

Training Scenario: STRA-BLU-2025.01

User Instructions

To practice corresponding transactions, use the test STRA-BLU-2024 protocol built within your website and the protocol summary below to work through the exercises that begin on page 3. We suggest adding your initials to the end of each Lot # or patient, so multiple users can practice the scenario.

Protocol Summary

Protocol Information

Protocol Number: STRA-BLU-2025

IRB: MG-01012024 (IRB status is active) Exp: 01 Jan 2027

Title: 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 18-21

PI: Test Doctor (testdoc@hotmail.coz)

Sponsor: Farmland

Manufacturer: Farmland

Agents and Storage

Blueberry 50mg tablets: will be supplied in 100-count bottles and should be stored from 20-25°C, with excursions permitted from 15-30°C.

Strawberry 100mg tablets: will be supplied in 30-count bottles and should be stored at <30°C.

Gatorade: will be supplied as 100mg/10mL solution for dilution and is compatible only on 0.9% Normal Saline. It should be infused over 30 minutes diluted in 100mL 0.9% Normal Saline. Vials can be stored at 15-30°C.

Normal Saline 0.9%: will be supplied by the site.

Randomization

Patients will be randomized (by pharmacy) to one of 2 regimens, for a total of 12 weeks of treatment. Patients may roll over to a maintenance phase thereafter for up to one year.

Regimen

Arm 1) Strawberry 100mg + Blueberry 50mg PO once daily x 1 week, then increase to Strawberry 100mg BID + Blueberry 50mg PO once daily x 11 weeks

Arm 2) Gatorade 100mg IV infusion over 30 minutes once weekly for 12 weeks

Dispensing Schedule

IWRS Required: No

Arm 1) Dispense at Visit 1, Visit 2, Visit 4, and Visit 8 (+/- 2-day window)

- Strawberry 100mg tablets: dispense 2 bottles at every visit
- Blueberry 50mg tablets: count out 30 tablets into light-resistant container and dispense at every visit.

Arm 2) Infuse Gatorade 100mg in NS 0.9% 100mL weekly Visits 1-12 (+/- 3 day window)

Arm 3) Dispense at Visits 13+ (+/- 2 day window) Strawberry 500mg bottle

Inventory

Initial Supply: Investigator will order IP to be shipped to pharmacy

Resupply Instructions: Manual resupply via email to supplier

Receiving Instructions: Email supplier once received utilizing instructions on the packing slip

Receiving in Vestigo Instructions: Receive all agents, following the packing slip

Training Exercises

1. Receiving Inventory

Receive the following packing slip into Vestigo as a new shipment.

Packing List Protocol: STRA-BLU-2024 Sponsor: Farmland Invoice Number: SB2024-01				
Drug	Lot	Item #	Quantity	Expiration
Blueberry 50mg tablets (100 tablets per bottle)	800M2	None	5 bottles	31 Dec 2024 <i>Blueberry tablets are expired, receive as "Unfit for Use" and send to quarantine. Then add the Return Comment of "Contacted sponsor for retest memo."</i>
Strawberry 100mg tablets (30 tablets per bottle)	600B3	None	30 bottles	31 Aug 2026
Gatorade 100mg/10mL Vial	500F6	None	10 vials	31 Dec 2025
Blueberry 50mg tablets (100 tablets per bottle)	400V8	40 41 42 43 44	1 bottle each	30 Sep 2026
Strawberry 100mg tablets (30 tablets per bottle)	300X7	2001 6011 3334 1042 7863	1 bottle each	31 Jul 2026

1. Search for test protocol by typing STRA-BLU-2025 into protocol search box on Vestigo home screen.
2. Click on the Inventory tab.
3. Click on Receive Inventory link.
4. Click Add New.
5. Adjust Service Date and time if needed. *Facility Receiving Shipment should default to facility you are logged in/Main facility on protocol.*
6. Consider filling in the Packing Slip/Invoice Number. *All other fields are optional.*
7. Choose the first Drug from Drug drop down.
8. Choose Add New Inventory.
9. Fill in LotNumber, Item Numbers (as needed), Quantity (note: if inventory is itemized then quantity = amount per item), Expiration Date, Item Status.
10. Click Save.

11. Scroll to top and choose next Drug. Repeat steps until all Drugs are added.
12. Once all drugs have been added, you may Edit or Delete as needed. Click on Next at the bottom to move on.
13. Click Next for this exercise. In your workflow *you can Save Progress and Close or Click Next*.
14. On the Confirm Receipt screen you can make Edits or Deletes, Complete Receipt or Save Progress and Close. Click Complete Receipt.
15. You should revert to the Shipment Receipt starting page. From here you can add files (like the shipping receipt) to your shipment by clicking on Manage Files, and then dragging/dropping chosen files. *Note, monitor visibility is adjustable when dragging and dropping files.*

2. Destruction of Quarantined Inventory

The sponsor emails the following memo. Please perform the following transactions in Vestigo:

Protocol: STRA-BLU-2024 Sponsor: Farmland Memo
Blueberry 50mg Lot: 800M2 expired 31 Dec 2024. Please destroy per SOP and send Certificate of Destruction to confirm destruction.

1. Within the protocol, click on Manage Drug Returns.

Notice the four tabs for the following:

- *Patient Returns – will show any patients returns being held*
 - *Items in Quarantine – will show any inventory currently in quarantine*
 - *Items Already Destroyed – will show any inventory that's been destroyed*
 - *Items Sent Back to Sponsor – will show any inventory marked as being returned to the sponsor*
2. Click on Items in Quarantine to find the blueberry that was quarantined during our shipment receipt.
 3. Check the box(s) for the quarantined blueberry in question.
 4. When item(s) are checked, you can choose from the following actions. For this exercise, click on Record Destruction.
 - Record Destruction
 - Record Return to Sponsor
 - Return from Quarantine
 5. You may choose to:
 - Adjust Destruction date/time if needed
 - Track Method of Destruction
 - Track 3rd Party Vendor
 - Destruction Authorization Number
 - Destruction Bin Number
 - Destruction Comments
 6. Click Save when done.
 7. Navigate to Items Already Destroyed. The blueberry should now be there.
 8. Next, click the blue button for Generate a Certificate of Destruction at the bottom of the Items Already Destroyed screen.
 9. Check the items that you want included in the Certificate of Destruction.
 10. Click Submit, and a pdf will generate.

3. Edit Inventory

The sponsor emails a retest date memo. Please update expiration date in Vestigo:

Protocol: STRA-BLU-2024 Sponsor: Farmland Memo			
Drug	Lot#	Current Expiration Date	New Expiration Date
Gatorade 100mg/10mL	500F6	31 Dec 2025	31 Dec 2026

1. Navigate to protocol and click on Inventory tab in protocol.
2. Click on View/Edit Inventory.
3. Select the drug, and Lot# within the filters. Note, can also uncheck the Status box to view/edit inventory with a QOH<0.
4. Click on Edit. *Note, you can also Click on Txns to view transactions against inventory.*
5. Choose the type of edit. For this exercise, choose Update an Expiration Date. *Note the other types of edits available. Note the yellow box that explains the difference between Update and Correct for expiration dates.*
6. Check the box(es) for the inventory in question.
7. Enter new expiration date.
8. Type in reason for edit (required).
9. Click Save Edit

4. Quarantining Inventory and Manage Drug Returns

The sponsor emails the following memo. Please put the affected inventory into quarantine in Vestigo.

Protocol: STRA-BLU-2024 Sponsor: Farmland Memo
Please note that some Gatorade 100mg/10mL vials, Lot # 500F6, were reported to contain particulate matter. Please quarantine while Farmland investigates.

1. Within the protocol, click on Adjust Inventory.
2. Select the inventory from the drop down and apply a lot# if desired to the filter.
3. Single Adjust will allow an increase or decrease of inventory. Bulk Decrease will only allow a decrease. You can choose either for this exercise.
4. You can adjust the Service date/time If needed.
5. Choose an Adjustment Reason. For this exercise choose Product Contaminated. *Note the other reasons available. Custom Adjust Reasons can be added in App Admin.*
6. Add Accountability Log comments as desired.
7. Click Save.

The sponsor then emails the following memo. Return the inventory into quarantine to usable inventory in Vestigo.

Protocol: STRA-BLU-2024 Sponsor: Farmland
Please note that Gatorade 100mg/10mL vials, Lot # 500F6, were found to be acceptable for use and are free of particulate matter.

1. Within the protocol, click on Inventory tab.
2. Click on Manage Drug Returns.
3. Click on Items in Quarantine.
4. Check the box for Gatorade that was placed into quarantine due to Product Contamination.
5. Select Return from Quarantine.

5. Enrolling Patients

You have already received confirmation of consent and enrollment, please enroll the following patients.

Patient	Date of Birth	PSN	Arm
Strawberry Shortcake	15 Apr 2007	AA00-7171	Arm 1
Rainbow Brite	18 Dec 2004	AA00-5157	Arm 2
Dennis Menace	06 Jun 2008	AA00-6218	Arm 1
Droopy Dog	04 Jul 1976	AA00-7412	Arm 1

Guidelines for enrolling TEST patients: You don't have to use the test names below, but make sure you use obvious TEST patient names. Use the option to generate a unique Vestigo MRN to avoid potential duplicates with future site MRNs.

1. Within the protocol, click on Patients and Subjects tab.
2. Click Enroll New Patient/Subject.
3. *You must do a search for the patient/subject first – enter in a name or MRN.*
4. Click on Add New.
5. For this exercise, generate a Vestigo MRN by clicking on Generate. Sites may choose to use their EMR MRNs for non-test protocols.
6. Enter First Name, Last Name, then choose gender and date of birth.
7. Click on Save Patient (Quick Add). Additional patient information can be added by clicking on Save Patient (Full Profile).
8. On the next page, choose the patient's enrollment arm.
9. Enter the Patient Study Number.
10. Click Enroll.
11. Enroll all three test subjects below.

6. Editing Patient Enrollment

The PI has decided not to proceed with Dennis Menace's enrollment. Please inactive them from the protocol.

Users may edit patient enrollment by:

1. Navigating to the Patients/Subjects tab in the protocol.
2. Click on Edit Enrollment next to one of the subjects
 - You may edit the Patient Profile by clicking on Edit Patient Profile
 - You may adjust the patient status to Inactive and choose an optional reason for unenrollment
 - You may adjust the enrollment arm by selecting a different Enrollment Arm. You will need to choose if the patient will be unenrolled from their current arm. This is mainly used for patients crossing arms.

7. Receiving Patient Specific Inventory

Please receive the following packing slip into Vestigo as a new shipment. Refer to exercise 1. As needed.

Packing List Protocol: STRA-BLU-2024 Sponsor: Farmland Invoice Number: SB2024-02					
Drug	Lot	Item #	Quantity	Expiration	PSN
Blueberry 50mg tablets (100 tablets per bottle)	111D4	80 81 82	1 bottle each	30 Sep 2026	AA00-7412
Strawberry 100mg tablets (30 tablets per bottle)	222G7	83 84 85	1 bottle each	31 Jul 2026	AA00-7171
Gatorade 100mg/10mL vial	500F6 <i>Note, you can choose to add to existing inventory when receiving since it should match inventory already received</i>	None	10 vials	31 Dec 2026	n/a

1. Follow steps 1-10 from exercise 1.
2. At the bottom of the screen, before clicking on Save after entering the inventory information, choose the patient to associate the inventory to – then click Save. Patient specific inventory may only be associated with a patient enrolled into the Arm that can receive the drug in question.
3. Follow the steps for all inventory listed. Note – not all inventory is patient specific.

8. Document Storage within the Protocol

Consider adding some documents to the test protocol

1. Within the Protocol, navigate to the Protocol Documents tab.
2. Click on Manage.
3. Click on Manage Files for the header where you'd like to store your document(s)
 - Consider adding this document to the one of the headers
 - Memos from the sponsor could be stored under one of the other headers, like "Communication/Memos."

Note, within the Protocol, shipping documents that are added to a shipment can be found under Transaction Documents. When monitors are granted access to protocol information, they can see these documents (and others) if monitor visibility is turned on.

9. Drug Accountability Record Form (DARF) Generation

Generate some DARFs to review the various transactions that have transpired.

1. Within the Protocol, navigate to the Inventory tab.
2. Click on Drug Accountability Records.
3. Select the Drug and apply any optional filters you like. You will want to check the box to Include Subject and Inventory Returns to see any inventory or patient returns related to the drug.
4. Run several different DARFs with applied filters to see all types of DARFs and how the filters will affect them.

10. Dispense to a Patient

Enter a prescription for each subject.

1. Within the protocol, click on the Patients/Subjects tab
2. Click on the MRN of a patient. This will open the profile.
 - Additional information can be added to the patient's profile by clicking on the plus sign
 - If a patient Alert is entered, that alert will populate every time a prescription is filled
3. Within the patient profile, click on the link for Add New Prescription
4. Choose the order to dispense. *Note, you must have already received inventory for what order you choose.*
5. Select the Dispensing Facility, and Schedule as needed.
6. Click on Select Inventory To Be Used
7. Enter the Dose Amount. Note, this is the dose that will display on the DARF transaction.
8. Enter the Dispensed Quantity for the inventory(ies) being used
9. Click Next and fill out/check over the rest of the prescription details.
 - Note, these are details that were added to the order build. Most fields can be adjusted/edited.
 - Refills can be added by adding a numerical value to Refills Written field.
10. Click Save at the bottom of the screen
11. You will have the option (at the bottom of the next screen) to go back to the Subjects tab, to the patient profile, or process a return. For this exercise choose to go back to the profile.
12. By using the links in the patient profile, please practice the following:
 - If refills were entered, click on the **refill** number in the processed prescription to process a refill
 - **Copy** a prescription by clicking on the Copy link of the processed prescription
 - **Edit** a prescription by clicking on the Edit link of the processed prescription
 - **Void** a prescription by clicking on the on the Edit link of the processed prescription and scrolling to the bottom of the screen. Note that you will need to choose what happens with the inventory and what happens to dispense fee(s).
13. Please practice by dispensing prescriptions for other subjects.

- Note that filling a prescription for subject(s) enrolled into Arm 2, have 2 drugs associated with the dispense, requires you track thaw and prep time, and will also navigate you to recording a patient drug return.
- Practice filling out the available fields on the patient return screen or click cancel to come back to it another time.

11. Dispense to a Patient via Patient Visit Pathway

Patient Visits are placeholders that clients can use to plan and process prescriptions through the placeholders. They are optional and can be used for some or all orders.

Add a patient visit to one of the test patients

1. Within protocol, click on Patients/Subjects tab.
2. Click on the MRN of one of the test patients.
3. Click on the link for Schedule a Patient Visit.
4. Select the protocol (this selection will always be presented even if the patient has only ever been enrolled in one protocol).
5. Select the order, schedule (if tracking), visit date, and visit notes (as needed)

Note that scheduled Visits can be found:

- In the patient profile
- On the Vestigo home screen within the Prescriptions alert tab under Patient Visits pending
- On the Vestigo calendar

Note that Patient Visits can be processed or dismissed.

12. Processing Patient Returns

Process a patient return for a prescription recently filled for one of the test subjects.

1. The pathway to the patient return can be found by:
 - Clicking on the Process Returns tab in the green banner (must know Vestigo prescription number)
 - Clicking on the Search Subjects and Rx's tab in the green banner, and then searching by the prescription number (must know Vestigo prescription number)
 - Navigating to the patient profile, and clicking on the Record a Patient Drug Return link
2. Once you have navigated to the patient return screen, click on Add New Return
3. Fill in Return Quantity (must be numerical, and can also be 0)
 - *Used and Missing quantity fields are optional*
 - *Return Units can be adjusted as needed*
 - *Return Log Comments can be added (optional)*
4. Decide if the return will be held, destroyed or returned to sponsor
Note, once a return is processed, it can be managed through the Manage Drug Returns link on the Inventory tab of the protocol
5. Within Manage Drug Returns:
 - Click on the date of the return to edit it as needed

- Check the box(es) of the return(s) to decide if it will be destroyed or returned to sponsor
- Complete the required and optional fields as needed

Note, once inventory has been destroyed, a certificate of destruction can be generated.

6. When navigating to the Items Already Destroyed queue within Manage Drug Returns, click on Generate a Certificate of Destruction at the bottom of the screen
7. Select which item(s) you want to include in the report, then click Submit