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09/09/2016

Dear DGI Certification Body,

Please allow this letter to serve as Two-ten Health Limited ("Salud") "Test requirement DTR 170.314.g.3 Safety Enhancement Design and attestation to the veracity and authenticity of the usability report

A handwritten signature in black ink that reads "Maeve McGrath".

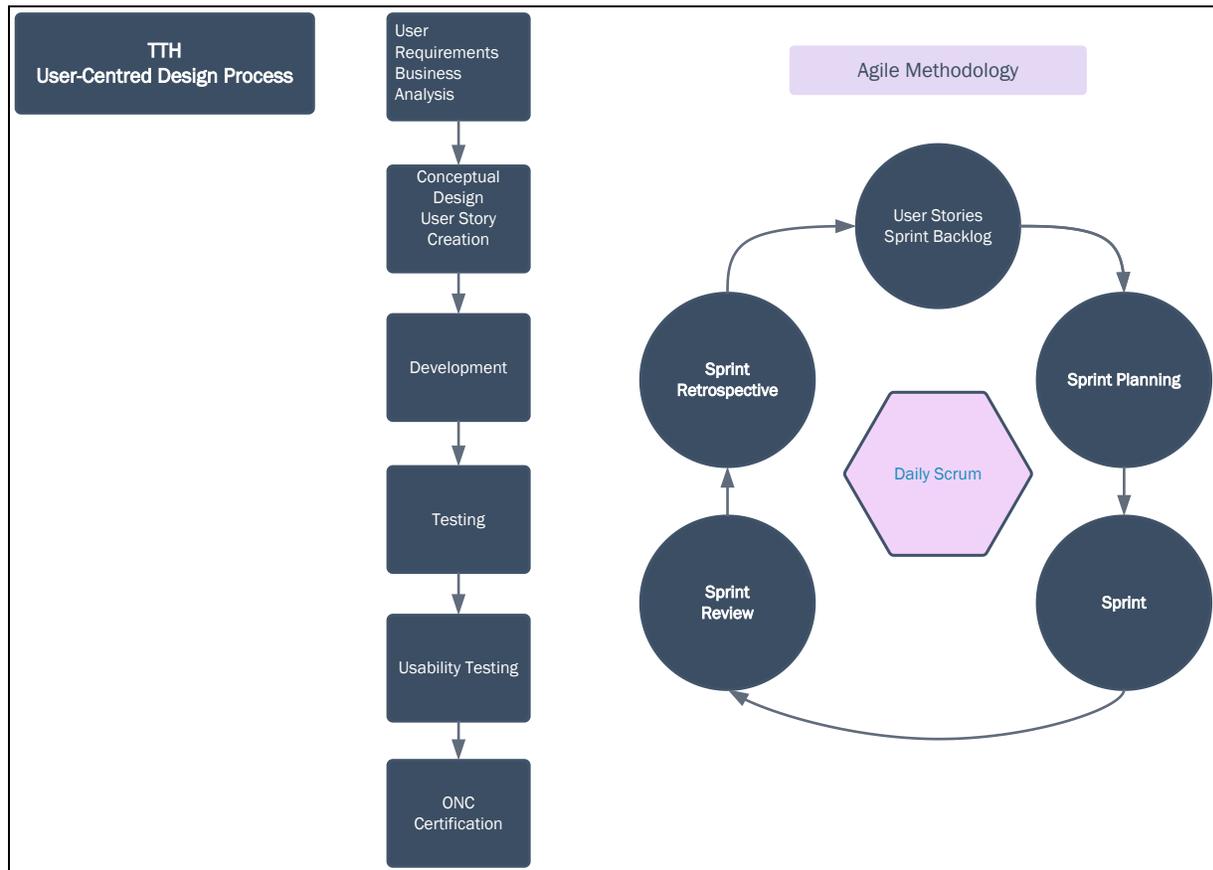
Dr Maeve McGrath  
Head of Operations

## Usability Report Checklist

- Name and Version of the product **P.2**  
Salud Version. V2016.1
- User Centered design process **P.2 & P.3**  
Internal developed process as documented in 170.314.g.4 “Quality management system” document sent to Drummond

## User Centered Design Process

A combination of SDLC and Agile project management is used in the development of the product



### User Requirements Business Analysis

The Business analysis team gathered the business requirements from the documentation provided

### Conceptual Design and User stories

Business Analyst creates a business process flow in Visio and a user story in Jira for Configuration, Development and Testing requirements. During the development process, if required, further updates to business process flows and User stories documentation are conducted.

### Development

The Development team review the process flows and user stories to understand the requirements and update the user stories as the development proceeds. Development of the requirements is completed in stages and passed to the testers for testing.

### Testing

The testers work closely with the Developers, testing the development in incremental stages and signing off on their completion.

### **Usability testing**

Usability testing is conducted by the testing team to ensure ease of use of software.

### **ONC certification**

Prior to ONC certification process, databases were prepopulated with data required during the actual certification process. Furthermore, test runs were performed by the TwoTen Health presenter to ensure the process was known and practiced in advance of the ONC Certification process.

### **Agile methodology**

**The agile methodology is used throughout the development life cycle. It is an iterative process**

- **User stories**
  - Created by the business analyst for each item within a module.
  - Contains a process flow and a user story outlining development requirements
- **Sprint Planning**
  - Planning of items to go into each development stage
- **Sprint**
  - Time set aside (two weeks) to develop planned items
- **Sprint Review**
  - Review of items developed during the previous stage
- **Sprint Retrospective**
  - Lessons learnt session to review lessons learnt over the course of the last sprint
- Date and location of the usability test **P.2**  
2<sup>nd</sup> September 2016, Ireland
- Test environment  
WebEx session with Boston University Training Room **P.3**
- Description of the intended users **P.3**  
Dental University students and supervisory Dentists  
  
Total number of participants: 5 **P. 3**  
Each person completed all tasks
- Description of participants: their experience and demographic characteristics **P.3**

	Description
Tester 1	Trainee Dentist, uses Salud on a frequent basis, Male
Tester 2	Trainee Dentist, uses Salud on a frequent basis, Male
Tester 3	Trainee Dentist, uses Salud on a frequent basis, Male
Tester 4	Dentist/ student supervisor, Male, originally from Czech Republic
Tester 5	Trainee Dentist, uses Salud on a frequent basis, Male

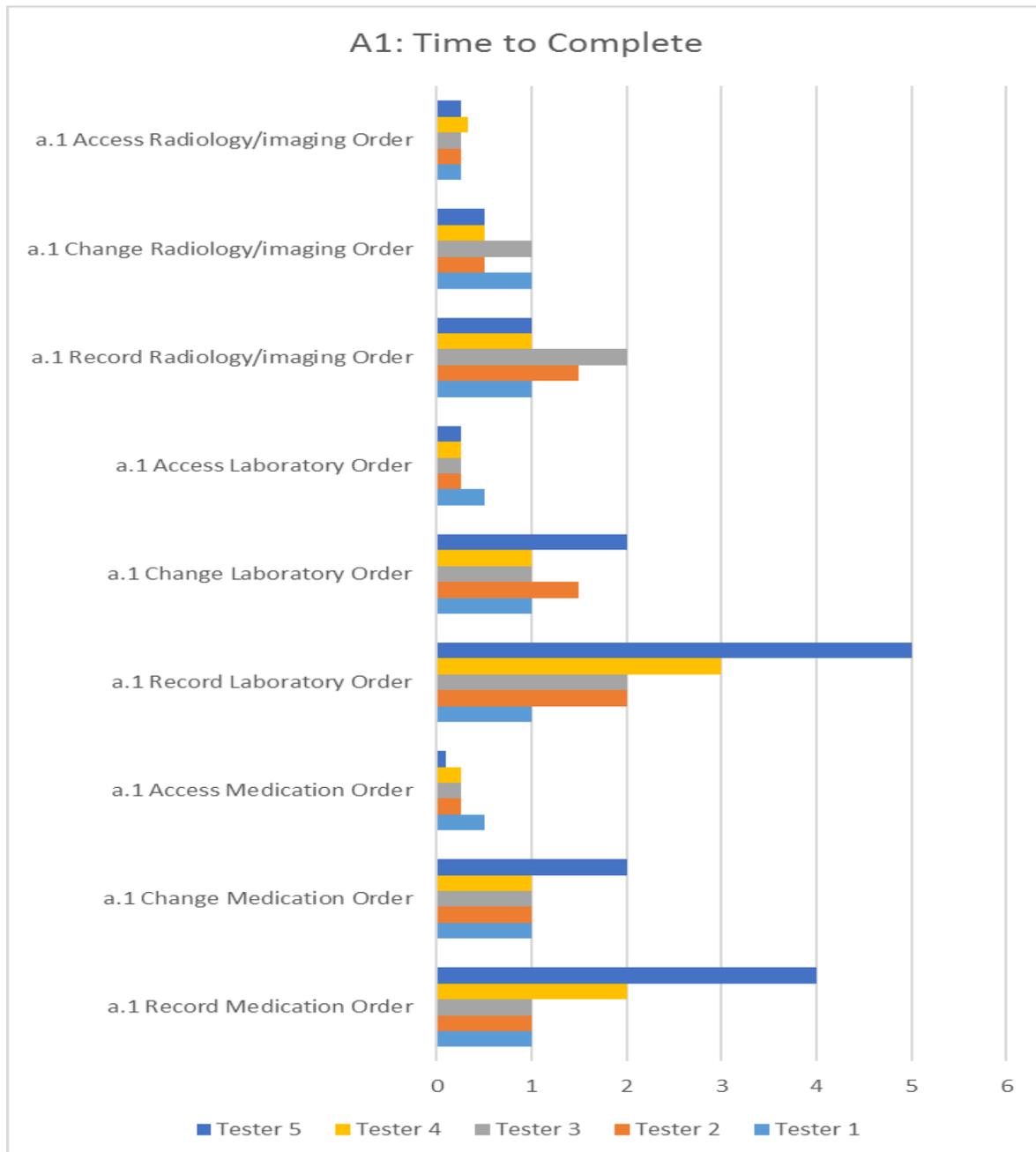
- Description of the user tasks that were tested **P.3**  
The tasks were performed as outlined in the proctor sheets

- The following Modules are included in our report. **P. 2**

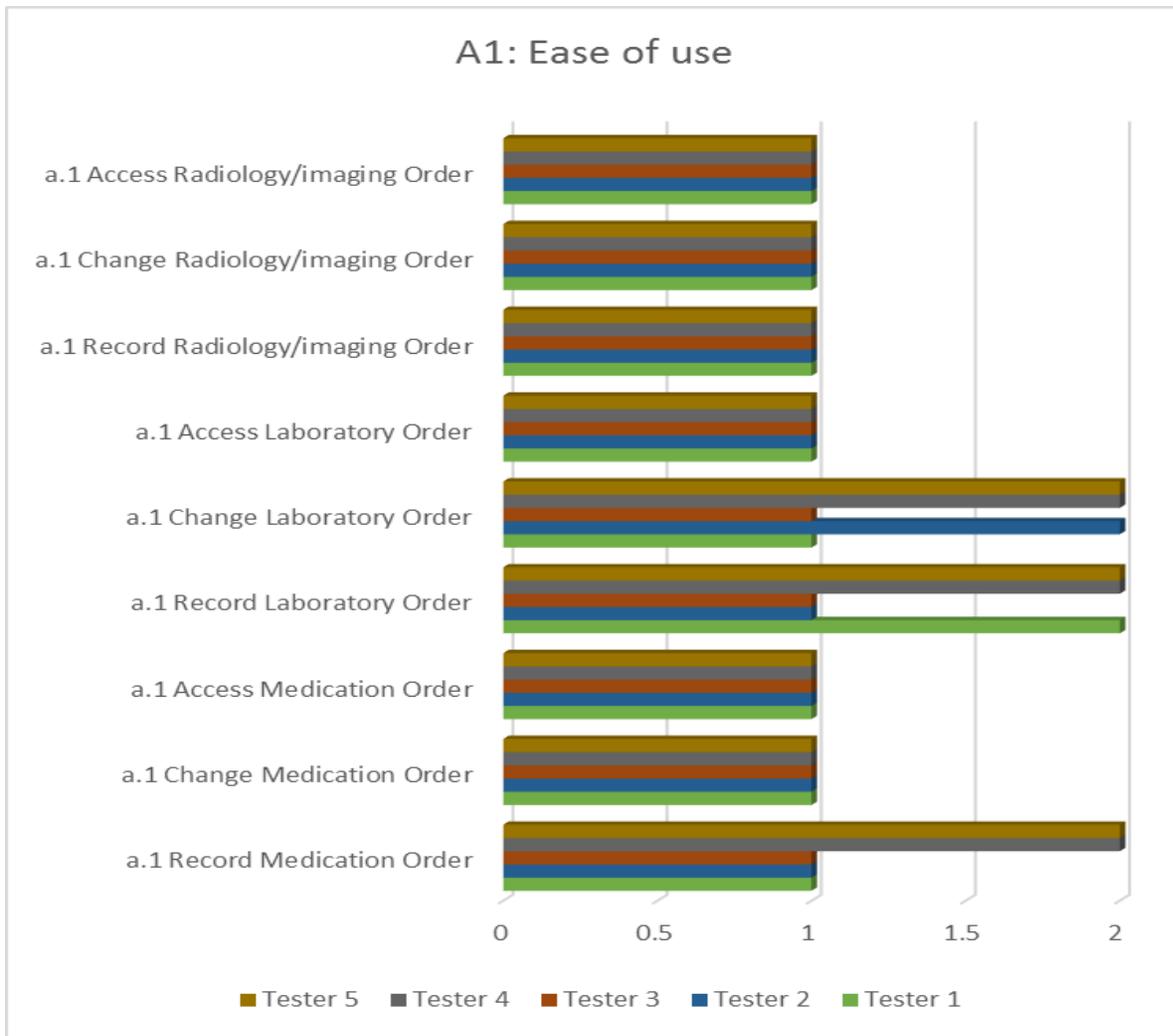
§170.314(a)(1)	Computerized provider order entry
§170.314(a)(2)	Drug to-Drug & Allergies intervention
§170.314(a)(3)	Demographics
§170.314(a)(6)	Medication list
§170.314(a)(7)	Medication allergy list
§170.314(a)(8)	Clinical decision support

## §170.314(a)(1) Computerized provider order entry

### Time to complete



## Ease of use



## User risk error



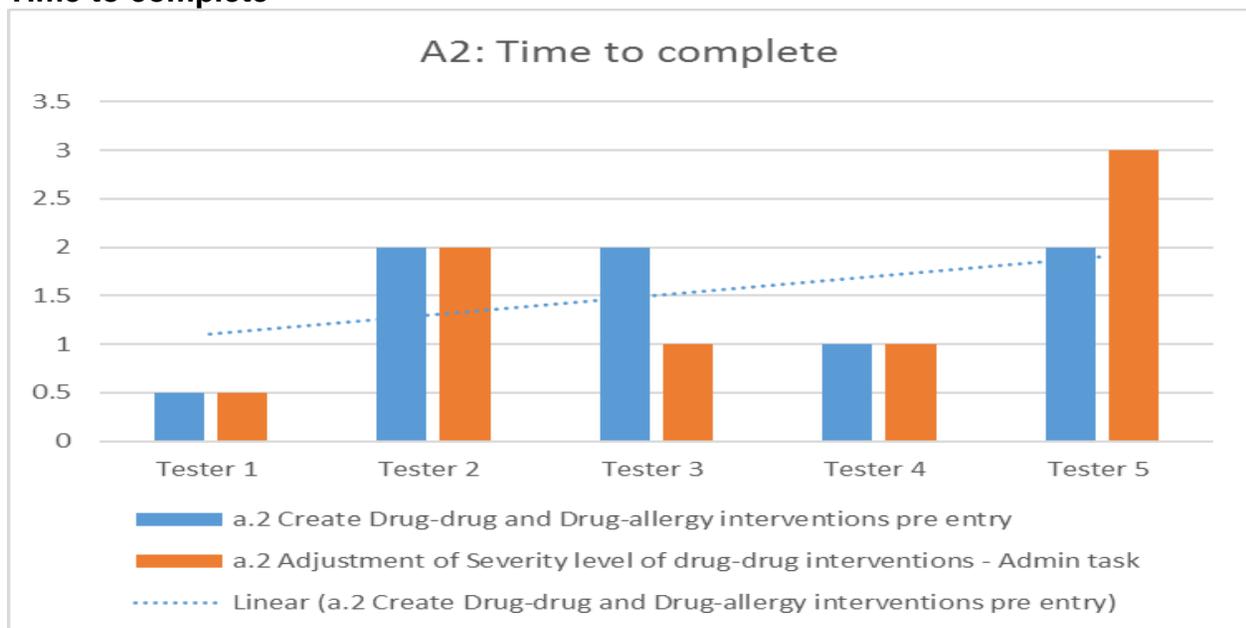
## Comments recorded

Module	Description:	Comment
§170.314(a)(1)	a.1 Record Medication Order	T1: Dosespot is a big improvement
§170.314(a)(1)	a.1 Change Medication Order	No comments recorded
§170.314(a)(1)	a.1 Access Medication Order	No comments recorded
§170.314(a)(1)	a.1 Record Laboratory Order	No comments recorded
§170.314(a)(1)	a.1 Change Laboratory Order	No comments recorded
§170.314(a)(1)	a.1 Access Laboratory Order	No comments recorded
§170.314(a)(1)	a.1 Record Radiology/imaging Order	No comments recorded
§170.314(a)(1)	a.1 Change Radiology/imaging Order	No comments recorded
§170.314(a)(1)	a.1 Access Radiology/imaging Order	T3: Nothing new

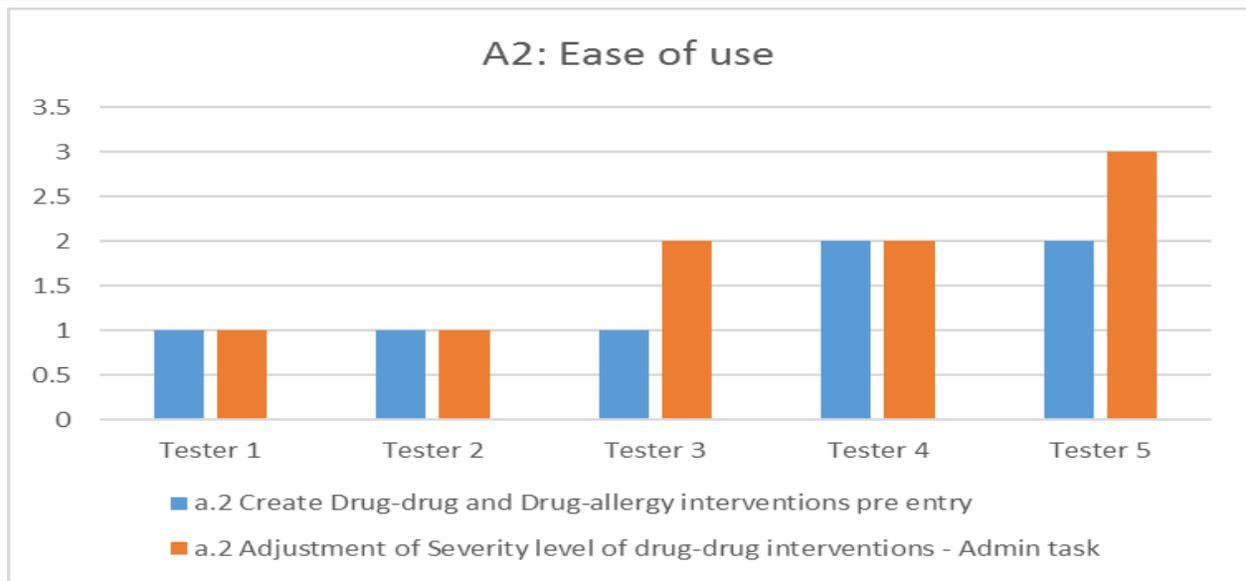
## A.2 Create Drug-drug and Drug-allergy interventions pre entry

### A.2 Adjustment of Severity level of drug-drug interventions - Admin task

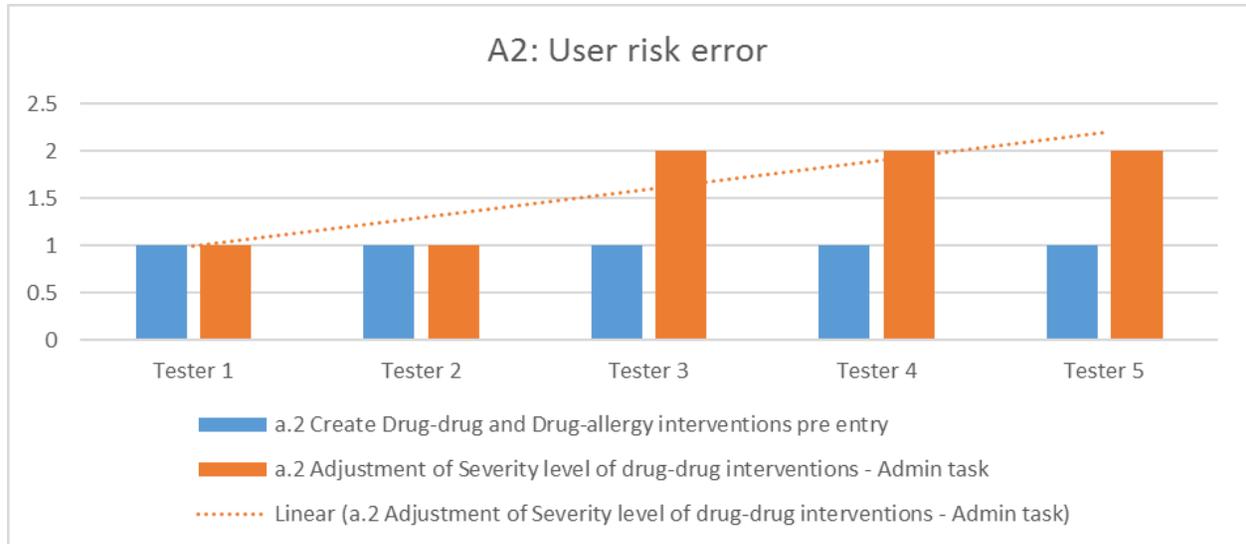
#### Time to complete



#### Ease of use



### User risk error

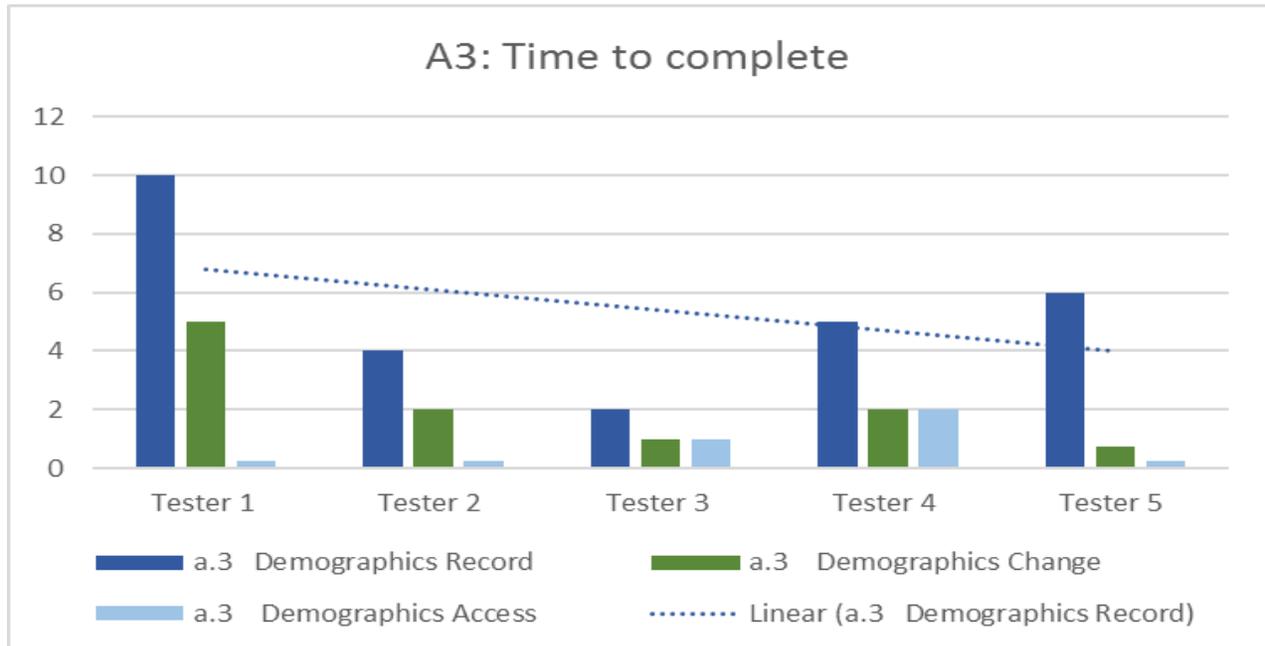


### Comments recorded

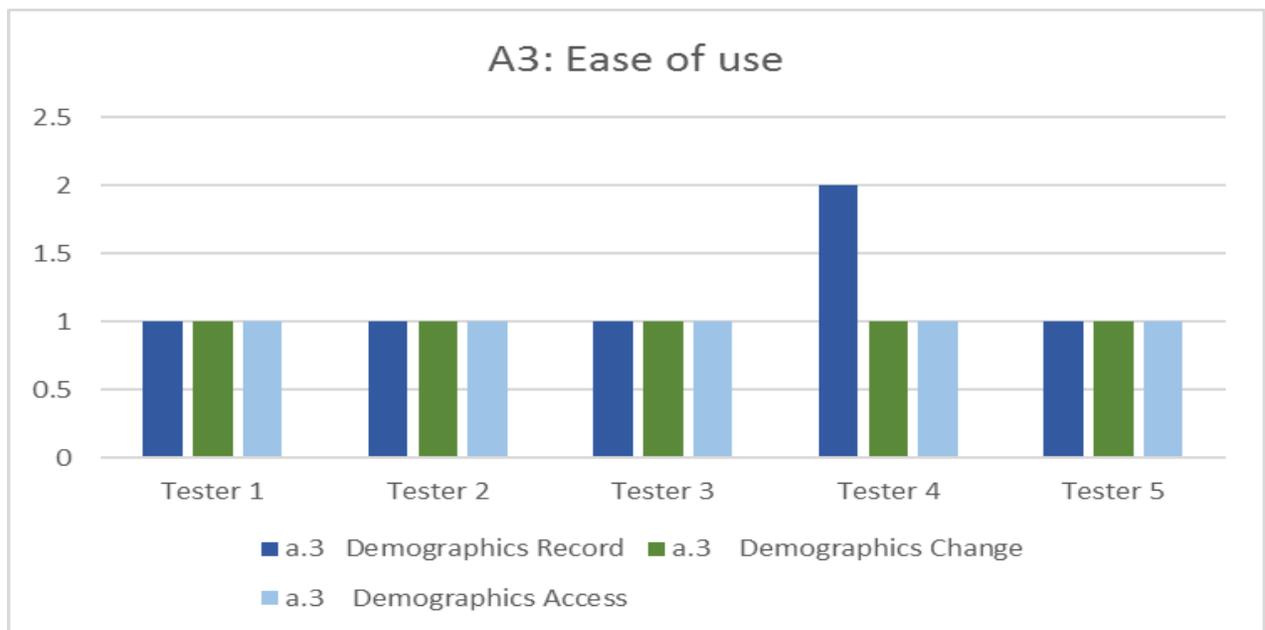
Area	Module	Description:	Comment
§170.314(a)(2)	§170.314(a)(2)	a.2 Create Drug-drug and Drug-allergy interventions pre entry	No comments recorded
§170.314(a)(2)	§170.314(a)(2)	a.2 Adjustment of Severity level of drug-drug interventions - Admin task	No comments recorded

### §170.314(a)(3) Demographics

#### Time to complete

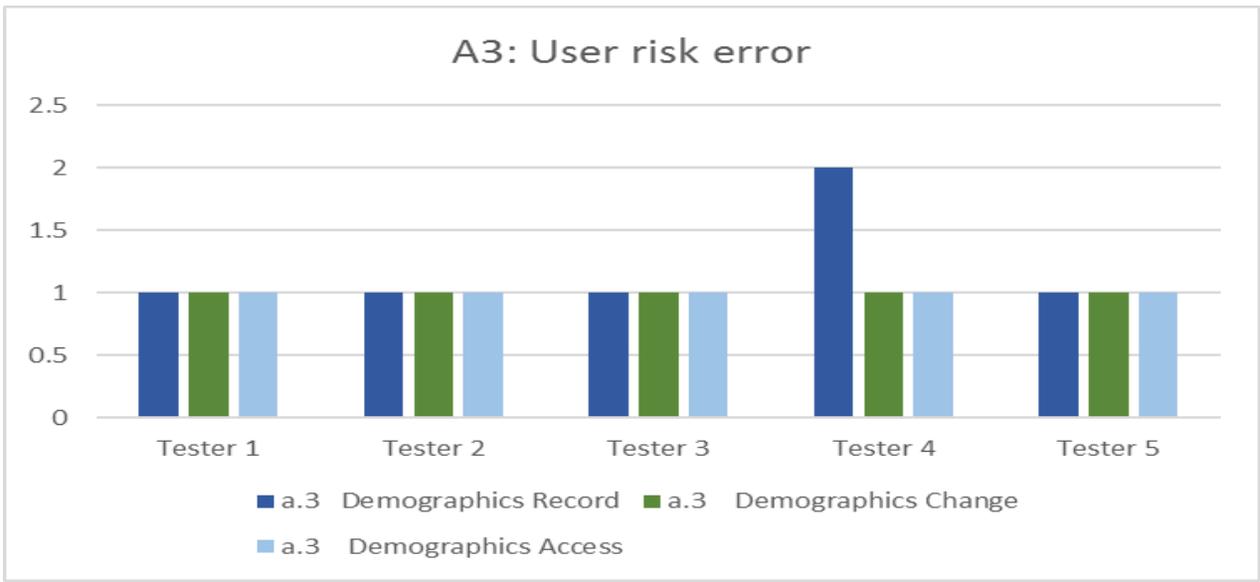


### Ease of use



### User risk error

### A3: User risk error

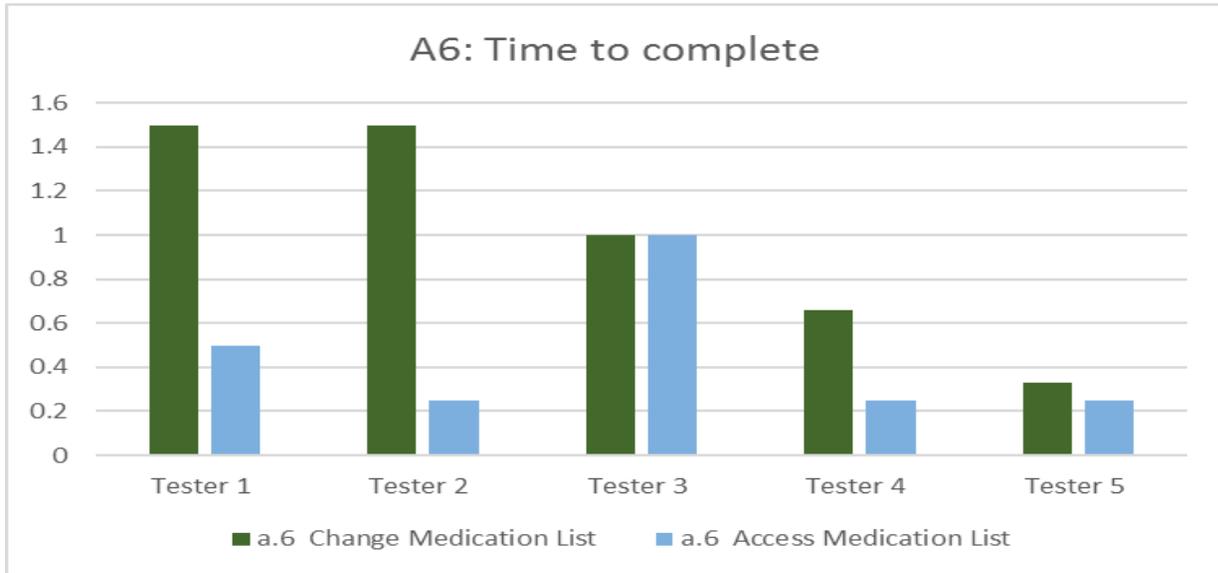


### Comments recorded

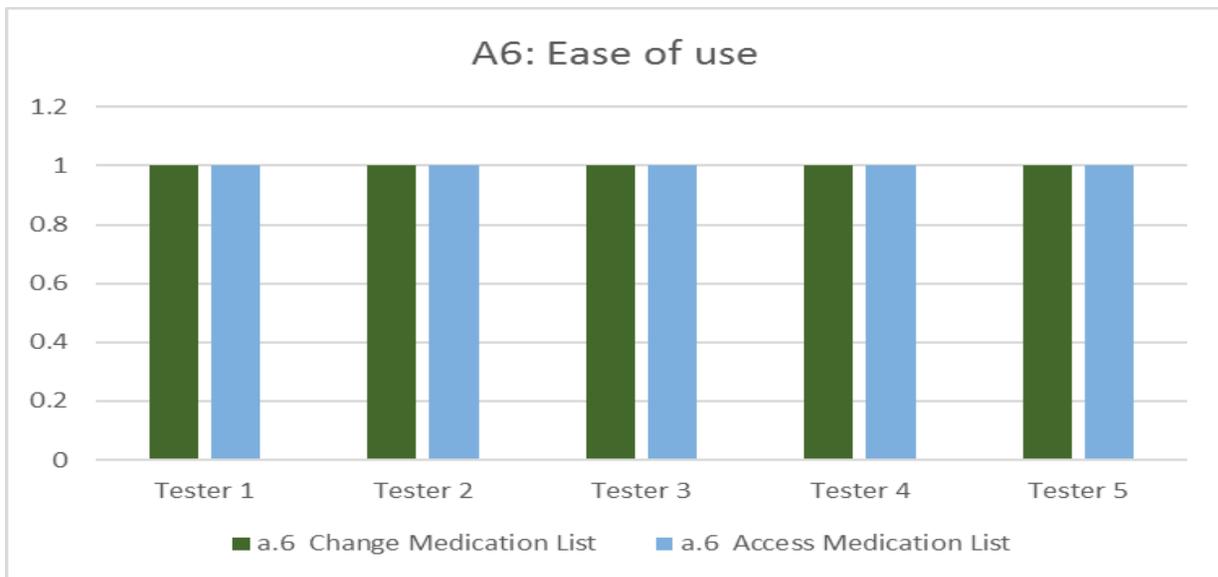
Module	Description:	Comment
§170.314(a)(3)	a.3 Demographics Record	T3: easy to use
§170.314(a)(3)	a.3 Demographics Change	No comments recorded
§170.314(a)(3)	a.3 Demographics Access	No comments recorded

# §170.314(a)(6) Medication list

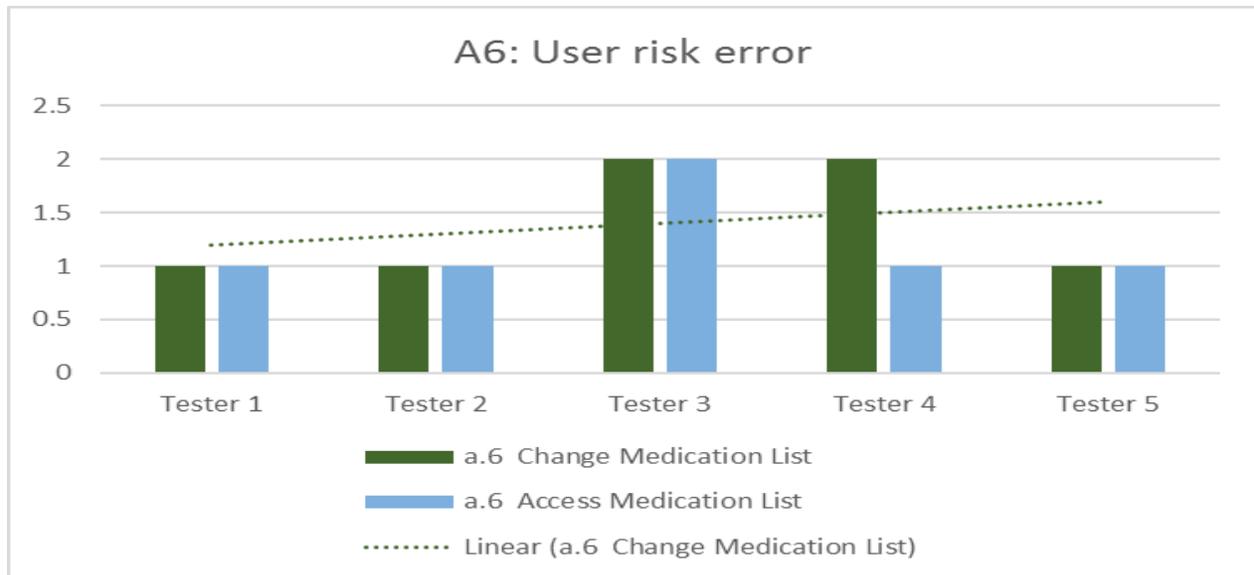
## Time to complete



## Ease of use



## User risk error

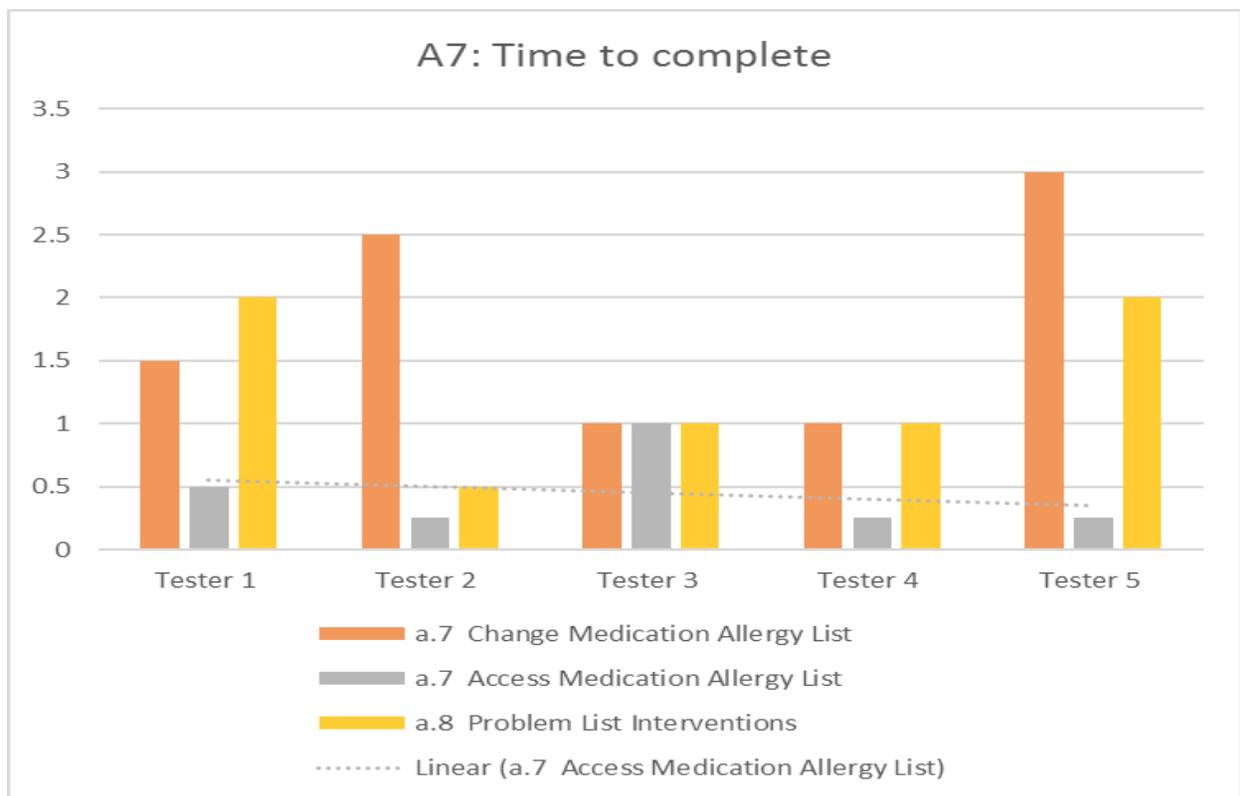


## Comments recorded

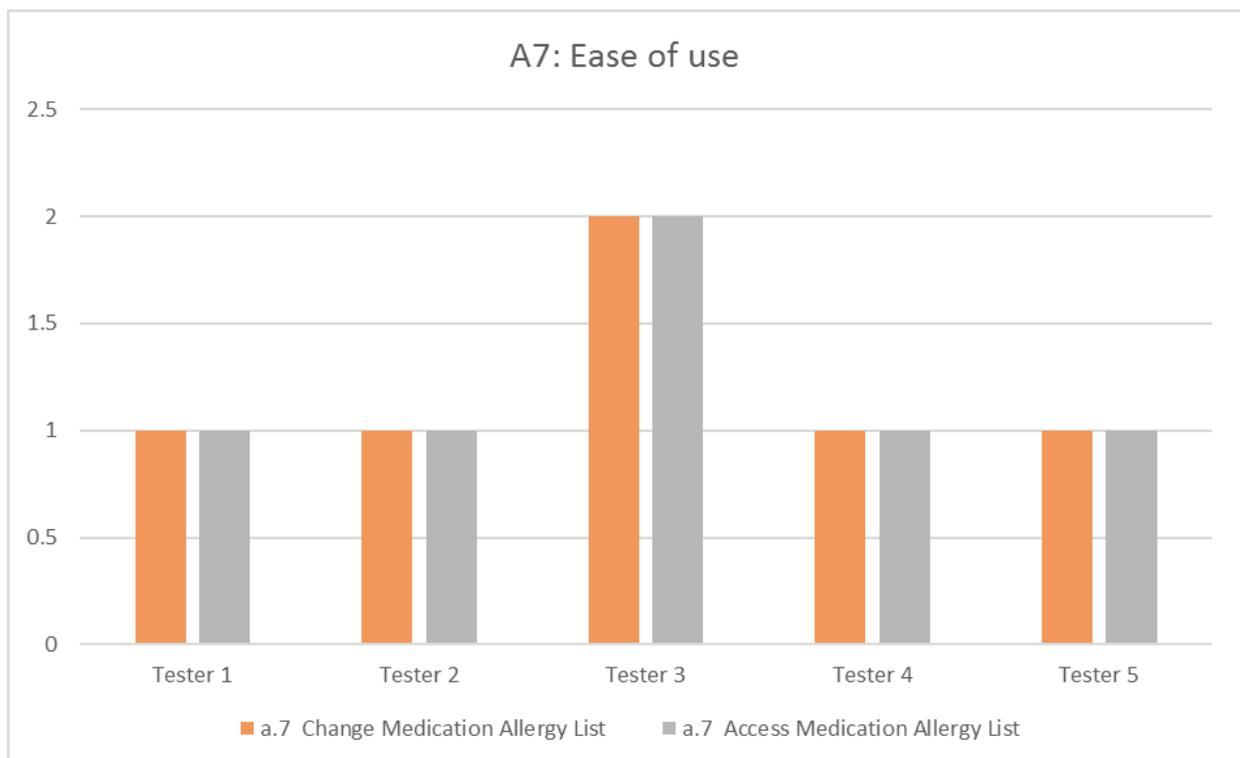
Module	Description:	Comment
§170.314(a)(6)	a.6 Change Medication List	T3: simple, easy to use T5: The more I see, it becomes easier to use
§170.314(a)(6)	a.6 Access Medication List	No comments recorded

## §170.314(a)(7) Medication allergy list

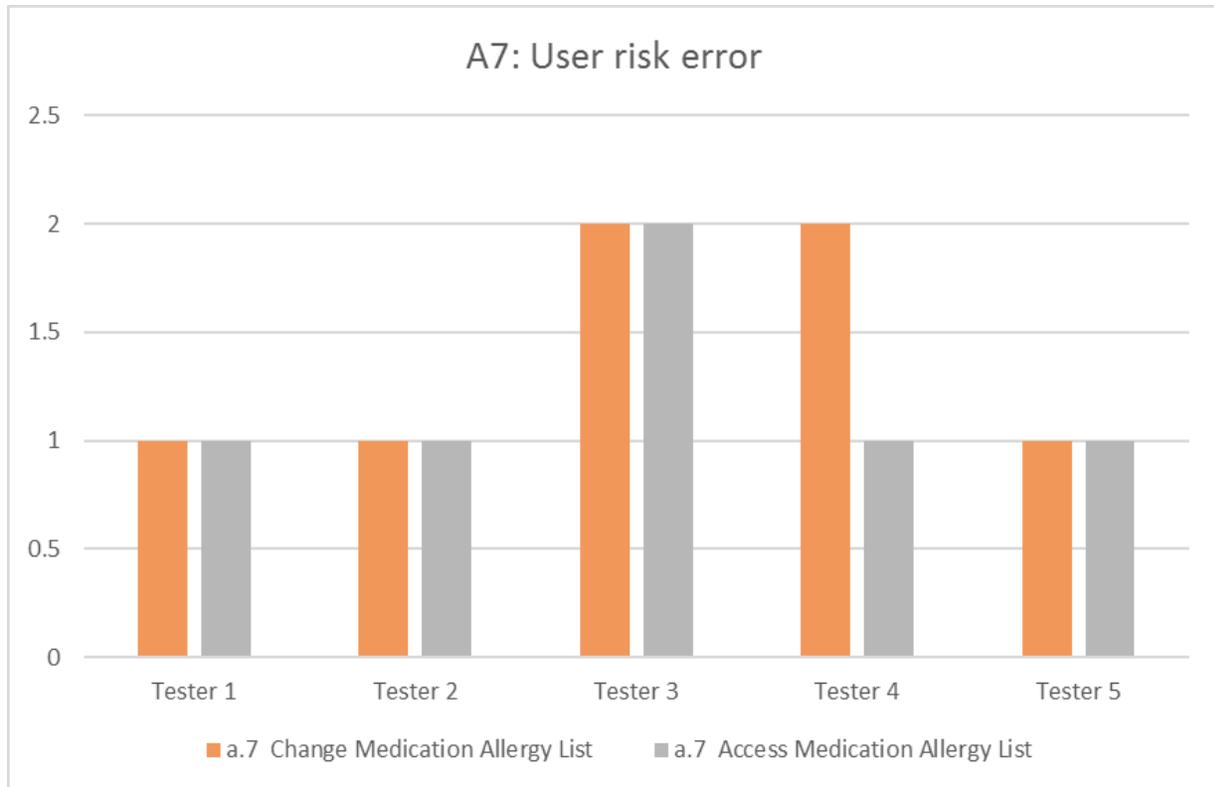
### Time to complete



### Ease of Use



## User risk error

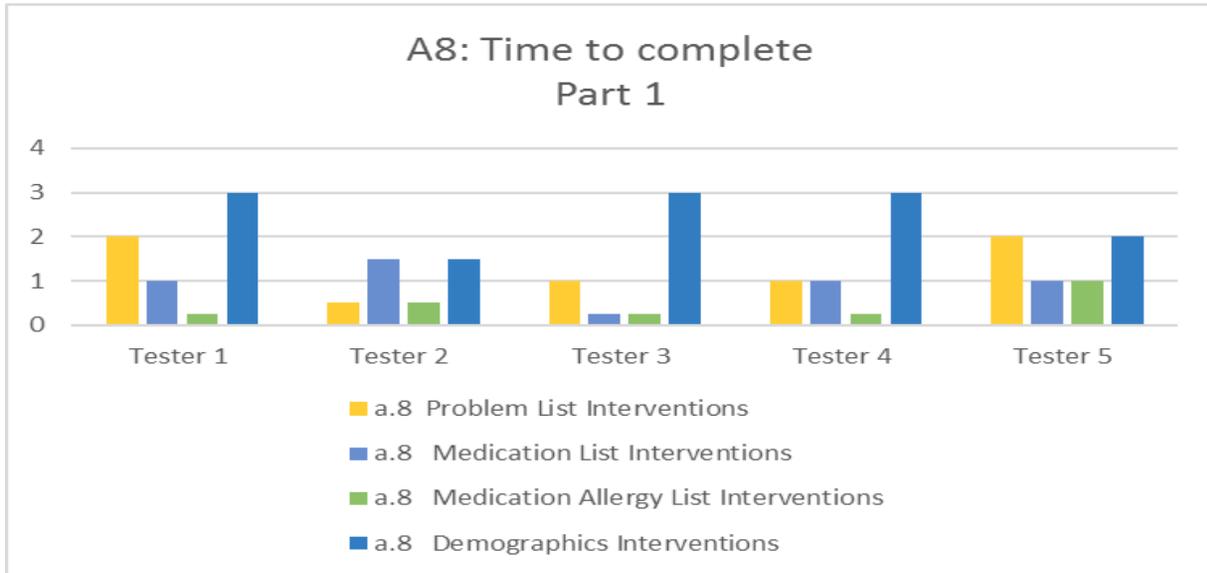


## Comments recorded

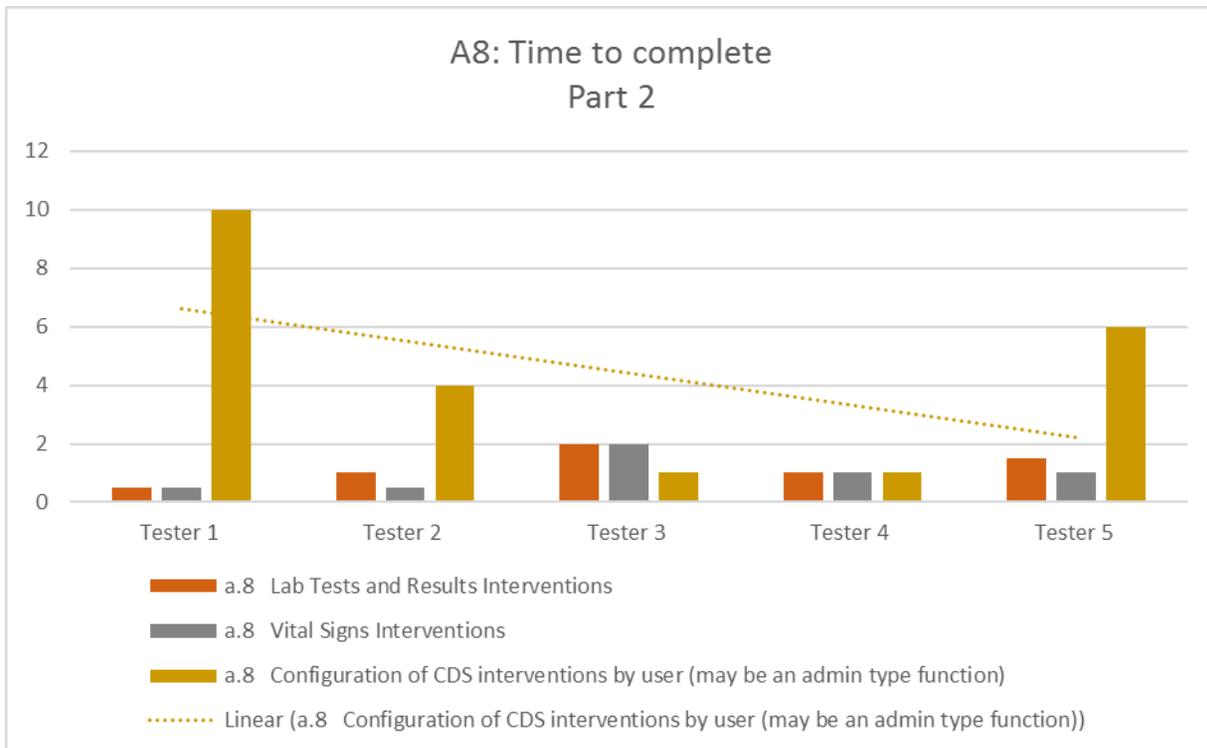
Module	Description:	Comment
§170.314(a)(7)	a.7 Change Medication Allergy List	T3: good, easy to read labels T5: getting easier
§170.314(a)(7)	a.7 Access Medication Allergy List	No comments recorded

# §170.314(a)(8) Clinical decision support

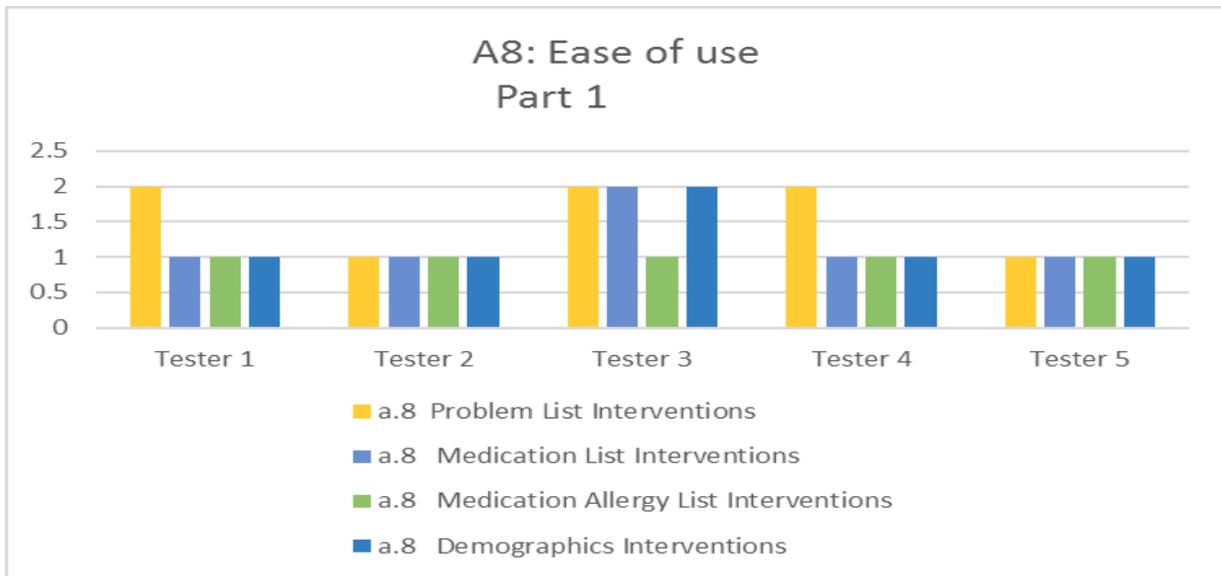
## Time to complete



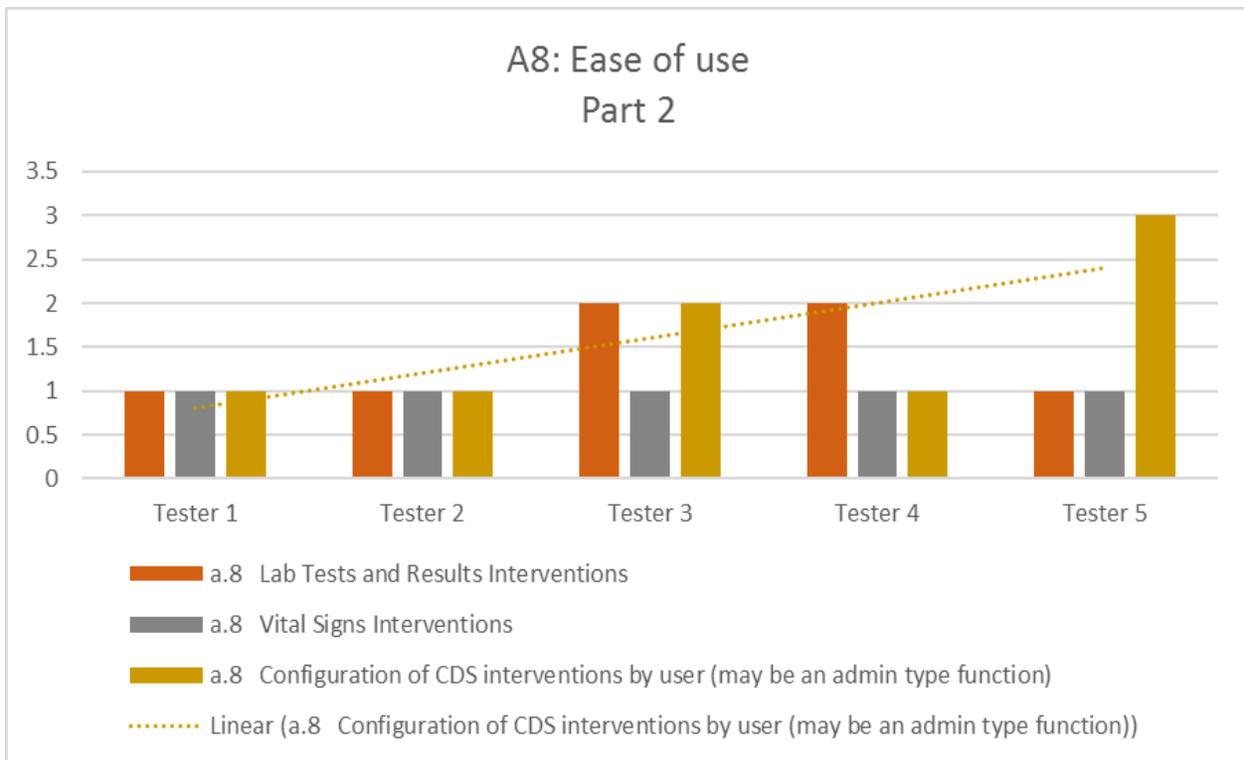
## Time to complete



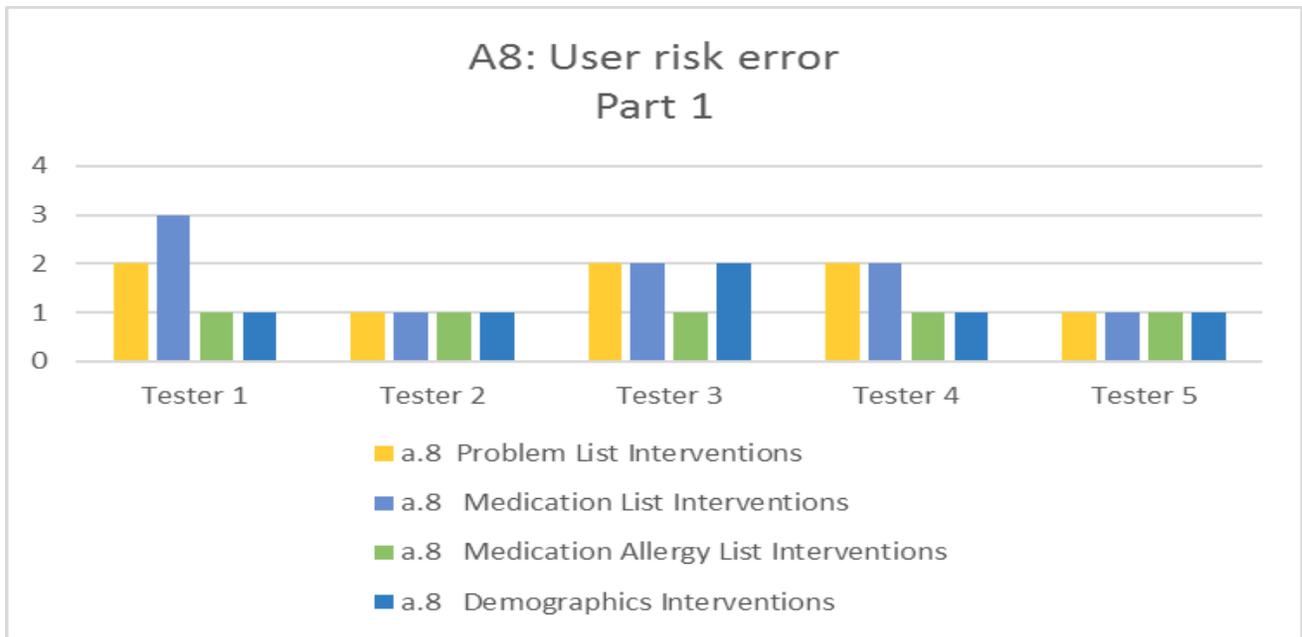
## Ease of use



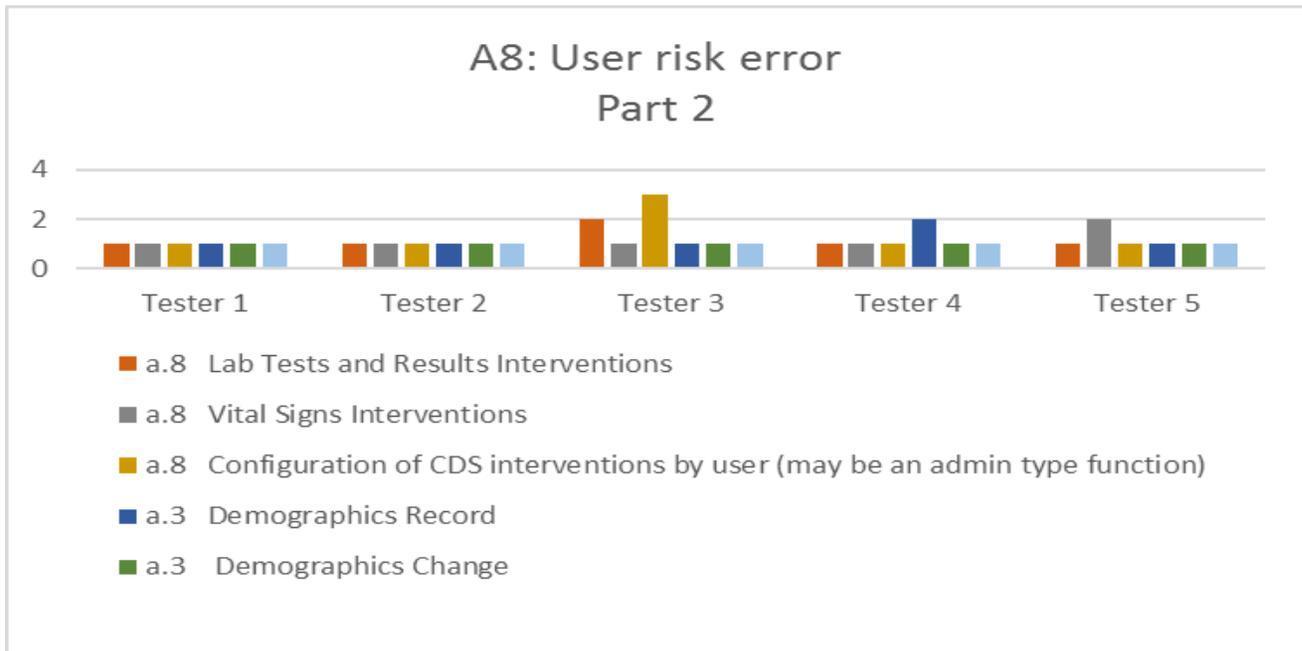
## Ease of use



## User risk error



## User Risk error



## Comments recorded

Module	Description:	Comment
§170.314(a)(8)	a.8 Problem List Interventions	T3: depending on what shows in box it could be confusing
§170.314(a)(8)	a.8 Medication List Interventions	T1: would be helpful and require less training if CDS in Dosespot was auto T2: would be nice to be automated instead of clicking med CDS T3: good to put drug allergy interactions in here, would be good to make this automatic message rather than click on this button T4: for dosespot to have drug intercatctions appear immediately
§170.314(a)(8)	a.8 Medication Allergy List Interventions	T2: Would be nice if allergies popped up on opening patient file( like latex allergy) T3: make automatic rather than click on button T5: helpful if it is dynamic feature
§170.314(a)(8)	a.8 Demographics Interventions	No comments recorded
§170.314(a)(8)	a.8 Lab Tests and Results Interventions	T3: don't make the user type in the %sign in description
§170.314(a)(8)	a.8 Vital Signs Interventions	T2: could you add to sideon same screen instead of as a popup? T3: easy to use
§170.314(a)(8)	a.8 Configuration of CDS interventions by user (may be an admin type function)	T2: A multiselect feature would be helpful to speed up the process T3: get rid of "%" when you type in stuff in

## Notes

- All testers are using the software in their current roles
- All times to complete estimated in minutes. 30 seconds equal to .5 of a minute
- Easy to do scoring based on 1 to 5, with 1 easy and 5 hard
- User risk error scoring based on 1 to 5, with 1 low and 5 high
- 5 Testers completed the tests

## Major test findings

- The findings and the comments reflect the the software is easy to use with only 2 tasks, “§170.314(a)(8) Configuration of CDS interventions by user” & “§170.314(a)(2) Adjustment of Severity level of drug-drug interventions” receiving a score of 3. In both instances by only one tester.
- Comments: T3: “simple, easy to use”, T5: “The more I see, it becomes easier to use”, T3: “good, easy to read labels” T5: “getting easier”
- 
- It is noticeable and acceptable that training and use of the software has a significant impact on the scoring as demonstrated by the comments recorded such as “T5: “The more I see, it becomes easier to use”
- The “Time to complete” average is 1.46 minutes supports the argument the software is easy to use and therefore efficient
- The “Ease of use” average is 1.2 minutes, this is in line with the comments recorded and also supports the argument the software is easy to use and therefore efficient
- The average “User risk error” is 1.2, this is very positive.
- The highest recorded value for “Time to complete” for any task was 10 minutes to “Configure of CDS interventions by a user” recorded by T1.
- The comments, such as T3: “Easy to use” “simple easy to use”, “good easy to read labels” T5: “getting easier” “straight forward”, “easy to use” “user friendly” further demonstrate and support the argument the software is easy to use
- The comments, “the more I see, it becomes easier to use” indicates there is a learning curve, however this is normal when a new version of a software product is developed and will be included in new product features training
- Items involving entering or change medication in general have a higher scoring, ranging between 2-4. The result is anticipated and would match the degree of diligence required if completing the task on paper.

## Identified areas of improvement

No areas identified