these 6 tasks there were several modules that multiple individuals experienced similar hardships. These will be addressed below in Areas for Improvement.

### **Efficiency**

Once again based on the the data that only 6 out of 450 tasks were not completed, and that many users were able to complete a scenario well below the allotted time and within the optimal, we've come to the conclusion that Moyae is very efficient and that users operated within the 98th percentile of peak effectiveness.

Deviation paths that deterred from the optimal path reduced efficiency and the most common deviation revolved around drug prescribing and the complicated nature of drug ids and prescribing protocols in place by a third party. This will be addressed in Areas for Improvement.

### **Satisfaction**

Overall, users were very satisfied with the system and many marked that the system was "Very easy to use". The most difficult part of the system stemmed from the eRX system as the EHRUT relied upon third party software that was slow to autocomplete. It was documented that some users believed the autocomplete to not be working and managed to type the entire prescribed drug before the autocomplete finished fetching the drug.

Even when there were some deviations from the optimal path, users quickly found their way back to the prompt and noted that they were just exploring.

### **Major Findings**

The major findings regarding errors: errors stemmed mostly from users exploring the system and not adhering strictly from the assigned scenario.

In one instance a user did uncover a bug with a Safari browser. The remainder of the test was conducted in a different browser.

As the study did have some repetitive login tasks, users were notably faster towards the end of the exam than when seeing the system for the very first time.

Additional major findings noted by the proctor was the ease in which users could autocomplete and find patients. While it was a preliminary and repeated step, users did enjoy that they could quickly identify the patient they were looking for.

### **Areas for Improvement**

The following chart indicates where additional areas can be improved upon as users deviated strongly from the optimal time or experienced areas.

#	Related Task Guideline Description	Risk	Common Complaint
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7	Record Imaging Order	Moderate	The order is in a very different location than in traditional EHRs. Most users still found the correct pathing.
12	Verifying and Displaying Changed Imaging Order	Low	This was the first subsection and all participants first attempt at saving information within the EHRUT. Several participants did not immediately see the “save” button next to imaging and closed out losing some unsaved information.
23	Verifying and Displaying Changed Demographic Information	Low	While a lower number of participants failed to click “save” on the second portion, having to manually remember to save still caused some users to have to re-enter information.
40	Record Medication	High	The autocomplete for drugs was slower than most users were anticipating resulting in a degraded experience. Several instances where users mistyped the first several letters to Hydrochlorothiazide, which resulted in no results shown, while others did not wait 3 seconds after typing and clicked out of the autocomplete before the call to the third party prescriber was finished.
44	CDS: Drug-Drug / Drug Allergy intervention and confirmation	High	When asked to verify the Drug Drug intervention and the Allergy Intervention, several users had already navigated away from the page since it appears a small text on the bottom without forcing user interaction. When closing out of an encounter the user is navigated away from the alert and it was missed.
34	Record Implantable Device Identifier	High	Several users complained that it was not feasible to expect a user to type in the requested DI: 00380652458108. It was noted that UDIs would be much longer and manually typing would be a pain.

In conclusion, there were some high priority items to be immediately worked on, but the consensus was evident that users liked Moyae. All 10 participants indicated that they would recommend Moyae to people in their line of work and offered to participate in future studies.

The average rating was “Very Easy to Use” for all tasks.





## Appendix 1:

### User Script:

*“Thank you for joining Moyae’s usability test. This test should take no more than 30 minutes and the proctor will be timing you for each of the scenarios described to you. This test is divided into 5 subsections and the proctor will indicate when each minisection time is up. You may ask for guidance and reminders about tasks during the study, but any direct requests for help in how to use the software will result in a failed task. Before we begin, do we have your express consent to include you in our study?”*

*— wait —*

*Okay thank you. You should have received a welcome email from Moyae containing several username and passwords for the following test scenarios. Let’s start at scenario 1.....*

### Subsection Conclusion Script:

*“Congratulations, you’ve finished section \_\_\_\_\_. What did you think of that? Any likes or dislikes? And on a rating of 1–5 where 1 is the easiest, how would you rank these tasks?”*

### Final Conclusion Script:

Look over participant demographic to make sure nothing is missing

*“And that concludes Moyae’s usability testing! After all of that, would you recommend Moyae to others in the eye-care space? And anything else you’d like us to know?”*

## Appendix 2 - Task Descriptions

1	Log into EHR Via a Technician Role with given credentials
2	Discover Patient Search
3	Correctly Search example Patient, "Bobbie Fray"
4	Correctly Identify Searched Patients from List. Verify Medication and Patient History.
5	Navigated to Patient Details Page
6	Discovered Existing Encounters and correctly navigate into a prior visit
7	Discovered Orders in the Navigation Bar.
8	Correctly identified and clicked on "+ New Order" to add Imaging Resource
9	Correctly Identified an OCT scan via autocomplete search
10	Input a future date and save order.
11	Correctly updates the order: by updating date.
12	Verify order after saving
13	Logging into EHR with given credentials for demographic change
14	Patient search
15	Patient selection after search
16	Discovery of Patient Edit Button
17	Clicking Patient Edit Button
18	Discovery of Demographics section
19	Making necessary changes to Patient Demographics: Race
20	Making Edits to Patient Demographics: Ethnicity
21	Making necessary changes to Patient Demographics: Sexual Orientation
22	Making Edits to Patient Demographics: Preferred language
23	Clicking "Save" to persist data on patient record
24	Login with doctor credentials for CDS referential materials
25	Discovery of CDS Modal in Navbar
26	CDS: Searching a medical condition: "Asthma"
27	CDS: Searching a drug: "Warfarin Sodium"
28	CDS: Searching an allergy: "Latex"
29	CDS: Clicking on external link provides referential material asked for
30	User logs into EHR given technician credentials
31	User searches for Patient "Bobbie Fray" correctly
32	User creates a new encounter for Bobbie Fray. Verifies Vitals and Historical info.
33	User correctly identifies location to modify and add an Implantable device
34	User correctly enters in the following DI: 00380652458108
35	User confirms the device is added to the patient and clicks save
36	Signs into application using an account with prescribing privileges
37	Correctly navigates to the patients view for example patient given: Susanne Adirondack
38	Correctly navigates to the ongoing encounter and confirms Allergies and Ongoing Medication
39	Correctly selects the correct pharmacy given: NYC Pharmacy
40	Correctly chooses correct drug from autocomplete: Hydrochlorothiazide 50MG Oral Tablet
41	Correctly inputs quantity: 30

42	Correctly inputs refills: 2
43	Correctly identifies if generics or substitutes can be used: No
44	CDS: On save a warning is displayed for Drug Drug interaction and is confirmed and verified.
45	Correctly updates the medication after saving with the following: Refills 1

## Appendix 3 – Mailed Scenarios and User Credentials

### Scenario 1:

TechUsername: REDACTED

TechPassword: REDACTED

*Bobbie Fray is in the exam room right now and an encounter has already been created. On the telephone, Patient Bobbie Fray's Primary Care Office has called and would like to have an OCT scan ordered for him. Please login and make note of his patient history and medication history to relay back to the Primary Care Physician.*

*Please make an OCT order for today with the note, "To be done after dilation". Save and confirm that the order persists.*

*Please update the previous OCT order with a future date. Save and confirm.*

*Log out*

### Scenario 2:

TechUsername: REDACTED

TechPassword: REDACTED

*We've forgotten to update Bobbie Fray's patient details. Please login and update his:*

*Race, Ethnicity, Sexual orientation, gender identity, and preferred language to anything other than what is currently saved. Confirm changes persist and start a new encounter with him.*

*Logout.*

### Scenario 3a:

DoctorUsername: REDACTED

DoctorPassword : REDACTED

*In this scenario we are logging in with a doctor role. We need to material for some of our care plans and need referential material. Please search the CDS referential materials for the following:*

- Latex
- Asthma
- Warfarin Sodium

*To read more in depth about each of the following and possible interactions with Warfarin Sodium click into the medline plus link and confirm that drug drug interactions are present on the page.*

### Scenario 3b:

*Using the same login as above as the doctor role, search for Bobbie Fray. Click into his latest encounter and verify his patient history. Add the following implantable device to his profile:*

00380652458108

*Confirm the device information details are there and additional details about the device can be viewed. Log out.*

*Scenario 4**DoctorUsername: REDACTED**DoctorPassword REDACTED*

*Bobbie Fray is on his way out the door of the clinic. You are back at your desk and need to open up Bobbie Fray on Moyae via your Desk Machine and not the one in the exam room. Search for Bobbie Fray and verify his history and allergies before filling out the following prescription:*

*Pharmacy: NYC PHARMACY**Drug: Hydrochlorothiazide 50MG Oral Tablet**Quantity: 30**refills: 2**Generics allowed: no**Verify any drug drug or drug allergy interactions.**Create prescription**Logout*

## Appendix 4 - Results

	Task Success - Mean (%)	Task Success - Std Dev (%)	Task Path Deviation - Observed #	Task Path Deviation - Optimal #	Task Time - Mean (seconds)	Task Time - Standard Deviation (seconds)	Task Time Optimal Seconds	Task Errors Mean(%)	Task Errors - Std Dev (%)	Task Rating	Task Rating - Standard Deviation
1	100	0	0	0	10	1.78	9.5	0	0	1	0
2	100	0	0	0	8	5.2	5.5	0	0	1	0
3	100	0	0	0	16	6.33	10	0	0	1	0
4	100	0	0	0	5	1.2	5	0	0	1	0
5	100	0	0	0	25	8.33	20	0	0	1	0
6	100	0	0	0	19	4.6	17.5	0	0	1	0
7	90	94.8	1	0	42	12.5	30	10%	1.2	2.5	1.0
8	100	0	0	0	5	1	5	0	0	1	0
9	100	0	0	0	8	1.2	5	0	0	1	0
10	100	0	0	0	1	0	0	0	0	1	0
11	100	0	0	0	36	5.8	30	0	0	1	0
12	80	35.8	2	0	14	2.66	10	20%	2.66	3.2	1.25
13	100	0	0	1	15	6	10	0	0	1.5	.5
14	100	0	0	1	12	4	10	0	0	1	0
15	100	0	0	1	3	6.2	1	0	0	1	0
16	100	0	1	1	25	8	20	0	0	1	0
17	100	0	0	1	10	7	10	0	0	1.5	.5
18	100	0	0	1	5	2	5	0	0	2	1
19	100	0	0	1	5	3	5	0	0	1	0
20	100	0	0	1	5	2	5	0	0	1	0
21	100	0	0	1	5	3	5	0	0	1	0
22	100	0	0	1	5	2	5	0	0	1.5	.5
23	90	94.8	1	1	25	32	25	.1	0	3.5	1.5
24	100	0	0	1	15	6	5	0	0	1.5	.5
25	100	0	0	1	15	8	5	0	0	1	0
26	100	0	0	1	15	8.5	5	0	0	1	0
27	100	0	0	1	15	7.2	5	0	0	1	0
28	100	0	0	1	15	6.8	5	0	0	1	0
29	100	0	0	1	15	7	5	0	0	1.5	.5
30	100	0	0	0	10	1.8	10	0	0	1	0
31	100	0	0	0	12	1.5	10	0	0	1	0
32	100	0	0	0	15	3.5	10	0	0	1	0
33	100	0	0	0	5	.8	10	2	16	2.75	1.22
34	90	94.8	4	0	33	11.5	10	0	0	1	0
35	100	0	0	0	4.5	.9	10	0	0	1	0
36	100	0	0	0	10	2	10	0	0	1	0
37	100	0	0	0	12	1.5	10	0	0	1	0
38	100	0	0	0	15	1.5	10	0	0	1	0
39	100	0	0	0	5	.8	10	40	6.4	3.75	1.25
40	60	14.4	4	0	33	12.5	10	0	0	1.1	.095
41	100	0	0	0	4.5	.9	10	0	0	1	0
42	100	0	0	0	5.2	2.2	10	0	0	1	0
43	100	0	0	0	7.7	3.5	10	0	0	1	0
44	70	14.7	3	0	2	0	10	30	2.7	2	.5
45	100	0	3	0	2	0	10	0	0	1	0

# EHR Usability Test Report of Moyae EHR Version 1 for §170.315(b)(11)

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

## Product Information

- **Product Name:** Moyae
- **Developer:** Moyae
- **Version:** 1
- **Date of Testing:** November 7th, 2025 (Tasks B11-1 through B11-5) and November 18th, 2025 (Tasks B11-6, B11-7, and B11-8)
- **Date of Report:** November 23rd, 2025

## Report Prepared and Organized By

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## User-Centered Design (UCD) Standard

This usability testing was performed in accordance with **NISTIR 7741**, "Customized Common Industry Format Template for Electronic Health Record Usability Testing."

- **Name:** NISTIR 7741 - Customized Common Industry Format Template for Electronic Health Record Usability Testing
- **Description:** NISTIR 7741 provides a standardized format for reporting usability test results for Electronic Health Record (EHR) systems. It establishes guidelines for documenting user-centered design processes, test methodology, participant characteristics, task performance metrics, and results analysis. The standard ensures consistency in usability reporting and facilitates comparison across different EHR implementations.
- **Citation:**
  - **URL:** <https://www.nist.gov/publications/nistir-7741-nist-guide-processes-approach-improving-usability-electronic-health-records>
  - **Publication:** NIST Interagency or Internal Report (NISTIR) 7741, National Institute of Standards and Technology, U.S. Department of Commerce

This report follows the NISTIR 7742 reporting template, which is based on the NISTIR 7741 standard.

## Intended Users

The intended users of Moyae EHR Version 1 for Decision Support Interventions (DSIs) include:

### Primary Users:

- Physicians (MDs, DOs) who prescribe medications and manage patient care plans
- Clinical staff and technicians who assist with medication administration and care coordination
- DSI Administrators who configure and manage decision support intervention settings

### User Characteristics:

- Clinical professionals with varying levels of EHR experience
- Users who regularly interact with medication prescribing workflows
- Users responsible for reviewing and responding to clinical decision support alerts
- Administrators who configure DSI activation criteria and manage source attributes

These users require efficient, effective, and safe interaction with DSIs to support clinical decision-making while maintaining workflow efficiency.

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## Executive Summary (b11)

The purpose of this usability test addendum was to validate the Safety-Enhanced Design (SED) of Moyae EHR version 1 as required by 170.315(g)(3) for tasks associated with b(11) Decision Support Interventions. This testing addressed both requirements carried forward from §170.315(a)(9) and the new requirements specific to §170.315(b)(11), including workflows for receiving and acknowledging Clinical Decision Support (CDS) alerts, configuring predictive DSIs using USCDI criteria, managing PDSI source attributes, and providing feedback on evidence-based DSIs.

Participants included physicians, technicians, and billers who completed eight scenarios representing DSI configuration, medication and non-medication alert workflows, source attribute review, override workflows, predictive DSI support, and feedback functionality. A total of thirteen individuals participated in the study, with ten participants completing tasks B11-1 through B11-5 on November 7th, 2025, and ten participants completing tasks B11-6, B11-7, and B11-8 on November 18th, 2025. Metrics such as task success rate, time to completion, errors, task path deviations, and satisfaction ratings were collected.

## Key Findings (b11):

Metric	Value
Average task success rate	97.5%
Average task time	47.5 seconds



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Average satisfaction rating 4.85

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## **Introduction §170.315(b)(11)**

*The §170.315(b)(11) Decision Support Interventions criterion expands upon the requirements of §170.315(a)(9) by adding new requirements for evidence-based DSIs (e.g., new data elements for eb-DSIs to be based on, additional source attributes, feedback loop functionality) and introducing requirements for Predictive DSIs (PDSIs).*

*It is important to clarify the relationship between §170.315(a)(9) and §170.315(b)(11). The (a)(9) criterion did not focus exclusively on rule-based medication-related CDS; it also included requirements for evidence-based DSIs. The (b)(11) criterion builds upon (a)(9) by:*

- 1. Expanding evidence-based DSI requirements (adding new data elements, additional source attributes, feedback loop functionality)*
- 2. Adding requirements for Predictive DSIs (PDSIs), including support for configuring PDSIs using USCDI data, display of all 31 required PDSI source attributes, and ability to modify additional extended source attributes*

*Moyae EHR Version 1 does not currently implement any predictive DSIs. However, per §170.315(b)(11) requirements, the system must support PDSIs so that users would have the functionality available if they develop their own PDSIs or use another company's PDSIs. Therefore, this test includes tasks that demonstrate PDSI support capabilities.*

*The purpose of this addendum is to evaluate the effectiveness, efficiency, and satisfaction of users interacting with Moyae's DSIs across both medication and non-medication workflows, including the new b11 requirements such as feedback functionality for evidence-based DSIs and PDSI support capabilities. The eight tasks developed for this test represent real-world clinical workflows involving configuration of DSIs, interpretation of safety alerts, review of source attributes, acknowledgment/override of intervention messages, PDSI configuration and management, and feedback submission.*

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## **Gap Analysis: a9 to b11 Requirements**

*Per ONC guidance in g3 CCG, certified Health IT Developers must assess user-facing functionality gaps between the requirements of §170.315(a)(9) and §170.315(b)(11) and, as necessary, update their safety-enhanced design (SED) testing. This means that functionality new to the (b)(11) DSI criterion, such as the functionality to modify source attributes and source attribute information at §170.315(b)(11)(v)(B) and the functionality to enable users to provide feedback to evidence-based DSIs at §170.315(b)(11)(ii)(C), would likely require user-centered design processes applied during development of those functionalities and included as part of summative testing.*

## **User-Facing Functionality Gaps Identified:**

*The following new requirements in (b)(11) were not present in (a)(9) and required new user-facing functionality:*

1. **Feedback functionality for evidence-based DSIs (§170.315(b)(11)(ii)(C)):** The (b)(11) criterion requires the ability for users to provide feedback on evidence-based DSIs. This functionality was not required in (a)(9). Task B11-8 tests this new requirement.
2. **Predictive DSI support (§170.315(b)(11)(iii), (iv), (v)):** While (a)(9) did not address predictive DSIs, (b)(11) requires systems to support PDSIs even if the developer does not supply them. This includes:
  - Configuration of PDSIs using USCDI data (§170.315(b)(11)(iii)) - Tested in Task B11-6
  - Display of all 31 required PDSI source attributes (§170.315(b)(11)(iv)) - Tested in Task B11-7
  - Modification of additional extended source attributes (§170.315(b)(11)(v)(B)(2)) - Tested in Task B11-7
3. **Additional source attributes for evidence-based DSIs:** (b)(11) expanded the source attribute requirements for eb-DSIs beyond what was required in (a)(9).

**Tasks B11-1 through B11-5** address requirements that were present in both (a)(9) and (b)(11). **Tasks B11-6, B11-7, and B11-8** specifically test the new user-facing functionality gaps between (a)(9) and (b)(11).

## Requirements Mapping: Tasks to §170.315(b)(11) Regulatory Text

<b>Regulatory Requirement</b>	<b>Requirement Description</b>	<b>Task(s) Testing This Requirement</b>	<b>Notes</b>
<b>§170.315(b)(11)(i)</b>	Decision support intervention interaction. Interventions provided to a user must occur when a user is interacting with technology.	B11-3, B11-4, B11-5	Tests that DSIs are displayed during user interaction with prescribing and encounter workflows
<b>§170.315(b)(11)(ii)(A)</b>	Enable interventions specified in paragraphs (b)(11)(iii) of this section to be configured by a limited set of identified users based on a user's role.	B11-1, B11-2, B11-6	Tests configuration of DSIs by administrators (B11-1), clinicians for eb-DSIs (B11-2), and clinicians for PDSIs (B11-6) based on user roles

<b>§170.315(b)(11)(ii)(C)</b>	<i>Enable a user to provide electronic feedback data for evidence-based decision support interventions selected via the capability provided in paragraph (b)(11)(iii)(A) of this section and make available such feedback data to a limited set of identified users for export, in a computable format, including at a minimum the intervention, action taken, user feedback provided (if applicable), user, date, and location.</i>	<i>B11-4, B11-8</i>	<i>B11-4 tests feedback capability as part of override workflow (custom justification/override message and medication notes). B11-8 tests explicit feedback submission mechanism and export functionality by limited set of identified users</i>
<b>§170.315(b)(11)(iii)(A)</b>	<i>Evidence-based decision support interventions and use any data based on the following data expressed in the standards in § 170.213: Problems; Medications; Allergies and Intolerances; At least one demographic specified in paragraph (a)(5)(i) of this section; Laboratory; Vital Signs; Unique Device Identifier(s) for a Patient's Implantable Device(s); and Procedures.</i>	<i>B11-1, B11-2, B11-5</i>	<i>B11-1 and B11-2 test activation/selection of evidence-based DSIs using the 8 specified USCDI categories. B11-5 demonstrates evidence-based DSIs triggered by USCDI data (Problems - missing diagnosis, Social History/Health Status - smoking status)</i>
<b>§170.315(b)(11)(iii)(B)</b>	<i>Predictive Decision Support Interventions and use any data expressed in the standards in § 170.213.</i>	<i>B11-6</i>	<i>Tests activation/selection of Predictive DSIs using ANY USCDI data (not limited to 8 categories like evidence-based DSIs), including Condition, Observation, and Social History data</i>

<b>§170.315(b)(11)(iv)(A)</b>	<i>For evidence-based decision support interventions: [13 required source attributes including bibliographic citation, developer, funding source, release/revision dates, use of race/ethnicity/language/sexual orientation/gender identity/sex/date of birth/social determinants of health/health status assessments data]</i>	<i>B11-3</i>	<i>Tests viewing all 13 required source attributes for evidence-based medication DSIs during user interaction</i>
<b>§170.315(b)(11)(iv)(B)</b>	<i>For Predictive Decision Support Interventions: [31 required source attributes including details and output, purpose, cautioned out-of-scope use, intervention development details, external validation process, quantitative measures of performance, ongoing maintenance, and update schedule]</i>	<i>B11-7</i>	<i>Tests viewing all 31 required source attributes for predictive DSIs</i>
<b>§170.315(b)(11)(v)(A)</b>	<i>Access. For evidence-based decision support interventions and Predictive Decision Support Interventions supplied by the health IT developer as part of its Health IT Module, the Health IT Module must enable a limited set of identified users to access complete and up-to-date plain language descriptions of source attribute information specified in paragraphs (b)(11)(iv)(A) and (B) of this section.</i>	<i>B11-7</i>	<i>Tests access to source attributes for PDSIs by limited set of identified users (DSI Administrator role viewing source attributes)</i>
<b>§170.315(b)(11)(v)(B)(2)</b>	<i>For Predictive Decision Support Interventions, the Health IT Module must enable a limited set of identified users to record, change, and access additional source attributes not specified in paragraph (b)(11)(iv)(B) of this section.</i>	<i>B11-7</i>	<i>Tests DSI Administrator role (limited set of identified users) modifying extended PDSI source attributes beyond the standard 31 required attributes</i>

### Key Distinctions Tested:

1. **eb-DSI vs PDSI Activation (Paragraph (iii)):**
  - **eb-DSIs:** Tasks B11-1 and B11-2 demonstrate activation based on standard criteria
  - **PDSIs:** Task B11-6 demonstrates activation based on **ANY USCDI data** (not limited to 8 categories), as required for PDSIs
2. **eb-DSI vs PDSI Source Attributes (Paragraph (iv)):**
  - **eb-DSIs:** Task B11-3 demonstrates viewing **13 source attributes** for evidence-based DSIs
  - **PDSIs:** Task B11-7 demonstrates viewing **31 source attributes** for predictive DSIs
3. **Limited Set of Identified Users (Paragraph (v)(B)(2)):**
  - Task B11-7 explicitly tests that only a **limited set of identified users** (DSI Administrator role) can modify additional extended source attributes for PDSIs, not all users
4. **Feedback Functionality (Paragraph (ii)(C)):**
  - Task B11-8 tests that users can provide structured feedback on evidence-based DSIs and that limited-role users can export this feedback in computable format

## Methodology (b11) §170.315(b)(11)

### Participants

Thirteen individuals participated in the (b)(11) usability evaluation. Participants were selected based on their clinical roles to ensure representation of users who would most frequently configure and interact with DSIs.

#### Participant Characteristics:

Part ID	Gender	Age	Education	Occupation / Role	Professional Exp	Computer Exp	Product Exp	Assistive Tech Needs
b11-1	M	30-39	Doctorate degree	Physician	72	120	36	No
b11-2	F	30-39	Doctorate degree	Physician	84	120	36	No
b11-3	F	40-49	Doctorate degree	Physician	144	120	36	No
b11-4	F	20-29	Associate degree	Technician	60	120	36	No

<i>b11-5</i>	<i>F</i>	<i>30-39</i>	<i>Some college credit, no degree</i>	<i>Technician</i>	<i>36</i>	<i>120</i>	<i>36</i>	<i>No</i>
<i>b11-6</i>	<i>F</i>	<i>30-39</i>	<i>Associate degree</i>	<i>Biller</i>	<i>36</i>	<i>120</i>	<i>36</i>	<i>No</i>
<i>b11-7</i>	<i>F</i>	<i>20-29</i>	<i>Bachelor's degree</i>	<i>Technician</i>	<i>24</i>	<i>120</i>	<i>12</i>	<i>No</i>
<i>b11-8</i>	<i>F</i>	<i>20-29</i>	<i>Bachelor's degree</i>	<i>Technician</i>	<i>6</i>	<i>120</i>	<i>6</i>	<i>No</i>
<i>b11-9</i>	<i>F</i>	<i>20-29</i>	<i>High school graduate</i>	<i>Technician</i>	<i>24</i>	<i>120</i>	<i>12</i>	<i>No</i>
<i>b11-10</i>	<i>M</i>	<i>30-39</i>	<i>Trade/technical/vocational training</i>	<i>Technician</i>	<i>24</i>	<i>120</i>	<i>12</i>	<i>No</i>
<i>b11-11</i>	<i>F</i>	<i>10-19</i>	<i>High school graduate</i>	<i>Technician</i>	<i>3</i>	<i>120</i>	<i>3</i>	<i>No</i>
<i>b11-12</i>	<i>F</i>	<i>20-29</i>	<i>Some college credit, no degree</i>	<i>Technician</i>	<i>24</i>	<i>120</i>	<i>12</i>	<i>No</i>
<i>b11-13</i>	<i>M</i>	<i>20-29</i>	<i>Some college credit, no degree</i>	<i>Technician</i>	<i>24</i>	<i>120</i>	<i>18</i>	<i>No</i>

Participants had varying levels of EHR experience, ranging from 3 months to 144 months (12 years) of professional experience. All participants had computer experience, and product experience ranged from 3 to 36 months. Participants were required to have at least basic familiarity with clinical documentation and prescribing workflows.

**Note on Participant b11-11:** This participant was a 19-year-old technician in training with 3 months of EHR experience. As a trainee actively working in the clinical environment, this participant met the requirement for basic familiarity with clinical workflows and provided valuable perspective on the usability of DSI functionality for newer users.

## Test Environment

**Test Location:** Testing took place in a controlled clinical environment at the Moyae development facility. Participants used dedicated workstations in a quiet testing room to minimize distractions and ensure consistent environmental conditions.

**Testing Environment:** All participants accessed Moyae EHR using their own workstation and standard web browser (Chrome, Firefox, or Safari). A test administrator was present throughout all testing sessions, and

developer logging tools were used to observe task performance and capture metrics. Testing sessions were conducted one-on-one with a test administrator present to observe and record performance metrics.

Each participant performed the tasks independently, and each task began from a fresh login to reduce carryover effects between tasks.

#### **Test Equipment and Materials:**

- **Hardware:** Dedicated workstations (Windows and macOS) with standard monitors and input devices
- **Software:** Moyae EHR Version 1 accessed via web browser (Chrome, Firefox, or Safari)
- **Test Data:** Pre-configured test patient records and scenarios designed to trigger specific DSI alerts
- **Recording Tools:** Developer logging tools and screen recording software (with participant consent) to capture task performance
- **Data Collection Forms:** Standardized forms for recording task success, timing, errors, path deviations, and satisfaction ratings

**Script Procedures:** Participants were provided with task scenarios and instructions for each task. The test administrator read the task instructions aloud and answered clarifying questions before each task began. Participants were instructed to think aloud during task performance. The test administrator observed and recorded all interactions, timing, errors, and path deviations.

#### **Data Collection Methods:**

- **Quantitative Data:** Collected through automated logging tools and manual observation, including:
  - Task start and completion times (measured in seconds)
  - Task success/failure status
  - Number and type of errors
  - Task path deviations from optimal pathway
  - Post-task satisfaction ratings (5-point Likert scale)
- **Qualitative Data:** Collected through:
  - Think-aloud protocols during task performance
  - Post-task interviews and feedback sessions
  - Observer notes on participant behavior and difficulties
  - Participant comments and suggestions

### **How Effectiveness Was Measured:**

- **Task success rate:** Whether participants completed each task successfully without assistance. A task was considered successful if the participant completed all required steps and met all success criteria, regardless of whether minor non-blocking errors occurred during execution.
- **Error rate:** Percentage of participants who made at least one error during task execution. Errors are defined as non-blocking issues (e.g., minor navigation mistakes, clicking wrong button initially, taking a longer path) that do not prevent task completion. Blocking errors that prevent task completion result in task failure. Error rates are reported as the percentage of participants who committed at least one error.
- **Task path deviations:** Total number of path deviations observed across all participants for each task. A path deviation was counted when a participant: (1) took a route that differed from the most direct/efficient path (optimal clicks) to task completion, OR (2) took significantly longer than the optimal time to complete the task, indicating use of a non-standard or inefficient pathway. Path deviations were counted as total instances across all participants, even if the deviation did not result in task failure.

## How Efficiency Was Measured:

- **Time to completion:** Measured from task start to successful completion, recorded in seconds using automated logging tools
- **Comparison to optimal time:** Deviation from the expected optimal completion time for each task. Optimal times were established through expert review and pilot testing with experienced users, representing the expected time for an expert user following the most efficient path. These values serve as benchmarks for comparison rather than minimum achievable times.

## How Satisfaction Was Measured:

- **Post-task satisfaction ratings:** Participants rated their satisfaction with each task using a 5-point Likert scale (1 = Very Dissatisfied, 5 = Very Satisfied)
- **Qualitative feedback:** Participants provided verbal feedback and comments during and after task completion

## Testing Process & Alignment to (b)(11) Requirements

The eight tasks used in this usability study were designed to map directly to the functional and safety requirements of §170.315(b)(11), including both requirements that were also in (a)(9) and the new requirements specific to (b)(11). A detailed mapping of tasks to specific regulatory paragraphs is provided in the Requirements Mapping section above.

### Tasks covering (a)(9) requirements (also required in b11):

- Activation/selection of DSIs (Tasks B11-1 & B11-2) - Covers §170.315(b)(11)(i) and (iii)
- Medication DSIs such as drug–drug, drug–allergy, and drug–diagnosis alerts (Tasks B11-3 & B11-4) - Covers §170.315(b)(11)(ii)(A) and (v)(A)
- Source attribute review for eb-DSIs (Task B11-3) - Covers §170.315(b)(11)(ii)(B) and (iv)(B)
- Non-medication DSIs such as ophthalmic procedure DSIs (Task B11-5) - Covers §170.315(b)(11)(ii)(A)
- Override workflows for DSI acknowledgment (Task B11-4) - Covers §170.315(b)(11)(v)(A)

### Tasks covering NEW (b)(11) requirements:

- Configure Predictive DSIs Using USCDI Criteria (Task B11-6) - Covers §170.315(b)(11)(iii) for PDSIs (ANY USCDI data, not just 8 categories)
- View All PDSI Source Attributes + Modify Additional Attributes (Task B11-7) - Covers §170.315(b)(11)(iv)(A) (31 PDSI attributes) and §170.315(b)(11)(v)(B)(2) (limited set of users modifying extended attributes)
- Provide Feedback on an EB-DSI + Export Feedback (Task B11-8) - Covers §170.315(b)(11)(ii)(C) (feedback functionality)

While Moyae does not currently implement production predictive DSIs, the system must support PDSIs per (b)(11) requirements. Tasks B11-6 and B11-7 demonstrate this support capability using placeholder PDSI functionality, specifically testing:

- PDSI activation based on **ANY USCDI data** (not limited to 8 categories like eb-DSIs)
- Display of all **31 required PDSI source attributes** (not just 13 like eb-DSIs)
- **Limited set of identified users** (DSI Administrator) ability to modify additional extended source attributes



Observers recorded quantitative and qualitative measures for each task, consistent with NISTIR 7741 UCD standard and NISTIR 7742 CIF reporting template methodology and §170.315(g)(3) Safety-Enhanced Design requirements.

## Test Tasks and Metrics — §170.315(b)(11)

Eight usability tasks were developed to evaluate Moyae's implementation of Decision Support Interventions (DSIs) as required under §170.315(b)(11). These tasks assess user ability to configure DSIs, activate medication and non-medication interventions, review required source attributes, respond to medication safety alerts, complete override workflows, acknowledge care-plan warnings, configure predictive DSIs using USCDI criteria, view and modify PDSI source attributes, and provide feedback on evidence-based DSIs.

**Participant Assignment:** Testing was conducted over two sessions. Tasks B11-1 through B11-5 were performed independently by ten participants (b11-1 through b11-10) on November 7th, 2025. Tasks B11-6, B11-7, and B11-8 (the new b11-specific requirements) were performed independently by ten participants on November 18th, 2025.

For the second testing session on November 18th, 2025, three participants from the first session (b11-5, b11-6, and b11-9) were not available due to scheduling conflicts. Three new participants (b11-11, b11-12, and b11-13) were recruited to participate in the second session. The ten participants who completed tasks B11-6, B11-7, and B11-8 were: b11-1, b11-2, b11-3, b11-4, b11-7, b11-8, b11-10, b11-11, b11-12, and b11-13. This participant group represents a diverse cross-section including physicians (b11-1, b11-2, b11-3) and technicians with varying experience levels.

All tasks followed NISTIR 7741 UCD standard and NISTIR 7742 reporting guidelines. Metrics collected included task success, time on task, path deviations, errors, and participant satisfaction using a 5-point Likert scale.

The consolidated results of all eight tasks are shown in the table below.

## Consolidated Performance Table — §170.315(b)(11)

Measure	N	Task Success Rate (%)	Path Deviation	Task	Time	Errors (%)	Task Path Deviations	Task Ratings 5 = easy
Task	#	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)		
B11-1, Activate / Configure Medication Decision Support	10	100% (0%)	0/0	28(8)	(8/10)	0% (0%)	0	5.00

<i>Interventions</i>								
<i>B11 -2, View Source Attributes for Medication DSI</i>	10	100% (0%)	0/0	32(10)	(12/20)	0% (0%)	0	4.90
<i>B11- 3, View Source Attributes for Medication DSI</i>	10	100%, (0%)	1/0	30(15)	(10/10)	10% (30%)	1	4.90
<i>B11-4, Respond to a Medication Safety Alert (DDI/DAI/DxI)</i>	10	100%, (0%)	0/0	60(10)	(18/30)	0% (0%)	0	5.00
<i>B11-5, Respond to an Ophthalmic Procedure DSI (Non-Medication)</i>	10	80%, (40%)	3/0	72(32)	(32/30)	20% (40%)	3	4.30
<i>B11-6, Configure Predictive DSIs Using USCDI Criteria</i>	10	100 (0%)	0/0	35(12)	(10/30)	0% (0%)	0	5.00
<i>B11-7, View All PDSI Source Attributes +</i>	10	100, (0%)	3/0	68(25)	(25/30)	10% (15%)	3	4.85

Modify  
Additional  
Attributes

B11-8,	10	100, (0%)	1/0	55(20)	(15/30)	10% (12%)	1	4.85
Provide Feedback on an EB-DSI + Export Feedback								

**Note:** Errors are defined as non-blocking issues (minor navigation mistakes, initial wrong clicks, longer paths) that do not prevent task completion. Error rates represent the percentage of participants who made at least one error. Task success indicates completion of all required steps and success criteria. Time Optimal values represent expert-estimated benchmarks based on pilot testing. Task Path Deviations are counted as total instances across all participants and include both: (1) deviations from the optimal click path, and (2) instances where participants took significantly longer than optimal time, indicating use of a non-standard or inefficient pathway.

Detailed workflow steps for each task are available in Appendix 2: B(11) Task Descriptions.

## Results and Data Analysis

### Major Test Findings

The usability testing revealed several key findings:

1. **Core DSI Functionality (Tasks B11-1 through B11-4):** All tasks achieved 100% success rates with minimal deviations, no errors, and high satisfaction ratings (4.9-5.0). These tasks validated DSI configuration, medication safety alert display, access to required source attributes, and override workflows. Participants found these workflows intuitive and efficient.
2. **Non-Medication DSI Workflow (Task B11-5):** This task involved non-medication DSIs during encounter completion, including "Missing Diagnosis" warnings and smoking cessation counseling prompts. This task showed greater variability, with an 80% success rate and higher error (20%) and deviation counts (3 path deviations), reflecting its increased complexity. The complexity was due to the multi-step nature of the workflow, integration with third-party software systems, and the need to wait for systems to sync back to Moyae. Two participants failed to complete the task, primarily due to confusion about the syncing process and timing of when to proceed after addressing DSIs. Despite the variability, most users completed the workflow successfully and reported positive satisfaction (4.3).
3. **Predictive DSI Support (Task B11-6):** All participants (100%) successfully configured predictive DSIs using USCDI criteria sourced from AWS HealthLake FHIR resources. The task demonstrated that clinicians can activate PDSIs based on any USCDI data (Condition, Observation, Social History) using FHIR data fields, with activation criteria persisting correctly after save. Mean completion time was 35 seconds (optimal: 25 seconds), indicating the workflow is efficient. Satisfaction was perfect (5.0). This task validated that Moyae supports PDSI configuration without requiring a predictive model to be supplied.

4. **PDSI Source Attributes Management (Task B11-7):** This task tested both viewing all 31 required PDSI source attributes (clinician role) and modifying additional extended source attributes (administrator role). All participants (100%) completed the task successfully. Mean completion time was 68 seconds (optimal: 45 seconds), with 3 path deviations observed, reflecting the complexity of navigating between viewing and editing modes. Satisfaction was high (4.85).
5. **Feedback Functionality (Task B11-8):** All participants (100%) successfully provided structured feedback on an evidence-based DSI and administrators were able to export feedback data in computable format. This new b11 requirement was well-received, with participants appreciating the ability to provide input on DSI accuracy and relevance. Mean completion time was 55 seconds (optimal: 40 seconds), with high satisfaction (4.85).

## Effectiveness Results

Overall task success rate across all eight tasks was **97.5%**. Tasks B11-1, B11-2, B11-3, B11-4, B11-6, B11-7, and B11-8 achieved 100% success rates. Task B11-5 achieved 80% success. The lower success rate in B11-5 reflects the increased complexity of this workflow, particularly the multi-step nature involving multiple non-medication DSIs triggered at encounter departure.

Error rates were low overall, with only Tasks B11-3, B11-5, B11-7, and B11-8 showing errors (10%, 20%, 10%, and 10% respectively). Most errors were minor navigation issues that did not prevent task completion.

## Efficiency Results

Mean task completion time across all tasks was **47.5 seconds**, with a standard deviation of 18.6 seconds. Tasks B11-1 through B11-4, which cover core DSI functionality, had mean completion times ranging from 28 to 60 seconds, all within acceptable ranges for clinical workflows. The new b11-specific tasks (B11-6, B11-7, B11-8) had mean completion times of 35, 68, and 55 seconds respectively, demonstrating efficient workflows for the new functionality.

Task path deviations totaled 8 across all tasks (Task B11-3 had 1 deviation, Task B11-5 had 3 deviations, Task B11-7 had 3 deviations, and Task B11-8 had 1 deviation). The higher deviation counts in B11-5 and B11-7 reflect the increased complexity of these workflows, particularly the multi-step nature of B11-5 and the role-switching requirement in B11-7.

## Satisfaction Results

Overall mean satisfaction rating across all tasks was **4.85** on a 5-point Likert scale, with a standard deviation of 0.25. Individual task satisfaction ratings ranged from 4.3 (Task B11-5) to 5.0 (Tasks B11-1, B11-4, and B11-6). The new b11-specific tasks (B11-6, B11-7, B11-8) received satisfaction ratings of 5.0, 4.85, and 4.85 respectively, indicating very positive user reception of the new functionality.

## Qualitative Feedback and User Comments

During and after task completion, participants provided qualitative feedback through think-aloud protocols and post-task interviews. Key themes and specific comments are summarized below:

### General Feedback:

- Participants found the DSI configuration workflows (Tasks B11-1 and B11-2) intuitive and straightforward
- Medication safety alerts (Tasks B11-3 and B11-4) were described as clear and appropriately timed
- Source attribute information was generally found to be accessible and informative

#### **Feedback on New b11 Functionality:**

##### **Task B11-8 (Feedback Functionality):**

- Several participants noted that their practice does not currently use the feedback loop functionality, indicating this is a new feature that may require workflow integration and training
- Some participants expressed confusion about the destination of feedback submissions, specifically whether feedback was being sent to rcopia (a third-party system) or Moyae EHR directly
- Participants who understood the feedback mechanism appreciated the ability to provide input on DSI accuracy and relevance
- Administrators found the export functionality useful for compliance and quality improvement purposes

##### **Task B11-6 (PDSI Configuration):**

- Participants found the PDSI configuration interface clear and easy to use
- The ability to configure activation criteria using USCDI-mapped patient data sourced from AWS HealthLake FHIR resources was well-received
- Participants appreciated the flexibility to configure triggers using various USCDI data elements (Condition, Observation, Social History)
- The verification step (reopening to confirm persistence) provided confidence that settings were saved correctly

##### **Task B11-7 (PDSI Source Attributes):**

- Clinicians appreciated having access to comprehensive source attribute information
- Administrators found the extended attributes section functional but noted it could be more discoverable (as reflected in the Areas for Improvement section)

##### **Task B11-5 (Non-Medication DSIs):**

- Some participants found the workflow for ophthalmic procedure DSIs complex, which aligns with the higher error rate and path deviations observed

#### **Recommendations Based on User Feedback:**

1. **Clarify Feedback Destination:** The interface should clearly indicate where feedback is being sent (Moyae EHR vs. third-party systems) to reduce user confusion
2. **Workflow Integration:** Practices may need guidance on how to integrate the feedback loop into their existing clinical workflows
3. **Training Considerations:** Since feedback functionality is new to many practices, training materials and user guidance may be beneficial

## **Areas for Improvement**

Based on the testing results and participant feedback, the following areas were identified for potential improvement:

1. **Task B11-5 (Non-Medication DSI - Encounter Completion):** The workflow for non-medication DSIs during encounter completion (Missing Diagnosis warnings and counseling prompts) could be improved to reduce path deviations and errors. Specific improvements to consider:

- **Third-Party Integration:** Provide clearer visual indicators or status messages when waiting for third-party software systems to sync with Moyae
  - **Timing Guidance:** Add guidance or prompts to help users understand when it is safe to proceed after addressing DSIs and waiting for system synchronization
  - **Workflow Simplification:** Consider streamlining the multi-step process of addressing multiple DSIs (diagnosis warning, counseling prompts) during encounter completion
  - **Error Prevention:** Two participants failed due to confusion about the syncing process - consider adding confirmation messages or progress indicators during synchronization
2. **Task B11-7 (PDSI Source Attributes):** The interface for accessing extended source attributes could be made more discoverable. Consider adding visual indicators or tooltips to guide administrators to the extended attributes section.
  3. **Task B11-8 (Feedback Functionality):** Based on participant feedback, the following improvements are recommended:
    - **Clarify Feedback Destination:** The interface should clearly indicate where feedback submissions are being sent (Moyae EHR vs. third-party systems such as rCopia) to eliminate user confusion
    - **Workflow Integration Guidance:** Provide documentation and training materials to help practices integrate the feedback loop into their existing clinical workflows, as many practices do not currently use this functionality
    - **Visual Indicators:** Consider adding clear labels or indicators showing the feedback submission destination
  4. **Overall:** Continue monitoring user feedback on DSI workflows and consider iterative improvements based on real-world usage patterns. Provide training and documentation for new b11 functionality, particularly the feedback loop feature.

## Limitations

The following limitations should be considered when interpreting the results of this usability study:

1. **Sample Size:** While thirteen participants is consistent with standard usability testing practices, results may not capture all potential user scenarios or edge cases.
2. **Controlled Environment:** Testing took place in a controlled environment rather than real-world clinical settings, which may affect generalizability of results to actual clinical workflows.
3. **Placeholder PDSI Functionality:** Tasks B11-6 and B11-7 tested PDSI support using placeholder functionality rather than production predictive DSIs. While this demonstrates system capability, actual PDSI implementations may vary.
4. **Participant Experience:** Participants had varying levels of EHR and product experience, which may have influenced task performance and satisfaction ratings.
5. **Task Ordering:** Tasks were performed in a specific order, which may have introduced learning effects or carryover between tasks despite fresh logins.
6. **Time Constraints:** Testing was conducted during scheduled sessions, which may not reflect the time pressures and interruptions common in real clinical environments.

Despite these limitations, the study provides valuable insights into the usability of Moyae EHR's Decision Support Interventions functionality and demonstrates compliance with §170.315(b)(11) requirements.

## Summary Interpretation

Tasks B11-1 through B11-4 achieved 100% success with minimal deviations, no errors, and high satisfaction ratings. These tasks validated DSI configuration, medication safety alert display, access to required source attributes, and override workflows.

Task B11-5 involved non-medication DSIs during encounter completion, including "Missing Diagnosis" warnings and smoking cessation counseling prompts. This task showed greater variability, with an 80% success rate and higher error (20%) and deviation counts (3 path deviations), reflecting its increased complexity. The complexity stemmed from the multi-step workflow, integration with third-party software systems, and the need to wait for systems to sync back to Moyae.

The new b11-specific tasks (B11-6, B11-7, B11-8) demonstrated successful implementation of the new requirements: PDSI configuration support, PDSI source attribute management, and feedback functionality. These tasks achieved 100% success rates and very positive user satisfaction (4.85-5.0), validating that Moyae EHR supports the expanded b11 requirements.

Overall, the results demonstrate that Moyae EHR supports the safe, effective, and efficient use of Decision Support Interventions required by §170.315(b)(11), including both the requirements carried forward from (a)(9) and the new requirements specific to (b)(11).

## Conclusions

Based on the comprehensive usability testing conducted in accordance with NISTIR 7741 UCD standard and reported using the NISTIR 7742 template, the following conclusions can be drawn:

1. **Compliance with §170.315(b)(11) Requirements:** Moyae EHR Version 1 successfully demonstrates compliance with all tested requirements of the b(11) Decision Support Interventions criterion, including both requirements carried forward from (a)(9) and the new requirements specific to (b)(11).
2. **Evidence-Based DSI Functionality:** Tasks B11-1 through B11-5 validated that the system effectively supports evidence-based DSI configuration, display, source attribute review, and override workflows, with high success rates (80-100%) and positive user satisfaction.
3. **Predictive DSI Support:** Tasks B11-6 and B11-7 demonstrated that the system supports predictive DSIs as required, including:
  - Activation based on ANY USCDI data (not limited to 8 categories) using USCDI-mapped patient data sourced from AWS HealthLake FHIR resources
  - Configuration of activation criteria using various USCDI data elements (Condition, Observation, Social History)
  - Display of all 31 required PDSI source attributes
  - Limited set of identified users (DSI Administrators) ability to modify extended source attributes
  - Support for PDSIs without requiring a predictive model to be supplied
4. **Feedback Functionality:** Task B11-8 validated the new feedback requirement, demonstrating that users can provide structured feedback on evidence-based DSIs and that limited-role users can export feedback data in computable format.
5. **Overall Usability:** The high success rates (97.5% average), reasonable completion times (47.5 seconds average), and positive satisfaction ratings (4.85 average) indicate that Moyae EHR's DSI functionality is usable, effective, and well-received by clinical users.
6. **Safety-Enhanced Design:** The testing methodology, participant selection, and comprehensive task coverage demonstrate that user-centered design processes were applied during development and included as part of summative testing, as required by §170.315(g)(3).

The results support the conclusion that Moyae EHR Version 1 meets the Safety-Enhanced Design requirements for §170.315(b)(11) Decision Support Interventions.

## Appendix 2: B(11) Task Descriptions

### Task B11-1: Activate / Configure Medication Decision Support Interventions

#### Regulatory Requirements:

- §170.315(b)(11)(ii)(A) - Enable interventions specified in paragraphs (b)(11)(iii) of this section to be configured by a limited set of identified users based on a user's role

**Goal:** Evaluate whether a clinical administrator can locate and configure medication-related DSIs (DDI, DAI, DDxI)

**Role:** Administrator

#### Steps:

1. Log in as an Admin user
2. Navigate to Patient Chart → Prescribe → Settings → Preferences
3. Under Alerts, enable all three interventions:
  - Drug–Drug Interaction (DDI) → Check "Require acknowledgement of Drug–Drug alerts"
  - Drug–Allergy Interaction (DAI) → Check "Require acknowledgement of Drug–Allergy alerts"
  - Drug–Diagnosis Interaction (DDxI) → Check "Require acknowledgement of Drug–Diagnosis alerts"
4. Save settings

#### Success Criteria:

- Each DSI category can be enabled
- Updated configuration is saved and displayed correctly

### Task B11-2: Clinician Configuration of Ophthalmic & Device DSIs

#### Regulatory Requirements:

- §170.315(b)(11)(ii)(A) - Enable interventions specified in paragraphs (b)(11)(iii) of this section to be configured by a limited set of identified users based on a user's role
- §170.315(b)(11)(iii)(A) - Evidence-based decision support interventions and use any data based on the following data expressed in the standards in § 170.213: Problems; Medications; Allergies and Intolerances; At least one demographic specified in paragraph (a)(5)(i) of this section; Laboratory; Vital Signs; Unique Device Identifier(s) for a Patient's Implantable Device(s); and Procedures

**Goal:** Evaluate whether a clinician can locate and activate ophthalmic and device-based DSI options within personal preferences.

**Role:** Ophthalmologist



**Steps:**

1. Log in as a clinician (Doctor role)
2. Open the top-right user profile menu
3. Select My Settings
4. Navigate to Clinical Decision Support Preferences
5. Toggle ON the following DSIs:
  - Implantable Device Alerts
  - Refraction Reminder Alerts
  - Care-Plan Warning Alerts
6. Save settings

**Success Criteria:**

- Clinician locates the correct setting panel
  - All specified DSIs are successfully enabled and saved
- 

## **Task B11-3: View Source Attributes for Medication DSI**

**Regulatory Requirements:**

- §170.315(b)(11)(i) - Decision support intervention interaction. Interventions provided to a user must occur when a user is interacting with technology
- §170.315(b)(11)(iv)(A) - For evidence-based decision support interventions: [13 required source attributes including bibliographic citation, developer, funding source, release/revision dates, use of race/ethnicity/language/sexual orientation/gender identity/sex/date of birth/social determinants of health/health status assessments data]

**Goal:** Verify that a user can locate and view required source attributes associated with evidence-based medication DSIs.

**Role:** Technician prescribing on behalf of supervising provider

**Steps:**

1. Begin a new medication order for Timolol
2. When the drug-drug interaction alert appears due to Metoprolol history, click "Info" or "Details"
3. Review the displayed source attributes, including:
  - Purpose statement
  - Evidence source or reference
  - Last update or version date
4. Close the information panel

**Success Criteria:**

- Alert displays correctly based on clinical history
  - User is able to locate and read source attribute details
-

## Task B11-4: Respond to a Medication Safety Alert (DDI/DAI/DDxI)

### Regulatory Requirements:

- §170.315(b)(11)(i) - Decision support intervention interaction. Interventions provided to a user must occur when a user is interacting with technology
- §170.315(b)(11)(ii)(C) - Enable a user to provide electronic feedback data for evidence-based decision support interventions selected via the capability provided in paragraph (b)(11)(iii)(A) of this section and make available such feedback data to a limited set of identified users for export, in a computable format, including at a minimum the intervention, action taken, user feedback provided (if applicable), user, date, and location

*Note: This task tests the feedback capability as part of the override workflow (custom justification/override message and medication notes), while Task B11-8 tests the explicit feedback submission mechanism and export functionality*

**Goal:** Evaluate the safety workflow for acknowledging and documenting DDI/DAI/DDxI alerts.

**Role:** Ophthalmologist

### Steps:

1. Prescribe Acetazolamide for patient David Vanwyk with documented sulfonamide allergy
2. Review the displayed medication allergy warning
3. Select an acknowledgment option
4. Enter a custom justification/override message
5. Complete the prescription and verify that:
  - The medication records correctly to the patient chart history on Moyae's history tab
  - Add a custom note to the medication and verify that it timestamps and dates the note

### Success Criteria:

- Alert displays correctly
- Override is documented
- Medication is recorded in history as intended

## Task B11-5: Respond to an Ophthalmic Procedure DSI (Non-Medication)

### Regulatory Requirement:

- §170.315(b)(11)(i) - Decision support intervention interaction. Interventions provided to a user must occur when a user is interacting with technology
- §170.315(b)(11)(iii)(A) - Evidence-based decision support interventions and use any data based on the following data expressed in the standards in § 170.213: Problems; Medications; Allergies and Intolerances; At least one demographic specified in paragraph (a)(5)(i) of this section; Laboratory; Vital Signs; Unique Device Identifier(s) for a Patient's Implantable Device(s); and Procedures

*Note: This task demonstrates evidence-based DSIs triggered by USCDI data (Problems - missing diagnosis, Social History/Health Status - smoking status), showing that activated evidence-based DSIs correctly use USCDI data categories to trigger interventions*

**Goal:** Assess workflows related to non-medication DSIs, including mandatory care-plan validation and risk-based counseling prompts.

**Role:** Ophthalmologist: [Doctor2@moyae.com](mailto:Doctor2@moyae.com) (has preset settings already checked)

**Steps:**

1. Log in as a clinician and open a patient encounter
2. Navigate to the Care Plan section
3. Select the Dry Eye care-plan template
4. Mark the patient as a current smoker
5. Attempt to complete or depart the encounter without entering a diagnosis
6. Review the DSI message: "No diagnosis selected. A care plan cannot be completed without a diagnosis."
7. Add a diagnosis or acknowledge the warning to continue
8. Review and address the displayed Smoking Cessation Counseling prompt
9. Save and exit

**Success Criteria:**

- Mandatory DSI appears when departing without diagnosis
- Smoking cessation alert appears due to risk factor
- User acknowledges or completes required intervention

**Note on Complexity:** This task involves integration with third-party software systems and requires waiting for systems to sync back to Moyae, which adds complexity and explains the higher variability in completion times and path deviations observed. The multi-step nature of addressing multiple non-medication DSIs during encounter completion also contributes to the complexity.

## Task B11-6: Configure Predictive DSIs Using USCDI Criteria

**Regulatory Requirement:**

- §170.315(b)(11)(iii)(B) - Predictive Decision Support Interventions and use any data expressed in the standards in § 170.213
- §170.315(b)(11)(ii)(A) - Enable interventions specified in paragraphs (b)(11)(iii) of this section to be configured by a limited set of identified users based on a user's role

**Goal:** Demonstrate that Moyae supports the activation and configuration of a Predictive Decision Support Intervention (PDSI) by allowing a clinician to choose activation criteria using USCDI-mapped patient data sourced from AWS HealthLake FHIR resources.

*This demonstrates support for PDSIs without supplying a predictive model.*

**Role:** Clinician

**Steps:**

1. Navigate to: My Settings → Decision Support → Predictive DSI Settings
2. Select the placeholder PDSI: "Vision Loss Risk Model (Predictive DSI Placeholder)"

3. Under *Activation Criteria*, configure USCDI-based triggers using FHIR data fields sourced from AWS HealthLake:
  - *Condition (USCDI: Condition):* Select *Diabetes Mellitus*
  - *Observation (USCDI: Laboratory/Observation):* Select *Hemoglobin A1c*, enter threshold > 7%
  - *Smoking Status (USCDI: Social History / Observation):* Select *Current Smoker*
4. Click *Save* to store the activation criteria
5. Reopen the same *Predictive DSI* entry and verify that all USCDI-based activation criteria persist as configured

**Success Criteria:**

- A clinician is able to:
    - Access the *Predictive DSI* configuration panel
    - Select the placeholder *PDSI* for editing
    - Configure one or more triggers using USCDI data elements (*Condition*, *Observation*, *Smoking Status*)
    - Save the configuration without errors
    - Reopen the configuration and verify that the settings persist
  - No predictive output, scoring, or model execution is required
- 

## Task B11-7: View All PDSI Source Attributes + Modify Additional Attributes

**Regulatory Requirements:**

- §170.315(b)(11)(iv)(B) - For Predictive Decision Support Interventions: [31 required source attributes including details and output, purpose, cautioned out-of-scope use, intervention development details, external validation process, quantitative measures of performance, ongoing maintenance, and update schedule]
- §170.315(b)(11)(v)(A) - Access. For evidence-based decision support interventions and Predictive Decision Support Interventions supplied by the health IT developer as part of its Health IT Module, the Health IT Module must enable a limited set of identified users to access complete and up-to-date plain language descriptions of source attribute information specified in paragraphs (b)(11)(iv)(A) and (B) of this section
- §170.315(b)(11)(v)(B)(2) - For Predictive Decision Support Interventions, the Health IT Module must enable a limited set of identified users to record, change, and access additional source attributes not specified in paragraph (b)(11)(iv)(B) of this section

**Goal:** Verify that the user can view all 31 required PDSI source attributes and that a limited-role user can modify additional extended source attributes.

**Roles:** Clinician (viewing) + DSI Administrator (editing - limited set of identified users)

**Steps (Clinician):**

1. From settings menu, open: *Decision Support* → *Predictive DSI Info*
2. Select: *"Vision Loss Risk Model (Predictive DSI Placeholder)"*
3. Click *"View Source Attributes"*
4. Scroll through all 31 PDSI source attributes (purpose, provenance, limitations, bias, interpretability method, model version, validation dataset, etc.)

The screen displays all required PDSI source-attribute categories grouped into sections.  
Scroll through the page and confirm the presence of each section:

- **Details & Output** (developer, funding, output description, output type)
- **Purpose of the Intervention** (intended use, populations, users, decision role)
- **Cautioned / Out-of-Scope Use** (risks, limitations, inappropriate uses)
- **Development & Input Features** (training data criteria, demographic representativeness, fairness approach, bias mitigation, input feature usage)
- **External Validation** (dataset description, testing party, representativeness, validation process)
- **Performance Metrics** (validity, fairness, external performance, outcome citations)
- **Ongoing Monitoring & Maintenance** (monitoring processes, update schedule, mitigation steps)

5. Confirm that **all required categories** appear on the PDSI information screen.

#### **Steps (Administrator):**

6. Log in as DSI Administrator
7. Navigate to: Admin → Decision Support → Predictive DSI Administration
8. Under "Additional (Extended) Source Attributes," modify:
  - Algorithm Revision Note
  - Local Calibration Adjustment
  - Manual Suppression Flag
9. Save changes
10. Reopen the model to confirm persistence

#### **Success Criteria:**

- Clinician sees all 31 required PDSI source attributes
- Administrator can edit extended source attributes beyond the standard 31
- Changes persist after saving
- Both viewing and editing workflows are functional

## **Task B11-8: Provide Feedback on an EB-DSI + Export Feedback**

**Regulatory Requirement:** §170.315(b)(11)(ii)(C) - Enable a user to provide electronic feedback data for evidence-based decision support interventions selected via the capability provided in paragraph (b)(11)(iii)(A) of this section and make available such feedback data to a limited set of identified users for export, in a computable format, including at a minimum the intervention, action taken, user feedback provided (if applicable), user, date, and location

**Goal:** Demonstrate that a clinician can give structured feedback on an evidence-based DSI and that a limited-role user can export the feedback in a computable format.

**Roles:** Clinician + Administrator

**Steps (Clinician):**

1. Prescribe Timolol for a patient on Metoprolol to trigger a DDI alert
2. When the alert appears, select "Provide Feedback" on the DSI alert
3. Enter structured feedback (e.g., "Severity overstated," "Evidence outdated," "Alert was helpful")
4. Submit feedback
5. Confirm feedback submission message

**Steps (Administrator):**

6. Log in as an Admin or Compliance Officer
7. Navigate to: Settings → Clinical Decision Support → Feedback Data → Export
8. Select date range: Last 30 days
9. Export feedback as a computable file (JSON/CSV format)
10. Open the exported file and confirm that the clinician's feedback is included with appropriate metadata

**Success Criteria:**

- Feedback entry interface is accessible from DSI alerts
- Structured feedback can be submitted
- Feedback is stored in computable form
- Limited-role user can export feedback data
- Exported data includes all required fields and metadata