



IRT User Manual

For Site Users

Prepared for:



E7389-G000-309

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Introduction

You have been provided access to the web-integrated Interactive Response System (IRT) for protocol E7389-G000-309. The instructions in this manual explain how and when to use the system to complete transactions and report events.

If at any time you have questions regarding the use of the system, please contact **IRT Support** 24 hours a day, 7 days a week.

Oracle IRT User Guide:

The User Guide provides an overview of the Oracle IRT application including details on how to navigate through the user interface and how to use the application to accomplish typical tasks you perform while running a clinical study.

This document is located in the upper-right corner of the main Oracle IRT application window. Click the Help icon to view the Oracle IRT User Guide.

To reach IRT Support:

- Dial the toll-free access number* and immediately select zero (0). Your call will be answered in the order it was received.
- Call IRT Support directly at +1877-487-7457. Your call will be answered in the order it was received.
- Email IRT Support at IRTSupport@phaseforward.com.

* IRT country-specific toll-free access numbers are available on page 6 of this manual and as a web-link in IRT (available on Home tab).

Materials you will receive

IRT Start-up Package

You have received an IRT start-up package that contains the following:

- User ID Envelope

You will receive User ID Envelope for every user at your site. One envelope needs to be provided to each user.

This envelope will contain a User ID and a default password (see below for more instructions).

IRT System User Authentication Form

You have also received a System User Authentication Form containing your personal User Authentication Code (UAC). This was sent to you via e-mail or fax (if no email address is available).

You will only need this form the first time you log in to the IRT (see below for more instructions).

If you did not receive the UAC, please contact your monitor to have it re-sent.

IMPORTANT:

- Your User ID and Password **must be kept confidential** at all times and **may NOT be shared** with anyone else.
- Please retain your User ID card through the entire course of the study. In case you forget your password, your password will be reset to this default password.
- If at any time you lose your Password or believe that someone else has access to it, please contact your CRA or IRT Support.
- If a User ID card was open or unsealed when you received it please contact your CRA or IRT Support immediately.

Logging in to the system

User ID and Password

Please choose a **User ID Card** that has been provided to your site; and have your personal **User Authentication Form** ready.

User ID:	[6-digit]
Password:	[5-digit] default
UAC:	[8-digit]

Web Login

INITIAL LOGIN PROCESS:

- 1) Browse to **http://irt.webcrf.net**
- 2) Enter your User ID and the password that are on the User ID Card.
Press *Enter* to continue.
- 3) You will be asked to enter a new 5-digit password and confirm.
Press *Update Password* to continue.
- 4) You will be asked to establish a 4-digit Personal Identification Number (PIN) and confirm.
Press *Submit* to continue.
- 5) Once you have successfully established your PIN, you will see the link for your protocol.
- 6) Once you click the protocol link, you will be asked to enter the User Authentication Code found on the User Authentication Form.
Press *Continue* to proceed.
- 7) You will be asked to enter your site number.
Press *Continue* to proceed.
- 8) Once you have successfully logged into the protocol, you will have access to the navigation panel and transaction tabs.

SUBSEQUENT LOGIN PROCESS:

- Browse to **http://irt.webcrf.net**
- Enter your User ID and your password. Press *Enter* to continue.
- Select the protocol link: E7389-G000-309
- Once you have successfully logged into the protocol, you will have access to the navigation panel and transaction tabs.

Phone Login

INITIAL LOGIN PROCESS:

- 1) Dial your country-specific toll-free number:

Country	Toll-free number
Argentina	08004441255
Australia	1800064850
Austria	0800296404
Belgium	080077451
Brazil	08008922174
Canada	(877) 339-4883
Chile	12300209366
Czech Republic	800700259
Denmark	80887378
France	805540276
Germany	0800 6644681
India	0008001007829
Israel	1809451255

Country	Toll-free number
Italy	800 917713
Netherlands	0800 0201185
New Zealand	0800449433
Poland	008004411961
Romania	8776850310
Russia	81080020332012
Singapore	8001012444
South Korea	00798142051255
Spain	900957899
Thailand	0018001562051255
United Kingdom	0800 876 6956
USA	(877) 859-2991

- 2) You will hear the following welcome message: "Welcome to the Phase Forward Interactive Response Technology System".
- 3) Enter **909** when asked for the 3-digit Study Code, or enter 0 for Support.
- 4) Select the language in which you want to continue by entering the 2-digit language code found in the table below.

5)

ID	Language
01	English
02	French
05	German
06	Italian
08	Portuguese
09	Spanish: Castillian
10	Spanish: Latin American
14	Czech

Country	Language
24	Polish
25	Romanian
26	Russian
45	Korean

- 6) Enter your User ID and password
- 7) You will be asked to enter a new 5-digit password and confirm.
- 8) You will be asked to establish a 4-digit Personal Identification Number (PIN)

- 9) You will be asked to enter the User Authentication Code found on the User Authentication Form.
- 10) You will be asked to enter your site number.
- 11) Once you have successfully logged into IRT, you will hear the following:
“Welcome to the Phase Forward Interactive Response Technology System for Protocol E7389-G000-309”
- 12) You will then hear the Main Menu.

SUBSEQUENT LOGIN PROCESS:

- Dial your country-specific toll-free number
- You will hear the following welcome message: “Welcome to the Phase Forward Interactive Response Technology System”.
- Enter **909** when asked for the 3-digit Study Code, or enter 0 for Support.
- Select the Language in which you want to continue.
- Enter your User ID and your password.
- You will be routed to the Transaction Main Menu

Transaction Main Menu

*****only applicable for the Investigator and the Study Coordinator*****

*****only applicable for the Investigator and the Site Coordinator*****

You will hear the following Main Menu Transaction choices

- Subject Menu, press 1
- Supplies Menu, press 2
- To Exit the System, press 0

For Subject-related activities you will then hear the following Main Menu choices:

- To Register a Subject into Screening, press 1
- To Register a Subject as a Screen Failure, press 2
- To Randomize a Subject, press 3
- To Register a Scheduled Visit, press 4
- To Register A Drug Replacement, press 5
- To Register an Off Treatment, press 6

Helpful hints for using the IRT system

Password and Initial Login:

- When you login to the system (either phone or web) for the first time with your User ID and default password (on User ID envelope), you will be asked to enter a new 5-digit password. Once changed, the password is the **same** for both the telephone and the Internet. You can change your password at any time by selecting the '**Change password**' option via the web. If you forget your password, select the '**Click here if you have forgotten your password**' link. Note that your **password will expire every 180 days**. The system will ask you to choose a new password at that time.
- When accessing a study protocol for the first time you will also be required to authenticate yourself to activate your access. You will be asked to enter your User Authentication Code (located on the User Authentication Form that was sent to you via fax or email) to proceed to the Main Menu. Please also complete and sign the User Authentication Form and maintain it with the study records to complete the authentication process.
- The system will ask you to establish and confirm a four-digit Personal Identification Number (PIN) for security purposes. This PIN will be used to identify you in case of a password re-set or for system-access related inquiries when you contact IRT Support. You can change your PIN at any time by selecting the '**Change PIN**' option via the web.

Confirmation Notification Preferences:

- After you complete a transaction in the IRT system, you will receive a written notification for the transaction. You will receive the notification by fax and/or e-mail, to the fax number and/or e-mail address as specified in your User Contact Information. You should retain these notifications for your study files.
- At any time during the study, you may change the method by which you receive confirmation notifications and alerts from the IRT system. To change your notification receipt preference, please use the '**Update Contact Information**' function available via the web. Note that r notifications will be sent via both email and fax if both your email address and fax number are provided in this section.
- All confirmation notifications can be re-transmitted via the web function '**Re-transmit Notification**'

Automatic Logout

- If the web-based system detects no activity for a period of 5 minutes, an automatic logout will occur. If you re-enter your User ID and Password, you will be returned to the function you were accessing when the timeout occurred.

Home Tab

Task Alerts (Web Only)

Upcoming visit information, warnings and other alerts specific to your role, location, and permissions are available on the Task Alerts page. Depending on your role, a listing of scheduled transactions may appear. Each alert is also a link to the specified transaction so that you can navigate immediately to the appropriate location in the system.

Enrollment Summary Report (Web Only)

This report displays the study and site totals in graph format and itemized listing per site.

Contact Information (Web only)

This function will allow you to change your contact information that is stored in our database. Once you click on the link, you will be able to change your e-mail address, fax number, etc...

On the title bar, click the Home tab.

On the navigation pane, click the Contact Information function

The system displays the following information:

First Name	Text box: edit your first name
Middle Initial	Text box: edit your middle initial
Last Name	Text box: edit your last name
Title	Text box: edit your title
Company	Text box: edit your company
E-mail	Text box: edit your e-mail address
Phone	Text box: edit your phone number - do not enter dashes
Fax	Text box: edit your fax number – do not enter dashes *
Address	Text box: edit your address
City	
State	
Zip code	
Country	
Language	Dropdown listing available languages
Time Zone	Dropdown of all timezones **
Phone Date Format	Dropdown: edit the way in which you enter dates (DD-MM-YYYY or MM-DD-YYYY)

* You must enter the fax number including 011, the country code and area code if located outside the USA and Canada. For example for Belgium Brussels, enter 011322XXXX; for UK

London, enter 01144208XXXX

*** This is the local time from GMT that will be reflected on written notifications. By default the timezone will be set as that of your location. Users will need to ensure they select the correct local time based off of the Greenwich Mean Time for their location. Changes to day light savings will required the user to update their local time at the user level to ensure the correct local time appears on subject activity related confirmation notifications. The following website can be used to assist you in selecting the correct local time <http://www.greenwichmeantime.com>*

Once you edit any data and click **Submit**, the system displays the message "Data Saved, Form has been submitted" indicating that the transaction is successful.

If there is an email address and fax number available, you will receive confirmation notifications via fax and email. You can delete your fax number if you wish to receive reports only via email.

Notifications (Web Only)

If you have not received a confirmation notification (e.g. Screening a subject), you can have this retransmitted to you.

On the title bar, click the Home tab.

On the navigation pane, click the Notifications function

The system allows you to select a notification by either of the following:

IRT asks for	You enter
Retransmission Type	Dropdown selection: By Notification Number, By Subject, By Notification Type

If you selected '**By Notification Number**':

- Enter the notification number in the text box and hit the Tab button

If you selected '**By Subject**':

- Select a subject number from the dropdown list
- This results in a dropdown list of all previously transmitted notifications for this subject
- Select the notification you would like to re-transmit

If you selected '**By Notification Type**':

- Select a notification type from the dropdown list
- This results in a dropdown list of all previously transmitted notifications from this type
- Select the notification you would like to re-transmit

Once you selected a notification, it will appear on screen for review.

Select in the dropdown list to which user you want to re-transmit the notification.

When you click **Re-transmit**, the system displays a message indicating that the notification has been resent.

Site User Manual (Web Only)

The site user manual is available for this protocol, to access the manual:

- On the title bar, click the Home tab.

- On the navigation pane, click the Site User Manual function.

Toll-Free Access Numbers (Web Only)

A list of toll-free numbers available for this protocol, to view the list:

- On the title bar, click the Home tab.

- On the navigation pane, click the Toll Free Access Numbers function.

Subjects Tab

Screening

This option will be used **to register a subject's screening** in IRT. Once all subject details have been entered, the system will assign a subject screening number. This will be 4 digits Side ID + 4 digits starting with 1001.

WEB:

On the title bar, click the **Subjects** tab.

Click on the **Screening** button.

The system requests the following information:

IRT asks for	You enter			
	Phone	Web		
Subject's Date of Birth	Date of Birth in the form DDMMYYYY	Date of Birth in the form MM/DD/YYYY		
Initials	6-digit initials code:	First, Middle and Last initial		
	A	B	C	D
	01	02	03	04
	E	F	G	H
	05	06	07	08
	I	J	K	L
	09	10	11	12
	M	N	O	P
	13	14	15	16
	Q	R	S	T
	17	18	19	20
	U	V	W	X
	21	22	23	24
	Y	Z	Dash	
	25	26	27	
		Note: For the countries listed below due to restrictions on collecting patient initials and date of birth together, the patient initials are entered but not saved in the system. Dummy initials are automatically generated by the IRT system.		
		Austria (AUT), Belgium (BEL), Czech Republic (CZE), Germany (GER), Italy (ITA), Netherlands (NED), Spain (ESP).		

IRT asks for	You enter	
	Phone	Web
Gender	Press 1 for Male Press 2 for Female	Dropdown: Male/Female
New subject? <i>Only for subjects that have the same demographics as a subject that has already been screened.</i>	Press 1 for Yes Press 2 for No <i>If 'No', follow to the next question.</i>	Dropdown: Yes/No <i>If 'No', follow to the next question.</i>
Re-screen? <i>If identical DOB and initials are entered as for an existing subject, the system will ask if this is a new subject or if this is an existing subject being re-screened. If a subject failed screening but later became eligible for the study and is re-screened, a new subject number is assigned for the re-screened patient.</i>	Press 1 for Yes Press 2 for No <i>If you select No, you will return to the Main Menu</i>	Dropdown: Yes/No <i>If you select No, you will return to the Main Menu</i>
Screening Date	Screening date in the form DDMMYYYY	Screening date in the form MM/DD/YYYY

Once you have entered and confirmed all the required information for the Subject, the system assigns the Subject Number. You will be given the following information:

“This Subject has been assigned number ____.”

IRT will tell you the screening is confirmed and you will return to the Main Menu. You will also receive a Screening Confirmation Report

Screen Failure

If a subject is not eligible for randomization, the subject will have to be registered as a **screen failure**.

WEB:

On the title bar, click the **Subjects** tab.

On the navigation panel, click the **Subject Transactions** function.

Locate the subject number, click on 'V' next to the subject number, and then click on **Screen Fail**.

The system requests the following information:

IRT asks for	You enter	
	Phone	Web
Subject Number	8-digit Subject Number	Dropdown: all Subjects in screening at your site
Confirm Subject Details <i>The IRT will tell you the demographics captured for this Subject. You must confirm that these are correct</i>	Press 1 for Yes Press 0 for No <i>If you select No, you will return to the Main Menu</i>	Dropdown: Yes/No <i>If you select No, you will return to the Main Menu</i>
Screen Fail Date	Screen fail date in the form DDMMYYYY	Screen fail date in the form MM/DD/YYYY

Once you have entered and confirmed all the required information, the system confirms the screen failure. You will also receive a Screen Failure Confirmation Report

Randomization (Baseline Visit)

This function is used to **randomize** a subject into the study.

If a drug order has been shipped to your site you may receive the following warning message, but you will be able to continue with the current transaction:

“Our records indicate that a Drug Order is in transit to your site. Once delivered, please register it in the Interactive Voice Response System as received to update your drug inventory.”

Note: Randomisation function is only completed by IRT when sufficient supplies of both treatment arms are available at site. If supplies are insufficient, there will be a warning note at the start of the randomisation process. In this case, please check if there are any outstanding drug orders to be confirmed as received, or if a drug order is in transit, or contact the CRA.

WEB:

On the title bar, click the **Subjects** tab.

On the navigation panel, click the **Subject Transactions** function.

Click on ‘V’ next to the subject number, and then click on **Randomization**.

The system requests the following information:

IRT asks for	You enter	
	Phone	Web
Subject Number	8 digit Subject Number	Dropdown: all Subjects in screening at your site
Confirm Subject Details <i>The IRT will tell you the demographics captured for this Subject. You must confirm that these are correct</i>	Press 1 for Yes Press 0 for No <i>If you select No, you will return to the Main Menu</i>	Dropdown: Yes/No <i>If you select No, you will return to the Main Menu</i>
Dacarbazine Dose?	Select the Dacarbazine dose. For 850 mg/m ² , press 1. For 1000 mg/m ² , press 2. For 1200 mg/m ² , press 3.	Select the Dacarbazine dose. Dropdown: 850 mg/m ² / 1000 mg/m ² / 1200 mg/m ²

Histology Stratum?	Provide the Subject's primary tumor diagnosis. For Adipocytic, press 1. For Leiomyosarcoma, press 2.	Provide this Subject's primary tumor diagnosis. Dropdown: Adipocytic / Leiomyosarcoma
Chemotherapy Regimen ?	Indicate the number of prior chemotherapy regimens for this Subject. For 2 prior regimens, press 1. For >2 prior regimens, press 2.	Indicate the number of prior chemotherapy regimens for this Subject. Dropdown: 2 Prior Chemotherapy regimens / >2 Prior Chemotherapy regimens
BSA?	Enter the Body Surface Area value for this Subject with one digit and two decimals, using the star for the decimal point.	Enter the Body Surface Area value for this Subject with one digit and two decimals.

Once you have entered and confirmed all the required information, you will receive the drug assignment for this Subject. You will be given the following information:

“Subject has been assigned to treatment arm ____ with Randomization number ____.

**Please dispense <QtyOfDrug> to the Subject by taking <QtyOfVials> of
<DrugUnitDescription> and <QtyOfVials> of <DrugUnitDescription> and <QtyOfVials> of
<DrugUnitDescription>.”**

IRT will tell you the randomization is confirmed and you will return to the Main Menu. You will also receive a Randomization Confirmation Report for the Subject.

If the Vial assigned is missing, damaged, or cannot be dispensed to the Subject, please use the function **Drug Replacement** to receive a new Vial (see below)

Scheduled Visit

If a drug order has been shipped to your site you may receive the following warning message, but you will be able to continue with the current transaction:

“Our records indicate that a Drug Order is in transit to your site. Once delivered, please register it in the Interactive Voice Response System as received to update your drug inventory.”

WEB:

On the title bar, click the **Subjects** tab.

On the navigation panel, click the **Subject Transactions** function.

Click on ‘V’ next to the subject number, and then click on **Scheduled Visit**.

The system requests the following information:

IRT asks for	You enter	
	Phone	Web
Subject Number	8-digit Subject Number	Dropdown: all randomized Subjects at your site
Confirm Subject Details <i>The IRT will tell you the demographics captured for this Subject. You must confirm that these are correct</i>	Press 1 for Yes Press 0 for No <i>If you select No, you will return to the Main Menu</i>	Dropdown: Yes/No <i>If you select No, you will return to the Main Menu</i>
Confirm Cycle Number <i>The IRT will tell you the current Cycle Number for this Subject. You must confirm that this is correct</i>	Press 1 for Yes Press 0 for No	Dropdown: Yes/No
Scheduled Visit Date?	Scheduled Visit date in the form DDMMYYYY	Scheduled Visit date in the form MM/DD/YYYY
Out of Visit window – do you wish to continue? <i>Note: only for subjects for which the system calculated that the subject is outside of window</i>	Press 1 for Yes Press 0 for No <i>If you select No, you will return to the Main Menu</i>	Dropdown: Yes/No <i>If you select No, you will return to the Main Menu</i>

Once you have entered and confirmed all the required information, you will receive the drug assignment for this Subject.

You will be given the following information:

“Please dispense <QtyOfDrug> to the Subject by taking <QtyOfVials> of <DrugUnitDescription> and <QtyOfVials> of <DrugUnitDescription> and <QtyOfVials> of <DrugUnitDescription>.”

IRT will tell you the drug assignment is confirmed and you will return to the Main Menu. You will also receive a Scheduled Visit Confirmation Report.

If the Vial assigned is missing, damaged, or cannot be dispensed to the Subject, please use the function **Drug Replacement** to receive a new Vial (see below)

Drug Replacement (Web only)

If a vial size assigned is **missing** or **damaged**, please use this function to assign different vial sizes.

WEB:

On the title bar, click the **Subjects** tab.

On the navigation panel, click the **Subject Transactions** function.

Click on 'V' next to the subject number, and then click on **Drug replacement**.

The system requests the following information:

IRT asks for	You enter	
	Phone	Web
Subject Number	N/A	Dropdown: all randomized Subjects at your site
Confirm Subject Details <i>The IRT will tell you the demographics captured for this Subject. You must confirm that these are correct</i>	N/A	Dropdown: Yes/No <i>If you select No, you will return to the Main Menu</i>
Vial type?	N/A	Select the type of vial that needs to be replaced. Dropdown: last assigned Vial types.
Lot ID?	N/A	Select Lot ID of the units you wish to replace Dropdown: all available lots of selected drug type
Quantity of Vials to be replaced?	N/A	Enter the quantity of <DUType> vials that need to be replaced.
Status of this Vial	N/A	Enter the status of the vials. Dropdown: damaged/missing.

Once you have entered and confirmed all the required information, you will receive the new assignment of the number of vials for the vial sizes.

You will be given the following information:

“Please dispense <Qty> vials of <DUType1> and <Qty> vials of <DUType2> <Qty> vials of <DUType3> to the Subject.”

IRT will tell you the drug assignment is confirmed and you will return to the Main Menu. You will also receive a Trial Supply Replacement Confirmation Report.

Off Treatment

Use this function for Subjects who have **withdrawn** from the study treatment.

Please ensure to report Off Treatments immediately, to ensure we do not continue to provide your site with drug for this Subject.

WEB:

On the title bar, click the **Subjects** tab.

On the navigation panel, click the **Subject Transactions** function.

Click on 'V' next to the subject number, and then click on **Off Treatment**.

The system requests the following information:

IRT asks for	You enter	
	Phone	Web
Subject Number	8-digit Subject Number	Dropdown: all randomized Subjects at your site
Confirm Subject Details <i>The IRT will tell you the demographics captured for this Subject. You must confirm that these are correct</i>	Press 1 for Yes Press 0 for No <i>If you select No, you will return to the Main Menu</i>	Dropdown: Yes/No <i>If you select No, you will return to the Main Menu</i>
Date of the last dose?	Date of last dose in the form DDMMYYYY	Date of last dose in the form MM/DD/YYYY

Once you have entered and confirmed all the required information, the system confirms the Off Treatment. You will also receive an Off Treatment Confirmation Report

Edit Subject Data (Web Only)

If you entered Subject information incorrectly, you can correct certain data fields via this function. Certain data fields are blocked for editing/deletion by the site staff, and so in this case please contact the CRA or IRT Support.

WEB:

On the title bar, click the **Subjects** tab.

On the navigation panel, click the **Subject Transactions** function.

Click on 'V' next to the subject number, and then click on **Edit Subject Data**.

You will be asked to select the Subject Number from a dropdown list. You will then be able to make the below edits:

Data point	Edit
Date of Birth	Yes
Initials	Yes
Gender	Yes
Screen Fail Date	Yes
Screen Fail Reason	Yes
Off Treatment Date	Yes
Off Treatment Reason	Yes

When you edit data, you will be asked to enter a reason for the change. When you click **Submit**, the system displays a message indicating that the transaction is successful.

You will also receive an Edit Subject Data Confirmation Report

Supplies Tab

Register Drug Order Receipt (Web only)

Every time you receive a drug order, **receipt needs to be registered** in IRT. From this moment on, the drug can be dispensed to Subjects.

WEB:

On the title bar, click the **Supplies** tab.

On the navigation panel, click the **Drug Order: Order Transaction** function.

Click on 'V' next to the drug order, and then click on **Confirm receipt**.

The system requests the following information:

IRT asks for	You enter	
	Phone	Web
Drug Order Number	N/A	Dropdown: all drug orders in transit to your site
Drug Order Complete and Undamaged?	N/A	Dropdown: Yes/No <i>If you select Yes, the shipment request will be confirmed as 'available'. If you select No, the next question will be asked</i>
Temperature Excursion Occur?	N/A	Dropdown: Yes/No <i>If you select Yes, the shipment request will be confirmed as 'quarantined'. If you select No, the next question will be asked</i>
Entire Drug Order Damaged?	N/A	Dropdown: Yes/No <i>If you select Yes, the shipment request will be confirmed as 'damaged'. If you select No, the next question will be asked</i>
Entire Drug Order Missing?	N/A	Dropdown: Yes/No <i>If you select Yes, the shipment request will be confirmed as 'missing'. If you select No, the next question will be asked</i>

IRT asks for	You enter	
	Phone	Web
Vial type?	N/A	Select the type of vial that needs to be replaced. Dropdown: last assigned Vial types.
Lot ID?	N/A	Select Lot ID of the units you wish to replace Dropdown: all available lots of selected drug type
Quantity of Vials to be replaced?	N/A	Enter the quantity of <DUType> vials that need to be replaced.
Status of this Vial	N/A	Enter the status of the vials. Dropdown: damaged/missing.

IRT will tell you the drug shipment is confirmed and you will return to the Main Menu. You will also receive a Register Drug Order Receipt Confirmation Report.

Please note that Vial cannot be assigned to Subjects until shipments are confirmed. Please confirm each order immediately upon receipt.

Re-supply of Vial will be processed regularly by the IRT system.

NOTE: If you have not registered receipt of a drug order after a certain period of time, an alert report will be sent to you asking you to confirm the drug order. If you have not received a drug order and receive this alert, please contact IRT Support immediately so we can trace the whereabouts of the order.

Update Site Inventory (Web only)

Whenever drug is missing or damaged after you confirmed a drug shipment, this needs to be reported in the IRT system to prevent this drug from being dispensed to a Subject. This will also ensure an adequate drug resupply to your site.

WEB:

On the title bar, click the **Supplies** tab.

On the navigation panel, click the **Inventory: Update Site Inventory** function.

The system requests the following information:

IRT asks for	You enter	
	Phone	Web
Entire Inventory Temperature Excursion?	N/A	Dropdown: Yes/No <i>If you select Yes, your entire inventory will be confirmed as 'quarantined'. If you select No, the next question will be asked</i>
Entire Inventory Damaged?	N/A	Dropdown: Yes/No <i>If you select Yes, your entire inventory will be confirmed as 'damaged'. If you select No, the next question will be asked</i>
Entire missing?	N/A	Dropdown: Yes/No <i>If you select Yes, your entire inventory will be confirmed as 'missing'. If you select No, the next question will be asked</i>
Lot ID?	N/A	Select Lot ID of the units you wish to replace Dropdown: all available lots of selected drug type
Quantity	N/A	Enter the number of Vials in lot that need a status update
Status	N/A	Dropdown: Damaged/Missing/ Temperature Excursion Select vial status

IRT asks for	You enter	
	Phone	Web
Another Quantity?	N/A	Dropdown: Yes/No <i>If you select Yes, it will go back to the Quantity question. If you select No, the next question will be asked</i>
Another Lot?	N/A	Dropdown: Yes/No <i>If you select Yes, it will go back to the Lot question. If you select No, the next question will be asked</i>
Another Drug Type?	N/A	Dropdown: Yes/No <i>If you select Yes, it will go back to the Drug Type question. If you select No, it will complete the transaction</i>

IRT will tell you the inventory is updated and you will return to the Main Menu. You will also receive an Update Site Inventory Confirmation Report.

Reports Tab

You will have the ability to view standard reports available for the site you are affiliated to. To access the reports:

On the title bar, click the **Reports** tab.

Sort – To sort a tabular report, click on the column header to sort by the data in that column. Clicking once sorts the table in ascending order, clicking twice sorts the table in descending order.

Group – To group together results with the same value, drag and drop the column header to the area immediately above the table. Click the + sign to the left of the table to expand the listing under a group. It is also possible to group by multiple columns and “nest” groupings.

Search – To jump to the first record in the table with a particular value, enter the value in the blue box under the column header and click the magnifying glass icon.

Export – To export a report to your computer, click the link in the upper right corner of the table.

Filter – Use this function to modify the display in all report modes and save your filters for future use. Filters can be applied in the interactive grid mode or create filter mode.

Click the Help icon to view the Phase Forward IRT User Guide for detailed instructions.

Frequently Asked Questions

I have forgotten my password: Please refer to the 'Helpful Hints' in this manual.

I am trying to log in the system for the first time, and am being asked for a UAC. Where can I find this: The UAC form should have been sent to you via e-mail or fax. If you have not received this form, please contact your CRA or IRT Support. They will be able to retransmit the form to you.

I am not receiving confirmation reports: Please check whether your contact information is correctly stored in our database. You can also retransmit confirmation reports.

I have received a drug allocation for my subject, but the vials are missing or damaged: Please use the Drug Replacement function (web only) to register the vials as missing/damaged in order for re-supplies to be sent when required.

How will I receive a drug resupply for my subjects: This will be handled automatically by the IRT system.

My internet connection is temporarily broken, and I have to contact the IRT urgently for a randomization/drug assignment: Please use the phone based system, or contact IRT Support.

I have made a data entry error, how can it be corrected: Some data fields can be corrected via the Edit Subject Data function. Some data fields are blocked from editing by the site user, and so in this case please contact the CRA or IRT Support.