Guidance for Compliance with 21 CFR Part 11 and Validation of Vestigo

Compliance with 21 CFR Part 11 requires actions by both McCreadie Group and the client. This document provides documentation of the actions taken by the McCreadie Group and functionality of Vestigo to be compliant and provides the client guidance on the steps needed to meet compliance. In this guide, the term “client” refers to the user of Vestigo at a clinical trial practice site. This document is made up of a series of Sections; a description of each section can be found on the next page.

Contents

Statement of Compliance

Vestigo is an application to help manage inventory accountability for Investigational Drug Services. As such, it performs record keeping functions subject to 21 CFR Part 11. The regulations require electronic features and controls as well as user policies and practices.

Vestigo undergoes rigorous internal testing for all development activities to ensure compliance with the regulation. Full compliance with 21 CFR Part 11 requires that the application be used in an environment with internal controls, local policies and procedures to ensure the application is used correctly.

For further information on how Vestigo complies with this regulation, please see the related document labeled **Statement of Compliance Vestigo and 21CFR Part11** on the Vestigo Help Center.

Description of Document Content

The following sections are included in this guide:

Section A lists the controls for 21 CRF Part 11

The section contains a chart with the Federal Code, McCreadie Group interpretation of the Code, McCreadie Group responsibility, and Client responsibility. Some sections will require only one party to comply and others where both parties must comply. Part of the Code concerns the software and how McCreadie group manages the software development process, and other parts of the Code concern how the Client interacts with and uses the software. 21 CFR Part 11.10(a) is a good example of how both parties need to validate the system. From the McCreadie Group perspective, we must provide a product and process that is validated (the software is designed to meet a functional requirement). Clients should validate that Vestigo meets their requirements. Some of the requirements may be part of organizational policy so the IDS does not need a separate policy or SOP, but there are some controls that may require a Pharmacy or IDS policy/SOP to meet.

The section includes a chart detailing the Federal Code, McCreadie Groups interpretation, responsibilities of McCreadie Group, and Client responsibilities. Some sections require compliance from only one party, while others need both parties to comply. The Code covers software management by McCreadie Group and client interactions with the software.

For instance, 21 CFR Part 11.10(a) requires both parties to validate the system: McCreadie Group must ensure the software meets functional requirements, and clients must confirm Vestigo meets their organizational requirements. Certain requirements might follow organizational policies, while others could necessitate more detailed policies/SOPs relevant to your dispensing location.

Section B is a sample Validation Plan

As part of 21 CFR Part 11 compliance, clients must validate the software used as part of the requirements listed within regulation. This is a common question you may get from sponsors/CROs/monitors and is also part of 21 CFR Part 11.

The McCreadie Group provides a vendor Certificate of Validation for Vestigo per our policies, but you as the client also need to validate Vestigo to ensure it meets your organizational requirements.

If your organization has its own validation plan you should use it, if not, we have provided a sample Validation Plan below for your use. The suggested validation path is to validate the creation of the drug accountability record form (DARF) that confirms that the inventory received and dispensed is appropriately reported on the DARF.

Section C is a sample regression test plan

The regression test plan outlines each step and its expected outcome. The sample plan includes protocol build, inventory receipt, dispensing, and DARF generation. Organizations may need to develop more detailed regression plans.

Section D is a sample document for Protocol, and Drug and Order builds

A QA document can enhance your quality assurance program by ensuring each protocol drug and order meets internal standards. It complements the validation document, which demonstrates Vestigo's overall suitability, while the protocol QA document confirms that individual protocols meet specific needs. This sample can be modified to organizational needs.

Section E is a template document to show that Vestigo training was completed

To comply with 11.10(i), organizations must ensure users document their knowledge of Vestigo. This document outlines key software areas. Organizations may have additional SOPs or documents to demonstrate competence, and this can be a supplemental document if needed.

Section A – 21 CFR Part 11 Controls

The section contains a chart with the Federal Code, interpretation of the Code, McCreadie Group responsibility, and Client responsibility.

21 CFR Part 11 Reference	Description	Interpretation	McCreadie Group / Vestigo Responsibility	Client Responsibility
11.10 (a)	Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.	How an organization proves (to itself and auditors) that the data in a computer system can be trusted. *See document "Suggested Validation of Vestigo."*	McCreadie Group Validates all major releases per our Validation Software Policy.	Client should validate the solution per Client policy.
11.10(b)	The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency. Persons should contact the agency if there are any questions regarding the ability of the agency to perform such review and copying of the electronic records.	How an organization makes sure that all electronic records that an auditor might want to see and/or copy can be provided in a language/format that humans (not just computers) can understand.	Vestigo generated drug accountability record forms (DARF) are generated in human readable format.	N/A
11.10 (c)	Protection of records to enable their accurate and ready retrieval throughout the records retention period.	How an organization protects documentation and keeps it readily available for as long as it's required to be stored.	All data is encrypted at rest and transit and all data is readily available for the duration of the contract. Once a protocol in closed by the site in Vestigo, certain	N/A

21 CFR Part 11 Reference	Description	Interpretation	McCreadie Group / Vestigo Responsibility	Client Responsibility
			functions related to inventory and dispensing transactions are disabled to prevent changes. A robust backup process is used to ensure retrieval is always available. Refer to the Information Security Policy.	
11.10 (d)	Limiting system access to authorized individuals.	How an organization ensures that only the right people have access to each computer system. *Document how you grant access to Vestigo.*	McCreadie Group defines in our Information Security Policy granting of access to appropriate systems.	Client documents which users are granted access to Vestigo. Consult organizational / departmental Policy and Procedure.
11.10(e)	Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying.	How an organization ensures that a complete history of an electronic record is automatically captured by a computer system, retained in the system for the right amount of time, and viewable by humans.	Every action performed by Vestigo is written to the log which records each action, when it occurred and who made the user was. These records are fully timestamped and cannot be edited.	Clients can only enter and update information through the user interface and do not have access to the database.

21 CFR Part 11 Reference	Description	Interpretation	McCreadie Group / Vestigo Responsibility	Client Responsibility
11.10 (g)	Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.	How an organization limits user access (system level and record level) and verifies that the users performing functions in the system are authorized to do so. *Document what roles and permissions are appropriate for that user.*	McCreadie Group defines in our Information Security Policy granting of access to appropriate systems.	Client documents which users' roles are available and how users are assigned those roles. Vestigo Report "Report of all Users and Roles" and "Security Objects for Roles" can be used for supporting documentation.
11.10 (h)	Use of device (e.g., terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction.	How an organization verifies that equipment being used for regulated purposes is functioning properly.	The system uses field-level validation and workflows to ensure the validity of the input data. Vestigo is always run over HTTPS thereby removing the possibility for a third party to modify data being transmitted.	N/A
11.10 (i)	Determination that persons who develop, maintain, or use electronic record/electronic signature systems have the education, training, and experience to perform their assigned tasks.	How an organization makes sure, only trained and qualified people perform functions on or within the system. *Document that users of Vestigo know how to use the system.*	N/A	Client documents that users are trained on Vestigo. Refer to organizational / departmental policy and procedure
11.10 (j)	The establishment of, and adherence to, written	How an organization holds	McCreadie Group defines in our Information	Document that users know not to share

21 CFR Part 11 Reference	Description	Interpretation	McCreadie Group / Vestigo Responsibility	Client Responsibility
	policies that hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature falsification.	individuals accountable for the integrity of their actions related to electronic records and electronic signature. *Document that users know not to share username and passwords and logging off/locking station when leaving. This may part of an existing organizational policy.*	Security Policy how users are not to share login credentials as well as defining actions if violated.	username and passwords and logging off/locking station when leaving. This may be part of an existing organizational policy.
11.10 (k) (1) & (k) (2)	11.10 (k): Use of appropriate controls overs systems documentation including: (1) adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance; and (2) revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation.	How an organization control documents related to system operation and maintenance and preserves the complete history of changes made to these documents.	McCreadie Group documentation related to Part 11 is stored in a protected McCreadie Group drive and documents are electronically signed with certified software.	N/A
11.50 (a)	Signed electronic records shall contain information associated with the signing that clearly indicates all of the	Any time an electronic record is signed, the following information must be visible and associated with the	The records record the username of the logged in user and a date/time the signature was	N/A

21 CFR Part 11 Reference	Description	Interpretation	McCreadie Group / Vestigo Responsibility	Client Responsibility
	following (1) the printed name of the signer; (2) the date and time when the signature was executed; (3) the meaning (such as review, approval, responsibility, or authorship) associated with the signature; and (4) the items identified in paragraphs (a)(1), (a)(2), and (a)(3) of this section shall be subject to the same controls as for electronic records and shall be included as part of any human readable form of the electronic record (such as electronic display or printout).	signature: • Printed name of signer • Date and time of signature • Meaning of signature (e.g., content is accurate, format is correct, data calculations were verified).	executed. The date/time are set on the server and the user has no ability to modify. The meaning of the signature is based on the role of the user. The meaning of the electronic signature is available on the electronic display when a user verifies and approves a dispense transaction.	
11.50 (b)	The system shall ensure the three signature elements (described in the previous requirement) of a signed electronic record are a part of any human readable form of the electronic record (e.g. electronic display or printout).	All records are presented in human readable format.	All items are included in the human readable forms.	N/A
11.70	Electronic signatures and handwritten signatures executed to electronic records shall be linked to their respective electronic records to	Any kind of signature (ink or electronic) executed to an electronic record must remain connected to that record	Records cannot be changed without an audit trail and the record creator cannot be removed.	Records cannot be changed without an audit trail and the record creator cannot be removed.

21 CFR Part 11 Reference	Description	Interpretation	McCreadie Group / Vestigo Responsibility	Client Responsibility
	ensure that the signatures cannot be excised, copied, or otherwise transferred to falsify an electronic record by ordinary means.	forever. It can't be removed, covered over, erased, transferred, etc.		
11.100 (a)	Each electronic signature shall be unique to one individual and shall not be reused by, or reassigned to, anyone else.	Vestigo does not allow users to have the same username *but it be good to document that in your SOP or refer to organizational policy.*	Vestigo by design does not permit a username to be duplicated or re-used.	Clients can refer to Vestigo functionality for proof.
11.100 (b)	Before an organization establishes, assigns, certifies, or otherwise sanctions an individual's electronic signature, or any element of such electronic signature, the organization shall verify the identity of the individual.	Before someone can use an electronic signature, his/her identity must be verified. *Document how you grant access to Vestigo to ensure the correct person has been granted access.*	N/A	Clients document how access is to Vestigo to ensure the correct person has been granted access.
11.100(c)	Persons using electronic signatures shall, prior to or at the time of such use, certify to the agency that the electronic signatures in their system, used on or after August 20, 1997, are intended to be the legally binding equivalent of traditional handwritten signatures.	Before an organization implements electronic signatures, it must notify the FDA of its intention and state that it will consider electronic signatures to be as legally binding as ink signatures.	McCreadie Group has submitted a letter to agency.	Per client organization policy and guidance.

21 CFR Part 11 Reference	Description	Interpretation	McCreadie Group / Vestigo Responsibility	Client Responsibility
11.200(a) (1)	(a)(1): Electronic signatures that are not based upon biometrics shall (i) employ at least two distinct identification components such as an identification code and password (ii) when an individual executes a series of signings during a single, continuous period of controlled system access, the first signing shall be executed using all electronic signature components; subsequent signings shall be executed using at least one electronic signature component that only executable by, and designed to be used only by, the individual.	The first time a user signs a record after logging into a system, the system must require them to enter ALL of the parts of their signature (i.e., user ID and password). Subsequent signings during that same session only require the use of ONE part (i.e., password). • Each time a user logs out and logs back in (or gets timed out by the system), the clock restarts and the first record signed after logging in must require ALL parts of the signature.	Vestigo employs username and password protection for all functions. Users must login to Vestigo for all sessions. Vestigo employs functionality available at the client-setting to require electronic signature when verifying a dispense. Users with verification permissions may enter authentic credentials at the time of approving the prescription dispense. Vestigo supports both biometric authentication factors and a unique pin designed by the individual.	Clients may use SSO solution to login into Vestigo or use Vestigo Credentials. Client may utilize functionality requiring electronic signature when verifying a Dispense. Users may create and employ a unique pin number or biometric scan when applying an E-signature.
11.200(a) (2)	Be used only by their genuine owners.	Electronic signatures can only be used by the individuals to whom they are assigned. *Reference previous SOP on not sharing usernames and desktop security.*	N/A	Reference previous SOP on not sharing usernames and desktop security

21 CFR Part 11 Reference	Description	Interpretation	McCreadie Group / Vestigo Responsibility	Client Responsibility
11.200(a) (3)	Electronic signatures that are not based upon biometrics shall be administered and executed to ensure that the attempted use of an individual's electronic signature by anyone other than its genuine owner requires collaboration of two or more individuals.	Electronic signatures can only be used by the individuals to whom they are assigned.	Per policy all user logins have username and password that shall not be shared.	Per Organizational Policy.
11.300(a)	Persons who use electronic signatures based upon use of identification codes in combination with passwords shall employ controls to ensure their security and integrity. Such controls shall include maintaining the uniqueness of each combined identification code and password, such that no two individuals have the same combination of identification and password.	No two users can have the same combination of user ID and password – each combination must be unique – and each user ID can only be assigned to one individual, ever (no re-use allowed).	The system will not allow duplication. Hashing is used to maintain integrity without storing actual information unencrypted.	Organization policy to prohibit duplicate usernames.
11.300(b)	Ensuring that identification code and password issuances are periodically checked, recalled, or revised (e.g., to cover such events as password aging).	Passwords must be checked, recalled, or changed from time to time. *If your site is integrated with your AD service (SAML) then this is handled with that policy. If you use*	N/A	For clients that are integrated with their AD service (SAML) then this is handled by organizational policy. Reference that policy.

21 CFR Part 11 Reference	Description	Interpretation	McCreadie Group / Vestigo Responsibility	Client Responsibility
		Vestigo Authentication, see the security section to set the recheck dates accordingly.		Client who use Vestigo for authentication can reference security section to set the recheck dates and password history accordingly that correspond with organizational policy.
11.300(c)	Following loss management procedures to electronically de-authorize lost, stolen, missing, or otherwise potentially compromised tokens, cards, and other devices that can bear or generate identification code of password information, and to issue temporary or permanent replacements using suitable, rigorous controls.	If a passcode token/device is lost or stolen, it must be deauthorized and a secure replacement must be issued.	N/A	N/A
11.300(d)	Use of transaction safeguards to prevent unauthorized use of passwords and/or identification codes, and to detect and report in an immediate and urgent manner any attempts at their unauthorized use to	Unauthorized attempts to access user IDs or passwords/passcodes must be detected and reported to the appropriate person/group in the organization for investigation.	All failed attempts to log in are recorded in logs and available for viewing for administrators.	Vestigo reports are available for monitoring.

21 CFR Part 11 Reference	Description	Interpretation	McCreadie Group / Vestigo Responsibility	Client Responsibility
	the system security unit, and, as appropriate, to organizational management.			
11.300(e)	Initial and periodic testing of devices, such as tokens or cards, that bear or generate identification code or password information to ensure that they function properly and have not been altered in an unauthorized manner.	Passcode tokens must be tested before they are issued for use and periodically while in use to make sure they're functioning correctly.	N/A	N/A

Section B – Sample Validation Plan

If your organization has its own validation plan you should use it, if not, we have provided a sample Validation Plan below for your use. The suggested validation path is to validate the creation of the accountability log (DARF) that confirms that the inventory received and dispensed is appropriately reported on the DARF.

Sections that are highlighted in yellow indicate client specific information that should be inserted.

Description of the System

Vestigo is a Software as a Solution (SaaS) product created and maintained by the McCreadie Group and offered as a web-based solution. Our instance of Vestigo is <https://xxxxxxx.vestigo.biz>

Environment Specifications

Vestigo is a web-based solution hosted by the McCreadie Group. As such, only a modern web browser is required to use it. The system is configured with SAML 2.0 authentication to the <Insert Client Name> AD and all users shall authenticate with their <Insert Client Name> credentials. OR the system is configured utilizing Vestigo/Okta authentication and users shall authenticate with their Vestigo specific credentials.

Assumptions, Limitations and Testing/Acceptance Criteria

The software is only available as a SaaS offering from McCreadie Group. The <Insert Client Name> has no access to the underlying infrastructure or code and thus will only be able to test end user functionality as a subscriber. The <Insert Client Name> may contract for a test instance due to organizational requirements.

The testing criteria will be to conduct tests of only the used functions in the software using test cases that mirror how the <Insert Client Name> intends to use the software for inventory management. The testing specifically excludes other product functionality that is not used by the <Insert Client Name>.

The software will be accepted if all the tests pass, and it is determined that the software meets the requirements listed.

FOR SITES USING SINGLE SIGN ON FOR VESTIGO AUTHENTICATION (SSO)

Please refer to your institution's SOPs regarding SSO Authentication. If someone no longer needs access to Vestigo but is still employed, you will want to inactivate access to Vestigo and have in your policy they will no longer have access to the software.

Validation User/Team and Responsibilities

This validation is being performed by XXXXXXXXX. Their responsibilities are to ensure that Vestigo meets the test cases presented and will work to provide inventory management for the <Insert Client Name>.

Functional Requirements

The software must do the following as inventory management solution:

1. Create User and Inactivate User
2. User creates a PIN to use for e-signature
3. Allow users to create a protocol with a specific drug
4. Allow inventory to be received for the specific drug
5. Allow inventory to be dispensed against a specific inventory item
6. Allow inventory drug return to be documented and destroyed
7. Create a Drug Accountability Report Form (DARF)

8. Protocol edits are recorded to the audit trail

Validation Plan and Test Specifications

Validation Protocol/Test Plan

The objectives of this test plan are to ensure that the system functions correctly for inventory management. The scope will be limited to only the features used by the <Insert Client Name> and not all product features. These features are outlined in the Test Cases below.

The system will be tested using Vestigo on a test protocol test case(s) that mirror the intended use of the service in Production.

Test Cases/Requirements Traceability Matrix - EXAMPLE

1. Test Case 1 – Create user and inactivate user

   The tester will create a user. Assign the new user the appropriate role for credentials. Ensure the user receives credentials and can access the system and then once the user is inactivated the user cannot access the system. **If site is on SSO, please refer to your current SOPs or IT Security for guidance.**

2. Test Case 2- New user creates a PIN to use for e-signature

   The tester will create a pin under user account to use on dispense and dispense verification requiring an e-signature.

3. Test Case 3 – Allow users to create a protocol with a specific drug

   The tester will build a protocol with a drug to a test protocol <insert protocol name/number>. If the user can create a protocol drug, the test is successful.

4. Test Case 4 – Allow inventory to be received for the specific drug

   The tester will receive inventory against the protocol drug added in test case 1. If the inventory is received accurately as entered, the test is successful.

5. Test Case 5 – Allow inventory to be dispensed against a specific inventory item

   The tester will dispense the inventory received in test case 2 against a patient on the test protocol. User will use the pin created in test case 2 to apply e-signature on dispense and dispense verification. If the dispense is captured successfully, the test is successful.

6. Test Case 6- Allow inventory drug return to be documented and destroyed

   The tester will record an inventory drug return against the dispense in test case 4. When entering the inventory return, the user will destroy the inventory. If the return and destruction were captured successfully, the test is successful.

7. Test Case 7 – Create a Drug Accountability Report Form (DARF)

   The tester will generate a DARF using the <insert DARF name>. If the DARF is generated and the data entered previously is displayed correctly, the test is successful.

8. Test Case 8 – Protocol edits are recorded to the audit trail.

   The tester will ensure protocol edits are recorded to the audit trail. If the audit trail shows edits in the log for the protocol, the test is successful.

Test Results

Provide screen shots or other appropriate documentation as proof.

1. Test Case 1 – Create and Inactivate User
   Test Outcome: PASSED
2. Test Case 2- User creates PIN number
   Test Outcome: PASSED
3. Test Case 3 – Allow users to create a protocol with a specific drug
   Test Outcome: PASSED
4. Test Case 4– Allow inventory to be create for the specific drug
   Test Outcome: PASSED
5. Test Case 5 – Allow inventory to be dispensed against a specific inventory item
   Test Outcome: PASSED
6. Test Case 6- Allow inventory drug return to be documented and destroyed
   Test Outcome: PASSED
7. Test Case 7 – Create a Drug Accountability Report Form (DARF)
   Test Outcome: PASSED
8. Test Case 8 – Protocol edits are recorded to the audit trail
   Test Outcome: PASSED

Validation Report

The product was tested against the following functional requirements and all tests passed without deviation.

1. Create user and inactivate user
2. User creates a PIN number
3. Allow users to create a protocol with a specific drug
4. Allow inventory to be received for the specific drug
5. Allow inventory to be dispensed against a specific inventory item
6. Allow inventory drug return to be documented and destroyed
7. Create a Drug Accountability Report Form (DARF)
8. Ensure edits are recorded to the protocol audit trail

Signature:_____Date:_____

Section C – Sample Regression Testing Plan

This is an example of regression test steps that outline the basic Vestigo functionality of transactions that are displayed on the DARF.

The following steps will take you through Vestigo and assist in completing the various functions. Complete all sections as indicated in these steps.

SAML/SSO Login

1. Login using site provided credentials.
2. Select a facility, if available.

Vestigo Login Credentials (if not using SAML/SSO)

1. Login using provided credentials.
2. Select a facility, if available.
3. Use my account to change your password.

Add Protocol

1. Select the Add New link on the Home page.
2. Select the Clinical Trials link at the bottom.
3. Search for a study.
4. Locate the NCT number.
5. Copy the NCT Number into the NCT field on Vestigo.
6. Click Search.
7. The study information should display on the next screen.
8. Click “Select” to the left of the study title.
9. If you have a CTMS interface, you will see any matches in your local CTMS. Click Skip Step.
10. On the next tab, the facility should be pre-selected as the facility you are logged into.
11. Enter a site number.
12. Select “Next.”

Main Tab

1. You will be automatically directed to the Main screen of the protocol. These fields will be filled in by data from Clinical Trials.
2. Edit the “Vestigo Protocol Number” field and add in a new number or add onto the number there.
3. Select “Add Protocol Identifier.”
    - 3.1 From the “Name” dropdown, select “Vestigo SecondID.”
    - 3.2 In the Identifier field, enter an identifier.
    - 3.3 Leave the “Protocol (NCI) Order on DARF” and “Protocol (Local) Order on DARF” as is.
    - 3.4 Select Save.
4. For Overall Status Code, set this Enrolling by Invitation or Recruiting.
5. Leave all other fields as is.
6. Select Save at the bottom of the screen.

Local Tab

1. At the top of the screen, select the “Add Facility” link.
2. In the “Protocol is available at these facilities” select a facility other than the one selected as Main Facility.

3. Toggle to Remote Facility Type.
4. Save.
5. Skip over Protocol Group and Binder Location, as these are optional fields.
6. Select dropdown for Protocol Sponsor Type – Industry.
7. Track IRB? Select Yes.
    7.1 Enter an IRB Number.
    7.2 IRB Status: toggle to Active.
    7.3 IRB Expiration: enter an expiration date.
8. Skip Miscellaneous 1 and 2.
9. Choose no for "Protocol Requires Inventory Tracking by Ordering Investigator".
10. Skip Patient Study Number Instructions, Randomization Instructions and Inventory Instructions. Leave these fields blank.
11. Select Save at the bottom of the screen.

Contacts Tab

1. Select Add New.
2. Find yourself in the drop-down.
3. In the role drop-down, select Primary Investigator.
4. Select Submit at the bottom.

Checklists Tab

There is nothing to test on this tab.

Budgets Tab

There is nothing to test on this tab.

Billing Tab

There is nothing to test on this tab.

Workload Tab

There is nothing to test on this tab.

Arms Tab

1. Select the Add New link.
2. Enter "Open Label" in Arm Description.
3. Save.

Drugs/Orders tab

1. In the Drugs section, Select Add New.
    1.1 For the Drug Description, enter a drug name.
    1.2 Skip Generic Name.
    1.3 In the Inventory Units field, select an inventory unit.
    1.4 For Drug Strength and Units, enter just a number in the Strength field and any unit in the Units field.
    1.5 In DAR Dose Form/Strength, enter the same number and unit as you did in 1.4.
    1.6 Drug Schedule, leave as is, Non-Controlled (default).
    1.7 Source, IDS (default).
    1.8 Inventory Tracking, Full (default).
    1.9 Select drop down for Drug Storage Requirements, select a type.
    1.10 Select drop down for Control Inventory Location, select a testing location.

a. If one does not exist, we recommend creating one for testing only.

1.11 For Receiving Location, leave as is, will default same location.
1.12 Skip Cycle Count Interval (Days).
1.13 For Temperature Excursion Action, select No Action (leave next box field empty).
1.14 Select drop down for Default Supplier, select any supplier.
1.15 Select drop down for Default Manufacturer, select any manufacturer.
1.16 Select a Default DARF, IDS.
1.17 Skip remaining fields.

2. Select Save at the bottom. In the Orders section, select Add New.
   2.1 In the Order Description, enter the same as the Drug Description.
   2.2 Skip Order Master Code.
   2.3 For Order Type, select Medication (default).
   2.4 Order Items, the drug built in section 1 should be defaulted.
   2.5 Select Add.
   2.6 Leave the Label Name as it defaults.
   2.7 Skip Patient Schedule Type.
   2.8 For Order Unit, select the same unit as the inventory unit.
   2.9 For Route, select anything.
   2.10 Add text to the Directions box.
   2.11 Add text to the Special Instructions box.
   2.12 Drug Expiration – Select default "Actual Drug Expiration."
   2.13 Double Check – leave un-checked.
   2.14 Thaw Time Required – leave un-checked.
   2.15 Preparation Time Required – leave un-checked.
   2.16 Requires Inventory Validation – leave un-checked. *This is only visible with Barcode Validation.*
   2.17 Patient Return Required – leave un-checked.
   2.18 Order is available in these arms, check the arm(s).
   2.19 Default Label – Dispensing label 2x4 (default).
   2.20 Barcode for Label – leave blank.
   2.21 Skip Dispensing Workload
   2.22 Track Cost – Leave un-checked.
   2.23 Select "Add New Dispense Fee."
      a. Select any fee dispensing fee from the drop down menu
      b. For account, leave as Do Not Bill.
      c. Leave toggled to On Dispense
      d. Select Save for fee
   2.24 Skip Default Workflow. *This is only visible with Chain of Custody.*
   2.25 Select Submit Order.

Protocol Documents (Have a sample document saved for this validation)

1. In the "Protocol Information" section, select "Add New."
2. Make sure checkboxes for Visible to Monitor and Visible on Protocol are checked.
3. Drag and Drop the sample document into the section.

You do not have to complete the remaining tabs of the Protocol Build. Now select "Back to Protocol Snapshot" to exit the build of the study.

Receive Inventory

1. Select Inventory Tab.

2. Select Receive Inventory.
3. Select Add New.
4. On the next screen, Service Date and Facility will be preselected, leave as is.
5. Leave other fields blank.
6. Select Next.
7. On the next screen, the drug created from previous steps should be defaulted.
8. Inventory type “Add New Inventory” will be preselected.
9. Enter a Lot Number.
10. Leave Item Number box blank.
11. For Quantity of Each, enter 2.
12. For Expiration, add an expiration date.
13. Leave all other fields as is.
14. Select Save.
15. Select Next at the bottom of the screen.
16. Select Next on Billing and Workload tab.
17. Select Complete Receipt.

To continue testing, select “Back to Protocol Snapshot.”

Enroll New Patient

1. Select Patient/Subjects Tab from protocol snapshot.
2. Select Enroll New Patient/Subject.
3. Select Name Search.
4. Select Add New.
5. Select the “Generate” a Vestigo MRN link.
6. In the first name text box enter a test subject name of your choice.
7. In the Last Name text box enter a test subject last name of your choice.
8. Skip Middle Name and Suffix.
9. In Gender, choose Unknown.
10. For Date of Birth, enter a DOB of your choice, example 01/01/2000.
11. Select Save Patient (Quick Add).
12. Enrollment Arm, select the arm from the dropdown.
13. Enter a Patient Study Number – Test01.
14. Leave all fields with the default values.
15. Select Enroll.

Dispense

1. Select Patient/Subjects Tab from protocol snapshot.
2. Select the MedRecNum (this will be the generated Vestigo MRN)
3. Select Add New Prescription.
4. Select the order description from the drop down.
5. Select the link “Select Inventory To Be Used.”
6. Enter in the Dose Amount field enter 1.
7. Leave Dose Unit as is.
8. Enter in the Dispensed Qty field, enter 1.
9. Select Next.
10. Leave all fields with their default values.
11. For Number of Labels, make sure all fields say 1.
12. Select Save.

12.1 If your site utilizes E-Signature, enter your pin.

Returns

1. From step 12 of previous section, scroll down and select “Return to Subject’s Profile.”
2. On the patient’s profile, select the link for “Record a Patient Drug Return.”
3. In the dropdown, select the top Rx. This will be the dispense you just did.
4. Select the Add New Return.
5. Do not adjust Return Date.
6. For Return Quantity, enter 1.
7. Skip Used and Missing Quantity
8. Skip Return Log comments
9. For disposition, select “Send to returns for later review and processing.”
10. Select Save Return.
11. You will be automatically navigated back to the Patient Profile.

Generate DARF

1. On the Inventory tab of protocol snapshot, select “Drug Accountability Records.”
2. Select the drug from the dropdown.
3. The Form should be preselected to IDS.
4. Check Include Subject and Inventory Returns.
5. Select Generate Accountability Record at the bottom.
6. The PDF DARF should download, select to Open.
7. Review DARF, make sure the receive, dispense, and return are listed correctly.
8. Return to Vestigo tab.
9. Select Close on the DARF pop out window.

Download Protocol Document

1. Navigate to the Protocol Documents tab.
2. In the Protocol Information section, select Download next to the document title to view the document you previously uploaded.
3. Verify the document was downloaded.
4. Close document and return to Vestigo.
5. On the protocol documents tab, click on Manage
6. Delete the file you uploaded previously by clicking the delete link and confirming the deletion.

Temperature Documents tab

1. Based on the inventory location you received the inventory to; you should see a temperature document on the tab.
    1.1 If you do not have a document, it is recommended to add one to the test inventory location.
2. Select Download.
3. Verify the document was downloaded.
4. Close document and return to Vestigo.

To continue testing, select the Protocol tab and then select the Inventory tab.

Adjust Inventory

1. Click the Adjust Inventory link on the Inventory tab.
2. Select the Drug from the Drug drop down.

3. Leave the “Only Show Inventory with a QOH > 0” checked.
4. Leave “Single Adjust” as the selection.
5. Select the remaining inventory in Inventory drop down.
6. For the Quantity, indicate a decrease of 1 in the field.
7. Leave the service date as default values.
8. In the Adjustment Reason dropdown, select Other.
9. Select the disposition “Send to Quarantine for later review and processing.”
10. Leave all other fields as default values.
11. Click Submit.

To continue testing, select the “Return to Protocol Snapshot” link.

Generate DARF (2nd time)

1. On the Inventory tab of protocol snapshot, select “Drug Accountability Records.”
2. Select the drug from the dropdown.
3. The Form should be preselected to IDS.
4. Check the box to include subject and inventory returns.
5. Select Generate Accountability Record at the bottom.
6. The PDF DARF should download, select to Open.
7. Review DARF to make sure the adjust shows.
8. Return to Vestigo tab.
9. Select Close on the DARF pop out window.

Audit Trail

1. On the Protocol Snapshot, click View Audit Trail.
2. Search with 21CFRPart11 Only checked.
    2.1 The audit trail must display a single change as specified by 21 CFR Part 11. This change will be an update to the protocol number.
3. Rerun the search with 21CFRPart11 Only unchecked.
    3.1 The audit trail should display eight records relating to:
        a. Protocol Number
        b. Protocol Sponsor Type
        c. IsIRBTracked
        d. IRBExpirationDate
        e. IRB Status
        f. Requires Inventory Tracking by Ordering Investigator
        g. Overall Status

Section D - Checklist to Validate a Protocol in Vestigo

Protocol#/IRB: _____ Built by: _____ Validated by _____

	Review and check for accuracy: - Main page - Local page - Contacts - Billing/Budget (if using) - Arms	Validated by _____
EACH DRUG	- Drug description & generic name - Inventory Units - Drug Strength & Units - DAR Dose Form/Strength - DAR Bottle Size - Drug Schedule - Supplier Code - Source - Hazardous Category Assessment - Default NDC - Inventory tracking - Drug Storage requirements - Control Inventory Location	- Receiving Location - Cycle Count Interval - Temperature Excursion Action and comments - Default Supplier/Manufacturer - Default DARF - Reorder type - Ordering instructions - Destruction instructions - Destruction and Return Requirements - Drug Comments - Required Verifications Validated by _____
EACH ORDER	- Order Description - Order Type - Order Items - Label Name - Ensure match for active & placebo drug in double-blind studies - Patient Schedule Type - Dosing Weight Required - Order Units - Default Dose Description - Route - Blinding - Directions - Special Instructions - Accountability Log Comments	- Drug Expiration - Double Check - Thaw Time Required - Preparation Time Required - Requires Inventory Validation (if applicable) - Patient Return Required - Arms - Default Label - Bar Code for Label - Dispensing Workload - Track Cost Impact Dispensing Fee - Default Workflow (if applicable) Validated by _____

Section E – Vestigo Training Checklist

This checklist can provide a document to demonstrate which functionality a specific user has completed and provides a place for sign off.

Pass	FUNCTION/MODULE
	Access to Vestigo & Main Page
	How to login
	Forgot password
	Overview of the home screen – menus, alert pain, protocol search, most recent list
	Main Menu
	My Account – default facility, change password, manage/view competencies/set up
	PIN for E-Signature
	Help and Support
	Vestigo Help Center – Contacting Support, user manuals, ongoing classes
	Vestigo Verify Help Center
	Application Administration – if applicable
	Client & Facility Settings
	Adding user accounts and assigning roles
	Manage roles & permissions
	Internal reviewers / protocol-specific user access
	Security settings
	Audit reports
	Add New Protocol
	Create Protocol – NCT# and search terms, process to add new protocol
	Link to clinicaltrials.gov
	Main Protocol Tab – Overview
	Protocol Identifiers – adding and display on DARF
	Protocol Summary
	Blinded Study flag
	Local Tab
	Adding additional facilities on the protocol if needed

Pass	FUNCTION/MODULE
	Protocol details
	IRB Tracking
	Protocol Settings – remove patient initials from DARF
	Require Shipment Receipt Verification for all drug builds
	Track Inventory by Ordering Investigator
	PSN Entry instruction field
	Randomization instruction field
	Inventory instruction field
	Contacts Tab – Overview
	Adding new contact from Address book
	Add new contact to the Address Book
	Add Contacts in Bulk
	Start and Stop Dates
	Checklists Tab – General Overview
	Budget Tab – General Overview
	Billing Tab – General Overview
	Workload Tab – General Overview
	Arms Tab
	Drugs/Orders Tab
	Drug Build – associated fields to inventory tab and DARF
	Order Build – associated fields to Prescription Details
	Copy as New process
	Access Codes
	Reports Tab – Overview
	Protocol Snapshot
	Binder Coversheet
	Print Protocol Label
	Edit Protocol
	Close Out Protocol
	View Audit Trail
	Inventory Tab

Pass	FUNCTION/MODULE
	Receive Inventory
	View/Edit Inventory
	Add DARF Note
	Adjust Inventory
	Immediate Transfer
	Send out Inventory
	Cycle Count
	Generate Drug Accountability Records – review different formats
	Par and Reorder Points
	Manage Drug Returns
	Items in Patient Returns
	Items in Quarantine
	Items already destroyed
	Items returned to sponsor
	Generating a Certificate of Destruction
	Record a Witness for Destruction
	Return Report
	Patient/Subject Enrollment
	Enrolling a New Patients
	Inactivate Patients (unenroll)
	Generate Vestigo MRN#
	Dispensing
	Edit RX
	Void RX
	Copy RX
	Refill RX
	Patient Visits
	Process Returns (from within patient profile)
	Billing
	Generate Ad-Hoc Charges
	Edit/View Charges

Pass	FUNCTION/MODULE
	Protocol Documents – Overview
	Transaction Documents - Overview
	Temperature Documents - Overview
	Document Management
	Upload document via drag and drop
	Create a document
	Edit a document
	Certify a document
	Visibility Settings
	Competency Access - Overview
	Monitor Visits Tab
	Adding new monitor
	Schedule monitor visit
	Reviewing past monitor visit details
	Reports
	Protocol Reports
	Inventory Reports
	Prescription Reports
	Workload Reports
	Application Administration – User Workload
	Address Book
	Inventory Management
	Cycle Count by location – relates to Inventory by Location (Cycle Count) Report
	Drug Search
	Inventory SendOut (Multiple Protocols) – if applicable
	Shipment Receive Search – uploading shipping receipts
	Temperature Excursion
	Temperature Documents
	Protocol Management
	Competency Management
	Facility Documents

Pass	FUNCTION/MODULE
	Manage Templates (Checklist, Workload and general Vestigo)
	Monitor Visits
	Vestigo Verify - Overview
	Process Returns (bulk by RX#)
	Search Subjects & Prescriptions
	Calendar
	User Forum
	Billing Management - if applicable
	Accounts
	Manage Fees
	Billing Reports
	Billing Set up
	Record Bulk Payment
	Manage Billing Account Types
	Bulk Charge Upload
	Billing Cycle Count
	Billing Portal

The training record should include a section for the trainee's name, as well as a validation block for the signature and date of both the trainee and the person verifying the completion of the training.

User Completing Training:_____Date:_____

Supervisor/Manager:_____Date:_____