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# EHR Usability Test Report of Clinical Document Exchange version 1.5

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

**Product Under Test:** Clinical Document Exchange version 1.5  
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## 1. Executive Summary

A usability test of Clinical Document Exchange version 1.5 (CDE), an electronic application for CDA exchange and reconciliation was conducted on July 24, 2018 at Melrose Wakefield Healthcare in Stoneham, Massachusetts by Iatric Systems, Inc. The purpose of this test was to test and validate the usability of the current user interface and provide evidence of usability in the EHR Under Test (EHRUT). During the usability test, 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 4 tasks typically conducted on CDE, such as:

- Patient Selection
- Reconciling Problems
- Reconciling Allergies
- Reconciling Medications

During the 60-minute one-on-one usability test, each participant was greeted by the administrator and asked to review and sign an informed consent/release form (included in Appendix 3); they were instructed that they could withdraw at any time. Participants were trained on new functionalities of the EHR at the start of the session. The majority of the participants currently do not use the products. Training Agenda/Outline and user logins and training patients were provided, but no training materials were given to the participants. A general overview of the testing process and expectations was presented. The application functionality was reviewed with the participants. Time was allotted for questions and additional practice if needed.

The administrator introduced the test and instructed participants to complete a series of tasks (given one at a time) using CDE. During the testing, the administrator timed the test and, along with the data loggers, recorded user performance data on paper and electronically. The administrator did not give the participant assistance in how to complete the task. Participant screens, head shots and audio were recorded for subsequent analysis.

The following types of data were collected for each participant:

- Number of tasks successfully completed within the allotted time without assistance
- Time to complete the tasks
- Number and types of errors
- Path deviations

- Participant’s verbalizations (comments)
- 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 and fill out a System Usability Scale (SUS). 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 CDE. Following is a summary of the performance and rating data collected on CDE.

**Figure 1 – Data Summary**

Measure Task	N	Task Success (%)	Path Deviation	Task Time (in seconds)	Errors	Task Ratings 1= difficult, 5= easy
	#	Mean (SD)	Deviations (Observed/Optimal)	Mean (SD)	Mean (SD)	Mean (SD)
Patient Identification and Selection	1	55 (30)	10/0	31.8 (18.1)	0 (0)	4.5 (0.67)
Problem Reconciliation	2	47 (66)	17/0	80.2 (22.1)	1 (0.6)	3.9 (0.7)
Allergy Reconciliation	3	100 (0)	7/0	59.6 (14.4)	0.1 (0.3)	4.3 (0.46)
Medication Reconciliation	4	60 (40)	6/0	49.0 (23.7)	0.1 (0.3)	4.3 (0.64)

The results from the System Usability Scale (SUS) scored the subjective satisfaction with the system based on performance with these tasks to be: 68.75.

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

- Major findings (found in Discussion of the Findings, section 4.2)
- Areas for improvement (found in Discussion of the Findings, section 4.2)

## 2. Introduction

The EHRUT tested for this study was Clinical Document Exchange version 1.5 (CDE). Clinical Document Exchange is a CDA exchange and reconciliation solution. The system can electronically transmit and receive a patients EHR records via HL7 3.0 standards. This exchange of information provides up-to-date patient data to the physician in the care setting allowing for

better patient care decisions and reducing the number of typographical errors that occur from transcribed or verbal exchange. The reconciliation component provides healthcare providers the ability to manually process the CDA that was received and review patient problems, allergies, and medications in a user-friendly interface prior to incorporating them into the patient's medical record. The usability testing attempted to represent realistic exercises and conditions.

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

## 3. Method

### 3.1 Participants

A total of 10 participants were recruited and selected to be tested on CDE. Participants in the test were hospital IT staff, physicians, and nurses. Participants were recruited by Mark-Harrison Nelson, who has been a Health IT professional for over 20 years. Mark-Harrison has supported/implemented several health IT initiatives during his time with Melrose-Wakefield (formerly Hallmark Health) and has prior experience as a Chem-Lab manager.

Participants had no direct connection to the development of or organization producing the EHRUT, CDE. Participants were not from the testing or supplier organization. And, participants were not current active users of the software, but were designated as intended end users of CDE. All participants completed a 30-minute training session prior to the usability test.

For the test purposes, end-user characteristics were identified and translated into a recruitment screener used to solicit potential participants; an example screener is provided in Appendix 1. Recruited participants had a mix of professional experience and EHR experience that we felt was representative of our target users. Most hospital employees that have historically used CDE are IT staff members, but could also include physicians and nurses, so we recruited a representative group. 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.

**Figure 2 – Participant Demographics Table**

	Part ID	Gender	Age Range	Education	Occupation/ Role	Professional Experience (at current position)	Computer Usage	EHR Experience	Assistive Technology Need
1	Tester1	Male	50-59	Bachelor's Degree	Sr. Systems Integration Analyst	Clinical Lab	144	84	No
2	Tester2	Female	50-59	Associate degree	Provider System Analyst	System Analyst	120	0	No
3	Tester3	Female	30-39	Bachelor's Degree	Clinical Analyst II	Clinical Analyst	240	0	No
4	Tester4	Female	30-39	Bachelor's Degree	Senior Clinical Analyst	Information Systems - Healthcare	300	0	No
5	Tester5	Male	40-49	Bachelor's Degree	Sr. Integration Coordinator	Interfaces/Integration	1000	20	No
6	Tester6	Female	60-69	Bachelor's Degree	Nursing Informatics Specialist	Nursing	122	0	No
7	Tester7	Male	30-39	Master's Degree	Physician/end user	Internal Medicine	144	48	No
8	Tester8	Male	30-39	Bachelor's Degree	Project Specialist	Meditech for 2 years, Meditech Consulting for 4 years, 2 years full time with Hospital	200	0	No
9	Tester9	Male	30-39	Bachelor's Degree	Systems Analyst II	Healthcare IT	72	0	No
10	Tester10	Female	40-49	Bachelor's Degree	Executive Director, IS	NA	480	36	No

10 participants (matching the demographics in the section on Participants) were recruited and all 10 participated in the usability test. Participants were scheduled for 60-minute sessions at the user's convenience. A spreadsheet was used to keep track of the participant schedule and included each participant's demographic characteristics, survey results, and user comments.

### 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 1 EHRs. Each participant used the system in a familiar and comfortable location and was provided with the same instructions. The system was evaluated for effectiveness, efficiency and satisfaction as defined by measures collected and analyzed for each participant:

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

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

### 3.3 Tasks

Several tasks were constructed that would be realistic and representative of the kinds of activities a user might do with this EHR, including:

1. Patient identification and selection.
2. Reconciliation of patient problems.
3. Reconciliation of patient allergies.
4. Reconciliation of patient medications.

Tasks were selected based on their frequency of use, criticality of function, and those that may be most troublesome for users.

### 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.

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 consisted of experienced usability practitioners.

The testing administrator was John Fellian, Product Owner, Team Leader, and developer of CDE at Iatric Systems. As the Product Owner and Lead developer on the Clinical Document Exchange (CDE) product, John has the most intimate knowledge of the functionality of the UI and how it was designed to be used. John has been the product owner for CDE at Iatric Systems since March of 2017. He has 12 years of experience in his position with Iatric Systems and has a Bachelor of Science Degree from Northeastern University.

The data logger and Meaningful Use expert was Jeremy Blanchard. Jeremy is the Director of Analytics at Iatric Systems and holds a Master of Science degree in Health Informatics from Northeastern University. He has held positions of developer and product owner for various products during his 11 years at Iatric Systems.

Each participant reviewed and signed an informed consent and release form (See Appendix 3). The administrator moderated the session including administering instructions and tasks. The administrator also obtained post-task rating data and took notes on participant comments. A second person served as the data logger and monitored task times, took notes on task success, path deviations, number and type of errors, and comments.

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

- As quickly as possible making as few errors and deviations as possible.
- Without assistance; administrators could 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 and verbalized, "Start." The task time was stopped once the participant indicated they had successfully completed the task and verbalized, "Done", or the data filing process began. Scoring is discussed below in Section 3.9.

Following the session, the administrator gave the participant 2 post-test questionnaires (the Final Questions survey and the System Usability Scale, see Appendix 5 and 6 respectively), and thanked everyone individually for their participation. Participants' demographic information, task success rate, time on task, errors, deviations, verbal responses, and post-test questionnaire were recorded into a spreadsheet.

### 3.5 Test Location

Testing was conducted remotely over an internet-based video conference. Participants used their personal workspaces and assumed keyboard and mouse control of an Iatric PC for the purposes of performing the testing steps. The administrator and data logger were able to see the desktop of the PC, the participants face via webcam, and audio via conference line. Each environment was of a minimal noise volume, comfortable to the user, and free of distractions.

### 3.6 Test Environment

The EHRUT would be typically used in a healthcare office or facility. In this instance, the testing was conducted over a GoToMeeting video conference. For testing, the participants assumed keyboard and mouse control of an Iatric owned Dell OptiPlex 7740 desktop computer running Windows 10. The participants used a wireless mouse and a keyboard when interacting with the EHRUT.

The EHRUT was used on a 24-inch screen, with 1920/1080 resolution and in conjunction with a built-in webcam. The application was set up according to the product owner's documentation describing the system set-up and preparation. The application itself was running on a platform using a training / test database on a LAN / 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 & Nondisclosure Form
2. Moderator's Guide
3. Post-test Questionnaire
4. System Usability Scale (SUS) Survey
5. Demographics Survey

Examples of these documents are found in Appendices 3-7 respectively. The Moderator's Guide was devised to capture required data. The participant's interaction with the EHRUT was captured and recorded digitally with screen capture software running on the test machine. A web camera recorded each participant's facial expressions synced with the screen capture, and verbal

comments were recorded with a microphone. The test moderator later analyzed the video recordings.

### 3.8 Participant Instructions

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

*I want to thank you for participating in this study. Your input is very important. Our session today will last no more than 60 minutes.*

*In this study, we are evaluating the usability of our clinical reconciliation system. I will provide a brief tutorial on how to use the system, then ask you to perform 4 tasks and complete some surveys afterwards. We would like to record this session using a webcam and screen recording device. All information 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. The administrator gave them task packets and the following instructions:

*Now we'll begin the study. This part will be recorded. You'll be asked to complete four tasks. I will read the scenario, then say "please start". Please begin working the task, feel free to perform whatever steps you feel necessary to complete the task as quickly and easily as possible. Due to the nature of the test, we are not allowed to guide you or give feedback to you during the test. Remember, our goal is to observe how you would complete the tasks on your own. You may ask specific questions regarding information that may be missing, but I cannot guide or direct you on how to complete a task.*

*When you have completed a task, say "done" out loud. I will ask you to rate the ease of completion for the task on a scale of 1 to 5. We will then move on to the next task and repeat until we've completed all 4 tasks.*

*Do you have any questions before we start?*

Participants were then shown the 4 tasks to complete. Tasks were displayed on the screen one at a time next to the EHR window, so the user could easily review the task instructions. After a task was completed the next task’s instructions were displayed. Tasks are listed in the moderator’s guide in Appendix 4.

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

## DATA SCORING

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

**Figure 3 – Observed Data Scoring Details**

Measures	Rationale and Scoring
<p><b>Effectiveness:</b></p> <p>Task Success</p>	<p>A task was counted as a “Success” if the participant was able to achieve the correct outcome, without assistance, within the time allotted on a per task basis.</p> <p>The total number of successes were calculated for each task and then divided by the total number of times that task was attempted. The results are provided as a percentage.</p> <p>Task times were recorded for successes. Observed task times divided by the optimal time for each task is a measure of optimal efficiency.</p> <p>Optimal task performance time, as benchmarked by expert performance under realistic conditions, is recorded when constructing tasks. Target task times used for task times in the Moderator’s Guide must be operationally defined by taking multiple measures of optimal performance and multiplying by some factor [e.g., 3] that allows some time buffer because the participants are presumably not trained to expert performance. Thus, if expert, optimal performance on a task was [30] seconds then allotted task time performance was [x * 3] seconds. This ratio should be aggregated across tasks and reported with mean and variance scores.</p>

<p><b>Effectiveness:</b> Task Failures</p>	<p>If the participant abandoned the task, did not reach the correct answer or performed it incorrectly, or reached the end of the allotted time before successful completion, the task was counted as a "Failures." No task times were taken for errors.</p> <p>The total number of errors was calculated for each task and then divided by the total number of times that task was attempted. Not all deviations would be counted as errors. This should also be expressed as the mean number of failed tasks per participant.</p> <p>On a qualitative level, an enumeration of errors and error types should be collected.</p>
<p><b>Efficiency:</b> Task Deviations</p>	<p>The participant's path (i.e., steps) through the application was recorded. Deviations occur if the participant, for example, went to a wrong screen, clicked on an incorrect menu item, followed an incorrect link, or interacted incorrectly with an on-screen control. This path was compared to the optimal path. The number of steps in the observed path is divided by the number of optimal steps to provide a ratio of path deviation.</p> <p>It is strongly recommended that task deviations be reported. Optimal paths (i.e., procedural steps) should be recorded when constructing tasks.</p>
<p><b>Efficiency:</b> Task Time</p>	<p>Each task was timed from when the administrator said "Begin" until the participant said, "Done." If he or she failed to say "Done," the time was stopped when the participant stopped performing the task. Average time per task was calculated for each task. Variance measures (standard deviation) were also calculated.</p>
<p><b>Satisfaction:</b> Task Rating</p>	<p>Participant's subjective impression of the ease of use of the application was measured by administering both a simple post-task question as well as a post-session questionnaire. After each task, the participant was asked to rate "Overall, this task was:" on a scale of 1 (Very Difficult) to 5 (Very Easy). These data are averaged across participants.</p> <p>Common convention is that average ratings for systems judged easy to use should be 3.3 or above.</p> <p>To measure participants' confidence in and likeability of the CDE product 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 6.</p>

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## 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. If able to obtain additional resources (such as more testing time or more usability team resources), it is preferable to test with participants on an individual basis. This will decrease the stress of perceived competition and eliminate interaction between participants. The usability testing results for the EHRUT are detailed in the Execute Summary on pg. 4 (see Table 1).

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. The results from the SUS (System Usability Scale) scored the subjective satisfaction with the system based on performance with these tasks to be: 68.75. Broadly interpreted, scores under 60 represent systems with poor usability; scores over 80 would be considered above average.

### 4.2 Discussion of the findings

To determine the success of CDE, the usability team analyzed the data while keeping several areas in mind: effectiveness, efficiency, satisfaction and areas for improvement. To gather conclusions about the effectiveness of CDE, the team analyzed success and failure rates of tasks. To look at efficiency, the task time and deviation data was noted and interpreted. For measures of satisfaction, the SUS scores and reported task ratings were analyzed. The team determined areas for improvement by taking note of verbalizations from participants, analyzing the Final Questions survey data for written comments, and relying on observations from the administrator and data loggers.

#### Effectiveness

Based on the success, failure and path deviation data, CDE can be described as effective. CDE tested well in terms of effectiveness; one out of four tasks had a 100% success rate.

Task 1 had a user request a restart due to not being able to see the full GoToMeeting screen and being at a disadvantage. We counted the first attempt at Task 1 for this user as a failure because

the screen issue was not brought to the administrator's attention until after the timer had already started.

Task 2 had a high error rate due to the user's interpretation of the scenario and was agreed among the testing team to be slightly ambiguous and could cause an error depending on how the user determined the data to be "medically relevant". The testing team did not update the script, so that all users were given the exact same opportunity for success.

Task 4 had 2 users that needed to restart the task due to exiting from the screen accidentally and needing to reset the scenario. The first attempts were counted as failures.

Due to the reconciliation functionality being new to all users who participated in the study some users took slightly longer than the allotted task time. We retained these times because as the users progressed through the task and their comfort level rose we saw progressively faster times. All users stated that the initial attempt is a little intimidating, but as you progress through the tasks the system becomes familiar quickly and easier to use.

## Efficiency

Based on the observations of task time and deviation data, this usability test helped the team determine that CDE can be considered efficient, but there is room for improvement. For instance, most of our optimal task times were 45-90 seconds on task. Most tasks were completed in less time than anticipated. Tasks 2, 3, and 4 are repetitive tasks requiring the user to perform similar actions to the preceding task. By the time the users got to Task 4, 6 of 10 users were able to complete the Task in 45 seconds or less, which greatly exceeded expectations.

In terms of average task success, even with our small data set of 10 participants, most performed well. Our participants had a 100% success rate with Task 3. Task 1 and Task 4 would have seen a 100% success rate as well, but 1 user had a non-product related issue and 2 users of Task 4 exited the screen which required a restart of the task.

We plan to account for some of the issues experienced by users that led to confusion or prevented a user from being able to successfully complete a task on their first attempt.

No users of the software had previous experience with the reconciliation functionality prior to the usability test and this led to some confusion and higher task times for some users.

## Satisfaction

Based on the task ratings and SUS results data, the participants were generally satisfied with the usability of CDE. The SUS score of 68.75 indicates that the participants perceived CDE as usable, but with room for improvement to become intuitive and more user-friendly. Most users scored the individual task as either Easy or Very Easy.

While task success rates may differ from this perceptive data, the usability team finds that overall, the participants were satisfied with most tasks and did not perceive them as particularly difficult. In addition, the comments from users indicated a positive experience with all starting they would recommend this functionality to colleagues.

These task ratings along with user comments indicate that participants were generally satisfied with CDE, but we could improve the systems by cutting down task times, improving screen controls, and providing better user feedback.

## Major Findings

The usability team found, based on observation of the participants, that the system is easy to use with the correct end user training, but could be more intuitive and user-friendly in future iterations.

The overall impression from our participants was that the system has a good workflow overall but needs to improve in user control and feedback. For example, on the review screen the user must hit enter or page down to move through all the lines on the screen. Typical workflow would be to have an escape key, either F11 or ESC, that would allow the user to exit with less button presses. Another example is during patient select the use must use the right CTRL key or the “snowflake” button on the right navigation, which proved laborious for users unfamiliar with this workflow. Finally, another common feedback was the exit prompt uses “F” to exit, but typical workflow would use “E” to exit and “F” to file.

Two users experienced a deficiency when entering through the screen, which would allow the user to exit from the screen without filing their changes in the patient record. Users who experienced this as well as other users requested an additional prompt which would tell the user they are about to exit the screen and would lose their current progress. Finally, two of the users experienced a bug where paging up on the list of problems would cause the final entry in the list

to no longer be visible. The team is going to try to replicate this item and prioritize it for resolution.

## Areas for Improvement

In general, the user feedback was positive both during the call as well as in the post testing survey. And, in addition to the pain points listed in the Major Findings section above, the consistent feedback from users was centered on providing additional functionality for filtering/sorting the lists of problems, medications, and allergies. Additional feedback requested enhancing the visuals on the screens to highlight items of significance so that the provider must spend less time reading each individual line. Some users indicated that on screen legends would be useful to know what some screen prompts meant as well as cleaning up some field labels to be less ambiguous. One user recommended branching the user out to an external website where the look and feel of the reconciliation routine could be modernized and made more user friendly. Another user indicated that they would like to see the ability to save and recall previously received CCDA documents so that provider could review them directly with the EHR.

In addition to the user feedback, the testing team noted areas for improving performance. Testing indicated that patients with large numbers of past medications take progressively longer to file changes. The testing team also noted additional screen inconsistency not noticed by the users.

## 5. Appendices

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

- 1: Recruiting screener
- 2: Participant Demographics
- 3: Non-Disclosure Agreement (NDA) and Informed Consent Form
- 4: Example Moderator's Guide
- 5: Final Questions Survey
- 6: System Usability Scale Questionnaire

### Appendix 1: Recruiting Screener

#### Participant selection

1. Participants should represent the typical end user of the CDE product who would perform the Clinical Reconciliation workflow on site.

2. The criterion requires a minimum of 10 participants.
  - a. We are required to track participant:
    - i. Gender
    - ii. Age
    - iii. Level of education
    - iv. Occupation
    - v. Professional Experience
    - vi. Computer Experience
    - vii. CDE Product Experience
    - viii. Whether or not the participant requires assistive technology to complete the testing.
  - b. Participants should:
    - i. Agree to being recorded during the testing session
    - ii. Be of varying age
    - iii. Be of varying ethnicity
    - iv. Include a mix of male and female participants
    - v. Reflect the CDE products Primary audience
    - vi. Have some experience using a computer as well as some experience using an EHR.
  - c. Participants should not:
    - i. Have a personal or financial interest in the product or Iatric.
    - ii. Have themselves or a family member with a commercial or research interest in EHRs or EHR consulting.
    - iii. Have participated in a recent focus group or usability test.
    - iv. Have themselves or anyone in their home who works in market research, usability research, web/application design, etc.

## Appendix 2: Participant Demographics

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

### Gender

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Men

5

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Women	5
Total (participants)	10

### Occupation/Role

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RN/BSN	3
Physician	1
Admin Staff	6
Total (participants)	10

### Collective Years of Experience

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Position years of experience	
Facility Use of EHR	10
All paper	X
Some paper, some electronic	X
All electronic	10
Total (Participants)	

## Appendix 3: Non-Disclosure (NDA) and Informed Consent form

### USABILITY STUDY CONSENT FORM

Iatric Systems, Inc. (“Iatric”) is conducting a usability study (the “Study”) for its Clinical Document Exchange™ software product (the “Software Product”). The purpose of the Study is to test the reconciliation component of a new release of the Software Product for certification purposes. Hallmark Health System, Inc. (“Hallmark”) is a current licensee in good standing of the Software Product and desires its employees to participate in the Study. The Study will be conducted remotely, using GoToMeeting or equivalent, and will be recorded both audio-visually and electronically. The undersigned Participant, an employee of Hallmark, has volunteered to participate in the Study and, as consideration for Iatric’s permission to participate in the Study, consents to the following terms:

1. Iatric will schedule date(s) and time(s) for Participant’s participation in the Study. The Study is estimated to take not more than one hour, and Participant is expected and agrees to perform a limited set of tasks using the Software Product prescribed by Iatric, all remotely.
2. Participant acknowledges that his or her voluntary participation in the Study will reveal to him or her technical and commercial information that Iatric considers and treats as confidential and proprietary. By way of illustration, but not limitation, such 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, and training methods and materials. Participant agrees that he or she will not disclose this information to any person other than Iatric and that he or she will not use this information except to participate in the Study.
3. Participant further agrees that all feedback, reports, and testing and Study results provided by him or her are assigned to Iatric and are likewise deemed the confidential and proprietary information of Iatric and subject to the nondisclosure and nonuse provisions of paragraph 2 above.
4. Participant acknowledges that Iatric will record Participant’s participation in the Study, which recording will consist of the capture of the Participant’s desktop, voice, and likeness and the identification of Participant not by name, but by a preassigned identification number. Iatric will use the recording for quality assurance purposes, for research, and for the purposes of the Study, which may include without limitation the disclosure of such recording to Iatric’s certification testing provider and others in connection with certification. Participant consents to such recording and the use and disclosure of such recording by Iatric and others for those purposes and releases all rights with respect thereto.

5. Participant is and remains free to withdraw this Consent in writing or discontinue participation at any time. Participant agrees to immediately raise any concerns or areas of discomfort with the Study administrator.

By his or her signature, below, the undersigned Participant acknowledges that he or she has read and understands this Consent form and agrees to its terms.

Participant's printed name: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

## Appendix 4: Example Moderators Guide

### PRIOR TO TEST SESSION

- Preparation
  - Reset Patient
    - Reset Routine (Name Removed)
    - Upload Document HHS.RESET.PATIENT.4.xml [urn 16] using CDE Document Upload utility. Select patient V00034447, which is the demo patient.
    - Use reconciliation worklist to remove all existing problems, allergies, and meds from patient. Add all problems, allergies, and meds from document:
      - Problems
        - Fever 06/22/15
        - Essential Hypertension
      - Allergies
        - Penicillin G MILD
        - Latex
      - Meds
        - Ceftriaxone Sodium 12H
        - Aranesp

- Remove Document for Worklist
- Upload Document HHS.RECONCILE.PATIENT.3.xml using CDE Document Upload utility. Select patient V00034447, which is the demo patient.
  - Problems
    - Overweight
    - Fever 06/01/15
  - Allergies
    - Ampicillin
    - Penicillin G SEVERE
  - Meds
    - Tylenol
    - Ceftriaxone Sodium 6H
- On Moderator's Computer
  - Open Workstation. Login with Test user "ZZ##### / #####"
  - Open Test Documents
  - Connect to GTM Session
  - Set GTM Lab/Preferences to Show GTM in Sharing (for webcam to be recorded)
  - Share Screen
- On Testers Computer
  - Share Webcam
- Introduction
  - Welcome / Thank You [p2]
    - Introduce yourself and Jeremy
  - *"I want to thank you for participating in this study. Your input is very important. Our session today will last no more than 60 minutes."*

*In this study, we are evaluating the usability of our clinical reconciliation system. I will provide a brief tutorial on how to use the system, then ask you to perform 4 tasks and complete some surveys afterwards. We would like to record this session using a webcam and screen recording device. All information you provide will be kept confidential and your name will not be associated with your*

*comments at any time.*

- Survey #1 [p3]
  - *"Before we get started, I need to learn some demographic information about you. I'm going to send you a survey in the chat window. Your participant ID is <Tester ##>. Please fill it out as best you can and let me know when you're done. Feel free to ask any questions."*
  - Send Survey #1: Demographics survey in Chat
- Training [p4]
  - IIM Document Worklist
    - KEY POINTS
      - Import Document Worklist
      - Right-ctrl to mark
      - OK / F12 to confirm
    - Script
      - *"This is the document import worklist. It lists all the documents that have been received and are ready to reconcile. To start the process, highlight an entry and press the right-ctrl button to mark the entry that you see a checkmark here (indicate checkmark). Just highlighting the entry isn't enough. Remember, right-ctrl, checkmark.*

*Once you have the checkmark, press OK (or F12). This will prompt you to confirm the selection, and confirm you want to start reconciling."*

  - Reconciliation
    - Overview
      - KEY POINTS
        - RECONCILIATION LETS USER COMBINE SOURCES

- RECONCILIATION COVERS PROBLEMS, ALLERGIES, HOME MEDS
  
- Problems / First Screen
  - KEY POINTS
    - DOCUMENT SOURCE IS CCD
    - INCLUDE YES / NO
    - INCLUDE NO MT REMOVES
    - DUPLICATE CODE FLAGGED
    - RESOLVE WITH YES/NO or MERGE
    - FINALIZE SCREEN
  - SCRIPT
    - *"What this shows are the problems that are on in your hospital's current record next to the problems we received in the document. The current hospital's problems have a source of "EPS". The document's problems have a source of "CCD".*

*So, using the "Inc?" Yes/No flag, you make decisions about each entry, then go down to this reconcile prompt to make everything permanent. We also have a finalized view screen, which will show you exactly what actions are going to be taken.*

*If there are two problems that have the same code, that is flagged as a duplicate. This little "\*" indicates the duplicate. The details of the problem may not match, and you have some tools to handle this. If you believe the "\*" entry is not accurate or necessary, you don't have to do anything. If you believe the "\*" entry is more*

*accurate, the easiest thing to do is set the current entry "N" and the CCD entry "Y". If it looks like the most accurate problem is a mix of both entries, you can set them both to "Y" and the system will walk you thru a merge process.*

*Now, let's make some choices and see how it looks on the finalized screen. Let's remove all the hospital entries and use only the CCD entries.*

*Here we see what is going to be active and what is going to be removed.*

*Exit this screen by either entering thru the entries or pressing pgdwn twice. Select "Yes" to return to the previous screen.*

*If you're satisfied with your choices, select "Y" on reconcile and press Enter."*

- Allergies
  - SCRIPT
    - *"This screen has all the same functionality. Here are our current allergies, labeled MRI, and here are the document's allergies, labeled CCD.*

*(make selections, finalize, reconcile)"*

- Medications
  - SCRIPT
    - *"Same as before, here are our current, medications, labeled RXM, and here are the*

*document's medications, labeled CCD.  
(make selections, finalize, reconcile)"*

- Pre-Test Instructions
  - *"Any questions?"*
  - Give user Control
  - *"Now we'll begin the study. This part will be recorded. You'll be asked to complete four tasks. I will read the scenario, then say "please start". Please begin working the task, feel free to perform whatever steps you feel necessary to complete the task as quickly and easily as possible. Due to the nature of the test, we are not allowed to guide you or give feedback to you during the test. Remember, our goal is to observe how you would complete the tasks on your own. You may ask specific questions regarding information that may be missing, but I cannot guide or direct you on how to complete a task.*

*When you have completed a task, say "done" out loud. I will ask you to rate the ease of completion for the task on a scale of 1 to 5. We will then move on to the next task and repeat until we've completed all 4 tasks.*

- *Do you have any questions before we start?"*
- Begin recording
- Show first task [p5]
- Show second task [p5]
- Show third task [p5]
- Show fourth task [p5]
- Turn Off User Control
- Post-Test Instructions
  - *"Thank you for participating. I have two surveys I'd like you to complete. The first is a usability survey. The second is a feedback survey. Please be honest with your feedback."*
  - Send usability survey
    - *"I've sent the usability survey in the chat. When you complete it, let me know and I'll send the next one."*
  - Send feedback survey
  - *"Once again, thank you! We really appreciate your participation"*

**CDE Task #1: Patient/Document Selection**

(15 Seconds,  
Max 30  
Seconds)

**Setup:** Screen will display starting point for this task which is the IIM Document Worklist Screen

**Administrator says:** “You are seeing a returning patient who was recently transferred from a local clinic. The clinic’s most recent medical record of the patient has been electronically transmitted to your hospital and you are ready to compare the clinic’s medical record with your hospital’s record. The patient’s name is SED00 IATRIC.

Locate the clinic’s medical record, confirm the patient’s account, and launch the clinical reconciliation work screens.”

**Task Time:** \_\_\_\_\_ Seconds

**Optimal Path:** Select Line 1 “IATRIC, SED00”. Press right-ctrl to check line. Press OK (F12) or Click Green Check. Press “Yes” on Process Messages prompt. Press “Yes” to Reconcile.

**Alternate Path:**

<input type="checkbox"/>	Correct
<input type="checkbox"/>	Minor Deviations / Cycles: Describe below
<input type="checkbox"/>	Major Deviations: Describe below
Comments:	

**Observed Errors and Verbalizations:**

**Administrator/Note Taker Comments:**

**CDE Task #2: Problem Reconciliation**

(45 Seconds,  
Max 90  
Seconds)

**Setup:** Screen will display starting point for this task which is the Reconciliation Problems page

**Administrator says:** “You are interviewing a returning patient, who was recently transferred from a local clinic. Their current medical record from the clinic has been imported and you are comparing it to the hospital’s record. While reviewing their problems, you notice several discrepancies. The patient confirms they were diagnosed as overweight, but it has been resolved and that they never had hypertension. They also state they had a fever on 06/01/15.

Reconcile the problems list. View finalized list and save reconciled problems.”

**Task Time:** \_\_\_\_\_ Seconds

**Optimal Path:** Cursor starts on “Incl?” field on line 1. On line 1, Overweight, erase “N” and type “Y”. Press Enter. On line 2, Fever, erase “Y” and type “N”. Press Enter. On line 3, Fever, erase “\*” and type “Y”. On line 4, Essential Hypertension, erase “Y” and type “N”. Press Enter. On “VIEW FINALIZED LIST?”, type “Y” and press Enter. Press PgDwn x2. Press “Yes” on Exit Prompt. On “RECONCILE PROBLEMS?”, Type “Y” and press Enter.

**Alternate Path:** Cursor starts on “Incl?” field on line 1. On line 1, Overweight, erase “N” and type “Y”. Press Enter. **On line 2, Press Enter. On line 3, Fever, erase “\*” and type “Y”. Press “Yes” on Merge Prompt. Press “Yes” on CCD Date.** On line 4, Essential Hypertension, erase “Y” and type “N”. Press Enter. On “VIEW FINALIZED LIST?”, type “Y” and press Enter. Press PgDwn x2. Press “Yes” on Exit Prompt. On “RECONCILE PROBLEMS?”, Type “Y” and press Enter.

<input type="checkbox"/>	Correct
<input type="checkbox"/>	Minor Deviations / Cycles: Describe below
<input type="checkbox"/>	Major Deviations: Describe below
Comments:	

**Observed Errors and Verbalizations:**

**Administrator/Note Taker Comments:**

**CDE Task # 3: Allergy Reconciliation**

(45 Seconds,  
max 90  
Seconds)

**Setup:** Screen will display starting point for this task which is the Reconciliation Allergies page

**Administrator says:** “You are interviewing a returning patient, who was recently transferred from a local clinic. Their current medical record from the clinic has been imported and you are comparing it to the hospital’s record. While reviewing their allergies, you notice several discrepancies. The patient confirms they have been diagnosed with an Ampicillin allergy and their allergy to Penicillin has gotten worse. They also state that they are no longer allergic to Latex.

Reconcile the allergies list. View finalized list and save reconciled allergies.”

**Task Time:** \_\_\_\_\_Seconds

**Optimal Path:** Cursor starts on “Incl?” field on line 1. On line 1, Ampicillin, erase “N” and type “Y”. Press Enter. On line 2, Penicillin, erase “Y” and type “N”. Press Enter. On line 3, Penicillin, erase “\*” and type “Y”. On line 4, Latex, erase “Y” and type “N”. Press Enter. On “VIEW FINALIZED LIST?”, type “Y” and press Enter. Press PgDwn x2. Press “Yes” on Exit Prompt. On “RECONCILE ALLERGIES?”, Type “Y” and press Enter.

**Alternate Path:** Cursor starts on “Incl?” field on line 1. On line 1, Tylenol, erase “N” and type “Y”. Press Enter. **On line 2, Press Enter. On line 3, Penicillin, erase “\*” and type “Y”. Press “Yes” on Merge Prompt. Press “Yes” on CCD Date. Press “Yes” on CCD severity.** On line 4, Latex, erase “N” and type “Y”. Press Enter. On “VIEW FINALIZED LIST?”, type “Y” and press Enter. Press PgDwn x2. Press “Yes” on Exit Prompt. On “RECONCILE ALLERGIES?”, Type “Y” and press Enter.

<input type="checkbox"/>	Correct
<input type="checkbox"/>	Minor Deviations / Cycles: Describe below
<input type="checkbox"/>	Major Deviations: Describe below

Comments:

**Observed Errors and Verbalizations:**

**Administrator/Note Taker Comments:**

**CDE Task # 4: Medication Reconciliation**

(45 Seconds,  
max 90  
Seconds)

**Setup:** Screen will display starting point for this task which is the Reconciliation Medications page

**Administrator says:** “You are interviewing a returning patient, who was recently transferred from a local clinic. Their current medical record from the clinic has been imported and you are comparing it to the hospital’s record.

While reviewing their medications, you notice several discrepancies. The patient confirms they have been prescribed Tylenol and their prescription for Ceftriaxone Sodium was adjusted to every 6 hours. They also state that they are no longer taking Aranesp.

Reconcile the medication list. View finalized list and save reconciled medications.”

**Task Time:** \_\_\_\_\_ Seconds

**Optimal Path:** Cursor starts on “Incl?” field on line 1. On line 1, Tylenol, erase “N” and type “Y”. Press Enter. On line 2, Ceftriaxone Sodium, erase “Y” and type “N”. Press Enter. On line 3, Ceftriaxone Sodium, erase “\*” and type “Y”. On line 4, Aranesp, erase “Y” and type “N”. Press Enter. On “VIEW FINALIZED LIST?”, type “Y” and press Enter. Press PgDwn x2. Press “Yes” on Exit Prompt. On “RECONCILE MEDICATIONS?”, Type “Y” and press Enter.

**Alternate Path:** Cursor starts on “Incl?” field on line 1. On line 1, Tylenol, erase “N” and type “Y”. Press Enter. **On line 2, Press Enter. On line 3, Ceftriaxone Sodium, erase “\*” and type “Y”. Press “Yes” on Merge Prompt. Press “Yes” on CCD Date. Press “Yes” on CCD Frequency.** On line 4, Aranesp,

erase "N" and type "Y". Press Enter. On "VIEW FINALIZED LIST?", type "Y" and press Enter. Press PgDwn x2. Press "Yes" on Exit Prompt. On "RECONCILE MEDICATIONS?", Type "Y" and press Enter.

<input type="checkbox"/>	Correct
<input type="checkbox"/>	Minor Deviations / Cycles: Describe below
<input type="checkbox"/>	Major Deviations: Describe below
Comments:	

**Observed Errors and Verbalizations:**

**Administrator/Note Taker Comments:**

## Appendix 5: Final Survey Questions

# CDE Customer Survey

1. What was your overall impression of this system?

Enter your answer

2. How does this system compare to similar systems that you have used?

Enter your answer

3. What could the system have done differently/better?

Enter your answer

4. Would you recommend this system to colleagues?

Enter your answer

## Appendix 6: System Usability Scale Questionnaire

1. Please review the following statements about the Iatric Clinical Document Exchange product and mark if you agree or disagree with each statement. \*

	Strongly Agree	Agree	Neither Agree Nor Disagree	Disagree	Strongly Disagree
I think that I would like to use this system frequently.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I found the system unnecessarily complex.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I thought the system was easy to use.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I think that I would need the support of a technical person to be able to use this system.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I found the various functions in this system were well integrated.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I thought there was too much inconsistency in this system.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I would imagine that most people would learn to use this system very quickly.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I found the system very cumbersome to use.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



I felt very confident using the system.

I needed to learn a lot of things before I could get going with this system.