Test Protocol - <Offering ID>
Document Number: <Document #>
Version Number: <#>

How to Use Template:

1. All sections with BLACK section header text are required.
2. All BLACK text shall remain in the document. **BLUE** text is to be deleted, modified and replaced with specific information. All **GREY** text is to be evaluated for relevance within the document, if the **GREY** text is relevant the text shall be turned BLACK, if the **GREY** text is not relevant it shall be deleted.
3. All template formatting should be maintained, Arial, 12 font, headers, list levels (as apply).
4. Sections or subsections that do not apply, leave blank and indicate “N/A.”
5. Sections or subsections that apply but do not have information are marked as “None.”
7. Delete this page after creating the document.

NOTE: For the approval sections, if the test protocol is for an automatic test protocol, use the test protocol approval box provided and one approval is needed for each automatic test protocol. If the test protocol has manual test cases, approval is needed for each manual test case.

<Type of Test Cases> Protocol
<Offering ID>

The Table of Contents shall be refreshed / updated for correct page numbers.

Contents

1 Purpose

<State the purpose for the Test Protocol.>

2 Scope

<Reference the approved Verification and Validation Plan for the project>

3 Definitions, Abbreviations, Acronyms

Terms listed here are found within the content of this document.

General terms are defined in black, the table should be sorted by Term, alphabetically.

Term	Definition	Abbrev./ Acronym
Offering or Solution	IBM Watson Health software, hardware, or services designed to deal with a problem or need, which is comprised of technology and/or support, and is packaged, sold, delivered and/or offered commercially.	
Project	A pre-defined objective (or set of objectives) with scope, activities, deliverables, and timeline assigned to a project team	
Quality Management System	A collection of business processes focused on achieving quality policy and quality objectives to meet customer and regulatory requirements (includes organizational structure, policies, procedures, and resources).	QMS
Record	A document retained as evidence of action that needs formal management under a QMS.	
Standard Operating Procedure	Established or prescribed methods to be followed routinely for the performance of designated operations or in designated situations	SOP
Watson Health	IBM Healthcare unit	WH

4 Assumptions

<List any key assumptions made during the development of the Test Cases that are not identified in the Test Plan.>

5 References/Procedures

<Reference applicable procedures and any related project-specific documents such as the SRS>

No.	Reference	Name
1	WH_QMS_SOP_0002	Design Control SOP
2	WH_QMS_SOP_0027	Verification and Validation SOP

6 Revision History

Track changes made to the plan, including original version

Version	Change	Revised By	Date (dd-MMM-yyyy)
1.0	Original	N/A	
2.0	Describe the section numbers that were changed and how it was changed.	Author Name	

7 Test Protocol

Build:	<Build #/ID>		
Test Case #:	<Test Case Identifier>	Run #:	<# >
Test Description:	<Test Description>		
Requirement(s) Referenced:	<Design Input Requirement ID(s)>		
Prerequisites:	<Pre-conditions and instructions for pre-execution setup>		
Classification:	☐ Verification ☐ Validation ☐ Verification and Validation		

<If Offering is a Class III Device, add a column indicating Pass/Fail for every test step>

Test Step No.	Test Instruction	Expected Result(s)	Actual Result(s)
1	<Instructions to Tester>	<Expected results of test instruction>	<Enter the observed result and include reference to any objective evidence> ☐ Meets expected results
2	<Instructions to Tester>	<Expected results of test instruction>	<Enter the observed result and include reference to any objective evidence> ☐ Meets expected results
3	<Instructions to Tester>	<Expected results of test instruction>	<Enter the observed result and include reference to any objective evidence> ☐ Meets expected results

<Add rows as needed>

Defects:

<Include list of defects and defect numbers>

Comments:

<Include any comments>

Test Case Approval (for manual tests) <include for each test case that is done manually, add along with manual test case; remove this section if this is an automatic test>

Test Outcome	☐ PASS ☐ FAIL	
Executed By:		Date Executed:
Signature:		
Reviewed By:		Date Reviewed:
Signature:		

<Add additional Test Cases and Test Case Approval (for manual tests) as needed>

Test Protocol - <Offering ID>
Document Number: <Document #>
Version Number: <#>

Test Protocol Approval

Protocol outcome	☐ PASS ☐ FAIL
Executed By (not needed for manual tests):	Date Executed (not needed for manual tests):
Signature (not needed for manual tests):	
Reviewed By (not needed for manual tests):	Date Reviewed (not needed for manual tests):
Signature (not needed for manual tests):	
Reviewed By (Q&R):	Date Reviewed:
Signature:	