# SOFTWARE TEST PLAN
## for the *FHIRStartersApp*

# In Support of the
## *Concussion and Traumatic Brain Injury in Pediatric Patients CDC Project*

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<u>Under</u>:
Contract No. N/A

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**REVISION RECORD**

| REVISION | DATE | REVISED BY | DESCRIPTION |
|---|---|---|---|
| - | 11/12/2017 | FHIR Starters | Initial Draft Release |

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# 1 SCOPE

## 1.1 <u>Identification</u>

This Software Test Plan (STP) describes plans for the acceptance test activities for the Concussion and Traumatic Brain Injury in Pediatric Patients Web Application herein shall be referred to as the FHIRStartersApp.

## 1.2 <u>System Overview</u>

FHIRStartersApp is a physician-facing web based application designed to provided clinical decision support when diagnosing mild traumatic brain injury (mTBI) in pediatric patients using evidence based guidelines and generating management plans for them.

### *1.2.1 <u>Background Information</u>*

As attention to concussion and traumatic brain injury (TBI) has grown in recent years, there has been an increase in the number of pediatric patients with concussion (also known as mild TBI, or mTBI). Many providers have insufficient time and training to systematically assess and manage patients with suspected mTBI. This project aims to assess the feasibility of using Fast Healthcare Interoperability Resources (FHIR) to promote evidence-based diagnosis and management of TBI in children. The aim is to improve medical diagnosis at the time of injury by using evidence based guidelines made more available to clinicians and improve communication between clinicians, families, and schools to improve post injury management. Interests have been made in the applicability of this technology in rural health systems and primary care providers' practices.

### *1.2.2 <u>Description and Features</u>*

The FHIRStartersApp is a web based app that can interface with any system of electronic health records (in hospital, urgent care or provider practices) for physician diagnosis and management of mild TBI using evidence based guidelines to provide clinical decision support along with generating management plans for pediatric patients.

The FHIRStartersApp will have the following features:

- Extensible CDS rule structure
- Responsive front-end to allow for retrieving EHR data using SMART-On-FHIR.
- Complies to a Docker image
- Output management plans based on survey results.

### *1.2.3 <u>Project Details</u>*

The FHIRStartersApp is developed and supported by the FHIR Starters of the Georgia Tech graduate course Introduction to Health Informatics (CS6440) Fall Semester 2017 for the Concussion and Traumatic Brain Injury in Pediatric Patients team at the Centers for Disease Control and Prevention. The primary operating sites for this software will be used where physicians are used to diagnose pediatric patients for possible mild TBI.

## 1.3 <u>Document Overview</u>

This document describes the software test environment, identifies the tests to be performed, and documents plans and schedules relating to the acceptance testing of the FHIRStartersApp.

The developed software will be open to the public as the overall project involves a government agency.

## 2 REFERENCED DOCUMENTS

The documents listed in Table 2-1 below are referenced or used as sources for the information contained herein. In the event of conflict between the documents referenced herein and the contents of this STP, the contents of this STP shall be considered a superseding requirement. The revisions and changes are identified only in this paragraph. All Standards and Government documents are available through normal Government stocking activities.

**Table 2-1: Referenced Documents**

| DOCUMENT NUMBER | REFERENCE NUMBER | REVISION | DOCUMENT TITLE |
|---|---|---|---|
| **Standard Documents** | | | |
| N/A | - | - | PCSI Self-Report Assessment Form Pre and Post injury Report Ages 13-18 |
| N/A | - | - | PCSI-C Post-Concussion Symptom Inventory for Children |
| N/A | - | - | Post-Concussion Return To School Letter |
| N/A | - | - | STAMP ACE Gradual Return to School Guide |
| **FHIR Starter Documents** | | | |
| FHIR Starters CDS Design | - | - | FHIR Starters CDS Design Notes |

# 3 SOFTWARE TEST ENVIRONMENT

### 3.1 <u>Test Site</u>

Software testing of the FHIRStartersApp requires one personal computer (PC) with an Internet connection.

### 3.2 <u>Software Items</u>

The following software items are required to test the FHIRStartersApp.

#### *3.2.1 <u>FHIRStartersApp</u>*

The FHIRStartersApp is the software under test.  It will be installed on a computer configured as specified by this document and referred to as the Test PC. The Test PC will be connected to the Internet for server communication.

#### *3.2.2 <u>Microsoft Office</u>*

The Microsoft Office 2016 is required to view documents during testing. It will be installed on the Test PC.

### 3.3 <u>Hardware Items</u>

The following hardware items will be required to perform the FHIRStartersApp testing.

#### *3.3.1 <u>Test PC</u>*

The Test PC will consist of a local area network (LAN) adapter and/or a wireless card adapter for internet connectivity.

### 3.4 <u>Other Materials</u>

None.

### 3.5 <u>Proprietary Nature, Acquirer's Rights, and Licensing</u>

There are no restrictive acquirer's rights or licensing issues associated with any of the FHIRStartersApp software.

### 3.6 <u>Installation Testing and Control</u>

The test environment will be installed, controlled, and maintained by the FHIR Starters.

### 3.7 <u>Participating Organizations</u>

Personnel from the FHIR Starters team will evaluate and conduct the acceptance test.   A final demonstration of the software will be provided to our course's Teacher Assistant after the project's end for course evaluation and validation of compliance.

### 3.8 <u>Personnel</u>

Table 3-1 identifies the personnel involved in execution of the FHIRStartersApp test procedures.

**Table 3-1: Personnel Needed for FHIRStartersApp Testing**

| Organization | Personnel | Role |
|---|---|---|
| FHIR Starters | Jan Marie Andersen | Quality Assurance Representative, observe and approve |
| FHIR Starters | Lamar Phillips | Quality Assurance Representative, conduct testing |
| FHIR Starters | Darryl Buswell Spencer Knight | Primary Software Developer(s), available to answer technical questions as necessary |

| Organization | Personnel | Role |
|---|---|---|
| Georgia Tech | Jonathan Bidwell | Teacher Assistant, evaluate and approve final project delivery |

### 3.9 Orientation Plan

No special training is required to test the FHIRStartersApp.

### 3.10 Tests to Be Performed

All tests identified in Section 5 below will be performed during the Acceptance Test Plan (ATP) of FHIRStartersApp v1.0 at the Test Site.

# 4 STANDARD TEST IDENTIFICATION

There are no availability requirements associated with FHIRStartersApp.

## 4.1 General Information

The fundamental test strategy employed to evaluate the FHIRStartersApp is to execute functionality test cases on a System Simulation by System Simulation basis. Additional testing involves qualifying the overall correct operation of the decision logic support system as well as the correctness of the management plan output by the results of the decision logic criteria. Successful completion of the functionality test and operability cases will demonstrate that the software fulfills the requirements specified in the Software Requirements Specification and the Software Development Plan.

### 4.1.1 Test Levels

Tests in this document are performed at the application's decision logic flow and user interface experience.

### 4.1.2 Test Classes

Table 4-1 describes the typical test classes and their associated descriptions:

**Table 4-1: Description of Test Cases**

| CLASS | DESCRIPTION |
|-------|-------------|
| MMI | Man Machine Interface testing to verify the communication between the operator and the software. |
| EI | Erroneous Input testing to verify the error handling of the software. |
| MC | Maximum Capacity testing to verify the software's upper bound of data storage. |
| OV | Output Validation testing to verify that the software produces an output that correctly reflects the input of the operator |

There are four "normal" qualification methods used to verify specification requirements: Inspection, Analysis, Demonstration, and Test. Each type of verification is defined below:

1. **Inspection** is the verification by examination of the item, reviewing descriptive documentation and comparing the appropriate characteristics with a predetermined standard to determine conformance to requirements without the use of special laboratory equipment or procedures.

2. **Analysis** is the verification by technical evaluation using mathematical representations, charts, graphs, circuit diagrams, data reduction, and/or representative data.

3. **Demonstration** is the verification by operation, movement, and /or adjustment of the item under specific conditions to perform the design functions without recording of quantitative data.

4. **Test** is the verification through systematic exercising of the applicable item under appropriate conditions with instrumentation to measure required parameters and the collection, analysis, and evaluation of quantitative data showing measured parameters meet or exceed specified requirements.

### 4.1.3 General Test Conditions

In the event of a test failure, modification to the application will be made and software tests will be rescheduled and executed to qualify the software.

### 4.1.4 Test Progression

The software testing should be performed in the order specified for best results. Initial tests are designed to install the application and utilize a synthetic dataset to construct a database for use for the following tests. Changes in the progression of the tests will not invalidate test results.

### 4.1.5 *Data Recording, Reduction, and Analysis*

The test operator will analyze the output data for compliance and will record the results manually. The forms necessary for recording test results will be available in the Software Test Description. These forms will be copied into the Software Test Report. The test report will contain fields to indicate if a specific test succeeded or failed and a user comments field where the operator described the degree of success or failure.

# 5 PLANNED TESTS

To minimize the amount of redundant information in the test case sections, the following test information applies to all test cases unless otherwise specifically stated:

1. No additional data recording requirements exist beyond those addressed in section 4.1.5.

2. Any security and/or privacy considerations for the test cases are specified in the Software Test Description.

3. The following sections describe the planned test cases for the FHIRStartersApp v1.0. The tests will be performed on the Test PC.

## 5.1 Install Test (STD-01)

The objective of this test is to verify successful installation of the application. The operator will verify that the installation builds and outputs a Docker image for running follow-on test.

**Table 5-1: Install Test Information**

| | |
|---|---|
| Test Type/Class | MMI, OV |
| Qualification Method(s) | Demonstration |
| Special Requirements | Prior to this test, the Test PC should be setup according to the description section 3. |
| Data Recording | None |
| Requirements Tested | N/A |

## 5.2 User Interface Test (STD-02)

The objective of this test is to verify the UI presented to the user shows all correct spellings, buttons, highlights, tooltips, application version and information, and Title Bar. The operator will perform the following verifications:

- Start the FHIRStartersApp and verify display of the home screen and its contents.
- Display the "About Box" and verify its contents.
- Verify the contents of the Title bar.
- Minimize the dialog to the Windows taskbar.
- The application name should be displayed in the title bar of the app.
- The major and minor application version number should be displayed in the title bar of the app.
- The FHIRStartersApp should provide a method for starting a diagnosis checklist for mTBI.
- The FHIRStartersApp should display the current user selected changes.
- The FHIRStartersApp should display the name of the current patient.
- The FHIRStartersApp should provide a method for the user to submit information to the server for diagnosis and output a management plan.
- The FHIRStartersApp should support printing the management plan generated. The printouts should include the following information in the header or footer:
  - Patient Name
  - Physician Name
  - Print Date
  - FHIRStartersApp Version Number (major, minor, and build)

**Table 5-2: User Interface Test Information**

| | |
|---|---|
| Test Type/Class | MMI, OV |
| Qualification Method(s) | Demonstration, Inspection |

| | |
|---|---|
| Special Requirements | None |
| Data Recording | None |
| Requirements Tested | N/A |

## 5.3 Unit Tests

The objective of this subsection of tests is to verify that the FHIRStartersApp generates the appropriate clinical decision support based on user input. Unit tests will be done to validate the many possible paths of outcome due to the inputs provided.

### 5.3.1 CDS Rules

#### 5.3.1.1 CDS Rule Test (STD-03)

The objective of this test is to ensure the proper clinical decision support logic is adhered to.

The operator will perform the following verifications via unit testing:

- Perform unit testing and record output results.
- Perform Ad Hoc unit tests to validate edge cases.

**Table 5-3: CDS Rule Test Information**

| | |
|---|---|
| Test Type/Class | MMI, OV |
| Qualification Method(s) | Demonstration, Test |
| Special Requirements | None |
| Data Recording | None |
| Requirements Tested | N/A |

# 6 TEST SCHEDULES

The test activities are cited below in Table 6-1.

**Table 6-1: Test Schedule**

| Test Activity | Expected Dates |
|---|---|
| Test Execution | November 27 – November 28, 2017 |
| Test Reporting | November 29 – November 30, 2017 |

# 7 REQUIREMENTS TRACEABILITY

None.

# 8 NOTES

### 8.1 <u>List of Acronyms and Abbreviations</u>

**Table 8-1: List of Acronyms and Abbreviations**

| ACRONYM | DEFINITION |
|---------|------------|
| ATP | Acceptance Test Plan |
| CDS | Clinical Decision Support |
| FHIR | Fast Healthcare Interoperability Resources |
| EHR | Electronic Health Record |
| EI | Erroneous Input |
| LAN | Local Area Network |
| MC | Maximum Capacity |
| MMI | Man Machine Interface |
| mTBI | Mild Traumatic Brain Injury |
| OS | Operating System |
| OV | Output Validation |
| PC | Personal Computer |
| QA | Quality Assurance |
| STD | Software Test Description |
| STP | Software Test Plan |
| TBI | Traumatic Brain Injury |