

## Vestigo and Vestigo Verify Version 5.5 Release Notes

**Expected Release Date:** November 16, 2023

Please view the recording of our [Vestigo Version 5.5 Webinar](#) on the Vestigo Help Center.

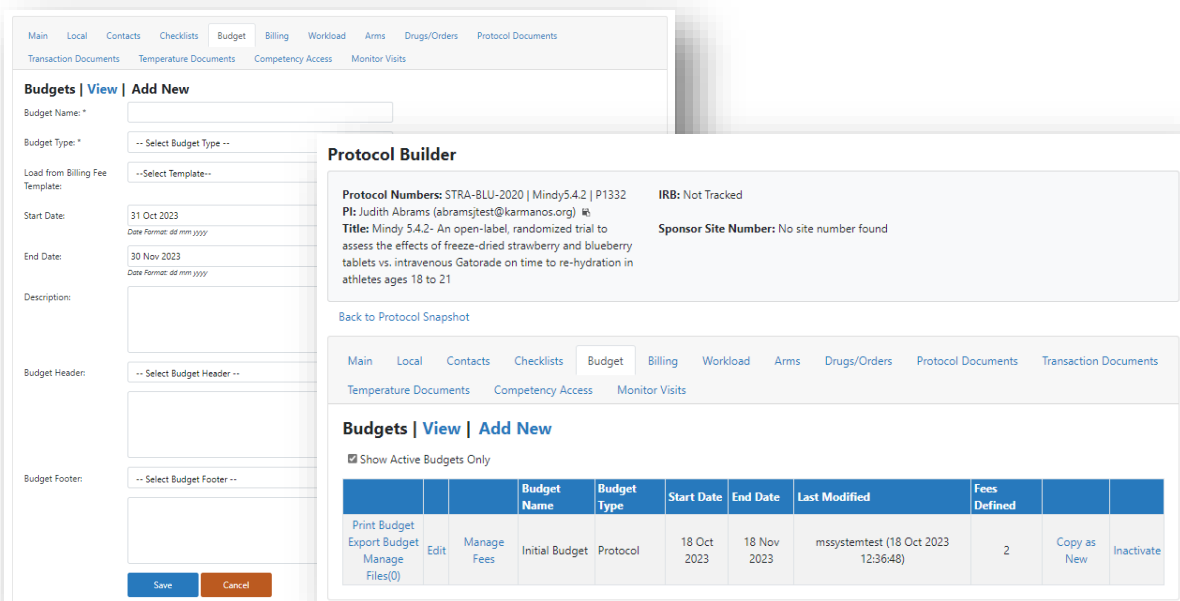
### Project Management

The 5.5 Vestigo Release includes project management features designed to save time and increase visibility by allowing you to track protocol processes within Vestigo that are currently being managed outside of Vestigo. It will also include an update to the protocol close-out process to ensure clarity and prevent errors.

### PROTOCOL BUDGETS

Sites will be able to create and download a Vestigo Protocol Budget for initial and amended budgets.

The Budget functionality will walk users through the process, adding a Vestigo Billing Templates or manually selecting fees, incorporating fee descriptions, dates for the negotiated budget, and other site and study details.



The screenshot displays the 'Protocol Builder' interface within the Vestigo application. The left sidebar shows navigation tabs: Main, Local, Contacts, Checklists, Budget, Billing, Workload, Arms, Drugs/Orders, and Protocol Documents. The 'Budget' tab is active, showing a form for creating a new budget. The form includes fields for Budget Name, Budget Type, Load from Billing Fee Template, Start Date, End Date, Description, Budget Header, and Budget Footer. The right pane shows the 'Protocol Builder' details, including Protocol Numbers, PI, Title, and Sponsor Site Number. Below this, there is a 'Back to Protocol Snapshot' link and a table of active budgets.

| Budgets   View   Add New                                     |               |             |                |            |             |               |                                     |   |             |
|--------------------------------------------------------------|---------------|-------------|----------------|------------|-------------|---------------|-------------------------------------|---|-------------|
| <input checked="" type="checkbox"/> Show Active Budgets Only |               |             |                |            |             |               |                                     |   |             |
|                                                              |               | Budget Name | Budget Type    | Start Date | End Date    | Last Modified | Fees Defined                        |   |             |
| Print Budget                                                 | Export Budget | Manage Fees | Initial Budget | Protocol   | 18 Oct 2023 | 18 Nov 2023   | mssystemtest (18 Oct 2023 12:36:48) | 2 | Copy as New |
| Manage Files(0)                                              | Edit          |             |                |            |             |               |                                     |   | Inactivate  |

### PROTOCOL CHECKLIST

To capture workflow processes outside Vestigo, sites can create Vestigo Protocol Checklist for various activities like study start up, audit preparation, and close out. Users can attach documents and assign tasks to users. Users can document the completion of those tasks, entering a completion date and any comments, if appropriate.

### Protocol Builder

**Protocol Numbers:** STRA-BLU-2020 | Mindy5.4.2 | P1332  
**PI:** Judith Abrams (abrams@karnanos.org) |  
**Title:** Mindy 5.4.2 - An open-label, randomized trial to assess the effects of freeze-dried strawberry and blueberry tablets vs. intravenous Gatorade on time to re-hydration in athletes ages 18 to 21  
**IRB:** Not Tracked  
**Sponsor Site Number:** No site number found

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[Transaction Documents](#) | [Temperature Documents](#) | [Competency Access](#)

#### Checklists | View | Add New | Load from Template

A Checklist can be loaded by choosing Load from Template or Add New. Checklist Templates can be found and managed by facility within the Protocol Management dropdown.

Checklist steps can be added and managed within Application Administration: Edit Client and Facility Settings: Manage Checklist Steps.

When adding a step, the steps will be displayed in the order specified, and files can be attached or managed for each step.

☒ Show Active Checklists Only

|      |                 | Type              | Name          | Description            | Steps Complete | Last Modified | Modified by |            |
|------|-----------------|-------------------|---------------|------------------------|----------------|---------------|-------------|------------|
| Edit | Manage Steps(2) | Audit Preparation | Audit Oct2023 | Sponsor audit for 2023 | 1/2            |               |             | Inactivate |

#### Manage Steps | Add New

|      |                 | Checklist Type    | Step Name                           | Description                    | Assigned User | Due Date    | Completed Date | Display Order |        |
|------|-----------------|-------------------|-------------------------------------|--------------------------------|---------------|-------------|----------------|---------------|--------|
|      | Manage Files(0) | Audit Preparation | Alliance Audit Prep/check inventory | Steps for Alliance Audit Prep/ | Mindy System  | 31 Oct 2023 | 18 Oct 2023    | 1             |        |
| Edit | Manage Files(0) | Audit Preparation | Audit Prep Step 1                   |                                | Mindy Pharm   | 20 Oct 2023 |                | 1             | Delete |

Close

#### Select and enter the title and description for the checklist. The Type cannot be

Type:

Name:

Description:

Save Cancel

## UPDATED PROTOCOL CLOSE OUT WORKFLOW

The 5.5 release includes a more defined and interactive close out process. This updated workflow for closing a protocol with guide users through a detailed process that incorporates all aspects of the protocol that need to be tended to for best practices when closing a protocol.

Sites can apply a Protocol Vestigo Close Out Checklist to ensure completeness, capture close out fees, review, and process remaining inventory on hand, in quarantine and returns, unenroll patients, and manage billing accounts all wrapped up in a swift seven step wizard.

### Step 1 - Review Protocol Close Out Checklists

The following Protocol Close Out Checklists have been created for this protocol. Please review all steps have been completed as required. You can move to the next steps and complete the closeout while Checklists are incomplete, but the protocol must be reactivated to manage steps.

|      |                 | Type               | Name                     | Description                    | Steps Complete | Last Modified     | Modified by         |
|------|-----------------|--------------------|--------------------------|--------------------------------|----------------|-------------------|---------------------|
| Edit | Manage Steps(5) | Protocol Close Out | Close Out Test Checklist | Grant study close out workflow | 0/5            | 31 Oct 2023 16:31 | BarrieIDSPharmacist |

Next

Cancel

### Step 2 - Remaining Inventory for this Protocol

The protocol cannot be closed until inventory has been removed.

The following items requires verification, therefore the only selectable disposition will be send these items to quarantine:

|                          | Drug                                       | Location         | Lot Number | Item | NDC | Expiration  | Supplier                 | PSN | QOH |
|--------------------------|--------------------------------------------|------------------|------------|------|-----|-------------|--------------------------|-----|-----|
| <input type="checkbox"/> | Blueberry 50mg tablet (100 tablets/bottle) | IDS New Location | Y9372934   |      |     | 10 Oct 2034 | Fisher Clinical Services |     | 70  |

### Step 3 - Manage Outstanding Drug Returns

All Patient Returns and Items in Quarantine must be destroyed or returned to sponsor before proceeding. The Next button will be disabled until both Patient Returns and Items in Quarantine grids are empty.

☐ Patient Returns ☒ Items in Quarantine

### Step 4 - Patient Unenrollment

The following patients are still in active enrollment for this protocol. Please select "Edit Enrollment" to unenroll patients individually or select "Process Bulk Unenrollment" to manage all patients. Close Out Protocol cannot be completed if patients are actively enrolled.

Nothing Found

[Download patient enrollment history for this protocol](#)

Next

Cancel

### Step 5 - Pending Protocol Charges

Protocol Close-Out Fees | [Add New](#)

| Service Date                                          | Name                             | Amount | Account             | Comments |                                        |
|-------------------------------------------------------|----------------------------------|--------|---------------------|----------|----------------------------------------|
| 31 Oct 2023<br><small>Date Format: dd mm yyyy</small> | Cancer Center Industry Close Out | 300    | STRA-BLU-2020 P1535 |          | <input type="checkbox"/> Do Not Charge |

Save

### Step 6 - Protocol Billing Accounts

Billing Accounts for this Protocol

Inactivate Billing Accounts that will no longer be in use. Accounts can be re-activated under Billing Management.

|            | Account                                  | Account Number | Account Active? | Account Billable? |
|------------|------------------------------------------|----------------|-----------------|-------------------|
| Inactivate | <a href="#">View</a> STRA-BLU-2020 P1535 | #12345         | True            | True              |

Next

Cancel

### Step 7 - Confirmation

Clicking Save will close out this protocol.

[Drug Accountability Records](#)

Protocol Close Out Workload | [Add New](#)

| Service Date                                          | Category       | SubCategory      | Time Spent |                                        |
|-------------------------------------------------------|----------------|------------------|------------|----------------------------------------|
| 31 Oct 2023<br><small>Date Format: dd mm yyyy</small> | Protocol Close | Simple Close Out | 30         | <input type="checkbox"/> Do Not Record |

New Protocol Status:

Completed

Close-Out Comments:

Close-Out Service Date:

31 Oct 2023 12:58

Save

Cancel

## Verifications and Quality Control

The 5.5 release addresses the growing need for documentation of verifications for Shipment Receipts, Patient Returns and Quarantined inventory. The following optional settings will be available to the drug and order builds of a protocol when reminders and verifications are required.

Each of the new functionalities listed below will also include a complementary alert:

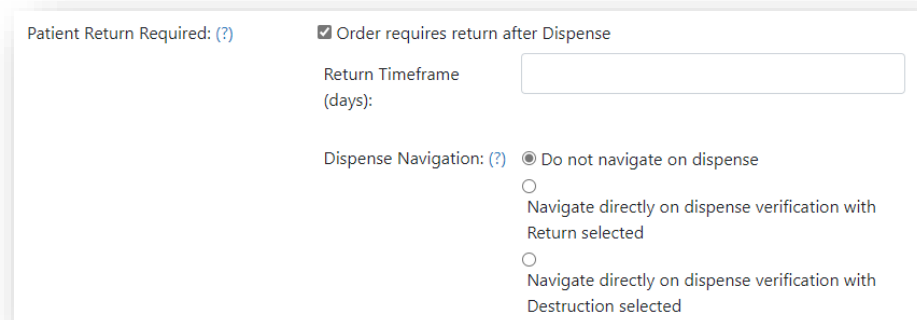
- There are Patient Drug Returns that are overdue.
- There are Patient Drug Returns needing verification.
- There are Items in Quarantine needing verification.
- There are Shipment Receipts needing verification.

### PATIENT DRUG RETURN REQUIREMENTS FOR PRESCRIPTIONS

There will be a new setting on the order build enabling sites to require a prescription return within a set number of days.

The version 5.5 release will also include a modification to the current “Automatic Destruction” option on the order build. The single option for destruction will be split into two options:

1. Navigate a verifying user to the prescription return screen defaulted to the disposition “Patient Returns.”
2. Navigate a verifying user to the prescription return screen defaulted to the disposition “Mark as Destroyed.”



The screenshot shows a settings dialog box titled "Patient Return Required: (?)". It contains the following options:

- ☒ Order requires return after Dispense
- Return Timeframe (days):
- Dispense Navigation: (?)
  - ☒ Do not navigate on dispense
  - ☐ Navigate directly on dispense verification with Return selected
  - ☐ Navigate directly on dispense verification with Destruction selected

### REQUIRING DRUG RETURN/QUARANTINE VERIFICATIONS

The drug build will have two new settings as well. These settings will require another user to verify prescription returns and inventory quarantines. There will also be an override option.

If a drug build is set to require prescription return verification, and the order build is set to navigate the verifying user to the prescription return screen defaulted to “Mark as Destroyed,” the prescription return will be defaulted to “Patient Returns” due to the requirement for the prescription return verification.

If these options on the drug build, all prescription returns, and quarantined inventory will need to be verified (or overridden) before that item is visible to the monitor to authorize for destruction or return to sponsor.

## Drug Returns

Return Service Date Range: 31 Mar 2023 through

Date Format: dd mm yyyy

☐ Patient Returns ☒ Items in Quarantine ☐ Items Already Destroyed ☐ Items Sent Back To Sponsor

Drugs can now be set to require a verification when entered as Patient Returns or Quarantine. Monitors same user who entered it, but that user can override the verification with provided security permissions.

### Items in Quarantine Requiring Verification

Action: ☒ Verify ☐ Override Verification

| #                        | Date        | Drug                                | Lot | Item | Return Qty |
|--------------------------|-------------|-------------------------------------|-----|------|------------|
| <input type="checkbox"/> | 20 Sep 2023 | Manago 75mg or Placebo Capsules (30 |     |      |            |
| <input type="checkbox"/> | 20 Sep 2023 |                                     |     |      |            |
| <input type="checkbox"/> | 20 Sep 2023 |                                     |     |      |            |

### Drug Returns

Return Service Date Range: 31 Mar 2023 through 31 Oct 2023

Filter Dates

Return Report

Date Format: dd mm yyyy

☒ Patient Returns ☐ Items in Quarantine ☐ Items Already Destroyed ☐ Items Sent Back To Sponsor

Drugs can now be set to require a verification when entered as Patient Returns or Quarantine. Monitors and Protocol-Specific Users will not see returns requiring verification in VestigoVerify until they have been verified by the same user who entered it, but that user can override the verification with provided security permissions.

### Patient Returns Requiring Verification

Action: ☒ Verify ☐ Override Verification

No returns found

Record Verification

Require Verification for Patient Returns: (?) ☒

Require Verification for Items in Quarantine: (?) ☒

## REQUIRING SHIPMENT RECEIPT VERIFICATIONS

Sites will be able to require shipment receipt verification (or override). This option will be available to set at the facility level, protocol level, and/or drug level. If a receipt requires additional verification, it must be done before completing the receipt. The shipment verification functionality will include self-verification and override options after a pre-determined time limit.

Shipment Receipt Verification: (?)

☒ Require verification on receipts that include this drug

Allow Self-Verification: (?)

☒ Allow users to self-verify shipment receipts that include this drug

Allow Self-Verification after 20 minutes of initial shipment entry.

### Inventory Requiring Shipment Receipt Verification

| Verify                   | Drug                                       | Lot #       | Item | Location     | NDC | Exp         | Supplier                 | Manufacturer | PSN      | Investigator Name  | Item Status | Qty Received | Override                 | Override Reason | Override Comments |
|--------------------------|--------------------------------------------|-------------|------|--------------|-----|-------------|--------------------------|--------------|----------|--------------------|-------------|--------------|--------------------------|-----------------|-------------------|
| <input type="checkbox"/> | Blueberry 50mg tablet (100 tablets/bottle) | E2392023344 | 77   | IDS BG Child |     | 25 Oct 2024 | Fisher Clinical Services | Abbot        | 1000-112 | Irene Investigator | Intact      | 30           | <input type="checkbox"/> |                 |                   |
| <input type="checkbox"/> | Blueberry 50mg tablet (100 tablets/bottle) | E2392023344 | 78   | IDS BG Child |     | 25 Oct 2024 | Fisher Clinical Services | Abbot        | 1000-112 | Irene Investigator | Intact      | 30           | <input type="checkbox"/> |                 |                   |

## Protocol Contacts: Start and Stop Dates

To align with NCI practices more clearly, we have updated our Protocol Contacts tab to include optional fields for start and stop date.

**Start Date:** The contact will be available for use in dropdowns on the date indicated as a start date.

**Stop Date:** The contact will become inactive on the study and no longer be available for selection on the date after the stop date entered.

**Protocol Builder**

Protocol Numbers: STRA-BLU-2020 | barrie 5.5 | P1526

PI: Ednas Allens, Mrs. (alledna1@gmail.coz)

Title: Barrie 5.5- An open-label, randomized trial to assess the effects of freeze-dried strawberry and blueberry tablets vs. intravenous Gatorade on time to re-hydration in athletes ages 18 to 21

IRB: Not Tracked

Sponsor Site Number: No site number found

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**Protocol Contacts** | [View](#) | [Add New](#) | [Select Contacts in Bulk](#)

☐ Show Active Contacts Only

|                      | Name                 | Role          | E-mail               | Phone              | Auth Prescriber? | NCI No. | NCI Exp. | Vestigo Access | Protocol-Specific Access | Start Date                | End Date |             |             |                            |
|----------------------|----------------------|---------------|----------------------|--------------------|------------------|---------|----------|----------------|--------------------------|---------------------------|----------|-------------|-------------|----------------------------|
| <a href="#">Edit</a> | <a href="#">View</a> | Allens, Ednas | Primary Investigator | alledna1@gmail.coz |                  |         |          | True           |                          | Vestigo Access (Inactive) | No       | 25 Oct 2023 | 31 Oct 2023 | <a href="#">Reactivate</a> |

**Protocol Builder**

Protocol Numbers: STRA-BLU-2020 | barrie 5.5 | P1526

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**Protocol Contacts** | [View](#) | [Add New](#) | [Select Contacts in Bulk](#)

☐ Show Active Contacts Only

|                      | Name                 | Role          | E-mail               | Phone              | Auth Prescriber? | NCI No. | NCI Exp. | Vestigo Access | Protocol-Specific Access | Start Date                | End Date |             |
|----------------------|----------------------|---------------|----------------------|--------------------|------------------|---------|----------|----------------|--------------------------|---------------------------|----------|-------------|
| <a href="#">Edit</a> | <a href="#">View</a> | Allens, Ednas | Primary Investigator | alledna1@gmail.coz |                  |         |          | True           |                          | Vestigo Access (Inactive) | No       | 25 Oct 2023 |

Select Contact | Add a New Contact to System

Ednas Allens Mrs.

Role in this Protocol

Primary Investigator

Authorized Prescriber?

☒ True ☐ False

Start Date: 25 Oct 2023 End Date: 31 Oct 2023

[Save](#) [Cancel](#)

When an end date is added, the contact will become an inactive contact on the protocol after that date. If the contact has a Protocol-Specific User account, their access to this protocol will end after the end date.

## START AND STOP DATE ON PROTOCOL AUTHORIZED PRESCRIBERS REPORT



**Protocol Authorized Prescribers**

Barrie 5.5- An open-label, randomized trial to assess the effects of freeze-dried strawberry and blueberry tablets vs. intravenous Gatorade on time to re-hydration in athletes ages 18 to 21 (STRA-BLU-2020 | barrie 5.5 | P1526)

Report Generated: 01 Nov 2023 16:15:59

| Authorized Prescriber | Suffix | Email              | Role in Protocol     | Phone | Site Name                         | Address | Create Date          | Create User      | Start Date  | Stop Date   |
|-----------------------|--------|--------------------|----------------------|-------|-----------------------------------|---------|----------------------|------------------|-------------|-------------|
| Allens, Ednas         |        | alledna1@gmail.coz | Primary Investigator |       | Outstanding Research Center - OCT |         | 26 Oct 2023 14:28:34 | BarrieStaffPharm | 25 Oct 2023 | 31 Oct 2023 |



- Redesign the Rx Detail panel to clearly identify prescription details, patient returns, Chain of Custody (if available), EMR interface (if available) and emphasize label reprints.

## Report Updates

- Add a column for "Voided Date" (for voided prescriptions) to the Protocol Dispensed Inventory Report.
- Add new columns including Cycle Count Interval Days to the Protocol Download Drugs report.
- Protocol Dispensing History Report (Excel Download (Dispensing Only)): New columns for "Requires Return", and "Return Completed".
- Protocol Inventory Report: "Verification Required" column will now also display "Not Required", "Required", "Not Complete", or "Required, Complete"
- Protocol Drug Status Report: New columns for "Requires Quarantine Verification", "Allow Self-Verification for Shipment Receipts", "Self-Verification Delay (Minutes)", "Quantity in Returns-Unverified", "Quantity in Quarantine – Unverified". Existing columns will be modified to indicate if "Verified/Not Requiring Verification" for Return/Quarantine.
- Dispensed Inventory Report: New columns for "Patient Return Required", "Patient Return Recorded", "Return Dismissed", "Return Dismissed By", "Return Dismissed Comments", and "Return Dismissed Date".
- Budget Report: this is a new report available to support the newly added Vestigo Budget functionality. It is available at the protocol level and within Billing Reports.
- Download Protocol Drugs Report: New columns for "Requires Return Verification", "Requires Quarantine Verification", "Requires Shipment Receipt Verification", "Allow Self-Verification for Shipment Receipts", and "Self-Verification Delay (Minutes)".
- Protocol Drug Status Report: New columns for "Requires Return Verification", "Requires Quarantine Verification", "Requires Shipment Receipt Verification", "Allow Self-Verification for Shipment Receipts", and "Self-Verification Delay (Minutes)".
- Shipment Receipts Report – Summary: New columns for "Shipment Receipt Verification Required", and "Verification Complete".
- Shipment Receipts Report – Detailed: New columns for "Shipment Receipt Verification Required", "Verification Complete", "Verification Required", and "Verified By".
- Download Protocols: New columns for "Protocol Mode" (Build/Live), Close Out Storage Location, and "Shipment Receipt Verification Required."
- Protocols – Last Activities: New column for "Protocol Mode (Live/Build)".
- Protocol Listing by Protocol Group: you will now have the option to include protocols in Build mode.
- Download All Contacts: New column for "Is Contact Active?".

Please contact [support@mccreadiegroup.com](mailto:support@mccreadiegroup.com) if you have any questions or concerns.