BCS Validation and UAT Plan: EDC
Project Code 1234

SAMPLE.

Version: 00

Effective Date: _SAMPLE_

www.mikeabrannon.com

BCS Validation and UAT Plan:
EDC Project Code 1234 SAMPLE

Signatures/Approvals

The signatures below indicate authoring and approval of the BCS Validation and UAT Plan: EDC Project Code 1234.

Document Author:

SAMPLE _____ _____
Mike Brannon Date
Validation Lead

Approved By:

SAMPLE _____ _____
John Doe Date
Project Code 1234 Project Manager

SAMPLE _____ _____
Jack Flash Date
Director, IT

SAMPLE _____ _____
Thomas Thumb Date
Director, Data Management (DM)

SAMPLE _____ _____
Ray Jay Date
Quality Assurance (QA) Specialist, QA

SAMPLE _____ _____
Jack Horner Date
Project Manager
SponsorCo

Table of Contents

1.0 Purpose

The purpose of this project-specific Validation and User Acceptance Testing (UAT) Plan is to describe the process for generating documented evidence for the customization and Validation of Release 1.0 of the Charon™ Electronic Data Capture (EDC) system for BCS Project Code 1234 in accordance to applicable Food and Drug Administration (FDA) regulatory requirements for Computerized Systems used in clinical investigations.

The Cerberus Study [5678-90] involves tracking the late-phase effectiveness of Wonderdrug, which provides relief for fibromyalgia patients. This three (3) year study will involve seven (7) research sites, five hundred (500) patients and fourteen (14) administrators.

2.0 Definitions and Acronyms

With the exception of the definitions and acronyms included below all applicable definitions for this Validation effort are provided in the document titled *BCS Computerized Systems Validation Strategy (version 00, effective 11-JUL-2014)*.

- CRF – paper Case Report Form used in the *EDC Requirements Specification* document.
- eCRF – electronic Case Report Form
- "Fail" Patient – test patients for which invalid, inaccurate and/or incomplete test data will be entered in order to confirm that edit checks are working properly, i.e., patients for which tests will be created to intentionally fail respective edit checks.
- "Pass" patients – test patients which will have no erroneous test data, i.e., patients for which tests will be created to intentionally pass all respective edit checks.

3.0 System-Related Information

3.1 System Overview

The details of the Charon™ EDC core system overview can be found in the document *BCS Validation Report: Charon™ Release 1.1 (version 00, effective date 25-MAR-2020*).

3.2 Validation Strategy Overview

The FDA does not provide specific requirements, guidance, or format regarding how to minimize risks, but encourages companies to base their Validation approach and its extent on a justified and documented risk assessment and a determination of the potential of the system to affect product quality and safety, and record integrity.

The core system's functionality was tested by BCS in accordance with the document titled *BCS User Requirements for EDC (version 00, effective date 16-MAR-2015)* and in *BCS EDC User Acceptance Testing Plan: Charon Release 1.1 (version 00, effective date 19-NOV-2015)* and

summarized in the *BCS Validation Report: Charon™ Release 1.1 (version 00, effective date 25-MAR-2020).*

The following quality-related risks were identified with this project-specific Validation effort.

- Every attribute may not be tested.
- Testing of every attribute may not be documented.
- The qualifications and training of the individuals testing the system may not be sufficiently documented.

To eliminate these risks, BCS Data Management Department staff perform extensive testing of the customized system. The details of this testing process (e.g., how BCS assures that everything is tested), specifics about which documentation will be generated as part of this effort, and a description of qualifications and training of the individual performing this work will be identified in Section 5.6.

The project-specific Validation strategy will allow for/assume the following without a need to explain it in the project-specific Validation Report:

- All functionality defined as critical by the client will be tested and validated accordingly.
- Testing that has been performed to date regarding Project Code 1234 by the DM Department staff – the testing having been performed prior to the formalization of this project-specific Validation and UAT Plan – will be retrospectively documented on the Project Specific Test Summary Log Template (Section 12: Attachment 1). If necessary, additional explanations and/or clarifications will be incorporated in the existing documentation rather than re-performing Validation activities and/or re-creating documentation. The details of the procedure that was/will be followed will be documented in Section 5.6.7.
- The configurations for each role will be documented during the project-specific UAT testing.
- As appropriate, referencing documents, rather than duplicating the information, to avoid duplication and discrepancies and to maintain proper traceability (e.g., referencing the definitions provided in the *Computerized Systems Validation Strategy* rather than duplicating these definitions in each Validation document).

Some of the activities outlined in this Validation and UAT Plan may be performed in parallel. For example, upon successful project-specific UAT completion (as determined by the Director, DM), the project-specific system may go into production while the project-specific Validation Report is being developed. If implemented for business reasons (e.g., to meet "the first patient in" Sponsor's timeline), this approach carries no regulatory risk because the process will be under control of the BCS Validation Project Team. Namely, the team will be aware of the project-specific plan requirements, review the scope of work, and agree on the business and regulatory appropriateness of actions. This strategy allows

for flexibility in implementing the project-specific Validation activities in a timely fashion while still maintaining regulatory compliance.
The System Owners are Thomas Thumb (Director, DM), representing the DM Department, John Doe (Project Code 1234 Project Manager) representing the Project Management Department, while Jack Horner, Project Manager is representing the Sponsor (SponsorCo).

The following individuals comprise the project-specific Validation Project Team:

- T. Thumb, Director, DM (BCS)
- J. Doe, Project Code 1234 Project Manager (BCS)
- J. Flash, Director, IT (BCS)
- M. Brannon, Validation Lead
- R. Jay, QA Specialist, QA (BCS)
- J. Horner, Project Manager, SponsorCo

The team will be supplemented by BCS staff as needed.

4.0 Validation Guidelines/Tools

SOP-BCS-IT-805: Computerized System Validation provides the minimum documentation requirements for each type of Validation document. SOP-BCS-DM-409: Project-Specific EDC Validation provides specific procedures for validating an EDC system.

4.1 Testing Standards

Testing standards and criteria for acceptance (e.g., at the project-specific Validation level) will be defined later in this document. The format / grammar of the testing standards may be modified, if necessary, in which case an explanation will be provided in the project-specific Validation Report.

4.2 Documentation Requirements for Plans and Reports

As part of this project-specific Validation effort, at a minimum, the following documents will be generated:

- *BCS Validation and UAT Plan: EDC Project Code* 1234 (this document)
- *EDC Requirements Specification [for SponsorCo Protocol 5678-90]* (see completed Attachment 4: User Requirements Version History [Section 12] for the final versions and effective dates)
- *EDC Edit Specifications* (see completed Attachment 4: User Requirements Version History [Section 12] for the final versions and effective dates)
- *BCS Validation Report: EDC Project Code 1234*

5.0 Validation Activities

5.1 Approved Vendor Technical Specifications

The details of the Charon™ EDC technical specifications are provided in the document titled *BCS Validation Plan: Charon™ Release 1.1 (version 00, effective date 22-OCT-2015).*

5.2 Vendor Audit

The details of the Charon™ EDC Vendor Audit are provided in the document titled *BCS Validation Plan: Charon™ Release 1.1 (version 00, effective date 22-OCT-2015).*

5.3 Approved User Requirements

The Sponsor Requirements will be provided in two (2) documents:

- *EDC Requirements Specification (including CRFs)*
- *Edit Specifications*

All new versions of the project specific documents will be developed by BCS and approved by the Sponsor. All requested and approved changes will be highlighted in the project-specific documents revised. These highlighted changes will require testing as outlined in Section 5.6 of this document.

Version control history of these documents is tracked in User Requirements Version History (Section 12.0, Attachment 4). Until these approved documents are received by BCS, the final UAT tests cannot be generated.

The *EDC Requirements Specification (for SponsorCo Protocol 5678-90)* is developed by BCS DM Department staff and is approved by the Sponsor. The approved CRFs in this document will be used to create the electronic Case Report Forms (eCRFs) used in the project-specific EDC system.

At a minimum, the *EDC Requirements Specification* document will include information for the following requirements:

- Formats (e.g., header, date fields)
- Code list
- Forms for enrollment, follow-up, and unscheduled visits (i.e. CRFs)

BCS DM Departmental staff will modify the Edit Specifications and highlight all newly created or revised edit checks designed to help ensure data quality during the data collection process. All highlighted revisions or additions of the edit checks will require Sponsor approval and testing as outlined in Section 5.6 of this document.

5.4 Installation Qualification

The Installation Qualification involves two (2) servers, a Validation Environment (for testing) and a Production Environment (for the actual study launch).

5.4.1 Validation Environment

The current Validation Environment CHARON03 was installed through Charon™ Release 1.1.9 as detailed in *BCS Installation Qualification: Charon™ Release 1.1 Software Server (version 00, effective date 15-JUL-2020)*.

The hotfix patch history was administered in the following sequence:

- Charon 1.0.1 Hotfix [12-JUL-2020]
- Charon 1.0.2 Hotfix [12-JUL-2020]
- Charon 1.0.3 Hotfix [12-JUL-2020]
- Charon 1.0.9 Hotfix [12-JUL-2020] (inclusive)
- Charon 1.0.15 Hotfix [12-JUL-2020] (inclusive)
- Charon 1.1 Hotfix [12-JUL-2020]

Every Vendor Hotfix and Patch is tested in a Validation Environment prior to application to any Production Environment. Each change is evaluated and assigned a category that determines the depth, breadth and documentation of the testing to be performed. All documentation of such testing is stored in the assigned Server binders, maintained in the IT Department.

5.4.2 Production Environment

The Production Environment will be the CHARON1/CHARON1DB Server set. At the time of this document's composition, the server set is 1.0. Upon the move to production, the system will be patched to match the Validation Server version 1.1.

5.5 Operational Qualification / Design-Level Validation

The details of the OQ/Design-Level Validation are provided in a document titled *BCS Validation Plan: Charon™ Release 1.1 (version 00, effective date 22-OCT-2015).*

5.6 User Acceptance Testing

BCS DM Department staff will configure the system in accordance with the project-specific requirements of the Sponsor-approved *EDC Requirements Specification (for SponsorCo Protocol 5678-90)* document, which includes approved CRFs. In addition, the system will undergo project-specific testing to ensure that the edit checks (i.e. Edit Specifications) and other project-specific requirements have been met and that the configured and customized system works as intended.

The details of the project-specific testing approach and the procedure followed for the project-specific testing will be outlined in this section. The project-specific UAT will be performed against the User Requirements, as defined in Section 5.3 of this document.

The project-specific UAT will be carried out in the test environment as well. The following activities will comprise project-specific testing:

- The requirements identified in the *EDC Requirements Specifications (for SponsorCo Protocol 5678-90)* document, as well as in the Edit Specification, will be linked to formal, project-specific tests to ensure that the respective requirement has been successfully met.
- System testers will perform the formal, project-specific UAT activities and generate/compile the required testing documentation. Testers will be provided with formal instructions regarding how to complete the required forms, how to handle anomalies, etc. The specifics of these activities will be documented in Section 5.6.13.
- The testing deviations will be handled as specified in the testing standards and resolved or justified prior to the customized system being used in the production environment. Any deviations from this requirement and respective justifications will be documented in the project-specific Validation Report.

5.6.1 System Description

This will be the production system for the SponsorCo Fibromyalgia Research Registry.

5.6.2 UAT Assumptions

- The IT Department has successfully installed the system and there are no outstanding issues from the IQ activities.
- The Sponsor-approved documentation, which is necessary for compiling the project-specific user requirements, is available.
- The current systems change control procedure (per BCS-SOP-IT-813: Systems Change Control) will be followed in the event that there are changes required to the system after the start of test development and during the UAT execution.

5.6.3 UAT Limitations

The Charon™ EDC System Release 1.1 application has the following limitation:

- Conditional form flow is not applicable for import data.
  - This limitation does not affect EDC Project Code 1234 study data or study conduct.

However, two (2) limitations previously identified have been corrected.

- Conditional form flow is applicable for single record elements and not for multi-record elements.

- See elements 6 and 7 under "What's New in this Release" Vendor Release Number: Charon: 1.1 Patch (version 00, effective date 14-OCT-2015)

- Queries cannot be generated for partial dates using Designer Work Bench (DWB); these queries will be generated outside of DWB on the back end.
  - See element 2 under "What's New in this Release" Vendor Release Number: Charon: 1.0.3 Patch (version 00, effective date 18-FEB-2015)

5.6.4 Addressing UAT Related Risks

This UAT effort for the newly added or modified project-specific attributes noted in the *EDC Requirements Specification* and *Edit Specifications* will address the following UAT related risks:

- The risk that testing newly added or modified attributes is incomplete.
- The risk that the testing of newly added or modified attributes is inadequately documented.
- The risk that the testing, review, and/or approval activities are performed by staff whose qualifications and/or training are not commensurate with the respective role/responsibility.

The testing process employed will ensure that ***every*** newly added or modified project-specific attribute of the system is thoroughly tested and that ***every*** test is appropriately documented. By testing every attribute, BCS will address the incomplete testing risk (i.e., not every attribute will be tested), identified in Section 5.6.4.1 of this plan. While the format of the respective tests is not the same as the format of the test scripts employed for the core system Validation effort, there is no risk because the testing and documentation will be thorough and, all testing can be re-performed, if necessary, as specified below.

5.6.4.1 Addressing Testing Risk

The Project Specific Test Summary Log will also be used as a 'traceability matrix' for the UAT process to confirm that each requirement regarding edit checks and CRF pages will be tested and independently checked for all newly added or revised changes. Each edit check and CRF page condition (e.g., inclusion of visit date) represents a user requirement. Each requirement will be assigned a requirement number using the following convention:

- Edit check numbers will be system-generated and relate to specific edit specification requirements (e.g., "Date of Visit is missing. Please provide Date of Visit"), which are identified in the approved *Edit Specifications.*
- CRF pages, as outlined in the approved *EDC Requirements Specification,* will have a page number

assigned. This number will have a prefix of "p" followed by whole consecutive numbers (e.g., the Informed Consent CRF page will be page "P1", the Demographics CRF page will be "P2").

Test numbers will be assigned such that each test number will be the same as the requirement number that the test relates to (e.g., test number "P1" will relate to requirement number "P1"). The test numbers will be recorded in the "number" field of the Project Specific Test Summary Log. Every edit check will have its own entry. In the case of CRF pages, each condition/attribute/field on a page will have its own entry in the Project Specific Test Summary Log, utilizing the "description" field for what specifically is being tested on each CRF page. As a result, every requirement may, by definition, have one (1) or more associated tests, and the Project Specific Test Summary Log eliminates the risk of incomplete testing.

For more details regarding the Project Specific Test Summary Log, see Section 5.6.7.5 of this document.

In addition to testing the requirements that will be summarized in the approved *EDC Requirements Specification* and the approved *Edit Specifications,* the DM Department will:

1. Confirm that the study roles are set up correctly as per the project specific requirements.
2. Confirm that the project-specific roles are consistent with the roles/permissions as tested in the core system Validation effort (i.e., each role was tested in the core system Validation effort).

5.6.4.2 Addressing Documentation Risk

The risk of having inadequate or incomplete documentation will be eliminated by collecting objective evidence throughout the process, the details of which are summarized in Section 5.6.4.2 of this document. All hard copies of every document listed will be retained in the Project Code 1234 Validation effort file. Instructions on how to complete the Project Specific Test Summary Log and the Project Specific Anomaly Log template (Section 12.0, Attachment 2) are also provided in Section 5.6.7.2.

For the UAT activities regarding the newly added or modified attributes:

- All expected results (e.g., Sponsor-approved *Edit Specifications*, Sponsor-approved *EDC Requirements Specification* against which QC [Quality Control] will be performed) will be pre-defined.
- All actual results will be compared against the expected results and the status supported by objective evidence

(e.g., screen prints will be taken for every attribute of the CRF page and query listings will be generated for every edit).

- All test data will be recorded and retained.
- All test numbers, respective requirements and testing will be documented.
- All anomalies will be formally documented and resolved.
- Every newly added or modified data point will be 100% QC'd and the QC documented.
- All signatures of the individuals performing tasks, and the respective dates, will be included in the appropriate documents, forms, etc.
- Testing will include challenges (e.g., "fail" test patients - see Section 5.6.7.1) and expected workflows (e.g. "pass" test patients).

5.6.4.3 Addressing Qualification / Training Risk

The Director, DM will select qualified individuals to execute individual steps of the system customization (modifications) and testing process, respectively. Qualifications will be established based on the individuals' education, experience and/or appropriate training. The evidence of the staff qualifications will be included in the staff training records.

5.6.5 Customization (Modifications) Process

The Sponsor modifications for Project Code 1234 require changes to eCRFs, Edit Specifications, query processes, etc. and are documented by highlighting the additions and revisions in the Sponsor-approved *EDC Requirements Specification* and *Edit Specifications* documents.

5.6.6 QC of Customization (Modifications) Process

5.6.6.1 Data Dictionary

The assigned DM Department staff will generate the *Data Dictionary* document from the EDC system. Assigned DM Department staff will QC each newly added or modified field on this document against the study-specific field attributes to ensure the variable names were set up correctly in the EDC system. The field attributes will serve as the expected results and the *Data Dictionary* document will serve as the actual results.

Notations regarding status of each field (e.g., a "checkmark" denoting that the field is correct or, if not correct, a notation of changes required) will be made directly on the *Data Dictionary* document in an acceptable regulatory manner per BCS-SOP-GA-100: Good Documentation Practice. The annotated *Data*

Dictionary document will be corrected, as necessary, and the process will be repeated until all fields are correct. The DM Department staff performing the QC will sign and date the annotated *Data Dictionary* document to signify that all fields are correct.

The annotated *Data Dictionary* document and evidence of the respective, documented QC review will be retained in the Project Code 1234 Validation effort file.

5.6.6.2 Code List

Assigned DM Department staff will generate a *Code List Report* from the EDC system. Other assigned DM Department staff will QC each newly added or modified field on this document against the code list section of the *EDC Requirements Specification* to ensure the respective code values and display orders are correct. The Code List in the *EDC Requirements Specification* will serve as the expected results and the *Code List Report* will serve as the actual results.

Notations regarding status of each field (e.g., a "checkmark" denoting that the field is correct or, if not correct, a notation of changes required) will be made directly on the report in an acceptable regulatory manner per BCS-SOP-GA-100. The annotated *Code List Report* will be corrected, as necessary, and the process will be repeated until all fields are correct. The staff generating the Code List and person(s) performing the QC will sign and date the annotated *Code List Report* to signify that all fields are correct.

The annotated *Code List Report* and evidence of the respective, documented QC review will be retained in the Project Code 1234 Validation effort file.

5.6.6.3 Help Text

Assigned DM Department staff will generate a document containing the Help Text details contained in the customized system (i.e. Help Text 'strings' that will appear within the Fibromyalgia Registry). Other assigned DM Department staff will QC each newly added or modified field on this document against the *Help Text Specifications* document. The Help Text details in the *Help Text Specifications* will serve as the expected results and the Help Text generated from the system will serve as the actual results. Notations regarding status of each field (e.g., a "checkmark" denoting that the field is correct or, if not correct, a notation of changes required) will be made directly on the report in an acceptable regulatory manner per BCS-SOP-GA-100. The annotated Help Text document will be corrected, as necessary, and the process will be repeated until all information is correct. The DM Department staff generating

the document and person(s) performing the QC will sign and date the annotated Help Text document to signify that all information is correct.

The annotated Help Text document and evidence of the respective, documented QC review will be retained in the Project Code 1234 Validation effort file.

5.6.7 Testing of the Customized EDC System

The following section describes the testing procedures to be used in this effort.

The Data Management Staff will be assigned different areas of the system (Edit Specifications, Edit Requirements Specification, Code List, Data Dictionary List, et al). The tests will be distributed for maximum efficiency of testing, so several associates may be assigned to testing one aspect of the system, dividing the tests so they do not overlap the efforts of other testers. The procedures used for all areas of testing are as follows:

5.6.7.1 "Pass" Patients and "Fail" Patients

The assigned DM Department staff will create test patients. The test patients will have data entered using the workflows (eCRF screen flow and inter-relationships) as defined in the *EDC Requirements Specification* and designed into the customized Project Code 1234 EDC system.

One (1) category of test patient will be "pass" patients. These will be test patients with no errors (e.g., no data input/errors that will cause an edit check to fire). These can be considered "calibration" patients in that this aspect of testing will confirm that the normal workflow of the customized system is operating as designed and that every requirement operates as intended, with no unintended errors (e.g., automatic calculations are correct, pre-fills are correct).

The second category of patient will be "fail" patients. These will be test patients set up to confirm that each known error condition causes an edit check to fire. The test conditions of these "fail" test patients will be such that they will introduce numerous possible errors into the normal workflow and will serve as system challenge testing. Fail patients will be documented in a report titled *Edit Specifications Test Patient Log,* which will be drafted by the assigned DM Department staff.

The remainder of this section provides details regarding how the "pass" and "fail" patients are utilized to test the customized system.

If, during development additional testing methods are utilized, these will be identified and addressed during the Validation Report, if applicable.

5.6.7.2 Creating Test Data for Entering into eCRFs

Test data will be generated to test the completeness and appropriateness of the newly added or revised eCRFs and edit checks. Each test patient will be created to test specific conditions. The number of test patients will depend on the number and complexity of the conditions to be tested.

Assigned DM Department staff will modify each of the paper CRFs of the Sponsor-approved *EDC Requirements Specification* document to add the following components to be used for testing purposes:

- Patient header information (test patient, site number and visit, if applicable)
- Page number reference P___ (will be recorded in the "number" column in the Project Specific Test Summary Log (e.g., P1, P2, P3)
- Test data created by/date: _____
- Test data entered by/date: _____
- Test case: _____ (defined test cases for each patient for example, edit specification number, algorithms, calculations, pre-fill data, etc.)
- Statement to indicate the QC review will be documented on Project Specific Test Summary Log.

The assigned DM Department staff will create test data for each test patient and sign the respective CRF page. The test data will be data values (e.g., dates, lab values) designed per test patient to achieve the desired outcomes (e.g., no errors, specific edit messages). The test data will be handwritten onto paper CRFs. This will serve as the source documentation for the UAT and will be retained in the Project Code 1234 Validation file. The test data will later be entered into the project-specific EDC system eCRFs.

The conditions to be tested (e.g., fields that should appear/disappear based on existence of data in other fields, accuracy of pre-fills, accuracy of calculations, edit checks to fire) and the expected results will be recorded on the CRF pages.

The "pass" and "fail" test patients cases used for testing purposes will also be identified (linked) on the Project Specific Test Summary Log in the 'Test Description' column (summary of what is being tested, e.g., edits, appear/disappear fields,

grayed out fields, pre-fill fields, auto calculated fields and email notifications).

5.6.7.3 Edit Specifications Test Patient Log

Based on the Sponsor-approved *Edit Specifications* document, assigned DM Department staff will generate the *Edit Specifications Test Patient Log* from the approved *Edit Specifications.* This document will include the Test Patient Site Number(s) and Test Patient Subject Number(s) that will be created on the test CRFs to ensure each edit check will fire when required or identify deviations (e.g., edit check not firing, incorrect message). Edit checks contained within the *Edit Specifications Test Patient Log* will be:

1. Designed to check for missing, out of range and consistency of the data.
2. Linked to the specific CRF pages.
3. Supported by the Edit Specifications.

5.6.7.4 Entering Test Data into the eCRFs

Assigned DM Department staff will enter the test data from the hardcopy CRFs into the project-specific EDC system eCRFs. The staff will be instructed to enter the data exactly as it is written on the CRFs and sign/date the respective CRF page.

5.6.7.5 Evaluating Test Results

Using the Project Specific Test Summary Log and, if appropriate, the Project Specific Anomaly Log, the assigned DM Department staff will generate QC evidence (e.g. screen prints, query listings) for each attribute/field/condition of the eCRFs and perform the following activities by comparing the actual results (generated screen prints of the eCRFs) to the expected results (hardcopy CRFs) to:

1. Confirm that all pre-filled information is filled in and is accurate;
2. Confirm that all automatic calculations are accurate;
3. Confirm that all data fields appear exactly as they were entered;
4. Confirm the necessary queries are generated for the appropriate patients based on the test data entered;
5. Confirm notification messages are displaying on the screen based on *EDC Requirements Specification* document;
6. Confirm the eCRF verbiage is correct and that it reflects what is in the *EDC Requirements Specification* document;
7. Confirm the flow of the eCRFs is correct per visit and that it reflects what is in the *EDC Requirements Specification* document.

See Section 5.6.10 of this document for instructions on how to generate and label screen prints. The hardcopy CRFs, screen prints of the eCRFs and the evidence of the respective QC review will be retained in the Project Code 1234 Validation effort file.

Using the Project Specific Test Summary Log and, if appropriate the Project Specific Anomaly Log (e.g. edit check not firing), the assigned DM Department staff will generate query listings for each edit check. These query listings, along with the documented evidence of QC, will be retained in the Project Code 1234 Validation effort file.

Assigned DM Department staff will confirm that the eCRFs are being stored in the database correctly (this will be done by exporting the test eCRF data from the EDC system - actual result). The exported eCRF data (actual results) will be compared back to the data created on the paper CRFs (expected results). All corrections that need to be made will be documented using the Project Specific Anomaly Log.

The documentation and the documented evidence of QC will be retained along with the respective eCRF pages in the Project Code 1234 Validation effort file.

With respect to edit checks, all edits (e.g. the expected edit messages) for the test patients documented in the *Edit Specifications Test Patient Log,* will be listed in the Project Specific Test Summary Log and results will be compared to the *Query List Report* generated by the assigned DM Department staff from the EDC system. This report will display the edit checks (e.g., actual messages) that fired (actual results) for the test patient data.

- If all expected edits did not fire for the test patient, then an anomaly will be written up on the Project Specific Anomaly Log requesting additional “fail” test patients to be created and added to the *Edit Specifications Test Patient Log.*

- If additional edits fired correctly based on the data entered in the EDC system eCRFs but is not listed on the Project Specific Test Summary Log the assigned DM staff will make a notation regarding status of query (e.g., a “checkmark”) denoting that the query fired correctly.

The *Query List Report* and the documented evidence of QC will be retained in the Project Code 1234 Validation effort file.

All changes to the documentation that will be collected in the process of system customization and testing will be made in accordance with BCS-SOP-GA-100.

5.6.8 Testing Exceptions and Documentation

If a test fails (e.g., the edit check does not fire when it should, the edit check fires when it should not or the information on the eCRF pages do not match the requirements listed in the approved document), the testing exception(s) will be documented using the Project Specific Anomaly Log. The fields in the Project Specific Anomaly Log template can be populated electronically, however, the initials/signature and dates must be handwritten. When populating the template electronically the fields on the log may be enlarged for entry; however, the field names will remain as outlined below.

The fields in the Project Specific Anomaly Log are illustrated in Attachment 2: Project Specific Anomaly Log Template and are interpreted as follows:

- Project Code - unique BCS identifier (number) assigned to each project.
- Reported by/Date - signature of the tester who encounters the error and the date on which the Project Specific Anomaly Log is completed.
- Anomaly Number - a number/character which should start with the testers initials and then a consecutive number that uniquely identifies the anomaly (e.g., JB1, JB2, etc.) and is required only if the Test Description fails.
- Number - unique identifier for each edit check or CRF page.
- Test Patient Number - unique identifier for each “pass” patient and “fail’ patient, and the number will be assigned in accordance with the *EDC Requirements Specification*
- Description - detailed description of the anomaly (e.g., a detailed explanation from the tester of the error encountered, including any error messages generated and the conditions/procedures which invoked the error. Screen prints should be included if necessary for clarification.)
- Resolution - explanation of the resolution action to be taken to resolve the anomaly. The resolution action may involve retesting, updating documentation, making a change to the trial, etc.
- Resolved by/Date - sign-off and respective date by the individual who implements the resolution.
- Reviewed by/Date - sign-off and respective date by the individual who reviews the Project Specific Anomaly Log for completeness and accuracy.
- Additional Comments - section for comments related to a specific anomaly. If comments are not necessary, check NA.

Copies of all testing documentation (the ones that passed or failed) will be retained in the Project Code 1234 Validation effort file.

If some of the fields on the Project Specific Anomaly Log will not pertain to specific tests, the tester will document the absence of the information as N/A. The completed Project Specific Anomaly Logs will be retained in the Project Code 1234 Validation effort file.

There will be no classification (e.g., cosmetic, insignificant, significant) of the project-specific anomalies. The reason for this decision is as follows: all of the anomalies, irrespective of their nature, will be closed and, where appropriate, the workarounds will be designed, prior to the system going into production.

All changes to the documentation will be made in accordance with BCS-SOP-GA-100.

5.6.9 Test Review Procedure (QC)

Every test that will be entered into the Project Specific Test Summary Log will be QC'd by a second individual to evidence review of the test conduct and test output and to determine the status (i.e. pass/fail) of the result of each test. This review will be documented as per this document, and all changes to the documentation will be made in accordance with BCS-GA-100.

After all of the project-specific testing is completed and QC'd and, after all of the anomalies are resolved, the Director, DM will perform an additional courtesy review of the overall project-specific testing, focusing on proper completion of the Project Specific Test Summary Log. This will be additional confirmation that all of the anomalies have been closed in a timely fashion and that, where appropriate, the workarounds have been implemented. This review will be documented on Project Specific Approval to Move to Production (Section 12.0, Attachment 3).

When necessary, the Sponsor can be provided these same test patients to enter into the EDC study test trial to test the system independently.

5.6.10 Screen Captures and Other Output

The tester will generate, properly label and initial and date suitable objective evidence to confirm test results. At a minimum, the information on each screen print, output, and report should contain when appropriate the edit/rule number, test patient number and test description, as defined in Section 5.6.7.2 of this document.

When more than one (1) screen print is necessary to capture all of the eCRF fields, the screen prints will be labeled with a -1, -2, etc. (e.g., P1-1, P1-2).

5.6.11 Acceptance Criteria

The acceptance criteria for the Project Code 1234 UAT will be as follows:

- An individual test (e.g., edit checks, eCRF page) will "pass" only if all anomalies will have been followed up and corrected and as required, re-tested. A test will "fail" if any exception is not corrected or if any testing exception has not been followed-up and evaluated via a Project Specific Anomaly Log.
- The overall Project Code 1234 Validation effort will pass only if all individual tests pass.
- The Project Specific Approval to Move to Production document will be the documented evidence of the overall success of the project-specific UAT effort.

5.6.12 Summarizing Test Results

The Director, DM will assign responsibility to one (1) or more individuals for compiling the information for the Project Specific Test Summary Log.

The Project Specific Test Summary Log will be used to document the execution of each test. The fields in the Project Specific Test Summary Log can be populated electronically, however, the initials/signature and dates must be handwritten. When populating electronically the fields on the log may be enlarged for entry; however, the field names will remain as outlined below.

The fields in the Project Specific Test Summary Log are illustrated in Attachment 1: Project Specific Test Summary Log template and are interpreted as follows:

- Project Code - unique BCS identifier (number) assigned to each project.
- Test Run Number - identifier of the consecutive number for each test run.
- Document(s) - section for referencing a version number of the *EDC Requirements Specification* and/or *Edit Specifications* document.
- Page X of Y - X represents the current page, and Y represents a total number of pages.
- Number - unique identifier for each edit check or CRF page.
- Test Patient Number - unique identifier for each "pass" patient and "fail' patient, and the number will be assigned in accordance with the *EDC Requirements Specification*
- Test Description - summary of what is being tested.
- Status - indication whether the test script has passed or failed (see Section 5.6.7.1 of this plan)

- Anomaly Number (If Status=Fail) - a number/character which should start with the testers initials and then a consecutive number that uniquely identifies the anomaly (e.g., JB1, JB2) and is required only if the Test Description fails
- QC (initials/date) - initials of the individual who verifies the accuracy of test-related information and its completion.

If some of the fields on the Project Specific Test Summary Log do not pertain to specific tests, the tester will document the absence of the information as N/A, and all changes to the documentation will be made in accordance with BCS-SOP-GA-100.

An abbreviations list will be created for use with the UAT which identifies each abbreviation acronym to be used during testing.

The completed Project Specific Test Summary Log(s) and the abbreviations list will be retained in the Project Code 1234 Validation effort file.

5.6.13 Tester Training

Each tester and test reviewer/approver will be educated about the proper way to generate/compile documented evidence during the project-specific UAT.

The training will be conducted by the individual(s) identified in Section 9.0 of this document. It will address, but may not be limited to, the following: a complete review of this document, how to label test execution deliverables (e.g., screen prints, reports, listings – Section 5.6.10 of this document); how to make changes to documents (e.g., single line-out, initial/date); how to confirm pre-fills and calculations on selected CRF pages; how to confirm that automatic inclusion/exclusion of fields based on other fields (e.g., dependencies) operates correctly; how to complete the Project Specific Test Summary Log and the Project Specific Anomaly Log (Section 5.6.12).

This training will be documented according to BCS procedures and retained in staff training files per BCS-SOP-GA-102: Training Program. A copy of this training documentation will be included in the Project Code 1234 Validation effort file.

5.6.14 Validation Staff Log

There will be a record kept of all individuals involved with this UAT execution using the Validation Staff Log (Section 12.0, Attachment 5). At a minimum, the record will contain the individuals' printed names, signatures, and initials. The accuracy and completeness of this information will be signified by the Validation Project Team project manager's signature and date.

5.7 Trace User Requirements for User Acceptance Testing

The Project Specific Test Summary Log will also serve as a traceability matrix to relate user requirements to the testing documentation created as part of the project-specific UAT effort. The purpose of the traceability requirements has been addressed in detail in the document titled in *BCS Validation Plan: Charon™ Release 1.1 (version 00, effective date 22-OCT-2015).* The traceability will proceed with the documentation described in Section 5.6.7.5 and will trace each requirement to the test documentation (e.g., eCRF, Query List), using the Project-Specific Test Summary Logs and the *Edits Specification Test Patient Log*. All failed tests must show where they were re-tested and passed.

In addition to the DM Department staff and, as part of the development of the Validation Report, the Validation Specialist will confirm traceability.

5.8 21 CFR Part 11 Compliance

The details regarding this section are provided in the document titled *BCS Validation Report: Charon™ Release 1.1 (version 00, effective date 25-MAR-2020).*

5.9 Validation Report

At the end of the project-specific Validation effort, Validation Project Team members will develop and/or approve the project-specific Validation Report. Following the outline of this plan, thereby ensuring that each element is addressed and summarized, the project-specific Validation Report will include the following at a minimum, as outlined in SOPs BCS-SOP-IT-805 and BCS-SOP-DM-409:

- Summary of the activities (including eCRF deployment and edit modifications) performed during this Validation effort and respective test results.
- Assessment of the anomalies and their impact, if any, on the project-specific Validation effort.
- Identification and justification of differences in activities performed from those specified in this plan.
- Identification of limitations on using the customized system as a result of testing.
- Conclusion as to the adequacy of the customized system for operational use.
- Conclusion as to the data integrity of the migrated system for operational use.
- Identification of the records to be included in the project-specific Validation effort file.
- Location of project-specific Validation effort file documentation.

6.0 Project Schedule

Although no formal project schedule will be developed for this project-specific Validation effort, the Validation Project Team project manager will be responsible for providing the Validation Project Team members with updates to the project schedule when necessary.

7.0 General Assumptions and Prerequisites

7.1 Policies and Procedures

Applicable policies and procedures will be available, or will be generated, that support the protection of records against corruption and loss. These policies will address, but not necessarily be limited to, the following areas:

- Back-up and Recovery
- Physical and Logical Security
- Hardware and Software Inventory / Maintenance
- Disaster Recovery

7.2 Change Control

All changes to the validated system will be made in accordance with BCS's system change control procedure Computerized Systems, BCS-SOP-IT-813, and utilizing the appropriate form.

7.3 Test Environment

The test environment (i.e. Validation Environment) will be as close as possible to the environment used in production (i.e. Production Environment). This environment will be controlled, and access limited to authorized individuals.

7.4 Training

All training will be performed and documented in accordance with BCS-SOP-GA-102. See Section 5.6.13 for more details.

7.5 Standard Operating Procedures

Any tasks performed during this Validation effort should utilize current Standard Operating Procedures and related documents (e.g., SOP Forms), in effect at the time of execution.

8.0 Validation Documentation

The project-specific Validation Documentation will consist of, but is not necessarily limited to, the following:

- Validation and UAT Plan (this document), including completed attachments in Section 12)
- Sponsor-approved *EDC Requirements Specification (including CRFs)*
- Sponsor-approved *EDC Edit Specifications*
- Tester training documentation (e.g., FORM 012: General Training Log)
- Testing documentation (e.g., tests, test results, test summary logs)
- Validation Report

The documentation will be stored electronically with the DM Department on a secured, limited access server, and the physical documents will be kept in the project-specific Validation effort file. Upon completion of the Validation effort, the Validation Documentation will be transferred to the Records Room for storage.

9.0 Roles and Responsibilities

The following table identifies the key project-specific Validation effort activities and the respective responsibility. In some cases, the name of the individuals who will be involved is not known at this time. This is identified with the notation "individual(s) to be identified." Individuals completing (developing) an activity may not approve/execute the activity they have completed (developed).

Table 1. Validation Effort Roles and Responsibilities

Activity	Responsible Individual(s)
Develop Validation and UAT Plan (this document)	Mike Brannon, Validation Lead
Approve Validation and UAT Plan	John Doe, Project Code 1234 Project Manager Thomas Thumb, Director, DM Jack Flash, Director, IT Ray Jay, QA Specialist, QA Jack Horner, Project Manager, SponsorCo
Develop EDC Requirements Specification, including CRFs	BCS DM Department staff
Approve EDC Requirements Specification, including CRFs	John Doe, Project Code 1234 Project Manager Jack Horner, Project Manager, SponsorCo
Develop EDC Edit Specifications	BCS DM Department staff
Approve EDC Edit Specifications	John Doe, Project Code 1234 Project Manager Jack Horner, Project Manager, SponsorCo
Tester training	Thomas Thumb, Director, DM And/or BCS DM Department staff
Develop UAT tests (including test data)	BCS DM Department staff
Perform UAT tests	BCS DM Department staff
Quality Control (QC) UAT tests	BCS DM Department staff
Review and approve UAT and move to production (Attachment 3)	Thomas Thumb, Director, DM
Develop Validation Report	Mike Brannon, Validation Lead

Activity	Responsible Individual(s)
Approve Validation Report	Thomas Thumb, Director, DM John Doe, Project Code 1234 Project Manager Jack Flash, Director, IT Jack Horner, Project Manager, SponsorCo

10.0 References

- BCS-SOP-GA-100: Good Documentation Practice
- BCS-SOP-GA-102: Training Program
- BCS-SOP-DM-409: Project-Specific EDC Validation
- BCS-SOP-IT-805: Computerized System Validation
- BCS-SOP-IT-813: Systems Change Control
- 21 CFR Part 11: "Electronic Records; Electronic Signatures Final Rule", Federal Register, March 1997
- Guidance for Industry: Computerized Systems Used in Clinical Investigations, May 2007
- Guidance for Industry: General Principles of Software Validation; Final Guidance for Industry and FDA Staff, January 2002
- Guidance for Industry: Part 11, Electronic Records; Electronic Signatures-Scope and Application, August 2003

11.0 Revision History

Version	Effective Date	Author	Revision
00	Current	Mike Brannon	Original

12.0 Attachments

Five (5) attachments are included:

- Attachment 1: Project Specific Test Summary Log Template
- Attachment 2: Project Specific Anomaly Log Template
- Attachment 3: Project Specific Approval to Move to Production
- Attachment 4: User Requirements Version History
- Attachment 5: Validation Staff Log

ATTACHMENT 1:
PROJECT SPECIFIC TEST SUMMARY LOG TEMPLATE

PROJECT CODE	TEST RUN NUMBER	DOCUMENT(S) [check box if none □]	PAGE X OF Y
			of

NUMBER (Edit/Rule)	TEST PATIENT NUMBER	TEST DESCRIPTION	STATUS	ANOMALY NUMBER (If Status=Fail)	QC (initials/date)
			□ Pass □ Fail		
			□ Pass □ Fail		
			□ Pass □ Fail		
			□ Pass □ Fail		
			□ Pass □ Fail		
			□ Pass □ Fail		
			□ Pass □ Fail		
			□ Pass □ Fail		
			□ Pass □ Fail		

ATTACHMENT 2:
PROJECT SPECIFIC ANOMALY LOG TEMPLATE

Project Code		Reported by / Date			
Anomaly Number		Number		Test Patient Number	
Description					
Resolution					
Resolved by/ Date					
Reviewed by / Date					
Additional Comments	**[check box if not applicable ☐]**				

ATTACHMENT 3:
PROJECT SPECIFIC APPROVAL TO MOVE TO PRODUCTION

Project Code		Charon™ Release Number	
UAT testing: I have reviewed the Project Specific Test Summary Logs and all associated Project Specific Anomaly Logs. All tests have been performed and all anomalies resolved appropriately. Therefore, this project can be moved into Production.			
Director, Data Management			
Signature	Title	Date	

ATTACHMENT 4:
USER REQUIREMENTS VERSION HISTORY

User Requirements Document Name	Version	Effective Date

The information above is accurate and complete.

Signature	Title	Date

ATTACHMENT 5:
VALIDATION STAFF LOG

Validation Effort Identification (system name, version number)	

Printed Name	Signature	Initials

The information above is accurate and complete.

Signature	Title	Date