Target Role: Inventory Manager

Role Description:

Responsible for creating shipment and inventory records, transferring inventory, recording wastage and excursion events in the COVaxon system

Permission Level: COVax Inventory Manager

- Edit-Access for Shipment, Inventory, Storage & Product tabs
- Read-Only Client Profile
- View Dashboards
- Read and Export Vaccine Inventory Report & Summary Client and Dose Administration Report

User Access with new AO & VE functionality:

- Inventory Managers can only create, manage, and transfer inventory associated to their profile AO
- Users can continue to see shipments across AOs, but they cannot edit the shipment if it does not belong to their AO
- All Users can create and manage Vaccination Events associated to the same AO as their profile AO

<u>Legend</u>



Pencil Icon

Click this to edit any data fields



Red Asterisks

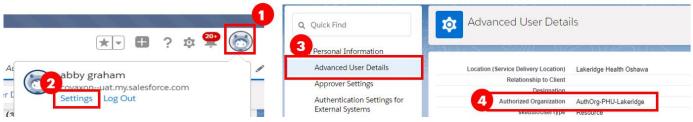
Indicates a required field



All COVID public health measures must be followed in alignment with this process.

There have been signficant changes to the inventory management process based on the data model design enhancements for Release 5.2. Refer to the "R5.2 $COVax_{ON}$ Functionality Changes" Document sent on February 25th for an end to end overview of these changes.

To check your Authorized Organization, go to Advanced User Details:



To create a New Vaccination event, see the "Creating Vaccination Events" Job Aid

For assistance, contact Information Technology Services (ITS):

- (416) 327-3512
- Toll Free 1-866-272-2794
- COvaxonsupport@ontario.ca
- Support hours are 7:00am to 8:00pm, 7 days a week

This document provides training on how to use the $COVax_{ON}$ system for the vaccine management process. Within the clinical package that each site received, there are additional forms and documentation that you will need to use alongside the $COVax_{ON}$ system.

Data Privacy Disclaimer:

Users with access to COVaxon can see the demographic details and health numbers of other clients in the system when searching for a particular person. The information is presented this way to help ensure that users access the correct client record and to reduce the risk of either not locating a client's record or improperly creating duplicate client records.

As required by PHIPA and under the terms of the Acceptable Use Policy, system users are only permitted to access the information of individuals to whom they are providing care or for other purposes that are specifically authorized.

The system records detailed audit transaction logs that inform the Ministry of Health of which client records were accessed by each user, and what actions they took in the system. Any concerns that are identified about improper access to the system will be investigated and appropriate actions taken.

Inventory Management Scenario Overview

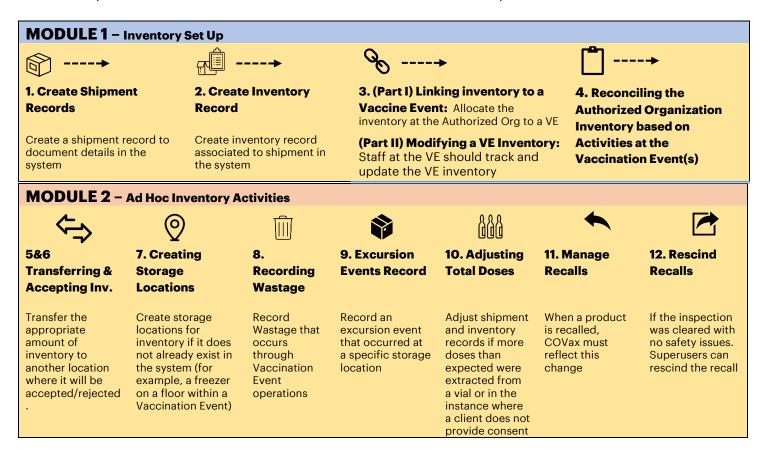
Target Role: Inventory Manager

Inventory is managed by Authorized Organizations (AOs), which typically includes two scenarios:

- 1. For Hospitals/Clinics Receiving Inventory: Shipments are received and inspected upon arrival. Inventory Managers will create a shipment and inventory record for each lot of inventory received which will be used for vaccinations at the clinic. The Public Health Unit (PHU) may request the hospital to act as a Vaccine Depot where they may manage and allocate inventory to other locations (Vaccination Events) such as Long-Term Care Homes.
- 2. For Public Health Units (PHU's) Receiving Inventory on Behalf of LTCHs, RHs and NHs: Shipments are received by the PHU at their main office storage, acting as the Vaccine Depot where they will be inspected, and a shipment record and a inventory record will be created in the system to reflect what is received. After the initial shipment of inventory arrives at the PHU, they may allocate inventory to the locations (Vaccination Events) such as Long-Term Care Homes.

Inventory Management Activities

The information below reflects the high-level process/activities Authorized Organizations must follow to manage the inventory within COVax_{ON}. Please refer to the section that is relevant to you.



MODULE 1: INVENTORY SET UP

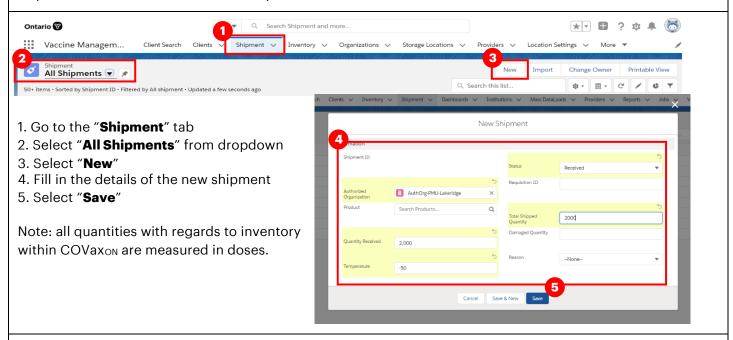
For a new lot of inventory that has been received at an Authorized Organization, create a shipment record and then create an inventory record within that shipment.

Target Role: Inventory Manager



1. Creating Shipment Records

Description: After a shipment is received and inspected, create a shipment record to document the shipment information in the COVax_{ON} system.



Shipment Details:

- Authorized Organization: Use the search bar to indicate the authorized organization (AO) the inventory is associated to (the party responsible for managing the inventory). This is a mandatory field and must be the same AO as on your User profile.
- o **Product:** This is a lookup field for products that already exist within the system (i.e. "PFIZER-BIONTECH COVID-19 mRNA", or "MODERNA COVID-19 mRNA-1273" for Moderna)
 - **Note**: products are pre-loaded and will not need to be created (only selected from shipments and inventory). To view the products available, navigate to the products tab and select the relevant product.
- Quantity Received: Indicates number of doses received. Note: Pfizer previously indicated that there are 5 doses per vial. This has now been changed to 6 doses per vial. Based on the vials received, the Inventory Manager will need to perform the calculation to enter the doses received. This will be the same quantity entered on the inventory record (explained below)
- o **Temperature:** Temperature of shipment (UOM: Celsius)
- Status: In most cases the status should be "Received", but if part of the shipment was rejected, the status could be "Partially Received"
- o Requisition ID: Can be entered if known for traceability to the order number
- Total Shipped Quantity: Enter quantity of doses that was shipped and planned to be received
- Damaged Quantity: Indicate the quantity of damaged doses (if any) that is recognized during shipment inspection
- o **Reason:** Indicates the reason for damage (select from dropdown)
- 5. Select "Save" or "Save & New" for multiple shipment records

Further Context

Target Role: Inventory Manager

- The Shipment ID will be pre-populated based on the numerical order of creation.
- Pfizer immunizations require both vaccine and diluent inventory, whereas Moderna immunizations only require a vaccine (no diluent). Therefore, the following need to be created:
 - o Pfizer: shipment and inventory records for vaccine and diluent
 - o Moderna: shipment and inventory records for vaccine only



2. Creating Inventory Records

Description:

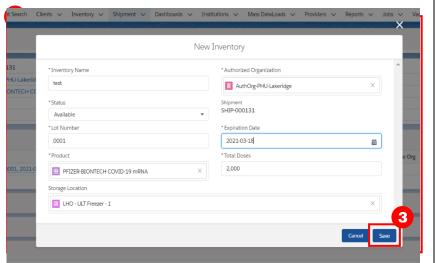
Once shipment is created, create an inventory record(s) associated to the shipment. Inventory records should be created for vaccine (Pfizer and Moderna) and diluent (Pfizer only) inventory that is received. A specific lot# of inventory can be managed by one Authorized Organization and "linked" to multiple Vaccine Events. As doses are administered during the Vaccination Event, doses will automatically decrement from the associated Inventory record

After creating a shipment, you will be brought to the shipment's page. Select "New Inventory"



- 2. Fill in new inventory details:
- Inventory Name*: Input "test" here and continue filling out the other fields. Once saved, this will auto populate with the below naming convention:
- [Product Trade Name] [Dosage] [Unit of Measure] - [Lot Number] [Expiry Date]

 Product Trade Name, Dosage and Unit of Measure are pulled from the product record associated with the inventory. Lot Number and Expiry Date are pulled from the entries on the inventory record.
- Status*: Select "Available" so the quantity of doses will be reflected as available in inventory
- Lot Number*: Associated with the batch of inventory for traceability
- Product: Will be pre-populated based on shipment (i.e. "PFIZER-BIONTECH COVID-19 mRNA", or "MODERNA COVID-19 Mrna-1273" for Moderna)
- **Storage Location:** Use this search field to identify the storage locations already created in the system (for example; Lakeridge Health Oshawa Freezer 1) if the accurate storage location does not exist in the system, refer to **Section 6: Creating Storage Locations.**
- **Authorized Organization*:** Use the search bar to indicate the authorized organization the inventory is associated to (the party responsible for managing the inventory). This is a mandatory field and must be the same AO as on your User profile.
- **Shipment:** Will be pre-populated with the shipment record associated to the inventory record being created.
- **Total Doses:** The quantity of doses associated with this lot# (same quantity as on the shipment record)
- Expiration Date*: YYYY-MM-DD



Target Role: Inventory Manager

3. Select "Save"

Key Tips

• Within the inventory record, there is an option to add files to the record (for example, a temperature logger). This can be done from the right side of the inventory record by selecting "Upload Files"



3. (Part I) Linking Inventory Records to Vaccine Events

Description: Super Users or Inventory Managers will link existing inventory records at the Authorized Organization to the Vaccination Event. This allows Vaccinators to be able to select the inventory when administering doses. The act of linking "existing inventory records" creates an "Event Inventory", which is a separate record that is tied to the main Authorized Organization inventory record. As doses are administered, it decrements from "Doses Available" from the linked Authorized Organization inventory record. **One Authorized Organization inventory record can be associated to more than one Vaccination Event.**

How:

Allocate Inventory to the Vaccination Event by going to the Inventory Record that should be linked to VE

- Select the arrow next to "Event Inventories"
- 2. Select New

Enter in the details for the inventory being used at the vaccination event

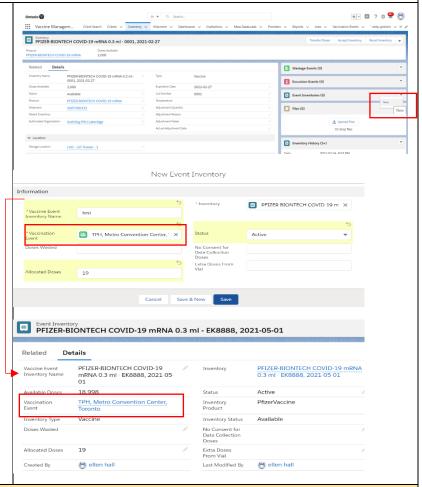
Vaccination Event Inventory Name: is auto populated with the same name as the linked AO inventory in the "Inventory" field on this screen to ensure consistency of the inventory naming convention.

Note: User must populate the "Vaccine Event Inventory Name" field with any placeholder, such as "**test**" and click save to have the field auto populated. (see example to the right)

Vaccination Event: Search and select the Vaccine Event to link the inventory to

Inventory: This field will be auto-populated with the inventory associated to that AO (this is the "linked" inventory described above that will be decremented as doses are administered)

Allocated Doses: enter the # of doses being allocated to that VE



Key Tips

Target Role: Inventory Manager

Note: the other fields such as "Doses Wasted", "Extra Doses from Vial", "Non-consent Doses", are not used initially when linking inventory. These fields are part of VE operations and are described below.

- Users may link the same inventory to multiple Vaccine Events by allocating various amounts of that Lot #
 across various VE, as long as it remains within the same Authorized Organization
- As long as the inventory remains **within the same Authorized organization**, Users no longer have to transfer/accept or reject inventory. Instead they can link it to a new Vaccine Event within their AO.



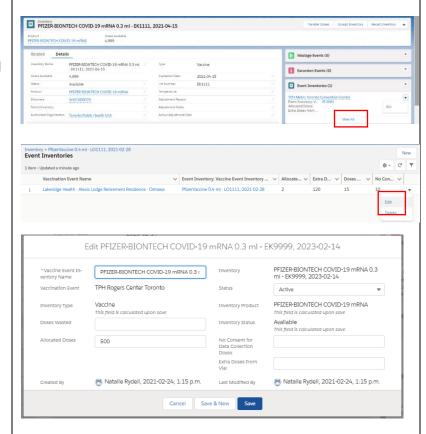
3. (Part II) Modifying Vaccine Events

Description: On a regular basis, staff at the VE (Super Users/Inventory Managers) should track and update the Vaccination Event inventory from the inventory tab based on any wastage, adjustments, etc., that occur at the Vaccination Event.

For this release, the updates to the Event Inventory do not automatically update the dose quantities on the main AO inventory record linked to the VE. The fields on the VE inventory are used for tracking doses available at the Vaccination event based on what was originally allocated to that event.

How:

- From the **inventory tab**, search and select the AO inventory record that was linked to the VE. The record can be edited from this view, by selecting the arrow and selecting "Edit", or by:
- 2. Under "Event Inventories" select "View All"
- This will allow users to see all Vaccination Event Inventory items associated to the AO inventory record.
- 4. Locate the VE Inventory item and click the arrow on the right-hand side of the screen and click "Edit".
- 5. Edit the relevant quantities for the following fields:
- 6. **Doses Wasted**: enter quantity of doses wasted through clinical operations
- 7. **No Consent for Data Collection Doses:**Enter quantity of clients that were administered a dose outside of COVaxoN (in the scenario that they did not consent to data collection in COVaxoN, but still received a dose, we have to account for one less dose in the system's inventory)
- 8. **Extra Doses from Vial**: enter quantity of extra doses achieved from vials
- 9. Select "Save"



• These fields are cumulative. Each day as new quantities are identified, add them to the existing quantity in the field.

Target Role: Inventory Manager

- Information should be provided to the Inventory Manager owning the main Authorized Organization record, so they can reconcile the adjustments made to the Event Inventory on the Authorized Organization Inventory.
- This could include a screenshot of the VE inventory record with the quantities they've updated, including additional details related to those adjustments. For example, along with the screenshot, notes such as "5 doses wasted due to broken vials on 2.25.2021)".

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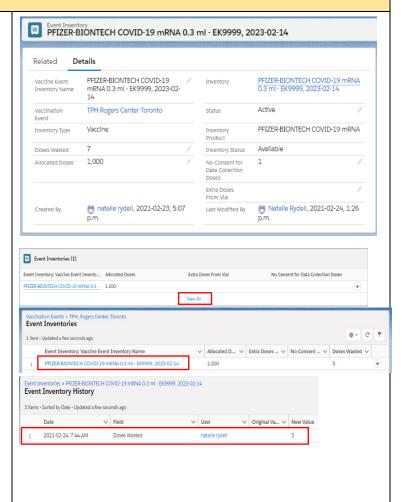
4. Reconciling the Authorized Org. Inventory based on Activities at the Vaccination Event

The Inventory Manager/Super User at the Authorized Organization should reconcile the AO inventory regularly based on any updates made to the VE inventory described above (i.e., wastage, adjustments, etc.).

For the Inventory Manager at the AO to make the required adjustments, they will require information from the staff at the VE outside of COVaxon. This could include a screenshot of the VE inventory (to the right) with the quantities they've updated, including additional details related to those adjustments. For example, along with the screenshot, notes such as "5 doses wasted due to broken vials on 2.25.2021)".

The AO Inventory Manager can select "View All" under "Event Inventories" from the Vaccination Event to see a full list of inventory records and adjustment quantities entered.

They can select a specific inventory and under the "Related Tab" of that Event Inventory, they can see a history of all changes made to the inventory



Target Role: Inventory Manager

MODULE 2: AD HOC INVENTORY ACTIVITIES

The following activities should be completed on an as-needed basis by Inventory Managers.



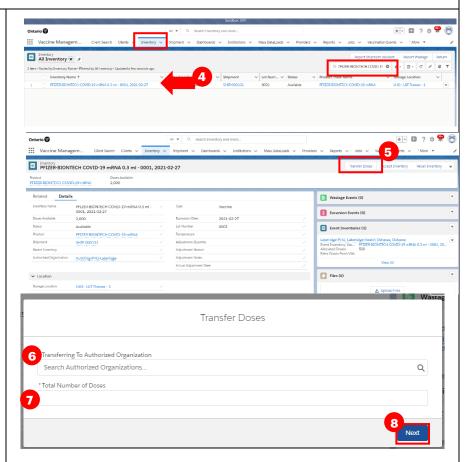
5. Transferring Inventory

Description:

Any transfers conducted within COVax_{ON} would be only if inventory is transferred from **one Authorized Organization to another Authorized Organization** (for example, a transfer of ownership between a public health unit to another public health unit). In this case, the following steps outline how to transfer doses.

How:

- 1. Select the "Inventory" tab
- 2. Ensure "**All Inventory**" is selected from the dropdown.
- 3. If necessary, use the search bar to locate the inventory that is being transferred.
- 4. Click on the relevant inventory record (initial inventory record from the shipment to the Vaccine Depot; PHU or hospital).
- 5. From the inventory's page, select "**Transfer Doses**"
- A pop-up will appear. Populate the "Transferring to Authorized Organization" field with the Authorized Organization name.
- Populate the "Total Number of Doses" with the number of doses being transferred
- 8. Click "Next" & "Next" again & then "Finish"



Further Context

An error message will return if a user tries to transfer more doses than are available – i.e. if you have 1500 doses to at the primary location, but you try to transfer 1600 doses to another location, you will receive an error

Reference the Authorized Organization tab if needed to confirm the correct name of the Authorized Organization you are transferring to.

Note: if a transfer was made from one Authorized Organization to another Authorized Organization, and doses need to be returned back, an **inventory adjustment should be made instead of a transfer**. Also, for any transfers that should not be accepted, it is recommended for the receiving site to accept the transfer, and for both sites to instead create adjustments to reflect the accurate inventory quantities instead of rejecting.

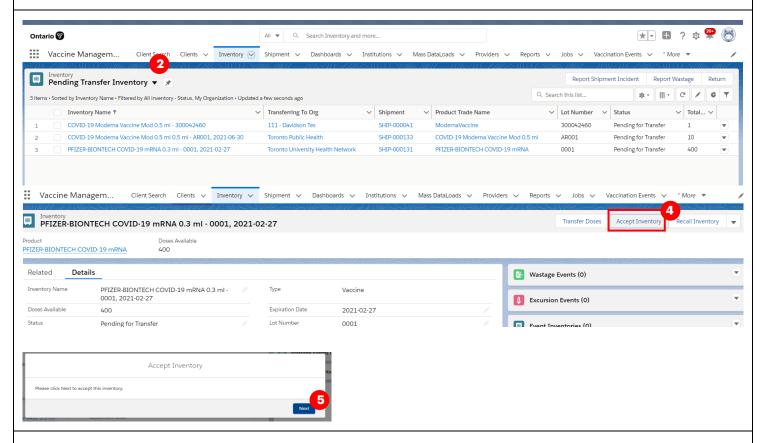
Target Role: Inventory Manager



Description: The receiving Authorized Organization will need to Accept the transfer

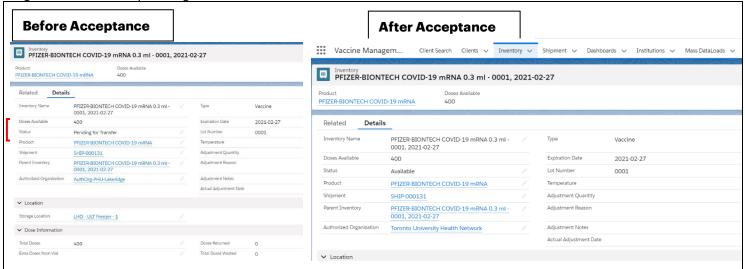
How:

- 1. Return to the "Inventory" tab
- 2. Ensure "Pending Transfer Inventory" is selected from the dropdown
- 3. Select the inventory item that is tagged to the receiving Authorized Organization
- 4. From the Inventory's page, select "Accept Inventory"



- 5. Click "Next"
- 6. Exit the window. To refresh the status and location of the transferred inventory, please click into the inventory's shipment, then re-open the inventory record to see the updated status and location.

Target Role: Inventory Manager



After Acceptance (Note: it may take a few moments for the transfer to refresh in the system)

- The inventory's status will move from "Pending for Transfer" to "Available" for the receiving location
- The inventory's location will change from the primary location to the receiving location

Further Context

- Do NOT edit any fields on the received inventory record before the inventory has been accepted
 - o If a user tries to update the status of the inventory from "Pending for Transfer" to "Available" before it has been properly accepted at that site, the inventory transfer will fail.
 - If a user tries to create an event (i.e. a wastage event) for the inventory before it has been properly accepted at the new site, the event will be unsuccessful
- Note: if a transfer was made from one Authorized Organization to another Authorized Organization, and
 doses need to be returned back, an inventory adjustment should be made instead of a transfer. Also, for
 any transfers that should not be accepted, it is recommended for the receiving site to accept the transfer,
 and for both sites to instead create adjustments to reflect the accurate inventory quantities instead of
 rejecting.



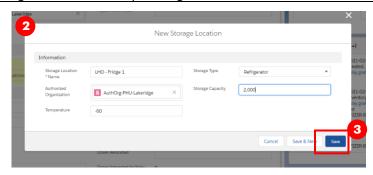
7. Creating Storage Locations

Description:

When populating the Storage Location field in an inventory record, if the accurate location does not exist in the system, use these steps to create a new location.



Target Role: Inventory Manager



How:

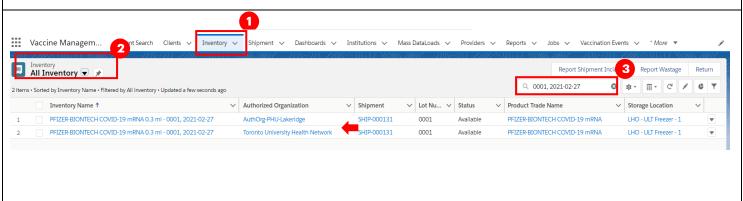
- 1. From the "New Inventory" window (shown in section 2 above), after searching, if the accurate storage location does not exist in the system, select "New Storage Location". A new window will open called "New Storage Location"
- 2. Fill in New Storage Location details:
 - **Storage Location Name*:** the naming convention may differ for each location, for example: *Toronto General Hospital Floor 1 Fridge 1*
 - **Authorized Organization:** Use the search bar to indicate the authorized organization the inventory is associated to (the party responsible for managing the inventory). This is a mandatory field and must be the same AO as on your User profile.
 - Storage Type: Indicates how the inventory is being stored (select from dropdown)
 - Storage Capacity: Number of doses that the storage location can hold (UOM: doses)
 - **Temperature:** Temperature of storage location (UOM: Celsius)
- 3. Select "Save". The storage location will be saved, and you will return to the New Inventory window. The storage location you created will be auto populated into the "Storage Location" field.



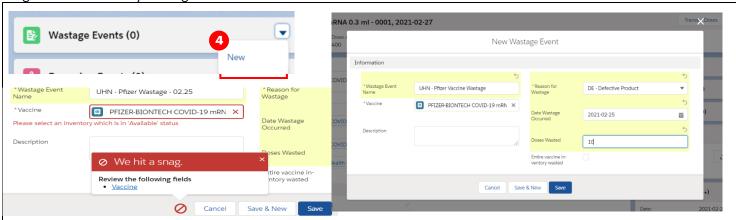
8. Recording Wastage

Description:

When wastage occurs and is identified through clinic operations, use this functionality to record wastage from the Inventory tab.



Target Role: Inventory Manager



How:

- 1. Go to the "Inventory" tab
- 2. Select "All Inventory" from dropdown
- 3. Select the desired inventory you wish to update. You can use the search bar to aid in your search. This will bring you to a specific inventory asset's page
- 4. From the inventory's page, select the dropdown next to "Wastage Events" and select "New". 4a) Note: If the vaccine inventory is not in the status "Available", the user will not be able to report a wastage event. When the user goes to save the wastage event, they will receive an error message and will be unable to save the event. To proceed, the user will need to return to the inventory record and select the status "available" to log the wastage event.
- 5. Fill in details of Wastage Event
 - Wastage Event Name*: Follow naming convention: [Location]-[Date]-[#] (see more details below)
 - Vaccine*: Use this search field to identify which vaccine you are recording wastage for
 - Reason for Wastage*: Select reason for wastage from dropdown list (new options are available)
 - Date Wastage Occurred: YYYY-MM-DD
 - Doses Wasted: Enter number of doses wasted
 - Entire Vaccine Inventory Wasted: Checkbox if it was the entire lot
- 6. Select "Save" or "Save & New" for multiple wastage events

Further Context

- Wastage Naming convention is: [Location] [Date] [#] (# would be if there are more than one wastage event on site per day) (i.e. "Lakeridge Health Oshawa 12/30/2020 1")
- The amount of "Doses Wasted" entered will automatically drawdown the available inventory of that item
- There are 2 methods for recording wastage in the COVax_{ON} system. It can also be recorded from the Inventory tab, by selecting the button on the top right called "Report Wastage". Both methods are acceptable for use.
- If a wastage event is unintentionally created, this can be rectified by editing the wastage event and changing the "Doses Wasted" number to be 0. The doses will then be added back to the "Available" doses. The wastage event will not be deleted
 - the "Available" doses. The wastage event will not be deleted

 Note: previously Pfizer stated that there were 5 doses per vial. This has been changed to 6 and therefore if
 upon receiving, the quantity received was calculated at 6 doses per vial, a wastage event can be created if
 less than 6 doses are extracted from a vial to adjust the inventory, using the "WR ID Insufficient Dose(s)

₩astage Events (1)

Broken Viles Lakeridge 1.2.2021 Doses Wasted: 0

From a Single/Multi-Dose Vial" wastage reason

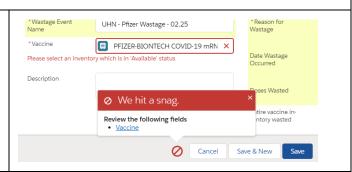
Target Role: Inventory Manager



9. Excursion Events

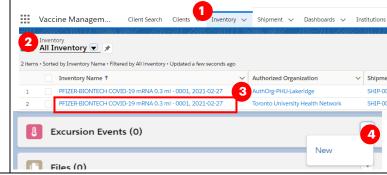
Description: In the case of an Adverse Storage Condition (ASC) that impacts all or a portion of a lot# of inventory, the "Report Excursion" functionality can be used to report the excursion event.

Note: If the vaccine inventory is not in the status "Available", the user will not be able to report an excursion event. If they try to create an excursion event, they will be unable to select the vaccine inventory and instead, they will receive the error shown. To proceed, they must return to the inventory record and set status to "Available".



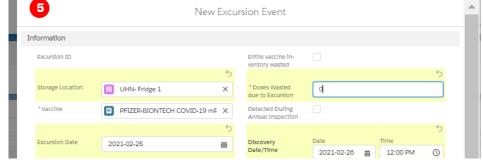
How:

- 1. Go to the "Inventory" tab
- 2. Select "All Inventory" from dropdown
- 3. Select the desired inventory you wish to update. You can use the search bar to aid in your search. This will bring you to a specific inventory asset's page.
- 4. From the inventory's page, select the dropdown next to "**Excursion Events**" and select "**New**".



5. Fill in the details of the Excursion Event:

- Storage Location: Use search bar to indicate which storage location experienced the excursion event
- **Vaccine*:** Select appropriate vaccine from search field
- Entire Vaccine Inventory
 Wasted: Use checkbox to

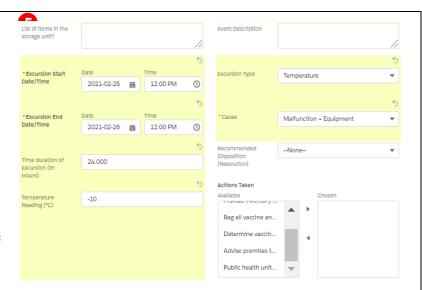


indicate if the entire inventory record was impacted by the excursion. **Do not fill in until after the inspection**

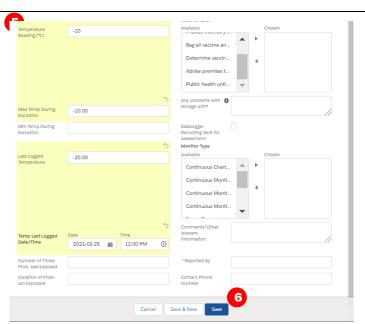
- **Doses Wasted Due to Excursion*:** This is a mandatory field. However, the PHU investigates all excursion events upon submission. Therefore, when filling in excursion event information, enter "0" wasted doses until the PHU has approved the event. Once approved, update the excursion field for the correct number of doses wasted.
- Detected During Annual Inspection: check this box if the event was found during Annual Inspection
- Discovery Date/Time: when the Inventory Manager discovered the excursion

Target Role: Inventory Manager

- Excursion Date: Select the calendar icon to choose the date of the excursion
- Excursion Start Date/Time*: time when the temperature went out of range
- Excursion End Date/Time*: time when the temperature was set back in range
- Time Duration of Excursion (hours): time elapsed between start time of excursion and end time
- Excursion Type: Select "Temperature"
- **Cause*:** Use the drop-down options to indicate the cause of the excursion
- Recommended Disposition (Resolution):
 Select viable or unusable from the drop
 down. Do not fill in until after the
 inspection



- Actions Taken: Select actions from the available category and use the arrows to move the applicable
 actions to "Chosen" category
- **Temperature Reading (°C):** Indicate the temperature that the storage location was at during the excursion event
- Max Temp During Excursion: Indicate the highest temperature during excursion
- **Min Temp During Excursion:** Indicate the lowest temperature during excursion
- Last Logged Temperature: last temperature showing on the data log
- Temp Last Logged Date/Time: Enter date/time
- Number of Times product was exposed: Indicate # of times vaccine was exposed to an excursion event (1 = first time)
- Duration of Product Exposure: Indicate the total exposure the product has experienced by referencing the "Time duration of Excursion" and "Number of times product was exposed"

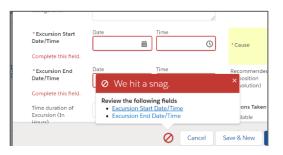


- Datalogger Recording Sent for Assessment: Select the checkbox if you have sent the log to the PHU for inspection
- **Monitor Type (Multi select):** Select the monitor type from the available options and use the right arrow to move the applicable option(s) to "Chosen" category
- Reported By*: Insert Inventory Manager who discovered the excursion event
- Contact #: Input telephone number for the owner of this record

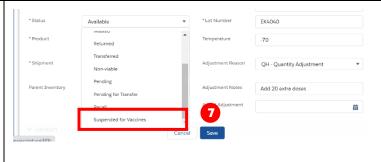
Target Role: Inventory Manager

6) Select "Save"

Note: If any of the **mandatory fields*** are not filled in when the user attempts to save the record, the system will produce an error and they will be unable to save the excursion event.

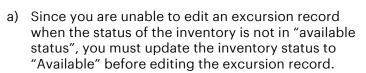


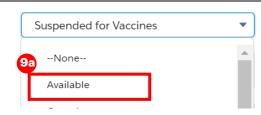
7) Return to the inventory record and change the status to **"Suspended Vaccines".** It should remain in this status <u>until the investigation of the event is complete.</u>



8) After/while creating the excursion event in $COVax_{ON}$, contact the PHU to inform them of the excursion. The PHU will perform an inspection of the incident. While the inspection occurs, the doses remain in "quarantine"

9) The PHU will contact your hub/location with the inspection results. Once the investigation is complete, the record can be updated with the correct number of impacted doses, by editing the excursion event record







- b) Select the drop down from the excursion event record and select "edit"
 - If all inventory was impacted by excursion: check "Entire vaccine inventory wasted" check box and indicate total number of doses wasted (these doses will automatically decrement from the total inventory available) See, O Doses Available on inventory record with the status changing to "complete". Also note the 9,144 wasted.
 - If a portion of inventory was wasted, leave check box blank and only fill in the # of doses wasted field. The doses indicated will also decrement from the total available.
 - If the entire inventory lot was unaffected from the excursion event, input "O doses Wasted Due to Excursion".



Target Role: Inventory Manager

10) Indicate the "**Recommended Disposition"** as **viable** or **unusable** depending on if the entire inventory was impacted by the excursion or not



- 11) Select "Save" on the excursion record
- 12) If the investigation determines that not all the inventory was impacted, you may return to the inventory record and ensure the inventory status is set to "Available" for the remaining doses.

Further Context

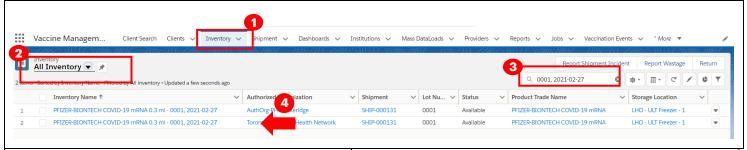
- The excursion event differs from the wastage record, as it is describing specifically an ASC (adverse storage condition) malfunction that occurred. Therefore, excursion events are only meant for users who are storing the inventory specifically at their location (meant for storage hubs) where the malfunction was storage related. Therefore, wastage that occurs at a clinic due to on-site error will be recorded as regular wastage events (see Section 8 above).
- If an excursion event is unintentionally created, this can be rectified by editing the excursion event and changing the "Doses Wasted due to Excursion" number to be 0. The doses will then be added back to the "Available" doses. The excursion event will not be deleted in the system and can still be viewed, however the doses wasted will be 0.



10. Adjusting Total Doses

Description:

Steps to adjust shipment and inventory records if the number of available doses is in need of adjustment. For example, more doses than expected were extracted from a vial or an immunization was recorded in an offline process (ex. if a client did not consent to digital data capture).



How:

- 1) Go to the "Inventory" tab.
- 2) Ensure "**All Inventory**" is selected from the dropdown.
- 3) Use the search bar to identify the inventory you would like to modify.
- 4) Select the relevant inventory, click the pencil icon
- 5) "Adjustment Quantity": Enter the quantity for the adjustment and add the "Adjustment Reason", "Adjustment Notes" and "Actual Adjustment Date".
- This is used for any other discrepancies or adjustments required outside of "Extra doses

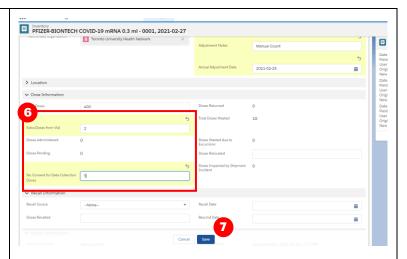
Inventory Name	PFIZER-BIONTECH COVID-19 mRNA 0.3 ml - 0001, 2021-0	Туре	Vaccine	
oses Available	390	* Expiration Date	2021-02-27	ä
itatus	Non-vlable •	*Lot Number	0001	
Product	PFIZER-BIONTECH COVID-19 mRNA X	5 perature		
Shipment		<u> </u>		5
		Adjustment Quantity	8	
arent Inventory	■ PFIZER-BIONTECH COVID-19 mRNA 0.3 ml - 000 ×			5
		Adjustment Reason	QH - Quantity Adjustment	*
Authorized Organization	Toronto University Health Network X			5
		Adjustment Notes	Manual Count	
				5
		Actual Adjustment Date	2021-02-25	m

Target Role: Inventory Manager

from vial", "Wastage", and "No Consent for Data

Collection Doses". For example, when performing a physical count

- 6) Extra Doses from Vial": Enter the quantity of extra doses from vial in this field and add the "Adjustment Reason", "Adjustment Notes" and "Actual Adjustment Date". Note: this will only be for lots of inventory received at 5 doses per vial. Since Pfizer has updated the vials to be 6 doses per vial, any shipments that had quantity received at 6 doses per vial will not require this adjustment.
- 7) "No Consent for Data Collection Doses": Enter the quantity of clients that did not consent to data collection and were therefore have no dose administration tracked in COVaxon, and and add the "Adjustment Reason", "Adjustment Notes" and "Actual Adjustment Date".



Users cannot modify total doses as these new fields accommodate the needs for adjustments.

Further Context

Note: if a transfer was made from one Authorized Organization to another Authorized Organization, and doses need to be returned back, an **inventory adjustment should be made instead of a transfer**.

When the inventory hits 0 doses available from being administered, the Inventory status will change to completed. If the Inventory Manager has not adjusted the total doses available for that inventory based on additional doses achieved from a vial, there will be a misalignment between actual doses and the doses in the system. To avoid delays to administering doses, the Inventory Manager will need to change the status of the inventory to available. Inventory can be administered if the doses available is 0 or negative, as long as the status is Available.



11. Managing Recalls

Description:

There are offline processes for communicating and handling vaccine recalls:

- Manufacturer determines there is an issue with a specified lot# and notifies Health Canada
- Health Canada identifies that a specified lot # had a higher AEFI rate than expected and notifies the provinces/territories
- Public Health Ontario may identify the source of an issue with a specified lot# and notify the ministry Health Canada (and often the manufacturer as well) will perform an investigation of the impacted lot and communicate to the Users (outside of the system) on next steps. **This is in the form of**

notice/recommendations to the province on further use of the vaccine (i.e. discard or lift the suspension so the vaccines can be distributed for use). Public Health Ontario/the Ministry of Health would inform the public health units who then inform their local providers (Users of COVaxon). Each location has a designated User (Super User or Inventory Manager) responsible for reflecting the recall within COVaxon. The User will follow the below process to recall the vaccine from the COVaxon system. For any locations where the impacted

Target Role: Inventory Manager

lot was transferred, it will need to be physically returned to the PHU and the User must recall all impacted inventory records.

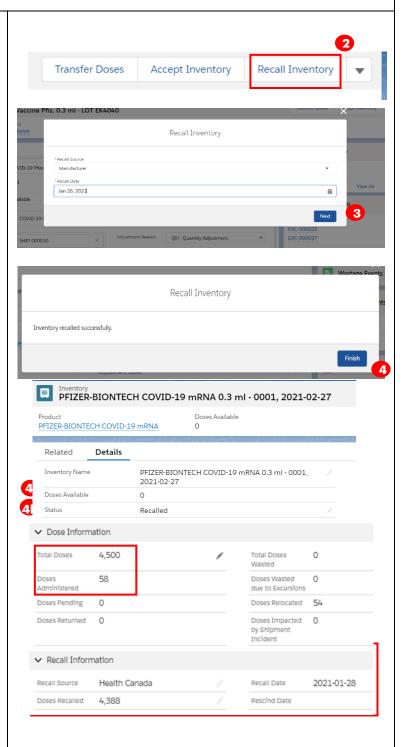
How:

- Identify the impacted lot # that has been recalled and all the associated inventory records (including any quantity that was transferred as a new inventory record from that lot to another location).
- 2) On the inventory page go to the right-hand corner and select "Recall Inventory" button
- 3) Recall Source: Select "Health Canada" Recall Date: Select the date that the lot was recalled.
- 4) Select "Next" and "Finish" the inventory recall record will then save, once saved the following occurs:
 - a. Available doses will now be set to 0 and in turn, the "Number of Doses Recalled" will be automatically populated with the previous number of doses that were available.
 - b. Inventory status will automatically update to "recalled"

In the example to the right, the user can see that the inventory record was comprised of 4500 doses. Before the recall, 58 doses had been administered. Once the product was recalled, the inventory status changed to "recalled" and the available doses became "O".

Based on the "recalled" status, vaccinators are now **unable** to administer additional doses, and under the Dose Information and Recall Information, users can see "4500 Total Doses, 58 Doses

Administered and 4388 Doses recalled"



Further Context

Target Role: Inventory Manager

- By saving the recall, this action will freeze the lot #s that were recalled and make the inventory unavailable for vaccinations. Functions like reporting wastage, excursion events, returning and transferring doses will also be unavailable. Therefore, the only way to "unfreeze" inventory is for a superuser to rescind a recall
- When the status is set to "Recalled" it cannot be changed to any other status. Only superusers will be able to modify the inventory record. Inventory Managers will be unable to edit a record once the status is changed from "available" to "recalled".
- When the status of an inventory record is changed to "Recalled", a notification will be sent to Super Users, Inventory Managers, Vaccinators and Site Staff (not Users with the Dashboard profile) in COVaxon so they are aware the recall has been reflected in the system and can no longer select that lot or administer doses. The notification is in the format of: Please note that [inventory name] has been recalled, this change is conducted by [last modified by]



Notifications

When inventory is in the recalled status, and additional doses are added to the "Total Doses" field, those additional doses will be added to the "Recalled Doses" quantity and will not be listed as available inventory. This can only be done by a Super User. The available inventory amount will continue to reflect O doses. This is to accommodate a situation whereby the number of total doses requires adjustment after a recall has already been made against that inventory. For example, when reconciling additional doses obtained from a vial, or other forms of inventory adjustments. **Note:** the best practice is to conduct adjustments on a regular basis, to avoid any lag in the inventory quantities reflecting the accurate inventory quantities.



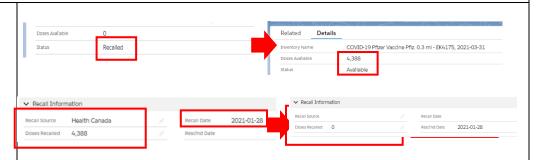
12. Rescinding a Recall

Description:

The PHU will advise of the outcome of the investigation and provide recommendations on the use of the vaccine (outside of COVaxon). If the investigation is cleared and there are no safety issues, they will notify all Users that the lot can be redistributed for administration. Only Site Super Users have the ability to rescind an inventory recall to reverse the recall and make the doses available in COVaxon.

How:

- 1. Change the status of the Inventory record from "Recalled" to "Available"
- 2. Enter the rescind date in the "Recall Information" section of the inventory page
- 3. Select Save
- 4. The doses that were initially recalled will now be associated to "Doses Available"



Note: If an inventory is recalled multiple times, users would need to remove the rescind date before recalling the inventory again. The history of the initial recall and rescind are captured in the inventory history.