How to Use the Form:

1. All BLACK text shall remain in the document. **BLUE** text serves as instructions, description, or examples and is to be deleted, modified and replaced. All **GREY** text is to be evaluated for relevance within the SOP, if the **GREY** text is relevant the text shall be turned BLACK, if the **GREY** text is not relevant it shall be deleted.

2. All text shall be BLACK when completed.

3. Delete this page after creating the document.

Verification and Validation Plan for <Offering ID>

VERIFICATION and VALIDATION PLAN APPROVALS

The following people acknowledge that:

The appropriate verification and validation activities are to be conducted for the <Offering ID>

<add signatures as necessary>

<FULL NAME> Project Leader	Date
<FULL NAME> Tester	Date
<FULL NAME> Development Manager	Date
<FULL NAME> Quality & Regulatory Representative	Date

Verification and Validation Plan for <Offering ID>

1 Purpose

This document outlines the Verification and Validation Plan for the <Offering ID>. This plan provides information regarding the scope of the verification and validation effort as well as verification and validation activities, approach, roles, responsibilities, and deliverables.

2 Definitions, Abbreviations, Acronyms

Terms listed here are found within the content of this document. <Add terms as needed>

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.	---
Defect Report	Form for reporting and tracking defects that occur	---
Watson Health	IBM Healthcare unit	WH
3rd Party Vendor	Provider of component software for the Offering	---

3 Scope

Describe the major functions that will be tested, including Part 11 controls (if applicable). Examples provided for illustrative purposes only.

- <ENUMERATE MAJOR AREAS OF TESTING>
- Display
- Access Control Security
- Audit Trail Functionality
- Electronic Signatures
- Privileged (Administrative) Functions
- Outputs/Reports
- Record/Database Updates
- *Error Conditions*

3.1 Exclusions and Limitations

Discuss what specifically is not being tested and why.

3.1.1 <ENUMERATE EXCLUSIONS>

3.2 Assumptions

Describe any assumptions regarding the project and the system being validated, including personnel, hardware, software, documentation, and the environment.

4 Risks / Contingencies

Discuss potential project, technical, regulatory risks. Include problems that might necessitate a change in approach (e.g. if a testing platform is not available, can a test area be set up on production?)

5 Verification and Validation Testing

5.1 Definition of Verification and Validation Approach

5.1.1 Procedures

Verification and Validation activities will be in accordance with the Design Controls SOP, version <VERSION No.> and the Design Validation SOP, <VERSION No.>.

Describe plan for verification and validation tests with clear indication of the category of test (i.e., verification, validation, or both).

Note: Verification includes functional, integration and system tests.

Validation includes any tests and efforts that demonstrates that the Offering meets the user requirements (e.g., integration, system, and usability tests such as User Acceptance Tests).

Describe any planned modifications or tailoring of the approach outlined in the SOPs mentioned above (if applicable).

Describe the Testing, pre-production, and production environment, including the transitions between environments.

Include plans for regression tests.

All plans should include plans for tests that affect patient safety, data integrity, or security.

5.1.2 Test Result Deviation Evaluation Criteria

Describe how defects and test results deviations will be evaluated (e.g., Defect Reports)

5.2 Resource Requirements

5.2.1 Hardware Environment

Describe any hardware that will be used.

5.2.2 Development and Test tools

<List all tools to be used for verification and validation, e.g., automated test tools, simulators, etc.)>

5.2.3 Software Requirements for Test Environment

Describe any special purpose software that will be used in the test environment, including any software tools or utilities that will be needed for testing (if applicable).

5.3 Planned Deviation

Describe any planned deviations

5.4 Schedule Considerations {OPTIONAL}

Provide high-level schedule with major milestones. The author may state that the Project Leader (or other member of management overseeing the project) will be responsible for developing and maintaining a more detailed schedule of deliverables and estimated creation dates.

5.4.1 Discuss any timing constraints with the testing. (e.g., system needs to be operational by the end of the first quarter).

5.4.2 Do things need to happen in a certain order? (e.g., need to acquire software licensing before installation)

5.4.3 Does it involve scheduling and coordination with other processes, projects, departments?

5.4.4 If there are no scheduling considerations, delete these subparagraphs and enter Not Applicable.

6 Verification and Validation Deliverables

The following deliverables comprise the verification and validation documentation for the < Offering ID > system.

Deliverable	**Included ?**	**Comment** (Required if "No" or "N/A" are entered under **Included** Column)
Verification and Validation Summary Report		
End user product documentation (e.g., user manual)		
Change Control Forms		

7 Revision History

Version	Change	Revised By	Date (dd-MMM-yyyy)
1.0	Original	N/A	
2.0	<Describe the changes that were introduced and where in the report such changes were made.>	<Author Name>	