



Fate Therapeutics FT576-101 Suvoda IRT Site User Training

**SYSTEM REGISTRATION | SUBJECT VISITS |
SHIPMENT RECEIPT | DRUG RECONCILIATION |
REPORTS & NOTIFICATIONS**

IRT VERSION 2.3.1 (PRESENTATION VERSION 0.2)

CONFIDENTIAL DOCUMENT

What is Suvoda IRT?

Investigative site users will use the Suvoda Interactive Response Technology (IRT) system to register subject screening, enrollment, and drug-dispensing visits.

Note that Suvoda IRT will be a separate component from the EDC system used to capture study subject data.

How will I be accessing Suvoda IRT?

You will be accessing Suvoda through an Internet browser.



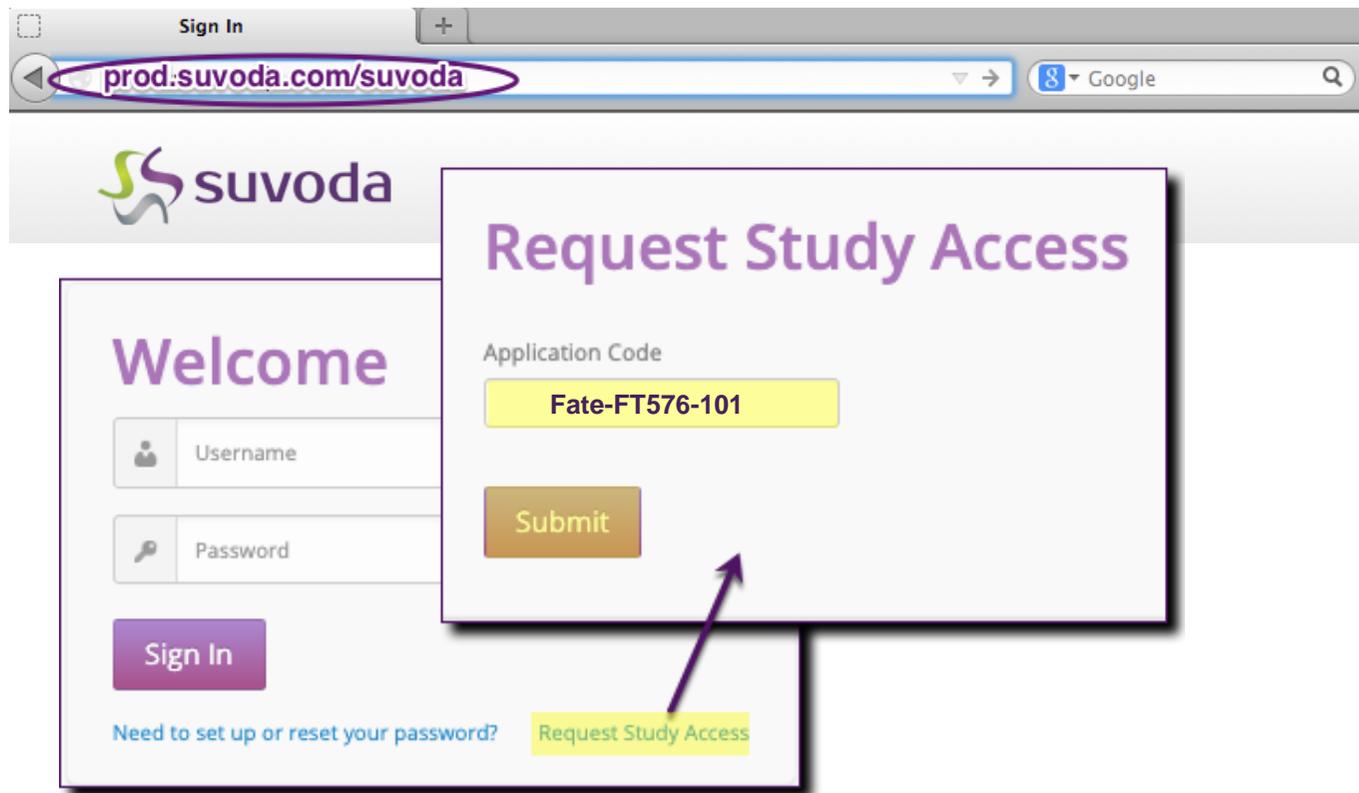
Recommended browsers to use are Mozilla Firefox and Google Chrome. Internet Explorer users may need to turn off Compatibility Mode before accessing the system.

I. Suvoda IRT Self-Registration

Users will create their own Suvoda account via a self-registration process and request access to the study-level system.

Requesting Study Access

1. Navigate to <https://prod.suvoda.com/suvoda>
2. Click Request Study Access
3. Enter Study Code: **Fate-FT576-101**



The screenshot shows a web browser window with the address bar containing prod.suvoda.com/suvoda. The page header includes the Suvoda logo. The main content area is divided into two sections: a 'Welcome' section on the left and a 'Request Study Access' section on the right. The 'Welcome' section contains a 'Sign In' button and a link for 'Need to set up or reset your password?'. The 'Request Study Access' section contains a form with the following elements:

- Request Study Access** (Section Header)
- Application Code
- Fate-FT576-101** (Application Code Input)
- Submit** (Submit Button)

A purple arrow points from the 'Request Study Access' link in the 'Welcome' section to the 'Request Study Access' form.

Option 1: Create New Suvoda Account

Create New Account
 Use Existing Account

Username *

First Name *

Last Name *

Email Address *

Site User? Yes No **Site Users Select 'Yes'**

Site

Inv. Last Name

Site City

Phone

Fax

Street

City

State

Zip

Country

Language *

Time Zone

I certify that this account reflects my identity and I acknowledge that using someone else's identity is considered fraud. I understand that the provided e-mail address is used to communicate sensitive information and should not be accessible to other users.

I certify that I have read and acknowledge the above statement

I have read and agree to [Suvoda's Privacy Policy and IRT Terms of Use](#)

Upon approval of your access request, you will receive instructions via email to set up your account password.

Check Acknowledgements

If your access request is approved, you will receive further instructions via email to set your password and complete your account set-up.

Option 2: Use Existing Suvoda Account

Create New Account

Use Existing Account 

User name *

Password *

Site User ? 

Site < Select >

Inv. Last Name

Site City

I certify that this account reflects my identity and I acknowledge that using someone else's identity is considered fraud. I understand that the provided e-mail address is used to communicate sensitive information and should not be accessible to other users.

I certify that I have read and acknowledge the above statement

Site Users Select 'Yes'

Check Acknowledgements

Access Request Approval

Upon submission of access request, a member of the sponsor administrative team will review and approve study access.

You will receive an email detailing whether your access request was approved/rejected.

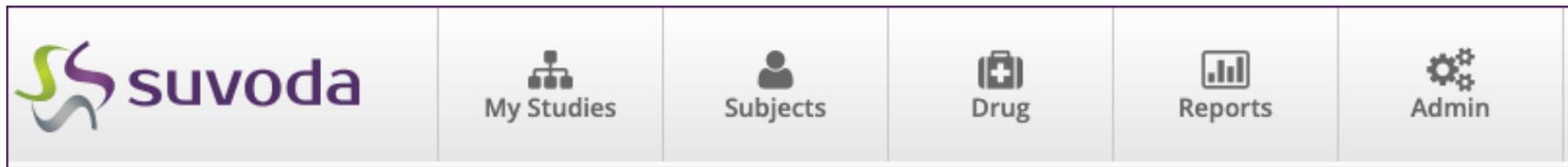
- If you do not receive this email, please check your SPAM/Junk mailbox for an email from suvodaIRT@suvoda.com
- If you do not locate the confirmation after checking your SPAM/Junk mailbox, please contact Suvoda Support for assistance.

II. IRT System Functionality

Overview of available functions for registering subject visits, receiving shipments, performing drug reconciliation steps, and viewing reports/notifications

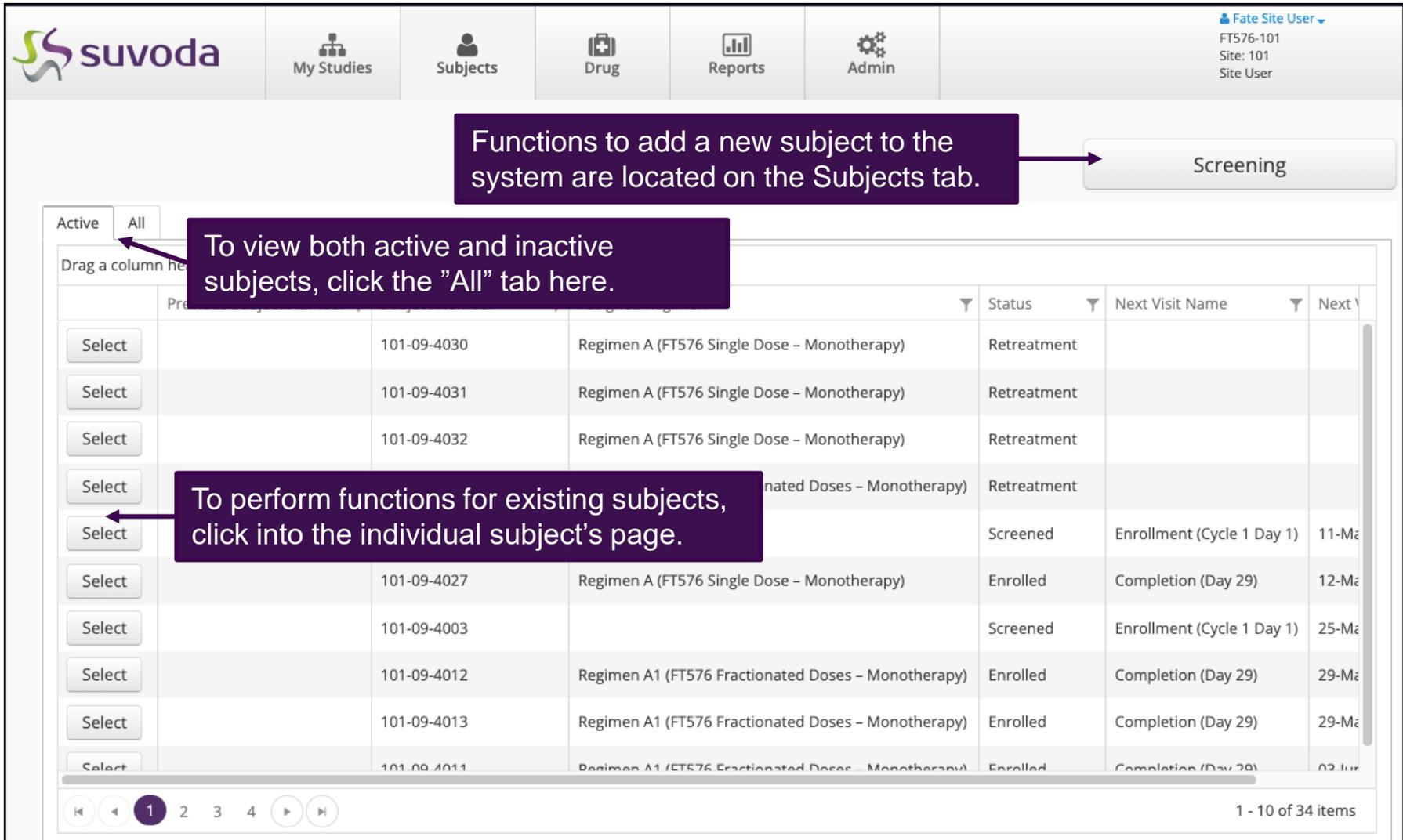
IRT System Navigation

The top-most toolbar will display the different areas of the application you can access as an investigator/site user. These may include the following:



- **My Studies** – view the protocols you can access with your account
- **Subjects** – perform subject-specific functions and drug dispensing
- **Drug** – receive shipments at site, update site inventory, and perform drug reconciliation steps
- **Reports** – access IRT reports and export functionality
- **Admin** – access notifications

Subject Functions



The screenshot shows the Suvoda web application interface. At the top, there is a navigation bar with the Suvoda logo and several menu items: My Studies, Subjects, Drug, Reports, and Admin. On the right side of the navigation bar, the user's identity is displayed as 'Fate Site User' with a dropdown arrow, and the site information 'FT576-101', 'Site: 101', and 'Site User' is shown below it.

The main content area is titled 'Subjects' and contains a table of subject records. Above the table, there are two tabs: 'Active' and 'All'. A callout box points to the 'All' tab with the text: 'To view both active and inactive subjects, click the "All" tab here.' To the right of the table, there is a 'Screening' button, with a callout box pointing to it that says: 'Functions to add a new subject to the system are located on the Subjects tab.'

The table has columns for 'Status', 'Next Visit Name', and 'Next V...'. Each row in the table has a 'Select' button on the left. A callout box points to one of these 'Select' buttons with the text: 'To perform functions for existing subjects, click into the individual subject's page.'

At the bottom of the table, there is a pagination control showing '1 - 10 of 34 items' and a set of navigation buttons (back, forward, first, last).

	Status	Next Visit Name	Next V...
Select	Retreatment		
Select	Screened	Enrollment (Cycle 1 Day 1)	11-Ma
Select	Enrolled	Completion (Day 29)	12-Ma
Select	Screened	Enrollment (Cycle 1 Day 1)	25-Ma
Select	Enrolled	Completion (Day 29)	29-Ma
Select	Enrolled	Completion (Day 29)	29-Ma
Select	Enrolled	Completion (Day 29)	02-Jun

Subject Functions

101-09-4060 | Screened

After selecting a specific subject, you can see their subject identifier and status here.

Subject Information

Subject Number 101-09-4060

Next Visit Name Enrollment (Cycle 1 Day) Next Expected Visit Date 01-Mar-2022

Visit Schedule

Visit Name	Expected Date (Range)	Actual Date	Drugs Assigned
Screening	-	01-Feb-2022	
Enrollment (Cycle 1 Day 1)	01-Mar-2022 (13-Feb-2022 - 12-Mar-2022)		

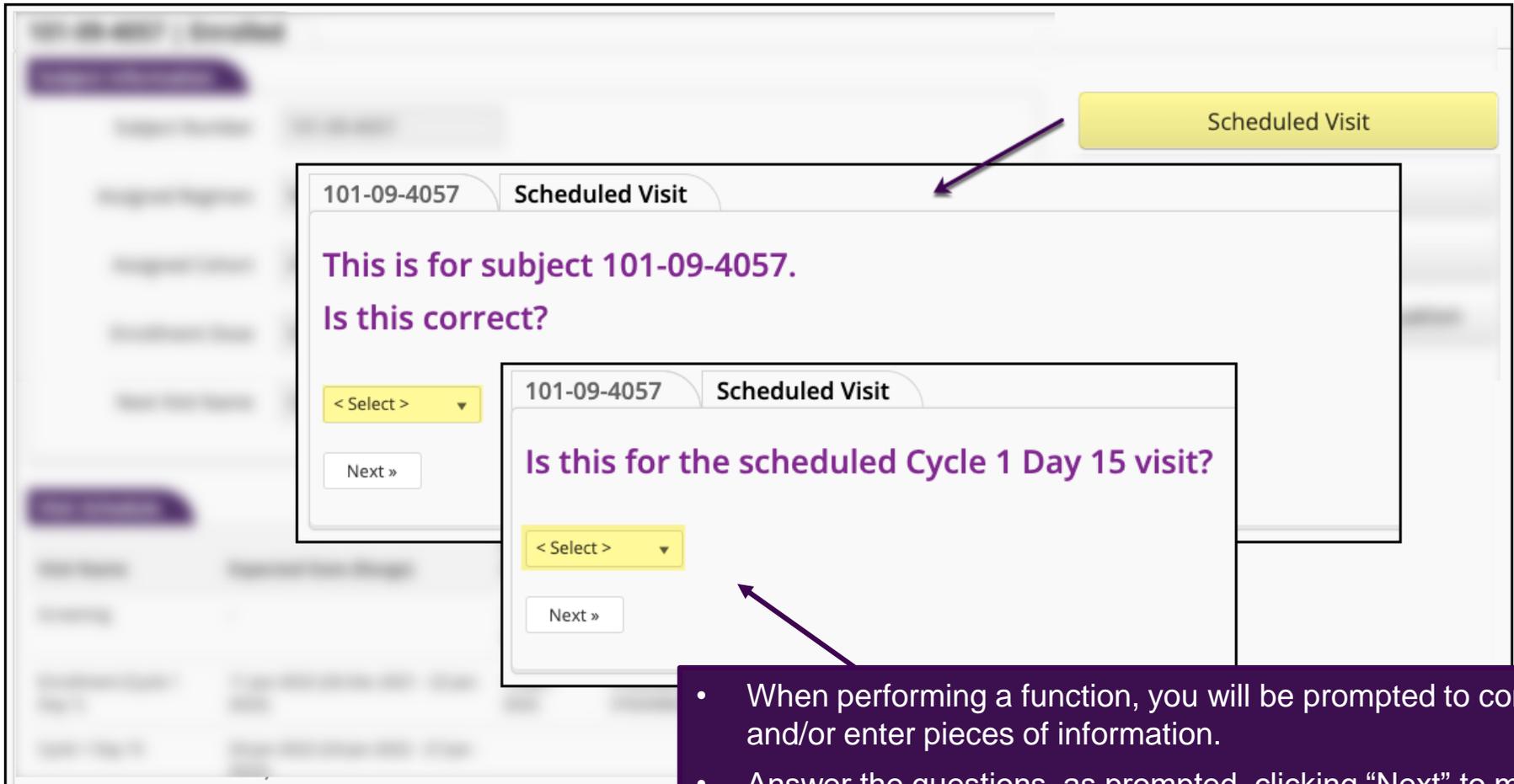
View visits that have been performed for this subject and upcoming scheduled visits.

Enrollment (Cycle 1 Day 1)

Screen Fail

Available functions that you can perform for a subject will appear here, varying based on your study design, your role, and on the subject's status.

Subject Functions



Scheduled Visit

101-09-4057 Scheduled Visit

This is for subject 101-09-4057.
Is this correct?

< Select >

Next >

101-09-4057 Scheduled Visit

Is this for the scheduled Cycle 1 Day 15 visit?

< Select >

Next >

- When performing a function, you will be prompted to confirm and/or enter pieces of information.
- Answer the questions, as prompted, clicking “Next” to move through the workflow.
- When you’ve reached the end of the workflow, you will receive a confirmation message that the transaction was completed.

Retreatment Visit

Subjects with evidence of clinical benefit may be eligible for additional retreatment cycles following the Completion (Day 29) visit. This function is used as a means of registering a retreatment visit after approval is received.

101-09-4002 | Completed - Initial

Subject Information

Subject Number

Assigned Regimen

Assigned Cohort

Enrollment Dose

Next Visit Name Next Expected Visit Date

Visit Schedule

Visit Name	Expected Date (Range)	Actual Date	Drugs Assigned
Screening	-	27-Apr-2021	
Enrollment (Cycle 1 Day 1)	25-May-2021 (09-May-2021 - 05-Jun-2021)	24-May-2021	57620083010000-125, 57620083010000-126
Completion (Day 29)	21-Jun-2021 (21-Jun-2021 - 24-Jun-2021)	21-Jun-2021	
Cycle 2 Day 1	24-Jun-2021		

Retreatment Visit

Site User Selected Drug IDs

- Based on the Assigned Dose Level you will be asked to select Drug Unit IDs for each Drug Type at all dispensing visits.
- Once you have made your selections, confirm your choice is accurate.

101-09-4055 **Scheduled Visit**

Please select the drug units to assign to the subject:

Drug Type	Quantity to Dispense	Drug Units
FT576 (5e+07 viable cells/unit)	3	<div style="background-color: yellow; height: 15px; width: 100%;"></div>
FT576 (3e+08 viable cells/unit)	0	57620083020003-153 57620083020003-155 57620083020003-157 57620083020003-158 57620083020003-159 57620083020003-160 57620083020003-161 57620083020003-162
FT576 (5e+08 viable cells/unit)	0	

Next »

101-09-4055 **Scheduled Visit**

You have indicated the following drug units should be dispensed to the subject:

Drug Type	Drug Units
FT576 (5e+07 viable cells/unit)	57620083020003-153, 57620083020003-155, 57620083020003-157

Is this correct?

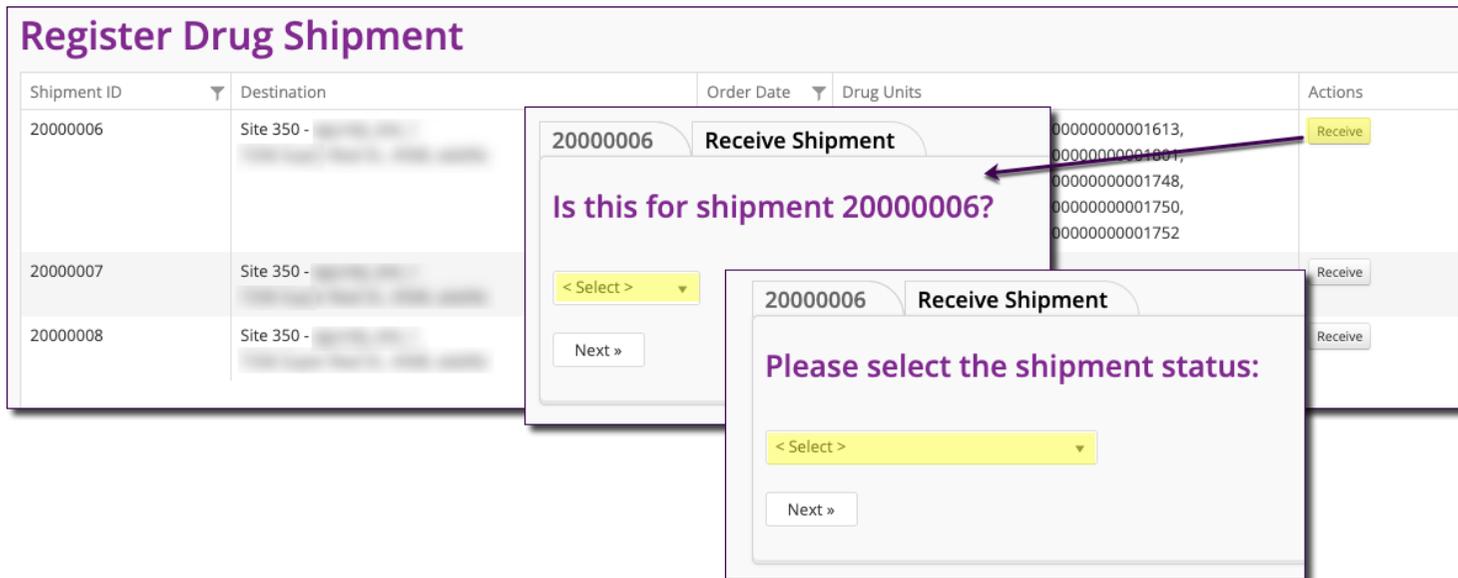
< Select > ▼

Next »

Drop-down displays Drug Unit IDs available at your site

Register Drug Shipment

To register shipments in the IRT system, select the “Register Drug Shipment” function > Click the “Receive” button to the right of the shipment you wish to register.



Register Drug Shipment

Shipment ID	Destination	Order Date	Drug Units	Actions
20000006	Site 350 - [blurred]		00000000001613, 00000000001661, 00000000001748, 00000000001750, 00000000001752	Receive
20000007	Site 350 - [blurred]			Receive
20000008	Site 350 - [blurred]			Receive

20000006 Receive Shipment

Is this for shipment 20000006?

< Select >

Next »

20000006 Receive Shipment

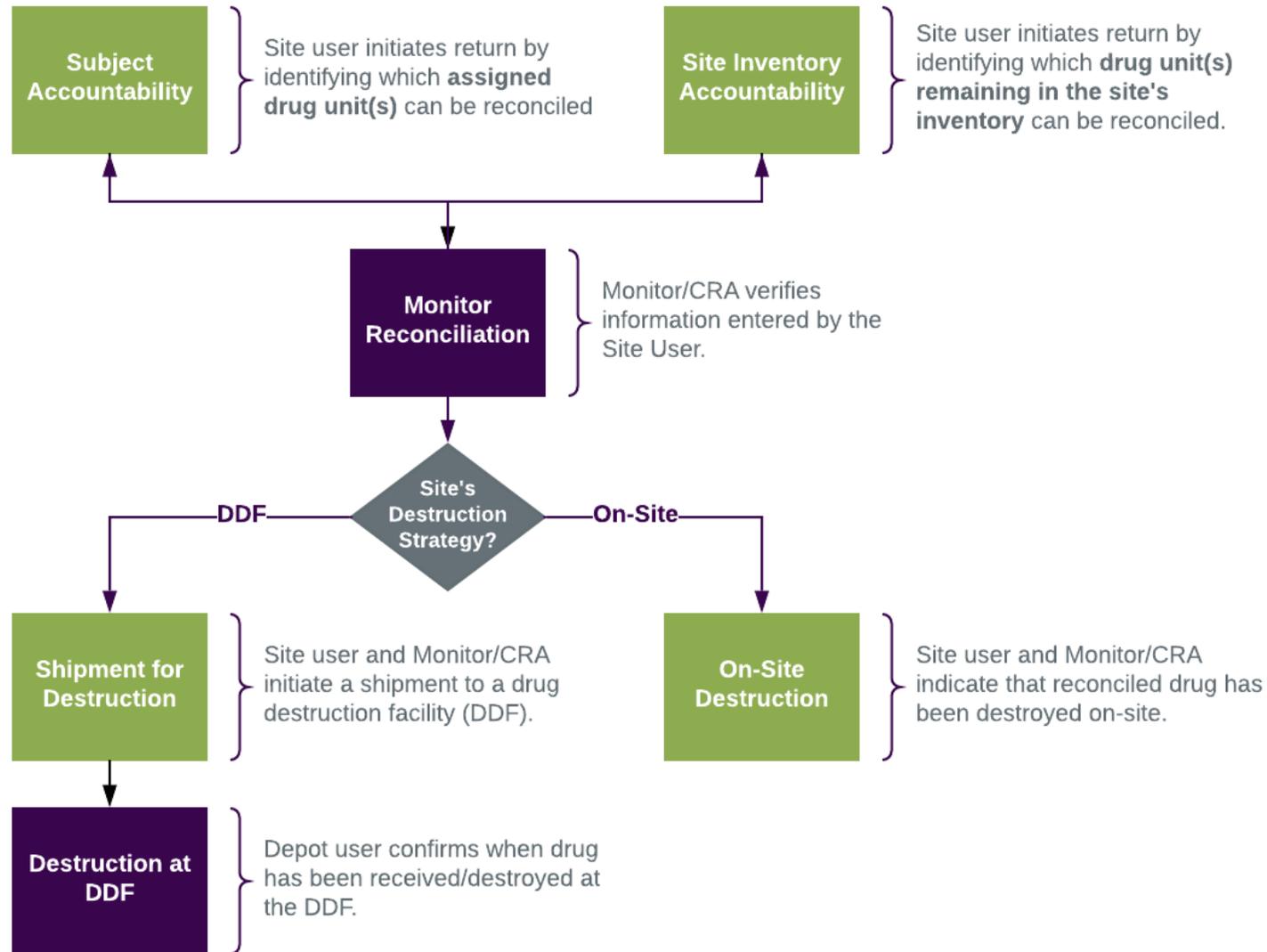
Please select the shipment status:

< Select >

Next »

- Click “Next” to proceed through the workflow and answer questions about the shipment’s status.
- When you’ve reached the end of the workflow, you will receive a confirmation message that the shipment was received in the system.

Drug Accountability & Destruction Overview



Subject & Site Inventory - Drug Accountability

Please note that in “Subject accountability”, the options should be selected as following:

- “Not Returned” - Product was missing.
 - (Quantity Dosed= 0, Quantity Remaining= 0, Quantity Missing= 1)
- “Returned – Used” – Product was dosed to patient.
 - (Quantity Dosed= 1, Quantity Remaining= 0, Quantity Missing= 0)
- “Returned – Unused” – Product was taken to bedside but later returned.
 - (Quantity Dosed= 0, Quantity Remaining= 1, Quantity Missing= 0)

Drug Destruction

Based on the destruction strategy assigned to your site, you perform either On-Site destruction or initiate a shipment for destruction to a return facility.

Destruction At Site

Site: Signature Process:

Serialized Drugs

<input type="checkbox"/>	Drug Unit ID	Unit Description	Reconciled Status	Quantity Remaining	Monitor Reconciliation Date	Site Comment	Monitor Comment
<input type="checkbox"/>	1000000...	Unit (1 Unit)	Unused	1	12-Aug-2021		

Site Signature
 By entering my username and password in the below fields I am applying my electronic signature to the destruction of the selected units.
 Username: *
 Password: *

Shipment For Destruction

Site: Signature Process:

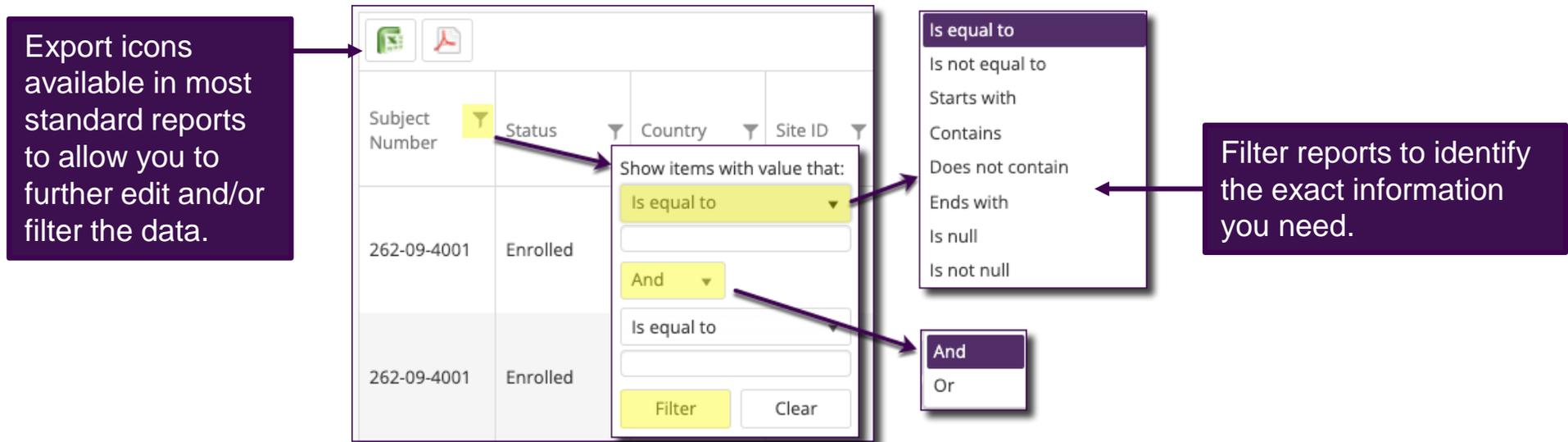
Serialized Drugs

<input type="checkbox"/>	Drug Unit ID	Unit Description	Reconciled Status	Quantity Remaining	Monitor Reconciliation Date	Site Comment	Monitor Comment
<input checked="" type="checkbox"/>	1000000...	Unit (1 Unit)	Unused	1	12-Aug-2021		

Tracking Number: *
 Courier: *
Site Signature
 By entering my username and password in the below fields I am applying my electronic signature to the shipment of the selected units for destruction.
 Username: *
 Password: *

Reports

- Pre-built reports available with information on subject visits, drug shipments, etc.
- Ad-hoc Report Builder tool allows users to create their own, custom reports using the datapoints captured by the IRT system.
- All reports can be viewed in the IRT system, with export options available on applicable reports.



The screenshot shows a report table with columns: Subject Number, Status, Country, and Site ID. Two rows of data are visible, both with Subject Number '262-09-4001' and Status 'Enrolled'. A filter dialog is open over the 'Status' column, showing 'Show items with value that:' followed by a dropdown menu set to 'Is equal to'. Below this are two input fields, one with 'And' as a connector. A 'Filter' button and a 'Clear' button are at the bottom of the dialog. To the right, a list of filter options is shown, including 'Is equal to', 'Is not equal to', 'Starts with', 'Contains', 'Does not contain', 'Ends with', 'Is null', and 'Is not null'. A separate dropdown shows 'And' and 'Or' options. Callout boxes provide context: one points to export icons (Excel and PDF) and another points to the filter options list.

Export icons available in most standard reports to allow you to further edit and/or filter the data.

Filter reports to identify the exact information you need.

Subject Number	Status	Country	Site ID
262-09-4001	Enrolled		
262-09-4001	Enrolled		

View/Re-Transmit Notifications

Once you click re-transmit, the system will send a copy of the notification to the email address associated with your user account in the system.

Notifications

E-mail Notifications

E-Mail Notifications

Drag a column header and drop it here to group by that column

Notification Type	Title	Generated On	Subject Number	Site	Depot	Country	Status	Select
Enrollment (Cycle 1 Day 1)	FT576-101: Enrollment (Cycle 1 Day 1) Confirmation - 350-09-4062	16-Sep-2021	350-09-4062	350		USA	Sent	View Retransmit
Screening	FT576-101: Screening Confirmation - 350-09-4061	15-Sep-2021						View Retransmit
Retreatment Visit	FT576-101: Retreatment Visit Confirmation - 350-09-4060	01-Sep-2021						View Retransmit
Completion (Day 29)	FT576-101: Completion (Day 29) Confirmation - 350-09-4060	28-Aug-2021						View Retransmit
Enrollment (Cycle 1 Day 1)	FT576-101: Enrollment (Cycle 1 Day 1) Confirmation - 350-09-4061	19-Aug-2021						View Retransmit

E-Mail Notifications
E-Mail Notification Details

Title: FT576-101: Screening Confirmation - 350-09-4061

Date/Time: 12-May-2021 11:52 PM

Transaction UTC Date Time	15-Sep-2021 01:00 PM
Transaction Local Date Time	15-Sep-2021 03:00 PM
User Name	[REDACTED]
Site Number	350
Investigator Last Name	Eevee
Subject Number	350-09-4061
Rescreened Subject	No
Screening Date	22-Jul-2021
Scheduled Enrollment (Cycle 1 Day 1) Date	19-Aug-2021

[Click here to view this subject's data.](#)

Close
Retransmit

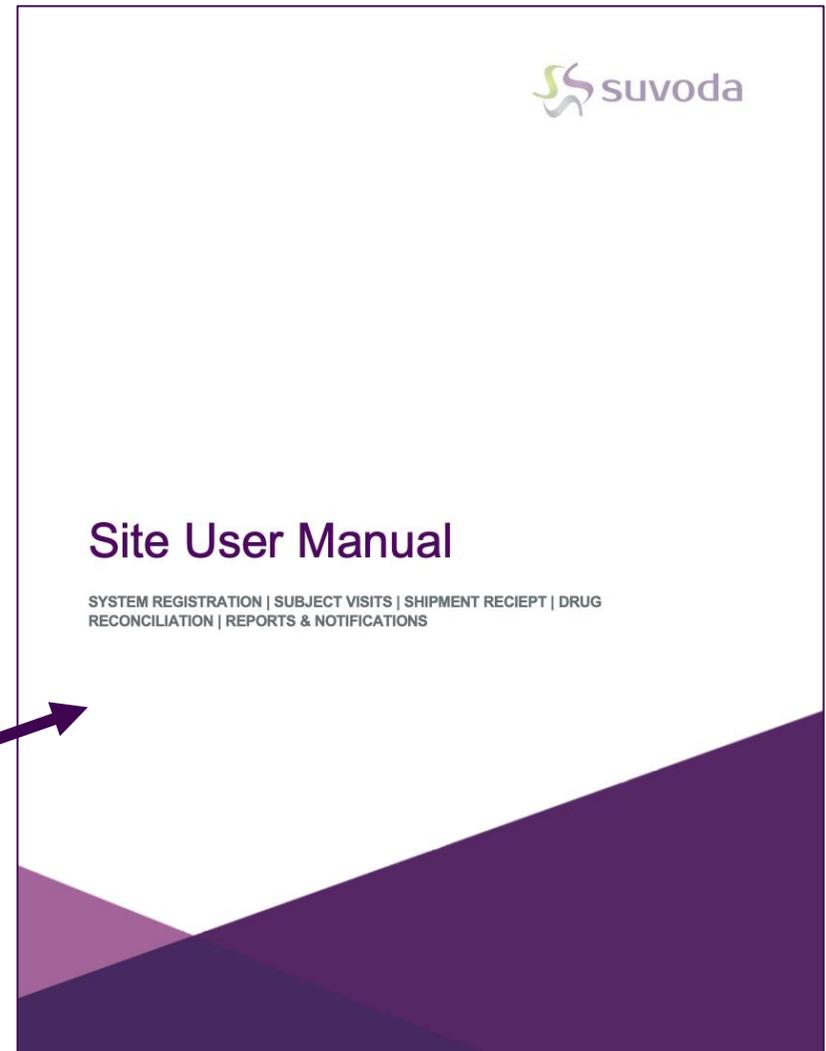
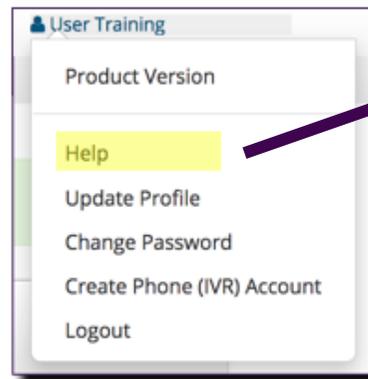
Contacting Suvoda Support

- **Why?** User access issues, data changes, general system questions
- **When?** 24/7, 365 days a year (including national/international holidays)
- **How?**
 - Email: support@suvoda.com
 - US Phone: 1-855-788-6321*
 - *Country specific toll-free numbers can be found at <https://www.suvoda.com/toll-free-numbers> (link provided in the Site User Manual)
 - For urgent issues, please call Suvoda Support in addition to sending an email. This will help lead to a timelier resolution.
- **What information do we need?**
 - Suvoda Username
 - Sponsor
 - Protocol
 - Site ID, Subject Number, any datapoints relevant to the situation

Additional Questions?

Access the Site User Manual in the “Help” section of Suvoda IRT.

1. Log into Suvoda IRT.
2. Click your name in the upper-right hand corner of the application.
3. Click “Help.”
4. View and download user manual.





Thank You

Contacts

Suvoda Support (support@suvoda.com)